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: CLAREMONT HOTEL

41 TUNNEL ROAD

BERKELEY, CALIFORNIA

DATE: JANUARY 23, 2013

10:30 A.M.

REPORTER: BETH C. DRAIN, CSR

CSR. NO. 7152

BRS FILE NO.: 92749

INDEX

ITEM DESCRIPTION	PAGE	NO.
REPORTS & DISCUSSION ITEMS		
1. CALL TO ORDER.		3
2. PLEDGE OF ALLEGIANCE.		4
3. ROLL CALL.		4
4. PRESENTATION REGARDING CIRM'S SCIENTIFIC PROGRESS.		6
5. CONSIDERATION OF IOM COMMITTEE REPORT ON CIRM AND PROPOSED RECOMMENDATIONS FROM CHAIR OF CIRM'S GOVERNING BOARD.		68
6. PUBLIC COMMENT	NO	NE

1	BERKELEY, CALIFORNIA; WEDNESDAY, JANUARY 23, 2013
2	10:30 A.M.
3	
4	CHAIRMAN THOMAS: IT'S AFTER 10:30. WE'D
5	LIKE TO CALL THIS MEETING TO ORDER AT EVERYBODY'S
6	EARLIEST CONVENIENCE. SO THOSE MEMBERS OF THE BOARD
7	WHO HAVE NOT YET TAKEN THEIR SEATS, IF YOU WOULD,
8	PLEASE DO SO AND WE WILL START.
9	I'D LIKE TO WELCOME EVERYBODY TO TODAY'S
10	BOARD WORKSHOP. WE APPRECIATE BOTH EVERYBODY'S
11	ATTENDANCE HERE TODAY AS WELL AS THE ATTENDANCE OF
12	THOSE LISTENING IN ON OUR WEB SITE FEED.
13	THE WORKSHOP TODAY, AS YOU'VE SEEN FROM
14	OUR POSTED AGENDA, IS GOING TO BE COMPRISED OF TWO
15	SEPARATE SEGMENTS. THE FIRST, WHICH WE WILL PROCEED
16	TO IMMEDIATELY, IS A REPORT BY DRS. FEIGAL AND OLSON
17	ON THE STATUS OF CIRM'S PORTFOLIO. THAT WILL BE
18	FOLLOWED BY A LUNCH FROM TWELVE TO ONE, AT WHICH
19	POINT WE WILL SWEAR IN NEW OR REAPPOINTED MEMBERS,
20	RECENTLY REAPPOINTED MEMBERS, AND PROCEED
21	IMMEDIATELY TO THE DISCUSSION OF THE IOM REPORT.
22	THAT SEGMENT IS SLATED TO BE FROM ROUGHLY
23	1:15 THROUGH FIVE OR SIX OR WHATEVER WE NEED TO WORK
24	OUR WAY THROUGH IT. AT THE CONCLUSION OF THE DAY,
25	WE WILL FINISH THE WORKSHOP. WE THEN WILL GO
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1	FORTHWITH TOMORROW INTO OUR REGULARLY SCHEDULED
2	BOARD MEETING, WHICH STARTS AT 9 O'CLOCK.
3	SO THAT IS THE AGENDA. WITHOUT FURTHER
4	ADO, LET ME NOW TURN IT OVER TO DRS. FEIGAL AND
5	OLSON TO GIVE A REPORT.
6	I ALWAYS GET THE SIGNALS. CAN WE PLEASE,
7	BEFORE WE DO ANYTHING, VERY IMPORTANT, PARTICULARLY
8	IN LIGHT OF THE RECENT SWEARING IN OF OUR PRESIDENT,
9	PLEASE STAND, IF YOU ARE ABLE, TO GIVE THE PLEDGE OF
10	ALLEGIANCE.
11	(THE PLEDGE OF ALLEGIANCE.)
12	CHAIRMAN THOMAS: THANK YOU, MARIA. LET'S
13	TRY THIS AGAIN. DRS. FEIGAL AND OLSON.
14	MS. BONNEVILLE: ROLL CALL.
15	CHAIRMAN THOMAS: WE NEED A ROLL CALL FOR
16	A WORKSHOP TOO. VERY IMPORTANT. MARIA, PLEASE.
17	MS. BONNEVILLE: DAVID BRENNER.
18	DR. BRENNER: HERE.
19	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
20	DR. DULIEGE: HERE.
21	MS. BONNEVILLE: MARCY FEIT. MICHAEL
22	FRIEDMAN.
23	DR. FRIEDMAN: HERE.
24	MS. BONNEVILLE: LEEZA GIBBONS. MICHAEL
25	GOLDBERG. SAM HAWGOOD. STEPHEN JUELSGAARD.
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1	DR. JUELSGAARD: HERE.
2	MS. BONNEVILLE: SHERRY LANSING. JACOB
3	LEVIN.
4	DR. LEVIN: HERE.
5	MS. BONNEVILLE: BERT LUBIN. MICHAEL
6	MARLETTA.
7	DR. MARLETTA: HERE.
8	MS. BONNEVILLE: SHLOMO MELMED. CLAIRE
9	POMEROY.
10	DR. POMEROY: HERE.
11	MS. BONNEVILLE: ROBERT PRICE. FRANCISCO
12	PRIETO.
13	DR. PRIETO: HERE.
14	MS. BONNEVILLE: CARMEN PULIAFITO. ROBERT
15	QUINT. DUANE ROTH. JOAN SAMUELSON. JEFF SHEEHY.
16	JONATHAN SHESTACK.
17	MR. SHESTACK: HERE.
18	MS. BONNEVILLE: OSWALD STEWARD.
19	DR. STEWARD: HERE.
20	MS. BONNEVILLE: JONATHAN THOMAS.
21	CHAIRMAN THOMAS: HERE.
22	MS. BONNEVILLE: ART TORRES.
23	MR. TORRES: HERE.
24	MS. BONNEVILLE: KRISTINA VUORI.
25	DR. VUORI: HERE.
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MS. BONNEVILLE: EUGENE WASHINGTON. DIANE
WINOKUR.
MS. WINOKUR: HERE.
CHAIRMAN THOMAS: THANK YOU, MARIA. AND A
SPECIAL WELCOME TO DIANE AT YOUR FIRST
WORKSHOP/MEETING. WELCOME. WE'RE DELIGHTED TO HAVE
YOU AS A MEMBER OF THE BOARD.
(APPLAUSE.)
CHAIRMAN THOMAS: MR. PRICE IS HERE, LET
THE RECORD SHOW. DR. FEIGAL.
DR. FEIGAL: OKAY. THANK YOU, VERY MUCH.
DR. OLSON AND I ARE VERY PLEASED TO PRESENT UPDATES
TO YOU ON THE SCIENTIFIC PROGRAMS FROM THE STATE
STEM CELL AGENCY. I FIRST ALSO WANT TO THANK THE
BOARD AS WELL AS THE STAFF BECAUSE THIS HAS REALLY
BEEN A JOINT EFFORT IN TERMS OF MOVING THESE
PROGRAMS FORWARD SO THAT THEY CAN ADVANCE TOWARDS
OUR MISSION. AND SO WE'RE REALLY DELIGHTED TODAY TO
BE ABLE TO TELL YOU ABOUT THE FORWARD PROGRESS FROM
EVERYTHING FROM TRAINING TO BASIC BIOLOGY TO TOOLS
AND TECHNOLOGY, EARLY TRANSLATION, AND THROUGH TO
OUR DISEASE TEAMS.
I CAN SAY THIS IS OBVIOUSLY A WORK IN
PROGRESS, BUT I DO WANT TO ACKNOWLEDGE THE
TREMENDOUS AMOUNT OF COMMITMENT, DEDICATION, AND
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1	WORK THAT THIS BOARD HAS PUT FORWARD, THAT OUR STAFF
2	HAS PUT FORWARD, AND PARTICULARLY TO PATIENT
3	ADVOCATES, DISEASE FOUNDATIONS, AND OUR RESEARCHERS
4	BOTH WITHIN ACADEMICS AND WITHIN THE COMMERCIAL
5	COMMUNITIES. IT'S REALLY BEEN A VILLAGE TO TRY AND
6	MOVE THIS FORWARD.
7	SO TODAY THIS IS REALLY A HIGH LEVEL
8	OVERVIEW OF THE STATUS UPDATE, SOME KEY PIECES OF
9	PROGRESS THAT WE WILL SHARE WITH YOU. YOU WERE
10	PROVIDED A PREREAD ABOUT TEN DAYS AGO THAT YOU
11	RECEIVED, I BELIEVE, BY E-MAIL THAT IS ALSO IN YOUR
12	BINDER. AND WE ARE GOING TO BE COMING BACK TO YOU
13	IN MARCH WITH A MORE FOCUSED, IN-DEPTH UPDATE OF THE
14	EARLY TRANSLATION PROGRAMS AND THE DISEASE TEAM
15	PROGRAMS. SO THERE'LL BE A CONTINUED OPPORTUNITY TO
16	HEAR ABOUT PROGRESS.
17	CIRM'S VISION AND STRATEGY ARE REALLY
18	BASED ON OUR MISSION. AND THE MISSION HASN'T
19	CHANGED SINCE CIRM WAS CREATED BACK IN 2004. AND
20	THAT REALLY IS TO ADVANCE THE SCIENCE, THAT WE HAVE
21	A BETTER UNDERSTANDING OF STEM CELL BIOLOGY SO THAT
22	WE HAVE A BETTER UNDERSTANDING OF THE DISEASE, BUT
23	MOST IMPORTANTLY TO ACCELERATE THAT UNDERSTANDING IN
24	THAT SCIENCE TOWARDS THERAPIES AND POTENTIAL CURES
25	FOR PATIENTS WHO HAVE CHRONIC DISEASES, CHRONIC
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1	INJURIES. THAT'S WHAT WE'RE REALLY ALL HERE FOR.
2	IN THE FIRST FIVE YEARS OF CIRM'S
3	EXISTENCE, WE REALLY WERE CULTIVATING THE FIELD. WE
4	WERE PLANTING THE SEEDS WITH PHYSICAL INFRASTRUCTURE
5	TO CONDUCT THE SCIENCE. AT THE TIME WE ALL REMEMBER
6	THERE REALLY NEEDED TO BE A SAFE HAVEN TO CONDUCT
7	THIS TYPE OF RESEARCH, AND WE WERE BRINGING IN THE
8	INTELLECTUAL CAPITAL TO PERFORM THAT RESEARCH. SO
9	THERE WAS A TREMENDOUS AMOUNT OF EXPLORATION AND
10	CULTIVATION OF THE FIELD.
11	THESE NEXT FIVE YEARS, WHICH IS WHAT WE'RE
12	IN RIGHT NOW, IS A TIME OF A DESIRE TO REALLY TRY
13	AND PRIORITIZE ON OUR INVESTMENTS AND MAKE SURE THAT
14	WE CAN BRING THE MOST PROMISING OF OUR PROGRAMS
15	FORWARD TO FRUITION SO THAT WE CAN REALLY ACCELERATE
16	WHERE WE NEED TO GO WITH DEVELOPING THERAPIES.
17	IN ADDITION, DURING THIS PERIOD, WE'RE
18	ADVANCING THE SCIENCE TOWARDS CLINICAL TRIALS FOR
19	PATIENTS SO THAT WE CAN SEE THAT PRELIMINARY
20	EVIDENCE OF SAFETY AND THERAPEUTIC BENEFIT. AND IN
21	ADDITION, THIS IS A TIME WHERE WE REALLY WANT TO
22	STRENGTHEN AND ENHANCE OUR PARTNERSHIPS WITH DISEASE
23	FOUNDATIONS, WITH PATIENT ADVOCATES, WITH INDUSTRY,
24	WITH OTHER ACADEMIC RESEARCHERS, WITH COLLABORATORS
25	BOTH WITHIN CALIFORNIA AND OUTSIDE OF CALIFORNIA AND

1	ACROSS THE WORLD. WE'RE REALLY WORKING ON THIS SO
2	THAT BY 2016, AS PART OF OUR STRATEGY, WE CAN
3	FACILITATE THE COMMERCIALIZATION OF THESE THERAPIES,
4	WE CAN ADVANCE THESE THERAPIES TO PATIENTS, AND THAT
5	WE REALLY WILL HAVE ENABLED A BUSINESS MODEL FOR
6	THESE STEM CELL-BASED THERAPIES TO GO FORWARD, NOT
7	JUST IN CLINICAL TRIALS, BUT INTO ACTUAL PRODUCTS
8	THAT CAN BE APPRECIATED MORE BROADLY BY PATIENTS WHO
9	NEED THEM.
10	SO WHERE HAVE THE DOLLARS BEEN INVESTED?
11	THIS IS A CHEVRON THAT YOU'VE SEEN MANY TIMES OVER
12	THE PAST YEARS SHOWING THAT WE'VE REALLY INVESTED
13	ANYWHERE FROM BASIC RESEARCH, WHICH IS THE DRIVING
14	ENGINE FOR DISCOVERY AND HELP UNDERPIN THE RATIONALE
15	FOR THE TYPES OF PROJECTS WE'RE GOING FORWARD WITH
16	THROUGH TO DISCOVERY, RESEARCH, PRECLINICAL
17	RESEARCH, AND THEN ALL ALONG THE IND-ENABLING PATH
18	SO THAT THESE THERAPIES CAN GET INTO PATIENTS WHO
19	NEED THEM.
20	AND WITHIN THE LAST FEW YEARS, OUR FIRST
21	1.7 BILLION HAS BEEN REALLY INVESTED IN THE
22	CATEGORIES THAT YOU SEE DEMARCATED BY THE BARS.
23	WE'VE INVESTED ABOUT 20 PERCENT OF THE 1.7 BILLION,
24	343 MILLION, INTO INFRASTRUCTURE, INTO PHYSICAL
25	INFRASTRUCTURE FACILITIES AND CORES. WE'VE INVESTED

1	ANOTHER 22 PERCENT INTO INTELLECTUAL INFRASTRUCTURE,
2	THE ACTUAL PEOPLE THAT ARE GOING TO BE THINKING OF
3	THE GREAT IDEAS MOVING THIS RESEARCH FORWARD. IT
4	TAKES RESEARCH LEADERS, IT TAKES LABORATORY PEOPLE
5	TO MOVE THIS THROUGH. IT TAKES A VARIETY OF
6	DIFFERENT TYPES OF EXPERTISE TO HAVE THE
7	INTELLECTUAL CAPITAL TO MOVE THIS FORWARD.
8	IN ADDITION, WE'VE INVESTED 20 PERCENT OF
9	OUR FUNDS INTO THE ACTUAL RESEARCH. THIS IS THE
10	PIPELINE OF FOUNDATIONAL RESEARCH FROM EVERYWHERE
11	FROM BASIC TO DISCOVERY TO PRECLINICAL RESEARCH.
12	AND THEN THE LAST CATEGORY YOU SEE IS THE
13	PIPELINE OF TRANSLATIONAL RESEARCH. THIS IS THE
14	PROPORTIONATELY LARGEST AMOUNT OF INVESTMENT OF OUR
15	FUNDS THAT WE'VE MADE. IT REPRESENTS 38 PERCENT.
16	SO ALTHOUGH THE NUMBERS OF AWARDS THAT WE MAKE FOR
17	TRANSLATIONAL RESEARCH ARE RELATIVELY SMALL, OF THE
18	OVER 560 AWARDS, ABOUT 77 OF THEM ARE WHAT WE WOULD
19	TERM TRANSLATIONAL. THEY MAKE UP THE LARGEST
20	FUNDING AMOUNT BECAUSE PROPORTIONATELY THEY'RE MORE
21	COMPLEX, THEY'RE MORE EXPENSIVE, AND THERE ARE MORE
22	STUDIES AND ACTIVITIES WE NEED TO DO IN ORDER FOR
23	THESE PROGRAMS TO REACH PEOPLE. AND THIS
24	REPRESENTS, AS I SAID, ABOUT 38 PERCENT OF OUR
25	BUDGET.

1	OUR CORE PROGRAMS WERE DESIGNED SO THAT
2	THERE WOULD BE A SEAMLESS PATHWAY FROM BASIC
3	DISCOVERY THROUGH TO CLINICAL TRIALS. WHAT YOU CAN
4	SEE HERE ACROSS THE CHEVRON IS YOU CAN SEE SOME OF
5	THE KEY MILESTONES. FOR EXAMPLE, AT THE END OF SOME
6	OF THE PRECLINICAL RESEARCH ACTIVITY, THE MAJOR GOAL
7	IS TO SELECT A DEVELOPMENT CANDIDATE THAT COULD
8	POTENTIALLY BE THE TARGET FOR FURTHER IND-ENABLING
9	WORK. AND THEN AT THE END OF PRECLINICAL
10	DEVELOPMENT, IT'S FILING THAT IND WITH THE FOOD AND
11	DRUG ADMINISTRATION WHO REVIEWS ALL THE DOCUMENTS OF
12	EVIDENCE TO ASSURE THEM THAT IT'S SAFE TO GO INTO
13	PEOPLE, AND THEN THE CONDUCT OF THE CLINICAL TRIALS.
14	SO WE'VE INVESTED IN TRAINING, IN BASIC
15	RESEARCH, IN TOOLS AND TECHNOLOGIES TO REALLY TRY
16	AND LOOK AT SOME OF THE OBSTACLES, BOTH FOR
17	TRANSLATIONAL RESEARCH, BUT ALSO FOR DISCOVERY
18	RESEARCH. IT COULD BE NONINVASIVE IMAGING, IT COULD
19	BE CULTURE MEDIA, IT COULD BE REAGENTS. IT COULD BE
20	A VARIETY OF THINGS THAT HELP MOVE THE FIELD FORWARD
21	IN A FASTER WAY.
22	THE EARLY TRANSLATIONAL RESEARCH, AS I
23	SAID, IS REALLY FOCUSED ON IDENTIFYING THE
24	PRECLINICAL PROOF OF CONCEPT AND THE EARLY
25	DEVELOPMENT CANDIDATES. AND THEN THE DISEASE TEAMS,

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1	OUR FIRST COHORT ACTUALLY STARTED WAY BACK IN SOME
2	OF THE PRECLINICAL RESEARCH WHERE THEIR GOAL WAS
3	ACTUALLY FILE AN IND TO ENTER CLINICAL TRIALS. AND
4	NOW OUR SUBSEQUENT COHORTS OF DISEASE TEAMS ARE
5	ACTUALLY WORKING WITH THE GOAL OF NOT JUST FILING
6	THAT IND, BUT OF COMPLETING A CLINICAL TRIAL. AND
7	THEN MOST RECENTLY IN A MORE CONCERTED EFFORT TO
8	REACH OUT TO INDUSTRY, WE PUT TOGETHER THE STRATEGIC
9	PARTNERSHIP PROGRAMS, WHICH REALLY IS TO ENABLE
10	EARLIER ENGAGEMENT WITH INDUSTRY TO HELP SHAPE THE
11	PROGRAMS THAT ARE GOING FORWARD SO THAT IF
12	MILESTONES ARE MET, THERE'S AN OPPORTUNITY FOR
13	FOLLOW-ON COMMITMENT TO MOVE THAT PROGRAM FORWARD.
14	\$3 BILLION SOUNDS LIKE A TREMENDOUS AMOUNT
15	OF MONEY AND IT IS, BUT WE KNOW IT'S NOT ENOUGH TO
16	BRING IT ALL THE WAY TO COMMERCIALIZATION. AND
17	WE'RE CRITICALLY IN NEED OF OUR PARTNERS WHO CAN
18	ACTUALLY TAKE THINGS FORWARD TO COMMERCIALIZATION.
19	SO JUST A SNAPSHOT OF SOME OF THE KEY
20	FACTS AND FIGURES IS THAT WE HAVE OVER 560 RESEARCH
21	AND FACILITIES AWARDS TO OVER 60 INSTITUTES AND
22	COMPANIES. WE'VE BUILT 12 NEW INSTITUTES AND
23	CENTERS OF REGENERATIVE MEDICINE ACROSS THE STATE OF
24	CALIFORNIA. WE HAVE OVER 1200 MAJOR SCIENTIFIC
25	PAPERS PUBLISHED. MANY OF THESE OF MAJOR SCIENTIFIC

1	IMPACT. WE'VE BROUGHT OVER 130 NEW MAJOR STEM CELL
2	RESEARCHERS TO CALIFORNIA. AND OF THOSE 560 AWARDS,
3	WE HAVE 77 THAT ARE CHARACTERIZED AS TRANSLATIONAL,
4	REALLY MOVING TOWARDS AND INTO THE CLINIC, 51 THAT
5	ARE EARLY TRANSLATIONAL, 24 DISEASE TEAMS, AND TWO
6	STRATEGIC PROGRAMS OF THE 1.7 BILLION THAT'S ALREADY
7	BEEN AWARDED.
8	THIS IS AN OUTLINE OF WHERE THE MONEY HAS
9	GONE AND IN WHAT TIME FRAME. SO YOU CAN SEE IN LATE
10	2005-2006 AND THEN YOU CAN SEE IT AS THE PURPLE BAR
11	AT THE BOTTOM THE AMOUNT OF DOLLARS THAT CIRM HAS
12	INVESTED IN TRAINING. SO THIS GOES WITH OUR
13	INTELLECTUAL CAPITAL, CAREER DEVELOPMENT, HELPING
14	PEOPLE NOT JUST ADVANCE THE SCIENCE, BUT ALSO JOBS.
15	THE GREEN IS THE AMOUNT OF MONEY THAT STARTED IN
16	2007 FOR BASIC RESEARCH. YOU CAN SEE THAT THE BASIC
17	RESEARCH IS CONTINUING THROUGHOUT THE LIFE SPAN OF
18	CIRM BECAUSE WE SEE THIS AS THE ENGINE OF DISCOVERY
19	THAT NEEDS TO CONTINUE.
20	AS I SAID BEFORE, THAT CHEVRON THAT YOU
21	SEE, IT'S PLACED AS UNIDIRECTIONAL, BUT IT'S REALLY
22	NOT. THERE'S ALL KINDS OF ITERATIVE DISCOVERIES
23	THAT TAKE PLACE BACK AND FORTH ALONG THAT SPECTRUM,
24	AND WE NEED TO CONTINUE TO HAVE THAT BASIC SCIENCE
25	ENGINE CONTINUE.
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1	THE RED IS OUR TOOLS AND TECHNOLOGIES, AND
2	THAT STARTED IN 2008. AND THAT WAS REALLY AN
3	ATTEMPT TO IDENTIFY WHAT SOME OF THE OBSTACLES ARE
4	IN MOVING THE STEM CELL FIELD FORWARD AND TRYING TO
5	DEVOTE A SUBSTANTIVE PART OF OUR FUNDING TOWARDS
6	TACKLING SOME OF THOSE OBSTACLES ON THE PATHWAY TO
7	TRANSLATION. AND THEN THAT OTHER COLOR, I'M NOT
8	SURE IF IT'S MAUVE OF WHAT COLOR YOU WANT TO CALL
9	IT, BUT BACK IN 2009, AS THE SCIENCE IS EVOLVING,
10	IT'S MATURING. WE WERE THEN AT A STAGE THAT WE
11	ACTUALLY COULD START INVESTING IN EARLY TRANSLATION
12	AND THE DEVELOPMENT OF CANDIDATES THAT COULD GO INTO
13	CLINICAL TRIALS. AND THEN IN 2010, WE COULD GO
14	BEYOND THAT TO ACTUALLY INVEST IN THESE
15	MULTIDISCIPLINARY DISEASE TEAMS THAT COULD ACTUALLY
16	TAKE THIS RESEARCH AND BRING IT INTO PATIENTS. AND
17	THAT'S THE ORANGE BAR THAT YOU SEE AT THE TOP.
18	SO THAT REPRESENTS THE MAJORITY OF WHERE
19	THE MONEY HAS GONE OF THE 1.7. THE CATEGORIES THAT
20	I HAVEN'T REPRESENTED THUS FAR, BUT THAT ARE IN YOUR
21	BROCHURE, YOUR PREREAD, IS THE PHYSICAL FACILITIES,
22	THE FACULTY AWARDS, THE OTHER TYPES OF FUNDING
23	INVESTMENTS THAT WERE TO HELP MOVE THE FIELD
24	FORWARD.
25	I'D ALSO LIKE TO ADD, IN ADDITION TO THE
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1	ADVANCES THAT YOU'RE GOING TO HEAR FROM DR. OLSON,
2	ON THE BASIC BIOLOGY, THE TOOLS AND TECHNOLOGIES,
3	THE EARLY TRANSLATION, THE TRAINING PROGRAMS, I CAN
4	SAY, AND YOU WILL HEAR THIS LATER, THIS YEAR WE ARE
5	ADVANCING CLINICAL TRIALS TO PATIENTS IN 2013. SO
6	OVERALL, I JUST WANT TO PUT THAT AS THE CONTEXT IS
7	THAT WE HAVE A LOT THAT WE'VE DONE IN THESE PAST
8	SEVERAL YEARS DUE TO THE TREMENDOUS AMOUNT OF
9	COMMITMENT, DEDICATION, AND HARD WORK OF A LARGE
10	VARIETY OF PEOPLE BOTH WITHIN THIS ROOM AND MANY
11	MORE OUTSIDE THIS ROOM.
12	AND SO WHAT I'M GOING TO DO NOW IS TURN IT
13	OVER TO DR. OLSON, WHO'S GOING TO TAKE YOU MAYBE
14	OVER THE NEXT 30 MINUTES THROUGH SOME OF THOSE
15	ADVANCES. THANK YOU.
16	DR. OLSON: GOOD MORNING AND THANK YOU.
17	FIRST, I'D LIKE TO START OFF WITH THE TRAINING
18	PROGRAM. CIRM AND THE BOARD RECOGNIZED VERY EARLY
19	THAT IN ORDER TO HAVE A LEADERSHIP POSITION IN STEM
20	CELL RESEARCH, IN ORDER TO GROW THE FIELD, THAT IT
21	REQUIRED A CRITICAL MASS OF STEM CELL SCIENTISTS AND
22	TECHNICAL STAFF THAT ARE CRUCIAL TO PROVIDING THE
23	INTELLECTUAL INFRASTRUCTURE AND FUTURE LEADERSHIP
24	AND WORKFORCE FOR A VIBRANT AND GROWING STEM CELL
25	RESEARCH ENTERPRISE. YOU CAN'T DO THE RESEARCH
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1	WITHOUT THE PEOPLE.
2	AND SO ACTUALLY OUR VERY FIRST AWARD WAS
3	THE TRAINING AWARD IN 2005. AND YOU CAN SEE IN THIS
4	SLIDE THE FUNDING THAT WE'VE DONE SINCE. WE'VE
5	ESSENTIALLY FUNDED 18 INSTITUTIONS TO A TOTAL OF
6	\$181 MILLION OR \$182 MILLION FOR BOTH A TRAINING
7	PROGRAM AND A BRIDGES PROGRAM.
8	AND LET ME JUST MAKE THE POINTS THAT CIRM
9	IS ARGUABLY THE LEADER AT THIS POINT IN POPULATING
10	THE FIELD WITH YOUNG SCIENTISTS WITH STEM CELL
11	KNOW-HOW. IF YOU THINK ABOUT IT, WE HAVE
12	ACTUALLY THE TRAINING PROGRAM WHICH TRAINS
13	PREDOCTORAL, POSTDOCTORAL, AND CLINICAL FELLOWS HAS
14	TRAINED 635 SO-CALLED CIRM SCHOLARS, THAT'S WHAT WE
15	CALL THOSE TRAINEES, AT 18 DIFFERENT INSTITUTIONS
16	AND IN 300 DIFFERENT LABS. NOT ONLY DO THEY CONDUCT
17	MENTORED LABORATORY RESEARCH IN STEM CELL RESEARCH,
18	BUT THEY ALSO TAKE COURSEWORK, WHICH IS AN IMPORTANT
19	PART OF THEIR TRAINING PROGRAM.
20	IN STEM CELL BIOLOGY, IT'S APPLICATION TO
21	HEALTH AND DISEASE. SO IT'S NOT JUST MANY OF OUR
22	TRAINEES CONDUCT PRETTY BASIC RESEARCH. THIS IS THE
23	ONE PLACE WHERE MODEL SYSTEM RESEARCH IS EASILY
24	CONDUCTED. AND JUST LEARNING HOW THE RESEARCH CAN
25	BE IMPORTANT FOR HOW HEALTH AND DISEASE. ALSO,

1	ANOTHER COURSE THAT WAS REQUIRED AS PART OF THE
2	PROGRAM WAS A COURSE IN THE ETHICAL, LEGAL, AND
3	SOCIAL ASPECTS OF STEM CELL RESEARCH. THIS REMINDS
4	US ALL THAT SCIENCE IS NOT CONDUCTED IN A VACUUM AND
5	THAT IT'S CONDUCTED WITH PEOPLE AND FOR PEOPLE. SO
6	THAT'S BEEN AN IMPORTANT PART OF IT.
7	THE BRIDGES PROGRAM TO DATE IS A NEWER
8	PROGRAM. IT'S TRAINED 482 CIRM INTERNS. AND THE
9	FOCUS OF THIS PROGRAM IS STUDENTS WHO ARE CANDIDATES
10	FOR UNDERGRADUATE AND FOR MASTER'S DEGREES,
11	ESPECIALLY THOSE AT THE CALIFORNIA STATE
12	UNIVERSITIES AND THE COMMUNITY COLLEGES. A PART OF
13	THIS PROGRAM INCLUDES TAKING A SHARED TECHNIQUES LAB
14	COURSE TO INTRODUCE STUDENTS TO THOSE TECHNIQUES
15	THAT MAY BE PARTICULARLY APPLICABLE TO STEM CELL
16	RESEARCH. AND, AGAIN, THEY HAVE MENTORED
17	INTERNSHIPS IN STEM CELL RESEARCH AND LABORATORIES
18	IN RESEARCH INTENSIVE UNIVERSITIES AND IN BIOTECH
19	COMPANIES.
20	IF YOU LOOK AT THE NEXT SLIDE, MANY OF OUR
21	CIRM SCHOLARS HAVE MOVED ON TO ADDITIONAL
22	POSTDOCTORAL TRAINING AND TO FACULTY AND INDUSTRY
23	POSITIONS. WHO ARE THESE PEOPLE? ONE OF THEM IS
24	LOUISE LAURENT. SHE WAS A CLINICAL FELLOW, A CIRM
25	SCHOLAR, A CLINICAL FELLOW IN THE UCSD TRAINING
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	17

1	PROGRAM. SHE TRAINED AS A CLINICAL FELLOW WITH JEAN
2	LORING AT THE SCRIPPS INSTITUTE FOR A YEAR IN
3	2006-7. HER CURRENT POSITION IS ACTUALLY AS AN
4	ASSISTANT PROFESSOR IN THE DEPARTMENT OF
5	REPRODUCTIVE MEDICINE AT UCSD.
6	AND ONE OF THE THINGS SHE HAS DONE IS
7	PUBLISHED A KEY PAPER ON DETERMINING THE ETHNIC
8	ORIGIN OF STEM CELL LINES AND THE PROFILE OF
9	COMMONLY USED LINES.
10	I WOULD POINT OUT THIS IS ONE OF THE
11	PHYSICIAN SCIENTISTS, ONE OF THE PEOPLE THAT WE KEEP
12	HOPING WE CAN TRAIN AND GET INVOLVED IN STEM CELL
13	RESEARCH BECAUSE IT'S THESE PEOPLE WHO BRING A
14	PERSPECTIVE, A CLINICAL PERSPECTIVE, TO THEIR
15	SCIENTIFIC RESEARCH. SO SHE'S ONE OF THOSE.
16	ANOTHER TRAINEE HAS BEEN MATHEW
17	BLURTON-JONES. HE'S FROM THE UCI TRAINING PROGRAM.
18	HE TRAINED UNDER DR. FRANK LAFERLA AT UCI. HE
19	CURRENTLY HAS A POSITION AS AN ASSISTANT PROFESSOR
20	AT THAT INSTITUTION. AND HE PUBLISHED AS A TRAINEE,
21	HE WAS A CONTRIBUTING AUTHOR ON A KEY PAPER SHOWING
22	THAT NEURAL STEM CELLS CAN IMPROVE COGNITION IN A
23	TRANSGENIC MOUSE MODEL OF ALZHEIMER'S DISEASE. THIS
24	IS ACTUALLY A FREQUENTLY CITED PAPER.
25	FINALLY, ANN ZOVEIN, SHE ACTUALLY IS A

1	MEMBER OF THE UCLA TRAINING PROGRAM. SHE'S AN M.D.,
2	AGAIN, TRAINED AS A CLINICAL FELLOW WITH DR. LUISA
3	IRUELA-ARISPE. I APOLOGIZE FOR WHAT I'M SURE IS A
4	MISPRONUNCIATION OF THAT NAME. SHE HAS ACTUALLY
5	MOVED TO UCSF AND IS AN ASSISTANT PROFESSOR OF
6	PEDIATRICS AND IN THE CARDIOVASCULAR RESEARCH
7	INSTITUTE THERE. HER FOCUS ACTUALLY IS ON STEM
8	CELLS IN DEVELOPMENT IN THE CARDIOVASCULAR SYSTEM IN
9	PARTICULAR. SHE HAS BEEN AWARDED THE BURROUGHS
10	WELLCOME CAREER AWARD.
11	SO THESE ARE JUST THREE SNAPSHOTS. WHAT
12	ABOUT THE BRIDGES PROGRAM? IN A SURVEY THAT WE
13	CONDUCTED IN 2011, TO WHICH THERE WERE RESPONSES
14	REGARDING 163 BRIDGES INTERNS, AT THAT TIME 52
15	PERCENT OF THEM ALREADY HAD JOBS AND 26 PERCENT WERE
16	EITHER ENROLLED OR ACCEPTED INTO GRADUATE OR
17	POSTDOCTORAL OR GRADUATE OR PROFESSIONAL DEGREE
18	PROGRAMS.
19	WE RECENTLY, ACTUALLY AT THE END OF 2012,
20	HAVE CONDUCTED A SIMILAR SURVEY. THE RESULTS ARE
21	NOT IN YET, BUT AT LEAST THEY'RE LOOKING VERY
22	COMPARABLE. AND ACTUALLY THESE RESULTS BEAR OUT
23	SOME OF THE THINGS WE HEAR AT BRIDGES MEETINGS FROM
24	PEOPLE SAYING THAT THESE ARE GREAT STUDENTS AND THEY
25	HIRE THEM.

1	SO ONE EXAMPLE IS MS. LAUGHING BEAR TORREZ
2	WHO WAS AT THE CALIFORNIA STATE UNIVERSITY IN SAN
3	BERNARDINO, PART OF THAT BRIDGES PROGRAM. SHE DID
4	AN INTERNSHIP AT UC RIVERSIDE. SHE GOT A MASTER'S
5	DEGREE AND A BUNCH OF HONORS TO GO WITH IT AND IS
6	CURRENTLY AN EXAMPLE OF A PERSON WHO HAS MOVED ON TO
7	GRADUATE WORK. SHE'S AT STANFORD UNIVERSITY.
8	ANOTHER EXAMPLE IS MR. ANDREW SINGH. HE
9	WAS WITH THE SAN JOSE STATE BRIDGES PROGRAM, DID AN
10	INTERNSHIP AT STANFORD WITH JULIAN SAGE, WHO'S
11	ACTUALLY ONE OF OUR GRANTEES. HE COMPLETED A
12	MASTER'S OF BIOTECHNOLOGY. HE'S MOVED TO INDUSTRY.
13	HE'S ACTUALLY A RESEARCH ASSOCIATE AT IPERIAN WHERE
14	HE WORKS WITH IPSC'S IN MODELING ALZHEIMER'S AND
15	OTHER DISEASES. SO AN EXAMPLE OF SOMEONE WHO GOT A
16	JOB IN INDUSTRY.
17	AND THEN FINALLY, MRS. KANOMI
18	SASAKI-CAPELA WHO WAS A POMONA BRIDGES PROGRAM
19	STUDENT, SCU POMONA. SHE WORKED WITH DR. VICTORIA
20	FOX ON RESEARCH ON THE STANDARDIZATION OF HUMAN
21	PLURIPOTENT STEM CELL CULTURES. SHE'S COMPLETED HER
22	BACHELOR'S DEGREE AND ACTUALLY HAS BEEN HIRED BY
23	THAT SAME INSTITUTION TO WORK IN THE CORE LABORATORY
24	AT USC.
25	SO JUST A COUPLE OF EXAMPLES OF PEOPLE WHO
	20
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1	HAVE GONE ON TO JOBS, WHO HAVE GONE ON TO GRADUATE
2	PROGRAMS, WHO HAVE GONE ON TO JOBS IN INDUSTRY, OR
3	HAVE GONE ON TO JOBS IN ACADEMIA.
4	I'D LIKE TO MOVE ON NOW TO THE BASIC
5	RESEARCH PROGRAM. THE OVERALL OBJECTIVE OF OUR
6	BASIC RESEARCH PROGRAM IS TO PROVIDE THE ESSENTIAL
7	SCIENTIFIC FOUNDATION FOR TRANSLATION AND FOR
8	CLINICAL ADVANCES. AND WE DO THIS BY SUPPORTING
9	RESEARCH THAT PROVIDES AN UNDERSTANDING OF
10	FUNDAMENTAL CELLULAR AND MOLECULAR PROCESSES
11	UNDERLYING STEM CELL BEHAVIOR AND BY FUNDING
12	RESEARCH THAT CAN OFFER US NEW INSIGHTS INTO DISEASE
13	MECHANISMS AND THEREBY PERHAPS INSPIRE NEW
14	THERAPEUTIC STRATEGIES.
15	I SUMMARIZE HERE THE PROGRAMS THAT I'M
16	GOING TO TALK ABOUT. THE SEED AND COMPREHENSIVE
17	PROGRAMS WERE ACTUALLY TWO OF OUR EARLIEST RESEARCH
18	PROGRAMS. AND I THINK YOU'RE WELL AWARE. I THINK
19	THE OUTGROWTH OF THEM HAS BEEN THE BASIC BIOLOGY
20	RESEARCH PROGRAMS, FOUR OF WHICH HAVE BEEN ACTUALLY
21	FUNDED BY THIS BOARD TO DATE, CONCEPT APPROVAL FOR A
22	FIFTH ONE. THIS IS SOMETHING THAT WE TRY AND OFFER
23	ROUTINELY BECAUSE WE BELIEVE THAT BUILDING THAT
24	CONTINUING RESEARCH INTO THESE KEY ASPECTS,
25	UNDERLYING MECHANISMS, HOW THINGS WORK, IS CRITICAL

1	FOR ALL SUBSEQUENT RESEARCH, INCLUDING TRANSLATIONAL
2	RESEARCH.
3	THIS IS JUST TO GIVE YOU A SENSE OF HOW
4	I GUESS IT SHOWS UP THERE WHERE IN THE SPECTRUM
5	THESE PROGRAMS FALL. BOTH THE SEED AWARDS AND THE
6	COMPREHENSIVE AWARDS WERE PREDOMINANTLY FOCUSED ON
7	WHAT I'LL CALL BASIC RESEARCH, AND THE BASIC BIOLOGY
8	IS DEFINITELY FOCUSED ON THAT.
9	I WANT TO TALK A LITTLE BIT ABOUT A KEY
10	ASPECT OF OUR BASIC RESEARCH PROGRAMS, PARTICULARLY
11	THE PROGRAMS THAT COMPRISE THIS BASIC RESEARCH
12	PROGRAM. WE SUPPORT BASIC RESEARCH ON HUMAN STEM
13	AND PROGENITOR CELLS. WHY IS THAT IMPORTANT TO US?
14	FIRST, A LOT OF PEOPLE THE NIH SPENDS MILLIONS OF
15	DOLLARS EVERY YEAR ON THE SUPPORT OF STEM CELL
16	RESEARCH AND MODEL SYSTEMS. CIRM, BECAUSE OF ITS
17	MISSION, HAS CHOSEN TO MORE NARROWLY FOCUS ITS BASIC
18	RESEARCH PROGRAMS. AND THE REASON FOR THIS IS WE
19	BELIEVE THAT STUDIES ON HUMAN SYSTEMS ARE MORE
20	DIRECTLY RELEVANT TO OUR MISSION OF STEM
21	CELL-DERIVED THERAPY DEVELOPMENT. WE KNOW THAT
22	HUMAN CELLS ARE MORE DIFFICULT TO WORK WITH, THEY
23	GROW SLOWER, THEY'RE MORE TECHNICALLY CHALLENGING,
24	AND SO THEY'RE LESS LIKELY TO BE PURSUED, AND IN
25	SOME SENSES MORE LESS LIKELY TO BE FUNDED.

1	ONE OF OUR INITIAL GOALS OR ONE OF THE
2	BOARD'S INITIAL GOALS, ONE OF THE INITIAL THINGS WE
3	WANTED TO DO WHEN THE INSTITUTE WAS FOUNDED, WAS TO
4	ATTRACT RESEARCH NEW TO HUMAN STEM CELL RESEARCH
5	INTO THE FIELD. WE DID THIS THROUGH THE SEED
6	PROGRAM AND THROUGH THE COMPREHENSIVE PROGRAM. THE
7	SEED PROGRAM IS ACTUALLY CLOSED. ACTUALLY THAT'S A
8	POINT I HAVE TO KEEP MAKING IS THAT A LOT OF THE
9	RESEARCH I'M GOING TO TELL YOU ABOUT, THE RFA'S
10	ACTUALLY ARE NOT CLOSED. RESEARCH IS STILL ONGOING.
11	THE SEED IS ACTUALLY A CLOSED PROGRAM.
12	AND AS I SAY, THE GOAL OF THIS WAS TO
13	ATTRACT INVESTIGATORS NEW TO EMBRYONIC STEM CELL
14	RESEARCH INTO THE FIELD TO CONDUCT RESEARCH ON THE
15	BIOLOGY, DERIVATION, AND APPLICATION OF HUMAN
16	EMBRYONIC STEM CELLS AND THEIR DERIVATIVES.
17	WERE WE SUCCESSFUL IN DOING THAT? WELL,
18	AT LEAST BY LOOKING AT THE CIRM PORTFOLIO, WE CAN
19	SAY 42 PERCENT OF THESE PEOPLE WHO MAYBE HAD NEVER
20	WORKED ON A STEM CELL IN THEIR LIFE, 42 PERCENT OF
21	THOSE INVESTIGATORS ACTUALLY HAVE GONE ON AND
22	SUCCESSFULLY COMPETED FOR 38 OTHER CIRM RESEARCH
23	GRANTS. THESE INCLUDE GRANTS NOT JUST IN BASIC
24	BIOLOGY, BUT NEW FACULTY AWARDS AND IN TRANSLATION.
25	I THINK GIVEN THAT, THAT PROBABLY ARGUES THAT WE DID
	23

1	A PRETTY GOOD JOB OF ATTRACTING SOME OF THOSE PEOPLE
2	INTO THE FIELD.
3	IN TOTAL, THE CIRM RESEARCH PROGRAM, THE
4	CIRM BASIC PROGRAM OUTLINED HERE SUPPORTS 164
5	PRINCIPAL INVESTIGATORS WHO ARE CONDUCTING RESEARCH
6	ON HUMAN STEM CELL BIOLOGY. SO WE THINK THAT'S A
7	GOOD THING.
8	WHO ARE THESE PEOPLE? WELL, ONE OF THEM
9	IS ROBERT BLELLOCH. AGAIN, HE IS A PHYSICIAN
10	SCIENTIST, AN M.D. PH.D. HE RECEIVED A SEED GRANT.
11	HE DISCOVERED THAT MICRO-RNA'S, TWO DISTINCT
12	MICRO-RNA'S, PLAY KEY REGULATORY ROLES IN CERTAIN
13	SELF-RENEWAL GENES. NOW WHY IS THIS IMPORTANT?
14	THIS IS IMPORTANT BECAUSE ONE OF THE THINGS YOU HAVE
15	TO BE CONCERNED ABOUT IF YOU ARE GOING TO DO
16	CLINICAL DEVELOPMENT OF A PLURIPOTENT DERIVED
17	THERAPY IS EXPANDING THOSE CELLS, STABLY EXPANDING
18	THOSE CELLS SUFFICIENTLY SO THAT THEY CAN GO INTO A
19	DIFFERENTIATION PATHWAY OR THEY CAN BE AVAILABLE TO
20	DO WHAT YOU WANT. AND SO THIS IS JUST A MECHANISM
21	THAT MAY PROVIDE SOME INSIGHT INTO HOW BETTER TO DO
22	THAT.
23	DR. BLELLOCH, IN ADDITION TO RECEIVING A
24	SEED AWARD, IS THE RECIPIENT OF A NEW FACULTY
25	PHYSICIAN SCIENTIST RESEARCH AWARD AND ALSO WAS

24

1	ACTUALLY NAMED BY THE ISSCR, I BELIEVE THREE YEARS
2	AGO, AS THE ISSCR YOUNG INVESTIGATOR OF THE YEAR.
3	SO HE'S DONE SOME REALLY IMPORTANT WORK IN THE
4	FIELD. HE CONTINUES TO WORK IN THE FIELD.
5	I'M GOING TO TALK NOW ABOUT THE OTHER
6	PROGRAM THAT'S NEAR TO CLOSING OUT IS OUR
7	COMPREHENSIVE RESEARCH PROGRAM. AND THE GOAL OF
8	THIS PROGRAM WAS TO SUPPORT STUDIES IN PLURIPOTENT
9	STEM CELL RESEARCH BY SCIENTISTS WHO HAD A RECORD OF
10	ACCOMPLISHMENT IN THE FIELD, IN THE STEM CELL
11	RESEARCH. SO THESE WERE NOT SCIENTISTS NEW TO THE
12	FIELD, BUT THESE WERE SCIENTISTS WHO PERHAPS WERE
13	NEW TO PLURIPOTENT STEM CELL RESEARCH, PARTICULARLY
14	ESC RESEARCH. AND THE IDEA WAS TO EXPAND THEIR
15	PROGRAMS OR TO TAKE THEM INTO PROMISING NEW
16	DIRECTIONS.
17	AND I THINK LARRY GOLDSTEIN PROBABLY NEEDS
18	NO INTRODUCTION TO THIS AUDIENCE, BUT DR. GOLDSTEIN
19	REALLY HAS MADE SOME SIGNIFICANT ADVANCES. HE
20	GENERATED IPSC FROM ALZHEIMER'S DISEASE PATIENTS.
21	HE DIFFERENTIATED THEM INTO NEURONS, AND HE WAS
22	ABLE, HE WAS THE FIRST TO IDENTIFY THAT NEURONS FROM
23	AD PATIENTS ACTUALLY DISPLAYED AN ABERRANT PHENOTYPE
24	OR ABERRANT PROPERTIES THAT ONE COULD CONSIDER
25	CONSISTENT WITH WHAT WE KNOW ABOUT THE BIOLOGY OF

1	ALZHEIMER'S DISEASE.
2	OBVIOUSLY THE POTENTIAL IMPACT OF THIS IS
3	THAT THIS PROVIDES A WAY PROVIDES ASSAY SYSTEMS
4	ESSENTIALLY FOR DISCOVERING DISEASE MECHANISM AND
5	ALSO ACTUALLY FOR ASKING THE QUESTION ARE THERE
6	MOLECULES, ARE THERE COMPOUNDS THAT REVERSE THESE
7	PROPERTIES, COULD NORMALIZE THESE PROPERTIES, WHICH
8	MAY PROVIDE AT LEAST COMPOUNDS TO BE FURTHER TESTED
9	FOR A POTENTIAL TREATMENT OR CURE FOR ALZHEIMER'S
10	DISEASE.
11	ANOTHER COMPREHENSIVE RESEARCHER IS DR.
12	DEEPAK SRIVASTAVA. IF YOU WANT TO TALK ABOUT A
13	PROMISING NEW DIRECTION, HE WAS ONE OF THE FIRST TO
14	REPORT THAT COMMITTED FIBROBLASTS, SO WE'RE TALKING
15	ABOUT FIBROBLASTS IN THE HEART, WHICH ARE SORT OF
16	THE CONNECTOR CELLS, THESE ARE NOT THE CELLS THAT
17	BEAT, THESE ARE THE CELLS THAT ARE, IF YOU WANT TO
18	CALL THEM, THE CONNECTIVE TISSUE, CAN BE DIRECTLY
19	REPROGRAMMED. THEY CAN BE TURNED INTO FUNCTIONAL
20	CARDIOMYOCYTES WITHOUT GOING THROUGH A PLURIPOTENT
21	OR PROGENITOR STATE. AGAIN, THIS MAY PROVIDE A
22	NOVEL STRATEGY FOR GENERATING NEW HEART CELLS FOR
23	THERAPEUTIC USE.
24	SO THESE ARE JUST A COUPLE OF EXAMPLES OF
25	PEOPLE WHO THE BOARD HAS FUNDED WHO ARE DOING SOME

1	OF THE LEADING WORK IN THE FIELD.
2	WHAT I'D LIKE TO DO NOW IS TALK A LITTLE
3	BIT ABOUT THE TOOLS AND TECHNOLOGIES PROGRAM. IN
4	ORDER TO HAVE RAPID PROGRESS IN A FIELD, YOU REALLY
5	DO NEED IN MANY CASES CERTAIN TOOLS AND TECHNOLOGIES
6	TO MAKE THAT HAPPEN. I CAN REMEMBER ONE OF THE
7	FIRST THINGS, I THINK IT WAS SHORTLY AFTER CIRM WAS,
8	MAYBE IT WAS BEFORE CIRM WAS FORMED, NO, IT WAS
9	SHORTLY AFTER CIRM WAS FORMED, DR. ZACH HALL HELD A
10	SYMPOSIUM. AND HE BROUGHT TOGETHER A LOT OF THE
11	PROMINENT STEM CELL RESEARCHERS, AND THERE WERE
12	TALKS, BUT THERE WAS BREAKOUT SESSIONS. AND EACH OF
13	THE BREAKOUT SESSIONS WAS ASKED TO DELIVER ON WHAT
14	ARE SOME OF THE KEY QUESTIONS THAT NEED ANSWERED.
15	AND A LOT OF IT WAS THE MOLECULAR TOOLS TO DO THE
16	JOB, THE BIOMARKERS THAT DEFINE SPECIFIC CELL TYPES.
17	SO IN RESPONSE TO THAT AND TO COMMENTS
18	THAT WE'VE HEARD ALL ALONG, I THINK, WE IMPLEMENTED
19	THE TOOLS AND TECHNOLOGIES PROGRAM. THE OBJECTIVE
20	OF THAT PROGRAM IS TO SUPPORT THE EARLY STAGE
21	DEVELOPMENT AND EVALUATION OF INNOVATIVE TOOLS AND
22	TECHNOLOGIES TO OVERCOME EXISTING ROADBLOCKS IN
23	BASIC AND IN TRANSLATIONAL RESEARCH. SO THE FIRST
24	TOOLS AND TECHNOLOGIES AWARD LOOKED AT TOOLS FOR
25	BOTH BASIC AND TRANSLATIONAL RESEARCH. THE SECOND
	27

1	WAS FOCUSED ON TRANSLATIONAL TOOLS AND TECHNOLOGIES.
2	THE FIRST AWARD HAS CLOSED. THE SECOND IS STILL
3	ACTIVE.
4	I WOULD SAY THAT I JUST THERE
5	ARE THIS PARTICULAR INITIATIVE HAS BEEN
6	PARTICULARLY POPULAR WITH COMPANIES, AND THEY HAVE
7	BEEN PARTICULARLY SUCCESSFUL IN THIS. SO SEVEN
8	COMPANIES HAVE RECEIVED A TOTAL OF NINE OF THE TOOLS
9	AND TECHNOLOGIES AWARDS.
10	WE WERE INTERESTED IN WHEN WE PUT OUT
11	THE RFA'S, WE'VE BEEN INTERESTED IN SPECIFIC TOOLS
12	AND TECHNOLOGIES IN THESE AREAS. AND THIS JUST
13	GIVES YOU A BREAKDOWN OF THE TWO PROGRAMS. WHEN WE
14	TALK ABOUT MARKERS AND ASSAYS, WE'RE TALKING ABOUT
15	BIOMARKERS AND ASSAYS THAT UTILIZE THEM. CELL LINE
16	DEVELOPMENT INCLUDES THE DEVELOPMENT OF REPORTER
17	LINES, INCLUDES THE DIFFERENTIATION PROTOCOLS. WE
18	TALK ABOUT BIOPROCESS. WE'RE TALKING ABOUT METHODS
19	FOR SCALE-UP, CRYO PRESERVATION, SCREENING,
20	TECHNOLOGIES THAT OFFER HIGH THROUGHPUT WAYS OF
21	DOING THINGS. TISSUE ENGINEERING. ARE THERE
22	SCAFFOLD TECHNOLOGIES THAT COULD IMPROVE
23	DIFFERENTIATION OR IMPROVE THE DELIVERY? SPECIFIC
24	CELL DELIVERY DEVICES, DISEASE MODELING SYSTEMS, AND
25	FINALLY IMAGING. IMAGING IS SO CRITICAL BOTH IN THE

1	CLINIC AND PRECLINICALLY. SO THESE ARE THE AREAS IN
2	WHICH WE'VE ASKED APPLICANTS TO FOCUS THEIR WORK.
3	I WANT TO TALK ABOUT A COUPLE OF EXAMPLES
4	AGAIN FROM THIS PROGRAM. THIS ONE IS FROM TOOLS AND
5	TECHNOLOGIES I. IT WAS TO VALA SCIENCES. THE PI
6	WAS DR. MCDONOUGH. WHAT CIRM DID WAS CONTRIBUTE TO
7	THE DEVELOPMENT OF TECHNOLOGY AND AN ASSOCIATED
8	INSTRUMENT CALLED A KINETIC IMAGING CYTOMETER THAT
9	ENABLES HIGH THROUGHPUT MEASUREMENTS OF THE
10	ELECTRICAL BEHAVIOR OF HEART CELLS AND SPECIFIC
11	SUBTYPES OF HEART CELLS IN A HETEROGENEOUS
12	POPULATION OF CELLS. SO IT ACTUALLY CAN LOOK AT
13	SINGLE CELL MEASUREMENTS WITHIN A POPULATION.
14	AND AS A RESULT OF ACTUALLY THIS
15	TECHNOLOGY, VALA SCIENCES HAS GOTTEN A CONTRACT FROM
16	THE EPA AS ONE OF THE CONTRACT PROVIDERS TO THEIR
17	TOXCAST PROGRAM. AND WHAT TOXCAST IS, IT USES
18	ADVANCED SCIENCE TOOLS TO HELP UNDERSTAND HOW THE
19	HUMAN BODY PROCESSES ARE IMPACTED BY EXPOSURE TO
20	CHEMICALS. AND IT HELPS TO DETERMINE WHICH
21	EXPOSURES ARE LIKELY TO LEAD TO ADVERSE HEALTH
22	EFFECTS. IN THE CONTEXT OF VALA'S TECHNOLOGY, WHAT
23	THEY'RE LOOKING FOR ARE ARRHYTHMIAS. THEY'RE
24	LOOKING FOR ABNORMAL CALCIUM SPIKES, ELECTRICAL
25	MEASUREMENTS.

