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: LUXE HOTEL, SUNSET BOULEVARD

11461 SUNSET BOULEVARD LOS ANGELES, CALIFORNIA

DATE: DECEMBER 12, 2012

9 A.M.

REPORTER: BETH C. DRAIN, CSR

CSR. NO. 7152

BRS FILE NO.: 92689

INDEX

ITEM DESCRIPTION	PAGE NO.
REPORTS & DISCUSSION ITEMS	
1. CALL TO ORDER.	4
2. PLEDGE OF ALLEGIANCE.	4
3. ROLL CALL.	4
4. CHAIRMAN'S REPORT.	183
5. PRESIDENT'S REPORT.	150
6. PRESENTATION AND DISCUSSION OF THE INSTITUTE OF MEDICINE REPORT ON CIRM.	8
ACTION ITEMS	
8. CONSIDERATION OF APPLICATIONS FOR RFA 12-01: CIRM NEW FACULTY PHYSICIAN SCIENTIST TRANSLATIONAL RESEARCH AWARDS.	66
CLOSED SESSION	
ACTION ITEMS	
10. CONSIDERATION OF BASIC BIOLOGY V CONCEPT PLAN.	119
11. CONSIDERATION OF FINAL ADOPTION OF CIRM CONFLICT OF INTEREST CODE AMENDMENTS.	137
12. CONSIDERATION OF APPOINTMENT OF NEW SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP.	117
13. CONSIDERATION OF AWARD OF SUPPLEMENTAL FUNDS TO EXISTING GRANTEE, VIACYTE.	109, 181

2

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I N D E X (CONT'D.)		
14. CONSIDERATION OF UPDATE TO CIRM'S RESPONSE TO THE PERFORMANCE AUDIT RECOMMENDATIONS.	139	
DISCUSSION ITEMS		
15. DISCUSSION OF A COMMERCIALIZATION AND INDUSTRY ENGAGEMENT PLAN.	141	
16. COMMUNICATIONS UPDATE.	170	
17. PUBLIC COMMENT.	NONE	
PROPOSED ADDITIONAL AGENDA ITEM	179	

	DARKISIERS REPORTING SERVICE
1	LOS ANGELES, CALIFORNIA;
2	WEDNESDAY, DECEMBER 12, 2012; 9 A.M.
3	
4	CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY.
5	I'D LIKE TO WELCOME YOU ALL ON THIS MOST UNUSUAL
6	12/12/12 TO THE DECEMBER MEETING OF THE ICOC HERE IN
7	BEAUTIFUL BRENTWOOD.
8	I'D LIKE TO START WITH CALLING THE MEETING
9	OFFICIALLY TO ORDER. AND, MARIA, WILL YOU PLEASE
10	LEAD US IN THE PLEDGE OF ALLEGIANCE.
11	(THE PLEDGE OF ALLEGIANCE.)
12	CHAIRMAN THOMAS: MARIA, WILL YOU PLEASE
13	CALL THE ROLL.
14	MS. BONNEVILLE: DAVID BRENNER. SUSAN
15	BRYANT.
16	DR. BRYANT: HERE.
17	MS. BONNEVILLE: FRANK CHISARI.
18	ANNE-MARIE DULIEGE. JAMES ECONOMOU.
19	DR. ECONOMOU: HERE.
20	MS. BONNEVILLE: MARCY FEIT.
21	MS. FEIT: HERE.
22	MS. BONNEVILLE: LEEZA GIBBONS.
23	MS. GIBBONS: HERE.
24	MS. BONNEVILLE: MICHAEL GOLDBERG. SAM
25	HAWGOOD.
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	DARRISIERS REPORTING SERVICE
1	DR. HAWGOOD: HERE.
2	MS. BONNEVILLE: STEPHEN JUELSGAARD.
3	DR. JUELSGAARD: HERE.
4	MS. BONNEVILLE: TED KRONTIRIS.
5	DR. KRONTIRIS: HERE.
6	MS. BONNEVILLE: SHERRY LANSING.
7	MS. LANSING: HERE.
8	MS. BONNEVILLE: BERT LUBIN. SHLOMO
9	MELMED. CLAIRE POMEROY.
10	DR. POMEROY: HERE.
11	MS. BONNEVILLE: ROBERT PRICE.
12	DR. PRICE: HERE.
13	MS. BONNEVILLE: FRANCISCO PRIETO.
14	DR. PRIETO: HERE.
15	MS. BONNEVILLE: CARMEN PULIAFITO.
16	DR. PULIAFITO: HERE.
17	MS. BONNEVILLE: ROBERT QUINT.
18	DR. QUINT: HERE.
19	MS. BONNEVILLE: DUANE ROTH. JOAN
20	SAMUELSON. JEFF SHEEHY.
21	MR. SHEEHY: HERE.
22	MS. BONNEVILLE: JONATHAN SHESTACK.
23	OSWALD STEWARD.
24	DR. STEWARD: HERE.
25	MS. BONNEVILLE: JONATHAN THOMAS.
	5

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1	CHAIRMAN THOMAS: HERE.
2	MS. BONNEVILLE: ART TORRES.
3	MR. TORRES: HERE.
4	MS. BONNEVILLE: CARL WARE.
5	DR. WARE: HERE.
6	CHAIRMAN THOMAS: THANK YOU. WE ARE GOING
7	TO HOLD OFF FOR A BIT ON THE CHAIR AND PRESIDENT'S
8	REPORT. WE'RE GOING TO MOVE FIRST TO THE REPORT BY
9	THE INSTITUTE OF MEDICINE AND HAVE DISTINGUISHED
10	GUESTS HERE, THE CHAIR AND VICE CHAIR OF THE IOM
11	COMMITTEE THAT DID THIS REPORT, DR. HAROLD SHAPIRO
12	AND DR. TERRY MAGNUSON.
13	AS YOU WILL ALL RECALL, A NUMBER OF MONTHS
14	AGO IN MID-2011 WE COMMISSIONED THE IOM TO DO A TOP
15	TO BOTTOM REVIEW OF CIRM, ITS PROCESSES, ITS
16	PROGRAMS, ITS FUNDING MODEL, AND A VARIETY OF OTHER
17	ATTENDANT ITEMS. THEY BEGAN THEIR STUDY IN OCTOBER
18	OF 2011 AND JUST RECENTLY HAVE RELEASED THE REPORT
19	WHICH WE'LL BE DISCUSSING HERE AT THE MEETING TODAY.
20	HAVING SOUGHT TO GET THEIR BLUE RIBBON
21	THOUGHTS AND EXPERTISE ON WHAT WE'RE DOING, WE ARE
22	VERY INTERESTED, OF COURSE, IN THE REPORT, WHICH WE
23	HAVE READ IN GREAT DETAIL, AND ARE GOING TO BE
24	TAKING THE NUMEROUS RECOMMENDATIONS OF THE IOM VERY
25	SERIOUSLY. AND ONCE WE'VE HAD THE DISCUSSION AND
	6

PRESENTATION BY DR. SHAPIRO, WE WILL SAY A FEW WORDS
ON THE PROCESS THAT WE HAVE PUT IN PLACE TO EVALUATE
THE REPORT AND WHAT WE WILL BE DOING GOING FORWARD
TO IMPLEMENT THE SUGGESTIONS.
SO WITHOUT FURTHER ADO, I'D LIKE TO TURN
IT OVER TO DR. SHAPIRO WHO WILL BE MAKING A
PRESENTATION. AND I BELIEVE, ARE YOU INVITING Q AND
A ALONG THE WAY, OR HOW WOULD YOU LIKE TO PROCEED?
DR. SHAPIRO: IT'S WHATEVER THE COMMITTEE
IS COMFORTABLE WITH. IF THEY HAVE QUESTIONS OR
CLARIFICATION OR ANYTHING, CERTAINLY INTERRUPT ME.
I WILL TRY TO KEEP MY PRESENTATION NO MORE THAN HALF
AN HOUR BECAUSE I KNOW YOU HAVE A FULL COPY OF THE
REPORT AND YOU'VE GOT THE POWERPOINT SLIDES. SO
I'LL TRY TO MOVE QUICKLY, BUT WHATEVER SUITS THE
BOARD WILL BE FINE WITH ME.
CHAIRMAN THOMAS: BEFORE I TURN IT OVER TO
DR. SHAPIRO, I WOULD LIKE JUST TO NOTE THAT, AS
YOU'VE READ THE REPORT, YOU WILL SEE THAT THERE ARE
MANY STATEMENTS IN THERE VALIDATING CIRM, ITS
PROCESS, WHAT IT WAS ABLE TO ACHIEVE IN THE YEARS
SINCE PROP 71 WAS PASSED, LOTS OF DISCUSSION ABOUT
THE FUNDING MODEL, ABOUT HOW CIRM HAS REALLY
ENERGIZED THE AREA OF STEM CELL RESEARCH WORLDWIDE,
GALVANIZED THE BIOTECH INDUSTRY IN CALIFORNIA, AND
7

1	SO ON. AND WE ARE VERY GRATEFUL THAT THE IOM HAS
2	MADE ALL OF THOSE STATEMENTS. PERHAPS DR. SHAPIRO
3	COULD AMPLIFY A BIT ON THOSE AS WELL AS FOR THE
4	NUMEROUS RECOMMENDATIONS THAT THEY'VE MADE ON HOW WE
5	COULD TAKE SOMETHING WHICH IS ALREADY A GREAT
6	EXPERIENCE AND IMPROVE IT EVEN EITHER. SO WITHOUT
7	FURTHER ADO, DR. SHAPIRO.
8	DR. SHAPIRO: THANK YOU VERY MUCH. I WANT
9	TO THANK THE BOARD FOR ITS WILLINGNESS TO SPEND SOME
10	TIME TO HEAR A LITTLE BIT ABOUT THIS REPORT. IT'S
11	MY GREAT OPPORTUNITY FOR MYSELF AND PROFESSOR
12	MAGNUSON SITTING RIGHT OVER HERE ON MY LEFT TO BE
13	HERE TODAY WITH YOU.
14	I REALLY WANT TO BEGIN BY THANKING THE
15	CIRM STAFF FOR THEIR COOPERATION. WE MADE MANY,
16	MANY REQUESTS AS WE WROTE OUR STUDY. THEY ALWAYS
17	RESPONDED IN FULL AND QUICKLY AND WITH VERY GOOD
18	GRACE, I HAVE TO SAY. I'M SURE THAT REFLECTS THE
19	ATTITUDE NOT ONLY OF STAFF, BUT THE BOARD AND
20	MANAGEMENT OF CIRM. WE ARE VERY, VERY GRATEFUL FOR
21	THAT.
22	IT'S CLEAR TO EVERYONE THAT THE ICOC, THE
23	BOARD, HAVE VERY MANY DISTINGUISHED AND EXPERIENCED
24	MEMBERS WITH A LIFETIME OF EXPERIENCE IN CIRM-LIKE
25	ACTIVITIES EITHER AS PATIENT ADVOCATES OR AS MEMBERS

1	OF THE BIOMEDICAL OR RESEARCH COMMUNITY OR PEOPLE
2	WITH INTEREST IN THAT PARTICULAR COMMUNITY. INDEED,
3	I HAVE TO SAY THAT, GIVEN THE COMPOSITION OF THE
4	BOARD AND QUALITY OF THE BOARD AND THE NUMBER OF
5	STUDIES THAT HAVE ALREADY TAKEN PLACE, I SAID TO
6	SOMEONE LAST NIGHT IT'S ONE OF THE MOST OVERSTUDIED
7	ORGANIZATIONS I'VE COME ACROSS IN THE VERY BRIEF
8	HISTORY THAT YOU HAVE. WHEN I WAS FIRST ASKED TO
9	TAKE THE CHAIRMANSHIP, MY FIRST RESPONSE WAS WHY DO
10	WE NEED ANOTHER STUDY OF CIRM? THERE'S BEEN SO MANY
11	STUDIES.
12	NEVERTHELESS, WHAT GOT ME INTERESTED WAS
13	THAT I DIDN'T KNOW A LOT OF THE DETAILS OF CIRM, BUT
14	I HAD BEEN CHAIRMAN OF THE NATIONAL BIOETHICS
15	ADVISORY COMMISSION WHEN HUMAN EMBRYONIC STEM CELLS
16	FIRST BECAME AN ETHICAL ISSUE, THAT BEING THE
17	THOMSON EXPERIMENTS WHICH CULTURED THE CELLS AND
18	STUDIED THEM AND SO ON. AS FAR AS I KNOW, THAT
19	COMMITTEE WAS THE FIRST TO OPINE IN AN OFFICIAL WAY
20	ON THE ETHICAL ISSUES. AND I THOUGHT THIS WOULD BE
21	AN OPPORTUNITY FOR ME TO SEE JUST WHERE THE SCIENCE
22	HAD COME AND HOW CIRM HAD DONE. SO IT'S ACTUALLY A
23	VERY GREAT PLEASURE TO DO THIS STUDY.
24	THE FIRST THING I'D LIKE TO SAY BEFORE I
25	GET TO THE POWERPOINT PRESENTATION AND SO ON IS YOU

1	ALL HAVE A GREAT DEAL TO CELEBRATE. WE RECOGNIZE
2	THAT THE COMMITTEE RECOGNIZES THAT CIRM IS
3	CERTAINLY A SOCIAL INNOVATION. MANY INNOVATIVE
4	ASPECTS OF CIRM'S OPERATIONS, SOME OF WHICH I'LL
5	DISCUSS, SOME OF WHICH ARE IN THE REPORT AND I WON'T
6	HAVE TIME TO DISCUSS THIS MORNING, BUT AS I'VE
7	ALREADY SAID, IT REALLY IS A SOCIAL INNOVATION.
8	THESE DON'T COME ALONG EVERY DAY IN THE BIOMEDICAL
9	RESEARCH COMMUNITY, AND CIRM DOES REFLECT AND IS A
10	REMARKABLE SOCIAL INNOVATION.
11	AND WE ALL OWE YOU A DEBT OF GRATITUDE,
12	THOSE OF YOU WHO HAVE HAD LEADERSHIP IN THIS EFFORT,
13	FOR ALL YOU HAVE DONE, NOT ONLY FOR CIRM ITSELF AND
14	CALIFORNIA, BUT FOR THE GENERAL AREA OF BIOMEDICAL
15	RESEARCH. YOU HAVE EVERY REASON TO FEEL VERY GOOD.
16	SELF-SATISFIED DOESN'T SOUND RIGHT. SOUNDS LIKE
17	THAT'S UNDESERVED SATISFACTION. BUT YOU HAVE A VERY
18	WELL-EARNED SATISFACTION WHICH I HOPE THAT YOU FEEL
19	BECAUSE IT'S VERY GENUINE FROM OUR POINT OF VIEW.
20	NOW, THERE'S MANY VERSIONS OF THIS REPORT.
21	IN A SENSE THIS IS TYPICAL OF AN IOM REPORT. WE
22	HAVE A TWO- OR THREE-PAGE VERSION, WE HAVE A SUMMARY
23	AT THE BEGINNING OF OUR REPORT, AND WE HAVE A PRESS
24	RELEASE. SO IF YOU WANT TO READ TWO PAGES, YOU GO
25	TO THE PRESS RELEASE. IF YOU WANT TO READ A QUICK

1	SUMMARY, WE HAVE ONE THAT'S THREE PAGES LONG, AND
2	THE SUMMARY IS ABOUT EIGHT PAGES LONG, THEN THERE'S
3	THE WHOLE REPORT. SO YOU CAN LOOK AT THIS IN ANY
4	WAY YOU LIKE THAT SUITS YOU. JUST DEPENDS HOW MUCH
5	DETAIL YOU WANT.
6	AND SO LET ME GO AHEAD NOW AND MAKE THE
7	PRESENTATION. I THINK I HAVE ABOUT 25 OR 26 SLIDES.
8	I WILL NOT GO OVER ALL OF THEM CAREFULLY. IT WILL
9	TAKE MUCH TOO LONG. I'LL TRY TO GO TO THE ONES I
10	THINK ARE MOST IMPORTANT AND HAVE MOST TO SAY AND
11	THINGS THAT MIGHT GENERATE SOME INITIAL DISCUSSION.
12	NOW, BEFORE I GET TO THAT, I JUST WANT TO
13	ADD ONE FURTHER THING. OUR HOPE IS IN MAKING THIS
14	STATEMENT AND THE REASON WE'VE DONE THE STUDY IS
15	THAT WE HOPE THAT OUR INDEPENDENT PERSPECTIVE WILL
16	BE OF ASSISTANCE TO YOU AS YOU TRY TO GUIDE CIRM
17	INTO THE FUTURE. WE DON'T PRETEND TO HAVE ALL THE
18	WISDOM. WE JUST HAVE DONE OUR BEST JOB IN THINKING
19	THIS PROBLEM THROUGH, THINKING OUR EVALUATION
20	THROUGH; AND WE KNOW THAT YOU, THIS BOARD HERE, IS
21	THE GROUP THAT'S IN THE BEST POSITION TO DECIDE JUST
22	HOW CIRM SHOULD MANAGE ITSELF AND GOVERN ITSELF
23	GOING AHEAD.
24	WE HAVE VARIOUS RECOMMENDATIONS, WHICH
25	I'LL COME TO IN A MOMENT. MANY OF THESE

1	RECOMMENDATIONS ARE IN SOME SENSE INDEPENDENT IN THE
2	SENSE THAT ONE DOESN'T HAVE TO TAKE THEM ALL. ONE
3	COULD TAKE SOME YOU LIKE AND SOME YOU DON'T LIKE
4	DEPENDING ON YOUR OWN REACTION TO THEM. AND SOME OF
5	THEM ARE INTERDEPENDENT; THAT IS, DEPENDENT ON EACH
6	OTHER, BUT MOSTLY THEY ARE SEPARATE RECOMMENDATIONS
7	WHICH YOU CAN CHOOSE TO ADAPT OR ADAPT PART OF OR
8	ADAPT SLOWLY OVER TIME. WE MAY NOT HAVE BEEN FULLY
9	WISE ON THESE ISSUES, BUT I WANT TO ASSURE YOU THAT
10	WE WERE NOT NAIEVE ABOUT IT EITHER.
11	THE KINDS OF CHANGES THAT WE ARE
12	RECOMMENDING WE KNOW TAKE TIME, NOT ONLY FOR YOUR
13	CONSIDERATION TO SEE IF YOU FIND THEY'RE USEFUL, BUT
14	EVEN IF YOU FIND THEM ALL USEFUL, IT WOULD TAKE SOME
15	TIME. SOME WILL REQUIRE WORKING WITH STATE
16	GOVERNMENT IN ORDER TO MAKE THESE CHANGES, SO WE'RE
17	VERY MUCH AWARE OF THAT. AND AS I SAID BEFORE, WE
18	ONLY HOPE THAT YOU CAN LOOK AT THESE, TAKE THEM
19	SERIOUSLY, AND THEN DECIDE WHAT'S IN CIRM'S BEST
20	INTEREST GOING FORWARD.
21	MS. LANSING: I JUST WANT TO PUT THIS IN A
22	CONTEXT. FIRST OF ALL, THANK YOU. I CANNOT THANK
23	YOU AND THE MEMBERS OF THE COMMITTEE ENOUGH FOR ALL
24	OF THE HARD WORK THAT YOU'VE DONE. I HAVE READ THE
25	REPORT, SHORT VERSION, THE LONG VERSION, WHATEVER.
	12

1	SO I JUST WANT TO PUT IN CONTEXT THAT, AND YOU
2	MENTIONED IT JUST BRIEFLY, THAT IN SOME OF THESE
3	THINGS, AND WE ARE GOING TO HAVE A WORKSHOP TO GO
4	THROUGH THEM AND JAMES IS GOING TO HAVE TO GUIDE US
5	THROUGH IT, SOME OF THESE THINGS, EVEN IF WE LIKE
6	THEM, OUR HANDS ARE TIED BECAUSE OF THE STATE LAW
7	AND THE CONSTITUTIONAL LAW, AND THEY REQUIRE A FULL
8	VOTE BY THE CITIZENS. SO I JUST WANT TO SAY THAT.
9	I'M NOT GOING TO ASK JAMES TO TELL US WHAT
10	EVERY RECOMMENDATION IS. BUT PERHAPS AT THE END,
11	SINCE SOME OF THEM ARE ABOUT PATIENT ADVOCATES, AT
12	THE END, NOT NOW, YOU COULD EXPLAIN TO US WHAT THE
13	CONSTITUTIONAL THING IS. I JUST WANT TO KNOW THAT.
14	DR. SHAPIRO: WE ARE QUITE AWARE THAT THIS
15	WOULD REQUIRE WHAT WE CALL COOPERATION OF STATE
16	GOVERNMENT AND THE VOTERS, AND WE ARE AWARE OF THAT.
17	WE'RE NOT THE EXPERTS IN THAT. YOU ARE THE EXPERTS
18	SITTING AROUND HERE.
19	MS. LANSING: I REALLY APPRECIATE, I WANT
20	TO BE VERY CLEAR, EVERYTHING THAT YOU'VE DONE AND
21	HOW VERY, VERY SERIOUSLY ALL OF THE MEMBERS OF THE
22	BOARD ARE TAKING THIS. BUT I WANT TO KNOW THE
23	CONTEXT, AT LEAST AT THE END, JAMES, OR THE
24	BEGINNING OF THE WORKSHOP, WHATEVER YOU'RE
25	COMFORTABLE DOING, SO THAT WE KNOW WHAT WE CAN
	13
	±-3

1	ADDRESS AND WHAT REQUIRES THE CITIZENS TO VOTE ON.
2	DR. SHAPIRO: OKAY. THIS IS THE
3	BACKGROUND OF THE REPORT. YOU READ THIS, YOU ALL
4	HAVE COPIES OF THIS. I'M NOT GOING TO READ THROUGH
5	THIS WHOLE THING. IT JUST TELLS YOU WHAT OUR
6	OBJECTIVES WERE AND SO ON. I JUST WANT TO LOOK TO
7	AT THE THIRD ITEM ON HERE, THE ONE THAT'S READING
8	DOWN HERE, THE THIRD ITEM. THE COMMITTEE WAS NOT
9	CHARGED, I WANT TO BE CAREFUL, WITH RIGOROUSLY
10	EVALUATING THE DETAILS OF CERTAIN SCIENTIFIC
11	CONTRIBUTIONS AND SO ON. THAT'S A VERY IMPORTANT
12	ISSUE, BEEN EVALUATED BY MANY PEOPLE. THAT'S NOT
13	WHAT WE DID. OUR FOCUS WAS ON THE QUALITY OF THE
14	PROCESSES IN PLACE AND WHETHER THEY SERVE THE
15	OBJECTIVES OF CIRM AND THE CITIZENS OF CALIFORNIA.
16	THIS IS ALSO QUITE CRITICAL AND RELATES TO
17	MS. LANSING'S COMMENT JUST MADE A FEW MOMENTS AGO
18	THAT IT IS, FIRST OF ALL, WE WERE NOT ASKED AND WE
19	DID NOT PRESUME TO OPINE ON THE WISDOM OF THE
20	CALIFORNIA VOTERS OR THE CALIFORNIA LEGISLATURE WITH
21	RESPECT TO PROP 71 AND SENATE BILL 1064. WE TOOK
22	THAT AS GIVEN. IT WASN'T OUR AFFAIR.
23	THE SECOND POINT I WANT TO MAKE, THE POINT
24	OF THE SLIDE IS THAT IN OUR OWN ASSESSMENT, WE DID
25	NOT LIMIT OUR CONSIDERATIONS TO THE PARAMETERS

1	IMPOSED BY EITHER PROPOSITION 71 OR 1064. QUITE
2	FRANKLY, IF WE HAD ACCEPTED THOSE, WE COULD HAVE
3	PACKED UP OUR BAGS AND GONE HOME. THERE WAS REALLY
4	NOTHING MUCH TO DO IF WE JUST ACCEPT THAT AS GIVEN
5	AND UNCHANGEABLE. SO WE MADE THAT DECISION EARLY
6	ON, THAT WE WOULD NOT CONFINE OUR RECOMMENDATIONS,
7	RECOGNIZING, AS MS. LANSING JUST POINTED OUT, THAT
8	THERE ARE SOME CONSTRAINTS HERE HOW QUICK YOU CAN
9	MOVE AND IF YOU CAN MOVE. WE CERTAINLY UNDERSTAND
10	THAT.
11	HERE'S THE COMMITTEE'S CHARGE. I'M NOT
12	GOING TO GO THROUGH THESE DETAILS HERE. YOU CAN
13	PICK THEM UP. WE DID LOOK AT CIRM'S INITIAL
14	PROCESSES, THE PROGRAMMATIC AND SCIENTIFIC SCOPE.
15	THIS IS WHAT WE WERE ASKED TO DO IN THE CHARGE. WE
16	LOOKED AT THE ORGANIZATION AND MANAGEMENT SYSTEMS.
17	AND YOU CAN LOOK AT THE DETAILS HERE AT YOUR
18	LEISURE. THE FUNDING MODEL, THE FUNDING MODEL WAS
19	VERY INNOVATIVE IN CERTAIN WAYS, AND TRIED TO REACH
20	SOME CONCLUSIONS REGARDING THAT AS A MODEL FOR
21	OTHERS OR AS A MODEL FOR CIRM. AND, OF COURSE,
22	CIRM'S INTELLECTUAL PROPERTY POLICY. THESE WERE THE
23	THINGS WE WERE ASKED TO DO, AND WE DID OUR BEST TO
24	LOOK AT ALL THESE FUNCTIONS.
25	I DON'T WANT TO STAY ON THIS SLIDE VERY

LONG EITHER. THESE ARE JUST THE 13 MEMBERS OF THE
COMMITTEE WHO, AS YOU SEE, HAD EXPERTISE IN A BROAD
SET OF ISSUES BECAUSE CIRM ITSELF HAS A VERY BROAD
SCOPE IN ITS OWN PORTFOLIO.
HERE I WANT TO SPEND JUST A FEW MOMENTS ON
THE METHODS WE USED. WE TRIED TO GATHER AS MUCH
INFORMATION AS WE COULD NOT ONLY ABOUT PROPOSITION
71 AND SENATE BILL 1064. WE LOOKED AT THE ECONOMIC
ANALYSIS REPORT THAT HAD BEEN THERE BEFORE. WE
LOOKED AT THE STRATEGIC PLANS THAT HAVE BEEN
DEVELOPED BY CIRM OVER TIME. WE LOOKED AT ALL THE
OUTSIDE EVALUATIONS THAT HAVE MADE OF CIRM, WHICH
WERE QUITE A FEW. WE MADE MANY REQUESTS FOR DATA.
I WON'T GO OVER THAT RIGHT NOW.
WE HELD PUBLIC MEETINGS. WE HAD INVITED
SPEAKERS; WE HAD OPEN FORUMS WITH THE PUBLIC. AS
YOU SEE ON THAT SLIDE HERE, WE MET IN WASHINGTON,
SAN FRANCISCO, AND IN IRVINE. THOSE ARE THE THREE
PLACES WE MET. WE ALSO HAD, SO TO SPEAK, ADJUNCT
MEETINGS MAINLY WITH THE GROUP THAT WAS WORKING ON
THE SCIENCE AND SCIENCE ISSUES IN TORONTO AND
BOSTON, TWO IMPORTANT CENTERS, NOT THE ONLY
IMPORTANT CENTERS, BUT TWO IMPORTANT CENTERS IN
REGENERATIVE MEDICINE.
WE MADE SITE VISITS TO UC DAVIS, STANFORD,
16

1	AND UCSF. I MYSELF MADE VISITS TO STANFORD AND
2	UCSF. PROFESSOR MAGNUSON, MY VICE CHAIR, WENT TO
3	DAVIS ALONG WITH OTHER MEMBERS OF THE COMMITTEE.
4	AND WE, OF COURSE, HAD A LARGE NUMBER OF INTERVIEWS
5	WITH VARIOUS PEOPLE IN INDUSTRY AND ACADEMIC LIFE,
6	SO ON AND SO FORTH. THE ONLY PURPOSE OF ALL THESE
7	SLIDES IS JUST TO SAY THAT WE DID OUR BEST TO GATHER
8	AS MUCH INFORMATION AND JUDGE THEM AS WE COULD.
9	FINALLY, WE SENT OUT A WHOLE SERIES OF
10	QUESTIONNAIRES TO DIFFERENT GROUPS. AS YOU CAN SEE
11	HERE, MEMBERS OF THIS BOARD, LEADERSHIP OF
12	CIRM-FUNDED INSTITUTIONS, CIRM PRINCIPAL
13	INVESTIGATORS, SO ON AND SO FORTH. WE TRIED TO BE
14	AS COMPREHENSIVE AS OUR RESOURCES AND TIME ALLOWED.
15	WE FOUND THEM INDEED EXTREMELY VALUABLE.
16	SO I'M NOT SURE QUITE HOW TO CHARACTERIZE
17	OUR KEY MESSAGES, BUT I'LL TRY IN A FEW MOMENTS.
18	FIRST OF ALL, THE FIRST BULLET ON THIS SLIDE REALLY
19	CANNOT BE OVERSTATED. I'VE ALREADY STATED YOU HAVE
20	EVERY REASON TO BE EXTRAORDINARILY SATISFIED WHAT
21	HAPPENED DURING THE FIRST PERIOD. I CALL IT THE
22	FIRST PERIOD SINCE 2006 OR 2004, WHICHEVER DATE YOU
23	WANT TO USE, AND BEFORE THAT IN PUTTING THE CAMPAIGN
24	TOGETHER. IT'S BEEN AN EXTRAORDINARY SUCCESS IN
25	ALMOST EVERY DIMENSION.
	17
	17

1	BUT WE DO THINK THAT AS CIRM GOES AHEAD,
2	IT'S JUST NOT NECESSARILY THE CASE THE STRUCTURE YOU
3	STARTED OUT WITH SHOULD REALLY SERVE CIRM BEST GOING
4	FORWARD. NOT EVERYTHING YOU DID WAS PERFECT, NOT
5	EVERYTHING WAS PUT IN PLACE, AND PROPOSITION 71
6	ISN'T PERFECT, AT LEAST NOT IN OUR JUDGMENT, SO
7	CONSIDERING SOME CHANGES IS REALLY VERY IMPORTANT.
8	AND THE THREE SUB-BULLETS UNDER THAT
9	SECOND POINT THERE TALK ABOUT A COHESIVE
10	LONGITUDINAL AND INTEGRATED EXTERNAL ADVICE. ONE OF
11	OUR MAIN RECOMMENDATIONS IS TO APPOINT AN EXTERNAL
12	SCIENTIFIC ADVISORY COMMITTEE ON A PERMANENT BASIS
13	TO ADVISE BOTH MANAGEMENT AND THE BOARD. I'LL TALK
14	A LITTLE LATER ABOUT RESTRUCTURING THE GRANT
15	APPLICATION PROCESS AND SO ON. AND WHILE, AS IT
16	SAYS HERE, THE GOVERNANCE STRUCTURE MAY HAVE BEEN
17	EVEN OPTIMAL IN THE INITIAL STAGE, WE HAVE SOME
18	SUGGESTIONS ABOUT HOW YOU MIGHT CONSIDER CHANGING.
19	SO HERE ARE THE KEY AREAS OF THE REPORT.
20	WE GO OVER THE INITIAL PROCESSES AND FUNDING MODEL
21	THAT CIRM PUT IN PLACE. WE THEN LOOKED AT THE
22	GOVERNANCE, ORGANIZATION, AND MANAGEMENT STRUCTURE.
23	WE HAVE RECOMMENDATIONS THERE. WE LOOKED AT THE
24	NATURE AND SCOPE OF THE ACCOMPLISHMENTS OF CIRM'S
25	SCIENTIFIC PROGRAM AND, OF COURSE, THEN CIRM'S
	18
	±0

1	INTELLECTUAL PROPERTY. THIS IS JUST REPEATING WHAT,
2	IN FACT, WE WERE ASKED TO DO.
3	NOW, LET'S TALK ABOUT EACH OF THESE
4	SEPARATELY. THIS IS THE INITIAL PROCESSES AND
5	FUNDING CONCLUSIONS. AND, AGAIN, I'M REPEATING
6	MYSELF, BUT I THINK THIS IS IMPORTANT TO US AND
7	IMPORTANT TO YOU, THAT AT THE TIME OF ITS
8	ESTABLISHMENT, SEEMS LIKE A LONG TIME AGO, BUT IT'S
9	NOT VERY LONG AGO, CIRM WAS AN EXCITING, NOVEL,
10	IMAGINATIVE, AND GENUINE SOCIAL INNOVATION. I KNOW
11	I'VE ALREADY SAID THAT ONCE OR TWICE. I'M SAYING IT
12	AGAIN NOW BECAUSE I THINK WHAT HAPPENED IN THOSE
13	INITIAL YEARS IS QUITE EXTRAORDINARY.
14	IT'S CLEAR THAT THE STABILITY OFFERED BY
15	THE NATURE OF PROPOSITION 71, THE FUNDING MODEL THAT
16	WAS PUT IN PLACE WAS VERY ADVANTAGEOUS FOR A NUMBER
17	OF REASONS. I WON'T GO INTO THEM. THE ONLY POINT I
18	WANT TO MAKE HERE IS CIRM HAS TAKEN FULL ADVANTAGE
19	OF THESE THINGS. HAVING PUT IT IN PLACE IS ONE
20	THING, BUT TAKING FULL ADVANTAGE OF THE STABILITY OF
21	FUNDING, PROTECTION FROM CURRENT CONTROVERSIES AND
22	SO ON WAS EXTRAORDINARILY IMPORTANT, AND CIRM HAS
23	TAKEN FULL ADVANTAGE OF THIS. AND FOR THAT YOU
24	DESERVE A GREAT DEAL OF CREDIT.
25	NOW, THERE WAS SOME INTEREST IN THE
	19

1	STATEMENT OF TASK REGARDING LONG-TERM ECONOMIC
2	IMPACT OF CIRM. THE SIMPLE AND VERY UNSATISFYING
3	CONCLUSION IS IT'S NOT POSSIBLE TO DO ANYTHING BUT
4	SPECULATE ON THAT AT THIS MOMENT. IT'S TRUE THAT
5	SPENDING \$300 MILLION A YEAR GENERATES ECONOMIC
6	ACTIVITY BESIDES SCIENTIFIC ACTIVITY; BUT THAT'S
7	ALSO TRUE THAT ANYTIME YOU SPEND \$300 MILLION
8	THOUGHTFULLY, IT GENERATES ECONOMIC ACTIVITY. CIRM
9	IN SOME SENSE IS NOT COMPLETELY UNIQUE IN THAT
10	RESPECT.
11	BUT WHAT IS REALLY MUCH MORE INTERESTING,
12	AND I THINK WHAT THE BOARD WISELY HAD IN ITS MIND,
13	IS THE LONG-TERM ECONOMIC IMPACT WHEN SOMETHING
14	ACTUALLY COMES OUT OF THE SCIENTIFIC PROGRAM. OUR
15	VIEW IS IT'S JUST NOT POSSIBLE TO DO ANYTHING BUT
16	SPECULATE ON THAT AT THE MOMENT. IT IS VERY, VERY
17	DIFFICULT TO GENERATE AND GET ESTIMATES OF ECONOMIC
18	RATE OF RETURN ON ANY INVESTMENT IN SCIENCE AND
19	TECHNOLOGY, BUT ESPECIALLY ONE THAT IS BOTH IN ONE
20	PARTICULAR POINT OF THE SCIENTIFIC FRONTIER AND
21	WHICH IS INTERACTING WITH WORK GOING ON ELSEWHERE
22	AROUND THE WORLD ALL THE TIME. YOU'RE HELPING YOUR
23	COLLEAGUES ELSEWHERE, THEY ARE HELPING YOU. AND
24	TRYING TO TEASE THAT OUT, THAT'S NOT POSSIBLE. IT
25	MAY NEVER BE POSSIBLE, BUT IT'S CERTAINLY NOT

1	POSSIBLE AT THIS TIME.
2	SO I THINK ONE HAS TO BE MODEST IN ANY
3	CLAIMS ONE MAKES IN THIS REGARD. CIRM HAS ENOUGH
4	PERFECTLY DEMONSTRABLE CLAIMS TO TALK ABOUT. AND
5	THIS IS ONE WHICH I THINK ONE JUST HAS TO SAY IT'S
6	SOMETHING WE'LL KNOW A LITTLE BIT MORE ABOUT IN THE
7	FUTURE.
8	WE HAVE A RECOMMENDATION WHICH IS REALLY
9	NOT WON'T BE ANY USE TO YOU. WE CALL IT A
10	SUSTAINABILITY PLATFORM. WON'T GO OVER THE DETAILS
11	HERE. JUST THAT WE THINK, AS I THINK CIRM IS
12	ALREADY DEEPLY ENGAGED IN, IT'S TIME TO DEVELOP SOME
13	SCENARIOS REGARDING HOW CIRM WILL PROCEED IN THE
14	FUTURE UNDER DIFFERENT ASSUMPTIONS ABOUT WHAT THE
15	STATE'S LEVEL OF SUPPORT MIGHT OR MIGHT NOT BE
16	DURING THAT PERIOD. WE THINK THAT'S SOMETHING WHICH
17	IS PART NOT ONLY OF INTERNAL DISCUSSION, BUT
18	EXTERNAL DISCUSSION BECAUSE CIRM HAS ASSETS. THOSE
19	ASSETS BELONG TO IT AND THEY NEED TO BE DEPLOYED
20	EFFECTIVELY IN THE FUTURE REGARDLESS OF WHAT THE
21	STATE FUNDING SCENARIO IS. AND WE THINK THAT THAT'S
22	IMPORTANT, AND IT NEEDS TO BE SUSTAINED AND
23	DISCUSSED WITH THE PUBLIC WHEN THE TIME COMES WHEN
24	YOU FEEL YOUR OWN THINKING HAS MADE SUFFICIENT
25	PROGRESS.

1	NOW, LET'S TALK ABOUT GOVERNANCE,
2	ORGANIZATION, AND SO ON AND SO FORTH. HERE I WILL
3	NOT GO THROUGH THE DETAILS OF THIS AT ALL BECAUSE
4	YOU HAVE IT ALL BEFORE YOU, AND I DON'T WANT TO TAKE
5	THE TIME.
6	PROBABLY IF I COULD TRY TO PUT MY FINGER
7	ON WHAT I THINK ARE THE MOST IMPORTANT ELEMENTS OF
8	THE GOVERNANCE STRUCTURE THAT WE THINK DESERVES SOME
9	ATTENTION AND ARE RELATED TO SOME OF THE ISSUES WE
10	WANT TO BRING UP WITH RESPECT TO SCIENTIFIC REVIEW
11	AND SO ON IS, FIRST OF ALL, WE THINK IT'S HELPFUL TO
12	SEPARATE MANAGEMENT FROM OVERSIGHT. IN OUR VIEW,
13	THE KEY FUNCTION OF THIS BOARD IS TO PROVIDE
14	LONG-TERM STRATEGIC PLANNING, LONG-TERM STRATEGIC
15	VIEWS OF WHAT PROGRAMS YOU WANT TO CARRY OUT, AND
16	PROVIDE INDEPENDENT OVERSIGHT OF MANAGEMENT.
17	TO THE EXTENT THE BOARD BECOMES FULLY
18	INVOLVED IN MANAGEMENT, YOU LOSE YOUR CAPACITY TO
19	HAVE ANY INDEPENDENT OVERSIGHT OF WHAT'S GOING ON.
20	WE THINK THE COMMITTEE, THAT INDEPENDENT OVERSIGHT
21	IS REALLY A CRITICAL ASPECT OF THIS GOING FORWARD.
22	AND SO WE THINK THAT, TO THE EXTENT THAT YOU COME TO
23	BELIEVE IT'S POSSIBLE OR DESIRABLE, TO THE EXTENT
24	YOU CAN SEPARATE YOURSELF FROM THE ONGOING
25	MANAGEMENT OF CIRM, I THINK EVERYONE IS WELL SERVED
	22

1	AND FOCUSED ON THE VERY LONG-TERM STRATEGIC
2	PLANNING, NOT EVEN VERY LONG-TERM STRATEGIC PLANNING
3	GENERALLY, WHICH PROGRAMS YOU WANT TO SPONSOR, BUT
4	NOT TO BE INVOLVED IN THE DAY-TO-DAY MANAGEMENT.
5	PROBABLY ONE OF THE IMPLICATIONS OF THAT
6	IS THE COMPOSITION OF THE WORKING GROUPS. RIGHT NOW
7	MEMBERS OF THE BOARD, NOT ALL MEMBERS OF THIS BOARD,
8	MEMBERS OF THE BOARD ARE FUNCTIONING AS MEMBERS OF
9	THE WORKING GROUP. SO THE MEMBERS OF THE BOARD ARE
10	INTIMATELY INVOLVED IN MANAGEMENT, AND IT'S VERY
11	HARD TO PROVIDE INDEPENDENT OVERSIGHT OF THOSE
12	WORKING GROUPS AND THE RECOMMENDATIONS THEY COME AND
13	BRING TO YOU REGARDING FUNDING AND SO ON. AND SO
14	OUR VIEW IS MEMBERS OF THIS BOARD OUGHT NOT TO SERVE
15	ON THE WORKING GROUPS. THE WORKING GROUPS ARE THE
16	HEART OF THE MANAGEMENT STRUCTURE AND REPORTS
17	THROUGH THEM, AND, OF COURSE, RESPONSIBLE TO THE
18	BOARD ULTIMATELY.
19	WE ALSO THINK THAT THE PATIENT ADVOCACY
20	COMMUNITY PLAYS A VERY IMPORTANT ROLE IN CIRM'S
21	OPERATIONS. AND THAT SHOULD CERTAINLY BE CONTINUED
22	AND EVEN ENHANCED BY, IN OUR VIEW, ONE WAY TO DO
23	THAT IS TO HAVE ADDITIONAL NOT HAVE BOARD MEMBERS
24	SERVE IN THE WORKING GROUPS, BUT PROVIDE AN EQUAL
25	NUMBER OF PATIENTS FROM THE PATIENT ADVOCACY

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1	COMMUNITY WHO WOULD BE APPOINTED TO THESE WORKING
2	GROUPS, SO THEY WOULD CONTINUE TO HAVE THE INPUT
3	WHICH WE THINK IS HIGHLY APPROPRIATE REGARDING THE
4	ONGOING GRANT REVIEW PROCESS. SO
5	MS. LANSING: I'M SORRY I'M THE ONLY ONE
6	THAT HAS ALL THESE QUESTIONS. SO WHAT YOU ARE
7	SUGGESTING, I WANT TO BE CLEAR I UNDERSTAND THIS
8	BECAUSE I DIDN'T GET THIS FROM THE REPORT, YOU'RE
9	SUGGESTING NOT TO HAVE PATIENT ADVOCATES ON ALL THE
10	COMMITTEES, BUT THAT THEY SHOULDN'T BE BOARD MEMBERS
11	AND THEY WOULD STILL BE VOTING MEMBERS THEN?
12	DR. SHAPIRO: YES. JUST AS IT IS NOW,
13	JUST THAT YOU HAVE OTHER PEOPLE THAT ARE PATIENT
14	ADVOCATES FROM THE PATIENT ADVOCACY COMMUNITY ON
15	THIS BOARD, WHICH CERTAINLY SHALL CONTINUE.
16	MS. LANSING: JAMES, IS THAT PART MAYBE
17	THIS ISN'T THE PLACE TO DO IT. IF YOU WANT TO, WE
18	CAN WAIT ON ALL THIS. IS THAT CONSTITUTIONALLY
19	PERMISSIBLE FOR US?
20	MR. HARRISON: I'LL JUST STATE BRIEFLY
21	THAT WE'RE PREPARING AN ANALYSIS OF ALL OF THE
22	RECOMMENDATIONS TO IDENTIFY WHICH COULD BE
23	ACCOMPLISHED BY POLICY, WHICH WOULD REQUIRE
24	LEGISLATION, AND WHICH WOULD REQUIRE ANOTHER VOTE OF
25	THE PEOPLE.
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	24

1	I'LL JUST STATE GENERALLY THE RULE IN
2	CALIFORNIA UNDER THE CONSTITUTION IS THAT AN
3	INITIATIVE CAN ONLY BE AMENDED BY ANOTHER VOTE OF
4	THE PEOPLE UNLESS IT EXPRESSLY PERMITS AMENDMENT BY
5	THE LEGISLATURE. PROP 71 DOES PERMIT AMENDMENT BY
6	THE LEGISLATURE TO FURTHER THE PURPOSES OF THE GRANT
7	AND LOAN PROGRAM. THERE ARE A NUMBER OF CASES THAT
8	ADDRESS THE SCOPE OF THE LEGISLATURE'S AUTHORITY
9	UNDER SIMILAR CIRCUMSTANCES. SO WE WILL PROVIDE YOU
10	WITH A DETAILED ANALYSIS RELATING TO EACH OF THE
11	RECOMMENDATIONS AND EXPLAINING WHY IT COULD EITHER
12	BE ACCOMPLISHED BY A POLICY, LEGISLATION, OR,
13	INSTEAD, WOULD REQUIRE ANOTHER BALLOT MEASURE.
14	MS. LANSING: THANK YOU. THAT'S SO
15	IMPORTANT FOR US BECAUSE I THINK THESE ARE ALL
16	REALLY INTERESTING, BUT IF OUR HANDS ARE TIED OR IF
17	THEY'RE NOT TIED, THAT MAKES OUR WORK
18	DR. SHAPIRO: FULLY UNDERSTAND AND
19	APPRECIATE THAT, AND THERE MAY BE OTHER ISSUES THAT
20	COME UP YOU WANT TO DISCUSS.
21	MS. LANSING: THERE MAY BE WAYS OF
22	ENHANCING THINGS EVEN IF OUR HANDS ARE TIED.
23	DR. SHAPIRO: WE ALSO THINK, AGAIN, TRYING
24	TO HIT ONLY THE MORE IMPORTANT PARTS OF THE
25	GOVERNANCE, WE ALSO THINK IT WOULD BE HELPFUL TO
	25
	25

1	HAVE MORE INDEPENDENT MEMBERS OF THE BOARD. WE
2	DON'T HAVE A PARTICULAR RECOMMENDATION, BUT, QUITE
3	FRANKLY, THE MAIN SENSE OF WHAT WE HAVE IS YOU
4	SHOULD INCREASE THE NUMBER OF INDEPENDENT MEMBERS OF
5	THE BOARD WHO DON'T HAVE SUCH A DIRECT STAKE IN THE
6	OUTCOME OF THE BOARD'S DECISIONS.
7	AND THAT'S SOMETHING WE JUST HOPE YOU WILL
8	CONSIDER. HOW TO DO IT, OVER WHAT TIME TO DO IT,
9	WHAT THE NUMBERS SHOULD ACTUALLY BE IS SOMETHING, OF
10	COURSE, YOU WILL HAVE SOME INPUT ON.
11	CHAIRMAN THOMAS: WHEN WE'RE TRYING TO
12	THINK ABOUT THE NOTION OF INDEPENDENT MEMBERS, IN
13	THE CONTEXT OF CONFLICT OF INTEREST, GENERALLY THAT
14	REFERS TO THOSE WITH POTENTIAL ECONOMIC INTEREST.
15	ARE YOU INCLUDING THE PATIENT ADVOCATES ON THE BOARD
16	FOR THE PURPOSES OF THAT CONFLICT OF INTEREST
17	ANALYSIS?
18	DR. SHAPIRO: YES, WE DO. WE THINK
19	FINANCIAL CONFLICT OF INTEREST IS NOT THE ONLY KIND
20	OF CONFLICT. I WANT TO BE CLEAR. CONFLICT OF
21	INTEREST DOES NOT DISQUALIFY SOMEONE FROM BEING ON
22	THE BOARD. THE ONLY THING THAT'S IMPORTANT IS THE
23	BOARD HAVE ITS OWN PROCEDURES ON MANAGING CONFLICT
24	OF INTEREST. AND WE THINK ONE OF THE WAYS OF DOING
25	THAT IS BY INCREASING THE NUMBER OF INDEPENDENT
	26
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1	MEMBERS ON THE BOARD, BUT YOU MAY HAVE OTHER WAYS
2	YOU WANT TO MANAGE IT. SO THAT I UNDERSTAND YOU'RE
3	NOT GOING TO HAVE ON THE BOARD SOMEONE WHO HAS NO
4	INTEREST AT ALL IN WHAT YOU DO. THAT'S SORT OF
5	SILLY. SO IF YOU TAKE THIS OUT TO SORT OF THE
6	ULTIMATE THING, YOU GET TO SOMETHING WHICH IS PRETTY
7	SILLY. BUT I THINK THE KIND OF CONFLICTS THAT EXIST
8	RIGHT NOW ARE VERY DIRECT AND VERY MAJOR, AND SO
9	THEY HAVE TO BE HANDLED IN SOME WAY.
10	YOU WILL HAVE TO DECIDE IN WHAT WAY YOU
11	WANT TO HANDLE THEM. AND OUR JUDGMENT IS THAT IT
12	WILL BE VERY HEALTHY FOR THE ORGANIZATION TO JUST
13	HAVE MORE INDEPENDENT MEMBERS AS ONE WAY OF DEALING
14	WITH THIS ISSUE. THERE MAY BE OTHER WAYS OF DEALING
15	WITH IT ALSO.
16	MR. TORRES: ON THAT ISSUE I THINK ON A
17	TELEPHONE CONVERSATION WE HAD EARLIER IN THE
18	PRELIMINARY REVIEW, I REFERENCED THIS SUBCONSCIOUS
19	BIAS THAT WAS IN THE REPORT THAT WAS AFFIRMED, AS
20	THE REPORT SAID, BY BEHAVIORAL AND PSYCHOLOGICAL
21	STUDIES. I NEVER GOT A COPY OF THOSE STUDIES, AND
22	I'M TRYING TO FIGURE OUT WHAT DID YOU ALL HAVE IN
23	MIND AS TO HOW TO MEASURE THAT SUBCONSCIOUS BIAS
24	THAT IS NOT RELATED TO FINANCIAL CONFLICT OF
25	INTEREST, BUT TO HOW YOU REFERENCE CERTAIN PEOPLE

1	WHO HAVE DISEASES. FOR EXAMPLE, I'M A COLON CANCER
2	SURVIVOR. DOES THAT MEAN I HAVE AN UNCONSCIOUS BIAS
3	TO SUPPORT SCIENTIFIC GRANTS THAT DEAL WITH COLON
4	CANCER? MY RECORD SHOWS THAT I HAVE NOT.
5	SO HOW DO I MEASURE THAT, WHETHER I'M
6	ALLOWED TO CONTINUE TO SERVE AS A PATIENT ADVOCATE,
7	IF I HAVE A, QUOTE, PSYCHOLOGICAL, BEHAVIORAL,
8	SUBCONSCIOUS BIAS AS THE REPORT ALLUDES TO?
9	DR. SHAPIRO: MANY CONFLICTS OF INTEREST
10	COULD BE HANDLED BY DISCLOSURE, NOT NECESSARILY BE
11	HANDLED BY HAVE YOU NOT SERVE ON THE BOARD. I'M NOT
12	SUGGESTING AND WE'RE SUGGESTING THAT PEOPLE WITH ANY
13	CONFLICT, WHETHER FINANCIAL OR OTHERWISE, NOT BE
14	ELIGIBLE FOR THIS BOARD. WE JUST THINK IT'S
15	IMPORTANT FOR THE BOARD TO MANAGE THIS CAREFULLY AND
16	THOUGHTFULLY, HAVE INTERNAL DISCUSSIONS ON IT. AND
17	I KNOW THAT WE PROMISED AND I'M GOING TO SEND YOU
18	SOME REFERENCES.
19	MR. TORRES: THANK YOU AGAIN BECAUSE
20	YOU'VE BEEN VERY FORTHCOMING IN ALL THE
21	CONVERSATIONS THAT YOU AND I HAVE HAD. BUT THE FACT
22	THAT, IN YOUR OPINION, THAT I DISCLOSED EARLY ON
23	BEFORE I WAS ELECTED VICE CHAIR OF THIS BOARD THAT I
24	AM A COLON CANCER SURVIVOR MIGHT BE SUFFICIENT TO
25	DEAL WITH THE PERCEIVED CONFLICT OF INTEREST.

