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: HILTON SFO BAYFRONT HOTEL

REFLECTIONS I & II 600 AIRPORT BOULEVARD BURLINGAME, CALIFORNIA

DATE: THURSDAY, OCTOBER 25, 2012

9 A.M.

REPORTER: BETH C. DRAIN, CSR

CSR. NO. 7152

BRS FILE NO.: 91124

INDEX PAGE NO. ITEM DESCRIPTION 1. CALL TO ORDER. 3 2. PLEDGE OF ALLEGIANCE. 3 3. ROLL CALL. 3 4. CHAIRMAN'S REPORT. 6 PRESIDENT'S REPORT. 11 ACTION ITEMS 6. CONSIDERATION OF APPLICATIONS FOR 53 RFA 12-05: CIRM STRATEGIC PARTNERSHIP I AWARDS. CLOSED SESSION NOT REPORTED ACTION ITEMS 8. CONSIDERATION OF DISEASE TEAM III 128 CONCEPT PLAN. 9. CONSIDERATION OF STRATEGIC 96 PARTNERSHIP II CONCEPT PLAN. NOT REPORTED CLOSED SESSION 10. DISCUSSION OF PERSONNEL ACTION ITEMS 11. CONSIDERATION OF CREATION OF A 185 DISCRETIONARY FUND FOR SUPPLEMENTS TO EXISTING GRANTS. 105 12. CONSIDERATION OF APPOINTMENT OF NEW SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP. 13. CONSIDERATION OF AMENDMENTS TO 106 THE GRANTS WORKING GROUP BYLAWS. 2

DARKISIERS REPORTING SERVICE	_
I N D E X (CONT'D.)	
14. CONSIDERATION OF INCLUDING BUDGET AS A FORMAL CRITERION FOR REVIEW OF RESEARCH APPLICATIONS.	145
15. CONSIDERATION OF RECOMMENDATIONS FROM THE GOVERNANCE SUBCOMMITTEE: A. PRESIDENTIAL SUCCESSION PLAN; B. MANNER OF DISQUALIFICATION FOR BOARD MEMBERS WHEN AN APPLICANT SELFIDENTIFIES; C. AMENDMENTS TO THE INTERNAL GOVERNANCE POLICY.	115
16. CONSIDERATION OF PROPOSED AMENDMENT TO REGULATION 100603 TO REQUIRE CIRM GRANTEES TO MAKE CIRM-FUNDED PUBLICATIONS AVAILABLE TO THE PUBLIC WITHIN 12 MONTHS OF PUBLICATION.	110
17. CONSIDERATION OF MINUTES FROM THE SEPTEMBER ICOC BOARD MEETING.	114
18. CONSIDERATION OF FINANCIAL AUDIT FOR FISCAL YEAR 2011-2012.	36
DISCUSSION ITEMS	
19. COMMUNICATIONS UPDATE.	195
20. PUBLIC COMMENT	90

1	BURLINGAME, CALIFORNIA; THURSDAY, OCTOBER 25, 2012
2	9 A.M.
3	
4	CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY.
5	IN THE AFTERMATH OF THE HISTORIC THREE HOME RUN GAME
6	WHICH, AS A DIEHARD DODGER FAN, EVEN I WILL ADMIT
7	WAS AN ACCOMPLISHMENT OF SOME NOTE.
8	WANTED TO WELCOME LET'S NOT GO
9	OVERBOARD, MR. JUELSGAARD.
10	MR. JUELSGAARD: YOU AIN'T SEEN NOTHING
11	YET.
12	CHAIRMAN THOMAS: LIKE TO WELCOME
13	EVERYBODY TO A RAINY SAN FRANCISCO, HOPEFULLY WON'T
14	DETER FROM GAME TWO TONIGHT, AND CALL THIS MEETING
15	TO ORDER. MARIA, WILL YOU PLEASE LEAD US IN THE
16	PLEDGE OF ALLEGIANCE.
17	(THE PLEDGE OF ALLEGIANCE.)
18	CHAIRMAN THOMAS: MARIA, WILL YOU PLEASE
19	CALL THE ROLL.
20	MS. BONNEVILLE: SUE BRYANT.
21	DR. BRYANT: HERE.
22	MS. BONNEVILLE: FRANK CHISARI.
23	DR. CHISARI: HERE.
24	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
25	DR. DULIEGE: HERE.
	4

1	MS. BONNEVILLE: JAMES ECONOMOU.
2	DR. ECONOMOU: HERE.
3	MS. BONNEVILLE: MARCY FEIT. ELIZABETH
4	FINI.
5	DR. FINI: HERE.
6	MS. BONNEVILLE: GARY FIRESTEIN.
7	DR. FIRESTEIN: HERE.
8	MS. BONNEVILLE: MICHAEL FRIEDMAN. LEEZA
9	GIBBONS. MICHAEL GOLDBERG.
10	MR. GOLDBERG: HERE.
11	MS. BONNEVILLE: SAM HAWGOOD.
12	DR. HAWGOOD: HERE.
13	MS. BONNEVILLE: STEPHEN JUELSGAARD.
14	DR. JUELSGAARD: HERE.
15	MS. BONNEVILLE: SHERRY LANSING. BERT
16	LUBIN. SHLOMO MELMED.
17	DR. MELMED: HERE.
18	MS. BONNEVILLE: PHIL PIZZO. CLAIRE
19	POMEROY.
20	DR. POMEROY: HERE.
21	MS. BONNEVILLE: ROBERT PRICE. FRANCISCO
22	PRIETO.
23	DR. PRIETO: HERE.
24	MS. BONNEVILLE: ROBERT QUINT. DUANE
25	ROTH. JOAN SAMUELSON. JEFF SHEEHY.
	5
	3

1	MR. SHEEHY: HERE.
2	MS. BONNEVILLE: JONATHAN SHESTACK.
3	MR. SHESTACK: HERE.
4	MS. BONNEVILLE: OSWALD STEWARD.
5	DR. STEWARD: HERE.
6	MS. BONNEVILLE: JONATHAN THOMAS.
7	CHAIRMAN THOMAS: HERE.
8	MS. BONNEVILLE: ART TORRES. KRISTINA
9	VUORI.
10	DR. VUORI: HERE.
11	CHAIRMAN THOMAS: THANK YOU, MARIA. WE'LL
12	PROCEED NOW TO THE CHAIR'S'S REPORT. IT'S BEEN A
13	BUSY SEVERAL WEEKS SINCE OUR LAST MEETING IN EARLY
14	SEPTEMBER. IMMEDIATELY FOLLOWING THAT MEETING, I
15	AND DRS. STEWARD AND PULIAFITO WENT BACK TO A REALLY
16	INTERESTING EVENT IN WASHINGTON, D.C., SPONSORED BY
17	FASTER CURES, THE MIKE MILKEN-BACKED ORGANIZATION
18	WHICH PROMOTES THE SPREAD OF INFORMATION ALL IN THE
19	INTEREST OF ACCELERATING SCIENCE. THEY HAD A,
20	QUOTE, UNQUOTE, CELEBRATION OF SCIENCE, WHICH IS A
21	THREE-DAY AFFAIR VERY SIMILAR IN FEEL TO THE MILKEN
22	GLOBAL CONFERENCE, FOR ANY OF THOSE WHO HAVE BEEN TO
23	ONE OF THOSE, WHERE IT WAS CHALK FULL OF PANELS,
24	SPEECHES, ALL SORTS OF TALKS ON THE MOST
25	CUTTING-EDGE WORK GOING ON PRINCIPALLY IN BIOLOGY.

1	THEY HAD A FULL DAY SANDWICHED IN THE
2	MIDDLE AT NIH WHERE FRANCIS COLLINS TOURED AROUND
3	THE NIH CAMPUS AND WAS FILMED TALKING TO NIH
4	RESEARCHERS WHO WOULD BE DESCRIBING THEIR
5	CUTTING-EDGE WORK. IT WAS FASCINATING. AND I THINK
6	THE EVENT WAS AIMED AT CONGRESS, WHO, OF COURSE, HAS
7	TO CONSIDER NIH BUDGETS AND HEALTHCARE IN GENERAL,
8	AND WAS ATTENDED BY ALL OF THE MAJOR CONGRESSIONAL
9	FOLK WHO ARE INTERESTED IN HEALTHCARE AND HAD THE
10	HEADS OF ALMOST ALL THE MAJOR DISEASE FOUNDATIONS,
11	HAD UNIVERSITY PRESIDENTS, IT HAD PHILANTHROPISTS
12	INTERESTED IN HEALTHCARE. IT JUST HAD PEOPLE FROM
13	ALL OVER. IT WAS A MOST INTERESTING DEAL.
14	AND ONE OF THE THINGS THAT WAS
15	PARTICULARLY INTERESTING WAS A SESSION EARLY THE
16	FIRST DAY OF ABOUT 60 OF US WHO GOT TOGETHER TO TALK
17	ABOUT ISSUES DEALING ON THE QUESTION OF HOW DO YOU
18	ACCELERATE THE SPEED OF SCIENTIFIC RESEARCH. THERE
19	WERE LOTS OF VERY GOOD IDEAS AND FOUND THE WHOLE
20	THING MOST WORTHWHILE.
21	IN ADDITION TO THAT, SINCE THE LAST
22	MEETING, THE CITY OF HOPE HAD THEIR ANNUAL
23	INTERNATIONAL STEM CELL SYMPOSIUM, WHICH THEY ALWAYS
24	DO IN CONJUNCTION WITH SCIENTISTS FROM ANOTHER
25	COUNTRY. THIS TIME IT FEATURED AND HIGHLIGHTED STEM
	7

1	CELL SCIENTISTS FROM CHINA WHO GAVE A NUMBER OF VERY
2	INTERESTING TALKS.
3	WE HAD A VERY NICE TOUR OF UCSF THAT WAS
4	GIVEN TO THE STATE CONTROLLER, JOHN CHIANG, WHO IS
5	VERY INTERESTED IN THE SCIENCE, AND DEAN HAWGOOD AND
6	ARNOLD KRIGSTEIN AND MEMBERS OF THE UCSF STAFF SPENT
7	A GOOD HOUR AND A HALF WITH THE CONTROLLER. MARIA
8	AND I WENT. AND IT WAS, I THINK, VERY, VERY
9	EYE-OPENING FOR HIM BECAUSE HE HADN'T ACTUALLY BEEN
10	TO ONE OF OUR STEM CELL CENTERS. AS SOMEBODY WHO
11	EXERCISES OVERSIGHT OVER BUDGETARY AND FINANCIAL
12	MATTERS, I THINK IT WAS VERY BENEFICIAL TO HAVE HIM
13	COME. AND WE WERE DELIGHTED TO BE ABLE TO HOST HIM.
14	WE'VE HAD A COUPLE OF SUBCOMMITTEES MEET
15	IN THE INTERIM, THE EVALUATION SUBCOMMITTEE AND THE
16	GOVERNANCE SUBCOMMITTEE. WE'VE ALSO HAD ANOTHER IN
16 17	GOVERNANCE SUBCOMMITTEE. WE'VE ALSO HAD ANOTHER IN THE LONG SERIES OF VERY INTERESTING GRANTS WORKING
17	THE LONG SERIES OF VERY INTERESTING GRANTS WORKING
17 18	THE LONG SERIES OF VERY INTERESTING GRANTS WORKING GROUP MEETINGS. THIS ONE ON NEW FACULTY AWARDS. WE
17 18 19	THE LONG SERIES OF VERY INTERESTING GRANTS WORKING GROUP MEETINGS. THIS ONE ON NEW FACULTY AWARDS. WE HAD A VERY GOOD EVENT DOWN AT USC WELCOMING DR.
17 18 19 20	THE LONG SERIES OF VERY INTERESTING GRANTS WORKING GROUP MEETINGS. THIS ONE ON NEW FACULTY AWARDS. WE HAD A VERY GOOD EVENT DOWN AT USC WELCOMING DR. ANDREW MCMAHON, EX OF HARVARD, WHO'S NOW THE HEAD OF
17 18 19 20 21	THE LONG SERIES OF VERY INTERESTING GRANTS WORKING GROUP MEETINGS. THIS ONE ON NEW FACULTY AWARDS. WE HAD A VERY GOOD EVENT DOWN AT USC WELCOMING DR. ANDREW MCMAHON, EX OF HARVARD, WHO'S NOW THE HEAD OF THE USC STEM CELL PROGRAM. AND THAT, I THOUGHT, WAS
17 18 19 20 21	THE LONG SERIES OF VERY INTERESTING GRANTS WORKING GROUP MEETINGS. THIS ONE ON NEW FACULTY AWARDS. WE HAD A VERY GOOD EVENT DOWN AT USC WELCOMING DR. ANDREW MCMAHON, EX OF HARVARD, WHO'S NOW THE HEAD OF THE USC STEM CELL PROGRAM. AND THAT, I THOUGHT, WAS A GREAT EVENT. DR. PULIAFITO SORT OF LED IT OFF.
17 18 19 20 21 22	THE LONG SERIES OF VERY INTERESTING GRANTS WORKING GROUP MEETINGS. THIS ONE ON NEW FACULTY AWARDS. WE HAD A VERY GOOD EVENT DOWN AT USC WELCOMING DR. ANDREW MCMAHON, EX OF HARVARD, WHO'S NOW THE HEAD OF THE USC STEM CELL PROGRAM. AND THAT, I THOUGHT, WAS A GREAT EVENT. DR. PULIAFITO SORT OF LED IT OFF. PRESIDENT MAX NIKIAS GAVE A VERY GOOD SPEECH

1	HIS PLANS FOR RECRUITMENT AND HOW TO TAKE THAT
2	PROGRAM TO EVEN GREATER HEIGHTS.
3	WE ALSO HAD THE LATEST INSTALLMENT OF THE
4	CLINICAL DEVELOPMENT ADVISORY PANEL, WHICH IS THE
5	PROGRESS REPORT OF DISEASE TEAMS THAT TAKES PLACE
6	PERIODICALLY. DR. FEIGAL PULLS TOGETHER A PANEL OF
7	EXPERTS WHO WERE THERE TO HEAR THE PROGRESS REPORTS
8	AND TO OFFER CRITIQUE, GUIDANCE, AND SUGGESTION TO
9	THE TEAMS, WHICH IS VERY WELL RECEIVED AND VERY
10	EXPERTLY GIVEN. I WANT TO COMMEND DR. FEIGAL FOR
11	PULLING TOGETHER, AS SHE ALWAYS DOES IN THESE
12	PANELS, AN EXPERT GROUP WHO REALLY DOES ADD A LOT OF
13	VALUE TO OUR DISEASE TEAMS AS THEY COME IN AND
14	PRESENT.
15	WE'VE ALSO, AS YOU KNOW, BASED ON THE
16	EXPERIENCES IN OUR JULY AND SEPTEMBER BOARD MEETINGS
17	WITH THE EXTRAORDINARY PETITION POLICY, WE DEEMED IT
17 18	WITH THE EXTRAORDINARY PETITION POLICY, WE DEEMED IT A GOOD IDEA TO PUT TOGETHER A TASK FORCE CHAIRED BY
	·
18	A GOOD IDEA TO PUT TOGETHER A TASK FORCE CHAIRED BY
18 19	A GOOD IDEA TO PUT TOGETHER A TASK FORCE CHAIRED BY DR. LUBIN TO ANALYZE OUR WHOLE PROCEDURE OF APPEAL
18 19 20	A GOOD IDEA TO PUT TOGETHER A TASK FORCE CHAIRED BY DR. LUBIN TO ANALYZE OUR WHOLE PROCEDURE OF APPEAL ON OUR MAJOR AWARDS. WE HAD THE FIRST MEETING OF
18 19 20 21	A GOOD IDEA TO PUT TOGETHER A TASK FORCE CHAIRED BY DR. LUBIN TO ANALYZE OUR WHOLE PROCEDURE OF APPEAL ON OUR MAJOR AWARDS. WE HAD THE FIRST MEETING OF THAT TASK FORCE YESTERDAY. AND I THINK THERE WAS A
18 19 20 21 22	A GOOD IDEA TO PUT TOGETHER A TASK FORCE CHAIRED BY DR. LUBIN TO ANALYZE OUR WHOLE PROCEDURE OF APPEAL ON OUR MAJOR AWARDS. WE HAD THE FIRST MEETING OF THAT TASK FORCE YESTERDAY. AND I THINK THERE WAS A LOT OF ROBUST DISCUSSION, A NUMBER OF VERY GOOD
18 19 20 21 22 23	A GOOD IDEA TO PUT TOGETHER A TASK FORCE CHAIRED BY DR. LUBIN TO ANALYZE OUR WHOLE PROCEDURE OF APPEAL ON OUR MAJOR AWARDS. WE HAD THE FIRST MEETING OF THAT TASK FORCE YESTERDAY. AND I THINK THERE WAS A LOT OF ROBUST DISCUSSION, A NUMBER OF VERY GOOD SUGGESTIONS MADE. THOSE SUGGESTIONS WILL BE ONE OF

1	THAT'S GOING TO BE A VERY CRITICAL DAY, THE DAY
2	BEFORE OUR JANUARY BOARD MEETING. MARIA, IT'S
3	JANUARY 24TH IS THE WORKSHOP, CORRECT?
4	MS. BONNEVILLE: 23D AND 24TH. 23D IS THE
5	WORKSHOP.
6	CHAIRMAN THOMAS: 23D IS THE WORKSHOP.
7	THE BOARD MEETING IS THE 24TH. THERE WILL BE A
8	NUMBER OF TOPICS COVERED THERE. THE WORKSHOP, IOM
9	REPORT, WHICH IS DUE OUT IN DECEMBER, WHICH WE'VE
10	WAITED NOW FOR THEIR EXPERT GUIDANCE WHICH WILL BE
11	ABOUT 15 MONTHS IN THE MAKING, WE ARE EXPECTING IT
12	IN DECEMBER. THAT WILL BE DISCUSSED BOTH AT THE
13	DECEMBER BOARD MEETING AND IMPLEMENTATION OF IDEAS
14	AT THE WORKSHOP. SO ENCOURAGE EVERYBODY TO PLEASE
15	TRY TO ATTEND THAT.
16	LAST, BUT NOT LEAST, I JUST WANTED TO
17	RELAY A FUN ANECDOTE. ON THE DAY DR. YAMANAKA WAS
18	AWARDED THE NOBEL PRIZE, WHICH I'M SURE ALAN WILL BE
19	DISCUSSING IN HIS REPORT, THERE WAS A RECEPTION AT
20	THE GLADSTONE INSTITUTE FOR HIM. HE WAS ACTUALLY IN
21	KYOTO THAT DAY AND THEY HAD HIM SKYPED IN. AND DR.
22	YAMANAKA, BEING A VERY HUMBLE GUY, HERE HE'S JUST
23	GOTTEN THE AWARD THAT'S AT THE ABSOLUTE PINNACLE,
24	AND SOMEBODY ASKED HIM, "SO WHAT WAS IT LIKE? TELL
25	US ABOUT THE PHONE CALL. HOW DID YOU FEEL? WHAT
	10

1	DID THEY SAY? GIVE US THE WHOLE STORY."
2	DR. YAMANAKA SAID, "WELL, I WAS ON THE
3	FLOOR FIXING OUR WASHING MACHINE AND THE PHONE RANG.
4	MY WIFE GOT IT. AND SHE SAID, 'IT'S FOR YOU.' AND
5	I HEARD SOMETHING ABOUT SWEDEN AND THE NOBEL PRIZE."
6	AND THAT WAS PRETTY MUCH IT. THAT WAS HIS FULL
7	REPORT ON RECEIVING THE PHONE CALL. IT WAS JUST A
8	VERY DR. YAMANAKA-LIKE MOMENT, VERY HUMBLE MAN WHOM
9	WE'RE OBVIOUSLY ENORMOUSLY PROUD. KUDOS TO DEAN
10	HAWGOOD FOR UCSF AND GLADSTONE INSTITUTE, AND IT WAS
11	A WONDERFUL DAY FOR YOU ALL AS WELL.
12	SO THAT CONCLUDES THE CHAIR'S REPORT. AS
13	I SAY, A LOT OF STUFF HAPPENING, A LOT OF GOOD
14	STUFF. AND I WANT TO TURN IT OVER NOW TO DR.
15	TROUNSON FOR THE PRESIDENT'S REPORT.
16	DR. TROUNSON: THANK YOU VERY MUCH, CHAIR.
17	JUST TO CONTINUE JUST BRIEFLY ON THE NOBEL PRIZE,
18	THE NOBEL PRIZE FOR MEDICINE WAS SHARED BY JOHN
19	GURDON AND SHINYA YAMANAKA, BOTH OF WHOM ARE CLOSE
20	FRIENDS OF MINE. AND, OF COURSE, SHINYA AS A MEMBER
21	OF THE GLADSTONE INSTITUTE IS HERE AROUND ABOUT ONE
22	WEEK A MONTH. SO HE HAS A LABORATORY THERE. SO A
23	VERY SIGNIFICANT PRESENCE IN CALIFORNIA.
24	YOU MAY NOT KNOW SO MUCH ABOUT JOHN
25	GURDON, BUT I SPENT THREE YEARS IN CAMBRIDGE IN THE
	11

1	EARLY '70S, WHICH DATES ME, I GUESS, BUT JOHN, WHO'S
2	79 YEARS OF AGE AT THE MOMENT, HE WAS REALLY AT HIS
3	PINNACLE IN THOSE DAYS, AT THE TOP OF HIS SCIENTIFIC
4	CAREER. AND HE WAS WORKING ON CLONING FROG CELLS
5	AND SHOWING THAT YOU COULD REPROGRAM CELLS IN THE
6	XENOPUS, SOUTH AFRICAN XENOPUS LAEVIS FROG FROM
7	SOUTH AFRICA.
8	YOU COULD TAKE CELLS FROM A TADPOLE AND
9	INTRODUCE THEM INTO THE FROG EGG AND THEY MAKE OTHER
10	TADPOLES AND FROGS, SO CLONE FROM THAT ANIMAL.
11	THESE WERE THE SORT OF LANDMARK EXPERIMENTS IN
12	REPROGRAMMING. AND THEY REALLY SET THE STAGE FOR US
13	BEING ABLE TO MANIPULATE LINEAGE DEVELOPMENT. MOST
14	PEOPLE THOUGHT IT WASN'T POSSIBLE TO CLONE FROM
15	CELLS OF THE MAMMAL BECAUSE OF THE FAILURES OF
16	SCIENTISTS AFTER JOHN GURDON'S LANDMARK WORK. OTHER
17	SCIENTISTS TRIED IN THE MOUSE, FOR EXAMPLE, AND
18	BASICALLY FAILED. THERE WERE SOME REPORTS OF WORK
19	IN SWITZERLAND, BUT THERE WAS A LOT OF DOUBTS OVER
20	THOSE EXPERIMENTS IN DUE COURSE.
21	IT WASN'T UNTIL DOLLY, THE SHEEP, THAT THE
22	FIRST MAMMALIAN CELL WAS CLONED. I'VE JUST
23	UNFORTUNATELY FINISHED WRITING AN OBITUARY FOR KEITH
24	CAMPBELL, WHO'S THE PERSON WHO ACTUALLY CLONED
25	DOLLY, THE SHEEP, AND WAS THE LEAD AUTHOR ON THAT
	12
	14

1	ARTICLE. SO THERE'S SOME IRONY IN ALL OF THIS WITH
2	THE NOBEL PRIZE AND THE LOSS OF KEITH CAMPBELL. THE
3	WHOLE AREA OF REPROGRAMMING IS REALLY NOW
4	ESTABLISHED WELL AND TRULY. AND I THINK SHINYA
5	YAMANAKA REALLY PROVIDED THE FINAL ABSOLUTE PROOF OF
6	HOW WE COULD ACTUALLY MANIPULATE THOSE CELLS BY
7	INTRODUCING TRANSCRIPTION FACTORS INTO THEM.
8	IT'S A WONDERFUL NOBEL PRIZE. IT'S AN
9	EXTREMELY INTERESTING HISTORY. I'M SURE WE'RE GOING
10	TO READ A LOT MORE ABOUT IT. I'M GOING TO BE IN
11	CAMBRIDGE IN DECEMBER AND WILL BE WITH JOHN GURDON.
12	BUT GURDON AND YAMANAKA ARE ACTUALLY HERE THIS NEXT
13	WEEK AT A VERY IMPORTANT MEETING THAT'S BEING HELD
14	AT THE GLADSTONE. AND SO IF ANYONE HAS GOT A MOMENT
15	IN TIME, THEY'D ENJOY GOING TO THAT MEETING, I'M
16	CERTAIN. UNFORTUNATELY I WON'T BE HERE. I'VE GOT
17	OTHER JOBS TO DO.
18	SO CHANGING A LITTLE BIT, BUT STAYING ON
19	THE SAME THEME, PICKING UP A PIECE OF SCIENCE WHICH
20	I THINK IS EXTRAORDINARY. IT'S JUST BEEN PUBLISHED
21	OCTOBER THE 4TH BY A GROUP IN JAPAN IN SCIENCE
22	EXPRESS. WITH IPS CELLS I HAVE A COUPLE OF
23	SLIDES WHICH SAID, WELL, WITH IPS CELLS YOU COULD
24	ALSO USE IPS CELLS FROM AN INDIVIDUAL TO MAKE NEW
25	SPERM AND EGGS. AND UNFORTUNATELY PEOPLE WITH

1	INFERTILITY AND STERILITY, AND IF YOU COULD DO THAT,
2	YOU COULD TAKE THE CELLS OF A PERSON AND REMAKE
3	THEIR SPERM OR THEIR EGGS, YOU WOULD PROVIDE A
4	SOLUTION TO THEIR STERILITY IN AN EXTRAORDINARY WAY.
5	WELL, THAT'S BEEN A SLIDE WHERE I THINK MAYBE THAT
6	WILL HAPPEN IN THE NEXT 10 OR 15 YEARS, BUT NOW IT'S
7	ALREADY HAPPENED.
8	SO WHAT THESE SCIENTISTS DID WAS TO TAKE
9	FEMALE EMBRYONIC STEM CELLS, XX EMBRYONIC STEM
10	CELLS, AND ALSO IPS CELLS THAT WERE MADE FROM FEMALE
11	MICE, AND THEY INDUCED THEM TO GROW INTO PRIMORDIAL
12	GERM CELLS USING TWO TRANSGENES, BLIMP1 AND STELLA.
13	THESE ARE TWO GENES WHICH ARE NECESSARY TO FORM GERM
14	CELL LINEAGE, NOT THE SOMATIC CELL LINEAGE, WHICH
15	FORMS ALL THE OTHER TISSUES, BUT THE GERM CELL,
16	WHICH ACTUALLY FORMS SPERM AND EGGS IN THE
17	CONTINUITY OF THE SPECIES. AND THEN THEY AGGREGATED
18	THOSE PRIMORDIAL GERM CELLS WITH OVARIAN SOMATIC
19	CELLS. SO THESE ARE CELLS THAT ARE IN THE OVARY,
20	BUT ARE NOT GERM CELLS. THEY'RE SOMATIC NERVE
21	CELLS, IF YOU LIKE, IN THE OVARY.
22	AND THERE'S ALSO SOME GOOD MESSAGES ABOUT
23	THIS. WHEN THEY AGGREGATED THOSE GERM CELLS
24	TOGETHER WITH THESE SOMATIC CELLS FROM THE OVARY,
25	THEN THE GERM CELLS UNDERWENT X REACTIVATION IMPRINT

1	ARRAYS, CYST FORMATION, AND MITOTIC CHROMOSOME
2	REDUCTION TO HAPLOIDY. THAT MEANS THAT THEY DID
3	EVERYTHING THAT YOU NEED TO DO TO BECOME AN EGG.
4	WHEN THEY TRANSPLANTED THIS MATERIAL UNDER
5	THE OVARIAN BURSA, WHICH IS WHERE THE OVARY NORMALLY
6	IS IN A MOUSE, THEY PRODUCED EGGS. AND WHEN THEY
7	MATURED THOSE EGGS, FERTILIZED THEM, THEY PRODUCED
8	BABY MICE. SO HERE ARE THE BABY MICE. I WON'T GO
9	INTO THE DETAILS OF THE EXPERIMENT. ON THE TOP
10	RIGHT, THESE ARE BABY MICE PRODUCED FROM SKIN CELLS,
11	SKIN CELLS, THAT HAVE BEEN DRIVEN INTO THE GERM
12	LINEAGE AND THEY PRODUCED BABY MICE. SO THESE WERE
13	THE BABY MICE PRODUCED FROM EMBRYONIC STEM CELLS.
14	AND IT WAS A REASONABLY EFFICIENT METHOD.
15	SO THEY ALSO DID IT DOWN ON THE LEFT-HAND
16	SIDE. THESE ARE THE BABY MICE PRODUCED FROM IPS
17	CELLS. SO THERE WAS REALLY NO DIFFERENCE IN THE
18	SUCCESS RATE OF THE TWO PROCEDURES. AND ONE OF
19	THOSE BABY MICE, THOSE VERY PINK BABY MICE OR ALMOST
20	RED, THERE'S A MOTHER THERE. THAT'S THE MOTHER
21	THAT'S GROWN UP AND NOW IS A MOTHER. SO THIS MOUSE
22	WAS FERTILE. THESE MICE ARE FERTILE. SO THEY'RE
23	NORMAL AND THEY'RE FERTILE. AND IT'S EXTRAORDINARY,
24	ABSOLUTELY EXTRAORDINARY.
25	SO IN THE MOUSE YOU CAN TAKE A CELL FROM
	15
	17

1	SKIN AND YOU CAN TURN IT INTO AN EGG AND YOU CAN
2	TURN IT INTO AN EMBRYO AND YOU CAN TURN IT INTO BABY
3	MICE WHICH REPRODUCE. ONE ARGUES, THEN, IF IPS
4	CELLS CAN DO THAT, IF THEY CAN DO THAT, THEN HOW
5	DIFFERENT ARE THEY FROM EMBRYONIC STEM CELLS? AND
6	WHAT IS THE ARGUMENT, WHAT'S THE ARGUMENT OUT THERE
7	THAT THEY'RE ANY DIFFERENT FROM EMBRYONIC STEM
8	CELLS? IT DOESN'T SEEM TO HOLD WATER THAT THESE
9	CELLS ARE REALLY ANY DIFFERENT FROM EMBRYONIC STEM
10	CELLS. SO POLITICALLY WHAT'S THE ARGUMENT THAT
11	EMBRYONIC STEM CELLS DID? THEY'VE BEEN REENGAGED IN
12	THE FORM OF IPS CELLS.
13	SO THIS, I THOUGHT, WAS AN EXTRAORDINARY
14	PIECE OF WORK FROM THE JAPANESE GROUP, BUT IT TELLS
15	US A LOT ABOUT HOW TO DO SOME OF THE WORK. AND I'VE
16	SAID IN SOME OF OUR STEM CELLS, CARDIAC CELLS AND
17	OTHER CELLS, THEY DON'T MATURE COMPLETELY JUST IN
18	THE DISH, AND YOU NEED TO COMBINE THEM WITH A
19	TISSUE, THE SOMATIC CELLS, WHERE THEY RESIDE BECAUSE
20	THERE'S INSTRUCTIONS IN THOSE SOMATIC CELLS WHERE
21	THEY RESIDE, IF YOU LIKE, WE CALL IT THE NICHE, THAT
22	INSTRUCT THOSE CELLS TO BECOME MATURE. SO A HEART
23	CELL CAN BECOME MATURE IN A HEART, LIVER CELL IN A
24	LIVER, AND SO ON. SO THIS IS A GOOD EXAMPLE OF HOW
25	TO COMPLETE THE MATURATION PROCESS, FUNCTIONAL

1	MATURATION PROCESS.
2	THE OTHER PIECE OF WORK I WANTED TO DRAW
3	YOUR ATTENTION TO IS SOMETHING THAT WE ARE ACTUALLY
4	FUNDING. AND I THINK IT'S REALLY, REALLY IMPRESSIVE
5	WORK FROM MARK TUSZYNSKI'S LAB IN THE UNIVERSITY OF
6	CALIFORNIA IN SAN DIEGO. AND THIS IS IN THE AREA OF
7	SPINAL INJURY AND SPINAL REPAIR. SO THEY TOOK
8	NEURAL STEM CELLS DERIVED FROM EMBRYONIC STEM CELLS
9	AND FETAL NEURAL STEM CELLS AND EMBEDDED THEM IN A
10	FIBRIN MATRIX, IN A SCAFFOLD, IN A THREE-DIMENSIONAL
11	SCAFFOLD. SO THEY EMBEDDED IT IN THIS GEL. AND
12	THEN THEY TRANSFERRED THIS GEL TO THE SPINAL CORD OF
13	RATS WHERE THEY ACTUALLY COMPLETELY RESECTED THE
14	SPINAL CORD. SO THERE WAS NO CONNECTION FROM ONE
15	END TO THE OTHER. SO THIS IS A REALLY MAJOR INJURY.
16	AND THEN THESE GRAFTS THAT THEY PUT IN
17	THERE IN THE FIBRIN DIFFERENTIATED INTO CELLS,
18	INCLUDING MOTOR NEURONS, WITH AXONS THAT EXTENDED IN
19	BOTH DIRECTIONS RIGHT ACROSS THAT INJURY SPACE. AND
20	THEY'RE ABLE TO SUPPORT ELECTRICAL RELAYS ACROSS
21	THAT TRANSECTION AND TO RECOVER MOTOR FUNCTION. SO
22	THIS IS AN EXTRAORDINARY DEVELOPMENT, I THINK. THIS
23	SHOWS THAT YOU CAN MAKE MOTOR NEURONS THAT ACTUALLY
24	CONNECT ONE END TO THE OTHER, AND THAT'S REALLY NOT
25	BEEN SHOWN BEFORE.

1	IT'S IMPORTANT TO ALSO UNDERSTAND THAT THE
2	ENDOGENOUS CELLS THAT ARE THERE CAN'T DO THAT. THEY
3	CAN'T DO THAT. SO IT'S ONLY THESE ONES THAT YOU PUT
4	IN THERE, THESE EXOGENOUS CELLS, THAT CAN DO IT. SO
5	THIS IS A TRANSLATIONAL STUDY OF OURS. JUST TO SHOW
6	YOU, THE GREEN IS WHERE THEY'VE SEPARATED THE SPINAL
7	CORD AND YOU CAN SEE THE SEE GREEN AXONS GOING DEEP
8	IN EITHER SIDE. IF YOU LOOK AT HERE, THEY'VE TAKEN
9	DIFFERENT SECTIONS OF THE SPINAL CORD DOWNSTREAM AND
10	UPSTREAM FROM WHERE THEY ARE, AND YOU CAN SEE THESE
11	BROWN SPOTS WHICH ARE THE AXONS THAT ARE TRAVELING
12	IN BOTH DIRECTIONS.
13	AND IF I WENT BACK TO SEE THAT GRAPH
14	THERE, THIS IS WHERE THEY DID YOU CAN SEE WHERE
15	THEY DID THE TRANSPLANT WITH NEURON ACTION
16	POTENTIALS, AND THE MOTOR ACTIVITY OF THE ANIMALS
17	RISES IN THE GRAFT. WHEN THEY CUT THE SPINAL CORD
18	AGAIN ABOVE THAT TRANSPLANT, THEY LOSE THE WHOLE
19	THING AGAIN. SO THESE ARE THOSE NEURONS THAT THEY
20	PUT IN. THAT DEMONSTRATES THAT THOSE WERE THE
21	NEURONS THAT GAVE THE MOTOR ACTIVITY. IT'S NOT SOME
22	EFFECT WHICH IS JUST TRAVELING IN A SPACE IN THE
23	CORD. IT'S ACTUALLY THE AXONS OF THOSE NEURONS THAT
24	ARE WORKING.
25	SO ANOTHER PAPER WHICH WAS PUBLISHED IN

1	NATURE IS ON THE TRANSPLANTATION OF ES CELL-DERIVED
2	OTIC PROGENITORS. THIS IS ALL ABOUT HEARING. THIS
3	WORK HAS COME FROM THE UNIVERSITY OF SHEFFIELD IN
4	THE UNITED KINGDOM. BUT, AGAIN, SHOW YOU THAT THESE
5	CELLS ARE ABLE TO FORM THE AUDITORY CELLS OF
6	HEARING. AGAIN, ON THAT GRAPH THAT'S SHOWN THERE,
7	YOU CAN SEE THE IMPROVEMENT IN MICE THAT HAVE LOST
8	THEIR COMPLETE HEARING.
9	SO THE UPPER PART SHOWS YOU THAT THE
10	ANIMALS START TO HEAR AGAIN. IT DOESN'T BRING THEM
11	RIGHT BACK TO NORMAL, BUT IT'S BRINGING BACK
12	HEARING. SO I THINK THESE KIND OF STUDIES WILL
13	TRANSFER TO DEAFNESS, THE TREATMENT OF DEAFNESS, IN
14	DUE COURSE.
15	AND THE LAST ONE I WANTED TO SORT OF BRING
16	TO YOUR ATTENTION, BECAUSE THERE'S SUCH A LOT OF
17	GOOD SCIENCE PUBLISHED IN THIS LAST MONTH, WAS THE
18	WORK BY STEM CELLS, INC., A COMPANY THAT WE'RE
19	SUPPORTING. AND THEY WERE DOING TRANSPLANTS INTO
20	SHIVERER MICE WITH NEURAL STEM CELLS. AND THESE
21	MICE HAVE A TOTALLY DEFECTIVE MYELINATION IN THE
22	CENTRAL NERVOUS SYSTEM AND THEY HAVE A MAJOR ATAXIA
23	BY TWO TO THREE WEEKS OF LIFE. WHEN THEY PLANTED
24	THESE HUMAN NEURAL STEM CELLS INTO THE BRAIN OF
25	THESE NEONATAL AND JUVENILE MICE, THEY WERE ABLE TO

1	SHOW THAT THEY GOT REMYELINATION IN A SIGNIFICANT
2	PART OF THE BRAIN.
3	SO THESE CELLS, WHEN YOU INTRODUCE THEM
4	INTO THE BRAIN, WILL PROVIDE YOU WITH REMYELINATION
5	ACROSS REALLY QUITE AN AREA OF THE BRAIN, AND YOU
6	GET ACTION POTENTIAL MEASUREMENTS THAT INCREASE AS A
7	RESULT OF THAT. SO THIS WAS, I THINK, ALSO ANOTHER
8	IMPORTANT PIECE OF WORK. SO SOMETIMES YOU CAN GO ON
9	AND ON AND ON ABOUT THE SCIENCE THAT'S OUT THERE,
10	BUT IT IS EXTRAORDINARY. AND I TRY TO CHOOSE THINGS
11	WHICH TO ME ARE REMARKABLE.
12	WE HAVE NEW APPOINTMENTS. STEVE TORRENCE
13	IS OUR LEAD ARCHITECT IN THE I.T. INDUSTRY. SO I'M
14	REALLY PLEASED STEVE HAS JOINED US. HE'S BEEN
15	WORKING WITH US AS A CONSULTANT FOR SOME TIME.
16	THERE'S BEEN SOME INTERNAL APPOINTMENTS
17	WHICH GIVE PEOPLE AN OPPORTUNITY TO PROGRESS IN THE
18	ORGANIZATION. SO IAN SWEEDLER HAS BEEN PROMOTED TO
19	DIRECTOR OF ALLIANCE MANAGEMENT TO HELP ME WITH ALL
20	OF THE WORK WITH THE MANY DIFFERENT COLLABORATIVE
21	FUNDING PARTNERS FROM AROUND THE WORLD. CHILA
22	SILVA-MARTIN, WHO YOU KNOW WELL, HAS BEEN PROMOTED
23	TO DIRECTOR OF FINANCE. AND PAUL FRECH WHO WAS
24	MOVED FROM THE OFFICE OF MANAGER POSITION TO GRANTS
25	REVIEWS SPECIALIST. SO HE WENT FROM THE FRONT

1	OFFICE INTO THE GRANTS REVIEW SPECIALIST POSITION.
2	SO GOOD FOR PAUL.
3	I NEED TO TELL YOU SOMETHING VERY BRIEFLY.
4	YOU'RE ALL AWARE OF ALL OF MY FAMILY LIVES IN
5	MELBOURNE, AND THERE ARE TIMES THAT THIS IS NOT
6	OPTIMUM FOR ME, CLEARLY. AND SO IN JANUARY AND
7	FEBRUARY, WHICH IS SUMMERTIME IN AUSTRALIA, I'VE
8	AGREED TO SPEND 50 PERCENT OF MY TIME THERE WITH MY
9	FAMILY AND 50 PERCENT AT A DISTANCE WORKING FOR
10	CIRM.
11	YOUNG ALEX IS ONLY 11 YEARS OLD AND MISSES
12	ME. I'M GOING TO TAKE THE SURFBOARDS AND TEACH HIM
13	TO SURFBOARD. RIGHT. I WANT TO PUT SOME QUALITY
14	TIME BACK IN MY FAMILY LIFE IN ORDER TO TRY AND KEEP
15	ESTABLISHED THOSE CONNECTIONS. ALSO, MY DAUGHTER,
16	WHO'S 34, NEARLY 35, SHE'S GETTING MARRIED IN
17	FEBRUARY AND WANTS TO GET MARRIED AT THE BEACH WHILE
18	I'M THERE.
19	SO I'LL BE DISTANT FOR THAT TIME. I'VE
20	DISCUSSED THIS WITH THE CHAIR. WE'RE COMFORTABLE IN
21	THOSE ARRANGEMENTS, BUT I WILL BE WORKING 50 PERCENT
22	OF THE TIME. SO I WILL BE AVAILABLE FOR THE
23	ORGANIZATION DURING THAT TIME. BUT THERE ARE
24	MOMENTS, THERE ARE MOMENTS IN ONE'S LIFE WHERE
25	YOU'VE ALSO GOT TO ATTEND TO SOME OTHER PRIORITIES

21

1	AS WELL. AN 11-YEAR-OLD WHO HASN'T SEEN ME MUCH
2	OVER A YEAR AND A HALF PROBABLY DESERVES A LITTLE
3	MORE TIME.
4	LOOKING AT THE RFA PROGRAM MOVING FORWARD,
5	STRATEGIC PARTNERSHIP I, VERY, VERY IMPORTANT
6	PROGRAM FOR OUR INDUSTRY ENGAGEMENT, THIS MEETING.
7	CONCEPT PROPOSAL FOR THE NEXT ONE. SO YOU'VE HARDLY
8	TAKEN A BREATH AND YOU'LL GET THE NEXT CONCEPT
9	PROPOSAL THIS MEETING. DISEASE TEAM III, AGAIN,
10	HARDLY TAKEN A BREATH, I KNOW, BUT YOU WILL GET THE
11	CONCEPT AT THIS MEETING. NEW FACULTY PHYSICIAN
12	AWARD, TRANSLATIONAL RESEARCH AWARD, GRANTS REVIEW
13	OF APPLICATIONS IN OCTOBER AND THE ICOC DECISION IN
14	DECEMBER. SO YOU'VE GOT THAT TO LOOK FORWARD TO.
15	IPS CELL INITIATIVE, THE GRANTS REVIEW IS,
16	AGAIN, IN DECEMBER. THE GENOMICS INITIATIVE, THE
17	GRANTS WORKING REVIEW WILL BE IN FEBRUARY. AND OUR
18	EARLY TRANSLATIONAL IV, THE RFA POSTING WILL BE IN
19	SEPTEMBER.
20	SO LOTS OF ACTIVITY. THE STAFF CAN HARDLY
21	BELIEVE THE ABILITY TO GET ACROSS THIS WHOLE
22	PROGRAM. THE STAFF ARE WORKING LIKE PEOPLE
23	POSSESSED, AND THEY'RE WORKING VERY LONG HOURS AND
24	DOING A FANTASTIC JOB. IF WE DROP THE BALL, THEY
25	PICK IT UP REALLY QUICKLY AGAIN. I'M INCREDIBLY

1	IMPRESSED WITH THE TEAM THAT WE HAVE.
2	MEETINGS AND WORKSHOPS HELD SINCE
3	SEPTEMBER MEETING, THERE'S BEEN A CIRM WEBINAR ON
4	IMMUNE RESPONSE IN STEM CELL THERAPIES. THEY HAD
5	LEADING EXPERTS FROM THE FDA, INDUSTRY, AND
6	ACADEMIA. THAT WAS HELD ON SEPTEMBER 27TH. A
7	COLLABORATIVE FUNDING PARTNER WORKSHOP WITH BRAZIL
8	AND ARGENTINA THAT WAS HELD IN OCTOBER. IT WAS VERY
9	SUCCESSFUL. AND I'VE ALSO NOW GOT AGREEMENTS FROM
10	THREE STATES IN BRAZIL TO CONTRIBUTE TO THE
11	COLLABORATIVE FUNDING OPPORTUNITIES.
12	THERE WAS A WORKSHOP AT THE CITY OF HOPE
13	ON INNOVATIVE PARTNERSHIPS WITH U.S. AND CHINA STEM
14	CELLS AND CANCER DISCOVERIES IN OCTOBER. AND
15	THERE'S A CIRM/FDA ROUNDTABLE ON BEST PRACTICES IN
16	CLINICAL DESIGN FOR FIRST-IN-HUMAN STEM CELL-BASED
17	THERAPIES THAT WAS CHAIRED BY ELLEN. AGAIN, HAD ALL
18	OF OUR FDA COLLEAGUES. IT WAS A VERY SUCCESSFUL
19	MEETING. WE HAD MEMBERS OF OUR DISEASE TEAMS THERE.
20	IT WAS A VERY IMPORTANT ENGAGEMENT WITH THE FDA AND
21	EXTREMELY WORTHWHILE. AND I THINK ALL OF THE
22	PEOPLE I HEARD FROM A LOT OF THE PEOPLE WHO WENT
23	THAT IT WAS REALLY A VERY, VERY USEFUL ENGAGEMENT.
24	UPCOMING MEETINGS, THERE'S A STEM CELL
25	ALPHA CLINICS WORKSHOP ON NOVEMBER THE 14TH AND 15TH

1	AT STANFORD. SO THOSE BOARD MEMBERS THAT ARE
2	INTERESTED PLEASE LET US KNOW. STEM CELLS ON THE
3	MESA, WE'RE HARDLY I GOT BACK AT 11:30 LAST
4	NIGHT, AND CANDACE SAYS THAT I GOT TO GET ON THE
5	PLANE AGAIN ON SATURDAY. AND I THINK I DON'T EVEN
6	HAVE TIME FOR LAUNDRY THESE DAYS. SO I APOLOGIZE IF
7	I LOOK MESSY, BUT THIS TRAVELING IS GETTING ME. BUT
8	IT'S A VERY IMPORTANT MEETING ON THE MESA, AGAIN,
9	FOR THE ENGAGEMENT WITH INDUSTRY.
10	THERE'S A CIRM GRANTEE MEETING ON MARCH
11	6TH TO THE 8TH. IT'S PROBABLY THE BEST STEM CELL
12	MEETING IN THE WORLD. SO I HOPE SOME OF YOU MIGHT
13	TAKE THE OPPORTUNITY TO BE WITH US AT LEAST AT SOME
14	PART OF THAT. IT HAS ALL OUR GRANTEES. THERE WILL
15	BE AROUND 400 PEOPLE AT THAT MEETING.
16	THERE'S A CIRM/NIH PARKINSON'S DISEASE
17	MEETING ON MARCH 21ST TO THE 22D. IT'S, AGAIN, IN
18	SAN FRANCISCO. AND IT HAS PEOPLE FROM ALL OVER THE
19	WORLD COMING TO ENGAGE TO TALK ABOUT HOW TO ACTUALLY
20	MOVE PARKINSON'S DISEASE FORWARD IN A VERY
21	SIGNIFICANT WAY.
22	SO I THINK YOU'VE HEARD A LOT ABOUT THE
23	MEETING ON THE MESA. JUST TO DESCRIBE TO YOU THAT
24	THERE'S EIGHT CIRM-FUNDED TEAMS PRESENTING THERE,
25	INCLUDING CAPRICOR. DR. SVENDSEN FROM CEDARS-SINAI,

1	THE REGENERATIVE PATCH TECHNOLOGIES. DR. ABOODY'S
2	COMPANY, THERABIOLOGICS. STEM CELLS, INC. GROUP
3	WILL BE THERE. DR. LAIRD AND DR. WHEELOCK FROM UC
4	DAVIS WILL BE THERE, AND VIACYTE WILL BE THERE. SO
5	IT'S A GREAT TEAM. SO THESE ARE SORT OF PRESENTING
6	THE FRONT EDGE, IF YOU LIKE, WHERE WE'RE GOING WITH
7	SOME OF OUR CLINICAL PROJECTS. BIOPHARMACEUTICAL
8	COMPANIES ATTENDING INCLUDE JOHNSON AND JOHNSON,
9	SHIRE, BAXTER, JANSSEN, J&J, PFIZER.
10	OUR COLLABORATIVE FUNDING PROGRAM, JUST TO
11	LET YOU KNOW THAT THERE WERE TWO PROJECTS AWARDED
12	FOR THE FIRST TIME TO FRENCH TEAMS AND TO INDIAN
13	TEAMS. SO THAT'S A VERY SIGNIFICANT STEP IN THE
14	DIRECTION OF COLLABORATING WITH BOTH FRANCE AND WITH
15	INDIA. SO WE'RE VERY PLEASED THAT THOSE PROJECTS
16	GOT THROUGH AND ARE BEING SUPPORTED BY THOSE
17	COUNTRIES.
18	FIVE COLLABORATIVE PARTNERS PARTICIPATED
19	IN THE EARLY TRANSLATIONAL IV RFA, INCLUDING
20	GERMANY, INDIA, NIH, AND CHINA. AND WE HAVE A
21	COLLABORATIVE MATCH-MAKING WEB SITE WHICH IS UNDER
22	DEVELOPMENT FOR JOINT PROJECTS BETWEEN CIRM AND
23	SCIENCE EXCHANGE. SO SCIENCE EXCHANGE IS HELPING US
24	PUT THIS TOGETHER TO ENABLE US TO LINK WITH OTHER
25	PEOPLE AROUND THE WORLD.
	25
	25