1	AND VALA IS ACTUALLY ONE OF FOUR
2	CONTRACTORS WHO WAS CHOSEN BY THE EPA FOR THIS
3	PROGRAM. AND SO THAT'S ACTUALLY PRETTY EXCITING.
4	THEY'VE ALSO FORMED A COLLABORATION WITH
5	VISTAGEN. VALA IS PROVIDING ESSENTIALLY THE
6	TECHNOLOGY PLATFORM OF THE SCREENING PLATFORM.
7	VISTAGEN IS PROVIDING THEIR HUMAN PLURIPOTENT STEM
8	CELL-DERIVED CARDIOMYOCYTES, AND THEY'RE OFFERING
9	THAT AS A SCREENING SERVICE FOR NEW DRUG CANDIDATES.
10	FIRST THEY'RE VALIDATING THE TECHNOLOGY, THAT IT
11	DOES A BETTER JOB THAN, SAY, ANIMAL MODELS OR OTHER
12	CELL LINES. THESE ARE SOME OF THE TOOLS AND
13	TECHNOLOGIES THAT IN SOME INSTANCES CAN BE USED TO
14	REPLACE ASSAYS, CELL LINE ASSAYS, THAT ARE NOT AS
15	PREDICTIVE OR ANIMAL MODELS OR DECIDE WHAT GOES INTO
16	ANIMAL MODELS SO THAT YOU DON'T NEED TO USE AS MANY
17	ANIMALS.
18	ANOTHER EXAMPLE THAT I WANT TO HIGHLIGHT
19	IS A TOOLS AND TECHNOLOGIES AWARD TO JEAN LORING AT
20	THE SCRIPPS RESEARCH INSTITUTE. AND THE GOAL HERE
21	WAS TO DEVELOP THE STEM CELL MATRIX DATABASE AND
22	ASSOCIATED BIOINFORMATICS TOOLS TO DEFINE COMMON
23	FEATURES OF ACTUALLY PLURIPOTENT AND DIFFERENTIATED
24	CELLS. AND THE IDEA HERE IS IF YOU CAN DEFINE A
25	GENE EXPRESSION OR AN EPIGENETIC SIGNATURE THAT IS
	30
	j JV

1	COMMON TO ALL PLURIPOTENT CELLS, THIS IS A RAPID WAY
2	OF SCREENING WITH YOUR COMPUTER WITHOUT DOING A WET
3	LAB EXPERIMENT WHETHER OR NOT YOU ACTUALLY HAVE
4	WELL, ACTUALLY YOU DO HAVE TO GO THE WET LAB
5	EXPERIMENT BECAUSE YOU HAVE TO HAVE THE GENE
6	EXPRESSION DATA, BUT IT ALLOWS YOU TO DETERMINE DO
7	YOU HAVE A PLURIPOTENT LINE. SO IT COULD
8	POTENTIALLY REPLACE A VERY CUMBERSOME IN VIVO
9	TERATOMA ASSAY OR AT LEAST COULD TELL YOU WHEN YOU
10	DRIVE IPS LINES, DO I HAVE A LINE THAT IS
11	PLURIPOTENT BECAUSE IT HAS A SIGNATURE THAT LOOKS
12	LIKE THAT OF MULTIPLE OTHER PLURIPOTENT LINES?
13	AT THIS POINT DR. LORING HAS UP TO 5,000
14	SAMPLES IN HER DATABASE. HER SIGNATURE HAS BEEN
15	THE SIGNATURES ARE BEING REFINED. SO IT WAS
16	INITIALLY ROUGHLY, I THINK, A FEW HUNDRED LINES AND
17	IT'S FAR LARGER NOW. IT IS PUBLICLY AVAILABLE OVER
18	THE WEB. THERE ARE OVER 1500 DATA UPLOADS. YOU
19	HAVE TO UPLOAD YOUR GENE EXPRESSION DATA IN ORDER TO
20	DO THE COMPARATIVE ANALYSIS TO SAY, YES, I HAVE A
21	CELL THAT LOOKS LIKE A PLURIPOTENT CELL OR NOT.
22	SO WHY IS THIS IMPORTANT? AS I SAY, IT
23	COULD PROVIDE A RESEARCH TOOL FOR ASCERTAINING
24	PLURIPOTENCY, FOR DO I HAVE A DIFFERENTIATED CELL
25	TYPE. SO SHE'S EXPANDING THIS TO DIFFERENTIATE.
	31

1	JUST TO GIVE YOU AN EXAMPLE THAT MAY BE DIRECTLY
2	RELEVANT TO US, OUR IPSC PROGRAM, WE'RE ASKING
3	PEOPLE TO DERIVE TAKE 3,000 PATIENTS AND DERIVE
4	9,000 LINES FROM THOSE. AND HOW ARE YOU GOING TO
5	CHARACTERIZE THOSE LINES TO KNOW THAT THEY'RE
6	PLURIPOTENT? YOU'RE NOT GOING TO BE ABLE TO DO
7	TERATOMA IN VIVO ASSAYS ON ALL OF THEM. SO TOOLS
8	LIKE THIS, TOOLS THAT RELY ON SORT OF SURROGATES FOR
9	PLURIPOTENCY, ARE GOING TO BECOME INCREASINGLY
10	IMPORTANT.
11	THERE ARE TWO OTHERS I WANT TO MENTION.
12	DR. LARRY COUTOURE AT THE BECKMAN RESEARCH INSTITUTE
13	OF THE CITY OF HOPE HAS DONE WORK IN THE BIOPROCESS
14	PRIORITY AREA. HE HAS DEVELOPED AN EFFICIENT AND
15	CGMP COMPLIANT SUSPENSION-BASED CULTURE SYSTEM FOR
16	HUMAN EMBRYONIC STEM CELLS, BASICALLY FOR
17	PLURIPOTENT STEM CELLS. HE'S ALSO GENERATED SOME
18	BANKS WHICH COULD BE MADE BROADLY AVAILABLE TO THE
19	RESEARCH COMMUNITY.
20	WHY IS THIS IMPORTANT? PLURIPOTENT STEM
21	CELLS ARE TYPICALLY GROWN AS ADHERENT CULTURES.
22	THAT MEANS THEY SIT ON A PLASTIC DISH. NOW, START
23	THINKING ABOUT HOW MANY PLASTIC BOTTLES YOU NEED TO
24	TREAT CERTAIN KINDS OF DISEASES. REALLY IT BECOMES
25	MIND-BOGGLING VERY, VERY QUICKLY. SUSPENSION
	32

1	CULTURE IS BASICALLY A PATH TO COMMERCIALIZATION.
2	CELLS DON'T JUST GO FROM GROWING ON PLASTIC. AS
3	MANY OF YOU PROBABLY KNOW, PLURIPOTENT CELLS ARE
4	TYPICALLY GROWN ON SO-CALLED FEEDER CELLS. NOT ONLY
5	DO THEY GROW ON PLASTIC, THEY HAVE TO GROW ON FEEDER
6	CELLS. SO IT'S ACTUALLY A VERY BIG DEAL TO DEVELOP
7	A TECHNOLOGY THAT ALLOWS YOU TO ADAPT A PLURIPOTENT
8	STEM CELL LINE TO NOT REQUIRING FEEDER CELLS TO
9	GROWING ON DEFINED MEDIA, YOU KNOW WHAT'S IN IT, AND
10	IT'S NOT NECESSARILY ANIMAL DERIVED, AND TO GROW IN
11	SUSPENSION CULTURE. SO WE'RE EXCITED ABOUT THAT.
12	AND FINALLY, FOR THE TOOLS AND
13	TECHNOLOGIES, I'D LIKE TO HIGHLIGHT DR. UNGER AT
14	FLUIDIGM WHO HAS DEVELOPED ONE OF THESE HIGH
15	THROUGHPUT SCREENING TOOLS. DR. UNGER HAS ACTUALLY
16	SUCCESSFULLY COMPETED FOR A SECOND TOOLS AND
17	TECHNOLOGIES AWARD TO CONTINUE TO DEVELOP THIS
18	TECHNOLOGY.
19	THEY HAVE OPTIMIZED AND SCALED UP A HIGHLY
20	ADVANCED MICROFLUIDIC CELL CULTURE SYSTEM WHICH IS
21	COMPATIBLE WITH MANUFACTURE. SO YOU CAN ACTUALLY
22	IT'S NOT A CUSTOM-BASED THING. THEY PRODUCE THE
23	PROTOTYPE INSTRUMENTS TO DRIVE THESE CHIPS. CIRM
24	FUNDING ACTUALLY HAS BEEN A CATALYST THAT ENABLED
25	THIS TO BE A FOCUS WITHIN THE COMPANY. SO THE

1	TECHNOLOGY IS BEING FURTHER DEVELOPED WITH A TOOLS
2	AND TECHNOLOGIES II AWARD. THE COMPANY IS ALSO
3	CO-FUNDING THAT. AND THE IDEA IS AT THE END OF THE
4	AWARD TO HAVE THREE COMPLEMENTARY INSTRUMENTS: A
5	CONTROLLER INSTRUMENT WHICH IS CAPABLE OF FULL
6	FLUIDIC AND ENVIRONMENTAL CONTROL ON ONE CHIP. SO
7	YOU CAN TEST A LOT OF DIFFERENT VARIABLES IN CULTURE
8	CONDITIONS. SO THAT'S WHAT FULL FLUIDIC AND
9	ENVIRONMENTAL CONTROL MEANS.
10	IT INCLUDES A HOTEL INSTRUMENT WHICH IS
11	CAPABLE OF LIMITED FLUIDIC AND ENVIRONMENTAL CONTROL
12	ON MULTIPLE TRIPS. THIS IS WHERE YOU PARK THEM TO
13	SEE IF THE CELLS GROW OR DIE AFTER YOU'VE TREATED
14	THEM WITH ALL THESE DIFFERENT CONDITIONS.
15	AND FINALLY, A READER WHICH IS CAPABLE OF
16	IMAGING THE CELLS IN THE CHIP IN PHASED CONTRAST AND
17	FLUORESCENT MODES. THIS IS READOUTS. WHAT CELLS
18	DIED UNDER WHAT CONDITIONS? SO THIS ALLOWS YOU TO
19	OPTIMIZE SURVIVAL CONDITIONS, PROLIFERATION
20	CONDITIONS, DIFFERENTIATION CONDITIONS. IT ALLOWS
21	YOU TO DO A LOT OF DIFFERENT THINGS.
22	OKAY. I'M NOW GOING TO MOVE TO THE EARLY
23	TRANSLATION PROGRAM AND REMIND YOU STEM CELL
24	RESEARCH IS MOVING PRETTY FAST. WE ARE ALREADY
25	SEEING THINGS. PEOPLE BELIEVE THAT THE FIELD HAS

PROGRESSED SO THAT WE CAN START THINKING ABOUT HOW
MIGHT WE TREAT DISEASE. WE ALSO KNOW THAT MANY OF
ADULT STEM CELL TYPES ARE IN THE CLINIC. BUT AN
IMPORTANT WHAT THE EARLY TRANSLATION PROGRAM DOES
IS IT ADDRESSES THE RESEARCH NECESSARY TO EXPLORE
THE APPLICATION OF THE BASIC STEM CELL SCIENCE
TOWARDS POSSIBLE TREATMENT OF HUMAN DISEASE AND
INJURY. IT'S REALLY THE VEHICLE WE HAVE FOR TESTING
NEW HYPOTHESES AND APPROACHES FOR THE TREATMENT OF
DISEASE AND INJURY.
SO THE PURPOSE OF THE PROGRAM IS TO
ACTUALLY FUND THOSE ACTIVITIES THAT COULD FACILITATE
OR MOVE PROMISING STEM CELL RESEARCH TOWARDS
CLINICAL TESTING.
NONE OF THE ET PROGRAMS ARE CLOSED YET.
THE ET I PROGRAM IS EXPECTED TO CLOSE THIS YEAR,
HOPEFULLY PROBABLY MORE LIKE TOWARDS THE END OF THIS
YEAR. THE OTHERS YOU CAN SEE THE PROJECTED DATES.
AND THE ET PROGRAM HAS EVOLVED A LITTLE
BIT. THE FIRST PROGRAM LOOKED AT BOTTLENECKS. THE
SUBSEQUENT PROGRAMS HAVE DONE WHAT WE CALL
DEVELOPMENT CANDIDATE FEASIBILITY AWARDS AND
DEVELOPMENT CANDIDATE AWARDS. SO THE BREAKDOWN IS
THERE.
LET ME TELL YOU A LITTLE BIT ABOUT WHAT WE
35

1	MEAN BY THOSE BOTTLENECKS AWARDS, TO RESOLVE A
2	SIGNIFICANT BOTTLENECK IN THE TRANSLATION OF STEM
3	CELL BIOLOGY. THERE WERE SEVEN OF THOSE AWARDS.
4	DEVELOPMENT CANDIDATE FEASIBILITY AWARDS ACTUALLY
5	ARE THIS HYPOTHESIS TESTING, AND REALLY THE END
6	POINT THERE IS A PROOF OF PRINCIPLE. DOES MY
7	HYPOTHESIS HOLD WATER? DOES IT MAKE SENSE? DOESN'T
8	NECESSARILY NEED TO BE AN IN VIVO MODEL. IT COULD
9	BE CELL TESTING. IF I BELIEVE THAT REMYELINATION BY
10	OLIGODENDROCYTES IS AN IMPORTANT HYPOTHESIS HERE, DO
11	MY CELLS DO THAT? DO I HAVE A COMPOUND THAT
12	SIMULATES THAT? THAT'S WHAT WE ASK OF THOSE AWARDS.
13	AND WE HAVE, I BELIEVE, 20 OF THOSE HAVE BEEN
14	AWARDED.
15	IN CONTRAST, THE DEVELOPMENT CANDIDATE
16	AWARDS ARE REALLY WE'RE ASKING YOU TO COMPLETE ALL
17	THE KEY ACTIVITIES. SO YOU HAVE PRESUMABLY, WHICH
18	IS WHY IT'S LIGHTER ON THE END FOR THE DC AWARDS,
19	YOU HAVE SOME AT LEAST IDEALLY PROOF OF CONCEPT THAT
20	YOUR HYPOTHESIS HAS SOME VALIDITY, BUT THEN IT'S
21	DOING ALL THE NECESSARY ACTIVITIES TO GET TO A POINT
22	WHERE YOU CAN TO ENABLE A ROBUST DECISION ON THE
23	POTENTIAL FOR THIS BENEFITING PEOPLE. MOVING INTO
24	DEVELOPMENT IS ACTUALLY A BIG DEAL. AS ELLEN
25	INDICATED IN HER INTRODUCTION, IND-ENABLING
	36
	j Ju

1	ACTIVITIES TO MOVE THINGS INTO PEOPLE ARE COMPLEX
2	AND VERY EXPENSIVE. AND SO ONE DOESN'T TAKE LIGHTLY
3	THE KINDS OF DECISIONS, THE COMPOUNDS THAT ACTUALLY
4	ONE CHOOSES TO MOVE INTO IND-ENABLING RESEARCH.
5	THIS IS ALWAYS A BIG DECISION IN ANY COMPANY. AND
6	SO WHAT WE ASK FOR OUT OF OUR DEVELOPMENT CANDIDATE
7	IS THEY COMPLETE THOSE ACTIVITIES THAT ENABLE MAKING
8	THAT DECISION.
9	THIS IS JUST TO SHOW YOU THAT AMONG THE
10	DCF'S, THE DEVELOPMENT CANDIDATE FEASIBILITY AWARDS,
11	AND THE DC AWARDS, THE SPECTRUM OF THE THERAPEUTIC
12	AREA SPECTRUM. AND ACTUALLY IT'S QUITE BROAD. AND
13	WHEN I SAY THERAPEUTIC AREA, YOU CAN PROBABLY I
14	CAN SEE IT HERE. NEURODEGENERATIVE DISORDERS, SO
15	THAT ENCOMPASSES ALZHEIMER'S DISEASE, PARKINSON'S.
16	SO WITHIN EVEN A GIVEN AREA, NEURODEGENERATIVE
17	DISEASE WHERE WE BELIEVE SOME OF THE LEARNINGS IN
18	ONE DISEASE COULD IMPACT THE OTHER. NONETHELESS YOU
19	HAVE SEVERAL DISEASES.
20	SO WE HAVE NINE THERAPEUTIC AREAS
21	REPRESENTED IN OUR DCF AWARDS, AND WE HAVE 15 IN OUR
22	DC AWARDS.
23	THIS IS SOMETHING THAT IS PROBABLY WORTH
24	THINKING ABOUT BECAUSE AT SOME POINT WHERE CAN WE
25	GET WE CANNOT MOVE ALL OF THE THINGS FORWARD TO

1	THE CLINIC. ACTUALLY ALL OF THEM MAY NOT PAN OUT
2	EITHER SCIENTIFICALLY OR ACTIVITYWISE. THE OTHER
3	THING THAT WE ASK WHEN WE CHOOSE A DEVELOPMENT
4	CANDIDATE IS IS THERE AN OPPORTUNITY THERE? WHAT IS
5	THE NEED?
6	SO WE'LL SEE HOW THAT DEVELOPS, BUT THIS
7	IS THE DISTRIBUTION OF BOTH THE NUMBERS OF PROGRAMS
8	AND THE DOLLARS.
9	AS FAR AS OUTCOMES GO TO DATE, ACTUALLY OF
10	THOSE THAT HAVE ACTUALLY MOVED INTO DISEASE TEAMS,
11	TO DATE TWO ET DEVELOPMENT CANDIDATE AWARDS HAVE
12	ACTUALLY CONTRIBUTED TO DISEASE TEAM AWARDS THAT
13	HAVE BEEN FUNDED BY THIS BOARD. ONE OF THEM WAS AN
14	AWARD TO FRANK LAFERLA AND UCI WHO WAS LOOKING AT A
15	NEURAL STEM CELL BASED-THERAPY FOR ALZHEIMER'S
16	DISEASE. AND AS YOU KNOW, THE STEM CELL
17	INC. PROGRAM, HE CONTRIBUTED A LOT OF WORK TO THAT
18	PROGRAM THROUGH THAT AWARD. SO IT'S AN ALLOGENEIC
19	NSC-BASED PROGRAM.
20	AND THEN SECOND WAS THE KLASSEN AWARD, AN
21	EARLY TRANSLATIONAL II AWARD ACTUALLY, THAT MOVED AT
22	THE SPEED OF LIGHT AND WAS TO TREAT RETINITIS
23	PIGMENTOSA. AND, AGAIN, THIS IS ALLOGENEIC RETINAL
24	PROGENITOR CELLS.
25	I WOULD ALSO POINT OUT THAT IN THE YOU
	38
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1	ARE GOING TO HEAR TOMORROW AS MOST OF THE ET I
2	AWARDS ARE JUST ENDING, IT IS POSSIBLE THAT THROUGH
3	THE ET I, ET ALLOWANCE PATHWAY THAT YOU'RE GOING TO
4	HEAR ABOUT TOMORROW AS AN OPTION FOR DISEASE TEAM
5	III PROGRAM, THAT MORE OF THE ET AWARDS WILL AT
6	LEAST APPLY TO MOVE INTO DISEASE TEAMS. SO THE
7	TIMING IS VERY GOOD IN THAT SENSE. AND JUST FROM
8	OUR KNOWLEDGE OF THE PROGRAMS, WE COULD EXPECT THAT
9	THERE WILL BE A FEW THAT WILL PURSUE THAT PATH.
10	MEANWHILE I WOULD LIKE TO GIVE YOU SOME
11	EXAMPLES FROM THIS PROGRAM. THESE ARE EXAMPLES FROM
12	THE BOTTLENECK PORTION OF THE PROGRAM. THIS IS DR.
13	LANGSTON WITH THE PARKINSON'S RESEARCH INSTITUTE.
14	AND THE GOAL OF HIS PROGRAM WAS TO DEVELOP A MODEL
15	FOR PARKINSON'S IN A DISH USING PATIENT-DERIVED
16	LINES TO STUDY DISEASE MECHANISMS. AND WHAT HE DID
17	WAS THEY HAVE ACTUALLY COLLECTED SAMPLES FROM A
18	NUMBER OF PARKINSON'S DISEASE PATIENTS AND FROM
19	CONTROLS WHO HAVE KNOWN CAUSATIVE MUTATIONS.
20	SO THIS IS THE LRRK2 MUTATION OR THE
21	SYNUCLEIN GENE MUTATION WHO ARE KNOWN TO SHOW
22	GREATER SUSCEPTIBILITY TO PARKINSON'S DISEASE. AND
23	WHAT HE HAS SHOWN IS IN COMPARISON TO CONTROL LINES,
24	THEY ARE GETTING READOUTS. ONE OF THE ONES THAT
25	THEY'VE PUBLISHED IS THAT THESE CELL LINES, LINES
	39
) J J

1	DERIVED FROM THESE PATIENTS ACTUALLY SHOW GREATER
2	SUSCEPTIBILITY TO CELLULAR TOXINS. THEY'RE LOOKING
3	AT A VARIETY OF OTHER READOUTS INCLUDING NEURITE
4	OUTGROWTHS. THEY, IN ESSENCE, HAVE CREATED A
5	PARKINSON IPS RESOURCE. AND THIS HAS ACTUALLY
6	RESULTED IN THEM ACHIEVING THEY HAVE A LOT OF
7	COLLABORATIONS NOW. THEY GOT SUPPLEMENTAL FUNDING
8	FROM ONE OF OUR COLLABORATIVE FUNDING PARTNERS,
9	BMBF, TO LOOK AT TO BETTER UNDERSTAND THE ALPHA
10	SYNUCLEIN ACCUMULATION IN THESE CELLS USING LIVE
11	CELL IMAGING. THEY ACTUALLY HAVE COLLABORATIONS
12	WITH SOME PHARMA COMPANIES, WITH A PHARMA COMPANY
13	NOW, TO SHOW PROOF OF PRINCIPLE THAT THESE CELL
14	LINES CAN BE SCREENED FOR REVERSAL OF PHENOTYPE WITH
15	SOME COMPOUNDS.
16	SO THEY ARE ACTUALLY THIS RESOURCE,
17	FUNDING OF CREATION OF THESE LINES,
18	CHARACTERIZATION, DEMONSTRATING OF DISEASE-SPECIFIC
19	PROPERTIES COMPARED TO NORMAL HAS BEEN VERY HELPFUL
20	IN ESSENTIALLY EXPANDING KNOWLEDGE ABOUT THIS AREA,
21	THE POTENTIAL FOR SCREENING FOR COMPOUNDS. AND
22	THEY'RE EXCITED.
23	FINALLY, I WOULD LIKE TO TALK ABOUT ONE
24	OTHER BIO BOTTLENECK PROGRAM THAT WAS FUNDED THROUGH
25	THE EARLY TRANSLATIONAL PROGRAM, AND THIS WAS A

40

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1	BOTTLENECK, AGAIN, MORE RELEVANT DISEASE MODELS. I
2	THINK YOU'VE ALL HEARD OF THE JACKSON LABORATORIES.
3	IT'S ONE OF THE MOST RESPECTED LABORATORIES IN THE
4	WORLD FOR BIOMEDICAL USING GENETICALLY DERIVED
5	MICE, MICE WITH ALL SORTS OF DIFFERENT GENE
6	MUTATIONS, AS A BIOMEDICAL RESEARCH TOOL. THEY DO
7	RESEARCH ON THIS. THEY ALSO MAKE SERVICES
8	AVAILABLE.
9	AND ONE OF THE THINGS THAT WE FUNDED WAS
10	WE ELIMINATED BOTTLENECKS TO TRANSLATION OF STEM
11	CELL RESEARCH BY DEVELOPING STANDARDIZED MOUSE
12	MODELS IN APPROPRIATE BACKGROUND. APPROPRIATE
13	GENETIC BACKGROUND OR APPROPRIATE BACKGROUND IS
14	REALLY IMPORTANT WHEN YOU'RE TALKING ABOUT CELL
15	THERAPIES. YOU CANNOT JUST PUT HUMAN CELLS INTO A
16	NORMAL MOUSE AND EXPECT TO SEE ANYTHING.
17	JACKSON IS ONE OF THE LEADERS IN
18	DEVELOPING IMMUNODEFICIENT MICE. AND THEN ANOTHER
19	THING ABOUT MODELS IS STANDARDIZED. WE'VE ALL HAD
20	EXPERIENCE WITH PRECLINICAL MODELS IN A LABORATORY
21	THAT, UNLESS YOU VERY CAREFULLY CONTROL FOR
22	CONDITIONS, YOU HAVE ONE EXPERIMENT THAT GIVES YOU X
23	RESULTS AND ANOTHER THAT GIVES YOU Y. SO WHAT THEY
24	HAVE DONE IS THEY HAVE REALLY DEVELOPED STANDARDIZED
25	MODELS, AND THEY HAVE RELEASED MOUSE MODELS NOW THAT

1	ARE AVAILABLE TO RESEARCHERS EITHER FOR USE IN THEIR
2	OWN LAB OR FOR CONTRACT SERVICES THROUGH THE JACKSON
3	LABORATORY FOR PARKINSON'S DISEASE, TYPE 1 DIABETES,
4	AND TWO MODELS OF MULTIPLE SCLEROSIS.
5	THESE ARE ACTUALLY CRITICAL TO
6	FACILITATING THE TRANSLATION OF HUMAN CELL-BASED
7	THERAPIES BECAUSE THEY ENABLE YOU TO LOOK AT DISEASE
8	MODIFYING ACTIVITY, THEY ENABLE YOU TO LOOK AT CELL
9	FATE AND MIGRATION, THEY HELP YOU DETERMINE DOSE AND
10	SAFETY IN A DISEASE SETTING. AND SO THIS IS ONE OF
11	THE OTHER EXAMPLES OF THE OUTCOMES OF RESEARCH THAT
12	CIRM HAS FUNDED.
13	SO AT THIS POINT, I'D LIKE TO TURN IT BACK
14	OVER TO ELLEN TO TALK ABOUT THE DISEASE TEAM
15	RESEARCH AWARDS.
16	DR. FEIGAL: THANK YOU. AND SO THAT WAS
17	REALLY TO GIVE YOU A TASTE OF SOME OF THE KEY
18	HIGHLIGHTS FROM OUR MANY CORE PROGRAMS GIVEN WE ONLY
19	HAVE A FINITE PERIOD OF TIME. WE'RE OBVIOUSLY NOT
20	GOING TO GO THROUGH 560 AWARDS ONE BY ONE, BUT WE
21	WERE TRYING TO DO BOTH IN THE PREREAD AND FROM THIS
22	PRESENTATION GIVE YOU A TASTE OF THE TYPE OF
23	ADVANCES THAT ARE MOVING FORWARD.
24	AND I ALSO JUST WANT TO LET YOU KNOW IN
25	MARCH AT THE MARCH ICOC BOTH PAT AND I WILL BE

1	COMING BACK TO YOU WITH MORE IN-DEPTH DETAILS ABOUT
2	BOTH THE DISEASE TEAM RESEARCH AWARDS AS WELL AS
3	ABOUT THE EARLY TRANSLATION AWARDS.
4	SO MOVING RIGHT ALONG WITH THE DISEASE
5	TEAM RESEARCH AWARDS, THIS IS REALLY FOCUSED ON
6	MOVING INTO THE CLINIC. SO WE'VE DONE THE BASIC
7	RESEARCH, WE'VE GOT THAT PRECLINICAL PROOF OF
8	CONCEPT, WE'RE READY TO GO. AND SO THIS IS REALLY
9	FOCUSED ON WHAT ARE THE ACTIVITIES WE NEED TO DO TO
10	ACTUALLY ENSURE WHAT WE'RE WORKING WITH. WE'VE GOT
11	AN IDEA OF WHAT THE DOSE MIGHT BE IN THE HUMAN, WHAT
12	THERAPEUTIC INDICATIONS MIGHT BE THE APPROPRIATE ONE
13	TO TEST THIS THERAPEUTIC APPROACH IN, AND THEN MAKE
14	SURE THAT THE ACTIVITIES THAT WE'RE DOING IN THIS
15	AWARD WILL MEET THE STANDARDS OF THE FOOD AND DRUG
16	ADMINISTRATION. SO THIS IS NOT JUST RESEARCH. THIS
17	IS ACTUALLY GOING DOWN A DEVELOPMENT PATHWAY.
18	THERE ARE SPECIFIC STANDARDS, THERE ARE
19	SPECIFIC TYPES OF THINGS THAT HAVE TO BE
20	ACCOMPLISHED BEFORE THESE TYPES OF THERAPIES CAN GO
21	INTO HUMAN BEINGS. EVEN THOUGH THESE ARE DISEASES
22	WITH HIGH UNMET CLINICAL NEED, THEY ARE VERY
23	DEBILITATING DISEASES. THERE'S STILL STANDARDS THAT
24	THE UNITED STATES HAS BEFORE THESE TYPES OF
25	THERAPIES CAN GET INTO HUMANS.

1	SO THIS IS EXACTLY THE TYPE OF RESEARCH
2	THAT IS NOT FUNDED BY TRADITIONAL FUNDING AGENCIES
3	OR IS HIGH RISK SO THAT INVESTORS OR OTHER COMPANIES
4	DON'T WANT TO FUND THIS. SO WE'RE IN THE SPACE OF
5	WHAT WE CALL THE VALLEY OF DEATH WHERE WE ARE TRYING
6	TO PROVIDE THE FUNDING TO GET INVESTIGATORS THROUGH
7	THIS AREA OF RESEARCH AND DEVELOPMENT SO THAT WE CAN
8	GO INTO THESE EARLY PHASE CLINICAL TRIALS.
9	SO AT THIS STAGE WHAT WE'VE DONE SO FAR IS
10	WE'VE AWARDED ONE COHORT OF DISEASE TEAMS WHERE THEY
11	WERE STARTING WITH THEIR GOAL OF FILING THAT IND TO
12	GET APPROVAL BY THE FOOD AND DRUG ADMINISTRATION,
13	AND THAT'S REQUIRED BEFORE IT CAN GO INTO HUMANS.
14	AND THEN THE SECOND COHORT OF DISEASE TEAMS, WE DID
15	THAT A COUPLE YEARS LATER. THE FIELD WAS MOVING;
16	THINGS WERE MATURING. WE TOOK MORE MATURE PROJECTS
17	AND NOW ASKED THEM TO HAVE A HIGHER GOAL. YOU HAVE
18	TO COMPLETE A CLINICAL TRIAL. SO THOSE DISEASE
19	TEAMS HAVE THE OPTION OF EITHER FILING THE IND OR
20	COMPLETING A CLINICAL TRIAL.
21	AND THEN WITH OUR RECENT STRATEGIC
22	PARTNERSHIP AWARDS, WHICH WILL NOT BE THE TOPIC OF
23	TODAY, ONCE AGAIN, WE'RE WORKING AT A MORE MATURE
24	TYPE OF PRODUCT WHERE THE GOAL THERE IS ACTUALLY TO
25	COMPLETE A CLINICAL TRIAL.

1	THIS IS WHAT WE'VE INVESTED SO FAR IN THE
2	TWO COHORTS OF DISEASE TEAM. I CAN TELL YOU NEXT
3	WEEK WE'RE GOING TO BE POSTING OR SOMETIME THIS
4	MONTH WE'RE GOING TO BE POSTING THE NEXT ITERATION
5	OF DISEASE TEAMS. SO THERE'S GOING TO BE CONTINUED
6	INVESTMENT IN THIS AREA.
7	BUT WITH THE FIRST COHORT OF DISEASE
8	TEAMS, IT WAS ACTUALLY THE TEAMS ACTUALLY DIDN'T
9	GET THE MONEY UNTIL 2010, AND THERE WERE 14
10	DIFFERENT TEAMS THAT WERE AWARDED WITH THAT FIRST
11	COHORT. ALL OF THOSE TEAMS HAD AS THEIR AIM FILING
12	AN IND SO THAT THEY HAD THE ABILITY TO ENTER A
13	CLINICAL TRIAL. IT WASN'T PAYING FOR THE CLINICAL
14	TRIAL, BUT IT WAS PAYING FOR ALL THE WORK THAT'S
15	NEEDED TO GET TO THE FILING. AND SO FAR THIS 228
16	MILLION HAS BEEN INVESTED IN THOSE 14 TEAMS.
17	THE SECOND COHORT OF DISEASE TEAMS, WHICH
18	WAS ACTUALLY JUST AWARDED LATE LAST YEAR, THERE ARE
19	11 TEAMS THAT WERE AWARDED. BETWEEN THE TWO, WE
20	HAVE 25 DIFFERENT PROGRAMS THAT HAVE BEEN AWARDED,
21	ONE IN 2010, ONE AT THE END OF 2012 TO A TOTAL OF
22	436 MILLION. SEVENTEEN OF THEM HAS AS THEIR MAIN
23	AIM FILING THAT IND. EIGHT OF THEM HAVE AS THEIR
24	MAIN AIM COMPLETING AN EARLY PHASE CLINICAL TRIAL.
25	DR. OLSON SHOWED YOU THE DIFFERENT
	45
	T.J.

1	THERAPEUTIC AREAS THAT THE DEVELOPMENT CANDIDATES
2	AND THE DEVELOPMENT CANDIDATE FEASIBILITY PROGRAMS
3	WERE FOCUSED ON. THESE ARE THE THERAPEUTIC AREAS
4	THAT OUR DISEASE TEAMS ARE FOCUSED ON. AS YOU CAN
5	TELL, WE'RE STILL QUITE AGNOSTIC IN TERMS OF THE
6	THERAPEUTIC AREA. IT'S PRETTY BROAD. AS I
7	MENTIONED, IN THE EARLY STAGES OF CIRM, WE'VE BEEN
8	EXPLORATORY. WE DON'T HAVE A CRYSTAL BALL. WE
9	DON'T KNOW WHERE THINGS ARE GOING TO WORK YET, BUT
10	WE'RE GETTING SOME CUES. AS WE GO FORWARD AND, AS
11	DR. OLSON MENTIONED, WE NEED TO PERHAPS BE MORE
12	STRATEGIC ABOUT WHAT PARTICULAR AREAS WE'RE
13	INVESTING IN SO THAT WE HAVE THE ABILITY TO MAKE OUR
14	DOLLARS GO TO THOSE MOST PROMISING AREAS. BUT AT
15	THIS POINT IN TIME, WE'RE FAIRLY BROAD IN TERMS OF
16	THE EXPLORATION OF ALL THESE DIFFERENT AREAS.
17	AND YOU CAN SEE THEY'RE COLOR CODED BOTH
18	BY THE AMOUNT OF MONEY THAT'S BEEN FUNDED, AND ALSO
19	INCLUDED IN THAT SLICE IS THE NUMBER OF AWARDS TO
20	THAT PARTICULAR AREA.
21	THE THERAPEUTIC MODALITY HAS ALSO BEEN
22	QUITE BROAD. THIS AGENCY WAS STARTED THINKING OF
23	HUMAN EMBRYONIC STEM CELLS, PLURIPOTENTIAL STEM
24	CELLS AS A MAJOR FOCUS. BUT AS THE SCIENCE HAS
25	EVOLVED AND THINGS HAVE PROGRESSED, WE'VE BEEN MORE

1	BROAD IN TERMS OF THE STEM CELL-BASED MODALITIES
2	THAT WE'RE WORKING WITH. SO THE PALE BLUE ARE THE
3	26 THESE PROGRAMS ARE INCLUDING ALL 51 EARLY
4	TRANSLATION AND DISEASE TEAM WORK. BUT TO DATE WE
5	HAVE A GOOD SUBSTANTIVE AMOUNT WORKING IN CELL
6	THERAPY. THE DARKER PURPLE ARE THE 23 IN GENE
7	MODIFIED CELL THERAPY. WHAT YOU ALSO SEE IN YELLOW
8	ARE THE SMALL MOLECULES, THE MONOCLONAL ANTIBODIES
9	IN THE PROTEINS THAT ARE ACTUALLY DIRECTED TO EITHER
10	ENDOGENOUS STEM CELLS OR DIRECTED TO THE CANCER STEM
11	CELL. ACTUALLY ATTACKING THE CANCER STEM CELL IS
12	THE TARGET. AND THEN IN THE RED WE HAVE THE CELL
13	THERAPY COMBINATION PRODUCTS. AND THEN IN THE SMALL
14	SLICE OF GREEN IS THE GENE MODIFIED, THESE ARE THE
15	GENETICALLY ENGINEERED CELL THERAPY PRODUCTS THAT
16	ARE ALSO A COMBINATION PRODUCT.
17	AND THEN LOOKING AT THE BOTTOM OF THE
18	SLIDE, YOU WILL SEE, BECAUSE WE'VE TERMINATED ONE
19	DISEASE TEAM TO DATE, YOU WILL SEE THE 24 REMAINING
20	DISEASE TEAMS, AND YOU ALSO SEE THE DIFFERENT
21	APPROACHES. WE HAVE ALLOGENEIC WHERE THEY'RE
22	GETTING CELLS FROM SOMEBODY ELSE, NOT FROM
23	THEMSELVES. AND SO THERE ARE ISSUES ABOUT THE HOST
24	IMMUNE RESPONSE AND IMMUNE REJECTION, AND HOW DO WE
25	ENSURE THAT THERE'S IMMUNE TOLERANCE OF THOSE CELLS

1	SO THAT THE CELLS CAN DO WHAT THEY NEED TO DO.
2	WE ALSO HAVE AUTOLOGOUS APPROACHES. WE'RE
3	ACTUALLY TAKING CELLS FROM THE PATIENT AND USING
4	THEM AND GENETICALLY ENGINEERING THEM OR
5	REPROGRAMMING THEM TO INDUCED PLURIPOTENT STEM CELLS
6	AND THEN MAKING CHANGES SO THAT THEY'RE EITHER
7	CORRECTING OR REPAIRING THE DEFECT AND THEN GIVING
8	IT BACK TO THAT PATIENT.
9	AND THEN WITH THE STRATEGIC PARTNERSHIP
10	AWARDS THAT HAVE BEEN AWARDED TO DATE, ONE IS AN
11	ALLOGENEIC APPROACH, ONE IS AN AUTOLOGOUS APPROACH.
12	BECAUSE THESE ARE COMPLEX
13	MULTIDISCIPLINARY AWARDS, THEY'RE ALSO EXTREMELY
14	EXPENSIVE. WE'VE PUT INTO PLACE MILESTONES. AND WE
15	WORK, THE CIRM OFFICER WORKS WITH THE DISEASE TEAM
16	PRIOR TO MONEY GOING OUT THE DOOR AFTER THE AWARDS
17	ARE MADE AT THE BOARD MEETING, BUT PRIOR TO MONEY
18	GOING OUT, WE WORK WITH THE TEAMS TO COME UP WITH
19	MUTUALLY AGREED UPON MILESTONES. THESE ARE GO/NO-GO
20	MILESTONES. THESE ARE REAL SHOW STOPPERS. WHAT
21	WOULD MAKE YOU WANT TO STOP THE AWARD? IT'S NOT
22	THAT ANYBODY IS BAD OR HAS DONE SOMETHING WRONG.
23	IT'S JUST THE DATA DOESN'T SUPPORT MOVING FORWARD.
24	WE ALSO HAVE PROGRESS MILESTONES SO THAT
25	WE CAN GAUGE THAT THEY'RE MOVING ALONG ON TRACK.

1	AND THEN WE HAVE SUCCESS CRITERIA. THESE ARE NOT IN
2	CONCRETE. THESE CAN BE REFINED AS THE DATA
3	SUGGESTS. SO WE HAVE THE FLEXIBILITY TO DO THAT.
4	BUT AS WE START THESE PROGRAMS, WE HAVE AN END GOAL
5	IN MIND AND WHAT WE NEED TO DO TO GET THERE. AND
6	THEN DURING THE CONDUCT OF THE RESEARCH, THESE ARE
7	AWARDS WHERE THERE'S VERY INTERACTIVE, ONGOING
8	DISCUSSIONS BETWEEN THE CIRM SCIENTISTS AND FUNDED
9	RESEARCH TEAMS.
10	WE GET UPDATED INTERVAL PROGRESS REPORTS.
11	AND IN ADDITION, WE'VE INSTITUTED LAST YEAR AN
12	IN-PERSON, IN-YOUR-FACE MEETING WITH EXTERNAL
13	CLINICAL DEVELOPMENT ADVISORS WITH THE DISEASE TEAM,
14	WITH THE CIRM SENIOR SCIENCE STAFF TO TRY AND LOOK
15	AT HOW THESE PROGRAMS ARE DOING. ARE THEY REACHING
16	THEIR MILESTONES? AND ALSO IT'S AN OPPORTUNITY FOR
17	THE TEAM, AND WE STRONGLY ENCOURAGE IT, TO LAY OUT
18	WHERE THEY'RE HAVING CHALLENGES, WHERE THEY'RE
19	HAVING PROBLEMS. AND THIS IS REALLY AN INTERACTIVE
20	DIALOGUE WHERE PEOPLE CAN TALK ABOUT WHAT SOME
21	SUGGESTED APPROACHES ARE.
22	OUR WHOLE AIM WITH PUTTING THIS IN PLACE
23	WAS TO BETTER POSITION THESE INVESTIGATORS TO BE
24	SUCCESSFUL. IF THEY'RE SUCCESSFUL, WE'RE
25	SUCCESSFUL. AND THEN WE HAVE MONEY TO CONTINUE TO

1	FUND THEM. SO SO FAR WE'VE DONE AN ASSESSMENT.
2	LAST YEAR AT THEIR 12- TO 18-MONTH MILESTONE I
3	SHOULD SAY 2011 AND THEN LAST YEAR BETWEEN JULY AND
4	THE END OF THE YEAR, WE HAD A SECOND EVALUATION WITH
5	THEM. AND WE DO MAKE REFINEMENTS BASED UPON THESE
6	ASSESSMENTS.
7	IN ADDITION TO THESE ONE-ON-ONE
8	INTERACTIONS WITH OUR DIFFERENT PROJECT TEAMS, WE
9	WORK EXTENSIVELY WITH THE FOOD AND DRUG
10	ADMINISTRATION. AND WE HAVE CONVERSATIONS WITH THEM
11	ABOUT OBSTACLES IN THE FIELD, WHERE CAN WE GO TO
12	MAKE THE REGULATORY PATHWAY MORE PREDICTABLE AND
13	CLEARER. AND THE FDA ACTUALLY APPRECIATES WORKING
14	WITH CIRM BECAUSE WE DON'T HAVE A PARTICULAR HORSE
15	IN THE RACE. WE JUST WANT THE BEST HORSE TO WIN AND
16	MAYBE MULTIPLE. AND SO THEY LOOK TO US AS A NEUTRAL
17	SOURCE THAT CAN HELP ALSO EDUCATE THEM IN TERMS OF
18	WHAT'S GOING ON WITH THE SCIENCE, WHAT'S GOING ON
19	WITH THE FIELD, AND WHAT SOME OF THE OBSTACLES ARE
20	THAT MIGHT BE HELPED BY TRYING TO PUT TOGETHER A
21	CLEARER PATHWAY ALONG THE REGULATORY PATH.
22	THIS IS GOING TO DECREASE THE RISK FOR THE
23	INVESTIGATORS MOVING THEIR PROJECTS FORWARD, AND
24	HOPEFULLY THE DECREASED REGULATORY RISK WILL ALSO
25	ATTRACT INVESTORS OR COMPANIES TO WANT TO GET INTO

1	THE FIELD AS WELL. AND THE WAY THAT WE PUT THIS
2	EDUCATIONAL WORK TOGETHER IS THROUGH CONFERENCES,
3	WEBINARS, ROUNDTABLES, AND SEMINARS. SO THESE ARE
4	AVAILABLE TO THE PEOPLE INVITED, BUT WE ALSO MAKE
5	THEM PUBLICLY AVAILABLE AT THE TIME, AND WE ALSO
6	ARCHIVE THEM ON OUR WEB SITE SO THAT PEOPLE WHO
7	WEREN'T ABLE TO PARTICIPATE IN PERSON CAN
8	PARTICIPATE LATER.
9	THIS IS WHERE OUR FIRST COHORT OF DISEASE
10	TEAMS ARE RIGHT NOW. SO THEY'RE NECK AND NECK GOING
11	DOWN THAT RACE. BASICALLY SEVEN OF THE TEAMS HAVE
12	ACTUALLY HAD SUCCESSFUL PRE-IND MEETINGS WITH THE
13	FDA AND DO HAVE A PATHWAY FORWARD TO GO FORWARD.
14	ONE OF THEM I CAN PUBLICLY STATE HAS HAD A FILED,
15	APPROVED IND, DID HAVE THEIR FIRST-IN-HUMAN CLINICAL
16	TRIAL FUNDED BY THE NATIONAL INSTITUTES OF HEALTH.
17	AND THEN SHOULD THE PHASE I RESULTS PROVE FAVORABLE
18	IN TERMS OF SAFETY INFORMATION, CIRM HAS ALREADY
19	COMMITTED TO FUND THE PHASE II CLINICAL TRIAL. SO
20	THIS IS IN THE CLINIC NOW IN 2013.
21	WE HAVE A VARIETY OF OTHER PROGRAMS THAT
22	ARE ALSO WORKING THEIR WAY TOWARDS THE CLINIC.
23	THIS IS AN EXAMPLE OF ONE MOVING TO THE CLINIC IN
24	HIV/AIDS. HERE WHAT THE INVESTIGATORS ARE DOING IS
25	REALLY TARGETING THE CORECEPTOR IN HIV, THE CCR5

1	CORECEPTOR. AND THIS PARTICULAR TEAM IS USING A
2	TECHNOLOGY OF ZINC FINGER NUCLEASE TO KNOCK OUT THAT
3	RECEPTOR SO THAT THE PATIENTS THEY'RE THEN
4	TRANSDUCING THIS INTO HEMATOPOIETIC STEM CELLS OF
5	THE PATIENT. SO THIS IS AN AUTOLOGOUS APPROACH. SO
6	THEY'RE USING GENETIC ENGINEERING.
7	AND THE GOAL HERE IS INITIALLY THEY'RE
8	GOING TO USE MODERATE MYELOABLATIVE THERAPY IN A
9	POPULATION OF PATIENTS THAT NORMALLY WOULD RECEIVE
10	MYELOABLATIVE THERAPY FOR THEIR DISEASE STATE AND
11	KNOCK OUT THE CELLS SO THAT THERE'LL BE A SELECTIVE
12	PRESSURE FOR THESE NEW ENGINEERED CELLS TO GROW AND
13	THAT THESE CELLS WILL BE RESISTANT TO FURTHER HIV
14	INFECTION. SO THAT'S GOING DOWN THE PATHWAY TOWARDS
15	THE CLINIC.
16	ANOTHER EXAMPLE IS A TEAM THAT'S MOVING TO
17	THE CLINIC IN A VERY RARE GENETIC DISORDER CALLED
18	DYSTROPHIC EPIDERMOLYSIS BULLOSA. THIS IS BASICALLY
19	A BLISTERING SKIN DISEASE. ALTHOUGH IT CAN AFFECT
20	OTHER EPITHELIAL TRACTS, LIKE IN THE GI TRACT OR THE
21	EYE, BUT BASICALLY THIS IS WORKING ON A PROOF OF
22	CONCEPT, A CLINICAL TRIAL, WHERE THEY'RE TAKING
23	PATIENTS WHO HAVE THIS TERRIBLE DISEASE, AND IT'S A
24	DEFECT IN COLLAGEN VII. THEY'RE TAKING THE
25	PATIENT'S OWN CELLS, THEY'RE REPROGRAMMING THEM TO
	52
	32

1	AN INDUCED PLURIPOTENT STATE, THEN CORRECTING THOSE
2	CELLS WITH THE CORRECT COLLAGEN VII GENE AND THEN
3	PUTTING THAT BACK INTO THE SAME PATIENT.
4	AND SO THEY'VE HAD SOME VERY GOOD
5	CONVERSATIONS WITH US, WITH THE AGENCY, WITH THE
6	FOOD AND DRUG AGENCY, AND ARE ACTUALLY TRYING TO
7	CHART A VERY INNOVATIVE PATHWAY FORWARD WITH A VERY
8	NOVEL STEM CELL-BASED TECHNOLOGY.
9	ANOTHER EXAMPLE OF MOVING TO THE CLINIC IS
10	IN CANCER. THIS IS A GROUP THAT ACTUALLY IS USING
11	STEM CELLS AS A DELIVERY PAYLOAD. HERE THEY'RE
12	WORKING ON A PARTICULAR TYPE OF BRAIN CANCER,
13	GLIOBLASTOMA, THAT HAS REALLY VERY MODEST
14	THERAPEUTIC OPTIONS. IT HAS A VERY HIGH MORTALITY
15	RATE. PEOPLE DIE FROM THIS DISEASE. AND BASICALLY
16	WHAT THEY'RE DOING IS TAKING STEM CELLS AND THEY'RE
17	TRANSDUCING THEM WITH A CONVERTING ENZYME AND THEN
18	INJECTING THESE PATIENTS WITH A CHEMOTHERAPY AGENT
19	THAT NORMALLY NEEDS TO BE METABOLIZED BY A
20	CONVERTING ENZYME TO GO INTO ITS VERY TOXIC
21	METABOLITE. AND YOU NEED THAT TOXIC METABOLITE TO
22	KILL THE TUMOR.
23	SO WHAT THIS TEAM IS DOING IS TAKING THESE
24	CELLS, LETTING A CONVERTING ENZYME RIDE IN WITH STEM
25	CELLS SO THAT THEY'LL HOME IN TO THE TUMOR TARGET.

