## 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: THE TECH MUSEUM OF INNOVATION 201 S. MARKET STREET SAN JOSE, CALIFORNIA

DATE: MONDAY, MAY 23, 2005 10:17 A.M.

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

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1	SAN JOSE	CALIFORNIA;	MONDAY,	MAY	23,	2005	
2		10:17	A.M.				

3

4 CHAIRMAN KLEIN: WE ARE CALLING THE MEETING TO ORDER. MY UNDERSTANDING IS THAT ENOUGH PLANES HAVE 5 6 ARRIVED THAT WE NOW HAVE A QUORUM. IN WELCOMING 7 EVERYONE TODAY TO THE SAN JOSE TECH MUSEUM, I WOULD 8 LIKE TO CALL YOUR ATTENTION TO THE FACT THAT UPSTAIRS 9 IN THE MUSEUM THERE IS A FABULOUS GENETICS EXHIBIT. 10 AND AFTER THE HEARING, ANY BOARD MEMBERS THAT ARE AVAILABLE, THE STAFF OF THE TECH MUSEUM HAS OFFERED TO 11 PROVIDE US A TOUR OF THAT GENETICS EXHIBIT. IT'S 12 SOMETHING THAT THEY AND THE CITY OF SAN JOSE SHOULD BE 13 14 EXTREMELY PROUD OF.

MEREDITH TAYLOR, THE ACTING PRESIDENT AND CEO
OF THE TECH MUSEUM OF INNOVATION AND HER TEAM ARE HERE.
MEREDITH, COULD YOU STAND FOR A MOMENT? MEREDITH BACK
THERE. MEREDITH IS STANDING RIGHT OUTSIDE. WHEN SHE
COMES IN BACK IN, I WILL INTRODUCE HER.

20 MAYOR GONZALES OF THE CITY OF SAN JOSE COULD 21 NOT BE HERE TODAY, NOR COULD THE VICE MAYOR. THE MAYOR 22 PERSONALLY SPOKE WITH ME AND THANKED US FOR HOLDING THE 23 MEETING IN SAN JOSE, AND HE HAS EMPHASIZED THAT SAN 24 JOSE IS LOOKING AT THE BAY AREA HEADQUARTERS, AND THE 25 OPPORTUNITY TO PARTICIPATE IN STEM CELL RESEARCH WITH

1 INSTITUTIONS OF THE BAY AREA HAS A TREMENDOUS

2 OPPORTUNITY. FROM HIS PERSPECTIVE, WE SHOULD PURSUE 3 THIS OPPORTUNITY ON A GLOBAL SCALE AND LEVERAGE THESE 4 OPPORTUNITIES WITH GLOBAL RESOURCES. HE WAS RECENTLY 5 IN CAMBRIDGE TO ADVANCE CERTAIN INITIATIVES OF THE CITY 6 OF SAN JOSE.

7 THE MAYOR, AS HIS PERSONAL REPRESENTATIVE AND 8 AS REPRESENTATIVE OF THE SAN JOSE CITY COUNCIL, HAS SENT COUNCILMAN FORREST WILLIAMS. FORREST WILLIAMS HAS 9 10 A DOCTORATE IN ELECTRICAL ENGINEERING AND COMPUTER SCIENCE. HE WAS WITH IBM FOR 35 YEARS WORKING ON THE 11 FRONTIERS OF STORAGE DEVELOPMENT. HE HAS NOW EMBARKED 12 13 ON ENHANCING AND SUPPORTING A NEW FRONTIER IN 14 BIOMEDICAL SCIENCE. THE BIOSCIENCE INCUBATOR IS, IN 15 FACT, IN HIS DISTRICT IN SAN JOSE. AND HE IS CHARGED 16 AS THE CHAIRMAN OF THE DRIVING STRONG ECONOMY 17 COMMITTEE, SO HE LOOKS AT BIOSCIENCE FROM A NUMBER OF HUMAN AND ECONOMIC PERSPECTIVES. 18 I'D LIKE TO ASK FORREST WILLIAMS IF HE WOULD 19 20 MAKE SOME WELCOMING COMMENTS.

21 DR. WILLIAMS: THANK YOU, CHAIRMAN BOB KLEIN. 22 I'D LIKE TO WELCOME ALL OF YOU HERE TO THE CITY OF SAN 23 JOSE. THE CITY OF SAN JOSE IS AN INNOVATIVE PLACE. 24 IT'S CREATIVE. WE HAVE KNOWN THIS FROM THE BEGINNING. 25 WE ARE HERE TO SUPPORT THIS EFFORT. THE VOTERS OF THE

STATE OF CALIFORNIA OVERWHELMINGLY SAID WE WANT YOU TO
 DO THIS. YOU HAVE PUT THE APPROPRIATE CONTROLS IN THE
 MEASURE TO INDICATE HOW YOU WILL MANAGE THIS PROJECT.

4 YOU ALSO SAID, THE VOTERS ALSO SAID THAT WE 5 BELIEVE THAT YOU WILL PROVIDE THE MEDICAL AND ETHICAL 6 STANDARDS FOR THIS PROPOSITION. IT ALSO SAID THAT YOU 7 WOULD HAVE A STRONG CONFLICT OF INTEREST POLICY. THEY 8 WERE CONFIDENT THAT YOU HAVE THE ABILITY TO DO THAT, 9 AND WE WANT YOU TO MOVE FORWARD.

YOUR ACTIVITY HAS BEEN LIKE A WHIRLWIND. YOU
HAVEN'T STOPPED SINCE THE PROPOSITION BECAME A BALLOT
FOR THE VOTERS' PERSPECTIVE. WE'RE PROUD OF THAT.
WE'RE HERE TO SERVE YOU, WORK WITH YOU, DO WHATEVER IT
IS THAT YOU NEED IN TERMS OF MAKING AND MOVING THIS
PROPOSITION AHEAD.

16 THE ICOC BOARD IN TERMS OF ITS INDEPENDENCE, 17 ITS OVERSIGHT, IT IS SIGNIFICANT. AND WE BELIEVE THAT 18 IN THE FUTURE THAT YOU WILL HAVE ALL OF THE NECESSARY 19 HANDLES THAT WILL ALLOW YOU TO PLAY IN THAT REALM OF 20 IMPOSSIBILITIES AND BRING REALITY TO THE THINGS THAT 21 THE PEOPLE OF THE STATE OF CALIFORNIA NEED. WE BELIEVE 22 IT'S THE NEXT FRONTIER.

23 I ALWAYS LIKE TO REFER TO THE WRIGHT
24 BROTHERS. YOU CAN IMAGINE WHAT WAS SAID WHEN THEY SAID
25 WE'RE GOING TO FLY. AND THEY WOULD SAY BIRDS FLY

1 BECAUSE THAT WAS THE THOUGHT OF MAN AT THE REALM OF 2 IMPOSSIBILITY, LOOKING AT IMPOSSIBILITY, BUT THEY PURSUED THE IMPOSSIBLE TO BRING IT TO REALITY. SO 3 4 TODAY WE CANNOT COMPREHEND OF NOT HAVING AN AIRPLANE. SO I WANT YOU TO BE IN THAT REALM, AND I WANT 5 6 YOU TO BRING FORTH TO THE PEOPLE OF THE STATE OF 7 CALIFORNIA, WITH ALL OF OUR HELP, THE THINGS THAT 8 THEY'VE ASKED YOU TO PROVIDE. WE REALLY, REALLY, 9 REALLY, REALLY APPRECIATE YOU BRINGING THE HEADQUARTERS 10 OF CIRM TO THE BAY AREA. WE WILL BE HERE FOR THAT, AND WE WILL STRIVE FOR ALL THAT YOU NEED IN ORDER TO BE 11 SUCCESSFUL. I WANT TO THANK YOU AGAIN ON BEHALF OF THE 12 13 MAYOR AND THE CITY OF SAN JOSE, AND ALL MY COLLEAGUES FOR BEING HERE TODAY. AND WE LOOK FORWARD TO CONTINUED 14 SUCCESS IN THE FUTURE. THANK YOU. 15

16 (APPLAUSE.)

17 CHAIRMAN KLEIN: I BELIEVE WE ALSO HAVE THE
18 BENEFIT OF CONGRESSMAN MIKE HONDA'S OFFICE SENDING A
19 REPRESENTATIVE HERE TODAY. IS THAT REPRESENTATIVE
20 HERE? IF YOU WOULD STAND FOR A MOMENT. THANK YOU VERY
21 MUCH FOR COMING.

ON OUR AGENDA WE PREVIOUSLY SUGGESTED THAT
OUR EXECUTIVE SESSION WOULD BE POTENTIALLY THREE HOURS.
WE EXPECT IT WILL BE AN HOUR TO AN HOUR AND A HALF, AND
WE'RE GOING TO MOVE ITEM 11 TO IMMEDIATELY AFTER

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1	LUNCH ITEM 10 TO IMMEDIATELY AFTER LUNCH. OTHERWISE
2	WE WILL MOVE FORWARD WITH THE AGENDA AS STATED.
3	MELISSA KING, WOULD YOU PLEASE LEAD US
4	THROUGH THE PLEDGE OF ALLEGIANCE.
5	(THE PLEDGE OF ALLEGIANCE.)
6	CHAIRMAN KLEIN: MELISSA KING, WOULD YOU
7	PLEASE LEAD US IN THE ROLL CALL.
8	MS. KING: DAVID BALTIMORE.
9	DR. BALTIMORE: HERE.
10	MS. KING: ROBERT BIRGENEAU. SUSAN BRYANT.
11	DR. BRYANT: HERE.
12	MS. KING: KEITH BLACK. MICHAEL FRIEDMAN.
13	MICHAEL GOLDBERG. BRIAN HENDERSON.
14	DR. HENDERSON: HERE.
15	MS. KING: ED HOLMES.
16	DR. HOLMES: HERE.
17	MS. KING: DAVID KESSLER.
18	DR. KESSLER: HERE.
19	MS. KING: BOB KLEIN.
20	CHAIRMAN KLEIN: HERE.
21	MS. KING: SHERRY LANSING. GERALD LEVEY.
22	DR. LEVEY: HERE.
23	MS. KING: TED LOVE.
24	DR. LOVE: HERE.
25	MS. KING: RICHARD MURPHY.

1		DR. MURPHY: HERE.
2		MS. KING: TINA NOVA.
3		DR. NOVA: HERE.
4		MS. KING: ED PENHOET.
5		DR. PENHOET: HERE.
б		MS. KING: PHIL PIZZO. CLAIRE POMEROY.
7		DR. POMEROY: HERE.
8		MS. KING: PHYLLIS PRECIADO. FRANCISCO
9	PRIETO.	
10		DR. PRIETO: HERE.
11		MS. KING: JEANNIE FONTANA FOR JOHN REED.
12		DR. FONTANA: HERE.
13		MS. KING: JOAN SAMUELSON.
14		MS. SAMUELSON: HERE.
15		MS. KING: DAVID SERRANO-SEWELL.
16		MR. SERRANO-SEWELL: HERE.
17		MS. KING: JEFF SHEEHY.
18		MR. SHEEHY: HERE.
19		MS. KING: JONATHAN SHESTACK.
20		MR. SHESTACK: HERE.
21		MS. KING: OSWALD STEWARD. LEON THAL. GAYLE
22	WILSON.	
23		MS. WILSON: HERE.
24		MS. KING: JANET WRIGHT.
25		DR. WRIGHT: HERE.

1 MS. KING: JUST A QUICK NOTE TO THE BOARD. 2 THE MICROPHONES ARE ACTIVATED BY YOUR VOICE, AND YOU NEED TO BE RELATIVELY CLOSE TO THEM, NOT TOO CLOSE LIKE 3 4 I AM TO THIS ONE RIGHT NOW, FOR THEM TO BE ACTIVATED. AND PROBABLY NO MORE THAN TWO AT ONCE WILL BE 5 6 ACTIVATED. AS SOON AS YOU STOP SPEAKING, IT WILL ALLOW 7 SOMEBODY TO START SPEAKING AND ACTIVATE THEIR 8 MICROPHONE. THEY'RE AUTOMATIC. THANK YOU. 9 CHAIRMAN KLEIN: THANK YOU VERY MUCH. I 10 REMIND THE PUBLIC THAT COMMENTS ARE LIMITED TO THREE MINUTES, BUT WE WELCOME WRITTEN SUBMISSIONS. AND WE'RE 11 HAPPY TO MAKE THOSE SUBMISSIONS AVAILABLE TO THE 12 13 PUBLIC. ARE THERE ANY PUBLIC COMMENTS BEFORE WE GO 14 15 INTO THE AGENDA? 16 MR. REED: MY NAME DON REED. LIKE EVERYONE 17 IN AMERICA, I HAVE A REASON TO DEFEND THE CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE. MY SISTER BARBARA 18 HAS CANCER. BECAUSE OF THE CIRM, SHE NOW HAS HOPE 19 20 INSTEAD OF ONLY ENDLESS SURGERIES AND LEUKEMIA BROUGHT 21 ON BY RADIATION THERAPY. MY SON ROMAN IS PARALYZED. BECAUSE OF THE 22 23 CIRM, HE BELIEVES HE WILL WALK AGAIN. HOW DO WE FEEL 24 ABOUT ATTACKS ON OUR OWN CALIFORNIA INSTITUTE OF 25 REGENERATIVE MEDICINE? WE MUST FEEL SOMEWHAT LIKE THE

WAY THE ENGLISH PEOPLE FELT IN WORLD WAR II WHEN NAZIS
 WERE RAINING BOMBS ON LONDON.

