

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: WESTIN BONAVENTURE HOTEL
404 FIGUEROA STREET
LOS ANGELES, CALIFORNIA

DATE: APRIL 28, 2009
4:30 P.M.

REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

BRS FILE NO.: 82460

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION NO.	PAGE
CALL TO ORDER	3
ROLL CALL	3
CONSENT ITEMS:	
APPROVAL OF TECHNICAL AMENDMENTS TO GRANTS	53
REPORTS:	
CHAIRMAN' S REPORT.	5
PRESIDENT' S REPORT.	8
COMMUNICATIONS REPORT	54
ACTION ITEMS:	
CONSIDERATION OF RECOMMENDATIONS FROM GRANTS WORKING GROUP ON EARLY TRANSLATIONAL RESEARCH AWARDS APPLICATIONS.	141
CLOSED SESSION	
CONSIDERATION OF NEW SCIENTIFIC MEMBERS FOR GRANTS WORKING GROUP.	72
CONSIDERATION OF EVALUATION PROCEDURES FOR PERFORMANCE EVALUATION FOR CHAIR, VICE-CHAIR, AND PRESIDENT.	
CONSIDERATION OF FEDERAL LEGISLATION, H. R. 1427 AND H. R. 1548.	85
CONSIDERATION OF COMMENTS ON NIH DRAFT GUIDELINES FOR RESEARCH UTILIZING HUMAN EMBRYONIC STEM CELLS.	74
PUBLIC COMMENT.	

BARRISTERS' REPORTING SERVICE

1 LOS ANGELES, CALIFORNIA; TUESDAY, APRIL 28, 2009

2 4:30 A.M.

3
4 VICE CHAIRMAN ROTH: SO I'M GOING TO CALL
5 THE MEETING TO ORDER. AND I WANT TO BEGIN BY JUST
6 EXPLAINING WHY CHAIRMAN KLEIN IS NOT HERE. HE'S
7 DEALING WITH A MEDICAL PROBLEM WITH HIS WIFE
8 DANIELLE AND IS EXPECTED TO BE HERE IN SEVERAL
9 HOURS. SO WHEN HE GETS HERE, IF HE SO CHOOSES TO
10 TELL US THE STATUS OF THAT, WE'LL LEARN OF IT AT
11 THAT TIME.

12 SO WITH THAT, PLEDGE OF ALLEGIANCE.

13 (THE PLEDGE OF ALLEGIANCE.)

14 VICE CHAIRMAN ROTH: OKAY. MELISSA, COULD
15 YOU PLEASE READ THE ROLL.

16 MS. KING: WE ARE JUST ABOUT TO GO THROUGH
17 THE ROLL CALL. THANK YOU SO MUCH FOR JOINING US.

18 RICARDO AZZIZ. ROBERT PRICE FOR ROBERT
19 BIRGENEAU.

20 DR. PRICE: HERE.

21 MS. KING: FLOYD BLOOM.

22 DR. BLOOM: HERE.

23 MS. KING: DAVID BRENNER.

24 DR. BRENNER: HERE.

25 MS. KING: JACOB LEVIN FOR SUSAN BRYANT.

BARRISTERS' REPORTING SERVICE

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DR. LEVIN: HERE.

MS. KING: MARSHA CHANDLER. MARCY FEIT.
MICHAEL FRIEDMAN. LEEZA GIBBONS. MICHAEL GOLDBERG.
SAM HAWGOOD.

DR. HAWGOOD: HERE.

MS. KING: BOB KLEIN. SHERRY LANSING.
GERALD LEVEY.

DR. LEVEY: HERE.

MS. KING: TED LOVE.

DR. LOVE: HERE.

MS. KING: ED PENHOET.

DR. PENHOET: HERE.

MS. KING: PHIL PIZZO. CLAIRE POMEROY.
FRANCISCO PRIETO. CARMEN PULIAFITO.

DR. PULIAFITO: HERE.

MS. KING: ROBERT QUINT. JEANNIE FONTANA
FOR JOHN REED.

DR. FONTANA: HERE.

MS. KING: DUANE ROTH.

MR. ROTH: HERE.

MS. KING: JOAN SAMUELSON. DAVID
SERRANO-SEWELL. JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. KING: JON SHESTACK. OSWALD STEWARD.

DR. STEWARD: HERE.

BARRISTERS' REPORTING SERVICE

1 MS. KING: ART TORRES.

2 MR. TORRES: HERE.

3 VICE CHAIRMAN ROTH: JUST FOR THE RECORD,
4 WE DO NOT HAVE A QUORUM AT THIS POINT. SO WHAT I
5 WOULD LIKE TO DO IS MOVE TO A PORTION OF THE
6 CHAIRMAN'S REPORT. OBVIOUSLY BOB IS NOT HERE TO
7 GIVE IT, BUT I'M GOING TO ASK JAMES.

8 (INTERRUPTION.)

9 VICE CHAIRMAN ROTH: JAMES, IF YOU AND
10 LYNN WOULD PLEASE GIVE US AN UPDATE ON THE STATUS OF
11 THE FINANCIAL SALE OF BONDS.

12 (INTERRUPTION.)

13 MR. HARRISON: ALL RIGHT. WITH THAT
14 INTRODUCTION, I'M JAMES HARRISON. AND BECAUSE
15 CHAIRMAN KLEIN IS NOT HERE, I WANTED TO GIVE A BRIEF
16 UPDATE REGARDING THE STATUS OF THE STATE'S RECENT
17 BOND SALE AND CIRM'S PARTICIPATION IN IT. AND FIRST
18 OF ALL, I SHOULD SAY THAT I WISH BOB WERE HERE
19 BECAUSE HE MADE A TREMENDOUS EFFORT, ALONG WITH LYNN
20 HARWELL, TO ACHIEVE THE RESULTS THAT WE WERE ABLE TO
21 ACHIEVE HERE. SO THERE'S A LOT OF CREDIT TO GO TO
22 BOB AND TO LYNN.

23 BUT LET ME TELL YOU WHAT HAPPENED. LAST
24 WEEK THE STATE DID A TAXABLE BOND SALE IN THE TOTAL
25 AMOUNT OF 6.85 BILLION. A PORTION OF THIS BOND SALE

BARRISTERS' REPORTING SERVICE

1 WAS WHAT ARE CALLED BUILD AMERICA BONDS, WHICH IS A
2 VEHICLE THAT WAS CREATED UNDER THE FEDERAL STIMULUS
3 PROGRAM PURSUANT TO WHICH A STATE CAN ISSUE TAXABLE
4 BONDS FOR WHAT ARE ESSENTIALLY TAX-EXEMPT PURPOSES
5 AND THEN GET A 35-PERCENT CASH SUBSIDY ON THE
6 INTEREST RATE BACK FROM THE FEDERAL GOVERNMENT. SO
7 IT'S HIGHLY BENEFICIAL TO THE STATE OF CALIFORNIA.

8 WE WORKED WITH THE TREASURER'S OFFICE TO
9 TRY TO DETERMINE WHETHER CIRM'S PROJECTS COULD FIT
10 WITHIN THE BUILD AMERICA BOND PROGRAM AND ULTIMATELY
11 DETERMINED THAT THE MAJOR FACILITIES PROGRAMS COULD
12 INDEED FIT WITHIN THE BUILD AMERICA BOND PROGRAM.

13 SO ULTIMATELY OUT OF THIS \$6.85 BILLION
14 BOND SALE, CIRM WILL RECEIVE \$505 MILLION. LET ME
15 BREAK THAT DOWN BECAUSE IT'S IMPORTANT TO
16 UNDERSTAND. AS YOU MAY RECALL, CIRM HAS A LOAN FROM
17 THE POOLED MONEY INVESTMENT ACCOUNT OF 250.64
18 MILLION. OF THAT 505 MILLION, THEN 250 MILLION WILL
19 GO BACK TO PAYING THE PMIA.

20 ON TOP OF THAT, CIRM WAS ABLE TO GET
21 APPROXIMATELY 32.05 MILLION FOR THREE OUTSTANDING
22 MAJOR FACILITIES PROJECTS: MERCED, SANTA CRUZ, AND
23 BUCK. THOSE ALL QUALIFIED UNDER THE BUILD AMERICA
24 PROGRAM, SO THE STATE WAS ABLE TO SELL THOSE BONDS
25 ON VERY FAVORABLE TERMS.

BARRISTERS' REPORTING SERVICE

1 IN ADDITION, OF THE 250 MILLION THAT WILL
2 BE REPAYED TO THE PMIA, APPROXIMATELY 195 MILLION OF
3 THAT WILL COME OUT OF THE BUILD AMERICA BOND
4 PROCEEDS, AGAIN, ON VERY FAVORABLE TERMS TO THE
5 STATE.

6 WHAT THAT LEAVES IS TWO OTHER COMPONENTS.
7 CIRM WILL GET APPROXIMATELY 200 MILLION FOR ITS
8 RESEARCH PROGRAMS OUT OF THIS BOND SALE. AND IN
9 ADDITION, WE WILL ALSO GET AND HAVE ACTUALLY ALREADY
10 RECEIVED A \$43 MILLION LOAN FROM THE POOLED MONEY
11 INVESTMENT ACCOUNT FOR THE SANFORD CONSORTIUM. SO
12 ALL OF OUR MAJOR FACILITIES NEEDS HAVE BEEN TAKEN
13 CARE OF BY THIS BOND SALE, AND IN ADDITION WE HAVE
14 \$200 MILLION IN ADDITIONAL FUNDING FOR OUR RESEARCH
15 PROGRAMS. SO IT'S A VERY FAVORABLE OUTCOME.

16 JOHN ROBSON WILL TELL YOU MORE ABOUT HOW
17 THIS AFFECTS CIRM'S FINANCES. IT'S IMPORTANT TO
18 NOTE THAT WE CONTINUE TO HAVE AUTHORITY UNDER THE
19 PRIVATE PLACEMENT RESOLUTION ADOPTED BY THE FINANCE
20 COMMITTEE, AND WE WILL CONTINUE TO WORK ON PRIVATE
21 PLACEMENTS TO ENSURE THAT WE MEET ALL OF OUR PROGRAM
22 NEEDS. BUT IT'S VERY GOOD NEWS. AND, AGAIN, A LOT
23 OF THE CREDIT GOES TO LYNN HARWELL AND TO BOB KLEIN
24 AND EVERYONE ELSE WHO WORKED WITH THEM. THANK YOU.

25 (APPLAUSE.)

BARRISTERS' REPORTING SERVICE

1 MR. TORRES: MR. CHAIRMAN, I WANT TO THANK
2 JAMES AND LYNN AND OBVIOUSLY BOB WHO WORKED VERY
3 HARD ON THIS, BUT LET'S KEEP IN MIND AS WELL THAT
4 WITHOUT THE HELP AND COORDINATION OF OUR STATE
5 TREASURER, MR. LOCKYEAR, AND HIS STAFF, A LOT OF
6 THIS WOULD NOT HAVE HAPPENED. THANK GOD THERE WAS A
7 GOOD MESH OF PEOPLE WORKING TOGETHER VERY
8 EFFECTIVELY. AND THE WAY THESE NUMBERS LOOK FOR
9 THESE INITIATIVES, I'M GLAD WE GOT OUR MONEY AHEAD
10 OF TIME.

11 VICE CHAIRMAN ROTH: OTHER COMMENTS OR
12 QUESTIONS FOR JAMES OR LYNN? SO THANK YOU, GUYS.
13 NICELY DONE.

14 ALL RIGHT. THE NEXT ITEM IS THE
15 PRESIDENT'S REPORT, ALAN.

16 AND FOR THE RECORD, LEEZA GIBBONS HAS
17 ARRIVED. IS THERE ANYBODY ON THE PHONE? IF THERE
18 ARE ANY PEOPLE ON THE PHONE, COULD YOU PLEASE TELL
19 US YOU'RE THERE? OKAY. LET'S GO AHEAD, ALAN.

20 DR. TROUNSON: THANK YOU VERY MUCH, DUANE.
21 AND WE'RE WISHING THE VERY, VERY BEST TO BOB AND
22 DANIELLE. IT'S A VERY TOUGH TIME FOR THEM. AND
23 THANK YOU FOR STEPPING IN AS CHAIR OF THIS SESSION.
24 HOPEFULLY THE NEWS FOR THEM WILL BE GOOD AS IT WAS
25 FOR ALL OF THE FINANCES OF THE OPERATIONS.

BARRISTERS' REPORTING SERVICE

1 SO I WANT TO BEGIN, IF I MAY, REALLY TO
2 TALK TO YOU AGAIN ABOUT, AS I USUALLY DO, ABOUT THE
3 SCIENCE AND WHAT'S HAPPENING IN THIS SPACE. AND
4 IT'S A VERY INTERESTING TIME, I THINK. THE FIRST
5 ONE I WANT TO BRING TO YOUR ATTENTION IS A STUDY
6 THAT WAS DONE IN A VERY INTERESTING WAY. IT'S HARD
7 FOR ME TO READ THAT. I DON'T HAVE ANYTHING A BIT
8 CLOSER. OLD MAN'S EYESIGHT DISAPPEARING A BIT.
9 THIS ONE IS A BIT CLOSER. THOSE RETINAL CELLS MIGHT
10 COME IN VERY HANDY SOON.

11 SO THIS IS WORK PUBLISHED BY THE
12 KAROLINSKA INSTITUTE IN SWEDEN. THERE'S BEEN A LOT
13 OF DEBATE ABOUT WHETHER THERE ARE STEM CELLS IN THE
14 HEART AND A LOT OF DISCUSSION ABOUT WHETHER THERE'S
15 ANY WAY IN WHICH YOU CAN INDUCE REGENERATION IN THE
16 HEART BY GETTING THOSE CELLS IN THE HEART TO
17 MULTIPLY. THEY TOOK ADVANTAGE, THESE SCIENTISTS AT
18 THE KAROLINSKA, OF THE NUCLEAR PROLIFERATION WORK.
19 WHAT HAPPENED WAS THAT DURING THE COLD WAR, THERE
20 WAS A LOT OF ATOMIC EXPLOSIONS HAPPENING. AND THERE
21 WAS -- IF YOU LOOK AT THE GRAPH ON THE LEFT-HAND
22 SIDE THERE, THE AMOUNT OF C-14 LABELED CARBON IN THE
23 ATMOSPHERE JUST WENT UP IN THAT GRAPH. YOU SEE THAT
24 REALLY SHARP RISE. THAT WAS CARBON 14 IN THE
25 ATMOSPHERE DUE TO THE NUCLEAR EXPLOSIONS THAT WERE

BARRISTERS' REPORTING SERVICE

1 GOING ON AROUND THE WORLD.

2 AND THEN WHEN YOU GOT THE PROLIFERATION
3 TREATIES THAT CAME INTO PLACE, YOU GOT A DECAY AWAY
4 ON THE LOWER PART OF THE CURVE. SO THEIR SCIENTISTS
5 TOOK ADVANTAGE OF THE INTEGRATION OF CARBON 14 FROM
6 THESE NUCLEAR BOMB TESTS BECAUSE IT'S ABSORBED INTO
7 DNA IN PLANTS AND THEN PLANTS INTO ANIMALS. SO YOU
8 GET AN EQUILIBRATION OF CARBON 14 ACROSS THE
9 POPULATION. AND IT'S A FAIRLY RAPID EQUILIBRATION
10 OF THE CARBON 14 AROUND THE WORLD; SO WHENEVER
11 THEY'RE LETTING OFF BOMBS SOMEWHERE, IT'S GOING TO
12 BE EQUILIBRATED FAIRLY QUICKLY.

13 THEY LOOKED AT THAT, AND THEN THEY HAD A
14 LOOK AT TAKING CARDIAC PUNCTURES FROM PATIENTS TO
15 LOOK AT WHAT HAPPENED AT DIFFERENT TIME POINTS IN
16 PEOPLE'S LIVES. AND GOING BACK, AGAIN ON THE BOTTOM
17 GRAPH THERE, THEY'RE TAKING SAMPLES FROM PATIENTS IN
18 THE '40S UP THROUGH THE '60S AND THEN INTO THE '80S,
19 LOOKING AT WHAT WAS REALLY HAPPENING FROM THE CARBON
20 14 DRAWN INTO PATIENTS.

21 THE NEXT SLIDE, THE IMPORTANT PART OF THIS
22 IS THAT THEY WERE ABLE TO SHOW THAT THERE'S A
23 DIFFERENCE BETWEEN A NUMBER OF CARDIOMYOCYTES FORMED
24 AT BIRTH. IF YOU LOOK AT THE LOWER PANEL THERE, THE
25 WHITE AREA IS THE CARDIOMYOCYTES THAT ARE PRESENT IN

BARRISTERS' REPORTING SERVICE

1 A PERSON AT BIRTH, AND THEN THE GRAY AREA IS THE
2 ADDITION. SO, IN FACT, I THINK I'VE GOT THAT THE
3 WRONG WAY AROUND. IT'S THE GRAY AREA WHICH IS THE
4 AMOUNT OF CELLS THAT ARE PRESENT AT BIRTH AND THE
5 WHITE AREA ABOVE IT IS THOSE THAT ARE REPLENISHED.
6 AND YOU CAN DEMONSTRATE THIS BY THE DIFFERENCE IN
7 THE CARBON 14 AT DIFFERENT TIMES.

8 SO THEY'RE ABLE TO CALCULATE THAT THERE'S
9 A GRADUAL DECREASE IN A TURNOVER OF CARDIOMYOCYTES
10 OF 1 PERCENT AT AROUND 25 YEARS OF AGE WHICH FELL TO
11 HALF OF THAT, ABOUT .45 PERCENT TURNOVER OF
12 CARDIOMYOCYTES AT THE AGE OF 75. SO THAT FEWER THAN
13 50 PERCENT OF CARDIOMYOCYTES ARE EXCHANGED DURING A
14 NORMAL LIFE SPAN. SO THERE IS SOME REPAIR POSSIBLE
15 IN THE HEART.

16 NOW, THE QUESTION IS CAN YOU UTILIZE THAT
17 FOR TRYING TO CORRECT INFARCTED HEARTS OR TISSUES
18 THAT HAVE BEEN BADLY DAMAGED? AND I THINK THE
19 QUESTION IS STILL OPEN, BUT IT'S VERY CLEAR THAT THE
20 HEART DOES HAVE SOME CAPACITY TO REPAIR ITSELF, BUT
21 IT'S SMALL. IT'S VERY SMALL, AND IT'S UNLIKELY TO
22 BE EASILY TRANSMITTED INTO REPAIR THAT'S GOING TO BE
23 MAJOR.

24 BUT I THOUGHT THIS WAS A PRETTY
25 INTERESTING PAPER BECAUSE OF THE WAY THE SCIENTISTS

BARRISTERS' REPORTING SERVICE

1 LOOKED AT THE USE OF THE ENVIRONMENTAL INFORMATION
2 TO CONNECT IT WITH THE ABILITY TO LOOK AT
3 REGENERATION IN A TISSUE LIKE HEART.

4 I THINK SOME WORK THAT WAS PUBLISHED IN
5 *NATURE BIOTECHNOLOGY* IN APRIL FROM THE UCSF GROUP
6 DEMONSTRATED THAT THESE SMALL MICRO-RNA'S, THESE ARE
7 VERY SMALL BITS OF RNA WHICH ARE SPECIFIC TO
8 EMBRYONIC STEM CELLS, THEY REALLY ENHANCE THE
9 PRODUCTION OF MOUSE-INDUCED PLURIPOTENTIAL STEM
10 CELLS. SO YOU CAN USE ONE OF THESE VERY SMALL
11 MOLECULES THAT IS RESIDENT IN ONE OF THESE
12 MICRO-RNA'S TO ACTUALLY REPLACE THE NEED FOR USING
13 CMYC. CMYC IS A GENE WHICH IS ASSOCIATED, VERY
14 STRONGLY ASSOCIATED, WITH CANCER AND IS ONE OF THE
15 BIG CONCERNS IN IPS TECHNOLOGY.

16 SO THIS WORK WAS REALLY STRONGLY ENDORSED
17 IN THE SCIENTIFIC LITERATURE AS BEING A VERY
18 IMPORTANT DEVELOPMENT. AND I THINK NOT ONLY THE
19 INTEREST FROM THE POINT OF VIEW OF TECHNOLOGICALLY
20 MAKING BETTER QUALITY IPS CELLS, BUT IT STARTS TO
21 TELL US A LOT ABOUT CANCER. SO THIS MODEL, I THINK,
22 WILL BE USED WIDELY FOR STUDYING CANCER BECAUSE IF
23 YOU CAN USE MICRO-RNA'S TO REPLACE ONE OF THESE
24 ONCOGENES, THEN IT'S GOT TO BE A TARGET FOR LATER ON
25 SEEING IF YOU CAN MANIPULATE THE SITUATION IN

BARRISTERS' REPORTING SERVICE

1 CANCER. SO A VERY STRONG PAPER OUT OF THE UCSF
2 GROUP AND WAS VERY WARMLY WELCOMED RIGHT ACROSS THE
3 SCIENTIFIC COMMUNITY.

4 THE NEXT ONE. THERE'S A REPORT THAT COMES
5 FROM THE GROUP AT THE BURNHAM INSTITUTE IN LA JOLLA.
6 I DIDN'T PICK THESE BECAUSE THEY WERE CALIFORNIA. I
7 PICKED THEM BECAUSE I THOUGHT THAT THEY'RE REALLY
8 GOOD PAPERS OUT OF THE LATEST LITERATURE. BUT
9 THEY'VE WORKED OUT A VERY RAPID AND UNIFORM
10 DIFFERENTIATION SYSTEM FOR NEURAL PRECURSOR CELLS.
11 THESE ARE NEURONS THAT ARE NEEDED DOWNSTREAM FOR
12 WORK ON NEURODEGENERATIVE DISORDERS. AND THEY'RE
13 ABLE TO SHOW THAT IF YOU USE THIS SYSTEM THAT
14 THEY'VE WORKED OUT, THAT YOU GET A VERY UNIFORM
15 PRODUCTION OF NEURAL STEM CELLS. AND THAT'S BEEN A
16 PROBLEM IN THE PAST. NORMALLY WHEN YOU ARE DOING
17 DIFFERENTIATION, YOU GET A GREAT VARIETY OR
18 HETEROGENEITY THERE THAT THEN MAKES IT DIFFICULT TO
19 WORK WITH THOSE AS A SINGLE POPULATION.

20 SO THESE CELLS IN CULTURE LOOK LIKE THEY
21 WORK AS FUNCTIONAL -- ELECTROPHYSIOLOGICALLY
22 FUNCTIONAL NEURONS, AND THEY ALSO WORK REALLY WELL
23 WHEN THEY TRANSPLANTED THEM INTO THE BRAINS OF
24 NEONATAL MICE. SO THESE ARE GOOD QUALITY NEURONS
25 BUILT IN A WAY WHICH I THINK IS GOING TO BE USEFUL

BARRISTERS' REPORTING SERVICE

1 FOR MANUFACTURING PURPOSES WHEN WE COME TO NEURAL
2 DEGENERATIVE DISEASES.

3 INTERESTING THAT THEY DIDN'T FIND ANY
4 TUMORS IN ANY OF THESE STUDIES. SO, AGAIN, THIS IS
5 REASSURANCE THAT DOING A DIFFERENTIATION USING THESE
6 KIND OF METHODS WORKS REALLY WELL. SO, AGAIN, I
7 THINK THIS IS A GOOD PAPER. IT'S NOT A JOURNAL THAT
8 I KNEW A LOT ABOUT, BUT I UNDERSTAND MARIE CSETE HAD
9 PUBLISHED A PAPER IN IT, SO IT MUST BE A GOOD
10 JOURNAL IF THAT'S THE CASE.

11 THERE'S BEEN SOME DOUBT ABOUT WHETHER IPS
12 CELLS CAN FORM FUNCTIONAL CELL TYPES ACROSS THE
13 BOARD. BUT THERE'S A VERY NICE PAPER PRODUCED BY
14 THE WISCONSIN GROUP, JAMIE THOMSON'S GROUP AT
15 WISCONSIN, THAT WAS PUBLISHED IN *CARDIAC RESEARCH*,
16 THAT SHOWED THAT IF YOU TAKE IPS CELLS, THAT YOU CAN
17 ACTUALLY MAKE CARDIOMYOCYTES THAT APPEAR TO BE
18 EQUIVALENT TO THOSE PRODUCED BY EMBRYONIC STEM
19 CELLS.

20 THERE'S BEEN SOME DOUBT ABOUT IT. THERE
21 HAVE BEEN PRIOR PUBLICATIONS THAT IPS CELLS WOULDN'T
22 FORM CARDIOMYOCYTES THAT HAD THE SAME REAL CAPACITY
23 AS EMBRYONIC STEM CELLS, BUT THIS GROUP HAS SHOWN
24 THAT YOU CAN. AND, OF COURSE, THAT'S VERY IMPORTANT
25 FROM THE POINT OF VIEW OF DRUG DISCOVERY WORK

BARRISTERS' REPORTING SERVICE

1 BECAUSE IF YOU'VE GOT CARDIOMYOCYTES NOW THAT YOU
2 CAN TAKE FROM IPS CELLS, YOU CAN START TO
3 INTERROGATE A LOT OF THE HETEROGENEITY OF CARDIAC
4 DISEASE. SO, AGAIN, I THINK A NICE SETTLING PAPER
5 IN THE TECHNOLOGIES AND WELCOME.

6 SO I THINK IT WOULD BE INTERESTING TO THE
7 BOARD TO KNOW THAT CHINA IS EMERGING AS A VERY MAJOR
8 NATION IN STEM CELL RESEARCH. IT'S VERY CLEAR THAT
9 THE CHINESE ARE GOING TO FINANCE STEM CELL RESEARCH
10 IN A VERY MAJOR WAY. THEIR VIEW IS THAT THIS IS THE
11 FRONT LINE OF A LOT OF THE MEDICINE THAT THEY WANT
12 TO PRACTICE IN. AND THERE'S A LOT OF GOOD WORK
13 COMING OUT OF CHINA. AND I THINK WE'LL HAVE TO KEEP
14 LOOKING AT THE CHINESE RESEARCH ENVIRONMENT BECAUSE
15 THERE ARE A LOT OF GOOD SCIENTISTS THERE, AND THEY
16 WILL CONTINUE TO BE SUPPORTED AS STRONGLY.

17 THIS GROUP IN BEIJING AT THE PEKING
18 UNIVERSITY, THE THIRD HOSPITAL IN BEIJING, SHOWED
19 THAT THEY'RE ABLE TO MAKE BETA ISLET CELLS THAT WERE
20 RESPONSIVE TO GLUCOSE, AND THAT THEY USED A
21 DIFFERENT SYSTEM, IF YOU LIKE, TO THE ONES THAT ARE
22 BEING USED CURRENTLY FOR BETA ISLET CELLS, BUT THE
23 CELLS THAT THEY PRODUCED WERE VERY EFFECTIVE, THEY
24 WERE RESPONSIVE TO GLUCOSE; AND WHEN THEY PUT THEM
25 INTO MICE IN SCAFFOLDS, THESE ARE MATERIALS THAT

BARRISTERS' REPORTING SERVICE

1 THEY SOW THE CELLS INTO, THESE CELLS WERE VERY
2 EFFECTIVE IN CURING THE DIABETES.

3 SO THERE'S A COUPLE OF DEMONSTRATIONS
4 HERE. THERE'S A NEW DIFFERENTIATION SYSTEM, BUT IT
5 SHOWS THAT SCAFFOLDING, WHICH WILL HOLD THE CELLS
6 TOGETHER, CAN SERVE AS A VERY GOOD VEHICLE FOR
7 INSULIN-LIKE CELL TRANSPLANTATION. SO WE'LL EXPECT
8 TO SEE MORE WORK FROM OUR CHINESE COLLEAGUES AS THEY
9 RAMP UP IN THESE AREAS.

10 I THINK IN THE AREA OF CANCERS, THERE WAS
11 AN INTERESTING PAPER THAT WAS PUBLISHED IN THE
12 *JOURNAL OF THE NATIONAL CANCER INSTITUTE* IN APRIL
13 WHERE THEY WERE LOOKING -- THIS IS A CLINICAL STUDY.
14 THEY EXAMINED 70 LUNG CANCER TUMORS FROM 23 FEMALE
15 AND 7 MALE PATIENTS, AND THEY'RE TRYING TO DETERMINE
16 WHETHER THE MULTIPLE TUMORS FROM ANY INDIVIDUAL
17 PATIENT SHARED A COMMON GENETIC PATH. NOW WE'RE
18 TRYING TO GET AT THIS QUESTION: WHAT IS A CANCER
19 STEM CELL?

20 INVESTIGATORS ANALYZED THE TUMORS FOR
21 CHROMOSOMAL LOSS AT SIX DIFFERENT LOCI, AND THEN
22 THESE LOCI WERE USUALLY ASSOCIATED WITH LUNG CANCER
23 AND FROM MUTATIONS IN THE P53 GENE, A GENE THAT'S
24 VERY FREQUENTLY ASSOCIATED WITH CANCER. AND THEY
25 ALSO ANALYZED X CHROMOSOME INACTIVATION. AND THEY

BARRISTERS' REPORTING SERVICE

1 FOUND THAT MULTIPLE TUMORS IN 23 OF THE 30 PATIENTS,
2 THAT'S 80 PERCENT, ALL AROSE FROM A SINGLE CANCER
3 CLONE, A SINGLE CELL.

4 SO THIS IS CHALLENGING AND THIS IS
5 INTERESTING. AND IF IT PROVES TO BE SUPPORTED BY
6 OTHER STUDIES, THAT THERE ARE SINGLE CELLS THAT ARE
7 CAPABLE OF SEEDING SERIOUS DISEASES LIKE LUNG
8 CANCER, IT REITERATES THE NEED FOR US TO REALLY
9 CAREFULLY ATTACK THESE VERY DANGEROUS CANCER STEM
10 CELLS.

11 I WANTED TO JUST BRIEFLY REPORT ON TWO
12 OTHER STUDIES, IF I MAY. YOU WILL BE AWARE THAT A
13 LOT OF WORK HAS BEEN DONE ON PRODUCTION OF BLOOD
14 CELLS FROM EMBRYONIC STEM CELLS. AN INTERESTING
15 PAPER BY SUSAN FISHER AND HER COLLEAGUES AT UCSF HAS
16 SHOWN THAT THE HUMAN PLACENTA IS A SOURCE FOR
17 HEMATOPOIETIC LINEAGES, THAT IS THE BLOOD FORMING
18 LINEAGES IN THE FETUS, IN THE PLACENTA ESSENTIALLY.
19 THE PLACENTA IS THE BLOOD FORMING ORGAN RATHER THAN
20 THE BONE MARROW. I THINK THAT'S WHAT'S HAPPENING
21 WITH THE DIFFERENTIATION OF BLOOD CELLS FROM
22 EMBRYONIC STEM CELLS. THEY'RE FORMING THESE SORT OF
23 CELLS RATHER THAN THE BONE MARROW-TYPE CELLS. AND
24 THIS IS REALLY ONE OF THE ROADBLOCKS IN BLOOD
25 FORMATION. SO WE'VE GOT TO GET OVER THIS.

BARRISTERS' REPORTING SERVICE

1 SO THIS WAS AN INTERESTING PAPER, I THINK,
2 THAT REITERATES THAT THE SITE OF PRODUCTION OF CELLS
3 NEEDS TO BE TAKEN ACCOUNT OF IN A DEVELOPMENTAL WAY,
4 AND WE'VE GOT TO WORK OUT WAYS TO GET OVER THE
5 PRODUCTION OF THE PLACENTAL BLOOD TYPE AND GET INTO
6 THE BONE MARROW.

7 I THINK THE NEXT ONE IS THE LAST ONE, AND
8 I THINK IT'S JUST COME OUT. IN FACT, I WAS GIVEN
9 THE PAPER A COUPLE WEEKS BEFORE IT CAME OUT. IT'S A
10 PAPER FROM SHEN DING'S LAB AT THE SCRIPPS INSTITUTE
11 AT LA JOLLA, THE GENERATION OF IPS CELLS USING
12 RECOMBINANT PROTEINS. THIS IS A VERY SIGNIFICANT
13 PAPER. I REPORTED TO YOU THE USE OF
14 RETROTRANSPOSONS IN THE LAST MEETING OR THE MEETING
15 BEFORE, I THINK THE LAST MEETING. THE PIGGYBAC
16 TRANSPOSON IS A VERY SMART TECHNOLOGY FOR MAKING IPS
17 CELLS.

18 WELL, SHEN DING, WHO'S A PARTICULARLY GOOD
19 CHEMIST, BASICALLY IS A BASIC CHEMIST ALONG WITH HIS
20 CAPACITY TO SORT OF MAKE AND SEE INTO PROTEINS AND
21 HOW TO TRANSFORM THEM, HE DID SOME VERY CLEVER
22 THINGS. I WAS INVOLVED IN A SIMILAR SORT OF WORK
23 BEFORE I LEFT MELBOURNE. HE MADE FOUR PROTEINS, AND
24 THIS IS IN THE MOUSE, MADE THEM FROM OCT-4, SOX-2,
25 KLF 4, AND CMYC IPS CELLS. HE MADE THE PROTEINS AND

BARRISTERS' REPORTING SERVICE

1 HE FUSED THEM WITH A POLYARGININE PROTEIN
2 TRANSDUCTION COMPONENT ATTACHED IT TO.

3 THE TRICK WITH THAT IS THAT IT'S DIFFICULT
4 TO GET PROTEINS INTO THE CELL UNLESS YOU PUT ON A
5 TRANSDUCTION MOLECULE. I WAS TRYING TO PUT A TAT
6 MOLECULE FROM THE HIV AREA INTO THE PROTEINS WE WERE
7 WORKING ON, BUT HE'S PUT THIS VERY SMART
8 POLYARGININE ATTACHMENT TO IT SO THAT THE PROTEINS
9 WENT INTO THE CELL AND WENT INTO THE NUCLEUS VERY
10 EASILY. AND THEY'RE ABLE TO CONVERT SOMATIC CELLS,
11 THAT IS, SKIN CELLS, VERY WELL TO INDUCE
12 PLURIPOTENTIAL STEM CELLS.

13 THE ADVANTAGE, OF COURSE, THAT THERE'S NO
14 GENES INVOLVED IN THIS. THERE'S NO INTEGRATION IN
15 THE GENOME. THERE WOULD BE NO RESIDUAL CONCERNS
16 ABOUT TRANSGENESIS IN THESE CELLS. THIS IS A VERY
17 IMPORTANT PIECE OF WORK, WHICH I THINK HERALDS THAT
18 THIS SCIENTIST, SHEN DING, HAS REALLY JOINED THAT
19 TOP CADRE OF TOP-LINE SCIENTISTS IN THE WORLD. AND
20 HIS PUBLICATIONS IN THE LAST COUPLE OF YEARS HAVE
21 BEEN JUST PHENOMENAL.

22 SO I THINK WE'RE GOING TO HAVE CELLS NOW
23 THAT WILL RIVAL EMBRYONIC STEM CELLS IN THE
24 CAPABILITY OF BEING USED. WE HAVE TO FIND OUT IF
25 THEY CAN ABSOLUTELY DO THE SAME JOB AS EMBRYONIC

BARRISTERS' REPORTING SERVICE

1 STEM CELLS NOW WE DON'T HAVE THE PROBLEM OF THE
2 RESIDUAL GENETICS IN IT.

3 SO AS YOU WILL SEE, A LOT OF THAT WORK HAS
4 COME FROM CALIFORNIAN SCIENTISTS. AND SO THIS IS
5 WHAT YOU'VE BEEN DOING. YOU'VE BEEN INITIATING THIS
6 KIND OF WORK. THIS STUDY WASN'T, IN FACT, IT WASN'T
7 ONE THAT WE FUNDED, BUT IT'S A LABORATORY WHICH WE
8 STRONGLY FUND.

9 MY PRIORITIES DURING THIS LAST MONTH, JUST
10 TO BRING YOU UP TO DATE, I'VE BEEN TALKING TO SENIOR
11 RESEARCHERS AND SEEING IF WE CAN HAVE REGULAR FORUMS
12 TOGETHER TO INFORM OURSELVES. THIS WHOLE AREA IS
13 MOVING SO QUICKLY, THAT THE MORE WE'RE ABLE TO MEET
14 WITH THE CALIFORNIAN SENIOR RESEARCHERS THE BETTER.
15 IT'S QUITE DIFFICULT TO SORT OF GET A FEELING FOR
16 WHERE THE FIELD IS GOING WHEN THERE'S SO MUCH
17 TRAFFIC IN DISCOVERY, BUT MARIE IS SPENDING A LOT OF
18 TIME OUT THERE AT MEETINGS AND KEEPING US WELL
19 INFORMED ABOUT WHAT'S GOING ON. BUT THE IDEA OF
20 BRINGING SOME OF THE SENIOR RESEARCHERS TOGETHER IN
21 REGULAR FORUMS WITH US HAS BEEN VERY STRONGLY AND
22 WARMLY RECEIVED BY A LOT OF THE SENIOR RESEARCHERS.

23 WE'VE BEEN WORKING ON PREAPPLICATIONS FOR
24 BASIC BIOLOGY RFA'S, AND THE APPLICATIONS ARE DUE
25 APRIL THE 30TH, THE PRIMARY APPLICATIONS. THE MAJOR

BARRISTERS' REPORTING SERVICE

1 FACILITIES PROGRAM, WE'VE BEEN MOVING TO COMPLETE
2 ALL OF THE PROCESS INVOLVED WITH THOSE, AND WE'RE
3 GETTING THERE VERY QUICKLY NOW. THERE'S VERY LITTLE
4 LEFT TO BE DONE. WE'VE GOT INTERNATIONAL AGREEMENTS
5 FOR COLLABORATIVE RESEARCH. I TALKED TO THE
6 WELLCOME TRUST IN UNITED KINGDOM. THEY'RE OPEN TO
7 CO-FUNDING WORK WHICH IS OF INTERNATIONAL
8 SIGNIFICANCE. SO TOO IS THE SCOTTISH NETWORK.
9 THEY'VE INDICATED THEY WANT TO WORK WITH US. WE'VE
10 SUGGESTED TO THEM THEY SHOULD WORK THROUGH THE MRC,
11 THAT WE ALREADY HAVE AN AGREEMENT WITH IN THE UK.

12 THE EU FRAMEWORK GROUPS HAVE INDICATED
13 THEY WOULD ALSO LIKE TO WORK TOGETHER WITH US WHERE
14 IT'S INTERNATIONALLY IMPORTANT. SO THAT'S ANOTHER
15 STRONG INDICATION THAT WE'RE WELCOMED IN THOSE
16 FRAMEWORK CONSIDERATIONS OF THEIR MAJOR FUNDING
17 OPPORTUNITIES. CHINA HAS BEEN APPROACHING US ABOUT
18 A RELATIONSHIP, AND WE'RE LOOKING VERY CAREFULLY AND
19 CLOSELY AT THAT.

20 WE'VE BEEN TRYING TO DEVELOP NETWORKS IN
21 UC SCIENCE AND INDUSTRY. WE'VE BEEN PLANNING
22 FINANCIAL STRATEGIC ADJUSTMENTS TO THE CIRM
23 ACTIVITIES. AND THE LAST WEEK, END OF LAST WEEK WAS
24 JUST A TREMENDOUS NEWS THAT WE'RE ABLE TO
25 PARTICIPATE IN SO MUCH MONEY COMING FROM THE BOND

BARRISTERS' REPORTING SERVICE

1 INITIATIVE. AND IT, I THINK, TOOK US A BIT BY
2 SURPRISE, A VERY WELCOME SURPRISE AT THAT.

3 WE'VE BEEN TRYING TO DEFINE THE OPTIMAL
4 CIRM STAFF PROFILE AS WE START TO APPROACH 50. AND
5 WE'VE HAD INTERESTING AND USEFUL DISCUSSIONS ON
6 THAT. AND WE'VE BEEN LOOKING AT THE POSSIBILITY OF
7 DEVELOPING A PROGRAM OF CIRM AWARDS FOR EXCELLENCE
8 FOR EXCELLENT OR VERY PRODUCTIVE SCIENTISTS. AND
9 THIS REALLY WAS EVOLVED FROM SOME DISCUSSIONS AND
10 MEETINGS THAT ED PENHOET AND I HAD AND THEN
11 DISCUSSIONS I HAD THEN WITH JOHN ROBSON ABOUT THE
12 POSSIBILITY OF CIRM LOOKING TO BE IN THE
13 MARKETPLACE, IF YOU LIKE, TO HELP SENIOR SCIENTISTS
14 OR SENIOR RESEARCHERS, SOME OF THESE MIDCAREER, VERY
15 PRODUCTIVE SCIENTISTS, COME TO CALIFORNIA.

16 WE'VE GOT SOME NEW INSTITUTIONS OPENING IN
17 INSTITUTIONS THAT COULD DO WITH SOME REALLY TOP-LINE
18 PRODUCTIVITY SCIENTISTS. WE ALSO WANT TO RECOGNIZE
19 THAT IN CALIFORNIA WE'VE GOT VERY HIGH PRODUCING
20 SCIENTISTS THAT WE WANT TO RECOGNIZE.

21 SO WE'VE HAD MEETINGS WITH THE FDA AND
22 WITH THE NIH LAST WEEK. AND THANKS TO DUANE AND TED
23 LOVE, WHO CAME WITH US TO MEET WITH THE FDA. IT WAS
24 A VERY POSITIVE MEETING. WE HAD A VERY LARGE
25 AUDIENCE OF MEMBERSHIP FROM THERE, AND DUANE OR TED

BARRISTERS' REPORTING SERVICE

1 MIGHT GIVE US A COMMENT ON THAT LATER, BUT IT WAS A
2 VERY PRODUCTIVE MEETING. THEY WERE VERY KEEN TO
3 CONTINUE A DIALOGUE WITH US. THEY RECOGNIZED THE
4 ISSUES THAT WE'RE -- OUR ISSUES THAT WERE IN PLACE,
5 AND THEY WERE ABLE TO INFORM US ABOUT SOME OF THE
6 THINGS THAT WE WERE DOING. IT WAS A VERY POSITIVE
7 MEETING, AND WE WILL WORK TOWARDS GETTING A
8 DIALOGUE, A CONTINUAL DIALOGUE, WITH THE FDA.

9 AND AT THIS POINT I WOULD LIKE, IF I MAY,
10 CHAIR, TO INTRODUCE ELONA BAUM TO YOU, ELONA WHO'S
11 JOINED US AS CHIEF COUNSEL. THIS POSITION HAS BEEN
12 ABSENT OR OPEN FOR SOME TIME BECAUSE TAMAR PACHTER
13 HAD THAT POSITION PREVIOUSLY. AND IAN SWEEDLER
14 STEPPED IN AS THE ACTING GENERAL COUNSEL.

15 WE'RE EXTREMELY FORTUNATE IN HAVING ELONA
16 JOIN US. SHE'S HAD 12 YEARS AT GENENTECH AND HAD
17 LED THEIR LEGAL SIDE AND THEIR STRATEGIC THINKING AT
18 GENENTECH FOR 12 YEARS. SHE'S GOT A PHENOMENAL
19 RECORD THERE. AND SHE WAS INVOLVED IN WORKING
20 THROUGH THE DEAL WITH GENENTECH AND ROCHE.

21 PRIOR TO THAT SHE HAD TWO YEARS AS
22 DIRECTOR OF THE REGULATORY POLICY AND STRATEGY
23 AGENCY AND THEN TEN YEARS AS AN ASSOCIATE, BEFORE
24 THAT GENERAL COUNSEL, AND SEVEN YEARS BEFORE THAT IN
25 PRIVATE PRACTICE. SHE IS AN EXCEPTIONAL PERSON, AND

BARRISTERS' REPORTING SERVICE

1 I REALLY DON'T HOW WE GOT HER TO ACCEPT THE JOB, BUT
2 SHE DID. AND WE WAITED FOR HER FOR A LONG PERIOD OF
3 TIME, AND I HOPE YOU WILL MAKE HER WELCOME BECAUSE
4 SHE'S REALLY -- SHE'S STEPPED DOWN SUBSTANTIALLY IN
5 SALARY AND EVERYTHING TO PUT HER CAPABILITY AND HER
6 STRATEGIC THINKING INTO CIRM, AND I JUST THINK
7 THAT'S FANTASTIC.

8 (APPLAUSE.)

9 DR. TROUNSON: I'M GOING TO GET ELONA TO
10 HELP DEVELOP THE RELATIONSHIP BETWEEN THE FDA AND
11 OURSELVES, AND SHE'LL BE LEADING THAT GROUP TO GET
12 US AN ONGOING RELATIONSHIP WITH THE FDA NOW THAT
13 WE'VE BROKEN, THE ICE BREAKER, IF YOU LIKE.