1	AND WE'VE GOT A COLLABORATIVE FUNDING
2	WORKSHOP HELD IN BRAZIL, AS I SAID, AND WE WILL BE
3	SIGNING SOME AGREEMENTS THERE WITH THE STATES.
4	THE WORKSHOP IN BRAZIL AND ARGENTINA
5	BROUGHT 12 SCIENTISTS THAT CAME FROM CALIFORNIA.
6	THEY WERE VERY IMPRESSIVE AND THEY LINKED IDEALLY
7	WITH OUR BRAZILIAN AND ARGENTINEAN COLLEAGUES. SO I
8	EXPECT A NUMBER OF COLLABORATIONS TO EVOLVE FROM
9	THAT MEETING.
10	AND THE GRANTS MANAGEMENT SYSTEM, WE'VE
11	GOT NEW FEATURES UP ON THAT NOW. AND IT'S A VERY
12	FUNCTIONAL SYSTEM. THE IP PROPERTY DISCLOSURES AND
13	UTILIZATION, PREFUNDING ADMINISTRATIVE REVIEW,
14	PROGRESS REPORT CHECKLISTS, REVIEWER'S SCOREBOOK,
15	AND CONFLICT OF INTEREST ENHANCEMENTS ARE ALL THERE.
16	NEXT IN THE PIPELINE IS PATENT ASSISTANCE,
17	SCIENTIFIC AND OUTCOMES CODING, NOTICE OF GRANT
18	AWARD, PAYMENTS AND PAY MEMOS AND SCHEDULE
19	NOTIFICATION. SO WE'RE NOW GETTING A VERY EFFECTIVE
20	AND A VERY MATURE PROGRAM THERE.
21	SO WITH THAT, I'D LIKE TO INVITE CHILA,
22	WHEREVER SHE IS, TO COME AND PROVIDE YOU BRIEFLY
23	WITH THE FINANCE REPORT.
24	MS. SILVA-MARTIN: THANK YOU. GOOD
25	MORNING. I'M GOING TO BE REPORTING ON OUR FINANCIAL

1	OPERATIONS FOR THE FIRST QUARTER OF THE 2013 FISCAL
2	YEAR. THE INFORMATION THAT I PROVIDE YOU, THE
3	NUMBERS THAT I PROVIDE YOU, ARE EXPENDITURES THAT
4	HAVE ACTUALLY BEEN RECORDED ON OUR FINANCIAL
5	STATEMENTS. SO THEY DON'T INCLUDE OUR LAGS, AND THE
6	LAGS CAN RUN ANYWHERE FROM FOUR TO \$600,000 A YEAR.
7	SO I JUST WANT TO MAKE YOU AWARE OF THAT.
8	SO FIRST UP, OUR CURRENT YEAR OPERATING
9	EXPENDITURES FOR THE FIRST QUARTER OF THE FISCAL
10	YEAR, WE RECORDED ABOUT \$3 MILLION IN EXPENDITURES
11	IN COMPARISON TO THE PRIOR FISCAL YEAR WHERE WE
12	RECORDED EXPENDITURES OF \$2.7 MILLION FOR THE SAME
13	TIME PERIOD. SO THERE'S REALLY BEEN NO SIGNIFICANT
14	CHANGES.
15	OUR GRANT DISBURSEMENTS FOR THE FIRST
16	QUARTER OF THE 2012-13 FISCAL YEAR WERE \$39 MILLION
17	AS COMPARED TO THE SAME PERIOD IN THE 11-12 FISCAL
18	YEAR, WHICH WERE 56.4, SO WE WERE A BIT HIGHER LAST
19	YEAR.
20	IN LOOKING OVER THE MORE DETAILED
21	EXPENDITURES IN THE NEXT CHART, I DO WANT TO REMIND
22	YOU THAT DURING THE 12-13 FISCAL YEAR BUDGET
23	DEVELOPMENT, WE DID RESTRUCTURE OUR CATEGORIES OF
24	EXPENDITURES TO PROVIDE FOR MORE TRANSPARENCY AND
25	CLARITY AND VISIBILITY IN THE REPORTING OF OUR

1	EXPENDITURES AND HOW WE'RE SPENDING OUR MONEY.
2	LOOKING AT THESE CATEGORIES, AS I SAID EARLIER,
3	THERE REALLY HASN'T BEEN A WHOLE LOT OF CHANGES FROM
4	THIS YEAR AS COMPARED TO LAST FISCAL YEAR. WE HAVE
5	EXPERIENCED SOME SLIGHT INCREASES IN SOME OF OUR
6	CATEGORIES. LIKE, FOR EXAMPLE, IN OUR EMPLOYEE
7	EXPENSES, WE'VE GONE UP A LITTLE BIT, BUT THAT'S
8	ATTRIBUTABLE TO THE FACT THAT WE'VE GONE FROM 47
9	POSITIONS THAT HAVE BEEN FILLED TO 54 DURING THE
10	SAME TIME PERIOD.
11	WE'VE GOT SOME INCREASES IN OUR REVIEWS
12	MEETINGS AND WORKSHOP CATEGORY EXPENDITURE, AND
13	THAT'S DUE TO THE FACT THAT WE'VE HAD AN INCREASED
14	NUMBER OF EVENTS DURING THE FIRST QUARTER OF THIS
15	FISCAL YEAR. ONE AREA WHERE WE DID EXPERIENCE SOME
16	DECREASE IS IN OUR MEMBERSHIP AND TRAINING CATEGORY.
17	AND THAT'S BECAUSE, AS YOU MAY RECALL, LAST YEAR WE
18	PAID FOR PATIENT ADVOCATES AND EARLY CAREER
19	SCIENTISTS TO ATTEND THE WORLD STEM CELL SUMMIT, AND
20	WE DID NOT INCUR THAT COST IN THIS FISCAL YEAR.
21	OTHER FINANCIAL NEWS IS THAT WE'VE JUST
22	CONCLUDED THE 2011-12 ANNUAL FINANCIAL AUDIT. AS
23	YOU KNOW, WE GO THROUGH AN ANNUAL FINANCIAL AUDIT
24	EVERY YEAR, AND THAT WAS CONCLUDED AND SHELLY
25	WALKER-DAVEY FROM MACIAS, GINI, AND O'CONNELL WILL

1	ACTUALLY REPORT THE RESULTS OF THAT AUDIT IN A FEW
2	MINUTES.
3	OUR AVAILABLE CASH AS OF SEPTEMBER 30,
4	2012, IS \$75.6 MILLION, WHICH IS A DECREASE FROM THE
5	LAST TIME I REPORTED OF \$29 MILLION. THIS MONEY IS
6	MADE UP OF MOSTLY COMMERCIAL PAPER AND BOND
7	PROCEEDS.
8	AND THEN, FINALLY, I WANTED TO PROVIDE YOU
9	JUST WITH A VERY HIGH LEVEL AWARDS WELL, I
10	BELIEVE THERE MAY BE SOMETHING IN YOUR BINDER.
11	THERE'S NOT. OKAY. WELL, I WILL THEN JUST VERBALLY
12	TELL YOU ON OUR AWARDS. ACTUALLY DR. OLSON HAS SOME
13	SLIDES THAT SHE WILL BE SHARING WITH YOU AND
14	PROVIDING YOU WITH MORE DETAIL ON OUR AWARDS
15	FORECAST. THEY ARE IN THE BINDER. OKAY.
16	AND SO JUST AT A VERY HIGH LEVEL, I JUST
17	WANTED TO LET YOU KNOW KIND OF WHERE OUR FUNDING
18	WHERE OUR BALANCE OF OUR FUNDING IS. SO IF YOU LOOK
19	AT THE DATA IN YOUR BINDER, IT'S A BAR CHART. IT'S
20	A BAR CHART WITH BLUE, PURPLE, AND GREEN BARS. KIND
21	OF LOOKS LIKE THIS. I APOLOGIZE FOR IT NOT BEING
22	THERE.
23	CHAIRMAN THOMAS: JUST GO AHEAD AND
24	DESCRIBE IT.
25	MS. SILVA-MARTIN: SO LET ME TELL YOU WHAT
	29

1	THIS INCLUDES. SO IF YOU LOOK AT THE BAR CHART, YOU
2	WILL SEE THAT THE BLUE ACTUALLY REPRESENTS WHAT YOU
3	HAVE ACTUALLY AWARDED. THAT'S A PRETTY SIGNIFICANT
4	AMOUNT OF OUR FUNDING. THAT REPRESENTS 60 PERCENT
5	OF THE FUNDING.
6	THE NEXT CATEGORY
7	MS. LANSING: CAN YOU PLEASE GIVE ME A
8	DOLLAR NUMBER BECAUSE I CAN'T FIND THE CHART?
9	MS. SILVA-MARTIN: IT'S APPROXIMATELY \$1.6
10	BILLION. AND THEN THE PURPLE CHART REPRESENTS WHAT
11	YOU'VE COMMITTED, BUT WE HAVEN'T ACTUALLY PUT ANY
12	AWARDS BECAUSE WE'RE STILL GOING THROUGH THE AWARD
13	PROCESS. AND THAT REPRESENTS APPROXIMATELY \$4
14	MILLION AND ABOUT 15 PERCENT. SO, AS YOU CAN SEE,
15	WE'VE ACTUALLY COMMITTED AND AWARDED 75 PERCENT OF
16	OUR FUNDING. SO WHAT WE HAVE LEFT IS WHAT'S IN THE
17	GREEN AREA, WHICH IS ABOUT 25 PERCENT OR \$700
18	MILLION THAT'S AVAILABLE FOR FUNDING.
19	SO I JUST WANTED TO PROVIDE YOU THAT DATA
20	TO ASSIST YOU AS YOU MOVE FORWARD IN MAKING FUNDING
21	DECISIONS.
22	MS. LANSING: WHEN DO WE ACTUALLY RUN OUT
23	OF MONEY, SO TO SPEAK?
24	MS. SILVA-MARTIN: WELL, WE'RE PROJECTING
25	ABOUT 19-20, FISCAL YEAR 2019-20.
	30
	JU

1	CHAIRMAN THOMAS: LET ME JUST CLARIFY THAT
2	A BIT OR ADD OTHER COLOR. I THINK, CHILA, THAT
3	we're anticipating making our last awards in 2017.
4	MS. SILVA-MARTIN: THAT'S CORRECT.
5	CHAIRMAN THOMAS: AS THEY ARE MULTIYEAR
6	AWARDS, THE MONEY WILL ACTUALLY RUN OUT IN 2020,
7	SOMETHING LIKE THAT. THE LAST AWARDS CURRENTLY ARE
8	SLATED FOR 2017
9	MS. SILVA-MARTIN: THAT'S CORRECT.
10	CHAIRMAN THOMAS: IF WE DO NOT HAVE
11	ADDITIONAL SOURCES OF FUNDING AT THAT POINT.
12	MS. LANSING: SO IS THIS AN APPROPRIATE
13	TIME TO ASK WHEN WE WOULD LIKE TO GO BACK INTO AND
14	TRY AND GET ANOTHER BOND OR WHATEVER?
15	CHAIRMAN THOMAS: SHERRY, IT'S J.T. THE
16	ISSUE OF HOW WE'RE GOING TO SUSTAIN OURSELVES IS ONE
17	THAT WE SPEND A LOT OF TIME THINKING ABOUT. WE'RE
18	EVALUATING A BUNCH OF ALTERNATIVES. THAT COULD BE
19	CERTAINLY ONE OF THEM, BUT THERE ARE OTHERS. AND IT
20	IS PROBABLY NOT YET A RIPE DISCUSSION TOPIC.
21	MS. LANSING: OKAY. FINE. I UNDERSTAND.
22	SO THIS IS WORK IN PROGRESS AND SOMEONE WILL REPORT
23	BACK TO US AT THE PROPER TIME.
24	CHAIRMAN THOMAS: YES.
25	MS. LANSING: THANK YOU.
	21

1	MS. SILVA-MARTIN: THIS REALLY CONCLUDES
2	MY PRESENTATION. ARE THERE ANY QUESTIONS?
3	MR. GOLDBERG: CHILA, THANK YOU VERY MUCH.
4	THERE USED TO BE A STANDARD SERIES OF CHARTS THAT
5	WERE USED IN THESE MEETINGS THAT SOME OF US, AT
6	LEAST THIS MEMBER, GOT USED TO. COULD YOU BRING
7	THEM BACK PARTICULARLY BECAUSE THE ONE THAT'S A
8	MULTIYEAR KIND OF CASH FLOW PLANNING KIND OF
9	SUMMARIZES EVERYTHING THAT I THINK IS RELEVANT ON
10	ONE PAGE.
11	MS. SILVA-MARTIN: IS THIS WHAT WE
12	PROVIDED A COUPLE YEARS AGO?
13	MR. GOLDBERG: AS FAR AS I KNOW, WE WERE
14	PROVIDING IT UP UNTIL AUGUST.
15	MS. SILVA-MARTIN: ABSOLUTELY. I'LL BE
16	HAPPY TO DO THAT.
17	MR. GOLDBERG: THANK YOU SO MUCH.
18	CONGRATULATIONS ON YOUR PROMOTION.
19	DR. JUELSGAARD: CHILA, SO WHEN WE WERE
20	BUDGETING A FEW MONTHS AGO, WE WERE PRESENTED WITH A
21	SERIES OF BREAKOUTS OF THOSE BUDGET NUMBERS BY
22	FUNCTIONAL AREAS.
23	MS. SILVA-MARTIN: THAT'S CORRECT.
24	DR. JUELSGAARD: WHAT I THINK WOULD BE
25	INTERESTING TO SEE IS JUST AS A PERCENTAGE AGAINST
	32

ا _ ا	
1	THAT BUDGET WHERE WE STAND FROM QUARTER TO QUARTER
2	AS WE MOVE FORWARD. SO HOW ARE THE DIFFERENT
3	FUNCTIONS LINING UP WITH RESPECT TO WHAT WE BUDGETED
4	THEM TO SPEND? IF WE COULD SEE SOMETHING LIKE THAT,
5	THAT WOULD CERTAINLY BE HELPFUL FOR ME.
6	MS. SILVA-MARTIN: ABSOLUTELY. I CAN PUT
7	THAT TYPE OF REPORT TOGETHER FOR YOU FOR THE NEXT
8	BOARD MEETING.
9	DR. JUELSGAARD: THANK YOU SO MUCH.
10	MS. SILVA-MARTIN: VERY WELCOME.
11	DR. LUBIN: ONE OF THE QUESTIONS THAT I
12	HAD, GIVEN WHAT ALAN PRESENTED AND GIVEN SOME OF
13	THESE REALLY EXCITING RESULTS IN THE BASIC RESEARCH
14	AND EARLY TRANSLATION, I'VE NEVER APPRECIATED A
15	CERTAIN PERCENTAGE OF WHAT WE INVEST IS GOING TO BE
16	IN THOSE AREAS AND THEN THE OTHERS IN DISEASE TEAM
17	AND BIGGER GRANTS. IS THERE A WAY TO TAKE A LOOK AT
18	THAT AGAIN IN TERMS OF THE PROGRESS WE'VE MADE IN
19	EACH OF THOSE AREAS, AND JUST BE SURE WE'RE ON
20	TARGET FOR WHAT WE WANT TO ACCOMPLISH?
21	MS. SILVA-MARTIN: YES, ABSOLUTELY.
22	ACTUALLY DR. OLSON WILL BE PRESENTING THAT LATER ON
23	TODAY.
24	DR. LUBIN: THANK YOU VERY MUCH.
25	CHAIRMAN THOMAS: JUST ALSO LIKE TO REMIND
	33

1	THE BOARD THAT, PER THE SLIDE THAT'S CURRENTLY UP
2	THERE, FOR THOSE OF YOU ON THE PHONE, THIS IS THE
3	ONE THAT TALKS ABOUT AVAILABLE CASH. IT NOTES THAT
4	WE ARE FUNDED BY BOND PROCEEDS AND COMMERCIAL PAPER.
5	WANTED TO REMIND EVERYBODY THAT WE'RE PRINCIPALLY
6	THESE DAYS FUNDED BY COMMERCIAL PAPER AS OPPOSED TO
7	BOND PROCEEDS THROUGH THE DISCUSSIONS THAT WE WORKED
8	OUT WITH THE DEPARTMENT OF FINANCE, THE STATE
9	TREASURER'S OFFICE WHERE WE'RE ABLE TO ACCESS
10	COMMERCIAL PAPER ON VERY SHORT NOTICE TO MEET OUR
11	ONGOING NEEDS AND DON'T NEED TO BE SITTING ON LARGE
12	RESERVES OF BOND PROCEEDS WHICH ARE EARNING LESS
13	THAN THE INTEREST RATE ON THE BONDS AND GENERATING
14	NEGATIVE CARRY TO THE DISADVANTAGE OF THE STATE.
15	SO WE HAVE A VERY EFFICIENT FINANCING
16	PROGRAM IN PLACE. WE HAVE ONGOING DISCUSSIONS WITH
17	THE OFFICES I MENTIONED WHERE WE GIVE THEM UPDATED
18	INFORMATION ON OUR NEEDS FOR THE FORWARD PERIODS AS
19	WE ARE GOING ALONG. I WANT TO SINGLE OUT LYNN
20	HARWELL, WHO'S SORT OF SPEARHEADED THE DISCUSSIONS
21	WITH THE DEPARTMENT OF FINANCE AND THE STATE
22	TREASURER'S OFFICE. SHE AND I HAVE SPENT A LOT OF
23	TIME WITH THOSE FOLKS, AND I THINK WE'RE VERY HAPPY
24	WITH THE FINANCING MECHANISM, WHICH IS A WIN-WIN FOR
25	THE STATE AND FOR US. JUST WANTED TO ADD THAT

1	LITTLE ADDITIONAL COMMENT.
2	ANY OTHER COMMENTS? SHERRY, I HOPE YOU'RE
3	FEELING OKAY.
4	MS. LANSING: I'M SORRY. CAN YOU HEAR ME
5	COUGHING?
6	A LOT OF US WEREN'T ON FOR THE ROLL CALL
7	BECAUSE OF THE FACT THAT THE PHONES WEREN'T WORKING.
8	SO I JUST WANT TO MAKE SURE YOU KNOW THE NUMBER OF
9	US, ABOUT FIVE OF US THAT ARE ON THE PHONE.
10	CHAIRMAN THOMAS: THANK YOU. ANY OTHER
11	COMMENTS ON THE FINANCIAL REPORT? THANK YOU, CHILA.
12	AND THANK YOU, DR. TROUNSON, FOR YOUR PRESIDENT'S
13	REPORT. MOST INTERESTING AS ALWAYS.
14	MS. BONNEVILLE: CAN WE JUST HEAR WHO'S ON
15	THE PHONE.
16	MS. LANSING: SHERRY.
17	MS. BONNEVILLE: DR. LUBIN, ARE YOU ON?
18	CHAIRMAN THOMAS: YES, HE'S ON.
19	MS. BONNEVILLE: IS ANYONE ELSE ON THE
20	LINE? THANK YOU.
21	CHAIRMAN THOMAS: OKAY. ON THE THEME OF
22	FINANCES, WE'RE GOING TO SKIP AN AGENDA DOWN TO NO.
23	18, WHICH IS CONSIDERATION OF THE FINANCIAL AUDIT
24	THAT CHILA MENTIONED FOR FISCAL YEAR 2011 AND 12.
25	WE HAVE WITH US SHELLY WALKER-DAVEY OF MACIAS, GINI
	35

1	& O'CONNELL, WHO'S GOING TO PRESENT THAT REPORT.
2	MS. WALKER-DAVEY: GOOD MORNING. THANK
3	YOU FOR HAVING ME. I'M SHELLY WALKER-DAVEY, AS
4	MENTIONED BEFORE, AND I'M THE ENGAGEMENT MANAGER FOR
5	THE FINANCIAL AUDIT. I SUPERVISE THE PLANNING, THE
6	FIELDWORK, AND THE FINAL REVIEW IN CONCURRENT WITH
7	OUR PARTNERS OF THE FINANCIAL STATEMENTS PREPARED BY
8	MANAGEMENT. I'M HERE TODAY TO PRESENT TO YOU TWO
9	AUDIT PRODUCTS AS A RESULT OF OUR AUDIT. ONE IS THE
10	REPORT TO THE OVERSIGHT COMMITTEE, WHICH WE CALL
11	REPORT TO THE BOARD, WHICH INCLUDES REQUIRED
12	COMMUNICATIONS THAT ARE PROFESSIONAL STANDARDS
13	REQUESTS THAT WE DO AS WELL AS THE FINANCIAL
14	STATEMENT.
15	AND I UNDERSTAND YOU HAVE A LOT OF
16	COMPREHENSIVE BUDGET-TO-ACTUAL AND PROJECTIONS ON
17	FINANCIAL INFORMATION, SO I'M GOING TO MAKE MY
18	PRESENTATION TO THE AUDIT FINANCIAL STATEMENT VERY
19	BRIEF, AND I WILL WRAP UP WITH ANY QUESTIONS ANYBODY
20	MAY HAVE.
21	I'M ASSUMING THESE ARE IN YOUR PACKETS.
22	THE REPORT TO THE INDEPENDENT CITIZENS OVERSIGHT
23	COMMITTEE, WE CALL THIS THE REQUIRED COMMUNICATIONS
24	TO THOSE IN CHARGE OF GOVERNANCE. AND I'M GOING TO
25	START WITH THAT AND JUST BRIEFLY HIGHLIGHT SOME OF

1	THE KEY POINTS. AND IF ANYBODY HAS ANY QUESTIONS,
2	YOU'RE WELCOME TO STOP ME.
3	CHAIRMAN THOMAS: TAB 18 FOR THOSE LOOKING
4	FOR THE DOCUMENTS.
5	MS. WALKER-DAVEY: I'LL GIVE YOU A MINUTE
6	OR TWO. SO IN PLANNING A FINANCIAL AUDIT, WE LOOK
7	AT INTERNAL CONTROLS OF AN ENTITY AND THE DESIGN OF
8	THOSE CONTROLS TO ENSURE THAT THERE ARE NO
9	MISSTATEMENTS IN THE FINANCIAL STATEMENTS. WE DON'T
10	ACTUALLY WE ARE NOT REQUIRED TO TEST AND
11	AUTHENTICATE ALL CONTROLS IF WE DON'T ACTUALLY
12	EXPRESS AN OPINION ON THAT. I WANT TO MAKE THAT
13	CLEAR.
14	IN REVIEWING INTERNAL CONTROL ISSUES, WE
15	LOOK AT A FEW POSSIBLE ERRORS. ONE IS CALLED A
16	SIGNIFICANT DEFICIENCY. ANOTHER IS CALLED MATERIAL
17	WEAKNESS. THAT WOULD IMPLY THAT THERE'S SOMETHING
18	IN THE CONTROL PROCESS IN A MAJOR TRANSACTION CYCLE,
19	SUCH AS DISBURSEMENTS OR RECEIPTS, THAT THERE MIGHT
20	BE ERROR IN THE PROCESS THAT'S NOT CAPTURED BY
21	MANAGEMENT IN THE NORMAL COURSE OF BUSINESS. THAT
22	WOULD BE A DEFICIENCY. OR IF THERE'S A SIGNIFICANT
23	ERROR THAT'S NEVER DISCOVERED AND ONLY SHOWS UP IN
24	THE AUDIT WOULD BE CONSIDERED A MATERIAL WEAKNESS.
25	PLEASED TO SAY WE HAVE NEITHER OF THOSE TYPES OF
	37
	-

1	INSTANCES DURING THE AUDIT. IN ANY CASE, IT'S A
2	MAIN ISSUE.
3	I'M GOING TO MOVE ON TO THE SECOND AND
4	THIRD PAGE OF THE REQUIRED COMMUNICATIONS. AND
5	THESE ARE OUR KEY POINTS OF WHAT WE DO AS PART OF
6	THE AUDIT AND PART OF OUR RESPONSIBILITY AS WELL AS
7	MANAGEMENT'S RESPONSIBILITY. FOR EXAMPLE, ONE THING
8	WE LOOK AT IS ACCOUNTING POLICIES BECAUSE THEY'RE AN
9	INTEGRAL PART OF THE FINANCIAL STATEMENTS. BY AND
10	LARGE ON THE GAP FINANCIAL STATEMENTS, CIRM DOESN'T
11	REALLY HAVE SIGNIFICANT LET ME BACK UP. WE
12	LOOKED AT THE KEY POLICIES. THEY WERE CONSISTENT
13	WITH THE KEY FACTORS. IT LOOKED CONSISTENT FROM THE
14	PRIOR YEAR. WE DIDN'T SEE A MAJOR CHANGE. SOME
15	ENTITIES HAVE ESTIMATES; NAMELY, LIKE, FOR EXAMPLE,
16	DEPRECIATION, BUT BECAUSE IT'S NOT A LARGE DOLLAR
17	AMOUNT, WE DON'T CONSIDER THAT NECESSARILY A
18	SIGNIFICANT ISSUE FOR CIRM, SO THERE AREN'T THAT
19	MANY ESTIMATES THAT MIGHT CAUSE CONCERN.
20	WE'RE PLEASED TO SAY WE HAD NO
21	DIFFICULTIES IN PERFORMING OUR AUDIT. WE
22	OCCASIONALLY HAVE CORRECTED UNCORRECTED
23	MISSTATEMENTS AS PART OF AN AUDIT. THOSE ARE
24	BASICALLY ERRORS WE MIGHT FIND DURING THE COURSE OF
25	THE AUDIT. IF THEY WERE MATERIAL, THEY WOULD APPEAR
	38

1	ON THIS REPORT. SOME OF THEM ARE VERY DE MINIMIS OR
2	IMMATERIAL AND ARE NOT REPORTED. WE'RE PLEASED TO
3	SAY WE DIDN'T HAVE ANY MATERIAL CORRECTIONS AS A
4	RESULT OF THE AUDIT EITHER CORRECTED OR NONCORRECTED
5	BY MANAGEMENT.
6	WE HAD NO DISAGREEMENTS WITH MANAGEMENT
7	DURING THE ENGAGEMENT. ALSO WE REQUEST A MANAGEMENT
8	REPRESENTATION LETTER AT THE END OF EACH ENGAGEMENT
9	BASICALLY DISCLOSING MANAGEMENT'S RESPONSIBILITY FOR
10	THE FINANCIAL STATEMENTS AS WELL AS HAVING DISCLOSED
11	ALL THE REQUIRED MINUTES, CONTRACTS, WHATNOT, AND WE
12	RECEIVED THAT LETTER, AND IT'S DATED OCTOBER 15TH.
13	OCCASIONALLY IT MIGHT BE IN A CASE OF AN
14	AUDIT WHERE MANAGEMENT MIGHT SEEK A SECOND OPINION
15	FROM ANOTHER CPA OR CPA FIRM. THIS MIGHT BE AN
16	INSTANCE WHERE SOMEONE WAS HAVING DIFFICULTIES WITH
17	AN AUDIT, BUT WE DIDN'T HAVE ANY AND WE'RE NOT AWARE
18	OF ANY SUCH COMMUNICATIONS DURING THE COURSE OF OUR
19	AUDIT.
20	OTHER FINDINGS AND ISSUES, OCCASIONALLY WE
21	DISCUSS ACCOUNTING APPLICATION PRINCIPLES AND
22	AUDITING STANDARDS WITH YOUR STAFF OR WITH CHILA,
23	FOR EXAMPLE, BUT THAT'S CONSIDERED A NORMAL PART OF
24	OUR PROFESSIONAL ENGAGEMENT AND DOES NOT HAVE ANY
25	CONDITION ON OUR RETENTION.
	39
	J J

1	FINALLY, WITH OTHER MATTERS, WE DO CERTAIN
2	INQUIRIES OF MANAGEMENT AND EVALUATE THE FORM OF
3	METHOD OF THE SUPPLEMENT INFORMATION. THAT'S MAINLY
4	THE DOLBY GRANT FUND. AND WE CAN RECONCILE THE
5	INFORMATION BACK TO OUR AUDITED FINANCIAL
6	STATEMENTS, AND THEY SEEMED TO BE REASONABLE.
7	SO THAT'S THE REQUIRED COMMUNICATIONS IN A
8	VERY BRIEF FORMAT. I REALIZE IT'S ABOUT A
9	THREE-PAGE DOCUMENT. I DIDN'T WANT TO READ IT
10	VERBATIM THIS MORNING. I KNOW YOU HAVE A LOT TO DO
11	TODAY.
12	I'M GOING TO MOVE ON TO THE FINANCIAL
13	STATEMENTS. THESE ARE GAP FINANCIAL STATEMENTS, AND
14	I'M GOING TO TURN TO PAGE 8. IT'S THE STATEMENT OF
15	NET ASSETS. IT'S BASICALLY THE BALANCE SHEET OF THE
16	ORGANIZATION, AND I'M GOING TO BRIEFLY GO OVER SOME
17	OF THE HIGHLIGHTS OF THAT AS WELL AS THE STATEMENT
18	OF ACTIVITIES AND JUST KEEP IT BRIEF BECAUSE THIS IS
19	A VERY BIRD'S EYE VIEW COMPARED TO THE INFORMATION
20	YOU LOOK AT ON YOUR REGULAR MEETINGS.
21	SO WE'RE PROUD TO ANNOUNCE THAT WE WERE
22	ABLE TO COLLECT ENOUGH EVIDENCE TO RENDER AN
23	UNQUALIFIED OPINION; THAT IS, A CLEAN OPINION ON THE
24	FINANCIAL STATEMENTS. AND AS PART OF OUR AUDIT, WE
25	LOOK AT, OF COURSE, SEVERAL OF THESE LINE ITEMS.

1	NAMELY, THE BIGGEST CHANGE FROM ONE YEAR TO THE
2	NEXT. I'M LOOKING AT THE STEM CELL FUND COLUMN, SO
3	THE FIRST LEFT COLUMN. LOANS RECEIVABLE INCREASED
4	MAINLY BECAUSE THERE WERE MORE NOTES DISTRIBUTED OR
5	MORE DISBURSEMENTS GIVEN OUT AS WELL AS AN INCREASE
6	ON INTEREST RECEIVABLE RELATED TO THOSE NOTES. THE
7	LONGER THOSE NOTES ARE OUTSTANDING, THE MORE THEIR
8	INTEREST IS ACCRETING. SO WOULD EXPECT TO SEE THAT.
9	JUST FROM A GAP PERSPECTIVE, I'M GOING TO
10	MOVE ABOUT MIDWAY DOWN THE LINE TO DEFERRED REVENUE.
11	AND IT'S RELATED TO HOW THE PRESENTATION IS ON A
12	GASB FORMAT. THIS \$24 MILLION NUMBER REPRESENTS THE
13	LOAN RECEIVABLE, INTEREST RECEIVABLE. IT'S OFFSET
14	BECAUSE OF THE WAY THE FUNDS MOVE, INFLOWS AND
15	OUTFLOWS. SO IF ANYBODY QUESTIONS THAT NUMBER,
16	THEY'RE RELATED, AND THEY ARE EFFECTIVELY CANCELED
17	ON THE RECONCILIATION.
18	SO THE BIGGEST CHANGE FROM ONE YEAR TO THE
19	NEXT, OF COURSE, IS THE LOAN RECEIVABLES AND THE
20	RELATED INTEREST RECEIVABLES.
21	MOVING ON TO THE STATEMENT OF ACTIVITIES,
22	THERE WERE SOME GO BONDS REVENUE RECEIVED OF \$50
23	MILLION. THERE WAS ONE LOAN THAT WAS REPAID OR
24	RETURNED BECAUSE THERE WERE SOME CONDITIONS RELATED
25	TO THAT LOAN THAT WERE BEING REASSESSED. THE MONEY

1	WAS RETURNED SO THE RECIPIENT DIDN'T INCUR ANY
2	ADDITIONAL INTEREST. THAT'S WHAT THAT COLLECTIONS
3	ON LOANS REPRESENTS. THERE WAS A SMALL AMOUNT OF
4	INTEREST RELATED TO THAT TIME WHEN THEY HELD THAT
5	NOTE THAT WAS REPAID.
6	AND THEN THE FINAL THING IS THE
7	INVESTMENTS ON EARNINGS IS CONSIDERABLY HIGHER FROM
8	LAST YEAR BECAUSE THERE WAS A LEGAL DETERMINATION
9	MADE DURING THE YEAR THAT THE INTEREST ON THE SMITH
10	ACCOUNT, THE MAIN CASH ACCOUNT, IT WAS INITIALLY
11	INTERPRETED AS BEING DUE BACK TO THE GENERAL FUND,
12	THE STATE'S GENERAL FUND. THERE WAS A LEGAL
13	DETERMINATION THAT IT IS NO LONGER REQUIRED TO BE
14	GIVEN BACK TO THE GENERAL FUND. IN FACT, IT BELONGS
15	TO CIRM. SO THERE'S ABOUT A \$1.7 MILLION DOLLAR
16	INCREASE IN THAT THAT IS PULLED INTO THE CIRM
17	ORGANIZATION.
18	MOVING DOWN TO EXPENSES, STATE OPERATIONS
19	ARE FAIRLY CONSISTENT FROM LAST YEAR. GRANTS AND
20	RESEARCH GRANTS HAVE INCREASED MAINLY BECAUSE OF THE
21	MULTIYEAR GRANTS AND EXPENDITURES RELATED TO THAT
22	ASPECT OF WHAT YOU DO.
23	AND THEN I'M GOING TO TURN BRIEFLY TO PAGE
24	10. IT'S THE BUDGET-TO-ACTUAL COMPARISON. I KNOW
25	THERE WAS SOME DISCUSSION ABOUT THIS WHEN WE WERE
	42

1	PREPARING THE FINANCIAL STATEMENTS. I JUST WANT TO
2	CLARIFY. WHEN WE ARE LOOKING AT THIS AT A GAP
3	PERSPECTIVE, THE ACTUAL EXPENDITURES ARE REFLECTED
4	ON THE PREVIOUS PAGE ON THE STATEMENT OF ACTIVITIES,
5	BUT THE BUDGET IS SLIGHTLY DIFFERENT. SO IT LOOKS
6	LIKE THERE'S A POSITIVE BUDGET AMOUNT OF \$52
7	MILLION, BUT THAT'S NAMELY A TIMING ISSUE. THERE
8	ARE LAGS OR DIFFERENT AWARDS ARE IN PROCESS, SO IT
9	MAY NOT ALIGN TO WHAT YOU'RE LOOKING AT WHEN YOU'RE
10	LOOKING AT YOUR QUARTERLY REVIEW. THIS IS BASICALLY
11	A SNAPSHOT OF WHAT WAS HAPPENING ON JUNE 30, 2012.
12	I JUST WANTED TO CLARIFY THAT BECAUSE THAT CAME UP
13	AS WE WERE FINALIZING THE REPORT.
14	AND I'M NOT GOING TO GO INTO THE NOTES TOO
15	MUCH BECAUSE THEY'RE FAIRLY CONSISTENT FROM LAST
16	YEAR. UNLESS SOMEONE HAS SOMETHING SPECIFIC TO ASK,
17	I WOULD LIKE TO COMPLETE MY PRESENTATION AND SAY
18	THANK YOU FOR LETTING US SERVE AS YOUR AUDITORS.
19	DOES ANYBODY HAVE ANY QUESTIONS?
20	CHAIRMAN THOMAS: ANY QUESTIONS FOR
21	SHELLY?
22	DR. JUELSGAARD: YES, SHELLY. SO ON THE
23	BALANCE SHEET PORTION OF YOUR PRESENTATION. SO I'M
24	AWARE THAT CIRM HOLDS CERTAIN WARRANTS ISSUED BY
25	COMPANIES, PUBLIC OR PRIVATE, IN ASSOCIATION WITH
	43
	T

1	CERTAIN FUNDING ARRANGEMENTS. ARE THOSE SHOWN ON
2	THE BALANCE SHEET PRESENTATION ANYWHERE?
3	MS. WALKER-DAVEY: WHEN YOU'RE SAYING
4	WARRANTS, ARE YOU REFERRING TO ACTUAL DISBURSEMENTS
5	OR COMMITMENTS?
6	DR. JUELSGAARD: I'M REFERRING TO WARRANTS
7	THAT WOULD BE CONVERTIBLE INTO STOCK. SO WARRANTS
8	TO PURCHASE STOCK AT A FIXED PRICE.
9	MS. WALKER-DAVEY: IT HAS NOT ACTUALLY
10	TRANSPIRED. I BELIEVE THAT'S REALLY TO ONE OF THE
11	NOTES, NOTES RECEIVABLES, SOME SORT OF COLLATERAL.
12	DR. JUELSGAARD: I THINK WE HAVE ACTUAL
13	WARRANTS IN HAND, IF I'M NOT MISTAKEN.
14	MS. WALKER-DAVEY: I DON'T THINK THEY'RE
15	DISCLOSED. IF THEY HAVE A DOLLAR VALUE, WE CAN
16	CERTAINLY REVIEW AND SEE IF THAT'S MATERIAL.
17	DR. JUELSGAARD: THEY DON'T APPEAR IN HERE
18	AND YOU'RE NOT AWARE THAT WE HOLD THOSE?
19	MS. WALKER-DAVEY: I AM AWARE THAT THERE'S
20	SOME RELATED TO ONE OF THE NOTES. I CAN'T REMEMBER
21	THE NAME OF THE ORGANIZATION THAT HAD SOME STOCK
22	HOLDING RELATED TO IT. I DIDN'T KNOW IF IT
23	TRANSPIRED OR NOT. WE CAN LOOK AT THAT AND SEE IF
24	IT'S MATERIAL, BUT IT DOESN'T SOUND LIKE IT WOULD
25	BE.

I	
1	DR. JUELSGAARD: NO, I'M NOT SURE THAT
2	IT'S MATERIAL, BUT I DIDN'T SEE ANYTHING LISTED
3	HERE. THAT ANSWERED MY QUESTION. THANKS.
4	MS. BAUM: JUST TO CLARIFY, WE HOLD
5	WARRANTS, NOT STOCK.
6	MS. WALKER-DAVEY: RIGHT. SO IT MAY NOT
7	BE IT MAY BE AN OPTION LIKE A COMMITMENT, BUT NOT
8	ACTUALLY A DOLLAR VALUE AT THIS POINT.
9	DR. JUELSGAARD: WELL, WARRANTS DO
10	TYPICALLY HAVE A VALUE, A BLACK-SCHOLES VALUE, THAT
11	YOU CAN DETERMINE FROM THEM.
12	MS. WALKER-DAVEY: BLACK-SCHOLES IS
13	RELATED TO FASB 157, AND THAT'S A FASB PRESENTATION.
14	THIS IS A GASB PRESENTATION. SO I'D HAVE TO SEE
15	MORE INTO WHAT THE DOLLAR VALUE IS TO DETERMINE
16	WHETHER IT SHOULD HAVE BEEN INCLUDED. MAYBE IF IT'S
17	SOMETHING THAT'S ONGOING, IT COULD BE ADDED TO THE
18	MDNA GOING FORWARD TO DISCLOSE WHAT IT IS.
19	DR. JUELSGAARD: I JUST WAS CURIOUS WHAT
20	THE VALUE WAS.
21	MS. WALKER-DAVEY: I'M NOT AWARE OF IT, SO
22	WE'LL HAVE TO FIND OUT FROM MANAGEMENT.
23	MR. JUELSGAARD: THANK YOU.
24	CHAIRMAN THOMAS: ANY OTHER QUESTIONS FOR
25	SHELLY? OKAY. THANK YOU. IT'S ALWAYS GREAT TO
	<i>1</i> E

45

1	HAVE AN UNQUALIFIED AUDIT. CONGRATULATIONS TO CHILA
2	AND OTHERS INVOLVED IN STEWARDING OUR FINANCES.
3	WE'RE VERY HAPPY TO GET THAT REPORT AND APPRECIATE
4	YOUR WORK ON THIS. SO THANK YOU VERY MUCH.
5	MS. WALKER-DAVEY: THANK YOU VERY MUCH.
6	CHAIRMAN THOMAS: WE'RE NOW GOING TO
7	REVERT BACK TO ITEM NO. 6, CONSIDERATION OF
8	APPLICATIONS FOR THE STRATEGIC PARTNERSHIP I AWARDS.
9	DR. OLSON.
10	DR. OLSON: NO, I AM NOT IMMEDIATELY GOING
11	TO GO INTO THE STRATEGIC PARTNERSHIP AWARDS, BUT
12	WHAT I AM GOING TO DO IS GIVE YOU AN UPDATE ON RFA
13	FUNDING AWARDED CONCEPTS IN FUTURE. AND YOU MAY
14	RECALL THAT AT OUR MARCH MEETING THIS YEAR, WE
15	DISCUSSED WITH THE BOARD AN RFA STRATEGIC FUNDING
16	PROPOSAL, WHICH, FOLLOWING THAT DISCUSSION, WAS
17	INCORPORATED INTO THE STRATEGIC PLAN THAT WAS
18	APPROVED BY THE BOARD AT THEIR MAY MEETING.
19	AT THAT TIME WE ALSO AGREED WITH THE BOARD
20	THAT IT WOULD BE A GOOD IDEA TO UPDATE THE BOARD
21	PERIODICALLY ON THE STATUS OF THAT STRATEGIC RFA
22	FUNDING. AND WE LAST DID SO IN AUGUST OF THIS YEAR
23	AT OUR TELEPHONIC MEETING WHEN WE ASKED YOU TO
24	APPROVE THE CONCEPT FOR THE ET IV PROGRAM, AND WE
25	USED THAT AS AN OPPORTUNITY. WHENEVER WE APPROVE A

CONCEPT, WE THOUGHT IT WOULD BE A GOOD TIME TO
UPDATE.
SO THAT'S WHAT I WOULD LIKE TO DO NOW
PRIOR TO YOUR CONSIDERATION OF THE SP I PROGRAM AS
WELL AS OTHER CONCEPTS PROPOSED AT THIS MEETING.
I JUST WANT TO LET YOU KNOW THAT ACTUALLY
AS OF AUGUST, WHICH WAS THE LAST TIME WE TALKED
ABOUT THIS, WE HAD AWARDED \$1.5 BILLION. THIS BOARD
HAD APPROVED FUNDING FOR \$1.5 BILLION. AS OF THIS
MONTH THAT NUMBER IS \$1.622 BILLION. AND YOU CAN
SEE THAT IN THE NEXT SLIDE.
BUT I'D LIKE TO HIGHLIGHT FOR YOU WHAT ARE
THE ELEMENTS THAT GO INTO THAT. SO IT DOES INCLUDE
THE 63 MILLION ADDITIONAL FUNDING THAT WAS APPROVED
BY THIS BOARD FOR THE DISEASE TEAM THERAPY
DEVELOPMENT AWARDS AT ITS 9/12 MEETING. IT ALSO
INCLUDES THE BALANCE SORRY. IT ALSO INCLUDES THE
BASIC BIOLOGY AWARDS, 38 MILLION IN BASIC BIOLOGY
AWARDS, THAT, AGAIN, WERE APPROVED BY THIS BOARD AT
THEIR SEPTEMBER BOARD MEETING. IT ASSUMES THAT THE
19.4 MILLION THAT WERE RECOMMENDED BY THE GRANTS
WORKING GROUP AND ARE SUBJECT TO DECISION BY THIS
BOARD FOLLOWING THIS PRESENTATION IS ALSO INCLUDED
IN THAT. SO IT ASSUMES THAT THOSE WOULD BE AWARDED.
IN AUGUST AS WELL WHAT WE HAD WAS IN THE
47

	-
1	CONCEPT APPROVED, THAT IS, CONCEPTS THAT HAVE BEEN
2	APPROVED BY THIS BOARD, WE HAVE 335 MILLION. AS OF
3	NOW, I'M MAKING AN ASSUMPTION, IT'S 423 MILLION.
4	AND BASICALLY WHAT THAT DOES IS WE TOOK OUT THE
5	MONEY THAT YOU HAD AS CONCEPT FOR THE BASIC BIOLOGY
6	PROGRAM, WHICH YOU APPROVED BEFORE, WE TOOK OUT THE
7	SP I MONEY, AND NOW I'M, AGAIN, MAKING THE
8	ASSUMPTION THAT THE DISEASE TEAM III CONCEPT
9	PROPOSAL WOULD BE APPROVED, MAKING THE ASSUMPTION
10	THAT THE SP II WOULD BE APPROVED. THOSE HAVE COME
11	OUT. THOSE WOULD MOVE INTO THE CONCEPT CATEGORY AND
12	EXPLAINS THAT.
13	IF YOU LOOK AT THIS PIE CHART, WHAT IT
14	SHOWS YOU IS THE DISTRIBUTION NOW OF AWARDED FUNDS.
15	AND WHAT YOU CAN SEE, AND THE CATEGORIES, I WILL
16	REMIND YOU, ARE FACILITIES CORE RESOURCES, WHICH IS
17	ROUGHLY THIS BOARD HAS APPROVED FUNDING OF \$340
18	MILLION OR WE HAVE AWARDED FUNDS OF 340 MILLION OR
19	ROUGHLY 21 PERCENT. TRAINING AND CAREER
20	DEVELOPMENT, ROUGHLY 320 MILLION. SO THEY'RE ALL
21	VERY COMPARABLE. DEVELOPMENT IS STARTING TO GROW A
22	BIT BECAUSE, AS WE'VE DISCUSSED BEFORE WITH THE
23	BOARD, DEVELOPMENT PROGRAMS ARE INHERENTLY MORE
24	EXPENSIVE, AND IT'S ALSO IN CONTEXT OF OUR MISSION
25	OF MOVING THINGS INTO THE CLINIC. SO WE'LL BE

1	SEEING INCREASES IN OUR DEVELOPMENT FUNDING AS WE
2	MOVE FORWARD.
3	THIS IS PARTICULARLY NOTICEABLE IF YOU
4	LOOK AT IN THE CONCEPT, IN THE DISTRIBUTION OF FUNDS
5	IN THE CONCEPT. AND I ALREADY INDICATED TO YOU THAT
6	AS OF MAKING THE ASSUMPTIONS I DID ABOUT
7	APPROVALS OF CONCEPTS THAT ARE COMING FORWARD TO YOU
8	AT THIS MEETING, YOU CAN SEE THAT THE ALLOCATION TO
9	DEVELOPMENT IS BECOMING A SIGNIFICANT PIECE, AT
10	LEAST IN WHAT YOU'VE SAID WE WILL BE IN THE RFA'S
11	WE ARE PROPOSING TO YOU.
12	SO FINALLY, I JUST WANTED TO REMIND YOU
13	THAT WE HAVE NOW AS OF AUGUST, WHEN I LAST PRESENTED
14	IT TO YOU, WE HAD 881 MILLION THAT WAS FUTURE
15	FUNDING THAT WE HAVE MODELS FOR. THAT ALSO INCLUDES
16	THE UNALLOCATED PIECE. NOW WE WOULD HAVE, ASSUMING,
17	AGAIN, THE CONCEPT PROPOSALS THAT ARE COMING FORWARD
18	TO YOU TODAY, ROUGHLY 682 MILLION AS OF THIS POINT.
19	SO I JUST WANT TO LEAVE YOU WITH THAT WE
20	ARE IMPLEMENTING ON THE FUNDING STRATEGY THAT WAS
21	PUT FORTH AND APPROVED BY THIS BOARD AT THE MAY
22	MEETING. AND THE UNALLOCATED FUNDS, WHICH IS A
23	THE UNALLOCATED FUNDS, WHICH IS 56 MILLION, BUT THAT
24	ALSO, DON'T FORGET, THERE'S ABOUT 661 TOTAL THAT IS
25	FUTURE FUNDING THAT IS LEFT TO BE APPROVED EITHER IN

1	CONCEPT AND THEN FUNDED. IF THERE ARE ANY
2	QUESTIONS, I'M HAPPY TO ANSWER THEM.
3	DR. LUBIN: I HAD A QUESTION ABOUT THE
4	BASIC RESEARCH PIE CHART. I FORGOT WHICH ONE OF THE
5	SLIDES YOU HAD, BUT IT WENT DOWN 11 PERCENT. YOU
6	HAVE THE RIGHT ONE UP NOW. AND IT WAS 17 BEFORE.
7	THAT WAS A DECISION WE MADE, OR THAT'S WHAT HAPPENED
8	AFTER ALL WAS SAID AND DONE WITH AWARDS?
9	DR. OLSON: NO. NO. IT'S NOT GOING
10	DOWN. THERE'S A DIFFERENCE THE PIE CHART, THAT
11	GRAPH SLIDE YOU WERE LOOKING AT, SLIDE 4, THE PIE
12	CHART ON THE LEFT IS ALREADY FUNDED PROGRAMS.
13	DR. LUBIN: I UNDERSTAND.
14	DR. OLSON: SO THE PIE CHART ON THE RIGHT
15	IS JUST THOSE PROGRAMS THAT ARE CONCEPT APPROVED.
16	SO I THINK PROBABLY WHAT WOULD BE CLEARER TO YOU
17	GOING FORWARD IS I SHOULD PUT IN TOTALS SO THAT YOU
18	CAN SEE WHEN WE ADD THEM ALL TOGETHER HOW IT COMES
19	UP. THE BASIC RESEARCH, THERE'S NO QUESTION, THE
20	FUNDING FOR THAT TENDS TO BE IN THE 30 TO \$35
21	MILLION RANGE. A GIVEN PROGRAM, WE RUN ROUGHLY ONE
22	OF THOSE A YEAR. THE DEVELOPMENT WE RUN THERE'S
23	JUST MORE MONEY INTO IT. SO AS A PERCENTAGE. AND
24	THE CONCEPT APPROVED WILL CHANGE. IT'S WHAT WE
25	HAVE. WE'RE EITHER OPEN FOR RFA'S, HAS BEEN TO
	Γ0
	50