1	DR. SHAPIRO: MY OWN VIEW, AS LONG AS
2	THOSE DISCUSSIONS ARE OPEN AND DISCUSSED AMONGST
3	YOURSELVES, THE BOARD, THAT'S JUST FINE. BUT I DO
4	THINK THERE IS NO SUBSTITUTE FOR HAVING, THIS IS MY
5	OWN VIEW, HAVING MORE INDEPENDENT MEMBERS OF THE
6	BOARD WHO DON'T HAVE SUCH A DIRECT CONFLICT. I'M
7	NOT TALKING ABOUT PATIENT ADVOCATES NECESSARILY, BUT
8	PEOPLE WHO ARE DIRECT RECIPIENTS OF GRANTS.
9	MR. SHEEHY: I GUESS I DO WANT TO KIND OF
10	DRILL DOWN ON THIS PATIENT ADVOCATE ISSUE BECAUSE
11	THE REPORT SAYS THAT THERE'S AN INHERENT CONFLICT
12	WITH THE PATIENT ADVOCATES. I KIND OF SCRATCH MY
13	HEAD BECAUSE I AM FROM THE HIV COMMUNITY, AND THAT'S
14	WHY I WAS PUT ON THIS BOARD. YOU KNOW, I LOST MY
15	DAD LAST WEEK TO ALZHEIMER'S. I LOST MY MOM TO
16	OVARIAN CANCER. IF I WERE TO QUEUE UP WHAT WAS MOST
17	IMPORTANT TO ME, IT'S A HARD RACE TO SAY WHAT'S
18	TOUGHER TO WATCH, YOUR MOTHER DIE FROM OVARIAN
19	CANCER OR YOUR FATHER FROM ALZHEIMER'S.
20	I GUESS WHAT YOU'RE TALKING ABOUT IS THAT
21	WE SHOULD ALL TALK ABOUT BEFORE WE ENGAGE IN ANY
22	DISCUSSION ABOUT HOW OUR FAMILY MEMBERS, OUR
23	IMMEDIATE FAMILY MEMBERS, HAVE BEEN IMPACTED BY THE
24	VARIOUS DISEASES AND CONDITIONS THAT WE MAY BE
25	VOTING ON. AND I WONDERED SHOULD WE ALL HAVE A
	29

1	DISCLOSURE THAT INCLUDES THE PERSONAL HEALTH
2	INFORMATION ABOUT OURSELVES, ABOUT OUR FAMILY
3	MEMBERS? AND SHOULD THAT ALSO PERTAIN TO STAFF?
4	I'VE HAD VERY INTERESTING DISCUSSIONS WITH STAFF
5	ABOUT THE IMPACT OF DISEASE ON THEM. AND I DON'T
6	KNOW WHERE YOU DRAW THE CIRCLE.
7	IT'S ALMOST IT'S HARD FOR ME TO SEE HOW
8	YOU MIGHT SAY I WOULD BE CONFLICTED WITH HIV WHERE I
9	REALLY DO HAVE A FAIRLY REASONABLE GRASP OF THE
10	SCIENCE AND WHAT'S GOING ON IN THE FIELD. AND SO
11	I'M MUCH MORE LIKELY TO BE RATIONAL IN MY
12	DECISION-MAKING AND, IN FACT, I'VE NOT SUPPORTED
13	GRANTS IN HIV THAT I DIDN'T THINK MOVED THE SCIENCE
14	FORWARD. WHEREAS, IN ANOTHER DISEASE, PERHAPS
15	ALZHEIMER'S, WHICH I CAN'T CLAIM A GREAT DEAL OF
16	KNOWLEDGE ABOUT THE PROCESSES AND THE STATE OF THE
17	SCIENCE, I MIGHT BE MORE PRONE TO BE EMOTIVE. AM I
18	JUST DISQUALIFIED AS A PATIENT ADVOCATE BECAUSE
19	THERE'S SOME SUGGESTION THAT PATIENT ADVOCATES I
20	JUST DON'T UNDERSTAND WHAT YOU SEE THE ROLE OF
21	PATIENT ADVOCATES IS IN THIS WHOLE PROCESS BECAUSE
22	WE HAVE SOMETHING, AND I TRIED TO EXPLAIN TO YOU,
23	YOU GAVE ME THE OPPORTUNITY, THE POWER AND THE
24	IMPACT.
25	IT SEEMS LIKE ONE OF YOUR KEY
	30
25	IT SEEMS LIKE ONE OF YOUR KEY 30

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1	RECOMMENDATIONS IS TO DECONSTRUCT THE ROLE OF THE
2	PATIENT ADVOCATES IN THIS ENTERPRISE. JUST
3	EVERYBODY TALKS ABOUT HIV AS A MODEL. AND WE DIDN'T
4	CREATE THAT MODEL. WE DIDN'T FURTHER THAT MODEL BY
5	TRYING TO CUT THE LEGS OFF PATIENT ADVOCATES AT THE
6	FIRST OPPORTUNITY. I THINK OTHER PEOPLE HAVE KIND
7	OF TAKEN THAT MODEL AND MOVED IT FURTHER.
8	I HAVE A CLOSE FAMILY MEMBER SUFFERING
9	FROM CANCER THEY INITIALLY DIAGNOSED AS BREAST
10	CANCER. SHE WAS ACTUALLY DISAPPOINTED IT WASN'T
11	BREAST CANCER BECAUSE OF THE INCREDIBLE WORK IN THE
12	BREAST CANCER COMMUNITY IN ADVANCING THERAPIES. AND
13	THERE'S SEVERAL PHENOMENAL GROUPS WORKING IN BREAST
14	CANCER. IT WOULD SEEM TO ME THE FUNDING, THE
15	ADVANCEMENT OF SCIENCE THAT TAKES PLACE WITH THE
16	ACTIVE, DYNAMIC PARTICIPATION OF PATIENT ADVOCATES
17	SHOULD BE SOMETHING THAT THE INSTITUTE OF MEDICINE,
18	THE BIOMEDICAL RESEARCH COMMUNITY AS A WHOLE WOULD
19	WANT TO FURTHER INSTEAD OF TRIP.
20	THERE'S SUCH A STRONG RELATIONSHIP BETWEEN
21	THE ABILITY OF OBTAINING FUNDING FOR ALL THE WORK
22	THAT WE'RE DOING AND THE HEAVY INVOLVEMENT,
23	COMMITTED, PASSIONATE WORK OF PATIENT ADVOCATES. I
24	JUST I SAID IN THE REVIEW GROUP, I CAN'T TELL YOU
25	HOW MANY TIMES REVIEWERS HAVE THANKED US FOR BEING

1	THERE, FOR OFFERING OUR INPUT. AND EVEN THOUGH
2	SOMETIMES THE STUFF WE SAY ISN'T RIGHT TO THE POINT
3	AND IT'S NOT SCIENTIFICALLY ACCURATE, WHAT WE BRING
4	IS A REAL-WORLD KIND OF DEALING WITH THE SUFFERING
5	THAT THESE DISEASES AND CONDITIONS, IT'S A REMINDER
6	OF THE REALITY, RIGHT, THAT FAMILIES AND INDIVIDUALS
7	ACROSS THIS COUNTRY LIVE WITH EVERY DAY, THE
8	TERRIBLE, HORRIBLE REALITY.
9	AND A LOT OF THESE SCIENTIFIC DISCUSSIONS,
10	WHICH I THINK IS WHERE YOU ARE KIND OF SUGGESTING WE
11	GO, ALMOST GETS ESOTERIC, ALMOST FAIRY FEEL LIKE,
12	WELL, THEY DIDN'T WRITE A GOOD PROPOSAL, THEY DIDN'T
13	DOT A T, THEY DIDN'T CROSS AN I, INSTEAD OF, LIKE,
14	THINKING THAT THEY'RE REAL PEOPLE WHOSE LIVES COULD
15	BE IMPACTED BY THE OUTCOMES OF THIS SCIENCE.
16	AND I JUST DON'T KNOW HOW YOU CAN
17	RECONCILE EVERYTHING YOU SAID IN YOUR FIRST SLIDE
18	ABOUT THE TREMENDOUS WORK OF PROP 71 AND CIRM AND
19	THE DEFENESTRATION OF THE PATIENT ADVOCATES THAT YOU
20	HAVE RECOMMENDED IN THIS PROPOSAL.
21	DR. SHAPIRO: WELL, FIRST OF ALL, VERY
22	SORRY TO HEAR ABOUT YOUR FATHER. I REMEMBER YOUR
23	TESTIMONY TO OUR COMMITTEE VERY WELL. I DON'T
24	THINK I DON'T RECOGNIZE OUR RECOMMENDATIONS THE
25	WAY YOU DESCRIBE THEM. WE HAD NO INTENTION TO
	2.2
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1	REDUCE THE ROLE OF PATIENT ADVOCATES WHATSOEVER. IN
2	FACT, A NUMBER OF PATIENT IF YOU WERE ADOPT EVERY
3	SINGLE ONE OF OUR RECOMMENDATIONS, THE NUMBER OF
4	PATIENT ADVOCATES WORKING WITHIN THE CIRM
5	ORGANIZATION WOULD, IN FACT, INCREASE, NOT DECREASE.
6	IT'S THE QUESTION OF JUST WHAT ROLE THEY WOULD HAVE
7	IF THEY'RE ON THE BOARD AND WHAT ROLE THEY WOULD
8	HAVE IN THE WORKING GROUPS.
9	SO, LASTLY, WE DIDN'T HAVE ANY NOTION THAT
10	PATIENT ADVOCATES SHOULD BE EXPELLED FROM THE
11	ORGANIZATION OR THEY SHOULD BE RELEGATED TO SOME
12	UNIMPORTANT. THAT WAS NOT OUR INTENTION AT ALL. I
13	DON'T WANT TO SORT OF ARGUE THIS OUT NOW, BUT I'M
14	JUST SAYING THAT THAT WAS CERTAINLY NOT OUR
15	INTENTION. I DON'T THINK THIS IS THE RESULT OF OUR
16	RECOMMENDATION.
17	MS. LANSING: JEFF, AND, AGAIN, I'M VERY
18	CURIOUS AS TO THE CONSTITUTIONALITY OF ALL THIS.
19	THAT'S REALLY SUCH A KEY THING. I WANT TO SORT OF
20	BE THE HENRY KISSINGER IN THIS, I DON'T KNOW WHAT
21	THE WORD IS, MEDIATOR IN THIS BECAUSE I THINK
22	EVERYTHING JEFF SAID IS TRUE. SPEAKING AS THE
23	CANCER PATIENT ADVOCATE, I THINK THAT EVERYONE
24	WORKED VERY HARD TO GET THIS BILL PASSED. AND A
25	HUGE COMPONENT OF WHY IT WAS PASSED WAS ALL THE

1	DISEASE GROUPS COMING TOGETHER AND ALL THE PATIENT
2	ADVOCATES COMING TOGETHER TO GET THIS PASSED.
3	AND WHEN WE TOOK OUR OATH, ALL OF US,
4	NEVER SAID THAT WE REPRESENT THE CANCER COMMUNITY OR
5	THE HIV. WE REPRESENT THE CITIZENS OF CALIFORNIA.
6	AND I THINK EVERY ONE US OF RECOGNIZES THAT A
7	BREAKTHROUGH IN ALZHEIMER'S CAN LEAD TO A
8	BREAKTHROUGH IN CANCER, CAN LEAD TO A BREAKTHROUGH
9	IN ANY OTHER DISEASE. THAT'S WHY I ASKED THE
10	QUESTION EARLIER ON BECAUSE WHEN I FIRST READ THE
11	REPORT, I SORT OF GOT THE SAME FEELING THAT YOU DO.
12	WHAT I THINK THE REPORT IS SUGGESTING IS
13	NOT THAT THE PATIENT ADVOCATES NOT CONTINUE TO SIT
14	ON THE BOARD AND NOT EVEN THAT THEY NOT PARTICIPATE,
15	BUT THAT WE GET INDEPENDENT PATIENT ADVOCATES TO SIT
16	IN ON THE COMMITTEES.
17	DR. SHAPIRO: DIFFERENT PEOPLE; THAT IS,
18	PATIENT ADVOCATES ON THE BOARD AS CURRENTLY IS THE
19	CASE. THERE'D BE ANOTHER SET OF PATIENT ADVOCATES
20	WORKING WITH THE WORKING GROUPS. I DON'T REALLY
21	WANT TO STAND HERE AND DEBATE THIS, BUT I JUST WANT
22	TO SAY THAT IF WE MADE A MISTAKE, WE MADE A MISTAKE.
23	BUT IT WAS CERTAINLY NOT OUR INTENTION TO DECREASE
24	THE ROLE OF THE PATIENT ADVOCATES. NOT OUR
25	INTENTION AT ALL. I UNDERSTAND EVERYTHING YOU'RE
	34
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1	SAYING.
2	MS. LANSING: I'M NOT SURE WE CAN DO THIS,
3	BY THE WAY, BUT I THINK THE SUGGESTION, IN ALL
4	FAIRNESS, WAS WE WOULD STILL BE ON THE BOARD, BUT
5	THE WORKING GROUPS WOULD BE COMPRISED OF INDEPENDENT
6	PATIENT ADVOCATES FROM EACH OF THE DISEASE GROUPS.
7	NOW, WHETHER WE THINK THAT'S A GOOD SUGGESTION OR
8	NOT IS WHAT WE'RE GOING TO TALK ABOUT IN THE
9	WORKSHOP.
10	THE THING THAT I THINK SOME OF US ARE
11	STRUGGLING WITH, AND, AGAIN, I THINK YOU'VE DONE AN
12	EXCELLENT JOB WITH THIS REPORT, IT IS NOT YOUR
13	PROBLEM AS TO WHAT WE CAN AND CAN'T DO. YOU'RE
14	SUPPOSED TO BE OBJECTIVE AND JUST LOOK AT IT. AND I
15	THINK THAT ALL YOU'RE HEARING FROM PROBABLY EVERYONE
16	IS GREAT RESPECT FOR WHAT YOU'VE DONE. I REALLY
17	WANT TO SAY THAT, AND I THINK IT'S A VERY GOOD
18	REPORT, AND I THINK YOU KIND OF DID IT IN A WAY THAT
19	WAS VERY UNDERSTANDABLE FOR THOSE OF US WHO ARE
20	PATIENT ADVOCATES OR FOR THOSE OF US WHO ARE
21	CONFLICTED AND RUN A HOSPITAL, WHATEVER, OR
22	INSTITUTION.
23	THE CONFLICT THAT YOU'RE FACING IS DO YOU
24	COMPROMISE THIS ORGANIZATION BY NOT HAVING THE BEST
25	PATIENT ADVOCATES AND THE BEST RUNNERS OF THE

1	HOSPITALS AND ASSUME THAT THEY CAN BE OBJECTIVE.
2	AND THAT'S THE ETERNAL QUESTION.
3	DR. SHAPIRO: THE CONFLICT OF INTEREST, I
4	WANT TO REPEAT SOMETHING I SAID BEFORE BECAUSE I
5	THINK IT'S A VERY IMPORTANT ISSUE. CONFLICT OF
6	INTEREST IS NOT SOMETHING THAT SHOULD SOMEHOW BAR
7	YOU FROM PARTICIPATING IN THIS ORGANIZATION IN ANY
8	WAY AS LONG AS THE CONFLICTS ARE OPEN AND MANAGED IN
9	SOME EFFECTIVE WAY.
10	AND THE ISSUE YOU RAISED, WHICH IS A VERY
11	IMPORTANT ISSUE, I'M VERY GLAD YOU RAISED IT, WAS
12	YOU HAVE A MEDICAL RECORD, YOUR FAMILY HAS A MEDICAL
13	RECORD. WHAT HAS TO BE REVEALED ABOUT THAT? THAT'S
14	A VERY DIFFICULT ISSUE BECAUSE YOU HAVE PRIVACY
15	ISSUES AND YOU HAVE CONFLICT OF INTEREST ISSUES. I
16	THINK THERE ARE WAYS TO HANDLE THAT. AND I THINK
17	IT'S NOT NECESSARY THAT ALL THESE BE REVEALED IN
18	PUBLIC. THEY CAN BE REVEALED THROUGH THE GENERAL
19	COUNSEL AND SO ON AND SO FORTH. THERE ARE LOTS OF
20	WAYS OF HANDLING THAT. I THINK THAT'S A VERY
21	IMPORTANT ISSUE, AND I'M GLAD YOU RAISED IT. BUT
22	NONE OF THESE ISSUES BAR PEOPLE FROM PARTICIPATING.
23	THAT'S MY POINT.
24	MS. LANSING: AND THE FACT THAT YOU HAVE
25	THAT CONFLICT OF INTEREST, AND THIS IS WHAT I WAS
	26
	36

1	TRYING TO CONCLUDE WITH, THE FACT THAT YOU ARE A
2	PATIENT ADVOCATE, YOU ARE A PATIENT ADVOCATE BECAUSE
3	YOU HAVE SPENT IN ALL CASES A LIFETIME OF COMMITMENT
4	TO TRYING TO FIND A CURE OR MAKE IT A CHRONIC
5	DISEASE. SO YOU BRING A BREADTH OF KNOWLEDGE, YOU
6	BRING A BREADTH OF PASSION, AND A BREADTH OF
7	COMMITMENT. AND THAT YOU DON'T WANT TO DILUTE, AND
8	HOW YOU BALANCE THAT IS THE CHALLENGE THAT WE HAVE
9	TO FACE.
10	DR. SHAPIRO: I AGREE WITH WHAT YOU SAY.
11	CHAIRMAN THOMAS: MR. SHEEHY AND DR.
12	PRIETO, DEAN POMEROY, AND I SAW ANOTHER HAND OVER
13	THERE, DR. PRICE.
14	MR. SHEEHY: FIRST OF ALL, I HAVE A
15	PROBLEM WITH THE IDEA THAT THERE'S AN INHERENT
16	CONFLICT OF INTEREST IN DISEASE ADVOCATES. THE
17	WHOLE REASON THAT WE'RE VALUABLE TO HAVE IN THE ROOM
18	IS THAT WE BRING A SPECIALIZED EXPERIENCE WITH THE
19	DISEASES UNDER DISCUSSION. WE REALLY BRING THE
20	VOICE OF THE CONSUMER. AND SO TO SAY THAT YOU MIGHT
21	SAY THAT I WOULDN'T BE ABLE TO PARTICIPATE OR THAT I
22	HAVE A CONFLICT OF INTEREST IN AN HIV GRANT, WHICH
23	THAT IS THE WHOLE REASON THAT I BRING VALUE TO THE
24	DISCUSSION, IS TROUBLING TO ME. AND I DON'T THINK
25	YOU FIND THAT REFLECTED IN OTHER AREAS.

1	THE FDA, FOR INSTANCE, DOESN'T ASK FOR
2	NONDISEASE-SPECIFIC PATIENT ADVOCATES. THEY DON'T
3	ASK A CANCER PATIENT ADVOCATE TO SIT IN ON THE
4	APPROVAL OF AN HIV THERAPEUTIC. IT HAS TO BE
5	SOMEONE WHO'S LIVING WITH HIV.
6	SO I DON'T SEE ANY EVIDENCE BASIS. YOU'VE
7	HAD NINE YEARS OF THIS BOARD AND THE WORKING GROUP.
8	I SEE NO EVIDENCE. WE'VE BEEN AUDITED BY THE
9	CONTROLLER'S OFFICE AND THE BUREAU OF AUDITS AT THE
10	STATE, AND THEY SAID WE HAD BETTER CONFLICT OF
11	INTEREST RULES THAN THE NIH. THERE'S NO EVIDENCE
12	BASIS FOR ALLEGING CONFLICT OF INTEREST AGAINST
13	PATIENT ADVOCATES, MYSELF SPECIFICALLY.
14	NO. 2, WHERE THE WORKING GROUP IS
15	CONCERNED, I THINK YOU VERY FUNDAMENTALLY
16	MISUNDERSTAND WHAT IS SO UNIQUE ABOUT PROP 71 ABOUT
17	OUR ENTERPRISE. IT'S ONE THING TO BE A PATIENT
18	ADVOCATE, AND I ACTUALLY GAVE YOU THIS HAS BEEN
19	PUBLISHED IN NATURE MEDICINE. IT'S NOT JUST A SEAT
20	AT THE TABLE. IT'S A REAL SEAT AT THE TABLE.
21	I GUESS <i>NATURE MEDICINE</i> FELT IT WAS
22	COMPELLING ENOUGH TO PUBLISH IT. I GUESS IT DIDN'T
23	MAKE IT INTO YOUR EVIDENCE BASIS FOR MAKING THESE
24	KINDS OF SUGGESTING THESE KINDS OF CHANGES. BUT
25	THE FACT THAT WE CAN HEAR THE DISCUSSION AND THEN
	38

1	COME HERE TO THE BOARD AND VOTE ON THOSE
2	RECOMMENDATIONS IS THE KEY ELEMENT IN THE INFLUENCE
3	AND POWER THAT PATIENT ADVOCATES CAN HAVE. WE'RE
4	NOT ALL POWERFUL. WE'RE A MINORITY ON THE BOARD.
5	WE CAN'T MOVE ANYTHING OUT OF THE GRANTS WORKING
6	GROUP WITHOUT SUPPORT FROM SCIENTIFIC MEMBERS OF THE
7	GRANTS WORKING GROUP. WE'VE NEVER MOVED ANYTHING
8	THAT DID NOT HAVE AND, IN FACT, WE GAVE YOU
9	DOCUMENTATION THAT SHOWED WE'VE NEVER MOVED ANYTHING
10	INDIVIDUALLY HERE AT THE BOARD. ALL THE THINGS THAT
11	WE HAVE GOTTEN THAT PATIENT ADVOCATES HAVE
12	ADVOCATED FOR, THE GRANTS HAVE HAD SUBSTANTIAL
13	SUPPORT FROM SCIENTIFIC MEMBERS OF THE BOARD.
14	SO I REALLY WAS HOPING FOR AN
15	EVIDENCE-BASED ANALYSIS OF WHAT WE DO. AND I'M
16	REALLY HAVING TROUBLE FINDING ANY EVIDENCE. AND THE
17	EVIDENCE THAT EXISTS IN OTHER SPHERES SUGGESTS THAT
18	PATIENT ADVOCATES PLAY AN IMPORTANT ROLE, ESPECIALLY
19	IN ADVOCATING WITHIN THE CONTEXT OF THE VERY DISEASE
20	FROM WHICH THEY HAVE BEEN DRAWN TO THE SEAT AT THE
21	TABLE, AND HERE YOU SEEM TO SAY THAT'S NOT A GOOD
22	IDEA. AND I JUST IF YOU HAD SOME EVIDENCE HERE,
23	I WOULD BE MORE COMFORTABLE, BUT THE ABSENCE OF
24	EVIDENCE AND JUST RHETORIC AND, FRANKLY, ALLEGATIONS
25	I FIND VERY TROUBLING.

DR. PRIETO: THANK YOU. I WAS GOING TO
SAVE FOR THE END, BUT NOW THAT WE'VE ENGAGED IN
DISCUSSION, I'LL GO AHEAD. I'M TRYING TO MAINTAIN
AN OPEN MIND ABOUT THIS PARTICULAR RECOMMENDATION
AND THE GENERAL IDEA THAT IT WOULD BENEFIT US TO
SEPARATE OVERSIGHT FROM MANAGEMENT, AND I UNDERSTAND
THAT CONCEPT. AND MY BASIC INTEREST IS THAT CIRM BE
THE MOST EFFECTIVE ORGANIZATION IT CAN POSSIBLY BE.
I'VE INVESTED A LOT OF TIME AND ENERGY HERE NOW.
ON THIS PARTICULAR ISSUE, I THINK I HAVE
AN INTEREST THAT CUTS BOTH WAYS. ON ONE HAND,
SEPARATING THE PATIENT ADVOCATES ON THE BOARD FROM
THOSE ON THE WORKING GROUP WOULD CUT MY WORKLOAD
TREMENDOUSLY. BUT ON THE OTHER, I THINK IT TOOK A
GREAT DEAL OF TIME FOR THOSE OF US WHO SIT AS
ADVOCATES ON THE GRANTS WORKING GROUP TO GAIN SOME
CREDIBILITY WITH THE SCIENTIST MEMBERS OF THAT GROUP
AND SHOW THEM THAT, IN FACT, WE WERE INTERESTED IN
BRINGING THE BEST SCIENCE AND BEST OPPORTUNITIES FOR
SUCCESS BACK TO THE BOARD.
I THINK WE HAVE THAT NOW, BUT I THINK IT
WOULD BE DIFFICULT OR ANOTHER HILL TO CLIMB FOR
ADVOCATES TO DO THAT. AS JEFF SAID, I THINK AS
BOARD MEMBERS WE DO SERVE A ROLE AS LIAISONS WITHOUT
THE CONFLICT, IF YOU WILL, THAT PERHAPS MEMBERS WHO
40

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1	REPRESENT ORGANIZATIONS THAT RECEIVE GRANTS, SINCE
2	WE DON'T DO THAT, WE CAN COME WITHOUT THAT POTENTIAL
3	CONFLICT AND SAY WE TOOK PART IN THIS DISCUSSION,
4	THIS WAS THE FLAVOR OF THE DISCUSSION, THESE WERE
5	THE SPECIFIC POINTS OR THE GENERAL FEELING OF WHY
6	THIS WAS OR WAS NOT A STRONG ENOUGH GRANT TO
7	RECOMMEND. AND I'M AFRAID IF PATIENT ADVOCATES ON
8	THAT GROUP DID NOT HAVE THE VOICE THAT WE HAVE HERE,
9	THAT THAT WOULD BE LOST.
10	DR. POMEROY: SO I'M GOING TO ADD MY
11	THANKS TO EVERYONE ELSE FOR ALL YOUR HARD WORK ON
12	THIS. AND I THINK YOU CAN FEEL THE PASSION AND
13	DEDICATION OF THE PEOPLE ON THE BOARD AS WE RESPOND
14	TO THESE RECOMMENDATIONS.
15	MY QUESTION IS ON A LITTLE DIFFERENT
16	ASPECT OF THIS. I'M INTRIGUED BY THE RECOMMENDATION
17	THAT THERE SHOULD BE MORE INDEPENDENT MEMBERS. MY
18	QUESTION IS HOW WOULD YOU GET INDEPENDENT SCIENTIFIC
19	EXPERTISE, SO I'M SWITCHING TO THAT CONSTITUENCY ON
20	THE BOARD, WITHIN THE IDEA THAT THERE MIGHT BE SOME
21	CONFLICT OF INTEREST FOR ANYONE AT AN INSTITUTION
22	THAT'S GETTING MONEY? MY SPECIFIC QUESTION IS,
23	PUTTING THE CONSTITUTIONALITY ASIDE, WOULD YOU
24	EXPAND THIS BEYOND PEOPLE WHO LIVE IN CALIFORNIA?
25	DR. SHAPIRO: WELL, I HADN'T THOUGHT. I

1	MYSELF HAVE NO OBJECTION TO THAT, BUT I DON'T THINK
2	THAT'S ABSOLUTELY NECESSARY. CALIFORNIA HAS A GIANT
3	POOL OF EXPERTISE IN THESE AREAS, AND I THINK THAT
4	WOULD NOT BE A PROBLEM. AGAIN, IT'S A MATTER OF
5	BALANCE.
6	IF ONE THOUGHT THAT PARTICULAR
7	RECOMMENDATION WAS USEFUL, ONE DOESN'T HAVE TO GO
8	ALL THE WAY IN THE FIRST DAY. TAKE A STEP, LEARN
9	WHAT TO DO, DOES IT HELP YOU, DOES IT NOT HELP YOU,
10	DOES IT WORK, DOESN'T WORK. I THINK THIS
11	ORGANIZATION IS SMART ENOUGH TO SAY, ALL RIGHT, THIS
12	RECOMMENDATION SEEMS SENSIBLE. LET'S JUST TRY IT.
13	LET'S SEE A LITTLE BIT. LET'S TRY IT IN A SMALL
14	WAY. IF IT WORKS, TAKE ANOTHER STEP. IF IT DOESN'T
15	WORK, TAKE A STEP BACK. AND I JUST THINK THAT THIS
16	IS VERY WELL WORTH CONSIDERING, AND THERE'S
17	DIFFERENT WAYS TO GET VOICES.
18	I UNDERSTAND THAT, FOR EXAMPLE, IF YOU
19	WOULD ACCEPT THE RECOMMENDATION IN PART, THAT THE
20	MEMBERS OF THE ICOC NOT SIT ON THE WORKING GROUPS,
21	YOU CAN SEE HOW THAT WORKS. TRY IT OUT IN ONE OF
22	THE WORKING GROUPS, SEE IF IT WORKS, SEE IF IT HELPS
23	YOU. NOTHING I HAVE SAID, WE HAVE SAID ABOUT
24	CONFLICT OF INTEREST REALLY DEBARS SOMEONE FROM
25	PLAYING A ROLE AT CIRM. ALL WE'RE SAYING IS THESE
	42
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1	THINGS HAVE TO BE RECOGNIZED AND MANAGED IN SOME
2	APPROPRIATE WAY. THAT'S ALL WE'RE SAYING. YOU CAN
3	ALL HAVE ALL KINDS OF CONFLICTS YOU WANT AS LONG AS
4	THEY ARE REVEALED AND DISCUSSED IN SOME SENSIBLE
5	WAY.
6	CHAIRMAN THOMAS: DR. PRICE.
7	DR. PRICE: I'M GLAD YOU ACTUALLY ENDED ON
8	THAT NOTE BECAUSE I THINK WE'D BE REMISS IF WE DO
9	NOT CHALLENGE THE NOTION, THE IMPLICATION THAT WE DO
10	NOT HAVE OR WE DO NOT MANAGE THE INSTITUTIONAL
11	CONFLICTS OF INTEREST. OUR ENTIRE VOTING SYSTEM,
12	DISCUSSION SYSTEM WITH REGARD TO GRANTS APPLICATIONS
13	IS DESIGNED PRECISELY FOR THAT REASON. THE
14	ANONYMITY WHICH WE APPLY TO ALL THE GRANT
15	APPLICATIONS WHEN THEY COME TO OUR BOARD IS DESIGNED
16	PRECISELY TO MANAGE THOSE CONFLICTS OF INTEREST.
17	AND IN SOME INSTANCES PEOPLE HAVE TO LEAVE
18	THE ROOM FOR THE DISCUSSION. SO WE'VE GONE TO GREAT
19	LENGTHS TO MANAGE THOSE CONFLICTS OF INTEREST, WHICH
20	WE RECOGNIZE. I JUST WANT TO LEAVE THAT FOR THE
21	RECORD.
22	CHAIRMAN THOMAS: JAMES, PERHAPS YOU COULD
23	JUST SAY A FEW WORDS ON OUR POLICY SINCE WE ARE ON
24	THE SUBJECT HERE JUST FOR THE RECORD.
25	MR. HARRISON: SO DR. PRICE IS CORRECT.
	43
	13

1	WE DO GO TO GREAT PAINS TO MANAGE AND PREVENT
2	CONFLICTS OF INTEREST FROM OCCURRING. AND PART OF
3	THAT ARISES OUT OF OUR BLIND REVIEW OF APPLICATIONS;
4	THAT IS, APPLICATIONS ARE PRESENTED TO YOU BY
5	APPLICATION NUMBER ONLY WITHOUT REFERENCE TO THE
6	INSTITUTION OR THE PRINCIPAL INVESTIGATOR. AND WE
7	PROVIDE EACH OF YOU WITH A LIST OF THE APPLICATIONS
8	IN WHICH YOU HAVE A CONFLICT BY NUMBER. AND IF ANY
9	OF YOU SHOULD DEIGN TO RAISE YOUR HAND TO SUGGEST
10	YOU WANT TO SPEAK ON SOMETHING FOR WHICH YOU HAVE A
11	CONFLICT, WE PROMPTLY CUT YOU OFF, MEANING NO
12	DISRESPECT.
13	BUT WE DO TAKE GREAT PAINS TO PREVENT
14	CONFLICTS OF INTEREST. AND THERE HAS NOT BEEN ANY
15	FINDING THAT WE'VE ACTUALLY HAD A CONFLICT OF
16	INTEREST ARISE IN CONNECTION WITH THE APPROVAL OF AN
17	AWARD AT THE BOARD ITSELF.
18	MS. LANSING: JUST TO FURTHER ADD TO THIS,
19	WE HAVE AND ACTUALLY I PERSONALLY LEAVE THE ROOM
20	BECAUSE I DON'T WANT THERE TO BE ANYTHING. AND
21	WE'VE ACTUALLY BEEN TALKING ABOUT EVEN FURTHER
22	EXTENDING IT TO EVERYONE LEAVE THE ROOM. LEAVING
23	THE ROOM IDENTIFIES WHAT INSTITUTION YOU'RE WITH
24	BECAUSE YOU LEAVE THE ROOM. THIS IS SOMETHING THAT,
25	AGAIN, THIS IS SOMETHING THAT WE HAVE TAKEN VERY

1	SERIOUSLY. AGAIN, I DON'T WANT THIS TO BE ABOUT
2	ANYTHING BUT GRATITUDE FOR WHAT YOU'VE DONE AND HOW
3	SERIOUSLY YOU'VE TAKEN THIS.
4	DR. SHAPIRO: I THINK IT'S QUITE CLEAR
5	THAT YOU HAVE TAKEN IT VERY SERIOUSLY.
6	MS. LANSING: I'M VERY GRATEFUL FOR THE
7	REPORT. I WANT TO BE CLEAR ABOUT THAT.
8	CHAIRMAN THOMAS: DR. JUELSGAARD.
9	DR. JUELSGAARD: DR. SHAPIRO, FIRST OF
10	ALL, I WANT TO THANK YOU AND THE INSTITUTE OF
11	MEDICINE FOR ALL THE WORK THAT YOU'VE DONE ON THIS
12	PARTICULAR SUBJECT AREA. IT WAS NOT EASY, AND I
13	REALLY APPRECIATE YOUR PATIENCE IN STANDING UP THERE
14	AND ENGAGING WITH US.
15	DR. SHAPIRO: UNIVERSITY PRESIDENT FOR 25
16	YEARS.
17	DR. JUELSGAARD: I'M SURE YOU'D RATHER BE
18	AT YOUR DESK RIGHT NOW. HAVING SAID THAT, THIS IS
19	MORE THAN JUST A CLARIFICATION, AND IT RELATES TO
20	THE DISCUSSION WE'RE HAVING BECAUSE THE SUGGESTION
21	THAT YOU'RE MAKING ABOUT CONFLICT OF INTEREST IN
22	THIS AREA IS A SOMEWHAT NOVEL ONE, AT LEAST IN MY
23	EXPERIENCE, BECAUSE MOST CONFLICT OF INTEREST
24	CENTERS AROUND ECONOMIC INTEREST OR FINANCIAL
25	INTEREST.
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1	SO THE REFERENCE POINT FOR HIGHLIGHTING
2	THIS AREA AS A POTENTIAL CONFLICT OF INTEREST, I
3	READ YOUR REPORT AND UNDERSTAND IT, IS MORE BASED ON
4	PSYCHOLOGY AND BEHAVIORAL ECONOMIC STUDIES. AND
5	THERE WAS NO CITING IN THE REPORT, AT LEAST THAT I
6	SAW, TO OTHER INSTITUTIONS THAT HAVE ADOPTED
7	POLICIES THAT LOOK AT THESE SORTS OF CONFLICTS OF
8	INTEREST. NOW, THERE MAY WELL HAVE BEEN SUCH
9	INSTITUTIONS THAT HAVE DONE SO THAT WEREN'T
10	REFERENCED HERE. BUT I'M CURIOUS. ARE YOU AWARE OF
11	OTHER INSTITUTIONS?
12	DR. SHAPIRO: I CAN'T NAME THEM RIGHT NOW,
13	BUT THE SAME COMMENT CAME UP BEFORE. WE WILL
14	PROVIDE YOU WITH THOSE REFERENCES.
15	MR. JUELSGAARD: THAT WOULD BE VERY
16	HELPFUL.
17	DR. SHAPIRO: I AGREE.
18	MR. TORRES: THANK YOU. I'VE JUST BEEN
19	PROVIDED WITH ONE DOCUMENT BY YOUR STAFF. I'LL GET
20	IT TO MR. JUELSGAARD AS WELL AS THE OTHER MEMBERS OF
21	THE BOARD.
22	DR. SHAPIRO: UNLESS THERE'S SOME OTHER
23	QUESTIONS RIGHT NOW, I'D LIKE TO
24	MR. SHESTACK: SORRY. I DIDN'T REALIZE
25	THE DISCUSSION OF THIS WOULD START RIGHT OUT THE
	46
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1	GATE. THAT WAS A LOT OF WORK, THIS REPORT, AND I'M
2	SURE WE APPRECIATE IT.
3	I HAVE TO SAY THAT I DON'T THINK I
4	DON'T BELIEVE THAT THE CONCLUSIONS ON CONFLICT OF
5	INTEREST ADVICE COULD BE POSSIBLY MORE INCORRECT
6	THAN THEY ARE. INSULTING IS TOO STRONG A WORD, BUT
7	ACTUALLY DOESN'T TAKE INTO CONSIDERATION THE DESIGN
8	OF THE PROPOSITION. THE DESIGN OF THE PROPOSITION
9	WAS TO KEEP THE WORKING GROUPS INCREDIBLY CLOSE TO
10	THE PEOPLE IN CALIFORNIA, WHICH IS WHY THE ADVOCATES
11	AND MANY OF THE OTHER MEMBERS ARE ACTUALLY APPOINTED
12	BY ELECTED OFFICIALS IN CALIFORNIA WHO THEY HAVE A
13	RELATIONSHIP WITH IN AREAS. THERE'S CONSTANT
14	QUESTION OVER WHETHER OR NOT THERE'S DUE DILIGENCE
15	AND FAIRNESS. IT'S NOT AS IF THE SELECT FEW OF THE
16	FACULTIES OF CALIFORNIA ARE REPRESENTED. ALL OF THE
17	FACULTIES OF ANY NOTE ARE REPRESENTED.
18	I HAVE NEVER BEEN ON A BOARD THAT WAS
19	ACTUALLY CONDUCTED MORE TRANSPARENTLY THAN THIS
20	BOARD AND IT'S REALLY IMPRESSIVE.
21	AND AS FOR THE ADVOCATES, I JUST WANT TO
22	SAY FROM A PERSONAL POINT OF VIEW WHAT THE ADVOCATES
23	ARE HERE TO DO IS TO ADVOCATE. THEY'RE HERE TO
24	ADVOCATE FOR THE SCIENCE IN THE PUBLIC INTEREST.
25	THEY MAY BE HERE TO ADVOCATE FOR A DISEASE THEY HAVE

