

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: UCI UNIVERSITY CLUB
UNIVERSITY OF CALIFORNIA, IRVINE
801 E. PELTASON DRIVE
IRVINE, CALIFORNIA

DATE: DECEMBER 7, 2006
9 A.M.

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

BRS FILE NO.: 74250

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I N D E X

| ITEM | DESCRIPTION | PAGE NO. |
|--|-------------|----------|
| CALL TO ORDER | | 3 |
| ROLL CALL | | 3 |
| APPROVAL OF MINUTES - OCTOBER 11, 2006 | | 5 |
| CHAIRMAN'S REPORT | | 6 |
| PRESIDENT'S REPORT | | 11 |
| CIRM STRATEGIC PLAN | | 48 |
| INTERIM CIRM POLICY FOR FOR-PROFIT ORGANIZATIONS | | 89 |
| INTELLECTUAL PROPERTY REGULATIONS FOR NONPROFIT ORGANIZATIONS | | 122 |
| GRANTS ADMINISTRATION POLICY FOR ACADEMIC AND NONPROFIT INSTITUTIONS REGULATIONS | | 178 |
| CIRM MEDICAL AND ETHICAL STANDARDS REGULATIONS | | 181 |
| REPORT OF CLOSED SESSION | | 156 |
| GOVERNANCE SUBCOMMITTEE | | 189 |
| FACILITIES WORKING GROUP - CONFIDENTIALITY POLICY AND CONFLICT OF INTEREST FORMS | | 159 |
| FACILITIES WORKING GROUP UPDATE | | 157 |
| PART-TIME CONTRACT SERVICES FOR PATIENT ADVOCATES | | 201 |
| PRESENTATION ON ALLOCATION OF FUNDS AVAILABLE FOR CIRM GRANT MAKING | | 206 |
| PUBLIC COMMENT | | 202 |
| ADJOURNMENT | | 210 |

1 IRVINE, CALIFORNIA; THURSDAY, DECEMBER 7, 2006

2 09:07 A.M.

3

4 CHAIRMAN KLEIN: ALL RIGHT. I THINK WE'RE
5 READY TO CONVENE. THE HONORABLE JEFF SHEEHY WE NEED AT
6 THE DAIS. WELCOME, EVERYONE, TO UC IRVINE WHERE WE ARE
7 DEEPLY GRATEFUL FOR THE HOSPITALITY. THANK YOU,
8 JEANNIE INGELS FOR HER TEAM, FOR ALL THEIR LOGISTIC
9 WORK. THANK YOU, DR. SUSAN BRYANT, DR. OS STEWARD, AS
10 MEMBERS OF THE BOARD. WE ARE VERY GRATEFUL FOR THE
11 OPPORTUNITY TO BE HERE.

12 AND WE WILL START WITH OUR PLEDGE OF
13 ALLEGIANCE AND ROLL CALL. WOULD YOU FIRST, MELISSA
14 KING, LEAD US IN THE PLEDGE OF ALLEGIANCE.

15 (THE PLEDGE OF ALLEGIANCE.)

16 CHAIRMAN KLEIN: MELISSA, WOULD YOU THEN LEAD
17 US IN THE ROLL.

18 MS. KING: RICARDO AZZIZ.

19 DR. AZZIZ: PRESENT.

20 MS. KING: PAUL JENNINGS FOR DAVID BALTIMORE.

21 DR. JENNINGS: HERE.

22 MS. KING: ROBERT BIRGENEAU. SUSAN BRYANT.

23 DR. BRYANT: HERE.

24 MS. KING: MARCY FEIT.

25 MS. FEIT: HERE.

1 MS. KING: MICHAEL FRIEDMAN.
2 DR. FRIEDMAN: HERE.
3 MS. KING: MICHAEL GOLDBERG.
4 MR. GOLDBERG: HERE.
5 MS. KING: BRIAN HENDERSON.
6 DR. HENDERSON: HERE.
7 MS. KING: ED HOLMES. DAVID KESSLER.
8 DR. KESSLER: HERE.
9 MS. KING: BOB KLEIN.
10 CHAIRMAN KLEIN: HERE.
11 MS. KING: SHERRY LANSING.
12 MS. LANSING: HERE.
13 MS. KING: LEONARD ROME FOR GERALD LEVEY.
14 DR. ROME: HERE.
15 MS. KING: TED LOVE. RICHARD MURPHY.
16 DR. MURPHY: HERE.
17 MS. KING: TINA NOVA.
18 DR. NOVA: HERE.
19 MS. KING: ED PENHOET.
20 DR. PENHOET: HERE.
21 MS. KING: PHIL PIZZO. CLAIRE POMEROY.
22 DR. POMEROY: HERE.
23 MS. KING: FRANCISCO PRIETO. JOHN REED.
24 DR. REED: HERE.
25 MS. KING: DUANE ROTH.

1 MR. ROTH: HERE.

2 MS. KING: JOAN SAMUELSON. DAVID
3 SERRANO-SEWELL.

4 MR. SERRANO-SEWELL: HERE.

5 MS. KING: JEFF SHEEHY.

6 MR. SHEEHY: HERE.

7 MS. KING: JON SHESTACK. OSWALD STEWARD.

8 DR. STEWARD: HERE.

9 MS. KING: LEON THAL.

10 DR. THAL: HERE.

11 MS. KING: JANET WRIGHT.

12 DR. WRIGHT: HERE.

13 CHAIRMAN KLEIN: THANK YOU VERY MUCH. ITEM
14 5, THE CHAIRMAN'S REPORT, IS NEXT ON THE AGENDA.

15 MS. KING: EXCUSE ME, BOB, WE ACTUALLY HAVE
16 THE CONSENT ITEM FIRST.

17 CHAIRMAN KLEIN: ITEM 4 IS ACTUALLY THE
18 MINUTES, THAT'S RIGHT. APPROVAL OF THE MINUTES FROM
19 OCTOBER 11, '06, IS THERE A MOTION TO APPROVE THESE
20 MINUTES?

21 DR. STEWARD: SO MOVED.

22 CHAIRMAN KLEIN: MOVED BY OS STEWARD. IS
23 THERE A SECOND?

24 DR. AZZIZ: SECOND.

25 CHAIRMAN KLEIN: SECOND BY DR. AZZIZ.

1 DISCUSSION ON THE MOTION? ANY COMMENTS FROM THE
2 PUBLIC? ALL IN FAVOR? OPPOSED? MOTION PASSES.

3 GO TO ITEM 5, THE CHAIRMAN'S REPORT. I WILL
4 REMIND US TODAY THAT IT IS A LITTLE LESS THAN TWO YEARS
5 SINCE THIS ENTITY WAS FIRST FORMED ON DECEMBER 17,
6 2004. IT'S A REMARKABLE AMOUNT OF WORK THAT HAS
7 OCCURRED IN THAT TIME PERIOD, AND I HOPE THE PUBLIC OF
8 CALIFORNIA JOINS ME IN MY ADMIRATION OF THE BOARD
9 MEMBERS WHO HAVE DEDICATED SO MUCH OF THEIR LIVES AND
10 THE STAFF THAT HAS DEDICATED SO MUCH OF THEIR LIVES TO
11 THIS ENDEAVOR AND THE TERRIBLY IMPORTANT WORK IN
12 SETTING UP AN ENTIRE AGENCY.

13 ON THE ONE HAND, I'M REMINDED OF VOLTAIRE'S
14 STATEMENT THAT IT IS THE BEST OF TIMES AND THE WORST OF
15 TIMES BECAUSE WE CAN CELEBRATE EVERYTHING THAT HAS BEEN
16 ACCOMPLISHED, AND YET WE'RE NOW IN A POSITION THAT WE
17 SEE HOW MUCH NEEDS TO BE DONE. BUT WE SHOULDN'T REALLY
18 LEAVE OURSELVES WITH VOLTAIRE'S POSITION BECAUSE
19 CALIFORNIA BY, I THINK, SENSE OF GENETIC LEGACIES, THE
20 PEOPLE OF CALIFORNIA ARE OPTIMISTIC OR THEY WOULDN'T
21 HAVE VOTED FOR THIS VISION; AND, THEREFORE, LET US
22 CELEBRATE WHAT WE HAVE ACCOMPLISHED AND LET US
23 CELEBRATE WHAT WE STILL HAVE TO DO. AND CERTAINLY WE
24 HAVE TEN DAYS LEFT BEFORE WE'RE THROUGH TWO YEARS, SO
25 WE HAVE PLENTY OF TIME, BUT THERE IS REMARKABLE

1 PROGRESS.

2 WE HAVE \$181 MILLION IN THE BANK. THAT'S
3 SUBSTANTIALLY BETTER THAN WE WERE ON DECEMBER 17TH,
4 2004. WE HAVE AN AGENCY WITH A GOLD STANDARD OF
5 MEDICAL AND ETHICAL PRACTICES AND PROCEDURES THAT HAS
6 BENEFITED TREMENDOUSLY WITH GREAT DEBT TO THE NATIONAL
7 ACADEMIES OF SCIENCE AND THE NATIONAL RESEARCH COUNCIL
8 WITH THE MOST COMPREHENSIVE SET OF MEDICAL AND ETHICAL
9 STANDARDS IN THE COUNTRY FOR STEM CELL RESEARCH. WE
10 HAVE TREMENDOUS INTELLECTUAL PROPERTY STANDARDS FOR
11 NONPROFITS, AND THE FOR-PROFIT STANDARDS WE WILL
12 EXAMINE TODAY.

13 WE HAVE, IN FACT, GONE THROUGH THIS LAST WEEK
14 A HISTORIC GRANT-MAKING PEER REVIEW CYCLE FOR OUR
15 GRANTS WORKING GROUP THAT THE PRESIDENT, I THINK, WILL
16 EXAMINE IN GREATER DEPTH, BUT IT IS A MILESTONE OF
17 TREMENDOUS IMPORTANCE IN THE CORE MISSION TO ADVANCE
18 THE SCIENCE. AND WE TAKE GREAT PRIDE IN THE 169
19 RESEARCH FELLOWS THAT ARE REPRESENTED IN MANY OF YOUR
20 INSTITUTIONS AND THEIR ENTHUSIASM AND DEDICATION AND
21 PASSION TO THIS AREA.

22 WE ALSO CAN CELEBRATE THE FACT THAT WE HAVE A
23 FEDERAL GOVERNMENT THAT WILL SOON BE SEATED IN THE
24 HOUSE AND THE SENATE WHERE WE HAVE STRONG SUPPORT IN
25 BOTH CHAMBERS FOR STEM CELL RESEARCH, SUPPORT THAT IS

1 DRIVEN BY A MATTER OF CONSCIENCE AND OPPORTUNITY TO
2 REALLY AFFECT THE FUTURE OF HUMAN SUFFERING AND
3 THERAPIES TO THE DEGREE THAT THEY WERE PREPARED TO
4 STAND UP AGAINST THE PRESIDENTIAL VETO. AND THOSE WHO
5 STOOD UP AGAINST THE PRESIDENTIAL VETO WERE REWARDED BY
6 THE PUBLIC IN THE LAST ELECTIONS, AND THEIR RANKS HAVE
7 BEEN ENHANCED.

8 ADDITIONALLY, WE HAVE THE BENEFIT THAT ON A
9 GLOBAL BASIS OTHER COUNTRIES ARE STEPPING FULLY UP TO
10 THE PLATE. AUSTRALIA THIS WEEK PASSED THROUGH THE
11 LOWER HOUSE A FULL RELAXATION OF THEIR LIMITATIONS ON
12 EMBRYONIC STEM CELL RESEARCH AND AN AUTHORIZATION FOR
13 SOMATIC CELL NUCLEAR TRANSFER, BECOMING A FULL PARTNER
14 IN THE GLOBAL STRATEGY TO IMPLEMENT THIS RESEARCH.

15 BUT CERTAINLY WE HAVE AMONG OUR CHALLENGES
16 THE TREMENDOUS NEED FOR NEW FACILITIES, AND IT IS ONE
17 OF THOSE ITEMS WITH GREAT LEAD-TIME THAT WE ARE YET TO
18 FOCUS WITH THE FULL FORCE OF OUR INSTITUTION. AND IT
19 IS OF IMPERATIVE NATURE THAT WE FOCUS IMMEDIATELY
20 BECAUSE THE INSTITUTIONS THAT ARE DOING THIS RESEARCH
21 IN CALIFORNIA ARE RUNNING OUT OF SPACE OR HAVE RUN OUT
22 OF SPACE.

23 IN ADDITION, WE NEED TO REMEMBER THAT IF OUR
24 300 MILLION WERE MERELY LEVERAGED ONE TO ONE, IT WOULD
25 CREATE 600 MILLION IN NEW FACILITIES. AND AT A

1 12-PERCENT INFLATION RATE, THAT'S \$72 MILLION IN BUYING
2 POWER WE LOSE FOR EVERY YEAR. 72 MILLION, I WILL
3 REMIND YOU, IS 25 PERCENT OF OUR ENTIRE GRANT MONEY TO
4 CREATE FACILITIES. SO WE MUST BE CREATIVE AND FOCUSED
5 IN ADDRESSING THIS VERY IMPORTANT NEED.

6 I HAVE SUGGESTED THIS LAST WEEK TO THE
7 FACILITIES COMMITTEE THAT WE CONSIDER AUGMENTING THE
8 STAFF THROUGH A SYSTEM OF REFUNDABLE DEPOSITS WHERE THE
9 INSTITUTIONS COULD, FOR EXAMPLE, PUT UP A THIRD OF 1
10 PERCENT OF THE APPLICATION FEE. IF THEY WERE NOT
11 AWARDED A GRANT, IT WOULD BE REFUNDED. IF THEY WERE,
12 IT WOULD BE FUNDED IN THE GRANT THAT WAS MADE. THIS
13 WOULD GIVE US, ON A CASH-FLOW BASIS, THE MONEY TO HIRE
14 PEOPLE FOR FACILITIES THAT WOULD SUBSTANTIALLY AUGMENT
15 THE MANPOWER WE HAVE ON STAFF WITHOUT DETRACTING FROM
16 THE SCIENTIFIC STAFF AT ALL. IT WOULD GIVE US THE
17 MONEY WHEN WE NEED IT ON A CASH-FLOW BASIS WHERE WE
18 NEED THE BULK OF THE WORK BEFORE THE GRANT IS MADE, NOT
19 AFTER THE GRANT IS MADE. IF WE SAVE SIX MONTHS FROM
20 THAT EXERCISE, IT WOULD SAVE US \$36 MILLION IN BUYING
21 POWER, GIVEN THE EXAMPLE FACTUALLY THAT I PRESENTED.

22 SO WE HAVE AREAS OF IMMEDIATE NEED FOR FOCUS.
23 WE HAVE THINGS TO CELEBRATE, AND WE HAVE SOME POTENTIAL
24 SOLUTIONS, BUT I EXPECT THAT THIS NEXT YEAR WE'RE GOING
25 INTO WILL BE EVERY BIT AS EXCITING AS THE YEAR WE HAVE

1 JUST LEFT.

2 IT IS WITH A SENSE OF GREAT ANTICIPATION,
3 THEN, THAT I WILL LOOK FORWARD TO THE NEXT TEN DAYS AND
4 NEXT YEAR AND THE ABILITY TO CELEBRATE THE WORK WE HAVE
5 BEFORE US, BUT IT IS A SENSE OF GREAT GRATITUDE WE HAVE
6 FOR THE BOARD AND STAFF FOR THEIR PASSIONATE
7 COMMITMENT, THEIR WONDERFUL SERVICE.

8 MARY MAXON HAS ANNOUNCED THAT SHE IS GOING TO
9 LOOK AT ADDITIONAL CHALLENGES. AND I'D LIKE TO VERY
10 SPECIFICALLY RECOGNIZE HERE THE TREMENDOUS CONTRIBUTION
11 THAT SHE HAS MADE.

12 (APPLAUSE.)

13 CHAIRMAN KLEIN: THANK YOU, MARY, AND THANK
14 ALL OF THE STAFF FOR THE DEEP PASSION AND COMMITMENT
15 THEY HAVE SHOWN.

16 I WOULD LIKE TO NOW TRANSITION TO THE
17 PRESIDENT'S REPORT BECAUSE CERTAINLY THE PRESIDENT HAS
18 GREAT ACCOMPLISHMENTS TO FOCUS US ON TODAY, GREAT STEPS
19 FORWARD IN OUR MILESTONES OF THIS AGENCY.

20 MS. LANSING: I'M USED TO HAVING A LOUD
21 ENOUGH VOICE. I JUST WANT TO ADD ON BEHALF OF ALL OF
22 THE BOARD WHAT AN EXTRAORDINARY JOB MARY HAS DONE AND
23 HOW SHE HAS DEDICATED HERSELF 24 HOURS A DAY, SEVEN
24 DAYS A WEEK, AND BEEN JUST AN INVALUABLE MEMBER OF
25 THIS, AND HOW MUCH WE'RE GOING TO MISS HER AND HOW

1 GRATEFUL WE ARE. AND THAT'S ON BEHALF OF ALL OF US
2 HERE.

3 (APPLAUSE.)

4 CHAIRMAN KLEIN: SHERRY, IN THE SAME SENSE AS
5 WELL, I THINK I WOULD LIKE TO RECOGNIZE THAT, ALTHOUGH
6 AMY LEWIS IS NOT HERE, AMY DUROSS LED THE TEAM THAT FOR
7 THE FIRST TIME IN THE STATE'S HISTORY EVER ISSUED \$45
8 MILLION NOW IN BOND ANTICIPATION NOTES, KEPT THIS
9 AGENCY ALIVE AND FUNCTIONING WITH GRANTS IN APRIL, AND
10 COMPLETED A TRANSACTION THAT, WHEN WE STARTED DOWN THE
11 PATH, PEOPLE THOUGHT WAS IMPOSSIBLE; BUT WITH THE
12 VISION AND DEDICATION AND TALENT OF PEOPLE LIKE AMY
13 DUROSS AND AMY LEWIS, IT BECAME VERY POSSIBLE AND WAS
14 ACCOMPLISHED. SO I'D LIKE TO RECOGNIZE THAT TREMENDOUS
15 EFFORT.

16 (APPLAUSE.)

17 CHAIRMAN KLEIN: ANY ADDITIONAL COMMENTS?
18 DR. HALL.

19 DR. HALL: THANK YOU, BOB. LET ME GIVE YOU
20 MY PRESIDENT'S REPORT. AND AS CUSTOMARY, WE START WITH
21 PERSONNEL MATTERS. AND I WANT TO SAY THAT WE HAVE
22 RECENTLY RECRUITED THREE NEW PEOPLE. KUMAR HARI,
23 PH.D., WHO AS A SCIENTIFIC OFFICER, WHO COMES TO US
24 WITH PREVIOUS EXPERIENCE IN TWO COMPANIES, ISIS AND
25 IBIS. I CAN'T REMEMBER WHICH CAME FIRST, BUT HE WAS

1 ASSOCIATED WITH BOTH OF THEM. ANYHOW, FROM THE SAN
2 DIEGO AREA, PH.D. FROM UC SAN DIEGO AND EXPERIENCE IN
3 THE PRIVATE SECTOR AND WONDERFUL COMPUTATIONAL SKILLS.
4 WE'RE DELIGHTED TO ADD HIM.

5 RUTH GLOBUS, A SCIENTIFIC OFFICER, WHO'S BEEN
6 AN INDEPENDENT INVESTIGATOR AT NASA AT MOFFET FIELD ON
7 THE PENINSULA. SHE'S BEEN INTERESTED IN THE EFFECTS OF
8 RADIATION ON BONE AND HAS DONE WORK ON ADULT STEM CELLS
9 AND THEIR ROLE IN BONE FORMATION.

10 AND FINALLY, MEYBEL CORTEZ, GRANTS TECHNICAL
11 ASSISTANT, WHO COMES TO US FROM KAISER PERMANENTE WHERE
12 SHE WAS A UNIT DIRECTOR. ALL THREE OF THESE REPRESENT
13 IMPORTANT ADDITIONS TO OUR TEAM, AND YOU WILL HAVE A
14 CHANCE TO GET TO MEET THEM AND KNOW THEM LATER ON.

15 WE HAVE SEVERAL RECRUITMENTS ONGOING. WE ARE
16 STILL RECRUITING FOR ONE MORE SCIENTIFIC OFFICER, A
17 PROGRAM REVIEW GRANTS TECHNICAL ASSISTANT, A SENIOR
18 OFFICER FOR FACILITIES, AND WE HAVE A VERY STRONG
19 CANDIDATE FOR THAT POSITION. AND WE'LL BE DISCUSSING
20 THAT PERHAPS LATER TODAY. FINALLY, WE HAVE AN ONGOING
21 RECRUITMENT FOR A CHIEF LEGAL OFFICER, A SEARCH THAT
22 WE'VE RECENTLY ACTIVATED, AND WE HAVE INTERVIEWED FIVE
23 PEOPLE FOR THAT POSITION AND HOPE TO BE MAKING AN
24 ANNOUNCEMENT SOON.

25 WE HAVE TWO PERSONNEL DEPARTURES THAT I WANT

1 TO MENTION TO YOU. KATE SHREVE HAS ANNOUNCED THAT SHE
2 IS LEAVING IN THE MIDDLE OF THIS MONTH, AT THE END OF
3 NEXT WEEK. AND I'M SURE ALL OF YOU KNOW KATE. SHE HAS
4 BEEN ABSOLUTELY TIRELESS IN HER EFFORTS FOR THE
5 INSTITUTE. WHEN I ARRIVED, SHE WAS THE MAINSTAY OF THE
6 SEARCH COMMITTEE FOR THE GRANTS REVIEW GROUP AND DID A
7 PRODIGIOUS AMOUNT OF WORK PREPARING MATERIALS FOR THAT,
8 I THINK DETAILED BIOGRAPHIES, AS I REMEMBER, OF OVER
9 180 DIFFERENT SCIENTISTS THAT WERE CONSIDERED BY THE
10 GROUP. SINCE THAT, WHEN GEOFF LOMAX WAS HIRED, SHE
11 ACTUALLY STARTED AS STAFF TO THE MEDICAL AND ETHICAL
12 STANDARDS COMMITTEE, AND SHE AND GEOFF WORKED ON THAT.
13 SHE THEN WAS THE CHAIR'S LIAISON TO THE GRANTS WORKING
14 GROUP. WHEN JORGE SANCHEZ LEFT, SHE BECAME MY
15 ASSISTANT FOR A WHILE, AND NOW HAS BEEN HELPING US OUT
16 WITH THE SCIENTIFIC STRATEGIC PLAN. KATE SHREVE IS
17 CLEARLY OUR ALL STAR UTILITY END FIELDER, WILLING TO
18 PLAY ANY POSITION AND DO ANYTHING TO FORWARD THE
19 MISSION, AND HER ENERGY AND DEDICATION AND HER GOOD
20 CHEER HAVE BEEN INVALUABLE TO US ALL.

21 SECOND, I WANT TO PAY MY OWN PERSONAL TRIBUTE
22 TO MARY MAXON, WHO HAS BEEN, IN MANY WAYS, MY FELLOW
23 CO-CONSPIRATOR. SHE'S BEEN A FOUNT OF ENERGY, WIT, AND
24 RAZOR SHARP INTELLECT. SHE HAS A STRONG SENSE OF THE
25 TASK AND HOW IT SHOULD BE DONE, AND HAS HELD US ALL TO

1 ACCOUNT ON OCCASION. FOR THAT, SHE'S BEEN AN IMPORTANT
2 PRESENCE BOTH SCIENTIFICALLY IN THE TASK THAT SHE HAS
3 BEEN DOING WHERE SHE NOW PROBABLY KNOWS MORE ABOUT IP
4 IN GRANTING AGENCIES THAN ANYBODY IN THE COUNTRY, AND,
5 FINALLY, AS A VERY IMPORTANT MEMBER OF THE LEADERSHIP
6 GROUP AT CIRM. SO WE WILL INDEED MISS HER AND ARE
7 VERY, VERY GRATEFUL FOR ALL THAT SHE'S DONE FOR THE
8 INSTITUTE.

9 NOW LET ME JUST MENTION BRIEFLY IN EARLY
10 NOVEMBER ARLENE CHIU AND I AND 15 SCIENTISTS FROM
11 CALIFORNIA WENT TO THE UK TO THE UK-CALIFORNIA STEM
12 CELL MEETING, JOINTLY SPONSORED BY THE MEDICAL RESEARCH
13 COUNCIL AND BY THE BIOTECHNOLOGY AND BIOLOGICAL
14 SCIENCES RESEARCH COUNCIL, BOTH IN THE UK, AND BY CIRM.
15 THE MEETING WAS HELD IN AN ABSOLUTELY CHARMING VILLAGE.
16 AND STEVE LYNN IS HERE, AND I'M GRATEFUL TO HIM FOR ALL
17 THE WORK HE DID IN PUTTING THIS TOGETHER. HE'S WITH
18 THE BRITISH CONSULATE IN SAN FRANCISCO. BUT OUR UK
19 COLLEAGUES WERE WONDERFUL HOSTS, AND WE WERE IN THIS
20 MARVELOUS HOTEL IN THE COTSWOLDS, WHOSE FIRST RECORDED
21 GUEST WAS 1542, WHICH WAS, I THINK, FOR AMERICANS, AT
22 ANY RATE, QUITE REMARKABLE. AND WE HAD AN EXCELLENT
23 MEETING.

24 JOHN GURDON, WHO IS A VERY FAMOUS
25 DEVELOPMENTAL BIOLOGIST, GAVE A KEYNOTE SPEECH. AND

1 FOR THOSE OF YOU WHO MAY KNOW, HE SHOWED SOME 30 YEARS
2 AGO, WAS THE FIRST TO SHOW, THAT YOU COULD TAKE A
3 NUCLEUS FROM AN ADULT CELL, IN THIS CASE XENOPUS, PUT
4 IT INTO A XENOPUS OOCYTE, AND YOU CAN GET A COMPLETE
5 ORGANISM OUT. AND THIS IN MANY WAYS LAID THE
6 FOUNDATION FOR WHAT WE'VE ALL BEEN DOING IN THIS AREA
7 EVER SINCE. HE IS STILL ACTIVE AND HAD INTERESTING AND
8 PROVOCATIVE IDEAS.

9 ONE OF THE FEATURES, AS YOU KNOW, IS THAT WE
10 HAD EARLY CAREER AND ESTABLISHED INVESTIGATORS
11 TOGETHER, AND THIS TURNED OUT TO BE EXTREMELY
12 SUCCESSFUL. AND I MIGHT SAY THAT FOR THOSE OF YOU WHO
13 HAVEN'T PARTICIPATED IN THESE KINDS OF MEETINGS,
14 USUALLY WHAT HAPPENS IS YOU HAVE A SORT OF TRAVELING
15 ROAD SHOW OF PEOPLE THAT YOU SEE IN A VARIETY OF
16 INTERESTING VENUES, ALL GIVING MORE OR LESS THE SAME
17 TALKS TO EACH OTHER AT MEETINGS AROUND THE WORLD.
18 THESE ARE ALL ESTABLISHED PEOPLE. AND WHO GETS LEFT
19 OUT ARE THE YOUNG PEOPLE. AND SO THE PEOPLE AT THE
20 SAME LEVEL ALL KNOW EACH OTHER, BUT THE NICE THING
21 ABOUT THIS MEETING WAS THE OPPORTUNITY TO GET TO KNOW
22 YOUNG PEOPLE. AND ACTUALLY BOTH THE UK SCIENTISTS AND
23 THE CALIFORNIA SCIENTISTS SAID THEY BENEFITED AS MUCH
24 FROM MEETING THEIR OWN COUNTRYMEN AS THEY DID FROM
25 MEETING THE PEOPLE IN THE OTHER COUNTRIES. SO THIS WAS

1 A REALLY NICE PART OF IT, AND WE HAD AN EXCELLENT
2 MEETING.

3 FOLLOWING THAT MEETING, SEVERAL OF US WENT TO
4 SHEFFIELD WHERE PETER ANDREWS HAS A MAJOR STEM CELL
5 OPERATION, AND THEN ON TO UNIVERSITY COLLEGE LONDON
6 WHERE CHRIS MASON HOSTED ME AT THAT POINT IN SEEING
7 THEIR REGENERATIVE MEDICINE AND TISSUE ENGINEERING
8 PROGRAM THERE, WHICH WAS VERY, VERY IMPRESSIVE.

9 SO IT WAS A WONDERFUL START FOR US. AND IT
10 WILL BE OUR TURN TO HOST THE NEXT MEETING, AND WE WILL
11 HAVE TO DO AN EXCELLENT JOB TO DO AS WELL AS THE UK
12 DID. ANYHOW, THIS WAS A WONDERFUL START TO OUR SORT OF
13 INTERNATIONAL SCIENTIFIC MEETINGS.

14 LATER IN THE MONTH, LAST WEEK, AS BOB
15 INDICATED, THE GRANTS REVIEW WORKING GROUP MET. AND
16 THIS WAS NOT ONLY HISTORIC, BUT THIS WAS AN
17 EXTRAORDINARY EXPERIENCE FOR THOSE OF US WHO
18 PARTICIPATED. THE TIMING WAS VERY ASTUTE BECAUSE THAT
19 SAME WEEK WE HAD \$181 DEPOSITED IN OUR ACCOUNT, JUST IN
20 TIME.

21 CHAIRMAN KLEIN: 181 MILLION.

22 DR. HALL: MILLION. I'M SORRY. EVEN BETTER.
23 SO THIS WAS VERY TIMELY. THE WORKING GROUP DID THE
24 HEROIC TASK OF EVALUATING 232 APPLICATIONS. LET ME
25 JUST POINT OUT THAT MANY STUDY SECTIONS AT NIH DON'T DO

1 THIS MANY IN A YEAR. SO THIS WAS AN EXTRAORDINARY
2 FEAT. IT WAS ORGANIZED TO THE TEE BY OUR STAFF. THE
3 REVIEWS RAN, IN GENERAL, FROM EIGHT IN THE MORNING TILL
4 NINE AT NIGHT WITH A LITTLE TIME OFF FOR LUNCH, A
5 LITTLE TIME OFF FOR SUPPER, AND THAT WAS IT. AND
6 PEOPLE WORKED VERY, VERY HARD. AND THERE WAS A
7 TREMENDOUS SENSE OF ACCOMPLISHMENT AND SUCCESS AT THE
8 END WHEN WE DID THIS.

9 IT INVOLVED 15 SCIENTISTS, SEVEN PATIENT
10 ADVOCATES, AND WE HAD 32 SPECIALISTS WHO CALLED IN TO
11 GIVE SPECIALIZED ADVICE ON PARTICULAR GRANTS. AND THE
12 ENTIRE SESSION WAS RUN UNDER THE VERY ABLE LEADERSHIP
13 OF DR. STUART ORKIN FROM HARVARD MEDICAL SCHOOL AND
14 JOAN SAMUELSON FROM THE ICOC. SO IT WAS REALLY
15 EXTRAORDINARY.

16 ONE OF THE NICE THINGS ABOUT IT WAS THAT WHAT
17 WE HEARD FROM OUR COLLEAGUES FROM OTHER STATES ABOUT
18 THE QUALITY OF THE SCIENCE AND THE PROCESS WAS VERY,
19 VERY COMPLIMENTARY. WE HAD HEARD IT SAID IN SOME
20 PLACES, I WON'T MENTION WHERE, THAT THEY HAD GIVEN OUT
21 MONEY FOR STEM CELL RESEARCH, AND THERE SEEMED TO BE
22 MORE MONEY THAN THERE WAS GOOD IDEAS. THAT WAS NOT THE
23 CASE HERE. EVERYBODY SAID WHAT EXTRAORDINARY SCIENCE
24 IT WAS AND HOW EXCITED THEY WERE TO COME, EVEN WITH ALL
25 OF THIS HARD WORK, AND TO PARTICIPATE AND TO LEARN

1 ABOUT WHAT WAS GOING ON IN CALIFORNIA.

2 AND THE OTHER POINT WAS THE PROCESS, AND
3 PEOPLE WERE UNIFORMLY COMPLIMENTARY ABOUT THAT. AND I
4 WANT TO ACKNOWLEDGE THE VERY HARD WORK OF DR. ARLENE
5 CHIU AND DR. GIL SAMBRANO, BOTH OF WHOM DID A GREAT
6 JOB.

7 (APPLAUSE.)

8 DR. HALL: THE HEAD OF THE STEM CELL RESEARCH
9 UNIT IN FLORIDA, STEM CELL PROGRAM IN FLORIDA, SAID TO
10 BOB KLEIN -- BOB, YOU TOLD ME THIS. IF I GET IT WRONG,
11 LET ME KNOW -- "EVERY REVIEW OUGHT TO BE RUN LIKE
12 THIS," HE SAID. SO THESE ARE PEOPLE WHO HAVE
13 PARTICIPATED IN REVIEWS FOR THE NIH, FOR PATIENT
14 GROUPS, FOR DISEASE ORGANIZATIONS. THEY'RE VERY
15 EXPERIENCED, AND WE CAME OUT LOOKING VERY, VERY GOOD.
16 AND AS I NOTED IN MY LETTER, THEY WILL GO BACK HOME AND
17 TELL THEIR COLLEAGUES, AND I THINK THIS WILL BE VERY
18 MUCH TO THE CREDIT, BOTH IN TERMS OF THE CONTENT AND
19 THE PROCESS, TO CIRM ACROSS THE COUNTRY AND BEYOND. SO
20 I WAS VERY PLEASED, AND WE WERE ALL VERY GRATIFIED. WE
21 WERE ACTUALLY SORT OF ALL ON A HIGH AFTER THAT MEETING
22 FOR A COUPLE OF DAYS. IT WAS REALLY WONDERFUL. AN
23 EXHAUSTED HIGH, I MIGHT ADD.

24 NOW, LET ME ALSO SAY THAT WHAT HAPPENS NEXT,
25 OUR STAFF, ALL OF US ACTUALLY, I HAVE BEEN GIVEN MY

1 ASSIGNMENT AS WELL, WILL BE PREPARING REVIEWS FOR EACH
2 OF THE 232 APPLICATIONS THAT REFLECT THE REVIEWER'S
3 COMMENT AND THE DISCUSSION. THEY WILL BE SENT ON A
4 CONFIDENTIAL BASIS TO EACH OF THE APPLICANTS, AND WE
5 WILL ALSO HAVE A SUMMARY OF THAT REVIEW, WHICH WILL BE
6 POSTED FOR THE NEXT MEETING. SO WE WILL THEN POST
7 SCIENTIFIC SCORES, REVIEWS, RECOMMENDATIONS FROM THE
8 WORKING GROUP FOR THE FEBRUARY ICOC MEETING, AND WE
9 WILL ALSO BE POSTING THOSE MEMBERS OF THE WORKING GROUP
10 WHO ARE RECUSED BECAUSE OF CONFLICT OF INTEREST. THIS
11 IS A SUGGESTION THAT JOHN SIMPSON MADE TO US, AND WE
12 THOUGHT IT WAS A WORTHWHILE ONE, AND WE WILL CARRY THAT
13 OUT.

14 SO LET ME, THEN, TALK A LITTLE BIT ABOUT THE
15 NEXT. THE PACE CONTINUES. WE'RE HARDLY OVER THIS ONE,
16 AND WE ARE ALREADY ORGANIZING THE NEXT ONE. AND, IN
17 FACT, GIL SAMBRANO, KATE SHREVE, AND OTHERS DID NOT
18 COME BECAUSE THEY'RE BACK AT HOME WORKING FOR THE NEXT
19 MEETING. WE HAVE RECEIVED 70 APPLICATIONS FOR THE
20 COMPREHENSIVE GRANTS RFA. THESE WILL BE EVALUATED AT
21 THE GRANTS WORKING GROUP MEETING ON JANUARY 8TH THROUGH
22 THE 10TH, AND THE RESULTS WILL BE BROUGHT TO THE MARCH
23 ICOC MEETING FOR APPROVAL.

24 WE ARE ALSO WORKING ON THE SHARED RESEARCH
25 LABORATORY FACILITIES RFA. THIS HAS GONE -- WITH

1 EVERYTHING ELSE, THIS HAS GONE A LITTLE BIT MORE SLOWLY
2 THAN WE HAD HOPED. WE NOW EXPECT THE RFA TO BE ISSUED
3 IN EARLY JANUARY. WE HOPE TO HAVE OUR SENIOR
4 FACILITIES LIAISON PERSON ON BOARD BY THEN. WE
5 ANTICIPATE REVIEWS BOTH BY THE GRANTS WORKING GROUP AND
6 THE FACILITIES WORKING GROUP IN MARCH AND APRIL OF
7 2007. AND THE CURRENT SCHEDULE WILL CALL FOR APPROVAL
8 AT THE JUNE ICOC MEETING, AND WE WILL DO EVERYTHING WE
9 CAN TO MEET THIS SCHEDULE BECAUSE, AS BOB KLEIN SAID IN
10 HIS REMARKS, SPACE FOR THIS RESEARCH IS SHORT AT
11 CALIFORNIA UNIVERSITIES IN GENERAL.

12 NOW, I'D LIKE TO THEN TURN AND COMMENT ON
13 SOMETHING ELSE IN THE NEXT SLIDE, PLEASE. THAT IS, AS
14 I'M SURE ALL OF YOU KNOW, WE HAVE HAD AN AUDIT, WHICH
15 WAS MANDATED BY THE JOINT LEGISLATIVE AUDIT COMMITTEE.
16 AND THIS IS A PERFORMANCE AUDIT, WHICH IS DIFFERENT
17 FROM OUR ANNUAL FINANCIAL AUDIT. AND I WILL START BY
18 SIMPLY SAYING THIS HAS BEEN AN INCREDIBLY EXHAUSTIVE
19 AND RIGOROUS AND STRENUOUS AUDIT. WE HAVE, UNTIL THE
20 RECENT ADDITIONS, A WORKFORCE OF ABOUT 20 PEOPLE. SO
21 WE HAD FOUR PEOPLE, 20 PERCENT OF OUR TOTAL, WHO SPENT
22 FOUR MONTHS WITH US GOING OVER EVERY DETAIL OF OUR
23 OPERATIONS AND INVESTIGATING EXHAUSTIVELY HOW OUR
24 POLICIES WERE DEVELOPED, HOW OUR PROCEDURES WERE
25 DEVELOPED, AND ASKING FOR DOCUMENTATION AT EVERY STEP

1 OF ALL OF THESE.

2 WE HAVE ANSWERED LITERALLY HUNDREDS OF
3 QUESTIONS, AND MANY OF US HAVE HAD DOZENS OF E-MAILS
4 WITH LONG DETAILED QUESTIONS THAT WE'VE HAD TO ANSWER.
5 SO THIS HAS BEEN A TREMENDOUS STRAIN ON THE STAFF AS WE
6 HAVE DEALT WITH THIS OVER THE LAST PERIOD OF TIME. SO
7 WE'VE BEEN IN EXISTENCE FOR ABOUT 20 MONTHS. THEY WERE
8 THERE ABOUT FOUR MONTHS. SO MEASURED EITHER IN TERMS
9 OF PERSONNEL OR TIME, ABOUT 20 PERCENT OF THE RESOURCES
10 OF THE INSTITUTE HAVE BEEN INVOLVED IN THIS AUDIT. SO
11 IT HAS REALLY BEEN QUITE SOMETHING.

12 NOW, THE REPORT WILL BE AVAILABLE IN
13 FEBRUARY. AND WE WILL HAVE FIVE DAYS TO RESPOND TO THE
14 REPORT, AND THEN THERE WILL BE A REJOINDER TO OUR
15 RESPONSE, AND THE AUDIT WILL BE PUBLISHED.

16 NOW, THE AUDIT ACTUALLY HAS BEEN BENEFICIAL
17 TO US IN SEVERAL WAYS, ONE OF WHICH IS THAT IN THE
18 COURSE OF THIS, WE HAVE IDENTIFIED, IN FACT, CHANGES
19 THAT COULD IMPROVE OUR POLICIES AND PROCEDURES. AND WE
20 HAVE DECIDED TO GO AHEAD AND IMPLEMENT SOME OF THESE
21 CHANGES RIGHT NOW. AND SEVERAL OF THE ITEMS THAT YOU
22 WILL HEAR ABOUT FROM LORI HOFFMAN THIS AFTERNOON ARE
23 IMPROVEMENTS THAT WE THINK COULD BE MADE IN OUR
24 POLICIES AND PROCEDURES THAT WOULD MAKE THEM EVEN MORE
25 RIGOROUS AND WOULD IMPROVE THEM. SO THAT WILL BE OUR

1 SORT OF INTRODUCTION TO THAT.

2 NEXT I WANTED TO BRING YOU UP TO DATE ON OUR
3 REGULATIONS. AND THE FIRST IS ACTUALLY QUITE AN
4 IMPORTANT THING. LAST MONTH WE NOW CELEBRATED THE FACT
5 THAT TWO OF OUR POLICIES HAVE NOW BECOME CALIFORNIA
6 REGULATIONS. THAT IS, THEY HAVE COMPLETED ALL OF THE
7 APA PROCEDURES, AND THEY ARE NOW WRITTEN INTO LAW OF
8 CALIFORNIA, AND THEY ARE OUR CONFLICT OF INTEREST
9 REGULATIONS FOR WORKING GROUPS AND OUR MEDICAL AND
10 ETHICAL STANDARDS.

11 WE HAVE TWO MORE IN THE FINAL STAGES THAT YOU
12 WILL BE CONSIDERING TODAY, OUR GRANTS ADMINISTRATION
13 POLICY AND OUR IP POLICY FOR NONPROFIT INSTITUTIONS.
14 AND IF THOSE GO THROUGH, THEY WILL THEN BE SUBMITTED TO
15 THE OFFICE OF ADMINISTRATIVE LAW, WHO WILL THEN GO OVER
16 THEM WITH A FINE-TOOTHED COMB. AND AT THE END OF THE
17 PERIOD, WHEN ALL CHANGES HAVE BEEN MADE AND ALL
18 QUESTIONS ANSWERED, THERE WILL BE A 30-DAY WAITING
19 PERIOD BEFORE THEY BECOME REGULATIONS.

20 LET ME POINT OUT -- CAN WE GO BACK. LET ME
21 POINT OUT THAT THE MEDICAL AND ETHICAL STANDARDS, WE
22 TOOK OUT TWO PIECES OF THAT. THIS ISN'T QUITE THE
23 ENTIRE POLICY. THERE WERE TWO SMALL PIECES THAT
24 REQUIRE FURTHER CONSIDERATION, AND YOU WILL BE DEALING
25 WITH THOSE LATER TODAY.

1 I'D ALSO LIKE TO TELL YOU ABOUT TWO SMALL,
2 BUT SORT OF INTERESTING SIDELIGHTS ON OUR MEDICAL AND
3 ETHICAL STANDARDS. THE FIRST IS THAT I PARTICIPATED IN
4 A PANEL AT UCSF LAST WEEK, WHICH CELEBRATED THE 25TH
5 ANNIVERSARY OF THE DISCOVERY OF STEM CELLS IN MICE BY
6 DR. GAIL MARTIN. AND ONE OF THE MEMBERS OF THAT PANEL
7 WAS DR. LORI ZOLOFT, KNOWN TO MANY OF YOU, AN ETHICIST
8 AT NORTHWESTERN. AND SHE SAID IN THE PANEL TO THE
9 AUDIENCE THAT SHE WAS A MEMBER OF THE EQUIVALENT OF THE
10 MEDICAL AND ETHICAL STANDARDS COMMITTEE OF THE STATE OF
11 ILLINOIS, AND THAT THEY HAD BEEN SO IMPRESSED BY WHAT
12 WE HAD DONE IN CALIFORNIA, THAT THEY WERE JUST GOING TO
13 BASICALLY ADOPT IT IN TOTO. SO A WONDERFUL TESTIMONY
14 TO THE WORK THAT WENT INTO THAT.

15 A SECOND --

16 DR. FRIEDMAN: ZACH, CAN I ASK IS THAT
17 CLONING POLICIES?

18 DR. HALL: RIGHT. GOOD. TOOK ME A MINUTE.
19 I'M A LITTLE SLOW THIS MORNING. GOT IT. IT'S
20 THERAPEUTIC CLONING.

21 ANOTHER IMPORTANT AND, I THINK, VERY
22 REVEALING SIDELIGHT ON THE QUALITY OF THE PEOPLE THAT
23 WE HAVE IS THAT ONE OF THE MEMBERS OF OUR MEDICAL AND
24 ETHICAL STANDARDS GROUP, DR. KEVIN EGGAN, HAS JUST BEEN
25 CHOSEN BY *PEOPLE MAGAZINE* AS THE SEXIEST GENIUS ALIVE.

1 GEORGE CLOONEY WAS THE SEXIEST MAN ALIVE. KEVIN
2 QUALIFIED IN THE REALM OF GENIUS. WE BENEFITED NOT
3 ONLY FROM HIS GENIUS, BUT PRESUMABLY FROM HIS SEX
4 APPEAL AS WELL IN DRAWING UP THESE STANDARDS.

5 ALL RIGHT. SO LET'S THEN MOVE ON TO ONE
6 FINAL ITEM ON THE OFFICIAL AGENDA HERE THAT I WOULD
7 LIKE TO DISCUSS WITH YOU. AND THAT IS WHILE I WAS IN
8 THE UK, I HAD THE OPPORTUNITY TO TALK WITH THE STEERING
9 COMMITTEE FOR THE OR GROUP FROM AN ONLINE PUBLISHING
10 GROUP CALLED *BIOMED CENTRAL*. AND THE ORIGIN OF THIS,
11 AS YOU KNOW, AS I HAVE PRESENTED PREVIOUSLY, WE HAVE
12 BEEN VERY INTERESTED FOR SOME TIME IN THE POSSIBILITY
13 OF HAVING AND HELPING TO MAKE HAPPEN A HIGH QUALITY,
14 OPEN ACCESS, WEB-BASED JOURNAL FOR STEM CELL RESEARCH.
15 THIS WOULD MEAN THAT ANYWHERE IN THE WORLD THAT IF
16 SOMEBODY WANTED TO GO AND OBTAIN THIS INFORMATION, THEY
17 CAN DO SO IMMEDIATELY WITHOUT A SIX-MONTH WAITING
18 PERIOD OR ANYTHING ELSE. AS SOON AS IT WAS ONLINE, IT
19 IS AVAILABLE.

20 WE HAD HAD DISCUSSIONS WITH THE PUBLIC
21 LIBRARY OF SCIENCE, WHICH IS ONE OF THE TWO MAIN GROUPS
22 THAT IS DOING THIS. AND THOSE DISCUSSIONS FOUNDERED.
23 WE TALKED TO THEM QUITE EXTENSIVELY, BUT THEY WERE AT A
24 STAGE IN THEIR DEVELOPMENT WHEN THEY FELT THEY SIMPLY
25 COULD NOT TAKE ON ANOTHER VENTURE. THE OTHER GROUP IS

1 A GROUP IN LONDON CALLED BIOMED CENTRAL THAT HAS BEEN
2 VERY, VERY SUCCESSFUL. AND, WHEREAS, THE PUBLIC
3 LIBRARY OF SCIENCE HAS SOUGHT TO HAVE HIGH IMPACT, HIGH
4 PRESTIGE JOURNALS, BIOMED CENTRAL HAS GONE ABOUT IT IN
5 A DIFFERENT WAY AND WITH WHAT SOME THINK A BETTER
6 BUSINESS MODEL. AND THAT IS WITH THE IDEA THAT THE
7 TRUE VALUE OF THE INTERNET IS THAT YOU REDEFINE WHAT IT
8 MEANS TO HAVE A JOURNAL. YOU BASICALLY HAVE PAPERS,
9 WHICH CAN BE PUT ON AT ANY TIME, AND THEN YOU HAVE A
10 VARIETY OF SEARCH ENGINES THAT PEOPLE CAN USE TO PULL
11 OUT THE INFORMATION THAT THEY HAVE.

12 THEY HAVE APPLIED THIS APPROACH, AND THEY NOW
13 HAVE WELL OVER A HUNDRED DIFFERENT ELECTRONIC JOURNALS.
14 AND THEY ARE, WE ARE TOLD BY THEIR OWN ACCOUNT, VERY
15 CLOSE TO RUNNING IN THE BLACK. SO THEY ARE DOING THIS
16 SUCCESSFULLY, AND I THINK SEEM WELL ON THE WAY TO
17 ESTABLISHING A VIABLE ECONOMIC MODEL FOR THIS
18 PUBLISHING.

19 SO THEY ARE INTERESTED IN THE POSSIBILITY OF
20 STEM CELL -- TWO THINGS, THE POSSIBILITY OF A STEM CELL
21 RESEARCH JOURNAL, AND ALSO THEY'RE INTERESTED IN
22 OPENING AN OFFICE IN CALIFORNIA. SO WE HAD DISCUSSIONS
23 WITH THEM, OR I DID. AND, MELISSA, IF I COULD SEE THE
24 NEXT SLIDE, PLEASE. WHAT WE DISCUSSED WAS HAVING AN
25 INTERNATIONAL OPEN-ACCESS JOURNAL THAT WOULD PUBLISH

1 ORIGINAL RESEARCH IN STEM CELL BIOLOGY AND REGENERATIVE
2 MEDICINE. IT WOULD ALSO HAVE COMMENTARY,
3 INTERPRETATION, AND ANALYSIS; THAT IS, SHORT ARTICLES
4 THAT WOULD EDUCATE, EXPLAIN, INTERPRET THE WORK THAT
5 WAS GOING ON. AND THIS WOULD BE AT A VARIETY OF
6 LEVELS, SOME OF IT RATHER SCIENTIFIC SORT OF NEWS AND
7 VIEWS IN NATURE, AND OTHER ARTICLES THAT WOULD BE AIMED
8 AT A LAY PUBLIC.

9 AND IN PARTICULAR WE HAVE INTEREST IN HAVING
10 ARTICLES THAT WOULD EXPLAIN TO PATIENTS WHO MAY HAVE A
11 DISEASE WHAT A PARTICULAR FINDING IN THAT FIELD MEANS.
12 FOR THOSE OF YOU WHO NOTICED, THERE WERE TWO PAPERS
13 PUBLISHED FROM HARVARD VERY RECENTLY ON STEM CELLS IN
14 HEART. AND I THINK THIS WILL BE A PERFECT EXAMPLE,
15 THEN, TO SAY WHAT DOES THIS MEAN? WHY IS THIS RESEARCH
16 IMPORTANT? WHAT'S THE NEXT STEP? AND AS OUR WORK THAT
17 WE FUND MOVES MORE AND MORE IN A CLINICAL DIRECTION,
18 THAT WILL BE MORE AND MORE IMPORTANT. I THINK HAVING
19 GOOD, CLEAR, AUTHORITATIVE ARTICLES THAT SAY WHAT
20 RESEARCH MEANS AND DOESN'T MEAN WILL BE VERY IMPORTANT.

21 NOW, THE IDEA OF THE WAY THIS MIGHT BE
22 ORGANIZED WOULD BE THAT IT WOULD HAVE THREE PARTS. THE
23 ORDINARY JOURNAL ARTICLES, THE COMMENTARY,
24 INTERPRETATION, AND ANALYSIS, WHAT WE CALL THE SORT OF
25 FRONT MATERIAL -- USUALLY IT'S IN THE FRONT OF THE

1 JOURNAL -- AND THEN POSSIBLY, THEY SUGGESTED, A
2 DATABASE OF ALL STEM CELL ARTICLES WHEREVER THEY'RE
3 PUBLISHED ANYWHERE IN THE WORLD THAT ANYBODY CAN
4 ACCESS. THE PUBLICATION PART OF IT FOR THE SCIENTIFIC
5 ARTICLES WOULD BE THEIRS, AND THIS WOULD BE FINANCED,
6 AS WITH ALL OPEN-ACCESS JOURNALS OF THIS SORT, BY
7 AUTHORS OR BY SPONSORING AGENCIES WHO WISH TO PUBLISH
8 THERE.

9 AND THE WAY WE DISCUSSED IT WITH THEM IS THAT
10 WE WOULD CONTRACT FOR THE PRODUCTION OF THE
11 INTERPRETIVE MATERIAL THAT WOULD THEN BE AVAILABLE, NOT
12 ONLY FOR US, BUT FOR ANYBODY IN THE WORLD WHO WANTED TO
13 USE THIS, SO ANYBODY COULD BUNDLE IT, USE IT. MY VIEW
14 IS THAT, AS PART OF OUR RESPONSIBILITIES TO THE PUBLIC
15 AND PART OF OUR EDUCATIONAL RESPONSIBILITY, AS WE HAVE
16 DISCUSSED IN THE STRATEGIC PLAN, THIS WILL BE A
17 WONDERFUL OPPORTUNITY TO HAVE THOSE ARTICLES WRITTEN.
18 THEY HAVE CONTACT WITH HIGH QUALITY WRITERS WHO COULD
19 DO THIS, AND SO WE WOULD THEN CONTRACT WITH THEM FOR
20 THAT. AND THEN IF WE WANTED HARD COPIES, WHICH I THINK
21 MIGHT BE USEFUL FOR OUR OWN PURPOSES, WE WOULD ALSO PAY
22 FOR THAT. BUT IN ANY CASE, THE ENTIRE CONTENTS WOULD
23 BE FREELY AVAILABLE ON THE WEB WHERE IT WILL LIE.

24 SO WHAT I WOULD LIKE FROM YOU IS I DON'T
25 THINK WE NEED A FORMAL RESOLUTION, BUT IF THERE IS

1 COMMENT OR ENCOURAGEMENT ON THE PART OF THE BOARD TO
2 CONTINUE THESE TALKS, WE WOULD BE HAPPY TO DO SO. IF
3 FOR SOME REASON YOU THINK THIS IS NOT THE WAY TO GO,
4 THEN I WOULD ALSO PAY ATTENTION TO THAT. BUT AT LEAST
5 WE HAVE HAD PRELIMINARY DISCUSSIONS. WE HAVE HAD NO
6 DISCUSSIONS OF HOW MUCH THIS MIGHT COST. BUT I SAID TO
7 THEM I WOULD LIKE TO BRING IT TO THE BOARD, DISCUSS IT
8 WITH THE BOARD; AND IF YOU ARE AGREEABLE, THEN WE WILL
9 GET A MORE DETAILED PROPOSAL TO BRING BACK. THAT WOULD
10 BE MY THOUGHT.