14 BOB KLEIN AND I ALSO MET WITH THE NIH. I
15 REQUESTED A MEETING WITH THE ACTING DIRECTOR AND THE
16 HEAD OF THE STEM CELL INITIATIVE. AND WE HAD A VERY
17 WARM MEETING THERE. I'D HAVE TO SAY IT WAS A VERY,
18 VERY POSITIVE MEETING. WE DID TALK ABOUT THE DRAFT
19 REGULATIONS. THEY THANKED US VERY MUCH FOR THE
20 THOUGHTFUL RESPONSE THAT WE HAD GIVEN IMMEDIATELY,
21 AND THEN WE WORKED OUR WAY THROUGH SOME OF THE
22 ISSUES THAT THEY HAVE, AND THEY RECOGNIZE THAT WE IN
23 THE FIELD HAVE SOME ISSUES WITH THE REGULATIONS AS
24 THEY'RE TERMED, PARTICULARLY THE ISSUES OF BEING
25 ABLE TO GRANDFATHER IN OR RECOGNIZE THE EMBRYONIC

BARRISTERS' REPORTING SERVICE

1 STEM CELLS, EVEN THE ONES THEY HAVE RECOGNIZED AS
2 THE PRESIDENTIAL LINES WOULDN'T FIT THE REGULATIONS
3 THAT THEY'RE PROPOSING.

4 SO THEY'VE GIVEN US SOME HELP IN
5 UNDERSTANDING WHAT THE ISSUES ARE AND SOME
6 RECOMMENDATIONS ABOUT HOW WE WOULD GO IN TERMS OF
7 RESPONDING. WE HAVE A PERIOD OF TIME. IT'S A
8 30-DAY TIME FROM LAST MONDAY, SO A WEEK IS ALREADY
9 GONE, SO WE'VE GOT THREE WEEKS LEFT. I'VE ASKED
10 ELONA TO JOIN UP WITH GEOFF LOMAX AND DON GIBBONS TO
11 HELP PRODUCE A DOCUMENT WHICH WILL COME TO A
12 STRATEGIC TEAM THAT WAS APPOINTED BY THE LEGISLATIVE
13 COMMITTEE TO HELP FASHION A DOCUMENT, A DOCUMENTAL
14 RESPONSE TO THE NIH DRAFT GUIDELINES.

15 SO THAT'S IN PLACE. AND THE WORK IS
16 ALREADY HARD GOING ON. WE'VE TALKED TO A LOT OF THE
17 SCIENTISTS, SENIOR SCIENTISTS, IN CALIFORNIA. WE'VE
18 GOT THEIR RESPONSES. WE ACTUALLY NEED TO MOTIVATE
19 THE FIELD TO RESPOND AND THEY WILL, BUT IT'S ALL
20 ABOUT -- IT'S ALL ABOUT GETTING THE RIGHT RESPONSE
21 AND THE NUMBER OF RIGHT RESPONSES GOING. SO THERE
22 WILL BE QUITE A LOT OF HARD WORK DONE ON THIS IN THE
23 NEXT WEEK OR SO TO GET THAT DOCUMENT FASHIONED FOR
24 OUR RESPONSE.

25 BUT THE OTHER PART THAT I WANTED TO SAY

BARRISTERS' REPORTING SERVICE

1 WAS THAT IN TERMS OF GRANT APPLICATIONS, THEY WERE
2 VERY MUCH OPEN TO WORKING WITH US IN WAYS WHICH THEY
3 WERE GOING TO MAKE SOME SUGGESTIONS BACK TO US. WE
4 WERE GOING TO MAKE SOME SUGGESTIONS TO THEM AS WELL.
5 THE IDEA OF BEING ABLE TO CO-FUND PROJECTS WHERE WE
6 ARE LIMITED IN FUNDING IN CALIFORNIA AND THEY COULD
7 HELP OUTSIDE CALIFORNIA IS SOMETHING THAT THEY WOULD
8 DEFINITELY CONSIDER. WE'RE LOOKING AT PROCESSES
9 WHERE THAT WOULD BE ABLE TO HAPPEN, AND WE'RE GOING
10 TO BE EXCHANGING SOME COMMUNICATIONS IN ORDER FOR
11 THAT TO HAPPEN. SO A VERY, VERY STRONG, POSITIVE
12 MEETING WITH THE NIH.

13 JUST GOT A COUPLE OF SLIDES LEFT. I'LL
14 PASS FOR THIS, BUT I THINK IT WOULD BE GOOD TO TALK
15 TO JOHN AND I ABOUT THIS. WE'LL BRING THIS BACK TO
16 THE BOARD AT A LATER TIME. BUT THIS IS THE
17 DEVELOPMENT OF THE CIRM INVESTIGATOR AWARDS, WHICH
18 WE THINK CONCEPTUALLY IS A GOOD THING TO DO IN
19 CALIFORNIA. WE'LL BRING A CONCEPT PLAN WHEN WE'VE
20 DEVELOPED IT FURTHER TO YOU. BUT WE'D BE VERY HAPPY
21 TO TALK TO INDIVIDUALS WHO ARE INTERESTED IN THIS OR
22 THINK THAT WE SHOULD GO ABOUT IT IN SOME DIFFERENT
23 WAY. SO IT'S SOMETHING THAT WE'VE HAD IN THE
24 PIPELINE.

25 THE DISEASE TEAM AWARDS, JUST TO TELL YOU,

BARRISTERS' REPORTING SERVICE

1 WE GOT 73 PRELIMINARY APPLICATIONS. EIGHTEEN WERE
2 DESIGNATED AS INTERNATIONAL COLLABORATIVE FUNDING
3 PARTNERS, SO 18 OF THE 73. THERE'S EVIDENCE OF NEW
4 PARTNERSHIPS AND COLLABORATIONS WITHIN CALIFORNIA IN
5 THESE TEAMS. THERE WAS HUMAN EMBRYONIC STEM CELLS
6 AS WELL AS IPS CELLS AND ADULT STEM CELLS ALL WELL
7 REPRESENTED IN THAT. SO INTERESTING, VERY
8 INTERESTING, I THINK YOU'D HAVE TO SAY. WE'VE BEEN
9 READING SOME OF THEM AND, OF COURSE, THE SCIENCE
10 TEAMS WILL BE READING THEM ALL. AND I HAVE TO SAY
11 SOME OF IT SOUNDS TERRIFIC AND OTHERS OF IT SOUND
12 VERY HOPEFUL IN THE KIND OF TIMEFRAMES, BUT STILL 73
13 TEAMS BELIEVE THAT THEY CAN GET UP THIS TRACK TO AN
14 IND IN FOUR YEARS, WHICH IS TREMENDOUS.

15 WE'RE LOOKING AT DIVERSITY ISSUES FOR
16 DIVERSITY OF THERAPEUTIC APPROACHES, SO
17 APPROXIMATELY TWO-THIRDS ARE CELL THERAPY, ONE-THIRD
18 IS SMALL MOLECULES OF BIOLOGICAL THERAPIES. SO
19 GIVES YOU A BIT OF A FRAME OF THE TYPE OF
20 APPLICATIONS THAT CAME.

21 JUST OF THE DISEASES, I SUPPOSE, BECAUSE
22 YOU'D BE INTERESTED: AUTOIMMUNE DISEASES, BURNS AND
23 SKIN WOUNDS, CANCER, CARDIOVASCULAR DISEASE,
24 DIABETES, EYE DISEASES, HEMATOPOIETIC DISORDERS,
25 HIV/AIDS, COUPLE OF VERY INTERESTING GRANTS THERE,

BARRISTERS' REPORTING SERVICE

1 INFERTILITY, KIDNEY DISEASE, LIVER DISEASE,
2 MUSCULOSKELETAL DISEASE, NEUROLOGICAL DISORDERS AND
3 INJURY, AND PERIPHERAL VASCULAR DISEASE, AS WELL AS
4 TRACHEAL STRICTURE. SO THERE'S A PRETTY BROAD
5 SPECTRUM OF THINGS THAT HAVE COME THROUGH IN THAT
6 PIPELINE, WHICH WILL BE REALLY INTERESTING TO FOLLOW
7 ON.

8 UPCOMING WORKSHOPS, THE AUTISM WORKSHOP,
9 JUST TO REMIND YOU, IS ON MAY 28TH AND 29TH.
10 THERE'S A CALIFORNIA/JAPAN COLLABORATION WORKSHOP ON
11 JUNE 8/9, AND AN ETHICS WORKSHOP ON JUNE 30TH, JULY
12 1ST.

13 THE AUTISM WORKSHOP, I SHOWED YOU THIS
14 LAST TIME, SO IT WAS MEANT TO BE AS A REMINDER OF
15 WHAT WE'RE DOING IN THAT. MARIE HAS BEEN BUSILY
16 ORGANIZING THIS. WE'VE HAD A LOT OF INPUTS INTO IT.
17 AND SO ANYONE WHO'S INTERESTED, ANY MEMBERS OF THE
18 BOARD, PLEASE TALK TO MARIE OR I OR ANY OF THE
19 MEMBERS OF STAFF. IT WOULD BE GOOD TO HAVE SOME OF
20 YOU INVOLVED, AS WE OFTEN DO.

21 THE ADVANCING THE FIELD INSTITUTIONAL
22 APPROACHES SUPPORTING ETHICS IN STEM CELL RESEARCH,
23 THIS IS A DAY-AND-A-HALF WORKSHOP TO BE HELD IN SAN
24 FRANCISCO AND IS DESIGNED TO EXAMINE INSTITUTIONAL
25 APPROACHES FOR ADDRESSING ETHICAL, LEGAL, AND POLICY

BARRISTERS' REPORTING SERVICE

1 ISSUES RELATING TO STEM CELL RESEARCH. SO WHO'S
2 ATTENDING? INSTITUTIONS CURRENTLY INVOLVED IN HUMAN
3 PLURIPOTENTIAL STEM CELL RESEARCH AND THOSE
4 CONSIDERING RESEARCH IN THE AREA. SO, AGAIN, GEOFF
5 LOMAX IS VERY MUCH INVOLVED IN THAT.

6 SO AS USUAL I WANT TO THANK ALL OF THE
7 STAFF THAT REALLY WORK AMAZINGLY HARD, JUST
8 INCREDIBLE. THEY ALL DO, AND EVERY ONE OF THEM
9 SIMPLY NEEDS A STRONG, STRONG ACCOLADE.

10 I WANT TO INTRODUCE -- ASK MARGARET, IF
11 SHE'S HERE, IF SHE'LL GIVE YOU AN UPDATE ON THE
12 FINANCES. AND THEN I'LL ASK JOHN ROBSON TO JUST
13 DETAIL THE OVERALL FINANCES OF THE INSTITUTION.

14 VICE CHAIRMAN ROTH: ALAN, BEFORE YOU STEP
15 AWAY, I WANT TO MAKE SURE IF ANY BOARD MEMBER HAD A
16 COMMENT OR A QUESTION FOR ALAN, WE'D TAKE IT NOW ON
17 HIS REPORT. THERE WAS A LOT IN THAT REPORT.

18 DR. TROUNSON: SORRY. THERE'S A LOT GOING
19 ON.

20 VICE CHAIRMAN ROTH: ANYONE HAVE A
21 FOLLOW-UP QUESTION? THE SCIENCE IS MOVING. I THINK
22 EVERY TIME YOU STAND UP HERE, IT TAKES A LITTLE
23 LONGER TO GET THROUGH IT, WHICH IS A GOOD SIGN.

24 I WAS IN A MEETING TODAY WITH A GROUP OF
25 LAYMEN WHO TOLD ME THAT THEY'RE JUST AMAZED AT THE

BARRISTERS' REPORTING SERVICE

1 PROGRESS OF STEM CELL RESEARCH. THESE ARE PEOPLE
2 THAT WOULDN' T HAVE KNOWN WHAT THAT WAS THREE YEARS
3 AGO. IT' S GRATIFYING TO SEE THE SCIENCE MOVING.

4 MR. SHEEHY: I JUST WANTED TO GET A SENSE
5 OF WHAT THE STRATEGIC PURPOSE OF THE EXCEPTIONAL
6 SCIENTIST PROGRAM IS, WHAT THE TIMELINE FOR THAT
7 COMING IN IS. JUST CURIOUS HOW THAT FITS WITH US
8 GETTING QUICKER TO THE CLINIC. I' M NOT SURE THAT
9 THE BROAD DISCOVERY SCIENCE THING IS NECESSARILY AT
10 THIS TIME -- THAT I UNDERSTAND HOW IT FITS AT THIS
11 TIME WHERE WE ARE IN TERMS OF DEVELOPMENT AS OPPOSED
12 TO SOMETHING THAT' S MORE FOCUSED ON PERHAPS
13 CHALLENGES TOWARD REALLY LIKE THE IMMUNOLOGY ROUND,
14 WHICH CLEARLY TO ME IS SOMETHING THAT WE NEED TO DO
15 IN ORDER TO GET INTO THE CLINIC.

16 DR. TROUNSON: JEFF, THEY MIGHT BE
17 IMMUNOLOGISTS, BUT THERE' S A CADRE OF INCREDIBLY
18 PRODUCTIVE SCIENTISTS OUT THERE. SOME OF THEM ARE
19 IN PLACES WHERE THERE' S A LOT OF SENIOR STAFF IN
20 THOSE INSTITUTIONS. SO THEY CAN' T MOVE UP, AND SO
21 THEY' RE LOOKING TO GO, IF YOU LIKE, GO SOMEWHERE
22 ELSE. AND THE IDEA THAT WE MIGHT BE ABLE TO DRAW
23 SOME OF THEM TO CALIFORNIA RATHER THAN THEM GOING
24 SOMEWHERE ELSE, I THINK, IS CERTAINLY ATTRACTIVE.
25 IT' S BEEN AN INPUT FROM THE INSTITUTIONS AND THE

BARRISTERS' REPORTING SERVICE

1 COMPANIES TO SEE IF WE COULD ATTRACT ANY OF THOSE
2 PEOPLE TO COME. WHILE WE NEED -- I THINK WE NEED TO
3 ALSO RECOGNIZE THE SCIENTISTS THAT ARE HERE BECAUSE
4 WE DON'T WANT THEM RECRUITED SOMEWHERE ELSE EITHER.

5 SO I THINK IT COULD BE IN IMMUNOLOGY, IT
6 COULD BE IN THE AREAS WHERE WE MIGHT BE A BIT
7 DEFICIENT OR DEFICIENT. WE'VE GOT SOME NEW
8 INSTITUTIONS BUILDING STEM CELL INSTITUTES AND
9 CENTERS, AND THEIR VIEW IS THAT THEY'RE LOOKING FOR
10 SOME OF THESE KEY SCIENTISTS TO COME. I THINK IT'S
11 OPEN, AND WE WANTED TO SORT OF STIMULATE, START THE
12 THINKING PROCESS. AND I THINK IT'S REALLY OPEN FOR
13 EVERYONE TO INPUT INTO IT.

14 I THINK I WAS ENCOURAGED BY ED AND BOB AND
15 DUANE IN THE INTERNAL DISCUSSIONS, BUT IT'S ALL A
16 MATTER OF OPPORTUNITY IN A WAY AND AN ABILITY TO
17 MAKE CALIFORNIA AN EVEN MORE PRODUCTIVE STEM CELL
18 RESEARCH PLACE IF WE CAN GET SOME OF THESE REALLY
19 HIGH PERFORMING SCIENTISTS.

20 MR. SHEEHY: HOW DOES THIS OVERLAY WITH
21 THE RECRUITMENTS THAT ARE ALREADY COMMITTED WITHIN
22 THE FACILITIES PROGRAM? AGAIN, JUST TRYING TO HAVE
23 A SENSE. WE'VE DONE NEW SCIENTISTS WHICH ARE AT A
24 DIFFERENT LEVEL, AND WE HAVE COMMITMENTS TO
25 RECRUITMENTS WITHIN THE FACILITIES PROGRAM. AGAIN,

BARRISTERS' REPORTING SERVICE

1 I'M JUST REALLY, I GUESS, FEELING THE URGE AS AN
2 ADVOCATE TO SEE DETERMINATION TO THE CLINIC. WE'VE
3 DONE A LOT OF INFRASTRUCTURE BUILDING. I'M JUST
4 TRYING TO HAVE A SENSE OF STRATEGIC PURPOSE.

5 VICE CHAIRMAN ROTH: OTHER COMMENTS?

6 DR. PENHOET: FOR THOSE OF YOU WHO KNOW
7 THE HOWARD HUGHES MEDICAL INSTITUTE, THE IDEA WOULD
8 BE THAT THESE WOULD BE SIMILAR TO HOWARD HUGHES
9 MEDICAL INSTITUTE INVESTIGATOR AWARDS. THEY
10 RECOGNIZE OUTSTANDING CONTRIBUTORS OVER A PERIOD OF
11 TIME, AND THE DETAILS OF WHO EXACTLY YOU WOULD WANT
12 TO INCLUDE IN SUCH A PROGRAM, WHAT STRATEGIC PURPOSE
13 IT WOULD SERVE BEYOND RECRUITING SOME PEOPLE TO FILL
14 KEY GAPS IN THE STATE IN TERMS OF OUR EXPERTISE, IF
15 YOU WILL, ALL THAT HAS TO BE WORKED OUT, JEFF. THIS
16 IS A VERY EARLY STAGE PROPOSAL. IT'S JUST IN THE
17 EARLY STAGE OF THINKING THROUGH HOW IT MIGHT WORK.

18 BUT THE IDEA IS TO PROVIDE SOME SECURE
19 FUNDING FOR A FEW OUTSTANDING PEOPLE. AND FOR THOSE
20 OF YOU WHO KNOW HHMI, AND MANY OF YOU AROUND THE
21 TABLE DO, THE IDEA WOULD BE SOMETHING ALONG SIMILAR
22 LINES TO WHAT HOWARD HUGHES DOES, OBVIOUSLY TAILORED
23 FOR OUR OWN USE AND, YOU KNOW, IN A SENSE DESIGNED
24 TO, AS I SAID, FILL GAPS WITHIN THE STATE IN TERMS
25 OF IF YOU LOOK AT THE OVERALL CAPACITY WE HAVE IN

BARRISTERS' REPORTING SERVICE

1 CALIFORNIA TO DO ALL THE THINGS THAT NEED TO BE DONE
2 IN THIS SPACE, THERE ARE SOME KEY ELEMENTS WHICH
3 PROBABLY ARE MISSING AND WHERE SOME GOOD PEOPLE
4 MIGHT FILL IN.

5 YOU KNOW, IT'S AN EARLY CONCEPT, AND WE
6 NEED TO PUT FLESH ON THESE BARE BONES. BUT ALAN AND
7 I AND BOB WANTED TO BRING AT LEAST A ROUGH IDEA
8 BEFORE YOU TODAY SO WE COULD GET INPUT, ETC. ,
9 WHETHER TO DEVELOP IT FURTHER.

10 DR. BRENNER: I WANTED TO ASK ALAN WHAT
11 HIS THOUGHTS WERE ABOUT THE RETENTION GRANTS. YOU
12 HAVE TO BE REMARKABLY AGILE TO RESPOND TO RETENTION
13 ISSUES.

14 DR. TROUNSON: I RECOGNIZE THAT. AND SO
15 WHAT WE DIDN'T WANT TO DO WAS IN A WAY LOOK TO HELP
16 RECRUITMENT OF SOME OF THESE REALLY FIRST CLASS
17 SCIENTISTS AND THEN LOSE OUR FIRST CLASS SCIENTISTS
18 FROM CALIFORNIA BECAUSE THERE WAS NO SIMILAR
19 OPPORTUNITY. AND, OF COURSE, WITH HOWARD HUGHES
20 FELLOWSHIPS, THEY CAN BE ATTRACTED TO OTHER PLACES
21 AS WELL. AND, OF COURSE, HOWARD HUGHES HAS BROUGHT
22 GOOD PEOPLE TO CALIFORNIA. SO I DON'T KNOW.

23 WE'RE STILL SORT OF STRUGGLING WITH --
24 WE'RE STILL THINKING ABOUT HOW IT MIGHT WORK, BUT WE
25 DO KNOW THAT THERE'S SOME PHENOMENAL SCIENTISTS WHO

BARRISTERS' REPORTING SERVICE

1 ARE KIND OF TRANSPORTABLE AT THE PRESENT TIME OR MAY
2 BE TRANSPORTABLE. AND WE WANT TO THINK ABOUT HOW WE
3 CAN BE IN THE MARKETPLACE RATHER THAN JUST LET THEM
4 SAY, WELL, THERE'S NOTHING MUCH HERE. THERE'S
5 SOMETHING AT AN INSTITUTE I DON'T WANT TO GO TO, BUT
6 IS THERE SOMETHING WHERE I WANT TO GO TO IS
7 SOMETIMES A DIFFERENT QUESTION. YOU MAY NOT HAVE
8 THAT CAPACITY TO SUPPORT SUCH A KEY INDIVIDUAL.

9 SO IT'S TRYING TO DEVELOP THE THINKING,
10 AND IT'S NOTHING IN CEMENT HERE, BUT WE WOULD
11 WELCOME ALL KINDS OF INPUTS INTO THIS AND SEE WHERE
12 IT CAN FLOAT TO. IT'S CLEARLY A WORLDWIDE THING. I
13 THINK THERE ARE PEOPLE OUTSIDE THE COUNTRY AS WELL
14 WHO, NOT ONLY TALKING ABOUT INTERNALLY, WHO MIGHT BE
15 ATTRACTED, FOR EXAMPLE, IN THE AREA OF IMMUNOLOGY.
16 WE'RE NOT OVERBURDENED WITH REALLY TOP-LINE
17 IMMUNOLOGISTS THAT HAVE AN INTEREST IN TOLERANCE.
18 WE HAVE A FEW GOOD ONES, BUT IT'S NOT OVERWHELMING
19 IN CALIFORNIA AT THE MOMENT, AS I JUDGE IT ANYWAY.

20 DR. PENHOET: BUT TIMING WOULD BE A
21 CHALLENGE, FOR SURE. AND THE OTHER ISSUE THAT I
22 THINK MOST OF YOU ARE PROBABLY AWARE, HOWARD HUGHES
23 MEDICAL INSTITUTE JUNIOR INVESTIGATOR AWARDS ARE NOT
24 PORTABLE. SO IF YOUNG OUTSTANDING SCIENTISTS HAVE A
25 JUNIOR INVESTIGATOR AWARD FROM HOWARD HUGHES, THEY

BARRISTERS' REPORTING SERVICE

1 CAN' T TAKE IT FROM ONE INSTITUTION TO ANOTHER, SO
2 THEY CAN' T MOVE TO CALIFORNIA AND BRING THEIR HUGHES
3 FUNDING WITH THEM. SO THAT IS A CHALLENGE FOR A
4 NUMBER OF OUTSTANDING YOUNG PEOPLE BECAUSE THAT' S A
5 MAJOR SOURCE OF REVENUE OBVIOUSLY FOR THEIR PROGRAM.

6 VICE CHAIRMAN ROTH: SO THANK YOU, ALAN.
7 MARGARET. AND WHILE MARGARET IS MAKING HER WAY UP.

8 MS. KING: JUST FOR THE RECORD, WE'VE HAD
9 A FEW PEOPLE JOIN THE MEETING. WE NOW HAVE SHERRY
10 LANSING AND DR. FRANCISCO PRIETO, DAVID
11 SERRANO-SEWELL, AND LEEZA GIBBONS. WE HAVE A QUORUM
12 IN THE ROOM, AND JON SHESTACK. THANK YOU. I JUST
13 ASSUMED HE WAS HERE THE WHOLE TIME.

14 AND ALSO WE HAVE A COUPLE PEOPLE ON THE
15 PHONE, AND I WANTED TO CHECK. DR. POMEROY, ARE YOU
16 ON THE LINE?

17 DR. POMEROY: YES, MA'AM.

18 MS. KING: AND MARCY FEIT.

19 MS. FEIT: YES.

20 MS. KING: THANK YOU. WE ARE WELL ABOVE A
21 QUORUM NOW, DUANE.

22 VICE CHAIRMAN ROTH: THANK YOU. SO WHILE
23 MARGARET IS MAKING HER WAY UP, TED, DID YOU HAVE ANY
24 COMMENTS ABOUT THE FDA MEETING THAT YOU WANTED TO
25 MAKE?

BARRISTERS' REPORTING SERVICE

1 DR. LOVE: AT THE LAST MEETING ART TORRES
2 ACCUSED ME OF TALKING SO MUCH, SO I WAS TRYING TO BE
3 QUIET. I DO WANT TO SAY ONE THING ABOUT THE FDA.
4 FIRST OF ALL, BEFORE I SAY THAT, I WANTED TO SAY
5 THAT, ALAN, I THINK THAT YOUR REPORTS STARTING WITH
6 THE UPDATE ON THE SCIENCE ARE REALLY EXCELLENT. I
7 JUST WANT TO ENCOURAGE YOU TO CONTINUE TO DO THAT.
8 IT'S A REALLY INSIGHTFUL REPORT.

9 IN TERMS OF THE FDA MEETING, ALL THE
10 POINTS THAT HAVE BEEN MADE I AGREE WITH. I THOUGHT
11 IT WAS A REALLY WELL-DONE MEETING. THE STAFF WAS
12 BRILLIANTLY PREPARED. THE INTERACTION WITH THE FDA
13 WAS THE MOST CORDIAL I'VE EVER SEEN. I'M USUALLY
14 THERE REPRESENTING COMPANIES, SO THERE IS A BIT OF
15 AN ARM'S LENGTH APPROACH TYPICALLY WITH COMPANIES,
16 BUT IT WAS REALLY WELL DONE.

17 THE ONE THING I DO WANT THE BOARD TO HEAR
18 THAT YOU PROBABLY WOULDN'T HAVE HEARD IS THAT I
19 THOUGHT ONE OF THE MOST IMPORTANT MEETINGS ACTUALLY
20 OCCURRED AFTER THE MEETING BECAUSE AFTER OUR FORMAL
21 MEETING, THERE WAS ACTUALLY SOMETHING I THINK THAT
22 WAS BILLED AS KIND OF A SYMPOSIUM WHERE DR. CSETE
23 KIND OF GAVE THE FDA AN UPDATE ON STEM CELL
24 RESEARCH. AND I CAN TELL YOU THAT EVERYONE FROM THE
25 FDA WAS ABSOLUTELY RIVETED FOR THE WHOLE MEETING,

BARRISTERS' REPORTING SERVICE

1 AND SO WERE WE, QUITE FRANKLY. SHE DID A BRILLIANT
2 JOB. AND I THINK IT REALLY DID DO A WONDERFUL
3 EFFORT TO REALLY ESTABLISH US ON A PAR
4 SCIENTIFICALLY PEER WITH THE FDA. I REALLY THINK WE
5 OUGHT TO GIVE A REAL HAND TO MARIE.

6 (APPLAUSE.)

7 VICE CHAIRMAN ROTH: I HAD THE SAME
8 IMPRESSION. USUALLY WHEN I'M AT THE FDA, THE
9 BUTTERFLIES AND THE NERVES ARE VERY HIGH. YOU
10 WALKED INTO THE ROOM, IT WAS VERY RELAXED, VERY
11 OPEN. THEY ANSWERED ALL THE QUESTIONS. THE BODY
12 CHEMISTRY WAS VERY GOOD. SO I WAS QUITE PLEASED
13 WITH THE MEETING. TO THE STAFF AND THE PEOPLE THAT
14 MADE THE PRESENTATIONS, GOOD JOB.

15 MS. FERGUSON: THANK YOU. GOOD AFTERNOON,
16 MEMBERS OF THE ICOC, CIRM STAFF, AND MEMBERS OF THE
17 PUBLIC. I'M HERE AGAIN TO UPDATE THE CIRM'S
18 OPERATING BUDGET. THIS IS ONLY WHAT CIRM SPENDS TO
19 OPERATE AND DOES NOT INCLUDE GRANT FUNDING, WHICH
20 WILL BE ADDRESSED DR. JOHN ROBSON.

21 OKAY. I WILL GIVE YOU AN OVERVIEW OF OUR
22 SPENDING CATEGORIES AND COMPARE THE 2008-9 BUDGET
23 ALLOCATIONS TO EXPENDITURES POSTED AS OF MARCH '09.
24 AND I'M GOING TO LOOK TO THIS SIDE TOO BECAUSE I
25 CAN'T SEE THAT FAR EITHER.

BARRISTERS' REPORTING SERVICE

1 ANYWAY, THE CATEGORIES ARE SALARIES AND
2 BENEFITS, WHICH ARE SELF-EXPLANATORY IN AND OF
3 THEMSELVES; INTERAGENCY AGREEMENTS, WHICH RECORD
4 AGREEMENTS MADE WITH STATE OF CALIFORNIA AGENCIES
5 FOR SERVICES THEY RENDER TO CIRM. OUR CURRENT
6 AGREEMENTS ARE FOR ACCOUNTING, PAYROLL, LEGAL, AND
7 I.T. SERVICES. EXTERNAL CONTRACTS, EXPENDITURES IN
8 THIS CATEGORY ARE FOR -- I LOST IT THERE AGAIN FOR A
9 SECOND. OKAY. EXPENDITURES IN THIS CATEGORY ARE
10 FOR CONTRACTS WITH OUTSIDE CONTRACTORS AND VENDORS
11 TO PROVIDE A VARIETY OF NECESSARY SERVICES TO CIRM.
12 SUCH SERVICES INCLUDE, BUT ARE NOT LIMITED TO,
13 AUDITING, GRANTS MANAGEMENT, I.T. SUPPORT, AND
14 CONSULTING, LEGAL, COMMUNICATIONS, WEBSITE
15 DEVELOPMENT, PRINTING, AND MAINTENANCE COSTS.

16 THE ICOC, SCIENCE WORK GROUP GRANTS,
17 STANDARDS, AND FACILITIES MEETINGS CATEGORY, AGAIN,
18 IN THIS CATEGORY ARE ANY AND ALL COSTS RELATED TO
19 CONDUCTING BOARD, WORK GROUP, AND SCIENTIFIC
20 MEETINGS. SUCH COSTS WOULD INCLUDE TRAVEL, THE
21 MEETING VENUES, AUDIOVISUAL, SUPPLIES, AND
22 TRANSCRIPTION SERVICES. OTHER TRAVEL ARE FOR COSTS
23 DIRECTLY RELATED TO TRAVEL OF CIRM STAFF FOR
24 OFFICIAL STATE BUSINESS BOTH WITHIN AND OUTSIDE OF
25 THE STATE OF CALIFORNIA.

BARRISTERS' REPORTING SERVICE

1 FURNITURE AND EQUIPMENT WOULD COVER ANY
2 REPLACEMENT NEEDS FOR THOSE TYPE OF ITEMS.

3 INFORMATION TECHNOLOGY INCLUDES THE COST FOR
4 NECESSARY I.T. ITEMS, SUCH AS, BUT NOT LIMITED TO,
5 PERSONAL COMPUTERS, SERVERS, AND OTHER NECESSARY
6 HARDWARE COMPONENTS, AS WELL AS SOFTWARE AND
7 SOFTWARE MAINTENANCE.

8 OTHER OE&E, WHICH STANDS FOR OTHER
9 OPERATING EXPENDITURES AND EQUIPMENT, INCLUDES
10 EXPENDITURES FOR THE OFFICE SUPPLIES, PAPER,
11 PRINTING, COMMUNICATIONS, TRAINING, PUBLICATIONS,
12 SUBSCRIPTIONS, CONFERENCE REGISTRATIONS, AND
13 MEMBERSHIPS.

14 NOW, IN COLUMN 1 IS THE ORIGINAL BUDGET
15 ALLOCATION THAT WAS APPROVED BY THE BOARD BACK IN
16 JUNE OF 2008. THAT WAS OUR OPERATING BUDGET FOR
17 FISCAL YEAR 08-09. COLUMN 2 IS A REPRESENTATION OF
18 THE EXPENDITURES THAT OCCURRED THROUGH FEBRUARY
19 2009. COLUMN 3 TAKES THOSE EXPENDITURES POSTED
20 THROUGH MARCH OF '09, AND THE FOURTH COLUMN SHOWS
21 THOSE CHANGES BETWEEN FEBRUARY AND MARCH IN
22 EXPENDITURES. THE COLUMN 5 SHOWS WHAT IS STILL
23 AVAILABLE TO BE USED TO TAKE CARE OF THOSE NECESSARY
24 EXPENSES TO CARRY US THROUGH JUNE 30TH, 2009. AND
25 THE LAST IS JUST A PERCENTAGE OF THE EXPENDITURES TO

BARRISTERS' REPORTING SERVICE

1 THE BUDGET ALLOCATION THAT HAVE OCCURRED.

2 AS DISPLAYED, THE EXPENDITURES INDICATE
3 THAT WE'VE USED 43 PERCENT OF OUR OPERATING EXPENSES
4 AND EQUIPMENT BUDGET AND 56 PERCENT OF OUR SALARIES
5 AND BENEFITS ALLOCATION. OVERALL WE'VE USED 50
6 PERCENT OF OUR APPROVED BUDGET ALLOCATION AT THIS
7 POINT IN TIME. HOWEVER, AGAIN, I WOULD LIKE TO
8 BRING TO THE BOARD'S ATTENTION THAT WE STILL HAVE
9 OUTSTANDING INVOICES OR EXPENDITURES THAT NEED TO BE
10 PAID THAT ARE NOT RECORDED BECAUSE OF LAGS IN
11 PAYMENT. THE NORMAL ONE-MONTH LAG FOR ANY SERVICES
12 OR GOODS THAT ARE PROCURED OR TRAVEL THAT OCCURS
13 WON'T HAPPEN OR GET PROCURED OR PAID UNTIL THE
14 FOLLOWING MONTH.

15 WE ALSO HAVE CONTRACTS OR INTERAGENCY
16 AGREEMENTS THAT CALL FOR A QUARTERLY PAYMENT OR
17 PAYMENT WHEN THE SERVICE OR GOOD HAS BEEN RECEIVED
18 OR COMPLETED. WE ANTICIPATE THAT DURING THE PERIOD
19 APRIL 2009 THROUGH JUNE 2009, THE FINAL TWO QUARTERS
20 FOR THOSE TYPES OF CONTRACTS OR INTERAGENCY
21 AGREEMENTS WILL POST. AND EVEN WITH THE MONTHLY
22 LAGS AND QUARTERLY PAYMENT REQUIREMENTS, THE CIRM IS
23 STILL CURRENTLY PROJECTED TO OPERATE UNDER THE
24 APPROVED BUDGET ALLOCATION.

25 SO AT THIS TIME I'M OPEN FOR ANY QUESTIONS

BARRISTERS' REPORTING SERVICE

1 OR CLARIFICATION.

2 VICE CHAIRMAN ROTH: QUESTIONS FOR
3 MARGARET?

4 MR. SHEEHY: CAN WE JUST GET A COPY OF THE
5 DOCUMENT?

6 MS. FERGUSON: YES.

7 VICE CHAIRMAN ROTH: I DON'T BELIEVE
8 THERE'S A COPY IN THE BOOK.

9 MR. SHEEHY: MAYBE --

10 MS. KING: YOU DON'T HAVE A COPY OF THE
11 DOCUMENT, BUT, JEFF, ARE YOU ASKING FOR THAT RIGHT
12 NOW BECAUSE I CAN CERTAINLY POST IT AFTER THE
13 MEETING.

14 MR. SHEEHY: AFTER THE MEETING JUST SO WE
15 HAVE IT.

16 VICE CHAIRMAN ROTH: WE'RE THREE-QUARTERS
17 THROUGH THE YEAR AND WE SPENT HALF OUR BUDGET.

18 MS. FERGUSON: YES. HOWEVER, TAKE INTO
19 CONSIDERATION THAT WE STILL HAVE AT LEAST A MONTH
20 LAG IN INVOICES.

21 VICE CHAIRMAN ROTH: BUT THAT WILL BE TRUE
22 AT THE END OF JUNE 30TH.

23 MS. FERGUSON: THAT'S TRUE, BUT AT JUNE
24 30TH, WE HAVE TO RECORD EVERYTHING.

25 VICE CHAIRMAN ROTH: THEN YOU'LL

BARRISTERS' REPORTING SERVICE

1 RECONCILE.

2 MS. FERGUSON: ABSOLUTELY.

3 VICE CHAIRMAN ROTH: YOU HAVE AN ESTIMATE
4 OF WHAT THAT RECONCILIATION WILL LOOK LIKE, HOW MUCH
5 IS OUT THERE IN THE LAG?

6 MS. FERGUSON: IN THE LAG, LOOKING AT THE
7 EXPENDITURES IN THE WAY THEY HAVE BEEN COMING
8 THROUGH, WE ANTICIPATE THAT WE SHOULD HAVE OR THAT
9 WE SHOULD SPEND UNDER OUR BUDGET ALLOCATION BY ABOUT
10 19 PERCENT.

11 VICE CHAIRMAN ROTH: SO YOU'RE 25 PERCENT
12 UNDER. YOU PROJECT THAT WOULD BE 19 OR 20 PERCENT?

13 MS. FERGUSON: RIGHT.

14 VICE CHAIRMAN ROTH: OTHER QUESTIONS FOR
15 MARGARET? IF NOT, THANK YOU VERY MUCH, MARGARET.
16 JOHN, ARE YOU UP NEXT?

17 DR. ROBSON: OKAY. SO WHAT A DIFFERENCE A
18 WEEK MAKES. I'VE BEEN GIVING YOU THESE OVERALL
19 REPORTS ON OUR FINANCES SINCE JANUARY, AND I'VE GOT
20 TO TELL YOU THEY HAVEN'T REALLY BEEN JOYOUS EVENTS.
21 WE'VE HAD SOME CASH FLOW CONCERNS. AND IF YOU
22 RECALL, BACK IN JANUARY, THE START OF THE YEAR, WE
23 HAD ABOUT \$160 MILLION IN THE BOND FUND, AND WE WERE
24 PROJECTING THAT WAS GOING TO LAST US THROUGH THIS
25 CALENDAR YEAR, MAYBE, BUT NOT BEYOND THAT.

BARRISTERS' REPORTING SERVICE

1 WE NOW, AS OF THIS WEEK OR NEXT WEEK, WE
2 HOPE, SHOULD HAPPEN IN THE NEXT FEW WEEKS, WE' LL
3 HAVE \$400 MILLION IN THE BANK. AND THAT' S GOING TO
4 CHANGE OUR FINANCIAL PICTURE CONSIDERABLY. SO I
5 THOUGHT I WOULD JUST SHOW YOU THE IMPLICATIONS OF
6 THAT NEW MONEY THAT' S COMING IN.

7 SO I' M GOING TO GO BACK TO SORT OF THE
8 MESSAGE I GAVE YOU IN JANUARY. I HAVE A POINTER, SO
9 WHEN I USE THE POINTER, I' LL USE IT ON THE SCREEN TO
10 THE RIGHT BECAUSE I DON' T WANT TO FRY ANYBODY' S
11 RETINA OVER THERE ON THE LEFT SIDE SIDE OF THE
12 TABLE.

13 IN JANUARY, IF YOU RECALL, I GAVE YOU
14 THREE SCENARIOS FOR OUR FUNDING NEEDS FOR THE PERIOD
15 BETWEEN JANUARY 1, 2009, AND DECEMBER 31ST OF 2010.
16 AND ONE OF THE SCENARIOS WAS HOW MUCH MONEY WOULD WE
17 NEED IF WE JUST FUNDED ONGOING PROGRAMS. THE SECOND
18 SCENARIO WAS TO FUND ONGOING PROGRAMS PLUS THOSE
19 PROGRAMS THAT HAD BEEN THROUGH ICOC CONCEPT
20 APPROVAL, AND THE THIRD SCENARIO WAS ALL OF BOTH OF
21 THOSE PLUS SOME ADDITIONAL PROGRAMS. I' M GOING TO
22 SHOW YOU JUST THE SECOND SCENARIO AND THE THIRD
23 SCENARIO AND HOW THE IMPLICATIONS HAVE CHANGED.

24 JUST TO REMIND YOU, THESE ARE THE PROGRAMS
25 THAT HAVE BEEN THROUGH ICOC APPROVAL. THEY HAVE NOT

BARRISTERS' REPORTING SERVICE

1 BEEN ACTED ON. IN JANUARY I ALSO LISTED BRIDGES AND
2 TRAINING II, BUT YOU'VE ALREADY MADE SOME DECISIONS
3 ON THOSE. I TOOK THEM OFF THE LIST.

4 SO WHAT THE BUDGET LINE IS THERE, THOSE
5 ARE THE TOTAL COMMITMENTS FOR THOSE THAT YOU HAD
6 ALLOCATED FOR THOSE VARIOUS PROGRAMS. AND THE
7 COLUMN ON THE RIGHT SHOWS WHAT THE EXPENDITURES
8 WOULD BE PRIOR TO OR UP UNTIL DECEMBER 31, 2010.

9 SO THE NEXT SLIDE SHOWS ONE OF THESE
10 DASHBOARD CHARTS TO SHOW THE IMPLICATIONS OF THAT
11 PROGRAM. THIS IS WHAT THE WORLD LOOKED LIKE TO US
12 IN JANUARY. SO JUST TO REMIND YOU HOW THIS CHART
13 WORKS, I'LL TAKE YOU THROUGH IT. IT'S NOT AS
14 COMPLICATED AS IT LOOKS.

15 THE BARS, THE VERTICAL BARS, INDICATE THE
16 EXPENDITURE IN EACH QUARTER. THAT'S THE QUARTER
17 FROM JANUARY 2009 UNTIL DECEMBER OF 2010. THE BLUE
18 PORTION OF THE BAR IS WHAT WE WERE PROJECTING TO
19 SPEND ON GRANTS, AND THE BEIGE PART IS WHAT WE ARE
20 SPENDING ON OPERATIONS. THE NUMBERS ON THE VERTICAL
21 AXIS ON THE LEFT REFER TO THOSE BARS. SO IF YOU
22 LOOK FOR THE FIRST QUARTER OF THIS YEAR, WE'RE
23 PROJECTING TO SPEND ABOUT \$30 MILLION ON GRANTS AND
24 OPERATIONS DURING THAT PERIOD.

25 THE GREEN LINE IS THE AMOUNT OF MONEY THAT

BARRISTERS' REPORTING SERVICE

1 WE ARE PROJECTING TO HAVE AVAILABLE TO SPEND. THIS
2 IS WHAT WAS IN THE BOND FUND. BEGINNING OF THE
3 YEAR, IT WAS 160 MILLION, SO BY THE END OF THE FIRST
4 QUARTER, IT WOULD BE DOWN TO ABOUT \$128 MILLION.
5 THE RED LINE ACROSS INDICATES ZERO IN THAT BANK
6 ACCOUNT. SO THE NUMBERS ON THE VERTICAL AXIS ON THE
7 RIGHT HERE REFER TO THE GREEN LINE. THAT'S THE
8 AMOUNT OF MONEY THAT'S AVAILABLE. ZERO IS RIGHT
9 ABOUT THERE. SO OUR OBJECTIVE, AS I SAID BEFORE, IS
10 TO KEEP THAT GREEN LINE ABOVE THE RED LINE.

11 SO AS THE WORLD LOOKED TO US IN JANUARY,
12 WE HAD MONEY THAT WE WOULD RUN OUT BY THE END OF THE
13 YEAR. SO NOW LET'S JUST -- THIS IS BASED ON ALL THE
14 CONCEPT APPROVED PROGRAMS PLUS THE ONGOING
15 COMMITMENTS.

16 SO NOW LET'S LOOK. THE NEXT SLIDE SHOWS
17 WHAT THE WORLD LOOKS LIKE TO US NOW WITH AN INFLUX
18 OF \$277 MILLION IN THIS SECOND QUARTER OF THIS YEAR.
19 SO NOW WE CAN FUND ALL OF THOSE PROGRAMS THROUGH THE
20 END OF 2010, AND WE'LL STILL HAVE ABOUT \$30 MILLION
21 IN THE BANK.

22 SO LET'S GO TO SCENARIO 3, WHICH IS IN THE
23 NEXT SLIDE. THESE WERE SOME PROGRAMS WE HAVEN'T
24 MADE FINAL DECISIONS ABOUT THESE AT ALL, BUT I JUST
25 PUT THESE UP TO SHOW YOU SOME EXAMPLES. IF WE WERE

BARRISTERS' REPORTING SERVICE

1 TO FUND THESE KINDS OF PROGRAM WITH THESE SORTS OF
2 DOLLAR COMMITMENTS, THEY WOULD INITIATE THEIR
3 FUNDING IN THE SECOND HALF OF NEXT YEAR, 2010. AND
4 THESE VARIOUS PROGRAMS, THIS IS THE AMOUNT THAT
5 ACTUALLY WOULD BE EXPENDED PRIOR TO THE END OF 2010.

