

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: MOSCONE CENTER SOUTH
747 HOWARD STREET
ROOM 304
SAN FRANCISCO, CALIFORNIA

DATE: WEDNESDAY, NOVEMBER 2, 2005
9: 52 A. M.

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

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1 SAN FRANCISCO, CALIFORNIA; WEDNESDAY, NOVEMBER 02, 2005

2 09:52 A.M.

3

4 CHAIRMAN KLEIN: IF WE COULD COME TO ORDER
5 HERE. SOUND WOULD BE BENEFICIAL. WE'RE IN A POSITION,
6 I BELIEVE, WHERE WE CAN START OUR AGENDA. I'D LIKE
7 TO -- ALL RIGHT. CAN EVERYONE HEAR? WE'RE GETTING AN
8 ECHO EVIDENTLY. ONE OF ME IS ENOUGH; TWO IS FAR TOO
9 MUCH. OKAY.

10 I'D LIKE TO THANK THE MEMBERS OF THE BOARD
11 AND MEMBERS OF THE PUBLIC FOR COMING TOGETHER ON THIS
12 HISTORIC OCCASION, THE ANNIVERSARY OF THE PASSAGE OF
13 PROPOSITION 71, AND ASSURE THE PUBLIC THAT IN SOME 50
14 PUBLIC MEETINGS WE'VE HAD SINCE THE PASSAGE OF THIS, WE
15 HAVE DONE EVERYTHING POSSIBLE TO ACHIEVE GREATER
16 TRANSPARENCY THAN PROMISED IN THE INITIATIVE, GREATER
17 TRANSPARENCY THAN HAS EVER EXISTED IN THE HISTORY OF
18 CALIFORNIA IN THE STARTUP OF A NEW AGENCY OF THE STATE.
19 AND ASSURE YOU THAT WE ARE COMMITTED TO FULFILL THE
20 MANDATE TO THE PUBLIC RESPONSIBLY, WITH FULL
21 ACCOUNTABILITY FOR THE VERY EARLIEST POSSIBLE TIME.

22 BEFORE GOING INTO OUR AGENDA, WE HAVE SPECIAL
23 THANKS TO THE HIV/AIDS SPOTLIGHT ORGANIZED BY JEFF
24 SHEEHY, A MEMBER OF OUR BOARD AND A GREAT ADVOCATE FOR
25 STEM CELL RESEARCH. JEFF HAS BEEN A CRITICAL MOVING

1 FORCE IN THE ADVOCACY COMMUNITY OF SAN FRANCISCO THAT
2 HAS LED MANY OF THE CLINICAL THERAPIES IN HIV/AIDS OVER
3 THE LAST 25 YEARS. BUT IT IS IMPORTANT TO REALIZE THAT
4 THE PRESENTATIONS TODAY BY DAVID BALTIMORE, WHO HAS AN
5 EXTRAORDINARY CAREER BEFORE OBTAINING HIS RECENT GLOBAL
6 CHALLENGE GRANT FROM THE GATES FOUNDATION FOR AIDS
7 RESEARCH, HAS MADE TREMENDOUS STRIDES IN BREAKING OUT
8 OF THE PAST THINKING PATTERNS AND STARTING ON A NEW
9 THEORY OF HOW WE CAN ADVANCE HIV/AIDS THERAPIES. AND
10 HE WAS JOINED THIS MORNING FROM UCLA BY JERRY ZACK,
11 DR. JERRY ZACK, AND DR. RON MITSUYASU. I WOULD LIKE TO
12 POINT OUT, AS DR. BALTIMORE DID THIS MORNING, THAT ALL
13 THREE OF THOSE SPEAKERS ARE FROM LOS ANGELES. SO I
14 THINK WE NEED TO SAY THANK YOU CAL TECH, THANK YOU
15 UCLA, THANK YOU L. A. L. A. IS PROVIDING TREMENDOUS
16 LEADERSHIP IN THE HIV/AIDS AREA.

17 WE'D ALSO LIKE TO THANK STAFF MEMBERS AMY
18 DALY AND ERIN ROBBINS FOR PULLING TOGETHER AS A SUPPORT
19 FUNCTION TO JEFF SHEEHY THIS TREMENDOUS SPOTLIGHT.
20 THANK YOU, JEFF.

21 (APPLAUSE.)

22 CHAIRMAN KLEIN: I'D LIKE TO MENTION THAT
23 THREE TO MY RIGHT IS MARCY FEIT, OUR NEWEST ICOC BOARD
24 MEMBER, ATTENDING HER FIRST MEETING. MARCY IS AN
25 INDIVIDUAL WHO HAS GONE THROUGH VERTICALLY THE ENTIRE

1 STRUCTURE OF HOSPITAL CARE DELIVERY IN CALIFORNIA,
2 STARTING OUT IN THE SURGICAL DEPARTMENT AND BECOMING
3 THE CEO OF VALLEY CARE HOSPITAL, A LEADING NONPROFIT
4 HOSPITAL IN THE TRI VALLEY AREA OF NORTHERN CALIFORNIA.
5 MARCY HAS SOME DISTINGUISHED PROGRAMS IN DIABETES THAT
6 SHE'S INTRODUCED IN HER HOSPITAL, AND SHE HAS SOME
7 EXTRAORDINARY PROGRAMS IN DEALING WITH CLINICAL PROGRAM
8 SPONSORSHIP IN THE STATE OF GEORGIA, A FORMER MEMBER OF
9 THE U. S. S. R. MARCY, I THINK, WILL BRING GREAT NEW
10 INSIGHTS FOR US TO THIS BOARD, AND I'D LIKE A ROUND OF
11 APPLAUSE FOR MARCY FEIT.

12 (APPLAUSE.)

13 CHAIRMAN KLEIN: MELISSA KING, IF YOU COULD
14 PLEASE GO THROUGH THE ROLL CALL.

15 MS. KING: DAVID BALTIMORE.

16 DR. BALTIMORE: HERE.

17 MS. KING: BOB PRICE FOR ROBERT BIRGENEAU.

18 DR. PRICE: HERE.

19 MS. KING: KEITH BLACK.

20 DR. BLACK: HERE.

21 MS. KING: SUSAN BRYANT.

22 DR. BRYANT: HERE.

23 MS. KING: MARCY FEIT.

24 DR. FEIT: HERE.

25 MS. KING: MICHAEL FRIEDMAN.

1 DR. FRIEDMAN: HERE.

2 MS. KING: MICHAEL GOLDBERG. BRIAN
3 HENDERSON.

4 DR. HENDERSON: HERE. ED HOLMES. DAVID
5 KESSLER.

6 DR. KESSLER: HERE.

7 MS. KING: BOB KLEIN.

8 CHAIRMAN KLEIN: HERE.

9 MS. KING: SHERRY LANSING.

10 MS. LANSING: HERE.

11 MS. KING: GERALD LEVEY. TED LOVE.

12 DR. LOVE: HERE.

13 MS. KING: RICHARD MURPHY.

14 DR. MURPHY: HERE.

15 MS. KING: TINA NOVA.

16 DR. NOVA: HERE.

17 MS. KING: ED PENHOET.

18 DR. PENHOET: HERE.

19 MS. KING: PHIL PIZZO.

20 DR. PIZZO: HERE.

21 MS. KING: CLAIRE POMEROY.

22 DR. POMEROY: HERE.

23 MS. KING: FRANCISCO PRIETO.

24 DR. PRIETO: HERE.

25 MS. KING: JOHN REED.

1 DR. REED: 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: JONATHAN SHESTACK. OSWALD
8 STEWARD.

9 DR. STEWARD: HERE.

10 MS. KING: LEON THAL.

11 DR. THAL: HERE.

12 MS. KING: GAYLE WILSON. JANET WRIGHT.

13 DR. WRIGHT: HERE.

14 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND IF
15 THE VICE CHAIR, DR. ED PENHOET, WILL NOW LEAD US IN THE
16 PLEDGE OF ALLEGIANCE.

17 (THE PLEDGE OF ALLEGIANCE.)

18 CHAIRMAN KLEIN: WE WILL MOVE TO THE CONSENT
19 ITEMS. WE HAVE THREE CONSENT ITEMS TO MOVE THROUGH.
20 FIRST CONSENT ITEM IS APPROVAL OF THE SEPTEMBER 9TH
21 MINUTES. THE SECOND CONSENT ITEM IS APPROVAL OF MARCY
22 FEIT AS AN ICOC PATIENT ADVOCATE MEMBER. SHE'S
23 APPOINTED BY LIEUTENANT GOVERNOR. AND THE THIRD
24 CONSENT ITEM IS APPROVAL OF THE REVISED CIRM CONFLICT
25 OF INTEREST CODES, THE DOCUMENTS WHICH ARE IN THE

1 BINDER.

2 AND, JAMES HARRISON, COULD YOU PROVIDE THE
3 COMMENT FOR THE PUBLIC RECORD RELATED TO THIS NEW CODE?
4 WE NEED TO MAKE A STATEMENT AS TO THE NEW CODE; IS THAT
5 CORRECT? THAT WE HAVE DONE A FULL REVIEW FOR PUBLIC
6 COMMENT.

7 MR. HARRISON: THAT'S CORRECT. WE'VE DONE A
8 FULL REVIEW OF PUBLIC COMMENTS, AND WE RECEIVED SOME
9 COMMENTS FROM THE FAIR POLITICAL PRACTICES COMMISSION,
10 WHICH IS THE STATE AGENCY WHICH IS CHARGED WITH
11 REVIEWING CONFLICT OF INTEREST CODES FOR STATE
12 AGENCIES. THE FPPC SUGGESTED SEVERAL MINOR AMENDMENTS,
13 WHICH WE'VE INCORPORATED. THE CONFLICT CODE WAS THEN
14 MADE AVAILABLE FOR AN ADDITIONAL 15-DAY PUBLIC COMMENT
15 PERIOD, AND WE HAVE NOT RECEIVED ANY FURTHER PUBLIC
16 COMMENTS.

17 CHAIRMAN KLEIN: THANK YOU VERY MUCH. IS
18 THERE A MOTION TO ACCEPT THE CONSENT ITEMS?

19 MR. SERRANO-SEWELL: SO MOVED.

20 CHAIRMAN KLEIN: IS THERE A SECOND?

21 UNIDENTIFIED BOARD MEMBER: SECOND.

22 CHAIRMAN KLEIN: MOTION AND SECOND. IS THERE
23 ADDITIONAL -- IS THERE BOARD DISCUSSION? IS THERE
24 PUBLIC DISCUSSION? SEEING NO PUBLIC DISCUSSION, CAN WE
25 CALL THE QUESTION. ALL IN FAVOR. OPPOSED? THANK YOU.

1 FOR THE CHAIRMAN'S REPORT, I'D LIKE TO START
2 WITH SOME FORMAL RESOLUTIONS FOR THE BOARD. THESE ARE
3 THANK-YOU RESOLUTIONS. IT TAKES A TREMENDOUS TEAM
4 ACROSS THIS STATE.

5 DR. MURPHY, WHAT ED PENHOET WAS SAYING IS IT
6 WILL CREATE AN ECHO, BUT YOU'RE NOT GETTING ADEQUATE
7 VOICE FROM THIS MIC OR I SHOULD SPEAK LOWER? THEY NEED
8 A LITTLE BIT MORE VOLUME.

9 THE THANK-YOU RESOLUTIONS ADDRESS A NUMBER OF
10 THE PARTIES IN THE STATE WHO HAVE RECOGNIZED THAT THE
11 LITIGATION AGAINST PROP 71 IS A REAL INTENT TO DELAY
12 THE IMPLEMENTATION OF AN INITIATIVE THAT CAME WITH A
13 MAJOR PUBLIC MANDATE, 59 PERCENT OF THE VOTERS, WHO
14 APPROVED THIS A YEAR AGO TODAY. WE HAVE 15 DIFFERENT
15 PATIENT GROUPS WHICH ARE ON THE BOARDS MOUNTED TO THE
16 RIGHT, TO MY RIGHT, AND 15 INSTITUTIONS ACROSS THE
17 STATE WHO HAVE JOINED AN AMICUS BRIEF OR FRIEND OF THE
18 COURT BRIEF SUPPORTING OUR LEGAL POSITION ON THE
19 CONSTITUTIONALITY OF PROPOSITION 71.

20 THOSE PATIENT GROUPS, AS THE AUDIENCE CAN SEE
21 AND AS I HOPE THE BOARD KNOWS, TAKE US FROM THE
22 CHRISTOPHER REEVE ORGANIZATION TO THE MS SOCIETY.
23 DAVID SERRANO-SEWELL, WE'RE VERY APPRECIATIVE OF YOUR
24 LEADERSHIP IN BRINGING THE NATIONAL MS SOCIETY INTO
25 THAT GROUP. THROUGH THE PARKINSON'S ACTION NETWORK,

1 THE MICHAEL J. FOX PARKINSON'S FOUNDATION, JUVENILE
2 DIABETES INTERNATIONAL BOARD, AND A NUMBER OF OTHER
3 LEADING PATIENT ADVOCACY ORGANIZATIONS.

4 AND THE INSTITUTIONS ON THE BOARD REPRESENT
5 INSTITUTIONS FROM ALL PARTS OF THE STATE, INCLUDING
6 CHILDREN'S HOSPITAL OF L.A., CHILDREN'S HOSPITAL OF
7 OAKLAND, AND A NUMBER OF OTHER DISTINGUISHED
8 ORGANIZATIONS WHO ARE NOT REPRESENTED BY INSTITUTIONS
9 ON OUR BOARD THAT ARE PART OF THE GREAT RESEARCH EFFORT
10 DEDICATED TO CHRONIC DISEASE IN THIS STATE.

11 THE FIRM OF MUNGER, TOLLES & OLSON, WHICH
12 HAPPENS TO BE WARREN BUFFET'S FIRM, A VERY FAMOUS LAW
13 FIRM IN THE UNITED STATES, HAS VOLUNTEERED THE WORK OF
14 FIVE OF THE PARTNERS ON THOSE AMICUS BRIEFS, WHICH IS A
15 HUGE BENEFIT TO THIS EFFORT. AND THE BOARD RESOLUTIONS
16 WOULD THANK THE FOLLOWING ATTORNEYS: MARK EPSTEIN, RON
17 OLSON, WHO ALSO HELPED US TREMENDOUSLY DURING
18 PROPOSITION 71, AND HE IS THE CO-CHAIRMAN OF THE
19 GOVERNOR'S ECONOMIC POLICY COUNCIL, O'MALLEY MILLER,
20 MICHAEL DOYEN, AND PAUL WATFORD.

21 THE -- COULD THE STAFF READ ONE OF THE
22 RESOLUTIONS FOR THE TEXT, AND THEN I WILL SEEK TO SEE
23 IF THERE IS A MOTION BY THE BOARD.

24 MS. DU ROSS: THE CALIFORNIA INSTITUTE FOR
25 REGENERATIVE MEDICINE IN DEEP APPRECIATION FOR HIS

1 OUTSTANDING COMMITMENT AND DEDICATION TO THE
2 ADVANCEMENT OF MEDICAL AND SCIENTIFIC RESEARCH, THROUGH
3 HIS GENEROUS AND EFFECTIVE PRO BONO WORK IN PREPARING
4 THE AMICUS CURIAE BRIEF FILED IN SUPPORT OF THE
5 CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE HEREBY
6 RECOGNIZES AND APPLAUDS MARK EPSTEIN.

7 CHAIRMAN KLEIN: SO THERE'S SIMILAR WORDING
8 FOR EACH OF THESE INDIVIDUALS TO THANK THEM FOR THE
9 CONTRIBUTION OF THEIR TIME AND EFFORT. WE WOULD LIKE
10 TO KNOW IF THERE IS A MOTION SUPPORTING THIS WORDING
11 AND ANY ADDITIONAL WORD THAT WOULD BE APPROPRIATE
12 BECAUSE THEY CONTINUE TO GIVE OF THEIR TIME GRACIOUSLY
13 EVERY DAY. IS THERE A MOTION?

14 DR. STEWARD: SO MOVED.

15 CHAIRMAN KLEIN: MOTION IS MOVED. IS THERE A
16 SECOND?

17 DR. WRIGHT: SECOND.

18 CHAIRMAN KLEIN: MOTION IS MADE AND THERE'S A
19 SECOND. IS THERE ANY PUBLIC COMMENT? BEING NO PUBLIC
20 COMMENT, ALL IN FAVOR. OPPOSED?

21 WE'D ALSO LIKE TO THANK WAREHAM DEVELOPMENT
22 AND THE CITY OF EMERYVILLE FOR SO GRACIOUSLY HOSTING US
23 IN OUR TEMPORARY HEADQUARTERS FREE OF CHARGE, FREE OF
24 CHARGE FOR THE SPACE, FREE OF CHARGE FOR UTILITIES,
25 WITHOUT ANY CHARGE FOR FURNITURE, FOR THEIR TREMENDOUS

1 RESPONSIVENESS, AND THE GREAT FACILITIES THAT THEY
2 PROVIDED FOR US DURING THIS PAST YEAR. WOULD LIKE TO
3 MAKE SURE THAT IN THIS MOTION WE CONTEMPLATE ACTUALLY
4 SENDING LETTERS ON BEHALF OF THE BOARD TO THE
5 INDIVIDUAL PRINCIPALS AS WELL AS TO THE COMPANIES AND
6 TO THE MEMBERS OF THE COUNCIL AND THE CHAMBER OF
7 COMMERCE OF EMERYVILLE, IN ADDITION TO THE INSTITUTIONS
8 THEMSELVES.

9 IS THERE A MOTION TO THANK THESE PARTIES FOR
10 THEIR TREMENDOUS CONTRIBUTION?

11 DR. HENDERSON: SO MOVED.

12 CHAIRMAN KLEIN: MOVED.

13 DR. WRIGHT: SECONDED.

14 CHAIRMAN KLEIN: AND SECONDED. IS THERE
15 PUBLIC COMMENT? CALLING THE QUESTION, ALL IN FAVOR.
16 OPPOSED?

17 AND FINALLY, I'D LIKE TO HAVE THE BOARD
18 CONSIDER A FORMAL THANK-YOU RESOLUTION TO THE CITY AND
19 COUNTY OF SAN FRANCISCO AND TO THE MEMBERS OF THE BOARD
20 OF SUPERVISORS AND VERY ESPECIALLY TO MAYOR NEWSOM AND
21 HIS PRINCIPAL STAFF ASSIGNED TO THE TASK OF THE
22 FACILITY AND GETTING US INTO THE FACILITY IN THIS
23 TREMENDOUS COMPETITION. THE STAFF MEMBERS SPECIFICALLY
24 WE WOULD CALL OUT WOULD BE JESS BLOUT AND JENNIFER
25 MOTTES. WE WOULD LIKE TO REALLY RECOGNIZE THE FACT

1 THAT THIS IS AN INCREDIBLE FACILITY THAT THEY HAVE
2 CREATED FOR US, AND WE ARE GREAT BENEFICIARIES OF THE
3 MOSCONE CENTER AND THE FREE MEETING SPACE, AS WELL AS
4 THE HEADQUARTERS SPACE, AND IN ADDITION TO 16,000 HOTEL
5 ROOMS, 2,000 OF WHICH ARE FREE. SO WE HAVE A
6 TREMENDOUS PACKAGE WE'RE BENEFITING FROM HERE THAT IS
7 LED BY MAYOR NEWSOM'S EFFORT.

8 WE WOULD, IN ADDITION TO THE MAYOR AND THE
9 GOVERNMENTAL ENTITIES, DO IN THIS RESOLUTION HOPEFULLY
10 A LETTER OF THANKS TO THE CHAMBER OF COMMERCE AND THE
11 OTHER PARTIES AND INDIVIDUALS WHO WERE PARTICIPANTS IN
12 THIS EFFORT. WE HAD A RIBBON-CUTTING CEREMONY
13 YESTERDAY. THE SPACE IS PHENOMENAL. THE CONSTRUCTION
14 IS ON TIME. IT IS BEAUTIFUL. AND WE WILL LOOK FORWARD
15 TO A RECEPTION TONIGHT.

16 IS THERE A MOTION TO THANK THESE PARTIES?

17 MR. SERRANO-SEWELL: CHAIRMAN KLEIN, BEFORE
18 WE CONSIDER THE MOTION, I WANT TO ASK IF YOU WOULD
19 CONSIDER ADDING A NAME OR SO TO THAT LIST. CERTAINLY
20 MAYOR NEWSOM AND HIS STAFF DESERVES THE CREDIT. HE DID
21 A FANTASTIC JOB, BUT I CAN TELL YOU, FROM MY LIMITED
22 INVOLVEMENT, THAT ANOTHER MEMBER OF THE MAYOR'S STAFF
23 WAS VERY HELPFUL, JEREMY HALOCY, ESPECIALLY IN THAT
24 EARLY PHASE, SO I HOPE HIS NAME WOULD BE INCLUDED AS
25 WELL.

1 CHAIRMAN KLEIN: THAT'S AN EXCELLENT
2 ADDITION. WE'D ASK FOR THEN A RESOLUTION INCLUDING
3 SPECIFICALLY RECOGNITION OF JEREMY HALOCY AS WELL.

4 MR. SERRANO-SEWELL: AND ALSO, YOU CAN SEE MY
5 INTEREST HERE, BUT --

6 CHAIRMAN KLEIN: I THINK WHAT WE SHOULD DO
7 IS, RECOGNIZING THAT DAVID IS CALLING MY ATTENTION TO
8 THE FACT THAT AS A PART OF THE TEAM IN ORDER TO
9 IMPLEMENT THIS, THE CITY ATTORNEY'S OFFICE AND A NUMBER
10 OF OTHER ADMINISTRATIVE AGENCIES OF THE CITY, INCLUDING
11 THE PLANNING DEPARTMENT, WERE EXTRAORDINARY IN THEIR
12 RESPONSIVENESS, AND WE SHOULD THANK THEM AS WELL. SO
13 WE HAVE AN IMPORTANT GROUP OF PEOPLE TO THANK IN SAN
14 FRANCISCO.

15 IF WE COULD, UNDERSTANDING THE SENSE OF THE
16 MOTION, GET AS AN AMENDED MOTION, ANYONE WOULD LIKE TO
17 MOVE AN AMENDED MOTION CONTAINING THOSE ITEMS.

18 DR. LOVE: SO MOVED.

19 CHAIRMAN KLEIN: IS THERE A SECOND?

20 MR. SERRANO-SEWELL: SECOND.

21 CHAIRMAN KLEIN: AND SECONDED. IS THERE A
22 PUBLIC COMMENT? SEEING NO PUBLIC COMMENT, I'D CALL THE
23 QUESTION UNLESS THERE'S ANY MORE BOARD COMMENTS. ALL
24 IN FAVOR. OPPOSED?

25 FINALLY, IN THE CHAIRMAN'S REPORT, I WOULD

1 LIKE TO BRIEFLY DESCRIBE FOR THE BOARD AND THE PUBLIC
2 MY RECENT TRIP THIS LAST MONTH AS A GUEST OF THE KOREAN
3 GOVERNMENT TO SOUTH KOREA. I MET WITH THE PRESIDENT OF
4 SOUTH KOREA, THE MINISTER OF HEALTH, THE MINISTER OF
5 SCIENCE, PROFESSOR HWANGN WOO SUK. IT IS THE CUSTOM IN
6 SOUTH KOREA TO, IN FACT, FOLLOW THE FIRST NAMES AFTER
7 THE LAST NAME. AND PROFESSOR AHN CURIE, WHO WAS THE
8 WOMAN PHYSICIAN SCIENTIST WHO REALLY LED THE
9 BREAKTHROUGH IN CREATING THE DISEASE-SPECIFIC LINES
10 PATTERNED AFTER PROFESSOR HWANGN'S WORK.

11 AND I'D LIKE YOU TO KNOW THAT THEY ARE REALLY
12 SERIOUSLY COMMITTED TO REACHING OUT TO THE OTHER TWO
13 CONTINENTS. OUR CONTINENT IS KNOWN AS THE NEW WORLD,
14 AND THE EUROPEAN CONTINENT AS WELL WITH HUBS FOR STEM
15 CELL RESEARCH. THERE'S IMPORTANT ISSUES TO BE
16 ADDRESSED BEFORE THERE CAN BE ANY PROPOSAL FOR A FORMAL
17 POSITION, BUT VERY SPECIFICALLY THEY'RE INTERESTED IN
18 MAKING CERTAIN THAT THEIR TECHNOLOGY AND KNOWLEDGE IS
19 AVAILABLE TO CALIFORNIA AND THE U.S. AS WELL AS TO
20 EUROPE AS SOON AS POSSIBLE.

21 IT IS THEIR INTENT TO SEND THEIR SCIENTISTS
22 TO BOTH CONTINENTS TO TRAIN OUR SCIENTISTS HERE, AS
23 WELL AS BRINGING SCIENTISTS FROM THE U.S., MANY OF WHOM
24 HAVE ACTUALLY GONE TO SOUTH KOREA TO LEARN THEIR
25 TECHNOLOGY, WHICH HAS AN EFFICIENCY RATE FOR NUCLEAR

1 TRANSFER THAT IS REMARKABLE AS AN IMPROVEMENT.

2 IN ADDITION, THEY SEEM TO BE EXTREMELY OPEN
3 TO HAVING JOINT APPROVAL WITH ANYTHING THEY DO IN
4 CALIFORNIA IN A TRAINING IN A HUB HERE FOR RESEARCH
5 WITH A CALIFORNIA AUTHORITY THAT COULD BE SET UP, SO WE
6 MAKE SURE THAT IT'S FOR THE BENEFIT OF CALIFORNIANS.
7 THEY ARE VERY OPEN AND INTEND TO ADVANCE A SET OF
8 STANDARDS WHERE THEY ARE FOLLOWING THE NATIONAL ACADEMY
9 STANDARDS, INCLUDING THE MODIFICATIONS WE MAKE TO THOSE
10 NATIONAL ACADEMY STANDARDS, IF ANY, TO RECONCILE THE
11 CALIFORNIA LAW AND PRACTICE.

12 AND FINALLY, I WOULD LIKE TO SAY IT IS THEIR
13 INTENT, AS STATED THUS FAR, TO PROVIDE THEIR RESEARCH
14 AVAILABLE ON AN AVAILABLE BASIS TO OTHER RESEARCHERS
15 FOR PATENTS THEY MAY HAVE ON NUCLEAR TRANSFER THAT THEY
16 ARE FILING ON A COST BASIS WHERE THE COST IS LIMITED,
17 TO THE EXTENT POSSIBLE, ONLY TO AIR FREIGHT OR OTHER
18 NECESSARY AND NOMINAL COSTS, ONLY HAVING THEIR PATENTS
19 EFFECTIVELY BRING IN A COST AT COMMERCIALIZATION
20 BECAUSE THEY FEEL THAT IT'S CRITICAL TO GET NEW LINES
21 INTO RESEARCHERS' HANDS AND RESEARCH INSTITUTIONS'
22 HANDS WITHOUT A HEAVY COST BURDEN.

23 THEY SPECIFICALLY WANT TO COUNTERBALANCE AND
24 CREATE A NEW MODEL TO LEAD AWAY FROM THE MODEL OF 5,000
25 PER LINE, PER RESEARCHER THAT HAS BEEN THE PRACTICE IN

1 THE PAST. AND THEY WOULD BE URGING AND HAVE URGED
2 WI -CELL TO CONSIDER THEIR COMPETITION AS A HEALTHY
3 MODEL TO POTENTIALLY FOLLOW.

4 WITH THE CONCLUSION OF THE CHAIRMAN'S REPORT,
5 I'D LIKE TO TURN TO THE -- TO THE PERSON WHO HAS
6 ENDLESS ENERGY IN LEADING OUR SCIENTIFIC VISION,
7 DR. ZACH HALL, AND THE TREMENDOUS ACCOMPLISHMENTS THAT
8 WE HAVE ACHIEVED IN THE SHORT PERIOD OF TIME UNDER HIS
9 LEADERSHIP AND ARLENE CHIU'S CAPABLE LEADERSHIP AS
10 WELL.

11 DR. HALL: THANK YOU, BOB. LET ME BEGIN, AS
12 I USUALLY DO, WITH A COUPLE OF PERSONNEL MATTERS. AND
13 I WANT TO, FIRST OF ALL, ANNOUNCE A NEW APPOINTMENT
14 THAT WE'VE MADE. AND THAT IS, WE'RE VERY FORTUNATE TO
15 HAVE DR. ALEXANDRA CAMPE COME ON BOARD AS OUR PERSONNEL
16 OFFICER. ALEXANDRA COMES TO US FROM THE HR AT UCSF.
17 WE WERE VERY FORTUNATE IN THAT SHE WORKED WITH US FOR
18 ABOUT SIX MONTHS ON LOAN FROM UCSF. AND WHEN SHE WENT
19 BACK TO UCSF, WE PUT THE JOB UP AND HAD A VARIETY OF
20 APPLICANTS FOR IT. AND WE WERE PLEASED TO SEE THAT SHE
21 WAS ONE OF THEM, AND WE ALL FELT SHE WAS THE MOST
22 QUALIFIED. AND SO WE'RE DELIGHTED TO HAVE HER JOIN US,
23 WHICH SHE WILL BE DOING IN ABOUT A WEEK.

24 I ALSO WOULD LIKE TO TAKE ADVANTAGE OF THE
25 FACT THAT WE'RE IN SAN FRANCISCO TODAY AND INTRODUCE TO

1 YOU PERSONALLY SEVERAL PEOPLE WHO I'VE DESCRIBED TO YOU
2 BEFORE, AND I WOULD JUST LIKE TO ASK SEVERAL PEOPLE
3 WHOM WE'VE HIRED OVER THE LAST FEW MONTHS TO STAND.
4 THE FIRST IS GIL SOMBRANO, WHO IS OUR SCIENTIFIC REVIEW
5 OFFICER; GEOFF LOMAX, WHO'S A SENIOR LIAISON TO THE
6 STANDARDS WORKING GROUP; ED DORRINGTON, WHOM I SAW
7 HERE, GREAT, WHO'S OUR CIO, CHIEF INFORMATION OFFICER;
8 AND FINALLY, JORGE SANCHEZ, WHO IS THE SENIOR EXECUTIVE
9 ASSISTANT TO THE PRESIDENT.

10 SINCE OUR LAST MEETING, THE BIGGEST
11 SCIENTIFIC EVENT, OF COURSE, WAS OUR VERY SUCCESSFUL
12 MEETING ON OCTOBER 1ST AND 2D IN SAN FRANCISCO, "STEM
13 CELL RESEARCH IN CALIFORNIA, CHARTING NEW DIRECTIONS."
14 MANY OF YOU WERE AT THIS MEETING, AND I THINK YOU
15 SHARED WITH US THE EXCITING TWO DAYS THAT WE SPENT
16 DISCUSSING WITH PEOPLE IN CALIFORNIA AND FROM AROUND
17 THE COUNTRY WHAT OPPORTUNITIES THERE WERE, WHAT OUR
18 CHALLENGES WERE. AND THIS WAS, I THINK, AN EXCITING
19 MEETING FOR ALL OF US.

20 IT WAS WEBCAST LIVE. THAT WEBCAST IS
21 ARCHIVED AND CAN BE ACCESSED ON OUR WEBSITE BY ANYBODY
22 WHO MISSED THE MEETING AND WOULD LIKE TO GO BACK AND
23 LISTEN TO PARTS OR EVEN ALL OF IT, IF YOU HAVE THE TIME
24 AND THE PATIENCE. AT ANY RATE, IT WAS FOR US A VERY
25 EXCITING START TO OUR SCIENTIFIC ACTIVITIES.

1 I SHOULD ALSO SAY THAT THE CONCLUDING
2 RECOMMENDATIONS OF THAT MEETING ARE ALSO ON OUR CIRM
3 WEBSITE.

4 AND FINALLY, WE ARE HAVING A SUMMARY OF THE
5 MEETING WRITTEN UP, WHICH WILL BE AVAILABLE, AND WE
6 HOPE THAT WILL BE COMPLETED IN JANUARY. I ALSO WOULD
7 LIKE TO PAY TRIBUTE TO DRS. ARLENE CHIU AND MARY MAXON,
8 WHO WORKED EXTREMELY HARD ON THIS MEETING AND HAVE
9 CONTINUED TO WORK ON IT. IN FACT, AS THEY HAVE
10 CONTINUED TO WORK, OUR COST HAS COME DOWN AND DOWN, AND
11 I'M VERY PLEASED TO SAY THAT THEY ACTUALLY ARE BRINGING
12 IN A MEETING WHICH IS ORIGINALLY BUDGETED AT \$215,000.
13 THEN WE ESTIMATED 175, AND NOW IT LOOKS LIKE IT'S GOING
14 TO COST US LESS THAN \$140,000. AND I CAN TELL YOU IN
15 THE STRAITENED FINANCIAL CIRCUMSTANCES THAT WE NOW
16 ENJOY, THIS IS A WELCOME AND WONDERFUL ACCOMPLISHMENT.
17 AND WE APPRECIATE IT. THE REASON IT'S LOW IS BECAUSE
18 OF THEIR HARD WORK. I CAN TELL YOU THAT RIGHT NOW.

19 SO I'D LIKE TO ASK FOR A ROUND OF APPLAUSE.

20 (APPLAUSE.)

21 DR. HALL: AND YOU WILL HEAR LATER, WE HAVE
22 ALREADY THOUGHT ABOUT HOW WE MIGHT USE THESE SAVINGS
23 FOR ANOTHER IMPORTANT MEETING. SO I'LL TALK ABOUT THAT
24 IN JUST A MOMENT.

25 NOW, THE OTHER MAIN ACTIVITY, OF COURSE, IS

1 THE OPENING OF OUR NEW HEADQUARTERS, WHICH IS NOT TOO
2 FAR FROM HERE ON 210 KING STREET. WE HAD A WONDERFUL
3 RIBBON-CUTTING CEREMONY WITH THE MAYOR AND OTHER CITY
4 OFFICIALS AND THE PEOPLE WHO CONTRIBUTED SO GENEROUSLY
5 TO THIS, THE ARCHITECTURAL FIRM, THE BUILDING FIRM,
6 FURNITURE PEOPLE, AND OTHERS YESTERDAY. AND TODAY
7 WE'RE GOING TO HAVE AN OPEN HOUSE AT THE CONCLUSION OF
8 THE MEETING. THE SPACE IS ABSOLUTELY GORGEOUS. IT'S
9 WONDERFUL SPACE. AND I LOOK FORWARD TO INVITE YOU ALL
10 AND LOOK FORWARD AND HOPE WE'LL SEE YOU THERE THIS
11 AFTERNOON. IT REALLY IS A THRILL FOR US TO MOVE INTO
12 THIS MAGNIFICENT NEW FACILITY.

13 AND WE WILL BE MOVING NOVEMBER 11TH. OUR
14 PHONE NUMBERS WILL CHANGE AT THAT PERIOD OF TIME. OUR
15 E-MAIL ADDRESSES WILL REMAIN THE SAME. AND FOR THOSE
16 OF YOU WHO MAY HAVE HAD SOME TROUBLE REACHING US OR
17 HEARING FROM US OVER THE LAST FEW DAYS, WE ATTEMPTED TO
18 MIGRATE OUR E-MAIL AND OTHER THINGS TO THE NEW SERVERS.
19 AND UNFORTUNATELY OVER THE WEEKEND IT TRIGGERED A
20 SECURITY ALARM IN THE STATE, AND WE WERE COMPLETELY
21 SHUT DOWN AND HAVE SPENT THE LAST SEVERAL DAYS TRYING
22 TO CONVINCING VARIOUS STATE AGENCIES THAT WE ARE NOT
23 TRYING TO BREAK INTO THE STATE'S E-MAIL SYSTEM, BUT
24 THIS WAS ENTIRELY UNINTENTIONAL. AND WE HAVE BEEN
25 WITHOUT E-MAIL ACTUALLY FOR THE LAST FOUR DAYS.

1 SO WE HOPE TO BE BACK ON TODAY, AND WE
2 APOLOGIZE FOR THAT AND ASK YOU TO BEAR WITH US THROUGH
3 THIS ACTUALLY QUITE ANNOYING, BUT RATHER COMICAL
4 EPISODE.

5 OKAY. THE OTHER THING I WANTED TO BRING YOU
6 UP TO DATE ON WAS THE STATUS OF OUR TRAINING GRANTS,
7 WHICH, AS YOU REMEMBER, WERE APPROVED FOR 16
8 INSTITUTIONS AT OUR LAST MEETING IN EARLY SEPTEMBER.
9 ARLENE CHIU AND HER STAFF HAVE BEEN WORKING VERY HARD
10 TO GO OVER THE BUDGETS AND THE APPROVED GRANT TO MAKE
11 SURE THAT ALL IS CORRECT, AND THEY NOW HAVE A CORRECTED
12 FIGURE OF 12.1 MILLION FOR THE FIRST YEAR OF THE
13 TRAINING GRANTS. THAT WILL RISE SLIGHTLY IN EACH
14 SUCCESSIVE YEAR, AND THE TOTAL FOR THE THREE YEARS IS
15 NOW ROUGHLY \$38 MILLION.

16 NOW, THESE GRANTS WILL BE READY TO GO OUT
17 WHEN THE MONEY COMES IN, BUT WE WILL NEED TO DO TWO
18 OTHER THINGS BEFORE WE SEND THEM OUT. AND YOU WILL
19 HEAR ABOUT BOTH OF THOSE LATER TODAY. ONE IS WE NEED
20 TO HAVE INTERIM REGULATIONS FOR OUR MEDICAL AND ETHICAL
21 STANDARDS IN PLACE, AND THE OTHER IS WE NEED TO HAVE AN
22 INTERIM GRANTS ADMINISTRATION POLICY FOR TRAINING
23 GRANTS. AND I WILL TALK TO YOU ABOUT THE FIRST A
24 LITTLE LATER ON IN THE MEETING, AND ARLENE CHIU WILL
25 DISCUSS THE SECOND WITH YOU.

1 NOW, THE NEXT THING I WANTED TO DISCUSS IS
2 WHAT I SEE AS A MAJOR CHALLENGE FOR THE NEXT SIX MONTHS
3 OR SO. AND THAT IS TO PUT TOGETHER A SCIENTIFIC
4 STRATEGIC PLAN THAT WILL GUIDE OUR PROGRAMS. WE ARE
5 INITIATING A LARGE AND AMBITIOUS RESEARCH PROGRAM IN A
6 NEW AREA OF RESEARCH, A PROGRAM WHICH WILL GO OVER
7 PROBABLY MORE THAN TEN YEARS AND WILL INVOLVE HUNDREDS
8 OR PERHAPS EVEN THOUSANDS OF GRANTS OVER THAT PERIOD OF
9 TIME.

10 NOW, IN ORDER TO HAVE OUR PROGRAM WORK AS WE
11 WANT IT TO, THAT IS, TO SUCCEED IN OUR GOAL OF USING
12 STEM CELL RESEARCH TO DEVELOP THERAPIES, WE NEED TO
13 ENGAGE IN A LARGE-SCALE PROCESS OF STRATEGIC PLANNING.
14 WE NEED TO IDENTIFY IDEAS FOR SCIENTIFIC AND
15 TRANSLATIONAL PROBLEMS AND OPPORTUNITIES TO TRANSLATE
16 THOSE IDEAS INTO A PLAN THAT IS EXPRESSED THROUGH OUR
17 GRANTS-MAKING PROCESS, AND WE NEED TO ACCOMPANY THIS BY
18 A FINANCIAL PLAN THAT WILL GIVE SOME IDEA OF HOW WE
19 WILL DISTRIBUTE FUNDS AMONG DIFFERENT PROJECTS AS WELL
20 AS OVER TIME. AND WE ENVI SAGE THAT THE FINAL PRODUCT
21 WILL BE AN OVERARCHING PLAN FOR ACTION WITH A SERIES OF
22 SEQUENTIAL PHASES WITH MILESTONES BY WHICH WE CAN
23 MEASURE OUR PROGRESS. AND WE DON' T BELIEVE THAT THIS
24 PLAN WILL BE SET IN STONE. IT WILL NEED TO BE
25 RESPONSIVE BOTH TO THE RESULTS THAT IT PRODUCES AND

1 ALSO TO NEW SCIENTIFIC DEVELOPMENTS, AND SO IT WILL
2 NEED TO BE REVIEWED, UPDATED, AND MODIFIED AT PERIODIC
3 INTERVALS.