11 DR. KESSLER: ZACH, ARE YOU LOOKING AT THE
12 OTHER OPPORTUNITIES WHERE TO PUBLISH? IF YOU DID HIGH
13 QUALITY WORK, BUT MAYBE IT WASN'T GROUNDBREAKING, IT
14 WASN'T *SCIENCE* OR *NATURE*, BUT IT WAS STILL IMPORTANT
15 WORK, DO YOU THINK THERE'S A LIMIT ON WHERE YOU WOULD
16 WANT TO PUT THIS?

17 DR. HALL: LET ME JUST SAY, FIRST OF ALL, I
18 SHOULD HAVE SAID THIS MORE EXPLICITLY. THAT IS THEIR
19 PHILOSOPHY. THEIR IDEA IS NOT TO CREATE *CELL*, TO
20 RECREATE *CELL AND STEM CELL RESEARCH*. BY THE WAY,
21 THERE IS SUCH A JOURNAL NOW THAT'S GOING TO BE CALLED
22 *CELL STEM CELL*. BUT WHERE YOU PICK OUT HIGH IMPACT,
23 HIGH VISIBILITY, SORT OF THE BEST OF THE BEST. THAT IN
24 A WAY IS THE *PLOS* MODEL. THEIR IDEA IS THAT YOU HAVE
25 RIGOROUS SCIENTIFIC REVIEW AND YOU DON'T ASK THE

1 GLAMOUR QUESTION, THE INTEREST QUESTION. YOU SAY IF
2 IT'S GOOD, WE'LL PUT IT IN HERE, AND THEN IT'S
3 AVAILABLE TO ANYBODY. AND THIS WAS MY POINT ABOUT, IN
4 THEIR VIEW, THE ONLINE JOURNAL CAN BE AS BIG OR AS
5 SMALL AS YOU WANT. YOU JUST HAVE A GOOD SEARCH ENGINE.

6 ONE MORE POINT. WE WOULD NOT REQUIRE CIRM
7 INVESTIGATORS TO PARTICIPATE IN THIS AT ALL, AND IT
8 WOULD BE FOR STEM CELL RESEARCHERS AROUND THE WORLD TO
9 USE. IT WOULD BE A SERVICE TO THE FIELD THAT WE WOULD
10 BE ABLE TO PROVIDE.

11 DR. KESSLER: BUT WITH REGARD TO IS THERE A
12 NEED, IF YOU'RE A RESEARCHER, WHAT'S YOUR ASSESSMENT OF
13 TODAY THE FORUMS WHERE YOU CAN PUT THIS WORK? WILL
14 THIS FIT A NICHE THAT DOESN'T EXIST? OR ARE THERE MANY
15 SUCH NICHEs THAT CURRENTLY EXIST?

16 DR. HALL: I WOULD SAY THERE IS NO SINGLE --
17 AT PRESENT THERE IS NO SINGLE HIGH QUALITY PLACE,
18 VENUE, DEDICATED TO STEM CELL RESEARCH. NOW, THE TIME
19 IS RIPE, AND SEVERAL PEOPLE ARE DOING THIS. AND I
20 THINK IF WE ARE GOING TO DO IT, WE WOULD NEED TO DO IT
21 NOW. WE SHOULD NOT WAIT SIX MONTHS OR A YEAR. THEY
22 ACTUALLY COULD GET THIS GOING VERY, VERY QUICKLY. PART
23 OF THE POINT IS THEY'RE VERY EXPERIENCED IN TERMS OF
24 THE PRODUCTION SIDE OF THIS, SO IT COULD BE DONE VERY
25 QUICKLY. BUT I DO KNOW, AS I INDICATED, ELSIVERE PRESS

1 WITH *CELL STEM CELL* WILL HAVE A HIGH VISIBILITY, HIGH
2 IMPACT JOURNAL. I THINK *NATURE* IS ALSO CONSIDERING
3 SOMETHING. THIS WOULD BE DIFFERENT FROM EITHER OF
4 THOSE IN THAT IT WOULD TAKE, NOT JUST THE GLAMOROUS
5 PAPERS, BUT IT WOULD TAKE ALL GOOD SCIENCE PAPERS. IF
6 IT'S GOOD SCIENCE, WE'LL TAKE IT. THEN IT WILL BE
7 AVAILABLE FOR WHOEVER WANTS IT.

8 DR. KESSLER: IS THERE ANY RISK THAT IF YOU
9 HAVE THREE OR FOUR ENTRIES INTO THE MARKET OVER THE
10 NEXT COUPLE OF YEARS -- *NATURE* HAS A SPECIALTY JOURNAL.
11 I ASSUME THAT'S WHAT THEY'RE DISCUSSING -- IS THERE ANY
12 RISK THAT WITH *CELL STEM CELL*, *NATURE STEM CELL*, THIS
13 BEING A LITTLE MORE -- WHAT'S THE RIGHT WORD? -- ALL
14 GOOD WORK. YOU'RE STILL -- YOU'RE GOING TO -- THE ICOC
15 WILL END UP BEING IN A LESS TOP-TIERED JOURNAL?

16 DR. HALL: I DON'T THINK THAT -- SEVERAL OF
17 THEIR JOURNALS, ALTHOUGH THEY HAVE NOT DONE THIS AS
18 A -- THEY HAVE NOT TARGETED THIS, SEVERAL OF THE
19 JOURNALS, IN FACT, DO HAVE VERY HIGH IMPACT RATINGS.
20 AND I THINK THE SUCCESS OF THE JOURNAL WILL DEPEND ON
21 THE RIGOR OF THE ARTICLES. I THINK THE COMBINATION OF
22 THE FRONT-END MATERIAL, PERHAPS THE DATABASE, AND THEN
23 THE IDEA OF BEING ABLE TO ACCESS THESE, I DON'T THINK
24 ANYBODY IS DOING AN OPEN-ACCESS JOURNAL. I HAVE NOT
25 HEARD THAT AT ALL.

1 SO THIS WOULD BE A NOVEL FEATURE THAT, I
2 THINK, WOULD BRING SOME UNIQUE CHARACTERISTICS. AND WE
3 HAVE HAD A DISCUSSION ABOUT THIS IN CONNECTION WITH THE
4 IP TASK FORCE AND A GROUP FROM UC WHO CAME OUT. I
5 THINK IN TERMS OF OUR RESPONSIBILITIES TO THE PUBLIC
6 AND OUR INTEREST IN HAVING INFORMATION BE FREELY
7 AVAILABLE, NOT ONLY TO SCIENTISTS WORLDWIDE, BUT ALSO
8 TO THE LAY PUBLIC, I THINK IT'S A REAL OPPORTUNITY FOR
9 US TO ADD SOMETHING THAT IS NOT THERE. NOBODY IS DOING
10 WEB-BASED OPEN ACCESS. AND I THINK I WOULD TRUST THEM
11 AND THEIR JUDGMENT THAT WE WILL BE ABLE TO GET GOOD
12 PAPERS BASED ON THEIR EXPERIENCE. THAT IS, THAT IT
13 WILL NOT BE A SECOND-TIER JOURNAL, WHICH IS I THINK
14 WHAT YOU'RE ASKING.

15 DR. BRYANT: WHEN THEY DO THE REVIEW, ARE
16 THEY -- THEY'RE JUST LOOKING FOR THINGS THAT ARE
17 OBVIOUSLY WRONG WITH IT? IS IT A PEER REVIEW IN THE
18 SENSE THAT THEY SEND IT OUT TO --

19 DR. HALL: FORGIVE ME FOR A MOMENT. I'M
20 GOING TO TALK CODE TO SUSAN. IT'S JBC, *JOURNAL OF CELL*
21 *BIOLOGY*. IT IS RIGOROUS. THAT'S THE ISSUE. IT'S
22 RIGOROUS, BUT THEY DON'T MIND PUBLISHING WORK THAT IS
23 ESSENTIALLY ARCHIVAL.

24 DR. BRYANT: IT'S NOT LIKE THE NEXT BIG STEP,
25 BUT IT'S IMPORTANT INFORMATION THAT NEEDS TO BE OUT

1 THERE.

2 DR. HALL: THEY HAVE A VERY INTERESTING VIEW
3 OF IT. I'M OF A GENERATION WHO GREW UP IN A WORLD
4 WHERE YOU HAVE HARD COPY. IN THE CONVERSATION I SAID
5 TO THEM, "YOU KNOW, THE NICE THING ABOUT THE HIGH
6 IMPACT THINGS IS YOU KNOW THAT ANYTHING YOU LOOK FOR IN
7 THERE IS APT TO BE GOOD, SO YOU'RE NOT WASTING YOUR
8 TIME." HE SAID, "NO, YOU DON'T UNDERSTAND." THEY
9 SAID, "YOU KNOW, STUDENTS NOW, THEY DON'T TAKE
10 JOURNALS." THE JOURNAL IS ELASTIC. THERE'S A WORLD OF
11 PAPERS OUT THERE, AND WHAT YOU WANT IS A WAY TO ACCESS
12 AND GET THE PAPERS YOU WANT TO YOU, AND ALL YOU HAVE TO
13 HAVE IS THE RIGHT SEARCH ENGINE, AND YOU JUST PULL THEM
14 OUT. THAT'S YOUR JOURNAL. YOU MAKE A PERSONALIZED
15 JOURNAL OUT OF IT.

16 IT'S BEEN FOR ME VERY INTERESTING AND
17 REQUIRED SOME REORIENTATION ON MY PART IN THINKING
18 ABOUT THIS, BUT THEY HAVE BEEN SUCCESSFUL. AS I SAY,
19 NOT ALL, BUT SEVERAL OF THEIR JOURNALS, THE ONE IN
20 *GENOME* AND *GENOMIC SCIENCE* IS APPARENTLY VERY HIGHLY
21 RATED. SAID THEY DIDN'T SET OUT TO DO IT, BUT IT
22 HAPPENED THAT WAY. AND I THINK IT REALLY DEPENDS ON IF
23 THEY GET GOOD REVIEWERS, WHICH WE WOULD CERTAINLY
24 ADVISE AND HELP THEM WITH, THEN I THINK THAT PROBLEM
25 WOULD BE TAKEN CARE OF. DOES THAT ANSWER YOUR

1 QUESTION?

2 DR. BRYANT: YEAH.

3 DR. MURPHY: ZACH, I WOULD PROCEED WITH GREAT
4 CAUTION HERE FOR A COUPLE OF REASONS. IT TROUBLES ME
5 THAT *PLOS*, WHICH I AGREE WITH YOU, IS AT A VERY HIGH
6 LEVEL NOW, IS NOT PURSUING THE IDEA OF A STEM CELL
7 JOURNAL WITH US, WHATEVER THE DETAILS OF THAT ARE.
8 BUT --

9 DR. HALL: I DON'T WANT TO GO INTO THE
10 DETAILS OF IT. I'D BE HAPPY TO HAVE A DISCUSSION WITH
11 YOU AT ANOTHER TIME.

12 DR. MURPHY: AGAIN, I GUESS, SECONDLY, I
13 WOULD BE CAREFUL ABOUT ASSOCIATING CIRM'S NAME AND
14 IDENTITY AND PRESTIGE WITH SOMETHING AT THIS STAGE THAT
15 IS FAIRLY UNFORMED AND AMORPHOUS. BECAUSE IF IT
16 DOESN'T GO WELL AND WE ARE ASSOCIATED WITH IT, WE COULD
17 BECOME -- WE COULD BECOME MARGINALIZED AS WELL. AND I
18 GUESS I'M NOT SAYING THAT YOU SHOULDN'T PURSUE IT, BUT
19 I THINK THAT WE HAVE A LONG WAY TO GO BEFORE AT LEAST
20 MY ENTHUSIASM FOR THE PROJECT WOULD BE GREAT BECAUSE,
21 AGAIN, I DON'T WANT CIRM'S NAME TO BE ASSOCIATED WITH
22 SOMETHING THAT MIGHT FLOUNDER.

23 I GUESS MY FINAL POINT IS I DON'T THINK WE
24 CAN BE EVERYTHING TO EVERYBODY. AND, YOU KNOW, GIVEN
25 ALL OF THE CHALLENGES THAT WE FACE IN FUNDING ALL OF

1 THESE GRANTS, IN BUILDING THE AGENCY, AND DOING ALL THE
2 THINGS WE HAVE TO DO, I'M A LITTLE BIT CONCERNED ABOUT
3 GETTING SO DIFFUSE IN THIS WAY BY MAKING OURSELVES PART
4 OF THE PUBLISHING INDUSTRY IN WHATEVER WAY, THAT WE MAY
5 NOT HAVE THE HORSES TO DO IT WELL.

6 DR. HALL: IT WOULD NOT BE OUR PUBLISHING
7 VENTURE IN A SENSE. IT WOULD BE COSPONSORED BY US. I,
8 FRANKLY, BELIEVE THAT WE HAVE A LOT OF GOOD WILL TO BE
9 GAINED FROM THAT. I THINK IT IS GOOD PUBLICITY FOR US,
10 FRANKLY. I THINK IT SHOWS OUR MISSION OF MAKING
11 SCIENCE IMMEDIATELY AVAILABLE, FREE TO ANYBODY IN THE
12 WORLD, AND OF TRYING TO INTERPRET THAT SCIENCE IN A
13 RESPONSIBLE WAY, I SEE, AS PART OF OUR MISSION. AND
14 THE ADVANTAGE OF DOING IT THIS WAY IS THAT WE CAN
15 ACTUALLY CONTRACT OUT TO A GROUP THAT DOES THIS WELL
16 RATHER THAN HAVING OURSELVES TO DO IT IN-HOUSE OR TO
17 FIGURE OUT HOW TO START UP SOMETHING NEW.

18 BUT IN THAT SENSE, IT WOULD TAKE NOT HUGE
19 PERSONNEL RESOURCES FROM US. WE'RE NOT GOING TO BE
20 RUNNING THIS THING. WE WILL MONITOR IT, WE WILL LOOK
21 AT THE RESULTS, AND WE WOULD PROBABLY ENTER INTO SOME
22 CONTRACT OVER A SEVERAL-YEAR PERIOD. IF IT DOESN'T
23 WORK, WE WOULD STOP. BUT I TAKE YOUR POINT, AND IF IT
24 IS THE FEELING OF THE BOARD THAT WE SHOULD JUST LET
25 THIS DROP, I WOULD BE HAPPY TO DO IT.

1 CHAIRMAN KLEIN: DR. HALL, I THINK IT'S AN
2 IMPORTANT IDEA. WE CLEARLY HAVE STRONG IDEAS HERE
3 GENERATING FOR AND AGAINST. I THINK WE NEED THE TIME
4 TO WORK THROUGH THIS. WHY DON'T I AGENDIZE THIS FOR
5 THE NEXT BOARD MEETING WHEN THERE'S TIME TO THINK
6 THROUGH THESE RESPONSES AND PEOPLE TO ORGANIZE THEIR
7 IDEAS?

8 DR. HALL: SO I WOULD LIKE, THEN, YOUR, NOT
9 FORMAL APPROVAL, BUT YOUR ENCOURAGEMENT, I GUESS, TO DO
10 TWO THINGS. ONE WOULD BE TO FLESH THIS OUT WITH THEM,
11 AND THE OTHER IS TO EXPLORE OTHER POSSIBLE PARTNERS IN
12 THIS VENTURE WITH US. AND I DON'T WANT TO OBVIOUSLY
13 DISCLOSE WHO THEY MAY BE, BUT I THINK WE COULD FIND
14 OTHER PARTNERS, SOMEONE THAT I'M THINKING OF IN THIS
15 COUNTRY, ONE ABROAD, THAT ACTUALLY MIGHT BE WILLING TO
16 COSPONSOR WITH US, WHICH WOULD PERHAPS SHARE SOME OF
17 THE RISK. BUT IN ORDER TO -- WHAT I'D LIKE TO DO IS
18 THEN TO BRING BACK SOMETHING THAT'S A LITTLE MORE
19 FLESHED OUT THAN WHAT WE HAVE HERE.

20 CHAIRMAN KLEIN: I THINK DR. POMEROY HAD
21 SOMETHING TO SAY, AND THEN DR. FRIEDMAN, DR. KESSLER.

22 DR. POMEROY: I WOULD BE VERY SUPPORTIVE OF
23 YOU CONTINUING TO EXPLORE THIS AND DEFINE IT MORE
24 PRECISELY FOR US. I THINK ONE OF THE RESPONSIBILITIES
25 THAT WE TOOK ON WAS TO GET THIS INFORMATION OUT TO THE

1 PUBLIC AND TO GET IT WIDELY DISTRIBUTED THROUGH THE
2 SCIENTIFIC COMMUNITY. AND CERTAINLY OPEN-ACCESS
3 JOURNALS ARE A WAY TO DO THAT.

4 ONE OF THE THINGS THAT WE VALUED ON THIS
5 BOARD, I THINK, IS TAKING RISKS, FINDING NEW WAYS OF
6 DOING THINGS. I THINK THIS IS A WONDERFUL EXAMPLE OF
7 THAT. IF I HAD MORE SPECIFICS, I WOULD BE VERY
8 INTERESTED IN DISCUSSING THEM.

9 DR. FRIEDMAN: JUST VERY QUICKLY. I AGREE
10 WITH BRINGING THIS BACK. WHAT I'D LIKE TO SEE IS I
11 THINK THE ADVANTAGES ARE PRETTY OBVIOUS, BUT WHAT I
12 DON'T QUITE UNDERSTAND SO WELL ARE WHAT THE
13 DISADVANTAGES OR DISINCENTIVES ARE. WHEN YOU BRING IT
14 BACK, IF YOU COULD GIVE US A SENSE OF HOW MUCH ENERGY
15 IS THIS GOING TO TAKE? HOW MANY FTE? WHAT COSTS?
16 OBVIOUSLY EVERYBODY IS VERY BUSY DOING ALL THESE OTHER
17 THINGS, AND WE WANT TO SEE WHAT THE MARGINAL COSTS
18 WOULD BE. WHETHER OR NOT THIS IS THE BEST PARTNER IN A
19 WAY IS LESS IMPORTANT TO ME AT THIS MOMENT AS COMPARED
20 TO IS THIS A GOOD IDEA FOR US TO DO. I CAN SEE A LOT
21 OF ATTRACTIONS, AND I'M NOT SURE I SEE THE DRAWBACKS.
22 AND YOU CAN PRESENT A VERY BRIEF OUTLINE OF THE PROS
23 AND CONS.

24 DR. HALL: I WILL EXPLORE IT MORE FULLY AND
25 TRY TO DO THAT. I WANTED TO AT LEAST ALERT YOU THAT

1 THESE WERE GOING IN. BEFORE WE INVESTED THE TIME AND
2 ENERGY IN FURTHER DISCUSSIONS, I WANTED TO BE SURE I
3 HAD SOME SENSE FROM THE BOARD THAT THIS WOULD BE
4 USEFUL.

5 DR. KESSLER: I JUST WANTED TO BE CLEAR THAT
6 THE QUESTIONS I ASKED IN THE BEGINNING IN NO WAY DAMPEN
7 THE ENTHUSIASM FOR THIS. WE TRUST YOU IMPLICITLY ON
8 THE SCIENTIFIC QUALITY. TO ME THIS IS JUST A QUALITY
9 ISSUE OF WHO WE HOOK UP WITH AND WHAT THE QUALITY OF
10 THE PRODUCT IS. IT'S NOT UNLIKE -- YOU KNOW, YOU CAN
11 ARGUE JNCI. WHERE IS THAT JOURNAL? SO IT'S A QUALITY
12 ISSUE. IF YOU THINK THIS IS GOING TO BE A QUALITY
13 PRODUCT, I THINK THAT REALLY IS A VERY IMPORTANT THING
14 FOR THIS BOARD.

15 DR. HALL: WE WOULD BRING INFORMATION THAT
16 WOULD LET YOU MAKE A BETTER EVALUATION. I JUST WANTED
17 TO GET A PRELIMINARY.

18 DR. JENNINGS: ONE BRIEF COMMENT. I
19 CERTAINLY URGE YOU TO LOOK AT MODELS OTHER THAN THE
20 FOR-PROFIT JOURNAL PUBLICATIONS, THINGS LIKE ELSIVERE
21 AND WILEY AND SO ON. THESE OPERATIONS HAVE A
22 HYPERINFLATION OVER THE LAST DECADE. PROVOSTS LIKE ME
23 AND OTHERS ARE CANCELING THESE JOURNALS IN ORDER TO
24 KEEP BUDGET UNDER CONTROL, AND WE'RE ACTIVELY LOOKING
25 FOR DIFFERENT BUSINESS MODELS. THE PROFESSIONAL

1 SOCIETIES AND THE OPEN WEB ACCESS JOURNALS HAVE COST
2 PER PAGE AND PER CITATION, BUT ANY MEASURES THAT ARE
3 MUCH MORE ECONOMICAL THAN THE FOR-PROFIT JOURNAL
4 PICTURE NOW, WHICH IS A CAPTIVE MARKET OF SEVERAL OF
5 THESE PUBLISHING HOUSES.

6 DR. HALL: AS MANY OF YOU KNOW, THERE'S A
7 VERY VIGOROUS -- HOW TO PUT IT -- THE TIMES ARE A
8 CHANGING IN THE WORLD OF SCIENTIFIC PUBLICATION. AND
9 SO THERE'S A LOT OF VIGOROUS DISCUSSION BETWEEN THOSE
10 WHO SEE THIS AS A KIND OF WAVE OF THE FUTURE AND THOSE
11 WHO DON'T OR WHO HAVE VESTED INTEREST IN THE WAY THINGS
12 ARE BEING DONE NOW. SO THAT IS A VERY ACTIVE
13 DISCUSSION. WE GOT THE FLAVOR OF SOME OF THAT WHEN
14 LARRY FROM UCSF -- DR. LARRY PITTS REPRESENTING THE UC
15 FACULTY SENATE CAME AND PRESENTED US WITH A DIFFERENT
16 THING, WHICH WAS AN ARCHIVING BASICALLY PROPOSAL THAT
17 THEY WISHED US TO SUPPORT. I THINK THIS ACTUALLY GOES
18 FURTHER THAN THAT, AND IT HAS NO REQUIREMENT TO IT. AS
19 I SAID, WE WOULD NOT REQUIRE ANYBODY TO PUBLISH IN THIS
20 AT ALL.

21 DO I UNDERSTAND THE SENSE OF THE COMMITTEE,
22 THEN, THAT WE WILL EXPLORE THIS FURTHER, COME BACK WITH
23 SOME DETAILS FLESHED OUT, AND SEE WHAT WE CAN DO?

24 DR. HENDERSON: COULD I RETURN TO AN EARLIER
25 PART OF YOUR PRESENTATION HAVING TO DO WITH THE REVIEW

1 OF THE GRANTS? AS I RECALL, WE ARE FUNDING A RATHER
2 SMALL SUBSET OF THIS, OR WE ARE PROGRAMMED TO FUND NO
3 MORE THAN ABOUT 15 PERCENT OF THESE GRANTS. AND I KNOW
4 WE WILL DEAL WITH ALL OF THIS IN FEBRUARY, BUT JUST TO
5 GIVE US SOME RUN-UP TIME TO A CENTRAL ISSUE TO ME, DO
6 YOU HAVE A SENSE FROM YOU OR YOUR COLLEAGUES FROM THE
7 REVIEW AND THE RANKING AS TO WHAT WOULD BE PERHAPS A
8 MORE REASONABLE CUTOFF. IN THE BEST OF ALL WORLDS,
9 WERE YOU TO MAKE A CUTOFF, WOULD IT BE AT 15 PERCENT?
10 WOULD IT BE AT 30 PERCENT?

11 AND I SAY THIS BECAUSE THIS IS PROBABLY THE
12 MOST IMPORTANT PART OF OUR GRANTS PROGRAM. WE'RE NOW
13 SEEDING SCIENCE IN CALIFORNIA. AND I PREFER WE FUND AS
14 MANY OF THESE THAT SEEM SCIENTIFICALLY MERITORIOUS AS
15 POSSIBLE IN THE FIRST ROUND TO GET AS MUCH GOING NO
16 MATTER HOW CROWDED THE LABS HAPPEN TO BE AT THE MOMENT,
17 BUT GET AS MANY PEOPLE PERSONALLY ENGAGED AS POSSIBLE.
18 AND SO IF WE NEED TO FUND MORE TO ACHIEVE THAT GOAL AND
19 COULD, I'D LIKE TO SEE US WORK ON THAT OVER THE NEXT
20 COUPLE OF MONTHS.

21 DR. HALL: LET ME JUST SAY THAT I THINK THESE
22 QUESTIONS SHOULD BE DISCUSSED WITHIN THE CONTEXT OF THE
23 SCIENCE. IT MAKES NO SENSE TO SAY A PRIORI ONE SHOULD
24 DO THIS, THAT, OR THE OTHER. I THINK WHAT YOU WANT TO
25 SEE IS WHAT THE SCIENCE IS. THERE WILL BE

1 RECOMMENDATIONS FROM THE WORKING GROUP ON THIS ISSUE,
2 AND I DO NOT WISH TO PRESENT THOSE PREMATURELY. I
3 THINK THEY WILL BE PRESENTED NEXT TIME SO THAT YOU CAN
4 SEE WHAT THE CHOICES ARE BASED ON WHAT SCIENCE WILL BE
5 FUNDED. BOB CAN CORRECT ME, BUT I THINK THERE WILL BE
6 MONEY TO GIVE MORE IF YOU WANT. ON THE OTHER HAND, WE
7 ALSO WILL NEED TO THINK ABOUT OTHER RFA'S THAT WE HAVE
8 AND WHAT CHOICES THAT MIGHT MEAN. IF WE DO A, THEN WE
9 DON'T DO B, AND WE WILL HAVE TO MAKE THAT VALUE
10 JUDGMENT AS WELL. SO I THINK THAT'S AN IMPORTANT
11 DISCUSSION.

12 WE HAVE ALREADY BEGUN TO DEVELOP SOME
13 PRELIMINARY MATERIAL ON THAT, AND THE WORKING GROUP HAS
14 SOME RECOMMENDATIONS ON THAT. BUT I THINK IT'S
15 PREMATURE TO HAVE THAT DISCUSSION, BUT WE CERTAINLY
16 WILL -- THAT WILL BE AT THE HEART OF THE NEXT MEETING.

17 CHAIRMAN KLEIN: I THINK DR. HALL IS CORRECT,
18 THAT ON A CASH-FLOW BASIS FROM THE FINANCIAL SIDE,
19 WE'VE IDENTIFIED RESOURCES THAT ARE AVAILABLE IF WE
20 FEEL THAT STRATEGICALLY WE WANT TO BROADLY SEED THE
21 FIELD TO BUILD A BROAD STRATEGIC PIPELINE FOR
22 COMPREHENSIVE GRANTS AND OTHER GRANTS THAT WILL DEVELOP
23 DOWNSTREAM.

24 DR. HENDERSON: YOU SORT OF OPENED THE DOOR
25 FOR THIS WHEN YOU SAID THE GRANTS WERE NOTED BY THE

1 REVIEWERS TO BE PARTICULARLY NOTEWORTHY. AND SO IN
2 SOME SENSE, I'M JUST TRYING TO PREPARE US FOR THE
3 POSSIBILITY THAT WE'RE GOING TO FACE THIS ISSUE IN A
4 MAJOR WAY.

5 DR. HALL: WELL, NOBODY SAID 80 PERCENT OF
6 THE GRANTS. THERE IS A RECOMMENDATION TO COME. I DO
7 NOT WISH TO DISCUSS THAT NOW. AND LET ME SAY THAT IT
8 IS ALWAYS THE PREROGATIVE OF THE ICOC TO MAKE THAT
9 CHOICE. IF YOU REMEMBER FOR THE TRAINING GRANTS, WE
10 WERE APPROVED TO FUND \$15 MILLION OR 14 MILLION, AND WE
11 FUNDED 12 BECAUSE THE ICOC FELT THAT THAT WAS
12 APPROPRIATE IN LIGHT OF THE QUALITY OF THE APPLICATIONS
13 RECEIVED. AND I THINK IT'S EXACTLY THE SAME JUDGMENT
14 THAT YOU WILL MAKE THIS TIME BALANCED OFF WITH WHAT
15 ELSE THAT MONEY MIGHT BE USED FOR. SO THAT WOULD BE
16 THE ISSUE.

17 OKAY. SO LET ME END ON A PERSONAL NOTE. I
18 WANT TO ANNOUNCE THAT I WILL BE STEPPING DOWN AS
19 PRESIDENT AND CHIEF SCIENTIFIC OFFICER OF CIRM. AND I
20 WILL BE DOING SO SOMETIME WITHIN THE NEXT SIX MONTHS.
21 IT IS MY HOPE THAT WE WILL BE ABLE TO APPROVE THE FUNDS
22 FOR TWO AND POSSIBLY THREE OF THE RFA'S THAT WE HAVE
23 BEEN CONSIDERING. BUT FOR A VARIETY OF REASONS, THIS
24 SEEMS LIKE A GOOD TIME FOR ME TO MAKE THAT STEP.

25 IT IS ALMOST ENTIRELY A PERSONAL DECISION

1 DRIVEN BY PERSONAL NEEDS. I'M AT THE TIME IN MY LIFE
2 WHERE I HAVE A NUMBER OF INTERESTS THAT I SIMPLY DON'T
3 HAVE TIME TO EXPLORE AS I WOULD LIKE. AND HAVING JUST
4 TURNED 69 A COUPLE MONTHS AGO, I FIND MYSELF LOOKING
5 AHEAD AND WANTING TO BE SURE THAT I HAVE THE TIME TO
6 EXPLORE THESE INTERESTS WHILE I HAVE THE MENTAL AND
7 PHYSICAL ABILITY TO DO SO. MY WIFE RETIRED THIS LAST
8 YEAR. WE HAVE A WONDERFUL HOME IN WYOMING. OUR PLAN
9 IS TO HAVE THAT AS OUR HOME BASE, AND WE LOOK FORWARD
10 VERY MUCH TO SORT OF REINVENTING OURSELVES IN THAT
11 CONTEXT.

12 WE HAVE BOTH LED LIVES IN WHICH IN THE LAST
13 TEN YEARS OR SO, WHEN OUR ACTIVITIES HAVE BEEN HIGHLY
14 REGIMENTED, MEETINGS OR REHEARSALS FROM MORNING TO
15 NIGHT, AND THE OPPORTUNITY TO HAVE THE TIME TO DO
16 THINGS THAT AREN'T POSSIBLE WITHIN THAT SCHEDULE IS
17 VERY, VERY APPEALING TO BOTH OF US.

18 I THINK IT IS A GOOD TIME TO DO SO FOR THE
19 FOLLOWING REASONS. I THINK THE INSTITUTE IS IN GOOD
20 SHAPE TO FIND A NEW AND ABLE PRESIDENT, AND I ANNOUNCE
21 AT THIS TIME IN ADVANCE SO THAT THAT PROCESS MIGHT BE
22 SET IN MOTION. I THINK WE ARE IN A VERY STRONG
23 POSITION. WE HAVE A VERY STRONG COURT RULING WHICH IS
24 EXTREMELY IMPORTANT. WE NOW HAVE MONEY IN THE BANK,
25 WHICH IS EXTREMELY IMPORTANT. WE WILL SOON HAVE A

1 RESEARCH GRANTS PROGRAM. WE NOW HAVE A TRAINING GRANTS
2 PROGRAM. WE HAVE OUR INFRASTRUCTURE ALL IN PLACE. I
3 HOPE BY THE END OF THIS MEETING, WE WILL HAVE AN
4 APPROVED SCIENTIFIC STRATEGIC PLAN THAT WILL BE IN
5 PLACE. AND I THINK IF SOME OF THE INTERNAL
6 ORGANIZATION PROBLEMS CAN BE WORKED OUT, I THINK WE'LL
7 BE IN A VERY STRONG POSITION TO LOOK FOR A NEW
8 PRESIDENT.

9 SO THERE WILL BE A TIME LATER FOR VALEDICTORY
10 REMARKS, AND I DON'T WANT -- I DON'T WANT TO GO INTO
11 THAT NOW. I JUST DON'T WANT TO DWELL ON THEM NOW, BUT
12 SIMPLY TO SAY THAT WE HAVE MUCH WORK AHEAD OF US IN THE
13 NEXT SIX MONTHS, AND I LOOK FORWARD TO WORKING WITH YOU
14 DURING THAT TIME, AS I HAVE IN THE PAST, TO MAKE THIS
15 GREAT PROJECT BLOSSOM AND COME ALIVE. THANK YOU VERY
16 MUCH.

17 CHAIRMAN KLEIN: DR. HALL, I'D LIKE THE BOARD
18 TO STAND IN APPRECIATION FOR YOUR GREAT SERVICE.

19 (APPLAUSE.)

20 DR. HALL: THANK YOU VERY MUCH. I APPRECIATE
21 THAT.

22 CHAIRMAN KLEIN: THANK YOU. AND WE'LL LOOK
23 FORWARD TO THE NEXT SIX MONTHS. IF THEY'RE AS
24 PRODUCTIVE AS THE YEARS HAVE BEEN TO DATE, WE'LL BE IN
25 ASTOUNDING GREAT SHAPE. SO WE THANK YOU.

1 MS. LANSING: AND WE'LL LOOK FORWARD TO
2 SAYING LOTS OF VALEDICTORY REMARKS, WHICH ALL OF US
3 DESPERATELY WANT TO SAY, BUT YOU HAVE TOLD US WE CAN'T.
4 LET THE RECORD SHOW THAT EVERY SINGLE MEMBER HERE WANTS
5 TO SAY EXTRAORDINARILY VALEDICTORY REMARKS, BUT I GUESS
6 WE'LL WAIT FOR SIX MONTHS TO DO IT.

7 DR. HALL: WE'LL HAVE REMARKS ON BOTH SIDES.
8 I HAVE SOME THINGS I WANT TO SAY ALSO ABOUT HOW MUCH
9 I'VE ENJOYED WORKING WITH ALL OF YOU, BUT WE'RE NOT
10 THERE YET. THIS IS JUST AN ANNOUNCEMENT OF WHERE WE
11 WILL BE SOMETIME IN THE FUTURE, AS I SAY, TO LET THE
12 PROCESS BEGIN TO FIND A SUCCESSOR WHO WILL LEAD THIS
13 WONDERFUL ORGANIZATION, THIS WONDERFUL PROJECT ON INTO
14 ITS NEXT PHASE.

15 MS. LANSING: CAN I JUST SAY ONE THING THAT
16 IS NOT -- I JUST HAVE TO SAY THIS BECAUSE THIS IS NOT
17 JUST ABOUT YOU, BUT I KNOW WE'RE GOING TO GET INTO THE
18 SCIENTIFIC GRANT THING. IT WAS JUST EXTRAORDINARY WHAT
19 YOU AND ARLENE AND EVERYBODY IN THE STAFF DID WITH THE
20 GRANTS, SO IT'S NOT REALLY A VALEDICTORY REMARK. IT'S
21 JUST A CONFIRMATION OF WHAT YOU SAID. JUST TO SAY THAT
22 THOUGH THERE ARE THESE TIMES WHERE PEOPLE ARE
23 ANNOUNCING THAT THEY'RE LEAVING, I THINK WHAT YOU SAID
24 IS CORRECT. EVERYBODY HAS BEEN SO MINDFUL -- I'VE BEEN
25 TWISTING ZACH NOT TO LEAVE FOR A YEAR, DO YOU KNOW, AND

1 AS HE TURNED CLOSE TO 70. SO I THINK EVERYBODY NOW
2 FEELS THAT WE'RE IN GOOD SHAPE AND THE ORGANIZATION CAN
3 CONTINUE. SO I'M GRATEFUL.

4 CHAIRMAN KLEIN: I'D ALSO SAY THAT DR. HALL
5 WAS CORRECT. I'M NOT GOING TO CROSS THE VALEDICTORY
6 REMARKS, BUT I'D LIKE TO SAY DR. HALL IS CORRECT, THAT
7 THE SCIENTIST MENTIONED ON OUR PEER REVIEW COMMITTEE
8 WAS, IN FACT, EXTREMELY PLEASED AND THOUGHT IT WAS A
9 MODEL OF HOW THIS PORTFOLIO BALANCING PART OF IT WORKED
10 WITH THE PATIENT ADVOCATES AND THE SCIENTISTS BOTH
11 PARTICIPATING. AND THE WHOLE PROCESS, HE ACTUALLY SAID
12 THAT HE THOUGHT THAT -- HE WISHED SOMEONE WERE TAKING
13 NOTES THAT COULD BE PUBLISHED ON THE OVERALL PROCESS
14 BECAUSE HE THOUGHT THIS WAS AN INNOVATIVE PROCESS THAT
15 SHOULD BE A MODEL FOR OTHER STATES.

16 DR. HALL: NEXT ITEM?

17 CHAIRMAN KLEIN: ARE WE PREPARED TO GO TO THE
18 NEXT ITEM? AND DR. HALL.

19 DR. HALL: YOU SCARED ME FOR A MOMENT THERE.
20 I AM NOT GOING TO TALK ABOUT INTELLECTUAL PROPERTY.

21 CHAIRMAN KLEIN: DR. HALL WILL ADDRESS THE
22 SCIENTIFIC STRATEGIC PLAN.

23 DR. HALL: OUR IP ACE WILL TAKE CARE OF THAT.

24 DR. MURPHY: ZACH, CAN I JUST ASK ONE. BOB,
25 MAY I JUST GO BACK FOR JUST ONE SECOND ON THE GRANTS

1 PROGRAM? ZACH, AS YOU WELL KNOW, ONE OF THE PROBLEMS
2 WE HAVE IS WE'RE GOING TO BE FUNDING THE COMPREHENSIVE
3 GRANTS AND SEED GRANTS IN THE SPRING, BUT THE RFA FOR
4 THE FACILITIES IS GOING TO GO A LITTLE BIT LATER.
5 THAT'S NOT GOING TO BE FUNDED TILL JUNE, AND THEN THOSE
6 ORGANIZATIONS THAT GET FUNDED ON FACILITIES GRANTS ARE
7 THEN GOING TO HAVE THE MONEY TO DO THE SMALL
8 FACILITIES. WHAT THAT LOOKS LIKE TO ME IS MAYBE A
9 THREE-, FOUR-, FIVE-MONTH LAG. AND CERTAINLY BETWEEN
10 THE TIME WHEN THE GRANTS ARE FUNDED AND THE FACILITIES
11 ARE AVAILABLE, IT'S GOING TO BE SIX OR SEVEN MONTHS,
12 AND WE'RE GOING TO HAVE A LOT OF FOLKS WHO ARE FUNDED,
13 BUT WITHOUT THE FACILITIES TO DO THE WORK. IT GOES
14 BACK TO BOB'S COMMENTS AT THE VERY BEGINNING.

15 IS THERE A WAY THAT WE CAN WORK THIS OUT SUCH
16 THAT THOSE FOLKS WHO WILL BE FUNDED WILL HAVE AN
17 OPPORTUNITY OR THEIR INSTITUTIONS WILL HAVE AN
18 OPPORTUNITY TO CREATE THE SPACE THAT THEY'RE GOING TO
19 NEED TO DO THEIR WORK? BECAUSE MY FEAR IS THAT IF
20 THEY'RE SHUT DOWN FOR SIX OR SEVEN MONTHS UNTIL THE
21 FACILITIES ARE READY IS GOING TO BE A LACK OF PROGRESS,
22 THERE'S GOING TO BE GREAT FRUSTRATIONS, ETC. IS THERE
23 SOME CREATIVE WAY THAT WE CAN DEAL WITH THAT PROBLEM?

24 DR. HALL: WE'RE MINDFUL OF THAT, AND WE WILL
25 CERTAINLY LOOK AT THAT QUESTION. AND I APPRECIATE YOUR

1 COMMENT ON IT. IT'S JUST WE HAD THE CHOICE OF DELAYING
2 THE SEED GRANTS OR OF GOING AHEAD. AND I THINK WE WILL
3 CERTAINLY LOOK AT POSSIBLE SOLUTIONS OR WAYS IN WHICH
4 WE MIGHT HELP, BUT IT'S ALSO TRUE THAT MOST
5 INSTITUTIONS HAVE SOME RESOURCES. RATHER THAN WAIT AND
6 NOT PUT THE MONEY OUT THERE UNTIL THE SPACE WAS
7 ACTUALLY ALREADY DEVELOPED, WE THOUGHT WE SHOULD GO
8 AHEAD AND LET INSTITUTIONS, EVEN IF THEY HAVE TO MAKE
9 SOME TEMPORARY ARRANGEMENT, THAT IS THE CHOICE.

10 AS YOU KNOW, WE HAVE NOT HAD FACILITIES
11 EXPERTISE. WE NOW HAVE LORI HOFFMAN, WHO BRINGS
12 EXPERIENCE IN THAT AREA. AND WE HOPE VERY SOON TO HAVE
13 A SENIOR FACILITIES, SOMEBODY WITH EXTENSIVE
14 EXPERIENCE. AND I THINK FOR US EVEN PUTTING TOGETHER
15 THE RFA HAS PROVED TO BE A CHALLENGE. IT'S JUST A NEW
16 KIND OF ACTIVITY. IT HAS THE COMPLICATION IT HAS TO BE
17 REVIEWED BY TWO DIFFERENT GROUPS. AND SO COORDINATING
18 ALL THAT. ALSO INSTITUTIONS THEMSELVES, WE FOUND OUT,
19 CAN'T PUT THESE TOGETHER ON A DIME. PARTICULARLY I
20 MIGHT ADD THE LARGER THE ORGANIZATION, THE MORE
21 DIFFICULT IT IS TO DO THIS IN A QUICK AND TIMELY WAY.
22 SO WE WILL HAVE TO GIVE SOME TIME LAG TO THAT. SO WE
23 WILL CERTAINLY CONSIDER SOME ALTERNATIVES, BUT I THINK
24 THE BASIC PARAMETERS WE CAN'T DO MUCH ABOUT BECAUSE
25 WE'RE TRYING TO DO THINGS AS QUICKLY AS POSSIBLE, BUT

1 CAN ONLY DO SO MUCH.

2 THE LAST THING WE WANT TO DO IS TO PUT OUT A
3 SHODDY PRODUCT, AN RFA THAT HAS NOT BEEN WELL THOUGHT
4 THROUGH. THEN WE'RE IN TROUBLE.

5 DR. MURPHY: I APPRECIATE THAT. IT WOULD BE
6 GREAT IF THERE COULD BE SOME ALTERNATIVE THAT WE MIGHT
7 CONSIDER IN THE INTERIM BECAUSE FOR MANY OF US THAT IS
8 A BIG NUMBER TO PUT OUT THERE WITHOUT ANY GUARANTEE
9 THAT IT'S GOING TO BE COVERED.

10 DR. HALL: ALL RIGHT. LET'S MOVE ON. WE
11 BRING TO YOU A REVISED SCIENTIFIC STRATEGIC PLAN BASED
12 ON YOUR COMMENTS FROM BEFORE. AND I ASK THAT YOU TURN
13 TO ITEM 7. ACTUALLY YOU EACH SHOULD HAVE A COPY OF THE
14 REVISED PLAN; IS THAT CORRECT? AND YOU ALSO SHOULD
15 HAVE UNDER TAB 7 A QUICK RUN-THROUGH OF THE CHANGES
16 THAT WE HAVE MADE SINCE THE OCTOBER DRAFT THAT YOU
17 CONSIDERED BEFORE.

18 WE HAVE RESPONDED IN THIS DRAFT TO
19 SUGGESTIONS BY THE ICOC AT THE OCTOBER MEETING, TO SOME
20 SUGGESTIONS FROM CIRM STAFF, INTERNAL SUGGESTIONS AND
21 CRITICISMS, AND ALSO TO SUGGESTIONS FROM THE PUBLIC.
22 AND I DON'T WANT TO GO OVER THESE IN GREAT DETAIL, BUT
23 I WOULD LIKE TO JUST HIT THE HIGHLIGHTS FOR YOU.

24 THE FIRST THING THAT WE DID WAS TO COMPLETELY
25 REWRITE THE EXECUTIVE SUMMARY. I HOPE YOU WILL FIND IT

1 MORE READABLE AND MORE INTERESTING. AND WHAT WE'VE
2 DONE IS NOT SIMPLY TO RECAPITULATE IN FORM. IT'S NOT
3 JUST A CONDENSED FORM OF THE MAIN BODY OF IT, BUT IS IN
4 SOME SENSE A NEW DOCUMENT. ONE OF THE THINGS THIS GAVE
5 US AN OPPORTUNITY TO DO WAS TO RESPOND TO DON REED'S
6 COMMENT THAT WE SHOULD EMPHASIZE THE ASPIRATIONAL GOALS
7 THAT WE HAVE, AND WE HOPE IN THE EARLY PART OF THIS
8 THAT THIS SERVES THAT FUNCTION AND REALLY HOLDS OUT AND
9 HIGHLIGHTS SOME OF THE LONG-TERM PROMISE OF STEM CELL
10 RESEARCH THAT HAS US ALL SO EXCITED.

11 WE LISTED ICOC NAMES ON THE INSIDE COVER, AS
12 BOB KLEIN SUGGESTED. AND WE HAVE ALSO IN THE BACK THE
13 ICOC LISTING. BOTH BOB KLEIN AND CLAIRE POMEROY
14 POINTED OUT AN OMISSION THAT WE HAD MADE, I GUESS, IS
15 THE EASIEST WAY TO CALL IT; THAT IS, THAT WE HAD NOT
16 ADEQUATELY SIGNALLED OUR INTEREST IN A BROAD RANGE OF
17 STEM CELL RESEARCH THAT WOULD INCLUDE ADULT STEM CELLS,
18 CORD CELLS, AND FETAL CELLS, CELLS FROM FETAL TISSUE.
19 AND WE HAVE NOW AMENDED THAT. EXACTLY WHERE THESE
20 THINGS HAVE BEEN DONE ARE SHOWN ON THIS TABLE. I WON'T
21 GO THROUGH THEM ALL. SOMEBODY ON OUR STAFF POINTED OUT
22 THAT WE HAD OMITTED CANCER STEM CELLS, WHICH IS, OF
23 COURSE, A VERY IMPORTANT ISSUE IN THE SENSE THAT THEY
24 SORT OF CHANGED THE WAY WE THINK ABOUT CANCER, SO WE
25 PUT A SHORT SECTION IN ON THAT.

1 AND THEN THE BIGGEST CHANGE IS THE
2 IMPLEMENTATION PLAN. SO I WOULD LIKE TO GO INTO THAT
3 IN SOME DETAIL, BUT LET ME ASK FIRST IF ANYBODY HAS ANY
4 QUESTIONS ON THE CHANGES THAT HAVE BEEN MADE TO THE
5 MATERIAL THAT'S ALREADY THERE?

6 IF NOT, THEN PERHAPS WE'LL MOVE ON TO THE
7 IMPLEMENTATION PLAN. AND ONCE AGAIN, I WANT TO THANK
8 PATRICIA OLSON, WHO IS STANDING BY MY SIDE HERE IN CASE
9 I SAY THE WRONG THING. TONY PILLARI REPRESENTING PRICE
10 WATERHOUSE COOPERS, ON A SEPARATE PROJECT THEY HAVE
11 HELPED US PUT TOGETHER THIS IMPLEMENTATION PLAN, WHICH
12 WAS EXTREMELY IMPORTANT FOR US.

13 WE CALL IT A "FAST START, THE FIRST 1,000
14 DAYS." I GUESS THAT LATTER PHRASE IS GETTING A LOT OF
15 PLAY THESE DAYS AFTER THE RECENT ELECTIONS, BUT AT ANY
16 RATE, OR VARIANCE ON IT. AND OUR THOUGHT IS THAT IT'S
17 IMPERATIVE THAT WE MOVE QUICKLY AS SOON AS WE HAVE
18 FUNDS BECAUSE OF THE DELAY THAT WE'VE HAD THAT HAS BEEN
19 UNAVOIDABLE. WE HAVE NOT BEEN ABLE TO GET THIS GOING
20 AS QUICKLY AS WE WANTED. SO WE WANT TO IMPLEMENT THE
21 PLAN AS QUICKLY AS POSSIBLE, AND WHAT LIMITS IS THE
22 TIMING OF THE PUBLIC BONDS, WHEN THOSE WILL BE
23 AVAILABLE, OUR ABILITY TO RAMP UP CIRM STAFF. AND I
24 CAN TELL YOU ONE OF THE CHALLENGES FOR THIS LAST TIME
25 IS THAT IT TAKES TIME TO HIRE PEOPLE, AND THEN THEY

1 CAN'T DROP WHAT THEY'RE DOING AND COME IMMEDIATELY.
2 ALTHOUGH I LISTED THOSE THREE STAFF, THEY HAVE JUST
3 ARRIVED AND ARE NOT REALLY ABLE TO HELP VERY MUCH IN
4 WHAT WE'RE DOING. SO THAT JUST TAKES A LITTLE TIME.

5 AND FINALLY, WE CONTINUE TO FACE THE
6 CHALLENGE OF GETTING OUR INFORMATION TECHNOLOGY AND
7 OTHER INFRASTRUCTURE UP. IN PARTICULAR, WE NEED TO BE
8 READY WHEN WE AWARD FUNDS TO BE ABLE TO HAVE ALL THE
9 SYSTEMS IN PLACE TO BE ABLE TO TRACK THE FUNDS AND TO
10 BE ABLE TO PROVIDE AN ACCOUNTING OF WHERE WE ARE AND
11 WHAT WE'RE DOING. SO THOSE ARE ALL LIMITATIONS TO WHAT
12 WE'RE DOING.

13 LET ME REVIEW FIRST THE -- WE DID AN ANALYSIS
14 OF HOW LONG IT TAKES TO DO AN RFA FROM ICOC CONCEPT
15 APPROVAL TO APPROVAL FOR FUNDING. AND DEPENDING ON THE
16 PARTICULAR GRANT AWARD, DEPENDING ON SCHEDULES, WHICH
17 ARE DIFFICULT, THIS CAN TAKE FROM SIX TO EIGHT MONTHS.
18 THIS STILL FALLS UNDER THE NIH LINE, WHICH IS NINE OR
19 MORE. BUT IT DEPENDS OBVIOUSLY ON HOW LARGE AND HOW
20 COMPLEX THE GRANTS ARE, FOR EXAMPLE. THE SHARED
21 FACILITIES AWARDS ARE GOING TO HAVE TO BE REVIEWED BY
22 TWO GROUPS, WHICH MAKES IT A LITTLE MORE DIFFICULT TO
23 DO. ON THE OTHER HAND, THOSE ARE IN SOME WAYS FOR THE
24 RENOVATIONS RELATIVELY SIMPLE REVIEWS IN A WAY. SO
25 THAT IS VERY VARIABLE.

1 NOW, THE OTHER POINT IS THAT GIVEN THIS
2 SCHEDULE, WE WOULD LIKE TO BEGIN ISSUING RFA'S BEFORE
3 THE PUBLIC BOND MONEY BECOMES AVAILABLE. LET ME SAY
4 THAT OUR ESTIMATE FOR THIS NOW IS -- AGAIN, I'D BE
5 HAPPY TO BE CORRECTED BY JAMES OR ANYONE ELSE -- BUT MY
6 READING OF IT IS THAT THE EARLIEST TIME WE WOULD HAVE
7 FUNDS AVAILABLE FROM THE PUBLIC BOND FUNDS WOULD BE THE
8 SUMMER OF 2007, AND THE LATEST TIME IS PROBABLY VERY
9 EARLY 2008. SO THOSE ARE THE BRACKETS WITHIN WHICH WE
10 WORK, WHICH DEPENDS REALLY ON WHETHER OR NOT THERE IS
11 AN APPEAL AND WHETHER THE SUPREME COURT AGREES TO HEAR
12 IT. IS THAT REASONABLE, JAMES OR BOB? JAMES, I CAN
13 SEE ALREADY, DOESN'T WANT TO BE -- DOESN'T WANT TO
14 COMMIT ON ANY OF THIS.

15 MR. HARRISON: I THINK THE BEST-CASE SCENARIO
16 IS REASONABLE. WORST-CASE SCENARIO --

17 DR. HALL: IS LONGER THAN THAT.

18 MR. HARRISON: -- IS PERHAPS LONGER THAN
19 THAT.

20 CHAIRMAN KLEIN: AS AN AGENCY, GIVEN THE
21 DESPERATE NEED FOR FUNDING THAT'S THERE AND BRILLIANT
22 IDEAS THAT HAVE SURFACED CERTAINLY IN THIS FIRST ROUND
23 AND I BELIEVE WILL BE FULFILLED AGAIN IN THE SECOND
24 ROUND, WORKING OFF OF THE BEST CASE, WE'RE ABLE TO MOVE
25 THOSE GRANTS FORWARD. AND, THEREFORE, IF WE ARE

1 FORTUNATE, WE WILL HAVE THE MONEY AT THE EARLIEST DATE.
2 WORKING OFF OF THE WORST CASE IS SELF-DEFEATING.
3 WORKING OFF THE BEST CASE REALLY REINFORCES OUR MISSION
4 AND HELPS SUPPORT THE SCIENTISTS AND THE INSTITUTIONS.