6 IF WE WERE TO PUSH PROGRAMS LIKE THAT
7 THROUGH, WHAT OUR FINANCE WOULD LOOK LIKE IS SHOWN
8 IN THE NEXT SLIDE, AGAIN, ON ONE OF THESE
9 DASHBOARDS. WE COULD STILL DO THAT, AND WE WOULD
10 STILL HAVE A POSITIVE BALANCE OF 17 MILLION. THIS
11 IS WITHOUT RAISING ANY MONEY BEYOND WHAT WE HAVE
12 JUST FOUND OUT ABOUT IN THE LAST WEEK. I SHOULD
13 SAY, I APOLOGIZE FOR NOT GETTING YOU THESE SLIDES IN
14 ADVANCE. I WOULD HAVE LIKED TO HAVE DONE THAT, BUT
15 I HOPE YOU CAN APPRECIATE WE ONLY FOUND THESE
16 NUMBERS OUT ON FRIDAY. WE WERE ONLY MAKING THE
17 SLIDES YESTERDAY. THEY WILL BE POSTED. YOU WILL
18 HAVE ACCESS TO THEM.

19 ONE OTHER THING I MIGHT MENTION HERE THAT
20 YOU MAY WANT TO CONSIDER. AT THE LAST MEETING YOU
21 MADE A DECISION ABOUT THE TRAINING II PROGRAM, TO
22 DELAY THAT INITIAL FUNDING FOR A YEAR. YOU APPROVED
23 THE GRANTS, BUT YOU SAID WE WOULD DELAY THE INITIAL
24 FUNDING FOR A YEAR. I'D JUST LIKE TO POINT OUT TO
25 YOU THAT NOW IF YOU WERE TO DECIDE -- YOU CAN'T DO

BARRISTERS' REPORTING SERVICE

1 IT AT THIS MEETING BECAUSE IT'S NOT AN ACTION
2 ITEM -- BUT IF YOU WANTED FOR YOUR CONSIDERATION IN
3 JUNE TO CONSIDER STARTING THAT PROGRAM NOW IN JUNE
4 IN THE THIRD QUARTER OF THIS CALENDAR YEAR, WE COULD
5 STILL DO THAT. THAT WOULD ADD ABOUT 13 MILLION TO
6 OUR COMMITMENT BETWEEN NOW AND THE END OF 2010. WE
7 WOULD STILL BE POSITIVE AT THAT POINT. THAT'S THE
8 PICTURE OF HOW THINGS LOOK RIGHT NOW.

9 BUT, OF COURSE, THE WORLD DOESN'T END IN
10 2010, AND I DON'T WANT YOU ALL TO GET TOO GIDDY OVER
11 OUR FINANCES. I JUST THOUGHT I WOULD SHOW YOU ONE
12 MORE SLIDE WHICH JUST SAYS WHAT HAPPENS AFTER
13 JANUARY 1ST OF 2011. THIS JUST SHOWS, THEN, THE
14 FIRST TWO QUARTERS OF 2011, AND YOU WILL SEE WE GO
15 DOWN QUITE QUICKLY BECAUSE SOME OF THE PROGRAMS
16 WE'VE STARTED NOW ARE GOING TO BE FAIRLY BIG TICKET
17 ITEMS.

18 SO WE DO NEED TO CONTINUE TO RAISE MORE
19 MONEY. BUT AS JAMES HARRISON POINTED OUT, WE HAVE
20 AUTHORIZATION IN THE PRIVATE PLACEMENT PROGRAM TO
21 RAISE ANOTHER 160 MILLION. THAT'S READY FOR US TO
22 DO RIGHT NOW AND WE'RE WORKING ON THAT. BOB IS
23 CERTAINLY WORKING ON THAT. SO THAT'S MY REPORT.
24 THINGS CERTAINLY LOOK MUCH BETTER. I CAN GO TO
25 MEETINGS NOW AND NOT FEEL LIKE I'M DRAGGING A WET

BARRISTERS' REPORTING SERVICE

1 BLANKET BEHIND ME ALL THE TIME. IT'S MADE ME SLEEP
2 BETTER, AND I HOPE THAT YOU'LL ALL SLEEP BETTER.

3 VICE CHAIRMAN ROTH: BETTER REPORT.

4 QUESTIONS AND COMMENTS FOR JOHN?

5 MS. LANSING: CONGRATULATIONS FROM ALL OF
6 US. I MISSED THE BEGINNING, BUT I KNOW HOW HAPPY WE
7 ALL ARE.

8 VICE CHAIRMAN ROTH: WE MISSED YOU. YOU
9 WERE ALWAYS THE CHEERLEADER HERE.

10 MS. LANSING: I'M EXCITED.

11 VICE CHAIRMAN ROTH: JUST TO BE ABSOLUTELY
12 CERTAIN, WE CALCULATE ALL THE OPERATING EXPENSES IN
13 ADDITION TO THE GRANT COMMITMENTS INTO THESE
14 NUMBERS.

15 DR. ROBSON: YEAH. THE BEIGE NUMBERS AT
16 THE BOTTOM OF THOSE VERTICAL BARS, THOSE ARE OUR
17 OPERATION COSTS FOR EACH QUARTER.

18 VICE CHAIRMAN ROTH: YOU'VE MADE SOME
19 ASSUMPTIONS ABOUT THE OPERATING BUDGET FOR --

20 DR. ROBSON: WE'VE PUT AN INFLATIONARY
21 INCREASE. YOU HAVE TO REMEMBER OUR OPERATIONS IS A
22 VERY SMALL PORTION OF OUR OVERALL OUTLAY.

23 VICE CHAIRMAN ROTH: I UNDERSTAND.

24 MR. SHESTACK: CASH BALANCE, IF YOU DID
25 THE ADDITIONAL PROGRAMS AT THE END OF 2010 --

BARRISTERS' REPORTING SERVICE

1 DR. ROBSON: BACK UP ONE.

2 MR. SHESTACK: -- IS HOW MUCH?

3 DR. ROBSON: THAT WOULD BE 17 MILLION. IF
4 WE DECIDED TO FUND THE TRAINING II PROGRAM EARLIER
5 THAN THE DECISION YOU MADE AT THE LAST MEETING, WE
6 COULD ACCOMMODATE THAT. THAT WOULD LEAVE US WITH A
7 BALANCE OF ABOUT FOUR MILLION WITHOUT ANY NEW FUNDS
8 RAISED.

9 MR. SHESTACK: THANK YOU.

10 VICE CHAIRMAN ROTH: SO ONE ITEM WE CAN
11 TAKE A FEW COMMENTS ON IS THE TRAINING GRANTS AND
12 WHETHER WE WANT TO MOVE THOSE BACK ON THE AGENDA FOR
13 JUNE. I ASSUME SO, BUT I'LL OPEN THE FLOOR.

14 MR. HARRISON: DUANE, BECAUSE THIS ITEM
15 ISN'T AGENDIZED AND BECAUSE WE HAVEN'T PREPARED
16 CONFLICTS FOR IT, I WOULD RECOMMEND THAT WE REFRAIN
17 FROM HAVING ANY SUBSTANTIVE DISCUSSION UNTIL THE
18 JUNE MEETING.

19 VICE CHAIRMAN ROTH: I'M NOT REALLY
20 LOOKING FOR DISCUSSION OTHER THAN COMMENTS ABOUT
21 WHETHER WE WANT STAFF TO CONSIDER AGENDIZING THAT
22 FOR THE NEXT MEETING.

23 DR. LOVE: I HAVE NO CONFLICTS, SO I'LL
24 SAY I'D LIKE TO SEE IT ON THE AGENDA FOR JUNE.

25 DR. ROBSON: THAT WOULD BE STAFF'S

BARRISTERS' REPORTING SERVICE

1 RECOMMENDATION AS WELL.

2 VICE CHAIRMAN ROTH: ANY OTHER COMMENTS
3 FOR JOHN?

4 MR. SHEEHY: I JUST WANT TO SAY THIS IS A
5 SUPERB JOB. THANK YOU, JOHN. THIS IS FABULOUS.

6 I'M WONDERING --

7 DR. ROBSON: IT'S A LOT EASIER WHEN YOU
8 HAVE ANOTHER 277 MILLION.

9 MR. SHEEHY: THIS IS GOING FORWARD. BUT
10 CAN WE START THINKING ABOUT WHEN OUR MILESTONE
11 GRANTS, WHEN THOSE ARE GOING TO GET TO CUT-OFF
12 POINTS? SO TOOLS AND TECHNOLOGY, THE EARLY
13 TRANSLATION TO DATE, AND THE DISEASE TEAMS ARE ALL
14 GOING TO HAVE MILESTONE JUNCTURES WHERE IF THEY
15 DON'T MAKE THEM, OUR OBLIGATIONS CEASE, AND THAT THE
16 GRANTS ARE OVER.

17 SO, AGAIN, GOING FORWARD, I THINK THIS IS
18 A SUPERB JOB, BUT MAYBE THIS IS SOMETHING WE CAN
19 START TO ADD IN SO THAT OUR FUTURE OBLIGATIONS DON'T
20 SEEM ENDLESS AS WE'RE DOING THESE RATHER LARGE GRANT
21 PROGRAMS. AND WE WON'T BE ABLE TO PROJECT OUT HOW
22 MUCH WE GET BACK, BUT AT LEAST WE'LL KNOW AT SOME
23 POINT THERE'S GOING TO BE A DAY OF RECKONING.

24 DR. ROBSON: WE'RE DOING THIS SAME KIND OF
25 ANALYSIS ON A MONTHLY BASIS WITH REAL NUMBERS, NOT

BARRISTERS' REPORTING SERVICE

1 JUST PROJECTIONS. SO WE'RE KEEPING TABS ON THIS.
2 WE'LL SEE HOW THE PROJECTED NUMBERS AND THE REAL
3 NUMBERS DIFFER IF THEY START TO DIFFER IF A PROGRAM
4 GETS TERMINATED FOR SOME REASON.

5 VICE CHAIRMAN ROTH: THIS ASSUMES FULL
6 FUNDING.

7 MR. SHEEHY: I MEAN LIKE THE SPECIFIC --
8 LIKE IN THE TOOLS AND TECHNOLOGY, THOSE GRANTS ALL
9 HAD WITHIN THOSE APPLICATIONS SPECIFIC MILESTONES.
10 IF THEY DON'T HIT THOSE MILESTONES, THOSE GRANTS
11 DON'T CONTINUE.

12 DR. ROBSON: NOT TOOLS AND TECHNOLOGY, NO.
13 THEY HAVE ANNUAL REVIEW AND SUCCESS CRITERIA.

14 MR. SHEEHY: BUT I JUST MEAN BECAUSE I
15 THINK WE'RE DOING THESE REALLY LARGE PROGRAMS THAT I
16 THINK, AT LEAST FOR ME MENTALLY, I SEE \$60 MILLION
17 OR \$210 MILLION AND THINKING THAT THAT'S AN
18 OBLIGATION THAT I'M GOING TO HAVE TO FULFILL. BUT
19 IN REALITY SOME PERCENTAGE, AND WE CAN'T PREDICT
20 WHAT PERCENTAGE, BUT SOME PERCENTAGE OF THOSE WILL
21 NOT SUCCEED AFTER MAYBE A COUPLE OF YEARS. THEIR
22 MILESTONES OR THEIR SUCCESS CRITERIA WON'T BE MET,
23 AND THAT MONEY WILL THEN COME BACK TO US TO BE
24 RECYCLED INTO NEW EARLY TRANSLATION OR NEW DISEASE
25 TEAMS. SO I JUST -- AGAIN, THIS IS A FUTURE POINT.

BARRISTERS' REPORTING SERVICE

1 DR. ROBSON: I THINK WE'RE NEW ENOUGH INTO
2 THESE PROGRAMS, THAT WE CAN'T REALLY PREDICT AT ALL.
3 WE DON'T HAVE A COMPARATOR HERE. SO I THINK WE JUST
4 HAVE TO WORK WITH THE PROJECTIONS AND THE AMOUNTS
5 THAT YOU FUND, AND THEN WE'LL WORK WITH THE REAL
6 NUMBERS AS THEY COME OUT.

7 VICE CHAIRMAN ROTH: SO THIS IS -- I THINK
8 THIS IS THE CONSERVATIVE WAY TO BUDGET, BUDGET FULL,
9 AND THEN WE WILL OVER TIME LEARN IF WE HAVE MONEY
10 RECYCLING BACK IN. OTHER COMMENTS?

11 MR. TORRES: I JUST WANTED TO SAY THANK
12 YOU AGAIN, JOHN, AND ALSO TO INDICATE TO THE MEMBERS
13 OF THE BOARD THAT BOB AND I ARE WORKING IN THE
14 PRIVATE PLACEMENT AREA TO BE LOOKING AT UNION
15 TRUSTEE FUNDS BECAUSE THE INITIATIVE REQUIRES A
16 PREVAILING WAGE BE PROVIDED. AND, THEREFORE, THESE
17 KINDS OF PROJECTS HAVE A DUAL PURPOSE, NO. 1,
18 CREATING JOBS IN CALIFORNIA FOR FACILITIES DOWN THE
19 ROAD AND, NO. 2, MAKING SURE THAT THE MEMBERSHIP OF
20 MANY OF THESE UNIONS WHICH ARE STILL SOLVENT -- I
21 CAN'T SPEAK FOR GM -- BUT THOSE THAT ARE STILL
22 SOLVENT WE NEED TO PURSUE BECAUSE THAT'S A DIRECT
23 INVESTMENT FROM CALIFORNIA TRUSTS FUNDS FROM THESE
24 UNIONS AND THE LABOR MOVEMENT INTO THIS INSTITUTE.
25 AND THERE'S NO OTHER INITIATIVE THAT REQUIRES THIS

BARRISTERS' REPORTING SERVICE

1 KIND OF AGENCY TO PROVIDE FOR A PREVAILING WAGE,
2 WHICH HAS A VERY POSITIVE IMPACT WITHIN CALIFORNIA.

3 VICE CHAIRMAN ROTH: GOOD POINT. AND
4 THAT'S THE WISDOM OF THE BOARD TO APPOINT TWO VICE
5 CHAIRS SO HE CAN TALK TO THE UNIONS BECAUSE THEY
6 WON'T TALK TO ME. GOOD LUCK.

7 SO WE HAVE A COUPLE MORE BOARD MEMBERS
8 THAT HAVE JOINED, RICARDO AZZIZ AND ROBERT QUINT.

9 I'D LIKE TO -- THANKS, JOHN. I'D LIKE TO
10 MOVE TO THE CONSENT ITEMS, AND THERE ARE TWO ON THE
11 AGENDA. WE'RE NOT GOING TO DEAL WITH NO. 4, BUT NO.
12 5 I WOULD ENTERTAIN A MOTION FOR APPROVAL. THIS IS
13 THE TECHNICAL AMENDMENTS TO GRANTS ADMINISTRATION
14 POLICY --

15 MS. LANSING: SO MOVED.

16 DR. PRIETO: SECOND.

17 VICE CHAIRMAN ROTH: -- FOR ACADEMIC AND
18 NONPROFIT. SHERRY LANSING AND FRANCISCO PRIETO.
19 BOARD DISCUSSION? ANY PUBLIC COMMENTS ON THIS? IF
20 NOT, ALL IN FAVOR? OPPOSED? ABSTAIN? MOTION
21 CARRIES.

22 MR. HARRISON: BECAUSE WE HAVE TWO MEMBERS
23 ON THE PHONE, WE NEED TO DO A ROLL CALL OF THE TWO
24 MEMBERS ON THE PHONE.

25 MS. KING: FOUR ARE MEMBERS JOINING BY

BARRISTERS' REPORTING SERVICE

1 PHONE. I'M GOING TO CALL YOUR NAME AND PLEASE VOTE
2 ON THE ITEM CURRENTLY ON THE FLOOR. CLAIRE POMEROY.

3 DR. POMEROY: YES.

4 MS. KING: MARCY FEIT.

5 MS. FEIT: YES.

6 MS. KING: OKAY. FOR THE RECORD, THAT
7 MOTION CARRIES.

8 VICE CHAIRMAN ROTH: THANK YOU. ITEM 8 --
9 WE'RE GOING TO -- ITEM 4 AND ITEM 8 ARE GOING TO BE
10 MOVED TO THE JUNE AGENDA. SO WE'RE GOING TO MOVE
11 NOW TO ITEM 9 AND ASK DON GIBBONS TO WALK US THROUGH
12 AGENDA ITEM 9.

13 MR. GIBBONS: THANK YOU, BOARD, VICE
14 CHAIRS, AND BOARD MEMBERS. I WANT TO JUST GIVE YOU
15 A BRIEF UPDATE ON SOME OF OUR PROGRAMS. WE HAVE
16 STARTED TO MOVE FORWARD FAIRLY RAPIDLY WITH SOME
17 PROGRAMS THAT WERE OUTLINED ACTUALLY IN THE 2006
18 STRATEGIC PLAN AND WAS PART OF THE REASON WHY I
19 AGREED TO COME TO THIS JOB IS BECAUSE OF THE
20 COMMUNITY OUTREACH EDUCATION THAT WAS A PART OF THAT
21 PLAN.

22 SO WE HAVE BEGUN A HIGH SCHOOL EDUCATION
23 INITIATIVE. THE PLAN ENVISIONED 1.5 MILLION
24 INVESTMENT IN EDUCATIONAL MATERIALS. I ACTUALLY
25 DON'T THINK IT WILL REQUIRE THAT LEVEL OF

BARRISTERS' REPORTING SERVICE

1 INVESTMENT, BUT THAT IS WHAT WAS IN THE ORIGINAL
2 PLAN. WE HAVE A CURRENT CONTRACT WITH LAUREL
3 BARCHAS. SHE IS A RECENT GRADUATE FROM BERKELEY AND
4 WAS VERY INVOLVED IN THE STUDENT STEM CELL SOCIETY
5 WHEN SHE WAS THERE. AND WHILE THERE THEY BEGAN A
6 PROGRAM OF UNDERGRADUATES AND GRADUATE STUDENTS AND
7 POST DOCS GOING INTO HIGH SCHOOLS WITH A ONE-DAY
8 LESSON PLAN SO THAT THERE WAS SOME LEVEL OF STEM
9 CELL SCIENCE AND STEM CELL POLICY IN HIGH SCHOOLS IN
10 THE BAY AREA.

11 I KNEW THAT ANY FULL-BLOWN EFFORT TO DO
12 CURRICULUM IN THIS STATE WOULD BE A TWO- OR
13 THREE-YEAR PROCESS. SO I THOUGHT WHILE THIS PROGRAM
14 IS ONGOING, LET'S SEE IF WE CAN CONTINUE IT. SO
15 I'VE ASKED HER TO CONTINUE THAT PROGRAM, EXTEND IT
16 TO OTHER REGIONS. THERE ARE STUDENTS, STEM CELL
17 SOCIETIES AT UC SANTA CRUZ AND AT IRVINE, SO SHE'S
18 MADE CONTACTS TO EXTEND THEM THERE. AND WE'RE
19 SEEING IF WE CAN'T STIR UP INTEREST IN SAN DIEGO AND
20 L.A. FOR STUDENT STEM CELL SOCIETIES THERE TO DO
21 THIS AS WELL.

22 I VIEW THIS AS A STOPGAP MEASURE TO GET A
23 LITTLE BIT OF STEM CELL SCIENCE INTO THE SCHOOLS
24 WHILE WE DEVELOP A MORE FORMAL CURRICULUM. IT'S
25 ALSO A BIT OF A RESEARCH PHASE. WE ARE DOING

BARRISTERS' REPORTING SERVICE

1 SURVEYS WITH THE STUDENTS AND THE TEACHERS DURING
2 THIS PROCESS AS THEY GO INTO CLASSROOMS. THERE ARE
3 17 LECTURES SCHEDULED IN THE BAY AREA ALREADY THIS
4 SPRING. AND WE'RE DOING ALSO INFORMAL INFORMATIONAL
5 INTERVIEWS WITH TEACHERS, AS MANY AS WE CAN FIND.

6 LAUREL WAS AT A MEETING THAT DUANE WAS THE
7 KICKOFF SPEAKER FOR SATURDAY IN SAN DIEGO THAT HAD
8 50 SCIENCE TEACHERS THERE. AND WHAT WE'RE TRYING TO
9 DETERMINE IS WHAT ARE THEIR NEEDS, WHAT IS THEIR
10 ACCEPTANCE LEVEL OF THIS MATERIAL. AND I THINK
11 DUANE WILL CONFIRM THAT TEACHERS THAT WERE THERE ON
12 SATURDAY WERE ANXIOUS TO GET THIS MATERIAL. THEY
13 WERE VERY MUCH LOOKING FORWARD TO BEING ABLE TO
14 BRING THIS INTO THEIR CLASSROOMS.

15 PART OF OUR CONTRACT WITH LAUREL IS DO A
16 WEBSITE WITHIN THE CIRM WEBSITE FOR TEACHERS.
17 BASICALLY THERE IS A CONSIDERABLE AMOUNT OF MATERIAL
18 OUT THERE THAT'S WEB BASED ON STEM CELL SCIENCE, SO
19 CAN WE CONSOLIDATE THAT IN A WAY THAT'S CONSTRUCTIVE
20 AND USEFUL FOR THE HIGH SCHOOL TEACHER COMMUNITY AND
21 GET THAT ON THE SITE THIS SUMMER.

22 AND THEN IF ALL THIS RESEARCH SHOWS THAT
23 IT IS WARRANTED, THEN I WOULD WORK WITH HER TO
24 DEVELOP AN RFP TO PUT OUT TO A FORMAL CURRICULUM
25 DEVELOPMENT COMPANY AND COME BACK TO YOU WITH A

BARRISTERS' REPORTING SERVICE

1 PROPOSAL TO EXPEND SOME LEVEL OF FUNDS TO DO THAT
2 FORMAL DEVELOPMENT.

3 I REPORTED AT OUR LAST MEETING THAT THE
4 DEPARTMENT OF EDUCATION DID INDEED AT ITS MARCH 11TH
5 MEETING VOTE TO MANDATE STEM CELL SCIENCE IN THE NEW
6 FRAMEWORK, WHICH IS A ROLLING FRAMEWORK. SCIENCE IS
7 ADDRESSED ABOUT ONCE EVERY SEVEN YEARS. AND WE GOT
8 IN AT THE RIGHT MOMENT TO PUT IT INTO THE FRAMEWORK,
9 AND THEY VOTED UNANIMOUSLY AT THAT MEETING TO PUT IT
10 IN THE FRAMEWORK, BUT THAT WOULD RESULT IN IT
11 ACTUALLY BEING IN THE CURRICULUM IN 2011. SO WE'RE
12 KIND OF ON THE RIGHT TIMEFRAME FOR THAT.

13 THERE IS A COROLLARY PIECE TO THIS THAT I
14 WILL COME BACK TO IN THE MORNING. THERE IS A LATE
15 AGENDA ITEM ADDED ON MONDAY BECAUSE OF A SENATE
16 HEARING WE FOUND OUT ABOUT LATE THAT SENATOR
17 STEINBERG, THE PRESIDENT PRO TEM IN THE SENATE, AND
18 SENATOR ROMERO, THE HEAD OF THE EDUCATION COMMITTEE,
19 HAVE PUT TOGETHER A BILL, SB 471, AND IT DOES A
20 NUMBER OF THINGS TO ENCOURAGE STEM CELL AND
21 BIOTECHNOLOGY RESEARCH IN THE STATE.

22 I'LL EXPLAIN IT IN DETAIL TOMORROW WHEN
23 IT'S AGENDIZED AS AN ACTION ITEM BECAUSE THEY WOULD
24 LIKE AN ENDORSEMENT OR AT LEAST A LETTER OF SUPPORT.
25 AND SO IF YOU FIRST AGREE TO TAKE ON THIS ADDED

BARRISTERS' REPORTING SERVICE

1 AGENDA ITEM IN THE MORNING, I WILL COME BACK TO YOU
2 WITH THAT BIT OF LEGISLATION.

3 ANOTHER THING THAT THE STRATEGIC PLAN 2006
4 CALLED FOR WAS IT WANTED CIRM TO REALLY ENABLE OUR
5 GRANTEES TO GET OUT TO THE PUBLIC. THERE'S A LOT OF
6 GOODWILL AMONGST FACULTY TO DO THIS, BUT IT TAKES A
7 LOT OF WORK TO CREATE THE FORUMS AND GIVE THEM THE
8 VENUE TO DO IT. HAD ABSOLUTELY NO PROBLEM
9 RECRUITING FACULTY IN L. A., SAN FRANCISCO, AND SAN
10 DIEGO. YOU CAN SEE THE DATES THAT WE HELD THE
11 FORUMS. WE REACHED NEARLY 600 PEOPLE IN THE LIVE
12 AUDIENCE. WE SENT FOLKS HOME WITH LITTLE PACKETS OF
13 MATERIAL IN A LAY LEVEL ABOUT THE SPEAKERS THAT THEY
14 HAD HEARD. AND THE ADVERTISING TO GENERATE THE
15 ATTENDANCE RESULTED IN NINE MILLION ADVERTISING
16 IMPRESSIONS.

17 LET ME EXPLAIN THAT BECAUSE I'M NOT A REAL
18 FAN OF SOME OF THESE ADVERTISING NUMBERS. 6.5
19 MILLION OF THOSE WERE FROM THE MUNI BILLBOARDS IN
20 THE TUNNELS AND THE SAN FRANCISCO BART AND MUNI
21 STATIONS. 6.5 MILLION INDIVIDUALS. THEY WERE UP IN
22 THE SUBWAYS FOR A MONTH. SO THAT'S MANY OF THE SAME
23 PEOPLE DAY AFTER DAY SEEING THOSE COUNTING AS
24 IMPRESSIONS. IN THE ADVERTISING COMMUNITY, THAT'S
25 ACTUALLY CONSIDERED GOOD BECAUSE IT REQUIRES

BARRISTERS' REPORTING SERVICE

1 MULTIPLE IMPRESSIONS TO ACTUALLY HAVE IT SINK IN.
2 AND TO ME IN MANY WAYS THIS CAMPAIGN WAS AS MUCH
3 ABOUT THE PEOPLE WHO SAW THE ADS AS IT WAS THE
4 PEOPLE WHO SHOWED UP.

5 SO THE NEXT SLIDE. IN THOSE ADS WE WERE
6 CONVEYING SEVERAL MESSAGES. WE WANTED TO REMIND
7 THEM OF PROP 71 AND WHAT IT WAS, THE FACT THAT THEY
8 VOTED FOR IT. WE WANTED TO HINT THAT WE WERE MAKING
9 PROGRESS TOWARD CURES, AND WE WANTED TO LET THEM
10 KNOW THAT WE WERE INVITING THEM IN, THAT WE WERE
11 TRYING TO BE TRANSPARENT AND INVITE THEM IN TO HEAR
12 ABOUT IT. SO THOSE MESSAGES GOING TO NINE MILLION
13 IMPRESSIONS WERE REALLY AS IMPORTANT AS THE MEETINGS
14 THEMSELVES.

15 HERE ARE THE SPEAKERS. EACH EVENT STARTED
16 WITH AN OVERVIEW, THEN SOMEONE TALKING ABOUT
17 CELL-BASED THERAPY, WHAT PEOPLE ARE EXPECTING, AND
18 THEN SOMEONE TALKING ABOUT NONCELL-BASED USES,
19 ASSAYS, THINGS THAT MOST OF THE PUBLIC HAVE NOT
20 REGISTERED YET AS BEING REAL STEM CELL ADVANCES.
21 THAT WAS ONE OF MY MAIN GOALS WAS TO GET THAT PIECE
22 OUT INTO THE PUBLIC.

23 THE NEW CIRM WEB PAGE, WE HAD SOME REAL
24 CONTRACTOR ISSUES. THEY WERE ALMOST FOUR MONTHS
25 LATE IN DELIVERING THE PRODUCT, BUT IT IS FINALLY IN

BARRISTERS' REPORTING SERVICE

1 OUR HANDS. WE' LL PROBABLY GO LIVE THIS WEEK AFTER
2 VERY MUCH WORK FROM AMY ADAMS, MY COLLEAGUE, AND
3 TODD DUBNICOFF. IT'S GOING TO BE VERY DIFFERENT.
4 WE HAVE VERY DIFFERENT AUDIENCES AT CIRM ABOUT WHAT
5 WE'RE TRYING TO ACCOMPLISH.

6 SO IT WILL BE A LANDING PAGE FOR
7 RESEARCHERS. THEY WANT DIFFERENT THINGS FROM OUR
8 WEBSITE. A LANDING PAGE FOR THE PUBLIC THAT WILL BE
9 VERY NEWS DRIVEN AND INFORMATION DRIVEN. AND THEN
10 FOR ALL OF YOUR MEETINGS AND REGULATIONS AND
11 WHATEVER, THERE'S A SEPARATE CIRM OPERATIONS BUTTON.
12 MOST IMPORTANT, THIS WILL MAKE MELISSA'S LIFE HEAVEN
13 COMPARED TO THE PAST, AN IN-HOUSE SERVER SO IF 5
14 O'CLOCK ROLLS AROUND AND SACRAMENTO SHUTS DOWN, WE
15 CAN STILL POST AGENDA ITEMS. IT SOUNDS SMALL, BUT
16 IT'S HUGE FOR THE CIRM STAFF.

17 AND IT'S GOING TO BE -- THIS NEW WEBSITE
18 IS GOING TO BE REALLY KEY TO US WORKING WITH PATIENT
19 ADVOCATES IN THE FUTURE. I DO THINK THAT WE NEED TO
20 GET CLOSER TO THE PATIENT ADVOCATE COMMUNITY, AND I
21 WANT TO VERY MUCH USE THIS WEBSITE TO DO THAT. AND
22 AS I MENTIONED, WE' LL BE ADDING A TEACHER SECTION
23 GOING FORWARD.

24 THIS IS THE LOOK OF THE NEW HOME PAGE.
25 THIS WAS AMY'S WORKING EDITION, SO IGNORE THE LITTLE

BARRISTERS' REPORTING SERVICE

1 EDITS. IT SAYS EDIT IN VARIOUS PLACES. THAT WON'T
2 BE THERE. BUT YOU CAN SEE IT'S NEWS DRIVEN. MOST
3 WEBSITES YOU'RE USED TO, THE NEWS IS FRONT AND
4 CENTER RATHER THAN BURIED UNDERNEATH THE OPERATIONS
5 OF THE INSTITUTE. AND THERE IS A FLASH ANIMATION AT
6 THE TOP THAT'S VERY PATIENT FOCUSED.

7 FOR THE RESEARCH COMMUNITY, WHAT THEY CARE
8 ABOUT, RFA'S AND HOW DEALING WITH THE GRANTS. AT
9 THE BOTTOM IS A ONE-PARAGRAPH EXPLANATION OF HOW WE
10 AWARD GRANTS, WHICH, UNTIL I DID THIS, DIDN'T
11 REALIZE IT HAD NEVER EXISTED.

12 CIRM OPERATIONS PAGE, AGAIN, IT LET'S YOU
13 GET TO YOUR COMMITTEES WITH ONE CLICK, GO DOWN, GET
14 TO YOUR COMMITTEES, GET TO YOUR AGENDA ITEMS.
15 THEY'RE NOT ALL BURIED. AND ON BOTH THESE PAGES YOU
16 SEE AT THE BOTTOM THERE, THERE'S A CALENDAR. ON THE
17 RESEARCH PAGE THERE'S A CALENDAR. THAT'S GOING TO
18 BE A GREAT PLACE THAT WILL BE A REMINDER FOR YOU
19 THAT'S NEVER EXISTED. IT LOOKS LIKE A NORMAL
20 MONTHLY CALENDAR. WE'LL HAVE RFA DEADLINES AND
21 DATES ON THERE FOR THE RESEARCH COMMUNITY, ALL OF
22 YOUR MEETINGS WILL BE ON THERE, AND IT WILL BE VERY
23 MUCH EASIER FOR YOU TO KEEP TRACK OF WHERE YOU ARE
24 SUPPOSED TO BE FOR OUR SAKE.

25 AND THIS IS FOR THE PUBLIC. THERE WILL

BARRISTERS' REPORTING SERVICE

1 ALWAYS BE A VIDEO UP FRONT AND CENTER. MANY OF
2 THESE WILL NOW -- OUR EARLY VIDEOS WERE PRODUCED BY
3 PROFESSIONAL VIDEOGRAPHERS WITH MUCH SCRIPTING FROM
4 AMY. GOING FORWARD, TODD AND AMY WILL BE SHOOTING
5 NEWS VIDEOS BASED ON MANY OF THOSE RESEARCH PAPERS
6 YOU'VE HEARD ALAN TALK ABOUT WITH A SUMMARY OF THE
7 RESEARCH PAPERS THAT ARE PUBLISHED BESIDE IT.

8 AND I THINK THAT A VALUABLE PIECE FOR THE
9 PUBLIC WILL BE AT THE BOTTOM RIGHT. YOU WILL SEE
10 THE GRANTS, AND YOU CAN NOW SORT THEM BY INSTITUTE
11 OR BY GRANT TYPE. GOING FORWARD, THERE WILL BE A
12 THIRD CATEGORY WHERE YOU CAN SORT THEM BY DISEASE.
13 WE'VE DELAYED THAT BECAUSE NIH WAS IN THE MIDDLE OF
14 A CATEGORIZATION PROJECT, AND WE WANTED TO MAKE SURE
15 WE WERE IN SYNC WITH THEM AND NOT DOING OUR GRANTS
16 WITH ONE SET OF DISEASE CATEGORIES AND NIH ANOTHER
17 BECAUSE WE WANTED TO VERY MUCH BE ABLE TO COMPARE
18 OUR PORTFOLIOS. THEY'VE COMPLETED THAT PROJECT, I
19 UNDERSTAND, NOW; SO GOING FORWARD, AS I CAN BORROW A
20 LITTLE BIT OF STEAM FROM THE SCIENCE OFFICE, WE'LL
21 BE DEVELOPING A THIRD VERSION OF THIS CHART THAT
22 WILL BE SORTED BY DISEASE.

23 NOW THIS WAS SORTED BY INSTITUTION. IF
24 YOU WANT TO JUST FIND YOUR OWN INSTITUTION, IT'S
25 VERY EASY TO GO UP TO THE TOP AND HAVE ONLY YOURS

BARRISTERS' REPORTING SERVICE

1 SHOW UP. THE LINKS GO STRAIGHT TO THE RESEARCH
2 SUMMARY AND THE ABSTRACT. IF THERE'S ANYTHING AT
3 ALL THAT WE'VE FOUND ABOUT THAT, THERE WILL BE ADDED
4 LINKS ON THERE. SO IF WE'VE GOT A VIDEO, THERE'S A
5 LINK TO THE VIDEO. IF THERE'S A PRESS RELEASE,
6 THERE'S A LINK TO THE PRESS RELIES. IF IT'S A
7 RESEARCH SUMMARY OF THE PAPER, IT'S LINKED. SO IT'S
8 GOING TO BE A VERY ROBUST WAY TO GET TO MORE
9 INFORMATION.

10 I ARRIVED HERE AT KIND OF A FLEXURE POINT
11 IN COMMUNICATIONS. I HAD BEEN READING SO MUCH ABOUT
12 THE FACT THAT YOUNG PEOPLE DON'T READ NEWSPAPERS.
13 ONLY 40 PERCENT OF THE COUNTRY IN TOTAL READS A
14 NEWSPAPER. SO I KNEW I HAD TO BUILD A NEW TYPE OF
15 COMMUNICATIONS OFFICE VERY FOCUSED ON MULTIMEDIA
16 EFFORTS. SO WE DID CREATE A YOUTUBE SITE. IT'S GOT
17 16 VIDEOS UP THERE NOW, MANY MORE TO COME. AROUND A
18 HUNDRED VIEWS A DAY. WE HAVE A FLICKR SITE, WHICH
19 IS THE LARGEST SITE IN THE WORLD FOR SHARING IMAGES.
20 THERE ARE OVER 50 IMAGES SUPPLIED BY OUR GRANTEE
21 INSTITUTIONS WITH MORE THAN 200 VIEWS A DAY. AND
22 THERE IS CAPTION MATERIAL HERE, LINKS OFF TO THE
23 INSTITUTION SITES, AND LOTS OF OPPORTUNITY TO GATHER
24 FACTS, NOT JUST PICTURES. AND THOSE HAVE BEEN USED
25 INCREDIBLY BY NEWSPAPER OUTLETS AROUND THE COUNTRY.

BARRISTERS' REPORTING SERVICE

1 AT THE TIME OF THE OBAMA DECISION, I LOVED
2 THAT THE *BOSTON GLOBE* RAN A PICTURE FROM HERE RATHER
3 THAN MY FORMER EMPLOYER, BUT IT'S BECOME VERY
4 POPULAR WITH THE MEDIA. WE DID START A FACEBOOK
5 SITE WITH THE GOAL OF REALLY FOCUSING ON SCIENCE AND
6 A SCIENCE DISCUSSION. IF ANY OF YOU ARE FAMILIAR
7 WITH THE CONSUMER BRIEFS, THOSE SHORT ABSTRACTS WE
8 DO OF PUBLISHED PAPERS, THEY'RE NOW POSTED ON
9 FACEBOOK AS THE FOUNDATION OF A BLOG ENCOURAGING
10 CONSUMERS TO ASK QUESTIONS OR MAKE COMMENT.

11 AS WE DO NEW BRIEFS, WE'RE ASKING THE
12 SCIENTISTS, WOULD YOU BE WILLING TO ANSWER QUESTIONS
13 FROM THE PUBLIC IF THEY POST THEM? SO THEY KNOW
14 GOING FORWARD THAT'S GOING TO BE ONE OF THE THINGS
15 WE'D LIKE TO CONSIDER AS A POTENTIAL OBLIGATION.

16 I DID THIS IN PART BECAUSE I THOUGHT THIS
17 IS A TOOL TO GET TO YOUNGER PEOPLE. THIS IS OUR
18 AUDIENCE ON YOUTUBE. THE LARGEST BAR IS 45 TO 54.
19 THE YOUNG PEOPLE I THOUGHT I WAS GOING TO GET IN THE
20 TOP BAR, THE 18 TO 23, IS THE EXACT SAME SIZE AS THE
21 BOTTOM BAR, WHICH IS THE OVER 65. SO WE'RE GETTING
22 ALL THE DEMOGRAPHICS.

23 AND NEXT ONE. THEY'RE NOT USING IT JUST
24 FOR FUN. YOUTUBE HAS AN INCREDIBLE DATA SYSTEM.
25 THE SEARCH TERMS IN WHICH TO FIND US COME UP IF

BARRISTERS' REPORTING SERVICE

1 THEY' RE USED OFTEN. EVERY SINGLE SEARCH TERM IN THE
2 TOP TEN IS A SERIOUS SEARCH TERM. THEY' RE COMING TO
3 YOUTUBE TO FIND OUT VALUABLE INFORMATION, NOT JUST
4 THE FUNNIEST PET TRICKS. AND I THINK THAT' S IT.

5 HERE' S THE FACEBOOK, AND YOU CAN SEE WE' RE
6 USING IT TO POST THINGS THAT DON' T REALLY HAVE A
7 PLACE ON OUR WEBSITE. ALAN MENTIONED THE SHEN DING
8 WORK. HE' S A CIRM RESEARCHER, BUT THIS PAPER WAS
9 NOT FUNDED BY US, SO WE CAN TALK ABOUT IT ON OUR
10 FACEBOOK SITE AS TO HOW IMPORTANT IT IS, NOTE THAT
11 HE' S A CIRM RESEARCHER, BUT THIS PAPER WAS NOT A
12 PART OF WHAT OUR WORK WAS. WE TRY KEEP THE RESEARCH
13 ON OUR SITE, CIRM-FUNDED RESEARCH.

14 SO IT' S, I THINK, AN INTERESTING TOOL. WE
15 HAVE NOT ADVERTISED THIS AT ALL. WE WANTED THE
16 WEBSITE TO GO LIVE BEFORE WE ADVERTISED IT. I THINK
17 ONCE WE GET OUT TO THE PATIENT ADVOCACY COMMUNITY,
18 WE' LL HAVE MANY HUNDREDS, IF NOT THOUSANDS OF FANS
19 TO THE SITE.

20 MICHAEL FRIEDMAN FROM CITY OF HOPE CAN
21 TELL YOU THAT ORGANIZATIONS THAT HAVE USED THIS FOR
22 THE PATIENT COMMUNITIES, THE PATIENTS LOVE IT AND
23 THEY' RE VERY ACTIVE AND VERY INVOLVED. I THINK
24 THAT' S IT. ANY QUESTIONS?

25 VICE CHAIRMAN ROTH: SO THANK YOU, DON.

BARRISTERS' REPORTING SERVICE

1 WHILE YOU'RE THINKING IF YOU HAVE ANY QUESTIONS TO
2 FOLLOW UP WITH DON, I'LL JUST COMMENT ON THIS
3 SATURDAY MORNING KEYNOTE THAT I GAVE, WHICH I THINK
4 I WAS THE MOST NERVOUS OF OF ANYTHING I'VE HAD TO DO
5 IN THE LAST YEAR AND A HALF. FIFTY SCHOOL TEACHERS
6 AND I'M GIVING A KEYNOTE ON SCIENCE.

7 I HAVE TO TELL YOU THAT I WAS JUST AMAZED
8 AT THE LEVEL OF SOPHISTICATION OF THEIR QUESTIONS
9 AND THEIR COMMENTS AND, MOST SURPRIISINGLY, THE
10 SIMPLE THINGS THEY ASKED US FOR. I THOUGHT THEY
11 WERE GOING TO ASK FOR ALL THIS HIGH TECH. NO. THEY
12 NEED VERY SIMPLE LITTLE FIVE-MINUTE TALKS VIDEOTAPED
13 WHERE SOMEBODY WALKS UP TO A BOARD AND SORT OF DRAWS
14 A CELL AND THINGS LIKE THAT.

15 THE TEACHERS END UP PAYING FOR EVERY
16 SINGLE THING THAT THEY BRING INTO CLASS. THIS ONE
17 VERY EXCITED TEACHER WHO WAS QUITE GOOD WAS TALKING
18 ABOUT HOW SHE USES PLAY DOUGH TO HELP THE STUDENTS
19 UNDERSTAND CELL DIVISIONS AND THINGS LIKE THAT. AND
20 IT THEN LED TO A DISCUSSION THAT SHE HAS TO GO BUY
21 THE PLAY DOUGH. AND JUST REALLY SIMPLE THINGS THAT
22 I THINK IF WE COULD FIND A WAY TO ADDRESS THOSE, AND
23 I ENCOURAGE YOU TO TALK WITH LARRY GOLDSTEIN AND
24 OTHERS WHO WERE AT THE MEETING, BUT I THINK WE WERE
25 ALL EXPECTING SOMETHING DIFFERENT THAN WHAT THEY

BARRISTERS' REPORTING SERVICE

1 ASKED US FOR.

2 FINALLY, JUST THE RANGE WAS EXTRAORDINARY.
3 HISPANIC TEACHERS WHO TEACH IN SPANISH ALL THE WAY
4 TO PH.D. IN BIOLOGY TEACHING THESE KIDS, BUT ALL OF
5 THEM, I WAS REALLY QUITE IMPRESSED.

6 MR. GIBBONS: THE MEETING WAS VERY
7 PRODUCTIVE IN THAT LAUREL, MY CONTRACTOR, MET WITH
8 SOME OF THE FOLKS WORKING AT UC SAN DIEGO THROUGH
9 BIO BRIDGE. AND BY THE DEADLINE ON MONDAY NIGHT, WE
10 HAD PUT A JOINT LETTER OF INTENT TO THE DEPARTMENT
11 OF EDUCATION FOR A CURRICULUM GRANT.

12 VICE CHAIRMAN ROTH: OTHER COMMENTS FOR
13 DON ON THE WEBSITE OR ANYTHING?

14 DR. AZZIZ: DON, THAT WAS MUCH IMPROVED
15 OVER OUR CURRENT WEBSITE. TWO QUESTIONS. YOU
16 MENTIONED THAT YOU WANTED TO BE FULLY FUNCTIONAL
17 BEFORE YOU ADVERTISE. IF YOU COULD BRIEFLY
18 SUMMARIZE FOR US HOW YOU ARE ACTUALLY GOING TO GET
19 THIS OUT TO THE PUBLIC SO THE PUBLIC IS AWARE OF
20 THIS WONDERFUL SET OF TOOLS.

21 THE SECOND IS, FOLLOWING UP ON THE
22 QUESTION ABOUT HISPANICS, DO WE HAVE, AND I MAY HAVE
23 MISSED IT, BUT DO WE HAVE MATERIAL FOR OUR
24 SPANISH-SPEAKING AUDIENCE?

25 MR. GIBBONS: WE DON'T YET. IT IS

BARRISTERS' REPORTING SERVICE

1 DEFINITELY ONE OF OUR LONG-TERM GOALS TO HAVE SOME
2 SUBSECTION OF THE SITE THAT IS TRANSLATED. WE JUST
3 HAVEN'T HAD THE RESOURCES UP TO THIS POINT.