TO PARAPHRASE WINSTON CHURCHILL WHEN HE SPOKE 3 4 AT THE IMPENDING NAZI INVASION, WE WILL FIGHT. WE WILL FIGHT NOT WITH GUNS OR VIOLENCE, BUT WITH E-MAILS, WITH 5 6 LETTERS TO EDITORS, WITH ORGANIZATIONS LARGE AND SMALL 7 ACROSS THIS NATION BECAUSE THIS IS FOR EVERYONE. WE WILL NEVER SURRENDER. WE WILL SO BEAR OURSELVES THAT 8 9 THE CIRM LASTS FOR A THOUSAND YEARS. MEN WILL STILL 10 SAY THIS WAS THEIR FINEST HOUR. THANK YOU ALL FOR YOUR LEADERSHIP. WE ARE WITH YOU. WE ARE READY. 11 CHAIRMAN KLEIN: THANK YOU VERY MUCH. ANY 12 13 ADDITIONAL PUBLIC COMMENT? I'D LIKE TO GO INTO ITEM 4, CONSENT ITEMS. 14 15 LAST MONTH'S BOARD MEETING MINUTES ARE ON OUR CONSENT 16 CALENDAR. IS THERE ANYONE WHO WOULD LIKE TO MAKE A MOTION TO PASS THIS CONSENT ITEM? 17 MR. SERRANO-SEWELL: SO MOVED. 18 CHAIRMAN KLEIN: IT'S BEEN MOVED. IS THERE A 19 20 SECOND? 21 DR. HOLMES: SECOND. CHAIRMAN KLEIN: MOVED AND SECONDED. IS 22 23 THERE ANY DISCUSSION? DR. PRIETO: MR. CHAIRMAN, JUST ONE COMMENT. 24 25 I NOTICE SHERRY LANSING IS MARKED AS ABSENT ON THE ROLL

1 CALL. I BELIEVE SHE WAS PRESENT AT THE MEETING. 2 CHAIRMAN KLEIN: YES. SHE DID COME IN AFTER THE ROLL CALL, SO WE'LL MAKE THAT CORRECTION. ANY 3 4 OTHER COMMENTS? 5 MS. WILSON: THEY HAVE ME AS ABSENT TOO, AND 6 I WAS THERE. 7 CHAIRMAN KLEIN: YES. OKAY. ANY PUBLIC 8 COMMENTS ON THIS ITEM? IS THE BOARD PREPARED TO CALL 9 THE QUESTION ON THIS ITEM? ALL IN FAVOR. OPPOSED? 10 AGENDA ITEM 5 IS CONSIDERATION OF THE ADOPTION OF THE NATIONAL ACADEMY OF SCIENCE MEDICAL AND 11 ETHICAL STANDARDS AS THE CALIFORNIA INSTITUTE OF 12 REGENERATIVE MEDICINE INTERIM STANDARDS. 13 I WOULD LIKE TO PROVIDE SOME BACKGROUND ON 14 15 THIS, AND THEN TURN TO ZACH HALL FOR A SPECIFIC REPORT 16 ON THIS ITEM. 17 AS THE BOARD MEMBERS KNOW, A WEEK AFTER THE ELECTION IN NOVEMBER 2D, 2004, I SPOKE TO BRUCE 18 ALBERTS, THE PRESIDENT OF THE NATIONAL ACADEMY OF 19 20 SCIENCE, WHICH INCLUDES, OF COURSE, THE NATIONAL 21 INSTITUTE OF MEDICINE AND THE NATIONAL ACADEMY OF ENGINEERING, ABOUT CONVENING AN OPEN MEETING IN IRVINE 22 23 FOR THE PUBLIC, THE PRESS, AND INTERESTED PARTIES THAT 24 HAD PARTICIPATED IN THE PASSAGE OF PROP 71 TO REALLY HIGHLIGHT AND FOCUS ON THE BEST MEDICAL AND ETHICAL 25

1 STANDARDS IN THE NATION.

2 IN AN UNPRECEDENTED FOCUSED ACTION, THE NATIONAL ACADEMY SCHEDULED AND PUT FORTH A WORKSHOP IN 3 4 IRVINE ON DECEMBER 6TH AND 7TH. NEVER BEFORE IN THEIR 5 HISTORY OR RECENT HISTORY HAVING PULLED TOGETHER A 6 NATIONAL WORKSHOP ON THAT SHORT NOTICE. BUT TWO FULL 7 DAYS WERE SPENT, AND THEIR PAPERS WENT UP ON WEBSITES 8 RELATED TO THE PROP 71 CAMPAIGN. THERE WERE HEARINGS 9 AROUND THE STATE FOR THOSE IDEAS TO BE DISCUSSED. 10 CONCURRENT WITH THAT, THE NATIONAL ACADEMY HAD MOBILIZED A NATIONAL TEAM OF THE BEST AND THE 11 12 BRIGHTEST, INCLUDING MANY OF THE PEOPLE AT THE WORKSHOP 13 ON DECEMBER 6TH AND 7TH, IN A TASK FORCE TO PRODUCE 14 MODEL NATIONAL STANDARDS IN THE HOPES THAT IF 15 CALIFORNIA ADOPTED THOSE STANDARDS, THAT THE OTHER 16 STATES WOULD FOLLOW AND WE'D HAVE CONSISTENT STANDARDS 17 ACROSS THE NATION, WHICH WOULD FACILITATE THE MOVEMENT BACK AND FORTH OF THE SCIENCE IN STEM CELL RESEARCH. 18 THE INDIVIDUALS INVOLVED IN WORKING ON THE 19 TASK FORCE UNDER THE NATIONAL ACADEMY'S PROCEDURES 20 21 CANNOT DISCUSS THE MATERIALS WHILE THEY ARE ON THE TASK 22 FORCE, BUT WE DID HAVE THE OPPORTUNITY TO RETAIN AS A 23 CONSULTANT TO THIS BOARD ALTA CHARO, ONE OF THE LEADING MEDICAL ETHICISTS OF THE NATION, WHO IS NOW A MEMBER OF 24 25 OUR STANDARDS WORKING GROUP, TO HELP GUIDE US THROUGH A

1 BOARD WORKSHOP ON MEDICAL ETHICS AND A BOARD

2 PRESENTATION ON MEDICINE ETHICS, AS WELL AS STAFF WORK3 THAT WAS DONE IN REVIEWING THESE POSITIONS.

4 AT THIS POINT THE ISSUE BEFORE US IS THAT I WOULD LIKE TO RECOMMEND THAT THE BOARD APPROVE THE 5 6 NATIONAL ACADEMY STANDARDS AS A MODEL FOR THE NATION OF 7 THE HIGHEST AND BEST STANDARDS IN STEM CELL RESEARCH. 8 THIS IS A PROPOSAL THAT WILL COME UNDER DISCUSSION IN 9 THIS MEETING AFTER DR. HALL HAS MADE A PRESENTATION, 10 AFTER BOARD DISCUSSION, AND PUBLIC DISCUSSION. BUT I WOULD LIKE TO EMPHASIZE THAT THIS IS INTENDED TO BE AN 11 12 ADOPTION ON A PROSPECTIVE BASIS; AND THAT IS, IT IS NOT 13 INTENDED THAT THESE STANDARDS WOULD INVALIDATE OR OTHERWISE TAKE OUT OF THE PROCESS ANY STEM CELL LINES 14 15 OR BIOLOGICAL MATERIALS OR RESEARCH THAT WAS DEVELOPED 16 BEFORE THESE STANDARDS, BUT IT WOULD BE APPLIED GOING 17 FORWARD.

AND THE PROPOSAL IS SPECIFICALLY UNDER 18 19 CONSIDERATION THAT WE WOULD ADOPT THE STANDARDS, AND 20 THEN SEND THEM TO OUR STANDARDS WORKING GROUP, WHO 21 WOULD GO THROUGH A 270-DAY PERIOD OF PUBLIC HEARINGS 22 FOR CONSIDERATION OF REFINEMENTS TO THE STANDARDS. 23 THERE ARE SPECIFIC COMMENTS I WOULD LIKE TO TAKE AFTER DR. HALL'S COMMENTS FROM DR. BALTIMORE. BUT WE HAVE AN 2.4 25 OUTSTANDING OPPORTUNITY FOR CALIFORNIA HERE TO AGAIN

1 LEAD THE NATION WITH THE HIGHEST AND BEST MEDICAL

2 STANDARDS THAT HAVE BEEN DEVELOPED BY THE BEST AND THE3 BRIGHTEST OF OUR NATION. DR. HALL.

4 DR. HALL: WHAT I'D LIKE TO DO IS TO LEAD YOU 5 BRIEFLY THROUGH THE GUIDELINES. I APOLOGIZE. I HAD 6 UNDERSTOOD IN PREPARING THIS THAT YOU ALL HAD COPIES OF 7 THEM AS PART OF YOUR MATERIAL TODAY. THEY ARE 8 AVAILABLE.

9 SO WE CAN GO THROUGH FAIRLY QUICKLY, BUT LET 10 ME JUST BEGIN BY SAYING THAT WITH THE DEFECTION OF NIH FROM THE FIELD OF HUMAN EMBRYONIC STEM CELL RESEARCH OR 11 AT LEAST FROM MUCH OF IT, WHAT RESULTED WAS A SORT OF 12 13 PATCHWORK OF LOCAL GUIDELINES DEVISED BY DIFFERENT 14 INSTITUTIONS IN DIFFERENT PLACES. AND THERE HAS BEEN 15 AN ABSENCE OF GENERALLY AGREED UPON GUIDELINES AND A 16 NATIONAL CONSENSUS.

17 IN ORDER TO ADDRESS THIS ISSUE AND TO PROMOTE RESPONSIBLE STEM CELL RESEARCH, THE NATIONAL ACADEMIES 18 UNDERTOOK TO DEVELOP THE GUIDELINES. AND THEY, THROUGH 19 20 THE NATIONAL RESEARCH COUNCIL AND THE INSTITUTE OF 21 MEDICINE, APPOINTED A COMMITTEE CO-CHAIRED BY RICHARD 22 HYNES OF MIT, A DISTINGUISHED BIOLOGIST, AND JONATHAN 23 MORENO, OF THE UNIVERSITY OF VIRGINIA, A VERY 24 DISTINGUISHED BIOETHICIST. THE TEN MEMBERS ON THE 25 COMMITTEE INCLUDED JANET ROWLEY, WHO IS ON OUR

STANDARDS WORKING GROUP, AS YOU KNOW; AND BOB KLEIN,
 THE CHAIRMAN, ALTA CHARO, WHO IS A LIAISON TO THE
 ORIGINAL STANDARDS COMMITTEE AT THE NATIONAL ACADEMY,
 IS ALSO A MEMBER OF OUR STANDARDS WORKING GROUP.

THE COMMITTEE HELD A TWO-DAY WORKSHOP ON THE 5 6 ISSUES. IT USED THE WEB AND OTHER MEANS TO SOLICIT 7 PUBLIC OPINION AND INVITED A NUMBER OF SPEAKERS TO 8 APPEAR BEFORE IT, AND THEN CARRIED OUT A SERIES OF 9 DRAFTING MEETINGS AND EXECUTIVE SESSION ABOUT WHICH THE 10 REPORT WAS DRAFTED. IT WAS THEN REVIEWED BY 14 EXPERT REVIEWERS, AND THE GUIDELINES WERE ANNOUNCED ON APRIL 11 12 26TH.

OUR STANDARDS COMMITTEE WILL GO THROUGH WHAT
I PRESUME WILL BE A ROUGHLY SIMILAR PROCESS OVER THE
NEXT SIX TO NINE MONTHS TO ADOPT OUR LONG-TERM
STANDARDS. IN THE MEANTIME, AS THE CHAIRMAN SAID, WE
WOULD LIKE TO ADOPT THESE INTERIM STANDARDS FOR HUMAN
EMBRYONIC STEM CELL WORK.