4 IN ADDITION TO THE SCIENTIFIC AGENDA, WE WILL
5 ALSO AS PART OF THE PLAN SEEK TO FOSTER A SCIENTIFIC
6 CULTURE IN WHICH OUR IDEAS CAN SUCCEED, TESTING NEW
7 MODELS OF GRANT MECHANISMS THAT CAN PROMOTE
8 INTERDISCIPLINARY AND INTERINSTITUTIONAL COLLABORATION
9 AND THAT CAN BRING TOGETHER BASIC AND CLINICAL
10 RESEARCHERS.

11 I SEE THIS AS OUR NEXT LARGE AND IMPORTANT
12 TASK. AND AS I TOLD YOU WHEN I SPOKE TO THE ICOC AND
13 THE PRESIDENTIAL SEARCH COMMITTEE, I SEE THIS AS MY
14 MAJOR RESPONSIBILITY AND AN EFFORT THAT I PERSONALLY
15 PLAN TO LEAD OVER THAT PERIOD OF TIME. WE WILL NEED TO
16 WORK CLOSELY BETWEEN CIRM AND THE ICOC, AND I LOOK
17 FORWARD TO THE APPOINTMENT OF AN ICOC SUBCOMMITTEE FOR
18 SCIENTIFIC STRATEGIC PLANNING AND LOOK FORWARD TO
19 WORKING WITH THE CHAIR AND CO-CHAIRS AND MEMBERS OF
20 THAT COMMITTEE WHEN THEY ARE APPOINTED.

21 WE ENVISAGE THAT THE FIRST STEP IN THE PLAN
22 WILL BE A PERIOD OF INFORMATION GATHERING, AND THE
23 SCIENTIFIC MEETING THAT WE JUST HAD WAS, I THINK, A
24 WONDERFUL START TO THAT, IN WHICH WE ASKED SCIENTISTS
25 FROM ALL OVER THE COUNTRY TO MAKE SUGGESTIONS FOR WHAT

1 OUR PRIORITIES SHOULD BE AND TO DESCRIBE WHERE WE ARE
2 AND WHAT WE NEED TO KNOW. WE WILL NEED TO HAVE, I
3 THINK, OTHER SMALL, MORE FOCUSED SCIENTIFIC MEETINGS,
4 MEETINGS WITH OTHER GROUPS, PERHAPS PATIENT ADVOCATES,
5 PERHAPS OUTSIDE SCIENTIFIC -- SORRY -- PERHAPS
6 REPRESENTATIVES OF THE PRIVATE SECTOR. WE ALSO WANT TO
7 HAVE INDIVIDUAL INTERVIEWS WITH EACH ICOC MEMBER AS
8 PART OF THIS PROCESS AND WITH BIOMEDICAL LEADERS.

9 SO WE SEE THIS AS A VERY LARGE-SCALE AND
10 INTENSIVE AND EXTENSIVE PROCESS THAT WE WILL BE
11 INVOLVED IN OVER THE PERIOD OF TIME. NOW, IT IS A VERY
12 LARGE UNDERTAKING, AND WE WILL NOT BE ABLE TO REALLY
13 BEGIN ON THIS UNTIL WE HAVE THE NECESSARY RESOURCES.
14 AND THAT IS, WE NEED ADDITIONAL SCIENTIFIC STAFF TO
15 HELP US CARRY THIS OUT, AND WE ALSO WILL NEED A
16 CONSULTANT, WE THINK, TO HELP US WITH MANY OF THE TASKS
17 THAT WE ENVI SAGE.

18 WE HAVE BEGUN PRELIMINARY DISCUSSIONS WITH AT
19 LEAST ONE POSSIBLE CONSULTANT, AND WE ARE MEETING WITH
20 ANOTHER LATER THIS MONTH. AND WE EXPECT AT SOME POINT
21 TO ASK THESE GROUPS TO MAKE FORMAL PROPOSALS TO US.

22 SO LET ME MOVE ON, THEN, TO SAY THAT IN THE
23 MEANTIME, WHILE WE ARE DOING THIS, WE ALSO HAVE SOME
24 SCIENTIFIC NEEDS THAT WE CAN MEET AND THAT SEEM TO BE
25 IMMEDIATE AND URGENT AND FAIRLY APPARENT. THAT IS

1 ABOUT WHICH WE THINK THERE CAN BE NOT MUCH DOUBT. AND
2 WE SEE TWO KINDS OF GRANTS THAT ARE IMPORTANT AT THIS
3 STAGE. FIRST ARE INNOVATION GRANTS, WHICH WOULD BE
4 RELATIVELY SMALL GRANTS OF MAYBE A COUPLE HUNDRED
5 THOUSAND DOLLARS FOR A COUPLE OF YEARS. THESE ARE VERY
6 TENTATIVE FIGURES, BUT TO GIVE YOU SOME IDEA THAT THESE
7 WOULD NOT BE LARGE GRANTS. THEY WOULD ALLOW PEOPLE TO
8 DO -- TO TRY OUT NEW IDEAS.

9 WE HOPE THEY WOULD ATTRACT SCIENTISTS WHO ARE
10 WELL ESTABLISHED IN OTHER RELATED FIELDS WHO MIGHT WISH
11 TO TAKE A FLY, WHO MIGHT WISH TO TRY OUT AN IDEA IN
12 STEM CELL RESEARCH, AND WE HOPE THEY WOULD ALLOW PEOPLE
13 TO PROVIDE PRELIMINARY DATA FOR MORE SUBSTANTIAL GRANTS
14 LATER ON. AND AS WE HAVE DISCUSSED BEFORE WHEN WE WERE
15 DISCUSSING CRITERIA, THESE ARE THE KINDS OF GRANTS FOR
16 WHICH THE IMPORTANT THING IS NOT EXTENSIVE PRELIMINARY
17 DATA SHOWING THAT IT'S LIKELY TO SUCCEED, BUT, IN FACT,
18 RATHER A GOOD IDEA AND EVIDENCE OF ABILITY TO GIVE THE
19 IDEA A GOOD TRY. THAT IS, I THINK WE WOULD NOT BE
20 AFRAID AT THIS STAGE TO TRY SOME RISKY THINGS, NOT ON A
21 LARGE SCALE, BUT ON A SMALL SCALE AS BEFITS OUR FUNDING
22 SITUATION RIGHT NOW.

23 AND WE SEE THAT IF WE'RE ABLE TO ATTRACT \$50
24 MILLION IN BRIDGE FUNDING, WHICH IS OUR FIRST GOAL,
25 THEN WE WOULD BE ABLE TO ISSUE AN RFA FOR THIS. AND WE

1 WOULD BRING A MORE DETAILED PROPOSAL FOR THE RFA TO THE
2 ICOC FOR APPROVAL.

3 THE SECOND NEED WHICH WE THINK IS VERY
4 IMPORTANT, IT'S A NEED THAT BOB KLEIN ACTUALLY POINTED
5 OUT TO ME SHORTLY AFTER I ARRIVED, AND IN MY
6 DISCUSSIONS WITH PEOPLE AROUND THE STATE, I THINK
7 THERE'S NO QUESTION THAT WE NEED THIS. AND THAT IS
8 SOME SORT OF SMALL-SCALE SPACE THAT WOULD ALLOW PEOPLE
9 TO DO HUMAN EMBRYONIC RESEARCH OUTSIDE THE FEDERAL
10 GUIDELINES. SOME INDIVIDUALS ALREADY HAVE THIS. SOME
11 INSTITUTIONS HAVE IT, BUT MANY DO NOT. AND SO WE THINK
12 THAT TO HELP PEOPLE ESTABLISH THIS SPACE, WE WOULD NEED
13 TO PROVIDE SOME FUNDS THAT WOULD LET THEM SET UP, SAY,
14 TWO OR THREE OR 4,000 SQUARE FEET WITH THE BASIC
15 EQUIPMENT. AND PROBABLY WE ENVISAGE ACTUALLY THAT
16 THERE WOULD BE STAFF WHO WOULD BE ASSOCIATED WITH THE
17 SPACE. AND THIS WOULD THEN ALLOW PEOPLE WHO ARE
18 ALREADY ENGAGED IN STEM CELL RESEARCH OR THOSE WHO ARE
19 NOT EQUIPPED TO DO RESEARCH OUTSIDE THE FEDERAL
20 GUIDELINES TO HAVE SPACE IN WHICH THEY COULD WORK.

21 AND WE DON'T NEED TO GO INTO THAT ISSUE
22 EXTENSIVELY HERE. WE DISCUSSED IT IN OUR FACILITIES
23 WORKING GROUP MEETING JUST THIS LAST WEEK, BUT IT IS A
24 PROBLEM FOR UNIVERSITIES, THAT THE QUESTION OF WHETHER
25 THEY CAN SHARE SPACE BETWEEN FEDERAL AND NONFEDERALLY

1 FUNDED RESEARCH IS UNCLEAR, AND DIFFERENT UNIVERSITIES
2 ARE TAKING DIFFERENT POSITIONS ON THIS. WE THINK IT'S
3 IMPORTANT IN ANY CASE TO PROVIDE SPACE THAT IS ENTIRELY
4 PAID FOR, NONE OF WHICH IS PAID FOR BY FEDERAL FUNDS,
5 THAT COULD BE USED FOR HUMAN EMBRYONIC STEM CELL
6 RESEARCH. AND WE SEE THIS AS AN EARLY AND URGENT NEED.

7 SO IF WE ARE ABLE, AFTER GETTING OUR FIRST 50
8 MILLION, IF WE ARE ABLE TO ATTRACT A SECOND 50 MILLION
9 IN BRIDGE FUNDING, WHICH I BELIEVE WE CAN DO, GIVEN THE
10 TALENTS OUT OF OUR CHAIR AND OTHERS, THEN I THINK THIS
11 WOULD BE A VERY IMPORTANT ITEM FOR US TO FUND.

12 SO I PRESENT THIS FOR INFORMATIONAL PURPOSES
13 AS WE MOVE FORWARD AND FOR YOUR COMMENT. AS WE MOVE
14 FORWARD, EACH OF THESE WILL BE BROUGHT INDIVIDUALLY TO
15 YOU FOR DISCUSSION AND COMMENT AS YOU WISH.

16 IF YOU WANT, WE CAN TAKE, AS YOU WISH, MR.
17 CHAIR, WE CAN TAKE COMMENTS OR QUESTIONS HERE OR WE CAN
18 MOVE ON.

19 CHAIRMAN KLEIN: I THINK THAT THERE'S SOME
20 BOARD QUESTIONS HERE. DR. PIZZO.

21 DR. PIZZO: ZACH, I WONDER IF YOU COULD BE A
22 LITTLE MORE EXPANSIVE IN THE TIMELINES AND HOW YOU
23 UNDERSTAND OR WOULD LIKE THE SCIENTIFIC ADVISORY
24 SUBCOMMITTEE TO BE PUT INTO PLACE? WHAT WOULD BE THE
25 PROCESS FOR THAT?

1 DR. HALL: LET ME DEAL WITH THAT. I WILL BE
2 GIVING A REPORT LATER ON THE MEETING OF OUR FACILITIES
3 WORKING GROUP. AND THAT IS CHAIRED BY RUSTY DOMS,
4 CO-CHAIRRED BY DAVID SERRANO-SEWELL. WE MET LAST WEEK,
5 AND THAT WAS ONE OF THE ISSUES THAT WE DISCUSSED, AND I
6 WANTED TO TALK ABOUT THAT, IF I MIGHT, WITH THE ICOC
7 JUST TO KEEP THEM APPRISED OF WHERE WE ARE.

8 CHAIRMAN KLEIN: THE OTHER THING RELATIVE TO
9 DR. PIZZO'S QUESTION IS THAT THE NEXT ITEM ON THE
10 AGENDA IN TERMS OF FORMATION OF STRATEGIC PLANNING
11 SUBCOMMITTEE, WE'RE GOING TO HAVE A DISCUSSION ABOUT
12 COMING BACK, FINDING OUT WHO THE VOLUNTEERS ARE FOR
13 THAT COMMITTEE, AND COMING BACK IN DECEMBER WITH A
14 TIMELINE AND A PROCESS AND A STRUCTURE THAT
15 INCORPORATES, I THINK, THE ANSWER TO THAT QUESTION.

16 DR. BALTIMORE: I GUESS JUST A MATTER OF
17 FACT. DO YOU KNOW WHETHER IT'S NECESSARY IN
18 CONSTRUCTING SPACE IN WHICH ONE CAN DO WORK WHICH WOULD
19 OTHERWISE NOT BE APPROPRIATE FOR FEDERAL FUNDING, THAT
20 YOU COULD BUILD THAT SPACE IN A BUILDING WHICH HAD
21 FEDERAL FUNDING IN ITS CONSTRUCTION?

22 DR. HALL: MY UNDERSTANDING IS THAT YOU CAN.
23 IT IS MURKY, AND IT'S ONE OF THE SITUATIONS WHERE
24 NOBODY WANTS TO QUITE SAY WHAT THE RULES ARE ON EITHER
25 SIDE OF THE DEBATE. OUR UNDERSTANDING IS NOW THAT IN

1 PRACTICE THAT IS POSSIBLE. SO THIS WOULD NOT -- YOU
2 COULD DO THIS WITH WITHIN PREEXISTING BUILDINGS, BUT IT
3 WOULD HAVE TO BE DONE, AS I UNDERSTAND IT, AGAIN, TO
4 TAKE THE SPACE OUT OF THE INDIRECT COST CALCULATION
5 THAT YOU HAVE. YOU CAN'T BE SUPPORTED IN THAT WAY BY
6 FEDERAL FUNDS, BUT OTHERWISE YOU SIMPLY SAY THIS IS FOR
7 SPACE THAT IS ENTIRELY FUNDED BY NONFEDERAL MONEY AND
8 IS, THEREFORE, AVAILABLE FOR THIS WORK.

9 AND WE KNOW ALREADY, FOR EXAMPLE, THAT WORK
10 GOES ON IN LABORATORIES THAT ARE FUNDED BY FOUNDATIONS
11 SUCH AS JDRF OR HOWARD HUGHES. THIS IS NOT NEW. THAT
12 WORK IS NOT LARGE-SCALE, BUT IT DOES GO ON. SO OUR
13 UNDERSTANDING IS THAT THAT WOULD BE FINE.

14 CHAIRMAN KLEIN: DR. HALL, BECAUSE THE LEGAL
15 ISSUES HERE HAVE SO MUCH INHERENT RISK IN THEM, MAYBE
16 EMBEDDED RISK IS THE RIGHT TERMINOLOGY, THAT IT WOULD
17 BE GOOD IF JAMES HARRISON COULD PARTICIPATE IN A CALL
18 WITH ME WITH HARVARD'S ATTORNEYS WHO ARE AVAILABLE TO
19 US TO RELATE THEIR RESEARCH, WHICH THEY'VE SPENT
20 CONSIDERABLE TIME AND MONEY, SO THAT WE CAN ACTUALLY
21 GET POTENTIALLY A JOINT MEMORANDA FROM THE HARVARD
22 ATTORNEYS WITH REVIEW FROM OUR COUNSEL AND THE ATTORNEY
23 GENERAL'S COUNSEL ON WHICH WE COULD HAVE A MORE REFINED
24 AND DISCIPLINED LEGAL ANALYSIS OF THESE QUESTIONS.

25 AND I WOULD REMIND EVERYONE IN THAT CONTEXT

1 THAT IN 2006, BEING AN ELECTION YEAR, THE CURRENT
2 INTERPRETATIONS RELY ON AN OMB CIRCULAR THAT HAS BEEN
3 PERMITTED BY THE WHITE HOUSE, BUT IT COULD BE CHANGED
4 OVERNIGHT SINCE IT IS NOT RELATED TO A LEGAL BASIS OF
5 ANY LAW PASSED BY CONGRESS. DR. BALTIMORE, WOULD THAT
6 BE HELPFUL?

7 DR. BALTIMORE: YES. I WOULD LIKE -- I WOULD
8 HOPE THAT YOU COULD PUBLISH SUCH AN ANALYSIS SO THAT
9 THE DIFFERENT FACILITIES AROUND THE STATE WOULD HAVE A
10 COMMON UNDERSTANDING.

11 DR. HALL: IT IS COMPLICATED, DAVID, IN THAT
12 IN THE END, IT SEEMS THAT THERE'S NOT GOING TO BE A
13 DEFINITIVE CLARIFICATION COMING. SO EACH INSTITUTION
14 HAS TO MAKE ITS DECISION. THAT'S WHAT --

15 DR. BALTIMORE: WELL, THE QUESTION REALLY
16 IS --

17 DR. HALL: WE WILL PROVIDE WHATEVER
18 INFORMATION WE COULD.

19 DR. BALTIMORE: IS THE SITUATION MURKY ENOUGH
20 THAT ONE WOULD BE TAKING A RISK BY BUILDING IN A
21 FACILITY THAT HAD ANY BACKGROUND FEDERAL FUNDING, IN
22 WHICH CASE THE ADVICE MIGHT BE TO ONLY DO SUCH
23 DEVELOPMENT OF SPACE IN BUILDINGS THAT WERE TOTALLY
24 PRIVATELY FUNDED?

25 DR. HALL: I THINK OUR UNDERSTANDING IS IS

1 THAT THAT NOW IS HAPPENING IN SEVERAL PLACES AND IS NOT
2 A PROBLEM. AS BOB SAYS --

3 DR. BALTIMORE: IF IT'S NOT CONTESTED, YOU
4 DON'T KNOW IF IT'S A PROBLEM.

5 DR. HALL: WELL, HARVARD IS -- DOUG MELTON'S
6 LAB AND OTHERS IS PROBABLY THE BEST. AND THEY, AS I
7 UNDERSTAND IT, I HAVE BEEN TOLD, THEY HAVE TAKEN A
8 POSITION THAT THIS IS AN ACCOUNTING PROBLEM AND NOT
9 ANYTHING MORE THAN THAT. AND THEY HAVE DONE A LOT OF
10 BACKGROUND LEGAL WORK.

11 I ALSO KNOW THAT SOME UNIVERSITIES HAVE TAKEN
12 THAT VIEW AND OTHERS HAVE SAID WE DON'T WANT TO TAKE
13 THAT CHANCE. AND WE CAN PROVIDE INFORMATION, BUT IN
14 THE END, THE INSTITUTIONS WILL HAVE TO DO WHAT THEY
15 CAN.

16 DR. PIZZO: JUST TO FOLLOW UP ON THAT.

17 CHAIRMAN KLEIN: THAT'S DEAN PIZZO AGAIN
18 SPEAKING.

19 DR. PIZZO: WE HAVE HAD PRETTY EXTENSIVE
20 DISCUSSIONS, OUR LEGAL COUNSEL, GENERAL COUNSEL'S
21 OFFICE WITH THE HARVARD LAWYERS, AND WE'RE UTILIZING
22 THE APPROACH THEY'RE TAKING, SO WE COULD SHARE WHAT
23 WE'VE LEARNED AS WELL WITH REGARD TO THAT. I THINK IT
24 IS AS YOU DESCRIBE. WE CAN COMPARTMENTALIZE AS THAT'S
25 THE IDEAL THING THAT CAN HAPPEN IN THE SAME BUILDING,

1 AND THAT'S THE WAY WE'RE ACTUALLY APPROACHING IT.

2 CHAIRMAN KLEIN: AND WE'RE GOING TO DO
3 DR. HENDERSON, THEN JEFF SHEEHY.

4 DR. HENDERSON: I THINK JUST CREATING A PAPER
5 TRAIL REGARDING THIS ISSUE OF ANY KIND WOULD BE A HELP,
6 WHERE WE TRY TO STAY FOCUSED ON THE QUESTION BECAUSE
7 THERE'S BOTH DIRECT COST FOR BUILDINGS AND THEN THERE'S
8 THE WHOLE INDIRECT COST RECOVERY ISSUE, WHICH IS
9 PERHAPS FUZZIER. BUT I THINK IT'S IMPORTANT TO CREATE
10 A PAPER TRAIL SO WE HAVE SOMETHING TO GO BACK TO.

11 DR. HALL: LET ME JUST SAY, AS I UNDERSTAND
12 THE HARVARD POLICY, I REALIZE I DIDN'T SAY THIS
13 CORRECTLY, AS I UNDERSTAND THE HARVARD POLICY, AND IF
14 ANYBODY KNOWS BETTER THAN THIS, PLEASE CORRECT ME, IT
15 IS THAT THEY HAVE DECIDED FURTHER THAN THAT, THAT
16 FEDERAL AND NONFEDERAL CAN GO ON IN THE SAME SPACE AS
17 LONG AS IT'S CLEAR WHAT'S WHAT. EVEN IN THE SAME ROOM
18 IS MY UNDERSTANDING. NOT ALL INSTITUTIONS ARE WILLING
19 TO TAKE THAT POSITION. MY UNDERSTANDING IS IF YOU SET
20 ASIDE A ROOM WITHIN THAT SPACE, THAT THAT -- NO ONE AT
21 THE PRESENT TIME WOULD CHALLENGE THAT.

22 NOW, THAT POLICY COULD CHANGE AS WE -- I
23 JUST -- MY OWN VIEW IS THAT WHATEVER THOSE POLICIES,
24 HOWEVER THAT SHAKES OUT, THAT I THINK IT WILL BE A
25 TREMENDOUS HELP TO THE EFFORT IN THIS STATE TO GET

1 SMALL, RELATIVELY SMALL AMOUNTS OF SPACE EQUIPPED,
2 STAFFED, AND AVAILABLE ON A SHARED BASIS FOR PEOPLE TO
3 USE, I THINK, WILL BE A TREMENDOUS HELP IN GETTING OUR
4 EFFORT OFF THE GROUND.

5 CHAIRMAN KLEIN: I WOULD SAY IF -- WE
6 CERTAINLY APPRECIATE TREMENDOUSLY DEAN PIZZO'S
7 SUGGESTION. IF THERE'S ANY OTHER INSTITUTIONS WHOSE
8 LAWYERS PARTICIPATE, IT WOULD BE HELPFUL, BUT GETTING
9 SOMETHING PUBLISHED WOULD BE EXTREMELY, I THINK,
10 HELPFUL TO INSTITUTIONS TO CLARIFY THIS AREA. JEFF
11 SHEEHY, YOU HAD A SPECIFIC COMMENT.

12 MR. SHEEHY: NOT RELATED TO THE FACILITIES,
13 BUT I ACTUALLY HAD TWO QUESTIONS OR COMMENTS. ONE IS A
14 HOPE THAT THE STRATEGIC PLAN WILL AT SOME POINT IN ITS
15 PROGRESSION GO THROUGH THE WORKING GROUPS OR THE
16 WORKING GROUPS WILL BE ABLE TO PROVIDE FEEDBACK.

17 AND THE SECOND IS THIS FIRST ROUND OF
18 INNOVATION GRANTS, I'M JUST CURIOUS. IT SEEMS TO ME
19 THAT WE HAVEN'T REALLY REACHED OUT TO THE FOR-PROFIT
20 COMMUNITY, AND THIS SEEMS THAT THIS MIGHT BE SOMETHING
21 THAT WE SHOULD THINK ABOUT INCLUDING OUTREACH TO THEM
22 IF THEY WANT TO APPLY FOR THESE GRANTS.

23 DR. HALL: I THINK WE IN PRINCIPLE WOULD BE
24 HAPPY TO DO THAT. WE ARE, AS YOU WILL HEAR IN A
25 MOMENT, WORKING ON OUR IP POLICY. AND I THINK THE

1 FIRST STEP IN THAT IS TO WORK THAT OUT FOR OUR
2 NONPROFITS, AND THEN I THINK AS SOON AS WE FEEL WE HAVE
3 A CLEAR POLICY AND CAN MOVE AHEAD WITH THE FOR-PROFITS,
4 I SEE NO REASON WHY THEY SHOULDN'T ALSO BE INCLUDED.

5 MR. SHEEHY: I THINK THE TRACK IS GOING
6 SIMULTANEOUS. I DON'T SEE ANY PROBLEM WITH THE
7 FOR-PROFIT BEING ANY MORE DIFFICULT IN TERMS OF IP THAN
8 A NON-FOR-PROFIT.

9 DR. HALL: I PREFER TO DEFER TO THE IP TASK
10 FORCE ON THAT ISSUE.

11 MR. SHEEHY: I THINK THE ADVERSE IS PROBABLY
12 MORE TRUE.

13 DR. HALL: MAYBE THAT COULD BE FURTHER
14 DISCUSSED IN A MOMENT.

15 I HAD ONE LAST ISSUE I WANT TO BRING UP
16 BEFORE THE ICOC. AND THAT IS THAT ONE OF THE THINGS
17 THAT RECENT EVENTS IN OUR SCIENTIFIC CONFERENCE HAVE
18 MADE CLEAR IS THE LIKELY FUTURE IMPORTANCE OF NUCLEAR
19 TRANSFER IN CREATING CELL LINES THAT CAN BE USED TO
20 CREATE, IN PARTICULAR, HUMAN CELLULAR MODELS OF
21 DISEASE, THAT CAN BE USED FOR TOXICOLOGY STUDIES, THAT
22 CAN BE USED IN A VARIETY OF WAYS TO FORWARD THE
23 RESEARCH. AND I THINK MANY OF US ARE VERY IMPRESSED BY
24 THE POTENTIAL OF THESE TECHNIQUES. AND ALSO AS
25 CHAIRMAN KLEIN MENTIONED, THE RECENT SUCCESS OF THE

1 SOUTH KOREANS HAS BEEN VERY IMPORTANT IN THIS REGARD.

2 ONE ISSUE THAT HAS BEEN VERY MUCH DISCUSSED
3 IN THE PUBLIC AND THE PRESS AND BY OTHERS IS THE
4 POSSIBLE HEALTH RISK TO DONORS OF OOCYTES FOR CREATION
5 OF THESE CELL LINES. AND WE ARE VERY CONCERNED WITH
6 THIS ISSUE. A NUMBER OF FIGURES HAVE BEEN USED, WIDELY
7 DIFFERENT FIGURES HAVE BEEN USED TO ADDRESS THIS ISSUE
8 BY DIFFERENT PEOPLE. AND SO WE BELIEVE THAT IT
9 WOULD -- IT IS OUR RESPONSIBILITY TO TRY TO BECOME
10 BETTER INFORMED ABOUT THIS AND ASK WHAT IS THE DATA,
11 WHAT IS THE BEST EVIDENCE. ARE THERE STUDIES THAT WE
12 MIGHT USEFULLY SPONSOR, AND ARE THERE BEST PRACTICES
13 THAT CAN REDUCE RISK?

14 AND SO WE HAVE CONCEIVED OF THE IDEA OF
15 HAVING A ONE-DAY CONFERENCE TO HEAR, A SCIENTIFIC
16 CONFERENCE, TO HEAR WHAT THE BEST EXPERTS IN THE FIELD
17 HAVE TO SAY ABOUT THIS. AND THE INTENT OF THE
18 CONFERENCE WOULD BE NOT TO DISCUSS POLICY OR ETHICAL
19 ISSUES, WHICH WE ALSO TAKE SERIOUSLY, BUT WHICH ARE
20 BEING DISCUSSED IN OTHER CONTEXTS IN THE STANDARDS
21 WORKING GROUP AND ELSEWHERE, BUT SPECIFICALLY TO FOCUS
22 ON THE SCIENTIFIC EVIDENCE AND TO ASSESS ITS QUALITY.

23 WE ENVISAGE SEVERAL WAYS IN WHICH WE MIGHT DO
24 THIS. WE COULD ORGANIZE A CONFERENCE OURSELVES, WE
25 COULD PUT OUT AN RFP FOR THE CONFERENCE, OR WE CAN ASK

1 AN OUTSIDE GROUP, SUCH AS THE HIGHLY RESPECTED GROUP,
2 SUCH AS THE NATIONAL ACADEMIES, TO ORGANIZE A MEETING
3 IN CALIFORNIA ON THIS TOPIC FOR US.

4 AND SO WHAT WE WOULD LIKE TO DO WOULD BE TO
5 EXAMINE THESE AND OTHER ALTERNATIVES AND THEN TO BRING
6 BACK IN DECEMBER A PROPOSAL FOR YOUR CONSIDERATION ON
7 THIS MATTER. THE PRELIMINARY DISCUSSIONS THAT WE'VE
8 HAD WITH A VARIETY OF PEOPLE HAVE BEEN VERY POSITIVE IN
9 SUPPORT OF HAVING SUCH A MEETING. AND ONE OF OUR
10 STANDARDS WORKING GROUP MEMBERS, WHO IS A NATIONALLY
11 PROMINENT PERSON IN REPRODUCTIVE ENDOCRINOLOGY, SAID
12 THERE REALLY HAS NOT BEEN A CONFERENCE LIKE THIS. IT
13 WOULD BE A NATIONAL SERVICE IF YOU WERE TO DO THIS.
14 AND MY BELIEF IS THAT, GIVEN THE INTEREST IN THE TOPIC,
15 GIVEN THE IMPORTANCE OF THE TECHNIQUE, AND THE FACT
16 THAT WE WILL ALMOST CERTAINLY BE DOING THIS, I THINK IT
17 IS OUR RESPONSIBILITY TO LOOK QUITE CAREFULLY AND
18 CRITICALLY AT THE SCIENTIFIC EVIDENCE AND SEE WHAT WE
19 KNOW.

20 SO I SIMPLY PROPOSE THIS. WE WILL FURTHER,
21 IF THIS BOARD IS SUPPORTIVE, WE WILL FURTHER EXPLORE
22 THIS IDEA AND THEN BRING BACK A SPECIFIC PROPOSAL AT
23 THE DECEMBER MEETING FOR SUCH A MEETING, IF YOU WOULD
24 LIKE US TO DO THAT.

25 CHAIRMAN KLEIN: DR. HALL, I THINK IT WOULD

1 BE ALSO VERY APPROPRIATE IF COUNSEL COULD HELP US AT
2 THE DECEMBER MEETING GIVE US AN UPDATE ON WHERE WE ARE
3 IN MEETING OUR RESPONSIVE OBLIGATION TO MR. HALPERN AND
4 OTHER GROUPS THAT HAVE ASKED FOR PUBLIC MEETINGS OR
5 HEARINGS TO ADDRESS A RANGE OF TOPICS. WE HAVE
6 ADDRESSED A NUMBER OF THOSE TOPICS. WE HAVE OTHERS TO
7 ADDRESS. WE HAVE LIMITED TIME, AND WE PROBABLY SHOULD
8 BE AWARE OF ALL OF THOSE OBLIGATIONS WHEN WE SET OUT
9 NEW AGENDAS, BUT THIS IS A CRITICAL AREA WHERE AN
10 INITIATIVE IN AN AREA, AS DR. HALL SAID, COULD HELP THE
11 NATION. AND WE SHOULD BE AWARE OF THE CONTRIBUTION WE
12 MAY BE MAKING BY HAVING THE CONFERENCE DR. HALL HAS
13 SUGGESTED IN TERMS OF THOSE PRIORITIES.

14 DR. BALTIMORE: IT IS MY UNDERSTANDING THAT
15 THE FEDERAL GOVERNMENT HAS NOT BEEN FUNDING WORK IN IN
16 VITRO FERTILIZATION, OTHER ARTIFICIAL REPRODUCTIVE
17 METHODS BECAUSE OF THE INTERSECTION WITH ISSUES OF
18 ABORTION AND OF THE SORT OF CREATION OF HUMAN BEINGS.
19 AND THAT ALTHOUGH WE HAVE A VERY ACTIVE IN VITRO
20 FERTILIZATION COMMUNITY IN THIS COUNTRY, IT REALLY GETS
21 NO RESEARCH SUPPORT. SO ANYTHING WE CAN DO IN
22 CALIFORNIA TO HELP WITH THAT PROBLEM IS, I THINK,
23 EXTREMELY WORTHWHILE AS A NATIONAL SERVICE, AS AN
24 INTERNATIONAL SERVICE, ALTHOUGH THERE IS A LOT MORE
25 WORK THAT GOES ON ABROAD THAN IN THE UNITED STATES.

1 AND SO THIS FIRST WHAT I WOULD SAY IS FIRST FORAY INTO
2 TRYING TO OPEN UP THESE DISCUSSIONS AND TO EVALUATE
3 EVIDENCE THAT EXISTS IS EXTREMELY VALUABLE.

4 CHAIRMAN KLEIN: I THINK DR. LEON THAL.

5 DR. THAL: DO YOU HAVE AN ESTIMATE ABOUT WHEN
6 THE FUNDING WOULD ACTUALLY START FOR THE TRAINING
7 GRANTS, BEST ESTIMATE?

8 DR. HALL: WELL, IT DEPENDS ON WHEN WE'RE
9 ABLE TO GET OUR BRIDGE FINANCING. AND THE GRANTS HAVE
10 BEEN APPROVED, AS YOU KNOW, AT OUR LAST MEETING. WE
11 ARE WORKING HARD ON THE TWO OTHER ELEMENTS THAT HAVE TO
12 BE IN PLACE; THAT IS, INTERIM REGULATIONS AND OUR
13 GRANTS ADMINISTRATION POLICY. I THINK BOTH OF THOSE
14 ARE COMING ALONG SATISFACTORILY. AND I THINK IF THE
15 BOARD AGREES WITH OUR EFFORTS IN THIS DIRECTION, THEN
16 WE COULD IN PRINCIPLE, I THINK, HAVE THESE OUT WHENEVER
17 THE MONEY CAME IN ANY TIME AFTER THE FIRST OF THE YEAR.

18 ANY OTHER COMMENTS ON THE MEETING OR THE
19 STRATEGIC PLAN IN PARTICULAR?

20 CHAIRMAN KLEIN: I'M SORRY. DR. SUSAN
21 BRYANT.

22 DR. BRYANT: I WAS JUST GOING TO SAY I THINK
23 ACTUALLY FROM BEING IN AN ACADEMIC INSTITUTION POINT OF
24 VIEW, THIS ISSUE ABOUT THE SAFETY OF EGG DONATIONS TO
25 WOMEN IS A MAJOR ISSUE AMONG FACULTY AND STUDENTS AND

1 SO FORTH. SO I CAN SEE THIS AS BEING EXTREMELY
2 VALUABLE BOTH HERE AND ELSEWHERE.

3 DR. WRIGHT: REPRESENTING NOT AN ACADEMIC
4 COMMUNITY, BUT WHEN THIS TOPIC CAME UP AND WE SEE IT IN
5 ALL THE REPORTS AND THE WEBSITES, ETC., I WAS
6 INTERESTED IN LEARNING MORE ABOUT THE RISKS AND TRIED
7 TO RESEARCH THAT MYSELF. AS YOU SAID, IT'S VERY
8 DIFFICULT. THERE'S NO SUMMARY DOCUMENT, NO CONSENSUS
9 STATEMENT. SO I THINK THIS WOULD BE A GREAT SERVICE.

10 CHAIRMAN KLEIN: THANK YOU. DR. HALL, I
11 WOULD ALSO LIKE TO SUPPLEMENT THE RESPONSE DEALING WITH
12 THE FUNDING FOR THE TRAINING GRANTS, AND TELL YOU THAT
13 MY INITIAL GOAL WAS TO ORIGINALLY DO THE BOND
14 ANTICIPATION NOTES TO FUND JUST THE TRAINING GRANTS.
15 WE HAVE SOME VERY IMPORTANT SUPPORT OUT THERE IN THE
16 COMMUNITY THAT HAS PRESENTED A LEADERSHIP CONCEPT THAT
17 WE SHOULD DO 50 MILLION IN THE BAN'S SO WE COULD HAVE
18 FUNDS AVAILABLE FOR THE SECOND PROGRAM, WHETHER IT'S
19 THE INNOVATION TRAINING GRANT -- INNOVATION RESEARCH
20 GRANT PROGRAM OR ANOTHER PROGRAM THAT THE BOARD MAY
21 SELECT TO PROCEED WITH.

22 AND WE HAVE INTERNALLY ACCEPTED THE CHALLENGE
23 OF ATTEMPTING TO MEET THAT \$50 MILLION GOAL, WHICH, OF
24 COURSE, TAKES MORE TIME. IF, IN FACT, IT PROVES TOO
25 DIFFICULT TO REACH THE \$50-MILLION NUMBER QUICKLY, THEN

1 IT WOULD BE PERHAPS PRUDENT TO STEP BACK AND FUND THE
2 INFRASTRUCTURE TRAINING GRANT PROGRAM BECAUSE WE NEED
3 TO MAINTAIN OUR MOMENTUM. BUT AS LONG AS IN THE NEAR
4 FUTURE IT APPEARS THAT WE CAN REACH THE LARGER PROGRAM,
5 EVEN THOUGH IT TAKES SOME ADDITIONAL TIME, THE
6 PRESIDENT HAS POINTED OUT THAT WITH A LIMITED STAFF
7 THEY'RE WORKING AS QUICKLY AS POSSIBLE FOR THE GRANTS
8 ADMINISTRATION POLICY AND THE OTHER INCREMENTS THAT ARE
9 IMPORTANT TO PUT IN PLACE SO WE HAVE REAL
10 ACCOUNTABILITY ON THIS ON THE GRANT ADMINISTRATION
11 PROGRAM. AND WE ARE CONSIDERING PART OF THIS UNDER
12 ITEM 16 TODAY.

13 SO AS DR. HALL HAS SAID, IT IS OUR GOAL TO
14 MOVE THIS MONEY OUT VERY QUICKLY, AND WE ARE SENSITIVE
15 TO TIME. WE ARE SENSITIVE TO MAINTAINING MOMENTUM. AT
16 THE MOMENT WE ARE WORKING EXTREMELY DILIGENTLY WITH
17 INTENSE COMMITMENT ON MEETING THIS HIGHER CHALLENGE
18 THAT HAS BEEN PUT BEFORE US OF TRYING TO FUND THE 50
19 MILLION. DR. THAL.

20 DR. THAL: AS A FOLLOW-UP, I WOULD JUST MAKE
21 THE COMMENT THAT I THINK IT'S GREAT TO GO AFTER MORE
22 MONEY. I THINK IT'S A QUESTION OF -- IT'S A TRADE-OFF
23 AGAINST TIME. AND I THINK TO -- GIVEN THE FACT THAT WE
24 APPROVED THE GRANTS AWHILE AGO, THAT I THINK WE WOULD
25 LIKE TO NOT DELAY THEM BEYOND JANUARY.