5 DR. HALL: SO FOR THE PURPOSES OF THIS PLAN,
6 WHAT WE HAVE DONE IS TO REALLY ASSUME THAT FUNDS WOULD
7 PROBABLY BE AVAILABLE AT THE BEGINNING OF 2008, AND
8 THIS WOULD BE, AS WE CALL IT, YEAR ONE IN THE PLAN.
9 NOW, NOT YEAR ONE FOR OUR EXISTENCE, BUT YEAR ONE IN
10 THE PLAN. AND IF WE WERE TO HAVE THE MONEY AVAILABLE
11 AT THE EARLIEST DATE, THEN I DON'T THINK WE WOULD BE
12 ABLE TO PREPARE MUCH FOR IT BECAUSE OF THE LIMITATIONS
13 THAT I MENTIONED BEFORE. BUT PARTICULARLY IF IT'S THE
14 LATER DATE, OUR DESIRE WOULD BE TO GO AHEAD AND BEGIN
15 ISSUING RFA'S, GO AHEAD AND HAVE OUR REVIEW COMMITTEES
16 AND HAVE APPROVAL, JUST AS WE DID WITH THE TRAINING
17 GRANTS, SO THAT EVERYTHING IS ALL TEED UP AND READY TO
18 GO. AND WHEN THE MONEY COMES IN, WE CAN START SENDING
19 THE CHECKS OUT THE DOOR. THAT WILL GET US STARTED AS
20 QUICKLY AS POSSIBLE.

21 AGAIN, WE WILL HAVE TO DO SOME RAMP-UP. AND
22 THEN ACCORDING TO THE KINDS OF CONSIDERATIONS THAT WE
23 WERE JUST TALKING ABOUT IN RESPONSE TO BRIAN
24 HENDERSON'S QUESTION, WE MAY OR MAY NOT HAVE SOME MONEY
25 LEFT OVER FROM THE CURRENT MONEY WE HAVE FROM THESE

1 COMMITMENTS THAT WOULD ALLOW US TO START YET ANOTHER
2 PROGRAM BEYOND THE ONES THAT WE HAVE NOW. SO THAT
3 WOULD DEPEND ON WHETHER OR NOT IF YOU OBVIOUSLY CHOOSE
4 TO INCREASE THE AMOUNT WE GIVE TO SEED GRANTS, THEN
5 THERE WOULD BE LESS FOR THAT. I THINK WE JUST HAVE TO
6 WAIT AND SEE FOR THAT. THERE'S NO WAY TO ANTICIPATE
7 THAT OR TO MAKE JUDGMENT NOW. I JUST WANTED TO POINT
8 THAT OUT TO YOU.

9 SO THEN THE QUESTION IS WHAT ARE OUR
10 PRIORITIES? AND THOSE ARE LISTED IN THE FAST START
11 SECTION WITH A LITTLE DISCUSSION ON EACH ONE. I'M NOT
12 GOING TO GO THROUGH ALL OF THEM, BUT I WANT TO MENTION
13 THEM BRIEFLY. FIRST OF ALL, WE CONTINUE TO BELIEVE
14 THAT INVESTMENT IN INTELLECTUAL CAPITAL, EARLY
15 INVESTMENT IN INTELLECTUAL CAPITAL, IS VERY, VERY
16 IMPORTANT. AS YOU KNOW, WE HAVE A PROGRAM THAT WOULD
17 FUND BEGINNING FACULTY, BOTH CLINICAL AND BASIC
18 SCIENCE, AND WOULD HELP THEM GET STARTED WITH SOME HELP
19 FOR SALARY AND HELP FOR RESEARCH. AND IF WE'RE GOING
20 TO DO THAT, NOW IS THE TIME TO DO IT EARLY ON. THOSE
21 ARE RELATIVELY SIMPLE GRANTS COMPARED TO OTHERS, AND WE
22 THINK WE COULD DO THOSE FAIRLY QUICKLY.

23 NOW, WE HAVE ANOTHER ISSUE THAT CAME UP
24 ACTUALLY OUT OF A DISCUSSION THAT WE HAD IN THE UK, AND
25 IT WAS NOT TIMED TO PUT THIS IN THE STRATEGIC PLAN THAT

1 YOU HAVE. BUT IF YOU ARE AGREEABLE, WE CAN ADD THAT.
2 AND HERE'S THE IDEA, THAT WE MIGHT OFFER A PROGRAM THAT
3 WOULD LET PEOPLE BRING SCHOLARS AND CLINICIANS FROM
4 OUTSIDE CALIFORNIA, OUTSIDE THE COUNTRY, ANYWHERE IN
5 THIS COUNTRY OR ABROAD, TO CALIFORNIA FOR A PERIOD OF
6 SIX MONTHS TO A YEAR ON A KIND OF SABBATICAL. AND WE
7 WOULD PAY SOME PORTION OF THEIR SALARY AND PROVIDE A
8 MODEST RESEARCH EXPENSE FOR THEM. WE'RE NOT GOING TO
9 OUTFIT A LAB FOR THEM, BUT WE'D PROVIDE, SAY, FOR A
10 TECHNICIAN AND SOME SUPPLIES THAT WOULD LET THEM WORK.

11 WE THINK THIS WOULD DO TWO THINGS, MAYBE
12 THREE THINGS. NO. 1 IS WE THINK THIS WOULD BE
13 WONDERFUL FOR ESTABLISHING COLLABORATIONS. BRING
14 SOMEBODY HERE, LET THEM WORK FOR A WHILE IN A LAB HERE,
15 AND THEN THIS WOULD THEN SET THE GROUNDWORK FOR A
16 COLLABORATIVE ENTERPRISE LATER. NO. 2, WE THINK THIS
17 MIGHT HELP SOME INSTITUTIONS IN A RECRUITING MODE.
18 SOMEBODY COMES, STAYS SIX MONTHS, A YEAR, DECIDES THEY
19 LIKE IT HERE, THEN THAT'S TERRIFIC. AND WE THINK THAT
20 WOULD BE VERY HELPFUL.

21 AND THEN I THINK THE THIRD THING IS THAT IF
22 WE WERE TO DO THIS, I THINK THERE WOULD BE OTHER
23 ORGANIZATIONS THAT WOULD SET UP RECIPROCAL PROGRAMS
24 THAT WOULD PROVIDE AN OPPORTUNITY FOR SOME OF OUR
25 PEOPLE TO GO TO OTHER STATES OR TO GO ABROAD IN ORDER

1 TO LEARN SPECIFIC TECHNIQUES OR TO CONTINUE THESE
2 COLLABORATIONS. THAT IS, IT'S CLEAR WE CANNOT FUND
3 OUTSIDE OF CALIFORNIA, BUT WE CAN FUND PEOPLE WHO WOULD
4 COME HERE, AND WE THINK THAT THERE WOULD BE INTEREST IN
5 OTHER ORGANIZATIONS IN DOING THE OPPOSITE.

6 SO WE HAVE NOT DEVELOPED THIS; BUT IF YOU
7 AGREE THAT THIS IS A GOOD IDEA, WE WOULD ADD IT TO THE
8 STRATEGIC PLAN, AND THEN WE WOULD GO AHEAD AND DEVELOP
9 AN RFA AND BRING IT TO YOU FOR CONCEPT APPROVAL AND
10 HAVE IT ALL DRESSED OUT. SO I LEAVE THAT AS A
11 QUESTION, AND I WOULD LIKE, AGAIN, SOME -- WHEN YOU
12 FINALLY VOTE ON THE STRATEGIC PLAN OR WHATEVER, TAKE
13 ACTION ON IT, PLEASE SAY THAT'S IN OR OUT.

14 NEXT, AS BOB KLEIN HAS SAID AND AS RICH
15 MURPHY'S REMARKS HAVE EMPHASIZED, THERE'S A HUGE NEED
16 FOR FACILITIES. THEY TAKE TIME. THE SOONER THE BETTER
17 WE GET STARTED ON THOSE. SO LARGE-SCALE FACILITIES
18 SHOULD BE VERY EARLY.

19 A FOURTH ONE IS PRECLINICAL DEVELOPMENT. WE
20 THINK THAT THERE MAY BE SOME OPPORTUNITIES OUT THERE TO
21 FUND WORK THAT IS READY FOR PRECLINICAL DEVELOPMENT.
22 WE OBVIOUSLY PLAN ON SPENDING MOST OF OUR MONEY IN THE
23 MIDPORTION OF THE TEN YEARS. MOST OF THE PRECLINICAL
24 DEVELOPMENT, WE THINK THAT WILL PEAK IN THE MIDPORTION,
25 BUT WE THINK THERE ARE THINGS OUT THERE NOW. AND THE

1 IDEA WOULD BE TO START IN A SMALL WAY FUNDING -- HAVE
2 AN EXPECTATION OF FUNDING UP TO A FEW GRANTS, WHATEVER
3 THAT MIGHT BE, SEE WHAT COMES UP, AND THAT WILL HELP
4 US, I THINK, ESTIMATE WHAT'S OUT THERE AND WHAT'S IN
5 DEVELOPMENT. SOME OF THIS IS IN PRIVATE COMPANIES, AND
6 WE DON'T ALWAYS KNOW EXACTLY WHAT STAGE THINGS ARE.
7 AND I THINK THIS WOULD BE AN OPPORTUNITY FOR EITHER
8 PRIVATE COMPANIES OR ACADEMIC-PRIVATE PARTNERSHIPS, HOW
9 MUCH THERE WOULD BE IN ACADEMIC INSTITUTIONS GOING IT
10 ALONE, I'M NOT SURE, BUT IF WE ARE TO MEET OUR FIVE-
11 AND TEN-YEAR GOALS, WE NEED TO GET THIS WORK STARTED;
12 AND, WHEREAS, WE THINK THE BULK OF IT WILL COME LATER,
13 WE'D LIKE TO GET STARTED NOW RATHER THAN WAIT LATER IF
14 THERE IS WORK OUT THERE THAT'S READY FOR PRECLINICAL
15 DEVELOPMENT.

16 SO THOSE ARE THE FIRST SET OF PRIORITIES.
17 AND NEXT, TRANSLATIONAL RESEARCH, VERY IMPORTANT. AND
18 WE, AS YOU RECALL, HAVE A PHASE I, PHASE II; THAT IS,
19 WE GET PEOPLE STARTED WITH THE PART 1 WITH MILESTONES.
20 IF THEY MAKE GOOD ON THAT, THEN WE FUND THEM LATER PART
21 2.

22 BIOLOGY OF STEM CELLS WE BADLY NEED, AS WE
23 ALL KNOW, MORE INFORMATION ABOUT HOW STEM CELLS WORK.
24 WE WANT TO DO THIS EARLY RATHER THAN LATER. NOW, HERE
25 COMES AN INTERESTING ISSUE. WE HAVE TWO RFA'S THAT ARE

1 VERY SPECIFIC AND ARE CLEAR-CUT NEEDS, THERE IS NO
2 DOUBT ABOUT IT, TO CREATE DISEASE-SPECIFIC CELL LINES
3 AND ALSO TO CREATE ALTERNATIVE DERIVATION METHODS.

4 NOW, SOME OF THE GRANTS THAT WILL COME
5 THROUGH IN THE SEED GRANTS PROGRAM AND THE
6 COMPREHENSIVE GRANTS PROGRAM MAYBE ALSO IN THE EARLY,
7 THE YOUNG SCIENTIST, YOUNG CLINICIAN AWARDS. SOME OF
8 THAT WILL FALL INTO THIS CATEGORY. AND WE ALREADY KNOW
9 FROM THE SEED GRANTS THAT THERE WILL BE AT LEAST SOME
10 THERE. AND WE ALSO, IF WE HAVE A BIOLOGY OF STEM
11 CELLS, WHICH IS AN OPEN-ENDED PROJECT, WE MAY FIND --
12 WE WILL GRADUALLY EDUCATE OURSELVES AS TO WHO IS DOING
13 THIS IN THE STATE, WHAT THE INTEREST IS, WHAT THE LEVEL
14 OF QUALITY IS, AND WE MAY FIND AT THE END OF THAT THAT
15 ACTUALLY WE DON'T NEED TO HAVE A SPECIFIC RFA, THAT WE
16 ALREADY THROUGH THESE OTHER MECHANISMS ARE FUNDING
17 ENOUGH GOOD WORK IN THESE AREAS, AND WE JUST CAN'T TELL
18 FROM THE APPLICATIONS THAT HAVE COME IN OR FROM OUR OWN
19 PERSONAL INFORMATION, THERE'S JUST NOT THAT MUCH MORE
20 OUT THERE TO DO. THESE MAY OR MAY NOT BE NEEDED.

21 ON THE OTHER HAND, WE MAY GO THROUGH THIS AND
22 SAY, GEE, THERE'S STILL GOOD WORK OUT THERE THAT WE
23 THINK COULD BE FUNDED. LET'S HAVE AN RFA, CALL IT OUT
24 SPECIFICALLY, AND SEE IF IT MEASURES UP. I THINK THESE
25 ARE THE KINDS OF CHOICES, AS YOU GO THROUGH THIS, AS WE

1 LEARN ABOUT WHO'S DOING WHAT IN THE STATE, WHAT THE
2 CAPABILITIES ARE, WE WILL BE ABLE TO MAKE THESE
3 DECISIONS GOING FORWARD.

4 AGAIN, TOOLS AND TECHNOLOGIES, PLANNING
5 GRANTS FOR DISEASE TEAMS, THESE WILL BE LARGE COMPLEX
6 EXERCISES, AND WE WANT TO OFFER GRANTS THAT LET PEOPLE
7 BEGIN PLANNING FOR THEM. AND THE TIME TO DO THAT IS
8 EARLY, NOT LATER.

9 STEM CELL BANK, WE NEED TO GET STARTED ON
10 THAT IF WE'RE GOING TO DO IT AS WELL AS THE KNOWLEDGE
11 BASE. AND FINALLY, STEM CELL RESEARCH AND SOCIETY, OUR
12 ETHICAL, LEGAL, AND SOCIAL THINGS. SO THESE ARE THE
13 THINGS THAT WE SEE OURSELVES BEING INTERESTED IN OVER
14 THE NEXT ROUGHLY 18 MONTHS.

15 SO LET'S NOW TALK SPECIFIC SCHEDULES. WE
16 IMAGINE OR PROPOSE THAT WE WILL ISSUE BETWEEN NOW AND
17 JUNE THE SHARED RESEARCH LABORATORIES, STEM CELL
18 TECHNIQUES COURSE RFA, WHICH WE'VE ALREADY TALKED
19 ABOUT. AND WE WILL DO OUR BEST TO GET THAT OUT AS SOON
20 AS POSSIBLE. WE THINK WE CAN DO IT IN JANUARY.

21 NO. 2, THE LARGE-SCALE RESEARCH FACILITIES,
22 WHICH YOU'VE ALREADY DISCUSSED, WE WANT TO GET THAT
23 GOING. SCIENTIFIC PERSONNEL DEVELOPMENT, WE WOULD
24 SUGGEST WOULD BE SOMETHING WE COULD DO EASILY, EARLY,
25 AND THEN THE PRECLINICAL PRODUCT DEVELOPMENT. AND IF

1 WE COULD DO THAT -- THAT'S THREE NEW RFA'S. IF WE
2 COULD GET THAT DONE AND EVERYTHING ELSE IN THE NEXT SIX
3 MONTHS WITH THE PERSONNEL THAT WE HAVE, I THINK WE'D BE
4 DOING VERY WELL INDEED.

5 THEN WE WERE PROJECTING -- IT'S NOT DETAILED
6 AS MUCH -- BUT OVER THE NEXT SIX MONTHS AFTER THAT
7 THEN, THESE WOULD BE RFA'S THAT WE WOULD CONSIDER:
8 TOOLS AND TECHNOLOGIES, BIOLOGY OF STEM CELLS, STEM
9 CELL RESEARCH AND SOCIETY, TRANSLATIONAL, DISEASE TEAM
10 TRAINING GRANTS, AND THEN I FAILED TO MENTION TECHNICAL
11 SUPPORT WHEN I SAID INVESTING IN HUMAN CAPITAL. WE
12 VERY MUCH WANT TO START TRAINING PEOPLE WHO CAN PROVIDE
13 TECHNICAL SUPPORT FOR THE WORK THAT WILL GO ON AND ALSO
14 A PROGRAM OF INTERNSHIPS.

15 NOW, HOW WILL THIS PLAY OUT IN TERMS OF THE
16 REVIEW? WE'VE ALREADY SAID THAT THE COMPREHENSIVE
17 GRANTS WE WILL REVIEW IN JANUARY. THE SHARED RESEARCH
18 LABORATORIES WE ARE NOW PLANNING FOR MAY/JUNE. I'M
19 SORRY. THAT'S APRIL/MAY. I BEG YOUR PARDON. ANYHOW,
20 LET'S SAY MAY. WE WANT TO BRING IT TO JUNE ICOC, SO
21 THAT WILL BE REVIEWED APRIL/MAY. I BEG YOUR PARDON ON
22 THAT. AND THEN SCIENTIFIC PERSONNEL DEVELOPMENT WOULD
23 BE JUNE/JULY THAT WE WOULD TRY TO REVIEW THAT THEN.

24 AND THEN IN THE SECOND HALF OF 2007, WE WOULD
25 HAVE REVIEWS FOR THE FOLLOWING: OUR RESEARCH

1 FACILITIES, PRECLINICAL PRODUCT DEVELOPMENT, TOOLS AND
2 TECHNOLOGIES, AND RESPONSIBILITY TO THE PUBLIC. ALL OF
3 THOSE WE WOULD TRY TO GET GOING. OKAY.

4 THEN HOW DOES THAT WORK OUT IN TERMS OF THE
5 ICOC FUNDING APPROVALS? WE WILL APPROVE IN FEBRUARY
6 THE SEED GRANTS, COMPREHENSIVE GRANTS. I MEANT TO
7 CHECK WITH MELISSA BEFORE THAT, BUT WE'RE PLANNING AN
8 APRIL MEETING; ISN'T THAT CORRECT?

9 MS. KING: ACTUALLY MARCH.

10 DR. HALL: MARCH MEETING. I COULDN'T
11 REMEMBER WHICH OF THOSE. AND THEN IN JUNE WE WILL HOPE
12 TO DO THE SHARED RESEARCH LABORATORIES.

13 AND THE NEXT SLIDE THEN SHOWS THE FUNDING
14 APPROVALS THAT WE WOULD EXPECT TO DO OVER THE NEXT SIX
15 MONTHS AFTER THAT. OKAY.

16 SO WHAT DOES ALL THIS MEAN? FIRST OF ALL, IT
17 MEANS WE HAVE A HUGE RAMP-UP JOB TO DO. THIS IS A
18 DAUNTING SCHEDULE OF REVIEWS AND APPROVALS, AND WE WILL
19 NEED TO IMPROVE OUR -- HOW TO PUT IT -- WE WILL NEED TO
20 UPGRADE, IF YOU WILL, OUR ACTIVITIES IN ALMOST EVERY
21 SPHERE IN ORDER TO HANDLE THIS WIDER BAND WIDTH; THAT
22 IS, IN TERMS OF OUR STAFF, IN TERMS OF HOW WE HANDLE
23 OUR REVIEWS, EVEN, AS WE'LL DISCUSS IN A MOMENT, HOW WE
24 HANDLE THESE AT ICOC MEETINGS. SO ALL OF THIS WILL
25 HAVE TO BE DONE, PLUS WE NEED TO GET OUR I.T. IN GOOD

1 SHAPE. AND BASICALLY WE WILL HAVE TO HAVE A HIGHLY
2 COORDINATED, HIGHLY STRUCTURED TEAM ON THE STAFF LEVEL
3 TO CARRY ALL THIS OUT, AND WE WILL HAVE TO DEVELOP
4 EFFICIENT PROCEDURES FOR HANDLING THESE THROUGH REVIEW
5 AND THROUGH ICOC MEETING APPROVAL AND ALSO THROUGH
6 AWARD.

7 IN THE INFRASTRUCTURE, THE I.T. SYSTEM IS
8 PREDOMINANT, AND WE'RE WORKING VERY HARD ON THAT NOW.
9 ALSO, WE WILL NEED, IF WE APPROVE THE FOR-PROFIT IP AND
10 HAVE GRANTS THAT GO TO THE PRIVATE SECTOR, WE WILL
11 PROBABLY SET UP AN OFFICE THAT WILL BE EITHER A PRIVATE
12 SECTOR OFFICE OR CONTRACT NEGOTIATION, HOWEVER WE TERM
13 IT, BUT IT WILL BE AN OFFICE THAT DEALS SPECIFICALLY
14 WITH STRUCTURING OUR GRANTS AND OUR CONTRACTS WITH THE
15 PRIVATE SECTOR. WE THINK THAT BY THE END OF 2007, WE
16 WILL NEED SOMETHING ON THE ORDER OF 25 NEW HIRES IN
17 ORDER TO IMPLEMENT THE PLAN. FOR THE REVIEWERS, WE
18 WILL NEED TO INCREASE THE NUMBER OF ALTERNATES, AND I
19 ALSO WANT TO POINT OUT THAT YOUR OWN JOB WILL BE
20 DAUNTING. AND WE ARE IN VERY ACTIVE DISCUSSION NOW
21 ABOUT WAYS IN WHICH WE CAN HAVE YOU CONSIDER AND
22 APPROVE THESE GRANTS IN A WAY THAT IS EFFICIENT OF YOUR
23 TIME AND YET THOROUGH AND WHICH WE ARE ABSOLUTELY
24 RIGOROUS ABOUT ANY CONFLICT OF INTEREST ISSUES THAT
25 ARISE.

1 SO THAT ESSENTIALLY IS MY MESSAGE. THIS IS
2 THE CHALLENGE THAT'S LAID OUT BEFORE US IN THE
3 IMPLEMENTATION PLAN. AS YOU WILL SEE, BOTH AT THE
4 LEVEL OF THE CIRM STAFF, AT THE LEVEL OF THOSE WHO HELP
5 US REVIEW GRANTS, AND FINALLY AT THE LEVEL OF THE ICOC
6 THE CHALLENGE IS DAUNTING. AND ONE OF THE THINGS THAT
7 WE HAVE BEEN DISCUSSING IS THAT IN THE REVIEW GRANTS
8 WORKING GROUP, THE BIGGEST BURDEN IN MANY WAYS IS ON
9 THE PATIENT ADVOCATES. THROUGH THE USE OF ALTERNATES
10 AND SPECIALISTS, WE CAN ROTATE REVIEWERS. WE WILL NOT
11 GET 15 REVIEWERS TO REVIEW OUR GRANTS. BUT WE HAVE AN
12 ALTERNATE SYSTEM SET UP. WE WILL BE ABLE TO DO THAT,
13 BUT THE PATIENT ADVOCATES, WE HAVE SIX PLUS BOB KLEIN
14 WILL BE THERE. THEY'RE REQUIRED TO BE THERE FOR ALL OF
15 THEM, AND SO WE ARE IN DISCUSSION ABOUT HOW WE MIGHT
16 HELP THEM DO THEIR JOB MORE EFFICIENTLY AND TO HELP
17 THEM WITH SOME OF THE MANPOWER NEEDS THAT THEY MAY
18 HAVE.

19 AND SO I DON'T KNOW IF ANYTHING IS GOING TO
20 BE SAID ABOUT THAT LATER, BUT JUST TO ADD HERE, I WAS
21 ASKED BY THE GOVERNANCE SUBCOMMITTEE TO SURVEY THE
22 PATIENT ADVOCATES, AND I'VE BEGUN THAT WITH SEVERAL OF
23 YOU, BUT TO DISCUSS WHAT YOUR NEEDS MIGHT BE AND HOW WE
24 CAN HELP. SO THAT CONCLUDES, THEN, THE PRESENTATION I
25 HAVE. I WOULD ASK AND OPEN TO ANY QUESTIONS AND WOULD

1 ASK ANY CHANGES YOU WISH TO MAKE OR SUGGESTIONS YOU
2 HAVE PLEASE LET US KNOW. WHAT I WOULD HOPE THAT IT
3 WOULD BE POSSIBLE TO DO WOULD BE TO GET THE PLAN
4 APPROVED EITHER AS IS OR WITH MODIFICATIONS THAT YOU
5 SUGGEST AND THAT WE CAN GO FORWARD FROM HERE.

6 AS YOU KNOW, IN SHERRY LANSING'S FAMOUS
7 PHRASE, THIS IS A LIVING PLAN. IT'S GOING TO CHANGE,
8 AND WE WILL BE CHANGING IT REGULARLY AS WE GO ALONG IN
9 RESPONSE TO VARIOUS CONTINGENT NEEDS AND OPPORTUNITIES.
10 BUT WE HOPE THAT IT SETS THE KIND OF FRAMEWORK THAT
11 WILL ALLOW THE INSTITUTE TO GO AHEAD WITH A STRONG
12 SENSE OF WHERE IT'S GOING AND WHAT IT'S DOING AND A
13 SERIES OF GUIDEPOSTS ALONG THE WAY BY WHICH IT CAN
14 JUDGE ITS PROGRESS. THANK YOU VERY MUCH.

15 CHAIRMAN KLEIN: DO WE HAVE COMMENTS FROM THE
16 BOARD?

17 DR. HENDERSON: I THINK IT IS A DAUNTING
18 SCHEDULE. I'D JUST LIKE TO ENCOURAGE YOU AND YOUR
19 COLLEAGUES TO MOVE AS QUICKLY AS WE CAN ON THE NEW
20 INVESTIGATOR AWARD ISSUE BECAUSE I THINK, AGAIN,
21 WITHOUT PERSONNEL, WE AREN'T GOING TO GET ANYTHING
22 DONE. AND, SECONDLY, WE NEED FACILITIES. AND WITH THE
23 LEAD-TIME TO BUILD THOSE FACILITIES, WE CAN HAVE ALL
24 THE RFA'S WE WANT; BUT IF WE DON'T HAVE ANY PLACE TO
25 WORK, WE'RE GOING TO FALL BEHIND. I KNOW THESE ARE

1 DAUNTING; BUT IF THERE'S ANY WAY TO EXPEDITE THE
2 PROCESS SO WE CAN MOVE THROUGH THESE MORE
3 EXPEDITIOUSLY, I THINK IT SORT OF KEEPS UP THE PRESSURE
4 ON ALL OF US.

5 DR. HALL: WE'RE WORKING VERY HARD ON THAT.
6 AND I, AGAIN, WANT TO SAY, IN RECOGNITION FOR STAFF, WE
7 HAVE BEEN WORKING ON FUMES THE LAST FEW MONTHS.
8 EVERYBODY IS GOING ALL OUT TO DO EVERYTHING WE CAN TO
9 GET THESE OUT BECAUSE, AS WONDERFUL IT WAS, THE
10 GOVERNOR'S ANNOUNCEMENT CAME AND CAUGHT US. WE HAD NOT
11 PLANNED FOR THIS OBVIOUSLY. AND SO WE HAVE ESSENTIALLY
12 ADDED THIS TO WHAT WE WERE ALREADY DOING AND ARE
13 GETTING THESE THINGS OUT. SO WE WILL MOVE AS QUICKLY
14 AS WE CAN. WE ARE THINKING VERY HARD ABOUT JUST THE
15 POINT YOU MENTIONED, HOW TO EXPEDITE THIS AT EVERY
16 LEVEL, HOW TO MAKE IT HAPPEN.

17 I THINK ONE OF THE MESSAGES FROM THE GRANTS
18 REVIEW WORKING GROUP WAS THAT THE METHODS THAT ARLENE
19 AND ED DORRINGTON AND GIL SAMBRANO AND THEIR COLLEAGUES
20 DEVELOPED WERE VERY SUCCESSFUL. AND I THINK IT IS
21 THOSE AS MUCH AS ANYTHING THAT DENNIS STEINDLER'S
22 REMARKS WERE DIRECTED TO, THE WAY THAT WAS ORGANIZED.
23 WE HAD 32 PEOPLE CALLING IN ON A CLOCKWORK SCHEDULE.
24 EVERYBODY LIKED THE I.T., THE WAY WE HAD IT SET UP IN
25 TERMS OF SYSTEMS. AND ALSO, THE WAY IN WHICH THE PART

1 2 WAS HANDLED UNDER JOAN SAMUELSON'S LEADERSHIP IN
2 WHICH, RATHER THAN GO THROUGH 232 GRANTS AND MAKE A
3 ONE-BY-ONE HEAD COUNT ON ALL OF THEM, WE ACTUALLY CAME
4 UP WITH WHAT WE THINK IS A VERY GOOD WAY THAT ACTUALLY
5 MIGHT BE USED BY THE ICOC AS WELL TO AVOID -- TO LET US
6 GIVE ADEQUATE CONSIDERATION, BUT SOMEHOW GET PAST THE
7 TEDIOUS AND ITERATIVE TASK OF SIMPLY TABULATING WHAT
8 EVERYONE IS DOING IN EVERY CASE.

9 AT ANY RATE, I TAKE YOUR POINT. WE HEAR IT.
10 WE'RE A LITTLE SCARED OURSELVES WHEN WE LOOK AT THAT
11 IMPLEMENTATION PLAN, AND WE ARE RUNNING SCARED, I'LL
12 TELL YOU, ON IT. SO WE'LL DO WHAT WE CAN.

13 DR. HENDERSON: IF I COULD JUST MAKE ONE MORE
14 COMMENT. THE OTHER THING IS THAT THE NIH REVIEW
15 PROCESS, THAT WE'RE ALL VERY ACCUSTOMED TO, IS RIGOROUS
16 AND EVERYBODY RESPECTS IT. WE ALL SORT OF KNOW WHAT
17 WE'RE GETTING INTO, BUT IT'S ALSO VERY PONDEROUS. AND
18 PARTICULARLY NOW WHERE FIRST APPLICATIONS ARE BEING
19 SORT OF UNIFORMLY PASSED FOR YET A SECOND TRY, YOU
20 KNOW, SECOND SUBMISSION, THE WHOLE PROCESS BECOMES SO
21 TEDIOUS AND SO TIME-CONSUMING OF REVIEWERS' TIME AND
22 STAFF TIME, YOU WONDER IF WE AREN'T LOSING TRACK OF THE
23 GOAL IN TRYING TO OVERWORK THE PROCESS. AND I THINK
24 HAVING A RIGOROUS PROCESS IS ABSOLUTELY CRITICAL; BUT
25 HAVING GONE THROUGH THE PROCESS, AGAIN, I URGE US TO

1 TAKE AS MUCH ADVANTAGE AS WE CAN OF IT TO FUND AS MANY
2 AS WE CAN SO WE DON'T CREATE THIS SORT OF PERPETUAL
3 MACHINE OF APPLICATION, REAPPLICATION, REAPPLICATION,
4 SPEND ALL OUR TIME ON THAT, AND NOT ON MOVING THE
5 SCIENCE FORWARD, YOU KNOW, IN A MORE CREATIVE WAY.

6 DR. HALL: WELL PUT. I TAKE YOUR POINT.
7 OKAY.

8 CHAIRMAN KLEIN: DR. HALL, AS DR. HENDERSON
9 MENTIONED ON FACILITIES, ASSUMING THAT THE RFA GOES OUT
10 WHEN SUGGESTED BY YOUR SCHEDULE, WHEN WOULD THE
11 FACILITIES GROUP REVIEW IT, AND WHEN WOULD IT COME TO
12 THE BOARD?

13 DR. HALL: WE WORKED BACKWARDS. IT WOULD
14 COME TO THE BOARD IN JUNE, AND WE'D HAVE A REVIEW IN
15 APRIL/MAY.

16 CHAIRMAN KLEIN: NOT SHARED LABS. MAJOR
17 FACILITIES.

18 DR. HALL: I WOULD PREFER -- WE HAVE BEEN --
19 MOST OF OUR TIME HAS BEEN SPENT ON THE FIRST OF THOSE,
20 AND WE WANT TO GET THAT SHARED FACILITIES ONE OUT. WE
21 DO HAVE A NEW FACILITIES PERSON COMING, AND WE WILL ASK
22 THAT PERSON -- I HOPE WE DO -- AND WE WILL ASK THAT
23 PERSON TO HAVE TWO PRIORITIES. ONE WILL BE TO PUT
24 TOGETHER A GRANTS ADMINISTRATION POLICY FOR US FOR
25 FACILITIES, WHICH WE WILL NEED IN PLACE BEFORE WE CAN

1 DO THIS, AND, NO. 2, TO START WORKING ON THAT LARGE
2 RFA. HOWEVER YOU PUT. THE OTHER ONE IS, OF COURSE,
3 THE SHARED FACILITIES. WE WANT TO GET THAT OUT.

4 SO WE WILL BE WHITTLING AWAY ON THAT, AND I
5 THINK IT'S A LITTLE TOO EARLY. WE'D LIKE TO DO IT, AS
6 I INDICATED, THIS SPRING, LATE THIS SPRING. I CAN'T
7 GIVE YOU A MONTH FOR WHEN WE MIGHT HAVE IT OUT.

8 ONE HESITATES BECAUSE, AS WITH THE SHARED
9 FACILITIES ONE, WE GIVE IT, AND THEN I DON'T WANT TO
10 GIVE IT AND THEN CHANGE IT AND CHANGE IT AND CHANGE IT.
11 SO LET ME JUST SAY THAT LATE SPRING WE WILL TRY TO DO
12 THAT. I WOULD NOT LIKE TO SPECIFY IT MORE THAN THAT.

13 CHAIRMAN KLEIN: I THINK WE HAD A COMMENT
14 OVER HERE.

15 DR. REED: I WON'T GET INTO THE SHARED
16 RESEARCH FACILITIES. AGAIN, I THINK THE POINT'S BEEN
17 MADE, THE IMPORTANCE.

18 THE OVERALL PLAN IS WONDERFUL. I WANT TO
19 CONGRATULATE YOU AND YOUR TEAM AND EVERYBODY WHO
20 PARTICIPATED. IT'S VERY COMPREHENSIVE IN ITS NATURE IN
21 TERMS OF THE APPROACH TO STEM CELL-BASED THERAPIES,
22 WHICH I ALSO SUPPORT.

23 IN THE FIRST THOUSAND DAYS, HOWEVER, I DIDN'T
24 REALLY GET A SENSE THAT THAT FIRST EARLY STAGE PROVIDES
25 AS A PRIORITY FUNDING FOR PROJECTS THAT THE NIH NO

1 LONGER FUNDS. I JUST WANTED TO CLARIFY THAT. WHAT I
2 MEAN IS THAT BECAUSE THE PLAN IS SO COMPREHENSIVE, THE
3 CURRENT PROPOSALS FOR RFA'S TEND TO EMPHASIZE RESEARCH
4 THAT'S BOTH FUNDED BY NIH AND RESEARCH THAT'S NOT
5 FUNDED BY NIH.

6 DR. HALL: THE CURRENT ONES ARE ALL
7 RESTRICTED TO HUMAN EMBRYONIC STEM CELL RESEARCH. AND
8 IN THE RFA'S, WE ASK THEM IN THEIR APPLICATIONS TO SAY
9 COULD THIS WORK BE FUNDED BY NIH. AND THERE WAS, I
10 WOULD SAY, FOR MOST OF THE GRANTS THAT WERE SUBMITTED,
11 THE ANSWER IS NO. AT LEAST EVERYBODY HAD A REASON,
12 SOMETIMES CONVINCING, SOMETIMES NOT, WHY IT COULDN'T.
13 THIS WAS VERY MUCH A CONSIDERATION IN THE WORKING
14 GROUP. AND ALTHOUGH IT WASN'T A RIGID RULE, I WOULD
15 SAY EVERYONE WAS VERY AWARE OF WHAT THE NIH WOULD NOT
16 FUND.

17 DR. REED: THAT'S THE TONE I WANTED TO SEE IN
18 THERE. YOU MENTIONED, FOR EXAMPLE, JUST A MOMENT AGO A
19 SLIDE ABOUT THE PRECLINICAL STUDIES, WHICH, AGAIN, I
20 SUPPORT THAT AS A PRIORITY; BUT, AGAIN, PRECLINICAL
21 STUDIES IN PARTICULAR THAT NIH WOULD NOT FUND WOULD BE
22 THE --

23 DR. HALL: NIH IN GENERAL, ALTHOUGH THERE'S
24 SOME MOVEMENT ON THAT, PRECLINICAL STUDIES, WHAT WE
25 MEAN IS NOT PRECLINICAL STUDIES, BUT PRECLINICAL

1 DEVELOPMENT. THAT IS, THE STAGE AT WHICH YOU HAVE A
2 PRODUCT, POTENTIAL PRODUCT, AND YOU NOW WANT TO SHOW
3 THAT YOU CAN GROW IT UP IN LARGE SCALE, THAT YOU DO
4 QUALITY CONTROL ON WHAT YOU'VE DONE, YOU CAN DO IT
5 REPRODUCIBLY, THAT YOU CAN SHOW EFFICACY, ALL THOSE
6 THINGS THAT BASICALLY IS MOVING TOWARD FDA APPROVAL.
7 AND SO THAT, I THINK, IS NOT -- WHAT WE HEARD IN OUR
8 MEETING WITH PEOPLE FROM THE PRIVATE SECTOR IS THAT
9 THIS IS AN ABSOLUTE CRYING NEED, THAT THEY OFTEN ARE
10 ABLE TO GET THINGS TO THIS STAGE AND CANNOT GET THE
11 CAPITAL TO MOVE THEM ALONG. SO WE HEARD THAT AND WANT
12 TO RESPOND TO IT AND WANT TO SEE IF THERE ARE GOOD
13 PROJECTS OUT THERE THAT ARE READY TO GO.

14 BUT SOMEBODY ELSE MAY, PATRICIA OR ARLENE OR
15 SOMEBODY WILL COMMENT ON THIS, BUT THIS IS NOT RIGHT
16 FOR NIH.

17 DR. REED: I WAS ONLY ASKING FOR
18 CLARIFICATION INASMUCH AS THE WORD "PRECLINICAL
19 DEVELOPMENT" CAN ENCOMPASS MANY THINGS. WHAT YOU'RE
20 TELLING ME IS EXACTLY WHAT I WAS HOPING TO HEAR. SO
21 THANK YOU FOR THAT CLARIFICATION.

22 DR. HALL: WE MADE THE DISTINCTION BETWEEN
23 PRECLINICAL RESEARCH, WHICH IS BROADER AND COULD HAVE
24 TO DO WITH STUDYING DISEASE MODELS AND TRYING TO FIND A
25 CANDIDATE, AND PRECLINICAL DEVELOPMENT, WHICH IN THE

1 PARLANCE STARTS WITH A CANDIDATE THERAPEUTIC, SPECIFIC
2 ONE.

3 I ALSO MIGHT ADD THAT THE ALTERNATE
4 DERIVATION METHODS AND DISEASE LINES, DEPENDING ON HOW
5 YOU DO IT, ARE BOTH THINGS THAT WOULD NOT BE FUNDED
6 NECESSARILY BY NIH, AND WE WILL HAVE OUR EYE ON THAT.
7 IF WE DON'T THINK THERE'S ENOUGH OF THAT WORK THAT'S
8 COME THROUGH AND THE OTHER THINGS, THEN WE WILL PUT OUT
9 A SPECIFIC RFA AND WE'LL TRY TO REEL THOSE APPLICATIONS
10 IN. SO WE DEFINITELY WANT TO GET THAT STARTED.

11 DR. REED: THANK YOU AGAIN FOR THAT
12 CLARIFICATION.

13 DR. PENHOET: CONGRATULATIONS, ZACH, TO YOU
14 AND THE ENTIRE STAFF FOR A DOCUMENT WELL DONE. I JUST
15 WANTED TO POINT OUT I HAVE HEARD FROM SOME BOARD
16 MEMBERS IN CONVERSATION THAT THIS STRATEGIC PLAN
17 DOESN'T COVER SOME ELEMENTS OF STRATEGY FOR CIRM. SO I
18 JUST WANT TO REINFORCE THE POINT THAT THIS IS A
19 SCIENTIFIC STRATEGIC PLAN, NOT AN OVERALL STRATEGIC
20 PLAN, SO THERE ARE ELEMENTS OF STRATEGY YET UNADDRESSED
21 FOR US, FUTURE FUNDING STRATEGIES, POLITICAL
22 STRATEGIES, ETC., WHICH ARE NOT ADDRESSED IN THIS.
23 THIS IS FOCUSED ON THE SCIENCE, SO IT'S A SCIENTIFIC
24 STRATEGIC PLAN. I THINK THAT'S REALLY WHAT WE'RE
25 EVALUATING HERE TODAY, NOT A MORE OVERARCHING STRATEGIC

1 DOCUMENT. PEOPLE HAVE BROUGHT THAT UP. I JUST WANTED
2 TO MAKE THAT POINT.

3 DR. HALL: THANK YOU VERY MUCH FOR MAKING
4 THAT EXPLICIT. AND OUR CHOICE IN DOING THAT WAS THAT
5 THIS IS OUR CORE MISSION. AND ONCE WE HAVE THIS, THEN
6 ONE CAN BUILD OUT FROM IT TO THEN SAY, WELL, THEN WHAT
7 SHOULD WE BE DOING IN THESE AREAS? BUT THIS IS THE
8 REAL HEART AND CORE OF WHAT WE'LL BE DOING. BUT THANK
9 YOU. THIS IS A SCIENTIFIC STRATEGIC PLAN, NOT MORE
10 THAN THAT.

11 CHAIRMAN KLEIN: DR. HALL, IN ADDRESSING THAT
12 ISSUE, FIRST OF ALL, I APPRECIATE EXPANDING THE MISSION
13 STATEMENT TO SPECIFICALLY ADDRESS THE OPPORTUNITIES IN
14 ADDRESSING ADULT STEM CELL RESEARCH, FETAL STEM CELL
15 RESEARCH, CORD BLOOD, ETC. HOPEFULLY WHEN WE GET TO
16 RFA'S THAT CAN LOOK AT THE INTERFACE BETWEEN EMBRYONIC
17 STEM CELL RESEARCH AND ADULT THERAPIES, FOR EXAMPLE,
18 WHERE WE'RE ADDRESSING DEVELOPING SCNT, IMMUNE SYSTEM
19 MATCHING TO EXPAND EXISTING ADULT THERAPIES FOR USING
20 IMMUNE EMBRYONIC STEM CELLS TO CREATE SOME SENSE OF
21 IMMUNE TOLERANCE TO EXPAND THE ADULT STEM CELL
22 THERAPIES THAT EXIST, WE CAN LOOK AT THOSE ON A
23 STRATEGIC SCIENTIFIC BASIS AS COMPARED TO THE
24 OPPORTUNITIES THAT MAY BE FURTHER OFF IN CELL
25 REPLACEMENT THERAPIES, FOR EXAMPLE. SO THAT ON A

1 SCIENTIFIC BASIS, WE COME TO THESE RFA'S WITH A REAL
2 STRATEGIC ANALYSIS OF THE PROS AND CONS, THE COSTS AND
3 BENEFITS THAT WE'RE LOOKING AT IN MAKING THESE
4 DECISIONS.

5 DR. HALL: THANK YOU. YES. I THINK THE IDEA
6 IS THAT THESE WILL BE CONSIDERED -- WE NOW HAVE A
7 CONTEXT TO MAKE WHATEVER DECISIONS WE NEED TO MAKE.

8 MS. SAMUELSON: I HAVE A REQUEST FOR
9 SOMETHING TO BE ELIMINATED FROM THE PLAN OR AT LEAST TO
10 BE SENT BACK FOR REVISION. AND IT'S ACTUALLY ON THE
11 SAME POINT WE'VE BEEN DISCUSSING JUST NOW. IT'S GOOD
12 THAT I'M ADDRESSING IT NOW. IT'S ON PAGE 56, I THINK.

13 CHAIRMAN KLEIN: 56; IS THAT RIGHT?

14 DR. HALL: THE SCHEMATIC?

15 MS. SAMUELSON: THE SCHEMATIC, YEAH. AND LET
16 ME EXPLAIN WHY. I THINK WE HAVE SUCCEEDED IN MOVING
17 WITH EXTREME URGENCY TO WHERE WE ARE NOW IN LAYING A
18 FOUNDATION FOR THE SUCCESS OF THIS ENTERPRISE. AND I
19 THINK YOU HAVE DRIVEN US WITH URGENCY, AND I THINK WE
20 ALL DESERVE TO RETIRE IN SIX MONTHS. AND MAYBE I'M
21 SPEAKING SIMPLY AS ONE OF THE PATIENT ADVOCATES AND
22 VICE CHAIR OF THE GRANTS WORKING GROUP BECAUSE I
23 CERTAINLY FEEL LIKE IT NOW AFTER LAST WEEK. AND THAT
24 IS A COMPLIMENT TO YOU AND TO ARLENE AND THE STAFF. IT
25 WAS DONE WITH BRILLIANT EFFICIENCY, BUT WE HAVE

1 ACCOMPLISHED AN ENORMOUS AMOUNT.

2 AND I THINK THE STRATEGIC PLAN IS AT THE SAME
3 POINT AS THE OVERALL ENTERPRISE. I THINK THAT THE
4 FOUNDATIONAL, CONCEPTUAL THINKING, THE STRATEGIC
5 PRINCIPLES, THE MISSION, AND THE VALUES, I THINK THEY
6 ARE RIGHT ON TARGET, AND I'M VERY PLEASED. I THINK WE
7 HAVE A LOT MORE THINKING TO DO ABOUT HOW WE GET TO THE
8 END GOAL. AND I THINK OUR CORE MISSION IS TO DEVELOP
9 CURES AND EFFECTIVE THERAPIES FROM THE FIELD OF
10 REGENERATIVE MEDICINE. AND WE HAVE TO KEEP OUR EYE ON
11 THAT TARGET AND THAT IT'S AN IMMENSELY DIFFICULT ONE.

12 AND THE REASON I'M ADDRESSING THIS CHART, AND
13 IT'S NOT TO PICK ON THE CHART, I THINK IT JUST REFLECTS
14 THAT OUR THINKING ISN'T AS ADVANCED AS IT NEEDS TO BE
15 AND AS SOON AS IS HUMANLY POSSIBLE TO STAY ON TARGET.
16 I THINK THIS SORT OF THING SHOULD BE TAKEN VERY
17 SERIOUSLY. IF YOU LOOK AT THE HISTORY OF SIMILAR KINDS
18 OF INITIATIVES, THE ONE THAT MOST COMES TO MIND FOR ME
19 IS THE DEVELOPMENT OF THE POLIO VACCINE. AND THAT WAS
20 DONE WITH EXTREME URGENCY SO AS NOT TO HAVE ONE MORE
21 SUMMER IN WHICH CHILDREN WERE STRICKEN WITH POLIO.

22 AND DR. MURPHY IS FAMILIAR WITH A BOOK THAT'S
23 A FAVORITE OF MINE ON THAT SUBJECT. AND, OF COURSE,
24 HIS INSTITUTE IS PART OF THE LEGACY FOR THE SUCCESS OF
25 THAT MISSION. AND THEIR SUCCESS WAS A PARTNERSHIP

1 AMONG ALL OF THE ENTITIES THAT ARE INCLUDED IN THIS
2 SCHEMATIC. AND THEY DROVE THROUGH TO THEIR ULTIMATE
3 SUCCESS OF GETTING THAT VACCINE TO THE PATIENTS -- TO
4 THE TARGET POPULATION, THE CHILDREN OF THE UNITED
5 STATES, SO THAT THEY WOULD NOT HAVE ANOTHER SUMMER WITH
6 MORE POLIO. AND THEY DID IT BRILLIANTLY WITH THE
7 PUBLIC ENGAGED AND THE MARCH OF DIMES AND WITH
8 BRILLIANT SCIENTISTS, DR. SALK AND OTHERS, AND WITH
9 PATIENT ADVOCATE ORGANIZATIONS DRIVING THE AGENDA.

10 AND I'M CONFIDENT THAT THE ONLY WAY WE'RE
11 GOING TO SUCCEED IS BY FIGURING OUT HOW WE BEST USE ALL
12 THE RESOURCES WE HAVE AVAILABLE TO US. IT'S, OF
13 COURSE, FAR MORE THAN CIRM. WE HAVE A VERY
14 ENTHUSIASTIC GOVERNOR, WHO'S VERY ENGAGED. WE HAVE THE
15 LEGISLATURE, WHICH IS VERY ENGAGED. WE HAVE THE COURT
16 SYSTEM WHICH IS COMPLETELY BACKING THE ENTERPRISE. WE
17 HAVE THE FIFTH, SIXTH, WHATEVER IT IS, LARGEST ECONOMY
18 IN THE WORLD, OUR STATE. WE HAVE, WHAT, 50 PERCENT,
19 BOB, OF THE BIOMEDICAL INDUSTRY IN THE UNITED STATES IN
20 THE STATE OF CALIFORNIA. WE HAVE AN IMMENSE RESOURCE
21 IN THE ACADEMIC MEDICAL INSTITUTIONS AS REFLECTED ON
22 THIS COMMITTEE. AND WE'RE GOING TO HAVE TO HAVE ALL OF
23 THOSE ENTITIES DRIVING THIS IN A REAL COLLECTIVE
24 ENTERPRISE THAT IS EXTREMELY WELL ORGANIZED AND IS VERY
25 STRATEGIC. I THINK THAT PIECE IS GOING TO BE EXTREMELY

1 HARD TO DO, BUT IT'S DOABLE BECAUSE WE HAVE THOSE
2 RESOURCES. AND WE'RE THE ONLY ONES WHO DO, SO WE'VE
3 GOT TO DO IT.

4 I THINK THAT'S OUR BIG JOB AHEAD. AND I
5 THINK THIS PLAN WILL CHANGE DRAMATICALLY WHEN WE REALLY
6 ENGAGE THAT, AS WILL THE GRANT MAKING THAT WE DO, AS
7 WILL THE WORK OF THE WORKING GROUP AND OF THIS
8 COMMITTEE. AND I THINK THAT'S THE WAY WE'LL HAVE TO
9 APPROACH IT. SO I WOULD ASK THAT WE TAKE THIS CHART
10 SERIOUSLY AND WE FIGURE OUT HOW IT REALLY SHOULD FLOW
11 AND HOW THE PIECES FIT TOGETHER, AND THAT THAT BE ONE
12 PIECE OF TACKLING THE OVERALL STRATEGIC PLAN, WHICH I
13 THINK IS THE REAL GOAL.

14 CHAIRMAN KLEIN: JOAN, YOU ARE SAYING THIS IS
15 A HISTORICALLY ACCURATE REFLECTION, BUT WHAT WE NEED IS
16 A NEW PARADIGM OF HOW TO USE THE RESOURCES WE UNIQUELY
17 HAVE IN CALIFORNIA TO DRIVE THIS MISSION?

18 MS. SAMUELSON: IN TERMS OF THE SCHEMATIC, I
19 THINK IF YOU LOOK AT, IT'S A PATH TO NOWHERE. THE
20 PATIENTS ARE ONE PLACE AND THE PUBLIC IS ANOTHER AND
21 ADVOCACY IS OVER HERE, AND THE ADVOCACY DOESN'T REALLY
22 LEAD INTO ANYTHING THAT I CAN UNDERSTAND.

23 CHAIRMAN KLEIN: YOU WANT A MORE STREAMLINED,
24 DIRECT, AND CONSOLIDATED APPROACH THAT BRINGS ALL THE
25 RESOURCES TOGETHER IN A NEW MODEL.

1 MS. SAMUELSON: YEAH.

2 DR. HALL: WE WOULD BE HAPPY, JOAN, TO
3 CONSIDER AN ALTERNATIVE. SO IF YOU WANT TO DEVELOP ONE
4 AND GIVE IT TO US, AND WE CAN EITHER ADD THAT IN LATER
5 OR WE COULD TAKE THIS OUT NOW OR WHATEVER YOU WOULD
6 LIKE. THIS IS MEANT -- I THINK IT CAME OUT OF AN EARLY
7 DISCUSSION THAT WE HAD IN WHICH WE WERE TRYING TO
8 FIGURE OUT HOW ALL THE PIECES FIT TOGETHER, AND WE WERE
9 ALL VERY STRUCK BY RICHARD INSEL'S PRESENTATION AND HIS
10 POINT THAT EVERYTHING STARTS AND ENDS WITH A PATIENT,
11 AND THAT WAS WHAT WE MEANT TO IMPLY HERE. BUT WE WOULD
12 BE CERTAINLY OPEN TO ANY ALTERNATIVE ARRANGEMENT OR
13 ALTERNATIVE REPRESENTATION OF ALL THESE THAT YOU WISH
14 TO SUGGEST.

15 MS. SAMUELSON: I'LL BE HAPPY TO BE INVOLVED,
16 NOT THAT I WANT TO VOLUNTEER FOR ANYTHING ELSE AT THIS
17 POINT, BUT I THINK IT'S ALL THE SAME WORK ACTUALLY.
18 THAT'S MY POINT.

19 DR. HALL: ONE POSSIBILITY WOULD BE TO LEAVE
20 THIS AND VIEW THIS AS SOMETHING THAT WE COULD CONTINUE
21 TO DEVELOP BECAUSE I THINK, JOAN, AS I HEAR YOU, THIS
22 IS NOT SOMETHING WE CAN SIT DOWN WITH A PEN AND PENCIL
23 IN THREE MINUTES AND DO. THIS IS AN ONGOING,
24 CONTINUING SORT OF WORK IN PROGRESS EVEN TO WORK OUT
25 THIS SCHEME HERE. SO --

1 DR. PENHOET: MAYBE MORE APPROPRIATE TO THE
2 BROADER TASK OF THE SORT OF NONSCIENTIFIC STRATEGY
3 BECAUSE SOME OF THOSE ARE NOT SCIENTIFIC STRATEGIC.
4 THEY'RE BEYOND THE SCIENCE. THAT'S WHAT I BROUGHT UP
5 EARLIER. YOU WANT TO TAKE THIS OUT BECAUSE YOU THINK
6 IT'S MISLEADING OR IT'S INCOMPLETE? IF IT'S
7 INCOMPLETE, I DON'T SEE PERSONALLY ANY HARM IN HAVING
8 IT STAY HERE, REALIZING THAT IT NEEDS FURTHER WORK.
9 BUT IF YOU THINK IT'S MISLEADING, THEN THAT WOULD BE A
10 GOOD REASON TO TAKE IT OUT.