NOW, THE ISSUES THAT THE COMMITTEE ADDRESSED
WITH THEIR GUIDELINES ARE THE DONATION OF BLASTOCYSTS,
GAMETES, AND SOMATIC CELLS, THE CHARACTERIZATION OF
STEM CELLS, SAFE HANDLING AND STORAGE OF BLASTOCYSTS
AND STEM CELL MATERIAL, THE PREREQUISITES TO HUMAN
EMBRYONIC STEM CELL RESEARCH, APPROPRIATE USES OF HUMAN
EMBRYONIC STEM CELL LINES, AND LIMITATIONS ON THEIR

1 USE, AND, FINALLY, SAFEGUARDS AGAINST MISUSE.

2 NOW, THEIR PRINCIPAL RECOMMENDATION WAS THAT THERE BE A DUAL LEVEL OF OVERSIGHT, THE FIRST BEING AT 3 4 THE INSTITUTIONAL LEVEL AND THE SECOND AT THE NATIONAL 5 LEVEL. I WILL ADDRESS NATIONAL LEVEL IN JUST A FEW 6 MOMENTS, BUT LET ME TALK FIRST ABOUT THE LOCAL 7 INSTITUTIONAL REGULATORY MECHANISM THAT THEY SUGGESTED 8 BECAUSE MUCH OF THEIR REPORT IS ORGANIZED AROUND THIS. 9 THEY SUGGESTED THAT RESEARCH INSTITUTIONS 10 SHOULD ESTABLISH WHAT THEY CALL EMBRYONIC STEM CELL RESEARCH OVERSIGHT COMMITTEES, ESCRO COMMITTEES, 11 SIMILAR TO IRB COMMITTEES, BUT DISTINCT FROM THEM AND 12 13 SERVING A DIFFERENT FUNCTION, AND I'LL ADDRESS THAT 14 MORE IN JUST A MOMENT. 15 THE ESCRO IS TO HAVE OVERSIGHT OF ALL HUMAN 16 EMBRYONIC STEM CELL RESEARCH AT A PARTICULAR INSTITUTION. IT IS TO DETERMINE APPROPRIATE LEVEL OF 17 REVIEW. IT IS TO REVIEW AND APPROVE RESEARCH PROTOCOLS 18 TO MAKE SURE THAT THERE IS COMPLIANCE WITH OTHER 19 REGULATORY BODIES, IF NEEDED, TO MAINTAIN A REGISTRY, 20 21 FACILITATE EDUCATION, AND TO ENSURE THAT INAPPROPRIATE 22 RESEARCH IS NOT DONE. 23 NOW, THE ESCRO COMMITTEES, ARE, FIRST OF ALL, TO ENSURE THAT THE PROVENANCE OF HUMAN EMBRYONIC STEM 24

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CELLS IS DOCUMENTED; THAT IS, FOR EACH LINE THAT'S

USED, TO KNOW WHERE IT CAME FROM AND UNDER WHAT
 CONDITIONS IT WAS CREATED. THIS WILL BE A VERY
 IMPORTANT PART OF THEIR ACTIVITIES.

4 SECONDLY, THERE SHOULD BE NO RESEARCH IN 5 WHICH HUMAN EMBRYONIC STEM CELLS ARE INTRODUCED INTO A 6 NONHUMAN PRIMATE BLASTOCYST OR IN WHICH ANY KIND OF 7 EMBRYONIC STEM CELL IS INTRODUCED INTO A HUMAN 8 BLASTOCYST.

9 THIRDLY, NO ANIMAL IN WHICH HUMAN EMBRYONIC
10 STEM CELLS HAVE BEEN INTRODUCED AT ANY STAGE OF
11 DEVELOPMENT SHOULD BE ALLOWED TO BREED.

12 NOW, THEY DO FORESEE THE NEED AND USEFULNESS 13 OF HAVING TO PUT HUMAN EMBRYONIC STEM CELLS INTO OTHER 14 ANIMALS, FOR EXAMPLE, MICE, FOR PARTICULAR EXPERIMENTAL 15 PURPOSES. THAT IS TO BE REGULATED CAREFULLY BY THE 16 COMMITTEE, BUT IN ANY CASE ANY ANIMAL THAT HAS 17 UNDERGONE THIS PROCEDURE SHOULD NOT BE ALLOWED TO 18 PROPAGATE.

SO THE OTHER FUNCTIONS OF THIS COMMITTEE ARE
 TO MAINTAIN A REGISTRY OF THE INVESTIGATORS AND THEIR
 RESEARCH AT THE PARTICULAR INSTITUTION, AND THEN TO
 ENSURE SUITABLE STANDARDS FOR WORK TO BE DONE AT
 INTERNATIONAL COLLABORATIONS WHERE GUIDELINES MAY BE
 DIFFERENT. WE ANTICIPATE THAT THERE WILL BE
 COLLABORATION ACROSS INTERNATIONAL BOUNDARIES. FOR

THOSE OF YOU WHO MAY HAVE NOTICED, THE KOREAN PAPER
 THAT WAS PUBLISHED LAST FRIDAY IN "SCIENCE" HAD ONE
 AMERICAN AUTHOR WHO'S AT THE UNIVERSITY OF PITTSBURGH,
 AND WHO INCIDENTALLY MADE THE COMMENT THAT IF HE WERE
 TO DO THIS WORK IN HIS HOME STATE, HE WOULD BE A FELON.
 BUT AT ANY RATE, WE ANTICIPATE INTERNATIONAL

7 COLLABORATIONS.

8 WE HAVE BEEN IN CONTACT WITH INVESTIGATORS 9 FROM A NUMBER OF COUNTRIES, AND SO THIS IS TO ENSURE 10 THAT ANY LINE THAT, FOR EXAMPLE, HAS BEEN DERIVED UNDER 11 THE GUIDELINES OF ANOTHER COUNTRY ARE SUITABLE FOR USE 12 HERE. IN FACT, THEY SAY THAT THE COMMITTEES MAY WISH 13 TO ADOPT MORE STRICT GUIDELINES IN LINE WITH THOSE IN 14 FOREIGN COUNTRIES, IF APPROPRIATE.

15 NOW, THE OTHER POINT IS THAT ALL BIOLOGICAL 16 MATERIALS AND HOW THEY'RE PROCURED NEED TO BE OVERSEEN BY THE ESCRO COMMITTEE. AND THEY POINT OUT THAT IRB'S 17 MAY NOT WAIVE THE REQUIREMENTS FOR INFORMED CONSENT FOR 18 ANYONE WHO DONATES BIOLOGICAL MATERIAL. THAT IS, THE 19 20 IRB MUST BE SURE THAT ANY DONOR OF A GAMETE GIVES 21 INFORMED CONSENT, AND THERE'S NO EXCEPTION TO THIS 22 GUIDELINE, EITHER EGG, SPERM, OR SOMATIC CELLS. 23 WHERE APPROPRIATE, INSTITUTIONAL GUIDELINES

FOR RECOMBINANT DNA RESEARCH AND ANIMAL CARE SHOULD BE FOLLOWED, AND THEY RECOMMEND THAT GOOD LABORATORY

1 PRACTICES SHOULD BE FOLLOWED WHERE POSSIBLE.

2 FINALLY, RESEARCH LEADING TO CLINICAL APPLICATION MUST BE IN COMPLIANCE WITH FDA REGULATIONS. 3 4 THEY HAVE SEVERAL RECOMMENDATIONS RELATED TO DONATION OF BIOLOGICAL MATERIALS. CONSENT MUST BE 5 6 OBTAINED FROM ALL GAMETE DONORS. NO CASH OR IN-KIND 7 PAYMENTS MAY BE PROVIDED FOR DONATING BLASTOCYSTS. AND 8 THEN THEY NOTED IN THE GUIDELINES ACTUALLY THAT THEY 9 WERE FOLLOWING PROPOSITION 71 IN PROPOSING THAT NO 10 REIMBURSEMENT ABOVE DIRECT EXPENSES TO WOMEN WHO DONATE OOCYTES FOR RESEARCH PURPOSES. 11 AND FINALLY, CONSENT FOR THE BLASTOCYST 12 DONATION SHOULD BE OBTAINED AT THE TIME OF DONATION, 13 14 CANNOT BE OBTAINED RETROACTIVELY. 15 FURTHER, THEY GIVE A NUMBER OF EXPLICIT 16 MINIMAL GUIDELINES FOR INFORMED CONSENT. THEY ARE VERY EXPLICIT THAT ANY DECISIONS MADE ABOUT DONATION OF 17 MATERIALS FOR RESEARCH SHOULD BE ABSOLUTELY SEPARATED 18 FROM ANY DECISIONS MADE ABOUT MEDICAL CARE FOR A 19 20 PATIENT. THAT IS, A DECISION TO EITHER TO PARTICIPATE 21 OR NOT TO PARTICIPATE SHOULD BE INDEPENDENT OF ANY 22 HEALTHCARE PROCEDURE OR ANY FERTILITY PROCEDURE THAT A PATIENT MAY BE UNDERGOING. AND THEY SUGGEST, IN FACT, 23 24 THAT THIS IS BEST DONE IF THE PEOPLE INVOLVED ARE 25 ENTIRELY SEPARATE.

1 THEY HAVE A COMBINATION FOR CLINICAL 2 PERSONNEL WHO MAY HAVE A CONSCIENTIOUS OBJECTION TO HUMAN EMBRYONIC STEM CELL RESEARCH, AND THEY SHOULD NOT 3 4 BE REQUIRED TO PARTICIPATE IN PROVIDING DONOR INFORMATION OR SECURING CONSENT. 5 6 AND FINALLY, THE GUIDELINES SAY THAT 7 RESEARCHERS MAY NOT REQUEST THAT MORE OOCYTES BE 8 DONATED THAN ARE REQUIRED FOR REPRODUCTIVE SUCCESS AND 9 HAVE IT EXPLICIT FOR THIRD PARTIES. 10 TWO RECOMMENDATIONS RELATED TO CELL BANKS. UNIFORM GUIDELINES FOR INFORMED CONSENT AND 11 SELF-CULTURE RECORDS SHOULD BE ADOPTED WHERE HUMAN 12 EMBRYONIC STEM CELLS ARE TO BE DEPOSITED IN A BANK. IN 13 OTHER WORDS, WHEN THESE BANKS ARE ESTABLISHED, ANY 14 15 RESEARCHER OR INVESTIGATOR THAT RECEIVES A CELL LINE 16 FROM THEM CAN BE ASSURED THAT THE LINE WAS DERIVED 17 UNDER APPROPRIATE CONDITIONS. AND THERE ARE ALSO SOME PRIVACY ISSUES HERE WHICH I WILL NOT GO INTO, BUT ARE 18 OUTLINED IN THE REPORT. 19 20 AND THEN FINALLY, THEY SAID THAT ANY CELL 21 BANK FACILITY SHOULD HAVE SPECIFIC RECOMMENDATIONS FOR 22 OBTAINING AND STORING CELL LINES IN ORDER TO DO THEIR 23 BUSINESS. 24 THEY HAVE TWO GENERAL RECOMMENDATIONS. ONE

IS TO ENSURE THE GENETIC DIVERSITY AMONG CELL LINES TO

25

PROVIDE POTENTIAL HEALTH BENEFITS TO ALL IN OUR
 SOCIETY.

AND FINALLY, THEY SUGGEST THAT THERE BE A 3 4 NATIONAL BODY THAT EXERTS CONTINUING ASSESSMENT AND DISCUSSION OF THE GUIDELINES. NOW, THE NATIONAL 5 6 ACADEMIES REPORT DID NOT GIVE ANY SUGGESTION OF WHO 7 THAT BODY MIGHT BE. A NUMBER OF US FEEL THAT THEY ARE, 8 IN FACT, THE LOGICAL BODY TO DO THIS. I THINK GIVEN 9 THE CURRENT SITUATION IN THE FEDERAL GOVERNMENT, 10 PARTICULARLY THE NIH IS NOT IN ANY POSITION TO DO IT, AND I THINK THE CARE AND RESPONSIBILITY WITH WHICH 11 THEY'VE GONE ABOUT THIS TASK RECOMMENDS THEM, I THINK 12 WE DO NOT WANT A VACUUM THERE FOR PEOPLE RUSHING IN TO 13 DO THIS. AND SO WITH YOUR PERMISSION, I JUST WOULD 14 15 LIKE TO SAY THAT I WILL SEND A LETTER TO THE NATIONAL 16 ACADEMY ON BEHALF OF CIRM RECOMMENDING THAT THE 17 NATIONAL ACADEMIES PROVIDE THIS NATIONAL OVERSIGHT 18 COMMITTEE. MR. CHAIRMAN, THESE ARE THE GUIDELINES IN 19 20 SHORT FORM OF THE NATIONAL ACADEMY OF SCIENCES REPORT. 21 I'D BE HAPPY TO ANSWER ANY OUESTIONS IF YOU HAVE THEM. CHAIRMAN KLEIN: THANK YOU VERY MUCH, DR. 22 23 HALL. I WOULD LIKE TO POINT OUT THAT IF ONE WERE 24 LOOKING FOR THE REFERENCE IN THE NATIONAL ACADEMY

21

REPORT TO THE SPECIFIC ATTRIBUTION OF THE STANDARD THAT

1 PROHIBITS COMPENSATION FOR EGG DONORS, IT'S

APPROXIMATELY PAGE 72. IT DEPENDS ON YOUR TEXT PRINT 2 SIZE, BUT IT IS REMARKABLE THAT THE NATIONAL ACADEMIES 3 4 WOULD POINT TO A STATE WITH A HIGHER STANDARD AND POINT TO PROPOSITION 71 AS THE HIGH STANDARD THEY CHOSE AS 5 6 THE MODEL FOR PROHIBITING COMPENSATION FOR EGG DONORS 7 TO MAKE CERTAIN THAT THIS DONATION IS MOTIVATED BY THE 8 MORAL DESIRE TO ADVANCE MEDICAL RESEARCH TO REDUCE 9 SUFFERING.