1	GRANTS WORKING GROUP, BUT HAS NOT YET COME TO THE
2	BOARD FOR ACTUAL FUNDING DECISIONS.
3	SO I DON'T THINK IT'S REALLY A GOOD
4	MEASURE OF THE PERCENTAGE OF MONEY THAT IS GOING TO
5	THE BASIC RESEARCH. IT IS A MEASURE OF WHAT THIS
6	BOARD HAS CURRENTLY APPROVED AT THE MOMENT FOR
7	FUNDING TO THAT CATEGORY. BUT THAT IS TOTALLY
8	CONSISTENT WITH OUR PLAN.
9	DR. LUBIN: THAT RELATED TO MY QUESTION
10	EARLIER IN TODAY'S PRESENTATION. I GUESS THE BOARD
11	FEELS COMFORTABLE WITH THIS? I MEAN I WAS
12	CONSIDERING WHAT ALAN HAD PRESENTED AS THE
13	SIGNIFICANT FINDINGS IN HIS MOST RECENT, BUT ALL OF
14	HIS PRESENTATIONS, AND THOSE COULD READILY BE
15	CLASSIFIED AS BASIC RESEARCH THINGS. AND THEY'RE
16	EXTREMELY EXCITING, AND I JUST DIDN'T WANT US TO
17	LOSE SIGHT OF THAT IN TERMS OF OUR PRIORITIZATION
18	FOR THE FUNDING THAT WE PROVIDE.
19	DR. OLSON: THERE WAS QUITE A DISCUSSION
20	AT THE PREVIOUS MEETINGS, AND I THINK THE BOARD WAS
21	COMFORTABLE AT THAT POINT WITH THE ALLOCATION TO
22	BASIC RESEARCH. I KNOW THAT WE WILL BE COMING TO
23	THIS BOARD AGAIN IN, I BELIEVE, DECEMBER WITH
24	ANOTHER PROPOSAL FOR A BASIC BIOLOGY PROGRAM. SO AT
25	THAT POINT THE AMOUNT OF MONEY, ASSUMING, AGAIN,

1	THAT THE BOARD AGREES TO THE CONCEPT, THAT AMOUNT
2	WOULD INCREASE. WE ARE COMMITTED AT THIS POINT AND
3	WE HAVE IN OUR FUTURE FUNDING STRATEGY, WE HAVE A
4	COMMITMENT TO FUNDING AT LEAST ONE BASIC RESEARCH
5	PROGRAM A YEAR.
6	DR. LUBIN: THANK YOU.
7	CHAIRMAN THOMAS: MR. SHEEHY.
8	MR. SHEEHY: THANK YOU, DR. OLSON. I HAD
9	ONE QUESTION. SO AS OUR DISEASE TEAM PROJECTS GET
10	ADJUSTED, AS THEY ARE MAKING OR NOT MAKING THEIR
11	MILESTONES, ARE THOSE ADJUSTMENTS REFLECTED IN THIS?
12	DR. OLSON: THOSE ADJUSTMENTS WILL BE
13	REFLECTED HERE.
14	MR. SHEEHY: SO ARE THEY IN THE
15	UNALLOCATED RIGHT NOW?
16	DR. OLSON: YES. ADJUSTMENTS WOULD GO
17	INTO THE UNALLOCATED CATEGORY.
18	MR. SHEEHY: MAYBE IT MIGHT BE HELPFUL TO
19	GET A LINE ON THAT. I THINK IT'S IMPORTANT TO
20	LET YOU WERE THERE YESTERDAY, DR. OLSON. I THINK
21	DR. LUBIN MADE THE IMPORTANT POINT THAT IT'S GOOD TO
22	LET PEOPLE KNOW HOW CAREFULLY WE'RE STEWARDING THE
23	TAXPAYERS' MONEY. THESE AWARDS, THEY LOOK GIGANTIC
24	GOING OUT, BUT THERE'S VERY HARD, CRISP MILESTONES
25	THAT STAFF IS DOING A GOOD JOB WITH THEIR GO/NO-GO
	52

1	DECISIONS, THE CDAP PROCESS, IN MAKING SURE THOSE
2	MILESTONES ARE HIT. WHEN THAT DOESN'T HAPPEN AND
3	THAT MONEY RETURNS, MAYBE THIS IS A GOOD PLACE TO
4	SHOW THAT.
5	DR. OLSON: THE UNALLOCATED BASICALLY ALSO
6	INCLUDES FUNDS THAT AREN'T USED FROM CONCEPT
7	APPROVED PROGRAMS. SO IF YOU HAVE A CONCEPT THE
8	EARLY TRANSLATION IS A GOOD EXAMPLE TOO WHERE WE
9	DIDN'T USE ALL THE MONEY. BUT WE CAN TRY AND
10	HIGHLIGHT THAT OR FIGURE OUT THE WAY TO HIGHLIGHT
11	THAT. THERE ARE ADJUSTMENTS ALL THE TIME IN THE
12	ACTUAL DOLLARS THAT ARE SPENT VERSUS. BUT YES.
13	MR. SHEEHY: JUST A THOUGHT. THANK YOU.
14	DR. OLSON: ARE THERE FURTHER QUESTIONS?
15	THANK YOU.
16	CHAIRMAN THOMAS: DR. CARAS WILL NOW, I
17	BELIEVE, PRESENT THE STRATEGIC PARTNERSHIP AWARD.
18	DR. FEIGAL: I'M JUST GOING TO START OUT.
19	I JUST WANTED TO START WITH A LITTLE BIT OF AN
20	INTRODUCTION BECAUSE THE NEXT THREE PRESENTATIONS
21	THAT YOU ARE GOING TO HEAR IS SETTING OUT OUR KEY
22	INITIATIVES FOR BRINGING AND ADVANCING THE STEM CELL
23	SCIENCE INTO CLINICAL TRIALS TO BRING THESE
24	THERAPEUTIC APPROACHES TO PATIENTS.
25	THIS IS A KEY PART OF OUR FIVE-YEAR
	53
	33

1	STRATEGIC PLAN THAT THE BOARD HAS DISCUSSED
2	EXTENSIVELY IN PRIOR DISCUSSIONS AND AGREED TO AT
3	YOUR MAY ICOC BOARD. SO I JUST WANTED TO START OUT
4	THAT WE ARE ABSOLUTELY DELIGHTED TO BE BRINGING YOU,
5	AND DR. CARAS WILL DO SO IN A MINUTE, THE
6	RECOMMENDATIONS FROM THE ROBUST PEER REVIEW FROM OUR
7	GRANT REVIEW GROUP OF THIS STRATEGIC PARTNERSHIP
8	FUNDING INITIATIVE.
9	AND THIS IS THE FIRST ROUND OF AN
10	INITIATIVE THAT WAS SPECIFICALLY GEARED TO INDUSTRY
11	WITH HAVING TWICE PER YEAR SOLICITATIONS. SO IT
12	WOULD BE TWO TIMES MORE THAN WHAT WE DO FOR
13	CONVENTIONAL RFA'S. IT IS TWICE AS RAPID. WE TURN
14	AROUND FROM SOLICITATION TO REVIEW TO COMING TO THE
15	BOARD, IT'S TWICE AS FAST AS OUR CONVENTIONAL RFA'S,
16	AND THERE'S ALSO TWICE AS MANY OPPORTUNITIES FOR
17	INDUSTRY NOW TO BE ABLE TO COME IN AND ACCESS CIRM
18	FUNDING.
19	SO THIS WAS DEFINITELY FELT TO BE A NEED
20	THAT THE AGENCY NEEDED TO DO IN ORDER TO ENTICE AND
21	ENCOURAGE AND ENGAGE WITH INDUSTRY SO THAT WE COULD
22	ACTUALLY FORGE AHEAD WITH CIRM'S MISSION, WHICH, AT
23	THE END OF THE DAY, IS TO ADVANCE THIS SCIENCE INTO
24	THERAPEUTIC APPLICATIONS FOR PATIENTS. THAT'S WHY
25	WE'RE HERE.

-	
1	SO AT THIS POINT I THINK YOU KNOW WE'VE
2	ALREADY MADE LOTS OF ADVANCES IN OUR TRANSLATIONAL
3	AND OUR DEVELOPMENT PORTFOLIO. OF THE NUMEROUS
4	AWARDS WE HAVE TO DATE, WE HAVE ABOUT 75 THAT ARE
5	TERMED TRANSLATIONAL. AS YOU KNOW, IN 2010 WE HAD
6	THE FIRST COHORT OF DISEASE TEAMS. AND YOU HEAR
7	ABOUT THEM PERIODICALLY FROM OUR PROGRESS UPDATES TO
8	YOU. YOU WILL HEAR OUR NEXT UPDATE IN THE FIRST
9	QUARTER OF NEXT YEAR.
10	IN ADDITION, YOU RECENTLY APPROVED, BOTH
11	AT YOUR JULY AND AT THE SEPTEMBER BOARD MEETING, 11
12	NEW DISEASE TEAMS. SO IN TOTAL WE HAVE 25 GOING
13	DOWN THE PATH TO FILE THAT IND WITH THE FDA TO ENTER
14	FIRST-IN-HUMAN CLINICAL TRIALS AND NOW ACTUALLY TO
15	COMPLETE THE CLINICAL TRIALS. SO WE'RE VERY PLEASED
16	TODAY TO PRESENT THE FIRST ROUND TO YOU. AND IT'S
17	GOING TO BE DR. INGRID CARAS.
18	MS. LANSING: CAN SOMEBODY PLEASE JUST
19	TELL ME, BECAUSE I DON'T HAVE THE SHEET, WHICH ONES
20	I'M RECUSED FROM?
21	MR. HARRISON: WE WILL E-MAIL THE SHEET TO
22	YOUR STAFF.
23	MS. LANSING: THANK YOU. THAT'S ALL I
24	NEED. THANKS.
25	DR. CARAS: GOOD MORNING. SO I'M GOING TO
	55

1	TALK ABOUT RFA 12-05, STRATEGIC PARTNERSHIP I
2	AWARDS. SO JUST AS A REMINDER, THE PURPOSE OF THE
3	SP INITIATIVE IS TO ATTRACT INDUSTRY ENGAGEMENT AND
4	INVESTMENT IN CIRM-FUNDED STEM CELL RESEARCH. AND
5	THE INTENTION OF THIS IS TO PROVIDE A SOURCE OF
6	CO-FUNDING IN THE EARLY STAGES OF DEVELOPMENT.
7	SECOND, TO ENHANCE THE LIKELIHOOD THAT CIRM-FUNDED
8	PROJECTS WILL OBTAIN FOLLOW-ON FINANCING FOR THE
9	LATER STAGES OF DEVELOPMENT; AND, THIRD, ENABLE
10	CIRM-FUNDED PROJECTS TO ACCESS THE EXTENSIVE
11	DEVELOPMENT EXPERIENCE THAT EXISTS WITHIN LARGE
12	BIOTECH AND PHARMA PARTNERS.
13	SO THIS INITIATIVE HAS TWO UNIQUE FEATURES
14	THAT SET IT APART FROM SOME OF THE OTHER CIRM
15	PROGRAMS. FIRST, IT REQUIRES APPLICANTS TO SHOW
16	THAT THEY HAVE FINANCIAL CAPACITY TO MOVE THE
17	PROJECT THROUGH DEVELOPMENT OR THAT THEY'RE ABLE TO
18	ATTRACT THE CAPITAL TO DO SO. AND THIS CAN BE
19	EVIDENCED BY ONE OR MORE OF THE FOLLOWING:
20	INVESTMENTS FROM A VARIETY OF NON-CIRM SOURCES,
21	SIGNIFICANT LIQUID ASSETS, AND/OR A DEVELOPMENT
22	AGREEMENT WITH A LARGE PHARMA OR BIOTECH COMPANY
23	THAT'S COMMITTED TO MOVE THE CANDIDATE THERAPEUTIC
24	THROUGH DEVELOPMENT PROVIDED THAT MILESTONES ARE
25	MET.

56

1	AND THE SECOND UNIQUE FEATURE IS THAT THIS
2	INITIATIVE REQUIRES APPLICANTS TO PROVIDE CO-FUNDING
3	FOR THE PROPOSED PROJECT IN THE FORM OF A ONE-TO-ONE
4	MATCH.
5	SO JUST SOME BACKGROUND. THE STRATEGIC
6	PARTNERSHIP INITIATIVE WAS APPROVED BY THIS BOARD IN
7	OCTOBER OF 2011 AND AMENDED IN SEPTEMBER OF THIS
8	YEAR. THE CURRENT CONCEPT DIRECTS CIRM TO IMPLEMENT
9	THE INITIATIVE USING AN RFA PROCESS. AND AS DR.
10	FEIGAL ALREADY MENTIONED, THE INTENT IS TO DO THIS
11	FAIRLY FREQUENTLY EVERY SIX TO NINE MONTHS,
12	APPROXIMATELY TWICE YEARLY.
13	RFA 12-05, STRATEGIC PARTNERSHIP I, IS THE
14	FIRST SOLICITATION UNDER THIS INITIATIVE. AND THE
15	AWARD AMOUNT WAS UP TO \$10 MILLION PER AWARD.
16	THIS DIAGRAM SHOWS WHERE STRATEGIC
17	PARTNERSHIP I FITS ALONG THE RESEARCH SPECTRUM
18	THAT'S FUNDED BY CIRM, AS WELL AS IN RELATION TO
19	SOME OF THE OTHER CIRM PROGRAMS. AND AS YOU CAN
20	SEE, SP I IS DESIGNED TO CAPTURE MATURE PROGRAMS
21	THAT ARE CLOSE TO OR ALREADY AT THE EARLY CLINICAL
22	DEVELOPMENT STAGE.
23	THE OBJECTIVE OF AN SP I AWARD IS
24	COMPLETION WITHIN FOUR YEARS OF AN EARLY STAGE
25	CLINICAL TRIAL. THE PROPOSED PROJECT CAN INCLUDE

1	PRECLINICAL IND-ENABLING WORK, BUT ALL APPLICANTS
2	MUST BE ABLE TO, IN ADDITION, COMPLETE A CLINICAL
3	TRIAL WITHIN THE FOUR-YEAR AWARD PERIOD.
4	SO, AGAIN, AS DR. FEIGAL ALREADY
5	MENTIONED, STRATEGIC PARTNERSHIP I IS, THUS, ALIGNED
6	WITH CIRM'S FIVE-YEAR STRATEGIC GOAL, WHICH IS TO
7	ATTRACT INDUSTRY ENGAGEMENT AND INVESTMENT IN
8	CIRM-FUNDED STEM CELL RESEARCH, AND IT'S ALSO
9	ALIGNED WITH CIRM'S FIVE-YEAR STRATEGIC CLINICAL
10	OBJECTIVE, WHICH IS TO ADVANCE STEM CELL SCIENCE
11	INTO CLINICAL TRIALS TO ACHIEVE THERAPEUTIC BENEFIT
12	TO PATIENTS.
13	THIS SHOWS ACTIVITIES THAT ARE IN SCOPE
14	UNDER THIS AWARD. THEY INCLUDE IND-ENABLING
15	ACTIVITIES TO SUPPORT A FIRST-IN-HUMAN CLINICAL
16	STUDY. IT ALSO INCLUDES ALL ACTIVITIES THAT WOULD
17	BE NECESSARY TO INITIATE AND COMPLETE AN EARLY
18	CLINICAL TRIAL. AND BY EARLY WE MEAN PHASE I, PHASE
19	I/II, OR A PHASE II.
20	IN ADDITION, IT WILL FUND SUPPORTING
21	ACTIVITIES TO ENABLE THE CLINICAL TRIAL. AN EXAMPLE
22	MIGHT BE THE MANUFACTURE OF THE CANDIDATE PRODUCT TO
23	CONDUCT THE TRIAL.
24	THESE ARE THE REVIEW CRITERIA. FIRST,
25	SIGNIFICANCE AND IMPACT. SECOND, THE RISK BENEFIT
	58
	Ju

1	ASSESSMENT FOR THE PROPOSED THERAPEUTIC IN THE
2	TARGET DISEASE. THIRD, DESIGN AND FEASIBILITY OF
3	THE PROPOSED PLAN. AND THIS INCLUDES THE
4	PRECLINICAL PLAN, THE MANUFACTURING STRATEGY, AND,
5	VERY IMPORTANT, THE DESIGN AND FEASIBILITY OF THE
6	PROPOSED CLINICAL TRIAL. FOUR IS THE EXPERIENCE AND
7	TRACK RECORD OF THE PI AND THE TEAM. AND FIFTH, THE
8	COLLABORATIONS, ASSETS, RESOURCES, AND ENVIRONMENT
9	THAT ARE AVAILABLE TO THE PROJECT.
10	EACH APPLICATION WAS REVIEWED BY FOUR TO
11	SIX REVIEWERS WITH SPECIFIC EXPERTISE IN A KEY AREA.
12	AND THESE INCLUDED THERAPY DEVELOPMENT, PRECLINICAL
13	PHARMACOLOGY AND TOXICOLOGY, MANUFACTURING,
14	CLINICAL/REGULATORY, SPECIFIC DISEASE EXPERTISE IN
15	THE TARGET DISEASE, AND ANY ADDITIONAL EXPERTISE AS
16	NEEDED; FOR EXAMPLE, GENE THERAPY.
17	THE GWG REVIEW MEETING TOOK PLACE
18	SEPTEMBER 12 TO 14 OF THIS YEAR. AND THIS SLIDE
19	SUMMARIZES THE OUTCOMES. ALL OF THE APPLICATIONS
20	THAT WERE REVIEWED WERE FROM INDUSTRY APPLICANTS.
21	TWO APPLICATIONS WERE RECOMMENDED FOR FUNDING BY THE
22	GWG, AND FOUR APPLICATIONS WERE NOT RECOMMENDED FOR
23	FUNDING.
24	THE NEXT SLIDE SHOWS YOU A SUMMARY OF
25	APPLICATION 6513, WHICH IS ONE OF THE TWO

1	APPLICATIONS RECOMMENDED FOR FUNDING. IT CONCERNS
2	PRECLINICAL AND CLINICAL TESTING OF A STEM
3	CELL-BASED COMBINATION PRODUCT FOR INSULIN-DEPENDENT
4	DIABETES. AND THE SLIDE SHOWS THE FUNDS THAT ARE
5	REQUESTED FROM CIRM ON THIS AWARD.
6	AND APPLICATION 6477 IS THE OTHER
7	APPLICATION THAT WAS RECOMMENDED. IT'S ENTITLED A
8	"PHASE I/II STUDY EVALUATING THE SAFETY AND EFFICACY
9	OF A GENE-MODIFIED STEM CELL THERAPY FOR
10	BETA-THALASSEMIA." AND, AGAIN, THE SLIDE SHOWS THE
11	AMOUNT OF FUNDS RECOMMENDED REQUESTED FROM CIRM.
12	SO THAT CONCLUDES WHAT I HAVE TO SAY ABOUT
13	SP I. I'LL BE HAPPY TO TAKE ANY QUESTIONS.
14	DR. LUBIN: COULD YOU REPEAT THE PREVIOUS
15	ONE BEFORE THE BETA-THALASSEMIA? WHAT WAS THE SP
16	NUMBER?
17	DR. CARAS: 6513.
18	DR. LUBIN: OKAY. THANK YOU.
19	CHAIRMAN THOMAS: MR. JUELSGAARD.
20	DR. JUELSGAARD: SO WE'RE GOING TO HEAR A
21	BIT ABOUT THE REVIEW OF THE GRANTS WORKING GROUP.
22	BUT AS A PREDICATE TO THAT, ONE OF THE THINGS THAT
23	WAS TO BE CONSIDERED WAS FINANCIAL CAPACITY AND
24	CO-FUNDING, WHICH I TAKE IT WAS NOT WITHIN THE SCOPE
25	OF WHAT THE GRANTS WORKING GROUP WAS TO DO. SO WE
	60
	· · · · · · · · · · · · · · · · · · ·

	DARKISIERS REPORTING SERVICE
1	HAVE REVIEWED THOSE, AND WE'RE SATISFIED WITH THE
2	TWO THAT ARE BEING, AT LEAST RECOMMENDED AT THIS
3	POINT, THAT THEY MEET THE CRITERIA THAT WERE
4	DEVELOPED FOR THAT?
5	DR. CARAS: YES. THERE WERE MINIMAL
6	ELIGIBILITY CRITERIA IN PLACE, AND THESE TWO
7	APPLICATIONS DID MEET THAT. MS. BAUM, DO YOU WANT
8	TO ADD ANYTHING TO THIS?
9	MS. BAUM: I THINK YOU SAID IT JUST
10	PERFECTLY. THANK YOU.
11	CHAIRMAN THOMAS: ANY OTHER QUESTIONS FOR
12	DR. CARAS?
13	SO THESE ARE THE TWO TIER I APPLICATIONS.
14	DO WE NEED MR. HARRISON, WE NEED A MOTION. YOU
15	SEE UP THERE THE SIX APPLICANTS, THE TWO TIER I THAT
16	HAVE BEEN RECOMMENDED. DO I HAVE A MOTION TO
17	APPROVE THE TIER I APPLICATIONS?
18	DR. PRIETO: SO MOVED.
19	CHAIRMAN THOMAS: I'M SORRY. WHO MOVED
20	THAT? DR. PRIETO. MR. SHEEHY SUGGESTS WE TAKE THEM
21	ONE AT A TIME. DR. PRIETO, YOU WANT TO MOVE THE
22	FIRST?
23	DR. PRIETO: YES.
24	CHAIRMAN THOMAS: THANK YOU. IS THERE A
25	SECOND?
	61
	01

1	DR. JUELSGAARD: I SECOND.
2	CHAIRMAN THOMAS: BEEN MOVED AND SECONDED.
3	ANY DISCUSSION BY MEMBERS OF THE BOARD ON THE FIRST
4	TIER I APPLICATION?
5	DR. TROUNSON: CHAIR, I'D LIKE TO JUST LET
6	YOU KNOW THAT, FROM THE POINT OF THE VIEW OF
7	MANAGEMENT, THIS IS CLEARLY A PROJECT WHICH WE'VE
8	BEEN CHAPERONING FOR SOME TIME, AS BOARD MEMBERS WHO
9	HAVE BEEN HERE FOR A WHILE KNOW. AND THIS WORK HAS
10	BEEN PROGRESSING EXTREMELY STEADILY IN THE RIGHT
11	DIRECTION. EACH TIME IT'S BEEN REVIEWED, IT'S BEEN
12	REVIEWED POSITIVELY. WE BELIEVE IT'S A VERY STRONG
13	PROJECT AND THAT IT'S, AGAIN, PROGRESSING IN THE
14	RIGHT DIRECTION.
15	THE IMPORTANT PART, I THINK, IN THIS
16	PROJECT, THAT IT LINKS UP WITH A VERY MAJOR INDUSTRY
17	GROUP. AND THEY'VE ALSO TAKEN A VERY HARD LOOK AND
18	CLOSE LOOK AT THE PROJECT AND FEEL STRONGLY THAT
19	THIS IS SOMETHING THAT HAS GOT ALL THE HALLMARKS OF
20	A PROJECT THAT MAY WELL SUCCEED. SO FROM THE POINT
21	OF VIEW OF MANAGEMENT, WE'RE VERY STRONGLY IN
22	SUPPORT OF IT. AND I THINK AT TIMES YOU WOULD LIKE
23	US TO INDICATE THAT TO YOU.
24	CHAIRMAN THOMAS: THANK YOU, DR. TROUNSON.
25	ANY OTHER COMMENTS BY MEMBERS OF THE BOARD? ANY
	62
	UL

1	COMMENTS BY MEMBERS OF THE PUBLIC? HEARING NONE, IS
2	THIS SOMETHING, MR. HARRISON, THAT DOES REQUIRE A
3	ROLL CALL VOTE? MARIA, PLEASE CALL THE ROLL.
4	MS. BONNEVILLE: SUE BRYANT.
5	DR. BRYANT: YES.
6	MS. BONNEVILLE: FRANK CHISARI.
7	DR. CHISARI: YES.
8	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
9	DR. DULIEGE: YES.
10	MS. BONNEVILLE: JAMES ECONOMOU.
11	DR. ECONOMOU: YES.
12	MS. BONNEVILLE: GARY FIRESTEIN.
13	DR. FIRESTEIN: YES.
14	MS. BONNEVILLE: MICHAEL FRIEDMAN. LEEZA
15	GIBBONS. MICHAEL GOLDBERG.
16	MR. GOLDBERG: YES.
17	MS. BONNEVILLE: STEVE JUELSGAARD.
18	MR. JUELSGAARD: YES.
19	MS. BONNEVILLE: BERT LUBIN.
20	DR. LUBIN: YES.
21	MS. BONNEVILLE: PHIL PIZZO. CLAIRE
22	POMEROY.
23	DR. POMEROY: YES.
24	MS. BONNEVILLE: ROBERT PRICE.
25	DR. PRICE: YES.
	63

1	MS. BONNEVILLE: FRANCISCO PRIETO.
2	DR. PRIETO: AYE.
3	MS. BONNEVILLE: ROBERT QUINT. DUANE
4	ROTH. JOAN SAMUELSON. JON SHESTACK.
5	MR. SHESTACK: YES.
6	MS. BONNEVILLE: OS STEWARD.
7	DR. STEWARD: YES.
8	MS. BONNEVILLE: JONATHAN THOMAS.
9	CHAIRMAN THOMAS: YES.
10	MS. BONNEVILLE: ART TORRES. KRISTINA
11	VUORI.
12	DR. VUORI: YES.
13	DR. FINI: YOU MISSED MY NAME.
14	MR. HARRISON: WE DON'T CALL MEMBERS WHO
15	ARE IN CONFLICT WITH AN APPLICATION. IF YOUR NAME
16	WASN'T CALLED, IT WAS FOR THAT REASON.
17	CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.
18	MOTION PASSES. CONGRATULATIONS.
19	MOVE ON NOW TO THE SECOND ITEM. DO WE
20	HEAR A MOTION TO APPROVE? LET'S NOT BE SHY.
21	DR. VUORI: I MOVE APPROVAL.
22	CHAIRMAN THOMAS: MOVED BY DR. VUORI.
23	DR. JUELSGAARD: SECOND THE MOTION.
24	CHAIRMAN THOMAS: SECONDED BY MR.
25	JUELSGAARD. ANY DISCUSSION BY MEMBERS OF THE BOARD?
	64

1	DR. TROUNSON.
2	DR. TROUNSON: SO, CHAIR, THIS
3	BETA-THALASSEMIA IS A VERY SERIOUS DISEASE. IT
4	AFFLICTS YOUNG PEOPLE GROWING UP. AS MANY OF YOU
5	KNOW, PARTICULARLY PEOPLE LIKE SAM HAWGOOD COULD
6	TELL YOU HOW DIFFICULT IT IS FOR FAMILIES TO LIVE
7	WITH THIS DISEASE. ONE OF THE OPPORTUNITIES HERE IS
8	TO INTRODUCE THE CORRECT DISEASE IN THE
9	HEMATOPOIETIC STEM CELL. AND THIS GROUP HAVE GOT
10	INCREDIBLY GOOD TECHNOLOGY TO DO THAT, AND THEY HAVE
11	BEEN WORKING IN THIS SPACE INTERNATIONALLY AND HAVE
12	BROUGHT THIS STUDY TO US BECAUSE THEY THINK THAT WE
13	CAN BE A MAJOR PARTICIPANT IN CORRECTING THIS VERY
14	SERIOUS DISEASE.
15	I THINK THESE ARE LANDMARK STUDIES WHICH
16	MAY MEAN THAT WE'LL ENCOURAGE OTHERS TO TACKLE SOME
17	OF THE RELATED DISEASES LIKE SICKLE CELL DISEASE AND
18	OTHERS AS WE MOVE FORWARD. IF YOU CAN GET
19	SUFFICIENT EXPRESSION OF THE GENE CONSTRUCT, THEN
20	YOU CLEARLY CAN BRING THESE PEOPLE OUT OF THAT
21	DISEASE CONDITION AND GET THEM INTO FULL HEALTH. SO
22	THIS IS A REALLY IMPORTANT PROJECT, WE FEEL, IN
23	MANAGEMENT. WE THINK THIS IS A GREAT TEAM. WE
24	THINK THEY'VE GOT A GREAT COMMITMENT TO CALIFORNIA
25	AND PUT THEIR HANDS UP STRONGLY. WE'RE VERY

65

1	SUPPORTIVE OF THIS PROJECT FROM THE POINT OF VIEW OF
2	MANAGEMENT.
3	CHAIRMAN THOMAS: THANK YOU, DR. TROUNSON.
4	ANY OTHER COMMENTS BY MEMBERS OF THE BOARD? ANY
5	COMMENTS BY MEMBERS OF THE PUBLIC? HEARING NONE,
6	LET'S PROCEED TO A ROLL CALL VOTE. MARIA.
7	MS. BONNEVILLE: SUE BRYANT.
8	DR. BRYANT: YES.
9	MS. BONNEVILLE: FRANK CHISARI.
10	DR. CHISARI: YES.
11	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
12	DR. DULIEGE: YES.
13	MS. BONNEVILLE: MARCY FEIT.
14	MS. FEIT: YES.
15	MS. BONNEVILLE: ELIZABETH FINI.
16	DR. FINI: YES.
17	MS. BONNEVILLE: GARY FIRESTEIN.
18	DR. FIRESTEIN: YES.
19	MS. BONNEVILLE: MICHAEL FRIEDMAN. LEEZA
20	GIBBONS. MICHAEL GOLDBERG.
21	MR. GOLDBERG: YES.
22	MS. BONNEVILLE: SAM HAWGOOD.
23	DR. HAWGOOD: YES.
24	MS. BONNEVILLE: STEVE JUELSGAARD.
25	MR. JUELSGAARD: YES.
	66

1	MS. BONNEVILLE: PHIL PIZZO. CLAIRE
2	POMEROY.
3	DR. POMEROY: YES.
4	MS. BONNEVILLE: ROBERT PRICE.
5	DR. PRICE: YES.
6	MS. BONNEVILLE: FRANCISCO PRIETO.
7	DR. PRIETO: AYE.
8	MS. BONNEVILLE: ROBERT QUINT. DUANE
9	ROTH. JOAN SAMUELSON. JEFF SHEEHY.
10	ME. SHEEHY: YES.
11	MS. BONNEVILLE: JON SHESTACK.
12	MR. SHESTACK: YES.
13	MS. BONNEVILLE: OS STEWARD.
14	DR. STEWARD: YES.
15	MS. BONNEVILLE: JONATHAN THOMAS.
16	CHAIRMAN THOMAS: YES.
17	MS. BONNEVILLE: ART TORRES. KRISTINA
18	VUORI.
19	DR. VUORI: YES.
20	CHAIRMAN THOMAS: THAT MOTION PASSES.
21	THAT IS THE SUM TOTAL OF OUR TIER I RECOMMENDATIONS.
22	AS YOU CAN SEE, THERE WAS A SIGNIFICANT DROP-OFF IN
23	SCORING FROM PROPOSALS II TO III. THE FOUR
24	REMAINING ARE ALL IN TIER III. ARE THERE ANY
25	QUESTIONS BY MEMBERS OF THE BOARD ABOUT TIER III OR
	67

1	ANY INTEREST IN MOVING ANY OF THE TIER III PROJECTS
2	UP TO TIER I?
3	HEARING NONE, MR. HARRISON, IS THE
4	APPROPRIATE MOVE HERE TO DO WE NEED A VOTE ON NOT
5	APPROVING TIER III? DR. TROUNSON.
6	DR. TROUNSON: SORRY, CHAIR. I JUST NEED,
7	I THINK, TO LET YOU KNOW THERE WAS AN EXTRAORDINARY
8	PETITION WHICH MIGHT, IF THE BOARD NEEDED TO
9	CONSIDER THAT, I'M NOT SUGGESTING THEY SHOULD, THAT
10	WE MIGHT HAVE TO GO INTO EXECUTIVE SESSION. JUST TO
11	BRING THAT TO YOUR ATTENTION.
12	CHAIRMAN THOMAS: SO THERE WAS AN
13	EXTRAORDINARY PETITION FILED. WAS IT ONE
14	EXTRAORDINARY PETITION, DR. TROUNSON, WITH RESPECT
15	TO ONE OF THE TIER III PROJECTS? MR. HARRISON, WHAT
16	IS THE APPROPRIATE WE NEED A MEMBER OF THE BOARD
17	TO ASK TO HEAR THAT BEFORE WE CONSIDER IT, CORRECT?
18	MR. HARRISON: CORRECT. THE POLICY IS
19	THAT THE BOARD DOESN'T ROUTINELY CONSIDER
20	EXTRAORDINARY PETITIONS. IT'S ONLY DISCUSSED IF A
21	BOARD MEMBER WISHES TO DISCUSS IT.
22	DR. JUELSGAARD: I REQUEST THAT WE HAVE
23	SUCH A DISCUSSION, PLEASE.
24	CHAIRMAN THOMAS: OKAY. SO, MR. HARRISON,
25	DOES THAT NEED TO BE DONE IN CLOSED SESSION?

1	MR. HARRISON: I THINK THE FIRST ORDER OF
2	BUSINESS WOULD BE TO ASK FOR A PRESENTATION BY
3	SCIENTIFIC STAFF REGARDING THE GRANTS WORKING
4	GROUP'S REVIEW OF THE APPLICATION. AND THEN IF IT'S
5	NECESSARY FOR FURTHER CONSIDERATION OF ANY
6	PROPRIETARY INFORMATION, WE CAN DISCUSS THAT IN A
7	CLOSED SESSION.
8	CHAIRMAN THOMAS: THANK YOU.
9	DR. POMEROY: PROCEDURAL QUESTION. DO I
10	HAVE A CONFLICT WITH THIS GIVEN THE INFORMATION IN
11	THE EXTRAORDINARY PETITION, SPECIFICALLY THE LAST
12	PARAGRAPH ON PAGE 3?
13	MR. HARRISON: YES, I THINK IT WOULD BE
14	BEST FOR YOU AND DR. PRIETO TO RECUSE YOURSELVES.
15	CHAIRMAN THOMAS: I BELIEVE DR. WHITTLESEY
16	WILL PRESENT ON THIS EXTRAORDINARY PETITION.
17	DR. WHITTLESEY: YES. THANK YOU, MR.
18	CHAIRMAN, MEMBERS OF THE BOARD. KEVIN WHITTLESEY,
19	MEMBER OF THE SCIENCE OFFICE. I'D BE HAPPY TO
20	PROVIDE YOU A SUMMARY OF THIS APPLICATION. THIS IS
21	APPLICATION NO. 6467. THE REDACTED TITLE IS
22	"TREATMENT FOR PATIENTS SUFFERING AN ACUTE ISCHEMIA
23	STROKE, A PHASE II CLINICAL STUDY."
24	THIS IS AN APPLICATION FOR THE USE OF AN
25	ADULT STEM CELL PRODUCT TO TREAT STROKE 24 TO 36
	69

1	HOURS AFTER ONSET OF THE STROKE. THE ONLY FDA
2	APPROVED THERAPY MUST BE ADMINISTERED WITHIN FOUR
3	AND A HALF HOURS OF STROKE ONSET. SO THERE IS A
4	SIGNIFICANT UNMET MEDICAL NEED.
5	THE PROPOSAL REQUESTED FUNDS TO CONDUCT
6	PROCESS DEVELOPMENT ACTIVITIES TO CHANGE FORMULATION
7	OF THE CELL THERAPY AS WELL AS TO CONDUCT A PHASE II
8	CLINICAL TRIAL.
9	WHILE REVIEWERS AGREED THERE WAS
10	SIGNIFICANT CLINICAL NEED, ISSUES WERE IDENTIFIED
11	WHICH RESULTED IN THE SCORE REFLECTED, WHICH FELL
12	BELOW TIER I. I'LL OUTLINE A FEW OF THOSE KEY
13	POINTS TO YOU.
14	AS MENTIONED, STROKE DOES REPRESENT A
15	SIGNIFICANT UNMET MEDICAL NEED SINCE THE ONLY WINDOW
16	OF THERAPY IS THIS VERY NARROW FOUR AND A HALF HOURS
17	AFTER STROKE ONSET. REVIEWERS, HOWEVER, DID NOT SEE
18	CONVINCING DATA THAT THIS CELL THERAPY APPROACH WITH
19	THE PROPOSED MECHANISM OF IMMUNE MODULATION WOULD
20	HAVE AN IMPACT ON STROKE.
21	IN THE AREA OF RISK BENEFIT, THIS CELL
22	THERAPY HAS BEEN USED IN OTHER CLINICAL TRIALS. SO
23	THERE IS REASONABLE ASSURANCE THAT RISK MAY BE LOW
24	AND OF SAFETY. HOWEVER, AS I MENTIONED, POTENTIAL
25	BENEFIT FOR STROKE IS UNCLEAR BASED ON THE DATA

1	PROVIDED.
2	POTENTIAL BENEFIT IS SUGGESTED FROM ONE
3	PRECLINICAL STUDY REPORT; HOWEVER, THAT WAS
4	PUBLISHED IN A JOURNAL OF MODEST IMPACT. AND THE
5	REMAINING SUPPORTED STUDIES WERE UNPUBLISHED.
6	IMPORTANTLY, IN THE DATA PROVIDED THERE WAS NO
7	QUANTITATIVE HISTOPATHOLOGY, WHICH IS AN IMPORTANT
8	GOLD STANDARD MEASURE OF OUTCOME, IN THIS PARTICULAR
9	INDICATION.
10	REVIEWERS DISCUSSED WHETHER TREATMENT
11	BENEFIT IS ACCEPTABLE IN A CLINICALLY MEANINGFUL
12	OUTCOME.
13	WITH RESPECT TO DESIGN AND FEASIBILITY,
14	THE IND HAS ALREADY BEEN APPROVED, WHICH IS AN
15	IMPORTANT REGULATORY MILESTONE; HOWEVER, THERE WERE
16	CONCERNS ABOUT FEASIBILITY OF THE TIMELINE, IN
17	PARTICULAR WITH RESPECT TO COORDINATING SOME OF THE
18	MANUFACTURING ACTIVITIES IN LINE AND SYNCHRONY WITH
19	THE PROPOSED CLINICAL STUDY AND THE TIMELINE OF THE
20	PROJECT.
21	PROPOSAL INCLUDES CHANGING THE
22	FORMULATION, AS I MENTIONED, WHICH IS A
23	SIGNIFICANT HAS SOME SIGNIFICANT LIMITATIONS
24	ASSOCIATED AND, AGAIN, REFLECTED ON THE FEASIBILITY
25	OF THE TIMELINE. REVIEWERS WERE NOT CLEAR ON THE

71

1	ABILITY TO SCALE PRODUCTION TO THE CAPACITY
2	REQUIRED, AGAIN, WITHIN THE PROPOSED TIMELINE. END
3	POINTS WERE JUDGED TO BE APPROPRIATE. ADDITIONAL
4	PHASE I DATA WITH STROKE PATIENTS WAS STRONGLY
5	SUGGESTED BY THE GRANTS WORKING GROUP BEFORE MOVING
6	INTO THE LARGER PHASE II TRIAL SINCE THIS MIGHT HELP
7	THEM NARROW THE DOSE RANGE FOR THE LARGER STUDY.
8	THERE WERE A FEW OTHER ADDITIONAL
9	COMMENTS. THOSE WERE PRIMARILY THE CRITICISMS MADE
10	BY THE GRANTS WORKING GROUP, WHICH AGAIN RESULT IN
11	THE SCORE REFLECTED. THIS ACTUALLY FELL INITIALLY
12	IN TIER II. THERE WAS A PROGRAMMATIC DISCUSSION
13	ABOUT THIS APPLICATION, WHICH REITERATED SOME OF THE
14	CONCERNS THAT I'VE ALREADY MENTIONED. A MOTION WAS
15	MADE TO MOVE IT PROGRAMMATICALLY INTO TIER III,
16	RECOMMENDED FOR FUNDING, AND THAT MOTION PASSED.
17	TIER III, NOT RECOMMENDED FOR FUNDING. THANK YOU.
18	THAT MOTION CARRIED, WHICH RESULTED IN THE POSITION
19	THAT YOU CURRENTLY SEE. I'D BE HAPPY TO ANSWER ANY
20	QUESTIONS, IF POSSIBLE.
21	CHAIRMAN THOMAS: MR. SHEEHY.
22	MR. SHEEHY: THERE WERE A COUPLE OF
23	PROBLEMS WITH THIS APPLICATION. AS FAR AS THE
24	SCIENCE GOES, I NOTICE THAT THEY JUST PUBLISHED ON
25	TRAUMATIC BRAIN INJURY. I DON'T KNOW A LOT ABOUT
	72
	<i>1 L</i>

1	NEUROLOGY. BUT WHAT THEY JUST PUBLISHED ON
2	TRAUMATIC BRAIN INJURY SEEMED PRETTY IMPRESSIVE OR
3	FAIRLY SUBSTANTIAL RESULTS. THE RELATIONSHIP
4	BETWEEN WHAT THEY PUBLISHED ON TRAUMATIC BRAIN
5	INJURY AND STROKE, I DON'T KNOW HOW THOSE CONDITIONS
6	DIFFER, HOW WE SHOULD EVALUATE THAT RECENT
7	PUBLICATION RELATED TO I MEAN IF THERE'S A LITTLE
8	NEUROLOGICAL EXPERTISE, THEY MIGHT BE ABLE TO PUT
9	THOSE TWO INTO CONTEXT BECAUSE I DID THINK THAT
10	THAT I MEAN SEPTEMBER 28TH, THAT WAS A PRETTY
11	DR. WHITTLESEY: IT'S A RECENT
12	PUBLICATION. CERTAINLY FROM A REGULATORY
13	PERSPECTIVE, ONE IMPORTANT ASPECT IS THAT YOU'VE
14	SHOWN PROOF OF CONCEPT IN THE PARTICULAR DISEASE
15	INDICATION THAT YOU'RE GOING INTO. SO OBVIOUSLY
16	THAT'S A CRITICAL DIFFERENCE. IF THERE'S A
17	NEUROLOGIST AMONGST US THAT WOULD LIKE TO COMMENT ON
18	THOSE DIFFERENCES, BUT CERTAINLY THAT IS AN
19	IMPORTANT ASPECT OF PROOF OF CONCEPT.
20	MR. SHEEHY: HOW IS TRAUMATIC BRAIN INJURY
21	DIFFERENT FROM STROKE? AND SOMETHING THAT HAD A
22	MEASURABLE IMPACT.
23	I THINK THERE WAS ANOTHER STRUCTURAL
24	DEFECT WITH THE GRANT I THINK WE SHOULD ADDRESS
25	SEPARATELY. JUST FROM A SCIENCE POINT OF VIEW.
	73
	/ J

1	DR. TROUNSON: I'M NOT GOING TO ANSWER IN
2	A NEUROLOGICAL WAY BECAUSE I DON'T THINK THEY REALLY
3	KNOW. THE PROBLEM IN SOME OF THESE STUDIES IS SO
4	THESE ANIMALS HAVE BEEN GIVEN AN INJECTION OF
5	MESENCHYMAL STEM CELLS, BONE-DERIVED STEM CELLS.
6	THEY CAN'T GET ACROSS THE BLOOD-BRAIN BARRIER UNLESS
7	YOU'VE GOT A SIGNIFICANT INJURY THAT'S ALLOWING THE
8	CELLS TO ACTUALLY PENETRATE THE BLOOD-BRAIN BARRIER
9	DON'T GET IN. IN FACT, MOST OF THOSE CELLS WILL BE
10	ACCUMULATED IN THE LUNG AND IN THE LIVER BEFORE THEY
11	DO ANYTHING.
12	WHAT'S HAPPENING IS A TROPHIC EFFECT, AND
13	THE PROPOSAL IS THROUGH THE IMMUNE CELLS, THAT IT
14	HAS AN EFFECT ON THE IMMUNE CELLS, AND THE IMMUNE
15	CELLS ARE THEN BECOMING INFLUENTIAL IN THE INJURY.
16	SO STROKE IS AN INJURY IN THE BRAIN. IT'S A
17	SPECIFIC INJURY CAUSED PARTLY THROUGH OXYGEN
18	DEPRIVATION, BUT MOSTLY THROUGH REOXYGENATION OF
19	THOSE AREAS WHICH CAUSES VERY TOXIC EFFECT ON THE
20	NEURONS.
21	IT'S A BRAIN INJURY. PHYSICALLY IT IS
22	DIFFERENT, JEFF, AND IT'S DIFFICULT TO KNOW HOW THAT
23	MIGHT RELATE TO STROKE. IN THE CASE OF A BRAIN
24	INJURY, PHYSICAL BRAIN INJURY, YOU MIGHT HAVE
25	DISRUPTED THE BLOOD-BRAIN BARRIER AND ALLOWED SOME
	74
	<i> </i>

1	OF THE CELLS OR SOME SORT OF THOSE CELLS ACROSS THAT
2	BLOOD-BRAIN BARRIER AS WELL. IT'S DEFINITELY NOT
3	EXACTLY EQUIVALENT.
4	BUT THE PROBLEM IS IN SOME OF THESE AREAS,
5	WE REALLY DON'T UNDERSTAND THE MECHANISM
6	PARTICULARLY WELL OR AT ALL IN A GENUINE SCIENTIFIC
7	WAY. SO IT'S RATHER DIFFICULT WHEN YOU DON'T REALLY
8	KNOW THE MECHANISM, THEN, TO REALLY BE ABLE TO DRAW
9	THE MECHANISM ACROSS FROM ONE TYPE OF CONDITION TO
10	ANOTHER. IF YOU KNEW THE EXACT MECHANISM, IT WOULD
11	BE KIND OF A BIT EASIER. BUT IN THIS CASE, IT'S
12	MEANT TO BE EITHER A TROPHIC EFFECT OR AN EFFECT
13	THROUGH THE IMMUNE CELLS.
14	CHAIRMAN THOMAS: YES. DR. CHIZARI.
15	DR. CHISARI: I'D LIKE TO SUPPORT WHAT DR.
16	TROUNSON SAID. I THINK FROM THE SKETCHY INFORMATION
17	THAT'S AVAILABLE TO US, IT SEEMS LIKE THIS APPROACH
18	IS INTENDED TO PROVIDE CELLS THAT WILL PRODUCE
19	FACTORS THAT WILL SUPPRESS AN INFLAMMATORY RESPONSE
20	SOMEPLACE IN THE BODY. IN THIS CASE IT WOULD BE THE
21	BRAIN AND IN THE CONTEXT OF ACUTE STROKE.
22	THE PROBLEM I HAVE WITH IT MAY BE A
23	NONPROBLEM BECAUSE I HAVEN'T BEEN ABLE TO GET ACCESS
24	TO THE PRIMARY DATA. SO WITH THE INFORMATION THAT
25	WE HAVE IN FRONT OF US, IT'S IMPOSSIBLE FOR ME TO
	75
	75

1	UNDERSTAND THE RATIONALE AND TO UNDERSTAND THE
2	MECHANISM. THAT MAY BE AN UNFAIR CRITICISM OF THE
3	PROPOSAL BECAUSE I DON'T HAVE THE PROPOSAL IN FRONT
4	OF ME.
5	DR. TROUNSON: I THINK THAT'S A PERFECTLY
6	REASONABLE SITUATION AT THE PRESENT TIME. IT MAY BE
7	THAT IN DUE COURSE WE WILL UNDERSTAND ALL OF THESE
8	MECHANISMS. CURRENTLY WE DON'T. AND THAT'S PART OF
9	THE PROBLEM IN THESE KIND OF STUDIES. BUT FDA, FOR
10	EXAMPLE, ARE NOT SO CONCERNED WITH MECHANISMS.
11	THEY'RE VERY CONCERNED WITH SAFETY. THESE CELLS
12	HAVE GOT A VERY GOOD SAFETY PROFILE. SO THE THOUGHT
13	THAT, WELL, THERE ARE PATIENTS WILLING TO TRY THIS.
14	WOULD YOU GET RESPONSE? IT MIGHT BE WORTHWHILE
15	TRYING.
16	BUT FROM OUR POINT OF VIEW, WE'D LIKE TO
17	SEE MECHANISMS SO WE KNOW WHAT WE CAN DO IF IT
18	DOESN'T WORK OR WHAT WE DO IN THE NEXT STAGE. AND
19	SO WHEN THE REVIEWERS ARE REVIEWING IT, THEY ALSO
20	LOOK AT THE SCIENTIFIC UNDERPINNING OF A STUDY.
21	SO IN THIS CASE IT'S A LITTLE WEAK, TO SAY
22	THE LEAST.
23	DR. CHISARI: I UNDERSTAND THAT AND I
24	AGREE WITH THAT. THE REVIEW THAT I WAS ABLE TO READ
25	HERE, HOWEVER, DIDN'T GO INTO THE BASIC MECHANISTIC

1	CONSIDERATIONS THAT WE'RE DISCUSSING RIGHT NOW. AND
2	IT SEEMS TO ME AS IF THIS IS SORT OF A WITCH'S BREW
3	THAT THEY'RE HOPING WILL BE PRODUCED THAT WILL REACH
4	THE INFLAMMATORY SITE IN THE BRAIN WITHOUT REALLY
5	KNOWING WHAT THE INFLAMMATORY PROCESS IS, WHAT THE
6	CELLS THE INFLAMMATORY CELLS THAT ARE CAUSING THE
7	PROBLEM THAT ARE AMPLIFYING THE LOSS OF TISSUE AND
8	THE SYMPTOMS OF THE STROKE. THEY DON'T KNOW AT
9	LEAST THEY'RE I DON'T KNOW WHAT THOSE CELLS ARE.
10	I DON'T KNOW WHETHER THEY KNOW WHAT THOSE CELLS ARE.
11	AND I DON'T KNOW IF THEY KNOW WHAT COMPONENT OF THE
12	PRODUCTION OF THE SOUP THAT'S PRODUCED BY THE CELLS
13	THEY'RE GOING TO ADMINISTER WILL ACTUALLY ADDRESS
14	THE UNDERLYING MECHANISM.
15	WITHOUT THAT KIND OF INFORMATION, I WOULD
16	COMPLETELY AGREE WITH THE SCIENCE REVIEW COMMITTEE
17	AND PLACE THIS IN THE UNFUNDABLE RANGE.
18	DR. WHITTLESEY: IF I COULD CHIME IN,
19	ACTUALLY YOUR POINT IS VERY WELL TAKEN. THAT WAS
20	THE CRUX OF THE ARGUMENT OF GWG IN THAT THE
21	MECHANISM OF ACTION PROPOSED WAS REALLY NOT WELL
22	UNDERSTOOD FOR EXACTLY THE REASONS THAT YOU NICELY
23	OUTLAID.
24	DR. TROUNSON: CHAIR, JUST IN ADDITION,
25	THERE IS A CONFIDENTIAL NOTE TO US THAT I NEED TO

