

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: STANFORD UNIVERSITY
FAIRCHILD AUDITORIUM
291 CAMPUS DRIVE
STANFORD, CALIFORNIA

DATE: TUESDAY, MARCH 1, 2005
9 A.M.

REPORTER: BETH C. DRAIN, CSR
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I N D E X

ITEM	DESCRIPTION	PAGE NO.
	CALL TO ORDER	004
	ROLL CALL	005
	INFORMATIONAL PRESENTATION ON STANDARDS AND GUIDELINES FOR PROTECTIONS AND ETHICS BY ALTA CHARO	009
	APPROVAL OF MINUTES FROM FEBRUARY 3, 2005	---
	INFORMATIONAL PRESENTATION BY CONTROLLER STEVE WESTLY ON FISCAL OVERSIGHT AND ACCOUNTABILITY	77
	CONSIDERATION OF APPOINTMENT OF INTERIM PRESIDENT	97
	CONSIDERATION OF CONFLICT OF INTEREST CODE FOR ICOC MEMBERS AND CIRM STAFF, CONFLICTS POLICY FOR ICOC MEMBERS AND INCOMPATIBLE ACTIVITIES STATEMENT FOR CIRM STAFF	153
	CONSIDERATION OF DELEGATION OF AUTHORITY TO CHAIR TO RESPOND TO PETITIONS FILED PURSUANT TO GOVERNMENT CODE SECTION 11340.6, INCLUDING PETITION FILED BY CHARLES HALPERN AND PHILIP R. LEE	126
	CONSIDERATION OF PROPOSED FRAMEWORK FOR INITIAL GRANTS PROGRAM	169
	CONSIDERATION OF STATUS REPORT FROM GRANTS WORKING GROUP SEARCH SUBCOMMITTEE	169
	CONSIDERATION OF STATUS REPORT FROM FACILITIES WORKING GROUP SEARCH SUBCOMMITTEE	

CONSIDERATION OF STATUS REPORT FROM STANDARDS
WORKING GROUP SEARCH SUBCOMMITTEE

CONSIDERATION OF STATUS REPORT FROM SITE
SEARCH SUBCOMMITTEE

CONSIDERATION OF STATUS REPORT FROM
PRESIDENTIAL SEARCH SUBCOMMITTEE 104

CONSIDERATION OF EXPENSE POLICY FOR ICOC
AND CIRM STAFF

PUBLIC COMMENT

ADJOURNMENT 183

1 STANFORD, CALIFORNIA; TUESDAY, MARCH 1, 2005

2

3 CHAIRMAN KLEIN: IF WE COULD BRING THE
4 MEETING TO ORDER. IF WE COULD COME TO ORDER, I THINK
5 IT WAS A GREAT PRIVILEGE TO HAVE THE PRESENTATIONS ON
6 CYSTIC FIBROSIS THIS MORNING. IT IS NOT POSSIBLE TO
7 WITNESS THESE PRESENTATIONS WITHOUT BEING INSPIRED TO
8 REDOUBLE OUR FOCUS ON OUR TASK. CERTAINLY WE HAVE OUR
9 CHALLENGES, BUT THOSE CHALLENGES, PUT IN PERSPECTIVE
10 WITH THOSE OF THE PATIENTS, SEEM TO BE QUITE
11 MANAGEABLE.

12 AND IT IS CERTAINLY IMPORTANT TO NOTE THAT
13 WITHOUT THE DEDICATED EFFORTS OF DOCTORS LIKE DR. MOSS,
14 THIS FUNDING WOULD NOT HAVE THE RELEVANCE AND URGENCY
15 THAT IT DOES FOR THE POTENTIAL THAT IT MAY LEAD TO OVER
16 A SIGNIFICANT PERIOD OF TIME TO IMPROVE THE PROGNOSIS
17 OF MANY CRITICAL DISEASES.

18 AS WE MOVE THROUGH THE STATE, WE END UP WITH
19 VARIOUS CONFIGURATIONS OF THE BOARD TABLES. I'M
20 INFORMED THAT THEY'RE GOING TO TRY AND RECONFIGURE
21 THESE TABLES DURING THE LUNCH BREAK SO THAT WE HAVE
22 ANOTHER MORE EFFECTIVE OPPORTUNITY WITHOUT THE PODIUM
23 THAT IS PRESENT CURRENTLY FOR THE PRESENTATIONS ON THE
24 SPOTLIGHT ON DISEASE.

25 DURING THE MEETING THIS MORNING, WE'LL ASK

1 THAT MEMBERS OF THE PUBLIC LIMIT THEIR COMMENTS TO
2 THREE MINUTES SO THAT WE CAN HAVE EVERYONE'S COMMENTS,
3 AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT WRITTEN
4 COMMENTS IN ADDITION TO THE THREE MINUTES IF THEIR
5 PRESENTATION REQUIRES GREATER DEPTH.

6 WE WILL START THE PRESENTATIONS THIS MORNING
7 WITH ROLL CALL, FOLLOWED BY A PRESENTATION BY ALTA
8 CHARO. WOULD MELISSA KING PLEASE CALL THE ROLL.

9 MS. KING: DAVID BALTIMORE.

10 DR. BALTIMORE: HERE.

11 MS. KING: ROBERT BIRGENEAU; KEITH BLACK;
12 SUSAN BRYANT.

13 DR. BRYANT: HERE.

14 MS. KING: MICHAEL FRIEDMAN.

15 DR. FRIEDMAN: PRESENT.

16 MS. KING: MICHAEL GOLDBERG.

17 DR. GOLDBERG: HERE.

18 MS. KING: BRIAN HENDERSON.

19 DR. HENDERSON: PRESENT.

20 MS. KING: ED HOLMES.

21 DR. HOLMES: HERE.

22 MS. KING: DAVID KESSLER.

23 DR. KESSLER: HERE.

24 MS. KING: BOB KLEIN.

25 CHAIRMAN KLEIN: HERE.

1 MS. KING: SHERRY LANSING.
2 MS. LANSING: HERE.
3 MS. KING: ROBERTO PECCHI HERE FOR GERALD
4 LEVEY.
5 DR. PECCHI: HERE.
6 MS. KING: TED LOVE.
7 DR. LOVE: HERE.
8 MS. KING: RICHARD MURPHY.
9 DR. MURPHY: HERE.
10 MS. KING: TINA NOVA.
11 DR. NOVA: HERE.
12 MS. KING: ED PENHOET.
13 DR. PENHOET: HERE.
14 MS. KING: PHIL PIZZO.
15 DR. PIZZO: HERE.
16 MS. KING: CLAIRE POMEROY.
17 DR. POMEROY: HERE.
18 MS. KING: PHYLLIS PRECIADO.
19 DR. PRECIADO: HERE.
20 MS. KING: FRANCISCO PRIETO.
21 DR. PRIETO: HERE.
22 MS. KING: JOHN REED.
23 DR. REED: HERE.
24 MS. KING: JOAN SAMUELSON.
25 MS. SAMUELSON: HERE.

1 MS. KING: DAVID SERRANO-SEWALL.
2 MR. SERRANO-SEWALL: HERE.
3 MS. KING: JEFF SHEEHY.
4 MR. SHEEHY: HERE.
5 MS. KING: JONATHAN SHESTACK.
6 MR. SHESTACK: HERE.
7 MS. KING: OSWALD STEWARD.
8 DR. STEWARD: HERE.
9 MS. KING: LEON THAL.
10 DR. THAL: HERE.
11 MS. KING: GAYLE WILSON.
12 MS. WILSON: HERE.
13 MS. KING: JANET WRIGHT.
14 DR. WRIGHT: HERE.
15 CHAIRMAN KLEIN: THANK YOU. THANK YOU. THE
16 FIRST ITEM OF BUSINESS THIS MORNING WILL FOLLOW THE
17 PLEDGE OF ALLEGIANCE, AND MELISSA KING WILL LEAD US IN
18 THAT.
19 (THE PLEDGE OF ALLEGIANCE.)
20 CHAIRMAN KLEIN: LAST NIGHT IN AN INTENSIVE
21 WORKSHOP SESSION, WHICH WAS A PUBLIC WORKSHOP, WE WERE
22 PRIVILEGED TO HAVE ALTA CHARO MAKE A TWO-HOUR
23 PRESENTATION ON STANDARDS. THERE WERE ELEVEN MEMBERS
24 OF THE BOARD WHO PARTICIPATED ALONG WITH A SIGNIFICANT
25 NUMBER OF PUBLIC MEMBERS IN THIS PRESENTATION. ALTA

1 CHARO HAS A LIMITED TIME FRAME THIS MORNING FOR HER
2 PRESENTATION, BUT MATERIALS FROM HER PRESENTATION LAST
3 NIGHT WOULD BE AVAILABLE TO THE BOARD MEMBERS AND TO
4 THE PUBLIC.

5 ALTA CHARO IS A PROFESSOR OF LAW AND
6 BIOETHICS AT THE UNIVERSITY OF WISCONSIN AT MADISON
7 WHERE SHE'S ON THE FACULTY OF THE LAW SCHOOL AND AN
8 ASSOCIATE DEAN. SHE'S ALSO ON THE FACULTY OF THE
9 MEDICAL SCHOOL'S DEPARTMENT OF MEDICAL HISTORY AND
10 BIOETHICS. SHE OFFERS COURSES ON HEALTH LAW,
11 BIOETHICS, BIOTECHNOLOGY LAW, FOOD AND DRUG LAW,
12 MEDICAL ETHICS, REPRODUCTIVE RIGHTS, TORTS, AND
13 LEGISLATIVE DRAFTING.

14 THIS IS A TREMENDOUS AND IMPRESSIVE SCOPE.
15 AND IN DECEMBER SHE WAS CHOSEN BY THE NATIONAL
16 ACADEMIES OF SCIENCE AS ONE OF THE BRIGHTEST MINDS IN
17 THE COUNTRY TO PROVIDE A PRESENTATION IN IRVINE AT THE
18 NATIONAL ACADEMY SITE ON THE STANDARDS FOR STEM CELL
19 RESEARCH. I THINK YOU WILL BE VERY IMPRESSED WITH HER
20 PRESENTATION THIS MORNING. AND I'D LIKE YOU TO BEAR IN
21 MIND THAT SHE HAS DIRECT FUNCTIONAL EXPERIENCE WITH
22 MEDICINE AS WELL IN THAT SHE HAS SERVED ON THE
23 UNIVERSITY OF WISCONSIN HOSPITAL CLINICAL ETHICS
24 COMMITTEE, THE UNIVERSITY'S INSTITUTIONAL REVIEW BOARD
25 FOR THE PROTECTION OF HUMAN SUBJECTS IN MEDICAL

1 RESEARCH, AND THE UNIVERSITY'S BIOETHICS ADVISORY
2 COMMITTEE.

3 SHE ALSO SERVES ON SEVERAL EXPERT ADVISORY
4 BOARDS, INCLUDING THE JUVENILE DIABETES RESEARCH
5 FOUNDATION, WI-CELL, THE WISCONSIN STEM CELL RESEARCH
6 PROGRAM, AND IN 1994 SHE SERVED ON THE NIH HUMAN
7 EMBRYONIC RESEARCH PANEL. FROM 1996 TO 2001 SHE WAS A
8 MEMBER OF PRESIDENT CLINTON'S NATIONAL BIOETHICS
9 ADVISORY COMMISSION, AND SHE'S BEEN A MEMBER OF THE
10 NATIONAL ACADEMY OF SCIENCE BOARD ON LIFE SCIENCES
11 SINCE 2001. SHE SERVES AS A MEMBER OF NAS AND IOM
12 COMMITTEES WORKING IN THIS AREA, AND I THINK YOU WILL
13 BE IMPRESSED WITH THE QUALITY AND DEPTH OF HER
14 KNOWLEDGE. AGAIN, HER PRESENTATION FROM LAST NIGHT AND
15 MATERIALS RELATED TO IT WILL BE AVAILABLE AS A
16 SUPPLEMENT TO WHAT SHE PRESENTS THIS MORNING. ALTA
17 CHARO.

18 MS. CHARO: THANK YOU VERY MUCH. MY
19 APOLOGIES FOR THOSE THAT ARE GOING TO GET NECK STRAIN
20 BECAUSE OF THE SETUP HERE. I SYMPATHIZE WITH THE
21 LOGISTICAL CHALLENGES.

22 I DO HAVE LIMITED TIME; HOWEVER, I WANTED TO
23 PREFACE MY REMARKS WITH A STATEMENT THAT WILL HELP
24 THOSE THAT WANT TO UNDERSTAND INTERCONNECTIONS, TO
25 UNDERSTAND MY OWN INTERCONNECTIONS, AND TO MAKE THEIR

1 OWN JUDGMENTS ABOUT WHETHER IT CONSTITUTES A CONFLICT
2 OF INTEREST.

3 AS BOB KLEIN HAD MENTIONED, AMONG THE MANY
4 THINGS I'VE DONE IN THE AREA GROSSLY RELATED TO EMBRYO
5 RESEARCH AND STEM CELL RESEARCH, I AM THE LIAISON FROM
6 THE BOARD ON LIFE SCIENCES AT THE NATIONAL ACADEMIES TO
7 THE COMMITTEE THAT IS CURRENTLY WORKING TO DRAFT
8 VOLUNTARY NATIONAL SELF-REGULATORY GUIDELINES IN THE
9 AREA OF STEM CELL RESEARCH. I'M A MEMBER OF THE ETHICS
10 ADVISORY BOARD FOR THE JUVENILE DIABETES RESEARCH
11 FOUNDATION, WHICH IS A GRANTOR IN THIS FIELD.

12 I WAS A MEMBER OF THE ETHICS AND SCIENCE
13 ADVISORY GROUP FOR CURES NOW, WHICH WAS A SOUTHERN
14 CALIFORNIA-BASED GROUP ACTIVE IN THE POLITICAL CAMPAIGN
15 TO MAINTAIN THE LEGALITY OF ALL FORMS OF EMBRYONIC STEM
16 CELL RESEARCH, I WAS A MEMBER AND CURRENTLY AM A MEMBER
17 OF THE UNIVERSITY OF WISCONSIN'S CAMPUS BIOETHICS
18 ADVISORY COMMITTEE, WHICH HAS SOME ROLE IN OVERSEEING
19 STEM CELL RESEARCH THERE, IN THAT CAPACITY HELPED TO
20 WRITE PORTIONS OF THE UW STEM CELL POLICY, WHICH WAS
21 DUPLICATED AND DISTRIBUTED OUTSIDE AS PART OF THE
22 HANDOUTS FOR AGENDA ITEM 5.

23 I'M CURRENTLY A MEMBER OF THE FACULTY
24 ADVISORY BOARD FOR UNIVERSITY OF WISCONSIN'S STEM CELL
25 RESEARCH PROGRAM, WHICH IS MADE UP OF RESEARCHERS AND A

1 FEW OTHER FACULTY ADVISORS, AS WELL AS ON THE ADVISORY
2 BOARD FOR WI-CELL, WHICH IS THE PRIVATE OFF-CAMPUS
3 ENTITY THAT PURSUES EMBRYONIC STEM CELL RESEARCH IN
4 MADISON, WISCONSIN.

5 I WOULD NOTE FOR YOU THAT IN ALL OF THOSE
6 CAPACITIES, I GET NO COMPENSATION EITHER DIRECT OR
7 INDIRECT EXCEPT FOR FREQUENT FLIER MILES AND
8 REIMBURSEMENT OF ACTUAL OUT-OF-POCKET EXPENSES SUBJECT
9 TO STATE LIMITATIONS. I AM ALSO A MEMBER OF THE HOWARD
10 HUGHES MEDICAL INSTITUTE'S BIOETHICS ADVISORY BOARD,
11 WHICH AMONG OTHER THINGS SETS RULES FOR THE ETHICAL
12 MANAGEMENT OF RESEARCH BY ITS OWN INVESTIGATORS AROUND
13 THE COUNTRY. FOR THAT I DO GET PAID A FLAT ANNUAL FEE.
14 I HAVE NOT AT ANY POINT ACTUALLY PARTICIPATED IN
15 SETTING STEM CELL POLICY FOR THEM. SO IF ANYBODY NEEDS
16 OR FEELS THE NEED TO PURSUE ANY OF THOSE, I'LL BE HAPPY
17 TO PROVIDE MORE INFORMATION.

18 THE LAST APOLOGY SEEMS TO BE THAT THERE'S NO
19 POWERPOINT FOR YOU ALL. AT THE TIME THAT I WAS
20 PREPARING THIS, IT WASN'T QUITE CLEAR WHAT THE
21 TECHNICAL CAPACITIES OF THE ROOM WOULD BE. FOR THOSE
22 IN THE AUDIENCE AS WELL AS THE MEMBERS OF THE ICOC,
23 THERE IS A HANDOUT THAT WE CAN USE TO KIND OF FOLLOW
24 ALONG TOPICALLY.

25 BECAUSE THERE IS ONLY A LIMITED AMOUNT OF

1 TIME THIS MORNING --

2 CHAIRMAN KLEIN: ALTA, GIVEN THAT YOU HAVE
3 SOME SLIDES, THOSE MEMBERS OF THE BOARD WHO ARE SEATED
4 WITH THEIR BACKS TO THE SCREEN COULD RELOCATE.

5 MS. CHARO: NO. NO. I DON'T HAVE SLIDES.
6 THERE'S A HANDOUT, WHICH I HOPE THAT ALL OF YOU HAVE IN
7 YOUR BOOKS. GIVEN THAT THERE'S A LIMITED AMOUNT OF
8 TIME THIS MORNING AND GIVEN THAT THE INITIATIVE ITSELF
9 LAID OUT CERTAIN MANDATORY AREAS OF ATTENTION FOR
10 STANDARD SETTING, IT SEEMED PERHAPS BEST TO START WITH
11 THOSE AREAS THAT YOU ARE REQUIRED TO ADDRESS BY VIRTUE
12 OF THE PASSAGE OF THE INITIATIVE. AND THEN TIME
13 PERMITTING, WE CAN IDENTIFY THOSE OTHER ISSUES THAT, IN
14 MY EXPERIENCE ON ALL THESE OTHER COMMITTEES, ARE LIKELY
15 TO COME UP AND REQUIRE OR AT LEAST SUGGEST THE NEED FOR
16 YOUR ATTENTION ONCE YOU HAVE COMPLETED YOUR MANDATED
17 TASKS.

18 NOW, ONE OF THE THINGS THAT'S IN THE
19 INITIATIVE THAT YOU ARE REQUIRED TO DO IS TO PAY
20 ATTENTION TO HUMAN SUBJECTS PROTECTIONS. IN THIS AREA
21 HUMAN SUBJECTS ARE RESEARCH PARTICIPANTS IN THE
22 FOLLOWING CAPACITIES: PEOPLE WHO ARE DONATING A
23 SOMATIC CELL FOR THINGS LIKE SOMATIC CELL NUCLEAR
24 TRANSFER. THAT MIGHT BE NOTHING MORE THAN SWABBING THE
25 INSIDE OF A CHEEK, BUT NONETHELESS THEY THEN BECOME A

1 RESEARCH SUBJECT. IT'S NOT BECAUSE THEY THEMSELVES ARE
2 BEING STUDIED, BUT THE INTERACTION WITH A PERSON TO
3 RETRIEVE THE BIOLOGICAL MATERIAL MAKES THAT PERSON A
4 RESEARCH SUBJECT IN THE CONTEXT OF THE OVERALL
5 PROTOCOL.

6 SIMILARLY, THE COLLECTION OF EGGS AND SPERM
7 IF YOU ARE MAKING NEW EMBRYOS EITHER BY IVF OR BY
8 SOMATIC CELL NUCLEAR TRANSFER MAKES THE EGG AND SPERM
9 DONORS INTO RESEARCH SUBJECTS.

10 AND THEN FINALLY, FOR PEOPLE WHO ARE GIVING
11 PERMISSION FOR THE USE OF THEIR SURPLUS EMBRYOS,
12 EMBRYOS THAT THEY HAVE ALREADY DECIDED NOT TO USE FOR
13 REPRODUCTIVE PURPOSES, THEY MAY OR MAY NOT BE
14 CONSIDERED RESEARCH SUBJECTS. HERE THERE'S NO PHYSICAL
15 INTERACTION WITH THOSE PEOPLE. THE ONLY INTERACTION
16 CONSISTS OF ASKING FOR THEIR CONSENT TO USE AN ALREADY
17 EXISTING EMBRYO. IF THAT IS THE ONLY INTERACTION, AND
18 IF THE EMBRYO IS GOING TO BE MANAGED IN A WAY THAT DOES
19 NOT REVEAL INFORMATION ABOUT THOSE DONORS' PERSONAL
20 IDENTITIES AND MEDICAL INFORMATION, THEN IN THIS ONE
21 SITUATION YOU ARE NOT GOING TO BE CONSIDERING THE
22 EMBRYO DONORS TO BE RESEARCH SUBJECTS.

23 THIS IS IMPORTANT BECAUSE NOT BEING RESEARCH
24 SUBJECTS MEANS THAT YOU WOULD BE EXEMPTED FROM MANY OF
25 THE FEDERAL RULES THAT GOVERN RESEARCH WITH HUMAN

1 SUBJECTS. AND SINCE EMBRYO DONATION IS LIKELY TO BE
2 THE MOST COMMON FORM OF COLLECTING BIOLOGICAL MATERIALS
3 FOR THE GENERATION OF NEW CELL LINES, IT SEEMS
4 IMPORTANT TO MAKE SURE THAT PEOPLE APPRECIATE THIS
5 PARTICULAR APPLICATION OF FEDERAL RULES. SO
6 ANONYMIZED, PROPERLY CODED EMBRYO COLLECTION FROM
7 PEOPLE WHO HAVE EXISTING EMBRYOS THAT ARE SURPLUS AT
8 IVF CLINICS WILL NOT TRIGGER HUMAN SUBJECTS PROTECTIONS
9 UNDER FEDERAL RULES.

10 ON THE OTHER HAND, IF THERE IS MEDICAL
11 INFORMATION ABOUT THE DONORS THAT IS BEING KEPT AND
12 ATTACHED TO THE CELL LINES, FOR EXAMPLE, TO COMPLY WITH
13 THE NEW DONOR SUITABILITY RULES THAT THE FDA HAS ISSUED
14 SO THAT DOWNSTREAM CLINICAL APPLICATIONS FOR TRANSPLANT
15 WITH TISSUES DEVELOPED FROM THOSE LINES CAN BE
16 ACCOMPANIED BY ADEQUATE INFORMATION ABOUT THE
17 UNDERLYING MEDICAL CONDITIONS OF THE DONORS AND ASSURE
18 THE SAFETY OF THE TISSUE, THERE IS THE POSSIBILITY,
19 THEN, THAT YOU MUST TREAT THESE EMBRYO DONORS AS
20 RESEARCH SUBJECTS.

21 AND THE KEY IN THIS AREA, AND IT'S GOING TO
22 COME UP REPEATEDLY, IS GOING TO BE THE MANAGEMENT OF
23 THAT INFORMATION. A SUFFICIENT LEVEL OF CODING AND A
24 SUFFICIENT AMOUNT OF ATTENTION TO CONFIDENTIALITY
25 PRACTICES THAT KEEP A COMPLETE FIREWALL BETWEEN THE

1 MEDICAL AND GENETIC INFORMATION NEEDED FOR THE
2 MANAGEMENT OF THE LINES SEPARATE FROM THE PERSONAL
3 IDENTITY FROM THE DONORS WILL ALLOW ONE TO CONTINUE TO
4 USE THOSE MATERIALS WITHOUT DEEMING THE DONORS
5 THEMSELVES SUDDENLY RESEARCH SUBJECTS. BUT AS SOON AS
6 THEIR PERSONAL IDENTITIES BECOME READILY ASCERTAINABLE,
7 THEN JUST WORKING WITH CELL LINES, JUST COLLECTING THE
8 EMBRYOS FUNCTIONALLY MEANS YOU ARE IN A POSITION TO BE
9 STUDYING THE DONORS AND NOT JUST THEIR MATERIALS, AND
10 IT'S THE ABILITY TO STUDY THE DONORS AS PEOPLE THAT
11 TRIGGERS THE NEED TO TREAT THEM AS RESEARCH SUBJECTS.

12 I'M SORRY TO BE KIND OF GOING OVER AND OVER
13 IT, BUT IT TURNS OUT THIS HAS BEEN A POINT OF
14 TREMENDOUS CONFUSION IN ALMOST EVERY SETTING I'VE BEEN
15 AT, AND IT ACTUALLY REQUIRED DIRECT COMMUNICATION WITH
16 THE OFFICE OF HUMAN RESEARCH PROTECTIONS TO GET A KIND
17 OF DEFINITIVE INTERPRETATION OF HOW THE FEDERAL RULES
18 WOULD OPERATE IN THIS AREA.

19 NOW, GIVEN THAT, THEREFORE, THERE IS A CADRE
20 OF PEOPLE WHO ARE LIKELY TO BE APPROACHED FOR CONSENT
21 TO GIVE THEIR EMBRYOS OVER TO RESEARCH, GIVEN THAT IN
22 MANY CASES THOSE PEOPLE MAY NOT BE COVERED BY EXISTING
23 RESEARCH PROTECTIONS UNDER FEDERAL RULES, ONE OF THE
24 DECISIONS THAT THIS BODY IS IN A POSITION TO MAKE IS
25 THE FOLLOWING. SHALL YOU FOLLOW THE FEDERAL RESEARCH

1 SUBJECT PROTECTIONS ONLY, OR SHALL YOU SUPPLEMENT THEM
2 BY REQUIRING RESEARCH PROTECTIONS FOR ALL EMBRYO DONORS
3 REGARDLESS OF WHETHER THEY TECHNICALLY MEET THE
4 DEFINITION OF RESEARCH SUBJECT?

5 RESEARCH PROTECTIONS REALLY, ALTHOUGH THERE
6 ARE MANY, MANY DETAILS IN THE FEDERAL REGS, REALLY
7 CONSIST OF TWO MAIN ITEMS. ONE, INFORMED CONSENT; TWO,
8 OVERSIGHT, MONITORING, AND APPROVAL BY AN INSTITUTIONAL
9 REVIEW BOARD; THAT IS, A BOARD THAT REVIEWS THE ETHICS
10 OF RESEARCH PROTOCOLS.

11 NOW, THE CONSENT ISSUE IN MANY WAYS IS TAKEN
12 CARE OF BY STATE LAW. YOU SIMPLY CAN'T TAKE EMBRYOS
13 FROM SOMEBODY WITHOUT THEIR CONSENT AS A MATTER OF
14 STATE LAW, WHETHER IT'S GROUNDED IN FAMILY LAW,
15 PROPERTY LAW, QUASI-PROPERTY LAW, OR ANY OTHER COMMON
16 LAW THEORY AS YET UNARTICULATED. THE KIND OF LEGAL
17 STATUS OF EMBRYOS IS QUITE VARIED DEPENDING UPON THE
18 STATE AND HOW THEY VIEW THEM.

19 BUT THE QUESTION OF IRB REVIEW IS ONE THAT IS
20 REALLY ABOUT WHETHER OR NOT YOU ARE GOING TO GO AHEAD
21 AND ABOVE AND BEYOND FEDERAL RULES REQUIRE THIS KIND OF
22 REVIEW BEFORE THE EMBRYOS CAN BE TAKEN FROM THESE
23 PARTIES. IN ADDITION, WITH REGARD TO HUMAN SUBJECTS
24 PROTECTIONS, IF YOU GO THIS ROUTE TO EXPAND IT AND EVEN
25 IF YOU DON'T, WHEN YOU HAVE TO ACTUALLY APPLY IT, THERE

1 ARE GOING TO BE SOME ADDITIONAL KIND OF NUTS AND BOLTS
2 DETAILS ABOUT HOW YOU ARE GOING TO GO ABOUT REVIEWING
3 THE CONSENT AND PROCUREMENT PROCESS FOR PEOPLE WHO ARE
4 DONATING EMBRYOS AS WELL AS OTHER BIOLOGICAL MATERIALS.

5 ONE MAJOR CONCERN THAT HAS COME UP IN OTHER
6 CONTEXTS, FOR EXAMPLE, IN THE CONTEXT OF FETAL TISSUE
7 RESEARCH, HAS BEEN HOW DO WE AVOID UNDUE INDUCEMENTS TO
8 ALTER BEHAVIOR THAT SHOULD REMAIN UNALTERED PRIOR TO
9 THE POINT OF DONATION. IN THE CONTEXT OF FETAL TISSUE
10 RESEARCH, IT WAS HOW DO WE MAKE SURE THAT PERSONAL
11 DECISIONS ABOUT ABORTIONS AND CLINICAL DECISIONS ABOUT
12 HOW TO PERFORM ABORTIONS ARE COMPLETELY UNAFFECTED BY
13 THE POSSIBILITY DOWNSTREAM OF USING TISSUE FROM A FETAL
14 CADAVER FOR RESEARCH PURPOSES. THE ANALOGY HERE IN THE
15 AREA OF EMBRYO DONATION WOULD BE HOW DO WE ASSURE THAT
16 THE CLINICAL EXPERIENCE OF PEOPLE WHO ARE ENTERING A
17 FERTILITY CLINIC IS ABSOLUTELY UNALTERED BY THE
18 POSSIBILITY DOWNSTREAM THAT THEY MIGHT BE DONATING SOME
19 OF THEIR SURPLUS EMBRYOS TO RESEARCH.

20 FOR SOME THE ANSWER HAS BEEN DON'T EVER
21 MENTION RESEARCH POSSIBILITIES UNTIL THE CLINICAL WORK
22 HAS BEEN COMPLETED, UNTIL PEOPLE HAVE MADE THEIR
23 DECISION ABOUT FURTHER USE, OFFERING UP FOR ADOPTION TO
24 OTHER COUPLES, OR DISCARD, AND ONLY AT THAT POINT
25 SIGNAL TO PEOPLE, IF THEY'VE CHOSEN DISCARD, THAT YOU

1 MIGHT ALSO CHOOSE RESEARCH, WHICH FUNCTIONALLY WILL
2 DISCARD THE EMBRYOS, BUT ALLOW RESEARCH AS WELL.

3 LOGISTICALLY THIS TURNS OUT TO BE PROBLEMATIC
4 BECAUSE, INDEED, IN MANY CIRCUMSTANCES PEOPLE ENTER THE
5 FERTILITY CLINICS ALREADY ASKING ABOUT THINGS LIKE
6 RESEARCH USES DOWNSTREAM, AND ONE WOULD NOT, BY VIRTUE
7 OF THE USUAL RULES OF MEDICAL ETHICS BE PERMITTED TO
8 LIE TO THEM AND SAY SUCH A THING DOESN'T EXIST. AND
9 THEREFORE, ONE GETS INTO A BIT OF A CONUNDRUM. AND IF
10 YOU LOOK AT OTHER GUIDELINES THAT HAVE BEEN ISSUED, FOR
11 EXAMPLE, ISRAELI GUIDELINES, SOME OF THEM ACTUALLY
12 SPECIFICALLY SAY ALL ENDSTREAM POSSIBILITIES SHOULD BE
13 MENTIONED AT THE OUTSET SO THAT PEOPLE UNDERSTAND THE
14 OPTIONS THAT WILL BE PRESENTED OVER TIME.

15 THE KEY, HOWEVER, IS IN THE WAY THESE
16 GUIDELINES ARE WRITTEN, TO MAKE SURE THAT THE ACTUAL
17 CONSENT, THE ACTUAL DECISION ABOUT DISPOSITION OF
18 EMBRYOS DOES NOT GET MADE UNTIL THE LAST MOMENT. THAT
19 IS, PEOPLE DO NOT DECIDE PROSPECTIVELY THAT THEY'RE
20 GOING TO BE DONATING X NUMBER OF EMBRYOS TO RESEARCH;
21 BUT ONLY AFTER THEY HAVE COMPLETED THEIR CLINICAL
22 EXPERIENCE, DO THEY ACTUALLY HAVE AN OPPORTUNITY TO
23 DISCUSS THIS AGAIN AND TO MAKE A FINAL DECISION ABOUT
24 THE DONATION PROCESS.

25 IN ADDITION, THERE ARE GUIDELINES IN

1 DIFFERENT COUNTRIES AND GUIDELINES THAT HAVE BEEN
2 SUGGESTED IN DIFFERENT JOURNAL ARTICLES THAT FOCUS ON
3 THE ROLE OF THE PERSONNEL TO, FOR EXAMPLE, DISCUSS
4 WHETHER OR NOT THERE IS A NEED FOR SOME DEGREE OF
5 SEPARATION BETWEEN THE PERSONNEL IN THE CLINICAL
6 SETTING AND THE INVESTIGATORS AND THE INVESTIGATIVE
7 TEAM THAT WANTS TO DERIVE A CELL LINE IN ORDER TO AVOID
8 ANY DEGREE OF PERCEPTION, ACTUAL OR NOT, WHETHER THERE
9 IS OR NOT, OF A KIND OF COLLABORATION TO STEER PEOPLE
10 TOWARD DONATION OF EMBRYOS RATHER THAN, AGAIN, KEEPING
11 THE CLINICAL EXPERIENCE COMPLETELY INDEPENDENT OF THE
12 RESEARCH POSSIBILITIES.

13 GIVEN THAT IRB REVIEW TENDS TO BE FAIRLY
14 STRUCTURED IN FEDERAL REGULATIONS, THERE WERE VERY
15 SPECIFIC REQUIREMENTS ABOUT THE MEMBERSHIP OF THE IRB,
16 ABOUT THE WAY THE MINUTES SHOULD BE TAKEN, AND ABOUT
17 THE FREQUENCY WITH WHICH PROTOCOLS MUST BE REVIEWED,
18 AGAIN, IN A KIND OF MONITORING CAPACITY, ETC., EVEN
19 VOTING RULES AND HOW THE QUORUM IS CALCULATED. GIVEN
20 THAT THERE ARE THESE VERY PARTICULARIZED RULES, ONE OF
21 THE OTHER QUESTIONS ABOUT OVERSIGHT OF THE CONSENT
22 PROCESS THAT YOU MIGHT WANT TO CONSIDER IS SHALL WE
23 EVER UNDER ANY CIRCUMSTANCES PERMIT INVESTIGATORS TO
24 FOLLOW A PROCESS IN A DIFFERENT STATE OR COUNTRY THAT
25 OFFERS SUBSTANTIVELY EQUIVALENT PROTECTIONS IN TERMS OF

1 CONCERN ABOUT INFORMED CONSENT, CONCERN ABOUT UNDUE
2 INDUCEMENTS, CONCERN ABOUT SEPARATION OF PERSONNEL, BUT
3 DOESN'T NECESSARILY FOLLOW ALL THE SAME PROCEDURAL
4 PATHWAYS TO ACCOMPLISHING THOSE GOALS.

5 I POINT THIS OUT TO YOU SIMPLY BECAUSE
6 EMBRYONIC STEM CELL RESEARCH IS INDEED A COLLABORATIVE
7 FIELD. AND FREQUENTLY THE COLLABORATIONS TAKE PLACE
8 ACROSS INSTITUTIONS, ACROSS STATE LINES, AND ACROSS
9 NATIONAL LINES. AND CURRENTLY THERE IS A FAIR DEGREE
10 OF VARIATION. WITHIN THE UNITED STATES IRB PROCEDURES
11 ARE UNIFORM BECAUSE THEY'RE DICTATED BY FEDERAL RULES;
12 BUT AS SOON AS YOU COLLABORATE TRANSNATIONALLY, YOU
13 WILL BE IN A SITUATION WHERE THERE ARE COLLABORATIVE
14 INVESTIGATORS WORKING WITH YOUR FUNDED INVESTIGATORS
15 WHO HAVE ALREADY GONE THROUGH A PROCEDURE IN THEIR OWN
16 COUNTRY; FOR EXAMPLE, GETTING A LICENSE FROM THE UNITED
17 KINGDOM'S HUMAN FERTILIZATION EMBRYOLOGY AUTHORITY.

18 YOU HAVE THE OPTION OF INSISTING UPON
19 MULTIPLE REVIEWS. YOUR INVESTIGATORS GET REVIEWED
20 HERE, THE COLLABORATORS REVIEWED THERE, EVERYBODY HAS
21 TO FOLLOW THEIR OWN RULES, OR YOU CAN HAVE A SYSTEM OF
22 COMITY IN WHICH THERE IS MUTUAL RECOGNITION, BUT THAT,
23 OF COURSE, WOULD REQUIRE SOME ATTENTION TO THE OTHER
24 COUNTRIES' SYSTEMS AND PROCESSES AND AN EVALUATION BY
25 SOMEBODY OF WHETHER OR NOT THEY COMPORT WITH YOUR

1 NOTION OF WHAT IS CONSISTENT WITH YOUR ETHICAL
2 STANDARDS.

3 NEXT, CONTINUING ON THE ISSUE OF INFORMED
4 CONSENT -- CONTINUING ON WITH INFORMED CONSENT, BECAUSE
5 THIS IS A VERY CONTROVERSIAL AREA OF RESEARCH AND A
6 VERY NEW AREA OF RESEARCH, THERE'S BEEN A LOT OF
7 ATTENTION, PARTICULARLY IN THE ACADEMIC LITERATURE, TO
8 IDENTIFYING THE ELEMENTS OF INFORMED CONSENT. THAT IS,
9 WHAT KIND OF INFORMATION MUST PEOPLE BE GIVEN BEFORE WE
10 CAN TRULY CONSIDER THEM INFORMED WHEN THEY MAKE A
11 VOLUNTARY DECISION TO DONATE. IT'S A PARTICULARLY
12 ACTIVE DISCUSSION IN THE UNITED STATES BECAUSE,
13 FRANKLY, WE'RE ABOUT 25 YEARS BEHIND THE REST OF THE
14 DEVELOPED WORLD IN EMBRYO RESEARCH BECAUSE OF A LACK OF
15 FEDERAL FUNDING IN THIS AREA SINCE 1980.

16 AS A RESULT, ALTHOUGH THERE'S BEEN A LOT OF
17 DISCUSSION AMONG ACADEMICS AND BIOETHICISTS ABOUT
18 CONSENT IN THE AREA OF EMBRYO RESEARCH, THERE'S BEEN
19 RELATIVELY LITTLE ON-THE-GROUND EMBRYO RESEARCH THROUGH
20 PRIVATE FUNDING, AND SO VERY LITTLE VETTING THROUGH
21 PRACTICAL EXPERIENCE OF WHAT KINDS OF CONSENT IS, IN
22 FACT, SATISFACTORY TO PEOPLE AS RESEARCH AREAS EVOLVE,
23 AS USES OF CELL LINES EVOLVE, AND AS CLINICAL
24 APPLICATIONS EVOLVE.

25 SO THERE'S A FAIRLY LONG LIST OF THINGS.

1 AGAIN, JUST THE QUESTION IS DO YOU THINK THAT THEY NEED
2 TO BE INCLUDED AS A REQUIREMENT FOR ALL CIRM-FUNDED
3 INVESTIGATORS? DO YOU THINK IT'S SIMPLY EXHORTATORY TO
4 THE LOCAL INSTITUTIONS WHERE THE IRB REVIEW IS TAKING
5 PLACE? OR DO YOU TAKE NO POSITION AT ALL ON WHETHER OR
6 NOT THESE ELEMENTS SHOULD BE INCLUDED? THE FOLLOWING
7 LIST OF ELEMENTS IS DRAWN FROM THE KIND OF COLLECTIVE
8 SET OF ELEMENTS THAT YOU WILL SEE IN GUIDELINES ALREADY
9 PUBLISHED FROM AROUND THE WORLD, THE U.K., SINGAPORE,
10 CANADA, ISRAEL, AND AUSTRALIA.

11 ONE OF THE FIRST QUESTIONS THAT HAS TO BE
12 ASKED IS FROM WHOM DOES CONSENT HAVE TO BE SOUGHT.
13 MOST TYPICALLY YOU THINK OF THE COUPLE, RIGHT, THE
14 PARENTS OF THE EMBRYO, BUT IT'S CERTAINLY NOT QUITE AS
15 STRAIGHTFORWARD AS THAT. ABOUT 8 TO 10 PERCENT OF THE
16 EMBRYOS THAT ARE CURRENTLY FROZEN IN THE UNITED STATES
17 ARE ESTIMATED -- THERE'S AN ESTIMATED 8 TO 10 PERCENT
18 OF THE EMBRYOS IN THE UNITED STATES THAT ARE UNDERSTOOD
19 TO HAVE DONOR GAMETES. THAT IS, A COUPLE COMES IN,
20 THEY WANT TO MAKE AN EMBRYO, ONE OR THE OTHER PARTNERS
21 IS INFERTILE OR HAS A GENETIC PROBLEM THAT HE OR SHE
22 DOES NOT WISH TO PASS ALONG; THEREFORE, THEY USE EITHER
23 DONATED SPERM OR, FAR LESS FREQUENTLY, DONATED EGGS.

24 BECAUSE DONATION PRACTICES HAVE USUALLY IN
25 THE UNITED STATES BEEN ANONYMOUS, YOU WILL HAVE SPERM

1 BANKS OR INDIVIDUAL PHYSICIANS RECRUITING DONORS AND
2 THEN PASSING ON THE GAMETES WITHOUT ANY PERSONAL
3 INFORMATION ABOUT THE DONORS, USUALLY JUST SOME MINIMAL
4 MEDICAL INFORMATION FOR THE FAMILY TO RETAIN. IT CAN
5 BE VERY DIFFICULT TO GO BACK AND IDENTIFY THOSE
6 ORIGINAL GAMETE DONORS. THE RECORDS MAY OR MAY NOT
7 EXIST, BUT CERTAINLY THEY WILL NOT HAVE BEEN UPDATED IF
8 THE DONATION WAS MADE MANY YEARS AGO. IT MAY BE JUST
9 LOGISTICALLY DIFFICULT TO IDENTIFY THE LOCATION AND
10 PHONE NUMBER OF THESE DONORS, EVEN IF YOU CAN IDENTIFY
11 THEM PERSONALLY.

12 IN ADDITION, THE DONORS HAD EXPECTED COMPLETE
13 ANONYMITY AT THE TIME OF DONATION AND MIGHT BE RATHER
14 SURPRISED TO BE RECONTACTED. NONETHELESS, THERE ARE
15 OTHER PEOPLE WHO HAVE ARGUED THAT IT IS ESSENTIAL THAT
16 PEOPLE WHO DONATED GAMETES, EXPECTING THEM TO BE USED
17 FOR REPRODUCTIVE PURPOSES, MUST BE RECONTACTED AND
18 ASKED IF IT IS ACCEPTABLE FOR THOSE RESULTING EMBRYOS
19 TO NOW BE USED FOR SOMETHING OTHER THAN REPRODUCTIVE
20 PURPOSE; FOR EXAMPLE, RESEARCH. THIS HAS BEEN ARGUED
21 IN A NUMBER OF ACADEMIC SETTINGS.

22 IT HAS THE OBVIOUS LOGISTICAL PROBLEM OF HOW
23 ONE WOULD GO ABOUT DOING IT. THERE IS, OF COURSE, THE
24 OPTION OF SIMPLY EXCLUDING FROM ELIGIBILITY FOR
25 DERIVATION PURPOSE ALL EMBRYOS THAT HAVE DONOR GAMETES

1 AS A WAY OF EVADING THE PROBLEM. THAT WILL
2 FUNCTIONALLY REDUCE BY ABOUT 10 PERCENT THE AVAILABLE
3 POPULATION OF EMBRYOS FOR CELL DERIVATIONS.

4 NONETHELESS, THERE IS NO SINGLE ANSWER THAT
5 HAS BEEN ADOPTED INTERNATIONALLY ON THIS QUESTION. IT
6 IS SIMPLY ONE THAT SEEMS TO APPEAR PERIODICALLY WITH
7 DIFFERENT COUNTRIES COMING TO DIFFERENT CONCLUSIONS
8 ABOUT HOW TO HANDLE IT.

9 NEXT, IN THE CONTEXT OF THE ACTUAL
10 INFORMATION THAT YOU'RE GOING TO BE GIVING OUT, WILL IT
11 INCLUDE THE FOLLOWING KINDS OF ITEMS THAT TEND TO
12 APPEAR IN THE INTERNATIONAL GUIDELINES, INFORMATION
13 ABOUT POSSIBLE CLINICAL USES, MANY OF WHICH MAY BE
14 MANY, MANY YEARS DOWN THE LINE. ANY RESTRICTIONS ON
15 SO-CALLED DIRECTED DONATION. DIRECTED DONATION MEANS I
16 DONATE MATERIALS ON THE CONDITION THAT THEY BE USED FOR
17 THE BENEFIT OF A PARTICULAR PERSON. OBVIOUSLY IN THE
18 CASE OF AUTOLOGOUS TRANSPLANTATION THAT FOLLOWS ON
19 SOMATIC CELL NUCLEAR TRANSFER, SOMETHING THAT IS STILL
20 OUT IN THE FUTURE, DIRECTED DONATION WOULD BE REQUIRED
21 BECAUSE IT'S AUTOLOGOUS TRANSPLANTATION TO ONE'S SELF.

22 OUTSIDE THAT ONE CONTEXT, HOWEVER,
23 RESTRICTIONS ON DIRECTED DONATION HAVE APPEARED IN
24 OTHER GUIDELINES. IN THIS CASE THE FETAL TISSUE
25 GUIDELINES THAT THE -- REGULATIONS THAT THE FEDERAL

1 GOVERNMENT HAS WHICH SPECIFICALLY PROHIBIT THE DIRECTED
2 DONATION OF FETAL TISSUE TO A PARTICULAR PERSON.

3 AGAIN, THE POINT OF THE DIRECTED DONATION
4 LIMITS HAS BEEN TO AVOID EVEN THE MEREST GLIMMER OF A
5 POSSIBILITY THAT SOMEBODY'S DECISION ABOUT DONATION
6 WILL BE INFLUENCED BY THE PROSPECT OF DIRECTLY
7 BENEFITING A KNOWN PERSON. AS FAR AS I KNOW, THERE HAS
8 NEVER BEEN ANY EMPIRICAL EVIDENCE THAT THIS HAS, IN
9 FACT, HAS AFFECTED ANYBODY'S DECISIONS; FOR EXAMPLE, IN
10 THE CONTEXT OF ABORTION AND FETAL TISSUE RESEARCH, BUT
11 EVEN AS A HYPOTHETICAL POSSIBILITY HAS DRIVEN THE
12 POLICY MAKING IN THIS AREA.