10 IN ADDITION, TO THE EXTENT THAT THERE'S ANY SPECIFIC ITEM IN THESE RECOMMENDATIONS THAT IS MORE 11 LIBERAL THAN THE INITIATIVE ITSELF, FOR EXAMPLE, WHERE 12 14 DAYS IS SPECIFIED AS THE LIMIT OF CELL DIVISION, AND 13 14 THE INITIATIVE SPECIFIES 12 DAYS, THEN THE INITIATIVE'S 15 MORE RESTRICTIVE STANDARD AS A MATTER OF STATE LAW 16 WOULD CONTINUE TO APPLY. WE HAVE A MORE CONSERVATIVE STANDARD IN THIS REGARD. 17

18 I'D LIKE TO CALL DR. DAVID BALTIMORE FOR HIS19 COMMENTS TO BEGIN THE BOARD DISCUSSION.

20 DR. BALTIMORE: FIRST OF ALL, LET ME SAY THAT 21 I THINK THAT THESE ARE A TERRIFIC SET OF GUIDELINES TO 22 GO FORWARD WITH, AND I HAVE NO PARTICULAR PROBLEM WITH 23 ANY OF THEM. AND I THINK THEY HAVE VERY THOUGHTFULLY 24 DEALT WITH MANY OF THE ISSUES.

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25 THERE'S ONE NIT IN HERE WHICH IS THE
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1 REQUIREMENT THAT ALL INSTITUTIONS CONDUCTING RESEARCH 2 SHOULD ESTABLISH AN ESCRO COMMITTEE, EMBRYONIC STEM CELL RESEARCH OVERSIGHT COMMITTEE. AND AS BRIAN 3 4 HENDERSON AND I WERE TALKING ABOUT THIS ON THE WAY HERE, WE THOUGHT IT MIGHT BE PREFERABLE TO HAVE ONE 5 6 COMMITTEE THAT DEALT WITH A NUMBER OF INSTITUTIONS 7 BECAUSE IT'S VERY HARD, PARTICULARLY CALTECH, TO FIND 8 PEOPLE WHO ARE INVOLVED IN ASSISTED REPRODUCTION AND 9 THE OTHER PARTICULAR EXPERTISE WHICH IS INDICATED IN 10 THIS OUTLINE FOR THE COMMITTEE.

11 ACTUALLY THE GUIDELINES DON'T PROHIBIT THAT. 12 AND SINCE I DON'T THINK WE WANT TO GET INTO A 13 DISCUSSION OF THE DETAILS OF THIS, SO I DON'T WANT TO 14 OPEN IT UP, I JUST SORT OF WANT TO PUT ON THE RECORD 15 THE UNDERSTANDING THAT A COMMITTEE COULD REPRESENT MORE 16 THAN ONE INSTITUTION.

17 CHAIRMAN KLEIN: DR. HALL, MY UNDERSTANDING IS THAT THERE IS NOT ANYTHING IN THE GUIDELINES THAT 18 19 WOULD PREVENT HAVING A MUCH HIGHER QUALITY BENEFIT OF INTERINSTITUTIONAL COMMITTEES AND THAT, THEREFORE, 20 21 MOVING FORWARD WITH THIS, UNDERSTANDING THAT 22 INTERINSTITUTIONAL COMMITTEES COULD FILL THIS ROLE 23 WOULD BE QUITE APPROPRIATE; IS THAT CORRECT? 24 DR. HALL: I THINK SO. I DON'T THINK THE 25 GUIDELINES SPEAK TO THIS IN ANY EXPLICIT WAY. BUT I

1 SEE NO PROHIBITION AGAINST THIS.

2 CHAIRMAN KLEIN: SO THAT WOULD BE ONE OF THE
3 BASIC UNDERSTANDINGS WE HAVE HERE IN THIS MOTION.
4 YES, JOAN SAMUELSON.

5 MS. SAMUELSON: I CAN UNDERSTAND THAT WE 6 MIGHT HAVE THE NECESSITY OF GOING AHEAD AND APPROVING 7 THESE GUIDELINES AND HAVE SOMETHING IN PLACE, AND I'M 8 PREPARED TO DO THAT. I JUST WONDER IF WE HAVE THE 9 POSSIBLE OPPORTUNITY OF HAVING OUR OWN STANDARDS 10 WORKING GROUP REVIEW THESE GUIDELINES AND GIVE US THE 11 BENEFIT OF THEIR EVALUATION BEFORE WE DO SO.

12 CHAIRMAN KLEIN: YES. THE CHAIRMAN OF OUR
13 STANDARDS WORKING GROUP HAS, IN FACT, REVIEWED THEM.
14 DR. HALL, WOULD YOU LIKE TO REPORT ON -- DEAN KESSLER,
15 DR. KESSLER, REPORT ON THAT COMMUNICATION AND ANY
16 ADDITIONAL COMMUNICATIONS WITH DR. HALL.

17 DR. KESSLER: JOAN, I THINK THE FEELING IS, 18 OF COURSE, THE STANDARDS WORKING GROUP WILL HAVE THE 19 OPPORTUNITY TO REVIEW THESE. AND, IN FACT, THEY ARE 20 GOING TO REVIEW THESE IN GREAT DEPTH. WITH THE 21 TRAINING GRANTS THAT WE'VE INITIATED THAT PROCESS, I 22 THINK IT WOULD BE UNFAIR TO THE WORKING GROUP IF WE 23 REQUIRE THEM TO DO THAT REVIEW IN HASTE.

24 SO I THINK WHAT WE WANT TO DO IS TO HAVE 25 SOMETHING IN PLACE, CERTAINLY SOMETHING THAT HAS HAD

1 THE KIND OF THOUGHTFUL AND DELIBERATE CONSIDERATION AS 2 THE NAS AND, IN FACT, TO DO EXACTLY WHAT YOU'RE ASKING, 3 BUT TO GIVE THEM TIME. NOT TO SAY FIRST MEETING YOU 4 HAVE TO ADOPT SOMETHING WITHOUT THE ABILITY TO DO THAT 5 IN-DEPTH. I THINK THAT'S MY SENSE OF THE PREFERENCE OF 6 THE LEADERSHIP. DR. HALL MAY WANT TO COMMENT.

7 DR. HALL: I SPOKE TO HARRIET RABB, WHO IS 8 THE CO-CHAIR OF OUR COMMITTEE, ABOUT THIS, AND THAT WAS 9 VERY MUCH THE FEELING THAT SHE EXPRESSED. I THINK 10 SHE'S STRONGLY SUPPORTIVE OF THE GUIDELINES. SHE SAID THAT SHE FORESAW THAT THE WORKING GROUP WOULD START 11 WITH THIS. IN CONSIDERING WHAT THE PERMANENT 12 GUIDELINES WOULD BE, THAT THEY WOULD BEGIN WITH A SORT 13 14 OF IN-DEPTH EXAMINATION OF THIS. AND JUST AS 15 DR. KESSLER SAID, OUR INTENT IS TO HAVE SOMETHING IN 16 PLACE THAT WE CAN MOVE FORWARD WITH. SHE FELT THAT RATHER THAN SAYING, YOU KNOW, WE'VE CALLED YOU HERE TO 17 QUICKLY LOOK OVER AND APPROVE THESE, THAT SHE WOULD 18 PREFER IF THE COMMITTEE TOOK THAT STEP AND THEN THEY 19 20 COULD GO FORWARD WITH THAT IN-DEPTH INVESTIGATION. 21 I THINK ALL THESE ISSUES WILL BE GONE INTO 22 VERY, VERY CAREFULLY. 23

CHAIRMAN KLEIN: I THINK THAT SPECIFICALLY
THE INITIATIVE SPELLS OUT THAT THE PROCESS WE HAVE IS
ONE WHERE THE PUBLIC AND THE RESEARCH INSTITUTIONS HAVE

1 THE BENEFIT OF IMMEDIATE CLARITY ON THE GUIDELINES 2 BECAUSE WE ADOPT INTERIM GUIDELINES, WHICH WOULD BE THE NATIONAL ACADEMY GUIDELINES HERE, BUT THEN WE HAVE THIS 3 4 EXTRAORDINARILY LONG PUBLIC HEARING AND REVIEW PROCESS TO BRING IN THE PUBLIC COMMENTS, THE INFORMATION 5 6 BROUGHT UP BY THE PRESS. WE HAVE AN ADMINISTRATIVE 7 PROCEDURES ACT REQUIREMENT THAT WE ACTUALLY PUBLISH 8 WHAT'S CONTEMPLATED OF CHANGES, THAT THOSE CHANGES THEN 9 BE COMMENTED ON THROUGH A PUBLIC HEARING PROCESS, AND 10 THEN WE GO THROUGH AND ADOPT FINAL GUIDELINES.

SO THE INTENT HERE IS TO GIVE THE PUBLIC THE 11 ADVANTAGE OF UNDERSTANDING THAT WE HAVE A NATIONAL 12 13 GROUP OF TREMENDOUS CREDENTIALS WHICH WAS -- NOT ONLY 14 DREW UP THOSE GUIDELINES, WAS THEN REVIEWED BY ANOTHER 15 PUBLIC REVIEW GROUP THAT EVERYONE KNOWS THROUGH THE 16 PUBLICATION WHO THEY ARE WITH THEIR CREDENTIALS. SO WE'VE GONE THROUGH THE DRAWING UP, THE CRITICAL REVIEW 17 WITHIN THE NAS, THE CRITICAL REVIEW BY THEM BY THE 18 REVIEW GROUP, AND AS PUBLICATION, THOSE HAVE BEEN 19 20 REVIEWED BY OUR CHAIRMAN OF OUR STANDARDS GROUP WORKING 21 GROUP. AND IT IS CONTEMPLATED THAT IN THE 270-DAY 22 PERIOD, WE WILL HAVE A COMPLETE VETTING IN THE PUBLIC 23 FORUM.

24 DR. HALL: LET ME JUST POINT OUT THAT IF WE25 ARE GET THE TRAINING GRANTS OUT THIS FALL, INSTITUTIONS

1 CAN'T SET THESE COMMITTEES UP IN A DAY. AND BECAUSE OF 2 PROPOSITION 71, THE CALIFORNIA INSTITUTIONS ACTUALLY WILL BE LEADING THE COUNTRY IN SETTING THESE VARIOUS 3 4 COMMITTEES UP. SO I THINK BY US PASSING THE STANDARDS NOW AS AN INTERIM STANDARD, THAT BASICALLY GIVES NOTICE 5 6 TO INSTITUTIONS HERE IS WHAT YOU WILL BE EXPECTED TO 7 DO, AND IT GIVES THE INSTITUTIONS TIME TO RESPOND IN A 8 THOUGHTFUL AND CAREFUL WAY TO ASSEMBLE THEIR COMMITTEES 9 SO THAT BY THE FALL THEY ARE IN PLACE SHOULD THAT 10 BECOME NECESSARY.

11 CHAIRMAN KLEIN: ADDITIONAL BOARD COMMENT?
12 DR. PRIETO: DR. HALL, I WAS WONDERING IF THE
13 GUIDELINES ADDRESS HOW INSTITUTIONS SHOULD GO ABOUT
14 APPOINTING THEIR ESCRO COMMITTEES OR IF WE WANT TO
15 PROVIDE SOME GUIDANCE.

16 DR. HALL: IT DOES NOT. IT LISTS THE KINDS 17 OF PERSONNEL THAT MIGHT BE THERE, MEMBERS OF THE LAY 18 PUBLIC, EXPERTS IN REPRODUCTIVE MEDICINE, MOLECULAR 19 BIOLOGISTS, DEVELOPMENTAL BIOLOGISTS, ETHICISTS. SO IT 20 DESCRIBES A VARIETY OF THE KINDS OF PEOPLE THAT MIGHT 21 BE ON SUCH A COMMITTEE.

I THINK THE GENERAL SENSE IS THAT
INSTITUTIONS WOULD TREAT IT AS SIMILAR IN-KIND TO AN
IRB, AN INSTITUTIONAL REVIEW BOARD, WHICH OVERSEES ALL
PATIENT-BASED RESEARCH OR RESEARCH INVOLVING HUMANS.