1	LET YOU KNOW AS WELL. THAT NEEDS TO BE DISCUSSED
2	BECAUSE IT'S AN INTELLECTUAL PROPERTY ISSUE AND
3	NEEDS TO BE DISCUSSED IN EXECUTIVE. BUT I JUST NOTE
4	THAT THAT'S THERE JUST IN CASE YOU WANT TO HEAR MORE
5	ABOUT THAT. AGAIN, NOT RECOMMENDING, BUT IF YOU DO.
6	DR. FEIGAL: I JUST WANT TO MENTION THAT
7	IMMUNE MODULATION IS NOT THE FIRST TIME THIS HAS
8	BEEN CONTEMPLATED IN STROKE. THERE HAVE BEEN
9	DECADES OF WORK TRYING TO LOOK AT IT WITH POWERFUL
10	IMMUNE MODULATING AGENTS BEING USED IN STROKE AND
11	HAVE NOT SHOWN ANY BENEFIT. SO I DO WANT TO BRING
12	THAT UP. IT'S A CONFIDENTIAL ISSUE.
13	DR. JUELSGAARD: SO IN YOUR RECITATION OF
14	THE REVIEW THAT THE GWG DID AND ALSO IN THE WRITTEN
15	MATERIALS THAT WERE PROVIDED TO US, THERE'S ONE
16	STATEMENT THAT I WOULD LIKE A LITTLE FURTHER
17	DISCUSSION OF AND THE RELEVANCE THAT IT PLAYS. SO
18	I'LL JUST READ. "POTENTIAL BENEFIT IS SUGGESTED BY
19	DATA FROM JUST ONE PRECLINICAL STUDY REPORT THAT WAS
20	PUBLISHED IN A JOURNAL OF MODEST IMPACT. OTHER DATA
21	CITED SUPPORTING BENEFIT ARE UNPUBLISHED." SO WHAT
22	ROLE DOES SOMETHING OF THAT SORT PLAY IN THIS
23	DECISION-MAKING?
24	DR. WHITTLESEY: SO THAT WOULD BE
25	SOMETHING THAT WOULD BE MORE APPROPRIATE OBVIOUSLY

1	TO GET INTO THE SPECIFICS OF THE GWG REVIEW. BUT
2	REALLY IN TERMS OF PEER REVIEW LITERATURE IS
3	OBVIOUSLY VERY IMPORTANT FOR THE EVALUATION OF THE
4	LEVEL OF EVIDENCE PROVIDED. SO
5	DR. JUELSGAARD: SO LET ME QUESTION THAT
6	WHEN IT COMES TO A PUBLIC COMPANY THAT'S DEVELOPING
7	A PRODUCT. SO IN MY EXPERIENCE A LOT OF THE
8	EVALUATION THAT GETS DONE INTERNALLY WITHIN A
9	COMPANY IS BASED ON DATA GENERATED INTERNALLY. THAT
10	MAY NOT BE PUBLISHED AT ALL FOR PROPRIETARY REASONS.
11	SO I JUST WONDER TO WHAT EXTENT THAT'S BEEN TAKEN
12	INTO ACCOUNT IN THE REVIEW THAT WAS DONE BY THE GWG.
13	I UNDERSTAND, AS A MATTER OF RESEARCH IN ACADEMIC
14	AND OTHER INSTITUTIONS OF THAT SORT, THAT
15	PUBLICATION OF FINDINGS IN JOURNALS IS VERY
16	IMPORTANT. AND, IN FACT, IN THE COMPANY THAT I WORK
17	FOR THAT WAS CLEARLY TRUE WITH REGARD TO THE
18	RESEARCH BEING DONE IN THE RESEARCH ORGANIZATION.
19	BUT WHEN YOU STARTED LOOKING AT OTHER TYPES OF
20	INFORMATION, DECISIONS HAD TO BE MADE WHETHER TO
21	PUBLISH THEM OR NOT, NOT ON THE BASIS OF HOW GOOD
22	THE SCIENCE WAS, BUT ON THE BASIS OF PROPRIETARY
23	INFORMATION AND COMPETITIVE ADVANTAGE.
24	DR. FEIGAL: I WANT TO CLARIFY SOMETHING.
25	THE DISCUSSION THAT ENSUED AT THE GRANT REVIEW GROUP
	79
	/ 9

_	
1	DID DEAL WITH THE COMPELLING NATURE OF THE DATA THAT
2	WAS PRESENTED REGARDLESS OF WHETHER IT WAS PUBLISHED
3	OR NOT PUBLISHED. THEY FELT THAT THE DATA THAT THEY
4	SAW WAS NOT COMPELLING TO PROVIDE THE IMPORTANCE OF
5	WHY WE SHOULD DO THIS IN THIS PARTICULAR PATIENT
6	POPULATION. THEY FELT IT WAS PARTICULARLY WEAK.
7	THE FACT THAT THERE'S ONE PEER REVIEW MAY HAVE
8	PLAYED, I WOULD SAY, A MINOR ROLE. I THINK THE MORE
9	MAJOR ROLE WAS THE DATA THAT ACTUALLY WAS PRESENTED
10	IN THE APPLICATION.
11	DR. JUELSGAARD: THANK YOU, DR. FEIGAL.
12	THAT'S VERY REASSURING BECAUSE I WAS A LITTLE
13	TROUBLED BY THE SENTENCES THAT I JUST READ OUT LOUD.
14	CHAIRMAN THOMAS: DR. SAMBRANO? NO. WE
15	HAVE ANY MORE COMMENTS BY MEMBERS OF THE BOARD? WE
16	HAVE A COMMENT FROM THE PUBLIC. HELLO, JEAN. HOW
17	ARE YOU?
18	DR. LORING: I'M THE PUBLIC THIS TIME.
19	I'M JEAN LORING. I'M FROM THE SCRIPPS RESEARCH
20	INSTITUTE. I'M NOT GOING TO DISAGREE WITH ANYTHING
21	SAID HERE. I FEEL THAT I ATTENDED A CONTRACT
22	RESEARCH ORGANIZATION MEETING SEVERAL WEEKS AGO.
23	THEY INVITED ME TO TALK ABOUT STEM CELLS. AND
24	SEVERAL OF THOSE GROUPS THAT SPOKE AT THAT MEETING
25	WERE USING MESENCHYMAL STEM CELLS FOR THERAPY FOR
	80

1	VIRTUALLY EVERYTHING. AND I THINK WE ALL AGREED
2	THAT THEY DO HAVE ANTI-INFLAMMATORY EFFECTS, AS DR.
3	TROUNSON POINTED OUT. I DON'T THINK THERE'S ANY
4	DOUBT OF THAT.
5	BUT I THINK THE CONCEPT HERE, AND I DON'T
6	KNOW WHICH COMPANY THIS IS THAT'S APPLYING FOR THIS
7	GRANT, BUT I KNOW ATHERSYS AND OSIRIS HAVE CLINICAL
8	TRIALS GOING ON RIGHT NOW FOR THINGS INCLUDING
9	STROKE AND BRAIN INJURY. AND THE KEY ELEMENT,
10	AGAIN, AS ALAN POINTED OUT, IS THAT THEY HAVE A GOOD
11	SAFETY PROFILE. SO THE IDEA BEHIND USING
12	MESENCHYMAL STEM CELLS AS OPPOSED TO CELLS THAT
13	MIGHT BE BETTER SUITED FOR THAT PARTICULAR PROCESS,
14	THAT PARTICULAR PROBLEM, MAYBE NEURAL STEM CELLS
15	WOULD BE BETTER, MAYBE SOME OTHER CELL TYPE WOULD BE
16	BETTER, BUT THESE ARE APPROVED BY THE FDA ASSUMING
17	THEY'RE USING THE SAME CELLS EVERYONE ELSE IS USING.
18	SO IT SEEMS TO BE AN IDEA OF WHETHER THEY
19	WANT TO TAKE THE CHANCE THAT THIS MIGHT HELP AND THE
20	EXPECTATION THAT IT WOULD NOT HURT. SO EVEN THOUGH
21	SCIENTIFICALLY I DON'T THINK IT'S THE RIGHT
22	APPROACH, I UNDERSTAND THAT THERE'S A REAL FORCE
23	HERE TO HAVE THE ONE OR TWO CELL TYPES THAT ARE
24	ACTUALLY APPROVED BY THE FDA APPLIED TO EVERY
25	POSSIBLE DISEASE TO SEE SIMPLY DOES IT WORK.
	81
	<u> </u>

1	CHAIRMAN THOMAS: THANK YOU, DR. LORING.
2	ANY OTHER COMMENTS BY MEMBERS OF THE PUBLIC? DR.
3	MELMED.
4	DR. MELMED: MR. CHAIRMAN, I'M A LITTLE
5	BIT UNCOMFORTABLE IN DISCUSSING THE SCIENCE WITHOUT
6	SEEING THE GRANT. SO CAN WE SEE THE GRANT IN
7	EXECUTIVE SESSION BECAUSE DISCUSSING THE SCIENCE
8	LIKE THIS FOR US IS LIKE A BLIND MAN IN A DARK ROOM.
9	CHAIRMAN THOMAS: YES, WE CAN. DR.
10	TROUNSON.
11	DR. TROUNSON: YEAH. IT'S A LOT OF WORK.
12	I'M NOT SURE WE'VE GOT THE TIME TO GET THROUGH THE
13	WHOLE GRANT, BUT I THINK THERE IS SOME INFORMATION.
14	DR. MELMED: I'M NOT SUGGESTING WE DO
15	THAT. I'M JUST SAYING, THEREFORE, WE SHOULDN'T BE
16	DISCUSSING IT.
17	DR. TROUNSON: I THINK, AS YOU SUGGEST,
18	THERE IS SOME INFORMATION FROM THE GROUP WHICH YOU
19	MIGHT WANT TO HEAR. AND YOU MIGHT WANT TO HEAR OUR
20	PERSPECTIVE ON IT FOR YOURSELF.
21	DR. STEWARD: ALONG THOSE LINES, I WONDER
22	IF WE CAN CONSIDER SOME THINGS IN PRIVATE CLOSED
23	SESSION, BUT NOT OTHERS. I JUST WONDER IF JAMES
24	WOULD RESTATE WHAT WE CAN ACTUALLY CONSIDER IN
25	CLOSED SESSION. WHAT I'M SAYING IS WE CAN'T

1	ACTUALLY REVIEW THE GRANT. I WANT TO MAKE THAT
2	CLEAR TO THE PUBLIC.
3	MR. HARRISON: YOU COULD, FOR EXAMPLE,
4	REVIEW PREPUBLICATION DATA OR OTHER PROPRIETARY
5	INFORMATION INCLUDED IN THE APPLICATION.
6	DR. MELMED: I'M NOT SUGGESTING WE DO
7	THAT. ALL I'M SAYING IS THAT WE'RE HAVING THIS
8	DISCUSSION, IT SHOULD BE A FAIR DISCUSSION BY SEEING
9	THE SCIENCE. I'M NOT SUGGESTING WE DO THAT.
10	CHAIRMAN THOMAS: POINT WELL TAKEN. DO WE
11	HAVE A DESIRE BY THE BOARD TO RETIRE TO EXECUTIVE
12	SESSION TO HEAR MORE ABOUT THIS?
13	DR. JUELSGAARD: I DESIRE.
14	CHAIRMAN THOMAS: OKAY. SO, MR. HARRISON,
15	COULD YOU READ THE RELEVANT CODE NUMBER? AND WE'LL
16	PROCEED NOW INTO EXECUTIVE SESSION FOR FURTHER
17	DISCUSSION.
18	MR. HARRISON: THE BOARD WILL BE CONVENING
19	IN CLOSED SESSION PURSUANT TO HEALTH AND SAFETY CODE
20	SECTION 125290.30(F)(3)(B) AND (C) TO CONSIDER
21	PROPRIETARY AND CONFIDENTIAL INFORMATION RELATED TO
22	THE STRATEGIC PARTNERSHIP FUNDING APPLICATIONS.
23	MS. FEIT: IF WE ARE CONFLICTED IN THIS
24	GRANT, SHOULD WE STAY HERE THEN AND NOT PARTICIPATE?
25	MR. HARRISON: CORRECT.
	83

ı	
1	CHAIRMAN THOMAS: YES. SO WE'RE GOING TO,
2	MEMBERS OF THE BOARD, HEAD OUT THE DOOR HERE BACK TO
3	THE ROOM WHERE BREAKFAST WAS BEING SERVED, WHICH IS
4	IMMEDIATELY OUT TO AND THE RIGHT.
5	MS. LANSING: I'M ACTUALLY NOT CONFLICTED
6	ON THIS, BUT I DON'T KNOW HOW TO CALL INTO EXECUTIVE
7	SESSION.
8	DR. POMEROY: SHERRY, YOU ARE CONFLICTED.
9	MS. LANSING: I AM? I WAS TOLD I WASN'T.
10	WELL, THANK YOU VERY MUCH.
11	DR. POMEROY: JUST ON THIS GRANT. NOT IN
12	GENERAL, SHERRY.
13	DR. LUBIN: I DON'T BELIEVE I'M CONFLICTED
14	ON THIS ONE. IS THERE A WAY TO HEAR THE DISCUSSION?
15	CHAIRMAN THOMAS: YES.
16	DR. LUBIN: CAN I STAY ON THE SAME LINE OR
17	DO I HAVE TO DIAL IN AGAIN?
18	CHAIRMAN THOMAS: WE HAVING SOME ISSUES?
19	MR. HARRISON: NO. IT'S THAT PART OF THE
20	BOARD TELEPHONE POLICY PROVIDES THAT MEMBERS WHO
21	PARTICIPATE TELEPHONICALLY DON'T PARTICIPATE IN THE
22	CLOSED SESSION DISCUSSION.
23	DR. LUBIN: FINE.
24	MS. LANSING: YOU WILL E-MAIL US WHEN TO
25	COME BACK ON. OKAY?
	84
	UT

1	
1	CHAIRMAN THOMAS: YES, WE WILL.
2	(THE BOARD THEN WENT INTO CLOSED
3	SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED. AT
4	THE CONCLUSION OF THE CLOSED SESSION, THE MEETING
5	CONTINUED AS FOLLOWS:)
6	CHAIRMAN THOMAS: SHERRY AND DR. LUBIN,
7	ARE YOU BACK ON? MEMBERS OF THE BOARD, WE'RE
8	WAITING TO GET SHERRY AND DR. LUBIN BACK ON THE
9	LINE. WE HAVING ANY LUCK OVER THERE, AMY?
10	SO WE'RE GOING TO PROCEED. THEY'LL
11	HOPEFULLY REJOIN MOMENTARILY. NOW RECONVENING POST
12	CLOSED SESSION. DO WE HAVE ANY MOTIONS TO MOVE 6467
13	FROM TIER III TO TIER I? HEARING NONE, I GUESS,
14	JAMES, THE NEXT ORDER OF BUSINESS IS?
15	MR. HARRISON: A MOTION FROM A MEMBER WHO
16	DOES NOT HAVE A CONFLICT WITH RESPECT TO ANY OF THE
17	APPLICATIONS IN TIER III TO CLOSE FUNDING WITH
18	RESPECT TO THOSE APPLICATIONS.
19	CHAIRMAN THOMAS: DO I HEAR A MOTION TO
20	THAT EFFECT?
21	DR. VUORI: SO MOVED.
22	CHAIRMAN THOMAS: MOVED BY DR. VUORI.
23	SECONDED
24	DR. STEWARD: SECOND.
25	CHAIRMAN THOMAS: BY DR. STEWARD. ANY
	0.5
	85

1	BOARD DISCUSSION? ANY COMMENTS FROM MEMBERS OF THE
2	PUBLIC? ACTUALLY HOLD ON ONE SECOND. WAIT TILL WE
3	JUST VOTE ON THIS AND THEN WE'RE ALL SAID AND DONE,
4	WHICH WILL BE TWO SECONDS, WE'LL BE READY FOR YOU.
5	ANY COMMENTS FROM MEMBERS OF THE PUBLIC ON
6	THESE ITEMS? OKAY. HEARING NONE, CALL THE ROLL,
7	PLEASE.
8	MR. HARRISON: THE MOTION IS TO CLOSE
9	FUNDING OR NOT TO FUND THE APPLICATIONS IN TIER III.
10	AND A REMINDER TO MEMBERS, THAT TO THE EXTENT THAT
11	YOU HAVE A CONFLICT WITH RESPECT TO ONE OF THOSE
12	FOUR APPLICATIONS, YOU SHOULD VOTE YES OR NO EXCEPT
13	FOR THOSE APPLICATIONS IN WHICH YOU HAVE A CONFLICT.
14	CHAIRMAN THOMAS: MR. HARRISON, FOLLOWING
15	THIS VOTE, THAT WILL CONCLUDE THE VOTE ON THIS
16	ENTIRE ITEM, CORRECT?
17	MR. HARRISON: CORRECT.
18	CHAIRMAN THOMAS: MARIA, PLEASE CALL THE
19	ROLL.
20	MR. SHEEHY: I THINK YOU HAVE A PUBLIC
21	COMMENT.
22	CHAIRMAN THOMAS: NO. IT'S NOT ON THE
23	MOTION.
24	MS. BONNEVILLE: SUE BRYANT.
25	DR. BRYANT: YES.
	86

i	
1	MS. BONNEVILLE: FRANK CHISARI.
2	DR. CHISARI: I'M NOT SURE I UNDERSTAND
3	THE MOTION.
4	MR. HARRISON: YES MEANS THAT YOU AGREE
5	THAT THE APPLICATIONS IN TIER III SHOULD NOT BE
6	FUNDED. IF YOU HAVE A CONFLICT WITH RESPECT TO ONE
7	OF THOSE APPLICATIONS, YOU SHOULD SAY YES EXCEPT FOR
8	THOSE APPLICATION WITH WHICH I HAVE A CONFLICT.
9	MS. SAMUELSON: SINCE YOU PAUSED FOR A
10	SECOND, MAY I ASK A QUESTION OF COUNSEL? I WAS NOT
11	PRESENT. I'M JOINING THE MEETING AND I WASN'T
12	PRESENT FOR THE CLOSED SESSION. I HAVE OTHER
13	REASONS FOR MY VOTE, AND I'M WONDERING IF NOT BEING
14	PRESENT THERE MEANS I SHOULD ABSTAIN OR HAVE THE
15	FREEDOM TO VOTE ON THE MERITS.
16	MR. HARRISON: IT'S YOUR CHOICE. YOU'RE
17	ALWAYS FREE TO ABSTAIN IF YOU FEEL THAT YOU DON'T
18	HAVE SUFFICIENT INFORMATION TO VOTE.
19	MS. SAMUELSON: THANK YOU.
20	MS. BONNEVILLE: SUE BRYANT.
21	DR. BRYANT: YES.
22	MS. BONNEVILLE: FRANK CHISARI.
23	DR. CHISARI: YES.
24	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
25	DR. DULIEGE: YES, EXCEPT FOR THE ONES FOR
	87

1	WHICH I HAVE A CONFLICT.
2	MS. BONNEVILLE: JAMES ECONOMOU.
3	DR. ECONOMOU: YES, EXCEPT FOR THE ONES
4	WITH WHICH I HAVE A CONFLICT.
5	MS. BONNEVILLE: MARCY FEIT.
6	MS. FEIT: YES, EXCEPT FOR THE ONES WITH
7	WHICH I HAVE A CONFLICT.
8	MS. BONNEVILLE: ELIZABETH FINI.
9	DR. FINI: YES, EXCEPT FOR THE ONES WITH
10	WHICH I HAVE A CONFLICT.
11	MS. BONNEVILLE: GARY FIRESTEIN.
12	DR. FIRESTEIN: YES, EXCEPT FOR THE ONES
13	WITH WHICH I HAVE A CONFLICT.
14	MS. BONNEVILLE: MICHAEL FRIEDMAN. LEEZA
15	GIBBONS. MICHAEL GOLDBERG.
16	MR. GOLDBERG: YES, EXCEPT FOR THE ONES
17	WITH WHICH I HAVE A CONFLICT.
18	MS. BONNEVILLE: SAM HAWGOOD.
19	DR. HAWGOOD: YES, EXCEPT FOR THE ONES
20	WITH WHICH I HAVE A CONFLICT.
21	MS. BONNEVILLE: STEVE JUELSGAARD.
22	MR. JUELSGAARD: ABSTAIN.
23	MS. BONNEVILLE: SHERRY LANSING. BERT
24	LUBIN.
25	DR. LUBIN: I'M SORRY. I JUST GOT ON THE
	88

	DARKISIERS REPORTING SERVICE
1	PHONE. I DON'T APPROVE. WAS IT APPROVE OR NOT
2	APPROVE?
3	MR. HARRISON: THE QUESTION ON THE TABLE,
4	DR. LUBIN, IS WHETHER YOU AGREE THAT THE
5	APPLICATIONS IN TIER III SHOULD NOT BE FUNDED.
6	DR. LUBIN: I AGREE.
7	MS. BONNEVILLE: SHLOMO MELMED.
8	DR. MELMED: YES, EXCEPT FOR THE ONES WITH
9	WHICH I HAVE A CONFLICT.
10	MS. BONNEVILLE: PHIL PIZZO. CLAIRE
11	POMEROY.
12	DR. POMEROY: YES, EXCEPT FOR THE ONES
13	WITH WHICH I HAVE A CONFLICT.
14	MS. BONNEVILLE: ROBERT PRICE.
15	DR. PRICE: YES.
16	MS. BONNEVILLE: FRANCISCO PRIETO.
17	DR. PRIETO: YES, EXCEPT FOR THE ONES WITH
18	WHICH I HAVE A CONFLICT.
19	MS. BONNEVILLE: ROBERT QUINT. DUANE
20	ROTH. JOAN SAMUELSON.
21	MS. SAMUELSON: YES.
22	MS. BONNEVILLE: JEFF SHEEHY.
23	MR. SHEEHY: YES, EXCEPT FOR THE ONES WITH
24	WHICH I HAVE A CONFLICT.
25	MS. BONNEVILLE: JON SHESTACK.
	80
	89

	BARRISTERS REPORTING SERVICE
1	MR. SHESTACK: YES.
2	MS. BONNEVILLE: OS STEWARD.
3	DR. STEWARD: YES.
4	MS. BONNEVILLE: JONATHAN THOMAS.
5	CHAIRMAN THOMAS: YES.
6	MS. BONNEVILLE: ART TORRES. KRISTINA
7	VUORI.
8	DR. VUORI: YES.
9	CHAIRMAN THOMAS: MR. HARRISON.
10	MR. HARRISON: WE'LL TABULATE THE RESULTS,
11	SO YOU MIGHT WANT TO MOVE ON TO THE NEXT ITEM.
12	CHAIRMAN THOMAS: LET'S MOVE ON TO PUBLIC
13	COMMENT. THANK YOU, GENTLEMEN, FOR WAITING.
14	DR. STEWARD: I'M SORRY FOR DOING THIS.
15	UNLESS IT'S ON AN ITEM THAT WE'RE DISCUSSING,
16	DOESN'T PUBLIC COMMENT COME AT THE END OF THE
17	MEETING?
18	CHAIRMAN THOMAS: THIS IS ON AN ITEM WE
19	ALREADY DISCUSSED.
20	DR. LAIKIND: THANK YOU. THANK YOU FOR
21	GIVING ME AN OPPORTUNITY TO SPEAK TO YOU. MY NAME
22	IS DR. PAUL LAIKIND. I'M THE PRESIDENT AND CEO OF
23	VIACYTE, WHICH IS THE COMPANY THAT IS DRIVING
24	FORWARD THE DIABETES PROJECT THAT YOU JUST AGREED TO
25	FUND. SO I WANT TO TAKE THIS OPPORTUNITY TO THANK
	90

1	THE MEMBERS OF THE GOVERNING BOARD, THE ICOC, AND,
2	MOST IMPORTANTLY, THE TAXPAYERS OF CALIFORNIA FOR
3	THE CONTINUED SUPPORT THAT THEY ARE PROVIDING TO
4	VIACYTE TO OUR PROGRAM.
5	CIRM'S SCIENTIFIC AND FINANCIAL SUPPORT
6	HAS ALLOWED US TO CARRY OUT OUR GROUNDBREAKING
7	RESEARCH WHICH WE HOPE WILL TRANSFORM THE WAY
8	PATIENTS WITH DIABETES ARE TREATED IN CALIFORNIA,
9	OUR NATION, AND THE WORLD. THANKS TO THE SUPPORT OF
10	CIRM, WE HAVE MADE TREMENDOUS PROGRESS TOWARDS A
11	CELL THERAPY PRODUCT THAT HOLDS THE PROMISE OF
12	ESSENTIALLY A CURE FOR TYPE 1 DIABETES AS WELL AS AN
13	IMPORTANT NEW TREATMENT FOR PATIENTS WITH INSULIN
14	REQUIRING TYPE 2 DISEASE.
15	MUCH HAS ALREADY BEEN ACCOMPLISHED IN
16	PURSUIT OF THIS VERY WORTHWHILE GOAL. AND WITH
17	CIRM'S CONTINUED HELP, WE WILL SOON KNOW WHETHER
18	THIS PROMISE OF A NEW ERA IN DIABETES TREATMENT WILL
19	BE FULFILLED.
20	CIRM HAS PLAYED A REALLY CRUCIAL ROLE IN
21	THE FIELD OF REGENERATIVE MEDICINE ESPECIALLY TODAY
22	WHEN THE COMMERCIAL FUNDING AVENUES HAVE BECOME MUCH
23	MORE RISK AVERSE. CIRM SUPPORT ENSURES THAT
24	PROMISING, INNOVATIVE CELL THERAPY TECHNOLOGIES ARE
25	FULLY EXPLORED. THIS WORK HAS THE POTENTIAL OF
	91
	J =

1	EASING THE BURDEN ON PATIENTS WHILE AT THE SAME TIME
2	STIMULATING CALIFORNIA'S ECONOMY AND CREATING JOBS.
3	FOR INSTANCE, CIRM SUPPORT HAS ALLOWED US TO HIRE
4	THE WORKFORCE WE NEED TO ACHIEVE SUCCESS. VIACYTE
5	HAS MORE THAN DOUBLED IN SIZE SINCE THE FUNDING WAS
6	INITIATED WITH THE DISEASE TEAM GRANT THAT WE
7	BENEFITED FROM.
8	WE'RE MANUFACTURING OUR CELL PRODUCT, OUR
9	IMMUNE PROTECTIVE DEVICE, AND THE COMBINATION
10	PRODUCT, VC01, WHICH IS MOVING TO THE CLINIC, ALL AT
11	OUR FACILITIES IN SAN DIEGO. MOREOVER, OTHER
12	CALIFORNIA BUSINESSES AND INSTITUTIONS HAVE AND WILL
13	CONTINUE TO PLAY A KEY ROLE IN OUR PRECLINICAL AND
14	CLINICAL DEVELOPMENT ACTIVITY.
15	CIRM SUPPORT HAS ALSO HAD A MULTIPLIER
16	EFFECT, ATTRACTING SUPPORT FOR OUR WORK AT VIACYTE
17	FROM OTHER ORGANIZATIONS SUCH AS JDRF, NESTLE
18	INSTITUTE FOR HEALTH SCIENCES, AND EVEN THE EUROPEAN
19	UNION HAS CONTRIBUTED.
20	IN ADDITION, THE ASSOCIATION WITH CIRM HAS
21	HELPED US TO ATTRACT THE INTEREST OF STRATEGIC
22	PARTNERS SUCH AS GLAXO-SMITH-KLINE, WHO IS
23	REPRESENTED HERE TODAY AS WELL. AND THIS GIVES US
24	THE RESOURCES AND INFRASTRUCTURE TO COMPLETE THE
25	DEVELOPMENT OF THE PRODUCT AND COMMERCIALIZE IT FOR
	0.2
	92

1	THE BENEFIT OF PATIENTS.
2	SO TO CLOSE, I JUST WANT TO ASSURE CIRM
3	AND THE CITIZENS OF CALIFORNIA THAT THE ENTIRE
4	VIACYTE TEAM IS COMMITTED TO USING THE FUNDING YOU
5	HAVE SEEN FIT TO PROVIDE US WISELY AND TO WORK
6	TIRELESSLY TO FULLY EXPLORE THE TREMENDOUS PROMISE
7	OF THIS TECHNOLOGY. AGAIN, I JUST WANT TO TAKE THE
8	OPPORTUNITY TO THANK YOU.
9	(APPLAUSE.)
10	CHAIRMAN THOMAS: THANK. YOU:
11	MR. GARDENER: GOOD MORNING. MY NAME IS
12	JASON GARDENER. I'M THE HEAD OF THE REGENERATIVE
13	MEDICINE UNIT AT GLAXO-SMITH-KLINE. AND I'D LIKE TO
14	MAKE A FEW FOLLOW-ON COMMENTS FROM PAUL ABOUT THE
15	SAME APPLICATION.
16	OUR CORE MISSION AT GLAXO-SMITH-KLINE AND
17	THE REGENERATIVE MEDICINE UNIT IS TO DEVELOP A
18	SUSTAINABLE PIPELINE OF REGENERATIVE MEDICINES THAT
19	WILL BRING SUBSTANTIAL CLINICAL BENEFIT TO PATIENTS.
20	I FIRST MET ALAN TROUNSON THREE YEARS AGO TO TALK
21	ABOUT THAT VISION AND THE SHARED VISION THAT CIRM
22	HAD. AND WE AGREED WE HAD REMARKABLE ALIGNMENT ON
23	THREE LEVELS. FIRST, THE CELL-BASED REGENERATIVE
24	MEDICINES COULD BE TRANSFORMATIVE FOR PATIENTS.
25	SECOND, THEIR DEVELOPMENT PATH IS COMPLEX AND HIGH

1	RISK. AND THIRD, THAT THIS PATH IS BEST NAVIGATED
2	IN PARTNERSHIP WITH GROUPS THAT SHARE THE SAME
3	VISION.
4	GSK HAS A CLEAR STRATEGY TO PARTNER WITH
5	EXTERNAL GROUPS THAT HAVE DEVELOPED DEEP TECHNICAL
6	EXPERTISE WHERE THE STRENGTHS OF GSK IN CLINICAL AND
7	REGULATORY AFFAIRS CAN COMPLEMENT TO MAKE MEDICINES.
8	WE HAVE PRIORITIZED DIABETES AS A KEY AREA WHERE
9	COMPELLING SCIENCE AND CLINICAL TRANSLATION CAN
10	CATALYZE TO MAKE REGENERATIVE MEDICINES.
11	VIACYTE HAS MADE TREMENDOUS PROGRESS IN
12	THIS FIELD USING STEM CELLS TO GENERATE ISLET
13	PROGENITORS, AND WE HAVE COMPLETED AN INTENSE
14	TECHNICAL AND FINANCIAL DILIGENCE OF THE PROGRAM.
15	AND THIS HAS BEEN REVIEWED BY MULTIPLE COMMITTEES IN
16	GLAXO-SMITH-KLINE. WE HAVE PROPOSED AN ALLIANCE TO
17	ENABLE GSK, VIACYTE, AND CIRM TO PROGRESS THIS
18	PROGRAM.
19	SUBJECT TO FINAL GSK APPROVAL, WE WOULD
20	INITIATE THE ALLIANCE CONTINGENT ON THE FUNDING FROM
21	CIRM, AND THE STRATEGIC PARTNERSHIP AWARD TODAY IS
22	CRUCIAL TO THIS ALLIANCE. AND THE MODEL IS AN EXACT
23	EXCELLENT EXAMPLE OF THREE GROUPS COMING TOGETHER TO
24	FORM AN ALLIANCE AROUND A POTENTIALLY INNOVATIVE
25	TRANSFORMATIVE MEDICINE. AND I'D LIKE TO THANK CIRM

1	AND OUR COLLEAGUES AT VIACYTE FOR GIVING US THE
2	OPPORTUNITY TO WORK TOGETHER. THANK YOU.
3	(APPLAUSE.)
4	CHAIRMAN THOMAS: THANK YOU. DR.
5	TROUNSON.
6	DR. TROUNSON: CHAIR, BOARD, THIS IS
7	REALLY ONE OF THE MOST IMPORTANT STEPS THAT WE TAKE
8	IN THE DIRECTION OF BRINGING THESE THERAPIES TO
9	PATIENTS. THIS IS VERIFICATION OF OUR PROGRAM. TO
10	HAVE JASON JOIN US THROUGH A PARTNERSHIP ARRANGEMENT
11	WITH GSK MEANS THAT A PROJECT THAT WE'VE SHEPHERDED
12	FROM THE BASIC SCIENCE THROUGH TO THE PRECLINICAL
13	WORK AND IS HEADING TO THE CLINIC WE'RE NOW GOING TO
14	DO IN PARTNERSHIP WITH A VERY MAJOR ORGANIZATION.
15	AND I THINK THIS WILL RESOUND IN
16	CALIFORNIA, I THINK IT WILL RESOUND IN THE UNITED
17	STATES, AND I THINK IT WILL RESOUND IN THE WHOLE
18	WORLD. AND I WANTED TO THANK JASON IN PARTICULAR
19	FOR STICKING WITH IT OVER THREE YEARS IN THESE
20	DISCUSSIONS. I WANT TO THANK ELONA BAUM FOR REALLY
21	TAKING UP THE REALLY HARD WORK OF ACTUALLY GETTING
22	THIS IN PLACE. AND FINALLY, I WANTED TO THANK PAUL
23	AND ALL THE PEOPLE AT VIACYTE FOR THE INCREDIBLE
24	ENERGY AND DEDICATION THAT THEY'VE HAD IN A SINGLE
25	PROJECT FOCUSED ON A SINGLE PRODUCT TO GET IT TO
	05

1	WHERE IT IS. AND I HOPE VERY MUCH THAT THIS IS
2	GOING TO TRANSLATE TO BENEFIT IN PATIENTS AND WILL
3	BE ONE OF THE STONES THAT WE CAN ALL TURN BACK ON
4	AND SAY THIS MADE PROPOSITION 71 ABSOLUTELY
5	WORTHWHILE NOT ONLY FOR CALIFORNIA, BUT I'D SUGGEST
6	FOR THE WHOLE WORLD.
7	CHAIRMAN THOMAS: THANK YOU, DR. TROUNSON.
8	THANK YOU, GENTLEMEN, FOR YOUR REMARKS. WE'RE
9	DELIGHTED TO BE ABLE TO CONTINUE OUR SUPPORT.
10	DELIGHTED THAT WE HAVE BEEN ABLE TO HELP FACILITATE
11	A PARTNERSHIP WHICH WE THINK WILL BE KEY GOING
12	FORWARD TO FURTHER DEVELOPMENT OF THE PRODUCT. AND
13	THANK YOU FOR YOUR COMMENTS VALIDATING WHAT CIRM IS
14	ALL ABOUT. I'M SURE THAT THIS WHOLE STORY WILL
15	FEATURE PROMINENTLY, MR. JENSEN, IN AN ARTICLE
16	YOU'RE ABOUT TO POST LATER THIS AFTERNOON.
17	WE WILL NOW MOVE ON TO ITEM NO. 9 ON THE
18	AGENDA, WHICH IS CONSIDERATION OF THE STRATEGIC
19	PARTNERSHIP II CONCEPT PLAN WHICH WAS ALREADY
20	PREVIEWED BY DR. FEIGAL. WE NOW WILL ASK DR. CARAS
21	TO WALK US THROUGH THAT. DR. CARAS.
22	DR. CARAS: WE JUST FINISHED TALKING ABOUT
23	STRATEGIC PARTNERSHIP I, BUT I WANT TO JUST VERY
24	BRIEFLY REREMIND YOU ABOUT THE BROADER INITIATIVE.
25	THIS INITIATIVE AS CURRENTLY APPROVED DIRECTS CIRM

1	TO IMPLEMENT THE PROGRAM USING AN RFA PROCESS. WE
2	WOULD LIKE TO DO THIS WITH A VERY RAPID TURNAROUND
3	WITH SOLICITATIONS TWICE PER YEAR AND WHERE EACH
4	SOLICITATION MAY DEFINE THE SPECIFIC SCOPE OF
5	RESEARCH WITHIN THE BROADER SCOPE OF THE CONCEPT.
6	IN ADDITION, THERE WILL BE ACTIVE MANAGEMENT OF
7	FUNDED DEVELOPMENT PROJECTS, WHICH INCLUDE
8	DISCUSSIONS WITH CIRM'S CLINICAL DEVELOPMENT
9	ADVISORY PANEL.
10	AGAIN, AS A QUICK REMINDER, THE PURPOSE OF
11	THE INITIATIVE IS TO ATTRACT INDUSTRY ENGAGEMENT AND
12	INVESTMENT TO CIRM-FUNDED STEM CELL RESEARCH.
13	VARIOUS REASONS TO DO THIS, TO PROVIDE CO-FUNDING
14	FOR EARLY STAGES OF DEVELOPMENT, TO ENHANCE THE
15	LIKELIHOOD THAT THERE WILL BE FOLLOW-UP FINANCING
16	FOR THE LATER STAGES, AND TO ENABLE THE PROJECTS TO
17	ACCESS THE DEVELOPMENT EXPERTISE WITHIN LARGE
18	COMPANIES.
19	THE TWO UNIQUE FEATURES OF THE INITIATIVE
20	IS THAT IT REQUIRES APPLICANTS TO SHOW THEY HAVE
21	FINANCIAL CAPACITY TO MOVE THE PROJECT THROUGH
22	DEVELOPMENT, WHICH CAN BE DONE IN A NUMBER OF WAYS,
23	INCLUDING THROUGH A PARTNERSHIP, AS WE JUST HEARD
24	ABOUT WITH THE APPLICATION THAT YOU JUST FUNDED.
25	AND SECOND, IT REQUIRES APPLICANTS TO PROVIDE

1	CO-FUNDING FOR THE PROPOSED PROJECT, AND THIS IS IN
2	THE FORM OF A ONE-TO-ONE MATCH.
3	SO WITH THAT BACKGROUND TO THE BROADER
4	CONCEPT, I'LL NOW MOVE ON AND TALK ABOUT THE CONCEPT
5	PROPOSAL FOR STRATEGIC PARTNERSHIP II. SO SP II IS
6	VERY SIMILAR TO STRATEGIC PARTNERSHIP I WITH THE
7	SAME SCOPE AND OBJECTIVE. IT KEEPS THE AWARD AMOUNT
8	AT \$10 MILLION PER AWARD, BUT IT DOES ALLOW THE
9	POSSIBILITY OF INCREASING THE AMOUNT TO 15 MILLION
10	UNDER EXCEPTIONAL CIRCUMSTANCES AND WITH ICOC
11	APPROVAL. THIS IS A MODIFICATION THAT WAS APPROVED
12	BY THE SCIENCE SUBCOMMITTEE ON OCTOBER THE 8TH,
13	RECENTLY.
14	THIS SHOWS THE SCOPE OF SP II. IT'S THE
15	SAME AS FOR SP I. AS YOU CAN SEE, THIS IS DESIGNED
16	TO CAPTURE MATURE PROGRAMS THAT ARE CLOSE TO OR AT
17	THE EARLY CLINICAL DEVELOPMENT STAGE.
18	AS WITH SP I, THE OBJECTIVE OF AN SP II
19	AWARD IS COMPLETION OF AN EARLY STAGE CLINICAL TRIAL
20	WITHIN FOUR YEARS. AGAIN, THE PROPOSED PROJECT CAN
21	INCLUDE PRECLINICAL IND-ENABLING WORK, BUT ALL
22	APPLICANTS MUST BE ABLE TO COMPLETE A TRIAL WITHIN
23	FOUR YEARS.
24	AS WITH SP I, SP II IS ALIGNED WITH CIRM'S
25	FIVE-YEAR STRATEGIC GOAL TO ATTRACT INDUSTRY
	98

1	ENGAGEMENT, AND IT'S ALSO ALIGNED WITH CIRM'S
2	FIVE-YEAR STRATEGIC CLINICAL OBJECTIVE TO ADVANCE
3	STEM CELL SCIENCE INTO CLINICAL TRIALS.
4	READINESS IS AN ELIGIBILITY CRITERION FOR
5	STRATEGIC PARTNERSHIP II. FOR PROJECTS THAT ARE AT
6	THE PRECLINICAL STAGE, THEY MUST HAVE ALREADY
7	SELECTED A SINGLE THERAPEUTIC DEVELOPMENT CANDIDATE.
8	THEY SHOULD HAVE SOME PRECLINICAL PROOF OF CONCEPT
9	WITH THIS CANDIDATE IN THE TARGET DISEASE OR INJURY.
10	AND THEY MUST HAVE ALREADY COMPLETED A PRE-IND
11	MEETING WITH THE FDA. FOR PROJECTS THAT ARE AT A
12	CLINICAL STAGE, THEY MUST HAVE FILED THEIR IND.
13	THESE ARE THE ACTIVITIES THAT WOULD BE IN
14	SCOPE. THEY ARE THE SAME AS FOR SP I. THEY INCLUDE
15	THE CONDUCT OF EARLY CLINICAL TRIALS, IND-ENABLING
16	PRECLINICAL ACTIVITY TO ENABLE A TRIAL, AND ANY
17	SUPPORTING ACTIVITIES THAT WOULD BE NECESSARY.
18	THE THERAPEUTIC CANDIDATE SHOULD BE ONE OF
19	THE FOLLOWING: A PRODUCT DERIVED FROM PLURIPOTENT
20	CELLS, ALLOGENEIC TISSUE DERIVED ADULT STEM CELLS OR
21	PROGENITOR CELLS FOR REPAIR AND REGENERATION, STEM
22	CELL ENGINEERED FUNCTIONAL TISSUES, SMALL MOLECULES
23	OR BIOLOGICS THAT TARGET ENDOGENOUS STEM CELLS FOR
24	REGENERATION AND REPAIR, AND GENETICALLY OR
25	PHARMACOLOGICALLY MODIFIED HEMATOPOIETIC STEM CELLS.

1	THIS RFA IS OPEN TO BOTH FOR-PROFIT AND
2	NOT-FOR-PROFIT INSTITUTIONS. ALL APPLICANTS MUST
3	PROVIDE EVIDENCE OF COMMERCIAL VALIDATION. SO IF
4	YOU'RE A FOR-PROFIT APPLICANT, YOU CAN DO THIS
5	EITHER BY FINANCIAL STRENGTH AND/OR VIA A
6	DEVELOPMENT AGREEMENT WITH A LARGE BIOTECH OR PHARMA
7	PARTNER. NOT-FOR-PROFIT APPLICANTS MUST HAVE A
8	DEVELOPMENT AGREEMENT WITH A LARGE BIOTECH OR PHARMA
9	PARTNER, AND THAT'S DEFINED AS HAVING A MARKET CAP
10	OF AT LEAST 500 MILLION.
11	THE OVERALL AWARD INFORMATION: UP TO \$40
12	MILLION ARE REQUESTED IN TOTAL COSTS TO SUPPORT THIS
13	SOLICITATION. WE'RE TARGETING TWO TO FOUR AWARDS.
14	AGAIN, THE AMOUNT WOULD BE 10 MILLION PER PROJECT,
15	UNDER EXCEPTIONAL CIRCUMSTANCES UP TO 15 MILLION.
16	THE AWARD TERM IS FOUR YEARS. ALL APPLICANTS MUST
17	PROVIDE CO-FUNDING IN THE FORM OF A ONE-TO-ONE
18	MATCH. AWARD MECHANISM WOULD BE A GRANT IF IT'S A
19	NOT-FOR-PROFIT ORGANIZATION AND A LOAN OR A GRANT IF
20	FOR-PROFIT.
21	LAST SLIDE IS THE PROVISIONAL TIMETABLE
22	FOR SP II. WE'RE GOING TO POST THE RFA NEXT MONTH,
23	NOVEMBER, WHICH IS ACTUALLY VERY SOON. THAT WOULD
24	BE FOR REVIEW BY THE GRANTS WORKING GROUP IN APRIL
25	OR MAY OF 2013, REVIEW AND APPROVAL BY THE ICOC IN
	100

1	JUNE OR JULY OF NEXT YEAR, AND THE EARLIEST FUNDING
2	OF AWARDS WOULD BE IN Q 3. THAT CONCLUDES WHAT I
3	HAVE TO SAY ABOUT SP II. I'LL BE HAPPY TO TAKE
4	QUESTIONS.
5	CHAIRMAN THOMAS: ANY QUESTIONS OR
6	COMMENTS BY MEMBERS OF THE BOARD ON THIS
7	PRESENTATION?
8	MS. SAMUELSON: QUICK ONE. ARE THERE
9	ANY SINCE OUR MISSION HAS A SCOPE OF ALL OF THE
10	TOOLS OF REGENERATIVE MEDICINE, THERE WAS A LONG
11	LIST OF MECHANISMS THAT ARE FUNDABLE. IS THERE
12	ANYTHING ELSE OUTSIDE THAT LIST THAT COULD
13	CONCEIVABLY BE AN IMPORTANT TOOL THAT WE SHOULD
14	CONSIDER? I'M WONDERING WHY WE DON'T JUST DEFINE IT
15	AS THAT WIDER SCOPE.
16	DR. FEIGAL: YEAH. THANK YOU FOR THE
17	QUESTION. PART OF OUR DELIBERATIONS IN THINKING
18	ABOUT THE STRATEGIC PARTNERSHIP VERSIONS IS THAT WE
19	DO HAVE THE OPPORTUNITY AS PART OF THE UMBRELLA
20	AGREEMENT OF THE OPPORTUNITY FUND TO MODIFY OR
21	CHANGE THE ITERATIONS AS THEY COME AROUND. FOR THIS
22	PARTICULAR ITERATION, WE THINK WHAT WE HAVE FOR THE
23	INCLUSION CRITERIA COVERS A BROAD WATERFRONT OF WHAT
24	COULD BE DONE.
25	IT COULD BE IN A SUBSEQUENT ITERATION,
	101
	101

1	WHICH WOULD JUST BE SIX MONTHS DOWN THE ROAD, WE
2	COULD MODIFY IT IN THAT ITERATION. IN ADDITION, WE
3	STILL DO HAVE THIS VERY EXCEPTIONAL PRESIDENTIAL
4	ROUTE WHERE IF THERE REALLY IS A KEY OPPORTUNITY, WE
5	COULD TAKE A LOOK AT IT AND MAKE A DECISION WHETHER
6	OR NOT TO INCLUDE IT. I DON'T KNOW IF THAT ANSWERS
7	YOUR QUESTION, BUT WE FEEL WHAT WE PUT IN THIS
8	PARTICULAR VERSION IS SOMETHING, GIVEN THE MATURITY
9	OF THE PROJECTS, THAT WE WANT TO SEE ENCOMPASSES
10	QUITE A BROAD RANGE OF WHAT WE THINK COULD COME IN.
11	MS. SAMUELSON: IS THERE ANYTHING THAT YOU
12	CAN THINK OF THAT'S EXCLUDED?
13	DR. FEIGAL: OH, THERE'S A UNIVERSE OF
14	THINGS THAT ARE POSSIBLE, BUT WE THINK THIS IS A
15	VERY COMPELLING, RATIONAL LIST OF WHAT WE COULD
16	DEFINE FOR THIS PARTICULAR VERSION.
17	MS. SAMUELSON: I WONDER WHY WE WOULDN'T
18	LEAVE THAT CREATIVE DEVELOPMENT TO THE SCIENTISTS
19	WHO MIGHT WANT TO APPLY. IF THEY HAVE A GREAT IDEA
20	AND IT'S NOT INCLUDED ON THAT LIST, WE MAY NEVER
21	HEAR ABOUT IT.
22	DR. FEIGAL: WELL, WE ALWAYS HAVE THE
23	OPPORTUNITY THAT THE PERSON WITH A GREAT IDEA CAN
24	CONTACT US AND WE CAN HAVE A CONVERSATION WITH THEM
25	AND SEE IF THERE'S WAYS TO ACCOMMODATE WHAT THEY'RE
	102

1	SUGGESTING. BUT EVERY RFA WE PUT OUT, BY
2	DEFINITION, HAS SOME SORT OF INCLUSION CRITERIA SO
3	THAT PEOPLE DO HAVE SOME IDEA OF WHAT WE'RE LOOKING
4	FOR. SINCE CIRM DOES HAVE A MISSION TO LOOK AT STEM
5	CELL-BASED THERAPIES, WE THOUGHT THAT THE LIST THAT
6	WE HAVE PROVIDED HERE IS CERTAINLY A LIST THAT TAKES
7	INTO ACCOUNT WHERE THE SCIENCE IS AND ALSO TAKES
8	INTO ACCOUNT WHAT CIRM'S MISSION IS.
9	MS. SAMUELSON: THANK YOU.
10	DR. CARAS: IF I COULD JUST ADD, I THINK
11	THAT STRATEGIC PARTNERSHIP ALONG WITH DISEASE TEAM,
12	BUT IN PARTICULAR THIS INITIATIVE, IS PROBABLY OUR
13	BEST CHANCE OF ACHIEVING THE STRATEGIC OBJECTIVE OF
14	GETTING THESE THERAPIES INTO THE CLINIC AND APPROVED
15	FOR THE BENEFIT OF PATIENTS.
16	CHAIRMAN THOMAS: ANY OTHER COMMENTS? I'D
17	LIKE TO MAKE ONE, WHICH IS I NOTE THAT YOU BUDGETED
18	FOR UP TO 40 MILLION IN AWARDS. I WOULD LIKE THE
19	BOARD, IN THE EVENT THAT WE END UP HAVING A LARGE
20	NUMBER OF PROJECTS THAT ARE RECOMMENDED BY THE
21	GRANTS WORKING GROUP FOR APPROVAL AND THAT THE
22	NUMBER MAY EXCEED 40 MILLION, THAT WE MAINTAIN SOME
23	FLEXIBILITY AND DEAL WITH THAT ISSUE IF IT COMES UP
24	SO THAT WE'RE NOT HAMSTRUNG BY AN ABSOLUTE CAP. I
25	WANT TO MAKE SURE WE CAPTURE ALL THE BEST PROJECTS
	103
	— * *