4 MR. TORRES: I WANT TO RESPOND TO THAT
5 BECAUSE I THINK WHAT RICARDO RAISED IS A VERY GOOD
6 POINT. THAT'S WHY DON AND I HAD PRELIMINARY
7 DISCUSSION LAST WEEK ON HOW WE REENERGIZE THE
8 DIVERSITY INITIATIVE OF CIRM.

9 ONE OF THE PROBLEMS WE HAD WHEN I SERVED
10 ON THE ORGAN TRANSPLANT BOARD, ONE LEGACY, WAS THERE
11 WAS A RESISTANCE BY AFRICAN-AMERICAN AND LATINO
12 FAMILIES TO BECOME ORGAN DONORS. AND SO DR. MENDEZ,
13 YOU KNOW VERY WELL HERE IN LOS ANGELES, INITIATED A
14 DIVERSITY PROGRAM. AND WE'RE GOING TO BE WORKING
15 WITH SOME OF THE PEOPLE THAT WERE SUCCESSFUL IN THAT
16 AREA IN TERMS OF OUTREACH ESPECIALLY TO LATINO AND
17 TO AFRICAN-AMERICAN AND ASIAN-AMERICAN COMMUNITIES
18 WHICH ARE OBVIOUSLY EMERGING COMMUNITIES IN
19 CALIFORNIA THAT WE WANT TO HIT UP. DON AND I ARE
20 WORKING ON THAT IN DIRECT RESPONSE TO WHAT CONCERNS
21 YOU RAISE AND LEGITIMATELY SO.

22 MR. GIBBONS: TO ANSWER YOUR FIRST
23 QUESTION, DR. AZZIZ, I'VE DEVELOPED A PATIENT
24 ADVOCACY E-MAIL LIST. AND WE WILL SEND OUT -- IT'S
25 DIRECTORS OF VARIOUS STATE CHAPTERS AND WHATEVER,

BARRISTERS' REPORTING SERVICE

1 AND WE WILL ASK THEM TO PLEASE ALERT THEIR
2 MEMBERSHIP THROUGH THEIR VARIOUS E-MAILS AND HAVE IT
3 GO THAT DIRECTION.

4 WE ALSO WORKED WITH OUR AGENCY WHEN WE DID
5 THE FLICKR SITE TO DO SOMETHING CALLED A SOCIAL
6 NETWORKING PRESS RELEASE, WHICH PUTS YOU INTO
7 TWITTER AND ALL THESE NEW MEDIA SORTS OF OUTLETS
8 KIND OF AUTOMATICALLY. AND THAT FIRST DAY WE DID
9 THAT, AMY, WE ENDED UP WITH 6,000 HITS ON FLICKR --
10 9,000 HITS IN ONE DAY FROM DOING A SOCIAL MEDIA
11 RELEASE. SO I THINK THAT WE CAN GET THE WORD OUT
12 AND GET THE PEOPLE TO SIGN UP, AND THEN IT WILL
13 START TO FEED ON ITSELF.

14 VICE CHAIRMAN ROTH: RICARDO, DID YOU HAVE
15 A SECOND QUESTION?

16 DR. AZZIZ: NO. I JUST WAS GOING TO
17 FOLLOW UP ON THE DIVERSITY ISSUE. I JUST WANT TO
18 MAKE SURE THAT, FOR THE RECORD, AND ART TORRES IS
19 ALREADY LEADING THAT, BUT THAT IS A FAIRLY CRITICAL
20 ISSUE FOR THIS INITIATIVE. OBVIOUSLY WE HAVE A
21 GREAT DIVERSITY IN OUR POPULATION. WHILE THEY MAY
22 NOT BE A SIGNIFICANT FACTOR IMMEDIATELY, THEY WILL
23 BE A SIGNIFICANT FACTOR AS SOON AS WE MOVE INTO THE
24 CLINICAL TRIALS. SO IT'S IMPORTANT FOR US TO HAVE
25 THEM ALREADY EDUCATED AND ON OUR SIDE.

BARRISTERS' REPORTING SERVICE

1 MR. GIBBONS: WE HAVE BEEN TALKING
2 INTERNALLY A LOT ABOUT THE NEED TO GET INTO THE
3 VARIOUS ETHNIC COMMUNITIES IN CALIFORNIA PRIOR TO
4 CLINICAL TRIALS AND DO SOME JUST BACKGROUNDING.
5 WHERE ARE THEY NOW? WHAT ARE THEIR FEELINGS? WHAT
6 IS THEIR TRUST LEVEL? SO WE ARE TALKING ABOUT
7 POTENTIALLY DOING A CONTRACT FOR THAT WORK.

8 VICE CHAIRMAN ROTH: FRANCISCO.

9 DR. PRIETO: I WANTED TO ASK YOU ALONG THE
10 LINES OF WHAT YOU MENTIONED ABOUT ADVERTISING
11 IMPRESSIONS. AND FOR THE WORKSHOP IN THE BAY AREA,
12 I THINK YOU'RE RIGHT, THAT THAT REALLY EXTENDS THE
13 IMPACT OR THE AWARENESS THAT PEOPLE HAVE
14 TREMENDOUSLY BEYOND JUST THE SMALL GROUP OR
15 RELATIVELY SMALL GROUP THAT ATTENDS. WAS THERE
16 ANYTHING LIKE THAT IN L. A. AND SAN DIEGO MARKETS?

17 MR. GIBBONS: WE DID ADVERTISING IN ALL
18 THREE MARKETS. WE DID SOMETHING DIFFERENT IN EACH
19 MARKET. IN L. A. WE ADVERTISED MOSTLY ON NPR. IN
20 SAN DIEGO WE ADVERTISED MOSTLY THROUGH THE SAN DIEGO
21 UNION'S ONLINE PRESENCE BECAUSE THEIR ONLINE
22 PRESENCE IS VERY STRONG DOWN THERE. IT TURNED OUT
23 THAT THE ONLINE ADVERTISING WAS NOT THE MOST
24 EFFECTIVE. THE E-MAIL LIST FROM THE VENUE, WHICH
25 WAS THE MUSEUM OF NATURAL SCIENCE AND HISTORY IN SAN

BARRISTERS' REPORTING SERVICE

1 DIEGO, WHICH HAS A SCIENCE LECTURE SERIES ALREADY,
2 WAS ACTUALLY THE STRONGEST DRIVER TO THAT EVENT AS
3 WELL AS SOME OTHER LISTS THAT WE ASKED DUANE'S HELP
4 IN GETTING ONTO THROUGH BIOCOM AND CONNECT AND OTHER
5 THINGS, THAT THE E-MAIL SYSTEM WAS THE STRONGEST IN
6 SAN DIEGO.

7 MS. GIBBONS: DON, YOU MENTIONED THAT THE
8 REASON THAT THE MATERIALS ON THE WEBSITE HADN'T BEEN
9 TRANSLATED TO SPANISH IN THIS CASE WAS LACK OF
10 FUNDING. DO YOU KNOW, HAVE YOU BUDGETED WHAT THAT
11 COST WOULD BE ASSOCIATED WITH THAT?

12 MR. GIBBONS: WE REALLY HAVEN'T. OUR
13 FIRST GOAL WAS TO GET THE DARN THING UP. AND IT'S
14 BEEN A BIT OF A BIGGER CHORE THAN WE THOUGHT IT WAS
15 GOING TO BE, BUT THEN WE'LL DO THE BUDGET.

16 COUPLE THINGS I WANTED TO DO IN THE
17 BUDGET, WE'LL BE ENTERING A BUDGET CYCLE FOR THE
18 NEXT FISCAL YEAR IN THE NEXT 30, 60 DAYS. I WANT TO
19 LOOK AT THAT FOR THE NEXT YEAR'S BUDGET AS WELL AS A
20 CIRM COMMUNITY INTRANET. I WANT OUR RESEARCHERS
21 CONNECTED THROUGH SOME -- I WANT US TO NOT JUST BE A
22 CHECK-WRITING SERVICE. I WANT THEM TO REALLY FEEL
23 CONNECTED AND FEEL LIKE WE'RE OFFERING THEM SOME
24 ONLINE SERVICES THAT THEY VALUE.

25 VICE CHAIRMAN ROTH: OKAY. ANYONE ELSE?

BARRISTERS' REPORTING SERVICE

1 IF NOT, THANK YOU VERY MUCH, DON. I REALLY
2 APPRECIATE IT.

3 ONE COMMENT, IF YOU CAN BUMP THAT FONT UP
4 BY TWO POINTS, I WOULD REALLY APPRECIATE IT.

5 WE'RE GOING TO MOVE NOW TO ITEM 12. I'M
6 GOING TO JUMP OVER ITEM 10. CHAIRMAN KLEIN WANTED
7 TO BE HERE FOR THAT DISCUSSION, IF POSSIBLE. IF WE
8 GET TO IT AFTER WE GET THROUGH THE REST OF THE
9 AGENDA, WE'LL START ON ITEM 10. BUT PAT OLSON IS
10 GOING TO TAKE US THROUGH ITEM NO. 12, WHICH IS
11 CONSIDERATION OF NEW SCIENTIFIC MEMBERS FOR THE
12 GRANTS WORKING GROUP.

13 DR. OLSON: THIS IS AGENDA ITEM NO. 12 IN
14 YOUR BINDER. AT THAT POINT YOU HAVE BIOSKETCHES FOR
15 THE FIVE NOMINEES THAT WE ARE BRINGING TO YOUR
16 ATTENTION FOR CONSIDERATION AS ALTERNATE MEMBERS OF
17 THE GRANTS WORKING GROUP.

18 THESE SCIENTISTS WILL EXPAND OUR OVERALL
19 EXPERTISE IN AREAS OF TRANSPLANTATION SURGERY, IN
20 THE IMMUNOBIOLOGY OF TRANSPLANTATION, AND REGULATORY
21 AFFAIRS, PARTICULARLY THAT ASSOCIATED WITH CGMP
22 PRODUCTION, IN QUALITY COMPLIANCE, AND IN ONCOLOGY
23 RESEARCH.

24 LET ME JUST REMIND YOU THAT AS ALTERNATE
25 MEMBERS OF THE GRANTS WORKING GROUP, THESE

BARRISTERS' REPORTING SERVICE

1 INDIVIDUALS MAY BE CALLED UPON TO PARTICIPATE AS AD
2 HOC REVIEWERS OR AS ACTUAL WORKING GROUP MEMBERS.
3 THEY ARE SUBJECT TO AND MUST AGREE TO ABIDE BY THE
4 SAME CONFLICTS OF INTEREST AND FINANCIAL DISCLOSURE
5 POLICY AS THE REGULAR WORKING GROUP MEMBERS.

6 IF YOU SHOULD APPROVE THE ADDITION OF
7 THESE FIVE MEMBERS TO THE WORKING GROUP, THIS WILL
8 BRING OUR TOTAL WORKING GROUP MEMBERS AND ALTERNATES
9 TO 92. AS I THINK YOU KNOW, OVER THE PAST FEW
10 MONTHS, WE'VE BEEN TRYING TO INCREASE OUR EXPERTISE
11 IN ESSENTIALLY TRANSLATIONAL-RELATED MATTERS, AND
12 THIS WILL CERTAINLY CONTRIBUTE TO THAT.

13 SO I WOULD LIKE TO REQUEST YOUR APPROVAL
14 AND THE APPOINTMENT OF THESE NOMINEES AS ALTERNATE
15 MEMBERS OF THE GRANTS WORKING GROUP.

16 VICE CHAIRMAN ROTH: OKAY. SO PERHAPS A
17 MOTION IS IN ORDER IF SOMEBODY WOULD LIKE TO MAKE
18 THAT.

19 DR. BLOOM: SO MOVED.

20 DR. LEVEY: SECOND.

21 VICE CHAIRMAN ROTH: DISCUSSION ON THESE
22 MEMBERS? QUESTIONS? HEARING NONE, PUBLIC COMMENTS
23 ON ANY OF THE REVIEWERS? IF NOT, WE'LL TAKE A VOICE
24 VOTE AND THEN POLL THE MEMBERS THAT ARE ON THE
25 PHONE.

BARRISTERS' REPORTING SERVICE

1 ALL IN FAVOR? OPPOSED? ABSTAIN? AND THE
2 TELEPHONE?

3 MS. KING: MARCY FEIT.

4 MS. FEIT: YES.

5 MS. KING: CLAIRE POMEROY.

6 DR. POMEROY: YES.

7 MS. KING: AND FOR THE RECORD, THAT MOTION
8 CARRIES.

9 VICE CHAIRMAN ROTH: THANK YOU VERY MUCH.
10 WE'RE GOING TO JUMP TO -- I'M TAKING THESE IN THE
11 ORDER THAT WAS REQUESTED. SO ITEM 16, AND I'M GOING
12 TO ASK GEOFF LOMAX TO HELP WALK US THROUGH THAT.
13 GEOFF.

14 DR. LOMAX: THANK YOU. MELISSA HAS
15 REQUESTED WE HAVE A SHORT BREAK. WE HAVE A FEW
16 SHORT SLIDES WE PREPARED JUST TO WALK THROUGH THIS
17 ITEM, AND WE BELIEVE SHE NEEDS A MOMENT TO PULL
18 THOSE SLIDES UP.

19 VICE CHAIRMAN ROTH: SO WHY DON'T YOU GO
20 AHEAD AND PULL THOSE OUT, AND WE'LL MOVE TO ANOTHER
21 ITEM. LET'S MOVE TO ITEM 14. AND I'M GOING TO ASK
22 NANCY IF YOU HAVE YOUR SLIDES READY. THIS ITEM IS
23 ONE THAT MAY RESULT --

24 MS. KING: I'M SORRY TO INTERRUPT YOU, BUT
25 IT'S ACTUALLY THE SAME MACHINE THAT I HAVE NANCY'S

BARRISTERS' REPORTING SERVICE

1 SLIDES THAT I NEED TO USE, SO I'M JUST SUGGESTING
2 THAT MAYBE WE JUST TAKE -- IF YOU GIVE ME TWO
3 MINUTES, I'LL BE ABLE TO HAVE GEOFF'S SLIDES UP.

4 VICE CHAIRMAN ROTH: I DON'T WANT TO LOSE
5 OUR QUORUM HERE, SO LET'S TAKE TWO QUICK MINUTES AND
6 WE'LL GET RIGHT BACK TO IT. THANKS.

7 (A RECESS WAS TAKEN.)

8 VICE CHAIRMAN ROTH: CAN WE GET EVERYBODY
9 BACK IN AND WE'LL CONTINUE ON? HI, JOAN.

10 MS. SAMUELSON: HI, DUANE.

11 VICE CHAIRMAN ROTH: ALL RIGHT. I THINK
12 GEOFF IS READY, SO WE'RE GOING TO PROCEED. ITEM 16.
13 GEOFF.

14 DR. LOMAX: THANK YOU, MR. CHAIRMAN. AS
15 YOU WILL -- I THINK, AS YOU ARE ALL AWARE, THE NIH
16 ANNOUNCED ON FAIRLY SHORT NOTICE THAT THEY WERE
17 GOING TO ISSUE DRAFT GUIDELINES FOR STEM CELL
18 RESEARCH FUNDED BY THE NIH, AND THAT WAS
19 APPROXIMATELY TEN DAYS AGO. SO I WANT TO QUICKLY
20 HIGHLIGHT A NUMBER OF STEPS WE TOOK IN ADVANCE OF
21 THE LEGISLATIVE SUBCOMMITTEE MEETING TO UPDATE THE
22 MEMBERSHIP.

23 AGAIN, IN ADVANCE OF THE LEGISLATIVE
24 SUBCOMMITTEE MEETING, WHICH WAS THIS MONDAY, WE
25 INITIATED A NUMBER OF ACTIVITIES TO LEAD UP TO THE

BARRISTERS' REPORTING SERVICE

1 DEVELOPMENT OF FORMAL PUBLIC COMMENTS TO THE NEW NIH
2 GUIDELINES. I'LL JUST QUICKLY INDICATE SOME OF
3 THESE STEPS, WHICH ARE ACTUALLY ONGOING, BUT WE
4 IMMEDIATELY DEVELOPED A POLICY REVIEW WHERE WE
5 COMPARED THE NIH GUIDELINES WITH THE PROPOSED
6 GUIDELINES TO OUR EXISTING REGULATIONS. THAT'S A
7 FAIRLY DETAILED APPENDIX WHICH, AGAIN, IS PART OF A
8 FORMAL REPORT WE PREPARED FOR THE LEGISLATIVE
9 SUBCOMMITTEE.

10 AND WITHIN THAT DOCUMENT WE HAVE A NUMBER
11 OF ITEMS WE'VE IDENTIFIED, WHICH ARE MORE, I WOULD
12 SAY, ON THE ORDER OF THINGS WE WOULD PROBABLY WANT
13 TO ASK THE NIH FOR CLARIFICATION, SORT OF PROCEDURAL
14 THINGS. WHAT DO YOU MEAN BY THIS, ETC., ETC., BUT I
15 WOULDN'T CHARACTERIZE THEM AS MAJOR SHORTCOMINGS IN
16 THE POLICY.

17 WE CONDUCTED A NUMBER OF KEY INFORMANT
18 INTERVIEWS, AND THE SORT OF MAJOR THEMES FROM THOSE
19 INTERVIEWS ARE PRESENTED AGAIN IN THIS FULL REPORT.
20 ON THE NEXT SLIDE I'LL JUST HIGHLIGHT A COUPLE OF
21 KEY ITEMS THAT HAVE COME UP.

22 WE'VE ALSO FOCUSED ON AN IMPACT ANALYSIS.
23 DR. TROUNSON INDICATED THERE WERE SOME CONCERNS
24 ABOUT HOW THE GUIDELINES MIGHT IMPACT THE
25 AVAILABILITY OF EXISTING HUMAN EMBRYONIC STEM CELL

BARRISTERS' REPORTING SERVICE

1 LINES IN RESEARCH. WE'VE DONE SOME OUTREACH TO OUR
2 OVERSIGHT COMMITTEE MEMBERSHIP IN THE STATE AND
3 GOTTEN SOME FEEDBACK THERE. AND THE BASIC MESSAGE
4 IS THERE'S SOME CONCERNS THAT THE CURRENT GUIDELINES
5 IN THEIR DRAFT FORM MAY RESULT IN MATERIALS NOT
6 BEING AVAILABLE TO RESEARCHERS, AND THAT MAY BE AN
7 ITEM WHICH WOULD BE SOMETHING WE'D LIKE TO COMMENT
8 ON DOWN THE STREAM.

9 WE'VE ALSO CONDUCTED A SURVEY OF NATIONAL
10 PARTNERS. WE'RE INVOLVED IN THE INTERSTATE ALLIANCE
11 ON STEM CELL RESEARCH, SO A NUMBER OF OTHER STATES
12 HAVE PEGGED THEIR STEM CELL PROGRAMS TO BE
13 GUIDELINES OF THE NATIONAL ACADEMIES. SO THE SAME
14 LEVEL OF ANALYSIS I TOUCHED ON IN ONE IS BEING
15 PERFORMED IN OTHER STATES, AND WE'RE HAVING A
16 MEETING OF THAT MEMBERSHIP ON MAY 5TH, AND WE'LL BE
17 ABLE TO COMPILE OUR FINDINGS THERE. SO WE'LL HAVE A
18 NATIONAL PERSPECTIVE AS WELL.

19 THE MAJOR THEMES, AGAIN, THESE ARE MOSTLY
20 FROM THE KEY INFORMANT INTERVIEWS. I'LL JUST TOUCH
21 ON THESE BRIEFLY. WE HAVE A LARGER PROCESS WHERE WE
22 ARE GOING TO BE ABLE TO DEVELOP THESE FOR THE BOARD.
23 SO I'LL JUST HIT THE HIGHLIGHTS AND THEN MOVE ON TO
24 THE PROCESS.

25 AGAIN, CONCERNS THAT ESTABLISHED LINES MAY

BARRISTERS' REPORTING SERVICE

1 NOT BE AVAILABLE GIVEN THE NATURE OF THE PROPOSED
2 GUIDELINES. AND IT MAY BE WORTH CONSIDERING SOME
3 TYPE OF GRANDFATHERING MECHANISM TO ENSURE THAT
4 OLDER MATERIALS THAT WERE DERIVED UNDER THE SORT OF
5 STANDARD OF CARE OF THEIR DAY COULD BE USED IN
6 NIH-FUNDED RESEARCH.

7 OUR GRANTEES AND THE RESEARCH COMMUNITY AT
8 THE MOMENT FEELS THERE MAY BE A LARGE BURDEN OF
9 PROOF PLACED ON THEM, AND SO THEY'RE VERY INTERESTED
10 IN IDENTIFYING MECHANISMS WHERE AS A COMMUNITY WE
11 CAN REGISTER LINES AND DEVELOP CONSENSUS ON WHAT
12 LINES WILL MEET THE STANDARDS, NOT JUST OLDER LINES,
13 BUT MOVING FORWARD PROSPECTIVELY AS WELL TO TRY TO
14 UNDERSTAND WHAT MATERIALS ARE RESEARCH COMPLIANT.

15 AND, AGAIN, THIS THIRD POINT, I THINK IT'S
16 A BIT MORE OF AN ISSUE FOR OUR GRANTEE INSTITUTIONS,
17 BUT PERHAPS IT MAY BE OF INTEREST TO MEMBERS OF THE
18 BOARD AS WELL. THERE ARE UNCERTAINTIES AT THE
19 MOMENT, AND THIS IS VERY PRELIMINARY, ABOUT IF YOU
20 HAD A MIXED FUNDING SITUATION WITH, SAY, CIRM AND
21 NIH FUNDS AND YOU WERE WORKING WITH MATERIALS THAT
22 DIDN'T MEET THE NIH GUIDELINES, WHAT WOULD BE THE
23 IMPACT OR THE RESULT OF THAT? AND, AGAIN, I SUSPECT
24 THOSE WILL BE QUESTIONS THAT WILL BE POSED BY OUR
25 RESEARCH INSTITUTIONS. IT'S A BIT LESS CLEAR FROM

BARRISTERS' REPORTING SERVICE

1 THE PERSPECTIVE OF OUR STANDARDS AND OUR STANDARDS
2 OF HOW WE MIGHT ADDRESS THAT, BUT, AGAIN, IT'S A
3 POINT THAT'S COME UP FREQUENTLY.

4 SO IF I CAN JUST GET THE FINAL SLIDE. TO
5 TOUCH ON THE NEXT STEPS IN THE PROCESS, WE CONTINUE
6 TO ENGAGE OUR STATE AND NATIONAL PARTNERS TO ENABLE
7 A CLEAR AND CONSISTENT UNDERSTANDING OF THE ISSUES.
8 THE ULTIMATE PRESENTATION TO NIH, WE'VE BEEN
9 ADVISED, SHOULD BE VERY CLEAR, VERY PRECISE, AND
10 IDEALLY QUITE VOLUMINOUS TO REFLECT KIND OF
11 CONSENSUS OF WHAT THE ISSUES ARE.

12 SO WE'RE CONTINUING TO TRY TO DISTILL DOWN
13 EACH OF THESE ISSUES IN THE MOST PRECISE FORMAT FOR
14 THE NIH. HAVING HAD TO RESPOND TO CLOSE TO 200
15 PUBLIC COMMENTS DURING THE DEVELOPMENT OF OUR
16 STANDARDS, I FEEL I HAVE SOME SENSITIVITY TO WHAT
17 THEY'RE SAYING IN TERMS OF WHAT THEY'RE LOOKING FOR
18 IN TERMS OF COMMENTS, SO WE'LL TRY TO GIVE THEM WHAT
19 THEY NEED, AND I THINK THAT WILL RESULT IN THE BEST
20 PRODUCT.

21 IN ADDITION, THE ICOC, THERE'S BEEN AN NIH
22 GUIDELINES RESPONSE TASK FORCE SET UP, AND THAT'S TO
23 MEET MAY 7TH, I BELIEVE. IS THAT THE STANFORD
24 EVENT? THE MAIN LOCATION WILL BE STANFORD
25 UNIVERSITY, AND IT WILL BE A TELECONFERENCE. AND

BARRISTERS' REPORTING SERVICE

1 THE IDEA THERE IS WE'LL HAVE AN OPPORTUNITY TO AGAIN
2 ENGAGE RESEARCHERS AT THAT SITE, AND THERE'S A
3 TENTATIVE DATE OF MAY 12TH FOR AN ICOC CALL TO
4 REVIEW THE FINAL RESPONSE, WHICH WOULD BE THE FORMAL
5 RESPONSE OF CIRM.

6 VICE CHAIRMAN ROTH: GEOFF, ARE YOU GOING
7 TO NAME THE MEMBERS OF THAT TASK FORCE?

8 DR. LOMAX: DO WE KNOW THEM?

9 VICE CHAIRMAN ROTH: THERE WERE A NUMBER
10 ON THE CALL THAT VOLUNTEERED.

11 MS. KING: I THINK IT WOULD BE BEST IF WE
12 DIDN'T NAME THEM JUST YET. SINCE IT'S A ONE-TIME
13 TASK FORCE, I'D RATHER NAME THEM WHEN WE KNOW WHO'S
14 COMING IF THAT'S OKAY.

15 SO RIGHT NOW, DUE TO THE TIGHT TIMEFRAME,
16 WE NEEDED TO SCHEDULE THE CALL FOR MAY 7TH SINCE I
17 ACTUALLY HAD TO POST IT YESTERDAY IN ORDER FOR US TO
18 BE ABLE TO DO IT IN THAT TIMEFRAME. THERE ARE A
19 NUMBER OF PEOPLE THAT HAVE BEEN ASKED TO BE ON THE
20 TASK FORCE, BUT WE'RE NOT YET CERTAIN WHO ALL WILL
21 BE ABLE TO.

22 VICE CHAIRMAN ROTH: SO THESE ARE MEMBERS
23 OF THE ICOC.

24 MS. KING: THEY ARE ALL MEMBERS OF THE
25 ICOC, THAT'S CORRECT. AND AS SUCH, THIS WILL BE A

BARRISTERS' REPORTING SERVICE

1 BAGLEY-KEENE-BOUND BODY, WHICH IS WHY I NEEDED TO
2 NOTICE THAT MEETING YESTERDAY. AND AS SOON AS WE
3 KNOW WHO WILL BE ON THIS TASK FORCE, I WILL POST
4 THAT ON OUR WEBSITE. I JUST AM NOT YET CERTAIN
5 WHO'S GOING TO BE ABLE TO JOIN AND WHO WILL NOT.

6 VICE CHAIRMAN ROTH: GEOFF, JUST TO BE
7 CLEAR, THIS TASK FORCE WILL WORK WITH YOU, WORK WITH
8 STAFF, AND DEVELOP A PROPOSAL WHICH WOULD COME
9 BEFORE US ON MAY 12TH.

10 DR. LOMAX: THAT IS CORRECT. IN THE
11 MEANTIME, OUR STAFF WORK IS REALLY FOCUSED ON
12 DEVELOPING THE EVIDENTIARY BASE WHICH WILL INFORM
13 THAT FINAL SET OF COMMENTS THAT WILL BE APPROVED BY
14 THE ICOC.

15 MR. TORRES: AS A RESULT OF THAT TASK
16 FORCE, TO GET THAT INPUT FROM AS MANY FOLKS AS
17 POSSIBLE, IT'S SO IMPORTANT TO DEVELOP A TEMPLATE
18 THAT WE CAN GENERATE FOR PEOPLE TO WRITE IN BECAUSE
19 THE RESPONSES ON THE COMMENT PERIOD, GOING BACK TO
20 WHAT DR. AZZIZ AND WE TALKED ABOUT, SAM RODRIGUEZ,
21 WHO HEADS UP THE NATIONAL LATINO EVANGELICAL
22 MOVEMENT, HAS ALREADY OPINED ON THESE NEW
23 REGULATIONS. WE HAVE TO BE READY TO RESPOND
24 AGGRESSIVELY, BUT RESPOND CONSISTENTLY AND
25 COHESIVELY WITH THE SAME MESSAGE SO THAT I THINK

BARRISTERS' REPORTING SERVICE

1 THAT WILL HELP NIH MOVE TOWARD, CLOSELY AS THEY CAN,
2 TO OUR POSITION GIVEN THE GROUNDSWELL OF SUPPORT
3 THAT WE HOPE TO GENERATE.

4 VICE CHAIRMAN ROTH: JUST TO FRAME THIS,
5 WE'VE GOT A VERY SHORT TIMEFRAME HERE TO GET OUR
6 RESPONSE TOGETHER. AND THE REASON WE NEED TO GET
7 OURS TOGETHER IS MANY PEOPLE ARE GOING TO RIDE ON
8 OUR RECOMMENDATION, SO THEY DON'T HAVE TIME TO DO
9 THIS WORK. THEY'RE GOING TO WAIT FOR US, SO WE
10 CAN'T WAIT TILL THE LAST FEW DAYS. WE'VE GOT TO GET
11 THIS, I THINK, IN SHAPE TO GO QUICKLY.

12 DR. LOMAX: THAT'S CORRECT. IN FACT, WE
13 PUSHED OUT THE DOCUMENT THAT WAS PRESENTED TO THE
14 LEGISLATIVE SUBCOMMITTEE, WHICH INCLUDED A LOT OF
15 SUBSTANTIVE DETAIL, TO OUR BROAD COMMUNITY IN
16 CALIFORNIA. AND THE FEEDBACK I'VE HAD TO DATE HAS
17 BEEN THAT THEY ARE VERY APPRECIATIVE OF THE SORT OF
18 LEVEL OF DRILL-DOWN, IF YOU WILL, SORT OF THE
19 CLARITY WHICH WE'LL BE ABLE TO SET THIS UP FOR THEM.
20 SO I THINK THEY'LL BE IN A POSITION TO BEGIN TO
21 DEVELOP COMMENTS BASED ON A QUALITY ANALYSIS. AND,
22 AGAIN, TO THE EXTENT WE ACTUALLY ARE SORT OF DOING
23 MORE OF A FRAMING OF IT, THAT WILL BE UP TO YOU ALL,
24 AND TIME IS OF THE ESSENCE.

25 VICE CHAIRMAN ROTH: LET ME ASK THE BOARD

BARRISTERS' REPORTING SERVICE

1 IF WE'RE COMFORTABLE WITH THAT PROCESS AND THE
2 METHODOLOGY THAT HAS BEEN PROPOSED AND ANY COMMENTS
3 OR QUESTIONS ON THAT.

4 DR. PRIETO: I HAVE A QUESTION FOR GEOFF
5 SORT OF GETTING INTO ONE OF THE ISSUES BROUGHT UP IN
6 THE MATERIALS THAT YOU CIRCULATED. I WONDER IF YOU
7 HAVE AN IDEA HOW MUCH DOES THE DICKEY-WICKER
8 AMENDMENT PREVENT THE NIH FROM GETTING CLOSER TO OUR
9 GUIDELINES?

10 DR. LOMAX: THAT AMENDMENT'S THE PRIMARY
11 CONSTRAINT FOR WHY THE GUIDELINES AUTHORIZE THE
12 UTILIZATION OF DERIVED LINES, BUT NOT THE FUNDING OF
13 THEIR ACTUAL DERIVATION. SO THAT'S A CONSTRAINT, A
14 FUNDAMENTAL CONSTRAINT, AND THIS IS WHY IT'S SORT OF
15 A GUIDELINE FOR UTILIZING STEM CELL LINES, BUT NOT
16 CREATING THEM WITH FEDERAL FUNDS.

17 VICE CHAIRMAN ROTH: SO WOULD IT BE SAFE
18 TO SAY THAT THAT'S A SEPARATE ISSUE THAT HAS TO BE
19 ADDRESSED INDEPENDENT OF GETTING WHAT THE PROPER
20 GUIDELINES SHOULD BE? WHETHER THEY CAN BE
21 IMPLEMENTED OR NOT MAY DEPEND ON THAT.

22 DR. LOMAX: THAT'S CORRECT. AGAIN, I
23 WOULD REFER YOU TO THE LEGISLATIVE SUBCOMMITTEE
24 DOCUMENT WHERE WE TRIED TO LAY OUT THE BROADER
25 POLICY CONTEXT AND LEGAL FRAMEWORK WHICH GUIDED THE

BARRISTERS' REPORTING SERVICE

1 NIH'S DECISION. AND WITHIN THAT WE TRIED TO OFFER
2 OUR VIEW OF WHERE THEY EXERCISED DISCRETION IN TERMS
3 OF THEIR STANDARD AND WHERE THEY WERE CONSTRAINED BY
4 ESTABLISHED FEDERAL LAW, WHICH IF YOU READ PRESIDENT
5 OBAMA'S EXECUTIVE ORDER, HE SPECIFICALLY SAID AS
6 ALLOWED BY LAW. SO WE TRIED TO MAKE THAT
7 DISTINCTION IN THE BACKGROUND MATERIALS.

8 VICE CHAIRMAN ROTH: OKAY. OTHER BOARD
9 COMMENTS? IF NOT, DO WE NEED TO TAKE A VOTE ON THIS
10 PROCESS OR JUST THE FACT THAT THERE'S --

11 MR. HARRISON: IF NO ONE HAS ANY
12 OBJECTION, I DON'T THINK IT'S NECESSARY BECAUSE
13 ULTIMATELY IT'S GOING TO COME BACK BEFORE THE BOARD
14 ON MAY 12TH FOR CONSIDERATION.

15 VICE CHAIRMAN ROTH: WITH THAT, GEOFF,
16 LET'S JUST THANK YOU FOR HAVING TO PUT THIS TOGETHER
17 UNDER FIRE, AND THERE WAS SOME CRITICISMS, BUT YOU
18 DID A GREAT JOB, AND I THINK EVERYBODY APPRECIATES
19 THAT. THANK YOU.

20 (APPLAUSE.)

21 DR. LOMAX: JUST FOR REFERENCE, IT'S TAB
22 16. DOCUMENTS ACTUALLY MADE IT IN THERE.

23 VICE CHAIRMAN ROTH: THERE'S A LOT OF
24 DETAIL IN 16, AND I'M SURE IF YOU HAVE A HUGE
25 INTEREST IN BEING INVOLVED HERE, THERE'S A WAY FOR

BARRISTERS' REPORTING SERVICE

1 YOU TO DO THAT.

2 OKAY. SO WE'RE GOING TO MOVE TO ITEM 14,
3 AND I'M GOING TO ASK NANCY KOCH TO COME UP AND FRAME
4 THIS ISSUE SO WE CAN TAKE A POSITION ON IT.

5 MS. KOCH: GOOD EVENING, EVERYBODY. I'VE
6 BEEN ASKED TO BRING YOU AN UPDATE ON SOME
7 LEGISLATIVE ACTIVITY THAT'S GOING ON IN WASHINGTON,
8 D.C., RELATING TO BIOSIMILAR LEGISLATION. I'M
9 WAITING FOR MY CLICKER SO I CAN MOVE THROUGH THE
10 SLIDES.

11 MOST OF YOU ARE PROBABLY FAMILIAR WITH
12 SOME OF WHAT'S GONE ON IN WASHINGTON IN PAST YEARS
13 WITH REGARD TO BIOSIMILARS AND CREATING A
14 REGULATORY -- AN ACCELERATED REGULATORY PATHWAY FOR
15 THEM. IT'S BEEN THE SUBJECT OF DEBATE FOR MANY
16 YEARS.

17 VICE CHAIRMAN ROTH: NANCY, CAN YOU PULL
18 THAT A LITTLE CLOSER?

19 MS. KOCH: BUT THE 111TH CONGRESS ACTUALLY
20 APPEARS ON THE VERGE OF TAKING ACTION, AND SO FOR
21 THAT REASON, WE WANT TO BRING IT TO THE ATTENTION OF
22 CIRM.

23 THERE HAVE BEEN BILLS INTRODUCED IN THE
24 HOUSE AND IN THE SENATE. WE'LL FOCUS TONIGHT MOSTLY
25 ON THE BILLS THAT ARE IN THE HOUSE BECAUSE THEY'RE

BARRISTERS' REPORTING SERVICE

1 SORT OF LEADING THE CHARGE, ONE BY REPRESENTATIVE
2 WAXMAN AND ONE BY REPRESENTATIVE ESCHOO. THEY ARE
3 BOTH ENJOYING STRONG BI PARTISAN SUPPORT. THERE ARE
4 DEMOCRAT MAJORITIES, OF COURSE, IN BOTH HOUSES OF
5 CONGRESS, AND THE OBAMA ADMINISTRATION HAS ALREADY
6 SIGNALLED BY PUTTING SAVINGS IN ITS FISCAL YEAR 2010
7 BUDGET THAT WOULD RESULT FROM PASSAGE OF BIOSIMILARS
8 LEGISLATION THAT THIS IS A PRIORITY ITEM.

9 YOUR BOARD PACKAGES CONTAINED COPIES OF
10 THE DRAFT BILLS AS WELL AS SOME ANALYSIS FROM THE
11 CONGRESSIONAL RESEARCH SERVICE, WHICH ARE OVER THERE
12 ON THE TABLE, AND A SIDE-BY-SIDE COMPARISON OF THE
13 WAXMAN AND ESCHOO PIECES OF LEGISLATION.

14 THIS IS A TIMELY MATTER FOR THE BOARD TO
15 CONSIDER BECAUSE IN THE NEXT 30 TO 60 DAYS, WE
16 EXPECT THERE TO BE SIGNIFICANT PROGRESS TOWARD
17 BRINGING THESE BILLS FORWARD AND ACTUALLY MOVING
18 THEM TOWARD LEGISLATION.

19 WHY IS THIS IMPORTANT TO CIRM? SOMEONE
20 ACTUALLY ASKED THAT VERY GOOD QUESTION DURING THE
21 LEGISLATIVE COMMITTEE MEETING THAT HAPPENED ON
22 MONDAY. THE SHORT ANSWER IS THAT WE EXPECT THAT
23 STEM CELL THERAPIES, WHICH WE'RE FUNDING, WILL BE
24 COVERED AS BIOLOGICS UNDER THESE PIECES OF
25 LEGISLATION; AND, THEREFORE, THESE LEGISLATIONS WILL

BARRISTERS' REPORTING SERVICE

1 HELP SET THE REGULATORY AND THE COMMERCIAL FRAMEWORK
2 WITHIN WHICH THE RESEARCH THAT WE ARE FUNDING WILL
3 FUNCTION WHEN IT COMES TO THE MARKET.

4 AND THE POLICY ISSUE HERE IS WHAT BALANCE
5 DO WE STRIKE ON ISSUES WHICH ARE ALL PART OF OUR
6 MISSION; THAT IS, WITH REGARD TO FOSTERING
7 INNOVATION, WITH REGARD TO PRICING AND
8 ACCESSIBILITY, AND WITH REGARD TO SAFETY OF THE
9 PRODUCTS.

10 NOW, THE CIRM LEGISLATIVE COMMITTEE HAS
11 FOR THIS REASON AND BECAUSE OF THE RELEVANCE TO US
12 CONSIDERED THIS LEGISLATION AND THIS ISSUE AT ITS
13 LAST TWO MEETINGS AND HAS MADE A RECOMMENDATION
14 WHICH WILL BE BROUGHT FORTH TO YOU TONIGHT TO
15 SUPPORT THE ESCHOO BILL THAT'S PENDING.

16 WHAT ARE BIOSIMILARS? AND HERE THERE ARE
17 PROBABLY 99 PERCENT OF THE PEOPLE IN THIS ROOM WHO
18 CAN DO THIS PART OF THE DISCUSSION BETTER THAN ME,
19 BUT FROM A LAYPERSON'S PERSPECTIVE, BIOLOGICAL
20 PHARMACEUTICALS ARE MADE FROM LIVING ORGANISMS.
21 THEY ARE LARGER AND MORE COMPLEX IN THEIR STRUCTURE
22 THAN CHEMICAL PHARMACEUTICALS, WHICH, IN TURN, ARE
23 SYNTHESIZED FROM CHEMICALS AND ARE MORE PREDICTABLE.
24 AND BECAUSE THEY'RE MORE PREDICTABLE, IT'S EASY TO
25 TELL WHETHER TWO PARTICULAR CHEMICAL COMPOSITIONS

BARRISTERS' REPORTING SERVICE

1 ARE SIMILAR OR IDENTICAL THAN IT IS TELL WHETHER TWO
2 BIOLOGICAL PHARMACEUTICAL PRODUCTS ARE SIMILAR OR
3 IDENTICAL.

4 IN FACT, IN 2007 THE FDA ACTING
5 CHAIRPERSON, JANET WOODCOCK, OPINED THAT WE ACTUALLY
6 HAD VERY LIMITED ANALYTICAL METHODS FOR DETERMINING
7 EQUIVALENCE AMONG BIOLOGICAL PHARMACEUTICAL
8 PRODUCTS, AND IT IS THAT COMPLEXITY THAT WE ARE ALL
9 WRESTLING WITH AS WE THINK ABOUT BIOSIMILAR
10 PRODUCTS.

11 NOW, FOR CHEMICAL PHARMACEUTICALS, WHICH
12 ARE EASY TO MANAGE AND MORE EASILY TO QUANTITATIVELY
13 EVALUATE, THERE IS, AS YOU KNOW, A PATHWAY. THE
14 INNOVATOR HAS TO GO TO THE FDA AND PROVE THE SAFETY
15 AND EFFICACY OF THEIR PRODUCT; AND TO GET TO THAT,
16 THEY HAVE TO GO THROUGH EXTENSIVE RESEARCH AND
17 DEVELOPMENT, THEY HAVE TO PAY FOR CLINICAL TRIALS.
18 IT'S COSTLY AND IT'S TIME-CONSUMING. AFTER THEY DO
19 THAT, THERE CAN BE A GENERIC COMPETITOR WHO COMES ON
20 THE MARKET AND SUBMITS TO THE FDA A REFERENCE TO THE
21 WORK DONE BY THE INNOVATOR BASICALLY SAYS I'M GOING
22 TO RELY ON YOUR FDA PREVIOUS FINDING OF SAFETY AND
23 EFFICACY FOR MY CHEMICAL PHARMACEUTICAL PRODUCT
24 BECAUSE WE'RE ESSENTIALLY IDENTICAL.

25 THAT GENERIC COMPETITOR HAS NOT HAD TO GO

BARRISTERS' REPORTING SERVICE

1 THROUGH THE ENTIRE RESEARCH AND DEVELOPMENT PATHWAY,
2 HAS NOT HAD TO PAY FOR CLINICAL TRIALS, AND,
3 THEREFORE, THEIR COST OF COMING TO MARKET IS LOWER,
4 AND THE COST THAT THEY'RE GOING TO CHARGE FOR THEIR
5 PRODUCT IS LOWER. TO PROTECT THE INNOVATOR IN THE
6 CHEMICAL PHARMACEUTICAL REALM, THEREFOR, UNDER THE
7 HATCH-WAXMAN ACT, THE INNOVATOR IS GIVEN FIVE YEARS
8 OF EXCLUSIVITY. THAT IS SOMETIMES REFERRED TO AS A
9 MONOPOLY. THE INNOVATOR IS GIVEN FIVE YEARS, A
10 PERIOD OF TIME, TO RECOUP THEIR INVESTMENT.

11 THERE IS CURRENTLY NO SIMILAR PATHWAY, NO
12 ACCELERATED REGULATORY PATHWAY FOR
13 BIOPHARMACEUTICALS; THAT IS, YOU CANNOT SIMPLY
14 REFERENCE A BIOLOGICAL PHARMACEUTICAL DATA THAT WAS
15 DONE BY AN INNOVATOR AND TAKE WHAT HAS SOMETIMES
16 BEEN REFERRED TO A FREE RIDE. NOW, WHY IS THAT
17 SIGNIFICANT? THAT'S SIGNIFICANT BECAUSE THE USE OF
18 BIOLOGICAL THERAPIES IS INCREASING DRAMATICALLY,
19 THEIR COST IS INCREASING AT A RATE THAT IS MUCH
20 FASTER THAN THE COST OF CHEMICAL PHARMACEUTICALS,
21 AND AT THE MACRO LEVEL, THE OVERALL BUDGET
22 IMPLICATIONS BOTH FOR INDIVIDUAL CONSUMERS AND FOR
23 GOVERNMENT PAYERS IS VERY SIGNIFICANT.

24 SO I THINK ALL OF THIS LEGISLATION HAS THE
25 GOAL OF CREATING A REGULATORY PATHWAY FOR THESE

BARRISTERS' REPORTING SERVICE

1 BIOSIMILARS THAT ENSURES PRODUCT SAFETY. EVERYONE
2 WANTS SAFE PRODUCTS, BUT THEY ALSO ARE TRYING TO
3 FIND A WAY TO EASE THE ENTRY OF BIO OR SPEED THE
4 ENTRY OF BIOSIMILARS INTO THE MARKET, INCREASE
5 COMPETITION WITH INNOVATORS, THEREBY LOWERING PRICES
6 FOR CONSUMERS. AS I SAID, THE OBAMA ADMINISTRATION
7 IN ITS FISCAL YEAR 2010 BUDGET HAS PROJECTED \$9.2
8 BILLION OF SAVINGS OVER THE NEXT TEN YEARS FROM THIS
9 PROCESS.