1 CHAIRMAN KLEIN: RIGHT. I THINK THAT'S
2 EXCELLENT ADVICE, AND WE WOULD TAKE IT VERY SERIOUSLY.
3 ON THE NEXT ITEM ON THE AGENDA, ITEM 10,
4 STRATEGIC CONSIDERATION OF THE FORMATION OF THE
5 STRATEGIC PLANNING SUBCOMMITTEE, A NUMBER OF BOARD
6 MEMBERS HAVE IDEAS THEY'VE PUT FORWARD INFORMALLY
7 INDIVIDUALLY ON THE STRATEGIC PLANNING SUBCOMMITTEE.
8 WHAT I WOULD LIKE TO DO AT THIS MEETING IS GET A SENSE
9 OF WHO IS WILLING TO VOLUNTEER FOR THIS COMMITTEE SO WE
10 CAN SEE WHAT KIND OF PERSONNEL POWER WE HAVE FROM THE
11 BOARD FOR THIS COMMITTEE AND COME BACK FOR ACTION AT
12 THE DECEMBER MEETING WITH THE FULL MISSION STATEMENT,
13 THE TIME FRAME THAT DR. PIZZO REFERRED TO, THE PROCESS
14 IN OUTLINE FORM SO THAT WE CAN HAVE A TIME TO
15 INCORPORATE THESE SUGGESTIONS OF VARIOUS BOARD MEMBERS
16 AND HAVE A VERY ORGANIZED PACKAGE TO PRESENT.
17 SO AT THIS TIME I WOULD MERELY ASK WHICH
18 BOARD MEMBERS MIGHT BE WILLING TO VOLUNTEER FOR THIS
19 COMMITTEE, UNDERSTANDING THAT THAT IS CONDITIONAL
20 BECAUSE THEY'LL WANT TO SEE THE WHOLE TIME FRAME AND
21 PRODUCTS AND MISSION STATEMENT. BUT AS A SHOWING OF
22 INTEREST, SO WE KNOW WHAT WE HAVE TO WORK WITH,
23 WHICH -- IF BOARD MEMBERS COULD JUST RAISE THEIR HAND
24 TO IDENTIFY WHO MIGHT BE WILLING TO SERVE ON THIS
25 COMMITTEE. I'M JUST GOING TO GO FROM LEFT TO RIGHT.

1 DR. SUSAN BRYANT, DR. LEON THAL, DR. PRIETO, DR. CLAIRE
2 POMEROY, DR. HENDERSON, DR. REED, DR. OS STEWARD.

3 LET ME GO THROUGH THIS AND THEN LET ME MAKE A
4 COMMENT. DR. TED LOVE, DR. KESSLER, DAVID
5 SERRANO-SEWELL, DR. PIZZO. JEFF SHEEHY IS INTERESTED,
6 ACCORDING TO DAVID. SHERRY LANSING, JOAN SAMUELSON,
7 DR. MICHAEL FRIEDMAN, DR. JANET WRIGHT.

8 I WANT TO TELL YOU THAT AFTER 50 PUBLIC
9 MEETINGS, IT IS EXTRAORDINARY THE COMMITMENT OF THIS
10 BOARD. IT IS IMPRESSIVE AND INSPIRING. THE -- WHEN WE
11 LAY OUT THIS PROCESS, IF THERE IS A PART OF THIS
12 PROCESS THAT CONTEMPLATES, AS I EXPECT IT WILL,
13 BRINGING THIS WHOLE PLAN BACK TO THE BOARD FOR REAL
14 SUBSTANTIVE MATTERS AND IN-DEPTH REVIEW, WE MAY FIND
15 THAT WE DON'T NEED AS MANY BOARD MEMBERS TO ACTIVELY BE
16 IN THE WORKING SUBCOMMITTEE. AND I THINK IT'S
17 IMPORTANT TO INFORM EVERYONE OF THE NUMBER OF MEETINGS
18 ANTICIPATED TO SEE WHETHER PEOPLE'S TIME WILL REALLY
19 PERMIT THIS PARTICIPATION. BUT IT IS INSPIRING
20 NEVERTHELESS. THANK YOU VERY MUCH.

21 MR. SERRANO-SEWELL: THIS IS A QUESTION
22 BETTER DIRECTED TO OUR GENERAL COUNSEL. THEY DON'T
23 HAVE TO ANSWER NOW, BUT MAYBE LATER, BUT IT'S SOMETHING
24 THAT I WANT -- A CONCEPT THAT I WANT TO --

25 CHAIRMAN KLEIN: I JUST WANT TO INTRODUCE

1 DAVID SERRANO-SEWELL FOR THE RECORD.

2 MR. SERRANO-SEWELL: IT'S A CONCEPT THAT I
3 WANT TO INTRODUCE FOR THIS STRATEGIC PLANNING
4 COMMITTEE. AND THAT IS, PERMITTING THE ICOC MEMBERS
5 THAT CANNOT APPOINT AN ALTERNATE, FOR THIS STRATEGIC
6 PLANNING COMMITTEE ONLY, THAT THOSE ICOC MEMBERS CAN
7 APPOINT A DESIGNEE TO THIS WORKING GROUP BECAUSE THERE
8 WILL BE LOTS OF MEETINGS. AND I KNOW THAT MAY TOUCH ON
9 A LOT OF QUESTIONS AND LEGAL DA-DA-DA-DA, SO IT'S A
10 CONCEPT I'D LIKE TO INTRODUCE. DON'T HAVE TO ANSWER IT
11 NOW. OF COURSE, IT'S -- I HAVE A PREFERENCE THAT FOR
12 THIS PLANNING COMMITTEE, THAT I HAVE THE OPTION TO
13 APPOINT A REPRESENTATIVE, A DELEGATE, AN ALTERNATE,
14 WHATEVER YOU WANT TO CALL, IT TO THIS WORKING GROUP.

15 CHAIRMAN KLEIN: I'LL ASK COUNSEL TO REPORT
16 BACK TO US AT THE DECEMBER MEETING ON THAT QUESTION.

17 MR. SERRANO-SEWELL: I NEED IT BEFOREHAND.

18 CHAIRMAN KLEIN: IN THE NEXT WEEK, WOULD THAT
19 WORK, NEXT TWO WEEKS.

20 MR. SERRANO-SEWELL: THANK YOU.

21 CHAIRMAN KLEIN: YES. COUNSEL SAYS THAT TIME
22 FRAME WILL WORK.

23 IT IS NOW WITH GREAT PLEASURE THAT I TURN
24 OVER THE CONSIDERATION OF THE REPORT ON INTELLECTUAL
25 PROPERTY TAX FORCE SUBCOMMITTEE TO OUR OWN DR. ED

1 PENHOET.

2 DR. PENHOET: THANK YOU. WE DO HAVE A TASK
3 FORCE AT WORK. UNDER TAB 11 IN YOUR BOOK, WE HAVE A
4 SHORT-TERM GANT CHART FOR WHAT WE HOPE TO ACCOMPLISH
5 BETWEEN NOW AND DECEMBER 6TH. YOU WILL SEE, IF YOU
6 LOOK AT THAT, WE DID HAVE A MEETING OF OUR TASK FORCE
7 ON OCTOBER 25TH TO HEAR TWO THINGS. PRIMARILY TO HEAR
8 A VERBAL DESCRIPTION OF THE CCST REPORT, WHICH I HOPE
9 ALL OF YOU HAVE RECEIVED AND HAVE HAD A CHANCE TO READ,
10 AND GIVEN THE OPPORTUNITY FOR THOSE OF US WHO WERE
11 THERE TO QUESTION THE REPRESENTATIVES OF CCST ABOUT THE
12 REPORT. AND THE SECOND PART OF THE -- WELL, THERE WERE
13 THREE PARTS OF THE MEETING.

14 THE SECOND PART WAS A PRESENTATION BY FRED
15 DOREY, AN ATTORNEY WHO'S A LONGTIME OBSERVER AND
16 PARTICIPANT IN MANY WAYS IN THE BIOTECHNOLOGY INDUSTRY,
17 ON THE IMPORTANCE OF INTELLECTUAL PROPERTY AND THE
18 RELATIONSHIPS BETWEEN UNIVERSITIES AND THE PRIVATE
19 SECTOR IN BUILDING CALIFORNIA'S BIOTECHNOLOGY INDUSTRY.

20 AND THEN THIRD OF ALL, WE HEARD COMMENTS FROM
21 A NUMBER OF MEMBERS OF THE AUDIENCE, WHICH ALSO WERE
22 PART OF THAT MEETING.

23 AS YOU CAN SEE, THE NEXT EVENT WAS HALLOWEEN,
24 NOT A COINCIDENCE PERHAPS. WE HAD A LEGISLATIVE
25 HEARING IN SAN FRANCISCO, WHICH TURNED OUT TO BE

1 ACTUALLY QUITE USEFUL AND TOOK UP MOST OF THE DAY ON
2 MONDAY HEARING A VARIETY OF DIFFERENT VIEWS ABOUT
3 INTELLECTUAL PROPERTY AND ADVICE FROM A NUMBER OF
4 PEOPLE TO US AND TO THE LEGISLATURE ABOUT HOW WE SHOULD
5 HANDLE THESE ISSUES.

6 THERE IS AN EXPECTATION TO THAT NOVEMBER
7 17TH, A VERY IMPORTANT STUDY WILL BE INTRODUCED BY THE
8 NATIONAL RESEARCH COUNCIL. THIS IS A STUDY WHICH HAS
9 BEEN GOING ON FOR SOME TIME RELATING TO THE PATENTING
10 AND USE OF PATENTS IN THE FIELD OF GENES AND PROTEINS.
11 STEM CELLS WERE NOT A SPECIFIC PART OF THIS REPORT,
12 WILL NOT BE A SPECIFIC PART OF THE REPORT, BUT I
13 BELIEVE THAT THE PRINCIPLES WHICH WILL BE ARTICULATED
14 IN THAT REPORT ARE LIKELY TO BE EASILY EXTENDED TO STEM
15 CELLS. SO WE LOOK FORWARD TO RECEIVING THAT ON THE
16 17TH.

17 NOVEMBER 22D WE' LL HAVE A SECOND IP TASK
18 FORCE MEETING AT STANFORD -- THANK YOU FOR HOSTING
19 US -- TO FURTHER CONSIDER WHAT WE' VE HEARD IN THESE
20 VARIOUS MEETINGS AND IN THE NRC REPORT WITH AN
21 INTENTION OF COMING TO A CONCLUSION ABOUT A
22 RECOMMENDATION TO THE ICOC FOR AN INTERIM POLICY ON OUR
23 MEETING OF DECEMBER 6TH. THE INTERIM POLICY WOULD
24 APPLY ONLY TO TRAINING GRANTS. SO IT'S A LIMITED
25 OBJECTIVE. AND THE PRIMARY PURPOSE OF TRAINING GRANTS

1 IS NOT TO GENERATE INTELLECTUAL PROPERTY OR TO DO
2 RESEARCH, BUT TO TRAIN PEOPLE. SO WE HOPE TO HAVE A
3 SIMPLE PROPOSAL IN PLACE BY THE DECEMBER 6TH MEETING.

4 WE WILL PRESENT OUR THOUGHTS TO THE STANDARDS
5 WORKING GROUP MEETING ON DECEMBER 1ST, AND THEN BRING
6 THAT POLICY TO YOU ON DECEMBER 6TH.

7 THE LONG-TERM GOALS OF OUR GROUP REMAIN TO
8 DEFINE A FINAL POLICY, WHICH WE HOPE TO HAVE IN PLACE
9 BY THE FEBRUARY BOARD MEETING SO THAT THAT CAN BE
10 APPLIED TO THE RESEARCH GRANTS THAT WE'LL MAKE GOING
11 FORWARD. SO WE STILL HAVE A LOT OF WORK IN FRONT OF
12 US.

13 LET ME TAKE JUST A FEW MINUTES, IF I MIGHT,
14 TO CHARACTERIZE WHAT WE'VE HEARD. ALTHOUGH WE HAVE ALL
15 GOTTEN COPIES OF THE CCST REPORT, I'LL JUST QUICKLY
16 READ WHAT THEIR PRINCIPAL RECOMMENDATIONS WERE.

17 NO. 1, TO PERMIT GRANTEES TO OWN THE IP
18 RIGHTS FROM CIRM-FUNDED RESEARCH. I THINK WITH FEW
19 EXCEPTIONS THIS HAS BEEN A DOMINANT THEME THROUGHOUT
20 MOST OF WHAT WE'VE HEARD, THAT IT'S LIKELY TO BE
21 IMPRACTICAL FOR CIRM TO OWN ALL THE TECHNOLOGY ITSELF.
22 FRANKLY, I THINK WE PROBABLY DON'T HAVE THE FINANCIAL
23 RESOURCES TO KEEP TRACK OF IT ALL, AMONG OTHER THINGS.

24 SECOND, THAT REQUIRE GRANTEE INSTITUTIONS TO
25 PROVIDE A PLAN DESCRIBING HOW IP WILL BE MANAGED BY

1 THEM FOR THE ADVANCEMENT OF SCIENCE AND CALIFORNIA
2 PUBLIC BENEFIT.

3 THE THIRD IS TO GRANT BASIC RESEARCH FUNDS
4 WITHOUT REQUIRING THAT GRANTEES COMMIT TO PROVIDING A
5 REVENUE STREAM TO THE STATE. IF, HOWEVER, A REVENUE
6 STREAM DEVELOPS OVER TIME, REVENUES WILL BE REINVESTED
7 IN RESEARCH AND EDUCATION. THIS IS A CONTROVERSIAL
8 RECOMMENDATION OF CCST, AND WE'LL HEAR MORE ABOUT THAT
9 LATER, I'M SURE.

10 FOUR, GENERALLY MAKE CIRM-DEVELOPED RESEARCH
11 TOOLS WIDELY AVAILABLE TO OTHER RESEARCHERS. A COMMON
12 THEME IN WHAT WE'VE HEARD FROM A NUMBER OF GROUPS.

13 FIVE, REQUIRE DILIGENT EFFORTS TO DEVELOP
14 CIRM-FUNDED IP INTO THERAPEUTICS AND DIAGNOSTICS THAT
15 CAN BENEFIT THE PUBLIC.

16 SIX, RETAIN WITHIN CIRM BAYH-DOLE-LIKE RIGHTS
17 TO STEP IN IF THE OWNER OF IP IS NOT UNDERTAKING
18 APPROPRIATE STEPS TO TRANSFER TECHNOLOGY TO BENEFIT THE
19 PUBLIC.

20 SEVEN, TO LEAVE LICENSE PARTICULARS TO THE
21 OWNER WHO IS IN THE BEST POSITION TO JUDGE HOW BEST TO
22 ENSURE THAT DISCOVERIES ARE MADE WIDELY AVAILABLE
23 THROUGH COMMERCIALIZATION OR OTHERWISE.

24 NO. 8, RESERVE THE RIGHT TO USE IP BY OR ON
25 BEHALF OF CIRM.

1 AND, 9, ESTABLISH AND MAINTAIN THE CIRM
2 DATABASE TO TRACK ALL IP GENERATED THROUGH CIRM
3 FUNDING.

4 SO THOSE ARE THE NINE RECOMMENDATIONS OF THE
5 CCST. WE DID, AS I SAID, HEAR A PRESENTATION ABOUT THE
6 IMPORTANCE OF THE ACADEMIC COMMUNITY AND OF THE
7 LICENSING PROVISIONS INHERENT IN BAYH-DOLE AND THE
8 GROWTH OF THE BIOTECH INDUSTRY. I WON'T REPEAT THAT
9 PRESENTATION HERE, BUT SIMPLY STATE THAT CALIFORNIA'S
10 LEADERS WHO HAVE POSITIONS IN BIOTECH TODAY IS ARGUABLY
11 BASED ON PRIMARILY ON THE STRENGTH OF THE ACADEMIC
12 RESEARCH IN THE STATE AND FACILE TRANSFER OF TECHNOLOGY
13 FROM THE UNIVERSITIES TO PRIVATE ENTERPRISE HERE.

14 THE MEETING ON MONDAY, AS I SAID, WAS
15 SPONSORED BY THE LEGISLATURE. THERE WERE THREE MEMBERS
16 OF THE ASSEMBLY AND ONE MEMBER OF THE SENATE IN THAT
17 MEETING. THE THREE MEMBERS OF THE ASSEMBLY WERE GENE
18 MULLIN, DAVE JONES, AND WILMA CHAN, AND THE ONE
19 REPRESENTATIVE FROM THE SENATE WAS DEBORAH ORTIZ.

20 THERE WERE A NUMBER OF PRESENTATIONS THERE
21 DURING THE DAY AS OBVIOUS. SENATOR ORTIZ OPENED THE
22 MEETING BY ARTICULATING SOME QUESTIONS OF HERS. WHO
23 OWNS THE RESULTS WAS ONE QUESTION. HOW TO ENSURE
24 RETURN ON INVESTMENT TO THE STATE. MADE THE POINT
25 NUMEROUS TIMES DURING THE DAY THAT DIRECT PAYMENTS MAY

1 FORCE THE USE OF TAXABLE BONDS. MAYBE I' LL JUMP AHEAD
2 A LITTLE BIT TO SAY THAT THERE WAS ALSO A PRESENTATION
3 BY THE STATE TREASURER' S OFFICE AND BOND COUNSEL ON
4 THIS ISSUE. I THINK THERE' S AN EMERGING CONSENSUS NOW
5 THAT IF THE STATE IS GOING TO BE -- RECEIVE
6 REMUNERATION AS A RESULT OF LICENSING OF TECHNOLOGY
7 FUNDED WITH THE USE OF STATE FUNDS, THAT THAT WILL
8 LIKELY FORCE THE USE OF TAXABLE BONDS TO FUND THAT
9 PORTION OF THE RESEARCH.

10 THERE ARE -- HOW SHALL I SAY -- THERE ARE
11 PIECES OF THIS AROUND THE MARGINS WHICH, WHILE YOU
12 MIGHT BE ABLE TO CARVE OUT CERTAIN KIND OF GRANTS, FOR
13 EXAMPLE, TRAINING GRANTS, IF THERE WAS NO IP ASSOCIATED
14 WITH A TRAINING GRANT, YOU MIGHT BE ABLE TO USE
15 NONTAXABLE BONDS FOR THAT PURPOSE, ETC. ; BUT THERE' S A
16 GROWING CONSENSUS, I BELIEVE, THAT IF THE PRIMARY
17 INTENT IS TO GENERATE RESEARCH WHICH RESULTS IN
18 TECHNOLOGY WHICH WOULD BE LICENSED AND RETURN REVENUES
19 TO THE STATE, THAT IT MIGHT BE FORCED TO USE TAXABLE
20 BONDS.

21 PROP 71 CLEARLY CALLS FOR THE USE OF TAXABLE
22 BONDS IF IT IS APPROPRIATE. SO IT BECOMES SIMPLY AN
23 ECONOMIC ISSUE GOING FORWARD.

24 THERE WAS A FAIR AMOUNT OF DISCUSSION ON
25 MONDAY OF WHAT THE EXCESS COST OF TAXABLE BONDS WOULD

1 BE IN THIS. OF COURSE, IT DEPENDS IN THE END ON THE
2 MIX AND ON THE DIFFERENTIAL RATES OF INTEREST
3 ASSOCIATED WITH TAXABLE VERSUS NONTAXABLE BONDS. AND
4 THE ESTIMATES RANGE FROM A LOW OF \$420 MILLION IN
5 EXCESS COST, IF IT WAS ALL FUNDED WITH TAXABLE BONDS,
6 TO A HIGH OF \$690 MILLION. SO THAT SEEMS TO BE THE
7 RANGE THAT PEOPLE ARE NOW TALKING ABOUT.

8 CLEAR, ANOTHER CONCERN ARTICULATED BY SENATOR
9 ORTIZ WAS TO ENCOURAGE DISSEMINATION. AND FINALLY, A
10 PLEA THAT WE TRY TO ATTEMPT TO ENSURE ACCESSIBILITY AND
11 AFFORDABILITY IN WHAT WE DO FOR CALIFORNIANS.

12 AND THEN FINALLY, SHE MADE A STATEMENT THAT
13 THE CCST REPORT GLOSSES OVER MANY IMPORTANT ISSUES.
14 THERE WERE SOME CRITICISMS OF THE CCST REPORT; BUT ON
15 THE OTHER HAND, MANY PEOPLE THOUGHT THE CCST DID A VERY
16 FINE JOB. THAT IS WHAT IT IS.

17 WILMA CHAN EXPRESSED CONCERNS THAT PROP 71
18 RAISED HIGH EXPECTATIONS ON THE PART OF CALIFORNIA
19 VOTERS AND THAT WE HAVE TO KEEP THAT IN MIND. AND SHE
20 EMPHASIZED AGAIN THAT THE STATE SHOULD RECEIVE SOME
21 KIND OF FINANCIAL BENEFIT AS A RESULT OF ITS
22 INVESTMENT.

23 FINALLY, DAVE JONES' CONCERNS WERE HE THOUGHT
24 THE VOTERS EXPECTED TO GET TREATMENTS. THEY EXPECTED
25 THEM TO BE ACCESSIBLE AND AFFORDABLE, AND THEY EXPECTED

1 TO GET SOME SHARE OF THE REVENUES THAT ASSOCIATE WITH
2 THIS.

3 THERE WAS, AS I SAID BEFORE, PRESENTATION BY
4 THE STATE TREASURER AND LEGISLATIVE COUNCIL PRIMARILY
5 AROUND THIS ISSUE OF TAXABLE VERSUS NONTAXABLE BONDS.
6 AND I THINK THAT'S AN ISSUE WE HAVE TO LOOK AT GOING
7 FORWARD TO SEE WHAT THE RELATIVE BENEFITS OF THE USE OF
8 REMUNERATION TO THE STATE WOULD BE. ONE OF THE
9 QUESTIONS STILL OVERHANGING THE ISSUE IS WHETHER THE
10 UNIVERSITY OF CALIFORNIA PER SE IS A STATE AGENCY; AND,
11 THEREFORE, IF THE UC COLLECTED ROYALTIES, WHETHER THAT
12 WOULD, IN FACT, BE A DE FACTO REMUNERATION TO THE
13 STATE.

14 REBECCA EISENBERG, WHO IS A VERY
15 KNOWLEDGEABLE PROFESSOR OF LAW AT THE UNIVERSITY OF
16 MICHIGAN, WAS ON THE PHONE ON MONDAY. SHE IS, BY THE
17 WAY, ONE OF THE AUTHORS OF THE UPCOMING REPORT THAT WE
18 EXPECT FROM THE NATIONAL RESEARCH COUNCIL. SHE HAD A
19 NUMBER OF THINGS THAT SHE ARTICULATED. VERY THOUGHTFUL
20 PRESENTATION, IN MY VIEW. FIRST OF ALL, SHE SAID WE
21 SHOULD BE CAREFUL NOT TO DEFINE CALIFORNIA OUTSIDE THE
22 U. S. RESEARCH COMMUNITY SO THAT WE SHOULD DEVISE A
23 POLICY WHICH IS COMPATIBLE WITH BAYH-DOLE. AND THIS,
24 AGAIN, IS A RECURRING THEME, AND I THINK SOMETHING WE
25 HAVE TO KEEP INTO ACCOUNT.

1 BAYH-DOLE HAS -- THERE ARE TWO ASPECTS OF
2 BAYH-DOLE. ONE THERE IS WHAT BAYH-DOLE IS AND HOW
3 BAYH-DOLE HAS BEEN IMPLEMENTED, WHICH ARE TWO DIFFERENT
4 THINGS.

5 AND I THINK WE HEARD FROM A NUMBER OF PEOPLE
6 THAT -- WELL, FIRST OF ALL, THE FEDERAL LAW SAYS IF
7 THERE'S \$1 OF FEDERAL MONEY THAT GOES INTO A PROGRAM,
8 YOU HAVE TO FOLLOW THE FEDERAL LAW, WHICH IS BAYH-DOLE.
9 BUT CLEARLY WITHIN BAYH-DOLE, YOU CAN FOLLOW THE LAW OF
10 BAYH-DOLE, WHICH IS FAIRLY SIMPLE, BUT NOT FOLLOW ALL
11 THE PRACTICES OF BAYH-DOLE. SO SHE WAS CLEAR ON THIS
12 COMPATIBILITY ISSUE AS OPPOSED TO ANY ATTEMPT TO ADOPT
13 BAYH-DOLE WITHOUT MODIFICATION.

14 SHE URGED US TO KEEP IP OPEN FOR RESEARCH
15 PURPOSES. THERE'S A NATIONWIDE NOW, I THINK, EFFORT TO
16 TRY TO CREATE A LAW, A FEDERAL LAW, TO CREATE A
17 RESEARCH EXCEPTION FOR PATENTED TECHNOLOGIES. AND THAT
18 WAS PART OF HER RECOMMENDATION. SHE DID SAY, BY THE
19 WAY, THAT SHE MIGHT HAVE A DIFFERENT SET OF
20 RECOMMENDATIONS IF SHE WAS IN FRONT OF THE U. S.
21 CONGRESS THAN SHE HAS FOR CALIFORNIA, BUT SHE KEPT
22 EMPHASIZING DO NOT MAKE AN ISLAND OF YOURSELF HERE TOO
23 SMALL IN THE GREAT SCHEME OF THINGS, TO CREATE A
24 COMPLETELY DIFFERENT SYSTEM THAN THE REST OF THE
25 COUNTRY.

1 SHE SAID WE COULD NOT CONSIDER A POLICY THAT
2 PROHIBITS IP GENERATION FROM CERTAIN KINDS OF GRANTS,
3 FOR EXAMPLE, TRAINING GRANTS, WHICH WOULD BE ONE SIMPLE
4 SOLUTION. SHE SAID -- HER ADVICE WAS NOT TO STRUCTURE
5 A PATENT POOL TOO EARLY IN THE PROGRAM. THAT IF YOU
6 WANTED TO MAKE POOL PATENTS, THAT YOU SHOULD DO SO WITH
7 SPECIFIC GOALS IN MIND.

8 AGAIN, ENSURE THAT DATA DISSEMINATION IS A
9 FEATURE OF OUR GUIDELINES. SHE RECOMMENDED AGAINST A
10 TAX ON THE ROYALTIES; THAT IS, DIRECT SHARING OF
11 ROYALTIES BETWEEN THE GRANTEES AND THE STATE. SHE
12 RECOMMENDED AGAINST A PREFERENCE FOR CALIFORNIA
13 COMMERCIAL ENTITIES, INTERESTINGLY ENOUGH, BELIEVING
14 THAT THE TECHNOLOGY SHOULD BE COMMERCIALIZED BY
15 WHATEVER ENTITY IS MOST LIKELY TO MAKE IT --
16 SUCCESSFULLY CARRY IT OUT. SHE DID RECOMMEND MARCH-IN
17 RIGHTS FOR PUBLIC HEALTH REASONS OR A FAILURE TO
18 DEVELOP.

19 AND THEN SHE WENT ON TO MAKE A FEW OTHER
20 RECOMMENDATIONS. SHE ALSO RECOMMENDED THAT WE USE
21 HEALTHCARE SYSTEM AND INSURANCE REGULATION RATHER THAN
22 IP TO ACHIEVE THE GOAL OF AFFORDABILITY.

23 MR. GOOZNER, WHO WAS ON A SUBSEQUENT PANEL,
24 RECOMMENDED THAT PATENT POOLING SHOULD BE SOMETHING WE
25 ENCOURAGE FROM THE BEGINNING, AND HE USED LINUX AND AG

1 POLICIES AS EXAMPLES OF THAT. HE ACTUALLY ADVOCATED A
2 PRICE FOR A SUCCESSFUL THERAPY DEVELOPMENT RATHER THAN
3 ONGOING, LONG-TERM ENGAGEMENT BY A COMPANY. ONCE THE
4 COMPANY HAD RECEIVED THE PRIZE, THAT THEN THE ACTUAL
5 PRODUCT WOULD BE AVAILABLE FOR GENERIC MANUFACTURER BY
6 THOSE.

7 MS. WASHBURN RECOMMENDED AN INDEPENDENT
8 OFFICE TO HANDLE IP WITH BROAD REPRESENTATION. SO THAT
9 IT'S ESSENTIALLY FOLLOWING UP ON THE POOL CONCEPT. SHE
10 EMPHASIZED SHARING TOOLS AND TECHNOLOGIES FOR RESEARCH
11 PURPOSES. AGAIN, A COMMON THEME. AND SHE RECOMMENDED
12 AGAINST CREATING A POLICY WHICH WAS INCONSISTENT WITH
13 BAYH-DOLE. AGAIN, ALTHOUGH SHE HAD SOME NOVEL IDEAS
14 WITH RESPECT TO HOW TO HANDLE THE IP, SHE ALSO BELIEVED
15 IN WAS IN CALIFORNIA'S INTEREST TO BE INCONSISTENT WITH
16 FEDERAL LAW IN THIS REGARD.

17 MR. BENNETT, DR. BENNETT FROM THE UNIVERSITY
18 OF CALIFORNIA EMPHASIZED THAT ONE IMPORTANT ASPECT OF
19 BAYH-DOLE WAS THE CLARITY OF IP OWNERSHIP, AND THAT
20 LOCAL ADMINISTRATION OF IP POLICIES WAS LIKELY TO BE
21 MOST EFFECTIVE GOING FORWARD.

22 WE THEN HEARD ABOUT SOME OTHER ALTERNATIVE IP
23 MODELS. I THINK THE MOST WELL DEVELOPED IS IAVI, WHICH
24 IS A GROUP DESIGNED PRIMARILY TO FURTHER INTEREST IN
25 AIDS VACCINES WHERE PEOPLE WHO GET IAVI MONEYS FOR

1 VACCINE DEVELOPMENT AGREE TO MAKE THE FRUITS OF THEIR
2 WORK AVAILABLE IN THE THIRD WORLD AT MODEST COST, AND
3 TALKED ABOUT THE WAYS OF DOING THAT IN HANDLING THE
4 ISSUE OF ESSENTIALLY A TWO-TIER PRICING SYSTEM WITH ONE
5 SET OF PRICES AVAILABLE FOR THIRD WORLD COUNTRIES AND
6 THEN ANOTHER SET FOR THE DEVELOPED WORLD.

7 GAVE NO SPECIFIC RECOMMENDATIONS TO US BEYOND
8 TELLING US HOW THEY HANDLE IT, BUT INDICATED THAT THEY
9 BELIEVED THAT THE CCST REPORT WAS, QUOTE, UNQUOTE, VERY
10 WELL DONE.

11 WE HEARD ABOUT SOME ALTERNATIVE IP MODELS
12 FROM CAROL MIMURA AT UC BERKELEY WHICH HAS STARTED
13 WHAT'S CALLED THE SOCIALLY RESPONSIBLE LICENSING
14 PROGRAM. AGAIN, A PROGRAM THAT IS NOW THREE YEARS OLD.
15 THEY HAVE A NUMBER OF AGREEMENTS. ITS EFFORT IS
16 PRIMARILY TO TRANSLATE U.S. TECHNOLOGY BASE INTO
17 PRODUCTS WHICH CAN BE VERY USEFUL IN THE THIRD WORLD.
18 AND THAT SHE DESCRIBED HOW THAT WORKS, AND IT'S BEEN
19 EFFECTIVE IN ACTUALLY GETTING SOME MODERN TECHNOLOGY AT
20 WORK IN THE THIRD WORLD, BUT HER COMMENTS ABOUT ITS
21 APPLICABILITY TO CALIFORNIA WERE NOT CLEAR. AND SHE
22 SAID THAT IN THE END YOU STILL HAVE TO ENSURE THAT
23 PRODUCT -- THE BENEFITS OF THE RESEARCH GET
24 COMMERCIALIZED.

25 AND THEN, FINALLY, THERE WERE A NUMBER OF

1 STAKEHOLDER AND PUBLIC COMMENTS FROM PUBLIC INTEREST
2 GROUPS AT THE END, SOME EMPHASIZING, AGAIN, THE RETURN
3 TO THE STATE, SOME URGING A MIXTURE OF TAX-EXEMPT AND
4 TAXABLE BONDS TO IMPLEMENT PROP 71, SOME RECOMMENDING
5 THAT WE LOOK AT MODELS IN CONNECTICUT AND WISCONSIN FOR
6 QUASI PUBLIC/NONPROFIT MODELS. AND THEN, FINALLY, A
7 RECOMMENDATION THAT THE EGG DONOR ISSUES BE CONSIDERED
8 IN DEVISING IP POLICY. I GUESS THERE WILL BE AN ISSUE
9 OF OWNERSHIP OF THE EGGS WHICH ARE TRANSFERRED.

10 SO THAT'S MAYBE A MORE FULSOME DESCRIPTION
11 THAN YOU WANTED TO HEAR THIS MORNING, BUT THAT'S THE
12 LAY OF THE LANDSCAPE HERE. BUT I THINK THE -- THERE
13 ARE SOME CONSISTENT THEMES GROWING OUT OF THIS. WE DO
14 HAVE A LOT OF WORK TO DO TO BALANCE THE VARIOUS
15 INTERESTS OF ACCESS AND AFFORDABILITY, ETC., WITH THE
16 REALITY THAT YOU ALSO HAVE TO PROVIDE ENOUGH INCENTIVE
17 TO PRIVATE SECTOR TO GO AHEAD AND DEVELOP THERAPIES AND
18 ENOUGH CERTAINTY ABOUT THEIR FUTURE THAT THEY'RE
19 WILLING TO TAKE THE RISK OF DEVELOPING THESE THERAPIES
20 AGAINST THE OTHER OBVIOUS ISSUES OF AFFORDABILITY, ETC.

21 SO WE HAVE A LOT OF WORK TO DO. WE'RE GOING
22 TO HAVE THIS MEETING ON THE 22D, AS I SAID. WE HOPE TO
23 HAVE A SIMPLE RECOMMENDATION FOR THE TRAINING GRANTS
24 ONLY ON DECEMBER 6TH. AND WE HOPE TO HAVE A POLICY TO
25 RECOMMEND TO YOU BY THE FEBRUARY BOARD MEETING SORT OF

1 ADDRESSING ALL OF THESE ISSUES.

2 WITH THAT, I'D BE HAPPY TO ANSWER ANY
3 QUESTIONS THAT YOU HAVE. FRANCISCO.

4 DR. PRIETO: GIVEN THE IMPORTANCE OF THIS AND
5 TO GET PAST THE LITIGATION AND OUR ISSUING BONDS, DO
6 YOU THINK IT'S APPROPRIATE THAT WE ASK THE IRS
7 OFFICIALLY FOR A RULING ON THE TAX-EXEMPT VERSUS
8 TAXABLE BONDS?

9 DR. PENHOET: THERE WAS A DISCUSSION AT THE
10 MEETING ON MONDAY BY BOND COUNSEL WHO POINTED OUT THE
11 IRS DOES NOT LIKE TO OPINE ON A MENU THAT YOU BRING
12 THEM AND WHERE THEY PICK AND CHOOSE. SO HE SAYS IT'S
13 VERY HARD TO GET A RULING FROM THEM UNLESS YOU HAVE A
14 SPECIFIC PROPOSAL TO LAY IN FRONT OF THEM. AT THE
15 MOMENT WE HAVE A PUNNETT SQUARE WITH LOTS OF VARIABLES
16 ON BOTH SIDES, SO IT'S A LITTLE HARD TO GET THEM TO
17 MAKE AN OPINION. BUT AS SOON AS WE ARE ABLE TO
18 ARTICULATE A POLICY WHICH IS CLEAR ABOUT WHAT WE WANT
19 TO DO, THEY'RE PREPARED TO GO AHEAD AND DO THAT.

20 CHAIRMAN KLEIN: IN THAT REGARD, I WOULD SAY
21 THAT FROM A PATIENT PERSPECTIVE IN TERMS OF BENEFIT TO
22 THE STATE, IF FUNDS WERE GOING INTO A NONPROFIT BENEFIT
23 MODEL, FOR EXAMPLE, A PORTION OF THE ROYALTIES WERE
24 GOING TO BENEFIT MODEL ACCESS FOR NEW THERAPIES FOR
25 PATIENTS IN CALIFORNIA, SO THAT WE COULD SHOW TO THE

1 STATE THAT IT WAS IN THE STATE'S HUGE ECONOMIC INTEREST
2 TO INTERVENE EARLY WITH NEW THERAPIES SO THAT IN SPINAL
3 CORD DAMAGE, FOR EXAMPLE, WHERE YOU INTERVENE AT ACUTE
4 INJURY STAGE AND DON'T HAVE SOMEONE SPENDING A LIFE
5 WITH HUGE MEDICAL COST IN A WHEELCHAIR OR IN DIABETES
6 YOU DON'T HAVE BLINDNESS AND KIDNEY LOSS. IF YOU CAN
7 AVOID MASSIVE DOWNSTREAM COST FOR THE STATE, THE STATE
8 IS BETTER OFF USING SOME OF THIS ROYALTY MONEY UP FRONT
9 FOR A MODEL ACCESS PROGRAM TO SHOW THAT THESE NEW
10 THERAPIES ARE BENEFICIAL TO THE STATE ECONOMICALLY AS
11 WELL AS REDUCING SUFFERING.

12 AND IN TERMS OF THAT MODEL, FROM A PATIENT
13 MODEL BENEFIT TO THE STATE, IT'S MY EXPECTATION WE CAN
14 GET AN IRS LETTER RULING FOR TAX-EXEMPT BOND USE, WHICH
15 IS VERY IMPORTANT IF WE'RE GOING TO ADDRESS THAT AREA.
16 SO THAT AREA OF BONDS, WHICH COULD BE A VERY
17 SUBSTANTIAL AREA OF THE BONDS, THAT BENEFITED FROM THAT
18 ROYALTY POLICY COULD BE TAX-EXEMPT BONDS, FOR EXAMPLE.

19 DR. MURPHY: THOSE OF US WHO HAVE WORKED WITH
20 BAYH-DOLE AND KNOW WHAT A POWERFUL ACT IT HAS BEEN AND
21 HOW IT'S BEEN A STIMULUS TO RESEARCH AND ALSO TO THE
22 ECONOMY, MY CONCERN ABOUT THIS IS, ONE, THAT WHATEVER
23 WE DO COULD HAVE RAMIFICATIONS IN OTHER STATES AS THEY
24 DEVELOP THE SAME KIND OF TECHNOLOGY. NO. 1.

25 NO. 2, IT COULD STIMULATE A RELOOK OR

1 RETHINKING ABOUT BAYH-DOLE FEDERALLY BECAUSE I CAN
2 UNDERSTAND THE REACTION WOULD BE, WELL, LOOK, IF
3 CALIFORNIA IS GOING TO KEEP IT FOR THEMSELVES, WHY ARE
4 WE, NIH, AND THE FEDS PUTTING MONEY INTO CALIFORNIA AND
5 NOT BENEFITING THAT WAY.

6 AND THE THIRD POINT IS DO WE HAVE ANY REPORT
7 AVAILABLE TO US THAT LOOKS AT THE EFFECT OF BAYH-DOLE
8 THROUGH NIH MONEY ON THE CALIFORNIA ECONOMY? BECAUSE I
9 CAN'T IMAGINE THAT THE NUMBERS WOULD BE ANYTHING LESS
10 THAN STARTLING, AND THAT WE COULD USE THOSE NUMBERS TO
11 BRING BACK TO GOVERNMENT, AND WE ALL REALIZE THAT
12 GOVERNMENT HAS GOT A POLITICAL HURDLE HERE, TO SHOW HOW
13 MANY COMPANIES HAVE STARTED, WHAT THE EFFECT OF
14 BAYH-DOLE HAS BEEN ON THE CALIFORNIA ECONOMY, AND THAT
15 CONTINUES TO BE ON THE CALIFORNIA ECONOMY, I THINK WE
16 SHOULD HAVE THAT INFORMATION IN OUR BACK POCKET.

17 DR. PENHOET: WELL, MARY, CAN I ASK YOU TO
18 GET COPIES OF THE FRED DOREY PRESENTATION FOR THE
19 ENTIRE BOARD TODAY BEFORE THEY LEAVE HERE BECAUSE A LOT
20 OF THAT INFORMATION IS CONTAINED WITHIN THAT DOCUMENT.
21 SO WE'D BE HAPPY TO SHARE IT. I THINK IT'S BEEN
22 CIRCULATED AMONG THE TASK FORCE, BUT I THINK WE CAN GET
23 COPIES FOR EVERYBODY TODAY.