1 SO OTHER THAN JUST TO SAY THE GENERIC 2 SUGGESTIONS FOR THE KINDS OF PEOPLE WHO SHOULD BE ON IT, IT MAKES NO EXPLICIT SUGGESTION FOR THAT. 3 4 CHAIRMAN KLEIN: DURING THE PUBLIC HEARING PROCESS, WE WILL HAVE THAT WELL DEVELOPED. 5 6 MR. SHESTACK: IS THERE ACTUALLY, JUST TO 7 UNDERSTAND, THIS IS A RECOMMENDATION TO THE ESCRO 8 COMMITTEES. IT'S NOT PROSCRIPTIVE. IS THERE ANY 9 REASON WHY ONE COULDN'T -- WHY THE STANDARDS GROUP, FOR 10 INSTANCE, MIGHT NOT DECIDE TO RECOMMEND THAT THE STATE OF CALIFORNIA FORM ONE CALIFORNIA ESCRO COMMITTEE TO 11 MAKE THINGS MOVE FASTER RATHER THAN EVERY INSTITUTION 12 13 HAVE TO DO IT? CHAIRMAN KLEIN: DURING THE PUBLIC HEARING 14 15 PROCESS, THAT'S CLEARLY AN OPTION. IT'S THERE. IN 16 FACT, YOU MIGHT HAVE AN OPTION WHERE YOU HAVE A 17 STATEWIDE AND THEN YOU HAVE A LOCAL OPTION. SO WHEN IT'S APPROPRIATE, THE INSTITUTION CAN DECIDE TO JOIN 18 THE STATEWIDE GROUP OR EXERCISE THE LOCAL OPTION IF 19 20 THEY HAVE TREMENDOUS LOCAL INSTITUTIONAL CAPACITY. 21 DR. HALL: LET ME JUST SAY THAT, HAVING DEALT 22 WITH ISSUES LIKE THIS IN OTHER CASES BEFORE, IT IS VERY 23 IMPORTANT FOR INTERINSTITUTIONAL COLLABORATION THAT ONE 24 INSTITUTION BE ABLE TO ACCEPT THE APPROVAL BY ANOTHER 25 INSTITUTION. I HAVE SEEN THIS WITH IRB'S WHERE

PARTICIPATING A INSTITUTION HAD TO HAVE ITS IRB PASS ON
 IT, AND IT MAKES FOR A VERY, VERY CUMBERSOME PROCEDURE.
 SO IF WE CAN ESTABLISH A SORT OF COMMONALITY SO THAT IF
 SOMEBODY AT UCLA WANTS TO COLLABORATE WITH SOMEBODY AT
 STANFORD AND IT'S ALREADY BEEN APPROVED, WE DON'T HAVE
 TO GO THROUGH IT ALL OVER AGAIN.

7 I THINK ONE OF THE POINTS OF HAVING THE 8 NATIONAL ACADEMY GUIDELINES IS THAT IF WE HAVE THESE 9 CONSENSUS GUIDELINES NATIONALLY, THEN A PROCESS LIKE 10 THAT IS MUCH EASIER TO DO AND WILL EXTEND, NOT ONLY WITHIN CALIFORNIA, BUT BEYOND CALIFORNIA BORDERS. I 11 THINK IT'S VERY MUCH IN OUR INTEREST TO WANT THAT TO 12 13 HAPPEN IN CALIFORNIA; THAT IS, IN THE INTEREST OF THE 14 CIRM.

15 CHAIRMAN KLEIN: ADDITIONAL BOARD COMMENTS?16 DR. KESSLER AND THEN DR. BRYANT.

DR. KESSLER: ZACH, I WAS WATCHING THE, I 17 STILL DO THIS, THE SUNDAY SHOWS YESTERDAY. AND 18 OBVIOUSLY THE NATION IS FOCUSED ON STEM CELL, 19 20 ESPECIALLY THIS WEEK. AND THERE WAS TALK ABOUT, OKAY, 21 IF YOU ALLOW CERTAIN LINES TO BE USED OR YOU EXPAND 22 CERTAIN LINES OR YOU ALLOW THOSE EMBRYOS THAT ARE THE 23 RESULT OF IN VITRO FERTILIZATION, THERE IS, QUOTE, A SLIPPERY SLOPE HERE. HELP -- ONE OF OUR JOBS IS TO BE 24 25 ABLE TO EDUCATE THE AMERICAN PUBLIC AND THEY HAVE

CONFIDENCE IN WHERE THE LINES ARE HERE ON WHAT IS
 ETHICALLY PERMISSIBLE AND WHAT IS NOT ETHICALLY
 PERMISSIBLE.

4 USING WORDS LIKE PRIMITIVE STREAK MAY BE FINE 5 FOR DEVELOPMENTAL BIOLOGISTS AND NEUROLOGISTS. IT'S 6 NOT GREAT FOR THE AVERAGE CITIZEN. SO I WAS WONDERING 7 WHETHER YOU COULD, AND I KNOW THIS MAY BE A LITTLE 8 HARD, HELP TALK FOR A MOMENT OR TWO WHAT DOES THE 9 PUBLIC HAVE TO KNOW ABOUT THESE GUIDELINES? WHERE DOES 10 IT DRAW THE LINE?

DR. HALL: I THINK ONE THING THEY'RE VERY 11 CLEAR ON IS THE FACT THAT NO ONE BELIEVES THAT 12 13 REPRODUCTIVE CLONING SHOULD GO FORWARD. AND ONE OF THE 14 EXPLICIT -- ACTUALLY IT WAS NOT INCLUDED IN THAT 15 SECTION OF THE REPORT THAT I READ FROM, BUT ONE OF THE 16 EXPLICIT PROHIBITIONS WAS AGAINST PUTTING ANY PRODUCT INTO A HUMAN UTERUS. AND UNDERSTAND THAT WHENEVER ONE 17 HAS A BLASTOCYST DEVELOPED IN VITRO, WHETHER THROUGH IN 18 VITRO FERTILIZATION OR THROUGH NUCLEAR TRANSFER, AS 19 20 LONG AS THAT IS IN VITRO, NOTHING IS GOING TO HAPPEN AS 21 FAR AS FORMATION OF AN INTACT ORGANISM. THAT CANNOT 22 HAPPEN.

23 SO YOU -- IN ORDER TO EVEN APPROACH THAT, IT 24 HAS TO BE IMPLANTED INTO A UTERUS. I THINK THAT IS AN 25 ABSOLUTE BARRIER ACTUALLY. NO IMPLANTATION SHOULD BE A

1 VERY CLEAR AND BRIGHT LINE. AND THEN THE OTHER, WHICH 2 YOU MENTIONED, WHICH CAN BE HANDLED EITHER THROUGH A DESCRIPTION OF DAYS OF DEVELOPMENT OR THROUGH THE MORE 3 4 ARCANE LANGUAGE THAT YOU DESCRIBE, IS THAT EVEN IN 5 VITRO, NOTHING SHOULD BE ALLOWED TO HAPPEN PAST 12 6 DAYS, LET'S SAY. 7 AND SO THIS MEANS THAT THERE IS NOTHING 8 RECOGNIZABLY ORGANISM-LIKE AT THAT POINT. IT IS STILL 9 A CLUMP OF CELLS. 10 DR. KESSLER: SO WHEN THE PUBLIC HEARS THE WORD "THERAPEUTIC CLONING" VERSUS "REPRODUCTIVE 11 CLONING, " WHAT ARE THEY SUPPOSED TO UNDERSTAND? 12 DR. HALL: WELL, THAT THERE'S NO ATTEMPT TO 13 PRODUCE AN ORGANISM HERE. THERE'S AN ATTEMPT TO 14 15 PRODUCE A CELL LINE THAT CAN BE USED FOR RESEARCH OR 16 THAT CAN BE USED FOR THERAPY. 17 ONE OF THE COMMENTARIES ON THE KOREAN ARTICLE POINTED OUT THAT THERAPEUTIC CLONING IS AT THIS MOMENT 18 A MISNOMER, AND THAT WE DON'T HAVE A PROVEN THERAPY 19 20 THAT CAN BE DERIVED FROM THIS, BUT SHOULD BE MORE 21 ACCURATELY CALLED FOR RESEARCH. BUT I THINK THE REASON WE ARE ALL HERE IS BECAUSE OF THE POSSIBLE THERAPEUTIC 22 23 USE OF THESE, AND THAT'S WHAT'S OF INTEREST TO US. 24 SO I THINK THE QUESTION IS WHETHER THE INTENT 25 IS TO HAVE AN ORGANISM DERIVED OR TO HAVE CELL LINES

DERIVED. AND AS I SAY, THE ABSOLUTE BARRIER THERE IS
 IMPLANTATION.

DR. KESSLER: EVEN UNDER THE KOREAN STUDY, 3 4 THE USE OF THE WORD "CLONING," I THINK, IS WHERE A LOT OF CONFUSION IN THE AMERICAN PUBLIC'S MIND, WHAT THAT 5 6 MEANS. SO YOU'RE SAYING THAT YOU CANNOT HAVE -- ONCE 7 YOU'RE DOING THIS IN VITRO, IT'S NOT POSSIBLE TO 8 HAVE --9 DR. HALL: SOMETHING LIKE A BABY GROW IN A PETRIE DISH. IS THAT WHAT YOU ARE ASKING? NO, 10 ABSOLUTELY NOT. 11 DR. KESSLER: SO IS THIS CLOSING? 12 DR. HALL: WELL, THAT'S THE WHOLE POINT OF 13 SAYING THAT IT SHOULD BE THE 12 DAYS OR 14 DAYS, THAT 14 NOTHING SHOULD BE ALLOWED IN VITRO BEYOND THAT BECAUSE 15 16 THERE IS NOTHING THAT IS RECOGNIZABLY LIKE AN EMBRYO BEFORE THAT PERIOD OF TIME JUST BY VISUAL INSPECTION. 17 DR. KESSLER: SO WE'RE NOT CLONING HUMAN 18 19 BEINGS? 20 DR. HALL: NO. WE'RE TAKING CELLS OUT AT A 21 VERY EARLY STAGE OF DEVELOPMENT AND CLONING CELLS. 22 DR. KESSLER: CLONING CELLS. 23 DR. HALL: YES, THAT'S THE DISTINCTION THAT 24 YOU'RE DRIVING AT. I WAS SLOW IN GETTING THE POINT YOU

32

WERE LOOKING FOR, BUT WE'RE CLONING CELLS. WE'RE NOT

1 CLONING ORGANISMS, WITHOUT DOUBT.

2 CHAIRMAN KLEIN: AND I THINK, DR. HALL, IT'S APPROPRIATE FOR THE PUBLIC TO, IN ORDER TO VISUALIZE 3 4 THIS, TO REALIZE THAT THE POINT OF A NEEDLE REALLY DWARFS THE SIZE OF THESE CELLS WE'RE TALKING ABOUT. 5 6 DR. HALL: IT IS -- YES. TO ALL APPEARANCES 7 IT'S A CLUMP OF CELLS THAT ARE UNDIFFERENTIATED. 8 CHAIRMAN KLEIN: I HAD SUGGESTED THAT DR. 9 SUSAN BRYANT WOULD BE NEXT AND THEN GO TO --10 DR. BRYANT: THIS IS CHANGING THE TOPIC SLIGHTLY BACK TO THE EARLIER TOPIC ABOUT WHERE THE 11 ESCRO SHOULD RESIDE. AND I WAS JUST WONDERING WHAT 12 13 PEOPLE ON THE ICOC FEEL ABOUT HAVING A CIRM ESCRO THAT WOULD TAKE CARE OF THAT LEVEL OF REVIEW FOR ALL 14 15 RECIPIENTS OF THAT GRANT. 16 CHAIRMAN KLEIN: I THINK, DR. RICHARD MURPHY. DR. MURPHY: SUSAN, I WOULD THINK THAT THAT 17 WOULD BE A VERY BAD IDEA. I THINK THAT INSTITUTIONS 18 NEED TO HAVE AN INDEPENDENT COMMITTEE THAT LOOKS AT --19 20 UNDER RESPONSIBLE GUIDELINES THAT LOOKS AT THE ISSUES 21 THAT ARE COMING UP WITHIN THAT ORGANIZATION. I LIKE 22 DAVID'S IDEA OR WHOEVER'S IDEA IT WAS, MAYBE ZACH, THAT 23 THOSE OF US WHO ARE IN BASIC RESEARCH INSTITUTIONS 24 SHOULD INDEED HAVE ACCESS TO FOLKS WHO ARE IN COMPANION 25 ORGANIZATIONS, BUT THAT DO HAVE A CLINICAL COMPONENT.