A SPECIAL KNOWLEDGE OF. MOST OF THEM THAT I KNOW
MAY HAVE HAD LEADERSHIP POSTS AT A SPECIFIC DISEASE
ORGANIZATION, BUT DO NOT CURRENTLY HOLD ONE, DO NOT
HAVE A FINANCIAL INTEREST.
I WANT TO JUST SPEAK FOR MY OWN EXAMPLE,
WHICH IS I HAVE COME TO MEETINGS AT CIRM FOR SEVEN
YEARS WAITING FOR AN AUTISM GRANT TO COME UP. AND
ONLY NOW AFTER SEVEN YEARS IS ANYTHING WITH
POTENTIAL IN THE FIELD COMING UP.
I THINK ALL OF US, ALL OF THE ADVOCATES
WHO HAVE COME UP THROUGH ADVOCACY ARE EXQUISITELY
TRAINED IN THE IDEA THAT A RISING TIDE FLOATS ALL
BOATS. WE KNOW HOW TO TAKE OUR TURN. WE KNOW HOW
TO LOOK OUT FOR THE BEST INTERESTS OF THE PATIENT
CONSTITUENCY WE REPRESENT AND ARE DEEPLY
COMPASSIONATE FOR ALL THE OTHERS. AND I THINK THERE
ISN'T A WHIFF OF BIAS ACTUALLY. AND OUR, IN FACT,
CHARGE IS TO ADVOCATE.
SO I THINK THAT I JUST SPEAK FOR THE
FELLOW ADVOCATES, THAT THEY HAVE DONE A MAGNIFICENT
JOB IN ADVOCATING, AND THAT THIS BOARD HAS DONE A
MAGNIFICENT JOB IN TRANSPARENCY. I ONLY WISH THAT
THE MEMBERS OF THE IOM HAD SPOKEN TO MORE OF THE
BOARD MEMBERS DIRECTLY ABOUT THEIR EXPERIENCE AND
WHAT THEY DO SO THAT POINT OF VIEW WOULD BE MORE
48

1	FULLY RECOGNIZED. AND I KNOW THAT THIS IS ONLY A
2	SMALL PART OF YOUR REPORT; HOWEVER, THIS IS THE PART
3	THAT UNFORTUNATELY PEOPLE WHO MAYBE, I WISH, KNEW
4	MORE WILL SEIZE ON, AND THEY'LL TALK ABOUT THIS
5	BECAUSE IT'S THE EASIEST PART TO TALK ABOUT BECAUSE
6	SOME OF THE OTHER PARTS ARE VERY COMPLEX AND INSIDE
7	BASEBALL.
8	I JUST WANT TO THANK YOU FOR YOUR HARD
9	WORK AND SAY THAT REALLY I THINK THIS BOARD IS
10	TRANSPARENT, IT IS NOT BIASED, AND THE ADVOCATES
11	HAVE DONE A TREMENDOUS JOB OF TRYING TO REMIND
12	PEOPLE ALL THE TIME THAT WE'RE NOT ONLY DISCUSSING A
13	DISEASE IN A DISH. WE'RE DISCUSSING DISEASES THAT
14	RUIN LIVES, AND THEY NEED TO BE REMINDED OF IT.
15	DR. SHAPIRO: YOUR BOARD WILL HAVE A
16	CHANCE TO THINK ABOUT THIS CAREFULLY OVER TIME. I
17	JUST WANT TO SAY ONCE AGAIN, I WON'T SAY IT ANOTHER
18	TIME, WE ARE NOT AGAINST PATIENT ADVOCATES. WE
19	SUPPORT THE ROLE OF PATIENT ADVOCATES AND FOR
20	VARIOUS REASONS. NOW, YOU MAY THINK THAT WE'VE DONE
21	IT THE WRONG WAY AND THAT'S FINE. IT'S UP TO YOUR
22	DECISION, BUT WE ACTUALLY SUPPORT THAT ROLE. AND
23	THE WAY WE THINK ABOUT IT, THE ROLE WOULD NOT
24	DECREASE GOING FORWARD. AND THAT'S JUST OUR VIEW.
25	I DON'T WANT TO ARGUE IT, AND I'M NOT HERE TO ARGUE

1	THAT.
2	MR. SHESTACK: I WOULD JUST SAY THAT THE
3	ROLE WOULD DECREASE, FOR INSTANCE, BY WHAT IS OF
4	INCREDIBLE VALUE. I THINK HAVING CONTINUITY BETWEEN
5	PEOPLE WHO HAVE BEEN AT A GRANTS WORKING GROUP OR A
6	STANDARDS WORKING GROUPS AND REPORT BACK AGAIN TO
7	THE BOARD BECAUSE THAT DIRECT LINE, THIS NOTION THAT
8	WE HAVE DIRECT LINE
9	DR. SHAPIRO: THERE IS THAT TENSION
10	BETWEEN THAT BENEFIT AND THE BENEFIT OF INDEPENDENT
11	OVERSIGHT. I UNDERSTAND THAT. YOU'LL HAVE TO IN
12	YOUR OWN GOOD TIME THINK ABOUT HOW THESE THINGS
13	BALANCE ONE AGAINST THE OTHER AND MAKE YOUR DECISION
14	WHICH YOU THINK ARE IN THE BEST INTEREST OF CIRM
15	OVER TIME.
16	MR. SHESTACK: THANK YOU VERY MUCH.
17	DR. SHAPIRO: LET ME JUST, IF IT'S ALL
18	RIGHT BECAUSE I KNOW I'M WAY OVER TIME HERE.
19	CHAIRMAN THOMAS: NO. NO. THIS IS VERY
20	IMPORTANT. TAKE AS MUCH TIME AS YOU NEED.
21	DR. SHAPIRO: I JUST WANT TO MOVE ON FROM
22	THAT TO DISCUSS SOME RECOMMENDATIONS THAT ARE ON THE
23	SLIDE UP HERE WITH RESPECT TO THE SCIENTIFIC
24	PROGRAM. AND YOU CAN READ THEM FOR YOURSELVES. I
25	DON'T WANT TO, AGAIN, GO OVER ALL THE DETAILS
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1	BECAUSE YOU HAVE A LOT OF OTHER THINGS TO DO TODAY.
2	PROBABLY THE MOST IMPORTANT OF THESE
3	RECOMMENDATIONS IS THE SUGGESTION THAT A SINGLE
4	EXTERNAL ADVISORY COMMITTEE BE APPOINTED TO BOTH
5	PROVIDE ADVICE TO THE BOARD AND TO MANAGEMENT
6	REGARDING LONG-TERM STRATEGIC AND PROGRAMMATIC
7	ISSUES. WE THINK IT'S IMPORTANT. IT'S DIFFERENT
8	FROM A BOARD WHICH YOU'VE GOT OF A LOT OF EXTERNAL
9	ADVICE HERE AT CIRM. YOU TEND TO GO YOU HAVE THE
10	EXTERNAL ADVISORY COMMITTEE, THEY REPORT ON
11	SOMETHING AND OTHER GROUPS REPORT ON OTHER THINGS.
12	WE THINK IT'S IMPORTANT FOR THAT GROUP, WHOEVER THEY
13	MAY BE AND WHOEVER MIGHT BE APPOINTED TO THAT GROUP,
14	BE IN PLACE OVER TIME SO THEY CAN LEARN AND YOU CAN
15	LEARN FROM THEM REGARDING THE SETTING OF YOUR BASIC
16	SCIENTIFIC AND PROGRAMMATIC, NOT ONLY SCIENTIFIC,
17	BUT PROGRAMMATIC RESPONSIBILITIES. WE THINK THAT'S
18	REALLY QUITE IMPORTANT.
19	THE LAST THING THAT I'LL MENTION NOW
20	BECAUSE I'M DOING BADLY AND TAKEN UP SO MUCH OF YOUR
21	TIME, THAT THERE ARE SOME IMPORTANT ASPECTS HERE
22	WHICH HAVEN'T FOUND THEIR WAY INTO CIRM'S PORTFOLIO.
23	AND PARTICULARLY WE THINK THERE ARE UNIQUE ETHICAL
24	ISSUES THAT COME UP WHEN THESE KINDS WHEN
25	REGENERATIVE MEDICINE GETS INTO THE CLINIC OR GETS
	51
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INTO CLINICAL TRIALS, WHICH WE THINK THAT CIRM CAN
PLAY A LEADERSHIP ROLE IN TRYING TO SPONSOR SOME NEW
THINKING ON THIS ISSUE TO TRY TO SORT OF ANTICIPATE
THE KINDS OF THINGS THAT WILL COME UP WHEN YOU
ACTUALLY MOVE INTO CLINICAL TRIALS.
THIS DOESN'T COST A LOT OF MONEY. IT'S A
VERY MODEST AMOUNT OF MONEY TO HAVE AT LEAST SOME
STUDIES IN THIS AREA, BUT WE THINK THAT'S REALLY
QUITE IMPORTANT.
LET ME FINALLY SAY A WORD ABOUT
INTELLECTUAL PROPERTY. WE ACTUALLY DON'T HAVE WHAT
IS A REAL RECOMMENDATION IN INTELLECTUAL PROPERTY.
WE THINK THAT CIRM HAS DONE AN EXCELLENT JOB OF
DISCUSSING INTELLECTUAL PROPERTY POLICIES WITH ALL
THE INTERESTED CONSTITUENCIES OVER A PERIOD OF TIME
AND HAVE COME TO A VERY UNDERSTANDABLE POLICY, AND
IT MAY BE INDEED EXACTLY THE RIGHT POLICY. WE THINK
THAT DESERVES CONTINUED CONSIDERATION BECAUSE WHEN
WE WENT OUT AND SPOKE TO PEOPLE IN INDUSTRY AND WE
WENT OUT AND SPOKE TO TECHNOLOGY TRANSFER OFFICES
AROUND, THEY ALL EXPRESSED CONCERN ABOUT HOW CIRM
WOULD DEAL WITH INTELLECTUAL PROPERTY.
NOW, YOUR ACTUAL POLICIES LEAVE A LOT OF
FLEXIBILITY. SO YOU DEAL WITH THIS AS THEY COME UP,
AND THAT'S VERY ADMIRABLE. YOU JUST TRY TO SEE,
52

1	LOOK, THERE ARE VARIOUS INTERESTS TO BE BALANCED
2	HERE, AND THE CASES WILL BALANCE THEM IN THE RIGHT
3	WAY. THAT VERY FLEXIBILITY, WHICH IS VERY
4	ADMIRABLE, I HAVE TO SAY, ALSO PRODUCES UNCERTAINTY
5	BY ITS VERY NATURE. PEOPLE ARE UNCERTAIN ABOUT JUST
6	WHAT THIS HOW THIS POLICY IS GOING TO PLAY OUT
7	AND YOU DON'T YET HAVE A LONG TRACK RECORD BECAUSE
8	YOU'RE SUCH A YOUNG ORGANIZATION.
9	SO I JUST THINK YOU SHOULD BE AWARE THAT
10	THERE IS A LOT OF UNCERTAINTY OUT THERE. THE FACT
11	THAT THIS POLICY DIFFERS IN IMPORTANT WAYS FROM THE
12	BAYH-DOLE POLICY IS ONE OF THE CAUSES CONCERN IS
13	TOO STRONG A WORD. PEOPLE UNDERSTAND WHY IT IS YOU
14	HAVE THE POLICIES YOU DO HAVE. IT IS PERFECTLY
15	UNDERSTANDABLE. IT MAY IN THE END BE THE BEST
16	POLICIES. WE'RE NOT COMPLETELY SURE OF THAT. WE
17	THINK IT DESERVES ONE THING WHICH WE THINK IT
18	DOES DESERVE SOME CONSIDERATION IS ONE OF THE
19	BENEFITS TO THE CITIZENS OF CALIFORNIA AND
20	REGENERATIVE MEDICINE OVERALL ABOUT HAVING POLICIES
21	THAT WERE MORE CONSISTENT WITH THE BAYH-DOLE
22	POLICIES.
23	NOW, I DON'T KNOW WHAT THE ANSWER TO THAT
24	IS. I JUST THINK IT'S SOMETHING WORTH CONSIDERING
25	AND THINKING CAREFULLY BECAUSE YOU THINK AHEAD WITH

1	DIFFERENT STATES HAVING DIFFERENT POLICIES AND
2	DIFFERENT INTELLECTUAL PROPERTY POLICIES, THAT DOES
3	CREATE A PROBLEM BECAUSE THE WORLD OF REGENERATIVE
4	MEDICINE IS NOT ONLY NATIONAL, BUT INTERNATIONAL.
5	AND PEOPLE WHO ARE GOING TO TRY TO COMMERCIALIZE
6	PRODUCTS IN THIS AREA AND SO ON WANT TO BE ABLE TO
7	DO SO IN A VERY LARGE LANDSCAPE. SO WE'RE NOT SURE
8	WHAT THE RIGHT ANSWER IS. AND HERE OUR
9	RECOMMENDATION IS BASICALLY SIMPLY YOU CONSIDER
10	THIS, CONTINUE TO CONSIDER IT AGAIN.
11	AND AS I SAID JUST A MOMENT AGO, IT'S BEEN
12	VERY ADMIRABLE IN THIS AREA JUST HOW OPEN CIRM HAS
13	BEEN IN THAT REGARD. AND I THINK THE CURRENT
14	POLICIES ARE A VERY REASONABLE BALANCE BETWEEN THE
15	VARIOUS CONSTITUENCIES WHO HAVE DIFFERENT INTERESTS
16	HERE. AND SO THAT IT'S A VERY MODEST
17	RECOMMENDATION; NAMELY, THAT WE CAME ACROSS IN
18	DISCUSSING, PARTICULARLY WITH PEOPLE IN INDUSTRY,
19	THAT SOME CONCERN IN THIS REGARD, THAT'S SOMETHING
20	FOR YOU TO CONSIDER AND TALK OVER AMONGST YOURSELVES
21	AND WITH OTHER PEOPLE IN INDUSTRY AS YOU GO AHEAD.
22	SO THERE ARE OTHER RECOMMENDATIONS IN
23	HERE. I DON'T WANT TO TAKE THE TIME TO GO OVER THEM
24	ALL. BUT I JUST WANT TO THANK YOU ALL FOR YOUR
25	ATTENTION AND TO SAY IT'S BEEN A VERY INTERESTING

1	EXPERIENCE, AND I LOOK FORWARD TO SEEING CIRM GO
2	FROM STRENGTH TO STRENGTH.
3	MR. TORRES: DR. SHAPIRO, ON PAGE 418 OF
4	THE REPORT IN RESPECT TO THE RECOMMENDATIONS ON
5	GRANT REVIEW AND FUNDING PROCESS, THE NOTION TO
6	ELIMINATE THE USE OF EXTRAORDINARY PETITIONS. AND
7	IT'S A CONVERSATION I'VE HAD WITH OUR PRESIDENT, AND
8	I BELIEVE AND I KNOW THAT HE'S THINKING ABOUT AND
9	STAFF IS THINKING ABOUT HOW TO DEVELOP A NEW PROCESS
10	THAT IS TRANSPARENT AND FAIR, BUT NOT THE PROCESS WE
11	HAVE NOW.
12	THE QUESTION I HAVE IS WHAT BROUGHT THE
13	CONCLUSION THAT THE BOARD SHOULD ONLY VOTE YES OR NO
14	ON APPLICATIONS?
15	DR. SHAPIRO: WE HAD A LOT OF CONVERSATION
16	ABOUT THAT PARTICULAR ISSUE. WE DO THINK IT'S
17	IMPORTANT TO ELIMINATE WHAT IS, I THINK,
18	EXTRAORDINARY PETITIONS SIMPLY BECAUSE IN OUR VIEW
19	IT UNDERMINES THE INTEGRITY OF THE REVIEW PROCESS,
20	WHICH IS A VERY CAREFUL AND OPEN ONE. SO WE THINK
21	THAT THAT PUTS THE BOARD IN A VERY DIFFICULT
22	POSITION, UNNECESSARY POSITION, AND WE THINK IT WILL
23	BE BETTER OFF IN OUR VIEW WITHOUT THAT.
24	ON THE ISSUE OF WHETHER THE BOARD SHOULD
25	VOTE ON A WHOLE SLATE OF GRANTS OR INDIVIDUAL
	55

1	GRANTS, I HAVE TO SAY IN OUR DISCUSSION WE HAD LOTS
2	OF BACK AND FORTH ON THAT ISSUE. AND IN PART IN OUR
3	MIND IT WAS RELATED TO THE NUMBER OF INDEPENDENT
4	BOARD MEMBERS YOU HAD. THAT IS, THE MORE
5	INDEPENDENT BOARD MEMBERS YOU HAVE, LESS IMPORTANT
6	THAT WOULD BE. AND SO WE PROBABLY DIDN'T MAKE THAT
7	AS CLEAR AS WE SHOULD HAVE IN THE REPORT, BUT THAT
8	JUST REFLECTS OUR THINKING AS WE WENT THROUGH.
9	MR. TORRES: THANK YOU VERY MUCH.
10	DR. PRIETO: I JUST WANT TO COMMENT
11	BRIEFLY ON THE INTELLECTUAL PROPERTY ISSUE THAT YOU
12	MENTIONED BECAUSE I THINK THAT WE DID I WAS PART
13	OF THE ORIGINAL INTELLECTUAL PROPERTY TASK FORCE
14	THAT WORKED FOR ABOUT TWO YEARS ON OUR POLICIES.
15	AND I THINK AT THE TIME THERE WAS A CONSCIOUS
16	DECISION MADE THAT WE WOULD MOVE AWAY FROM THE
17	BAYH-DOLE MODEL OR THE SCHEMA THAT PRECEDED
18	BAYH-DOLE. WE SORT OF CONSIDER THOSE AS AN ALL OR
19	NOTHING AND THAT WE WOULD TRY TO FIND A MIDDLE
20	GROUND. I THINK PART OF THAT CAME OUT OF THE
21	PROMISE IN THE INITIATIVE THAT IF THERE WERE SOME
22	RETURN FROM OUR EFFORTS, ASIDE FROM OBVIOUSLY THE
23	TREATMENT OF DISEASES, BUT IF THERE WERE THE
24	POTENTIAL FOR SOME FINANCIAL RETURN, THAT SOME OF
25	THAT WOULD COME DIRECTLY BACK TO THE PEOPLE OF

1	CALIFORNIA. SO WE TRIED TO TAKE A MIDDLE GROUND IN
2	ORDER TO BE FAITHFUL TO THAT PROMISE.
3	DR. SHAPIRO: AS I SAID A MOMENT AGO, I
4	THINK YOU AND OTHERS WHO WORKED ON THAT CAME TO A
5	VERY REASONABLE POSITION. WE'RE JUST POINTING OUT
6	THAT THIS IS WORTH CONTINUED THINKING AS YOUR
7	EXPERIENCE KIND OF INDICATES. IT'S POSSIBLE,
8	ALTHOUGH I DON'T WANT TO IT'S POSSIBLE THAT YOU
9	WOULD ACTUALLY GENERATE MORE MONEY BY USING THE
10	BAYH-DOLE PROCEDURE IN SOME WAY THAN THE OTHER WAY
11	AROUND. THAT'S AN OPEN ISSUE. WE DON'T HAVE A
12	STRONG VIEW ON THAT. WE JUST THINK THAT YOU SHOULD
13	CONTINUE TO MONITOR THE SITUATION AND DECIDE IN YOUR
14	OWN MIND WHAT'S BEST FOR THE CITIZENS OF CALIFORNIA.
15	AND IT MAY BE THE EXISTING POLICY.
16	DR. PRIETO: MR. JUELSGAARD AND THIS
17	COMMITTEE ARE STILL LOOKING AT THAT. WE CERTAINLY
18	HAVE MAINTAINED AN OPEN MIND AND ARE CONSIDERING
19	THAT. I JUST WANTED TO ILLUMINATE A LITTLE BIT OF
20	WHAT OUR THINKING WAS.
21	DR. SHAPIRO: I UNDERSTAND. WE WERE
22	ACTUALLY VERY IMPRESSED WITH THE PROCESS ON THE
23	INTELLECTUAL PROPERTY. AS WE SAW THROUGH THE
24	MATERIALS HOW CAREFULLY VARIOUS INTERESTS WERE
25	BALANCED AND LISTENED TO, EVERYBODY HAD A CHANCE FOR

INPUT, AND YOU RECEIVED A LOT OF INPUT, SO WE WERE
VERY IMPRESSED BY THAT PROCESS.
MR. SHESTACK: I JUST WONDERED IF I
THINK ONE OF THE THINGS THAT WENT ON IN THE
DISCUSSION OF INTELLECTUAL PROPERTY WAS THE HOPE
THAT PERHAPS THAT BY VIRTUE OF THE SIZE OF THE
BUDGET OF CIRM AND HOW EARLY AND AGGRESSIVELY IN THE
GAME WE WERE FUNDING, THAT WE WOULD ACTUALLY BE A
MARKET MAKER IN STANDARDS OF INTELLECTUAL PROPERTY.
AND IF THEY WERE SLIGHTLY MORE PROGRESSIVE THAN
PERHAPS IN WISCONSIN, MAYBE BY VIRTUE OF OUR SUCCESS
OR PRODUCTIVITY, THAT MIGHT
DR. SHAPIRO: I UNDERSTAND THAT. AS I
SAID, AS I'VE TRIED TO SAY, I THINK YOU HAVE A VERY
DECENT AND OPEN AND TRANSPARENT POLICY, WHICH IS
UNDERSTANDABLE IN TERMS OF THE VARIOUS INTERESTS
THAT NEED TO BE LISTENED TO HERE. ALL WE'RE SAYING
IS THIS SHOULD CONTINUE TO BE MONITORED IN VIEW OF
YOUR EXPERIENCE AND SEE IF ANY CHANGES ARE DESIRED.
THAT'S REALLY ALL WE'RE SAYING. WE UNDERSTAND THE
PROCESS, THINK IT'S A GOOD ONE, AND JUST THINK THAT
IT SHOULD BE CONTINUED. THAT'S ALL.
MR. SHESTACK: DON'T PEOPLE RECUSE
THEMSELVES, MOVING FROM THE BLOCK VOTES AND MOVING
SOMETHING UP AND OUT OF THE TIER AT THE BOARD LEVEL;
58

1	IS THAT CORRECT? SO THAT IS SOMETHING, JUST FOR THE
2	RECORD, EVEN IN THAT VERSION OF THE PROCESS, WE'RE
3	TRYING TO ADDRESS IT.
4	DR. STEWARD: LET ME ADD MY THANKS TO ALL
5	OF YOU FOR THE HARD WORK THAT YOU PUT IN. I HAD
6	ACTUALLY THREE QUESTIONS. I HOPE I WON'T SEEM TO
7	DOMINATE.
8	DR. SHAPIRO: ARE ANY OF THEM COMPOUND
9	QUESTIONS?
10	DR. STEWARD: SO THE FIRST IS AT LEAST ONE
11	AND MAYBE SOME OF OUR CRITICS HAVE EMPHASIZED WHAT
12	THEY FEEL IS AN IMPORTANT THING, THAT IT WOULD BE
13	ADVANTAGEOUS TO HAVE THE GRANTS WORKING GROUP REVIEW
14	OPEN TO THE PUBLIC OR A PUBLIC DOCUMENT. I DID FIND
15	COMMENTS IN THERE REGARDING THAT, AND IT REAFFIRMED
16	OUR POSITION OVER THE YEARS THAT THAT SHOULD BE A
17	CONFIDENTIAL MEETING. I JUST WONDERED IF YOU COULD
18	EXPAND ON THAT A LITTLE BIT.
19	DR. SHAPIRO: WE AGREE WITH THAT. WE
20	DON'T HAVE ANY CONCERN. WE THINK THE WORK OF THESE
21	WORKING GROUPS REALLY CAN'T GO ON EFFECTIVELY IN
22	SOME KIND OF OPEN MEETING. YOU MIGHT WANT TO DECIDE
23	TO REPORT IN A GENERAL NATURE WHAT GOES ON AND SO
24	ON, BUT THE WORKING GROUP ITSELF, THAT'S THE
25	INDIVIDUAL GRANTS, IN OUR VIEW NEEDS TO BE A CLOSED

1	MEETING.
2	DR. STEWARD: THANK YOU VERY MUCH.
3	THE SECOND QUESTION IS WITH REGARD TO THE
4	ROLE OF THE PATIENT ADVOCATES ON THE WORKING GROUPS
5	AND, IN FACT, ON THE BOARD AS WELL. IN A COUPLE OF
6	WAYS YOUR RECOMMENDATIONS DIFFER FROM WHAT I WOULD
7	CONSIDER TO BE AT LEAST ONE TYPE OF MODEL FOR WHAT
8	WE ARE. AND I TALKED HERE ABOUT NIH COUNCIL WHERE
9	MEMBERS OF THE PUBLIC SERVE AND VOTE AND MOVE THINGS
10	FORWARD. AND SO THE TWO KEY DIFFERENCES ARE, IN
11	FACT, THAT ASPECT, THE ROLE. AND THE SECOND IS THAT
12	COUNCIL CERTAINLY DOESN'T VOTE EN BLOC EITHER AND
13	HAS THE ABILITY TO MOVE THINGS UP OR DOWN.
14	I WONDER IF YOU HAD THOUGHT, DISCUSSED
15	THAT IN YOUR MEETINGS AND HOW THAT RELATES TO THE
16	RECOMMENDATION.
17	DR. SHAPIRO: FIRST OF ALL, NIH COUNCIL,
18	PROBABLY MANY PEOPLE HERE HAVE SAT ON THOSE COUNCILS
19	OVER TIME, HAS A RATHER, IN MY VIEW, MUCH MORE
20	LIMITED ROLE FOR PATIENT ADVOCACY THAN DOES CIRM.
21	SO IN THAT CASE CIRM IS AHEAD OF THE NIH COUNCIL.
22	AND IT IS TRUE THAT THE NIH COUNCILS CAN DO THIS
23	GRANT BY GRANT, SO TO SPEAK, AND MOVE IT AROUND,
24	ALTHOUGH THAT IS NOT VERY GENERAL. IT'S ALSO TRUE
25	THAT THE NIH COUNCILS, AT LEAST THAT I'VE SERVED ON,

1	HAVE MORE INDEPENDENT MEMBERS. AS I SAID A FEW
2	MOMENTS AGO, THE MORE INDEPENDENT MEMBERS YOU HAVE,
3	THIS CHANGES THE BALANCE HERE QUITE A BIT. MAYBE IN
4	THAT CASE YOU WOULD WANT TO MARRY THESE TWO
5	DIFFERENT THINGS IN A SLIGHTLY DIFFERENT WAY.
6	DR. STEWARD: MY THIRD QUESTION ACTUALLY
7	GOES BACK TO ONE OF THE EARLIER QUESTIONS. SO THE
8	CONCEPT OF A MORE OR LESS PERMANENT SCIENCE ADVISORY
9	COMMITTEE IS VERY INTERESTING. AND THE QUESTION
10	ARISES SHOULD THESE PEOPLE BE OUT OF CALIFORNIA?
11	AND THEN, OF COURSE, YOU RAISED THE OTHER ISSUE OF
12	CALIFORNIANS GENERALLY LIKE TO MAKE DECISIONS ON TAX
13	MONEY MADE BY CALIFORNIANS. DID YOU TALK ABOUT
14	THAT?
15	DR. SHAPIRO: YES, WE DID. IT'S AN
16	ADVISORY COUNCIL, OF COURSE. IT'S NOT DECISIONS,
17	JUST ADVISING YOU. AND WE THINK THAT THEY SHOULD
18	HAVE A VERY LARGE REPRESENTATION OF PEOPLE OUTSIDE
19	OF CALIFORNIA, PROBABLY THE MAJORITY.
20	AGAIN, I DON'T WANT I'M HOPING WHEN YOU
21	THINK ABOUT IT, ANY OF US THINK ABOUT IT AND DISCUSS
22	IT, WE DON'T GET HUNG UP ON WHAT I CONSIDER SMALLER
23	ISSUES. SHOULD IT BE 40 PERCENT? SHOULD IT BE 55
24	PERCENT? SHOULD IT BE 30 PERCENT, 70 PERCENT? I
25	THINK THOSE ARE OPEN ISSUES WHICH YOU CAN LEARN BY
	61
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1	EXPERIENCE. BUT WE DO THINK THAT HAVING THAT
2	COUNCIL IS REALLY VERY IMPORTANT. THIS IS NOT ONLY
3	OUR IDEA. THIS CAME UP BEFORE IN OTHER STUDIES OF
4	CIRM. THIS IS NOT AN IDEA THAT'S ORIGINAL WITH US.
5	THE EXTERNAL PANEL HAD MADE A VERY SIMILAR
6	RECOMMENDATION. WE THINK THAT'S JUST TO YOUR
7	BENEFIT, AND I THINK YOU SHOULD TAKE ADVANTAGE OF
8	THE FACT THAT THERE'S SO MANY TALENTED PEOPLE AROUND
9	THE COUNTRY WHO WANT TO HELP YOU. YOU'VE GOT ALL
10	THESE SCIENTISTS WHO WORK ON THESE WORKING GROUPS
11	OUTSIDE OF CALIFORNIA THAT PUT AN ENORMOUS AMOUNT OF
12	TIME AND EFFORT ONLY BECAUSE THEY'RE INTERESTED IN
13	WHAT YOU ARE DOING AND THEY THINK WHAT YOU'RE DOING
14	HAS TREMENDOUS SOCIAL BENEFIT, WHICH I AGREE WITH.
15	I THINK YOU CAN HARNESS SOME OF THAT INTO
16	SOME TYPE OF EXTERNAL ADVISORY PANEL AND NOT BE ON A
17	PROJECT-BY-PROJECT BASIS, BUT WOULD BE A PERMANENT
18	PART OF THE ORGANIZATION WITH SOME KIND OF ROTATING
19	MEMBERSHIP.
20	DR. POMEROY: SINCE OS TOOK THREE
21	QUESTIONS, I'M ACTUALLY GOING TO ASK ZERO AND JUST
22	MAKE ONE QUICK COMMENT. I WANTED TO HIGHLIGHT AND
23	THANK YOU FOR ONE OF YOUR RECOMMENDATIONS BECAUSE I
24	DON'T WANT IT TO GET LOST. THAT'S RECOMMENDATION
25	4-3 ABOUT PUTTING SOME MONEY INTO THE ETHICAL

1	ASPECTS OF STEM CELL RESEARCH.
2	EARLY ON IN THIS BOARD WE HAD SOME
3	CONVERSATIONS ABOUT SETTING ASIDE SOME MONEY FOR
4	ELSI-RELATED THINGS, ETHICAL, LEGAL, AND SOCIAL
5	IMPLICATIONS OF STEM CELL RESEARCH. AND I THINK
6	THAT WE LOST A LITTLE BIT OF FOCUS ON THAT, AND I
7	THINK THIS IS AN OPPORTUNITY TO COME BACK TO THAT.
8	SO I WANTED TO HIGHLIGHT THIS PARTICULAR
9	RECOMMENDATION AND THANK YOU FOR IT.
10	DR. SHAPIRO: THANK YOU VERY MUCH. THAT'S
11	THE BOTTOM ONE ON THIS SLIDE HERE, ESSENTIALLY A
12	SUMMARY OF THAT AT THE BOTTOM ON THE SLIDE. I'M
13	SORRY I DIDN'T HAVE TIME TO GO THROUGH ALL THE
14	DETAIL ON THE SLIDE. THANK YOU VERY MUCH FOR THAT
15	COMMENT.
16	CHAIRMAN THOMAS: ADDITIONAL QUESTIONS FOR
17	DR. SHAPIRO? BEFORE YOU SIT DOWN, DR. SHAPIRO,
18	AGAIN, VERY MUCH LIKE TO THANK YOU AND THE COMMITTEE
19	FOR YOUR VERY LENGTHY, REASONED, AND THOUGHTFUL
20	PROCESS THAT WENT INTO THIS. WE PRIOR TO THE
21	ISSUANCE OF THE REPORT HAD ALREADY SET FORTH A
22	PROCESS THAT THE BOARD WAS GOING TO UNDERTAKE TO
23	EVALUATE THE REPORT, WHICH WILL INVOLVE GOING FIRST
24	TO A JANUARY WORKSHOP AT WHICH THE VARIOUS
25	RECOMMENDATIONS MADE BY THE REPORT WILL BE TAKEN UP

1	IN CONSIDERABLE DETAIL TOWARDS DEVELOPING A GAME
2	PLAN GOING FORWARD TO CONSIDER AND IMPLEMENT CHANGES
3	THAT ARISE AS A RESULT OF THESE RECOMMENDATIONS.
4	THAT WILL BE FOLLOWED BY A LENGTHY DISCUSSION
5	THEREAFTER TO ACTUALLY PROCEED WITH IMPLEMENTATION
6	STEPS.
7	THE SUBJECT MATTER OF THE VARIOUS
8	RECOMMENDATIONS SQUARELY FIT WITHIN THE TASKS OF
9	VARIOUS SUBCOMMITTEES ON OUR BOARD. SO WE'LL BE
10	LOOKING TO THOSE SUBCOMMITTEES TO SORT OF LEAD THE
11	ANALYSIS IN EACH OF THE RECOMMENDATIONS THAT FIT
12	THEIR SUBJECT MATTER.
13	ALSO LIKE TO SAY, FOR THE BOARD'S
14	PURPOSES, THAT GOING FORWARD I'VE ASKED DR. SHAPIRO
15	AND DR. MAGNUSON IF I CAN CONTINUE TO DIALOGUE WITH
16	THEM WITH RESPECT TO THE RECOMMENDATIONS AS WE GO
17	THROUGH THE PROCESS BECAUSE I THINK IT WOULD BE VERY
18	VALUABLE TO HAVE THEIR ONGOING INPUT. AND THEY HAVE
19	AGREED THAT THAT WOULD BE SOMETHING THEY'D BE HAPPY
20	TO DO. I THINK IT'S IMPORTANT FOR CONTINUITY SAKE
21	IN THE PROCESS THAT WE DO JUST THAT.
22	SO I WANT MEMBERS OF THE PUBLIC WHO ARE
23	LISTENING TO UNDERSTAND THAT WE WILL BE VERY SERIOUS
24	IN ANALYZING AND IMPLEMENTING RECOMMENDATIONS AND
25	ARE FIXED TO DO JUST THAT ONCE WE COME BACK. I'D

1	LIKE TO SEE IF THERE ARE MEMBERS OF THE PUBLIC ON
2	THE PHONE.
3	DR. SHAPIRO: I JUST WANT TO MAKE SURE, IF
4	YOU DON'T MIND, EVERYONE HAS HAD A CHANCE TO MEET
5	DR. MAGNUSON, WHO'S SITTING OVER HERE. HE'S BEEN
6	VICE CHAIR OF THE COMMITTEE AND, IN PARTICULAR,
7	WORKED VERY HARD ON THE SCIENTIFIC PROGRAM
8	RECOMMENDATIONS THAT WE MADE.
9	CHAIRMAN THOMAS: THANK YOU. DO WE HAVE
10	COMMENTS BY MEMBERS OF THE PUBLIC? LET'S START HERE
11	AND THEN WE'LL GO TO OUR SITES ON THE PHONE.
12	COMMENTS BY MEMBERS OF THE PUBLIC? SEEING NONE, DO
13	WE HAVE COMMENTS BY MEMBERS OF THE PUBLIC ON THE
14	PHONE? ANYBODY ON MUTE? OKAY. WELL, I BELIEVE
15	THEN THAT CONCLUDES OUR DISCUSSION. ONCE AGAIN,
16	PLEASE CONVEY OUR THANKS TO THE COMMITTEE.
17	(APPLAUSE.)
18	CHAIRMAN THOMAS: I THINK LET'S TAKE A
19	FIVE-MINUTE BREAK HERE. AND WE HAVE A NUMBER OF
20	ITEMS ON THE AGENDA THAT REQUIRE WE ATTEND TO
21	IMMEDIATELY WITH VOTES. SO WE'RE ACTUALLY GOING TO
22	FURTHER PUT OFF THE CHAIR AND PRESIDENT'S REPORT TO
23	A BIT LATER. SO, PLEASE, LET'S TAKE A FIVE-MINUTE
24	BREAK AND COME BACK.
25	(A RECESS WAS TAKEN.)
	65

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1	CHAIRMAN THOMAS: MEMBERS OF THE BOARD,
2	COULD YOU PLEASE TAKE YOUR SEATS? THANK YOU.
3	WE'RE GOING TO NOW TAKE UP ITEM 8, WHICH
4	IS THE CONSIDERATION OF THE APPLICATIONS FOR RFA
5	12-01, THE NEW FACULTY PHYSICIAN SCIENTIST
6	TRANSLATIONAL RESEARCH AWARDS.
7	DR. OLSON: WHAT I'D LIKE TO DO MAYBE
8	BEFORE THE BOARD GOES INTO ESSENTIALLY THE NEW
9	FACULTY PHYSICIAN SCIENTIST AND THE BASIC BIOLOGY
10	CONCEPT, SO THINGS WHERE YOU'RE GOING TO TALK ABOUT
11	DISBURSING MONEY AND ALLOCATING FUNDING, I'D LIKE TO
12	JUST GIVE YOU AN UPDATE ON THE FUNDING ALLOCATION.
13	YOU MAY RECALL THAT OVER THE PAST SIX
14	MONTHS WE'VE AGREED THAT WHENEVER WE HAVE CONCEPT
15	APPROVALS, WE'LL UPDATE THE BOARD ON WHERE WE ARE
16	WITH RESPECT TO THAT. SO THIS IS AN UPDATE FROM THE
17	OCTOBER MEETING. AND I HAVE CHANGED THE FORMAT A
18	LITTLE BIT. I HOPE IT'S CLEARER FOR YOU. AND I
19	ALSO WANT TO ACKNOWLEDGE THAT CHILA AND LYNN BOTH
20	HELPED ME WITH THIS, SO THEY BOTH CONTRIBUTE TO
21	THIS.
22	IN THE FIRST SLIDE, THIS IS BASICALLY THE
23	BIG-PICTURE SLIDE. THIS BASICALLY SAYS, OKAY,
24	HERE'S WHERE YOU ARE IN YOUR FUNDING AND HOW MUCH
25	YOU'VE ACTUALLY AWARDED AS OF OCTOBER AND AS OF

1	DECEMBER, HOW MUCH YOU'VE APPROVED IN CONCEPT AS OF
2	OCTOBER AND OF DECEMBER, AND HOW MUCH IS IN FUTURE
3	EITHER ALLOCATED, AS DISCUSSED IN THE STRATEGIC PLAN
4	THAT YOU APPROVED IN MARCH, OR THAT IS FUTURE, BUT
5	IS UNALLOCATED DUE TO VARIOUS THINGS THAT WE'VE
6	TALKED ABOUT IN THE SUBSEQUENT THINGS IN WHICH I'LL
7	UPDATE YOU ON HERE.
8	SO I WOULD NOW LIKE TO HIGHLIGHT KEY
9	CHANGES IN EACH OF THESE CATEGORIES STARTING WITH
10	THE AWARDED CATEGORY. AND, AGAIN, I BELIEVE YOU ALL
11	HAVE THIS IN YOUR BINDER OR IN YOUR ELECTRONIC FILE,
12	ONE OR THE OTHER. SO IF YOU LOOK IN THE AWARDED
13	CATEGORY, AGAIN, I WOULD NOTE THAT WHAT WE DO IN
14	THIS IS I UPDATE IT FOR THIS MEETING SUCH THAT
15	AWARDS THAT WERE RECOMMENDED BY THE GRANTS WORKING
16	GROUP ARE INCLUDED IN THIS CATEGORY.
17	SO WHAT HAS HAPPENED IS THERE'S BEEN A NET
18	CHANGE OF ABOUT 37.8 MILLION FROM OCTOBER TO NOW.
19	AND WHAT THAT INCLUDES IS RECOMMENDED AWARDS WHICH
20	ARE COMING TO YOU TODAY WHICH ARE ROUGHLY 36 MILLION
21	RECOMMENDED BY THE GRANTS WORKING GROUP FOR THE NEW
22	FACULTY III PHYSICIAN SCIENTIST. SO IF YOU APPROVE
23	WHAT HAS BEEN RECOMMENDED BY THE GRANTS WORKING
24	GROUP, THERE WILL BE AN ADDITIONAL 36 MILLION HERE.
25	AND THAT FALLS IN THE CATEGORY OF TRAINING CAREER
	67
	07

1	DEVELOPMENT. SO WE LOOK AT THIS AS A CAREER
2	DEVELOPMENT AWARD.
3	THERE'S ALSO GOING TO BE A THREE MILLION
4	MAJOR SUPPLEMENT COMING TO YOU LATER TODAY, AND THAT
5	WOULD BE IN THE DEVELOPMENT. THE PATENT ASSISTANCE
6	FUND, WHICH WE TALKED ABOUT AT VARIOUS BOARD
7	MEETINGS, HAS NOW BEEN IMPLEMENTED AND IS IN THE
8	BASIC RESEARCH CATEGORY BECAUSE A LOT OF THE
9	PATENT A LOT OF PATENTS ARE ACTUALLY FILED IN A
10	BASIC RESEARCH PROGRAM. I WOULD ALSO NOTE THAT
11	THERE'S BEEN A DECREASE IN ROUGHLY 6.4 MILLION
12	BECAUSE A VISITING FACULTY SUPPLEMENT PROGRAM WHICH
13	THIS BOARD APPROVED ROUGHLY TWO YEARS AGO, A LITTLE
14	OVER TWO YEARS AGO, IT'S REACHED THE END OF ITS
15	TENURE AND VERY LITTLE THAT PROGRAM JUST HAS NOT
16	HAD A LOT OF PICKUP, AND SO WE ARE MOVING THAT MONEY
17	BACK. SO THAT ACCOUNTS FOR THE CHANGES IN THAT
18	CATEGORY.
19	IN THE CONCEPT APPROVED CATEGORY, WE HAVE
20	A NET CHANGE OF 48 MILLION FROM OCTOBER TO NOW. AND
21	WHAT THAT INCLUDES IS, AND LISA WILL GO INTO A
22	LITTLE BIT MORE, IS A DECREASE IN 80 MILLION FROM
23	THE NEW FACULTY WHICH WAS CONCEPT APPROVED AND NOW
24	IS EITHER AWARDED OR GOING TO UNALLOCATED.
25	SIMILARLY, WE'RE GOING TO ASK YOU, WE'RE
	68

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1	GOING TO BE COMING TO YOU WITH A CONCEPT FOR BASIC
2	BIOLOGY, SO THAT IS 40 MILLION ADDED TO THAT, AND
3	THOSE ARE THE MAIN CHANGES TO THAT.
4	AND THEN, FINALLY, IN THE FUTURE, I JUST
5	WANT TO NOTE THAT THERE IS 732.5 MILLION IN BOTH
6	ALLOCATED, ACCORDING TO THE STRATEGIC PLAN THAT YOU
7	APPROVED EARLIER THIS YEAR, BUT ACTUALLY THERE'S A
8	SIGNIFICANT POT, AS YOU CAN SEE. I THINK IT'S,
9	WHAT, 141 MILLION IN UNALLOCATED. SO THESE ARE
10	MONIES THAT CAN BE USED TO WE TALKED ABOUT A
11	RESEARCH AND ETHICS, WE HAVE TALKED IN THE PAST
12	ABOUT, AGAIN, DOING ANOTHER EXTENSION OR DOING
13	ANOTHER TRAININGS PROGRAM OR A BRIDGES PROGRAM OR
14	EVEN CONTINUING BASIC BIOLOGY. SO THERE IS MONEY
15	AVAILABLE, BUT 732 MILLION AT THE MOMENT IS WHAT IS
16	LEFT FROM WHAT YOU'VE ALREADY CONCEPT APPROVED
17	AND/OR AWARDED.
18	SO I JUST WANTED TO REMIND YOU OF THAT.
19	SO THE CHANGES THERE ARE THE FACT THAT THE BASIC BIO
20	V PROGRAM THAT WILL BE BROUGHT TO YOU FOR CONCEPT
21	APPROVAL, THAT WAS 35 MILLION THAT ACTUALLY WAS IN
22	THE ALLOCATED CATEGORY. WE'RE GOING TO ASK THAT YOU
23	TAKE FIVE MILLION FROM THE UNALLOCATED CATEGORY.
24	WE'VE ALREADY STATED THAT YOU ARE GOING TO, IF YOU
25	GO AS RECOMMENDED FOR THE NEW FACULTY PHYSICIAN