13 NEXT, SOME KIND OF NOTICE ABOUT THE KIND OF
14 INFORMATION ABOUT THE DONORS AND THEIR MEDICAL RECORDS
15 THAT WILL BE RETAINED TO ACCOMPANY THE CELL LINES ALONG
16 WITH THE METHODS BY WHICH THAT INFORMATION WILL BE KEPT
17 SEPARATE FROM THE DONORS' IDENTITIES. THIS IS
18 SOMETHING THAT IS NOT ONLY COMING UP IN GUIDELINES
19 AROUND THE WORLD AS A MATTER OF MEDICAL ETHICS, IT'S
20 ALSO COMING UP BECAUSE OF ITS DIRECT IMPLICATIONS FOR
21 WHETHER OR NOT WORK WITH THE RESULTING CELL LINES
22 CONSTITUTES FUNCTIONALLY WORK ON THE DONORS. WE'LL GET
23 TO THAT IN A MOMENT. AND ALSO TO KIND OF ANTICIPATE
24 SOMETHING COMING UP NEXT OR ALMOST NEXT, IT WILL AFFECT
25 HOW YOU MANAGE THE MEDICAL PRIVACY PROTECTIONS THAT ARE

1 REQUIRED UNDER THE FEDERAL HEALTH INSURANCE PORTABILITY
2 AND ACCOUNTABILITY ACT, THE SO-CALLED HIPPA PRIVACY
3 RULE.

4 ITEM D ON MY LIST OF ELEMENTS IN INFORMED
5 CONSENT THAT NEEDED SOME ATTENTION AND DECISION-MAKING
6 BY THE ICOC OR BY THE STANDARDS COMMITTEE, WHETHER OR
7 NOT THE DONORS ARE GOING TO HAVE ANY CHOICE ABOUT
8 WHETHER OR NOT THEY WOULD IN THE FUTURE EVER BE
9 RECONTACTED FOR ANY PURPOSE. THIS CAN BECOME A VERY
10 COMPLEX ISSUE. LET ME JUST GIVE AN EXAMPLE OF A
11 SITUATION THAT MIGHT ILLUMINATE IT.

12 YOU COLLECT EMBRYOS FROM EMBRYO DONORS, AND
13 YOU DERIVE A NEW EMBRYONIC STEM CELL LINE. THE LINE
14 THEN IS USED FOR RESEARCH BY RESEARCHERS AT
15 INSTITUTIONS A, B, AND C THROUGHOUT CALIFORNIA. THE
16 RESEARCHERS AT INSTITUTION C, WORKING JUST WITH THE
17 CELL LINE, AND THE CELL LINE IS CODED CELL LINE 1234,
18 ALONG WITH SOME MEDICAL AND GENETIC INFORMATION FROM
19 THE DONORS WITH NO PERSONAL IDENTITIES. AND
20 INVESTIGATORS AT INSTITUTION C, WORKING WITH CELL LINES
21 DISCOVER SOMETHING VERY INTERESTING. THEY MAKE AN
22 OBSERVATION ABOUT A PARTICULAR GENETIC MUTATION, ONE
23 THAT PERHAPS AT THE TIME OF THE DONATION WAS NOT KNOWN
24 TO HAVE CLINICAL SIGNIFICANCE TO ANY PHYSICIAN, BUT
25 SINCE THEN, BECAUSE OF THE EVOLVING NATURE OF MEDICAL

1 RESEARCH, AS WE SAW TODAY IN THE CF TALK, HAS NOW COME
2 TO BE UNDERSTOOD TO BE POTENTIALLY CLINICALLY
3 SIGNIFICANT.

4 NOW THE RESEARCHERS AT INSTITUTION C ARE
5 FACED WITH AN INTERESTING QUESTION. WE SEE SOMETHING
6 IN THE CELLULAR MATERIAL THAT WAS DERIVED FROM THE
7 EMBRYOS THAT WERE DONATED. IT'S POSSIBLE, THEREFORE,
8 THAT WE'VE LEARNED SOMETHING THAT MIGHT BE OF INTEREST
9 TO THOSE INDIVIDUALS WHO DONATED, MIGHT EVEN BE OF
10 PERSONAL BENEFIT MEDICALLY. OF COURSE, WE'VE CAREFULLY
11 MADE IT IMPOSSIBLE FOR THE RESEARCHERS TO KNOW THE
12 PERSONAL IDENTITY OF THESE DONORS. TWO QUESTIONS. DO
13 YOU WANT TO MAKE IT POSSIBLE TO RECONTACT THOSE DONORS
14 UNDER ANY CIRCUMSTANCES? IF SO, THEN YOU'RE GOING TO
15 NEED TO GIVE DONORS A CHOICE TO SAY YEA OR NAY TO THIS
16 BECAUSE SOME PEOPLE SIMPLY DON'T WANT TO KNOW
17 INFORMATION, ESPECIALLY INFORMATION THAT MIGHT NOT BE
18 USEFUL IMMEDIATELY, INFORMATION THAT'S AMBIGUOUS,
19 INFORMATION ABOUT DISEASES THAT HAVE NO CURE.

20 JUST AS AN ASIDE, MANY PEOPLE HERE WHO
21 PRACTICE MEDICINE IN THE REPRODUCTIVE AREA ARE PROBABLY
22 FAMILIAR WITH THE RANGE OF PRENATAL TESTS THAT NOW GIVE
23 RESULTS ABOUT SEEMING ABNORMALITIES FOR WHICH THERE IS
24 NO KNOWN CLINICAL SEQUELAE. JUST DON'T KNOW WHAT IT
25 MEANS. YOU TELL WOMEN THAT THEY'VE GOT THIS

1 ABNORMALITY, BUT YOU CAN'T TELL THEM WHETHER OR NOT
2 IT'S A PROBLEM, AND IT'S QUITE ANXIETY INDUCING. THERE
3 ARE REASONS WHY PEOPLE SOMETIMES DON'T WANT TO HAVE
4 INFORMATION. OTHER PEOPLE WANT IT ALL AND WOULD RATHER
5 MANAGE IT THEMSELVES.

6 SO WE HAVE TO DECIDE WHETHER OR NOT YOU WANT
7 TO MAKE IT POSSIBLE TO SEND THAT INFORMATION BACK UP
8 THE LINE TO ORIGINAL DONORS. IF SO, THEY HAVE TO BE
9 GIVEN A CHOICE ABOUT WHETHER OR NOT TO RECEIVE THE
10 INFORMATION, AND IN ADDITION, YOU HAVE TO ANTICIPATE A
11 METHOD BY WHICH YOU CAN -- SOMEBODY EVALUATES WHETHER
12 OR NOT THE INFORMATION IS IMPORTANT ENOUGH TO SEND UP
13 THE LINE, HOW SHOULD IT BE MANAGED SO THAT THE
14 INFORMATION IS USEFUL WITHOUT BEING UNDULY ANXIETY
15 PROVOKING, WHO SHOULD ACTUALLY DELIVER THE INFORMATION.
16 THE INVESTIGATORS, FOR EXAMPLE, ARE NOT CLINICAL
17 PRACTITIONERS, CERTAINLY NOT IN THE BEST POSITION TO
18 DELIVER MEDICAL INFORMATION. YOU CAN IMAGINE HERE SOME
19 VERY SIGNIFICANT LOGISTICAL PROBLEMS.

20 YOU ARE NOT ON YOUR OWN IN THIS AREA. THIS
21 COMES UP IN ALL TISSUE REPOSITORIES. IT IS NOT UNIQUE
22 TO EMBRYONIC STEM CELL RESEARCH OR EMBRYO RESEARCH.
23 AND POLICIES ABOUT THIS ARE IN PLACE AT MOST, IF NOT
24 ALL, TISSUE BANKS AND IN MANY HOSPITALS WHERE TISSUES
25 ARE COLLECTED, FOR EXAMPLE, RESIDUAL TISSUE FROM

1 SURGICAL PROCEDURES OR EXTRA BLOOD FROM BLOOD DRAWS, SO
2 THERE ARE MANY EXAMPLES OF EXTANT GUIDELINES ON HOW TO
3 EITHER ELIMINATE THE POSSIBILITY OF RECONTACT IN ORDER
4 TO KEEP THINGS SIMPLE; OR IF YOU WOULD LIKE TO MAXIMIZE
5 POTENTIAL BENEFIT TO DONORS, TO PERMIT RECONTACT WITH A
6 VERY DETAILED PROTOCOL FOR HOW TO GO ABOUT IT.

7 IRB'S ARE OFTEN VERY IMPORTANT IN THIS
8 PROCESS AND IN SOME CASES SERVE AS THE VEHICLE BY WHICH
9 INFORMATION IS BROUGHT INTO A BODY FOR EVALUATION AND A
10 PROTOCOL FOR RELEASING IT TO THE DONORS OR PATIENTS IS
11 THEN DEVELOPED.

12 ITEM E WITH REGARD TO ELEMENTS OF INFORMED
13 CONSENT. HOW MUCH SHOULD BE TOLD TO YOUR POTENTIAL
14 DONORS ABOUT THE RANGE OF RESEARCH USES? THERE ARE
15 RESEARCH USES THAT ARE COMING DOWN THE PIKE THAT ARE
16 PROBABLY GOING TO SOUND VERY ALARMING TO MOST MEMBERS
17 OF THE PUBLIC. THESE MIGHT INCLUDE GENETIC
18 MANIPULATION OF THE EMBRYONIC STEM CELLS. THAT IS
19 ALREADY GOING ON IF ONLY TO JUST INSERT MARKERS SO THAT
20 ONE CAN ACTUALLY OBSERVE WHERE THE CELLS ARE
21 DIFFERENTIATING. AND SECOND, THE COMBINATION OF HUMAN
22 AND NONHUMAN CELLS, SUCH AS THE EXPERIMENTS THAT HAVE
23 ALREADY BEEN DONE WITH NONHUMAN CELLS INTO CHICKEN EGGS
24 IN ORDER TO BE ABLE TO SEE HOW THE STEM CELLS ARE
25 DIFFERENTIATING, VERY HELPFUL TO PUT THEM INTO A

1 DIFFERENT ORGANISM SO THAT YOU CAN CLEARLY DISTINGUISH
2 BETWEEN THE STEM CELLS, WHICH CAME FROM ORGANISM A AND
3 THE EXISTING TISSUE WHICH CAME FROM ORGANISM B. AS
4 SOON AS YOU TALK ABOUT HUMAN/NONHUMAN COMBINATIONS OF
5 ANY SORT, EVEN IF THEY ARE, IN FACT, ALREADY PREVALENT.

6 THERE MIGHT EVEN BE SOMEBODY HERE WHO'S HAD A
7 PIG VALVE PUT INTO THEM FOR HEART VALVE TRANSPLANT.
8 HUMAN/NONHUMAN COMBINATIONS RAISE EYEBROWS, RAISE
9 ANTENNAE, AND FOR SOME PEOPLE MIGHT SIMPLY VIOLATE
10 THEIR OWN PERSONAL NOTIONS OF WHAT WE OUGHT TO BE DOING
11 WITH THE NATURAL WORLD. GENETIC ENGINEERING FALLS INTO
12 THE SAME CATEGORY. SHOULD THESE KINDS OF POTENTIAL
13 RESEARCH USES OF STEM CELL LINES BE SPELLED OUT TO
14 POTENTIAL DONORS? AND GIVEN THAT WE CAN'T ANTICIPATE
15 EVERY POSSIBLE EXPERIMENT THAT MAY COME TO BE SEEN AS
16 IMPORTANT, HOW DO YOU COMMUNICATE TO PEOPLE A RANGE OF
17 RESEARCH POSSIBILITIES THAT AREN'T YET KNOWN?

18 AND FINALLY, IN THAT CONTEXT, IF YOU DECIDE
19 TO DO THIS, TO TRY TO SPELL OUT THESE RESEARCH USES TO
20 GIVE PEOPLE MORE AND MORE INFORMATION ABOUT THIS BEFORE
21 THEY DONATE, HOW MUCH DO YOU EXPECT THAT TO LIMIT YOU?
22 THAT IS, IF YOU DID NOT KNOW OF A PARTICULAR EXPERIMENT
23 AT THE TIME THE DONATION WAS MADE, DOES THAT MEAN THIS
24 CELL LINE CANNOT BE USED FOR ANY EXPERIMENT THAT WAS
25 NOT SPECIFICALLY NOTICED TO THE DONORS, OR IS THERE

1 SOME KIND OF BROAD CATCHALL FOR ALL POTENTIAL RESEARCH
2 USES TO WHICH PEOPLE CAN CONSENT, A KIND OF WAIVER IN
3 WHICH PEOPLE ESSENTIALLY ARE WAIVING THEIR PRIVILEGE OF
4 HEARING A DETAILED RECITATION OF PERMISSIBLE USES WITH
5 NO FURTHER USE PERMITTED.

6 THESE ARE THE KINDS OF NUTS AND BOLTS DETAILS
7 THAT OFTEN HAVE TO GET IRONED OUT BEFORE CONSENT
8 PROCESS CAN BEGIN. AND THERE ARE EXAMPLES OF CONSENT
9 FORMS THAT HAVE BEEN USED IN OTHER INSTITUTIONS THAT
10 ACTUALLY HAVE WORKED THROUGH THESE PROBLEMS TO THEIR
11 OWN POLICY RESOLUTION. AND I'VE INCLUDED JUST ONE
12 EXAMPLE IN THE HANDOUTS. IT IS ONE OF MANY. AND I
13 DON'T BELIEVE ANYBODY WOULD ARGUE THERE IS A SINGLE
14 RIGHT ANSWER TO THESE QUESTIONS SO MUCH AS THESE ARE
15 QUESTIONS THAT MUST BE ANSWERED AT SOME POINT, AND THEN
16 THE CONSENT PROCESS AND THE DOCUMENTATION MUST REFLECT
17 THOSE POLICY DECISIONS.

18 NEXT ITEM ON THE LIST OF MANDATED TASKS FOR
19 THE ICOC IS TO SET STANDARDS ON THE PROHIBITION ON
20 COMPENSATION FOR RESEARCH DONORS AND PARTICIPANTS,
21 WHICH I READ AS APPLYING EQUALLY TO EMBRYO EGGS, SPERM,
22 AND SOMATIC CELL DONATION. IT SAYS IN THE INITIATIVE
23 QUITE SPECIFICALLY THAT IT'S LIMITED TO REIMBURSEMENT,
24 THAT IT IS NOT A PAYMENT SO THAT WE ARE NO LONGER ASKED
25 TO DEBATE THE QUESTION, THE ETHICS, OR THE LOGISTICS OF

1 THE SALE OF HUMAN TISSUE IN THESE CONTEXTS.

2 NEVERTHELESS, EVEN THE CONTEXT OF
3 REIMBURSEMENT HAS SOME AMBIGUITIES BUILT INTO IT. MANY
4 PEOPLE MAY THINK THAT THEY'RE ALREADY ANSWERED BY THE
5 LANGUAGE. SOMETIMES YOU MAY FIND IT WORTHWHILE TO
6 SIMPLY MAKE IT THAT MUCH MORE EXPLICIT SO THERE'S NO
7 POSSIBILITY FOR CONFUSION.

8 ONE IS WHAT CONSTITUTES THE LIMIT ON
9 REIMBURSEMENT. ACTUAL OUT-OF-POCKET COULD BE QUITE
10 OUTLANDISH IF SOMEBODY CHOSE TO SPEND A GREAT DEAL OF
11 MONEY IN THE CONTEXT OF TRANSPORT TO THE SITE FOR
12 DONATION. SO IS THERE GOING TO BE A LIMITATION TO
13 REASONABLE OUT-OF-POCKET EXPENSES, AS IS TYPICALLY THE
14 CASE IN STATE REIMBURSEMENT RULES? BUT IF THERE IS,
15 THEN THERE IS GOING TO HAVE TO BE SOME PERSON SOMEWHERE
16 WHO MAKES A JUDGMENT ABOUT WHAT CONSTITUTES REASONABLE.
17 SO JUST AS A LOGISTICAL MATTER, AS SOON AS YOU ADD A
18 GLOSS, YOU'VE ALSO GOT TO ADD A PERSON.

19 SECOND, ALTHOUGH IT SAYS NO PAYMENT, ONLY
20 REIMBURSEMENT, AND FORGIVE ME IF I WAS MISREADING IT, I
21 DIDN'T SEE AN EXPLICIT DEFINITION OF REIMBURSEMENT THAT
22 WOULD ABSOLUTELY CLEARLY PRECLUDE REIMBURSEMENT FOR
23 LOST TIME AT WORK OR LOST WAGES. IF THAT'S THERE AND I
24 MISSED IT, I APOLOGIZE. IF IT'S NOT THERE AND IT'S
25 ONLY IMPLICIT IN THE NO-PAYMENT PROVISION, IT IS

1 SOMETHING WHICH YOU CAN CERTAINLY MAKE MORE EXPLICIT AS
2 YOU WRITE THE GUIDELINES THAT FOLLOW ON THESE RULES.

3 AND THEN FINALLY, AGAIN, IMPLICIT, BUT NOT
4 EXPLICIT, WITHIN THIS PROVISION IS WHETHER OR NOT THERE
5 IS A PROHIBITION ON IN-KIND INCENTIVES OR REWARDS OR
6 THANK YOUS OF ANY SORT. AND ONE THAT HAS BEEN RAISED
7 AS A MATTER OF CONCERN BY SOME AS A POTENTIAL GOOD
8 INDUCEMENT BY OTHERS HAS BEEN DISCOUNTS ON FERTILITY
9 PROCEDURES. THIS IS DECRIED BY SOME AS AN UNDUE
10 INDUCEMENT TO RELEASE EMBRYOS FOR RESEARCH. FOR OTHERS
11 WHO SEE IVF AS OUT OF REACH FOR POOR PEOPLE AND WOULD
12 LIKE TO SEE IT EXPANDED, THEY SEE IT AS AN OPPORTUNITY
13 TO MAKE MORE AVAILABLE.

14 REGARDLESS OF WHERE YOU STAND ON THIS, IT'S
15 IMPORTANT THAT PEOPLE ABSOLUTELY UNDERSTAND AT THE
16 CLINIC LEVEL WHETHER OR NOT THEY'RE ENTITLED TO GIVE
17 ANYTHING IN THE NATURE OF A DISCOUNT OR EVEN JUST
18 ALLOWING SOMEBODY TO GO TO THE HEAD OF THE LINE AND
19 SKIP THE USUAL APPOINTMENT PROCESS. SO ATTENTION TO
20 IN-KIND AS WELL AS CASH ISSUES CAN HELP YOU BE
21 EXPLICIT, CLEAR, BEYOND CONFUSION IN THE APPLICATION OF
22 YOUR STANDARDS.

23 NEXT, PATIENT PRIVACY LAWS. PROP 71 ASKED
24 YOU TO SET STANDARDS THAT ASSURE COMPLIANCE WITH STATE
25 AND FEDERAL PATIENT PRIVACY LAWS. NOW, THERE ARE GOING

1 TO BE TWO MAJOR SOURCES FOR PATIENT PRIVACY RULES IN
2 THE UNITED STATES. ONE, AS PREVIOUSLY MENTIONED, IS
3 GOING TO BE THE RULES GOVERNING RESEARCH WITH HUMAN
4 SUBJECTS. WHERE THOSE ARE TRIGGERED, THERE ARE GOING
5 TO BE A VARIETY OF RULES ABOUT HOW TO MAINTAIN THE
6 CONFIDENTIALITY OF THE DONORS AND KEEP THAT SEPARATE
7 FROM THE MEDICAL OR GENETIC INFORMATION THAT YOU ARE
8 GOING TO WANT TO COLLECT AND HAVE ASSOCIATED WITH CELL
9 LINES SO THAT OVER THE YEARS AS THEY'RE USED, YOU WILL
10 NEVER LOSE TRACK OF ANY RATHER PERTINENT INFORMATION
11 ABOUT THEIR ORIGINS MEDICALLY SPEAKING.

12 THOSE PRIVACY PROTECTIONS TEND TO BE OVERSEEN
13 BY AN IRB. SO THE INVESTIGATORS OR PEOPLE PROPOSING TO
14 DO A DERIVATION, FOR EXAMPLE, WOULD LAY OUT THEIR
15 PROPOSAL FOR HOW TO MAINTAIN THE CONFIDENTIALITY. WHAT
16 WILL THE CODING SYSTEM BE? HOW WILL THE CODE BE
17 BROKEN, IF NEEDED, AND WHO HOLDS THE KEYS TO BREAKING
18 THE CODE? AND WHAT STRICTURES ARE THEY UNDER TO NOT
19 BREAK IT EXCEPT UNDER CERTAIN CIRCUMSTANCES? AND PROP
20 71, OF COURSE, SAYS THIS IS NOT INTENDED TO BREACH ANY
21 OTHER LAWS OUT THERE ABOUT PRIVACY, SO KEEP IN MIND
22 THERE ARE SOMETIMES CRIMINAL LAW IN OTHER SETTINGS
23 WHICH WILL TRUMP ALL OF YOUR RULES ABOUT MEDICAL
24 PRIVACY. EVEN THERE, THERE ARE EXTRA OPPORTUNITIES FOR
25 THINGS SUCH AS CERTIFICATES OF CONFIDENTIALITY FROM THE

1 FEDERAL GOVERNMENT TO TRY TO PROTECT PEOPLE.

2 MOST OF THESE SITUATIONS ARE UNLIKELY TO
3 OCCUR, BUT IRB'S ARE GOOD AT ANTICIPATING THEM BECAUSE
4 THEY HAVE THAT KIND OF EXPERIENCE WITH THESE MORE
5 REMOTE SITUATIONS ABOUT BREACH OF CONFIDENTIALITY.

6 PROBABLY A LITTLE LESS FAMILIAR TO THE
7 RESEARCH COMMUNITY, ONLY FAMILIAR TO THE CLINICAL
8 COMMUNITY, ARE THE PROVISIONS OF THE HIPPA PRIVACY
9 RULE. NOW, THE HIPPA PRIVACY RULE BASICALLY SAYS THAT
10 YOU CAN'T DISCLOSE MEDICAL INFORMATION ABOUT PATIENTS
11 WITHOUT THEIR AUTHORIZATION. IF YOU ARE ONE OF THE,
12 AND MOST PEOPLE HERE WILL BE, MOST OF THE INSTITUTIONS
13 HERE WILL BE ONE OF THESE SO-CALLED COVERED ENTITIES,
14 THE ENTITIES THAT ARE COVERED BY THIS LAW, THAT WOULD
15 SEEM TO MAKE IT IMPOSSIBLE TO TRANSMIT INFORMATION
16 ABOUT THE DONOR'S MEDICAL CONDITIONS AND GENETIC
17 CONDITIONS DOWN THE LINE WITH THE CELL LINES EXCEPT
18 THAT HIPPA HAS ITS OWN SET OF EXCEPTIONS.

19 FIRST, THE BIGGEST, OBVIOUSLY, YOU CAN GET
20 THE AUTHORIZATION, SO DONORS CAN SIGN AN AUTHORIZATION
21 AT THE OUTSET TO ALLOW FOR THE RELEASE OF THE
22 INFORMATION. SECOND, EVEN UNDER HIPPA, SUFFICIENT
23 DEGREE OF CODING AND OBSCURING OF PERSONAL IDENTITY
24 WILL ALLOW YOU TO USE MEDICAL INFORMATION WITHOUT AN
25 EXPLICIT AUTHORIZATION, BUT ONLY IF, NOT ONLY DO YOU

1 HAVE THIS CODING AND OBSCURING, BUT YOU ALSO HAVE A
2 PLAN TO PREVENT THE BREACH OF CONFIDENTIALITY AND YOU
3 CAN SHOW THAT THIS IS OF MINIMAL RISK TO THE PRIVACY OF
4 THE PATIENTS, AND YOU CAN SHOW THAT IT REALLY WASN'T
5 PRACTICAL TO GET THEIR AUTHORIZATION TO BEGIN WITH.

6 IF YOU MEET ALL THOSE CONDITIONS, ONE CAN USE
7 MEDICAL INFORMATION EVEN UNDER THE HIPPA PRIVACY RULE
8 WITHOUT AN EXPLICIT AUTHORIZATION. IF YOU CAN'T MEET
9 THOSE CONDITIONS, THEN YOU ARE GOING TO NEED TO GET
10 AUTHORIZATION, OR YOU CAN APPROACH AN IRB OR A PRIVACY
11 BOARD TO SEE IF THERE'S ANY OTHER CONDITION ON WHICH TO
12 WAIVE OR ALTER THE NATURE OF THE AUTHORIZATION
13 REQUIRED.

14 PRIVACY BOARDS ARE SLIGHTLY DIFFERENT IRB'S.
15 MOST INSTITUTIONS HAVE BOTH AN IRB AND A PRIVACY BOARD.
16 HIPPA DOES ALLOW IRB'S TO FUNCTION AS PRIVACY BOARDS
17 UNDER SOME CIRCUMSTANCES. SO IN SOME INSTITUTIONS YOU
18 MAY FIND THAT THE TWO COMMITTEES HAVE BEEN MERGED.

19 SO HERE ARE THE QUESTIONS FOR THE ICOC AND
20 YOUR STANDARDS COMMITTEE ON THOSE ISSUES. FIRST, DO
21 YOU FEEL THE NEED, BASED UPON WHAT I'VE DESCRIBED AS
22 THE EXISTING FEDERAL PROTECTIONS, TO ADD ANY ADDITIONAL
23 LAYERS OF PATIENT PROTECTION? FOR EXAMPLE, JUST AS
24 YOU'RE ALLOWED TO ADD IRB REVIEW FOR SITUATIONS THAT
25 ARE NOT CURRENTLY REQUIRED TO UNDERGO IRB REVIEW, YOU

1 COULD SAY NO EXCEPTIONS TO THE AUTHORIZATION AND
2 CONSENT RULES. WE WILL NEVER WAIVE THAT AT ALL.
3 THAT'S UP TO YOU. BUT THAT WOULD BE GOING BEYOND THE
4 FEDERAL RULES, AND THIS IS A DECISION THAT IS UP TO THE
5 STANDARDS COMMITTEE.

6 SECOND, ARE YOU GOING TO IN ANY WAY WANT CIRM
7 OR ANY OTHER INSTITUTION OR COMMITTEE TO COORDINATE,
8 OVERSEE, DOCUMENT, VERIFY COMPLIANCE BY INVESTIGATORS
9 AND THEIR INSTITUTIONS WITH THESE VARIOUS IRB AND HIPPA
10 PRIVACY BOARD REGULATIONS? CURRENTLY THAT IS SIMPLY AN
11 INSTITUTIONAL MATTER. IT IS NOT NECESSARILY
12 COORDINATED. GRANTORS WILL ASK FOR, FOR EXAMPLE, AN
13 NIH GRANT WILL REQUIRE SOME EVIDENCE OF AN IRB REVIEW,
14 BUT THAT IS NOT SOMETHING YOU MUST FOLLOW AS A PATTERN
15 OF BEHAVIOR. SO SOME GRANTORS DO THIS AND REQUIRE SOME
16 DOCUMENTATION OF COMPLIANCE. OTHERS DON'T.

17 ALSO IN THE REALM OF PRIVACY AND PERHAPS
18 SOMETHING THAT'S NOT COME TO YOUR ATTENTION AS OF YET,
19 THERE IS THE INTERACTION BETWEEN U.S. PRIVACY RULES AND
20 EUROPEAN RULES THAT'S WORTH AT LEAST A MOMENT'S
21 THOUGHT. THE EUROPEANS IN VARIOUS CAPACITIES AT THE
22 LEVEL OF THE EUROPEAN UNION AND INDIVIDUAL COUNTRIES
23 AND THE COUNCIL OF EUROPE, EACH DIFFERENT ENTITIES WITH
24 DIFFERENT JURISDICTION AND DEGREES OF ENFORCEABILITY,
25 HAVE ALL BEEN WORKING FOR THE LAST FEW YEARS ON PRIVACY

1 PROTECTIONS IN GENERAL, INCLUDING PROTECTIONS FOR
2 MEDICAL INFORMATION. AND THERE IS NOW A EUROPEAN DATA
3 DIRECTIVE WHICH SPELLS OUT CONDITIONS FOR THE
4 TRANSMITTAL OF INFORMATION TO INVESTIGATORS, INCLUDING
5 INVESTIGATORS IN OTHER COUNTRIES.

6 THE BOTTOM LINE IS THIS. THE EUROPEAN
7 COUNTRIES THAT HAVE SIGNED ONTO THIS, AND IT'S PRETTY
8 MUCH THE EUROPEAN UNION, PLUS, I THINK IT WAS, NORWAY,
9 ICELAND, AND ONE OTHER COUNTRY, WHICH MEANS IT'S
10 COVERING A LOT OF THE POTENTIAL COLLABORATOR COUNTRIES
11 IN THE STEM CELL AREA, THE EUROPEAN COUNTRIES WILL
12 PROHIBIT THE TRANSMITTAL OF DATA THAT IS CONSIDERED
13 CONFIDENTIAL, LIKE MEDICAL PRIVACY DATA, UNLESS THEY'RE
14 ASSURED THAT THE RECIPIENT INSTITUTION IS IN A
15 JURISDICTION THAT ALSO HAS ADEQUATE PROTECTION FOR
16 MEDICAL PRIVACY. IF NOT, THEN THE INDIVIDUAL
17 INVESTIGATOR AND INSTITUTION WILL HAVE TO NEGOTIATE
18 SOME SPECIAL PROTECTIONS FOR THAT TRANSMITTAL ONLY.
19 YOU CAN CREATE WHAT THEY CALL SO-CALLED SAFE HARBOR
20 PROVISIONS. BETTER IF I CAN HAVE A WHOLE JURISDICTION
21 WHOSE LAWS AND REGULATIONS ARE CONSIDERED, YOU KNOW, AS
22 CATEGORICALLY TO MEET THESE REQUIREMENTS.

23 I WILL TELL YOU THAT AS OF WHEN I LAST
24 CHECKED A COUPLE OF WEEKS AGO, THE UNITED STATES,
25 DESPITE THE IRB PROTECTIONS AND DESPITE THE EXISTENCE

1 OF HIPPA, IS NOT ON A NATIONAL LEVEL CONSIDERED TO HAVE
2 ADEQUATE PROTECTIONS FOR THE EUROPEAN DATA PRIVACY
3 PROVISIONS; AND IT'S, THEREFORE, WORTH HAVING, PERHAPS,
4 A CONVERSATION WITH ONE'S COUNTERPARTS ABOUT EXACTLY
5 WHAT PROTECTIONS ARE LACKING IN OUR SYSTEM IN THEIR
6 PERCEPTION TO SEE WHETHER OR NOT THE CALIFORNIA-FUNDED
7 RESEARCHERS CAN COLLECTIVELY BE GIVEN A SYSTEM THAT
8 MEETS THE REQUIREMENTS AND SIMPLIFIES THIS PROCESS OF
9 COLLABORATION.

10 LAST ON THE LIST OF MANDATED ITEMS WAS TIME
11 LIMITS WITH REGARD TO THE MANAGEMENT OF EMBRYOS. THE
12 INITIATIVE SETS A LIMIT OF 8 TO 12 DAYS FOR THE
13 MAINTENANCE OF A FRESH OR THAWED EXTRA-UTERINE EMBRYO.
14 I WILL JUST POINT OUT TO YOU INTERNATIONALLY IT HAS
15 TENDED TO BE 14 DAYS OR WHEN THE PRIMITIVE STREAK FIRST
16 APPEARS, WHICHEVER OCCURS FIRST. THE ORIGIN OF THE
17 14-DAY/PRIMITIVE STREAK RESTRICTION LIES WITH MARY
18 WARNOCK OF THE WARNOCK COMMISSION IN THE 1980S IN THE
19 UNITED KINGDOM BECAUSE THEY'VE BEEN FUNDING EMBRYO
20 RESEARCH ALL ALONG; WHEREAS, WE STOPPED IN 1980,
21 THEY'VE HAD COMMISSIONS ALL ALONG WORKING OUT THE RULES
22 FOR THE ETHICAL MANAGEMENT OF EMBRYO RESEARCH AND SO
23 HAVE TENDED TO SET THE TONE FOR THE INTERNATIONAL STAGE
24 AND FOR AMERICAN ETHICAL THINKING BECAUSE THEY'VE
25 SIMPLY BEEN OUT THERE AHEAD OF US IN BOTH THE RESEARCH

1 AND THE NEED TO GOVERN RESEARCH.

2 NOW, REALISTICALLY, FROM WHAT I UNDERSTAND,
3 BUT I DEFER TO THE SCIENTISTS ON THE ICOC, WHETHER IT'S
4 14, 12, OR 8 IS IN SOME FASHION NOT REALLY ALL THAT
5 RELEVANT SINCE NOBODY REALLY KNOWS HOW TO CULTURE AN
6 INTACT OUT FOR EIGHT DAYS AT THIS POINT. SO IN SOME
7 WAYS THESE KIND OF LIMITS ARE SOMEWHAT ARBITRARY
8 BECAUSE RIGHT NOW THEY'RE NOT TECHNICALLY ACHIEVABLE.
9 NONETHELESS, YOU HAVE THE OPTION, FOR WHATEVER REASON,
10 OF PICKING A PARTICULAR DAY IN ORDER TO CLARIFY OR TO
11 KEEP IT AS A RANGE OF DAYS IF YOU SEE SOME ADVANTAGE TO
12 THAT. AND YOU CAN ALSO DECIDE WHETHER OR NOT YOUR
13 FUNDED RESEARCHERS MUST COMPLY WITH ONE LIMIT SET BY
14 YOUR STANDARDS COMMITTEE OR WHETHER THEY CAN COMPLY
15 WITH ANY NUMBER OF DIFFERENT LIMITS THAT ARE SET BY
16 THEIR INDIVIDUAL INSTITUTIONS, WHICH ALL WITHIN THEIR
17 RANGE OF VARIATIONS NONETHELESS MEET YOUR INITIATIVE
18 CONSTRAINTS OF NO MORE THAN 8 TO 12 DAYS.

19 AND THAT ACTUALLY RAISES, I THINK, A MORE
20 GLOBAL POINT THAT I'D LIKE TO MENTION BEFORE THEN JUST
21 QUICKLY RUNNING THROUGH THE ADDITIONAL TOPICS THAT YOU
22 MIGHT WANT TO ADDRESS WHEN YOU HAVE AN OPPORTUNITY TO
23 GO BEYOND THE MANDATED TASKS. THAT IS, THAT THERE'S A
24 VERY BIG DECISION TO BE MADE ABOUT WHETHER YOU WANT
25 YOUR STANDARDS TO BE ENTIRELY UNIFORM, CENTRALLY

1 WRITTEN, DIRECTIVE, AND UNIFORMLY APPLIED TO ALL
2 CALIFORNIA -- ALL CIRM-FUNDED INVESTIGATORS REGARDLESS
3 OF THEIR INSTITUTION, OR IF WHAT YOU WANT TO DO ARE
4 WRITE GUIDELINES THAT SET BANDS OF PERMISSIBLE
5 DECISION-MAKING, FOR EXAMPLE, 8 TO 12 DAYS, AND THEN
6 ALLOW LOCAL VARIATION BY THE LOCAL IRB'S BASED UPON
7 THEIR OWN BELIEFS, THEIR OWN EXPERIENCES.

8 THE ADVANTAGE TO LOCAL VARIATION IS NOT ONLY
9 DO INSTITUTIONS TEND TO LIKE THEIR OWN AUTONOMY, NOT
10 ONLY DO THEIR GENERAL COUNSELS TEND TO FEEL LESS
11 NERVOUS WHEN THEY HAVEN'T GIVEN UP THE AUTHORITY TO
12 MAKE THE RULES TO SOMEBODY ELSE, BUT IN ADDITION,
13 ALLOWING VARIATION ALLOWS YOUR INSTITUTIONS TO ACT AS A
14 NATURAL SOCIAL LABORATORY FOR EXPERIMENTING WITH THE
15 DIFFERENT WAYS IN WHICH THE STANDARDS CAN BE APPLIED TO
16 SEE WHICH ONES IN PRACTICE ACTUALLY ARE BEST, MOST
17 WORKABLE, ETC.

18 THE DISADVANTAGE IS THAT IN MANY SETTINGS,
19 BOTH INSTITUTION TO INSTITUTION OR STATE TO STATE OR
20 U.S. TO NON-U.S. SETTING, THERE ARE GOING TO BE
21 LIMITATIONS ON WHETHER PEOPLE ARE ALLOWED TO USE ONE
22 ANOTHER'S LINES DEPENDING UPON THE ORIGINAL CONDITIONS
23 UNDER WHICH THE LINES WERE DERIVED. THAT IS, IF I WERE
24 AN AUSTRALIAN RESEARCHER SUBJECT TO THE TWO PIECES OF
25 LEGISLATION IN AUSTRALIA IN 2002, ONE ON STEM CELL

1 RESEARCH AND ONE ON CLONING, IF I WANT TO COLLABORATE
2 WITH A CALIFORNIA RESEARCHER, I NEED TO KNOW WHETHER OR
3 NOT THE STEM CELL LINE I'M WORKING WITH HAS AT ITS
4 ORIGIN EMBRYO CREATED WITH NUCLEAR TRANSFER BECAUSE IF
5 IT DOES, AUSTRALIAN LAW NOW FORBIDS THE IMPORTATION OF
6 THAT CELL LINE.

7 NOW, YOU CAN SEE IN A LESS DRAMATIC WAY
8 SIMILAR KINDS OF THINGS. THE QUESTION ABOUT THE
9 DEFINITION OF REIMBURSEMENT AND WHETHER SOMEBODY MIGHT
10 CONSIDER SOME FORMS OF REIMBURSEMENT TO BE FUNCTIONALLY
11 A PAYMENT MIGHT BECOME A STICKING POINT WHEN YOU WANT
12 TO COLLABORATE ACROSS LINES WITH A JURISDICTION THAT
13 HAS A STRICTER DEFINITION OF A PROHIBITION ON PAYMENT.
14 THERE MIGHT BE DIFFERENCES IN OPINION ABOUT THE PRECISE
15 CONTOURS OF WHAT MUST GO INTO THE INFORMED CONSENT TO
16 MAKE IT VALID. SO THE MORE THAT YOU MAKE YOUR RULES
17 ABSOLUTELY UNIFORM AND DIRECTIVE, THE MORE THAT YOU
18 GUARANTEE THE INTERCHANGEABILITY OF LINES AMONG
19 CALIFORNIA INSTITUTIONS AND THE EASIER IT IS FOR ALL
20 THE CALIFORNIA-GENERATED LINES TO BE MARKED AS HAVING
21 MET CERTAIN KEY REQUIREMENTS A, B, C, D, E, F, G THAT
22 ALLOW COLLABORATORS IN OTHER STATES AND OTHER COUNTRIES
23 TO KNOW AT A GLANCE EXACTLY WHICH CONDITIONS APPLY TO
24 THE PROVIDENCE AND, AGAIN, FACILITATE THE COLLABORATIVE
25 PROCESS, LET THE FOREIGN COLLABORATORS KNOW AT A GLANCE

1 THAT IT CAN'T POSSIBLY MEET IT.

2 IN THE ABSENCE OF UNIFORM RULES, IT WILL
3 REQUIRE KIND OF DETAILED, LINE-BY-LINE PARTICULARIZED
4 REVIEW OF THE PROVIDENCE IN ORDER TO ACHIEVE THAT.

5 CHAIRMAN KLEIN: ALTA CHARO, AT THIS JUNCTURE
6 IT MIGHT BE RELEVANT FOR THE PUBLIC AND THE BOARD, MOST
7 OF THE BOARD MEMBERS ARE AWARE OF THIS, TO JUST
8 INDICATE WHAT THE CHARGE WAS TO THE NATIONAL ACADEMIES
9 IN TRYING TO DEVELOP A MODEL FOR A UNIFORM NATIONAL
10 STANDARD. AND YOU MIGHT REFER TO THE TIMING FOR THE
11 NATIONAL ACADEMIES' PROPOSAL OF THAT STANDARD. IT IS
12 THE NATIONAL ACADEMIES' DESIRE THAT CALIFORNIA ADOPT
13 THE NATIONAL ACADEMIES' STANDARDS BECAUSE THAT, AS THE
14 DOMINANT PLAYER IN THE COUNTRY, WOULD PROVIDE A MODEL
15 THAT OTHER STATES HOPE THEY WOULD FOLLOW, CREATING A
16 NATIONAL CONSISTENCY OR UNIFORMITY. PERHAPS YOU COULD
17 ADDRESS THAT CHARGE AND THE TIMING ISSUES.

18 MS. CHARO: THE NATIONAL ACADEMIES OF
19 SCIENCES BEGAN A PROJECT, IT'S A JOINT PROJECT, OF THE
20 INSTITUTE OF MEDICINE AND THE NATIONAL RESEARCH
21 COUNCIL, WHICH ARE ELEMENTS OF THE NAS. IT WAS
22 AUTHORIZED LAST SPRING AND WILL PROBABLY RESULT IN A
23 PUBLICATION THIS APRIL THAT WILL CONSIST OF MODEL
24 NATIONAL GUIDELINES FOR THE CONDUCT OF EMBRYONIC STEM
25 CELL RESEARCH. THESE GUIDELINES OBVIOUSLY HAVE NO

1 FORCE BECAUSE THE NAS CERTAINLY IS NOT AN ENFORCEMENT
2 AGENCY, BUT VOLUNTARY ADOPTION BY MANY INSTITUTIONS AND
3 INVESTIGATORS WOULD ALLOW FOR THE KIND OF
4 INTERCHANGEABILITY THAT I JUST NOW DESCRIBED AS WELL,
5 WE HOPE, AT THE NAS TO ALLAY SOME PUBLIC CONCERNS ABOUT
6 THE GAPS IN REGULATORY COVERAGE EVEN THOUGH THERE IS
7 FAIRLY EXTENSIVE REGULATORY COVERAGE BETWEEN THE RULES
8 FROM THE FDA ABOUT TISSUE TRANSPLANTATION, THE RULES
9 ABOUT BIOSAFETY, THE RULES ABOUT ANIMAL MANAGEMENT,
10 ETC.

11 NOW, THE CHARGE COVERS MORE THAN WHAT WAS
12 JUST OUTLINED HERE IN YOUR MANDATED TASKS. THE CHARGE
13 TALKS, NOT ONLY ABOUT WHETHER AND HOW TO DERIVE NEW
14 LINES AND BY WHICH MEANS, USE OF SURPLUS EMBRYOS, USE
15 OF DELIBERATELY CREATED IVF EMBRYOS, USE OF
16 DELIBERATELY CREATED EMBRYOS USING NUCLEAR TRANSFER,
17 BUT IT ALSO COVERS THE QUESTION OF WHAT RULES, IF ANY,
18 SHOULD GOVERN THE ACTUAL RESEARCH IN THE LABORATORY
19 WITH THE RESULTING STEM CELL LINES THEMSELVES.

20 KEEPING IN MIND THAT UNLESS THOSE LINES
21 SOMEHOW PERSONALLY IDENTIFY THE DONORS, RESEARCH WITH A
22 LINE ITSELF, YOU HAVE AN EXISTING LINE, YOU MAKE YOUR
23 REQUEST TO A STEM CELL BANK, YOU GET THE LINE, YOU'RE
24 GOING TO DO YOUR LAB RESEARCH, THAT KIND OF RESEARCH IS
25 CURRENTLY SUBJECT TO SOME REGULATION, FOR EXAMPLE, IF

1 YOU'RE GOING TO DO GENETIC WORK WITH IT OR IF YOU'RE
2 GOING TO WORK WITH AN ANIMAL IN CONJUNCTION WITH IT,
3 BUT IN TERMS OF SUBSTANTIVE LIMITS ON WHAT YOU CAN AND
4 CANNOT DO IN YOUR LABORATORY, THERE ARE VERY FEW
5 BECAUSE IN GENERAL IN THE U.S. WE DON'T LIMIT
6 LABORATORY RESEARCH.

7 PART OF THE CHARGE FOR THE NAS WAS TO ASK
8 WHETHER THIS WAS AN APPROPRIATE WAY TO GO; AND IF NOT,
9 WHAT CHANGE SHOULD BE MADE AND HOW SHOULD IT BE
10 IMPLEMENTED. THAT MEANS THAT THE NAS GUIDELINES WILL
11 COVER, AT LEAST IF THEY MEET THEIR CHARGE, WILL COVER
12 ALL THE TOPICS THAT I'VE ADDRESSED SO FAR HERE FOR YOU,
13 BUT WILL ALSO COVER IN THAT LIST OF THINGS THAT I
14 MENTIONED NOT OUR LIST YET FOR MANDATED TOPICS, THINGS
15 LIKE WHETHER OR NOT YOU WANT TO BEGIN TO TALK ABOUT THE
16 POSSIBILITIES FOR STEM CELL BANKING AND THE MANAGEMENT
17 OF A STEM CELL BANK, WHETHER PHYSICAL OR VIRTUAL, IN
18 ORDER TO MANAGE BOTH THE TECHNICAL ISSUES AROUND
19 UNDERSTANDING THE QUALITY CONTROL ISSUES, FOR
20 CHARACTERIZATION, AND KNOWING THE NUMBER OF PASSAGES,
21 ETC., BUT ALSO THESE ETHICAL ISSUES ABOUT UNDERSTANDING
22 THE PROVIDENCE OF EACH CELL LINE.

23 SO STEM CELL BANKING IS CERTAINLY A TOPIC
24 THAT IS WITHIN THE CHARGE OF THE NATIONAL ACADEMY OF
25 SCIENCES. IN ADDITION, UNDERSTANDING THE FULL RANGE OF

1 POTENTIAL SOURCES FOR EMBRYONIC STEM CELLS. YOU WILL
2 NOTICE THAT NONE OF OUR DISCUSSION HAS TOUCHED UPON
3 ADULT STEM CELLS, EMBRYONIC GERM CELLS, NONHUMAN
4 EMBRYONIC STEM CELLS. AND FOR EACH OF THOSE TOPICS,
5 THERE IS GOING TO BE SOME OVERLAP IN THE ETHICAL
6 ISSUES. THEY WON'T BE IDENTICAL, BUT THERE WILL BE
7 SOME OVERLAP. IT MIGHT BE OVERLAP IN ISSUES
8 SURROUNDING RESEARCH USES OF THE RESULTING LINES, BUT
9 NO OVERLAP IN THE PROCUREMENT PROCESS OR FOR EMBRYONIC
10 GERM CELLS WHICH COME FROM FETAL TISSUE. IT COULD BE
11 SOME OVERLAP IN THE PROCUREMENT ISSUES, BUT WITH A
12 DIFFERENT OVERLAY BECAUSE OF SPECIFIC FEDERAL LAW ON
13 FETAL TISSUE RESEARCH.

14 SO THOSE ARE THE KINDS OF TOPICS THAT, AGAIN,
15 IF YOU LOOK AT THE PUBLIC CHARGE, IT'S PRESENT NAS.EDU
16 IS THE WEBSITE FOR THE NATIONAL ACADEMIES; AND IF YOU
17 LOOK UP THE BOARD ON LIFE SCIENCES' CURRENT PROJECTS,
18 YOU WILL SEE THE CHARGE OF THAT COMMITTEE. YOU CAN SEE
19 THE KIND OF SCOPE OF WORK THAT WAS LAID OUT FOR THE
20 COMMITTEE.

21 AND IN THAT CONTEXT, I BELIEVE THAT IF THERE
22 EVER WERE A KIND OF NOT CONFLICT OF INTEREST, BUT A
23 KIND OF CONVERGENCE OF LOYALTIES, IT WOULD BE THIS
24 MOMENT BECAUSE I REALLY DO BELIEVE THAT THE NAS, HAVING
25 THE ADVANTAGE OF HAVING STARTED SEVERAL MONTHS AGO, AND

1 HAVING THE ADVANTAGE OF NOT ONLY PULLING TOGETHER A
2 COMMITTEE WHOSE MEMBERSHIP IS PUBLICLY LISTED, BUT ALSO
3 USING THE NAS PROCESS FOR REVIEW. I DON'T KNOW WHO THE
4 REVIEWERS ARE GOING TO BE. THAT'S KEPT CONFIDENTIAL.
5 EVEN THE COMMITTEE MEMBERS DON'T KNOW IT, BUT THE
6 REVIEW NAMES WILL BE MADE PUBLIC AT THE TIME THE
7 REPORT'S MADE PUBLIC, SO THAT'S WHEN WE'LL LEARN WHO
8 REVIEWED IT. THAT REVIEW PROCESS IS DESIGNED TO
9 ACHIEVE SOME DEGREE OF BALANCE, NOT ONLY IN TERMS OF
10 EXPERTISE, BUT IN TERMS OF ATTITUDE ABOUT THE
11 UNDERLYING MATERIAL.