10 I WANT TO ADD HERE THAT THE ACTUAL COST
11 SAVINGS ESTIMATES VARY WIDELY, AND YOUR MATERIALS
12 HAVE A DIFFERENT RANGE OF COST SAVINGS REFLECTED,
13 BUT I DON'T THINK IT'S MUCH DISPUTED THAT THERE
14 WOULD BE SOME COST SAVINGS ACHIEVED FROM GREATER
15 COMPETITION.

16 THE LEVERS THAT ARE USED IN THE DIFFERENT
17 REGULATORY PROPOSALS ARE THE SAME; THAT IS, THEY ARE
18 ALL DEALING WITH REFERENCE TO AN INNOVATOR PRODUCT.
19 THEY'RE ALL DEALING WITH DATA EXCLUSIVITY. THEY'RE
20 DEALING WITH MARKET EXCLUSIVITY. BUT THE WAY THAT
21 THEY'RE BALANCING THOSE, THE WAY THAT THEY'RE USING
22 THOSE TOOLS IS QUITE DIFFERENT. WHAT DUANE HAS
23 ASKED ME TO FOCUS ON A LITTLE BIT IS SOME OF THOSE
24 DIFFERENCES.

25 THEY FALL INTO BASICALLY FIVE CATEGORIES,

BARRISTERS' REPORTING SERVICE

1 AND I WON'T GO THROUGH THEM ALL IN DETAIL, BUT THESE
2 ARE THE MAIN ONES. I'M GOING TO SKIP QUICKLY TO THE
3 TOPIC WHICH HAS ACTUALLY GOTTEN THE ABSOLUTE MOST
4 ATTENTION IN THE LITERATURE AND ON THE BLOGS, AND
5 THAT RELATES TO MARKET AND DATA EXCLUSIVITY.

6 THE CONCEPT HERE IS THAT THERE IS A PERIOD
7 OF TIME ESTABLISHED FOR AN INNOVATOR OF A BIOLOGICAL
8 PHARMACEUTICAL TO RECOUP THEIR INVESTMENT. THAT IS,
9 TO HAVE SOME TIME WHERE THEY ARE NOT FACING
10 COMPETITION FROM ANYONE WHO HAS NOT INCURRED SIMILAR
11 COSTS, WHERE THEY ARE NOT SUBJECT TO SOMEONE CITING
12 OR REFERENCING THEIR CLINICAL STUDIES AT NO COST.

13 THE WAXMAN PROPOSAL WOULD ALLOW ONLY
14 BETWEEN THREE AND FIVE YEARS OF EXCLUSIVITY. THE
15 ESCHOO PROPOSAL ALLOWS BETWEEN 12 AND 14 AND A HALF
16 YEARS. AND THAT SPREAD IS QUITE SIGNIFICANT. FROM
17 THE POINT OF VIEW OF SOMEONE WHO'S DETERMINING WILL
18 I MAKE AN INVESTMENT, IF I'M A VENTURE CAPITALIST,
19 WILL I PUT THE MONEY IN? IF I'M A COMPANY, WILL I
20 INVEST IN THIS? THIS DETERMINES HOW LONG YOU HAVE
21 TO GET YOUR INVESTMENT BACK.

22 THERE'S ANOTHER PIECE OF EXCLUSIVITY
23 THAT'S BUILT INTO THESE PROPOSALS THAT IS DIFFERENT
24 ALSO THAT'S IN ADDITION TO THE TIMEFRAMES WE JUST
25 MENTIONED. WHEREAS, REPRESENTATIVE WAXMAN WOULD

BARRISTERS' REPORTING SERVICE

1 ALLOW BIOSIMILAR APPLICANTS TO FILE FOR AN FDA
2 APPROVAL AND REFERENCE THE INNOVATOR DATA AT ANY
3 TIME, REPRESENTATIVE ESCHOO'S PROPOSALS WILL NOT
4 ALLOW THE REFERENCE TO THE INNOVATOR PROJECT UNTIL
5 AT LEAST FOUR YEARS AFTER THE INNOVATOR PRODUCT HAS
6 BEEN LICENSED OR UNTIL THE FDA HAS GIVEN
7 CLASS-SPECIFIC GUIDANCE. SO THIS IS A FURTHER DELAY
8 AND COULD BE IN ADDITION TO THE 12 TO 14 YEARS.

9 FOR PERSPECTIVE, THE EUROPEAN UNION HAS
10 RECENTLY GRAPPLED WITH THIS EXACT SET OF ISSUES, AND
11 THEY ADOPTED A TEN-YEAR EXCLUSIVITY PERIOD FOR
12 BIOSIMILARS, SORT OF COMFORTABLY BETWEEN THE WAXMAN
13 AND ESCHOO PROPOSALS.

14 I WANT TO MENTION QUICKLY THAT THESE
15 PIECES OF LEGISLATION ALSO ADDRESS
16 INTERCHANGEABILITY. I THINK OF INTERCHANGEABILITY
17 AS BEING SORT OF BIOSIMILAR PLUS. IT'S AN IMPORTANT
18 CONCEPT BECAUSE IN MANY STATE REGIMES, PHARMACIES
19 ARE ALLOWED TO AUTOMATICALLY SUBSTITUTE A GENERIC
20 FOR AN INNOVATOR PRODUCT WITHOUT GOING TO A DOCTOR
21 AND ASKING FOR FURTHER INFORMATION OR FURTHER
22 GUIDANCE. AND REPRESENTATIVE WAXMAN AND
23 REPRESENTATIVE ESCHOO AGREE THAT TO QUALIFY FOR
24 INTERCHANGEABILITY, YOU WOULD HAVE TO BE BIOSIMILAR.

25 REPRESENTATIVE WAXMAN THEN SETS OUT A

BARRISTERS' REPORTING SERVICE

1 TEST, AND REPRESENTATIVE ESCHOO DOES THE SAME THING.
2 THE TESTS ARE ACTUALLY RELATIVELY CLOSE TO ONE
3 ANOTHER. THE DIFFERENCE HERE, AGAIN, IS IN THE
4 TIMING. REPRESENTATIVE ESCHOO WOULD NOT ALLOW ANY
5 DETERMINATIONS OF INTERCHANGEABILITY BEFORE THE FDA
6 ISSUES PRODUCT CLASS-SPECIFIC GUIDANCE, WHICH, OF
7 COURSE, CAN TAKE TIME AND ALLOWS FOR PUBLIC COMMENT.

8 NOW, SEVERAL PEOPLE HAVE ASKED WHAT ABOUT
9 PATENTS? WHY IS THIS ADDITIONAL REGULATORY
10 PROTECTION NECESSARY WHEN WE HAVE PATENT PROTECTION?
11 AND THE ANSWER TO THAT IS THIS: CHEMICAL
12 PHARMACEUTICAL PATENTS TEND TO BE COOKBOOK PATENTS.
13 THEY SAY EXACTLY WHAT THE CHEMICAL PHARMACEUTICAL IS
14 MADE OF OR IS COMPRISED OF. AND TO ESTABLISH
15 EQUIVALENCE TO THOSE FOR PURPOSES OF FDA APPROVAL,
16 THE GENERIC MUST BASICALLY FOLLOW THE SAME RECIPE;
17 AND, THEREFORE, THERE'S GOING TO BE FOR MOST CASES,
18 UNLESS YOU HAVE A REALLY CLEVER LAWYER, DEAD-ON
19 PATENT INFRINGEMENT. THE GENERIC WILL FALL WITHIN
20 THE INNOVATOR'S CLAIM.

21 THAT IS NOT NECESSARILY TRUE; IN FACT,
22 IT'S LESS LIKELY TO BE TRUE IN THE CASE OF A
23 BIOLOGICAL WHERE, BECAUSE OF THE DIFFERENCE OF THE
24 NATURE OF THE PRODUCT BECAUSE OF THE DIFFERENCES
25 THAT WE TALKED ABOUT EARLIER, IT IS QUITE POSSIBLE

BARRISTERS' REPORTING SERVICE

1 THAT THE CLAIMS, THE PATENT CLAIMS, OF THE INNOVATOR
2 WILL NOT BE INFRINGED BY OR COULD BE MORE EASILY
3 DESIGNED AROUND BY THE REFERRING ENTITY.

4 I ALSO WANT TO LET YOU KNOW THAT THE
5 PATENT TERM UNDER CURRENT LAW IS 20 YEARS FROM
6 FILING. AND, OF COURSE, THESE PATENTS ARE TYPICALLY
7 FILED VERY EARLY ON IN THE RESEARCH AND DEVELOPMENT
8 PROCESS. SO ALL THE TIME THAT YOU ARE GOING THROUGH
9 YOUR RESEARCH PIPELINE AND THROUGH THE CLINIC, YOUR
10 PATENT CLOCK IS TICKING, AND IT IS EATING AWAY AT
11 THE AVAILABILITY FOR PATENT PROTECTION. AND SO FOR
12 THOSE REASONS, MANY PEOPLE FEEL, AND I WOULD SUPPORT
13 THIS, THAT THERE IS NOT ADEQUATE PATENT PROTECTION
14 FOR BIOLOGICALS, THAT THERE NEEDS TO BE SOME
15 REGULATORY SUPPLEMENT, AND THAT'S WHAT'S BEING AIMED
16 AT HERE.

17 DUANE, WE HAVE A RESOLUTION FROM THE
18 LEGISLATIVE COMMITTEE, WHICH JAMES HARRISON HAS, AND
19 I BELIEVE YOU HAVE A COPY OF AS WELL, WHICH WE CAN
20 PRESENT. I'D BE HAPPY TO TAKE ANY QUESTIONS ON THE
21 IMPACT OF THESE PIECES OF LEGISLATION TO CIRM'S
22 MISSION OR HAVE FURTHER QUESTIONS.

23 VICE CHAIRMAN ROTH: GREAT. THANKS,
24 NANCY. I THINK YOU COVERED IT. IT'S A COMPLICATED
25 AREA, AND I THINK YOU MADE IT REASONABLY CLEAR.

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: I'M JUST AS A LAYPERSON
2 WONDERING WHY THEY WOULDN'T HAVE THE SAME
3 RESTRICTIONS THAT THEY HAD ON GENERICS. WHY WOULD
4 THEY BE TALKING ABOUT, INSTEAD OF FIVE YEARS, THREE
5 YEARS AND TEN YEARS?

6 MS. KOCH: MY UNDERSTANDING IS THAT THE
7 RESEARCH AND DEVELOPMENT CYCLE FOR A CHEMICAL
8 PHARMACEUTICAL IS GOING TO BE SIGNIFICANTLY SHORTER
9 THAN WHAT YOU'D EXPECT FOR A BIOLOGICAL PRODUCT
10 BECAUSE OF THE COMPLEXITY OF WHAT YOU'RE DEALING
11 WITH.

12 VICE CHAIRMAN ROTH: ONE OTHER VERY
13 IMPORTANT THING THAT NANCY ALLUDED TO, BACK WHEN THE
14 GENERIC SMALL MOLECULE LEGISLATION WAS PASSED, YOUR
15 PATENTS WERE 17 YEARS FROM THE DATE OF ISSUANCE,
16 WHICH MEANT IT COULD TAKE THREE, FOUR, FIVE YEARS,
17 AND WITH CONTINUATIONS EVEN LONGER. SO WHILE YOUR
18 PRODUCT WAS BEING REVIEWED AT THE FDA, YOUR PATENT
19 REALLY WASN'T RUNNING. THAT CHANGED TO NOW IT'S 20
20 YEARS FROM DATE OF FILE. AS SOON AS YOU FILE, AND
21 AS NANCY SAID, YOU FILE VERY EARLY, AND THEN YOU'VE
22 GOT 20 YEARS. IF IT TAKES YOU SEVEN, EIGHT, NINE
23 YEARS, TEN YEARS TO GET THROUGH THE FDA, YOUR PATENT
24 LIFE IS DIMINISHED CONSIDERABLY.

25 SO LET ME OPEN IT UP FOR COMMENTS AND

BARRISTERS' REPORTING SERVICE

1 QUESTIONS NOW.

2 MS. SAMUELSON: THANK YOU. TO TRY TO
3 UNDERSTAND A LITTLE BETTER THE DIFFERENCES BETWEEN
4 THE TWO, ARE THERE TWO COMMUNITIES THAT ARE
5 DIFFERENT AT ALL WHO ARE SUPPORTING WAXMAN'S BILL
6 VERSUS ESCHOO'S, AND CAN YOU CHARACTERIZE THOSE? IS
7 ESCHOO'S SILICON VALLEY?

8 MS. KOCH: I CAN TAKE A SHOT AT IT. THE
9 GENERIC PHARMACEUTICAL COMMUNITY IS VERY MUCH IN
10 SUPPORT OF REPRESENTATIVE WAXMAN'S PROPOSAL BECAUSE
11 FOR THEM IT'S FASTER ACCESS TO MARKET. BIO, FOR
12 EXAMPLE, CAME OUT AGAINST REPRESENTATIVE WAXMAN'S
13 PROPOSAL, SAYING THAT IT DID NOT STRIKE THE RIGHT
14 BALANCE. AND I SUSPECT AS BETWEEN THE WAXMAN AND
15 ESCHOO PROPOSALS, THEY WOULD VERY MUCH BE IN FAVOR
16 OF ESCHOO. DUANE, YOU MIGHT HAVE SOME PERSPECTIVE
17 ON THAT.

18 VICE CHAIRMAN ROTH: SOME OF MY COLLEAGUES
19 HERE CAN SPEAK TO THAT AS WELL. BUT I THINK THAT
20 THE WAY NANCY ANSWERED THAT IS CORRECT, THAT SOME
21 ARE MORE INTERESTED IN GETTING THE PRICES DOWN AS
22 QUICKLY AS POSSIBLE, AND OTHERS ARE INTERESTED IN
23 MAKING SURE THERE'S A PROPER INCENTIVE FOR PEOPLE TO
24 TAKE INCREDIBLE RISK ON THE FIRST PRODUCT THROUGH
25 THE FDA. SO THE INNOVATOR WILL TAKE THE LONGEST TO

BARRISTERS' REPORTING SERVICE

1 GET THROUGH THE FDA. WITNESS GERON' S TREMENDOUS
2 DELAY IN GETTING APPROVAL JUST FOR THE PHASE I TO
3 START, AND THEY' LL GO THROUGH EVERY STEP OF THE WAY
4 BECAUSE NOBODY KNOWS. AND SO YOU ALWAYS ASK FOR
5 MORE AND MORE AND MORE DATA.

6 ONCE YOU' VE DONE THAT AND EVERYBODY KNOWS
7 THE PATHWAY TOWARDS APPROVAL, THEN IT BECOMES MUCH
8 SIMPLER. FROM OUR PERSPECTIVE, I THINK THE ISSUE
9 REALLY COMES DOWN TO DO WE WANT TO SUPPORT THE
10 TREMENDOUS INCENTIVE TO SEE PEOPLE TAKE THAT FIRST
11 RISK ON A BRAND NEW INNOVATIVE PRODUCT, OR ARE WE
12 MORE INTERESTED IN GENERICS. THAT' S WHAT IT COMES
13 DOWN TO FOR US. THERE ARE OTHER ISSUES, BUT FROM MY
14 STANDPOINT.

15 MR. SHESTACK: DO YOU MEAN FOR US OR DO
16 YOU MEAN YOU AS --

17 VICE CHAIRMAN ROTH: WHEN I SAY FOR US,
18 I' M TALKING ABOUT CIRM AND THE WHOLE STEM CELL AREA
19 WHICH WILL BE COVERED BY THIS LEGISLATION. AND THE
20 QUESTION IS, AND I THINK WE ALL KNOW, WE' VE SAT IN
21 THIS MEETING LONG ENOUGH TO HEAR, THERE' S A
22 TREMENDOUS PROBLEM WITH TRANSLATIONAL VENTURE
23 CAPITAL SUPPORT, ALL OF THOSE THINGS WHICH ARE
24 GREATLY IMPACTED BY THESE KINDS OF LEGISLATION.

25 I SHOULD PROBABLY TURN TO OTHER PEOPLE WHO

BARRISTERS' REPORTING SERVICE

1 HAVE MORE EXPERIENCE THAN I.

2 DR. PENHOET: NOT NECESSARILY MORE
3 EXPERIENCE, BUT I THINK THE TIMELINE ISSUE IS
4 CRITICAL. JUST TO GIVE YOU A SPECIFIC EXAMPLE,
5 CHIRON DEVELOPED A DRUG FOR MULTIPLE SCLEROSIS,
6 ACTUALLY DEVELOPED BY CETUS, OUR PREDECESSOR
7 COMPANY. IT TOOK 16 YEARS FROM THE TIME THE
8 RESEARCH WAS STARTED TILL THE DRUG WAS APPROVED BY
9 THE FDA. SO AT THAT POINT THERE WOULD HAVE BEEN
10 FOUR YEARS LEFT OF PATENT LIFE UNDER THE NEW PATENT
11 SYSTEM, SO THE TIMELINES CAN BE VERY LONG.

12 AND I THINK THAT'S THE CRITICAL ISSUE HERE
13 IS REALLY FOR THESE KINDS OF PRODUCTS, AND THE
14 EQUIVALENT OF BIOSIMILARS CAN BE ESTABLISHED, BUT
15 STILL IT'S NOT EASY TO ACTUALLY PROVE THAT A COMPLEX
16 MOLECULE IS THE SAME OR DIFFERENT THAN AN EXISTING
17 MOLECULE MADE BY A DIFFERENT PATHWAY. AND FOR
18 CELLS, I THINK IT'S GOING TO BE AN EXTRAORDINARY
19 CHALLENGE ACTUALLY TO SHOW CONSTANCY OF ONE BATCH TO
20 THE OTHER, LET ALONE TO SAY A NEW PERSON'S CELL LINE
21 IS THE SAME AS SOMEBODY'S FORMER CELL LINE.

22 I THINK THIS IS AN AREA WHERE -- FINALLY,
23 I JUST HAVE TO ADD, THE VENTURE COMMUNITY TODAY IS
24 LARGELY TURNING ITS BACK ON BIOTECHNOLOGY GENERALLY,
25 BUT ESPECIALLY ON COMPLEX THERAPIES LIKE STEM CELLS.

BARRISTERS' REPORTING SERVICE

1 SO STEM CELL COMPANIES, EVEN WITH THE EXISTING
2 FRAMEWORK AND WITHOUT THE BIOSIMILAR ISSUES BEING
3 APPROACHED, HAVING A VERY HARD TIME JUSTIFYING
4 INVESTMENTS IN THINGS WITH THIS LENGTH OF TIMELINE.

5 SO CIRM'S INTEREST, IT SEEMS TO ME, ARE --
6 WELL, WE DESPERATELY NEED INDUSTRY PARTICIPATION IN
7 ORDER FOR US TO BE SUCCESSFUL WITH OUR PROJECTS. SO
8 WITHOUT SOME KEY INCENTIVES FOR PEOPLE TO INVEST IN
9 THIS FIELD, I THINK IT'S GOING TO BE VERY HARD TO
10 ATTRACT FURTHER INVESTMENT.

11 THE OTHER SIDE OF THE ISSUE IS CLEAR. THE
12 COSTS ARE HIGH, AND GENERICS HAVE BEEN VERY
13 EFFECTIVE IN LOWERING DRUG COSTS OVERALL. SO THERE
14 IS A ROLE FOR BIOSIMILARS IN THE LONG RUN. THERE'S
15 NO DOUBT ABOUT THAT. PEOPLE CAN'T GET PROTECTION
16 FOREVER BECAUSE THEY INVENTED THE THERAPY, BUT THE
17 CRITICAL ISSUE IS HOW MUCH TIME THEY HAVE TO
18 ACTUALLY RECOUP THEIR INVESTMENTS, IN MOVING THESE
19 FORWARD, REALLY WHETHER PEOPLE ARE GOING TO INVEST
20 IF THE TIMELINES ARE VERY SHORT. AND SO IT'S REALLY
21 A BALANCE BETWEEN PROVIDING LOW COST, HIGH QUALITY
22 THERAPIES TO THE PUBLIC ON THE ONE HAND, BUT AT THE
23 SAME TIME NOT DISCOURAGING INNOVATION. AND THESE
24 TWO THINGS ARE TWO ENDS OF A SPECTRUM HERE, BUT
25 CLEARLY RIGHT NOW THERE'S A REAL CHALLENGE, FOR

BARRISTERS' REPORTING SERVICE

1 SURE, TO GET PEOPLE TO INVEST IN THIS FIELD IN PART
2 BECAUSE OF THESE ISSUES.

3 DR. PRIETO: I WONDER ISN'T IT GOING TO BE
4 AS IMPORTANT OR MORE IMPORTANT THAN HAVING AN
5 APPROPRIATE LENGTH OF TIMELINE TO HAVE VERY ROBUST
6 STANDARDS FOR WHAT CONSTITUTES BIOEQUIVALENTS?
7 THAT'S GOING TO BE THE CRITICAL ISSUE HERE AND THE
8 MOST DIFFICULT TO DETERMINE FOR COMPLEX --

9 MS. KOCH: ON THAT POINT THERE'S
10 SIGNIFICANT DIFFERENCE BETWEEN THESE STATUTES WHERE
11 REPRESENTATIVE ESCHOO IS MORE DEFERENTIAL TO THE FDA
12 IN LETTING THE FDA DEFINE WHAT IS SATISFACTORY IN
13 TERMS OF BIOSIMILARITY. AND REPRESENTATIVE WAXMAN
14 HAS OFFERED A DEFINITION GIVING THE FDA, THEREFORE,
15 LESS DISCRETION.

16 VICE CHAIRMAN ROTH: AGAIN, THE WAXMAN
17 BILL SORT OF DICTATES TO THE FDA WHAT THAT MEANS.
18 THE ESCHOO BILL SAYS LET THE SCIENTIST AT THE FDA
19 DECIDE WHAT IT MEANS ON A PRODUCT-BY-PRODUCT BASIS.
20 THAT'S THE DIFFERENCE BETWEEN THE TWO.

21 MS. LANSING: WELL, I'LL BE BRIEF, BUT I
22 THINK YOU FRAMED THE QUESTION VERY WELL WHEN YOU
23 SAID DO WE WANT PEOPLE -- INDUSTRY TO TAKE THE
24 RISKS, OR DO WE WANT TO PROTECT THE COST OF THE
25 DRUGS. OF COURSE, WE WANT TO PROTECT THE COST OF

BARRISTERS' REPORTING SERVICE

1 THE DRUGS BECAUSE OF ACCESS, BUT THERE WILL BE NO
2 DRUGS UNLESS WE PROTECT THE PEOPLE WHO ARE WILLING
3 TO TAKE THE RISK. SO FOR ME, OF COURSE, I DO WANT
4 ACCESS TO THE DRUGS. I WANT TO MAKE THAT CLEAR. I
5 DON'T WANT THIS TO BE MISINTERPRETED, BUT FOR ME THE
6 MOST IMPORTANT THING WE HAVE TO DECIDE TODAY, AND I
7 FEEL VERY STRONGLY, IS WE MUST ENCOURAGE PEOPLE TO
8 TAKE THE RISK, AND WE MUST PROTECT THEM TO TAKE THE
9 RISK, OR THERE WILL BE NO DRUGS TO HAVE ACCESS TO.

10 VICE CHAIRMAN ROTH: YOU CAN'T HAVE
11 GENERICS WITHOUT AN INNOVATOR. THAT'S THE POINT.

12 DR. LOVE: I WAS GOING TO SAY A SIMILAR
13 THING TO WHAT SHERRY JUST SAID, AND THAT IS THAT
14 CLEARLY THE WAXMAN BILL IS ON THE SIDE OF TRYING TO
15 MAKE GENERICS MORE READILY AVAILABLE IN THE
16 BIOLOGICAL WORLD AND SAVE COSTS, AND THE ESCHOO BILL
17 IS, AT LEAST IN MY VIEW, MUCH MORE BALANCED IN TERMS
18 OF TRYING TO PROTECT THE INNOVATOR.

19 AND TO ED'S POINT, THE INDUSTRY HAS
20 BASICALLY ALWAYS HAD THE PROTECTION THAT THESE
21 GENERICS ARE NOT COMING. AND EVEN WITH THAT KIND OF
22 PERCEPTION, IT'S ALREADY BECOMING INCREASINGLY MORE
23 DIFFICULT TO FUND BIOTECHNOLOGY. EVEN THE ESCHOO
24 BILL IS ALREADY, IF YOU WILL, A BURDEN ON AN ALREADY
25 STRUGGLING INDUSTRY. BUT THE POINT ABOUT SAFETY, I

BARRISTERS' REPORTING SERVICE

1 THINK, IS ONE THAT WE REALLY HAVE TO EMPHASIZE. AT
2 LEAST IN MY VIEW, IT IS ABSOLUTELY CRITICAL THAT THE
3 FDA BE SUPPORTED AND DEFENDED, AS THE ESCHOO BILL
4 DOES, AROUND HAVING THE AUTHORITY TO LOOK AT THESE
5 MOLECULES, TO REQUIRE CLINICAL TRIALS.

6 I CAN TELL YOU THAT AS AN INNOVATOR, WHEN
7 YOU MAKE A NEW PRODUCT AND YOU CHANGE THE
8 MANUFACTURING, YOU ARE REQUIRED BY THE FDA TO DO
9 YOUR PHASE III TRIALS OVER AGAIN IF YOU'VE DONE THEM
10 ALREADY BECAUSE THE FDA WILL NOT BELIEVE THAT EVEN
11 YOU CAN MAKE YOUR PRODUCT WITH A DIFFERENT METHOD TO
12 THE SAME STANDARDS THAT YOUR EARLIER PRODUCT WAS
13 MADE.

14 SO IT HAS BEEN A TOTAL STANDARD FROM THE
15 FDA ALL ALONG TO REQUIRE A NEW MANUFACTURING CHANGE
16 REALLY DOES MEAN THAT YOU HAVE TO REDEMONSTRATE
17 SAFETY AND EFFICACY. SO I THINK THAT IS A REAL
18 LACKING, AT LEAST FROM MY PERSPECTIVE, ON THE
19 WAXMAN, AND THE ESCHOO BILL CONTEMPLATES THAT AND
20 INTEGRATES THAT.

21 MS. SAMUELSON: I COMPLETELY AGREE WITH
22 THE LAST FEW COMMENTS. JUST A QUESTION. MR.
23 WAXMAN'S NO DUMMY, AND HE'S BEEN A BIG SUPPORTER OF
24 THESE NEW INNOVATIONS IN THE PAST, THE AUTHOR OF THE
25 FETAL TISSUE BILL AND SO ON.

BARRISTERS' REPORTING SERVICE

1 HAVE YOU TALKED TO HIS STAFF? WHAT'S
2 THEIR RATIONALE, UNDERSTANDING THAT IT COULD PROLONG
3 THE DISCOVERY AT THE LEAST?

4 MS. KOCH: I'VE NOT SPOKEN TO HIS STAFF.
5 I THINK THE RATIONALE IS FAIRLY WELL SET OUT IN THE
6 LEGISLATION ITSELF AND IN THE STATEMENTS THAT WERE
7 MADE AROUND THE LEGISLATION. REPRESENTATIVE WAXMAN
8 CLEARLY BELIEVES THAT IF WE BRING FORWARD
9 COMPETITIVE PRODUCTS MORE QUICKLY, IT WILL DRIVE THE
10 PRICE DOWN. THAT'S JUST A SORT OF FUNDAMENTAL
11 ECONOMIC PRINCIPLE, AND HE BELIEVES THAT HE'S GIVEN,
12 I THINK, ENOUGH GUIDANCE TO THE FDA AND CAN RELY
13 ENOUGH ON THEM TO FOLLOW THE GUIDANCE THAT WE WILL
14 HAVE ADEQUATE SAFETY MECHANISMS IN PLACE.

15 NOW, HE HAS BEGUN TO COMPROMISE. LAST
16 YEAR WHEN HE BROUGHT FORWARD LEGISLATION, IT HAD
17 ZERO EXCLUSIVITY, PERIOD, WHATSOEVER. AND NOW HE'S
18 BRINGING FORWARD SOMETHING THAT HAS A THREE- TO
19 FIVE-YEAR EXCLUSIVITY PERIOD, SO HE SEEMS TO BE
20 HEADING TOWARD A RECOGNITION THAT THERE NEEDS TO BE
21 SOME PRESERVATION, SOME HOLDING OF A LEVEL PLAYING
22 FIELD FOR THE INNOVATORS SO THAT THEY WILL INVEST
23 AND THEN THEY CAN RECOUP INVESTMENTS. AND I THINK
24 HE'S JUST STRIKING THE BALANCE.

25 VICE CHAIRMAN ROTH: I THINK YOU ARE GOING

BARRISTERS' REPORTING SERVICE

1 TO FIND IN THE SENATE THAT THERE'S BEEN A BILL
2 ALMOST IDENTICAL TO WAXMAN INTRODUCED BY SENATOR
3 SCHUMER AND A NUMBER OF OTHER SIGNATORS, AND THERE
4 WILL BE MOST LIKELY AN ESCHOO BILL BY KENNEDY. AND
5 THERE'S A FEW OTHERS THAT ARE GOING TO BE ON THAT
6 SIDE.

7 MR. TORRES: I JUST WANTED TO ADD THAT IN
8 CONVERSATIONS I'VE HAD WITH REPRESENTATIVE ESCHOO,
9 I'VE NOT SPOKEN DIRECTLY TO HENRY ON THIS MATTER,
10 BUT IT'S CLEAR THAT THIS IS NOT THE END OF THE DAY.
11 THAT WE'RE PROBABLY GOING TO END UP IN A CONFERENCE
12 COMMITTEE AND HOPEFULLY WORK SOMETHING OUT WITH ALL
13 THE PARTIES.

14 BUT HAVING SAID THAT, I ALSO COME FROM A
15 COMMUNITY THAT WANTS ACCESSIBILITY, BUT I'M ALSO
16 VERY MUCH AWARE, BEING EDUCATED BY SOME OF THE FOLKS
17 ON THIS BOARD, THAT YOU CAN'T HAVE ACCESSIBILITY
18 UNLESS THERE'S SOMETHING TO ACCESS TO. AND I THINK
19 THAT WE HAVE TO BE VERY SENSITIVE TO THAT, AND
20 THAT'S WHY TRUSTING BOTH HENRY AND ANNA ON THEIR
21 COMMITMENTS AND ON THEIR INTEGRITY, I THINK IT'S
22 IMPORTANT THAT WE SIDE ON THAT ISSUE OF MAKING IT
23 POSSIBLE TO AT LEAST TAKE A POSITION THAT WE BELIEVE
24 THAT INVESTMENT NEEDS TO BE PROTECTED SO THAT WE CAN
25 HAVE THAT INVESTMENT IN THE FIRST PLACE.

BARRISTERS' REPORTING SERVICE

1 SO I WOULD MOVE THAT WE ADOPT THE MOTION
2 TO SUPPORT THE ESCHOO BILL.

3 DR. PULIAFITO: SECOND.

4 VICE CHAIRMAN ROTH: SECOND WAS --

5 DR. PRICE: I'D LIKE TO RAISE ANOTHER
6 QUESTION HERE, A DIFFERENT KIND OF --

7 VICE CHAIRMAN ROTH: WE'RE IN DISCUSSION,
8 SO GO AHEAD.

9 DR. PRICE: I'D LIKE TO RAISE A DIFFERENT
10 KIND OF QUESTION. IT'S NOT THE PREFERENCE FOR ONE
11 OR THE OTHER BILL. I'M CONVINCED, FOR ALL THE
12 REASONS MENTIONED, THAT THE ESCHOO BILL IS
13 PREFERABLE WITH REGARD TO OUR ULTIMATE MISSION. MY
14 QUESTION IS WHAT IS THE VALUE AS OPPOSED TO THE COST
15 OF CIRM WEIGHING IN ON THIS ISSUE? FIRST, I ASK DO
16 WE REALLY MATTER THAT MUCH? IT SEEMS TO ME WE
17 DON'T. LET'S NOT BE A LITTLE BIT -- LET'S NOT
18 ENGAGE IN HUBRIS HERE. WHICHEVER BILL PASSES, I
19 DON'T THINK WHETHER WE WEIGH IN OR NOT IS GOING TO
20 BE THE DECISIVE TIPPING FACTOR.

21 ON THE OTHER HAND, THE ISSUE OF ACCESS AND
22 PRICE HAS BEEN A POLITICAL ALBATROSS FOR US EVER
23 SINCE PROP 71 PASSED. AND ASIDE FROM US, THE WHOLE
24 MATTER OF GENERICS IS A POLITICAL TIME BOMB. IT'S A
25 HAND GRENADE. JUST WITNESS AL GORE AND THE SOUTH

BARRISTERS' REPORTING SERVICE

1 AFRICAN ISSUES OVER GENERICS FOR HIV DRUGS.

2 I WONDER WHY DO WE WANT, WHY DO WE NEED TO
3 TAKE A PUBLIC STAND ON THIS AND THUS ENTANGLE US IN
4 THIS ISSUE AND MAKE US A TARGET ONCE AGAIN FOR THOSE
5 IN CALIFORNIA AND ELSEWHERE THAT WANT TO MAKE THE
6 CASE THAT WE ADJUST AND THE ICOC ADJUST BASICALLY
7 THE FRONT RUNNERS FOR THE BIOTECH INDUSTRY, WHICH
8 HAS UNDERLIED A LOT OF THE CRITICISM OF THIS BOARD
9 ON THE ISSUE OF ACCESSIBILITY TO GENERICS.

10 SO MY QUESTION IS IS IT REALLY -- IS IT A
11 VALUE FOR US OR IS THE COST HIGHER THAN ANY
12 POTENTIAL VALUE?

13 DR. AZZIZ: I DID WANT TO ECHO THE SAME
14 ISSUE. I THINK THAT THAT'S A VERY GOOD POINT.
15 WEIGHING IN ON A SPECIFIC BILL DOES INDICATE THAT
16 WE'RE WEIGHING AGAINST A SPECIFIC BILL. NOW, I'M
17 NOT SURE THAT I WANT TO TACKLE REPRESENTATIVE WAXMAN
18 ON THIS ISSUE AT THIS PARTICULAR POINT. I DO THINK
19 WE CAN ISSUE A STATEMENT, STATING THAT WE WOULD
20 PREFER A BALANCE WHERE WE RECOGNIZE THAT LONGER
21 PERIODS OF TIME MAY BE MORE AMENABLE TO INVESTMENT,
22 ETC. BUT I'M NOT EVEN SURE THAT 12 YEARS AND 13 OR
23 FOURTEEN AND A HALF OR EIGHT OR TEN IS REALLY WHAT
24 WE SHOULD BE AT THIS POINT POLITICALLY PUTTING OUR
25 HAT IN. I THINK THAT THAT WOULD BE PERHAPS MORE

BARRISTERS' REPORTING SERVICE

1 DANGEROUS THAN SIMPLY ISSUING SOME GENERAL
2 GUIDELINES FOR WISDOM, IF YOU WOULD, FOR PEOPLE TO
3 CONSIDER AS OPPOSED TO TAKING ONE EXTREME.

4 MS. LANSING: YOU KNOW, I THOUGHT WE HAD
5 TO WEIGH IN. THAT'S REALLY AN INTERESTING POINT
6 THAT YOU BROUGHT UP. I THOUGHT THIS WAS SOMETHING
7 WE HAD TO DO. I DIDN'T REALIZE THAT WE HAD THE
8 CHOICE, SO THAT'S MY FAULT.

9 I THINK THAT THERE'S WAYS OF WEIGHING IN.
10 I THINK THAT A LOT OF US HAVE ACCESS TO WAXMAN.
11 HE'S CERTAINLY SOMEBODY THAT WE ALL KNOW, LOOKING AT
12 SOMEONE NODDING HIS HEAD WHO I THINK KNOWS HIM VERY,
13 VERY WELL AND CERTAINLY HAS, WITH OUR VICE CHAIRMAN,
14 THE GREATEST CREDIBILITY OF ACCESS. AND I THINK A
15 GROUP OF US CAN EXPRESS OUR CONCERNS. WE DON'T HAVE
16 TO NECESSARILY MAKE A STATEMENT THAT LOOKS LIKE
17 WE'RE ANTI SOMETHING AS MUCH AS WE CAN HAVE A
18 DIALOGUE, WHICH I THINK IS PROBABLY A HEALTHY WAY TO
19 DO THESE THINGS.

20 VICE CHAIRMAN ROTH: SO I'M GOING TO TAKE
21 OFF MY CHAIR HAT FOR A MINUTE AND TALK JUST TO THIS
22 ISSUE. FIRST OF ALL, WE WOULD NOT TAKE A POSITION
23 AGAINST WAXMAN. WE'D TAKE A POSITION FOR ESCHOO.
24 THAT'S THE MOTION THAT'S ON THE TABLE.

25 NO. 2, I WANT TO MAKE SURE THAT EVERYBODY

BARRISTERS' REPORTING SERVICE

1 UNDERSTANDS THAT WE WOULD BE, IN MY OPINION, AN
2 INNOCENT BYSTANDER TO SOMETHING THAT COULD HAVE A
3 DRAMATIC IMPACT ON AN AREA THAT I'VE NEVER IN MY
4 ENTIRE CAREER SEEN IT SO DIFFICULT TO FINANCE IN.
5 THERE ARE SO MANY ISSUES HERE ABOUT STEM CELL
6 THERAPY AND WHO'S GOING TO PAY FOR IT, HOW'S IT
7 GOING TO BE REGULATED.

8 THERE ARE PEOPLE THAT FLAT OUT BELIEVE
9 THESE PRODUCTS WILL NEVER BECOME COMMERCIAL. WHEN
10 YOU'RE IN THAT KIND OF AN ENVIRONMENT, WE CAN CHOOSE
11 NOT TO AND SAY LET INDUSTRY FIGHT THAT OUT, OR WE
12 CAN CHOOSE TO SAY, LOOK, IT'S REALLY IMPORTANT THAT
13 WE TAKE INCREDIBLE RISK ON THESE PRODUCTS BECAUSE I
14 THINK IT ACTUALLY WILL HAVE AN INVERSE RESPONSE.
15 WHEN PEOPLE SEE THAT YOU CAN GET 12 YEARS MARKET
16 EXCLUSIVITY, EVEN IF YOUR PATENTS EXPIRE BECAUSE,
17 YOU KNOW, YOU CAN GO TO THEM AND SAY, WELL, WE FILED
18 THIS PATENT FOUR YEARS AGO, AND THEY'RE SAYING, "AND
19 BY THE TIME YOU GET THROUGH, YOU ARE GOING TO HAVE
20 HOW MUCH LEFT?" TURN IT AROUND AND SAY IF YOU GET
21 THERE FIRST AND YOU DO YOUR INVESTMENT, YOU'RE GOING
22 TO GET 12 YEARS OF MARKET EXCLUSIVITY SO IT CAN
23 ACTUALLY PULL MONEY INTO WHAT WE THINK WE NEED.

24 MS. LANSING: I TOTALLY AGREE WITH WHAT
25 YOU'RE SAYING, BUT I'M LISTENING TO -- THE QUESTION

BARRISTERS' REPORTING SERVICE

1 IS NOT WHAT WE AGREE ON. AND YOU CAN GET A SENSE OF
2 THE BOARD, YOU CAN TAKE A VOTE AND SEE. I THINK YOU
3 ARE GOING TO FIND THAT THE MAJORITY AGREES WITH WHAT
4 YOU JUST SAID.

5 NOW THE QUESTION IS HOW DO WE TAKE THAT
6 STAND? WHAT IS THE WAY FOR US TO BE THE MOST
7 EFFECTIVE? I DON'T HAVE THE ANSWER, BUT I'M
8 PERSUADED BY WHAT YOU JUST SAID, AND I'D ACTUALLY BE
9 CURIOUS. VICE CHAIRMAN, I'M CURIOUS AS TO WHAT YOU
10 THINK IS THE BEST WAY TO PRESENT THIS. THERE'S MANY
11 WAYS THAT ONE CAN TAKE A STAND.

12 MR. TORRES: WE COULD FORM A COMMITTEE TO
13 SIT DOWN WITH BOTH HENRY AND ANNA AND EXPRESS OUR
14 CONCERNS. THAT'S ONE APPROACH. WE CAN PASS A
15 RESOLUTION TODAY SUGGESTING THAT WE SUPPORT THE
16 CONCEPT OF MARKET EXCLUSIVITY TO A CERTAIN POINT,
17 ASSUMING THAT THAT MIGHT BE AMENDED DOWN THE ROAD,
18 WITHOUT SAYING WE SUPPORT THE ENTIRETY OF THE ESCHOO
19 BILL VERSUS HENRY'S BILL. AND THE OTHER ALTERNATIVE
20 IS TO NOT TAKE A POSITION AT ALL, BUT CONTINUE A
21 DIALOGUE.

22 MS. LANSING: WHAT IS YOUR -- I REALLY
23 RESPECT YOUR BACKGROUND IN THIS. WHAT IS YOUR --
24 HOW DO YOU THINK WE CAN BE THE MOST EFFECTIVE? I
25 THINK WE'RE ALL IN AGREEMENT ON THIS.

BARRISTERS' REPORTING SERVICE

1 MR. TORRES: I THINK THE MOST EFFECTIVE IS
2 TO BE MAKING SOME KIND OF A STATEMENT ON WHERE WE
3 ARE AS A CALIFORNIA INSTITUTION AND WHAT THIS
4 LEGISLATION CAN IMPORT OR HAVE AN IMPACT ON
5 ACCESSIBILITY AND INVESTMENT.

6 MS. LANSING: THAT'S ALL I NEEDED TO KNOW.

7 MR. TORRES: MAYBE THE MORE, AND I HATE TO
8 SAY THIS, MAYBE THE MORE GENERIC APPROACH IN TERMS
9 OF DEALING WITH THIS ISSUE IS TO SAY THIS IS THE
10 CONCEPT THAT WE BELIEVE NEEDS TO BE PART OF ANY
11 LEGISLATION, AND THAT'S MARKET EXCLUSIVITY AND A
12 CERTAIN TIMEFRAME, AND THEN MOVE FROM THERE.

13 VICE CHAIRMAN ROTH: I THINK WHAT ART SAID
14 EARLIER, THIS IS GOING TO BE A DISCUSSION; BUT I
15 THINK IF YOU FAIL TO WEIGH IN NOW, YOU'RE NOT GOING
16 TO BE.

17 MS. LANSING: I'M CONVINCED.

18 MR. SHESTACK: I JUST REALLY -- ACTUALLY I
19 HAVE TO AGREE WITH ROBERT PRICE. WHY IMPORT
20 PROBLEMS FROM THE FUTURE? I JUST DON'T SEE HOW WE
21 WILL ACTUALLY AFFECT THE DEBATE, INFORM THE DEBATE.
22 I DON'T WANT TO READ A CRUMMY EDITORIAL ABOUT IT IN
23 THE *SACRAMENTO BEE* SAYING THEY WE'RE LIKE SUCKS FOR
24 BIOTECH. IT'S JUST -- I THINK -- AND BIOTECH WILL
25 FIGHT IT OUT WITHOUT US. I'M REALLY CONFIDENT THAT

BARRISTERS' REPORTING SERVICE

1 THEY WILL PROBABLY BE ABLE TO TAKE CARE OF IT. AND
2 WE HAVE MANY THINGS WE NEED TO DO AND FUND, AND THE
3 BEST WAY WE CAN AFFECT THE PROCESS AND THE PRODUCT
4 IS TO GET OUR STUFF FUNDED AND OUT THE DOOR AND
5 SUPPORT BIOTECH IN CALIFORNIA INTO DOING THE WORK.
6 AND LET THE LEGISLATORS WORRY ABOUT THIS AT LEAST
7 FOR A YEAR, NOT TAKE A STANCE ON IT NOW WHEN WE'VE
8 JUST MADE A LOT OF GAINS IN THIS FIELD.