1	AND THEN WHEN THAT CHEMOTHERAPY GETS INJECTED,
2	NORMALLY THE CELLS IN THE BRAIN DON'T HAVE THAT
3	CONVERTING ENZYME. AND SO WHAT THIS IS IS TRYING TO
4	PROVIDE VERY LOCALIZED SPECIFIC TREATMENT TO THE
5	BRAIN TUMOR. SO THAT'S A LONG ABOUT WAY OF TRYING
6	TO EXPLAIN WHAT THEY'RE DOING.
7	SO HERE IT'S NOT REPAIR AND REGENERATION.
8	HERE IT'S USING THAT AS A DELIVERY VEHICLE TO
9	DELIVER A PAYLOAD.
10	THIS IS NOT YET PUBLISHED, SO YOU WON'T
11	SEE IT IN YOUR HANDOUT, BUT I WAS TOLD I COULD USE
12	IT JUST IN A PRESENTATION. WHAT THIS TEAM HAS DONE
13	IS THEY DEVELOPED AN IMAGING AGENT THAT'S ABLE TO
14	IMAGE THE NEURAL STEM CELLS. SO THEY'RE TAKING A
15	NANOPARTICLE, A REALLY SMALL ION PARTICLE, AND IT
16	HAS A CONTRAST WHERE IT'S ACTUALLY BLACKNESS. IT'S
17	HYPOATTENUATED. IN THE VERY FAR LEFT-HAND CORNER IS
18	THE TUMOR PREOP, AND THEN THEY RESECT THE TUMOR.
19	AND THEN THEY INJECT IN TEN PLACES AROUND THE
20	RESECTION CAVITY THESE NEURAL STEM CELLS THAT ARE
21	LOADED WITH THE CONVERTING ENZYME. AND YOU SEE THAT
22	BY THE RED ARROWS, THE SLIDE NO. 2 ON THE TOP. AND
23	THEN THEY TOOK IMAGES. THESE ARE NONINVASIVE IMAGES
24	WITH MRI SCANS. SO THEY SHOW AT ONE DAY, AT TEN
25	DAYS, AND THEN OUT TO 31 DAYS THAT THEY CAN SEE
	54
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1	THESE NEURAL STEM CELLS.
2	AND SO THIS IS, AS OPPOSED TO HAVING TO GO
3	IN AND CHOP OUT A PIECE OF THE BRAIN AND SEE WHETHER
4	THE STEM CELLS ARE THERE, WHICH IS CERTAINLY THINGS
5	THEY HAVE DONE IN THE ANIMALS, BUT AS YOU CAN
6	IMAGINE, NOT SOMETHING YOU WANT TO DO IN THE HUMAN.
7	THEY'RE TRYING TO FIND A NONINVASIVE WAY TO IMAGE
8	WHAT'S HAPPENING TO THE STEM CELLS. SO THIS IS VERY
9	EXCITING. THIS IS THE FIRST-IN-HUMAN USE OF THIS
10	NOVEL AGENT. AND IT'S BEEN ALREADY IN AT LEAST ONE
11	PATIENT, AND THESE ARE THEIR PRELIMINARY RESULTS SO
12	FAR.
13	IN ADDITION, THIS TEAM HAS ALSO SPUN OUT A
14	COMPANY. WE'RE TRYING TO WORK WITH THE TEAM NOT
15	JUST ON THE RESEARCH, BUT ON WAYS THEY CAN GET
16	FOLLOW-ON FINANCING. SO THIS IS A COMPANY THAT'S
17	BEEN SPUN OUT. THE PI IS NOW FOUNDER AND CHIEF
18	SCIENTIFIC OFFICER OF THIS COMPANY AND IS WORKING ON
19	WAYS TO TRY AND LEVERAGE CIRM FUNDING WITH FUNDING
20	THAT'S EXTERNAL TO CIRM SO THAT THEY HAVE THE
21	ABILITY TO MOVE FORWARD.
22	SO IN A SUMMARY OF AT LEAST THE FIRST
23	COHORT OF DISEASE TEAMS, OVER HALF OF THE DISEASE
24	TEAM I'S HAVE SUCCESSFULLY ADVANCED THROUGH THEIR
25	PRE-IND MEETING WITH THE FDA TOWARDS AN APPROVABLE

1	IND. THIS IS A VERY SOUND ACCOMPLISHMENT TO HAVE
2	THAT KIND OF REGULATORY MILESTONE MET. AND THEY
3	HAVE A CLEARER PATHWAY TOWARDS WHAT THEY NEED TO
4	FILE THAT IND TO GET INTO CLINICAL TRIAL.
5	WE HAVE ONE CLINICAL TRIAL THAT'S ALREADY
6	STARTING IN 2013, AND WE EXPECT ONE TO TWO MORE THIS
7	YEAR. WE ANTICIPATE FIVE CLINICAL TRIALS BY THE END
8	OF 2014.
9	ANOTHER AIM THAT WE HAVE AT CIRM IS THAT
10	WE'RE TRYING GET THESE TEAMS TO LEVERAGE CIRM
11	FUNDING. FIVE OF THESE DISEASE TEAMS DO HAVE
12	COLLABORATIVE FUNDING PARTNERS. ONE HAS A
13	COLLABORATION WITH A DISEASE FOUNDATION, TWO OF
14	THESE TEAMS HAVE COMPANIES AS EITHER THE PI OR THE
15	CO-PI, AND TWO HAVE FOUNDED COMPANIES. WE HAVE
16	PRELIMINARY INFORMATION ON INVENTION DISCLOSURES,
17	IMPENDING PATENT APPLICATIONS WHICH WE'LL BE ABLE TO
18	COME BACK TO YOU IN MARCH WITH FURTHER DETAILS. AND
19	TO DATE WE HAVE 18 SCIENTIFIC PUBLICATIONS FROM THIS
20	FIRST COHORT OF TEAMS.
21	I SHOULD MENTION THEY'RE ONLY ABOUT 30
22	MONTHS INTO THEIR FOUR-YEAR TRACK TOWARDS DELIVERING
23	ON FILING AN IND.
24	I THOUGHT THE NEXT TWO SLIDES JUST MIGHT
25	BE OF INTEREST TO YOU. THESE ARE ACTUALLY PROVIDED

1	BY THE FDA. AND THESE ARE THE APPLICATIONS THAT ARE
2	COMING INTO THE FDA BETWEEN 2004 AND 2012. I THINK
3	WHAT'S INTERESTING IS THE SOLID BLUE, THE ROYAL
4	BLUE, ARE APPLICATIONS COMING IN FROM COMMERCIAL
5	INDUSTRY ENTITIES. AND THE OTHER SHADE OF BLUE IS
6	COMING IN FROM ACADEMICS, FROM RESEARCHERS. I THINK
7	WHAT YOU SEE FOR FILES THAT HAVE BEEN SUBMITTED TO
8	THE OFFICE OF CELL, TISSUE, AND GENE THERAPY, WHICH
9	IS THE OFFICE AT THE FDA WHERE STEM CELL-BASED
10	THERAPIES COME IN, ABOUT ANYWHERE FROM TWO TO
11	FOURFOLD MORE ARE COMING IN FROM ACADEMIC
12	INVESTIGATORS. SO WE FEEL THAT ACTUALLY WORKING
13	HEAVILY WITH OUR ACADEMIC INVESTIGATORS IS SOMETHING
14	WE SHOULD CONTINUE TO BE DOING TO TRY AND BETTER
15	POSITION THESE INVESTIGATORS TO BE SUCCESSFUL, NOT
16	JUST FOR THE FIRST IN HUMAN, BUT SO THAT THEY CAN
17	ACTUALLY MOVE ON TO DEVELOP A PRODUCT. AND SO IT'S
18	ALSO CRITICALLY IMPORTANT THAT WE LEVERAGE WITH
19	COMPANIES.
20	THIS OTHER SLIDE THAT WAS PROVIDED BY THE
21	FDA AND IS ALSO PUBLISHED AT THIS POINT IS SHOWING
22	YOU THE EXPERIENCE THE FDA HAS WITH STEM CELLS. SO
23	YOU CAN SEE IT BASED ON THE STEM CELL TYPE AND ALSO
24	THE TISSUE THAT IT'S COMING FROM. AND I THINK THEIR
25	BIGGEST EXPERIENCE TO DATE HAS BEEN WITH MESENCHYMAL

1	AND WITH BONE MARROW, WHICH IS WHAT WE'D ALL EXPECT.
2	THEY HAVE MUCH LESS EXPERIENCE WITH PLURIPOTENTIAL
3	STEM CELLS. AND THAT'S WHY, AS I SAID BEFORE, THIS
4	IS NEW THE FOR THE FDA, IT'S NEW FOR THE
5	INVESTIGATORS, IT'S NEW FOR CIRM, AND WE'RE REALLY
6	CHARTING A PATHWAY HERE TO MOVE THIS INTO THE
7	CLINIC.
8	SO AT THE END, I ALSO WANT TO ACKNOWLEDGE,
9	AS I DID AT THE BEGINNING, THE BOARD, OUR STAFF, OUR
10	INVESTIGATORS, OUR DISEASE GROUPS, BUT IN PARTICULAR
11	WE WANT TO THANK MEMBERS OF THE SCIENCE AND THE
12	INFORMATICS TEAMS, ESPECIALLY DRS. STEFFEN, YAFFE
13	SAMBRANO, LEWIS, THOMPSON, THAKAR, KADYK, COLLINS,
14	SHEPARD, MARTIN, AND TORRENCE FOR THEIR HELP WITH
15	THIS PROJECT. THANK YOU VERY MUCH, AND WE HOPE THIS
16	HAS BEEN INFORMATIVE FOR YOU. AND I THINK WE MIGHT
17	HAVE TIME FOR QUESTIONS. THANKS VERY MUCH.
18	(APPLAUSE.)
19	CHAIRMAN THOMAS: THANK YOU VERY MUCH,
20	ELLEN AND PAT, FOR A MOST COMPREHENSIVE AND
21	FASCINATING RUN THROUGH THE STATE OF THE UNION HERE
22	AS WE STAND TODAY AT CIRM WITH THE MANY PROJECTS WE
23	FUNDED AND THIS GREAT PROGRESS AND PROMISE THAT THEY
24	REPRESENT. WE HAVE A FEW MINUTES LEFT IF THERE ARE
25	COMMENTS OR QUESTIONS FOR EITHER ELLEN OR PAT FROM

1	MEMBERS OF THE BOARD.
2	MR. SHEEHY: THIS IS JUST A COMMENT. AND
3	THANK YOU. I THINK STAFF, TREMENDOUS PRESENTATION,
4	TREMENDOUS WORK BY STAFF OVER THE YEARS. AND I
5	THINK WE'VE REALLY DONE A LOT OF GREAT SCIENCE HERE
6	AT THIS INSTITUTE.
7	BUT I DID WANT TO JUST NOTE FOR THE RECORD
8	THAT TWO OF THESE GRANTS WERE MOVED UP IN
9	PROGRAMMATIC REVIEW AT THE WORKING GROUP. JUST SO
10	WE HAVE THAT IN THE RECORD, THE LORING TOOLS AND
11	TRANSLATION GRANT AND THE EPIDERMOLYSIS BULLOSA.
12	BOTH OF THOSE GRANTS WERE MOVED UP AT THE WORKING
13	GROUP DURING PROGRAMMATIC REVIEW.
14	I ALSO WOULD LIKE TO NOTE THAT A COUPLE OF
15	THE GRANTS THAT WERE HIGHLIGHTED WERE MOVED THROUGH
16	AN EXTRAORDINARY PETITION AT THE BOARD. SO THE
17	JACKSON LABS GRANT AND THE ABOODY GRANT WERE BOTH
18	MOVED THROUGH EXTRAORDINARY PETITION. I JUST WANT
19	TO GET THOSE ON THE RECORD. IF WE'RE HIGHLIGHTING
20	THESE GRANTS POINTING TO OUR SUCCESS, I THINK IT'S
21	VERY IMPORTANT THAT WE NOTE THAT SOME OF THE
22	THOUGHTFUL WORK THAT'S BEEN DONE BY PATIENT
23	ADVOCATES, BOTH IN THE WORKING GROUP AND BY
24	SCIENTISTS AND PATIENT ADVOCATES HERE AT THE BOARD
25	IN LISTENING AND BEING RECEPTIVE, HAS ACTUALLY MOVED

1	SOME FAIRLY INCREDIBLE SCIENCE FORWARD. AND WE'VE
2	GOT SOME REAL MEASURABLE OUTCOMES FROM HAVING DONE
3	SO. THANK YOU.
4	CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.
5	ADDITIONAL COMMENTS?
6	MS. SAMUELSON: COULD WE HAVE THOSE
7	SCIENTISTS STAND SO WE CAN SEE THEM AND GIVE THEM AN
8	OVATION?
9	CHAIRMAN THOMAS: ELLEN, JOAN ASKED THAT
10	THE SCIENTISTS ON THE STAFF THAT YOU REFERENCED
11	PLEASE STAND SO WE CAN GIVE THEM PROPER
12	ACKNOWLEDGMENT.
13	DR. FEIGAL: WE WILL DO THAT ALTHOUGH SOME
14	OF THEM WILL BE STANDING IN THEIR OFFICES BACK AT
15	CIRM, SO YOU MAY NOT BE ABLE TO SEE THEM. BUT I CAN
16	RENAME EVERYBODY. DR. SAMBRANO IS HERE.
17	(APPLAUSE.)
18	DR. FEIGAL: I'M NOT SURE. EVERYBODY ELSE
19	IS BUSY WORKING BACK AT THE OFFICE. SO THEY'RE
20	PROBABLY INTENTLY LISTENING, AND I HOPE THEY RECEIVE
21	YOUR ACKNOWLEDGEMENT.
22	MS. SAMUELSON: THANKS VERY MUCH.
23	(APPLAUSE.)
24	DR. DULIEGE: TO BOTH OF YOU AND TO
25	EVERYBODY, CONGRATULATIONS. MOST IMPRESSIVE
	60
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1	PRESENTATION.
2	ELLEN, I WAS PARTICULARLY IMPRESSED BY
3	YOUR CONFIDENCE ABOUT THE NUMBER OF PRODUCTS THAT
4	SEEMS TO BE MAKING IT TO THE PRE-IND PROCESS, WHICH
5	WE KNOW IS EXTREMELY DIFFICULT. YOU THINK ABOUT
6	HALF OF THEM ARE QUITE LIKELY TO MAKE IT THROUGH AN
7	IND. INDEED AT THE BEGINNING YOU ALSO SAID THAT THE
8	GOAL WAS TO HAVE POTENTIALLY, POTENTIALLY, A
9	COMMERCIALIZED PRODUCT OR AT LEAST WAY TO
10	COMMERCIALIZATION BY 2016, WHICH IS ACTUALLY A VERY
11	SHORT AMOUNT OF TIME FOR DEVELOPMENT.
12	SO IF YOU WANTED TO EXPAND A BIT ABOUT
13	YOUR HOPE OF THIS MOVING THROUGH THE NEXT STAGE AND
14	TO WHICH EXTENT THE FDA HAS BEEN HELPFUL IN
15	FACILITATING THIS PROCESS OF MOVING THROUGH IND.
16	DR. FEIGAL: I THINK WHAT WE'RE TRYING TO
17	DO, CIRM'S FOCUS IS ON THE EARLY STAGE. AND WE NEED
18	PARTNERS EITHER WITH INVESTORS, COMPANIES TO TAKE IT
19	THROUGH REGISTRATION AND COMMERCIALIZATION.
20	WHAT I INTENDED TO COMMUNICATE IS THAT
21	WE'RE DOING THE GROUNDWORK TO TRY AND MAKE SURE THAT
22	THERE'S THE POTENTIAL, SHOULD MILESTONES BE MADE,
23	THAT THERE ARE PARTNERS OR COLLABORATORS WHO CAN
24	TAKE IT ALL THE WAY TO FINISH LINE. WE KNOW WE
25	WON'T BE ABLE TO DO THAT UNLESS WE DECIDE WE'RE

1	SOMEHOW CHANGING OUR MISSION AND ADDING LOTS MORE
2	MONEY INTO THE PURSE.
3	IN TERMS OF HOW THE FDA IS HELPFUL,
4	THEY'VE BEEN VERY ACCESSIBLE. THEY HAVE BEEN VERY
5	OPEN TO HAVING COMMUNICATION WITH US, WITH OUR
6	INVESTIGATORS, WITH PEOPLE WE BRING TO THE TABLE.
7	AND WE FIND THAT VERY POSITIVE, VERY CONSTRUCTIVE.
8	I THINK OUR GOAL THAT WE ALL WANT IS THAT
9	WE WANT THEM TO SEE HIGH QUALITY GOOD APPLICATIONS
10	COME INTO THEM BECAUSE I THINK THAT MAKES THEIR
11	WORKLOAD EASIER. AND ALSO I THINK THEY TOO IN THE
12	END WOULD LIKE TO SEE PRODUCTS GET APPROVED AS WELL
13	BECAUSE I THINK, AT THE END OF THE DAY, THEY DO WANT
14	PRODUCTS TO GET OUT THERE TO PATIENTS.
15	SO I WOULD SAY THE COMMUNICATION HAS BEEN
16	HELPFUL. THEY HAVE BEEN AVAILABLE FOR PROVIDING
17	INPUT ON PAPERS THAT WE'RE WORKING ON, ON WORKSHOPS
18	THAT WE PUT TOGETHER. THEY'VE ACTUALLY TROOPED OUT
19	TO COME TO MEETINGS THAT WE PUT ON. THEY'VE SHOWN
20	UP. IF THEY CAN'T COME OUT, THEY PARTICIPATE
21	REMOTELY BY TELECON. WE HAVE ROUNDTABLES IN
22	WASHINGTON, D.C. SO I'D SAY THE COMMUNICATION, AND
23	THEY BRING NOT JUST ONE PERSON, PROBABLY 15 TO 20
24	PEOPLE TO THE TABLE. AND SO IT'S, I THINK, A REAL
25	COMMITMENT ON THEIR PART GIVEN THE OTHER TYPES OF

1	ACTIVITIES THEY HAVE TO BE INVOLVED WITH.
2	SO I WOULD SAY THEY'VE BEEN RECEPTIVE TO
3	OUR SUGGESTIONS ON WAYS TO WORK TOGETHER.
4	CHAIRMAN THOMAS: OTHER COMMENTS OR
5	QUESTIONS? WOULD ANYBODY FROM THE PUBLIC LIKE TO
6	COMMENT? MR. REED.
7	MR. REED: I HAD TWO QUESTIONS. ONE, IS
8	THIS PRESENTATION AVAILABLE ON THE WEB? THANK YOU
9	VERY MUCH. WHAT'S IT CALLED? POSTED UNDER THE
10	AGENDA.
11	SECONDLY, THERE WAS A SLIDE WHICH I
12	THOUGHT WAS FASCINATING WHICH SHOWED THE COMPARISON
13	OF THE ACADEMIC INSTITUTIONS AND THE PRIVATE
14	INSTITUTIONS, AND I WONDER IF I COULD HAVE THAT
15	SLIDE EXPLAINED A LITTLE BIT MORE.
16	DR. FEIGAL: ARE YOU TALKING ABOUT FDA
17	SLIDE ON COMMERCIAL SPONSORS VERSUS ACADEMIC
18	SPONSORS? SO I CAN PUT THE SLIDE UP. AND THAT'S
19	BASICALLY JUST APPLICATIONS COMING IN TO THE FDA TO
20	THE OFFICE OF CELL, TISSUE, AND GENE THERAPY AND
21	JUST SHOWING WHERE THEY'RE COMING FROM. AND THEN
22	THERE'S ACTUALLY A PAPER THAT'S BEEN PUBLISHED THAT
23	I HAVE AS A REFERENCE HERE. I DON'T SEE THAT. I
24	DON'T. MAYBE IT'S JUST A SLIDE THEN. BUT THE NEXT
25	SLIDE ACTUALLY HAS A REFERENCE TO THE PAPER. IT'S

1	IN THE AUGUST 2012. LET ME READ IF OFF THE SLIDE.
2	IN SCIENCE TRANSLATIONAL MEDICINE, VOLUME IV, ISSUE
3	147. IT'S ON THE SLIDE SO YOU CAN SEE THE
4	REFERENCE. I CAN TALK TO YOU OFFLINE ABOUT THE
5	REFERENCE. DID THAT ANSWER YOUR QUESTION THOUGH?
6	MR. REED: IT WAS I WANT TO KNOW A LOT
7	MORE BECAUSE PEOPLE SAY THAT THE ACADEMICS ARE NOT
8	AS VALUABLE AS THE PRIVATE ENTERPRISE, AND IT SEEMS
9	LIKE THAT'S JUST THE OPPOSITE. SO I'D LIKE TO KNOW
10	A LOT MORE ABOUT THAT.
11	DR. FEIGAL: THAT WHAT? I'M NOT SURE WHAT
12	YOUR INTERPRETATION WAS OF THAT.
13	MR. REED: I HEAR A LOT, NOT A LOT, BUT I
14	HEAR COMMENTS THAT THE ACADEMICS ARE NOT AS
15	PRODUCTIVE AS PRIVATE ENTERPRISE. IT SEEMED LIKE
16	JUST THE OPPOSITE. SO I WOULD LIKE TO HEAR A LOT
17	MORE ABOUT THAT.
18	DR. FEIGAL: CERTAINLY I DIDN'T SAY THAT.
19	WHAT I WAS TRYING TO COMMUNICATE IS THAT A LARGE
20	NUMBER OF APPLICATIONS ARE COMING FROM ACADEMICS.
21	ACADEMICS, IN GENERAL, DEVELOPING A PRODUCT IS NOT
22	USUALLY THE GOAL AT AN ACADEMIC INSTITUTION. IT'S
23	ABOUT ENHANCING KNOWLEDGE, WRITING SCIENTIFIC
24	PAPERS, GETTING YOUR GRANTS AWARDED, BUT DEVELOPING
25	A PRODUCT IS NORMALLY SOMETHING THAT'S IN THE

1	COMMERCIAL DOMAIN. AND SO WHAT WE'RE THINKING,
2	WITHOUT OVERINTERPRETING A SLIDE, IS THAT THERE'S A
3	LOT OF ACTIVITY COMING FROM ACADEMIC CENTERS.
4	WHAT WE'RE TRYING TO DO HERE AT CIRM, AT
5	LEAST WITH THE ACADEMIC INVESTORS WE'RE LOOKING AT,
6	IS MAKING SURE THAT IT'S NOT JUST ANOTHER RESEARCH
7	EXPERIMENT THAT'S DONE IN HUMANS, BUT THAT IT HAS
8	THE POTENTIAL TO ACTUALLY BE A PRODUCT.
9	SO ANYWAY, WHAT I CAN DO, THOUGH, IS
10	PERHAPS FIND THE MORE FULL SLIDE DECK FOR YOU, AND
11	THEN THAT REFERENCE MIGHT GO INTO MORE DETAILS. BUT
12	I CERTAINLY WASN'T OR NEVER INTENDED THAT WE WERE
13	STATING THAT ACADEMICS AREN'T PRODUCTIVE.
14	DR. MARLETTA: I DON'T WANT TO WADE INTO
15	THE ARGUMENT OF WHETHER ACADEMICS ARE PRODUCTIVE OR
16	NOT, BUT I THINK I EQUATE THIS MORE WITH IN SOME
17	WAYS BIOENGINEERING. THERE'S FUNDAMENTAL DISCOVERY
18	THAT'S DONE IN ACADEMIC SETTINGS BY ENGINEERS,
19	BIOENGINEERS IN PARTICULAR BECAUSE IT'S MOST
20	RELEVANT PERHAPS HERE. BUT THEY CAN EASILY ADAPT
21	THOSE FUNDAMENTAL DISCOVERIES TO A PRODUCT, TO SOME
22	GOAL LINE THAT THEY WANT TO CROSS. AND I SEE IN
23	MANY WAYS THE KINDS OF RESEARCH GOING ON IN THE
24	ACADEMIC CENTERS IN STEM CELLS WITH THAT SAME
25	OPPORTUNITY, THAT THERE'S A REAL END POINT IN MIND.

1	AND I GUESS THE POINT I'D LIKE TO
2	EMPHASIZE IS THAT WE ACADEMICS DON'T JUST SIT AROUND
3	WATCHING THE IVY GROW; BUT THAT, IN FACT, WE DO
4	THINK VERY DEEPLY ABOUT THE APPLICATION OF THE WORK.
5	I JUST THINK IT'S CLOSER HERE, AND THAT'S WHAT I
6	THINK THAT GRAPH REALLY REPRESENTS.
7	DR. FEIGAL: I THINK THE OTHER THING, WHAT
8	WE WERE TRYING TO GET ACROSS IS STATE FUNDING OR
9	GOVERNMENT FUNDING WILL ONLY TAKE YOU SO FAR. A LOT
10	OF THE DEEP POCKETS ARE IN INDUSTRY. AND SO TO
11	ACTUALLY PROVIDE THE MONEY TO GET YOU ALL THE WAY
12	THROUGH IS PROBABLY MORE MONEY THAN WE HAVE IN OUR
13	ENTIRE FUNDING R & D. AND SO IT WAS JUST THE
14	REALITY OF HOW MUCH MONEY. UNLESS WE DID MUCH FEWER
15	PROJECTS, THERE'S PROBABLY ONLY A HANDFUL THAT WE
16	COULD TAKE ALL THE WAY THROUGH JUST BECAUSE IT'S
17	EXTREMELY EXPENSIVE.
18	CHAIRMAN THOMAS: OTHER COMMENTS OR
19	QUESTIONS? OKAY. WELL, THIS CONCLUDES THE MORNING
20	SESSION. THANK YOU VERY MUCH, ELLEN AND PAT, AGAIN
21	FOR A MOST FASCINATING DESCRIPTION OF WHERE THINGS
22	STAND AS OF TODAY. MARIA, DID YOU WANT TO SAY
23	SOMETHING ABOUT LUNCH?
24	MS. BONNEVILLE: LUNCH IS DOWNSTAIRS IN
25	THE MERITAGE RESTAURANT. YOU'RE GOING TO GO PAST
	66
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1	REGISTRATION ON THE RIGHT. AND WE SHOULD COME BACK
2	UP AROUND 1:15 TO RESTART.
3	CHAIRMAN THOMAS: RECONVENE AT 1:15.
4	THANK YOU, EVERYBODY.
5	(A RECESS WAS TAKEN.)
6	CHAIRMAN THOMAS: IF WE COULD HAVE
7	EVERYBODY, ALL BOARD MEMBERS, PLEASE TAKE YOUR SEATS
8	AGAIN. I'D LIKE TO WELCOME EVERYBODY BACK TO PART 2
9	OF TODAY'S BOARD WORKSHOP. WE'RE GOING TO BEGIN.
10	WE HAVE A NUMBER OF MEMBERS OF THE BOARD WHO WERE
11	REAPPOINTED AS MEMBERS OF THE BOARD WHO NEED TO BE
12	SWORN IN. SO WE'RE GOING TO HAVE A BIT OF AN
13	UNORTHODOX MOMENT WHERE WE'D LIKE THE FOLLOWING
14	PEOPLE TO PLEASE STAND AND, AS I RECITE THE OATH OF
15	OFFICE, IF YOU COULD ALL DO THIS TOGETHER RATHER
16	THAN SERIALLY, WE WILL GET EVERYBODY SWORN IN AND
17	PROCEED WITH THE REST OF THE MEETING.
18	SO WOULD THE FOLLOWING MEMBERS OF THE
19	BOARD PLEASE STAND: MARCY FEIT, SHERRY LANSING,
20	FRANCISCO PRIETO, ROBERT QUINT, JOAN SAMUELSON,
21	CLAIRE POMEROY, AND DAVID BRENNER, AND SAM AS WELL.
22	I JUST ASSUMED YOU'RE ALWAYS AROUND, SAM, SO IT'S
23	OKAY. SO EVERYBODY PLEASE RAISE YOUR RIGHT HAND.
24	(BOARD MEMBERS WERE THEN SWORN IN.)
25	CHAIRMAN THOMAS: CONGRATULATIONS.
	67

1	(APPLAUSE.)
2	CHAIRMAN THOMAS: I AM NOW GOING TO MOVE
3	TO THE OTHER END OF THE ROOM AND WE'LL BEGIN THE
4	NEXT SEGMENT.
5	LADIES AND GENTLEMEN OF THE BOARD,
6	DISTINGUISHED GUESTS, BOTH IN PERSON AND ON THE AIR,
7	WE NOW COME TO A SEGMENT OF THE WORKSHOP THAT I
8	THINK I CAN SAY HAS BEEN QUITE ANTICIPATED WITH
9	INTEREST WHICH IS THE RESPONSE OF THE CIRM BOARD TO
10	THE IOM REPORT ISSUED LAST DECEMBER.
11	I HAVE A NUMBER OF OPENING REMARKS I WOULD
12	LIKE TO MAKE BEFORE WE GET TO THE SLIDE
13	PRESENTATION, WHICH IS THE MEAT OF WHAT I WANT TO
14	DISCUSS, BUT THERE ARE A FEW THINGS I BELIEVE NEED
15	TO BE ON THE TABLE IN ADVANCE.
16	FIRST OF ALL, I WANT TO REITERATE THE
17	EXTRAORDINARY QUALITY OF BOTH THE PRESENTATION THIS
18	MORNING AND THE WORK DESCRIBED IN THAT PRESENTATION.
19	I THINK ANYBODY WHO WAS HERE SITTING THROUGH THAT
20	REALLY SHOULD FEEL ENORMOUSLY PROUD THAT THE STATE
21	OF CALIFORNIA THROUGH THE VEHICLE OF PROP 71 HAS
22	BEEN ABLE TO FUND EXTRAORDINARY RESEARCH BOTH ACROSS
23	THE RESEARCH SPECTRUM AND ACROSS A WIDE VARIETY OF
24	CURRENTLY INCURABLE DISEASES OR CONDITIONS.
25	AND I WOULD ASK AS WE PROCEED THROUGH THIS
	68

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1	DISCUSSION THAT EVERYBODY KEEP THAT PRESENTATION
2	FIRST AND FOREMOST IN MIND AS THE REAL STORY OF WHAT
3	WE'RE TYING TO ACCOMPLISH HERE THROUGH CIRM AND ITS
4	ONGOING EFFORTS.
5	THIS IS ALL GOING TO BE ABOUT WE HAVE A
6	GREAT THING. HOW CAN WE MAKE OURSELVES EVEN BETTER?
7	ON THE ISSUE OF MAKING OURSELVES BETTER, WE'VE HAD
8	THREE EXTERNAL REVIEWS TO DATE PLUS VARIOUS
9	FINANCIAL AND OPERATIONAL AUDITS. THE EXTERNAL
10	REVIEWS FROM THE LITTLE HOOVER COMMISSION, THE
11	EXTERNAL ADVISORY PANEL, AND MOST RECENTLY THE IOM
12	HAVE HAD A NUMBER OF CONSISTENT THEMES THAT FLOWED
13	THROUGHOUT.
14	THE LATEST REPORT BY THE IOM HAD A
15	PARTICULARLY LENGTHY SET OF RECOMMENDATIONS. I,
16	LIKE YOU, READ THAT REPORT AND WAS SOMEWHAT
17	OVERWHELMED BY THE BREADTH AND EXTENT OF THE
18	RECOMMENDATIONS. THEN I TOOK A STEP BACK TO
19	CONSIDER IT IN MORE DETAIL.
20	WINSTON CHURCHILL ONCE SAID, "TO IMPROVE
21	IS TO CHANGE. TO BE PERFECT IS TO CHANGE OFTEN."
22	CIRM AT THIS POINT IS MIDLIFE IN ITS CYCLE. AS THE
23	IOM REPORT MADE ABUNDANTLY CLEAR, BOB KLEIN AND THE
24	AGENCY DID AN AMAZING JOB IN CREATING ITSELF FROM
25	SCRATCH AND PUTTING IN PLACE A SERIES OF FACILITIES

1	AND PROGRAMS THAT HAVE ENABLED WORLD-CLASS RESEARCH
2	AND DOING SO IN A CONTEXT OF UTMOST SCIENTIFIC AND
3	ETHICAL INTEGRITY.
4	WHAT THEY ARE SAYING IS THAT ALL THE
5	INTERNAL STRUCTURES AND PROTOCOLS PUT IN PLACE WERE
6	GREAT TO GET US TO WHERE WE ARE, BUT AT MIDLIFE
7	THOSE STRUCTURES AND PROTOCOLS CAN BE FURTHER
8	REFINED TO MAKE CIRM EVEN BETTER.
9	WITH THAT IN MIND, I TOOK A FRESH LOOK AT
10	THE IOM RECOMMENDATIONS AND BEGAN TO DEVELOP A PLAN
11	TO COMPREHENSIVELY AND SUBSTANTIVELY ADDRESS THE
12	FULL SLATE OF RECOMMENDATIONS. IT IS THAT PLAN THAT
13	I WISH TO SHARE WITH YOU TODAY.
14	IN THE PROCESS OF DEVELOPING THIS PLAN, I
15	SPOKE TO A NUMBER OF STAKEHOLDERS BOTH WITHIN AND
16	OUTSIDE CIRM. THESE INCLUDED ALL THE CONSTITUTIONAL
17	OFFICERS AND/OR THEIR STAFF, A NUMBER OF MEMBERS OF
18	THE BOARD, AND I WANT TO POINT OUT, BEING VERY AWARE
19	OF THE PUBLIC MEETING RULES, IT WAS A DISTINCT
20	MINORITY, CIRM STAFF, PATIENT ADVOCATES, BOB, AS
21	HE'S KNOWN ON A FIRST-NAME BASIS, AND LAST, BUT NOT
22	LEAST, AS I SUGGESTED I WOULD AT THE END OF THE IOM
23	PRESENTATION IN DECEMBER, I HAVE SPOKEN EXTENSIVELY
24	SINCE THEN WITH DR. HAROLD SHAPIRO, THE CHAIR OF THE
25	IOM COMMITTEE THAT ISSUED THE REPORT.

1	AS ONE WOULD EXPECT, DIFFERENT PEOPLE LIKE
2	DIFFERENT ASPECTS OF THE PLAN. MOST LIKED THE
3	MAJORITY OF THE SUGGESTIONS. FEW, IF ANY, LIKED
4	THEM ALL. WHAT TO DO WITH THAT? AS CONTEMPORARY
5	AUTHOR LARRY WALL RECENTLY NOTED, WE ALL AGREE ON
6	THE NECESSITY OF COMPROMISE. WE JUST CAN'T AGREE ON
7	WHEN IT'S NECESSARY TO COMPROMISE.
8	LADIES AND GENTLEMEN, I WOULD SUBMIT THAT
9	THIS IS ONE OF THOSE TIMES THAT WE MUST MOVE FORWARD
10	DECISIVELY AND COMPROMISE FOR THE GREATER GOOD. WE
11	MUST GET PAST LONG-STANDING CRITICISM ON STRUCTURE
12	AND PROTOCOL THAT HAS FOR TOO LONG STOLEN FOCUS IN
13	THE PRESS AND WITH OUTSIDE OTHER OBSERVERS FROM THE
14	INCREDIBLE SCIENTIFIC WORK THAT WE'VE ENABLED AND
15	THAT YOU HEARD SO ELOQUENTLY ABOUT FROM DRS. FEIGAL
16	AND OLSON IN THIS MORNING'S SESSION.
17	TO PARAPHRASE THE IOM, CIRM IS AT THE
18	CENTER OF THE STEM CELL UNIVERSE, IS GALVANIZING
19	STEM CELL RESEARCH, NOT JUST IN CALIFORNIA, BUT
20	NATIONALLY AND WORLDWIDE, AND IS GREATLY
21	ACCELERATING THE PACE OF RESEARCH EVERYWHERE IN THE
22	INCREASINGLY IMPORTANT FIELD OF REGENERATIVE
23	MEDICINE.
24	TO MEMBERS OF THE PRESS, BOTH ATTENDING
25	AND LISTENING TO THIS MEETING, I, WE, AT CIRM WANT
	71
	71

1	THESE TO BE THE CENTRAL FOCUS OF YOUR STORIES GOING
2	FORWARD.
3	BECAUSE OF PUBLIC MEETING RESTRICTIONS,
4	MOST OF YOU WILL BE HEARING THIS PLAN FOR THE FIRST
5	TIME. I WANT TO WALK YOU THROUGH A PRESENTATION ON
6	THE PLAN AND REQUEST THAT YOU LET ME GET THROUGH IT
7	IN ITS ENTIRETY BEFORE COMMENTING. WE WILL THEN
8	PROCEED TO A ROBUST BOARD DISCUSSION FOLLOWED BY
9	PUBLIC COMMENT.
10	I BELIEVE YOU WILL FIND THE PLAN TO BE A
11	DRAMATIC AND SUBSTANTIVE RESPONSE TO THE IOM REPORT,
12	ONE THAT HAS INTERWOVEN PARTS THAT TOGETHER FORM A
13	COMPREHENSIVE ROAD MAP FOR MOVING FORWARD. WITH THE
14	UNDERSTANDING YOU WILL ALL HAVE ELEMENTS YOU DON'T
15	LIKE, I ASK THAT YOU CAREFULLY CONSIDER THE PLAN AS
16	ONE REPORTER'S BEST ATTEMPT TO MOVE US FORWARD FROM
17	THIS POINT ON.
18	SO WITH THOSE OPENING COMMENTS, I WOULD
19	NOW LIKE TO PROCEED TO THE SLIDE SHOW ITSELF. AS I
20	SAID, THERE WERE A NUMBER OF RECOMMENDATIONS IN THE
21	IOM REPORT. AND YOU NOW, I BELIEVE, HAVE THE SLIDES
22	IN FRONT OF YOU, SO YOU SCAN TRACK IT THERE OR ON
23	THE SCREEN AS YOU WISH.
24	THE RECOMMENDATIONS ADDRESSED INCLUDE
25	CONFLICTS, INCREASED INDUSTRY INVOLVEMENT, APPEALS
	72

1	AND GRANT REVIEW PROCESS, PROGRAMMATIC REVIEW AND
2	THE ROLE OF PATIENT ADVOCATES, CHAIR AND PRESIDENT
3	DIVISION OF RESPONSIBILITIES, INTELLECTUAL PROPERTY
4	ISSUES, FINANCIAL SUSTAINABILITY, OTHER ISSUES THAT
5	I WOULD CALL SQUARELY WITHIN THE WHEELHOUSE OF THE
6	SCIENCE STAFF, INCLUDING WORKING GROUP MAKEUP AND
7	REPORTING, THE SCIENTIFIC ADVISORY BOARD, RFA
8	DEVELOPMENT, REGULATORY INVOLVEMENT, ETC. AND
9	LASTLY, ONCE WE HEAR THE PLAN IN ITS ENTIRETY, WHAT
10	WOULD BE REQUIRED TO EFFECT CHANGE.
11	BEFORE WE GET TO CONFLICTS, I JUST HAVE A
12	COUPLE OF OPENING THOUGHTS BEFORE WE HIT THAT SLIDE.
13	NO. 1, THE APPEARANCE OF ECONOMIC CONFLICT HAS BEEN
14	THE SINGLE BIGGEST ISSUE THAT HAS FOLLOWED CIRM FROM
15	INCEPTION. SUCH WAS THE IOM'S CONCERN, THAT IT
16	RECOMMENDED THAT THE BOARD COULD ONLY VOTE ON THE
17	SLATE RECOMMENDED BY THE GRANTS WORKING GROUP AND
18	NOT BE ABLE TO ADDRESS ANY INDIVIDUAL GRANTS.
19	HAVING SAID THAT, DR. SHAPIRO MADE IT VERY
20	CLEAR AT HIS PRESENTATION TO THE BOARD IN DECEMBER
21	THAT IF WE ADDRESSED THE ECONOMIC CONFLICT ISSUE,
22	THAT WOULD ALLEVIATE THE NEED TO VOTE ON THE SLATE
23	ONLY. IT IS WITH THAT THOUGHT IN MIND THAT I NOW
24	ADDRESS THE CONFLICTS ISSUE IN THE PRESENTATION.
25	CONFLICTS: THE IOM REPORT RECOMMENDS
	73

1	MAXIMIZING THE NUMBER OF INDEPENDENT BOARD VOTES ON
2	GRANTS. WHEN THEY SAY ECONOMIC WHEN THEY SAY
3	INDEPENDENT, WHAT THEY'RE REFERENCING IS IS
4	ECONOMICALLY INDEPENDENT. CURRENTLY THERE ARE 13
5	PERMANENT BOARD SLOTS WITH MEMBERS APPOINTED FROM
6	INSTITUTIONS ELIGIBLE FOR FUNDING. THAT IS THE
7	CENTRAL FOCUS OF ALL THE REPORTS WE'VE HAD ON US AND
8	ALL OF THE PRESS THAT'S FOCUSING ON THE CONFLICT
9	ISSUE.
10	I PROPOSE, AND THIS IS, I UNDERSTAND, VERY
11	DRAMATIC, THAT THESE 13 INSTITUTIONAL MEMBERS, WE
12	WOULD DEVELOP A POLICY BY THE BOARD THAT WOULD ASK
13	THAT THEY VOLUNTARILY ABSTAIN FROM VOTING ON ALL
14	GRANTS BROUGHT BEFORE THE BOARD FOR APPROVAL. THIS
15	REDUCES THE BOARD TO 16 ELIGIBLE MEMBERS TO VOTE ON
16	GRANTS, ALL ECONOMICALLY INDEPENDENT UNLESS THEY ARE
17	OTHERWISE CONFLICTED.
18	ELIMINATING ECONOMIC CONFLICTS FREES THE
19	BOARD TO DISCUSS INDIVIDUAL GRANTS THOUGH IN A
20	PROGRAMMATIC REVIEW FORMAT WHICH I'LL DESCRIBE
21	LATER. VERY IMPORTANTLY, INSTITUTIONAL MEMBERS CAN
22	STILL PARTICIPATE IN THE DISCUSSIONS AND GIVE THE
23	BOARD THE FULL ADVANTAGE OF ITS CONSIDERABLE
24	EXPERTISE, BUT AT THE END CANNOT VOTE ON THE
25	APPROVAL OF GRANTS. THAT WILL DEAL DEFINITIVELY

1	WITH THE ECONOMIC CONFLICT ISSUE.
2	THIS PROPOSED SOLUTION IS SOMETHING THAT
3	I'VE DEVELOPED IN CONSULTATION WITH MANY PEOPLE AND
4	IS ONE THAT WE'RE NOT SURE IF IT'S GOING TO BE
5	ULTIMATELY THE BEST WAY TO ADDRESS THIS ISSUE OR
6	NOT, BUT I BELIEVE IT'S THE BEST THING TO PUT IN
7	PLACE RIGHT NOW, BUT WE WANT TO SEE IF IT WORKS. SO
8	WHAT I'M PROPOSING IS IT BE PUT IN PLACE FOR A
9	ONE-YEAR TRIAL PERIOD TO SEE IF IT'S EFFECTIVE. I
10	BELIEVE IT WILL BE. IF IT'S NOT EFFECTIVE, WE'LL
11	REVISIT AND PUT IN PLACE A PREFERABLE ALTERNATIVE AT
12	THAT TIME.
13	ON THE ISSUE OF INCREASING INDUSTRY
14	INVOLVEMENT, THE IOM REPORT RECOMMENDED SUCH
15	INCREASED INVOLVEMENT. TO GET THE GREATEST IMPACT
16	IN THIS REGARD, I BELIEVE THE PRESIDENT AND STAFF
17	COULD INCREASE INDUSTRY PARTICIPATION ON THE GRANTS
18	WORKING GROUP AND THE CLINICAL DEVELOPMENT ADVISORY
19	PANELS AS WELL AS A MATERIAL NUMBER OF INDUSTRY
20	REPRESENTATIVES ON THE RECOMMENDED SCIENTIFIC
21	ADVISORY BOARD REPORTING TO THE PRESIDENT.
22	WE'VE HAD A LOT OF DISCUSSIONS ABOUT THIS,
23	DR. TROUNSON, DR. FEIGAL, ETC., AND I BELIEVE THEY
24	ARE IN FIRM AGREEMENT ON THIS SUGGESTION.
25	WE ALSO WOULD WANT, FURTHER TO WHAT THE

1	IOM WAS HEARING FROM INDUSTRY ITSELF, TO ENCOURAGE
2	ADDITIONAL INDUSTRY INPUT INTO THE ACTUAL DRAFTING
3	OF RFA'S.
4	ON THE ISSUE OF APPEALS AND THE GRANTS
5	REVIEW PROCESS, I THINK IT'S IMPORTANT TO NOTE THAT
6	THROUGH THE ANNALS OF CIRM, THE BOARD HAS ACTUALLY
7	APPROVED RECOMMENDATIONS FROM THE GRANTS WORKING
8	GROUP MORE THAN 90 PERCENT OF THE TIME. SO THERE'S
9	GREAT CONFORMITY IN OPINION, BUT NOT UNANIMITY, BUT
10	GREAT CONFORMITY IN WHAT THE BOARD DOES IN RESPONSE
11	TO THE SCIENTISTS AT THE PEER REVIEW GROUP.
12	THE IOM REPORTS RECOMMENDS THAT WE
13	ELIMINATE OUR EXTRAORDINARY APPEALS PROCESS. WE'VE
14	HAD THIS IN PLACE FOR A WHILE. AS WE ALL KNOW,
15	THERE HAVE BEEN ISSUES WITH THIS. WE'VE BEEN
16	EXAMINING THE PROPER PROTOCOL TO PUT IN PLACE TO
17	ALLOW FOR THE BEST APPELLATE PROCESS POSSIBLE. AND
18	SO RATHER THAN ELIMINATING EXTRAORDINARY APPEALS,
19	I'M PROPOSING THAT WE REDIRECT ALL SUCH THESE
20	ARE, GENERALLY SPEAKING, SCIENTIFIC APPEALS ON A
21	VARIETY OF FRONTS THAT WE REDIRECT ALL SCIENTIFIC
22	APPEALS TO STAFF WHO WILL EVALUATE THEM TO SEE IF
23	THE GRANTS WORKING GROUP OR SUBSET THEREOF SHOULD
24	CONSIDER THEM FOR FURTHER REVIEW.
25	THIS IS A REVISED VERSION OF THE

1	ADDITIONAL ANALYSIS PROCEDURE THAT I INSTITUTED LAST
2	SUMMER. THERE WILL BE CRITERIA SET FORTH FOR THE
3	APPELLATE PROCESS, WHETHER IT'S NEW INFORMATION OR A
4	MATERIAL DISPUTE OF FACT THAT THOSE PROPOSERS FELT
5	EXISTED BETWEEN THEIR PROPOSAL AND WHAT THE GRANTS
6	WORKING GROUP DECIDED, ETC. ONCE THE APPEALS ARE
7	FINISHED, THE RECOMMENDATIONS, WHICH TAKE INTO
8	ACCOUNT THE ORIGINAL SCORING OF THE GRANTS WORKING
9	GROUP AS AMENDED BY ANY ADDED IN THE APPELLATE
10	PROCESS, WOULD THEN GO TO THE BOARD.
11	PROGRAMMATIC REVIEW AND THE ROLE OF
12	PATIENT ADVOCATES: THE IOM REPORT RECOMMENDS
13	AGAINST HAVING VOTING PATIENT ADVOCATE BOARD MEMBERS
14	ON THE GRANTS WORKING GROUP. CURRENTLY PATIENT
15	ADVOCATES RUN PROGRAMMATIC REVIEW, WHICH IS, AS YOU
16	KNOW, THE SECOND PART OF THE GRANTS WORKING GROUP
17	MEETINGS. THERE ARE A NUMBER OF THOSE OF YOU WHO
18	ATTEND THESE MEETINGS AND I THINK DERIVE GREAT
19	BENEFIT FROM THAT AND, AS A RESULT, ARE IN A
20	POSITION TO DRIVE THE PROGRAMMATIC REVIEW
21	DISCUSSION. THE CHAIR, ME, CURRENTLY ATTENDS EX
22	OFFICIO. I HAVE NO VOTING RIGHTS, JUST OBSERVING
23	RIGHTS.
24	NOW, ONE THING THAT WASN'T ADDRESSED IN
25	THE IOM REPORT, WHICH I THINK IS VERY IMPORTANT, IS,

1	AND I'VE HEARD THIS SINCE I STARTED NOW 19 MONTHS
2	AGO, PER THE STAFF HERE AT CIRM AND THE SCIENTISTS
3	ON THE GRANTS WORKING GROUP, THERE'S BEEN A QUESTION
4	AS TO WHY WE HAVE PROGRAMMATIC REVIEW AT THE GRANTS
5	WORKING GROUP. WHY ISN'T THAT SOMETHING MORE
6	PROPERLY DONE IN FRONT OF THE ICOC ITSELF GIVEN THE
7	TYPES OF ISSUES THAT ARE DISCUSSED, WHICH ARE
8	LARGELY NONSCIENTIFIC.
9	AND SO HAVING HEARD THAT QUESTION OVER AND
10	OVER AND OVER, TOOK TO HEART THAT SUGGESTION, AND MY
11	PROPOSAL WOULD BE THAT WE NOW MOVE PROGRAMMATIC
12	REVIEW TO THE BOARD. WE HAVE THE GRANTS WORKING
13	GROUP ITSELF DOING SOLELY SCIENTIFIC DISCUSSION.
14	THE PATIENT ADVOCATES WHO ARE HERETOFORE VOTING
15	MEMBERS OF THE GRANTS WORKING GROUP WOULD NO LONGER
16	HAVE A VOTE. THEY WOULD BE ABLE TO ATTEND AND
17	PARTICIPATE IN THAT SO AS TO INFORM THE RUNNING OF
18	THE PROGRAMMATIC REVIEW, WHICH WOULD NOW, UNDER MY
19	PROPOSAL, BE MOVED TO THE BOARD AFTER THE GRANTS
20	WORKING GROUP HAD FINISHED.
21	VERY IMPORTANTLY, WE ARE NOW, AS I SAID
22	EARLIER, OKAY TO HAVE PROGRAMMATIC REVIEW AT THE
23	BOARD LEVEL BECAUSE WE'VE NOW DEALT WITH THE
24	ECONOMIC CONFLICTS ISSUE. A CENTRAL PART OF THE
25	PROGRAMMATIC REVIEW CHAIN WILL BE THAT ONCE THE
	70
	78

1	GRANTS WORKING GROUP HAS FINISHED ITS WORK, STAFF
2	WILL THEN TAKE A FRESH LOOK AT THE GRANTS WORKING
3	GROUP PROPOSALS AND WILL RECOMMEND ANY PROJECTS THEY
4	FEEL WARRANT FURTHER DISCUSSION AT THE BOARD LEVEL
5	IN PROGRAMMATIC REVIEW.
6	PROGRAMMATIC REVIEW ITSELF MAY LEAD TO
7	ADDITIONAL FUNDED PROJECTS, AS IT HAS ON OCCASION IN
8	THE GRANTS WORKING GROUP. AND JUST TO BE TOTALLY
9	FAIR, IT MAY BE POSSIBLE THAT SOME COULD BE, AND
10	THIS HAS ONLY HAPPENED IN A VERY LIMITED NUMBER OF
11	TIMES, REMOVED FROM THE LIST. AS I UNDERSTAND IT,
12	THAT'S ONLY HAPPENED IN INSTANCES WHERE WE'VE
13	ALREADY FUNDED SOMETHING THAT IS ESSENTIALLY A
14	DUPLICATE STUDY, AS AN EXAMPLE, THAT WE FEEL WE
15	DON'T NEED TO HAVE TWO IDENTICAL PROJECTS GOING ON
16	AT THE SAME TIME.
17	ONCE YOU'VE HAD PROGRAMMATIC REVIEW AT THE
18	BOARD LEVEL, YOU WOULD THEN HAVE A FULL SLATE OF
19	PROJECTS TO VOTE ON. AND THE NONECONOMICALLY
20	CONFLICTED BOARD MEMBERS WILL VOTE ON THAT ENTIRE
21	SLATE AT THE CONCLUSION OF THAT PROGRAMMATIC REVIEW
22	PROCESS.
23	ON THE ISSUE OF THE CHAIR AND PRESIDENT
24	DIVISION OF RESPONSIBILITIES, THE IOM AND OTHERS,
25	RUTH, HAVE EXPRESSED CONCERNS IN THE PAST CONCERNING

1	OVERLAPPING RESPONSIBILITIES BETWEEN THE CHAIR AND
2	THE PRESIDENT. THE REPORT RECOMMENDS DELEGATION OF
3	OPERATIONAL ROLES OF THE CHAIR AND THE VICE CHAIRS
4	TO THE PRESIDENT. I SEE IT A LITTLE DIFFERENTLY,
5	PERHAPS NOT SURPRISINGLY.
6	MY VIEW IS THE PRESIDENT, WHO IS ALWAYS AN
7	EMINENT SCIENTIST, IS VERY WELL EQUIPPED TO RUN THE
8	FULL SCIENTIFIC OPERATION AND ALL THE ASPECTS THAT
9	IT ENTAILS. AND I WOULD SORT OF DUB THIS THE INSIDE
10	TASKS OF THE AGENCY. THAT WOULD INCLUDE, IF WE
11	INDEED HAVE ANOTHER CFO, THAT WOULD BE REPORTING TO
12	THE PRESIDENT UNDER THIS CONSTRUCT. THE CHAIR IS
13	NOT SCIENTIFICALLY VERSED IN A MANNER TYPICALLY TO
14	BE ABLE TO BE INVOLVED IN THE OPERATIONAL DAY-TO-DAY
15	ON THE SCIENCE SIDE AND SHOULD LEAVE THAT TO THE
16	PRESIDENT AND STAFF TO HANDLE.
17	SIMILARLY, THE PRESIDENT AND THE STAFF ARE
18	NOT EQUIPPED FROM A SKILL SET POINT OF VIEW TO
19	HANDLE WHAT THE LITTLE HOOVER COMMISSION DUBBED
20	EXTERNAL AFFAIRS. AND IN THAT EXTERNAL AFFAIRS
21	GROUP I WOULD LUMP THINGS LIKE FINANCIAL
22	SUSTAINABILITY, TRYING TO FIGURE OUT HOW TO RAISE
23	ADDITIONAL FUNDS TO KEEP THE CIRM OPERATION GOING
24	LONG-TERM. GOVERNMENT RELATIONS, EXTENSIVE WORK ON
25	THAT FRONT. BOND FINANCING WHICH IS, FOR THOSE WHO
	80

1	AREN'T INVOLVED IN IT, A RATHER ESOTERIC WORLD OF
2	FINANCE WHICH IS PART FINANCE AND ACTUALLY LARGER
3	PART POLITICAL. AND COMMUNICATIONS WITH WHAT I CALL
4	THE OUTSIDE WORLD OR BEYOND THE SCIENTIFIC MEDIA FOR
5	THE BOARD SPEAKING TO THAT OUTSIDE WORLD. I DUB
6	THESE THE OUTSIDE TASKS.
7	I WOULD SUBMIT TO YOU, MEMBERS OF THE
8	BOARD, THAT THIS INSIDE/OUTSIDE COMBINATION GIVES
9	CIRM THE FULL COVERAGE OF ALL AREAS NEEDED TO MAKE
10	THE AGENCY FUNCTION ON ALL CYLINDERS. AND, IN FACT,
11	FAR FROM IT BEING OVERLAPPING RESPONSIBILITIES AND
12	STEPPING ON TOES, THE CHAIR AND THE PRESIDENT
13	ACTUALLY HAVE UNDER THIS CONSTRUCT A VERY GOOD
14	SYMBIOTIC RELATIONSHIP THAT ALLOWS THE AGENCY TO GET
15	THE BIGGEST BANG FOR THE CALIFORNIA TAXPAYER BUCK.
16	UNDER THIS CONSTRUCT AS WELL, ALL THOSE
17	WHO, OF COURSE, ARE WORKING ON THE INSIDE TASKS,
18	WHICH IS THE OPERATIONS OF THE AGENCY, WOULD REPORT
19	TO THE PRESIDENT. THOSE WORKING ON ALL THE THINGS
20	WITH THE CHAIR ON THE OUTSIDE WOULD REPORT TO THE
21	CHAIR.
22	ON THE ISSUE OF INTELLECTUAL PROPERTY, THE
23	IOM SUGGESTS THAT THE IP REGS OF THE AGENCY HAVE
24	GREATER CONFORMITY WITH THE BAYH-DOLE ACT. THESE
25	RECOMMENDATIONS WE'RE NOT GOING TO DISCUSS TODAY.
	81
	U T

INSTEAD, WE'RE GOING TO REFER THEM TO THE CIRM
INDUSTRY AND IP SUBCOMMITTEE FOR A FULL AIRING. I
WOULD ASK THAT THAT SUBCOMMITTEE, IN THE CONTEXT OF
THESE DISCUSSIONS, DO A THOROUGH RECITATION AND
REVIEW OF ALL THE EFFORTS THAT HAVE BEEN PUT IN TO
DATE IN DEVELOPING THE IP REGS WITH PARTICULAR
EMPHASIS ON THE THREE GOALS THAT WE'VE ALWAYS HAD IN
FRONT OF US IN PROMULGATING THOSE REGS, WHICH ARE
AFFORDABLE COST TO CALIFORNIA CITIZENS OF THERAPIES
OR CURES DEVELOPED BY THE SCIENTISTS FUNDED BY THE
AGENCY, ACCESSIBILITY TO THOSE THERAPIES AND CURES
FOR THE CITIZENS OF CALIFORNIA, AND, IMPORTANTLY,
RETURN ON INVESTMENT TO THE STATE FOR THE
CONSIDERABLE AMOUNT OF FUNDING THAT IT IS PUTTING
INTO THIS VIA PROP 71.
I WANT TO SAY THAT IN THE COURSE OF THE
DEVELOPMENT OF THESE REGS, WE'VE ADJUSTED TO MAKE
THEM MORE ATTRACTIVE TO INDUSTRY TO THIS POINT WHILE
ENSURING THAT RETURN TO THE STATE.
THE IOM REPORT ON ANOTHER RELATED MATTER
IN IP RECOMMENDS THAT WE DEVELOP A METHOD OF HOW TO
ENFORCE THE IP REGS IF AND WHEN CIRM HANDS OVER THE
KEYS TO ANOTHER GOVERNMENTAL AGENCY WHO WILL BE IN
CHARGE OF ALL OF THE PROJECTS AND THE CIRM
PORTFOLIO. AND, OF COURSE, WE FULLY PLAN TO DO JUST
82

1	THAT.
2	ON THE ISSUE OF SUSTAINABILITY, I WILL SAY
3	THE BOARD AND STAFF WERE VERY PLEASED WITH THE
4	SIGNIFICANT NUMBER OF VALIDATING COMMENTS THAT WERE
5	IN THE REPORT AND THAT THEY THOUGHT SO HIGHLY OF
6	WHAT CIRM HAS DONE TO DATE AND THE PORTFOLIO THAT'S
7	IN PLACE AND WHERE WE CONTINUE TO HEAD, THAT THEY
8	LISTED SUSTAINABILITY AS ONE OF THE VERY TOP
9	PRIORITIES. THIS IS A TOPIC, AGAIN, FOR A LATER
10	DAY.
11	I'M CURRENTLY CONSIDERING A VARIETY OF
12	OPTIONS. I ASSURE YOU THIS ISSUE IS VERY MUCH ON
13	THE FRONT BURNER, LOOKING AT A VARIETY OF THINGS
14	INCLUDING SOME IDEAS ON A VENTURE PHILANTHROPY FUND
15	AND OTHER IDEAS. BUT AS THOSE ARE A LITTLE MORE
16	FULLY BAKED, I WILL BE BACK TO THE BOARD IN DUE
17	COURSE TO DISCUSS THOSE AT THAT TIME.
18	I HAVE A SLIDE HERE ENTITLED "OTHER."
19	THESE REFLECT ADDITIONAL SUGGESTIONS IN THE IOM
20	REPORT. ONE DEALS WITH THE WORKING GROUPS. IT
21	SUGGESTED THEY REPORT TO THE PRESIDENT. AS YOU
22	KNOW, WE HAVE THE GRANTS WORKING GROUP, THE
23	STANDARDS WORKING GROUP, AND THE FACILITIES WORKING
24	GROUP. THE REPORT SUGGESTS THEY ALL REPORT TO THE
25	PRESIDENT. I FULLY ADVOCATE THAT WE SHOULD BE DOING

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1	JUST THAT.
2	I WOULD SAY THAT WITH REGARDS TO THE
3	MEMBERSHIP OF THESE WORKING GROUPS, I WOULD ADD A
4	BIT OF A WRINKLE. WE'VE NOW UNDER MY PLAN DISCUSSED
5	HOW THERE WILL BE NO BOARD MEMBERS WHO ARE VOTING
6	MEMBERS OF THE GRANTS WORKING GROUP HENCEFORTH.
7	HOWEVER, WITH RESPECT TO THE STANDARDS WORKING
8	GROUP, BECAUSE FREQUENTLY THAT GROUP DEALS WITH
9	NONFINANCIAL ISSUES IN THE ETHICAL OR POLICY SPHERE,
10	I BELIEVE THAT THE GROUP COULD BENEFIT FROM THOSE
11	WITH SKILL SETS IN THAT REGARD FROM THE BOARD.
12	LIKEWISE, THE FACILITIES WORKING GROUP, WHICH
13	PROBABLY ISN'T GOING TO HAVE A WHOLE LOT OF
14	ADDITIONAL ACTION, BUT IF IT DOES, THERE ARE THOSE
15	WITH FINANCE AND REAL ESTATE EXPERTISE ON THE BOARD
16	THAT I BELIEVE SHOULD CONTINUE TO SERVE ON THAT
17	WORKING GROUP TO FURTHER INFORM THOSE DISCUSSIONS.
18	THEN, AS I SAID, THERE ARE A NUMBER OF
19	MATTERS IN THE IOM REPORT THAT ARE PROPERLY
20	ADDRESSED AND HANDLED BY STAFF AND WILL BE SO
21	HANDLED. THESE INCLUDE THE ESTABLISHMENT OF A
22	SCIENTIFIC ADVISORY BOARD REPORTING TO THE
23	PRESIDENT, HELPING TO ADVANCE REGENERATIVE MEDICINE
24	IN THE DEVELOPMENT OF THE REGULATORY PATHWAY,
25	DEVELOPMENT OF RFA'S, ETC., ALL THESE THINGS