12 SO WHEN THEY DO COME OUT, THEY WILL HAVE BEEN
13 VETTED AS BEST AS YOU CAN VET THEM IN THAT CONTEXT, BUT
14 THEY WILL BE USELESS IF THEY'RE NOT ADOPTED.
15 CALIFORNIA AND CIRM NOW ARE BASICALLY, YOU ARE THE \$300
16 MILLION GORILLA. AND SO IF YOU FIND THAT THOSE
17 GUIDELINES PROVIDE A USEFUL FRAMEWORK AND INTRIGUING
18 GUIDANCE FOR YOUR OWN STANDARD SETTING PROCESS, THEN TO
19 THE EXTENT THAT THIS GROUP USES ANY OR ALL OF THAT
20 MATERIAL, IT GIVES FORCE AND EFFECT TO THE EFFORTS OF
21 THE NATIONAL ACADEMIES.

22 IN THE SUBSEQUENT PUBLIC FORA HERE IN
23 CALIFORNIA, THERE'S A PROCESS THAT ALLOWS FOR EVEN MORE
24 VETTING ACROSS A MUCH BROADER SPECTRUM, WHICH WILL THEN
25 FEED BACK INTO ANY SUBSEQUENT PROJECTS AT THE NAS TO

1 TRY TO LOOK AGAIN AT THE STANDARDS AND WHETHER OR NOT
2 THEY NEED TO BE CHANGED. SO I DO SEE A TREMENDOUS
3 OPPORTUNITY FOR MUTUAL ADVANTAGE IN EXPERTISE AND
4 WORKLOAD BETWEEN YOUR WORK AND THAT OF THE NATIONAL
5 ACADEMIES.

6 CHAIRMAN KLEIN: FOR THE PUBLIC'S BENEFIT,
7 WHAT ALTA CHARO IS REFERENCING IS THAT SINCE THE
8 INITIATIVE CALLS FOR ADOPTING INTERIM REGULATIONS AND
9 THEN HAVING A 270-DAY PERIOD OF PUBLIC HEARINGS, ALL
10 SUBJECT TO THE ADMINISTRATIVE PROCEDURES ACT, WHICH
11 INCLUDES POSTING AND PUBLIC COMMENTS, THAT EVEN IF THEY
12 WERE ADOPTED, AS THE NATIONAL ACADEMY STANDARDS WERE
13 ADOPTED, THEY WOULD STILL GO THROUGH THE 270-DAY PUBLIC
14 HEARING PROCESS, WHICH WOULD PROVIDE THE FEEDBACK TO
15 THE NATIONAL ACADEMIES. AND, OF COURSE, THERE WOULD BE
16 THE INPUT FROM THE NATIONAL ACADEMIES ON THAT FEEDBACK,
17 BUT THAT IS, OF COURSE, ONE OF THE OPTIONS.

18 AND I WOULD ALSO POINT OUT THAT THE
19 UNIVERSITY OF WISCONSIN, THE JUVENILE DIABETES RESEARCH
20 FOUNDATION HAVE ALREADY ADOPTED STANDARDS IN THIS AREA
21 THAT COVER MANY OF THE TOPICS, IF NOT IN MOST CASES
22 MOST OF THE TOPICS THAT ARE BEING COVERED, AS ANOTHER
23 BENCHMARK TO LOOK AT THE INQUIRY INTO STANDARDS.

24 MS. CHARO: INDEED, AND LET ME CLOSE WITH
25 THIS ONE LAST OBSERVATION BECAUSE I KNOW THAT YOU MAY

1 HAVE QUESTIONS, AND YOU ALSO NEED TO MOVE ON. I KNOW
2 AT THE END OF LAST NIGHT'S PRESENTATION THAT THERE WAS
3 A GENERAL SENSE, NOT ONLY THAT THE ROOM WAS WAY TOO
4 HOT, BUT THAT THERE WAS WAY TOO MUCH MATERIAL AND IT
5 WAS ALL RATHER OVERWHELMING, AND I WOULDN'T WANT TO
6 LEAVE YOU WITH THE SENSE THAT THIS IS AN IMPOSSIBLE
7 TASK. THERE REALLY ARE SOME TEMPLATES OUT THERE.

8 THE NAS GUIDELINES, WE'RE HOPING, WILL BE A
9 VERY WELL DEVELOPED TEMPLATE. THE UNIVERSITY OF
10 WISCONSIN GUIDELINES ARE LESS WELL DEVELOPED TEMPLATE
11 BECAUSE THEY HAVEN'T HAD QUITE THE SAME DEGREE OF
12 REPEATED ATTENTION AS SOME OTHERS. THE JDRF GUIDELINES
13 GET REPEATEDLY REVISED. AND IF YOU LOOK AT THE JDRF
14 WEBSITE, YOU WILL SEE THAT THERE WERE DIFFERENT
15 ITERATIONS AS NEW QUESTIONS AROSE AND WERE PRESENTED TO
16 THE COMMITTEE.

17 AND, OF COURSE, THERE ARE THE TEMPLATES OF
18 THE EXISTING GUIDELINES IN COUNTRIES THAT HAVE ENACTED
19 THEM OBVIOUSLY WITH DIFFERENT SUBSTANTIVE DIFFERENCES.
20 SOME PLACES YOU CAN'T MAKE EMBRYOS FOR RESEARCH, OTHERS
21 YOU CAN, SOME PLACES HAVE CENTRAL LICENSING
22 AUTHORITIES, OTHERS ARE MORE DECENTRALIZED. BUT IN
23 TERMS OF THE POLICY DECISIONS WITHIN THOSE PROCEDURAL
24 SETUPS, AUSTRALIA, SINGAPORE, ISRAEL, THE UNITED
25 KINGDOM, ALL PROVIDE FAIRLY DETAILED SETS OF

1 GUIDELINES, AGAIN, AVAILABLE ON THE WEB.

2 I THINK I MAY HAVE DISTRIBUTED SOME OF THEM
3 PRIOR TO THE MEETING. SO THAT USING THOSE AS A
4 STARTING POINT FOR THINKING ABOUT THE FRAMEWORK ALLOWS
5 ONE TO ESSENTIALLY GO THROUGH YOUR OWN LIST OF
6 QUESTIONS THAT YOU MUST ANSWER AND LOOK AT HOW THEY
7 ANSWERED IT AND ASK DO WE LIKE HOW THEY DO IT? IF NOT,
8 HOW WOULD WE CHANGE IT? AND AT THE END DO WE STILL
9 HAVE QUESTIONS THAT THEY LEFT UNANSWERED? OR DID THEY
10 HAVE QUESTIONS THEY ANSWERED WE NEVER THOUGHT TO ASK?

11 SO IT'S NOT AS OVERWHELMING AS IT SEEMS WHEN
12 YOU TAKE ADVANTAGE OF THE EXISTING MATERIALS AS A
13 STARTING POINT FOR YOUR THINKING. I ONLY HOPE THAT
14 THIS WAS PART OF THE EFFORT TO HELP YOU IN THAT
15 DIRECTION. THANK YOU.

16 (APPLAUSE.)

17 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
18 IT'S A PRIVILEGE FOR THE INSTITUTE TO HAVE ALTA CHARO
19 CONSULTANT TO THE INSTITUTE IN HELPING US THROUGH THIS
20 PROCESS.

21 I'D LIKE TO OPEN THIS FIRST TO BOARD COMMENTS
22 AND THEN PUBLIC COMMENTS AND PUBLIC QUESTIONS
23 SPECIFICALLY. I WOULD LIKE TO CALL THE ATTENTION TO
24 THE BOARD AND THE PUBLIC THAT THE INSTITUTE HAS
25 STRUCTURALLY THIS ADVISORY COMMITTEE ON STANDARDS

1 THAT'S INTENDED TO BE A DYNAMIC BODY THAT CONTINUALLY
2 CAN LOOK AT FACT PATTERNS AND UPDATE STANDARDS OVER
3 TIME AS CONDITIONS AND FACTS CHANGE.

4 ONE OF THE THINGS THAT IS RECOMMENDED IN ALTA
5 CHARO'S STRUCTURE IS, IN FACT, TO EMPOWER A BODY TO DO
6 THAT. AND SHE MIGHT ADDRESS THE PROCESS APPROACH.
7 ONCE YOU HAVE A BASIC SET OF STANDARDS, THE PROCESS
8 APPROACH AT WISCONSIN TO INCORPORATE THE ABILITY TO
9 CONTINUE TO RESPOND TO FACTS OVER TIME. MAYBE WE COULD
10 LEAD WITH THAT POINT AND THEN FOLLOW WITH OTHER BOARD
11 QUESTIONS.

12 MS. CHARO: THIS CAME UP LAST NIGHT, SO I
13 APPRECIATE YOU SUGGESTING THAT WE GO OVER IT AGAIN. MY
14 APOLOGIES TO THOSE THAT WERE THERE LAST NIGHT FOR ALL
15 THESE REDUNDANCIES. THERE ARE DIFFERENT APPROACHES TO
16 THE STYLE OF YOUR GUIDELINES. YOU CAN HAVE ABSOLUTE
17 RULES THAT COVER ABSOLUTELY EVERY SITUATION, TRY TO
18 ANTICIPATE EVERY POSSIBLE SITUATION. OR YOU CAN GO FOR
19 SOMETHING THAT'S MORE PROCESS ORIENTED IN WHICH YOU
20 CREATE A PROCESS THAT SEEMS FAIR AND USEFUL, BUT YOU
21 DON'T NECESSARILY KNOW WHAT THE OUTCOME IS GOING TO BE,
22 KIND OF LIKE FRACTILE GEOMETRY, OR YOU CAN COMBINE
23 THEM.

24 WHAT WE FOUND AT UNIVERSITY OF WISCONSIN IS
25 THAT IF YOU STARTED WITH VERY LARGE CATEGORIES, IN OUR

1 CASE WE HAD CATEGORIES OF THINGS THAT WERE SEEMINGLY
2 UNPROBLEMATIC, CATEGORIES OF THINGS THAT RAISED
3 QUESTIONS, BUT NEEDED VERY DETAILED ATTENTION, AND
4 CATEGORIES OF THINGS THAT ABSOLUTELY SHOULD BE
5 PROHIBITED BECAUSE OF SAFETY CONCERNS, ETHICAL CONCERNS
6 ABOUT THE WELFARE OF HUMANS OR ANIMALS, AND YOU START
7 WITH THOSE BROAD CATEGORIES. THEN WITHIN THEM YOU CAN
8 THEN BEGIN TO FOCUS ON PROCESS.

9 SO IN THE MIDDLE CATEGORY THINGS THAT MIGHT
10 BE PROBLEMATIC AND MIGHT NOT, AND IT DEPENDS ON THE
11 DETAILS OF WHAT YOU ARE DOING, WE ASKED FOR A PROCESS
12 BY WHICH INVESTIGATORS PRESENT THEMSELVES TO THIS
13 COMMITTEE AND DISCUSS EXACTLY WHAT THEY'RE PLANNING TO
14 DO, WHY THEY NEED TO DO IT, WHAT PRECAUTIONS THEY ARE
15 TAKING, AND TAKE GUIDANCE FROM THIS COMMITTEE AS TO
16 WHETHER OR NOT IT OUGHT TO BE DONE.

17 THE COMMITTEE TECHNICALLY REPORTS TO THE DEAN
18 OF THE GRADUATE SCHOOL, WHO HOLDS THE AUTHORITY OVER
19 THE INVESTIGATORS, SO THE COMMITTEE DOESN'T ACTUALLY
20 GOVERN THE INVESTIGATORS. THE COMMITTEE ADVISES THE
21 DEAN, WHO IN TURN IS IN CHARGE OF THE INVESTIGATORS, SO
22 IT'S AN INDIRECT AUTHORITY. SO HERE'S AN EXAMPLE. AN
23 INVESTIGATOR WANTS TO LOOK AT THE IN VIVO
24 DIFFERENTIATION PROPERTIES OF A PARTICULAR EMBRYONIC
25 STEM CELL LINE THAT IS BEING DIFFERENTIATED INTO A

1 PARTICULAR KIND OF TISSUE, AND TO DO THIS IS PROPOSING
2 AN EXPERIMENT IN WHICH YOU WOULD USE A HUMAN/NONHUMAN
3 COMBINATION. WANTS TO TAKE SOME EMBRYONIC STEM CELLS,
4 HUMAN EMBRYONIC STEM CELLS, AND DIFFERENTIATE THEM INTO
5 A SHEEP PANCREAS. OKAY. WHY DO YOU NEED TO DO THIS?
6 WRONG PHRASING. I'M NOT A SCIENTIST. I COMPLETELY
7 BELIEVE YOU.

8 THEY WANT TO LOOK AT THE WAY IN WHICH THE --
9 I KNOW THAT THEY WANTED IT DIFFERENTIATED INTO TISSUE,
10 FOR EXAMPLE, OF PANCREATIC TISSUE. THEY WANTED TO LOOK
11 AT THE GRAFTING. THEY WANTED TO SEE IF IT GRAFTS
12 PROPERLY.

13 DR. BALTIMORE: THEY DIDN'T PUT IT INTO A
14 SHEEP. THEY IMPLANTED IT.

15 MS. CHARO: IMPLANT. THANK YOU. I WILL
16 STAND CORRECTED. THIS IS HELPFUL. THANK YOU. THEY
17 WANT TO IMPLANT IT INTO A SHEEP PANCREAS. WE WOULD
18 WANT TO KNOW THE PRECISE CONTOURS OF THE EXPERIMENT.
19 WE WANT TO KNOW EXACTLY WHAT STAGE OF DEVELOPMENT THE
20 SHEEP IS AT. ARE WE TALKING ABOUT EARLY FETAL STAGES,
21 LATE FETAL STAGES, LIVE BORN? IF THEY WERE TALKING
22 ABOUT AN EXPERIMENT IN WHICH THEY WANTED TO USE
23 EMBRYONIC STEM CELLS EVEN AT AN EARLIER STAGE, FOR
24 EXAMPLE, AT THE BLASTOCYST STAGE, DOES IT RAISE
25 DIFFERENT QUESTIONS THAN IF YOU ARE DOING IT AT A LATER

1 STAGE DEVELOPED FETUS IN TERMS OF THE MIGRATION THROUGH
2 THE RESULTING FETAL BODY AND THE ABILITY TO MIGRATE
3 INTO OTHER ORGAN SYSTEMS? AND ARE THERE DIFFERENT
4 ORGAN SYSTEMS THAT RAISE DIFFERENT ISSUES; FOR EXAMPLE,
5 NEUROLOGICAL VERSUS NON-NEUROLOGICAL PATTERNS.

6 SO WE FELT THAT IT WAS IMPOSSIBLE TO ACTUALLY
7 WRITE HARD AND FAST RULES AHEAD OF TIME. WHAT WE DID
8 KNOW WAS THAT WE COULD IDENTIFY WITH GROSS CATEGORIES
9 THE THINGS THAT NEEDED MORE DISCUSSION. AND ONLY WITH
10 A SPECIFIC PROTOCOL AND SPECIFIC PROTECTIONS COULD WE
11 ACTUALLY GIVE ANY OPINION AS TO WHETHER OR NOT THIS WAS
12 UNSAFE, ENDANGERED ANIMAL WELFARE, ENDANGERED HUMAN
13 WELFARE, OR FOR ANY OTHER REASON SHOULD NOT BE PURSUED
14 ON THE UNIVERSITY OF WISCONSIN CAMPUS AT THIS TIME, AND
15 WE WOULD MAKE OUR DECISION AND THEN FORWARD IT TO THE
16 DEAN OF THE GRADUATE SCHOOL.

17 CHAIRMAN KLEIN: THANK YOU VERY MUCH. I
18 THINK DR. KESSLER HAS A QUESTION.

19 DR. KESSLER: YOU COVERED THE GROUND ON
20 PROCUREMENT, ON DERIVATION, ON BANKING, AND ON
21 LABORATORY RESEARCH OF HUMAN EMBRYONIC STEM CELLS AND
22 EMBRYOS. WHAT DO YOU THINK TRIGGERS FDA'S JURISDICTION
23 WHEN USED IN HUMANS WITH REGARD TO REGULATION AS A
24 BIOLOGIC?

25 MS. CHARO: BOY, THAT'S A SETUP FROM THE

1 FORMER COMMISSIONER OF THE FDA. OKAY. AND I WILL ONCE
2 AGAIN BE HAPPY TO BE CORRECTED, IF NEED BE. MY
3 UNDERSTANDING WAS THAT IF YOUR END PRODUCT IS GOING TO
4 BE TRANSPLANTED INTO HUMANS, THAT YOU WILL BE
5 TRIGGERING THE TISSUE TRANSPLANTATION REGULATIONS,
6 WHICH, AS I UNDERSTAND IT, ARE ALSO PART OF THE
7 REGULATION OF BIOLOGICS. SO THAT ALTHOUGH YOUR INITIAL
8 RESEARCH IN THE LABORATORY IN AND OF ITSELF MAY NOT BE
9 SUBJECT TO FDA REGULATION, IF YOU WERE TO USE THAT
10 LABORATORY CREATED TISSUE DOWN THE LINE FOR TISSUE
11 TRANSPLANT, THEN YOU'D HAVE TO WORRY ABOUT THE
12 MANAGEMENT OF THAT MATERIAL FROM ITS ORIGINS IN ORDER
13 TO MAKE SURE THAT YOU MET THINGS LIKE THE NEW DONOR
14 SUITABILITY RULES WITH REGARD TO SCREENING OF DONORS
15 FOR THINGS LIKE INFECTIOUS DISEASE BEFORE YOU CAN USE
16 THAT TISSUE FOR TRANSPLANTATION OR TO DEAL WITH
17 XENOTRANSPLANTATION REGULATIONS FOR LINES THAT WERE
18 ORIGINALLY CULTURED, FOR EXAMPLE, ON MOUSE FEEDER
19 CELLS.

20 SO THAT MY UNDERSTANDING IS THAT THE
21 REGULATION DOESN'T KICK IN UNTIL YOU GET DOWN THE LINE
22 TO THE CLINICAL APPLICATIONS, BUT THEN THE EFFECT OF
23 THE REGULATION IS TO LOOK RETROSPECTIVELY AT WHAT
24 PREVIOUSLY HAD BEEN AN UNREGULATED PURELY LABORATORY
25 AREA OF RESEARCH.

1 I ALSO WAS VERY INTERESTED IN TRYING TO
2 UNDERSTAND THE DEGREE TO WHICH THE FDA'S HUMAN SUBJECTS
3 PROTECTIONS WOULD ALSO BE KIND OF RETROACTIVELY
4 IMPLICATED; THAT IS, IF YOU WERE PLANNING TO USE TISSUE
5 FOR TRANSPLANTATION IN 2011, WOULD THE FDA NOT ONLY BE
6 INTERESTED IN SAFETY ISSUES THAT MIGHT PREDATE GETTING
7 THE IND, BUT WOULD THEY ALSO WANT TO LOOK AT THE
8 PROVIDENCE OF THE CELL LINES AND MAKE SURE THAT THE
9 ORIGINAL DERIVATIONS MET FDA HUMAN SUBJECTS
10 REGULATIONS? I'LL BE HONEST. I CAN'T FIND ANYBODY AT
11 YOUR FORMER AGENCY THAT CAN TELL ME THE ANSWER TO THAT.

12 DR. KESSLER: YOU'RE FOCUSED ON THE TISSUE
13 TRANSPLANT REGULATIONS APPROPRIATELY. BUT STEM CELLS
14 WILL BE USED IN THE CURE, PREVENTION, MITIGATION OF
15 DISEASE. SO I ASSUME THAT TRIGGERS THE IND
16 REQUIREMENTS ALSO WHEN INTRODUCED INTO HUMANS.

17 MS. CHARO: I HOPE I ACTUALLY SAID THE
18 LETTERS IND WITH REGARD TO THE TISSUE TRANSPLANT, BUT
19 FOR THE CURE, MITIGATION, ETC. OF DISEASE, I WOULD
20 ASSUME IT WOULD REQUIRE AT SOME POINT SOME KIND OF
21 TRANSPLANTATION. I'M NOT SURE I CAN QUITE IMAGINE AN
22 APPLICATION THAT DOESN'T REQUIRE TRANSPLANT IN ORDER TO
23 CURE OR MITIGATE.

24 DR. KESSLER: RIGHT, BUT BASICALLY ANY TIME
25 ANY OF OUR GRANTEEES ARE GOING INTO HUMANS, THEY'RE

1 GOING TO TRIGGER FDA REGULATION.

2 MS. CHARO: ABSOLUTELY. I THINK ONE OF THE
3 THINGS THAT I ALWAYS FOUND VERY CONFUSING AND,
4 THEREFORE, I'M GOING TO ASSUME OTHER PEOPLE DO TOO, IS
5 THAT THINGS THAT ARE CONSIDERED TO BE BIOLOGICS,
6 REGULATED AS BIOLOGICS, WHICH MEANS THAT THE PUBLIC
7 HEALTH SERVICE ACT IS INVOKED WITH REGARD TO INFECTIOUS
8 DISEASE CONTROL ARE ALSO TREATED AS EITHER DRUGS OR
9 DEVICES. SO YOU WILL EITHER GET AN INVESTIGATIONAL NEW
10 DRUG EXEMPTION IF YOU ARE GOING TO REGULATE IT WITH THE
11 PREMARKET APPROVALS OF A DRUG, OR YOU WILL GET THE
12 INVESTIGATIONAL DEVICE EXCEPTION IF YOU ARE GOING TO
13 MARKET IT AS THE KIND OF DEVICE.

14 YOU CAN IMAGINE SOME BIOLOGICS ACTUALLY
15 FUNCTIONING LIKE DEVICES; FOR EXAMPLE, A SKIN BANDAGE
16 MADE OUT OF CELLULAR MATERIAL MIGHT, I DON'T KNOW, BE
17 REGULATED AS A DEVICE. I SUPPOSE IT'S A LITTLE HARD TO
18 ASSESS UNTIL YOU LOOK AT THE DETAILS OF ITS
19 FUNCTIONING.

20 SO I DO APPRECIATE THAT THE INVESTIGATORS
21 WILL HAVE TO GET AN IND OR AN IDE BEFORE THEY CAN GO
22 INTO HUMAN TRIALS. I THINK WHAT I'M TRYING TO
23 EMPHASIZE IS THAT, AS I STRUGGLED THROUGH THESE
24 REGULATIONS, IT SEEMED TO ME THAT IN THE EARLY STAGES
25 OF RESEARCH, INVESTIGATORS HAD NO NEED TO GO TO THE FDA

1 FOR PERMISSION TO BEGIN THEIR LABORATORY WORK. BUT IF
2 THEY FAILED TO ANTICIPATE THE FDA REGULATIONS WHEN THEY
3 DID THEIR LABORATORY WORK, THEY MIGHT RENDER THEIR CELL
4 LINES LESS USEFUL IN THE FUTURE WHEN CLINICAL
5 APPLICATIONS WERE WAITING. IT'S NOT ONLY DONOR
6 SUITABILITY RULES, IT'S ALSO THINGS LIKE GOOD
7 LABORATORY PRACTICES AND OTHER PURELY KIND OF QUALITY
8 CONTROL MEASURES THAT ARE ASSOCIATED WITH MANAGEMENT OF
9 MATERIALS THAT ULTIMATELY ARE GOING TO BE USED AS DRUGS
10 AND DEVICES.

11 DR. KESSLER: THE THRUST OF MY QUESTION WAS,
12 EVEN AFTER THE PRESENTATION LAST NIGHT AND A WONDERFUL
13 PRESENTATION THIS MORNING, THERE'S A WHOLE ANOTHER
14 LAYER OF FEDERAL OVERSIGHT THAT WE'RE GOING TO HAVE TO
15 BE DEALING WITH.

16 CHAIRMAN KLEIN: THANK YOU VERY MUCH, DR.
17 KESSLER. I POINT OUT THAT IT IS TREMENDOUSLY FORTUNATE
18 FOR THIS INSTITUTE TO HAVE ON THE BOARD BOTH
19 DR. KESSLER, FORMER FDA COMMISSIONER, FOLLOWED BY
20 DR. FRIEDMAN AS FDA COMMISSIONER. SO IT'S
21 EXTRAORDINARY EXPERTISE WE HAVE IN THE BOARD IN MANY
22 AREAS TO HELP US THROUGH THIS PROCESS AND IN SETTING
23 MODEL STANDARDS THAT MAY AFFECT THE NATION. THAT'S A
24 TREMENDOUS BENEFIT TO THE COUNTRY. WE APPRECIATE THEIR
25 SERVICE ALONG WITH ALL THE GREAT TALENT THAT'S ON THIS

1 BOARD.

2 OTHER BOARD MEMBERS?

3 DR. STEWARD: A QUESTION. SO I GUESS THE
4 DOCUMENT 125.300 HEALTH AND SAFETY CODE OF THE STATE OF
5 CALIFORNIA COVERS A LOT OF THIS, BUT MAYBE IN A MORE
6 AMBIGUOUS WAY THAN YOU'RE TALKING ABOUT. I GUESS MY
7 QUESTION IS, AS WE THINK ABOUT THIS, TO WHAT EXTENT
8 DOES REMOVING AMBIGUITY ACTUALLY CREATE THE RISK OF
9 COMING INTO VIOLATION OF THE SPIRIT OF THE REGULATIONS?
10 HOW DOES THAT ALL WORK?

11 MS. CHARO: CAN YOU REMIND ME WHICH -- I
12 DON'T HAVE THE NUMBERS MEMORIZED. WHICH ONE IS
13 125.300?

14 DR. STEWARD: I JUST PULLED THIS UP FROM THE
15 HEALTH AND SAFETY CODE CALIFORNIA DERIVATION AND USE OF
16 HUMAN STEM CELLS. SO THEY USE THE TERM "POLICY," AND
17 I'M NOT QUITE SURE WHAT THAT MEANS. IS THIS LAW? I'D
18 ASK THIS OF ANYONE WHO KNOWS. OR DOES POLICY MEAN
19 ADVISORY?

20 MS. CHARO: THIS IS THE CALIFORNIA STATUTE
21 THAT WAS PASSED AND GOVERNS ALL THE NON-CIRM RELATED --
22 NIN-CIRM FUNDED RESEARCH IN CALIFORNIA.

23 CHAIRMAN KLEIN: THAT'S CORRECT.

24 MS. CHARO: THERE ARE GOING TO BE SOME
25 ADVANTAGES TO HAVING COMMON UNDERSTANDINGS AS BETWEEN

1 CIRM AND NON-CIRM FUNDED RESEARCH IN CALIFORNIA.
2 THERE'S NO QUESTION ABOUT THAT. AND I UNDERSTAND THAT
3 THERE WAS A COMMITTEE THAT WAS SUPPOSED TO BE SET UP TO
4 BEGIN THE IMPLEMENTATION OF THAT CALIFORNIA STATUTE. I
5 DON'T PARTICULARLY KNOW EXACTLY HOW FAR ALONG THEY ARE,
6 BUT IT WOULD CERTAINLY SUGGEST SOME COLLABORATION TO
7 MAKE SURE THAT YOU'RE NOT UNDERMINING ONE ANOTHER'S
8 EFFORTS TO COME TO A COMMON UNDERSTANDING AT THE
9 INSTITUTIONS. THE LAST THING YOU WANT IS THE
10 INSTITUTIONS, ONCE AGAIN, AS THEY NOW ARE WITH FEDERAL
11 OR NONFEDERAL FUNDING, TO HAVE TO WORRY CONSTANTLY
12 ABOUT THE SOURCE OF FUNDING AND THE DIFFERING RULES
13 THAT FOLLOW.

14 DR. STEWARD: CAN I ASK A FOLLOW-UP. I THINK
15 YOUR ANSWER IMPLIES THAT THESE APPLY TO DIFFERENT
16 THINGS, BUT MY READING OF THIS IS ACTUALLY EITHER A
17 POLICY OR RULE OR LAW THAT APPLIES TO USE OF HUMAN
18 EMBRYONIC STEM CELLS IN THE STATE OF CALIFORNIA
19 REGARDLESS OF FUNDING SOURCE.

20 MS. CHARO: I UNDERSTOOD THE INITIATIVE TO
21 HAVE SAID THAT THE INITIATIVE WOULD HAVE ITS OWN
22 STANDARDS AND WOULD NOT NECESSARILY BE SUBJECT TO THAT
23 LAW.

24 CHAIRMAN KLEIN: AND THIS IS AN ITEM THAT WAS
25 SPECIFICALLY DISCUSSED LAST NIGHT AND WOULD BE WORTH

1 YOUR ADDRESSING. ONE OF THE MAJOR PROBLEMS IN THIS
2 AREA OVER THE LAST 25 YEARS IS LACK OF STABILITY IN
3 FUNDING AND STANDARDS. AND ALTA CHARO COMMENTED
4 INDEPENDENTLY LAST NIGHT ON THE IMPORTANCE OF STABILITY
5 IN RULES FOR THE SCIENTIST IN THE FIELD, AS WELL AS
6 RECRUITING NEW INDIVIDUALS IN THE FIELD AND HOW THE
7 LACK OF THE STABILITY IN STANDARDS HAS LED TO A LACK OF
8 INDIVIDUALS IN THE INTELLECTUAL PIPELINE.

9 MAYBE YOU COULD RELATE TO THAT BECAUSE THE
10 INTENT OF THE INITIATIVE IS TO CREATE A SET OF
11 STANDARDS THAT WILL NOT CHANGE OR BE MANIPULATED EVERY
12 TWO YEARS OR FOUR YEARS AS ELECTIONS OCCUR. ALTA CHARO
13 SERVED ON PRESIDENT CLINTON'S COMMISSION THAT WENT
14 THROUGH A VERY LONG PROCESS TO SET STANDARDS FOR THE
15 NATION. IN 1994, WHEN THEY SUBMITTED THOSE STANDARDS,
16 ON THE VERY DAY THEY WERE SUBMITTED, A PRESIDENTIAL
17 LETTER WAS ISSUED WITHDRAWING THOSE STANDARDS BECAUSE
18 THE HOUSE ELECTIONS HAD GONE AGAINST CLINTON IN '94.
19 AND IN ORDER TO GET THE NIH FUNDING, THEY COULDN'T
20 ALLOW THESE STANDARDS TO GO INTO PLACE BECAUSE IT WOULD
21 HAVE TRIGGERED THE RELEASE OF FUNDING FOR STEM CELL
22 RESEARCH, WHICH THE NEW MEMBERSHIP OF THE HOUSE
23 OPPOSED.

24 SO THE STABILITY OF THESE REGULATIONS AND
25 STABILITY OF FUNDING, IF YOU COULD COMMENT ON THE

1 IMPORTANCE OF THAT TO THIS FIELD.

2 MS. CHARO: AND ALTHOUGH I APPRECIATE YOUR
3 TELLING THAT STORY, I WILL HAVE TO JUST DEFEND MY
4 PRESIDENT A LITTLE BIT BECAUSE HE ONLY OBJECTED TO ONE
5 PARTICULAR ASPECT, AND THE REST HE MADE NO MENTION
6 ABOUT. AND DR. HAROLD VARMIS WAS IN A POSITION TO
7 IMPLEMENT THE REMAINING RECOMMENDATIONS ABOUT FEDERAL
8 FUNDING IN EMBRYO RESEARCH, BUT WAS CUT OFF BY THE
9 DICKIE WICKER AMENDMENT IN CONGRESS, WHICH ENDED THE
10 POSSIBILITY OF FEDERAL FUNDING.

11 BUT IN TERMS OF THE GENERAL NOTION, A
12 PERMANENT SET OF STANDARDS CERTAINLY ALLOWS FOR PEOPLE
13 TO PLAN WHAT WOULD OTHERWISE BE IMPOSSIBLE PROJECTS.
14 THE INVESTMENT, THE START-UP IN TERMS OF BUILDING YOUR
15 PHYSICAL LABORATORY, GETTING YOUR MATERIALS, BEGINNING
16 YOUR CULTURES, AND HIRING YOUR POST-DOCS AND GETTING
17 YOUR GRAD STUDENTS, ETC. ALL REQUIRES A LONG LEAD-TIME.
18 AND IN A FIELD THAT IS DOMINATED BY ACADEMIA IN WHICH
19 PEOPLE NEED TO BE ABLE TO MAKE SURE THAT THEY'RE GOING
20 TO BE GETTING GRANTS AND HAVING PUBLICATIONS SO THEY
21 CAN MOVE FROM GRAD TO POST-DOC TO ASSISTANT PROFESSOR
22 TO TENURED PROFESSOR, IT IS NOT GOING TO BE ATTRACTIVE
23 TO PEOPLE IF THEY FEEL THAT THEY ARE CONSTANTLY AT RISK
24 EITHER OF A SHUTDOWN IN FUNDING OR OF A CHANGE IN
25 GROUND RULES THAT MIGHT MAKE THEIR PREVIOUS WORK

1 UNACCEPTABLE AND UNUSABLE.

2 SO STABILITY IS CRUCIAL TO CREATE THAT
3 PIPELINE; AND AS YOU MENTION, FOR 25 YEARS THE ABSENCE
4 OF FEDERAL FUNDING FOR EMBRYO RESEARCH HAS VIRTUALLY
5 ELIMINATED THE PIPELINE IN HUMAN EMBRYO RESEARCH IN THE
6 UNITED STATES, VERY FEW PEOPLE RELEVANT TO WHAT WE
7 WOULD HAVE HAD AND RELATIVE TO WHAT YOU SEE IN OTHER
8 COUNTRIES WHERE THE FUNDING HAS GONE FORWARD. AND
9 WE'RE JUST BEGINNING TO BUILD THAT PIPELINE NOW.

10 THAT SAID, THERE IS A CONNECTION BETWEEN YOUR
11 COMMENT AND OZZIE STEWARD'S COMMENT ABOUT THE INTERPLAY
12 BETWEEN THE CALIFORNIA LAW THAT GOVERNS THE NON-CIRM
13 FUNDED RESEARCH HERE AND THE CIRM-FUNDED RULES. IT'S
14 POSSIBLE TO WRITE STANDARDS THAT ARE SPECIFIC, BUT THAT
15 YOU UNDERSTAND WITH SUFFICIENT LAWYERING OR PERSONAL
16 EXPERIENCE WILL SHOW THEMSELVES TO HAVE SOME
17 AMBIGUITIES. AND IT'S ALSO POSSIBLE WITHOUT FORMALLY
18 REVISING STANDARDS TO BUILD AN INTERPRETIVE GLOSS BASED
19 ON EXPERIENCE. IT IS POSSIBLE FOR INSTITUTIONS TO
20 COLLABORATE IN FORA, WHETHER ELECTRONIC THROUGH LIST
21 SERVES OR IT'S PHYSICAL THROUGH PERIODIC MEETINGS IN
22 WHICH THEY TALK ABOUT THE IMPLEMENTATION OF STANDARDS,
23 TALK ABOUT WHERE THEY FOUND AMBIGUITIES, TALK ABOUT
24 WHERE THEY FOUND THEY DIDN'T WORK, AND BEGIN TO BUILD
25 AN INTERPRETIVE GLOSS HOW TO UNDERSTAND THE WORDS AS

1 WRITTEN SO THAT THE STANDARDS STAY STABLE, BUT THE
2 UNDERSTANDINGS DEEPEN.

3 THERE DOES COME A POINT WHERE THE ACTUAL
4 STANDARDS THEMSELVES HAVE TO BE CHANGED, BUT OFTEN IT'S
5 JUST A MATTER OF UNDERSTANDING HOW TO INTERPRET THOSE
6 WORDS, NOT CHANGING THOSE WORDS, AND OBVIOUSLY THIS IS
7 RATHER SIMILAR TO THE PROCESS BY WHICH STATUTES REMAIN
8 UNCHANGED, BUT DEVELOP AN INTERPRETIVE GLOSS OVER THE
9 COURSE OF TIME WITH CASES. IT'S A WAY TO ALLOW
10 YOURSELF TO WORK WITH SOMEBODY WHO'S GOT A SLIGHTLY
11 DIFFERENT SET OF RULES TO COME TO SOME COMMON LANGUAGE
12 AND THEN OVER TIME LOOK AT THE INTERPRETATIONS AND SEE
13 IF YOU CAN MAKE THEM CONSISTENT ACROSS THE STATE.

14 CHAIRMAN KLEIN: THANK YOU. I'D LIKE TO, IF
15 I COULD, GIVEN THE TIME CONSIDERATIONS HERE, GO TO THE
16 PUBLIC. ARE THERE PUBLIC COMMENTS ON THIS POINT?
17 BEFORE THAT, DR. FRANCISCO PRIETO.

18 DR. PRIETO: JUST A COUPLE OF COMMENTS AND
19 MAYBE -- I DON'T WANT TO OPEN IT UP TO ANY MORE
20 QUESTIONS, BUT GIVEN THE IMPORTANCE TO THIS UNDERTAKING
21 OF THE ULTIMATE CRITICAL IMPLICATIONS, WHICH I THINK WE
22 CANNOT ANTICIPATE, ALL THE POSSIBILITIES ARE ALMOST
23 ENDLESS, I THINK WHAT WE CAN DO IS MANDATE IN THE MORE
24 GENERAL TERMS YOU WERE TALKING ABOUT THE PROCESS,
25 PROCESS STANDARDS, AND THE AVAILABILITY OF DATA FOR

1 REVIEW DOWN THE ROAD.

2 GIVEN THAT, IT SEEMS TO ME THAT THE STEM CELL
3 BANKING THAT YOU'RE TALKING ABOUT WOULD ALMOST
4 NECESSARILY BECOME THE STANDARD, THE WORLDWIDE
5 STANDARD, FOR THIS SORT OF RESEARCH. AND MY QUESTION
6 WOULD BE WHO ESTABLISHES AND FUNDS SUCH A BANK? WHO
7 MAINTAINS IT? WOULD WE WANT TO JUST ENCOURAGE THIS AS
8 A CONSORTIUM OF THE RESEARCH INSTITUTIONS IN
9 CALIFORNIA?

10 MS. CHARO: IT'S A VERY GOOD QUESTION. I
11 DON'T KNOW THAT ANYBODY IS IN A POSITION TO COMPLETELY
12 ANSWER IT YET. WE'VE SEEN IN THE AREA OF THE FEDERALLY
13 FUNDED RESEARCH ON THE APPROVED FOR FEDERAL FUNDING
14 LINES A MOVE BY THE NIH TO CREATE A KIND OF VIRTUAL
15 STEM CELL BANK. WE'RE BEGINNING TO SEE SOME INTEREST
16 ACROSS EUROPE IN SOME KIND OF COLLABORATION, AT LEAST
17 WITH SOME KIND OF LISTING INTERNATIONALLY OF ALL THE
18 LINES AND CRUCIAL DETAILS ABOUT THEM.

19 THAT DOESN'T ANSWER THE QUESTION OF THE
20 ACTUAL MAINTENANCE OF THE LINES, BUT AT LEAST IT GETS
21 YOU TO THE KIND OF INTELLECTUAL BANKING; THAT IS,
22 INFORMATION BANKING, IF NOT THE ACTUAL PHYSICAL LINE
23 BANKING. BUT THERE'S MORE TO BANKING OBVIOUSLY. IT'S
24 THE QUALITY CONTROL OF THE ACTUAL MAINTENANCE OF THE
25 BIOLOGICAL MATERIALS. IT'S THE STANDARDIZATION OF THE

1 MATERIAL TRANSFER AGREEMENTS AND OTHER INTELLECTUAL
2 PROPERTY ISSUES, A WHOLE HOST OF THINGS THAT GO ALONG
3 WITH IT. IT CAN EITHER BE DONE AS A KIND OF LOOSE
4 ASSOCIATION, OR YOU CAN HAVE A SINGLE PHYSICAL BANK.

5 I DON'T KNOW WHERE THE FINANCING WOULD COME
6 FROM. CERTAINLY THE FEDERAL GOVERNMENT IS NOT IN A
7 POSITION TO DO IT BECAUSE THEY WILL NOT PARTICIPATE IN
8 THE FACILITATION OF RESEARCH WITH LINES THAT ARE
9 ELIGIBLE ONLY FOR PRIVATE FUNDING. MAYBE THAT WILL
10 CHANGE BECAUSE TECHNICALLY IT WOULDN'T FUND RESEARCH
11 THAT VIOLATES THE PRESIDENT'S POLICY TO JUST CREATE A
12 STEM CELL BANK THAT INCLUDES THE LINES THAT REQUIRE
13 PRIVATE FUNDING, BUT I DON'T SENSE ANY MOVEMENT ON
14 NIH'S PART TO TAKE OVER THIS TASK.

15 IT IS A TASK THAT YOU COULD TAKE ON FOR
16 YOURSELVES. IT'S A TASK THAT YOU COULD TAKE ON UNDER
17 ANY NUMBER OF CIRCUMSTANCES IN WHICH IT'S DONE AS A
18 SERVICE TO THE CALIFORNIA INSTITUTIONS, IT'S DONE AS A
19 PAID SERVICE TO THE CALIFORNIA INSTITUTIONS, COULD BE
20 FREE TO CALIFORNIA, BUT YOU HAVE TO MAKE EVERYBODY ELSE
21 IN THE WORLD PAY YOU FOR IT. THERE'S ANY NUMBER OF
22 WAYS YOU COULD SET THIS UP. YOU CAN APPROACH EXISTING
23 TISSUE BANKS AND ASK THEM TO TAKE ON THE TASK FOR A
24 FEE.

25 THE WORLD CAN DO WITHOUT IT. IT SIMPLY IS

1 SOMETHING THAT FACILITATES CAREFUL TRACKING OF BOTH THE
2 ETHICAL ISSUES SURROUNDING THE PROVIDENCE AND THE
3 TECHNICAL ISSUES SURROUNDING THE MAINTENANCE AND THE
4 INFORMATIONAL ISSUES SURROUNDING THE DISTRIBUTION TO
5 WHOM, WHAT DATES, ETC. THAT MANY PEOPLE WOULD FIND
6 ADVANTAGEOUS.

7 CHAIRMAN KLEIN: THANK YOU. I'M GOING TO GO
8 TO PUBLIC COMMENT AND COME BACK TO JOAN SAMUELSON FOR
9 ANOTHER QUICK COMMENT. ANY PUBLIC COMMENT?

10 MS. DARNOFSKI: MARCY DARNOFSKI FROM THE
11 CENTER FOR GENETICS IN SOCIETY. I WANTED TO COMMEND
12 ALTA CHARO ON THAT VERY WELL PUT TOGETHER AND HELPFUL
13 PRESENTATION OF THE HUGE VARIETY OF ISSUES THAT FACE
14 YOU AS YOU MOVE FORWARD AND SAY THAT I THINK IT REALLY
15 HIGHLIGHTS THE IMPORTANCE THAT THESE DISCUSSIONS ARE
16 OPEN TO THE PUBLIC AS THEY WERE LAST NIGHT AND TODAY'S
17 IS. AND SPECIFICALLY THAT THE STANDARDS WORKING GROUP
18 SHOULD HOLD ITS MEETINGS IN ADHERENCE TO THE OPEN
19 MEETINGS LAW THAT WE HAVE IN CALIFORNIA AND FOLLOW THE
20 OTHER LEGAL PROTECTIONS THAT WE HAVE IN CALIFORNIA SO
21 THAT MEMBERS OF THE PUBLIC CAN PARTICIPATE AS THESE
22 VERY SIGNIFICANT RULES AND STANDARDS ARE BEING
23 DEVELOPED. AND I THINK THAT WILL ENCOURAGE THE
24 STABILITY THAT YOU'RE LOOKING FOR, AND IT WILL
25 ENCOURAGE PUBLIC CONFIDENCE IN THE WORK THAT YOU ARE

1 DOING, IMPORTANT WORK THAT YOU ARE DOING.

2 SO I THINK THAT A META COMMENT ON THE
3 IMPORTANCE OF THE STANDARDS WORKING GROUPS AND THE
4 OTHER WORKING GROUPS AS MUCH AS POSSIBLE BE OPEN AND
5 SUBJECT TO CONFLICT OF INTEREST RULES AS WELL.

6 THE OTHER COMMENT I WANTED TO MAKE WAS THERE
7 ARE, OF COURSE, MANY ISSUES THAT ALTA DIDN'T GET A
8 CHANCE TO ADDRESS. ONE OF THE ONES I THINK IS VERY
9 IMPORTANT TO THE WOMEN'S HEALTH COMMUNITY IS THE
10 QUESTION OF PROTECTION OF WOMEN WHO WILL BE PROVIDING
11 EGGS. THERE ARE A RANGE OF ISSUES HERE. THE RISKS OF
12 THESE PROCEDURES. THE HORMONES THAT ARE TYPICALLY
13 ADMINISTERED ARE SUBSTANTIAL, BUT WE DON'T HAVE GOOD
14 DATA ON IT. THAT LACK OF INFORMATION MAKES INFORMED
15 CONSENT VERY DIFFICULT.

16 I THINK THERE ARE PROTECTIONS THAT CAN EASILY
17 BE PUT INTO PLACE, INCLUDING THAT WOMEN PROVIDING EGGS
18 SHOULD HAVE THEIR OWN PHYSICIAN RESPONSIBLE FOR THEIR
19 HEALTH. OF COURSE, THIS WOULD BE TRUE FOR RESEARCH
20 SUBJECTS IN CLINICAL TRIALS AS WELL. SO THAT THERE WAS
21 NO CONFLICT BETWEEN THE PROTECTION OF THE EGG
22 PROVIDER'S HEALTH AND ANY KIND OF RESEARCH ENTERPRISE
23 THAT SAME INSTITUTION OR INDIVIDUAL WOULD BE ENGAGED
24 IN.

25 I THINK THE QUESTION OF REIMBURSEMENT VERSUS

1 PAYMENT IS A VERY TRICKY ONE, AS YOU MENTIONED. IF
2 REIMBURSEMENT AMOUNTS ARE SET HIGH, THEY DO CONSTITUTE
3 AN INDUCEMENT FOR PEOPLE WHO DON'T HAVE A LOT OF MONEY;
4 AND GIVEN THE LEVEL OF RISKS AND THE LACK OF DATA,
5 THAT'S, I THINK, SOMETHING WE REALLY IMPORTANTLY TO
6 HAVE TO CONSIDER. THANKS.

7 CHAIRMAN KLEIN: THANK YOU VERY MUCH FOR YOUR
8 COMMENT. I WOULD ALSO CALL THE ATTENTION TO THE
9 COMMITTEE AND THE AUDIENCE THAT THE PROVISION AT
10 125.290.35(B).5 ON LIMITING THE REIMBURSEMENT
11 SPECIFICALLY GIVES EXAMPLES ONLY OF STRICT THIRD-PARTY
12 REIMBURSEMENT. TO BE VERY CLEAR ABOUT THE INTENT, NOT
13 TO PROVIDE COMPENSATION, BUT ONLY THIRD-PARTY
14 REIMBURSEMENT TO REMOVE INDUCEMENT. AND IT'S ALWAYS
15 IMPORTANT TO ARTICULATE THAT IN GREATER DETAIL WHEN YOU
16 GET THE CHANCE TO DO FULL STANDARDS, BUT I THINK THE
17 TEMPLATE IS CLEAR IN INTENT.