9 VICE CHAIRMAN ROTH: SO WE'LL TAKE A FEW
10 MORE. TED.

11 DR. LOVE: I AGREE. WE DON'T WANT TO BE
12 IN THE NEWSPAPERS AS BEING PEOPLE WHO BLINDLY
13 ENDORSE BIOTECH, BUT I DO THINK WE OUGHT TO BE
14 WILLING TO STAND UP FOR WHAT WE THINK IS RIGHT. AT
15 THE END OF THE DAY, I THINK THIS IS A GROUP WHICH IS
16 FUNDAMENTALLY TRYING TO SUPPORT INNOVATION THAT WILL
17 ADVANCE THERAPIES. AND AT THE END OF THE DAY, IT IS
18 VERY CLEAR THAT HAVING THE FINANCIAL RESOURCES,
19 HAVING THE BIOTECH INDUSTRY, HAVING THE FDA IN A
20 POSITION OF STRENGTH TO REALLY LOOK AT THE SAFETY OF
21 THESE PRODUCTS IS IMPORTANT. SO THAT'S WHY, QUITE
22 FRANKLY, I DO THINK PEOPLE DO CARE WHAT WE SAY. I
23 ACTUALLY --

24 DR. PRICE: IT'S NOT WHETHER THEY CARE,
25 BUT WHETHER IT WILL AFFECT THE OUTCOME OF THE

BARRISTERS' REPORTING SERVICE

1 LEGISLATION.

2 DR. LOVE: I'M NOT SURE IT WILL AFFECT THE
3 OUTCOME OF THE LEGISLATION, BUT I THINK WE WERE AT
4 THE FDA LAST WEEK, FOR EXAMPLE. I THINK THE FDA
5 WOULD LIKE TO SEE US BEING A VOICE FOR THE ROLE THAT
6 THEY PLAY IN THE PROTECTION OF OUR CITIZENS AROUND
7 PRODUCTS. I THINK THAT THEY LOOK TO US TO BE A
8 VOICE IN THAT IN THIS KIND OF SITUATION.

9 MS. GIBBONS: I THINK THAT'S IT EXACTLY
10 THOUGH, TO BE A VOICE. AND CAN'T WE PLAY A ROLE AS
11 BEING PART OF THE EDUCATION PROCESS AND ALLOWING
12 OTHERS TO SHARE IN OUR PASSIONATE DISCOURSE AND JUST
13 ADDING MORE ENLIGHTENMENT AND ILLUMINATION TO THIS
14 FOR LAY PEOPLE OBVIOUSLY IN PARTICULAR, BUT ISN'T
15 THAT PART OF OUR FUNCTION AS WELL?

16 VICE CHAIRMAN ROTH: WELL, YOU KNOW, IT'S
17 INNOVATION AND TRANSLATION AND ALL THE THINGS WE
18 TALK ABOUT IN THE STRATEGIC PLAN, THAT'S WHY THINGS
19 LIKE THIS, WHICH WILL AFFECT WHAT WE PASS ON, I
20 THINK ARE PROBABLY IMPORTANT.

21 MS. GIBBONS: I GOT TO SAY WITH THE
22 WEBSITE AND SOME OF THE YOUTUBE VIDEOS AND THINGS
23 THAT DON HAS HAD UP, THEY'RE REALLY EFFECTIVE.
24 THEY'RE REALLY -- I THINK THEY DO A GREAT JOB OF
25 JUST GETTING OUT THE INFORMATION WITHOUT THE

BARRISTERS' REPORTING SERVICE

1 CONTROVERSY, BUT ALLOWING A VERY THOUGHTFUL APPROACH
2 THAT, AS A LAYPERSON, I REALLY APPRECIATED AND THINK
3 REFLECTS REALLY WELL ON US.

4 MR. SERRANO-SEWELL: I SORT OF MOVED FROM
5 LEANING TOWARDS BEING NEUTRAL AND BEING MORE ALIGNED
6 WITH PROFESSOR PRICE. BUT LAST NIGHT ART AND I HAD
7 A CHANCE TO SPEAK WITH CAL NEUROALLIANCE IN
8 SACRAMENTO, VERY LARGE GROUP OF PEOPLE. IT WAS
9 REALLY CLEAR THAT THEY DID NOT MIND AT ALL THAT CIRM
10 HAS TAKEN POSITIONS IN THE PAST. THEY DIDN'T MIND
11 THAT WE HAVE TAKEN POSITIONS IN THE PAST ON STATE
12 LEGISLATION. THEY'RE VERY AWARE OF IT BECAUSE IT
13 DOES GET QUOTED IN THE PAPER, BUT THEY DIDN'T SEEM
14 TO MIND BECAUSE OUR POSITIONS HAVE ALWAYS BEEN WELL
15 THOUGHT OUT. THEY MAY DISAGREE ON A POLICY LEVEL,
16 BUT THERE'S NEVER BEEN ANY PERSONAL ANIMOSITY OR
17 PRO-ANNA AND ANTI-HENRY OR VICE VERSA.

18 IT'S MERELY WHERE WE STAND FROM OUR
19 RESPECTIVE FIELDS AND OUR VIEWS, AND I THINK THE
20 CONSENSUS THAT I'M GETTING IS THAT THERE ARE SOME
21 KEY ISSUES THAT WE FEEL VERY STRONGLY ABOUT.
22 PERHAPS ANNA'S BILL IS NOT THE BEST ARTICULATION OF
23 IT JUST YET, BUT WHERE THINGS WEIGH OUT, WE OUGHT TO
24 SAY PUBLICLY THAT THAT'S OUR PREFERENCE. THE BEST
25 WAY TO DO THAT I'LL LOOK TO EVERYBODY ELSE IN TERMS

BARRISTERS' REPORTING SERVICE

1 OF LEADERSHIP, BUT THAT'S THE OUTCOME I HOPE WE CAN
2 HAVE.

3 VICE CHAIRMAN ROTH: SO IF WE COULD, I'M
4 GOING TO CALL FOR PUBLIC COMMENTS OR ALAN.

5 DR. TROUNSON: SORRY. I THINK IT'S A VERY
6 IMPORTANT DISCUSSION BECAUSE IT'S QUITE DIFFICULT.
7 NO. 1, WE ACTUALLY DON'T KNOW WHAT A BIOSIMILAR IS,
8 THE DEFINITION OF A BIOSIMILAR. WILL ANY OF THE
9 CELL THERAPIES DEVELOPED BY ONE OR OTHER COMPANY OR
10 ACADEMIC INSTITUTION BE CONSIDERED BIOSIMILAR AT
11 ALL? SO IN SOME RESPECTS WE REALLY DON'T KNOW THAT.
12 AND PARTICULARLY, I HAVEN'T EXPLORED THAT WITH THE
13 FDA. I DON'T KNOW IF YOU HAVE, DUANE. I DON'T
14 THINK THEY WOULD HAVE A VIEW AT THIS POINT IN TIME
15 EITHER.

16 SO I THINK THAT IS ONE THING. IT'S A BIG
17 LEAP INTO THE UNKNOWN REALLY IN SOME RESPECTS. BUT
18 CIRM IS ABOUT INNOVATION, VERY CLEAR. WE'RE NOT
19 ABOUT THE GENERICS. WE'RE TRYING TO INNOVATE IN
20 THIS SPACE. SO IF IT IS GENUINELY AN ISSUE THAT
21 STOPS INNOVATION, THEN I THINK THAT'S WHERE WE
22 SHOULD BE. WE SHOULD BE ASSISTING THE INNOVATION
23 PROCESS BECAUSE WHAT -- WE KNOW THAT WE'VE GOT TO
24 DEVELOP THESE AS CHEAP AS POSSIBLE; BUT IF WE ARE
25 NOT INNOVATION, IF IT'S NOT ABOUT INNOVATION, IT'S

BARRISTERS' REPORTING SERVICE

1 ESSENTIALLY, MY UNDERSTANDING, IT'S NOT ABOUT CIRM.

2 SO I THINK WE HAVE TO THINK WHETHER THIS
3 IS A ROADBLOCK TO INNOVATION. AND I'M NOT REALLY
4 SURE ABOUT THAT, GIVEN THAT THERE'S NOT A GOOD
5 DEFINITION, BUT I THINK WE HAVE TO BE WARY THAT WE
6 SHOULDN'T PUT SOMETHING OR LET SOMETHING HAPPEN THAT
7 PREVENTS US FROM DELIVERING ON WHAT WE'RE INTENDED
8 TO DO.

9 MR. TORRES: MR. CHAIRMAN, I WOULD LIKE TO
10 PROVIDE A SUBSTITUTE MOTION. AND THAT IS SHOULD WE
11 TAKE A POSITION FIRST. AND DEPENDENT UPON THAT
12 VOTE, THEN HAVE A VOTE ON WHAT THE POSITION SHOULD
13 BE.

14 VICE CHAIRMAN ROTH: SO YOU'RE WITHDRAWING
15 YOUR --

16 MR. TORRES: I'M WITHDRAWING MY ORIGINAL
17 MOTION.

18 VICE CHAIRMAN ROTH: AND THE SECOND,
19 THAT'S OKAY WITH THE SECOND?

20 DR. LEVEY: YES.

21 MR. TORRES: I JUST MADE THE NEW MOTION;
22 AND THAT IS TO TAKE A SENSE OF THE BODY TO SEE
23 WHETHER WE WANT TO TAKE A POSITION OR NOT. IF THERE
24 IS A SENSE OF TAKING A POSITION, THEN HAVE A VOTE ON
25 THE POSITION.

BARRISTERS' REPORTING SERVICE

1 VICE CHAIRMAN ROTH: IS THERE A SECOND ON
2 THAT?

3 DR. PULIAFITO: SECOND.

4 VICE CHAIRMAN ROTH: WE HAVE A MOTION AND
5 A SECOND ON WHETHER WE SHOULD TAKE A POSITION
6 BETWEEN THESE TWO BILLS. AND WE'LL OPEN IT FOR
7 DISCUSSION AND --

8 MS. SAMUELSON: I'D LIKE TO --

9 DR. LEVEY: I'D JUST LIKE TO MAKE ONE
10 COMMENT. I DON'T KNOW HOW IMPORTANT WE ARE IN THE
11 INFINITE SCHEME OF THINGS, BUT WE ARE A UNIQUE BODY
12 IN THE UNITED STATES. THERE IS NOTHING LIKE THIS
13 INSTITUTE, AND THERE'S NOTHING LIKE THIS BOARD. AND
14 I THINK WE OWE IT, IN TERMS OF PUBLIC POLICY, ON AN
15 ISSUE OF THIS TO MAKE A COMMENT. WHETHER PEOPLE
16 LISTEN OR NOT, I DON'T KNOW HOW THESE THINGS WILL
17 GET DECIDED. OBVIOUSLY THEY'RE COMPLEX POLITICALLY.
18 BUT I THINK WE OWE EVERYONE COMMENT ON IMPORTANT
19 PUBLIC POLICY ISSUES THAT WILL IMPACT THE STEM CELL
20 RESEARCH, AND I THINK IT DOES.

21 SO I WOULD HOPE THE BOARD WOULD TAKE THE
22 POSITION OF BEING IN FAVOR OF MAKING A COMMENT.

23 VICE CHAIRMAN ROTH: OTHER COMMENTS? LET
24 ME, FOR THE RECORD, NOTE THAT CHAIRMAN KLEIN HAS
25 ARRIVED, AND I WILL SURRENDER THIS IF YOU WANT OR I

BARRISTERS' REPORTING SERVICE

1 WILL CONTINUE ON.

2 DR. STEWARD: I NEED CLARIFICATION ON THE
3 MOTION. I UNDERSTOOD THE MOTION TO BE SHOULD THE
4 BOARD VOICE AN OPINION, BUT I THINK, DUANE, YOU SAID
5 SHOULD THE BOARD WEIGH IN ON ONE OR THE OTHER OF
6 THESE BILLS. THEY'RE TWO SEPARATE ISSUES.

7 VICE CHAIRMAN ROTH: SHOULD WE TAKE A
8 POSITION IS THE MOTION.

9 DR. STEWARD: THAT'S FINE.

10 MS. SAMUELSON: I HAVE PERHAPS A
11 SUBSTITUTE PROCEDURE. I WOULD PREFER THAT WE DO A
12 LITTLE BIT OF DUE DILIGENCE. I THINK IT'S A GOOD
13 IDEA FOR US TO CONTACT THE TWO MEMBERS AND
14 UNDERSTAND A LITTLE BETTER, FOR ONE THING, THE
15 SITUATION WITH THE BIOCOMMUNITY. IT SOUNDS LIKE
16 THEY'RE UNANIMOUS, AND THERE IS A HUGE PROBLEM, BUT
17 IT WOULD BE NICE TO JUST PUT A LITTLE FLESH ON THE
18 BONES, AND ALSO TO UNDERSTAND -- TO MAKE CONTACT AT
19 LEAST WITH MR. WAXMAN, HIS OFFICE. HAVING DONE
20 THAT, THEN WE COULD PERHAPS AT THE NEXT MEETING ON
21 SOME SHORT TIMEFRAME ANYWAY TAKE A POSITION.

22 MR. TORRES: THAT'S AN EXCELLENT POINT,
23 AND WE DID MAKE CONTACT. WE INVITED THEM TODAY, AND
24 THEY MAY SHOW UP TOMORROW, STAFF WILL, MAYBE, SO WE
25 HAVE TRIED TO MAKE CONTACT TO HAVE THEM HAVE INPUT

BARRISTERS' REPORTING SERVICE

1 INTO THE BOARD DELIBERATIONS.

2 CHAIRMAN KLEIN: IT'S AN EXPLICIT INTENT
3 OF THE INITIATIVE FOR US TO EXPRESS OPINIONS. IT
4 SPECIFICALLY REFERS TO OUR RELATIONSHIPS WITH
5 CONGRESS. AND WE HAVE HAD A HISTORY OF TAKING
6 POSITIONS ON LEGISLATION THAT IS IMPORTANT TO OUR
7 MISSION. I THINK THAT THERE MAY BE LEGISLATION
8 COMES UP RELATED TO THE FDA AND OTHER CRITICAL
9 ELEMENTS IN OUR PIPELINE WHERE WE'RE GOING TO HAVE
10 TO TAKE A POSITION.

11 SO AS TO THIS PARTICULAR MOTION, I THINK
12 THAT'S VERY IMPORTANT. AND, ART, MAYBE YOU COULD
13 COMMENT IN TERMS OF THE EXPECTED PROCEDURE AND
14 FUTURE CONFERENCE COMMITTEES WHICH WILL ALLOW US TO
15 TAKE A SECOND POSITION IF, IN FACT, MORE INFORMATION
16 BECOMES AVAILABLE.

17 MR. TORRES: I DID.

18 VICE CHAIRMAN ROTH: HE ALREADY ADDRESSED
19 THAT.

20 DR. PRIETO: WE ARE THE MOST IMPORTANT
21 FUNDER IN THE UNITED STATES OF THIS RESEARCH THAT WE
22 HOPE WILL LEAD TO THE BIOLOGICAL PRODUCTS THAT WILL
23 RESULT IN TREATMENTS AND CURES FOR CURRENTLY
24 INCURABLE DISEASES. SO I THINK IT'S ENTIRELY
25 APPROPRIATE THAT WE DO WEIGH IN ON THIS AND GIVE OUR

BARRISTERS' REPORTING SERVICE

1 OPINION AS TO WHAT WE THINK WILL LEAD TO THOSE
2 TREATMENTS AND CURES.

3 DR. AZZIZ: I HAVE TO AGREE THAT, WHILE
4 WE'LL HAVE DISCUSSION LATER AS TO EXACTLY WHAT WE
5 SAY, WE CLEARLY ARE A RECOGNIZED AUTHORITY. SO NOT
6 WEIGHING IN AT A CRUCIAL TIME WHEN, IN FACT, PEOPLE
7 MAY NOT EVEN UNDERSTAND WHAT THIS -- HOW THIS
8 IMPACTS ON STEM CELL WOULD BE IRRESPONSIBLE. SO I
9 THINK WE DO NEED TO WEIGH IN.

10 MR. SHESTACK: WHEN IS THIS COMING UP FOR
11 A VOTE IN THE HOUSE?

12 VICE CHAIRMAN ROTH: IT COULD BE IN THE
13 NEXT TWO, THREE WEEKS IS WHAT I'VE BEEN TOLD. YOU
14 NEVER KNOW WITH WHAT'S GOING ON IN WASHINGTON RIGHT
15 NOW.

16 SO CAN I, WITH THE BOARD'S CONSENT, ASK
17 FOR PUBLIC COMMENTS?

18 MR. SIMPSON: JOHN SIMPSON WITH CONSUMER
19 WATCHDOG. I DON'T DISPUTE THE NOTION THAT YOU
20 SHOULD AT APPROPRIATE TIMES MAKE APPROPRIATE
21 POSITIONS KNOWN ON VARIOUS PIECES OF LEGISLATION.
22 BUT FROM WHAT I'M HEARING, I DO THINK THAT THIS IS
23 PREMATURE. I HAVE TO AGREE WITH WHAT DR. PRICE
24 SAID. I THINK THERE'S A TREMENDOUS DOWNSIDE TO
25 WEIGHING ON THIS SPECIFIC BILL AT THIS SPECIFIC

BARRISTERS' REPORTING SERVICE

1 TIME.

2 SO I GUESS YOU'RE GOING TO VOTE ON WHETHER
3 YOU SHOULD TAKE A POSITION. I THINK YOU MIGHT WANT
4 TO BE TAKING A POSITION TO STRIKE A BALANCE AND SAY
5 THAT WHATEVER LEGISLATION ULTIMATELY COMES OUT NEEDS
6 TO STRIKE THE BALANCE BETWEEN INNOVATION AND
7 AFFORDABILITY AND ACCESS. OTHERWISE YOU WILL
8 CERTAINLY BE FACING CRIES FROM PEOPLE LIKE ME WHO
9 HAVE SOMETIMES USED SUCH PHRASES AS NO BLANK CHECK
10 FOR BIOTECH AND OTHER SUCH SOUND BITES.

11 THIS IS JUST NOT THE RIGHT TIME TO BE
12 WEIGHING IN ON THIS. I THINK YOU REALLY OWE IT TO
13 YOURSELVES TO HAVE SOME SORT OF DIALOGUE WITH BOTH
14 OF THE LEGISLATORS INVOLVED IN THIS. I KNOW WHERE I
15 COME DOWN. IF I SEE ALL OF BIOTECH LINING UP ON ONE
16 BILL AND HENRY WAXMAN ON THE OTHER SIDE, IT'S NO
17 QUESTION FOR ME TO KNOW WHICH WAY TO GO. AND THAT'S
18 WHAT SCARES ME ABOUT THAT.

19 SO I THINK YOU'RE GETTING A LITTLE TOO FAR
20 TOO FAST, AND MAYBE A LITTLE BIT OF MISSION CREEP
21 HERE. IT'S ONE THING TO BE DOING POSITIONS ON
22 CALIFORNIA LEGISLATION, BUT THIS IS SPECIFIC BILLS
23 AND SO ON. I THINK YOU'RE GOING THE WRONG WAY.

24 MS. SAMUELSON: THIS IS WHY I THINK WE
25 NEED TO DO SOME DUE DILIGENCE. I'VE BEEN WAITING

BARRISTERS' REPORTING SERVICE

1 FOR THIS DEBATE FOR A LONG TIME. I THINK WE MIGHT
2 VERY WELL NEED TO PICK BETWEEN THOSE TWO POLES. WE
3 HAVE BEEN STRIKING A BALANCE, AND I'M NOT SURE THAT
4 IT WORKS TO CARE ABOUT PRICE NOW WHEN WE DON'T HAVE
5 ANY CURES TO PRICE. I THINK WE HAVE TO FIGURE THAT
6 OUT. AND IF THAT'S THE ISSUE, THEN WE NEED TO DO
7 IT.

8 VICE CHAIRMAN ROTH: ANYBODY ELSE?

9 DR. FONTANA: I JUST WOULD LIKE TO SAY,
10 WITH ALL DUE RESPECT TO THE LEGISLATIVE
11 SUBCOMMITTEE, OF WHICH DUANE AND ART, AND I'M SORRY
12 I CAN'T REMEMBER THE STAFFER'S NAME, DID AN
13 OUTSTANDING JOB PRESENTING THE BILLS. THERE'S A LOT
14 OF LITERATURE IN OUR BOOKS IF YOU'VE READ IT, AND
15 THEY DID SPEAK WITH THE DIFFERENT PARTIES, AND THEIR
16 MEMBERS HAVE, I THINK, A VERY GOOD APPROACH TO THIS.
17 AND I DO THINK IT'S IMPORTANT THAT WE MAKE A
18 POSITION, AND I THINK THAT THE LEGISLATIVE
19 SUBCOMMITTEE VOTED ON IT, WE APPROVED IT, AND WE'RE
20 BRINGING IT HERE FOR YOUR REVIEW AND UNDERSTANDING.

21 VICE CHAIRMAN ROTH: SO ARE WE READY TO
22 VOTE? LET'S HAVE A ROLL CALL VOTE.

23 DR. STEWARD: COULD I JUST ASK FOR A
24 SPECIFIC RESTATEMENT OF THIS MOTION? THIS IS NOT A
25 MOTION TO APPROVE ONE OR THE OTHER OF THESE BILLS.

BARRISTERS' REPORTING SERVICE

1 VICE CHAIRMAN ROTH: IT IS NOT A MOTION TO
2 APPROVE ONE OR THE OTHER. THE MOTION THAT'S ON THE
3 TABLE IS --

4 MR. TORRES: MY INTENT WAS TO GIVE US AN
5 OPPORTUNITY TO FIGURE OUT WHETHER WE WANT TO TAKE A
6 POSITION BEFORE WE GO ON RECORD AS TAKING A POSITION
7 ONE WAY OR THE OTHER. SO THAT IF WE VOTE TO SAY
8 THAT WE WANT TO TAKE A POSITION, THEN WE OUGHT TO
9 NOODLE IT AROUND TONIGHT, OBVIOUSLY NOT IN VIOLATION
10 OF BAGLEY-KEENE, BUT CLEARLY NOODLE IT ABOUT AS TO
11 WHAT THAT POSITION SHOULD BE. IS IT ONE OR THE
12 OTHER, OR IS IT SOMETHING ELSE THAT WE OUGHT TO BE
13 TALKING ABOUT AS A BODY?

14 DR. AZZIZ: BUT I DO NEED A CLARIFICATION.
15 IS THE MOTION TO TAKE A POSITION ABOUT THE TOPIC OR
16 THE ISSUE, OR IS THE MOTION TO TAKE A POSITION ABOUT
17 THE BILL? WE NEED TO MAKE SURE WE ARE CLEAR IN THIS
18 MOTION BECAUSE TAKING A POSITION --

19 VICE CHAIRMAN ROTH: I'M GOING TO ASK
20 JAMES TO --

21 MR. TORRES: IT GOES TO ME, THE MAKER OF
22 THE MOTION, AND MY INTENT IS WHETHER WE DO ONE OR
23 THE OTHER, WHETHER WE TAKE A POSITION ON CONCEPT OR
24 WHETHER WE TAKE A POSITION ON LEGISLATION, THAT'S
25 FOR US TO DETERMINE AS A BODY. WE'RE THE

BARRISTERS' REPORTING SERVICE

1 DETERMINERS.

2 DR. AZZIZ: BUT THE VOTE YES OR NO IS
3 ABOUT ONE MOTION. SO WE'RE TRYING FIGURE OUT WHICH
4 IS THE MOTION.

5 MR. TORRES: THE MOTION IS DO WE TAKE A
6 POSITION ON THIS ISSUE. IT COULD VERY WELL BE A
7 POSITION FOR OR AGAINST A PARTICULAR BILL.

8 DR. AZZIZ: CORRECT, EXACTLY, BUT IT'S ON
9 THIS ISSUE.

10 VICE CHAIRMAN ROTH: IF YOU VOTE YES, YOU
11 SAY, YES, WE SHOULD TAKE A POSITION.

12 MS. KING: RICARDO AZZIZ.

13 DR. AZZIZ: FOR.

14 MS. KING: ROBERT PRICE.

15 DR. PRICE: ABSTAIN.

16 MS. KING: FLOYD BLOOM.

17 DR. BLOOM: YES.

18 MS. KING: DAVID BRENNER.

19 DR. BRENNER: YES.

20 MS. KING: JACOB LEVIN.

21 DR. LEVIN: YES.

22 MS. KING: MARCY FEIT.

23 MS. FEIT: YES.

24 MS. KING: LEEZA GIBBONS.

25 MS. GIBBONS: YES.

BARRISTERS' REPORTING SERVICE

1 MS. KING: SAM HAWGOOD.
2 DR. HAWGOOD: YES.
3 MS. KING: BOB KLEIN.
4 CHAIRMAN KLEIN: YES.
5 MS. KING: GERALD LEVEY.
6 DR. LEVEY: YES.
7 MS. KING: TED LOVE.
8 DR. LOVE: YES.
9 MS. KING: ED PENHOET.
10 DR. PENHOET: YES.
11 MS. KING: CLAIRE POMEROY.
12 DR. POMEROY: YES.
13 MS. KING: FRANCISCO PRIETO.
14 DR. PRIETO: YES.
15 MS. KING: CARMEN PULIAFITO.
16 DR. PULIAFITO: YES.
17 MS. KING: ROBERT QUINT.
18 DR. QUINT: YES.
19 MS. KING: JEANNIE FONTANA.
20 DR. FONTANA: YES.
21 MS. KING: DUANE ROTH.
22 MR. ROTH: YES.
23 MS. KING: JOAN SAMUELSON.
24 MS. SAMUELSON: YES.
25 MS. KING: DAVID SERRANO-SEWELL.

BARRISTERS' REPORTING SERVICE

1 MR. SERRANO-SEWALL: YES.

2 MS. KING: JEFF SHEEHY.

3 MR. SHEEHY: ABSTAIN.

4 MS. KING: JON SHESTACK.

5 MR. SHESTACK: NO.

6 MS. KING: OSWALD STEWARD.

7 DR. STEWARD: YES.

8 MS. KING: ART TORRES.

9 MR. TORRES: YES.

10 MS. KING: FOR THE RECORD, THAT MOTION
11 CARRIES WITH TWO ABSTENSIONS AND ONE NO VOTE.

12 VICE CHAIRMAN ROTH: OKAY. SO WE HAVE TWO
13 CHOICES. WE CAN CONTINUE NOW TO WORK TOWARDS MAKING
14 A DECISION. WE CAN TAKE A BREAK FOR DINNER.

15 DR. FONTANA: I MOVE A MOTION TO VOTE THE
16 BOARD SUPPORTS THE ESCHOO BILL.

17 DR. PULIAFITO: SECOND.

18 VICE CHAIRMAN ROTH: THERE'S A MOTION ON
19 THE TABLE. DISCUSSION?

20 DR. STEWARD: SO I HAVE TO VOTE AGAINST
21 THAT BECAUSE, WITH ALL DUE RESPECT TO THE VERY HARD
22 WORK THAT THE LEGISLATIVE SUBCOMMITTEE PUT TOGETHER
23 ON THIS, LISTENING TO THE OTHER COMMENTS AROUND THE
24 ROOM, I THINK WE'RE ON OUR STRONGEST GROUND MAKING A
25 STATEMENT BASED ON PRINCIPLES RATHER THAN ON

BARRISTERS' REPORTING SERVICE

1 SPECIFIC BILLS. I COULD STRONGLY SUPPORT A WELL
2 THOUGHT OUT SUMMARY OF THE ISSUES AND A CLEARLY
3 STATED POINT OF VIEW ON THOSE ISSUES, BUT I WOULD
4 HAVE TO VOTE AGAINST SUPPORTING ONE OR THE OTHER OF
5 THESE BILLS AT THIS POINT IN TIME.

6 DR. PRIETO: I THINK I HAVE TO AGREE WITH
7 OS, THAT I WOULD FAVOR A MOTION THAT SETS FORTH THE
8 PRINCIPLES THAT I THINK WE AGREE ARE MOST WELL
9 EXPRESSED IN THE ESCHOO BILL, BUT SETTING FORTH
10 THOSE PRINCIPLES AND THAT WE AGREE WITH THOSE AND
11 SUPPORT THOSE AND WOULD LIKE TO SEE THOSE COME OUT
12 OF WHATEVER LEGISLATION IS FINALLY ADOPTED.

13 CHAIRMAN KLEIN: IF THERE WERE A LONG
14 DELIBERATIVE PROCESS OF PRINCIPLES, I THINK WITH
15 SUBSTANTIAL REPRESENTATION AND A LOT OF COMMITTED
16 TIME, IT MIGHT HAVE AN EFFECT. IN WASHINGTON TODAY
17 IT'S NOT GOING TO HAVE AN EFFECT. EITHER WE'RE FOR
18 ONE BILL OR ANOTHER BILL.

19 I WOULD SAY THAT IF WE TAKE A POSITION ON
20 A BILL, AND AS IT DEVELOPS, THERE'S MORE INFORMATION
21 THAT COMES FORWARD, AND AS IT GOES TO THE SENATE, WE
22 COULD IN THE JUNE MEETING ASK AGAIN FOR
23 REPRESENTATION IF MORE INFORMATION COMES OUT, AND WE
24 COULD MODIFY OUR POSITION. BUT YOU'RE EITHER A
25 FACTOR OR YOU ARE NOT RELEVANT TO THE DEBATE. AND

BARRISTERS' REPORTING SERVICE

1 IT'S NOT THE TYPE OF AN ENVIRONMENT WHERE I THINK
2 THAT THE PRINCIPLES WILL HAVE A BIG IMPACT.

3 VICE CHAIRMAN ROTH: OTHER COMMENTS?

4 MS. SAMUELSON: I'D MUCH PREFER TO WAIT
5 UNTIL THE NEXT MEETING IF THAT TIME IS AVAILABLE TO
6 US. IF IT ISN'T, I'D AT LEAST LIKE TO NOODLE IT
7 AROUND. I'D LIKE TO READ THE MATERIALS IN THE
8 BINDER, WHICH I CONFESS I HAVEN'T DONE, JUST TO BE
9 PREPARED MYSELF.

10 DR. PENHOET: WELL, AS YOU KNOW, I JUST
11 STRONGLY SUPPORTED A POSITION WHICH IS WE SHOULD
12 TAKE A POSITION ON THIS ISSUE. BUT I ACTUALLY AGREE
13 WITH OS AND WITH FRANCISCO. I THINK THAT WE CAN
14 INDICATE OUR SUPPORT FOR THE GENERAL APPROACHES
15 ESCHOO IS TAKING WITHOUT PICKING SIDES IN A BATTLE.
16 AND I THINK THERE ARE TWO OR THREE KEY ELEMENTS OF
17 THE ESCHOO PROPOSAL VIS-A-VIS THE WAXMAN PROPOSAL
18 THAT WE CAN WEIGH IN ON PRINCIPLE AND NOT HAVE TO
19 ENGAGE IN CHOOSING SIDES BETWEEN TWO PEOPLE, BOTH OF
20 WHOM HAVE GOOD INTENT IN SOME WAY, SHAPE, OR FORM
21 WITH RESPECT TO WHAT THEY'RE DOING.

22 I GUESS I WOULD -- I DON'T GUESS. I WOULD
23 STRONGLY FAVOR AN APPROACH WHERE WE SPEND SOME TIME
24 WORKING OUT THE KEY PRINCIPLES. THAT EXTENSION OF
25 THE PERIOD OF TIME IS CRITICAL. HAVING THE FDA

BARRISTERS' REPORTING SERVICE

1 DECIDE WHAT'S BIOSIMILAR AND WHAT'S NOT IS ALSO
2 CRITICAL, IT SEEMS TO ME. SO WITHOUT CALLING IT OUT
3 BY NAME, I THINK WE CAN EFFECTIVELY ACCOMPLISH THE
4 SAME THING, BUT REALLY LEAN ON PRINCIPLE RATHER THAN
5 ON SIMPLY SUPPORTING ONE BILL VERSUS ANOTHER BILL.

6 VICE CHAIRMAN ROTH: OTHER COMMENTS?

7 DR. AZZIZ: I WOULD LIKE TO SUPPORT THAT
8 STANCE. I DO THINK WE NEED TO TAKE A HIGH ROAD
9 HERE. THERE ARE LOTS OF COMPLEXITIES IN THIS
10 LEGISLATIVE DEBATE. AND AS TEMPTING AS IT IS TO
11 JUMP RIGHT INTO THE FRAY, I THINK THAT IT WOULD BE
12 PREMATURE BECAUSE IT'S A COMPLEX ISSUE THAT WE
13 SHOULD PROVIDE A LEARNED RESPONSE. WE MAY NOT
14 AFFECT THIS PARTICULAR LEGISLATION OR WE MIGHT; BUT,
15 NEVERTHELESS, WE DO NEED TO COME ACROSS AS BEING A
16 RESOURCE NATIONALLY AND GLOBALLY FOR THIS ISSUE.

17 SO WE DO NEED TO THINK IT THROUGH. WE
18 NEED TO PRESENT SOME POSITION THAT IS LEARNED, IF
19 YOU WOULD, OR HIGHER RATHER THAN JUMPING INTO THE
20 FRAY LEGISLATIVELY.

21 DR. PENHOET: IF I MIGHT ADD ONE COMMENT.
22 YOU KNOW, I'M ACTING CHAIR OF A GROUP CALLED
23 SCIENCE, TECHNOLOGY, AND ECONOMIC POLICY BOARD OF
24 THE NATIONAL ACADEMIES. AND THIS GROUP IS
25 STRUGGLING WITH THIS VERY ISSUE: HOW YOU BALANCE

BARRISTERS' REPORTING SERVICE

1 COST VERSUS INNOVATION. IT'S THE MOST IMPORTANT
2 ISSUE IN HEALTHCARE RIGHT NOW GOING FORWARD.

3 AND I THINK WHATEVER -- IF WE TAKE A
4 MORE -- RATHER THAN SAYING X VERSUS Y, WE ACTUALLY
5 TAKE A MORE REASONED POSITION, I THINK, WE AFFECT
6 NOT ONLY THIS BILL, BUT OTHER ASPECTS OF POLICY
7 WHICH ARE ALSO GOING TO BE VERY IMPORTANT GOING
8 FORWARD. AND SO I DO THINK WE CAN HAVE A BROADER
9 IMPACT BY ACTUALLY DEALING WITH THE ISSUES RATHER
10 THAN MAKING A SIMPLE CHOICE BETWEEN TWO ALTERNATIVES
11 IF WE TAKE THE TIME TO DO THAT. IT TAKES A LITTLE
12 WORK TO DO THAT, BUT I THINK THAT THE MOST IMPORTANT
13 ELEMENTS SHOULD BE FAIRLY CLEAR TO US AT THIS POINT
14 IN TIME.

15 MR. TORRES: I THINK THAT WE CAN FULFILL
16 BOTH BY THE FACT THAT WE ALREADY HAVE AN ICOC
17 TELEPHONIC MEETING SCHEDULED. WE CERTAINLY CAN
18 NOTICE WE'LL ALSO TAKE UP THIS OTHER MATTER IN
19 ADDITION TO THE PROPOSAL ON THE NIH GUIDELINES AND
20 STILL KEEP WITHIN A RELEVANT TIMEFRAME SO THAT WE
21 CAN GET A SENSE OF WHERE WE ARE ON THESE PRINCIPLES
22 AND TAKE A LITTLE MORE TIME TO DO THAT. AND I KNOW
23 WHERE I STAND ON THE ISSUE. I'VE ALREADY TAKEN A
24 POSITION, BUT WE'RE A DELIBERATIVE BODY. AND WE
25 NEED TO TAKE THE INPUT FROM ALL OF US AT THE SAME

BARRISTERS' REPORTING SERVICE

1 TIME. AND I THINK MAYBE THAT'S THE BETTER APPROACH
2 TO GO IN THIS, MS. FONTANA.

3 DR. FONTANA: OKAY. SO I'LL MAKE AN
4 AMENDMENT TO THE MOTION, THAT WE WILL FOCUS ON THE
5 PRINCIPLES OF THE BILLS AND THAT WE'LL PRESENT IT TO
6 THE ICOC TELECONFERENCE ON MAY 12TH.

7 MS. GIBBONS: SECOND.

8 VICE CHAIRMAN ROTH: IS THAT AGREEABLE TO
9 THE SECOND?

10 DR. PULIAFITO: YES.

11 VICE CHAIRMAN ROTH: THAT WAS AGREED.
12 OKAY. SO NEW MOTION ON THE TABLE, THAT WE ASK FOR
13 CONSIDERATION OF THESE COMPARATIVE THINGS AND
14 DEVELOP THE PRINCIPLES THAT WE WOULD SUPPORT AND
15 THINGS THAT POTENTIALLY WE'D NOT SUPPORT AND BRING
16 THAT FORWARD ON MAY 12TH. DISCUSSION?

17 DR. PENHOET: COULD WE SPEND A LITTLE MORE
18 TIME AND GIVE THE GROUP SOME GUIDANCE ABOUT THOSE
19 PRINCIPLES TONIGHT BECAUSE I'M AFRAID ON MAY 12TH WE
20 WON'T HAVE TIME TO GO THROUGH THE ENTIRE, QUOTE,
21 UNQUOTE, THOUGHTFUL AGENDA. SO IF WE COULD
22 ACTUALLY -- NANCY HAS FORTUNATELY FOR US DEFINED
23 THESE ISSUES QUITE CAREFULLY, AND I THINK WE CAN GO
24 THROUGH AND TRY TO ACTUALLY SAY YES OR NO WITHOUT A
25 DETAILED ANALYSIS; BUT, YES, WE DO FAVOR AN

BARRISTERS' REPORTING SERVICE

1 EXTENSION OF TIME; YES, WE FAVOR THE FDA
2 DECISION-MAKING IN THESE THINGS, ETC.

3 SO IF WE COULD AT LEAST HAVE THE
4 CATEGORIES DEFINED TONIGHT AND SOME ROUGH SCOPING OF
5 THOSE CATEGORIES SO THAT ON THE 12TH WE DON'T HAVE
6 TO DO THIS WORK FROM SCRATCH BECAUSE I'M AFRAID THAT
7 IT WOULD BE VERY DIFFICULT TO DO THAT IN A
8 TELEPHONIC MEETING. DOES THAT MAKE SENSE?

9 VICE CHAIRMAN ROTH: I THINK THAT WOULD BE
10 VERY IMPORTANT TO DO, AND I WANT TO JUST GO BACK TO
11 WHAT BOB SAID. THIS IS AN ISSUE WHERE THERE'S
12 ALREADY TWO EXISTING BILLS. IT ISN'T THAT THEY'RE
13 COMING TO US AND ASKING US WHAT DO WE THINK. THESE
14 ARE GOING TO MOVE. THEY'RE GOING TO BE VOTED ON BY
15 CONGRESS. AND IF YOU DON'T HAVE A PRETTY STRONG
16 POSITION ONE WAY OR THE OTHER, I THINK BOB IS
17 ABSOLUTELY RIGHT. IT'S GOING TO BE MEANINGLESS.

18 SO I THINK YOU ARE GOING, EVEN GOING
19 THROUGH THIS PROCESS, YOU ARE GOING TO HAVE TO AT
20 SOME TIME MAKE A DECISION WHICH OF THESE TWO ARE YOU
21 GOING TO SUPPORT. AND THEN THE COMPROMISE, WHICH
22 ART REFERS TO, IS GOING TO HAPPEN, AND THAT'S WHEN
23 YOU CAN MAKE CHANGES. BUT ESCHOO IS NOT ASKING US
24 FOR OUR OPINION AND NEITHER IS WAXMAN. THEY'VE
25 WRITTEN THOSE DOWN, AND YOU'RE GOING TO HAVE TO

BARRISTERS' REPORTING SERVICE

1 DECIDE, AND WE CAN DO IT SORT OF BIG BULLET POINT BY
2 BIG BULLET POINT ON WHAT WE AGREE ON.

3 SO WHY DON'T WE, NANCY, WALK US THROUGH
4 THOSE. LET ME JUST SAY ON THE SAFETY ISSUE, I DON'T
5 THINK YOU HAVE TO SPEND A LOT OF TIME ON THAT
6 BECAUSE THAT'S GOT TO BE DEALT WITH ONE WAY OR THE
7 OTHER. I DON'T THINK WE HAVE TO SPEND A GREAT DEAL
8 OF TIME. IT'S MORE ON THE TIME -- THE FDA GUIDANCE,
9 DATA EXCLUSIVITY, AND INTERCHANGEABILITY. THOSE ARE
10 THE ISSUES THAT ARE ACTUALLY UP THERE.

11 SO YOU WANT TO TAKE THEM ONE BY ONE. SO,
12 NANCY, WALK THROUGH BULLET NO. 1.

13 MS. KOCH: SO WITH REGARD TO DATA
14 REQUIREMENTS FOR BIOSIMILARS, MY ANALYSIS IS THAT
15 THE FUNDAMENTAL DATA THAT WOULD BE REQUIRED UNDER
16 BOTH BILLS IS VERY SIMILAR, FOCUSING ON SAFETY,
17 PURITY, POTENCY, THE MECHANISM OF ACTION, THE ROUTE
18 OF ADMINISTRATION, DOSAGE FORM, PROPOSED CONDITION
19 OF USE, AND ATTENTION TO GMP COMPLIANCE OF A
20 PRODUCTION FACILITY.

21 THE MOST SIGNIFICANT DIFFERENCE THAT HAS
22 COME OUT OF MY READING OF THE PROPOSED BILLS IS THAT
23 REPRESENTATIVE WAXMAN'S LEGISLATION WOULD ACTUALLY
24 ALLOW THE FDA IN ITS DISCRETION, THE SECRETARY, TO
25 WAIVE ANY PORTION OF ANY OF THOSE REQUIREMENTS.

BARRISTERS' REPORTING SERVICE

1 WHEREAS, REPRESENTATIVE ESCHOO WOULD ALSO ALLOW
2 WAIVER, BUT WOULD NOT ALLOW WAIVER OF IMMUNOGENICITY
3 STUDIES UNLESS AND UNTIL THERE WAS PRODUCT
4 CLASS-SPECIFIC GUIDANCE. SO SHE HAS A FLOOR OR A
5 THRESHOLD THAT HAS TO BE CROSSED BEFORE THE
6 SECRETARY COULD WAIVE IMMUNOGENICITY REQUIREMENTS.
7 AND IMMUNOGENICITY APPEARS TO BE ONE OF THE MOST
8 CHALLENGING ASPECTS OF ASSESSING BIOSIMILARITY.

9 I THINK IT'S FAIR TO CONCLUDE THAT UNDER
10 THE ESCHOO LEGISLATION, YOU'D BE MORE LIKELY TO SEE
11 IMMUNOGENICITY STUDIES REQUIRED.

12 VICE CHAIRMAN ROTH: COMMENTS ON THAT ONE?

13 DR. AZZIZ: JUST TO BE CLEAR FOR THE
14 RECORD, THE MOTION WAS MODIFIED AND HAS PASSED; IS
15 THAT CORRECT, THAT WE'RE GOING TO PRODUCE A GENERAL
16 STATEMENT, OR ARE WE STILL DISCUSSING THE POSSIBLE
17 MOTION?

18 VICE CHAIRMAN ROTH: WE TOOK A VOTE TO
19 TAKE A POSITION.

20 DR. AZZIZ: SO ED HAS SUGGESTED THAT WE
21 HAVE AN EXTENDED DISCUSSION TO GIVE SOME GUIDANCE TO
22 THE LEGISLATIVE SUBCOMMITTEE. I'M NOT QUITE SURE
23 THAT WE'VE FORGOTTEN THAT WE ACTUALLY HAVE A MOTION
24 ON THE TABLE.

25 VICE CHAIRMAN ROTH: THE MOTION ON THE

BARRISTERS' REPORTING SERVICE

1 TABLE IS THAT.

2 DR. AZZIZ: IS WHAT?

3 VICE CHAIRMAN ROTH: THE MOTION WAS
4 MODIFIED.

5 DR. AZZIZ: NO. NO. THE MOTION ON THE
6 TABLE, INITIALLY THERE WAS A NUMBER OF DIFFERENT
7 PERMUTATIONS, SPEAK UP ON THE BILL, NOT SPEAK UP ON
8 THE BILL. CAN WE JUST CLOSE THAT ITEM AND THEN GO
9 ON TO THAT?

10 VICE CHAIRMAN ROTH: THAT'S PASSED. THAT
11 PASSED THAT WE WOULD TAKE A POSITION.

12 MS. GIBBONS: ISN'T THE MOTION THAT WE
13 WANT TO VOTE ON -- THAT WE WANT TO VOTE IN PRINCIPLE
14 AND NOT REJECT ONE OR THE OTHER?

15 VICE CHAIRMAN ROTH: THAT'S CORRECT.

16 MS. GIBBONS: DO WE FEEL THAT WE ALL HAVE
17 ENOUGH INFORMATION TO VOTE IN PRINCIPLE WITHOUT
18 GOING THROUGH THIS?

19 VICE CHAIRMAN ROTH: THAT'S WHAT WE'RE
20 GOING TO DO IS GO THROUGH THESE AND HAVE A
21 DISCUSSION.

22 DR. STEWARD: I THINK THAT WHAT RICARDO IS
23 ASKING IS THAT WE JUST GO AHEAD AND VOTE THE MOTION,
24 GET THAT OFF THE TABLE, AND THEN WE CAN DISCUSS THE
25 DETAILS OF IT, WHICH I THINK WOULD BE EASIER TO GET

BARRISTERS' REPORTING SERVICE

1 DONE WITH.

2 DR. AZZIZ: YOU STATED BETTER THAN I
3 COULD, OS. BECAUSE, IN FACT, THE PRINCIPLES ARE
4 GOING TO BE DETERMINED AND PRESENTED BY THE
5 LEGISLATIVE SUBCOMMITTEE. WE'RE JUST GIVING SOME
6 GUIDANCE. THAT'S NOT SOMETHING FOR US TO VOTE AT
7 THIS TIME, SO I'D SUGGEST WE VOTE. THEN IF WE WANT
8 TO HAVE THE TIME TO COMMENT AND GIVE OUR THOUGHTS TO
9 THE LEGISLATIVE SUBCOMMITTEE, WE CAN DO THAT. FIRST
10 VOTE.