11 MS. SAMUELSON: I DO THINK IT'S MISLEADING
12 BECAUSE I DON'T THINK IT AT ALL REFLECTS HOW ALL THOSE
13 PIECES WILL SERIOUSLY BE --

14 DR. HALL: WE'LL TAKE IT OUT AND YOU CAN --

15 MS. SAMUELSON: -- INTEGRATED.

16 DR. HALL: WE'LL HAPPILY JUST OMIT IT. I
17 ADMIT IT WAS MEANT TO CONVEY THE COMPLEXITY OF IT. I
18 WAS GOING TO SAY IT DOESN'T CLARIFY, BUT IT WAS MEANT
19 TO JUST SAY LOOK AT ALL THE MOVING PARTS WE'VE GOT, AND
20 HERE'S ONE EFFORT TO TRY TO PUT THEM TOGETHER. I'D BE
21 HAPPY TO HAVE THAT BE WORKED ON OUTSIDE OF THIS PLAN.

22 MS. SAMUELSON: IF THAT'S AN IMPORTANT THING
23 TO HAVE SCHEMATICALLY, AND I THINK THAT PROBABLY IS
24 WHERE WE ARE, ALL THESE PIECES SHOULD BE OUTSIDE MAYBE
25 WITH ARROWS GOING INTO THE MIDDLE AND A QUESTION MARK

1 OR TO BE CONTINUED, BUT I DON'T THINK THAT THE WAY
2 THEY'RE STRUCTURED.

3 CHAIRMAN KLEIN: I THINK WE HAVE A RESOLUTION
4 SUGGESTED BY DR. HALL OF LEAVING IT OUT WHILE THIS IS
5 FOCUSED ON AS AN IDENTIFIED NEED TO SET UP A NEW MODEL
6 TO REALLY ADVANCE THIS ON A CONSORTIUM APPROACH THAT
7 BRINGS ALL THE RESOURCES TOGETHER IN A STREAMLINED
8 FASHION.

9 DR. PENHOET: BUT I HOPE THIS WON'T DELAY THE
10 APPROVAL OF THIS SCIENTIFIC STRATEGIC PLAN. THIS
11 SHOULD BE AN IMPORTANT ELEMENT OF THE NEXT STEP IN
12 STRATEGY.

13 MS. SAMUELSON: LET ME JUST SAY ONE MORE
14 THING, AND I'M SORRY FOR MONOPOLIZING THE TIME. I
15 DON'T UNDERSTAND ACTUALLY THE REAL DIFFERENCE BETWEEN
16 THE SCIENTIFIC STRATEGIC PLAN AND ONE THAT IS
17 ACCOMPLISHING OUR ENDS, AND I THINK THAT THE CONNECTION
18 BETWEEN THEM HAS TO BE UNDERSTOOD QUICKLY. BUT I DO
19 THINK THAT THIS IS A WONDERFUL FOUNDATION. IT'S A
20 GREAT PLACE TO START.

21 DR. PENHOET: WHICH IS WHAT IT WAS INTENDED
22 TO BE.

23 CHAIRMAN KLEIN: DAVID SERRANO-SEWELL.

24 MR. SERRANO-SEWELL: IF THIS IS THE RIGHT
25 TIME TO MOVE FOR ITS APPROVAL, THAT'S WHAT I WOULD DO

1 WITH THE CAVEAT THAT THIS PAGE 56 BE OMITTED FOR NOW
2 AND HAVE IT WORKED ON WITH DR. HALL AND TO COME BACK AT
3 A LATER DATE WHEN IT'S WORKED OUT. I'D LIKE TO MAKE
4 THAT MOTION.

5 ALSO JUST A REALLY QUICK COMMENT, AND THAT
6 BEING THE INTERNATIONAL SORT OF FELLOWSHIP COMPONENT
7 THAT YOU DISCUSSED. I HOPE THAT WILL BE INCLUDED IN
8 THIS PLAN.

9 I HAD THE HONOR OF GOING TO ISRAEL ALMOST TWO
10 YEARS AGO AS PART OF A BAY AREA DELEGATION. WE SPENT
11 HALF THE DAY AT HADASSAH SCHOOL OF MEDICINE AND THE
12 HOSPITAL ITSELF. I THINK THE GROUP HONORED OUR
13 CHAIRMAN A YEAR OR SO AGO. ANYWAYS, THEY HAVE A VERY
14 STRONG STEM CELL PROGRAM. BRILLIANT SCIENTISTS, WE MET
15 WITH THEM, THEY WANTED TO TALK. FIRST QUESTION IS HOW
16 CAN WE COLLABORATE WITH CALIFORNIA'S EFFORT BECAUSE IT
17 WAS ALL THE RAGE AT THE TIME. IT HAD JUST PASSED. OF
18 COURSE, WE CAN'T FUND MONIES OUTSIDE OF CALIFORNIA, BUT
19 I THINK THIS IS A REALLY GOOD WAY TO BRING PEOPLE INTO
20 THE FOLD. IT WILL DO ALL THE THINGS THAT YOU SAID,
21 ZACH; AND, THAT IS, THERE WILL BE SOME RECIPROCAL
22 EFFORTS, SOME PEOPLE WILL STAY, SOME PEOPLE WILL LEAVE.
23 NONETHELESS, IT'S SORT OF THE RIGHT THING TO DO. AS
24 JOAN SAYS, CALIFORNIA STANDING ALONE IS THE SIXTH
25 LARGEST, WHATEVER, WE'RE AN IMPORTANT FORCE IN THIS

1 GLOBAL EFFORT. I HOPE THAT WE INCLUDE IT IN THE
2 SCIENTIFIC PLAN. MY MOTION STANDS.

3 CHAIRMAN KLEIN: SO YOUR MOTION IS TO APPROVE
4 IT INCLUDING THE SABBATICAL PROPOSAL.

5 MR. SERRANO-SEWELL: YES.

6 DR. AZZIZ: ACTUALLY I WAS JUST GOING TO
7 SECOND IT AND SIMPLY ENFORCE THAT. I DO THINK THAT
8 PROPOSAL FOR SABBATICAL NEEDS TO BE INCLUDED IN THE
9 STRATEGIC PLAN.

10 CHAIRMAN KLEIN: DR. HALL HAS VERY WELL LAID
11 OUT THAT IN REAL TIME THIS IS A PLAN THAT WILL CREATE A
12 FRAMEWORK, BUT WILL BE RESPONSIVE TO OPPORTUNITIES, SO
13 IT CAN BE ADJUSTED AT ANY MEETING AS AN OPPORTUNITY
14 ARISES OR AS WE IDENTIFY MORE INFORMATION THAT BEARS ON
15 ONE OF THE STRATEGIC GOALS. SO THIS IS A FLEXIBLE
16 DOCUMENT.

17 ADDITIONAL COMMENTS FROM THE BOARD?

18 DR. HENDERSON: ARE WE MOVED AND SECONDED?

19 CHAIRMAN KLEIN: CALL THE QUESTION.

20 DR. HENDERSON: NO. NO. YOU'RE INCLUDING
21 THE SABBATICAL. I DON'T UNDERSTAND THE SABBATICAL
22 PIECE SO MUCH. I MEAN IT CONCERNS ME SOMEWHAT. FIRST
23 OF ALL, SCIENTISTS VISITING HERE LEAVE. THEY CAN'T
24 APPLY FOR A GRANT. YOU CAN'T -- I DON'T REALLY THINK
25 WE WANT TO SEND CALIFORNIA SCIENTISTS ON TAXPAYER

1 DOLLARS TO DISTANT LOCATIONS.

2 DR. HALL: WE WILL NOT.

3 DR. HENDERSON: I THINK IT REALLY NEEDS
4 PRETTY CLEAR DEFINITION AND SOME RESTRAINT ON THIS
5 BECAUSE IT CONCERNS ME HOW -- I DON'T REALLY SEE HOW
6 IT'S GOING TO BE THAT BIG A HELP TO US. AND MANY OF
7 THESE SORT OF VISITS ARE ALREADY INCLUDED IN NORMAL
8 UNIVERSITY OR OTHER RESEARCH INSTITUTE BUSINESS. YOU
9 COULD BE FLOODED WITH WHAT COULD BE FAIRLY TRIVIAL
10 REQUESTS THAT ARE HARD TO MONITOR, HARD TO TELL WHETHER
11 THERE'S A GOOD OUTCOME OR NOT, WHETHER IT'S USEFUL OR
12 NOT, AND THEY'RE COMPETING FOR MONEY FOR INVESTIGATORS
13 AND THE SUPPORT OF JUNIOR AND NEW FACULTY. IT'S THE
14 SAME MONEY. I DON'T KNOW HOW MUCH YOU'RE TALKING ABOUT
15 SETTING ASIDE FOR THIS. AND SO I JUST HAVE A CONCERN
16 DROPPING THINGS IN AT THIS STAGE. I WOULD PREFER IT'S
17 AN ADDENDUM LATER ON --

18 MS. LANSING: ME TOO.

19 DR. HENDERSON: -- WHEN IT'S WELL THOUGHT
20 OUT.

21 CHAIRMAN KLEIN: SHERRY, DID YOU WANT TO
22 ADDRESS THIS?

23 MS. LANSING: WE JUST -- WE WERE AT THIS END
24 OF THE TABLE. WE JUST DON'T UNDERSTAND IT. AND IT'S
25 JUST BEING THROWN TO US BECAUSE EITHER WE DON'T

1 UNDERSTAND HOW AN OUTSIDE INVESTIGATOR -- YOU KNOW, WE
2 WENT TO ISRAEL, WE'RE ENCOURAGING PEOPLE TO APPLY FOR
3 GRANTS, AND TO FIND AFFILIATION WITH A CALIFORNIA
4 INSTITUTION. SO WE'RE CONFUSED ABOUT THE WHOLE THING.
5 SO I GUESS AT THIS PARTICULAR TIME, IT SEEMS LIKE WE
6 NEED MORE INFORMATION BEFORE WE DROP IT IN AS TO HOW
7 IT'S GOING TO BE ADDITIVE.

8 CHAIRMAN KLEIN: THE QUESTION IS TO YOU,
9 DAVID, WHETHER YOU WOULD WISH TO AMEND YOUR MOTION.

10 MR. SERRANO-SEWELL: I DON'T WANT TO GET INTO
11 LIKE WE START VOTING ON SHOULD WE INCLUDE THE
12 SABBATICAL THING OR NOT RIGHT NOW BECAUSE I'M HEARING
13 WHAT MY COLLEAGUE'S SAYING. WE'RE JUST BEING
14 INTRODUCED TO THE TOPIC TODAY, SO IF WE CAN APPROACH IT
15 IN A WAY THAT THE MOTION -- I COULD SORT OF MODIFY THE
16 MOTION.

17 CHAIRMAN KLEIN: ALL RIGHT.

18 MR. SERRANO-SEWELL: I'M OPEN TO SOME
19 ASSISTANCE, CHAIRMAN, IN HOW TO PROPERLY WORD IT.
20 MAYBE IT'S SOMETHING ALONG THE LINES OF WHAT WE JUST
21 DID FOR THE SCHEMATIC CHART. THAT IS, WE ASK THE
22 PRESIDENT TO COME UP WITH A FIRMER PROPOSAL FOR OUR
23 CONSIDERATION THAT FLESHES OUT THESE ISSUES.

24 CHAIRMAN KLEIN: SO YOUR MOTION WOULD BE TO
25 APPROVE THE STRATEGIC PLAN, BUT FOR THE PRESIDENT TO

1 COME BACK AT A LATER BOARD MEETING WITH A FEASIBILITY
2 STUDY OF THE SABBATICAL PROGRAM.

3 MR. SERRANO-SEWELL: IS THAT ACCEPTABLE TO
4 EVERYONE?

5 MS. LANSING: PERFECT. WE JUST DON'T
6 UNDERSTAND IT.

7 MR. SERRANO-SEWELL: THAT WOULD BE THE
8 MODIFIED MOTION.

9 CHAIRMAN KLEIN: DOES THE SECOND ACCEPT THE
10 MODIFICATION?

11 DR. AZZIZ: THAT'S FINE.

12 CHAIRMAN KLEIN: THE MOTION HAS BEEN MODIFIED
13 BY THE MAKER AND THE SECOND. IS THERE ADDITIONAL
14 DISCUSSION? PUBLIC COMMENT?

15 MR. REED: FIRST, I THINK THAT THE
16 ASPIRATIONAL SECTION IS STRONG AND SAYS WHAT PATIENT
17 ADVOCATES CARE ABOUT AND NEED TO HEAR. AND WE KNOW
18 THAT EVERYONE FEELS THE SAME WAY ABOUT THAT. DR. HALL
19 HAS DONE A FANTASTIC JOB ALL THE WAY AROUND. I KNOW
20 THIS IS NOT THE TIME TO SAY ALL THE THINGS THAT ARE IN
21 ALL OUR HEARTS.

22 I REALLY THINK THIS IS WONDERFUL ABOUT THE
23 SABBATICAL IDEA. I THINK THIS COULD BRING OUR TWO
24 NATIONS TOGETHER AND BRING THE BEST OF BOTH
25 COMMUNITIES, THEIR ADVANCES, THE THINGS THAT THEY HAVE

1 FOUND, THEIR PRACTICAL EXPERIENCE. I THINK THIS
2 REALLY, REALLY BRINGS THE BEST OF BOTH WORLDS TOGETHER.
3 I HOPE THAT IS APPROVED AND BROUGHT FORWARD THE BEST
4 WAY POSSIBLE. THANK YOU.

5 MR. SIMPSON: JOHN SIMPSON FROM THE
6 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I JUST
7 WANTED TO COMMEND THE STAFF AND ALL OF YOU FOR WHAT I
8 THINK IS A WONDERFUL PLAN. I THINK IT'S VERY
9 REALISTIC, AND I THINK THAT'S VERY IMPORTANT.

10 I WOULD ADD TO THAT, THOUGH, THAT NO MATTER
11 HOW GOOD THE SCIENTIFIC PLAN IS, THERE ARE OTHER
12 POLICIES THAT ARE EXCEEDINGLY IMPORTANT THAT YOU'LL BE
13 TALKING ABOUT LATER TODAY. IF THOSE AREN'T IN PLACE
14 THE RIGHT WAY, I THINK THAT THE PLAN DOES NOT CARRY THE
15 DAY. I'M TALKING SPECIFICALLY ABOUT THE INTELLECTUAL
16 PROPERTY. I'LL HAVE MORE TO SAY ABOUT THAT THEN.

17 ONE OTHER THING, IF I QUICKLY COULD BECAUSE I
18 DID NOT COMMENT ON DR. HALL'S PRESENTATION, THERE IS NO
19 DOUBT THAT THE STAFF AND THE WORKING GROUP DID A
20 PHENOMENAL, HISTORICAL, AND IMPORTANT ACTIVITY WHEN
21 THEY MADE THEIR RECOMMENDATIONS LAST WEEK. BUT I JUST
22 WANTED TO POINT OUT THAT IN THE STATE OF CONNECTICUT,
23 WHERE THEY THE PREVIOUS WEEK AWARDED TO A POOL OF 70
24 APPLICANTS 20 GRANTS ABOUT \$20 MILLION, THEY WERE ABLE
25 TO COME UP WITH A SYSTEM THERE WHERE EVERYONE KNEW WHO

1 APPLIED AND WHO DIDN'T GET GRANTS. AND I WOULD SUBMIT
2 THAT KNOWING WHO DOES NOT GET THE GRANT IS EVERY BIT AS
3 IMPORTANT WHEN YOU'RE DEALING WITH PUBLIC MONEY AS WHO
4 ULTIMATELY GETS IT.

5 I'M GRATIFIED THAT YOU TOOK MY SUGGESTION TO
6 LIST THE PEOPLE WHO ARE CONFLICTED. THAT'S A GOOD STEP
7 IN THE RIGHT DIRECTION, BUT I WOULD SUGGEST THAT THE
8 CONNECTICUT MODEL IS SOMETHING THAT YOU SHOULD LOOK
9 CLOSELY AT FOR WHEN THE MATERIAL FINALLY COMES TO THE
10 BOARD. EVERYONE'S NAMES ARE AVAILABLE, AN ABSTRACT IS
11 AVAILABLE, AN ABSTRACT OF THE PEER REVIEWERS' COMMENTS
12 IS AVAILABLE, THE SCIENTIFIC SCORE IS AVAILABLE, AND IT
13 SEEMED TO WORK VERY WELL IN CONNECTICUT. AND IT WOULD,
14 IN FACT, BUILD GREAT PUBLIC TRUST IN YOUR ENTERPRISE,
15 WHICH IS AN IMPORTANT THING TO DO. THANK YOU.

16 MS. FOGEL: HI. THANK YOU. I'M SUSAN FOGEL,
17 THE PRO CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH. AND
18 WE TOO APPRECIATE THE MUCH MORE GROUNDED VIEW OF THE
19 STRATEGIC PLAN.

20 THERE'S TWO THINGS I WANTED TO COMMENT ON.
21 ONE, WE COMPLETELY SUPPORT MR. SIMPSON'S COMMENTS ABOUT
22 MORE TRANSPARENCY, NOT ONLY WHO, BUT ALSO WHAT. I
23 THINK IT'S REALLY IMPORTANT FOR THE PUBLIC TO KNOW WHAT
24 TYPES OF RESEARCH PROPOSALS ARE COMING FORWARD AND WHAT
25 YOU'RE NOT FUNDING, NOT ONLY WHAT YOU ARE FUNDING.

1 BUT THE OTHER THING I WANT TO ADDRESS IS THE
2 WHOLE ISSUE OF THE EGG DONORS AND EGG RESEARCH. I
3 APPRECIATE THAT THROUGHOUT THE PLAN THERE'S LANGUAGE
4 THAT SAYS IT'S URGENT TO FIND WAYS OF NOT USING WOMEN
5 TO PRODUCE BIOLOGICAL MATERIALS FOR THIS RESEARCH, BUT
6 IT'S NOT FUNDED UNTIL YEARS DOWN THE ROAD. THIS SHOULD
7 BE A NO. 1 PRIORITY.

8 THE EARLIEST STAGES OF THE RESEARCH IS WHEN
9 FOLKS ARE GOING TO BE LOOKING FOR THE MOST EGG DONORS.
10 WE KNOW THE KOREANS USED THOUSANDS OF EGGS IN THEIR
11 UNSUCCESSFUL ATTEMPTS. WE KNOW SCIENTIFIC PROCESSES
12 GET MORE EFFICIENT. SO THE MOST WOMEN ARE GOING TO BE
13 AT THE HIGHEST RISK ON DAY ONE, AND WE THINK THAT OUGHT
14 TO BE PART OF THE RIGHT -- THE RIGHT START RIGHT OUT OF
15 THE GATE, THAT WE'RE PAYING ATTENTION TO WOMEN'S
16 HEALTH. THANK YOU.

17 CHAIRMAN KLEIN: DR. HALL, DO YOU HAVE A
18 COMMENT ON THAT POINT? I WASN'T SURE IF YOU HAD A
19 COMMENT ON THAT POINT.

20 DR. HALL: LATTER POINT. AS YOU KNOW, WE ARE
21 CONCERNED ABOUT THIS. WE HAD A WONDERFUL SYMPOSIUM PUT
22 ON FOR US BY THE INSTITUTE OF MEDICINE. YOU WILL BE
23 HEARING FROM THAT LATER. OUR "CIRM AND SOCIETY"
24 ENVISAGES ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF
25 STEM CELL RESEARCH. AND WE IMAGINE THAT EGG DONORS

1 WILL BE IMPORTANT THERE. THAT'S ONE OF THE ISSUES
2 AROUND EGG DONATION. THAT'S ONE OF THE THINGS THAT ARE
3 UP THERE.

4 AND THEN I THOUGHT I MADE THE POINT CLEAR,
5 SUSAN, THAT EVEN IF WE DON'T HIGHLIGHT IT AT THE
6 BEGINNING, WE RESERVE THAT IN CASE IT DOESN'T COME
7 THROUGH OTHERWISE. AND I THINK WHAT WE'LL FIND IS THAT
8 THESE KINDS OF EXPERIMENTS WILL COME IN, EVEN THOUGH
9 THE TITLE DOESN'T SAY THIS IS DERIVATION OF OTHER
10 METHODS, THAT THEY'LL COME IN UNDER BROAD RESEARCH
11 INITIATIVES.

12 MS. FOGEL: I APPRECIATE THAT, BUT WHAT WE'RE
13 ASKING IS THAT BE HIGHLIGHTED FROM THE BEGINNING RATHER
14 THAN IN CASE THEY DON'T COME THROUGH, THEN WE'LL FUND
15 IT IN 2009. THAT'S OUR REQUEST.

16 DR. HALL: THANK YOU FOR THE SUGGESTION.

17 I WOULD ALSO SAY TO JOHN SIMPSON THAT IT WILL
18 BE VERY APPARENT WHAT SCIENCE IS NOT FUNDED. YOU WILL
19 SEE THE TITLES OF ALL THE GRANTS AND ABSTRACTS OF ALL
20 THE GRANTS, AND I THINK THAT WILL TELL YOU EXACTLY
21 WHAT'S NOT FUNDED. IT SEEMS TO US THAT'S THE IMPORTANT
22 THING, AND THAT'S WHAT WE WOULD STRESS. THAT'S THE
23 WHOLE POINT OF HAVING THESE CONSIDERED PUBLICLY BY THE
24 ICOC, AND THAT IS THE KINDS OF SCIENCE, AND THE TITLES
25 WOULD BE RIGHT THERE.

1 MR. SERRANO-SEWELL: MR. CHAIRMAN, IF THERE'S
2 NO FURTHER PUBLIC COMMENT, I WOULD CALL THE QUESTION.

3 CHAIRMAN KLEIN: QUESTION HAS BEEN CALLED.
4 WITHOUT OBJECTION, I'D LIKE TO CALL FOR THE VOTE. ALL
5 IN FAVOR? OPPOSED? MOTION PASSES. THANK YOU VERY
6 MUCH, DR. HALL. THANK YOU, STAFF. IT'S A GREAT TEAM.

7 (APPLAUSE.)

8 DR. HALL: I'D LIKE A SPECIAL ROUND OF
9 APPLAUSE FOR PATRICIA OLSON AND TONY PILLARI, WHO DID
10 AN ABSOLUTE GREAT JOB.

11 (APPLAUSE.)

12 CHAIRMAN KLEIN: THE THOUGHT WOULD BE THAT
13 SINCE INTELLECTUAL PROPERTY REQUIRES GREAT
14 CONCENTRATION, WE HAVE A FIVE-MINUTE BREAK.

15 (A RECESS WAS TAKEN.)

16 DR. PENHOET: HALF OF OUR BOARD MEMBERS HAVE
17 RETURNED. THE OTHER HALF ARE DRIFTING IN. WELL, TO
18 REWARD THOSE OF YOU WHO HAVE RETURNED TO YOUR SEATS, I
19 WILL START NOW. WE'RE GOING TO DISCUSS TWO THINGS
20 TODAY. ONE IS THE REMAINING ISSUES ASSOCIATED WITH THE
21 NOT-FOR-PROFIT POLICY, WHICH, AS YOU KNOW, HAS GONE
22 THROUGH MUCH OF THE PROCESS OF TURNING OUR POLICY INTO
23 REGULATIONS. THERE ARE A COUPLE OF ISSUES WHICH REMAIN
24 IN THE NON-PROFIT POLICY THAT SCOTT TOCHER WILL TAKE
25 YOU THROUGH AFTER I FINISH THE DISCUSSION OF THE

1 FOR-PROFIT POLICY.

2 BUT THE BULK OF OUR DISCUSSION TODAY FOCUSES
3 ON FOR-PROFIT POLICY. THE NEXT SLIDE REITERATES FOR
4 YOU THE YEOMAN'S WORK DONE BY THIS TASK FORCE. THE
5 GREEN BARS INDICATE TASK FORCE MEETINGS. AS YOU CAN
6 SEE, WE'VE HAD FIVE OF THOSE MEETINGS, FOUR TASK FORCE
7 MEETINGS AND THIS MEETING -- FIVE TASK FORCE MEETINGS.
8 AND I THINK IT'S BEEN A VERY RICH PROCESS IN THE SENSE
9 WE'VE GOTTEN LOTS OF INPUT FROM MANY DIFFERENT SOURCES,
10 AS YOU CAN SEE HERE ON THIS SLIDE. WE HAD A
11 PARTICULARLY PRODUCTIVE MEETING IN NOVEMBER.
12 PERSONALLY I WAS CONCERNED THAT WE MIGHT NOT BE ABLE TO
13 REACH CONSENSUS ON OUR TASK FORCE BECAUSE WE HAD SOME
14 WIDELY DIVERGENT VIEWS ON JUST ONE OR TWO ISSUES GOING
15 INTO THAT MEETING. BUT THANKS TO SOME VERY HARD WORK,
16 ESPECIALLY ON THE PART OF DUANE ROTH AND JEFF SHEEHY,
17 WE MANAGED TO EMERGE FROM THE NOVEMBER MEETING WITH A
18 UNANIMOUS CONSENSUS IN OUR GROUP THAT SUPPORTS THE
19 POLICY THAT WE'RE HERE TO DISCUSS TODAY.

20 SO I JUST WANT TO TAKE THIS OPPORTUNITY TO
21 THANK THE TASK FORCE WHICH HAS BEEN TREMENDOUSLY
22 DILIGENT IN ITS WORK AND VERY THOUGHTFUL, I THINK, IN
23 THE WAY THE WORK HAS BEEN CARRIED OUT. I'D ALSO, OF
24 COURSE, LIKE TO ADD MY THANKS TO ALL THE LAUDATORY
25 COMMENTS ALREADY MADE ABOUT MY TRUSTED DEPUTY, MARY

1 MAXON, WITHOUT WHOM NONE OF THIS WOULD HAVE GOTTEN
2 DONE. AMONG ALL OF MARY'S OTHER GREAT QUALITIES IS HER
3 ABILITY TO STAY THE COURSE THROUGH TURBULENT TIMES. I
4 THINK MORE THAN ANY OTHER PERSON MARY HAS BEEN CAUGHT
5 IN THE CROSSFIRE FOR TWO YEARS BECAUSE WE'VE HAD VERY
6 WIDELY DIVERGENT VIEWS ABOUT HOW INTELLECTUAL PROPERTY
7 POLICIES SHOULD BE ARTICULATED AND CARRIED OUT. AND
8 THOSE WIDELY DIVERGENT VIEWS OFTEN FOCUSED THEIR FIRE
9 ON MARY, WHO WAS IN THE MIDDLE OF ALL THIS, AND
10 THROUGHOUT THE ENTIRE PERIOD OF TRYING TO BE
11 THOUGHTFUL, LISTEN TO ALL POINTS, BUT KEEP MOVING
12 FORWARD, MARY HAS DONE A MARVELOUS JOB OF DOING THAT.
13 SO, MARY, AGAIN I THANK YOU FOR ALL YOUR WONDERFUL HELP
14 WITH THIS PROJECT.

15 THE NEXT SLIDE SHOWS THE PROPOSED PRINCIPLES
16 THAT WE DISCUSSED WITH YOU LAST TIME. THESE WERE THE
17 PRINCIPLES THAT WERE APPROVED EARLY ON IN THE PROCESS
18 AND FORMED THE FOUNDATION OF OUR WORK FOR THE
19 FOR-PROFIT POLICY. THEY'RE SUMMARIZED HERE WITH A
20 COUPLE OF -- WITH AN INDICATION IN THE LIGHTER COLORED
21 TYPE OF THINGS THAT WE HAVE DELETED FROM OUR WORK. AS
22 SEE GRANTEES WILL OWN THE INTELLECTUAL PROPERTY. NOW
23 WE'RE TALKING ABOUT THE FOR-PROFIT POLICY. THAT THE
24 PUBLICATION REQUIREMENTS WILL BE BASICALLY THE SAME AS
25 THEY ARE IN THE NON-PROFIT POLICY. THAT

1 PUBLICATION-RELATED MATERIALS SHARING IS SIMILAR, AS
2 YOU WILL SEE, WITH SOME DIFFERENCE FROM THE
3 NOT-FOR-PROFIT POLICY. WE DELETED THE SECTIONS IN THIS
4 THAT REFER TO FUNDING STRATEGIES; THAT IS, WHETHER
5 THESE FUNDS ARE PROVIDED BY GRANTS OR LOANS.

6 OUR GROUP DECIDED THAT THE FUNDING MECHANISM
7 WAS BEYOND THE PURVIEW OF INTELLECTUAL PROPERTY; AND,
8 THEREFORE, WE DELETED FROM OUR WORK ANY DISCUSSION OR
9 REFERENCE TO THE SOURCE OF THE FUNDING FOR COMPANIES.
10 SO WE DON'T DEAL WITH LOANS AS A SEPARATE ITEM HERE.

11 IF THE ICOC DECIDES AT SOME POINT TO MAKE
12 LOANS TO COMPANIES FOR ANY REASON, THAT WILL BE DEALT
13 WITH AS A STRATEGY FOR FUNDING, AND THOSE LOANS WILL BE
14 SUBJECT TO THE SAME INTELLECTUAL PROPERTY RULES, BUT WE
15 DON'T DEAL WITH FUNDING MECHANISMS IN OUR DOCUMENT. WE
16 FELT THAT IT WENT BEYOND THE PURVIEW OF OUR TASK FORCE.

17 AND FOURTH BULLET POINT THERE OR THE FIFTH
18 SAYS THAT IF THE COMMERCIAL AWARDEE CHOOSES TO LICENSE
19 PATENTED INVENTIONS TO THIRD PARTIES, THAT THE
20 REQUIREMENTS FOR SUCH A LICENSE WOULD BE SIMILAR TO THE
21 REQUIREMENTS THAT ARE IN THE NOT-FOR-PROFIT POLICY
22 DOCUMENT. ONE DIFFERENCE, WHICH IS SIGNIFICANT IN
23 TERMS OF HOW IT LOOKS, BUT ACTUALLY THE SAME IN TERMS
24 OF THE REALITY OF WHAT THE STATE WILL GET, IS THAT THE
25 NOT-FOR-PROFIT POLICY, AS YOU WILL SEE, CALLS FOR THE

1 COMPANIES WHO RECEIVE FUNDING FROM US TO PROVIDE 17
2 PERCENT OF THEIR ROYALTY REVENUES BACK TO THE STATE
3 AFTER THOSE ROYALTY REVENUES HAVE EXCEEDED \$500,000.
4 THAT PIECE IS EXACTLY THE SAME AS THE NOT-FOR-PROFIT
5 POLICY.

6 THE NOT-FOR-PROFIT POLICY SAYS THAT THE
7 NOT-FOR-PROFIT ENTITIES WILL SHARE 25 PERCENT OF THEIR
8 REVENUES AFTER THEY PAID THE INVENTOR'S SHARE. SO IN
9 SURVEYING THE INSTITUTIONS OF THE STATE, TYPICALLY
10 INVENTORS GET ABOUT A THIRD OF THE GROSS ROYALTY
11 REVENUES THAT ARE PAID TO THEIR HOME INSTITUTIONS.
12 OKAY. SO THE 25 PERCENT IS 25 PERCENT OF TWO-THIRDS OR
13 67 PERCENT. THE 17 PERCENT GIVES CREDIT TO THE
14 FOR-PROFIT COMPANIES FOR THE INVENTOR'S SHARE BECAUSE
15 THEY EMPLOYED THESE PEOPLE, THEY'VE CONDUCTED THE
16 INVENTIVE ACT, BUT 17 PERCENT IS 25 PERCENT OF 68
17 PERCENT. SO IT'S BASICALLY THE SAME ON THE GROSS
18 NUMBER, BUT IT'S THE WAY IT'S CALCULATED. SO THE
19 NOT-FOR-PROFITS PAY 25 PERCENT OF THE REVENUES AFTER
20 DEDUCTING THE INVENTOR'S SHARE, AND FOR COMPANIES THAT
21 PAY 17 PERCENT, IT'S THE SAME PERCENTAGE -- IT'S THE
22 SAME DOLLAR AMOUNT BASED ON THE GROSS ROYALTY REVENUES.

23 THERE'S BEEN A FAIR AMOUNT OF
24 MISUNDERSTANDING ABOUT THAT. I WANT TO EMPHASIZE AGAIN
25 BECAUSE THIS GETS MORE OFTEN MISUNDERSTOOD, I THINK,

1 THAN ANY OTHER ASPECT OF OUR POLICY, THAT 25 PERCENT IS
2 25 PERCENT OF THE ROYALTY. IT'S NOT A 25-PERCENT
3 ROYALTY. AND WE DO NOT IN EITHER CASE, EITHER IN THE
4 NOT-FOR-PROFIT OR FOR-PROFIT CASE, WE DO NOT DICTATE
5 THE TERMS OF THE LICENSING AGREEMENTS OTHER THAN THE
6 ACCESS FEATURES, ETC., THAT WE WILL DISCUSS LATER.
7 THOSE TERMS ARE DONE BY EITHER THE FOR-PROFIT ENTITY OR
8 THE NOT-FOR-PROFIT ENTITY. THOSE LICENSES ARE DONE BY
9 THEM USING WHATEVER TERMS THEY BELIEVE ARE APPROPRIATE
10 AND ARE IN THEIR BEST INTEREST. WE ARE COUNTING ON
11 THEM THAT IF THEY DO WHAT'S IN THEIR BEST INTEREST,
12 VIS-A-VIS MAXIMIZING THEIR RETURNS ON THE INVESTMENTS
13 THAT WE AND THEY HAVE MADE IN THIS TECHNOLOGY, THAT WE
14 WILL GET OUR SHARE OF THAT. SO IT'S 25 PERCENT OF THE
15 ROYALTY OR 17 PERCENT OF THE ROYALTY.

16 IF COMMERCIAL ENTITIES CHOOSE TO DEVELOP THE
17 PRODUCTS THEMSELVES RATHER THAN LICENSE TO THIRD
18 PARTIES, THEN WE HAVE A NEW SET OF RULES THAT HAVE TO
19 COME INTO PLAY BECAUSE THE NOT-FOR-PROFITS DON'T
20 GENERALLY COMMERCIALIZE PRODUCTS. THAT'S NOT THE
21 REASON THEY'RE IN BUSINESS. SO WE HAVE A NUMBER OF
22 FEATURES THAT WE'LL SHARE WITH YOU TODAY TO DEAL WITH
23 THE CASE WHERE COMPANIES DEVELOP THESE PRODUCTS
24 THEMSELVES RATHER THAN LICENSE THE TECHNOLOGY TO THIRD
25 PARTIES. AND WE RECOGNIZED IN OUR WORK THAT THE STATE

1 OF CALIFORNIA HAS AN INTEREST TO ACTUALLY INCENT
2 COMPANIES TO FORWARD-INTEGRATE THEMSELVES IN THE STATE
3 TO DO MANUFACTURING, TO DO SALES AND MARKETING, TO
4 BUILD A FULLY INTEGRATED ORGANIZATION. SO ALTHOUGH WE
5 ANTICIPATE A FAIR AMOUNT OF LICENSING, WE ALSO WANTED
6 TO MAKE SURE THAT THE POLICIES IN PLACE, WHEN COMPANIES
7 WILL MAKE THE INVESTMENT TO FORWARD-INTEGRATE RATHER
8 THAN LICENSING OUT THE TECHNOLOGY, WHICH WILL BENEFIT
9 CALIFORNIA, ARE REASONABLE FOR THEM.

10 AGAIN, ANOTHER PROVISION ABOUT LOANS WHICH
11 WE'VE DELETED. WE DID DISCUSS THAT FOR GRANTS THAT IT
12 WOULD BE REASONABLE FOR THE STATE TO GET A ONE-TIME
13 BLOCKBUSTER PAYMENT, AND WE FLESH THAT OUT LATER ON IF
14 IT TURNS OUT WE HAVE FUNDED SOMETHING WHICH IS VERY
15 SUCCESSFUL.

16 AND THEN, FINALLY, WE HAD A QUESTION ABOUT
17 WHENEVER WE PROVIDE FUNDING TO A COMPANY IS AT WHAT
18 POINT DOES OUR FUNDING QUALIFY US TO ASK THE COMPANIES
19 TO PROVIDE THE ACCESS PLANS THAT WE'VE TALKED ABOUT AND
20 THE DISCOUNTED PRICING TO PUBLICLY FUNDED AGENCIES
21 WITHIN CALIFORNIA. AGAIN, AN ASPECT SOMETIMES
22 MISUNDERSTOOD, THESE LAST PROVISIONS ARE ONLY RELATED
23 TO PRODUCTS COMMERCIALIZED IN CALIFORNIA. WE SAY
24 NOTHING ABOUT WHAT COMPANIES WILL DO WITH THEIR
25 PRODUCTS OUTSIDE THE STATE OF CALIFORNIA.

1 THOSE ARE THE PRINCIPLES UPON WHICH WE'VE
2 BEEN WORKING. THE NEXT SLIDE SIMPLY SUMMARIZES KEY
3 ELEMENTS OF THE TWO STRATEGIES OR THE TWO POLICIES, AS
4 YOU WILL. ON THE LEFT NOT-FOR-PROFIT, AGAIN, LICENSING
5 25 PERCENT OF REVENUES IN EXCESS OF PAYMENTS TO
6 INVENTORS AND THAT AN ACCESS PLAN IS REQUIRED OF
7 LICENSEES, THAT SHARING OF PUBLICATION-RELATED
8 BIOMEDICAL MATERIALS IS REQUIRED, AND WE DON'T
9 ANTICIPATE ANY SELF-DEVELOPMENT; THAT IS,
10 COMMERCIALIZATION BY THE NOT-FOR-PROFIT AGENCIES.
11 THERE IS SOME CONCERN THAT SOME OF THE ELEMENTS IN THE
12 LICENSING PROVISION MAY DISCOURAGE LICENSEES FROM
13 TAKING LICENSES TO THIS TECHNOLOGY. AND WE HAVE TO
14 KEEP THAT IN THE BACK OF OUR MINDS GOING FORWARD.
15 THESE POLICIES CAN BE CHANGED. AND IF SOME OF THESE
16 THINGS IN THE FUTURE, WHEN LICENSING DISCUSSIONS BECOME
17 ESSENTIALLY LIVE, IF WE FIND THAT ANY OF THESE POLICIES
18 REPRESENT A SIGNIFICANT BARRIER TO COMMERCIALIZATION,
19 THEREFORE, BRINGING THE FRUITS OF THE LABOR TO THE
20 PUBLIC, THAT WE CAN REVISIT THESE ISSUES. AND I THINK
21 THAT'S -- I JUST WANTED TO MAKE SURE THAT EVERYONE
22 UNDERSTOOD THAT THESE POLICIES, ALTHOUGH THEY BECOME
23 LAW, CAN BE CHANGED BY US BY REEXAMINING THESE IN THE
24 FUTURE. BUT FOR NOW, AT LEAST, THESE ARE THE POLICIES
25 WE HAVE ON THE NOT-FOR-PROFIT SIDE.

1 ON THE FOR-PROFIT SIDE, IT'S VERY SIMILAR.
2 SHARING BIOMEDICAL MATERIALS IS REQUIRED; HOWEVER, IN
3 THIS CASE, UNLESS SUCH SHARING DAMAGES THE COMPANY IN
4 SOME WAY. IF THEY CAN SHOW THAT BY PROVIDING
5 MATERIALS, ETC., TO THEIR COMPETITORS, FOR EXAMPLE, IT
6 WOULD DAMAGE THEIR COMPETITIVE POSITION, WE WOULD WAIVE
7 THAT REQUIREMENT. IN THIS CASE WE DO ANTICIPATE
8 FORWARD-INTEGRATION BY SOME OF THESE COMPANIES,
9 SELF-DEVELOPMENT OF PRODUCTS RATHER THAN LICENSING.
10 THERE WE HAVE EXPECTED RETURN AT THE TIME OF CREATION
11 OF REVENUES WHICH IS CAPPED AT THREE TIMES THE AMOUNT.
12 THIS WAS A SUBSTANTIAL ISSUE BROUGHT TO US BY INDUSTRY,
13 THAT THEY WERE WILLING TO PAY BACK, BUT THEY WANTED TO
14 KNOW WITH SOME CERTAINTY WHAT THEIR TOTAL OBLIGATION
15 WOULD BE. AFTER A LOT OF DISCUSSION, WE SETTLED ON THE
16 3 X AMOUNT PAYABLE ONLY IF THE PROJECT IS SUCCESSFUL.

17 THE SECOND ONE IS THAT WE HAVE A TIERED
18 BLOCKBUSTER PAYMENT WHICH IS ANOTHER 3 X TIMES THE
19 AMOUNT EXPECTED WHEN REVENUES REACH MULTIPLES OF \$250
20 MILLION A YEAR. SO IN A GIVEN YEAR, THE REVENUES REACH
21 \$250 MILLION, THEN THE COMPANY WOULD PAY ANOTHER 3 X.
22 IF THEY REACH \$500 MILLION, AS YOU WILL SEE, THEY WILL
23 PAY AN ADDITIONAL 3 X. SO IF A COMPANY REACHES \$500
24 MILLION IN SALES, THEY WILL HAVE EFFECTIVELY PAID BACK
25 NINE TIMES THE ORIGINAL INVESTMENT. THE 3 X, WHICH IS

1 NOT A BLOCKBUSTER PAYMENT, AN ADDITIONAL 3 X AT TWO
2 FIFTY, AND A THIRD ONE AT 500. BEYOND 500 WE HAVE A
3 DIFFERENT MECHANISM FOR DEALING WITH THAT, AS YOU WILL
4 SEE IN A MOMENT. WE ALL HOPE THAT WILL HAPPEN SOMEDAY.
5 AS YOU CAN SEE HERE, IF REVENUES EXCEED \$500 MILLION A
6 YEAR AND THE CIRM-FUNDED PATENT IS INVOLVED, THEN A
7 1-PERCENT ROYALTY WOULD BE EXPECTED FOR REVENUES IN
8 EXCESS OF \$500 MILLION FOR THE LIFE OF THE PATENT.

9 AND THEN FINALLY, WE DISCUSSED A LOT ABOUT
10 WHAT LEVEL OF INVESTMENT BY CIRM WOULD TRIGGER THE
11 ACCESS AND PRICING FEATURES THAT WE HAVE BUILT INTO OUR
12 PROPOSAL. AFTER A LOT OF DISCUSSION, WE DECIDED THAT
13 THE ANSWER SHOULD BE THE FIRST DOLLAR IN; THAT IS, IF
14 YOU TAKE ANY LEVEL OF CIRM FUNDING, THAT YOU SHOULD BE
15 WILLING TO AGREE TO THE ACCESS PROGRAMS.

16 THE NEXT SLIDE SUMMARIZES THIS SAME
17 INFORMATION IN A VERY GRAPHIC FORM, AS YOU CAN SEE.
18 FOR SELF-DEVELOPED PRODUCTS, COMMERCIALIZATION OCCURS,
19 ALL GRANTEES RETURN 3 X OF THE TOTAL GRANT AWARD. AND
20 IF THEY ACHIEVE BLOCKBUSTER STATUS, WHICH WE'VE DEFINED
21 AS \$250 MILLION, AND WE'VE INVESTED LESS THAN \$5
22 MILLION IN THE PROJECT, THEN THEY'LL PAY THE
23 BLOCKBUSTER FEES THAT I JUST TOLD YOU ABOUT. THESE
24 WILL STOP AT 500, SO THERE'LL BE A CAP OF 9 X TOTAL FOR
25 THOSE INVESTMENTS. IF BLOCKBUSTER STATUS IS ACHIEVED

1 AND WE'VE INVESTED MORE THAN \$5 MILLION AND IF A CIRM
2 PATENT IS INVOLVED, THEN THEY'LL PAY THE BLOCKBUSTER
3 PAYMENT PLUS A 1-PERCENT ROYALTY ON ALL SALES ABOVE
4 \$500 MILLION.

5 THIS PARTICULAR CHART, I THINK, WE HAVE TO
6 JEFF AND DUANE ROTH FOR WORKING CAREFULLY THROUGH AND
7 SUGGESTING AT OUR LAST MEETING. I THINK IT'S SOMETHING
8 WE NOW UNANIMOUSLY SUPPORT.

9 THE NEXT SLIDE IS THE FEATURES OF ACCESS TO
10 RESULTANT THERAPIES THAT WE HAVE DISCUSSED. AND WE
11 SAID, AND THIS IS BASICALLY THE SAME AS IN THE
12 NON-PROFIT POLICY, AT THE TIME OF COMMERCIALIZATION,
13 FOR-PROFIT ENTITIES WILL PROVIDE A PLAN FOR ACCESS TO
14 RESULTANT THERAPIES FOR UNINSURED CALIFORNIA RESIDENTS.
15 THIS DOES NOT SPECIFY EXACTLY WHAT THAT PLAN WILL BE.
16 IT SAYS THAT THEY WILL PROVIDE A PLAN. AND IN RESPONSE
17 TO A NUMBER OF CONCERNS FROM INDUSTRY ABOUT THE TIMING
18 OF THIS FEATURE, WE AGREED TO MAKE IT AT THE TIME OF
19 COMMERCIALIZATION, NOT BEFORE, BECAUSE IT'S HARD TO
20 ANTICIPATE EXACTLY HOW THIS WOULD WORK UNLESS YOU'RE
21 ACTUALLY AT THE POINT OF COMMERCIALIZING IT.

22 THE SECOND FEATURE IS THAT FOR-PROFIT
23 GRANTEES WILL PROVIDE DISCOUNT PRICING FOR THERAPIES
24 FOR CALIFORNIA RESIDENTS WHOSE THERAPIES ARE PURCHASED
25 WITH PUBLIC FUNDS. AGAIN, THIS IS A VERY CONTROVERSIAL

1 ASPECT OF THIS POLICY, WITHOUT DOUBT. WE HAVE HAD, AND
2 WE'LL GO THROUGH SOME OF THIS IN MORE DETAIL WHEN SCOTT
3 COMES UP HERE, WE'VE HAD SOME DIFFICULTY IN FINDING
4 BENCHMARKS FOR THE SO-CALLED LOWEST AVAILABLE PRICE
5 THAT ARE PRACTICAL BENCHMARKS.

6 WE HAVE DECIDED TO DELETE REFERENCES TO THESE
7 PRICING FEATURES FOR PRODUCTS OTHER THAN THERAPIES,
8 WHETHER THEY BE DRUGS OR OTHER FORMS OF THERAPY. THERE
9 ARE NOT GOOD BENCHMARKS FOR PRICING DIAGNOSTICS IN THIS
10 REGARD, AND GENERALLY DIAGNOSTICS ARE VERY LOW PRICED
11 COMPARED TO THERAPIES. AND SO THE CONCERN OF OUR GROUP
12 REALLY WAS THE PRICE OF THERAPIES, NOT SOME OF THE
13 OTHER COMPONENTS THAT MIGHT COME OUT OF THIS. SO WE
14 FOCUSED ON THERAPIES, EITHER DRUGS OR OTHER FORMS OF
15 THERAPY. AS SCOTT WILL TELL YOU, THERE ARE VERY FEW
16 BENCHMARKS FOR THERAPIES OTHER THAN DRUGS TODAY. OTHER
17 KINDS OF THERAPIES, TRANSPLANTS TODAY, ORGAN
18 TRANSPLANTS, FOR EXAMPLE, IT'S VERY HARD TO FIND ANY
19 SORT OF UNIFORM WAY OF ESTABLISHING THE LOWEST PRICES
20 FOR TRANSPLANTS. AND SO THAT PART OF BOTH THE
21 NOT-FOR-PROFIT POLICY AND THE FOR-PROFIT POLICY ARE
22 STILL WORKS IN PROGRESS TO FIND EXACTLY THOSE
23 BENCHMARKS THAT WE NEED TO PUT INTO THE LAW.

24 WE SAY HERE THAT IN THE UNFORTUNATE EVENT OF
25 LIMITED THERAPEUTIC AVAILABILITY, PREFERENCE WILL BE

1 GIVEN TO CALIFORNIA RESIDENTS WHERE POSSIBLE. AND THIS
2 IS AN ELEMENT, WHEN I SAID WE HAD UNANIMOUS APPROVAL OF
3 THE WORKING GROUP FOR THE POLICIES I'M PRESENTING TO
4 YOU TODAY, THE ONE EXCEPTION WAS THAT TED LOVE
5 ABSTAINED IN THE VOTE ON THIS PIECE OF THE POLICY.
6 TED'S CONCERN IS IF THIS IS A LAW AND THE COMPANY IS
7 FACED WITH SOME OTHER VERY COLD REALITIES ABOUT NOT
8 BEING ABLE TO ACTUALLY LIVE UP TO THIS, AND A TYPICAL
9 EXAMPLE IS IF SOMEONE DEVELOPS A NEW DRUG OR A NEW
10 THERAPY WHERE THEY HAVE LIMITED CAPACITY TO
11 MANUFACTURE.

12 I HAVE PERSONAL EXPERIENCE WITH THIS. WHEN
13 WE DEVELOPED BETA SERUM FOR MULTIPLE SCLEROSIS, WE HAD
14 LIMITED CAPACITY TO PRODUCE THAT PRODUCT AT CHIRON FOR
15 ABOUT A YEAR. WE HAD TO INTRODUCE A LOTTERY SYSTEM
16 ESSENTIALLY FOR WHICH PATIENTS WOULD GET THE THERAPY
17 AND WHICH PATIENTS WOULDN'T. AND IT WAS, TO BE FRANK
18 WITH YOU, ONE OF THE MOST DIFFICULT THINGS THAT I FACED
19 IN MY BUSINESS CAREER WAS RUNNING THIS IN A COMPLETELY
20 FAIR WAY. AND WE HAD LOTS OF PRESSURES FROM DIFFERENT
21 ORGANIZATIONS. THERE MAY BE OTHER FUNDERS, THERE MAY
22 BE PRESSURE FROM THE FEDERAL GOVERNMENT, THERE MAY BE
23 RULES BY THE FDA; SO ALTHOUGH WE HAVE THIS IN OUR
24 DOCUMENT TODAY AS SOMETHING THAT WE MIGHT MOVE FORWARD
25 THROUGH THE REGULATORY PATHWAY, I THINK IN REFLECTION

1 THAT MANY OF US BELIEVE THIS IS BEST DEALT WITH AS A
2 POLICY RATHER THAN A LAW BECAUSE OF THE DIFFICULT
3 POSITION WE MAY, IN FACT, PUT COMPANIES IN IN TRYING TO
4 COMPLY WITH THIS GOING FORWARD. I SEEK YOUR GUIDANCE
5 ON THIS ISSUE WHEN WE DISCUSS THESE POLICIES.

6 AND ALL OF THESE REQUIREMENTS ARE TRIGGERED,
7 AS I SAID, BY THE FIRST DOLLAR APPLIED TO A CIRM-FUNDED
8 PROJECT THAT LEADS TO A COMMERCIAL PRODUCT.

9 WE GO NOW SPECIFICALLY THROUGH THE DOCUMENT.
10 AS WE DO, THROUGHOUT THIS THERE ARE MANY SIMILARITIES
11 WITH THE NOT-FOR-PROFIT POLICY, AND WE DON'T WANT TO
12 READ THROUGH ALL OF THOSE. SO WE'VE HIGHLIGHTED IN
13 BLUE FOR YOUR VIEWING PLEASURE THOSE PARTS OF THIS
14 WHICH ARE UNIQUE TO THE FOR-PROFIT PIECE.

15 SO IF WE CAN GO TO THE NEXT SLIDE. FIRST IS
16 REPORTING REQUIREMENTS. IN THE CASE OF PATENT
17 APPLICATIONS AND PATENTS, CIRM ASKS FOR DISCLOSURES OF
18 THOSE TO CIRM BY COMPANIES WHO FILE SUCH PATENTS, BUT
19 WE WANT TO MAKE SURE THAT THEY ARE HELD IN CONFIDENCE
20 AND THAT THEY CAN BE EXEMPTED FROM THE CALIFORNIA
21 PUBLIC RECORDS ACT. THIS IS OBVIOUSLY A VERY CRUCIAL
22 ISSUE FOR COMPANIES WHO ARE DEVELOPING INTELLECTUAL
23 PROPERTY.

24 THE NEXT SLIDE, THE REPORTING REQUIREMENTS,
25 THE COMPANIES MUST LET US KNOW WHEN THEIR PATENTS

1 ISSUED, INCLUDING THE PATENT NUMBER, ETC., AT ISSUANCE.
2 THIS IS SIMPLY A TRANSPARENCY ISSUE SO THAT WE CAN ALSO
3 TRACK THIS IN THE FUTURE.

4 NO. 5 THERE SAYS IN THE EVENT OF A REVENUE
5 STREAM CREATED AS A CONSEQUENCE OF THESE INVENTIONS,
6 THE AWARDEE ORGANIZATION SHALL KEEP ACCURATE RECORDS,
7 ETC. AND THE RECORDS ARE IMPORTANT BECAUSE IT MAY BE
8 POSSIBLE THAT SOME OF THIS WORK WOULD BE FUNDED BY
9 THIRD PARTIES, AND WE HAVE TO FIGURE OUT A FAIR
10 APPORTIONMENT OF THE REVENUES THAT COME IN.

11 PUBLICATION REQUIREMENTS ARE BASICALLY THE
12 SAME AS THE NOT-FOR-PROFIT POLICY. HOWEVER, THE
13 SHARING, AS I SAID BEFORE, HAS BEEN MODIFIED FOR
14 COMPANIES IN THE FOLLOWING WAYS. UNLESS A SPECIAL CASE
15 COULD BE MADE TO CIRM THAT DOING SO WOULD ENDANGER THE
16 COMPETITIVE POSITION OF THE COMPANY, AN AWARDEE SHALL
17 SHARE BIOMEDICAL MATERIALS. SO THIS IS A CARVE-OUT IN
18 NOT FORCING COMPANIES TO GIVE THESE MATERIALS, FOR
19 EXAMPLE, TO A DIRECT COMPETITOR.