1	SCIENTIST, THERE WILL BE A CONSIDERABLE 43 MILLION
2	THAT WILL GO INTO THE UNALLOCATED POOL.
3	SO BASICALLY WE ARE EXECUTING ON OUR
4	FUNDING STRATEGY. WE'RE DOING WHAT WE HAD SAID
5	WE'RE GOING TO DO, AND THAT'S JUST THE UPDATE. SO
6	WITH THAT, I WILL NOW TURN IT OVER TO LISA KADYK,
7	DR. LISA KADYK, WHO WILL REMIND YOU ABOUT THE NEW
8	FACULTY PHYSICIAN SCIENTIST FOR TRANSLATIONAL
9	MEDICINE PROGRAM.
10	CHAIRMAN THOMAS: THANK YOU, DR. OLSON.
11	DR. KADYK: SO, MR. CHAIRMAN AND MEMBERS
12	OF THE BOARD, I'M HERE TO PRESENT TO YOU FOR YOUR
13	CONSIDERATION RECOMMENDATIONS FROM THE GRANTS
14	WORKING GROUP FOR APPLICATIONS FOR THE NEW FACULTY
15	PHYSICIAN SCIENTIST TRANSLATIONAL RESEARCH AWARDS.
16	JUST TO REMIND YOU, THE CONCEPT FOR THIS PARTICULAR
17	RFA WAS APPROVED BACK IN SUMMER OF 2011.
18	AND THE THOUGHT BEHIND THAT AROSE OUT OF
19	DISCUSSIONS THAT APPARENTLY TOOK PLACE BOTH WITHIN
20	GRANTS WORKING GROUP MEETINGS AS WELL AS BOARD
21	MEETINGS IN WHICH IT WAS NOTED THAT PHYSICIANS DOING
22	TRANSLATIONAL RESEARCH ARE BECOMING SOMEWHAT OF A
23	RARE BREED, SO PEOPLE WHO ARE M.D.'S AND WORKING IN
24	THE CLINIC AND ALSO TRYING TO RUN RESEARCH LABS.
25	AND IT WAS FELT THAT THE REASONS FOR THAT
	70
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1	ARE TWOFOLD. FIRST OF ALL, THERE'S A LOT OF
2	PRESSURES FOR DOING CLINICAL DUTIES ALREADY WHICH
3	MAKES IT HARD TO ALSO MAINTAIN A RESEARCH LAB AND,
4	FURTHERMORE, THAT FUNDING FOR SUCH TYPES OF RESEARCH
5	IS BECOMING MORE AND MORE DIFFICULT TO OBTAIN AND
6	UNPREDICTABLE. SO IT'S BEEN VERY CHALLENGING FOR
7	PHYSICIAN SCIENTISTS TO CARRY OUT RESEARCH.
8	AND SO THE GOAL BEHIND THIS AWARD, A
9	CAREER DEVELOPMENT AWARD, IS TO REALLY ENCOURAGE
10	CAREER DEVELOPMENT OF THIS CATEGORY OF RESEARCHER
11	AND PARTICULARLY THOSE WORKING IN TRANSLATIONAL STEM
12	CELL RESEARCH. SO THIS AWARD WAS DESIGNED TO ACCEPT
13	PROPOSALS ADDRESSING TRANSLATIONAL RESEARCH,
14	INCLUDING CANDIDATE DISCOVERY, PRECLINICAL RESEARCH,
15	AND PRECLINICAL DEVELOPMENT, AS WELL AS PROPOSALS
16	THAT MIGHT ADDRESS A TRANSLATIONAL HURDLE.
17	AND THE PROJECTS ARE INTENDED TO BE FUNDED
18	FOR UP TO FIVE YEARS FOR A TOTAL OF UP TO \$2 MILLION
19	OVER THE TERM OF THE AWARD. AND LAST YEAR \$80
20	MILLION WAS APPROVED BY THE BOARD TO BE SET ASIDE
21	FOR THESE AWARDS, AND IT WAS ANTICIPATED
22	APPROXIMATELY 20 AWARDS WOULD BE RECOMMENDED.
23	I SHOULD POINT OUT THAT OF THIS \$80
24	MILLION, SOME OF IT WAS ALSO TO BE SET ASIDE FOR THE
25	CIRM MEDICAL SCHOOL LOAN REPAYMENT PROGRAM FOR THOSE
	71
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1	CANDIDATES WHO MIGHT STILL HAVE MEDICAL SCHOOL LOANS
2	TO REPAY.
3	AND SO THE REVIEW PROCESS WAS, FIRST OF
4	ALL, THAT THE APPLICANTS FILE A LETTER OF INTENT TO
5	ESTABLISH THEIR ELIGIBILITY. AS YOU CAN TELL BY THE
6	LENGTHY NAME OF THIS AWARD, IT'S A VERY ACTUALLY
7	NARROW GROUP OF PEOPLE OR NARROW DEFINITION OF
8	ELIGIBILITY HERE. SO THE APPLICANT MUST HAVE AN
9	M.D. OR EQUIVALENT DEGREE. THEY MUST BE LICENSED TO
10	PRACTICE MEDICINE IN CALIFORNIA, ALSO BE WITHIN THE
11	FIRST SIX YEARS OF STARTING THEIR FIRST INDEPENDENT
12	FACULTY POSITION, AND BE WILLING TO COMMIT AT LEAST
13	33 PERCENT EFFORT TO THIS AWARD, AND, FINALLY, THEY
14	NEEDED TO BE NOMINATED BY THEIR INSTITUTION IN ORDER
15	TO APPLY FOR THIS AWARD.
16	AND THE RULES THERE WERE THAT INSTITUTIONS
17	THAT HAVE A MEDICAL SCHOOL WERE ALLOWED TO NOMINATE
18	UP TO FOUR CANDIDATES, AND THOSE THAT DO NOT HAVE A
19	MEDICAL SCHOOL COULD NOMINATE TWO.
20	SO APPLICATIONS WERE DUE IN THE SUMMER,
21	AND THEY WERE REVIEWED ON OCTOBER 11TH AND 12TH.
22	AND THE REVIEW CRITERIA WERE FOURFOLD. OF COURSE,
23	THE RESEARCH PLAN WAS VERY IMPORTANT, AND REVIEWERS
24	LOOKED AT THE RATIONALE, SIGNIFICANCE, POTENTIAL
25	IMPACT ON DISEASE, AS WELL AS THE DESIGN AND
	72

1	FEASIBILITY OF THE PROPOSAL.
2	THIS IS A CAREER DEVELOPMENT AWARD, SO IT
3	WAS ALSO VERY IMPORTANT TO EVALUATE THE PRINCIPAL
4	INVESTIGATOR IN TERMS OF HIS OR HER QUALIFICATIONS
5	AND POTENTIAL, AS WELL AS HIS OR HER CAREER
6	DEVELOPMENT AND MENTORING PLANS. AND THERE WAS A
7	SPECIFIC REQUIREMENT THAT THEY HAVE NAMED MENTORS
8	FOR THIS AWARD.
9	ALSO, THE REVIEWERS LOOKED AT
10	INSTITUTIONAL COMMITMENT TO THE PI IN TERMS OF
11	PROVIDING DEDICATED TIME FOR THIS AWARD AS WELL AS
12	LABORATORY SPACE AND FACILITIES, AND ALSO THE
13	INSTITUTIONAL TRACK RECORD FOR WORKING IN THIS TYPE
14	OF TRANSLATIONAL AND STEM CELL RESEARCH AS WELL AS
15	THE FUTURE PLANS FOR THAT INSTITUTION. AND THEN,
16	FINALLY, RESPONSIVENESS TO THE RFA. AND SOME OF THE
17	KEY REQUIREMENTS THERE WERE THAT THE APPLICANT BE
18	PROPOSING WORK USING HUMAN CELLS AND THAT IT BE
19	TRANSLATIONAL RESEARCH OR ELSE ADDRESSING A
20	TRANSLATIONAL HURDLE AND ALSO UNLIKELY OR UNABLE TO
21	RECEIVE FEDERAL FUNDING.
22	AND SO AT THE END OF THE GRANTS WORKING
23	GROUP SCIENTIFIC REVIEW, A GRAPH WAS MADE OF THE
24	SCORE DISTRIBUTION. AND THE GRANTS WORKING GROUP
25	DIVIDED, AS IS NORMALLY THE CASE, THE SCORES INTO

73

1	THREE CATEGORIES, TIER I, II, AND III WITH TIER I
2	BEING THE HIGHEST AND MOST LIKELY TO BE RECOMMENDED
3	AND TIER III IN THE LOWER CATEGORY. AND THEN DURING
4	THE PROGRAMMATIC REVIEW, THOSE TIERS WERE RESOLVED
5	INTO EITHER TIER I, RECOMMENDED FOR FUNDING, OR TIER
6	III, NOT RECOMMENDED FOR FUNDING. SO THAT'S JUST AN
7	IDEA OF WHAT THE DISTRIBUTION LOOKED LIKE.
8	SO AT THE END OF THAT PROGRAMMATIC REVIEW,
9	A VOTE WAS TAKEN. AND IN THE END TWELVE OF THE
10	APPLICATIONS WERE RECOMMENDED FOR FUNDING. AS PAT
11	SAID, THAT COMES TO JUST OVER \$36 MILLION. AND YOU
12	WILL NOTE THAT IS SIGNIFICANTLY UNDER THE BUDGET
13	THAT WAS APPROVED BY THE ICOC, AND I'D LIKE TO JUST
14	COMMENT ON THAT.
15	I THINK THIS IS ACTUALLY NOT DUE TO AN
16	EXTRAORDINARY SEVERITY OF THE SCIENTIFIC REVIEW IN
17	THIS CASE, BUT RATHER REFLECTS THE BASIC PREMISE
18	BEHIND THESE AWARDS, WHICH IS THAT THESE PHYSICIAN
19	SCIENTISTS ARE RELATIVELY RARE. WE ONLY GOT 27
20	APPLICATIONS. SO, IN FACT, THE GRANTS WORKING GROUP
21	RECOMMENDED TO FUND 45 PERCENT OF THEM, WHICH IS
22	ACTUALLY A FAIRLY HIGH PERCENTAGE.
23	SO WITH THAT, I BELIEVE THAT'S MY LAST
24	SLIDE. ARE THERE ANY QUESTIONS?
25	CHAIRMAN THOMAS: MR. HARRISON, CAN YOU

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1	JUST REMIND US OF THE PROCEDURE HERE, PLEASE?
2	MR. HARRISON: YES. THE NEXT STEP IN OUR
3	PROCESS IS FOR BOARD MEMBERS TO IDENTIFY ANY
4	PARTICULAR APPLICATION ABOUT WHICH THEY WOULD LIKE
5	TO HEAR ADDITIONAL INFORMATION. STAFF WOULD THEN
6	MAKE A PRESENTATION REGARDING THAT APPLICATION, AND
7	BOARD MEMBERS COULD ASK ANY QUESTIONS THEY HAVE.
8	ONCE WE'VE HAD A DISCUSSION ABOUT APPLICATIONS IN
9	WHICH MEMBERS HAVE AN INTEREST, WE CAN ENTERTAIN
10	MOTIONS AND PUBLIC COMMENT.
11	CHAIRMAN THOMAS: DEAN PULIAFITO.
12	DR. PULIAFITO: THE FACT THAT WE I'D
13	LIKE TO SAY GREAT JOB, GREAT PROGRAM. I WOULD SAY,
14	JUST BEING FROM THE MEDICAL SCHOOL ENVIRONMENT, IT
15	TAKES TIME FOR PEOPLE TO LEARN ABOUT THESE KIND OF
16	PROGRAMS. AND IT MAY BE POSSIBLE THAT WE CAN DO
17	THIS AGAIN WITH THE LEFTOVER MONEY. SO I SAY
18	THAT AND I SEE THE OTHER DEAN NODDING HER HEAD.
19	I SAY THAT BECAUSE I THINK WE SHOULD DO MERITOCRACY
20	HERE, AND WE SHOULDN'T JUST THE AVAILABILITY OF
21	THE EXTRA MONEY SHOULD NOT DRIVE US TO APPROVE
22	THINGS THAT WERE NOT IN TIER I. THANK YOU.
23	MR. TORRES: I'D LIKE TO HEAR STAFF
24	RECOMMENDATIONS ON THE EXTRAORDINARY PETITION FOR
25	APPLICATION RM 3-06502.
	7-

DR. SAMBRANO: MR. CHAIRMAN, MEMBERS OF
THE BOARD, SO THIS APPLICATION 6502 RELATES TO AN
ATTEMPT TO DEVELOP A BIOLOGICAL PACEMAKER. AND THE
GOAL HERE IS TO BASICALLY BRIDGE WHAT WOULD BE
ELECTRONIC PACEMAKERS IN CASES WHERE AN INFECTION
HAS NECESSITATED THE REMOVAL OF THE ELECTRONIC
DEVICE AND YOU THEN REQUIRE ANTIBIOTIC TREATMENT
SYSTEMICALLY FOR ABOUT TWO OR MORE WEEKS BEFORE
REPLACING IT WITH ANOTHER. SO THE IDEA IS THAT THAT
GAP IN TIME COULD POTENTIALLY BE ACCOMMODATED BY A
BIOLOGICAL PACEMAKER.
THE IDEA BEHIND THIS IS THIS IS AN INITIAL
SET OF STUDIES THAT WOULD EVENTUALLY PERHAPS LEAD TO
THE DEVELOPMENT OF A BIOLOGICAL PACEMAKER IN THE
FUTURE THAT WOULD JUST REPLACE ELECTRONIC DEVICES.
THE REVIEWERS CERTAINLY APPRECIATED THE
APPROACH AND THE GOAL OF DEVELOPING A BIOLOGICAL
PACEMAKER. I THINK WHAT WAS REALLY A QUESTION WAS
THE OVERALL DESIGN OF THIS PROPOSAL AND THE
RATIONALE BEHIND DOING THIS IN PATIENTS THAT ARE IN
NEED OF BEING BRIDGED FROM ONE DEVICE TO THE NEXT.
SO THE PROPOSAL BRINGS FORTH A COMPARISON
BETWEEN A GENE THERAPY APPROACH AS WELL AS A CELL
THERAPY APPROACH WHICH REVIEWERS VIEWED AS HAVING
TWO DIFFERENT REQUIREMENTS OF EXPERTISE THAT WERE
76

NOT NECESSARILY BEING BROUGHT FORTH BY THE APPLICANT
AND THE TEAM.
SO IN THEIR VIEW, THEY CERTAINLY THOUGHT
THAT THIS WAS SOMETHING THAT WOULD REQUIRE THE
SELECTION OF ONE APPROPRIATE SINGLE THERAPEUTIC TO
BRING FORWARD RATHER THAN EXPLORING TWO POTENTIAL
ONES.
I THINK THEY WERE ALSO DIVIDED ABOUT THE
RATIONALE BEHIND DOING THIS. CERTAINLY PATIENTS
THAT ARE IN NEED OF THIS BIOLOGICAL PACEMAKER AND IN
NEED OF THIS BRIDGING ARE ALREADY UNDERGOING
ANTIBIOTIC THERAPY AND ARE IN A CONDITION WHERE THE
INTRODUCTION OF NEW CELLS MAY BRING ABOUT
COMPLICATIONS THAT WERE NOT NECESSARILY DISCUSSED OR
CONSIDERED.
THE RISKS OF THIS THERAPY WERE ALSO NOT
VERY WELL DISCUSSED IN THE APPLICATION, SUCH AS THE
POSSIBILITY OF TERATOMA FORMATION, IMMUNE REJECTION,
AND OTHER ITEMS AS WELL.
IN TERMS OF THE PI, THE PI IS A
WELL-TRAINED CARDIOLOGIST, HAS A STRONG BACKGROUND
IN ELECTROPHYSIOLOGY, HAS RELEVANT PUBLICATIONS IN
THE AREA, BUT REVIEWERS FELT THAT THE APPLICANT DOES
LACK EXPERTISE WITH HUMAN EMBRYONIC STEM CELLS THAT
WOULD BE REQUIRED TO SUPPORT THE PROPOSED STUDIES.
77

1	THIS DID LEAD REVIEWERS TO QUESTION WHETHER THE
2	APPLICANT WOULD BE ABLE TO ACHIEVE THE OVERALL GOALS
3	OF THE APPLICATION.
4	IN ADDITION, ALTHOUGH THEY CERTAINLY
5	RECOGNIZE THE PRIMARY MENTOR AS HAVING BOTH A VERY
6	STRONG LETTER OF SUPPORT AND BEING A VERY QUALIFIED
7	MENTOR, THEY THOUGHT THE OVERALL DEVELOPMENT PLAN
8	WAS WEAK. AND THEY SAW AS EVIDENCE OF THE LACK OF
9	MENTORING THE POORLY WRITTEN APPLICATION.
10	THE INSTITUTIONAL COMMITMENT, I THINK
11	REVIEWERS, AGAIN, FELT WAS LACKING, CERTAINLY NOT
12	COMPARABLE TO OTHER APPLICATIONS THEY SAW. THEY
13	THOUGHT THAT THE INSTITUTION ITSELF AND THE
14	PROTECTED RESEARCH TIME WAS APPROPRIATE; HOWEVER,
15	THE COMMITMENT FROM THE INSTITUTION, SPECIFICALLY IN
16	TERMS OF LABORATORY SPACE THAT WOULD BE PROVIDED,
17	WAS RATHER MINIMAL, AND THE AMOUNT OF START-UP FUNDS
18	THAT THE APPLICANT WOULD BE RECEIVING WAS NOT VERY
19	CLEAR.
20	I THINK THERE WAS ALSO A QUESTION IN
21	GENERAL ABOUT RESPONSIVENESS TO THE RFA. SOME
22	QUESTIONED THE RESPONSIVENESS OF A GENE THERAPY
23	APPROACH AND CERTAINLY FELT THAT THE HUMAN EMBRYONIC
24	STEM CELL COMPONENT MAY HAVE BEEN INCLUDED IN TERMS
25	OF JUST BEING RESPONSIVE TO THIS RFA.

1	SO, IN GENERAL, THAT'S THE VIEW FROM THE
2	GRANTS WORKING GROUP ON THIS PROPOSAL.
3	CHAIRMAN THOMAS: QUESTIONS?
4	MR. TORRES: ANY REBUTTALS FROM THE FOLKS
5	THAT ARE HERE?
6	DR. MARBAN: THANK YOU, SENATOR TORRES.
7	SO I'M THE MENTOR IN QUESTION. THE APPLICANT IS
8	HERE WITH ME AS IS A PATIENT ADVOCATE. THE FACT
9	THE IDEA THAT HUMAN EMBRYONIC STEM CELLS ARE THROWN
10	IN HERE AS AN AFTERTHOUGHT FLIES IN THE FACE OF THE
11	FACT THAT WE HAVE PUBLISHED WORK ON HUMAN EMBRYONIC
12	STEM CELLS AS BIOLOGICAL PACEMAKERS AND DID SO THREE
13	YEARS AGO, AND THE PAPER GOT AN AWARD OF THE BEST
14	PAPER PUBLISHED IN THE JOURNAL CIRCULATION, WHICH IS
15	THE HIGHEST IMPACT CARDIOLOGY JOURNAL IN THE WORLD.
16	THE OTHER APPROACH THAT'S COMPETING HERE
17	IS IN PRESS AND WILL APPEAR NEXT WEEK IN NATURE
18	BIOTECHNOLOGY. AND WE'VE ALREADY GOTTEN MEDIA
19	INQUIRIES FROM SEVERAL COUNTRIES AROUND THE WORLD,
20	AND IT'S JUST STARTING TO PUBLICIZE THIS WORK. IT'S
21	DIRECT REPROGRAMMING OF PREEXISTING REGULAR HEART
22	CELLS INTO PACEMAKER CELLS. AND THE IDEA OF
23	COMPARING TWO LEAD CANDIDATES, BOTH OF WHICH HAVE
24	BEEN IN RODENT MODELS IN A LARGE ANIMAL SETTING, I
25	THINK, IS A VERY COMPELLING ONE AND SHOULDN'T
	79
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1	DETRACT.
2	THERE WAS OBVIOUSLY SOME DIFFERENCE OF
3	OPINION IN THE WORKING GROUP ON THESE ISSUES. IT
4	WASN'T VIEWED WITH UNANIMITY, AND THEY WERE VOICED
5	AND VERBALLY SO. BUT I'M NOT HERE TO QUESTION THE
6	REVIEW SO MUCH AS TO ARGUE FOR THE FACT THAT THIS
7	APPLICATION, WHICH CAME IN AT 58.75, WHICH IS JUST A
8	HAIR BELOW THE CUTOFF OF 61 HERE IN A GROUP OF
9	APPLICATIONS OF RARE INDIVIDUALS, RARIFIED
10	INDIVIDUALS THAT WE MUST RECRUIT INTO THE STEM CELL
11	COMMUNITY, THAT IT WOULD BE A DISSERVICE TO THE
12	CITIZENS OF CALIFORNIA NOT TO EXTEND THAT PAYLINE
13	DOWN SOME TO INCLUDE THIS APPLICATION.
14	THIS WOULD ALSO BALANCE THE CIRM
15	TRANSLATIONAL PORTFOLIO IN A VERY IMPORTANT WAY.
16	THERE IS NO FOCUS AT CIRM ON APPLICATIONS HAVING TO
17	DO WITH CARDIAC RHYTHM DISORDERS. THESE ARE THE
18	MAJOR CAUSE OF SUDDEN DEATH WORLDWIDE. OVER 250,000
19	PEOPLE A YEAR IN THE UNITED STATES DIE OF SUDDEN
20	CARDIAC DEATH DUE TO CARDIAC ARRHTHYMIAS. AND THERE
21	IS NOT A SINGLE GRANT IN THE CIRM TRANSLATIONAL
22	PORTFOLIO ON THIS MATTER.
23	I THINK IT IS A COMPELLING ISSUE. IT
24	ADDRESSES HUMAN EMBRYONIC STEM CELLS, IT USES
25	STATE-OF-THE-ART REPROGRAMMING. THE APPLICANT IS

80

1	SUPERB. AND I HOPE THAT YOU WILL NUDGE DOWN THE
2	PAYLINE TO ACCOMMODATE THIS WORTHY APPLICATION.
3	I'D ALSO LIKE TO INTRODUCE OUR PATIENT
4	ADVOCATE AT THIS POINT.
5	MS. FEVERSTEIN: I HAVE HAD A PACEMAKER
6	SINCE 2004. I HAVE HAD MANY, MANY, MANY, MANY
7	ISSUES WITH THIS PACEMAKER. I WASN'T AWARE I WAS
8	GOING TO GET ONE, AND I WOKE UP WITH ONE. I HAVE
9	HAD PAIN. IT HAS SHOCKED ME. I CAN'T GO INTO
10	AIRPORTS. I CAN'T GO INTO COURTHOUSES. I CANNOT GO
11	VARIOUS AND SUNDRY PLACES BECAUSE IF I WALK INTO ANY
12	OF THOSE MACHINES, I WILL DIE.
13	THE THOUGHT OF AN ELECTRONIC OR A STEM
14	CELL PACEMAKER BEING IMPLANTED IN ME WHICH WOULD
15	CHANGE THE WAY THAT I LIVE IS UNBELIEVABLY
16	UPLIFTING. IF I HAVE TO CONTINUE TO LIVE WITH THIS
17	AND I WILL BECAUSE THAT'S THE ONLY WAY I CAN LIVE.
18	I PACE TO LIVE. I DON'T HAVE A DEFIBRILLATOR. IT'S
19	A FULL ON, IT GOES ALL THE TIME. AND I CONTINUE TO
20	HAVE ISSUES. I HAD AN EMERGENCY OPERATION TO
21	REPLACE THE ENTIRE PACEMAKER BECAUSE IT FAILED. AND
22	I WOULDN'T HAVE KNOWN IT FAILED AND I WOULDN'T HAVE
23	DROPPED DEAD IF I HADN'T BEEN AT A NORMAL CHECKUP.
24	SO IF YOU APPROVE THIS APPLICATION, IT
25	WOULD ENHANCE MY LIFE DOWN THE ROAD. THANK YOU.

1	CHAIRMAN THOMAS: ANY OTHER PUBLIC COMMENT
2	ON THIS ITEM? DR. TROUNSON, COULD YOU JUST GIVE US
3	YOUR THOUGHTS, PLEASE?
4	DR. TROUNSON: SO I'M CLEARLY VERY
5	SYMPATHETIC TO ALL OF THESE APPLICANTS, ALL OF THESE
6	M.D. PH.D.'S. BUT IN DISCUSSION WITH DR. FEIGAL,
7	SHE AND I DON'T THINK THAT THERE WAS REALLY ANYTHING
8	THAT WOULD HAVE ALTERED THE REVIEWERS' MARK THAT WAS
9	BROUGHT FORWARD IN THE EXTERNAL PETITIONS IN ANY OF
10	THEM IN THIS CASE.
11	I THINK IT WAS WELL DEBATED AT THE REVIEW.
12	I THINK THE MARK IS APPROPRIATE. AND I THINK IF YOU
13	WANT TO MOVE THIS, IT HAS TO BE REALLY FOR STRICTLY
14	PROGRAMMATIC REASONS. WE CAN'T REALLY HELP YOU ON
15	THE SCIENTIFIC SIDE BECAUSE I DON'T THINK THERE'S
16	REALLY ANYTHING THAT REALLY WASN'T DISCUSSED BY THE
17	REVIEWERS THERE THAT WOULD REALLY CHANGE OUR
18	RECOMMENDATION.
19	SO DR. FEIGAL AND I ARE IN CONCERT ON
20	THIS, AND WE BELIEVE THAT THE REVIEWERS' SCORES ARE
21	REASONABLE.
22	CHAIRMAN THOMAS: SENATOR TORRES.
23	MR. TORRES: WHAT WAS THE SCORE ON THIS
24	GRANT?
25	DR. SAMBRANO: THIS WAS A 59.
	82

1	MR. TORRES: 59. AND THE FUNDING LEVEL
2	WAS AT 65?
3	DR. SAMBRANO: SO THE ORIGINAL LINES WERE
4	DRAWN AT 66 OR ABOVE AND THEN 61 OR BELOW. SO THAT
5	ESTABLISHED THE INITIAL TIERS I AND TIERS II. THERE
6	WAS AN APPLICATION 6525 THAT WAS MOVED UP, AND
7	THAT'S WHY THAT'S IN TIER I. BUT THE ORIGINAL LINE,
8	IF YOU WILL, WAS AT 66.
9	MR. TORRES: WHAT OTHER OPTIONS ARE
10	AVAILABLE IF THIS PROPOSAL IS NOT MOVED TOWARD
11	FUNDING FOR THIS TYPE OF RESEARCH?
12	DR. SAMBRANO: WELL, THERE'S EARLY
13	TRANSLATIONAL. DEPENDING ON THE PROPOSAL, IT COULD
14	BE TOOLS AND TECHNOLOGIES, BUT THERE ARE OTHER
15	OPTIONS.
16	MR. TORRES: AND THE TIMELINESS OF THOSE
17	OTHER OPTIONS?
18	DR. SAMBRANO: WELL, WE'RE CURRENTLY UNDER
19	THE EARLY TRANSLATIONAL REVIEW RIGHT NOW. SO IT
20	WOULD NOT BE UNTIL CERTAINLY LATE NEXT YEAR.
21	DR. PRIETO: I GUESS I'M JUST A LITTLE
22	CONCERNED REGARDING OUR PROCESS IN THAT THE
23	EXTRAORDINARY PETITION HERE, IT SEEMS TO ME IS
24	MAKING AN ARGUMENT PURELY ON PROGRAMMATIC GROUNDS.
25	THERE'S NO CONTESTING FACTUAL ISSUES OR
	83

1	MISINTERPRETATION OF THE SCIENTIFIC DATA THAT LED TO
2	THE SCORE. JUST AN OBSERVATION. I'M NOT SURE THAT
3	GIL NEEDS TO RESPOND TO IT.
4	CHAIRMAN THOMAS: ANY OTHER COMMENTS ON
5	THIS APPLICATION?
6	MR. TORRES: I KNOW HOW TO READ VOTES, SO
7	I WILL MOVE ON.
8	CHAIRMAN THOMAS: THANK YOU. ARE THERE
9	ANY OTHER APPLICATIONS THAT MEMBERS OF THE BOARD
10	WOULD LIKE TO HEAR A REPORT ON? MR. JUELSGAARD.
11	DR. JUELSGAARD: I'D LIKE TO HEAR A REPORT
12	ON 06525. THIS IS THE ONE THAT IS IN TIER I
13	RECOMMENDED FOR APPROVAL. SO I BEGIN BY NOTING THAT
14	THERE'S A FAIRLY LARGE STANDARD DEVIATION OF 12
15	THAT'S REPORTED ON WHAT WE RECEIVED.
16	AND THE SECOND THING I WOULD NOTE IN
17	LOOKING AT THE MATERIALS ASSOCIATED WITH THIS,
18	THERE'S AN INDICATION THAT THE INDIVIDUAL WHO'S
19	INVOLVED HAS RECEIVED IN THE PAST SEVERAL OF THESE
20	AWARDS. AND I'M CURIOUS IN PARTICULAR AS TO HOW
21	MUCH FUNDING THIS PARTICULAR INVESTIGATOR HAS
22	RECEIVED FROM CIRM FOR VARIOUS PAST PROJECTS, IF
23	THAT FIGURE IS AVAILABLE.
24	DR. OLSON: I WOULD HAVE TO TAKE A FEW
25	MINUTES PROBABLY TO TELL YOU EXACTLY HOW MUCH

1	FUNDING HE HAS. I DO NOT HAVE OFF THE TOP OF MY
2	HEAD THE EXACT AMOUNT OF FUNDING THE APPLICANT HAS
3	RECEIVED FROM CIRM. I DO KNOW THAT THE APPLICANT
4	HAS RECEIVED PREVIOUS FUNDING FROM CIRM. SO I CAN
5	GET THAT INFORMATION FOR YOU.
6	DR. JUELSGAARD: SO THE CONCERN IS
7	SEVERAL. IT DOESN'T SAY HAS RECEIVED MONEY. SO THE
8	QUESTION IS IS THERE AN ISSUE ABOUT HOW MANY TIMES
9	ANY ONE INDIVIDUAL CAN KEEP COMING TO THIS
10	ORGANIZATION FOR YET ANOTHER AWARD IN THIS AREA?
11	AND PERHAPS THERE ISN'T. PERHAPS IT SHOULD BE
12	OPEN-ENDED. I JUST DON'T KNOW. BUT AT LEAST TO
13	HAVE SOME GROUNDING IN THE AMOUNT OF MONEY WOULD BE
14	HELPFUL, AT LEAST FOR ME TO THINK ABOUT IT.
15	DR. OLSON: CIRM HAS LIMITS ON THE NUMBER
16	OF ACTIVE AWARDS THAT AN APPLICANT MAY HOLD AT ANY
17	ONE TIME. SO IT HAS LIMITS ON THAT AS A PI OR AS A
18	CO-PI. THAT'S WRITTEN INTO VIRTUALLY EVERY RFA.
19	SO, NOW, AS FAR AS LOOKING AT PAST
20	FUNDING, THAT'S NOT USUALLY A CONSIDERATION AS TO
21	WHETHER AN APPLICANT CAN COME OR NOT. I THINK YOU
22	ARE HIGHLIGHTING AN ISSUE THAT WAS NOTED BY THE
23	GRANTS WORKING GROUP AND WAS DEBATED, NOT ONLY
24	DURING THE ACTUAL SCIENTIFIC REVIEW, BUT ALSO DURING
25	THE PROGRAMMATIC REVIEW, THAT THIS APPLICANT

BASICALLY IS A VERY SUCCESSFUL PERSON IN HIS OR HER
FIELD, BUT IS MOVING BUT THE POINT WAS MADE BY
SOME AND OBVIOUSLY CONVINCINGLY ENOUGH THAT AT LEAST
THE ENTIRE GRANTS WORKING GROUP CHOSE TO VOTE TO
RECOMMEND FOR FUNDING.
THE POINT WAS MADE THAT THE APPLICANT IS
MOVING INTO ANOTHER AREA OF RESEARCH THAT IS
CONSIDERED, WHAT DO I WANT TO SAY, A LITTLE BIT MORE
SPECULATIVE, AND THAT, THEREFORE, WOULD BE LESS
LIKELY TO BE FUNDED BY OTHER SOURCES. AND SO IN
THAT SENSE, IT WAS A NEW CAREER DIRECTION. BUT AS I
SAY, THIS WAS A POINT OF DEBATE AMONG THE GRANTS
WORKING GROUP.
SO YOU CAN SEE WHERE THEY FELL. IT ENDED
UP BEING RECOMMENDED FOR FUNDING. I'D BE HAPPY TO
GO THROUGH THE ENTIRE REVIEW SUMMARY, IF YOU'D LIKE,
BUT I'M RESPONDING IN PARTICULAR TO YOUR QUESTION.
DR. JUELSGAARD: I'M JUST INTERESTED IN
THIS ONE PARTICULAR ASPECT. SO UNDER THE
RESPONSIVENESS, I'LL READ JUST FROM THE FIRST OF THE
TWO PARAGRAPHS ON RESPONSIVENESS, THE LAST SENTENCE,
WHICH SAYS, "IT IS NOT CLEAR THAT THIS AWARD IS
NECESSARY TO THE SUCCESS OF THIS CANDIDATE AS A
PHYSICIAN SCIENTIST. AND IN THAT REGARD THE
APPLICATION IS MINIMALLY RESPONSIVE TO THE OBJECTIVE
86

	DAKKIDIEKO KEIOKIING DEKVICE
1	OF THE RFA."
2	I GUESS THAT'S WHAT I'M FOCUSED ON. SO
3	WHAT'S THE PURPOSE OF THESE AWARDS IN PARTICULAR AS
4	WERE OUTLINED BEFORE? THESE ARE PEOPLE WHO ARE SORT
5	OF COMING UP IN THE WORLD. THAT'S WHAT I
6	UNDERSTOOD. AND THE QUESTION IS, GREAT, IT'S A
7	BRAND-NEW AREA OF ENDEAVOR. I GOT THAT. I
8	UNDERSTAND THAT. BUT FOR ME THE CRITICAL NATURE IS
9	WHEN IS ENOUGH ENOUGH IN SORT OF BRINGING SOMEBODY
10	NEW FORWARD ENOUGH INTO THE PHYSICIAN SCIENTIST AREA
11	THAT WE SHOULD SAY, OKAY, FINE, WE'VE DONE OUR JOB
12	BY YOU. NOW IT'S UP TO YOU TO FIGURE OUT OTHER
13	FUNDING SOURCES? I'LL STOP THERE.
14	CHAIRMAN THOMAS: DR. KRONTIRIS.
15	DR. KRONTIRIS: I GUESS I JUST WANTED SOME
16	CLARIFICATION FROM YOU ON THIS. IT'S INTERESTING
17	THAT IT'S KIND OF A TWIST ON OUR USUAL DISCUSSION.
18	BUT WAS IT ULTIMATELY DECIDED THAT THIS CANDIDATE
19	FIT THE CRITERIA FOR THE AWARD?
20	DR. OLSON: THE CANDIDATE MET THE
21	ELIGIBILITY CRITERIA. THE CANDIDATE MET THE
22	ELIGIBILITY CRITERIA.
23	DR. KRONTIRIS: THEN I THINK THAT'S WHERE
24	WE ARE.
25	DR. OLSON: MR. JUELSGAARD IS ASKING A
	87
	01

1	DIFFERENT QUESTION. HE'S ASKING DID THE CANDIDATE
2	MEET THE RESPONSIVENESS CRITERIA, WHAT THE GOAL OF
3	THE RFA WAS. I THINK IT DEPENDS ON HOW YOU CHOOSE
4	TO INTERPRET THAT.
5	CHAIRMAN THOMAS: ANY OTHER COMMENTS?
6	QUESTIONS? YES, DR. CHISARI.
7	DR. CHISARI: SO THERE ARE TWO COMMENTS IN
8	THIS REVIEW THAT WE'VE BEEN PROVIDED WITH THAT ARE
9	OF SIGNIFICANT CONCERN TO ME, AND PERHAPS YOU CAN
10	PROVIDE SOME INSIGHT. THE FIRST ONE IS THAT, I'LL
11	READ NOW, "THE REVIEWERS GENERALLY FOUND THE
12	EXPERIMENTAL PLAN TO BE NOVEL, BUT THERE WERE
13	CONSIDERABLE QUESTIONS REGARDING THE RATIONALE OF
14	USING EMBRYONIC STEM CELLS AS OPPOSED TO IPS CELLS
15	GIVEN ALLOGENEIC BARRIER." AND SOME OF THE
16	REVIEWERS SUGGESTED THAT IPS CELLS BE USED FROM THE
17	BEGINNING OF THE PROJECT.
18	SO MY FIRST QUESTION IS CAN YOU DESCRIBE
19	WHAT THE DISCUSSION WAS AROUND THAT PARTICULAR
20	ISSUE?
21	DR. OLSON: I THINK OBVIOUSLY IF YOU'RE
22	TALKING ABOUT AN AUTOIMMUNE DISEASE, I THINK THERE
23	WERE SOME CONCERNS AND THIS WAS DO RECALL THAT
24	THESE ARE IN ORDER OF WHAT THE REVIEWERS CONSIDERED
25	IMPORTANT OR RELEVANT TO THAT. BUT THEY DID THINK
	88

1	THAT YOU DO HAVE TO ASK THE QUESTION OF AN
2	ALLOGENEIC THERAPY IN THAT CONTEXT. SO I THINK THAT
3	WAS THE QUESTION, BUT I THINK WE ALL RECOGNIZE THAT
4	THERE ARE CONSIDERATIONS WITH A PERSONALIZED IPSC
5	THERAPY. AND SO I THINK AS ADVANCES ARE BEING MADE
6	IN SORT OF A, WHAT SHALL I SAY, IMPROVING ACCEPTANCE
7	OF ALLOGENEIC THERAPIES OR IN SOME CONTEXT, WOULD
8	THIS BE VIABLE. SO I LEAVE IT AT THAT.
9	DR. CHISARI: HOW DID THE GROUP COME DOWN
10	ON THAT ISSUE?
11	DR. OLSON: THEY CAME DOWN THAT IT WAS A
12	CONCERN ALBEIT NOT AS IMPORTANT AS OTHER CONCERNS AS
13	FAR AS THE DESIGN AND FEASIBILITY AND THE RATIONALE.
14	DR. CHISARI: THE OTHER QUESTION IS AT THE
15	END OF THE RESEARCH PLAN CRITIQUE, IT'S IN THE
16	CATEGORY OF MINOR CONCERNS, IT SAYS HERE SOME
17	REVIEWERS RAISED MINOR CONCERNS REGARDING THE
18	RELEVANCE, RELEVANCE, OF STUDYING INFLAMMATORY BOWEL
19	DISEASE IN AN ANIMAL MODEL THAT IS NOT
20	IMMUNOCOMPETENT.
21	GIVEN THAT THE PATHOGENESIS OF
22	INFLAMMATORY BOWEL DISEASE IS IMMUNE MEDIATED, AND
23	APPARENTLY IN AIM 3 OF THIS APPLICATION, THEY'RE
24	GOING TO BE USING IMMUNO-INCOMPETENT MICE, A MOUSE
25	MODEL, WILL THE RELEVANCE OF THE EXPERIMENTS IN AIM

	DARKISIERS REPORTING SERVICE
1	3 BE APPLICABLE TO THE HUMAN DISEASE?
2	DR. OLSON: I THINK YOU HIGHLIGHT AN ISSUE
3	THAT BASICALLY PLAGUES ALL HUMAN-DERIVED THERAPIES
4	IN THE CONTEXT OF A PRECLINICAL MODEL AND
5	PARTICULARLY THOSE THAT INVOLVE AN AUTOIMMUNE
6	COMPONENT. SO THAT'S THE KIND OF SITUATION WHERE
7	YOU EITHER DO A HOMOLOGOUS SPECIES MODEL. BUT IF
8	YOU ARE ACTUALLY TRYING TO TEST, YOU CAN TEST THE
9	NOTION OF CAN IT ENGRAFT IN THAT KIND OF MODEL, CAN
10	IT FUNCTION. WHAT YOU CANNOT TEST IS THE IMPACT OF
11	AUTOIMMUNITY ON IT.
12	SO IT'S IN THAT CONTEXT THAT YOU CAN SAY
13	IS WHAT YOU HAVE DEVELOPED FUNCTIONAL, BUT YOU
14	CANNOT ADDRESS THE IMPACT OF THE AUTOIMMUNITY
15	WITHOUT GOING TO OTHER KINDS OF MODELS.
16	DR. CHISARI: THE FUNDAMENTAL
17	DR. OLSON: AND THAT COULD BE I'M
18	SORRY. GO AHEAD.
19	DR. CHISARI: THE FUNDAMENTAL PATHOGENESIS
20	OF INFLAMMATORY BOWEL DISEASE IS THAT IT'S AN
21	AUTOIMMUNE INFLAMMATORY DISEASE.
22	DR. OLSON: YES, IT IS AN AUTOIMMUNE
23	DISEASE. THAT IS CORRECT.
24	DR. CHISARI: IF THE ANIMAL MODEL, WHICH
25	IS ONLY ONE OF THREE AIMS, BUT IF THAT MODEL IS ONE
	90

1	THAT DOES NOT REPRODUCE THE UNDERLYING FUNDAMENTAL
2	PATHOGENESIS OF THE HUMAN DISEASE, COULD YOU EXPLAIN
3	WHY
4	DR. OLSON: WHAT YOU DO NOT HAVE IS YOU DO
5	NOT HAVE A PROOF OF DISEASE ACTIVITY, BUT YOU MAY
6	WELL GET A PROOF OF BIOLOGICAL ACTIVITY. THAT IS,
7	CAN THIS DO CAN THIS INTEGRATE, CAN IT INTEGRATE
8	AND CAN IT BE FUNCTIONAL IN THAT KIND OF MODEL. I
9	AGREE WITH YOU. YOU WILL NOT GET DISEASE MODIFYING
10	ACTIVITY IN THAT KIND OF MODEL, BUT YOU WILL GET
11	BIOLOGICAL ACTIVITY. SO THAT IS A STEP. IT'S SORT
12	OF PROOF OF BIOLOGICAL CONCEPT, BUT NOT PROOF OF
13	DISEASE MODIFYING CONCEPT.
14	DR. CHISARI: THANK YOU.
15	DR. PULIAFITO: TO ME THE RED FLAG IS THIS
16	SEEMS LIKE A WELL-FUNDED INVESTIGATOR THAT'S GOT
17	LOTS OF YOUNG INVESTIGATOR AWARDS. DOESN'T TO ME
18	REALLY MEET THE INTENT OF THIS RFA.
19	DR. OLSON: AND THAT IS YOUR DECISION AS A
20	BOARD TO MAKE.
21	DR. JUELSGAARD: SO BASED ON THE ONE, THE
22	LACK OF KNOWLEDGE ABOUT THE AMOUNT OF MONEY THAT
23	THIS INVESTIGATOR HAS RECEIVED BEFORE
24	DR. OLSON: I CAN SPEAK TO THAT NOW. THE
25	APPLICANT HAS PREVIOUSLY RECEIVED \$3.2 MILLION FROM
	91
	

1	CIRM. I WOULD POINT OUT THAT'S CONSIDERABLY LESS
2	THAN MANY INVESTIGATORS.
3	DR. JUELSGAARD: SO THIS INDICATED IT HAD
4	SEVERAL AWARDS, AND THAT SEEMS LIKE ONLY ONE; IS
5	THAT RIGHT?
6	DR. OLSON: OTHER AWARDS, NOT NECESSARILY
7	FROM CIRM.
8	DR. KRONTIRIS: COULD I JUST MAKE A
9	COMMENT? THIS IS KIND OF AN EXAMPLE OF MAKING SOME
10	FAIRLY DETAILED INQUIRIES INTO THE NATURE OF THIS
11	REVIEW AND THE CANDIDATE BLINDED TO REALLY IMPORTANT
12	ASPECTS OF THE REVIEW THAT I THINK WE SIMPLY HAVE TO
13	TRUST, AND IT SOUNDS LIKE FROM THE DISCUSSION THE
14	GRANTS WORKING GROUP WENT THROUGH. WE DON'T KNOW
15	WHO THE CANDIDATE IS, WHAT THEIR STATE OF CAREER IS,
16	HOW PRODUCTIVE THEY HAVE BEEN, WHAT'S HAPPENED IN
17	TERMS OF THE TOTALITY OF THEIR GRANT REVIEW. ALL OF
18	THESE THINGS GRANTS WORKING GROUP COMMITTEE WOULD
19	HAVE GONE THROUGH AND COME ULTIMATELY TO SOME
20	DECISION ABOUT AND THEY HAVE. AND TO QUESTION THESE
21	CLEARLY LEGITIMATE ISSUES THAT ARE BOTHERING PEOPLE
22	WITHOUT HAVING KNOWLEDGE OF THE FACTS SEEMS TO ME
23	NOT PRODUCTIVE.
24	CHAIRMAN THOMAS: MR. HARRISON, AT THIS
25	POINT, DO WE ENTERTAIN A MOTION TO FUND TIER I, OR

1	SHOULD WE GO TO PUBLIC COMMENT ON ANY OTHER
2	PROPOSALS IN ADVANCE?
3	MR. HARRISON: I WOULD RECOMMEND THAT YOU
4	TAKE ANY OTHER PUBLIC COMMENT, AND THEN YOU CAN ASK
5	WHETHER ANY MEMBER WOULD LIKE TO MAKE A MOTION WITH
6	RESPECT TO A PARTICULAR APPLICATION. IF THERE ARE
7	NONE, THEN YOU CAN MOVE TO A BLOC VOTE ENCOMPASSING
8	THOSE IN TIER I AND IN TIER III.
9	CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.
10	DO WE HAVE MEMBERS OF THE PUBLIC WHO'D LIKE TO
11	COMMENT AT THIS POINT? IN SO DOING, PLEASE GIVE
12	YOUR NAME TO START.
13	DR. MEMARZADEH: SO GOOD MORNING,
14	EVERYONE. I AM SANAZ MEMARZADEH. I AM A
15	GYNECOLOGIST BY TRAINING AND A GYNECOLOGIC SURGEON.
16	I'M ALSO A PH.DTRAINED MOLECULAR BIOLOGIST. I
17	HAVE SUBMITTED AN APPLICATION TO CIRM FOCUSING ON
18	IDENTIFYING REAL TREATMENTS FOR A DISEASE CALLED
19	ENDOMETRIOSIS. ENDOMETRIOSIS IS CHRONIC,
20	DEBILITATING, PAINFUL, INCURABLE, AND VERY
21	PREVALENT. IT AFFECTS 10 PERCENT OF WOMEN DURING
22	THEIR REPRODUCTIVE LIVES. THIS IS THE PRIME OF A
23	WOMAN'S LIFE.
24	AS GYNECOLOGISTS WE DON'T KNOW HOW TO
25	TREAT ENDOMETRIOSIS. AND THE REASON FOR THAT IS WE
	93

1	DON'T UNDERSTAND WHAT CAUSES IT. AS A RESULT, A
2	WOMAN WHO IS AFFECTED BY ENDOMETRIOSIS ENDS UP
3	UNDERGOING MULTIPLE SURGERIES, ULTIMATELY RESULTING
4	IN REMOVAL OF REPRODUCTIVE ORGANS AND, IN ESSENCE,
5	FEMALE CASTRATION.
6	TO MY KNOWLEDGE CIRM HAS NOT FUNDED WORK
7	RELATED TO GYNECOLOGIC DISEASES. I AM HERE TODAY TO
8	PETITION FOR FUNDING OF MY APPLICATION PRIMARILY
9	BECAUSE I DO BELIEVE SOME KEY POINTS WERE MISSED
10	DURING THE REVIEW PROCESS.
11	FIRST, IT WAS QUESTIONED IF THE CIRM GRANT
12	WOULD HELP MY CAREER DEVELOPMENT. FIVE-YEAR STABLE
13	FUNDING THROUGH CIRM WOULD ALLOW ME TO BECOME A
14	LEADER IN THE FIELD OF GYNECOLOGIC RESEARCH.
15	GYNECOLOGIC DISEASES ARE SO POORLY STUDIED AND WE
16	DESPERATELY NEED LEADERS IN THIS FIELD.
17	SECOND, MY CHOICE OF MENTORS WAS
18	QUESTIONED. I HAVE PICKED MY TWO MENTORS SPECIFIED
19	IN THE APPLICATION FOR A VERY SPECIFIC REASON. BOTH
20	HAVE BEEN SUCCESSFUL IN TAKING A TREATMENT FROM THE
21	LABORATORY INTO THE CLINIC. DR. OWEN WITTE WAS
22	INSTRUMENTAL IN DEVELOPMENT AND CLINICAL TESTING OF
23	GLEEVEK, THE FIRST TARGETED THERAPY FOR LEUKEMIAS.
24	MY SECOND MENTOR, DR. JOHN GLASBY WORKED ALONGSIDE
25	DR. DENNY SLAMON IN TAKING HERCEPTIN FROM THE LAB

1	INTO CLINIC FOR TREATMENT OF PATIENTS FOR BREAST
2	CANCER.
3	I PLAN TO TAKE FULL ADVANTAGE OF THESE
4	WONDERFUL MENTORS AND ALSO THE GREATER COMMUNITY AT
5	UCLA AND OTHER MENTORS IN REPRODUCTIVE BIOLOGY SUCH
6	AS DR. DANIEL DEMESICK (PHONETIC).
7	THIRD AND LAST, THE ABILITY OF A SPECIFIC
8	HORMONAL DEFECT IN ENDOMETRIOSIS WAS QUESTIONED.
9	MANY INVESTIGATORS AND EXPERTS IN THE FIELD HAVE
10	ALREADY DEMONSTRATED THAT THIS SPECIFIC HORMONAL
11	DEFECT DOES EXIST. WHAT IS NOT KNOWN IS EXACTLY
12	WHAT CELLS ARE AFFECTED BY THAT DEFECT AND WHAT IS
13	THE MECHANISM OF THIS HORMONAL PROBLEM.
14	OUR PRELIMINARY DATA SUGGESTS THAT
15	ENDOMETRIOSIS MAY VERY WELL BE A STEM CELL DISEASE.
16	SIMPLY PUT, IT COULD HAPPEN BECAUSE THERE'S A
17	MISCOMMUNICATION BETWEEN THE ENDOMETRIAL STEM CELL
18	AND ITS NEIGHBORS. IN MY PROPOSAL I PLAN TO FOCUS
19	ON THIS SPECIFIC MECHANISM OF DISEASE, LOOKING
20	PARTICULARLY AT THE ENDOMETRIAL STEM CELLS AND ITS
21	NEIGHBORS. I THEN PLAN TO TEST DRUGS THAT CAN
22	TARGET THOSE SPECIFIC DEFECTS IN AN IN VIVO MODEL
23	FOR THE TREATMENT OF ENDOMETRIOSIS.
24	THE OUTCOME WILL BE EVIDENCE-BASED,
25	EFFECTIVE TREATMENTS WITHOUT THE NEED FOR SURGERY.