24 THERE'S NO DOUBT CALIFORNIA IS THE LEADING
25 CENTER IN THE WORLD IN BIOTECHNOLOGY, AND IT'S BECAUSE

1 WE HAVE THE LEADING UNIVERSITIES WHO STARTED THIS
2 FIELD. IT'S EASY TO TRACE IN THAT CASE.

3 DR. BRYANT: I'D JUST LIKE TO SAY, HAVING
4 SERVED ON THE WORKING GROUP FOR THE CCST, THAT I FEEL
5 LIKE ANYTHING LESS THAN CONSISTENCY WITH BAYH-DOLE
6 WOULD BE A TOTAL GAMBLE. WE WOULD BE ENDANGERING THE
7 \$3 BILLION THAT THE STATE HAS GIVEN US, NOT SERVING THE
8 STATE. SO I THINK ALL THE EVIDENCE SHOWS THAT
9 EXPERIMENTS THAT HAVE BEEN DONE TO TRY AND ALTER
10 BAYH-DOLE HAVE BEEN UNSUCCESSFUL. I THINK IT WOULD BE
11 IRRESPONSIBLE TO GAMBLE WITH THE MONEY THAT WE'VE BEEN
12 GIVEN.

13 CHAIRMAN KLEIN: I WOULD -- WHY DON'T WE DO
14 JEFF FIRST BECAUSE I'VE ALREADY SPOKEN ONCE.

15 MR. SHEEHY: I UNDERSTAND THE CONCERN ABOUT
16 BAYH-DOLE FROM A ROYALTIES ISSUE, BUT I DON'T THINK WE
17 SHOULD BE SO UNRECEPTIVE TO OTHER IDEAS BECAUSE IT DOES
18 SEEM THAT WHERE BAYH-DOLE HAS HAD A NEGATIVE SIDE
19 EFFECT IN TERMS OF EXCESSIVE PATENTING. AND SO WE
20 SHOULD, IN ORDER TO ADVANCE THE SCIENCE, BE WILLING TO
21 LOOK AT ALTERNATIVE MODELS THAT LEAD TO MORE SHARING OF
22 KNOWLEDGE AND RESOURCES.

23 I MEAN THE SCIENTISTS, PEOPLE ACTUALLY DOING
24 THE SCIENCE, SEEM TO BE ASKING THIS, I THINK, TO LOOK
25 AT THOSE TYPES OF MODELS.

1 DR. PENHOET: IF I MIGHT ADD, I BELIEVE THAT
2 THE ISSUE OF COMPATIBILITY WITH BAYH-DOLE AND HOW
3 BAYH-DOLE IS ACTUALLY CARRIED OUT IN PRACTICE ARE TWO
4 DIFFERENT ISSUES, AND WE HAVE TO BE CAREFUL TO
5 DISTINGUISH BETWEEN THE TWO. SO WE, TO FOLLOW UP ON
6 JEFF'S COMMENT, WE COULD HAVE A POLICY WHICH SAYS THE
7 HEART OF BAYH-DOLE IS OWNERSHIP OF THE TECHNOLOGY BY
8 THE GRANTEE INSTITUTION. YOU COULD HAVE A POLICY WHICH
9 SAID THAT. YOU COULD STILL HAVE A POLICY WHICH SAYS
10 THAT IN DOING SO, THE UNIVERSITIES WOULD MAKE, FOR
11 EXAMPLE, THE RESULTS OF THEIR WORK FREELY ACCESSIBLE ON
12 A RESEARCH-ONLY BASIS TO ALL OTHER INSTITUTIONS
13 PARTICIPATING IN CIRM OR WITHIN THE STATE OR ANYWHERE
14 THAT'S COMPATIBLE WITH BAYH-DOLE, BUT NOT IDENTICAL TO
15 HOW BAYH-DOLE HAS BEEN IMPLEMENTED.

16 DR. BRYANT: THAT'S PRETTY MUCH THE WAY THAT
17 IT OPERATES NOW IS THAT THERE'S A RESEARCH -- FOR
18 RESEARCH USES, THERE ARE NONEXCLUSIVE AVAILABILITY AND
19 AN EXCLUSIVE IF YOU'RE GOING TO BE GOING INTO
20 COMMERCIALIZATION. I MEAN I AGREE.

21 DR. REED: THE OTHER POINT I WOULD MAKE IS
22 THAT WITH RESPECT TO ANY CONCERNS ABOUT PATENTS
23 BLOCKING THE ABILITY TO USE TECHNOLOGY FOR RESEARCH
24 PURPOSES, THE SUPREME COURT RECENTLY RULED ON THAT
25 ISSUE AND PROVIDED A REINTERPRETATION OF THOSE STATUTES

1 TO THE EXTENT THAT IT LIBERALIZED ACCESS TO TECHNOLOGY
2 FOR THE PURPOSE OF DEVELOPING NEW THERAPIES. SO I
3 THINK SOME OF THOSE CONCERNS THAT MAY HAVE EXISTED IN
4 THE PAST HAVE BEEN AMELIORATED TO A LARGE EXTENT BY
5 THIS RECENT SUPREME COURT RULING.

6 CHAIRMAN KLEIN: I WOULD LIKE TO ADD TO THE
7 COMMENTS BY SAYING THAT A PROGRAM, A NONPROFIT PROGRAM,
8 FOR MODEL ACCESS FOR LOW INCOME AND MODERATE INCOME
9 PATIENTS TO NEW THERAPIES COULD BE VIEWED AS AN
10 EXTENSION OF THE RESEARCH PROGRAM. CERTAINLY DURING
11 RESEARCH, MEDI-CAL AND MEDICARE PROVIDE THAT VERY LOW
12 INCOME INDIVIDUALS HAVE ACCESS TO PARTICIPATION IN
13 CLINICAL TRIALS ON THESE NEW THERAPY AREAS. BUT IF A
14 PORTION OF THE ROYALTIES WENT TO PROVIDING MODEL ACCESS
15 AFTER CLINICAL TRIALS, I THINK IT WOULD BE VIEWED AS AN
16 EXTENSION OF THE RESEARCH APPLICATIONS, IF YOU'RE
17 CREATIVE.

18 NEVERTHELESS, I WOULD ALSO LIKE TO SAY THAT,
19 JUST AS A HISTORICAL STATEMENT, WE NEED TO HAVE IN
20 CONTEXT THE FACT THAT DURING THE CAMPAIGN, THE ECONOMIC
21 PROJECTIONS WERE THAT 92 TO 98 PERCENT OF THE ECONOMIC
22 BENEFIT TO THE STATE, THE REAL PAYBACK, THE DRIVING
23 FORCE IS THE POTENTIAL THAT THESE -- THIS KNOWLEDGE
24 WOULD ENHANCE EXISTING THERAPIES AND WE AT LEAST REDUCE
25 THE COST OF SIX OF 70 CONDITIONS BY 1 TO 2 PERCENT.

1 BECAUSE OF THE ENHANCED KNOWLEDGE, WE CAN ENHANCE
2 EXISTING THERAPIES. AND SECONDLY, WE WOULD CREATE NEW
3 JOBS AND NEW TAX REVENUES. THAT'S 92 TO 98 PERCENT OF
4 THE BENEFIT.

5 WE NEED TO KEEP IN MIND THE LIMITED RANGE OF
6 BENEFIT WE'RE TALKING ABOUT HERE. AND IN TERMS OF THE
7 SPECIFIC PROJECTIONS ON IP, I ENDED UP ON MONDAY ON A
8 PANEL AT THE MILKEN STATE OF THE STATE WITH SUSAN
9 HACKWOOD, DIRECTOR OF THE CALIFORNIA COUNCIL ON SCIENCE
10 AND TECHNOLOGY. AND BEFORE AND AFTER THE PANEL, WE
11 DISCOVERED THERE MAY BE SOME FACTUAL DIFFERENCES THAT
12 WILL BRING THEIR PROJECTIONS MUCH CLOSER TO THE ONES
13 MADE DURING THE CAMPAIGN. MAINLY, THEIR FIGURES THAT
14 THEY'VE BEEN TALKING ABOUT IN IP REVENUE ARE IN PRESENT
15 DOLLAR VALUES. THE PROJECTIONS IN THE CAMPAIGN MADE IT
16 CLEAR THAT THERE WILL NO IP REVENUES FOR ABOUT 14
17 YEARS. YOU GOT TO DEVELOP ALL THESE THINGS. YOU GOT
18 TO GO THROUGH APPLIED SCIENCE, TRANSLATIONAL MEDICINE,
19 CLINICAL TRIALS, AND GET A DRUG INTO THE MARKET. SO
20 THERE'S NO THERAPY IP REVENUE PROJECTED FOR 14 YEARS,
21 AND THE AVERAGE COLLECTION IS 24 YEARS OUT.

22 THAT MEANS IF YOU LOOK AT THE 500 MILLION
23 PROJECTED AS THE LOW RANGE OF THE CONSERVATIVE CASE,
24 THE IP REVENUES IN THE PROP 71 CAMPAIGN, THAT'S
25 EQUIVALENT TO \$125 MILLION IN CURRENT REVENUE. IF

1 THEIR SLIDE THAT SUGGESTS 300 MILLION CREATES 10
2 MILLION IN PRESENT VALUE, THAT IS EQUIVALENT TO SAYING
3 IT CREATES 400 MILLION IN FUTURE VALUE. WE NEED TO
4 MAKE SURE WE'RE DEALING WITH THE SAME NUMBERS IN
5 ECONOMIC TERMS, AND WE'LL BRING OURSELVES MUCH CLOSER
6 TOGETHER.

7 ADDITIONALLY, IT'S MY UNDERSTANDING THAT WHEN
8 THE PROJECTIONS WERE DONE BY THE CALIFORNIA COUNCIL,
9 THEY DID NOT CONSIDER THAT WE WOULD EVER FUND ANY ADULT
10 STEM CELL, FETAL STEM CELL, OR CORD BLOOD RESEARCH. SO
11 WE HAVE NONE OF THE BENEFIT OF THOSE AREAS OF
12 SCIENTIFIC DISCOVERY BEING FURTHER ALONG. AND THAT IS,
13 IN FACT, NOT PROP 71 BECAUSE CERTAINLY THIS BOARD HAS
14 SAID PREVIOUSLY THAT IF IT'S THE BEST SCIENCE UNDER
15 VITAL RESEARCH OPPORTUNITIES, WE DEFINITELY CAN FUND
16 ADULT STEM CELL, CORD BLOOD STEM CELL RESEARCH, AND
17 FETAL STEM CELL RESEARCH. IT IS PART OF THE SCOPE OF
18 WHAT WE'RE CHARGED WITH.

19 SO I WOULD SAY THAT HOPEFULLY BEFORE THE
20 FINAL REPORT IS ISSUED, SOME OF THESE DIFFERENCES IN
21 ASSUMPTIONS COULD BE TAKEN INTO ACCOUNT, WHICH WILL
22 BRING THE NUMBERS MUCH CLOSER TOGETHER BETWEEN THOSE
23 THAT WERE DONE DURING THE CAMPAIGN.

24 DR. PENHOET: I CLOSE BY ADDING THAT WE
25 EMPHASIZED THE CCST REPORT IS NOT PROSCRIPTIVE FOR US.

1 IT'S AN IMPORTANT DOCUMENT. IT WAS THOUGHTFULLY DONE
2 BY A NUMBER OF VERY GOOD PEOPLE WHO ARE FAMILIAR WITH
3 THE FIELD, BUT IT'S A RECOMMENDATION TO US. IT'S NOT A
4 MANDATE TO US. AND WE'RE VERY OPEN-MINDED TO HEAR LOTS
5 OF DIFFERENT POINTS OF VIEW. WE HAVE HEARD A NUMBER OF
6 THEM ON MONDAY. WE LOOK FORWARD TO HEARING SOME MORE
7 ON NOVEMBER 22D. AND THE POLICY WILL BE OURS IN THE
8 END, AND SO WE HAVE TO COME UP.

9 DR. LOVE: I HAD JUST A QUESTION TO ASK ABOUT
10 THIS CONCEPT OF FINANCIAL BENEFIT TO THE STATE.
11 OBVIOUSLY THERE ARE A LOT OF WAYS THAT THE STATE COULD
12 DERIVE FINANCIAL BENEFIT. AND ONE OF THOSE WAYS
13 RELATES TO THE VERY SPECIFIC ISSUE OF ROYALTIES COMING
14 DIRECTLY BACK TO THE STATE. SO I GUESS THE QUESTION
15 REALLY IS WHEN WE GET THIS FEEDBACK ABOUT BENEFIT TO
16 THE STATE, ARE PEOPLE ALMOST ALWAYS TALKING ABOUT AT
17 LEAST INCLUSION OF SOME MINIMAL AMOUNT OF ROYALTIES?
18 AND I GUESS EVEN MORE SPECIFICALLY, AS AN ICOC, SHOULD
19 WE FEEL THERE IS AN OBLIGATION TO, IN FACT, COME UP
20 WITH A STRUCTURE THAT PAYS ROYALTIES BECAUSE OF
21 COMMITMENTS DURING THE CAMPAIGN? OR SHOULD WE, IN
22 FACT, FEEL THAT IF WE DECIDE THAT THAT STRUCTURE IS
23 NOT, IN FACT, IN THE BEST INTEREST OF ADVANCING WHAT
24 WE'RE PRIMARILY HERE TO DO, WHICH IS STEM CELL
25 THERAPIES, THAT WE HAVE THE FREEDOM TO, IN FACT, COME

1 UP WITH A STRUCTURE THAT PROVIDES BENEFIT, BUT DOES NOT
2 INCLUDE DIRECT ROYALTIES?

3 DR. PENHOET: I'LL LET BOB ADDRESS WHAT THE
4 ISSUES ARE RELATED TO PROP 71. I THINK THE CLIMATE
5 THAT WE'RE DEALING WITH OUT THERE GENERALLY IS WHAT
6 PEOPLE WOULD LIKE TO DO IS GET REMUNERATION TO THE
7 STATE USING TAX-EXEMPT BONDS. THAT SEEMS NOT TO BE ONE
8 OF THE QUADRANTS WHERE WE CAN PLAY. SO WE HAVE TO
9 FIGURE OUT A BUSINESS ANALYSIS OF THIS TO TRY TO FIGURE
10 OUT WOULD YOU MAKE MORE MONEY ON ROYALTY REVENUE
11 RETURNS TO THE STATE THAN YOU WOULD PAY IN EXCESS
12 INTEREST AS A RESULT OF USING TAXABLE BONDS?

13 UNFORTUNATELY, NO ONE CAN ANSWER THAT
14 QUESTION TODAY. THERE ARE PRECEDENTS FOR IT IN
15 HISTORY, BUT IT'S IMPOSSIBLE TO KNOW WHAT THE VALUE OF
16 TECHNOLOGY THAT YOU HAVEN'T INVENTED YET IS. SO YOU
17 HAVE TO MAKE YOUR BEST GUESS.

18 I THINK, THOUGH, THERE'S A BIAS AND A BELIEF
19 IN MOST PEOPLE'S MIND THAT PART OF THE CONTRACT WAS
20 THAT THERE WOULD BE REMUNERATION TO THE STATE. HAVING
21 SAID THAT, I THINK IF WE HAVE A POWERFUL SET OF
22 ARGUMENTS FOR A DIRECT REMUNERATION SHARING IN THE
23 BUSINESS RESULTS, IF WE HAVE A POWERFUL ARGUMENT WHY
24 THAT WOULD BE DELETERIOUS TO THE PROGRAM OVERALL, WE
25 SHOULD MAKE THAT ARGUMENT, I GUESS.

1 CHAIRMAN KLEIN: I WOULD SAY AS FROM A
2 PATIENT ADVOCATE POSITION AND FROM 70 DIFFERENT PATIENT
3 ADVOCACY ORGANIZATIONS THAT ENDORSE THIS INITIATIVE, IT
4 APPEARS VERY CLEARLY TO BE A DIRECT BENEFIT TO THE
5 STATE. IF WE USE OUR ROYALTIES TO BENEFIT A NONPROFIT
6 PROGRAM AFFILIATED WITH DIFFERENT INSTITUTIONS OR EVEN
7 REGIONALIZED, THAT PROVIDES ACCESS TO NEW THERAPIES
8 THAT COME OUT OF THIS RESEARCH. FROM A PATIENT
9 PERSPECTIVE, THIS IS, AND FROM THE FAMILIES, NEARLY
10 HALF THE FAMILIES IN THE STATE ARE AFFECTED BY CHRONIC
11 DISEASE. THIS APPEARS TO BE A VERY DIRECT REPAYMENT TO
12 THE STATE.

13 IF YOU WOULD USE THE THEORY THAT THE ONLY
14 DIRECT REPAYMENT TO THE STATE IS AGAINST THE STATE BOND
15 REVENUES, SOMETHING THAT WE DID NOT ASSERT DURING THE
16 CAMPAIGN, TO MY KNOWLEDGE, THEN YOU ARE DEALING IN AN
17 AREA WHERE YOU ARE GOING TO USE TAXABLE BONDS. BUT IF
18 YOU'RE DOING IT IN AN AREA WHERE YOU'RE GOING TO
19 PROVIDE PATIENT BENEFIT AND ACCESS, LOW AND MODERATE
20 INCOME ACCESS, WHICH HAS BEEN A TRADITION IN CALIFORNIA
21 UNDER VARIOUS PROGRAMS OF OUR HEALTH DEPARTMENT, IT
22 APPEARS TO BE AN AREA WHERE YOU CAN DEFINITELY
23 CREATIVELY, WITH IRS APPROVAL, CREATE A PROGRAM
24 HOPEFULLY THAT IS CONSISTENT WITH BAYH-DOLE AND
25 MINIMALLY MODIFIES THAT CONCEPT WHERE YOU USE

1 TAX-EXEMPT BONDS.

2 SO ON THE ONE HAND, I BELIEVE, JUST SPEAKING
3 AS AN INDIVIDUAL, THAT IT IS IMPORTANT TO DEAL WITH
4 SOME OF THOSE PATIENT ACCESS ISSUES WITH ROYALTY
5 REVENUES. IT'S FOR THE BOARD TO DECIDE WHAT'S BEST IN
6 THE INTEREST OF THE STATE. BUT IP POLICY IT IS ALSO
7 IMPORTANT TO NOTE IS NOT JUST ROYALTIES. THE ISSUE IN
8 THE STANDARDS COMMITTEE HAS ALREADY ADOPTED A PROVISION
9 THAT ALL STEM CELL LINES THAT ARE DEVELOPED WILL GO TO
10 A STEM CELL BANK. NOW, THAT'S PART OF IP POLICY, TO
11 MAKE SURE THAT THERE'S BROAD ACCESS TO THE SCIENCE
12 THAT'S DEVELOPED WITH THIS RESEARCH FUNDING BECAUSE
13 IT'S CRITICAL TO PATIENTS AND THE STATE TO MOVE THIS
14 RESEARCH FORWARD.

15 SO THE SHARING AND AVAILABILITY OF RESEARCH
16 INFORMATION IS A VITAL PART OF THE IP POLICY, PROBABLY
17 A LOT MORE IMPORTANT THAN THE IP ROYALTIES. SO WE NEED
18 TO BE VERY CLEAR WHEN WE DEVELOP OUR IP POLICY AND
19 INFORM THE PUBLIC ABOUT HOW OUR IP POLICY IS GOING TO
20 HELP ACCELERATE THE RESEARCH AND MAKE INFORMATION
21 AVAILABLE FOR RESEARCH AND AVOID OBSTACLES IN THE
22 RESEARCH. THAT IS A CRITICAL ELEMENT THAT THE PEOPLE
23 BEHIND PROP 71, THE PATIENT GROUPS, THE INSTITUTIONS,
24 THE MEDICAL GROUPS, BELIEVED WAS MADE PART OF OUR CORE
25 MISSION.

1 MR. SHEEHY: ACTUALLY I WANTED TO -- THERE'S
2 A COUPLE OF THINGS. ONE, IN TERMS OF THE TAXABILITY OF
3 THE BONDS, AND I THINK MAYBE ED OR MARY MAY HAVE A
4 BETTER MEMORY THAN I DO BECAUSE I DIDN'T BRING MY
5 NOTES, BUT IT SEEMED THAT BOND COUNSEL SAID EVEN UNDER
6 THE BAYH-DOLE SCHEMATA, THAT IF AN INSTITUTION THAT WE
7 GIVE FUNDS LICENSES -- GOES AHEAD AND LICENSES AND
8 MAKES MONEY, THAT THAT CAN HAVE A NEGATIVE IMPACT ON
9 THE ISSUANCE OF TAX-EXEMPT BONDS. IT SEEMED THAT IN
10 THAT DISCUSSION, THAT EVEN THOUGH WE WERE GRANTING TO A
11 THIRD PARTY, THAT THIRD PARTY WAS, INDEED, MAKING
12 MONEY, I CAN'T REMEMBER WHAT THE CONDITIONS WERE. BUT,
13 FOR INSTANCE, WE WERE TO MAKE A GRANT TO A COMPANY, BUT
14 THAT DISCUSSION WAS BROUGHT UP, THAT TAXABILITY COULD
15 BE IMPACTED EVEN IF THE MONEY THAT WAS BEING WAS BEING
16 MADE AT AN INSTITUTIONAL LEVEL.

17 I JUST CAN'T COMPLETELY REMEMBER THAT
18 DISCUSSION. I DO THINK ON THE ROYALTIES ISSUE, I THINK
19 THAT'S A DECISION WE'RE GOING TO HAVE TO MAKE, AND I'M
20 GLAD THAT YOU RAISED IT. I THINK THERE IS THE
21 EXPECTATION THAT THE ROYALTY STREAM WILL OCCUR. I
22 THINK IF YOU LOOK AT THE LANGUAGE OF PROP 71, AND MAYBE
23 JAMES MIGHT INFORM US ON THAT, THE LANGUAGE SEEMS
24 PRETTY EXPLICIT IN THE STATUTE THAT -- I THINK THE WORD
25 "ROYALTIES" IS ACTUALLY USED. SO I CAN IMAGINE THAT WE

1 HAVE PROBLEMS IF WE DON'T TRY TO THINK CREATIVELY ABOUT
2 ROYALTIES.

3 I DON'T THINK WE'RE GOING TO BE ABLE --
4 PERSONALLY I DON'T THINK POLITICALLY IT'S GOING TO BE
5 FINESSABLE. BUT I ALSO THINK -- I THINK THERE'S BEEN
6 SOMEWHAT OF AN OBSESSION WITH THE TAXABILITY OF THE
7 BONDS. AND I THINK THAT TREASURER ANGELIDES' LETTER
8 WAS VERY INFORMATIVE, THAT THIS NEED NOT BE SUCH A
9 TREMENDOUS OBSTACLE TOWARDS US MOVING FORWARD. THE
10 STATUTE GIVES US THE ABILITY TO ISSUE BOTH TAXABLE AND
11 TAX-EXEMPT BONDS, AND HE SEEMED TO SUGGEST THAT A HALF,
12 MAYBE A QUARTER POINT OF INTEREST WOULD BE THE
13 DIFFERENCE. I THINK THAT WE NEED -- PERHAPS SENATOR
14 ORTIZ IS CONCERNED ABOUT THAT, BUT I DON'T THINK WE
15 NEED TO GET BOGGED DOWN ON THAT MYSELF.

16 MS. SAMUELSON: ON THE POINT THAT TED RAISED,
17 ANOTHER COMMENT ON THAT, AND I THINK IT'S GREAT, THAT,
18 ED, WE HAVE YOUR COMMITTEE AND WE HAVE THE STANDARDS
19 WORKING GROUP, AND THE MEETINGS OF THE FULL COMMITTEE
20 IN WHICH NOT ONLY TO EDUCATE OURSELVES SUFFICIENTLY,
21 THAT WE CAN MAKE INFORMED DECISION ABOUT THIS IMMENSELY
22 COMPLICATED AREA, BUT THAT WE CAN EDUCATE THE PUBLIC
23 ABOUT WHY WE'RE MAKING VARIOUS DECISIONS. AND THERE'S
24 SO MANY THINGS YOU TOUCHED ON. I'M PROBABLY ONE OF THE
25 LEAST INVOLVED IN THIS FIELD, SO I'M APPRECIATIVE OF

1 HOW -- THE COMPLEXITY OF IT AND HOW MUCH I DON'T KNOW.

2 AND THE ISSUE THAT TED RAISED IS JUST ONE OF
3 MANY. AND THAT IN AND OF ITSELF IS IMMENSELY
4 COMPLICATED AND HIGHLY POLITICAL AND IMPORTANT. SO I'M
5 GLAD THIS IS A DELIBERATIVE PROCESS AND WE'RE TAKING
6 OUR TIME WITH IT.

7 I THINK WE HAVE THE ABILITY TO COME OUT AT
8 ANY WAY WE WANT, FRANKLY, ON THAT ISSUE. AND I'M JUST
9 GOING TO READ PART OF WHAT I GUESS IS THE TEXT OF THE
10 ACT. I'M ASSUMING SO. IT'S FROM A LETTER THAT
11 TREASURER ANGELIDES SENT TO ZACH AND, I GUESS, COPIED
12 ALL OF US ON. I LOOKED CAREFULLY AT THE WORDING. IT
13 TALKS ABOUT SETTING STANDARDS THAT BALANCE THE
14 OPPORTUNITY TO BENEFIT FROM PATENTS, ROYALTIES, ETC.,
15 WITH THE NEED TO ENSURE THAT ESSENTIAL MEDICAL RESEARCH
16 IS NOT UNREASONABLY HINDERED BY THOSE AGREEMENTS.

17 THE WAY I READ THAT, AND I THINK THIS IS THE
18 WAY THE PROPOSITION WAS SOLD AND THE WAY THAT IT WAS
19 ENACTED, IS THAT THE MOST IMPORTANT ELEMENT IS TO GET
20 CURES, PERIOD. I DON'T THINK VOTERS WENT TO THE POLLS,
21 THE SEVEN MILLION CALIFORNIANS WHO SUPPORTED PROP 71,
22 THOUGHT, OH, GOOD. THIS IS A GOLD RUSH FOR THE STATE
23 COFFERS. THAT IS NOT THE REASON THEY VOTED FOR IT. I
24 THINK WE CAN COMFORTABLY ASSUME THAT. IT'S AN
25 IMPORTANT CRITERIA AND I THINK IMPORTANT TO THE VOTERS,

1 AND WE HAVE TO BE RESPONSIBLE ABOUT IT, BUT I THINK THE
2 MOST IMPORTANT THING IS THAT WE GET EFFECTIVE THERAPIES
3 AND CURATIVE RESULTS, WHICH IS IN AND OF ITSELF AN
4 IMMENSELY DIFFICULT THING TO DO.

5 ONE OTHER POINT. AND, OF COURSE, IF WE DO
6 THAT, THERE'S A LOT OF DATA THAT SUGGESTS THAT THERE
7 WILL BE SUBSTANTIAL ECONOMIC BENEFIT TO THE STATE BY
8 DOING SO.

9 CHAIRMAN KLEIN: I SPECIFICALLY REMEMBER
10 WRITING THE PROVISION AND ARGUING THE PROVISION DURING
11 THE CAMPAIGN. AND I CAN TELL YOU THAT YOU ARE QUITE
12 RIGHT, JOAN. YOU WERE THERE AT A NUMBER OF THOSE
13 DEBATES. SPECIFICALLY AN EXAMPLE THAT I USE MANY TIMES
14 IS THAT YOUR ORPHAN DISEASES OR SMALL POPULATION
15 DISEASES, THAT IT MAY WELL NOT BE IN THE STATE'S
16 INTEREST TO PUT AN ADDITIONAL BURDEN ON THESE DISEASES,
17 WHICH SOMETIMES ARE NOT EVEN ECONOMICAL, DISREGARDING
18 ANY ROYALTIES. YOU MAY EVEN NEED SUBSIDIES TO MAKE
19 THOSE THERAPIES ECONOMICAL. THEY JUST DON'T HAVE THE
20 SCALE. SO THAT VERY SPECIFICALLY IT WAS INTENDED TO BE
21 ABLE TO NOT HAVE ROYALTIES ON PARTS OF THE RESEARCH,
22 AND THAT WAS USED OVER AND OVER AND OVER AGAIN AS
23 EXAMPLES, THAT THIS IS NOT THE CORE OF OUR MISSION.

24 AND WE NEED TO BE RESPONSIBLE IN THIS AREA TO
25 SEE WHAT REVENUES CAN BE GENERATED, BUT WE NEED TO

1 BALANCE IT AGAINST OUR PRIMARY MISSION, WHICH IS TO
2 ADVANCE MEDICAL RESEARCH AND CREATE ECONOMICALLY
3 FEASIBLE NEW THERAPIES.

4 DR. LOVE: I JUST WANTED TO SAY ONE FINAL
5 THING. AS A MEMBER OF THE IP TASK FORCE AT THE MEETING
6 THAT WE HAD IN SACRAMENTO, I PERSONALLY FELT JUST AN
7 ENORMOUS WEIGHT OF PRESSURE AROUND A VARIETY OF POINTS,
8 POLITICAL, PRIOR COMMITMENTS, TRYING TO ADVANCE THESE
9 THERAPIES, WHICH I THINK IS THE FUNDAMENTAL TASK HERE,
10 TO TRYING TO MAKE THINGS AFFORDABLE. AND I GOT TO SAY
11 THAT I THINK MY BIGGEST CONCERN IS THAT IF WE TAKE ON
12 TOO MANY OF THESE THINGS, ALL OF WHICH ARE WONDERFUL
13 THINGS TO TAKE ON, WE MAY END UP NOT ACCOMPLISHING OUR
14 CENTRAL MISSION.

15 DR. BALTIMORE: I'M SORRY I HAD TO BE OUT
16 DURING YOUR DISCUSSION. AND SO I MAY NOT BE TOTALLY IN
17 ORDER, BUT I DO THINK, LISTENING TO THIS DISCUSSION,
18 THAT THERE'S A VERY IMPORTANT DISTINCTION FROM A
19 UNIVERSITY'S POINT OF VIEW, FROM I THINK ANY ENTITY'S
20 POINT OF VIEW. AND THAT IS THAT YOU DON'T WANT TO
21 INTERFERE WITH THE INTERNAL PROCESSES OF RESEARCH AND
22 RESEARCH FUNDING BY AN IP POLICY. AND, THEREFORE,
23 SAYING THAT WE SHOULD RETHINK BAYH-DOLE WOULD ISOLATE
24 ALL CALIFORNIA-FUNDED RESEARCH FROM FEDERALLY FUNDED
25 RESEARCH IN A TOTALLY UNPRODUCTIVE WAY AND WOULD BE AN

1 INCENTIVE FOR SCIENTISTS AT THE UNIVERSITY TO NOT LOOK
2 TO THE CALIFORNIA INITIATIVE FOR FUNDING AND TO NOT GET
3 INVOLVED IN HUMAN STEM CELL RESEARCH BECAUSE OF THE
4 CONFUSION OF IP POLICY.

5 ASKING THE UNIVERSITIES OR THE RESEARCH
6 INSTITUTES OF CALIFORNIA TO RETURN A CERTAIN FRACTION
7 OF THE ROYALTIES OR LICENSING INCOME, AND I POINT OUT
8 THE LICENSING INCOME IS A LOT MORE IMPORTANT THAN
9 ROYALTIES GENERALLY, IS A RELATIVELY CLEAN SITUATION.
10 AND AS LONG AS THE AMOUNT DOES NOT, AGAIN, MAKE IT
11 COUNTERPRODUCTIVE FOR INDIVIDUAL RESEARCH SCIENTISTS TO
12 BE INVOLVED, THAT IS, ALLOWS THE INSTITUTIONS TO
13 CONTINUE WITH THEIR STANDARD PRACTICE OF RETURN TO THE
14 INVESTIGATOR OR RETURN TO THE INSTITUTION, BUT TAKES
15 SOME CUT OF THAT FOR THE STATE, I THINK WE CAN LIVE
16 WITH IT. AND WE CAN LIVE WITH IT PARTLY BECAUSE IT
17 DOESN'T INTERFERE WITH OUR INTERNAL PROCESSES AND
18 ALLOWS US TO CONTINUE TO SEE THE FUNDING OF UNIVERSITY
19 RESEARCH AS A TOTAL ENTITY, NOT AS SOMETHING WHICH WE
20 HAVE TO COMPARTMENTALIZE THE RULES IN ORDER TO SATISFY.

21 MR. SHEEHY: I REALLY HATE TO STEP INTO THIS
22 BECAUSE I THINK PART OF OUR PROBLEM THAT WE'RE FACING
23 IS TO SOME DEGREE WITH THE PUBLIC PERCEPTION WE'RE
24 TALKING ABOUT APPLES AND ORANGES. NOW, ONE COULD
25 ARGUE, AND I AM A LITTLE BIT OF BIAS, BUT TO HAVE --

1 FOR US TO DO BAYH-DOLE WITH UC, I MEAN UC PROVIDES
2 ENORMOUS PUBLIC BENEFIT TO THE CITIZENS OF CALIFORNIA.
3 BUT PEOPLE SEEM TO THINK THAT THAT BAYH-DOLE MODEL THEN
4 APPLIES TO, LET'S SAY, CHIRON INDEPENDENTLY.

5 AND SO MAYBE IF WE HAD A LITTLE MORE CLARITY
6 THAT WHAT WE'RE TALKING ABOUT IN TERMS OF BAYH-DOLE,
7 THE ARRANGEMENTS THAT WE'RE MAKING WITH ACADEMIC
8 RESEARCH INSTITUTIONS OR RESEARCH -- NONPROFIT RESEARCH
9 INSTITUTIONS, WHICH WE ALL KNOW PROVIDE ENORMOUS
10 BENEFIT ON A DAILY BASIS TO THE CITIZENS OF CALIFORNIA
11 AND HAVE BEEN THE ENGINES OF ECONOMIC GROWTH IN THIS
12 ECONOMY, BUT THAT IF WE DO END UP MAKING ARRANGEMENTS
13 WITH PRIVATE INDUSTRY THAT ARE DIRECT, THAT WE HAVE A
14 DIFFERENT SCHEME WHEN THAT COMES INTO PLAY. AND ONE
15 WOULD HOPE THAT AT SOME POINT WE ARE MAKING THOSE KINDS
16 OF ARRANGEMENTS BECAUSE THAT GENERALLY INDICATES THAT
17 WE'RE ACTUALLY PRODUCING A PRODUCT THAT'S GOING TO END
18 INSIDE OF SOMEBODY AND ACTUALLY PROVIDE A CURE.

19 BUT I THINK SOME CLARITY ON THAT AND SOME
20 DISCUSSION MIGHT ILLUMINATE SOME OF THIS. AND I THINK
21 FROM A BUSINESS -- I'M NOT A BUSINESSMAN, BUT I THINK
22 MOST BUSINESS FOLKS ARE USED TO GOING TO PEOPLE FOR
23 CAPITAL AND MAKING SOME ARRANGEMENT THAT ENABLES THE
24 PERSON PROVIDING THE CAPITAL TO GET SOME RETURN ON
25 PROVIDING THAT CAPITAL. I DON'T THINK WE NEED TO BE

1 ONEROUS ABOUT DOING THAT, BUT I THINK WE CAN MAKE THAT
2 KIND OF ARRANGEMENT.

3 BUT IT SEEMS -- ONE OF THE THINGS THAT'S
4 ALWAYS CONFUSED ME IN HAVING THIS DISCUSSION IS THAT
5 THERE SEEMS TO BE BAYH-DOLE, WHICH WORKS VERY WELL. IN
6 THE HIV/AIDS FIELD, AS WE WERE TALKING ABOUT THIS
7 MORNING, NIGHT BECAME DAY TEN YEARS AGO, AND ACADEMIC
8 RESEARCH FUNDED BY THE NIH LED THE WAY. BUT THEN WE DO
9 HAVE THIS INDUSTRY ISSUE, AND THAT COULD REQUIRE -- WE
10 COULD HAVE TWO DIFFERENT POLICIES THAT ARE GREATLY
11 DIFFERENT AND COULD MAYBE ADDRESS SOME OF OUR CRITICS'
12 ISSUES.

13 DR. BALTIMORE: BAYH-DOLE DOESN'T HAVE
14 ANYTHING TO DO WITH INDUSTRY. AND FURTHERMORE,
15 BAYH-DOLE DOESN'T HAVE ANYTHING TO DO WITH PATENTING.
16 YOU SAID EARLIER THAT RESEARCH SHARING IS IMPORTANT,
17 AND MAYBE BAYH-DOLE GETS IN THE WAY OF THAT. THAT'S
18 NOT WHAT BAYH-DOLE IS ABOUT. BAYH-DOLE IS ONCE YOU'VE
19 PATENTED SOMETHING, HOW DO YOU GO ABOUT LICENSING IT.
20 AND IT PROVIDES A FRAMEWORK FOR THAT WHICH IS VERY
21 EFFECTIVE AND HAS BEEN -- AND I THINK THE SUGGESTION
22 THAT WE UNDERSTAND HOW EFFECTIVE IT HAS BEEN FOR THE
23 STATE IS A VERY, VERY GOOD SUGGESTION BECAUSE I'M SURE
24 IT'S BEEN VERY POWERFUL FOR THE STATE. BUT IT'S ABOUT
25 UNIVERSITY FUNDING AND RESEARCH INSTITUTE FUNDING.

1 IT'S NOT ABOUT CORPORATE FUNDING AT ALL.

2 DR. PENHOET: ANY FURTHER COMMENTS? WELL,
3 ALL OF US ON THE IP TASK FORCE WELCOME INPUT OVER THE
4 NEXT 30 DAYS AND WITH A LIMITED GOAL OF PROVIDING
5 FRAMEWORK FOR IP FOR THE TRAINING GRANTS, BUT
6 ESPECIALLY OVER THE 90-DAY PERIOD WHICH WILL GET US TO
7 THE FEBRUARY MEETING. AND THIS IS A COMPLEX ISSUE.

8 AND I WANT TO CLOSE BY SIMPLY EMPHASIZING
9 AGAIN IT'S ENTIRELY POSSIBLE AND PROBABLY DESIRABLE FOR
10 US TO DEVELOP A POLICY WHICH IS OUR OWN. AND THE ONLY
11 CONSISTENT MESSAGE THAT WE'VE GOTTEN IS JUST MAKE SURE
12 IT'S NOT INCOMPATIBLE WITH BAYH-DOLE, BUT IT DOESN'T
13 HAVE TO BE BAYH-DOLE PER SE. SO I THINK THAT'S SORT OF
14 THE FRAMEWORK THAT MOST OF US ON THE COMMITTEE ARE
15 EMBRACING AS WE GO FORWARD IN OUR WORK. WE'RE GLAD TO
16 HEAR ANY OTHER INPUT THAT YOU MIGHT HAVE. THANK YOU.

17 CHAIRMAN KLEIN: WE'LL TAKE A FIVE-MINUTE
18 BREAK BEFORE WE GO ON TO ITEM 12. I THINK EVERYONE
19 MIGHT NEED SOME LITTLE BREAK HERE.

20 (A RECESS WAS TAKEN.)