20 FINALLY, IF THE REQUESTS BECOME ONEROUS OR IN
21 DIRECT CONFLICT WITH THE BUSINESS OF THE AWARDEE, THE
22 FOR-PROFIT AWARDEES CAN APPEAL TO CIRM FOR ALTERNATIVE
23 ARRANGEMENTS. THIS IS A PARTICULAR ISSUE FOR THE
24 COMPANIES THAT ARE ENGAGED IN THE TOOLS BUSINESS,
25 MAKING REAGENTS AND OTHER THINGS USED IN THIS AREA, AND

1 SO THIS IS A REFLECTION OF THE REALITY OF THEIR
2 BUSINESS CONCERNS THAT LED US TO MODIFY THIS SECTION
3 ACCORDINGLY, AS YOU SEE HERE.

4 THE NEXT SLIDE, AGAIN, DEALS WITH PATENTS AND
5 IS FUNDAMENTALLY THE SAME AS WHAT WE JUST COVERED.
6 IT'S JUST A NOTIFICATION ISSUE.

7 THIS ONE IS THE SAME IN LICENSING AS IS THE
8 NEXT ONE AFTER THIS. AND SO IF YOU GO TO G, THE NEXT
9 ONE, REVENUE SHARING FEATURES ARE DIFFERENT. SO IN THE
10 EVENT OF THE CREATION OF REVENUE STREAMS FROM
11 CIRM-FUNDED PATENTED INVENTIONS LICENSED TO THIRD
12 PARTIES, AS I REFERRED TO BEFORE, THE NET REVENUES ARE
13 DEFINED AS THE GROSS REVENUES MINUS DIRECT COSTS
14 INCURRED IN THE GENERATION OF PROTECTION OF THE PATENTS
15 FROM WHICH THE REVENUES ARE RECEIVED. IN THE
16 NOT-FOR-PROFIT IT'S MINUS INVENTOR'S SHARE, SO THAT'S
17 TAKEN OUT OF HERE.

18 IN THE BOTTOM SAYS AWARDEES MUST SUBMIT
19 CALCULATIONS DETAILING CIRM'S CONTRIBUTION TO THE
20 INVENTION, AND CIRM RESERVES THE RIGHT ESSENTIALLY TO
21 AUDIT THOSE CALCULATIONS.

22 PRESS RELEASES, H, NEXT SLIDE. I'M SORRY. I
23 SKIPPED OVER G. THIS IS AN IMPORTANT SLIDE. THANK
24 YOU, MARY. IN THE EVENT OF CREATION OF REVENUE STREAMS
25 FROM SELF-COMMERCIALIZED PRODUCTS THAT RESULT IN

1 CIRM-FUNDED PATENTED INVENTIONS, FIRST OF ALL, AWARDEE
2 ORGANIZATIONS SHALL SHARE THE REVENUES WITH THE STATE
3 OF CALIFORNIA, ETC., IN THE FORM OF ROYALTIES TO BE
4 CAPPED AT THREE TIMES THE TOTAL AWARD MONEY, ADJUSTED
5 AS ABOVE USING A CONSUMER PRICE INDEX CALCULATION.
6 AWARDEE ORGANIZATIONS MUST SUBMIT CALCULATIONS
7 DETAILING CIRM'S CONTRIBUTION TO THE RESULTANT PRODUCT,
8 AND CIRM RESERVES THE AUDITING RIGHTS.

9 IN THE EVENT THAT REVENUES FROM CIRM-FUNDED
10 PROJECTS ACHIEVE BLOCKBUSTER STATUS, ONE, FOR GRANTS
11 THAT LEAD TO VERY SUCCESSFUL COMMERCIAL PRODUCTS, A
12 ONETIME BLOCKBUSTER PAYMENT EQUAL TO THREE TIMES THE
13 ORIGINAL AWARD IS EXPECTED EACH TIME REVENUES EXCEED A
14 MULTIPLE OF \$250 MILLION A YEAR. THAT'S NOT EVERY
15 YEAR, HOWEVER, I WANT TO EMPHASIZE. THAT'S A ONE-TIME
16 PAYMENT. WHEN THEY REACH THAT THRESHOLD, THEY'LL PAY
17 IT. IF THEY STAY AT \$300 MILLION A YEAR FOR THE NEXT
18 TEN YEARS, THEY WON'T HAVE TO KEEP PAYING THAT EVERY
19 YEAR. IT'S A ONE-TIME PAYMENT. BOB.

20 CHAIRMAN KLEIN: ON G I, ROMAN I, THE
21 REFERENCE TO BEING DEPOSITED IN THE STATE'S GENERAL
22 FUND IS DIRECTLY TIED TO THE FACT THAT THESE ARE
23 ROYALTIES. SO IF, IN FACT, THERE WERE A LOAN PROGRAM,
24 LOAN PROCEEDS COME BACK TO THIS AGENCY FOR OTHER
25 MEDICAL RESEARCH, IT'S A DIFFERENT STRUCTURE. SO THIS

1 IS SPECIFICALLY AS TO A ROYALTY STRUCTURE.

2 DR. PENHOET: YES. THANK YOU.

3 AND THEN BLOCKBUSTER STATUS, 250 AND 500, AS
4 WE SAID BEFORE. IN THE EVENT THAT THE CIRM INVESTED
5 MORE THAN \$5 MILLION IN AGGREGATE IN A RESEARCH PROJECT
6 AND A CIRM-FUNDED PATENTED INVENTION WAS INVOLVED IN
7 THE ACHIEVEMENT OF BLOCKBUSTER REVENUES EQUIVALENT TO
8 OR GREATER THAN \$500 MILLION A YEAR, THEN CIRM WOULD
9 REQUIRE THE PAYMENT OF A 1-PERCENT ROYALTY ON REVENUES
10 IN EXCESS OF \$500 MILLION FOR THE LIFE OF THE PATENT.

11 NOW WE CAN GO TO H, PRESS RELEASE
12 REQUIREMENTS. WE HAD A LOT OF DISCUSSION WITH THIS AT
13 THE LAST BOARD MEETING. WE HAVE MODIFIED THIS, AND
14 SCOTT WILL TAKE YOU THROUGH IT FOR THE NOT-FOR-PROFIT,
15 BUT THEY MUST NOTIFY US PRIOR TO PRESS RELEASE FOR
16 EVENTS THAT ARISE AS A CONSEQUENCE OF THE FUNDING BY
17 CIRM BY CONTACTING THE CIRM COMMUNICATIONS OFFICER. SO
18 NO LONGER REQUIRE REVIEW OF THE PRESS RELEASES OR JOINT
19 PRESS RELEASES, BUT WE DO STILL REQUIRE THAT WE'RE
20 NOTIFIED SO WE KNOW WHAT'S COMING.

21 AND THEN BASICALLY UNDER I, THE MARCH-IN
22 RIGHTS ARE VERY SIMILAR. THERE ARE JUST SOME WORDING
23 CHANGES HERE, AND I THINK WE CAN SKIP OVER THAT.

24 SO THAT IS, IN ESSENCE, THE ENTIRETY OF THE
25 NOT-FOR-PROFIT POLICY. IF WE CAN GO BACK AND JUST PUT

1 UP THE SLIDE, WHICH IS THE THIRD ONE FROM THE
2 BEGINNING, MELISSA, OF THAT FLOW CHART, THAT'S A GOOD
3 PLACE TO LEAVE UP AS WE HAVE THIS DISCUSSION. BUT AT
4 THIS POINT I WOULD BE VERY HAPPY TO ENTERTAIN QUESTIONS
5 FROM THE GROUP ABOUT ANYTHING THAT WAS JUST PRESENTED
6 HERE. WE ARE HERE TO SEEK YOUR APPROVAL FOR THIS TODAY
7 SO THAT WE CAN MOVE IT INTO THE REGULATORY PROCESS,
8 WHICH FOR THE NOT-FOR-PROFIT HAS TAKEN US ABOUT SIX
9 MONTHS, I GUESS, SCOTT, AND I DON'T EXPECT THAT -- OR
10 MORE, AS MARY POINTS OUT. I DON'T EXPECT THIS WILL BE
11 ANY SHORTER. THERE WILL BE OBVIOUSLY MORE
12 OPPORTUNITIES FOR PUBLIC COMMENT, MORE MEETINGS AS WE
13 GO THROUGH THIS PROCESS, BUT WE WANT TO GO INTO THAT
14 PROCESS WITH AN APPROVAL FROM THIS BOARD OF THIS POLICY
15 AS WE SEEK TO GENERATE THE SPECIFIC LANGUAGE RELATING
16 TO THE REGULATIONS THAT WE WANT TO PUT IN PLACE, AND WE
17 CONTINUE TO HAVE THOSE DISCUSSIONS.

18 WITH THAT COMMENT, DR. KESSLER.

19 DR. KESSLER: ED, TWO QUESTIONS. THANKS FOR
20 ALL THE INCREDIBLE HARD WORK. THIS IS VERY COMPLICATED
21 AND YOU WALK A TERRIFIC BALANCING LINE HERE, AND I
22 THINK YOU'VE DONE VERY ADMIRABLY ON THAT.

23 THE PLAN THAT YOU CALL FOR, THE SLIDE, THE
24 WORDS WERE PLAN FOR ACCESS TO UNINSURED. AGAIN, THAT'S
25 NOT GOING TO BE PART OF THE REGULATION NECESSARILY?

1 DR. PENHOET: NO. THE PLAN FOR ACCESS FOR
2 UNINSURED WILL BE PART OF THE REGULATION. THE ONLY
3 PART OF THIS WHICH WILL NOT -- MY PROPOSAL IS THAT IT'S
4 POLICY RATHER THAN REGULATION IS THE PIECE WHICH SAYS,
5 AND YOU WOULD UNDERSTAND THIS BETTER THAN ANYONE EXCEPT
6 MICHAEL PROBABLY, THE PIECE WHICH SAYS THAT IF THERE IS
7 A SHORT SUPPLY, CALIFORNIANS WILL GET PREFERABLE ACCESS
8 TO THE SHORT SUPPLY.

9 DR. KESSLER: LET'S STAY WITH THE PLAN FOR A
10 SECOND. THAT WOULD BE THE PART OF THE REGULATION.

11 DR. PENHOET: THE PLAN FOR ACCESS AS WE'RE
12 CURRENTLY PROPOSING IT TO YOU IS THAT BECOMES PART OF
13 THE REGULATION.

14 DR. KESSLER: NOW THE QUESTION IS WHAT HAS TO
15 BE IN THAT PLAN? IF YOU SAY A PLAN FOR ACCESS FOR THE
16 UNINSURED, NOW, DOES THAT MEAN I HAVE TO PLAN TO
17 PROVIDE ACCESS TO ALL UNINSURED?

18 DR. PENHOET: WE DELIBERATELY LEFT IT --

19 DR. KESSLER: YOU CAN'T. THAT'S MY CONCERN.
20 IF YOU ARE GOING TO PUT THIS IN REGULATION AND HAVE THE
21 FORCE OF LAW, WE DON'T HAVE A CHOICE TO BE AMBIGUOUS.

22 DR. PENHOET: WE THOUGHT WE DID IF WE LEFT
23 THE LANGUAGE -- THE REQUIREMENT --

24 DR. KESSLER: YOU CAN DO THAT. BUT THAT'S
25 JUST, WITH ALL DUE RESPECT, TO THOSE WHO HAVE TO COMPLY

1 WITH THE REGULATION, IT PUTS THEM IN AN UNTENABLE
2 POSITION. IS A PLAN A PIECE OF PAPER? IS IT ACCESS
3 FOR 5 PERCENT OR 20 PERCENT? HOW IS THAT ENFORCEABLE?
4 AGAIN, I'M BEING OVERLY PERHAPS LEGALISTIC, BUT WE JUST
5 CAN'T -- YOU CAN'T -- IF YOU ARE GOING TO DO
6 REGULATIONS, YOU'RE GOING TO HAVE THE FORCE OF LAW, WE
7 HAVE AN OBLIGATION NOT TO BE VAGUE.

8 DR. PENHOET: WELL, THE WISDOM OF THE GROUP
9 WAS THAT WE WISHED TO LEAVE THIS TO THE INVENTIVENESS
10 OF THE COMPANIES TO COME UP WITH A PLAN. LET ME SAY
11 WHAT OUR INTENT WAS. AND, OF COURSE, WE CAN MOVE ON TO
12 ANOTHER. THE INTENT WAS THAT WE WOULD FORCE THEM TO
13 HAVE A PLAN, BUT THAT WE WOULD NOT BE PROSCRIPTIVE
14 TODAY ABOUT WHAT WAS IN THE PLAN. AND WE HAD, I THINK,
15 A CONSENSUS THAT THE PLANS, FIRST OF ALL, IF YOU LOOK,
16 MOST COMPANIES WHO WORK IN AREAS OF GREAT CONCERN TO
17 PUBLIC HEALTH DO END UP WITH PLANS FOR ACCESS, AND THAT
18 THEY DIFFER FROM ONE COMPANY TO THE NEXT. AND THAT IT
19 WOULD BE VERY DIFFICULT FOR US NOW TO PROSCRIBE
20 PRECISELY WHAT WOULD BE IN SUCH A PLAN IN THE FUTURE
21 FOR PRODUCTS THAT WE DON'T REALLY HAVE TODAY.

22 AND JEFF SHEEHY -- I'M SORRY HE'S NOT HERE.
23 I'M SORRY, JEFF. SOMEHOW I NEVER SEE YOU, JEFF. JEFF
24 HAS HAD A LOT OF EXPERIENCE. HE COULDN'T BE SITTING
25 ANY CLOSER TO YOU.

1 DR. KESSLER: I UNDERSTAND. THE INTENT IS
2 GREAT, AND IF YOU WANT TO FUDGE -- YOU WANT TO GIVE
3 AMBIGUITY HERE, THAT'S FINE. YOU JUST CAN'T DO
4 AMBIGUITY BY REGULATION.

5 DR. PENHOET: WELL, THE REGULATION FOR THAT
6 HAS BEEN APPROVED FOR NOT-FOR-PROFIT POLICY, AND
7 BASICALLY THE REGULATION SAYS JUST WHAT THIS SAYS, THAT
8 THEY MUST PROVIDE A PLAN. IT DOESN'T SPECIFY WHAT'S IN
9 THE PLAN.

10 MR. SHEEHY: YOU KNOW, THERE WAS SOME
11 DISCUSSION FROM MY ESTEEMED COLLEAGUE DUANE ROTH ABOUT
12 TYING THIS TO THE PREVAILING INDUSTRY STANDARD. AND
13 THAT MIGHT BE -- THAT'S THE REAL DRIVER HERE IS THAT,
14 FOR THE MOST PART, MOST COMPANIES MAKE THESE PLANS, ARE
15 GOOD CITIZENS AND ARE VERY PROACTIVE AND RECOGNIZE THAT
16 THERE ARE PEOPLE IN THIS COUNTRY AND AROUND THE WORLD
17 THAT CAN'T ACCESS THESE THERAPIES BECAUSE THEY DON'T
18 HAVE INSURANCE. AND SO WOULD THAT BE SUFFICIENT, IF WE
19 PUT IN LANGUAGE THAT SUFFICIENTLY --

20 DR. KESSLER: SOMEONE IS GOING TO SUE ONE DAY
21 WITH THAT LANGUAGE AND SAY YOU HAVE NOT PROVIDED ACCESS
22 TO A HUNDRED PERCENT OF THE UNINSURED. IT'S A PLAN TO
23 MAKE ACCESS TO THE UNINSURED. AND WE HAVE -- WE JUST
24 HAVE TO BE SPECIFIC ON WHAT WE'RE GOING TO REQUIRE
25 HERE.

1 MR. SHEEHY: MY POINT IS IF WE -- WE MAY SEND
2 THIS PART BACK FOR A LITTLE FINE-TUNE, BUT WHAT ABOUT A
3 REFERENCE TO INDUSTRY STANDARD BECAUSE THERE IS, I
4 THINK, SOME SORT OF INDUSTRY STANDARD. WE COULD FALL
5 SOMEWHERE WITHIN THE TOP, BUT SOME INDUSTRY STANDARD.

6 DR. KESSLER: IF YOU WANT TO GIVE CERTAIN
7 EXAMPLES OF PLANS THAT COULD BE ACCEPTABLE, MY CONCERN
8 IS JUST LEAVING IT THAT VAGUE COULD BE INTERPRETED TO
9 MEAN THAT SOMEBODY IS REQUIRED TO PROVIDE ACCESS, AND I
10 DON'T THINK THAT'S WHAT YOUR INTENT IS.

11 DR. PENHOET: WE COULD ADD THE WORD "ALL" TO
12 DEFINE THE CLASS MORE PRECISELY. ALL UNINSURED
13 CALIFORNIANS, FOR EXAMPLE.

14 DR. THAL: I TOTALLY AGREE. I DON'T THINK
15 THAT YOU'RE GOING TO BE ABLE TO SPECIFY THE PLAN AT
16 THIS TIME. I DON'T THINK IT MAKES ANY SENSE TO SPECIFY
17 THE PLAN. WE HAVE NO IDEA WHAT THE ANIMAL IS GOING TO
18 LOOK LIKE FIVE OR TEN YEARS FROM NOW. I THINK THAT THE
19 STATEMENT THAT IT'S GOING TO COVER ALL UNINSURED WILL
20 SUFFICE. AS YOU HAVE ALREADY MENTIONED, THERE ARE MANY
21 COMPANIES THAT HAVE PUT IN PLACE EXACTLY SUCH PLANS.

22 DR. KESSLER: YOU'RE GOING TO COVER ALL --
23 PROVIDE ACCESS TO ALL UNINSURED?

24 DR. PENHOET: IF YOU WANT MORE PRECISE
25 DEFINITION OF THE CLASS, I.E., UNINSURED PEOPLE, THAT

1 WOULD BE ONE WAY TO DEFINE THEM.

2 DR. KESSLER: THE REQUIREMENT IS TO PROVIDE
3 ACCESS TO THIS THERAPY FOR ALL UNINSURED PEOPLE WHO
4 NEED ACCESS. THAT'S THE REQUIREMENT?

5 DR. BRYANT: NO, NOT THE WAY IT'S WRITTEN.

6 CHAIRMAN KLEIN: I THINK DR. BRYANT HAS A
7 COMMENT.

8 DR. BRYANT: I THINK THAT SAYING RIGHT NOW,
9 WITHOUT KNOWING ANY MORE DETAILS, THAT AN AGENT -- AN
10 ENTITY WOULD HAVE TO PROMISE TO COVER ALL UNINSURED
11 MIGHT BE A DEAL KILLER FOR THE WHOLE PROCESS BECAUSE
12 HOW WOULD WE KNOW? I MEAN THE NUMBER OF UNINSURED
13 COULD GO THROUGH THE ROOF IN THE NEXT COUPLE OF YEARS.
14 I MEAN I'M NOT SUGGESTING WE SHOULDN'T TRY, BUT I THINK
15 IT SHOULD BE SOMETHING THAT WOULD BE A GOOD-FAITH
16 EFFORT TO PROVIDE THE UNINSURED AT A REASONABLE RATE
17 THAT DOESN'T BANKRUPT THE COMPANY. I MEAN I THINK IF
18 THE COMPANY GOES OUT OF BUSINESS BECAUSE OF THIS,
19 WHAT'S THE POINT?

20 DR. PENHOET: THERE ARE FOUR MILLION
21 UNINSURED PEOPLE IN CALIFORNIA. NOT ALL OF THEM NEED
22 STEM CELLS.

23 MR. ROTH: IF YOU LOOK AT PAGE 33 ON DOWN
24 UNDER ACCESS HERE, YOU WILL SEE WE DID TIE THE ACCESS
25 PLAN TO CALIFORNIA RX FOR DRUGS. THE PROBLEM -- WE CAN

1 TIE THIS EXACTLY THE CALIFORNIA RX IF IT COVERED
2 BIOLOGICS. THAT'S WHERE WE RAN INTO PROBLEMS. IF WE
3 COULD WRITE SOMETHING THAT SAID -- DRUGS IS IN HERE.
4 IT'S CLEARLY STATED. IT'S TIED TO THAT POLICY. SO
5 WHATEVER CALIFORNIA HAS AS A REQUIREMENT FOR CALIFORNIA
6 RX WOULD BE GREAT IF IT INCLUDED BIOLOGICS.

7 SO WE COULD SAY THAT IF AT THAT TIME OF
8 COMMERCIALIZATION THERE ISN'T A CALIFORNIA RX THAT
9 COVERS BIOLOGICS OR OTHER PRODUCTS, THEN THE COMPANY
10 MUST PRESENT A PLAN THAT SUBSTANTIALLY FOLLOWS THAT
11 GUIDELINE.

12 DR. KESSLER: THAT WOULD BE TERRIFIC.

13 DR. PENHOET: THE OTHER THING I REMIND YOU
14 ABOUT THIS IS THAT THERE IS NOTHING -- IF THE PLANS
15 WHICH COME FORWARD IN THE INITIAL ROUNDS, WHENEVER THAT
16 MIGHT BE, ARE UNRESPONSIVE TO THE NEED, WE HAVE TO --
17 WE CAN ALWAYS GO BACK AND PUT MORE FLESH ON THE BONES
18 OF WHAT THOSE PLANS SHOULD LOOK LIKE. AT THE MOMENT
19 WE'RE COUNTING ON THE, YOU KNOW, ON THE INVENTIVENESS
20 AND GOODWILL OF THE COMMERCIALIZING ENTERPRISES TO COME
21 UP WITH PLANS. IF THEY'RE TOTALLY UNRESPONSIVE TO THE
22 NEED AT THE TIME, WE CAN GO BACK AND REFINE THIS MORE
23 CAREFULLY. THESE ARE NOT SET IN STONE. WE CAN REVISIT
24 ANY OF THESE ISSUES ON A REAL-TIME BASIS.

25 CHAIRMAN KLEIN: I THINK DR. KESSLER'S POINT,

1 AS AN FDA COMMISSIONER, HE'S LOOKED AT THESE ISSUES
2 DEEPLY, IS THAT IF IT'S A POLICY, YOU FUNCTIONALLY
3 MIGHT BE ABLE TO GO BACK AND REVISIT IT; BUT IF IT'S A
4 REGULATION AND THERE'S A LAWSUIT, YOU CAN'T ACTUALLY
5 REVISIT IT. IT'S TIED UP IN THE COURTS AND WILL BE FOR
6 YEARS, AND THE THERAPY IS NOT GOING TO GO ANYWHERE.
7 IT'S GOING TO BE PARALYZED BY THE COURT SYSTEM.

8 WE HAD A BRILLIANT DEMONSTRATION OF HOW THAT
9 CAN BE DONE, WHICH WE'VE JUST OVERCOME WITH THE MONEY
10 WE HAVE IN THE BANK. SO I THINK DR. KESSLER'S POINT IS
11 MAYBE TO MOVE IT INTO THE POLICY SIDE WHERE THEN YOU
12 CAN ACCOMPLISH WHAT YOU'RE DESCRIBING. IS THAT YOUR
13 POINT, DR. KESSLER?

14 DR. KESSLER: I THINK THAT THERE ARE A NUMBER
15 OF DIFFERENT OPTIONS THAT HAVE BEEN SUGGESTED THAT ARE
16 VERY THOUGHTFUL. I JUST THINK GIVING A LITTLE --
17 EITHER TYING IT TO THE CALIFORNIA RX PLAN OR MOVING --
18 IF IT IS AMBIGUOUS, THEN IT SHOULD BE POLICY AND IT
19 SHOULDN'T BE REGULATION. IF WE CAN GIVE SOME KIND OF
20 STANDARD FOR WHAT WOULD BE AN ACCEPTABLE PLAN, THEN I
21 WOULD FEEL MORE COMFORTABLE ON THE REGULATION.

22 DR. PENHOET: IF I MIGHT INTERJECT, I BELIEVE
23 THAT DUANE'S COMMENT ABOUT CALRX PRICING FOR THINGS
24 WHICH ARE PURCHASED WITH PUBLIC FUNDS, NOT TO THE
25 ACCESS FOR UNINSURED. UNINSURED DON'T GET CALRX

1 EITHER. AND ACCESS PLANS ARE FREQUENTLY FREE. THEY'RE
2 NOT --

3 DR. KESSLER: THERE ARE A COUPLE OF -- AS
4 JEFF MENTIONED, THERE ARE SOME INDUSTRY STANDARDS
5 TODAY. THERE ARE SOME PLANS THERE. AND MAYBE THERE
6 CAN BE SOME WORK TO TRY TO GIVE A SENSE OF WHAT THOSE
7 ARE SO THAT IT COULD REALLY HAVE THE FORCE OF A
8 REGULATION. YOU JUST HAVE TO GIVE THEM SOME IDEA OF
9 WHAT TO DO.

10 CAN I JUST RAISE ONE OTHER -- ALSO A POINT.
11 ON THE 3 X AND ON THE IF THERE'S BLOCKBUSTER STATUS,
12 IT'S A GREAT POLICY. IT WALKS THAT PERFECT BALANCING.
13 IT'S REASONABLENESS. MY ONLY QUESTION IS IS IT
14 ADMINISTRATABLE? CAN YOU REALLY TIE BACK, CAN YOU DO
15 THE ALLOCATION BACK TO THAT PATENT? WHAT HAPPENS IF
16 YOU HAVE MULTIPLE PATENTS? WHAT HAPPENS IF YOU HAVE
17 MULTIPLE PRODUCTS? ARE YOU GOING TO REALLY KNOW
18 WHETHER THIS GRANT TRIGGERS THIS THRESHOLD, OR IS IT
19 GOING TO AGAIN BE AMBIGUOUS?

20 DR. PENHOET: WELL, YOU KNOW, HOPEFULLY WE'RE
21 DEALING WITH COMPANIES WHO ARE HONEST, AND WE HAVE
22 AUDITING RIGHTS, AND I THINK WE CAN TRACK THIS. AND
23 THE 3 X, THE NICE THING ABOUT 3 X IS IT DOESN'T DEAL
24 WITH PROPORTIONAL FUNDING OR ANYTHING ELSE. IT'S A
25 FLAT FEE, 3 X. ALL WE HAVE TO SHOW IS THAT CIRM

1 FUNDING WAS INVOLVED IN THE DEVELOPMENT OF THE PRODUCT.

2 DR. KESSLER: BUT IF YOU HAVE A PRODUCT,
3 LET'S SAY THERE'S MULTIPLE COMPANIES INVOLVED WITH
4 MULTIPLE PATENTS, AND THIS GRANT REALLY WAS AT THE
5 PERIPHERY OF THIS PRODUCT. HOW DO YOU REALLY ALLOCATE
6 WHETHER THOSE REVENUES ABOVE THE THRESHOLD CAN BE THE
7 RESULT OF THAT PATENT? CAN YOU REALLY -- DO WE HAVE
8 THE EXPERTISE TO DO THAT? I UNDERSTAND GOOD FAITH, I
9 UNDERSTAND THERE'S SOME REASONABLENESS, BUT, AGAIN,
10 WE'RE DOING THIS BY REGULATION. IS THIS
11 ADMINISTRATABLE?

12 DR. PENHOET: ONE OF THE REASONS WE HAVE 3 X
13 IS FOR THAT REASON. IF THEY'VE TAKEN SOME OF OUR MONEY
14 AND WE CAN REASONABLY SHOW THAT IT WAS INVOLVED IN THIS
15 PROJECT, WE WILL GET THE 3 X. IT'S NOT A ROYALTY.
16 IT'S NOT ANY OTHER FORM. IT'S A FLAT AMOUNT. IF OUR
17 MONEY WENT INTO THE PROJECT, FOR EXAMPLE, AND THE
18 PAYBACK, OF COURSE, IS RELATED. IF WE MADE A MINOR
19 CONTRIBUTION FUNDING-WISE, WE ONLY GET 3 X OF WHAT WE
20 PUT IN.

21 DR. KESSLER: I UNDERSTAND THE 3 X, AND
22 THAT'S GREAT POLICY. MY QUESTION IS WE'RE REASONABLY
23 INVOLVED IN THIS PROJECT, OUR GRANT WAS REASONABLY
24 INVOLVED, CAN YOU REALLY TRACK THINGS WHEN YOU ARE
25 GOING TO HAVE MULTIPLE PATENTS, MAYBE MULTIPLE

1 COMPANIES, THAT'S MY QUESTION. WHAT'S THE STANDARD TO
2 KNOW WHETHER THIS GRANT WAS ASSOCIATED WITH THIS
3 REVENUE?

4 DR. PENHOET: WELL, I BELIEVE WE CAN. FIRST
5 OF ALL, AS I'VE EMPHASIZED BEFORE, WE HAVE TO BUILD A
6 SMALL STAFF INSIDE CIRM TO ESSENTIALLY CONTRACT WITH
7 EVERY COMPANY TO WHOM WE MAKE A GRANT OR A LOAN. WE
8 HAVE OUTSOURCED THAT TO THE UNIVERSITIES WHEN WE FUND
9 UNIVERSITIES IN THE NOT-FOR-PROFIT POLICY. IN THIS
10 CASE WE HAVE TO HAVE THE STAFF WHO WILL NEGOTIATE EACH
11 AND EVERY ONE OF THESE CONTRACTS WITH THE COMPANIES.
12 AND PART OF THEIR EXPERTISE WILL HAVE TO BE EVALUATION
13 OF THESE THINGS AND MONITORING OF WHAT THEY'RE DOING.
14 IT'S A RESPONSIBILITY WE CAN'T GET AWAY FROM. AND I
15 SUSPECT, DEPENDING ON HOW MANY GRANTS WE MAKE TO
16 COMPANIES, WE WILL HAVE A STAFF THREE TO FIVE PEOPLE
17 INSIDE CIRM WHOSE FULL-TIME JOB IT IS TO MAKE THESE
18 GRANTS TO COMPANIES AND TO MONITOR THEIR PERFORMANCE.
19 AND I BELIEVE WE CAN DO THAT. I THINK IT'S DONE
20 ROUTINELY IN LOTS OF COMPANY ENVIRONMENTS WHERE THEY'VE
21 TAKEN MONEY FROM VARIOUS DIFFERENT SOURCES AND
22 APPORTIONED THAT OUT. I THINK THAT PART CAN BE DONE.
23 I'M NOT WORRIED ABOUT THAT.

24 DR. MAXON: WE'VE ALSO ADDED A SPECIAL
25 REPORTING REQUIREMENT JUST FOR THIS PURPOSE. REPORTING

1 REQUIREMENT A NO. 5 WAS ADDED SPECIFICALLY FOR THIS
2 PURPOSE.

3 CHAIRMAN KLEIN: DR. PENHOET, I WOULD ASSUME
4 THAT WE WOULD HAVE THE ABILITY FOR PART OF THAT STAFF
5 TO CONTRACT IT OUT TO EXPERTS WHO WERE WELL ESTABLISHED
6 IN THE FIELD WHO COULD ON A CONTRACT BASIS DO THE
7 MONITORING FOR US.

8 DR. PENHOET: YES.

9 DR. NOVA: JUST A SMALL POINT. WHEN YOU HAVE
10 TECHNOLOGY TRANSFER FROM THE UNIVERSITY TO ANY
11 COMMERCIAL COMPANY, THEY SEND YOU A FORM EVERY YEAR
12 ASKING YOU WHAT THE STATUS OF WHAT YOU'VE LICENSED FROM
13 THEM, AND YOU'RE REQUIRED TO FILL THAT OUT AND TELL
14 THEM WHERE THE PRODUCT IS. TO DR. KESSLER'S POINT, IT
15 IS SOMETIMES VERY COMPLEX ON WHAT GETS LOST, AND
16 SOMETIMES IT'S IN A PART OF A LICENSE. AND IT IS
17 COMPLEX, SO I THINK IT MIGHT TAKE A BIGGER TEAM FROM A
18 BUSINESS STANDPOINT TO REALLY TRACK ALL OF THIS, BUT
19 WE'LL GET TO THAT AS WE GROW.

20 SECOND POINT, JUST THERE WAS A COMMENT IN
21 THERE ABOUT GIVING COPIES OF DISCLOSURES TO CIRM AS THE
22 DISCLOSURES ARE GENERATED IN PREPATENT APPLICATIONS.
23 THERE'S JUST A LOT OF RESISTANCE TO DISCLOSURES BEING
24 RELEASED AND COPIES GOING OUT OF THE COMPANY. I DON'T
25 KNOW IF MAYBE PUTTING IN A COPY OF THE PATENT

1 APPLICATION RATHER THAN A DISCLOSURE MAY BE SOMETHING
2 THAT THE COMPANIES WOULD BE A LITTLE BIT MORE RETICENT
3 TO DO. JUST A COMMENT, SMALL COMMENT.

4 DR. MAXON: A 2, IT THAT YOUR QUESTION? IT
5 SAYS ALL DISCLOSURES OF SUCH INVENTIONS SHALL CONTAIN
6 SUFFICIENT DETAIL OF THE INVENTION. IT DOESN'T ASK FOR
7 AN INVENTION DISCLOSURE.

8 DR. NOVA: I TOOK THAT AS AN INVENTION
9 DISCLOSURE.

10 CHAIRMAN KLEIN: DUANE, I THINK CLAIRE HAD A
11 COMMENT AND THEN WE CAN GO TO YOU.

12 DR. POMEROY: JUST A POINT OF CLARIFICATION.
13 WE'RE TRYING TO ENCOURAGE ACADEMIC UNIVERSITY
14 INTERACTIONS. SO IF A UNIVERSITY CAME IN WITH AN
15 INDUSTRY PARTNER, HOW WOULD WE APPLY THE FOR-PROFIT
16 VERSUS THE NOT-FOR-PROFIT RULES?

17 DR. PENHOET: WELL, IF WE CO-FUNDED A
18 PROJECT, I THINK IT WOULD HAVE TO BE DONE IN
19 PROPORTIONAL PARTS. AND SO IF YOU GOT A MILLION
20 DOLLARS AND SOME COMPANY IN SACRAMENTO GOT ANOTHER
21 MILLION, YOU EACH GOT A MILLION OUT OF THIS PROJECT, IF
22 THE PROJECT WAS SUCCESSFUL, THE COMPANY WOULD HAVE TO
23 PAY THREE TIMES THEIR ONE MILLION. AND BASICALLY ONE
24 OF THE NICE ASPECTS OF THE SYMMETRY OF ALL THE OTHER
25 REQUIREMENTS, WHETHER IT'S A LICENSE OR A

1 COMMERCIALIZATION, ARE ACTUALLY THAT WE DON'T HAVE TWO
2 DIFFERENT SETS OF RULES WHICH APPLY TO THOSE. WE TRIED
3 TO KEEP IT AS CONSISTENT AS POSSIBLE ACROSS THE
4 FOR-PROFIT AND NOT-FOR-PROFIT POLICY. ONE REASON WAS
5 PRECISELY TO ADDRESS THIS ISSUE. WE DON'T HAVE A
6 COMPLETELY DIFFERENT UNIVERSE OF RULES DEPENDING ON WHO
7 TOOK THE MONEY. WE THINK THAT PART SHOULD MAKE IT
8 EASIER ACTUALLY.

9 CHAIRMAN KLEIN: DR. PENHOET, THAT'S A VERY
10 IMPORTANT CLARIFICATION. SHOULD IT BE ADDED TO THE
11 NARRATIVE SO PEOPLE CAN ANTICIPATE WHAT WE'RE THINKING?

12 DR. PENHOET: SURE.

13 MR. ROTH: THAT WAS THOUGHT ABOUT. AND IF
14 YOU LOOK AT THE MINUTES OF THE MEETING ON NOVEMBER 9TH,
15 WE WALKED THROUGH THIS AND DECIDED THAT THE POLICY
16 WORKED. IF YOU'RE A COMPANY AND YOU GET PART OF A
17 GRANT, YOU PAY BACK THREE TIMES IF THERE'S
18 COMMERCIALIZATION. IF YOU'RE AN ACADEMIC CENTER AND
19 YOU LICENSE THE PATENT TO SOMEONE ELSE, YOU FOLLOW THE
20 NON-PROFIT. WE FELT, IN CONSIDERING IT, THAT IT WOULD
21 COME UP, BUT THAT THE POLICY ACTUALLY WOULD WORK ON
22 BOTH SIDES.

23 DR. HENDERSON: I MOVE APPROVAL OF THIS
24 POLICY.

25 CHAIRMAN KLEIN: THERE'S A MOTION.

1 DR. WRIGHT: SECOND.

2 CHAIRMAN KLEIN: THERE'S A MOTION AND A
3 SECOND. AND THERE'S A QUESTION IN THE APPROVAL THAT
4 YOU'RE MOVING. IS IT BEING MOVED AS PRESENTED, OR ARE
5 YOU ADDRESSING AT ALL DR. KESSLER'S POINT?

6 DR. HENDERSON: YEAH. I THINK WE WANT
7 FURTHER CLARIFICATION ON THE POINT MADE BY DR. KESSLER.

8 CHAIRMAN KLEIN: WOULD THAT CLARIFICATION BE
9 TO HAVE THAT SECTION AS A POLICY AT THIS TIME, WHICH
10 WOULD ALLOW TIME TO DEFINE IT, OR WHAT WAS YOUR
11 THINKING?

12 DR. HENDERSON: I THINK WE CERTAINLY DON'T
13 WANT A REGULATION.

14 CHAIRMAN KLEIN: AND THERE'S A MOTION ON THE
15 FLOOR, SO THERE'S DISCUSSION. JEFF SHEEHY AND THEN
16 DR. KESSLER.

17 MR. SHEEHY: I COULDN'T SUPPORT THIS IF WE
18 PUT ACCESS AS A POLICY. SO I'D RATHER KICK IT BACK TO
19 STAFF. AND MAYBE IF THIS WOULD BE A FRIENDLY
20 AMENDMENT, TO COME UP WITH A REGULATION THAT'S
21 SUFFICIENTLY BROAD AS TO NOT DETER COMPANIES FROM
22 WANTING TO PARTICIPATE, BUT YET SUFFICIENTLY STRINGENT
23 SO THAT WE CAN LEGITIMATELY REPRESENT TO THE VOTERS AND
24 TO THE LEGISLATURE THAT THERE WILL BE AN ACCESS PLAN.
25 I POSIT AS ONE OPTION TO LOOK AT SOME KIND OF SCALE

1 LOOKING AT INDUSTRY STANDARD, THAT THE PLAN FIT WITHIN
2 SOME CERTAIN PERCENTILE OF THE TYPICAL INDUSTRY PLANS
3 THAT ARE CURRENTLY BEING PRESENTED. I THINK WE CAN
4 RELY ON -- HOPEFULLY WE WILL STILL DR. MAXON AWHILE
5 LONGER, HER CREATIVITY, TO ENSURE DUANE AND TINA AND
6 TED CAN HELP US OUT WITH SOME OF THE LANGUAGE TO GET
7 SOMETHING THAT WORKS.

8 CHAIRMAN KLEIN: WE CERTAINLY NEED TO
9 COMMEND, JEFF, YOU AND DUANE ROTH FOR YOUR TREMENDOUS
10 CONTRIBUTION TO THIS EFFORT.

11 DR. PENHOET: AT THIS POINT I HAVE TO ADD
12 ANOTHER COMMENT, TWO OTHER COMMENTS. NO. 1, DR. MAXON
13 HAS AGREED TO VOLUNTEER HER TIME TO US TO FINISH THIS
14 POLICY THROUGH TO THE END. THANK YOU, MARY, FOR DOING
15 THAT.

16 THE SECOND ONE IS THAT THIS PRECISE LANGUAGE
17 IS PART OF THE NOW APPROVED POLICY FOR THE
18 NOT-FOR-PROFITS ON THE ISSUE OF ACCESS. IT IS BEFORE
19 THE OFFICE OF ADMINISTRATIVE LAW AS WE SPEAK. THEY
20 WILL OPINE ON WHETHER IT'S TOO VAGUE TO BE WORKABLE OR
21 NOT. BUT IF WE DECIDE TO CHANGE IT FOR THE
22 FOR-PROFITS, I BELIEVE WE ALSO HAVE TO CHANGE IT FOR
23 THE NOT-FOR-PROFITS, WHICH WILL MEAN THAT WE HAVE TO GO
24 BACK AND WITHDRAW IT FROM CONSIDERATION BY THE OAL AND
25 TAKE IT THROUGH THAT PROCESS AGAIN. WE'RE WILLING TO

1 DO THAT.

2 THE ALTERNATIVE IS LEAVE THAT ONE IN PLACE,
3 BUT IF IT BECOMES A REGULATION, IT WILL BE HARDER TO
4 GET IT BACK THAN IT CURRENTLY IS. I BELIEVE, JAMES, WE
5 CAN MAKE A REQUEST TO WITHDRAW THAT FROM THE CURRENT
6 DOCKET IN FRONT OF THE OAL; IS THAT RIGHT? IT'S
7 ALREADY WAY DOWN THE ROAD. IT'S BEEN THROUGH ALL THE
8 HEARINGS.

9 MR. TOCHER: THAT PROVISION IS ALREADY PART
10 OF THE EMERGENCY PACKAGE THAT HAS ALREADY BEEN APPROVED
11 BY THE OFFICE OF ADMINISTRATIVE LAW AND IS, IN FACT, IN
12 EFFECT RIGHT NOW. IT IS ALSO A COMPONENT OF THE
13 PERMANENT PACKAGE THAT YOU APPROVED JUST AT OUR LAST
14 MEETING TO TAKE THE PLACE OF THE EMERGENCY ONES ONCE
15 THEY EXPIRE. ONE ASPECT OF THAT IS A REGULATION WHICH
16 IS UP ON TODAY'S AGENDA ON THE NEXT AGENDA ITEM WHICH
17 CONTAINS THIS PROVISION AS WELL.

18 DR. PENHOET: COULD I ASK JAMES HARRISON TO
19 COMMENT ON THIS ISSUE?

20 MR. HARRISON: I JUST WANTED TO MAKE ONE
21 POINT OF CLARIFICATION, WHICH IS THAT THE REGULATION IS
22 VERY SPECIFIC IN REQUIRING THAT LICENSEES HAVE PLANS IN
23 PLACE TO PROVIDE ACCESS. THE REQUIREMENT IS THAT THERE
24 BE A PLAN. IT DOESN'T REQUIRE A SPECIFIC PLAN. IT
25 DOESN'T REQUIRE STRICT COMPLIANCE WITH THE PLAN. THE

1 REQUIREMENT IS THAT THERE'S A PLAN IN PLACE AND THAT
2 THAT BE AVAILABLE TO THE ICOC FOR ITS REVIEW.

3 DR. KESSLER: SO, AGAIN, WHAT IS A COMPANY TO
4 DO, JIM? IS A SIMPLE SHEET OF PAPER AND I SEE A PLAN
5 AND THERE'S NOTHING ON IT, DOES THAT MEET IT OR DOES
6 THAT NOT? SO WHAT MAY WORK HERE IS TO LEAVE THE
7 LANGUAGE IN THE REG AS A PLAN IN BOTH DOCUMENTS, BUT
8 FOR US TO ISSUE -- I DON'T KNOW IF WE CAN -- POLICY
9 GUIDANCE ON WHAT A SUFFICIENT PLAN WOULD BE SO WE
10 INTERPRET THE PLAN BY GUIDANCE. IS THAT POSSIBLE?

11 MR. HARRISON: UNFORTUNATELY NOT. I THINK IN
12 THAT CASE WE NEED TO AMEND THE REGULATION TO CLARIFY
13 THE INTENT.

14 DR. KESSLER: YOU CAN'T HAVE ANY COMPLIANCE
15 GUIDANCE ON WHAT A PLAN IS, WHAT A SUFFICIENT PLAN IS?

16 MR. HARRISON: THE OFFICE OF ADMINISTRATIVE
17 LAW TAKES THE VIEW THAT GUIDANCE OF THAT SORT, IF IT IS
18 IN FOR THE FORM OF IMPOSING ADDITIONAL REQUIREMENTS --

19 DR. KESSLER: THERE'S NO ADDITIONAL
20 REQUIREMENT. IT JUST CLARIFIES -- IT'S CLARIFYING WHAT
21 WOULD BE, IN FACT, A SAFE HARBOR FOR THE DEFINITION OF
22 A PLAN.

23 MR. HARRISON: THEY UNFORTUNATELY HAVE
24 TRADITIONALLY FROWNED ON ATTEMPTS AT CLARIFYING
25 POLICIES OF THAT NATURE.

1 CHAIRMAN KLEIN: FROWN MEANS THAT THEY HAVE
2 SAID YOU CAN'T DO IT. SO, DR. KESSLER, DO YOU HAVE
3 ADVICE HERE? JEFF SHEEHY HAS MADE A SUGGESTION THAT IN
4 ORDER TO GET GOOD REGULATORY LANGUAGE, WE KEEP THAT
5 PORTION OUT UNTIL WE CAN GET SOME SPECIFICITY, AND
6 SUGGESTED SOME OPTIONS OF SPECIFICITY. WHAT IS YOUR
7 SUGGESTION?

8 DR. KESSLER: I THINK JEFF'S SUGGESTION IS AN
9 EXCELLENT ONE. REALITY IS WE'RE A LIVING, EVOLVING
10 BODY. WE DID THE LAST REGULATION IN GOOD FAITH. WE'RE
11 ACTUALLY NOT CHANGING ANYTHING. THERE'S NOT A
12 DIFFERENCE REALLY IN POLICY. WE'RE JUST TRYING TO
13 LEARN AND CLARIFY THAT. SO I THINK JEFF'S SOLUTION IS
14 AN EXCELLENT ONE. I WOULD BE VERY HESITANT BECAUSE OF
15 IF I WERE A COMPANY AND I SAW A PLAN AND I HAD NO IDEA
16 WHETHER THAT WAS EVERYBODY OR ANYONE, MORE SPECIFICITY
17 OF THE NATURE JEFF SUGGESTED, I THINK, WOULD HELP
18 SIGNIFICANTLY HERE. SO I WOULD WORK TO GET THAT
19 SPECIFICITY INTO THIS ONE, EVEN RECOGNIZING THAT IT
20 WASN'T IN THE OTHER ONE.

21 MR. SHEEHY: THE OTHER THING IS IF IT'S JUST
22 ANOTHER SENTENCE, HOW HARD IS IT -- IN OTHER WORDS, IF
23 IT'S JUST THIS LANGUAGE EXISTS IN THE NOT-FOR-PROFIT
24 AND WE END UP ADDING A CLARIFYING SENTENCE OR A
25 DEFINING SENTENCE OR SOMETHING THAT'S MORE DEFINITIVE,

1 HOW HARD WOULD IT BE TO INSERT NEW LANGUAGE RATHER THAN
2 CHANGE THE EXISTING LANGUAGE.

3 DR. PENHOET: YOUR ADDITION WOULD BE "WOULD
4 PROVIDE A PLAN CONSISTENT WITH THE THEN EXISTING
5 INDUSTRY STANDARDS." WOULD THAT --

6 MR. SHEEHY: YEAH. I THINK WE SHOULD THINK
7 ABOUT IT. AND HOPEFULLY -- I HAVE FAITH IN YOUR OFFICE
8 AND MARY TO KIND OF COOK THIS FOR A LITTLE BIT AND TO
9 TALK TO SOME OF THE PEOPLE WITH SOME EXPERTISE AND COME
10 BACK WITH SOMETHING.

11 CHAIRMAN KLEIN: CERTAINLY IT WOULD BE A
12 BENEFIT, AS JEFF POINTS OUT, TO GIVE CERTAINTY TO THE
13 PEOPLE OF CALIFORNIA THAT WE HAVE A REAL REGULATION
14 HERE AND GIVING SOME TIME JUST TO COME UP WITH THE
15 RIGHT SENTENCE OR TWO OR A PARAGRAPH TO GIVE THE
16 SPECIFICITY SO THAT THE BENEFICIARIES KNOW THEY HAVE
17 SOMETHING AND THE COMPANIES KNOW WHAT TO EXPECT.

18 MR. SHEEHY: HOWEVER, THAT LANGUAGE WOULD BE
19 ADEQUATE IF YOU WANTED TO PUT IN STAKEHOLDER LANGUAGE
20 IN ORDER THAT THESE CAN BE EMERGENCY REGULATIONS SO
21 THAT FOR-PROFITS COULD START COMPETING ON GRANTS. SOME
22 OF THESE FUTURE ROUNDS, I THINK IT MIGHT BE POSSIBLE
23 FOR THEM TO COMPETE. THESE TIMELINES GET VERY
24 CONFUSING FOR ME. AS IT STANDS RIGHT NOW, THEY CAN'T
25 COMPETE BECAUSE THEY'RE NOT IN PLACE.

1 CHAIRMAN KLEIN: SO, JEFF, WHAT'S THE STATUS?
2 ARE YOU ASKING DR. HENDERSON TO MAKE A FRIENDLY
3 AMENDMENT? WHAT IS YOUR SUGGESTION?

4 MR. SHEEHY: MAYBE IF I CAN GET SOME
5 CLARIFICATION ON WHAT IMPACT -- WHATEVER WE DO, WHAT
6 IMPACT IT HAS ON THE ABILITY OF A FOR-PROFIT TO COMPETE
7 FOR A GRANT IN A FUTURE ROUND. I KNOW ONCE WE ADOPT
8 THESE, THESE BECOME EFFECTIVE REGULATIONS. AND
9 PRESUMABLY IF WE ISSUED AN RFA TOMORROW, A FOR-PROFIT
10 COULD THEN APPLY BASED ON THESE REGULATIONS.

11 CHAIRMAN KLEIN: SCOTT.

12 DR. PENHOET: I BELIEVE THAT --

13 MR. TOCHER: I WAS JUST GOING TO SAY WHAT
14 YOU'RE APPROVING TODAY IS PERMISSION FOR STAFF TO TAKE
15 THESE POLICIES AND THESE GUIDEPOSTS AND THESE ISSUES
16 AND CONVERT THEM INTO ACCEPTABLE REGULATORY LANGUAGE
17 THAT GETS FILED WITH OAL THAT THEN INITIATES THE
18 PROCESS. THEY DON'T BECOME EFFECTIVE. THAT INITIATES
19 THE PROCESS WHERE THEN WE RECEIVE PUBLIC COMMENT, WE
20 REFINE THEM FURTHER, WE PUT THE MEAT ON THE BONES WHERE
21 WE CAN, AND THEN IT'S SUBMITTED ONE LAST TIME TO OAL
22 FOR A FINAL APPROVAL, AND THAT'S WHERE THEY WILL GO
23 THROUGH IT WITH A FINE-TOOTHED COMB.

24 DR. KESSLER: SO WE CAN JUST INSERT LANGUAGE
25 TODAY INTO ED'S SLIDE THAT'S CONSISTENT WITH JEFF, THAT

1 PLANS SHOULD BE CONSISTENT WITH PREVAILING STANDARDS AT
2 THE TIME, AND THEN YOU CAN WORK ON DEVELOPING THE
3 ACTUAL REG.

4 MR. TOCHER: THAT'S CORRECT.

5 DR. KESSLER: QUESTION IS CAN WE --

6 CHAIRMAN KLEIN: AND IN TERMS OF THE
7 NON-PROFIT POLICY, WE HAVE AN EMERGENCY REG IN PLACE
8 RIGHT NOW. YOU COULD ACTUALLY WITHDRAW THE SUBMISSION
9 FOR THE PERMANENT REG ON THE NON-PROFIT, SO YOU HAVE A
10 CONSISTENT POLICY.

11 MR. TOCHER: THE ISSUE OF CONSISTENCY IS
12 SLIGHTLY MORE COMPLICATED ONLY BECAUSE OF THE DIFFERENT
13 STAGES THAT THEY ARE IN THE OAL REVIEW. IF WE WISH TO
14 MAKE CHANGES TODAY, FOR INSTANCE, TO THE NOT-PROFIT
15 REGULATION, WHICH COVERS THIS AREA, WE WOULD NEED TO
16 OPEN THAT UP FOR ANOTHER PERIOD OF PUBLIC COMMENT
17 BEFORE WE COULD SUBMIT IT TO OAL.

18 CHAIRMAN KLEIN: RIGHT. BUT YOU WOULD HAVE
19 YOUR EMERGENCY REGS STILL IN PLACE.

20 MR. TOCHER: THAT'S RIGHT.

21 CHAIRMAN KLEIN: SO WE CONTINUE TO BE
22 OPERATIONAL, BUT WE COULD, IN FACT, WITHDRAW THE
23 PERMANENT VERSION OF JUST THAT ONE SECTION AND KEEP
24 OPERATING AND GIVE US THE TIME TO RECONCILE THE
25 FOR-PROFIT AND NON-PROFIT LANGUAGE. WE WOULD HAVE TO

1 COME BACK AND RESUBMIT IT AND COME TO THIS BOARD.

2 MR. TOCHER: THAT'S RIGHT. AND ALSO, IF YOU
3 WANT TO WAIT ON THE PERMANENT VERSION OF THIS IN THE
4 NON-PROFIT TO COINCIDE WITH THE DEVELOPMENT IN THE
5 FOR-PROFIT, JUST BE AWARE THAT IT WOULD PROBABLY HAVE
6 TO COME BACK FOR ANOTHER EMERGENCY READOPTION OF THE
7 EXISTING POLICY, AND THAT IS BECAUSE THE FOR-PROFIT
8 REGULATION ADOPTION PROCESS IS GOING TO TAKE A MATTER
9 OF MONTHS. THERE'S A 45-DAY PERIOD FOR PUBLIC COMMENT
10 INITIALLY. THERE WOULD BE THE ONGOING REVISING THAT
11 TAKES PLACE WHICH IS ADDITIONAL PERIODS OF PUBLIC
12 COMMENT. SO YOU'RE LOOKING AT ANOTHER SIX MONTHS
13 PROBABLY.

14 DR. PENHOET: CAN WE WITHDRAW JUST THIS ONE
15 PIECE OF THE FOR-PROFIT POLICY, OR IF WE WITHDRAW IT,
16 DO WE HAVE --

17 MR. TOCHER: THE NON-PROFIT?

18 DR. PENHOET: THE NON-PROFIT. I'M SORRY.

19 MR. TOCHER: YOU CAN WITHDRAW -- IF YOU
20 WITHDRAW THIS REGULATION AND WE MOVE FORWARD WITH THE
21 OTHERS, THIS REGULATION APPLIES TO LICENSING
22 REQUIREMENTS. YOU COULD MOVE FORWARD WITH THE
23 REMAINDER FOR THE NOT-PROFIT AND ENACT REGULATIONS, BUT
24 YOU WOULD NOT HAVE A REGULATION COVERING LICENSES FOR
25 PATENTED INVENTIONS; IN OTHER WORDS, 100306.