84

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1	PROPERLY WITHIN THE JURISDICTION OF THE PRESIDENT.
2	AND WE'VE HAD DISCUSSIONS ABOUT THIS, AND THOSE WILL
3	PROCEED ACCORDINGLY.
4	OKAY. THAT'S THE PLAN. WHAT'S REQUIRED
5	TO MAKE CHANGES? THERE ARE A LOT OF CHANGES HERE.
6	WELL, WE'VE CONSTRUCTED THIS IN SUCH A WAY THAT WE
7	BELIEVE THAT WE CAN ACCOMPLISH EVERYTHING I'VE JUST
8	LAID OUT THROUGH BOARD ACTION AND WILL NOT REQUIRE
9	EITHER LEGISLATION OR AN ADDITIONAL BALLOT MEASURE.
10	NOW, TO THE EXTENT THAT THAT PROVES NOT TO BE THE
11	CASE AND CERTAIN THINGS ARE DEEMED TO BE REQUIRING
12	OF LEGISLATION, WE'LL DEAL WITH IT AT THAT TIME.
13	BUT WE BELIEVE, AS WE STAND HERE TODAY, WITH THIS
14	PLAN THAT THAT WILL NOT BE NECESSARY.
15	WHAT WILL BE NECESSARY IS THE AMENDMENT OF
16	A NUMBER OF EXISTING CIRM LANGUAGE THAT YOU FIND IN
17	BYLAWS AND EXISTING REGS AND POLICIES, ETC. MR.
18	HARRISON, BASED ON WHAT WE COME OUT FROM THIS
19	DISCUSSION, WILL MAKE THE APPROPRIATE CHANGES TO
20	THOSE VARIOUS THINGS AND WILL PRESENT THAT TO THE
21	BOARD AT THE MARCH MEETING.
22	THE INTERESTING THING HERE IS CHANGES, IF
23	WE ARE CORRECT, THAT WE CAN DO THIS WITHOUT
24	LEGISLATION OR BALLOT MEASURE, CAN BE IMPLEMENTED
25	IMMEDIATELY. SO WHAT WE HAVE HERE IN SHORT IS A, I
	85

1	BELIEVE, DRAMATIC, SUBSTANTIVE RESPONSE TO EVERY IOM
2	RECOMMENDATION. WE ARE ABLE TO PUT ALL OF THESE
3	DIFFERENT COMPONENTS INTO OPERATION WITHOUT NEED FOR
4	EXTERNAL VALIDATION, AND IN DOING SO, WILL BE ABLE
5	TO IMPLEMENT THE VARIOUS STEPS RIGHT AWAY, AND I
6	BELIEVE WILL IMMEDIATELY GET US TO A POINT WHERE WE
7	HAVE BEEN DEEMED TO REALLY HAVE DONE WHAT WE WERE
8	SUPPOSED TO IN RESPONSE TO THIS IOM REPORT AND WILL
9	HAVE BEEN VIEWED AS HAVING DONE SO FROM A GOVERNMENT
10	STANDPOINT IN WARP SPEED.
11	SO WITH THAT, I WOULD LIKE TO CONCLUDE MY
12	PRESENTATION AND THROW THE PLAN TO YOU ALL FOR YOUR
13	COMMENTS. SENATOR TORRES.
14	MR. TORRES: YES, MR. CHAIRMAN. I WANT TO
15	THANK YOU FOR ALL THE THOUGHTFUL WORK THAT YOU,
16	STAFF, AND MANY OF US HAVE DONE IN RESPECT TO THESE
17	ISSUES. I WOULD ALSO REFERENCE A LETTER BY DR. TED
18	LOVE, WHO SERVED AS SCIENTIFIC OFFICER HERE AS WELL
19	AS A MEMBER OF OUR BOARD, A VERY THOUGHTFUL LETTER
20	THAT OUGHT TO BE LOOKED AT BY THE BOARD MEMBERS.
21	THE ISSUE BEFORE US IS TIMING. THE ISSUE
22	BEFORE US IS SHOWING RESPONSIBILITY SO THAT WE CAN
23	MOVE ON. WE HAVE THOUGHT THAT THIS MIGHT BE A
24	BETTER WAY TO GO BECAUSE IT ACCELERATES THE PROCESS
25	SO THAT THE GENERAL PUBLIC UNDERSTANDS THAT WE TAKE

1	THESE RECOMMENDATIONS SERIOUSLY, SO SERIOUSLY THAT
2	WE'RE MOVING AS QUICKLY AS WE CAN WITHOUT SUBJECTING
3	OURSELVES TO A LEGISLATIVE TIMETABLE, WHICH WOULD
4	LAST UNTIL SEPTEMBER OF THIS YEAR, AND ANY SIGNATURE
5	BY THE GOVERNOR WOULDN'T AFFECT IT UNTIL JANUARY 1
6	OF 2014. IN MY OPINION, THAT WOULD BE TOO LATE.
7	I ALSO WANT TO THANK SENATOR JERRY HILL, I
8	BELIEVE HIS STAFF IS HERE AS WELL, FOR GRACIOUSLY
9	PUTTING IN A WHAT WE CALL SPOT BILL JUST IN CASE WE
10	MIGHT NEED SOMETHING IF, IN FACT, THE BOARD ACTIONS
11	THAT WE TAKE AND THE REGULATORY NATURE AND CLEARLY
12	THE TIMING IS NOT SUFFICIENT AND REQUIRES US TO GO
13	SOMEWHERE WITH SOME OF THESE RECOMMENDATIONS THROUGH
14	THE LEGISLATIVE PROCESS, BUT CERTAINLY NOT ALL.
15	THE IOM REPORT PRESENTED TO THIS BOARD AND
16	THE STAKEHOLDERS A CHALLENGE. AND THAT IS TO COME
17	UP WITH RECOMMENDATIONS THAT WE COULD IMPLEMENT
18	QUICKLY, EFFECTIVELY, AND SUBSTANTIVELY. I BELIEVE
19	THAT THIS DOCUMENT HELPS US DO THAT. AND I WOULD
20	JUST URGE YOU TO CONSIDER IT SERIOUSLY AS WE MOVE
21	FORWARD, KNOWING ALL ALONG THAT WE HAVE OTHER
22	ALTERNATIVES AVAILABLE IF, IN FACT, THE BOARD ACTION
23	ISN'T SUFFICIENT, WHICH I THINK IT WILL BE, IN
24	RESPECT TO THESE ISSUES AND HOW WE MOVE FORWARD.
25	CHAIRMAN THOMAS: DUANE.
	87
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1	MR. ROTH: SO THANK YOU ALSO FOR THAT
2	PRESENTATION. I'VE HEARD PIECES OF THIS, BUT NOT
3	ALL OF IT. AND I HAVE TO COMMEND YOU FOR A VERY
4	THOUGHTFUL APPROACH TO THIS.
5	I GUESS MY COMMENTS WOULD BE THAT MANY OF
6	THESE ISSUES ARE NOT NEW, AND WE'VE BEEN STRUGGLING
7	WITH THEM FOR A WHILE. AND I THINK IT'S TIME NOW
8	THAT WE DO EVERYTHING WE CAN TO TRY TO ADDRESS THEM.
9	THIS IS THE THIRD, AS YOU MENTIONED, THE THIRD
10	REVIEW WE'VE HAD, AND REALLY THE SAME ISSUES COME
11	UP.
12	MY VIEW ON THE ECONOMIC CONFLICT, I THINK
13	YOU'VE COME UP WITH A REALLY INTERESTING WAY TO
14	SOLVE THAT CONFLICT AND I SUPPORT THAT.
15	THE APPEALS HAS BEEN SOMETHING THAT WE
16	WERE WORKING ON FAR SOONER THAN THE IOM REPORT.
17	THAT'S NOT WHAT PROMPTED IT. BERT, YOU'VE BEEN
18	HEADING THAT TASK FORCE BECAUSE WE KNEW THAT WE HAD
19	TO FIGURE THAT OUT. IT WASN'T WITHOUT NOTICE THAT
20	IT HAD EVOLVED OVER TIME, AND IT WAS STARTING TO GET
21	REALLY OUT OF CONTROL. AND WE TOOK ACTION AND
22	FORMED A COMMITTEE AND SAID LET'S TRY TO DEAL WITH
23	THIS. SO IT'S NOT LIKE IOM IS THE REASON WE SHOULD
24	DO THAT. IT WAS ONGOING AND NEEDS TO CONTINUE AND
25	ACCELERATE.

1	THE PROGRAMMATIC REVIEW, I LIKE YOUR
2	SOLUTION. I WOULD MAKE AN ALTERNATIVE PROPOSAL,
3	THAT REALLY WHAT WE'RE DISCUSSING HERE IS PORTFOLIO
4	AND WEAKNESS IN THE PORTFOLIO. AND IF THE BOARD IS
5	GOING TO DEAL WITH THIS, WE SHOULD DEAL WITH IT
6	PROSPECTIVELY BASED ON A REPORT FROM STAFF THAT SAYS
7	IN THIS DISEASE AREA, WE REALLY DON'T HAVE MUCH, OR
8	IN THIS TECHNOLOGY, WE DON'T HAVE SOME OF THE THINGS
9	WE NEED. AND WE COULD PROSPECTIVELY CALL THOSE
10	MATERIAL WEAKNESSES IN OUR PORTFOLIO AND MAKE SURE
11	THAT THE GRANTS WORKING GROUP AND OTHERS ARE AWARE
12	OF THOSE KINDS OF NEEDS THAT WE HAVE SO THEY CAN
13	POTENTIALLY DEAL WITH THEM. BUT I LIKE PORTFOLIO
14	MUCH BETTER THAN PROGRAMMATIC.
15	I THINK WE REALLY NEED TO LOOK AT OUR
16	PORTFOLIO CONTINUOUSLY, BUT DO IT PROSPECTIVELY, NOT
17	WHEN THERE'S A GRANT OVER HERE THAT SOMEBODY SAYS WE
18	HAVE A WEAKNESS THERE. MAYBE WE DO, BUT MAYBE AFTER
19	FURTHER THOUGHT OR INPUT FROM SCIENTIFIC ADVISORS,
20	WE'D FIND THAT IT'S LESS. SO WE CAN, I THINK, WORK
21	ON THAT.
22	THE LAST ONE I'M GOING TO COMMENT ON IS
23	GOVERNANCE. ALL OF YOU KNOW I WAS PROBABLY THE MOST
24	OUTSPOKEN ON THE GOVERNANCE MODEL OF ANY OF THE
25	BOARD MEMBERS, AND WE DEALT WITH THIS DURING THE

1	CHANGE IN CHAIRS. AND I, FOR ONE, AM NOT WILLING TO
2	GO DOWN THAT PATH AGAIN. WE DISCUSSED IT, WE
3	REVIEWED IT, AND WE HAVE A WORKING GROUP NOW OR
4	WORKING RELATIONSHIP BETWEEN THE CHAIR AND THE
5	PRESIDENT THAT IS VERY, VERY GOOD. IT'S NOT PERFECT
6	AND THERE'S SOME THINGS THAT NEED TO BE DONE, BUT
7	THEY AREN'T THINGS IN TERMS OF STRUCTURAL CHANGE
8	THAT I THINK WE NEED TO MAKE.
9	SO AS LONG AS THIS CONTINUES AND THERE'S
10	RESPECT AND WE CAN FIX SOME OF THESE WHAT I'LL CALL
11	AGGRAVATIONS BETWEEN THE GROUPS, I THINK WE HAVE A
12	CHANCE TO MOVE THAT FORWARD. SO THAT HAS TO BE ONE
13	THAT I THINK WE AGREE TO DISAGREE AND SAY THAT WE'VE
14	CROSSED OVER THAT, AND THERE'S NOT GOING TO BE
15	ANYTHING GAINED FROM TRYING TO RESTRUCTURE IT AT
16	THIS POINT OF THE AGENCY'S HISTORY. THOSE ARE MY
17	COMMENTS.
18	CHAIRMAN THOMAS: THANK YOU. MICHAEL.
19	DR. FRIEDMAN: THANK YOU. I'VE GIVEN A
20	LOT OF THOUGHT TO THE IOM CRITIQUE AND REFLECTED ON
21	THE PRIVILEGE THAT IT IS TO SERVE ON THIS GROUP AND
22	UNDERSTAND THE RESPONSIBILITY THAT WE HAVE IN DOING
23	SO. I, TOO, AS PREVIOUS SPEAKERS, TAKE THE COMMENTS
24	OF THE IOM REPORT VERY SERIOUSLY. I WOULDN'T SPEND
25	TIME ASKING THE QUESTION IS THE CRITICISM FAIR

1	BECAUSE I DON'T THINK THAT'S THE RIGHT QUESTION. I
2	THINK THE RIGHT QUESTION IS IS THE CRITICISM
3	NOTEWORTHY AND IMPORTANT, AND CAN IT BE DEALT WITH.
4	AND THE ANSWER TO THAT QUESTION IN MY MIND IS YES.
5	DO I THINK THAT ALL THE PROPOSALS THAT
6	YOU'RE MAKING ARE THE IDEAL OR BEST WAY TO SOLVE
7	THINGS? I DON'T NECESSARILY. BUT WHAT I DO BELIEVE
8	IS, AND HERE I'M ECHOING ART AND DUANE, THAT IT IS
9	IMPORTANT TO TAKE ACTION AND TO BE RESPONSIVE AND TO
10	SHOW THAT WE ARE SENSITIVE TO THE ISSUE.
11	WE RECOGNIZE THAT THERE'S AN APPEARANCE OF
12	CONFLICT OF INTEREST FOR A VERY LONG TIME. I WANT
13	TO BE VERY CLEAR ABOUT THE FACT THAT IN EVERY
14	INTERACTION I'VE EVER HAD PUBLICLY OR IN EXECUTIVE
15	SESSION, PRIVATELY DEALING WITH ANY INDIVIDUAL OR
16	DEALING WITH GROUPS, I HAVE NEVER SEEN ANYTHING IN
17	THIS BOARD OR ANY OF ITS MEMBERS THAT REPRESENTED IN
18	MY MIND ANYTHING CLOSE TO A CONFLICT OF INTEREST. I
19	HAVE NEVER SEEN THAT. I BELIEVE PEOPLE ARE OF THE
20	HIGHEST INTEGRITY. I THINK YOU'RE ALL TERRIBLY
21	SERIOUS. WE DON'T AGREE ON THINGS SOMETIMES, BUT
22	THAT'S THE NATURE OF THIS WORK.
23	ON THE OTHER HAND, IS THERE AN APPEARANCE
24	OF CONFLICT OF INTEREST, AND THE ANSWER HAS TO BE
25	YES. AND WHAT WE DO UNDERSTAND IN THESE

1	CIRCUMSTANCES IS NOT JUST MANAGE THE REALITY OF
2	CONFLICT OF INTEREST, BUT MANAGE THE APPEARANCE OF
3	CONFLICT OF INTEREST. AND I UNDERSTAND THAT PEOPLE
4	WHO FEEL THAT WAY AND WHO CRITICIZE US ARE CONFUSING
5	CAUSE AND EFFECT WITH MERE ASSOCIATION. THEY SEE
6	PEOPLE SITTING AROUND A TABLE WHO REPRESENT
7	INTERESTS THAT COULD ULTIMATELY BE POINTED BACK TO
8	AN INSTITUTION, ALTHOUGH I DON'T BELIEVE THAT'S THE
9	CASE, BUT SOME PEOPLE SEE THAT, AND THEY BELIEVE
10	BECAUSE THAT EXISTS, THERE MUST BE SOME CONFLICT OF
11	INTEREST.
12	THERE'S NO WAY TO DEAL WITH THAT EXCEPT TO
13	REMOVE THE APPEARANCE. AND I REALLY ENDORSE AND
14	SUPPORT THE RECOMMENDATION THAT YOU'VE MADE.
15	AS I SAID, IT'S A PRIVILEGE FOR ME TO
16	SERVE ON THIS GROUP. I ENJOY VOTING. I ENJOY
17	DISCUSSING. I ENJOY UNDERSTANDING AND OFFERING
18	ADVICE WHERE THAT'S EVER POSSIBLE, BUT I AM
19	ABSOLUTELY PREPARED TO ABSTAIN AND NOT VOTE ON A
20	SINGLE OTHER GRANT IN ORDER TO ADDRESS THIS PROBLEM.
21	AND DO I CONFUSE THE FACT THAT THE ARGUMENT THAT ONE
22	MAKES IS THE SAME AS THE VOTE? I DON'T. I THINK
23	THE DISCUSSION AND THE ARGUMENT IS ACTUALLY MORE
24	VALUABLE, MORE IMPORTANT. DO I ALWAYS AGREE WITH
25	THOSE PEOPLE WHO DO NOT REPRESENT INSTITUTIONS? NO.