21 CHAIRMAN KLEIN: IF WE COULD RECONVENE. WE
22 HAVE A LOT OF ITEMS TO COVER, AND WE'D GREATLY
23 APPRECIATE IT IF WE COULD MOVE FORWARD. OKAY. IF WE
24 CAN RECONVENE, PLEASE. AND MY UNDERSTANDING IS THAT
25 THERE'S A LOT OF FEEDBACK OFF OF THE LAPEL MIC. YOU

1 FIXED IT.

2 DR. HALL: I BRING YOU FOUR ITEMS OF BUSINESS
3 FROM THE STANDARDS WORKING GROUP MEETINGS. AND THEY
4 CONCERN THE CIRM INTERIM GUIDELINES BASED ON NATIONAL
5 ACADEMY GUIDELINES FOR -- I'M SORRY. THAT SHOULD BE
6 INTERIM REGULATIONS. I BEG YOUR PARDON -- BASED ON
7 NATIONAL ACADEMY GUIDELINES FOR HUMAN EMBRYONIC STEM
8 CELL RESEARCH. THE WORKING GROUP PROCEDURES, THE
9 BYLAWS FOR THE STANDARDS WORKING GROUP, AND RECOMMENDED
10 NEW MEMBERS.

11 SO LET ME REMIND YOU THAT BEFORE CIRM CAN
12 AWARD ANY GRANTS, WE MUST HAVE IN PLACE REGULATIONS
13 THAT GOVERN RESEARCH ON HUMAN EMBRYONIC STEM CELLS.
14 AND WE ADOPTED THE NATIONAL ACADEMY GUIDELINES IN MAY,
15 SHORTLY AFTER THEY CAME OUT. OUR STANDARDS WORKING
16 GROUP MET IN EARLY AUGUST AND POINTED OUT THAT -- I'M
17 SORRY -- MET IN EARLY JULY, I THINK IT WAS, AND POINTED
18 OUT AT THAT MEETING THAT THE GUIDELINES HAD SEVERAL
19 VERSIONS OF WHAT THEY RECOMMENDED. AND WHAT WE NEEDED
20 WAS PRECISE AND REGULATORY LANGUAGE, AND THERE WERE
21 SEVERAL ISSUES THAT APPLIED TO CIRM, AND SO THE
22 GUIDELINES WERE REWRITTEN, THEN, INTO REGULATIONS BY
23 JAMES HARRISON AND BY OUR STAFF. AND THEN THEY WERE
24 PRESENTED TO THE STANDARDS WORKING GROUP, WHO MADE A
25 FEW SMALL CHANGES AND THEN APPROVED THEM ON AUGUST 3D.

1 AND THESE WERE PRESENTED AT THE SEPTEMBER 9TH ICOC
2 MEETING.

3 AND THEY ARE FOUND UNDER TAB 12 IN YOUR
4 BOOKS. I THINK THAT SHOULD BE THE FIRST ITEM. IT WAS
5 DISCUSSED AT THE SEPTEMBER -- THESE REGULATIONS WERE
6 DISCUSSED AT THE SEPTEMBER 9TH ICOC MEETING. AND IT
7 WAS MOVED AT THAT TIME THAT THEY BE CONSIDERED AT THIS
8 MEETING FOR ACTION.

9 NOW, IN THE INTERIM WE HAD DISCUSSIONS WITH
10 SEVERAL INSTITUTIONS, INCLUDING STANFORD, AND A MEMBER
11 OF THE STANFORD LEGAL AFFAIRS OFFICE POINTED OUT TO US
12 SOMETHING OF WHICH WE HAD BEEN UNAWARE. AND THAT IS
13 THAT IN THE PROCESS OF CONVERTING THE NATIONAL ACADEMY
14 GUIDELINES TO OUR OWN REGULATORY LANGUAGE, WE HAD
15 INTRODUCED AN INADVERTENT DEVIATION FROM THE NATIONAL
16 ACADEMY GUIDELINES. THE DEVIATION WAS A SMALL ONE, BUT
17 TURNED OUT TO HAVE RATHER LARGE CONSEQUENCES. AND SO
18 WE WANT TO RECOMMEND A MODIFICATION TO RESTORE THE
19 ORIGINAL MEANING, AND ALSO WE WOULD LIKE TO RECOMMEND
20 THAT THE MODIFIED GUIDELINES BE APPROVED.

21 SO LET ME, FIRST OF ALL, TAKE YOU THROUGH THE
22 MISTAKE THAT CREPT IN HERE INADVERTENTLY. THE ORIGINAL
23 LANGUAGE FROM THE NATIONAL ACADEMY GUIDELINES TALKED
24 ABOUT A VARIETY OF CONDITIONS IN AND AROUND DONOR
25 CONSENT FOR OOCYTE DONATION. AND THEY SAID THAT DONORS

1 COULD BE OFFERED THE OPTION OF AGREEING TO SOME FORMS
2 OF HUMAN EMBRYONIC STEM CELL RESEARCH, BUT NOT OTHERS.
3 AND WHEN THIS WAS PUT INTO REGULATORY LANGUAGE, IT WAS
4 CHANGED TO DONORS SHALL BE OFFERED THE OPTION OF
5 AGREEING TO SOME FORMS OF HUMAN EMBRYONIC STEM CELL
6 RESEARCH, BUT NOT OTHERS. SO THIS BECAME PRESCRIPTIVE,
7 AND THIS HAS A MAJOR EFFECT BECAUSE MOST IRB'S NOW DO
8 NOT REQUIRE THIS LAYERED CONSENT. AND SO IF WE NOW
9 MAKE IT A REQUIREMENT, THEN THIS CREATES AN UNINTENDED
10 PERTURBATION IN THE WAY THAT PEOPLE ARE DOING BUSINESS.

11 SO WE WOULD LIKE TO RECOMMEND THAT THE
12 WORDING BE CHANGED BACK TO DONORS COULD BE OFFERED THE
13 OPTION OF AGREEING TO SOME FORMS OF HUMAN EMBRYONIC
14 STEM CELL RESEARCH, BUT NOT OTHERS. SO THAT IS THE
15 FIRST THING THAT WE WOULD DO.

16 AND LET ME REMIND YOU THAT THESE ARE INTERIM
17 REGULATIONS. AND I WANT TO WALK YOU THROUGH THE
18 LANGUAGE. WE ACTUALLY HAVE GOTTEN CONFUSED OURSELVES
19 IN TALKING ABOUT THE VARIOUS VERSIONS OF THESE, AND SO
20 WE HAVE ADOPTED THE FOLLOWING CONVENTIONS, WHICH I HOPE
21 WILL BE USEFUL TO ALL OF US. WE START WITH THE
22 NATIONAL ACADEMY GUIDELINES FOR HUMAN EMBRYONIC STEM
23 CELL RESEARCH. WE THEN HAVE WRITTEN AND APPROVED
24 SO-CALLED INTERIM REGULATIONS BASED ON THE NATIONAL
25 ACADEMY GUIDELINES. AND IT'S THESE THAT WE MUST PASS

1 BEFORE WE CAN AWARD THE TRAINING GRANTS.

2 NOW, AS YOU RECALL, THIS IS SUBJECT TO THE
3 ADMINISTRATIVE PROCEDURES ACT. AND SO THERE IS A LONG
4 PROCESS THAT WE MUST GO THROUGH IN ORDER TO COME UP
5 WITH FINAL REGULATIONS. AND THAT PROCESS IS THAT WE,
6 FIRST OF ALL, COME UP WITH DRAFT REGULATIONS. AND IT
7 IS THESE DRAFT REGULATIONS THAT THE STANDARD WORKING
8 GROUP IS NOW WORKING ON. ACCORDING TO THE TIMETABLE,
9 THESE WILL BE PRESENTED FOR APPROVAL TO THE ICOC IN
10 EARLY FEBRUARY, AND THEN SUBMITTED TO THE OFFICE OF
11 ADMINISTRATIVE LAW. AND AFTER A PERIOD OF PUBLIC
12 COMMENT AND POSSIBLE MODIFICATION, THESE WOULD THEN
13 BECOME FINAL REGULATIONS.

14 SO THE ONLY ISSUE ON THE TABLE RIGHT NOW ARE
15 THE INTERIM REGULATIONS WHICH WILL BE IN FORCE UNTIL
16 THE STANDARDS WORKING GROUP COMMITTEE HAS DONE ITS WORK
17 AND THE REGULATIONS HAVE GONE THROUGH THE OFFICE OF
18 ADMINISTRATIVE LAW. AND THEN AT SOME POINT NEXT JUNE,
19 END OF JUNE, I THINK IT IS, WE WOULD QUALIFY FOR THAT.

20 NOW, THE CLOCK FOR THE OAL PROCEDURE STARTS
21 WITH THE ADOPTION OF THE INTERIM REGULATIONS BY THE
22 ICOC, SO THAT WILL BEGIN THE PROCEDURE. IT IS ALSO
23 TRUE, AS I SAID, THAT WE NEED TO HAVE THESE GUIDELINES
24 IN PLACE IN ORDER TO DO OUR WORK.

25 NOW, I SENT OUT A MEMO TO MEMBERS OF THE

1 VARIOUS INSTITUTIONS INVOLVED AND THE ICOC JUST TO
2 POINT OUT THAT WE HAD DONE OUR BEST TO ADHERE TO THE
3 NATIONAL ACADEMY GUIDELINES IN DOING THIS. AND WE
4 TRIED TO ENUMERATE THE INSTANCES IN WHICH WE HAD
5 DEVIATED FROM THOSE. BUT THE INTENT WAS TO STAY AS
6 CLOSE AS POSSIBLE TO THOSE IN ACCORDANCE WITH
7 CALIFORNIA LAW AND OUR OWN CIRM REGULATIONS. AND
8 THERE'S CERTAINLY NO INTENT TO INTRODUCE MAJOR NEW
9 POLICY WITH THOSE GUIDELINES.

10 SO I APOLOGIZE FOR THE COMPLEXITY OF THIS.
11 AND IF I CAN ANSWER ANY QUESTIONS OR OFFER ANY
12 CLARIFICATIONS ABOUT THIS, I WOULD BE HAPPY TO DO IT.

13 CHAIRMAN KLEIN: DR. HENDERSON.

14 DR. HENDERSON: YOU WANT THESE INTERIM
15 GUIDELINES TO BECOME INTERIM REGULATIONS; IS THAT
16 CORRECT?

17 DR. HALL: YES. WE'D LIKE TO ASK APPROVAL
18 FOR THE INTERIM REGULATIONS BASED ON THE NATIONAL
19 ACADEMY GUIDELINES WITH THE ONE CHANGE THAT I
20 MENTIONED.

21 DR. HENDERSON: I'D LIKE TO SO MOVE.

22 DR. WRIGHT: SECOND.

23 CHAIRMAN KLEIN: THERE'S A MOTION AND A
24 SECOND. AND CAN EVERYONE HEAR ME BACK THERE WITH THIS
25 PARTICULAR MIC ON? YES. OKAY. DISCUSSION BY THE

1 BOARD? QUESTIONS BY THE BOARD?

2 MS. SAMUELSON: I HAVE A QUESTION, WHETHER
3 THAT ONE CHANGE OR ANYTHING ELSE IS AGREED TO BY THE
4 WORKING GROUP.

5 MS. LANSING: TOTAL CONSENSUS, I THINK.

6 CHAIRMAN KLEIN: THE QUESTION WAS WHETHER
7 THERE WAS A CONSENSUS ON EVERYTHING. SHERRY LANSING,
8 THE CO-CHAIR OF THE COMMITTEE, INDICATED THERE WAS.

9 DR. PRICE: COULD I ASK A QUESTION ABOUT THE
10 CHANGE FROM SHALL TO COULD? WHO MAKES THE DECISION ON
11 THE COULD?

12 DR. HALL: THE INSTITUTION.

13 DR. PRICE: INSTITUTION. ESCRO COMMITTEE,
14 THE IRB, WHAT?

15 DR. HALL: IT'S UP TO -- IT'S NOT SPECIFIED.
16 THAT OPTION IS I THINK IT WAS INTENDED IN THE ORIGINAL
17 DOCUMENT TO OFFER SOME POSSIBILITIES WITHIN THE OVERALL
18 GUIDELINES. AND WITHOUT SAYING YOU HAVE TO DO THIS, IT
19 SAID IF YOU WANT -- YOU MIGHT, FOR INSTANCE, WISH TO DO
20 THIS AS PART OF YOUR PROCEDURES, BUT THERE'S NO
21 REQUIREMENT. AND IT WOULD BE UP TO YOUR ESCRO OR IRB
22 COMMITTEE TO MAKE THAT DECISION.

23 DR. BALTIMORE: YOU KNOW, THAT MAKES IT
24 DIFFICULT FOR AN INSTITUTION TO SIMPLY SAY THEY WILL
25 ADOPT THESE AS THEIR GUIDELINES. SO I THINK IT MIGHT

1 BE USEFUL IN TALKING -- IN CORRESPONDING WITH
2 INSTITUTIONS TO ENUMERATE THE PLACES IN THERE WHERE
3 THERE ARE DECISIONS THAT HAVE TO BE MADE. I DON'T KNOW
4 IF THERE ARE ANY OTHERS OR NOT.

5 DR. HALL: WELL, I WOULD SAY THAT'S NOT A
6 CONSCIOUS DECISION. IT ONLY SAYS IF SOMEBODY WISHES TO
7 DO THAT, IF THEY WANT TO PUT THAT INTO A PROTOCOL. THE
8 UNIVERSITY DOESN'T EVEN HAVE TO DECIDE ITSELF TO
9 REQUIRE IT OR NOT. THAT'S UP TO IT TO DO; BUT IF
10 SOMEBODY CAME IN AND PUT IT IN A PROTOCOL, THEN AS FAR
11 AS WE'RE CONCERNED, THAT WOULD BE FINE. AND THE
12 INSTITUTION MAY FEEL THE SAME WAY WITHOUT HAVING -- THE
13 INSTITUTION DOESN'T HAVE TO HAVE A PRESCRIPTIVE RULE
14 THERE EITHER.

15 DR. BALTIMORE: BECAUSE YOU SAID THIS WAS A
16 CHOICE TO BE MADE BY THE SORT OF REGULATORY AUTHORITY
17 IN THE INSTITUTION, BUT NOW YOU'RE SAYING IT'S A CHOICE
18 TO BE MADE BY THE PEOPLE WRITING PROTOCOLS.

19 DR. HALL: WELL, IT COULD BE A CHOICE OF THE
20 INSTITUTION IF THEY WISH TO MAKE THAT CHOICE. BUT ALL
21 WE SAY IS IT IS AN OPTION UNDER THE GUIDELINES. THAT
22 WAS BECAUSE IT WAS IN THE ORIGINAL NATIONAL ACADEMY
23 GUIDELINES, AND OUR INTENT WAS TO FOLLOW THAT AS
24 CLOSELY AS POSSIBLE.

25 DR. BALTIMORE: I UNDERSTAND IT IS

1 ORIGINALY.

2 DR. HALL: SO IT DOESN'T REQUIRE UNIVERSITIES
3 TO DO ANYTHING ACTUALLY EXCEPT TO SAY THAT IF SOMEBODY
4 WANTS TO DO THAT, IT'S AN OPTION OPEN TO THEM. WE
5 DON'T OBJECT.

6 DR. BALTIMORE: ONE THING A UNIVERSITY CAN'T
7 DO IS TO SAY WE'RE GOING TO TAKE THE CIRM REGULATIONS
8 AND MAKE THEM OUR BASIS FOR OVERSIGHT BECAUSE THERE ARE
9 CHOICES TO BE MADE IN THERE. SO THEY'RE NOT
10 DEFINITIVE. AND I'M JUST SAYING IT WOULD BE HELPFUL TO
11 KNOW HOW MANY PLACES, SO YOU DON'T HAVE TO READ EVERY
12 WORD. IT WOULD BE HELPFUL TO KNOW HOW MANY PLACES
13 THERE ARE CHOICES.

14 DR. HALL: ONE OF THE THINGS THAT WE WILL DO
15 GOING FORWARD IN WORKING ON THE DRAFT REGULATIONS, THAT
16 IS, THE NEXT VERSION, IS TO WORK WITH INSTITUTIONS AT
17 SOME POINT TO SAY TAKE A LOOK AT THIS. WHAT QUESTIONS
18 DO YOU HAVE ABOUT IT? HOW CAN WE HELP YOU IN DOING
19 THIS?

20 ONE OF THE THINGS, LET ME SAY, THAT WE'VE
21 WANTED TO DO, AS DR. PIZZO AND OTHERS HAVE MADE CLEAR
22 TO US, THAT IT'S VERY IMPORTANT THAT INSTITUTIONS NOT
23 HAVE MULTIPLE SETS OF STANDARDS FOR THIS WORK. AND
24 THERE WILL BE WORK THAT GOES ON OUTSIDE CIRM, IT'S NOT
25 FUNDED BY US, THAT MAY BE FUNDED BY JDRF OR SOMEBODY

1 ELSE. AND SO I THINK ALL OF US WOULD LIKE TO SEE THE
2 NATIONAL ACADEMY GUIDELINES BE THE GOLD STANDARD HERE.
3 THEY, AS WRITTEN, AS WE HAVE SAID, WEREN'T A
4 SATISFACTORY REGULATORY DOCUMENT, AND THEN SOME SMALL
5 THINGS NEEDED TO BE CHANGES, WHICH ARE ENUMERATED IN
6 THE DOCUMENT THAT I SENT OUT. WE VERY MUCH WANT TO
7 WORK WITH INSTITUTIONS. OUR INTENT IS NOT TO SET UP
8 ROADBLOCKS HERE OR TO HAVE HIDDEN TRAPS, BUT TO WORK
9 WITH THE INSTITUTIONS TO MAKE IT WORK AS SMOOTHLY AS
10 POSSIBLE.

11 CHAIRMAN KLEIN: DR. HALL, I THINK DR.
12 BALTIMORE'S POINT IS IF WE COULD JUST WRITE A LETTER
13 FROM YOU TO THE INSTITUTIONS JUST POINTING WHERE THERE
14 WERE POTENTIAL DECISIONS THAT COULD BE MADE.

15 DR. HALL: SURE.

16 MS. LANSING: I JUST WANT TO REEMPHASIZE THAT
17 WE USED THE NATIONAL ACADEMY OF SCIENCE GUIDELINES AS
18 THE BASIS FROM WHICH TO DO IT. AND I ALSO WANT TO
19 REEMPHASIZE THAT WE'RE TRYING TO BE CONSISTENT AND TO
20 SAY TO YOU THAT THESE ARE SIMPLY INTERIM GUIDELINES.
21 THIS IS REALLY A WORK IN PROGRESS SO THAT WE CAN GIVE
22 OUT THE GRANTS. AND IT WILL BE A CONTINUAL WORK IN
23 PROGRESS EVEN THOUGH WE'RE GOING TO COME BACK IN 270
24 DAYS WITH A MORE REFINED VERSION.

25 DR. PIZZO: JUST A FOLLOW-UP BECAUSE I THINK

1 THE SAME ACTUALLY WOULD APPLY TO THE NATIONAL ACADEMY
2 GUIDELINES AS WELL. THEY ARE A WORK IN PROGRESS, AND
3 THERE WERE INCONSISTENCIES IN THAT DOCUMENT AS WELL. I
4 THINK THAT IT WILL FIND ITS WAY TO GREATER SOLIDITY AS
5 WE GET MORE EXPERIENCE.

6 MS. LANSING: AS THE SCIENCE KEEPS CHANGING,
7 WE HAVE TO KEEP CHANGING.

8 CHAIRMAN KLEIN: AND, DR. HALL, IF I COULD
9 ALSO ASK YOU. I HAD POSED A QUESTION EARLIER THAT WITH
10 THE NUCLEAR TRANSFER TECHNIQUES AND KOREAN
11 DISEASE-SPECIFIC LINES THAT ARE BEING CREATED AND THE
12 ABILITY TO DO DISEASE-SPECIFIC THERAPIES, WHETHER IN
13 THESE INTERIM GUIDELINES IF THERE'S ANYTHING THAT WOULD
14 CONFLICT WITH THE ABILITY TO DEVELOP DISEASE-SPECIFIC
15 THERAPIES BECAUSE WHEN THE NATIONAL ACADEMY, OF COURSE,
16 CREATED THESE, THE KOREAN BREAKTHROUGH HADN'T OCCURRED
17 YET.

18 DR. HALL: NO. AS FAR AS I KNOW, THERE ARE
19 NO OBSTACLES TO DOING THAT WORK. GUIDELINES FOR GAMETE
20 DONATION AND SO FORTH, BUT THERE ARE NO OBSTACLES THAT
21 WOULD PREVENT THAT WORK FROM GOING FORWARD. IN FACT,
22 WE ARE VERY MUCH INTERESTED IN SEEING THAT.

23 CHAIRMAN KLEIN: ON PAGE 8 AND SUB C WHERE IT
24 SAYS ESTABLISH A SECURE SYSTEM FOR PROTECTING THE
25 PRIVACY OF DONORS, THE KOREAN APPROACH OF HAVING DOUBLE

1 ENCRYPTION AND THEN HAVING THREE DIFFERENT PARTIES
2 HAVING TO CONCUR AND THEY PUT IN THE CODE TO ACCESS THE
3 INFORMATION SO THEY CAN THEN -- WE REALLY TRACE THE
4 RESULTS FOR A SPECIFIC THERAPY. THAT WOULD BE
5 REASONABLY INCLUDED WITHIN THE UNDERSTANDING OF THIS C
6 IN PAREN?

7 DR. HALL: I WOULD HAVE TO -- I MEAN TO GIVE
8 A COMMENT ON THAT, I WOULD HAVE TO SEE IN SPECIFIC WHAT
9 THE KOREAN PROCEDURES ARE. AS YOU DESCRIBE THEM, IT
10 SEEMS TO ME THEY WOULD BE, BUT IT WILL BE UP TO THE
11 INDIVIDUAL ESCRO'S TO LOOK AT THAT QUESTION IN DETAIL.

12 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

13 DR. WRIGHT.

14 DR. WRIGHT: I HAVE A QUESTION ABOUT -- IT'S
15 ON PAGE 8, ITEM B, LETTER B. AND I REALIZE -- WELL,
16 I'LL JUST ASK MY QUESTION. B SAYS THAT CELL LINES
17 DERIVED OR MODIFIED WITH CIRM FUNDS HAVE TO BE SHARED
18 AND THEN DEPOSITED IN A BANK IN A TIMELY MANNER. THAT
19 SEEMS TO ME TO PLACE RESPONSIBILITY ON CIRM SHOULDERS
20 FOR OVERSIGHT OF THAT, BOTH SHARING AND DEPOSITING IN A
21 TIMELY MANNER. AND I DON'T SEE ANYTHING IN THESE
22 GUIDELINES.

23 DR. HALL: SO WE ARE ENGAGED, THE STANDARDS
24 WORKING GROUP IS ENGAGED IN VERY DETAILED AND EXTENSIVE
25 DISCUSSION ABOUT EXACTLY HOW TO HANDLE THAT ISSUE OF

1 WHAT CONSTITUTES TIMELY, HOW WILL IT BE POLICED. AND
2 SINCE WE AS YET, OUR OWN PLANS FOR ESTABLISHING A STEM
3 CELL BANK ARE AS YET UNCLEAR, WE HOPE THAT WILL COME
4 OUT OF THE STRATEGIC PLAN, A STRATEGY FOR DOING THAT
5 AND A NECESSITY AND SO FORTH THAT THAT WILL MAKE CLEAR.
6 WE RIGHT NOW -- SO THEY'RE WRESTLING WITH A WAY TO TRY
7 TO PUT THIS TOGETHER. WE THINK IN THE INTERVENING
8 PERIOD THAT IT'S UNLIKELY THAT THERE WILL BE LINES
9 ISOLATED USING CIRM FUNDS BEFORE THIS PROCESS IS DONE.

10 SO WE THOUGHT TO LEAVE IT IN THAT. EXPRESS
11 THE INTENT, CLEAR INTENT OF THE WORKING GROUP, BUT NOT
12 TRY TO DECIDE WHAT CONSTITUTES A REASONABLE TIME AND
13 HOW IT WOULD BE ENFORCED. WE WILL DEAL WITH THOSE
14 ISSUES IN TIME, I CAN ASSURE YOU.

15 DR. BALTIMORE: I ACTUALLY HADN'T FOCUSED ON
16 THAT UNTIL YOU RAISED IT, BUT IT SAYS THAT ARE MODIFIED
17 IN ANY WAY WITH CIRM FUNDS. THAT PRESUMABLY MEANS THAT
18 ANY TIME YOU PUT A GENE INTO A STEM CELL, YOU HAVE TO
19 DEPOSIT THAT IN A BANK. THAT'S -- IT'S NOT A MATTER OF
20 OPENNESS. THAT'S JUST AN ONEROUS REQUIREMENT. AND
21 SINCE MODIFICATION IS NOT DEFINED THERE, I DON'T KNOW
22 WHAT ELSE THERE MIGHT BE THAT'S IN THE SAME ORDER.

23 DR. HALL: WELL, AGAIN --

24 DR. BALTIMORE: YOU TRY THIS AND YOU TRY
25 THAT, EVERY ONE OF THOSE CAN'T GO INTO A BANK.

1 DR. HALL: THERE IS A LOT OF DISCUSSION ABOUT
2 HOW TO HANDLE THAT AND TO RELATE IT TO EITHER PATENT OR
3 PUBLICATION DATES, FOR EXAMPLE. AND THIS EXPRESSED A
4 CLEAR INTENT OF THE WORKING GROUP. I THINK THAT LINES
5 BE SHARED AND NOT ONLY LINES THAT WERE DERIVED, BUT
6 ALSO SIGNIFICANT LINES THAT WERE -- THAT REPRESENTED
7 MODIFICATION OF ORIGINAL LINES. I THINK THE -- IF YOU
8 HAVE A SUGGESTION OF AN ALTERNATE WORDING THAT YOU
9 WOULD LIKE TO SUGGEST, I'D BE HAPPY TO HAVE IT.

10 YOU KNOW, MY OWN VIEW IS THIS IS GOING TO
11 BE -- THESE GUIDELINES ARE GOING TO BE IN PLACE FOR A
12 RELATIVELY SHORT PERIOD OF TIME, AND WE ARE NOT GOING
13 TO HAVE MONEY OUT UNTIL SOME MONTHS FROM NOW. AND SO I
14 THINK WE HAVE SORT OF THE CHICKEN AND THE EGG. IF
15 WE'RE GOING TO BE ABLE TO GET THE MONEY OUT QUICKLY, WE
16 HAVE TO HAVE THESE INTERIM GUIDELINES DONE. AND I JUST
17 THINK IF YOU HAVE A SUGGESTION, I'M HAPPY TO HAVE IT.
18 THE THING THAT I THINK WOULD BE HARDEST FOR US NOW
19 WOULD BE TO GO BACK AND GO THROUGH ALL THE DISCUSSION
20 WE'RE GOING THROUGH FOR THE DRAFT REGULATIONS IN ORDER
21 TO SETTLE THIS ISSUE.

22 DR. BALTIMORE: I UNDERSTAND THAT, BUT I
23 THINK, AS WE LOOK FORWARD, SOMETHING LIKE SIGNIFICANTLY
24 MODIFIED.

25 DR. HALL: YES. YES. OBVIOUSLY IT NEEDS TO

1 BE SOMETHING THAT'S PRODUCTIVE. AS YOU SAY, IF YOU DO
2 SOMETHING THAT DOESN'T WORK, LAST THING YOU WANT TO BE
3 REQUIRED TO DO.

4 MS. LANSING: I JUST WANT TO ADD THIS IS LIKE
5 IT WAS A BIG ISSUE FOR US. AND WE WOULD WELCOME HELP
6 IN WORDING THAT COULD HELP US. PLEASE, AS WE START TO
7 CONTINUE THIS DISCUSSION.

8 CHAIRMAN KLEIN: ALL RIGHT. IS THERE -- DR.
9 OS STEWARD.

10 DR. STEWARD: I'M SORRY IF I MISSED THIS, BUT
11 YOU MENTIONED THAT RESEARCH DOLLARS WOULD NOT BE GOING
12 OUT THE DOOR FOR A WHILE. WHAT ABOUT PEOPLE WHO ARE
13 BEING PAID AS TRAINEES ON THE TRAINING GRANT? ACTUALLY
14 THIS COULD COME UP A LITTLE BIT SOONER DEPENDING ON
15 WHAT THOSE INDIVIDUALS GOT INVOLVED IN.

16 DR. HALL: YES. I THINK THE TRAINING FUNDS,
17 WE'LL HEAR MORE ABOUT THIS LATER, BUT I THINK THE
18 TRAINING FUNDS WILL NOT BE GOING OUT IMMEDIATELY. IT
19 WILL BE, I THINK, A MATTER OF SEVERAL MONTHS LIKELY
20 BEFORE WE'RE ABLE TO PROVIDE THOSE FUNDS. ASSUMING
21 THIS GOES THROUGH TILL JUNE, IT'S POSSIBLE WE'LL RUN
22 INTO SOME SITUATION, AND I THINK WE WILL JUST TRY TO
23 DEAL WITH IT WITH COMMON SENSE AND GOODWILL. BUT I
24 THINK WE FACE THE PROBLEM OF TRYING TO PUT THE INTERIM
25 STANDARDS IN PLACE WHILE WE HAVE AN EXTENSIVE

1 DISCUSSION ABOUT WHAT THE RIGHT REGULATION SHOULD BE --
2 I'M SORRY. I SHOULD HAVE SAID INTERIM REGULATIONS --
3 ABOUT WHAT THE RIGHT REGULATION SHOULD BE.

4 AND IF WE HOLD UP THIS UNTIL WE'VE SETTLED
5 THAT, THEN WE DELAY THE WHOLE PROCESS. AND I THINK, AS
6 I SAY, IF YOU HAVE A SUGGESTION FOR A MODIFICATION THAT
7 YOU WOULD LIKE TO SUGGEST THAT COULD BE DONE HERE, THAT
8 WOULD BE FINE. BUT WE DO NEED TO ACT ON THIS RATHER
9 THAN SEND IT BACK TO THE STANDARDS WORKING GROUP
10 BECAUSE OTHERWISE WE'RE JUST TIED UP.

11 DR. STEWARD: ACTUALLY MY QUESTION IS MORE
12 SORT OF, I GUESS, PROCEDURAL. THAT IS, DOES A TRAINEE
13 WHO IS PAID ON THE TRAINING GRANT COUNT AS EXPENDITURE
14 OF CIRM FUNDS FOR RESEARCH? IN OTHER WORDS, DOES
15 EVERYTHING THAT'S WRITTEN HERE APPLY TO THAT TRAINING
16 WHETHER OR NOT THEY'RE BEING FUNDED BY CIRM TO DO THEIR
17 RESEARCH?

18 DR. HALL: IF A TRAINEE IS FUNDED BY US, AND
19 THEY WERE TO DERIVE A NEW CELL LINE, THEN WE WOULD
20 REQUIRE THAT THAT CELL LINE BE MADE AVAILABLE.

21 CHAIRMAN KLEIN: WELL, PERHAPS I DIDN'T
22 UNDERSTAND. WE'RE TRYING TO GET THE INFRASTRUCTURE
23 TRAINING GRANT FUNDS OUT BY THE FIRST OF THE YEAR. ARE
24 WE SAYING SOMETHING ANY DIFFERENT FROM THAT?

25 DR. HALL: ISN'T THAT SEVERAL MONTHS FROM

1 NOW? NOVEMBER, DECEMBER, FIRST OF THE YEAR WOULD BE
2 JANUARY. THAT'S WHAT I WAS THINKING ABOUT. IF WE PASS
3 THESE TODAY, THEN WE WILL HAVE NEW STANDARDS IN PLACE
4 BY JUNE 30TH. AND I THINK THE LIKELIHOOD OF A TRAINEE
5 MAKING A MAJOR -- DOING SOMETHING MAJOR IN THAT TIME.
6 IF WE HAVE THOSE WONDERFUL TRAINEES, WHO KNOWS WHAT
7 THEY'LL DO, BUT MANY OF THEM WILL BE IN COURSEWORK.
8 OTHERS WILL BE GETTING STARTED. AS I SAY, I THINK THIS
9 EXPRESSES THE INTENT OF THE WORKING GROUP. AND IF
10 SPECIFIC INSTANCES COME UP, WE WILL DEAL WITH IT WITH
11 COMMON SENSE AND GOODWILL. AND I THINK WE CAN SORT IT
12 OUT.

13 SO I JUST THINK WE CANNOT FOR AN INTERIM
14 STANDARD -- FOR AN INTERIM REGULATION -- I'M SORRY.
15 WE'VE HAD THIS ON THE DOCKET FOR SEVERAL MONTHS NOW,
16 AND I THINK I WOULD SUGGEST WE -- IF YOU HAVE ALTERNATE
17 WORDING, PLEASE PROPOSE IT. OTHERWISE, PLEASE PASS IT.

18 CHAIRMAN KLEIN: ANY ADDITIONAL QUESTIONS
19 FROM THE BOARD?

20 MS. SAMUELSON: I HAVE A QUESTION. I'M NOT
21 TRYING TO MAKE EXTRA WORK. BUT I'M WONDERING IF IT
22 WOULD BE POSSIBLE TO GET A SHORT SUMMARY OF THE
23 DIFFERENCES BETWEEN THIS DOCUMENT AND THE NATIONAL
24 ACADEMY GUIDELINES?

25 DR. HALL: YES. THEY WERE SENT OUT TO ALL

1 I COC MEMBERS ON -- WHAT'S THE DATE? -- OCTOBER 6TH. WE
2 SENT OUT A MEMORANDUM IN WHICH WE DESCRIBED THE
3 PROCESS, WE DESCRIBED THE DEVIATION, AND WE WENT
4 THROUGH EACH SIGNIFICANT DEVIATION. WE CAN GET YOU A
5 COPY OF THAT. BE HAPPY TO DO IT. IN FACT, I HAVE ONE
6 HERE IF YOU'D LIKE.

7 MS. SAMUELSON: SOUNDS LIKE I NEED ONE.
8 GREAT. THANK YOU.

9 CHAIRMAN KLEIN: OKAY. ANY OTHER ADDITIONAL
10 BOARD COMMENT?

11 DR. WRIGHT: I JUST MOVE WE ACCEPT THE
12 INTERIM REGULATIONS WITH THE CORRECTION FROM SHALL TO
13 COULD.

14 CHAIRMAN KLEIN: SECOND?

15 DR. BALTIMORE: THAT WAS ALREADY DONE.

16 CHAIRMAN KLEIN: THE PRIOR MOTION INCLUDED
17 THE MODIFICATION. PRIOR MOTION INCLUDED THE
18 MODIFICATIONS. WE'RE COVERED.

19 DR. BALTIMORE: YOU CALLED THE QUESTION,
20 RIGHT?

21 MS. LANSING: WE JUST CALLED THE QUESTION.

22 CHAIRMAN KLEIN: WE NEED PUBLIC COMMENT. ANY
23 PUBLIC COMMENT? THERE WAS A PRIOR MOTION THAT'S STILL
24 ON THE TABLE WITH THE SECOND.

25 DR. HALL: JANET WAS THE PRIOR SECOND.

1 DR. WRIGHT: I WAS THE PRIOR SECOND. YOU' D
2 THINK I' D REMEMBER THAT.

3 CHAIRMAN KLEIN: NO PUBLIC COMMENT ON THIS.
4 THEN I WOULD CALL THE QUESTION. ALL IN FAVOR.
5 OPPOSED?

6 WE' LL MOVE TO THE NEXT ITEM. DR. HALL.

7 DR. HALL: OKAY. THE NEXT TWO ITEMS ARE ALSO
8 IN YOUR TAB 12. AND THAT IS, AND WE WOULD LIKE TO
9 RECOMMEND TWO OTHER DOCUMENTS FOR APPROVAL BY THE ICOC.
10 AND THESE ARE THE STANDARD WORKING GROUP PROCEDURES AND
11 THE STANDARDS WORKING GROUP BYLAWS.

12 NOW, THE PROCEDURES, WHICH WERE APPROVED
13 ORIGINALLY BY THE ICOC, WERE THEN SUBSEQUENTLY
14 DISCUSSED AND REVISED SLIGHTLY BY THE STANDARDS WORKING
15 GROUP, AND THEY ARE IN YOUR NOTEBOOKS. THEY STATE THE
16 COMMITMENT OF THE STANDARDS WORKING GROUP TO PUBLIC
17 MEETINGS WITH PUBLIC COMMENT DURING EACH MEETING AND
18 THE COMMITMENT TO PUBLIC VOTES ON ALL DECISIONS AND
19 RECOMMENDATIONS WITH OPPORTUNITY FOR PUBLIC COMMENT
20 BEFORE EACH VOTE.

21 THE WORKING GROUP WILL MEET IN CONFIDENTIAL
22 SESSION ONLY IF NEEDED TO REVIEW A COMPLAINT REGARDING
23 COMPLIANCE WITH ANY FINAL ACTION TO BE TAKEN IN A
24 PUBLIC MEETING.

25 I THINK -- SO WE WOULD RECOMMEND THE APPROVAL

1 OF THESE PROCEDURES BY THE ICOC WITH ANY MODIFICATION
2 YOU THINK NECESSARY. IS THERE A --

3 DR. BALTIMORE: SO MOVED.

4 CHAIRMAN KLEIN: IS THERE A SECOND?

5 MR. SHEEHY: SECOND.

6 CHAIRMAN KLEIN: MOVED AND SECONDED.

7 DISCUSSION BY THE BOARD? DISCUSSION BY THE BOARD. BY
8 THE PUBLIC?

9 MR. SERRANO-SEWELL: CALL THE QUESTION.

10 CHAIRMAN KLEIN: NO DISCUSSION. CALL THE
11 QUESTION. ALL IN FAVOR. OPPOSED? MOTION PASSES.

12 AND NEXT ITEM, DR. HALL.

13 DR. HALL: SECOND IS THE BYLAWS, WHICH HAVE
14 ALSO BEEN RECOMMENDED BY THE WORKING GROUP FOR APPROVAL
15 TO THE ICOC. THEY ARE SIMILAR IN THEIR FORM TO THE
16 BYLAWS PREVIOUSLY RECOMMENDED BY THE GRANTS WORKING
17 GROUP AND APPROVED BY THE ICOC WITH APPROPRIATE CHANGES
18 TO REFLECT THE DIFFERENT FUNCTION OF THE WORKING
19 GROUPS. AND WE ALSO RECOMMEND APPROVAL OF THESE
20 BYLAWS. I THINK YOU WILL RECOGNIZE THEIR FORM.

21 CHAIRMAN KLEIN: IS THERE A MOTION?

22 DR. PIZZO: SO MOVED.

23 CHAIRMAN KLEIN: MOVED. IS THERE A SECOND?

24 DR. REED: SECOND.

25 CHAIRMAN KLEIN: MOVED AND SECONDED. IS

1 THERE COMMENT? NO COMMENT. FROM THE PUBLIC? SEEING
2 NO COMMENT, CALL THE QUESTION. ALL IN FAVOR. OPPOSED?
3 MOTION PASSES.

4 IF WE COULD FIRST HAVE --

5 MS. LANSING: ARE WE DONE WITH THAT SECTION?
6 I JUST WANTED TO ADD, BECAUSE I THINK WE'RE DONE WITH
7 THE STANDARDS -- DO THE ONE MORE, THEN I WANT TO ADD
8 SOMETHING.

9 DR. HALL: I HAVE TWO MORE THINGS. ONE, I
10 WANTED TO GET A CORRECTION FROM JAMES, IF I MIGHT, THAT
11 MY UNDERSTANDING IS BECAUSE THESE ARE INTERNAL
12 PROCEDURES THAT REGULATE HOW WE WORK, BUT DON'T HAVE
13 IMPACT ON THE PUBLIC, THEY ARE NOT SUBJECT TO APA AND
14 THEY'RE OUR OWN. SO THESE ARE THEN OUR
15 RECOMMENDATIONS. WE CAN CHANGE THEM AS WE WISH. THEY
16 CAN BROUGHT BACK TO THIS COMMITTEE FOR CHANGE, IF
17 NECESSARY.