1	THAT ARE OUT THERE.
2	SO, JAMES, DO WE HAVE TO APPROVE THIS VIA
3	VOICE VOTE?
4	MR. HARRISON: YES.
5	CHAIRMAN THOMAS: SO ALL THOSE IN FAVOR OF
6	THE
7	MR. HARRISON: WE NEED A MOTION.
8	CHAIRMAN THOMAS: WE NEED A MOTION. YES,
9	THAT WOULD HELP.
10	MS. LANSING: SO MOVED.
11	CHAIRMAN THOMAS: SO MOVED BY SHERRY.
12	SECONDED BY
13	DR. POMEROY: SECOND.
14	CHAIRMAN THOMAS: BY DEAN POMEROY.
15	THANK YOU. WE NOW HAVE A MOTION AND SOMETHING TO
16	VOTE ON. THANK YOU FOR MAKING THAT SALIENT POINT,
17	MR. HARRISON. ALL THOSE IN FAVOR OF THIS MOTION TO
18	APPROVE THE STRATEGIC PARTNERSHIP II CONCEPT PLAN
19	PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MR.
20	HARRISON, I BELIEVE THAT MOTION CARRIES, CORRECT?
21	SORRY. ALTHOUGH WE DID HEAR SOME VOTES.
22	MS. LANSING: I VOTED YES.
23	CHAIRMAN THOMAS: DR. LUBIN.
24	DR. LUBIN: YES.
25	CHAIRMAN THOMAS: WE'RE UNANIMOUS. WE'RE
	104

GOING TO SKIP DOWN NOW TO ITEM NO. 12, WHICH IS
CONSIDERATION OF THE APPOINTMENT OF NEW SCIENTIFIC
MEMBERS OF THE GRANTS WORKING GROUP. DR. SAMBRANO.
DR. SAMBRANO: MEMBERS OF THE BOARD, WE'RE
COMING TODAY TO BRING FOR YOUR CONSIDERATION 12
NOMINEES OF THE GRANTS WORKING GROUP THAT ARE GOING
TO BRING KEY SCIENTIFIC EXPERTISE IN QUITE A VARIETY
OF AREAS, INCLUDING GMP MANUFACTURING AND BANKING.
THE NOMINEES ARE LISTED IN YOUR BOOKS. I WILL JUST
NAME EACH OF THE CANDIDATES. VANIA BROCCOLI.
CHAIRMAN THOMAS: THAT'S IN TAB 12.
DR. SAMBRANO: ULRICH BROECKEL, DANIEL
DOHERTY, MERI FIRPO, BRUCE GELB, DEREK HEI, DARRELL
KOTTON, JOSEPH LANING, JACOB MCCAJULEY, AARMO
PALOTIE, LUDOVIC VALLIER, AND RICHARD WADE-MARTINS.
AND SO WE SEEK YOUR APPROVAL AND
APPOINTMENT OF THESE NOMINEES AS MEMBERS OF THE
GRANTS WORKING GROUP.
CHAIRMAN THOMAS: DO I HEAR A MOTION TO
THAT EFFECT?
DR. HAWGOOD: SO MOVED.
CHAIRMAN THOMAS: SECONDED BY
MR. SHEEHY: SECOND.
CHAIRMAN THOMAS: MR. SHEEHY. ANY
DISCUSSION BY MEMBERS OF THE BOARD? DR. SAMBRANO,
105

1	I'D JUST LIKE TO COMMENT THAT WITH EACH PASSING
2	GRANTS WORKING GROUP MEETING, I'M TREMENDOUSLY
3	IMPRESSED, AS ARE WE ALL, THE REALLY HIGH CALIBER OF
4	ALL THE PEOPLE WHO ARE WILLING TO HELP US IN OUR
5	ENDEAVOR. AND CONGRATULATE YOU AND ALL MEMBERS OF
6	THE STAFF WORKING IN CONNECTION WITH THIS FOR
7	CONTINUING TO FIND TOP-FLIGHT PEOPLE WORLDWIDE TO
8	HELP ADVANCE OUR CAUSE.
9	ARE THERE ANY COMMENTS BY MEMBERS OF THE
10	PUBLIC? HEARING NONE, I BELIEVE THIS IS ANOTHER
11	VOICE VOTE. SO ALL THOSE IN FAVOR PLEASE SAY AYE.
12	OPPOSED? I HEARD DR. LUBIN. SHERRY.
13	MS. LANSING: YES, AYE.
14	CHAIRMAN THOMAS: IT'S UNANIMOUS. THANK
15	YOU VERY MUCH. ON TO ITEM NO. 13, CONSIDERATION OF
16	THE AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS TO
17	INCLUDE THE ROLES AND RESPONSIBILITIES OF THE
18	PARTICIPANTS IN THE GRANTS WORKING GROUP. MR.
19	HARRISON.
20	MR. HARRISON: GOOD MORNING. THIS IS ITEM
21	13 IN YOUR BINDERS, AND THIS WILL BE A VERY BRIEF
22	ITEM. AS YOU KNOW, THE GRANTS WORKING GROUP DIFFERS
23	IN SOME SIGNIFICANT WAYS FROM NIH PEER REVIEW
24	GROUPS, IN PART BECAUSE IT INCLUDES PATIENT
25	ADVOCATES. AS YOU ALSO KNOW, HAVING JUST APPROVED
	106
	1

1	THE ADDITION OF NEW SCIENTIFIC MEMBERS TO THE GRANTS
2	WORKING GROUP, YOU REALIZE THAT WE HAVE ADDED
3	NUMEROUS MEMBERS OVER THE YEARS TO ENSURE THAT WE
4	HAVE THE EXPERTISE AND NUMBERS NECESSARY TO REVIEW
5	THE APPLICATIONS THAT ARE SUBMITTED TO CIRM.
6	IN LIGHT OF THAT, WE THOUGHT IT WOULD BE
7	USEFUL TO AMEND THE BYLAWS FOR THE GRANTS WORKING
8	GROUP TO MORE CLEARLY DELINEATE THE ROLES AND
9	RESPONSIBILITIES OF EACH OF THE PARTICIPANTS IN THE
10	GRANTS WORKING GROUP PROCESS.
11	AS YOU WILL SEE IN YOUR MATERIALS, WE HAVE
12	DRAFTED A PARAGRAPH DESCRIBING THE ROLE OF THE
13	SCIENTIFIC MEMBERS, PARAGRAPH DESCRIBING THE ROLE OF
14	THE PATIENT ADVOCATE MEMBERS, SCIENTIFIC STAFF, AND
15	THE PRESIDENT OF CIRM. WE HAVE BROUGHT THIS
16	PROPOSAL TO THE SCIENCE SUBCOMMITTEE, WHICH
17	RECOMMENDED IT FOR YOUR APPROVAL BY A VOTE OF TEN TO
18	ONE. AND WE ALSO PRESENTED IT TO THE GRANTS WORKING
19	GROUP AT ITS MEETING IN SEPTEMBER. THE GRANTS
20	WORKING GROUP ALSO RECOMMENDED APPROVAL OF THESE
21	CHANGES.
22	SO UNLESS YOU HAVE QUESTIONS, WE WOULD
23	RECOMMEND THAT THE BOARD APPROVE THE STATEMENT OF
24	ROLES AND RESPONSIBILITIES AND DIRECT STAFF TO
25	INCORPORATE THEM INTO THE GRANTS WORKING GROUP
	107
	101

1	
1	BYLAWS. I'D BE HAPPY TO ANSWER ANY QUESTIONS.
2	MS. LANSING: I'D LIKE TO MOVE THE ITEM.
3	CHAIRMAN THOMAS: MOVED BY SHERRY.
4	MR. SHEEHY: SECOND.
5	CHAIRMAN THOMAS: SECONDED BY MR. SHEEHY.
6	ANY DISCUSSIONS BY MEMBERS OF THE BOARD?
7	DR. PRICE: I HAVE A QUESTION. IT'S
8	ABOUT MY QUESTION IS ABOUT THE SECTION ON THE
9	ROLE OF SCIENTIFIC MEMBERS, AND IT'S ABOUT THE LAST
10	SENTENCE OF THE NEXT TO LAST PARAGRAPH, WHICH BEGINS
11	SCIENTIFIC MEMBERS ARE EXPECTED TO CONSIDER AND ENDS
12	WITH WITH THEIR OWN INDEPENDENT SCIENTIFIC JUDGMENT.
13	SO WHAT I DON'T KNOW, BECAUSE I DON'T KNOW
14	WHAT THE PROCEDURES THAT FOLLOW IN THE GRANTS
15	WORKING GROUP, IS WHEN THESE CONFIDENTIAL SCORES
16	YOU'RE REFERRING TO, WHICH ONES ARE THEY? DO THEY
17	DO A SCORE AT THE END OF THE DISCUSSION WHICH IS
18	CONFIDENTIAL?
19	MR. HARRISON: CORRECT. IN FACT, IT'S NOW
20	DONE ONLINE. EACH MEMBER AFTER LISTENING TO THE
21	PRESENTATION BY THE PRIMARY AND SECONDARY REVIEWERS
22	AND THE DISCUSSION OF THE GROUP AT LARGE ASSIGNS A
23	SCIENTIFIC SCORE. AND THAT SCORE IS CONFIDENTIAL.
24	WHAT YOU RECEIVE IS THE TABULATION OF THE AVERAGE OF
25	THOSE SCORES.
	108
	100

1	DR. PRICE: THAT'S FINE. I WAS JUST
2	CONCERNED THAT SOMEBODY MIGHT READ THIS TO SAY THAT
3	A MEMBER OF THE GROUP CAN CHANGE AN INITIAL SCORE,
4	WHICH IS THEIR INDEPENDENT SCIENTIFIC JUDGMENT.
5	FOLLOW WHAT I I WANT TO MAKE I'M NOT SURE IF
6	IT NEEDS TO BE REWORDED, BUT I ALWAYS WORRY THAT
7	SOMEBODY WOULD COME ON AND SAY, WELL, THE PERSON
8	CHANGED THEIR SCORE, AND THAT'S NOT THEIR
9	INDEPENDENT SCIENTIFIC JUDGMENT.
10	MR. HARRISON: RIGHT. WE CERTAINLY DON'T
11	MEAN TO CONVEY THAT, SO WE'LL MODIFY THE LANGUAGE TO
12	MAKE THAT CLEAR.
13	CHAIRMAN THOMAS: ANY OTHER COMMENTS BY
14	MEMBERS OF THE BOARD? ANY COMMENTS FROM MEMBERS OF
15	THE PUBLIC? HEARING NONE, PROCEED AGAIN TO A VOICE
16	VOTE. ALL THOSE IN FAVOR PLEASE SAY AYE.
17	MS. LANSING: AYE.
18	DR. LUBIN: AYE.
19	CHAIRMAN THOMAS: OPPOSED? ABSTENTIONS?
20	WE HEARD SHERRY AND DR. LUBIN. THANK YOU VERY MUCH.
21	NOW WE WILL PROCEED TO ITEM NO. 16. WE'RE
22	REALLY DOING OUR BEST HERE TO NOT ONCE GO
23	SEQUENTIALLY ACCORDING TO THE NUMBERS LISTED ON THE
24	AGENDA. ITEM 16 WILL BE PRESENTED BY MR. TOCHER,
25	WHICH IS CONSIDERATION OF PROPOSED AMENDMENT TO
	100
	109

1	REGULATION 100603 TO REQUIRE CIRM GRANTEES TO MAKE
2	CIRM-FUNDED PUBLICATIONS AVAILABLE TO THE PUBLIC
3	WITHIN 12 MONTHS OF PUBLICATION.
4	MR. TOCHER: THAT'S RIGHT. THANK YOU,
5	CHAIR. AS YOU KNOW, CIRM'S IP POLICIES ADDRESS MANY
6	DIFFERENT COMPONENTS SUCH AS REVENUE SHARING AND
7	DISCLOSURE OF CIRM-FUNDED INVENTIONS AND
8	TECHNOLOGIES. ANOTHER IMPORTANT COMPONENT OF OUR IP
9	POLICY CONCERNS PUBLICATION REQUIREMENTS WHEN OUR
10	RESEARCHERS PUBLISH ABOUT CIRM-FUNDED RESEARCH.
11	WHILE CIRM DOES NOT REQUIRE OUR GRANTEES
12	TO PUBLISH, IT DOES HAVE SOME REQUIREMENTS WHEN THEY
13	ELECT TO DO SO, SUCH AS TO PROVIDE ATTRIBUTION TO
14	CIRM IN THE PUBLICATION AND TO NOTIFY CIRM ABOUT A
15	PUBLICATION AND TO PROVIDE A SUMMARY OF THE RESEARCH
16	FINDINGS THAT ARE PUBLISHED.
17	EARLIER THIS YEAR CIRM WAS APPROACHED BY A
18	MEMBER OF THE LEGISLATURE TO CONSIDER ALIGNING
19	CIRM'S PUBLICATION REQUIREMENTS WITH THAT OF THE
20	NIH, WHICH REQUIRES THAT PUBLICATIONS FOR NIH-FUNDED
21	RESEARCH BE MADE PUBLICLY AVAILABLE AFTER 12 MONTHS
22	THAT THEY HAVE BEEN PUBLISHED. SO THE BOARD
23	AUTHORIZED STAFF TO BEGIN THE AMENDMENT PROCESS
24	EARLIER THIS YEAR TO ALIGN OUR PUBLICATION
25	REQUIREMENTS WITH THAT OF NIH.
	110

ı	
1	AND SO THE AMENDMENTS MAINTAIN THE
2	NOTIFICATION REQUIREMENT AND ATTRIBUTION AND THE
3	SUMMARY THAT MUST BE PROVIDED TO CIRM ABOUT THE
4	RESEARCH, BUT ALSO NOW INCLUDES LANGUAGE THAT
5	REQUIRES RESEARCHERS TO MAKE PUBLICLY AVAILABLE
6	THEIR PUBLICATION WITHIN 12 MONTHS OF THE DATE OF
7	PUBLICATION. AND THEY CAN DO THAT BY SEVERAL WAYS:
8	SUBMITTING TO PUBMED CENTRAL, OR, IF THAT'S NOT
9	POSSIBLE, MAKING THE MANUSCRIPT OR FINAL ARTICLE
10	AVAILABLE TO CIRM.
11	WE SENT THIS OUT FOR PUBLIC COMMENT
12	ACCORDING TO THE PROCESS ADMINISTERED BY THE OFFICE
13	OF ADMINISTRATIVE LAW. THAT COMMENT PERIOD CLOSED.
14	THERE WERE NO COMMENTS. SO THIS IS THE FINAL STEP
15	LOOKING FOR THE BOARD TO GIVE FINAL APPROVAL TO THE
16	AMENDMENTS THAT IT INITIATED EARLIER THIS YEAR.
17	CHAIRMAN THOMAS: IS THERE MOTION TO THAT
18	EFFECT?
19	MS. LANSING: I'LL MOVE IT.
20	DR. STEWARD: SECOND.
21	CHAIRMAN THOMAS: MOVED BY SHERRY,
22	SECONDED BY DR. STEWARD. ANY DISCUSSION BY MEMBERS
23	OF THE BOARD?
24	DR. POMEROY: I JUST HAVE ONE QUESTION.
25	I'M VERY SUPPORTIVE OF THIS. BUT HOW OFTEN HAS THAT
	111
	111

	BARRISIERS REPORTING SERVICE
1	NOT HAPPENED TO DATE? IN OTHER WORDS, WOULD THIS
2	JUST SORT OF FORMALIZE SOMETHING THAT'S REALLY BEEN
3	HAPPENING QUITE EFFECTIVELY, OR HAVE THERE BEEN
4	EXAMPLES WHERE PUBLICATIONS WERE NOT MADE AVAILABLE
5	WITHIN 12 MONTHS?
6	MR. TOCHER: IT HAS NEVER BEEN A
7	REQUIREMENT OF CIRM'S PROCESS. SO UNLESS THERE WAS
8	AN NIH COMPONENT TO THE FUNDING OF THE RESEARCH THAT
9	WAS PUBLISHED, IT IS NOT SOMETHING THAT WE'VE
10	REQUIRED THEM TO DO BEFORE.
11	DR. POMEROY: WERE THEY DOING IT? THAT'S
12	WHAT I'M ASKING.
13	MR. TOCHER: NOT TO MY KNOWLEDGE.
14	MS. BAUM: I DON'T THINK WE KNOW ONE WAY
15	OR ANOTHER.
16	MS. SAMUELSON: I HAVE A QUESTION, MR.
17	CHAIRMAN. I HAVE AN ASSUMPTION ABOUT WHAT THE
18	DIFFERENCE IS. CAN YOU EXPLAIN, I'M SURE, THE
19	DIFFERENCE BETWEEN PUBLICATION AND PUBLICLY
20	PUBLISHED AND PUBLICLY AVAILABLE?
21	MR. TOCHER: WELL, OFTENTIMES MANUSCRIPTS
22	ARE PUBLISHED BY PEER REVIEW JOURNALS, BUT ARE
23	RESTRICTED IN TERMS OF THEIR ACCESS TO EITHER
24	SUBSCRIBERS OR ANOTHER SMALLER UNIVERSE. SO THIS
25	REQUIREMENT WILL MAKE SURE THAT IT'S BROADLY
	142
	112

1	AVAILABLE TO THE PUBLIC IN GENERAL REGARDLESS OF
2	SUBSCRIPTION STATUS.
3	MS. SAMUELSON: OKAY. THAT'S WHAT, I
4	GUESS, I MEAN, REGARDLESS OF THE COST.
5	DR. BRYANT: SO I'M SURPRISED TO LEARN
6	THAT THERE ARE STILL JOURNALS THAT DON'T ALLOW
7	PUBLIC ACCESS AFTER A YEAR. I'M NOT AWARE OF THAT.
8	MR. TOCHER: THAT DON'T ALLOW?
9	DR. BRYANT: I THOUGHT IT WAS PRETTY
10	STANDARD NOW.
11	MR. TOCHER: I THINK IT'S A MOVING AND
12	DEVELOPING CONCEPT THAT IS GROWING IN POPULARITY, I
13	GUESS, BECAUSE LARGELY THE NIH HAS BEEN A DRIVER OF
14	THIS POLICY FOR SEVERAL YEARS.
15	CHAIRMAN THOMAS: ANY OTHER COMMENTS BY
16	MEMBERS OF THE BOARD? COMMENTS BY MEMBERS OF THE
17	PUBLIC? PROCEED TO VOICE VOTE. ALL THOSE IN FAVOR
18	OF THIS MOTION PLEASE SAY AYE.
19	MS. LANSING: AYE.
20	DR. LUBIN: AYE. OPPOSED? ABSTENTIONS?
21	WE'RE GOOD.
22	MR. TOCHER: THANK YOU.
23	CHAIRMAN THOMAS: GOING TO MOVE ON TO
24	ALWAYS WHAT IS A VERY IMPORTANT
25	MR. HARRISON: JUST TO CLARIFY, MEMBERS
	113

_	
1	LANSING AND LUBIN VOTED YES BY PHONE.
2	MS. LANSING: YES, WE DID.
3	CHAIRMAN THOMAS: WE CAN HEAR THE
4	MELODIOUS TONES OVER THE VOICE VOTE.
5	MS. LANSING: YOU CAN HEAR MY COUGHING;
6	YOU CAN HEAR MY YES.
7	CHAIRMAN THOMAS: YES.
8	DR. LUBIN: SHERRY AND I HAVE PRACTICED ON
9	THIS.
10	CHAIRMAN THOMAS: SO WE'RE GOING TO MOVE
11	NOW TO ALWAYS ONE OF THE MOST IMPORTANT AND IN-DEPTH
12	ITEMS ON THE AGENDA, WHICH IS THE APPROVAL OF THE
13	LAST BOARD MINUTES. DO I HEAR MOTION TO APPROVE?
14	MS. LANSING: SO MOVED.
15	CHAIRMAN THOMAS: MOVED BY SHERRY.
16	MS. SAMUELSON: SECONDED.
17	CHAIRMAN THOMAS: SECONDED BY JOAN. ALL
18	THOSE IN FAVOR PLEASE SAY AYE.
19	MS. LANSING: AYE.
20	DR. LUBIN: AYE.
21	CHAIRMAN THOMAS: OPPOSED? MOTION
22	CARRIES. WE'RE GOING TO GO NOW TO ITEM 19.
23	MS. LANSING: CAN WE GO TO GOVERNANCE AS
24	LONG AS JAMES IS THERE?
25	CHAIRMAN THOMAS: YES, WE CAN. WE CAN DO
	114

1	THAT. LET'S GO TO ITEM 15, THEN, AT SHERRY'S
2	REQUEST.
3	MS. LANSING: SO I'LL SET IT UP. JAMES,
4	CAN YOU COME TO THE PODIUM TO EXPLAIN THESE THREE
5	ITEMS WE'VE GONE THROUGH WITH GOVERNANCE. CLAIRE
6	AND MYSELF AND THE ENTIRE GOVERNANCE COMMITTEE, AND
7	WE ENDORSE THESE RECOMMENDATIONS VERY STRONGLY, BUT
8	THEY HAVE BEEN REVIEWED AND RE-REVIEWED.
9	CHAIRMAN THOMAS: THANK YOU. AND MR.
10	HARRISON HAS NOW ARRIVED AT THE PODIUM AND READY TO
11	ADDRESS THESE ISSUES.
12	MR. HARRISON: THANK YOU. AS SHERRY SAID,
13	THE GOVERNANCE SUBCOMMITTEE MET THIS WEEK TO
14	CONSIDER THREE DIFFERENT ITEMS. THE FIRST IS A
15	PRESIDENTIAL SUCCESSION PLAN. SOME OF YOU MAY
16	RECALL THAT SB 1064, WHICH WAS PASSED BY THE
17	LEGISLATURE BACK IN 2010, REQUIRED CIRM TO ENGAGE IN
18	SUCCESSION PLANNING TO ENSURE A SMOOTH TRANSITION OF
19	AUTHORITY AND A SMOOTH TRANSFER OF KNOWLEDGE IN THE
20	EVENT OF A LEADERSHIP CHANGE.
21	THE BOARD ENGAGED IN THAT PROCESS WITH
22	RESPECT TO THE LEADERSHIP OF THE BOARD ITSELF, AND
23	WE'RE NOW BRINGING FOR YOUR CONSIDERATION A PROPOSAL
24	THAT DEALS WITH SUCCESSION AT CIRM AT THE LEVEL OF
25	THE PRESIDENT.

115

1	THE PROPOSED SUCCESSION PLAN, WHICH IS IN
2	YOUR BINDER UNDER ITEM 15, CONTAINS FIVE DIFFERENT
3	ELEMENTS. FOR THOSE OF YOU WHO HAVE BEEN WITH CIRM
4	FROM THE START, YOU WILL REMEMBER THAT CIRM HAS
5	ENGAGED IN TWO PRESIDENTIAL SEARCHES. AND IN BOTH
6	CASES IT ESTABLISHED A PRESIDENTIAL SEARCH
7	SUBCOMMITTEE TO CONDUCT THE SEARCH. AND ONE ELEMENT
8	OF THE SUCCESSION PLAN WOULD BE TO RECOMMEND THAT
9	YOU AUTHORIZE THE CHAIR TO REESTABLISH A
10	PRESIDENTIAL SEARCH COMMITTEE AND TO APPOINT ITS
11	MEMBERS WHEN SUCH A NEED ARISES SO THAT WE CAN MOVE
12	QUICKLY IF NEED BE TO BEGIN THE PROCESS OF
13	CONDUCTING A SEARCH FOR A NEW PRESIDENT.
14	THE SECOND ELEMENT PERTAINS TO AN
15	EXECUTIVE SEARCH FIRM. IN THE CASE OF BOTH OF THE
16	PREVIOUS SEARCHES, CIRM DID ENGAGE AN EXECUTIVE
17	SEARCH FIRM TO ASSIST IT IN THE PROCESS. SO, AGAIN,
18	TO EXPEDITE THAT IN THE EVENT THE NEED ARISES, WE
19	WOULD REQUEST THAT YOU DIRECT STAFF TO PREPARE A
20	REQUEST FOR PROPOSALS SO THAT IT CAN BE READY TO BE
21	ISSUED WHEN THE NEED ARISES. AND ALSO AUTHORIZE THE
22	PRESIDENTIAL SEARCH SUBCOMMITTEE TO SELECT AN
23	EXECUTIVE SEARCH FIRM AND TO APPROVE A CONTRACT WITH
24	THE FIRM, AGAIN, IN THE NAME OF SPEED.
25	THE NEXT ELEMENT OF THE PLAN IS TO

116

1	RECONSIDER THE CRITERIA AND DESIRED QUALIFICATIONS
2	FOR PRESIDENT. WHEN CIRM CONDUCTED ITS LAST TWO
3	SEARCHES, THE BOARD AND THE PRESIDENTIAL SEARCH
4	SUBCOMMITTEE DEVOTED A SUBSTANTIAL AMOUNT OF TIME TO
5	DEFINING THE CRITERIA AND THE DESIRED QUALIFICATIONS
6	FOR PRESIDENT. THOSE ARE IN THE ATTACHMENT TO THE
7	PRESIDENTIAL SEARCH SUBCOMMITTEE IF YOU WOULD LIKE
8	TO LOOK AT THEM.
9	OBVIOUSLY CIRM IS NOW A MUCH MORE MATURE
10	ORGANIZATION THAN IT WAS THEN. PRESIDENT TROUNSON
11	HAS BEEN WITH US FOR ALMOST FIVE YEARS NOW. AND IF
12	AND WHEN A NEED ARISES FOR A NEW PRESIDENT, IT WOULD
13	BE APPROPRIATE TO CONSIDER WHETHER THE CRITERIA AND
14	DESIRED QUALIFICATIONS THAT WERE PREVIOUSLY
15	ESTABLISHED ARE STILL THE RIGHT ONES. SO AT THE
16	APPROPRIATE TIME, WE'D RECOMMEND THAT THE BOARD ASK
17	THE PRESIDENTIAL SEARCH SUBCOMMITTEE TO CONSIDER
18	THOSE AND RECOMMEND DESIRED CRITERIA AND
19	QUALIFICATIONS TO THE BOARD.
20	THE NEXT ITEM IN THE PRESIDENTIAL
21	SUCCESSION PLAN RELATES TO AN INTERIM PRESIDENT.
22	AGAIN, AS WITH THE PREVIOUS ITEMS, BECAUSE THE NEED
23	IS NOT YET APPARENT AND BECAUSE THE PARTICULAR
24	QUALIFICATIONS AND PROCESS FOR SELECTION OF AN
25	INTERIM PRESIDENT WILL DEPEND UPON MANY FACTORS THAT
	117

1	WE DON'T YET KNOW, INCLUDING THE LENGTH OF
2	TRANSITION AND THINGS OF THAT NATURE, WE SUGGEST
3	THAT YOU CONSIDER BOTH THE CRITERIA FOR AN INTERIM
4	PRESIDENT AS WELL AS THE APPROPRIATE PROCESS AT THE
5	TIME THE NEED RISES. THE BOARD HAS BEEN SERVED BY
6	FOUR INTERIM PRESIDENTS, SO IT HAS DIFFERENT MODELS
7	IT CAN CONSIDER WHEN NECESSARY.
8	AND THEN THE FINAL ASPECT OF THE
9	SUCCESSION PLAN IS TO CONSIDER WAYS IN WHICH CIRM
10	CAN ENSURE A SMOOTH TRANSFER OF KNOWLEDGE TO NEW
11	LEADERSHIP. AGAIN, WE NOW HAVE THE BENEFIT OF BEING
12	A MORE ESTABLISHED ORGANIZATION WITH MANY STAFF
13	MEMBERS WHO HAVE BEEN WITH CIRM ALMOST FROM THE
14	START AND WITH MANY OF YOU WHO HAVE SERVED FROM THE
15	START. SO THERE'S A SUBSTANTIAL BODY OF
16	INSTITUTIONAL KNOWLEDGE THAT NOW EXISTS.
17	OBVIOUSLY THERE ARE WAYS IN WHICH TO
18	ENSURE THAT IN THE TRANSITION A NEW PRESIDENT HAS
19	THE BENEFIT OF THAT INSTITUTIONAL KNOWLEDGE,
20	INCLUDING THE POSSIBILITY, AGAIN, DEPENDING UPON THE
21	CIRCUMSTANCES, OF A TRANSITION PERIOD WHERE THE
22	OUTGOING PRESIDENT AND THE INCOMING PRESIDENT
23	OVERLAP AS OCCURRED WITH DR. MURPHY AND DR.
24	TROUNSON. THE GOVERNANCE SUBCOMMITTEE CONSIDERED
25	THIS ITEM AND TOOK A VOTE AND RECOMMENDED YOUR

118

1	APPROVAL.
2	SO, SHERRY, I CAN STOP THERE, OR WE CAN
3	MOVE ON TO THE NEXT ITEM AT YOUR DISCRETION.
4	MS. LANSING: I THINK THAT'S A VERY FULL
5	EXPLANATION. I GUESS I WOULD JUST ASK IF THERE ARE
6	ANY QUESTIONS FROM MEMBERS OF THE COMMITTEE
7	BOARD, I SHOULD SAY. IF THERE ARE ANY QUESTIONS
8	FROM MEMBERS OF THE PUBLIC, I GUESS. GREAT. AS
9	ALWAYS, JAMES, YOU GAVE A FULL EXPLANATION. SO
10	LET'S GO ON TO THE NEXT ONE.
11	MR. HARRISON: GREAT. THE NEXT ITEM THAT
12	THE GOVERNANCE SUBCOMMITTEE CONSIDERED WAS A
13	PROPOSED POLICY TO GOVERN THE MANNER OF
14	DISQUALIFICATION. UNDER STATE LAW, NONE OF YOU ARE
15	REQUIRED TO LEAVE THE ROOM WHEN YOU HAVE A FINANCIAL
16	INTEREST IN AN APPLICATION THAT'S UNDER
17	CONSIDERATION. BUT CHAIR LANSING REQUESTED THAT WE
18	CONSIDER WHETHER A POLICY WAS APPROPRIATE UNDER VERY
19	SPECIFIC CIRCUMSTANCES.
20	AS YOU KNOW, FOR THE MOST PART,
21	APPLICATIONS ARE PRESENTED TO YOU ON A BLIND BASIS,
22	SO THE NAME OF THE INSTITUTION AND THE NAME OF THE
23	PRINCIPAL INVESTIGATOR ARE NOT PRESENTED TO YOU AS
24	PART OF THE PACKAGE FOR YOUR CONSIDERATION. ON
25	OCCASION, HOWEVER, AS WE ALL WELL KNOW, APPLICANTS
	119

1	SUBMIT EXTRAORDINARY PETITIONS AND SELF-IDENTIFY
2	THEMSELVES OR THEY APPEAR AT BOARD MEETINGS AND
3	OFFER PUBLIC COMMENTS.
4	AND THIS PROPOSED POLICY WOULD ADDRESS
5	THOSE SPECIFIC CIRCUMSTANCES AND WOULD REQUIRE A
6	MEMBER TO LEAVE THE ROOM WHEN THE MEMBER HAS A
7	FINANCIAL INTEREST IN AN APPLICATION THAT'S UNDER
8	DISCUSSION BY THE BOARD. SO SIMPLE FILING OF AN
9	EXTRAORDINARY PETITION WOULD NOT REQUIRE YOU TO
10	LEAVE THE ROOM.
11	AND THE APPLICANT HAS SELF-IDENTIFIED BY
12	FILING AN EXTRAORDINARY PETITION OR BY MAKING PUBLIC
13	COMMENT. SO IF A MEMBER, FOR EXAMPLE, ASKED FOR A
14	BOARD DISCUSSION REGARDING A PARTICULAR APPLICATION
15	AND THE APPLICANT HAS SELF-IDENTIFIED IN ONE OF
16	THOSE TWO WAYS, AT THAT POINT IN TIME, WE WOULD ASK
17	YOU TO LEAVE THE ROOM AND REJOIN THE BOARD AFTER IT
18	HAS CONCLUDED ITS DISCUSSION AND ANY ACTION ON THAT
19	APPLICATION.
20	SO IT'S A FAIRLY NARROW POLICY, BUT IT
21	WOULD BE A DEPARTURE FROM OUR CURRENT PRACTICE. SO
22	WE PRESENTED IT TO THE GOVERNANCE SUBCOMMITTEE FOR
23	ITS CONSIDERATION, AND THE GOVERNANCE SUBCOMMITTEE
24	UNANIMOUSLY RECOMMENDED YOUR APPROVAL OF THAT
25	POLICY. AGAIN, I'LL PAUSE FOR QUESTIONS, SHERRY.

120

1	MS. LANSING: AGAIN, ARE THERE ANY
2	QUESTIONS? WE JUST REALLY FEEL THAT THIS IS REALLY
3	VERY, VERY IMPORTANT FOR PERCEPTION AND SO THAT
4	NOBODY CAN BE ACCUSED OF ANY CONFLICTS.
5	DR. LUBIN: SO I KNOW WE'VE DISCUSSED THIS
6	BEFORE, AND MAYBE YOU'VE DONE IT OFF LINE RATHER
7	THAN OPENLY. I GUESS MY QUESTION WAS IF A GRANT
8	THAT YOU'RE IN CONFLICT THEN BECAUSE YOU'RE AT THE
9	INSTITUTION WHERE THE GRANT IS SUBMITTED, ARE YOU
10	REQUESTED TO LEAVE THE ROOM DURING THE DISCUSSIONS
11	OF THAT APPLICATION?
12	MS. LANSING: THIS IS NARROWER THAN THAT.
13	JAMES, YOU WANT TO EXPLAIN IT? THIS IS FINANCIAL
14	INTEREST ONLY.
15	DR. LUBIN: I SAW THAT.
16	MR. HARRISON: THAT'S CORRECT. IT'S BOTH
17	LIMITED TO A FINANCIAL INTEREST, BUT ALSO, DR.
18	LUBIN, ONLY IN SITUATIONS WHERE THE APPLICANT HAS
19	SELF-IDENTIFIED TO THE BOARD BY COMING FORWARD WITH
20	AN EXTRAORDINARY PETITION OR MAKING COMMENTS DURING
21	PUBLIC SESSION BECAUSE, OTHERWISE, THE MEMBERS OF
22	THE BOARD, OTHER THAN YOU, IF YOU'RE AT THE
23	INSTITUTION THAT HAS SUBMITTED THE APPLICATION,
24	DON'T KNOW WHAT INSTITUTION THE APPLICATION COMES
25	FROM BECAUSE IT'S PRESENTED TO THE BOARD ON A BLIND
	121
	121

1	BASIS.
2	SO IN OUR VIEW, IT WOULD NOT MAKE SENSE TO
3	REQUIRE BOARD MEMBERS TO LEAVE THE ROOM WHEN THEY
4	DON'T KNOW THE IDENTITY OTHER MEMBERS DON'T KNOW
5	THE IDENTITY OF THE INSTITUTION. IN FACT, IT WOULD
6	TEND TO UNDERCUT THE POLICY BECAUSE IF DR. PRICE,
7	FOR EXAMPLE, GOT UP AND LEFT WHEN WE WERE TALKING
8	ABOUT APPLICATION XYZ, THEN MEMBERS MIGHT REALIZE
9	IT'S AN APPLICATION SUBMITTED BY UC BERKELEY.
10	MS. LANSING: THIS IS A VERY IMPORTANT
11	DISTINCTION. I WANT TO MAKE THIS VERY CLEAR SINCE
12	I'M THE ONE THAT'S BEEN MOST CONCERNED ABOUT THIS.
13	IF YOU LEFT, THEN IT WOULD BE IDENTIFYING YOU. SO
14	THIS IS A VERY NARROW POLICY ONLY WHEN SOMEONE COMES
15	FORWARD AND SELF-IDENTIFIES THE INSTITUTION, THEN
16	EVERYONE KNOWS. SO THEN I THINK IT BEHOOVES YOU TO
17	LEAVE.
18	DR. LUBIN: FROM OUR PERSPECTIVE,
19	EVERYBODY KNOWS WHEN THEY'RE IN CONFLICT BECAUSE
20	THEY SIGN A FORM OF WHICH APPLICATIONS
21	MS. LANSING: BUT ONLY YOU KNOW THAT.
22	DR. LUBIN: I UNDERSTAND THAT.
23	MS. LANSING: SO IF YOU LEFT, THEN YOU
24	WOULD BE TELLING THE OTHER BOARD MEMBERS WHICH
25	INSTITUTION IT WAS. ONLY YOU KNOW THAT AND YOUR
	122
	1

1	SILENCE DURING THAT PARTICULAR PERIOD DOESN'T MEAN
2	YOU'RE IN CONFLICT TO THE OTHER BOARD MEMBERS.
3	DR. LUBIN: IS IT A PROBLEM THAT OTHERS
4	KNOW THAT IT CAME FROM YOUR INSTITUTION?
5	MR. HARRISON: I'LL ADDRESS THAT. FROM A
6	LEGAL STANDPOINT, DR. LUBIN, IT'S NOT A PROBLEM; BUT
7	AS PART OF OUR POLICY AND BEST PRACTICES, STAFF
8	PRESENTS APPLICATIONS TO YOU ON A BLIND BASIS. AND
9	THAT'S BOTH TO ASSIST US WITH BOTH THE APPEARANCE OR
10	PERCEPTION OF A CONFLICT OF INTEREST AND TO ENSURE
11	THAT DECISIONS ARE MADE ON THE MERITS OF THE
12	SCIENTIFIC APPLICATION RATHER THAN ON THE IDENTITY
13	OF THE INSTITUTION OR THE PRINCIPAL INVESTIGATOR.
14	DR. LUBIN: I UNDERSTAND THAT.
15	DR. PRICE: IT MAY NOT BE A LEGAL PROBLEM,
16	BUT FROM A POLITICAL SCIENCE POINT OF VIEW, OUR
17	POLICY PREVENTS WHAT IS CALLED LOGROLLING. SO THAT
18	IF I KNOW AND YOU KNOW EVERYTHING THAT'S ON THERE,
19	YOU AND I, BERT, CAN AGREE THAT I'LL VOTE FOR A
20	CHORI PROPOSAL AND YOU'LL VOTE FOR A BERKELEY
21	PROPOSAL. IF WE DON'T KNOW ANYTHING ABOUT THE
22	IDENTITY OF THE PROPOSALS, WE CAN'T ENGAGE IN THAT
23	KIND OF PRACTICE, WHICH IS USED ALL THE TIME IN
24	LEGISLATURES AT THE STATE AND NATIONAL LEVEL.
25	DR. LUBIN: THAT MAKES SENSE TO ME. I
	123
	143

1	UNDERSTAND THAT. I'M FINE WITH THIS DISCUSSION. I
2	JUST WANTED TO BE SURE WE DISCUSSED IT A LITTLE BIT.
3	IT'S FINE. I DON'T THINK WE HAVE TO CARRY IT OUT
4	FURTHER FROM MY PERSPECTIVE.
5	MS. LANSING: GREAT. ARE THERE ANY OTHER
6	QUESTIONS FROM ANYONE ON THE BOARD OR THE PUBLIC?
7	GOOD. I'M VERY PLEASED WITH THIS ONE. JAMES, YOU
8	WANT TO GO TO THE NEXT?
9	MR. HARRISON: SO THE FINAL ITEM THE
10	GOVERNANCE SUBCOMMITTEE CONSIDERED WAS AN ITEM
11	PROPOSING AMENDMENTS TO THE INTERNAL GOVERNANCE
12	POLICY. YOU ALL WILL RECALL THAT IN JUNE OF 2011
13	YOU APPROVED A REORGANIZATION OF FUNCTIONS RELATING
14	TO FINANCE AND COMMUNICATIONS, AND YOU DIRECTED US
15	TO INCORPORATE THOSE CHANGES INTO THE INTERNAL
16	GOVERNANCE POLICY.
17	SO WHAT WE'VE BROUGHT BACK TO YOU TODAY IS
18	A DRAFT THAT ACCOMPLISHES THREE THINGS. ONE, IT
19	CONFORMS THE POLICY TO THE BOARD'S DECISION
20	REGARDING THE ALLOCATION OF DUTIES AS BETWEEN THE
21	CHAIR AND THE PRESIDENT IN THE AREAS OF FINANCE AND
22	COMMUNICATIONS.
23	SECOND, IT INCORPORATES DELEGATION OF
24	AUTHORITY TO THE CHAIR FOR EMPLOYMENT DECISIONS
25	RELATING TO STAFF IN THE OFFICE OF THE CHAIR, AGAIN,
	124

1	AS PREVIOUSLY APPROVED BY THE BOARD.
2	AND FINALLY, WE'VE ATTEMPTED TO STREAMLINE
3	THE POLICY BY ELIMINATING A COUPLE OF ITEMS, IN
4	PARTICULAR A DESCRIPTION OF THE INTERNAL OFFICES AT
5	CIRM ESTABLISHED BY THE PRESIDENT IN RECOGNITION OF
6	THE FACT THAT FROM TIME TO TIME THINGS CHANGE AND
7	THE PRESIDENT MAY DECIDE THAT DIFFERENT OFFICES ARE
8	MORE APPROPRIATE THAN THE ONES SET FORTH IN THE
9	PREVIOUS VERSION OF THE INTERNAL GOVERNANCE POLICY,
10	AND ALSO ELIMINATING A REFERENCE TO AN INTERNAL
11	EXECUTIVE COMMITTEE MEETING.
12	WE PRESENTED THIS TO THE GOVERNANCE
13	SUBCOMMITTEE, AND, AGAIN, IT UNANIMOUSLY RECOMMENDED
14	YOUR APPROVAL OF THESE PROPOSED AMENDMENTS. SHERRY,
15	I'D BE HAPPY TO ANSWER ANY QUESTIONS.
16	MS. LANSING: ARE THERE ANY QUESTIONS FROM
17	MEMBERS OF THE BOARD? FROM THE PUBLIC? ONCE AGAIN,
18	JAMES, THANK YOU FOR YOUR WONDERFUL EXPLANATIONS.
19	THANK YOU TO THE MEMBERS OF THE SUBCOMMITTEE FOR ALL
20	THEIR HARD WORK. DO WE NEED A VOTE ON ALL OF THIS?
21	CHAIRMAN THOMAS: YES, WE DO.
22	MS. LANSING: SO CAN I ASK FOR APPROVAL OF
23	ALL THREE ITEMS THEN?
24	DR. POMEROY: MOVE APPROVAL.
25	MS. LANSING: CAN I HAVE A SECOND? THAT
	125

1	WAS CLAIRE, I THINK.
2	MR. SHEEHY: SECOND.
3	CHAIRMAN THOMAS: SECONDED BY MR. SHEEHY.
4	MS. LANSING: SO ALL IN FAVOR.
5	DR. LUBIN: YES.
6	CHAIRMAN THOMAS: LET'S HEAR SOME AYES OUT
7	THERE.
8	MS. LANSING: ARE THERE ANY OPPOSED?
9	THANK YOU VERY MUCH. AND, AGAIN, THANK YOU TO
10	EVERYONE INVOLVED. THANKS FOR THE APPROVAL.
11	CHAIRMAN THOMAS: SHERRY, I'D LIKE TO
12	THANK YOU AGAIN FOR YOUR GREAT GUIDANCE AS CHAIR OF
13	THE GOVERNANCE SUBCOMMITTEE IN NAVIGATING THROUGH
14	THESE TOPICS. AND VERY HAPPY TO HAVE PASSED THESE,
15	AND THEY'RE ALL VERY IMPORTANT.
16	MS. LANSING: THANK YOU. IT'S A PLEASURE.
17	THANK YOU.
18	CHAIRMAN THOMAS: SO WE'VE NOW REACHED THE
19	LUNCH HOUR. WE ARE GOING TO GO ACROSS TO THE LUNCH,
20	WHICH IS GOING TO ALSO INVOLVE A CLOSED SESSION,
21	WHICH MR. HARRISON WILL GIVE US THE SERIAL NUMBER
22	FOR.
23	MR. HARRISON: THE BOARD WILL BE CONVENING
24	IN CLOSED SESSION TO DISCUSS PERSONNEL PURSUANT TO
25	GOVERNMENT CODE SECTION 11126 AND HEALTH AND SAFETY
	126

1	CODE SECTION 125290.30(F)(3)(D).
2	CHAIRMAN THOMAS: THANK YOU VERY MUCH.
3	MS. LANSING: JAMES, ARE WE ALLOWED TO
4	PARTICIPATE IN THAT BY PHONE?
5	MR. HARRISON: YES, YOU ARE.
6	MS. LANSING: WHEN DO YOU THINK EVERYONE
7	WILL BE READY?
8	MR. HARRISON: PROBABLY ABOUT FIVE
9	MINUTES.
10	DR. LUBIN: IS THERE ANOTHER DIAL-IN
11	NUMBER THAN THE ONE WE'RE ON NOW? DO WE HAVE TO
12	HANG UP OR STAY ON?
13	MS. BONNEVILLE: I SENT YOU AND TANYA THE
14	NEW NUMBER.
15	CHAIRMAN THOMAS: MEMBERS OF THE PUBLIC,
16	WE'RE GOING TO LOOK TO RECONVENE AT APPROXIMATELY 1
17	O'CLOCK. THANK YOU.
18	(A LUNCH RECESS WAS TAKEN AT WHICH
19	TIME THERE WAS ALSO A CLOSED SESSION, NOT REPORTED
20	NOR HEREIN TRANSCRIBED.)
21	CHAIRMAN THOMAS: MEMBERS OF THE BOARD,
22	PLEASE TAKE YOUR SEATS. WE CAN RESUME. SHERRY AND
23	BERT, ARE YOU BACK ON? WE'RE GOING TO PROCEED HERE.
24	OKAY. WE'RE NOW RESUMING AFTER CLOSED SESSION.
25	PROCEED FIRST WITH ITEM NO. 8, CONSIDERATION OF THE
	127
	127

1	DISEASE TEAM III CONCEPT PLAN. DR. FEIGAL. DR.
2	BETTINA "GIANTS FAN" STEFFEN IS GOING TO BE
3	PRESENTING.
4	DR. STEFFEN: I'M GOING TO TAKE IT FOR
5	EVERYTHING IT'S WORTH RIGHT NOW.
6	MR. HARRISON: FOR THE RECORD, BEFORE
7	BETTINA BEGINS, THERE'S NO ACTION TO REPORT FROM
8	CLOSED SESSION.
9	CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.
10	MS. GIANTS FAN.
11	DR. STEFFEN: GOOD AFTERNOON. AND TODAY
12	I'M GOING TO PRESENT THE CONCEPT PLAN FOR THE
13	DISEASE TEAM THERAPY DEVELOPMENT AWARDS ROUND III
14	FOR YOUR CONSIDERATION. AND FOR NEW MEMBERS AND TO
15	REMIND YOU ABOUT THE DISEASE TEAM PROGRAM, THIS IS
16	OUR THIRD ITERATION. AND THE TWO PRIOR ROUNDS THAT
17	DR. FEIGAL MENTIONED THIS MORNING WERE AWARDED IN
18	OCTOBER OF 2009 AND MOST RECENTLY IN SEPTEMBER 2012.
19	AND WITH ADVANCING SCIENCE IN THE FIELD,
20	WE ARE TAKING THIS PROGRAM AND ADVANCING IT TOWARDS
21	LATER STAGES OF DEVELOPMENT TO ATTRACT MORE MATURE
22	PROJECTS. FOR EXAMPLE, IN THE DISEASE TEAM I,
23	FILING AN IND, AN INVESTIGATIONAL NEW DRUG
24	APPLICATION, WITH THE FDA WAS THE GOAL FOR THOSE
25	TEAMS. AND IN THE DISEASE TEAM II ROUND, WE HAD THE
	128

IND GOAL, BUT WE ALSO HAVE ASKED TEAMS TO CONSIDER
COMPLETION OF AN EARLY CLINICAL TRIAL. AND WE GOT A
MIX IN THE TYPES OF PROJECTS GOING FOR THOSE GOALS.
SO YOU WILL HEAR THAT WE'RE ADVANCING THAT A LITTLE
BIT FURTHER IN THIS ROUND.
WE CONTINUE OUR ACTIVE MANAGEMENT OF THESE
TRANSLATIONAL PROJECTS. SCIENCE OFFICERS ARE IN
TOUCH WITH THEIR TEAMS AT A MINIMUM QUARTERLY AND
SOMETIMES MORE FREQUENTLY. AND IN ADDITION, WE ARE
COMPLETING OUR ANNUAL REVIEW OF THE TEAMS WITH THE
ASSISTANCE OF OUR CLINICAL DEVELOPMENT ADVISORY
PANEL, AND WE'LL BE REPORTING TO THE BOARD AND
MEMBERS OF THE PUBLIC IN THE FIRST QUARTER OF 2013
AN UPDATE ON THOSE PROJECTS.
YOU'VE SEEN THIS DIAGRAM BEFORE, AND WE'RE
FOCUSED ON THE RED BAR, WHICH IS THE DISEASE TEAM
THERAPY DEVELOPMENT AWARD. THE THIRD ROUND, YOU CAN
SEE IT HAS ADVANCED FROM THE TWO BARS ABOVE IT FROM
PRECLINICAL RESEARCH. WE'RE NOW PICKING UP PROJECTS
THAT ARE IN PRECLINICAL DEVELOPMENT AND GOING OUT AS
FAR AS EARLY CLINICAL TRIALS.
THIS MAY LOOK FAMILIAR TO YOU, LIKE THE
STRATEGIC PARTNER INITIATIVE, BUT THERE'S A REASON
FOR THIS. AND WE'RE VERY INTERESTED IN ADDRESSING
THAT CRITICAL FIVE-YEAR STRATEGIC GOAL TO ADVANCE
129

1	STEM CELL SCIENCE TO CLINICAL TRIALS AND ACHIEVE
2	THERAPEUTIC BENEFIT TO PATIENTS. SO LIKE THE
3	STRATEGIC PARTNERSHIP FUND, THE GOAL HERE FOR THIS
4	ROUND OF DISEASE TEAMS IS TO COMPLETE AN EARLY STAGE
5	CLINICAL TRIAL, WHICH WE CONSIDER PHASE I, PHASE
6	I/II, OR PHASE II TRIALS WITHIN THAT FOUR-YEAR
7	FRAMEWORK. AND WE MAY HAVE SOME PROJECTS THAT
8	INCLUDE SOME IND-ENABLING WORK.
9	THE ELIGIBILITY OF THE PROJECTS, SO THESE
10	PROJECTS ARE EXPECTED TO BE AT A CERTAIN STAGE OF
11	MATURITY IN THIS ROUND. AND WE'LL DEFINE THAT FOR
12	BOTH PRECLINICAL STAGE PROJECTS AND FOR CLINICAL
13	STAGE. FOR THE PRECLINICAL PROJECTS, LIKE LAST
14	DISEASE TEAM ROUNDS, WE EXPECT THAT A SINGLE
15	THERAPEUTIC DEVELOPMENT CANDIDATE IS ALREADY
16	SELECTED. WE FIND THAT THOSE THAT ARE COMPARING
17	THERAPIES OR POTENTIAL THERAPIES IS A BETTER AWARD
18	TYPE TO DO IN THE EARLY TRANSLATION SETTING. WE
19	EXPECT THAT THESE TEAMS WOULD HAVE STRONG
20	PRECLINICAL PROOF OF CONCEPT IN THE TARGET DISEASE
21	OR INJURY. AND THEN THE THIRD ONE IS WE'RE LOOKING
22	FOR PROJECTS THAT ARE REALLY CONSIDERED CLINICAL
23	TRIAL READY. SO THAT THEY'VE ALREADY ACCUMULATED
24	THEIR EVIDENCE AND THEY'VE SAT WITH THE FDA FOR OUR
25	OBJECTIVE MEASURE, WHICH IS TO HAVE CONDUCTED THEIR

130

1	PRE-IND MEETING WITH THE FDA.
2	FOR CLINICAL STAGE PROJECTS, WE WOULD
3	EXPECT THAT TEAMS WOULD HAVE ALREADY FILED THEIR
4	IND.
5	AGAIN, TO REMIND YOU WHY THIS PROGRAM, AND
6	THE STRATEGIC PARTNERSHIP ALSO, AND WHY CIRM IS
7	DIFFERENT FROM OTHER FUNDING AGENCIES IS WE'RE ONE
8	OF THE FEW ORGANIZATIONS THAT WILL FUND ALL THE
9	ACTIVITIES THAT ARE NECESSARY TO FILE AN IND OR RUN
10	A CLINICAL STUDY, WHICH INCLUDES THINGS LIKE
11	PRODUCTION OF THE ACTIVE MATERIAL FOR THAT STUDY.
12	SO THE IN-SCOPE ACTIVITIES ON THE
13	LEFT-HAND SIDE OF THE SLIDE, WE SUPPORT THE
14	ACTIVITIES TO ACTUALLY CONDUCT THE CLINICAL TRIALS,
15	A MINIMAL AMOUNT OF IND-ENABLING PRECLINICAL
16	ACTIVITIES AND SUPPORTING ACTIVITIES, WHICH MIGHT BE
17	MANUFACTURING OF THE ACTUAL PRODUCT, IT MIGHT BE
18	PROCESS DEVELOPMENT WORK TO TAKE SOME OF THESE MORE
19	COMPLICATED THERAPIES AND PROCESSES TO LARGER SCALE
20	TO SUPPORT LARGER TRIALS.
21	THOSE THINGS THAT ARE OUT OF SCOPE ARE
22	RESEARCH LEADING TO CANDIDATE SELECTION THAT'S
23	WELL COVERED IN OUR EARLY TRANSLATIONAL AWARD AND
24	PHASE III TRIALS.
25	THERAPEUTIC CANDIDATES WILL BE EITHER
	131

1	EXPECTED TO BE DERIVED FROM OR COMPRISED OF
2	PLURIPOTENT DERIVED CELLS, ALLOGENEIC TISSUE-DERIVED
3	STEM CELLS, OR PROGENITOR CELLS FOR REPAIR OR
4	REGENERATION, ENGINEERED FUNCTIONAL TISSUES FOR
5	IMPLANTATION, SMALL MOLECULES OR BIOLOGICS TARGETING
6	ENDOGENOUS STEM CELLS FOR REGENERATION AND REPAIR,
7	AND GENETICALLY OR PHARMACOLOGICALLY MODIFIED HSC'S.
8	SO WE THINK THESE PRODUCT TYPES ARE WELL SUPPORTED
9	TO MEET CIRM'S MISSION.
10	THOSE THAT ARE ELIGIBLE FOR THE DISEASE
11	TEAM III ARE ALL ACADEMIC NOT-FOR-PROFIT AND
12	FOR-PROFIT RESEARCH INSTITUTIONS. SO ALL COMERS TO
13	THIS TYPE OF AWARD. AND OUR PROPOSED AWARD FOR THIS
14	ROUND, WE WOULD SUGGEST UP TO FIVE AWARDS WITH
15	JUSTIFIABLE PROJECT COSTS BETWEEN FIVE AND \$20
16	MILLION PER AWARD, WHICH BRINGS THE TOTAL FOR THIS
17	ROUND OF DISEASE TEAM THERAPY DEVELOPMENT AWARDS TO
18	\$100 MILLION.
19	WE ARE LOOKING FOR CO-FUNDING AT THE
20	CLINICAL STAGE FOR PROJECTS THAT ARE SMALL MOLECULE
21	AND BIOLOGIC APPROACHES. AND THE REASON TO DO THIS
22	IS WE CONTINUE TO WANT TO TRY TO ATTRACT INDUSTRY
23	AND BIOTECHNOLOGY TO THOSE PRODUCTS THAT ARE REALLY
24	IN THEIR SWEET SPOT. SO WE WOULD LIKE TO SEE THE
25	COMMITMENT ABOUT TAKING THESE PROJECTS FORWARD.