1 DR. PENHOET: THAT WHOLE CATEGORY.

2 MR. TOCHER: THAT WHOLE CATEGORY.

3 CHAIRMAN KLEIN: SO YOU CAN'T WITHDRAW JUST
4 THE SUBSET?

5 MR. TOCHER: THAT SUBDIVISION OF THE REG, NOT
6 WITHOUT OPENING IT UP TO ANOTHER NOTICE PERIOD, WHICH
7 IS ESSENTIALLY WHAT YOU'RE SUGGESTING BE DONE ANYWAY.

8 CHAIRMAN KLEIN: CLAIRE, DID YOU HAVE A
9 SUGGESTION?

10 DR. POMEROY: THAT WE DEAL WITH THE
11 FOR-PROFIT RIGHT NOW.

12 DR. PENHOET: MAY I GET SOME CLARIFICATION?
13 CAN WE ADOPT AN EMERGENCY FOR-PROFIT REGULATION TODAY
14 BASED ON THIS AS ARTICULATED HERE SO THAT WE CAN MAKE
15 GRANTS TO COMPANIES IN THE MEANTIME?

16 MR. HARRISON: YES. WHAT YOU'RE ASKING THE
17 BOARD TO ADOPT TODAY ARE INTERIM POLICIES UNDER OUR
18 PROVISION IN THE ACT ITSELF THAT PERMITS THE BOARD TO
19 ADOPT SUCH POLICIES FOR A PERIOD OF 270 DAYS WHILE THEY
20 GO THROUGH THE PROCESS OF ADMINISTRATIVE LAW REVIEW.

21 CHAIRMAN KLEIN: OKAY. AND IN TERMS --

22 DR. PENHOET: I MIGHT POINT OUT ONE FINAL
23 COMMENT ABOUT THIS JUST TO GIVE YOU SOME PERSPECTIVE,
24 AND MAYBE WE'LL HEAR FROM SOME OF OUR COLLEAGUES IN
25 INDUSTRY, THERE HAS BEEN SOME CONCERN EXPRESSED BY

1 INDUSTRY THAT SMALL COMPANIES MIGHT HAVE A VERY HARD
2 TIME COMING UP WITH AN ACCESS PLAN THAT THEY COULD
3 AFFORD IF IT WAS BASED ON LARGE COMPANY STANDARDS. SO
4 GENENTECH IS IN A QUITE DIFFERENT POSITION TO PROVIDE
5 ACCESS PLANS THAN A START-UP FOR WHOM THIS MIGHT BE THE
6 FIRST PRODUCT, FOR EXAMPLE. I KNOW THAT IS AN INDUSTRY
7 CONCERN. I DON'T KNOW QUITE HOW TO DEAL WITH IT.

8 CHAIRMAN KLEIN: PERHAPS WE SHOULD HEAR FROM
9 DUANE ROTH, GET PUBLIC COMMENT, AND THEN THE BOARD CAN
10 DECIDE WHAT THEY WANT TO DO IN ADDRESSING THE MOTION
11 THAT'S ON THE TABLE FOR US.

12 MR. ROTH: I HAVE A SEPARATE ISSUE WHICH
13 DEALS WITH THE THREE TIMES, THREE TIMES, AND 1 PERCENT.
14 WE HAVE AN INCONSISTENCY BETWEEN WHAT THE COMMITTEE
15 APPROVED ON NOVEMBER 9TH AND WHAT WE HAVE HERE. AND IT
16 DEALS WITH THE TASK FORCE VOTED UNANIMOUSLY FOR THREE
17 TIMES FOR EVERYBODY, WHATEVER YOU TAKE; AND THEN WHEN
18 IT HIT 250 MILLION OR GREATER, IT WAS ANOTHER THREE
19 TIMES; AND THEN YOU WENT TO THE 1-PERCENT ROYALTY, BUT
20 IT WASN'T THE 250, 500, 750, AND SO ON. SO IT WAS TO
21 BE TIERED THREE TIMES; AND THEN IF YOU HIT 250 MILLION
22 IN REVENUES ON ONE YEAR, ANOTHER THREE TIMES. SO IF
23 YOU TOOK A MILLION, YOU PAID BACK SIX MILLION. THEN IF
24 THERE WAS A PATENT AND YOU CROSSED THE \$500 MILLION
25 THRESHOLD, 1-PERCENT ROYALTY.

1 ED, WHEN I GO BACK AND READ ON PAGE 72, YOU
2 AND I HAD THAT CONVERSATION IN THE TRANSCRIPT AND
3 CHANGED IT, BUT IT DIDN'T GET PICKED UP HERE.

4 DR. PENHOET: WHAT WE TOOK FROM THE MEETING,
5 AND WE SENT THIS SLIDE TO YOU, WAS THAT THERE WOULD BE
6 NO FURTHER PAYMENTS BEYOND THE \$500 MILLION THRESHOLD.
7 THERE'S NO 750 OR A BILLION OR BILLION TWO, ETC. IT'S
8 CAPPED AT 500 MILLION, BUT THE 3 X, WHAT WE TOOK FROM
9 THE CONVERSATION WAS THAT THERE ARE A MAXIMUM OF THREE
10 3 X PAYMENTS.

11 MR. ROTH: WE CAN DO WHATEVER WE WANT, BUT
12 IT'S VERY CLEAR IN HERE IT WAS TO BE TWO 3 X PAYMENTS.

13 DR. PENHOET: WE DIDN'T UNDERSTAND IT THAT
14 WAY.

15 MR. ROTH: YOU MADE THE COMMENT 255, 750, AND
16 I RESPONDED, NO, THAT'S NOT IT. AND THEN WE WENT
17 THROUGH AND YOU CLARIFIED THAT THERE WOULD BE TWO FOR A
18 MAXIMUM OF SIX TIMES AND THEN 1-PERCENT ROYALTY.

19 CHAIRMAN KLEIN: I THINK IN HELPING THIS
20 ALONG, ONE, IS THERE ANOTHER COMMITTEE MEMBER SO WE CAN
21 POOL KIND OF OUR AGGREGATE KNOWLEDGE? AND THEN
22 DR. AZZIZ HAS A COMMENT.

23 DR. AZZIZ: I ACTUALLY JUST HAVE A QUESTION
24 OF CLARIFICATION. I'M SURE IT'S ALREADY BEEN DONE.
25 BUT THIS IS 250 MILLION PER YEAR ON 250 MILLION AND

1 THEN 500 MILLION. SO IF A COMPANY IS MAKING 200
2 MILLION PER YEAR, THIS IS NOT CUMULATIVE AT ANY POINT.

3 DR. PENHOET: NO, IT'S NOT. IN ANY SINGLE
4 YEAR -- THAT'S THE DEFINITION OF A BLOCKBUSTER. IF IT
5 REACHES \$250 MILLION IN A SINGLE YEAR, IT TRIGGERS THE
6 PAYMENT ONE TIME. IF ON A SUBSEQUENT EVENT IT REACHES
7 \$500 MILLION --

8 DR. AZZIZ: ON ANY OCCASION.

9 DR. PENHOET: WE DID DISCUSS HAVING THIS GO
10 TO 750, A BILLION, ETC. WE DECIDED TO STOP IT AT 500
11 MILLION. THAT'S MY RECOLLECTION OF THE CONVERSATION.

12 CHAIRMAN KLEIN: IS THERE ADDITIONAL COMMENTS
13 FROM COMMITTEE MEMBERS?

14 DR. BRYANT: MY MEMORY IS PROBABLY FAULTY,
15 BUT I THOUGHT IT WAS 250 MILLION EACH TIME IT HAPPENED
16 TO THREE TIMES, AND THEN THE 1 PERCENT ON TOP.
17 OBVIOUSLY I DON'T REMEMBER.

18 CHAIRMAN KLEIN: SO, JANET, WOULD YOU ADDRESS
19 THE ISSUE AS WELL?

20 DR. WRIGHT: I JUST REMEMBER IT THE WAY SUSAN
21 DESCRIBED IT AND THE WAY IT'S WRITTEN UP HERE.

22 CHAIRMAN KLEIN: ALL RIGHT. SO OBVIOUSLY
23 THERE WAS A NUMBER OF DISCUSSIONS. AND, DUANE, IT
24 APPEARS THAT THE COLLECTIVE MEMORY SEEMS TO REFLECT
25 WHAT'S THERE, ALTHOUGH CLEARLY THERE WAS ANOTHER

1 DISCUSSION ON THE ITEM THAT YOU HAVE. DR. MURPHY.

2 DR. MURPHY: QUESTION FOR ZACH AND FOR ED.
3 JUST AN OPERATIONAL QUESTION. AS THIS BEGINS AND AS WE
4 FUND OUR SEED GRANTS AND OUR COMPREHENSIVE GRANTS, MY
5 GUESS IS THAT PEOPLE ARE GOING TO BE LICENSING IDEAS
6 AND TECHNOLOGY VERY, VERY QUICKLY. HOW QUICKLY DO WE
7 AT CIRM STAFF UP TO BE ABLE TO PROVIDE OUR INSTITUTIONS
8 THE SUPPORT AND THE GUIDANCE AND THE PARTNERSHIPS IN
9 GETTING ALL OF THIS STUFF MADE OFFICIAL SO THAT WE KNOW
10 WHERE WE'RE COMING FROM?

11 DR. HALL: WE CERTAINLY ARE ASKING FOR
12 NOTIFICATION. I WOULD BE VERY SURPRISED -- THERE MAY
13 BE DISCLOSURES ARISING OUT OF THE FIRST YEAR'S
14 RESEARCH, BUT I WOULD BE VERY SURPRISED IF THERE WAS
15 VERY MUCH AT THE END OF ONE YEAR.

16 DR. MURPHY: IN TERMS OF INCOME. I WOULD
17 AGREE WITH THAT.

18 DR. HALL: NO. NO. JUST IN TERMS OF NOW
19 YOU'VE MADE A DISCOVERY AND YOU MAKE A DISCLOSURE TO
20 YOUR TECH TRANSFER OFFICE, AND THAT'S USUALLY A FORMAL
21 MATTER. YOU'VE GOT THE DATASET OUT, YOU'VE GOT
22 EVERYBODY SIGNED OFF ON IT, AND THEN THEY MAKE A
23 DECISION ABOUT WHETHER OR NOT TO FILE A PATENT ON IT.
24 AND BOTH OF THOSE SHOULD BE REPORTED TO US IF IT'S
25 SUPPORTED BY US. MY GUESS IS THAT THERE WILL BE LAG

1 PHASE BETWEEN THE TIME THE WORK IS DONE AND COMPLETED
2 AND THE TIME IT'S IN GOOD SHAPE ENOUGH TO GO AHEAD AND
3 FILE A DISCLOSURE AND MAKE A PATENT APPLICATION. SO I
4 THINK IT WILL BE AWHILE YET. I DON'T THINK THIS IS
5 GOING TO HAPPEN WITHIN MONTHS OF US SENDING OUT THE
6 MONEY.

7 DR. MURPHY: BUT WHEN OUR OFFICES OF
8 TECHNOLOGY TRANSFER GO THROUGH THAT DISCLOSURE PROCESS,
9 ARE WE AT CIRM PREPARED TO PARTICIPATE IN THOSE
10 DISCUSSIONS? THAT'S MY QUESTION.

11 DR. HALL: WELL, NO. IT'S THE INSTITUTION'S
12 RESPONSIBILITY TO MAKE THE DECISION ABOUT WHETHER OR
13 NOT TO PATENT IT. THERE IS AN OBLIGATION TO HAVE A
14 DISCLOSURE AND THEN TO REPORT TO US THAT YOU HAVE THAT.
15 BUT WE DO NOT ADVISE YOU ABOUT WHETHER OR NOT YOU
16 SHOULD PATENT OR NOT. THAT'S UP TO YOUR TECH TRANSFER
17 OFFICER, AND WE DON'T ADVISE YOU ABOUT WHO YOU SHOULD
18 LICENSE TO. WE DO HAVE GUIDELINES FOR THE STRUCTURE OF
19 IT, BUT NOT BEYOND THAT.

20 DR. PENHOET: WE PLAY NO ROLE WHATSOEVER. IF
21 YOU'RE A NOT-FOR-PROFIT, YOU CAN CONTINUE TO DO YOUR
22 WORK EXACTLY AS YOU DO IT TODAY EXCEPT WHEN YOU MAKE A
23 LICENSE TO A THIRD PARTY, YOU HAVE TO TAKE THESE THINGS
24 INTO ACCOUNT. THE THIRD PARTY WILL HAVE TO AGREE TO
25 THESE FEATURES. WE WON'T BE INVOLVED IN THE

1 NEGOTIATION. WE WON'T HAVE ANY APPROVAL RIGHTS OVER
2 THE QUALITY OF THE DEAL YOU MADE WITH X, Y, OR Z. THE
3 ONLY INTRUSION WE MAKE INTO YOUR NORMAL PROCESS IS TO
4 ASK YOU TO ENSURE THAT YOUR LICENSE CONTAINS THESE
5 TERMS. ALL YOU HAVE TO DO IS AFTER THE FACT SHOW US
6 THAT YOU HAVE COMPLIED WITH THAT.

7 HAVING SAID THAT, IF WE WANT TO MAKE GRANTS
8 TO COMPANIES, WE WILL INEVITABLY HAVE TO NEGOTIATE
9 EVERY -- WITH EACH COMPANY INDEPENDENTLY EVERY GRANT
10 BECAUSE WE HAVE BEEN TOLD BY THE ORGANIZATIONS WHICH DO
11 THIS TODAY, AND THERE ARE NUMBER OUT THERE,
12 FOUNDATIONS, ETC., THAT EVERY TIME THEY MAKE A GRANT TO
13 A COMPANY, THEY HAVE TO ENTER INTO A NEGOTIATION AND IT
14 CAN BE PROTRACTED AND DIFFICULT BECAUSE ALL OF THIS
15 LANGUAGE WILL HAVE TO BE CONTRACTUAL LANGUAGE FOR THE
16 COMPANY. SO WE WILL HAVE TO HIRE SOME PEOPLE -- AS
17 SOON AS WE WANT TO MAKE GRANTS TO A COMPANY, WE'LL HAVE
18 TO STAFF UP TO START TO ADDRESS THAT PARTICULAR ISSUE.
19 AND SO IT COULD BE VERY SOON. THE COMPANIES WON'T GO
20 FORWARD WITH THIS WITHOUT SOME LEGAL AGREEMENT WITH US
21 AS TO HOW IT'S GOING TO WORK.

22 CHAIRMAN KLEIN: DR. MURPHY MAY ALSO BE
23 ASKING THE QUESTION ABOUT TECHNICAL ISSUES OF JUST
24 UNDERSTANDING WHAT THESE REGULATIONS MEAN. FOR
25 EXAMPLE, IS THERE AN INVENTION DISCLOSURE? IS THAT

1 WHAT YOU'RE MEANING, AS TINA ASKED, SO THAT WE HAVE
2 SOMEONE EXPERT ON OUR STAFF ON THIS PARTICULAR SUBJECT
3 THAT CAN EXPLAIN TO THE NON-PROFIT OR THE FOR-PROFIT
4 SECTOR WHAT WE MEAN IN THESE REGULATIONS?

5 DR. MURPHY: I THINK I WOULD JUST SAY MY
6 GUESS IS IT'S GOING TO MOVE VERY QUICKLY ONCE THESE
7 GRANTS GO OUT TO PROFITS OR NOT-FOR-PROFITS, SO I THINK
8 WE SHOULD BE PREPARED FOR THAT.

9 CHAIRMAN KLEIN: WE MIGHT BE ABLE TO GET AN
10 ATTORNEY WHO COULD VERY QUICKLY --

11 DR. HENDERSON: CAN WE CALL THE QUESTION?

12 CHAIRMAN KLEIN: WE HAVE TO HAVE PUBLIC
13 DEBATE. SO PUBLIC COMMENT ON THIS ISSUE.

14 MR. SIMPSON: FOR THE RECORD, I WAS AT THE
15 MEETING, AND I RECALL IT AS OUTLINED THERE ON THE 3 X.
16 THAT'S WHAT I TOOK FROM THE CONVERSATION AT THE TIME.

17 I HAVE A VERY SERIOUS CONCERN ABOUT WHAT YOU
18 PUT ON PAGE 39, LETTER F, WHICH IS THE AWARDEES AGREE
19 TO PROVIDE TO PATIENTS WHOSE THERAPIES WILL BE
20 PURCHASED IN CALIFORNIA BY PUBLIC FUNDS THE THERAPY AT
21 A DISCOUNT PRICE. I THINK THIS IS INTENDED TO BE SORT
22 OF A PAYBACK TO ALL CALIFORNIANS. THE PROBLEM I HAVE
23 IS THERE IS NO -- IN THIS PROPOSED REGULATION, THERE IS
24 NO MECHANISM WHATSOEVER FOR ESTABLISHING THAT DISCOUNT
25 PRICE. SO IT WOULD SEEM TO ME ARE YOU SAYING THAT THIS

1 WILL BE DEVELOPED IN THE FORMAL REGULATORY LANGUAGE AS
2 IT GOES THROUGH THE NEXT PROCESS?

3 DR. PENHOET: THAT IS WHAT WE'RE SAYING. AND
4 SCOTT TOCHER IS THE NEXT ITEM ON OUR AGENDA, AND HE
5 WILL ADDRESS THAT ISSUE FOR YOU. YES, THESE ARE IN A
6 SET OF PRINCIPLES THAT GUIDE THE PRECISE LANGUAGE OF
7 THE OAL PROCESS. AND SO THAT IS THE INTENTION, YES.

8 MR. SIMPSON: THAT'S A SCARY CONCEPT.

9 THEN THE NEXT THING WHERE YOU TIE DRUGS TO
10 THE CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM, TO
11 MY KNOWLEDGE, THAT DOES NOT COVER THINGS THAT ARE
12 PURCHASED WITH PUBLIC FUNDS. THAT PROGRAM, IN FACT, IS
13 INTENDED TO PROVIDE TO UNDERINSURED AND UNINSURED
14 PRESCRIPTION DRUGS. AND IT KICKS IN AND HAS SOME SORT
15 OF PROVISION, AND THIS IS WHERE I HAVE A GREAT DEAL OF
16 DIFFICULTY UNDERSTANDING THINGS. OUR ORIGINAL
17 REGULATION USED THE BEST MEDICAID PRICE OR NOT TO
18 EXCEED MEDICAID AS THE BENCHMARK FOR ANYTHING GOING TO
19 PUBLIC FUNDS.

20 CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM
21 USES BEST MEDICAID PRICE AS ONE OF ITS BENCHMARKS,
22 WHICH IT WOULD SEEM TO ME THAT WE COULD AS WELL, AND I
23 THOUGHT THAT THERE HAD BEEN FAIRLY GENERAL AGREEMENT
24 AND ACCORD, THAT THAT WAS THE WAY TO GO IF YOU WERE
25 TRYING TO MAXIMIZE THE LOWEST PRICE POSSIBLE TO ALL

1 THINGS PURCHASED WITH CALIFORNIA FUNDS. SO I'M A
2 LITTLE BIT AT A LOSS TO UNDERSTAND WHAT'S AT STAKE
3 HERE.

4 DR. PENHOET: SCOTT WILL ADDRESS THOSE ISSUES
5 IN HIS UPCOMING PRESENTATION.

6 MR. JACKSON: I'M JIMMY JACKSON, VICE
7 PRESIDENT OF PUBLIC POLICY FOR BIOCOM, REPRESENTING 500
8 BIOSCIENCE COMPANIES IN THE SAN DIEGO AND SOUTHERN
9 CALIFORNIA AREA. WE HAVE SUBMITTED A LETTER, SO I
10 WON'T REITERATE SOME OF THE THINGS THAT WERE IN THE
11 LETTER TO THE IP TASK FORCE. ONE THING I DO WANT TO
12 POINT OUT FOR COUNSEL, THOUGH, AND FOR CONSIDERATION IN
13 THIS DISCUSSION OF THE CALIFORNIA DISCOUNT PRESCRIPTION
14 PLAN BENCHMARK IS THAT ACCORDING TO THE TERMS OF AB
15 2911 THAT INFORMATION, THE NEGOTIATION AND THE PRICES,
16 ARE CONSIDERED CONFIDENTIAL AND CORPORATE PROPRIETARY
17 INFORMATION. I WOULD QUESTION WHETHER THIS COMMISSION
18 WOULD HAVE ACCESS TO THOSE PRICES. SO I JUST DON'T
19 WANT YOU TO SET UP A SYSTEM THAT IS DOOMED TO FAILURE
20 BEFORE YOU EVER GET OUT OF THE BOX, AND THEN WE'RE HERE
21 THREE MONTHS FROM NOW HAVING THIS EXACT SAME
22 DISCUSSION.

23 DR. PENHOET: DO YOU HAVE AN ALTERNATIVE TO
24 SUGGEST TO US?

25 MR. JACKSON: I DO NOT AT THIS TIME, BUT I

1 WAS NOT AWARE THAT CALRX HAS BEEN USED AS THE BENCHMARK
2 UNTIL THIS MORNING.

3 DR. PENHOET: SCOTT WILL DISCUSS. THIS HAS
4 BEEN A VERY LONG AND ARDUOUS PROCESS TO TRY TO COME UP
5 WITH A WORKABLE SYSTEM FOR THIS PRICING ISSUE. AND
6 SCOTT EXPENDED A LOT OF EFFORT ON THIS AND CONSULTED
7 WITH MANY DIFFERENT --

8 MS. FOGEL: SUSAN FOGEL. FIRST OF ALL, I
9 WANT TO REALLY COMMEND YOU FOR STRUGGLING WITH THIS
10 ISSUE OF AFFORDABILITY BECAUSE IT'S THE COMMITMENT THAT
11 YOU ALL MADE TO THE PUBLIC. AND I APPRECIATE ALL THE
12 TIME THAT'S GOING INTO IT.

13 I TOO AM CONCERNED. MY WORK IS LOW INCOME
14 HEALTHCARE. I'M REALLY CONCERNED THAT DISCOUNT DOES
15 NOT TRANSLATE TO AFFORDABILITY, NOT ONLY AFFORDABILITY
16 TO PEOPLE WHO ARE UNINSURED, BUT AFFORDABILITY TO THE
17 PUBLIC PROGRAM. WHAT WE DON'T WANT TO SET UP IS A
18 SITUATION WHERE YOU AGREE TO A PRICING SYSTEM THAT THE
19 PUBLIC PROGRAM THEN SAYS, WELL, WE'RE NOT GOING TO
20 COVER IT BECAUSE WE CAN'T AFFORD IT. SO THERE HAS TO
21 REALLY BE A BETTER LOOK AT TAGGING TO MEDICAID,
22 MEDI-CAL PRICING.

23 THE OTHER THING, IN TERMS OF WHAT THIS PLAN
24 OR PROGRAM LOOKS LIKE FOR COVERING THE UNINSURED, IT
25 ALSO NEEDS TO INCLUDE THE UNDERINSURED BECAUSE JUST

1 BECAUSE YOU ACTUALLY HAVE INSURANCE DOESN'T MEAN THAT
2 YOU CAN AFFORD, BASED ON COPAYMENTS, MAYBE YOUR
3 INSURANCE WON'T COVER IT, SO I THINK WE HAVE TO LOOK AT
4 A BROADER DEFINITION OF WHO NEEDS TO BE COVERED BY
5 THESE PLANS. AND I TOTALLY SUPPORT MR. SHEEHY'S
6 STATEMENT THAT THIS SHOULD NOT BE APPROVED WITHOUT SOME
7 GOOD LANGUAGE. AND THERE ARE MODELS OUT THERE, DRUG
8 COMPANIES WHO HAVE PLANS FOR PROVIDING DRUGS TO
9 LOW-INCOME PEOPLE. AND I THINK WE SHOULD JUST WORK A
10 LITTLE HARDER AND FIND SOME GOOD MODELS TO OFFER.

11 AND THE THIRD THING IS THAT WHILE A POLICY
12 GUIDANCE MAY NOT HAVE THE FORCE OF LAW OR REGULATION,
13 THERE CERTAINLY IS LOTS OF PRECEDENT IF YOU JUST LOOK
14 AT MEDICAID, FOR EXAMPLE, EVERY MONTH WE HAVE ALL
15 COUNTY LETTERS. THERE ARE OTHER LEVELS OF PUBLIC
16 POLICY GUIDANCE THAT DON'T HAVE THE FORCE OF
17 REGULATION, BUT AT LEAST ARE ENFORCEABLE AT SOME LEVEL
18 AND GIVE PEOPLE A GOOD IDEA OF WHAT YOU'RE LOOKING AT.
19 AND IF EACH OF THESE -- AND ONE WAY OF ADDRESSING THIS
20 IS MAKING IT PART OF THE CONTRACT NEGOTIATION SO IF A
21 COMPANY COMES TO YOU FOR MONEY AND DOESN'T HAVE A
22 SUFFICIENT PLAN FOR CREATING A PROGRAM OF ACCESS, YOU
23 CAN REJECT THEIR APPLICATION. THERE ARE OTHER WAYS OF
24 INCORPORATING CLEAR CRITERIA THAT GIVE BUSINESS AND
25 INSTITUTIONS SOME CLARITY ABOUT WHAT YOU'RE LOOKING FOR

1 ALSO THAT YOU CAN BRING TO THE NEGOTIATING TABLE TO
2 MAKE SURE THAT PEOPLE REALLY STEP UP TO THE PLATE
3 BECAUSE A PLAN, YOU KNOW, CAN BE INCREDIBLY INADEQUATE
4 AND STILL, AS MR. HARRISON SAID, IT COULD STILL COMPLY
5 WITH THE REGULATION BECAUSE IT'S A PLAN.

6 CHAIRMAN KLEIN: IS THAT THE END OF PUBLIC
7 COMMENT? AND WHAT IS THE ADVICE HERE? DR. KESSLER AND
8 JEFF SHEEHY, HAVE WE REFINED THE REQUEST TO THE MAKER
9 OF THE MOTION? ARE WE ASKING FOR A MODIFICATION AND
10 WHAT WOULD THAT BE?

11 MR. SHEEHY: DID ANYBODY WRITE DOWN THE
12 LANGUAGE? YOU HAD GREAT LANGUAGE.

13 MR. HARRISON: I THINK THE LANGUAGE WAS
14 CONSISTENT WITH THEN EXISTING INDUSTRY STANDARDS.

15 MR. SHEEHY: SO THAT'S AN ADEQUATE
16 PLACEHOLDER, I THINK, TO MOVE US FORWARD IF THAT'S OKAY
17 WITH THE MAKER OF THE MOTION.

18 CHAIRMAN KLEIN: MAKER OF THE MOTION AND THE
19 SECOND? THE MAKER OF THE MOTION AND THE SECOND BOTH
20 ACCEPT THAT MODIFICATION OF THE MOTION. SINCE WE HAVE
21 AMENDED THE MOTION, I THINK I NEED TO ASK IF THERE'S
22 ANY ADDITIONAL PUBLIC COMMENT ON THAT. SEEING NO
23 PUBLIC COMMENT, I'D LIKE TO CALL THE QUESTION. ALL IN
24 FAVOR. OPPOSED? THANK YOU. THAT WAS AN EXTREMELY
25 THOUGHTFUL DISCUSSION. AND THANK YOU. DR. PENHOET,

1 YOU HAVE AN ADDITIONAL ITEM.

2 DR. PENHOET: I JUST WANT TO BE CLEAR AS WE
3 LEAVE THIS MEETING THAT WE HAVE ADOPTED THESE AS
4 INTERIM REGULATIONS, SO WE ARE NOW CAPABLE OF MAKING
5 GRANTS TO FOR-PROFIT INSTITUTIONS; IS THAT CORRECT,
6 JAMES?

7 MR. HARRISON: I'M SORRY.

8 DR. PENHOET: WE HAVE NOW ADOPTED THESE AS
9 INTERIM REGULATIONS, SO WE COULD MAKE A GRANT TO A
10 FOR-PROFIT INSTITUTION AS OF TODAY.

11 MR. HARRISON: THAT'S CORRECT. THESE RULES
12 WOULD APPLY TO ANY FOR-PROFIT GRANTEEES. JUST TO
13 CLARIFY, THE LAST MOTION CARRIED FOR THE RECORD.

14 CHAIRMAN KLEIN: WITHOUT OPPOSITION.

15 DR. PENHOET: THE NEXT ISSUE IS REALLY TWO
16 ISSUES THAT SCOTT IS GOING TO DISCUSS WITH YOU. ONE OF
17 THEM I ALREADY PRESAGED FOR YOU, WHICH IS THE ISSUE OF
18 PRESS RELEASES AS WE DISCUSSED LAST TIME. THE SECOND
19 ONE IS THE WHOLE TROUBLING AREA OF DISCOUNT PRICING AND
20 HOW TO FIND A WORKABLE SOLUTION TO THE PROBLEM, AND
21 SCOTT HAS PUT AN ENORMOUS AMOUNT OF EFFORT INTO THIS
22 PROJECT. SO, SCOTT, PLEASE COME FORWARD AND GIVE US
23 THE BENEFIT OF YOUR HARD WORK.

24 MR. TOCHER: THANK YOU, ED AND MARY.
25 ACTUALLY THE HARD WORK CONTINUES. I DON'T MEAN TO

1 IMPLY, GIVEN WHERE WE ARE, THAT THIS PROCESS IS OVER,
2 MUCH TO THE CHAGRIN OF DR. MAXON AND MYSELF AND THE
3 TASK FORCE WORK GROUP MEMBERS.

4 THERE ARE -- THESE TWO REGS BEFORE YOU IN
5 ITEM 9 ARE THE TWO REMAINING REGULATIONS THAT COMPOSE
6 THE POLICIES FOR THE GRANTS TO NON-PROFIT
7 ORGANIZATIONS. AS I SAID A FEW MOMENTS AGO, YOU
8 ALREADY APPROVED THE BULK OF THESE REGULATIONS LAST
9 OCTOBER, AND THESE ARE THE TWO THAT REMAIN FOR YOUR
10 CONSIDERATION IN ORDER TO SUBMIT THE ENTIRE PACKAGE TO
11 OAL.

12 DEALING WITH THE EASY ONE FIRST, WHICH IS THE
13 SECOND REGULATION THAT'S 100309, YOU RECALL THAT THAT
14 REGULATION WAS AMENDED AT THE BOARD'S SUGGESTION AT THE
15 LAST MEETING REGARDING PRESS RELEASE REQUIREMENTS, TO
16 DELETE THE REQUIREMENT THAT THE GRANTEES COOPERATE IN
17 THE FASHIONING OF JOINT PRESS RELEASES WITH THE CIRM.
18 SO THAT REGULATION WAS SET OUT FOR NOTICE FOR PUBLIC
19 COMMENT. THE SECOND SENTENCE WAS STRUCK. AND SO THE
20 VERSION THAT YOU SEE BEFORE YOU REFLECTS THE VERSION
21 THAT THE BOARD WISHED AS OF LAST OCTOBER.

22 SO WE WILL BE ASKING YOU FOR APPROVAL OF THAT
23 REGULATION TO SEND IT FORWARD TO OAL.

24 THE FIRST REGULATION, 100306 IS WHAT WE'VE
25 BEEN TALKING ABOUT IN THE CONTEXT OF THE FOR-PROFIT

1 POLICY. AND THE PARTICULAR PROVISION THAT WE HAVE BEEN
2 WORKING ON IS FOUND ON PAGE 2 OF THE DRAFT, AND THAT IS
3 SPECIFICALLY SUBDIVISION D.

4 GENERALLY THIS REGULATION --

5 CHAIRMAN KLEIN: SCOTT, CAN I ASK YOU A
6 QUESTION? ARE WE GOING TO NEED SEPARATE MOTIONS ON
7 EACH OF THESE?

8 MR. TOCHER: IT MIGHT BE CLEANER TO.

9 CHAIRMAN KLEIN: I THINK LEGALLY. SO IS
10 THERE A MOTION IN ORDER HERE?

11 DR. MURPHY: SO MOVED ON THE PRESS RELEASE.

12 CHAIRMAN KLEIN: MOTION BY DR. MURPHY. IS
13 THERE A SECOND?

14 DR. JENNINGS: SECOND.

15 CHAIRMAN KLEIN: THERE'S A SECOND BY DR.
16 JENNINGS. IS THERE ANY DISCUSSION ON THE BOARD? ANY
17 DISCUSSION OF THE PUBLIC? CALL THE QUESTION. ALL IN
18 FAVOR? OPPOSED? LET THE RECORD SHOW IT PASSED WITHOUT
19 OPPOSITION.

20 NEXT ITEM.

21 MR. TOCHER: THANKS. SO THIS REGULATION
22 COVERS LICENSING REQUIREMENTS FOR CIRM-FUNDED PATENTED
23 INVENTIONS. SUBDIVISION D ADDRESSES A SUBSET OF THAT
24 ISSUE, WHICH IS WHEN EXCLUSIVE LICENSES ARE AGREED TO
25 BETWEEN GRANTEE ORGANIZATIONS AND LICENSEES. IN THE

1 BEGINNING, THE TASK FORCE WITH THE ICOC'S APPROVAL HAS
2 BEEN OPERATING WITH THE GOAL THAT CALIFORNIANS SHOULD
3 NOT BE REQUIRED TO PAY ANY MORE THAN NECESSARY FOR
4 CIRM-FUNDED PATENTED INVENTIONS. AND SPECIFICALLY WITH
5 REGARD TO EXCLUSIVE LICENSEE SITUATIONS, THE GOAL IS TO
6 PROVIDE THE LOWEST PRICE POSSIBLE.

7 LANGUAGE EVOLVED THAT EVENTUALLY PEGGED THAT
8 TO THE FEDERAL MEDICAID PRICE, BUT THOSE THREE LITTLE
9 WORDS REALLY CARRY AN ENORMOUS BODY OF LAW AND
10 PROCEDURE INVOLVED IN ACTUALLY TARGETING AND
11 IDENTIFYING WHAT THE FEDERAL MEDICAID PRICE IS. IN
12 THEORY, IT SOUNDS SIMPLE, BUT THERE ARE VIRTUALLY
13 ENTIRE TREATISES DEVOTED TO ATTEMPTING TO DESCRIBE DRUG
14 PRICING IN THE UNITED STATES UNDER THE FEDERAL SYSTEM.

15 THE FEDERAL MEDICAID PRICE IS REALLY JUST ONE
16 PRICE OF MANY, MANY DIFFERENT PRICES THAT THE FEDERAL
17 GOVERNMENT, AND THROUGH ITS PURCHASING PROGRAMS AND
18 EVENTUALLY STATES, PAY FOR DRUGS. I AM ABSOLUTELY NO
19 EXPERT ON IT, BUT I HAVE LEARNED ENOUGH TO KNOW IT IS
20 EXTRAORDINARILY COMPLICATED. AND THE PROBLEM THAT WE
21 ENCOUNTERED IS THAT IN SOME CASES ATTEMPTING TO
22 DESCRIBE OR IDENTIFY A LOWEST PRICE FOR CALIFORNIANS
23 CAN END UP TRIGGERING WHAT'S CALLED A NEW BEST PRICE
24 RECALCULATION. AND THAT HAS ENORMOUS DOWNSTREAM
25 EFFECTS AND NATIONAL EFFECTS FOR DRUGS PROVIDED AT THE

1 FEDERAL LEVEL AND THROUGH THE STATES.

2 SO I THINK THERE WAS UNANIMOUS INTENTION ON
3 BEHALF OF THE PUBLIC, THE RELATED COMMUNITY, THE TASK
4 FORCE, AND THE ICOC THAT THAT WAS SOMETHING THAT NEEDED
5 TO BE AVOIDED. IN ADDITION, COMPLICATIONS WITH
6 IDENTIFYING WHO THE TARGET POPULATION WOULD BE, HOW THE
7 SYSTEM WOULD BE ADMINISTERED, WHO WOULD BE RESPONSIBLE
8 FOR AUDITING. FOR INSTANCE, FEDERAL MEDICAID PRICE IS
9 NOT A PRICE THAT IS FIXED AT ANY ONE GIVEN POINT IN
10 TIME, BUT IS BASED ON CALCULATIONS ON PAST PRICES THAT
11 ARE PROVIDED TO A STATE. THEY INVOLVE REBATES AFTER
12 THE FACT. AND SO THE PRICE IS ACTUALLY IDENTIFIED
13 ACTUALLY SOME POINT DOWN THE ROAD.

14 SO BETTER WE THOUGHT WOULD BE TO PEG THE
15 PRICE FOR NOW TO SOMETHING THAT IS ACTUALLY NOT A
16 FEDERAL SYSTEM, BUT A SYSTEM WITHIN THE STATE THAT IS
17 ALREADY ADMINISTERED BY THE STATE. AND THIS IS
18 SOMETHING WHICH ALREADY IDENTIFIED ITS TARGET
19 POPULATION, IT DOESN'T REQUIRE THE ICOC TO DEVELOP A
20 WHOLE NEW ENTIRE DRUG PRICING AND MONITORING SCHEME,
21 BUT ALLOWS US TO USE ONE THAT, ALBEIT NEW, IS CREATED
22 AND ADMINISTERED ALREADY BY THE STATE OF CALIFORNIA.

23 ONE OF THE COMMENTERS IDENTIFIED AN ISSUE
24 WITH REGARD TO THE FACT THAT THE NEGOTIATIONS AND
25 PRICES ARE CONFIDENTIAL INFORMATION. THAT WAS A

1 DEVELOPMENT FROM PREVIOUS VERSIONS OF THIS DRUG PROGRAM
2 IN PRIOR LEGISLATIVE SESSIONS WHERE THE LACK OF
3 CONFIDENTIALITY ENDED UP MAKING THE PLANS UNWORKABLE.
4 THE INDUSTRY CAN WORK WELL AS LONG AS THIS INFORMATION
5 THAT THEY SUBMIT TO THE STATE AND SUBMIT TO AUDITORS IS
6 KEPT CONFIDENTIAL. AND IT ACTUALLY POINTS UP ONE OF
7 THE, I THINK, BENEFITS OF MOVING IN THE DIRECTION THAT
8 THE TASK FORCE IS RECOMMENDING BECAUSE IT MEANS THAT
9 THE INFORMATION THAT IS PROVIDED TO THE STATE IS NOT
10 INFORMATION THAT THE ICOC NEEDS TO CONCERN ITSELF WITH.

11 THE AUDITING FUNCTIONS AND PROGRAM COMPLIANCE
12 REQUIREMENTS WILL BE TAKEN CARE OF WITHIN THE CALRX
13 SYSTEM. AND SO I THINK THAT IT'S JUST ONE OF THOSE
14 ISSUES THAT SHOWS WHY THIS SYSTEM IS PREFERABLE TO THE
15 PRIOR VERSION OF IDENTIFYING THE FEDERAL MEDICAID
16 PRICE.

17 SECONDLY, AS ED POINTED OUT EARLIER, THE TASK
18 FORCE DECIDED THAT THESE MECHANISMS OBVIOUSLY ARE
19 INSUFFICIENT AT THE MOMENT TO FIX PRICES IN AN
20 UNDERSTANDABLE AND CLEAR WAY WITH REGARD TO THERAPIES.
21 SO THE NOTION IS WITH THIS DRAFT AND WITH THE TASK
22 FORCE RECOMMENDATION IS, INSTEAD OF HOLDING UP THE
23 ENTIRE REGULATION PROCESS, WHEN WE KNOW WE CAN AT LEAST
24 WORK WITH SOMETHING WITH REGARD TO DRUGS, THAT THERE
25 ARE SYSTEMS OUT THERE THAT WE CAN USE TO IMPLEMENT A

1 POLICY WITH RESPECT TO DRUG PRICING, LET US CONTINUE TO
2 WORK ON IDENTIFYING THE PROPER FRAMEWORK FOR THERAPIES
3 IN THE CONTEXT AS WE ARE IN THE FOR-PROFIT POLICY. AND
4 WHEN WE FIND THAT SOLUTION, WE CAN COME BACK AND AMEND
5 THE NON-PROFIT IN A MANNER THAT CONFORMS THE TWO
6 POLICIES, BUT LET US AT LEAST MOVE FORWARD WITH THIS
7 SYSTEM IN THE CONTEXT OF DRUG PRICING.

8 SO THAT'S WHY THERAPIES HAVE BEEN REMOVED
9 FROM THIS REGULATION. IT'S NOT A PERMANENT FIX, OR I
10 SHOULDN'T SAY FIX, IT'S NOT A PERMANENT DELETION, BUT
11 RATHER ONE THAT LETS US MOVE FORWARD WITH WHAT WE HAVE
12 WHILE WE CONTINUE TO EXPLORE THIS EXTREMELY COMPLICATED
13 AND DIFFICULT ISSUE.

14 SO THAT IS THE SUBDIVISION, THEN, THAT YOU
15 SEE THERE IN SUBDIVISION D. IT ALSO ENSURES THAT THE
16 REGULATION DOES NOT INADVERTENTLY INCREASE COSTS FOR
17 CALIFORNIANS. THEREFORE, THERE'S A PROVISION THAT
18 ENSURES THAT THE REGULATION IS NOT CONSTRUED TO APPLY
19 IN CIRCUMSTANCES WHERE CALIFORNIANS WOULD OTHERWISE GET
20 A LOWER PRICE FOR THEIR MEDICATIONS.

21 AND WITH THAT, I THINK THAT THAT DESCRIBES
22 SORT OF THE BACKGROUND OF HOW WE ARRIVED HERE.

23 DR. PENHOET: JUST ONE CLARIFYING POINT.
24 WHEN WE TALK ABOUT THERAPIES IN THIS CONTEXT, THEY'RE
25 NONDRUG THERAPIES. THE DRUGS WILL BE COVERED BY THIS.

1 IT'S THERAPIES OTHER THAN DRUGS.

2 MR. TOCHER: THAT'S CORRECT.

3 CHAIRMAN KLEIN: BOARD COMMENT?

4 MR. ROTH: I'D MAKE A MOTION TO APPROVE.

5 CHAIRMAN KLEIN: MOTION BY DUANE ROTH. IS
6 THERE A SECOND? SECOND BY DR. REED. IS THERE
7 DISCUSSION FROM THE BOARD?

8 MS. SAMUELSON: YES, ONE COMMENT, BUT I HAVE
9 A QUESTION FIRST. ED, COULD YOU EXPLAIN WHAT YOU SAID
10 THAT -- I'M NOT UNDERSTANDING HOW PRICES ARE
11 INDEPENDENT OF THERAPIES.

12 DR. PENHOET: THEY'RE NOT. FIRST OF ALL, WE
13 ORIGINALLY HAD THE BROADER COVERAGE FOR PRICING OF
14 THINGS LIKE DIAGNOSTICS, REAGENTS, ETC. WE DECIDED
15 THAT THOSE WERE SMALL ENOUGH, AND THOSE GENERALLY ARE
16 NOT REGULATED BY ANYBODY, SO IT'S VERY HARD TO FIGURE
17 OUT PRICES, AND THEY'RE LOW PRICED. SO WE THOUGHT WE
18 SHOULD CONCENTRATE OUR EFFORT ON THERAPIES AND DRUGS,
19 WHICH ARE THE HIGH-COST ITEMS. THAT WAS THE FIRST
20 DECISION.

21 AND THEN THERE IS NO PRECEDENT OUT THERE THAT
22 WE FIND SO FAR FOR HOW PRICING OF NONDRUG THERAPIES ARE
23 REGULATED, IF AT ALL. SO, FOR EXAMPLE, LIVER
24 TRANSPLANTS, TRANSPLANTS ARE PROBABLY THE MOST
25 EQUIVALENT TO WHAT A STEM CELL THERAPY MIGHT BE.

1 MR. ROTH: OR A BLOOD TRANSFUSION.

2 DR. PENHOET: YEAH, A BLOOD TRANSFUSION, ANY
3 OF THESE THINGS. SO THOSE ARE GENERALLY NOT SUBJECT TO
4 THE SAME RULES AS DRUGS ARE VIS-A-VIS PRICING BECAUSE
5 DRUGS ARE BY FAR THE BIGGEST CATEGORY OF EXPENSE. SO
6 WE FOUND WHAT WE THINK IS A GOOD SYSTEM FOR DRUGS, BUT
7 CALRX ONLY APPLIES TO DRUGS. IT DOESN'T APPLY TO OTHER
8 FORMS OF THERAPIES. SO THAT'S WHAT WE'RE REALLY
9 STRUGGLING WITH IS TO TRY TO FIND SOME BENCHMARKS FOR
10 OTHER FORMS OF THERAPY. SO WHAT WE'RE SAYING NOW IS
11 LET'S PUT THIS IN PLACE FOR THE DRUGS THAT MAY EMERGE
12 TO OUR PROGRAMS AND CONTINUE TO WORK ON TRYING TO FIND
13 SOME LOW COST BENCHMARKS FOR NONDRUG THERAPIES.

14 MS. SAMUELSON: OKAY. ONE QUICK COMMENT. I
15 DON'T WANT TO OPEN UP A WHOLE NEW FIELD HERE FOR
16 DISCUSSION, BUT I THINK THIS IS AN EXAMPLE OF WHY WE
17 HAVE TO HAVE AS CLEAR AS POSSIBLE STRATEGIC PLANS AS WE
18 APPROACH EVERYTHING WE'RE DOING IN OUR WORK.

19 PARKINSON'S, FOR EXAMPLE, THERE REALLY HASN'T
20 BEEN ONE SIGNIFICANT IMPROVEMENT ON SINEMET IN 40
21 YEARS. I'M TOLD ALL THE TIME BY PRIVATE INDUSTRY THAT
22 IT'S NOT LUCRATIVE ENOUGH TO GET INTO THE FIELD. SO
23 WHAT WE DO WITH PRICING, HOW WE EFFECT IT MOST LIKELY
24 IS GOING TO HAVE SOME UNINTENDED CONSEQUENCES IN THE
25 PACE TO THE CLINIC AND TO THE PATIENT. AND I'LL TELL

1 YOU, WAKING UP WITH PARKINSON'S EVERY DAY, IT WOULD BE
2 MY DREAM COME TRUE TO HAVE A HIDEOUSLY EXPENSIVE
3 THERAPY AVAILABLE TO ME TOMORROW, AND THEN THE DAY
4 AFTER THAT I WOULD START WORKING ON COMPLAINING ABOUT
5 THE PRICE. BUT IT'S ABSOLUTELY IN THAT ORDER. AND
6 I'LL BET YOU PEOPLE WITH ANY OTHER DISEASE FEEL THE
7 SAME WAY.

8 I HAVE NO SOLUTION TO ANY OF THAT, BUT IT'S
9 COMPLEX AND IT'S IN OUR LAP.

10 DR. PENHOET: JUST TO BE CLEAR, WE'RE NOT
11 TALKING ABOUT PRICING FOR PEOPLE WHO ARE INSURED, AND
12 WE'RE ONLY TALKING IN THIS CASE FOR PRICING FOR PEOPLE
13 WHOSE THERAPIES ARE PAID FOR BY PUBLIC FUNDS IN
14 CALIFORNIA. THAT'S THE SUBSET WE'RE TALKING ABOUT. SO
15 WE ARE NOT ATTEMPTING TO SET PRICES FOR THE INSURED
16 POPULATION. IT'S CONFINED TO A SUBSET OF PUBLIC FUNDS
17 USED. THAT'S WHAT ALL THESE REFER TO, JOAN.

18 MS. SAMUELSON: WOULDN'T IT STILL, THOUGH,
19 PERHAPS HAVE AN IMPACT ON THE PACE TO DEVELOPMENT?

20 DR. PENHOET: TO BE CLEAR, I THINK OUR
21 COLLEAGUES IN INDUSTRY WOULD PREFER TO SEE ALL OF THESE
22 FEATURES DISAPPEAR FROM OUR PROGRAM, BUT WE HAVE
23 DIFFERENT POINTS OF VIEW. AND THAT'S BEEN THE TWO
24 SIDES WE'VE BEEN TRYING TO BALANCE IN OUR WORK.

25 CHAIRMAN KLEIN: ALL RIGHT. THERE'S A MOTION

1 AND THERE'S A SECOND; IS THAT CORRECT? SO ANY
2 ADDITIONAL DISCUSSION BY THE BOARD? DISCUSSION BY THE
3 PUBLIC?

4 MR. SIMPSON: JOHN SIMPSON FROM THE
5 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. TWO
6 CONCERNS. I DON'T THINK THIS DOES WHAT THE VICE
7 CHAIRMAN JUST SUGGESTED THAT IT DOES. IT DOES NOT TIE
8 LOWER PRICES FOR ANYTHING FOR ALL PUBLICLY FUNDED
9 PROGRAMS. IT MERELY SAYS THAT THE DRUGS AND ONLY DRUGS
10 WILL BE AVAILABLE THROUGH CALRX AND THE FACT OF THE
11 MATTER IS THAT ANY DRUG IN CALIFORNIA WOULD COME UNDER
12 CALRX ANYWAY. SO I THINK THE LANGUAGE HERE IS
13 RELATIVELY -- IT DOES NOT DO WHAT YOUR POLICY GOAL,
14 WHICH IS TO MAKE A REDUCED PRICE FOR ALL DRUGS THAT ARE
15 PURCHASED WITH PUBLIC FUNDS. THAT'S NOT WHAT YOUR
16 REGULATION SAYS AS IT'S PROPOSED.

17 THE SECOND THING IS I THINK IT IS A VERY
18 DANGEROUS IDEA TO PUT IN A REGULATION THAT YOU KNOW
19 DOESN'T DO THE POLICY THAT YOU WANT TO ACCOMPLISH,
20 WHICH IS DEAL WITH THERAPIES, AND SORT OF SAY SOMEWHERE
21 DOWN THE ROAD WE'LL DO THIS. I THINK THAT THE
22 APPROPRIATE COURSE IS TO LEAVE THIS OPEN. AND YOU HAVE
23 AT THE MOMENT AN INTERIM REG AND DON'T PUT THIS IN AS A
24 PERMANENT REGULATION. GET THE LANGUAGE CORRECT BECAUSE
25 THIS IS NOT DOING WHAT YOU HAVE SUGGESTED SINCE THE

1 ORIGINAL POLICY WAS PASSED FEBRUARY 10TH BY THE ICOC.
2 IT DOES NOT ACCOMPLISH YOUR GOALS. THANK YOU.

3 MR. TOCHER: TAKING JOHN'S POINTS, SECOND
4 POINT FIRST, UNFORTUNATELY THE OFFICE OF ADMINISTRATIVE
5 LAW REQUIRES A VERY HIGH DEGREE OF CLARITY AND
6 CERTAINTY, AS DR. KESSLER WAS DISCUSSING EARLIER IN A
7 DIFFERENT CONTEXT. IF WE WERE TO INCLUDE A PROVISION
8 IN REGULATION WHICH TIED THERAPY PROVISIONS TO A
9 PRICING MECHANISM THAT ONLY APPLIED TO DRUGS, I VERY
10 MUCH DOUBT THAT OAL WOULD ALLOW SUCH A REGULATION TO GO
11 INTO EFFECT BECAUSE IT'S NOT A SYSTEM THAT IS APT FOR
12 FIXING A PRICE ON THERAPIES. SO YOU'D BE REQUIRING THE
13 REGULATED COMMUNITY TO PROVIDE THERAPIES, NONDRUG
14 THERAPIES, IN ACCORDANCE WITH THE PRICING SYSTEM THAT
15 DOESN'T APPLY TO NONDRUG THERAPIES.

16 MR. SIMPSON: THE POINT WAS YOU NEED TO FIND
17 ONE BEFORE THE REGULATION GOES IN. THAT'S ALL. WE
18 KNOW WE NEED TO FIND THAT ACCORDING TO THE POLICY OF
19 THE BOARD.

20 MR. TOCHER: WE KNOW WE NEED TO FIND IT, AND
21 THAT'S SOMETHING THAT IS GOING TO BE AN ONGOING
22 PROCESS. IF WE DON'T HAVE IT TODAY, I THINK THAT THE
23 TASK FORCE IS SAYING LET'S STILL MOVE FORWARD IN THE
24 AREAS WHERE WE KNOW WE CAN MAKE PROGRESS AND LET'S NOT
25 HOLD IT UP.

1 CHAIRMAN KLEIN: I THINK WE HAVE THE
2 COMMENTS. ARE THERE ADDITIONAL PUBLIC COMMENTS?
3 ADDITIONAL BOARD COMMENTS? CALL THE QUESTION. ALL IN
4 FAVOR? OPPOSED? LET THE RECORD SHOW IT PASSED WITHOUT
5 OPPOSITION.

6 I THINK THAT WE'RE READY FOR -- IS THERE
7 ADDITIONAL THAT YOU HAVE, SCOTT?

8 MR. TOCHER: NOT ON ITEM 9.

9 CHAIRMAN KLEIN: OKAY. I THINK WE'RE READY
10 FOR A REFUELING STOP. AND WOULD THE STAFF TELL US
11 WHERE THE LUNCH WILL BE. IN THE LIBRARY. WE WILL
12 ADJOURN IN THE LIBRARY. THAT'S FOR THE BOARD.

13 WE ARE GOING INTO CLOSED SESSION ON THE ITEMS
14 LISTED, BOTH PENDING LITIGATION AND ON PERSONNEL. WE
15 WILL HOPE TO BE BACK IN AN HOUR. WE HAVE ASPIRATIONS.

16 (A RECESS WAS TAKEN.)