18 MR. HARRISON: THAT'S CORRECT WITH THE
19 EXCEPTION OF THE MEETING PROCEDURES, WHICH WERE PART OF
20 THE POLICY ENHANCEMENTS ADOPTED BY THE ICOC. AND A
21 PART OF THAT POLICY ENHANCEMENT WAS A PROVISION THAT
22 THE ICOC WOULD GIVE NOTICE TO THE PUBLIC AND THE
23 LEGISLATURE IF IT INTENDED TO MODIFY ANY OF THE MEETING
24 PROCEDURES AND THEN APPROVE THE MODIFICATIONS BY A
25 70-PERCENT VOTE.

1 DR. HALL: THANK YOU. I HAD FORGOTTEN THAT.
2 ONE FINAL ITEM OF BUSINESS, SHERRY, AND
3 THEN --

4 MS. LANSING: I'M OKAY. FORGET IT.

5 DR. HALL: WE HAVE TWO NEW MEMBERS OF THE
6 STANDARDS WORKING GROUP, WHICH WERE CHOSEN BY THE
7 STANDARDS SUBCOMMITTEE AT ITS RECENT MEETING. AND
8 THEIR CREDENTIALS ARE IN YOUR BOOK. ONE IS DR. JOHN
9 WAGNER OF THE UNIVERSITY OF MINNESOTA. HE'S A
10 PROFESSOR OF PEDIATRICS AND SCIENTIFIC DIRECTOR OF
11 CLINICAL RESEARCH IN BLOOD AND MARROW TRANSPLANT
12 PROGRAM THERE AND ALSO A SCIENTIFIC DIRECTOR OF THE
13 STEM CELL INSTITUTE AT THE UNIVERSITY OF MINNESOTA.
14 HE'S AN EXPERT IN THE FIELD OF HEMATOPOETIC STEM CELL
15 TRANSPLANTATION AND HAS WRITTEN A NUMBER OF ORIGINAL
16 PAPERS AND BOOKS. VERY HIGHLY RESPECTED.

17 THE SECOND IS DR. PATRICIA KING, WHO'S THE
18 CARMACK WATERHOUSE PROFESSOR OF LAW, MEDICINE, ETHICS,
19 AND PUBLIC POLICY AT THE GEORGETOWN UNIVERSITY LAW
20 CENTER. SHE SERVED AS THE CO-CHAIR FOR POLICY ON THE
21 NIH EMBRYO RESEARCH PANEL AND ON THE WORKING GROUP TO
22 ADVISE NIH ON GUIDELINES AND OVERSIGHT FOR STEM CELL
23 RESEARCH. SO SHE'S VERY EXPERIENCED IN THIS FIELD.
24 SHE IS A MEMBER, I MIGHT ADD, OF THE INSTITUTE OF
25 MEDICINE.

1 AND SO OUR RECOMMENDATION WOULD BE FOR THE
2 ICOC TO APPROVE BOTH OF THESE APPOINTMENTS TO THE
3 STANDARDS WORKING GROUP.

4 MR. SERRANO-SEWELL: SO MOVED.

5 CHAIRMAN KLEIN: MOVED -- A MOTION. IS THERE
6 A SECOND?

7 DR. PRIETO: SECOND.

8 CHAIRMAN KLEIN: THERE'S A SECOND FROM DR.
9 PRIETO. ANY ADDITIONAL COMMENTS?

10 MS. SAMUELSON: ONE QUICK COMMENT. I HAD THE
11 PLEASURE OF INTERVIEWING THESE TWO CANDIDATES WITH JEFF
12 SHEEHY, AND THEY'RE OUTSTANDING. CREDIT TO OUR WORK.

13 DR. PIZZO: RECOGNIZING THAT THEY ARE
14 OUTSTANDING, I WONDER WHETHER YOU COULD JUST COMMENT ON
15 THE PROCESS FOR HOW THEY WERE SELECTED. WAS THERE --

16 DR. HALL: A SUBCOMMITTEE CHAIRED BY
17 DR. KESSLER OF THE ICOC. IT'S THE ORIGINAL
18 SUBCOMMITTEE THAT CHOSE MEMBERS. IT RECONVENED. AS
19 YOU RECALL, HARRIET RABB HAD TO STEP DOWN. AND WE ALSO
20 HAD HAD A SCIENTIST WHO WITHDREW BECAUSE THEY WISH TO
21 APPLY TO THE ICOC OF THE ORIGINAL GROUP. SO THOSE TWO
22 NEEDED REPLACEMENT. THERE IS A THIRD REPLACEMENT, AND
23 THAT IS THAT MARCY FEIT, AS I UNDERSTAND, WILL REPLACE
24 PHYLLIS PRECIADO ON THIS WORKING GROUP, IF THAT IS
25 CORRECT.

1 GIVEN THOSE, THEN THE COMPLEMENT OF MEMBERS
2 IS NOW ONCE AGAIN COMPLETE.

3 CHAIRMAN KLEIN: ANY OTHER BOARD QUESTIONS?
4 ANY PUBLIC COMMENT? SEEING NO PUBLIC COMMENT, CALL FOR
5 THE QUESTION. ALL IN FAVOR. OPPOSED? MATTER PASSES.

6 DR. HALL: THANK YOU VERY MUCH, MR. CHAIRMAN.
7 THAT'S ALL I HAVE TO SAY.

8 DR. MURPHY: ZACH, THE TRAIN HAS LEFT THE
9 STATION ON THIS ONE, AND I'M SORRY I DIDN'T RAISE IT
10 EARLIER. BUT ON THE STANDARDS WORKING GROUP FOR
11 SCIENTIFIC AND MEDICAL ACCOUNTABILITY, I THINK WE NEED
12 TO BE PREPARED, AS YOU WELL KNOW, THAT IF WE DO RUN
13 INTO AN ACCOUNTABILITY PROBLEM OR AN ETHICAL PROBLEM IN
14 RESEARCH, THAT EACH OF OUR NONPROFITS HAS THEIR OWN
15 RESEARCH INTEGRITY OFFICER. THERE'S A VERY INTRICATE
16 PROCESS THAT GOES ON WITH NIH. AND ONE OF THE KEY
17 ELEMENTS OF THAT IS CONFIDENTIALITY SO PEOPLE DON'T GET
18 ACCUSED OF SOMETHING THAT EVENTUALLY IT TURNS OUT NEVER
19 HAPPENED.

20 SO I THINK AS WE LOOK AT THIS, OBVIOUSLY
21 WE'RE GOING TO HAVE TO BE VERY CAREFUL TO INTERCALATE
22 VERY WELL WITH THE HOME INSTITUTION AND NIH POLICY AND
23 THE RESEARCH INTEGRITY OFFICERS.

24 DR. HALL: ABSOLUTELY. AS I NOTED,
25 CONFIDENTIAL SESSIONS ARE FOR JUST THOSE INSTANCES.

1 CHAIRMAN KLEIN: OKAY. THANK YOU, DR. HALL.
2 WE WILL ADJOURN -- WE WILL ADJOURN THE PUBLIC SESSION,
3 ENTER INTO THE CLOSED SESSION. DURING THE CLOSED
4 SESSION, WE WILL GO THROUGH DISCUSSIONS OF LITIGATION
5 AND PERSONNEL. IF THERE'S ANY ACTION, WE WILL REPORT
6 BACK TO THE PUBLIC ON ACTIONS THAT ARE REQUIRED TO BE
7 REPORTED.

8 THE STAFF WOULD PLEASE -- AMY DUROSS, WOULD
9 YOU TELL US WHERE THE MEETING WILL BE? NEXT TO THE
10 IMMEDIATE RIGHT. AND WE WILL BE EATING DURING THE
11 CLOSED SESSION TO MOVE THIS FORWARD. SO THERE WILL NOT
12 BE A SEPARATE LUNCH BREAK.

13 JAMES, COULD YOU PLEASE TELL US HOW LONG YOU
14 EXPECT THE CLOSED SESSION TO TAKE?

15 MR. HARRISON: FORTY-FIVE MINUTES.

16 CHAIRMAN KLEIN: FORTY-FIVE MINUTES IS OUR
17 COUNSEL'S SUGGESTED TIME. WE WILL TRY TO ADHERE TO
18 THAT. THANK YOU VERY MUCH.

19 (A RECESS WAS TAKEN.)

20 CHAIRMAN KLEIN: ALL RIGHT. IF WE CAN
21 RECONVENE, PLEASE. I THINK WE NEED THE BOARD MEMBERS
22 HERE. WILL COUNSEL CONFIRM A QUORUM, PLEASE? WHILE
23 COUNSEL IS CONFIRMING THE QUORUM, I WOULD SAY THAT
24 THERE IS NO ACTION TAKEN AND, THEREFORE, NO ACTION TO
25 REPORT IN THE EXECUTIVE SESSION.

1 MR. HARRISON: YOU HAVE A QUORUM.

2 CHAIRMAN KLEIN: WE HAVE A QUORUM. ITEM 15
3 IS THE NEXT ITEM, CONSIDERATION OF REPORT FROM THE
4 FACILITIES WORKING GROUP. DR. HALL.

5 DR. HALL: I JUST WANT TO MAKE A BRIEF REPORT
6 ON THE FIRST MEETING OF THE FACILITIES WORKING GROUP,
7 WHICH MET LAST FRIDAY. WE HAD AN EXCELLENT MEETING.
8 AND THE MAIN ITEM ON THE AGENDA WAS TO DISCUSS THE
9 OVERALL GRANTS PROGRAM OF THE INSTITUTE AND THE ICOC
10 AND TO SEE HOW THE FACILITIES FIT INTO THAT. AND THEN
11 TO TALK ABOUT HOW THE FACILITIES WORKING GROUP MIGHT
12 WORK.

13 THE WORKING GROUP IS DEVELOPING A SET OF
14 PROCEDURES AND BYLAWS, SUCH AS THOSE YOU SAW TODAY FOR
15 THE STANDARDS WORKING GROUP. AND THESE WILL BE
16 ADDRESSED IN FUTURE MEETINGS.

17 THE WAY IN WHICH THE FACILITIES GRANT
18 APPLICATIONS WILL WORK PRESENTS A SPECIAL CHALLENGE IN
19 THAT BOTH THE GRANTS WORKING GROUP AND THE FACILITIES
20 WORKING GROUP WILL NEED TO MAKE EVALUATIONS FOR THESE
21 FACILITIES GRANTS. AND THE EVALUATIONS WILL NEED TO BE
22 COORDINATED IN SOME WAY. A NUMBER OF INTERESTING AND
23 INNOVATIVE IDEAS WERE RAISED AT THE MEETING ABOUT HOW
24 THIS MIGHT BE DONE, AND IT WAS AGREED THAT THE STAFF
25 AND THE WORKING GROUP LEADERS WOULD WORK WITH JAMES

1 HARRISON TO SEE WHAT CAN AND CANNOT BE DONE BEFORE A
2 SPECIFIC RECOMMENDATION IS MADE TO THE ICOC.

3 AND I FAILED TO MENTION THE WORKING GROUP IS
4 CHAIRED BY RUSTY DOMS FROM LONG BEACH, AND IT'S
5 CO-CHAIRRED BY DAVID SERRANO-SEWELL.

6 IN ANOTHER ISSUE, THE ICOC IN MAY PASSED A
7 MOTION ASKING STAFF TO ISSUE A REQUEST FOR LETTERS OF
8 INTENT FOR DIFFERENT TYPES OF FACILITIES THAT COULD BE
9 BUILT AROUND THE STATE TO FACILITATE STEM CELL
10 RESEARCH. THESE LETTERS OF INTENT WOULD THEN BE USED
11 AS THE BASIS FOR CASE STUDIES TO BE MADE BY THE
12 FACILITIES WORKING GROUP THAT WILL THEN GUIDE FUTURE
13 FACILITIES GRANTS.

14 THESE WOULD REPRESENT, AT LEAST FROM THE
15 MINUTES OF THE VARIOUS MEETINGS, THESE WOULD REPRESENT
16 AN INVENTORY OF IDEAS OR CONCEPTS THAT REFLECT THE
17 THINKING AROUND THE STATE. AT THE MEETING ON FRIDAY,
18 IT WAS DECIDED THAT A SUBCOMMITTEE OF THE WORKING GROUP
19 WILL DISCUSS EXACTLY WHAT WILL BE ASKED FOR, WHO THE
20 REQUESTS WILL BE DIRECTED TO, AND HOW THE INFORMATION
21 WILL BE RECEIVED AND ORGANIZED. AND WE LOOK FORWARD TO
22 FUTURE RESULTS FROM MEETINGS OF THIS WORKING GROUP.

23 CHAIRMAN KLEIN: THANK YOU VERY MUCH. IS
24 THERE ANY BOARD DISCUSSION OF THE REPORT ON THE
25 FACILITIES COMMITTEE? IS THERE ANY PUBLIC COMMENT?

1 OKAY. THANK YOU.

2 WE' LL MOVE FORWARD TO THE CONSIDERATION OF
3 INTERIM GRANTS ADMINISTRATION POLICY FOR TRAINING
4 GRANTS.

5 DR. HENDERSON: MR. CHAIRMAN, COULD I TRY TO
6 CAPTURE WHAT YOU WERE JUST TALKING ABOUT, ZACH, IN THE
7 CONTEXT OF WHERE WE' RE TRYING TO GO. THE TIMELINE TO
8 GETTING NEW FACILITIES UP FOR THIS SORT OF AN EFFORT IS
9 PRETTY SUBSTANTIAL. SO YOU' RE GOING TO TRY TO TAKE AN
10 INVENTORY OF WHAT --

11 DR. HALL: SO THERE' S SOME CONFUSION ABOUT
12 THIS, AND I THINK THE SUBCOMMITTEE IS GOING TO SORT
13 THAT OUT. ON THE ONE HAND, THERE WAS TALKED ABOUT AN
14 INVENTORY OF AVAILABLE SPACE IN THE STATE FOR HUMAN
15 STEM CELL RESEARCH. ON THE OTHER HAND, THERE WAS
16 DISCUSSION IN SOME OF THE MINUTES BOTH OF ICOC MEETINGS
17 AND OF THE FACILITIES SUBCOMMITTEE OF AN INVENTORY OF
18 CONCEPTS OR IDEAS FOR FACILITIES THAT MIGHT BE
19 CONTEMPLATED AT VARIOUS INSTITUTIONS AROUND THE STATE.
20 AND IT WOULD BE A WAY OF SORT OF GIVING THE FACILITIES
21 WORKING GROUP A HEADS-UP ABOUT POSSIBILITIES THAT WERE
22 OUT THERE. AND THEN AS I UNDERSTAND IT, SELECTING
23 CERTAIN ONES OF THESE CONCEPTS FOR THEN CASE STUDIES BY
24 THE FACILITIES WORKING GROUP OF HOW A FACILITY ACTUALLY
25 LIKE THIS MIGHT BE FUNDED AND MIGHT WORK.

1 DR. HENDERSON: TO SOME EXTENT THIS WOULD BE
2 PART OF THEIR STRATEGIC PLANNING PROCESS AS WELL, I
3 WOULD THINK, OF THE WHOLE.

4 DR. HALL: YES.

5 DR. HENDERSON: WHOLE THING WE HAVE UNDER WAY
6 HERE, RIGHT, BECAUSE WE CAN'T DO IT WITHOUT FACILITIES
7 TO WORK IN.

8 DR. HALL: I WOULD PRESUME SO. AND I SUPPOSE
9 YOU COULD REGARD THIS AS PART OF THE INFORMATION
10 GATHERING FOR THAT PROCESS.

11 DR. HENDERSON: YEAH. THANK YOU.

12 DR. PIZZO: FOLLOWING UP ON THAT COMMENT, I'M
13 SURE THIS IS TRUE FOR OTHER CENTERS AS WELL, BUT
14 FACILITIES IS GOING TO BE THE RATE LIMITING STEP FOR
15 MAKING PROGRESS GOING FORWARD FOR SURE. IT IS ALREADY.
16 IT CERTAINLY IS IMPACTING US IN TERMS OF ACTIVITIES AT
17 HAND, RECRUITMENTS, AND THE LIKE.

18 ONE OF THE THINGS THAT I THINK WILL BE VERY
19 IMPORTANT TO DO IS, AS WE IDENTIFY WHAT WE'RE LOOKING
20 AT, SO THIS REALLY FOLLOWS YOUR COMMENT ABOUT INVENTORY
21 OF STEM CELL RESEARCH BASE, IS ON THE ONE HAND, ONE CAN
22 ENVISION ADVANTAGES FOR SEPARATE SPACE, AS WE TALKED
23 ABOUT THIS MORNING. THE DISADVANTAGE OF ISOLATING THE
24 SPACE IS THAT WE RUN THE RISK OF NOT HAVING OTHER
25 DISCIPLINES BEYOND THE BIOLOGY OF STEM CELL RESEARCH

1 IMPACT ON ITS FUTURE, MEANING THAT I THINK THAT ONE OF
2 THE KEY SUCCESSES GOING FORWARD IS TO REALLY ENHANCE
3 THE RESEARCH ENVIRONMENTS THAT ARE, I'LL SPEAK FOR THE
4 ACADEMIC INSTITUTIONS, AT LEAST ONE LIKE OURS, WHERE
5 THE REAL PAYOFF IS GOING TO BE NOT JUST BY WHAT HAPPENS
6 IN OUR SCHOOLS OF MEDICINE, BUT WHAT HAPPENS BECAUSE OF
7 THE INTERACTIONS WITH OUR SCHOOLS OF ENGINEERING AND
8 THE PHYSICAL SCIENCES AND THE LIKE.

9 SO I HOPE THAT WE'LL THINK QUITE BROADLY
10 ABOUT THE WAY WE CONSIDER SPACE. SPACE THAT MIGHT BE
11 PROTECTED FOR FUNDING THAT COULDN'T BE -- FOR SUPPORT
12 THAT COULDN'T BE DONE THROUGH FEDERAL DOLLAR, AND THEN
13 SPACE THAT REALLY ENHANCES THE CREATIVITY THAT WILL
14 EMANATE FROM OUR UNIVERSITIES IN WAYS THAT I THINK WILL
15 MAKE US REALLY THE FUTURE LEADERS.

16 DR. HALL: WELL, LET ME DISTINGUISH TWO
17 THINGS. THIS MORNING WE WERE TALKING ABOUT RELATIVELY
18 SMALL PIECES OF SPACE --

19 DR. PIZZO: THAT'S RIGHT. I UNDERSTAND THAT.

20 DR. HALL: -- WHICH COULD BE EASILY
21 INTEGRATED INTO WHATEVER IS GOING ON AROUND. IT IS --
22 A SECOND QUESTION, IS IT A USEFUL THING TO HAVE A STEM
23 CELL RESEARCH BUILDING OR STEM CELL RESEARCH WING ON A
24 BUILDING, OR HOW WOULD THAT -- I THINK, YOU KNOW,
25 THROUGH -- IF THERE WERE AN RFA ISSUED, THROUGH THE

1 REQUESTS THAT MIGHT COME IN, I WOULD THINK UNIVERSITIES
2 WOULD BE FREE TO PROPOSE WHATEVER CONCEPT THEY WISH.
3 TO ENHANCE THE RESEARCH IS GOING TO BE THE AIM. IF
4 STANFORD WERE TO SAY WE THINK WE'RE GOING TO DO THIS
5 BEST BY PUTTING IN ENGINEERS ALONGSIDE OUR BIOLOGISTS,
6 THEN I THINK THAT'S A QUITE A REASONABLE THING.

7 DR. PIZZO: EXACTLY. THAT'S BASICALLY WHAT
8 I'M GETTING AT IS THAT I THINK WE WANT TO BE THINKING
9 BOLDLY.

10 DR. HALL: ONE OTHER POINT I JUST WANTED TO
11 MAKE, AND THAT IS, THIS MORNING WE WERE TALKING ABOUT
12 SORT OF SPACE THAT WOULD BE A SAFE HAVEN FOR RESEARCH
13 OUTSIDE THE GUIDELINES. AND THERE MAY WELL BE, I
14 WOULDN'T ANTICIPATE THAT IF WE WERE TO CONTRIBUTE TO
15 LARGE FACILITIES, THAT EVERY SINGLE EXPERIMENT IN THAT
16 THING WOULD HAVE TO BE OUTSIDE THE FEDERAL GUIDELINES,
17 BUT I WOULD HOPE THAT WE COULD CONSIDER STEM CELL
18 RESEARCH BROADLY CONSIDERED WITHIN, LET'S SAY, A WING
19 OF A BUILDING OR A FLOOR OF A BUILDING OR MAYBE AN
20 ENTIRE BUILDING.

21 DR. PIZZO: RIGHT. I AGREE WITH THAT, OF
22 COURSE, AND I THINK THE SORT OF PUNCTUATION POINT THAT
23 I WANT TO PUT ON THIS FOR THE RECORD IS THAT JUST AS WE
24 HAVE IN OUR LAST SESSION SAID THAT OUR FUTURE DEPENDS
25 ON HAVING A PIPELINE OF TRAINEES WHO WILL DO THE

1 RESEARCH GOING FORWARD, THEIR FUTURES AND OUR
2 COLLECTIVE OPPORTUNITIES DEPEND UPON HAVING THE
3 FACILITIES TO CARRY OUT THAT RESEARCH. SO I THINK THAT
4 IF YOU ASKED ME WHAT IS AMONG THE HIGHEST PRIORITIES
5 THAT I SEE GOING FORWARD, IT IS FUNDING FOR SPACE THAT
6 WILL ALLOW THIS RESEARCH TO TAKE PLACE BECAUSE IT'S
7 GOING TO BE YEARS BEFORE WE HAVE IT. AND IF WE DON'T
8 GET STARTED ON THAT SOON, WE'RE GOING TO, I THINK, MISS
9 THE OPPORTUNITY THAT REALLY STANDS BEFORE US.

10 DR. HALL: YES. LET ME JUST SAY ANOTHER WORD
11 ABOUT THAT. I ENTIRELY AGREE THAT THAT IS AN EARLY AND
12 URGENT NEED, AND WE NEED TO GET ON IT RIGHT AWAY. AND
13 IT IS ALSO COMPLICATED, IT SEEMS TO ME, BY SOME OF THE
14 INSTITUTIONAL CONSTRAINTS. I THINK FOR THE KINDS OF
15 JUSTIFICATION THAT I KNOW ABOUT IN THE UNIVERSITY OF
16 CALIFORNIA FOR A BUILDING, DR. KESSLER AND OTHERS WHO
17 MAY BE HERE MIGHT CORRECT ME ON THIS, BUT MY
18 UNDERSTANDING IS IT WOULD BE VERY DIFFICULT TO SAY TO
19 THE REGENTS -- ACTUALLY WE HAVE A REGENT, SHERRY
20 LANSING -- BE VERY DIFFICULT TO SAY, WELL, WE THINK
21 WE'RE GOING TO GET SOME MONEY FROM CIRM. AND ON THAT
22 BASIS WE WANT TO GO AHEAD BECAUSE YOU CERTAINLY HAVE TO
23 HAVE FINANCING FOR THE BUILDING LAID OUT. IT HAS TO BE
24 WITHIN THE CONSTRAINTS OF THE UNIVERSITY SYSTEM AND THE
25 CONSTRAINTS OF YOUR OWN CAMPUS.

1 I THINK ALL OF THOSE -- I THINK WE NEED TO DO
2 SOME WORK ON HOW WE CAN MAKE THAT HAPPEN AS QUICKLY AS
3 POSSIBLE. AND IT SEEMS TO ME THAT'S IMPORTANT.

4 LET ME ADD ONE OTHER THING, AND THAT IS THAT
5 WE BADLY NEED ON OUR STAFF A PERSON WITH EXPERTISE IN
6 THIS AREA. AND THIS WORKING GROUP SHOULD HAVE, IN MY
7 VIEW, A PERSON EXPERIENCED WITH CONSTRUCTION, WHO CAN
8 CARRY ON THESE CONVERSATIONS, WHO'S FAMILIAR ALSO WITH
9 FINANCING AND CAN REALLY PROVIDE THAT SORT OF
10 EXPERTISE. WE AT PRESENT DON'T HAVE IT, AND I LOOK
11 FORWARD VERY MUCH TO THE AVAILABILITY OF FUNDS TO
12 EXPAND OUR STAFF IN THIS AREA. AND I THINK THAT IS ONE
13 OF THE CONSTRAINTS BEFORE WE'RE ABLE TO DO THE KIND OF
14 JOB THAT I THINK WE OUGHT TO BE ABLE TO DO WITH RESPECT
15 TO FACILITIES.

16 DR. HENDERSON: DO WE HAVE SOME SORT OF A
17 TIMELINE IN MIND AS TO WHAT WE'RE GOING TO DO ABOUT
18 THIS HUGE ISSUE, IN WHAT ORDER AND WHEN? WELL, THIS
19 WHOLE QUESTION OF HOW WE GET FACILITIES PLANNED AND
20 BUILT, HOW DO YOU GO ABOUT THAT THROUGH THAT COMMITTEE?

21 DR. HALL: SO THE COMMITTEE IS WORKING ON THE
22 QUESTION OF HOW TO CARRY OUT ITS OWN ACTIVITIES. I'M
23 NOT QUITE SURE IF THIS IS WHAT YOU MEANT. BUT
24 INTERNALLY IN TERMS OF HOW IT WOULD COORDINATE WITH THE
25 GRANTS COMMITTEE, HOW IT WOULD WORK WITH ICOC, AND MY

1 HOPE IS THAT FAIRLY SOON THEY CAN BRING OUT A PROPOSAL
2 TO BE CONSIDERED BY THIS COMMITTEE.

3 THERE IS ANOTHER ISSUE, AND THAT IS HOW TO
4 WORK WITH UNIVERSITIES IN ORDER TO MAKE THE PROCESS
5 HAPPEN THERE, AND TO BE AWARE OF THE CONSTRAINTS THAT
6 EACH UNIVERSITY HAS. AND I THINK IT WILL BE THE RARE
7 CASE THAT WE CAN GO IN AND JUST SAY WE'RE GOING TO SET
8 UP A BUILDING, AND WE DON'T HAVE TO ANSWER TO ANYBODY
9 BUT OURSELVES. I THINK ALL OF US IN UNIVERSITIES KNOW
10 THAT BUILDINGS ARE VERY COMPLICATED TO PUSH THROUGH.
11 SOMETIMES EIR'S ARE REQUIRED OR OTHER THINGS. SO IT'S
12 NOT AN EASY MATTER. AND I THINK THAT WHOLE PROCESS AND
13 HOW TO DO IT REQUIRES SOME THOUGHT.

14 DR. PIZZO: JUST TO, AGAIN, STAY ON THAT
15 THEME BECAUSE IT IS SO COMPLICATED AND BECAUSE THE
16 PLANNING IS SO VARIEGATED FROM ONE CENTER TO ANOTHER,
17 IT ONLY UNDERSCORES THE IMPORTANCE OF STARTING THAT
18 PROCESS NOW. EVEN THOUGH WE RECOGNIZE THAT IT MAY TAKE
19 ONE, TWO, OR MORE YEARS BEFORE THERE'S FUNDING
20 AVAILABLE, WE MIGHT -- WE WOULD ALL BENEFIT FROM HAVING
21 EVERYTHING AT AN APPROPRIATE STARTING GATE SO THAT WE
22 DON'T DELAY IT EVEN ANOTHER HANDFUL OF YEARS BEYOND
23 THEN.

24 DR. HALL: I FULLY SUPPORT THAT. WHAT IS
25 CONSTRAINING US RIGHT NOW I WOULD SAY MORE THAN

1 ANYTHING IS OUR INABILITY TO HIRE TRAINED PERSONNEL IN
2 THAT AREA THAT COULD BRING THAT SORT OF EXPERTISE TO
3 OUR STAFF.

4 CHAIRMAN KLEIN: I WOULD SUPPLEMENT THE
5 COMMENTS BY SAYING THAT THE COMMITTEE SPECIFICALLY DID
6 DISCUSS THE FACT THAT THERE ARE INSTITUTIONS THAT WILL
7 DISCOVER WITHIN THIS INVENTORY OF SPACE WHO ARE
8 DOWNSTREAM IN THIS PROCESS AND WHO HAVE PLANS IN
9 PROCESS, AND THEY CAN PROJECT WHEN THOSE PLANS WOULD BE
10 AT A POINT THAT THEY COULD USE FINANCING. WE COULD
11 HAVE A COMPETITIVE ROUND POTENTIALLY AMONG THOSE
12 INSTITUTIONS THAT WERE DOWNSTREAM IN THIS PROCESS, GIVE
13 THEM A CONDITIONAL AWARD, IF THE ICOC BELIEVED THIS WAS
14 THE BEST SERVICE OR MISSION, THAT WOULD SAY IF WE
15 SUCCEED IN OUR MAINTAINING THE CONSTITUTIONALITY OF
16 PROP 71, AS WE EXPECT, WE WILL USE OUR BONDS TO FUND A
17 PORTION OF THE BUILDING. THIS IS WHAT WE WOULD FUND
18 CONDITIONALLY. THAT WOULD ALLOW INSTITUTIONS TO DECIDE
19 IF THEY WANTED TO ASSUME THE RISK OF OUR BEING
20 SUCCESSFUL IN THE LITIGATION.

21 AND AS YOU KNOW FROM THE INITIATIVE, IT'S
22 SUGGESTED THAT THE GOAL OF THE INITIATIVE WAS TO GET
23 THE SPACE BUILT WITHIN FIVE YEARS. ONE YEAR IS GONE.
24 THAT MEANS WE HAVE AN AGGRESSIVE GOAL TO MEET. NEVER
25 SET AN AGGRESSIVE GOAL, SO IT'S AN UNUSUAL CHALLENGE WE

1 HAVE, BUT IT IS, IN FACT, A CHALLENGE THAT WILL BE
2 POTENTIALLY VERY DEMANDING.

3 DR. HALL: LET ME MAKE --

4 DR. MURPHY: ZACH, I THINK WE SHOULD BE
5 PREPARED TO DO THIS WELL, BUT I ALSO DON'T WANT TO GET
6 INTO THE POSITION WHERE THE CIRM BECOMES THE PLACE TO
7 SAY WE WILL BUILD A BUILDING AND THEY WILL COME. I
8 THINK WE HAVE TO MAKE ABSOLUTELY CERTAIN THAT IT'S THE
9 SCIENCE THAT IS BEING GENERATED BY THE INSTITUTIONS
10 THAT DEMAND THE SPACE, AND THAT WE RESPOND TO IT RATHER
11 THAN WE BECOMING THE PROACTIVE FORCE.

12 DR. HALL: THAT'S A VERY GOOD POINT. AND I
13 WOULD SAY THAT WAS EXPRESSED TIME AND TIME AGAIN AT THE
14 FACILITIES WORKING GROUP MEETING. MR. KASHIAN, AMONG
15 OTHERS, WAS VERY CLEAR ABOUT THIS. NO POINT IN PUTTING
16 UP A FACILITY UNLESS IT'S GOING TO BE USEFUL FOR THE
17 SCIENCE AND THE SCIENTISTS ARE FOR IT. AND I THINK
18 THAT WE HAVE TO -- WE HAVE TO WORK OUT THE PROCESS, BUT
19 I THINK THERE'S NO DISAGREEMENT ABOUT THE DESIRABILITY
20 OF HAVING THE SCIENTIFIC JUDGMENT THAT SAYS THIS IS
21 EITHER SUITABLE AND USEFUL OR NOT.

22 DR. MURPHY: BY THE HOME INSTITUTION.

23 DR. HALL: YES. THE OTHER -- AS WE DISCUSS
24 THIS, I REALIZE THAT THE OTHER DIFFICULTY IN A WAY IS
25 THAT ALTHOUGH WE HAVE THESE VERY TALENTED PEOPLE FROM

1 THE REAL ESTATE FIELD AND DEVELOPMENT ON OUR COMMITTEE,
2 AND WE HAVE A GROUP OF PATIENT ADVOCATES, ONE OF THE
3 THINGS THAT WE DO NOT HAVE REPRESENTED IS AN
4 UNDERSTANDING OF THE INSTITUTIONAL PROCESSES FOR
5 DEVELOPING BUILDINGS. AND I THINK WE NEED TO THINK
6 ABOUT HOW WE CAN BRING THAT SORT OF EXPERTISE AND
7 COMMUNICATION IN. AND MAYBE IT WOULD EVEN BE WORTH
8 HAVING SOMEBODY FROM A PRIVATE UNIVERSITY AND SOMEBODY
9 FROM UNIVERSITY OF CALIFORNIA OR SOMEBODY EVEN FROM A
10 SMALL RESEARCH INSTITUTION TO COME IN AND TALK ABOUT
11 HOW IT'S DONE IN THEIR INSTITUTION.

12 DR. PIZZO: I'D BE HAPPY TO VOLUNTEER SOMEONE
13 TO DO THAT BECAUSE I THINK THIS DIALOGUE IS REALLY
14 CRITICAL. AND MY GUESS IS THAT EACH OF OUR
15 INSTITUTIONS ARE TRYING TO HANDLE THIS IN DIFFERENT
16 WAYS. WE'RE RIGHT NOW LEASING SPACE AT ANOTHER SITE AS
17 A SEGUE TO BUILDING SPACE. WE ALREADY HAVE THE PLANS
18 FOR THE BUILDING, BUT WE KNOW WE NEED TO HAVE A
19 PASSAGEWAY TO GET THERE. AND SO THESE TIMELINES ARE
20 ALL PRETTY CRITICAL AS WE REALLY THINK ABOUT HOW TO DO
21 THIS IN THE BEST WAY.

22 DR. HALL: WELL, THIS IS VERY USEFUL BECAUSE
23 I THINK THAT'S SOMETHING WE DEFINITELY NEED IS SOME
24 SORT OF INFORMATION AND SPOKESPERSON, IF YOU WILL, FROM
25 SORT OF THE INSTITUTIONAL POINT OF VIEW, WHICH I THINK

1 WE WERE -- NONE OF US HAVE THAT EXPERTISE.

2 CHAIRMAN KLEIN: SINCE THE INITIATIVE HAS A
3 PRIORITY IN IT FOR FACILITIES THAT CAN BE CONSTRUCTED
4 WITHIN TWO YEARS OF THE GRANT BEING MADE, IT MAY BE
5 HELPFUL TO THE INSTITUTIONS TO TAKE THAT PRIORITY BACK
6 TO THEIR INSTITUTIONAL STRUCTURE AND REALLY MOTIVATE
7 THEIR GOVERNING BOARDS OR WITHIN THE UC SYSTEM MOTIVATE
8 THE PRESIDENT'S OFFICE TO UNDERSTAND WHAT CAN BE DONE
9 TO ACCELERATE THE PROCESS TO MEET THAT PRIORITY.

10 DR. REED: POINT OF CLARIFICATION ON WHERE
11 THE LEASING OF SPACE AS OPPOSED TO CONSTRUCTION OF NEW
12 SPACE NOW RESIDES. IS THAT STILL GOING TO BE WITH THIS
13 SAME FACILITIES WORKING GROUP? AND HOW DOES THAT
14 RELATE TO THESE SMALL FACILITIES OPPORTUNITIES? WILL
15 THAT BE ALSO HANDLED WITHIN THE SAME -- BY THE SAME
16 WORKING GROUP?

17 DR. HALL: YES. OUR EXPECTATION IS THAT THE
18 SMALL FACILITIES, AND IN SOME CASES PEOPLE WILL BE ABLE
19 TO TAKE SPACE THEY ALREADY HAVE, AND IN OTHER CASES,
20 THEY MAY WISH TO LEASE IT OR RENT IT. I THINK THE
21 TIMELINE WE'RE INTERESTED IN THERE WOULD NOT PERMIT
22 MAJOR CONSTRUCTION OF A NEW FACILITY OR A NEW BUILDING,
23 BUT RENOVATION, LEASING, SOMETHING OF THAT SORT, I
24 THINK WE WOULD ALL CONSIDER.

25 I THINK THE URGENCY THERE IS TO BE SURE THERE

1 IS A NUMBER OF PLACES ACROSS THE STATE, THAT THERE IS A
2 PLACE THAT WORK CAN GO ON ON HUMAN EMBRYONIC STEM CELLS
3 OUTSIDE THE FEDERAL GUIDELINES.

4 CHAIRMAN KLEIN: ALL RIGHT. ANY MORE
5 COMMENTS FROM THE BOARD? NO COMMENTS. ANY COMMENTS
6 FROM THE PUBLIC? NO COMMENTS FROM THE PUBLIC.

7 WE'LL MOVE FORWARD TO THE CONSIDERATION OF
8 THE INTERIM GRANTS ADMINISTRATION POLICY FOR TRAINING
9 GRANTS.

10 DR. CHIU: GOOD AFTERNOON. THE CIRM STAFF
11 HAS BEEN WORKING ON A GUIDING STATEMENT THAT GIVES
12 APPLICANTS AND GRANTEEES INFORMATION ABOUT OUR PROCESSES
13 AND PROCEDURES AND ALSO A STATEMENT THAT TELLS THEM
14 WHAT WE EXPECT FROM THEM IF THEY ACCEPT A CIRM AWARD.

15 NOW, OUR GOAL IS TO PROVIDE YOU FOR YOUR
16 REVIEW AND APPROVAL A COMPREHENSIVE CIRM GRANTS
17 ADMINISTRATION POLICY, BUT WE'RE NOT THERE YET. TODAY
18 WHAT I'D LIKE TO DO IS TO PROVIDE AN UPDATE ON OUR
19 PROGRESS IN CRAFTING THIS DOCUMENT.

20 SO I'D LIKE TO PROVIDE A LITTLE BIT OF
21 BACKGROUND AND DISCUSS THE PURPOSE OF SUCH A POLICY
22 STATEMENT, AND THEN PRESENT A BRIEF REVIEW OF ITS
23 CONTENTS, AND END WITH THE CURRENT STATUS OF DIFFERENT
24 DRAFTS OF THIS DOCUMENT.

25 AS YOU MAY RECALL, AT THE LAST ICOC MEETING,

1 THE BOARD APPROVED 16 TRAINING GRANT APPLICATIONS FOR
2 FUNDING. WELL, IN ORDER FOR CIRM TO IMPLEMENT THESE
3 AWARDS ONCE BRIDGE FUNDING BECOMES AVAILABLE, WE HAVE
4 TO SET UP THE NECESSARY INFRASTRUCTURE. AND THAT MEANS
5 BEFORE FUNDING CAN TAKE PLACE, WE SEE THREE TASKS.
6 FIRST, WE NEED TO REVIEW THE BUDGET OF EACH APPROVED
7 APPLICATION FOR ANY CHANGES THAT YOU APPROVED FOR
8 ARITHMETIC ERRORS AND TO SCREEN OUT CHARGES THAT ARE
9 NOT ALLOWABLE AS DEFINED IN THE ORIGINAL RFA.

10 THIS TASK HAS BEEN COMPLETED BY GRANTS
11 MANAGEMENT EFFORTS, WHICH CURRENTLY CONSIST OF ONE
12 CONSULTANT, DR. PATRICIA OLSON. SO AS OF NOW, WE HAVE
13 PRECISE FINAL BUDGETS FOR EACH OF THE APPROVED
14 APPLICATIONS.

15 SECOND, WE NEED TO FIND A WAY TO MAKE THE
16 APPROVED PAYMENTS. THIS MEANS DEVELOPING A PROCEDURE
17 WITH THE STATE CONTROLLER'S OFFICE SO THAT THE STATE
18 CAN TRANSFER THE APPROPRIATE FUNDS TO EACH GRANTEE IN A
19 RESPONSIBLE AND IN A TRACEABLE MANNER. WALTER BARNES,
20 ED DORRINGTON, OUR I.T. CHIEF, AND I ARE IN THE PROCESS
21 OF DEVELOPING SUCH A PROCESS.