11 MS. SAMUELSON: I HAVE A QUESTION. IF I
12 WERE SUPPORTING VOTING, I THINK YOU SAID A MONTH; IS
13 THAT RIGHT?

14 VICE CHAIRMAN ROTH: NOBODY KNOWS. IT'S
15 GOING TO HAPPEN FAIRLY SOON.

16 MS. SAMUELSON: BUT I DON'T WANT TO VOTE
17 ON PRINCIPLE. I WANT TO VOTE ON A BILL.

18 VICE CHAIRMAN ROTH: JOAN, YOU'RE MAKING
19 ME -- YOU'RE MAKING MY HEAD HURT, JOAN. SAY IT
20 AGAIN. YOU WANT TO VOTE ON A BILL EVENTUALLY.

21 MS. SAMUELSON: YEAH. AND THIS MOTION
22 SUGGESTS THAT WE WOULD ONLY BE VOTING A SET OF
23 PRINCIPLES.

24 VICE CHAIRMAN ROTH: THAT'S CORRECT.

25 MS. SAMUELSON: SOMETHING MORE GENERAL.

BARRISTERS' REPORTING SERVICE

1 VICE CHAIRMAN ROTH: THAT' S CORRECT.

2 MS. SAMUELSON: SO I DON' T WANT TO DO
3 THAT, SO I GUESS I JUST OPPOSE THE WHOLE THING.

4 VICE CHAIRMAN ROTH: YOU WOULD VOTE NO.

5 DR. LEVEY: LISTEN, I' M ALL IN FAVOR, AS I
6 SAID, OF THIS BODY MAKING, TAKING A STAND AND MAKING
7 AN OPINION. BUT I CAN ONLY SPEAK FOR MYSELF. I
8 HAVEN' T GONE THROUGH THIS LEGISLATION IN DETAIL
9 BEFORE I VOTE. THIS IS NO WAY TO EDUCATE PEOPLE ON
10 HOW TO DEAL WITH THIS ISSUE. CAN' T WE HAVE THROUGH
11 THE WEEKEND OR SO TO READ THIS MATERIAL, AND THEN
12 WHOEVER HAS AN OPINION JUST WRITE SOMETHING UP AND
13 MAYBE WE HAVE A CONFERENCE CALL AND DECIDE WHAT TO
14 DO WITH THIS? I DON' T THINK THIS IS ANY WAY TO
15 EDUCATE OURSELVES. I' D LIKE TO TAKE AN OPINION, BUT
16 I' D LIKE TO BE EDUCATED AND NOT DO ANY HARM BY DOING
17 IT.

18 VICE CHAIRMAN ROTH: OKAY. OTHER BOARD?
19 MARI E.

20 DR. CSETE: I WOULD JUST LIKE TO
21 RESPECTFULLY SUGGEST THAT SEEMS TO BE A GREAT
22 OPPORTUNITY TO ALSO REMIND THE FEDERAL GOVERNMENT
23 THAT THE FDA NEEDS SIGNIFICANT SUPPORT. YOU' RE
24 ADDING BURDEN TO THEM IN THESE KINDS OF DUTIES, AND
25 I KNOW CHAIRMAN KLEIN HAS TAKEN AN OPPORTUNITY TO DO

BARRISTERS' REPORTING SERVICE

1 THAT. SO IN YOUR STATEMENT, I HOPE YOU WOULD
2 SUPPORT THAT.

3 VICE CHAIRMAN ROTH: GOOD POINT. SO BACK
4 TO THERE'S A MOTION AND A SECOND. WE'VE HAD THE
5 DISCUSSION ON THIS MOTION. THIS MOTION IS ABOUT
6 TAKING A POSITION ON THE PRINCIPLES. AND PUBLIC
7 COMMENT? SEEING NONE, LET'S CALL THE QUESTION.
8 ROLL CALL VOTE.

9 MS. KING: RICARDO AZZIZ.

10 DR. AZZIZ: FOR.

11 MS. KING: ROBERT PRICE.

12 DR. PRICE: FOR.

13 MS. KING: FLOYD BLOOM.

14 DR. BLOOM: YES.

15 MS. KING: DAVID BRENNER.

16 DR. BRENNER: FOR.

17 MS. KING: JACOB LEVIN.

18 DR. LEVIN: YES.

19 MS. KING: MARCY FEIT.

20 MS. FEIT: YES.

21 MS. KING: LEEZA GIBBONS.

22 MS. GIBBONS: YES.

23 MS. KING: SAM HAWGOOD.

24 DR. HAWGOOD: YES.

25 MS. KING: BOB KLEIN.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: ABSTAIN.
2 MS. KING: GERALD LEVEY.
3 DR. LEVEY: YES.
4 MS. KING: TED LOVE.
5 DR. LOVE: YES.
6 MS. KING: ED PENHOET.
7 DR. PENHOET: YES.
8 MS. KING: CLAIRE POMEROY.
9 DR. POMEROY: YES.
10 MS. KING: FRANCISCO PRIETO.
11 DR. PRIETO: YES.
12 MS. KING: CARMEN PULIAFITO.
13 DR. PULIAFITO: YES.
14 MS. KING: ROBERT QUINT.
15 DR. QUINT: YES.
16 MS. KING: JEANNIE FONTANA.
17 DR. FONTANA: YES.
18 MS. KING: DUANE ROTH.
19 MR. ROTH: ABSTAIN.
20 MS. KING: JOAN SAMUELSON.
21 MS. SAMUELSON: NO.
22 MS. KING: DAVID SERRANO-SEWELL.
23 MR. SERRANO-SEWELL: NO.
24 MS. KING: JEFF SHEEHY.
25 MR. SHEEHY: ABSTAIN.

BARRISTERS' REPORTING SERVICE

1 MS. KING: JON SHESTACK. OSWALD STEWARD.

2 DR. STEWARD: YES.

3 MS. KING: ART TORRES.

4 MR. TORRES: AYE.

5 MS. KING: COUNSEL, IT LOOKS LIKE THE
6 MOTION CARRIES.

7 VICE CHAIRMAN ROTH: SO IN TERMS OF
8 PROCESS TO GET TO A POSITION ON THE PRINCIPLES, MAY
9 I SUGGEST THAT WE PUSH THAT TO STAFF AND THE
10 SUBCOMMITTEE TO BRING FORWARD A RECOMMENDATION ON
11 THOSE PRINCIPLES? I'M SENSITIVE TO GERRY LEVEY'S
12 COMMENT THAT HE'D LIKE SOME MORE SUBSTANCE AROUND
13 THESE POINTS, SO WE CAN LOOK AT BOTH, AND THEN BRING
14 THAT FORWARD.

15 SECONDLY, I THINK JOAN IS MAKING THE POINT
16 THAT IT DOES NOT PRECLUDE AT THAT POINT OF TAKING A
17 POSITION ON ONE OR THE OTHER BILLS; IS THAT CORRECT,
18 THAT IF, FOR EXAMPLE, THERE WAS A BROAD AGREEMENT ON
19 THE PRINCIPLES ON ONE VERSUS THE OTHER, THAT THERE
20 COULD BE A POSITION ON THE BILLS?

21 CHAIRMAN KLEIN: FOR THE LEGISLATIVE
22 SUBCOMMITTEE, WE'RE GOING TO MAKE ANOTHER EFFORT TO
23 ASK BOTH AUTHORS AND THEIR STAFFS TO PROVIDE
24 MATERIALS DIRECTLY TO THE BOARD MEMBERS THEIR OWN
25 PRESENTATION, SO THE BOARD MEMBERS HAVE AN

BARRISTERS' REPORTING SERVICE

1 UNFILTERED KIND OF OPPOSING PERSPECTIVE TO STUDY.

2 SO WE' LL TRY AND HIGHLIGHT FOR YOU WHEN
3 YOU GET THOSE WHAT THE TIMEFRAME IS THAT' S LEFT, AND
4 WE' LL TRY AND EXPEDITE GETTING THOSE OUT.

5 VICE CHAIRMAN ROTH: SO WITH THAT, I
6 SUGGEST WE BREAK FOR DINNER. AND, JAMES.

7 MR. TORRES: AND NOTICE THIS DISCUSSION
8 FOR THE MAY 12TH.

9 MR. HARRISON: YES. WE' LL NOTICE IT FOR
10 MAY 12TH.

11 VICE CHAIRMAN ROTH: AND, JAMES, WHILE
12 WE' RE IN CLOSED SESSION, CAN WE DEAL WITH THE CLOSED
13 SESSION ISSUES IF THERE ARE QUESTIONS ON ANY GRANTS,
14 OR DO WE HAVE TO DO THAT LATER?

15 MR. HARRISON: IT' S ENTIRELY UP TO YOU.
16 ORDINARILY WE HAVE AN OPEN SESSION PRESENTATION
17 FIRST AND THEN GO INTO CLOSED SESSION AFTER THE
18 BOARD HAS HAD A CHANCE TO ASK QUESTIONS OF STAFF.

19 VICE CHAIRMAN ROTH: SO WE' LL BREAK FOR
20 DINNER, AND WE WILL NOT GO INTO CLOSED SESSION.
21 WE' LL HAVE A SEPARATE CLOSED SESSION FOR THAT. SO
22 THANK YOU. I' M MORE THAN HAPPY TO TURN THIS
23 MICROPHONE BACK OVER TO BOB.

24 MS. SAMUELSON: THANK YOU.

25 (APPLAUSE.)

BARRISTERS' REPORTING SERVICE

1 (A RECESS WAS TAKEN.)

2 CHAIRMAN KLEIN: ALL RIGHT. WE'RE GOING
3 TO CONVENE, AND WE'RE GOING TO GO IMMEDIATELY INTO
4 THE GRANT REVIEW ITEM ON THE AGENDA. THIS IS ITEM
5 10, CONSIDERATION OF RECOMMENDATIONS FROM THE GRANT
6 WORKING GROUP ON EARLY TRANSLATIONAL RESEARCH. SO
7 IF THE STAFF WOULD GATHER ANY BOARD MEMBERS WHO ARE
8 NOT CURRENTLY IN THE ROOM BECAUSE WE WILL PROCEED
9 IMMEDIATELY. WE HAVE SOME VERY DISTINGUISHED
10 MEMBERS WHO ARE FLOATING IN THE HALLS. ALL RIGHT.
11 JOAN AND JEANNIE, WE ARE RECONVENING. SO, DR.
12 PRIETO, I THINK WE'RE READY TO GO.

13 IF YOU WOULD BEGIN THE STAFF'S
14 PRESENTATION PLEASE, DOCTOR.

15 DR. CANET-AVILES: MR. CHAIRMAN, BOARD
16 MEMBERS, STAFF, MEMBERS OF THE AUDIENCE, TODAY I
17 WOULD LIKE TO PRESENT THE RECOMMENDATIONS PUT FORTH
18 BY THE GRANTS WORKING GROUP IN FEBRUARY FOR THE
19 EARLY TRANSLATIONAL RESEARCH AWARD. THIS IS AGENDA
20 NO. 10 IN YOUR BINDERS.

21 I WILL FIRST BRIEFLY REMIND YOU OF THE
22 OBJECTIVES AND REVIEW CRITERIA OF THE EARLY
23 TRANSLATION INITIATIVE BEFORE PRESENTING THE GRANTS
24 WORKING GROUP RECOMMENDATIONS.

25 THE EARLY TRANSLATIONAL RESEARCH PROGRAM

BARRISTERS' REPORTING SERVICE

1 WAS DESIGNED TO SUPPORT TWO CATEGORIES OF RESEARCH.
2 THE FIRST CATEGORY IS FOR PROJECTS THAT RESULT IN A
3 DEVELOPMENT CANDIDATE THAT ADDRESS AN UNMET MEDICAL
4 NEED. AND THE SECOND CATEGORY IS FOR RESEARCH THAT
5 OVERCOMES A CRITICAL BOTTLENECK TO THE ADVANCEMENT
6 OF NOVEL CELL THERAPIES INTO THE CLINIC. THOSE TWO
7 CATEGORIES WERE TO PROVIDE FUNDING TO ENSURE THAT
8 PROMISING DISCOVERIES IN STEM CELL RESEARCH CAN BE
9 TRANSLATED TO POTENTIAL STEM CELL-BASED CURES,
10 THERAPIES, AND DIAGNOSTICS FOR THE BENEFIT OF
11 PATIENTS.

12 THIS PROGRAM WAS ALSO THE FIRST ONE TO
13 ENGAGE IN AN INTERNATIONAL COLLABORATIVE FUNDING
14 PARTNERSHIP. IN THIS RFA, CIRM HAD A COLLABORATIVE
15 FUNDING PARTNERSHIP WITH THE STATE OF VICTORIA IN
16 AUSTRALIA.

17 THE FIRST CATEGORY OF PROJECTS IN THIS RFA
18 ARE THE DEVELOPMENT CANDIDATE PROJECTS, AS I
19 MENTIONED. NOW, APPLICATIONS FOCUSED ON THE
20 IDENTIFICATION OF A DEVELOPMENT CANDIDATE HAVE BEEN
21 A PRIORITY OF THIS AWARD. A DEVELOPMENT CANDIDATE
22 IS A SMALL MOLECULE, BIOLOGIC, OR STEM CELL-DERIVED
23 CELL THERAPY FOR WHICH THERE ARE COMPELLING DATA
24 DEMONSTRATING REPRODUCIBLE, DISEASE MODIFYING
25 ACTIVITY IN ANIMAL MODELS OF DISEASE AS WELL AS

BARRISTERS' REPORTING SERVICE

1 COMPLETED SUPPORTING ACTIVITIES SUFFICIENT TO
2 CONSIDER INITIATION OF IND ENABLING PRECLINICAL
3 DEVELOPMENT ACTIVITIES.

4 IN PARTICULAR, CIRM CONSIDERED A PRIORITY
5 OF APPLICATIONS PROPOSING A DEVELOPMENT CANDIDATE
6 BASED ON STRONG SCIENCE THAT ADDRESSES AN UNMET
7 MEDICAL NEED AND IS ACHIEVABLE IN THE THREE YEARS OF
8 FUNDING. THE EXAMPLES OF KEY ACTIVITIES TO ACHIEVE
9 A THERAPEUTIC DEVELOPMENT CANDIDATE WERE LISTED IN
10 THE APPENDIX A ON THE RFA AND HAVE BEEN ATTACHED TO
11 YOUR FOLDERS.

12 THE SECOND CATEGORY OF AWARDS IS THE
13 CATEGORY THAT ADDRESSES BOTTLENECKS FOR THE
14 TRANSLATION OF BASIC RESEARCH INTO THERAPIES. CIRM
15 PRIORITIZED APPLICATIONS THAT TARGET BOTTLENECKS TO
16 CELL THERAPY AS OPPOSED TO SMALL MOLECULES OR
17 ANTIBODIES. PARTICULARLY CELL THERAPIES DERIVED
18 FROM HUMAN PLURIPOTENT STEM CELLS OR APPLICATIONS
19 THAT UTILIZE STEM CELLS TO DEVELOP BETTER, MORE
20 PREDICTIVE DISEASE MODELS HAVE BEEN A PRIORITY AND
21 ARE STILL A PRIORITY FOR CIRM.

22 SPECIFICALLY STRONG APPLICATIONS THAT
23 ADDRESS THE FIVE TYPES OF BOTTLENECKS DESCRIBED IN
24 THE RFA WILL BE PRIORITIZED: THE DEVELOPMENT OF
25 METHODS, INCLUDING ANIMAL MODELS, TO MONITOR IMMUNE

BARRISTERS' REPORTING SERVICE

1 RESPONSE, REJECTION, OR INDUCED TOLERANCE; THE
2 DEVELOPMENT OF NONINVASIVE METHODS TO TRACK
3 MIGRATION, INTEGRATION, AND/OR FATE OF IN VIVO
4 TRANSPLANTED STEM CELLS; PRETRANSPLANT MANIPULATION
5 OF CELLS TO PREVENT TERATOMA FORMATION; THE
6 DEVELOPMENT OF CELL DIFFERENTIATION, SELECTION,
7 AND/OR PURIFICATION METHODS THAT RESULT IN HIGHER,
8 MORE CONSISTENT YIELD OF CELLS OF THE DESIRED
9 PHENOTYPE, AND THAT ARE SCALABLE AND COST-EFFECTIVE;
10 THE DEVELOPMENT OF DISEASE MODELS THAT OVERCOME
11 LIMITATIONS OF CURRENT MODELS AND ARE MORE
12 PREDICTIVE OF THERAPEUTIC RESPONSE IN HUMANS WAS THE
13 FIFTH BOTTLENECK. PROPOSALS TARGETING BOTTLENECKS
14 THAT WERE NOT HIGHLIGHTED ABOVE REQUIRED SUBSTANTIAL
15 ADDITIONAL JUSTIFICATION.

16 NOW, I WOULD LIKE TO SPEND SOME TIME
17 REMINDING YOU OF THE EVALUATION CRITERIA FOR THESE
18 AWARDS. THESE CRITERIA HAVE BEEN PROVIDED TO YOU IN
19 YOUR FOLDERS IF YOU WANT TO READ THEM WITH MORE
20 DETAIL.

21 THE FIRST EVALUATION CRITERIA WAS THE
22 SCIENTIFIC BASIS, RATIONALE, AND IMPACT OF THE
23 PROJECT. IN THIS SENSE BOTH DEVELOPMENT CANDIDATES
24 AND BOTTLENECK PROPOSALS HAD TO PROVIDE STRONG AND
25 SUPPORTIVE EVIDENCE FOR THE PROPOSED RESEARCH. THE

BARRISTERS' REPORTING SERVICE

1 SECOND CRITERIA FOR REVIEW --

2 MS. SAMUELSON: WHERE ARE YOU READING
3 FROM?

4 DR. CANET-AVILES: I'M READING FROM THE
5 SLIDES. I'M JUST EXPLAINING A LITTLE BIT MORE, AND
6 IN YOUR FOLDERS YOU HAVE A BIT MORE.

7 SO THE SECOND CRITERIA FOR REVIEW OF
8 PROPOSALS WAS THE DESIGN AND FEASIBILITY OF THE
9 RESEARCH PLAN. IN THIS SENSE BOTH DEVELOPMENT
10 CANDIDATES AND BOTTLENECK PROPOSALS SHARE MOST OF
11 THE CRITERIA. IN THE PARTICULAR CASE OF
12 APPLICATIONS FOCUSED ON DEVELOPMENT CANDIDATES, THE
13 TARGET PROFILE FOR THE PROPOSED DEVELOPMENT
14 CANDIDATE HAD TO BE APPROPRIATE AND ACHIEVABLE. FOR
15 APPLICATIONS ADDRESSING A BOTTLENECK, THE SUCCESS
16 CRITERIA HAD TO BE ESTABLISHED FOR ASSESSING WHETHER
17 THE BOTTLENECK HAD BEEN OVERCOME.

18 THE THIRD REVIEW CRITERIA WAS THE
19 EVALUATION OF QUALIFICATIONS OF THE PI AND THE
20 RESEARCH TEAM PUT TOGETHER FOR THIS RFA.

21 AND THE LAST CRITERIA THAT WE ASKED
22 REVIEWERS TO ASSESS WAS WHETHER THE RESOURCES AND
23 ENVIRONMENT WERE CRITICAL TO THE SUCCESS OF THE
24 PROJECT AND WERE AVAILABLE THROUGH THESE RESOURCES.
25 THE GRANTS WORKING GROUP WERE INSTRUCTED TO

BARRISTERS' REPORTING SERVICE

1 PRIORITIZE APPLICATIONS FOCUSED ON THE
2 IDENTIFICATION OF A DEVELOPMENT CANDIDATE.

3 I'M JUST GOING TO GO THROUGH THE CONCEPT
4 APPROVAL THAT AT THE BOARD LAST AUGUST YOU APPROVED
5 THIS CONCEPT FOR THE EARLY TRANSLATIONAL RFA, WHICH
6 INCLUDED THE FUNDING TARGETS LISTED ON THIS SLIDE
7 WITH A TOTAL OF TEN GRANTS, WHICH UP TO \$60 MILLION
8 TOTAL FUNDS FOR THIS RFA AND SIX MILLION TOTAL COST
9 OVER THREE YEARS PER GRANT.

10 NOW, I'M JUST GOING TO GO THROUGH THE
11 TABLE WITH THE SUMMARY OF THE GRANTS WORKING GROUP
12 RECOMMENDATIONS ON THE OVERALL TOTALITY OF THE
13 APPLICATIONS REVIEWED UNDER THIS RFA. THE GRANTS
14 WORKING GROUP PLACED THE APPLICATIONS INTO THREE
15 TIERS. TIER 1 CONTAINS THE APPLICATIONS RECOMMENDED
16 FOR FUNDING BY THE GRANTS WORKING GROUP. AT THE
17 TIME OF THE GRANTS WORKING GROUP MEETING, WHICH WAS
18 FEBRUARY OF 2009, THERE WERE CONCERNS ABOUT ADEQUACY
19 OF FUNDS. THE GRANTS WORKING GROUP IDENTIFIED A SET
20 OF GRANTS WITHIN TIER 1 THAT THEY RECOMMENDED FOR
21 FUNDING PRIORITY SHOULD FUNDS BE LIMITED.

22 THE TWO GROUPS OF EIGHT AND SEVEN GROUPED
23 APPLICATIONS SIMPLY REPRESENTS THIS FACT, BUT WE
24 ACKNOWLEDGE THAT AS OF LATE LAST WEEK THE
25 CIRCUMSTANCES NO LONGER EXIST.

BARRISTERS' REPORTING SERVICE

1 TIER 2 IS 12 APPLICATIONS, AND
2 APPLICATIONS IN TIER 2 ARE RECOMMENDED FOR FUNDING
3 ONLY IF FUNDS ARE AVAILABLE.

4 AND TIER 3, FINALLY, ARE APPLICATIONS THAT
5 ARE NOT RECOMMENDED FOR FUNDING.

6 CHAIRMAN KLEIN, THIS CONCLUDES MY SUMMARY
7 PRESENTATION ON THESE EARLY TRANSLATIONAL RESEARCH
8 AWARDS.

9 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
10 THANK YOU FOR THE EXTRAORDINARY WORK THAT THE STAFF
11 PUT INTO THIS RFA. WE CERTAINLY HAVE SOME EXCELLENT
12 CHOICES BEFORE US.

13 JEFF SHEEHY, WOULD YOU LIKE TO COMMENT AND
14 PROVIDE SOME FRAMEWORK FOR THE DISCUSSION?

15 MR. SHEEHY: JUST TO AGAIN NOTE THE
16 EXTRAORDINARY WORK OF STAFF. AND, AGAIN, I THINK WE
17 SHOULD COMMEND MARIE CSETE, ALAN, AND THE REST OF
18 STAFF FOR THE EXTRAORDINARY VARIETY OF REVIEWERS
19 THAT THEY'RE ABLE TO PROVIDE.

20 AS WE START MOVING -- I DON'T THINK PEOPLE
21 REALLY THINK ABOUT THIS, BUT AS WE START MOVING DOWN
22 THE DEVELOPMENT PIPELINE, WE NEED TO GET A WHOLE NEW
23 SET OF REVIEWERS. WE HAD A LOT OF VERY FABULOUS
24 BASIC SCIENTISTS WHO DID THE REVIEW FOR A LOT OF
25 WHAT WE'VE DONE UP TO THIS POINT. WE BASICALLY HAVE

BARRISTERS' REPORTING SERVICE

1 HAD TO RECRUIT A WHOLE NEW CREW OF PEOPLE, AND THEY
2 ARE EXTRAORDINARY. AND THE DILIGENCE THAT THEY
3 BRING TO OUR EFFORT IS REALLY AN ENORMOUS BENEFIT
4 FOR US. AND THE ABILITY TO RECRUIT THESE
5 EXCEPTIONAL SCIENTISTS WE REALLY OWE OUR LEADERSHIP
6 AND OUR SCIENCE TEAM A GREAT DEAL OF THANKS BECAUSE
7 THE REVIEW OF OUR GRANTS CONTINUES TO BE
8 EXTRAORDINARY QUALITY, AT LEAST FROM WHAT I'VE BEEN
9 ABLE TO OBSERVE IN THE WORKING GROUP MEETINGS.

10 THE WORKING GROUP DID LOOK AT THE GRANTS
11 IN TIER 1. WE WERE ASSUMING THAT WE WOULD BE UNDER
12 ENORMOUS AMOUNTS OF FINANCIAL PRESSURE. IN GENERAL,
13 THE -- WELL, BASICALLY THEY DID KEEP THE QUALITY
14 FOLLOWED IDENTICALLY TO THE SCORES. IF YOU NOTICE,
15 THE SCORES ARE STILL IN THE SAME ORDER. WHATEVER
16 CHANGES WERE MADE, THERE WERE A COUPLE OF MINOR
17 CHANGES BETWEEN APPLICATIONS THAT HAD IDENTICAL
18 SCORES. SO 177 MIGHT HAVE BEEN PREFERABLE TO
19 ANOTHER. I'M JUST USING THAT AS AN EXAMPLE. BUT
20 THE ONLY TIME THAT THEY REALLY LOOKED AT SHIFTING
21 GRANTS WITHIN TIER 1 WAS WHEN THERE WERE GRANTS WITH
22 IDENTICAL SCORES.

23 AND IT WAS AN UNUSUAL CIRCUMSTANCE IN THAT
24 WE WERE UNDER ENORMOUS AMOUNT OF FINANCIAL DURESS,
25 SO WE SPENT MORE TIME ON TIER 1 THAN WE TYPICALLY DO

BARRISTERS' REPORTING SERVICE

1 IN A WORKING GROUP IN A PROGRAMMATIC REVIEW OF THE
2 WORKING GROUP SCORES.

3 HAVING SAID THAT, I THINK THE TOP TIER,
4 ALL SCORES IN THE TOP QUARTILE, THEY'RE ALL ABOVE
5 75. AND I THINK IT'S A GREAT GROUP, THOUGH THERE
6 WERE A COUPLE OF QUESTIONS ABOUT ONE, MAYBE TWO
7 APPLICATIONS IN TIER 2 THAT I THINK WE MIGHT WANT TO
8 BRING UP BEYOND WHICH ANY INDIVIDUAL MEMBER MAY WANT
9 TO DISCUSS.

10 I KNOW FOR SURE THAT THERE WAS ONE
11 APPLICATION THAT RAISED SOME DIVISION WITHIN THE
12 WORKING GROUP, PERHAPS THE STARKEST DIVISION I THINK
13 I'VE SEEN IN ANY WORKING GROUP MEETING I'VE SEEN SO
14 FAR.

15 SO I GUESS WE'RE GOING STRAIGHT UP. THIS
16 GIVES -- THIS SHOWS WHAT WE'VE DONE. AND HOW WOULD
17 YOU -- ONE OF THE PROBLEMS WE HAVE IS WE'RE OVER
18 BUDGET, SO, YOU KNOW, AT SOME POINT WE'RE GOING TO
19 HAVE TO ADDRESS THAT. THERE WAS A SENSE WITHIN THE
20 WORKING GROUP THAT SOME OF THE BUDGETS WERE
21 EXCESSIVE. STAFF DOES HAVE THE ABILITY IN THIS
22 ROUND, AM I CORRECT, DR. OLSON, THAT STAFF HAS --
23 SOMETIMES WE HAVEN'T TOLD PEOPLE. I WANT TO BE
24 CLEAR THAT I GET THIS OUT RIGHT, WHETHER THERE IS
25 INDEED --

BARRISTERS' REPORTING SERVICE

1 DR. OLSON: STAFF WILL BE WORKING WITH
2 WHOEVER YOU APPROVE FOR FUNDING DURING THE
3 PREFUNDING ADMINISTRATIVE REVIEW TO ADDRESS BUDGETS.

4 MR. SHEEHY: TYPICALLY WE HAVEN'T BEEN IN
5 A POSITION TO ADDRESS BUDGETS. THE OTHER THING TO
6 NOTE ABOUT THIS, AS I WAS SAYING EARLIER, THIS IS A
7 MILESTONE -- THESE GRANTS ARE MILESTONE GRANTS. SO
8 IF THEY'RE NOT MAKING PROGRESS, I DON'T KNOW WHERE
9 THE MILESTONES ARE AT, BUT IF AT CERTAIN -- PERHAPS
10 WE COULD REFERENCE THAT. IF THEY'RE NOT MAKING
11 THEIR MILESTONES, THE GRANTS END. SO THE
12 COMMITMENTS ARE NOT ENDLESS. IF THEY'RE NOT MOVING
13 TOWARDS AN IND OR TOWARDS SOLVING THEIR DEVELOPMENT,
14 THEIR ROADBLOCK PROBLEM, THE GRANTS END AT A CERTAIN
15 POINT IF THEY'RE NOT GETTING WHERE THEY WANT TO GO.

16 CHAIRMAN KLEIN: JEFF, WOULD YOU LIKE DR.
17 OLSON TO DISCUSS FOR THE BENEFIT OF THE PUBLIC AND
18 THE MEMBERS SOME OF THE MILESTONES IN THE DIFFERENT
19 CATEGORIES, SUBCATEGORIES, THAT WE'LL BE CLOSELY
20 SCRUTINIZING?

21 DR. OLSON: I JUST WANT TO MAKE THE POINT
22 THAT CERTAINLY FOR A BOTTLENECK, WHAT WE ASKED
23 PEOPLE FOR WAS SUCCESS CRITERIA. AND THEY HAVE LAID
24 OUT TIMELINES WHEREBY HOW THEY ARE MEASURING THEIR
25 PROGRESS AND THEIR CRITERIA FOR SUCCESS ALONG THE

BARRISTERS' REPORTING SERVICE

1 WAY.

2 FOR DEVELOPMENT CANDIDATES, AGAIN, THEY
3 HAVE A SET OF ACTIVITIES THAT THEY'RE TRYING TO DO.
4 AND IN ORDER TO ACHIEVE THE THREE-YEAR TARGET, IT
5 WOULD BE HELPFUL -- YOU ALMOST NEED TO PACE YOURSELF
6 TO GET THERE. SO THE IDEA IS WE ARE HOPING -- WE
7 ARE USING THE TIMELINES THAT THEY PUT FORTH, THE
8 MILESTONES THAT THEY PUT FORTH AS A GUIDELINE TO
9 THEIR PROGRESS. AND I THINK THERE IS A LITTLE BIT
10 OF A DIFFERENCE IN MY MIND BETWEEN THESE AND SORT OF
11 YOUR VERY -- YOUR MORE RESEARCH-TYPE GRANTS. THESE
12 ARE WHAT I'LL CALL MORE MISSION-FOCUSED GRANTS. AND
13 SO WE ARE REALLY TRYING TO -- WE WOULD LIKE TO WORK
14 WITH THEM, AND WE HOPE THAT THEY ARE GOING TO BE
15 SUCCESSFUL IN MOVING THESE THINGS FORWARD.

16 I THINK THE TYPE OF CRITERIA THAT COUNTS
17 AS A MILESTONE IS VERY DEPENDENT ON THE TYPE OF
18 ACTIVITY. BUT THAT WAS SOMETHING WE SPECIFICALLY
19 ASKED THEM FOR AND FOR TIMELINES. SO THAT'S
20 SOMETHING THAT I THINK WE'LL ALL BE FOLLOWING.

21 CHAIRMAN KLEIN: AND YOU, JEFF, MENTIONED
22 THAT IN TIER 2 THERE'S AN ANOMALY IN THAT THERE IS A
23 SPECIFIC GRANT IN THIS ROUND WHERE ESSENTIALLY
24 THERE'S A REAL SPLIT IN THE REVIEWER SCORING.
25 ESSENTIALLY HALF THE SCORES WERE IN THE 80S AND HALF

BARRISTERS' REPORTING SERVICE

1 OF THEM WERE IN THE 40S.

2 AND, DR. CSETE, MAYBE YOU COULD COMMENT ON
3 THE BASIS FOR THE SPLIT AND DISTINGUISH WHETHER
4 THAT'S A SCIENTIFIC DISAGREEMENT OR WHETHER YOU
5 THINK THAT SPLIT REPRESENTED A DIFFERENCE OF OPINION
6 ON OTHER CRITERIA.

7 DR. CSETE: DO WE WANT TO SAY WHICH GRANT
8 IT IS?

9 MR. SHEEHY: BOB, WE SHOULD PROBABLY
10 ANNOUNCE THE GRANTS AND CONFLICTS. I'M NOT SURE
11 THERE ARE CONFLICTS, MAYBE A HANDFUL.

12 CHAIRMAN KLEIN: WHY DON'T WE GIVE THE
13 GRANT NUMBER, AND THEN WE'LL IDENTIFY CONFLICTS
14 BEFORE WE HAVE ANY DISCUSSION, BUT THE INITIAL
15 INTENT --

16 DR. CSETE: 1232 IS THE GRANT. SO THIS
17 WAS AN UNUSUAL GRANT IN MANY RESPECTS. IT WAS
18 UNUSUAL SCIENTIFICALLY IN THAT I WOULD SAY IT'S A
19 UNIQUE GRANT ACROSS ALL OUR PROGRAMS. WE HADN'T
20 SEEN ANYTHING LIKE THIS. BASICALLY -- HOW MUCH CAN
21 I SAY ABOUT THE GRANT?

22 SO BASICALLY THIS WAS AN APPLICATION TO
23 DEVELOP STANDARDIZED ANIMAL MODELS FOR USE BY OUR
24 GRANTEES. AND THE BASIS OF THE ANIMAL MODELS WAS TO
25 TAKE PHARMACOLOGICALLY OR OTHERWISE INDUCED MOUSE

BARRISTERS' REPORTING SERVICE

1 MODELS AND CROSS THEM WITH IMMUNOSUPRESSED MOUSE
2 MODELS SO THAT THESE DISEASE-SPECIFIC MODELS COULD
3 BE USED AS RECIPIENTS FOR VARIOUS KINDS OF STEM CELL
4 TRANSPLANTS.

5 AND THE PRIMARY REVIEWERS OF THIS GRANT
6 WERE WILDLY ENTHUSIASTIC ABOUT IT, AS WERE ABOUT
7 HALF OF THE GRANTS WORKING GROUP. THE MAIN
8 DISCUSSION THAT HAPPENED DURING THE REVIEW WAS THAT
9 SOME OF THE INVESTIGATORS SAID, "I'M NOT REALLY SURE
10 THERE'S A MARKET FOR THIS." I'M NOT REALLY SURE
11 THAT EVEN THOUGH THERE'S GREAT VIRTUE IN HAVING
12 STEREOTYPIC DEFINED ANIMAL MODELS THAT ALL LABS
13 WOULD BE USING SO THAT THEY COULD TALK TO EACH OTHER
14 ABOUT THEIR RESULTS IN A FUNDAMENTALLY MORE EVEN
15 WAY, THE MAIN ARGUMENT BY THE PEOPLE WHO FELT THIS
16 SHOULDN'T BE FUNDED WAS THAT OUR GRANTEES WOULD NOT
17 BE INTERESTED IN THESE MODELS. IT WAS A MARKET
18 NEGATIVE AGAINST IT AND NOT A SCIENTIFIC NEGATIVE.

19 I HAVE TO SAY THAT I THINK THAT THE
20 GRANTEES WERE SPEAKING AS INDIVIDUAL SCIENTIFIC
21 INVESTIGATORS AND NOT SPEAKING PROGRAMATICALLY FOR
22 CIRM. AND I THINK THE SCIENTIFIC STAFF ALL FELT
23 THAT, ESPECIALLY AFTER WE TALKED TO SOME OF OUR
24 INVESTIGATORS, THAT THIS REPRESENTED A VALUABLE
25 RESOURCE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: OKAY. AND AS YOU WILL
2 NOTE IN THE PUBLIC SUMMARIES OF THIS, THESE WERE
3 MOUSE MODEL -- IMMUNODEFICIENT MOUSE MODELS FOR
4 DIABETES, PARKINSON'S, SPINAL CORD INJURY, STROKE,
5 TRAUMATIC BRAIN INJURY, AND MYOCARDIAL INFARCTION.

6 DR. CSETE: LET ME ALSO SAY THAT I THINK
7 THAT THIS REPRESENTS SOMETHING MORE FLEXIBLE THAN
8 EVEN A LIST OF THOSE DISEASES BECAUSE THIS IS AN
9 APPLICANT GROUP THAT COULD REALLY CREATE
10 IMMUNOSUPRESSED MODELS OF ANYTHING THAT CAME ALONG.
11 THAT'S THEIR BUSINESS.

12 CHAIRMAN KLEIN: OKAY. AND I THINK THAT
13 THOSE WHO SPOKE IN FAVOR OF THIS EMPHASIZED THAT
14 HAVING BENCHMARK MODELS THAT WERE CONSISTENT BETWEEN
15 DIFFERENT LABS AND HAVING THEM IN PLACE COULD SAVE A
16 SUBSTANTIAL LENGTH OF TIME AND HAVE CONSISTENT
17 MODELS FOR COMPARING DISEASE RESEARCH BETWEEN
18 DIFFERENT GROUPS. AND HAVING AN EXPERT GROUP THAT
19 COULD MAINTAIN THOSE MODELS WOULD ALSO SAVE TIME AND
20 MONEY.

21 THE PRIMARY REVIEWER'S, I THINK, POINT OF
22 VIEW HERE WAS THAT GETTING THOSE MODELS DEVELOPED IS
23 OFTEN SUCH A HUGE LEAD-TIME ISSUE IN MOVING RESEARCH
24 DOWNSTREAM, THAT THIS COULD REALLY STREAMLINE
25 RESEARCH IN THESE AREAS AND OTHER AREAS IF THIS

BARRISTERS' REPORTING SERVICE

1 PARTICULAR GRANT PROVED OUT AND ESTABLISHED THIS AS
2 AN APPROPRIATE RESOURCE TO HELP LABORATORIES
3 THROUGHOUT THE STATE.

4 MR. SHEEHY: IF I COULD ADD ONE, I DO
5 THINK THAT THIS MIGHT BE ONE WHERE WE DO RELY AND
6 ASK STAFF TO ACTIVELY MANAGE BECAUSE THERE IS GOING
7 TO BE THIS RELATIONSHIP BETWEEN WHAT THEY DEVELOP
8 AND WHAT PEOPLE WANT TO USE. AND THERE WERE SOME
9 SCIENTISTS IN THAT GROUP WHO SAID, "I WOULD USE
10 THIS. THIS WOULD BE A GREAT BOON TO ME," AND OTHER
11 SCIENTISTS SAID I WOULDN'T.

12 PART OF IT I THINK -- THEY COVERED A WHOLE
13 LIST OF DISEASES, AND SOME DISEASES SAID I WOULD NOT
14 USE IT. SOME WHO WERE EXPERT IN OTHER DISEASES SAID
15 A STANDARDIZED MODEL THAT WE CAN USE ACROSS THE
16 FIELD WOULD BE A GREAT ADVANTAGE FOR ALL OF US
17 BECAUSE OUR DATA CAN BE SHARED. IT WOULD BE HUGELY
18 VALUABLE WHERE ANOTHER SCIENTIST SAYS, "I MAKE ALL
19 MY OWN ANIMAL MODELS."

20 CHAIRMAN KLEIN: DR. AZZIZ.

21 DR. AZZIZ: JUST A QUESTION OF
22 CLARIFICATION SINCE WE ARE TALKING ABOUT A SPECIFIC
23 APPLICATION. THERE IS CORRESPONDENCE REGARDING THE
24 EXTRAORDINARY PETITION CONCERNING THIS APPLICATION.
25 IN THE SUMMARY STATEMENT TO US, IT STATES THAT THE

BARRISTERS' REPORTING SERVICE

1 PETITION DOES NOT PRESENT COMPELLING EVIDENCE THAT
2 THAT SHOULD ALTER THE RECOMMENDATIONS OF THE SCORE
3 OF THE GRANTS WORKING GROUP. I'M A LITTLE BIT
4 CONFUSED AS TO WHETHER THERE IS OR IS NOT. I DON'T
5 KNOW IF THIS IS THE TIME TO DO THIS. I JUST WANT TO
6 MAKE SURE THAT I'M NOT OUT OF TURN.

7 CHAIRMAN KLEIN: I THINK IT'S APPROPRIATE
8 TO GET CLARIFICATION BEFORE THE EXECUTIVE SESSION
9 HERE.

10 DR. TROUNSON: I THINK --

11 DR. CSETE: WE DO NOT CHANGE THE SCORE.
12 BUT I THINK THAT IF YOU LOOK AT THE RESPONSE A
13 LITTLE FARTHER DOWN, WE DID NOTE THAT WE FELT THAT
14 THE ANIMAL MODELS WERE A CRITICAL RESOURCE FOR THE
15 GRANTEES, AND THAT THE PROPOSAL HAS THE POTENTIAL TO
16 HAVE HIGH IMPACT.

17 CHAIRMAN KLEIN: SO, AS I UNDERSTAND, YOUR
18 COMMENT IS THAT THE SCORE PROPERLY REFLECTS THE
19 SPLIT, WHICH IS --

20 DR. CSETE: THE SCORE REFLECTS THE SPLIT.

21 CHAIRMAN KLEIN: -- IMPORTANT INFORMATION
22 FOR US. BUT, IN FACT, WHAT YOU'RE TELLING US IS
23 THAT, FROM A SCIENTIFIC POINT OF VIEW, THESE MODELS
24 APPEAR TO BE A CRITICAL RESOURCE. AND SO THE BOARD
25 HAS TO EVALUATE THIS FEASIBILITY ISSUE OF WILL THIS

BARRISTERS' REPORTING SERVICE

1 CRITICAL -- IS IT A CRITICAL RESOURCE FROM OUR
2 VIEWPOINT, WILL IT BE USED, BECAUSE THAT WAS A
3 TURNING POINT.

4 DR. PENHOET: I MIGHT POINT OUT THAT IN
5 THE REPRESENTATIVE CELL THERAPY DEVELOPMENT
6 ACTIVITIES, REPRODUCIBLE DISEASE MODIFYING ACTIVITY
7 IN RELEVANT MODELS IS ONE OF THE CRITERIA FOR MOVING
8 FORWARD WITH THE OVERALL PROCESS. THERE'S GOING TO
9 BE MORE THAN ONE MODEL FOR EACH DISEASE, I'M SURE,
10 BUT THIS IS A BIG AREA OF LACK THROUGHOUT THE WHOLE
11 INDUSTRY. SO IF HALF THE SCIENTISTS DON'T USE IT,
12 STILL THE OTHER HALF DO. IT'S A BIG NUMBER.

13 DR. AZZIZ: BUT, AGAIN, TO CLARIFY.
14 QUESTION. I DO RESPECT THE FACT THAT THE SCORES
15 WERE THE SCORES AND YOU JUST MATHEMATICALLY DIVIDED
16 THEM AND THAT'S FINE. IT IS ALSO TRUE THAT YOUR
17 STATEMENT EARLIER FELT THAT SOME OF THE REVIEWERS
18 HAD NOT TAKEN PROGRAMMATIC VIEW OF THE APPLICATION,
19 HAD TAKEN SORT OF A SELF-SCIENTIFIC VIEW OF THE
20 UTILITY THEMSELVES.

21 DR. CSETE: I THINK THAT'S TRUE.

22 DR. AZZIZ: I'M JUST A LITTLE CONCERNED
23 JUST BECAUSE THE STATEMENT SEEMED TO CONTRADICT A
24 BIT OF WHAT YOU ARE SAYING. SO WE JUST NEED TO
25 UNDERSTAND WHETHER YOU VALUED THOSE NEGATIVE INPUTS

BARRISTERS' REPORTING SERVICE

1 TO THE EXTENT THAT YOU VALUE THE POSITIVE INPUTS.

2 DR. CSETE: WELL, I THINK THERE'S TWO
3 THINGS. THE NEGATIVE INPUTS IN TERMS OF SCIENTIFIC
4 CRITIQUE OF THE GRANT WERE NOT REALLY VERY STRONG.
5 THE MAJOR DISCUSSION HAPPENED AROUND THIS ISSUE OF
6 WOULD THIS BE USED IF WE FUNDED IT.

7 AND WHAT I MEANT BY PROGRAMMATIC IS PEOPLE
8 WERE THINKING MORE ON THE INDIVIDUAL LAB BASIS.
9 THEY WERE THINKING AS INDIVIDUAL INVESTIGATORS.
10 THAT'S HOW THE DISCUSSION REALLY PLAYED OUT. AND WE
11 WERE THINKING MORE OF ALL OF OUR INVESTIGATORS
12 COLLECTIVELY, AND WE CAN'T REALLY EXPECT OUR
13 REVIEWERS TO THINK ABOUT THAT THE SAME WAY AS WE DO.