17 CHAIRMAN KLEIN: WE'RE LIVE. WE WANT TO
18 IMMEDIATELY ENERGIZE THIS BECAUSE WE'RE GOING TO LOSE A
19 QUORUM HERE EARLIER THAN WE EXPECTED GIVEN SOME NEW
20 CHANGE IN PLANE RESERVATIONS. I WANT TO PICK UP HERE.
21 LORI, IS IT POSSIBLE, BECAUSE GETTING THE CAPITAL
22 EQUIPMENT DEFINITION ONLINE IS VERY IMPORTANT, THAT WE
23 START WITH THAT AS A QUICK ITEM. IS THAT POSSIBLE?
24 I'M GOING TO ASK LORI HOFFMAN TO BEGIN, AND WE'RE GOING
25 TO TRY AND HOPEFULLY DO ITEM --

1 MR. HARRISON: WE SHOULD TAKE ACTION ON THE
2 ITEM THAT CAME OUT OF CLOSED SESSION FIRST.

3 CHAIRMAN KLEIN: LORI, IF YOU'LL JUST STAND
4 BY RIGHT THERE. YOU DON'T NEED TO LEAVE.

5 DR. HALL, WOULD YOU LIKE TO ADDRESS AS A
6 REPORT THE ITEM OUT OF CLOSED SESSION ON PERSONNEL?

7 DR. HALL: OKAY. THE BOARD APPROVED A
8 VARIANCE IN SALARY FOR OUR SENIOR LIAISON OFFICER FOR
9 FACILITIES, AND THE BOARD APPROVED A SALARY OF 158,
10 WHICH IS \$8,000 OVER THE LIMIT. AND THE CANDIDATE, WHO
11 I THINK I CAN ANNOUNCE, IS MR. RICK KELLER, WHO IS AT
12 UC DAVIS WHERE HIS OFFICIAL TITLE IS --

13 MS. HOFFMAN: ASSISTANT VICE CHANCELLOR OF
14 CAPITAL PLANNING AND RESOURCE MANAGEMENT.

15 DR. HALL: YES. HE BRINGS DECADES OF
16 EXPERIENCE WITH CAPITAL PROJECT MANAGEMENT AND PLANNING
17 AND IS ACTUALLY AN UNUSUALLY CAPABLE PERSON. WE DID
18 NOT EXPECT TO GET SOMEBODY THIS SENIOR TO APPLY. AND
19 FOR VARIOUS REASONS, THIS WILL REPRESENT A LESS THAN
20 5-PERCENT INCREASE OR ABOUT A 5-PERCENT INCREASE OVER
21 HIS CURRENT SALARY WHEN IT'S DISCOUNTED FOR RETIREMENT
22 BENEFITS. SO THE BOARD APPROVED THAT.

23 DR. POMEROY: SINCE JAMES IS SAYING THAT WE
24 NEED TO OFFICIALLY MAKE A MOTION IN PUBLIC SESSION, I
25 MOVE APPROVAL OF THAT SALARY.

1 DR. HENDERSON: I SECOND IT.

2 DR. PENHOET: ALL IN FAVOR?

3 CHAIRMAN KLEIN: OPPOSED? DO WE HAVE A
4 QUORUM SEATED?

5 MR. HARRISON: WE DO.

6 CHAIRMAN KLEIN: THANK YOU. THANK YOU VERY
7 MUCH.

8 MR. HARRISON: FOR THE RECORD, THE MOTION
9 CARRIED WITHOUT OPPOSITION.

10 CHAIRMAN KLEIN: THANK YOU, JAMES. AND
11 THERE'S A COUPLE OF OTHER ITEMS WE'RE TRYING TO MOVE ON
12 QUICKLY WHILE WE HAVE A QUORUM. ONE OF THOSE, I THINK,
13 LORI HOFFMAN CAN ADDRESS IS ITEM 16. IT COMES FROM THE
14 FACILITIES WORKING GROUP AS THE DEFINITION OF CAPITAL
15 EQUIPMENT TO ALLOW PEOPLE THE CLARITY IN MOVING AHEAD
16 WITH THEIR SHARED LAB GRANTS AND OTHER ENDEAVORS.

17 MS. HOFFMAN: THANK YOU. TODAY I BRING
18 FORWARD FOR CONSIDERATION THE DEFINITION OF CAPITAL
19 EQUIPMENT. THE PRESIDENT AND THE FACILITIES WORKING
20 GROUP RECOMMENDS TO THE ICOC FOR APPROVAL THE FOLLOWING
21 DEFINITIONS FOR CAPITAL AND RESEARCH EQUIPMENT. RATHER
22 THAN HAVING ME READ THIS --

23 DR. HALL: TAB 16; ISN'T THAT CORRECT?

24 MS. HOFFMAN: RATHER THAN HAVING ME READ THE
25 DIFFERENCES, LET ME JUST SAY THAT FOR PURPOSES OF THE

1 FACILITIES GRANTS IN THE FUTURE, CAPITAL EQUIPMENT OR
2 WHAT WE WILL REFER TO AS FIXED EQUIPMENT WITH THE
3 FOLLOWING DEFINITIONS WILL APPLY TO THE FACILITY
4 GRANTS. AND RESEARCH EQUIPMENT, WHICH IS MOVABLE OR
5 INSTRUMENTATION, THEN THOSE FUNDS WILL APPLY TO THE
6 RESEARCH GRANTS. I OPEN IT UP FOR QUESTIONS.

7 CHAIRMAN KLEIN: LORI, THIS IS CONSISTENT
8 WITH THE DISCUSSION LAST BOARD MEETING WHERE DR.
9 BALTIMORE AND OTHERS WERE ACTIVELY INVOLVED IN THE
10 DISCUSSION. WE MADE IT CLEAR THAT UNDER FACILITIES,
11 WE'RE TALKING ABOUT BUILT-IN EQUIPMENT LIKE MAJOR AIR
12 HANDLING EQUIPMENT FOR GMP LABS, BUILT-IN FIXTURES, AS
13 WE WOULD THINK OF THEM. AND CERTAINLY AS A PART OF
14 RESEARCH, PEOPLE ARE USED TO THE FACT WE NEED HIGH
15 SPEED CELL SORTERS AND OTHER MOVABLE EQUIPMENT, WHICH
16 IS MORE CLASS II EQUIPMENT. BUT CAPITAL EQUIPMENT WILL
17 BE RESTRICTED, AS I UNDERSTAND YOUR STATEMENT, TO THE
18 FIXTURES THAT GO WITH THE FACILITIES AND, THEREFORE,
19 ARE PROPERLY IN THE FACILITIES COMMITTEE.

20 MS. HOFFMAN: THAT'S CORRECT, BOB. CERTAINLY
21 AS IS SEEN ON ATTACHMENT 1, WE HAVE SURVEYED BOTH AT
22 THE FEDERAL LEVEL, STATE LEVEL, PUBLIC AND PRIVATE
23 UNIVERSITIES WITHIN CALIFORNIA, AND THIS CERTAINLY IS
24 IN COMPLIANCE WITH THAT.

25 CHAIRMAN KLEIN: WE ARE CONSISTENT WITH THEIR

1 POLICY. ANY OTHER DISCUSSION?

2 DR. HENDERSON: MOVE APPROVAL.

3 CHAIRMAN KLEIN: MOVE APPROVAL. IS THERE A
4 SECOND?

5 DR. BRYANT: SECOND.

6 CHAIRMAN KLEIN: SECOND BY DR. BRYANT. IS
7 THERE ADDITIONAL DISCUSSION FROM THE BOARD? NO
8 DISCUSSION FROM THE BOARD. IS THERE DISCUSSION FROM
9 THE PUBLIC? NO DISCUSSION FROM THE PUBLIC. I CALL THE
10 QUESTION. ALL IN FAVOR? OPPOSED? LET THE RECORD SHOW
11 THAT IT PASSED UNANIMOUSLY WITH NO OPPOSITION.

12 NEXT ITEM IS ITEM 15. THAT ITEM RELATES TO
13 THE FACILITIES WORKING GROUP. AND AT TAB 15, WE WILL
14 HAVE THE SUGGESTED LANGUAGE. SCOTT TOCHER, COULD YOU
15 COMMENT ON THE PURPOSE OF THIS AND ITS ORIGIN AS WELL
16 AS THE CLARIFICATION IN LANGUAGE THAT I'VE BROUGHT TO
17 YOUR ATTENTION?

18 MR. TOCHER: THE DOCUMENTS HERE UNDER TAB 15
19 ARE STATEMENTS OF THE CONFIDENTIALITY POLICY AND
20 CONFLICTS OF INTEREST POLICIES THAT GOVERN THE
21 FACILITIES WORKING GROUP, WHICH IS GEARING UP. THESE
22 POSTREVIEW AND PREREVIEW CERTIFICATION FORMS AND
23 CONFIDENTIALITY POLICIES LARGELY MIRROR THOSE THAT YOU
24 HAVE ALREADY ADOPTED IN THE CONTEXT OF THE GRANTS
25 WORKING GROUP, BUT WITH MINOR REVISIONS THAT TAKE INTO

1 ACCOUNT THE NATURE OF THE DIFFERENCES BETWEEN THE TWO
2 GROUPS.

3 MORE SPECIFICALLY, THE LAST DOCUMENT IS A
4 FOUR-PAGE REGULATION, REGULATION 100004, AND THIS IS
5 THE CONFLICT OF INTEREST PROVISIONS THAT APPLY TO THE
6 FACILITIES WORKING GROUP. THIS IS AN EXISTING
7 REGULATION, ONE ALREADY IN EFFECT. AND AS A RESULT OF
8 THE AUDIT PROCESS, NOT GOING INTO WHAT SPECIFIC
9 RECOMMENDATIONS MAY COME OUT OF IT, THERE ARE SOME
10 CONSISTENCY ISSUES THAT WE'VE IDENTIFIED THAT WE
11 RECOMMEND THE ICOC CONSIDER TO AMEND THE REGULATION.

12 THESE SUGGESTIONS ARE UNDERLINED. HOWEVER,
13 IN THE DOCUMENT CONVERSION PROCESS, SOME OF THE
14 UNDERLINING WAS INADVERTENTLY ELIMINATED. I COULD JUST
15 POINT THEM OUT TO YOU ON PAGE 2. AGAIN, WE'RE ON
16 REGULATION 100004, LINE 14. THIS DETAILS PROFESSIONAL
17 CONFLICTS OF INTEREST AND DEFINES THEM. AND WHAT WE'VE
18 DONE IS CONSISTENT WITH THE GRANTS WORKING GROUP.
19 WE'RE ADDING THERE ON LINE 14, THE LANGUAGE "OR HAVE
20 BEEN ENGAGED IN DURING THE LAST THREE YEARS." AND THIS
21 IS TO ENCOMPASS JOINT PROJECTS WITH WHICH THE MEMBER
22 HAS ENGAGED IN THE PAST THREE YEARS IN ADDITION TO
23 CURRENT PROJECTS.

24 WE'VE ALSO INCLUDED A DEFINITION OF PERSONAL
25 CONFLICTS OF INTEREST, WHICH IS UNDERLINED. AND THEN

1 FINALLY, ON THE LAST PAGE, PAGE 4, LINES 3 AND 4, WE'VE
2 ADDED THE LANGUAGE AT THE VERY END OF THE SENTENCE,
3 WHICH READS, "OR PARTICIPATE IN THE SCORING OF THE
4 APPLICATION." THIS IS, AGAIN, CONSISTENT WITH WHAT WAS
5 DONE IN THE GRANTS WORKING GROUP CONFLICTS OF INTEREST
6 REGULATION AND APPEARS REALLY JUST TO MEND AN
7 INADVERTENT OMISSION.

8 SO WHAT WE WOULD LIKE IS APPROVAL TO NOTICE
9 THIS CHANGE WITH OAL, TO HAVE IT GO THROUGH THE OAL
10 ADOPTION PROCESS, AND BE AMENDED TO INCLUDE THE
11 LANGUAGE I'VE JUST IDENTIFIED.

12 DR. WRIGHT: SO MOVED.

13 CHAIRMAN KLEIN: ARE WE FIRST GOING TO
14 APPROVE THE POLICY, OR ARE WE GOING TO GO TO THE
15 REGULATION?

16 MR. TOCHER: IN HOWEVER ORDER YOU PREFER,
17 BOB. I KNOW THAT YOU HAVE A SUGGESTION FOR THE POLICY.

18 CHAIRMAN KLEIN: ON THE POLICY AND THE OTHER
19 DOCUMENTS, CURRENTLY IT SAYS THAT YOU WON'T -- A MEMBER
20 OF THE FACILITIES WORKING GROUP, INCLUDING THE BOARD
21 MEMBERS, WON'T TALK TO ANY OTHER PERSON OTHER THAN THE
22 STAFF ATTACHED TO THAT COMMITTEE. AND CERTAINLY WE MAY
23 NEED TO TALK TO OUR ATTORNEYS, WE MAY NEED TO TALK TO
24 OTHER BOARD MEMBERS WITH WHOM THERE'S NOT A CONFLICT.
25 SO MY UNDERSTANDING, SCOTT, IT WAS NOT INTENDED TO

1 PREVENT DISCUSSIONS WITH OTHER BOARD MEMBERS OR OTHER
2 CIRM STAFF OR OUR ATTORNEYS?

3 MR. TOCHER: THAT'S CORRECT.

4 CHAIRMAN KLEIN: SO IF WE COULD, IN WHATEVER
5 MOTION THERE IS, ADOPT THAT CLARIFICATION TO THE POLICY
6 AND THE OTHER ELEMENTS OF THIS PACKAGE.

7 MR. TOCHER: THAT'S CORRECT. THAT WOULD BE
8 FINE.

9 CHAIRMAN KLEIN: IS ANYONE WILLING TO MAKE A
10 MOTION SO WE CAN HAVE A DISCUSSION OF THIS ITEM?

11 MR. SERRANO-SEWELL: SO MOVED.

12 CHAIRMAN KLEIN: MOVED BY DAVID
13 SERRANO-SEWELL WITH THE CLARIFYING LANGUAGE?

14 MR. SERRANO-SEWELL: YES.

15 CHAIRMAN KLEIN: IS THERE A SECOND?

16 DR. AZZIZ: SECOND.

17 CHAIRMAN KLEIN: SECOND, DR. AZZIZ. SO WE
18 HAVE A MOTION ON THE TABLE. NOW, JAMES.

19 MR. HARRISON: JUST TO BE CLEAR, DOES THE
20 MOTION PERTAIN TO THE POLICY ALONE, OR DOES IT ALSO
21 ENCOMPASS THE REGULATION? THE REASON I RAISE THE
22 QUESTION IS THAT, AS YOU ALL WILL RECALL, WE ADOPTED
23 THE CONFLICT OF INTEREST POLICY FOR THE GRANTS WORKING
24 GROUP, WHICH IS NOW IN REGULATION 100004 PURSUANT TO
25 OUR CONSULTATION WITH STAFF AND MEMBERS OF THE

1 LEGISLATURE. AND THIS IS A PROVISION THAT, IN ORDER TO
2 MODIFY, WE NEED TO APPROVE BY A 70-PERCENT VOTE OF THE
3 ICOC AFTER NOTICE TO THE LEGISLATURE, WHICH WE HAVE
4 PROVIDED. SO THIS IS AN ITEM, THE REGULATION, THAT WE
5 SHOULD HANDLE SEPARATELY JUST TO MAKE CLEAR.

6 CHAIRMAN KLEIN: ALL RIGHT. SO WHAT WE
7 SHOULD DO IS HANDLE THE REGULATION AND THE FORMS, AND
8 THEN WE'LL COME BACK LATER AND DEAL WITH THE POLICY
9 AFTER WE'VE PROVIDED NOTICE TO CONFORM IT.

10 MR. HARRISON: NO. NO. NO. I'M SORRY.
11 IT'S ONLY THE REGULATION. WE'VE PROVIDED THE NOTICE
12 FOR THE REGULATION, WHICH IS THE ONLY THING THAT WE
13 NEED TO PROVIDE THE NOTICE FOR. BECAUSE THE REGULATION
14 HAS A DIFFERENT THRESHOLD FOR APPROVAL, WE NEED A
15 70-PERCENT VOTE. BASED ON OUR BYLAWS, WE SHOULD HAVE A
16 SEPARATE VOTE.

17 CHAIRMAN KLEIN: I THINK DAVID WAS MEANING TO
18 HAVE SEPARATE MOTIONS.

19 MR. SERRANO-SEWELL: YES. THAT WAS MY
20 INTENTION.

21 CHAIRMAN KLEIN: SO TO CLARIFY IT, WE HAVE
22 SEPARATE MOTIONS, AND THE NOTICE HAS BEEN CLARIFIED AS
23 ALREADY BEEN GIVEN. THANK YOU VERY MUCH. OKAY. SO IS
24 THERE ANY DISCUSSION?

25 MR. ROTH: JUST A QUESTION, BOB, ON WHAT YOU

1 SAID JUST BEFORE THIS IN TERMS OF CONFLICTS -- I
2 UNDERSTAND THE FACILITIES WORKING GROUP WOULD SIGN AND
3 ABIDE BY THIS. WHO ELSE?

4 CHAIRMAN KLEIN: THIS ADDRESSES THE
5 FACILITIES WORKING GROUP.

6 MR. ROTH: JUST THE FACILITIES WORKING GROUP.
7 I THOUGHT YOU TALKED ABOUT "AND THE ICOC BOARD."

8 CHAIRMAN KLEIN: WE'RE MAKING IT CLEAR IN THE
9 CLARIFICATION THAT BOARD MEMBERS ON THE FACILITIES
10 WORKING GROUP CAN TALK TO OTHER BOARD MEMBERS. OKAY.

11 MR. ROTH: I UNDERSTAND.

12 CHAIRMAN KLEIN: AS WELL AS OUR COUNSEL AND
13 MEMBERS OF THE STAFF. OKAY. IS THERE ADDITIONAL --

14 MR. SHEEHY: I'M NOT COMFORTABLE YET WITH --
15 I MEAN CAN WE TABLE THIS FOR FURTHER DISCUSSION, THIS
16 POLICY PIECE? I'M JUST NOT COMFORTABLE WITH THE
17 CONFIDENTIALITY. THE FACILITIES WORKING GROUP DOES NOT
18 HAVE THE SAME REQUIREMENTS FOR CONFIDENTIALITY THAT THE
19 GRANTS WORKING GROUP DOES AND DOESN'T HAVE THE SAME
20 RATIONALE. YOU KNOW, IT SEEMS LIKE WE'VE STARTED --
21 THERE'S TOO MUCH SYMMETRY HERE. I THINK THE GREATEST
22 DEGREE OF TRANSPARENCY THAT WE CAN ALLOW IN ANY KIND OF
23 FACILITIES DISCUSSION WILL BENEFIT ALL OF US. AND, YOU
24 KNOW, WE REALLY HAVEN'T GONE THROUGH THE WHOLE PROCESS
25 OF HOW WE'RE GOING TO CONSIDER THESE GRANTS.

1 WE HAD THE SHORT-TERM, THE SHARED FACILITIES
2 THING, BUT WHEN WE START TALKING ABOUT MAJOR
3 FACILITIES, WE'RE NOT GOING TO GO INTO CLOSED -- YOU
4 KNOW, IT'S NOT GOING TO BE ALL HUDDLED IN AND QUIET AND
5 THEN WE COME OUT AND TELL PEOPLE WE JUST SPENT \$25
6 MILLION AND YOU GOT IT AND YOU DIDN'T. WE HAVE TO --
7 WE HAVE TO BE A LITTLE MORE THOUGHTFUL ABOUT THAT.

8 I WOULD PREFER NOT TO PUT IN PLACE ANYTHING
9 THAT WOULD BE ANYTHING LESS THAN AN INTERIM POLICY JUST
10 TO COVER OUR NEXT GRANT, JUST TO COVER THE SHARED
11 FACILITIES GRANT, BECAUSE PROCEDURES AND POLICIES FOR
12 THE FACILITIES WORKING GROUP, TO ME, ARE STILL A WORK
13 IN PROGRESS.

14 CHAIRMAN KLEIN: MY UNDERSTANDING AND, SCOTT,
15 PLEASE CORRECT THIS, IS THAT THIS ONLY CONTROLS WHEN
16 WE'RE IN CONFIDENTIAL SESSION. IS THAT A CORRECT
17 STATEMENT?

18 MR. TOCHER: IT WOULD COVER MATERIAL THAT IS
19 DISCUSSED THAT IS -- THAT OCCURS IN CLOSED SESSION,
20 THAT'S CORRECT.

21 CHAIRMAN KLEIN: TO THE EXTENT THAT IT IS NOT
22 ALSO DISCUSSED IN PUBLIC SESSION.

23 MR. TOCHER: CORRECT. THAT'S RIGHT. BECAUSE
24 THEY MUST NOT DISCLOSE THE IDENTITY OF THE APPLICANTS
25 AND THE INSTITUTIONS THEY REPRESENT.

1 CHAIRMAN KLEIN: SO THIS DOES NOT PREJUDGE
2 WHAT WE COVER IN PUBLIC SESSION.

3 MR. TOCHER: CORRECT.

4 CHAIRMAN KLEIN: JEFF.

5 MR. SHEEHY: I CAN'T SUPPORT IT. I'LL
6 SUPPORT IT AS AN INTERIM POLICY.

7 CHAIRMAN KLEIN: OKAY. IS THIS AS AN INTERIM
8 POLICY?

9 MR. SERRANO-SEWELL: LET'S JUST TAKE THE
10 VOTE, BOB. IF JEFF WANTS TO VOTE NO ON IT, HE'S
11 ENTITLED TO DO SO. THAT'S FINE.

12 DR. AZZIZ: THIS CAN BE MODIFIED LATER. WE
13 END UP WITH TOO MANY TEMPORARY POLICIES THAT WE'RE NOT
14 GOING TO BE ABLE TO FUNCTION. WHY DON'T WE JUST
15 DISCUSS IT AND VOTE AND --

16 CHAIRMAN KLEIN: AS A MATTER OF LAW, IF YOU
17 WOULD JUST TELL US, SCOTT, AS A MATTER OF LAW, IS IT AN
18 EMERGENCY POLICY?

19 MR. TOCHER: IT'S NOT SUBJECT TO THE
20 REGULATORY APA PROCESS. THIS IS A POLICY THAT THE
21 BOARD ADOPTS FOR THIS WORKING GROUP.

22 CHAIRMAN KLEIN: APPRECIATE IT. SO THIS CAN
23 BE CHANGED MUCH MORE EASILY --

24 MR. TOCHER: THAT'S RIGHT.

25 CHAIRMAN KLEIN: -- IN ADDRESSING JEFF'S

1 CONCERN.

2 MR. SHEEHY: HAS IT BEEN ADOPTED AT THE
3 WORKING GROUP?

4 CHAIRMAN KLEIN: HAS IT BEEN ADOPTED AT THE
5 WORKING GROUP?

6 MR. SHEEHY: DON'T POLICIES FOR THE WORKING
7 GROUP HAVE TO ORIGINATE WITH THE WORKING GROUP?

8 MR. TOCHER: THIS IS NOT A POLICY THAT WAS
9 CRAFTED THROUGH THE WORKING GROUP. IN THE PAST, IF I'M
10 NOT MISTAKEN, THESE PARTICULAR TYPES OF POLICIES WERE
11 BROUGHT DIRECTLY TO THE ICOC IN THE CONTEXT OF THE
12 GRANTS WORKING GROUP, FOR INSTANCE.

13 MR. SHEEHY: THIS IS --

14 MR. SERRANO-SEWELL: JAMES, IS THAT YOUR
15 UNDERSTANDING?

16 MR. SHEEHY: I'M REALLY OPPOSED TO IT.

17 CHAIRMAN KLEIN: JEFF, I WILL TELL YOU THAT I
18 WOULD COMMIT TO BRINGING IT BACK AS A BOARD AGENDA ITEM
19 BEFORE WE GO BEYOND THE SHARED LAB SPACE SO THAT YOU
20 KNOW THAT WE'RE GOING TO BRING THIS BACK AS YOU
21 REQUESTED.

22 MR. SHEEHY: OKAY. THAT'S FINE.

23 MR. SERRANO-SEWELL: THAT'S FINE.

24 CHAIRMAN KLEIN: ANY ADDITIONAL DISCUSSION?
25 ANY PUBLIC DISCUSSION? SEEING NONE, I CALL THE

1 QUESTION. ALL IN FAVOR? OPPOSED?

2 MR. SHEEHY: OPPOSE.

3 CHAIRMAN KLEIN: ALL RIGHT. AND STAFF WOULD
4 PLEASE CALENDAR THIS TO BRING THIS BACK AT THAT TIME.

5 MR. TOCHER: THE REGULATION?

6 CHAIRMAN KLEIN: THE REGULATION AT THIS TIME.

7 MR. HARRISON: STATE WHAT THE VOTE WAS FOR
8 THE RECORD.

9 CHAIRMAN KLEIN: UNANIMOUS EXCEPT FOR JEFF'S
10 VOTE. I SHOULDN'T HAVE SAID UNANIMOUS. ALL THE
11 MEMBERS OF THE BOARD EXCEPT JEFF SHEEHY VOTED FOR IT.
12 AND ON THE RECORD, WE ARE COMMITTING TO BRING THIS BACK
13 SO THAT BEFORE WE GO IN FACILITIES BEYOND THE SHARED
14 LAB SPACE, WE HAVE THIS AT THE BOARD AGAIN.

15 MR. TOCHER: NOW A MOTION FOR THE REGULATION.

16 CHAIRMAN KLEIN: NOW IT'S FOR THE REGULATION.

17 MR. TOCHER: THAT'S RIGHT. FOR 100004, FOR
18 APPROVAL TO MOVE FORWARD WITH THE OAL ADOPTION PROCESS,
19 BUT WE DON'T HAVE A MOTION YET.

20 CHAIRMAN KLEIN: IS THIS AN INTERIM POLICY?

21 MR. TOCHER: NO. THIS WOULD BE TO AMEND AN
22 EXISTING REGULATION.

23 CHAIRMAN KLEIN: TO AMEND AN EXISTING
24 REGULATION.

25 MR. TOCHER: THAT'S RIGHT.

1 MR. ROTH: I'LL MAKE A MOTION TO APPROVE.

2 DR. POMEROY: SECOND.

3 CHAIRMAN KLEIN: MOTION HAS BEEN MADE BY
4 DUANE ROTH, SECONDED BY DR. CLAIRE POMEROY.
5 DISCUSSION?

6 DR. JENNINGS: WHY IS A STUDENT AT AN
7 INSTITUTION CONSIDERED A CONFLICT OF INTEREST?

8 THE REPORTER: I'M SORRY, DR. JENNINGS. I
9 CAN'T HEAR YOU.

10 DR. JENNINGS: WHY IS A STUDENT CONSIDERED --
11 AN IMMEDIATE FAMILY MEMBER IS A CURRENT STUDENT IN AN
12 INSTITUTION -- CONSIDERED A CONFLICT OF INTEREST SINCE
13 A STUDENT HAS NO AUTHORITY FOR EXPENDITURES OR
14 DECISIONS ON FACILITIES OF THIS NATURE? JUST SEEMED
15 LIKE OVERKILL.

16 MR. TOCHER: I THINK THAT THE JUSTIFICATION
17 OF THESE PARTICULAR DEFINITIONS IN A PERSONAL CONTEXT
18 IS THAT IT'S DIFFERENT FROM A FINANCIAL CONFLICT OF
19 INTEREST, WHICH IS THE CONTEXT THAT YOU'RE DESCRIBING
20 WHERE THERE MIGHT BE A FINANCIAL INCENTIVE OF SOME SORT
21 THAT WOULD SHAPE A PERSON'S DECISION-MAKING. HERE THE
22 ADVICE TO US WAS THAT DEFINING A PERSONAL CONFLICT OF
23 INTEREST IN A WAY THAT IS SIMILAR TO THE GRANTS WORKING
24 GROUP ENCOMPASSES A DIFFERENT TYPE OF POTENTIAL
25 CONFLICT OF INTEREST WHERE YOUR INTEREST IS NOT PERHAPS

1 FINANCIAL, BUT, AS IT SAYS, PERSONAL.

2 DR. JENNINGS: THAT'S OKAY, BUT IT JUST
3 SEEMED A REAL STRETCH TO ME. THAT'S ALL.

4 DR. AZZIZ: A POINT OF CLARIFICATION. THIS
5 REFERS TO THE DEFINITION OF WHO STATES THEY MAY HAVE A
6 POTENTIAL CONFLICT OF INTEREST. THIS DOES NOT
7 AUTOMATICALLY EXCLUDE OR INCLUDE PEOPLE; IS THAT
8 CORRECT? THESE DEFINITIONS, YOU HAVE TO REPORT THEM.
9 THAT'S WHY --

10 MR. TOCHER: YOU DO HAVE TO REPORT THEM. AND
11 THEY WOULD CONSTITUTE A CONFLICT OF INTEREST IN THE
12 CIRCUMSTANCES OF A GRANTEE APPLICANT SATISFYING AND THE
13 MEMBER SATISFYING ONE OF THESE CRITERIA.

14 CHAIRMAN KLEIN: MY UNDERSTANDING IN THE
15 PRIOR ANSWER TO THE QUESTION ABOUT A STUDENT IS IF THE
16 STUDENT WERE PAYING TUITION, FULL TUITION, AND THERE
17 WAS NO GRANT ASSISTANCE, THAT IT WOULD NOT BE A
18 CONFLICT. SO THIS SEEMS TO BE A CHANGE.

19 MR. TOCHER: WELL, LET ME READ THE
20 DEFINITION. A PERSON HAS A PERSONAL CONFLICT OF
21 INTEREST IF HE OR SHE HAS AN IMMEDIATE FAMILY MEMBER
22 WHO IS A CURRENT STUDENT OR FACULTY MEMBER OF THE
23 APPLICANT INSTITUTION.

24 CHAIRMAN KLEIN: I HAVE A PROBLEM WITH THAT
25 TOO UNLESS THEY'RE ON SCHOLARSHIP. THERE'S NO

1 CONSIDERATION FROM THE INSTITUTION. THEY'RE ACTUALLY
2 PAYING THE INSTITUTION FOR TUITION.

3 DR. JENNINGS: YOUR KID IS A LIT MAJOR AT
4 BERKELEY AND BERKELEY APPLIES, IT'S A CONFLICT OF
5 INTEREST?

6 CHAIRMAN KLEIN: I THINK WE'RE OVERREACHING.

7 MR. TOCHER: YOU'RE CERTAINLY FREE TO MAKE
8 ANY AMENDMENTS HERE BECAUSE THIS IS THE LANGUAGE THAT
9 WE WILL PROPOSE TO OAL TO BEGIN THE NOTIFICATION
10 PROCESS.

11 CHAIRMAN KLEIN: DOCTOR, ARE YOU MAKING A
12 PROPOSAL TO AMEND THAT TO REMOVE THE STUDENT?

13 DR. JENNINGS: I WOULD SAY WHO IS A CURRENT
14 FACULTY MEMBER, SO THE STUDENT OR, I WOULD SUGGEST THAT
15 THE WORD "STUDENT OR" BE ELIMINATED FROM THAT TOP OF
16 PAGE 3.

17 CHAIRMAN KLEIN: IS THERE A SECOND TO THAT
18 MOTION?

19 DR. AZZIZ: SECOND.

20 CHAIRMAN KLEIN: DR. AZZIZ WILL SECOND IT.
21 IS THERE DISCUSSION TO THAT AMENDMENT OR TO THAT
22 MOTION?

23 DR. ROME: WHAT ABOUT EMPLOYEE?

24 MR. TOCHER: THAT'S ALREADY --

25 CHAIRMAN KLEIN: WHAT IS BEING SUGGESTED IS

1 THAT THE MOTION INCORPORATE A PROHIBITION OF AN
2 EMPLOYEE OR A FACULTY MEMBER. IS THAT A FRIENDLY
3 AMENDMENT YOU WOULD ACCEPT?

4 DR. POMEROY: THAT'S ALREADY IN HERE UNDER
5 F 1 OR MAYBE IT ISN'T.

6 CHAIRMAN KLEIN: THAT'S A DISCLOSURE ITEM.
7 WOULD THE PERSON MAKING THE MOTION BE WILLING TO ACCEPT
8 AN INSERTION OF THE WORD "EMPLOYEE" TO SUBSTITUTE FOR
9 THE WORD "STUDENT"?

10 DR. JENNINGS: SOME EMPLOYEES I THINK IT'S
11 RELEVANT, BUT MANY IT WOULD NOT BE, JANITORS AND PEOPLE
12 WORKING PHYSICAL PLANT AND SO ON. IT'S SIMPLY NOT A
13 RELEVANT EXCLUSION. THERE ARE EMPLOYEES HIGHER UP IN
14 THE MANAGEMENT WHERE IT WOULD BE A RELEVANT THING TO
15 DO. I DON'T KNOW IF YOU MAKE THE DISTINCTION HERE.

16 CHAIRMAN KLEIN: DR. PENHOET --

17 DR. JENNINGS: IT SAYS EMPLOYEES.

18 CHAIRMAN KLEIN: DR. PENHOET, WOULD YOU LIKE
19 TO COMMENT ON THIS?

20 DR. PENHOET: YOU KNOW, I THINK YOU START
21 SPLITTING HAIRS HERE. IT'S TOO HARD TO PARSE ALL
22 EMPLOYEES IN CATEGORIES FOR THIS PURPOSE. SO I DO
23 THINK PERSONALLY IF SOMEBODY HAS A FAMILY MEMBER WHO'S
24 AFFILIATED WITHIN AN INSTITUTION, RECEIVES
25 COMPENSATION, THEY MIGHT HAVE A BIAS, YOU KNOW,

1 FRANKLY, EVEN WITH STUDENTS. IF YOU'VE EVER RAISED
2 MONEY FOR A UNIVERSITY, AS MANY OF YOU HAVE, WHO DO YOU
3 GO TO? PARENTS OF STUDENTS. SO I'M HAPPY TO TAKE OUT
4 THE STUDENTS, BUT I THINK IF YOU START PARSING WHAT THE
5 DEFINITION OF EMPLOYEE IS --

6 MR. ROTH: I WAS GOING TO SUGGEST TAKE OUT
7 THE WORD "INSTITUTION." INSTEAD OF -- IF YOU TAKE THE
8 WORD "INSTITUTION" OUT, IF THEY HAVE A STUDENT OR A
9 FACULTY MEMBER OF THE APPLICANT, THEN THERE WOULD BE A
10 CONFLICT, NOT OF THE INSTITUTION, BUT OF THE APPLICANT,
11 I THINK THERE WOULD BE --

12 CHAIRMAN KLEIN: THIS IS FOR FACILITIES. SO
13 THE INSTITUTION IS THE -- OKAY. SO THE QUESTION, I
14 BELIEVE, TO DR. JENNINGS IS, AS THE MAKER OF THE
15 MOTION, WOULD YOU SUBSTITUTE THE WORD "EMPLOYEE" FOR
16 "STUDENT"?

17 DR. JENNINGS: NO.

18 MS. LANSING: I WOULD LEAVE THIS ALONE. I
19 THINK IN THE BEGINNING, I WOULD RATHER ERR ON THE SIDE
20 OF CAUTION. I WOULD RATHER BE REALLY STRICT. LET'S
21 SEE IF THIS CAUSES PROBLEMS. IF WE FIND THAT WE DON'T
22 HAVE ENOUGH PEOPLE TO VOTE ON THINGS, WE CAN ALWAYS
23 COME BACK AND ADJUST IT.

24 CHAIRMAN KLEIN: I WOULD ACTUALLY OBJECT TO
25 THAT ON THE THEORY THAT HAVING STUDENTS AT AN

1 INSTITUTION SHOULDN'T DISQUALIFY YOU FROM PARTICIPATING
2 AS LONG AS THEY'RE NOT SCHOLARSHIP STUDENTS.

3 DR. HENDERSON: WHAT IF THEY'RE POSTDOCTORAL
4 STUDENTS WORKING IN SOMEBODY'S LAB?

5 MS. LANSING: YOU'RE NOT GOING TO BE ABLE TO
6 PARSE IT. AND YOU DO, WHERE YOUR KID GOES TO SCHOOL,
7 YOU CHEER THEIR FOOTBALL TEAM ON, YOU CHEER THE SCHOOL
8 ON.

9 DR. STEWARD: IN FACT, JUST TO AMPLIFY THAT,
10 AGAIN, WHAT WE'RE LOOKING AT HERE IS AN EXCESS OF
11 CAUTION, WHICH IS ENTIRELY APPROPRIATE. LET'S SUPPOSE
12 THAT A STUDENT SUDDENLY GETS A VERY LUCRATIVE
13 SCHOLARSHIP. IT COULD BE IN ENGLISH FROM AN
14 INSTITUTION THAT WAS AN APPLICANT. IT'S THE APPEARANCE
15 OF POSSIBLE CONFLICT OF INTEREST. WHAT IF A STUDENT
16 GETS IN? I WOULD ACTUALLY EVEN ADD THE WORD "WHO IS A
17 CURRENT OR PENDING STUDENT." I'M SERIOUS. I'M
18 SERIOUS. JUST TO AVOID ANY APPEARANCE.

19 MS. LANSING: THAT'S A PROBLEM. THEN IT
20 WOULD BE EVERYONE IS A PENDING STUDENT.

21 CHAIRMAN KLEIN: OKAY. WE HAVE A MOTION
22 THAT'S PENDING TO ELIMINATE STUDENT AND LEAVE FACULTY
23 MEMBER. THE QUESTION IS WHAT DO THE MAKERS OF THE
24 MOTION WANT TO DO? DO WE PROCEED WITH A VOTE, OR DO WE
25 MODIFY IT? IT'S YOUR PLEASURE.

1 MR. ROTH: I MADE THE MOTION, I THINK, SO
2 I WILL NOT ACCEPT ANY AMENDMENTS. VOTE ON IT THE WAY
3 IT IS.

4 DR. STEWARD: THAT'S MY POINT. COULD YOU
5 JUST CLARIFY? THE WAY IT IS STATED HERE --

6 MR. ROTH: THE WAY IT IS STATED HERE, KEEP IT
7 THE WAY IT IS FOR NOW.

8 CHAIRMAN KLEIN: THE MOTION --

9 MR. HARRISON: JUST TO BE CLEAR. WE HAVE TWO
10 MOTIONS THAT WERE MADE, THE ORIGINAL MOTION AND THEN AN
11 AMENDMENT TO THE MOTION. WE HAVE TO VOTE ON THE
12 AMENDMENT FIRST UNLESS THE MOTION IS WITHDRAWN. THAT'S
13 TRUE. THE CURRENT AMENDMENT THAT IS NOW PENDING,
14 UNLESS IT'S TABLED OR WITHDRAWN, IS TO REMOVE THE WORD
15 "STUDENT OR" FROM THE REGULATION. SO THAT'S WHAT YOU
16 HAVE TO VOTE ON FIRST.

17 CHAIRMAN KLEIN: DR. JENNINGS MADE THE
18 PROPOSAL ON THE AMENDMENT. THAT'S WHY I WAS TRYING TO
19 FIND OUT WHAT HIS POSITION WAS.

20 DR. AZZIZ: JUST TO REMIND THE BOARD, THE
21 EMPLOYEE ISSUE HAS ACTUALLY NOT BEEN VOTED ON AT ALL.

22 MR. HARRISON: THAT'S CORRECT.

23 DR. AZZIZ: THAT HAS TO BE BROUGHT UP AS A
24 SEPARATE AMENDMENT.

25 MR. HARRISON: CORRECT.

1 CHAIRMAN KLEIN: DR. JENNINGS.

2 DR. JENNINGS: HEARING THE DISCUSSION, I
3 THINK I WILL WITHDRAW THE MOTION.

4 CHAIRMAN KLEIN: AND THE SECOND WITHDRAWS THE
5 MOTION?

6 DR. AZZIZ: YES. I'LL WITHDRAW THE MOTION
7 BECAUSE I PROPOSE ANOTHER MOTION.

8 CHAIRMAN KLEIN: ALL RIGHT. JAMES, SHOULD WE
9 SEE IF THERE'S ANOTHER AMENDMENT BEFORE WE ADDRESS THE
10 MOTION?

11 MR. HARRISON: YES.

12 CHAIRMAN KLEIN: THAT'S MY THOUGHT. ANOTHER
13 MOTION?

14 DR. AZZIZ: ANOTHER MOTION, AND THAT IS TO
15 ADD THE WORD "CURRENT EMPLOYEE, STUDENT, OR FACULTY
16 MEMBER." ADD THE WORD "EMPLOYEE."

17 CHAIRMAN KLEIN: OKAY. THAT'S A MOTION. IS
18 THERE A SECOND?

19 DR. PENHOET: SECOND.

20 CHAIRMAN KLEIN: SECOND. I THANK YOU. AND
21 SECOND WAS DR. PENHOET.

22 MR. SHEEHY: IT'S NOT CLEAR TO ME TO WHOM
23 THIS APPLIES. DOES THIS APPLY MERELY TO THE NON-ICOC
24 MEMBERS OF THE WORKING GROUP BECAUSE THAT'S NOT STATED
25 THAT CLEARLY IN THE LANGUAGE?

1 MR. TOCHER: THAT'S RIGHT. IT'S TO NON-ICOC
2 MEMBERS.

3 MR. SHEEHY: THAT MIGHT COLOR PEOPLE'S
4 THOUGHTS.

5 CHAIRMAN KLEIN: OKAY. WE HAVE AN AMENDMENT
6 THAT HAS A MOTION AND A SECOND. IS THERE FURTHER
7 DEBATE ON THAT AMENDMENT? IS THERE PUBLIC COMMENT ON
8 THE AMENDMENT?

9 MR. SIMPSON: I BELIEVE ON PAGE 2 ALREADY, I
10 DON'T KNOW THAT YOU NEED TO INSERT THE LANGUAGE.
11 DOESN'T THAT TALK ABOUT A MEMBER OR HIS --

12 DR. AZZIZ: THAT'S ACTUALLY DISCLOSURE.

13 CHAIRMAN KLEIN: OKAY. ANY ADDITIONAL PUBLIC
14 COMMENT? SEEING NONE, CALL THE QUESTION. ALL IN
15 FAVOR? LET THE RECORD SHOW THAT -- ARE THERE ANY
16 OPPOSED? LET THE RECORD SHOW THAT IT WAS PASSED
17 UNANIMOUSLY AS AN AMENDMENT.

18 NOW WE GO TO THE MOTION. WOULD YOU LIKE TO
19 RESTATE THE MOTION?

20 MR. ROTH: MOTION IS TO APPROVE THE POLICY AS
21 AMENDED WITH THE WORD "EMPLOYEE."

22 CHAIRMAN KLEIN: OKAY. AND THERE IS A SECOND
23 FOR THIS MOTION THAT IS PENDING. ANY ADDITIONAL
24 DISCUSSION? ANY PUBLIC DISCUSSION? SEEING NONE, I
25 CALL THE QUESTION. ALL IN FAVOR? OPPOSED? LET THE

1 RECORD SHOW IT PASSED UNANIMOUSLY WITH NONE OPPOSED.

2 THANK YOU. ALL RIGHT. DR. HALL, I THINK
3 THAT NUMBER -- WE NEED VOTES ON 10 AS WELL. LET'S TRY.
4 DR. HALL, DO YOU THINK NO. 10 IS A QUICK ITEM?

5 DR. HALL: SCOTT IS GOING TO HANDLE THAT. WE
6 HOPE SO.

7 MR. TOCHER: ITEM 10 IS FINAL ADOPTION OF THE
8 GRANTS ADMINISTRATION POLICY. THIS IS THE POLICY
9 STATEMENT THAT APPLIES TO ALL CIRM APPLICANTS AND
10 GRANTEES FROM ACADEMIC AND NONPROFIT INSTITUTIONS. BY
11 ACCEPTING A CIRM GRANT AWARD, THE GRANTEE AGREES TO
12 COMPLY WITH THE PROVISIONS OF THIS POLICY FOR THE
13 ENTIRE PROJECT PERIOD OF THE GRANT.

14 WE HAVE CONCLUDED THE PUBLIC COMMENT PERIOD,
15 AND YOU APPROVED THIS BACK IN JUNE TO NOTICE IT WITH
16 OAL. AND WE DID THAT, AND THERE HAVE BEEN A HANDFUL OF
17 COMMENTS. THEY BE HAVE BEEN HELPFUL, BUT MINOR IN
18 NATURE, DEALING REALLY JUST WITH A COUPLE OF ISSUES OF
19 THE DEFINITION OF HUMAN EMBRYONIC STEM CELLS, SOME
20 ELIGIBILITY REQUIREMENTS, AND PROCEDURES REGARDING
21 COMPLIANCE WITH THE HANDLING OF BIOHAZARDOUS MATERIALS.
22 OTHER THAN THAT, THE POLICY COMES BACK TO YOU VIRTUALLY
23 UNCHANGED. AND WITH YOUR APPROVAL, WE WILL TAKE THIS
24 TO OAL FOR THE FINAL 30-DAY REVIEW BEFORE IT BECOMES AN
25 OFFICIAL REGULATION.

1 CHAIRMAN KLEIN: ALL RIGHT. IS THERE A
2 MOTION ON THIS ITEM SO WE CAN DISCUSS IT?
3 DR. STEWARD: SO MOVED.
4 CHAIRMAN KLEIN: MOVED BY DR. OS STEWARD.
5 SECOND?
6 DR. ROME: SECOND.
7 CHAIRMAN KLEIN: SECOND BY DR. ROME. IS
8 THERE A DISCUSSION BY THE BOARD? SEEING NONE --
9 DR. POMEROY: JUST ONE QUICK QUESTION WHICH I
10 NEVER THOUGHT OF BEFORE. DOES THIS APPLY TO FOR-PROFIT
11 ACADEMIC INSTITUTIONS? FOR-PROFIT ACADEMIC
12 INSTITUTION.
13 DR. HALL: IT'S NONPROFIT RESEARCH
14 INSTITUTIONS.
15 DR. POMEROY: SO IT'S NOT FOR -- SO IT HAS TO
16 BE FOR NONPROFIT ACADEMIC.
17 DR. HALL: WE WILL HAVE A SEPARATE GRANTS
18 ADMINISTRATION POLICY FOR FOR-PROFIT INSTITUTIONS.
19 DR. POMEROY: FOR-PROFIT ACADEMIC
20 INSTITUTIONS?
21 CHAIRMAN KLEIN: FOR-PROFIT ACADEMIC
22 INSTITUTIONS?
23 DR. POMEROY: THAT WAS THE QUESTION.
24 CHAIRMAN KLEIN: FOR-PROFIT ACADEMIC
25 INSTITUTIONS.

1 DR. POMEROY: THEY DO EXIST.

2 DR. HALL: SUCH AS UNIVERSITY OF PHOENIX?

3 DR. POMEROY: YES. I JUST THINK IT NEEDS TO
4 BE CLARIFIED OF WHERE THEY FALL.

5 DR. HALL: WE HAVE NOT FACED THAT PROBLEM
6 BEFORE.

7 DR. POMEROY: I KNOW. IT NEVER OCCURRED TO
8 ME BEFORE.

9 DR. HALL: IS THERE SUCH AN INSTITUTION IN
10 CALIFORNIA THAT IS A POTENTIAL CLIENT? DO WE KNOW OF
11 AN INSTITUTION? WE DO HAVE A LIST OF THE INDEPENDENT
12 INSTITUTIONS? I HAVEN'T SEEN ANYTHING THAT QUALIFIED.

13 DR. POMEROY: IF IT'S NOT PERTINENT, I ACCEPT
14 THAT.

15 CHAIRMAN KLEIN: ALL RIGHT. ANY OTHER PUBLIC
16 COMMENT? JAMES, ARE WE IN ORDER, AND DO WE HAVE A
17 QUORUM?

18 MR. HARRISON: I BELIEVE WE'RE ONE SHY AT
19 THIS TIME.

20 CHAIRMAN KLEIN: WE HAVE DR. BERNIE LO, WHO
21 HAS BEEN KIND ENOUGH TO TRAVEL DOWN HERE, I THINK, FOR
22 THE NEXT ITEM, NO. 12, BUT WE NEED A QUORUM FOR THIS
23 VOTE AND THE NEXT ITEM.

24 SO CALL THE QUESTION. ALL IN FAVOR?
25 OPPOSED? WE ARE GOOD, ACCORDING TO OUR COUNSEL. LET

1 THE RECORD SHOW EVERYONE WHO WAS PRESENT HERE VOTED
2 YES, AND THERE WERE NO OPPOSED, AND WE HAD A QUORUM.

3 DR. LO, IF YOU COULD ADDRESS THIS GROUP.
4 THANK YOU SO MUCH FOR COMING DOWN HERE AND YOUR
5 TREMENDOUS SERVICE IN THE MEDICAL AND ETHICAL
6 STANDARDS.

7 DR. LO: IT'S MY PLEASURE TO COME DOWN HERE.
8 I FIRST JUST WANT TO THANK THE ICOC. AS YOU KNOW, THE
9 MES REGULATIONS WERE APPROVED AND ARE NOW IN EFFECT AS
10 OF NOVEMBER, END OF NOVEMBER.

11 I COME HERE TODAY, IF SOMEONE COULD SWITCH ON
12 THE LCD, WITH THREE ITEMS THAT NEED TO BE TAKEN CARE OF
13 THAT WERE LEFT OVER FROM THE MATERIALS APPROVED BY THE
14 OAL. THESE ITEMS HAVE TO DO WITH, FIRST, USE OF FETAL
15 TISSUE FOR CIRM-FUNDED RESEARCH; SECONDLY, SOME CHANGES
16 TO THE SECTION ON RECORDKEEPING IN THE REGULATION; AND,
17 THIRD, SOME CHANGES IN THE SECTION ON MATERIALS
18 SHARING.

19 I'LL START WITH THE FETAL TISSUE SECTION.
20 THERE SHOULD BE SOME SLIDES COMING UP. LET ME FIRST
21 SAY THAT THESE ARE REGULATIONS WHICH WE'D LIKE YOU TO
22 AUTHORIZE TO BEGIN THE OAL ADOPTION PROCESS. CURRENTLY
23 WE HAVE INTERIM REGULATIONS, AND WE ALSO WOULD LIKE YOU
24 IN A SEPARATE ACTION TO APPROVE AN EXTENSION BY
25 EMERGENCY ADOPTION OF THOSE EXISTING INTERIM

1 REGULATIONS. THIS WOULD COVER THE POSSIBILITY THAT A
2 CIRM-FUNDED TRAINEE OR SOMEONE IN THE CURRENT ROUND OF
3 APPLICATIONS FOR CIRM FUNDING IS PROPOSING TO USE
4 FETALLY DERIVED STEM CELLS.

5 THIS IS SECTION 100085. WE REALLY ARE NOT
6 PROPOSING ANY CHANGES OTHER THAN MINOR WORDING CHANGES
7 IN THE INTERIM REGULATIONS. I WOULD LIKE TO REMIND YOU
8 THAT THESE INTERIM REGULATIONS ARE BASED ON AND
9 CONSISTENT WITH FEDERAL POLICY WHICH REQUIRES SEVERAL
10 CONSIDERATIONS TO BE FOLLOWED. FIRST, THAT THERE MAY
11 BE NO DIRECTED DONATION OF FETAL TISSUE FOR
12 TRANSPLANTATION. SECONDLY, THAT THE DECISION BY THE
13 WOMAN WHO'S PREGNANT TO TERMINATE PREGNANCY MUST BE
14 MADE PRIOR TO ANY DECISION TO DONATE. THIS IS AN
15 ATTEMPT TO SEPARATE THOSE TWO DECISIONS. THE PRINCIPAL
16 INVESTIGATOR IN THE RESEARCH PROJECT ON THE INTERIM
17 REGULATIONS MAY NOT BE INVOLVED IN THE DECISION TO
18 TERMINATE PREGNANCY UNLESS SO CERTIFIED. ALSO THERE'S
19 A BAN ON PAYMENT FOR FETAL TISSUE FOR CIRM-FUNDED
20 RESEARCH. THAT'S IN A SEPARATE SECTION. I JUST WANT
21 TO MAKE SURE THAT YOU REALIZE THAT THAT IS NOT
22 SOMETHING THAT WAS OMITTED.

23 SO THE REGULATIONS WE'RE PROPOSING ACTUALLY
24 PUT THIS INTO REGULATORY LANGUAGE FOR CIRM-FUNDED
25 RESEARCH.

1 WE MADE ONLY MINOR WORDING CHANGES IN THE
2 INTERIM REGULATIONS THAT YOU PASSED ON 4/4/06. THESE
3 WERE -- THERE ARE NO OBJECTIONS IN PUBLIC COMMENT IN A
4 WORKING GROUP MEETING OF THE SWG. THE SENSE OF THAT
5 MEETING NOVEMBER 23D WAS TO RECOMMEND THE ICOC APPROVE
6 LANGUAGE FOR FINAL REGULATIONS.

7 SO THE NEXT SLIDE WE'RE ASKING FOR TWO ACTION
8 ITEMS. FIRST, TO AUTHORIZE EXTENSION OF THE EXISTING
9 INTERIM REGULATIONS TO COVER -- TO AVOID A POSSIBLE GAP
10 IN REGULATIONS. SO WE WOULD BE GRATEFUL IF SOMEONE
11 COULD MOVE THAT, THE ICOC WOULD APPROVE THAT.

12 SECONDLY, WE'RE ASKING FOR THE ICOC TO
13 CONSIDER APPROVAL OF THE LANGUAGE IN YOUR BRIEFING
14 BOOKS TO INITIATE THE OAL ADOPTION PROCESS. SO DO YOU
15 WANT, MR. PRESIDENT --

16 CHAIRMAN KLEIN: LET'S DEAL WITH THESE ONE AT
17 A TIME. SO THE FIRST REQUEST IS TO AUTHORIZE EXTENSION
18 BY EMERGENCY ADOPTION OF EXISTING INTERIM REGULATIONS.
19 IS ANYONE PREPARED TO MAKE A MOTION?