22 THIRD, WE HAVE TO MAKE SURE THAT EACH -- THAT
23 THE GRANTEES AND RECIPIENTS UNDERSTAND THEIR ROLES AND
24 RESPONSIBILITIES WHEN THEY ACCEPT SUCH AN AWARD FROM
25 THE CIRM.

1 AND THAT LEADS ME TO THE PURPOSE OF A GRANTS
2 ADMINISTRATION POLICY. IT SERVES TWO PURPOSES, SUCH A
3 POLICY. IT GIVES THE APPLICANTS INFORMATION, AS I
4 SAID, ABOUT US AND IT ALSO TELLS THEM WHAT WE EXPECT.
5 SO THE POLICY STATEMENT WILL SET OUT THE TERMS AND
6 CONDITIONS OF GRANT AWARDS FROM THE CIRM, AND IT WILL
7 TELL THE RECIPIENTS WHAT THOSE RESPONSIBILITIES ARE.

8 NOW, THIS INFORMATION IS DIRECTED NOT JUST AT
9 THE PI, BUT ALSO AT THE RECIPIENT INSTITUTIONS.

10 AND FINALLY, THE RECIPIENT INSTITUTIONS AND
11 PI'S MUST AGREE TO COMPLY WITH THESE GUIDANCES AND
12 PROCEDURES BEFORE THEY CAN RECEIVE FUNDS FROM US.

13 SO WHAT IS COVERED IN SUCH A POLICY
14 STATEMENT? WELL, THE CONTENTS WILL INCLUDE INFORMATION
15 THAT WOULD BE USEFUL TO APPLICANTS AND GRANTEES SUCH AS
16 WHO ARE THE CIRM STAFF MEMBERS THAT THEY'RE LIKELY TO
17 INTERACT WITH AND WHAT ARE THEIR ROLES? WHAT ARE OUR
18 ELIGIBILITY REQUIREMENTS FOR INSTITUTIONS AND FOR PI'S?
19 AND WE'LL PROVIDE GENERAL INFORMATION ON SUBMITTING
20 APPLICATIONS, HOW APPLICATIONS ARE REVIEWED, AND HOW
21 THEY'RE APPROVED FOR FUNDING BY THE BOARD.

22 THE GRANTS ADMINISTRATION POLICY WILL ALSO
23 SPELL OUT TERMS AND CONDITIONS OF AWARD, WHICH INCLUDE
24 THINGS LIKE HOW PAYMENT IS MADE, WHAT COSTS ARE
25 ALLOWABLE, AND WHAT ARE NOT ALLOWED, WHAT TO DO IF

1 CHANGES NEED TO BE MADE AFTER A GRANT HAS BEEN AWARDED;
2 FOR EXAMPLE, ISSUES ABOUT REBUDGETING. OR WHAT IF THE
3 PI MOVES AWAY FROM THE INSTITUTION OR EVEN
4 OUT-OF-STATE?

5 NOW, THE CIRM POLICY ABSOLUTELY WILL HAVE
6 INFORMATION ON INTELLECTUAL PROPERTY THAT IS CURRENTLY
7 BEING DEVELOPED. THAT WILL BE INCLUDED WHEN IT HAS
8 BEEN APPROVED BY THIS BOARD. A POLICY ON SHARING
9 RESEARCH DATA OR RESOURCES WILL BE PUT IN IT AS WELL AS
10 PROCEDURES FOR ANNUAL REPORTS ON SCIENTIFIC PROGRESS
11 AND ON BUDGETARY PROGRESS.

12 THE POLICY STATEMENT WILL ALSO INCLUDE CIRM
13 REQUIREMENTS ON MATTERS SUCH AS USE OF HUMAN EMBRYONIC
14 STEM CELLS, USE OF VERTEBRATE ANIMALS, USE OF
15 BIOHAZARDOUS MATERIALS, AND TREATMENT OF HUMAN PATIENTS
16 AND HUMAN SUBJECTS WHEN CLINICAL STUDIES ARE IN
17 PROGRESS. AND IN ALL OF THESE, WE'LL BE GUIDED BY THE
18 DECISIONS THAT COME OUT OF THE STANDARDS WORKING GROUP
19 THAT YOU'VE HEARD ABOUT TODAY.

20 EARLIER IN THE YEAR CIRM CONTRACTED THE FIRM
21 OF LMI TO RESEARCH FOR US TO IDENTIFY AND TO COMPARE
22 THE POLICIES THAT WERE USED BY A NUMBER OF PUBLIC AND
23 PRIVATE GRANT-MAKING AGENCIES, INCLUDING THE AMERICAN
24 CANCER SOCIETY, THE JUVENILE DIABETES RESEARCH
25 FOUNDATION, THE CALIFORNIA SPECIAL RESEARCH PROGRAMS

1 FOR BREAST CANCER, TOBACCO, AND AIDS, THE AMERICAN
2 HEART ASSOCIATION, AND THE NATIONAL INSTITUTES OF
3 HEALTH.

4 THEIR COMPREHENSIVE REPORT COVERED A LONG
5 LIST OF TOPICS REGARDING POLICIES SUCH AS THE TYPES OF
6 SUPPORT, ROLES AND RESPONSIBILITIES OF ORGANIZATIONAL
7 STAFF, PUBLIC POLICY REQUIREMENTS, INTELLECTUAL
8 PROPERTY, ETC. THEIR RESEARCH PROVIDED INFORMATION ON
9 PROCEDURES SUCH AS HOW DIFFERENT AGENCIES NOTIFIED
10 SUCCESSFUL APPLICANTS AND THEIR REPORTING REQUIREMENTS.

11 USING THIS MATERIAL AS A STARTING POINT, A
12 CIRM TEAM HAS BEEN MEETING REGULARLY TO DEVELOP A FIRST
13 DRAFT OF AN INTERIM GRANTS ADMINISTRATION POLICY
14 STATEMENT. OUR TEAM CONSISTS OF ZACH HALL, MARY MAXON,
15 WALTER BARNES, GIL SOMBRANO, CHRISTINA OLSSON, AND
16 MYSELF, AND MORE RECENTLY WE WERE JOINED BY DAN BEDFORD
17 FROM THE FIRM OF ORRICK, HERRINGTON & SUTCLIFFE, WHO IS
18 PROVIDING HIS LEGAL EYE AND HIS SERVICES PRO BONO.
19 WE'RE VERY APPRECIATIVE OF HIS HELP.

20 AS A RESULT OF THIS GROUP ACTIVITY, WE HAVE
21 NOW COME UP WITH A DRAFT OF AN INTERIM CIRM GRANTS
22 ADMINISTRATION POLICY FOR TRAINING GRANTS. AND THIS
23 DRAFT HAS BEEN POSTED ON THE WEBSITE AND CAN BE FOUND
24 IN TAB 16 OF YOUR BINDERS. WE HOPE TO ASK FOR YOUR
25 APPROVAL WHEN THIS DRAFT HAS BEEN FINALIZED, MOST

1 LIKELY AT THE DECEMBER MEETING, SO THAT TRAINING GRANTS
2 CAN BE AWARDED IN A TIMELY FASHION WHEN FUNDS BECOME
3 AVAIL ABLE.

4 AT THE SAME TIME WE'RE DEVELOPING A DRAFT OF
5 A MORE COMPREHENSIVE INTERIM GRANTS ADMINISTRATION
6 POLICY THAT WILL COVER ALL AWARDS. NOW, THIS MUCH MORE
7 COMPLETE DOCUMENT WILL, IN TURN, FORM THE BASIS FOR
8 DEVELOPING THE INTERIM GRANTS ADMINISTRATIVE
9 REGULATIONS THAT WILL BE SUBMITTED TO THE OFFICE OF
10 ADMINISTRATIVE LAW FOR REVIEW AND THE APA PROCESS.

11 SO IN SUMMARY, WE HOPE YOU HAVE TIME TO TAKE
12 A LOOK AT BINDER -- TAB 16 IN YOUR BINDERS, AND WE' LL
13 BE COMING BACK FOR YOUR APPROVAL OF THIS WORKING
14 DOCUMENT IN THE DECEMBER MEETINGS. THANK YOU. HAPPY
15 TO TAKE QUESTIONS.

16 DR. PENHOET: ANY QUESTIONS FOR ARLENE?

17 DR. HALL: LET ME JUST SAY THAT THE TRAINING
18 GRANT PARTS OF THIS, AS WE SAID EARLIER, IS SOMETHING
19 THAT NEEDS TO BE IN PLACE BEFORE WE CAN ISSUE ANY
20 MONEY. AND SO OUR HOPE IS THAT WE CAN BRING THIS BACK
21 IN DECEMBER. IF YOU HAVE ANY QUESTIONS ABOUT IT IN THE
22 MEANTIME, YOU CAN LET US KNOW. AND ARLENE AND HER TEAM
23 HAVE DONE A TREMENDOUS JOB ON THIS. I MUST SAY THAT
24 THIS REPRESENTS QUITE A BIT OF WORK. WE STARTED ON
25 THIS ACTUALLY BACK -- NOT TOO LONG AFTER I GOT HERE, WE

1 ENGAGED THE CONSULTANTS TO HELP US. SO THIS HAS BEEN A
2 WORK IN PROGRESS OVER A LONG PERIOD OF TIME, AND IT'S
3 BEEN QUITE A JOB TO PUT THIS TOGETHER BECAUSE, AS YOU
4 KNOW, IT HAS ALL THESE ISSUES, SOME OF WHICH HAVE TO BE
5 DECIDED IN OTHER VENUES, LIKE OUR INTELLECTUAL PROPERTY
6 POLICIES, FOR EXAMPLE.

7 DR. BALTIMORE: I READ THIS THING THROUGH
8 BECAUSE WE GOT IT BEFOREHAND, AND IT SEEMED ACTUALLY
9 VERY THOUGHTFUL AND VERY COMPLETE. SO MY QUESTION IS
10 IS THERE ANY PARTICULAR PART OF IT THAT YOU WOULD LIKE
11 TO SEE DISCUSSED FURTHER, OR IS THERE A REASON IT
12 COULDN'T BE MOVED NOW?

13 DR. HALL: THERE IS ONE ISSUE, AND THAT IS
14 THE QUESTION OF IP POLICY. THAT IS ONE ISSUE THAT
15 NEEDS TO BE DECIDED. AND THE QUESTION IS WE WANTED TO
16 BE SURE THAT PEOPLE HAD A CHANCE TO LOOK AT IT AND TO
17 HAVE ANY QUESTIONS. BUT THE IP POLICY, WE EITHER HAVE
18 TO -- IN FACT, ED, LET ME TURN IT OVER TO YOU TO
19 COMMENT ON THAT.

20 DR. PENHOET: WE WON'T HAVE A RECOMMENDATION
21 UNTIL THE NEXT BOARD MEETING. YOU CAN APPROVE THE REST
22 OF THIS POLICY WITH THE EXCEPTION OF THE IP PIECE.

23 DR. HALL: I THINK WE HAVE THREE CHOICES FOR
24 THE IP. LET ME JUST SAY THIS. I GUESS WE HAVE ONLY
25 TWO. WE STATE A SPECIFIC POLICY OR WE DO NOT HAVE ONE.

1 THE OTHER POSSIBILITY WOULD BE TO SAY IN THE
2 TRAINING GRANT THAT THE IP FOR THE TRAINING GRANTS
3 WOULD BE GOVERNED BY WHATEVER -- IN RETROSPECT BY
4 WHATEVER POLICY WE FINALLY DECIDE ON. AND THEN IF
5 PEOPLE SAY WE DON'T KNOW WHAT WE'RE GETTING, THEN YOU'D
6 SAY, WELL, JUST DON'T TAKE THE GRANT. I THINK THOSE
7 ARE THREE OPTIONS; IS THAT CORRECT, ED, OF WAYS TO
8 HANDLE IT WITH THE TRAINING GRANT ONE?

9 WE DO NEED --

10 DR. PENHOET: WE HAVE TO HAVE AN INTERIM
11 POLICY IN PLACE BEFORE WE SEND ANY MONEY TO ANYBODY.

12 DR. HALL: EXACTLY. WE COULD HAVE THAT
13 INTERIM POLICY SAY SIMPLY, I THINK, THAT THE -- YOU
14 WOULD BE GOVERNED BY, JAMES, YOU CORRECT ME IF I'M
15 WRONG, THAT THE INTELLECTUAL PROPERTY PART OF TRAINING
16 GRANT AWARDS IN THIS INTERIM THING WOULD BE GOVERNED BY
17 THE POLICY TO BE CITED IN THE FUTURE, WHICH WOULD BE --
18 APPLY ON A RETROACTIVE BASIS.

19 DR. PENHOET: RETROACTIVELY APPLIED.

20 DR. HALL: I THINK THAT'S A LEGITIMATE
21 SOLUTION. SO ANY ONE OF THOSE THREE, I THINK, ARE
22 POSSIBLE. AND WHATEVER THE COMMITTEE WOULD LIKE. OF
23 COURSE, THE MORE -- WE'RE ALWAYS EAGER TO SEE THINGS
24 GET PASSED AND MOVE ON. SO IT'S UP TO THE COMMITTEE.

25 DR. PENHOET: I THINK THAT'D BE PROBABLY A

1 FALLBACK POSITION, ZACH. IF WE CAN HAVE AN INTERIM
2 POLICY BY THE 6TH OF DECEMBER, WE WOULD LIKE TO PRESENT
3 IT. IF WE CAN'T, WE CAN RELY UPON RETROACTIVE --
4 RETROSPECTIVE LOOK AT THE IP POLICY, WHICH PEOPLE WOULD
5 HAVE TO AGREE TO ABIDE BY IN RETROSPECT.

6 DR. HALL: SO THE QUESTION WOULD BE WHETHER
7 OR NOT TO PASS EVERYTHING BUT THE IP POLICY TODAY.
8 THAT WOULD BE A POSSIBILITY.

9 MS. SAMUELSON: I WOULD PREFER NOT TO, ED. I
10 JUST RECEIVED THIS STUFF AND GOT A CHANCE TO LOOK AT IT
11 QUICKLY THIS MORNING FOR THE FIRST TIME. BUT IT DOES
12 PRESENT -- IT DOES REFER TO SOME POLICY ISSUES THAT
13 ARE -- THERE'S JURISDICTIONAL OVERLAP, IF YOU WILL,
14 WITH THE WORKING GROUP, AND I'D LIKE TO GIVE IT SOME
15 THOUGHT ABOUT WHETHER WE WOULD WANT THEM WEIGHING IN ON
16 ANY OF IT.

17 DR. HALL: WHATEVER THE COMMITTEE WANTS TO
18 DO.

19 DR. CHIU: I WOULD AGREE WITH JOAN, THAT THE
20 CLOCK MIGHT START WHEN WE RECEIVE YOUR APPROVAL. AND
21 SINCE WE'RE NOT EXACTLY SURE WHEN FUNDING WOULD START,
22 THE IDEA WAS TO GIVE YOU A HEADS-UP SO YOU CAN HAVE
23 TIME TO REVIEW THE DOCUMENT. AND I HOPE WE'LL GET YOUR
24 APPROVAL COME DECEMBER 6TH FOR FUNDING IN JANUARY.

25 DR. PENHOET: THIS DOCUMENT -- THESE

1 GUIDELINES WOULD NOT BE USED FOR ANY PURPOSE WHATEVER
2 BETWEEN NOW AND DECEMBER 6TH. SO IN ONE SENSE THERE'S
3 NO URGENCY TO APPROVE THEM TODAY. BUT IT'S ALWAYS NICE
4 TO GET THINGS DONE.

5 DR. STEWARD: I GUESS AT WHAT POINT WOULD
6 THERE BE OPPORTUNITY TO TALK ABOUT SPECIFIC POINTS IN
7 IT? WOULD THAT BE THE DECEMBER 6TH MEETING?

8 DR. PENHOET: ALSO TODAY'S MEETING.

9 DR. HALL: TODAY.

10 DR. STEWARD: CAN I BRING UP THEN A POINT?
11 AND IT HAS TO DO --

12 DR. PENHOET: IN FACT, IF I MIGHT INTERJECT.
13 THE MORE POINTS WE CAN GET IN THE OPEN TODAY, THE MORE
14 FEEDBACK THEY CAN HAVE TO REFINE THE DOCUMENT.

15 DR. HALL: ABSOLUTELY. THAT'S WHY WE BROUGHT
16 IT UP TODAY TO GET IT ON THE TABLE.

17 DR. PENHOET: THIS IS THE TIME TO DO THAT.

18 DR. STEWARD: OKAY. ONE OF THE -- JUST
19 READING THIS OVER, ONE OF THE THINGS THAT IS OF CONCERN
20 TO ME IS THE TRAINING PERIOD. AND JUST TO SORT OF PUT
21 THIS IN CONTEXT, ONE HAS TO BALANCE BETWEEN HOW LONG A
22 TRAINEE NEEDS TO SPEND IN THE ACTIVITY TO HAVE IT
23 USEFUL. BUT -- AND THAT IS ALWAYS A GOOD CRITERION. I
24 THINK THE APPOINTMENT TO 12 CONSECUTIVE MONTHS IS A
25 GOOD SOLUTION TO THAT. WHERE ONE RUNS INTO TROUBLE

1 WITH THIS IS IN RECRUITING M.D. TRAINEES AND TRYING TO
2 INTEGRATE INTO, FOR EXAMPLE, RESIDENCY PROGRAMS. AND
3 AT TIMES ONE NEEDS TO HAVE SITUATIONS WHERE A RESIDENT,
4 FOR EXAMPLE, MIGHT WORK FOUR MONTHS, SIX MONTHS
5 RESIDENCY, GO BACK TO A RESIDENCY TRAINING PROGRAM,
6 COME BACK IN, BACK OUT AGAIN.

7 SO I WANTED TO ASK WHAT THE THOUGHT WAS ALONG
8 THOSE LINES.

9 DR. HALL: I WOULD SAY I THINK THAT BEARS
10 SOME THOUGHT. I WOULD SAY THE PROBLEM WITH IT IS IF
11 YOU -- THE LAST THING WE WANT IS TO HAVE PEOPLE
12 SUPPORTING SUMMER STUDENTS OR PEOPLE USING IT AS A
13 PATCHWORK. YOU'VE GOT SOMEBODY ARRIVES THERE EARLY IN
14 THE YEAR, THEIR NIH GRANT DOESN'T START, SO YOU PUT
15 THEM IN AND TRADE THEM. WE ACTUALLY DON'T WANT THAT.

16 I THINK THE RIGHT SOLUTION MIGHT BE IF
17 THAT -- THAT IT WOULD BE POSSIBLE TO DO THAT WITH --
18 WHAT'S THE WORD I'M LOOKING FOR? -- WITH APPROVAL FROM
19 THE STAFF. JUST LOOK AT IT ON AN AD HOC BASIS, SO
20 YOU'D WRITE A LETTER AND SAY THIS IS A VERY TALENTED
21 PERSON. IT TURNS OUT THEY CAN DO THIS, THIS, AND THIS,
22 AND WE'D LIKE TO DO THAT. I THINK IF WE WRITE IT IN
23 AND DON'T HAVE THAT, I'VE BEEN HEAD OF A TRAINING
24 PROGRAM MYSELF, AND I KNOW THE TEMPTATION. YOU
25 BASICALLY TRY TO PATCH TOGETHER SUPPORT FROM ANY TOOL

1 AT HAND. AND WE WANT CONTINUITY.

2 AND I THINK IT'S THE CASE THAT THE STIPEND
3 CAN BE FOR ONE YEAR, BUT WE WANT THEM ASSOCIATED WITH A
4 TRAINING PROGRAM FOR AT LEAST TWO YEARS SO THAT IT'S,
5 AGAIN, NOT A QUESTION OF MOVING FUNDS AROUND, BUT OF
6 HAVING PEOPLE WHO ARE REALLY IDENTIFIED WITH THE
7 EFFORT. THAT'S OUR MAIN CONCERN. THAT'S REALLY THE
8 THING WE'RE TRYING TO DO.

9 DR. STEWARD: IF THERE COULD BE SOME
10 INDICATION OF THAT LEVEL OF FLEXIBILITY. AGAIN, I
11 THINK IT ESPECIALLY APPLIES TO M.D. TRAINEES THAT NEED
12 TO BE WORKED IN.

13 DR. HALL: WE CAN MAKE THAT AMENDMENT TO SAY
14 WITH PRIOR APPROVAL THAT WOULD BE POSSIBLE.

15 DR. PENHOET: BRINGS UP THE GENERAL QUESTION.
16 PERHAPS, ZACH, EXCEPTIONS TO THE POLICY GENERALLY, HOW
17 WOULD THEY BE HANDLED? LET'S SAY IN HIS CASE HE DID
18 WANT -- IF YOU LEFT IT THE WAY IT WAS AND HE WANTED AN
19 EXCEPTION FOR AN M.D. COMING IN WHO WOULD WORK SIX
20 MONTHS AND THEN DO A ROTATION AND THEN COME BACK IN
21 THREE MORE MONTHS, WOULD YOU HAVE THE AUTHORITY TO
22 GRANT THOSE EXCEPTIONS? OR HOW WOULD THEY BE HANDLED?

23 DR. HALL: WELL, IT WOULD COME BACK TO ARLENE
24 AS HEAD OF PROGRAM AND REVIEW. AND IF THERE WERE SOME
25 COMPLICATED DECISION THAT SHE FELT SHE NEEDED TO ASK MY

1 OPINION ON, I'D BE HAPPY TO, BUT I THINK IT WOULD BE
2 HERS AND HER STAFF'S TO MAKE THAT JUDGMENT. IS THAT
3 WHAT YOU MEAN?

4 DR. PENHOET: I'M A LITTLE CONCERNED BECAUSE
5 OF APA. THIS HAS A LITTLE DIFFERENT CONNOTATION WITH
6 REGARD TO FLEXIBILITY BECAUSE IF YOU ARE CHANGING WHAT
7 BECOMES A REGULATION, THEN -- MR. HARRISON, MAYBE
8 YOU'LL ADDRESS THIS ISSUE.

9 DR. HALL: THESE WILL BECOME CALIFORNIA
10 REGULATIONS.

11 MR. HARRISON: THE RULES AND PROCEDURES THAT
12 APPLY TO THE RECIPIENTS OF GRANTS WILL ULTIMATELY BE
13 ADOPTED AS REGULATIONS PURSUANT TO THE ADMINISTRATIVE
14 PROCEDURE ACT, WHICH DOES NOT ALLOW AD HOC EXCEPTIONS,
15 IF YOU WILL, UNLESS A PROCEDURE IS BUILT INTO THE
16 REGULATIONS THEMSELVES. AND IT CAN BE TO PROVIDE FOR
17 SUCH AN EXCEPTION. YOU JUST NEED TO BUILD IN THE
18 EXCEPTION IN THE STANDARDS THAT WILL APPLY.

19 DR. HALL: WE DO THAT WITH BUDGETS. FOR
20 EXAMPLE, WE SAY THAT IF YOU WANT TO REBUDGET ON YOUR
21 GRANT BEYOND CERTAIN LIMITS, YOU CAN'T DO THAT WITHOUT
22 PRIOR APPROVAL. BASICALLY IT MEANS YOU COME AND YOU
23 MAKE THE CASE. IT MEANS YOU CAN'T BE CAVALIER ABOUT
24 IT, BUT YOU COME AND MAKE THE CASE AND SAY THAT MY
25 CENTRIFUGE DIED AND I NEED A NEW ONE, AND I'D LIKE TO

1 USE SOME OF THIS MONEY TO HELP PAY FOR THAT. AND IF
2 IT'S SCIENTIFICALLY JUSTIFIED, WE DO THAT.

3 NOW, THOSE ARE STANDARD THINGS IN FEDERAL
4 GRANTS. I PRESUME IF YOU SAY YOU CAN'T REBUDGET OVER
5 THESE BOUNDARIES WITHOUT EXPRESS PERMISSION OR
6 APPROVAL, I THINK THAT'S OKAY. IS IT NOT?

7 DR. CHIU: WE HAVE A LIST OF PRIOR APPROVALS,
8 CONDITIONS WHERE PRIOR APPROVALS COULD ALLOW, BUT
9 GENERALLY WE WOULD BE LOOKING FOR THESE RESTRICTIONS.

10 DR. HALL: SO IN THIS CASE, IF I UNDERSTAND,
11 IF WE SPECIFY THAT YOU COULD NOT -- I CAN'T PHRASE IT
12 NOW. YOU MUST SERVE CONTINUOUSLY FOR A YEAR EXCEPT
13 UNDER EXCEPTIONAL CIRCUMSTANCES WITH PRIOR APPROVAL BY,
14 AND THEN SAY WHO THAT IS. I THINK THAT THAT WOULD WORK
15 UNDER THE APA, AND IT WOULD SERVE THE PURPOSES OF THE
16 INSTITUTIONS. I PRESUME THIS WILL BE A RELATIVELY RARE
17 THING.

18 DR. STEWARD: ACTUALLY I'M NOT SURE. I THINK
19 THAT THIS IS AN AREA WHERE, IN FACT, WE MIGHT BE SEEING
20 A LOT OF M.D. TRAINEES WANTING TO COME IN AND REALLY
21 TRYING TO WORK THIS OUT IN A CREATIVE WAY. I GUESS
22 WHAT CONCERNS ME ABOUT THE LANGUAGE AS YOU JUST
23 EXPRESSED IT IS THAT FOR INDIVIDUALS WHO MIGHT NOT BE
24 SO CLEVER AT READING BETWEEN THE LINES AND
25 UNDERSTANDING THAT THIS REALLY COULD BE DONE, IT MIGHT

1 BE A VERY HIGH BAR. AND I JUST WONDER IF, ESPECIALLY
2 FOR M.D. TRAINEES, IT MIGHT BE SOMETHING THAT COULD BE
3 WRITTEN INTO THE DOCUMENT WHERE IT WOULD BE CLEAR THAT
4 THERE COULD BE SOME FLEXIBILITY.

5 DR. HALL: REMEMBER, THE TRAINEES ARE
6 SELECTED BY IN ALL CASES THE COMMITTEE IN THE PROGRAM,
7 WHO PRESUMABLY IS KNOWLEDGEABLE ABOUT THIS AND WOULD BE
8 ABLE TO ADVISE AN APPLICANT WHETHER THIS WAS POSSIBLE
9 OR NOT. AND I THINK ONCE WE WERE TO DO IT -- WE CAN
10 THINK OF OTHER WAYS TO DO IT. WE COULD MAKE AN
11 EXCEPTION FOR M.D.'S, ALTHOUGH I WOULD NOT LIKE TO SEE
12 THESE USED FOR SUMMER WORK. BUT IT SEEMS TO ME THAT I
13 THINK IT WOULD BE BAD POLICY TO HAVE -- TO SAY YOU
14 COULD ALLOW PEOPLE TO GO IN AND OUT ON THESE. I THINK
15 IT'S NOT GOOD AT ALL. AND SO MAYBE WE CAN COME UP WITH
16 SOME SORT OF WORDING THAT WOULD HELP THAT PROBLEM,
17 BUT --

18 DR. PENHOET: BUT THE GENERAL CASES IN EACH
19 OF THESE REGULATIONS WHERE WE DO ANTICIPATE SOME NEED
20 FOR FLEXIBILITY, THAT ANTICIPATION HAS TO BE BUILT INTO
21 THE LANGUAGE. OTHERWISE YOU WON'T HAVE ANY
22 FLEXIBILITY.

23 DR. HALL: THAT'S RIGHT.

24 THE OTHER POINT IS THIS IS, AS ALWAYS, IT
25 SEEMS, AN INTERIM REGULATION AND WOULD BE IN EFFECT FOR

1 ABOUT A YEAR OR NINE MONTHS, I GUESS, 270 DAYS.
2 ANYHOW, THAT'S THE OTHER -- IT'S NOT OUR LAST CHANCE AT
3 IT IS WHAT I'M SAYING.

4 CHAIRMAN KLEIN: I'D JUST LIKE TO COMMENT.
5 JAMES, IT'S MY UNDERSTANDING THAT WHEN YOU HAVE THE
6 EXCEPTION, THAT YOU NEED TO HAVE SOME BASIC OBJECTIVE
7 CRITERIA STATED AS TO THE SCOPE OF DECISIONS WITHIN THE
8 EXCEPTION. AND SO IT MIGHT BE HELPFUL IF YOU AND
9 ARLENE WERE TO MEET SO AS TO ADDRESS THE M. D. TRAINING
10 PROGRAM. SOMEONE WOULD BASICALLY UNDERSTAND THE SCOPE
11 OF WHAT WOULD BE CONSIDERED IN THIS DECISION.

12 DR. PENHOET: OTHER COMMENTS? OKAY. WE'LL
13 MOVE ON TO NEXT AGENDA ITEM, WHICH IS CONSIDERATION OF
14 INTERIM CRITERIA FOR REVIEW OF RESEARCH GRANT
15 APPLICATIONS.

16 DR. HALL: I DON'T THINK I NEED TO STAND UP
17 FOR THIS, BUT IF YOU WILL LOOK AT YOUR TAB NO. 17,
18 THERE IS UNDER THAT TAB A RECOMMENDATION FOR INTERIM
19 CRITERIA FOR REVIEW OF RESEARCH GRANT APPLICATIONS.
20 AND THIS WAS A DOCUMENT THAT YOU SAW IN YOUR SEPTEMBER
21 MEETING. WE, THE RESEARCH GRANT WORKING GROUP, MET IN,
22 I THINK IT WAS, AUGUST 2D AND 3D. AND THE FIRST PART
23 OF THAT MEETING WAS A PUBLIC MEETING AT WHICH
24 ESSENTIALLY THIS DOCUMENT WAS PRESENTED AND DISCUSSED,
25 AND IT WAS APPROVED WITH SLIGHT MODIFICATIONS WHICH

1 WERE MADE. WE THEN BROUGHT IT TO THE SEPTEMBER ICOC
2 MEETING, AND THERE WAS SOME DISCUSSION ABOUT HAVING A
3 NAME CHANGE FOR THE MEETING. AND THAT WAS DECIDED --
4 WE DECIDED NOT TO DO THAT.

5 SO WE HAVE NOW THE ORIGINAL FULL NAME OF THE
6 MEETING IN THE DOCUMENT, WHICH HAS BEEN REVISED. AND
7 SO THIS NOW -- THE DOCUMENT AS REVISED AS YOU SUGGESTED
8 LAST TIME IS THE DOCUMENT THAT WAS PASSED BY THE
9 STANDARDS WORKING GROUP IN EARLY AUGUST AND RECOMMENDED
10 TO YOU FOR APPROVAL. AND WE WENT OVER IT AND DISCUSSED
11 IT LAST TIME. WE'D BE HAPPY TO DISCUSS IT MORE IF YOU
12 WISH AT THIS TIME.

13 CHAIRMAN KLEIN: I'D LIKE TO OPEN THIS FOR
14 BOARD COMMENTS. I WOULD ALSO SAY THAT JOAN SAMUELSON
15 HAS SOME VERY GOOD SUGGESTIONS LOOKING TO THE FUTURE
16 WHERE WE CAN ADDRESS THIS BOTH WITH INPUT BACK TO THE
17 BOARD FROM THE WORKING GROUP AND FROM THE STRATEGIC
18 PLANNING PROCESS WHERE THERE ARE CRITERIA THAT MAY VARY
19 BY THE TYPE OF GRANT OR THE AREA OF FOCUS AND
20 PRIORITIES OF FUNDING WHICH MAY REALLY CREATE A MORE
21 COMPLETE PROCESS THAN IS CONTEMPLATED HERE.

22 THIS IS, AS DR. HALL HAS SAID, IS THE INTERIM
23 PROCESS THAT THE STANDARDS GROUP HAS REVIEWED PURSUANT
24 TO OUR PRIOR COMMENTS.

25 MR. SHEEHY: I'M JUST TRYING TO UNDERSTAND

1 THIS. SO IS THIS GOING TO GO INTO THE ADMINISTRATIVE
2 PROCEDURES, THE APA?

3 DR. HALL: THIS WILL BE THE INTERIM
4 STANDARDS. ONCE WE PASS THIS, IT WILL START THE CLOCK
5 TO DRAFT FINAL STANDARDS OVER A PERIOD OF 270 DAYS,
6 JUST AS WE DO WITH THE STANDARDS WORKING GROUP. SO
7 THIS IS AN INTERIM DOCUMENT.

8 MR. SHEEHY: THAT'S FINE. AND DOES THE
9 GRANTS WORKING GROUP GET ANOTHER -- THIS WILL GO BACK
10 TO THE GRANTS --

11 DR. HALL: NO. NO. THE GRANTS WORKING
12 GROUPING APPROVED THIS WITH MINOR -- THEY SUGGESTED
13 CHANGES. THE ONLY CHANGE THAT'S BEEN MADE, AS FAR AS I
14 CAN RECALL SINCE THEN, IS TO CHANGE THE NAME BECAUSE WE
15 HAD A DISCUSSION AT THE ICOC MEETING. THIS IS
16 ESSENTIALLY THE DOCUMENT THAT WAS PASSED -- APPROVED BY
17 THE STANDARDS WORKING GROUP AND RECOMMENDED FOR
18 APPROVAL TO THE ICOC. AND SO -- I'M SORRY. I
19 MISSPOKE. THE GRANTS WORKING GROUP.

20 MR. SHEEHY: I GUESS THE THING THAT I DIDN'T
21 UNDERSTAND WHEN I VOTED ON THIS AT THE GRANTS WORKING
22 GROUP WAS THAT THIS WAS GOING TO BE PART OF THE
23 ADMINISTRATIVE CODE. I THOUGHT THAT THESE WERE JUST
24 CRITERIA. YOU KNOW, ONCE THEY'RE PART OF THE
25 ADMINISTRATIVE CODE, THEY HAVE A DIFFERENT QUALITY THAN

1 SOMETHING THAT WE MAY ADOPT THAT WE CAN CHANGE. BUT
2 THIS, ONCE IT GOES IN, AND THIS COULD POTENTIALLY BE
3 CHANGED IN THE INTERIM.

4 DR. HALL: EXACTLY RIGHT.

5 MR. SHEEHY: BUT WHAT I'M CONCERNED IS THAT
6 THE APPROPRIATE DISCUSSION DIDN'T TAKE PLACE AT THE
7 GRANTS WORKING GROUP BECAUSE WE DIDN'T KNOW THAT WE
8 WERE CREATING SOMETHING THAT'S GOING TO BE SET INTO
9 CODE TO LAST FOR THE ENTIRETY OF THIS ENTITY.

10 DR. HALL: SO LET ME MAKE A POINT THAT WAS
11 SIMILAR TO THE POINT WE MADE WITH STANDARDS. YOU
12 ALWAYS FACE A CHOICE IN THESE THINGS, AND THAT IS SHALL
13 YOU HAVE THE LONG DISCUSSION BEFORE YOU DO THE INTERIM
14 DOCUMENT, OR WILL THE INTERIM DOCUMENT SERVE YOU WHILE
15 YOU HAVE THAT LONG DISCUSSION? AND I THINK THAT'S THE
16 QUESTION. IN ORDER TO HAVE THE FINAL DOCUMENT, SINCE
17 IT DOES GO THROUGH THIS PROCESS, THEN WE WILL HAVE TO
18 PRESUMABLY HAVE A DISCUSSION IN THE STANDARDS WORKING
19 GROUP ABOUT THAT DOCUMENT AND THEN AMEND IT AS WE HAVE
20 BEEN DOING WITH THE STANDARDS. SAME THING.

21 MR. SHEEHY: I MEAN IF IT'S A SIMILAR
22 PROCESS, I'M VERY COMFORTABLE WITH THAT. IF THE
23 RESEARCH WORKING GROUP WILL GET AN OPPORTUNITY MUCH IN
24 THE SAME WAY AS THE STANDARDS WORKING GROUP SO THAT
25 THOSE SCIENTISTS CAN WEIGH IN ON THIS, THEN THAT'S

1 FINE.

2 CHAIRMAN KLEIN: THAT'S A VERY GOOD
3 CLARIFICATION. I THINK WHAT'S IMPORTANT HERE TO
4 RECOGNIZE IS THAT WE HAD A VERY CLEAR DISCUSSION AT THE
5 WORKING GROUP PUBLIC SESSION THAT THIS WAS GOING INTO
6 THE CODE. I THINK JEFF IS QUITE PROPER. NONE OF US
7 EXPECT THIS TO BE THE FINAL VERSION. IT'S GOING TO GO
8 BACK THROUGH WORKING GROUP SUGGESTIONS AND STRATEGIC
9 PLAN SUGGESTIONS, AND WE'RE GOING TO END UP WITH A MORE
10 COMPLETE DOCUMENT. BUT FOR THE PURPOSES OF BEING AN
11 INTERIM DOCUMENT, THIS WAS SPECIFICALLY WHAT WAS
12 CONTEMPLATED AND WHAT WAS PASSED.

13 DR. HALL: THIS GIVES US A BASIS, FOR
14 EXAMPLE, FOR WRITING AN RFA FOR INNOVATION GRANTS.

15 CHAIRMAN KLEIN: OKAY.

16 DR. BLACK: ZACH, LET ME -- ELIGIBILITY FOR
17 FEDERAL FUNDING. IT LOOKS LIKE WE'RE ESSENTIALLY SORT
18 OF DRIVING GRANTS TOWARDS EMBRYONIC OR FETAL STEM CELLS
19 WITH UNAPPROVED LINES ESSENTIALLY BY THIS CRITERIA. IS
20 THAT THE OBJECTIVE OF THE GROUP?

21 DR. HALL: THE LANGUAGE HERE REFLECTS THE
22 LANGUAGE IN THE PROPOSITION.

23 CHAIRMAN KLEIN: SO TO BE --

24 DR. HALL: CORRECT ME IF I'M WRONG, BOB.

25 CHAIRMAN KLEIN: IT'S A TWO-TIERED SYSTEM AS

1 WRITTEN IN THE PROPOSITION WHERE THERE'S A PREFERENCE
2 FOR EMBRYONIC STEM CELL RESEARCH FOR UNAPPROVED LINES,
3 BUT THE OTHER VITAL RESEARCH OPPORTUNITIES CREATES A
4 VERY CLEAR CASE, WHICH WE'VE SUPPORTED TIME AND TIME
5 AGAIN, THAT THE WORKING GROUP CAN BY A TWO-THIRDS VOTE
6 ADVANCE TO SUPPORT VITAL RESEARCH OPPORTUNITIES, WHICH
7 WE HOPE WILL COVER ADULT STEM CELLS, CORD BLOOD STEM
8 CELLS, CELL SIGNALING, CELL GROWTH FACTORS, AND OTHER
9 AREAS WHERE WE CAN MAKE CRITICAL PROGRESS.

10 DR. BLACK: IS THE STUDY SECTION GOING TO BE
11 GIVEN SOME GUIDANCE AS TO WEIGHTING OF THESE VARIOUS
12 CRITERIA?

13 DR. HALL: WELL, THE CRITERIA ARE MEANT TO
14 SERVE FOR A VARIETY OF GRANT TYPES. IN EACH CASE IN
15 THE RFA WE WOULD STATE, FOR EXAMPLE, FOR AN INNOVATION
16 RFA, YOU WOULD WANT TO WEIGHT THE CRITERIA OF
17 INNOVATION RATHER HEAVILY, AND FEASIBILITY PERHAPS NOT
18 SO HEAVILY, AS OPPOSED TO A GRANT WHERE YOU ARE GIVING
19 SOMEBODY A SEVERAL MILLION DOLLAR GRANT OVER FIVE
20 YEARS. YOU WOULD WANT EVIDENCE FOR FEASIBILITY THERE.
21 YOU MIGHT WEIGHT THAT MORE HEAVILY.