1 I THINK FOR US TO RELY ON A CIRM COMMITTEE 2 WOULD DELAY THE PROCESS TREMENDOUSLY. I THINK IT WOULD TAKE AWAY HOME RULE, WHICH IS CRITICAL. AND I THINK 3 4 THAT THE CIRM COMMITTEE WOULD HAVE SO MUCH TO DO, THAT DECISIONS WOULD NEVER GET MADE. 5 6 DR. BRYANT: I UNDERSTAND AND AGREE. 7 CHAIRMAN KLEIN: DR. PRIETO. 8 DR. PRIETO: RESPONDING TO DR. KESSLER'S 9 COMMENTS, I THINK THERE'S A SIMPLER AND MORE DIRECT WAY 10 TO PHRASE THIS IN WHAT WE SAY TO THE PUBLIC. I THINK THAT SOME PEOPLE INVOLVED IN THIS RESEARCH HAVE SAID 11 THAT USE OF THE WORD "CLONING" IS UNFORTUNATE, AND 12 THAT'S WHY OTHER TERMINOLOGY LIKE NUCLEAR TRANSFER HAS 13 COME UP. BUT I THINK THE MORE DIRECT THING TO SAY IS 14 15 THAT THESE ARE CELLS THAT HAVE NEVER SEEN AND WILL 16 NEVER SEE THE INSIDE OF A UTERUS, AND THAT WE WILL NOT 17 FUND RESEARCH WHERE THAT OCCURS. DR. HALL: IT WAS POINTED OUT TO ME, JUST TO 18 MAKE THE POINT, THAT CLONING REALLY REFERS TO MAKING A 19 20 COPY OF, REPRODUCING AN EXACT COPY OF. AND WHETHER 21 THAT'S DNA OR WHETHER IT'S A CELL OR WHETHER IT'S AN

22 ORGANISM, THE WORD ITSELF --

23 DR. PRIETO: I THINK IN THE POPULAR MIND
24 CLONING BRINGS TO MIND THE IMAGE OF DOLLY, THE SHEEP,
25 AND THAT WE'LL REPRODUCE ORGANISMS. I THINK THAT'S THE

1 POINT WE NEED TO MAKE, THAT WE'RE NOT IN THAT BUSINESS, 2 AND WE DON'T INTEND TO BE IN THAT BUSINESS. DR. HENDERSON: I'D LIKE TO MOVE APPROVAL OF 3 4 THE GUIDELINES AS INTERIM GUIDELINES FOR THIS 5 ORGANIZATION. 6 DR. BRYANT: SECOND. 7 CHAIRMAN KLEIN: THERE'S A MOVAL AND A 8 SECOND, AND THAT'S WITH THE UNDERSTANDING ARTICULATED 9 BY DR. BALTIMORE. AND THIS IS A PROSPECTIVE 10 APPLICATION OF THESE GUIDELINES; IS THAT CORRECT, DR. HENDERSON? 11 DR. HENDERSON: YES. 12 13 CHAIRMAN KLEIN: I WOULD -- THAT MOTION, WE NEED TO FIRST HAVE PUBLIC COMMENT. JOAN, WOULD YOU 14 LIKE TO MAKE A COMMENT BEFORE WE HAVE PUBLIC COMMENT? 15 16 MS. SAMUELSON: I RECOMMEND THAT WE ADD --17 WITH THIS APPROVAL WE ISSUE SOME SORT OF STATEMENT ALONG THE LINES OF WHAT DR. PRIETO IS SAYING, THAT SAYS 18 THAT WE'RE NOT IN THE BUSINESS OF CLONING ANYTHING, OF 19 20 REPRODUCING HUMAN ORGANISMS, ANIMALS, OR ANYTHING ELSE 21 SO THAT IT'S VERY CLEAR AND PLAIN LANGUAGE. 22 CHAIRMAN KLEIN: ON AN AFFIRMATIVE STATEMENT, 23 I THINK THAT WOULD TAKE THE POINT OF SAYING THAT WE ARE 24 MOVING THIS RECOMMENDATION AND EMPHASIZING THAT 25 CALIFORNIA HAS PUT A PROHIBITION OF HUMAN REPRODUCTIVE

CLONING IN THE STATE CONSTITUTION, AND IT IS ALSO A
 MATTER OF STATE LAW, SO WE HAVE DOUBLE PROTECTION IN
 CALIFORNIA TO MAKE IT EXTRAORDINARILY CLEAR WHAT OUR
 PURPOSE IS.

5 DR. LEVEY: YES. IN THIS DOCUMENT, JOAN, IT 6 DOES MAKE IT PERFECTLY CLEAR THAT THERE SHOULD NOT BE 7 REPRODUCTIVE CLONING.

8 CHAIRMAN KLEIN: JOAN IS AWARE OF THAT, BUT 9 SHE WANTS, THOUGH, FOR THE RESOLUTION PURPOSES, TO MAKE 10 IT CLEAR TO THE PUBLIC, THAT THIS IS A VERY CLEAN LINE 11 IN ADDITION TO WHAT'S IN THE STANDARDS THAT WE'RE 12 ADOPTING.

MS. SAMUELSON: IT'S JUST TO PUT IT IN VERY
PLAIN ENGLISH, NOT USING IN VITRO OR ANY OTHER WORDS
THAT AREN'T OBVIOUS TO THE LAY PUBLIC.

16 CHAIRMAN KLEIN: PUBLIC COMMENT. SEEING NO
17 PUBLIC COMMENT --

MR. REED: I WOULD JUST LIKE TO AGREE WITH 18 19 JOAN SAMUELSON, THAT WE REALLY NEED TO MAKE IT CLEAR. 20 JUST MAKE -- TAKE A COUPLE SENTENCES, SAY SOMETHING 21 LIKE THE FACT THAT THERE IS NO SPERM, NO UTERUS, NO 22 PREGNANCY, NO BABY AT ALL, JUST OVERKILL THAT BECAUSE 23 THAT'S THE NO. 1 THING THAT THEY KEEP HITTING US AGAIN 24 AND AGAIN AND AGAIN WITH IT. IT MUST BE CRYSTAL CLEAR. 25 THANK YOU.

1 CHAIRMAN KLEIN: DR. PAUL BERG. WE HAVE THE 2 HONOR TODAY OF HAVING DR. PAUL BERG, WHO WON A NOBEL 3 PRIZE FOR RECOMBINANT DNA, AND ONE OF THE GREAT 4 ADVISORS, SCIENTIFIC ADVISORS, IN THE COURSE OF THIS 5 INITIATIVE. IT IS A DISTINCT PRIVILEGE, DR. BERG, TO 6 HAVE YOU WITH US.

7 DR. BERG: THANK YOU. I JUST WANTED TO GET 8 UP AND MAKE ONE COMMENT. I THINK A VERY USEFUL TERM, 9 TO SORT OF DEFRAY THE CONCERN ABOUT THE GENERAL PUBLIC, 10 IS TO KEEP REFERRING TO WHAT WE'RE MAKING AS PATIENT-SPECIFIC STEM CELLS. I THINK I LIKE THAT TERM. 11 I HEARD IT FIRST FROM AN AUSTRALIAN INVESTIGATOR. I 12 13 THINK ACTUALLY, IF I'M NOT MISTAKEN, THE SOUTH KOREANS 14 HAVE BEGUN TO USE THE SAME TERM.

15 WE CAN TALK ABOUT PATIENT-SPECIFIC STEM CELLS 16 AND DISEASE-SPECIFIC STEM CELLS. THAT'S WHAT THE 17 PROGRAM IS ABOUT. I THINK EMPHASIZING THAT HAS A 18 CONNOTATION WHICH I THINK IS VERY HELPFUL. IT 19 EMPHASIZES THE DISEASE THERAPY IDEA WITHOUT USING THE 20 TERMS "THERAPEUTIC CLONING." IT'S DISEASE-SPECIFIC AND 21 PATIENT-SPECIFIC STEM CELLS.

22 MR. SHESTACK: I JUST WANTED TO -- FOR OUR 23 OWN COMMUNICATIONS IN THE FUTURE, I NOTICED THIS IN THE 24 KOREAN ARTICLE, AND I FIND THAT WHEN WE TALK ABOUT 25 THERAPEUTIC CLONING, IT ALWAYS INCLUDES ITS COROLLARY,

WHICH IS REPRODUCTIVE CLONING. AND CLONING MEANS TO
 MOST PEOPLE MAKING LITTLE COPIES OF LITTLE PEOPLE. AND
 IF WE CAN ACTUALLY -- AND DOESN'T -- IN THE WHOLE
 EXPRESS WHAT IT IS WE'RE DOING OR TRYING TO DO. SO I
 WOULD SUGGEST THAT WE ACTUALLY START INTERNALLY TRYING
 TO CHANGE OUR VOCABULARY ON THIS, AND PERHAPS THE REST
 OF THE WORLD WILL FOLLOW.

8 CHAIRMAN KLEIN: I THINK DR. BERG'S DIRECTION9 IS AN EXCELLENT ONE IN THAT REGARD.

10 DR. POMEROY: JUST ONE SORT OF ADDITIONAL POINT TO CLARIFY THE MOTION, THAT THE IMPLICATION OF 11 ADOPTING THESE AS INTERIM STANDARDS IS THAT WE WILL 12 13 HAVE AN EXTENSIVE PUBLIC HEARING PROCESS ABOUT THESE. 14 AND THAT IF THERE IS ANYTHING THAT'S NOT APPROPRIATE TO 15 THE STATE OF CALIFORNIA, THAT'S SOMETHING THAT THE 16 STANDARDS GROUP WILL MAKE RECOMMENDATIONS TO US ABOUT. I THINK IT'S VERY IMPORTANT TO MAKE THAT PROCESS CLEAR. 17 CHAIRMAN KLEIN: I THINK IT'S -- IN MAKING 18 19 THE MOTION, IT'S OUR UNDERSTANDING THAT, IN FACT, WE 20 WILL BE ADOPTING THESE AS INTERIM REGULATIONS, BUT 21 PURSUANT TO THE INTENDED STRUCTURE LAID OUT IN THE 22 INITIATIVE, THESE WOULD THEN BE REFERRED TO THE 23 STANDARDS WORKING GROUP, AND THE STANDARDS WORKING 24 GROUP WILL BEGIN THIS PROCESS OF PUBLIC HEARINGS WITH 25 OVERSIGHT BY THE BOARD.

1 ALL RIGHT. SO IS THE MAKER OF THE MOTION, IS 2 IT ACCEPTABLE TO HAVE THAT UNDERSTANDING? DR. HENDERSON: CERTAINLY IS. ALSO, I MIGHT 3 ADD, THE COMMENT DR. HALL MADE ABOUT DIRECTLY 4 CONTACTING THE ACADEMY ABOUT ITS CONTINUED LEADERSHIP 5 6 IN THIS AREA IS AN IMPORTANT THING TO DO AS WELL. 7 CHAIRMAN KLEIN: OKAY. SO AS I UNDERSTAND 8 THE MOTION THAT WE'RE GOING TO VOTE ON, WE ARE 9 PROPOSING TO ADOPT THESE REGULATIONS. I WILL GET TO 10 THE PUBLIC COMMENT IN JUST A SECOND. WE ARE PROPOSING TO ADOPT THESE REGULATIONS PROSPECTIVELY APPLIED SO 11 THAT IT DOES NOT LIMIT THE USE OF EXISTING STEM CELL 12 LINES OR BIOLOGICAL MATERIALS OR RESEARCH. IT IS 13 SPECIFICALLY UNDERSTOOD THAT INSTITUTIONS CAN 14 15 COLLABORATIVELY FULFILL THE REQUIREMENTS IN THE REVIEW 16 FUNCTIONS. IT IS SOMETHING THAT SPECIFICALLY WAS NOT 17 ADDRESSED, BUT IT IS OUR UNDERSTANDING THAT IT WILL ENHANCE THE QUALITY OF THAT REVIEW FUNCTION IF WE 18 PROCEED WITH THAT UNDERSTANDING, AND THAT WE ARE 19 20 REFERRING THIS TO THE STANDARDS WORKING GROUP TO BEGIN 21 THE HEARING PROCESS THAT IS LAID OUT AND SPECIFIED, INCLUDING THE PUBLIC HEARING AND ADMINISTRATIVE 22 23 PROCEDURES ACT PUBLICATIONS. 24 ADDITIONAL PUBLIC COMMENT?

25 MR. CLAEYS: I JUST WANTED TO UNDERSCORE A

1 POINT THAT WAS MADE EARLIER ABOUT THE NUMBER OF WAYS 2 THAT THE CIRM AND THE ICOC ARE LEADING THE COUNTRY. I THINK THERE'S A TREMENDOUS OPPORTUNITY AND 3 4 RESPONSIBILITY TO LEAD IN EDUCATING THE PUBLIC AND IN EDUCATING COMMENTATORS. I HAPPENED TO SEE THE SAME 5 6 SHOW, I BELIEVE, THAT DR. KESSLER SAW. AND THE 7 SLIPPERY SLOPE THAT THE COMMENTATOR REFERRED TO WAS A 8 LOGICAL SLOPE, BUT SCIENTIFICALLY COMPLETELY INVALID. 9 HE WAS TALKING ABOUT THE GROWING NEED TO 10 HARVEST OLDER AND OLDER CELLS OR OLDER AND OLDER FETUSES AND USING VERY INFLAMMATORY RHETORIC, WHEN, IN 11 FACT, AS WE ALL KNOW, THE GOAL IS TO GET YOUNGER AND 12 UNDIFFERENTIATED CELLS. AND THERE WAS NOBODY EQUIPPED 13 ON THAT PANEL TO COUNTER WHAT HE HAD TO SAY, AND SO 14 15 THAT MISIMPRESSION WAS LEFT OUT THERE FOR EVERYBODY WHO 16 WAS WATCHING. 17 AND SO I THINK THERE'S A TREMENDOUS OPPORTUNITY HERE TO COUNTER THOSE ARGUMENTS AND TO 18 EDUCATE THE PUBLIC AND THE PUBLIC COMMENTATORS. 19 20 CHAIRMAN KLEIN: WELL, I SPECIFICALLY 21 RECOGNIZE YOU HAVE, I BELIEVE, A STRONG BACKGROUND WITH THE MICHAEL J. FOX FOUNDATION NATIONALLY. WOULD YOU 22 23 LIKE TO IDENTIFY FOR THE PUBLIC AND BOARD MEMBERS, WHO DON'T KNOW YOUR BACKGROUND, YOUR BACKGROUND EXPERIENCE? 24 MR. CLAEYS: NO. MY NAME IS MICHAEL CLAEYS. 25

1 I DID WORK FOR THE PARKINSON'S ACTION NETWORK AND THE 2 MICHAEL J. FOX FOUNDATION, AND THROUGH THAT EXPERIENCE HAD THE BENEFIT OF SITTING IN THE ROOM WITH A LOT OF 3 4 SCIENTISTS WHO TALKED ABOUT THESE ISSUES. BUT ALSO HAD THE BENEFIT OF UNDERSTANDING THE NEED TO TAKE THOSE 5 6 CONVERSATIONS FROM THE LAB OR FROM THE SCIENTIFIC 7 DISCUSSION AND TRANSLATE THEM TO THE PUBLIC AND TO 8 POLICYMAKERS.