18 DR. REED: MY NAME IS DON REED. BASICALLY I
19 WOULD JUST LIKE TO SAY THAT I APPRECIATE THE
20 OPPORTUNITY AS A MEMBER OF THE PUBLIC TO BE A PART OF
21 THE BIRTH OF THIS GIGANTICALLY IMPORTANT ENTERPRISE. I
22 TRY TO GO TO AS MANY OF THESE AS I CAN, AND IT REALLY
23 IS AMAZING THE DEGREE OF OPENNESS THAT IS AVAILABLE TO
24 THE PUBLIC THAT CHOOSES TO TAKE PART IN THIS.

25 I'D LIKE TO SAY ON A PERSONAL NOTE, YESTERDAY

1 I TOOK MY SON DOWN TO SOUTHERN CALIFORNIA. HE AND I
2 RECEIVED AN AWARD, THE WILLIE SHOEMAKER AWARD FOR
3 ADVANCING SPINAL CORD INJURY RESEARCH AWARENESS. AND
4 DURING THAT TIME, WHICH WAS A TIME TO HONOR MY SON, HE
5 HAD TO BE HUMILIATED. HE HAD TO BE PICKED UP AND
6 CARRIED SEVERAL TIMES. HE HAD TO BE CARED FOR -- HE'S
7 NOT HERE SO I CAN SAY THIS -- LIKE AN INFANT IN MANY
8 WAYS. HERE'S THIS GIGANTIC NOBLE MAN, HAS TO GO
9 THROUGH HELL AS PART OF HIS DAILY LIFE.

10 THE WORK THAT YOU ARE DOING NOW, ALL THESE
11 COMPLICATED THINGS THAT YOU'RE STRUGGLING THROUGH WILL
12 BE TREMENDOUSLY SIGNIFICANT TO MANY PEOPLE LIKE MY SON
13 AND THE PEOPLE THAT WE HEARD ABOUT TODAY. SO THANK YOU
14 FOR DOING WHAT YOU ARE DOING.

15 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
16 CERTAINLY YOUR LEADERSHIP WITH THE ROMAN REED ACT OVER
17 A NUMBER OF YEARS AND THE STATE APPROPRIATIONS THAT
18 HELP THE ROMAN REED CENTER AT UC IRVINE ADVANCE THE
19 RESEARCH WITH EMBRYONIC STEM CELLS HAS BEEN AN
20 IMPORTANT TRAILBLAZER IN THIS STATE, AND WE ALL HAVE
21 GREAT GRATITUDE FOR THAT.

22 ARE THERE OTHER PUBLIC COMMENTS? WELL, WE
23 HAVE THE MIRACULOUS EVENT OF BEING ON SCHEDULE WITH A
24 SHORT COMMENT BY MEMBER SAMUELSON AND FOLLOWED BY THE
25 STATE CONTROLLER, WHO WE'RE PRIVILEGED TO HAVE HERE.

1 JOAN.

2 MS. SAMUELSON: WITH THAT PRESSURE, I'LL BE
3 BRIEF, AND I KNOW YOU TALK FAST. MY QUESTION IS
4 THERE'S THIS 270-DAY OR SOMETHING PUBLIC HEARING
5 PROCESS AND OUR OWN PROCEDURES. I'M WONDERING IF IT
6 MAKES ANY SENSE TO CONSIDER SOME KIND OF MELDING OF
7 THEM, WHICH WOULD GIVE THE TRANSPARENCY AND MAYBE BE A
8 USEFUL PROCESS TO MOVE TOWARD THE STABILITY OF
9 REGULATIONS THROUGH DEVELOPING THE SAME ONES WITH ALL
10 THE INPUT FROM OUR VARIOUS SOURCES BEING PROVIDED AT
11 THE SAME TIME. IS THAT JUST OVERENGINEERING, OR IS
12 THERE SOME --

13 MS. CHARO: I APOLOGIZE. IT MAY BE MY
14 RELATIVE UNFAMILIARITY WITH SOME OF THE DETAILS OF YOUR
15 INTERNAL WORKING PROCESSES, BUT MELDING WHAT EXACTLY?
16 YOU'VE GOT THE PUBLIC COMMENT PERIOD AND X. WHAT'S X
17 THAT YOU WERE TALKING ABOUT MELDING?

18 MS. SAMUELSON: X IS OUR OWN PROCESS FOR
19 DEVELOPING OUR STANDARDS.

20 MS. CHARO: I'M NOT SURE I KNOW WHAT THAT
21 PROCESS IS, DO YOU?

22 CHAIRMAN KLEIN: I THINK THAT JOAN SAMUELSON
23 IS REFERRING TO THE FACT THAT WE HAVE A PROCESS THAT'S
24 DETAILED IN THE INITIATIVE FOR ADOPTING INTERIM
25 STANDARDS, AND WHETHER AS A BENCHMARK -- THOSE INTERIM

1 STANDARDS HAVE TO BE AT LEAST THE NIH STANDARDS AS A
2 FLOOR. THEY'RE INTERNATIONALLY AND NATIONALLY VETTED
3 STANDARDS. BUT THE DESIRE IS TO IMPROVE ON THOSE
4 STANDARDS AND TO FIND A WAY, IF POSSIBLE, TO CREATE
5 NATIONAL UNIFORMITY, WHICH WILL HELP THE RESEARCH IN
6 CALIFORNIA AS WELL AS IN THE OTHER STATES.

7 IF THE NATIONAL ACADEMY STANDARDS ARE EARLY
8 ENOUGH AS BENCHMARKED TO ADOPT IN SOME FORM, THEY COULD
9 PERHAPS ENHANCE THE NATIONAL INSTITUTES OF HEALTH
10 STANDARDS, AND THEN IT'S FOLLOWED, WHATEVER THOSE
11 INTERIM STANDARDS ARE THAT ARE ADOPTED, BY A 270-DAY
12 PUBLIC HEARING PROCESS WHERE WE TRY AND REALLY IMPROVE
13 AND EXAMINE WHICHEVER SET OF STANDARDS WE START OFF AS
14 THE INTERIM STANDARDS.

15 MS. CHARO: THERE'S ABSOLUTELY NO PROBLEM
16 WITH THE PRELIMINARY STEPS TAKING PLACE WITH ALL THE
17 HELP YOU CAN GET. I THINK IN LAST NIGHT'S MORE
18 EXTENDED DISCUSSION WE STARTED WITH THE SCOPE OF
19 COVERAGE. AN INITIAL QUESTION ABOUT HOW MUCH YOU WANT
20 TO HAVE COVERED UNDER THE STANDARDS NOW AND HOW MUCH
21 YOU'D LIKE TO PUT OFF TO ANOTHER DAY IS A DISCUSSION
22 THAT BENEFITS FROM LOTS OF INPUT ACROSS PUBLIC AND
23 RESEARCH COMMUNITIES, THEN IDENTIFYING WHICH THINGS ARE
24 EASY AND WHICH THINGS NEED FURTHER DISCUSSION FOR
25 POLICY MAKING, ALL OF WHICH CAN EASILY PRECEDE THE

1 ADOPTION, THE FORMAL ADOPTION, OF ANYTHING AS AN
2 INTERIM STANDARD, WHICH THEN BEGINS TO TRIGGER YOUR
3 PUBLIC FORUM MEETINGS.

4 SO THERE ARE THESE KINDS OF INCREMENTAL STEPS
5 THAT CAN BE TAKEN PRIOR TO THE ADOPTION OF THE
6 STANDARDS, MANY OF WHICH BENEFIT FROM COMMENTS FROM THE
7 PUBLIC.

8 CHAIRMAN KLEIN: I THINK, FOR THE BENEFIT OF
9 THE PUBLIC, IN THE DISCUSSION LAST NIGHT, IT WAS
10 POINTED OUT THAT IN THE PENDING DISCUSSION ON GRANTS,
11 IT HAS BEEN DISCUSSED THAT CLINICAL GRANT APPLICATIONS
12 WOULD POTENTIALLY NOT BE RECEIVED IN THE INITIAL ROUNDS
13 BECAUSE THOSE STANDARDS MAY TAKE MORE TIME TO DEVELOP.
14 ADDITIONALLY, IT'S A PENDING DISCUSSION ITEM THAT
15 PRIVATE COMPANY GRANTS MIGHT NOT BE RECEIVED IN THE
16 INITIAL ROUND BECAUSE THOSE STANDARDS MIGHT TAKE MORE
17 TIME TO DEVELOP.

18 SO THE POINT IS THAT IT'S POSSIBLE FOR THE
19 BOARD TO DECIDE ON A SEGMENT OF STANDARDS THEY FEEL
20 VERY COMFORTABLE WITH, ACCEPT GRANTS THAT ARE ADDRESSED
21 IN THAT SEGMENT OF STANDARDS, AND THEN NOT DEAL WITH
22 CLINICAL OR OTHER AREAS UNTIL THEY'VE HAD A TIME TO
23 BECOME COMFORTABLE WITH THAT AREA OF STANDARDS.

24 MS. CHARO: JUST BY WAY OF INFORMATION,
25 THERE'S ANOTHER WAY ALSO TO SLICE UP THE UNIVERSE THAT

1 MAY HELP YOU IN YOUR GRANT PROCESS. THAT IS, SOME
2 PARTS OF THIS UNIVERSE ARE MORE HEAVILY REGULATED
3 ALREADY BY THE FEDERAL GOVERNMENT. AS AN EXAMPLE WHAT
4 DR. KESSLER WAS SUGGESTING, THAT ANYTHING THAT HAS TO
5 GO THROUGH AN IND PROCESS IS ALREADY SUBJECT TO A VERY
6 STRICT REGULATORY SYSTEM WITH REPEATED MEETINGS AND
7 EXAMINATIONS OF THE SAFETY AND ETHICS OF THE CLINICAL
8 TRIALS, SO THERE ARE GOING TO BE ASPECTS EVEN WITHIN
9 THE WORLD OF CLINICAL TRIALS MAY ACTUALLY HAVE THE
10 ADVANTAGE OF ALREADY HAVING VERY DETAILED STRUCTURED
11 OVERSIGHT.

12 THERE MAY ALSO BE SOME THAT ARE CLEARLY
13 WITHIN THE PURVIEW OF YOUR IRB'S AND, THEREFORE, HAVE
14 STRUCTURED OVERSIGHT SUBJECT TO FEDERAL REGULATIONS.
15 AND THOSE AREAS MAY BE ONES WHERE THERE'S LESS OF A GAP
16 TO BE FILLED IN.

17 CHAIRMAN KLEIN: I'M GOING TO GIVE
18 DR. BALTIMORE THE CLOSING COMMENT HERE BEFORE WE MOVE
19 TO THE STATE CONTROLLER.

20 DR. BALTIMORE: THIS MAY BE A REAL CONFUSION
21 OR AN APPARENT ONE. BUT AT THE MOMENT, PARTICULARLY
22 FEDERALLY FUNDED RESEARCH, THE IRB FUNCTIONS AT THE
23 LOCAL INSTITUTIONAL LEVEL. WHEN YOU TALK ABOUT
24 DEVELOPING STANDARDS FOR AN ORGANIZATION, WHICH IN THIS
25 CASE IS A FUNDING ORGANIZATION, HOW ARE THOSE STANDARDS

1 APPLIED AT THE INSTITUTIONAL LEVEL?

2 MS. CHARO: WELL, I CAN TELL YOU HOW IT WORKS
3 WITH JDRF, FOR EXAMPLE. JDRF FUNDS RESEARCH. THOSE
4 INVESTIGATORS HAVE TO GO TO THEIR LOCAL IRB'S FOR
5 APPROVAL. JDRF HAS STANDARDS THAT MAY IN MANY CASES GO
6 BEYOND WHAT THE LOCAL IRB'S HAVE EVER THOUGHT ABOUT.
7 THEY CERTAINLY GO BEYOND ANYTHING IN THE FEDERAL
8 REGULATIONS. SO A JDRF INVESTIGATOR CAN ONLY GET
9 FUNDED IF THE PROTOCOL MEETS JDRF'S RULES, THEN GOES TO
10 THE IRB. AND THE ROLE OF THE IRB IS TO MAKE SURE THAT
11 NONE OF THE RULES THAT JDRF LAID DOWN ARE INCONSISTENT
12 WITH THE IRB'S RULES. THEY DON'T HAVE TO BE IDENTICAL.

13 THE IRB MIGHT BE MORE LIBERAL THAN JDRF, BUT
14 SO LONG AS JDRF'S RULES ARE NOT INCONSISTENT, THAT PART
15 IS OKAY. AND THEN THE IRB MAY ADD EXTRA THINGS THAT
16 JDRF DIDN'T THINK ABOUT THAT CAME OUT OF THE WORLD OF
17 IRB REVIEW. AND THEN THE INVESTIGATOR HAS TO GO BACK
18 TO JDRF AND MAKE SURE THAT ANYTHING ADDED BY IRB
19 DOESN'T VIOLATE WHAT JDRF WANTS FOR ITS GRANTEES. AND
20 SO LONG AS EVERYBODY IS COMPLEMENTING ONE ANOTHER AS
21 OPPOSED TO CONFLICTING WITH ONE ANOTHER, ONE CAN SIMPLY
22 OPERATE IN CONFORMITY WITH BOTH SETS OF RULES.

23 IT'S NOT THAT BAD. IT'S NOT THAT BAD.

24 CHAIRMAN KLEIN: I THINK WE OWE ALTA CHARO A
25 GREAT ROUND OF APPLAUSE FOR COMING ALL THE WAY OUT

1 HERE.

2 (APPLAUSE.)

3 CHAIRMAN KLEIN: WE THANK HER FOR HER
4 CONTINUED ASSISTANCE. THE NEXT ITEM ON OUR AGENDA IS
5 GOING TO BE THE PRESENTATION BY STATE CONTROLLER STEVE
6 WESTLY. WE'RE GOING TO MOVE THE ADOPTION -- APPROVAL
7 OF PRIOR MINUTES TO THE AFTERNOON SESSION.

8 I WANT TO REMIND EVERYONE THAT IT'S
9 PARTICULARLY APPROPRIATE THAT STEVE ADDRESSES US HERE
10 AT STANFORD SINCE HE HAS TAUGHT AT THE STANFORD
11 BUSINESS SCHOOL, BECAUSE HE IS PART OF THE LEGEND OF
12 THE BAY AREA IN BEING ONE OF THE GREAT PIONEERS THAT
13 BROUGHT US EBAY. AND BOTH IN ITS MARKETING AND ITS
14 INTERNATIONAL DIVISIONS IN ITS EARLY DAYS, HE HAD THE
15 CAPACITY TO BRING A VISION TO LIFE, WHICH HE IS HELPING
16 US TO DO AGAIN.

17 AS A MEMBER OF THE CONSTITUTIONAL OFFICERS OF
18 THE STATE, HE MONITORS THE STATE'S CASH FLOW, AUDITING,
19 HE'S THE WATCHDOG FOR THE STATE, HE'S A MEMBER OF 57
20 BOARDS AND COMMISSIONS. ALL THE MEMBERS OF THIS BOARD
21 WILL APPRECIATE THE SIGNIFICANCE OF THAT. AND HE'S A
22 MEMBER OF THE FRANCHISE TAX BOARD, THE BOARD OF
23 EQUALIZATION, CALPERS AND CALSTRS.

24 SO THE STATE CONTROLLER IS A TREMENDOUSLY
25 IMPORTANT INDIVIDUAL IN THIS STATE. AS I SAID, HE

1 SIGNED ON VERY EARLY TO PROP 71. HE HAD THE VISION OF
2 WHAT THIS COULD DO FOR THE STATE, AND WE VERY ARE
3 DEEPLY INDEBTED FOR THAT AND THE COOPERATION HE HAS
4 BROUGHT TO US IN THE DEVELOPMENT OF OUR ACCOUNTABILITY
5 STANDARDS, OUR AUDITING, AND OUR PROGRAMS TO DATE ON
6 CONTINUING BASIS. STEVE WESTLY.

7 (APPLAUSE.)

8 MR. WESTLY: THANK YOU, BOB. I'M ABSOLUTELY
9 DELIGHTED TO BE HERE WITH THE COMMITTEE MEMBERS, FIVE
10 OF WHOM I APPOINTED. I'M DELIGHTED TO HAVE YOU HERE.
11 AS BOB MENTIONED, I HAVE TWO DEGREES FROM STANFORD.
12 EVEN MORE AMAZINGLY, I SERVED FOR 19 YEARS AS A
13 FRESHMAN ADVISOR IN LOGANITA (PHONETIC). AND AS
14 DR. PIZZO KNOWS, IF YOU'VE EVER EATEN THE FOOD SERVICE
15 THERE, YOU APPRECIATE WHAT A COMMITMENT THAT IS TO THE
16 UNIVERSITY.

17 NOW, LET ME JUMP RIGHT INTO THIS. FIRST, I
18 WANT TO THANK EACH AND EVERY ONE OF YOU. YOU ARE SOME
19 OF NOT ONLY THE BRIGHTEST PEOPLE, BUT THE BUSIEST
20 PEOPLE IN THE WORLD, AND THE FACT THAT YOU'RE GIVING
21 YOURSELVES, PUTTING YOURSELVES INTO THE PUBLIC
22 SPOTLIGHT, CHARTING ABSOLUTELY NEW TERRITORY TO MAKE
23 HISTORY AND DO SOMETHING UPON WHICH PEOPLE'S LIVES
24 DEPEND ON, I JUST WANT TO SALUTE ALL OF YOU FOR DOING
25 THIS.

1 WE'RE CREATING A LITTLE HISTORY HERE.
2 THERE'S A GREAT DEBATE ABOUT OPENNESS, TRUST,
3 ACCOUNTABILITY. I'M HERE FULLY COMMITTED TO YOU TO
4 MAKE SURE THAT TOGETHER AS A GROUP WE'RE SUCCESSFUL IN
5 CONTINUING TO EARN THE PUBLIC TRUST. I WANT TO START
6 OUT BY THANKING YOU FOR YOUR COMMITMENT TO OPENNESS.
7 HAVING PUBLIC MEETINGS IN FACILITIES LIKE THIS IS A
8 HUGE STEP FORWARD.

9 SO LET ME BEGIN WITH A NUMBER OF POINTS THAT
10 ARE AIMED AT BEING HELPFUL TO YOU. WE HAVE COMMITTED
11 ONE OF MY SENIOR AND, FRANKLY, THE MOST SENIOR
12 FINANCIAL ACCOUNTABILITY EXPERTS IN STATE GOVERNMENT,
13 WALTER BARNES. HE WAS ON MY STAFF, AND WE HAVE
14 DEDICATED HIM TO THIS EFFORT BECAUSE BOB AND I FELT IT
15 WAS SO ESSENTIAL TO ENSURE THAT YOU LIFT IT OFF QUICKLY
16 TO HAVE SOMEONE WITH THAT EXPERTISE. AND WALTER IS NOW
17 COMMITTED TO YOU FULL TIME.

18 SECOND -- BY THE WAY, WALTER BRINGS NOT ONLY
19 FINANCIAL OVERSIGHT BACKGROUND, AUDITS EXPERIENCE WITH
20 THE STATE -- WALTER, I'M AFRAID TO ASK. HOW MANY YEARS
21 OF STATE SERVICE DO YOU HAVE?

22 MR. BARNES: THIRTY-NINE, GOING ON 40.

23 (APPLAUSE.)

24 MR. WESTLY: WALTER KNOWS EVERY IN AND OUT OF
25 SACRAMENTO. HE'LL BE EXTREMELY HELPFUL TO YOU TO MAKE

1 SURE THAT YOU ADHERE TO THE SPIRIT AS WELL AS THE CODE
2 OF THE LAW THAT I KNOW YOU WILL WANT. YOU HAVE THE
3 FULL SUPPORT OF THE STATE CONTROLLER'S OFFICE. WE WILL
4 HELP YOU SET UP. WE WANT TO HELP ENSURE THERE'S A
5 SUCCESSFUL LAUNCH HERE WHERE WE DO EVERYTHING, AGAIN
6 DOTTING EVERY I, CROSSING EVERY T, AND MAKING SURE WE
7 ADHERE TO THE SPIRIT AS WELL AS THE LETTER OF THE LAW.

8 AS YOU KNOW, I WAS HONORED TO BE AT THE
9 INITIAL KICKOFF MEETING. THAT WAS THE FUN PART. NOW
10 YOU'RE WORKING THROUGH THE DETAILS. I WANT TO BE HERE
11 WITH YOU FOR THAT AS WELL. MANY OF YOU KNOW I WILL
12 CHAIR THE FAOC, WHICH WILL BE CONVENING SOMETIME NEXT
13 YEAR, BUT WE'RE GOING TO HELP YOU IN THE INTERIM GET
14 THOSE RIGHT AUDIT STANDARDS SET UP. WE'LL ALSO BE
15 PROACTIVELY SUGGESTING IDEAS FOR YOU TO CONSIDER TO
16 MAKE SURE THAT WE MEET ALL OF THE STANDARDS OF PUBLIC
17 ACCOUNTABILITY.

18 NOW, A QUICK MINUTE ABOUT THE CONTROLLER'S
19 OFFICE ROLE. I'M THE STATE OF CALIFORNIA'S CHIEF
20 FISCAL OFFICER. I'M ALSO THE PRIMARY AUDITOR, IN MANY
21 WAYS THE CHIEF ACCOUNTANT. I PAY THE STATE'S BILLS,
22 INCLUDING YOUR TAX REFUNDS. BE NICE TO ME. I AUDIT
23 ALL STATE EXPENDITURES. AND AS, ACCORDING TO THE
24 LANGUAGE OF THE INITIATIVE, YOU ARE TECHNICALLY A STATE
25 AGENCY, IT'S MY RESPONSIBILITY TO AUDIT ALL CLAIMS AND

1 PAYMENTS FROM THE INSTITUTE. WE WILL DO THAT. WE'LL
2 WORK CLOSELY WITH YOU ON THAT. WE'LL AUDIT ON A CLAIM
3 BASIS AS WELL AS FOUR TO SIX MONTHS. WE'LL START DOING
4 SOME TEST AUDITS JUST TO MAKE SURE THAT EVERYTHING IS
5 DONE APPROPRIATELY.

6 THE ONE THING IN THIS WORLD YOU KNOW, YOU
7 DON'T WANT SURPRISES LATER, SO WE'RE IN HERE FROM
8 GROUND ZERO WORKING WITH YOU TO MAKE SURE THINGS ARE
9 DONE RIGHT AND THE RIGHT PROCESSES ARE PUT IN PLACE.
10 WE'LL ALSO RECOMMEND IMPROVEMENTS WITH EVERY AUDIT WE
11 ISSUE, AND WE'LL DO IT IN A COLLABORATIVE WAY.

12 NEXT, HELPING THE ICOC. THE FAOC WILL REVIEW
13 YOUR INDEPENDENT AUDIT EACH YEAR. THAT IS OUR
14 STATUTORY REQUIREMENT. MY OFFICE WANTS TO HELP PUT
15 FISCAL CONTROLS IN PLACE NOW SO THE REVIEWS WILL BE A
16 SUCCESS WHEN WE DO THEM IN A YEAR. I WANT TO URGE YOU
17 TO PUT PERFORMANCE CONTROLS IN PLACE NOW SO YOU CAN
18 CLEARLY REPORT TO THE TAXPAYERS ON THE WORK YOU'RE
19 DOING; I.E., SET SOME OF YOUR OWN STANDARDS THAT YOU
20 HOPE TO REPORT BACK ON.

21 ALL OF THE EYES OF THE WORLD ARE ON THE
22 CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE. I
23 THINK YOU ALL KNOW THE BROMIDE, THE SINCEREST FORM OF
24 FLATTERY IS IMPERSONATION. FOLKS, THERE'S AT LEAST
25 SEVEN STATES LOOKING AT DOING THE EXACT SAME THING YOU

1 ARE, AS WELL AS ANOTHER HALF A DOZEN COUNTRIES, BUT WE
2 CAN AID THE WORLD BY GETTING IT RIGHT HERE FIRST. I
3 FULLY INTEND TO HELP ENSURE YOU DO THAT.

4 MY STAFF IS NOW REVIEWING BEST PRACTICES AT
5 OTHER UNIVERSITIES' RESEARCH INSTITUTIONS, NOT JUST
6 AROUND THE COUNTRY, BUT THE WORLD. WE'LL SHARE THESE
7 WITH YOU. OBVIOUSLY PEOPLE DO MAKE MISTAKES, AND WE'RE
8 MAKING A LITTLE HISTORY HERE. WE'RE TRYING TO LEARN AS
9 MUCH AS WE CAN FROM OTHER ENTERPRISES AND TO SHARE THAT
10 WITH YOU UP FRONT.

11 AT THIS POINT I WOULD JUST LIKE TO PAUSE FOR
12 A MOMENT TO INTRODUCE AND INVITE TO THE PODIUM VINCE
13 BROWN ON MY STAFF. VINCE IS ONE OF THE MOST SEASONED
14 EXECUTIVES IN THE STATE OF CALIFORNIA. HE'S MY CHIEF
15 OPERATING OFFICER. BEFORE COMING TO WORK IN THE
16 CONTROLLER'S OFFICE, HE OVERSAW A GROUP OF JUST UNDER
17 3,000 PEOPLE AT CALPERS. HE'S A PROFESSIONAL
18 ADMINISTRATOR AND ONE OF THE BEST WE HAVE AND AN EXPERT
19 IN THE AUDIT AREA. SO I'D LIKE VINCE TO COME AND SAY A
20 FEW WORDS, AND THEN I'LL CLOSE WITH SOME FINAL
21 THOUGHTS.

22 MR. BROWN: GOOD MORNING. I'M GOING TO BE
23 VERY BRIEF. I KNOW YOU'VE HAD A LONG MORNING AND HAVE
24 A LONGER AFTERNOON. FOR THE RECORD, I'M VINCE BROWN.
25 I'M THE CHIEF OPERATING OFFICER FOR THE STATE

1 CONTROLLER. OUR STAFF HAS SUBMITTED AN AGENDA ITEM FOR
2 YOUR REVIEW THAT PROVIDES DETAILS, BOTH THE ROLE OF THE
3 OVERSIGHT COMMITTEE, AS WELL AS A REVIEW OF SOME OF THE
4 BEST PRACTICES THAT WE HAVE LOOKED AT.

5 JUST IN A NUTSHELL, THE OVERSIGHT COMMITTEE'S
6 ROLE, AND AS STEVE WESTLY WE WILL PROBABLY CONVENE
7 SOMETIME IN 2006, DEPENDING ON WHEN YOUR FIRST
8 FINANCIAL AUDIT IS COMPLETED, BUT OUR PRIMARY ROLE IS
9 TO REVIEW THAT ANNUAL FINANCIAL AUDIT, REVIEW THE STATE
10 CONTROLLER'S ANNUAL REPORT OF THAT AUDIT, AND REVIEW
11 THE FINANCIAL PRACTICES OF THE INSTITUTE. AND TOWARDS
12 THAT END, WE ARE WORKING VERY CLOSELY WITH WALTER TO
13 MAKE SURE THAT YOU GET YOUR INTERNAL CONTROLS IN PLACE
14 SO THAT YOU DON'T HAVE ANY PROBLEMS PAYING YOUR BILLS
15 AND CUTTING THE CHECKS.

16 WE WILL ALSO PROVIDE RECOMMENDATIONS TO THE
17 ICOC AND THE INSTITUTE IN REGARDS TO FINANCIAL
18 PRACTICES AND PERFORMANCE. AND FINALLY, WE WILL
19 CONDUCT THAT PUBLIC MEETING, BUT WE WILL ALSO EVALUATE
20 PUBLIC COMMENTS AND INCLUDE APPROPRIATE SUMMARIES IN
21 THE CONTROLLER'S ANNUAL REPORT.

22 AS I NOTED, TO ASSIST THE ICOC, WE HAVE
23 IDENTIFIED THE BEST PRACTICES OF BOTH THE NATIONAL
24 SCIENCE FOUNDATION, THE NATIONAL INSTITUTES OF HEALTH,
25 AND THE STEM CELL RESEARCH FOUNDATION, WHICH IS SORT OF

1 A NEW GROUP THAT DEALS WITH PRIVATE PRACTICE AND VERY
2 SMALL GRANTS. ATTACHMENT A OF OUR AGENDA ITEM COMPARES
3 GRANT ADMINISTRATION AND FISCAL PRACTICES FOR YOUR
4 CONSIDERATIONS.

5 CHAIRMAN KLEIN: VINCE, IF I CAN HELP THE
6 BOARD, WE'RE LOOKING AT TAB 7.

7 MR. BROWN: BRINGS BACK THE OLD PERS DAYS
8 WHEN MY CHAIR WOULD SAY LET'S GO TO THIS TAB.

9 BOTH THE NSF AND NIH RELY ON UNIFORM
10 GUIDELINES AND PROCEDURES TO ADMINISTER AND ACCOUNT FOR
11 GRANTS. BOTH THE NSF AND NIH EMPLOY A PEER REVIEW
12 PROCESS TO EVALUATE GRANTS BEFORE FORWARDING TO A
13 SECOND ADVISORY GROUP, AND WE UNDERSTAND THAT YOUR
14 WORKING GROUP WILL PERFORM THAT FUNCTION FOR YOU, AND I
15 THINK THAT'S A VERY POSITIVE STEP. BOTH THE NSF AND
16 NIH REQUIRE THEIR GRANTEES TO FOLLOW AUDIT REQUIREMENTS
17 SPECIFIED IN OMB CIRCULAR A133. I WON'T GET INTO THE
18 TECHNICAL NUANCES. THAT'S FOR THE ACCOUNTANTS TO TALK
19 ABOUT, BUT THERE IS A PARADIGM OUT THERE FOR YOU.

20 OUR RESEARCH ALSO DISCLOSED SOME PROBLEMS OF
21 NSF AND NIH GRANTS THAT WE IDENTIFY IN ATTACHMENT B. I
22 WON'T GO INTO ANY GREAT DETAIL THERE, BUT THOSE ARE
23 SOME TROUBLE SPOTS THAT YOU SHOULD BE LOOKING AT AS YOU
24 GO THROUGH YOUR EARLY GRANT PROCESS. I THINK IT'S
25 ABSOLUTELY CRITICAL THAT YOU BE AWARE OF THESE SO THAT

1 YOU DON'T SUFFER ANY OF THE CONSEQUENCES THAT MAY HAVE
2 OCCURRED FOR BOTH THE NSF AND THE NIH.

3 FINALLY, ATTACHMENT C OUTLINES INTERNAL
4 CONTROL MEASURES THAT PROVIDE PROPER ACCOUNTABILITY
5 OVER PUBLIC FUNDS. SPECIFICALLY, YOU MAY WISH TO
6 PURSUE THE FOLLOWING ACTIONS: REVIEW AND CONSIDER
7 INCORPORATING SOME OF THE FEDERALLY ADOPTED GUIDELINES
8 INTO THE INSTITUTE'S GRANT MAKING PROCESS, CONSIDER
9 ADOPTING THE PEER REVIEW, AS WE HAVE TALKED ABOUT, AND
10 YOU HAVE THAT IN PLACE, CONSIDER ADOPTING SOME OF THE
11 STEM CELL RESEARCH FOUNDATION FUNDING REQUIREMENTS FOR
12 SMALL PROJECTS AND AWARDS OF LESSER AMOUNTS.

13 IF YOU ARE GOING TO GO IN THAT DIRECTION,
14 THEY SORT OF HAVE A FRAMEWORK THAT YOU MIGHT BE ABLE TO
15 UTILIZE. AND CLEARLY CLARIFY AUDIT REQUIREMENTS FOR
16 THE INSTITUTES AND ITS GRANTEES. THAT'S ABSOLUTELY
17 CRITICAL. WE'VE HAD A NUMBER OF PROBLEMS AT THE STATE
18 LEVEL WITH GRANTS WITHOUT APPROPRIATE FISCAL CONTROLS
19 GOING OUT FOR FUNDING WHERE WE HAVE PROBLEMS AFTER THE
20 FACT. SO YOU REALLY NEED TO HAVE A SOLID FRAMEWORK
21 BEFORE YOU ISSUE THESE GRANTS BECAUSE AS WE'RE GOING
22 THROUGH SOME PARKS AND REC GRANTS RIGHT NOW AND SOME
23 OTHER AUDITS THAT WE'RE DOING, THINGS GET OUT THE DOOR.
24 IT'S NOT VERY COMPLIMENTARY IN THE PRESS. LET ME JUST
25 PUT IT THAT WAY.

1 IN CONCLUSION, I THINK YOU'RE TAKING THE
2 RIGHT PROACTIVE STEPS. WE WANT TO WORK VERY CLOSELY
3 WITH YOU TO HELP YOU ESTABLISH BOTH YOUR INTERNAL
4 CONTROLS AND HELP YOU IN SETTING UP A FRAMEWORK FOR
5 YOUR GRANTS. AS I SAID, WE LOOK FORWARD TO WORKING
6 WITH THE ICOC AND THE INSTITUTE.

7 WITH THAT, I'LL TURN BACK IT OVER TO STEVE.

8 MR. WESTLY: THANK YOU, VINCE. AS YOU KNOW,
9 PROP 71 REQUIRED ADMINISTRATIVE COSTS BE CAPPED AT 3
10 PERCENT. THIS IS ONE OF THE THINGS WE WANT TO CLOSELY
11 WORK WITH YOU ON TO MAKE SURE WE UNDERSTAND WHAT ALL IS
12 INCLUDED IN THAT LIMIT SO THERE ARE NO SURPRISES LATER.
13 THIS IS FOR BOTH ADMINISTRATIVE COSTS AS WELL AS FOR
14 RESEARCH. WE'RE WORKING NOW WITH THE ATTORNEY
15 GENERAL'S OFFICE TO GET A CLEAR-CUT OPINION SO WE KNOW
16 EXACTLY WHAT IS IN AND OUTSIDE OF THAT RULE. AND WE'LL
17 CONTINUE TO HELP YOU WITH THIS SORT OF ISSUE SO
18 EVERYBODY KNOWS THE GROUND RULES IN FRONT IN ADVANCE SO
19 WE CAN MAKE SURE THAT WE'RE COMPLYING WITH THEM.

20 WE'LL ALSO MAKE SURE THAT THE INDEPENDENT
21 AUDIT WILL INCLUDE A REVIEW OF ALL ADMINISTRATIVE
22 COSTS. WE'LL ALSO BE DOING TRACKING OF THE PROGRESS
23 AND REPORTING ON PROP 71 OVER TIME. AGAIN, DURING THE
24 PROPOSITION, WHICH I WAS VERY INVOLVED IN, WE TALKED
25 ABOUT HOW THIS WOULD CREATE NEW JOBS IN CALIFORNIA AS

1 WELL AS REVENUES, RESEARCH LEADING TO CURES. WE TALKED
2 ABOUT REQUIRING PEOPLE TO SUBMIT GRANT PROPOSALS TO
3 IDENTIFY SPECIFIC PERFORMANCE MEASURES TO EVALUATE THE
4 JOB. HOW MANY JOBS WE THINK WILL BE CREATED? HOW MUCH
5 REVENUE MIGHT COME BACK TO THE STATE? WHAT WILL BE THE
6 IMPACTS TO THE LOCAL ECONOMY? HOW MUCH REVENUE
7 POTENTIAL COULD COME FROM SOME OF THESE ROYALTIES?
8 WHAT POTENTIAL CURES MAY OCCUR AND WHEN?

9 THESE ARE THE FUNDAMENTAL QUESTIONS THAT ARE
10 NOT EASY TO QUANTIFY; BUT I THINK IF WE PUT FORWARD
11 SIMPLE, STRAIGHTFORWARD GUIDELINES, WE'LL NOT ONLY BE
12 DOING THE COMMITTEE A GREAT SERVICE, BUT THE PUBLIC AS
13 A WHOLE. AGAIN, WE'RE CREATING HISTORY HERE. WE'RE
14 DOING SOMETHING FUNDAMENTALLY NEW. IT'S UP TO US TO
15 PROACTIVELY SET SIMPLE, COMMON SENSE STANDARDS SO THE
16 PUBLIC CAN SAY WE GOT A RETURN ON OUR INVESTMENT. SO
17 WE WILL PROVIDE AN ANNUAL REPORT TO THE TAXPAYERS WITH
18 THIS EXTRA PERFORMANCE DATA INCLUDED. I WILL CONTRACT
19 FOR A PERFORMANCE AUDIT EACH YEAR.

20 I JUST WANT TO CONCLUDE HERE, AND THEN WE'LL
21 TAKE ANY QUESTIONS IF YOU WOULD LIKE. LITERALLY THE
22 ENTIRE WORLD IS WATCHING WHAT WE'RE DOING. I THINK 50
23 YEARS FROM NOW PEOPLE WILL LOOK BACK AND SAY THIS IS
24 ONE OF THE MOST DEFINING THINGS THE STATE OF CALIFORNIA
25 HAS EVER DONE. FOLKS, I DON'T MEAN TO PUT A LOT OF

1 PRESSURE ON YOU. YOU COME UP WITH THE RIGHT CURES, YOU
2 MAY ALL BE HERE IN 50 YEARS.

3 THE TAXPAYERS OF THE STATE HAVE TAKEN A BOLD
4 RISK, BECAUSE THIS IS A RISK. THEY'VE STEPPED UP TO
5 THE PLATE. I WANT TO DO EVERYTHING I CAN TO HELP
6 ENSURE PUBLIC CONFIDENCE ALONG THE WAY. THEY MADE A
7 SMART BET BECAUSE I BELIEVE IT IS. MY STAFF IS 100
8 PERCENT COMMITTED TO WORKING WITH YOU AND HAVE BEEN
9 FROM DAY ONE. I KNOW YOU WILL BE SUCCESSFUL. WE WANT
10 TO HELP TAKE CARE OF THESE ISSUES SO YOU CAN FOCUS ON
11 THE ONES WHERE MANY OF YOU HAVE THE GREATEST EXPERTISE.
12 AND THAT IS FINDING CURES THAT WILL CHANGE THE WORLD.

13 I WANT TO THANK ALL OF YOU, AND I'M HAPPY TO
14 STAY IF THERE IS A QUESTION OR TWO THAT EITHER VINCE OR
15 I MIGHT ANSWER FOR YOU.

16 CHAIRMAN KLEIN: THANK YOU.

17 (APPLAUSE.)

18 CHAIRMAN KLEIN: I'D LIKE TO POINT OUT THAT
19 THIS IS AN EXTRAORDINARY LEVEL OF COOPERATION WITH THE
20 CONTROLLER'S OFFICE REALLY WORKING WITH US AS A TEAM IN
21 LEADING US IN THE STANDARDS FOR ACCOUNTABILITY, FOR
22 ACCOUNTING, FOR PROGRAM MANAGEMENT. WE'RE GREATLY
23 APPRECIATIVE. WITH VINCE BROWN AND HIS TEAM, WHEN YOU
24 HAVE THE BENEFIT OF REALLY GETTING DOWN AND DRILLING TO
25 THE LEVEL THAT YOU ARE TALKING ABOUT, IS IT THE HOWARD

1 HUGHES FOUNDATION THAT HAS THE BEST DEFINITION OF COST
2 IN THIS AREA OR THE FEDERAL GOVERNMENT. THEIR RESEARCH
3 IS SO THOROUGH, THAT WE REALLY HAVE A TRUE PARTNER HERE
4 WHO IS INVESTING THE TIME TO REALLY LEARN THE AREA AND
5 HELP GUIDE US THROUGH THIS PATH SO THAT WE HAVE
6 EXCELLENT ACCOUNTABILITY. AND THE BUSINESS PRACTICE,
7 THE BEST PRACTICE MODEL, WE'RE SETTING UP HERE, OF NOT
8 ONLY HELPING TO SET UP THE SYSTEM, BUT COMING BACK AND
9 DOING TEST AUDITS FOR US TO HELP US LEARN THE SYSTEM
10 BETTER IS GREATLY APPRECIATED AND TRULY A MARK OF A
11 BEST PRACTICE THAT HASN'T EXISTED PREVIOUSLY IN THE
12 STATE. SO WE'RE DEEPLY INDEBTED TO, STEVE, YOU AND
13 YOUR LEADERSHIP.

14 MR. WESTLY: AS GAYLE KNOWS, COLLABORATION IS
15 NOT ALWAYS THE RULE IN SACRAMENTO. WE'RE HOPING THAT
16 WE CAN GET IT RIGHT HERE. WHO KNOWS, IT MAY BE
17 CATCHING. ANY OTHER QUESTIONS OR THINGS WE CAN SPEAK
18 TO? IF NOT, PLEASE DON'T -- DR. LOVE.

19 DR. LOVE: I JUST HAD A QUESTION ABOUT THE
20 OVERALL PROCESS AND THEN A QUESTION THAT KIND OF
21 FOLLOWS FROM THAT. IF I THINK I UNDERSTAND IT
22 REASONABLY WELL, THE CIRM WILL ESSENTIALLY BE THE
23 COMPANY THAT IS BEING AUDITED, AND YOUR OFFICE WILL BE
24 THE EQUIVALENT OF THE EXTERNAL AUDITOR, THE KPMG OR THE
25 NY. AND IF THAT STRUCTURE ISN'T KIND OF CORRECT, WOULD

1 THIS COMMITTEE HAVE AN AUDITING SUBCOMMITTEE THAT WOULD
2 HAVE TO BE RUN AS AN AUDIT COMMITTEE?

3 CHAIRMAN KLEIN: WE ACTUALLY HAVE THE CHARGE
4 OF GETTING AN INDEPENDENT AUDIT THAT IS DONE, AND THEN
5 WE HAVE THE EXTRAORDINARY RESPONSE OF STEVE CHAIRING AN
6 OVERSIGHT COMMITTEE THAT REVIEWS THAT INDEPENDENT AUDIT
7 AND TESTS THE ISSUES OF FINANCIAL ACCOUNTABILITY AND
8 PERFORMANCE IN A PUBLIC HEARING. SO IT'S AN
9 UNPRECEDENTED SECOND LEVEL OF OVERSIGHT WITH STEVE'S
10 COMMITTEE CHAIRING THIS OVERSIGHT IN A PUBLIC HEARING
11 AND PUBLISHING A REPORT EVERY YEAR.

12 MR. WESTLY: BOB'S EXACTLY RIGHT. THESE ARE
13 LARGE NUMBERS. THE PUBLIC WANTS TO KNOW THERE'S EVERY
14 LEVEL OF SCRUTINY. SO FIRST, AS THE STATE'S PRIMARY
15 AUDITOR, WE'LL BE DOING ONGOING AUDITS AS A STATE
16 AGENCY.

17 SECOND, YOU'RE REQUIRED TO DO YOUR OWN AUDIT.
18 I CHAIR THIS ENTITY, THE FAOC, WHICH WE'RE IN THE
19 PROCESS OF APPOINTING TOP FLIGHT PEOPLE TO EVALUATE
20 THAT AS WELL. IT'S A DOUBLE-BLIND CHECK. WE WANT TO
21 MAKE SURE WE GET IT RIGHT FOR THE PUBLIC. I THINK, BY
22 THE WAY, AS MORE PEOPLE IN THE LEGISLATURE AND THE
23 PUBLIC UNDERSTAND THE EXTRAORDINARY LENGTHS WE'RE GOING
24 TO, NOT ONLY TO ENSURE OPENNESS, BUT TO ENSURE
25 ACCOUNTABILITY AND THAT EVERY DOLLAR IS SPENT, NOT

1 PERFECTLY BECAUSE THAT NEVER HAPPENS, BUT AS WISELY AS
2 CAN BE AND THAT NOT A SINGLE DOLLAR IS WASTED, I THINK
3 PEOPLE WILL REALIZE HOW THOUGHTFUL THIS WHOLE PROCESS
4 IS.

5 ANY OTHER QUESTIONS? I KNOW THIS IS NOT THE
6 MOST SCINTILLATING SUBJECT. THE DISTINGUISHED
7 GENTLEMAN AT THE MICROPHONE.

8 MR. HALPERN: MR. CONTROLLER, I SHARE YOUR
9 PLEASURE IN SEEING HOW OPENLY THIS PROCEEDING IS GOING
10 FORWARD AND THE CLOSE ATTENTION TO THE PRACTICES OF THE
11 ICOC. I WANT TO RAISE JUST TWO QUESTIONS THAT I'D LIKE
12 TO PRESENT TO YOU.

13 FIRST OF ALL, RELATES TO THE OPERATING BUDGET
14 OF THE ICOC. YOU REFER TO THE 3-PERCENT CAP, BUT IT
15 WOULD SEEM TO ME THAT THE PUBLIC WOULD BE REASSURED IF
16 WE HAD A LOOK AT THE OPERATING BUDGET THAT HAD BEEN
17 DISCUSSED AND APPROVED BY THE ICOC. THAT SEEMS TO ME
18 AN IMPORTANT DIMENSION OF ANY KIND OF PROGRAM.

19 SECOND QUESTION RELATES TO THE PENDING
20 LITIGATION IN THE STATE SUPREME COURT WHICH CHALLENGES
21 THE CONSTITUTIONALITY OF THE GOVERNING STRUCTURE OF THE
22 CIRM. DO YOU FORESEE THAT THOSE PENDING CONSTITUTIONAL
23 CHALLENGES ARE LIKELY TO HAVE ANY IMPACT ON THE
24 SALABILITY OF THE BONDS WHICH WILL FUND THE GRANT
25 PROGRAM OF THE CIRM?

1 MR. WESTLY: LET ME TAKE THE SECOND QUESTION
2 FIRST. I CANNOT COMMENT ON ANY PENDING LITIGATION. WE
3 BELIEVE THAT THE LITIGATION, AS I UNDERSTAND IT, IS
4 WITHOUT MERIT. WE DO NOT BELIEVE IT WILL IMPACT THE
5 BOND SALE, BUT I WILL LEAVE THAT FOR THE LAWYERS.

6 AS TO THE QUESTION OF THE BUDGET, I THINK
7 MR. KLEIN IS BEST ABLE TO SPEAK TO THAT. I BELIEVE IT
8 IS HIS FULL INTENT TO MAKE A BUDGET PUBLIC, BUT I'D
9 LIKE BOB TO PERHAPS SPEAK TO THAT FIRST.

10 CHAIRMAN KLEIN: CERTAINLY. WE'RE VERY
11 HOPEFUL THAT TODAY, IF THE BOARD DECIDES TO CONFIRM THE
12 INTERIM PRESIDENT, THAT WITH THE APPOINTMENT OF THE
13 INTERIM PRESIDENT, WE WILL BE ABLE TO REFINE OUR BUDGET
14 ON AN OPERATING BASIS, BRING THAT BACK TO THE BOARD FOR
15 APPROVAL IN A PUBLIC HEARING, AND BE ABLE TO MOVE
16 FORWARD WITH THE CHIEF EXECUTIVE OFFICER HAVING SIGNED
17 OFF ON AN OPERATING BUDGET.