22 THE POINT IS THAT RATHER THAN HAVING TO DO
23 IT -- THIS IS A REGULATION; AND RATHER THAN HAVING TO
24 DO EACH TIME A DIFFERENT ONE, WHAT WE'D LIKE IS A
25 FRAMEWORK WITHIN WHICH WE WILL SAY IN THE RFA

1 PARTICULARLY, EMPHASIS WILL BE GIVEN -- IT WILL BE
2 JUDGED ON THE FOLLOWING CRITERIA, PARTICULARLY EMPHASIS
3 WILL BE GIVEN TO THESE CRITERIA.

4 CHAIRMAN KLEIN: DR. HALL, IS IT APPROPRIATE
5 TO SAY, AS A CLARIFICATION FOR DR. BLACK, THAT IF WHEN
6 YOU DO AN RFA FOR INNOVATION, IT WILL COME BACK TO THIS
7 BOARD? THE BOARD WILL LOOK AT THOSE CRITERIA, DECIDE
8 IF THEY HAVE SUGGESTIONS OR CHANGES, AND THE RFA WILL
9 BE APPROVED HERE BEFORE IT'S ISSUED?

10 DR. HALL: WHAT I WOULD LIKE TO HAVE, AND
11 THIS IS A GOOD CHANCE TO DO THAT, I WOULD LIKE IT IF WE
12 COULD GET A CONCEPTUAL APPROVAL WITH ALL THE IMPORTANT
13 POINTS FOR EACH RFA AND NOT HAVE TO BRING THE
14 FUNDAMENTAL DOCUMENT BACK TO THIS COMMITTEE TO GO OVER.
15 IT SLOWS US DOWN, AND I WOULD HOPE THAT WE WOULD HAVE
16 YOUR CONFIDENCE IN BEING ABLE TO DRAFT THE RFA BASED ON
17 THE ELEMENTS THAT WE WOULD PRESENT TO YOU AND RECEIVE
18 YOUR DIRECTION ON.

19 CHAIRMAN KLEIN: AT THE TIME OF A CONCEPTUAL
20 APPROVAL ON SOMETHING LIKE CRITERIA, IT SEEMS THAT THE
21 BOARD WOULD BE VERY INTERESTED IN REVIEWING THOSE
22 CRITERIA AS PART OF THIS CONCEPTUAL APPROVAL.

23 DR. HALL: ABSOLUTELY. SO WE WOULD SAY --
24 THAT WOULD ABSOLUTELY BE PART OF IT. MY ONLY POINT IS
25 THAT THE WRITING, THE CRAFTING OF THESE AND PUTTING IN

1 THE EXACT LANGUAGE TAKES TIME; AND IF WE HAVE TO GET
2 CONCEPTUAL APPROVAL, CRAFT IT TO BRING IT BACK, THEN
3 THAT IS A PROCEDURE THAT, TO MY MIND, I WOULD HOPE WE
4 COULD AVOID.

5 MR. SERRANO-SEWELL: I HAVE CONFIDENCE IN
6 YOU, ZACH, AND YOUR STAFF TO UNDERSTAND WHEN YOU COME
7 BEFORE US AND YOU ASK FOR A CONCEPTUAL APPROVAL, THAT
8 YOU CAN DIGEST IT AND HAVE THE RFA WRITERS INCORPORATE
9 THOSE CONCEPTS IN THE RFA. BUT I HAVE TO TELL YOU I'LL
10 BE LOOKING TO ENSURE THAT THOSE CONCEPTS ARE SO
11 INCLUDED IN THE RFA. IN MY EXPERIENCE IT'S ON A
12 COMMITTEE BY -- COMMISSION-BY-COMMISSION BASIS. SOME
13 COMMISSIONS INSIST ON SEEING THE ACTUAL RFA DOCUMENT
14 AND APPROVING IT WHILE OTHERS GO THE ROUTE THAT YOU ARE
15 RECOMMENDING, WHICH IS HAVING THE CONCEPTUAL APPROVAL.

16 MY ONLY CONCERN IS THAT WHEN WE SPEAK
17 CONCEPTUALLY, I MEAN IT'S SUBJECTIVE IN SOME RESPECT.
18 MIGHT MEAN SOMETHING TO ME AND SOMETHING TO SOMEBODY
19 ELSE. BUT WHEN YOU COME TO US YOU'RE SPECIFIC ENOUGH
20 TO SAY THE WEIGHTING IS -- FOR THIS PARTICULAR RFA,
21 WE'RE GOING TO WEIGHT THESE VARIOUS FACTORS, AND THIS
22 IS WHAT IT WOULD LOOK LIKE. THAT'S FOR MY COMFORT
23 LEVEL.

24 DR. HALL: ABSOLUTELY. AND IF YOU RECALL THE
25 WAY WE DID THE TRAINING GRANT ONE, WE LAID OUT HERE'S

1 WHAT WE WOULD REQUIRE OF PEOPLE OF EACH INSTITUTION,
2 HERE'S WHAT WE WOULD TRY TO PROMOTE, HERE'S THE KIND OF
3 MONEY WE WOULD GIVE. WE ACTUALLY WENT THROUGH IT IN
4 QUITE A BIT OF DETAIL. AND IN THAT PARTICULAR CASE, I
5 THINK WE ACTUALLY DID BRING THE RFA BACK. MY
6 PREFERENCE WOULD BE I HOPE THAT PROCESS GAVE YOU
7 CONFIDENCE ENOUGH IN OUR ABILITIES TO TRANSLATE YOUR
8 WISHES INTO A DOCUMENT THAT WE COULD DO THAT.

9 I THINK PARTICULARLY NOW, WHEN WE'RE TRYING
10 TO GET STARTED, WE MAY BE WORKING ON FAIRLY SHORT
11 NOTICE. I WOULD, FOR ONE, LIKE TO BE ABLE TO SAY THAT
12 AS SOON AS WE HAVE THE MONEY, THAT WE'RE ABLE TO MOVE
13 QUICKLY ON THAT FIRST ROUND OF RFA'S AND GET IT OUT
14 THERE BECAUSE I THINK A POINT THAT DR. PIZZO MADE
15 INFORMALLY EARLIER, THAT IF WE DON'T HAVE SOME MOMENTUM
16 HERE, WE'RE IN DANGER OF, I THINK, LOSING THE
17 CONFIDENCE OF THE SCIENTIFIC AND OTHER COMMUNITIES.

18 CHAIRMAN KLEIN: JOAN SAMUELSON.

19 MS. SAMUELSON: HERE'S THE WAY I SEE IT AS
20 THE VICE CHAIR OF THE WORKING GROUP. THAT WE HAVE A
21 DOCUMENT WHICH CAN BE USED AS THE BASIS FOR ISSUING
22 GRANTS IF WE WERE SO FORTUNATE AS TO BE ABLE TO GET
23 MONEY IN SOME SHORT TIME FRAME, AND WE ALL HOPE WE DO.
24 BUT AT THE SAME TIME WE HAVE THE ABILITY, AS WE HAVE
25 WITH AT LEAST A COUPLE OR THREE OTHER DOCUMENTS, I

1 THINK, THAT WE'VE -- WE ARE -- THAT THE WORKING GROUP
2 WILL BE REEVALUATING, THAT WE HAVE THE ABILITY TO DO
3 THIS. IT'S IMPORTANT, I THINK, TO UNDERSTAND THAT THIS
4 WAS REVIEWED BY THE WORKING GROUP WHEN IT FIRST SAT
5 DOWN TO BEGIN TO DO BUSINESS FOR THE FIRST TIME.

6 AND THIS WAS APPROVED BEFORE THE WORKING
7 GROUP WENT THROUGH THE FIRST PROCESS OF SCORING AND
8 THEN MAKING FINAL DECISIONS, RECOMMENDATIONS ON THE
9 TRAINING GRANTS. AND IN THAT DISCUSSION, WHICH WAS A
10 WONDERFULLY INTERESTING AND FRUITFUL, I THOUGHT,
11 DISCUSSION, THERE WERE LOTS OF POINTS AND QUESTIONS
12 ABOUT THE PROCESS AND THE END GOALS AND SO ON RAISED
13 THAT I THINK MIGHT HAVE WEIGHED IN ON THIS HAD THE
14 ORDER BEEN REVERSED. SO I THINK IT'S IMPORTANT THAT
15 THEY HAVE THE OPPORTUNITY TO HAVE THE BENEFIT OF ALL
16 THAT HAS GONE ON SINCE AND REEVALUATE IT, BUT IT'S A
17 WORKING TOOL FOR NOW.

18 DR. HALL: WE DON'T EXPECT TO HAVE ANOTHER
19 MEETING OF THE GRANTS WORKING GROUP UNTIL AFTER WE'VE
20 ISSUED OUR NEXT RFA. AND SO IN THAT SENSE, WE WOULD
21 LIKE TO ASK AND REQUEST YOUR APPROVAL OF THESE INTERIM
22 CRITERIA FOR REVIEW OF RESEARCH GRANT APPLICATIONS
23 AMENDED AS YOU SEE FIT.

24 CHAIRMAN KLEIN: ADDITIONAL BOARD COMMENT?
25 DR. POMEROY AND THEN FOLLOWED BY DR. BALTIMORE.

1 DR. POMEROY: ZACH, I THINK THIS IS A GREAT
2 START. AND RECOGNIZING THAT IT'S A LIVING DOCUMENT,
3 I'D LIKE TO MAKE THREE SPECIFIC SUGGESTIONS FOR YOU ALL
4 TO CONSIDER AS IT LIVES AND EVOLVES.

5 THE FIRST IS PERHAPS MINOR, BUT I THINK A
6 REFERENCE TO THE RESPONSIVITY OF THE APPLICATION TO THE
7 RFA MIGHT BE A NICE SPECIFIC CRITERIA TO HAVE IN THERE
8 SINCE THERE IS SUCH A BROAD RANGE.

9 SECOND ONE, OF THE THINGS THAT WE'VE TALKED
10 ABOUT A LOT HERE IS THE IMPORTANCE OF COLLABORATION AND
11 THE FACT THAT WE'RE TRYING TO ENCOURAGE MORE TEAM
12 SCIENCE AND LOOKING AT NEW WAYS AND OUTREACH, AND I
13 KNOW THAT SOME OF THESE ARE MORE COLLABORATIVE
14 MECHANISMS THAN OTHERS. BUT SOME RECOGNITION OF THAT
15 VALUE THAT WE ATTRIBUTED TO MULTIDISCIPLINARY, TO
16 COLLABORATION PERHAPS COULD BE INCORPORATED INTO THIS.

17 AND THEN THE THIRD COMMENT IS THE ONE THAT I
18 WOULD ASK YOU TO CONSIDER MOST SERIOUSLY. AND THAT IS
19 THAT THE RESEARCH MEETS THE HIGHEST ETHICAL STANDARDS.
20 THERE IS NO REFERENCE IN HERE TO ETHICAL CONSIDERATIONS
21 AS PART OF THE CRITERIA. NOW, I KNOW THAT'S BECAUSE WE
22 HAVE SEPARATE DOCUMENTS THAT ADDRESS THAT, BUT I THINK
23 IT MIGHT BE A VERY NICE MESSAGE TO SEND, THAT THAT WILL
24 BE CONSIDERED. AND IF THE SCIENTIFIC PEOPLE HAVE ANY
25 CONCERNS ABOUT THE ETHICS OF IT, THAT THAT WILL BE

1 INCORPORATED INTO THEIR DISCUSSIONS OF EACH GRANT.
2 THANK YOU.

3 DR. HALL: WE COULD HAVE CERTAINLY HAVE A
4 SENTENCE AT THE BEGINNING, AND I DON'T HAVE THAT NOW,
5 BUT WE HAD IT AT THE BEGINNING OF -- IT IS A SENTENCE
6 THAT WE HAVE IN OUR LIBRARY OF STOCK SENTENCES THAT
7 SAYS THAT WE SEEK TO FUND RESEARCH THAT ADVANCES STEM
8 CELL RESEARCH, THAT ADVANCES TOWARD THERAPIES UNDER THE
9 HIGHEST POSSIBLE MEDICAL AND ETHICAL STANDARDS. WE
10 COULD CERTAINLY MODIFY THIS. IN FACT, IF YOU AGAIN
11 TRUST US TO FIND THE RIGHT LANGUAGE FOR THAT, WE COULD
12 START IT WITH THAT SENTENCE. THAT SENTENCE, I THINK,
13 WOULD BE VERY GOOD.

14 AND I WOULD SUGGEST, IF WE MIGHT, THAT WE
15 TAKE THE OTHER TWO UNDER CONSIDERATION AS WE DEVELOP
16 THE MORE COMPLETE DOCUMENT.

17 DR. POMEROY: THANK YOU.

18 CHAIRMAN KLEIN: SO, DR. POMEROY, IS THAT A
19 MOTION YOU ARE MAKING TO PASS THIS WITH INCORPORATING
20 THOSE COMMENTS?

21 DR. POMEROY: I WOULD BE GLAD TO TAKE
22 DR. HALL'S SUGGESTION THAT AT THIS POINT WE JUST ADD
23 THE ONE SENTENCE ABOUT SEEKING TO FUND RESEARCH OF THE
24 HIGHEST SCIENTIFIC AND ETHICAL QUALITY, AND THAT THE
25 OTHER TWO COULD BE CONSIDERED LATER. SO IF THAT'S

1 ACCEPTABLE, I WILL MAKE THAT MOTION AS AN AMENDMENT TO
2 THIS DOCUMENT.

3 CHAIRMAN KLEIN: ALL RIGHT. AND BEFORE GOING
4 TO DR. BALTIMORE, IS THERE A SECOND TO THAT MOTION?

5 DR. PRIETO: SECOND.

6 CHAIRMAN KLEIN: MOTION IS MADE AND SECONDED.
7 DR. BALTIMORE, DID YOU HAVE A COMMENT?

8 DR. BALTIMORE: WHY DON'T YOU VOTE ON THAT?
9 IT'S NOT RELEVANT TO THAT.

10 CHAIRMAN KLEIN: OKAY. SO DR. BALTIMORE HAS
11 INDICATED THAT HIS COMMENT IS NOT RELEVANT TO THIS
12 MOTION. IS THERE ANY ADDITIONAL COMMENTS ON THIS
13 MOTION?

14 DR. BALTIMORE: SORRY. MAYBE I MISUNDERSTOOD
15 THE MOTION. THE MOTION IS TO ADOPT WITH THAT. I
16 THOUGHT IT WAS JUST TO AMEND. SORRY.

17 DR. POMEROY: PERHAPS IT WOULD BE EASY. MY
18 MOTION WAS INTENDED TO JUST AMEND THIS DOCUMENT, NOT TO
19 VOTE ON THE DOCUMENT.

20 CHAIRMAN KLEIN: OKAY. APPRECIATE THE
21 CLARIFICATION.

22 DR. BALTIMORE: I READ YOUR MIND.

23 CHAIRMAN KLEIN: AND THE SECOND AGREES WITH
24 THAT CLARIFICATION? YES. ANY ADDITIONAL DISCUSSION ON
25 THAT? IS THERE DISCUSSION FROM THE PUBLIC ON THAT

1 AMENDMENT? NO DISCUSSION ON THE PUBLIC. CALL THE
2 QUESTION. ALL IN FAVOR. OPPOSED? MOTION PASSED.

3 DR. BALTIMORE.

4 DR. BALTIMORE: THERE'S SOMETHING I DON'T
5 UNDERSTAND ABOUT THE DOCUMENT. IT STARTS OFF SAYING IN
6 THE FIRST STAGE THE SCIENTIFIC MERIT, SECOND STAGE
7 RECOMMEND FOR APPROVAL BY THE WORKING GROUP, WHICH
8 PRESUMABLY MEANS THAT NOW THE PATIENT ADVOCATES GET A
9 CHANCE TO --

10 DR. HALL: THE ENTIRE GROUP, INCLUDING
11 SCIENTISTS AND PATIENT ADVOCATES.

12 DR. BALTIMORE: -- GET A CHANCE TO WEIGH IN
13 ON IT.

14 DR. HALL: AND THAT PART IS CHAIRED BY THE
15 CO-CHAIR.

16 DR. BALTIMORE: YOU THEN HAVE BELOW IT FOR
17 SCIENTIFIC EVALUATION THE FOLLOWING CRITERIA. BUT
18 AFTER THAT IT SAYS IN DECIDING WHICH GRANTS TO
19 RECOMMEND, THE FOLLOWING CRITERIA ARE BE CONSIDERED IN
20 REVIEWING THE ENTIRE PORTFOLIO OF GRANTS THAT WILL BE
21 RECOMMENDED FOR FUNDING. SO THAT'S NOT AT ALL PARALLEL
22 TO THE PREVIOUS CONSIDERATIONS, AND I DON'T REALLY
23 UNDERSTAND WHAT THAT'S SUPPOSED TO MEAN. THAT IS, ARE
24 YOU GOING TO MOVE UP GRANTS AND MOVE DOWN GRANTS BASED
25 ON THE ENTIRE PORTFOLIO OF GRANTS? IS THAT WHAT'S

1 MEANT?

2 DR. HALL: YES. BOTH THINGS. BOTH THAT AND
3 ALSO WE HAVE THE CONSIDERATION FROM A PERSPECTIVE OF
4 PATIENT ADVOCATES THAT MAY ADD ADDITIONAL INFORMATION
5 ABOUT THESE. AND ACTUALLY I HAVE AN EXAMPLE THAT I'VE
6 USED SEVERAL TIMES BEFORE WHEN I WAS ON A COMMITTEE
7 LIKE THIS IN WHICH ONE OF THE PATIENT ADVOCATES POINTED
8 OUT THAT A PARTICULAR PROBLEM FOR WHICH THERE WAS A
9 GRANT AND WHICH THE SCIENCE WAS, I WOULD SAY, SO-SO
10 WAS, IN FACT, AN INCREDIBLY IMPORTANT PROBLEM FOR THOSE
11 WITH THE DISEASE AND THEIR FAMILIES. IF ANY PROGRESS
12 COULD BE MADE ON THAT, IT WOULD MAKE A HUGE CHANGE IN
13 QUALITY OF LIFE. NOBODY ON THE COMMITTEE KNEW THAT.
14 IT IMMEDIATELY RAISED IT UP, AND IT WAS FUNDED.

15 I GUESS IT WAS THAT THAT WE HAD IN MIND IN
16 SUGGESTING THAT. WE WOULD WELCOME OTHER ALTERNATIVES,
17 BUT ALSO IT IS A QUESTION -- A TIME TO LOOK AT THE
18 OVERALL BALANCE AND TO SAY -- I'M SURE YOU'VE BEEN IN
19 COMMITTEES WHERE YOU DO THIS. YOU SAY WE'VE GOT SO
20 MUCH MONEY, YOU DRAW THE LINE, AND YOU SAY, LOOK,
21 HERE'S SOME JUST BELOW THE LINE. AS WE LOOK IT, WE'VE
22 GOT FOUR GRANTS THAT ARE ALMOST IDENTICAL UP HERE, AND
23 HERE'S ONE THAT IS REALLY DIFFERENT AND LET'S CONSIDER
24 MOVING IT.

25 IT'S THOSE KINDS OF THINGS. AND JOAN

1 PRESIDED OVER THE DISCUSSION OF THIS AT THE LAST
2 STANDARDS WORKING GROUP VERY SUCCESSFULLY, AND I WOULD
3 SAY THERE WAS A LOT OF DISCUSSION ABOUT THE PARTICULAR
4 APPLICATIONS. SO THAT WAS WHAT WAS INTENDED, BOTH OF
5 THOSE THINGS.

6 DR. BALTIMORE: SO THAT'S WHY THEY'RE NOT
7 PARALLEL WITH EACH OTHER?

8 DR. HALL: YES. IT WAS TRYING TO ACCOMPLISH
9 TWO AIMS.

10 DR. PRICE: I'M NOT SURE IF THIS IS A
11 DISTINCTION WITHOUT A DIFFERENCE, BUT IT MAKES A LITTLE
12 MORE SENSE TO ME IF THAT SECTION, SECTION WHICH BEGINS
13 IN DECIDING WHICH GRANTS TO RECOMMEND AND THE PORTFOLIO
14 IDEA PRECEDES THE CRITERIA FOR SCIENTIFIC EVALUATION.
15 SO THERE'S -- SO THAT THE SECTION ON SCIENTIFIC
16 EVALUATION COULD SAY IN LIGHT OF THE ABOVE OR IN
17 CONSIDERATION OF THE ABOVE.

18 DR. HALL: NO. NO. THEY'RE MISSING A POINT
19 HERE. BY PROPOSITION 71, LET ME JUST -- THE FIRST
20 STAGE OF THIS IS A SCIENTIFIC EVALUATION, RIGHT, IN
21 WHICH THE 15 SCIENTIST MEMBERS RATE EACH GRANT AND COME
22 OUT WITH A NUMBER.

23 DR. PRICE: SOMEBODY ELSE IS GOING TO DO THE
24 OTHER.

25 DR. HALL: NO. THEN THE FULL COMMITTEE, AND

1 THE FULL COMMITTEE IS PRESENT FOR ALL OF THIS AND
2 PARTICIPATE IN THE DISCUSSION, BUT THE ONLY ONES VOTING
3 ARE THE SCIENTISTS. THEN THE FULL COMMITTEE LOOKS AT
4 THE RESULTS OF THAT RANKING BASICALLY, AND YOU DON'T
5 HAVE THE PORTFOLIO INFORMATION UNTIL YOU'VE RANKED
6 THEM. AND THEN YOU SAY AMONG THE ONES THAT ARE AT THE
7 TOP, WE THINK THAT THIS IS -- ANY AGENCY, HERE'S AN
8 INCREDIBLY IMPORTANT DISEASE, ONE JUST BELOW THE LINE,
9 WE SHOULD REALLY MOVE THIS UP. IT'S THAT SORT OF
10 CONSIDERATION.

11 DR. STEWARD: I'M NOT SURE IT'S APPROPRIATE
12 TO WORDSMITH TOO MUCH WITH THIS DOCUMENT, BUT GIVEN
13 THAT IT IS A WORKING DOCUMENT AND GIVEN THAT THERE
14 MIGHT BE A VARIETY OF DIFFERENT STYLES OF GRANTS THAT
15 YOU WOULD BE WANTING TO CONSIDER, INCLUDING ONES THAT
16 REALLY HAD A DEFINABLE GOAL, ONE THING THAT I DON'T SEE
17 IN THIS IS ANYTHING RELATING TO MILESTONES. I WAS
18 WONDERING IF THAT HAD BEEN DISCUSSED AT ALL. THE
19 PHRASE THAT I WOULD THINK OF IS WHERE APPROPRIATE DOES
20 THE GRANT IDENTIFY QUANTITATIVE MILESTONES THAT MIGHT
21 BE USED TO JUDGE PROGRESS?

22 DR. HALL: WE'D BE HAPPY TO ADD THAT EITHER
23 IMMEDIATELY, OR WE COULD PUT IT IN THE CATEGORY OF
24 CONSIDERING IT AS WE FILL THAT OUT. I THINK THE KEY
25 PHRASE THERE IS "WHERE APPROPRIATE." AS YOU RECOGNIZE

1 IN SOME CASES IT IS APPROPRIATE AND OTHER CASES IT'S
2 NOT. BUT AS FAR AS I'M CONCERNED, I'D BE HAPPY TO ADD
3 THAT IF YOU WISH, IF IT'S THE WISH OF THIS COMMITTEE.

4 CHAIRMAN KLEIN: WOULD YOU LIKE TO MAKE THAT
5 A MOTION?

6 DR. STEWARD: I WOULD LIKE TO MAKE THAT A
7 MOTION.

8 CHAIRMAN KLEIN: FINE. IS THERE A SECOND?

9 DR. HALL: COULD YOU READ YOUR SENTENCE SO WE
10 BE SURE WE HAVE IT EXACTLY?

11 DR. STEWARD: OKAY.

12 DR. HALL: YOU WANT TO FINISH IT FIRST?

13 DR. STEWARD: I'LL READ YOU WHAT I HAVE. SO
14 WHERE APPROPRIATE ARE THERE IDENTIFIABLE MILESTONES
15 THAT CAN BE USED TO ASSESS PROGRESS TOWARDS A GOAL OR
16 SOMETHING ALONG THOSE LINES.

17 DR. HALL: FINE. WE WILL WORDSMITH THAT.
18 THAT'S ENOUGH.

19 CHAIRMAN KLEIN: I BELIEVE DR. BLACK HAS A
20 COMMENT.

21 DR. BLACK: ZACH, DO YOU THINK IT WOULD BE
22 APPROPRIATE TO HAVE SOME SORT OF PRESUBMISSION REVIEW
23 FOR THAT LAST SECTION ON SORT OF FEDERALLY FUNDED
24 GRANTS SO THAT A POTENTIAL APPLICANT CAN SEND IN SORT
25 OF A PRELIMINARY PLAN OF WHAT THEY'RE PLANNING TO

1 SUBMIT TO FIND OUT IF THE AGENCY WILL ACCEPT A GRANT
2 BEFORE THEY GO THROUGH THE EFFORT OF WRITING A GRANT,
3 THEN SAY THIS IS GOING TO BE FEDERALLY FUNDED AND NOT
4 APPROPRIATE. SO THAT THAT LAST SECTION BECOMES SORT OF
5 A PRESCREENING REVIEW RATHER THAN SORT OF A CRITERIA
6 THAT CAN BOUNCE THE GRANT OUT FOR REVIEW.

7 DR. HALL: WE WOULD PREFER TO HANDLE THAT ON
8 AN INFORMAL BASIS. THAT IS, IF THE RFA IS WELL
9 WRITTEN, THEN PEOPLE WILL UNDERSTAND. AND WE WILL
10 STATE THAT. AND FOR EXAMPLE, IN THE TRAINING GRANT
11 RFA, WE STATED THIS IS NOT -- THE WORK IS NOT CONFINED
12 TO HUMAN EMBRYONIC STEM CELL RESEARCH. BUT IN THE
13 PARTICULAR RFA, WE WILL STATE THAT, AND THEN WHAT
14 HAPPENS IS PEOPLE'S CALL. AND OUR PROGRAM STAFF THEN
15 ADVISES THEM.

16 IF WE SET UP A FORMAL REVIEW PROCESS, FIRST
17 OF ALL, I THINK IT'S LEGALLY COMPLICATED BECAUSE WE
18 HAVE TO GO THROUGH -- WE HAVEN'T THOUGHT IT THROUGH,
19 BUT I THINK WE'D HAVE TO GO THROUGH THE FULL RIGMAROLE
20 BEFORE WE CAN DENY ANYBODY THE ABILITY TO APPLY.

21 DR. BLACK: I'M JUST ASKING A QUESTION OF
22 PROCESS FOR THE STUDY SECTION, WHATEVER WE'RE GOING TO
23 CALL IT. WILL THE STUDY SECTION, IF THE GRANT IS THEN
24 ACCEPTED ADMINISTRATIVELY BY THE AGENCY, WILL THE STUDY
25 SECTION STILL BE INSTRUCTED TO GRADE THE GRANT OR WEIGH

1 THE GRANT BASED ON THIS CRITERIA OF ELIGIBILITY FOR
2 FEDERAL FUNDING?

3 DR. HALL: WELL, I THINK THE ISSUE ALWAYS
4 THAT THE WORKING GROUP WILL FACE IS, OKAY, HERE'S
5 SOMETHING THAT'S NOT OUTSIDE THE FEDERAL GUIDELINES.
6 IS THIS COMPELLING, OF VITAL URGENCY, COMPELLING. AND
7 PEOPLE WILL MAKE THE CASE THAT IT IS OR IT IS NOT. AND
8 IT WILL RISE OR FALL ON THAT. THERE WILL BE, I'M SURE,
9 A KIND OF A TRADE-OFF IN TERMS OF QUALITY AND DIRECT
10 RELEVANCE. BUT I THINK, AS THE CHAIR HAS INDICATED,
11 THE INTENT IS NOT TO BOX THIS IN TO BE JUST ON WORK
12 OUTSIDE THE FEDERAL GUIDELINES BECAUSE WE THINK THERE'S
13 A LOT OF IMPORTANT AND VALUABLE WORK THAT WE WILL NEED
14 TO ADVANCE THAT WILL BE RELATED, BUT NOT --

15 MS. SAMUELSON: ON THAT POINT, YOU SHOULD
16 KNOW THAT THERE WAS A LOT OF VALUABLE DISCUSSION ON
17 MANY OF THESE SAME POINTS THAT TOOK PLACE IN THE
18 CONTEXT OF SCORING AND EVALUATING AND DECISION-MAKING
19 ABOUT THE TRAINING GRANTS AFTER THIS HAD BEEN ARRIVED
20 AT. SO I THINK THEY'D HAVE ADDITIONAL -- I KNOW
21 THEY'LL HAVE ADDITIONAL COMMENTS, INCLUDING SOME OF THE
22 ONES THAT HAVE BEEN RAISED.

23 CHAIRMAN KLEIN: AND, DR. BLACK, IT WOULD BE
24 APPROPRIATE TO STATE, COUNSEL, CORRECT ME IF I'M WRONG,
25 THAT WHILE THE STAFF CAN ADVISE THEM OF THE STAFF'S

1 OPINION, IF AN APPLICANT DECIDES TO APPLY, THE
2 COMMITTEE, THE WORKING GROUP, CAN COME TO A DIFFERENT
3 CONCLUSION THAN THE STAFF MIGHT. AND THE WORKING GROUP
4 DOES NOT HAVE THE ABILITY TO KILL THE GRANT THERE
5 BECAUSE THEY'RE AN ADVISORY BODY, SO THEY HAVE TO
6 FORWARD THE GRANT TO THE BOARD. AND THEN THE BOARD
7 MAKES THE FINAL DECISION ABOUT THE ADEQUACY OF FUNDING.
8 IS THAT A PROPER STATEMENT, JAMES?

9 MR. HARRISON: YES.

10 CHAIRMAN KLEIN: THE -- DOES THAT PROPERLY
11 RESPOND, DR. BLACK, TO YOUR QUESTION?

12 DR. POMEROY: I'D LIKE TO SECOND THE MOTION
13 THAT'S ON THE FLOOR.

14 CHAIRMAN KLEIN: MOTION HAS BEEN MADE AND
15 SECONDED. IS THERE ADDITIONAL DISCUSSION FROM THE
16 BOARD? IS THERE ADDITIONAL DISCUSSION FROM THE PUBLIC?
17 SEEING NO PUBLIC DISCUSSION, CALL FOR THE QUESTION.
18 ALL IN FAVOR. OPPOSED? THANK YOU.

19 IS THERE A MOTION AT THIS TIME TO PASS THE
20 DRAFT AS AMENDED?

21 DR. PENHOET: SO MOVED.

22 UNIDENTIFIED BOARD MEMBER: SECOND.

23 CHAIRMAN KLEIN: MOVED AND SECONDED.
24 DISCUSSION FROM THE BOARD? DISCUSSION FROM THE PUBLIC?
25 CALLING THE QUESTION, ALL IN FAVOR. OPPOSED. THANK

1 YOU VERY MUCH.

2 WE' D LIKE TO AT THIS POINT ASK, AFTER
3 THANKING DR. ARLENE CHIU AND DR. ZACH HALL FOR THE
4 PRESENTATION ON A NUMBER OF COMPLICATED TASKS TODAY, WE
5 WANT TO TELL YOU HOW MUCH WE APPRECIATE THE DEDICATION
6 THAT KEEPS MOVING US FORWARD HERE.

7 WE' D LIKE TO AT THIS TIME ASK FOR ANY PUBLIC
8 COMMENT THAT MIGHT BE ON A GENERAL TOPIC AREA.

9 MS. SAMUELSON: WE WOULD LISTEN TO YOU
10 WITHOUT THE JACKET, DON.

11 CHAIRMAN KLEIN: WE' D LIKE TO RECOGNIZE DON
12 REED.

13 MR. REED: THANK YOU VERY MUCH. I JUST WANT
14 TO SAY WHAT A GLORIOUS BUILDING THIS IS, HOW SUITABLE
15 AND FITTING THAT SUCH A GLORIOUS UNDERTAKING SHOULD
16 HAVE A TREMENDOUS BACKGROUND AS WELL.

17 COUPLE OF POINTS. FIRST OFF, THE FARMER DOES
18 NOT EAT THE SEED CORN. IT' S PLANTED AND THE PROCEEDS
19 GO FROM THAT. PROPOSITION 71 OFFERS AN OPPORTUNITY, A
20 CHOICE OF WHICH WAY TO GO. IF YOU THINK ABOUT THE
21 EXPENSES THAT THE NATION IS UNDERGOING FOR CHRONIC
22 DISEASE, TO ME THERE CAN BE NO CHOICE. THERE IS NO
23 CHOICE TO MAKE.

24 ALZHEIMER' S, WE HEARD A STATEMENT AT LEAST
25 \$50,000 A YEAR FOR ONE PERSON. FIVE MILLION

1 ALZHEIMER'S SUFFERERS. THAT'S \$250 BILLION. THAT'S
2 ONE-EIGHTH OF ALL THE FEDERAL INCOME TAXES FROM ALL
3 SOURCES IN THE UNITED STATES.

4 THERE'S NO WAY THAT A REVENUE STREAM COMING
5 FROM US CAN MATCH THAT; BUT WE CAN MATCH THE BENEFITS
6 THAT COULD COME IF WE PUT OUR MONEY INTO RESEARCH TO
7 CURE AND LOWER THESE COSTS GIGANTICALLY.

8 SECONDLY, I FEAR IF WE VEER FROM THE
9 BAYH-DOLE ACT SUBSTANTIALLY, WE RUN THE RISK OF CUTTING
10 OURSELVES OFF FROM FEDERAL GRANTS. AS YOU KNOW, THE
11 ROMAN REED ACT IS VERY SMALL, BUT WE ONLY SPEND ABOUT A
12 MILLION DOLLARS, MILLION AND A HALF A YEAR, BUT WE GET
13 ABOUT FIVE TIMES THAT MUCH BACK IN MATCHING GRANTS. WE
14 DON'T WANT TO EVER PUT OURSELVES IN A LOCKED-IN
15 SITUATION WHERE WE LOCK OURSELVES OUT FROM MATCHING
16 GRANTS FROM THE NIH.

17 GRANTED, RIGHT NOW WE HAVE AN ADMINISTRATION
18 THAT'S NOT PARTICULARLY FOND OF EMBRYONIC STEM CELL
19 RESEARCH, BUT THERE'S A LOT OF STUFF THAT WE HAVE THAT
20 THEY WILL ALLOW MATCHING GRANTS ON. ALSO THREE YEARS
21 FROM NOW, SITUATION MAY CHANGE.

22 FINALLY, I KNOW YOU AS A GOVERNMENT AGENCY
23 CANNOT TAKE A POLITICAL STAND, BUT AS ONE INDIVIDUAL
24 SPEAKING TO OTHER INDIVIDUALS, I'D ASK YOU REALLY LOOK
25 CAREFULLY AT PROPOSITION 73. IT'S BILLED AS A PARENTAL

1 NOTIFICATION ACT, BUT IT CONTAINS POTENTIALLY DEADLY
2 LANGUAGE WHICH COULD REESTABLISH PERSONHOOD AT THE
3 INSTANT OF CONCEPTION, WHICH COULD BE DEVASTATING TO
4 EMBRYONIC STEM CELL RESEARCH.

5 IT'S INTERESTING THAT SOME OF THE PEOPLE WHO
6 HELPED TO WRITE IT ARE CONNECTED WITH THE LEGAL DEFENSE
7 FOUNDATION, WHICH IS ONE OF THE ORGANIZATIONS SUING THE
8 CIRM. I WOULD URGE YOU TO DO WHATEVER YOU CAN AS
9 INDIVIDUALS TO REACH OUT TO YOUR NETWORKS. STILL NOT
10 TOO LATE TO DO E-MAILS AND LETTERS TO EDITORS. DO WHAT
11 YOU CAN TO LET PEOPLE KNOW THAT WHAT WE HAVE IS WORTH
12 FIGHTING FOR. THANK YOU VERY MUCH.

13 CHAIRMAN KLEIN: THANK YOU VERY MUCH. ANY
14 OTHER PUBLIC COMMENT? SEEING NO OTHER PUBLIC COMMENT,
15 ASKING, COUNSEL, ANYTHING ELSE TO COVER. I WOULD --

16 DR. PENHOET: FINAL NOTE. YOU ASKED EARLIER
17 ABOUT INFORMATION ON CALIFORNIA BIOTECH INDUSTRY.
18 THANKS TO TRICIA SHIVERA'S HARD WORK, YOU HAVE TWO
19 PRESENTATIONS THAT WERE A PRESENTATION AND A BACKGROUND
20 DOCUMENT THAT WERE MADE AT OUR LAST IP TASK FORCE
21 MEETING IN FRONT OF YOU.

22 CHAIRMAN KLEIN: IF WE CAN ALL DO AS WELL AS
23 THE VICE CHAIRMAN IN PRODUCING RESULTS, WE'LL BE
24 WELL-SUITED.

25 WE WILL, SHOCKING, I KNOW, BUT WE WILL

1 ADJOURN THE MEETING. AND I THANK YOU ALL.

2 NOW, MY UNDERSTANDING IS THAT STAFF IS GOING
3 TO SET UP CABS TO TAKE US OVER TO THE NEW FACILITY. IS
4 THAT CORRECT?

5 MS. KING: THAT IS TRUE. THAT WAS A REQUEST
6 YOU MADE, BOB, AND WE'RE HAPPY TO DO THAT. THE ONE
7 ISSUE IS THAT THE PLAN IS FOR THE EVENT TO START
8 BETWEEN 5:00 AND 5:30, AND IT'S NOT EVEN 3 O'CLOCK.

9 CHAIRMAN KLEIN: IS THE -- IS IT POSSIBLE FOR
10 THE BOARD TO GO OVER?

11 MS. KING: IT IS POSSIBLE FOR THAT TO HAPPEN.
12 HOWEVER, THERE IS A FINAL WALK-THROUGH WITH THE
13 ARCHITECT HAPPENING AT 3:30. PERHAPS THIS IS TOO MUCH
14 INFORMATION, BUT --

15 CHAIRMAN KLEIN: WE COULD ALL PROVIDE OUR
16 COMMENTS.

17 MS. KING: I'M SURE THE ARCHITECT WOULD
18 WELCOME COMMENTS FROM EACH OF YOU.

19 CHAIRMAN KLEIN: PERHAPS AN APPROPRIATE
20 APPROACH WOULD BE -- WHAT IS THE DESIRE OF THE BOARD
21 HERE? PERHAPS THE BOARD MIGHT WANT TO TAKE SOME TIME,
22 MAKE A FEW PHONE CALLS, AND GO OVER AT 4 O'CLOCK.

23 MS. KING: THAT SOUNDS GOOD TO ME, AND I'M
24 HAPPY TO AND WE HAVE OTHER STAFF MEMBERS WHO WILL WORK
25 WITH ME ON THIS TO HELP EVERYBODY GET THERE.

1 CHAIRMAN KLEIN: THE GOAL WILL BE TO GET CABS
2 IN THE FRONT AT 4 O' CLOCK.

3 MS. KING: IF YOU DROVE, I CAN TELL YOU WHERE
4 TO PARK IF YOU WANT TO DRIVE. SOME OF YOU CAN WALK IF
5 YOU WOULD RATHER WALK. IT'S A NICE DAY.

6 (THE MEETING WAS THEN CONCLUDED AT 02:46
7 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

MOSCONE CENTER SOUTH
747 HOWARD STREET, ROOM 304
SAN FRANCISCO, CALIFORNIA
ON
WEDNESDAY, NOVEMBER 2, 2005

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

BETH C. DRAIN, CSR 7152
BARRISTERS' REPORTING SERVICE
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