9 AND MUCH GETS LOST IN THAT TRANSLATION, AS 10 I'M SURE YOU WELL KNOW, AND I THINK THAT THERE'S A REAL OPPORTUNITY HERE FOR THE MEMBERS OF THIS BOARD AND THE 11 PUBLIC FORUM, THAT IS THE PUBLIC PLATFORM, AND THE 12 ATTENTION THAT YOU ALL HAVE RIGHT NOW OF THE COUNTRY 13 AND THE WORLD TO LEAD IN THIS ADDITIONAL WAY OF 14 15 EDUCATING THE PUBLIC, CHANGING THE RHETORIC THAT 16 SURROUNDS THESE SCIENTIFIC TECHNOLOGIES, AND TO REALLY RAISE THE BAR IN THAT WAY AS YOU'RE ENDEAVORING TO 17 RAISE THE BAR IN SO MANY OTHER WAYS. 18 CHAIRMAN KLEIN: THANK YOU VERY MUCH. WE 19

20 HAVE A MOTION. THERE WAS A CALL FOR THE QUESTION. IF 21 WE'RE PREPARED FOR THAT, WE'D ASK ALL IN FAVOR SAY AYE. 22 OPPOSED? PASSED UNANIMOUSLY.

AND LET US COMMUNICATE TO THE NATIONAL
ACADEMY OUR DEEP GRATITUDE FOR THE TREMENDOUS EFFORT
THAT THEY MADE. AND I THINK IT'S APPROPRIATE TO ALSO

COMMUNICATE TO THE REVIEW GROUPS AROUND THE COUNTRY
 THAT GAVE THEIR BEST AND BRIGHTEST FOR THE REVIEW OF
 THE NATIONAL ACADEMY STANDARDS. HOPEFULLY THIS IS A
 GREAT DAY FOR THE NATION AND FOR CALIFORNIA IN SETTING
 THE BAR HIGH IN ADOPTING STANDARDS DEVELOPED WITH THE
 BEST MINDS IN THE NATION IN MEDICAL THERAPIES.

7 I'D LIKE, RECOGNIZING THAT DR. PAUL BERG IS 8 HERE, AND KNOWING THAT HE HAS SOME TIME CONSTRAINTS, 9 I'D LIKE TO IN THE CHAIRMAN'S REPORT, WHICH IS REALLY 10 TO FOCUS ON STATE AND FEDERAL LEGISLATION TODAY, TO 11 REVERSE THE ORDER AND TO BEGIN THE REVIEW WITH STATE 12 LEGISLATION WITH INPUT FROM DR. PAUL BERG.

DR. BERG, IF WE COULD GET YOUR COMMENTS, ANDWE THANK YOU VERY MUCH FOR COMING.

DR. BERG: THANK YOU FOR THE OPPORTUNITY TO PRESENT MY VIEWS ON SCA 13 CONCERNING THE OPERATION OF CIRM. IN MY VIEW, IF PASSED, THE PROVISIONS WOULD RCIPPLE CIRM'S ABILITY TO OPERATE AND IMPERIL THE PROGRESS OF STEM CELL RESEARCH IN CALIFORNIA.

20 SENATOR ORTIZ' SPONSORSHIP OF SCA 13 IS ALL 21 THE MORE SURPRISING CONSIDERING THAT SHE WAS ONE OF THE 22 ORIGINATORS OF THE PROP 71 INITIATIVE, UNDERSTOOD FULL 23 WELL HOW CIRM WOULD OPERATE, AND CAMPAIGNED ACTIVELY 24 AND PASSIONATELY FOR ITS PASSAGE. SO IT'S DOUBLY 25 PUZZLING THAT SCA 13 IS BEING RUSHED THROUGH THE

LEGISLATURE EVEN BEFORE THE ADMINISTRATIVE MANDATE SET
 FORTH IN THE BALLOT INITIATIVE HAVE EVEN BEEN
 IMPLEMENTED.

4 DURING MORE THAN 50 YEARS AS A SCIENTIST, I'VE SERVED EXTENSIVELY ON BOTH NIH, NSF, AND A VARIETY 5 6 OF INSTITUTIONAL ADVISORY BOARDS, MOST OF THEM 7 IMPANELED TO EVALUATE AND AWARD RESEARCH IN TRAINING 8 GRANTS AT BOTH ACADEMIC AND RESEARCH INSTITUTIONS. IN 9 NO CASE WAS THERE EVER A QUESTION OF HOLDING THOSE 10 REVIEWS IN A PUBLIC FORUM. RELYING ON THE PEER REVIEW SYSTEM FOR EVALUATING THE MERITS OF PROPOSALS 11 12 NECESSITATES A FRANK AND FREQUENTLY BRUISING EXCHANGE 13 OF VIEWS AMONG THE REVIEWERS, OFTEN LEADING TO OPPOSING CONCLUSIONS, BUT IN THE END A CONSENSUS VALUATION IS 14 15 MOST FREQUENTLY REACHED.

16 THAT WILL NOT HAPPEN IN AN OPEN MEETING WHERE 17 THE COMMENTS ARE LIKELY TO BE MUTED AND CIRCUMSPECT. REVIEWS OF RESEARCH, AS WELL AS THE POTENTIAL AND 18 19 PROSPECT FOR FURTHER PROGRESS ARE LIKELY TO BE TIMID AND UNTRUSTWORTHY IN OPEN MEETINGS. I PREDICT THAT A 20 21 SUBSTANTIAL NUMBER OF THE OUTSTANDING SCIENTISTS THAT 22 HAVE ALREADY BEEN RECRUITED TO EVALUATE FUNDING 23 PROPOSALS FOR CIRM WILL NOT TOLERATE OPEN MEETINGS AND 24 MAY RENEGE ON THEIR AGREEMENT TO SERVE.

25 FURTHERMORE, GRANT APPLICANTS WILL BE

UNWILLING TO HAVE THEIR IDEAS, PRELIMINARY RESULTS, AND
 EXPERIMENTAL PROTOCOLS DISCLOSED IN A PUBLIC MEETING.
 IF FORCED TO DO SO, THE QUALITY OF THE SUBMISSIONS WILL
 CERTAINLY BE COMPROMISED.

5 TURNING TO ANOTHER PROVISION IN SCA 13, YOU 6 ARE UNDOUBTEDLY AWARE THAT THE CURRENT NIH GUIDELINES 7 ADDRESSING CONFLICT OF INTEREST HAVE DRAWN THE IRE AND 8 RIDICULE OF THE ENTIRE SCIENTIFIC COMMUNITY, EVEN THOSE 9 WHO ARE CHARGED WITH ENFORCING THEM. INDEED, THERE IS 10 PRESENTLY SUFFICIENT BACKTRACKING AND EVEN INDICATIONS OF DRASTIC REVISIONS EMANATING FROM THE OFFICIALDOM 11 THAT PROMULGATED THEM. 12

I JUST CAME FROM MEETING WITH THE SECRETARY 13 OF THE HHS, WHO BRIEFED US ON SOME OF THE REVISIONS 14 15 THAT ARE TRYING TO SOFTEN THE IMPACT OF THE ORIGINAL 16 PUBLISHED GUIDELINES. BEAR IN MIND IN THAT FEW, IF ANY, OF THE INDIVIDUALS WHO ACT IN AN ADVISORY CAPACITY 17 FOR THE NIH OR, I SUSPECT, HHS ARE OBLIGED TO ABIDE BY 18 THE PROPOSED DIVESTITURE RULES. BUT WHAT LOGIC CAN 19 20 THEY BE IMPOSED ON INDIVIDUALS WHEN NOT EMPLOYEES OF 21 THE STATE AND WHO VOLUNTARILY COMMIT SUBSTANTIAL TIME AND ENERGY IN ADVISORY CAPACITIES GENERALLY WITH 22 23 MINIMAL MONETARY COMPENSATION.

I DARE SAY THAT THE ICOC COULD NOT EXIST IN
ITS PRESENT FORM IF ITS MEMBERS WERE REQUIRED TO

1 CONFORM TO THE CURRENT NIH CONFLICT OF INTEREST POLICY. 2 I BELIEVE THAT THE ICOC SHOULD CONSIDER ADOPTING THE CONFLICT OF INTEREST POLICY THAT HAS BEEN IN EFFECT FOR 3 4 THE NATIONAL ACADEMIES OF SCIENCE AND THE NATIONAL 5 RESEARCH COUNCIL COMMITTEES AND COMMISSIONS. MEMBERS 6 OF THESE ADVISORY BODIES DECLARE ALL POTENTIAL 7 CONFLICTS OF INTEREST, FINANCIAL AND OF COMMITMENT, AND 8 FOR THE PUBLIC RECORD. ONLY IN UNUSUAL CIRCUMSTANCES 9 DOES THAT DISQUALIFY A PANEL MEMBER FROM ACTUALLY 10 PARTICIPATING IN THE DISCUSSIONS AND DECISIONS. THERE'S NOT TIME TO COMMENT ON THE OTHER 11 PROVISIONS OF SCA 13, BUT EFFORTS TO PROSCRIBE COMPLEX 12 13 MEDICAL COVERAGE SCHEDULES FOR DELIVERY OF THERAPIES 14 DERIVED FROM CIRM-SPONSORED RESEARCH IS AT PRESENT PREMATURE AND UNWARRANTED. THE SAME CAN BE SAID FOR 15 16 INCORPORATING MANDATES FOR RECOUPING THE COSTS FOR OUTLAYS FOR PATENT APPLICATIONS. PRESUPPOSITIONS THAT 17 THERE WILL BE SUBSTANTIAL ROYALTY STREAMS FROM CIRM'S 18 PATENTED RESEARCH DISCOVERIES ARE COUNTING ONE'S 19 20 CHICKENS LONG BEFORE THEY'VE EVEN BEEN CONCEIVED. 21 THANK YOU. CHAIRMAN KLEIN: THANK YOU, DR. BERG. IT IS, 22 23 AGAIN, A PRIVILEGE TO HAVE YOU HERE. 24 DR. BERG FOCUSED ON SCA 13, AND I WANT TO SAY

25 THAT UNDER THE REVIEW OF STATE LEGISLATION, WE WILL

ALSO BE REVIEWING THE ASSEMBLY RESOLUTIONS, SEVERAL OF
 WHICH WE ARE SUPPORTIVE OF ON A STAFF LEVEL, AND WE'RE
 BRINGING THEM TO THE BOARD WITH RECOMMENDATIONS FOR
 SUPPORT FOR THE BOARD TO DETERMINE WHETHER THE BOARD
 WOULD LIKE TO SUPPORT THEM AT THE BOARD LEVEL.
 BUT SINCE WE HAVE STARTED ON SCA 13, I

BELIEVE IT WOULD BE APPROPRIATE TO COMPLETE THAT ITEM
BEFORE GOING TO THE OTHER ITEMS UNDER THE STATE
LEGISLATION.

10 AS BACKGROUND, IT IS IMPORTANT TO NOTE THAT WE ARE DISCUSSING THIS LEGISLATION AND WHETHER WE ARE 11 12 GOING TO TAKE A POSITION IN OPPOSITION BASED UPON ITS CURRENT LANGUAGE. AND DR. BERG'S DESCRIPTION, THAT 13 THIS LEGISLATION WOULD CRIPPLE THE INSTITUTE, I 14 15 BELIEVE, IS QUITE APPROPRIATE GIVEN ITS CURRENT 16 LANGUAGE. THAT DOES NOT MEAN THAT THE LANGUAGE CANNOT BE CHANGED IN THE FUTURE. 17

I WOULD ALSO CALL TO YOUR ATTENTION THAT
SENATOR ORTIZ MAY HAVE MANY OF THE SAME GOALS THAT WE
DO, BUT IT IS THE LANGUAGE ITSELF THAT IS CRIPPLING OR
POTENTIALLY CRIPPLING TO THE INSTITUTION. SO WHILE WE
CAN BE SUPPORTIVE OF COMMON GOALS, THE LANGUAGE IS
EXTRAORDINARILY IMPORTANT. AND IF THE LANGUAGE IS NOT
CLEAR, THAT ITSELF IS A RISK TO THE INSTITUTE.