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1
     BUT I THINK IT'S A WONDERFUL GROUP OF WELL-MEANING
 2
     AND INTELLIGENT PEOPLE WHO ARE TRYING TO DO THE
 3
     RIGHT THING. AND I CAN CERTAINLY SUPPORT THAT PART
 4
     OF THE RECOMMENDATION THAT YOU'VE COME UP WITH.
 5
               I WON'T REALLY DEAL WITH THE OTHER ASPECTS
     OF WHAT YOU'RE RECOMMENDING. I THINK THEY'RE
 6
 7
     WORKABLE. I THINK THEY'RE REASONABLE. I THINK
     THEY'RE APPROPRIATE. AND AS A PACKAGE, I'M
 8
 9
     CERTAINLY PREPARED TO SUPPORT THIS. THANK YOU.
10
               CHAIRMAN THOMAS: THANK YOU. SHERRY.
11
               MS. LANSING: I JUST WANT TO, FIRST OF
12
     ALL, THANK YOU BECAUSE THE IOM REPORT WAS AN
13
     ENORMOUS THING FOR ALL OF US TO LOOK AT, AND THE
14
     SOLUTIONS DO NOT COME EASY. I TOO WANT TO STATE
15
     THAT I DON'T AGREE WITH A LOT OF THE IOM REPORT.
16
     I'M SAYING THIS PERSONALLY. I TOO HAVE NEVER EVER
17
     SEEN ANYTHING THAT REPRESENTED ANY ARM TWISTING OR
     ANY CONFLICT OF INTEREST. AND EVERY TIME THAT I'VE
18
19
     ENGAGED WITH ANY BOARD MEMBER, THE INTEGRITY OF THAT
20
     BOARD MEMBER HAS BEEN IMPECCABLE. AND SO I DON'T
21
     AGREE WITH THE FACT THAT WE HAVE A CONFLICT OF
22
     INTEREST.
23
               BUT I DO KNOW THAT THAT IS MY PERSONAL
     OPINION, HAVING WORKED WITH THIS GROUP, AND I DO
24
25
     KNOW THAT THE PERCEPTION IS THAT WE HAVE A HUGE
```

1	CONFLICT OF INTEREST. AND IT HAS BEEN THERE FROM
2	THE BEGINNING, AND IT ALMOST SEEMED LIKE A SNOWBALL,
3	JUST GATHERING SPEED AS IT WENT ALONG. AND
4	UNFORTUNATELY PERCEPTION BECOMES REALITY. THAT'S AN
5	OLD MOVIE EXPRESSION. PERCEPTION DOES BECOME
6	REALITY. AND THAT HAS BECOME THE REALITY.
7	AND SO I FEEL VERY, VERY STRONGLY THAT WE
8	HAVE TO ADDRESS THESE ISSUES, OR IT WILL HARM OUR
9	ABILITY TO DO THE WORK THAT THIS GREAT BOARD AND ALL
10	THE SCIENTISTS AROUND THE STATE ARE DOING. AND IT
11	WILL BECOME THE ISSUE RATHER THAN, AS YOU SAID IN
12	THE BEGINNING OF YOUR REMARKS, WE WANT THE ARTICLES
13	AND EVERYBODY TO PAY ATTENTION TO THE SCIENTIFIC
14	WORK THAT'S BEING DONE. WE WANT THE STAKEHOLDERS,
15	THE VOTERS, TO TALK ABOUT THAT, NOT ABOUT ANY OTHER
16	ISSUE.
17	I THINK THAT WITH CONSULTATION, HOWEVER
18	YOU'VE DONE IT, J.T., YOU'VE JUST DEMONSTRATED
19	EXTRAORDINARY LEADERSHIP IN ATTACKING EACH OF THE
20	ISSUES THAT THE IOM HAS RAISED. AND SO AS I GO DOWN
21	THEM, I FULLY AGREE UNDER THESE CIRCUMSTANCES THAT
22	THE INSTITUTIONS SHOULD ABSTAIN FROM VOTING, BUT ARE
23	ALLOWED TO TALK, AND SO WE GET THE BENEFIT OF THEIR
24	GREAT SCIENTIFIC KNOWLEDGE. I THINK THAT HAVING
25	INDUSTRY TO THE GRANTS WORKING COMMITTEE IS A GOOD

1	IDEA. I THINK WE ACTUALLY HAD TALKED ABOUT THAT
2	ONCE BEFORE. AND I THINK THE APPEALS PROCESS IS
3	ANOTHER THING WHERE PERCEPTION HAS BECOME REALITY.
4	AND EVERY ARTICLE THAT I READ BRINGS THAT UP.
5	EVERYBODY I TALK TO IN THE LEGISLATURE SEEMS TO BE
6	VERY, VERY DISTURBED BY THAT. AGAIN, I DON'T FEEL
7	THAT ANYONE ON THIS BOARD HAS BEEN COMPROMISED OR
8	ACTED IN AN UNETHICAL WAY DURING THAT PROCESS, BUT
9	AGAIN, I COME BACK TO PERCEPTION IS REALITY. SO I
10	ENDORSE THAT AND OBVIOUSLY THE PROGRAMMATIC REVIEW
11	AS WELL.
12	AND I THINK THAT THE PRESIDENT AND THE
13	CHAIR IS AN ISSUE THAT WE DEALT WITH QUITE A LONG
14	TIME AGO AND PERHAPS SOME OF THAT IS A HANGOVER FROM
15	BEFORE.
16	SO I REALLY WANT TO THANK YOU, J.T. AND
17	ANYONE WHO CONTRIBUTED TO ALL OF THIS, ADDRESSING
18	ALL OF THESE ISSUES, AND SAY THAT I FULLY ENDORSE
19	THEM. I THINK THEY WILL ALLOW US TO CONTINUE
20	FUNCTIONING AND DO THE BEST SCIENCE AND TAKE THE
21	ARTICLES OFF OF THINGS THAT ARE PERCEIVED TO BE TRUE
22	AND REALLY LET US GO ABOUT OUR WORK. BUT I CAN'T
23	THANK YOU ENOUGH FOR, FIRST OF ALL, THIS INCREDIBLE
24	PRESENTATION, WHICH MADE IT VERY, VERY CLEAR, AND
25	THE THOUGHTFUL WAY THAT YOU'VE DEALT WITH IT. AND I

1	SAY TO US I ENDORSE THIS. I WOULD CALL FOR A VOTE
2	IF WE'RE SUPPOSED TO OR WHATEVER.
3	CHAIRMAN THOMAS: THANK YOU. MR.
4	JUELSGAARD.
5	DR. JUELSGAARD: I JUST I'M IN
6	AGREEMENT WITH THE OTHER SPEAKERS AND WHAT'S BEEN
7	SAID SO FAR. AND I WANT TO MAKE TWO POINTS OUT OF
8	ALL OF THE THINGS YOU'VE PRESENTED VERY CLEAR FROM
9	MY POINT OF VIEW. THE FIRST HAS TO DO WITH THIS
10	ISSUE OF CONFLICT OF INTEREST, IN PARTICULAR, OF 13
11	MEMBERS OF THIS BOARD.
12	SO I'VE BEEN ON THE BOARD FOR A LITTLE
13	OVER A YEAR AND A HALF NOW. AND I WILL JUST ECHO
14	WHAT OTHERS HAVE SAID. AND THAT IS I HAVE NEVER
15	SEEN AN ISSUE WITH CONFLICT OF INTEREST IN ALL OF
16	THE DELIBERATIONS THAT HAVE GONE ON. I PERSONALLY
17	HAVE NEVER WITNESSED ONE. AND SO I UNDERSTAND THAT
18	THERE'S A PERCEPTION AMONGST SOME QUARTERS THAT
19	THERE IS A CONFLICT OF INTEREST, AND I CAN ACCEPT
20	THAT PEOPLE HAVE THAT PERCEPTION.
21	BUT TO THE EXTENT THAT I VOTE, AND IF I
22	DO, I VOTE IN SUPPORT OF, IN ESSENCE, ASKING 13
23	MEMBERS TO ABSTAIN FROM VOTING. I DO IT NOT BECAUSE
24	I BELIEVE THAT THEY HAVE A CONFLICT OF INTEREST OR
25	I'VE WITNESSED SUCH A THING, BUT I DO IT ESSENTIALLY

1	BECAUSE OTHERS PERCEIVE THAT THERE IS SUCH A THING.
2	AND IT IS ON THAT POINT THAT I'M AGREEING. I JUST
3	WANT TO BE VERY CLEAR ABOUT THAT FROM MY PERSONAL
4	POINT OF VIEW, NOT SUGGESTING AT ALL THAT WE HAVE A
5	PROBLEM THAT WE NEED TO FIX, BUT WE HAVE A
6	PERCEPTION ISSUE THAT WE NEED TO FIX.
7	AND THEN THE SECOND IS THE GOVERNANCE
8	STRUCTURE AND IN PARTICULAR THE ROLE OF THE CHAIR
9	AND THE ROLE OF THE PRESIDENT. SO THERE ARE A LOT
10	OF WAYS THAT YOU CAN ASSEMBLE A GOVERNANCE
11	STRUCTURE. AND THERE ARE SOME OF THEM THAT ARE
12	COMMON AND ARE USED IN MANY DIFFERENT PUBLIC OR
13	PRIVATE ENTERPRISES. WE HAVE ONE HERE THAT'S A
14	LITTLE MORE UNIQUE PERHAPS THAN MOST. BUT AGAIN, IN
15	THE LITTLE MORE THAN A YEAR AND A HALF THAT I'VE
16	BEEN A MEMBER OF THIS GROUP, I THOUGHT THAT THE
17	ORGANIZATIONAL STRUCTURE WORKS EXTREMELY WELL IN
18	THIS ORGANIZATION.
19	IT REMINDS ME A LITTLE BIT OF WHAT
20	HAPPENED WITH REGARD TO THE COMPANY THAT I USED TO
21	WORK FOR, GENENTECH, ONCE IT WAS ACQUIRED BY ROCHE.
22	SO ROCHE BROKE GENENTECH INTO TWO PARTS, BUT THEY
23	WORKED TOGETHER. ONE IS CALLED GENENTECH RESEARCH
24	AND EARLY DEVELOPMENT OR GRED, AND IT'S ESSENTIALLY
25	RESPONSIBLE FOR ALL OF THOSE EARLY SCIENTIFIC
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	97

ENTERPRISES, AND IT HAS A CEO WHO OVERSEES ALL THAT.
AND THEN THE SECOND GENENTECH IS THE ONE THAT'S
RESPONSIBLE FOR THE COMMERCIAL ACTIVITIES, FOR THE
HUMAN RESOURCE ACTIVITIES, FOR THE CORPORATE
COMMUNICATIONS, PUBLIC RELATIONS ACTIVITIES, THE
LEGAL ACTIVITIES, ETC.
AND THOSE TWO ORGANIZATIONS WORK
HARMONIOUSLY TOGETHER, LOCATED ON THE SAME CAMPUS IN
SOUTH SAN FRANCISCO AND WORK EXTREMELY WELL
TOGETHER. SO THERE FOR ME IS A SIMILARITY AS TO THE
STRUCTURE THAT GOES ON HERE. THE DIVISION OF
RESPONSIBILITIES IS PERHAPS A LITTLE DIFFERENT AT
ARE THE MARGIN, BUT ONLY AT THE MARGIN. OTHERWISE I
THINK THEY'RE, FOR ME, QUITE SIMILAR AND I THINK
THEY WORK VERY, VERY WELL. SO I DON'T PERCEIVE ANY
NEED TO CHANGE THE ORGANIZATIONAL STRUCTURE AT LEAST
VIS-A-VIS THE CHAIRMAN OF THE BOARD AND THE
PRESIDENT OF THE ORGANIZATION.
AS TO THE REST OF PROPOSALS, I THINK THEY
MAKE EMINENT SENSE AND I'M SUPPORTIVE OF THEM.
CHAIRMAN THOMAS: DEAN POMEROY.
DR. DULIEGE: JON, YOU MENTIONED IN YOUR
INTRODUCTORY COMMENTS THAT YOU HAD ADDITIONAL
DISCUSSION WITH THE IOM. I ASSUME WITH THE
CHAIRPERSON OF THE COMMISSION. WOULD YOU CARE TO
98

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1	COMMENT ABOUT WHAT YOU LEARNED THROUGH THESE
2	ADDITIONAL DISCUSSIONS?
3	CHAIRMAN THOMAS: SURE. WELL, AGAIN, IT
4	WAS VERY CLEAR AT THE END OF THE MEETING IN
5	DECEMBER, FOLLOWING DR. SHAPIRO'S PRESENTATION, THAT
6	I WANTED TO KEEP IN TOUCH BECAUSE THIS IS THEIR
7	REPORT. WE ASKED FOR THIS REPORT. WE HIGHLY VALUE
8	THEIR INPUT. AND I WANTED TO DEVELOP A PLAN THAT IS
9	SOMETHING THAT WOULD FULLY EMBRACE THE SPIRIT OF THE
10	REPORT.
11	SO TOWARDS THAT END, IN THE COURSE OF
12	TALKING TO MANY PEOPLE ABOUT WHAT TO DO IN
13	DEVELOPING THIS PLAN, I HAD A NUMBER OF
14	CONVERSATIONS WITH DR. SHAPIRO. AND I IN THOSE
15	CONVERSATIONS LAID OUT EXACTLY THE PLAN THAT YOU'VE
16	SEEN BEFORE YOU TODAY TO GET HIS INPUT. AND WE
17	TALKED ABOUT IT, AND HE HAD A COUPLE OF TWEAKS HERE
18	AND THERE THAT HE SUGGESTED, WHICH I INCORPORATED.
19	BUT BY AND LARGE THESE WERE VERY PRODUCTIVE
20	DISCUSSIONS.
21	AND I THINK IT MIGHT BE USEFUL FOR THE
22	BOARD TO KNOW THAT LAST EVENING I GOT AN E-MAIL FROM
23	DR. SHAPIRO, WHICH I WILL READ. I GUESS WE'RE GOING
24	TO DISTRIBUTE, BUT THOSE WHO ARE ON THE PHONE, I'D
25	LIKE TO READ THIS, WHICH DR. SHAPIRO GAVE ME FULL

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1	PERMISSION TO DO, SO YOU ALL HEAR WHAT HE HAD TO
2	SAY, WHICH IS: "J.T., THANK YOU VERY MUCH FOR
3	SHARING WITH ME A SERIES OF PROPOSALS THAT YOU
4	INTEND TO DISCUSS WITH THE ICOC AT ITS UPCOMING
5	MEETING. WHILE I CONTINUE TO STRONGLY SUPPORT ALL
6	THE RECOMMENDATIONS OF THE IOM REPORT, I ALSO
7	UNDERSTAND THAT MANY OF OUR RECOMMENDATIONS EITHER
8	NEED THE APPROVAL OF OTHERS AND/OR CAN BE ONLY
9	IMPLEMENTED OVER TIME.
10	"OF COURSE, THE FIRST STEP IS THAT THE
11	ICOC MUST DECIDE WHAT CHANGES IT WISHES TO PURSUE.
12	IN ANY CASE, THE PROPOSALS YOU SHARED WITH ME
13	REPRESENT A VERY THOUGHTFUL AND SIGNIFICANT RESPONSE
14	TO OUR RECOMMENDATIONS AND WILL, I BELIEVE, SERVE
15	THE LONG-TERM INTERESTS OF THE CITIZENS OF
16	CALIFORNIA AND THE FIELD OF REGENERATIVE MEDICINE.
17	"IN PARTICULAR, THESE PROPOSALS TAKE A
18	SIGNIFICANT STEP TOWARDS DEALING WITH THE FINANCIAL
19	CONFLICTS OF INTEREST, ENHANCING THE CREDIBILITY AND
20	INTEGRITY OF THE SCIENTIFIC REVIEW PROCESS,
21	INCREASING THE ROLE OF INDUSTRY REPRESENTATIVES,
22	FURTHER CLARIFYING THE ROLES OF THE PRESIDENT AND
23	THE BOARD CHAIR, AND ESTABLISHING THE SCIENTIFIC
24	ADVISORY BOARD AS THE IOM COMMITTEE RECOMMENDED.
25	"WHILE I CANNOT SPEAK FOR THE IOM OR THE
	100

1	COMMITTEE THAT PRODUCED THE REPORT, I WANT TO
2	REITERATE THAT I THINK THESE PROPOSALS REPRESENT A
3	THOUGHTFUL AND VERY SIGNIFICANT STEP FORWARD.
4	HAROLD T. SHAPIRO."
5	SO I THINK THAT I WAS VERY PLEASED TO GET
6	DR. SHAPIRO'S COMMENTS. I THINK THEY REFLECT THAT
7	WE ARE WELL ON THE RIGHT TRACK AND HAVE DEVELOPED
8	SOMETHING THAT HE VIEWS AS VERY RESPONSIVE AND IN
9	KEEPING WITH THE SPIRIT OF THE IOM REPORT.
10	ADDITIONAL COMMENTS? DEAN POMEROY.
11	DR. POMEROY: SO I TOO WOULD LIKE TO THANK
12	YOU, J.T., FOR I KNOW THE MANY, MANY HOURS THAT YOU
13	PUT INTO GETTING INPUT, LISTENING TO PEOPLE,
14	THINKING THROUGH ALL OF THE OPTIONS HERE. AND I
15	THINK THE REASON YOU DID THAT, THE REASON THAT WE
16	HAD THE IOM REPORT IN THE FIRST PLACE, AND THE
17	REASON THAT EVERYBODY COMES AND SPENDS SO MUCH TIME
18	HERE IS BECAUSE WE ALL BELIEVE SO PASSIONATELY IN
19	THIS CAUSE. AND WHEN YOU BELIEVE PASSIONATELY IN A
20	CAUSE, SOMETIMES YOU NEED TO PUT ASIDE YOUR OWN
21	FEELINGS AND THINK ABOUT WHAT'S BEST TO ACHIEVE THE
22	MISSION OF THE ORGANIZATION.
23	AND SO IN THAT SPIRIT, I DEFINITELY
24	SUPPORT AND ENDORSE THE PROPOSALS THAT YOU'VE
25	OUTLINED FOR US. I WANTED TO SPECIFICALLY ADDRESS

1	THE CONFLICT OF INTEREST SITUATION AND THE PROPOSAL
2	THAT THE INSTITUTIONAL REPRESENTATIVES NOT VOTE.
3	THIS IS NECESSARY FOR ENSURING THE PUBLIC
4	TRUST. AND WE ARE A PUBLIC ORGANIZATION, AND I
5	THINK THAT CALLS UPON ALL OF US TO MAKE THIS SMALL
6	COMPROMISE IN ORDER TO GET TO THAT LARGER GOAL OF
7	ENSURING THE PUBLIC TRUST AND ACCOMPLISHING OUR
8	MISSION.
9	AND ALONG THOSE LINES, I WOULD ALSO SAY
10	THAT THE OTHER PROPOSALS, I THINK, DO THE SAME
11	THING, MORE INDUSTRY INVOLVEMENT, MOVING
12	PROGRAMMATIC REVIEW OR PORTFOLIO MANAGEMENT OR
13	HOWEVER YOU VIEW IT TO THE LARGER BOARD LEVEL.
14	AND I WANTED TO SPECIFICALLY END BY
15	COMMENTING ON THE ALLOCATION OF RESPONSIBILITIES
16	BECAUSE, YES, WE HAD THIS DISCUSSION WITH LOTS OF
17	THOUGHT AWHILE BACK. AND I THINK MY VIEWS WERE
18	CLEAR TO EVERYBODY ON THIS BOARD, BUT I LISTENED TO
19	MY COLLEAGUES. I RESPECT THE DECISION THAT WAS
20	MADE. I THINK IT WAS A THOUGHTFUL DECISION, AND WE
21	MADE IT, AND IT'S WORKING. AND IT'S TIME TO MOVE
22	FORWARD FOR THE LARGER GOOD.
23	SO IN THAT SPIRIT, I WOULD ENDORSE THE
24	PROPOSALS AS WRITTEN.
25	CHAIRMAN THOMAS: THANK YOU. MR.
	102

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1	SHESTACK.
2	MR. SHESTACK: THANKS. FIRST, EVERYBODY
3	IS IN A YES, THANK YOU FOR THAT. THIS WAS A
4	TREMENDOUS AMOUNT OF WORK. AND I WANT TO SAY
5	EVERYONE IS IN A RUSH TO APPLAUD IT, AND I AGREE
6	WITH THAT, BUT I HOPE THAT WE WILL NOT VOTE ON IT AS
7	A WHOLE, BUT WILL DISCUSS IT PIECE BY PIECE. THERE
8	ARE TOO MANY THERE ARE JUST TOO MANY IMPORTANT
9	PARTS TO IT. AND I THINK IT WAS A PRETTY THOUGHTFUL
10	RESPONSE.
11	I WANT TO JUST SPEAK PURELY FROM A
12	PERSONAL POINT OF VIEW AND SAY THAT I THINK THE IOM
13	REPORT SHOWS A FUNDAMENTAL LACK OF UNDERSTANDING OF
14	THE MISSION AND THE HISTORY OF THIS ORGANIZATION.
15	IT SHOWS A FUNDAMENTAL MISUNDERSTANDING IN ITS
16	UNDERSTANDING OF ACCOUNTABILITY AND OVERSIGHT, THAT
17	THIS IS NOT THE NIH. THIS WAS CREATED BY THE VOTERS
18	OF CALIFORNIA. THE MEMBERS OF THE BOARD BY AND
19	LARGE ARE PICKED BY ELECTED OFFICIALS IN CALIFORNIA.
20	THEY ARE VERY CLOSE TO THE VOTERS OF CALIFORNIA, AND
21	THEY ARE THERE TO ADVOCATE. THEY ARE THERE TO HAVE
22	A POINT OF VIEW AND CONSTANTLY KEEP IN MIND WHAT
23	WILL HELP THE CITIZENS OF CALIFORNIA.
24	THE IOM REPORT REALLY IN MANY WAYS ROLLS
25	BACK THE CLOCK IN MANY STANDARDS. OUR GROUP IS

103

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1	SLOPPY, BUT IT IS FORWARD THINKING, AND IT IS
2	INTERESTING, AND SOMETIMES THERE ARE DIFFERENCES OF
3	OPINIONS AS WE ARE FINDING OUR WAY.
4	BUT THE IOM REPORT TAKES AS ITS STARTING
5	POINT NIH AS A STANDARD OF PERFECTION. WELL,
6	OVERSIGHT IN NIH HAPPENS ON A HUNDRED-YEAR TIMELINE.
7	WE WORK ON A TEN-YEAR TIMELINE. SO THAT MEANS YOU
8	HAVE TO HAVE MUCH MORE OVERSIGHT AND CONTACT BETWEEN
9	STAFF AND BOARD IF YOU WANT ACTUAL CHANGES TO
10	HAPPEN. IT'S WHY, BY THE WAY, THE IDEA OF WHATEVER
11	CHANGES WE PUT IN NOW BEING SUNSETTED AND LOOKING AT
12	THEM AFTER A YEAR AND SAYING ARE THEY GOOD IS A
13	GREAT IDEA BECAUSE WE NEED TO DO THAT. WE NEED TO
14	BE ABLE TO CONSTANTLY REVISE AND SHIFT.
15	THE OTHER THING THE IOM RECOMMENDATIONS
16	DO, WHETHER OR NOT WE TAKE THEM, IS IT SOLIDIFIES
17	POWER AND DISCRETION IN STAFF. IT BASICALLY MAKES
18	THE TIMELINE FOR OVERSIGHT FROM THE BOARD TO BE SORT
19	OF ALMOST IMPERTINENT AND NOT MATTER, AND IT TAKES
20	DECISION-MAKING AND PUTS IT ALL IN STAFF. AND I
21	JUST WANT TO REMIND PEOPLE OF A COUPLE BASIC THINGS.
22	ONE, IN TERMS OF CONFLICT, MAYBE THERE'S
23	THIS PERCEPTION, BUT IN TERMS OF THE ESSENCE OF
24	CONFLICT, 100 PERCENT OF ALL GRANT WORKING GROUP
25	MEMBERS ARE FROM OUT OF CALIFORNIA. THEY ARE PICKED
	104

BY STAFF FOR THEIR OBJECTIVITY. AND THE FEW MEMBERS
OF THE ICOC WHO COME TO THOSE MEETINGS, LIKE SOME OF
THE ADVOCATES, DO NOT SCORE. WE VOTE IN THE LAST
PART OF PROGRAMMATIC REVIEW, BUT IT'S ONE OR TWO
VOTES OUT OF A GROUP OF 30, AND WE DO NOT SCORE. WE
ARE NOT PART OF THAT PROCESS.
SO I JUST THINK THAT WE SORT OF THE IOM
PUT A LOT OF WORK INTO THIS, BUT I WANT TO SAY THAT
THEIR STANDARDS ARE OLD-FASHIONED STANDARDS. AND
THEIR STANDARDS ARE NOT THE STANDARDS THAT PROP 71
HAD, WHICH WAS A DIRECT TIE TO THE NEEDS OF THE
CITIZENS OF CALIFORNIA, SEEING THAT THERE WAS A VOID
IN STEM CELL SCIENCE, SEEING THAT THERE WAS
POTENTIAL TO HELP THE LIVES OF THEIR FAMILY MEMBERS,
THEMSELVES, THEIR CHILDREN, AND CREATED A STRUCTURE
WITH IMPERFECTIONS TO DO IT.
I'M NOT SAYING SOME OF THESE PROPOSALS
AREN'T GOOD, BUT I JUST WANT TO SAY THAT
ADVOCATES FOR INSTANCE, STAFF WAS OVERCONSULTED,
ADVOCATES WERE UNDERCONSULTED IN THE IOM REPORT, AND
WE SHOULDN'T. AND I PERSONALLY DON'T FORGET IT.
SO IN TERMS OF SPECIFIC THINGS, I THINK
THAT THE DEANS HAVE DONE A STELLAR JOB. AND AS LONG
AS THEY ARE STILL INFORMING OUR DISCUSSION,
WHATEVER, IF THEY CHOOSE TO BE GRACIOUS ABOUT THIS,
105

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1	IT'S PROBABLY A GOOD IDEA. I DON'T KNOW.
2	I THINK THE IDEA OF PROGRAMMATIC REVIEW,
3	PROGRAMMATIC REVIEW IS SO INCREDIBLY VALUABLE. IT'S
4	VALUABLE TO HAVE IT IN THE GRANTS REVIEW PROCESS
5	BECAUSE YOU HAVE THE FULL BENEFIT OF ALL OF THE
6	ASSEMBLED WISDOM OF THE GRANT REVIEW HEARING OTHER
7	PERSPECTIVES AND THEN POSSIBLY RETHINKING THEIR
8	RESPONSE.
9	IF WE DO IT ONLY IN ICOC SESSION, YOU
10	WON'T ACTUALLY HAVE THE FULL BENEFIT OF ALL OF THEIR
11	INTELLIGENCE AND INFORMATION AND PERSPECTIVE. AND I
12	THINK THAT, WHILE MAYBE SOLVING SOMETHING IN TERMS
13	OF THE LETTER OF THE RECOMMENDATION, IT ACTUALLY
14	GIVES US LESS INFORMATION, NOT MORE. AND SO I DON'T
15	THINK THAT I'M IN FAVOR OF THAT. AND AS FAR AS
16	THE I'D LIKE TO FIND A VARIATION ON IT.
17	AND AS FAR AS THE APPLICATION PROCESS FOR
18	THE SPECIAL PROPOSALS, THAT IS A MESSY PROCESS, BUT
19	IT IS ALSO A GLORIOUS PROCESS. THE PROCESS BY WHICH
20	THE ICOC, ONCE IN A BLUE MOON, SEES AND MEETS WITH
21	AND HEARS FROM THE ADVOCACY COMMUNITY, MAYBE IT'S
22	TEDIOUS WHEN SOMEONE IS DEFENDING LIKE A
23	PARTICULARLY LAME PROPOSAL, IT CERTAINLY IS, BUT
24	WHEN THEY HEAR THE FULL FORCE OF THE ADVOCACY
25	COMMUNITY TALKING ABOUT AN UNMET NEED OR PERCEIVED

1	OPPORTUNITY, THAT IS WHAT WE ARE HERE TO DO.
2	IT'S NOT A SLIPPERY SLOPE. OUR JOB IS TO
3	PUT DOWN ROOTS IN THE SLIPPERY SLOPE AND SAY WE WILL
4	STOP SLIDING HERE AND WE WILL LISTEN TO THIS ALS
5	GROUP OR WE WILL LISTEN TO THIS DUCHENNES MUSCULAR
6	DYSTROPHY GROUP AND HEAR WHAT THEY REALLY HAVE TO
7	SAY AND NOT JUST LOOK AT OUR SCORECARDS.
8	WE HAVE A RESPONSIBILITY TO LOOK THOSE
9	PEOPLE IN THE FACE, AND THAT IS WHAT THOSE
10	EXTRAORDINARY PROPOSALS ARE OFTEN ABOUT. SO I WOULD
11	LIKE TO BE VERY CAREFUL AS WE RETOOL THAT PROCESS TO
12	MAKE IT NEATER AND LESS CHAOTIC AND NOT UPSETTING TO
13	THE PRESS OR TO PEOPLE IN SACRAMENTO, BUT TO
14	UNDERSTAND THAT IS PART OF OUR RESPONSIBILITY, TO
15	LOOK AT THOSE PEOPLE AND LISTEN TO THEM AND TAKE
16	SOME OF WHAT THEY HAVE TO SAY INTO CONSIDERATION.
17	SO THANK YOU VERY MUCH.
18	CHAIRMAN THOMAS: THANK YOU, MR. SHESTACK.
19	I WOULD NOTE ON A COUPLE OF YOUR POINTS,
20	NO. 1, ON THE ISSUE OF BEING ABLE TO HAVE AN
21	INFORMED DISCUSSION, PROGRAMMATIC REVIEW OF THE
22	BOARD, NOT ONLY WILL, OF COURSE, THE PATIENT
23	ADVOCATES WHO HAVE BEEN IN THE GRANTS WORKING GROUP
24	ROOM BE ABLE TO INFORM, BUT REMEMBER STAFF IS THERE
25	THROUGHOUT AND INTEGRAL TO THE WHOLE PROCESS, AND
	107
	107

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1	THEY'LL BE ABLE TO INFORM ON ISSUES OF SCIENTIFIC
2	NOTE.
3	MR. SHESTACK: I UNDERSTAND. ALTHOUGH IT
4	PUTS AN AWFUL LOT OF PRESSURE ON THE MEMORY OF THE
5	ADVOCATES WHO HAVE BEEN IN THAT. I JUST WANTED TO
6	SAY THAT THAT PROCESS, IT'S A SMALL PERCENTAGE OF
7	THE TIME, BUT THAT PROCESS, WHICH SORT OF LIKE
8	FORCES THE GROUP TO RETHINK A LITTLE BIT AT THE END
9	OF THE DAY THEIR CONCLUSIONS IN A GESTALT WAY AND A
10	HOLISTIC WAY RATHER THAN JUST READ DOWN A LIST OF
11	SCORES, IS A VALUABLE PROCESS EVEN IF SOME PEOPLE
12	FIND IT ANNOYING. IT IS ULTIMATELY ENRICHING TO OUR
13	DECISION PROCESS AND IS WHAT ENABLES
14	YOU SAID SOMETHING VERY INTERESTING. YOU
15	SAID 90 PERCENT OF ALL THE DECISIONS ARE THE SAME IN
16	THE ICOC AS THE GRANT WORKING GROUP. I THINK YOU
17	MIGHT NOT HAVE THAT RIGHT. MY GUESS IS IT'S MORE
18	LIKE 95 OR 96.
19	CHAIRMAN THOMAS: I SAID OVER 90 PERCENT.
20	MR. SHESTACK: IT'S LIKE 95 OR 96 PERCENT.
21	PEOPLE SHOULD UNDERSTAND THAT ICOC ALMOST NEVER
22	CHANGES ANYTHING FROM GRANT RECOMMENDATION. WHEN IT
23	DOES, IT IS TO ADD SOMETHING, NOT TO TAKE OUT. SO I
24	WOULD SAY THAT IT'S NOT EVEN CHANGING SCIENTIFIC
25	RECOMMENDATIONS SO MUCH AS IT IS LOWERING THE
	100
	108

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1	PAYLINE, WHICH IS EXACTLY IN THE PURVIEW OF
2	OVERSIGHT OF THE ICOC.
3	CHAIRMAN THOMAS: RIGHT. WHICH, BY THE
4	WAY, IS WHAT PROGRAMMATIC REVIEW IS ALL ABOUT.
5	THE OTHER POINT I WANTED TO MAKE IS WE'RE
6	NOT AT ALL SAYING THAT PATIENT ADVOCATES WON'T HAVE
7	A VOICE. REMEMBER, IF WE HAVE PROGRAMMATIC REVIEW
8	IN THE BOARD, THERE'S ALWAYS FULL OPPORTUNITY FOR
9	COMMENT BY THE PATIENT ADVOCATES WITH RESPECT TO
10	PARTICULAR THINGS THAT ARE BEING DISCUSSED THROUGH
11	THE PUBLIC COMMENT VEHICLE.
12	YES, DR. MARLETTA.
13	DR. MARLETTA: J.T., YOU MUST HAVE
14	CONSIDERED, WHEN YOU ARRIVED AT THE CONCLUSION THAT
15	INSTITUTIONAL MEMBERS SHOULDN'T BE ALLOWED TO VOTE,
16	THE VARIOUS SORT OF FORMATS IN WHICH PEER REVIEW IS
17	DONE WHEN THERE'S POTENTIAL GRANTS THAT COULD COME
18	TO THAT INSTITUTION. IN PRIVATE FUNDING AGENCIES,
19	LIKE HOWARD HUGHES MEDICAL INSTITUTE THAT HAS TWO
20	LEVELS OF ADVISORY BOARDS ULTIMATELY PASSING
21	JUDGMENT, WHERE IT IS SIMPLY YOU RECUSE YOURSELF
22	FROM VOTING WHEN THE TIME COMES. YOU MUST HAVE
23	CONSIDERED THAT BEFORE YOU CAME TO ACTUALLY WHAT I
24	CONSIDER TO BE A RATHER DRACONIAN STEP, WHICH IS TO
25	CREATE A SECOND CLASS CITIZENRY WITHIN THIS
	109

1	COMMITTEE.
2	SO MICHAEL AND I THIS MICHAEL DOESN'T
3	AGREE WITH THAT MICHAEL. I ACTUALLY DON'T THINK
4	THAT THAT IS THE RIGHT STEP TO TAKE. MY OWN ROLE
5	THAT WOULD CHANGE, GRANTED I COULD BE HERE TO SPEAK
6	UP, MUCH LIKE I'M DOING NOW, BUT PREVENTED FROM
7	VOTING IS A STEP THAT I THINK WE SHOULD BE VERY
8	CAUTIOUS BEFORE WE AGREE. AND I GUESS I'M GOING TO
9	BE THIS TIDAL WAVE THAT'S SWEEPING ALONG THAT
10	SAYS THAT EVEN THAT IS SOMETHING THAT WE ALL AGREE
11	UPON, I DON'T.
12	I THINK THAT THE ESTABLISHMENT OF A
13	SCIENTIFIC ADVISORY BOARD MAKES A HUGE AMOUNT OF
14	SENSE. FRANKLY, FOR WHAT DRIVES ME AND MY INTEREST
15	IN MY INSTITUTION, WHICH IS THE SCIENCE OF STEM CELL
16	BIOLOGY, THAT MAY BE A BETTER PLACE FOR ME TO BE
17	THAN TO BE ON A COMMITTEE WHERE I CAN CERTAINLY
18	WEIGH IN ON WHAT I THINK SCIENTIFICALLY, BUT IN THE
19	END I DON'T VOTE.
20	CHAIRMAN THOMAS: THANK YOU, DR. MARLETTA
21	YES, IN ANSWER TO YOUR QUESTION, I WEIGHED THAT VERY
22	CAREFULLY. THAT'S BASICALLY WHAT WE DO NOW, WHICH,
23	AS A NUMBER OF MEMBERS HAVE COMMENTED, THEY VIEW AS
24	HAVING WORKED VERY WELL TO DATE WITH NO EVIDENCE OF
25	ACTUAL CONFLICT. AND THAT IS CERTAINLY A POINT OF

1	VIEW THAT I THINK EMPIRICALLY IS BORNE OUT.
2	ON THE OTHER HAND, WHAT WE'RE DEALING WITH
3	HERE IS THIS WHOLE PERCEPTION ISSUE. AND THE
4	PERCEPTION ISSUE IS WHAT GETS US IN TROUBLE. AND
5	BECAUSE OF THAT, I WEIGHED A BUNCH OF ALTERNATIVES
6	BESIDES THE STATUS QUO, AND I WILL SAY NONE OF THEM
7	PARTICULARLY APPEALING AT ALL, BUT NECESSARY IN THE
8	FACE OF THIS SET OF RECOMMENDATIONS, AND AS A RESULT
9	LANDED ON THIS AS, YES, IT IS DRACONIAN, BUT I
10	BELIEVE THAT WE HAVE TO DO SOMETHING DRACONIAN OR
11	WE'RE NEVER GOING TO PUT THIS ISSUE TO BED, AND IT'S
12	GOING TO CAUSE US HEARTBURN GOING FORWARD
13	INDEFINITELY.
14	DR. MELMED: POINT OF INFORMATION. CAN
15	YOU CLARIFY FOR US WHO THOSE PEOPLE ARE WHO WOULDN'T
16	VOTE BECAUSE THERE ARE PEOPLE IN THE ROOM WHO ARE
17	INDEPENDENT APPOINTEES WHO ARE NOT MEDICAL SCHOOL
18	DEANS. KRISTINA AND MICHAEL AND MYSELF, FOR
19	EXAMPLE, ARE THEY INCLUDED IN YOUR LIST?
20	CHAIRMAN THOMAS: YES.
21	DR. MELMED: WHY?
22	DR. PRICE: BECAUSE THEY GET GRANTS.
23	CHAIRMAN THOMAS: THAT'S THE ISSUE. IT'S
24	VOTING MEMBERS FROM INSTITUTIONS THAT ARE ELIGIBLE
25	FOR GRANT FUNDING. AND THE STAT THAT IS OUT THERE,
	111

	<u> </u>
1	AND I WON'T VOUCH FOR ITS ACCURACY, BUT HAS BEEN
2	BANDIED ABOUT SOMETHING TO THE EFFECT IN THE REPORT,
3	BUT CERTAINLY PICKED UP BY PRESS, IS 90 PERCENT OF
4	THE FUNDING GOES TO INSTITUTIONS WITH VOTING MEMBERS
5	REPRESENTED ON THE BOARD IN THESE 13 SLOTS.
6	DR. MELMED: SO COULD YOU CLARIFY FOR US
7	WHO WOULD BE VOTING?
8	CHAIRMAN THOMAS: WOULD BE THE REMAINDER
9	OF THE 29 MEMBERS OF THE BOARD.
10	DR. MELMED: COULD YOU TELL US, NOT THE
11	PEOPLE, BUT WHO THEY REPRESENT?
12	MR. HARRISON: YES. SO THAT WOULD INCLUDE
13	THE REPRESENTATIVES FROM LIFE SCIENCE COMMERCIAL
14	ENTITIES, THE PATIENT ADVOCATES, AND THE CHAIR AND
15	THE VICE CHAIR.
16	DR. MELMED: LIFE SCIENCE ENTITIES CAN
17	VOTE, BUT NONPROFITS CANNOT?
18	MR. ROTH: JUST TO CLARIFY, JAMES, THE
19	CRITERIA TO SERVE AS A LIFE SCIENCE MEMBER IS YOU
20	CAN'T APPLY FOR GRANTS. YOU CAN'T BE IN A COMPANY
21	THAT APPLIES FOR GRANTS.
22	MR. HARRISON: CORRECT. JUST TO BE CLEAR,
23	THE PROPOSAL THE CHAIRMAN HAS MADE GOES TO THOSE
24	INDIVIDUALS WHO ARE APPOINTED FROM INSTITUTIONS THAT
25	ARE DESIGNATED IN THE LAW AND, AS A MATTER OF FACT,
	112

1	ARE ELIGIBLE FOR AND SOMETIMES RECEIVE. JUST TO BE
2	CLEAR, THERE ARE FIVE MEMBERS APPOINTED FROM THE
3	UNIVERSITY OF CALIFORNIA CAMPUSES WITH MEDICAL
4	SCHOOLS, THERE ARE FOUR INDIVIDUALS APPOINTED FROM
5	CALIFORNIA UNIVERSITIES OTHER THAN THOSE UC CAMPUSES
6	WITH MEDICAL SCHOOLS, AND THERE ARE FOUR INDIVIDUALS
7	APPOINTED FROM NONPROFIT RESEARCH INSTITUTIONS.
8	SO THAT'S THE SUBSET THAT THIS RULE WOULD
9	APPLY TO.
10	CHAIRMAN THOMAS: OS.
11	DR. STEWARD: SO WE'RE STARTING TO DRILL
12	DOWN A LITTLE BIT INTO THE DETAILS, BUT I ACTUALLY
13	WANTED TO JUST GO BACK UP AND TALK ABOUT THE GENERAL
14	CONCEPT. AND JUST LET ME SAY, J.T., AND ECHO THE
15	WORDS OF OTHERS, THAT I THINK THAT THIS IS A VERY
16	INTERESTING PROPOSAL, AND I REALLY APPLAUD YOU FOR
17	ALL THE HARD WORK INTO IT.
18	FROM MY OWN PERSPECTIVE, THE THING THAT
19	WAS PARTICULARLY DISTRESSING ABOUT THE IOM REPORT
20	WAS THE POSSIBILITY THAT SOME OF THE ACTIONS THAT
21	COULD HAVE BEEN TAKEN WOULD HAVE DISEMPOWERED THE
22	PATIENT ADVOCATES. AND I JUST WANT TO SAY THAT THE
23	THING ABOUT THIS ORGANIZATION THAT IS SO SPECIAL IS
24	EXACTLY THE ROLE THAT THE PATIENT ADVOCATES PLAY IN
25	THE DECISION-MAKING PROCESS.
	113
	1

1	AND SO I THINK THE PLAN THAT YOU PUT
2	TOGETHER HERE PRESERVES THAT. AND I REALLY APPLAUD
3	YOU FOR HAVING THOUGHT THROUGH THAT VERY CAREFULLY.
4	I ALSO JUST WANT TO TOUCH ON A COUPLE OF
5	OTHER THINGS, AND THIS IS LARGELY FOR THE RECORD.
6	THIS ORGANIZATION HAS THE MOST EXTRAORDINARY PLANS
7	AND OPERATIONAL PROCEDURES TO MANAGE THE REALITY OF
8	CONFLICTS OF INTEREST. WE HAVE BEEN IN THIS
9	BUSINESS NOW FOR SEVEN YEARS, EIGHT YEARS, AND IT IS
10	TRULY EXTRAORDINARY. I PARTICIPATE IN A LOT OF
11	OTHER ACTIVITIES, AND THERE'S NOTHING LIKE WHAT GOES
12	ON HERE IN TERMS OF MANAGING ACTUAL CONFLICT OF
13	INTEREST.
14	IT STARTS AT THE LEVEL OF THE
15	CONSIDERATION OF GRANTS WHERE PEOPLE ARE IDENTIFIED
16	AS BEING IN CONFLICT AND THEY CANNOT CONTRIBUTE TO
17	THE DISCUSSION. PEOPLE CANNOT VOTE ON PROPOSALS
18	COMING TO THEIR OWN INSTITUTIONS. IN THE GRANTS
19	WORKING GROUP, PEOPLE WHO ARE IN CONFLICT FOR ANY
20	REASON, AND THAT CAN BE SCIENTIFIC OR ASSOCIATION
21	WITH AN INSTITUTION, ACTUALLY LEAVE THE ROOM DURING
22	THE DISCUSSIONS. THAT HAS BEEN CARRIED FORWARD
23	RECENTLY INTO OUR OPERATIONS WHERE ONCE A GRANT
24	BECOMES IDENTIFIED THROUGH THE SELF-IDENTIFICATION
25	PROCESS OF AN EXTRAORDINARY PETITION, THEN WE HAVE
	114

1	ALSO TAKEN TO LEAVING THE ROOM.
2	ALL OF THESE THINGS ARE EXTRAORDINARY. SO
3	I THINK THAT WE SHOULD JUST SAY FLAT OUT THAT THE
4	MANAGEMENT OF THE ACTUALITY IS SUPERB HERE. HAVING
5	SAID THAT, AND DESPITE ALL THAT, THERE IS AN
6	APPEARANCE OF CONFLICT OF INTEREST. AND I DO THINK
7	THAT WE HAVE TO DEAL WITH THAT.
8	SO THE OTHER THING THAT I'D LIKE TO JUST
9	SAY IS THAT THE SPECIAL THING ABOUT THIS
10	ORGANIZATION IS ITS TRANSPARENCY, ACCOUNTABILITY
11	OVERSIGHT, AND THE FACT THAT WE REMAIN HIGHLY
12	RESPECTFUL OF THE WILL OF THE CITIZENS OF CALIFORNIA
13	AS EXPRESSED IN PROP 71. AND I JUST WANT TO
14	COMPLIMENT YOU, J.T., FROM WHAT I CAN TELL, I'M
15	OBVIOUSLY NOT AN EXPERT IN THE LAW, BUT IT SEEMS
16	LIKE EVERYTHING THAT YOU'VE SUGGESTED IS AT LEAST
17	NOT COUNTER TO THE WILL THAT IS EXPRESSED IN PROP
18	71. SO CONGRATULATIONS ON THAT.
19	GOVERNANCE STRUCTURE, I ABSOLUTELY AGREE
20	THAT WE WORKED HARD IN THINKING THIS THROUGH. THERE
21	WAS A GREAT DEAL OF DISCUSSION. MOST IMPORTANTLY,
22	THE PEOPLE THAT WERE HIRED WERE HIRED ON THE BASIS
23	OF KNOWLEDGE, SKILLS, AND ABILITY AS DEFINED IN THAT
24	POSITION. AND THAT'S WHAT WE HAVE. SO THAT'S WHAT
25	I THINK IS VERY IMPORTANT TO GO FORWARD IN EXACTLY
	115

1	THE WAY THAT WE HAVE. WE CAN ALWAYS REVISIT IT AT
2	SOME POINT IN TIME, BUT RIGHT NOW IT'S REALLY PRETTY
3	GOOD.
4	THERE ARE A FEW DETAILS THAT, AS YOU SAID,
5	THERE'S GOING TO BE SOMETHING FOR EVERYBODY TO HATE
6	IN THIS. THERE ARE A FEW DETAILS THAT I'D LIKE TO
7	DISCUSS MORE. ONE OF THEM IS ACTUALLY THE I
8	DON'T EVEN WANT TO USE THE WORD BECAUSE WHEN WE TALK
9	ABOUT PROGRAMMATIC REVIEW, AND I THINK DUANE EVEN
10	SAID IT, PORTFOLIO REVIEW, ACTUALLY IT'S MUCH MORE
11	THAN THAT AT THE LEVEL OF THE BOARD.
12	THIS IS THE OPPORTUNITY FOR THE PATIENT
13	ADVOCATES TO STAND UP AND SAY THIS IS A GRANT THAT'S
14	WORTH TAKING A SWING AT THIS. EVEN IF THE SCIENCE
15	ISN'T QUITE ALL THERE, AND WE'VE HEARD JOAN DO THIS
16	SO MANY TIMES BEAUTIFULLY, YOU KNOW, LET'S TAKE A
17	CHANCE ON THIS. SO I WOULD RATHER COME UP WITH A
18	DIFFERENT NAME FOR IT. IT'S MORE THAN PROGRAMMATIC
19	OR PORTFOLIO REVIEW. THAT'S ONE OF THE AREAS I'D
20	LIKE TO SEE A LITTLE BIT MORE DISCUSSION AS FAR AS
21	REALLY COMING DOWN TO THE DETAILS OF THIS.
22	CHAIRMAN THOMAS: THANK YOU, OS. I WOULD
23	SAY THAT, REMEMBER, THIS IS SORT OF A FRAMEWORK
24	HERE, AND THERE ARE A LOT OF THINGS THAT HAVE
25	DETAILS THAT WOULD NEED TO BE WORKED OUT. I'M HAPPY

1	TO DISCUSS HERE. I THINK IT CAN JUST AS
2	PRODUCTIVELY BE DONE IN SORT OF SUBGROUPS. VERY
3	IMPORTANT POINT.
4	DR. PRIETO HAS HAD HIS HAND UP FOR QUITE
5	SOME TIME.
6	DR. PRIETO: WITHOUT SAYING HOW I'LL VOTE
7	ON THIS, I DID WANT TO MAKE SOME COMMENTS. FIRST OF
8	ALL, WITH REGARD TO DR. MARLETTA'S COMMENTS AND THIS
9	NONVOTING ROLE, I WOULD SAY THIS IS SOMEWHAT
10	ANALOGOUS TO THE ROLE THAT THE PATIENT ADVOCATES
11	HAVE PLAYED DURING SCIENTIFIC REVIEW AT THE GRANTS
12	WORKING GROUP FOR SEVERAL YEARS NOW. AND IT DOES
13	NOT MEAN THAT WE DON'T GET INTO THE DISCUSSION. WE
14	HAVE THE RIGHT TO WEIGH IN. SOME OF US HAVE MORE
15	SCIENTIFIC BACKGROUND THAN OTHERS, BUT WE ALL CAN
16	STUDY AND PLAY AN ACTIVE ROLE AND WE HAVE, BUT WE
17	DON'T GET TO PUT IN A NUMERICAL SCORE DURING THAT
18	PART OF THE EVALUATION. THAT'S JUST OUR ROLE.
19	I WAS SKEPTICAL ABOUT THE IOM REPORT AND
20	THEIR PROPOSALS PARTICULARLY BECAUSE I THINK THAT
21	CIRM HAS REALLY BLAZED A TRAIL IN TERMS OF THE ROLE
22	OF PATIENT ADVOCATES. AND I THOUGHT THAT THEIR
23	PROPOSAL WOULD INCREASE THE NUMBER OF ADVOCATES, AS
24	THEY SAID, BUT MARGINALIZE THE ROLE. AND I THINK
25	IT'S IMPORTANT THAT ADVOCATES AND THE PUBLIC
	117
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1	CONTINUE TO BE ABLE TO WEIGH IN IN A MEANINGFUL WAY
2	WHEN WE DISCUSS WHAT YOU'RE CALLING PROGRAMMATIC
3	REVIEW, WHAT HAS COME UP AS APPEALS, BUT THAT WE GET
4	TO DISCUSS THINGS LIKE OS JUST MENTIONED. WHAT IS
5	OUR RISK TOLERANCE? WILL WE TAKE A SWING AT
6	SOMETHING THAT OTHER FUNDERS MIGHT NOT? THAT WAS
7	SOMETHING THAT I THINK PROP 71 WAS EXPLICITLY SET UP
8	TO DO, TO FUND AN AREA OF SCIENCE THAT OTHERWISE
9	MIGHT NOT BE FUNDED. SO I THINK THE SHAPE AND THE
10	AMOUNT OF PUBLIC INPUT THAT'S ALLOWED IS CRITICAL.
11	AND I'LL JUST SAY ONE OTHER THING ABOUT
12	THE INTELLECTUAL PROPERTY PART OF IT. I KNOW YOU
13	HAVEN'T ADDRESSED THAT IN ANY DETAIL. BUT I DO TAKE
14	ISSUE WITH THEIR SUGGESTION THAT WE CONFORM WITH
15	BAYH-DOLE BECAUSE I SERVED ON THE INITIAL TASK FORCE
16	ON INTELLECTUAL PROPERTY. I DECIDED NOT TO TAKE
17	THAT ON DURING OUR CURRENT SECOND ROUND BECAUSE YOU
18	GIVE ME ENOUGH WORK TO DO HERE.
19	WE SPECIFICALLY MADE A DECISION TO ADOPT A
20	NEW MODEL, AND PART OF THAT WAS TO KEEP FAITH WITH
21	THE COMMITMENTS THAT WERE MADE TO THE PEOPLE OF
22	CALIFORNIA IN THE CAMPAIGN FOR PROP 71. AND I THINK
23	WE'VE DONE A PRETTY GOOD JOB OF THAT.
24	MS. WINOKUR: I WONDER IF YOU WOULD REPEAT
25	THE NUMBER OF VOTING MEMBERS WHEN A PROPOSAL IS FROM

1	ONE OF THE UC CAMPUSES. HOW MANY OF US ARE LEFT WHO
2	CAN VOTE ON IT?
3	MR. HARRISON: SO LET ME FIRST MAKE CLEAR
4	THAT WE WILL CONTINUE TO DO OUR CONFLICT REVIEW AS
5	ALWAYS. SO EACH OF YOU WILL CONTINUE TO FILL OUT
6	THE FORM IDENTIFYING THOSE INSTITUTIONS WITH WHICH
7	YOU HAVE SOME ECONOMIC INTEREST, AND YOU WILL BE
8	DISQUALIFIED FROM PARTICIPATING IN AND VOTING ON
9	THOSE APPLICATIONS.
10	WHAT WE'RE TALKING ABOUT IS A SEPARATE
11	SUBSET OF THE BOARD WHICH IS COMPOSED OF THOSE
12	MEMBERS APPOINTED FROM THE FIVE UNIVERSITY CAMPUSES
13	WITH MEDICAL SCHOOLS, THE FOUR CALIFORNIA
14	UNIVERSITIES OTHER THAN THOSE FIVE, AND FOUR
15	NONPROFIT RESEARCH INSTITUTIONS. SO THERE ARE A
16	TOTAL OF 13 MEMBERS WHO WE WOULD ASK TO ABSTAIN FROM
17	PARTICIPATING IN A VOTE TO APPROVE APPLICATIONS.
18	THAT WOULD LEAVE, UNLESS THEY ARE OTHERWISE
19	CONFLICTED, 16 MEMBERS. THOSE 16 INCLUDE TEN
20	PATIENT ADVOCATES, FOUR MEMBERS APPOINTED FROM LIFE
21	SCIENCE COMMERCIAL ENTITIES, AS DUANE ROTH OBSERVED
22	ARE NOT APPLICANTS FOR CIRM FUNDING, AND THE CHAIR
23	AND THE STATUTORY VICE CHAIR.
24	MS. WINOKUR: IT SEEMS TO ME THAT WE'RE
25	LOSING A LOT OF THIS BOARD WHICH IS APPOINTED TO
	119

1	SERVE A PURPOSE OF PARTICIPATING WITH THAT PROPOSAL,
2	AND I'M JUST CONCERNED ABOUT IT. BECAUSE THERE ARE
3	13 LEFT, BUT THERE COULD BE OTHER CONFLICTS WITH
4	THOSE 13, AND WE WOULD BE LEFT WITH EVEN LESS.
5	CHAIRMAN THOMAS: YES, THAT IS CORRECT,
6	ALTHOUGH GENERALLY THE OTHERS AREN'T YOU DON'T
7	HAVE THAT MANY THAT WOULD BE OTHERWISE CONFLICTED.
8	MS. WINOKUR: YOU HAVE 13 TO START WITH.
9	CHAIRMAN THOMAS: I UNDERSTAND.
10	MR. SHESTACK: DIANE MAKES AN IMPORTANT
11	POINT BECAUSE, FOR INSTANCE, IT DOES PUT A
12	TREMENDOUS AMOUNT OF PRESSURE ACTUALLY. I DON'T
13	KNOW IF THE LIFE SCIENCE MEMBERS ARE ALLOWED TO
14	HAVE JAMES, YOU CAN TELL ME. ARE THEY ALLOWED TO
15	HAVE PROXIES, SURROGATES? BUT, FOR INSTANCE, THE
16	ADVOCATES, BY A QUIRK OF THE LAW, ARE NOT ALLOWED TO
17	HAVE SURROGATES VOTE FOR THEM, WHICH THEN PUTS A
18	TREMENDOUS PRESSURE ON THEM TO ATTEND AND TO HAVE
19	ATTENDED ALL THE PREVIOUS GRANT REVIEW MEETINGS AND
20	BE FULLY INFORMED.
21	AND THE OTHER THING I WANT TO SAY IS THAT
22	THE UNINTENDED CONSEQUENCES OF THIS RECOMMENDATION,
23	ALTHOUGH I THINK IT'S PRETTY SOLOMONICALLY
24	BRILLIANT, IS THAT I THINK SO MANY OF OUR DEANS WHO
25	HAVE THE OPPORTUNITY TO HAVE PROXIES WILL TAKE THAT
	120

1	OPPORTUNITY IF THEIR VOTE IS NOT EVEN IF IT'S A
2	CEREMONIAL VOTE, EVEN IF 98 PERCENT OF THE TIME THEY
3	JUST ARE RUBBER STAMPING THE GRANT WORKING GROUP
4	RECOMMENDATIONS, I FEAR THAT IF THEY HAVE NO VOTE,
5	THEY WILL NOT WANT TO ATTEND. IF THEY DON'T WANT TO
6	ATTEND, THEN WE HAVE LOST A TREMENDOUS AMOUNT OF
7	WISDOM AND DISCERNMENT THAT THEY ADD TO THE ROOM ALL
8	THE TIME.
9	ONE OTHER THING ABOUT THE PROGRAMMATIC
10	REVIEW IS ONE OF THE GREAT THINGS ABOUT HAVING
11	PORTFOLIO OR PROGRAMMATIC REVIEW IN THE GRANTS
12	WORKING GROUP IS THAT ADVOCATE COMMUNITIES GET TO
13	TALK TO STAFF AND ASK THEM QUESTIONS IN A WAY THAT
14	THEY DON'T WANT TO DO IN A WHOLE ICOC MEETING, WHICH
15	IS A PUBLIC MEETING WHERE THERE'S PRESSURE TO KEEP
16	IT WITHIN A CERTAIN PERIOD OF TIME. AND IT ALLOWS
17	FOR A FREE KIND OF INFORMED DISCUSSION AND POINTS OF
18	INFORMATION THAT, AGAIN, IS VALUABLE AND DEEPENS THE
19	PROCESS.
20	I JUST WANT TO ITERATE WHAT SO MANY OTHER
21	PEOPLE HAVE SAID. HAVING SERVED ON SO MANY BOARDS
22	THAT WERE NOT UP TO THE PAR, THE EXCELLENCE OF THIS,
23	EVEN IF THERE ARE CONFLICTS, STAFF AND BOARD, PEOPLE
24	ARE SO AWARE OF THEIR CHARGE FROM THE CITIZENS OF
25	CALIFORNIA AND FEEL THIS URGE TO BE TRANSPARENT.
	101
	121

1	IT'S AMAZING. AND THAT WE ARE DEFENDING OURSELVES
2	BECAUSE WE ARE SOMEHOW NOT TRANSPARENT ENOUGH IS
3	DEPRESSING TO ME BECAUSE I'VE BEEN IN BOARDS THAT
4	ARE NOT TRANSPARENT.
5	CHAIRMAN THOMAS: THANK YOU. VERY GOOD
6	OBSERVATIONS ALSO. COUPLE OF COMMENTS ON THAT. ONE
7	IS I WANT TO REMIND THE BOARD THAT CLEARLY VOTING ON
8	GRANTS IS SORT OF THE BIG TICKET, GLAMOROUS THING
9	THAT THE BOARD DOES. THERE'S A LOT OF OTHER STUFF
10	THE BOARD DOES TOO, STRATEGIC PLANNING, A BUNCH OF
11	DIFFERENT THINGS, THAT THIS WOULDN'T HAVE ANY IMPACT
12	AT ALL ON. SO I WOULD LIKE TO THINK THAT THERE
13	WOULD BE MORE THAN ENOUGH TO DISCUSS AMONGST MEMBERS
14	OF THE BOARD AT A REGULAR MEETING TO ENCOURAGE THE
15	MEMBERS OF THE 13 TO ATTEND.
16	ALSO NOTE THAT YOU MENTIONED THE WORD
17	"TRANSPARENT," MR. SHESTACK. I WOULD SUBMIT THAT IN
18	THE INTEREST OF TRANSPARENCY TO THE CALIFORNIA
19	PEOPLE, YOU'RE ACTUALLY BETTER SERVED BY HAVING
20	PROGRAMMATIC DISCUSSION DONE AT THE BOARD LEVEL
21	WHERE THE PUBLIC CAN HEAR AND NOT IN THE CONFINES OF
22	THE GRANTS WORKING GROUP.
23	MS. LANSING: I JUST HAVE TO RESPOND TO
24	WHAT JON SAID. YOU KNOW HOW MUCH I RESPECT YOU. I
25	HAVE NOT BEEN ABLE TO VOTE ON A GRANT, I THINK,
	122
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1	PRETTY MUCH SINCE I GOT HERE BECAUSE OF UC. I HAVE
2	A REALLY GOOD ATTENDANCE RECORD. I JUST WANT TO SAY
3	THAT MY PASSION AND MY INTEGRITY HAS NEVER BEEN
4	QUESTIONED BECAUSE I HAVEN'T BEEN ABLE TO VOTE ON A
5	GRANT. AND I ACTUALLY WAS VERY COMFORTABLE WITH
6	THAT, BUT IT HAS NEVER DISSUADED ME FROM ATTENDING A
7	MEETING.
8	I KNOW PERSONALLY ALL THE PEOPLE, AS YOU
9	DO, WHO ARE REPRESENTING THESE INSTITUTIONS THAT
10	WOULD NOT BE ABLE TO VOTE, AND THEY WILL BE HERE
11	WITH THE SAME PASSION AND THE SAME INTENSITY, AND
12	THEY WILL SPEAK UP ABOUT WHAT THEY ADVOCATE AND CARE
13	FOR. SO I JUST WANT TO SAY THAT. I THINK IT IS
14	SUCH A GREAT BOARD, AND WE'RE ALL HERE BECAUSE WE'RE
15	PASSIONATE ABOUT THIS MISSION, AND WE'RE NOT HERE
16	BECAUSE WE CAN VOTE. WE'RE HERE BECAUSE WE CAN
17	ADVOCATE, AND THAT'S REALLY WHAT WE'RE TRYING TO DO.
18	MR. SHESTACK: YOU MAY BE RIGHT.
19	MS. LANSING: BUT I HAVE TO JUST GO BACK.
20	AGAIN, I JUST RESPECTFULLY DISAGREE WITH THAT,
21	PASSIONATELY, I GUESS, DISAGREE. I WANT TO JUST SAY
22	I COME BACK TO SOME FACTS. I DEFEND AND I STARTED
23	FROM THE BEGINNING IN SAYING I DON'T AGREE WITH WHAT
24	THE IOM SAID. I DON'T AGREE WITH WHAT THE HOOVER
25	COMMISSION SAID. I COULD GO DOWN THROUGH THE
	123
	TCJ

AUDITS, WHATEVER. BUT THAT'S BECAUSE I'M INTENSELY
INVOLVED IN THIS BOARD. AT SOME POINT YOU HAVE TO
SAY THERE IS A PERCEPTION THAT THERE IS A CONFLICT
OF INTEREST. THERE IS A PERCEPTION THAT THE APPEALS
PROCESS DOESN'T WORK. THERE IS A PERCEPTION ON ALL
OF THESE ISSUES. AND WE HAVE LOST, NOT BECAUSE
WE'VE DONE ANYTHING WRONG, BUT, AS CLAIRE SAID, IT'S
A MATTER OF TRUST.
AND I USE THAT EXPRESSION BECOMES REALITY,
AND WE CAN'T FIGHT THAT ANYMORE. WE HAVE TWO
CHOICES REALLY. MAYBE WE HAVE MORE, BUT TWO BROAD
CHOICES. WE CAN SAY, OKAY. WE'RE RIGHT AND WE'RE
IGNORING ALL OF THIS, AND WE'RE JUST MOVING ON. AND
WE CAN DO THAT. AND THEN IF I WAS THE LEGISLATURE,
QUITE HONESTLY, ART, YOU KNOW BETTER THAN DO I, THEY
HAVE THE RIGHT TO TRY AND GET THE VOTES. I'M NOT SO
SURE IT WOULD BE SO DIFFICULT SINCE THAT SEEMS TO BE
THE PERCEPTION OF EVERY REPORT THAT WE'VE GOTTEN,
NOT JUST THIS BEING THE LAST ONE, BUT FOR YEARS.
AND THEY COULD PROBABLY, ART, CORRECT ME, I DON'T
KNOW IF THIS IS TRUE, BUT I GUESS IF THEY GET
TWO-THIRDS VOTE, THEY CAN ACTUALLY ENFORCE THIS; IS
THAT CORRECT?
MR. TORRES: MORE THAN TWO-THIRDS, 70
PERCENT.
124

1	MS. LANSING: OKAY. I'M NOT SO SURE IT
2	WOULD BE SO HARD TO GET SINCE THAT'S THE PERCEPTION.