132

1	WITH RESPECT TO THE AWARD INSTRUMENT,
2	GRANTS ARE AVAILABLE TO EVERYONE, AND FOR-PROFIT
3	ENTITIES MAY CHOOSE EITHER A LOAN OR A GRANT.
4	OUR PROVISIONAL TIMETABLE, AND WE WENT
5	OVER SEVERAL POSSIBLE STRATEGIES IN THE APPLICATION
6	PROCESS IN OUR SCIENCE SUBCOMMITTEE, AND WE AGREED
7	THAT WE WOULD DO THIS ROUND WITH A LETTER OF INTENT
8	AND FIRM ELIGIBILITY CRITERIA IN ORDER TO POST THE
9	RFA IN JANUARY OF 2013 WITH FUNDING ONE CALENDAR
10	YEAR LATER IN JANUARY OF 2014. AND THE REASON THAT
11	THIS IS VERY IMPORTANT THIS ROUND IS THAT OUR
12	DISEASE TEAM I APPLICANTS, MOST OF THEM COME UP ON
13	THE END OF THEIR FOUR-YEAR PERIOD BETWEEN FEBRUARY
14	AND JUNE OF 2014. SO WE'D LIKE TO BE POISED AND
15	READY TO SUPPORT THOSE TEAMS THAT GO THROUGH A
16	GRANTS WORKING GROUP AND PROPOSE PROJECTS OF MERIT,
17	SO THAT TIMING IS CRITICAL FOR US.
18	THAT CONCLUDES THE CONCEPT PROPOSAL FOR
19	THE DISEASE TEAM III, AND I'D BE HAPPY TO ENTERTAIN
20	QUESTIONS.
21	CHAIRMAN THOMAS: MR. JUELSGAARD.
22	DR. JUELSGAARD: SO IN LOOKING AT THIS
23	PROPOSAL VERSUS THE ONE THAT WAS EARLIER THIS
24	MORNING FOR STRATEGIC PARTNERSHIP II, JUST LOOKING
25	AT THE ELIGIBILITY CRITERIA. SO THEY READ SIMILARLY
	133
	±33

1	EXCEPT THAT IN THIS PROPOSAL WE INCLUDE THE WORD
2	"ACADEMIC" FOR ELIGIBILITY CRITERIA WHICH WASN'T IN
3	THE STRATEGIC PARTNERSHIP II PROPOSAL, BUT THERE'S
4	ALSO THE ADDITION OF THE WORD "RESEARCH
5	INSTITUTIONS." AND SO JUST FOR MY EDIFICATION, CAN
6	YOU GIVE ME THE DISTINCTION JUST SO WE'RE CLEAR
7	ABOUT A FOR-PROFIT INSTITUTION FOR THE STRATEGIC
8	PARTNERSHIP FUND VERSUS A FOR-PROFIT RESEARCH
9	INSTITUTION FOR THIS FUND? HOW DO YOU DIFFERENTIATE
10	THE TWO?
11	DR. STEFFEN: I'LL TAKE HELP ON THAT. I
12	KNOW WHAT I HAVE IN MIND. I DON'T WANT TO SAY
13	INSTITUTIONS.
14	DR. FEIGAL: THESE ARE THE SAME
15	ELIGIBILITY FOR-PROFIT, IF IT'S FOR PROFIT, IT'S
16	FOR PROFIT. IF IT'S A NOT-FOR-PROFIT, IT CAN BE AN
17	ACADEMIC OR IT CAN BE A NOT-FOR-PROFIT RESEARCH
18	INSTITUTION. DOES THAT ANSWER YOUR QUESTION?
19	DR. JUELSGAARD: YES, BUT THEN IT LEADS TO
20	ANOTHER QUESTION. IN THE STRATEGIC PARTNERSHIP
21	FUND, WE LIMITED IT TO 10 MILLION. THIS HAS A CAP
22	OF 20 MILLION. WE SAID THE FOR-PROFIT ENTITIES HAD
23	TO PROVE COMMERCIAL VIABILITY; THAT IS, THEY HAD TO
24	BE ABLE TO CO-FUND AS DETERMINED AHEAD OF TIME,
25	ETC., WHICH AREN'T INCLUDED IN HERE.
	134

1	SO THERE'S SOME DIFFERENCES BETWEEN THE
2	TWO. AND IF I WERE A FOR-PROFIT INSTITUTION, THIS
3	SEEMS TO BE THE DIRECTION I WOULD LIKE TO GO. I CAN
4	GET MORE MONEY AND I DON'T HAVE TO WORRY ABOUT
5	PROVING MY FINANCIAL VIABILITY BECAUSE WE'RE NOT
6	REQUIRING THAT.
7	DR. FEIGAL: SO ARE YOU ASKING THE
8	QUESTION WHY DON'T WE JUST HAVE ONE INITIATIVE, OR
9	ARE YOU ASKING WHAT'S DIFFERENT?
10	DR. JUELSGAARD: I'M ASKING WHETHER THERE
11	ARE TWO DIFFERENT PATHWAYS. SO AN INSTITUTION COULD
12	CHOOSE BETWEEN THE TWO BECAUSE THEN, AS I POINTED
13	OUT, I MAY BE WRONG, BUT IT SEEMS TO ME THIS WOULD
14	BE A PREFERABLE ONE FOR A FOR-PROFIT ENTITY.
15	DR. FEIGAL: OKAY. SO WE DISCUSSED THIS
16	EXTENSIVELY IN TERMS OF INCENTIVES AND OTHER ISSUES.
17	ONE IS TIMING. OFTEN FOR COMPANIES TIME IS MONEY.
18	AND WITH THE STRATEGIC PARTNERSHIP WE'RE DOING IT
19	TWICE A YEAR AND WE HAVE VERY FAST TURNAROUND. SO
20	THAT WHAT WE'RE PLANNING TO DO WITH STRATEGIC
21	PARTNERSHIP IS AFTER APPROVAL, OF COURSE, POST IT IN
22	NOVEMBER, TURN IT AROUND VERY QUICKLY SO THAT BY, I
23	BELIEVE IT WAS, APRIL OR MAY OF EARLY NEXT YEAR,
24	THEY'D ALREADY BE REVIEWED AND THEY'D GET AN ANSWER
25	BACK SOON AFTER THAT AND FUNDING WOULD COME.
	135
	1

1	WITH THIS ONE, IT'S A DIFFERENT TIME
2	FRAME. WE ANTICIPATE THESE ARE FOR MIGHT BE MORE
3	ATTRACTIVE ACTUALLY TO ACADEMICS WHERE THE TIMING
4	MAY NOT BE QUITE SO URGENT AS AN INDUSTRY WHO'S
5	DEPENDENT ON THAT FUNDING AND HAS A VERY DIFFERENT
6	KIND OF TIMELINE AND URGENCY TO GET THINGS DONE
7	QUICKLY. WITH AN ACADEMIC, WE FEEL THAT THEY'RE
8	MORE RESEARCH ORIENTED AND MAY NOT HAVE A PARTNER.
9	SO ONE THING I THINK YOU ALSO NOTICE IS
10	DIFFERENT, WE DID NOT REQUIRE A ONE-TO-ONE FUNDING
11	MATCH FOR THIS TYPE BECAUSE WE FEEL FOR CERTAIN
12	TYPES OF APPROACHES FOR THE AUTOLOGOUS CELL THERAPY
13	THAT'S ENGINEERED, WE THINK THAT WOULD HAVE A
14	DIFFICULT TIME GETTING PARTNERED OR MAY, AND FOR
15	ALLOGENEIC CELL THERAPY APPROACHES, WE THINK THAT
16	ALSO COULD HAVE DIFFICULTY. SO WE'RE ONLY REQUIRING
17	IT AND NOT EVEN REQUIRING A ONE-TO-ONE, BUT SOME
18	CO-FUNDING FOR SMALL MOLECULES OR BIOLOGIC
19	APPROACHES. SO THERE ARE DIFFERENCES.
20	ALSO, WHAT WE TRIED TO DO WITH THIS LATEST
21	ITERATION OF SP II WAS UNDER EXCEPTIONAL
22	CIRCUMSTANCES INCREASE THE FUNDING UP TO 15 MILLION
23	WHERE THEY COULD APPROPRIATELY JUSTIFY IT. AND I
24	THINK WHAT YOU WILL NOTICE WITH THE BUDGET LET ME
25	GO BACK. RIGHT THERE. 20 ISN'T A GIVEN. THE NEXT
	126
	136

1	THING YOU'RE GOING TO HEAR ABOUT IS A DISCUSSION
2	ABOUT HOW BUDGET SHOULD COME INTO PLAY IN EVALUATING
3	THESE PROPOSALS. SO WE'RE THINKING JUSTIFIABLE
4	PROJECTS MAY BE MORE IN THE RANGE OF FIVE UP TO 20.
5	SO THE 20 IS A CEILING, BUT IT'S NOT A GIVEN THAT
6	YOU CAN COME IN WITH THAT.
7	SO WE'RE TRYING TO PUT SOME ADDITIONAL
8	PARAMETERS IN PLACE TO HAVE MORE SCRUTINY OF THE
9	BUDGETS THAT COME IN. SO FOR A VARIETY OF REASONS,
10	I THINK THE BIGGEST ONE IS THE TIMING FOR WHY
11	FOR-PROFITS MIGHT BE PARTICULARLY ATTRACTED TO THE
12	STRATEGIC PARTNER AND THE FAST TURNAROUND AND THE
13	ABILITY TO GO IN MORE QUICKLY.
14	DR. JUELSGAARD: MR. CHAIRMAN, CAN I ASK
15	JUST ONE MORE FOLLOW-UP QUESTION?
16	CHAIRMAN THOMAS: YOU CAN ASK AS MANY AS
17	YOU LIKE, MR. JUELSGAARD.
18	DR. JUELSGAARD: I JUST HAVE ONE. SO IT
19	REALLY DEALS WITH THE WORD "BIOLOGIC" IN TERMS OF
20	APPROACHES. SO WHEN YOU USE THE TERM "BIOLOGIC,"
21	WHAT IS ENCOMPASSED BY THAT TERM?
22	DR. FEIGAL: WE WOULD DEFINE IT AS
23	MONOCLONAL ANTIBODIES OR PROTEINS. WE'RE NOT
24	TALKING ABOUT THE CELL THERAPIES.
25	DR. JUELSGAARD: OKAY. THANK YOU.
	137

1	CHAIRMAN THOMAS: OTHER COMMENTS,
2	QUESTIONS, ETC.?
3	DR. CHISARI: DO YOU HAVE A CONTINGENCY
4	PLAN FOR THE HAPPY EVENT WHEN YOU GET TEN TIER I
5	APPLICATIONS FOR THIS PROGRAM?
6	DR. STEFFEN: I THINK IT'S TO COME BACK TO
7	THE BOARD IF WE WERE IN THAT TERRIFIC SITUATION, WE
8	HAD A BUCKET OF UNALLOCATED FUNDS THAT ARE
9	DESIGNATED FOR DEVELOPMENT THAT MAY NOT HAVE BEEN
10	AWARDED IN PREVIOUS ROUNDS THAT WE COULD UTILIZE.
11	THAT WOULD BE A HAPPY DAY.
12	DR. CHISARI: YOU'D COME BACK TO THE BOARD
13	FOR THAT?
14	DR. STEFFEN: AT THE TIME OF PRESENTATION,
15	YEAH.
16	CHAIRMAN THOMAS: MUCH AS I COMMENTED ON
17	THAT POINT ON THE STRATEGIC PARTNERSHIP FUND II
18	WHERE THEY HAD THE 40 MILLION CAP, THAT IF WE DO
19	HAVE THE HAPPY CIRCUMSTANCE OF A BUNCH OF LIGHTS-OUT
20	PROJECTS THAT GO OVER THE BUDGETED AMOUNT, WE WILL
21	ASK THE BOARD'S FLEXIBILITY IN CONSIDERING THOSE AT
22	THAT TIME. THAT'S AN EXCELLENT QUESTION.
23	DR. PRIETO: I GUESS I HAD SIMILAR
24	QUESTIONS TO MR. JUELSGAARD'S. AND WONDERING REALLY
25	IN A LARGER SENSE WHAT'S THE MOST EFFECTIVE USE OF
	138

1	OUR REMAINING MONEY AND WHETHER THE STRATEGIC
2	PARTNERSHIPS AREN'T MORE IN LINE OR THAT SORT OF
3	GENERAL APPROACH ISN'T MORE IN LINE WITH WHAT WE'RE
4	TRYING TO DO IF WE ARE TRYING TO DRIVE POTENTIAL
5	THERAPIES INTO THE CLINIC RAPIDLY. DO WE NEED THIS
6	AS A SEPARATE RFA, OR IS THERE A WAY TO COMBINE
7	THESE GOALS?
8	DR. STEFFEN: I THINK THAT WE DID CONSIDER
9	COMBINING THEM. AND FOR REASONS TO KEEP THEM
10	SEPARATE IS, ONE, TO PROTECT A SPACE WHERE PROJECTS
11	THAT MAY BE DESIGNATED AT SOMETHING LIKE ORPHAN
12	TECHNOLOGIES OR THAT MAY BE INCREMENTALLY MOVING
13	PRACTICE ALONG. IT MAY NOT HAVE THE COMMERCIAL
14	STRENGTH TO ATTRACT A PARTNER TO THE STRATEGIC
15	PARTNER. SO WHILE THAT'S GOOD SCIENCE AND GOOD FOR
16	MEDICINE, THIS KIND OF KEEPS A PROTECTED SPACE FOR
17	PROJECTS AT THE SAME DEVELOPMENT STAGE THAT WE CAN
18	PERHAPS GET THEM TO WHERE THEY WOULD BE COMMERCIALLY
19	VIABLE.
20	MS. BAUM: I WANTED TO ADD TO THAT, THAT
21	WE CERTAINLY THINK THAT IT'S VERY ADVANTAGEOUS FOR
22	US TO MAINTAIN TWO SEPARATE PROGRAMS. WE DID HAVE A
23	VERY DETAILED CONSIDERATION OF THIS INTERNALLY. WE
24	BELIEVE THAT THE STRATEGIC PARTNERSHIP FUND, AS
25	DESIGNATED EARLIER, HAS ADDED BENEFIT OF BEING

139

1	ESSENTIALLY AN INDUSTRY ONLY FORUM. AND WE THOUGHT
2	THAT WITH THAT COMES A LOT OF OTHER ADVANTAGES.
3	DR. JUELSGAARD: SO THIS ISN'T A QUESTION,
4	BUT FORM OF A COMMENT. IT WORRIES ME JUST A LITTLE
5	BIT THAT WE WOULD NOT INCLUDE IN THIS PROGRAM WHEN
6	DEALING WITH A FOR-PROFIT COMPANY A CONSIDERATION OF
7	COMMERCIAL VIABILITY. I THINK WHEN WE'RE TALKING
8	ABOUT LARGE ACADEMIC INSTITUTIONS OR LARGE NONPROFIT
9	RESEARCH INSTITUTIONS, I DON'T THINK THAT'S REALLY
10	THAT MUCH OF A CONSIDERATION. BUT WE ALL KNOW THE
11	WORLD OF VERY SMALL PRIVATELY HELD COMPANIES AND
12	SOMETIMES THE SHOESTRINGS BY WHICH THEY OPERATE
13	WHICH CAN BECOME UNDONE SOMEWHAT QUICKLY SOMETIMES.
14	SO I WOULD SUGGEST FOR THIS PROGRAM, IF
15	WE'RE GOING TO CONSIDER FOR-PROFIT ENTITIES TO
16	PROVIDE TO, THAT WE INCLUDE A MEASURE MUCH LIKE WE
17	DO FOR THE STRATEGIC PARTNERSHIP FUND WHERE YOU GUYS
18	AT THE STAFF LEVEL REVIEW THEIR COMMERCIAL
19	VIABILITY.
20	MS. BAUM: CAN I ADD THAT COMMERCIAL
21	VALIDATION OR VIABILITY IN THE CONTEXT OF THE
22	STRATEGIC PARTNERSHIP FUND WAS TWOFOLD. FOR THE
23	NONPROFIT, IT MEANT THAT THEY HAD A PARTNER TOO. SO
24	I THINK WHAT YOU'RE SAYING HERE, THOUGH, IT'S A
25	FOR-PROFIT, THEY CAN GO EITHER HAVE A PARTNER OR, AS
	140

1	IN STRATEGIC PARTNERSHIP FUND, THEY HAVE TO HAVE
2	EVIDENCE OF HAVING RAISED A CERTAIN OF AMOUNT OF
3	FUNDING WITHIN A CERTAIN PERIOD OF TIME. AND THAT
4	SEEMS EXTREMELY LOGICAL. WE DO THAT INDIRECTLY
5	ANYWAY WHEN WE DO OUR DUE DILIGENCE IN THE PAST.
6	BUT TO MAKE THAT A REQUIREMENT, IT'S SOMETHING THAT
7	WE COULD DO EITHER AT PFAR OR AS PART OF A CONCEPT.
8	MS. SAMUELSON: WHEN YOU'RE CRAFTING THIS
9	COMBINATION OF GRANTS AND RFA'S FOR THE OVERALL
10	PORTFOLIO, DO YOU LOOK AT ALL AT THE INTERNATIONAL
11	PORTFOLIO? AND HOW CAN YOU DO THAT? DO YOU AND HOW
12	DO YOU GO ABOUT IT?
13	DR. STEFFEN: WHEN YOU SAY THE
14	INTERNATIONAL PORTFOLIO, ARE YOU THINKING ABOUT OUR
15	PROJECTS WITH OUR COLLABORATIVE FUNDING PARTNERS?
16	MS. SAMUELSON: ACTUALLY BEYOND THAT
17	BECAUSE PRESUMABLY A CURE COULD COME FROM ANYWHERE.
18	AN EFFECTIVE THERAPY COULD BE INVENTED BY SOMEBODY
19	ANYWHERE, AND THEIR PROGRESS IS INFLUENCED CERTAINLY
20	BY US, AT LEAST SOME OF IT, I'M ASSUMING. BUT
21	BEYOND, THE COLLECTIVE GROUP OF INITIATIVES AND
22	MONEY ARE WHAT ARE FUELING ADVANCES. AND I WOULD
23	THINK YOU WOULD NEED TO HAVE AN OVERALL PERSPECTIVE
24	OF THAT.
25	DR. STEFFEN: I THINK I HAVE TWO ANSWERS
	1 41
	141

1	OF THE APPLICATIONS WE APPROVED TODAY IN THE
2	STRATEGIC PARTNERSHIP. AND THAT IS AND I'M GLAD
3	TO SEE THAT THERE'S BEEN A CHANGE IN THAT WE'RE NOT
4	REQUIRING ALL APPLICANTS TO PROVIDE MATCHING FUNDS.
5	AND I SO I ASSUME THAT THAT WILL BE WHAT WE'RE
6	ADOPTING TODAY IS WHAT'S ON THE SLIDES AND NOT
7	WHAT'S IN THE BOOK.
8	THE BLUEBIRD APPLICATION WE APPROVED
9	EARLIER IS THE AUTOLOGOUS GENE THERAPY HEMATOPOIETIC
10	STEM CELL APPLICATION THAT ACTUALLY WOULD NOT HAVE
11	BEEN PICKED BY BLUEBIRD UNTIL AFTER AN ACADEMIC
12	RESEARCH INSTITUTION DID A VERY, VERY SMALL
13	PHYSICIAN-INITIATED TRIAL TO DETERMINE SOME
14	PRELIMINARY SAFETY AND EFFICACY DATA THAT THEN MADE
15	IT AN INTERESTING TARGET FOR A FOR-PROFIT PARTNER.
16	AND CIRM HAS DEVELOPED A PARTICULAR EXPERTISE, I
17	THINK, BOTH IN HIV, WE'RE WORKING IN SICKLE CELL,
18	NOW WE'VE ADDED B-THALASSEMIA. WE APPROVED IN OUR
19	LAST DISEASE TEAM ROUND AN AUTOLOGOUS GENE-MODIFIED
20	HEMATOPOIETIC STEM CELL PROJECT FOR MELANOMA.
21	SO THIS IS BECOMING A VERY INTERESTING
22	PART OF OUR PORTFOLIO, I THINK, THAT REALLY, IN
23	TERMS OF TECHNOLOGY, HAS BECOME VERY, VERY RIPE FOR
24	DEVELOPMENT, BUT INCLUDES SIGNIFICANT RISK,
25	ESPECIALLY THE GENOTOXICITY RISK IS VERY HIGH AND

143

i	
1	DOES NOT REALLY INVITE, ESPECIALLY IN PHASE I
2	CLINICAL TRIAL, THE KIND OF CO-FUNDING THAT WE WOULD
3	GET THROUGH OUR STRATEGIC PARTNERSHIP FUNDING. SO I
4	DO THINK THAT THIS DUAL TRACK APPROACH IS VERY
5	APPROPRIATE BY STAFF.
6	AND I WOULD NOTE TOO ON THE BUDGET ISSUE,
7	I THINK WE REALLY WILL GET SOME VERY REAL CLARITY,
8	AND WE ARE UNLIKELY TO SEE ANOTHER SPATE OF \$19.99
9	MILLION APPLICATIONS WHEN WE PUT IN PLACE I HOPE
10	WHEN WE COME TO THAT, WE'LL PUT IN SOME GUIDELINES
11	THAT PERHAPS WOULD PERSUADE APPLICANTS TO BE A
12	LITTLE BIT MORE CONSERVATIVE WITH THEIR BUDGETS SO
13	IT WILL LOOK MORE LIKE WHAT WE'RE DOING IN STRATEGIC
14	PARTNERSHIP AND LESS LIKE WHATEVER THE MARKET WILL
15	BEAR.
16	CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.
17	ANY OTHER COMMENTS, MEMBERS OF THE BOARD? OKAY.
18	ANY COMMENTS FROM MEMBERS OF THE PUBLIC? SEEING
19	NONE, MR. HARRISON, WE PROCEED TO A VOICE VOTE. DO
20	WE HAVE A MOTION TO APPROVE THIS CONCEPT PLAN?
21	MS. LANSING: I'LL MOVE IT.
22	CHAIRMAN THOMAS: I THINK THAT WAS JOAN
23	MOVING AND
24	MS. LANSING: THAT WAS SHERRY.
25	CHAIRMAN THOMAS: SHERRY MOVING, JOAN
	4.4.4
	144

1	SECONDING. ALL THOSE IN FAVOR PLEASE SAY AYE.
2	OPPOSED? ABSTENTIONS? THANK YOU, BETTINA.
3	WOULD LIKE TO NOTE FOR EVERYBODY'S BENEFIT
4	THAT BETTINA'S SON CAUGHT A FOUL BALL AT THE GAME
5	LAST NIGHT.
6	(APPLAUSE.)
7	CHAIRMAN THOMAS: I WOULD NOTE THAT I'D BE
8	SLIGHTLY MORE IMPRESSED IF IT WAS HIT BY MATT KEMP,
9	BUT UNFORTUNATELY HE'S PLAYING GOLF THESE DAYS. SO
10	JUST HAVE TO DEAL WITH THAT. MATT KEMP, FOR ALL YOU
11	SCIENTIST, NONSPORTS FANS, IS THE ALL STAR DODGER
12	CENTER FIELDER.
13	MOVING ON TO ITEM NO. 11, CONSIDERATION OF
14	CREATION DO YOU WANT TO GO INTO THE BUDGET RIGHT
15	NOW? SKIPPING AROUND, AS IS OUR WONT, WE'RE GOING
16	TO NOW MOVE TO ITEM 14, CONSIDERATION OF INCLUDING
17	BUDGET AS A FORMAL CRITERION FOR REVIEW OF RESEARCH
18	APPLICATIONS. DR. FEIGAL.
19	DR. FEIGAL: THANK YOU VERY MUCH. YOU ARE
20	GOING TO GET SICK OF HEARING FROM ME IN A MINUTE.
21	BASICALLY THIS IS AN IMPORTANT TOPIC. IT'S BEEN
22	DISCUSSED AT TWO PRIOR SCIENCE SUBCOMMITTEES. AND
23	THIS IS THE ISSUE OF RAISING THE LEVEL OF SCRUTINY
24	OF BUDGETS PARTICULARLY FOR LARGE, COMPLEX AWARDS,
25	SUCH AS THE EARLY TRANSLATION DEVELOPMENT CANDIDATE,

1	THE DISEASE TEAMS, THE STRATEGIC PARTNERSHIP, TO A
2	HIGHER LEVEL. SO THAT'S WHAT WE'RE GOING TO TALK
3	ABOUT RIGHT NOW.
4	SO WE REALLY FEEL THAT BUDGETARY REVIEW OF
5	CIRM RESEARCH AWARDS IS A VERY KEY AND CRITICAL
6	PART. THE SCIENCE IS A VERY KEY AND IMPORTANT PART
7	THAT DRIVES WHAT WE DO, BUT WE ALSO NEED TO
8	RECOGNIZE CIRM'S RESPONSIBILITY TO BE GOOD STEWARDS
9	OF TAXPAYER DOLLARS. AND WHAT WE ARE PROPOSING IS
10	TO AUGMENT THE CURRENT PROCEDURES TO INCREASE BUDGET
11	SCRUTINY AS PART OF THE PRIMARY REVIEW PROCESS.
12	ALL APPLICATIONS, NOT JUST THE LARGE,
13	EXPENSIVE ONES, FOR CIRM AWARDS SHOULD BE CAREFULLY
14	EXAMINED FOR BUDGETARY APPROPRIATENESS, BUT
15	PARTICULARLY WHAT I'M PROPOSING HERE ARE SOME
16	CHANGES FOR CIRM'S TRANSLATIONAL AND DEVELOPMENT
17	INITIATIVES. AND AS STATED EARLIER, WE'RE THINKING
18	OF THE SCOPE OF THE EARLY TRANSLATION DEVELOPMENT
19	CANDIDATE AWARDS, THE DISEASE TEAM AWARDS, AND THE
20	STRATEGIC PARTNERSHIP AWARDS.
21	LET ME JUST GIVE YOU A FEW EXAMPLES. BY
22	THE WAY, YOU ALL HAVE THE PREREAD THAT SHOULD HAVE
23	BEEN SENT TO YOU AT LEAST TEN DAYS BEFORE THIS
24	MEETING. SO I'M JUST REALLY GIVING YOU SOME KEY
25	HIGHLIGHTS FROM WHAT'S ALREADY IN THAT PREREAD.

1	SOME KEY EXAMPLES ARE THAT WHAT WE HAVE
2	FOUND IS THE BUDGET IS REALLY NOT ALIGNED WITH THE
3	PROGRAM DELIVERABLES IN THE MILESTONES, AND THEY ARE
4	INCLUDING ACTIVITIES THAT REALLY AREN'T RELEVANT TO
5	THE PROJECT OBJECTIVES OR THAT ARE OUT OF SCOPE, OR
6	THE BUDGET MAY CONTAIN INADEQUATE EXPENSES FOR KNOWN
7	COSTS. AN EXAMPLE WE'VE SEEN WHERE THEY'VE ASKED
8	FOR A HUNDRED THOUSAND FOR A GOOD MANUFACTURING
9	PRACTICE RUN OF A BIOLOGIC, AND WHICH IS GENERALLY
10	ACCEPTED KNOWLEDGE THAT THE ACTUAL EXPENSES ARE
11	TYPICALLY MUCH GREATER. OR THE BUDGET SIGNIFICANTLY
12	EXCEEDS THE KNOWN COSTS, OR IT SEEMS EXCESSIVE, AND
13	IT DOESN'T HAVE ADEQUATE JUSTIFICATION FOR THE
14	COSTS.
15	FOR EXAMPLE, WE'VE SEEN WHERE THEY'RE
16	ASKING FOR EXPENSES OF \$100,000 PER PATIENT FOR A
17	PROCEDURE IN WHICH WE ALREADY KNOW MEDICARE
18	REIMBURSEMENT IS SET AT 15,000. THE COST
19	ALLOCATIONS ARE NOT DONE PROPERLY. THE APPLICANT IS
20	DEVELOPING THE SAME THERAPEUTIC CANDIDATE IN
21	MULTIPLE DIFFERENT THERAPEUTIC INDICATIONS. THEY'RE
22	APPLYING TO CIRM WITH THAT THERAPEUTIC CANDIDATE FOR
23	ONE INDICATION, BUT THEY'RE ASKING FOR THE
24	MANUFACTURING COST FOR ALL THE OTHER THINGS THAT
25	THEY'RE DOING. THAT'S NOT APPROPRIATE.
	147
	<u> </u>

1	CHAIRMAN THOMAS: THAT NEVER HAPPENS.
2	DR. FEIGAL: AND UNLESS THE BUDGET AND THE
3	FINANCIAL ISSUES ALONG WITH POTENTIAL SOLUTION ARE
4	ADDRESSED IN THE GRANT REVIEW GROUP SUMMARIES, IT
5	CAN BE CHALLENGING AT TIMES FOR THE CIRM OFFICERS TO
6	ADDRESS AND NEGOTIATE THESE ISSUES POST-ICOC
7	APPROVAL.
8	SO THOSE ARE JUST SOME EXAMPLES OF WHAT
9	DROVE US TO WANT TO RAISE THE ATTENTION TO YOU OF
10	THIS AS AN ISSUE AND OUR SUGGESTIONS FOR HOW TO
11	ADDRESS IT. SO, IN GENERAL, WE'VE HAD THE TWO
12	SCIENCE SUBCOMMITTEE DISCUSSIONS, ONE IN JULY AND
13	MOST RECENTLY IN OCTOBER. AND, IN GENERAL, THE
14	DISCUSSION WAS FAVORABLE TOWARDS HAVING BUDGET
15	CONSIDERATION DURING THE GWG SESSION.
16	THE PRIMARY FOCUS THAT WE HEARD FROM THE
17	SCIENCE SUBCOMMITTEE AT A GWG SHOULD BE ON THE
18	SCIENTIFIC MERIT, AND THE BUDGETARY CONSIDERATIONS
19	SHOULD ONLY IMPACT ON THE SCORING FOR A PROJECT IF
20	IT IMPACTED IN THE DESIGN AND FEASIBILITY OF THE
21	PROJECT. SO WE WANT TO HEAR WHAT THE REMARKS ARE
22	AND WHAT THE COMMENTS ARE, BUT THE GENERAL CONSENSUS
23	WAS THAT IT SHOULDN'T IMPACT ON THE FINAL SCORE
24	UNLESS IT REALLY IMPACTED ON THE DESIGN AND THE
25	CONDUCT OF THAT PROJECT.
	148
	1 TU

1	HERE ARE THE RECOMMENDATIONS THAT WE'RE
2	ASKING YOU TO CONSIDER TODAY: TO ASSIST THE GRANT
3	REVIEW GROUP REVIEW, WE WANT TO GET THE APPROPRIATE
4	EXPERT ON BUDGET AND FINANCIAL MATTERS. IT COULD BE
5	A SPECIALIST OR IT COULD BE ASSIGNED TO ONE OR MORE
6	GRANT REVIEW GROUP REVIEWERS WHO HAVE THE
7	APPROPRIATE BACKGROUND AND EXPERTISE. THEY WILL
8	REVIEW THOSE APPLICATIONS FOR SOUND BUDGETING AND
9	PROVIDE COMMENTS AND QUESTIONS AT THE GRANT REVIEW
10	GROUP FOR CONSIDERATION BY THE OTHER REVIEWERS
11	BEFORE THE FINAL SCORES ARE ENTERED. AND IF THE
12	FINANCIAL AND BUDGETARY MATTER POTENTIALLY DIRECTLY
13	IMPACTS ON THE DESIGN OR THE FEASIBILITY OF
14	CONDUCTING THE PROJECT, THE GRANT REVIEW GROUP MIGHT
15	CONSIDER THIS ISSUE IN THE SCORING. OTHERWISE, THE
16	BUDGETARY AND THE FINANCIAL ISSUES AND QUESTIONS
17	WOULD NOT CONTRIBUTE TO THE FINAL SCORE. WE WOULD
18	CAPTURE THE INFORMATION, BUT WE WOULD PROVIDE
19	GUIDANCE THAT IT SHOULDN'T BE IMPACTING ON THE
20	SCORE.
21	I'LL GIVE YOU AN EXAMPLE JUST TO MAKE IT A
22	LITTLE BIT MORE TANGIBLE FOR YOU. LET ME JUST RUN
23	THROUGH SOME OF THE ADDITIONAL RECOMMENDATIONS.
24	WE FEEL THAT TWO IMPORTANT GOALS FOR THIS
25	ENHANCED BUDGET ASSESSMENT PROCESS WOULD BE, ONE, TO
	149

1	PROVIDE A CLEAR MEASURE OF MERIT OR LACK THEREOF FOR
2	AN APPLICATION'S BUDGET AND PROVIDE A CLEAR NOTICE
3	AND INCENTIVE TO APPLICANTS THAT A REASONABLE AND A
4	JUSTIFIABLE BUDGET IS AN IMPORTANT CRITERION TO BE
5	JUDGED. AND WE THOUGHT TO BEST ACHIEVE THESE GOALS,
6	BUDGET ASSESSMENT NEEDS TO BE INCORPORATED INTO THE
7	SCORE PROVIDED BY REVIEWERS, BUT THE DEGREE TO WHICH
8	THE BUDGET ASSESSMENT IMPACTS THE OVERALL SCORE
9	WOULD BE CAPTURED.
10	JUST TO GIVE YOU AN EXAMPLE, IF SOMEBODY
11	WOULD NORMALLY HAVE A SCIENTIFIC SCORE OF 70, BUT
12	LET'S SAY THAT THE BUDGET WAS SLOPPILY DONE,
13	INAPPROPRIATELY DONE, AND THEY WANTED TO SUBTRACT
14	FIVE OR TEN POINTS FROM THAT SCORE, THEIR FINAL
15	SCORE MIGHT BE 60, BUT WE WOULD CAPTURE WHAT THEIR
16	SCIENTIFIC SCORE WITHOUT THE BUDGET IMPACT WAS, THE
17	70, WE WOULD CAPTURE WHAT THE BUDGET IMPACT WOULD
18	BE, A MINUS 10, SO THAT THE FINAL SCORE WOULD BE 60,
19	BUT WE WOULD CAPTURE ALL THAT INFORMATION.
20	WE'VE HAD EXTENSIVE CONVERSATIONS WITH DR.
21	SAMBRANO, WHO HEADS THE REVIEW GROUP, TO SEE IS THIS
22	SOMETHING THAT IS FEASIBLE AND DOABLE WITHIN THE
23	GRANT REVIEW PROCESS. AND I'VE BEEN ASSURED THAT
24	THIS COULD BE READILY IMPLEMENTED IF THAT BODY
25	DECIDED THAT MIGHT BE AN APPROPRIATE COURSE TO TAKE.
	150

T20

1	SO THAT WHEN THE GRANT REVIEW GROUP
2	PROVIDED THEIR RECOMMENDATIONS, WE WOULD CAPTURE IN
3	A SUMMARY THAT WOULD BE BROUGHT FORWARD TO THIS
4	BOARD, AND WE WOULD BE ABLE TO CAPTURE AND IDENTIFY
5	WHAT IMPACT WAS REALLY ON THE SCIENCE, WHAT IMPACT,
6	IF ANY, WAS MADE FROM THE BUDGET REVIEW. IN MOST
7	INSTANCES, WE THINK THE IMPACT WILL BE ZERO BECAUSE
8	THEY MAY JUST BE CARELESS THAT THEY DID THAT AND
9	STAFF CAN CORRECT NORMALLY DURING PREFUNDING
10	ADMINISTRATIVE REVIEW. BUT IF IT REALLY DID IMPACT
11	ON THE DESIGN OR THE CONDUCT OF FEASIBILITY OF
12	ACTUALLY DOING THE PROJECT, IT WOULD HAVE AN IMPACT
13	AND IT WOULD BE CAPTURED IN THE SCORE THAT YOU WOULD
14	SEE.
15	SO THE REVIEW SUMMARIES THAT WILL COME TO
16	YOU WOULD IDENTIFY THE SCIENTIFIC, THE BUDGET, OR
17	OTHER ISSUES. AND THEN TO THE EXTENT THAT, SAY, A
18	POTENTIAL RESOLUTION WAS ENDORSED BY THE GRANT
19	REVIEW GROUP, THEY COULD ALSO IDENTIFY A POTENTIAL
20	RESOLUTION SHOULD THE ICOC APPROVE A GIVEN AWARD
21	THAT DID HAVE BUDGET ISSUES.
22	AND THEN THE OTHER THING WE WANTED TO MAKE
23	CLEAR AND WE WANTED TO HAVE AN EXPLICIT
24	RECOMMENDATION, THAT CIRM OFFICERS SHOULD BE
25	PROVIDED EXPLICIT DISCRETION TO CONSIDER THESE
	151
	1 ±3±

,	BARRISIERS REPORTING SERVICE
1	BUDGET COMMENTS AS WELL AS THE NONBUDGET
2	RECOMMENDATIONS IN THE NEGOTIATIONS WITH APPLICANTS.
3	SO WE THINK THOSE PROPOSED CHANGES WHICH
4	WE'RE SUGGESTING TO YOU FOR YOUR CONSIDERATION TODAY
5	DO ALIGN WITH CIRM'S MISSION, THAT INCREASING THE
6	IMPORTANCE OF BUDGETARY REVIEW WILL ENCOURAGE
7	APPLICANTS TO PROPOSE RIGOROUS, REALISTIC, AND
8	VETTED BUDGETS, AND IT WILL FURTHER CIRM'S MISSION
9	TO BE GOOD STEWARDS OF TAXPAYER DOLLARS, AND THAT
10	THESE PROPOSED CHANGES WOULD NOT SIGNIFICANTLY
11	INCREASE THE WORKLOAD BURDEN ON GRANT REVIEW GROUP
12	MEMBERS, AND WOULD EXPLICITLY ACKNOWLEDGE THAT
13	PROGRAM GOALS, SCIENTIFIC PLANS, ACCURATE BUDGETING,
14	AND PRUDENT SPENDING ARE INEXTRICABLY LINKED.
15	THANK YOU FOR YOUR ATTENTION, AND I'D BE
16	HAPPY TO ANSWER ANY QUESTIONS.
17	CHAIRMAN THOMAS: MR. SHEEHY.
18	MR. SHEEHY: I GUESS I THOUGHT THAT IS
19	THIS THE PROPOSAL FROM STAFF, OR DO WE HAVE ANOTHER
20	POTENTIAL
21	DR. FEIGAL: NO. THIS IS THE PROPOSAL,
22	BUT IF YOU'D LIKE TO HAVE ADDITIONAL COMMENTS FROM
23	DR. SAMBRANO.
24	MR. SHEEHY: I THINK WE GOT A LITTLE BIT
25	MORE INTO THE WEEDS BECAUSE WE COULDN'T REALLY DRAW
	152

1	A CONCLUSION AT THE SCIENCE SUBCOMMITTEE. AND I
2	THINK WE WERE LOOKING AT SOMETHING THAT MORE CLEARLY
3	DELINEATED WHAT WAS THE BUDGET CONSIDERATION, WHAT
4	WAS THE SCIENCE CONSIDERATION BECAUSE THE BUDGET IS
5	PRETTY CURABLE. DEFECTS IN SCIENCE ARE A DIFFERENT
6	ORDER OF MAGNITUDE, AND I DON'T WHERE ARE WE ON
7	THIS BECAUSE YOU AND I HAD A DISCUSSION REALLY
8	TRYING TO GET INTO THE MECHANICS BECAUSE WE WERE A
9	LITTLE BIT
10	DR. SAMBRANO: I THINK DR. FEIGAL IS
11	TRYING TO INCORPORATE THAT INTO THE SLIDES, AND SO
12	THE EXAMPLE SHE GAVE WAS FROM THAT DISCUSSION. SO I
13	CAN KIND OF GO OVER IT MAYBE THE WAY I HAD DESCRIBED
14	IT IN WRITING, AND MAYBE THAT MIGHT BE CLEARER.
15	SO THE IDEA BEHIND THIS IS IN TRYING TO
16	COME UP WITH A WAY TO IMPLEMENT WAS THAT THERE'S TWO
17	IMPORTANT GOALS. I THINK DR. FEIGAL ALREADY STATED
18	THEM. ONE, THAT WE WANT TO MAKE SURE WE HAVE A
19	CLEAR MEASURE OF THE MERIT FOR AN APPLICATION'S
20	BUDGET. I THINK THAT'S ONE IMPORTANT ASPECT. AND
21	THE SECOND WAS THAT WE HAVE TO PROVIDE A CLEAR
22	INCENTIVE AND NOTICE TO APPLICANTS THAT THE BUDGET
23	MUST BE REASONABLE, AND IT MUST BE JUSTIFIED, AND
24	THAT THAT WILL BE JUDGED AND SCORED BY REVIEWERS.
25	SO IN THINKING ABOUT, AGAIN, THE
	153
	±33

1	MECHANICS, ONE METHOD FOR DOING THIS WOULD BE TO
2	ESSENTIALLY HAVE EACH REVIEWER ENTER THEIR OVERALL
3	FINAL SCORE FOR AN APPLICATION. AND SO, AGAIN, WE
4	CAN USE AN EXAMPLE OF 70. AND THEN IN ADDITION, SO
5	THEY WOULD HAVE, INSTEAD OF JUST A SINGLE SCORE BOX,
6	THEY WOULD HAVE TWO. THEY'D ENTER THE OVERALL SCORE
7	OF 70, AND IN ADDITION WOULD ENTER THE NUMBER OF
8	POINTS THAT THEY MIGHT DEDUCT FOR ANY BUDGET ISSUES.
9	SO SAY ANYWHERE FROM ZERO TO 20 POINTS.
10	AND SO AN APPLICATION THAT MIGHT HAVE
11	SCORED A 75 INSTEAD HAS A SCORE OF 70 BECAUSE THAT
12	PARTICULAR REVIEWER DEDUCTED FIVE POINTS FOR THE
13	BUDGET.
14	YOU HAVE 15 SCIENTIFIC REVIEWERS WHO ARE
15	GIVING DIFFERENT SCORES. SO NORMALLY WE GIVE YOU
16	THE AVERAGE OF THOSE SCORES. SO SIMILARLY, WE WOULD
17	THEN CALCULATE WHAT THE AVERAGE OF THAT DEDUCTION
18	AMONG REVIEWERS WOULD BE, AND SO YOU'D HAVE AN
19	AVERAGE SCORE OF 70 AND AN AVERAGE DEDUCTION OF
20	FIVE. AND SO THOSE TWO ELEMENTS WOULD BE PRESENTED
21	TO YOU SO THAT YOU HAVE AN ACCURATE MEASURE OF BOTH
22	WHAT THE SCIENTIFIC MERIT IS AND WHAT THE MERIT OF
23	THE BUDGET IS, OR HOW MUCH WAS DEDUCTED BECAUSE OF
24	THOSE ELEMENTS.
25	LET ME SEE IF I HAVE ANY MORE HERE. THE
	154
	L