18 WE HAVE TAKEN THE PRECAUTION OF LIMITING
19 STAFF HIRES UNTIL WE HAVE THE INTERIM PRESIDENT,
20 LIMITING THE EXPENDITURES SO THAT WE COULD RETAIN THE
21 MAXIMUM FLEXIBILITY OF THE PRESIDENT IN THE BUDGETING
22 PROCESS AND IN THE PERSONNEL POLICIES. SO WE LOOK
23 FORWARD TO BRINGING THAT TO THE PUBLIC.

24 AND, OF COURSE, WE ARE CURRENTLY BENEFITING
25 FROM THE INTERNAL GUIDANCE FROM WALTER BARNES IN THE

1 CONTROLLER'S OFFICE IN SETTING UP OUR ACCOUNTS SO THEY
2 CAN BE TRACKED PROPERLY AND AUDITED PROPERLY IN
3 CONJUNCTION WITH THAT BUDGET.

4 MR. HALPERN: I HAD A CHANCE TO BRIEFLY READ
5 THE MATERIALS. ONE OF THE THINGS I NOTICE THAT WAS
6 MISSING WAS ONE OF THE IMPORTANT PARTS OF OFFICE OF
7 MANAGEMENT BUDGETS OVERSIGHT OF THE NIH AND NATIONAL
8 SCIENCES FOUNDATION IS THE GOVERNMENT PERFORMANCE AND
9 RESULTS ACT, WHICH PUBLICLY PUBLISHED STRATEGIC PLANS
10 AND STRATEGIC GOALS, AND AT THE END OF CERTAIN TIME
11 PERIODS MUST REPORT TO THE PUBLIC ON HOW WELL THEIR
12 OFFICIALS ACTUALLY FULFILLED THOSE GOALS, BASICALLY
13 WHAT THE TAXPAYERS ARE GETTING FOR THEIR MONEY.

14 IS THERE ANY INTENTION TO HAVE SOME SORT
15 SIMILAR STRUCTURE IN CIRM?

16 CHAIRMAN KLEIN: CERTAINLY. IN THE
17 INITIATIVE, WE REQUIRE A STRATEGIC PLAN TO BE
18 DEVELOPED. WE HAVE BEEN PROCEEDING AS WE'VE STRUCTURED
19 AND RECRUITED THE COMMITTEES TO MOVE FORWARD WITH
20 DISCUSSION PURPOSES VARIOUS PROGRAMS ON AN INTERIM
21 BASIS. BUT WITH THE HIRING OF THE INTERIM PRESIDENT,
22 IF THAT IS CONFIRMED TODAY, WE WILL HAVE THE
23 OPPORTUNITY TO MOVE FORWARD WITH CREATING A COMMITTEE
24 ON STRATEGIC PLAN FOR THE INSTITUTE. AND PART OF THE
25 OVERSIGHT FUNCTION OF THE CONTROLLER'S COMMITTEE IS TO

1 LOOK AT PERFORMANCE OBJECTIVES NOT ONLY IN TERMS OF THE
2 ECONOMIC RESULTS, BUT THE STRATEGIC RESULTS OF THAT
3 PLAN.

4 MR. WESTLY: LET ME JUST ADD MY VIEW ON IT.
5 I AGREE WITH EVERYTHING BOB SAID. ONE OF THE CHARGES
6 OF THIS COMMITTEE IS TO COME UP WITH A STRATEGIC PLAN.
7 THAT'S WHOLLY APPROPRIATE AND WE'LL BE LOOKING AT
8 PROACTIVE WAYS WE CAN EVALUATE THE SUCCESS OF THE PLAN.

9 LET ME CARRY IT A STEP FURTHER. FOR MANY
10 PEOPLE HERE THE TERM "AUDIT" JUST SOUNDS BORING,
11 FRIGHTENING, AND CERTAINLY OBTUSE. WE'RE TRYING TO
12 MAKE IT AS CLEAR AS WE CAN TO ENSURE PUBLIC TRUST. IN
13 VERY SIMPLE TERMS, IT'S A CONCEPT OF TWO TYPES OF
14 AUDIT. FISCAL AUDITS ESSENTIALLY CONCERN MONEY BEING
15 SPENT WHERE YOU SAY IT IS. WE WILL DO THAT. THERE'S
16 ALSO THIS CONCEPT OF PERFORMANCE AUDITS. THESE ARE
17 MUCH TOUGHER BECAUSE THEY'RE SUBJECTIVE, BUT EQUALLY
18 IMPORTANT. WAS THE MONEY SPENT IN THE MOST EFFECTIVE
19 WAY POSSIBLE? THIS IS WHY I SPECIFICALLY SUGGESTED
20 SOME STANDARDS.

21 AGAIN, THIS IS ALL NEW TERRA FIRMA HERE THAT
22 WE MIGHT EVALUATE OURSELVES ON, BOB AND THE GROUP, AND
23 THERE ARE SOME EXTRAORDINARY MINDS AT THE TABLE THAT
24 WILL HOPEFULLY SET SOME STANDARDS BY WHICH YOU WILL
25 GAUGE YOUR OWN SUCCESS, AND WE WILL COME BACK EACH YEAR

1 AND EVALUATE YOUR SUCCESS ON THOSE STANDARDS.

2 THE ONLY OTHER THING I WOULD ADD TO THAT IS
3 THAT I THINK THERE'S KIND OF A PUBLIC COVENANT HERE.
4 THE PUBLIC HAS MADE A RISK, AN INVESTMENT, AND ONE OF
5 THE HOPES WAS THAT THERE WOULD BE SOME LEVEL OF
6 PAYBACK. I'VE TALKED TO BOB AND SOME OF THE OTHER
7 MEMBERS. WE CERTAINLY HOPE THAT IF SOME OF THIS
8 TECHNOLOGY BECOMES COMMERCIALIZED, WE DO INDEED FIND
9 CURES, THAT THE STATE WILL RECEIVE SOME BENEFITS FOR
10 ITS INVESTMENT. THERE'S BEEN LOT OF WORK DONE IN THIS
11 AREA, MUCH OF IT, IN FACT, AT STANFORD. WE'RE HOPING
12 TO LEARN FROM BEST PRACTICES AROUND THE STATE TO PUT IN
13 PLACE FAIR STANDARDS THAT WILL CREATE THE RIGHT
14 INCENTIVES SO THAT THE PUBLIC OF THE STATE AND THE
15 TAXPAYER CAN GET SOME BENEFIT FROM THE SUCCESS.

16 I'LL TAKE MAYBE ONE MORE QUESTION. I KNOW
17 THERE'S A PACKED AGENDA FOR THE REST OF THE DAY. I
18 KNOW YOU NEED TO FLY OFF TO FAR-FLUNG PLACES. BUT ARE
19 THERE ANY OTHER QUESTIONS? TERRIFIC. THANK YOU FOR
20 LETTING ME BE HERE TODAY.

21 (APPLAUSE.)

22 MR. WESTLY: I APPRECIATE YOUR WORK YOU ARE
23 DOING PUTTING YOURSELVES IN THE PUBLIC SPOTLIGHT. IF
24 ANYBODY INVITES YOU TO DINE AT STIRRUM HALL
25 RESPECTFULLY DECLINE.

1 CHAIRMAN KLEIN: AND IN PURSUIT OF THOSE
2 GOALS OF COMING TO A POINT WHERE WE CAN MOVE FORWARD
3 WITH THE OPERATIONS OF THIS INSTITUTION, WE HAVE A
4 CLOSED SESSION NOW TO DISCUSS OUR CLOSED SESSION
5 CONFIRMATION OF INTERIM PRESIDENT FOR THE CALIFORNIA
6 INSTITUTE OF REGENERATIVE MEDICINE, WHICH WILL BE
7 FOLLOWED BY AN OPEN SESSION WHERE WE WILL DISCUSS THE
8 RESULTS OF THAT CLOSED PERSONNEL SESSION. AND SO IF WE
9 CAN ADJOURN MEMBERS OF THE PUBLIC AND MEDIA, IF YOU
10 COULD PLEASE MAKE YOUR WAY TO THE OUTSIDE, AND WE WILL
11 HOPEFULLY BE BRIEF AND TRY AND RECONVENE WITHIN 30
12 MINUTES APPROXIMATELY.

13 (THE MEETING WAS THEN ADJOURNED TO
14 CLOSED SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED.
15 THE OPEN MEETING WAS THEN RECONVENED AT 01:51 P.M. AS
16 FOLLOWS:)

17 CHAIRMAN KLEIN: WE'RE GOING TO DO THIS VERY
18 QUICKLY. IN THIS PROCESS WE APPRECIATE YOUR PATIENCE.
19 WE ARE GOING TO CONTINUE THE EXECUTIVE SESSION IN THE
20 AFTERNOON. AND WE'RE -- IN THIS OPENING SESSION, SINCE
21 WE DID NOT FINALIZE OUR POINTS, WE WILL NOT HAVE AN
22 ANNOUNCEMENT AT THIS TIME. IT WILL BE AFTER OUR
23 CONTINUED EXECUTIVE SESSION. I THINK WE'RE ALL VERY
24 PLEASED WITH THE PROGRESS WE'VE MADE, AND WE HAVE THE
25 ADVANTAGE THAT EVERYONE CAN NOW EAT LUNCH. WE

1 APPRECIATE YOUR PATIENCE. WITH THAT, WE'RE GOING TO
2 RECONVENE, HOW QUICKLY, IN ABOUT 45 MINUTES.

3 DR. PIZZO: IT WILL TAKE YOU TIME TO GET TO
4 WHERE YOU'RE GOING.

5 CHAIRMAN KLEIN: FORTY-FIVE MINUTES IS THE
6 SUGGESTION FROM OUR HOST, AND I TAKE THAT SUGGESTION.
7 WE WILL RECONVENE IN 45 MINUTES.

8 (A LUNCH RECESS WAS TAKEN.)

9 AFTERNOON SESSION ICOC BOARD MEETING
10 02:40 P.M.

11 CHAIRMAN KLEIN: IF THE STAFF OF THE ICOC
12 COULD ASK THE OTHER MEMBERS WHO MAY BE IN THE LOBBY
13 TO -- HOW CLOSE ARE WE TO HAVING ALL THE MEMBERS, IF
14 THE STAFF COULD INDICATE? WHAT WE'D LIKE TO DO IS
15 WE'RE GOING TO GO INTO OPEN SESSION, HOPEFULLY GO INTO
16 A VERY SHORT EXECUTIVE SESSION, CONTINUATION OF THE
17 PRIOR EXECUTIVE SESSION, VERY SHORT, COME BACK INTO
18 OPEN SESSION AND PROCEED. ALL RIGHT.

19 JUST SO THAT ALL THE MEMBERS OF THE PUBLIC
20 UNDERSTAND, WE'RE GOING TO -- WE ARE OPENING UP IN OPEN
21 SESSION. WE'RE GOING TO GO IMMEDIATELY HERE INTO
22 EXECUTIVE SESSION. SO WE'RE GOING TO BE CALLING YOU
23 BACK IN A VERY FEW MINUTES. YES, I'D LOVE TO NOT GO
24 THROUGH THE PROCESS, BUT I'M TRYING TO DO THIS
25 PROPERLY.

1 WE ARE OPENING UP IN OPEN SESSION ONLY TO
2 ANNOUNCE THAT WE NEED A FEW MORE MINUTES IN OUR
3 EXECUTIVE SESSION THAT WE CARRIED OVER FROM RIGHT
4 BEFORE LUNCH. WE'LL TRY TO KEEP THAT VERY SHORT, AND
5 THEN WE'LL COME BACK INTO OPEN SESSION. SO WE'LL
6 HOPEFULLY LIMIT THIS TO 15 TO 20 MINUTES. WE HAVE
7 OPENED IN PUBLIC SESSION. WE ARE NOW GOING INTO CLOSED
8 SESSION.

9 (THE BOARD THEN WENT INTO CLOSED
10 SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED. AT THE
11 CONCLUSION OF THE CLOSED SESSION, THE MEETING CONTINUED
12 IN OPEN SESSION AS FOLLOWS:)

13 CHAIRMAN KLEIN: WE'RE RECONVENING IN PUBLIC
14 MEETING. IN THIS PUBLIC MEETING I WOULD POINT OUT THAT
15 IT'S CONSISTENT WITH THE INITIATIVE, IT IS REQUIRED
16 THAT EVERY EXPENDITURE THAT IS AN APPROVAL OF ANY MAJOR
17 APPOINTMENT, ANY GRANT, ANY STANDARD HAS TO BE APPROVED
18 IN A PUBLIC MEETING. AND THE ITEM ON THE AGENDA TODAY
19 IS TO HIRE AN INTERIM PRESIDENT AND SENIOR SCIENCE
20 ADVISOR AS ONE POSITION. WE WILL CONDUCT THIS MEETING
21 WITH A MOTION THAT WILL BE PUT ON THE TABLE, THERE WILL
22 BE BOARD COMMENT, AND THEN THERE WILL BE PUBLIC
23 COMMENTS ON THIS AS IS TRUE OF EVERY ITEM ON THE
24 AGENDA.

25 SO TO REPORT OUT FROM YOU, THE BOARD REACHED

1 A SENSE THAT THEY WISH TO BRING TO THE PUBLIC MEETING
2 DISCUSSION OF A MOTION TO HIRE ZACH HALL AS THE INTERIM
3 PRESIDENT. HE WILL ALSO CARRY THE TITLE OF INTERIM
4 PRESIDENT AND SENIOR SCIENCE ADVISOR. WE ARE
5 EXTRAORDINARILY PRIVILEGED TO HAVE DR. HALL WITH HIS
6 TREMENDOUS EXPERIENCE IN THIS POSITION, ASSUMING BOARD
7 CONFIRMATION.

8 THE SALARY UNDER DISCUSSION IS RELATIVELY
9 CLOSE TO THE SALARY HE HAD AT USC IN A POSITION WHERE
10 HE WAS NOT THE HEAD OF THE MEDICAL SCHOOL, BUT AN
11 ASSOCIATE DEAN. IT IS HIGHER THAN THAT SALARY TO
12 REFLECT THE FACT THAT HE IS THE CHIEF EXECUTIVE OFFICER
13 OF THIS INSTITUTION, AND THE PEOPLE OF THE STATE OF
14 CALIFORNIA, WHEN THEY VOTED FOR THIS INITIATIVE, VOTED
15 FOR A SALARY INDEX THAT WOULD LEAD US TO COMPARABILITY
16 IN CHOOSING THE BEST AND BRIGHTEST MINDS TO REALLY PUSH
17 FORWARD THE FRONTIERS OF MEDICAL RESEARCH AND SCIENCE.
18 AND THAT WAS IDENTIFIED AS BEING THE SALARIES AT THE UC
19 CAMPUSES THAT WERE INVOLVED IN THE BOARD OF THIS
20 INITIATIVE AS WELL AS THE RESEARCH INSTITUTIONS THAT
21 WERE APPOINTED BY CONSTITUTIONAL OFFICERS OF THE STATE
22 OF CALIFORNIA TO THIS BOARD.

23 THE SALARY THAT IS UNDER DISCUSSION IS
24 \$389,004. AND THE QUESTION BEFORE US IS IS THERE A
25 MOTION FROM THE BOARD TO APPOINT THE INTERIM PRESIDENT,

1 ZACH HALL AS INTERIM PRESIDENT AND SENIOR SCIENCE
2 ADVISOR WITH THE SALARY OF \$389,004?

3 DR. MURPHY: SO MOVED.

4 CHAIRMAN KLEIN: LET US TAKE DR. MURPHY AS
5 THE MOTION AND THE SECOND WOULD BE.

6 DR. PIZZO: I'M HAPPY TO SECOND.

7 CHAIRMAN KLEIN: THERE'S A MOTION AND A
8 SECOND. AT THIS POINT WE'LL HAVE BOARD DISCUSSION
9 FOLLOWED BY PUBLIC DISCUSSION. THE ISSUE OF THE
10 APPOINTMENT IS OPEN TO COMMENT AS WELL AS THE SALARY.

11 ARE THERE BOARD MEMBERS WHO WOULD LIKE TO
12 COMMENT ON THIS MOTION?

13 DR. BALTIMORE: I'VE KNOWN ZACH HALL FOR
14 DECADES. I DON'T EVEN WANT TO EMBARRASS HIM OR MYSELF
15 WITH HOW MANY. AND HE HAS A REMARKABLE SET OF
16 CREDENTIALS FOR THIS POSITION, HAVING BEEN A SCIENTIST
17 HIMSELF OF GREAT RENOWN, HAVING LED AN INSTITUTE OF THE
18 NATIONAL INSTITUTES OF HEALTH AND, THEREFORE, BEING
19 VERY COGNIZANT OF THE COMPLEXITY OF A LEADERSHIP
20 POSITION IN SCIENCE WHERE YOU HAVE RESPONSIBILITIES TO
21 THE PUBLIC AS WELL AS TO THE DISEASE SPECIFIC GROUPS.

22 HE'S BEEN AN ADVISOR AND HAD IMPORTANT
23 EXECUTIVE RESPONSIBILITIES BOTH AT USC AND AT UCSF.
24 AND I THINK WE'RE JUST PLAIN LUCKY THAT HE WAS WILLING
25 TO TAKE THIS INTERIM POSITION, WHICH IS FOR A YEAR.

1 AND I CAN ATTEST, BEING AN EXECUTIVE OF AN INSTITUTION,
2 THAT THE SALARY IS COMMENSURATE WITH SOMEBODY OF HIS
3 SKILLS AND RESPONSIBILITY.

4 CHAIRMAN KLEIN: THANK YOU VERY MUCH. ARE
5 THERE OTHER BOARD COMMENTS?

6 DR. PIZZO: ONLY CONCURRENCE.

7 CHAIRMAN KLEIN: ONLY CONCURRENCE. ALL
8 RIGHT. I WOULD TELL THE PUBLIC THAT WE, IN RESEARCHING
9 THE COMPARABILITY OF SALARY, WE BELIEVE THAT IT IS, IN
10 FACT, IN THE LOWER PORTION OF THE RANGE IDENTIFIED BY
11 SPENCER STUART, AN EXPERT IN THIS FIELD, AND IT IS
12 BELOW THAT OF MANY OF THE DEANS IN HIGH COST AREAS IN
13 THIS STATE REPRESENTED ON THIS BOARD AND, IN FACT,
14 SPECIFIED AS THE COMPARABLE POSITIONS THROUGH THE
15 INITIATIVE ITSELF.

16 IS THERE PUBLIC COMMENT? PUBLIC COMMENT.
17 WE'LL TALK -- START WITH MR. HALPERN. AND MR. HALPERN
18 IS VERY FAMILIAR WITH THE THREE MINUTES, AND WE DO
19 ALREADY HAVE THE PLEASURE OF HIS WRITTEN COMMENTS.

20 MR. HALPERN: THANK YOU. I WANT TO EXPRESS
21 GREAT ENTHUSIASM FOR DR. HALL'S SELECTION AS INTERIM
22 PRESIDENT. I'M FAMILIAR WITH HIS CREDENTIALS AND HIS
23 EXPERIENCE. AND I THINK WE IN CALIFORNIA ARE VERY
24 FORTUNATE TO HAVE A PERSON OF HIS EXPERIENCE AND
25 IMMINENCE SERVING IN THIS INTERIM POSITION.

1 I AM, HOWEVER, TROUBLED BY THE SALARY OF
2 \$389,000. I DON'T THINK IT REFLECTS ON HIM TO NOTE
3 THAT THAT IS \$100,000 MORE THAN THE HIGHEST PAID
4 INSTITUTE DIRECTOR AT THE NATIONAL INSTITUTES OF
5 HEALTH, AND I THINK THAT IS APPROPRIATE MEASURE. A
6 SALARY OF \$290,000 WOULD NOT BE OUT OF LINE WITH THE
7 UNIVERSITY OF THE CALIFORNIA MEDICAL SYSTEM. IT ISN'T
8 AT THE HIGHEST RANGES, BUT NEITHER IS IT OUT OF LINE.
9 AND I WOULD URGE THE ICOC TO CONSIDER THAT.

10 IT'S PARTICULARLY IMPORTANT THAT SALARIES BE
11 DEALT WITH PRUDENTLY WHEN THE ORGANIZATION IS STILL
12 OPERATING WITHOUT A BUDGET. IF THERE WERE A BUDGET
13 WHICH SET A SALARY SCALE AT AN APPROPRIATE LEVEL, THEN
14 I THINK THE PUBLIC WOULD HAVE MUCH MORE CONFIDENCE IN
15 THIS RATHER THAN HAVE IT BE A KIND OF AD HOC
16 DETERMINATION WITH ONE STAFF MEMBER PAID \$155,000 AND
17 NOW WE'RE PROPOSING \$389,000. SO I WOULD MAKE THOSE
18 POINTS.

19 DR. LEE'S AND MY PETITION ALSO SUGGESTS THAT
20 NIH CONFLICT OF INTEREST RULES APPLY TO THE CHAIR, VICE
21 CHAIR, THE PRESIDENT, AND THE INTERIM PRESIDENT. AND I
22 HOPE THAT ICOC HAS MADE AN INQUIRY TO ASSURE THAT THE
23 PERSON WHO SERVES AS INTERIM PRESIDENT IS SOMEONE WHO
24 WOULD PASS MUSTER AT NIH. I'M SURE WHEN HE WAS AN NIH
25 INSTITUTE DIRECTOR, HE MET THEIR CONFLICT OF INTEREST

1 STANDARDS. I THINK IF HE IS TO ASSUME LEADERSHIP OF
2 THIS IMPORTANT INSTITUTION, I THINK HE SHOULD ALSO MEET
3 THE CURRENT NIH CRITERIA FOR CONFLICT OF INTEREST.
4 THANK YOU.

5 CHAIRMAN KLEIN: THANK YOU VERY MUCH, MR.
6 HALPERN, AND I APPRECIATE THE FACT THAT YOU JOINTLY
7 WITH US RECOGNIZE THE SPECIAL QUALITIES AND TREMENDOUS
8 RECORD OF ZACH HALL AS AN INDIVIDUAL DEDICATED TO
9 MEDICAL RESEARCH.

10 ARE THERE OTHER PUBLIC COMMENTS?

11 MR. REED: I WOULD JUST LIKE TO SAY THAT I
12 THINK THAT THE SALARY IS ENTIRELY REASONABLE. I THINK
13 THAT ANOTHER WAY TO LOOK AT IT IS AS A PUBLIC
14 CORPORATION, \$3 BILLION PUBLIC CORPORATION, A PRIVATE
15 CORPORATION WOULD HAVE NO PROBLEMS GIVING A FAR HIGHER
16 SALARY THAN \$389,004.

17 DR. HALL IS, AS THE PREVIOUS SPEAKER
18 MENTIONED, A RENOWNED INDIVIDUAL FOR HIS WORK AT NINDS.
19 I WOULD POINT OUT, THOUGH, THAT THERE IS A DIFFERENCE
20 BETWEEN MOVING INTO AN ESTABLISHED ORGANIZATION WHICH
21 THE JOB REQUIREMENTS ARE CLEARLY LAID OUT AND MOVING
22 INTO SOMETHING LIKE THIS WHICH HAS BASICALLY TWO JOBS,
23 NOT ONLY THE ACTUAL WORK, BUT ALSO BUILDING THE ENTIRE
24 ENTERPRISE. HE WILL BE THE PUBLIC FACE FOR OUR
25 ORGANIZATION, CALIFORNIA'S ORGANIZATION, AND GREAT

1 THINGS, ENORMOUS THINGS, WILL BE EXPECTED OF HIM.

2 SO I WOULD DEFINITELY SUPPORT AN EVEN HIGHER
3 SALARY. IT THINK THIS IS ENTIRELY REASONABLE.

4 CHAIRMAN KLEIN: THANK YOU VERY MUCH. I
5 THINK THAT'S AN IMPORTANT POINT, THAT WE'RE CALLING ON
6 SOMEONE TO HELP LEAD US IN BUILDING AN ENTIRELY NEW
7 INSTITUTION, AS WE DISCUSSED THIS MORNING WITH ALTA
8 CHARO, HOPEFULLY WITH STANDARDS THAT ARE A MODEL FOR
9 THE NATION. CERTAINLY WE'RE INSPIRED BY THE TASK ALTA
10 CHARO SET OUT BEFORE US. I KNOW THAT ZACH HALL IS AS
11 WELL.

12 ARE THERE OTHER PUBLIC COMMENTS? SEEING NO
13 OTHER PUBLIC COMMENTS, I'D LIKE TO CALL FOR A VOTE.
14 DOES THIS -- SINCE WE HAVE A VERY HIGH DEGREE OF
15 COMFORT WITH THIS CANDIDATE, DO WE NEED A ROLL CALL
16 VOTE?

17 MR. HARRISON: DO NOT.

18 CHAIRMAN KLEIN: ALL IN FAVOR. OPPOSED.

19 FOR THE RECORD, JON SHESTACK LEFT ME A NOTE
20 THAT HE HAD TO LEAVE FOR A PLANE, BUT HE IS COMPLETELY
21 IN SUPPORT OF ZACH HALL IN THIS CANDIDACY.

22 WELL, IT IS A PRIVILEGE. I WOULD LIKE TO SAY
23 THAT ON BEHALF OF THE BOARD, WE'D LIKE TO RECOGNIZE
24 ZACH HALL AND THANK HIM FOR JOINING US IN THIS GREAT
25 EFFORT AND CHALLENGE. AND WE FEEL VERY PRIVILEGED TO

1 HAVE YOU WITH US. THANK YOU, ZACH.

2 (APPLAUSE.)

3 CHAIRMAN KLEIN: ALL RIGHT. BEING MINDFUL OF
4 THE SCHEDULE, WE'RE GOING TO MOVE IMMEDIATELY TO THE
5 PRESIDENTIAL SEARCH COMMITTEE SUBMISSION WHICH HAS BEEN
6 DEVELOPED WITH THE PRESIDENTIAL SEARCH COMMITTEE AND
7 SPENCER STUART'S FIRM. WHAT'S IMPORTANT HERE IS A
8 CONFIRMATION FOR SPENCER STUART'S FIRM AND THE BOARD
9 AND THE PUBLIC OF WHAT THE CRITERIA WILL BE IN
10 SEARCHING OUT A PERMANENT PRESIDENT.

11 AND IF YOU GO TO TAB 17 IN YOUR BINDER, YOU
12 HAVE THE SAME MATERIALS AS THE PUBLIC HAS ON THIS ITEM.
13 THE ITEM HAS A DESCRIPTION OF THE POSITION, IT HAS A
14 DESCRIPTION, A GENERAL DESCRIPTION ACTUALLY, OF THE
15 INSTITUTE ITSELF, THEN OF THE POSITION, KEY
16 RELATIONSHIPS, AND KEY SELECTION CRITERIA.

17 WHILE WE'RE OPEN TO COMMENTS OF THE BOARD AND
18 PUBLIC ON ALL THESE ITEMS, I'D LIKE THE BOARD, IF THEY
19 COULD, TO LOOK AT PAGE 4, CANDIDATE SPECIFICATIONS, KEY
20 SELECTION CRITERIA. WHILE THIS HAS BEEN VETTED BEFORE
21 THE PRESIDENTIAL SELECTION COMMITTEE, IT'S IMPORTANT
22 THAT WE GET THIS RIGHT FOR THE WHOLE BOARD. AND SO ARE
23 THERE BOARD COMMENTS ON THE IDEAL EXPERIENCE?

24 NOW, IT WAS DISCUSSED IN PUBLIC, AND SPENCER
25 STUART INTENDS TO RELAY THE INFORMATION TO CANDIDATES,

1 THAT IT WILL BE A COMBINATION OF THESE SPECIFIC
2 CREDENTIALS. WE'RE NOT APT TO FIND A CANDIDATE WITH
3 EVERY ONE OF THESE BEING SATISFIED. THAT'S NOT IN THE
4 REAL WORLD, BUT WE WANT AS MUCH VALUE AND AS MUCH
5 LEADERSHIP AND SCIENTIFIC EXPERTISE AS WE CAN ACHIEVE.

6 IT HAS BEEN EMPHASIZED THAT THE RECORD OF
7 SCIENTIFIC ACCOMPLISHMENT AND PROFESSIONAL REPUTATION
8 IS CENTRAL TO THE TASK. BUT IT WOULD BE IMPORTANT TO
9 KNOW IF THERE'S ANY AMENDMENTS FROM THE BOARD TO THIS
10 DESCRIPTION OF EXPERIENCE AND CRITICAL COMPETENCIES.

11 YES, DR. MURPHY.

12 DR. MURPHY: MR. CHAIRMAN, YESTERDAY, AS YOU
13 KNOW, THE COMMITTEE MET AND CAREFULLY ASSESSED THIS
14 DOCUMENT. AND WE MADE A NUMBER OF RECOMMENDATIONS FOR
15 CHANGES IN TEXT THAT ARE NOT INCLUDED IN THE CURRENT
16 DOCUMENT. THE QUESTION IS WHEN WOULD THOSE BE
17 PRESENTED, AND WILL THOSE BE INCLUDED NOW OR AT A LATER
18 DATE?

19 CHAIRMAN KLEIN: SPENCER STUART ATTEMPTED TO
20 INCLUDE THOSE, BUT IT IS NOT EVIDENT TO ME THAT THEY
21 CAPTURED THE SENSE OF ALL OF THOSE CHANGES. THEY
22 PROVIDED THIS OVERNIGHT TO US AS THEIR BEST EFFORT TO
23 CAPTURE THEM. I THINK FOR THE BENEFIT OF THE PUBLIC
24 AND THE BOARD TO FOCUS ON THOSE THAT ARE NOT INCLUDED
25 SO THAT WE CAN MAKE CERTAIN THAT IT IS CAPTURED ON THE

1 RECORD.

2 DR. MURPHY: DO WE HAVE A RECORD OF THE
3 CHANGES THAT WERE MADE YESTERDAY?

4 CHAIRMAN KLEIN: WE DO. WE HAVE AT THE STAFF
5 LEVEL A WRITTEN RECORD OF THE CHANGES, AND WE CAN
6 CONFORM WHAT THEY HAVE PROVIDED US WITH TO THAT RECORD.
7 I WOULD SAY THAT, FOR EXAMPLE, UNDER IDEAL EXPERIENCE,
8 WE SPECIFICALLY USED WORDING IN THAT SECTION, FOR
9 EXAMPLE, THAT I'VE JUST TRIED TO CAPTURE ORALLY, THAT
10 TALKED ABOUT THE FACT THAT THESE -- SOME COMBINATION OF
11 THESE WOULD BE REALIZED, BUT NOT ALL OF THEM. BUT WE
12 HAVE A WRITTEN RECORD OF THOSE THAT WE CAN -- THAT WE
13 CAN, AT YOUR SUGGESTION, CAPTURE.

14 I WOULD LIKE, TO THE EXTENT POSSIBLE, TO
15 RECOUNT THOSE TO THE EXTENT THEY'RE NOT TECHNICAL FOR
16 THE BENEFIT OF ALL THE BOARD MEMBERS.

17 UNDER SCIENTIFIC CREDIBILITY, WE SPECIFICALLY
18 REFERENCED THAT THERE WERE A NUMBER OF FORMS OF
19 SCIENTIFIC CREDIBILITY WHICH WOULD BE APPROPRIATE,
20 INDEXES OF A SUCCESSFUL CANDIDATE. AND IT WAS NOT
21 NECESSARY, FOR EXAMPLE, THAT PATENTS OR IP WOULD BE A
22 COMPONENT OF THAT CREDIBILITY.

23 THERE IS A SPECIFIC WORDING TO MAKE IT CLEAR
24 THAT OVERSIGHT OF THE CONTRIBUTIONS TO THE CREATION OF
25 SUCCESSFUL THERAPEUTIC PRODUCTS WOULD BE BETTER

1 WORDING, FOR EXAMPLE. WHY THEY DID NOT, IN THE
2 OVERNIGHT DRAFTING, CAPTURE THEM ALL I CANNOT EXPLAIN,
3 BUT WE DO HAVE AN EFFECTIVE RECORD OF ALL OF THOSE
4 ITEMS.

5 DR. PRECIADO: IT'S DIFFICULT FOR ME. I KNOW
6 WE DID MAKE MANY CHANGES TO THE REPORT, AND WE DON'T
7 HAVE THAT IN FRONT OF US. AND SO IT SEEMS ALMOST
8 REDUNDANT, AS THOUGH WE'RE GOING TO START ALL OVER
9 AGAIN MAKING CHANGES TO THE REPORT WHEN, IF WE HAD WHAT
10 WE ORIGINALLY WORKED ON, IT WOULD MAKE IT MUCH EASIER.

11 CHAIRMAN KLEIN: LET ME ASK THIS QUESTION.
12 IT DEPENDS ON THE MEMBERSHIP HERE OF THE BOARD AND
13 THEIR DESIRE; BUT ONE OF OUR AVENUES, SINCE THEY DID
14 NOT CAPTURE ALL OF THESE CHANGES, THAT WE CAN TAKE AS A
15 PATH IS KNOWING THAT WE'VE GONE THROUGH METICULOUSLY
16 AND MADE THOSE CHANGES, WHAT WE COULD DO IS ASK THE
17 BOARD, AND THIS IS THE SECTION WHERE WE MADE THOSE
18 CHANGES IS UNDER IDEAL EXPERIENCE AND CRITICAL
19 COMPETENCIES FOR SUCCESS, WE COULD ASK THE BOARD FOR
20 ADDITIONAL CHANGES BEYOND THOSE THAT WERE RECORDED IN
21 THE TRANSCRIPT, BECAUSE WE ACTUALLY HAVE AN ACTUAL
22 TRANSCRIPT OF THAT MEETING, SO THAT WE COULD PICK UP
23 ANY ADDITIONAL ITEMS THAT THIS BOARD HAS.

24 THIS BOARD ACTUALLY DELEGATED TO THAT
25 COMMITTEE TO REVIEW WITH SPENCER STUART THESE CRITERIA.

1 SO WE ARE BRINGING IT BACK TO THIS BOARD TO MAKE
2 CERTAIN THAT THEY ARE REVISED COMPLETELY. BUT IF THERE
3 ARE ITEMS THIS BOARD SEES THAT STAND OUT, IF THEY COULD
4 MENTION THOSE ITEMS ON THE RECORD, WE COULD VOTE TO
5 RECONCILE AND ADD THOSE TO THE PRIOR CHANGES AND ADOPT
6 IT WITH THE PRIOR CHANGES FROM THAT COMMITTEE.

7 DR. BRYANT: I JUST DUG OUT YESTERDAY'S
8 VERSION. I THINK THIS IS EXACTLY THE SAME. I DON'T
9 THINK ANY OF THE CHANGES GOT IN.

10 DR. HENDERSON: THAT'S MY PROBLEM TOO. THEY
11 HAVEN'T MADE ANY CHANGES.

12 DR. PIZZO: MAYBE WHAT YOU RECEIVED WAS NOT
13 THEIR VERSION. MAYBE YOU JUST GOT THE WRONG ONE
14 BECAUSE I HAVE THE ONE FROM YESTERDAY AS WELL.

15 CHAIRMAN KLEIN: THEIR E-MAIL, IT APPEARS
16 THAT WHAT THEY DID IS INSTEAD OF E-MAILING THE
17 CORRECTED VERSION --

18 DR. PIZZO: I THINK THAT'S RIGHT. THEY JUST
19 PROBABLY DIDN'T DO THE ATTACHMENT CORRECTLY.

20 DR. PRECIADO: DO WE HAVE SOMEONE FROM
21 SPENCER STUART HERE?

22 CHAIRMAN KLEIN: WE DON'T, I BELIEVE, HAVE
23 ANYONE FROM SPENCER STUART HERE, DO WE?

24 DR. HENDERSON: COULD WE SEND THIS BACK TO
25 SPENCER STUART AND PASS ON THIS ISSUE AT THIS TIME

1 SINCE WE HAVE A LOT OF OTHER THINGS WE COULD DEAL WITH?
2 TO RECREATE YESTERDAY'S IS ANOTHER HOUR OF WASTED TIME,
3 NOT WASTED, REPEATED TIME.

4 MS. LANSING: I AGREE WITH YOU.

5 CHAIRMAN KLEIN: I AGREE. I WOULD LIKE TO
6 SAY I COMPLIMENT THE COMMITTEE FOR YESTERDAY. WE DID
7 EXTREMELY FOCUSED AND DILIGENT WORK ON IT. BUT I WOULD
8 SAY IT WOULD PROBABLY HELP US IF, JUST IN THIS CRITICAL
9 AREA THAT WE FOCUSED MOST OF OUR TIME ON, IF THERE'S
10 ANY COMMENT MADE BY ANY MEMBER OF THE BOARD THAT WE
11 COULD BRING BACK TO THAT SO WE CAN JUST COMPLETE THAT
12 EXPERIENCE.

13 DR. BALTIMORE: IN THE INTEREST OF MOVING
14 AHEAD, WHAT'S WRITTEN IN THESE KINDS OF DOCUMENTS
15 DOESN'T HAVE AN ENORMOUS EFFECT ON THE CANDIDATES THAT
16 YOU FIND IN THE END ANYWAY. THEY'RE SORT OF A WISH
17 LIST. I WOULD BE PERFECTLY COMFORTABLE, IF IT'S
18 APPROPRIATE, MOVING THAT WE ACCEPT THIS WITH THE
19 MODIFICATIONS THAT YOUR COMMITTEE HAS MADE,
20 UNDERSTANDING THAT THOSE MODIFICATIONS COULD ONLY HAVE
21 STRENGTHENED IT.

22 CHAIRMAN KLEIN: IF I COULD ADD TO THAT WITH
23 THE FACT THAT TO CONFIRM THAT THE COMMITTEE -- THAT THE
24 CORRECTIONS ARE MADE PROPERLY, THAT WE WILL
25 RECONVENE -- WE'RE GOING TO RECONVENE THAT COMMITTEE

1 ANYWAY, AND WE WILL CONFIRM IN THAT MEETING THAT ALL
2 THE CORRECTIONS WERE MADE PROPERLY. IT WAS -- JUST A
3 CONFIRMATION OF THE DELEGATION OF AUTHORITY IS
4 ESSENTIALLY WHAT IT IS BECAUSE THE COMMITTEE DID HAVE
5 THE DELEGATED AUTHORITY ON THOSE CRITERIA. DR. STEWARD
6 AND THEN JOAN.

7 DR. STEWARD: I WAS GOING TO SAY EXACTLY THE
8 SAME THING. IF THIS ENTIRE GROUP DOESN'T NEED TO, IN
9 FACT, APPROVE THE FINAL DOCUMENT, THEN I WOULD SUGGEST
10 THAT WE DELEGATE THAT AUTHORITY AS APPROPRIATE TO THE
11 SEARCH COMMITTEE AND ALLOW THEM TO NEGOTIATE THE FINAL
12 LANGUAGE IN THE DOCUMENT WITHOUT PUTTING THIS OFF UNTIL
13 THE NEXT FORMAL ICOC MEETING.

14 CHAIRMAN KLEIN: ALL RIGHT. AND ANY COMMENTS
15 COULD ALSO BE RECEIVED BY THAT SEARCH COMMITTEE FROM
16 OTHER BOARD MEMBERS IN WRITING, WHICH WE WOULD READ
17 INTO THE RECORD AT THE SEARCH COMMITTEE MEETING.

18 MS. SAMUELSON: UNLESS WE HAVE SOME ENORMOUS
19 TIME PRESSURE, I WOULD MUCH RATHER DO THIS IN A
20 DELIBERATE WAY THAT ALLOWS THE ENTIRE COMMITTEE TO BE
21 ABLE TO WEIGH IN ON THE SPECIFICS OF THE JOB
22 DESCRIPTION AND THE OTHER DETAILS. THIS IS AN
23 ENORMOUSLY IMPORTANT DECISION. AND IT'S NOT ONLY THAT
24 THE WRONG DOCUMENT IS HERE, BUT THERE WASN'T ANY TIME
25 FOR ANYBODY TO REVIEW IT. WE GOT TENS OF PAGES

1 OVERNIGHT, AND I TRIED LATE INTO LAST NIGHT TO ABSORB
2 IT ALL, AND I COULDN'T.

3 CHAIRMAN KLEIN: THE BENEFIT OF THE CURRENT
4 TIMETABLE THAT WE ARE ON IS THAT IT ALLOWS THE
5 POTENTIAL RECRUITEE TO HAVE AN OFFER PRIOR TO THE
6 SUMMER RECESS. SO IF WE HAVE A CANDIDATE WITH
7 CHILDREN, AS EXPLAINED BY SPENCER STUART, THAT WE CAN
8 MAKE AN OFFER THAT WOULD OPTIMIZE THEIR ABILITY TO
9 RELOCATE.

10 NOW, GIVEN THAT, AS DR. BALTIMORE SAYS, THAT
11 THIS DOCUMENT NEEDS TO COMMUNICATE THE BASIC MESSAGE,
12 BUT, IN FACT, WE WILL BRING BACK TO THIS BOARD, AS WE
13 DESCRIBED, BOTH AN INTERVIEW REGIME AMONG MULTIPLE
14 PAIRS OF INDIVIDUALS AND A PUBLIC INTERVIEW -- EXCUSE
15 ME -- AN EXECUTIVE SESSION INTERVIEW WITH THE BOARD.

16 BUT, JOAN, TO FOLLOW THROUGH WITH THE SPIRIT
17 OF YOUR COMMENT, WHAT WE CAN DO IS GIVING THE SPENCER
18 STUART COMFORT TO MOVE AHEAD BECAUSE WE'LL BRING IT
19 BACK TO THE PRESIDENTIAL SEARCH COMMITTEE SO THAT WE'VE
20 CONFIRMED ALL THE CHANGES ARE PROPERLY MADE, WE'LL ALSO
21 AT THE NEXT BOARD MEETING BRING BACK THE CORRECTED
22 VERSION, AND OPEN IT TO DISCUSSION AT THAT BOARD
23 MEETING, IF THERE'S ADDITIONAL AMENDMENTS THAT NEED TO
24 BE MADE SO THAT THEY WOULD BE ADVISED THAT THERE ARE
25 ADDITIONAL COMMENTS THAT COULD BE ADDED, BUT THEY WILL

1 HAVE 95 PERCENT OF THE SUBSTANCE TO WORK WITH.

2 DR. PRECIADO: ARE WE SUGGESTING THAT THEY
3 WOULD GO AHEAD?

4 CHAIRMAN KLEIN: THEY WOULD GO AHEAD WITH
5 THEIR PROCESS BECAUSE THEY'RE WORKING ON THE LONG LIST.
6 THEY WON'T IN THIS TIME PERIOD BE WORKING ON THEIR
7 SHORT LIST, SO THEY'LL BE WORKING ONLY ON THEIR LONG
8 LIST DURING THIS TIME PERIOD.

9 DR. PRECIADO: I MYSELF DON'T FEEL
10 COMFORTABLE WITH THAT. I THINK, FIRST OF ALL, WE DID
11 WORK ON THIS YESTERDAY, AND WE WERE TOLD WE WOULD HAVE
12 THAT, THE CHANGES, AND WE DON'T HAVE THE CHANGES, AND
13 WE DON'T HAVE SPENCER STUART HERE. AND I JUST FEEL
14 UNCOMFORTABLE WITH THAT. I WOULD RATHER US REALLY LOOK
15 AT THE DOCUMENT AGAIN AS A SUBCOMMITTEE WITH SPENCER
16 STUART OR HAVE THE CHANGES BEFORE US SO THAT WE CAN
17 ACTUALLY READ THEM AND THEN BRING THEM TO THE BOARD.

18 CHAIRMAN KLEIN: THE PROPOSAL IS, IN FACT, TO
19 BRING THEM BACK TO THE SUBCOMMITTEE.

20 DR. PRECIADO: OKAY.

21 CHAIRMAN KLEIN: AND MAKE SURE THE CHANGES
22 ARE CORRECT. THAT IS THE PROPOSAL.

23 DR. PRECIADO: OKAY. EXCUSE ME.

24 CHAIRMAN KLEIN: AND THEN -- BUT THE PROPOSAL
25 IS THAT WE BRING THEM BACK TO THE SUBCOMMITTEE, MAKE

1 SURE THE CHANGES ARE CORRECT, AND THEN INDICATE TO
2 SPENCER STUART THAT THEY CAN BEGIN WORKING ON THIS, BUT
3 WE'RE BRINGING IT BACK TO THE BOARD AT THE NEXT BOARD
4 MEETING FOR CONFIRMATION THAT THE BALANCE OF THE BOARD
5 AGREES WITH THOSE CHANGES.

6 DR. PRECIADO: BUT THE BOARD -- SPENCER
7 STUART WILL START WORKING WITHOUT THE APPROVAL OF THE
8 BOARD THOUGH?

9 CHAIRMAN KLEIN: NO.

10 DR. PRECIADO: I'M SORRY.

11 CHAIRMAN KLEIN: THEY ONLY WORK WITH THE
12 APPROVAL OF THE BOARD. THE ISSUE IS DO THEY HAVE
13 ENOUGH INFORMATION HERE TO WORK ON THE LONG LIST, WHICH
14 MIGHT BE A HUNDRED CANDIDATES, OR DO THEY NEED TO WAIT
15 FOR THE LONG LIST. AND IT IS THE PLEASURE OF THE
16 BOARD, WHATEVER YOU WOULD LIKE US TO DO.

17 DR. BRYANT: I WAS JUST WONDERING. EARLIER
18 YOU SAID THAT YOU WOULD TAKE INPUT FROM THE REST OF THE
19 BOARD THAT WANTED TO GET IT INTO THIS DRAFT. ARE WE
20 STILL SAYING THAT, OR DO YOU WANT TO WAIT UNTIL THE
21 NEXT ICOC MEETING?

22 CHAIRMAN KLEIN: I WAS SUGGESTING THAT IN THE
23 NEXT TWO WEEKS THE REST OF THE BOARD COULD CHOOSE TO
24 MAKE WRITTEN COMMENTS, WHICH WE WOULD READ IN PUBLIC
25 INTO THE PUBLIC RECORD.

1 MS. WILSON: SO WITHIN THE NEXT TWO WEEKS, WE
2 WILL HAVE RECEIVED ALL THESE CHANGES THAT YOU MADE
3 YESTERDAY?

4 CHAIRMAN KLEIN: YOU WILL RECEIVE THE CHANGES
5 THAT HAVE BEEN MADE FROM OUR RECORDS BECAUSE WE DO HAVE
6 A RECORD OF THEM, SO WE CAN MAKE SURE THEY ARE MADE.
7 AND THEN WE CAN SEND THOSE OUT POSTED ON THE WEB, SO
8 THE PUBLIC HAS IT, AND THEN RECEIVE WRITTEN COMMENTS
9 THAT ARE SENT DIRECTLY TO THE SUBCOMMITTEE, WHICH WOULD
10 THEN BE READ INTO THE RECORD AT THE PUBLIC MEETING, SO
11 THE PUBLIC BENEFIT FROM ALL THOSE CHANGES.

12 MS. LANSING: I'M ALSO VERY CONFUSED. ISN'T
13 THERE A SIMPLER WAY TO DO THIS? I'M JUST TRYING TO
14 FIGURE THIS OUT AS I TALK. THEY OBVIOUSLY MADE A
15 MISTAKE IS WHAT WE BELIEVE. LET'S HOPE THAT'S WHAT IT
16 IS AND THEY DIDN'T MISUNDERSTAND THEIR MISSION. SO I'M
17 JUST GOING TO ASSUME THEY MADE A MISTAKE AND SENT THE
18 WRONG DOCUMENT, WHICH MEANS THAT WE SHOULD BE ABLE TO
19 GET THAT DOCUMENT BY TOMORROW MORNING BECAUSE IT SHOULD
20 BE DONE. SO CAN'T WE ALL GET THAT DOCUMENT TOMORROW
21 MORNING? IS THERE ANYTHING WRONG WITH THAT?