3	AND SINCE THEY REPRESENT THE PEOPLE AND THERE'S BEEN
4	THESE REPORTS, SO THAT CAN HAPPEN TO US. I WOULD
5	LIKE US TO CONTROL OUR DESTINY. I WOULD LIKE US TO
6	PUT INTO PROCESS SOMETHING THAT WE CAN SEE IF IT
7	WORKS AND NOT HAVE SOMETHING DICTATED TO US.
8	WHEN I READ THE IOM REPORT, YEAH, MY FIRST
9	REACTION WAS THEY'RE WRONG. I'M RIGHT. I'M DONE.
10	THAT'S NOT HELPFUL. DO YOU KNOW? NOW, I THINK WHAT
11	J.T. HAS DONE, HONESTLY IN ALL OF THEM, IS A REALLY,
12	REALLY BRILLIANT SOLUTION. AND I ACTUALLY AGREE
13	WITH ALL OF THE SUGGESTIONS. AND I URGE US TO MOVE
14	FORWARD FOR A YEAR AND OBVIOUSLY SEE IF IT WORKS.
15	IF YOU'RE RIGHT, JON, AND PEOPLE DON'T SHOW UP AND
16	IF YOU'RE RIGHT AND THE WHOLE THING FALLS PART,
17	WELL, THEN WE HAVE TO CHANGE IT. AND WE COULD
18	CHANGE IT SOONER.
19	CHAIRMAN THOMAS: DR. LEVIN AND THEN DR.
20	VUORI.
21	DR. LEVIN: THANKS, J.T. THESE ARE SOME
22	BROAD AND SWEEPING CHANGES, AND MAYBE WE HAVE TO
23	DISCUSS EACH ONE OF THEM INDIVIDUALLY TO COME TO
24	CONSENSUS, BUT I AGREE WITH SHERRY, ALWAYS PRETTY
25	MUCH, AND EVERYONE ELSE, THAT THIS IS AN ISSUE
	125
	123

1	THAT'S PLAGUED US FOR MANY YEARS AND THAT WE'RE A
2	PUBLIC INSTITUTION, AND THAT IF WE'RE GOING TO
3	RETAIN PUBLIC TRUST, WE HAVE TO MAKE SOME BROAD AND
4	SWEEPING CHANGES.
5	SO I APPLAUD ALL THIS WORK AND THE RISK
6	THAT'S TAKEN AND HOW THOUGHTFUL IT'S BEEN PUT
7	TOGETHER.
8	I DO HAVE JUST A FEW QUICK COMMENTS THAT I
9	DON'T THINK HAVE BEEN ADDRESSED ON A FEW OF THESE.
10	MAYBE THE FIRST IS A POINT OF INFORMATION FOR JAMES
11	BECAUSE HE MENTIONED IT. FOR THE CONFLICTS, AT THE
12	MOMENT PEOPLE WHO ARE INDIVIDUALLY CONFLICTED
13	ECONOMICALLY ON ANY GRANT DON'T SPEAK AT ALL, MUCH
14	LESS VOTE. IS THAT GOING TO BE RETAINED BECAUSE
15	THAT WASN'T MENTIONED IN THE DESCRIPTION?
16	MR. HARRISON: YES. MEMBERS WOULD
17	CONTINUE TO BE PROHIBITED BOTH FROM PARTICIPATING
18	AND VOTING ON APPLICATIONS IN WHICH THEY HAVE A
19	DIRECT FINANCIAL CONFLICT.
20	DR. LEVIN: INDIVIDUAL. I THINK THAT'S
21	VERY IMPORTANT TO KEEP.
22	MR. SHESTACK: BUT WE VOTE EN BLOC. SO
23	THAT MEANS THEY'RE PROHIBITED FROM DISCUSSING THE
24	WHOLE BLOC.
25	DR. LEVIN: THEY CAN'T DISCUSS THE
	126

1	INDIVIDUAL APPLICATIONS.
2	MR. HARRISON: AS A REMINDER, TYPICALLY
3	THE WAY WE DEAL WITH REVIEW OF APPLICATIONS IS TO
4	DISCUSS INDIVIDUAL APPLICATIONS FIRST SO THAT
5	MEMBERS WHO MAY BE CONFLICTED FROM ONE APPLICATION
6	BUT NOT ANOTHER CAN PARTICIPATE IN ONE DISCUSSION
7	BUT NOT THE OTHER. ONCE WE'VE EXHAUSTED THE
8	DISCUSSION OF INDIVIDUAL APPLICATIONS AND HAVE A
9	FINAL SLATE OF AWARDS, A MOTION IS MADE TO APPROVE
10	THE SLATE, AND MEMBERS VOTE YES OR NO WITH THE
11	EXCEPTION OF THOSE APPLICATIONS FOR WHICH THEY HAVE
12	A CONFLICT.
13	DR. LEVIN: SO ESSENTIALLY THE PROCESS IS
14	IDENTICAL TO WHAT IT IS NOW EXCEPT FOR DURING THE
15	VOTING PROCESS, THE 13 INSTITUTIONAL REPRESENTATIVES
16	DON'T CAST A VOTE, BUT OTHERWISE NOTHING IS
17	CHANGING?
18	MR. HARRISON: TO BE TECHNICALLY PRECISE,
19	THEY WOULD ABSTAIN.
20	MR. SHESTACK: FROM THE TIER VOTES.
21	MR. HARRISON: FROM EITHER AN INDIVIDUAL
22	VOTE OR AN EN BLOC VOTE.
23	DR. LEVIN: MY SECOND POINT, WITH
24	INCREASED INDUSTRY INVOLVEMENT, OBVIOUSLY THIS IS A
25	PLACE THAT THE INSTITUTION HAS BEEN MOVING AND THAT
	127
	1 <i>L I</i>

1	EVERYBODY TELLS US THAT IT'S IMPORTANT, BUT I THINK
2	WE NEED TO BE CAREFUL WHEN BRINGING MORE AND MORE
3	INDUSTRY MEMBERS INTO THE GRANTS WORKING GROUP THAT
4	THEY'RE FULLY INFORMED AND ON BOARD WITH OUR MISSION
5	AND WHAT THE INSTITUTE IS TRYING TO DO. AND I HAD
6	SOME CONCERNS ABOUT THAT EVEN IN THE LAST ROUND OF
7	DISEASE TEAMS THAT WAS DISPROPORTIONATELY INDUSTRY
8	MEMBERS AND VOTED EXTREMELY CONSERVATIVELY.
9	IF YOU RECALL, I THINK \$113 MILLION WORTH
10	OF GRANTS WERE RECOMMENDED FOR FUNDING IN A ROUND
11	THAT HAD BEEN ALLOCATED \$240 MILLION. AND PERHAPS
12	THAT'S BECAUSE, WHILE CIRM HAS A MISSION OF BOLD AND
13	VISIONARY ACTION AND INVESTING IN HIGH RISK, HIGH
14	PAYOFF RESEARCH AND TAKING A CHANCE TO MAKE A BIG
15	DIFFERENCE, INDUSTRY IS USED TO SPENDING ITS OWN
16	MONEY AND BEING CONSERVATIVE AND NOT TAKING RISK AND
17	SO MAY HAVE BEEN MORE CONSERVATIVE THAN ANY PREVIOUS
18	ROUND.
19	I THINK WE'VE SEEN THIS PROGRESSION THAT A
20	LOWER AND LOWER PERCENTAGE OF WHAT HAS BEEN
21	ALLOCATED FOR ANY ROUND IS BEING RECOMMENDED FOR
22	FUNDING EACH TIME. SO JUST URGE US TO MAKE CLEAR
23	WHAT THE CRITERION ARE AND WHAT OUR GOALS ARE AS AN
24	ORGANIZATION WITH THE GRANTS WORKING GROUP REVIEW IF
25	WE'RE GOING TO BE INCLUDING MORE AND MORE PEOPLE
	128

1	OUTSIDE OF THE FIELD AND OUTSIDE OF BASIC RESEARCH
2	AND SCIENCE.
3	CHAIRMAN THOMAS: THANK YOU, DR. LEVIN.
4	THAT'S VERY PERCEPTIVE.
5	MR. ROTH: I JUST WANT TO CORRECT ONE
6	THING ABOUT RISK AND INDUSTRY. WHEN I STARTED OUT,
7	I HAD HAIR LIKE YOURS. TO SAY THAT INDUSTRY DOESN'T
8	TAKE RISKS WOULD NOT BE APPROPRIATE. I THINK
9	INDUSTRY TAKES EXTRAORDINARY RISK.
10	DR. FRIEDMAN: WHEN I STARTED OUT, I HAD
11	HAIR LIKE YOURS.
12	CHAIRMAN THOMAS: OKAY.
13	DR. LEVIN: ONE FINAL SMALL POINT. IF THE
14	APPEALS PROCESS, AS SOMEONE MENTIONED A FEW MEETINGS
15	AGO, AS PART OF OUR APPEALS PROCESS AND AS CRITERION
16	THAT STILL MADE IT INTO THIS RECOMMENDATION WAS THE
17	AVAILABILITY OF NEW INFORMATION, AND AS FAR AS I
18	KNOW, THERE'S NO MAJOR GRANTING AGENCY THAT ALLOWS
19	NEW INFORMATION THAT WAS PRODUCED OR DISCOVERED OR
20	REPORTED AFTER THE GRANT WAS SUBMITTED TO BE
21	INCLUDED IN REVIEW. AND I UNDERSTAND THAT WE HAVE A
22	SHORTER TIMELINE AND WANT TO GET THINGS OUT, BUT I
23	THINK THAT ALLOWING THAT AS A REASON FOR
24	RECONSIDERATION OF A GRANT OPENS UP A HUGE CAN OF
25	WORMS THAT WE'VE DISCUSSED ON THIS BOARD BEFORE.
	129
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1	IT'S REALLY HARD TO DECIDE WHAT QUALIFIES. DOES IT
2	NEED TO BE PUBLISHED? DOES IT NEED TO BE PATENTED.
3	AND SO IT'S GOING TO ALLOW FOR JUST AS
4	MANY EXTRAORDINARY PETITIONS OR RE-REVIEW REQUESTS
5	AS WE HAD BEFORE, AND WE MAY WANT TO CONSIDER
6	WHETHER THAT'S, EVEN THOUGH IT'S NICE TO BE ABLE
7	FOLD EVERYTHING IN AND BE THE MOST TIMELY AS
8	POSSIBLE, WHETHER THAT'S REALLY THE MOST PRUDENT WAY
9	TO GO FORWARD.
10	CHAIRMAN THOMAS: THANK YOU, DR. LEVIN.
11	THOSE ARE ALL POINTS THAT STAFF HEARS, AND THEY'RE
12	ALL VERY PERCEPTIVE POINTS. I WOULD NOTE THAT YOU
13	COULD HAVE A DEVELOPED SET OF CRITERIA, WHICH WE
14	REALLY HAVEN'T DONE, ON NEW INFORMATION OR ANYTHING
15	ELSE THAT FORMS THE BASIS OF APPEAL THAT CAN INFORM
16	THAT PROCESS.
17	OKAY. I'M BEING TOLD THAT WE NEED TO TAKE
18	A BREAK. DR. VUORI WILL START WHEN WE RESUME. FIVE
19	MINUTES. FIVE-MINUTE BREAK. WE'RE ON A ROLL,
20	FOLKS. LET'S KEEP GOING. THANK YOU.
21	(A RECESS WAS TAKEN.)
22	CHAIRMAN THOMAS: IF EVERYBODY COULD
23	RESUME YOUR SEAT, PLEASE. EVERYBODY, AGAIN, PLEASE
24	TAKE YOUR SEATS. WELCOME BACK, EVERYBODY. WE'RE
25	GOING TO RESUME.
	120

1	ACTUALLY MARCY HAS TO LEAVE, SO I WANTED
2	TO CALL ON HER FIRST AND THEN BACK TO DR. VUORI.
3	MS. FEIT: SORRY. I APOLOGIZE. I HAVE A
4	BOARD MEETING. I HAVE A CHAIRMAN WAITING FOR ME.
5	I WANTED TO THANK J.T. FOR A REAL FOCUSED
6	RESPONSE BECAUSE I THINK THAT'S WHAT IT IS. AND I
7	HOPE THAT WE WILL TAKE THE TIME AS A BOARD TO VET IT
8	OUT CAREFULLY, AND PARTICULARLY IN LIGHT AND
9	COMPARISON WITH PROP 71 BECAUSE I THINK THAT IS A
10	MISSION FOR US AND THAT IS A COMMITMENT WE'VE MADE
11	UNLESS IT'S CHANGED.
12	BUT I WANT TO SAY THAT NONE OF US AGREE
13	WITH EVERYTHING THERE. WE'RE JUST NOT GOING TO.
14	BUT WE HAVE MOMENTUM, AND THE REPORT THIS MORNING
15	JUST REALLY LAYS OUT THE WORK THAT EVERYONE HAS DONE
16	AND CONTRIBUTED TO THIS MOVEMENT IN CALIFORNIA. AND
17	I REFLECT BACK ON ALL THE WORK THAT'S BEEN DONE IN
18	ALL OF THE DIFFERENT COMMITTEES IN CIRM, AND WE'VE
19	ESTABLISHED STANDARDS FOR STEM CELL RESEARCH THAT
20	EVERYONE ALL OVER THE WORLD IS SAYING CAN WE COPY
21	THAT, WILL YOU LEND US HOW YOU'RE DOING THIS.
22	SO WHILE THAT REPORT MAY HAVE BEEN
23	CRITICAL WITH THINGS WE DON'T LIKE TO HEAR AND WANT
24	TO ACCEPT IN SOME WAYS, WE KNOW WE'VE DONE A
25	FANTASTIC JOB. WE KNOW WHERE WE'RE AT. AND I JUST
	131

1	HOPE THAT WE DON'T ALLOW SOMETHING LIKE THIS TO
2	HINDER OUR MOMENTUM GOING FORWARD, THAT WE KEEP
3	MOVING FORWARD IN A VERY POSITIVE WAY LIKE WE HAVE.
4	AND IT WAS A WONDERFUL REPORT THIS MORNING TO BE
5	ABLE TO GO THROUGH AND SEE JUST WHERE WE ARE.
6	J.T., THANK YOU FOR GETTING US FOCUSED.
7	AND I LOOK FORWARD TO HAVING THE DISCUSSIONS TO VET
8	OUT EACH ISSUE BECAUSE I THINK WE NEED TO TAKE MORE
9	TIME DOING THAT. THANK YOU.
10	CHAIRMAN THOMAS: THANK YOU, MARCY. DR.
11	VUORI.
12	DR. VUORI: THANK YOU, J.T. SO LIKE ALL
13	OF US, WHEN I READ THE IOM REVIEW, I CERTAINLY HAD
14	VERY MIXED FEELINGS ABOUT THE MESSAGE AND THE
15	FAIRNESS EVEN OF THE REPORT. BUT AT THE END OF THE
16	DAY, I THINK CIRM'S MISSION IS LARGER THAN THAT
17	REPORT. IT'S LARGER THAN THIS BOARD. WE AS A BOARD
18	ARE REALLY RESPONSIBLE AS GUARDIANS OF CIRM'S
19	MISSION, AND WE NEED TO ENSURE THE SUCCESS OF CIRM
20	IN A MANNER THAT REALLY MEETS THE APPROVAL AND THE
21	RESPECT AND THE TRUST OF THE CITIZENS OF CALIFORNIA.
22	THAT'S REALLY OUR SOLE PRIORITY.
23	I MAY THINK THAT THE AND HAVE COMPLETE
24	FAITH IN THE INTEGRITY OF THE PROCESSES THAT THIS
25	BOARD UNDERTAKES. AT THE END OF THE DAY, IT'S THE

1	PUBLIC TRUST THAT MATTERS TO US AS A STATE-FUNDED
2	AGENCY. AND IT IS OUR REAL RESPONSIBILITY TO
3	ADDRESS THE PERCEIVED CONFLICT OF INTEREST THAT HAS
4	BEEN PRESENTED TO US NOW I THINK AT LEAST THREE
5	TIMES. AND I THINK WE NEED TO ADDRESS IT IN A
6	MANNER THAT FURTHER INSTILLS PUBLIC TRUST IN OUR
7	CAPABILITY TO TAKE THAT RESPONSIBILITY THAT THIS
8	BOARD HAS VERY SERIOUSLY.
9	SO I THANK J.T. FOR ALL HIS WORK, HOW HE
10	HAS LAID OUT THE RESPONSE TO THE IOM REPORT. I'M IN
11	FULL SUPPORT OF THE ENTIRETY OF THAT PROPOSAL.
12	I WOULD MAKE A COMMENT, FROM A SOMEWHAT
13	PERSONAL PERSPECTIVE, THAT I UNDERSTAND THAT I WOULD
14	BE ONE OF THOSE REPRESENTATIVES WHO NO LONGER WOULD
15	VOTE ON THIS BOARD. DO I VIEW THAT AS AN IMPORTANT
16	ACTIVITY? OF COURSE. AND I THINK IT'S CERTAINLY
17	ONE MECHANISM HOW I FEEL THAT MANY OF US CAN ADD
18	VALUE TO THE BOARD FUNCTIONS. AT THE SAME TIME I
19	THINK THIS IS AN OPPORTUNITY TO THINK ABOUT THE
20	BOARD'S ROLE IN ADDITION TO ELIMINATING THIS
21	CONFLICT OF INTEREST OR PERCEIVED CONFLICT OF
22	INTEREST IN A WAY THAT WE CAN ELEVATE THE BOARD TO A
23	MORE STRATEGIC LEVEL WHERE WE SHOULD HAVE FULL
24	CONFIDENCE IN THE WORKING GROUP, GRANTS WORKING
25	GROUP, IN EVALUATING AND RANKING THE GRANT

1	APPLICATIONS. AND THE BOARD'S ROLE REALLY WOULD BE
2	THE PROGRAMMATIC REVIEW OR PORTFOLIO ANALYSIS
3	IDEALLY PROSPECTIVELY, UNDERSTANDING THAT THAT MAY
4	NOT ALWAYS HAPPEN.
5	AND I THINK WITH THAT SAID, AGAIN, I HAVE
6	FULL SUPPORT FOR J.T.'S PROPOSAL.
7	CHAIRMAN THOMAS: THANK YOU. DR. LUBIN.
8	DR. LUBIN: SO I HAVE THREE QUESTIONS.
9	ONE, J.T., WAS IT YOUR GOAL AND PLAN THAT WE MAKE A
10	VOTE ON THIS DOCUMENT TODAY?
11	CHAIRMAN THOMAS: IDEALLY I WOULD LIKE TO
12	DO THAT, YES.
13	DR. LUBIN: WE DON'T HAVE TO DISCUSS THAT
14	FURTHER. I JUST WANTED TO UNDERSTAND THAT.
15	SECONDLY, AS WAS INDICATED, I WAS ASKED TO
16	HEAD A TASK FORCE ON THE APPEAL GRANT REVIEW
17	PROCESS. WE HAD TWO MEETINGS AND MADE NO PROGRESS
18	WHATSOEVER. THERE'S SOME STATEMENTS IN HERE THAT
19	ARE THINGS THAT WE BROUGHT UP IN THOSE DISCUSSIONS,
20	AND I'D LIKE TO HEAR MORE DISCUSSION AROUND THE
21	TABLE ABOUT THAT ONE SECTION, IF ANYONE WANTS TO
22	DISCUSS IT, BECAUSE WHEN WE BROUGHT THIS UP AT THE
23	SMALLER MEETINGS AT CHILDREN'S IN OAKLAND, WE MADE
24	NO PROGRESS WHATSOEVER.
25	AND THEN I THINK THE THIRD THING THAT'S
	134

1	REALLY IMPORTANT FOR US ALL TO THINK ABOUT IS THE
2	FUTURE OF CIRM AFTER THE FUNDING CYCLE THAT WE HAVE
3	NOW IS OVER. AND PART OF, I THINK, WHEN BOB PUT
4	THIS TOGETHER WITH THE IOM, IT WAS TO GET A BLESSING
5	SO THAT WE COULD GO BACK, RAISE MORE MONEY, CONTINUE
6	THIS WORK. AND I HAVEN'T HEARD ANYONE, ALTHOUGH
7	IT'S STATED IN HERE, ONE WORD "SUSTAINABILITY,"
8	ANYONE REALLY TALK ABOUT WHAT WE WOULD DO. AND I
9	FEAR IF WE DON'T MAKE SOME OF THESE CHANGES, WE'RE
10	NOT GOING TO BE IN A POSITION TO BE ABLE TO GO BACK
11	TO THE VOTERS WITH THEIR BLESSING FOR THE FUTURE.
12	SO I'D LIKE TO HEAR SOME DISCUSSION ABOUT
13	THAT, BUT I WOULD REALLY LIKE TO HEAR ON PAGE 4
14	COMMENTS FROM PEOPLE ON THE BOARD ABOUT THE APPEALS
15	GRANT REVIEW PROCESS IN PARTICULAR, WHICH THE IOM
16	REPORT RECOMMENDS ELIMINATING EXTRAORDINARY APPEALS.
17	CHAIRMAN THOMAS: CAN I, BEFORE THERE'S
18	COMMENT ON THAT, JUST RESPOND? ON THE
19	SUSTAINABILITY ISSUE, I THINK IT'S A VERY IMPORTANT
20	POINT THAT YOU RAISE, DR. LUBIN, WHICH IS IF WE
21	DON'T ACT, WE WILL HAVE GREAT DIFFICULTY IN
22	SUSTAINING THE EFFORT. AND THE LAST THING WE WANT
23	TO DO IS BE IN A POSITION WHERE WE HAVE ALL THIS
24	WONDERFUL RESEARCH THAT WE HEARD ABOUT THIS MORNING
25	BE IN MIDSTREAM AND HAVE FUNDING END AND NOT BE ABLE
	135
	

TO CONTINUE THE WORK TO FRUITION. SO SUSTAINABILITY
IS A HUGE ISSUE, AND PUBLIC CREDIBILITY IS CENTRAL
TO THAT.
WITH RESPECT TO WHAT WE'RE GOING TO DO
ABOUT SUSTAINABILITY, I WANT TO BE ON THE RECORD
AGAIN AS SAYING WE'RE EVALUATING A BUNCH OF
DIFFERENT THINGS. IT MIGHT BE GO BACK TO THE
VOTERS. IT MIGHT BE A NUMBER OF OTHER THINGS. WE
HAVE MADE NO DECISIONS ON THAT FRONT, BUT I WILL SAY
REGARDLESS OF WHAT THE DECISION IS, IF WE DON'T HAVE
CREDIBILITY, WE WILL NOT HAVE A CHANCE TO ACHIEVE
THE GOAL OF SUSTAINING THE AGENCY.
ANYBODY WANT TO COMMENT?
DR. STEWARD: ACTUALLY I WAS GOING TO
COMMENT ON THAT, BUT ONE OTHER THING. JUST LET ME
SAY I'M TOTALLY IN FAVOR OF ELIMINATING THE
EXTRAORDINARY APPEALS PROCESS.
AND THE POINT THAT I WANT TO MAKE IS THAT
DOESN'T MEAN THAT IT CHANGES IN ANY WAY THE
OPPORTUNITY FOR PUBLIC COMMENT AND ESPECIALLY
COMMENT BY PEOPLE WHO REPRESENT DISEASES AND
DISORDERS THAT WE ALL CARE ABOUT. THAT, AS I
UNDERSTAND IT, WILL REMAIN IN PLACE AND REMAIN A
VERY IMPORTANT PART OF OUR MEETING STRUCTURE.
IN FACT, I HAVE TO SAY I DON'T THINK THAT
136

1	THE EXTRAORDINARY APPEALS PROCESS ACTUALLY DID THAT.
2	MORE OFTEN THAN NOT, IT WENT TO THE HEART OF THE
3	REVIEW AND A DISPUTE ABOUT PARTICULAR OPINIONS. AND
4	IT WAS ONLY LATER, WHEN THE PATIENTS WEIGHED IN,
5	THAT IT WAS REALLY IN THE AREA THAT WAS IMPORTANT
6	FOR US TO CONSIDER AT THAT POINT. JUST TO SAY, THAT
7	DOESN'T CHANGE WHAT CAN HAPPEN.
8	AND ALSO TO POINT OUT, BY THE WAY, THAT
9	GIVEN THAT WE ARE A STATE AGENCY AND OFFER THE
10	OPPORTUNITY FOR PUBLIC COMMENT, AMONGST THE PUBLIC
11	COULD BE THE APPLICANT LIMITED TO HIS THREE-MINUTE
12	PRESENTATION.
13	CHAIRMAN THOMAS: CORRECT. ANY MEMBER OF
14	THE PUBLIC CAN TESTIFY.
15	DR. STEWARD: THE SECOND THING, COULD I
16	JUST GO ON TO ONE OTHER THING, AND I KNOW THERE ARE
17	GOING TO BE COMMENTS ON THIS, BUT I ACTUALLY WANTED
18	TO GO BACK TO A POINT THAT JON SHESTACK RAISED
19	BECAUSE IT'S REALLY IMPORTANT. AND IT HAS TO DO
20	WITH WHAT HAPPENS AT THE GRANTS WORKING GROUP DURING
21	THE FINAL STAGE THAT WE CALL PROGRAMMATIC REVIEW.
22	BUT, AGAIN, I DON'T THINK THAT THAT'S THE RIGHT WORD
23	FOR IT.
24	WHAT REALLY HAPPENS THERE, AND IT'S
25	SOMETHING THAT'S DONE IN OTHER GRANT REVIEW GROUPS

1	AS WELL, BUT NOT, BY THE WAY, AT NIH, AND THAT IS TO
2	THROW UP ON THE BOARD THE SCORES OF ALL THE GRANTS
3	AND SEE IF IT MAKES SENSE. IT GIVES THE REVIEWERS,
4	THE SCIENTIFIC REVIEWERS, A CHANCE TO LOOK AT THEM
5	AND SAY, WHOA, THAT DOESN'T MAKE ANY SENSE THAT IT
6	ENDED UP DOWN THERE. SOMETIMES THINGS HAPPEN IN THE
7	COURSE OF A REVIEW SESSION THAT YOU KIND OF LOSE
8	TRACK OF, AND IT'S A VERY IMPORTANT OPPORTUNITY FOR
9	EVERYBODY TO GO BACK AND LOOK AND TO CONSIDER THE
10	ORDER AND TO CONSIDER WHERE THE LINE OUGHT TO BE
11	DRAWN, LISTENING TO BOTH THE SCIENCE AND PATIENT
12	ADVOCATES AT THAT TIME.
13	AGAIN, I DON'T THINK THERE'S ANY PROBLEM
14	WITH THE PATIENT ADVOCATES NOT VOTING, BUT HAVING
15	THAT OPPORTUNITY, WHATEVER YOU WANT TO CALL IT, I
16	WOULD REALLY STRONGLY ENCOURAGE THAT WE LEAVE IN
17	PLACE.
18	MR. SHESTACK: I WOULD JUST SAY AS A
19	PATIENT ADVOCATE, I DON'T CARE PARTICULARLY ABOUT MY
20	VOTE IN THAT PROCESS BECAUSE I'M LIKE ONE OF 30 AND
21	I'M RARELY THE DECIDING VOTE AND I HAVEN'T BEEN PART
22	OF THE SCORING, BUT I CARE VERY MUCH ABOUT HAVING
23	THAT PROCESS. IT'S ALMOST LIKE A MINI COUNCIL AT
24	THE END OF A GRANT REVIEW SECTION. AND ONCE IN A
25	WHILE SOME REAL INSIGHT COMES OUT OF IT, AND PEOPLE
	138

JUST GET A CHANCE TO LOOK AT THE GESTALT AND GO,
WHOA, THIS MIGHT HAVE BEEN A MISTAKE OR WE COULD DO
BETTER. IT'S NOT MY VOTE. IT IS THE OPPORTUNITY TO
MAKE SURE THAT THAT DISCUSSION HAPPENS, I THINK, IS
EXTRAORDINARILY VALUABLE.
BUT IF THIS IS THE TIME TO DISCUSS THE
SPECIAL PETITIONS PROCESS.
DR. LUBIN: I JUST WONDERED IF PEOPLE WANT
TO WEIGH IN ON THAT.
MR. SHESTACK: I FEEL IT'S A CORE PART OF
WHO WE ARE THAT THERE IS THAT ABILITY. IT CAN BE
LIMITED AND NEATENED AND BE EXCLUDED TO NEW
INFORMATION, BUT IT'S PART OF WHAT KEEPS US SPECIAL
AND RESPONSIVE AS THINGS CHANGE. USUALLY IT'S A
WASTE OF TIME. OCCASIONALLY THERE'S BEEN TRULY NEW
INFORMATION THAT HAS MADE A DIFFERENCE IN THE
SUBSTANCE OF HOW THE GROUP HAS DECIDED, I BELIEVE.
CHAIRMAN THOMAS: KEEP IN MIND WE'RE NOT
AT ALL RECOMMENDING TO DO AWAY WITH THE APPELLATE
PROCESS. WE'RE JUST REDIRECTING IT SO IT GETS INTO
STAFF AND THE GRANTS WORKING GROUP AND HAS AN
OPPORTUNITY TO BE EVALUATED ON A SCIENTIFIC BASIS,
WHICH, IN MY OPINION, YOU MAY DISAGREE, MAKES A LOT
OF SENSE.
DR. STEWARD: COULD YOU JUST ROLL THAT OUT
139

1	A LITTLE BIT BECAUSE I THINK IT'S REALLY IMPORTANT
2	TO ADDRESS JON'S POINT. AS I UNDERSTAND IT, THAT
3	REALLY WOULD BE THE POINT AT WHICH THERE COULD BE
4	CONSIDERATION OF IMPORTANT NEW DATA.
5	CHAIRMAN THOMAS: YES. IT WOULD WORK THAT
6	IF THERE IS AN APPEAL, IF SOMEBODY WAS NOT APPROVED
7	FOR FUNDING, THEY WOULD BE ABLE TO APPEAL. AND
8	THOSE APPEALS BY AND LARGE ARE ON A VARIETY OF
9	SCIENTIFIC BASES, DISPUTES OF FACT, NEW INFORMATION,
10	WHATEVER. THAT WOULD GO TO STAFF AND THEY WOULD
11	EVALUATE AND THEN WOULD MAKE RECOMMENDATIONS TO THE
12	GRANTS WORKING GROUP, AS I PROPOSE IT TO BE
13	CONSTRUCTED, FOR RE-REVIEW. AND THEN WHEN ALL THAT
14	IS SAID AND DONE, ANYTHING THAT'S ADDED TO THE SLATE
15	THAT THE GRANTS WORKING GROUP HAS WOULD THEN GO TO
16	THE BOARD. THE BOARD HAS PROGRAMMATIC REVIEW UNDER
17	MY CONSTRUCT AND DISCUSSES THINGS.
18	AND BY THE WAY, IT'S POSSIBLE THAT THE
19	BOARD MIGHT SAY THERE'S A SCIENCE QUESTION. WE
20	SHOULD HAVE THE GRANTS WORKING GROUP LOOK AT IT
21	AGAIN. SO THEY CAN, IN THEORY, WHO KNOWS IF THAT
22	WOULD HAPPEN, IN THEORY SEND SOMETHING BACK FOR
23	ADDITIONAL SCIENTIFIC REVIEW.
24	ANYWAY, THE POINT OF ALL THIS IS TO HAVE
25	THE SCIENTIFIC APPEALS VETTED BY THE PEOPLE WHO ARE
	140
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1	BEST SUITED TO UNDERTAKE THEM, WHICH IS THE GRANTS
2	WORKING GROUP AND STAFF.
3	DR. PRICE: THAT MAY ALL BE TRUE, BUT IN
4	THE LAST ANALYSIS, THE STAFF IS GOING TO RECOMMEND
5	TO THE BOARD FOR A VOTE. AND AS WE KNOW, ANY TIME
6	WE HAVE A VOTE, THERE ARE PUBLIC COMMENTS. AND SO
7	WE'RE BACK EXACTLY INTO THE SAME SITUATION WE WERE
8	BEFORE IS THAT THOSE PEOPLE WHO MADE APPEALS CAN
9	MAKE THEIR PRESENTATION TO THE BOARD FOR BETTER OR
10	WORSE, BUT I DON'T REALLY SEE THAT THIS IS GOING TO
11	CHANGE A HUGE AMOUNT WITH RESPECT TO WHAT WE'VE BEEN
12	DOING FOR THE LAST EIGHT MONTHS.
13	MR. SHESTACK: PEOPLE WON'T RELITIGATE THE
14	FINE POINTS OF THEIR GRANT.
15	CHAIRMAN THOMAS: YES. IT'S MEANT TO
16	AVOID HAVING SCIENTIFIC APPEALS GO TO THE BOARD,
17	WHICH IN MY OPINION IS NOT THE PROPER BODY TO BE
18	EVALUATING.
19	DR. PRICE: YOU CAN NEVER GET TOO MANY
20	BITES AT THE APPLE.
21	CHAIRMAN THOMAS: THAT'S TRUE, BUT IT'S UP
22	TO BOARD DISCIPLINE TO UNDERSTAND THAT IT'S BEEN
23	RE-REVIEWED BY THE PEOPLE WHO SHOULD BE REVIEWING IT
24	AND FOR THE BOARD TO ACT ACCORDINGLY.
25	MR. SHEEHY: AND MAYBE, NOT TO TAKE ISSUE
	141

1	WITH DR. LUBIN, BUT MAYBE IT WOULD BE HELPFUL,
2	INSTEAD OF TRYING TO WORK THROUGH ALL THE DETAILS OF
3	THESE TODAY, I DON'T THINK THAT'S REALLY OUR GOAL.
4	MY HOPE IS AND MY ASSUMPTION IS THAT WE'RE LOOKING
5	AT A BROAD PACKAGE OF IDEAS THAT WE'RE GOING TO MAKE
6	A DECISION TOMORROW WHETHER OR NOT TO MOVE FORWARD
7	WITH, AND THEN WE'RE GOING TO TAKE THEM INDIVIDUALLY
8	AND ACTUALLY CRAFT POLICY AND NEW REGS IN A VERY
9	DELIBERATE MANNER. AM I CORRECT IN THINKING THAT
10	THAT'S GOING TO BE THE PROCESS?
11	CHAIRMAN THOMAS: YES, THAT'S CORRECT,
12	OTHER THAN TO SAY THAT I'M LOOKING, SINCE WE HAVE
13	SOME MEMBERS WHO ARE HERE TODAY IN THE DISCUSSION
14	AND WON'T BE HERE TOMORROW, I WOULD LIKE TO HAVE A
15	VOTE AT THE END OF THIS DISCUSSION AS OPPOSED TO
16	TOMORROW.
17	MR. SHEEHY: CAN I KEEP I HAVEN'T
18	SPOKEN, SO I KNOW A LOT OF PEOPLE HAVE HAD AN
19	OPPORTUNITY. I JUST WANT TO GET SOME CLARITY ON A
20	COUPLE OF POINTS. AND THESE PROPOSALS, THESE ARE
21	ALL SUNSETTED, RIGHT? SO I WANT TO BE CLEAR THAT
22	WE'RE TALKING ABOUT PROPOSALS THAT WILL HAVE A
23	SUNSET IN A YEAR, AND THEN WE WILL LOOK AT THEM AND
24	THEN MAKE A DECISION WHETHER WE WANT TO RENEW THEM.
25	CHAIRMAN THOMAS: THE INTENT, WHEN I
	142
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1	INTRODUCED THE ONE-YEAR IDEA, WAS APPLICABLE
2	SPECIFICALLY TO THE CONFLICT OF INTEREST SITUATION.
3	IT WASN'T MEANT TO APPLY TO EVERYTHING; BUT IF
4	THAT'S THE BOARD'S CHOOSING, WE COULD DO THAT AS
5	WELL. BUT I SPECIFICALLY RAISED IT IN CONNECTION
6	WITH THE CONFLICTS ISSUE.
7	MR. SHEEHY: SO I COULD TENTATIVELY
8	SUPPORT THIS, AGAIN, WITH THE NOTION THAT WE HAVE A
9	SUNSET ON EVERYTHING. I AM CONCERNED ABOUT THE
10	PROGRAMMATIC REVIEW PART. I REMEMBER SITTING DOWN
11	WITH ZACH HALL AND ARLENE CHIU WHEN THAT PROCESS WAS
12	DEVELOPED. THAT PROCESS WAS DEVELOPED IN A WAY TO
13	GIVE A ROLE TO PATIENT ADVOCATES. I CERTAINLY CAN'T
14	IMAGINE THAT I'M NOT GOING TO VOTE AT THE WORKING
15	GROUP BECAUSE I WILL SUE. I HAVE THAT RIGHT PER
16	PROP 71 TO VOTE ALONG WITH THE OTHER MEMBERS.
17	I THINK THAT OUR ROLE IN THE WORKING
18	GROUP, AND I THINK THE IOM SLANDER OF OUR ROLE IN
19	THE WORKING GROUP, IS REALLY OFFENSIVE. I'M LOOKING
20	HERE AT SOMETHING CALLED THE CONGRESS
21	CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAM,
22	WHICH IS AT THE DEPARTMENT OF DEFENSE WEB SITE,
23	CDMP.ARMY.MIL. AND IT TALKS ABOUT THE ROLE OF
24	CONSUMER REVIEWERS, WHICH ARE PART OF THEIR PEER
25	REVIEW PROCESS. CONSUMERS REPRESENT THE COLLECTIVE

1	VIEWS OF SURVIVORS, PATIENTS, FAMILY MEMBERS, AND
2	PERSONS AFFECTED BY AND AT RISK FOR CERTAIN
3	CONDITIONS, DISEASES, AND INJURIES. THEY EVALUATE
4	RESEARCH STUDY APPLICATIONS FOR RELEVANCE TO THE
5	CONSUMER COMMUNITY'S NEEDS AND CONCERNS AND ACTIVELY
6	PARTICIPATE IN PEER REVIEW PANEL DISCUSSIONS. THEY
7	PARTICIPATE AS A FULL MEMBER OF THE REVIEW PANEL
8	WITH FULL VOTING MEMBER STATUS.
9	I THINK PROP 71 SEEKS TO REPLICATE THAT.
10	THE SAME THING HAPPENS AT THE FDA FOR APPROVAL OF
11	NEW THERAPIES AND DEVICES. THEY ACTIVELY HAVE
12	MEMBERS OF THE PATIENT COMMUNITY WHO ACTUALLY
13	UNDERSTAND THE DISEASES THAT YOU'RE TRYING TO MAKE A
14	DIFFERENCE IN PARTICIPATE. SO I DON'T REALLY GET
15	THE EVIDENCE BASIS BY WHICH THE IOM THOUGHT THAT
16	WHAT WAS GOOD ENOUGH FOR THE DEPARTMENT OF DEFENSE,
17	WHAT IS GOOD ENOUGH FOR THE FOOD AND DRUG
18	ADMINISTRATION SOMEHOW IS INSUFFICIENT FOR THE
19	PEOPLE OF CALIFORNIA.
20	I WANT TO MAKE SURE THAT OUR ROLES ARE
21	STILL ROBUST. PROP 71 EXISTS BECAUSE OF THE
22	PATIENTS. AND I'M AWARE OF THE PROBLEMS IN
23	SACRAMENTO, BUT I'M HAPPY TO GO TO SACRAMENTO WITH
24	EVERYBODY I KNOW WITH HIV AND TALK TO THEM ABOUT THE
25	IMPORTANCE OF THIS EFFORT. AND I THINK I'M LOOKING

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1
     AT JOAN NODDING, AND I THINK PARKINSON'S FOLKS, I
 2
     SEE JUDY NODDING, PEOPLE FROM THE HUNTINGTON'S
 3
     COMMUNITY. I SEE BILL REMAK FROM THE HEP C AND
 4
     LIVER DISEASE COMMUNITY. I'M SURE JON WILL BE THERE
 5
     WITH FOLKS FROM THE AUTISM COMMUNITY. I SEE DON
 6
     REED, ROMAN REED.
 7
               MR. TORRES: TO WHAT END?
               MR. SHESTACK: TO THE END TO PRESERVE THE
 8
 9
     ROLE OF PATIENT ADVOCATES IN THIS UNIQUE EXPERIMENT.
10
               MR. TORRES: IN THE GRANTS REVIEW PROCESS.
               MR. SHEEHY: AGAIN, THE DEVIL IS IN THE
11
12
     DETAILS. AND ALSO I THINK WE HAVE TO REMEMBER WHY
13
     WE'RE HERE. AND IT'S NOT FOR ANY OTHER REASON THAN
     TO MAKE DIFFERENCES IN THE LIVES OF PEOPLE WHO ARE
14
15
     LIVING WITH THESE TERRIBLE DISEASES AND CONDITIONS.
16
     THAT'S WHY WE EXIST. AND I KNOW A LOT OF WHAT WE'RE
17
     DOING IS DEFENSIVE, BUT THERE IS A ROLE FOR THOSE OF
     US WHO HAVE BEEN FIGHTING FOR THIS. WE FOUGHT ALL
18
19
     ALONG. WE PARTICIPATED. IT'S BEEN HARD FOR A LOT
20
     OF US TO PARTICIPATE IN THIS. I'VE SEEN JOAN LOCKED
21
     FROZEN IN SO MANY MEETINGS, YOU KNOW. IT'S NEVER
22
     BEEN EASY FOR ANY OF US TO PARTICIPATE IN THIS. AND
23
     I DON'T THINK THAT THIS IS -- I CANNOT PERSONALLY
24
     GIVE UP SOMETHING THAT THE VOTERS GAVE THE PATIENTS
25
     OF CALIFORNIA JUST BECAUSE IT'S POLITICALLY
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1	EXPEDIENT.
2	SO I HOPE AS WE MOVE FORWARD WITH THESE
3	PROPOSALS THAT WE RECOGNIZE BOTH THE IMPORTANCE OF
4	THE ROLE OF THE PATIENT ADVOCATES WHO HAVE BEEN
5	UNJUSTLY SLANDERED BY THE INSTITUTE OF MEDICINE ON
6	THE BASIS OF ZERO EVIDENCE, CONTRARY TO WHAT HAPPENS
7	AT THE DEPARTMENT OF DEFENSE, CONTRARY TO WHAT
8	HAPPENS AT THE FOOD AND DRUG ADMINISTRATION. WE'VE
9	PARTICIPATED, WE FOUGHT. WE MOVED GOOD SCIENCE. WE
10	JUST TALKED ABOUT THIS MORNING TWO APPLICATIONS THAT
11	WERE MOVED UP IN EXTRAORDINARY STAFF PICKED THESE
12	OUT. I DIDN'T PICK THEM OUT THROUGH AN
13	EXTRAORDINARY PETITION, TWO THAT WERE MOVED UP THAT
14	ARE HIGH LIT THAT WERE MOVED UP DURING PROGRAMMATIC
15	REVIEW AT THE GRANTS WORKING GROUP.
16	WE HAVE TO KEEP FAITH WITH THE PATIENTS OF
17	CALIFORNIA AND THE COMMUNITIES THAT SUPPORT THEM.
18	AND AS WE MOVE FORWARD WITH THESE CHANGES, WE CANNOT
19	ACCEPT ANY DIMINUTION OF WHAT WE GAINED WITH THAT
20	VOTE EIGHT YEARS AGO. SO IN GENERAL I AM
21	SUPPORTIVE, BUT, AGAIN, THE DEVIL IS IN THE DETAILS.
22	AND I HOPE THAT AS WE MOVE FORWARD, WE WILL BE VERY
23	CAREFUL TO DO THIS IN A DELIBERATE, CAUTIOUS MANNER
24	THAT DOES NOT SACRIFICE WHAT WE WON AT THE BALLOT.
25	CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.
	146

1	MR. TORRES: AS A COLON CANCER SURVIVOR, I
2	DON'T THINK I'VE BEEN IN ANY WAY DIMINISHING MY
3	ROLE. IN FACT, I THINK THAT THE WHOLE ISSUE HAS
4	ALWAYS BEEN A DEBATE ON WHETHER PROGRAMMATIC REVIEW
5	OUGHT TO BE AND END AT THE BOARD, NOT IN A PEER
6	REVIEW PROCESS. THAT'S BEEN THE NOTION I'VE
7	RECEIVED OVER THE LAST FEW YEARS.
8	AND TO SUGGEST THAT WE ARE OPERATING IN A
9	POLITICALLY EXPEDIENT MANNER I THINK REALLY PUTS US
10	BENEATH, AND I REJECT THAT. I DON'T THINK WE'RE
11	OPERATING HERE IN A POLITICALLY EXPEDIENT MANNER.
12	WE'RE OPERATING AS RESPONSIBLE CITIZENS TO MAINTAIN
13	THE MISSION OF THIS AGENCY, WHICH YOU SUPPORTED AND
14	WHEN I WAS CHAIRMAN OF THE DEMOCRATIC PARTY
15	SUPPORTED IN 2004. I CERTAINLY DON'T WANT TO
16	DIMINISH THE ROLE OF PATIENT ADVOCATES; BUT AT THE
17	SAME TIME, I DON'T THINK WE'RE DOING THAT. IF
18	YOU'RE SUGGESTING THAT THE ROLE OF PATIENT ADVOCATES
19	IS DIMINISHED BY NOT HAVING THEM VOTE AT THE END OF
20	THE DAY IN THE PEER REVIEW PROCESS AND SHIFTING THAT
21	RESPONSIBILITY TO THE BOARD PROCESS WHERE WE WOULD
22	SIT AND BRING UP THOSE ISSUES THAT WE FOUND IN THE
23	REVIEW PROCESS, WE DO THAT ANYWAY UNDER THE CURRENT
24	SYSTEM.
25	SO I THINK THAT IN TERMS OF PUTTING A
	147

1	SUNSET CLAUSE ON EVERY PROVISION IN THIS BROAD
2	CONCEPT, I DON'T THINK IT'S THE RIGHT WAY TO GO. I
3	THINK THE RIGHT WAY TO GO IS AS THE CHAIRMAN HAS
4	OUTLINED, AND THAT IS TO MOVE FORWARD WITH A
5	CONCEPTUAL BIG PICTURE, LET OUR LEGAL PUT TOGETHER
6	THE REGULATIONS AND THE LANGUAGE BECAUSE THIS IS NOT
7	GOING TO BE DONE TODAY. ALL WE'RE VOTING ON TODAY
8	IS THE CONCEPTUAL NOTION OF WHERE WE WANT TO GO SO
9	THAT WE LET PEOPLE KNOW, NOT IN AN OFFENSIVE MANNER,
10	BUT AS AN OFFENSE TO SAY THIS IS WHAT WE HAVE TAKEN
11	SERIOUSLY. THIS IS WHERE WE INTEND TO MOVE.
12	THE DOOR IS NOT CLOSED YET BECAUSE IN
13	MARCH WE'RE GOING TO TAKE UP, AS YOU SAY, THE DEVIL
14	IN THE DETAILS. AND THEN AT THAT TIME YOU CAN
15	EXERCISE YOUR RIGHT TO SUE IF THAT'S YOUR
16	PREROGATIVE; BUT AT THE END OF THE DAY, I THINK WE
17	NEED TO MAKE SURE THAT WE HAVE AN AGREEMENT, A
18	CONSENSUS ON THE CONCEPTS, AND THEN LET TIME ELAPSE
19	A LITTLE BIT, NOT THAT LONG, TILL MARCH, AND FIGURE
20	OUT HOW TO BEST IMPLEMENT THOSE CONCEPTS THROUGH
21	REGULATIONS. I'M SURE YOUR INPUT WILL BE THERE AS
22	IT ALWAYS IS AND IS WELCOMED IN TERMS OF MAKING SURE
23	THAT THE DETAILS ARE REFLECTIVE OF WHAT YOUR
24	PRIORITIES ARE, NOT YOU ALONE, IN TERMS OF ALL OF
25	OUR PRIORITIES AS PATIENT ADVOCATES.

1	MR. SHESTACK: FIRST OF ALL, I DON'T HAVE
2	PRIORITIES SEPARATE FROM WHAT I PERCEIVE TO BE THE
3	PRIORITIES OF PEOPLE, THE PATIENTS.
4	MR. TORRES: THAT'S WHAT I JUST SAID.
5	MR. SHEEHY: AND, YOU KNOW, I WAS NOT
6	SAYING I WOULD NOT SUPPORT. BASED ON WHAT YOU'VE
7	SAID, I DON'T BELIEVE THAT I CAN SUPPORT IT, SO THIS
8	WON'T BE A CONSENSUS AGREEMENT. I THINK IT SHOULD
9	BE SUNSETTED. ANY GOOD EXPERIMENT REQUIRES
10	EVALUATION. AND THE PART THAT INVOLVES PATIENT
11	ADVOCATES IS GOING TO BE THE PART THAT ISN'T
12	SUNSETTED IS KIND OF MYSTERIOUS TO ME. I DON'T SEE
13	WHAT THE PROBLEM WITH THE PATIENT ADVOCATES AT THE
14	WORKING GROUP THAT'S DRIVING THIS. I WISH SOMEBODY
15	COULD SHOW ME THE PART OF THE IOM REPORT THAT REALLY
16	TALKS ABOUT THE ROLE OF THE PATIENT ADVOCATES IN THE
17	WORKING GROUP THAT IT'S SUCH A GREAT PROBLEM. AND
18	I'D LIKE TO BE ABLE TO GET SOME EVIDENCE BASIS FOR
19	MAKING THAT A PROBLEM.
20	THEY GENERICALLY SAID THAT PATIENT
21	ADVOCATES HAVE A CONFLICT OF INTEREST WITH THE
22	DISEASE THEY REPRESENT, BUT THE DEPARTMENT OF
23	DEFENSE DOESN'T FEEL THAT. THE FDA DOESN'T FEEL
24	THAT. SO I JUST DON'T GET THE BASIS FOR THEM MAKING
25	THAT ASSUMPTION. AND I DON'T THINK IT'S SO
	149

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1	UNREASONABLE TO SAY THAT IF WE'RE GOING TO
2	CHANGE I JUST DON'T KNOW WHY PROP 71 WHERE IT
3	APPLIES TO PATIENT ADVOCATES PARTICIPATION IN THE
4	WORKING GROUP SUDDENLY IS NO LONGER VALID. I'M JUST
5	DISTURBED THAT WE'RE GOING TO THROW THAT OUT THE
6	WINDOW.
7	WHAT WE'RE TALKING ABOUT IN TERMS OF
8	CONFLICT OF INTEREST IS VOLUNTARY. WHAT YOU'RE
9	TALKING ABOUT WITH PATIENT ADVOCATES IS ACTUALLY
10	REMOVING CERTAIN PARTICIPATION BY REGULATION AT THE
11	BOARD AND DOING IT ONCE AND MAKING IT LAST FOREVER.
12	AND SO YOU'RE TALKING ABOUT A ONE-YEAR VOLUNTARY
13	ABSTENTION BY CERTAIN MEMBERS OF THE BOARD THAT
14	WOULD BE REVISITED IN A YEAR. BUT WHERE THE PATIENT
15	ADVOCATES ARE CONCERNED, YOU'RE FUNDAMENTALLY
16	CHANGING THEIR ROLES ON THE WORKING GROUP AND YOU'RE
17	SAYING WE'RE GOING TO DO THIS FOREVER AND WE'RE
18	GOING TO PUT IT INTO REGULATION.
19	MR. TORRES: IT HASN'T HAPPENED YET
20	THOUGH.
21	MR. SHEEHY: I DON'T SEE THAT'S WHAT
22	YOU JUST SAID.
23	MR. TORRES: NO. I SAID THAT'S OBVIOUSLY
24	AN OPTION THAT'S ON THE TABLE, BUT IT HASN'T
25	HAPPENED BECAUSE, AS I SAID BEFORE, WE HAVEN'T SEEN
	150
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1	THE DETAILS, AND THE DETAILS MAY VERY WELL INCLUDE A
2	SUNSET ON THAT PROVISION.
3	MR. SHEEHY: YOU JUST SAID YOU DIDN'T
4	SUPPORT A SUNSET FOR THAT PROVISION.
5	MR. TORRES: I SAID WHAT I SAID.
6	CHAIRMAN THOMAS: HE IS WHO YOU THINK HE
7	IS, THE FAMOUS DENNIS GREEN QUOTE.
8	MR. ROTH: YOU STARTED THIS OUT BY SAYING
9	THERE'S SOMETHING TO DISLIKE FOR EVERYONE, AND I
10	THINK WE'RE GETTING PRETTY MUCH TO EVERYONE.
11	THE SECOND POINT THAT'S BEEN MADE
12	REPEATEDLY IS THIS IS THREE FOR THREE, GUYS. AND
13	IT'S IMPORTANT THAT WE DON'T JUST KEEP SAYING THEY
14	DON'T GET IT. WE KEPT ELEVATING AND I, FOR ONE,
15	DIDN'T THINK WE NEEDED THE IOM TO DO ANOTHER STUDY
16	BECAUSE WE HAD ALREADY HAD CRITIQUE THAT WE COULD
17	HAVE ACTED ON, BUT WE'VE GOT IT. IT IS A GOLD
18	STANDARD. AND, THEREFORE, WE HAVE TO TRY TO DO
19	SOMETHING HERE, OR WE'RE GOING TO LOSE MUCH MORE
20	THAN SOME OF THE THINGS WE'RE TALKING ABOUT. WE
21	LOSE OUR CREDIBILITY WITH THE TAXPAYERS AND THE
22	VOTERS. THERE WILL NOT BE MORE MONEY COMING TO THIS
23	INSTITUTE IF WE DON'T DO THAT.
24	THE BIG TRAGEDY WOULD BE WE REALLY
25	ELIMINATE OUR ABILITY FOR THIS TO GO FORWARD IF WE
	151

1	FIND A WAY TO DO THAT.
2	AND THE OTHER THING YOU SAID, J.T., IS
3	ABOUT COMPROMISE. YOU KNOW, ALL OF YOU, THAT I'M
4	ONE OF THE FEW REPUBLICANS ON THIS BOARD, AND I'M
5	LEARNING A LOT ABOUT COMPROMISE. I AM LEARNING AN
6	AWFUL LOT ABOUT COMPROMISE. IT'S NOT EASY. AND
7	IT'S SOMETHING
8	DR. PRICE: YOU'RE THE ONLY REPUBLICAN
9	LEFT IN THE COUNTRY.
10	MR. ROTH: I COULD BE. I'M TRYING, GUYS.
11	BUT HAVING SAID THAT, I WOULD REALLY LIKE US TO TAKE
12	A VOTE ON THIS WITH THE CAVEAT THAT THERE HAS TO BE
13	RULEMAKING, THERE HAS TO BE MORE DISCUSSION AROUND
14	EACH OF THESE ISSUES. BUT IN CONCEPT I THINK WHAT
15	J.T. AND ALL THE WORK THAT HAS BEEN PUT IN THIS WITH
16	STAFF INPUT AND OTHERS HAS BEEN QUITE COMPELLING,
17	AND I THINK WE CAN FIGURE OUT THE NUANCES AS WE GO
18	FORWARD.
19	BUT I WOULD MOVE THAT WE ACCEPT THIS IN
20	CONCEPT WITH THE DETAILS TO COME BACK AND BE
21	DISCUSSED AT THE FINAL DECISION-MAKING IN MARCH.
22	CHAIRMAN THOMAS: YES.
23	MS. SAMUELSON: I HAVEN'T HAD AN
24	OPPORTUNITY TO SPEAK.
25	CHAIRMAN THOMAS: THAT WAS SORT OF A
	152

1	GENERIC MOVE. WE'LL HOLD THAT IN ABEYANCE SO
2	EVERYBODY CAN SPEAK.
3	DR. PRIETO: I'M NOT SURE YOU'RE HEARING
4	THAT MUCH DIFFERENCE OF OPINION HERE AMONG AT LEAST
5	THOSE OF US IN THE ADVOCATE COMMUNITY, BUT WHAT
6	YOU'RE HEARING IS THAT THERE IS A LOT OF PASSION
7	ABOUT THIS CAUSE. AND WE ARE HERE, AS JON SHESTACK
8	SAID, BECAUSE WE WANT OUR VOICE TO BE HEARD. AND
9	THAT'S MORE IMPORTANT THAN A SPECIFIC VOTE OR VOTING
10	IN ONE PLACE VERSUS ANOTHER.
11	I'LL ADDRESS SOMETHING HE MENTIONED TO ME
12	THIS MORNING. I DON'T KNOW, JON, IF YOU WANTED TO
13	SAY THIS. BUT I WANTED TO CORRECT A PARTICULAR
14	ERROR MADE BY THE IOM IN THEIR REPORT, WHICH WAS THE
15	STATEMENT THAT THE ADVOCATES ARE PAID BY THE
16	ORGANIZATIONS THEY REPRESENT TO BE HERE.
17	MR. SHESTACK: WE DON'T REPRESENT THEM
18	ACTUALLY. THERE IS A FORMAL TIE BETWEEN US AND
19	ADVOCACY.
20	DR. PRIETO: THAT IS NOT ONLY NOT THE
21	CASE. MOST OF US, IN FACT, PERHAPS UNIQUELY, HAVE
22	TO GIVE UP SOMETHING, TAKE UNPAID DAYS, TAKE LEAVE,
23	SACRIFICE SOMETHING FROM OUR REGULAR JOBS, WHICH ALL
24	OF US HOLD, IN ORDER TO BE HERE. AND THE REASON
25	WE'RE HERE IS BECAUSE WE BELIEVE IN THE CAUSE.

1	I HAVE NO PROBLEM WITH THE IDEA OF, AS
2	J.T. PROPOSED, THAT THIS WOULD, WHETHER YOU CALL IT
3	SUNSET OR REEVALUATION, THAT WE WOULD LOOK AT THIS
4	AGAIN AFTER A YEAR AND SEE IF IT WORKS. I THINK
5	THAT'S JUST A REASONABLE THING WITH ANY CHANGE IN
6	POLICY.
7	AND I HAD A COUPLE OF SPECIFIC REALLY KIND
8	OF NUTS-AND-BOLTS QUESTIONS. ONE WAS AS WE MOVE
9	INTO THE CLINIC, THIS IS COMPLETELY CHANGING THE
10	SUBJECT, BUT AS WE MOVE INTO THE CLINIC AND WE
11	FORESEE THAT WE MAY HAVE MORE APPLICATIONS FROM
12	PURELY INDUSTRY, OUTSIDE NONREPRESENTED
13	ORGANIZATIONS, WOULD THE SAME VOTING RULES APPLY?
14	AND THE OTHER, I GUESS I WOULD LIKE TO
15	HEAR A LITTLE BIT MORE ABOUT THE ROLES OF THE CDAP
16	AND THE SCIENTIFIC ADVISORY COMMITTEE, WHETHER THOSE
17	WOULD OVERLAP OR MERGE OR HOW THAT WOULD BE
18	EXPANDED.
19	CHAIRMAN THOMAS: FIRST QUESTION, THE
20	ANSWER WOULD BE YES. SECOND QUESTION, DR. FEIGAL,
21	WOULD YOU LIKE TO TAKE THAT ONE?
22	DR. FEIGAL: YEAH. I MEAN WE STILL NEED
23	TO THINK THROUGH WHAT WE WANT WITH THE SCIENTIFIC
24	ADVISORY BOARD. AS YOU KNOW, THAT'S ALREADY WITHIN
25	THE AUTHORITY OF THE OFFICE OF THE PRESIDENT TO PUT
	154
	⊥ J⊤

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

1	TOGETHER, SO IT DOESN'T REALLY REQUIRE ANY KIND OF
2	LEGISLATIVE ACTION OR ANY BOARD ACTION. BUT WHAT IT
3	WOULD BE, WHAT WE'RE THINKING OF IT IS MORE BIG
4	PICTURE ISSUES ABOUT INPUTS INTO DIRECTIONS THAT WE
5	TAKE SCIENTIFICALLY. AND WE'RE THINKING IT COULD BE
6	POPULATED BY SCIENTISTS REPRESENTING A SPECTRUM OF
7	DIFFERENT AREAS WITH INDUSTRY REPRESENTATION. WE
8	COULD HAVE A VARIETY OF STAKEHOLDERS AS PART OF
9	THAT.
10	BUT I SEE THE CDAP AS SOMETHING VERY
11	DIFFERENT. THOSE ARE ALREADY FUNDED PROJECTS, AND
12	THOSE ARE ACTUALLY THOSE EXTERNAL EXPERTS, MANY
13	OF WHOM DO HAVE A LOT OF EXPERIENCE DEVELOPING
14	PRODUCTS, ARE REALLY TO HELP THAT TEAM. SO I WOULD
15	SAY IT'S MORE IN THE WEEDS WITH THAT PARTICULAR
16	GROUP.
17	SO I SEE THEM AS COMPLEMENTARY USE OF
18	EXTERNAL ADVISORS. IT'S POSSIBLE SOME OF THEM MIGHT
19	BE APPROPRIATE FOR THE LARGER PICTURE, BUT I SEE
20	THEM AS SEPARATE ENTITIES. DID THAT ANSWER YOUR
21	QUESTION?
22	DR. PRIETO: YES.
23	MS. SAMUELSON: I REALLY THINK THAT WE
24	DESERVE A DAY TO THINK ABOUT THIS. THERE'S SOME
25	ISSUES RAISED BY ELLEN THAT I HAD FORGOTTEN WERE IN

155

1	THE GROUP. AND THE SCIENTIFIC ADVISORY BOARD IS A
2	VERY IMPORTANT ISSUE. WE HAD A GRANTS WORKING GROUP
3	THAT WAS A LIMITED NUMBER, THAT WAS PREMIERE
4	SCIENTISTS, AND THEY CONTINUED TOGETHER ADVISING US,
5	AND WE BECAME A WORKING UNIT. AND THAT BENEFITED
6	ALL THE WAY TO THE ICOC DELIBERATIONS AS WELL. THAT
7	DISAPPEARED INTO THIS MUCH LARGER GROUP OF ADVISORS,
8	AND I DON'T THINK IT'S AS EFFECTIVE. AND I THINK IT
9	IS EFFECTIVELY THE SCIENTIFIC ADVISORY BOARD THAT
10	THE IOM IS TALKING ABOUT.
11	WE HAVEN'T EVEN TALKED ABOUT THAT. IT'S
12	OBVIOUSLY VERY IMPORTANT. SO I AGREE THAT WE SHOULD
13	BE GETTING BACK TO THE IOM QUICKLY, BUT I THINK WE
14	NEED TO BE SURE THAT WE'RE RESPONDING ON EVERYTHING
15	AND THAT WE DON'T WANT TO BE SAYING THAT JUST A
16	SKELETAL ASSESSMENT OF OUR VIEWS PREDETERMINE HOW WE
17	FEEL ABOUT HOW WE'RE VOTING.
18	THEN I HAVE A FEW POINTS. ALL OF THIS HAS
19	BEEN TOUCHED ON BY SOMEBODY, BUT THESE ARE THINGS I
20	THINK ARE IMPORTANT, SO I'LL TRY TO BE QUICK.
21	FIRST OF ALL, JEFF TELLS THE TRUTH AS HE
22	ALWAYS DOES. IN THAT DEFENSE FUNDING, THEY HAVE
23	FUNDED PARKINSON'S RESEARCH, AND IT HAS BEEN SOME OF
24	THE BEST SPENT MONEY WITHOUT QUESTION IN THE
25	PARKINSON'S PORTFOLIO OVER THE LAST COUPLE DECADES

1	THAT I'VE BEEN LOOKING. AND THERE'S A LOT ABOUT THE
2	EXISTING PROP 71 LAW ABOUT THE GRANTS PROCESS THAT
3	IS GREAT. AND I JUST SWORE TO UPHOLD AND DEFEND THE
4	CONSTITUTION OF THE STATE OF CALIFORNIA AGAINST ALL
5	ENEMIES DOMESTIC AND FOREIGN. SO I'M FEELING A
6	SPECIAL OBLIGATION THERE.
7	HAVING SAID THAT, I AM INTRIGUED WITH
8	J.T.'S PROPOSAL BECAUSE WE DON'T HAVE WE HAVE A
9	TWO-TIERED SYSTEM, RIGHT. I HATE IT WHEN THE
10	INSTITUTIONAL MEMBERS LEAVE THE ROOM JUST WHEN WE'RE
11	GETTING INTO SOMETHING REALLY GNARLY THAT CONCERNS
12	THE PORTFOLIO THAT THEY'RE EXPERT IN. AND ACTUALLY
13	REVIEWING THE IOM REPORT REMINDED ME OF SOMETHING
14	THAT I DON'T THINK WE EVER REALLY TALKED ABOUT,
15	WHICH IS NOT ONLY IS THERE THAT EXPERTISE AMONG THIS
16	GROUP OF SCIENTISTS, BUT THE ONES WHO ARE HEADING
17	UNIVERSITY PROGRAMS, AND SOME ARE SOMETIMES THE
18	CHANCELLOR, HAVE UNIQUE POWER TO HELP US ACCELERATE
19	DELIVERY OF CURES.
20	THAT'S WHAT WE'RE SUPPOSED TO BE DOING. I