1	OTHER ASPECT IS THAT IN TERMS OF IMPLEMENTING, THE
2	OTHER IMPORTANT THING IS THAT WE'RE GOING TO HAVE TO
3	PROVIDE SOME GUIDANCE TO REVIEWERS AS TO HOW THIS IS
4	BEING UTILIZED. OBVIOUSLY THAT IS GOING TO BE KEY.
5	AND THIS IS ALSO SOMETHING THAT NEEDS TO BE PLACED
6	IN THE RFA SO THAT IT'S CLEAR TO APPLICANTS THAT
7	THIS IS HOW IT WILL BE ASSESSED AND THE POTENTIAL
8	IMPACT THAT IT MAY THEN HAVE ON THEIR SCORE.
9	SO I THINK THAT'S THE SUMMARY OF WHAT WE
10	DISCUSSED. IS THAT MORE CONSISTENT WITH WHAT YOU
11	WERE THINKING?
12	MR. SHEEHY: IT IS. I JUST WANTED I'D
13	LIKE TO HEAR FROM OTHER MEMBERS BECAUSE WE HAD A LOT
14	OF DEBATE. WE TALKED ABOUT IT AND WE GOT KIND OF
15	CAUGHT UP. WE COULDN'T REALLY GET TO A CONCLUSION.
16	BUT I DO THINK WE NEED TO ADDRESS THE BUDGET ISSUE,
17	BUT I REALLY THINK THAT THERE'S CLEAR DEMARCATION
18	ABOUT WHAT YOU GOT FOR A SCIENTIFIC SCORE AND THEN
19	WHAT PENALTIES YOU ACCRUED. BECAUSE THE BUDGETS,
20	ALMOST EVERY REVIEW A REVIEWER WILL GET UP AND SAY
21	THIS BUDGET IS OUTRAGEOUS. AND OUR ONLY REDRESS IS
22	REALLY POSTAWARD, WHICH AT THAT POINT STAFF IS
23	REALLY NOT IN A POSITION TO EFFECTIVELY NEGOTIATE
24	THE BUDGET IN THE WAY THAT THEY SHOULD TO PROPERLY
25	PROTECT TAXPAYER DOLLARS.
	155

1	I DO THINK IT'S CLEAR THAT IT BE SEPARATED
2	BECAUSE WE DON'T WANT TO HURT A PROJECT THAT HAS
3	GOOD SCIENCE BECAUSE THEY WROTE A BAD BUDGET. AND
4	THIS IS SOMETHING THAT THEY WOULD BE ABLE TO CURE
5	EITHER WITH AN EXTRAORDINARY PETITION OR POSTAWARD
6	WITH STAFF, BUT SOMETHING THAT WOULD BE VERY CLEAR
7	WHAT THE QUESTION IS.
8	DR. BRYANT: YES. I JUST WANT TO SAY I
9	THINK THAT THAT CLARIFICATION, I THINK THIS IS A
10	GOOD WAY TO GO. IT THINK IT'S ABSOLUTELY ESSENTIAL
11	TO KEEP THE SCIENTIFIC MERIT SEPARATE FROM THE COST,
12	AND I ALSO THINK IT'S IMPORTANT TO CONTROL THE COST.
13	SO I THINK YOUR METHOD A LOT OF IT WILL DEPEND ON
14	HOW YOU END UP PRESENTING TO US. I WOULD PREFER A
15	LIST OF SCIENTIFIC MERIT AND THEN TAKE AWAY WHATEVER
16	WE WANT TO FROM THAT LATER.
17	DR. JUELSGAARD: YES. FIRST OF ALL, I
18	VERY HEARTILY SUPPORT THE NOTION OF BUDGETARY
19	OVERSIGHT ON THESE PROJECTS. JUST SO I CAN BETTER
20	UNDERSTAND WHAT YOUR PROPOSAL IS. SO I WANT TO GO
21	BACK TO ONE OF THE EXAMPLES THAT DR. FEIGAL
22	PRESENTED IN THIS PRESENTATION EARLIER ON. IT WAS
23	AROUND AN ENTITY DEVELOPING A PRODUCT FOR THREE
24	DIFFERENT INDICATIONS. AND SO YOU WOULD HAVE A
25	MANUFACTURING RUN TO PRODUCE THE CLINICAL MATERIAL
	156
	156

1	TO DO THAT, BUT ALL OF THOSE COSTS ASSOCIATED WITH
2	THAT PRODUCTION RUN ARE NOW BEING CHARGED TO THE
3	CIRM-FUNDED PROJECT. AND THE WAY IT WAS PRESENTED,
4	AND I BELIEVE THAT'S RIGHT, THAT SEEMS
5	INAPPROPRIATE.
6	SO TODAY BEFORE HAVE WE DONE ANYTHING
7	AROUND THIS? HOW WOULD YOU DEAL WITH THAT? AND
8	THEN SUBSEQUENT TO THE APPROVAL OF THIS PROPOSAL,
9	HOW WOULD YOU DEAL WITH IT DIFFERENTLY?
10	DR. FEIGAL: WELL, AS I SAID BEFORE, OUR
11	SENSE IS THAT THE SCORE SHOULD ONLY BE IMPACTED IF
12	IT IMPACTS ON DESIGN AND FEASIBILITY. IF WE DON'T
13	FEEL IT IMPACTS ON DESIGN AND FEASIBILITY, THEN I
14	WOULD SAY OUR GUIDANCE TO THE REVIEWER WOULD BE NOT
15	TO DEDUCT FROM THE SCIENTIFIC SCORE FOR THIS, BUT TO
16	CAPTURE THE REMARKS THAT ARE BROUGHT FORWARD. AND
17	SO IF THE REVIEWERS THOUGHT IT DIDN'T IMPACT, THEY
18	ASKED FOR TOO MUCH, BUT AT THE END OF THE DAY, WE
19	DIDN'T THINK IT WOULD IMPACT ON THE DESIGN OR
20	FEASIBILITY OF CONDUCTING THAT PROJECT IN THAT
21	INDICATION, THEN OUR GUIDANCE TO THE REVIEWER WOULD
22	BE DON'T DEDUCT FROM YOUR SCIENTIFIC SCORE, BUT
23	WE'LL MAKE SURE AND CAPTURE IT.
24	IF PEOPLE FEEL THAT IT ACTUALLY IMPACTS ON
25	THE DESIGN OR THE ABILITY FOR THIS PARTICULAR ENTITY

1	TO DO WHAT THEY NEED TO DO, THEN WE WOULD RECOMMEND
2	THAT THEY SUBTRACT POINTS. SO NOT ALL OF MY
3	EXAMPLES WERE EXAMPLES OF WHERE I THOUGHT THEY
4	NEEDED TO HAVE THEIR SCIENTIFIC SCORE DEDUCTED.
5	THEY WERE JUST EXAMPLES OF THINGS THAT HAPPENED THAT
6	AREN'T BEING CAPTURED AT ALL RIGHT NOW.
7	DR. JUELSGAARD: THE EXAMPLE THAT I JUST
8	ASKED ABOUT, IS IT DEALT WITH DIRECTLY AT SOME
9	POINT, OR WE JUST FUND FOR, IN ESSENCE, CLINICAL
10	MATERIAL?
11	DR. FEIGAL: LET ME CLARIFY. WE DO GO
12	THROUGH THE BUDGET METICULOUSLY BEFORE ANY MONEY
13	GOES OUT THE DOOR. WHAT I WAS JUST SAYING TO YOU IS
14	THAT WHEN THE BOARD APPROVES A CEILING, SOMETIMES
15	THERE'S TREMENDOUS RESISTANCE IN TERMS OF US GETTING
16	DOWN TO THE APPROPRIATE LEVEL. WE CERTAINLY DO
17	THAT. I'M JUST SAYING THE LIFE WOULD BE MADE MUCH
18	EASIER IF SOME OF THESE GLARING EXAMPLES WERE
19	POINTED OUT, PRESENTED TO YOU SO THAT WE HAVE
20	SOMEBODY BACKING IT UP WHEN WE'RE GOING INTO THESE
21	RATHER INTERESTING NEGOTIATIONS WITH EITHER ACADEMIC
22	CENTERS OR COMPANIES.
23	NO, WE ABSOLUTELY MAKE SURE THAT MONEY
24	GOES TO APPROPRIATE PLACES. OUR LIVES WOULD JUST BE
25	MADE EASIER IF WE HAD THAT ADDITIONAL SENSE OF

1	SUPPORT AND BACKING.
2	DR. JUELSGAARD: SO I GUESS WHAT IT COMES
3	DOWN TO FOR ME IS THE WORRY ABOUT CONFLATING THESE
4	TWO, RIGHT. SO SCIENCE ON THE ONE HAND AND BUDGET
5	ON THE OTHER AND, IN ESSENCE, PENALIZING THE SCIENCE
6	FOR BUDGETARY REASONS AS OPPOSED TO DEALING WITH THE
7	BUDGET AS A BUDGET AND MAKING IT A VERY BINARY
8	DECISION, EITHER WE'RE GOING TO SUPPORT THAT BUDGET
9	OR WE AREN'T. I GUESS IT'S JUST A WORRY BECAUSE I
10	DON'T KNOW EXACTLY WHERE THE LINES COME IN TERMS OF
11	THESE SUBJECTIVE ANALYSES BY GRANTS WORKING GROUP
12	MEMBERS AROUND BUDGET ISSUES.
13	DR. FEIGAL: I THINK WHAT WE SAID, LET ME
14	JUST REITERATE, IF WE THINK IT IMPACTS ON THE DESIGN
15	OR THE ABILITY TO CONDUCT THE PROJECT, THEN WE FEEL
16	THAT THERE SHOULD BE POINTS SUBTRACTED BECAUSE
17	USUALLY THAT DOESN'T HAPPEN IN ISOLATION. WE'RE NOT
18	TALKING ABOUT RESEARCH WHERE COSTS AREN'T KNOWN.
19	THESE ARE USUALLY KNOWN COSTS. AND LET'S JUST SAY
20	SOMEBODY IS UNDERASKING FOR SOMETHING THAT MIGHT
21	REALLY GREATLY JEOPARDIZE THE ABILITY TO EVEN DO THE
22	PROJECT, THEN ONE MIGHT THINK THAT THAT ALSO MIGHT
23	HAVE IMPACT ON THE CREDIBILITY OF THE TEAM THAT
24	ACTUALLY PUT THE BUDGET TOGETHER.
25	SO I'M JUST SAYING FOR THESE TYPES OF
	159
	1

1	PROJECTS THAT ARE GOING DOWN A REGULATORY
2	DEVELOPMENT PATHWAY, THERE ARE KNOWN COSTS. AND IF
3	THEY THEMSELVES DON'T KNOW IT, IT'S BETTER BEFORE
4	THEY SUBMIT THE APPLICATION TO GET THE BUDGETARY
5	EXPERTISE THEY NEED TO PUT TOGETHER A REASONABLE AND
6	FEASIBLE BUDGET. SO I DON'T KNOW IF I MADE THAT
7	CLEAR, BUT WE THINK IT WILL BE UNCOMMON INSTANCES
8	WHERE IT SHOULD IMPACT ON SCIENTIFIC SCORE.
9	MR. JUELSGAARD: SO JUST SORT OF ONE FINAL
10	QUESTION AND THEN I'LL END. SO WHEN YOU CONSIDER
11	THESE GRANTS FOR FOR-PROFIT INSTITUTIONS FOR A
12	MOMENT, FOR COMPANIES, PRIVATE OR PUBLIC, SO ONE OF
13	THE COSTS THAT'S EMBEDDED IN THE COST STRUCTURE OF A
14	PUBLIC OR PRIVATE COMPANY ARE WHAT ARE CALLED
15	OVERHEAD COSTS. AND THE QUESTION IS ALWAYS ONE OF
16	ALLOCATING THEM. SO THERE ARE COSTS FOR HUMAN
17	RESOURCES, THERE ARE COSTS FOR LEGAL, THERE ARE
18	COSTS FOR INFRASTRUCTURE, ETC. THAT ARE TRULY A PART
19	OF AN ORGANIZATION'S COST.
20	BUT THE QUESTION IS SHOULD ANY OF THAT GET
21	ALLOCATED WHEN YOU'RE DEALING WITH A SPECIFIC
22	PROJECT. SHOULD THE PROJECT BEAR SOME OF THAT COST
23	BECAUSE IT MAY BE USING SOME OF THOSE RESOURCES OR
24	NOT? HOW DO WE TREAT THAT AT THIS POINT?
25	DR. FEIGAL: ACTUALLY I WAS TALKING MORE
	160

1	ABOUT THE DIRECT RESEARCH COSTS, NOT ABOUT THE
2	INDIRECTS AND FACILITIES UNLESS GIL WANTS TO ADDRESS
3	THAT.
4	DR. SAMBRANO: SO LIKE ANY OTHER GRANTEE,
5	THERE ARE PROVISIONS FOR PROVIDING INDIRECT COSTS AS
6	WELL AS FACILITIES COSTS. AND SO THERE ARE SPECIFIC
7	PERCENTAGES FOR FOR-PROFIT INSTITUTIONS. TYPICALLY
8	FOR THE INDIRECT COSTS OR AT LEAST WHAT WE CONSIDER
9	THE ADMINISTRATIVE PORTION OF INDIRECT COST IS ABOUT
10	20 PERCENT. AND THE FACILITIES PORTION IS TYPICALLY
11	ABOUT 35 PERCENT OF THE AWARD AMOUNT. SO THAT IS
12	TYPICALLY HOW IT'S DONE. WITH ACADEMIC
13	INSTITUTIONS, IT VARIES. SO THEY TEND TO MIMIC IN
14	MANY WAYS THE RATES THAT ARE PROVIDED BY NIH, WHICH
15	HAVE BEEN NEGOTIATED WITH FEDERAL AGENCIES AND
16	THEY'VE ARRIVED AT SPECIFIC PERCENTAGES THAT WOULD
17	BE APPROPRIATE FOR EACH OF THE INDIRECT COSTS AND
18	FACILITY SUBCATEGORIES.
19	DR. JUELSGAARD: SO JUST ONE QUICK
20	COMMENT. I SAID THERE WASN'T ANY MORE, BUT JUST IN
21	REACTION TO THAT. I DON'T KNOW HOW MUCH THAT YOU'VE
22	PRESSURE TESTED THE NOTION OF THESE PERCENTAGES FOR
23	FOR-PROFIT INSTITUTIONS. BUT OFF THE TOP OF MY
24	HEAD, THEY JUST SOUND A LITTLE HIGH, THOSE KIND OF
25	PERCENTAGES ALLOCATED TO FACILITIES OR ALLOCATED TO

1	NONFACILITIES.
2	DR. SAMBRANO: SO THERE'S ALSO YOU
3	KNOW, THIS IS THE CAP, IF YOU WILL. SO WHEN
4	SOMEBODY PREPARES A BUDGET AND REQUESTS, WHETHER
5	IT'S THEIR INDIRECT COST OR THEIR FACILITIES COST,
6	THIS WILL BE A CAP. THEY CAN REQUEST LESS, AND THE
7	AMOUNT SHOULD BE APPROPRIATE TO WHAT THE INSTITUTION
8	IS USED TO HAVING IN TERMS OF OVERHEAD, AND IT WILL
9	DIFFER. AND IT ALSO HAPPENS THAT SOME INSTITUTIONS
10	CHOOSE TO REQUEST LESS IN TERMS OF FACILITIES OR
11	INDIRECT COST SO THAT THEY CAN ACTUALLY, IN TURN,
12	COLLECT MORE ON THE DIRECT PROJECT COSTS. SO I
13	THINK IT ALSO VARIES FROM APPLICANT TO APPLICANT.
14	DR. FEIGAL: WE CAN GET INTO MORE DETAILS
15	IF YOU'D LIKE ABOUT THE INDIRECTS, BUT THERE IS A
16	CAP FOR FOR-PROFITS. AND AS GIL SAID, THERE IS SOME
17	FLEXIBILITY WITH UNIVERSITIES. AND MANY
18	FOR-PROFITS, WHEN THEY COME IN HERE, THEY'RE MAINLY
19	ASKING, MANY OF THEM ARE ASKING FOR THE DIRECT
20	RESEARCH COSTS. SO THAT IS WHERE THE CIRM MONEY
21	WOULD BE GOING. AND, ANYWAY, I JUST WANTED TO
22	CLARIFY. IT IS DIFFERENT BETWEEN FOR-PROFITS AND
23	UNIVERSITIES.
24	CHAIRMAN THOMAS: I THINK WE HAD DEAN
25	POMEROY, DR. CHISARI, MR. SHEEHY, DR. PRICE, AND
	162
	102

1	JOAN.
2	DR. POMEROY: RECOGNIZING THAT WE DON'T
3	ALWAYS NEED TO DO EVERYTHING THE WAY THE NIH DOES,
4	IT'S STILL USEFUL TO THINK ABOUT THE WAY NIH DOES DO
5	THESE GRANT REVIEWS FOR ME. THAT IS, THAT THERE'S
6	EXTENSIVE DISCUSSION AND A SCIENTIFIC SCORE IS
7	GIVEN, AND THAT IS COMPLETED AND STOPPED, AND THEN
8	THERE'S A BUDGETARY DISCUSSION, WHICH IS ALSO VERY
9	CAREFULLY RECORDED WITHOUT A SCORE. AND IT IS VERY
10	CLEAR THAT IT IS ESSENTIAL TO KEEP THE SCIENTIFIC
11	SCORE CLEAN FROM THE BUDGETARY DISCUSSION.
12	SO WHAT WOULD BE THE JUSTIFICATION,
13	BECAUSE THEY HAVE RESPONSIBILITIES FOR BUDGETARY
14	OVERSIGHT TOO, WHAT WOULD BE THE JUSTIFICATION FOR
15	US DOING IT DIFFERENTLY?
16	DR. FEIGAL: WELL, THERE'S MANY THINGS
17	THAT WE DO DIFFERENTLY THAN THE NIH. AND ONE OF
18	THEM IS THE AMOUNT THAT WE GIVE OUT IS GREATLY
19	DIFFERENT. \$20 MILLION AWARDS. I DON'T THINK ANY
20	NIH GRANT GOES TO THAT AMOUNT. SO I THINK THE
21	MAGNITUDE OF WHAT WE GIVE OUT IS ACTUALLY QUITE A
22	BIT MORE THAN WHAT YOU WOULD GET FOR THE USUAL NIH
23	RESEARCH GRANT.
24	BUT I THINK IN TERMS OF YOUR SUGGESTION,
25	WE ALREADY HAVE IN OUR REVIEW CRITERIA THAT PEOPLE

1	SHOULD BE CONSIDERING BUDGET ISSUES THAT COULD
2	IMPACT ON THE DESIGN AND FEASIBILITY OF THE PROJECT.
3	AND THAT'S ALREADY GUIDANCE THAT IS GIVEN TO
4	REVIEWERS. WHAT WE'RE NOTICING IS THAT THERE REALLY
5	IS NOT WHAT WE WOULD CALL A SIGNIFICANT DISCUSSION
6	OF THE BUDGET AT ANY POINT IN THE DISCUSSION OF THE
7	PROJECT. AND SO WE THINK THAT WE ALREADY HAVE
8	WRITTEN THAT IF IT IMPACTS DESIGN OR FEASIBILITY, IT
9	REALLY DOES IMPACT THE SCIENCE. WE DON'T THINK THE
10	BUDGET IS JUST THIS THING THAT ORBITS AROUND, BUT IT
11	ACTUALLY, ALTHOUGH IT'S NOT SCIENCE, IT DOES IMPACT
12	ON YOUR ABILITY TO DO THE SCIENCE.
13	SO IF SOMEBODY HAS PROPOSED A BUDGET THAT
14	REALLY MAKES CONDUCTING THAT SCIENTIFIC RESEARCH
15	IMPOSSIBLE TO DO, THAT DOES NEED TO HAVE SOME SORT
16	OF REFLECTION IN A SCORE, AT LEAST THAT'S OUR
17	SUGGESTION, THAT IT DOES HAVE SOME IMPACT ON THE
18	SCORE.
19	DR. FIRESTEIN: COULD I JUST CLARIFY ONE
20	THING? THERE ARE MANY GRANTS AT THE NIH THAT EXCEED
21	\$20 MILLION.
22	DR. POMEROY: THANK GOODNESS FOR MANY OF
23	OUR INSTITUTIONS. IF I COULD JUST RESPOND, THAT'S
24	THE FIRST POINT IS THAT
25	DR. FEIGAL: I'M TALKING FOR A PROJECT,
	164
	40.

1	NOT FOR A CANCER CENTER, NOT FOR A MAJOR THIS IS
2	FOR ONE RESEARCH PROJECT.
3	DR. POMEROY: I THINK THE POINT STANDS.
4	BUT SECOND OF ALL, THERE'S A BIG
5	DIFFERENCE BETWEEN ADJUSTING A SCIENTIFIC SCORE FOR
6	FEASIBILITY, WHICH I DON'T THINK ANYBODY ARGUES
7	WITH, AND THEN HAVING A DISCUSSION ABOUT
8	APPROPRIATENESS OF THE BUDGET. AND I JUST THINK
9	IT'S IMPORTANT THAT WE KEEP THOSE TWO ISSUES
10	SEPARATE.
11	DR. VUORI: CAN I QUICKLY COMMENT MAYBE TO
12	CLARIFY A LITTLE BIT WHAT CLAIRE SAID. IN SOME WAYS
13	THE BUDGET DOES COME TO THE SCIENTIFIC SCORE IN THE
14	NIH SYSTEM IF THE BUDGET IS COMPLETELY MISALIGNED
15	WITH THE SCIENCE. IN OTHER WORDS, IT'S VERY CLEAR
16	THAT THE SCIENTIST SIMPLY DOESN'T UNDERSTAND HOW TO
17	PROCEED AND, HENCE, THE SCORE IS PROBABLY GOING TO
18	BE JUST VERY POOR.
19	DR. CHISARI: SO ACTUALLY I AGREE WITH ALL
20	THE COMMENTS THAT CLAIRE MADE AND THAT KRISTINA MADE
21	AND GARY MADE. I FEEL VERY STRONGLY THAT THE
22	SCIENTIFIC MERIT IS WHAT SHOULD BE THE BOTTOM LINE.
23	THERE CERTAINLY MUST BE DISCUSSION OF BUDGET. AND
24	THAT PERHAPS IS SOMETHING THAT STAFF OR WHOEVER IS
25	HEADING UP THE GWG FOR THAT PARTICULAR MEETING
	165
	103

1	EMPHASIZES TO THE MEMBERS OF THE GWG AT ALL
2	MEETINGS. BUT TO DOWNGRADE A GRANT THAT HAS
3	OUTSTANDING SCIENTIFIC MERIT BECAUSE OF BUDGETARY
4	CONCERNS, I THINK, IS NOT IN CIRM'S INTEREST.
5	I COULD ASK YOU ALSO WHY DON'T YOU GIVE
6	THE MEMBERS OF THE GWG THE OPPORTUNITY TO INCREASE
7	THE SCORE IF THEY THINK IT'S A REAL BARGAIN FOR
8	CIRM?
9	DR. FEIGAL: THAT COULD BE A
10	RECOMMENDATION YOU GIVE TO US.
11	DR. CHISARI: AND THE LAST POINT THAT I'D
12	LIKE TO MAKE SO THE FIRST POINT AND MOST
13	IMPORTANT POINT I'D LIKE TO MAKE IS I DON'T SEE THE
14	NEED FOR THIS AS LONG AS YOU IMPLEMENT A VERY, VERY
15	STRONG EMPHASIS ON BUDGETARY CONSIDERATIONS THAT
16	THEN GET REPORTED BACK TO THE STAFF, AND THEN
17	EMPOWER THE STAFF TO DEAL WITH THOSE CONCERNS AND
18	NEGOTIATE DOWNWARD, IF NECESSARY, BASED ON INPUT
19	THAT THE STAFF GETS FROM PERHAPS MEMBERS OF THIS
20	BOARD OR OTHER MEMBERS OF THE STAFF.
21	THE PLEA THAT I MAKE IS IF YOU FIND THAT
22	HAVING TWO SCORES IS HELPFUL, PERHAPS IN DEALING
23	WITH APPLICANTS THAT DON'T GET A FUNDABLE, WHAT YOU
24	WOULD OTHERWISE CALL A FUNDABLE SCIENTIFIC SCORE,
25	JUST THE PURE SCIENTIFIC SCORE, AND NOW IT'S

1	DOWNGRADED FURTHER, YOU HAVE ANOTHER SCORE YOU CAN
2	TALK TO THEM ABOUT AND SAY, WELL, THE SCIENCE WAS
3	WEAK AND THE FUNDING PROPOSAL WAS ALSO WEAK.
4	THE POINT THAT I WOULD LIKE TO MAKE IS
5	THAT IF YOU DO USE TWO SCORES, THAT YOU ONLY USE THE
6	SCIENTIFIC SCORE TO DECIDE WHETHER A GRANT IS IN
7	TIER I OR TIER III, THAT THE SECOND SCORE NOT BE
8	USED TO PUT A GRANT IN TIER I OR TIER III. AND THEN
9	YOU COULD BRING THE TIER I'S AND TIER III'S TO THIS
10	GROUP WITH SUGGESTIONS THAT MAYBE THIS TIER I GRANT
11	IS A LITTLE BIT OVERFUNDED, AND THEN YOU COULD GET
12	PERHAPS SUPPORT FROM THIS GROUP SAYING, HEY, THAT
13	TIER I GRANT, EVEN IF YOU THINK IT'S TOO HIGH, LET'S
14	KEEP IT IN TIER I, BUT WE THINK YOU OUGHT TO GO
15	AHEAD AND NEGOTIATE THAT BUDGET DOWNWARDS. I JUST
16	THINK YOU NEED MORE FLEXIBILITY THAN THIS PARTICULAR
17	PROCESS THAT HAS BEEN DESCRIBED TO US WILL ALLOW
18	YOU.
19	DR. FEIGAL: THAT'S FINE. I DO WANT TO
20	CLARIFY. WE DID HAVE DISCUSSIONS, NOT WITH THE
21	ENTIRE BOARD, BUT WITH THE SCIENCE SUBCOMMITTEE FOR
22	TWO TIMES BEFORE COMING HERE. SO WE HAVE HEARD A
23	LOT OF DIFFERENT TYPES OF SUGGESTIONS. AND THIS WAS
24	AN ATTEMPT TO TRY AND INCORPORATE THE SUGGESTIONS
25	THAT WE HEARD.
	167
	10/

1	CHAIRMAN THOMAS: I'LL JUST NOTE FOR THE
2	RECORD HERE THIS WHOLE DISCUSSION AROSE THROUGH A
3	POSTMORTEM THAT WAS HAD AT A DISEASE TEAM REVIEW
4	SESSION EARLIER IN THE YEAR WHERE THE MEMBERS OF THE
5	GRANTS WORKING GROUP, WHEN ASKED HOW CAN THINGS BE
6	IMPROVED, THE PROCESS TWEAKED TO MAKE IT BETTER,
7	TALKED ABOUT THE FACT THAT THE BUDGETARY
8	CONSIDERATIONS WERE SO OUT OF WHACK AND SOME OF
9	THESE THINGS, AS ELLEN SET FORTH, THESE EXAMPLES OF
10	THINGS THAT CAME UP NEEDED TO BE SOMEHOW FACTORED
11	IN. SO THIS IS SORT OF STRAIGHT FROM THE HORSE'S
12	MOUTH OF THE REVIEWERS THEMSELVES.
13	WHAT FORM THAT TAKES IS UP TO OUR
14	DISCRETION OBVIOUSLY, BUT THAT'S WHERE IT AROSE.
15	AND THERE'S EVEN A FAIRLY EXTREME PROPOSAL IN THERE
16	TO MIMIC THE IT'S THE STATE OF NEW YORK FUND, WAS
17	IT, THAT ACTUALLY HAS 30 PERCENT OF THE SCORING IS
18	BUDGETARY, WHICH WE DIDN'T WANT TO DO OBVIOUSLY.
19	BUT JUST TO GIVE YOU AN IDEA FOR HOW STRONGLY THE
20	OPINIONS WERE THAT YOU NEEDED TO HAVE BUDGETING
21	ALIGNED WITH THE SCIENCE TO MAKE THE WHOLE THING FIT
22	TOGETHER. SO MR. SHEEHY.
23	MR. SHEEHY: WELL, I HAVE TO SAY I'M NOT
24	REALLY SURE WHAT WE'RE VOTING ON RIGHT HERE BECAUSE
25	IT DOESN'T RESEMBLE MY UNDERSTANDING, AT LEAST THE

1	WAY IT'S BEEN DESCRIBED. WHAT I UNDERSTOOD COMING
2	IN IS THAT WHAT WE WERE THINKING ABOUT IS THAT WE
3	WOULD CREATE AN ADDITIONAL FIELD IN THEIR SCOREBOOK.
4	SO THEY WOULD ORIGINALLY PUT DOWN A SCIENCE SCORE.
5	THEY'D HEAR FROM BUDGETARY SPECIALISTS AND TAKE INTO
6	ACCOUNT BUDGETARY CONSIDERATION. FEASIBILITY HAS
7	ALWAYS BEEN AN ISSUE FOR THE REVIEW GROUP. SO IF
8	YOU CAN'T WRITE A BUDGET THAT REFLECTS THE SCIENCE
9	YOU'RE TRYING TO DO, THEN MOST PEOPLE DON'T THINK
10	YOU CAN DO THE SCIENCE.
11	SO IT WAS MORE ABOUT PEOPLE JUST IN A
12	WAY WE'VE BEEN GENEROUS WITH BUDGETS BECAUSE THE
13	FIELD NEEDED TO BE PUSHED FORWARD. MY UNDERSTANDING
14	ON WHAT I THOUGHT THE PROPOSAL WOULD BE IS THAT
15	FIRST YOU GET ENTERED A CLEAR SCIENTIFIC SCORE, AND
16	THEN THE REVIEWERS WOULD HEAR BUDGETARY
17	CONSIDERATIONS, AND THOSE BUDGETARY CONSIDERATIONS
18	THE REVIEWERS COULD EXPRESS AS A DEDUCTION FROM THE
19	SCIENTIFIC SCORE. BOTH SCORES COULD GO FORWARD. SO
20	IF YOU HAD A GRANT THAT WAS PULLED OUT OF FUNDING
21	BECAUSE OF OUT OF A FUNDABLE RANGE BECAUSE OF THE
22	BUDGET, THE REVIEW GROUP COULD STILL RECOMMEND FOR
23	FUNDING WITH THE CONDITION THAT THE BUDGET BE
24	CHANGED TO REFLECT THOSE BUDGETARY CONSIDERATIONS.
25	AND PART OF THIS WAS TO GIVE EVERYBODY A STICK TO

1	ENFORCE A GOOD BUDGET, GOOD BUDGETING, BECAUSE WE'RE
2	NOT GETTING GOOD BUDGETING. NOT EVERYBODY. IT'S IN
3	A FEW OUTLIERS.
4	THEN WHEN IT CAME FORWARD TO US, WE WOULD
5	ALSO GET TWO VERY DISTINCT POINTS OF REFERENCE SO
6	THAT WE WOULD KNOW. THIS WAS THE SCIENTIFIC SCORE.
7	THE INITIAL PROPOSAL THAT WAS BROUGHT TO US AT THE
8	SCIENCE SUBCOMMITTEE WAS THAT YOU WOULD BEFORE
9	YOU ASSIGNED YOUR SCIENTIFIC SCORE, YOU WOULD HAVE
10	THIS DISCUSSION ABOUT BUDGETS. IF YOU FELT IT
11	AFFECTED FEASIBILITY, YOU COULD DROP DOWN THE SCORE.
12	MY SENSE WAS THAT IF YOU HEARD SOMEBODY BASICALLY
13	TEARING APART AN APPLICATION BECAUSE THEY WERE
14	EGREGIOUS IN BUDGET, YOU WERE GOING TO BRING DOWN
15	THE SCORE ANYWAY, AND THERE WOULD BE NO WAY TO
16	CAPTURE IN ANY MEASURABLE WAY.
17	WHAT I WAS HOPING IS THAT WE WOULD HAVE A
18	PROPOSAL IN FRONT OF US THAT WOULD CLEARLY SEPARATE
19	THE TWO SO THAT WE WOULD GET A CLEAN SCIENCE SCORE
20	AND WE WOULD GET A FAIRLY NICE STICK IN ORDER TO
21	START THE SELF-POLICING WHICH I THINK WOULD COME
22	FAIRLY QUICKLY. BASICALLY THAT'S WHAT HAPPENS IN
23	NEW YORK IS THAT PEOPLE KNOW THAT THEY'RE GOING TO
24	BE HEAVILY PENALIZED FOR BAD BUDGETS, SO THEY REALLY
25	WORK HARD ON PROVIDING GOOD BUDGETS UP FRONT SO WE
	170

1	DON'T HAVE TO GO THROUGH THIS ALL THE TIME.
2	BUT I'M NOT SURE WHAT WE'RE VOTING ON
3	TODAY, AND I'M NOT REALLY SURE WHAT THE PROPOSAL IS,
4	AND I WOULD ALMOST RECOMMEND GOING BACK TO THE
5	SCIENCE SUBCOMMITTEE TILL WE HAVE SOMETHING THAT HAS
6	SOME MORE CLARITY.
7	DR. FEIGAL: CAN I ASK A QUESTION?
8	CHAIRMAN THOMAS: CERTAINLY.
9	DR. FEIGAL: SO IT SOUNDS, FROM WHAT I'M
10	HEARING, AND I THINK HEARING IT OVERWHELMINGLY, THAT
11	YOU DON'T WANT THINGS THAT AREN'T SCIENCE TO IMPACT
12	THE SCIENTIFIC SCORE. I THINK WE'RE PROBABLY ALL ON
13	THE SAME PAGE ABOUT THAT. SO WHAT I'M ASKING THE
14	QUESTION OF IS IT THE SEQUENCE? ARE YOU SUGGESTING
15	MAYBE THERE ONLY BE A DISCUSSION ABOUT THE SCIENCE
16	AND PEOPLE COME TO A SCORE AND THEN THERE'S A
17	DISCUSSION ABOUT BUDGET ISSUES? AND THE QUESTION IS
18	DO WE TRY AND QUANTITATE THAT, HOW EGREGIOUS OR
19	NONEGREGIOUS, OR DO PEOPLE JUST THINK THESE ARE
20	COMMENTS THAT GO BACK TO STAFF AND WE CAN WORK
21	THROUGH HOW TO CARRY THEM THROUGH?
22	WHAT I THOUGHT I HEARD ACTUALLY FROM SOME
23	MEMBERS OF THE SCIENCE SUBCOMMITTEE IS THAT THEY
24	ACTUALLY SUGGESTED TO US THAT WE FIND A WAY TO
25	QUANTITATE SOME OF THOSE ISSUES. AND THAT WAS THE
	171

1	REASON WHY THIS OTHER SCORE THAT GIL MENTIONED, THIS
2	OTHER COLUMN FOR THE BUDGET, WAS BROUGHT UP.
3	CHAIRMAN THOMAS: DR. PRICE HAS BEEN LONG
4	SUFFERING AND WAITING. THEN DR. STEWARD ONLY LESS
5	SO. AND THEN DR. BRYANT AND DR. VUORI.
6	DR. PRICE: I'M REALLY SKEPTICAL ABOUT THE
7	IDEA OF ADDING ANOTHER SCORE, HAVING THE GRANTS
8	WORKING GROUP PROVIDE A NUMBER WHICH SOMEHOW IS A
9	METRIC OF HOW OUT OF WHACK THE BUDGET IS WITH THE
10	PROJECT, AND THEN ADDING THAT UP, ADDING IT INTO THE
11	SCIENTIFIC SCORE TO COME OUT WITH SOME AVERAGE. I
12	THINK THAT JUST ADDS A DEGREE OF RANDOMNESS TO WHAT
13	IS ALREADY UNFORTUNATELY IT'S THE BEST PROCESS WE
14	HAVE, BUT THERE IS A DEGREE OF RANDOMNESS IN IT
15	ALREADY. THAT RANDOMNESS IS ABOUT PEOPLE WHO ARE
16	EXPERT IN WHAT THEY'RE REVIEWING.
17	NOW WE'RE TURNING TO PEOPLE TO MAKE
18	JUDGMENTS ABOUT FINANCIAL AND BUDGET ISSUES WHICH
19	THEY'RE NOT EXPERT ON. AND WHY ASSUME THEY HAVE A
20	COMMON STANDARD THAT A THREE DEDUCTION FROM ONE
21	PERSON IS THE EQUIVALENT TO A FIVE DEDUCTION FROM
22	ANOTHER? I HAVE NO CONFIDENCE IN THAT AT ALL. I
23	JUST THINK IT ADDS A DEGREE OF RANDOMNESS TO THE
24	PROCESS. I WOULD BE MUCH MORE COMFORTABLE WITH THE
25	REVIEW JUST FOCUSING ON DESIGN AND FEASIBILITY AFTER
	172
	

1	THE SCIENTIFIC SCORES ARE IN, A MESSAGE GOES OUT TO
2	CIRM SAYING WE HAVE QUESTIONS ABOUT WHETHER THIS
3	BUDGET WHETHER THIS PROJECT IS FEASIBLE GIVEN THE
4	BUDGET THAT'S BEEN PRESENTED. AND THEN THE
5	MANAGEMENT CAN INFORM THE BOARD ABOUT THIS WHEN WE
6	COME TO MAKE OUR ACTUAL DECISION ABOUT WHETHER WE'RE
7	GOING TO FUND SOMETHING OR NOT.
8	DR. STEWARD: SO JUST FOR THE NEW PEOPLE
9	ON THE BOARD, I'M THE ONLY ONE ON THE GRANTS WORKING
10	GROUP WHO BOTH LISTENS TO THAT AND I'M ALSO AN NIH
11	GRANTEE AND ALSO REVIEW NIH GRANTS. SO I SAY THAT
12	JUST SO YOU KNOW. AND THE REASON THAT I AM ON THAT
13	GRANTS WORKING GROUP IS BECAUSE I'M ON THIS BOARD AS
14	A PATIENT ADVOCATE.
15	SO WHAT JEFF SAID IS ABSOLUTELY TRUE. LET
16	ME SEE IF I CAN PUT THIS IN PERSPECTIVE. IT ISN'T
17	JUST THAT THERE IS A SCIENTIFIC REVIEW AND THE
18	REVIEWERS ARE SAYING THE BUDGETS ARE RIDICULOUS.
19	THEY DO SAY THAT, BY THE WAY. WHAT THEY ARE TELLING
20	US IS THAT THE WORK IS NOT WELL-PLANNED, THAT THE
21	BUDGETS THAT ARE PROPOSED ARE NOT CAREFULLY DESIGNED
22	IN RELATION TO THE PROJECT. THAT'S WHAT THEY'RE
23	TELLING US.
24	WHAT'S HAPPENING IS THE SCIENCE IS
25	DEFINED, THERE'S NO JUSTIFICATION OF THE BUDGET AT

_ 1	
1	ALL. IF THE LIMIT OF THE GRANT IS \$20 MILLION, IT'S
2	\$20 MILLION OR \$19,999,000. AND THERE'S BEEN A GOOD
3	DEAL OF FRUSTRATION AMONGST THE SCIENTIFIC MEMBERS
4	OF THE GRANTS WORKING GROUP BECAUSE THAT INDICATES
5	POOR PLANNING OF THE SCIENCE.
6	SO THEY'RE ASKED TO REVIEW THE SCIENCE,
7	BUT KIND OF IGNORE THIS OTHER ASPECT OF THE PLANNING
8	THAT WE ALL WOULD NORMALLY HAVE TO DO. I THINK THIS
9	IS WHAT WE'RE DEALING WITH HERE, HOW TO CAPTURE
10	THAT. AND I THINK THERE'S SEVERAL SUGGESTIONS THAT
11	YOU GUYS HAVE MADE AND WE DISCUSSED IN THE SCIENCE
12	SUBCOMMITTEE, AND I DON'T HAVE AN ANSWER TO WHAT'S
13	THE RIGHT ONE EITHER. THIS SEEMS AS REASONABLE AN
14	ANSWER AS ANY. BUT THAT'S THE FRUSTRATION OF THE
15	GRANTS WORKING GROUP MEMBERS. THIS IS A PART OF THE
16	SCIENTIFIC JUDGMENT, BUT THEY CAN'T CONSIDER IT.
17	OKAY.
18	CHAIRMAN THOMAS: THANK YOU, DR. STEWARD.
19	WE HAVE DR. BRYANT, DR. VUORI, DR. ECONOMOU, DR.
20	MELMED HAS HIS HAND UP.
21	MS. SAMUELSON: I'VE BEEN WAITING FOR A
22	WHILE.
23	CHAIRMAN THOMAS: I FORGOT. JOAN WAS
24	ACTUALLY AFTER DR. PRICE.
25	MS. SAMUELSON: WELL, FOLLOWING ON WHAT OS
	174
	174

SAID, THIS IS A REAL-LIFE SCENARIO THAT I THINK
SUGGESTS THAT PARKINSON'S WILL BE ONE DISEASE THAT
WOULD BE PREJUDICED BY THIS. IT'S A NEW FIELD AND
SCIENTISTS WHO ARE TRYING TO EVALUATE THE PROJECT
COST WHEN IT HASN'T BEEN DONE BEFORE. AND IT TURNS
OUT THAT TO DO THE EVALUATION OF SURGERIES TO TEST
THE EFFICACY OF A CELL TRANSPLANT, FOR EXAMPLE, NOT
ONLY REQUIRES THAT YOU GET IMAGING EQUIPMENT, BUT
YOU ACTUALLY HAVE TO DESIGN IT AND DO HARDWARE AND
SOFTWARE THAT'S FOR A MONKEY THAT IS UNIQUELY
SIMILAR TO THE HUMAN, BUT THAT THERE NEVER HAS BEEN
SOFTWARE DESIGNED FOR. THAT'S GOING TO BE A MUCH
MORE EXPENSIVE ITEM THAN JUST STUFF OFF THE SHELF.
AND I'VE SEEN BUDGETS RIDICULED WHEN IT
WAS THIS SORT OF NEW FRONTIER PROJECT THAT DIDN'T
HAVE A LOT OF EXPERIENCE IN THE FIELD. AND THEY
WERE DOING THEIR BEST. IT WASN'T THAT THEY HAD
INCAPACITY TO EVALUATE FEASIBILITY. IT'S
EVERYBODY'S GUESS. THANK YOU.
DR. BRYANT: OKAY. I HAVE A SUGGESTION.
I DON'T KNOW IF THIS WILL WORK, BUT DON'T TRY FOR A
COMBINED SCORE. SO GET THE SCIENTIFIC SCORE SO ALL
THE ONES THAT ARE SCIENTIFICALLY CONSIDERED
EXCELLENT AND FEASIBLE, NOT CONSIDERING THE BUDGET,
GIVE THEM THAT SCORE, BUT THEN AMONG THOSE GIVE A
175

1	PERCENTAGE AS TO HOW MUCH FUNDING YOU THINK WOULD BE
2	WORTH THIS COULD BE DONE FOR. SO IF IT'S AN
3	ON-TARGET GRANT, IT GETS A HUNDRED PERCENT. IF IT'S
4	A VERY INFLATED GRANT, IT WOULD GET 50 PERCENT. AND
5	THEN THAT MIGHT BEGIN TO INFLUENCE THE DECISION
6	ABOUT WHETHER TO FUND IT OR NOT BECAUSE THAT WOULD
7	INCORPORATE THE IDEA THAT OS MENTIONED, THAT IT'S A
8	SIGN OF NOT HAVING A REALISTIC SENSE HOW TO DO THE
9	SCIENCE IF IT'S SO FAR OFF. BUT IF IT'S BETWEEN 50
10	AND A HUNDRED, YOU COULD NEGOTIATE DOWNWARDS AND
11	STILL GET A REASONABLE PRODUCT FROM THAT PROPOSAL.
12	DR. STEWARD: J.T., WHEN YOU HAVE A CHANCE
13	AGAIN ME DOWN HERE.
14	CHAIRMAN THOMAS: DID WE LOSE DR. VUORI?
15	WE DID. OKAY. DR. ECONOMOU.
16	DR. ECONOMOU: SO THERE'S THIS CURIOUS
17	OBSERVATION THAT WHENEVER THERE'S A DEFINED UPPER
18	LIMIT TO A FUNDING LEVEL, THAT THE BUDGETS THAT COME
19	IN ARE WITHIN ONE TO TWO PERCENTAGE POINTS OF THAT
20	MAXIMUM LIMIT. SO I'M ASSUMING, OF COURSE, THAT
21	THERE'S A RIGOROUS PREREVIEW BY STAFF OF THE BUDGET
22	SO THAT IT'S SCALED APPROPRIATELY TO THE PROJECT. I
23	SHOULD KNOW THE ANSWER TO THIS. HOW DO YOU GO BACK
24	AND AUDIT THEN? HOW DO YOU GO BACK AND THEN AUDIT
25	GRANTS THAT HAVE BEEN EXPENDED TO MAKE CERTAIN THAT
	176
	176

1	THEY SPENT IT ON WHAT THEY SAID THEY WOULD?
2	WE HAVE AUDITS ALL THE TIME ON OUR CAMPUS
3	TO MAKE CERTAIN THAT WE'RE NOT BUYING WE'RE NOT
4	SPENDING THE MONEY ON SOMETHING THAT WE SHOULDN'T BE
5	SPENDING IT ON.
6	DR. SAMBRANO: I THINK THERE'S A COUPLE OF
7	WAYS. ONE OF THEM HAS ALREADY BEEN MENTIONED
8	SEVERAL TIMES, WHICH IS THE CDAP PROCESS BY WHICH
9	THERE ARE CLEAR MILESTONES THAT ARE TIED TO
10	BUDGETARY AMOUNTS. ASSUMING THAT THEY HAVE A
11	JUSTIFIED BUDGET TO REACH THAT MILESTONE, THERE IS
12	AN ONGOING PROCESS TO ASSESS THAT. NOW, THERE'S
13	ALSO A COMPLIANCE COMPONENT THAT CIRM ENGAGES IN,
14	BUT IT'S NOT DONE WITH EVERY SINGLE GRANT
15	APPLICATION. WE DO THAT KIND OF ON AN AD HOC.
16	SINCE WE CAN'T CHECK EVERY SINGLE ONE, WE HAVE A
17	COMPLIANCE OFFICER AND OUR FINANCE OFFICER THAT
18	VISITS THE INSTITUTION, AND THEY IDENTIFY SPECIFIC
19	GRANT APPLICATION GRANTS AND THEY WILL GO OVER
20	THE EXPENDITURES AND BUDGETS TO ENSURE THAT THEY ARE
21	APPROPRIATE. BUT THAT CAN ONLY BE DONE WITH A FEW
22	AND SELECT ONES.
23	CHAIRMAN THOMAS: I THINK DR. MELMED, THEN
24	DR. FIRESTEIN.
25	DR. FIRESTEIN: THANKS. SO I ADMIRE THE
	177
	177

1	DESIRE TO INCENTIVIZE PEOPLE TO PROVIDE EXCELLENT
2	BUDGETS. THIS IS NOT A PROBLEM THAT IS UNIQUE TO
3	THIS PARTICULAR FUNDING MECHANISM. BUT ALTHOUGH I'M
4	SORT OF AT THE TAIL END OF THIS DISCUSSION, OR AT
5	LEAST I HOPE I AM, I AGREE WITH CLAIRE, WHAT CLAIRE
6	HAD SAID EARLIER ABOUT MAKING SURE THAT AT LEAST WE
7	ARE SIMILAR IN SPIRIT TO WHAT HAPPENS AT THE NIH.
8	WE ARE NOT OBLIGATED TO DO WHAT THEY DO, BUT THEY
9	HAVE BEEN DEALING WITH BUDGETS IN THE TENS OF
10	MILLIONS OF DOLLARS EVEN FOR INDIVIDUAL PROJECTS OR
11	FOR U AWARDS FOR MANY YEARS.
12	AND I THINK THAT IT IS CRITICAL TO HAVE A
13	PRISTINE SCIENTIFIC SCORE. AND THEN, OF COURSE, IF
14	THE BUDGET IS ENTIRELY OUT OF WHACK, AS WAS
15	MENTIONED EARLIER, THAT IS PART OF THE SCIENTIFIC
16	REVIEW WHERE SOMEONE CLEARLY DOESN'T KNOW WHAT IT
17	TAKES TO DO A PROJECT, AND THEY PROBABLY CAN'T DO
18	THE PROJECT ANYWAY. BUT THE POINT IS THAT THEN A
19	POST HOC REVIEW OF THE BUDGET OR IN SOME CASES EVEN
20	A PRE-HOC REVIEW OF THE BUDGET CAN BE PERFORMED TO
21	MAKE SURE IT'S IN LINE. THE NIH DOES THIS ALL THE
22	TIME WITH PROGRAM PROJECT GRANTS. THEY DO IT ALL
23	THE TIME WITH CONTRACTS, FOR EXAMPLE, WHERE THE
24	PROTOCOLS ARE PRESPECIFIED, AND YOU PRENEGOTIATE
25	WITH THE FUNDING AGENCY ON A BUDGET THAT AT LEAST

1	FITS WHAT THEY ANTICIPATE IT TO COST WITHIN THAT
2	PROPOSAL.
3	SO MY SUGGESTION IS THAT WE CONTINUE TO
4	FOCUS PRIMARILY ON THE SCIENCE, THAT A SEPARATE
5	DECISION BE MADE ON THE BUDGET. I COMPLETELY AGREE
6	WITH I FORGOT WHO SAID THAT ASSIGNING A SCORE OF
7	MINUS ONE FOR HAVING ONE TOO MANY TECHNICIANS OR
8	MINUS FIVE FOR HAVING TOO MANY PATIENTS ENROLLED, I
9	DON'T EVEN KNOW HOW A SCIENTIFIC REVIEW COMMITTEE
10	WOULD MAKE THAT ASSESSMENT, AND I THINK IT WOULD
11	ONLY END UP MUDDYING THE PICTURE FOR A CRITICAL
12	REVIEW OF WHAT THE BUDGET SHOULD ACTUALLY LOOK LIKE.
13	AND THE NIH CONSTANTLY DOWN-NEGOTIATES AND WORKS
14	WITH YOU ON THE BUDGET FOR ANYTHING THAT'S RELATED
15	TO A CLINICAL TRIAL.
16	CHAIRMAN THOMAS: DR. STEWARD WAS NEXT.
17	DR. STEWARD: I ACTUALLY AM JUST GOING TO
18	TRY TO GO BACK TO WHAT JEFF SAID. I THINK THAT THIS
19	HAS BEEN A REALLY GREAT DISCUSSION AND A LOT OF
20	IDEAS, BUT I THINK THAT PROBABLY, RATHER THAN TRYING
21	TO REWRITE ANYTHING RIGHT NOW, WE SHOULD SEND THIS
22	BACK TO THE SCIENCE SUBCOMMITTEE AND HAVE MORE
23	DISCUSSIONS, MAYBE HAVE MORE INPUT FROM THE BOARD
24	WITH SPECIFIC IDEAS, AND THEN TRY TO COME BACK
25	THE SCIENCE SUBCOMMITTEE TRY TO COME BACK AT THE
	179