1	I KNOW THAT I CAN DO THIS AT UCLA, AND I'M ASKING
2	FOR YOUR HELP IN FUNDING THIS GRANT THAT WILL
3	SIGNIFICANTLY ACCELERATE THIS WORK. THANK YOU SO
4	MUCH.
5	CHAIRMAN THOMAS: THANK YOU, DOCTOR. NEXT
6	PUBLIC COMMENT, PLEASE.
7	DR. DAMOISEAUX: MY NAME IS DR.
8	DAMOISEAUX. I'M THE SCIENTIFIC DIRECTOR OF THE
9	MOLECULAR SCREENING SHARED RESOURCE AT UCLA. I
10	WOULD LIKE TO PETITION YOU TO FUND DR. SANAZ'
11	RESEARCH.
12	I'M VERY FAMILIAR WITH HER RESEARCH, AND I
13	CAN SPEAK A LOT TO HER SCIENTIFIC EXCELLENCE. BUT
14	HERE TODAY I AM AS A HUSBAND OF A WONDERFUL WIFE WHO
15	IS AFFECTED WITH ENDOMETRIOSIS. AND THAT DIAGNOSIS
16	CAME DOWN ABOUT FOUR YEARS AGO. AFTER A JOURNEY OF
17	ABOUT TWO YEARS AND GOING THROUGH SIX OB-GYNS, WE
18	FINALLY ENDED UP GETTING THIS DIAGNOSIS AND WERE
19	ABLE TO DO SOMETHING ABOUT THIS. AT THE SAME TIME,
20	I STARTED TO REVIEW THE SCIENTIFIC LITERATURE AND
21	FOUND PRETTY MUCH NOTHING. I DIDN'T FIND ANYTHING
22	THAT WAS FUNDED BY THE NIH IN ANY MAJOR SCALE. I
23	DIDN'T FIND ANY FUNDING SOURCES OUTSIDE OF THE NIH.
24	SO I THINK THIS IS YOUR FIRST OPPORTUNITY TO TEAR
25	INTO THIS DISEASE AND BE LEADING IN THE NATION.

1	SO AFTER REVIEWING ALL OF THIS AND LOOKING
2	AT THE OPTIONS, MY WIFE DECIDED TO HAVE LUPRON,
3	WHICH IS BASICALLY, AS DR. SANAZ POINTED OUT, A
4	CHEMICAL CASTRATION OF THE FEMALE ORGANS. SHE WENT
5	INTO PREMATURE MENOPAUSE. A WONDERFUL WIFE OF 30
6	YEARS FELT ALL OF A SUDDEN 50 YEARS OLD. SO I'M NOT
7	SURE IF ANY OF YOUR WIVES OR IF ANY OF YOU HAVE
8	EXPERIENCED THIS, BUT I CAN TELL YOU IT'S PRETTY
9	HORRIBLE.
10	SO RIGHT NOW THIS IS THE ONLY OPTION,
11	HORMONAL ABLATION THERAPY. AND WHAT'S REALLY,
12	REALLY NEEDED IS TO DISSECT THE BIOLOGY BEHIND IT.
13	I THINK THERE'S A LOT OF BIOLOGY TO BE HAD BECAUSE
14	ENDOMETRIOSIS IS BASICALLY, IF YOU WANT, A
15	NONCANCEROUS GROWTH OF ENDOMETRIAL TISSUE IN ALL
16	SORTS OF ORGANS OF THE BODY. SO, FOR EXAMPLE,
17	ENDOMETRIAL LESIONS HAVE BEEN FOUND IN THE BOWEL, IN
18	THE LUNGS, EVEN IN THE BRAIN, BUT THEY DON'T TURN
19	INTO A FULL-BLOWN CANCER TYPICALLY. ACTUALLY IT WAS
20	FAIRLY RARELY.
21	REALLY GREAT QUESTION HERE IS WHY. IN
22	ORDER TO BE ABLE TO GO AFTER THESE QUESTIONS THAT
23	WILL TELL US A LOT ABOUT CANCER STEM CELLS AND A LOT
24	OF OTHER THINGS THAT ARE REALLY IMPORTANT AND AREN'T
25	ANSWERED, I REALLY WOULD LIKE YOU TO FUND HER
	^7
	97

1	PROPOSAL. THANK YOU.
2	CHAIRMAN THOMAS: THANK YOU. NEXT
3	SPEAKER, PLEASE. AND DO REMEMBER PLEASE KEEP YOUR
4	COMMENTS TO THREE MINUTES.
5	DR. CINGOLANI: GOOD MORNING. MY NAME IS
6	EUGENIO CINGOLANI. I AM APPLYING FOR THE
7	APPLICATION FOR DEVELOPMENT OF A BIOLOGICAL
8	PACEMAKER. AS A LITTLE BIT OF BACKGROUND, I AM A
9	CARDIOLOGIST, CLINICAL ELECTROPHYSIOLOGIST, TAKING
10	CARE OF PATIENTS WITH THESE CONDITIONS. PRIOR TO
11	THIS, I SPENT THREE YEARS AT HOPKINS STUDYING CELL
12	BIOLOGY TO TRY TO DEVELOP NEW THERAPIES TO HELP MY
13	PATIENTS.
14	I BELIEVE THAT THIS IS A REALLY
15	UNDERSERVED POPULATION WHERE SOME CONDITIONS CAN
16	HAPPEN TO ELECTRONIC DEVICES AND SOME ALTERNATIVES
17	NEEDS TO TREAT OUR PATIENTS. I'M LUCKY ENOUGH TO
18	HAVE A TERRIFIC MENTOR AND COMMENTERS WITH DIFFERENT
19	EXPERTISE TO HELP ME DEVELOP MY PROJECT. AND I
20	THINK THIS IS VERY IMPORTANT FOR OUR PATIENTS.
21	I DO THINK THAT WITH A DEVELOPMENT AND THE
22	HELP OF CIRM, WE CAN DEVELOP NOW THAT WE HAVE JUST
23	DEVELOPED A NEW TECHNIQUE THAT IS CLINICALLY
24	FEASIBLE TO DELIVER THESE BIOLOGICAL PACEMAKERS AND
25	ALSO DEVELOP NEW WAYS TO REPROGRAM OUR OWN CELLS TO
	0.0
	98

1	DEVELOP PACEMAKERS TO HELP THIS PARTICULAR SUBSET OF
2	PATIENTS. I DO THINK THAT THE RISKS ARE QUITE
3	COMMON AND MILLIONS OF CALIFORNIANS AND AMERICANS
4	SUFFER FROM THIS, AND THEY CAN BE HELPED WITH THE
5	PRESENT PROPOSAL.
6	AND THE SCORE OF THE PROPOSAL WAS JUST
7	ABOVE THE LINE OF 59, AND I THINK IT'S VERY CLOSE TO
8	THE PAYLINE. AND I WILL BE REALLY SUPPORTIVE IF YOU
9	COULD HELP ME WITH THIS MY APPLICATION. THANK YOU.
10	MS. FORMAN: MY NAME IS ARIELLE FORMAN.
11	I'M ACTUALLY GOING TO GO BACK TO THE ENDOMETRIOSIS
12	GRANT PROPOSAL. I'M JUST A PATIENT. AND LIKE HIS
13	WIFE, I'VE GONE THROUGH IT ALL FOR ABOUT THE PAST
14	FIVE YEARS. I'VE GONE THROUGH MULTIPLE SURGERIES
15	TRYING TO SAVE MY UTERUS SO THAT I CAN EVENTUALLY
16	HAVE CHILDREN BECAUSE I AM A YOUNG ADULT.
17	NOW, THIS PROBLEM NOT ONLY AFFECTS ME, IT
18	AFFECTS MY WORK, MY BOYFRIEND, VERY SUPPORTIVE OF
19	THAT. BUT I HAVE TO MAKE A PRIVATE ISSUE PUBLIC IN
20	THAT IF I'M SITTING AT MY DESK AND ALL OF A SUDDEN I
21	START BASICALLY HEMORRHAGING, I HAVE TO HIGHTAIL IT
22	OUT OF THERE SO I DON'T MAKE A MESS. I'M IN PAIN.
23	HAVE TO DO IT.
24	AND ALL MY OPTIONS SO FAR HAVE BEEN
25	LAPAROSCOPIC SURGERY TO TRY AND GET THE
	99
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ENDOMETRIOSIS AND I GUESS THEY CALL IT, LIKE, BACK
BLEEDING OUT OF THERE. AND THEN ALSO UP TO AN
ABLATION TO BURN OFF THE INSIDE OF THE UTERUS SO THE
BLOOD DOESN'T COME OUT. NONE OF THOSE HAVE WORKED.
I'VE TRIED LUPRON, WHICH CAUSED EARLY MENOPAUSE.
AND ALL OF A SUDDEN MY FINGERNAILS BROKE OFF, MY
HAIR FELL OUT, I'M GETTING HOT FLASHES EVEN WITH THE
HORMONE REPLACEMENT THERAPY. I'M 35 YEARS OLD. IT
WAS JUST A HORRIBLE PREVIEW OF WHAT'S GOING TO
HAPPEN IF IT CONTINUES AND THERE'S NO EASY CURE FOR
THIS WHERE ALL OF A SUDDEN I'M GOING TO HAVE TO GET
MY WHOLE UTERUS AND OVARIES TAKEN OUT AND GO THROUGH
MENOPAUSE AT THE YOUNG AGE AND HORMONE REPLACEMENT.
SO I REALLY HOPE YOU GUYS TAKE THAT INTO
CONSIDERATION TO WORK FOR FUNDING TO DO SOME
RESEARCH FOR THE ENDOMETRIOSIS.
CHAIRMAN THOMAS: THANK YOU. NEXT,
PLEASE.
DR. DENG: MY NAME IS SOPHIE DENG. I'M A
CORNEA SPECIALIST AT THE JULES STEIN EYE INSTITUTE.
MY APPLICATION IS TO REGENERATE FUNCTIONAL LIMBAL
STEM CELLS FROM HUMAN SKIN STEM CELLS. AND THIS IS
COMPLEMENTARY TO MY PREVIOUS TRANSLATIONAL AWARD,
WHICH IS EXPANSION OF AUTOLOGOUS LIMBAL STEM CELLS
FOR TRANSPLANTATION.
100

1	BECAUSE THE AWARD, WE HAVE ABLE TO DEVELOP
2	A NOVEL THREE-DIMENSIONAL CULTURE SYSTEM TO EXPAND
3	THE HUMAN LIMBAL STEM CELLS IN CULTURE. AND I ALSO
4	APPLIED FOR A PROVISIONAL PATENT AS WELL. BECAUSE
5	THIS AWARD BE ABLE TO DEVELOP TWO SYMBIOTIC FREE
6	CULTURE SYSTEM FOR TRANSPLANTATION PURPOSE, AND
7	WE'RE ON OUR WAY MOVE THIS ONE INTO CLINIC. SO FROM
8	OUR TRACK RECORD BECAUSE OF THE FUNDING FOR MY
9	PREVIOUS GRANT SO THAT WE ARE MOVING TOWARDS THE
10	CLINIC IS THE GOAL OF THE PROJECT.
11	AS FOR THIS KIND OF PROPOSAL IS TO
12	GENERATE THE LIMBAL STEM CELLS WHEN THE PATIENT HAVE
13	A BILATERAL DISEASE THAT THEY DON'T HAVE ANY MORE
14	LIMBAL STEM CELL LEFT TO BE EXPAND AND TO BE
15	TRANSPLANTED. AND WE SPECIFICALLY LOOK INTO THE
16	HUMAN SKIN STEM CELLS BECAUSE THEY COME FROM THE
17	SAME DEVELOPMENTAL LINEAGE. AND ONE CRITICISM FROM
18	THE REVIEWER WAS THAT THE DESIGN OF THE PROJECT WAS
19	OVERSIMPLIFIED AND NOT EXCEPTIONALLY NOVEL.
20	IT SHOULD BE NOTED IT'S A COMPLICATED,
21	COMPLEX SYSTEM BECAUSE WE DON'T KNOW MUCH ABOUT THIS
22	TRANSDIFFERENTIATION. WE ACTUALLY USE A FUNCTIONAL
23	ASSAY AS OUTCOME TO STUDY THIS PROCESS. WE PLAN TO
24	COME BACK TO THE BASIC SCIENCE LATER TO LOOK INTO
25	THIS COMPLEX BIOLOGY. WE DID NOT OVERLOOK THIS
	101
	<u> </u>

1	UNDERLYING BIOLOGY PROBLEM.
2	ALSO TAKE INTO CONSIDERATION THIS
3	TRANSLATIONAL RESEARCH, THE GOAL IS NOT ABOUT
4	NOVELTY OF THE APPROACH. IT'S ABOUT HOW SAFE, HOW
5	PRACTICAL, HOW EASY TRANSLATING INTO THE CLINIC. I
6	THINK THAT WAS SOMETHING THAT WAS ALSO OVERLOOKED.
7	SO AS MENTIONED AS CLEARLY STATED IN THE
8	FINAL COMMENTS THAT YOU SUCCESSFUL, THIS PROPOSAL
9	CAN INDEED LEAD TO A NEW THERAPY AND IS EXACTLY THE
10	GOAL OF THIS PROPOSAL. SO TO ME AS A CLINICIAN, AS
11	SURGEON, I THINK THAT THE OUTCOME IS HOW TO
12	TRANSLATE THE FINDING IN THE LABORATORY TO RESEARCH.
13	IF THIS IS SUCCESSFUL, I THINK IT'S GROUNDBREAKING.
14	IT'S NOT A SIMPLE OVERSIMPLIFIED PROPOSAL. I THINK
15	THE OUTCOME, IT SHOULD BE IMPORTANT IN TREATING THIS
16	POPULATION OF PATIENTS.
17	AND FINALLY IS ONE REVIEWER MENTIONED THAT
18	IMPACT OF THIS BILATERAL DISEASE IS NOT VERY
19	PREVALENT. HOWEVER, THIS PATIENT, BOTH EYES ARE
20	INFECTED. THEY CANNOT SEE, THEY CANNOT FUNCTION.
21	NOT ONLY THAT THEY ARE FEASIBLE, BUT ALSO THEY COST
22	THE SOCIETY THE MOST BECAUSE THEY NEED CARETAKERS.
23	SO ACTUALLY ECONOMICALLY THESE PATIENT IS MOST
24	COSTLY TO THE SOCIETY. I THINK THIS UNDERESTIMATE.
25	IN JULES STEIN ALONE WE HAVE ESTIMATE
	102

1	ABOUT 300 TO 500 PATIENT ALONE IN OUR INSTITUTE. SO
2	THIS IS NOT A LOW PREVALENT DISEASE. ACTUALLY
3	PEOPLE OVERLOOK THE IMPACT OF THE DISEASE TO THE
4	SOCIETY. THANK YOU VERY MUCH FOR CONSIDERATION.
5	CHAIRMAN THOMAS: THANK YOU. ANY OTHER
6	COMMENTS FROM MEMBERS OF THE PUBLIC?
7	MR. SHEEHY: COULD I JUST ASK DR. DENG?
8	THIS IS A BIT OF A SIDEBAR. I HATE TO DISTRACT, BUT
9	SINCE THIS HAS BEEN A SUBJECT EARLIER THIS MORNING.
10	SO THE GRANT, THE EARLY TRANSLATIONAL
11	GRANT THAT WE MOVED UP THROUGH EXTRAORDINARY
12	PETITION HAS LED TO A NEW PRODUCT THAT YOU PATENTED.
13	DR. DENG: THAT'S CORRECT.
14	MR. SHEEHY: I ALSO NOTE THAT THE
15	CALIFORNIA STEM CELL REPORT ALSO TALKS ABOUT AN
16	EXTRAORDINARY PETITION THAT'S RESULTED IN MAJOR
17	SCIENTIFIC PUBLICATION. WHEN SOME OF THESE THINGS
18	WORK OUT, I DON'T THINK THAT WE REALLY WE HEARD
19	ABOUT PATIENT ADVOCATES AND WHAT A PROBLEM WE ARE
20	AND HOW CONFLICTED WE ARE. AND I CAN REMEMBER I
21	SPECIFICALLY ADVOCATED FOR DR. DENG'S PROJECT A
22	COUPLE YEARS AGO, AND NOW THERE'S A PATENT. AND I
23	JUST THINK THERE'S A LITTLE LACK OF EVIDENCE BASIS
24	AND A LITTLE NAIVETY ON SOME FOLKS' PART. BUT THANK
25	YOU.

ı	DARKISIERS REPORTING SERVICE
1	DR. DENG: THANK YOU.
2	CHAIRMAN THOMAS: ANY FURTHER PUBLIC
3	COMMENT? SEEING AND HEARING NONE, ARE THERE ANY
4	PROPOSALS THAT MEMBERS OF THE BOARD WOULD LIKE TO
5	MAKE A MOTION TO ELEVATE FROM TIER III TO TIER I?
6	HEARING NONE, IS THERE A MOTION FROM MEMBERS OF THE
7	BOARD TO APPROVE TIER I AS CURRENTLY CONSTITUTED FOR
8	FUNDING? DR. PRICE.
9	DR. PRICE: SHOULD WE ASK THE QUESTION THE
10	OTHER WAY AROUND?
11	CHAIRMAN THOMAS: MR. HARRISON, WHAT IS
12	PROPER PHRASING OF THE QUESTION HERE?
13	MR. HARRISON: WHETHER ANY MEMBER WOULD
14	LIKE TO MAKE A MOTION TO MOVE AN APPLICATION FROM
15	TIER I TO TIER III.
16	CHAIRMAN THOMAS: THANK YOU. WELL NOTED,
17	DR. PRICE. ANY SUCH MOTION BY ANY MEMBERS OF THE
18	BOARD?
19	MR. HARRISON: THEN IF I COULD SUGGEST IF
20	WE COULD ASK A MEMBER WHO DOES NOT HAVE AN INTEREST
21	IN AN APPLICATION EITHER IN TIER I OR TIER III TO
22	MAKE A MOTION TO APPROVE THE FUNDING OF APPLICATIONS
23	IN TIER I AND TO CLOSE FUNDING ON THOSE IN TIER III.
24	DR. PRICE: I SO MOVE.
25	CHAIRMAN THOMAS: MOVED BY DR. PRICE.
	104
	104

	DARRISIERS REPORTING SERVICE
1	SECONDED BY
2	MR. JUELSGAARD: SECOND THE MOTION.
3	CHAIRMAN THOMAS: MR. JUELSGAARD. IS
4	THERE DISCUSSIONS BY MEMBERS OF THE BOARD ON THIS
5	MOTION? HEARING NONE, IS THIS A ROLL CALL, MR.
6	HARRISON? MARIA, PLEASE TAKE THE ROLL.
7	MS. BONNEVILLE: AND IF YOU COULD ANSWER
8	THE ONES WITH WHICH I AM NOT IN CONFLICT.
9	MS. BONNEVILLE: ROBERT PRICE.
10	DR. PRICE: YES, EXCEPT FOR THOSE WITH
11	WHICH I HAVE A CONFLICT.
12	MS. BONNEVILLE: DAVID BRENNER. SUE
13	BRYANT.
14	DR. BRYANT: YES, EXCEPT FOR THOSE WITH
15	WHICH I HAVE A CONFLICT.
16	MS. BONNEVILLE: FRANK CHISARI.
17	DR. CHISARI: AYE, EXCEPT FOR THOSE WITH
18	WHICH I HAVE A CONFLICT.
19	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
20	JAMES ECONOMOU. MARCY FEIT.
21	MS. FEIT: YES, EXCEPT FOR THOSE WITH
22	WHICH I HAVE A CONFLICT.
23	MS. BONNEVILLE: LEEZA GIBBONS.
24	MS. GIBBONS: YES.
25	MS. BONNEVILLE: MICHAEL GOLDBERG. SAM
	105
	200

1	HAWGOOD.
2	DR. HAWGOOD: YES, EXCEPT FOR THOSE WITH
3	WHICH I HAVE A CONFLICT.
4	MS. BONNEVILLE: STEPHEN JUELSGAARD.
5	MR. JUELSGAARD: YES.
6	CHAIRMAN THOMAS: MARIA, DR. ECONOMOU
7	RE-ENTERED THE ROOM HERE. DR. ECONOMOU, WE HAVE A
8	THE MOTION APPROVAL IF TIER I.
9	DR. ECONOMOU: YES, EXCEPT FOR THOSE WITH
10	WHICH I HAVE A CONFLICT.
11	MS. BONNEVILLE: TED KRONTIRIS.
12	DR. KRONTIRIS: YES, EXCEPT FOR THOSE WITH
13	WHICH I HAVE A CONFLICT.
14	MS. BONNEVILLE: SHERRY LANSING.
15	MS. LANSING: YES, EXCEPT FOR THOSE WITH
16	WHICH I HAVE A CONFLICT.
17	MS. BONNEVILLE: BERT LUBIN. SHLOMO
18	MELMED. CLAIRE POMEROY.
19	DR. POMEROY: YES, EXCEPT FOR THOSE WITH
20	WHICH I HAVE A CONFLICT.
21	MS. BONNEVILLE: ROBERT PRICE.
22	DR. PRICE: YES.
23	MS. BONNEVILLE: FRANCISCO PRIETO.
24	DR. PRIETO: YES, EXCEPT FOR THOSE WITH
25	WHICH I HAVE A CONFLICT.
	106

	BARRISIERS REPORTING SERVICE
1	MS. BONNEVILLE: CARMEN PULIAFITO.
2	DR. PULIAFITO: YES, EXCEPT FOR THOSE WITH
3	WHICH I HAVE A CONFLICT.
4	MS. BONNEVILLE: ROBERT QUINT.
5	DR. QUINT: YES.
6	MS. BONNEVILLE: DUANE ROTH. JOAN
7	SAMUELSON.
8	MS. SAMUELSON: YES.
9	MS. BONNEVILLE: JEFF SHEEHY.
10	MR. SHEEHY: YES, EXCEPT FOR THOSE WITH
11	WHICH I HAVE A CONFLICT.
12	MS. BONNEVILLE: JONATHAN SHESTACK.
13	MR. SHESTACK: YES.
14	MS. BONNEVILLE: OSWALD STEWARD.
15	DR. STEWARD: YES, EXCEPT FOR THOSE WITH
16	WHICH I HAVE A CONFLICT.
17	MS. BONNEVILLE: JONATHAN THOMAS.
18	CHAIRMAN THOMAS: YES.
19	MS. BONNEVILLE: ART TORRES.
20	MR. TORRES: AYE.
21	MS. BONNEVILLE: CARL WARE.
22	DR. WARE: YES, EXCEPT FOR THOSE WITH
23	WHICH I HAVE A CONFLICT.
24	CHAIRMAN THOMAS: MR. HARRISON.
25	MR. HARRISON: WE NEED TO LOOK AT EACH
	107
	107

1	ADDITION AND THE QUODIN DECLIDEMENTS DECAUSE THEY
	APPLICATION AND THE QUORUM REQUIREMENTS BECAUSE THEY
2	VARY. SO IF YOU'D LIKE, YOU CAN PROCEED ONTO
3	ANOTHER, AND THEN WE'LL MAKE CLEAR THAT THE MOTION
4	CARRIED.
5	CHAIRMAN THOMAS: FAIR ENOUGH. WE'RE
6	GOING TO MOVE NOW TO ITEM 13.
7	MR. SHEEHY: I JUST WANTED TO ECHO DR.
8	PULIAFITO'S EARLIER COMMENTS. AND I THINK IF DR.
9	PIZZO WAS STILL WITH US, HE WOULD ALSO SUGGEST THAT
10	I THINK WE WEREN'T THINKING ABOUT THIS BEING
11	ONE-OFF, BUT I HOPE STAFF WILL CONSIDER REPEATING
12	THIS RFA AT SOME POINT IN THE NOT TOO DISTANT
13	FUTURE. I THINK WE HEARD WHEN WE PROPOSED THIS ONE,
14	THAT THIS IS A VERY GOOD WAY TO POPULATE A
15	DIMINISHING FIELD OF CLINICIAN SCIENTISTS. AND I
16	CERTAINLY WAS IMPRESSED WITH THE APPLICATIONS WE
17	GOT.
18	I THINK THE HIGH SUCCESS RATE IS PARTIALLY
19	DUE TO THE FACT THAT WE HAD INSTITUTIONAL LIMITS,
20	AND THE INSTITUTIONS VERY DILIGENTLY, I THINK,
21	COMPETED THESE OUT AND SENT US SOME PHENOMENAL
22	APPLICANTS. I JUST HOPE THAT SOME CONSIDERATION
23	STRATEGICALLY WOULD BE MADE TOWARDS CONSIDERING
24	KEEPING THIS RFA IN OUR PORTFOLIO.
25	CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.
	108

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1	MR. HARRISON: THE MOTION DID PASS.
2	CHAIRMAN THOMAS: THANK YOU. ON TO ITEM
3	13, WHICH IS CONSIDERATION OF THE AWARD OF
4	SUPPLEMENTAL FUNDS TO AN EXISTING GRANTEE, VIACYTE.
5	I BELIEVE DR. OLSON IS GOING TO PRESENT.
6	MR. HARRISON: THE MEMBERS IN CONFLICT ON
7	THIS APPLICATION ARE FEIT, HAWGOOD, LANSING,
8	PULIAFITO, AND SHEEHY.
9	DR. OLSON: I CAN START NOW. OKAY. IN
10	2010 VIACYTE RECEIVED A DISEASE TEAM I AWARD IN THE
11	AMOUNT OF \$20 MILLION TO DEVELOP A COMBINATION CELL
12	THERAPEUTIC DERIVED FROM HUMAN EMBRYONIC STEM CELLS
13	FOR THE TREATMENT OF PATIENTS WITH TYPE 1 DIABETES
14	AND ALSO POTENTIALLY TYPE 2 DIABETES. AT ITS
15	PERIODIC ASSESSMENT BY CIRM'S CLINICAL DEVELOPMENT
16	ADVISORY PANEL, THE PROGRAM HAS RECEIVED STRONG
17	ENDORSEMENT FOR THE OUTSTANDING CALIBER OF ITS
18	PROGRESS.
19	AND YOU MAY RECALL EARLIER THIS YEAR WHEN
20	DR. FEIGAL GAVE AN UPDATE FOLLOWING THE FIRST
21	CLINICAL DEVELOPMENT REVIEW, AND AT THAT POINT CIRM
22	NOTED THAT THERE WOULD BE A NEED FOR SUPPLEMENTAL
23	FUNDING TO THE VIACYTE DISEASE TEAM I AWARD TO
24	ENABLE THEM TO CONTINUE THEIR PROGRESS TOWARDS
25	FILING AN IND TO ENTER FIRST-IN-HUMAN CLINICAL
	109
J	

1	TRIALS.
2	AT THE OCTOBER 25TH BOARD MEETING, THE
3	BOARD AWARDED 10 MILLION TO VIACYTE UNDER THE
4	STRATEGIC PARTNERSHIP AWARD PROGRAM FOR A
5	CONTINUATION OF ITS PROGRAM TO FILE AN IND, ENTER
6	THE CLINIC, AND COMPLETE AN EARLY PHASE CLINICAL
7	STUDY THAT IN THAT CASE INCLUDES STRONG POTENTIAL
8	FOR THE ACHIEVEMENT OF A CLINICAL PROOF OF CONCEPT.
9	THIS ACTION WAS TAKEN BY THE BOARD FOLLOWING A
10	STRONG FUNDING RECOMMENDATION BY THE GRANTS WORKING
11	GROUP AND A HIGH SCIENTIFIC SCORE IN RECOGNITION OF
12	A PROJECT THAT HAD MADE STRONG PROGRESS TOWARDS WHAT
13	WAS CITED BY THE GRANTS WORKING GROUP AS THE HOLY
14	GRAIL OF DIABETES TREATMENT.
15	AS YOU KNOW, AT THAT MEETING A
16	REPRESENTATIVE FROM VIACYTE'S POTENTIAL PARTNER,
17	GSK, WAS PRESENT AND ACKNOWLEDGED VIACYTE'S
18	TREMENDOUS PROGRESS IN THE FIELD AND INFORMED THE
19	BOARD THAT GSK HAD ALREADY CONDUCTED AN INTENSE
20	TECHNICAL AND FINANCIAL DUE DILIGENCE OF THE PROGRAM
21	WHICH HAD BEEN REVIEWED BY MULTIPLE COMMITTEES
22	WITHIN GSK. AND THAT PENDING FINAL APPROVAL, GSK
23	WAS INTERESTED IN AN ALLIANCE TO ENABLE GSK,
24	VIACYTE, AND CIRM TO PROGRESS THE PROGRAM WITH THE
25	NOTION THAT UPON SUCCESS AT THE INITIAL

110

1	CIRM-VIACYTE-GSK PROGRAM, THAT GSK WOULD
2	SUBSEQUENTLY CARRY THE PROGRAM FORWARD.
3	WE HAVE RECENTLY BEEN INFORMED AND HAVE
4	INFORMED THE BOARD THAT GSK DID NOT OBTAIN THAT
5	FINAL APPROVAL REQUIRED DUE TO BUSINESS REASONS AND
6	IN THE CONTEXT OF GSK'S OVERALL RESEARCH AND
7	DEVELOPMENT PORTFOLIO AND INVESTMENT NEED, AND NOT
8	AS A RESULT OF ANY SCIENTIFIC OR TECHNICAL
9	ASSESSMENT OF VIACYTE'S PROGRAM.
10	AT YOUR LAST BOARD MEETING AND AT OUR LAST
11	BOARD MEETING, YOU APPROVED THE CONCEPT PROPOSAL FOR
12	EXTRAORDINARY SUPPLEMENTS TO EXISTING AWARD. THAT
13	CONCEPT PROVIDES FOR LEVEL ONE MINOR SUPPLEMENTS AS
14	WELL AS LEVEL TWO MAJOR SUPPLEMENTS. THE LEVEL TWO
15	MAJOR SUPPLEMENTS WAS INTENDED TO SUPPORT GRANTEES
16	TO ENHANCE PROBABILITY OF CONVERSION OF FUNDED
17	PROGRAMS THAT COULD GIVE UNEXPECTED AND
18	TRANSFORMATIONAL BENEFITS AND RAISE PROJECTS TO A
19	HIGH PROBABILITY OF CLINICAL BENEFIT.
20	THE AWARD PROVIDED FOR UP TO 3 MILLION,
21	AND, IN THE CONTEXT OF FDA-MANDATED REQUIREMENTS,
22	ALSO ALLOWED FOR A CDAP REVIEW TO PROVIDE A
23	RECOMMENDATION TO THIS BOARD.
24	SO CIRM IS PROPOSING THAT A LEVEL TWO
25	MAJOR SUPPLEMENT AWARD IN THE AMOUNT OF \$3 MILLION
	111

1	BE PROVIDED TO VIACYTE. AT ITS NOVEMBER 29TH CDAP
2	MEETING, SO A MEETING OF THE CLINICAL DEVELOPMENT
3	ADVISORY PANEL, WHICH WAS HELD JUST A COUPLE OF
4	WEEKS AGO, VIACYTE WAS ASSESSED BY THE PANEL.
5	AGAIN, THE ADVISORS WERE VERY POSITIVE, STATING THAT
6	THE PROGRAM IS VIEWED AS ONE OF CIRM'S TOP PROGRAMS
7	WITH AN ABILITY TO ESTABLISH EARLY IN CLINICAL
8	DEVELOPMENT A CLINICAL PROOF OF CONCEPT AND A STRONG
9	POTENTIAL TO PROCEED TO COMMERCIAL THERAPEUTIC.
10	VIACYTE, IN ADDITION, PRIOR TO THE CDAP
11	MEETING AND WAS DISCUSSED AT CDAP, HAS HELD A
12	PRE-IND MEETING WITH THE FDA PRIOR TO CONDUCTING THE
13	CRITICAL ACTIVITIES NECESSARY FOR ACTUALLY FILING
14	THE IND IN APPROXIMATELY 12 MONTHS.
15	THE FDA DID HAVE SOME SPECIFIC
16	RECOMMENDATIONS OR MODIFICATIONS TO VIACYTE'S
17	PROPOSED ACTIVITIES TO BE UNDERTAKEN OR COMPLETED
18	PRIOR TO IND FILING. THESE ACTIVITIES WERE
19	DISCUSSED AT THE CDAP MEETING WITH VIACYTE AND
20	ENDORSED BY CDAP, AND IT IS THESE ACTIVITIES THAT
21	WOULD BE THE SUBJECT OF THE REQUESTED SUPPLEMENT FOR
22	THE FUNDING OVER A SIX-MONTH PERIOD.
23	SO, IN SUMMARY, THE CDAP RECOMMENDED
24	PROVIDING STRONGLY RECOMMENDED PROVIDING
25	SUPPLEMENTAL FUNDING IN ORDER TO ENSURE THAT THE

112

1	PROJECT STAYS ON CRITICAL PATH WHILE ADDITIONAL
2	FUNDING SOURCES ARE SECURED BY VIACYTE.
3	SO THE RECOMMENDATION IS, FOLLOWING
4	ENDORSEMENT OF THE CLINICAL DEVELOPMENT ADVISORS,
5	CIRM RECOMMENDS THAT A LEVEL TWO MAJOR SUPPLEMENT IN
6	THE AMOUNT OF \$3 MILLION BE AWARDED TO VIACYTE SO
7	THAT IT MAY CONTINUE TO CONDUCT RESEARCH THAT IS ON
8	THE CRITICAL PATH FOR AN IND FILING AS RECOMMENDED
9	BY THE FDA IN ITS RECENT PRE-IND MEETING.
10	MR. TORRES: SO MOVED.
11	CHAIRMAN THOMAS: MOVED BY SENATOR TORRES.
12	IS THERE A SECOND?
13	DR. PRIETO: SECOND.
14	CHAIRMAN THOMAS: SECONDED BY DR. PRIETO.
15	ANY DISCUSSION BY MEMBERS OF THE BOARD?
16	DR. JUELSGAARD: DR. OLSON, COULD YOU
17	ADVISE ME OF WHAT CDAP TOOK INTO ACCOUNT WITH
18	RESPECT TO THE FINANCIAL SITUATION OF VIACYTE AT
19	THIS POINT?
20	DR. OLSON: CDAP WAS INTERESTED IN KNOWING
21	WHAT PATHS VIACYTE WAS PURSUING, AND THEY DID TAKE
22	THAT INTO CONSIDERATION.
23	DR. JUELSGAARD: COULD YOU BE PERHAPS A
24	BIT MORE DESCRIPTIVE OF THAT?
25	DR. OLSON: I THINK THAT'S PROBABLY MORE
	113

1	APPROPRIATELY DISCUSSED IN A CLOSED SESSION. DR.
2	TROUNSON PERHAPS CAN RESPOND MORE.
3	DR. TROUNSON: SO WE'VE BEEN KEPT WELL
4	INFORMED OF THE SITUATION ALL ALONG. YOU WOULD BE
5	PROBABLY AWARE, ALTHOUGH MAY NOT REMEMBER, BUT THIS
6	PROJECT IS BEING CO-FUNDED BY THE JDRF. I THINK
7	IT'S VERY LIKELY THAT THEY'RE GOING TO PROVIDE A
8	SIMILAR AMOUNT OF MONEY. I CAN JUST SAY THAT THAT
9	SEEMS LIKELY. THAT'S ALL I'VE HEARD, THAT IT SEEMS
10	LIKELY. AND THAT THEY'RE ON TRACK WITH DISCUSSIONS
11	WITH OTHER INSTITUTIONS, WHICH WE REALLY CAN'T GIVE
12	YOU ANY MORE INFORMATION ON AT THIS POINT IN TIME,
13	BUT THEY'RE VERY MUCH ON TRACK.
14	ALL I WOULD SAY, I THINK, STEVE, IS IF IT
15	DOES WORK ITSELF OUT, I THINK WE MIGHT END UP WITH A
16	BETTER SITUATION BECAUSE IT'S BEEN A LITTLE
17	COMPLICATED. AND I HOPE THAT WE'LL BE IN A BETTER
18	SITUATION THAN THE ONE THAT WE THOUGHT WE WERE IN.
19	DR. JUELSGAARD: DR. TROUNSON, SO CAN I
20	SEEK YOUR ASSURANCE THAT FROM A FINANCIAL POINT OF
21	VIEW VIACYTE HAS A VIABLE PATH FORWARD IN ORDER TO
22	RAISE ENOUGH MONEY TO CONTINUE THIS PROJECT INTO THE
23	FORESEEABLE FUTURE?
24	DR. TROUNSON: ALL I CAN SAY IS THAT I'M
25	CONFIDENT THAT THE TEAM IS MOVING FORWARD IN A VERY
	114
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1	APPROPRIATE WAY. I DON'T THINK I CAN GIVE YOU ANY
2	GUARANTEES OF THAT BECAUSE I'M NOT INVOLVED IN THOSE
3	DISCUSSIONS, NOR WOULD IT BE APPROPRIATE FOR ME TO
4	GIVE A GUARANTEE. BUT I BELIEVE THAT THEY'RE DOING
5	EVERYTHING VERY APPROPRIATELY AT THE PRESENT TIME,
6	AND I HAVE A HIGH DEGREE OF CONFIDENCE IN THE CEO IN
7	THE WAY HE'S APPROACHING THAT. AND I THINK WE WILL
8	PROBABLY HAVE AN OUTCOME BY THE MIDDLE OF NEXT YEAR
9	THAT WILL BE SATISFYING. THAT'S ALL I CAN SAY TO
10	YOU AT THIS POINT.
11	DR. KRONTIRIS: LET ME KIND OF ASK THE
12	SAME QUESTION ANOTHER WAY AROUND, AND YOU CAN DECIDE
13	WHETHER THAT CAN BE ANSWERED IN THIS SESSION OR NOT.
14	THERE ARE TWO PRECONDITIONS HERE FOR THE
15	AWARD THAT ARE LISTED IN THE REPORT, ONE BEING
16	HAVING RAISED A CERTAIN AMOUNT OF MONEY AND AMOUNT
17	OF CASH AND TWO BEING A LETTER OF INTENT FROM A
18	PHARMACEUTICAL PARTNER. SO DO ONE OR BOTH OF THESE
19	CONDITIONS STILL OBTAIN?
20	DR. TROUNSON: CAN I JUST ANSWER THAT THIS
21	IS REALLY A SUPPLEMENT TO THE DISEASE TEAM GRANT,
22	WHICH IS A PREVIOUS GRANT. THEY HAVE SIX MONTHS
23	FROM THE TIME OF THE SP AWARD TO MAKE ONE OF THOSE
24	CONDITIONS. SO WE'LL HAVE TO WAIT AND SEE WHETHER
25	THEY DO. WE'RE HOPING CLEARLY THAT THEY WILL DO
	115
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1	THAT AND THEN BE BACK ON TRACK. BUT THIS IS A
2	SUPPLEMENTARY AWARD TO THEIR ORIGINAL DISEASE TEAM.
3	DR. POMEROY: SO I REMAIN UNCLEAR ON
4	EXACTLY WHAT THE \$3 MILLION WILL BE SPENT ON IN THE
5	NEXT SIX MONTHS AND WHAT THE DELIVERABLE WOULD BE
6	FOR THAT \$3 MILLION.
7	DR. TROUNSON: I THINK WE WOULD HAVE TO GO
8	INTO EXECUTIVE.
9	DR. POMEROY: THAT'S FINE, BUT I DON'T
10	FEEL PERSONALLY COMFORTABLE AUTHORIZING \$3 MILLION
11	WITH NO IDEA OF HOW IT'S TO BE USED.
12	DR. TROUNSON: WE'RE PREPARED TO PROVIDE
13	YOU THAT. IT'S JUST THAT WE COULDN'T I THINK IT
14	WOULDN'T BE APPROPRIATE TO DO IT PUBLICLY.
15	CHAIRMAN THOMAS: I'M ADVISED BY THE
16	POWERS THAT BE IN THE CORNER OVER THERE THAT CLOSED
17	SESSION WOULD HAVE TO BE AT 2:30. SO IF THAT'S THE
18	WISH OF THE BOARD, WE'LL TABLE THE TOPIC.
19	MR. HARRISON: IT'S A PUBLIC NOTICE
20	REQUIREMENT. WE WERE NOT ABLE TO AGENDIZE THIS ITEM
21	FOR A CLOSED SESSION UNTIL EARLIER THIS WEEK. AS A
22	RESULT, WE HAVE TO WAIT UNTIL 2:30 IN ORDER TO
23	CONSIDER IT IN ORDER TO COMPLY WITH THE LAW.
24	MR. SHESTACK: IS IT AN ISSUE OF JUST
25	AGENDIZING CLOSED SESSION IN GENERAL OR THIS
	116
	TTO