21	BELIEVE WE'RE NOT DOING IT ENOUGH. I'M VERY PROUD
22	OF EVERYTHING WE'VE DONE. THE PRESENTATION BY ELLEN
23	AND DR. OLSON WERE SPLENDID IN THAT REGARD, BUT WE
24	COULD BE DOING MORE, I'M CERTAIN OF IT. AND AT A
25	RECENT MEETING WE WERE TOLD THAT WE HAD, I THINK,
	157

1	700 MILLION NET LEFT TO SPEND. THERE'S OTHER
2	NUMBERS THAT ARE A LITTLE HIGHER, BUT I THINK WE
3	HAVE TO SPEND EVERY NICKEL OF THAT MORE CAREFULLY
4	THAN WE HAVE THE PREVIOUS. IT DOESN'T MEAN THAT IT
5	WAS CARELESS. IT WAS BY NO MEANS. BUT I THINK WE
6	HAVE TO GET REAL STINTING ABOUT HOW THAT MONEY IS
7	SPENT AND HAVE A TRANSLATIONAL PORTFOLIO THAT IS
8	UNIQUELY, ENTIRELY TRANSLATIONAL, SPLENDIDLY
9	TRANSLATIONAL WITH WHATEVER BASIC RESEARCH NEEDS TO
10	SUPPORT IT.
11	HOW DO WE DO THAT? THE PHRASE I LIKE THE
12	MOST, J.T., WAS TRIAL PERIOD. I THINK THERE ARE A
13	FEW THINGS THAT WE NEED TO DO, AND MAYBE IT'S IN THE
14	SAME TRIAL PERIOD WE WOULD BE CONSIDERING HOW WELL
15	OUR REFORMS OR CHANGES IN OUR STRUCTURE, HOW WELL
16	THEY'RE GOING.
17	THE FIRST IS TO CONSIDER TRANSLATION. AND
18	TO DO THAT EFFECTIVELY, I THINK WE HAVE TO STOP
19	ISSUING GRANTS AND MAKING FUNDING DECISIONS AND DO
20	AN ASSESSMENT. WE HAVE NEVER DONE THAT. I KNOW
21	I'VE ASKED A FEW TIMES AND OTHER PEOPLE HAVE ASKED
22	STAFF WHAT THE RESULTS OF OUR SPENDING THUS FAR HAVE
23	BEEN. AND WE DON'T REALLY GET ENOUGH INFORMATION
24	FOR US AS A FIDUCIARY BOARD THAT IS SWORN TO UPHOLD
25	AND DEFEND BLAH, BLAH. THAT'S A WEIGHTY

1	RESPONSIBILITY, AND WE REALLY MUST UNDERSTAND OUR
2	PORTFOLIO. AND I KNOW I DON'T.
3	I KNOW WE HAVEN'T FUNDED ANY AUTISM. WHEN
4	JON SHESTACK, THE FATHER OF A 20-YEAR-OLD MAN WITH
5	AUTISM, TOLD US AT A RECENT MEETING THAT NOT ONE
6	NICKEL HAD BEEN SPENT ON AUTISM, IT JUST SHOCKED ME.
7	AND THERE ARE PROBABLY OTHER SITUATIONS LIKE THAT,
8	AND WE HAVE TO AT LEAST ANSWER THE QUESTION WHY. IT
9	DOESN'T MEAN NECESSARILY THAT WE WOULD CHANGE OUR
10	DECISIONS, BUT WE HAVE TO HAVE AN ANSWER.
11	AND YOU TAKE THAT ALL THE WAY THROUGH
12	OTHER FUNDED PROGRAMS, AND WE HAVE TO KNOW WHAT
13	WE'RE DOING SO THAT WE WILL KNOW HOW TO SPEND THE
14	NEXT NICKEL. I THINK WE HAVE TO DO THAT, AND THAT
15	WOULD BE A DIFFICULT TASK, AND I THINK WE HAVE TO
16	SUSPEND SOME OTHER THINGS.
17	AND CERTAINLY AT THE RATE IF WE'RE
18	SPENDING AT A RATE WHERE WE NOW HAVE ONLY \$700
19	MILLION LEFT, WE'RE GOING TO BE DONE WITH BUSINESS
20	SOONER THAN EIGHT YEARS FROM NOW. SO THAT WOULDN'T
21	BE BY ANY MEANS SLOWING US DOWN. I THINK MARCY WAS
22	THE ONE WHO SAID WE CAN'T HINDER OUR MOMENTUM. I
23	AGREE COMPLETELY, BUT THAT DOESN'T MEAN NECESSARILY
24	THAT WE KEEP SPENDING THE WAY WE HAVE.
25	I THINK WE NEED TO INCREASE TRANSPARENCY.
	159

1	I THINK ONE OF THE PREMIERE REASONS THAT WE ARE
2	CONSTANTLY ACCUSED OF CONFLICT OF INTEREST, AND I
3	TOO DO NOT SEE IT, IS THAT OUR PROCESS IS VERY
4	SECRET. AND I WON'T TAKE THE TIME NOW TO TALK ABOUT
5	WHY, BUT ISSUES OF CONFLICT OF INTEREST KIND OF GET
6	INTERTWINED WITH WHO'S ON WHAT SIDE OF THAT AND
7	WHO'S LEFT IN THE ROOM AT WHAT TIME, AND IT BECOMES
8	VERY ARCANE. AND IT IS JUST BEWILDERING. I KNOW
9	THAT THERE WERE A LOT OF PEOPLE WHO USED TO COME UP
10	TO ME AT THE TIME OF THE CAMPAIGN FOR PASSAGE OF
11	PROP 71 AND IN THE FIRST YEAR OR TWO AFTER, AND YOU
12	COULD TELL THEY FELT THEY OWNED THIS LAW. NOW THEY
13	SAY, OH, YEAH. NOW, I VOTED FOR THAT. HOW IS IT?
14	THEY HAVE NOT A CLUE.
15	I THINK THAT LACK OF UNDERSTANDING OF WHAT
16	WE'RE DOING, WHICH GOES ALL THE WAY TO US BECAUSE OF
17	THE LEAVING OF THE ROOM BUSINESS, INFECTS WHAT WE'RE
18	DOING. I THINK WE HAVE TO LOOK AT THAT.
19	I THOUGHT THERE WAS ONE MORE. I THINK I
20	AM CURRENTLY ENTRANCED WITH A CONCEPT WHICH COMES
21	FROM THE IOM REPORT. THEY DIDN'T MENTION IT. BUT
22	THE THOUGHT OF LOSING THE INSTITUTIONAL MEMBERS
23	REALLY MADE ME START THINKING ABOUT THE ROLES THAT
24	THEY PLAY. AND I STARTED IMAGINING A REAL
25	COLLABORATION BETWEEN THOSE OF YOU IN THOSE ROLES

1	AND THE CIRM AND WITH OUR COLLABORATORS AROUND THE
2	COUNTRY AND THEN OUR COLLABORATORS INTERNATIONALLY
3	AND YOURS.
4	TO ELIMINATE REDUNDANCY, THERE HAS TO BE
5	SOME, THERE MIGHT BE A LOT I TAKE IT WE DON'T
6	KNOW AND TO INCREASE COLLABORATIONS WHERE THEY
7	COULD BE AND TO MAKE IT TRULY A GLOBAL EFFORT. THE
8	IOM HASN'T ASKED US TO BE THE GLOBAL LEADER. THEY
9	CRITICIZED US PRIMARILY, IT SEEMS, AND I CAN
10	UNDERSTAND AND APPRECIATE IT, BUT THE EAP, THE
11	EXTERNAL ADVISORY PANEL, BEGGED US TO BE THE GLOBAL
12	LEADER. I THINK WE'RE INCHING CLOSER TO IT, BUT WE
13	REALLY SHOULD TAKE THAT ON. AND IMAGINE DOING THAT
14	WITH THE APPROVAL AND SOPHISTICATION OF THE
15	CHANCELLORS OF FIVE UC UNIVERSITIES AND STANFORD AND
16	THE SALK AND ETC. THAT TRULY COULD BE A HISTORIC
17	ENTERPRISE. AND I THINK THAT'S WHAT WE SHOULD BE
18	REACHING FOR. THANK YOU.
19	CHAIRMAN THOMAS: THANK YOU, JOAN. BEFORE
20	I CALL ON PEOPLE, I HAVE A COUPLE RESPONSES TO A
21	NUMBER OF YOUR POINTS I JUST WANT TO PUT OUT THERE.
22	NO. 1, I DON'T THINK THIS IS THE
23	APPROPRIATE FORUM TO BE DISCUSSING THE MAKEUP OF THE
24	SCIENTISTS IN THE GRANTS WORKING GROUP. THAT COULD
25	BE THE GRIST FOR ANOTHER MILL, BUT I DON'T THINK

1	THIS IS THE TIME WE REALLY WANT TO GET INTO THAT,
2	THOUGH THEY'RE CERTAINLY VERY INTERESTING POINTS.
3	THE SCIENTIFIC ADVISORY BOARD YOU'RE
4	SAYING IS SOMETHING WE NEED TO THINK THROUGH MORE
5	CAREFULLY. STAFF IS, I ASSURE YOU, THINKING ABOUT
6	THAT VERY CAREFULLY. AND THE ONLY THING THAT I
7	THINK WE SHOULD BE IN FACT, THEY ALREADY HAVE THE
8	ABILITY FULLY WITHIN THEIR PROVINCE TO FORM A
9	SCIENTIFIC ADVISORY BOARD. THE ONLY THING I WANT TO
10	DO WITH RESPECT TO THAT ELEMENT IN TODAY'S
11	DISCUSSION IS JUST TO ACKNOWLEDGE THAT THEY'RE DOING
12	THAT. I DON'T THINK WE NEED TO GET INTO THE
13	DETAILS.
14	ON THE NOTION OF SPREADING DOLLARS AROUND
15	MORE CAREFULLY AND STOPPING GRANTS AND EVALUATING
16	WHERE WE ARE AND ALL THAT STUFF, THAT'S REALLY ALL
17	STRATEGIC PLANNING TYPE OF STUFF, WHICH IS CERTAINLY
18	SOMETHING BEST TAKEN UP BY THE BOARD. AGAIN, THAT'S
19	NOT REALLY I THINK TODAY'S DISCUSSION IS NOT THE
20	BEST SPOT FOR THAT, THOUGH THOSE ARE VERY IMPORTANT
21	ISSUES, NO QUESTION.
22	I'LL JUST CORRECT FOR THE RECORD THAT YOU
23	MENTIONED FUNDING WON'T LAST EIGHT YEARS. I THINK
24	WE ANTICIPATE AT THE PACE WE'RE GOING, ELLEN, 2017,
25	CORRECT, TO MAKE THE LAST NEW AWARDS, WHICH WILL BE
	162

1	SPREAD OUT OVER A PERIOD OF YEARS.
2	MS. SAMUELSON: BUT WE'RE SPENDING MORE
3	MONEY THAN JUST THE NEW AWARDS.
4	CHAIRMAN THOMAS: NO. NO. I'M JUST
5	SAYING THAT ON OUR CURRENT PACE, MAKING OUR LAST NEW
6	AWARDS WOULD BE IN 2017 IF WE DON'T FIGURE OUT A WAY
7	TO GET SOME MORE FUNDING, WHICH IS THE WHOLE
8	SUSTAINABILITY ISSUE.
9	LASTLY, WHEN YOU SAY YOU'RE CONCERNED THE
10	IOM DOESN'T RECOGNIZE US AS A GLOBAL LEADER, I THINK
11	IF YOU READ THROUGH THERE AND PARSE OUT ALL OF THE
12	POSITIVE STATEMENTS, WHICH ARE A GREAT MANY, YOU
13	WILL ACTUALLY SEE THAT THEY DO BELIEVE WE ARE A
14	WORLD LEADER AND ARE DOING A GREAT JOB FOR THE
15	REASONS I ARTICULATED EARLY ON. AND WE, OF COURSE,
16	ASPIRE TO BE THAT AND PLAN TO CONTINUE BEING THAT.
17	DR. STEWARD: I KNOW THERE'S GOING TO BE A
18	LOT OF OTHER DISCUSSION, BUT I WONDER IF WE COULD
19	TAKE THIS OPPORTUNITY TO HEAR FROM THE MEMBERS OF
20	THE PUBLIC AND THEN COME BACK TO THE BOARD. WE'VE
21	GOT A LOT OF PEOPLE SITTING OUT THERE WHO'VE COME A
22	LONG WAY, AND I JUST THOUGHT IT MIGHT BE NICE TO DO
23	THAT NOW BEFORE WE'RE DEAD TIRED AT THE END OF THE
24	DAY.
25	CHAIRMAN THOMAS: SURE. WE HAVE RUTH
	163

1	HOLTON-HODSON FROM THE STATE CONTROLLER'S OFFICE I
2	KNOW HAS SOME PREPARED REMARKS. SO WHY DON'T WE
3	START WITH RUTH, THEN WE'LL GO TO BOB, AND THEN
4	WE'LL GO TO DON AND OTHER MEMBERS OF THE PATIENT
5	ADVOCATE PUBLIC. THANK YOU.
6	MS. HOLTON-HODSON: THANK YOU, J.T. GOOD
7	AFTERNOON. I'M RUTH HOLTON-HODSON, THE DEPUTY
8	CONTROLLER FOR HEALTH AND CONSUMER POLICY. ON
9	BEHALF OF JOHN CHIANG, WHO CHAIRS THE CITIZENS
10	FINANCIAL OVERSIGHT AND ACCOUNTABILITY COMMISSION, I
11	WANTED TO STATE HIS SUPPORT FOR SEVERAL OF THE IOM'S
12	GOVERNANCE REFORMS. BUT, FIRST, I WANTED TO EXTEND
13	THE CONTROLLER'S SUPPORT FOR THE PROPOSAL THAT THE
14	CHAIR HAS LAID OUT. HE HAS BEEN, I THINK, VERY
15	THOUGHTFUL, AND WE THINK IT'S A VERY POSITIVE
16	APPROACH THAT ADDRESSES KEY ISSUES RAISED BY THE IOM
17	AND WOULD SEND AN IMPORTANT MESSAGE, AS MANY OF YOU
18	HAVE ALREADY STATED, TO THE PUBLIC THAT THE ICOC HAS
19	HEARD THE CONCERNS AND, MOST IMPORTANTLY, TAKEN THEM
20	SERIOUSLY.
21	HOWEVER, THERE IS ONE ISSUE THAT THE
22	CONTROLLER WANTED ME TO RAISE, AND YOU WILL NOT BE
23	SURPRISED BY IT. THAT IS THE ONE WHICH YOU HAVE
24	HEARD US RAISE BEFORE. AND THAT IS THE SEPARATION
25	OF OPERATIONS FROM OVERSIGHT.

1	WHILE THE CHAIR'S PROPOSAL CLARIFIES THE
2	DUTIES OF THE PRESIDENT AND CHAIR SO THEY DO NOT
3	OVERLAP, WHICH OBVIOUSLY WE THINK IS A GOOD THING
4	AND WE CERTAINLY UNDERSTAND THAT AND APPRECIATE THAT
5	CIRM HAS BEEN OPERATING MUCH BETTER WITH THOSE
6	DUTIES MORE CLEARLY SPELLED OUT, THERE IS STILL THE
7	CENTRAL PROBLEM OF THE CHAIR BEING ENGAGED IN THE
8	DAY-TO-DAY OPERATIONS. AND THIS IS COMPLETELY
9	CONTRARY TO GOOD GOVERNANCE BEST PRACTICES.
10	THE CONTROLLER RECOGNIZES THAT UNDER PROP
11	71 THAT THE CHAIR AND THE VICE CHAIR HAVE SPECIFIED
12	STATUTORY DUTIES; HOWEVER, AS THE ICOC COUNSEL HAS
13	OPINED IN THE PAST, THE BOARD HAS SOME DISCRETION AS
14	TO HOW THOSE DUTIES ARE CARRIED OUT AND COULD
15	REQUEST THE CHAIR AND VICE CHAIR DELEGATE THESE
16	DUTIES TO STAFF TO THE EXTENT PERMITTED BY LAW.
17	THE IOM REPORT IS, AS MANY OF YOU POINTED
18	OUT, THE THIRD REVIEW OF THE AGENCY THAT HAS RAISED
19	THIS ISSUE OF PROBLEMATIC GOVERNANCE STRUCTURE. IT
20	IS THE CONTROLLER'S HOPE THAT THIS TIME THE ICOC
21	WILL ACT UPON THOSE RECOMMENDATIONS AND SEPARATE
22	OPERATIONS FROM OVERSIGHT.
23	SPECIFICALLY AS TO THE CONFLICT OF
24	INTEREST ISSUES, THE CONTROLLER RECOGNIZES THAT THE
25	BOARD HAS STRICT CONFLICT OF INTEREST AND RECUSAL
	165
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1	POLICIES AND THAT WE HAVEN'T ACTUALLY SEEN ANY REAL
2	CONFLICT OF INTEREST. BUT, AGAIN, ECHOING MANY OF
3	YOUR COMMENTS ABOUT THE IMPORTANCE OF THE PERCEPTION
4	AND DEALING WITH THAT ISSUE, AS THE IOM REPORT
5	EMPHASIZES, THE CURRENT STRUCTURE CREATES A STRONG
6	PERCEPTION OF A CONFLICT OF INTEREST WHICH IS
7	DAMAGING AND, I WOULD SAY, VERY DAMAGING TO THE
8	PUBLIC'S TRUST IN THE ICOC GRANT DECISIONS.
9	REQUIRING THE INSTITUTIONS TO ABSTAIN FROM
10	VOTING ON GRANTS, AS THE CHAIR PROPOSES, WILL GO A
11	LONG WAY IN ADDRESSING THESE PERCEIVED CONFLICTS OF
12	INTEREST.
13	ON SOME OF THE OTHER IOM RECOMMENDATIONS,
14	THE CONTROLLER DOES NOT AGREE WITH THE IOM'S
15	RECOMMENDATIONS TO REVISE ITS CONFLICT OF INTEREST
16	POLICIES TO CONSIDER AN INDIVIDUAL'S INTEREST IN A
17	PARTICULAR DISEASE AS A CONFLICT. HE BELIEVES THAT
18	THE PATIENT ADVOCATES PLAY A CRITICAL ROLE IN
19	ENSURING THAT THE VOICES OF THOSE MOST AFFECTED BY
20	THE DISEASES FOR WHICH STEM CELLS ARE SO PROMISING
21	ARE HEARD.
22	FINALLY, A WORD ON THE IP REGULATIONS.
23	YOU WILL NOT BE SURPRISED THAT WE WOULD STRONGLY
24	CONCUR WITH THE CHAIR THAT PROP 71'S PROMISE TO THE
25	TAXPAYERS REGARDING ACCESS PRICING AND REVENUE

1	SHARING SHOULD BE MAINTAINED. THANK YOU.
2	MR. KLEIN: FOR THOSE THAT ARE NOT
3	PRESENT, MY NAME IS BOB KLEIN, CHAIR EMERITUS OF
4	THIS DISTINGUISHED ORGANIZATION. AND I CERTAINLY
5	WOULD LIKE TO ADD MY LOUD APPLAUSE TO THE SCIENTIFIC
6	PRESENTATION MADE TODAY, EXTRAORDINARY EFFORTS BY
7	THE SCIENTIFIC STAFF AND BY THIS BOARD, AND THE
8	THOUSANDS OF HOURS OF DEDICATION THAT HAVE MADE SUCH
9	INCREDIBLE PROGRESS IN MAKING THIS ORGANIZATION THE
10	CENTER HUB OF A GLOBAL COLLABORATION OF MORE THAN 16
11	COUNTRIES, SEVERAL STATES, AND ALL OF THE LEADING
12	INSTITUTIONS PUBLIC AND PRIVATE IN THE STATE OF
13	CALIFORNIA.
14	IT IS IMPORTANT TO STATE THAT I BELIEVE
14	
15	THIS IS A CONSTRUCTIVE PROPOSAL THAT I AM SUPPORTIVE
	THIS IS A CONSTRUCTIVE PROPOSAL THAT I AM SUPPORTIVE OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE
15	
15 16	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE
15 16 17	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE ADVISABLE. THIS IS A SCIENTIFIC ORGANIZATION. WE
15 16 17 18	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE ADVISABLE. THIS IS A SCIENTIFIC ORGANIZATION. WE CAN THINK OF THIS AS A CLINICAL TRIAL. WE CAN SEE
15 16 17 18 19	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE ADVISABLE. THIS IS A SCIENTIFIC ORGANIZATION. WE CAN THINK OF THIS AS A CLINICAL TRIAL. WE CAN SEE HOW THE PATIENT DOES AND ANALYZE IT AT THE END OF
15 16 17 18 19 20	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE ADVISABLE. THIS IS A SCIENTIFIC ORGANIZATION. WE CAN THINK OF THIS AS A CLINICAL TRIAL. WE CAN SEE HOW THE PATIENT DOES AND ANALYZE IT AT THE END OF THAT YEAR, LEARNING HOW TO REFINE IT.
15 16 17 18 19 20 21	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE ADVISABLE. THIS IS A SCIENTIFIC ORGANIZATION. WE CAN THINK OF THIS AS A CLINICAL TRIAL. WE CAN SEE HOW THE PATIENT DOES AND ANALYZE IT AT THE END OF THAT YEAR, LEARNING HOW TO REFINE IT. WE SHOULD, THOUGH, LOOK AT THE HISTORY AS
15 16 17 18 19 20 21 22	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE ADVISABLE. THIS IS A SCIENTIFIC ORGANIZATION. WE CAN THINK OF THIS AS A CLINICAL TRIAL. WE CAN SEE HOW THE PATIENT DOES AND ANALYZE IT AT THE END OF THAT YEAR, LEARNING HOW TO REFINE IT. WE SHOULD, THOUGH, LOOK AT THE HISTORY AS WELL AND UNDERSTAND THAT THIS WHOLE CONFLICTS
15 16 17 18 19 20 21 22 23	OF. I DO THINK THAT A ONE-YEAR SUNSET WOULD BE ADVISABLE. THIS IS A SCIENTIFIC ORGANIZATION. WE CAN THINK OF THIS AS A CLINICAL TRIAL. WE CAN SEE HOW THE PATIENT DOES AND ANALYZE IT AT THE END OF THAT YEAR, LEARNING HOW TO REFINE IT. WE SHOULD, THOUGH, LOOK AT THE HISTORY AS WELL AND UNDERSTAND THAT THIS WHOLE CONFLICTS STRUCTURE HAS BEEN BUILT ON THE NATIONAL ACADEMY OF

1	PRESIDENT, BRUCE ALBERTS, IF HE WOULD CALL A SPECIAL
2	CONFERENCE OF THE LEADING PEOPLE IN THE COUNTRY ON
3	STEM CELL RESEARCH, ON ETHICS, ON CONFLICTS, WHICH
4	THEY DID.
5	THE GENERAL COUNSEL FOR THE NATIONAL
6	ACADEMY PRESENTED A SPECIAL PAPER TO THE GENERAL
7	ASSEMBLY AT THAT, SOME 200 PEOPLE REPRESENTING THE
8	BEST AND BRIGHTEST IN THE COUNTRY, AND THE AGENCY
9	TOOK GUIDANCE FOR WHAT WAS CONSIDERED ACTUALLY
10	UNACHIEVABLE, WHICH WAS TO HAVE ALL OF OUR PEER
11	REVIEWERS COME FROM OUT OF THE STATE OF CALIFORNIA,
12	WHICH HAD NEVER BEEN DONE BEFORE. IT WAS A HALLMARK
13	OF A NEW STANDARD IN AVOIDING CONFLICTS.
14	SO IT IS PARTICULARLY IMPORTANT TO
15	RECOGNIZE THAT SUBSTANTIALLY OVER 90 PERCENT OF ALL
16	THE BOARD'S DECISIONS HAVE, IN FACT, FOLLOWED THOSE
17	OUT-OF-STATE SCIENTISTS, WHICH THE BOARD MEMBERS
18	HAVE COMMENTED ON TODAY ARE THE ONLY ONES WHO CAN
19	SCORE IN THE SCIENTIFIC PEER REVIEW SESSION.
20	IT IS SPECIFICALLY ALSO IMPORTANT THAT
21	THOSE 95 OR SO PERCENT DECISIONS THAT ARE IN
22	CONFORMANCE WITH PEER REVIEW REPRESENT OVER 92
23	PERCENT OF ALL THE FUNDS OF THIS AGENCY.
24	IT IS IMPORTANT TO RECOGNIZE THAT WHEN
25	CRITICS ASKED THE STATE LEGISLATURE TO AUDIT THIS
	168
	108

AGENCY, AN INDEPENDENT AUDIT OF THE STATE OFFICE OF
AUDITORS, THAT THAT AUDIT SHOWED THAT NOT ONLY WERE
THERE NO CONFLICTS THAT THEY COULD IDENTIFY, BUT OUR
CONFLICTS STANDARDS WERE BETTER DEVELOPED AND, IN
FACT, WENT FURTHER THAN THE NATIONAL INSTITUTE OF
HEALTH IN MANY AREAS.
IT IS IMPORTANT TO NOTE THAT WHEN THE
CRITICS THEN AGAIN CAME BACK TWO YEARS LATER AND
ASKED THE CONTROLLER'S OFFICE TO CONDUCT AN AUDIT,
THEIR INDEPENDENT AUDIT CONCURRED WITH THE
LEGISLATURE'S AUDIT, FOUND NO CONFLICTS AND FOUND
OUR STANDARDS TO BE IN EXCESS OF THOSE THAT MANY OF
THE PANELS OF THE NIH USE. IN FACT, NONE OF THE
STATES OR ANY OTHER GOVERNMENTAL BODY USES A GROUP
OF PEER REVIEWERS WHO CANNOT, ANY ONE OF THEM,
QUALIFY FOR A GRANT OR A LOAN.
SO IN THAT CONTEXT, IT IS IMPORTANT THAT
HOWEVER WE EVOLVE, THERE IS AN APPEARANCE ISSUE
THAT'S IMPORTANT TO PUBLIC TRUST. AND I THINK THIS
IS A VERY CONSTRUCTIVE PROPOSAL TO ADDRESS THOSE
ISSUES. LIKE THE BIOLOGY WE LOOK AT, WE NEED TO BE
ORGANIC AND RESPONSIVE, ENTREPRENEURIAL, AND, AS
YOUR CHAIRMAN SAID IN QUOTING WINSTON CHURCHILL,
CHANGE IS REALLY ESSENTIALLY A PART OF OUR LIFE IF
WE ARE GOING TO LIVE IN RESPONSE TO THE CHANGING
169

1	CHALLENGES WE FACE, PARTICULARLY IN A SOCIETY LIKE
2	THE ONE WE HAVE IN THIS COUNTRY.
3	I WOULD LIKE TO COMMENT THAT I THINK IT IS
4	VERY IMPORTANT TO MAINTAIN, WHEN YOU SET THE
5	CRITERIA, A SUFFICIENTLY BROAD ROOM FOR THE BOARD IN
6	PROGRAMMATIC REVIEW TO RESPOND TO ISSUES LIKE
7	SCIENCE POLICY ISSUES BECAUSE YOU WILL REMEMBER
8	THERE WAS A CANCER STEM CELL DISEASE TEAM WHERE THE
9	PRESIDENT, ALAN TROUNSON, CAME TO THE BOARD AND SAID
10	IN PEER REVIEW WE HAD THE PROBLEM THAT WE ONLY HAD A
11	DISTRIBUTION OF REVIEWERS WHO ESSENTIALLY DIDN'T
12	BELIEVE CANCER STEM CELLS EXISTED. AND IT WAS
13	EXPLAINED TO THEM IN PEER REVIEW THAT THE BOARD HAD
14	MADE A SCIENTIFIC JUDGMENT AS A MATTER OF POLICY
15	THAT THE BOARD WOULD LOOK FOR EMPIRICAL EVIDENCE ON
16	CANCER STEM CELL, FUND THIS RESEARCH, SEE IF IT
17	BENEFITED THE PATIENT, AND REACH AN EMPIRICAL AND
18	SCIENTIFIC CONCLUSION RATHER THAN A SCIENTIFIC
19	IDEOLOGY A PRIORI.
20	IT'S IMPORTANT, AS DR. KEITH YAMAMOTO SAID
21	IN HIS 2007 REVIEW OF THE NIH PEER REVIEW PROCESS,
22	THAT PARTICULAR ATTENTION BE PAID TO THE
23	RISK-BENEFIT RATIO. HE SAID THAT IN PEER REVIEW THE
24	HISTORY OF SCIENCE IS IT IS TOO RESTRICTIVE OR
25	CONSERVATIVE IN LOOKING AT THE RISK-BENEFIT RATIO
	170
	170

AND THERE NEEDS TO BE MORE BETS PLACED ON GOAL THAT
AMOUNT TO REACHING INTO NEW AREAS. IT IS A VERY
IMPORTANT AREA THAT NEEDS TO BE RETAINED IN THE
DEFINITION OF CRITERIA.
AND CERTAINLY WITHIN THE APPEALS CONTEXT,
THE SCIENTIFIC STAFF BRINGS AT TIMES TO THE BOARD
INDICATIONS OF TECHNICAL MISTAKES, THAT PEER REVIEW
IS GIVEN INFORMATION THAT HAS MISLED THEM IN THEIR
SCORING AS OCCURRED IN DISEASE TEAM I AS WAS
REFERENCED BY JEFF SHEEHY. KAREN ABOODY'S GRANT IN
DISEASE TEAM I, THE SCORING WAS BELOW THE FUNDING
LINE. DR. TROUNSON AND THE SCIENTIFIC STAFF
PRESENTED TO THE BOARD THAT A SPECIALIST HAD
INDICATED TO THE PEER REVIEW THAT THE CHEMO AGENT
WAS NOT EFFECTIVE, WHICH RESULTED IN A DOWNGRADING.
THAT WAS FOUND TO BE INCORRECT, AND THE STAFF
RECOMMENDED APPROVING THAT GRANT, WHICH DID OCCUR.
SO THE ABILITY IN THE CRITERIA TO DEAL
WITH SCIENTIFIC MISTAKES AS WELL AS NEW INFORMATION,
I THINK, WILL BE VERY IMPORTANT.
I WOULD INDICATE THAT IN GRANTS WORKING
GROUP, ADDRESSING, JEFF, THE POINT THAT YOU RAISED,
UNDER THE INITIATIVE IT WILL BE IMPORTANT THAT THE
PATIENT ADVOCATES DO, WHILE NOT UNDER THIS PROPOSAL,
ADDRESS INDIVIDUAL GRANTS BECAUSE IT WILL BE DOING
171

1	FULL PROGRAMMATIC REVIEW IN FRONT OF THE BOARD, THEY
2	WILL NEED TO VOTE CONCURRENCE WITH THE PORTFOLIO OF
3	RECOMMENDATIONS FROM THE SCIENTISTS. AND THEY WILL
4	NEED TO VOTE CONCURRENCE WITH THE MINORITY REPORTS
5	IN ORDER FOR SCIENTIST MINORITY REPORTS, TO THE
6	EXTENT THERE ARE ANY, TO GET TO THE BOARD JUST AS A
7	MATTER OF TECHNICAL PROCESS.
8	SO THEY WILL HAVE A VOTING ROLE, BUT IT IS
9	A SUBSTANTIAL BENEFIT, I THINK, TO HAVE PROGRAMMATIC
10	REVIEW IN FRONT OF THE FULL BOARD WITH FULL
11	TRANSPARENCY.
12	I WOULD JUST LIKE TO SAY, IN ENDING, THAT
13	IT'S ALWAYS A PRIVILEGE TO ADDRESS THIS GROUP AS IT
14	WAS A PRIVILEGE TO SERVE WITH THIS GROUP. THE
15	EXTRAORDINARY EXPERIENCE AND DEDICATION OF LIVES
16	REPRESENTED ON THIS BOARD BOTH THROUGH PATIENT
17	ADVOCATES, THROUGH MEMBERS OF THE BIOTECH COMMUNITY
18	WHO HAVE DEDICATED THEIR LIVES TO TRYING TO MOVE
19	SCIENCE TO THE CLINIC, TO THE DEANS OF THE MEDICAL
20	SCHOOLS, ALL THE WAY TO THE PRESIDENTS OF THE
21	INDIVIDUAL INSTITUTES, THE SCOPE OF DEDICATION IN
22	THE RESEARCH HOSPITALS, AND THE DEDICATION TO MOVING
23	ALL OF THIS RESEARCH THROUGH CLINICAL TRIALS TO
24	PATIENTS, I KNOW OF NO BOARD IN THE COUNTRY, I KNOW
25	OF NO BOARD IN THE WORLD WITH THE SCOPE OF
	172

1	EXPERIENCE, DEDICATION, AND PASSION OF THIS BOARD.
2	SO IT IS ALWAYS A GREAT PRIVILEGE TO ADDRESS YOU.
3	THANK YOU.
4	(APPLAUSE.)
5	MR. DON REED: I ASKED FOR AND RECEIVED
6	PERMISSION TO READ DR. JEAN LORING'S LETTER TO YOU.
7	"I'M THE DIRECTOR OF ONE OF CIRM'S SHARED
8	LABORATORIES WHICH HAS PROVIDED FORMAL TRAINING IN
9	RESEARCH AND ETHICS TO HUNDREDS OF YOUNG STEM CELL
10	SCIENTISTS. MY CIRM FUNDING SUPPORTS THE STEM CELL
11	GENOMICS RESEARCH THAT IS THE MAIN FOCUS OF THE LAB.
12	"THE IOM REPORT RECOMMENDS A NUMBER OF
13	CHANGES IN CIRM'S POLICIES. ONE OF THESE
14	RECOMMENDATIONS IS OF ESPECIALLY GREAT CONCERN TO
15	ME, THE SUGGESTION THAT PATIENT ADVOCATES SHOULD
16	HAVE MUCH LESS INFLUENCE IN CIRM'S DECISIONS ABOUT
17	WHAT RESEARCH SHOULD BE FUNDED. PATIENT ADVOCATES
18	ARE EXTREMELY VALUABLE TO US RESEARCHERS. MOST OF
19	US STEM CELL RESEARCHERS HAD NEVER MET A PATIENT
20	ADVOCATE AND PERHAPS EVEN A PATIENT BEFORE CIRM WAS
21	FOUNDED. IN MY 20 YEARS OF BEING FUNDED BY THE NIH,
22	THE FUNDING AGENCY NEVER ONCE SUGGESTED THAT I
23	SHOULD TALK TO PEOPLE WHO HAVE THE DISEASE OR HAVE
24	RELATIVES WITH THE DISEASE THAT I WAS RECEIVING
25	FUNDING TO STUDY.
	173
	1

1	"WITH MY FIRST CIRM GRANT, I STARTED
2	MEETING PATIENT ADVOCATES, AND I CAN'T IMAGINE
3	PURSUING A DISEASE-RELATED RESEARCH PROJECT WITHOUT
4	THEM. I LEARNED A GREAT DEAL FROM THE ADVOCATES ON
5	THE ICOC, AND I GREATLY ENJOY TALKING WITH THEM.
6	THEY'RE A WONDERFUL SOURCE OF KNOWLEDGE. JEFF
7	SHEEHY TAUGHT ME ABOUT HIV/AIDS AND PATIENT
8	ACTIVISM. I LEARNED ABOUT PARKINSON'S DISEASE FROM
9	JOAN SAMUELSON, AUTISM FROM JON SHESTACK AND DAVID
10	SERRANO-SEWELL. DIANE WINOKUR EDUCATED ME ABOUT MS
11	AND ALS.
12	"PROFESSIONAL RESEARCH SCIENTISTS ARE
13	COMPETITIVE BY NATURE. A CONVERSATION BETWEEN
14	SCIENTISTS IS OFTEN CONSTRAINED BY OUR SECRECY. WE
15	NEED TO PUBLISH OR PERISH, BUT ADVOCATES HAVE NO
16	SUCH CONSTRAINTS, WHICH MAKES ICOC MEETINGS MORE
17	ENJOYABLE AND INFORMATIVE THAN MANY SCIENTIFIC
18	MEETINGS. PATIENT ADVOCACY HAS MADE ME A BETTER
19	SCIENTIST. ADVOCACY MAKES CIRM-FUNDED RESEARCH
20	BREATHTAKINGLY RELEVANT, UNIQUELY POWERFUL TO CHANGE
21	THE COURSE OF MEDICINE."
22	THIS IS THE BOOK OF THE IOM PROPOSAL, 167
23	PAGES. I STUDIED IT, READ NOTES. THIS IS 30
24	MAGAZINE ARTICLES ABOUT THE IOM REPORT. NONE OF
25	THEM TOOK OUR SIDE. THAT'S THE REASON BY TAKING THE
	174

1	PATH OF CAESAR'S WIFE TO BE ABOVE EVEN THE
2	POSSIBILITY APPROACH, YOU HAVE DONE THE RIGHT THING.
3	BUT I WANT TO TELL YOU WHAT I FEEL ABOUT
4	THE IOM. THE IOM REPORT IS A ONE-SIDED DOCUMENT.
5	APART FROM THE COMMENTS OF BOARD MEMBERS, PATIENT
6	ADVOCATE INPUT IS EXCLUDED FROM THE STUDY. WHERE
7	ARE THE VOICES OF THE DOZENS OF PATIENT ADVOCATE
8	GROUPS WHICH SUPPORTED CIRM? WHERE ARE THE COMMENTS
9	OF THE INTERNATIONAL SOCIETY OF STEM CELL
10	RESEARCHERS, THE COALITION FOR THE ADVANCEMENT OF
11	MEDICAL RESEARCH, THE CALIFORNIA MEDICAL
12	ASSOCIATION, THE STUDENT SOCIETY FOR STEM CELL
13	RESEARCH, THE CHRISTOPHER REEVE PARALYSIS
14	FOUNDATION, JUST TO NAME A FEW?
15	THE STUDY USES WHAT I CONSIDER DECEPTIVE
16	LANGUAGE. FOR EXAMPLE, CRITICS OF THE PROGRAM, SOME
17	WHO OPPOSE EVERY STEP OF THE WAY, THESE ARE CALLED
18	STAKEHOLDERS AND ARE FEATURED PROMINENTLY IN THE
19	REPORT. SUPPORTERS OF THE PROGRAM, LIKE PATIENTS
20	AND THEIR FAMILIES, ARE APPARENTLY NOT CONSIDERED
21	STAKEHOLDERS, AND THEY ARE LEFT OUT.
22	WHEN THE REPORT SUGGESTS REMOVING THE
23	ICOC'S AUTHORITY IN DECIDING WHO GETS GRANT MONEY,
24	THAT IS TRIVIALIZED BY BEING CALLED DAY-TO-DAY
25	ACTIVITIES. FUNDING DECISIONS ARE NOT MINOR CHORES.
	175

1	THEY ARE THE CENTRAL REASON FOR THIS PROGRAM'S
2	EXISTENCE.
3	UNDER THE NEW PROPOSALS, THE BOARD WOULD
4	ONLY BE ALLOWED TO VOTE ON THE RESEARCH PROPOSALS AS
5	A BLOCK OF GRANTS, PERHAPS DOZENS AT A TIME. THIS
6	WOULD NOT ONLY VIOLATE PROP 71 GUIDELINES, WHICH
7	CALL FOR PUBLIC DISCUSSION OF GRANT PROPOSALS, BUT
8	ALSO DENY THE PUBLIC ITSELF ANY MEANINGFUL ROLE IN
9	THE DECISION-MAKING PROCESS. IF THE BOARD ONLY
10	VOTES ON GROUPS OF PROJECTS AS A BLOCK, THERE IS NO
11	OPPORTUNITY FOR INDIVIDUAL DISCUSSION.
12	AS FOR THE ICOC BOARD, AFTER ITS AUTHORITY
13	HAD BEEN STRIPPED AWAY, IT WOULD BE OFFERED BUSY
14	WORK TO OCCUPY ITS TIME. THE BOARD MIGHT BEGIN
15	REINVESTIGATING ETHICAL STANDARDS, WHICH HAS ALREADY
16	BEEN EXTENSIVELY DONE IMMEDIATELY AFTER THE ELECTION
17	WHEN A MAJOR CONFERENCE WAS DONE UNDER THE AUSPICES
18	OF THE NATIONAL ACADEMY OF SCIENCES.
19	THE STUDY RECOMMENDS THE BOARD DO
20	STRATEGIC PLANNING, WHICH WOULD BE USEFUL. HAD NOT
21	BOTH FIVE- AND TEN-YEAR STRATEGIC PLANS ALREADY BEEN
22	COMPLETED?
23	THE BOARD WOULD, OF COURSE, WORK ON
24	SUSTAINABILITY. SHOULD WE ASK FOR VOLUNTARY
25	CONTRIBUTIONS OR ANOTHER ROUND OF FUNDING? BUT
	176
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-	THESE ARE HARRING SUPERTITIES FOR THE TOOCLE CRUSTAL
1	THESE ARE HARDLY SUBSTITUTES FOR THE ICOC'S CRUCIAL
2	WORK ON GRANT APPROVAL.
3	ANOTHER BLOW OF OPEN GOVERNMENT, THE
4	PUBLIC APPEALS PROCESS WOULD BECOME SECRET.
5	PRESENTLY IF A SCIENTIST FEELS HIS OR HER PROJECT
6	WAS REJECTED UNFAIRLY, AN APPEAL CAN BE MADE BEFORE
7	THE ICOC PUBLICLY, EVERYTHING TRANSPARENT. THAT
8	WOULD BE TAKEN AWAY.
9	THE MOST IMPORTANT PURPOSE OF THE ICOC WAS
10	MANDATED BY PROPOSITION 71. THE INITIATIVE SOUGHT
11	TO FUND THE BEST SCIENCE POSSIBLE BY BRINGING
12	TOGETHER THE MULTIPLE VIEWPOINTS OF A GROUP OF
13	DISTINGUISHED EXPERTS. THAT IS WHAT CALIFORNIA
14	VOTED FOR AND THAT IS WHAT WE GOT.
15	IT IS MY HOPE AND BELIEF THAT THE BOARD
16	WILL DO AS IT HAS ALWAYS DONE, STUDYING THE
17	CRITICISM CAREFULLY, SEEKING GENUINE IMPROVEMENTS,
18	POSITIVE CHANGES THAT CAN BE MADE WITHOUT
19	COMPROMISING THE INTENT OF PROP 71. BUT THE REPORT
20	AS IT READS NOW, THE IOM REPORT, WOULD DENY PUBLIC
21	INPUT IN THE GRANT-MAKING PROCESS, GUT THE
22	LEADERSHIP OF AN EXPERT BOARD, IGNORE PATIENT
23	ADVOCATES AS SIGNIFICANT PARTNERS, AND REPLACE OPEN
24	GOVERNMENT WITH DECISIONS MADE IN SECRET. THIS MUST
25	AND WILL BE REJECTED. THANK YOU.

MR. SHESTACK: COULD YOU MAKE YOUR
MR. SHESTACK. COOLD TOO MAKE TOOK
COMMENTS AVAILABLE TO US SOMEHOW? THANK YOU VERY
MUCH.
MR. ROMAN REED: THANK YOU, HONORABLE
MEMBERS OF THE ICOC. I AM ROMAN REED. AS A PATIENT
ADVOCATE, IT WAS AN HONOR TO HAVE CALIFORNIA
LEGISLATION NAMED AFTER ME, THE ROMAN REED SPINAL
CORD INJURY RESEARCH ACT, WHICH PROVIDED \$15 MILLION
TO CALIFORNIA RESEARCHERS AS WELL AS HELPING THEM
ATTRACT AN ADDITIONAL \$85 MILLION IN ADDITIONAL
ADD-ONS FROM NIH AND OTHER SOURCES. I WAS ALSO ONE
OF THE HUNDREDS OF PATIENT ADVOCATES WHO CAME
TOGETHER AND HELPED PASS PROPOSITION 71 IN 2003.
THE PATIENT ADVOCATES HAVE ALWAYS BEEN
PROUD TO DO FOR THE SCIENTISTS WHAT SOMETIMES THEY
CANNOT EVEN DO FOR THEMSELVES, PROVIDE MONEY FOR
RESEARCH. BUT WE IN THE PATIENT ADVOCATE COMMUNITY
ALSO HAVE A MOTTO: NOTHING ABOUT US WITHOUT US.
THESE ARE OUR BODIES, AND OUR VOICES MUST BE HEARD.
AND THE IOM COMPLETELY MISSES THE BOAT WITH THEIR
REPORT, AND THEIR RECOMMENDATIONS WOULD
SYSTEMATICALLY EXCLUDE PATIENT ADVOCATES, DENYING US
REAL PARTICIPATION.
UNTIL NOW THE CALIFORNIA STEM CELL PROGRAM

1	HAS BEEN A SHINING STAR IN INCLUSION OF PATIENTS AND
2	PATIENT ADVOCATES IN DECISION-MAKING PROCESSES. YOU
3	HAVE LISTENED TO OUR VOICES. YOU TOOK A TIP FROM
4	THE U.S. FDA. "THE FDA INCLUDES PATIENT ADVOCATE
5	REPRESENTATIVES ON ADVISORY COMMITTEE PANELS THAT
6	REVIEW PRODUCTS AND THERAPIES RELATED TO SERIOUS AND
7	LIFE-THREATENING DISEASES." AND THAT'S WHAT YOU
8	HAVE DONE.
9	OUR 29 MEMBERS OF THE ICOC, THE PROGRAM'S
10	PUBLICLY APPOINTED BOARD OF DIRECTORS, TEN ARE
11	PATIENT ADVOCATES. WE DO KNOW THAT'S ROUGHLY
12	EQUIVALENT TO THE NUMBER OF AMERICANS, ONE IN THREE,
13	WHO HAVE A CHRONIC DISEASE OR DISABILITY LIKE
14	MYSELF. NOT ONLY DO PATIENT ADVOCATES ON THE BOARD
15	HAVE VOTING RIGHTS ON INDIVIDUAL RESEARCH PROJECTS,
16	BUT WE ADVOCATES IN THE PUBLIC OFFER INPUT BEFORE
17	IMPORTANT DECISIONS ARE MADE. THAT IS CRUCIAL.
18	THIS TREATS PATIENTS LIKE PARTNERS, LIKE OUR VOICES
19	MATTER. IT IS WHAT CALIFORNIA VOTERS SAID YES TO.
20	IT IS IN OUR STATE CONSTITUTION NOW, BUT THE IOM
21	RECOMMENDATIONS WOULD PUT THIS UNIQUE AND PRODUCTIVE
22	PARTNERSHIP AT RISK.
23	SPECIFICALLY ON PAGE 14, SECTION 3 OF THE
24	SHAPIRO REPORT, WE FIND THESE WORDS. "THE COMMITTEE
25	BELIEVES THAT PERSONAL CONFLICTS OF INTEREST ARISING

1	FROM ONE'S OWN OR A FAMILY MEMBER'S AFFILIATION WITH
2	A PARTICULAR DISEASE CAN CREATE BIAS." IF THIS NEW
3	DEFINITION OF CONFLICT OF INTEREST CALLED THE,
4	QUOTE, UNQUOTE, PERSONAL CONFLICT OF INTEREST WAS
5	APPLIED, ANYONE WITH A CHRONIC ILLNESS OR WHOSE
6	FAMILY HAD ONE MIGHT NOT BE ELIGIBLE TO VOTE ON THE
7	BOARD. WITH A HUNDRED MILLION AMERICANS SUFFERING
8	FROM CHRONIC DISEASE, AND THOSE FOLKS HAVE FOLKS
9	RELATED TO EVERYONE ELSE, IT'S GOING TO BE HARD TO
10	EVEN FIND A QUORUM, FOR CRYING OUT LOUD.
11	IT MUST ALSO BE UNDERSTOOD THAT IF THE
12	BOARD, THE ICOC, GIVES UP ITS RESPONSIBILITY, ITS
13	RESPONSIBILITY, FOR DECIDING INDIVIDUAL RESEARCH
14	GRANTS, THAT CUTS PATIENT ADVOCATES OUT OF THE LOOP.
15	IF YOUR RIGHT TO SPEAK IS GONE, SO IS OURS. AND
16	THESE ARE OUR BODIES, AND OUR VOICES MUST BE HEARD.
17	IT IS SAID THAT ALLOWING THE ICOC TO VOTE
18	ON INDIVIDUAL RESEARCH GRANTS MAY HAVE DELETERIOUS
19	EFFECTS. THEY MIGHT ACTUALLY DISAGREE WITH THE
20	OUT-OF-STATE DOMINATED GRANTS WORKING GROUP, WHICH
21	HAS FIRST REVIEW OF PROJECTS. THAT GETS THE
22	SITUATION EXACTLY BACKWARDS. THE GRANTS WORKING
23	GROUP IS THERE TO ASSIST THE ICOC, NOT VICE VERSA.
24	PATIENT ADVOCATES RESPECT SCIENTISTS
25	WHOLEHEARTEDLY. YOU'RE DOING THE WORK OF OUR LIVES
	180
	100

1	TO SAVE OUR LIVES, MUCH AS WE RESPECT DOCTORS, BUT
2	WE ARE NOT PASSIVE. TO PARAPHRASE THE POET WILLIAM
3	PETER HENRY, WE ARE THE MASTERS OF OUR OWN FATE. WE
4	ARE THE CAPTAINS OF OUR SOULS. THE CIRM EXISTS
5	TODAY BECAUSE WE PATIENTS ARE ACTIVE PARTICIPANTS IN
6	THE GREAT AFFAIRS OF OUR LIVES. JUST AS SCIENTISTS
7	OFTEN DISAGREE WITH EACH OTHER, SO WE IN THE PATIENT
8	COMMUNITY SOMETIMES DISAGREE WITH OUR OWN SELVES.
9	WE TAKE OPPOSING POSITIONS. WE ARE EXPERTS
10	OURSELVES WITH AN AWARENESS OF CHRONIC DISEASE. WE
11	LIVE CHRONIC DISEASE NO OTHER OUTSIDER COULD EVER
12	MATCH.
13	IT IS IMPLIED THAT WE ARE BIASED IN FAVOR
14	OF OUR OWN CHRONIC CONDITION. THIS IS
15	MISAPPREHENSION. THIS IS FALSE. I WOULD GIVE ONE
16	OF MY LEGS ANY DAY OF THE WEEK AND TWICE ON SUNDAY.
17	THE FIRST LESSON AN ADVOCATE LEARNS IS THAT WE ARE
18	FEW IF WE ARE ISOLATED, BUT WE ARE STRONG WHEN WE
19	ARE TOGETHER.
20	AS JOHN F. KENNEDY SAID, A RISING TIDE
21	LIFTS ALL BOATS. WE WILL SUCCEED ONLY IN
22	PARTNERSHIP. THERE IS A LINE IN THE SAND THAT WE
23	MUST NOT CROSS. THE ICOC MUST RETAIN THE RIGHT TO
24	REVIEW, REJECT, OR SUPPORT INDIVIDUAL RESEARCH
25	GRANTS. THIS BUSINESS ABOUT UP OR DOWN VOTE ON A

1	WHOLE BUNCH OF GRANTS AT ONCE IS A DEAL BREAKER, AND
2	IT WILL NOT STAND. IF WE HOPE TO CONTINUE AND HAVE
3	PATIENT ADVOCATE ENTHUSIASM, OUR VOICES MUST BE
4	HEARD AT THE TABLE.
5	YOU CAME HERE TO BRING YOUR EXPERTISE AND
6	BE A PART OF THOSE DECISIONS, NOT EVER GIVE UP THAT
7	RESPONSIBILITY. TAKE YOUR STAND AT THE TABLE THE
8	PATIENT ADVOCATES HELPED CREATE. THANK YOU SO MUCH.
9	(APPLAUSE.)
10	MS. MINER: HI. MY NAME IS KAREN MINER.
11	I AM COFOUNDER OF CALIFORNIANS FOR CURES. I'VE BEEN
12	WORKING FOR MEDICAL RESEARCH SINCE 1998. IT WAS
13	VERY EXCITING TO HEAR ALL THAT HAS BEEN ACCOMPLISHED
14	THIS MORNING IN THAT REPORT WITH HUMANS. WE'VE BEEN
15	HEARING A LONG TIME ABOUT ALL THE GREAT NEWS WITH
16	RATS. SO THAT WAS VERY EXCITING.
17	WHAT I'D LIKE TO SAY IS THAT PROP 71 LED
18	TO THE WORLD'S GREATEST STEM CELL PROGRAM. IT'S
19	BEEN AN UNQUALIFIED SUCCESS. I DON'T WANT TO SEE IT
20	UNDERMINED. SOME OF THE THINGS THE REPORT SAYS, I
21	WONDER IF THEY'RE TALKING ABOUT THE SAME PROGRAM
22	THAT I'M TALKING ABOUT. CALIFORNIA INSTITUTE OF
23	REGENERATIVE MEDICINE DOES EXACTLY WHAT IT WAS SET
24	OUT TO DO, AND THAT'S TO FUND SCIENTIFIC RESEARCH.
25	IT DOES IT BETTER THAN ANYBODY ELSE IN THE WORLD,
	182

1	AND THAT'S SOMETHING THAT EVERYBODY KNOWS.
2	THE ICOC IS THE GOVERNING BOARD. THAT'S
3	YOUR JOB. YOU DO IT WELL. YOU DO IT WITH HONOR.
4	AND I HAVE TO TELL YOU, LISTENING TO EVERYONE TODAY,
5	I AM SO IMPRESSED, NOT AMAZED BECAUSE I KNOW, BUT
6	I'M SO IMPRESSED WITH THE PASSION. IT IS WONDERFUL
7	AND I THANK YOU VERY MUCH, BUT PLEASE DON'T GIVE UP
8	YOUR AUTHORITY. DISCUSS THE RECOMMENDATIONS OF THE
9	IOM REPORT, OF COURSE, BUT DON'T GIVE UP YOUR
10	RESPONSIBILITY TO SPEAK AND VOTE AND DECIDE ON
11	INDIVIDUAL STEM CELL PROJECTS.
12	PROP 71 WAS CREATED BY PATIENT ADVOCATES.
13	IT WAS PUSHED INTO LAW BY PATIENT ADVOCATES FOR THE
14	BENEFIT OF PATIENTS CURRENT AND FUTURE. IT WORKS
15	BEST WHEN WE ALL WORK TOGETHER, PATIENT ADVOCATES,
16	SCIENTISTS, PHYSICIANS, BUSINESS PEOPLE, AND OTHERS.
17	THE ICOC UNITES ALL OF US. THANK YOU.
18	(APPLAUSE.)
19	MR. KNOEPFLER: HI. MY NAME IS PAUL
20	KNOEPFLER. I'M ACTUALLY A STEM CELL SCIENTIST WHO
21	HAS RECEIVED CIRM FUNDING. SO FIRST OF ALL, I WANT
22	TO THANK YOU GUYS FOR ENTRUSTING ME WITH THE SUPPORT
23	FOR MY LAB FOR THE WORK THAT WE'RE DOING.
24	I MAY BE THE ONLY CIRM-FUNDED SCIENTIST
25	HERE, AND I DON'T CLAIM TO SPEAK FOR THE OTHERS, BUT
	183

1	I HOPE I CAN KIND OF BRING A UNIQUE PERSPECTIVE.
2	WHEN I FIRST READ THE IOM REPORT, I WAS KIND OF
3	TAKEN ABACK, AND IT REMINDED ME OF SOME OF MY
4	REACTIONS TO SOME OF MY GRANTS CRITIQUES THAT I
5	SOMETIMES GET FROM CIRM AND NIH. YOU'RE KIND OF IN
6	SHOCK. HOW COULD THEY SAY THAT? AND SO I KIND OF
7	REACTED ANGRILY IN MY OWN WAY TO THE IOM REPORT.
8	I THINK WE ALSO NEED TO MAYBE THINK ABOUT
9	OUR RESPONSE TO THE REPORT IN A VERY CAREFUL WAY.
10	AND I THINK THAT'S OBVIOUSLY SOMETHING THAT'S BEING
11	DISCUSSED HERE. BUT ONE OF MY SAGE MENTORS TOLD ME,
12	WHEN YOU GET ONE OF THESE GRANT CRITIQUES, YOU CAN
13	READ IT, YOU CAN GET UPSET, BUT TAKE YOUR TIME TO
14	FIGURE OUT THE BEST RESPONSE. YOU DO NEED TO
15	RESPOND. YOU CAN'T JUST TELL THEM THEY'RE AN IDIOT
16	OR SOMETHING LIKE THAT.
17	SO SOME OF THE THINGS IN THE PROPOSED CIRM
18	RESPONSE TO ME SEEMED VERY THOUGHTFUL AND LOGICAL.
19	OTHER ONES TO ME RAISED CONCERNS ABOUT MINIMIZING
20	THE ROLE OF PATIENT ADVOCATES. ESPECIALLY I MYSELF
21	AM A CANCER SURVIVOR, AND I CONSIDER MYSELF BOTH A
22	STEM CELL SCIENTIST AND PATIENT ADVOCATE. AND SO I
23	WOULD JUST URGE TO TAKE A VERY DELIBERATIVE
24	RESPONSE. AND I PERSONALLY AS A STEM CELL SCIENTIST
25	MEMBER OF THE PUBLIC PATIENT ADVOCATE, TO ME IT
	184

1	SEEMS LIKE VOTING TODAY WOULD BE TOO SOON. AND
2	MAYBE SOME PEOPLE WON'T BE HAPPY WITH ME SAYING
3	THAT. AND I KNOW WE LIVE IN A REALLY RAPID PACED
4	WORLD, AND I'M ACTUALLY ALSO A STEM CELL BLOGGER.
5	AND I'VE ALREADY BLOGGED FROM THIS MEETING, AND SOME
6	OF THE READERS HAVE SAID TO ME, WELL, PAUL, WHAT DO
7	YOU THINK OF CIRM'S PROPOSED CHANGES? AND THE TRUTH
8	IS I'M NOT SURE. I HAVEN'T HAD ENOUGH TIME TO
9	REALLY THINK ABOUT THEM CAREFULLY.
10	AND I THINK THERE'S SOME BRILLIANT ASPECTS
11	TO THE RESPONSE, BUT I WOULD BE A LITTLE
12	UNCOMFORTABLE TAKING ONE SIDE OR THE OTHER OR VOTING
13	ON ALL OF THESE RECOMMENDATIONS AS ONE GROUP. SO I
14	JUST URGE YOU GUYS TO NOT FEEL LIKE THERE'S SOME
15	SORT OF RUSH. AND TO MY KNOWLEDGE, I DON'T THINK
16	YOU HAVE ANY SPECIFIC DEADLINE TO RESPOND TO THIS
17	REPORT. AND SO IT MIGHT ALSO BE PRUDENT TO GIVE
18	MORE TIME FOR PUBLIC RESPONSE GIVEN THAT MANY OF US
19	IN THE PUBLIC HAVE ONLY LITERALLY HAD A FEW HOURS TO
20	READ AND TRY TO DIGEST THE PROPOSED CHANGES. WE
21	REALLY MAYBE WE DON'T REALLY FULLY UNDERSTAND
22	THEM WITHIN THE CALIFORNIA PUBLIC YET AS WELL.
23	SO I THINK THAT'S THE MAIN THINGS I WANTED
24	TO SAY. AND THANK YOU AGAIN.
25	(APPLAUSE.)
	185
	200

1	MR. REMAK: HELLO. MY NAME IS BILL REMAK.
2	AND EIGHT YEARS AGO, WHEN THE DREAMERS OF
3	PROPOSITION 71 WERE LOOKING AT HOW WE COULD FIND
4	CURES, WE AS A PATIENT ADVOCATE LOOKED AT DEVELOPING
5	SOME COMMON GROUND FOR ALL THE CHRONIC DISEASE
6	GROUPS, NATIONAL DISEASE ORGANIZATIONS THAT HAD
7	AFFILIATES IN CALIFORNIA, AND WE CREATED THE
8	CALIFORNIA CHRONIC CARE COALITION.
9	AND ON THAT BASIS, WHERE WE FOUND COMMON
10	GROUND AND COMMON THREAD OF ALL OF US BEING IN THE
11	SAME BOAT TO RESOLVE THE BARRIERS AND THE STRUGGLES
12	THAT PEOPLE WITH CHRONIC DISEASE HAVE, WE ALSO
13	LOOKED AT CIRM AS A VEHICLE TO IMPROVE TECHNOLOGY
14	AND FIND CURES AND END SUFFERING. AND THE COMMON
15	THREAD YOU ALL HAVE, BEING A VERY DIVERSE GROUP, BUT
16	ALSO SHARING ALL THE WISDOM AS A CROWD OR A GROUP
17	THAT YOU BRING TO THIS ISSUE, AND HAVING THE BEAUTY
18	OF THE GOVERNANCE TO RESOLVE ON YOUR OWN WITHOUT
19	INTERFERENCE THIS WONDERFUL COLLABORATION BETWEEN
20	YOUR GROUP AND THE GOVERNING BOARD, WE THINK THAT
21	THAT SHOULD GO UNIMPEDED. AND I SPEAK AS AN
22	ADVOCATE WHO'S HELPED CREATE THE CALIFORNIA CHRONIC
23	CARE COALITION, WHICH INCLUDES AARP, ADA, CANCER
24	SOCIETY, HEART ASSOCIATION, AND SO ON.
25	WE THINK THAT YOU HAVE AN INCREDIBLE

OPPORTUNITY AND YOU HAVE THE ABILITY TO SUSTAIN
THIS. WITH THE KNOWLEDGE YOU HAVE, WORK OUT
WHATEVER DIFFICULTIES THERE ARE, WITH YOUR COMBINED
KNOWLEDGE COME TO A RESOLUTION, AND MOVE IT FORWARD
BECAUSE ESSENTIALLY WE'RE ALL IN THE SAME BOAT.
YOU'RE ALL PATIENTS. OKAY. THANK YOU.
(APPLAUSE.)
MR. MARINO: HI. MY NAME IS TONY MARINO
FROM SENATOR JERRY HILL'S OFFICE. I JUST WANTED TO
REITERATE A PREVIOUS COMMENT, THAT MAYBE THE BOARD
RECONSIDER THE VALUE OF VOTING TODAY ON THIS
PROPOSAL. I THINK EVERYONE IS PRETTY COMFORTABLE
THAT THE WORK THE BOARD HAS DONE HAS BEEN OF VALUE.
AND WITHOUT I THINK EVERYONE HERE FEELS THAT
THEY'VE DONE THE BEST JOB THEY CAN DO AND AN HONEST
JOB, AND THAT THE PROBLEM IS A LOT OF PERCEPTION.
AND I'M AFRAID THAT IF YOU VOTE TODAY, THAT MIGHT
ONLY ENHANCE THE PERCEPTION OF SOMEHOW SHOVING
SOMETHING THROUGH.
AND THE BIGGEST PART OF THIS, THE BIGGEST
PART THAT YOU NEED TO ADDRESS IS THE PUBLIC TRUST.
AND I THINK THAT GIVING A LITTLE MORE TIME FOR THE
PUBLIC TO DIGEST THIS WILL DEFINITELY FURTHER THAT.
CERTAINLY HAVE NO COMMENTS ON THE PROPOSAL
ITSELF OR THE ACADEMY'S REPORT. THAT'S JUST MY
187

1	THOUGHT. THANK YOU.
2	MR. TORRES: MR. CHAIRMAN, I THINK IT'S
3	IMPORTANT BECAUSE EVEN A LEGISLATIVE STAFF PERSON
4	MISUNDERSTOOD WHAT THE PROCESS IS THAT WE'RE GOING
5	TO FOLLOW. AND THAT IS WE'RE NOT RUSHING TO
6	JUDGMENT. WE'RE TAKING STEPS AD SERIATIM.
7	AND THE FIRST STEP IS TO PUT CONCEPTS OUT
8	THERE THAT WE CAN REVIEW SO THAT EVERYBODY HAS AN
9	INPUT INTO THOSE CONCEPTS, NOT RUSHING THROUGH IT,
10	BUT PUTTING IT OUT THERE SO THAT WE GIVE DIRECTION
11	TO OUR LEGAL COUNSEL TO COME UP WITH THE WAYS BY
12	WHICH THESE CONCEPTS COULD BE IMPLEMENTED. BUT THE
13	ULTIMATE DECISION ON HOW THEY'RE GOING TO BE
14	IMPLEMENTED OR IF THEY'RE GOING TO BE IMPLEMENTED
15	HAS TO BE LEFT TO THE BOARD ULTIMATELY. AND THAT
16	WON'T TAKE PLACE UNTIL MARCH.
17	WE'RE NOT I HOPE YOU TAKE THE MESSAGE
18	BACK TO JERRY, SENATOR HILL, THAT WE'RE NOT RUSHING
19	THROUGH THIS. WE'RE TAKING STEPS ONE STEP AT A TIME
20	TO MAKE SURE THAT PUBLIC INPUT BECAUSE I'M VERY
21	SENSITIVE TO THE PATIENT ADVOCATES CONCERNS FOR
22	PUBLIC INPUT, ALL OF US ARE, AND TO MAKE SURE THAT
23	WE TAKE THOSE STEPS DILIGENTLY AND PATIENTLY AND
24	WITH ALL DUE RESPECT TO ALL OF THE STAKEHOLDERS IN