22 CHAIRMAN KLEIN: WE CAN. I WOULD LIKE TO
23 TAKE THE STAFF NOTES AND RECONCILE IT AGAINST EVERY
24 SINGLE CHANGE NOW THAT I KNOW THAT THEY HAVE CREATED A
25 DRAFT THAT THEY FORWARDED TO US AS THE CORRECTED DRAFT

1 THAT WAS NOT THE FORWARDED DRAFT. I WOULD LIKE TO TAKE
2 AN ADDITIONAL PRECAUTION TO RECONCILE AGAINST EVERY
3 CHANGE.

4 MS. LANSING: SO IN THREE DAYS WE CAN GET,
5 LIKE BY MONDAY WE'LL GET THE NEXT -- THE THING. IS
6 THERE A WAY THAT WE CAN HAVE A TELECONFERENCE THAT'S
7 OPEN TO THE PUBLIC AND GET IT DONE THAT WAY OR NO?

8 CHAIRMAN KLEIN: THE PROBLEM IS GETTING
9 EVERYONE, IT WOULD BE A 29-MEMBER TELECONFERENCE AND
10 DIFFICULT ON DATES. THE SUBCOMMITTEE WILL HAVE A
11 TELECONFERENCE MEETING.

12 DR. PIZZO.

13 DR. PIZZO: MY COMMENT IS PROCEDURAL ALONG
14 THE SAME LINE OF THE TELECONFERENCE, AND THIS WAS A
15 TOPIC THAT WAS BROUGHT UP ONCE BEFORE. I THINK JOAN
16 RAISED IT INITIALLY. AND THAT IS, WILL WE, AS WE GO
17 FORWARD, FOR THESE SUBCOMMITTEES HAVE SOME GREATER
18 FLEXIBILITY IN SIZE BECAUSE, YOU KNOW, I COULD JUST SAY
19 PERSONALLY YESTERDAY I VERY MUCH WANTED TO BE ON THE
20 CALL, BUT IT WAS JUST IMPOSSIBLE BECAUSE OF OTHER
21 CONVERGING RESPONSIBILITIES. AND IT BECOMES A
22 FIVE-HOUR SCHEDULE DEAL TO GO UP TO SAN FRANCISCO AND
23 BACK AND PARTICIPATE IN THE CALL.

24 SO IF WE COULD MOVE IN SOME CAPACITY TO HAVE
25 GREATER FLEXIBILITY TO JOIN THESE CALLS WITH THE

1 PROVISIONS OF BAGLEY-KEENE, THAT WOULD MAKE, I THINK,
2 THE PROCESS GO SO MUCH BETTER FOR ALL OF US.

3 CHAIRMAN KLEIN: I THINK THAT THAT'S AN
4 EXCELLENT POINT TO BRING UP. AND IN THAT REGARD, TO
5 THE EXTENT THAT THE INSTITUTIONS THAT ARE PRESENT HERE
6 IN HOSTING THESE CAN VOLUNTEER A STAFF MEMBER AT THE
7 INSTITUTION SO THAT WE CAN THEN HAVE ADDITIONAL SITES
8 BECAUSE WE ARE SO CONSTRAINED WITH STAFFING.

9 DR. PIZZO: WE'D BE HAPPY TO DO THAT.

10 DR. BRYANT: SO WOULD WE.

11 CHAIRMAN KLEIN: THAT WOULD ALLOW US TO
12 EXPAND THE NUMBER OF SITES FOR PUBLIC ACCESS, WHICH
13 WOULD BE A BENEFIT TO THE PUBLIC, AND IT WOULD ALLOW US
14 TO MINIMIZE THE TRAVEL TIME FOR MEMBERS THAT ARE
15 PARTICIPATING IN THE CALL. PLEASE REMEMBER THE ROOM
16 HAS TO ACCOMMODATE 50 PEOPLE, BUT WE NOW HAVE ENOUGH OF
17 A HIGHLY ARTICULATED SCHEDULE OF REQUIREMENTS FROM THE
18 ATTORNEY GENERAL'S OFFICE, THAT WE CAN GIVE THEM TO
19 EVERYONE. BUT THERE NEEDS TO BE A STAFF MEMBER THAT
20 WILL CONFIRM THAT THE PUBLIC HAS ACCESS AND THAT THE
21 PUBLIC -- ALL THE PUBLIC'S RIGHTS TO COMMENT IN PUBLIC
22 ARE, IN FACT, FOLLOWED.

23 DR. PIZZO: I THINK WE'LL CERTAINLY BE
24 RESPONSIVE TO THAT AND FOLLOW THE LETTER OF THE LAW.
25 WHAT WILL BE ALSO IMPORTANT, BECAUSE THIS IS WHAT

1 HAPPENED YESTERDAY, UNDERSTANDABLY, IS THAT IT HAS TO
2 BE GIVEN IN PUBLIC NOTICE AT THE SAME TIME THAT THE
3 MEETING IS BEING SET UP, SO WE JUST HAVE TO BE ABLE TO
4 NOW, AS WE'RE GOING FORWARD, ANTICIPATE AND, IN
5 ESSENCE, TAKE A ROLL CALL OF THE COMMITTEE MEMBERS TO
6 DETERMINE WHO NEEDS TO BE OR WHO WANTS TO SET UP A
7 SEPARATE SITE SO THAT THERE'S TIME TO GET THE SITE SET
8 UP AND TO MAKE IT A PUBLIC NOTICE SO WE CAN ACTUALLY DO
9 IT. OTHERWISE WE'RE GOING TO BE IN THE SQUANDERED
10 POSITION.

11 CHAIRMAN KLEIN: LET ME ASK JUST BY A SHOW OF
12 HANDS WHICH MEMBERS ARE PREPARED TO HAVE THEIR SITE BE
13 A PUBLIC SITE? COULD STAFF WRITE THESE DOWN, PLEASE.
14 AMY DUROSS.

15 MS. DUROSS: WHAT?

16 CHAIRMAN KLEIN: WRITE DOWN ALL THESE
17 MEMBERS' NAMES. WE'LL PUT IT INTO THE RECORD.
18 DR. WRIGHT, DR. BIRGENEAU, DR. FRIEDMAN, DR. BALTIMORE,
19 DR. POMEROY, JOAN SAMUELSON, DR. HOLMES, DR. LOVE, DR.
20 HENDERSON, DR. PIZZO, DR. MURPHY, DR. BRYANT, DR.
21 PRECIADO, DR. REED, FOR DR. LEVEY, YES. OKAY.

22 AND I WOULD ALSO SAY WHAT WE NEED TO DO IS,
23 WE WILL, IF ALL OF YOU WOULD DESIGNATE YOUR
24 REPRESENTATIVES IN THE NEXT THREE DAYS AND GET THE
25 NAMES TO US, WE'LL CREATE A CALL WHERE THE ATTORNEY

1 GENERAL'S OFFICE GOES OVER THE PROCEDURES WITH THE
2 PERSON WHO WILL, IN FACT, CONDUCT THOSE MEETINGS SO
3 THAT WE HAVE CONSISTENCY BECAUSE THAT'S BEEN VERY
4 IMPORTANT TO GET OFF TO THE PROPER START WITH
5 CONSISTENCY OF HOW THOSE MEETINGS WERE CONDUCTED.

6 DR. BALTIMORE: COULD SOMEBODY SEND US,
7 THOUGH, THE REQUIREMENTS OF THE INDIVIDUAL, WHAT THEY
8 HAVE TO DO?

9 CHAIRMAN KLEIN: YES.

10 DR. BALTIMORE: SO IN CHOOSING A PERSON, WE
11 CHOOSE THE RIGHT PERSON.

12 CHAIRMAN KLEIN: JAMES HARRISON.

13 MR. HARRISON: I'D LIKE TO MAKE JUST ONE
14 CLARIFICATION. ORIGINALLY FOR THE FIRST SERIES OF
15 TELECONFERENCE MEETINGS, WE WANTED TO HAVE THEM IN
16 SITES THAT COULD ACCOMMODATE UP TO 50 PEOPLE BECAUSE OF
17 THE LEVEL OF PUBLIC INTEREST. THAT'S NOT A REQUIREMENT
18 SPECIFIED IN THE CODE. AS LONG AS THE FACILITY IS ADA
19 COMPLIANT AND CAN ACCOMMODATE THE MEMBERS OF THE PUBLIC
20 WHO WISH TO ATTEND FROM THAT SITE, THAT'S SUFFICIENT.

21 CHAIRMAN KLEIN: THANK YOU VERY MUCH. THAT'S
22 A PENDING REQUEST WE'VE HAD ABOUT -- FOR A WHILE.
23 THANK YOU VERY MUCH FOR RECOGNIZING THAT. BASICALLY,
24 JUST FOR THE PUBLIC'S BENEFIT, IN MONITORING HOW MANY
25 PUBLIC MEMBERS HAVE SHOWN UP, IT'S QUITE CLEAR THAT

1 THEY CANNOT NECESSARILY HAVE 50 MEMBERS AND STILL QUITE
2 PROPERLY ACCOMMODATE THE PUBLIC. AND WITH MORE SITES
3 AVAILABLE, IT SHOULD, IN FACT, EVEN BE EASIER TO
4 ACCOMMODATE THE PUBLIC. WE NEED A GUIDELINE THAT'S AN
5 OBJECTIVE FIGURE THAT SHOULD BE IN THE WRITTEN TEXT.
6 AND JAMES HARRISON, COULD YOU OVERSEE THIS WRITTEN
7 TEXT?

8 MR. HARRISON: YES. WE'LL PREPARE SOME
9 GUIDANCE FOR YOUR STAFF MEMBERS WHO ARE VOLUNTEERING TO
10 ASSIST.

11 CHAIRMAN KLEIN: COUNSEL WILL DO THAT IN
12 CONJUNCTION WITH THE ATTORNEY GENERAL'S OFFICE WHO WILL
13 SIGN OFF ON THAT TEXT.

14 DR. HOLMES: IT SEEMS WE WERE DISCUSSING TWO
15 ISSUES. ONE WAS THE JOB DESCRIPTION, WHICH SEEMS LIKE
16 A PROCESS IS UNDERWAY. THE SECOND WAS WHAT COULD WE
17 ASK SPENCER STUART TO DO IN THE MEANTIME. I WANTED TO
18 RETURN TO THE LATTER POINT, THAT I PERSONALLY FEEL
19 COMFORTABLE WITH HAVING SPENCER STUART CONTINUE TO WORK
20 TO TRY TO BUILD THE LONG LIST, AS YOU CALL IT, SO THAT
21 WE DON'T LOSE TIME. I THINK THERE'S ENOUGH INFORMATION
22 HERE TO INFORM THEM IN A GENERAL WAY TO TRY TO GO AHEAD
23 AND BUILD THAT LIST. SO I WOULD HOPE THEY COULD
24 CONTINUE WORKING UNLESS I MISUNDERSTOOD WE NEEDED TO
25 MAKE A COMMENT ABOUT THAT OR MAYBE YOU ALREADY DECIDED.

1 CHAIRMAN KLEIN: NO. NO. I THINK WE'RE
2 GOING TO TAKE A VOTE HERE. SO WE ARE TRYING TO FIND
3 WHAT OUR POINT IS AT WHICH ACTION IS APPROPRIATE.

4 DR. REED: A POINT OF CLARIFICATION. AND
5 THAT IS, DOES THIS JOB SPECIFICATION REQUIRE BOARD
6 APPROVAL?

7 CHAIRMAN KLEIN: THE BOARD -- ACTUALLY BOARD
8 DELEGATED TO THE PRESIDENTIAL SEARCH COMMITTEE. WE'RE
9 BRINGING THIS BACK OUT OF AN ABUNDANCE OF CARE TO MAKE
10 CERTAIN THAT WE HAVE THE PROCESS, WE HAVE THE BOARD
11 CONSTANTLY INFORMED ON THIS ISSUE.

12 DR. REED: THAT BEING THE CASE, AT THE RISK
13 OF BEING REDUNDANT, I WOULD SUGGEST THAT THIS CONCEPT
14 OF MOVING FORWARD WITH FORMULATING A LONG LIST, WHILE
15 WE HAVE A CHANCE FOR THIS SPECIFICATION TO WORK ITS
16 FULL WAY BACK TO THE BOARD OVER THE NEXT FEW WEEKS,
17 WOULD BE PERFECTLY ACCEPTABLE, AT LEAST TO ME.

18 CHAIRMAN KLEIN: OKAY. AND AGAIN, TO HONOR
19 THE POINT PREVIOUSLY RAISED, FIRST OF ALL, IS SOMEONE
20 WILLING TO MAKE THAT INTO A FORMAL MOTION?

21 DR. BALTIMORE: I THINK I DID.

22 CHAIRMAN KLEIN: DR. BALTIMORE DID ACTUALLY,
23 AND I BELIEVE I MODIFIED THE MOTION TO SAY THAT WE
24 WOULD BRING IT BACK TO THE BOARD FOR THE NEXT BOARD
25 MEETING WHILE INFORMING SPENCER STUART MORE ACCURATELY

1 ON THE CHANGES WE HAD EXPECTED THEM TO MAKE IN THE
2 INTERIM.

3 DR. BALTIMORE: I WOULD ACCEPT THAT.

4 DR. WRIGHT: SECOND.

5 CHAIRMAN KLEIN: IS THERE ADDITIONAL COMMENT
6 FROM THE BOARD? ADDITIONAL -- IS THERE COMMENT FROM
7 THE PUBLIC?

8 MR. HALPERN: CHARLES HALPERN. I WAS THE
9 PUBLIC AT YESTERDAY'S MEETING OF THE PRESIDENTIAL
10 SEARCH COMMITTEE. I WANTED TO NOTE A COUPLE OF THINGS
11 ABOUT THAT.

12 FIRST OF ALL, IT WAS NOT AN OFFICIAL MEETING.
13 NONE OF THE DISCUSSION COULD BE REDUCED TO RESOLUTION
14 BECAUSE THERE WAS NO QUORUM PRESENT. SO IT'S NOT AS IF
15 A COMMITTEE MET AND MADE CERTAIN RESOLUTIONS, AND NOW
16 THEY'RE BEING PRESENTED HERE. THAT COMMITTEE DID NOT
17 MEET YESTERDAY. THERE WAS A DISCUSSION. THERE WERE
18 SOME VERY IMPORTANT POINTS MADE AND RECEIVED, BUT THERE
19 HAS BEEN NO COMMITTEE ACTION.

20 A POINT THAT I THINK IS URGENTLY NEEDED IN
21 THE DESCRIPTION IS A STATEMENT THAT THE ICOC IS
22 INTERESTED IN A PRESIDENT WHO IS NOT HAMPERED BY
23 CONFLICT OF INTEREST. AND THIS STATEMENT IS SILENT ON
24 THAT POINT. AND IN FORMING A LONG LIST, I THINK THE
25 COMMITTEE -- EXCUSE ME -- SPENCER STUART SHOULD HAVE

1 THAT UPPERMOST IN MIND. AND AS PEOPLE ARE DECIDING
2 WHETHER THEY WANT A JOB AS PRESIDENT OR NOT, THEY
3 SHOULD UNDERSTAND THAT RIGOROUS CONFLICT OF INTEREST
4 PRINCIPLES WILL APPLY.

5 I WOULD HOPE THEY WOULD BE THE NIH
6 PRINCIPLES. AGAIN, I FIND IT INCONGRUOUS THAT THIS
7 IMPORTANT BEACON EFFORT WOULD BE HEADED BY PEOPLE WHO
8 COULD NOT GET A JOB AT THE NIH. I WOULD URGE THAT THE
9 CONFLICT OF INTEREST PRINCIPLES BE INCLUDED.

10 SECOND, ON THE POINT OF SALARIES, I NOTE THAT
11 WHEN SPENCER STUART MADE ITS PRESENTATION IN JANUARY,
12 THEY WERE LOOKING AT \$400,000 AS THE FLOOR. THAT WAS
13 AS LOW AS THEY WERE GOING TO SEARCH FOR. BUT WE KNOW
14 THAT THE INTERIM PRESIDENT OF EXCEPTIONAL QUALIFICATION
15 HAS COME FOR LESS THAN 400,000. I WOULD SUGGEST THAT
16 WAS AN INAPPROPRIATE FLOOR. TO MY WAY OF THINKING
17 \$400,000 SHOULD BE THE CEILING. THE LANGUAGE AT THE
18 BOTTOM OF PAGE 5 OF SPENCER STUART'S WRITE-UP IS
19 INCREDIBLY VAGUE ON COMPENSATION AND IT SHOULD BE
20 CLEARER.

21 THE THIRD POINT THAT I WANT TO MAKE IS THIS.
22 THAT THIS COMMITTEE HAS AN OBLIGATION TO MAKE THIS JOB
23 AS ATTRACTIVE AS POSSIBLE. WE'RE NOT GOING TO ATTRACT
24 PEOPLE HERE TO CALIFORNIA BECAUSE THE SALARY IS SO
25 HIGH. WE'RE GOING TO ATTRACT PEOPLE HERE BECAUSE THE

1 JOB IS SO ATTRACTIVE. AS WRITTEN, THIS JOB
2 DESCRIPTION -- I URGE YOU TO READ IT CAREFULLY BECAUSE
3 IT DESCRIBES A COO, CHIEF OPERATING OFFICER, POSITION.

4 DR. PRECIADO YESTERDAY RAISED THE QUESTION,
5 WELL, WHO'S REALLY IN CHARGE. I BELIEVE THOSE ARE HER
6 VERY WORDS. AND ANYONE WHO'S THINKING OF APPLYING HERE
7 WOULD READ THIS AND ASK THAT VERY QUESTION. WHO'S
8 REALLY IN CHARGE? WELL, WHEN YOU SEE THAT IT'S THE
9 BOARD CHAIR WHO HAS ACCESS TO THE ICOC, WHOSE JOB IS TO
10 MANAGE THE ICOC AGENDA AND WORK FLOW, INCLUDING ALL
11 EVALUATIONS AND APPROVALS OF SCIENTIFIC AND MEDICAL
12 WORKING GROUPS, ETC., THEN YOU'RE PRETTY CLEAR WHO'S IN
13 CHARGE. THE LANGUAGE IS QUITE CLEAR.

14 I THINK THIS COMMITTEE OUGHT TO TAKE THIS
15 OPPORTUNITY TO RETHINK THAT QUESTION AND SEE IF THERE
16 ISN'T A WAY TO MAKE THE PRESIDENT'S JOB MORE
17 ATTRACTIVE, SO IT ISN'T SO CLEARLY A NO. 2 POSITION.
18 THANK YOU.

19 CHAIRMAN KLEIN: THANK YOU, MR. HALPERN. AND
20 I WILL POINT OUT THAT PART OF THIS MOTION IS TO BRING
21 THIS -- THAT WE ARE TAKING THIS TO A COMMITTEE ACTION,
22 PRESIDENTIAL SEARCH COMMITTEE, WHERE IT WILL BE
23 CONFIRMED WITH A QUORUM WITH A RESOLUTION. THE
24 COMMITTEE DID MEET YESTERDAY. THERE WASN'T A QUORUM,
25 SO WE COULDN'T PASS THE RESOLUTION, BUT THERE WAS A

1 VERY HEALTHY DEBATE ON THE SUBJECT AND A DISCUSSION OF
2 THE POINTS THAT YOU'VE RAISED.

3 SO ARE THERE OTHER PUBLIC COMMENTS? SEEING
4 NO OTHER PUBLIC COMMENTS, ARE THERE MEMBER COMMENTS?

5 DR. PRIETO: JUST ONE. I HAVE NO PARTICULAR
6 PROBLEM DELEGATING THIS DECISION, AS WE DID AT OUR LAST
7 MEETING, TO THE PRESIDENTIAL SEARCH COMMITTEE, BUT I
8 THINK WE HAVE TO APPRECIATE THAT, AS A PUBLIC
9 ENTERPRISE, WE ARE SOMETIMES GOING TO HAVE TO SACRIFICE
10 EFFICIENCY FOR OPENNESS.

11 CHAIRMAN KLEIN: GREAT.

12 DR. BALTIMORE: MY POINT IS SLIGHTLY OFF THE
13 POINT, BUT I DON'T THINK THERE'S ANY BETTER TIME TO
14 MAKE IT. I AM SURPRISED THAT SPENCER STUART IS NOT
15 REPRESENTED AT THIS MEETING, AND IT WOULD SEEM TO ME
16 THAT THEY SHOULD BE AT EVERY MEETING WHERE THAT'S ANY
17 DISCUSSION OF ANYTHING THAT RELATES TO THEM. THEY
18 SHOULD HAVE HEARD THIS DISCUSSION. THEY SHOULD
19 UNDERSTAND THE VARIOUS CONCERNS AROUND THE TABLE. AND
20 AS I SAY, I JUST SIMPLY DO NOT UNDERSTAND. IF THEY
21 WERE RUNNING A SEARCH FOR ME, THEY WOULD HAVE BEEN
22 HERE.

23 DR. PRECIADO: I JUST -- THANK YOU FOR SAYING
24 THAT BECAUSE I THINK -- I JUST WANT TO SAY TO MR.
25 HALPERN. I KNOW WE DIDN'T HAVE A QUORUM, BUT WE REALLY

1 WORK HARD. SO I DON'T WANT TO DEMEAN THE PROCESS THAT
2 WE'RE GOING THROUGH JUST TO GET TO THE POINT WHERE WE
3 ARE.

4 SECONDLY, SPENCER STUART SHOULD BE HELD
5 ACCOUNTABLE, AS WE ARE BEING HELD ACCOUNTABLE, AND I
6 EXPECT THEY WILL BE AT EVERY SINGLE MEETING AS WE GO
7 THROUGH THIS.

8 CHAIRMAN KLEIN: IT'S SURPRISING TO ME. THEY
9 SPECIFICALLY HAD THREE MEMBERS AT THE LAST MEETING, AND
10 THERE WILL BE A VERY SIGNIFICANT DISCUSSION WITH THEM.

11 DR. PIZZO: THEY WERE THERE LAST TIME.

12 DR. SERRANO-SEWALL: CALL THE QUESTION.

13 CHAIRMAN KLEIN: THE QUESTION HAS BEEN
14 CALLED. DOES THIS REQUIRE A ROLL CALL VOTE? NO. ALL
15 IN FAVOR. OPPOSED. THANK YOU VERY MUCH. AND WE WILL
16 NOT ONLY, AGAIN, BE HOLDING THIS IN PRESIDENTIAL SEARCH
17 COMMITTEE WITH A QUORUM WITH A RESOLUTION BEFORE IT'S
18 APPROVED, BUT WE'LL BRING IT BACK TO THE BOARD AS WELL
19 AT THE NEXT MEETING. THANK YOU VERY MUCH.

20 WE HAVE A TIMETABLE THAT WE HAVE TO MEET, AND
21 COUNSEL HAS REMINDED ME THAT WE HAVE TO ADDRESS AT THIS
22 SESSION A PETITION THAT WE RECEIVED FROM MR. HALPERN
23 AND DR. LEE. THAT PETITION IS A PART OF THE ITEMS THAT
24 YOU HAVE IN YOUR BINDER. COULD I ASK STAFF WHICH TAB
25 IS THAT ITEM FOR THE PETITION?

1 MR. HARRISON: ELEVEN.

2 CHAIRMAN KLEIN: COULD COUNSEL PLEASE EXPLAIN
3 TO THE PUBLIC AND THE BOARD THE TIMETABLE IN WHICH WE
4 HAVE TO RESPOND TO A PETITION FILED UNDER THIS SECTION
5 OF THE HEALTH AND SAFETY CODE?

6 MR. HARRISON: THE BOARD HAS 30 DAYS TO
7 RESPOND FROM THE DATE OF THE FILING THE PETITION EITHER
8 TO REJECT THE PETITION OR TO ACCEPT SOME OR ALL OF THE
9 RECOMMENDATIONS.

10 CHAIRMAN KLEIN: AND THAT 30 DAYS WILL RUN
11 BEFORE THE NEXT BOARD MEETING; IS THAT CORRECT?

12 MR. HARRISON: THAT'S CORRECT.

13 CHAIRMAN KLEIN: THE ISSUE BEFORE US IN THIS
14 PETITION INVOLVES CONFLICT OF INTEREST STANDARDS,
15 COMPENSATION, WORKING GROUPS, GRANT MAKING PROCEDURES,
16 ALL VERY IMPORTANT AREAS THAT HOPEFULLY WE'LL HAVE
17 THOUGHTFUL CONSIDERATION OF. IT IS IMPORTANT TO NOTE
18 THAT WE'RE GOING TO HAVE PUBLIC MEETINGS TO DISCUSS
19 THESE AREAS. THE ISSUE IS HOW CAN WE DECIDE ALL OF
20 THEM OVERNIGHT. WE'RE CLEARLY TRYING TO PROCEED AS
21 REASONABLY WITH AS MANY CHECKS AND BALANCES AS POSSIBLE
22 WITH A VERY LIMITED STAFF, WHICH WE'VE INTENTIONALLY
23 KEPT LIMITED SO THAT THE INTERIM PRESIDENT WOULD HAVE
24 THE ABILITY TO HIRE THE MOST STAFF POSSIBLE. AND SO
25 THE DESIRE HERE IS TO MOVE FORWARD IN A JUDICIOUS WAY

1 TO HAVE THE OPPORTUNITY TO DEBATE ALL OF THESE ISSUES
2 IN PUBLIC FORUMS, AND THE CONSIDERATION OF THE BOARD IN
3 REACHING THESE ITEMS AND THE DECISION ON THESE ITEMS.

4 THE IMMEDIATE ISSUE TO REQUEST IS WE HAVE THE
5 RIGHT WITHIN THIS 30 DAYS TO DENY THE PETITION,
6 INDICATING IN WRITING WHY IT HAS REACHED A DECISION ON
7 THE MERITS OF THE PETITION OR TO SCHEDULE THE MATTER
8 FOR PUBLIC HEARING IN ACCORDANCE WITH THE
9 ADMINISTRATIVE PROCEDURES ACT.

10 IT IS BENEFICIAL THAT WE HAVE THIS PETITION
11 IN THE SENSE THAT WE ARE PROMPTED TO DEVELOP A PROCESS
12 FOR RESPONDING EFFICIENTLY AND EFFECTIVELY TO
13 ADMINISTRATIVE PROCEDURES ACT REQUESTS, WHICH, NO
14 DOUBT, WE'LL HAVE MORE OF.

15 THE INTERIM SOLUTION, WHILE WE TRY AND GET
16 THE TIME TO ADDRESS THESE MEANINGFUL QUESTIONS IN
17 PUBLIC FORUMS, WOULD BE TO DELEGATE AUTHORITY TO THE
18 CHAIRPERSON, THE VICE CHAIRPERSON, THE PRESIDENT, THEIR
19 DESIGNEES, OR ANY COMBINATION THAT YOU WOULD LIKE.
20 WOULDN'T WANT TO PUT THIS ON ZACH HALL'S FIRST DUTIES,
21 BUT TO ACT ON BEHALF OF RESPONDING TO THE
22 ADMINISTRATIVE PROCEDURES ACT REQUEST.

23 THE PROCESS TO DATE IS WE RECEIVED THIS
24 PETITION ON FEBRUARY 16TH, THE STAFF RESPONDED IN
25 WRITING ACKNOWLEDGING AS REQUIRED BY THE CODE, ON

1 FEBRUARY THE 17TH WE RECEIVED IT. STAFF AND LEGAL
2 COUNSEL REVIEWED THE PETITION, MEMORANDA, AND APPENDIX,
3 AND ARE PREPARED TO WORK WITH THE CHAIR, VICE CHAIR,
4 AND/OR PRESIDENT TO RESPOND TO THE PETITION ON ITS
5 MERITS BY MARCH 18TH, WHICH IS THE 30-DAY MARK. I
6 WOULD ACTUALLY SAY THAT WE SHOULD BACK THAT UP AND MAKE
7 SURE WE RESPOND SEVERAL DAYS IN ADVANCE OF THAT DATE TO
8 GIVE OURSELVES A MARGIN.

9 ALTERNATIVELY, WE COULD TRY AND TAKE THE DAY
10 TODAY TO DISCUSS EACH ONE OF THESE AND TO DEVELOP
11 POLICIES. THAT WOULD BE VERY DIFFICULT TO ACHIEVE IN A
12 MEANINGFUL WAY. CERTAINLY WE WANT MORE MEMBERS OF THE
13 PUBLIC TO KNOW WE WERE GOING TO DISCUSS EACH ITEM.
14 WE'D WANT THE PUBLIC TO BE ABLE TO ADDRESS IT ON BOTH
15 SIDES OF EACH ISSUE, AND THE PUBLIC HAS HAD NO
16 EFFECTIVE NOTICE THAT WE WOULD HAVE A PUBLIC DEBATE ON
17 EACH OF THESE ITEMS TODAY. SO IF WE'RE GOING TO
18 INVOLVE THE PUBLIC MEANINGFULLY IN THIS PROCESS, IT
19 SEEMED TO BE MORE APPROPRIATE TO ALLOW THE STAFF TO
20 RESPOND TO THIS ON AN INTERIM BASIS AND MEANINGFULLY
21 SET UP, AS WE HAVE ALWAYS INTENDED TO DO, AGENDIZED
22 ITEMS WITH PUBLIC SPEAKERS, LIKE ALTA CHARO THIS
23 MORNING, EXPERT SPEAKERS THAT CAN HELP US ADDRESS IT
24 AND HELP US RESPOND IN THE MOST RESPONSIBLE FASHION.

25 WHAT IS THE PLEASURE OF THE BOARD?

1 MS. SAMUELSON: I HAVE AN INFORMATIONAL
2 QUESTION TO COUNSEL. IS IT THE CASE IN THIS SORT OF
3 PETITION, AS IT OFTEN IS IN LITIGATION, THAT EXTENSIONS
4 FOR SOME PERIOD OF TIME TO EXTEND THE TIME TO ANSWER
5 ARE GRANTED AS A MATTER OF COURTESY AMONG COLLEAGUES?
6 IT SEEMS TO ME --

7 CHAIRMAN KLEIN: CAN JAMES HARRISON ADDRESS
8 THIS, PLEASE?

9 MR. HARRISON: I'M SORRY. I WAS INTERRUPTED
10 FOR A MOMENT. IS THE QUESTION WHETHER THERE IS THE
11 POSSIBILITY OF AN EXTENSION OF TIME? UNFORTUNATELY,
12 THE CODE PROVIDES ONLY 30 DAYS FOR A RESPONSE.

13 DR. THAL: PROCEDURAL QUESTION. DO ALL OF
14 THESE NEED TO BE CONSIDERED AT ONCE? IS THIS A
15 SINGLE -- THERE ARE FIVE SEPARATE ITEMS. ARE THESE
16 ALL -- OR SEVEN SEPARATE ITEMS. DO WE DEAL WITH ALL OF
17 THESE AT ONE TIME? BECAUSE IN A SENSE WE'VE ALREADY
18 DEALT WITH ONE OF THEM, AND THAT RELATES TO THE SALARY
19 ISSUE.

20 CHAIRMAN KLEIN: YOU CANNOT RESPOND
21 EFFECTIVELY TO THE PETITION UNLESS YOU RESPOND TO ALL
22 THE POINTS. SO WE HAVE TO GIVE THEM A RESPONSE IN
23 WRITING THAT ADDRESSES THE ENTIRE PETITION.

24 MR. HALPERN: MR. CHAIRMAN, CHARLES HALPERN,
25 THE CO-PETITIONER WITH DR. PHILIP LEE.

1 CHAIRMAN KLEIN: EXCUSE ME, MR. HALPERN.
2 YOU'RE OUT OF ORDER.

3 MR. HALPERN: MAY I MAKE A POINT OF ORDER
4 BASED ON MY CONVERSATION WITH MR. HARRISON?

5 CHAIRMAN KLEIN: POINT OF ORDER IS ACCEPTED.

6 MR. HALPERN: THANK YOU. THE POINT OF ORDER
7 IS THIS, THAT THE PETITIONERS CAN WAIVE THE 30-DAY
8 LIMITATION. THANK YOU.

9 CHAIRMAN KLEIN: WOULD YOU BE WILLING TO
10 WAIVE THIS 30-DAY REQUIREMENT?

11 MR. HALPERN: MAY I HAVE FIVE MINUTES TO
12 SPEAK TO THE PETITION AND THAT QUESTION?

13 CHAIRMAN KLEIN: I THINK THAT -- LET THE
14 BOARD FINISH ITS DISCUSSION. AND THEN, MR. HALPERN, WE
15 GREATLY APPRECIATE YOUR WILLINGNESS TO DISCUSS THAT
16 ITEM. IF THE BOARD COULD PLEASE FINISH THEIR
17 DISCUSSION FIRST.

18 MR. HALPERN: THAT WOULD BE FINE. AT YOUR
19 PLEASURE.

20 CHAIRMAN KLEIN: DAVID SERRANO-SEWALL HAS A
21 QUESTION OF COUNSEL.

22 MR. SERRANO-SEWALL: I HAVE A COUPLE OF
23 QUESTIONS FOR COUNSEL. AND THAT IS, WHAT DOES THIS
24 PETITION ENABLE THE PETITIONER TO DO? WHAT IS IT THAT
25 THEY SEEK? CAN YOU GIVE US JUST A THUMBNAIL SKETCH OF

1 THE GOVERNMENT CODE AND WHAT RIGHTS IT GRANTS TO THE
2 PETITIONER?

3 MR. HARRISON: THE PETITIONER SUBMITTED THIS
4 PETITION PURSUANT TO A PROVISION IN THE ADMINISTRATIVE
5 PROCEDURE ACT WHICH PERMITS A CITIZEN TO REQUEST A
6 STATE AGENCY TO ADOPT REGULATIONS. THE CODE REQUIRES
7 THAT THE AGENCY RESPOND IN WRITING ON THE MERITS OF
8 EACH OF THE PROPOSED REGULATIONS WITHIN 30 DAYS.

9 MR. SERRANO-SEWELL: THANK YOU.

10 CHAIRMAN KLEIN: I WOULD ALSO BRING TO THE
11 BOARD'S ATTENTION WE WANT TO GET TO AT LEAST ADOPTING A
12 CONFLICT CODE FOR THE EMPLOYEES. WE JUST HIRED A
13 PRESIDENT. WE WANT TO GET A CONFLICTS CODE FOR
14 EMPLOYEES IN PLACE. WE HAVE OTHER ITEMS ON THIS
15 AGENDA. YES, DR. HENDERSON.

16 DR. HENDERSON: JUST TO PUT A MOTION ON THE
17 TABLE, THAT THIS ITEM BE REFERRED TO THE CHAIR OR THE
18 VICE CHAIR AND THE PRESIDENT TO FORMULATE A RESPONSE,
19 AND THAT WE DELEGATE THIS AUTHORITY TO YOU IN THE
20 INTEREST OF BOTH BEING COMPLETE AND RESPONSIVE.

21 DR. REED: SECOND.

22 CHAIRMAN KLEIN: ANY DISCUSSION OF THE
23 MOTION? DR. PRIETO.

24 DR. PRIETO: I HAVE SOME CONCERNS ABOUT THAT
25 BECAUSE I THINK THERE ARE SOME SUBSTANTIVE POINTS HERE

1 THAT WE, AT LEAST, NEED TO GIVE THE SENSE OF THE
2 COMMITTEE ON. AND SOME OF THESE POINTS, I FEEL, ARE
3 RELATIVELY NONCONTROVERSIAL, OR I WOULD HAVE LITTLE
4 PROBLEM WITH ITEMS 5 AND 6, FOR EXAMPLE. I THINK SOME
5 OF THE OTHERS DISCUSSES THE NIH GUIDELINES. I THINK
6 WE'VE EXPRESSED OUR SENSE BEFORE THAT WE FEEL THAT THE
7 NIH GUIDELINES AND STANDARDS ARE A MINIMUM THAT WE HOPE
8 TO HOLD TO. AND I THINK IT BEHOOVES US TO GIVE AT
9 LEAST A LITTLE BIT OF GUIDANCE AND NOT JUST HAND THIS
10 OVER TO YOU.

11 CHAIRMAN KLEIN: FOR EXAMPLE, DR. PRIETO, ON
12 ITEMS 5 AND 6, THERE CAN BE SUBSTANTIAL DIFFERENCES IN
13 THE BOARD. AND TO PROPERLY HAVE THE BOARD HAVE INPUT
14 ON THIS, ARE WE PREPARED AT THIS TIME TO HAVE A GENERAL
15 DISCUSSION OF IT? WE ARE DEFINITELY GOING TO HAVE A
16 VERY MAJOR DISCUSSION, WHICH THE PUBLIC SHOULD BE
17 INVITED TO AND GIVEN NOTICE OF, BECAUSE THE PUBLIC HAS
18 SOME VERY IMPORTANT THINGS TO SAY ON BOTH SIDES. AND
19 THERE ARE VERY LEGITIMATE CONCERNS AND VERY LEGITIMATE
20 POTENTIAL ISSUES HERE.

21 DR. PIZZO: JUST WITH REGARD TO ONE OF THE
22 ISSUES YOU RAISE, WHICH IS CONFLICT OF INTEREST, I
23 THINK THIS IS A VERY BOTH IMPORTANT, BUT COMPLICATED
24 TOPIC IN MANY DIFFERENT WAYS. AND I MUST TELL YOU THAT
25 RIGHT NOW TODAY I'M NOT PRECISELY SURE WHAT THE NIH

1 GUIDELINES ARE. I KNOW WHAT HAS BEEN IMPOSED BY THE
2 NIH DIRECTOR CURRENTLY IN TERMS OF A ONE-YEAR BAN OF
3 VARIOUS ACTIVITIES, BUT THAT DOESN'T DEFINE WHAT THE
4 GUIDELINES ARE. SO I THINK WE NEED TO HAVE SOME VERY
5 THOUGHTFUL DISCUSSION ABOUT THIS.

6 AND I THINK IT SHOULD BE -- THIS PARTICULAR
7 TOPIC SHOULD BE ONE THAT HAS PUBLIC HEARING AND
8 PARTICIPATION AROUND BECAUSE I DARE SAY THAT THE
9 CONSEQUENCES OF THE NIH ISSUE HAS HAD IMPLICATIONS FOR
10 ALL OF US IN VERY MANY DIFFERENT WAYS, AND THIS IS
11 SOMETHING THAT A LOT OF LIGHT SHOULD BE SHOWN ON AS WE
12 HAVE THE DISCUSSION.

13 DR. PRIETO: I WOULD AGREE ABSOLUTELY. AND
14 IF PETITIONER IS WAIVING HIS RIGHT TO A RESPONSE WITHIN
15 30 DAYS, I JUST WANT TO BE SURE THAT WE DON'T CLOSE THE
16 DOOR AND MAKE A DEFINITIVE RESPONSE TO THESE WITHOUT
17 HAVING FULLY DISCUSSED IT.

18 CHAIRMAN KLEIN: ALL RIGHT. DR. FRIEDMAN.

19 DR. FRIEDMAN: I WOULD AGREE WITH THAT AND
20 SAY THAT THESE ARE SUCH IMPORTANT ITEMS, THAT IT MIGHT
21 BE APPROPRIATE NOW, BECAUSE I'M SURE MY SENSE FROM MR.
22 HALPERN IS THAT HE WANTS SERIOUS AND THOUGHTFUL
23 ANSWERS, NOT QUICK AND TIMELY ANSWERS, BUT THOUGHTFUL
24 AND EXCELLENT ANSWERS. I WONDER IF I MIGHT ASK, MR.
25 CHAIRMAN, THAT WE SUSPEND OUR COMMENTS WITH THE

1 OPPORTUNITY TO COME BACK AND MAKE MORE TIME TO HEAR
2 FROM MR. HALPERN SINCE THERE IS THE CHANCE AT LEAST HE
3 WILL DELAY OUR NEED TO RESPOND QUICKLY, AND THAT WOULD
4 GIVE US THEN AN EXTRA AMOUNT OF TIME FOR CONSIDERATION
5 FOR PUBLIC AND OUR BOARD CONSIDERATION.

6 DR. REED: THANK YOU, MR. CHAIRMAN. I WOULD
7 LIKE LEGAL GUIDANCE ON WHAT CONSTITUTES AN ADEQUATE
8 RESPONSE TO A PETITION OF THIS SORT. WOULD IT BE
9 SUFFICIENT, FOR EXAMPLE, FOR US TO MERELY REPLY THAT
10 THESE ARE ISSUES THAT WE'RE STILL WORKING ON AND THAT
11 WHEN FULL PUBLIC COMMENTARY AND INPUT HAS BEEN
12 PROVIDED, ALONG WITH BOARD DISCUSSION, THAT WE WILL
13 HAVE ANSWERS? WOULD THAT BE AN ADEQUATE RESPONSE TO
14 PROVIDE WITHIN A 30-DAY TIME LIMIT?

15 CHAIRMAN KLEIN: COUNSEL?

16 MR. HARRISON: WELL, LIKE WITH LOTS OF THINGS
17 IN THE LAW, IT'S NOT EXACTLY CLEAR. THE CODE REQUIRES
18 A RESPONSE ON THE MERITS. ONE CAN CERTAINLY TAKE THE
19 POSITION THAT A RESPONSE THAT INDICATES THAT THESE ARE
20 SERIOUS ISSUES THAT REQUIRE CONSIDERATION, AND THAT THE
21 BOARD INTENDS TO CONSIDER, IS A RESPONSE ON THE MERITS.

22 CHAIRMAN KLEIN: FOR THE BENEFIT OF THE
23 PUBLIC, IT WOULD BE HELPFUL IF WE SUBSTANTIVELY LAID
24 OUT SOME OF THE THINGS WE'RE DOING UNDER EACH OF THESE
25 CATEGORIES TO PREPARE FOR THAT RESPONSE. BUT AT THIS

1 MOMENT, I THINK DR. FRIEDMAN'S SUGGESTION IS VERY
2 TIMELY AT THIS POINT.

3 MR. HALPERN, THANK YOU FOR YOUR PATIENCE.
4 AND COULD YOU NOW ADDRESS THE SUBJECT ABOUT THE
5 POTENTIALLY WAIVING?

6 MR. HALPERN: THANK YOU, MR. CHAIRMAN, AND
7 THANK YOU, DR. FRIEDMAN, FOR YOUR SUGGESTION BECAUSE I
8 DO HOPE THAT I CAN MAKE A SUGGESTION THAT WILL SERVE
9 THE NEEDS OF THE ICOC AND ALSO MOVE THIS PROCESS
10 FORWARD WITH THE FULLEST PUBLIC PARTICIPATION.

11 I WANT TO NOTE, FIRST OF ALL, THAT DR. LEE
12 AND I HAVE FILED THIS PETITION SOME TWO WEEKS AGO AND
13 THAT SINCE THEN SEVEN OTHER ORGANIZATIONS HAVE JOINED
14 IN IT IN WHOLE OR IN PART, INCLUDING SOME VERY
15 WELL-ESTABLISHED ORGANIZATIONS IN THE STATE THAT HAVE A
16 LONG AND HONORABLE RECORD FOR PARTICIPATING IN
17 GOVERNMENTAL PROCEEDINGS OF THIS FASHION.

18 AND I ALSO WANT TO NOTE THAT THE
19 ADMINISTRATIVE PROCEDURE ACT, AND PARTICULARLY THIS
20 PETITION PROVISION, WHICH WE'RE RESPONDING TO, IS THE
21 WAY THE STATE LEGISLATURE HAS ARRANGED FOR CONVERSATION
22 TO TAKE PLACE BETWEEN CITIZEN ORGANIZATIONS AND CITIZEN
23 GROUPS AND STATE AGENCIES. SO WE'RE TALKING ABOUT
24 SOMETHING THAT IS REALLY CORE TO THE DEMOCRATIC PROCESS
25 IN THIS STATE.

1 AND I THINK THE IDEA OF CUTTING OFF THE RIGHT
2 TO PETITION, WHICH IS THE PROPOSAL THAT WAS CIRCULATED
3 WITH THE AGENDA, IS A VERY POOR IDEA IN THAT RESPECT.
4 I HAVE AN IDEA THAT I THINK WILL MEET OUR NEEDS IN THE
5 PUBLIC AND THE NEEDS OF THE ICOC.

6 AND THAT IS THIS, THAT THE ICOC TODAY APPOINT
7 A SUBCOMMITTEE TO MEET WITH DR. LEE AND ME AND THE
8 OTHERS WHO HAVE SUPPORTED OUR PETITION AND ALSO TO PUT
9 OUT A PUBLIC NOTICE SO THAT OTHER PEOPLE WHO WANT TO
10 SPEAK TO ANY OF THE SEVEN POINTS RAISED IN OUR PETITION
11 ALSO HAVE AN OPPORTUNITY TO PARTICIPATE.

12 THAT SUBCOMMITTEE WOULD MEET ON THESE
13 PROPOSED REGULATIONS AND WOULD REPORT BACK AT THE APRIL
14 MEETING, HOPEFULLY, WITH SOME RECOMMENDED RESOLUTION.
15 IF SOME COULD BE RESOLVED AT THAT POINT, FINE. IF
16 OTHERS HAD TO GO OVER, THEY COULD GO OVER TO THE MAY
17 MEETING. ALL OF THESE ARE CENTRAL TO THE WAY THIS
18 ORGANIZATION DOES BUSINESS. NONE OF THEM ARE
19 PERIPHERAL OR MARGINAL.

20 SO MY SUGGESTION IS THAT THAT KIND OF OPEN
21 PROCESS WITH A SUBSET OF THIS GROUP OF 29 BEGIN
22 PROMPTLY AND HOPEFULLY PERMIT AN APRIL FINAL RESOLUTION
23 BY THE ENTIRE ICOC AT THE APRIL MEETING. IF THAT KIND
24 OF PROCEDURE WERE ACCEPTED BY THE ICOC, THEN WE WOULD
25 WAIVE OUR RIGHT TO A 30-DAY SUBSTANTIVE RESPONSE TO OUR

1 PETITION.

2 CHAIRMAN KLEIN: I THINK DAVID SERRANO-SEWALL
3 HAS AN OUTSTANDING REQUEST. IF I COULD RECOGNIZE THAT.
4 ALSO POINT OUT TO THE MEMBERS THAT IF WE APPOINT A
5 SUBCOMMITTEE OF THIS BOARD, WE NOW HAVE ANOTHER PUBLIC
6 BODY. AND ONE OF THE COMMITMENTS WE MADE TO THE PUBLIC
7 IS THAT THE PUBLIC GETS TO BE HEARD BEFORE THE FULL
8 BOARD. SO WE'RE TAKING THIS -- THESE VERY IMPORTANT
9 ISSUES OFF LINE FROM FULL PUBLIC DEBATE TO MEETINGS
10 WITH A SELECT GROUP OF PEOPLE, HOWEVER WELL
11 INTENTIONED, IN THE STATE RATHER THAN LETTING THE
12 PUBLIC MAKE THEIR CASE BEFORE THE FULL BOARD. THAT'S
13 AN ISSUE TRYING TO RETAIN OUR INTEGRITY OF OUR RESPONSE
14 TO THE FULL PUBLIC.