1	PARTICULAR ISSUE?
2	MR. HARRISON: IT'S FOR THIS PARTICULAR
3	ITEM.
4	CHAIRMAN THOMAS: OKAY.
5	MS. BAUM: I WOULD URGE THAT BOARD MEMBERS
6	MAKE ALL DUE EFFORT TO STAY HERE UNTIL AFTER THAT
7	CLOSED SESSION SO WE CAN MAINTAIN A QUORUM. THANK
8	YOU.
9	CHAIRMAN THOMAS: ANY OTHER QUESTIONS OF
10	DR. OLSON FOR THE MOMENT? THANK YOU. WE'LL TAKE
11	THIS UP IN CLOSED SESSION.
12	WE HAVE THE SPOTLIGHT COMING UP IN FIVE
13	MINUTES HERE. IS THERE ANYTHING, MARIA, THAT YOU
14	WOULD RECOMMEND WE HIT IN THE FIVE MINUTES?
15	DR. SAMBRANO, WE'RE GOING TO NOW ITEM NO.
16	12, CONSIDERATION OF APPOINTMENTS OF NEW SCIENTIFIC
17	MEMBERS OF THE GRANTS WORKING GROUP.
18	DR. SAMBRANO: SO WE'RE BRINGING FOR YOUR
19	CONSIDERATION EIGHT NOMINEES FOR GRANTS WORKING
20	GROUP MEMBERS. THESE, MORE SPECIFICALLY, BRING
21	EXPERTISE IN THE AREAS OF SYSTEMS BIOLOGY AND
22	GENOMICS. THEY ARE LISTED ALONG WITH THEIR BIOS IN
23	YOUR BOOKS.
24	THESE ARE DRS. STEPHEN FRIEND, CHRISTIE
25	GUNTER, LEROY HOOD, JOHN MADDICK, ALEXANDER
	117
	117

1	MEISSNER, MAYNARD OLSON, JARED ROACH, AND ZAIM
2	SERANI. SO WE'RE REQUESTING YOUR APPROVAL ON
3	APPOINTMENT OF THESE NOMINEES AS MEMBERS OF THE
4	GRANTS WORKING GROUP.
5	MR. TORRES: SO MOVED.
6	DR. POMEROY: SECOND.
7	CHAIRMAN THOMAS: MOVED BY SENATOR TORRES,
8	SECONDED BY DEAN POMEROY. ANY DISCUSSION BY MEMBERS
9	OF THE BOARD ON THIS SUBJECT? ALL THOSE IN FAVOR
10	IS THERE ANY PUBLIC COMMENT ON THIS SUBJECT?
11	HEARING NONE, ALL THOSE IN FAVOR PLEASE SAY AYE.
12	OPPOSED? MEMBERS ON TELEPHONE.
13	MS. FEIT: AYE.
14	MS. SAMUELSON: AYE.
15	DR. WARE: AYE.
16	CHAIRMAN THOMAS: THANK YOU. ANY NOES ON
17	THIS ITEM? ABSTENTIONS? MOTION PASSES. THANK YOU.
18	OKAY, MARIA, WE SHOULD NOW GRAB LUNCH IN
19	THE ADJOURNING ROOM, AND PLEASE RETURN FOR WHAT I AM
20	TOLD IS A MOST EXCITING SPOTLIGHT PRESENTATION.
21	(A RECESS WAS TAKEN.)
22	CHAIRMAN THOMAS: WE'RE NOW GOING TO GO
23	BACK TO OUR AGENDA. WE'RE GOING TO TAKE UP ITEM NO.
24	10, CONSIDERATION OF BASIC BIOLOGY V CONCEPT PLAN.
25	DR. SHEPARD. LET'S TAKE A THREE- OR FOUR-MINUTE
	118

BREAK AND LET EVERYBODY MOBILIZE.
(A RECESS WAS TAKEN.)
CHAIRMAN THOMAS: COULD EVERYBODY PLEASE
TAKE THEIR SEATS. WE'RE NOW GOING TO PROCEED WITH
ITEM NO. 10, CONCEPT PROPOSAL FOR BASIC BIOLOGY
AWARDS NO. 5. KELLY, PLEASE PROCEED.
DR. SHEPARD: THANK YOU, MR. CHAIRMAN,
MEMBERS OF THE BOARD, AUDIENCE, AND ALL THOSE
LISTENING. IT'S MY PLEASURE TO PRESENT FOR YOUR
CONSIDERATION TODAY THE CONCEPT APPROVAL BASIC
BIOLOGY AWARDS V. THIS IS AGENDA ITEM NO. 10 IN
YOUR MATERIALS.
I'D LIKE TO BEGIN BY JUST GIVING A BRIEF
GENERAL OVERVIEW OF THE GOALS OF THE BASIC BIOLOGY
AWARDS. THESE ARE, OF COURSE, ONE OF CIRM'S CORE
RECURRING RFA PROGRAMS, THE GOAL OF WHICH IS TO
FOSTER CUTTING-EDGE RESEARCH INTO FUNDAMENTAL
MECHANISMS OF HUMAN STEM CELL BEHAVIORS. THESE
AWARDS SUPPORT STUDIES TACKLING SIGNIFICANT BUT
UNRESOLVED ISSUES THAT ARE PERTINENT TO THE
UNDERSTANDING OF THE CONTROL OF STEM CELL FATE.
FOCUS AREAS OF THESE AWARDS INCLUDE BASIC
MECHANISMS OF HUMAN PLURIPOTENT AND ADULT STEM
CELLS; ELUCIDATION OF THE MOLECULAR DETERMINANTS OF
CELL FATE DECISIONS, FOR EXAMPLE, SELF-RENEWAL AND
119

1	DIFFERENTIATION; THE MECHANISMS, IN OTHER WORDS, THE
2	MOLECULAR AND CELLULAR PATHWAYS BY WHICH LINEAGES
3	ARE SPECIFIED. IN OTHER WORDS, DERIVING MATURE,
4	FUNCTIONAL ADULT TISSUES OF VARIOUS TYPES FROM STEM
5	CELLS. AND IN MORE RECENT ROUNDS OF THESE AWARDS,
6	WE'VE ALSO FUNDED BASIC RESEARCH INTO THE MOLECULAR
7	MECHANISMS OF DISEASE INSOFAR AS HUMAN STEM CELLS
8	ARE USED AS IN VITRO TOOLS TO ENABLE STUDIES.
9	TO DATE WE'VE ISSUED FOUR RFA'S UNDER THE
10	BASIC BIOLOGY INITIATIVE, AND WE'VE IMPLEMENTED 83
11	THREE-YEAR GRANTS UNDER THIS PROGRAM.
12	NOW, BEFORE I MOVE INTO BASIC BIOLOGY V, I
13	WANT TO PAUSE FOR JUST A MOMENT TO REMIND EVERYONE
14	THAT JUST RECENTLY, THIS YEAR IN FACT, WE UNDERWENT
15	SOME MAJOR UPDATES TO CIRM'S STRATEGIC PLAN WHICH
16	GUIDES OUR THINKING AND OUR FUTURE INITIATIVES.
17	THIS PROCESS TOOK INTO ACCOUNT PAST SUCCESSES AND
18	WHAT STILL REMAINS TO BE DONE IN ORDER FOR US TO
19	MOST EFFECTIVELY AND SUCCESSFULLY REALIZE CIRM'S
20	MISSION.
21	NOW, A DIRECTIVE IN THE 2012 STRATEGIC
22	PLAN WITH RESPECT TO OUR BASIC BIOLOGY PROGRAM, AND
23	I'VE QUOTED IT HERE, IS TO FOSTER AN ENGINE OF
24	DISCOVERY AND TRANSFORMATIVE RESEARCH. IN OTHER
25	WORDS, THE CHALLENGE TO OUR TEAM AT CIRM WAS TO TRY
	120

1	TO DEVISE STRATEGIES AND IMPLEMENT THEM IN OUR
2	ONGOING AND FUTURE PROGRAMS THAT WOULD EVEN FURTHER
3	ALLOW US TO ACHIEVE HIGH-IMPACT TRANSFORMATIVE
4	DISCOVERY.
5	WHEN YOU THINK ABOUT BASIC RESEARCH AND
6	ENABLING TRANSFORMATIVE DISCOVERY, THERE ARE A
7	COUPLE OF STRATEGIES BY WHICH THIS MIGHT BE
8	ACHIEVED. ONE STRATEGY IS GOING DIRECTLY AFTER KEY
9	QUESTIONS THAT COULD BE ANSWERED BY THE BASIC STEM
10	CELL BIOLOGY. AND THAT'S THE TACTIC THAT WE HAVE
11	BEEN UTILIZING IN OUR BASIC BIOLOGY AWARDS
12	MECHANISM. HOWEVER, SOMETIMES THERE ARE
13	TRANSFORMATIVE DISCOVERIES THAT OCCUR FROM
14	UNEXPECTED SOURCES. SOMETIMES THEY CAN STEM FROM
15	TESTING FROM AN ENTIRELY NEW IDEA OR NEW A WAY OF
16	THINKING, ASKING PROVOCATIVE QUESTIONS OR BRINGING
17	CLEVER INSIGHTS TO BEAR, OR TECHNOLOGIES ON A
18	QUESTION THAT IT MIGHT NOT HAVE BEEN PREVIOUSLY
19	ASKED IN THE PAST. IT MIGHT NOT HAVE BEEN
20	TECHNICALLY FEASIBLE.
21	SO WITH THESE IDEAS IN MIND, WE ARE
22	PROPOSING TO INCORPORATE A NEW ELEMENT INTO BASIC
23	BIOLOGY V. WE'D LIKE TO BUILD ON OUR SUCCESSFUL
24	TEMPLATE THAT WE'VE UTILIZED FOR THE PAST FOUR
25	ROUNDS AND INCORPORATE SOME NEW ELEMENTS THAT I

121

1	WOULD JUST LIKE TO GO BRIEFLY OVER WITH YOU IN THE
2	FOLLOWING TWO SLIDES.
3	SO WE'RE PROPOSING THAT THE BASIC BIOLOGY
4	AWARD V INITIATIVE WOULD FUND TWO TYPES OF BASIC
5	RESEARCH INTO STEM CELL BIOLOGY. THESE WOULD BE
6	SUBMITTED THROUGH ONE OF TWO TRACKS. SO THE FIRST
7	TRACK WE'RE CALLING THE FUNDAMENTAL MECHANISMS
8	TRACK. THE TYPE OF RESEARCH SUBMITTED THROUGH THIS
9	TRACK IS ESSENTIALLY THE SAME AS WHAT WE'VE TARGETED
10	SUCCESSFULLY IN PREVIOUS ROUNDS OF BASIC BIOLOGY.
11	SO IN OTHER WORDS, THE PROJECTS WILL BE SIMILAR TO
12	THOSE. IN OTHER WORDS, THEY ARE RIGOROUS STUDIES
13	UTILIZING HUMAN STEM CELLS THAT WILL SIGNIFICANTLY
14	ADVANCE THE FIELD. THE FOCUS OF THESE
15	INVESTIGATIONS, AGAIN, ARE ON CELLULAR AND MOLECULAR
16	MECHANISMS THAT ARE PARTICULAR TO STEM CELL
17	FUNCTION, CELLULAR DIFFERENTIATION, OR DISEASE
18	MECHANISM.
19	THESE STUDIES MUST BE BASED ON COMPELLING
20	PRELIMINARY DATA AND STRONG SCIENTIFIC RATIONALE TO
21	SUPPORT THEIR FEASIBILITY. THESE ARE THREE-YEAR
22	AWARDS, AND WE'RE PROPOSING JUSTIFIABLE DIRECT
23	PROJECT COSTS OF UP TO \$250,000 PER YEAR PER AWARD.
24	THE SECOND TRACK WE'RE CALLING THE
25	EXPLORATORY CONCEPTS TRACK. AGAIN, THIS IS A

122

1	COMPLEMENTARY APPROACH TO ENABLE POTENTIALLY
2	TRANSFORMATIVE DISCOVERIES. FOR THIS TYPE OF AWARD,
3	THE RESEARCH PROPOSED WOULD BE TO TEST A HIGHLY
4	NOVEL HYPOTHESIS THAT, IF PROVEN, WOULD CHALLENGE
5	DOGMA AND RESULT IN A TRANSFORMATIVE DISCOVERY FOR
6	THE STEM CELL FIELD. IN OTHER WORDS, THIS IS HIGH
7	RISK, BUT POTENTIALLY VERY HIGH GAIN
8	EXPLORATORY-TYPE PURSUITS. AS SUCH, WE PROPOSE THAT
9	A TWO-YEAR DURATION WITH JUSTIFIABLE DIRECT PROJECT
10	COSTS OF UP TO \$200,000 WOULD BE APPROPRIATE.
11	SO THE TOTAL ALLOCATION WE WOULD REQUEST
12	FOR THE BASIC BIOLOGY V AWARDS IS \$40 MILLION TO
13	SUPPORT UP TO 30 BASIC BIOLOGY V AWARDS. WE
14	ENVISION THAT THE MAJORITY OF THESE WOULD BE
15	SUPPORTED THROUGH THE FUNDAMENTAL MECHANISM TRACK
16	SIMILAR TO WHAT WE'VE CAPTURED WITH PREVIOUS ROUNDS.
17	HOWEVER, WE WOULD ALSO LIKE TO ATTRACT A NUMBER OF
18	EXPLORATORY CONCEPT-TYPE RESEARCH PROJECTS. WE
19	WOULDN'T DICTATE THE SPECIFIC NUMBERS OF EACH. WE
20	WOULD LEAVE THAT UP TO THE WISDOM AND JUDGMENT OF
21	OUR GRANTS WORKING GROUP, INCLUDING BOTH THE
22	SCIENTIFIC MERIT DISCUSSION AND THE PROGRAMMATIC
23	REVIEW.
24	THE ELIGIBILITY FOR THE BASIC BIOLOGY
25	AWARDS ARE STANDARD AND SIMILAR TO THE ONES WE'VE
	123

1	USED IN THE PAST. PI'S MUST HOLD A THE PRINCIPAL
2	INVESTIGATORS MUST HOLD A PH.D., M.D., OR EQUIVALENT
3	DEGREE AND BE WILLING TO COMMIT A MINIMUM OF 20
4	PERCENT EFFORT. AN ELIGIBLE PI MAY SUBMIT THROUGH
5	ONE TRACK, EITHER THE FUNDAMENTAL MECHANISM TRACK OR
6	THE OTHER, THE EXPLORATORY CONCEPT TRACK, BUT NOT
7	BOTH. AND WHERE THEY APPLY WOULD BE WHAT IS THE
8	BEST FIT FOR THE TYPE OF RESEARCH PROJECT THEY ARE
9	INTERESTED IN PURSUING.
10	IN TERMS OF INSTITUTIONAL ELIGIBILITY,
11	THIS RFA WOULD BE OPEN TO ALL ACADEMIC, NONPROFIT,
12	AND FOR-PROFIT INSTITUTIONS IN CALIFORNIA. WE'RE
13	NOT PROPOSING ANY INSTITUTIONAL LIMITS. RATHER,
14	WE'RE PROPOSING TO USE THE PRELIMINARY APPLICATION
15	REVIEW PROCESS TO SELECT MOST COMPETITIVE,
16	COMPELLING, AND RESPONSIVE PROPOSALS TO MOVE FORWARD
17	WITH FULL APPLICATIONS TO BE EVALUATED BY THE GWG.
18	TO BE ELIGIBLE FOR THESE AWARDS, PROJECTS
19	SUBMITTED THROUGH FUNDAMENTAL MECHANISMS STUDIES
20	MUST UTILIZE HUMAN STEM CELLS OR THEIR DERIVATIVES.
21	THOSE SUBMITTED THROUGH THE EXPLORATORY CONCEPT
22	STUDIES MAY UTILIZE HUMAN AND OR, WITH COMPELLING
23	JUSTIFICATION, VERTEBRATE ANIMAL MODEL SYSTEMS
24	STUDIES WOULD BE CONSIDERED.
25	TRANSLATIONAL RESEARCH PROJECTS ARE OUT OF
	124

1	SCOPE AS HAS ALWAYS BEEN TRUE FOR BASIC BIOLOGY, AND
2	CIRM HAS SEVERAL RECURRING AND OTHER RFA PROGRAMS
3	THAT CAPTURE THIS TYPE OF RESEARCH. AND THE
4	EXPLORATORY CONCEPT STUDIES MUST BE DIRECTLY RELATED
5	TO STEM CELL BIOLOGY, DIRECT REPROGRAMMING, OR
6	DETERMINATION OF CELL FATE AND IDENTITY.
7	THE PROVISIONAL TIMELINE FOR THE BASIC
8	BIOLOGY AWARDS ARE AS FOLLOWS: FOLLOWING CONCEPT
9	APPROVAL, WE WOULD RELEASE THE RFA IN JANUARY,
10	TOWARDS THE END OF JANUARY 2013. THE PRELIMINARY
11	APPLICATION WOULD BE DUE THE FOLLOWING MARCH. AND
12	FOLLOWING THE PREAPPLICATION REVIEW, AN INVITATION
13	FOR FULL APPLICATIONS WOULD BE EXPECTED AROUND JUNE
14	OF 2013. THOSE WOULD BE REVIEWED BY THE FULL
15	WORKING GROUP IN SEPTEMBER OF 2013, AND THE EARLIEST
16	BOARD APPROVAL OF FUNDING, WE WOULD HOPE TO BE ABLE
17	TO BRING THESE TO YOU NEXT DECEMBER, ABOUT A YEAR
18	FROM NOW.
19	IN SUMMARY, WE'RE REQUESTING APPROVAL FOR
20	A BUDGET OF UP TO \$40 MILLION TO SUPPORT UP TO 30
21	BASIC BIOLOGY V AWARDS IN TOTAL. THE AWARDS WOULD
22	CONSIST OF TWO TYPES, THOSE ADDRESSING FUNDAMENTAL
23	MECHANISMS OF HUMAN STEM CELLS AND THOSE TESTING
24	EXPLORATORY NEW CONCEPTS.
25	THANK YOU VERY MUCH. I'LL BE HAPPY TO
	125
	1

1	TAKE ANY QUESTIONS.
2	MR. SHESTACK: I JUST HAVE A COUPLE QUICK
3	QUESTIONS. I THOUGHT IN THE WRITE-UP IT SAID THAT
4	STUDIES ON DIFFERENTIATION WERE OUTSIDE THE SCOPE OF
5	THIS.
6	DR. SHEPARD: DIFFERENTIATION FROM
7	PLURIPOTENT STEM CELLS IN PARTICULAR IS A KEY
8	PRIORITY OF THESE AWARDS. IT HAS BEEN AND IT
9	CONTINUES TO BE ONE OF OUR MAJOR PRIORITIES.
10	MR. SHESTACK: I MISREAD IT.
11	AND THEN DO YOU ENVISION WHEN YOU SAY THE
12	EXPLORATORY TRACK IS SORT OF HIGH RISK, HIGH REWARD,
13	IS THAT SIGNIFICANTLY DIFFERENT FROM THE WAY IT'S
14	BEEN IN THE BASIC BIOLOGY TRACK BEFORE?
15	DR. SHEPARD: WELL, THE FUNDAMENTAL
16	MECHANISMS TRACK IS SIMILAR TO WHAT WE'VE DONE
17	BEFORE. I WOULDN'T CALL THESE EXTREMELY HIGH RISK
18	THE USUAL WAY WE'VE DONE IT. THEY HAVE TO BE BASED
19	ON COMPELLING PRELIMINARY DATA FOR ONE AND OTHER
20	STRONG SCIENTIFIC RATIONALE. THOSE ARE ELEMENTS
21	THAT SPEAK TO THEIR FEASIBILITY.
22	NOW, FOR THE EXPLORATORY CONCEPTS, WE
23	STILL WANT THEM TO PROPOSE PROJECTS THAT ARE
24	TECHNICALLY FEASIBLE; HOWEVER, THE BURDEN OF HAVING
25	COMPELLING PRELIMINARY DATA IS NOT THERE. IT COULD
	126

BE HELPFUL TO THEM, BUT REALLY IT'S MORE ABOUT THE
IDEA. WE WILL BE LOOKING FOR HIGHLY NOVEL IDEAS
THAT COULD BE REALLY GROUNDBREAKING, A NEW
HYPOTHESIS THAT REALLY CHALLENGES WHAT WE ALREADY
KNOW, BECAUSE IF THESE ARE THE TYPES OF HYPOTHESES,
THAT IF YOU FIND SOMETHING NEW, HAVE THE POTENTIAL
TO REALLY ADVANCE THE FIELD IN A GREAT LEAP RATHER
THAN IN AN INCREMENTAL STEP. OF COURSE, THAT'S ALSO
TRUE THROUGH THE FUNDAMENTAL MECHANISM TRACK IF
WE'RE ABLE TO OVERCOME A LONG-STANDING QUESTION OF
STEM CELL BIOLOGY BY TACKLING IT HEAD-ON.
MR. SHESTACK: DO YOU FEEL AND DOES THE
SCIENTIFIC STAFF FEEL THAT, EVEN THOUGH THIS WOULD
BE THE FIFTH TRACK, THAT WE SHOULD STILL BE SPENDING
THIS AMOUNT OF MONEY IN AWARDING UP TO 20 AWARDS IN
THIS TRACK?
DR. SHEPARD: UP TO 30. WE DO FEEL THAT
THERE'S STILL A LOT OF BASIC BIOLOGY THAT NEEDS TO
BE DONE. THE \$40 MILLION THAT WE'RE REQUESTING IS A
SLIGHT BIT MORE. IT'S FIVE MILLION MORE THAN WE
REQUESTED LAST YEAR FOR BASIC BIO IV. WE REQUESTED
35 MILLION, BUT WE ENDED UP AWARDING \$38 MILLION IN
AWARDS AFTER BOARD APPROVAL. AND THAT IS CONSISTENT
WITH WHAT'S BEEN AWARDED EVERY ROUND. IT'S ALWAYS
BEEN 25 AND 30 PROJECTS AT APPROXIMATELY 35 TO \$40
127

1	MILLION. AND WE DON'T ANTICIPATE THAT THIS TOTAL
2	ALLOCATION WILL INCREASE AS THE YEARS GO BY;
3	HOWEVER, THE INTEREST IN BASIC BIOLOGY AND THE NEED
4	FOR IT IS VERY REAL.
5	WE RECEIVED 357 PRELIMINARY APPLICATIONS
6	FOR BASIC BIOLOGY V. THIS HAS SURPASSED. THE BASIC
7	BIOLOGY PROGRAM RECEIVES MORE APPLICATIONS AND
8	GENERAL INTEREST THAN MANY OF OUR OTHER PROGRAMS.
9	AND SO WE FEEL THAT THE NUMBERS WE'RE ASKING FOR IS
10	REASONABLE GIVEN WHAT WE CAN DO. ALTHOUGH I THINK
11	THERE'S A LOT MORE INTEREST AND COMPETITION FOR
12	THOSE AWARDS THAN WE ARE IN THEORY ABLE TO SUPPORT.
13	MR. SHESTACK: THANK YOU. THANK YOU VERY
14	MUCH.
15	DR. JUELSGAARD: SO JUST A LITTLE
16	EXPLANATION. I DID SOME MATH ON WHAT YOU'RE
17	PROPOSING, THE 20 FUNDAMENTAL MECHANISM AWARDS AND
18	THE 10 EXPLORATORY CONCEPT AWARDS BASED ON THE
19	MAXIMUM AMOUNT OF 250,000 A YEAR WITH THE FIRST,
20	200,000 WITH RESPECT TO THE SECOND, ASSUMING
21	EVERYBODY GOT THE MAXIMUM AMOUNT OF MONEY THAT WE'RE
22	RECOMMENDING. WHEN YOU ADD THEM TOGETHER, YOU COME
23	UP WITH A TOTAL 20 MILLION OUT OF THE 40 MILLION
24	THAT YOU'RE RECOMMENDING BE THE POOL. SO AM I TO
25	ASSUME SO THOSE ARE THE DIRECT COSTS.
	128

1	SO AM I TO ASSUME THAT THE OTHER 20
2	MILLION, THEN, ARE GOING TO BE ALLOCATED TOWARDS THE
3	INDIRECT COST? IS IT TYPICALLY ONE-FOR-ONE?
4	MR. SHESTACK: THESE ARE MULTIYEAR AWARDS.
5	DR. JUELSGAARD: THIS IS CONSIDERING THE
6	MULTIPLE YEARS. FIFTEEN MILLION FOR THE FIRST AND
7	FIVE FOR THE SECOND.
8	DR. SHEPARD: THE INDIRECTS AREN'T IN THE
9	DIRECT PROJECT COSTS AND IT VARIES FROM INSTITUTION
10	TO INSTITUTION. WE BASED THE NUMBERS FIRST OF
11	ALL, WHEN WE HAVE BASED ON OUR OWN EXPERIENCE
12	WITH JUST THE FUNDAMENTAL MECHANISM TRACK TYPE OF
13	AWARDS, WE GENERALLY GET ANYWHERE BETWEEN 25 AND 30
14	THAT WE ARE ABLE TO AWARD WITHIN THAT BUDGET. NOW,
15	WE'VE REDUCED THE DIRECT PROJECTS COST FROM 300,000
16	A YEAR TO 250,000 A YEAR FOR THOSE AWARDS. SO
17	THAT'S A SLIGHT REDUCTION.
18	AND ALSO FOR THE EXPLORATORY CONCEPT
19	AWARDS, WE WENT AND LOOKED AT OTHER SIMILAR FUNDING
20	MODELS, AND BASED ON OUR OWN EXPERIENCE, WHAT WE
21	THOUGHT WOULD MAKE SENSE FOR THAT.
22	WE DON'T KNOW HOW MANY OF EACH AWARD WILL
23	BE GRANTED, BUT WHAT WE WOULD LIKE TO DO IS WE WOULD
24	LIKE TO HAVE A SIMILAR AND NOT SIGNIFICANTLY REDUCED
25	NUMBER OF THE TRADITIONAL THREE-YEAR AWARDS THAT WE
	129

1	SUPPORT, BUT WE WANT TO BE ABLE TO ACCOMMODATE AS
2	MANY OF THE EXPLORATORY CONCEPT AWARDS AS THE REVIEW
3	DETERMINES ARE HIGHLY MERITORIOUS. SO THE NUMBERS,
4	THERE'S A LITTLE WIGGLE ROOM IN THERE, BUT WE FEEL
5	THAT IT'S APPROPRIATE TO GET APPROXIMATELY THE RIGHT
6	NUMBER OF AWARDS THAT WE'RE ABLE TO ADMINISTER.
7	DR. JUELSGAARD: ACTUALLY MY QUESTION GOES
8	TO A SOMEWHAT DIFFERENT ISSUE, AND THAT'S THE AMOUNT
9	OF MONEY THAT'S GOING TO THE INSTITUTION FOR
10	INDIRECT COST, NOT THE AMOUNT OF MONEY THAT'S GOING
11	FOR DIRECT COSTS.
12	WHAT I'M SEEING IS, IF I DO THE MATH
13	CORRECTLY, AN EQUAL ALLOCATION BETWEEN DIRECT COST
14	AND INDIRECT COST. AND MY QUESTION IS IS THAT
15	TYPICAL? IS THAT THE WAY IT WORKS? WE DO DRAW A
16	LINE ON THE MAXIMUM AMOUNT OF INDIRECT COSTS AS A
17	PERCENTAGE OF THE DIRECT COST THAT WE'RE WILLING TO
18	BEAR? I JUST DON'T KNOW QUITE HOW THAT WORKS.
19	DR. SHEPARD: IT DOES VARY, BUT WE DO HAVE
20	A LIMIT. MAYBE DR. OLSON WOULD SPEAK TO THAT.
21	DR. OLSON: I JUST WANT TO REMIND YOU THAT
22	IT'S A DIRECT FACILITIES COST AS WELL AS AN INDIRECT
23	COST THAT IS NOT CAPTURED IN THE DIRECT PROJECT
24	COSTS. THAT FIGURE CAN VARY FROM ABOUT 1.45 UP TO,
25	AS YOU NOTE, DOUBLE, A HUNDRED PERCENT. SO IT TENDS
	120
	130

1	TO AVERAGE AT ABOUT 65 PERCENT OF, AT LEAST THE LAST
2	TIME I CHECKED, THE COMBINATION OF THE DIRECT
3	FACILITIES COST, WHICH IS A NEGOTIATED NUMBER, AND
4	WE BASE THAT ON WHAT THE INSTITUTE HAS NEGOTIATED
5	WITH THE NIH. SO WE ACCEPT THAT AS THE COST. AND
6	THEN THE INDIRECT RATE IS SET BY THE RFA. IT'S
7	TYPICALLY 20 PERCENT.
8	DR. STEWARD: I KNOW I SOUND LIKE A BROKEN
9	RECORD, BUT AT LEAST I'M CONSISTENT. MY ISSUE WAS
10	ALWAYS BEING OVERLY RESTRICTIVE IN THESE AND
11	LIMITING THE SCOPE BECAUSE, IN GENERAL, THE PI'S OUT
12	THERE ARE THE ONES WITH INCREDIBLY CREATIVE IDEAS
13	AND ARE REALLY DRIVING THE SCIENCE. SO THAT'S A
14	STATEMENT.
15	THE QUESTION IS ON WHAT BASIS DID YOU
16	CHOOSE THE RESTRICTIONS THAT YOU'RE APPLYING TO THIS
17	ROUND? FOR EXAMPLE, THAT NEW APPROACHES FOR
18	GENERATING IPS CELLS WOULD BE OUT OF SCOPE AND
19	TRANSLATIONAL RESEARCH IN PARTICULAR, THE KINDS OF
20	TESTING OF CELL POPULATIONS AND DISEASE MODELS.
21	REALLY, EXACTLY THE SAME THING WE JUST SAW IN THE
22	SPOTLIGHT PRESENTATION, THOSE SEEM TO BE THINGS THAT
23	WE WOULD WANT TO KEEP IN SCOPE.
24	DR. SHEPARD: TRANSLATIONAL RESEARCH HAS
25	NEVER BEEN IN SCOPE WITH THE BASIC BIOLOGY AWARDS

131

WE DO HAVE OTHER RFA PROGRAMS THAT DO FUND THE TYPE
OF RESEARCH THAT YOU'RE SPEAKING OF.
DR. BRYANT: I'D JUST LIKE TO SAY THAT I'M
COMPLETELY DELIGHTED TO SEE THE SECOND NEW
INITIATIVE HERE. I THINK IT'S LONG OVERDUE.
THERE'S NOWHERE THAT YOU CAN GET FUNDING FOR THAT
KIND OF THING, AND I THINK IT COULD BE
TRANSFORMATIONAL. THANK YOU.
CHAIRMAN THOMAS: DR. CHISARI.
DR. CHISARI: I ECHO THAT. I'M EXTREMELY
EXCITED AND GRATIFIED THAT CIRM IS UNDERTAKING THIS
INITIATIVE. I HOPE IT'S NOT THE LAST UNTIL WE HAVE
A STEM CELL CURE FOR ALL THE DISEASES THAT STEM
CELLS CAN ADDRESS.
UNDER THE DEFINITION OR SCOPE OF THE
FUNDAMENTAL MECHANISMS TRACK, THE THIRD BULLET POINT
ENDS WITH DISEASE MECHANISM. AND SO WHEN SCIENTISTS
TRY TO ADDRESS A DISEASE MECHANISM THAT AFFECTS
HUMANS WITHOUT IT BEING INVASIVE, IT PRETTY MUCH
REQUIRES DOING EXPERIMENTS ON HUMAN CELLS IN A DISH
OR IN VERTEBRATE ANIMALS. AND I THINK SOMEWHERE IN
HERE YOU EMPHASIZE OR YOU STATE THAT WITH COMPELLING
REASONS, VERTEBRATE ANIMALS MAY BE USED. WHAT WOULD
YOU DEFINE AS COMPELLING?
DR. SHEPARD: WELL, THAT'S A GOOD
133

1	QUESTION. SO IN PAST ROUNDS OF BASIC BIOLOGY, WHEN
2	WE JUST HAD THE ONE TRACK, IT WAS ALWAYS PRIORITIZED
3	ON THE HUMAN STEM CELL STUDIES, BUT THERE WAS THIS
4	CLAUSE IN THE RFA THAT SAID IF YOU FEEL THAT YOUR
5	WORK IS PARTICULARLY GROUNDBREAKING AND AN ANIMAL
6	MODEL SYSTEM IS NECESSARY, YOU CAN PROPOSE THAT.
7	WHAT WE ENDED UP HAVING WAS REVIEW CRITERIA THAT
8	WERE CENTERED ON HOW MECHANISTIC THE RESEARCH IS AND
9	THE PRIORITY WAS HUMAN STEM CELLS.
10	WE THOUGHT BY HAVING ANOTHER TRACK, IF
11	PEOPLE ARE GOING TO CLAIM THAT THEIR STUDIES ARE
12	TRULY GROUNDBREAKING AND THOSE STUDIES ARE
13	JUSTIFIED, THEN THAT WOULD BE A REVIEW CRITERIA IN
14	AND OF ITSELF. AND THOSE TYPES OF AWARDS WOULD BE
15	EVALUATED AGAINST OTHERS MAKING THAT CLAIM RATHER
16	THAN AGAINST 300 PLUS TYPES OF RESEARCH THAT ARE
17	MORE FOCUSED ON THE HUMAN STEM CELL BIOLOGY.
18	SO THAT WAS ONE WAY WE TRIED TO BETTER
19	DEAL WITH THOSE TYPES OF APPLICATIONS AND BETTER
20	INCREASE THE POTENTIAL OF CAPTURING THE TRULY
21	GROUNDBREAKING TYPE STUDIES UNDER THIS PROGRAM.
22	WITH RESPECT TO DISEASE MECHANISM, THE
23	SLIDES I PRESENTED ARE JUST A VERY BRIEF OVERVIEW OF
24	THE PROGRAM. IN THE RFA THERE'S MORE DETAILS. AND
25	THE BASIC BIOLOGY RFA STARTED IN ITS FIRST ITERATION
	134

1	AS PURELY BEING ABOUT STEM CELL BIOLOGY. BUT AROUND
2	THAT TIME IS WHEN PEOPLE REALLY BEGAN TO APPRECIATE
3	THE VALUE OF IPSC CELLS FOR DISEASE MODELING. AND
4	DISEASES, OF COURSE, ARE WELL WITHIN CIRM'S MISSION,
5	AND WE THOUGHT THAT AS LONG AS THE STUDIES ARE
6	RESPONSIVE TO THE RFA, WHICH IS THEY ARE PURSUING
7	MOLECULAR AND CELLULAR MECHANISMS, IT WOULD BE
8	APPROPRIATE TO STUDY DISEASES UNDER THIS INITIATIVE
9	INSOFAR AS THE HUMAN STEM CELLS ARE WHAT MAKE THAT
10	POSSIBLE. AND WHAT SETS THE DISEASE IN A DISH
11	STUDIES IN BASIC APART FROM THE DISEASE IN A DISH
12	STUDIES THAT ARE SUPPORTED THROUGH OUR TOOLS AND
13	TECHNOLOGY PROGRAM AND OUR EARLY TRANSLATION PROGRAM
14	IS THE FOCUS IS ON UNDERSTANDING WHAT IS GOING WRONG
15	IN THE DISEASE AT THE CELLULAR AND MOLECULAR LEVEL.
16	WE HAD PATIENT ADVOCATES TODAY TALKING
17	ABOUT ENDOMETRIOSIS AND HOW NOBODY KNOWS ABOUT THE
18	BASIC BIOLOGY OF THAT. THIS IS WHERE YOU COULD
19	STUDY THE BASIC BIOLOGY OF THAT; WHEREAS, OUR OTHER
20	PROGRAMS, EARLY TRANSLATION, IS WHERE YOU TAKE A
21	DISCOVERY THAT'S BEEN MADE AND TRANSLATE IT INTO A
22	THERAPY. SO WE'RE TRYING TO CAPTURE
23	DISEASE-IN-A-DISH-TYPE STUDIES AT EVERY LEVEL AT THE
24	BEGINNING WHERE YOU NEED TO UNDERSTAND THE MECHANISM
25	TO THE POINT WHERE YOU ARE SCREENING FOR DRUGS THAT
	135

1	COULD MODIFY A PHENOTYPE.
2	SO THIS IS WHERE WE'RE CAPTURING THE MORE
3	EARLY STAGE STUDIES UNDER THIS INITIATIVE.
4	DR. CHISARI: WELL, YOU'VE JUST EXPLAINED
5	IT VERY, VERY CLEARLY. I HOPE THAT IT'S EXPLAINED
6	THAT CLEARLY IN THE RFA SO THAT YOU DON'T ENCOURAGE
7	HUNDREDS OF SCIENTISTS TO WRITE APPLICATIONS THAT
8	WILL WIND UP NOT BEING COMPELLING ENOUGH TO BE
9	COMPETITIVE.
10	DR. SHEPARD: WE GET VERY MANY
11	APPLICATIONS, SO WE'RE TRYING TO BE AS CLEAR AS
12	POSSIBLE SO THAT WHEN PEOPLE SUBMIT APPLICATIONS,
13	THEY ARE WHAT WE'RE LOOKING FOR. AND IF THEY DON'T
14	UNDERSTAND WHAT WE'RE LOOKING FOR, WE WANT TO MAKE
15	IT CLEAR SO THAT THEY CRAFT THEIR PROPOSALS SO THAT
16	IT DOES ANSWER THE TYPE OF QUESTIONS THAT WE FEEL
17	HAVE THE BEST POTENTIAL OF ADVANCING THE FIELD.
18	DR. CHISARI: THANK YOU.
19	CHAIRMAN THOMAS: THANK YOU. DO WE HEAR A
20	MOTION TO APPROVE?
21	DR. CHISARI: SO MOVE.
22	MS. GIBBONS: SECOND.
23	CHAIRMAN THOMAS: MOVED BY DR. CHISARI,
24	SECONDED BY LEEZA. IS THERE ANY FURTHER DISCUSSION
25	BY MEMBERS OF THE BOARD? ANY DISCUSSION BY MEMBERS
	136

1	OF THE PUBLIC? CAN THIS BE A VOICE VOTE, MR.
2	HARRISON?
3	MR. HARRISON: YES, EXCEPT FOR THE MEMBERS
4	ON THE PHONE.
5	CHAIRMAN THOMAS: ALL THOSE IN FAVOR
6	PLEASE SAY AYE. OPPOSED? MEMBERS ON THE PHONE
7	PLEASE CAST YOUR VOTES.
8	MS. SAMUELSON: YES.
9	DR. HAWGOOD: AYE.
10	DR. WARE: AYE.
11	MS. FEIT: YES.
12	CHAIRMAN THOMAS: THANK YOU VERY MUCH.
13	THE MOTION PASSES. THANK YOU, DR. SHEPARD.
14	DR. SHEPARD: THANK YOU.
15	CHAIRMAN THOMAS: NOW PROCEEDING TO ITEM
16	11, CONSIDERATION OF FINAL ADOPTION OF THE CIRM
17	CONFLICT OF INTEREST CODE AMENDMENTS. MR. TOCHER.
18	MR. TOCHER: GOOD AFTERNOON. THIS ITEM
19	COMES BACK TO YOU FROM EARLIER THIS YEAR CONCERNING
20	AMENDMENTS TO CIRM'S CONFLICT OF INTEREST CODE.
21	THIS IS THE CODE THAT DESCRIBES THE LEVELS OF
22	DISCLOSURE FOR MEMBERS OF THIS BOARD AS WELL AS
23	STAFF AT CIRM.
24	THE POLITICAL REFORM ACT REQUIRES AGENCIES
25	TO CONDUCT A BIENNIAL REVIEW OF ITS CODE AND TO
	137

1	EXAMINE WHETHER NEW POSITIONS AND EXISTING POSITIONS
2	ARE ASSIGNED THE CORRECT LEVEL OF DISCLOSURE ON
3	THEIR STATEMENTS OF ECONOMIC INTERESTS.
4	EARLIER THIS YEAR CIRM STAFF MET WITH THE
5	FAIR POLITICAL PRACTICES COMMISSION, WHICH OVERSEES
6	THIS AGENCY'S CODE ADOPTION, AND IDENTIFIED
7	POSITIONS THAT THE AGENCY THOUGHT SHOULD BE REVIEWED
8	FOR POSSIBLE NARROWING OF THE DISCLOSURE CATEGORIES
9	FOR THESE DUTIES. THIS INCLUDES MEMBERS OF CIRM'S
10	EXECUTIVE STAFF AS WELL AS MEMBERS OF THIS BOARD.
11	HOWEVER, THE GOVERNANCE SUBCOMMITTEE TO THE BOARD,
12	CHAIRED MY MEMBER LANSING, RECOMMENDED THAT CIRM AND
13	THE ICOC NEVERTHELESS MAINTAIN THE BROADEST
14	DISCLOSURE LEVEL POSSIBLE FOR MEMBERS OF THE BOARD
15	AND CIRM'S EXECUTIVE STAFF, BUT DO FOLLOW THROUGH
16	FOR CIRM NONEXECUTIVE STAFF AND REVIEW THOSE
17	POSITIONS FOR THE APPROPRIATE LEVEL OF DISCLOSURE.
18	THAT RECOMMENDATION WAS FOLLOWED BY THE
19	BOARD, AND STAFF THEN OVER THE PAST SEVERAL MONTHS
20	HAS WORKED TO IMPLEMENT THAT RECOMMENDATION BY
21	REVIEWING CIRM'S CODE FOR NONEXECUTIVE STAFF. THAT
22	PROCESS HAS CONCLUDED. WE HAVE WORKED CLOSELY WITH
23	FPPC STAFF TO REVIEW JOB DESCRIPTIONS AND WHAT THE
24	APPROPRIATE LEVELS OF DISCLOSURE WOULD BE. THOSE
25	CHANGES AND PROPOSED AMENDMENTS HAVE BEEN CIRCULATED
	138
	

1	FOR PUBLIC COMMENT. NONE HAS BEEN RECEIVED BY BOTH
2	THE FPPC AND CIRM. AND SO THE PROCESS IS AT ITS
3	CONCLUSION, AND WE AWAIT THE BOARD'S FINAL ADOPTION
4	OF THESE AMENDMENTS, WHICH, AGAIN, MAINTAIN THE
5	BROADEST DISCLOSURE FOR ICOC MEMBERS AND FOR CIRM
6	EXECUTIVE STAFF.
7	CHAIRMAN THOMAS: YOU NEED A MOTION?
8	MR. TOCHER: CORRECT.
9	CHAIRMAN THOMAS: DO I HEAR A MOTION?
10	DR. PULIAFITO: SO MOVED.
11	MS. LANSING: SECOND.
12	CHAIRMAN THOMAS: MOVED BY DEAN PULIAFITO,
13	SECOND BY SHERRY. ANY DISCUSSION BY MEMBERS OF THE
14	BOARD? DISCUSSION BY MEMBERS OF THE PUBLIC?
15	HEARING NONE, WE'LL PROCEED TO A VOICE VOTE. ALL
16	THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? VOTES ON
17	THE PHONE, PLEASE.
18	MS. SAMUELSON: AYE.
19	MS. FEIT: AYE.
20	DR. HAWGOOD: YES.
21	CHAIRMAN THOMAS: THANK YOU VERY MUCH.
22	MOTION CARRIES. THANK YOU, MR. TOCHER.
23	WE'RE GOING TO GO ITEM 14, WHICH I'M
24	INFORMED IS ACTUALLY NOT AN ACTION ITEM, BUT A
25	DISCUSSION ITEM. SO THAT IS DISCUSSION OF UPDATE TO
	139

1	CIRM'S RESPONSE TO THE PERFORMANCE AUDIT
2	RECOMMENDATIONS. I BELIEVE, ALEX, YOU ARE GOING TO
3	GIVE US THIS DISCUSSION.
4	MS. CAMPE: CHAIRMAN AND MEMBERS OF THE
5	BOARD, THANK YOU FOR YOUR TIME TODAY. I'M HERE
6	ACTUALLY TO UPDATE YOU ON THE PERFORMANCE AUDIT
7	REPORT THAT WE RECEIVED IN MAY OF 2012 AND TO SHARE
8	WITH YOU WHAT THE PROGRESS HAS BEEN WITH THAT
9	REPORT.
10	FIRST OF ALL, WE WERE INFORMED THAT WE
11	WERE IN FULL COMPLIANCE WITH THAT PERFORMANCE AUDIT.
12	THEY HAD RECOMMENCED 24 RECOMMENDATIONS FOR IMPROVED
13	PERFORMANCE FOR CIRM. WE HAVE TAKEN THOSE SERIOUSLY
14	AND HAVE LOOKED AT ALL OF THEM. AND ALL OF YOU
15	ACTUALLY HAD RECEIVED A COPY OF THAT REPORT MANY
16	MONTHS AGO. I'VE ALSO SHARED A LINK WITH YOU WHERE
17	IT IS NOW ON THE WEB SITE.
18	SO OF THE 24 RECOMMENDATIONS, TO DATE
19	SEVEN ARE COMPLETED. THE NEWLY COMPLETED ONES THAT
20	YOU CAN NOW BE AWARE OF IS THAT THE BOND FORECASTING
21	PROCEDURES HAVE BEEN COMPLETED. WE HAD AN IP MODULE
22	THAT WAS UPDATED TO INCLUDE SPECIFIC QUESTIONS ABOUT
23	COMMERCIALIZATION ACTIVITY. WE HAD A FORMAL
24	ONBOARDING PROGRAM THAT WAS COMPLETED. AND WE ALSO
25	HAD A GRANTS MANAGEMENT SYSTEM MODULE RELEASE TO