25	THE PROCESS.
	188
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1	I JUST WANT TO MAKE SURE THAT WE
2	UNDERSTAND, AT LEAST FROM WHAT I UNDERSTAND, THE
3	PROCESS BY WHICH WE'RE MOVING IT, AND THAT IS ONE
4	STEP AT A TIME. THE FIRST IS TO DEAL WITH THE
5	CONCEPTS AS A WHOLE, A MACRO VIEW, AND THEN TO SEE
6	WHAT COUNSEL COMES UP WITH. AS JEFF SAID, THE DEVIL
7	IS THE DETAILS, AND HE'S RIGHT. AT THAT POINT WE
8	JUST NEED TO SEE WHAT ARE THE ISSUES THAT WILL OCCUR
9	ONCE WE DECIDE TO LOOK AT THIS IN A MUCH MORE
10	DEFINITIVE WAY.
11	CHAIRMAN THOMAS: THANK YOU, SENATOR
12	TORRES. I'D LIKE TO ECHO THAT COMMENT. WHAT WE'RE
13	TRYING TO DO HERE IS TO PUT OUT A FRAMEWORK THAT
14	WILL INFORM DISCUSSION GOING FORWARD. AND THERE
15	WILL BE PLENTY OF OPPORTUNITY FOR SUGGESTIONS ON HOW
16	TO ARRIVE AT THE DETAILS FOR IMPLEMENTING THE STEPS.
17	BUT IT'S MY VIEW, WITH THIS REPORT OUT THERE, THAT
18	IT'S VERY IMPORTANT TO TAKE THE INITIAL STEPS OF
19	PUTTING TOGETHER A FRAMEWORK THAT WE CAN VOTE ON,
20	AND THEN COME BACK WITH THE BENEFIT OF PATIENT
21	ADVOCATE INPUT, OTHER BOARD INPUT, STAFF INPUT,
22	EVERYBODY'S INPUT AND HAVE SORT OF THE FINAL FORM
23	THAT FILLS THE MEAT ON THE BONES AT OUR MARCH
24	MEETING.
25	I WOULD LIKE TO THINK THIS IS NOT RUSHING
	189

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1	TO ANYTHING. THIS IS JUST TRYING TO GET A FRAMEWORK
2	OUT THERE.
3	I WANTED TO MAKE A COUPLE OF OTHER POINTS.
4	ONE IS WITH RESPECT TO INDIVIDUAL ASPECTS. THE WAY
5	I PUT THIS THING TOGETHER IS IT'S A VERY SORT OF
6	COHERENT WHOLE. AND MY PERSONAL OPINION IS, NOT
7	THAT ANYBODY'S SUGGESTING WE DO SO, BUT IF WE START
8	PULLING THINGS OUT OF IT, IT CAN UNRAVEL AND CAUSE A
9	LOT OF CONCERN. SO I CONTINUE TO ADVOCATE FOR
10	PASSAGE OF THIS FRAMEWORK AS A COHERENT WHOLE.
11	I DO WANT TO TAKE WHAT ROMAN SAID. AS I
12	TOLD YOUR DAD AND I TOLD YOU, THAT IT IS ABSOLUTELY
13	MY INTENTION TO KEEP THE PATIENT ADVOCATES FULLY
14	EMPOWERED. AND I BELIEVE THAT I'VE IN PUTTING THIS
15	PLAN TOGETHER, WHICH IS NOT EASY, IN CASE ANYBODY
16	THOUGHT IT WAS, THAT THAT GOAL, I THINK, HAS BEEN
17	ACHIEVED. SO I FULLY HEAR YOU. THE NOTION THAT WE
18	ARE PARTNERS OF THE PATIENT ADVOCATES IS IN ALL BOLD
19	AND CAPITAL LETTERS. WE'RE COMPLETELY WITH YOU ON
20	THAT.
21	MR. TORRES: HERE. HERE.
22	DR. PRICE: CAN I ASK A POINT OF
23	INFORMATION? I'D LIKE TO KNOW WHAT IT MEANS IN
24	TERMS OF WHAT WE'RE COMMITTING TO, WHAT AM I
25	COMMITTING TO WHEN I VOTE FOR THIS OUTLINE TODAY?
	190

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1	SO TO BE SPECIFIC, I VOTE FOR THIS TODAY. DOES THAT
2	MEAN IN MARCH I CAN VOTE TO REJECT THE IDEA THAT THE
3	PATIENT ADVOCATES IN THE GRANTS WORKING GROUP WILL
4	LOSE THEIR VOTE? IS THAT PARTICULAR ELEMENT IN THIS
5	OUTLINE NOW FIXED?
6	CHAIRMAN THOMAS: THAT IS AN ELEMENT IN
7	THE OUTLINE.
8	DR. PRICE: IS IT FIXED? THAT'S THE
9	QUESTION.
10	CHAIRMAN THOMAS: I DO WANT TO TAKE MR.
11	SHEEHY'S COMMENTS TO HEART. THE REASON THAT THAT'S
12	THERE IS THAT IS A FUNDAMENTAL ELEMENT OF THE
13	CONFLICT OF INTEREST THAT'S BEEN IDENTIFIED. AND
14	MOVING THE PROGRAMMATIC REVIEW TO THE BOARD, WHICH
15	AMONG OTHER THINGS WILL GIVE MUCH MORE GREATER
16	TRANSPARENCY, I'VE SHIFTED THE FOCUS OF THE PATIENT
17	ADVOCATE ROLE AND PARTICIPATION IN PROGRAMMATIC TO
18	THE BOARD. BUT, YES, IT IS IN HERE BECAUSE THAT IS
19	DIRECTLY AS I WAS SAYING, IT'S ONE OF THE
20	INTERWOVEN PIECES OF THIS THING.
21	WITH RESPECT TO MR. SHEEHY'S COMMENTS THAT
22	THE PROGRAMMATIC REVIEW PROCESS AS I PROPOSED AND
23	THE ROLE OF THE PATIENT ADVOCATES SHOULD LIKEWISE
24	HAVE A ONE-YEAR TRIAL PERIOD, I HEAR WHAT YOU ARE
25	SAYING, AND I'M FULLY AMENABLE TO THAT AS A FRIENDLY
	101

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1	AMENDMENT TO THE APPROACH.
2	MR. SHESTACK: SO THERE'S AN AMENDMENT
3	PROCESS OR THERE ISN'T?
4	CHAIRMAN THOMAS: I'M SORRY. I THOUGHT WE
5	WERE FINISHED. EXCUSE ME. MORE PUBLIC COMMENT.
6	THANK YOU.
7	MS. ROBERSON: THANK YOU. MAYBE THIS IS A
8	MOOT POINT AFTER WHAT J.T. JUST SAID. BUT I'M JUDY
9	ROBERSON. I'M FROM SACRAMENTO. I'M A VOLUNTEER
10	PATIENT ADVOCATE FOR HUNTINGTON'S AND HAVE BEEN FOR
11	21 YEARS SINCE MY HUSBAND WAS DIAGNOSED IN THIS 30S
12	WITH HUNTINGTON'S DISEASE, AND FOUR OF OUR LOVED
13	ONES, INCLUDING MY HUSBAND TIM, HAS DIED FROM HD AND
14	17 OTHERS IN MY FAMILY, INCLUDING MY CHILDREN AND
15	GRANDCHILDREN, ARE LIVING AT RISK FOR DEVELOPING
16	THIS FATAL BRAIN DISEASE CAUSED BY JUST ONE FAULTY
17	GENE.
18	HD HAS NO TREATMENT, NONE, NOT ONE. IT'S
19	JUST AS COMMON AS ALS AND CYSTIC FIBROSIS, BUT
20	NOBODY REALLY KNOWS MUCH ABOUT IT. IN JUNE OF 2008,
21	I WAS ASKED TO ATTEND AN ICOC MEETING FOR CIRM AND
22	ADVOCATE DR. LESLIE THOMPSON FROM UCI A GRANT FOR
23	HUNTINGTON'S DISEASE THAT SCORED TWO POINTS BELOW
24	THE RECOMMENDED LEVEL FOR FUNDING. IT WAS CALLED
25	THE GRAY ONE. I'M NOT SURE IF IT STILL IS.
	103
	192

1	BUT AT THE TIME, IF THERE WAS A QUESTION
2	ABOUT THE REVIEWER'S COMMENTS, THE RESEARCHER DIDN'T
3	HAVE A ROUTE TO GIVE REBUTTALS. I THINK THAT'S BEEN
4	RECTIFIED. BUT AT THE TIME THE ONLY PERSON WHO
5	COULD HAVE TIME AT AN ICOC MEETING WAS PATIENT
6	ADVOCATES. SO I DROVE TO BURLINGAME AND GAVE A
7	THREE-MINUTE TALK TO WHY HER GRANT SHOULD BE FUNDED.
8	AND TO CLARIFY SOME OF THE POINTS OF
9	CONFUSION, DR. JEAN LORING AND OTHERS IN THE
10	AUDIENCE CAME TO THE MICROPHONE TO ADVOCATE FOR
11	DR. THOMPSON'S GRANT. THE ICOC DISCUSSED IT AND
12	UNANIMOUSLY VOTED FOR IT. SO THAT WAS \$1.4 MILLION
13	BACK IN JUNE 2008. AND I'M SO HAPPY TO REPORT I GOT
14	AN E-MAIL YESTERDAY FROM LESLIE THOMPSON THAT THERE
15	HAVE BEEN FOUR OTHER GRANTS, MULTIPLE MILLION DOLLAR
16	GRANTS, THAT HAVE ADDED ON TO THAT GRANT. SO YOUR
17	MONEY, SEED MONEY, THEY STARTED AN INTERNATIONAL
18	CONSORTIUM WITH TEN DIFFERENT RESEARCHERS:
19	DR. STEVE FINKBEINER AT GLADSTONE, DR. CLIVE SVENSEN
20	AT CEDARS-SINAI, JUST TO NAME A FEW.
21	SO YOUR \$1.4 MILLION GRANT WAS APPROVED
22	BECAUSE A PATIENT ADVOCATE SPOKE UP. THANK YOU.
23	I WANTED TO SAY THAT BECAUSE OF THEM, THEY
24	HAVE STARTED WHAT'S CALLED DISEASE IN A DISH WHERE
25	THEY TAKE A LITTLE BIT OF SKIN SAMPLE FROM A
	193
	100

1	PATIENT, SOMEBODY YOUNG, LIKE PATIENT EMILY KROLL
2	WHO HAD JUVENILE HD, DIED AT AGE 21. HER CELLS
3	CONTINUE TO LIVE ON AS IPS CELLS. SO RESEARCH IS
4	BEING DONE ON HUNTINGTON'S BECAUSE OF THIS DISEASE
5	IN A DISH BECAUSE OF YOU.
6	ALSO PATIENT ADVOCATES LIKE MYSELF AND
7	OTHERS RAISE MONEY TO HELP TO PAY FOR THE INITIAL
8	RESEARCH FOR DR. JAN NOLTA'S RESEARCH FOR
9	HUNTINGTON'S AT UC DAVIS, AND SHE ALONG WITH DR.
10	VICKI WHEELOCK HAVE RECEIVED NUMEROUS GRANTS FROM
11	CIRM.
12	IN JULY OF 2012, THEY RECEIVED A \$19
13	MILLION GRANT FOR TRANSLATIONAL MEDICINE FOR THE
14	FIRST HUNTINGTON'S DISEASE CLINICAL TRIAL USING
15	ADULT STEM CELLS. WE'RE SO PROUD OF THEM FOR
16	SCORING IN FIRST PLACE, AND THE WHOLE WORLD FOR
17	HUNTINGTON'S, ALL THE PATIENTS ARE WAITING AND
18	WATCHING TO SEE THIS CLINICAL TRIAL GET GOING.
19	ABOUT THE FDA, AT A TIME LIKE THIS, WHEN
20	THE FDA IS FOCUSED ON APPOINTING FAMILY DISEASE
21	ADVOCATES TO SIT ON EVERY FDA ADVISORY COMMITTEE,
22	I'M CONCERNED THAT THE IOM RECOMMENDS AT THE SAME
23	TIME REDUCING OR ELIMINATING THE PATIENT ADVOCATES,
24	THEIR VOICE AND THEIR EXPERTISE.
25	SADLY I'M AN EXPERT IN HUNTINGTON'S. IN
	194

1	LATE 2009 I WAS NOMINATED TO JOIN THE FDA AS THE
2	FIRST VOTING PATIENT ADVOCATE FOR HUNTINGTON'S
3	DISEASE. AND I WAS OFFICIALLY NOMINATED 18 MONTHS
4	AGO. I MEAN APPOINTED.
5	SO ALL THESE STORIES ARE TO GIVE YOU AN
6	IDEA OF HOW IMPORTANT PATIENT ADVOCATES ARE IN THE
7	ROLE OF DISEASE AND IN INFORMATION. AND I ALSO
8	THINK CIRM NEEDS PATIENT ADVOCATES BECAUSE WE TEACH
9	OTHER PEOPLE IN THE COMMUNITY WHO CIRM IS, WHAT'S
10	THE FUNCTION OF NOW WE CALL IT THE STATE STEM CELL
11	AGENCY, BUT ALMOST NOBODY KNOWS ABOUT IT. SO THAT'S
12	OUR ROLE. AND I WANT TO THANK EVERYBODY FOR YOUR
13	DEDICATION AND DEVOTION TO STEM CELL RESEARCH.
14	YOU'RE OUR BIG HOPE.
15	(APPLAUSE.)
16	MS. ROTCHY: HELLO. I'M SUSAN ROTCHY.
17	I'M A PATIENT ADVOCATE. I'VE BEEN HELPING FUND
18	RESEARCH NOW FOR ALMOST 15 YEARS. I'VE BEEN INJURED
19	17 YEARS. I ASSISTED WITH PROP 71. IT WAS PATIENT
20	ADVOCATES THAT REALLY PUSHED THIS BILL THROUGH.
21	IT'S REALLY IMPORTANT TO HEAR OUR VOICES,
22	AND I'M GLAD TODAY THAT I SAW PASSION WITH ALL THE
23	SCIENTISTS AND ADVOCATES HERE AT THE TABLE. YES,
24	THERE IS CONFLICT OF INTEREST IN THE MEDIA, THE
25	PRESS. OUTSIDERS DO SEE THAT CONFLICT OF INTEREST,
	195

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1	BUT WHAT I SAW TODAY IS NOT A CONFLICT OF INTEREST.
2	BUT YOU HAVE TO REMEMBER EVERYBODY HAS A CONFLICT OF
3	INTEREST. YOU HAVE A LOVED ONE THAT YOU'RE LOOKING
4	AT THAT GRANT. YOU'RE JUST TEMPORARILY NOT DISABLED
5	RIGHT NOW. THAT'S ALL. BUT YOUR TIME WILL COME.
6	YOU'LL BE TAKING CARE OF THAT LOVED ONE, THAT
7	MOTHER-IN-LAW THAT YOU HAVE TO GIVE UP YOUR JOB TO
8	TAKE CARE OF THEM, OR GIVE UP HALF YOUR SALARY JUST
9	SO THEY QUALIFY FOR MEDICARE AND MEDI-CAL. JUST
10	REMEMBER THAT.
11	BUT IT'S PATIENT ADVOCATES WHEN YOU HEAR
12	THE STORIES BECAUSE RIGHT NOW YOU'RE JUST
13	TEMPORARILY NOT DISABLED. SO IT IS REALLY IMPORTANT
14	THAT WE ARE HERE AT THE TABLE. AND I'M REALLY HAPPY
15	THAT WE'RE GOING TO BE HERE AT THE TABLE. THANK
16	YOU.
17	(APPLAUSE.)
18	CHAIRMAN THOMAS: OKAY. I'D LIKE TO THANK
19	EVERYBODY WHO CAME TO SPEAK TODAY. YOUR VOICE IS
20	SINGULARLY IMPORTANT. AND AS I SAID, WE REMAIN
21	FULLY COMMITTED TO WORKING WITH YOU TO CONTINUE THE
22	MISSION. SO THANK YOU VERY MUCH, ALL OF YOU, FOR
23	COMING.
24	DR. MELMED.
25	DR. MELMED: THANK YOU, J.T. AND ECHO MY
	196

1	COLLEAGUES EARLIER CONGRATULATING YOU FOR A VERY
2	REASONED AND DIPLOMATIC DOCUMENT THAT YOU PRESENTED
3	US. I'M NOT GOING TO REPEAT WHAT MANY PEOPLE
4	SMARTER THAN MYSELF HAVE SAID IN THE ROOM THIS
5	AFTERNOON, BUT JUST TO MAKE ONE COMMENT ABOUT THE
6	CONFLICT OF INTEREST, WHAT I PREFER TO CALL DUALITY
7	OF INTEREST. AND THE OPERATIVE DESCRIPTOR, I THINK,
8	FOR CONFLICT OF INTEREST OR DUALITY OF INTEREST
9	REALLY IS THE PERCEPTION.
10	AND BECAUSE OF THE PUBLIC PERCEPTION THAT
11	WE'RE FACING, I THINK THAT ALL OF US, OR AT LEAST
12	SPEAKING FOR MYSELF, WOULD FEEL THAT TRANSCENDING
13	THIS NEGATIVE PUBLIC PERCEPTION IS WORTH WHAT YOU
14	ARE PROPOSING. AND BECAUSE OF THE MISSION AND THE
15	ULTIMATE IMPORTANCE OF OUR VALUE-DRIVEN MISSION HERE
16	IN THIS COMMITTEE, I WOULD CERTAINLY SUPPORT THE
17	PROPOSAL FOR RECUSAL THAT YOU PUT FORWARD.
18	CHAIRMAN THOMAS: THANK YOU. ANNE-MARIE.
19	DR. DULIEGE: LIKEWISE, I'M NOT GOING TO
20	REPEAT WHAT HAS BEEN SAID SO OFTEN. AND ALSO I WILL
21	BE ONE OF THE PEOPLE THAT WILL NOT BE HERE TOMORROW,
22	SO THERE'S A FEW POINTS I WANTED TO MAKE.
23	I THINK AND BY THE WAY, MANAGING
24	PERCEPTIONS IS WHAT WE SPEND OUR LIVES DOING IN
25	GENERAL RATHER THAN MANAGING REALITY. SO I THINK IT

1	IS INDEED A GOOD POLICY TO REASSESS WHAT WE'RE GOING
2	TO DO OR THE DECISIONS MADE IN THE NEXT COMING MONTH
3	AND TO REASSESS THEM IN A GIVEN PERIOD OF TIME. BUT
4	I WOULD ARGUE NOT TO WAIT FOR A FULL YEAR FOR
5	REASSESSMENT. VERY MUCH LIKE WHEN YOU MANAGE A
6	PATIENT AND INDUCE A LOT OF CHANGES FOR THESE
7	PATIENTS, YOU'RE GOING TO LET TREATMENT DO ITS
8	EFFECT, BUT YOU'RE NOT GOING TO WAIT A YEAR TO
9	REASSESS IT. AND I WOULD THINK THAT IF WE MAKE
10	SUBSTANTIAL CHANGES, WE SHOULD REASSESS IN A
11	SIX-MONTH PERIOD OF TIME.
12	I REALLY APPLAUD BRINGING THE PROGRAMMATIC
13	REVIEW AT THE LEVEL OF THE BOARD BECAUSE IT WILL
14	REALLY GIVE THE BOARD THE OPPORTUNITY TO BETTER
15	UNDERSTAND AND BETTER INFLUENCE THE PORTFOLIO. AND
16	GIVEN THAT TIME FLIES QUICKLY, THAT WE HAVE LESS
17	TIME NOW FOR THE FUTURE AND ARGUABLY LESS MONEY,
18	GIVING MORE ONTO THE BOARD THE RESPONSIBILITY OF
19	INFLUENCING PORTFOLIO OVERALL IS A GOOD THING.
20	AND JUST TO CORRECT WHAT HAD BEEN SAID, I
21	DID NOT READ THAT THE SCIENTIFIC APPEAL WOULD BE
22	REMOVED FROM THE ICOC RESPONSIBILITY. WHAT I HEARD
23	IS, RATHER, IN THE PROPOSAL THAT YOU MADE, JON, A
24	GOOD THING, WHICH IS, FIRST, IT WOULD GO BACK TO THE
25	WORKING GROUP, TO GIVE BACK TO THE WORKING GROUP,

1	WHICH HAS SPENT SOME TIME READING THESE GRANTS, THE
2	TIME TO REASSESS THE VALUE OF THE SCIENTIFIC APPEAL
3	AND THEN BRING THE RECOMMENDATIONS BACK TO THE ICOC.
4	SO LESS TIME ON INDIVIDUAL GRANTS, NOT THAT IT'S NOT
5	IMPORTANT, BUT AT LEAST IT WILL HAVE BEEN FIRST
6	REASSESSED BY THE WORKING GROUP AND BROUGHT BACK TO
7	THAT. MORE TIME OF THE ICOC ON THE PORTFOLIO AND A
8	SECOND LEVEL OF REVIEW ON INDIVIDUAL APPEALS, AND I
9	THINK THAT'S ACTUALLY VERY GOOD.
10	FINALLY, PERCEPTION OF CONFLICT OF
11	INTEREST, MANY PEOPLE FROM INSTITUTIONS HAVE
12	ADMITTED THAT THEY WOULD ACCEPT TO MANAGE THIS TO
13	NOT VOTE, BUT I HEAR A VERY EXTRAORDINARILY
14	DIFFERENT STAND ON THE PART OF PATIENT ADVOCATES
15	REGARDING THEIR FRANK LACK OF DESIRE REALLY, LACK OF
16	ACCEPTANCE TO GIVE UP ON THEIR VOTE. AND INDEED
17	THERE MAY BE A DIFFERENCE HERE THAT WE WOULD HAVE TO
18	CONSIDER IN THE DIALOGUE THAT WE'LL HAVE OVER THE
19	NEXT COMING MONTH.
20	DEANS, HEADS OF INSTITUTIONS HAVE BEEN
21	HEARD CONSTANTLY WITH OR WITHOUT VOTES.
22	HISTORICALLY PATIENTS HAVE NOT ALWAYS BEEN HEARD
23	WITHOUT A VOTE, AND I THINK THAT'S A FUNDAMENTAL
24	DIFFERENCE. THINGS CHANGE OVER TIME, FOR SURE,
25	AND WE NEED TO BE SENSITIVE TO THIS. AND I THINK
	199

1	I'LL FINISH HERE.
2	CHAIRMAN THOMAS: THANK YOU. ARE THERE
3	FURTHER COMMENTS BY MEMBERS OF THE BOARD?
4	DR. BRENNER: FIRST OF ALL, I WANT TO
5	CONGRATULATE YOU BECAUSE I THINK YOU GUYS DID AN
6	ENORMOUSLY GOOD JOB. I ALSO LIKE IF I UNDERSTAND
7	CORRECTLY, I LIKE THE WAY YOU PHRASE THE APPEALS. I
8	LIKE THE IDEA THAT THE GRANTS WORKING GROUP WOULD
9	LOOK AT IT. AND THEN REALLY IF THERE'S SOMETHING
10	THEY MISSED OR A MISTAKE OR SOMETHING, CORRECT IT.
11	I DIDN'T LIKE THE IDEA THAT THEY'D ALL COME BACK
12	ANYWAY, THAT THEY WOULD COME BACK WITH STRONG
13	RECOMMENDATIONS. OTHERWISE I THINK YOU CAN GET
14	STUCK IN THE SAME CYCLE WE'RE IN NOW WHERE
15	EVERYTHING COMES BACK AND WE GET THIS BIASED VIEW.
16	I GUESS THE DEVIL IS IN THE DETAILS, BUT
17	THE WAY IT WAS WRITTEN I THINK WAS CLEARER THAN
18	THAT.
19	THE OTHER THING I WANT TO EMPHASIZE IS
20	WHAT JOAN RAISED, WHICH IS THAT PROGRAMMATIC REVIEW,
21	I THINK, SHOULD BE PROACTIVE. I THINK IT'S VERY
22	DIFFICULT WHEN YOU BRING UP A GRANT OUT OF ORDER AND
23	SAY IT'S REALLY A SHAME WE DON'T HAVE THIS DISEASE
24	REPRESENTED IN OUR PORTFOLIO. I THINK IT'S MUCH
25	BETTER TO DO IT PROACTIVELY AND SAY WE DON'T HAVE
	200

1	THIS REPRESENTED IN OUR PORTFOLIO. LET'S SOLICIT
2	GRANTS IN THIS DISEASE AND THEN EVALUATE THEM
3	THROUGH THE REGULAR CHANNELS AS PART OF OUR RFA
4	BECAUSE THEN YOU CAN REALLY CAST A MUCH WIDER NET
5	AND DEVELOP REALLY MUCH BETTER GRANTS IN A DISEASE
6	AREA.
7	AND SO I THINK THAT WE SHOULD I DON'T
8	THINK WE SHOULD STOP DOING GRANTS, BUT I THINK WE
9	SHOULD LOOK AT OUR PORTFOLIO REALLY SERIOUSLY AND
10	HAVE STAFF BRING FORWARD AREAS THAT THEY THINK WE
11	SHOULD ADDRESS AS A BOARD THAT ARE INTERESTING TO
12	US.
13	CHAIRMAN THOMAS: I THINK THAT WAS
14	CONTEMPLATED IN THE PROGRAMMATIC REVIEW PROCESS.
15	AND THAT, I THINK, IS A VERY GOOD IDEA. IT'S ALWAYS
16	GOOD TO KNOW WHAT WE HAVE, WHAT WE'RE WEAK ON, ALL
17	THAT SORT OF THING, ABSOLUTELY.
18	MR. SHESTACK: YOU SAY THAT, BUT WE DON'T
19	DO THAT. WE SPECIFICALLY FOR YEARS HAVE NEVER DONE
20	IT. WHEN WE ASK STAFF TO BE DISEASE SPECIFIC, THEY
21	GET A LITTLE BIT CLOSER AND A LITTLE BIT CLOSER, BUT
22	IT HAS ACTUALLY SORT OF BEEN POLICY TO NOT BE
23	VERY DISEASE TEAMS, YES, ARE SPECIFIC, BUT TO PUT
24	OUT AN RFA THAT DISEASE SPECIFIC IS SOMETHING THAT
25	WE'VE NEVER DONE.

. 1	CHATRAN THOMAS. The NOT CURE THATIS HAVE
1	CHAIRMAN THOMAS: I'M NOT SURE THAT'S WHAT
2	DEAN BRENNER WAS SUGGESTING.
3	DR. BRENNER: EMPHASIZE THAT WE'RE
4	PARTICULARLY INTERESTED IN DISEASES WHEN WE PUT OUT
5	AN RFA. SAY WE RECOGNIZE THIS AS AN UNFULFILLED
6	AREA FOR US.
7	CHAIRMAN THOMAS: THANK YOU. DEAN
8	HAWGOOD.
9	DR. HAWGOOD: I ALSO WOULD LIKE TO SUPPORT
10	THE CONCEPT PAPER, THE SLATE OF MATERIALS, AND JUST
11	PUT FORWARD AS A POSSIBLE SOLUTION TO WHAT I SEE
12	TRYING TO DISENTANGLE THE CRITICALLY IMPORTANT ROLE
13	OF PATIENT ADVOCATES FROM THIS CONFLICT OF INTEREST
14	ISSUE AND PUT FORWARD AS A THOUGHT EXERCISE WHETHER
15	IT WOULD POSSIBLE, JUST AS WE APPOINT SCIENTISTS TO
16	THE SCIENTIFIC REVIEW WHO ARE NOT ATTACHED TO THE
17	BOARD IN ANY WAY, THAT WE APPOINT PATIENT ADVOCATES
18	TO THE SCIENTIFIC REVIEW WORK GROUPS WHO ARE NOT
19	ATTACHED TO THE BOARD IN ANY WAY AND, THEREFORE,
20	DISENTANGLE THE ROLE OF THE PATIENT ADVOCATES ON THE
21	BOARD FROM A DIRECT VOTING ROLE IN THE SCIENTIFIC
22	REVIEW COMMITTEE, BUT PRESERVING A VOTING ROLE FOR
23	PATIENT ADVOCATES ON THE SCIENTIFIC REVIEW
24	COMMITTEE. I JUST PUT IT FORWARD FOR CONSIDERATION.
25	CHAIRMAN THOMAS: I'VE GIVEN THAT ONE A
	202

1	LOT OF THOUGHT. IT'S MY OPINION THAT HAVING A
2	SECOND SLATE OF PATIENT ADVOCATES IS NOT THE BEST
3	WAY TO GO FOR THE FOLLOWING REASONS. I BELIEVE THAT
4	THERE'S GREAT VALUE IN HAVING THE BOARD PATIENT
5	ADVOCATES BEING THERE WHO HAVE CONTINUITY, WHO HAVE
6	INSTITUTIONAL MEMORY, WHO ARE ABLE TO INFORM THEIR
7	LEADING OF THE PROGRAMMATIC REVIEW AT THE BOARD
8	LEVEL BY HAVING BEEN INVOLVED IN THAT.
9	SECONDLY, IF YOU DID HAVE A SECOND SET OF
10	PATIENT ADVOCATES, AND BELIEVE ME IT'S ALWAYS
11	PREFERABLE TO HAVE MORE INPUT THAN NOT, BUT IF YOU
12	HAD THAT, THEIR ROLES, I UNDERSTAND FROM TALKING
13	WITH OS WITH RESPECT TO HOW OTHER AGENCIES AND
14	EVERYTHING ELSE, WOULD ESSENTIALLY BE A PROGRAMMATIC
15	ROLE. THEY WOULDN'T BE INVOLVED IN THE SCIENTIFIC
16	SCORING, SO YOU'D END UP HAVING TWO PROGRAMMATIC
17	REVIEWS, WHICH I'M NOT SURE IS WHAT WE WANT TO DO.
18	BUT I JUST THINK THAT THE OVERRIDING
19	CONTINUITY AND INSTITUTIONAL MEMORY ASPECT OF IT TO
20	ME ARGUES HAVING IT DONE THE WAY I SET FORTH, FOR
21	WHAT THAT'S WORTH.
22	MR. ROTH: SO I WOULD LIKE, ONCE AGAIN, TO
23	GET MY MOTION BACK ON THE FLOOR. AND I BELIEVE WE
24	ARE READY TO VOTE ON THIS CONCEPT PLAN AND THEN
25	BRING IT BACK IN MARCH, AND WE'LL GO THROUGH THE

1	DETAILS AT THAT TIME. THERE'S BEEN SOME WONDERFUL
2	INPUT TODAY. YOU SHOULD TAKE THAT INTO
3	CONSIDERATION WHEN YOU DO THE RULEMAKING. BRING IT
4	BACK TO US, AND WE'LL VOTE INDIVIDUALLY, IF PEOPLE
5	WANT TO DO THAT, ON EACH OF THE ITEMS IN MARCH, BUT
6	I THINK WE'RE READY TO MOVE FORWARD. EVERYBODY HAS
7	HAD THEIR SAY TONIGHT. SOME OF THE PEOPLE WON'T BE
8	HERE TOMORROW. I DON'T WANT TO POSTPONE THIS ANY
9	LONGER. I THINK WE NEED TO TAKE ACTION TODAY.
10	MS. LANSING: I'D LIKE TO SECOND IT.
11	CHAIRMAN THOMAS: IT'S BEEN MOVED AND
12	SECONDED. MR. HARRISON, HOW WOULD WE PHRASE EXACTLY
13	WHAT WE'RE VOTING ON?
14	MR. ROTH: I THINK IT'S THE CONCEPT THAT'S
15	EMBODIED IN
16	CHAIRMAN THOMAS: IN THE OUTLINE.
17	MR. ROTH: IN THE OUTLINE. AND THEN
18	ASK FOR STAFF AND COUNSEL AND OTHERS THAT WANT TO
19	GET INVOLVED IN DRAFTING
20	CHAIRMAN THOMAS: BOARD MEMBERS, PATIENT
21	ADVOCATES, ETC.
22	MR. ROTH: YES.
23	MR. SHESTACK: WHAT IS THE AMENDMENT
24	PROCESS? ZERO?
25	CHAIRMAN THOMAS: WHAT'S THE AMENDMENT
	204
	204

1	PROCESS?
2	MR. ROTH: AT THIS POINT I WOULD NOT THINK
3	WE'D AMEND THIS DOCUMENT. WE'LL DO THAT WHEN WE
4	VOTE INDIVIDUALLY IN MARCH.
5	DR. LUBIN: THIS IS TO KEEP IT ON THE
6	BOARD UNTIL MARCH?
7	CHAIRMAN THOMAS: THIS IS TO PUT THE
8	FRAMEWORK IN PLACE THAT WE'RE GOING TO FOLLOW WITH
9	THE DETAILS TO BE WORKED OUT AT THE MARCH BOARD
10	MEETING.
11	DR. FRIEDMAN: MR. CHAIRMAN, I THINK THE
12	OTHER THING, I THINK, THAT YOU WANT TO MAKE SURE WE
13	GET IS ROBUST INPUT FROM THE PUBLIC AS WELL DURING
14	THAT TWO-MONTH PERIOD, JUST TO NOTE THAT IN THE I
15	KNOW IT WAS IMPLIED IN WHAT YOU WERE SAYING.
16	CHAIRMAN THOMAS: ABSOLUTELY. VERY
17	CRITICAL POINT. THANK YOU, DR. FRIEDMAN.
18	MR. SHESTACK: I DON'T MIND DOING THIS,
19	BUT WE'VE GOTTEN IT TODAY. OTHER PEOPLE SAW IT
20	EARLIER. AND I'M JUST TRYING TO REALLY UNDERSTAND
21	EXACTLY WHAT THE RECOMMENDATIONS ARE. I UNDERSTAND
22	THE RECOMMENDATION ABOUT THE RECUSAL FOR VOTING BY
23	THE DEANS, BY THE 13 OR 14 MEMBERS, IN ICOC
24	MEETINGS, BUT IT DOES NOT MEAN THEY RECUSE
25	THEMSELVES FROM DISCUSSION.
	205

1	CHAIRMAN THOMAS: CORRECT.
2	MR. SHESTACK: BUT THEY'RE RECUSED FROM A
3	VOTE.
4	CHAIRMAN THOMAS: JON, UNLESS THEY HAVE AN
5	INSTITUTIONAL CONFLICT WITH A PARTICULAR GRANT BEING
6	DISCUSSED AS THEY CURRENTLY THAT'S CURRENTLY THE
7	WAY IT IS.
8	MR. SHESTACK: OKAY. AND THEN FOR THE
9	APPEALS, I'M TRYING TO UNDERSTAND HOW THIS IS
10	ACTUALLY DIFFERENT FROM THE PROCESS WE HAVE TODAY
11	OTHER THAN AT ONE POINT THE PROCESS GOT VERY
12	RAUCOUS, BUT WHAT IS THE ACTUAL
13	CHAIRMAN THOMAS: THE DIFFERENCE IS IS
14	THAT THE SCIENTIFIC APPEALS WOULD NOT COME TO THE
15	BOARD. IT WOULD GO STRAIGHT TO STAFF. THEY WOULD
16	EVALUATE AND DECIDE WHAT SHOULD GO FOR FURTHER
17	REVIEW TO THE GRANTS WORKING GROUP, AND THE GRANTS
18	WORKING GROUP WILL MAKE THEIR ANALYSIS AND EITHER
19	AMEND WHAT THEY WERE GOING TO SEND TO THE BOARD FOR
20	PROGRAMMATIC REVIEW OR NOT.
21	MR. SHESTACK: AS OPPOSED TO TODAY WHERE
22	OCCASIONALLY OR AT ONE MEETING I ATTENDED THE BOARD
23	SENT SOMETHING BACK FOR RE-REVIEW. DIDN'T MOVE IT,
24	BUT SENT SOMETHING BACK FOR RE-REVIEW. THAT WOULD
25	NOT BE A BOARD FUNCTION.
	206
	206

1	CHAIRMAN THOMAS: THAT'S NOT GOING TO
2	HAPPEN AT THE BOARD, CORRECT. THIS FULLY EMBODIES
3	THAT THEORY. THE REASON I PUT THAT IN PLACE WAS
4	PRECISELY BECAUSE IT WAS MY VIEW THAT THE ANALYSIS
5	WAS PROPERLY DONE BY THE PEER REVIEW GROUP BECAUSE
6	THE BOARD ISN'T EQUIPPED AS IT'S HEARING SOMETHING
7	ON THE SPOT TO MAKE A DETERMINATION WHETHER A
8	SCIENTIFIC APPEAL HAD MERIT.
9	MR. SHESTACK: RIGHT. BUT THE
10	RECOMMENDATION THE BOARD MADE ONLY WAS TO EXAMINE
11	IT. IT WASN'T AN ACTUAL RE-REVIEW.
12	CHAIRMAN THOMAS: NO. NO. IT WAS
13	CALLED ADDITIONAL ANALYSIS, AND IT WAS FOR A SUBSET
14	OF THE GRANTS WORKING GROUP TO RE-REVIEW.
15	MR. SHESTACK: RIGHT. SO THE BOARD WOULD
16	NO LONGER BE ABLE TO RECOMMEND SOMETHING FOR
17	ADDITIONAL ANALYSIS? THAT WOULD BE EXCLUSIVELY A
18	STAFF
19	CHAIRMAN THOMAS: IT WOULD BE A STAFF
20	THING. IT WOULD COME BACK. NOW, IF IN PROGRAMMATIC
21	REVIEW THE BOARD HAD A SCIENTIFIC QUESTION, IT WOULD
22	HAVE THE ABILITY, IF IT WANTED FURTHER INPUT FROM
23	THE PEER REVIEW GROUP, TO ASK FOR REVIEW AT THAT
24	POINT. YOU CAN NEVER HAVE TOO MUCH GOOD SCIENTIFIC
25	REVIEW.
	207

1	MR. SHESTACK: AND THEN PROGRAMMATIC
2	REVIEW RIGHT NOW OCCURS ACTUALLY SORT OF DE FACTO AT
3	ICOC LEVEL AND AT GRANT WORKING GROUP LEVEL WITH
4	VOTING WITH THE ADVOCATES VOTING, BUT NOT
5	SCORING. AND THIS PROPOSITION, TO CLARIFY, SAYS
6	THERE WOULD BE NO PROGRAMMATIC DISCUSSION AT GRANT
7	WORKING GROUP?
8	CHAIRMAN THOMAS: THERE WOULD BE THE
9	GRANTS WORKING GROUP WOULD BE SCIENTIFIC REVIEW.
10	THE PATIENT ADVOCATES THERE ARE FULLY FREE TO
11	PARTICIPATE, BUT THERE'S NOT GOING TO BE A
12	PROGRAMMATIC REVIEW.
13	MR. SHESTACK: BUT THEY DON'T ACTUALLY
14	PARTICIPATE UNTIL THE PROGRAMMATIC REVIEW PART OF
15	THE SESSION.
16	CHAIRMAN THOMAS: THAT'S TYPICALLY THE
17	CASE, YES, BUT THEY CAN IF THEY HAPPEN TO HAVE, AS
18	FRANCISCO SAID, SCIENTIFIC EXPERTISE THAT IS HELPFUL
19	IN THE DISCUSSION OR QUESTIONS.
20	MR. SHESTACK: MY RECOLLECTION WAS THAT OS
21	HAD SAID THAT HE THOUGHT THAT THAT PROCESS WAS,
22	PARTICULARLY AS A SCIENTIST AND AN ADVOCATE, A
23	VALUABLE PROCESS. THE VOTING PART WAS NOT
24	IMPORTANT, BUT THE PROCESS OF EXAMINATION OF THE
25	GESTALT OF GRANTS WAS IMPORTANT. I WOULD HATE TO
	208
	400

1	SEE IT GONE.
2	AND THEN FOR THE FURTHER CLARIFICATION
3	CHAIRMAN THOMAS: CAN I JUST STOP ON THAT
4	POINT? I THINK THAT'S ONE OF THE DETAILS THAT WILL
5	BE WORKED OUT.
6	MR. SHESTACK: DOES THAT GO TO EACH LEVEL?
7	CHAIRMAN THOMAS: THE DETAILS THAT'S NOT
8	GOING TO BE WORKED OUT ARE NOT GOING TO CHANGE UNTIL
9	WE HAVE OUR TRIAL PERIOD. UNDER MY PLAN THE PATIENT
10	ADVOCATES WOULD NOT HAVE THEIR PROGRAMMATIC VOTE AT
11	THE GRANTS WORKING GROUP. THEY WOULD HAVE IT AT THE
12	BOARD. BUT THE DISCUSSION AND WHAT THE SCIENTISTS
13	WANT TO DO ABOUT EVALUATING, ETC. AND PATIENT
14	ADVOCATE INPUT, THEY'RE FREE TO SPEAK FOR SURE.
15	MR. SHESTACK: AND THE OTHER THING ON THE
16	SEPARATION, SO I UNDERSTAND, THIS WOULD BASICALLY
17	KEEP THE CURRENT RESPONSIBILITIES BETWEEN THE CHAIR
18	AND THE PRESIDENT AS THEY ARE WITH EXPERTISE LIKE IN
19	FINANCIAL ISSUES AND EXTERNAL THINGS BEING KEPT
20	WHERE IT IS. SO NOT EXACTLY THE CONTROLLER'S
21	RECOMMENDATION, BUT THE GROUP HAS DECIDED IN THE
22	PAST.
23	CHAIRMAN THOMAS: IT'S NOT REALLY THE
24	CONTROLLER'S RECOMMENDATION WITH ALL DUE RESPECT TO
25	MY FRIEND RUTH.
	209
	203

1	MR. SHESTACK: BUT IT DOES MAKE SENSE IN
2	TERMS OF THE FINANCIAL EXPERTISE IS OUTSIDE OF THE
3	PRESIDENT'S OFFICE. IT HAPPENS TO BE IN THE CHAIR'S
4	OFFICE.
5	CHAIRMAN THOMAS: I THINK SO.
6	MR. SHESTACK: SO IT WOULD BE THE SAME.
7	THANK YOU FOR THE CLARIFICATION.
8	DR. FEIGAL: AT SOME POINT I'D LIKE TO
9	MAKE SOME COMMENTS.
10	CHAIRMAN THOMAS: DR. FEIGAL, PLEASE.
11	THIS IS A GOOD TIME.
12	DR. FEIGAL: I THINK THE ONLY THING I
13	WOULD JUST WANT TO RAISE FOR THE RECORD IS THAT I
14	THINK THERE ARE SOME CONTINUING ISSUES THAT WILL
15	REQUIRE ADDITIONAL DISCUSSION BETWEEN THE
16	PRESIDENT'S OFFICE AND THE CHAIR. I THINK WHAT J.T.
17	HAS DONE WITH HIS PROPOSAL, CHAIRMAN THOMAS, HAS
18	MADE THE CHANGE THAT IF WE SEE THE NEED FOR A CFO,
19	THAT THAT WOULD BE REPORTING TO THE PRESIDENT.
20	RIGHT NOW I BELIEVE IT WAS A DUAL ROLE, AND THAT WAS
21	CHANGED.
22	CHAIRMAN THOMAS: CORRECT. I WILL SAY,
23	HOWEVER, THAT I WOULD KEEP THE BOND FINANCING IN THE
24	OFFICE OF THE CHAIR.
25	DR. FEIGAL: SO THE ONLY THING I DO JUST
	210

1	WANT TO SAY FOR THE RECORD IS I THINK THERE STILL
2	ARE SOME DISCUSSION ITEMS THAT WILL CONTINUE BETWEEN
3	THE CHAIR AND THE OFFICE OF THE PRESIDENT BECAUSE I
4	THINK THEY'RE NOT EXACTLY ALIGNED.
5	MR. ROTH: I THINK WE HAVE AN AGREEMENT ON
6	THAT WE WILL SIT DOWN AND DISCUSS THIS.
7	CHAIRMAN THOMAS: CORRECT.
8	MR. TORRES: BUT WE'VE VISITED THIS
9	BEFORE, AND IT TOOK TWO YEARS OF OUR ENERGY AND
10	SWEAT TO COME TO A CONCLUSION, WHICH THEN THE BOARD
11	VOTED UNANIMOUSLY TO ADOPT THE INTERNAL GOVERNANCE
12	PROCEDURES WHICH WE NOW HAVE IN PLACE. I THINK
13	THAT'S WHAT MY OTHER VICE CHAIR WAS TALKING ABOUT AS
14	WELL EARLIER.
15	DR. FEIGAL: ALL I'M DOING WITH THIS IS
16	FOR THE RECORD JUST LETTING IT BE CLEAR
17	MR. TORRES: THAT'S ALL I'M DOING AS WELL
18	FOR THE RECORD.
19	DR. FEIGAL: FOR OUR ISSUES. THAT'S
20	ALL I'M DOING. CLEAR.
21	MR. TORRES: THAT'S ALL I'M DOING TOO FOR
22	THE RECORD. IT WAS PASSED UNANIMOUSLY BY THE BOARD.
23	CHAIRMAN THOMAS: WHAT WE'RE GOING TO VOTE
24	ON TODAY IS THE FRAMEWORK WITH RESPECT TO THE CHAIR
25	AND THE PRESIDENT THAT I SET FORTH IN THE PLAN.
	211
	411

MS. SAMUELSON: ANOTHER QUESTION ABOUT THE
PLAN. DOES IT INCLUDE EQUAL PARTICIPATION IN
DISCUSSIONS BY ALL THE SCIENTIFIC MEMBERS, THE
INSTITUTIONAL MEMBERS, AS WELL AS THE PATIENT
ADVOCATES? AND THEN I HAVE THE SAME QUESTION FOR
ACCESS TO DOCUMENTS, THE APPLICATIONS AND CRITIQUES
AND SO ON.
CHAIRMAN THOMAS: YOUR FIRST QUESTION IS
IN WHICH CONTEXT, IN THE BOARD?
MS. SAMUELSON: IN THE CONTEXT OF ANY
CONTEXT IN WHICH THERE'S A PROPOSAL TO CHANGE THE
STATUS, EITHER GRANTS WORKING GROUP OR THE BOARD.
CHAIRMAN THOMAS: I THINK IF THE QUESTION
IS
MS. SAMUELSON: MAYBE WE SHOULD SEPARATE
IT OUT.
CHAIRMAN THOMAS: IF THE QUESTION IS WILL
PATIENT ADVOCATES BE ABLE TO PARTICIPATE IN THE
GRANTS WORKING GROUP DISCUSSION, YES. WILL THE
INSTITUTIONAL MEMBERS BE ABLE TO PARTICIPATE IN THE
BOARD DISCUSSIONS? YES. JUST NO VOTES IN EITHER
CONTEXT.
MS. SAMUELSON: SO ONE OF THE AWKWARD AND
UNPRODUCTIVE THINGS THAT NOW HAPPENS, WHICH IS THAT
THERE CAN'T BE A DISCUSSION LATER, WHENEVER LATER,
212

1	ABOUT ANY SORT OF CONTENT OF A GRANT THAT WAS
2	PROPOSED THAT ONE OF THE REVIEWERS WAS RECUSED FROM.
3	SO THAT WOULD NO LONGER BE AN OBSTACLE TO A
4	PRODUCTIVE DISCUSSION?
5	CHAIRMAN THOMAS: WELL, YOU MEAN RECUSED
6	BECAUSE IT'S THEIR INSTITUTION?
7	MS. SAMUELSON: WELL, WHATEVER REASON THAT
8	THEY WERE BEFORE. I'M TRYING TO SEE THE COMPARABLE
9	SITUATION THAT WILL ARISE BECAUSE THAT WOULD BE A
10	VERY ATTRACTIVE COMPONENT TO ME, TO HAVE THE FREE
11	DISCUSSION AMONG ALL OF THE MEMBERS OF THE WORKING
12	GROUP OR THE ICOC.
13	CHAIRMAN THOMAS: IT'S IMPORTANT TO NOTE
14	THAT IF YOU ARE, FOR EXAMPLE, AN INSTITUTIONAL
15	MEMBER AND A GRANT COMES UP IN PROGRAMMATIC REVIEW
16	DISCUSSION THAT PERTAINS TO YOUR INSTITUTION, YOU
17	ARE STILL CONFLICTED OUT OF THAT DISCUSSION JUST AS
18	IT IS TODAY.
19	MS. SAMUELSON: BUT NOT AS BROADLY
20	CHAIRMAN THOMAS: JAMES, WOULD YOU LIKE TO
21	COMMENT ON THIS?
22	MR. HARRISON: THOSE RULES WOULD BE
23	EXACTLY THE SAME. TO THE EXTENT THAT A MEMBER HAS
24	AN ACTUAL CONFLICT AS OPPOSED TO WHAT WE'RE
25	ADDRESSING AS A DUALITY OF INTEREST OR A PERCEPTION
	213
	213

1 OF CONFLICT, THE RULES WOULD BE EXACTLY THE SAME.	
2 THAT INDIVIDUAL WOULD BE PRECLUDED FROM	
3 PARTICIPATING IN ANY DISCUSSION OR EVEN ATTEMPTING	
4 TO INFLUENCE THE OUTCOME OF A DECISION BY DISCUSSING	
5 IT WITH OTHER MEMBERS.	
6 MS. SAMUELSON: THAT IS RESTRICTED TO	
7 LET'S SAY IT'S A MEMBER WHO IS A BOARD MEMBER AT	
8 BECAUSE OF THEIR INSTITUTION AND THEIR INSTITUTION	
9 IS THE APPLICANT.	
10 CHAIRMAN THOMAS: CORRECT.	
MS. SAMUELSON: THAT'S THE SOLE INSTANCE	
12 IN WHICH THAT'S APPLIED, RIGHT?	
CHAIRMAN THOMAS: REMEMBER, THAT WOULD	
14 APPLY WHETHER IT'S A MEMBER OF AN INSTITUTION OR	
15 IT'S A PATIENT ADVOCATE WHO HAS AFFILIATION WITH THE	
16 SAME INSTITUTION GIVING RISE TO A POTENTIAL CONFLICT	
17 JUST AS IT IS NOW.	
MS. SAMUELSON: AFFILIATION BEING AS AN	
19 EMPLOYEE.	
CHAIRMAN THOMAS: FOR EXAMPLE, UCSF, MR.	
SHEEHY, FOR EXAMPLE, NOT TO SINGLE YOU OUT, MR.	
22 SHEEHY, BUT IT'S AN INSTRUCTIVE EXAMPLE. AND ON	
THAT NOTE, WE'LL SEGUE OVER TO COMMENT BY MR.	
24 SHEEHY.	
MR. SHEEHY: I JUST WANTED TO CLARIFY	
214	

1	ABOUT MY DIGGING IN ON A VOTE AT THE WORKING GROUP.
2	IN MY VISION OF HOW THIS WOULD WORK, I ACTUALLY AM
3	SUPPORTIVE OF HAVING PROGRAMMATIC REVIEW AT THE
4	BOARD. BUT IN MY VISION FOR THIS, AND WHAT I'VE
5	HEARD FROM SCIENTISTS BECAUSE A LOT OF THE
6	SCIENTISTS HAVE NEVER ENJOYED PROGRAMMATIC REVIEW,
7	SOME DO, BUT MANY DON'T, IS THAT THERE WOULD BE MORE
8	OR LESS A FAIRLY PURE REPORTING OF THE SCIENTIFIC
9	SCORES, WHICH IS WHAT THEY'D LIKE TO DO. WHAT I'M
10	WORRIED ABOUT THE VOTE IS ON THE POLICY ISSUES. I'M
11	WORRIED ABOUT THE VOTE AT THE STANDARDS WORKING
12	GROUP. I'M WORRIED ABOUT LOSING THE RIGHT TO
13	PARTICIPATE AS A FULL MEMBER.
14	BUT I DON'T THINK INDIVIDUAL GRANTS SHOULD
15	ACTUALLY BE LOOKED AT AT THE WORKING GROUP UNDER
16	THIS SCHEME. WHAT YOU MIGHT USE THEM TO DO IS TO
17	SET A LINE, BUT THAT'S ALL THEY WANT TO DO ANYWAY.
18	THEN THEY WANT TO GET ON THEIR PLANE. ABOUT HALF TO
19	TWO-THIRDS WANT TO GET ON THEIR PLANE AND GO HOME,
20	WHICH IS FINE. THAT'S FAIR. AND I THINK THAT'S
21	WHAT YOU'RE TRYING TO ADDRESS, AND THAT KIND OF
22	ADDRESSES THAT DUAL VOTE BECAUSE IT'S REALLY NOT A
23	VOTE. THEY'RE GOING TO PICK A NUMBER, 70, 65.
24	SO I'M VERY COMFORTABLE WITH THE WORKING
25	GROUP NOT DOING PROGRAMMATIC REVIEW. WHAT I GET
	215

1	WORRIED ABOUT IS THAT IT BECOMES A DE FACTO
2	PROGRAMMATIC REVIEW BECAUSE THERE'S A DISCUSSION OF
3	INDIVIDUAL GRANTS AFTER THERE'S BEEN THE SCIENTIFIC
4	SCORING. TO BE A TRUE PROGRAMMATIC REVIEW, THE
5	SCIENTIFIC SCORES SHOULD BE SENT UP WITH SOME
6	RECOMMENDED FUNDING LINE. AND THEN UP HERE AT THE
7	BOARD, WE'LL DO WHAT WE'VE BEEN DOING AT THE WORKING
8	GROUP.
9	NOW, I'M VERY SUPPORTIVE OF THAT. I THINK
10	THAT IT PROVES TRANSPARENCY, LET'S MORE PEOPLE BE
11	INVOLVED. BUT MY CONCERN AND WHAT I'M TRYING TO GET
12	AT IS I DON'T WANT TO LOSE A FORMAL VOTING RIGHT AT
13	THAT PLACE, AND I DON'T WANT TO SEE THAT DEVOLVE
14	INTO SORT OF A DE FACTO PROGRAMMATIC REVIEW WHERE
15	YOU HAVE THE SCIENTISTS KIND OF PLAYING AROUND WITH
16	THEIR GRANTS, WHICH THEY DON'T WANT TO DO. IN
17	CONTRADICTION TO OS, I REALLY DON'T THINK THEY OUGHT
18	TO REALLY LOOK AT THEM, THEY DON'T WANT TO, AFTER
19	THEY'VE SCORED THEM, AND WE CAN KIND OF HAVE THAT UP
20	HERE. THAT'S WHAT I'M TALKING ABOUT.
21	SO WHEN YOU START TALKING ABOUT TAKING
22	AWAY OUR VOTE, THAT'S WHERE I GET KIND OF CONFUSED
23	ON THAT. AND THE WAY I KIND OF UNDERSTOOD THAT WE
24	WERE PROCEEDING WAS ALONG THE LINES OF PURELY
25	SENDING THE SCORES UP WITH SOME SORT OF FUNDING

I	
1	LEVEL INDICATED AND LETTING THE BOARD DO THAT WORK
2	THAT'S BEEN DONE AT THE WORKING GROUP. SO THAT'S
3	WHERE I'M CONFUSED. THAT'S WHERE MY UNDERSTANDING
4	HAS BEEN OFF BASE.
5	IN GENERAL, I SUPPORT WHAT I JUST
6	DESCRIBED AND WOULD THINK IT WOULD BE A GREAT
7	EXPERIMENT. I THINK THAT ADDRESSES WHAT THE IOM WAS
8	WORRIED ABOUT, THAT WE GOT TWO BITES AT THE APPLE.
9	CHAIRMAN THOMAS: YES. AND BOARD
10	VOTING YES, THAT'S RIGHT. SHERRY, I THINK WE'RE
11	GETTING CLOSE TO A VOTE HERE.
12	JEFF, I THINK THE POINT, ALL OF THE POINTS
13	YOU RAISE ARE THE DETAILS WE'LL WORK OUT BETWEEN NOW
14	AND MARCH. POINT TAKEN. AND SO THANK YOU.
15	ANY OTHER COMMENTS? HEARING NONE, MR.
16	HARRISON, COULD YOU JUST REPEAT THE MOTION AND WE
17	WILL TAKE A ROLL CALL VOTE.
18	MR. HARRISON: THE MOTION IS TO APPROVE
19	THE CONCEPT PLAN AS OUTLINED IN THE POWERPOINT
20	PRESENTED BY THE CHAIRMAN WITH DIRECTION TO STAFF TO
21	DRAFT PROPOSALS TO IMPLEMENT THE CONCEPTS WITH INPUT
22	FROM BOARD MEMBERS CONSISTENT WITH BAGLEY-KEENE,
23	PATIENT ADVOCATES, AND MEMBERS OF THE PUBLIC, AND
24	PRESENT THE PROPOSALS TO THE BOARD FOR ITS
25	CONSIDERATION IN MARCH.
	24-

,	DARKISIERS REPORTING SERVICE
1	CHAIRMAN THOMAS: I WOULD LIKE TO ADD TO
2	THAT, MR. HARRISON, AS I DID, A FRIENDLY AMENDMENT,
3	WHICH WOULD INCLUDE A ONE-YEAR TRIAL PERIOD, AND
4	I'LL TAKE ANNE-MARIE'S ADVICE, UP TO ONE YEAR. IF
5	WE SEE THINGS AREN'T WORKING, OBVIOUSLY WE DON'T
6	WANT TO GO A YEAR INTO IT MAKES PERFECT SENSE. WITH
7	RESPECT TO THE PROGRAMMATIC REVIEW ELEMENT AND THE
8	PATIENT ADVOCATE ROLE, AS WELL AS THE CONFLICTS
9	RESOLUTION THAT I PUT FORTH, TO HAVE THAT ON AN UP
10	TO ONE-YEAR TRIAL PERIOD.
11	MR. ROTH: AMENDMENT IS ACCEPTED.
12	MS. LANSING: YES.
13	MS. WINOKUR: IN ONE SENTENCE YOU SAID BY
14	THE MEMBERS AND THE ADVOCATES.
15	CHAIRMAN THOMAS: WHICH SENTENCE WAS THAT?
16	MS. WINOKUR: WELL
17	CHAIRMAN THOMAS: BEEN A LOT OF SENTENCES
18	TODAY.
19	MS. WINOKUR: MY POINT IS THAT THE
20	ADVOCATES ARE MEMBERS.
21	CHAIRMAN THOMAS: MEMBERS, I MEAN THE
22	GROUP OF 13 INSTITUTIONAL MEMBERS.
23	MS. WINOKUR: CALL THEM INSTITUTIONAL
24	MEMBERS.
25	CHAIRMAN THOMAS: I'M TRYING, BUT
	218

1	OCCASTONALLY I LARSE THTO SHORTHAND OVAY WITH
	OCCASIONALLY I LAPSE INTO SHORTHAND. OKAY. WITH
2	THAT, I THINK WE ARE PREPARED FOR A VOTE, MR.
3	HARRISON.
4	MR. HARRISON: YES.
5	MS. BONNEVILLE: DAVID BRENNER.
6	DR. BRENNER: APPROVE.
7	MS. BONNEVILLE: ANNE-MARIE DULIEGE.
8	DR. DULIEGE: APPROVE.
9	MS. BONNEVILLE: MARCY FEIT. MICHAEL
10	FRIEDMAN.
11	DR. FRIEDMAN: YES.
12	MS. BONNEVILLE: LEEZA GIBBONS. MICHAEL
13	GOLDBERG.
14	MR. GOLDBERG: YES.
15	MS. BONNEVILLE: SAM HAWGOOD.
16	DR. HAWGOOD: YES.
17	MS. BONNEVILLE: STEPHEN JUELSGAARD.
18	DR. JUELSGAARD: AYE.
19	MS. BONNEVILLE: SHERRY LANSING.
20	MS. LANSING: YES.
21	MS. BONNEVILLE: JACOB LEVIN.
22	DR. LEVIN: YES.
23	MS. BONNEVILLE: BERT LUBIN.
24	DR. LUBIN: YES.
25	MS. BONNEVILLE: MICHAEL MARLETTA.
	219

1	DR. MARLETTA: ABSTAIN.
2	MS. BONNEVILLE: SHLOMO MELMED.
3	DR. MELMED: YES.
4	MS. BONNEVILLE: CLAIRE POMEROY.
5	DR. POMEROY: YES.
6	MS. BONNEVILLE: ROBERT PRICE.
7	DR. PRICE: YES.
8	MS. BONNEVILLE: FRANCISCO PRIETO.
9	DR. PRIETO: AYE.
10	MS. BONNEVILLE: CARMEN PULIAFITO. ROBERT
11	QUINT.
12	DR. QUINT: YES.
13	MS. BONNEVILLE: DUANE ROTH.
14	MR. ROTH: YES.
15	MS. BONNEVILLE: JOAN SAMUELSON.
16	MS. SAMUELSON: NO. STRICTLY ON TIMING
17	CONCERN WITH THE COMMENTS THAT THE PUBLIC HAS NOT
18	HAD TIME TO RESPOND.
19	MS. BONNEVILLE: JEFF SHEEHY.
20	MR. SHEEHY: YES.
21	MS. BONNEVILLE: JONATHAN SHESTACK.
22	MR. SHESTACK: YES.
23	MS. BONNEVILLE: OSWALD STEWARD.
24	DR. STEWARD: YES.
25	MS. BONNEVILLE: JONATHAN THOMAS.
	220

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1	CHAIRMAN THOMAS: YES.
2	MS. BONNEVILLE: ART TORRES.
3	MR. TORRES: AYE, EXCEPT FOR THOSE WITH
4	WHICH I HAVE A CONFLICT. I ALWAYS WANTED TO SAY
5	THAT.
6	MS. BONNEVILLE: KRISTINA VUORI.
7	DR. VUORI: YES.
8	MS. BONNEVILLE: EUGENE WASHINGTON. DIANE
9	WINOKUR.
10	MS. WINOKUR: YES.
11	CHAIRMAN THOMAS: MR. HARRISON.
12	MS. SAMUELSON: I WOULD LIKE TO CHANGE MY
13	VOTE TO YES.
14	CHAIRMAN THOMAS: LET THE RECORD SO
15	INDICATE.
16	MR. HARRISON: THE MOTION CARRIES.
17	MS. LANSING: CAN I SAY SOMETHING FOR ONE
18	SECOND? I JUST WANT TO SAY SOMETHING. I KNOW THIS
19	HAS BEEN A VERY, VERY DIFFICULT PROCESS FOR ALL OF
20	US. AND I JUST WANT TO COMMEND OUR LEADER J.T.
21	BECAUSE THE AMOUNT OF WORK
22	(APPLAUSE.)
23	CHAIRMAN THOMAS: THANK YOU.
24	MS. LANSING: I'M GOING TO FINISH MY
25	SENTENCE DESPITE THE APPLAUSE. THE AMOUNT OF WORK
	221

1	THAT WENT INTO THIS IS EXTRAORDINARY. AND TO GET
2	THIS KIND OF A VOTE FROM THIS BOARD THAT IS SO
3	PASSIONATE AND CARES SO MUCH IS REALLY THE EXAMPLE
4	OF TRUE LEADERSHIP. AND SO I WANT TO SAY AGAIN ON
5	BEHALF OF ALL OF US HOW GRATEFUL WE ARE TO HAVE YOU.
6	CHAIRMAN THOMAS: THANK YOU. YOU'RE ALL
7	OVERLY KIND, AND I JUST WANT TO THANK EVERYBODY FOR
8	THEIR PARTICIPATION TODAY. I THINK THIS WAS AN
9	EXTREMELY IMPORTANT STEP. WE'LL BE VIEWED AS VERY
10	RESPONSIVE, AS WE'VE SAID, AND WE CAN NOW PROCEED TO
11	HAVE ALL STAKEHOLDERS GIVE INPUT TO FILL IN THE
12	DETAILS AS WE PROCEED TO MARCH.
13	SO I WILL TURN SHERRY'S THANK YOU AROUND
14	TO ALL OF YOU AND ALL OF YOU IN THE AUDIENCE AS WE
15	MOVE ON HERE. AND I THINK WE'VE DONE THE RIGHT
16	THING, AND IT WILL BE VIEWED AS SUCH.
17	I'D LIKE TO END ON ONE LAST NOTE, WHICH IS
18	I DON'T KNOW IF EVERYBODY KNOWS, CLAIRE, WOULD YOU
19	LIKE TO MAKE AN ANNOUNCEMENT TO EVERYBODY?
20	DR. POMEROY: THANK YOU, J.T. I WANT TO
21	LET EVERYBODY KNOW HOW MUCH I ENJOYED BEING ON THIS
22	COMMITTEE, AND I WILL CONTINUE TO DO SO RIGHT UP
23	UNTIL THE TIME THAT I TAKE MY NEW ROLE AS PRESIDENT
24	OF THE LASKER FOUNDATION THIS SPRING. THANK YOU
25	VERY MUCH.
	222
	222

1	(APPLAUSE.)
2	CHAIRMAN THOMAS: IT'S COLD RIGHT NOW BACK
3	IN NEW YORK, CLAIRE.
4	DR. POMEROY: WITH LOTS OF INTELLECTUAL
5	EXCITEMENT AS THERE IS HERE TODAY.
6	CHAIRMAN THOMAS: THANK YOU. THANK YOU.
7	AND, LADIES AND GENTLEMEN, MARIA WOULD LIKE TO
8	COMMENT ON DINNER, VERY IMPORTANT.
9	MS. BONNEVILLE: IT IS IMPORTANT. WE'RE
10	GOING TO HAVE APPETIZERS AT 6:00 AND THEN DINNER IS
11	AT 6:30. YOU HAVE AN HOUR TO YOURSELVES. I'M SURE
12	YOU'LL LIKE THAT, THE PEACE AND QUIET. AND IT'S
13	DOWNSTAIRS IN THE ROOM NEXT TO THE PARAGON
14	RESTAURANT. I THINK IT'S CALLED THE PANORAMA ROOM.
15	SO THERE YOU GO.
16	CHAIRMAN THOMAS: THANK YOU. WE STAND
17	ADJOURNED UNTIL 9 A.M. TOMORROW MORNING FOR THE
18	REGULARLY SCHEDULED MEETING OF THE BOARD. THANK YOU
19	AGAIN.
20	(THE WORKSHOP WAS THEN CONCLUDED AT
21	04:59 P.M.)
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23	
24	
25	
	223

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

CLAREMONT HOTEL
41 TUNNEL ROAD
BERKELEY, CALIFORNIA
ON
JANUARY 23, 2013

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

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