15 THAT DOES NOT MEAN THAT WE COULD NOT HAVE THE
16 PRESIDENT, THE VICE CHAIR, OR THE CHAIR AT YOUR
17 DISCRETION MEET WITH MR. HALPERN, MR. LEE, AND OTHERS
18 TO GET THEIR INPUT TO THE PROCESS THAT COULD HELP US
19 ADVANCE THE PUBLIC HEARINGS AND ADVANCE THE INPUT TO
20 THAT PROCESS.

21 MR. SERRANO-SEWALL: THANK YOU, CHAIRMAN
22 KLEIN AND COLLEAGUES. TO DR. HENDERSON'S MOTION, AND
23 THAT IS, SHOULD THE ICOC DELEGATE TO THE CHAIR, THE
24 VICE CHAIR, THE ACTING PRESIDENT THE LIMITED AUTHORITY,
25 PERHAPS, TO RESPOND TO THIS PARTICULAR PETITION, NOT TO

1 RESPOND TO THE ISSUES THAT ARE RAISED IN THE PETITION?
2 THAT'S A MATTER OBVIOUSLY FOR THE ICOC. AND I THINK
3 THAT THIS BODY HAS DONE NOTHING TO DISABUSE THE PUBLIC
4 OF THE NOTION THAT WE INTEND TO CONDUCT OUR BUSINESS IN
5 PRIVATE. EACH ONE OF US MADE A COMMITMENT TO OUR
6 APPOINTING OFFICERS THAT WE WOULD BE TRANSPARENT, THAT
7 WE WOULD BE OPEN. WE HAVE ATTORNEYS AT EVERY MEETING.
8 WE'RE IN FULL COMPLIANCE WITH BAGLEY-KEENE. AND THAT'S
9 WHAT WE HAVE TO DO. IT'S NOT SOMETHING YOU NEGOTIATE.
10 YOU DO THAT.

11 AND FOR THE ISSUES THAT COUNSEL RAISED, THE
12 30-DAY ISSUE, CERTAINLY THERE ARE OPTIONS; HOWEVER,
13 THERE'S A LOT OF PRESSING ISSUES FOR US TO ADDRESS, A
14 LOT OF IMPORTANT BUSINESS, WE'RE NOT GIVING ANYONE
15 SHORT SHRIFT. WE'RE JUST SAYING IN THIS INSTANCE FOR
16 THIS PETITION IT'S ADVISABLE TO DELEGATE IT TO THE
17 AFOREMENTIONED.

18 AND LET ME FURTHER ADD MY OWN LITTLE TWO-CENT
19 OBSERVATION, AND I'M CERTAINLY NOT PRIVY TO ANY LEGAL
20 STRATEGY FROM THE PETITIONERS, BUT IT STRIKES ME THAT
21 SUCH A PETITION COULD BE USED TO SEEK DECLARATORY
22 JUDICIAL INTERVENTION AND RELIEF SO THEY CAN
23 DEMONSTRATE TO THE COURT, NOT SAYING THEY'RE GOING TO,
24 BECAUSE I'M NOT PRIVY TO THEIR STRATEGY, BUT SUCH AN
25 APPLICATION COULD BE SUBMITTED IN AN APPLICATION TO

1 COURT THAT THEY'VE EXHAUSTED THEIR ADMINISTRATIVE
2 REMEDIES. I'M NOT SAYING THIS IS WHERE THIS IS GOING.
3 I DON'T THINK SO. WHY? BECAUSE WE'RE GOING TO RESPOND
4 TO THESE ISSUES IN A DELIBERATE AND FORTHRIGHT MANNER.
5 I HAVE EVERY FAITH IN BOB AND ED AND ZACH THAT THEY
6 WILL PROVIDE A THOUGHTFUL, CAREFUL ANALYSIS BASED ON
7 THE MERITS.

8 CHAIRMAN KLEIN: AND LET ME SAY IN THAT, JUST
9 BEING CAREFUL LEGALLY, IT WOULD BE ANY TWO, AS I
10 UNDERSTAND IT, OUT OF THE THREE OF US BECAUSE ONCE YOU
11 DESIGNATE THREE OF US, THEN YOU HAVE A COMMITTEE.

12 DR. PIZZO: ZACH IS NOT A MEMBER OF THE
13 COMMITTEE.

14 CHAIRMAN KLEIN: IS THAT ACCEPTABLE?

15 MR. HARRISON: IF THEY DELEGATE TO THE CHAIR,
16 YOU HAVE AN INHERENT AUTHORITY TO WORK WITH THE
17 PRESIDENT TO RESPOND, SO THE DELEGATION SHOULD BE TO
18 YOU AS CHAIR.

19 CHAIRMAN KLEIN: IS THERE ANY PROBLEM IN
20 DELEGATING TO -- THAT'S FINE. MY VICE CHAIR IS SAYING
21 HE'S COMFORTABLE WITH THE DELEGATION TO ME.
22 EVERYTHING -- ALL THE DELEGATIONS AND ALL THE USE OF
23 THE DELEGATED POWERS WOULD BE LIMITED TO THIS PETITION
24 AND, IN FACT, WOULD BE REPORTED BACK TO THE BOARD.

25 MR. SHEEHY: I JUST WANTED TO MAKE A POINT.

1 IF SO MANY ORGANIZATIONS HAVE SIGNED ONTO THIS
2 PETITION, I'M EXTREMELY UNCOMFORTABLE NEGOTIATING WITH
3 ONLY ONE OF THE SIGNATORIES. I THINK OUR BURDEN IS TO
4 RESPOND TO THIS WITHIN THE TIME FRAME UNLESS WE HAVE
5 REPRESENTATIVES OF ALL THE SIGNATORIES HERE WITH WHICH
6 TO NEGOTIATE. SO I WOULD HOPE WE COULD GO AHEAD AND
7 PROCEED TO A VOTE ON THIS MOTION.

8 CHAIRMAN KLEIN: I THINK IT'S AN IMPORTANT
9 POINT THAT IF YOU HAVE -- IT'S BEEN REPRESENTED THERE
10 ARE A NUMBER OF PEOPLE SIGNED ON, SO NO ONE CAN WAIVE
11 THE PRIVILEGE OR THE RIGHTS. BUT WE DO APPRECIATE, MR.
12 HALPERN, THE GESTURE DEFINITELY. AND THAT DOESN'T STOP
13 US FROM SITTING DOWN WITH YOU AND GETTING YOUR INPUT.

14 DR. PIZZO.

15 DR. PIZZO: I WANT TO JUST ALSO SUPPORT THE
16 PROPOSITION OF MR. SERRANO-SEWALL BECAUSE I THINK
17 THAT -- ALSO THAT COMES FROM DR. HENDERSON -- I THINK
18 THAT WE WANT TO HAVE THIS DISCUSSION TAKE PLACE IN A
19 PUBLIC SETTING AND TO HAVE FULL DIALOGUE AROUND IT
20 THAT'S FULLY ENGAGING. THESE ARE VERY IMPORTANT ISSUES
21 FOR SURE. AND AT THE SAME TIME, I THINK IT'S VERY
22 PRUDENT TO DELEGATE TO THE CHAIR THE RESPONSIBILITY TO
23 HAVE THE DISCUSSION WITH THE PETITIONER SO THAT WE CAN
24 BENEFIT FROM THAT AND THEN BRING IT BACK TO A PUBLIC
25 FORUM.

1 CHAIRMAN KLEIN: OKAY. MR. HALPERN,
2 APPRECIATING THAT YOU HAVE MADE A COMMENT BEFORE, ARE
3 THERE OTHER MEMBERS OF THE PUBLIC THAT WOULD LIKE TO
4 COMMENT? YES, THERE IS ANOTHER MEMBER OF THE PUBLIC.

5 MS. FOGEL: THANK YOU. MY NAME IS SUSAN
6 FOGEL. I'M ONE OF THE CO-FOUNDERS OF THE PRO CHOICE
7 ALLIANCE FOR RESPONSIBLE RESEARCH. AND WE ARE -- I AM
8 A MEMBER OF THE PUBLIC, AND WE ARE ONE OF THE
9 ORGANIZATIONS WHO ARE SUPPORTING THIS PETITION.

10 AND I STRONGLY URGE YOU TO ALL OF YOU TO TAKE
11 RESPONSIBILITY THAT YOU AGREED TO SERVE THE PUBLIC, NOT
12 TO DELEGATE THIS DISCUSSION BEHIND CLOSED DOORS, WHICH
13 IS WHAT A DELEGATION TO THE CHAIR WOULD DO, BUT TO HAVE
14 A PUBLIC DISCUSSION OF THE PETITION AND OF THE ISSUES
15 THAT ARE RAISED IN IT. ONE OF THE MOST CRITICAL THINGS
16 THAT WE ARE SUPPORTING IS THAT NO MONEY GO OUT THE DOOR
17 UNTIL THESE FOUNDATIONAL ISSUES ARE RESOLVED.

18 WE SPENT THE WHOLE MORNING TALKING ABOUT
19 OPENNESS. AND ALTA CHARO TALKED ABOUT OPENNESS AND
20 TRANSPARENCY. YOU SPOKE ABOUT OPENNESS AND
21 TRANSPARENCY. MR. SPOKE ABOUT OPENNESS AND
22 TRANSPARENCY. AND HERE IS A PUBLIC REQUEST TO HAVE A
23 FULL-BLOWN DISCUSSION OF THE FOUNDATIONAL ISSUES UPON
24 WHICH THIS WHOLE INSTITUTION IS GOING TO BE BUILT, AND
25 WE'RE TALKING ABOUT CLOSED DISCUSSIONS. SO I URGE YOU

1 TO NOT DELEGATE THIS AND, RATHER, TO SCHEDULE SOME OPEN
2 MEETINGS ON THESE ISSUES.

3 YOU JUST HAD A WHOLE BUNCH OF PEOPLE WHO
4 AGREED TO BE SITES FOR PUBLIC MEETINGS. AND THERE'S
5 TIME TO WORK WITH THE PETITIONERS TO GET AN EXTENSION
6 OF TIME SO THAT WE CAN HAVE THIS PUBLIC DISCUSSION
7 RATHER THAN NIPPING IT IN THE BUD. THANK YOU.

8 DR. PIZZO.

9 DR. PIZZO: I JUST WANTED TO SAY, AS I SAID
10 EARLIER, THAT PUBLIC DISCUSSION IS PRECISELY WHAT WE'RE
11 LOOKING FOR. AND I THOUGHT THAT WAS VERY MUCH THE
12 INTENT OF MY DIALOGUE EARLIER, THAT WE HAVE THESE
13 ISSUES BROUGHT FORTH FOR FULL DISCUSSION, BOTH WITH THE
14 ICOC AND WITH THE PUBLIC AT A PUBLIC FORUM.

15 CHAIRMAN KLEIN: RIGHT. AND I THINK TO
16 REEMPHASIZE THE POINT, IT'S CLEARLY BEEN STATED, THE
17 INTENT IS TO HAVE PUBLIC MEETINGS ON THESE WITH
18 SUFFICIENT NOTICE TO THE PUBLIC THAT THE ENTIRE PUBLIC
19 CAN SHOW UP. WHILE WE CAN RESPECT AND APPRECIATE THE
20 CONTRIBUTION THAT'S DESIRED TO BE MADE BY FIVE OR SIX
21 OR SEVEN GROUPS, THAT'S NOT THE PUBLIC. THE PUBLIC
22 HAPPENS TO BE 30 MILLION PEOPLE, AND THEY NEED NOTICE
23 AND THEY NEED AN OPPORTUNITY TO SHOW UP. WE ACCEPT THE
24 FACT AND RECOGNIZE AND HAVE TALKED ABOUT HOLDING PUBLIC
25 HEARINGS. WE INTEND TO HOLD PUBLIC HEARINGS ON THESE

1 MATTERS. IT'S VERY CLEAR.

2 FURTHERMORE, THE INITIATIVE MAKES IT VERY
3 CLEAR. WE CANNOT HAVE RESEARCH GRANTS WITHOUT
4 STANDARDS IN PLACE. THERE'S NO QUESTION ABOUT THAT.
5 AND ANY STATEMENT TO THE CONTRARY IS A
6 MISREPRESENTATION OF THE INITIATIVE. IT REQUIRES IT.

7 MR. REED: AS ANOTHER MEMBER OF THE PUBLIC, I
8 THINK IT'S IMPORTANT THAT WE PROCEED WITH ALL SPEED. I
9 THINK THAT WE RUN A RISK OF ESTABLISHING MORE AND MORE
10 COMMITTEES TO STUDY MORE AND MORE ISSUES. WHAT IS TO
11 GUARANTEE THAT THERE WILL NOT BE OTHER ISSUES THAT WILL
12 REQUIRE MORE AND MORE THINGS? IN THE MEANTIME WE'RE
13 DELAYING, DELAYING, DELAYING. WE HAVE PATIENTS WHO ARE
14 SUFFERING NOW. WE ARE IN A PUBLIC FORUM RIGHT NOW.
15 WE'RE DEBATING THIS IN A PUBLIC MANNER. THERE IS
16 ADEQUATE PROCEDURE SET UP FOR PUBLIC DEBATE. WE'RE
17 DOING IT NOW. WE CAN DO IT AGAIN.

18 THE IDEA OF SETTING UP MORE AND MORE
19 COMMITTEES TO HAVE MORE AND MORE DIFFERENT DELAYING
20 THINGS, I WOULD QUESTION THE VALIDITY OF MORE AND MORE
21 DELAYS. WE'VE GOT PEOPLE THAT ARE SUFFERING NOW.

22 CHAIRMAN KLEIN: THANK YOU VERY MUCH.

23 MS. MC VAY: MY NAME IS KAY MC VAY. I'M WITH
24 THE CALIFORNIA NURSES ASSOCIATION, AND WE DO SUPPORT
25 THIS PETITION. WE THINK THAT THERE NEEDS TO BE VERY

1 THOUGHTFUL INVESTIGATION AND COMMITMENT TO THE VERY
2 THING THAT I'M HERE TO MAKE SURE IS HAPPENING, AND IT'S
3 AN OPEN MEETING WITH OPEN DISCUSSION WHERE YOU REALLY
4 GO INTO WHAT'S GOING TO HAPPEN TO PATIENTS.

5 MY BIGGEST INTEREST, MY MAIN INTEREST, IS
6 WHAT HAPPENS TO PATIENTS. THAT'S WHY THIS PETITION
7 CAME FORWARD. IT IS NOT SOMETHING THAT WAS DONE
8 LIGHTLY. IT WAS DONE WITH FULL THOUGHT ABOUT HOW
9 PATIENTS ARE CARED FOR AND HOW THIS ORGANIZATION IS
10 GOING TO AFFECT THEIR CARE. AND WE WANT TO SAFEGUARD
11 THEM.

12 SO YOU TAKE 30 DAYS. THAT MIGHT MAKE A HUGE
13 DIFFERENCE IN HOW YOU FUNCTION AND HOW YOU GO FORWARD
14 TO REALLY ACHIEVE THE GOALS THAT I'M SURE EACH AND
15 EVERY ONE OF YOU ARE ON THIS COMMITTEE TO MAKE SURE
16 HAPPENS.

17 MR. FRANK: GOOD AFTERNOON, MR. KLEIN, LADIES
18 AND GENTLEMEN. TERRY FRANK WITH CALIFORNIANS AWARE. I
19 THINK THERE'S LITTLE AMBIGUITY LEFT ABOUT WHAT IS BEING
20 DELEGATED HERE AND WHAT A RESPONSE MEANS. IF, AS
21 MR. HARRISON SUGGESTS, A RESPONSE WITHIN THE MEANING OF
22 THE LAW ON THE MERITS CAN BE ONE THAT SAYS WE TAKE YOUR
23 ISSUES SERIOUSLY AND WE'RE GOING TO GIVE THEM SERIOUS
24 CONSIDERATION, YOU CAN SAY THAT RIGHT NOW. THE ICOC
25 OBVIOUSLY FEELS THAT WAY. YOU CAN MAKE A RESPONSE TO

1 THAT EFFECT RIGHT NOW WITHOUT COMMITTING YOURSELF TO
2 ANY SUBSTANCE.

3 ON THE OTHER HAND, IF RESPONSE MEANS A HARD,
4 DETERMINATIVE RESPONSE WILL GIVE YOU THIS, WE WON'T
5 GIVE YOU THAT, GO AWAY, THEN IT'S CLEARLY SOMETHING
6 THAT I DON'T BELIEVE CAN BE DELEGATED TO MR. KLEIN OR
7 ANYONE ELSE. THAT'S AN ACT OF RULEMAKING, AND IT'S ONE
8 THAT IS YOUR RESPONSIBILITY.

9 SO IF YOU GO FOR INTERPRETATION A, THEN THE
10 ICOC CAN TODAY, BASED ON THE RECORD OF WHAT'S BEEN SAID
11 AROUND THE TABLE, INDEED TELL THE PETITIONERS THAT THE
12 PETITION IS IN HAND, IT'S BEING TAKEN SERIOUSLY, AND IT
13 WILL BE DOCKETED FOR A DELIBERATIVE DISCUSSION AT THE
14 NEXT MEETING. THANK YOU.

15 DR. BARGLOW: MY NAME IS RAYMOND BARGLOW.
16 I'M REPRESENTING TODAY THE STEM CELL ACTION NETWORK,
17 WHICH IS A NATIONWIDE PATIENT ADVOCACY ORGANIZATION.
18 WE'RE ALSO -- OUR ORGANIZATION ALSO BELONGS TO THE
19 COALITION FOR THE ADVANCEMENT OF MEDICAL RESEARCH.

20 I BELIEVE THIS DISCUSSION IS A VERY IMPORTANT
21 ONE. WE PATIENTS AND THEIR FAMILIES AND FRIENDS, AND
22 OBVIOUSLY I CAN'T SPEAK FOR ALL PATIENTS, BUT I SPEAK
23 FOR A VERY ACTIVIST GROUP THAT'S BEEN CENTRAL, I THINK,
24 TO ADVANCING THE CAUSE OF STEM CELL RESEARCH, BOTH HERE
25 IN CALIFORNIA AND NATIONWIDE.

1 WE APPRECIATE AND APPLAUD THE PRIORITY THAT
2 THE INSTITUTE IS GIVING TO ADVANCING STEM CELL SCIENCE
3 AND MOVING IT FROM THE LAB TO THE BEDSIDE IN A TIMELY
4 WAY, WHICH IS THE POINT THAT DON REED MADE. SOME
5 MISSTEPS AND SOME CONFUSION ARE INEVITABLE IN EMBARKING
6 ON AN UNDERTAKING OF THIS MAGNITUDE AND COMPLEXITY.
7 HOWEVER, WE'VE BEEN PAYING CLOSE ATTENTION TO THE
8 ESTABLISHMENT OF THE CALIFORNIA INSTITUTE FOR
9 REGENERATIVE MEDICINE AND ARE IMPRESSED WITH THE
10 DILIGENCE OF INSTITUTE PERSONNEL, INCLUDING THE HEARING
11 THE ICOC HAS GIVEN THIS MORNING TO PROFESSOR ALTA
12 CHARO'S DISCUSSION OF ETHICS.

13 WHILE ACKNOWLEDGING THAT IMPLEMENTATION OF
14 PROPOSITION 71 SHOULD BE SUBJECT TO CAREFUL AND ONGOING
15 CRITICAL SCRUTINY, AND I APPRECIATE THE WORK THAT
16 CHARLES HALPERN AND OTHERS HAVE DONE TO KEEP THE ISSUES
17 IN FRONT OF THE PUBLIC, ALTHOUGH THAT PUBLIC IS VERY
18 DIVERSE, I DON'T BELIEVE THAT THE PUBLIC IS ENTIRELY
19 REPRESENTED BY THE SEVEN GROUPS.

20 WE NOTE THAT THE MEASURE PLACES FULL
21 AUTHORITY FOR IMPLEMENTATION SQUARELY IN THE HANDS OF
22 THE INSTITUTE, WHICH IS A COMMITTEE WHOSE MEMBERS ARE
23 PUBLIC APPOINTED AND ENTRUSTED WITH IMPLEMENTATION.
24 THE ICOC AND THE CIRM WORKING GROUPS ARE
25 CONSCIENTIOUSLY BEGINNING TO DO THEIR WORK AND SHOULD

1 BE ALLOWED TO CONTINUE DOING SO.

2 WE ARE CONCERNED ABOUT THE EFFORT ON THE PART
3 OF A FEW CRITICS WHO HAVE APPOINTED THEMSELVES
4 GUARDIANS OF THE PUBLIC INTEREST TO SHAPE INSTITUTE
5 POLICIES. AND WE'RE DISMAYED BY THE MASSIVE PUBLICITY
6 CAMPAIGN OF MISINFORMATION THAT THESE CRITICS HAVE
7 LAUNCHED TO DISCREDIT THE INSTITUTE.

8 THE LAWSUITS BEING FILED BY THE CRITICS ARE
9 BASED LARGELY, NOT ENTIRELY, BUT LARGELY UPON EXTREMIST
10 RELIGIOUS AND IDEOLOGICAL AGENDAS. AND THEY ARE AT
11 ODDS, WE BELIEVE, WITH THE INSTITUTE MISSION, WHICH IS
12 TO ADVANCE STEM CELL RESEARCH AND FIND EFFECTIVE
13 TREATMENTS FOR DEVASTATING ILLNESSES. SO THAT'S THE
14 OPINION OF SOME STEM CELL ACTIVISTS WHO COME FROM THE
15 PATIENT ADVOCACY COMMUNITY.

16 CHAIRMAN KLEIN: THANK YOU VERY MUCH. ONE
17 MORE PUBLIC COMMENT.

18 MR. REYNOLDS: THANK YOU. I'M JESSE REYNOLDS
19 FROM THE CENTER FOR GENETICS IN SOCIETY, AND THE
20 CENTER, ALONG WITH THE GROUPS, THE PRO CHOICE ALLIANCE
21 FOR RESPONSIBLE RESEARCH, CALPERG, THE CALIFORNIA
22 NURSES ASSOCIATION, CALIFORNIANS AWARE, THE GREEN
23 LINING INSTITUTE, REDEFINING PROGRESS, AND THE
24 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS HAVE SIGNED
25 ON IN SUPPORT OF THIS PETITION.

1 I THINK THAT THE DIVERSITY OF THE INTERESTS
2 OF THESE GROUPS AND THE FACT THAT NONE OF THESE GROUPS
3 OPPOSE EMBRYONIC STEM CELL RESEARCH, MOST OF THEM
4 EXPLICITLY SUPPORT IT, SPEAKS TO THE HONESTY AND THE
5 IMPORTANCE OF THE ACTUAL ITEMS ON THE PETITION. THIS
6 IS NOT AN ATTEMPT TO STOP EMBRYONIC STEM CELL RESEARCH.
7 WE WANT IT TO BE DONE RIGHT.

8 AND WE FEEL THAT ANY EFFORT TO TAKE THIS
9 DISCUSSION OF THESE VERY IMPORTANT ITEMS, WHICH
10 CHAIRMAN KLEIN SAID WERE VERY IMPORTANT ISSUES THAT DID
11 NEED TO BE DISCUSSED IN PUBLIC, ANY EFFORT TO TAKE
12 THESE ISSUES AND MOVE THEIR DISCUSSION BEHIND CLOSED
13 DOORS IS A DISSERVICE TO THE PETITIONERS, IT'S A
14 DISSERVICE TO THESE GROUPS. IN FACT, IT IS A
15 DISSERVICE TO THE INSTITUTE ITSELF AND TO THE PEOPLE OF
16 CALIFORNIA. THANK YOU.

17 CHAIRMAN KLEIN: POINT OF INFORMATION. IS
18 THE CENTER FOR GENETICS IN SOCIETY PART OF THE GROUP
19 THAT YOU IDENTIFIED?

20 MR. REYNOLDS: YES. THAT IS GROUP THAT I AM
21 AFFILIATED WITH, AND IT IS ONE OF THE GROUPS THAT
22 ENDORSED THE PETITION.

23 CHAIRMAN KLEIN: IS WESLEY SMITH PART OF THAT
24 GROUP?

25 MR. REYNOLDS: NO. WE HAVE NO RELATIONSHIP

1 WITH WESLEY SMITH.

2 CHAIRMAN KLEIN: SO YOU ARE SUPPORTIVE OF
3 STEM CELL RESEARCH; IS THAT RIGHT?

4 MR. REYNOLDS: WE SUPPORT EMBRYONIC STEM CELL
5 RESEARCH AND, IN FACT, THE PUBLIC FUNDING OF EMBRYONIC
6 STEM CELL RESEARCH.

7 CHAIRMAN KLEIN: THANK YOU. WE HAVE GONE
8 THROUGH THE COMMENTS, AND YOU HAVE HAD A COMMENT. IN
9 RESPECTING -- WE HAVE CONFLICTS OF INTEREST ISSUES
10 POLICY WE NEED TO GET ADDRESSED. THERE ARE THINGS THAT
11 YOU WANT TO ADDRESS THAT MATERIALLY AND SUBSTANTIVELY
12 WILL HELP MOVE THE POLICY FORWARD IN, I THINK, THE
13 DIRECTION THAT YOU WOULD LIKE TO SEE ADDRESSED, BUT WE
14 SUBSTANTIVELY HAVE TO HAVE THE TIME TO DEAL WITH THAT.

15 DR. FRIEDMAN.

16 DR. FRIEDMAN: IF I MAY, I'D LIKE TO SUGGEST
17 A MODIFICATION TO DR. HENDERSON'S EARLIER COMMENTS. I
18 WOULD LIKE TO SUGGEST THAT THE ICOC TODAY IN THE MOST
19 RESPECTFUL AND SOBER WAY RECOGNIZE THAT THESE ARE
20 IMPORTANT TOPICS, THAT WE MAKE A DECISION HERE AND NOW
21 THAT OUR FORMAL RESPONSE WILL BE THESE ARE SO
22 IMPORTANT, THAT WE WILL LAY THESE OUT IN PUBLIC
23 MEETINGS. AND JUST TO REPEAT WHAT YOU SAID EARLIER,
24 CHAIRMAN, THAT WE WILL NOT BE DISPENSING FUNDS TO
25 GRANTS UNTIL THESE POLICIES ARE EXPLICITLY DEALT WITH

1 IN THE MOST SERIOUS WAY, SAY, YES, THANK YOU FOR
2 POINTING THESE OUT, AND OUR FORMAL RESPONSE IS WE WILL
3 HOLD PUBLIC DISCUSSIONS PROPERLY NOTICED, PROPERLY
4 PREPARED FOR, AND THAT'S HOW WE WILL DEAL WITH THIS.
5 AND I SUGGEST, MR. CHAIRMAN, THAT BE OUR FORMAL
6 RESPONSE TODAY, AND THAT WE NOT GIVE IT TO YOU AND A
7 SUBGROUP TO WORK ON.

8 CHAIRMAN KLEIN: WELL, THE -- I SUGGEST THAT
9 THAT'S A GOOD PUBLIC RESPONSE AS AN OPTION. SOMEBODY
10 NEEDS TO BE ABLE TO BE AUTHORIZED TO WRITE A WRITTEN
11 RESPONSE TO CONFORM WITH THE ADMINISTRATIVE CODE.

12 DR. FRIEDMAN: EXPRESSING THAT SENTIMENT.

13 CHAIRMAN KLEIN: SO THERE WAS A MOTION ON THE
14 TABLE. THERE'S BEEN AN AMENDMENT SUGGESTED. DOES THE
15 MAKER OF THE MOTION ACCEPT THE AMENDMENT?

16 DR. HENDERSON: YES.

17 CHAIRMAN KLEIN: AMENDMENT HAS BEEN ACCEPTED
18 TO THE MOTION. COMMENTS ON THE MOTION? OSWALD
19 STEWARD. DR. STEWARD.

20 DR. STEWARD: CAN WE HAVE AN INDICATION FROM
21 COUNSEL ABOUT WHETHER THAT WOULD BE APPROPRIATE AS A
22 SUBSTANTIVE RESPONSE?

23 MR. HARRISON: I THINK THAT THAT APPROACH IS
24 ARGUABLY A SUBSTANTIVE RESPONSE, BUT THAT POSITION IS
25 NOT ENTIRELY CLEAR. WHAT YOU'D BE SUGGESTING IS THAT

1 YOU'LL CONSIDER THESE ISSUES, THAT THEY'RE SERIOUS
2 ISSUES, AND THAT YOU WILL NOTICE PUBLIC HEARINGS TO
3 DISCUSS THEM. WHAT THE CODE REQUIRES IS THAT YOU
4 CONSIDER THEM ON THE MERITS WITHIN 30 DAYS. SO IN THE
5 ABSENCE OF SOME ASSURANCE FROM THE PETITIONERS
6 THEMSELVES, ALL OF THEM, THAT THEY'D BE WILLING TO
7 EXTEND THAT TIME SO THAT YOU COULD NOTICE PUBLIC
8 HEARINGS TO DISCUSS ALL OF THESE ISSUES IN THEIR
9 ENTIRETY, IT'S A --

10 CHAIRMAN KLEIN: COUNSEL, IT DOESN'T REQUIRE
11 US TO HAVE PUBLIC MEETINGS WITHIN 30 DAYS. IT REQUIRES
12 THAT WE HAVE A RESPONSE WITHIN 30 DAYS.

13 MR. HARRISON: THAT'S CORRECT.

14 CHAIRMAN KLEIN: SO WE CAN HAVE A RESPONSE
15 WITHIN 30 DAYS, BUT THE RESPONSE CAN MEMORIALIZE THE
16 FACT THAT WE INTEND, WE'VE ALWAYS INTENDED, AND WE WILL
17 RECOGNIZE -- WANT RECOGNITION THAT WE'VE ALWAYS
18 INTENDED ON EACH OF THESE ITEMS TO HAVE PUBLIC
19 HEARINGS, AND THAT WE WILL HOLD PUBLIC HEARINGS ON
20 THESE WHERE THE WHOLE PUBLIC IS INVITED, NOT A SMALL
21 SEGMENT OF THE PUBLIC. AND THAT, IN FACT, THERE WILL
22 BE NO RESEARCH GRANTS UNTIL THERE ARE STANDARDS IN
23 PLACE.

24 NOW, WE CAN PROVIDE A RESPONSE THAT THEN ALSO
25 RECOGNIZES THE STEPS WE'RE TAKING TO GET TO A

1 MEANINGFUL SET OF PUBLIC HEARINGS IN THAT PROCESS; IS
2 THAT CORRECT, COUNSEL?

3 MR. HARRISON: THAT IS CORRECT, BUT YOU
4 SHOULD KNOW THAT THERE'S SOME VULNERABILITY THAT ONE
5 COULD TAKE THE POSITION THAT THAT IS NOT A SUBSTANTIVE
6 RESPONSE ON THE MERITS.

7 CHAIRMAN KLEIN: I WOULD ASK THAT WE AMEND IT
8 TO GIVE ME DISCRETION TO WORK WITH COUNSEL --

9 DR. FRIEDMAN: ACCEPTED.

10 DR. HENDERSON: ACCEPTED.

11 CHAIRMAN KLEIN: -- TO MAKE SURE WE HAVE A
12 SUBSTANTIVE RESPONSE.

13 DR. PIZZO: CALL THE QUESTION.

14 CHAIRMAN KLEIN: THE QUESTION HAS BEEN
15 CALLED. ALL IN FAVOR. OPPOSED. THANK YOU.
16 APPRECIATE IT. APPRECIATE IT, MR. HALPERN. APPRECIATE
17 ALL OF THE DIFFERENT ORGANIZATIONS' INPUT, AND WE DO
18 BELIEVE, AS WE'VE PREVIOUSLY STATED, THESE ARE VERY
19 IMPORTANT PUBLIC MEETINGS THAT WE WILL HAVE WITH PUBLIC
20 DEBATE, INCLUDING PUBLIC REPRESENTATION OF BOTH SIDES
21 OF THESE ISSUES. THANK YOU.

22 IT'S VERY IMPORTANT THAT WE, NOW THAT WE HAVE
23 A PRESIDENT AND WE ARE BEGINNING TO BUILD A STAFF, THAT
24 WE AT LEAST TODAY ADDRESS THE EMPLOYEE CONFLICTS
25 ISSUES. I WOULD SUGGEST THAT FROM THE LAST MEETING WE

1 HAVE A DRAFT OF SOME IDEAS DEALING -- FROM COUNSEL WHO
2 TRIED TO CAPTURE THE SENSE OF THE PRIOR MEETING ON SOME
3 IDEAS DEALING WITH CONFLICT ON THE MEMBERS. I'D LIKE
4 THE MEMBERS TO CONSIDER THAT FOR THE NEXT MEETING, BUT
5 I WANT TO GET AT LEAST, WITH THE LIMITED TIME
6 AVAILABLE, THE EMPLOYEE CONFLICTS POLICY IN PLACE
7 TODAY.

8 IF WE CAN DO THAT, AND IF YOU GO TO TAB 10,
9 THE CONFLICTS OF INTEREST CODE OF THE CALIFORNIA
10 INSTITUTE FOR REGENERATIVE MEDICINE IS A DISCLOSURE
11 CODE THAT DOES ADDRESS THE BOARD AND THE EMPLOYEES, BUT
12 IT IS THE DISCLOSURE CODE THAT HAS ALREADY BEEN
13 ADDRESSED BY THE BOARD IN THEIR FILING OF FORM 700. IS
14 THAT A CORRECT STATEMENT, COUNSEL, THAT THE DESIGNATED
15 EMPLOYEE CATEGORY FOR DISCLOSURE FOR THE BOARD MEMBERS
16 AS REPRESENTED HERE ON THIS CONFLICT OF INTEREST CODE
17 HAS BEEN SATISFIED AND IS CONTINUING TO BE SATISFIED BY
18 FORM 700 DISCLOSURE OF THE BOARD?

19 MR. HARRISON: YES. ALL THE BOARD MEMBERS
20 DISCLOSED UNDER THE HIGHEST DISCLOSURE THRESHOLD,
21 SECTION 87200 OF THE POLITICAL REFORM ACT. AND THE
22 SAME DISCLOSURE CATEGORY WOULD CONTINUE TO APPLY TO THE
23 BOARD MEMBERS.

24 CHAIRMAN KLEIN: BUT WE ARE INCLUDING THE
25 PRESIDENT, THE CHIEF SCIENTIFIC OFFICER, THE ETHICS

1 OFFICER, AND OTHER INDIVIDUALS AT THE POLICY LEVEL OF
2 THE INSTITUTE EMPLOYEE STAFF IN THIS DISCLOSURE
3 CATEGORY. ALL RIGHT. IS THERE --

4 DR. BALTIMORE: COULD I MAKE TWO POINTS? ONE
5 IS MAYBE IT WOULD BE EASIER IF COUNSEL SAT AT THE TABLE
6 AND TOOK A MICROPHONE AND DIDN'T HAVE TO GO BACK AND
7 FORTH ALL THE TIME.

8 THE OTHER --

9 MR. HARRISON: THIS IS FINE. I'LL PERCH.

10 DR. BALTIMORE: THAT WILL KEEP US ALL IN
11 BETTER POSITION.

12 AND THE OTHER IS THAT UNDER CATEGORY 1, AND I
13 HAD THIS DISCUSSION AT LUNCH, AND I THINK IT JUST NEEDS
14 CLARIFICATION, UNDER CATEGORY 1 IT SAYS A DESIGNATED
15 EMPLOYEE IN THIS CATEGORY SHALL REPORT ALL INVESTMENTS,
16 BUSINESS POSITIONS, AND INCOME, INCLUDING GIFTS, LOANS,
17 TRAVEL, AND ALL INTEREST IN REAL PROPERTY LOCATED IN
18 THE STATE OF CALIFORNIA. WHAT WE FILLED OUT FOR FORM
19 700 WAS NOTHING LIKE THAT AS THAT'S WRITTEN IN ENGLISH.

20 NOW, I SAY AS THAT WAS WRITTEN IN ENGLISH
21 BECAUSE AT LUNCH WE HAD A DISCUSSION IN WHICH IT WAS
22 SAID, WELL, IF YOU TREAT ALL THESE WORDS AS LEGAL WORDS
23 FOR THE STATE OF CALIFORNIA REGULATIONS, THEN IT LOOKS
24 LIKE FORM 700. BUT IT IS ENGLISH AND IT DOESN'T LOOK
25 LIKE FORM 700.

1 MR. HARRISON: THAT'S CORRECT. THESE ARE ALL
2 DEFINED TERMS UNDER THE POLITICAL REFORM ACT.

3 CHAIRMAN KLEIN: JAMES HARRISON, COULD WE
4 HAVE THE ATTORNEY GENERAL, TED PRIMM, DEPUTY ATTORNEY
5 GENERAL, PLEASE ADDRESS THIS BECAUSE HE IS AN EXPERT IN
6 THIS PARTICULAR SUBJECT. I BELIEVE, TED, THEY'RE
7 HOLDING UP A MICROPHONE FOR YOU.

8 MR. PRIMM: WELL, I WAS THE ONE THAT HAD THE
9 DISCUSSION AT LUNCH. AND THE DIFFICULTY IS THAT, FOR
10 EXAMPLE, YOU ALL ARE DISCLOSING UNDER A CATEGORY THAT'S
11 SET OUT FOR STATEWIDE ELECTED OFFICERS, FOR EXAMPLE.
12 YOU DISCLOSE IN THE SAME ONE. WHAT THAT SAYS IS YOU
13 WILL DISCLOSE ALL INVESTMENTS, ALL INTERESTS IN REAL
14 PROPERTY, AND ALL SOURCES OF INCOME. AND THEN WE HAVE
15 DEFINITIONS OF EACH OF THOSE TERMS, WHICH INCLUDE SOME
16 FAIRLY LONG EXEMPTIONS FROM THOSE. FOR EXAMPLE, UNDER
17 SOURCE OF INCOME, THERE ARE LIKE 12 EXCEPTIONS. UNDER
18 INVESTMENTS THERE ARE A GROUP OF EXCEPTIONS ALSO. AND
19 THOSE EXCEPTIONS ARE THE KINDS OF THINGS THAT
20 DR. BALTIMORE IS TALKING ABOUT.

21 SO THAT, FOR EXAMPLE, WHEN THEY TALK ABOUT AN
22 INVESTMENT IN A BUSINESS ENTITY, THAT DOES NOT INCLUDE
23 A BUSINESS ENTITY THAT DOES NOT DO BUSINESS IN
24 CALIFORNIA. AND IT DOES NOT INCLUDE MUTUAL FUNDS.
25 THOSE ARE SPECIFICALLY EXCLUDED.

1 IF WE ARE TO TRY TO PUT ALL OF THESE
2 EXCEPTIONS ACTUALLY INTO THE CODE, THEN THIS THING IS
3 GOING TO BECOME PAGES LONG OF LEGAL --

4 DR. BALTIMORE: COULD YOU JUST SAY AS DEFINED
5 IN THE CODE AND GIVE A REFERENCE SO THAT --

6 MR. PRIMM: SURE. IF YOU WANT TO DO
7 SOMETHING LIKE THAT, WE CAN DO THAT. I THINK THAT'S
8 UNDERSTOOD, BUT I HAVE NO PROBLEM WITH THE FACT THAT WE
9 CAN SAY SOMETHING IN THERE THAT THE TERMS THAT ARE
10 BEING USED IN CODE ARE THE ONES --

11 DR. BALTIMORE: THAT WAY WE KNOW IT ISN'T
12 ENGLISH. IT'S LEGALESE.

13 MR. PRIMM: IT WILL STILL BE LEGALESE, BUT
14 MAYBE IT WILL BE MORE HELPFUL, AND THAT'S FINE.

15 DR. GOLDBERG: I THINK THE SIMPLE CRITERIA IS
16 I THINK WE'RE ALL COMFORTABLE WITH FORM 700 AND THE
17 CRITERIA THERE. I THINK WHAT'S UNCOMFORTABLE ABOUT
18 THIS LANGUAGE IS TO THE EXTENT THAT IT CONSTRUES OR
19 IMPLIES ANYTHING DIFFERENT THAN THAT, THAT'S ALL.

20 MR. PRIMM: THE FORM 700 ITSELF IS A LITTLE
21 BIT MISLEADING AS A CONCEPT BECAUSE THAT VERY SAME FORM
22 IS USED FOR PEOPLE LIKE THE GOVERNOR FILES A FORM 700.
23 AND SOMEBODY IN AN AGENCY WHO ONLY HAS TO DISCLOSE SOME
24 NARROW PIECE OF ECONOMIC INTEREST USES THE SAME FORM.
25 IT'S THIS THING CALLED THE DISCLOSURE CATEGORY THAT'S

1 THE OVERLAY. FOR EXAMPLE, THE VERY SAME FORM THAT YOU
2 FILL OUT IS GOING TO BE FILLED OUT BY THE PEOPLE IN
3 CATEGORY 1, 2, AND 3. IN CATEGORY 1 THEY'RE GOING TO
4 BE FILLING OUT EVERYTHING. IN CATEGORY 3 IT'S GOING TO
5 BE A MUCH MORE NARROW GROUP OF ECONOMIC INTERESTS. BUT
6 THEY'RE STILL GOING TO APPEAR ON THE SAME FORM USING
7 THE SAME DEFINITIONS.

8 CHAIRMAN KLEIN: IS IT PROPER TO SAY THAT WE
9 FILE FOR FORM 700 UNDER CATEGORY 1 AS BOARD MEMBERS?

10 MR. PRIMM: THAT'S CORRECT.

11 CHAIRMAN KLEIN: OKAY. AND THAT IS THE
12 STANDARD WE'RE BEING HELD TO, AND WE ARE HOLDING THE
13 PRESIDENT, THE ETHICS OFFICER, THE CHIEF SCIENTIFIC
14 OFFICER, THE PEOPLE MAKING POLICY TO THE SAME STANDARDS
15 WE'RE BEING HELD TO. THAT'S WHAT WE'RE ACCOMPLISHING
16 HERE. IS THAT A CORRECT STATEMENT?

17 MR. PRIMM: THAT'S A CORRECT STATEMENT.

18 CHAIRMAN KLEIN: SO THAT'S A MATTER OF RECORD
19 TO CLARIFY THE RECORD. AND ALL OF THESE TERMS HAVE
20 BEEN DEBATED BY THE LEGISLATURE, ADOPTED BY THE
21 LEGISLATURE, REVIEWED BY THE FAIR POLITICAL PRACTICES
22 COMMISSION, OR OTHER GROUPS AS APPROPRIATE, COMMENTED
23 ON IN THE LEGISLATIVE SESSIONS, AND THE LEGISLATURE AND
24 THE STATUTES, IT IS STATUTES, AS I UNDERSTAND, TED,
25 THAT WE'RE REFLECTING; IS THAT RIGHT?

1 MR. PRIMM: IT WAS AN INITIATIVE JUST LIKE
2 PROP 71. SO IT WAS ADOPTED BY THE PEOPLE, AND THEN
3 IT'S BEEN IMPLEMENTED THROUGH REGULATIONS OF THE
4 POLITICAL PRACTICES COMMISSION.

5 CHAIRMAN KLEIN: I APPRECIATE THE CORRECTION.

6 DR. PRIETO: COULD I MAKE A MOTION, THEN,
7 THAT WE ADD THE LANGUAGE SUGGESTED BY DR. BALTIMORE TO
8 THIS CATEGORY?

9 CHAIRMAN KLEIN: OKAY. IS THERE A SECOND?

10 DR. WRIGHT: SECOND.

11 CHAIRMAN KLEIN: SECOND. THERE'S A MOTION ON
12 THE FLOOR. ARE THERE ADDITIONAL COMMENTS FROM THE
13 BOARD? ARE THERE COMMENTS FROM THE PUBLIC? NO
14 COMMENTS FROM THE PUBLIC. CALL FOR THE QUESTION.

15 DR. POMEROY: ARE WE VOTING ON JUST THE
16 AMENDMENT OR THE ENTIRE QUESTION?

17 CHAIRMAN KLEIN: LET'S VOTE FIRST ON THE
18 AMENDMENT AND THEN ON THE MOTION ITSELF. ALL IN FAVOR.
19 CALLING THE QUESTION ON THE MOTION.

20 DR. POMEROY: CAN I MAKE ONE COMMENT BEFORE
21 WE DO THAT? I THINK IT'S A TECHNICAL POINT, BUT WE ARE
22 LISTED ON PAGE 1 OF 2 OF APPENDIX A AS DESIGNATED
23 EMPLOYEES. AND I BELIEVE THAT NEEDS TO SAY EMPLOYEE OR
24 OFFICIAL BECAUSE WE ARE NOT EMPLOYEES.

25 CHAIRMAN KLEIN: THAT IS A CORRECT STATEMENT.

1 IT NEEDS TO SAY DESIGNATED -- LET'S HAVE TED PRIMM
2 ADDRESS THIS.

3 MR. PRIMM: RIGHT NOW YOU DISCLOSE PURSUANT
4 TO A SECTION THAT SAYS WHEN A NEW BOARD IS CREATED, IT
5 FILES UNDER THE SAME CATEGORY AS THE GOVERNOR UNTIL A
6 CODE IS ADOPTED. SO NOW WE'RE IN THE PROCESS OF GOING
7 THROUGH THE CODE PROCESS. AND BECAUSE YOU'RE NOT
8 LISTED AS WHAT WE CALL AN ARTICLE II FILER ACTUALLY IN
9 THE STATUTE WITH A DEFINED DISCLOSURE CATEGORY, YOU ARE
10 WHAT WE CALL A DESIGNATED EMPLOYEE. THAT EVEN THOUGH
11 YOU'RE A BOARD MEMBER OF A VERY IMPORTANT BOARD, FOR
12 PURPOSES OF CONFLICT OF INTEREST CODE, YOU'RE A
13 DESIGNATED EMPLOYEE.

14 CHAIRMAN KLEIN: IS THAT FOR DISCLOSURE
15 PURPOSES ONLY?

16 MR. PRIMM: YEAH. THE STATUTE STILL DEFINES
17 YOUR DISQUALIFICATION.

18 CHAIRMAN KLEIN: THANK YOU FOR THE
19 CLARIFICATION.

20 MR. PRIMM: THE OTHER THING WE SHOULD CLARIFY
21 IS WE'RE NOT ACTUALLY ADOPTING THIS CODE TODAY. THIS
22 HAS NOW STILL GOT TO GO THROUGH THE PROCESS OF BEING
23 APPROVED BY THE FAIR POLITICAL PRACTICES COMMISSION AND
24 NOTICED IN A FORMALIZED PROCESS.

25 CHAIRMAN KLEIN: IS IT APPROPRIATE TO SAY

1 WE'RE ADOPTING FOR THE INSTITUTE SUBJECT TO THEIR
2 APPROVAL?

3 MR. PRIMM: WELL, WHAT YOU ARE DOING AT THIS
4 POINT IS THAT YOU'RE ADOPTING FOR PURPOSES OF US
5 NOTICING IT AND MOVING FORWARD IN THE PROCESS.

6 CHAIRMAN KLEIN: THAT'S GREAT.

7 MR. GOLDBERG: SECOND.

8 CHAIRMAN KLEIN: SO WE HAVE A MOTION ON THE
9 FLOOR.

10 DR. PIZZO: COULD YOU RESTATE THE MOTION?

11 CHAIRMAN KLEIN: AND THE MOTION IS TO APPROVE
12 THIS WITH THE AMENDMENT THAT WAS APPROVED. AND THERE
13 IS A SECOND ALREADY MADE AND PENDING. I CALL FOR THE
14 QUESTION ON THIS ITEM. ALL IN FAVOR. OPPOSED? OKAY.