140

1	OBTAIN REQUIRED INVENTION DISCLOSURE FORMS AND
2	INVENTION UTILIZATION FORMS.
3	CURRENTLY WE ALSO HAVE 14 ONGOING FOCUS
4	ASPECTS TO THE 24 RECOMMENDATIONS. AND THEN,
5	FINALLY, WE HAVE 13 STILL IN PROGRESS. AND WE'RE
6	ALL WORKING VERY HARD TO COMPLETE THOSE BY JUNE OF
7	2013.
8	SO THAT REALLY WRAPS UP MY UPDATE TO WHERE
9	WE'RE AT WITH REGARDS TO THE PERFORMANCE AUDIT. I'M
10	HAPPY TO ANSWER ANY QUESTIONS YOU MAY HAVE.
11	CHAIRMAN THOMAS: THANKS, ALEX. I THINK
12	THE PROCESS IS COMING ALONG VERY WELL. WE'RE BEING
13	VERY RESPONSIVE TO THE AUDIT, AND WE'LL CONTINUE TO
14	BE SO UNTIL WE HAVE ALL ITEMS TAKEN CARE OF. SO
15	THANK YOU VERY MUCH.
16	GOING TO GO NOW TO ASK A QUESTION.
17	ALAN, HOW LONG DO YOU EXPECT THE PRESIDENT'S REPORT
18	TO BE? TRYING TO BUDGET TIME HERE.
19	DR. TROUNSON: THREE AND A HALF MINUTES.
20	JUST A LITTLE LONGER THAN FIVE MINUTES.
21	CHAIRMAN THOMAS: LET'S GO THEN TO ITEM
22	15, DISCUSSION OF COMMERCIALIZATION OF THE INDUSTRY
23	ENGAGEMENT PLAN. ELONA.
24	MS. BAUM: THANK YOU VERY MUCH. THIS IS A
25	DISCUSSION ITEM AS WELL, AND IN MANY WAYS IT FOLLOWS
	141

1	THE PERFORMANCE AUDIT BECAUSE IT HAS ITS GENESIS
2	FROM THAT AUDIT. I WANT TO GIVE YOU A LITTLE
3	CONTEXT. AS I MENTIONED, THE MOSS ADAMS REPORT, THE
4	PERFORMANCE AUDIT, HAD SUGGESTED THAT ALTHOUGH WE
5	HAD COMMERCIALIZATION AND INDUSTRY ENGAGEMENT
6	ACTIVITIES ONGOING FOR PROBABLY A YEAR AND A HALF OR
7	EVEN MORE, THERE WAS NEVER A FORMAL REPORT THAT HAD
8	BEEN PREPARED THAT OUTLINED WHAT OUR CORE STRATEGIC
9	OBJECTIVES WERE AND DEFINED ANY OF OUR INITIATIVES.
10	SO WHAT THIS REPORT IS, WHICH YOU HAVE IN
11	YOUR BINDER, IS ESSENTIALLY A COMPENDIUM OF WHAT WE
12	HAVE BEEN DOING. AND THEN I'VE ALSO LISTED SOME
13	OTHER POTENTIAL INITIATIVES THAT WILL BE CONSIDERED
14	IN THE FUTURE POSSIBLY AND SOME THAT WE COULD BRING
15	TO YOU THAT AREN'T EVEN LISTED THERE. BUT I WANTED
16	TO GIVE YOU A SENSE THAT THIS IS CONSIDERED A LIVING
17	DOCUMENT, THAT CERTAINLY THE STRATEGIC PRIORITIES
18	THAT I'M OUTLINING WITHIN THE DOCUMENT ARE LIKELY TO
19	BE CONSISTENT AND NOT CHANGED, BUT, AGAIN, THE
20	INITIATIVES ARE EXPECTED TO VARY.
21	I WANTED TO ALSO GIVE YOU SOME BACKGROUND
22	AS TO WHY WE'RE EMPHASIZING INDUSTRY ENGAGEMENT AND
23	COMMERCIALIZATION ACTIVITIES. AS YOU ALL KNOW, THE
24	FOCAL POINT OF PROPOSITION 71 HAS BEEN TO INVEST IN
25	RESEARCH THAT WILL HELP ACCELERATE THE DEVELOPMENT
	142
	<u> </u>

1	OF TRANSFORMATIVE NEW THERAPIES FOR PATIENTS. I
2	THINK WE HAVE HEARD TIME AND TIME AGAIN WITHIN THE
3	IOM REPORT, WITHIN THE BLUE RIBBON PANEL THAT'S
4	REVIEWED CIRM, AND OTHER TIMES AS WELL THAT INDUSTRY
5	ENGAGEMENT IS ABSOLUTELY FRONT, CENTER, AND CRITICAL
6	TO ACHIEVE THIS END.
7	SO YOU WILL SEE STRATEGIC PRIORITIES AND
8	OBJECTIVES THAT ARE GEARED TOWARDS ACHIEVING THAT
9	OBJECTIVE. BUT IN ADDITION, IF YOU EVEN GO TO THE
10	VERY FIRST PAGE OF PROP 71, YOU WILL SEE THAT THERE
11	ARE ECONOMIC DEVELOPMENT COMPONENTS TO PROPOSITION
12	71. AND I QUOTED A COUPLE OF STATEMENTS THAT APPEAR
13	IN PROP 71, SUCH AS "TO ADVANCE THE BIOTECH INDUSTRY
14	IN CALIFORNIA TO WORLD LEADERSHIP AS AN ECONOMIC
15	ENGINE FOR CALIFORNIA." THAT'S ONE QUOTE THAT
16	APPEARS IN PROP 71. ANOTHER QUOTE BEING "TO BENEFIT
17	THE CALIFORNIA ECONOMY BY CREATING PROJECTS, JOBS,
18	AND THERAPIES THAT WILL GENERATE MILLIONS OF DOLLARS
19	IN TAX REVENUES."
20	I'M HAPPY TO SAY WE'VE BEEN VERY
21	SUCCESSFUL IN THAT FRONT. WITH THAT SAID, LET ME
22	JUST GO OVER SOME OF THE STRATEGIC OBJECTIVES AND
23	INITIATIVES THAT ARE GEARED TO SUPPORT THE PROP 71
24	GOALS AND OBJECTIVES.
25	SO THERE'S ESSENTIALLY FOUR STRATEGIC
	1/13

1	GOALS OR OBJECTIVES THAT ARE BEING PROPOSED. I'LL
2	LIST THEM, AND THEN IN THE NEXT COUPLE SLIDES I'LL
3	OUTLINE THE RATIONALE BEHIND THEM.
4	SO THE FIRST ONE IS TO ATTRACT FOLLOW-ON
5	FINANCING AND CO-FUNDING FOR CIRM-FUNDED RESEARCH.
6	AND I'LL EXPLAIN A LITTLE BIT WHAT I MEAN BY
7	FOLLOW-ON IN A MINUTE.
8	THE NEXT IS OBVIOUSLY TO SUPPORT COMPANY
9	CREATION. THAT'S FUNDAMENTAL TO PROP 71. AND
10	SUPPORT THEIR GROWTH AND POSSIBLY EVEN RELOCATION OF
11	COMPANIES INTO CALIFORNIA. CERTAINLY THE HIGH
12	IMPACT COMPANIES WILL BE CONSIDERED.
13	AGAIN, WE'RE ALSO SEEKING, AS YOU'VE SEEN
14	IN OTHER INITIATIVES, TO OBTAIN EARLY ENGAGEMENT OF
15	TOP TIER BIOPHARMACEUTICAL COMPANIES IN ORDER TO
16	ACCESS THEIR EXPERTISE AND FUNDING. AND ALSO TO
17	ASSUME A LEADERSHIP ROLE IN THE FIELD SO THAT WE CAN
18	SUPPORT AREAS THAT ARE NOT NECESSARILY REQUIRED
19	FUNDING, BUT REALLY REQUIRE SOME LEADERSHIP FOR THE
20	INDUSTRY TO PROGRESS. AND I'LL EXPLAIN A LITTLE BIT
21	WHAT I MEAN ABOUT THAT IN A SECOND.
22	FOLLOW-ON FINANCING, WHAT DOES THAT MEAN?
23	WHAT THAT MEANS IS LINKING OUR PROGRAMS TO POTENTIAL
24	FUTURE SOURCES OF FUNDING. HOPEFULLY EVERYONE
25	UNDERSTANDS WHEN I USE THAT TERM, "FOLLOW-ON

144

	-
1	FUNDING," WHAT I MEAN BY THAT. OF COURSE, WE WANT
2	TO LEVERAGE OUR FUNDING. SO IF WE'RE ABLE TO OBTAIN
3	CO-FUNDING TODAY FOR PROJECTS AND HAVE A PARTNER
4	THAT'S HELPING US ALONG, THAT ALLOWS OUR FUNDING TO
5	LAST LONGER. SO THAT'S ANOTHER OBJECTIVE. AND
6	THAT'S WHAT IS MEANT BY THAT FIRST STRATEGIC
7	OBJECTIVE THAT I JUST LISTED.
8	I'VE ALREADY EXPLAINED THAT ENGAGING
9	PHARMA, BIOPHARMA EARLY IS BENEFICIAL BECAUSE WE GET
10	TO ACCESS THEIR VERY KEY AND CORE EXPERTISE IN MANY
11	AREAS. AND ALSO THEY ARE, FRANKLY, A SOURCE OF
12	CO-FUNDING AND FOLLOW-ON FINANCING. AND THAT'S WHY
13	YOU SEE THE STRATEGIC PARTNERSHIP FUND DESIGNED AS
14	IT IS.
15	THIRDLY, AS MENTIONED, WE WANT TO SUPPORT
16	THE GROWTH OF COMPANIES. WE DO HAVE SOME SPINOUT
17	COMPANIES ARISING FROM CIRM FUNDING, AND WE WILL
18	CONTINUE TO MONITOR THOSE. IN ADDITION, WE WANT TO
19	SUPPORT THOSE YOUNG COMPANIES AS BEST AS ABLE. BUT
20	WE NEED TO DO THAT IN AREAS WHERE THEY ARE FOCUSED
21	ON CIRM'S MANDATE. THERE'S A NUMBER OF COMPANIES IN
22	CALIFORNIA THAT IDENTIFY THEMSELVES AS BEING IN THE
23	STEM CELL INDUSTRY. BUT YOU WILL NOTE THAT IN A
24	NUMBER OF INSTANCES, THEY'RE NOT DOING RESEARCH THAT
25	IS THE FOCAL POINT OF PROP 71.

1	AND THEN WE'LL HAVE INDUSTRY INITIATIVES
2	THAT WILL ENABLE US TO ACCOMPLISH THIS. IT DOESN'T
3	ALL HAVE TO BE IN THE FORM OF FUNDING, BUT WE CAN
4	HELP WITH ORGANIZING WORKSHOPS, ETC., TO ACHIEVE
5	THAT GOAL. THAT GETS TO THE INITIATIVES.
6	WE, FINALLY, WANT TO MAINTAIN A LEADERSHIP
7	ROLE, AS I JUST STATED, IN THE BUSINESS AREA SO THAT
8	WE CAN FOCUS ON REIMBURSEMENT ISSUES, ACCESS TO
9	CAPITAL, DEFINING BUSINESS MODELS. THESE, AGAIN,
10	DON'T TAKE A LOT OF FUNDING. WHAT THEY REQUIRE IS
11	THAT WE TAKE A LEADERSHIP ROLE. WE'RE OUT IN THE
12	PUBLIC, WE'RE ORGANIZING THE KEY THOUGHT LEADERS,
13	WE'RE PERFORMING WORKSHOPS IN ORDER TO ENGAGE IN
14	THOSE ISSUES. WE DO THIS ALONGSIDE OTHER
15	INDUSTRY-ORIENTED GROUPS LIKE THE ALLIANCE FOR
16	REGENERATIVE MEDICINE. SO THAT'S OUR FOURTH KEY
17	OBJECTIVE.
18	AND THEN IN TERMS OF EXISTING AND
19	POTENTIAL INITIATIVES, THE TBD'S THAT YOU SEE ON THE
20	SLIDE BEFORE YOU MEANS THOSE HAVE NOT BEEN PROVIDED
21	TO THE BOARD YET. AND WE ARE NOT ASKING FOR YOUR
22	PERMISSION. THEY MIGHT COME AT A LATER DATE. THE
23	FIRST THREE WE'VE TALKED ABOUT A LOT. THEY'RE THE
24	SUPPORTING A PARTNERING FORUM AT THE STEM CELL
25	MEETING ON THE MESA. I THINK WE'VE ALL FELT THAT
	146
	± 10

THAT'S BEEN VERY SUCCESSFUL AND A VERY WORTHWHILE
ACTIVITY TO DO.
WE'VE ALREADY ESTABLISHED A BUSINESS
DEVELOPMENT FUNCTION. YOU WILL HEAR THAT WE'VE
HIRED I DON'T WANT TO BLOW ALAN'S COVER, BUT HE
WILL BE INTRODUCING ONE OR OUR NEW MEMBERS OF OUR
STAFF AND WE'LL HAVE A NICE PICTURE, I HOPE, OF NEIL
LITTMAN. I DIDN'T PUT IT ON HERE BECAUSE I THOUGHT
HE WOULD PRECEDE ME. SO WE'RE EXTREMELY LUCKY TO
HAVE ADDED THAT NEW EXPERTISE, AND WE WILL USE AND
TAKE ADVANTAGE OF THAT.
WE ARE MOVING AHEAD WITH SOME OTHER
POTENTIAL IDEAS. AND, AGAIN, WE WILL COME TO YOU
WITH THE SPECIFICS AS NEEDED AND ASK FOR FUNDING IF
NEEDED. SOME OF THESE COULD INCLUDE A
PRECOMPETITIVE CONSORTIA THAT WE'RE THINKING ABOUT.
WE MIGHT, BUT NOT NECESSARILY WILL, ASK FOR PROGRAMS
THAT WILL ENHANCE RELOCATION SUPPORT FOR COMPANIES
THAT PERFORM HIGH IMPACT ACTIVITIES THAT WILL
BENEFIT CALIFORNIA. AND AN INTERESTING IDEA COULD
BE THAT, EVEN IF WE DON'T GET DIRECT FUNDING FROM
THEM, IDENTIFY THE BIG BIOPHARMAS THAT WANT TO
COLLABORATE IN ONE WAY OR ANOTHER WITH US EITHER BY
PROVIDING IN-KIND SERVICES OR JUST ALLOWING OUR
RESEARCHERS TO KNOW WHO'S EVEN IN THE FIELD, WHO
147

1	WANTS TO START INVESTING AND INVESTIGATING
2	REGENERATIVE MEDICINE. SO WE MIGHT JUST ON OUR WEB
3	SITE IDENTIFY WHAT WE CONSIDER TO BE INDUSTRY
4	COLLABORATORS OR POTENTIAL INDUSTRY COLLABORATORS.
5	THESE ARE JUST A COUPLE IDEAS. WE'LL HAVE MORE THAT
6	WE'LL PROVIDE FOR YOU AS WE CONTINUE.
7	I THINK A LOT OF WHAT WE HAD NEED TO DO IS
8	JUST OLD-FASHIONED BUSINESS DEVELOPMENT. IT'S ABOUT
9	CREATING RELATIONSHIPS. IT'S ABOUT IDENTIFYING WHAT
10	THE VC'S WANT AND WHAT THE BIOPHARMAS ARE INTERESTED
11	IN AND LINKING UP WHEN WE SEE THE OPPORTUNITY. SO
12	THAT'S A LOT OF THE WORK THAT GOES ON BEHIND THE
13	SCENES. YOU DON'T ALWAYS HAVE TO HAVE A GLITZY
14	INITIATIVE TO ACCOMPLISH THIS. IT'S A LOT OF HARD
15	WORK AND IT'S THE OLD-FASHIONED WAY. WE WILL BE
16	CREATIVE, THOUGH, IN TRYING TO ORGANIZE OTHER TYPES
17	OF INITIATIVES.
18	FINALLY, I DON'T HAVE A SLIDE ON THIS,
19	BUT, OF COURSE, METRICS ARE VERY IMPORTANT. AND ON
20	THE LAST PAGE OF THE REPORT THAT I PROVIDED YOU, I
21	GIVE AN INDICATION OF HOW I THINK WE CAN MEASURE OUR
22	SUCCESS. THE OBVIOUS WAY IS TO LOOK AT HOW MUCH
23	CO-FUNDING. THAT'S A VERY OBJECTIVE WAY TO MEASURE
24	HOW SUCCESSFUL WE'VE BEEN. OTHER WAYS ARE TO LOOK
25	AT NEW STEM CELL COMPANIES THAT WE HAVE, QUOTE, SPUN

1	OUT OR HELPED SPIN OUT OF ACADEMIA AND/OR RECRUIT TO
2	CALIFORNIA. SO WE'LL BE TRYING TO FIND WAYS TO
3	TRACK THAT TYPE OF INFORMATION. ALSO TRYING TO FIND
4	WAYS OF CREATING AND TRACKING INDUSTRY RELATIONSHIPS
5	THAT WE HELP FOSTER.
6	SO WE WILL AT SOME POINT IN TIME PROVIDE
7	THAT INFORMATION TO YOU. AND THE POINT OF THIS
8	EXERCISE RIGHT NOW IS TO ASK IF YOU HAVE ANY OTHER
9	INPUT AND TO LET YOU KNOW THAT WE ARE FOCUSED ON
10	THIS, AND WE DO BELIEVE IT WAS A GOOD SUGGESTION BY
11	ADAMS AND MOSS TO PUT THIS IN A FORMAL WRITTEN
12	DOCUMENT, BUT WANTED TO REMIND EVERYBODY THAT THE
13	ACTIVITY HAS BEEN ONGOING.
14	SO THANK YOU VERY MUCH FOR YOUR
15	CONSIDERATION. AND IF YOU HAVE ANY INPUT, IT'S MUCH
16	APPRECIATED.
17	CHAIRMAN THOMAS: THANK YOU, ELONA. ANY
18	COMMENTS ON THIS? THIS IS A TOPIC WE DISCUSS AT
19	EXECUTIVE COMMITTEE IN GREAT DETAIL IN MANY
20	DIFFERENT SESSIONS. OBVIOUSLY ONE THAT'S VERY KEY
21	TO MOVING FORWARD HERE, AS HAS BEEN NOTED BY VARIOUS
22	PARTIES, MOST RECENTLY THIS MORNING. SO ANYBODY HAS
23	THOUGHTS ALONG THE WAY HOW TO INCREASE INDUSTRY
24	ENGAGEMENT, PLEASE DO CONTACT ELONA AND CONTINUE THE
25	DIALOGUE.
	149
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1	DR. TROUNSON: NOTHING MUCH MORE EXCEPT TO
2	SAY THAT THIS IS A LIVING DOCUMENT. AND WE WANT TO
3	MOVE FORWARD ON WHAT MIGHT BE SOME RELATIVELY BIG
4	INITIATIVES, AND WE'LL KEEP YOU INFORMED ABOUT THAT.
5	I DID SAY AT MY REVIEW THAT WE WERE GOING TO PRODUCE
6	A WHITE PAPER ON PUBLIC/PRIVATE FUNDING THAT MIGHT
7	BE OF INTEREST. SO WE'LL BE LOOKING TO KEEP THIS A
8	LIVING DOCUMENT. AND I'LL CERTAINLY ASK ELONA TO
9	PERIODICALLY UPDATE YOU AND PROVIDE YOU WITH AN
10	UPDATED FORM OF THIS STRATEGIC DOCUMENT.
11	AND FEEL FREE TO LOOK IT OVER AND LET US
12	KNOW IF YOU FEEL THAT THERE'S SOME OTHER THINGS THAT
13	WE COULD DO OR SOME THINGS THAT WE COULD DO
14	DIFFERENTLY. I THINK WE'RE LOOKING FOR WAYS OF
15	MAXIMIZING OUR INTEGRATION WITH BUSINESS FOR THE
16	INSTITUTE.
17	CHAIRMAN THOMAS: THANK YOU. ALAN, AS
18	LONG AS YOU'RE SPEAKING, WHY DON'T WE SEGUE NEATLY
19	INTO THE PRESIDENT'S REPORT.
20	DR. TROUNSON: THANK YOU VERY MUCH, CHAIR.
21	SO AS USUAL, I WANTED TO JUST POINT OUT A COUPLE OF
22	THE REALLY MAJOR DEVELOPMENTS THAT I THINK HAVE BEEN
23	HAPPENING IN THE AREA. AND THIS FIRST ONE IS ABOUT
24	SOMATIC COPY NUMBER IN SKIN CELLS. SO THIS RESEARCH
25	GROUP, MOSTLY FROM YALE UNIVERSITY, PUBLISHED IN
	150
	130

1	NATURE IN NOVEMBER, MADE 20 IPS CELL LINES FROM
2	SEVEN INDIVIDUALS. AND THEY WERE USING WHOLE GENOME
3	SEQUENCING AS A WAY OF LOOKING AT THE GENOME IN
4	THESE IPS CELLS AND IN THE PARENTAL FIBROBLASTS THAT
5	WENT UP TO MAKE THIS.
6	THEY HAD ON AVERAGE TWO COPY NUMBER
7	VARIANTS. THAT'S WHAT THEY CALL IF THERE'S A
8	VARIANT IN THE GENE NUMBERS IF THAT'S A VARIATION.
9	AND THESE ARE EITHER DELETIONS OR REPLICATIONS OF
10	DNA THAT WERE NOT APPARENT IN FIBROBLASTS. AND OVER
11	50 PERCENT OF THIS IS DUE TO LOW FREQUENCY SOMATIC
12	MOSAIC MUTATION IN THE FIBROBLASTS THEMSELVES.
13	NOW, THEY WENT ON TO ESTIMATE THAT AROUND
14	a third, 30 percent, of skin fibroblasts that we
15	HAVE HAVE THIS COPY NUMBER VARIATION, SUGGESTING A
16	VERY WIDESPREAD MOSAICISM IN BODY TISSUES, AND MUCH
17	LARGER THAN HAS BEEN APPRECIATED BEFORE. SO THIS IS
18	SKIN. WE DON'T KNOW WHAT IT IS IN BRAIN OR LIVER OR
19	OTHER TISSUES. SO THESE HAVE MAJOR IMPLICATIONS FOR
20	GENOME ANALYSIS, FOR EXAMPLE, BASED ON BLOOD
21	SAMPLING. THEY MAY NOT INDICATE AT ALL WHAT WE'RE
22	AT RISK OF BECAUSE THOSE COPY NUMBER VARIATIONS MAY
23	PREDISPOSE YOU TO SOMETHING THAT'S TOTALLY
24	UNEXPECTED FROM A BLOOD SAMPLING. WE DON'T REALLY
25	KNOW WHAT THE VARIATIONS ARE IN BRAIN AND OTHER
	151

1	TISSUES.
2	SO THESE COPY NUMBER VARIATIONS HAVE BEEN
3	IMPLICATED IN CANCER, BUT THESE STUDIES SUGGEST THAT
4	MANY NORMAL TISSUES HAVE THESE, NOT ONLY CANCER
5	TISSUES, BUT NORMAL TISSUES. SO, AGAIN, IT SORT OF
6	THROWS A QUESTION INTO WHETHER COPY NUMBER VARIATION
7	IS SUCH A CRITICAL ELEMENT BY ITSELF IN CANCER.
8	WHEN YOU'RE MAKING IPS CELLS DERIVED FROM
9	A SINGLE OR FEW CELLS, AS THEY ARE, IS THIS A
10	GENUINE READOUT OF THE INDIVIDUAL? IT'S A GOOD
11	QUESTION. WHAT ARE YOU READING OUT? YOU'RE READING
12	A BIT OF YOU, BUT NOT THE ENTIRETY OF YOU. AND IT
13	MAY NOT INCLUDE RELEVANT MUTATIONS.
14	SO IT'S A VERY INTERESTING ASPECT OF
15	SCIENCE THAT'S BROUGHT OUR ATTENTION. THIS WOULDN'T
16	HAVE HAPPENED UNLESS WE'D BEEN ABLE TO UTILIZE THESE
17	CELLS IN THIS WAY. AND IT DOES BRING TO ATTENTION
18	WHAT WE'RE REALLY TALKING ABOUT IN TERMS OF THE
19	GENOME HEALTH AND NORMALITY OF CELLS IN THE BODY.
20	A SECOND PAPER BY LEE, ET AL. FROM JOHN
21	COOKE'S LABORATORY IN STANFORD IS ALSO VERY
22	INTERESTING. IT WAS ACTIVATION OF INNATE IMMUNITY
23	IS REQUIRED FOR EFFICIENT NUCLEAR REPROGRAMMING. SO
24	IPS CELLS ARE NORMALLY MADE FOR RETROVIRAL
25	TRANSDUCTION OF THESE KEY TRANSCRIPTION FACTORS.

152

1	BUT YOU CAN MAKE IPS CELLS FROM PROTEINS, THESE CELL
2	PERMANENT PROTEINS THAT ARE THE TRANSCRIPTION
3	FACTORS, BUT THESE PROTEINS ARE VERY MUCH LESS
4	EFFICIENT THAN THE VIRAL TRANSDUCTION.
5	SO THE TEAM LOOKED AT THIS, AND THE
6	QUESTION WAS DOES THE RETROVIRAL APPROACH ACTUALLY
7	ACTIVATE THE SIGNALING PATHWAYS NECESSARY FOR
8	REPROGRAMMING? DOES THE ACTUAL VIRUS, IS THAT
9	IMPORTANT IN REPROGRAMMING THESE CELLS?
10	AND WHAT HAPPENS IS A VIRUS TRIGGERS THE
11	CELL'S INNATE IMMUNE RESPONSE VIA A TOLL-LIKE`
12	RECEPTOR, TOLL-LIKE RECEPTOR 3, WHICH ACTUALLY
13	UNWINDS THE CHROMATIN, EXPOSING SILENCED GENES TO
14	ACTIVATION. SO THAT'S HOW IT WORKS. AND THAT'S
15	WHAT HAPPENS WHEN YOU GET A VIRAL INFECTION. YOU
16	WANT THE BODY TO RESPOND. SO THEY RESPOND THROUGH
17	THIS INNATE IMMUNITY PATHWAY.
18	SO IF YOU BLOCK TOLL-LIKE RECEPTOR, YOU
19	BLOCK REPROGRAMMING. AND ADDING IT REALLY DOES
20	INCREASE THE EFFICIENCY OF REPROGRAMMING. SO
21	THERE'S A PLASTIC CELL STATE WHEN CHALLENGED BY A
22	PATHOGEN IN YOUR BODY. YOU BECOME MUCH MORE PLASTIC
23	BECAUSE YOU WANT TO RESPOND IN A WAY IN WHICH YOU
24	WANT TO DEFEAT THAT PATHOGEN OR VIRUS.
25	AND THAT'S TERMED TRANSFLAMMATION. SO A
	153

1	NEW WORD, "TRANSFLAMMATION." DON'T FORGET IT.
2	TRANSFLAMMATION. ALLOWING REPROGRAMMING, IN FACT,
3	HAS BETTER ACCESS TO GENES REQUIRED FOR PLURIPOTENCY
4	AND DIRECT TRANSDIFFERENTIATION. A VERY IMPORTANT
5	ELEMENT. AND THIS WAS WORK FROM STANFORD
6	UNIVERSITY, AND IT'S OPENED OUR EYES AGAIN, YET
7	AGAIN, ABOUT REPROGRAMMING.
8	THE NEXT ONE WAS REALLY ABOUT MAKING
9	YOU KNOW WE'VE BEEN HAVING TROUBLE MAKING
10	HEMATOPOIETIC STEM CELLS THAT ARE ABLE TO ENGRAFT IN
11	THE BODY. WE CAN MAKE THEM FROM EMBRYONIC STEM
12	CELLS, BUT THEY WON'T ENGRAFT. SO THIS TEAM HAVE
13	SHOWN THAT THEY CAN MAKE LONG-TERM ENGRAFTING
14	HEMATOPOIETIC STEM CELLS. IN THIS CASE THEY DID IT
15	FROM MOUSE EMBRYONIC STEM CELLS IN SERUM AND STROMAL
16	FREE CONDITION. AND THEY USE THE HOXB4
17	TRANSCRIPTION FACTOR TO OVEREXPRESS IN THESE
18	EMBRYONIC STEM CELLS. AND THEY'RE ABLE TO MAKE
19	HEMATOPOIETIC STEM CELLS AND PROGENITOR CELLS THAT
20	WERE ACTUALLY VERY SIMILAR TO WHAT'S IN THE MOUSE
21	BODY, VERY, VERY SIMILAR.
22	SO WHAT DOES THIS MEAN FOR THE HUMAN
23	BECAUSE THIS IS IN THE MOUSE? AND HOXB4 IS
24	SOMETHING THAT PEOPLE ARE CONCERNED ABOUT BECAUSE
25	HOXB4 CAN RELATE TO CANCER. SO WHAT THIS PAPER

154

1	POINTS OUT IS THE NEED TO WORK ON THE SMALL
2	MOLECULES THAT WILL MIMIC THE HOXB4 AND TO UTILIZE
3	THIS SYSTEM IN HUMAN STUDIES INVOLVING
4	PLURIPOTENTIAL STEM CELLS. I THINK IT'S JUST A NEAT
5	PIECE OF WORK.
6	ANOTHER PAPER FROM THE LITERATURE CAME OUT
7	IN NATURE COMMUNICATIONS, AND THIS IS ABOUT THE GENE
8	CALLED RB, WHICH IS A CELL CYCLE INHIBITOR OR A
9	TUMOR SUPPRESSOR. AND THAT'S PRESENT IN HUMAN
10	EMBRYONIC STEM CELLS, AND IT RESTRICTS THE CELL
11	CYCLE. SO IT INDUCES CELL CYCLE ARREST AND INDUCES
12	DIFFERENTIATION BY HAVING EFFECT ON MULTIPLE
13	TRANSCRIPTION FACTORS AND CELL DEATH.
14	AND IF YOU INACTIVATE THIS FAMILY OF GENES
15	IN EMBRYONIC STEM CELLS, YOU WILL GET A G2M ARREST.
16	SO THE CELL CYCLE WILL ARREST AND YOU WILL GET DEATH
17	THROUGH ACTIVATION OF THE P53 PATHWAY, WHICH IS AN
18	ONCOGENE PATHWAY. AND LOSS OF RB FAMILY FUNCTION
19	PROMOTES GENOMIC INSTABILITY. SO HENCE THIS
20	ACTIVITY OF THIS FAMILY OF GENES IS ESSENTIAL FOR
21	SELF-RENEWAL AND SURVIVAL OF EMBRYONIC STEM CELLS.
22	AND WE HAVE TO TAKE CARE OF THIS GENE WHEN WE'RE
23	WORKING WITH THESE CELLS.
24	NOW, FINALLY, I THOUGHT THIS WAS AN
25	INTERESTING PAPER FROM A CHINESE GROUP WHO USED
	155
	1

1	EMBRYONIC STEM CELLS TO VACCINATE AGAINST CANCER.
2	AND SO YOU WOULD THINK WHAT? AND WHEN I READ IT, I
3	THOUGHT WHAT? AND THESE MICE AND RATS HAVE BEEN
4	IMMUNIZED WITH INACTIVATED HUMAN EMBRYONIC STEM
5	CELLS. SO THEY STOPPED THEM FROM MULTIPLYING. YOU
6	CAN PREVENT THEM FROM MULTIPLYING. AND THEY GAVE
7	THEM TO RATS THAT WERE THEN CHALLENGED WITH THE
8	HUMAN OVARIAN CANCER CELLS.
9	THEY SHOWED THAT THESE VACCINATED MICE AND
10	RATS SHOWED CONSISTENT CELLULAR AND HUMORAL IMMUNE
11	RESPONSES AGAINST OVARIAN CANCERS WITH ANTITUMOR
12	IMMUNE PROTECTION, WHICH IS REALLY INTERESTING.
13	AND THE REASON WHY IS THAT HUMAN EMBRYONIC
14	STEM CELLS HAVE SEVERAL ONCOGENES AND TUMOR
15	SUPPRESSOR GENES THAT ARE SHARED IN COMMON WITH
16	OVARIAN CANCERS AND PROBABLY MAKES THEM A VERY
17	SUITABLE ANTIGEN VEHICLE FOR VACCINATION AGAINST
18	OVARIAN CANCERS. IT'S SOMETHING JUST OUT OF THE
19	BOX, AND SOMETHING, WHEN I READ IT, I THOUGHT WHAT,
20	BUT I THINK IT'S A VERY INTERESTING PIECE OF WORK.
21	AND IT MAY BE USED, MIGHT BE USED PERHAPS IN THE
22	FUTURE. I'M UNSURE ABOUT THAT, BUT I'M RELATING
23	SOMETHING WHICH SURPRISED ME. AND IT APPEARED IN
24	ONE OF THESE INTERNATIONAL JOURNALS OF MOLECULAR
25	MEDICINE.

1	MS. LANSING: ANYTHING FOLLOWING UP ON
2	THIS?
3	DR. TROUNSON: NOT YET BECAUSE IT'S JUST
4	PUBLISHED IN NOVEMBER, AND THEY HAD PUBLISHED A
5	COUPLE OF OTHER PAPERS, BUT MOSTLY THE FIELD IGNORED
6	IT, SHERRY, BECAUSE WHY WOULD YOU WOULD USE
7	EMBRYONIC STEM CELLS FOR VACCINATION? I THINK
8	RESPONDED IN THE SAME WAY I DID. HUMAN EMBRYONIC
9	STEM CELLS, THEY HAVE THEIR OWN PROPENSITY TO FORM
10	MULTICELLULAR TUMOR ITSELF. SO WHY WOULD YOU DO
11	THAT?
12	WELL, THEY INACTIVATED THOSE CELLS. AND
13	IT'S THE ANTIGENS THAT THEY'RE EXPRESSING THAT THE
14	IMMUNE SYSTEM REACTS TO, MAKES ACTIVATED T-CELLS AND
15	ANTIBODIES THAT THEN GOES AFTER THE CANCER. SO I
16	THINK IT'S A VERY INTERESTING APPROACH.
17	MS. LANSING: WHEN YOU HEAR SOMETHING LIKE
18	THIS AND YOU KNOW IN OVARIAN CANCER THAT THERE IS
19	NOTHING REALLY THAT CAN DETECT IT, AND IT'S REALLY
20	PRETTY MUCH, THERE ARE RARE EXCEPTIONS, IF YOU CATCH
21	IT IN TIME, YOU'RE FINE, BUT VERY RARELY IS IT EVER
22	CAUGHT IN TIME. AS THIS BODY WHAT CAN WE DO WHEN WE
23	READ SOMETHING LIKE THIS? I'M NOT SUGGESTING THAT
24	WE DO IT, BUT WHAT CAN WE DO TO DRAW IT TO A DRUG
25	COMPANY'S ATTENTION? WHAT CAN WE DO TO MOVE IT
	157

1	FORWARD IN A WAY? EVEN WITHIN THE CANCER COMMUNITY.
2	YOU HEAR SOMETHING LIKE THAT AND NO ONE IS PAYING
3	ATTENTION TO IT, AND IT WOULD BE A SIMPLE THING TO
4	SEE IF THERE'S ANY VALIDITY TO IT.
5	DR. TROUNSON: WE HAVE A NUMBER OF
6	DIFFERENT MECHANISMS THAT ALLOWS US TO WORK IN
7	ASSOCIATION WITH COUNTRIES LIKE CHINA. WE COULD DO
8	SOME COLLABORATIVE RESEARCH WITH THEM IF THEY COME
9	INTO THE GRANTS WORKING GROUP, APPLY TOGETHER WITH A
10	CALIFORNIA RESEARCHER, AND IT MIGHT BE INTERESTING
11	IF THEY DID. SO I'M GOING TO SEE I WANT TO TALK
12	MORE TO THE SCIENCE COMMUNITY AND SEE HOW THEY FEEL
13	HERE IN CALIFORNIA. BUT IF THERE WAS SOMEBODY, IT
14	COULD BE ENCOURAGING THAT THEY LINK UP WITH THIS
15	GROUP AND SEE IF THIS RESEARCH REALLY HAS SOMEWHERE
16	TO GO FOR PATIENTS.
17	MS. LANSING: WELL, COULD YOU KEEP ME
18	POSTED?
19	DR. TROUNSON: ABSOLUTELY.
20	DR. STEWARD: IF I COULD JUST AMPLIFY ON
21	THAT A LITTLE BIT. NINDS HAS AN INTERESTING PROGRAM
22	THAT WAS ESTABLISHED. I ACTUALLY THINK THAT ARLENE
23	STARTED IT A NUMBER OF YEARS AGO. AND THE PROGRAM
24	IS TO ACTUALLY HAVE A CONTRACT TO REPLICATE
25	INTERESTING FINDINGS BECAUSE, OF COURSE, THE FIRST
	158
	130

1	THING IS JUST TO SAY WHETHER IT CAN BE REPLICATED.
2	AND JUST TO THROW THAT OUT THERE AS A
3	POSSIBLE CONSIDERATION FOR CIRM, JUST AN INTERESTING
4	MECHANISM. AND SOME OF THESE THINGS ARE OUT THERE
5	AND INTERESTING, AND SOME OF THEM JUST GO AWAY
6	REALLY QUICKLY.
7	DR. TROUNSON: OS IS MAKING A VERY VALID
8	POINT. WHEN YOU SEE SOMETHING, LIKE THIS IS VERY
9	INTERESTING, IT'S REALLY IMPORTANT TO GET THE SECOND
10	OR THIRD STUDY FROM INDEPENDENT LABS. SO THEN YOU
11	CAN FEEL SOME CONFIDENCE IT'S A REALISTIC APPROACH,
12	AND IT MIGHT BE SOMETHING THAT'S WORTH FOLLOWING UP.
13	HE'S MAKING A VERY, VERY SALIENT POINT HERE.
14	WE HAVE A NUMBER OF NEW APPOINTMENTS.
15	CATHERINE PRIEST HAS JOINED US FROM GERON AS A PH.D.
16	SCIENCE OFFICER. GREAT TO HAVE HER ON BOARD.
17	NEIL LITTMAN, WHO'S BEEN APPOINTED AS THE
18	BUSINESS DEVELOPMENT OFFICER. NEIL WAS HERE. SO I
19	THINK THAT'S GREAT. HE'S FROM MOST RECENTLY BURRILL
20	& COMPANY. HE'S GOT A LOT OF ENERGY, AND HE'LL NEED
21	IT BECAUSE WE'VE GOT A LOT OF PEOPLE TO SATISFY OUT
22	THERE. AND CLEARLY THERE WAS A REQUIREMENT FOR US
23	TO HAVE A MENTORING PROCESS TO HELP BUSINESS ACCESS
24	US. AND SO NEIL HAS GOT THE JOB OF SORT OF LINKING
25	US TOGETHER AND CREATING OPPORTUNITIES. SO HE'S GOT
	159

1	THE KIND OF PERSONALITY AND THE SKILL SPACE TO DO
2	THAT. SO I'M VERY PLEASED NEIL IS WITH US. IT'S A
3	GREAT ADDITION, AND CERTAINLY GOING TO HELP ELONA
4	AND MYSELF VERY MUCH BECAUSE WE SPEND A LOT OF TIME
5	IN THIS INTERFACE.
6	PAUL STEIN, I THINK, IS HERE IS OUR NEW
7	DEPUTY GENERAL COUNSEL. PAUL HAS TAKEN OVER IAN'S
8	POSITION BECAUSE HE MOVED TO TAKE OVER NANCY'S
9	POSITION. SO EVERYBODY IS TAKING OVER SOMEDAY
10	SOMEONE WILL TAKE OVER MY POSITION. THIS IS A
11	PROCESS WHERE WE'VE GOT ANOTHER VERY GOOD PERSON ON
12	BOARD. HE'S MOST RECENTLY AT THE CALIFORNIA
13	ATTORNEY GENERAL'S OFFICE, AND ALREADY HE'S MAKING A
14	GREAT IMPACT FOR US.
15	ANOTHER PERSON, MARIA MILLAN, WHO'S AN
16	M.D. MEDICAL OFFICER, MOST RECENTLY AT STEM CELLS,
17	INC., AND SHE'S JUST JOINED US. AND IT'S TERRIFIC
18	TO HAVE ANOTHER MEDICAL GRADUATE TO JOIN THE TWO
19	MEDICAL GRADUATES. I THINK WE'VE GOT JUST TWO
20	MEDICAL GRADUATES, ELLEN AND BETTINA. AND THAT WILL
21	BE GREAT BECAUSE YOU NEED THESE PEOPLE WHEN WE'RE IN
22	THIS TRANSLATIONAL SPACE.
23	I'M ALSO ENCOURAGING US TO FINISH OFF THE
24	MEDICAL TEAM BY NEGOTIATING WITH ONE OTHER PERSON
25	WHO HAS A MEDICAL DEGREE. AND IF WE'RE ABLE TO GET

1	THAT PERSON ON BOARD, WE WOULD HAVE A COMPLETE
2	MEDICAL TEAM, AND THAT WOULD BE TERRIFIC. SO WE'RE
3	IN THAT PROCESS AT THE MOMENT.
4	OUR RFA PROGRAM, STRATEGIC PARTNERSHIPS
5	POSTED NOVEMBER, WEBINAR IN DECEMBER. SO THIS IS
6	THE SECOND ONE OF THOSE. SO THIS IS FAST
7	APPROACHING. AND WE UNDERSTAND THAT THERE IS QUITE
8	A LOT OF INTEREST OUT THERE. SO WE'LL BE INTERESTED
9	TO SEE WHICH COMPANIES COME INTO THAT.
10	THE IPS CELL INITIATIVE, WE HAD A GRANTS
11	WORKING GROUP REVIEW, AND THAT WILL WHEN DOES
12	THAT COME FORWARD TO THE BOARD? MARCH. SO WE'VE
13	HAD THAT REVIEW. IT WAS A VERY INTERESTING
14	DIFFERENT REVIEW. JEFF WAS THERE, OTHER MEMBERS OF
15	THE BOARD WERE THERE. I THINK IT WAS REALLY VERY
16	STIMULATING. IT WAS RATHER DIFFERENT TO THE ONES
17	THAT WE HAD HAD BEFORE.
18	MR. SHEEHY: I THINK YOU SHOULD REALLY
19	GIVE A SHOUT-OUT TO YOUR STAFF ON THIS ONE, ALAN.
20	JUST A TREMENDOUS JOB. THERE WERE THREE MOVING
21	PARTS, AND I THINK ALL OF US HAD A LOT OF
22	TREPIDATION ON HOW THIS WOULD ALL WORK. KUDOS TO
23	YOU AND TO YOUR STAFF. THEY PERFORMED BRILLIANTLY.
24	DR. TROUNSON: I THINK IT WAS GREAT.
25	SO YOU KNOW THE BASIC BIOLOGY HAS BEEN
	161
	101

1	HERE AND THE NEW FACULTY POSITION, THAT'S DONE.
2	DISEASE TEAM III WILL BE POSTED IN JANUARY. THE RFA
3	WILL BE POSTED IN JANUARY. AND THE GENOMICS
4	INITIATIVE, THE GRANTS WORKING GROUP IS GOING TO
5	HAPPEN IN FEBRUARY. SO THEY SHANGHAIED ME OUT OF
6	THE BEACH IN FEBRUARY. I'M BACK FOR TWO DAYS WHICH
7	I NEED TO DO FOR THE GENOMICS INITIATIVE. IT'S
8	SOMETHING THAT I PUSHED TO GET IT, AND SO GIL SAID
9	YOU HAVE NO OPTION. YOU'VE GOT TO COME.
10	EARLY TRANSLATIONAL IV, THE PRE-APP REVIEW
11	IS CURRENTLY UNDER WAY.
12	THE WORKSHOPS AND MEETINGS WE'VE HELD
13	RECENTLY, THE STEM CELL MEETING ON THE MESA, ALPHA
14	CLINICS WORKSHOP, A MEETING WITH THE UNITED KINGDOM
15	HOUSE OF LORDS, SCIENCE AND TECHNOLOGY SELECT
16	COMMITTEE, THAT HAPPENED IN DECEMBER.
17	UPCOMING MEETINGS, THE CIRM GRANTEE
18	MEETING, WHICH IS HAPPENING IN MARCH. PARKINSON'S
19	DISEASE WORKSHOP, THAT'S HAPPENING IN MARCH AS WELL.
20	SO WE'RE GOING TO BE BUSY, BUSY, BUSY IN MARCH.
21	SO JUST A QUICK SUMMARY OF A COUPLE OF
22	THESE MEETINGS. THE MEETING ON THE MESA, 10 TO 29
23	PERCENT INCREASE IN INVESTOR AND PARTNERING FORUM
24	FROM LAST YEAR. AND THE PARTNERING MEETING
25	SCHEDULES AS SHOWN HERE. IT WAS A VERY BUSY AND

1	ACTIVE MEETING. I THINK MEMBERS OF THE BOARD WHO
2	WERE THERE, STEVE JUELSGAARD WAS THERE AND OTHERS.
3	I THINK IT WAS A PRETTY GOOD SHOW REALLY AND REALLY
4	HAD A CONSIDERABLE COMPONENT OF OUR TEAMS PRESENT
5	THERE. I THINK IT'S A GREAT INITIATIVE. AND THANKS
6	TO ELONA FOR GETTING THAT UP AND GETTING US REALLY
7	INVOLVED.
8	SO THE ATTENDEES ARE SHOWN IN THIS, SO YOU
9	WILL SEE THIS IN YOUR FOLDERS, SO I WON'T GO IN ANY
10	DETAILS ON IT, BUT YOU CAN HAVE A LOOK AT THE KIND
11	OF PARTNERING FOCUS THAT THEY HAD, THE ATTENDEES.
12	THE ALPHA CLINIC WORKSHOP, I WANT TO THANK
13	NATALIE DEWITT, WHO PUT ON A GREAT WORKSHOP AT
14	STANFORD FOR TWO DAYS. JEFF WAS THERE. HE'S
15	EVERYWHERE, BUT HE DEFINITELY WAS THERE. I THOUGHT
16	IT WAS A GREAT WORKSHOP. DIFFERENT AGAIN, RIGHT?
17	MR. SHEEHY: IT HAS THE POSSIBILITY TO
18	REALLY BE AN HISTORIC EFFORT. AND, AGAIN, STAFF,
19	YOUR LEADERSHIP, ALAN, WAS TREMENDOUS. IT WAS
20	BRILLIANT.
21	DR. TROUNSON: IT WASN'T MINE. IT WAS
22	NATALIE. I JUST PUT A BIT OF ENZYME IN THE SYSTEM,
23	BUT IT WAS A GREAT SHOW. SHE DID A SPECTACULAR JOB.
24	SHE'S NOW WRITING UP THE WHITE PAPER. I THINK YOU
25	WILL GET IT HOPEFULLY IN JANUARY. LOOK AT HER

1	SMILING. SO WE'RE PUSHING STAFF HARD TO GET THAT.
2	SO A WHITE PAPER WILL COME TO YOU AS A RESULT OF
3	THAT WORKSHOP. AND THEN WE HOPE TO COME TO YOU IN
4	MARCH AND TALK ABOUT THE ALPHA CLINICS WITH YOU TO
5	SEE WHETHER YOU'D BE SUPPORTIVE OF THAT PROGRAM.
6	HOUSE OF LORDS, SELECT COMMITTEE ON
7	SCIENCE AND TECHNOLOGY WAS A GREAT MEETING AGAIN.
8	IT WAS PUT ON BY IAN SWEEDLER. FANTASTIC. AND
9	CANDACE BAGLEY DID ALL THE ORGANIZING FOR THAT. AND
10	WE HAD, I DON'T KNOW HOW MANY PEOPLE, 30
11	PARTICIPANTS FROM CALIFORNIA CAME AT THEIR OWN COST
12	TO MEET WITH THE HOUSE OF LORDS AT DIFFERENT TIMES.
13	THEY WERE ORGANIZED BY IAN AND CANDACE.
14	AND THE HOUSE OF LORDS WENT AWAY SAYING
15	THIS IS FANTASTIC. CIRM IS FANTASTIC. WE'VE BEEN
16	VERY INFORMED ABOUT WHAT'S HAPPENING. AND THEY'RE
17	GOING TO WRITE A REPORT TO THEIR PARLIAMENT. AND I
18	THINK THERE'S ALSO SOME VERY NICE QUOTES. "WE
19	LOOKED AROUND THE WORLD TO SEE WHERE THINGS WERE
20	BEING DONE WELL, AND WE THOUGHT THAT CIRM IS THE
21	PLACE TO GO." WELL, THEY DID AT ONE STATE SAY THEY
22	WANTED TO CLONE ME. I WANTED TO CLONE IAN AND
23	CANDACE RATHER THAN ME. I THINK IT WAS A VERY GOOD
24	SESSION. WE WENT BROADLY ACROSS ALL OF THE THINGS
25	THAT WE DO.