14 DR. TROUNSON: I THINK THERE'S AN
15 IMPORTANT PRINCIPLE HERE, THAT WE'RE NOT TRYING TO
16 ADJUST THE SCORES. WE'RE LOOKING AT THE ARGUMENTS
17 AND SYNTHESIZING THEM. AND THERE WAS A DISAGREEMENT
18 HERE, AND WE THINK IT'S APPROPRIATE TO REFLECT THAT
19 THERE WAS A DISAGREEMENT. AND SO WE DON'T BELIEVE
20 THAT THERE WERE GROUNDS PUT FORWARD TO ADJUST THE
21 SCORES. BUT PROGRAMATICALLY, AS YOU CAN SEE IN
22 OTHER AREAS, YOU CAN ACTUALLY MAKE MOVES WITH
23 PROJECTS THAT HAVE MERIT THAT YOU BELIEVE FILL A
24 SLOT THAT WE BASICALLY DON'T HAVE.

25 SO THAT I THINK IT'S APPROPRIATE TO

BARRISTERS' REPORTING SERVICE

1 DETERMINE THIS ON A PROGRAMMATIC LEVEL RATHER THAN
2 TRYING TO REFLECT US RESCORING PROJECTS. I THINK IT
3 JUST FITS MORE COMFORTABLY WITH THE GRANTS WORKING
4 GROUP, I SUSPECT. AND YOU HAVE OUR INPUTS THROUGH
5 THE CHIEF SCIENTIFIC OFFICER AND MYSELF AND OTHERS,
6 THAT WE DO THINK THAT THIS HAS GOT VALUE, BUT THERE
7 ARE OTHER PROJECTS ALSO THAT HAVE VALUE, BUT THIS
8 HAS PARTICULAR VALUE BECAUSE THERE'S -- WHEN YOU ARE
9 GOING TO GO AND STUDY SOMETHING, YOUR FAVORITE CELL,
10 YOU OFTEN HAVE TO PUT ON IT A SKID BACKGROUND. YOU
11 CAN DO THAT. THAT'S NOT AN IMPOSSIBLE TASK. IT'S
12 JUST A TIME-CONSUMING TASK.

13 AND THE OTHER THING, IT WAS NICELY
14 STANDARDIZED SO YOU CAN BUY IN THE MICE, AND THOSE
15 MICE WILL BE EQUIVALENT TO WHAT SOMEBODY ELSE BUYS.
16 IT WILL BE EASIER TO EXAMINE RESPONSES ACROSS A
17 NUMBER OF INVESTIGATORS.

18 SO IT DEFINITELY HAS SOME MERIT FOR THIS
19 TRANSLATIONAL AREA. BUT WE WOULDN'T WANT TO CHANGE
20 THE SCORING.

21 CHAIRMAN KLEIN: OKAY. THANK YOU.

22 MR. ROTH: SO I THINK THE SAME QUESTION
23 THAT DR. AZZIZ RAISED IS THE ONE THAT CONCERNS ME.
24 WE HAVE THREE THINGS THAT HAPPEN. ONE, WE SCORE
25 THEM, AND THEN WE HAVE A PROGRAMMATIC REVIEW TO MAKE

BARRISTERS' REPORTING SERVICE

1 THESE KINDS OF ADJUSTMENTS. AND THEN WE HAVE
2 EXTRAORDINARY PETITIONS WHICH COME IN.

3 SO I'VE READ THE EXTRAORDINARY PETITIONS,
4 ALL FIVE, AND THEY SAID BASICALLY THE SAME THING,
5 THAT WE'VE READ ON IT. AND IT DOESN'T SAY WE DON'T
6 CHANGE THE SCORE.

7 DR. CSETE: LET ME SPEAK TO THAT TOO.

8 MR. ROTH: THAT AFTER THE RECOMMENDATIONS
9 OR SCORE OF THE GRANTS WORKING GROUP, THAT THERE'S
10 NO CHANGE. SO I DON'T KNOW HOW TO READ THE OTHER
11 FOUR EXTRAORDINARY PETITIONS IN LIGHT OF THAT FIRST
12 PARAGRAPH. SO MAYBE IT'S JUST WORDING BECAUSE I DO
13 SEE DOWN BELOW THAT YOU MAKE A RECOMMENDATION THAT
14 THIS IS AN IMPORTANT GRANT.

15 DR. CSETE: I THINK THE FIRST PARAGRAPH
16 ADDRESSES PROCESS. SO LET ME JUST SAY SOMETHING
17 ABOUT THE WAY THE SCORES WERE DISTRIBUTED. THERE
18 WERE SUFFICIENT GOOD SCORES IN THIS THAT THERE COULD
19 HAVE BEEN A MINORITY REPORT ON THE SECOND DAY WHEN
20 WE WENT THROUGH THE PROGRAMMATIC REVIEW. THE
21 PRIMARY REVIEWER AND THE MOST ENTHUSIASTIC PERSON
22 WHO SPOKE TO THE GRANT WAS NOT PRESENT ON THE SECOND
23 DAY OF THE REVIEW PROCESS. SO THAT WAS A LITTLE BIT
24 OF A DISADVANTAGE.

25 MR. SHEEHY: CAN I ADD, THE MOTION FOR A

BARRISTERS' REPORTING SERVICE

1 MINORITY REPORT FAILED BY ONE VOTE.

2 DR. CSETE: CORRECT.

3 MR. SHEEHY: THERE WAS A MOTION FOR A
4 MINORITY REPORT THAT DID FAIL BY ONE VOTE.

5 CHAIRMAN KLEIN: IF SHE HAD BEEN THERE, WE
6 WOULD HAVE HAD A MINORITY REPORT.

7 MR. SHEEHY: I WOULD HAVE BEEN SURPRISED
8 IF SHE HAD NOT SUPPORTED THE MOTION SINCE SHE WAS
9 EXTREMELY -- THAT REVIEWER WAS EXTREMELY
10 ENTHUSIASTIC.

11 MS. SAMUELSON: HAVE WE EVER HAD ONE?

12 CHAIRMAN KLEIN: YES, WE HAVE.

13 DR. CSETE: SO WE ARE ALSO RESPONDING --
14 BY HAVING THIS DISCUSSION, WE ARE ALSO RESPONDING TO
15 THE LETTER FROM THE APPLICANT.

16 CHAIRMAN KLEIN: ALL RIGHT. GIVEN THE
17 COMMENTS WE'VE HAD, WOULD THE STAFF LIKE TO CALL UP
18 ANY SPECIAL FEATURES OR ANY SPECIAL NOTES ON ANY OF
19 THE OTHER EXTRAORDINARY PETITIONS? IS THERE ANY
20 OTHER EXTRAORDINARY PETITION WHERE THERE'S SOMETHING
21 THAT YOU'D LIKE US TO HIGHLIGHT?

22 MS. SAMUELSON: THERE ARE FIVE; IS THAT
23 RIGHT?

24 CHAIRMAN KLEIN: YES.

25 DR. TROUNSON: MR. CHAIRMAN, WE'VE GONE

BARRISTERS' REPORTING SERVICE

1 THROUGH THEM IN SOME DETAIL. WE'VE HAD A STAFF
2 MEMBER LOOKING AT THEM VERY CLOSELY. AND GIL
3 SAMBRANO CAME BACK FROM LEAVE AND ALSO WENT THROUGH
4 THEM IN SOME DETAIL. AND MARIE HAS SEEN THEM; I'VE
5 ENDORSED THEM. I ACTUALLY DON'T THINK THAT, GIVEN
6 THE DISCUSSIONS THAT HAPPENED AT THE GRANTS WORKING
7 GROUP, AND, AS JEFF SAYS, THE GROUP THERE DOES
8 DISCUSS MOST OF THESE ISSUES VERY BROADLY. WHAT
9 HAPPENS UNFORTUNATELY IS IT'S JUST A DISAGREEMENT
10 BETWEEN SCIENTISTS, AND THIS IS PART OF THE
11 SCIENTIFIC PROCESS. PEOPLE DO DISAGREE. AND THAT'S
12 HOW SCIENCE MOVES FORWARD.

13 BUT THE REVIEW PROCESS IS WHEN WE LOOKED
14 AT THE ARGUMENTS, WHICH WAS POSED BY THE APPLICANTS
15 WHO RESPONDED, THAT WE DIDN'T BELIEVE THAT THOSE
16 ISSUES WERE NOT EXAMINED IN SUFFICIENT DETAIL FROM
17 OUR NOTES, THE NOTES OF THE MEETING, TO WARRANT ANY
18 SORT OF REAL CHANGE OR ANYTHING THAT WE SHOULD BRING
19 TO YOUR ATTENTION AS SPECIAL.

20 CHAIRMAN KLEIN: ALL RIGHT. THANK YOU.
21 WE WILL HAVE ADDITIONAL TIME TO ADDRESS THESE AFTER
22 THE EXECUTIVE SESSION. JOAN, DO YOU WANT TO MAKE A
23 COMMENT AT THIS POINT?

24 MS. SAMUELSON: JUST A SMALL COMMENT ON
25 THE SAME SUBJECT. WE STILL HAVE THE DISCRETION TO

BARRISTERS' REPORTING SERVICE

1 PAY ATTENTION TO THESE OTHER GRANTS?

2 CHAIRMAN KLEIN: ABSOLUTELY. PUBLIC
3 COMMENT, JOHN.

4 MR. SIMPSON: JOHN SIMPSON WITH CONSUMER
5 WATCHDOG. I'M A LITTLE BIT PUZZLED, DISTRESSED, AND
6 AMAZED. WE HAD UNDERSTOOD THAT EXTRAORDINARY
7 PETITIONS WERE PUBLIC RECORD AND WOULD BE POSTED
8 BEFORE THE MEETING AS PART OF THE AGENDA. THEY'RE
9 NOT AVAILABLE TO THE PUBLIC. SO I'M WONDERING IF WE
10 COULD PLEASE SEE THEM.

11 CHAIRMAN KLEIN: CERTAINLY.

12 DR. TROUNSON: THEY WERE POSTED.

13 MS. KING: WE JUST GOT THEM LAST NIGHT.
14 SO UNFORTUNATELY THEY HAVEN'T BEEN POSTED. HOWEVER,
15 THEY ARE AVAILABLE, AS FAR AS I KNOW, FOR THE
16 PUBLIC. THEY HAVE BEEN PRINTED FOR THE PUBLIC. IT
17 WAS A VERY TIGHT TIMEFRAME FOR THOSE OF US THAT WERE
18 PUTTING THE MEETING TOGETHER WHEN WE GOT THEM LAST
19 NIGHT. AS FAR AS I KNOW, THEY ARE ON THE TABLE; IS
20 THAT CORRECT, JENNA?

21 CHAIRMAN KLEIN: SO WHAT IS THE RESPONSE,
22 JENNA, TO THAT POINT?

23 MS. SAMUELSON: MR. CHAIRMAN, THIS IS A
24 RHETORICAL QUESTION. STAFF, CAN WE ASSUME THAT IN
25 THE FUTURE, THE FIVE-DAY TURNAROUND WILL PROVIDE

BARRISTERS' REPORTING SERVICE

1 ENOUGH TIME TO GET IT FROM STAFF UPON RECEIPT TO
2 MELISSA OR WHOEVER AND THEN --

3 CHAIRMAN KLEIN: I THINK THE PROBLEM,
4 JOAN, IS THAT THE FIVE DAYS GIVES THEM ENOUGH TIME
5 TO ANALYZE THEM. NORMALLY -- THE OTHER POINT, AND
6 LET ME ASK FOR CLARIFICATION, MELISSA. MY
7 UNDERSTANDING IS THAT ONE OF OUR LIMITING FACTORS
8 HAS BEEN THAT WE'RE DEPENDENT UPON A STATE SYSTEM,
9 CENTRALIZED SYSTEM, FOR POSTING. THEY WORK CERTAIN
10 HOURS. UNLIKE OUR STAFF, THEY DON'T WORK WEEKENDS.
11 AND THEY ARE VERY GOOD PEOPLE. THEY JUST DON'T WORK
12 ON THE SAME BASIS THAT WE DO. WE'RE GOING TO SOON
13 GET CONTROL OF OUR POSTING. IS THAT A CORRECT
14 STATEMENT?

15 MS. KING: THAT IS A CORRECT STATEMENT,
16 ALSO JUST OUR NORMAL DEADLINE TO RECEIVE DOCUMENTS
17 FROM OUR COLLEAGUES FOR MEETINGS IN ORDER TO PRODUCE
18 THEM EVEN. WE HAD TO GO TO KINKO'S THIS AFTERNOON
19 HERE TO EVEN JUST MAKE COPIES OF THESE BECAUSE OF
20 ALL THAT WE NEEDED TO DO BETWEEN LAST NIGHT AND WHEN
21 THE MEETING STARTED. SO REALLY WHAT WE NEED IS WE
22 NEED TO BE ABLE TO RECEIVE THEM FROM OUR COLLEAGUES
23 AT LEAST THREE DAYS BEFORE THE MEETING.

24 CHAIRMAN KLEIN: I THINK THE POINT IS FIVE
25 DAYS WAS INTENDED TO GIVE THE PEOPLE FILING THEM THE

BARRISTERS' REPORTING SERVICE

1 MAXIMUM AMOUNT OF TIME. AND IF IT TAKES THAT --

2 MS. SAMUELSON: MAY HAVE NEEDED.

3 CHAIRMAN KLEIN: THAT INCLUDES A WEEKEND

4 IN THIS CASE, SO THAT THERE ISN'T SUFFICIENT --

5 THERE HASN'T BEEN SUFFICIENT TIME.

6 DR. OLSON: I JUST WANTED TO MAKE THE

7 POINT THAT IF YOU WILL LOOK AT THESE EXTRAORDINARY

8 PETITIONS, YOU WILL NOTICE THAT AT LEAST HALF OF

9 THEM, AND I THINK MAYBE THREE OF THEM, CAME IN AFTER

10 THE FIVE WORKING DAYS. SO STAFF REALLY TRIED TO

11 BASICALLY PROVIDE A REASONED RESPONSE ON ALL OF

12 THESE. AND THAT COUPLED WITH POSTING ISSUES, SO I

13 ACTUALLY AM VERY PROUD THAT THE STAFF MANAGED TO GET

14 OUT THESE EXTRAORDINARY PETITIONS ON ALL OF THESE

15 DESPITE THE FACT THAT MOST OF THEM CAME IN IN LESS

16 THAN FIVE BUSINESS DAYS PRIOR TO THAT. AND WHEN WE

17 HAD REALLY PUSHED TO GET OUT THE SUMMARY REPORTS TO

18 ALL THE REVIEWERS OR TO ALL THE APPLICANTS IN ENOUGH

19 TIME TO GIVE THEM AN OPPORTUNITY TO DO IT. THERE

20 ARE ALL THESE PARAMETERS, AND I APPRECIATE THE --

21 MS. SAMUELSON: MAY I SAY, MY QUESTION, IF

22 IT SOUNDED LIKE IT WAS A CRITICISM OF STAFF, I SO

23 APOLOGIZE BECAUSE THE BURDEN YOU ARE UNDER IS

24 EXTRAORDINARY. AND THIS WAS A PROCEDURE THAT WE

25 CRAFTED.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: WHICH WE'RE LEARNING
2 FROM.

3 MS. SAMUELSON: YES. AND THERE ARE
4 COMPETING NEEDS ON ALL SIDES.

5 DR. TROUNSON: CHAIR, IN THIS PARTICULAR
6 INSTANCE, I RECEIVED THE DRAFTS FROM THE STAFF ON
7 MONDAY MORNING. MONDAY IS ONE HELL OF A KIND OF A
8 DAY, BUT I ACTUALLY READ THEM AND SENT THEM BACK TO
9 STAFF FOR REVISIONS. SO THAT'S WHY I DIDN'T OKAY
10 THEM UNTIL LATER IN THE AFTERNOON, AND THEN THEY GOT
11 TO MELISSA IN THAT WAY. BUT I ACTUALLY SENT THEM
12 BACK TO STAFF BECAUSE I HAD OTHER THOUGHTS ABOUT
13 THEM, AND I FELT THAT THEY SHOULD EXAMINE SOME OTHER
14 ISSUES IN THE PROJECT.

15 IN THIS PARTICULAR INSTANCE, IT WAS WE
16 WERE PUSHING BACK AND FORTH AND BACK TO GET A
17 QUALITY OUTPUT, HAVE CONSIDERATION OF ALL OF THE
18 ISSUES THAT WERE SUBSTANTIVE WITHIN THOSE GRANTS.
19 AND I THINK I DO APOLOGIZE FOR NOT GETTING TO YOU IN
20 TIME, BUT I THINK GETTING THE QUALITY TO YOU IS
21 PROBABLY JUST AS IMPORTANT.

22 CHAIRMAN KLEIN: QUALITY IS PROBABLY MORE
23 IMPORTANT.

24 MR. SHEEHY: I JUST THINK WE SHOULD TAKE A
25 MINUTE AND THINK ABOUT THE LAST WEEK FOR STAFF AND

BARRISTERS' REPORTING SERVICE

1 JUST ACKNOWLEDGE THE EXTRAORDINARY WORK OF ALL THESE
2 INDIVIDUALS. YOU KNOW, IT'S BEEN PERILS OF PAULINE.

3 (APPLAUSE.)

4 MR. SHEEHY: SO FOR AN AGENCY THAT'S
5 LIMITED BY LAW TO A CERTAIN SIZE, WHEN I SAW THAT
6 GRAPH, I SAW A VERY LITTLE BROWN AREA AND A BIG AREA
7 OF MONEY GOING OUT THE DOOR TO ACTUALLY PAY FOR
8 SCIENCE. DR. ROBSON -- WE'RE GETTING A LOT DONE ON
9 A VERY TIGHT SCHEDULE RUNNING AS FAST AS WE CAN.
10 AND SORRY, JOHN, EVERYBODY IS DOING THE BEST THEY
11 CAN, AND WE'VE BEEN UNDER INCREDIBLE DURESS. AND
12 FOR US THAT ARE HERE AS BOARD MEMBERS, OUR JOBS
13 HAVEN'T BEEN ON THE LINE FOR THE LAST THREE OR FOUR
14 MONTHS NOT KNOWING WHETHER THERE WOULD BE MONEY TO
15 KEEP THE AGENCY AFLOAT. SO I JUST APPLAUD PEOPLE
16 FOR STAYING WITH US, FOR WORKING AS HARD AS THEY DO,
17 AND I DON'T THINK ANYBODY ON STAFF NEEDS TO
18 APOLOGIZE. THIS IS A GREAT PRODUCT. IT'S VERY
19 INFORMATIVE, AND THEY'RE DOING AN INCREDIBLE JOB.

20 CHAIRMAN KLEIN: I THINK IT'S WORTH
21 REPEATING, JOHN SIMPSON, FOR YOUR BENEFIT -- I THINK
22 YOU WERE OVER AT THE TABLE -- THAT THREE OF THESE
23 WERE ACTUALLY RECEIVED LESS THAN FIVE DAYS BEFORE
24 THE MEETING, WHICH CREATED AN ADDITIONAL BURDEN ON
25 STAFF. BUT WE HAVE A PUBLIC COMMENT. DR. NOLTA.

BARRISTERS' REPORTING SERVICE

1 DR. NOLTA: I WOULD ALSO LIKE TO THANK YOU
2 ALL FOR THE INCREDIBLE AMOUNT OF WORK THAT YOU'VE
3 BEEN DOING.

4 CHAIRMAN KLEIN: DR. NOLTA, IF YOU COULD
5 SPEAK A LITTLE CLOSER TO THAT MIC.

6 DR. NOLTA: JAN NOLTA, STEM CELL PROGRAM
7 DIRECTOR AT UC DAVIS. I WORKED IN THE
8 XENOTRANSPLANTATION FIELD FOR 20 YEARS, AND I WANTED
9 TO SPEAK TO THE UTILITY OF THAT GRANT THAT WAS
10 DISCUSSING THE IMMUNE DEFICIENT MOUSE. SO THE GREAT
11 TRAGEDY IN THE FIELD OF HUMAN STEM CELL
12 TRANSPLANTATION IS THAT WE CANNOT USE THE MANY
13 EXCELLENT TRANSGENIC MOUSE MODELS OF DISEASE. NO
14 MATTER WHAT WE DO, THE HUMAN CELLS ARE SIMPLY
15 REJECTED IN NORMAL MICE. AND SO ALL OF THESE
16 TRANSGENIC MODELS OF PARKINSON'S, OF HUNTINGTON'S
17 DISEASE THAT WE'D LIKE TO USE, WE CAN'T TRANSPLANT
18 THE HUMAN CELLS INTO THEM, EVEN INTO THE BRAIN.

19 SO I REALLY THINK THAT WE HAVE TO USE
20 CHEMICAL INJURY OF THE IMMUNE DEFICIENT MICE AND
21 THEN THE HUMAN CELLS IN GRAFT. IT'S NOT RIGHT.
22 IT'S NOT THE RIGHT DISEASE. FROM WHAT I HEARD ABOUT
23 THIS PROJECT, I REALLY THINK THAT IT WOULD
24 REVOLUTIONIZE THE FIELD AND WHAT WE'RE ALL DOING.

25 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

BARRISTERS' REPORTING SERVICE

1 OKAY. IS THERE ADDITIONAL -- JEFF, WOULD YOU LIKE
2 TO MAKE ADDITIONAL COMMENTS, OR IS THERE ADDITIONAL
3 BOARD COMMENTS BEFORE WE ADJOURN TO EXECUTIVE
4 SESSION?

5 DR. LOVE: I JUST WASN'T SURE IF WE SHOULD
6 CONTEMPLATE WHETHER OR NOT THIS FIVE-DAY TIME WINDOW
7 IS SOMETHING THAT WE NEED TO THINK ABOUT CHANGING.
8 AT ONE POINT I HEARD FIVE BUSINESS DAYS, THEN I
9 HEARD FIVE DAYS. AND THERE JUST MAY NOT BE ENOUGH
10 TIME. SO ONE ISSUE IS JUST A PROCEDURAL ISSUE. WE
11 THINK ABOUT WHETHER OR NOT WE'VE LEARNED FROM THIS
12 THAT WE REALLY HAVE NOT CREATED AN ADEQUATE WINDOW
13 TO PROPERLY WORK THROUGH THE PROCESS. IT'S A
14 QUESTION.

15 DR. OLSON: I JUST WANTED TO MAKE ONE
16 POINT. IT'S A BALANCE BETWEEN BECAUSE WE'RE ALWAYS,
17 WHAT DO I SAY, WE'RE ON A TIME CRUSH USUALLY TO GET
18 THE SUMMARIES OUT TOO. SO I THINK WE TRY AND MAKE
19 SURE THAT THE APPLICANTS HAVE ADEQUATE TIME SO THAT
20 THEY CAN GET A PETITION IN. THE FIVE -- I DON'T
21 KNOW IF IT'S BUSINESS OR WORKING. WORKING DAYS, IT
22 IS THE FIVE WORKING DAYS, IF WE WOULD GET THEM IN
23 BEFORE THAT, WE CAN EASILY HANDLE IT. WE HAVE MADE
24 A COMMITMENT TO IT. IT'S JUST THE APPLICANTS TAKE
25 THEIR TIME TOO. THEY ARE BUSY PEOPLE AS WELL.

BARRISTERS' REPORTING SERVICE

1 DR. TROUNSON: SO, TED, WHAT'S HAPPENING
2 IS THAT WE'RE PREPARED TO ADDRESS ALL OF THEM THAT
3 COME IN. BECAUSE, YOU KNOW, IN FAIRNESS TO THOSE
4 SCIENTISTS WHO FEEL, AND TO THE BOARD, BECAUSE
5 THERE'S GOING TO BE DECISIONS MADE ON THOSE, WE'RE
6 NOT STICKING TO THE RULE, IF YOU LIKE. BUT WE'D
7 MUCH RATHER THEY COME IN FIVE DAYS BEFORE, BUT WE'RE
8 JUST DEALING WITH ALL OF THEM IN FAIRNESS TO THE
9 SCIENTISTS AND I THINK IN FAIRNESS TO YOU ON THE
10 BOARD BECAUSE IF THERE IS AN ISSUE, I THINK THAT
11 MAYBE WE SHOULD TELL YOU BECAUSE OTHERWISE WE GO
12 PAST THIS FUNDING POINT.

13 SO IT'S A DILEMMA FOR US, AND WE'VE ERRED
14 ON THE SIDE OF BEING HELPFUL.

15 CHAIRMAN KLEIN: SO POTENTIALLY THE BOARD
16 COULD -- I MEAN THE STAFF COULD THINK ABOUT WHETHER
17 YOU NEED TO MODIFY IT, COME BACK AT THE JUNE MEETING
18 AND GIVE US SOME ADVICE, BUT WE APPRECIATE THE
19 TENSION DR. OLSON POINTS OUT WITH TRYING TO KEEP THE
20 TIMEFRAME OF GETTING TO THE BOARD AS SHORT AS
21 POSSIBLE WHILE RECOGNIZING THE LEGITIMACY OF THE
22 COMMENTS THAT COME IN.

23 DR. PENHOET: MY ONLY POINT IS IF WE DON'T
24 HAVE A FIRM DEADLINE AND WE'RE WILLING TO ACCEPT 60
25 PERCENT OF THEM AFTER THE DEADLINE, THEN WE HAVE NO

BARRISTERS' REPORTING SERVICE

1 DEADLINE BECAUSE THE PRACTICE BECOMES THE POLICY.
2 SO I THINK WE, IN EFFECT, IF WE EVEN EXAMINE THESE
3 THREE THAT WERE LATE, I THINK WE'RE SETTING A NEW
4 POLICY WHICH SAYS WE HAVE NO DEADLINE. WE'LL TAKE
5 THEM WHENEVER YOU SEND THEM IN. I DON'T THINK
6 THAT'S THE RIGHT THING TO DO TO OUR STAFF.

7 MR. ROTH: I WANT TO SECOND THAT. NOW
8 PRECEDENT IS SET AND WE GET ONE A DAY LATE NEXT
9 TIME, AND THEY'LL WANT US TO REVIEW IT.

10 DR. PENHOET: I DON'T THINK WE HAVE A
11 BASIS FOR TURNING ANY DOWN IN THE FUTURE. THEY CAN
12 BRING THEM TO US AT THE MEETING.

13 CHAIRMAN KLEIN: SO, DR. PENHOET, I THINK
14 ONE QUERY WE MIGHT MAKE IN DECIDING WHETHER WE'RE
15 GOING TO LOOK AT THESE IS THAT SINCE STAFF WAS
16 TRYING TO ACCOMMODATE CONTENT AND GETTING US AN
17 EVALUATION, THERE MAY HAVE BEEN COMMUNICATIONS WITH
18 THESE INDIVIDUALS WHO SUBMITTED THEM WHERE THEY
19 BELIEVE AT THIS MEETING THAT THEY WOULD BE
20 CONSIDERED; WHEREAS, IN FUTURE MEETINGS, I THINK
21 YOUR COMMENT, DUANE ROTH'S COMMENT IS WE NEED TO
22 HAVE A VERY CLEAR MESSAGE. YOU'VE GOT TO MEET THE
23 DEADLINE OR WE'RE INSTRUCTING STAFF NOT TO REVIEW
24 THEM.

25 SO I THINK WE CAN GRANDFATHER THE ONES AS

BARRISTERS' REPORTING SERVICE

1 A LEARNING EXPERIENCE BECAUSE OF THE COMMUNICATIONS
2 THAT WENT ON IN THIS LAST TIME AS STAFF TRIED TO
3 WORK AS HARD AS POSSIBLE TO GET AS MUCH CONTENT TO
4 US AS POSSIBLE, BUT HAVE A CLEAR MESSAGE GOING
5 FORWARD. DOES THAT SEEM APPROPRIATE, DR. PENHOET?

6 DR. PENHOET: THAT WOULD BE MY SUGGESTION.
7 I THINK OTHERWISE THE PRACTICE BECOMES THE POLICY.

8 CHAIRMAN KLEIN: STAFF, WHAT WE'LL DO IS
9 WE DEEPLY APPRECIATE ALL THE WORK YOU DID TO TRY AND
10 HELP PEOPLE IN THIS CASE, BUT WE'RE GOING TO HAVE A
11 CLEAR COMMUNICATION GOING FORWARD. AND WE MIGHT
12 JUST POST SOMETHING TO THAT EFFECT.

13 MS. SAMUELSON: THAT STILL MAY NOT PROVIDE
14 ENOUGH TURNAROUND TIME FROM WHAT I'VE HEARD. MY
15 SUGGESTION IS THAT RATHER THAN DRAFT IT BY COMMITTEE
16 NOW, THAT WE HAVE STAFF COME BACK WITH A
17 RECOMMENDATION FOR A PROCEDURE IF --

18 CHAIRMAN KLEIN: RIGHT.

19 MS. SAMUELSON: WHEN WE WEIGH IN FROM THE
20 WORKING GROUP OR --

21 CHAIRMAN KLEIN: I THINK THAT'S VERY
22 APPROPRIATE.

23 DR. TROUNSON: THAT WOULD BE HELPFUL,
24 CHAIR, JUST TO TAKE UP THESE ISSUES. AND I THINK WE
25 OUGHT TO -- WE'LL GO BACK TO THE SCIENTISTS AND SAY,

BARRISTERS' REPORTING SERVICE

1 LOOK, WE CAN'T HELP YOU UNLESS YOU DO IT -- GET IT
2 IN EARLIER FOR US. I KNOW WE'RE PUTTING THEM UNDER
3 PRESSURE, AND WE OFTEN HAVE THESE TELEPHONE
4 CONVERSATIONS GOING ON TRYING TO RESOLVE THEIR
5 ISSUES, AND THEN THEY COME WITH THIS. SO, YOU KNOW,
6 IT'S SORT OF -- IF YOU ALLOW US TO COME BACK, I'VE
7 UNDERSTOOD EXACTLY WHAT YOU'RE SAYING, AND A POLICY
8 SHOULD BE A POLICY. IF YOU LET US JUST CHEW OVER
9 IT, WE'LL CONFIRM IT TO YOU WHETHER IT'S APPROPRIATE
10 AT THE NEXT MEETING, BUT WE TAKE THE POINT.

11 CHAIRMAN KLEIN: I THINK THAT'S
12 APPROPRIATE. THANK YOU, DR. TROUNSON, AND THANK THE
13 STAFF FOR THEIR SPECIAL EFFORTS.

14 DR. AZZIZ: I DO, AT THE RISK OF BEING
15 DISSONANT, I DO NOT WANT US TO MICROMANAGE TO THIS
16 LEVEL. I THINK WE'RE SPENDING AN AWFUL LOT OF TIME
17 ON THINGS THAT REALLY THIS IS A STAFF FUNCTION, NOT
18 A BOARD FUNCTION. SO I REALLY WANT TO THANK THE
19 STAFF FOR WHAT YOU DO. CERTAINLY YOU SHOULD FOLLOW
20 YOUR RULES, BUT I DO THINK WE'RE SPENDING A LOT OF
21 TIME ON SOMETHING THAT IS NOT OUR PURVIEW.

22 CHAIRMAN KLEIN: I THINK I'VE REQUESTED
23 THEIR ADVICE. ONE MORE PUBLIC COMMENT, DR. JENSEN.

24 MR. JENSEN: I'M DAVE JENSEN WITH THE
25 CALIFORNIA STEM CELL REPORT. I AGREE WITH DR.

BARRISTERS' REPORTING SERVICE

1 AZZIZ. I THINK THIS IS A STAFF FUNCTION THAT SHOULD
2 BE ENTIRELY HANDLED. YOU'VE SET A DEADLINE, AND IT
3 SHOULD BE ADHERED TO.

4 DOES RAISE A QUESTION. HAVE APPLICATIONS
5 FOR GRANTS BEEN ACCEPTED AFTER THE POSTED DEADLINE?
6 IF WE'RE PLAYING WITH THE DEADLINES ON THIS ONE --

7 CHAIRMAN KLEIN: I BELIEVE WE HAVE A VERY
8 CRISP POLICY ON THAT. DR. OLSON.

9 MR. JENSEN: I THINK YOU HAVE A CRISP
10 POLICY --

11 DR. OLSON: NO.

12 MR. JENSEN: -- ON THESE EXTRAORDINARY
13 PETITIONS.

14 CHAIRMAN KLEIN: OKAY. THANK YOU. WITH
15 THAT, I'D LIKE TO ADJOURN FOR EXECUTIVE SESSION.

16 MS. SAMUELSON: BOB, I HAVE A COUPLE OF
17 QUESTIONS THAT I THINK ARE POLICY ISSUES. LET ME
18 JUST QUICKLY SAY WHAT THEY ARE, AND THEN WE'LL SEE
19 HOW THEY GET DEALT WITH.

20 AND THE FIRST MAY ALREADY BE RESOLVED. IT
21 SEEMS TO ME IMPORTANT THAT, ESPECIALLY WITH THE
22 FUNDING HAVING IMPROVED, THAT WE RESOLVE THAT WE
23 WILL REVIEW THE GRANTS ON THEIR MERIT SEPARATE FROM
24 ANY SORT OF FISCAL STANDARD, FISCAL LEVEL, FUNDING
25 LEVEL, AND THEN HANDLE THAT SEPARATELY.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: WE'RE GOING TO REVIEW
2 THEM ON THEIR SCIENTIFIC MERIT, AND THEN THE GRANT
3 ADMINISTRATION POLICY WILL DEAL WITH ANY ISSUES THAT
4 ARE ADMINISTRATIVE.

5 MS. SAMUELSON: AND THE OTHER ONE, AND
6 THIS MAY NOT BE THE TIME TO REVIEW IT, BUT IT SEEMED
7 TO ME IMPORTANT, GIVEN THE WIDE RANGE IN THE GRANT
8 AMOUNTS SELECTED BY THE GRANT APPLICANTS, AND THE
9 FACT THAT WE HAVEN'T -- AND THE MONEY IS TIGHT, NO
10 MATTER HOW MUCH MONEY WE NOW HAVE COMPARED TO WHAT
11 WE THOUGHT WE HAD, THAT WE CONSIDER ADJUSTING SOME
12 OF THOSE DOWNWARD IF THEY'RE -- FOR ONE THING, SOME
13 OF THEM ARE IN EXCESS OF THE MAXIMUM THAT WE SAID
14 WOULD BE PERMITTED AND IN MANY CASES IS MAYBE TWICE
15 WHAT SOME OF THE OTHER GRANTS TOTAL.

16 CHAIRMAN KLEIN: RIGHT. SO I THINK IT'S
17 COMPLETELY APPROPRIATE FOR THAT TO BE A MOTION AFTER
18 EXECUTIVE SESSION WHEN WE CONSIDER THESE GRANTS. I
19 WOULD INDICATE THAT MY UNDERSTANDING IS THAT ALL OF
20 THE GRANTS ARE WITHIN THE BUDGET BECAUSE WHAT WE DID
21 IS SET 1.2 MILLION A YEAR IN DIRECT COST AS A
22 BUDGET, AND THE INDIRECTS HAVE CREATED IN SOME CASES
23 A HIGHER TOTAL THAN THE GENERAL TARGET THAT WAS SET
24 FORWARD, BUT THEY ARE CONSISTENT WITH THE REQUEST
25 FOR APPLICATIONS. IS THAT A CORRECT STATEMENT, DR.

BARRISTERS' REPORTING SERVICE

1 OLSON?

2 DR. OLSON: THAT IS A CORRECT STATEMENT;
3 HOWEVER, I WOULD ALSO LIKE TO MAKE ONE ADDITIONAL
4 POINT. AND THAT IS THAT MANY OF OUR SCIENTISTS ARE
5 RESEARCHERS -- WELL, THEY'RE ALL RESEARCHERS, AND
6 THEY'RE USED TO HITTING THE TOP, YOU KNOW, THE
7 MAXIMUM AMOUNT OF FUNDING AVAILABLE. SO I THINK
8 HERE -- AND I THINK IT'S ACTUALLY A NONTRIVIAL TASK
9 TO ADJUST A GRANT. SO I WOULD JUST, IF IT WAS THE
10 BOARD'S RECOMMENDATION TO TAKE A CLOSE LOOK, WHICH
11 WE HAVE ALREADY STARTED DOING TO SOME EXTENT, AT
12 THOSE GRANTS THAT YOU WERE FUNDING, THEN WE WOULD
13 HOPE THAT YOU WOULD TRUST US TO TRY AND WORK WITH
14 THE GRANTEE TO COME UP WITH A REASONABLE BUDGET THAT
15 MADE SENSE.

16 CHAIRMAN KLEIN: SO, JOAN, I THINK
17 CONSISTENT WITH YOUR POINT, THE PEER REVIEW
18 COMMITTEE ALREADY MADE THE COMMENT TO THE STAFF, AND
19 THE STAFF HAS INITIATED A PROGRAM OF SCRUTINIZING
20 THESE BUDGETS IN DETAIL. AND IT'S THEIR INTENT TO
21 MAKE SURE WE'RE GETTING THE VALUE FOR THIS, BUT I
22 THINK THE STAFF'S COMMENT IS IT'S DIFFICULT WITHOUT
23 HAVING VERY DETAILED BUDGETS TO MAKE INFORMED
24 DECISIONS, BUT THEY ARE FOCUSED ON MAKING CERTAIN
25 THAT WE ARE NOT OVERBUDGETING ANY ITEM. IS THAT A

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1 FAIR STATEMENT, DR. OLSON?

2 DR. OLSON: THAT IS CORRECT.

3 DR. LEVIN: CAN I JUST ASK ONE QUESTION
4 ABOUT THE INDIRECT COST? THERE'S A MAXIMUM OF 3.6
5 MILLION IN DIRECT COST FOR ALL THESE GRANTS, BUT
6 SOME OF THEM ARE MORE THAN TWICE THAT, MEANING THAT
7 THERE'S INDIRECT COST RATE OF OVER A HUNDRED
8 PERCENT, MAYBE 150 ON SOME OF THESE GRANTS. THE TOP
9 GRANT IS 6.6 MILLION.

10 CHAIRMAN KLEIN: NOT QUITE TWICE, BUT
11 SIGNIFICANT.

12 DR. LEVIN: SO IS THERE ANY EFFORT TO
13 NEGOTIATE? I KNOW THAT THE CIRM INDIRECT COST RATE
14 IS NEGOTIATED WITH THE UNIVERSITY OF CALIFORNIA
15 INSTITUTIONS. IS IT NEGOTIATED WITH THE PRIVATE
16 INSTITUTIONS AS WELL, OR IS THAT SOMETHING THAT'S
17 EVER BEEN ON THE TABLE?

18 CHAIRMAN KLEIN: IT'S ABSOLUTELY BEEN ON
19 THE TABLE, AND THE HISTORY OF THIS IS THAT WE
20 FOLLOWED THE NIH INDIRECT RATE NEGOTIATIONS. DR.
21 OLSON, WOULD YOU LIKE TO COMMENT?

22 DR. OLSON: YES. THAT IS A CORRECT
23 STATEMENT. WE USE AS OUR BASIS FOR DISCUSSION THE
24 RATE THAT HAS BEEN NEGOTIATED WITH THE NIH. SO
25 THESE ARE -- THEY'RE ALL ESSENTIALLY TREATED THE

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1 SAME. THERE IS JUST QUITE A WIDE VARIANCE IN
2 FACILITIES COST, FOR EXAMPLE, BETWEEN INSTITUTIONS.

3 CHAIRMAN KLEIN: ALL RIGHT. WITH THOSE
4 COMMENTS, WE'RE GOING TO ADJOURN TO EXECUTIVE
5 SESSION. MY SENSE OF THIS IS THAT WE'RE PROBABLY
6 GOING TO BE IN EXECUTIVE SESSION AND JUST COME BACK
7 HERE TO ADJOURN TONIGHT. I WOULD THINK THAT WE'D BE
8 TAKING ACTION IN THE MORNING, BUT I WANT TO ASK THE
9 BOARD FOR THEIR ADVICE.

10 MS. SAMUELSON: I THINK IT'S TOO LATE TO
11 DO JUSTICE TO THESE GRANTS. THEY'RE REALLY
12 WONDERFUL. AND IT'S 9:30, WHICH IS OUR QUITTING
13 TIME. I JUST DON'T THINK IT'S APPROPRIATE TO PUSH
14 OURSELVES ANY MORE AND THINK WE'LL PRODUCE A QUALITY
15 PRODUCT.

16 CHAIRMAN KLEIN: SO QUESTION FOR THE
17 BOARD. WOULD YOU LIKE TO GO INTO EXECUTIVE SESSION
18 FIRST THING IN THE MORNING?

19 DR. PULIAFITO: YES. I THINK THAT'S A
20 REASONABLE THING TO DO.

21 CHAIRMAN KLEIN: ALL RIGHT. CLEARLY WE
22 HAVE A CONSENSUS OF OPINION. LET ME ASK FOR AN
23 UNORTHODOX SHOW OF HANDS. WHO WOULD LIKE TO HAVE
24 THE EXECUTIVE SESSION IN THE MORNING?

25 MS. SAMUELSON: AS OPPOSED TO?

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1 CHAIRMAN KLEIN: AS OPPOSED TO NOW. WHO
2 WOULD LIKE TO HAVE THE EXECUTIVE SESSION NOW? OKAY.
3 I THINK WE'RE GOING TO DO IT IN THE MORNING. AND
4 I'D LIKE TO TAKE SPECIAL RECOGNITION OF THE FACT
5 THAT WE DO HAVE A NUMBER OF MEMBERS OF THE BOARD
6 THAT HAVE MULTIPLE CHALLENGES BESIDES THEIR REGULAR
7 SCHEDULE. AND THE BENEFIT OF DOING THE MORNING IS
8 THEY'LL BE ABLE TO CONTRIBUTE COMPLETELY.

9 MR. SHEEHY: I WOULD JUST LIKE TO ASK THAT
10 WE DO THE EXECUTIVE SESSION AND WE DO THE GRANT --
11 THAT THIS BE OUR FIRST ORDER OF BUSINESS BECAUSE I
12 DO THINK THAT, NOW THAT WE HAVE FUNDS, I THINK THIS
13 IS AN EXCITING ROUND. HAVING SAT THROUGH THE
14 REVIEW, I REALLY THINK THAT WE NEED TO MOVE ON THIS.
15 AND THIS IS EXCITING FOR ME AS A PATIENT AND A
16 PATIENT ADVOCATE, AND I -- YOU KNOW, WE GOT THROUGH
17 A LOT OF BUSINESS TODAY ANYWAY, SO I WOULD HOPE THIS
18 WOULD BE THE FIRST THING, EVERYBODY WILL BE FRESH,
19 WE CAN TACKLE IT, AND GET TO SOME CONCLUSIONS.

20 CHAIRMAN KLEIN: AND WE DO HAVE AT 8:30 A
21 SPOTLIGHT ON MACULAR DEGENERATION, AND WE DO HAVE
22 SOME GRANTS UP FOR MACULAR DEGENERATION, SO WE'RE
23 GOING TO BE FULLY INFORMED TOMORROW. BUT, DR.
24 PULIAFITO, WE'RE LOOKING FORWARD TO THAT SESSION.
25 AND PLEASE, WE'RE GOING TO BE CONVENING IN THE MAYER

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1 AUDITORIUM FOR THAT SESSION, AND PLEASE TRY AND BE
2 THERE ON TIME. IS THERE A SHUTTLE?

3 MS. PRYNE: WE HAVE A CHARTER BUS
4 AVAILABLE STARTING 7:30. IT'S ONLY GOING TO BE ONE
5 LARGE LIKE GREYHOUND BUS SIZE, NOT SEVERAL SMALLER
6 SHUTTLE BUSES.

7 CHAIRMAN KLEIN: SO YOU EITHER MAKE THE
8 BUS AT 7:30 OR TAKE A TAXI.

9 THE MEETING STARTS AT 8:30. SO THE
10 QUESTION, JENNA, WHY ARE WE TAKING A BUS AT 7:30,
11 THE MEETING STARTS AT 8:30?

12 MS. PRYNE: BECAUSE OF TRAFFIC
13 CONSIDERATIONS, AND IT WILL GIVE PEOPLE A CHANCE TO
14 HAVE BREAKFAST.

15 CHAIRMAN KLEIN: BREAKFAST WILL BE THERE.
16 ALL RIGHT. THANK YOU. WITH THAT, I THINK WE'RE
17 GOING TO ADJOURN FOR THE NIGHT, AND WE THANK YOU
18 VERY MUCH.

19 (THE MEETING WAS THEN ADJOURNED AT
20 09:27 P.M.)

21
22
23
24
25

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REPORTER' S CERTIFICATE

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

BONAVENTURE HOTEL
404 FIGUEROA STREET
LOS ANGELES, CALIFORNIA
ON
APRIL 28, 2009

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.



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