15 I WOULD LIKE TO GO TO THE ITEM NO. 10 B -- TO
16 THE 10 C, WHICH DEALS WITH THE STATEMENT OF
17 INCOMPATIBLE ACTIVITIES. JAMES, COULD YOU PLEASE
18 DISCUSS FOR EMPLOYEES WHY A STATEMENT OF INCOMPATIBLE
19 ACTIVITIES IS CALLED FOR UNDER THE STATE STATUTE?

20 MR. HARRISON: YES. GOVERNMENT CODE SECTION
21 19990 REQUIRES THAT EACH STATE AGENCY ADOPT A STATEMENT
22 OF INCOMPATIBLE ACTIVITIES THAT SETS FORTH THE ITEMS
23 THAT YOU SEE HERE IN ADDITION TO ANY OTHER POLICIES THE
24 AGENCY WISHES TO ADOPT AS WELL AS PROCEDURES FOR
25 HANDLING ANY VIOLATIONS OF THE INCOMPATIBLE ACTIVITIES

1 STATEMENT.

2 IT IS SUBJECT TO APPROVAL OF THE
3 DEPARTMENT -- DPA, PERSONNEL ADMINISTRATION, AFTER YOUR
4 APPROVAL.

5 DR. BRYANT: SO FOR THE PURPOSES OF THIS, ARE
6 WE EMPLOYEES OR NOT?

7 CHAIRMAN KLEIN: THIS DOES NOT ADDRESS US,
8 AND WE ARE NOT EMPLOYEES FOR PURPOSES OF THIS
9 STATEMENT, ARE WE?

10 MR. HARRISON: CORRECT. YOU'RE DESIGNATED
11 EMPLOYEES UNDER THE POLITICAL REFORM ACT FOR FILING
12 PURPOSES. YOU'RE NOT EMPLOYEES FOR PURPOSES OF THE
13 INCOMPATIBLE ACTIVITIES STATEMENT.

14 CHAIRMAN KLEIN: THESE ARE THE REAL
15 EMPLOYEES.

16 MR. HARRISON: THESE ARE THE STAFF OF THE
17 INSTITUTE.

18 CHAIRMAN KLEIN: OKAY. ALL RIGHT.

19 DR. HENDERSON: MOVE APPROVAL.

20 CHAIRMAN KLEIN: IS THERE A SECOND?

21 DR. BALTIMORE: SECOND.

22 CHAIRMAN KLEIN: IS THERE BOARD DISCUSSION?

23 DR. PIZZO: YES. I HAVE JUST ONE MINIMAL
24 QUESTION. AND THAT IS UNDER NO. 4, GIFTS EXCEPTION,
25 WHERE IT'S, QUOTE, DE MINIMIS VALUE. DOES THAT HAVE IN

1 THE STATE A NUMBER ASSOCIATED WITH IT AS IT DOES IN
2 OTHER ENTITIES LIKE \$25 OR \$10? HOW DO WE DEFINE THAT?

3 CHAIRMAN KLEIN: YES. I, IN FACT, HAD FOUR
4 DISCUSSIONS ON THIS QUESTION. AND JAMES HARRISON,
5 WOULD YOU PLEASE ADDRESS THAT ISSUE?

6 DR. PIZZO: SORRY TO ASK A DE MINIMIS
7 QUESTION.

8 CHAIRMAN KLEIN: THERE IS ANOTHER STANDARD
9 WHICH SPECIFICALLY LAYS OUT FOR GUIDANCE THAT \$50 OR
10 LESS OR \$360 A YEAR THAT ARISES IN A DIFFERENT CONTEXT.
11 JAMES, WOULD YOU PLEASE ADDRESS IT?

12 MR. HARRISON: YES. THERE ARE TWO DIFFERENT
13 RULES AT ISSUE HERE. ONE IS THE POLITICAL REFORM ACT
14 RULE WHICH LIMITS THE PUBLIC OFFICIALS TO ACCEPTING
15 GIFTS FROM A SINGLE SOURCE IN THE AGGRAVATE VALUE OF NO
16 MORE THAN \$360 PER YEAR WITH GIFTS AGGREGATING \$50 OR
17 MORE HAVING TO BE DISCLOSED. THIS IS A DIFFERENT RULE
18 THAT COMES IN A DIFFERENT PROVISION OF THE GOVERNMENT
19 CODE THAT DOES NOT ASSIGN A VALUE, BUT MERELY PROHIBITS
20 THE ACCEPTANCE OF GIFTS WHEN IT CAN BE REASONABLY
21 SUBSTANTIATED THAT THE PURPOSE OF MAKING THE GIFT WAS
22 TO INFLUENCE THE ACTION OF THE STAFF MEMBER.

23 DR. PIZZO: SO IT'S REALLY INFLUENCE.

24 CHAIRMAN KLEIN: OKAY. ADDITIONAL BOARD
25 COMMENT? PUBLIC COMMENT? SEEING NO PUBLIC COMMENT,

1 THERE IS A MOTION ON THE FLOOR. I'D LIKE TO CALL THE
2 QUESTION ON THE MOTION. ALL IN FAVOR. OPPOSED.

3 WELL, I THANK THE BOARD FOR AN IMPORTANT STEP
4 FORWARD FOR GIVING CLEAR GUIDANCE ON CONFLICTS
5 POSITIONS FOR EMPLOYEES. DOES NOT MEAN THAT THIS IS
6 THE TOTAL SUM OF PROVISIONS WE WILL HAVE FOR EMPLOYEES,
7 BUT IT MEANS IT'S A MEANINGFUL AND IMPORTANT
8 SUBSTANTIVE START TO THIS PROCESS. AND WE WILL BE
9 ADDRESSING A NUMBER OF THESE OTHER ISSUES IN PUBLIC
10 HEARINGS, INCLUDING ISSUES OF STOCK OWNERSHIP AND OTHER
11 CONFLICTS ISSUES IN OUR GENERAL FURTHER DISCUSSION OF
12 CONFLICTS.

13 SUBPART B IS FURTHER REFINEMENT FOR THE
14 BOARD, BUT IT'S ONLY IN A DRAFT POSITION COMING FROM
15 COMMENTS MADE AT THE LAST MEETING. THE LAST MEETING
16 THERE WERE ONLY PART OF THE BOARD MEMBERS PRESENT FOR
17 THAT, SO I'D LIKE TO CARRY THIS TO THE NEXT BOARD
18 MEETING WHEN THE BOARD HAS A CHANCE TO LOOK AT IT AND
19 GIVE COMMENTS.

20 AND SO WE WILL GO -- YES. OSWALD STEWARD.

21 DR. STEWARD: IN LOOKING THIS OVER, IT IS
22 CERTAINLY A VERY COMPLICATED ISSUE. AND WHERE I'M
23 GOING IS WHETHER THIS IS AN ISSUE THAT ACTUALLY SHOULD
24 BE DEALT WITH, FIRST, PERHAPS BY THE DULY CONSTITUTED
25 STANDARDS COMMITTEE WHEN IT IS IN PLACE AND THEN

1 BROUGHT BACK TO THE BOARD, RATHER THAN HAVING THE BOARD
2 ITSELF STRUGGLE WITH THESE ISSUES RIGHT NOW. I DON'T
3 SEE THIS AS BEING A PARTICULARLY TIME CRITICAL
4 DISCUSSION, AND THAT WOULD GIVE IT A CHANCE TO BE
5 REVIEWED BY A PANEL THAT WAS APPROPRIATELY CONSTITUTED
6 TO ACTUALLY DO THAT AND, IN FACT, ASSIGNED WITH THE
7 TASK OF DEVELOPING STANDARDS.

8 CHAIRMAN KLEIN: WHAT'S THE PLEASURE OF THE
9 BOARD ON THIS?

10 MS. LANSING: I AGREE.

11 CHAIRMAN KLEIN: THIS IS ITEM B OF THE ITEMS
12 THAT WE JUST COVERED. IT'S A DRAFT.

13 MR. SERRANO-SEWELL: GOT IT. THANKS.

14 CHAIRMAN KLEIN: AND THE QUESTION IS WHETHER
15 THE NEXT LAYER OF ISSUES WOULD BE ADDRESSED BY THE
16 STANDARDS, ACTUALLY STANDARDS WORKING GROUP. AND DR.
17 PIZZO.

18 DR. PIZZO: I CAN CERTAINLY UNDERSTAND THE
19 RELEVANCE OF THAT. THE ONLY QUESTION THAT I HAVE IS
20 REALLY JUST TIME LINE. THE STANDARDS WORKING GROUP,
21 I'M SURE, HAS A LOT ON ITS PLATE, AND THEY MAY NOT GET
22 TO THIS FOR SOME TIME. AND THIS DOES RELATE TO THE
23 ICOC SPECIFICALLY. AND, THEREFORE, I ACTUALLY THINK
24 WE'RE BETTER SERVED BY HAVING IT COME DIRECTLY HERE.
25 AND I WOULD PREFER THAT WE FOLLOW THE CHAIR'S ORIGINAL

1 GUIDANCE AND STUDY THIS AND BRING THIS BACK FOR REVIEW
2 IN OUR APRIL MEETING.

3 CHAIRMAN KLEIN: MAYBE AS A SUGGESTION AFTER
4 THE BOARD MEMBERS HAVE A CHANCE TO STUDY IT, WE CAN
5 CONSIDER WHETHER THE BOARD HAS ENOUGH INFORMATION TO
6 ACT, OR WHETHER THEY WANT TO ACT AT THE TIME WE ADDRESS
7 OTHER CONFLICTS ISSUES THAT HAVE BEEN RAISED, SUCH AS
8 STOCK OWNERSHIP OR OTHER ISSUES, OR DO WE WANT TO MAKE
9 INCREMENTAL PROGRESS. WE HAVE AN OPTION OF REFERRING
10 IT TO OUR STANDARDS SEARCH COMMITTEE AS AN OPTION, BUT
11 WE CAN MAKE THAT DECISION AT THE NEXT BOARD MEETING.

12 DR. PIZZO: WE'D HAVE TO HAVE IT ON THE
13 AGENDA FOR THE NEXT MEETING, SO AS LONG AS IT'S ON THE
14 AGENDA, WE CAN DEAL WITH IT.

15 CHAIRMAN KLEIN: WOULD THAT BE ACCEPTABLE?

16 DR. STEWARD: SURE.

17 CHAIRMAN KLEIN: IS THAT THE SENSE OF THE
18 BOARD? ANY --

19 DR. MURPHY: MR. CHAIRMAN, I AGREE WITH THAT
20 COMMENT, BUT I THINK THERE ALSO IS SOME VALUE IN
21 CONTEMPLATING THE IDEA OF HAVING AN EXTERNAL GROUP LOOK
22 AT THIS BECAUSE WE ARE GOING TO BE PUT IN THE POSITION
23 OF MAKING RULES FOR OURSELVES. WHILE I HAVE ABSOLUTE
24 CONFIDENCE WE CAN DO THAT IN A REASONABLE WAY, I THINK
25 THAT TO HAVE AN OUTSIDE GROUP LOOK AT OUR DECISIONS OR

1 PERHAPS GUIDE US IN DECISIONS I THINK WOULD BE VERY
2 USEFUL.

3 CHAIRMAN KLEIN: IS THERE AN OUTSIDE GROUP
4 YOU WOULD LIKE US TO SEEK COUNSEL FROM; FOR EXAMPLE,
5 THE NATIONAL ACADEMIES?

6 DR. MURPHY: I THINK THE NATIONAL ACADEMY
7 WOULD BE AN IDEAL SOURCE OF OUTSIDE OPINION.

8 CHAIRMAN KLEIN: ALL RIGHT. THEN WITH THAT
9 DIRECTION, LET ME START, AT LEAST, BY CONTACTING THE
10 NATIONAL ACADEMIES AND GETTING INPUT THERE THAT WE CAN
11 CONSIDER. AND THEN IF THE BOARD AT THE NEXT MEETING
12 FINDS THAT THERE'S ADDITIONAL INFORMATION, PERHAPS ZACH
13 HALL CAN BE HELPFUL IN IDENTIFYING OTHER PROFESSIONAL
14 ASSOCIATIONS IN THE INTERIM AS WELL THAT COULD BE
15 HELPFUL IN PROVIDING GUIDANCE HERE. I THINK IT'S AN
16 EXCELLENT IDEA THAT WE BENCHMARK OURSELVES ON OTHER
17 OUTSTANDING GROUPS IN THE COUNTRY THAT HAVE VERY HIGH
18 STANDARDS.

19 DR. PIZZO: JUST A MODIFICATION OF THIS AND
20 TO MAKE IT MORE SPECIFIC, AND HE CAN DELEGATE, IF
21 NECESSARY, BUT I WOULD GO DIRECTLY TO BRUCE ALBERTS ON
22 THIS BECAUSE OF THE RECENT ROLE THAT HE'S PLAYED IN
23 THIS WHOLE CONFLICTS. HE'S THE PRESIDENT OF THE
24 NATIONAL ACADEMY AT LEAST THROUGH, I THINK IT'S, JUNE
25 OR SOMETHING. SO I'D JUST START THERE AND LET HIM GIVE

1 YOU --

2 DR. BALTIMORE: POSSIBLY THROUGH APRIL, WHICH
3 IS WHEN THE ANNUAL MEETING IS.

4 CHAIRMAN KLEIN: WE'LL ADDRESS HIM
5 IMMEDIATELY IN THAT CASE. ALL RIGHT. PUBLIC COMMENT
6 ON THIS ITEM. MR. HALPERN.

7 MR. HALPERN: THANK YOU, MR. CHAIRMAN. THERE
8 WAS A LOT OF COMMITMENT TO OPEN PROCESS EXPRESSED
9 EARLIER. I WANT TO SUGGEST THAT THIS 10 B ITEM IS ONE
10 THAT'S PECULIARLY APPROPRIATE FOR PUBLIC COMMENT. AND
11 I URGE YOU TO TAKE THIS DRAFT 10 B AND PUT IT ON YOUR
12 WEBSITE AND CIRCULATE IT WIDELY AND MAKE SURE THAT
13 THERE'S AN OPPORTUNITY FOR REAL PUBLIC INPUT ON THIS
14 BECAUSE THE CONFLICT OF INTEREST ISSUES, AS IT APPLIES
15 TO THE MEMBERS OF THE ICOC, ARE THINGS WHICH HAVE
16 HELPED TO UNDERMINE THE PUBLIC CREDIBILITY OF THIS
17 BODY. AND TO HAVE THAT KIND OF PUBLIC PARTICIPATION IN
18 THAT WAY IS A VERY GOOD WAY, I THINK, TO DEAL WITH THAT
19 PROBLEM.

20 CHAIRMAN KLEIN: WELL, MR. HALPERN, I'M GLAD
21 THAT YOU AGREE WITH WHAT WE'VE DONE BECAUSE IT IS ON
22 THE WEBSITE. AS A MEMBER OF THE PUBLIC, DOCUMENTS IN
23 THIS MEETING AND CERTAINLY THE NATIONAL ACADEMIES'
24 INPUT WILL BE PUT ON THE WEBSITE AS WELL AS PART OF THE
25 CONTRIBUTION TO THE PUBLIC'S INFORMATION ON THIS ITEM.

1 OKAY.

2 I DON'T THINK I NEED A MOTION ON THIS. THIS
3 IS INFORMATIVE TO THE STAFF AS TO HOW TO PROCEED.

4 IF WE CAN GO -- WE NEED A SECOND EXECUTIVE
5 SESSION DEALING WITH LITIGATION. I'M INSTRUCTED BY
6 COUNSEL IT'S IMPORTANT THAT I PROPERLY READ THE
7 REFERENCE TO THE LITIGATION IN ANNOUNCING THAT SESSION.

8 IT'S ITEM 16, STAFF TELLS ME. THERE'S A
9 DIFFERENCE BETWEEN WHAT THE TWO GROUPS ARE DISCUSSING.
10 ONE IS WHAT ITEM IS IT IN THIS BOOK AND WHAT ITEM IS IT
11 IN YOUR TABS? IT IS TAB 8.

12 THE ICOC WILL CONDUCT A CLOSED SESSION TO
13 CONSIDER TWO PIECES OF LITIGATION FILED ON 2/23/05 AND
14 2/24/05 RESPECTIVELY. PEOPLE'S ADVOCATE VS.
15 INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE, CALIFORNIA
16 SUPREME COURT NO. S131655, AND CALIFORNIANS FOR PUBLIC
17 ACCOUNTABILITY AND ETHICAL SCIENCE VS. CALIFORNIA
18 INSTITUTE FOR REGENERATIVE MEDICINE, CALIFORNIA SUPREME
19 COURT NO. S131677. I COULDN'T MEMORIZE THAT. SO WE
20 WILL GO INTO EXECUTIVE SESSION TO CONSIDER THOSE ITEMS.
21 I THANK THE PUBLIC FOR THEIR UNDERSTANDING. IF THE
22 PUBLIC COULD ADJOURN FROM THE ROOM SO THAT WE CAN
23 ADVANCE THE MEETING WITH THAT CONSIDERATION.

24 (THE MEETING WAS THEN ADJOURNED TO
25 EXECUTIVE SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED.

1 THE MEETING THEN RETURNED TO PUBLIC SESSION AT 05:17
2 P.M AS FOLLOWS:)

3 CHAIRMAN KLEIN: OKAY. THANK YOU VERY MUCH.
4 WE'RE GOING TO PICK UP AGENDA ITEM 12, AND WHAT TAB IS
5 IT? WE'RE GOING TO -- ED PENHOET IS GOING TO ADDRESS
6 THIS ITEM FOR ED HOLMES. THE PURPOSE OF THIS
7 DISCUSSION ON THE GRANT ITEM IS THAT THIS IS A
8 CONTINUED ITEM FROM THE LAST SESSION. WE INTEND TO
9 HAVE A VERY FULL DEBATE ON THE GRANT PROGRAM. WE
10 INTEND TO HAVE A VERY FULL DEBATE ON THE GRANT PROGRAM
11 AND HOPEFULLY WITH OUR INTERIM PRESIDENT. WE WILL HAVE
12 GREAT LEADERSHIP IN SHAPING THAT DEBATE AND THE
13 SCIENTIFIC MEMBERSHIP THAT CAN ASSIST US IN LEADING US
14 IN THAT DISCUSSION.

15 I THINK THE QUESTION AT HAND IS WHETHER PRIOR
16 TO THE NEXT MEETING WE CAN DO SOME RESEARCH FOR THE
17 BOARD TO BRING BACK MATERIALS AT THE NEXT MEETING THAT
18 WOULD BE A PART OF THAT. AND IT'S AN INFORMATIONAL
19 ITEM SINCE IT WAS CONTINUED FROM THE LAST MEETING TO
20 JUST INDICATE THE RESEARCH AND SEE IF IT'S THE SENSE OF
21 THE COMMITTEE THAT WE DO RESEARCH TO BRING BACK FOR
22 YOUR CONSIDERATION.

23 ED, WOULD YOU LIKE TO REPORT FOR THE GRANT
24 COMMITTEE.

25 DR. PENHOET: I WILL. SO I'M SPEAKING FOR ED

1 HOLMES, WHO HAS LEFT. SO WE'RE NOW SWITCHING THE ORDER
2 OF 12 AND 13, SO THIS IS A REPORT FROM ED HOLMES --
3 THIS IS A REPORT FROM ED HOLMES, WHO IS THE CHAIR OF
4 THE GRANTS SUBCOMMITTEE.

5 ED'S COMMENT IS THIS SUBCOMMITTEE HAS NOT MET
6 SINCE THE BOARD MET AS A WHOLE ON FEBRUARY 3D. DESPITE
7 A CONCERTED EFFORT, WE WERE UNABLE TO SCHEDULE A DATE
8 ON WHICH A QUORUM OF SUBCOMMITTEE MEMBERS WERE ABLE TO
9 MEET IN THE INTERIM PERIOD SINCE THE LAST ICOC MEETING.
10 HOWEVER, SINCE FEBRUARY 3D CONSIDERABLE PROGRESS HAS
11 BEEN MADE IN CARRYING OUT THE APPROVED DESIGN FOR
12 POPULATING THE GRANTS WORKING GROUP WITH SCIENTIFIC
13 MEMBERS.

14 FEBRUARY 14, 2005, WAS THE DEADLINE FOR
15 SUBMITTING NOMINATIONS TO THE GRANT WORKING GROUP
16 SEARCH SUBCOMMITTEE. THIS COMMITTEE CURRENTLY HAS A
17 BROAD DATABASE OF OVER 660 POTENTIAL CANDIDATES
18 GENERATED FROM A VARIETY OF SOURCES, AND I MIGHT ADD,
19 INCLUDING A NUMBER OF PEOPLE ON THIS BOARD. THESE
20 NAMES HAVE BEEN EVENLY DIVIDED AMONG THE SIX TWO-PERSON
21 INTERVIEW TEAMS OF THIS SUBCOMMITTEE AND WILL BE
22 DISTRIBUTED TO THOSE TEAMS BY THE END OF THIS WEEK, THE
23 CURRENT WEEK.

24 THE INTERVIEW TEAMS WILL BE EXPECTED TO
25 COMPLETE THE INTERVIEW PROCESS WITHIN SIX WEEKS OF

1 RECEIVING THE NAMES OF THE CANDIDATES, WHICH BRINGS US
2 TO APRIL 18TH, FOR INFORMATION PURPOSES. INTERVIEW
3 TEAMS WILL RECEIVE THE PACKET THAT WILL INCLUDE
4 INTERVIEW GUIDANCE AS WELL AS CIRM STAFF CONTACT
5 INFORMATION FOR ANY QUESTIONS OR COMMENTS THAT MAY
6 ARISE IN THE COURSE OF INTERVIEWING THE CANDIDATES.

7 AT THIS POINT, I WOULD LIKE TO THANK THE
8 STAFF FOR A MARVELOUS JOB IN ASSEMBLING ESSENTIALLY A
9 VERY NICE DOSSIER ON MORE THAN 600 PEOPLE.

10 THE NEXT SUBCOMMITTEE MEETING IS SCHEDULED
11 FOR MARCH 18, 2005. I'D LIKE TO MAKE A RECOMMENDATION
12 TO THE BOARD THAT THE GRANTS WORKING GROUP SEARCH
13 SUBCOMMITTEE BE EMPOWERED TO CONVENE AS A GROUP ON THIS
14 DATE, MARCH 18TH, TO DISCUSS THE TYPES OF GRANTS WHICH
15 WILL BE CONSIDERED IN THE FIRST GRANT FUNDING CYCLE FOR
16 THE PURPOSE OF MAKING RECOMMENDATIONS TO THE BOARD. IF
17 THE BOARD ENDORSES THIS PROPOSAL, THE MARCH 18TH
18 MEETING WOULD BE LARGELY DEVOTED TO A DISCUSSION OF THE
19 TYPES OF GRANTS IN ADDITION TO PROGRESS REPORTS BY THE
20 INTERVIEW TEAMS.

21 SO SPECIFIC PROPOSAL IS THAT YOU AUTHORIZE
22 THE GRANTS WORKING GROUP TO HAVE THE MEETING ON THE
23 18TH LARGELY DEVOTED TO THE DISCUSSION OF THE KINDS OF
24 GRANTS THAT WE SHOULD THINK ABOUT GIVING IN THE FIRST
25 PLACE. THAT'S ED HOLMES' SPECIFIC PROPOSAL TO THIS

1 GROUP.

2 AT THAT POINT, I GUESS WE WOULD LIKE TO HAVE
3 SOME COMMENT.

4 CHAIRMAN KLEIN: I'D LIKE TO INDICATE THAT
5 THE FIRST ROUND ARE OPERATIVE WORDS HERE. WE'RE NOT
6 TALKING -- IT'S VERY IMPORTANT THAT, WITH THE HELP OF
7 THE NEW INTERIM PRESIDENT, THAT WE BEGIN TO CREATE A
8 PROCESS TO GET A STRATEGIC PLAN IN PLACE THAT LOOKS AT
9 OUR LONG-TERM PROGRAM; BUT IN THE FIRST ROUND, IT HAS
10 BEEN RAISED WHETHER IT IS APPROPRIATE TO LOOK AT
11 LEAD-TIME GRANTS SPECIFICALLY. THE ISSUE IS SEED MONEY
12 GRANTS, FOR EXAMPLE, WHICH MAY BE IMPORTANT TO ALLOW
13 INSTITUTIONS TO HAVE THEIR RESEARCHERS PROPERLY OBSERVE
14 METICULOUSLY ALL OF THE NIH RULES AND SEGREGATE COSTS
15 PROPERLY AND HAVE THESE RESEARCHERS HAVE THE FUNDING TO
16 GET THEIR PRELIMINARY DATA. BUT THOSE AND OTHER ISSUES
17 THAT MAY HAVE A TIME SENSITIVITY OR BE LEAD-TIME, HAVE
18 A LEAD-TIME IMPORTANCE, COULD BE AN ITEM APPROPRIATE
19 FOR AN INITIAL ROUND ALONG WITH OTHERS.

20 NOW, IN THAT REGARD, SEPARATE FROM RESEARCH
21 GRANTS, I'D LIKE TO ASK ED PENHOET. THE ISSUE HAS BEEN
22 DISCUSSED AND WAS ADDRESSED BY ALTA CHARO LAST NIGHT
23 AND TODAY THAT BECAUSE OF THE INSTABILITY IN STANDARDS
24 IN THIS COUNTRY AND FUNDING, THE PIPELINE IS
25 ESSENTIALLY EMPTY ON THE INTELLECTUAL INFRASTRUCTURE,

1 THE NEW POSTDOCTORATE FELLOWS, AND POSTDOCTORAL
2 CLINICIANS AND GRADUATE STUDENTS WHO WOULD MAN THIS
3 AREA AND BE DRIVING THE HUMAN RESOURCES COMMITTED TO
4 THIS RESEARCH IN THESE LABS. MANY OF THE BEST MINDS IN
5 THE COUNTRY ARE TREMENDOUSLY ENCOURAGED BY US PASSING
6 THIS INITIATIVE, BUT THERE'S NO FUNDING MECHANISM TO
7 GET THIS INTELLECTUAL INFRASTRUCTURE IN PLACE.

8 AND I'D LIKE, ED PENHOET, IF YOU CAN DISCUSS
9 THE ISSUE ABOUT RESEARCHING AND BRINGING BACK TO THIS
10 BOARD A PROPOSAL FOR THE NEXT MEETING THAT DISCUSSES
11 FOR FULL DEBATE AT THAT TIME, NOW NOT, BUT FULL DEBATE
12 AT THAT TIME WHETHER WE CAN DO SOMETHING MEANINGFUL
13 WITH INTELLECTUAL INFRASTRUCTURE TRAINING CONTRACTS,
14 WHERE THESE WOULD BE CONTRACTS WITH THE UNIVERSITIES
15 AND NONPROFIT INSTITUTIONS THAT HAVE POSTDOCTORATE
16 FELLOWS, AND WHAT PROCESS WE WOULD DO TO HAVE PEER
17 REVIEW OF ANY PROPOSALS FOR THESE CONTRACTS.

18 DR. PENHOET: SO AGAIN, THIS IS A SECOND
19 PROPOSAL SIMPLY TO GAIN YOUR AUTHORITY FOR US
20 INTERNALLY AS STAFF WORK TO DEVELOP A PROPOSAL
21 SPECIFICALLY FOR THE TRAINING, A TRAINING PROGRAM. SO
22 THIS WOULD -- OUR DESIRE WOULD BE TO FUND THE TRAINING
23 OF ESSENTIALLY THE YOUNG INTELLECTUALS THAT ARE GOING
24 TO BE REQUIRED TO CARRY OUT THIS WORK ON AN ACCELERATED
25 BASIS.

1 AND WHAT WE ESSENTIALLY SEEK TO DO IS, FIRST
2 OF ALL, TO HAVE CONVERSATIONS WITH A NUMBER OF
3 POTENTIAL GRANTEES TO UNDERSTAND THEIR TRAINING
4 INTEREST. OUR VIEW IS THAT TRAINING SHOULD INCLUDE
5 MINIMALLY CLASSROOM AND EXPERIMENTAL COURSES AS WELL AS
6 RESEARCH EXPERIENCE AND THAT THE TRAINING PROGRAMS MUST
7 HAVE COURSES IN SOCIAL, LEGAL, AND ETHICAL IMPLICATIONS
8 OF STEM CELL RESEARCH. WE SEE THE TRAINING IMPERATIVE
9 AS A BROAD IMPERATIVE. AND I THINK THE NEED TO
10 ACCELERATE TRAINING IS OBVIOUS IF WE'RE GOING TO
11 EFFECTIVELY UTILIZE GRANT FUNDS LATER ON. WE NEED
12 TRAINED PEOPLE THAT ARE CAPABLE OF CARRYING OUT THE
13 WORK THAT WE SEEK TO FUND IN TERMS OF GRANT FUNDING
14 GOING FORWARD.

15 SO IN ADDITION TO THE WORK OF THE GRANTS
16 WORKING SUBCOMMITTEE, WE WOULD LIKE YOUR CONCURRENCE,
17 LED BY ZACH HALL, NEW CIRM PRESIDENT, THAT WE DEVELOP A
18 PROPOSAL FOR YOU IN THE APRIL BOARD MEETING WHICH WOULD
19 SEEK TO ENHANCE, ADD TO, ACCELERATE THE FUNDING OF
20 TRAINING WITHIN THE STATE, AND WE BELIEVE THAT THAT
21 TRAINING COULD BE ADEQUATELY DONE ACTUALLY THROUGH A
22 CONTRACT MECHANISM RATHER THAN A GRANT MECHANISM; THAT
23 IS, THEY'D BE PERFORMING A SERVICE FOR CIRM BY TRAINING
24 PEOPLE IN THIS FIELD AND THAT, OF COURSE, WE WOULD SET
25 UP A PEER REVIEW PROCESS FOR THIS, TAKING NAMES THAT

1 HAVE BEEN SUBMITTED TO US BY A VARIETY OF DIFFERENT
2 SOURCES AS PEOPLE WHO WOULD BE SKILLED IN EVALUATING
3 TRAINING PROPOSALS.

4 SO ESSENTIALLY WE HAVE TWO PROPOSALS IN FRONT
5 OF YOU. ONE IS TO SEEK YOUR AGREEMENT THAT THE NEXT
6 SUBCOMMITTEE MEETING OF THE GRANTS WORKING GROUP COULD
7 BE DEVOTED TO THE BROADER ISSUE OF THE EARLY GRANTS,
8 FIRST WAVE OF GRANTS, IF YOU WILL, THAT ARE RESEARCH
9 GRANTS. AND THAT SEPARATELY FROM THAT, THE STAFF OF
10 THE CIRM LED BY ZACH HALL WOULD DEVELOP A PROPOSAL TO
11 BRING TO YOU ALSO IN THE APRIL BOARD MEETING WHICH
12 WOULD BE SPECIFICALLY DEVOTED TO TRAINING. AND IT'S
13 LIKELY TO HAVE CHARACTERISTICS OF A CONTRACT BEING
14 PERFORMED FOR CIRM RATHER THAN A TYPICAL GRANT.

15 CHAIRMAN KLEIN: BUT IN MAKING IT VERY CLEAR,
16 WE'RE NOT ASKING FOR APPROVAL OF ANY PROGRAM.

17 DR. PENHOET: NEITHER ONE.

18 CHAIRMAN KLEIN: WE'RE NOT ASKING THAT THE
19 INFRASTRUCTURE PROGRAM BE APPROVED OR ANYTHING THAT
20 WOULD GO ON THE GRANT COMMITTEE BE APPROVED. WE'RE
21 ASKING FOR A PRIORITIZATION OF TIME TO DO RESEARCH TO
22 BRING BACK ITEMS TO BE FULLY DEBATED DE NOVO BEFORE
23 THIS BOARD SO THAT WE CAN GET THE RESOURCES. AND I
24 THINK IT'S VERY HELPFUL THAT INTERIM PRESIDENT IS ON
25 BOARD NOW THAT CAN HELP LEAD US THROUGH THIS PROCESS.

1 AND, ZACH, ON THE TRAINING PROGRAM, DO YOU
2 FEEL IT'S APPROPRIATE THAT BY THE NEXT BOARD MEETING
3 YOU COULD BRING BACK A CONCEPTUAL DESIGN?

4 DR. HALL: YES.

5 CHAIRMAN KLEIN: TIME BEING WHAT IT IS --

6 DR. POMEROY: BOB, I HAVE A QUESTION. I
7 THINK THIS RAISES AN ISSUE. I'M VERY EXCITED THAT WE
8 ARE MOVING ON WITH THE PROCESS OF DEFINING THE FIRST
9 ROUND OF GRANTS. THAT'S GREAT. THAT'S WHAT WE'RE ALL
10 HERE FOR. BUT THE GROUP KEEPS BEING REFERRED TO AS THE
11 GRANTS WORKING GROUP. NOW, IT'S A SEARCH COMMITTEE.

12 CHAIRMAN KLEIN: SEARCH COMMITTEE.

13 DR. POMEROY: I THINK IT WOULD BE HELPFUL FOR
14 ME IF WE COULD DEFINE WHAT THE RESPONSIBILITIES OF A
15 SEARCH COMMITTEE ARE VERSUS A POLICY MAKING COMMITTEE
16 BECAUSE IT SEEMS TO ME THAT THE SEARCH COMMITTEE IS
17 KIND OF TAKING ON THE ROLE OF A POLICY MAKING COMMITTEE
18 ABOUT GRANTS. AND I UNDERSTAND THAT WAS AN INTERIM
19 THING WHEN THERE WAS SORT OF THIS GAP; BUT WHEN IS THIS
20 GOING TO TRANSITION? AND HOW IS IT GOING TO TRANSITION
21 FROM BEING A SEARCH -- PRESUMABLY THE SEARCH COMMITTEE
22 WILL END WHEN THE PEOPLE ARE APPOINTED TO THE WORKING
23 GROUP.

24 DR. PRECIADO: WE ARE AT 5:30 AND I FEEL
25 REALLY RUSHED. WE HAVE DR. BRYANT HERE READY TO LEAVE.

1 CHAIRMAN KLEIN: THE IMPORTANCE HERE, DR.
2 PRECIADO, IS THAT WHAT WE'RE DISCUSSING HERE ARE NOT
3 ACTION ITEMS TO CREATE PROGRAMS. WE'RE JUST TRYING TO
4 PRIORITIZE TIME TO DO RESEARCH TO BRING YOU ITEMS TO BE
5 FULLY DEBATED. WE'RE NOT ASKING ANYONE TO APPROVE ANY
6 PROGRAMS. AND THE ITEM THAT DR. CLAIRE POMEROY IS
7 RAISING IS SOMETHING THAT WE SHOULD PUT ON THE AGENDA
8 TO DEAL WITH WITH FULL DISCUSSION. BUT WHAT WE ARE
9 ASKING, DR. PRECIADO, IS JUST A SENSE OF THE BOARD THAT
10 IT'S CORRECT TO MOVE FORWARD WITH THE RESEARCH SO THAT
11 THE BOARD THEN HAS MATERIAL INFORMATION BEFORE IT WHEN
12 WE THEN TRY AND DEBATE THESE ITEMS BECAUSE WITHOUT
13 PROPER PREPARATION, IT'S DIFFICULT FOR THE BOARD TO
14 HAVE A MEANINGFUL DISCUSSION.

15 DR. REED: DOES THIS REQUIRE A MOTION TO
16 APPROVE THIS USE OF THE STAFF'S TIME?

17 CHAIRMAN KLEIN: WELL, IT'S A MOTION SENSE OF
18 THE BOARD. WE'RE NOT APPROVING ANYTHING, BUT A SENSE
19 OF THE BOARD THAT THIS IS BY DIRECTION, THAT THIS IS A
20 PROPER USE OF OUR TIME.

21 MS. LANSING: WE AGREE THAT THIS IS WHAT THE
22 COMMITTEE SHOULD BE DOING.

23 DR. BRYANT: SO MOVED.

24 DR. PRIETO: SECOND. DOES THIS REQUIRE A
25 MOTION OR IS THIS MERELY SENSE OF THE BOARD?

1 CHAIRMAN KLEIN: WE CAN DO IT AS A SENSE OF
2 THE BOARD. THAT'S FINE.

3 DR. PENHOET: WE'RE NOT DELEGATING ANY
4 AUTHORITY TO THE GRANTS WORKING GROUP.

5 DR. PRIETO: MY UNDERSTANDING IS WE'RE NOT --
6 THIS IS NOT AUTHORIZING ACTION. YOU'RE ESSENTIALLY
7 SURVEYING WHAT'S OUT THERE, BRINGING INFORMATION BACK
8 TO THE BOARD, PREPARING IT FOR US IN A FORM THAT WE CAN
9 USE.

10 CHAIRMAN KLEIN: EXACTLY.

11 DR. PENHOET: IN A PUBLIC MEETING ON MARCH
12 18TH WHERE THE PUBLIC WILL BE ALSO INVITED TO
13 PARTICIPATE.

14 CHAIRMAN KLEIN: AND IT'S USEFUL IN THIS TO
15 EXPLAIN TO THE PUBLIC THE PROCESS BECAUSE THEN THE
16 PUBLIC CAN GO TO THE COMMITTEE MEETING KNOWING WHAT TO
17 EXPECT. SO WE'RE TRYING TO GET THE INFORMATION OUT
18 THERE TO THE PUBLIC AND TO THE BOARD.

19 MR. SERRANO-SEWELL: BOB, I DON'T WANT TO
20 DWELL ON THE POINT. I SUPPORT THE CHAIRMAN'S EFFORTS.
21 I THINK THIS IS A PROPER, PRUDENT WAY TO GO,
22 ABSOLUTELY, HUNDRED PERCENT, BUT LET'S DO RECOGNIZE
23 THAT THE GRANTS WORKING SEARCH GROUP, AS DR. POMEROY
24 HAS NOTED, THEIR DELEGATION OF AUTHORITY, AS I
25 UNDERSTAND IT, HAS SOMEWHAT EXPANDED. WE HAD THE

1 CHICKEN AND EGG CONVERSATION AT OUR LAST MEETING, BUT
2 LET'S DO ACKNOWLEDGE THAT THEY ARE GETTING INTO
3 RESEARCHING AND MAKING RECOMMENDATIONS ON FIRST-CYCLE
4 GRANTS AND WHATNOT. AND IT'S NOT JUST RECOMMENDATIONS
5 TO POPULATE THE MEMBERSHIP. IT'S ALSO --

6 CHAIRMAN KLEIN: IT WAS RAISED --

7 MR. SERRANO-SEWELL: -- OTHER ISSUES AS
8 OUTLINED BY ED.

9 CHAIRMAN KLEIN: WHAT IS APPROPRIATE HERE TOO
10 IS THAT THE SEARCH COMMITTEE, IN TRYING TO RECRUIT
11 MEMBERS, THE GRANT SEARCH COMMITTEE, HAS BEEN PUT WITH
12 THE TASK OF TRYING TO EXPLAIN TO THE MEMBERS IT'S
13 RECRUITING WHAT KIND OF GRANTS THEY WOULD BE LOOKING
14 AT. SO WE NEED TO BE ABLE TO DISCUSS THAT AT THE NEXT
15 MEETING AND CREATE SOME GUIDANCE TO THAT SEARCH
16 COMMITTEE AND DEFINE THE POLICY MAKING ROLE SEPARATE
17 FROM THE RECRUITING ROLE, BUT GIVE THEM ADEQUATE
18 DIRECTION SO THEY CAN PROPERLY RECRUIT. DR. PRIETO.

19 DR. PRIETO: I DO THINK WE HAVE A LITTLE BIT
20 OF A CHICKEN AND EGG PROBLEM HERE, BUT I THINK IT'S
21 IMPORTANT THAT WE FUNDAMENTALLY CONSIDER THESE SEARCH
22 COMMITTEES AS SEARCH COMMITTEES, AND THAT WE'RE PUTTING
23 THE WORKING GROUPS IN PLACE TO DO THE ONGOING WORK.

24 CHAIRMAN KLEIN: WE UNDERSTAND THAT.

25 DR. STEWARD: IT SEEMS TO ME THAT WHAT YOU'RE

1 REALLY SUGGESTING IS THAT THE CIRM UNDER ZACH'S
2 GUIDANCE PUT THESE PROPOSALS TOGETHER AND SEEK OUT THIS
3 INFORMATION, NOT THE SEARCH COMMITTEE, WITH PERHAPS THE
4 SEARCH COMMITTEE'S HELP. AM I MISUNDERSTANDING THAT?

5 CHAIRMAN KLEIN: THERE'S TWO DIFFERENT
6 FUNCTIONS. THE TRAINING PROGRAM, WE'RE ASKING ZACH TO
7 BRING THAT BACK WITH RECOMMENDATIONS. ON THE OTHER
8 PROGRAMS, THE GRANT COMMITTEE IS PROPOSING TO DISCUSS
9 THIS ISSUE AND BRING BACK TO THE BOARD INFORMATION
10 RELATED TO LEAD-TIME ISSUES THAT ARE TIME SENSITIVE.

11 DR. POMEROY: SO JUST ONE FINAL TIME MAKE THE
12 POINT, AND THEN I REALLY WILL STOP. WE NEED TO QUIT
13 CALLING IT THE GRANT COMMITTEE. WE NEED TO CALL IT THE
14 GRANTS WORKING GROUP SEARCH COMMITTEE. IT'S A SEARCH
15 COMMITTEE.

16 CHAIRMAN KLEIN: POINT WELL TAKEN. AND IT'S
17 VERY HELPFUL, AS TIME GOES ON, AND WE'RE ALL TIRED, TO
18 HELP BECAUSE IT BENEFITS THE PUBLIC AS WELL TO KEEP
19 CORRECTING USE OF THE TERMS.

20 ONE MOMENT.

21 MR. HALPERN: DR. PENHOET RECOGNIZED ME. I'M
22 SORRY, MR. CHAIRMAN.

23 DR. PENHOET: SORRY ABOUT THAT.

24 CHAIRMAN KLEIN: GO AHEAD.

25 MR. HALPERN: DO WE HAVE A CONSENSUS THEN

1 THAT I MAY SPEAK?

2 CHAIRMAN KLEIN: YES.

3 MR. HALPERN: THANK YOU. I WANT TO MAKE FOUR
4 BRIEF POINTS. THE FIRST ONE IS DR. LEE AND I HAVE
5 SUGGESTED IN OUR PETITION THAT THERE BE NO GRANTS MADE
6 UNTIL THE GUIDELINES ARE IN PLACE AND UNTIL POTENTIAL
7 APPLICANTS HAVE AN OPPORTUNITY, ARE GIVEN SUFFICIENT
8 TIME SO THEY CAN FORMULATE THEIR PLANS. THAT'S NOT A
9 FEW WEEKS FOR A COMPLEX PROPOSAL. OTHERWISE, WE'RE
10 CONCERNED THAT THE PEOPLE WHO HAVE THE CHAIRS AROUND
11 THIS TABLE AND THE INSTITUTIONS THEY REPRESENT MAY HAVE
12 AN UNFAIR ADVANTAGE OVER OTHER PEOPLE WHO ARE LESS
13 ABLE.

14 SECOND, THE STRATEGIC PLAN SHOULD PRECEDE THE
15 DEVELOPMENT EVEN OF STRATEGIES FOR FIRST-ROUND GRANTS.
16 FIRST, YOU HAVE TO MAKE THE JUDGMENT. I THINK I HAVE
17 90 SECONDS LEFT, MR. CHAIR. EVEN THE FIRST-ROUND
18 GRANTS YOU WANT TO FIT INTO AN OVERALL STRATEGY. WHY
19 TRAINING GRANTS? AND HOW MUCH SHOULD IT BE? \$20
20 MILLION? \$10 MILLION? THOSE OF US WHO THINK OF THOSE
21 SUMS AS BEING ENORMOUS SUMS WANT TO KNOW THAT THE
22 PARTICULAR AMOUNT FITS INTO AN OVERALL LONG-TERM
23 STRATEGY. THANK YOU.

24 CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND I
25 WELCOME YOU, MR. HALPERN, TO THE FULL DISCUSSION OF

1 THAT ITEM BECAUSE WE HAVE FULL PUBLIC DEBATE ON THAT
2 ITEM WHEN IT IS BROUGHT BACK TO THE BOARD. WE'RE
3 MERELY GETTING RESEARCH SO THAT WE CAN DISCUSS IT
4 MEANINGFULLY WITH SUBSTANCE. AND WE JUST APPRECIATE --
5 PLEASE APPRECIATE THE FACT THAT BY TRYING TO TELL THE
6 PUBLIC WHAT DIRECTION WE'RE TRYING TO DO RESEARCH,
7 WE'RE TRYING TO GIVE THE PUBLIC SOME LEAD-TIME SO THAT
8 THEY CAN BE PREPARED FOR THESE SESSIONS AND KNOW WHAT
9 THE SUBJECT MATTER MIGHT BE SO THEY CAN BE MORE
10 MEANINGFUL IN SUBSTANTIVE DISCUSSION OF THESE SUBJECTS.

11 I THINK THAT WE HAVE GONE THROUGH THE AGENDA
12 IN A REMARKABLY CREATIVE WAY. WE APPRECIATE THE
13 COMMENTS. AND I WOULD SAY THAT WE ARE MEETING WITH A
14 NUMBER OF THE DIFFERENT -- WITH SOME OF THE GROUPS THAT
15 HAVE BEEN ENUMERATED IN THE PETITION. WE'RE HAPPY TO
16 MEET WITH INDIVIDUALS AND DISCUSS CONCEPTS. I'VE MET
17 WITH MR. HALPERN. I'VE MET WITH THE GREEN LINE
18 INSTITUTE. IN FACT, WE'RE WORKING WITH THEM ON SOME
19 IDEAS, AND WE'RE HAPPY TO MEET WITH INDIVIDUAL
20 ORGANIZATIONS. BUT THE PUBLIC IS THE PUBLIC AT LARGE,
21 AND THE PUBLIC AT LARGE IS WITH WHOM WE NEED TO
22 INTERCHANGE -- HAVE INTERCHANGES IN THE PUBLIC DEBATE
23 OF THESE VERY IMPORTANT SUBJECTS THAT ARE IN THESE
24 PETITIONS.

25 AND I WILL SAY THAT IN THIS DISCUSSION THAT

1 WE CAN AS WELL UNDER CERTAIN CIRCUMSTANCES WHERE THERE
2 ARE GROUPS THAT CAN BE PUT TOGETHER THAT MIGHT HAVE
3 DIVERSE OPINIONS, BOTH FOR AND AGAINST A POSITION,
4 MIGHT CONVENE VARIOUS GROUPS TO GET A DISCUSSION OF
5 TOPICS THAT WOULD HELP BUILD AN UNDERSTANDING OF WHAT
6 THE ISSUES ARE ON BOTH SIDES BEFORE BRINGING IT OUT FOR
7 PUBLIC DEBATE. BUT WE'RE GOING TO TRY AND MOVE FORWARD
8 WITH AS MUCH PUBLIC DEBATE AS POSSIBLE. I THANK THE
9 PUBLIC, I THANK THE BOARD MEMBERS. THE MEETING STANDS
10 ADJOURNED.

11 (THE MEETING WAS THEN ADJOURNED AT 05:37
12 P.M.)

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