1	NEXT BOARD MEETING WITH SOMETHING THAT WOULD BE MORE
2	IN LINE OR PERHAPS IN LINE WITH WHAT EVERYONE HAS
3	SAID RATHER THAN TRYING TO REWRITE IT RIGHT NOW. I
4	MAKE THAT MOTION.
5	CHAIRMAN THOMAS: I SEE A LOT OF HEAD
6	NODDING IN THE AFFIRMATIVE AROUND THE HORSESHOE.
7	DR. JUELSGAARD: I SECOND THAT MOTION.
8	CHAIRMAN THOMAS: IT'S BEEN MOVED AND
9	SECONDED. ANY FURTHER IS THAT SOMETHING THAT
10	REQUIRES A MOTION, JAMES?
11	MR. HARRISON: NO, BUT ONE IS ON THE
12	TABLE, SO WE MIGHT AS WELL VOTE ON IT.
13	DR. FEIGAL: MAYBE AFTER YOU VOTE, I'D
14	STILL LIKE TO POSE A QUESTION TO YOU BECAUSE I THINK
15	WE HAVE A BROADER ISSUE WE'RE TRYING TO ADDRESS. IT
16	WOULD BE NICE TO TRY AND MAYBE CLARIFY THAT FOR YOU.
17	MS. LANSING: CAN YOU RESTATE THE MOTION
18	JUST FOR THOSE OF US ON THE PHONE?
19	MR. HARRISON: THE MOTION IS TO REFER
20	CONSIDERATION OF BUDGET REVIEW OF THE CIRM
21	APPLICATIONS BACK TO THE SCIENCE SUBCOMMITTEE FOR
22	FURTHER EVALUATION.
23	CHAIRMAN THOMAS: MR. SHEEHY.
24	MR. SHEEHY: I ACTUALLY THINK I AGREE THAT
25	WE SHOULD FINALIZE THIS POLICY THROUGH ANOTHER
	180

1	SUBCOMMITTEE MEETING. BUT I ACTUALLY THINK WE HAVE
2	THE OUTLINES OF WHAT WE WANT TO ACCOMPLISH. I THINK
3	THE BROAD CONTOURS OF WHAT SHOULD BE THE POLICY
4	SHOULD BE A CLEAN SCIENCE SCORE, A SEPARATE
5	DISCUSSION OF THE BUDGET, SPECIFIC ITEMS NOTED THAT
6	ARE OUT OF WHACK. I THINK EITHER PERCENTAGE OF
7	AWARD OR SPECIFIC DOLLAR AMOUNTS PUT FORWARD AS
8	RECOMMENDATIONS FROM THE COMMITTEE PER GRANT. SO IF
9	YOU THINK THE BUDGET, THEY HAVE TOO MANY TECHS OR
10	THEY ENROLLED TOO MANY PATIENTS, YOU SAY I'M GOING
11	TO TAKE THAT'S 10 PERCENT OF YOUR AWARD OR IT'S
12	\$2 MILLION, AND WE APPROVE THIS AWARD UP TO 90
13	PERCENT OF YOUR, 80 PERCENT OF YOUR AWARD, OR WE
14	APPROVE THIS AWARD UP TO 18 MILLION INSTEAD OF 20
15	MILLION, BUT THAT WE THEN EXPRESS THIS NOT
16	NUMERICALLY, BUT AS A PERCENTAGE OR AN ACTUAL
17	MONETARY AMOUNT OF THE REQUEST FOR BUDGET, AND WE
18	ACTUALLY IDENTIFY THE ITEMS THAT ARE EXCESSIVE OR
19	EXCISED. TO ME THAT SOUNDS LIKE THE CONTOURS OF
20	SOMETHING THAT WOULD BE WORKABLE. THEN YOU HAVE THE
21	COLLECTIVE WISDOM OF THE WORKING GROUP BECAUSE I GET
22	YOUR POINT, THAT YOU HAVE
23	DR. PRICE: WHY AREN'T WE MAKING THAT
24	DECISION? WHY IS THE GRANTS WORKING GROUP MAKING
25	THAT DECISION? THE STAFF CAN BRING THAT ANALYSIS OF
	101
	181

1	THE BUDGET TO US AND SAY THIS IS IN TIER I, BUT IT'S
2	NOT FEASIBLE GIVEN THE BUDGET, AND WE CAN DECIDE
3	WHAT TO DO WITH IT.
4	MR. SHEEHY: DR. PRICE, ONE POINT IS THAT
5	WE DO HAVE A RATHER LIMITED STAFF UNLESS WE WERE TO
6	BRING ON A COUPLE OF REAL BUDGET EXPERTS. WE SAW
7	THIS THEY'LL BRING IN BUDGET SPECIALISTS. PLUS
8	YOU NEED SCIENTISTS WHO ARE ACTUALLY WORKING IN THE
9	LAB. WE HAVE HAD SOME DIALOGUES ON BUDGET. AND
10	MATT PLUNKETT INTRODUCED SOME BUDGET CONSIDERATIONS,
11	AND WE IMMEDIATELY HAD PUSHBACK FROM SOME OF THE
12	WORKING GROUP MEMBERS THAT HE WAS WRONG ON HIS
13	ESTIMATIONS. THEY ACTUALLY SAID HIS THOUGHT OF
14	OVERAGES WERE ACTUALLY UNDERAGES, THAT HE DIDN'T
15	REALLY HAVE A GOOD SENSE OF WHAT THE COSTS WERE.
16	YOU REALLY NEED A DIVERSITY OF OPINION ON
17	COST, AND YOU NEED TO HAVE IT FROM PEOPLE WHO ARE
18	ACTUALLY WORKING IN THE SCIENCE BECAUSE ONE OF THE
19	THINGS IS, REMEMBER THE BREADTH OF SCIENCE WE COVER,
20	ANYTHING FROM SMALL MOLECULES TO AUTOLOGOUS
21	GENE-MODIFIED CELLS, EMBRYONIC STEM CELLS, TO THIS
22	TO THAT TO THAT. IT'S VERY HARD TO CAPTURE EITHER
23	SCIENTIFICALLY OR IN TERMS OF BUDGET THAT EXPERTISE.
24	THE STAFF HAS DONE A GREAT JOB IN ALMOST EVERY
25	INSTANCE OF BRINGING IN OUTSIDE EXPERTS NO MATTER
	182

1	WHAT THE ISSUE IS.
2	CHAIRMAN THOMAS: THE QUESTION HAS
3	ACTUALLY BEEN CALLED HERE. ELLEN, DO YOU NEED TO
4	RESPOND BEFORE WE TAKE A VOTE?
5	DR. FEIGAL: YOU CAN TAKE A VOTE AND THEN
6	I CAN MAKE A COMMENT.
7	CHAIRMAN THOMAS: OKAY. I ASSUME THIS IS
8	ANOTHER VOICE. ALL THOSE IN FAVOR PLEASE SAY AYE.
9	OPPOSED? ABSTENTIONS? OKAY. MOTION PASSES.
10	DR. FEIGAL: THE POINT I WAS TRYING TO GET
11	ACROSS, IT COULD BE THE STAFF. WE DO HAVE PEOPLE
12	WITH EXPERTISE IN BUSINESS AND KNOW WHAT COSTS ARE,
13	OR WE HAVE BROAD CONNECTIONS WHERE WE CAN BRING THAT
14	EXPERTISE IN. BUT RIGHT NOW THERE'S A FEELING THAT
15	THERE'S NOT THE EMPOWERMENT TO ACTUALLY BRING THOSE
16	ISSUES TO THE TABLE AND TO TRY AND IMPLEMENT IT.
17	DOES IT HAVE TO BE DONE AT THE GRANT
18	REVIEW GROUP? NO, BUT IT NEEDS TO BE DONE
19	SOMEWHERE. AND SO THIS WAS A SUGGESTION. IT'S BEEN
20	BROUGHT UP AT THE GRANT REVIEW GROUP THAT THERE'S
21	NOT ENOUGH ATTENTION ON THE BUDGETS THAT THEY'RE
22	LOOKING AT. SOMETIMES I THINK I'VE SHARED WITH YOU
23	THAT IT LOOKS LIKE PEOPLE HAVE DIVIDED BY FOUR TO
24	ARRIVE AT VERY COMPLICATED BUDGETS AS OPPOSED TO
25	DOING IT BASED UPON THE ACTIVITIES THEY REALLY NEED

1	TO ACCOMPLISH.
2	SO WE'RE JUST SAYING THAT THERE IS AN
3	ISSUE. WE'RE TRYING TO THINK OF WAYS TO ADDRESS IT.
4	WHETHER OR NOT IT IMPACTS ON A SCIENTIFIC SCORE, I
5	THINK WE'RE IN AGREEMENT IT SHOULDN'T UNLESS IT
6	MAKES DOING THE PROJECT COMPLETELY INFEASIBLE. I
7	THINK WE'RE ALL IN AGREEMENT ON THAT. WE'RE JUST
8	TRYING TO FIND A PROCESS, WHETHER IT'S STAFF,
9	WHETHER IT'S PULLING IN THE SPECIALISTS. WE'RE
10	HAPPY TO ENTERTAIN THOSE POSSIBILITIES. BUT WHAT WE
11	WOULD LIKE FROM YOU IS THE EMPOWERMENT TO ACTUALLY
12	START WORKING ON THE SOLUTION. IF YOU'D LIKE US TO
13	GO BACK TO SCIENCE SUBCOMMITTEE FOR A THIRD TIME, WE
14	CAN DO THAT. WHAT WE WANT TO DO AT THE END OF THE
15	DAY, I THINK WE'VE HEARD WHAT YOUR SUGGESTIONS ARE.
16	AND IF YOUR MAIN SUGGESTION IS WE DON'T WANT IT TO
17	IMPACT ON THE SCIENTIFIC SCORE, YOU CAN ALSO SUGGEST
18	THAT YOU PUT IT BACK TO US TO COME UP WITH A
19	SOLUTION THAT DOES NOT IMPACT ON THE SCIENTIFIC
20	SCORE AND LET US TRY AND IMPLEMENT THAT. IT'S JUST
21	A SUGGESTION.
22	CHAIRMAN THOMAS: THE WISHES OF THE BOARD
23	ARE TO GO BACK TO SCIENCE SUBCOMMITTEE IN WHICH THAT
24	INPUT WILL MOST DEFINITELY BE GIVEN AND DISCUSSED.
25	BUT I THANK EVERYBODY ON THE BOARD. THIS IS A VERY
	184
	1 ±0 1

1	IMPORTANT ITEM. I THINK THE DISCUSSION HAS BEEN
2	VERY ROBUST AND LOTS OF GOOD VIEWS ON THE TABLE, AND
3	WE'LL LEAVE IT UP TO MR. SHEEHY AND DR. STEWARD TO
4	SET UP THE SCIENCE SUBCOMMITTEE FOR FURTHER
5	DISCUSSION TOWARDS THE END OF GETTING FINAL
6	RESOLUTION ON THIS IMPORTANT TOPIC AT THE DECEMBER
7	BOARD MEETING.
8	OKAY. NEXT ITEM IS ITEM 11. WE'RE COMING
9	DOWN THE HOME STRETCH HERE, FOLKS, FOR YOU GIANTS
10	FANS. CONSIDERATION OF CREATION OF A DISCRETIONARY
11	FUND FOR SUPPLEMENTS TO EXISTING GRANTS. DR.
12	TROUNSON.
13	DR. TROUNSON: THANK YOU VERY MUCH, CHAIR.
14	DIDN'T KNOW I'D GET THERE. SO ITEM NO. 11, REALLY I
15	DON'T HAVE A POWERPOINT, SO YOU'VE GOT THAT IN YOUR
16	DOCUMENTS UNDER ITEM 11.
17	WHAT WE'RE SEEKING HERE IS THE OPPORTUNITY
18	THAT ARISES OCCASIONALLY THAT PRESENTS WITH A UNIQUE
19	OPPORTUNITY TO TURN A GRANTED STUDY, ONE WE'VE
20	ALREADY GRANTED, INTO A VERY MAJOR DEVELOPMENT IN
21	SCIENCE OR OPPORTUNITY IN TRANSLATIONAL MEDICINE.
22	WHILE THESE ARE RARE MOMENTS, THEY DO ARISE. AND AT
23	PRESENT WE CAN ONLY ADVISE GRANTEES TO REAPPLY FOR
24	THE NEXT APPROPRIATE RFA, OFTEN A YEAR OR MORE
25	BEFORE THEY CAN EXPECT ANY SUPPORT.

1	THE CAPACITY TO CONSIDER AN EXCEPTIONAL
2	PROPOSAL THAT ARISES DURING A PERIOD OF A FUNDED
3	PROJECT IN WHICH ADDITIONAL FUNDING WOULD BE ONGOING
4	CIRM-FUNDED PROJECT TO ACHIEVE A VERY SIGNIFICANT
5	TRANSFORMATIONAL OR TRANSLATIONAL RESULT WOULD BE
6	IMPORTANT FOR CIRM'S MISSION. THESE SUPPLEMENTS
7	WOULD BE CAREFULLY CONSIDERED, RARE AS EVENTS, AND
8	LIMITED IN SCOPE AND SIZE.
9	SO WE'RE PROPOSING TWO TYPES OF
10	OPPORTUNITIES HERE. ONE I'VE JUST NOMINATED AS
11	LEVEL ONE WHICH ARE MINOR SUPPLEMENTS IN MY MIND,
12	WHICH IS A MODEST TIME-DEPENDENT SUPPLEMENT
13	AUTHORIZED ADMINISTRATIVELY THROUGH A PRIOR APPROVAL
14	REQUEST. MAXIMUM INCREASE WOULD BE THE LESSER OF 10
15	PERCENT OF THE ORIGINAL AWARD OR UP TO 500,000.
16	THEY WOULD ONLY BE AWARDED ONCE DURING THE LIFETIME
17	OF A SPECIFIC AWARD. THEY MAY NOT BE REQUESTED
18	UNTIL AFTER THE PROJECT HAS COMPLETED THE FIRST YEAR
19	AND MAKING SATISFACTORY PROGRESS. THEY WOULD ONLY
20	BE AVAILABLE IF THE SUPPLEMENT WILL ALLOW THE
21	GRANTEE TO PURSUE A CRITICAL RESEARCH STUDY BASED ON
22	VERY EXCITING NEW APPROACH RESEARCH RESULTS THAT
23	ELEVATE THE SIGNIFICANCE OF THE PROJECT
24	SUBSTANTIALLY OR ALLOW THE GRANTEE TO MAKE USE OF
25	SPECIALIZED RESOURCES NOT AVAILABLE WHEN THE PROJECT
	186

1	BEGAN.
2	THE PRESIDENT WOULD SEEK ADVICE FROM TWO
3	MEMBERS OF THE GRANTS WORKING GROUP, THE PROGRAM
4	OFFICER ON THE AWARD, AND SENIOR MANAGEMENT IN
5	MAKING A DECISION TO AGREE OR DENY THE SUPPLEMENT.
6	AND THE RECOMMENDATIONS FOR A MINOR SUPPLEMENT WOULD
7	BE REPORTED TO THE BOARD AT THE NEXT AVAILABLE BOARD
8	MEETING. TOTAL FUNDS TO BE AWARDED AS SUPPLEMENTARY
9	FUNDS LIMITED TO FOUR MILLION OR BOARD REPLENISHMENT
10	BY REQUEST.
11	NOW, IN TERMS OF A POSSIBLE EXAMPLE, YOU
12	MAY BE WONDERING, AND THEY COME VERY OCCASIONALLY,
13	BUT I CAN GIVE YOU AN EXAMPLE. I'LL NOT TELL YOU
14	WHETHER THIS WOULD REALLY BE AWARDED OR NOT BECAUSE
15	I'VE NEVER EXPLORED IT WITH ANYBODY ON THE GRANTS
16	WORKING GROUP. BUT A REQUEST CAME TO ME, WHICH I
17	HAVEN'T BEEN ABLE TO RESPOND TO, WHERE THE
18	UNIVERSITY WAS PROVIDED WITH 24 MONKEYS THAT HAD
19	PARKINSON'S DISEASE. THESE ANIMALS WERE IN SOME
20	STUDY SOMEWHERE AND THEY WERE DONATED TO THE
21	UNIVERSITY.
22	NOW, THE RESEARCH GROUP THAT HAS A
23	TRANSLATIONAL PROJECT WITH US ASKED IF IT WAS
24	POSSIBLE FOR US TO CONSIDER THIS SUDDEN OPPORTUNITY,
25	THAT THEY COULD USE THE CELLS THAT THEY WERE

187

1	DEVELOPING IN A SMALL STUDY TO SEE WHETHER THIS
2	COULD BE REALLY RELEVANT TO PARKINSON'S DISEASE.
3	THEY'RE DEVELOPING THESE CELLS WITH A VIEW OF
4	APPLYING THEM TO PARKINSON'S DISEASE AND THEY'RE
5	WORKING ON RODENTS AND REALLY HADN'T THOUGHT THAT
6	THE MONKEY OR THE PRIMATE WAS REALLY AVAILABLE IN
7	THIS REGARD.
8	AND IF IT WAS SUCCESSFUL, COULD THEY COME
9	BACK TO US AND SAY COULD THEY IN A SECOND YEAR DO A
10	MORE SUBSTANTIVE STUDY. THESE FUNDS WOULD BE
11	LIMITED IN THAT REGARD TO \$500,000, WHICH WOULD
12	CLEARLY BE POSSIBLE IN THIS PARTICULAR INSTANCE.
13	NOW, I HAVEN'T BEEN ABLE TO REPLY TO THOSE
14	SCIENTISTS. THEY'RE HIGHLY REGARDED PEOPLE. I
15	ACTUALLY THINK A LOT ABOUT THEIR PARTICULAR STUDY,
16	BUT I'M NOT TRYING TO MAKE A JUDGMENT ON WHETHER
17	THIS SHOULD BE SUPPORTED, BUT GIVING YOU AS AN
18	EXAMPLE.
19	OCCASIONALLY I HEAR OTHER OPPORTUNITIES
20	FOR WHICH WE'VE HAD TO PASS BY ESSENTIALLY BECAUSE
21	WE'VE HAD NO SUPPLEMENT.
22	THE SECOND LEVEL WAS MAJOR SUPPLEMENTS.
23	THESE MAY BE EXCEPTIONAL THERE MAY BE EXCEPTIONAL
24	CIRCUMSTANCES IN SUPPLEMENTARY FUNDING THAT WILL
25	ALLOW A CURRENT CIRM PROJECT TO ACHIEVE
	188

1	TRANSFORMATIONAL RESULTS THAT WOULD CHANGE THE FIELD
2	OF STEM CELL RESEARCH OR ESTABLISH PROOF OF CONCEPT
3	FOR A NEW THERAPY. THE MAXIMUM INCREASE, IT WOULD
4	BE THE LESSER OF 50 PERCENT OF THE ORIGINAL AWARD OR
5	AN AMOUNT UP TO \$3 MILLION. SO THIS WOULD BE A
6	LARGER AWARD. THE GRANTEE MAY NOT SUBMIT A REQUEST
7	UNTIL THE PROJECT HAD COMPLETED THE FIRST YEAR AND
8	MAKING SATISFACTORY PROGRESS. THE GRANTEE WOULD
9	SUBMIT A BRIEF PROPOSAL. THE PRESIDENT, FOLLOWING
10	DISCUSSIONS WITH THE PROGRAM OFFICER ON THE AWARD
11	AND SENIOR MANAGEMENT, WOULD HAVE THE SOLE
12	DISCRETION TO DECIDE WHETHER A FULL APPLICATION
13	WOULD BE PERMITTED. AND A FULLY DOCUMENTED
14	APPLICATION WOULD BE REVIEWED BY CDAP FOR AN
15	FDA-MANDATED SUPPLEMENT. SO IF THAT WAS MANDATED BY
16	THE FDA, WE'D ASK THE CDAP GROUP TO GIVE US ADVICE
17	ON THAT. OR AN SP AWARD OR A FULL GRANTS WORKING
18	GROUP RECOMMENDATION FOR OTHER SUPPLEMENTS AND A
19	FINAL DECISION BY THE ICOC FOR A MAXIMUM OF \$12
20	MILLION IN THIS PARTICULAR AREA. NOW, WE'RE LIKELY
21	TO SEE SOME OF THESE COMING FORWARD.
22	SO MY RECOMMENDATION IS THERE ARE TWO
23	RECOMMENDATIONS. ONE, THAT THE ICOC ENDORSE A PRIOR
24	APPROVAL REQUEST FOR MINOR SUPPLEMENTS BY THE
25	PRESIDENT TO AWARDED GRANTEES TO MAKE AN EXCEPTIONAL

1	IN SCIENCE OR TECHNOLOGY AS RECOMMENDED IN THE
2	CONCEPT PROPOSAL THAT ARE DESCRIBED AND ALLOCATED A
3	FUND OF \$4 MILLION FOR THAT.
4	SECONDLY, THAT THE ICOC SUPPORT THE
5	PROCESS BY WHICH A MAJOR SUPPLEMENT COULD BE AWARDED
6	TO A CURRENT GRANTEE TO ENHANCE THE PROBABILITY OF
7	CONVERSION OF A FUNDED PROJECT TO UNEXPECTED
8	TRANSFORMATIONAL BENEFITS AND RAISE TRANSLATIONAL
9	PROJECTS TO A HIGH PROBABILITY OF CLINICAL BENEFIT.
10	AND THE ALLOCATED FUND THERE WOULD BE AT THE LEVEL
11	OF \$12 MILLION.
12	CHAIRMAN THOMAS: QUESTIONS FOR DR.
13	TROUNSON?
14	DR. BRYANT: I HAVE A COMMENT. THE
15	MAXIMUM AMOUNTS THAT YOU COULD GIVE TO EACH AWARDEE
16	ARE HUGE AMOUNTS OF MONEY, 500,000 IN THE ONE CASE,
17	AND SEVERAL MILLION IN THE OTHER.
18	DR. TROUNSON: 10 PERCENT OF THE GRANT.
19	DR. BRYANT: TO HAVE THAT WITHOUT PEER
20	REVIEW SEEMS TO ME TO BE UNUSUAL. I CAN'T IMAGINE.
21	IS THERE ANY OTHER AGENCY THAT WOULD GIVE OUT THAT
22	KIND OF MONEY WITHOUT PEER REVIEW?
23	DR. TROUNSON: WHAT WE'RE SAYING IS THAT
24	WE WOULD TAKE ADVICE IN THE CASE OF A MINOR
25	SUPPLEMENT, IF YOU'RE SPEAKING TO THAT, FOR TWO
	190

1	GRANTS WORKING GROUP MEMBERS. BUT WE'RE BASICALLY
2	SAYING WE WOULD TRY TO BE RESPONSIVE TO THOSE
3	REQUESTS OF US THAT WOULD REALLY MAKE A DIFFERENCE.
4	OTHERWISE WE HAVE TO BYPASS ON THOSE OPPORTUNITIES.
5	DR. BRYANT: I JUST THINK THAT A LITTLE
6	BIT MORE THAN THAT WOULD BE NECESSARY FOR UP TO
7	WHAT WAS THE AMOUNT ON THAT ONE?
8	DR. TROUNSON: IT WAS 10 PERCENT OF THE
9	AWARD IN THE CASE OF THE MINOR ONE OR UP TO 500,000.
10	DR. BRYANT: AND THE LARGER ONES ARE UP TO
11	THREE MILLION.
12	DR. TROUNSON: UP TO BUT, AGAIN, 30
13	PERCENT OF THE AWARD OR UP TO THREE MILLION. THAT
14	INVOLVES THE FULL GRANTS WORKING GROUP. RIGHT. SO
15	YOU HAVE TO GO TO THE FULL GRANTS WORKING GROUP FOR
16	THAT AND THEN TO THE ICOC. IN THOSE ONES IT IS FULL
17	REVIEW, FULL PEER REVIEW.
18	DR. BRYANT: I'M OKAY WITH THAT.
19	DR. DULIEGE: I WANT TO SAY I STILL AGREE
20	WITH THE PROPOSAL THAT GIVES ENOUGH LEEWAY TO THE
21	WORKING GROUPS AND TO THE PRESIDENT TO GIVE,
22	RELATIVELY SPEAKING, SMALL AMOUNT OF MONEY. I'M NOT
23	SAYING 500 IS A SMALL AMOUNT, BUT IT'S 10 PERCENT OF
24	THE GRANT OR UP TO 10 PERCENT OF THE GRANT WHILE
25	WHEN YOU GO ABOVE THAT CLEARLY NEEDS TO COME BACK TO
	191
	TJT

1	PEER REVIEW. I THINK THIS DISCRIMINATION IS
2	JUSTIFIED.
3	CHAIRMAN THOMAS: MR. SHESTACK.
4	MR. SHESTACK: CLARIFICATION. THE 12
5	MILLION IS BECAUSE IT WOULD BE UP TO POTENTIALLY
6	FOUR TIMES A YEAR, THREE TEAMS A YEAR, OR HOW WOULD
7	YOU
8	DR. TROUNSON: JON, I WOULD THINK WE MIGHT
9	GIVE ONE A YEAR FOR FOUR YEARS.
10	MR. SHESTACK: TWELVE MILLION WAS THE
11	TOTAL FOR THE PROGRAM?
12	DR. TROUNSON: YEAH. IT MIGHT BE TWO ONE
13	YEAR, NONE THE NEXT ONE. I'M THINKING THAT THESE
14	ARE VERY RARE INCIDENTS. WE DON'T WANT TO BE
15	FLUSHED WITH THINGS THAT PEOPLE THINK THAT WOULD
16	IMPROVE. THIS HAS TO BE VERY SPECIAL AS THE EXAMPLE
17	THAT I TRIED TO GIVE YOU, THAT OUT OF BLUE YOU GET A
18	RESOURCE.
19	MR. SHESTACK: I ACTUALLY THINK THIS IS A
20	GREAT IDEA BECAUSE I THINK IT ALLOWS IT SETS
21	FORTH IT ALLOWS US TO BE VERY NIMBLE, BUT SETS UP
22	A PROCESS SO IT DOES NOT SEEM AS AD HOC AS SOMETIMES
23	THE PROCESS MIGHT SEEM TO OTHERS. SO I JUST WANTED
24	TO UNDERSTAND THE NUMBERS, BUT I THINK IN GENERAL
25	IT'S A GOOD IDEA. PARTICULARLY NOW AS OPPORTUNITIES
	192

1	SEEM TO BE ACCELERATING AND WE'RE POTENTIALLY
2	GETTING TO THE END OF OUR LIFE SPAN, IT WOULD BE
3	GOOD TO DO SOMETHING LIKE THIS TO EXPEDITE.
4	CHAIRMAN THOMAS: MR. JUELSGAARD.
5	DR. JUELSGAARD: I MOVE THAT WE ADOPT THE
6	PROPOSAL AS PRESENTED BY DR. TROUNSON.
7	CHAIRMAN THOMAS: IT'S BEEN MOVED. IS
8	THERE A SECOND?
9	DR. PRICE: SECOND.
10	CHAIRMAN THOMAS: SECONDED BY DR. PRICE.
11	ANY FURTHER DISCUSSION BY MEMBERS OF THE BOARD? ANY
12	COMMENTS BY MEMBERS OF THE PUBLIC? MR. HARRISON,
13	THIS IS A MONETARY ITEM. WHAT DOES THIS REQUIRE
14	FROM A VOTING PERSPECTIVE?
15	MR. HARRISON: A VOICE VOTE IS FINE
16	ALTHOUGH YOU NEED TO POLL MEMBERS WHO ARE ON THE
17	PHONE, WHO INCLUDE DR. WARE AND SHERRY LANSING.
18	CHAIRMAN THOMAS: THANK YOU. SO ALL THOSE
19	FAVOR IN THE ROOM PLEASE SAY AYE. OPPOSED?
20	ABSTENTIONS?
21	DR. STEWARD: ABSTENTION.
22	DR. BRYANT: ABSTENTION.
23	CHAIRMAN THOMAS: DRS. STEWARD AND BRYANT
24	ABSTAIN. SHERRY.
25	MS. LANSING: YES.
	102
	193

1	CHAIRMAN THOMAS: DR. WARE.
2	DR. WARE: YES.
3	CHAIRMAN THOMAS: OKAY. NOW WE'RE REALLY
4	DOWN TO THE HOME STRETCH. THE LAST CALENDARED ITEM
5	IS A COMMUNICATIONS REPORT. KEVIN.
6	DR. STEWARD: AS LONG AS KEVIN IS STILL
7	COMING UP, COULD WE ASK THAT ANY TIME THOSE FUNDS
8	ARE ACTUALLY TAPPED, THAT YOU REPORT BACK ON HOW
9	THEY HAVE BEEN SPENT?
10	DR. TROUNSON: THAT'S EXACTLY WHAT'S IN
11	THAT CONCEPT. AT THE NEXT AVAILABLE MEETING, OS, WE
12	WOULD REPORT IT TO YOU. SO YES.
13	DR. STEWARD: I DIDN'T CATCH THAT. THANK
14	YOU.
15	MS. SAMUELSON: ISN'T IS A PREAPPROVAL?
16	IT'S NOT. IT'S JUST NOTICE AFTER THE FACT?
17	DR. TROUNSON: IT WAS A REQUEST FOR
18	PREAPPROVAL, BUT WE WOULD REPORT IT TO YOU. AND
19	CLEARLY, YOU HAVE THE OPPORTUNITY TO SAY, WELL, FROM
20	NOW ON WE DON'T LIKE THAT. BUT ESSENTIALLY IT IS A
21	PREAPPROVAL, AND I NEED TO REPORT THAT AS SOON AS
22	I'VE MADE THAT TO THE NEXT BOARD MEETING, IN THE
23	CASE OF THE MINOR ONE, OTHERWISE THE MAJOR ONES ALL
24	GO TO THE GRANTS WORKING GROUP.
25	MS. SAMUELSON: I SEE. PREAPPROVAL MEANS
	104
	194

1	BEFORE ANY DECISION BY CIRM.
2	DR. TROUNSON: AS WE DID FOR CONFERENCE
3	GRANTS. I ONLY NEED TO REPORT THAT TO YOU AT THE
4	NEXT MEETING.
5	MS. SAMUELSON: THAT'S NOT MY
6	UNDERSTANDING OF PREAPPROVAL.
7	CHAIRMAN THOMAS: KEVIN.
8	MR. MCCORMACK: CHAIRMAN THOMAS, MEMBERS
9	OF THE BOARD, GOOD AFTERNOON. I SUSPECT THIS WILL
10	BE A LITTLE LESS INTERESTING THAN THE TWO PREVIOUS
11	CONVERSATIONS, AT LEAST I HOPE SO.
12	I WANTED TO START TODAY BY READING YOU AN
13	EXCERPT FROM AN ARTICLE I READ RECENTLY. IT WAS
14	WRITTEN BY ONE OF THE BOARD MEMBERS, DR. PRIETO, FOR
15	AN ARTICLE HE WAS WRITING FOR A JOURNAL ABOUT HIS
16	EARLY EXPERIENCES WHEN HE FIRST JOINED THE BOARD AND
17	SAYING THAT EVEN THOUGH HE WAS A TRAINED PHYSICIAN
18	AND HAVING DONE SOME RESEARCH, HE FOUND THE SHEAR
19	DENSITY OF THE SCIENCE THAT HE WAS ENCOUNTERING AT
20	THE ICOC A LITTLE DAUNTING.
21	THIS IS WHAT HE WROTE. "EVEN WITH MY
22	MEDICAL TRAINING, THE SCIENTIFIC MATERIAL I HAD TO
23	LEARN ABOUT WAS A BIT DAUNTING. I HAD NO IDEA WHEN
24	I JOINED THE BOARD THAT SONIC HEDGEHOG IS A
25	MAMMALIAN SIGNALING PATHWAY AND NOT JUST A VIDEO

160 S. OLD SPRINGS ROAD, SUITE 270, ANAHEIM, CALIFORNIA 92808 1-800-622-6092 1-714-444-4100 EMAIL: DEPO@DEPO1.COM

1	GAME. FURTHERMORE, ARTICLES ABOUT LONG NONCODING
2	RNA'S AND NOTCH SIGNALING RARELY MADE IT ONTO MY
3	READING LIST."
4	THAT STRUCK A CHORD BECAUSE WHEN I CAME ON
5	BOARD, I FELT VERY MUCH THE SAME. I DON'T HAVE A
6	SCIENCE BACKGROUND. AND SO SITTING IN SOME OF THE
7	MEETINGS, I FELT LIKE PEOPLE WERE TALKING ANOTHER
8	LANGUAGE AT TIMES. SO WHEN YOU SAW THIS NEW YORKER
9	CARTOON, THIS IS PRETTY MUCH HOW I FELT THE FIRST
10	FEW WEEKS I WAS HERE. I'M THE TOASTER, BY THE WAY.
11	AND HE'S SAYING, "I'M IN WAY OVER MY HEAD."
12	THEN I REALIZED THAT THE JOB OF
13	COMMUNICATIONS IS NOT TO UNDERSTAND EVERY SINGLE
14	ASPECT OF WHAT'S GOING ON, AND I'M PICKING THAT UP
15	AS I GO ALONG. IT'S FUN AND ENGAGING. MY JOB IS TO
16	TRANSLATE THAT TO THE OUTSIDE WORLD, TO TAKE IT TO
17	OTHER PEOPLE SO ALL THE OTHER TOASTERS CAN HAVE A
18	CLUE ABOUT WHAT WE'RE DOING HERE AND WHY WE'RE DOING
19	IT AND HOW WE'RE DOING IT.
20	AND WE'RE HAVING SOME SUCCESS IN DOING
21	THAT. I THINK SOME OF YOU HAVE SEEN THESE ARTICLES
22	ALREADY. IN SEPTEMBER FORTUNE MAGAZINE DID A
23	WONDERFUL PIECE ABOUT THE BUSINESS OF STEM CELLS.
24	AND THEY TOOK AN IN-DEPTH LOOK AT THE STEM CELL
25	AGENCY ITSELF, AT CIRM, LOOKING AT WHAT WE DO AND
	196

HOW WE DO IT AND WHY. IT WAS A REALLY THOUGHTFUL,
WELL-DONE PIECE, AND IT WAS A GREAT PROMOTION, I
THINK, FOR THE WORK THAT WE'RE DOING.
A FEW WEEKS AGO THE SAN FRANCISCO
CHRONICLE DID A HUGE PIECE IN ITS NEW HEALTH SECTION
ON IPS CELLS. AND THIS CAME OUT SHORTLY AFTER DR.
YAMANAKA WON THE NOBEL PRIZE. THEY WERE ABLE TO
EXPLORE MANY DIFFERENT ASPECTS OF THIS, AND THEY DID
A PIECE ABOUT US AS WELL. THEY SPOKE MOSTLY TO OUR
GRANTEES, TO THE PEOPLE WHO ARE USING THESE CELLS,
AND EXPLORING THE POTENTIAL.
I THINK THE TWO THINGS THAT WE HAVE TO
REMEMBER ABOUT THESE IS THAT BOTH THESE ARTICLES
TOOK A LOT OF HARD WORK, THE FORTUNE ARTICLE IN
PARTICULAR. MY COLLEAGUE DON GIBBONS SPENT MONTHS,
LITERALLY HOURS ON THE PHONE WITH THE REPORTER
WALKING HIM THROUGH EVERYTHING WE DID, HOW WE DID
IT, PUTTING HIM IN TOUCH WITH OTHER PEOPLE SO THAT
THE REPORTER GOT A REALLY GOOD SENSE OF WHAT'S
INVOLVED IN WHAT WE DO AND IN WHAT STEM CELL
RESEARCH AROUND THE COUNTRY HAS THE POTENTIAL TO DO.
AND THE END RESULT WAS A WONDERFUL PIECE.
WITH THE CHRONICLE AS WELL, WE WORKED WITH
THE REPORTER FOR MANY MONTHS BEFORE THE PIECE CAME
OUT. SHE HAD BEEN WORKING ON THIS FOR A LONG TIME
197

1	BEFORE DR. YAMANAKA GOT HIS NOBEL PRIZE, SO THE
2	TIMING WAS GREAT. BUT IT TOOK A LOT OF WORK TO GET
3	TO THAT POINT.
4	SOMETIMES THINGS COME ALONG A LITTLE
5	FASTER. TV, ABC 7, THE LOCAL ABC 7 STATION HERE IN
6	SAN FRANCISCO, DID A COUPLE OF PIECES RECENTLY ON
7	SOME OF OUR GRANTEES, SOME OF THE WORK WE'RE DOING
8	ON THE BRIDGES PROGRAM. AND THE NICE THING ABOUT TV
9	STORIES LIKE THIS IS THAT THEY OFTEN GET SYNDICATED
10	THROUGHOUT THE STATE. SO OTHER STATIONS AROUND
11	CALIFORNIA WILL GET TO SEE THE WORK THAT WE'RE
12	DOING. SO IT GETS A MUCH WIDER AUDIENCE IN A SENSE
13	THAN A NEWSPAPER ARTICLE, AS GOOD AS THAT IS.
14	WE DON'T JUST USE THE TRADITIONAL MEDIA.
15	OBVIOUSLY WE WANT TO USE AS MANY DIFFERENT FORMATS
16	AS WE CAN. SOCIAL MEDIA IS ANOTHER AREA WE'RE
17	LOOKING AT ENORMOUSLY. BUT ONE OF THE MOST
18	IMPORTANT PARTS OF THAT, PERHAPS THE HUB OF ALL OUR
19	SOCIAL MEDIA WORK, IS OUR WEB SITE. QUITE FRANKLY,
20	OUR WEB SITE RIGHT NOW IS, IT'S OLD, IT'S CLUTTERED.
21	IT DOES A GREAT JOB, BUT IT'S TRYING TO DEAL WITH SO
22	MANY DIFFERENT AUDIENCES. SO AMY ADAMS HAS BEEN
23	WORKING REALLY HARD OVER THE LAST YEAR OR SO TO TRY
24	AND CHANGE THAT, TO UPDATE IT, TO FRESHEN IT. AND
25	WE'RE HOPING TO LAUNCH, IN FACT, WE'RE GOING TO
	198

ı	
1	LAUNCH IN JANUARY A NEW WEB SITE. AND IT WILL HAVE
2	A LOT OF NEW FEATURES, BUT PARTICULARLY IT'S GOING
3	TO LOOK MORE STREAMLINED. IT'S GOING TO LOOK MORE
4	CONTEMPORARY. IT WILL BE MUCH MORE VISUALLY
5	APPEALING TO SOMEONE WHO COMES TO IT THE FIRST TIME.
6	IT WILL BE EASIER TO NAVIGATE SO THAT PEOPLE CAN
7	FIND THE INFORMATION THEY WANT WHEN THEY WANT IT.
8	SOME OF THE OTHER FEATURES ON THERE, IT
9	WILL HAVE MORE INFORMATION ABOUT PROGRESS THAT OUR
10	GRANTEES ARE DOING, PUBLICATIONS LISTED PERHAPS,
11	PROGRESS REPORTS POSTED. IT WILL HAVE A LIST OF ALL
12	THE GRANTEES. SO IN A SENSE WE'LL BE WORKING ON
13	WHAT ONE OF THE OTHER ICOC MEMBERS, LEEZA GIBBONS,
14	SUGGESTED WAS A WALL OF HEROES, PROFILES OF THE
15	PEOPLE WHO WE FUND WHO ARE DOING THE WORK SO THAT
16	PEOPLE HAVE A BETTER SENSE OF WHERE THE MONEY IS
17	GOING AND WHO IT'S GOING TO, HOW THEY'RE USING IT.
18	IT WILL HAVE EASIER ACCESS TO THE MORE
19	THAN 180 VIDEOS THAT WE ALREADY HAVE AND ALL THE NEW
20	ONES THAT WE'RE PUTTING TOGETHER AND PREPARING. AND
21	IT WILL HAVE CLEARER INFORMATION ABOUT OUR VALUE TO
22	THE STATE SO THAT SOMEONE COMING TO IT CAN GET A
23	MUCH BETTER SENSE, WHETHER THEY'RE A RESEARCHER OR
24	JUST A GENERAL MEMBER OF THE PUBLIC WANTING
25	INFORMATION ABOUT WHAT WE DO. IT WILL BE MUCH
	199
	TJJ

1	EASIER FOR THEM TO FIND THE INFORMATION THAT THEY'RE
2	LOOKING FOR.
3	ONE OF THE OTHER TOOLS WE'RE USING,
4	THOUGH, IS JUST PERSON TO PERSON. ONE OF THE MOST
5	VALUABLE THINGS YOU CAN DO IS HAVE A CONVERSATION
6	WITH SOMEONE, TALK TO THEM AND MAKE THEM UNDERSTAND
7	THE IMPORTANCE OF WHAT YOU'RE DOING. SO A COUPLE OF
8	WEEKS AGO IN LATE SEPTEMBER WE HELD A COMMUNICATIONS
9	WORKSHOP WHERE ABOUT TWO DOZEN MEMBERS OF STAFF GAVE
10	UP FOUR HOURS OF THEIR MONDAY MORNING TO COME IN AND
11	LEARN FROM GREAT TRAINERS AND FROM THE REST OF THE
12	COMMUNICATIONS TEAM HOW TO TALK ABOUT THE WORK THAT
13	THEY DO IN WAYS THAT PEOPLE OUTSIDE OF HERE, PEOPLE
14	WHO ARE LAY PEOPLE, WOULD UNDERSTAND.
15	AND THE IDEA IS JUST TO BREAK DOWN SOME OF
16	THE COMPLEX ISSUES INTO READILY ACCESSIBLE LANGUAGE
17	TO BE ABLE TO GO OUT AND DO, NOT JUST MEDIA
18	INTERVIEWS BECAUSE OBVIOUSLY THOSE ARE IMPORTANT,
19	BUT TO BE ABLE TO GIVE LECTURES, TO GIVE TALKS AT
20	SCHOOLS AND OTHER PLACES. IT WAS A REALLY WONDERFUL
21	WORKSHOP, I THINK.
22	I KNOW THAT THE TRAINERS WHO CAME IN WERE
23	VERY IMPRESSED WITH THE LEVEL OF ENERGY AND THE
24	COMMITMENT FROM EVERYONE WHO WAS THERE, THE
25	QUESTIONS THAT WERE ASKED AND THE CURIOSITY. I KNOW
	200

1	THE TEAM, DON, AMY, TODD, AND MYSELF, WERE REALLY
2	IMPRESSED WITH SOME OF THE IDEAS THAT PEOPLE CAME UP
3	WITH, FROM BEING ABLE TO TRANSLATE AND GIVE
4	REAL-WORLD EXAMPLES OF SOME OF THE THINGS THAT THEY
5	DO EVERY DAY. WE GOT SOME GREAT IDEAS WHICH WE'RE
6	GOING TO SHAMELESSLY STEAL AND CLAIM AS OUR OWN.
7	AND SOME OF THE STAFF GOT A CHANCE TO USE
8	THOSE SKILLS FAIRLY QUICKLY AFTERWARDS. ON WORLD
9	STEM CELL DAY, WE HELPED CONNECT A LOT OF TEACHERS
10	WITH RESEARCHERS. THEY WANTED RESEARCHERS AND OTHER
11	PEOPLE TO COME INTO THE CLASSROOMS AND TALK TO THEIR
12	STUDENTS ABOUT STEM CELLS, ABOUT WHAT WAS GOING ON
13	AND EVERYTHING. THIS YEAR WE MORE THAN DOUBLED THE
14	NUMBER OF CLASSROOMS WE WERE ABLE TO REACH, 150
15	CLASSROOMS, 4,000 STUDENTS. THIS IS STATEWIDE. I
16	DON'T THINK A LOT OF PEOPLE UNDERSTAND THAT A LOT OF
17	OUR GRANTEES WILL COME TO US AND A LOT OF SCHOOLS
18	AROUND THE STATE WILL COME TO US AND SAY WE'RE
19	LOOKING FOR SOMEONE TO HELP US PROVIDE LECTURES AND
20	TALKS AND INFORMATION ABOUT STEM CELLS.
21	DON GIBBONS, AGAIN, AND JENNA PRYNE DID
22	SOME AMAZING WORK ON CONNECTING UP VARIOUS PEOPLE.
23	DEAN POMEROY AND HER TEAM AT UC DAVIS DID A
24	WONDERFUL JOB OF REACHING OUT TO MANY, MANY SCHOOLS
25	IN THE AREA. EVEN WHEN THEY COULDN'T REACH THEM
	201

1	PHYSICALLY WITH ACTUAL LECTURERS OR STUDENTS, THEY
2	PROVIDED VIDEO LINKS SO THAT THEY WERE ABLE TO KIND
3	OF GET THE WORD OUT TO LOTS OF THE STUDENTS. IT WAS
4	A REMARKABLE DAY.
5	AND I WOULD LIKE TO END AT THIS POINT BY
6	READING TO YOU TWO LETTERS FROM SOME STUDENTS IN
7	SOUTHERN CALIFORNIA. DR. MICHAEL TEITELL AT UCLA
8	WENT AROUND A NUMBER OF DIFFERENT SCHOOLS AND GAVE
9	TALKS TO DOZENS OF CLASSES ON ONE DAY. IT WAS
10	REALLY A QUITE REMARKABLE PERFORMANCE. MANY OF THE
11	STUDENTS WROTE TO THANK HIM FOR WHAT HE DID AND FOR
12	THE TIME THAT HE PUT IN. ONE OF THE STUDENTS SAID,
13	"I'VE ALWAYS BEEN A LITTLE CONFUSED ABOUT STEM
14	CELLS. LISTENING TO YOUR PRESENTATION HAS OPENED MY
15	EYES. HONESTLY, I THOUGHT IT WOULD BE A BORING
16	EXPERIENCE. HOWEVER, I WAS PLEASANTLY SURPRISED. I
17	DID NOT DRIFT OUT OF YOUR PRESENTATION ONCE."
18	AND THEN ANOTHER SAID, "TODAY YOU'VE
19	INSPIRED ME MORE TO FOLLOW UP TO MY DREAM AND GOAL
20	TO BE INVOLVED IN SCIENCE A BIT MORE. THANK YOU FOR
21	BEING AN INSPIRATION."
22	I THINK THAT KIND OF SUMS UP WHAT THE
23	GOALS OF COMMUNICATIONS ARE. WE HOPE THAT WHEN WE
24	GO OUT, WHATEVER FORM WE DO IT IN, WE WILL INFORM,
25	EDUCATE, AND EVEN INSPIRE PEOPLE, BUT AT THE VERY
	202
	LUL

1	LEAST, WE WANT TO MAKE PEOPLE INTERESTED IN
2	SOMETHING THAT TO BEGIN WITH PERHAPS THEY HAD NO
3	IDEA THEY CARED ABOUT. THAT'S IT. THANK YOU VERY
4	MUCH. BE HAPPY TO ANSWER ANY QUESTIONS.
5	CHAIRMAN THOMAS: I'D LIKE TO THANK YOU,
6	KEVIN AND DON AND AMY AND TODD FOR ALL THE HARD WORK
7	YOU'RE DOING. AS YOU KNOW, WE PUT RENEWED EMPHASIS
8	ON COMMUNICATIONS TO GET OUR STORIES OUT IN A WAY
9	THAT WILL ACCURATELY DEPICT WHAT WE'RE DOING, THE
10	GREAT WORK WE'RE DOING, MUCH LIKE THE INSPIRING
11	PIECE MR. JENSEN IS WRITING ON VIACYTE, WHICH, BY
12	THE WAY, I TRUST YOU ARE GOING TO CC YOUR FRIEND
13	MR. HILDSIK AT THE SAME TIME.
14	SO I THINK THAT ALL OF THIS IS REALLY
15	GOOD, AND WE WILL CONTINUE TO EXPAND THE
16	COMMUNICATIONS EFFORTS TO LET THE PEOPLE OF
17	CALIFORNIA KNOW WHAT THEY'RE GETTING FOR THEIR
18	TAXPAYER DOLLAR AND TO TELL THE STORY AS IT
19	PROGRESSES THROUGH THE RESEARCH BEING UNDERTAKEN BY
20	ALL THE MANY WONDERFUL PROJECTS THAT WE'RE FUNDING.
21	SO THANK YOU, KEVIN.
22	ANY OTHER COMMENTS BY MEMBERS OF THE
23	BOARD? HEARING NONE, DO WE HAVE ANY PUBLIC, GENERAL
24	PUBLIC COMMENT ON ANYTHING THAT ANYONE WANTS TO SAY
25	ANYTHING ABOUT? HEARING NONE, I BELIEVE I CAN NOW
	203

```
1
     ENTERTAIN A MOTION TO ADJOURN SO THAT MR. JUELSGAARD
 2
     AND OTHERS CAN GET TO AT&T ON TIME.
 3
                MS. LANSING: I WILL MOVE ADJOURNMENT.
 4
                CHAIRMAN THOMAS: THANK YOU, SHERRY.
 5
     SECONDED BY? SOMEBODY HAS GOT TO SECOND.
 6
                     (MULTIPLE SECONDS.)
 7
                CHAIRMAN THOMAS: THANK YOU VERY MUCH.
 8
     WE'LL SEE EVERYBODY IN DECEMBER.
 9
                     (THE MEETING WAS THEN CONCLUDED AT
10
     3:15 P.M.)
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
                               204
```

REPORTER'S CERTIFICATE

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

HILTON SFO BAYFRONT HOTEL 600 AIRPORT BOULEVARD REFLECTION I & II BURLINGAME, CALIFORNIA ON OCTOBER 25, 2012

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

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