20 MS. LANSING: I AM.

21 CHAIRMAN KLEIN: IS THERE A SECOND?

22 DR. AZZIZ: SECOND.

23 CHAIRMAN KLEIN: DR. AZZIZ. IS THERE
24 DISCUSSION? IS THERE PUBLIC DISCUSSION? CALL THE
25 QUESTION. ALL IN FAVOR? OPPOSED? ALL RIGHT. THE

1 MOTION PASSES WITHOUT OPPOSITION.

2 JAMES, WE HAVE A QUORUM, CORRECT?

3 MR. HARRISON: WE DO.

4 CHAIRMAN KLEIN: NEXT ITEM.

5 DR. LO: IF YOU COULD FLIP TO THE PREVIOUS

6 SLIDE, WE WOULD LIKE YOU TO AUTHORIZE APPROVAL OF THE

7 LANGUAGE IN YOUR BRIEFING BOOK FOR SECTION 100085 TO BE

8 SUBMITTED TO THE OAL TO INITIATE THE REGULATORY

9 PROCESS.

10 DR. POMEROY: SO MOVED.

11 MS. LANSING: SECOND.

12 CHAIRMAN KLEIN: DR. KESSLER JUST WALKED OUT.

13 THESE ARE ITEMS THAT HAVE BEEN GREATLY DEBATED.

14 MR. HARRISON: WE ACTUALLY HAVE 19 WITHOUT

15 HIM, I BELIEVE.

16 MS. LANSING: YOU CAN LEAVE. WE WERE WRONG.

17 CHAIRMAN KLEIN: FOR THE PUBLIC, PLEASE BRING

18 ANY ITEM UP. THE BOARD HAS HAD THE ADVANTAGE OF

19 DEBATING THESE IN GREAT DETAIL BEFORE, SO WE CAN MOVE

20 QUICKLY ITEMS THAT HAVE HAD THOUGHTFUL CONSIDERATION

21 BEFORE. BUT ON THE PUBLIC SIDE, PLEASE, IF YOU HAVE

22 ANY ITEM, PLEASE BRING IT UP. OKAY. SO, DR. LO, COULD

23 YOU STATE YOUR REQUEST?

24 DR. LO: OUR REQUEST IS THAT THE ICOC ADOPT

25 THE PROPOSED LANGUAGE FOR 100085 AND THAT WE SUBMIT

1 THAT TO OAL FOR FORMAL APPROVAL AS REGULATION.

2 CHAIRMAN KLEIN: SHERRY LANSING HAS MADE THAT
3 MOTION, AND THE SECOND IS DR. AZZIZ. IT'S THE
4 OPPOSITE. DR. POMEROY WITH DR. LANSING.

5 MS. LANSING: I WISH I WAS A DOCTOR, BUT MS.
6 LANSING.

7 CHAIRMAN KLEIN: TODAY YOU ARE. TODAY YOU
8 ARE. OKAY.

9 SO ANY ADDITIONAL DISCUSSION BY THE BOARD?
10 ANY DISCUSSION BY THE PUBLIC? PLEASE, IF YOU HAVE
11 ANYTHING HERE, THE BOARD HAS HAD A CHANCE TO REALLY
12 LOOK AT THESE ITEMS. OKAY. SEEING NONE, CALL THE
13 QUESTION. ALL IN FAVOR? OPPOSED? RECORD WILL SHOW
14 THAT THE BOARD VOTED UNANIMOUSLY WITH NO OPPOSITION AND
15 THERE WAS A QUORUM PRESENT. DR. LO.

16 DR. LO: THANK YOU. I'LL TRY AND BE AS BRIEF
17 AS POSSIBLE. NEXT SLIDE, THE SECOND SET OF REGULATIONS
18 WE'D LIKE YOU TO CONSIDER ARE SECTION 100120, WHICH HAS
19 TO DO WITH RECORDKEEPING. WHEN WE SUBMITTED TO OAL,
20 THEY IDENTIFIED A NUMBER OF PROBLEMS WITH THE LANGUAGE
21 THAT WAS APPROVED BY ICOC ON 8/2/06 AND DECLINED TO
22 APPROVE THAT LANGUAGE.

23 SECTION 100120 WAS WITHDRAWN FROM THE
24 REGULATORY PROCESS TO ALLOW THE ADOPTION OF THE OTHER
25 SECTIONS TO PROCEED. AND AS I SAID, THOSE HAVE BEEN

1 APPROVED AS OF NOVEMBER 22D.

2 WE HAVE REVISED THE LANGUAGE IN SWG, AND WE
3 POSTED FOR AN ADDITIONAL 15 DAYS OF PUBLIC COMMENT AS
4 THE REGULATIONS REQUIRE.

5 WHAT WE WOULD LIKE TO DO NOW IS FOR YOU TO
6 CONSIDER FOR YOUR APPROVAL THE REVISED 100120, WHICH IS
7 IN YOUR BRIEFING BOOK, SO THAT WE CAN RESUBMIT TO OAL
8 FOR FINAL ADOPTION.

9 CHAIRMAN KLEIN: COULD YOU, FOR THE BENEFIT
10 OF THE PUBLIC AND OTHER MEMBERS HERE, EVEN THOUGH THE
11 MATERIALS ARE IN THE BACK OF THE ROOM, SUMMARIZE THE
12 EFFECT OF THAT SECTION?

13 DR. LO: YES. THIS SECTION REQUIRES
14 RECORDKEEPING BY THE GRANTEE'S INSTITUTION. A NUMBER
15 OF ITEMS WERE DELETED BECAUSE THE OAL THOUGHT THAT, FOR
16 INSTANCE, THE TERM "MATERIALS" WAS UNDEFINED. THEY
17 DIDN'T KNOW WHETHER THAT INCLUDED DERIVATIVES OR NOT OR
18 WHATEVER. ANOTHER ITEM, E, WAS THOUGHT TO BE
19 REDUNDANT. IT MERELY SAID THEY HAVE TO COMPLY WITH
20 OTHER ADDITIONAL REQUIREMENTS. WE DO WANT TO RETAIN
21 THE ITEM THAT EVERY GAMETE, SOMATIC CELL, OR EMBRYO
22 DONATED, OR ANY PRODUCT OF SCNT, THERE MUST BE A RECORD
23 OF THAT TO DETERMINE WHETHER THOSE MATERIALS COMPLY
24 WITH THE OTHER REGULATIONS. TO MAKE THIS OPERATIONAL,
25 THESE RECORDS MUST BE MADE AVAILABLE AT CIRM'S REQUEST.

1 SO WE'RE SAYING THE INSTITUTION MUST KEEP THOSE RECORDS
2 AND THAT THEY MUST BE MADE AVAILABLE TO CIRM UPON
3 REQUEST OF CIRM.

4 CHAIRMAN KLEIN: IS THERE A MOTION?

5 DR. POMEROY: SO MOVED.

6 CHAIRMAN KLEIN: BY DR. CLAIRE POMEROY.

7 DR. BRYANT: SECOND.

8 CHAIRMAN KLEIN: SECOND BY DR. SUSAN BRYANT.

9 IS THERE A DISCUSSION BY THE BOARD? IS THERE
10 DISCUSSION BY THE PUBLIC? SEEING NO DISCUSSION BY THE
11 PUBLIC, CALL THE QUESTION. ALL IN FAVOR? OPPOSED?
12 LET THE RECORD SHOW IT PASSED UNANIMOUSLY AT THE BOARD
13 AND A QUORUM WAS PRESENT. THERE WAS NO OPPOSITION.

14 DR. LO, HAVE YOU COMPLETED YOUR ITEM?

15 DR. LO: A FINAL ISSUE WE'D LIKE TO BRING TO
16 YOU IS THE SECTION ON MATERIALS SHARING, WHICH IS
17 SECTION 100130, AND I UNDERSTAND WE HAVE SOME TECHNICAL
18 PROBLEMS. WE'RE TRYING TO GET THIS UP ON THE SCREEN
19 FOR YOU.

20 CHAIRMAN KLEIN: CAN YOU REPEAT THE SECTION
21 AGAIN, PLEASE?

22 DR. LO: 100130 ON MATERIALS SHARING. IT'S
23 NOT IN YOUR BINDER. I UNDERSTAND. I APOLOGIZE FOR
24 THAT. THE OAL IDENTIFIED PROBLEMS WITH THE LANGUAGE
25 THE ICOC APPROVED LAST AUGUST, AND THAT SECTION WAS

1 ALSO WITHDRAWN TO ALLOW THE REST OF THE REGULATIONS TO
2 GO THROUGH THE REGULATORY PROCESS.

3 NOW, SINCE THEN, OF COURSE, AS YOU DISCUSSED
4 THIS MORNING, THERE ARE EXTENSIVE CIRM POLICIES FOR
5 BOTH NONPROFIT AND FOR-PROFIT IP POLICIES. AND WE
6 BELIEVE ON THE SWG THAT THOSE POLICIES, WHICH ARE VERY
7 DETAILED AND VERY THOUGHTFUL AND RECEIVED GREAT
8 SCRUTINY FROM THE ICOC, REALLY MAKE THE SECTION THAT
9 WAS ORIGINALLY PROPOSED BY SWG FOR THE MES STANDARDS TO
10 BE UNNECESSARY.

11 SO WHAT WE'VE DONE IS STRUCK THROUGH THE
12 ENTIRE SECTION WHICH YOU HAD APPROVED BACK IN AUGUST ON
13 THE GROUNDS THAT NOT ONLY WAS IT FELT BY OAL TO CONTAIN
14 SOME LANGUAGE PROBLEMS, BUT ALSO THAT IT'S REALLY BEEN
15 NOW SUPERSEDED BY THE IP POLICIES FOR BOTH FOR-PROFIT
16 AND NONPROFIT INSTITUTIONS. SO WE'D LIKE YOU TO
17 WITHDRAW THAT SECTION FROM THE MES REGULATIONS.

18 DR. HENDERSON: SO MOVED.

19 MR. ROTH: SECOND.

20 CHAIRMAN KLEIN: MOVED BY DR. HENDERSON AND
21 SECONDED BY DUANE ROTH. BOARD DISCUSSION? PUBLIC
22 DISCUSSION? DON'T HOLD BACK ON THIS DELETION. SEEING
23 NONE, CALL THE QUESTION. ALL IN FAVOR? OPPOSED? I
24 WANT A CONFIRMATION WE HAVE A QUORUM.

25 MR. HARRISON: WE DO.

1 CHAIRMAN KLEIN: THANK YOU. WE'D LIKE TO
2 MOVE TO THE LAST ITEM. DR. LO, THANK YOU SO MUCH FOR
3 YOUR TREMENDOUS SERVICE.

4 (APPLAUSE.)

5 CHAIRMAN KLEIN: THE ITEM IS 14. DR. SHERRY
6 LANSING, AN HONORARY DOCTORATE OF CALIFORNIA INSTITUTE
7 OF REGENERATIVE MEDICINE.

8 MS. LANSING: IF WE ALL JUST STAY, I THINK,
9 MAYBE FOR 20 MINUTES, WE CAN GET THIS DONE. THE
10 GOVERNANCE SUBCOMMITTEE -- WE'LL TRY TO DO THIS FAST,
11 BUT NOT TOO FAST IF YOU HAVE QUESTIONS -- MET THIS PAST
12 MONDAY, DECEMBER 4TH, AND WE HAD A TERRIFIC MEETING,
13 AND WE DISCUSSED A NUMBER OF ITEMS WHICH WE'RE GOING TO
14 PRESENT TO YOU FOR YOUR REVIEW.

15 AND THE FIRST ITEM FOR YOUR CONSIDERATION IS
16 THE CIRM BUDGET FOR THE CURRENT FISCAL YEAR 2006 AND
17 2007. AND WE HAD TO REVISE THE BUDGET, AS ALL OF YOU
18 KNOW, IN ORDER TO REFLECT THE GOOD NEWS, THE INCREASE
19 IN AVAILABLE FUNDING DUE TO THE CLOSING OF THE SECOND
20 ROUND OF 31 MILLION IN BOND ANTICIPATION NOTES AND THE
21 \$150 MILLION APPROVED BY OUR INCREDIBLE GOVERNOR. SO
22 THIS IS ALL GOOD NEWS WHY WE'RE ADJUSTING THE BUDGET.

23 NOW LORI HOFFMAN, WHO'S OUR NEW CHIEF
24 FINANCIAL AND ADMINISTRATIVE OFFICER, IS GOING TO
25 PRESENT TO YOU THE HIGHLIGHTS OF THIS AMENDED BUDGET,

1 WHICH WE IN THE GOVERNANCE COMMITTEE VOTED TO APPROVE.

2 MS. HOFFMAN: THANK YOU. WELL, IN THE
3 INTEREST OF TIME, I WILL BE BRIEFER THAN USUAL. SO
4 ALLOW ME TO BEGIN BY SAYING THAT -- NOT THAT QUICK.
5 ALLOW ME TO SAY THAT, JUST FOR A FRAME OF REFERENCE,
6 THE BOARD DID APPROVE THE AUGUST '06 BUDGET. SO WITH
7 THAT, LET ME SHOW YOU -- NEXT SLIDE, PLEASE -- ALL THAT
8 HAS BEEN ACCOMPLISHED SINCE THAT TIME, WHICH INCLUDES
9 NEW STAFFING HERE AT CIRM AS WELL AS THOSE ISSUES THAT
10 YOU'VE HEARD TODAY AS WELL.

11 BUT WE HAVE MUCH TO STILL ACCOMPLISH. WE
12 HAVE ADDED SOME GOALS WHICH ALSO INCLUDES THE HIRING OF
13 THE CHIEF LEGAL COUNSEL AS WELL AS CO-SPONSORING OF AN
14 ONLINE PUBLICATION, WHICH YOU DISCUSSED EARLIER TODAY.

15 THIS IS AN EFFORT TO -- CAN YOU ALL SEE THAT?
16 THIS IS OUR EFFORT TO SHOW THE SOURCES OF FUNDS
17 AVAILABLE TO US. IT INCLUDES 3 PERCENT FOR GENERAL
18 ADMINISTRATION AND 3 PERCENT FOR GRANTS ADMINISTRATION
19 ON THE FIRST BAN'S, ON THE SECOND BAN'S, AND ON THE
20 \$150 MILLION OF GENERAL FUND LOAN MONEY. IT ALSO
21 INCLUDES A SUBTRACTION OR A REPAYMENT OF THE GENERAL
22 FUND LOAN START-UP FUNDS THAT WE COULD REPAY THIS YEAR
23 IF THERE WAS AVAILABLE CASH FLOW OR NOT. BUT ASSUME
24 THAT WE DO PAY IT BACK THIS YEAR, THIS FISCAL YEAR, WE
25 WILL HAVE \$11.7 MILLION.

1 IN ADDITION TO THAT, WE'VE HAD NUMEROUS
2 GENEROUS GIFTS. THE GIFTS LISTED HERE ARE ALL THOSE
3 THAT WE HAVE RECEIVED. WE STILL HAVE OUTSTANDING
4 COMMITMENTS OF \$330,000. SO WE HAVE A TOTAL CURRENTLY
5 OF \$17.22716 MILLION.

6 THIS IS OUR USES OF FUNDS FROM INCEPTION TO
7 DATE. SO IT INCLUDES THE THREE FISCAL YEARS, AND
8 CERTAINLY THE THIRD IS THE CURRENT ONE THAT WE'RE IN,
9 THE EXPENDITURES FOR THE BEGINNING PART OF THIS FISCAL
10 YEAR, AS WELL AS THE BUDGETED AMOUNTS FOR THE REMAINDER
11 OF THIS FISCAL YEAR. IF THIS BUDGET IS APPROVED, THE
12 BALANCE AVAILABLE FOR '07-'08 WOULD BE THE \$2.8
13 MILLION.

14 NOW, IN ADDITION, THE CHAIR HAS STATED
15 EARLIER TODAY THAT BECAUSE OF THE AUTHORIZATION FROM
16 THE FINANCE COMMITTEE OF \$250 MILLION, ASSUMING A 3
17 PERCENT, 3 PERCENT IS AVAILABLE TO US FOR GENERAL AND
18 GRANT ADMINISTRATION, THERE IS AN ADDITIONAL \$3.3
19 MILLION THAT WE COULD USE IN '07-'08.

20 CHAIRMAN KLEIN: LORI, TO BE CLEAR FOR
21 EVERYONE, INCLUDING THE AUDIENCE, IT'S THE 3 PERCENT
22 AND 3 PERCENT ON THE ADDITIONAL \$55 MILLION IN THAT
23 AUTHORIZATION?

24 MS. HOFFMAN: THAT'S CORRECT. THE \$3.3
25 MILLION DOES NOT REPRESENT 3 PERCENT AND 3 PERCENT OF

1 THE TWO FIFTY, BUT THE \$55 MILLION. SO WE'VE ALREADY
2 ASSUMED IN THE FIRST TABLE THE SOURCES OF FUNDS, THE
3 195 MILLION, WHICH IS THE TWO BAN'S, AND THE \$150
4 MILLION OF GENERAL FUND MONEY. THANK YOU.

5 SO, FIRST, YOU'LL SEE A LINE ITEM, THE
6 SALARIES AND BENEFITS. I DO WANT TO POINT OUT THAT
7 THERE IS A LIABILITY HERE ON THE BENEFITS SIDE THAT WE
8 WILL SEE IN THE COMING YEARS THAT HAS TO DO WITH THE
9 CALPERS RETIREMENT SYSTEM. AND CERTAINLY, WHEN I
10 PRESENT '07-'08'S BUDGET TO YOU AT THE END OF THIS
11 FISCAL YEAR, WE CAN GO INTO DETAIL ON THAT.

12 NEXT, THIS NEXT PIECE IS THE INTERAGENCY
13 AGREEMENTS AS WELL AS THE EXTERNAL CONTRACTS. AT THE
14 GOVERNANCE SUBCOMMITTEE, THERE WERE SEVERAL QUESTIONS
15 REGARDING THIS. LET ME JUST SAY IN GENERAL THAT THIS
16 REPRESENTS THE FUNDS TO DATE WE HAVE PAID AND EXPECT TO
17 PAY TO REMCHO AS WELL AS TO THE DEPARTMENT OF JUSTICE
18 AS WELL AS TO THE STATE CONTROLLER'S OFFICE. IN YOUR
19 AUGUST '06 BUDGET, THERE WAS A DEFERRED PAYMENT FOR
20 THOSE THREE. SO THIS BUDGET ASSUMES ALL OF THOSE
21 PAYMENTS WILL BE MADE.

22 THIS IS A CUMULATIVE TOTAL OF \$1.19 MILLION,
23 WHICH REPRESENTS ALL THE MEETINGS FOR THE FISCAL YEAR
24 FOR THE ICOC, THE SUBCOMMITTEES, AS WELL AS THE WORKING
25 GROUPS.

1 THIS SLICE OF THE BUDGET REPRESENTS THOSE
2 EXPENSES RELATED TO IN-HOUSE IN TERMS OF OUR OWN TRAVEL
3 AT CIRM AS WELL AS FURNISHINGS AND OTHER.

4 SO NOW WE HAVE A SUBTOTAL OF -- A TOTAL
5 BUDGET OF \$8.3 MILLION, AND THEN WE'RE GOING TO
6 SUBTRACT OUT, AS PROVIDED FOR IN PROPOSITION 71, THAT
7 LEGAL COSTS CAN BE -- LEGAL COST ATTRIBUTED TO -- I'M
8 JUST GOING TO READ FROM THE PROPOSITION. LEGAL COSTS
9 OF THE INSTITUTE INCURRED TO NEGOTIATE STANDARDS WITH
10 FEDERAL AND STATE GOVERNMENTS AND RESEARCH INSTITUTIONS
11 TO IMPLEMENT STANDARDS OR REGULATIONS TO RESOLVE
12 DISPUTES OR CARRY OUT ALL OTHER ACTIONS NECESSARY TO
13 DEFEND AND/OR ADVANCE THE INSTITUTE'S MISSION SHALL BE
14 CONSIDERED A DIRECT RESEARCH FUNDING COST. THEREFORE,
15 WE'RE TAKING IT AS A BALLOON OFF THE ADMINISTRATIVE
16 BUDGET FOR THEN THE TOTAL OF \$7.25 MILLION.

17 AND WITH THAT, I OPEN IT UP FOR ANY
18 QUESTIONS.

19 MS. LANSING: IS THERE ANY BOARD COMMENT ON
20 THE AMENDED BUDGET? PUBLIC COMMENT ON THE AMENDED
21 BUDGET? IS THERE A MOTION, THEN, TO APPROVE THIS
22 BUDGET?

23 DR. HENDERSON: SO MOVED.

24 DR. WRIGHT: SECOND.

25 MS. LANSING: IS THERE DISCUSSION ON THE

1 MOTION? ALL IN FAVOR.

2 CHAIRMAN KLEIN: PUBLIC COMMENT.

3 MS. LANSING: PUBLIC COMMENT? ALL IN FAVOR?

4 CHAIRMAN KLEIN: LET IT BE KNOWN IN THIS

5 GROUP THAT THE MEN'S ROOM IS NOT A SAFE PLACE TO ESCAPE

6 WORK.

7 SO THERE'S A MOTION ON THE FLOOR AND A SECOND

8 TO APPROVE THE AMENDED BUDGET.

9 DR. PENHOET: FORTUNATELY I STUDIED IT

10 BEFOREHAND SO I CAN MAKE AN INFORMED VOTE.

11 MS. LANSING: ALL IN FAVOR? ANY OPPOSED?

12 OKAY. THE MOTION CARRIES.

13 CHAIRMAN KLEIN: AND THEN VERY QUICKLY, LORI,

14 WOULD YOU LIKE TO ADDRESS ITEM A AND C, WHICH I THINK

15 ARE BEST PRACTICES THAT WE'VE ALL STUDIED BEFORE? ARE

16 WE LOSING OUR QUORUM HERE?

17 MS. KING: AS SOON AS DR. AZZIZ RETURNS,

18 WHICH HE WILL, WE'LL BE FINE.

19 CHAIRMAN KLEIN: JAMES, WOULD YOU ADVISE US

20 ON WHAT WE NEED FOR A QUORUM?

21 MR. HARRISON: JUST DR. AZZIZ.

22 CHAIRMAN KLEIN: LORI, WOULD YOU PROCEED?

23 MS. LANSING: AS WE WENT THROUGH OUR OWN

24 WORK, WE SAW WAYS THAT WE COULD IMPROVE SOME OF OUR

25 POLICY ON TRAVEL AND CONTRACTING. AND SO I'D LIKE TO

1 ASK LORI TO SHOW YOU HOW WE CAN IMPROVE SOME OF OUR
2 PRACTICES. AND IT'S JUST AN EXAMPLE OF HOW WE'RE
3 CONSTANTLY WORKING ON DOING EVEN BETTER.

4 MS. HOFFMAN: I'LL ACTUALLY JUST GO RIGHT TO
5 THE POLICIES. HOW'S THAT? LET'S JUST GO RIGHT TO IT.

6 SO I'LL TAKE 14 A, WHICH IS THE CONSIDERATION
7 OF PROPOSED AMENDMENTS TO THE POLICY ON CONTRACTING AND
8 SERVICES OF INDEPENDENT CONSULTANTS. THE PRESIDENT AND
9 THE GOVERNANCE SUBCOMMITTEE RECOMMENDS TO THE ICOC FOR
10 APPROVAL THE POLICIES AS ATTACHED ON THIS ITEM AND
11 LABELED ATTACHMENT 1.

12 AS PROVIDED FOR IN PROP 71, SPECIFICALLY THE
13 HEALTH AND SAFETY CODE, THE INSTITUTE SHALL BE GOVERNED
14 BY THE COMPETITIVE BIDDING REQUIREMENTS APPLICABLE TO
15 THE UNIVERSITY OF CALIFORNIA SET FORTH IN ARTICLE 1,
16 ETC. THEREFORE, WHAT WE'VE DONE HERE IS TAKEN THE
17 CONTRACTING POLICIES FROM THE UNIVERSITY OF CALIFORNIA
18 AS THEY ARE NOTED IN BUSINESS AND FINANCE PUBLICATION
19 34 AND MODIFIED THEM TO CIRM'S NEEDS.

20 THERE ARE A FEW MAJOR PROCEDURAL CHANGES. I
21 WILL NOTE THE FIRST. IT'S THE THRESHOLD FOR
22 SOLICITATION. OUR CURRENT PRACTICES AND POLICIES STATE
23 THAT CONTRACTS WITH INDEPENDENT CONTRACTORS AND
24 CONSULTANTS ARE NOT REQUIRED TO BE COMPETITIVELY BID;
25 HOWEVER, IF THE SERVICES WILL BE NEEDED FOR AN EXTENDED

1 PERIOD OF TIME, BIDDING SHOULD BE CONSIDERED. WE HAVE
2 STRENGTHENED THAT AND, IN FACT, FOLLOWED UC POLICY.
3 ANYTHING ABOVE \$15,000 WILL BE COMPETITIVELY BID.

4 THE NEXT IS THE APPROVAL LEVELS FOR
5 CONTRACTING AND INDEPENDENT CONSULTING SERVICES. THIS
6 IS ACTUALLY NOT A CHANGE REQUIRED CERTAINLY UNDER
7 BUSINESS AND FINANCE PUBLICATION 34. THIS IS A
8 CURRENTLY ADOPTED POLICY AS OF JULY 5TH, 2005, WITH THE
9 THRESHOLD LEVELS FOR APPROVAL. AND ANYTHING 100,000
10 AND LESS IS PRESIDENTIAL. ONE HUNDRED THOUSAND TO 250
11 IS THE GOVERNANCE SUBCOMMITTEE, AND ANYTHING ABOVE 250
12 IS ICOC.

13 WE ARE REQUESTING AN INCREASED DELEGATION OF
14 AUTHORITY FROM ZERO TO 250,000 FOR THE PRESIDENT, 250
15 TO 500 FOR THE GOVERNANCE SUBCOMMITTEE, AND THEN THE
16 ICOC WILL SEE ANYTHING OVER 500,000.

17 CHAIRMAN KLEIN: IS THIS A SEPARATE ITEM FROM
18 A?

19 MS. HOFFMAN: THIS IS 14 A.

20 CHAIRMAN KLEIN: THIS IS PART OF THE
21 CONTRACTING?

22 MS. LANSING: THIS IS THE CONTRACTING.

23 MS. HOFFMAN: THAT'S CORRECT. AND THEN THE
24 LAST MAJOR CHANGE IS THE REPORTING REQUIREMENTS. AND
25 YOU WILL NOTE THAT THE CHANGE THAT WE ARE MAKING IT TO,

1 AS STATED ON PAGE 11, I HAVE CHANGED IT HERE AFTER
2 DISCUSSION AND THEN APPROVAL AND RECOMMENDATION TO THE
3 ICO FROM THE GOVERNANCE SUBCOMMITTEE. SO WE HAD
4 ORIGINALLY SUGGESTED THAT THERE BE QUARTERLY REPORTS TO
5 THE GOVERNANCE SUBCOMMITTEE, AND THE SUBCOMMITTEE HAS
6 DECIDED THAT A REPORT AT EACH OF THEIR MEETINGS WILL BE
7 PROVIDED, AND THEN THERE WILL BE AN ANNUAL REPORT TO
8 THE ICOC. SO WITH THAT --

9 MS. LANSING: IS THERE ANY BOARD COMMENT ON
10 THE POLICY FOR CONTRACTING? IS THERE ANY PUBLIC
11 COMMENT ON THIS POLICY?

12 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR
13 TAXPAYER RIGHTS. WE WERE AT THE COMMITTEE MEETING, AND
14 WE THINK THESE ARE ALL WONDERFUL IMPROVEMENTS IN THE
15 POLICY AND WE COMMEND THEIR PASSAGE.

16 MS. LANSING: GREAT. IS THERE A MOTION TO
17 APPROVE THIS POLICY?

18 DR. FRIEDMAN: SO MOVED.

19 DR. ROME: SECOND.

20 CHAIRMAN KLEIN: DO WE WANT TO STATE HERE WHO
21 MADE THE MOTION?

22 MS. KING: DR. FRIEDMAN MADE THE MOTION AND
23 DR. ROME WAS THE SECOND.

24 MS. LANSING: OKAY. ANY MORE COMMENT? THEN
25 ALL IN FAVOR? ANY OPPOSED? THE MOTION PASSES.

1 NOW I THINK WE NEED TO GO TO, AM I RIGHT, TO
2 THE TRAVEL POLICY AMENDMENTS. AND, AGAIN, I JUST WANT
3 TO STATE THAT ALL OF THESE WERE LOOKED AT BY THE
4 GOVERNANCE COMMITTEE, AND THAT'S WHY WE'RE BRINGING
5 THEM TO YOU BECAUSE WE RECOMMEND THEM.

6 MS. KING: ITEM 14 C.

7 MS. HOFFMAN: I BRING 14 C AND D TO YOU. THE
8 BACKGROUND FOR 14 C AND D ARE THE SAME. AS YOU CAN SEE
9 WITHOUT ME GOING INTO THE TWO PAGES OF BACKGROUND, THE
10 ICOC HAS SPENT AN INORDINATE AMOUNT OF TIME DISCUSSING
11 TRAVEL POLICY. BUT, AGAIN, WE BELIEVE THAT IN TERMS OF
12 A BEST PRACTICE, THE UC POLICY IS AVAILABLE TO US AND
13 SO, THEREFORE, WE HAVE TAKEN THE UC TRAVEL POLICY,
14 ADOPTED IT FOR CIRM STAFF AND WORKING GROUP MEMBERS
15 ONLY. SO WHAT WE ARE PROPOSING TODAY IS NOT A CHANGE
16 TO THE POLICIES THAT YOU'VE BEEN DELIBERATING OVER THE
17 LAST YEAR AND A HALF. IN FACT, THOSE WILL REMAIN IN
18 PLACE FOR ICOC MEMBERS. SO THIS POLICY IS FOR CIRM
19 STAFF AND WORKING GROUP MEMBERS ONLY.

20 AND I WILL SAY THAT FOR THE MOST PART IT
21 CLARIFIES AMBIGUITIES AND STRENGTHENS AND GIVES A
22 CLEARER PROCESS AND PROCEDURE FOR REIMBURSEMENT FOR
23 CIRM STAFF AND WORKING GROUP MEMBERS, THAT WE WOULD
24 LIKE TO TAKE THIS POLICY AND IMPLEMENT THE PROCEDURES.

25 SO WITH THAT, I WILL TURN TO THE

1 RECOMMENDATIONS AND THERE ARE TWO HERE. SO I THINK,
2 AND I WILL DEFER TO LEGAL COUNSEL, BUT THE FIRST WOULD
3 BE THE APPROVAL AND ADOPTION OF THE POLICIES AND
4 PROCEDURES GOVERNING TRAVEL FOR CIRM STAFF AND WORKING
5 GROUP MEMBERS AS SEEN IN ATTACHMENT 1. ANY QUESTIONS?

6 DR. POMEROY: MOVE APPROVAL.

7 MS. LANSING: OKAY. THERE'S NO BOARD
8 COMMENT. IS THERE ANY PUBLIC COMMENT ON THIS?

9 IS THERE A MOTION TO APPROVE THIS TRAVEL
10 POLICY?

11 DR. POMEROY: YES.

12 DR. AZZIZ: SECOND.

13 MS. LANSING: IS THERE ANY DISCUSSION ON THIS
14 MOTION? ANY PUBLIC DISCUSSION? OKAY. ALL IN FAVOR?
15 ANY OPPOSED? MOTION CARRIES.

16 MS. HOFFMAN: THE NEXT IS 14 D, AND I WILL
17 READ THE RECOMMENDATION AND THEN SPEAK TO IT BRIEFLY.
18 WE ARE SEEKING THE DELEGATION OF AUTHORITY FOR THE
19 POLICY AND PROCEDURES GOVERNING TRAVEL FOR CIRM STAFF
20 AND WORKING GROUP MEMBERS TO THE GOVERNANCE
21 SUBCOMMITTEE. WHAT WE HAVE ALSO DONE AND PROVIDED IN
22 YOUR BINDER AT THE FOLLOWING TAB, REFERENCED AGENDA
23 14 D, IS THE ICOC GOVERNANCE SUBCOMMITTEE MISSION
24 STATEMENT. WHAT WE WOULD PROPOSE TO DO IS TO BRING
25 BACK TO YOU AT YOUR FEBRUARY MEETING STANDING ORDERS

1 FOR THE GOVERNANCE SUBCOMMITTEE, WHICH INCLUDES THE
2 MISSION STATEMENT AS WELL AS THE BEGINNINGS OF THE
3 DELEGATIONS OF AUTHORITY SO THAT THE BOARD, IN EFFECT,
4 IS ACTING IN ITS GOVERNANCE ROLE, AND THE GOVERNANCE
5 SUBCOMMITTEE IS FLUSHING OUT THE DISCUSSIONS AND THE
6 ISSUES BEFORE WE GET TO THE BOARD.

7 SO, AGAIN, THIS DELEGATION OF AUTHORITY IS
8 ONLY FOR THE POLICY THAT YOU HAVE JUST ADOPTED, AND
9 THAT POLICY IS ONLY RELATED TO CIRM STAFF AND WORKING
10 GROUP MEMBERS. IS THERE ANY DISCUSSION, ANY QUESTIONS?

11 CHAIRMAN KLEIN: I THINK I MADE THE
12 SUGGESTION WE DELEGATE TO THE GOVERNANCE SUBCOMMITTEE
13 IN ORDER TO FOCUS THE BOARD AGENDA ON THE MOST
14 SUBSTANTIVE MATERIAL, GIVING MORE TIME FOR
15 CONSIDERATION TO THE SUBSTANTIVE POLICY ISSUES WHERE
16 THE WHOLE BOARD'S INPUT WAS NEEDED. CERTAINLY THE
17 GOVERNANCE SUBCOMMITTEE THOROUGHLY LOOKS AT EACH OF
18 THESE ISSUES, SO I'D LIKE TO MAKE A MOTION TO APPROVE
19 THIS ITEM.

20 MS. LANSING: SECOND?

21 DR. HENDERSON: SECOND.

22 MS. LANSING: ANY BOARD COMMENT?

23 DR. POMEROY: SHERRY, I THINK AT THE
24 GOVERNANCE SUBCOMMITTEE, WE DECIDED TO -- WE APPROVED
25 CHANGING CHAIR TO CHAIRPERSON THROUGHOUT THIS DOCUMENT.

1 AND THAT DOESN'T SEEM TO HAVE SHOWN UP HERE.

2 MS. LANSING: PLEASE DO THAT. CHAIRPERSON.

3 MS. HOFFMAN: IT WILL SHOW UP IN THE FEBRUARY
4 ITEM.

5 MS. LANSING: CHAIRPERSON. POLITICALLY
6 CORRECT. ANY OTHER DISCUSSION FROM THE BOARD? ANY
7 PUBLIC COMMENT? ALL IN FAVOR? ALL OPPOSED? MOTION
8 PASSES.

9 JUST ONE LAST ITEM FOR POINT OF INFORMATION.
10 I THINK WE'VE TALKED ABOUT THIS. WE DISCUSSED A FUTURE
11 PLAN THAT WE'RE GOING TO BE LOOKING AT TO PROVIDE
12 POSSIBLY SOME ADMINISTRATIVE HELP FOR THE PATIENT
13 ADVOCATES WHO, AS WE HAVE ACKNOWLEDGED, ARE ON MORE
14 COMMITTEES, AND IT'S BECOME AN INCREDIBLY CHALLENGING
15 SITUATION. SO WE DON'T HAVE A RECOMMENDATION AT THE
16 MOMENT. ZACH IS GOING TO BE WORKING WITH THE PATIENT
17 ADVOCATES AND WITH COUNSEL AND IS GOING TO COME BACK TO
18 ALL OF US AT THE GOVERNANCE COMMITTEE WITH A PROPOSAL.
19 AND WHEN WE FEEL GOOD ABOUT IT, WE'RE GOING TO COME TO
20 YOU, BUT PLEASE KNOW, ALL OF THE PATIENT ADVOCATES,
21 THAT WE ARE ADDRESSING THIS ISSUE WITH THE DEEPEST
22 CONCERN AND VERY, VERY SERIOUSLY.

23 DR. HALL: JUST TO SAY THAT I WILL BE
24 CONTACTING EACH OF YOU. SEVERAL OF YOU I'VE SPOKEN TO
25 YOU ALREADY. BUT JUST TO DO A SURVEY OF WHAT YOUR

1 NEEDS ARE AND HOW WE MIGHT BE ABLE TO HELP MEET THEM.
2 AND THEN WE WILL ON THAT BASIS, AS SUGGESTED BY THE
3 SUBCOMMITTEE, MAKE AN ASSESSMENT OF WHAT IS NEEDED AND
4 THEN TRY TO PLAN FOR HELPING OUT. SO WE ARE, ALONG
5 WITH THE SUBCOMMITTEE, VERY CONCERNED ABOUT THIS ISSUE
6 AND WANT TO DO WHAT WE CAN TO HELP.

7 MS. LANSING: OKAY. ARE THERE ANY OTHER
8 COMMENTS? WITH THAT, THANK YOU VERY MUCH FOR STAYING.

9 CHAIRMAN KLEIN: OKAY. WE HAVE SOME
10 ADDITIONAL ITEMS ON THE AGENDA, BUT DO NOT NEED ACTION
11 ON ITEMS ON 17, WE DO NOT NEED ACTION ON ITEM 18. WE
12 DO NOT NEED ACTION ON NO. 19, AS SHERRY LANSING HAS
13 JUST SAID, NOR DO WE NEED ACTION ON ITEM 20, BUT PUBLIC
14 COMMENT. I'D LIKE TO REINVITE THE PUBLIC, IF THERE'S
15 ANY ITEM THAT THEY FEEL THEY DIDN'T GET A CHANCE TO
16 COMMENT ON, I'D LIKE TO INVITE YOU TO COMMENT BECAUSE
17 YOU'VE HAD SOME MORE TIME TO THINK ABOUT IT. WE WANT
18 TO MAKE SURE THAT WE DON'T OVERLOOK ANY PUBLIC COMMENTS
19 IN THIS SESSION. IS THERE ANY OTHER PUBLIC COMMENT?
20 WE HAVE TWO PUBLIC COMMENTS. FIRST SUSAN AND THEN
21 JOHN.

22 MS. FOGEL: I WANT TO RAISE AN ISSUE THAT I'M
23 HOPING YOU WILL CONSIDER PERHAPS AT A FUTURE MEETING OR
24 THROUGH ONE OF THE COMMITTEES OR PROCESSES. AND THAT
25 IS THE ISSUE OF KIND OF STATEWIDE DATA COLLECTION AND

1 MONITORING. WE SUBMITTED COMMENTS TO THE MEDICAL AND
2 ETHICAL STANDARDS REGULATIONS, REQUESTING SOME DATA
3 COLLECTION, FOR EXAMPLE, HEALTH OUTCOMES FOR WOMEN WHO
4 PROVIDE EGGS FOR RESEARCH, SOME REALLY CLEAR COLLECTION
5 OF DATA, SOME OF WHICH IS NOW ON THE PRIVATE SIDE
6 REQUIRED UNDER SB 1260, BUT, OF COURSE, ISN'T REQUIRED
7 BY CIRM. WE WERE TOLD AT THAT POINT IT WASN'T
8 APPROPRIATE FOR THE MEDICAL AND ETHICAL STANDARDS, BUT
9 IT WOULD BE DEALT WITH IN THE GRANTS. WELL, IT WASN'T
10 DEALT WITH IN THE GRANTS EITHER.

11 WE'RE REALLY CONCERNED THAT EVEN THE
12 RECORDKEEPING YOU APPROVED TODAY, IT'S AT THE REQUEST
13 OF CIRM. AND WE KNOW THAT CIRM IS GOING TO HAVE
14 LIMITED STAFF AND LIMITED FUNDING FOR OVERSIGHT AND
15 MONITORING. AND WE REALLY ENCOURAGE YOU TO CREATE SOME
16 KIND OF MECHANISM FOR REPORTING THAT WILL BE FOR YOUR
17 USE, BUT ALSO PUBLICLY AVAILABLE, SO YOU CAN BE REALLY
18 TRACKING IN A COMPREHENSIVE, AGGREGATE WAY WHAT'S
19 HAPPENING AT THE GROUND AS THESE RESEARCH PROJECTS MOVE
20 FORWARD.

21 CHAIRMAN KLEIN: THANK YOU, SUSAN. AND I
22 WOULD ALSO SAY -- WE NEED TO HEAR FROM DR. HALL FOR A
23 MOMENT -- LIKE TO SAY THAT FOR THOSE OF YOU WHO DO NOT
24 HAVE A PLANE, LORI HOFFMAN HAS SOME SLIDES ON ITEM 20,
25 EVEN THOUGH WE DON'T HAVE A VOTE. IT'S SOME VERY

1 INFORMATIVE INFORMATION ON ALLOCATION OF FUNDS FOR
2 GRANT MAKING. SO WE HAVE DR. HALL AND THEN JOHN
3 SIMPSON.

4 DR. HALL: JUST TO SAY THAT AS PART OF THE
5 STRATEGIC PLAN, SUSAN, WE ENVISAGE FUNDING LONG-TERM
6 FOLLOW-UP STUDIES. I THINK MICHAEL FRIEDMAN SUGGESTED
7 THE IMPORTANCE OF THIS AT OUR LAST MEETING, AND WE
8 EXPECT TO BE MAKING GRANTS FOR THAT.

9 CHAIRMAN KLEIN: MR. SIMPSON.

10 MR. SIMPSON: TWO POINTS. NO. 1, I THINK
11 PROBABLY MOST OF YOU KNOW THAT OUR FOUNDATION HAS
12 CHALLENGED THE WARF PATENTS, AND THAT THE PTO HAS, IN
13 FACT, ORDERED THAT THEY BE REEXAMINED. I WOULD SUGGEST
14 TO THE CHAIRMAN THAT PERHAPS HE AGENDIZE FOR THE NEXT
15 MEETING A RESOLUTION IN SUPPORT OF THAT CHALLENGE AND
16 SUPPORTING THE NOTION THAT THE PATENTS BE REEXAMINED
17 AND THAT BE ON THE AGENDA.

18 THE SECOND THING I WANTED TO SAY WAS THAT
19 IT'S BEEN EXACTLY A YEAR, I THINK, SINCE I'VE BEEN
20 COMING TO THESE MEETINGS AS PART OF OUR PROJECT. AND
21 WHILE WE SOMETIMES HAVE DIFFERENCES OF OPINION ABOUT
22 THINGS, I'VE ALWAYS TRIED TO BE A CONSTRUCTIVE CRITIC.
23 AND I HAVE, INDEED, APPRECIATED THE RESPONSIVENESS ON
24 THE PART OF ALL THE CIRM STAFF AND ALSO THE MEMBERS OF
25 THE BOARD. AND I ALSO REALIZE THAT THIS IS SOMETHING

1 OF A HISTORIC TIME. THE MONEY IS ACTUALLY FINALLY
2 GOING OUT THE DOOR. WE'RE ALL TREMENDOUSLY EXCITED
3 ABOUT THAT. AND WE ALL, AS I SAID, WE SOMETIMES COME
4 AT THINGS FROM A DIFFERENT POINT OF VIEW. I WANT TO
5 THANK ALL OF YOU FOR THE TREMENDOUS DEVOTION TO THIS
6 PROJECT THAT YOU'VE PUT FORTH, AND I DON'T THINK MOST
7 PEOPLE REALIZE THAT. I DO BECAUSE I'VE BEEN TO ALL OF
8 THESE MEETINGS. SO I JUST WANT TO THANK YOU FOR THAT.

9 THE OTHER THING I WANT TO TELL YOU IS THAT
10 CIRM ISN'T THE ONLY THING THAT GETS FUNDED. OUR
11 PROJECT HAS GOTTEN ANOTHER YEAR'S WORTH OF FUNDING FROM
12 THE NATHAN CUMMINGS FOUNDATION, SO WE'LL CONTINUE TO
13 HAVE OUR DIALOGUES OVER THE NEXT YEAR. THANK YOU VERY
14 MUCH.

15 (APPLAUSE.)

16 CHAIRMAN KLEIN: JOHN, DOES THAT MEAN THAT
17 CIRM GETS A VERY HIGH GRADE FOR BEING RESPONSIVE TO THE
18 PUBLIC CONCERNS YOU'VE PUT ON THE TABLE IN THE LAST
19 YEAR?

20 MR. SIMPSON: I WOULD SAY I WOULD APPRECIATE
21 THE MANY THINGS THAT YOU HAVE DONE, BUT THERE'S ALWAYS
22 SOMETHING MORE TO REACH FOR.

23 CHAIRMAN KLEIN: GREAT. PROGRESS IS OUR MOST
24 IMPORTANT PRODUCT.

25 MS. LANSING: LET ME JUST SAY THAT ACTUALLY,

1 JOHN, YOU ARE A JOY TO WORK WITH. JOHN HAS BEEN AT ALL
2 OF OUR GOVERNANCE COMMITTEES, AND I FIND YOUR INPUT
3 EXTREMELY HELPFUL, THOUGHTFUL.

4 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND,
5 LORI HOFFMAN, YOU HAVE SOME SLIDES TO EDUCATE US ON THE
6 FUNDS AVAILABLE FOR GRANT MAKING.

7 MS. HOFFMAN: AT THE REQUEST OF THE BOARD AND
8 THE PRESIDENT, I PRESENT TO YOU THE CALCULATIONS FOR
9 THE ALLOCATION OF FUNDS AVAILABLE FOR RESEARCH,
10 RESEARCH FACILITIES, GENERAL ADMINISTRATION, GRANT
11 ADMINISTRATION, AND OTHER AUTHORIZED EXPENSES OF THE
12 INSTITUTE AS PROVIDED FOR IN PROP 71. I DO NOT PRESENT
13 THESE FIGURES TO YOU TODAY AS A PRODUCT OF MY OWN WORK.
14 THIS PRESENTATION IS A RESULT OF SEVERAL DISCUSSIONS, A
15 LEGAL ANALYSIS, AND CONSENSUS BY THE PRESIDENT, THE
16 CHAIR, AND THE VICE CHAIR, AS WELL AS OUTSIDE COUNSEL.

17 CIRM IS AUTHORIZED TO SELL BONDS IN THE TOTAL
18 AMOUNT OF \$3 BILLION. AS PROVIDED FOR IN PROP 71, NO
19 MORE THAN 3 PERCENT OF THE PROCEEDS OF THE BONDS
20 AUTHORIZED SHALL BE USED FOR THE INSTITUTE'S GENERAL
21 ADMINISTRATION, WHICH INCLUDES GENERAL OPERATIONS AND
22 RELATED PERSONNEL.

23 AS THE BOARD MAY RECALL, THE INSTITUTE'S
24 OPERATING COSTS ARE GREATLY REDUCED BY THE HEADQUARTERS
25 PACKAGE PROVIDED BY THE CITY OF SAN FRANCISCO WITH A

1 TOTAL VALUE OF OVER \$18 MILLION OVER THE NEXT TEN
2 YEARS.

3 NO MORE THAN 3 PERCENT OF THE TOTAL
4 AUTHORIZED \$3 BILLION SHALL BE USED FOR THE INSTITUTE'S
5 GRANT ADMINISTRATION COSTS, WHICH INCLUDES DEVELOPMENT,
6 OVERSIGHT, AND ADMINISTRATION OF THE GRANT-MAKING
7 PROCESS, OPERATION OF THE GRANTS AND FACILITIES WORKING
8 GROUP, AS WELL AS RELATED PERSONNEL COSTS.

9 SO THESE TWO LINES REPRESENT \$180 MILLION
10 AVERAGED OVER THE LIFE OF THE INSTITUTE. AND AS I
11 DISCUSSED IN MY EARLIER PRESENTATION ON THE BUDGET,
12 CIRM HAS RECEIVED MANY GENEROUS GIFTS TO SUPPLEMENT THE
13 FUNDS MADE AVAILABLE FOR ADMINISTRATION THROUGH PROP 71
14 THAT ARE NOT REPRESENTED HERE.

15 NEXT, THE CALCULATION OF BOND ISSUANCE COSTS,
16 THESE COSTS ARE CONSERVATIVELY ESTIMATED AT .08 PERCENT
17 BASED ON CURRENT COSTS AS PROVIDED BY BOND CONSULTANTS
18 TO THE STATE OF CALIFORNIA. BOND ISSUANCE COSTS
19 INCLUDE LEGAL, UNDERWRITING, ACCOUNTING, COMMISSION,
20 AND REGISTRATION EXPENSES INCURRED IN PREPARING AND
21 SELLING THE BOND ISSUE.

22 NEXT, WE HAVE ESTIMATED THE CAPITALIZED
23 INTEREST COSTS OF UP TO \$52 MILLION. THIS IS BASED ON
24 THE ASSUMPTION THAT CIRM WILL BE ABLE TO ISSUE BONDS AT
25 THE END OF THE 2007 CALENDAR YEAR. PER PROP 71,

1 INTEREST COSTS FOR CIRM BONDS SHALL BE CAPITALIZED FOR
2 THE FIRST FIVE CALENDAR YEARS AFTER THE PROPOSITION
3 TOOK EFFECT. THE INSTITUTE HAS PROJECTED THESE COSTS
4 UNTIL THE END OF 2009, AT WHICH TIME INTEREST COSTS
5 WILL BE PAID FOR FROM THE GENERAL -- FROM THE STATE
6 GENERAL FUND. INTEREST COSTS HAVE ALREADY BEGUN ON THE
7 BAN'S AND THE \$150 MILLION GENERAL FUND LOAN.

8 PLEASE NOTE THAT ANY NET SAVINGS OR INTEREST
9 EARNED ON THE BONDS THAT IS NOT CALCULATED IN THIS
10 NUMBER WILL RESULT IN AN INCREASE IN PROGRAM FUNDS.

11 CHAIRMAN KLEIN: AND ON THIS ITEM, IT WOULD
12 BE OUR GOAL TO CUT THIS ITEM IN HALF, WHICH WOULD GIVE
13 US ANOTHER 26 MILLION. AND IF WE CAN, IN FACT, DO A
14 LITTLE BIT BETTER THAN THAT, WE COULD HAVE POTENTIALLY
15 30 MILLION OR MORE FOR PROGRAMS THAT OTHERWISE ARE
16 GOING TO BE EATEN UP BY CAPITALIZED INTEREST.

17 MS. HOFFMAN: CURRENTLY PROJECTING THAT UP TO
18 \$52 MILLION NEEDS TO BE AVAILABLE FOR CAPITALIZED
19 INTEREST COSTS, WE NOW HAVE \$2.744 BILLION AVAILABLE
20 FOR GRANT MAKING.

21 NEXT SLIDE IS UP TO 10 PERCENT OF THE AMOUNT
22 AVAILABLE FOR GRANTS MAY BE USED FOR RESEARCH
23 FACILITIES GRANTS. SO WE HAVE \$274.4 MILLION FOR THE
24 RESEARCH FACILITY GRANTS. AND AT LEAST 90 PERCENT OF
25 THE GRANTS AVAILABLE FOR -- AT LEAST 90 PERCENT OF THE

1 AMOUNT AVAILABLE FOR GRANTS MUST BE USED FOR RESEARCH
2 GRANTS.

3 AND AS I IDENTIFIED IN MY EARLIER
4 PRESENTATION, LEGAL COSTS OF THE INSTITUTE WILL REDUCE
5 THIS AMOUNT AT UP TO A \$3 MILLION NUMBER.

6 AND WITH THAT --

7 CHAIRMAN KLEIN: ALL RIGHT. I'D LIKE TO
8 POINT OUT TO THE BOARD THAT THERE'S AN INTERNAL
9 DISCIPLINE BUILT INTO PROP 71 SUCH THAT EVERY TIME WE
10 ISSUE BONDS, WE HAVE TO RECONCILE TO NO MORE THAN THE
11 2, 3-PERCENT PORTIONS OUT OF THOSE BONDS. SO WE HAVE
12 KIND OF A TRUING-UP TEST EVERY TIME WE ISSUE BONDS.

13 NOW, AT THE TIME WE ISSUE BONDS, WE CAN
14 SEPARATELY HAVE OTHER PROGRAMS THAT ARE NOT READY TO
15 ISSUE BONDS, SO WE HAVE COMMERCIAL PAPER OUTSTANDING,
16 BUT WE ALWAYS HAVE TO REMEMBER THAT WE'RE GOING TO BE
17 FACED WITH THIS DISCIPLINE WHEN WE DO ISSUE BONDS ON
18 THE PROGRAM OF MAKING SURE THAT WE LIVE WITHIN THE 2,
19 3-PERCENT TEST. THAT INTERNAL DISCIPLINE PROTECTS THE
20 LONG-TERM OPERATING BUDGET OF THE AGENCY AND ASSURES
21 THE PUBLIC THAT WE'RE LIVING PURSUANT TO THE
22 INITIATIVE.

23 ARE THERE ANY OTHER QUESTIONS FOR LORI?

24 MS. HOFFMAN: THANK YOU.

25 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND

1 LORI HOFFMAN IS A TREMENDOUS ADDITION TO THE STAFF, A
2 GREAT ASSET. AND WE THANK THE UC PRESIDENT'S OFFICE
3 FOR GIVING UP SUCH A WONDERFUL PERSON TO HELP GUIDE OUR
4 FUTURE.

5 I THINK THAT WE HAVE CONCLUDED THE DAY EXCEPT
6 IF THERE'S ANY OTHER PUBLIC COMMENT ON THIS ITEM.
7 SEEING NO PUBLIC COMMENT, I WOULD THANK YOU. AND I
8 DEEPLY APPRECIATE, AGAIN, THE COMMITMENT OF THE BOARD
9 IN MAKING THIS MIRACLE CONTINUE TO HAPPEN.

10 (APPLAUSE.)

11 CHAIRMAN KLEIN: WE STAND ADJOURNED.

12 (THE MEETING WAS THEN ADJOURNED AT 03:18
13 P.M.)

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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

UCI UNIVERSITY CLUB
UNIVERSITY OF CALIFORNIA, IRVINE
801 E. PELTASON DRIVE
IRVINE, CALIFORNIA
ON
DECEMBER 7, 2006

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

BETH C. DRAIN, CSR 7152
BARRISTER'S REPORTING SERVICE
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