1	THE GRANTS MANAGEMENT SYSTEM, THERE WAS A
2	RECENT RELEASE FEATURES ON THAT. A PATENT
3	ASSISTANCE FUND, SCIENTIFIC OUTCOMES CODING,
4	SCHEDULE NOTIFICATION. ALL OF THESE THINGS MEAN A
5	LOT TO US. IN THE NEXT PIPELINE WILL BE NOTICE OF
6	GRANT AWARDS, PAYMENTS, AND PAY MEMOS, AND REVIEWER
7	DATABASE. THIS IS AN ELECTRONIC SYSTEM THAT'S
8	REALLY HELPING US DO THINGS.
9	IF I CAN SEGUE NOW TO CHILA, IF I MAY, IF
10	THAT'S OKAY, SHE'LL QUICKLY PRESENT THE FINANCES TO
11	YOU. BUT BEFORE I GO, THIS IS CLEARLY THE LAST
12	BOARD MEETING THIS YEAR. AND I WANTED TO THANK YOU,
13	BUT I WANTED ALSO TO THANK ALL THE MEMBERS OF
14	MANAGEMENT FOR A FANTASTIC YEAR. I THINK IT'S BEEN
15	A REALLY, REALLY GREAT YEAR. AND EVERYBODY HAS
16	WORKED SO INCREDIBLY HARD, I CAN'T BELIEVE IT.
17	I'LL BE PASSING THE BATON OVER TO ELLEN
18	FEIGAL, WHO WILL BE ACTING PRESIDENT FROM THE 20TH
19	OF DECEMBER. AND SHE WILL BE THE PERSON THAT CAN
20	TAKE ALL THE ACCOLADES AND ALL THE CRITICISMS. I
21	HAVE ABSOLUTE CONFIDENCE IN ELLEN, AND I KNOW SHE'LL
22	WORK VERY MUCH WITH YOU AND THE BOARD, CHAIR, AND I
23	THINK THERE WILL BE NO HICCUP AT ALL IN THE
24	ORGANIZATION. BUT FEEL FREE, AS YOU DO, TO TALK TO
25	ME. PLEASE TALK TO ELLEN WHILE I'M NOT HERE. I

1	WILL BE AT THE END OF A TELEPHONE, BUT I'LL PROBABLY
2	HAVE A BEER AND I'LL PROBABLY BE SITTING ON THE
3	BEACH. I WON'T MAKE MUCH OF AN APOLOGY FOR DOING
4	THAT BECAUSE IT'S TIME I NEED TO PUT INTO MY FAMILY
5	TO GET THEM BACK ON.
6	WITH THAT, CHILA, CAN YOU DO THE FINANCES.
7	MS. SILVA-MARTIN: THANK YOU, DR.
8	TROUNSON. MR. CHAIRMAN, MEMBERS OF THE BOARD, I
9	KNOW THAT WE'RE PRESSED FOR TIME, SO I WILL PROVIDE
10	YOU WITH A BRIEF REPORT ON CIRM'S FINANCES.
11	FIRST OF ALL, OUR OPERATIONAL EXPENDITURES
12	FOR THE FIRST FIVE MONTHS OF THE FISCAL YEAR ARE ON
13	TRACK. WE HAVE HAD NO OVERAGES IN ANY OF OUR
14	CATEGORIES. WE HAVE EXPERIENCED A LITTLE BIT OF
15	SAVINGS, AND THAT'S IN OUR SALARIES AND BENEFITS
16	CATEGORY. AND THAT'S BECAUSE, AS YOU KNOW, WE HAD
17	SEVERAL VACANCIES AT THE BEGINNING OF THE FISCAL
18	YEAR. BUT AS BOTH DR. TROUNSON AND ELONA HAVE
19	REPORTED, WE'RE HAPPY TO REPORT THAT WE FILLED MOST
20	OF THOSE VACANCIES. SO WE DON'T ANTICIPATE THAT
21	TYPE OF SAVINGS FOR THE REST OF THE FISCAL YEAR.
22	ALTHOUGH THE SLIDE SAYS IN MARCH, I'M
23	ACTUALLY WORKING WITH THE DEPARTMENT OF GENERAL
24	SERVICES, SO I'M HOPING TO BE ABLE TO DO THIS IN
25	JANUARY, IS TO PROVIDE YOU WITH OPERATING
	166

1	EXPENDITURES FOR THE FIRST HALF OF THE FISCAL YEAR,
2	AND I WILL PROVIDE THAT REPORT IN JANUARY.
3	OUR GRANT DISBURSEMENTS FOR THROUGH
4	NOVEMBER HAVE BEEN \$65.5 MILLION AS COMPARED TO THE
5	PREVIOUS PERIOD OF 11/12 WHERE WE DISTRIBUTED \$88.8
6	MILLION. WE HAVE A VERY HEALTHY CASH BALANCE. AS
7	OF NOVEMBER 30, 2012, WE HAVE \$61.5 MILLION. THIS
8	REPRESENTS A DECREASE OF \$14.1 MILLION, WHICH IS
9	WHAT I REPORTED BACK IN SEPTEMBER. AND THE CASH
10	BALANCE IS MADE UP MOSTLY OF COMMERCIAL PAPER AND
11	NOW A LITTLE BIT OF BOND PROCEEDS.
12	AND I HAVE TO TELL YOU THAT LYNN HARWELL
13	FROM THE OFFICE OF THE CHAIR WORKS ON A DAILY BASIS
14	WITH THE STATE TREASURER'S OFFICE AND DEPARTMENT OF
15	FINANCE TO ENSURE THAT WE HAVE SUFFICIENT FUNDS.
16	AND IN NOVEMBER, AS PART OF HER EFFORT, WE WERE ABLE
17	TO RECEIVE \$15 MILLION IN COMMERCIAL PAPER.
18	I WANTED TO REPORT TO YOU BRIEFLY ON OUR
19	ADMINISTRATIVE EXPENDITURES. AND THIS NEXT PIE
20	CHART CAPTURES OUR EXPENDITURES AGAINST THE
21	6-PERCENT CAP. AS THE BLUE SLICE OF THE CHART
22	REPRESENTS, AS OF JUNE 30, 2012, WE HAVE SPENT \$61.4
23	MILLION OF OUR \$180 MILLION ALLOCATION FOR GRANT AND
24	GENERAL ADMINISTRATION. THAT REPRESENTS ABOUT 34
25	PERCENT OF THE BUDGET. THE ORANGE SLICE REPRESENTS
	167

1	WHAT WE HAVE BUDGETED TO SPEND FOR GENERAL AND ADMIN
2	IN THE CURRENT FISCAL YEAR, AND THAT REPRESENTS
3	\$14.9 MILLION OR 8 PERCENT.
4	AT THIS TIME IN THE FISCAL YEAR, I DON'T
5	ANTICIPATE MUCH OF A SAVINGS, BUT WE MAY HAVE ABOUT
6	5-PERCENT SAVINGS IN THIS FISCAL YEAR. AND SO THEN
7	WHAT THAT LEAVES IS WHAT'S REPRESENTED IN THE GREEN
8	SLICE OF THE PIE, AND THAT'S A LITTLE BIT UNDER \$104
9	MILLION AVAILABLE FROM THE FISCAL YEAR 2013-14, AND
10	BEYOND.
11	IN THE NEXT CHART, THE EXPENDITURE CAP IS
12	JUST PROVIDED IN MORE DETAIL. SO THE CUMULATIVE
13	EXPENDITURES ARE REPRESENTED BY THE TWO LINES, AND
14	THEY CORRESPOND TO THE NUMBERS ON THE LEFT-HAND
15	SIDE. SO FOR GENERAL ADMINISTRATION THROUGH JUNE
16	2012, WE HAVE SPENT \$36.2 MILLION. SIMILARLY, FOR
17	OUR GRANT EXPENDITURES THROUGH JUNE 30, 2012, WE
18	SPENT \$25.3 MILLION. AND THEN THE BAR CHARTS
19	REPRESENT THE YEARLY EXPENDITURES, AND THEY
20	CORRESPOND TO THE NUMBERS ON THE RIGHT-HAND SIDE.
21	AND SO, FOR EXAMPLE, IN THE CURRENT FISCAL YEAR, WE
22	ARE BUDGETED TO SPEND \$3.5 MILLION IN GRANT
23	ADMINISTRATION AND \$6.4 MILLION IN GENERAL
24	ADMINISTRATION.
25	AND THEN, ALTHOUGH WE'RE ONLY SIX MONTHS
	168

1	INTO THE CURRENT FISCAL YEAR, IT'S REALLY TIME TO
2	BEGIN DEVELOPMENT OF THE 2013-14 FISCAL YEAR BUDGET.
3	SO THIS NEXT SLIDE REPRESENTS OUR TIMELINE FOR THAT.
4	WHAT WE PLAN TO DO, THE FINANCE STAFF WILL
5	DISTRIBUTE THE CURRENT YEAR DATA AS WELL AS BUDGET
6	TEMPLATES TO THE COST CENTER MANAGERS IN JANUARY.
7	THEY'LL BE PROVIDED ABOUT THREE TO FOUR WEEKS TO
8	TURN THOSE DOCUMENTS AROUND. AND THEN IN FEBRUARY
9	WE'LL BEGIN AN INTERNAL REVIEW OF THOSE BUDGET
10	DOCUMENTS AND PUT TOGETHER A PRELIMINARY BUDGET FOR
11	PRESENTATION TO THE FINANCE SUBCOMMITTEE IN MARCH,
12	AS WELL AS PROVIDING YOU WITH A HIGH LEVEL OVERVIEW
13	OF THAT BUDGET AT THE MARCH MEETING. WE'LL FINALIZE
14	THE BUDGETS AND THEN BRING THEM BACK TO YOU FOR
15	FINAL REVIEW AND APPROVAL IN MAY.
16	AND I'M NOT GOING TO GO OVER THE NEXT
17	SLIDE BECAUSE ACTUALLY DR. OLSON ALREADY COVERED IT
18	IN QUITE A BIT OF DETAIL. AND THAT REALLY CONCLUDES
19	MY PRESENTATION. ARE THERE ANY QUESTIONS?
20	CHAIRMAN THOMAS: ANY QUESTIONS FOR CHILA?
21	MS. FEIT: I JUST WANT TO MAKE A COMMENT.
22	ON BEHALF OF MICHAEL GOLDBERG AND I, WE WANT TO
23	THANK THE STAFF FOR FOLLOWING UP ON ALL THE
24	REQUESTS. THE BUDGETED DEVELOPMENT TIMELINE WAS
25	SOMETHING THAT WE HAD REQUESTED TO ENSURE THAT THE
	169
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1	BOARD, THE ICOC BOARD, HAS TIME TO COMMENT ON THE
2	BUDGET BEFORE IT'S FINALIZED. AGAIN, I WANT TO
3	THANK STAFF. THEY DO KEEP US INFORMED EVERY STEP OF
4	THE WAY OF HOW OUR EXPENSES AND ALLOCATIONS ARE
5	PROGRESSING. SO THANK YOU TO STAFF FOR DOING A
6	GREAT JOB.
7	CHAIRMAN THOMAS: THANK YOU, CHILA, FOR A
8	VERY THOROUGH REPORT. WE APPRECIATE IT VERY MUCH.
9	LET'S MOVE TO COMMUNICATIONS UPDATE. KEVIN.
10	MR. MCCORMACK: CHAIRMAN THOMAS, MEMBERS
11	OF THE BOARD, LET ME WISH YOU HAPPY HOLIDAYS. AND I
12	WANTED TO THANK ALAN FOR GIVING US A NEW WORD TO
13	WORK WITH IN OUR NEXT ROUND OF COMMUNICATIONS,
14	TRANSFLAMMATION. I LIKE THAT.
15	I THOUGHT I'D BEGIN TODAY BY LOOKING INTO
16	THE ISSUE THAT I THINK HAS DOMINATED MOST OF OUR
17	ATTENTION FOR THE PAST WEEK, AND THAT'S OBVIOUSLY
18	THE IOM REPORT.
19	I HAVE TO SAY WHEN I FIRST SAW THE REPORT
20	AND WAS READING THROUGH THE RECOMMENDATIONS AND THE
21	FINDINGS, I HAD RATHER A SINKING FEELING BECAUSE IT
22	WAS OBVIOUSLY QUITE A CRITICAL REPORT. BUT I HAVE
23	TO SAY THAT WHEN I LOOKED AT THE MEDIA COVERAGE, I
24	WAS PLEASANTLY SURPRISED. I FOUND IT, FOR THE MOST
25	PART, QUITE BALANCED AND GENERALLY NEUTRAL. BY THAT
	170

I MEAN IT DIDN'T DEAL WITH ANY OF THE CRITICISMS OR
RECOMMENDATIONS, BUT THAT IT DIDN'T GO TO SOME OF
OUR MORE VOCAL CRITICS WHO WOULD ORDINARILY HAVE
TAKEN THIS OPPORTUNITY TO PILE ON AND REALLY TELL
EVERYONE HOW BAD WE WERE.
THEY BASICALLY DEALT WITH SOME OF THE
PRAISE THAT THE IOM REPORT GAVE US AND THEN WENT
THROUGH THE RECOMMENDATIONS IN JUST A FAIRLY BASIC
AND FACTUAL MANNER. SO I THOUGHT IT WAS QUITE GOOD
FROM THAT PERSPECTIVE.
SOME OF THEM EVEN COVERED THE LIMITS OF
THE ICOC AND THEIR ABILITY TO CHANGE THINGS, AND
THAT SOME OF THE MORE SERIOUS RECOMMENDATIONS WOULD
REQUIRE EITHER A VOTE OR INITIATIVE OR A VOTE OF THE
LEGISLATURE. SO, AGAIN, I THOUGHT THAT WAS QUITE
GOOD.
TALKING TO FRIENDS OF MINE OUTSIDE THE
BUSINESS, AS IT WERE, AND THE GOOD THING ABOUT
HAVING FRIENDS LIKE THIS IS THAT THEY'RE NOT SHY
ABOUT TELLING YOU WHAT THEY THINK, IS FOR THE MOST
PART THEY THOUGHT THE REPORTS WERE EITHER NEUTRAL OR
THEY DIDN'T CARE. THEY JUST THOUGHT GOVERNMENT
RECOMMENDATIONS OR GOVERNMENT CHANGES. WHEN THEY
SUPPORTED STEM CELLS AND STEM CELL RESEARCH, THEY
DID SO FOR REASONS OF LOOKING FOR THERAPIES AND
171

1	CURES. AND NO ONE TO THIS DAY HAS EVER COME UP TO
2	ME AND SAY, "OH, YOU WORK FOR THE STEM CELL AGENCY.
3	HOW'S THAT GRANTS WORKING GROUP PATIENT ADVOCATE
4	ELEMENT WORKING?"
5	SO IT WAS VERY MUCH IF YOU WERE HERE, I
6	THINK WE TAKE THEM VERY SERIOUSLY OBVIOUSLY, AND
7	THERE ARE A LOT OF THINGS THAT WE HAVE TO DO TO
8	CONSIDER THEM. BUT FOR THE GENERAL PUBLIC, IT
9	DIDN'T SEEM TO ME THAT THERE WAS MUCH OF KIND OF A
10	REACTION TO IT. LOOKING THROUGH SOME OF THE
11	COMMENTS THAT WERE POSTED ON NEWSPAPER WEB SITES
12	THAT PRINTED ARTICLES, AGAIN, IT WAS VERY GENERAL
13	AND NOT TERRIBLY CRITICAL OF US. SO I THINK IN THAT
14	SENSE IT WAS QUITE GOOD.
15	IN FACT, ONE OF THE REPORTS THAT I SAW WAS
16	ARIN ALLDAY IN THE SAN FRANCISCO CHRONICLE, AND I
17	THINK THIS WAS KIND OF TYPICAL OF MANY OF THE
18	REPORTS. AND IT SAID, "CALIFORNIA STEM CELL FUNDING
19	AGENCY HAS HAD PROPOUND IMPACT ON SCIENTIFIC
20	ADVANCEMENT SINCE IT WAS CREATED IN 2004, BUT IT'S
21	IN NEED OF SIGNIFICANT RECONSTRUCTING TO ADDRESS
22	CONCERNS ABOUT THE POTENTIAL FOR CONFLICT OF
23	INTEREST AND MISMANAGEMENT, ACCORDING TO AN
24	INDEPENDENT REVIEW RELEASED THURSDAY." SO I THOUGHT
25	THAT WAS GOOD.
	172
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1	AND THERE WERE A COUPLE OF OTHER
2	EDITORIALS THAT FOLLOWED UP ON THAT, REPEATING VERY
3	MUCH THAT SAME KIND OF FEELING. SO I THINK IT'S
4	GOING TO SUGGEST THAT THE MEDIA ARE GOING TO BE
5	FOLLOWING UP ON THIS, AND THEY'LL HAVE INTEREST IN
6	SEEING WE ACT AND HOW WE REACT TO THE
7	RECOMMENDATIONS IN THE COMING MONTHS. SO THAT'S
8	CERTAINLY SOMETHING WE NEED TO TAKE INTO
9	CONSIDERATION.
10	MOVING TO SOMETHING ALTOGETHER MORE
11	DELIGHTFUL, THIS IS A YOUNG LADY THAT MANY OF US MET
12	AT THE ALPHA STEM CELL CLINIC WORKSHOP AT STANFORD.
13	HER NAME IS KATIE SHARIFY. FOR MOST OF US, UNTIL WE
14	MET HER IN PERSON, WE KNEW HER AS PATIENT NO. 4 IN
15	THE GERON STEM CELL SPINAL INJURY CLINICAL TRIAL.
16	FOR A LOT OF THE TALKS AT THE ALPHA STEM CELL CLINIC
17	WORKSHOP, VERY TECHNICAL. IT WAS ABOUT HOW DO YOU
18	PUT ON CLINICAL TRIALS, A LOT OF THE ISSUES THAT
19	NEEDED TO BE RESOLVED.
20	KATIE CAME AT IT FROM A VERY DIFFERENT
21	PERSPECTIVE, FROM THE PATIENT PERSPECTIVE, FROM
22	SOMEONE WHO WAS BADLY INJURED IN A CAR ACCIDENT AS A
23	TEENAGER, WOKE UP IN THE INTENSIVE CARE UNIT WITH
24	HER PARENTS SAYING WE'VE GOT SOMETHING THAT'S GOING
25	TO FIX YOU, IT'S GOING TO CURE YOU. AND THEN

173

1	LEARNING THAT HER PARENTS, WHO HAD A VERY POOR GRASP
2	OF ENGLISH, HAD MISUNDERSTOOD WHAT THEY'D BEEN TOLD.
3	AND SO THE DOCTORS HAD TO EXPLAIN TO HER EXACTLY
4	WHAT WAS INVOLVED IN THE TRIAL.
5	KATIE TALKED ABOUT THE PRESSURE FOR
6	SOMEONE WHO HAS BEEN THROUGH SUCH A HORRENDOUS
7	ACCIDENT TO HAVE TO MAKE A DECISION ABOUT WHETHER TO
8	GET INVOLVED IN A CLINICAL TRIAL IN A VERY SHORT
9	SPACE OF TIME. ALL THE EMOTIONS RUNNING THROUGH
10	HER, AND SOMEONE IS SAYING DO YOU WANT TO DO THIS?
11	YOU REALLY ONLY HAVE ABOUT TWO DAYS TO DECIDE.
12	AND SO I WANTED TO PLAY YOU A SHORT
13	EXCERPT FROM A VIDEO WE SHOT OF THAT.
14	(THE VIDEO WAS THEN SHOWN, NOT
15	REPORTED OR HEREIN TRANSCRIBED.)
16	MR. MCCORMACK: I THINK FOR ME ONE OF THE
17	INTERESTING AND MOVING PARTS OF THAT WAS WHERE KATIE
18	TALKED ABOUT SHE REALIZED THE THERAPY WAS UNLIKELY
19	TO GIVE HER THE ABILITY TO WALK AGAIN. SHE SAID IT
20	MIGHT AT THE MOST GIVE HER A SENSE OF BEING ABLE TO
21	MOVE HER BIG TOE OR SOMETHING EQUALLY OF THAT SCOPE.
22	BUT SHE SAID WHAT MATTERED TO HER ULTIMATELY WAS
23	THAT SHE DIDN'T CARE ABOUT MOVING HER BIG TOE. SHE
24	WANTED TO MOVE THE SCIENCE FORWARD. AND IT WAS SUCH
25	A POWER SPEECH. I THINK IT HAS A WONDERFUL IMPACT
	174

1	ON EVERYONE WHO WAS THERE. A LOT OF THE RESEARCHERS
2	AFTERWARDS TALKED ABOUT HOW IT REALLY HELPED INFORM
3	THEM ABOUT AN ASPECT OF THE CLINICAL TRIALS THAT
4	THEY DON'T ALWAYS THINK ABOUT, ABOUT AN ELEMENT THAT
5	REALLY SHOULD BE FUNDAMENTAL AND CENTRAL TO
6	EVERYTHING WE DO, WHICH IS THE PATIENT EXPERIENCE
7	AND HOW WE CAN HELP THEM AND HOW WE CAN BEST INFORM
8	THEM ABOUT WHAT THEY'RE GOING THROUGH AND WHAT IT
9	MAY DO FOR THEM.
10	SO FOR THAT I THOUGHT IT WAS A WONDERFUL
11	THING. IT WAS ACTUALLY A REALLY GOOD INTERVIEW BY
12	MY COLLEAGUE AMY ADAMS. IT WAS A LUNCHTIME SESSION,
13	AND AMY DID A GREAT JOB IN KEEPING IT REALLY
14	INFORMATIVE AND THOUGHTFUL, BUT ALSO KATIE IS
15	WONDERFULLY ARTICULATE AND KEPT IT REALLY FUNNY AS
16	WELL.
17	AND TODD SHOT THIS VIDEO AND EDITED IT,
18	AND IT'S ABOUT A 28-MINUTE VIDEO, BUT I THINK IT'S A
19	REALLY GOOD ONE. IF YOU WANT PEOPLE TO UNDERSTAND
20	WHAT IT'S LIKE FOR A PATIENT TO GO THROUGH SOMETHING
21	LIKE THIS, THROUGH AN ACTUAL CLINICAL TRIAL, IT'S A
22	REALLY GOOD VIDEO TO DIRECT THEM TOWARDS. IT'S 28
23	MINUTES LONG, AS I SAID; BUT IN THE FEW WEEKS THAT
24	IT'S BEEN UP, IT'S ALREADY HAD MORE THAN 2,000 HITS.
25	SO CLEARLY IT'S SOMETHING THAT PEOPLE ARE INTERESTED

1	IN, AND PEOPLE FIND IT VERY ENGAGING ONCE THEY START
2	TO WATCH IT.
3	FOLLOWING UP ON THAT, DON GIBBONS AND I
4	WENT TO THE WORLD STEM CELL SUMMIT IN BEAUTIFUL
5	DOWNTOWN WEST PALM BEACH, FLORIDA, LAST WEEK. WE
6	DIDN'T ACTUALLY GET TO SEE WEST PALM BEACH. WE SAW
7	A NUMBER OF CONFERENCE ROOMS, BUT THEY WERE VERY
8	LOVELY. I THINK, AGAIN, FOR ME THERE WERE A NUMBER
9	OF VERY INTERESTING TALKS, BUT I THINK THE BEST PART
10	IS THE OPPORTUNITY TO MEET PATIENT ADVOCATES AND
11	PATIENT ADVOCATE GROUPS FROM AROUND THE COUNTRY
12	BECAUSE IT GIVES YOU A DIFFERENT SENSE, ANOTHER
13	PERSPECTIVE ON HOW FORTUNATE WE ARE HERE IN
14	CALIFORNIA.
15	I THINK THE MESSAGE THAT WE BOTH CAME AWAY
16	WITH, WE MET WITH A NUMBER OF DIFFERENT GROUPS BOTH
17	AT THE DINNER AND AT THE EVENT AND THEN PRIVATE
18	MEETINGS, IS THAT CALIFORNIA IS REALLY THE ENVY OF
19	SO MANY OTHER STATES, AND THAT THE STEM CELL AGENCY
20	IS WIDELY RESPECTED. WE'RE HELD UP AS THE GOLD
21	STANDARD. PEOPLE LOOK TO US FOR LEADERSHIP. PEOPLE
22	LOOK TO US TO KIND OF SET THE PACE.
23	MANY STATES AROUND THE COUNTRY, AND WE
24	TALKED TO PEOPLE FROM NEBRASKA, TEXAS, MISSOURI,
25	THEY'RE FACING CONSTANT CHALLENGES TO THE WORK THAT
	176
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1	THEY DO, EVEN POLITICAL CHALLENGES AND NONPOLITICAL
2	CHALLENGES. IN NEBRASKA, EVEN THOUGH THE
3	LEGISLATURE HAS PASSED LAWS ALLOWING STEM CELL
4	RESEARCH, AT THEIR UNIVERSITY, THEY'RE FACING A
5	CHALLENGE FROM A NEWLY ELECTED BOARD OF REGENTS WHO
6	HAVE THE MAJORITY OPPOSED TO EMBRYONIC STEM CELL
7	RESEARCH. SO THEY FACE CHALLENGES ON MANY FRONTS.
8	AND SO FOR THEM, IT CAN BE QUITE ISOLATING. FOR
9	THEM, THEY WERE LOOKING TO US FOR LEADERSHIP AND
10	ALSO AN OPPORTUNITY TO HELP KIND OF CONNECT THEM TO
11	SOMETHING THAT'S WORKING AND RESOURCES.
12	AND SO DON AND I WERE MORE THAN HAPPY TO
13	TALK WITH THEM AND BE ABLE TO KIND OF TALK ABOUT THE
14	RESOURCES WE HAVE THAT WE CAN SHARE WITH THEM THAT
15	THEY CAN USE FOR THEIR OWN PURPOSES SO THAT EACH
16	GROUP, THEN, DOESN'T HAVE TO CREATE ITS OWN WORK
17	FROM SCRATCH, THAT THEY CAN TAP INTO WHAT WE'VE
18	ALREADY DONE, AND BUILD ON THAT. HOPEFULLY OVER THE
19	NEXT YEAR OR SO, WE'LL BE ABLE TO CREATE A NATIONAL
20	NETWORK OF PATIENT ADVOCACY GROUPS. SO WE'RE GOING
21	TO WORK TOGETHER AND SUPPORT EACH OTHER AND BUILD ON
22	THE NETWORK THAT WE ALREADY HAVE.
23	FINALLY, I JUST WANTED TO GIVE YOU A
24	COUPLE OF UPDATES. I TOLD YOU ABOUT TODD SHOOTING
25	THE VIDEO HERE. TODD HAS ALSO ANOTHER VIDEO GETTING

1	POSTED IN THE NEXT COUPLE OF WEEKS, FEATURING DR.
2	XIANMIN ZENG FROM THE BUCK INSTITUTE FOR RESEARCH ON
3	AGING. IT'S THE LATEST IN OUR SERIES ON ASK THE
4	EXPERT. DR. ZENG TALKS ABOUT PARKINSON'S DISEASE,
5	AND IT'S REALLY GOING TO BE FASCINATING STUFF.
6	AND THEN ALSO THE NEW WEB SITE WILL BE
7	READY TO LAUNCH IN JANUARY. AND AT THE NEXT BOARD
8	MEETING, AMY ADAMS WILL WALK YOU THROUGH IT TO
9	EXPLAIN THE NEW DESIGN, WHY WE DID IT THIS WAY, AND
10	HOW IT'S SO MUCH BETTER, NOT JUST THE PUBLIC IN
11	TERMS OF MATERIAL THEY'RE INTERESTED IN, BUT FOR
12	RESEARCHERS AND SCIENTISTS WHO WANT TO ACTUALLY LOOK
13	AT GRANTS AND EVERYTHING ELSE. SO IT WILL BE A MUCH
14	BETTER WEB SITE, MORE FUNCTIONAL FOR EVERYONE. SO
15	WITH THAT, I'M HAPPY TO ANSWER ANY QUESTIONS.
16	CHAIRMAN THOMAS: QUESTIONS? COMMENTS?
17	BEEN A BUSY STRETCH.
18	MR. MCCORMACK: IT WAS FUN. THAT WAS ONE
19	OF THE THINGS AT THE WORLD STEM CELL SUMMIT, DON AND
20	I SPENT HALF THE TIME ACTUALLY TRYING TO GET READY
21	FOR THE IOM REPORT. SO THERE WERE A LOT OF REALLY
22	GOOD TALKS THAT WE DIDN'T GET A CHANCE TO HEAR.
23	OVERALL IT WORKED WELL.
24	MS. GIBBONS: JUST A BRIEF QUESTION ABOUT
25	THE SPOTLIGHT THAT WE SAW TODAY. WHAT'S THE
	178

1	TIMETABLE ON WHEN THOSE ARE POSTED SO WE CAN START
2	SHARING THAT?
3	MR. MCCORMACK: AS SOON AS TODD CAN FINISH
4	EDITING IT, WE'LL GET IT UP. AS SOON AS THAT
5	HAPPENS.
6	MS. GIBBONS: YOU GUYS WILL JUST LET US
7	KNOW WHEN IT'S POSTED.
8	MR. MCCORMACK: ABSOLUTELY. WE'LL SHARE
9	THAT WITH EVERYONE. WE'RE SHAMELESS IN SHARING.
10	DON'T WORRY. THIS MONTH, IN TIME FOR CHRISTMAS.
11	CHAIRMAN THOMAS: ANY OTHER THOUGHTS,
12	COMMENTS? VERY GOOD. THANK YOU, KEVIN. SO WE'VE
13	GOT FIVE MINUTES OR SO UNTIL CLOSED SESSION. SO I
14	THINK LET'S JUST TAKE A BREAK.
15	MR. HARRISON: WE ACTUALLY FIRST HAVE TO
16	ENTERTAIN A MOTION BY THE BOARD TO ADD THE ITEM TO
17	THE AGENDA BASED ON THE FACT THAT IT CAME TO THE
18	BOARD'S ATTENTION AFTER THE AGENDA WAS POSTED, AND
19	THERE'S A NEED TO TAKE IMMEDIATE ACTION.
20	DR. POMEROY: SO MOVED.
21	CHAIRMAN THOMAS: MOVED BY DEAN POMEROY.
22	SECONDED BY
23	DR. BRYANT: SECOND.
24	CHAIRMAN THOMAS: DR. BRYANT. THANK
25	YOU. ALL IN FAVOR PLEASE SAY AYE. OPPOSED? THOSE
	179
	113

1	ON THE PHONE.
2	MS. SAMUELSON: NOT OPPOSED.
3	MS. FEIT: AYE.
4	DR. WARE: AYE.
5	CHAIRMAN THOMAS: THANK YOU. MOTION
6	CARRIES. SO WE WILL, AFTER MR. HARRISON READS THE
7	APPROPRIATE CODE NUMBER NO. I'M GETTING THIS
8	FROM MARIA. WHAT DOES THAT MEAN? WE WILL ADJOURN
9	TO CLOSED SESSION WHICH WILL BE BEGIN AT 2:30. WE
10	WILL RECONVENE THEREAFTER FOR FURTHER PUBLIC
11	DISCUSSION ON THE MATTER, AND WE'LL CLOSE WITH THE
12	CHAIRMAN'S REPORT. MR. HARRISON, THE CODE NUMBER
13	PLEASE.
14	MR. HARRISON: THE BOARD WILL BE CONVENING
15	IN CLOSED SESSION TO CONSIDER PREPUBLICATION DATA,
16	PROPRIETARY INFORMATION, AND OTHER CONFIDENTIAL
17	INFORMATION RELATED TO THE PROPOSAL TO AWARD VIACYTE
18	A SUPPLEMENTAL AWARD PURSUANT TO HEALTH AND SAFETY
19	CODE SECTION 125290.30(F)(3)(B) AND (C).
20	AND IF MEMBERS COULD REMEMBER TO PLEASE
21	SIGN THEIR CONFLICT CERTIFICATIONS AND HAND THEM
22	BACK TO AMY CHEUNG, WE WOULD APPRECIATE IT. THANK
23	YOU.
24	(THE BOARD THEN WENT INTO CLOSED
25	SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED.)
	180

1	CHAIRMAN THOMAS: DO WE HAVE THOSE ON THE
2	PHONE BACK ON THE PHONE? I BELIEVE, MR. HARRISON,
3	THERE WAS A MOTION ON THE FLOOR WITH RESPECT TO ITEM
4	13; IS THAT CORRECT?
5	MR. HARRISON: THAT'S CORRECT. THERE'S A
6	MOTION PENDING TO APPROVE SUPPLEMENTAL FUNDING OF \$3
7	MILLION TO VIACYTE. THE MAKER WAS TORRES AND THE
8	SECOND WAS PRIETO.
9	CHAIRMAN THOMAS: OKAY. IS THERE ANY
10	DISCUSSION BY MEMBERS OF THE BOARD ON THE SUBJECT?
11	ANY DISCUSSION BY MEMBERS OF THE PUBLIC ON THE
12	SUBJECT? HEARING NONE, MR. HARRISON, IS THIS ROLL
13	OR VOICE?
14	MR. HARRISON: THIS IS A ROLL CALL VOTE.
15	MS. BONNEVILLE: DAVID BRENNER. SUE
16	BRYANT.
17	DR. BRYANT: YES.
18	MS. BONNEVILLE: FRANK CHISARI.
19	DR. CHISARI: YES.
20	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
21	JAMES ECONOMOU.
22	DR. ECONOMOU: YES.
23	MS. BONNEVILLE: LEEZA GIBBONS.
24	MS. GIBBONS: YES.
25	MS. BONNEVILLE: MICHAEL GOLDBERG.
	181

1	STEPHEN JUELSGAARD.
2	DR. JUELSGAARD: YES.
3	MS. BONNEVILLE: TED KRONTIRIS. BERT
4	LUBIN. CLAIRE POMEROY.
5	DR. POMEROY: YES.
6	MS. BONNEVILLE: ROBERT PRICE.
7	DR. PRICE: YES.
8	MS. BONNEVILLE: FRANCISCO PRIETO.
9	DR. PRIETO: YES.
10	MS. BONNEVILLE: ROBERT QUINT.
11	DR. QUINT: YES.
12	MS. BONNEVILLE: DUANE ROTH. JOAN
13	SAMUELSON.
14	MS. SAMUELSON: I'M GOING TO HAVE TO
15	ABSTAIN BECAUSE I COULDN'T HEAR THE DISCUSSION.
16	MS. BONNEVILLE: JONATHAN SHESTACK.
17	MR. SHESTACK: YES.
18	MS. BONNEVILLE: OSWALD STEWARD.
19	DR. STEWARD: YES.
20	MS. BONNEVILLE: JONATHAN THOMAS.
21	CHAIRMAN THOMAS: YES.
22	MS. BONNEVILLE: ART TORRES.
23	MR. TORRES: AYE.
24	MS. BONNEVILLE: CARL WARE.
25	DR. WARE: ABSTAIN.
	182

1	MR. HARRISON: THE MOTION CARRIES.
2	MR. TORRES: WHAT WAS THE VOTE?
3	MR. HARRISON: THIRTEEN IN FAVOR, TWO
4	ABSTENTIONS.
5	CHAIRMAN THOMAS: THANK YOU. THAT
6	CONCLUDES THE AGENDA. LET ME FINISH RATHER
7	UNORTHODOXLY WITH THE CHAIRMAN'S REPORT. WANT TO
8	SAY, FIRST OF ALL, THIS HAS BEEN AN AMAZING YEAR OF
9	ACTIVITY AND INTENSE WORK BY EVERYBODY CONCERNED
10	HERE.
11	AS WE NOTED, WE'VE HAD NINE RFA'S THAT HAD
12	GRANTS WORKING GROUP MEETINGS THIS YEAR, WHICH BY
13	ANY ACCOUNT IS AN EXTRAORDINARY AMOUNT, WHICH, OF
14	COURSE, COULDN'T BE MADE POSSIBLE WITHOUT AN
15	INCREDIBLE AMOUNT OF WORK BY ALAN AND ELLEN AND PAT
16	AND GIL AND ALL THE SCIENCE STAFF AND ALL THE
17	SUPPORT STAFF. AND I THINK IT'S SOMETHING THAT THE
18	AGENCY AS A GROUP SHOULD BE REALLY PROUD OF. THIS
19	IS SOMETHING THAT CONTINUES OUR MISSION.
20	WE HAD THIS YEAR, AS WE ALWAYS DO, A
21	COUPLE OF ITEMS THAT WERE FIRST OF THEIR KIND,
22	CUTTING-EDGE INITIATIVES THAT KEEP TRACK REAL-TIME
23	OF DEVELOPMENTS IN REGENERATIVE MEDICINE AND KEEP
24	CIRM ON THE FOREFRONT NATIONALLY AND WORLDWIDE. AND
25	IT'S SOMETHING THAT IS JUST A TESTAMENT TO
	102
	183

1	EVERYBODY'S CONSIDERABLE HARD WORK AND WE SEE THE
2	RESULTS. WE SEE THE PORTFOLIO WE HAVE, WE SEE,
3	NOTWITHSTANDING A FEW ISSUES, THE GENERAL ACCLAIM
4	THAT WE AROUND THE WORLD GET AND FOR ALL WE DO.
5	SO FIRST OF ALL, JUST MAKE THAT COMMENT.
6	WITH RESPECT TO THE LAST STRETCH SINCE THE
7	LAST BOARD MEETING, IT'S BEEN A BUSY TIME FOR THE
8	CHAIR. WE HAD THE MEETING ON THE MEETING THE MESA,
9	A KEYNOTE AT THE WORKING TO WALK SYMPOSIUM HELD IN
10	IRVINE, THE ALPHA CLINIC MEETING, WHICH I WANT TO
11	ECHO WHAT MR. SHEEHY SAID TO DR. TROUNSON, WAS
12	EXTRAORDINARY AND CONGRATULATE NATALIE AS WELL FOR
13	THAT. ALWAYS TOUGH TO PULL OFF FIRST-TIME MEETINGS
14	ON NEW CONCEPTS, AND IT WAS VERY, VERY EXCITING.
15	WE HAD THE STANFORD SYMPOSIUM ON
16	REGENERATION AND SPINAL CORD INJURY. THE CDAP
17	MEETING, THE WORLD STEM CELL SUMMIT, THE HOUSE OF
18	LORDS MEETING THAT ALAN REFERENCED, THE IPSC CELL
19	BANKING INITIATIVE, AND, OF COURSE, ALL THE DEALINGS
20	THAT LED UP TO THE RELEASE OF THE IOM STUDY. VERY
21	BUSY STRETCH. I GUESS FITTING FOR A VERY BUSY YEAR.
22	I JUST WANT TO CIRCLE BACK AND CLOSE ONE
23	LAST WORD ABOUT THE STAFF. EVERY MONDAY MORNING
24	THERE'S A STAFF MEETING WHICH ALAN, ELLEN, OR ELONA
25	VARIOUSLY LEAD, DEPENDING ON WHO HAPPENS TO BE THERE
	184

1	AT THAT TIME. AND THERE WAS A REPORT SPECIFICALLY
2	ON THE GRANTS WORKING GROUP FOR THE IPS CELL BANKING
3	INITIATIVE.
4	DR. GRIESHAMMER IN THE COURSE OF THAT
5	REPORT SAID I WANT EVERYBODY TO UNDERSTAND WHAT WENT
6	INTO THIS FIRST OF ITS KIND EVENT. AND SHE
7	PROCEEDED TO LIST ALL THE DIFFERENT ROLES FILLED BY
8	MEMBERS OF STAFF TO MAKE THAT CELL BANK GRANTS
9	WORKING GROUP MEETING HAPPEN. AND IT WAS QUITE
10	STUNNING. AND I BELIEVE SHE ESSENTIALLY MENTIONED
11	VIRTUALLY EVERY SINGLE PERSON IN THE ENTIRE
12	OPERATION HAVING A HAND IN SOME ASPECT OF THAT. AND
13	AS YOU SAT THERE LISTENING TO IT, YOU WOULD ONLY BE
14	ADDITIONALLY IMPRESSED WITH THE HIGH CALIBER OF THE
15	STAFF AND THE HIGH CALIBER OF THE MISSION AND HOW
16	WE'RE GOING ABOUT FULFILLING IT. AND TO ME THAT WAS
17	ONE OF THE GREAT MOMENTS OF THE ENTIRE YEAR BECAUSE
18	IT TIED ALL THIS HARD WORK TOGETHER.
19	SO CONGRATULATIONS, ALAN, TO YOU AND TO
20	ELLEN, PAT, ETC., ALL THE STAFF FOR A TRULY
21	PHENOMENAL JOB. WE LOOK FORWARD TO BIGGER AND
22	BETTER NEXT YEAR. WE HAVE LOTS OF THINGS
23	CALENDARED, LOTS OF VERY INTERESTING ACTIVITIES
24	AHEAD OF US. AND AS WE CONTINUE ALONG AND MAKING
25	PROGRESS IN OUR GOAL OF ALLEVIATING HUMAN SUFFERING,
	185

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1
     I THINK WE CAN ALL BE VERY PROUD OF WHAT WE'VE ALL
 2
     BEEN ABLE TO DO.
 3
                SO ON THAT NOTE, HAPPY HOLIDAYS TO
 4
     EVERYBODY. THANK YOU VERY MUCH FOR ALL YOUR HARD
 5
     WORK. DR. PRIETO HAS A COMMENT.
 6
                DR. PRIETO: I WOULD JUST LIKE TO SECOND
 7
     J.T.'S COMMENTS ABOUT OUR STAFF AND THANK YOU FOR
 8
     EVERYTHING YOU'VE DONE. I WISH EVERY ORGANIZATION
 9
     THAT I WORKED WITH HAD A STAFF THIS GOOD.
10
                CHAIRMAN THOMAS: THANK YOU.
11
                     (APPLAUSE.)
                CHAIRMAN THOMAS: HAPPY HOLIDAYS. WE'LL
12
13
     SEE EVERYBODY IN JANUARY. THANK YOU VERY MUCH.
14
                     (THE MEETING WAS THEN CONCLUDED AT
     03:01 P.M.)
15
16
17
18
19
20
21
22
23
24
25
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REPORTER'S CERTIFICATE

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

LUXE HOTEL, SUNSET BOULEVARD 11461 SUNSET BOULEVARD LOS ANGELES, CALIFORNIA ON DECEMBER 12, 2012

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

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