25 AS WE'VE SEEN, THE OPPOSITION HAS A VERY

AGGRESSIVE LITIGATION STRATEGY. AND WITH LANGUAGE THAT
 IS UNCLEAR, WE HAVE FULL KNOWLEDGE THAT THE OPPOSITION,
 ONCE WE GET THROUGH WITH THE CONSTITUTIONAL CHALLENGES
 TO THE BONDS, WOULD THEN TURN TO EXPLORE THE ABILITY TO
 LITIGATE ON ANY AREA OF AMBIGUITY INTRODUCED BY NEW
 LEGISLATION.

7 SO WE HAVE TO BE VERY CAREFUL TO MAKE CERTAIN 8 THAT WE BRING TO THE ATTENTION OF THE LEGISLATURE THAT 9 RUSHING THROUGH A PROCESS IN WHICH WE ARE NOT ABLE TO 10 BE HEARD ON THESE ISSUES IS A GRAVE RISK FOR THIS 11 INITIATIVE.

12 THE ISSUES WITH THIS LEGISLATION, FRANKLY, 13 AROSE AFTER THE CAMPAIGN WAS OVER. AS PAUL BERG 14 POINTED OUT, DURING THE CAMPAIGN, SENATOR ORTIZ DEBATED 15 THE OTHER SIDE OF ALMOST ALL OF THESE POSITIONS. AND I 16 PERSONALLY ONLY LEARNED OF THESE ISSUES ABOUT A WEEK 17 AFTER THE CAMPAIGN WAS OVER WHEN, FOR THE FIRST TIME, SENATOR ORTIZ AT A MEETING I WAS AT AT STANFORD 18 UNIVERSITY RAISED THE ISSUES. AND I WOULD LIKE TO 19 20 COMMUNICATE THAT I IMMEDIATELY AFTER HER PRESENTATION 21 INDICATED THAT I'D LIKE HER TO REALIZE THAT WE TOOK HER 22 POSITIONS VERY SERIOUSLY, WOULD LIKE TO GET TOGETHER 23 WITH THE SCIENCE COMMITTEE TO DISCUSS THEM, ON LEGAL 24 ISSUES TO GET TOGETHER WITH ANY OF THE ATTORNEYS AND 25 ANYONE THAT SHE WISHED TO HAVE ATTEND.

1 SENATOR ORTIZ DECIDED THAT THEY DID NOT WANT 2 TO MEET WITH ANY OF THOSE GROUPS. AND WHEN SHE WAS INVITED TO THE WORKSHOP OF THE NATIONAL ACADEMIES TO 3 4 DISCUSS MANY OF THE ISSUES ON WHICH SHE HAS A PROBLEM 5 WITH, INCLUDING CONFLICTS OF INTEREST, INCLUDING 6 CONSENT, INFORMED CONSENT, THAT WAS ON DECEMBER 6TH AND 7 7TH, SHE CHOSE NOT TO ATTEND THOSE MEETINGS AND, IN 8 FACT, RELEASED A NEWS RELEASE ON THE SAME DAY AS THE 9 BEGINNING OF THOSE MEETINGS INDICATING THAT SHE WAS 10 GOING TO GO OFF IN ANOTHER DIRECTION WITHOUT CONFERRING WITH THE BEST AND BRIGHTEST MINDS OF THE NATION, WHICH 11 THE NATIONAL ACADEMY HAD MADE THIS EXTRAORDINARY EFFORT 12 13 TO BRING TO CALIFORNIA.

SO IT'S OUR HOPE THAT WE CAN, AFTER TAKING 14 15 THE POSITION THAT WE DO TODAY, AGAIN CONTINUALLY REACH 16 OUT TO SENATOR ORTIZ BECAUSE I BELIEVE WE HAVE THE SAME GOALS. THE ISSUE IS WE DON'T UNDERSTAND WHERE THESE 17 POSITIONS CAME FROM. THESE POSITIONS THAT ARE IN SCA 18 13, I BELIEVE, WOULD DESTROY THE PROP 71 AND THE 19 INSTITUTE AND OUR ABILITY TO FUND THE BEST AND THE 20 21 BRIGHTEST SCIENCE IN THIS STATE.

IT IS HAS BEEN EXTREMELY FRUSTRATING TO TRY
AND GET OUR POSITION REPRESENTED OR THE POSITIONS OF
OTHER EXPERTS IN THE STATE REPRESENTED. ON THE INITIAL
INFORMATIONAL HEARING OF SENATOR ORTIZ, WE ACTUALLY HAD

AN EXTRAORDINARILY DIFFICULT TIME IN EVEN DEALING WITH
 THE STAFF OF THE SENATE HEALTH COMMITTEE BECAUSE THEY
 REFUSED TO ALLOW THE SUGGESTED WITNESSES THAT WERE
 EXPERTS IN THESE AREAS TO TESTIFY.

AND IN SPECIFIC, DR. SUSAN HACKWOOD, WHO IS 5 6 EXECUTIVE DIRECTOR OF THE CALIFORNIA COUNCIL ON SCIENCE 7 AND TECHNOLOGY, AFTER TWO WEEKS OF VERY STRONG 8 DISCUSSION, WHEN WE POINTED OUT THE ASSEMBLY CONCURRENT 9 RESOLUTION 252 HAD MANDATED THAT THE INTELLECTUAL 10 PROPERTY POLICY OF THE STATE BE RESEARCHED BY A TASK FORCE OF THE CALIFORNIA COUNCIL OF SCIENCE AND 11 TECHNOLOGY, THE STATE EQUIVALENT OF THE NATIONAL 12 13 ACADEMIES, AND THAT WE BELIEVE THAT THEIR EXECUTIVE DIRECTOR SHOULD BE INVITED TO SPEAK AT THAT INITIAL 14 15 HEARING, THE STAFF AGREED TO HAVE DR. SUSAN HACKWOOD ON 16 THE AGENDA. AND THEN A FEW DAYS LATER REMOVED HER FROM 17 THE AGENDA, NOT ALLOWING HER TO BE A WITNESS. WE ALSO ARE EXTRAORDINARILY TROUBLED BY THE 18 FACT THAT IT APPEARS THAT THE HEARINGS, FOR EXAMPLE, IN 19 20 THE CONSTITUTIONAL -- THE SENATE ELECTIONS COMMITTEE, 21 WHICH CONSIDERS CONSTITUTIONAL AMENDMENTS, WAS SCHEDULED SPECIFICALLY ON THE DAY WE HAD A PRESIDENTIAL 22 23 SEARCH PUBLIC HEARING NOTICED AND SCHEDULED. 24 SO WE ARE NOT BEING GIVEN AN ADEQUATE

25 OPPORTUNITY TO BRING FORWARD THE EXPERTS AROUND THE

1 STATE. IN PARTICULAR THIS WAS TROUBLING BECAUSE IT HAS 2 PREVIOUSLY BEEN SCHEDULED TO HAVE THAT HEARING A MONTH IN THE FUTURE. SO WE WERE ABLE -- WE WOULD THEN HAVE 3 4 BEEN ABLE TO BRING EXPERTS FROM AROUND THE STATE TO THAT HEARING. BUT NOT ONLY WAS IT RESCHEDULED, MOVING 5 6 IT UP A MONTH, BUT WE WERE NOT TOLD UNTIL LATE ON A 7 FRIDAY AFTERNOON WITH THE HEARING THEN BEING SET ON THE 8 FOLLOWING WEDNESDAY, GIVING US 48 HOURS BEFORE THAT 9 HEARING OCCURRED. WE SENT A LAWYER REPRESENTING THE 10 INSTITUTE, GIVEN THAT WE HAVE ONLY ONE GOVERNMENT RELATIONS PERSON ON THE STAFF, AND WE HAD PUBLIC 11 HEARINGS IN PROGRESS THAT THE AUTHOR WAS AWARE OF, SO 12 13 THAT WE WOULD AT LEAST BE ABLE TO GET ON THE RECORD. 14 NOW, I WILL POINT OUT AS WELL THAT 15 EXTRAORDINARILY IMPORTANT INFORMATION HAS NOT SURFACED 16 IN THIS PROCESS, INCLUDING IN THE SENATE HEALTH 17 COMMITTEE. THERE WAS A VERY THOUGHTFUL LETTER EXPRESSING SERIOUS CONCERNS ON THIS LEGISLATION THAT 18 WAS BROUGHT FORTH AND SIGNED BY JOINTLY THE PRESIDENT 19 20 OF STANFORD, DR. HENNESSEY, THE PRESIDENT OF USC, 21 DR. SAMPLE; THE PRESIDENT OF CALTECH, OUR OWN DR. DAVID 22 BALTIMORE; AND THE PRESIDENT OF THE ENTIRE US SYSTEM, 23 DR. BOB DYNES. SO THAT LETTER, WE KNOW, WAS IN THE HANDS OF THE AUTHOR AS CHAIRPERSON, YET IT WASN'T READ 2.4 25 INTO THE RECORD, AS FAR AS WE CAN TELL. IT WASN'T

1 DISTRIBUTED TO THE PUBLIC. AND SO THE PUBLIC HAD NO 2 WAY OF KNOWING THAT, IN FACT, THERE WAS VERY SERIOUS CONCERNS EXPRESSED IN AN EXTRAORDINARY LETTER BY FOUR 3 4 OF THE MOST EMINENT EDUCATORS IN THE STATE OF 5 CALIFORNIA REPRESENTING EXTRAORDINARY UNIVERSITIES. 6 THIS IS NOT THE POLICY AND PROCESS THAT I'M 7 AWARE OF BECAUSE, OF COURSE, AS PART OF MY PERSONAL 8 HERITAGE, I HAD THE PRIVILEGE OF WORKING FOR THE 9 LEGISLATURE, BOTH IN THE ASSEMBLY AND THE SENATE, IN 10 WRITING THE CALIFORNIA HOUSING FINANCE AGENCY STATUTE IN 1976 AND 1977, WHICH WAS AN EXTREMELY THOUGHTFUL 11 PROCESS WITH FULL HEARINGS, WITH THE FULL RIGHT OF 12 13 WITNESSES, WITH NOTICE THAT WAS PARTICULAR OUTREACH TO 14 MAKE SURE PEOPLE COULD PARTICIPATE IN THOSE HEARINGS. 15 NOW, WE ARE VERY HOPEFUL THAT THIS THURSDAY 16 WE WILL HAVE AN OPPORTUNITY TO PARTICIPATE IN AN APPROPRIATIONS HEARING THAT WILL OCCUR WITH SENATOR 17 MIGDEN BEING THE CHAIR OF THE APPROPRIATIONS COMMITTEE. 18 THIS WILL BE OUR FIRST OPPORTUNITY. NOW, WE UNDERSTAND 19 20 THAT APPROPRIATIONS DOES FOCUS ON FINANCIAL ISSUES, AND 21 THERE ARE MANY ISSUES OF SUBSTANCE WE DIDN'T HAVE AN 22 OPPORTUNITY TO PRESENT ON AND ISSUES RELATED TO WHETHER 23 THE PROPER -- WHETHER THE MATTERS IN THIS 24 CONSTITUTIONAL AMENDMENT ARE PROPERLY IN A

25 CONSTITUTIONAL AMENDMENT WE WOULD HAVE REALLY WANTED TO

1 BE ABLE TO ADDRESS THOROUGHLY WITH EXPERTS IN THE

2 CONSTITUTIONAL AMENDMENT COMMITTEE.

BUT I UNDERSTAND AS EARLY AS THIS MORNING 3 4 THERE WERE ATTEMPTS TO, IN FACT, POTENTIALLY REMOVE OUR 5 RIGHTS TO HAVE THAT ABILITY TO DO THE PRESENTATION ON 6 THURSDAY. BUT IT'S MY UNDERSTANDING THAT SENATOR 7 MIGDEN IS INSISTING THAT WE REALLY HAVE AN OPPORTUNITY 8 TO MAKE A PRESENTATION. THERE WAS AN ATTEMPT BY AUTHOR 9 TO SCHEDULE THE HEARING IN THAT COMMITTEE TODAY, 10 ANOTHER NOTICED HEARING THAT THE AUTHOR WAS AWARE WE WOULD HAVE THE BOARD TIED UP IN AND OUR LEADERSHIP TIED 11 UP IN TO DISCUSS LEGISLATION. 12

NOW, ON THE OTHER SIDE I WOULD SAY THAT I 13 HAVE GREAT FAITH IN THIS LEGISLATIVE PROCESS THAT THERE 14 WILL BE OPPORTUNITIES. AND, IN FACT, I WOULD POINT OUT 15 16 IN ITEMS WE WILL COVER LATER THAT THE ASSEMBLY HAS BEEN VERY THOUGHTFUL IN ITS APPROACH AND HAS, IN SETTING UP 17 THIS EXPERT GROUP, THE CALIFORNIA COUNCIL ON SCIENCE 18 AND TECHNOLOGY, THEY LOOKED FORWARD FROM LAST FALL IN 19 20 PASSING THE RESOLUTION TO INITIATE THAT PROCESS, 21 UNDERSTANDING IT WOULD BE A LONG PROCESS.

AND ON DECEMBER 17TH, THE VERY FIRST DAY WHEN I WAS ELECTED, I ACCEPTED THE INVITATION OF THE SCIENCE AND TECHNOLOGY COUNCIL TO HAVE TWO OF OUR BOARD MEMBERS SERVE ON THAT TASK FORCE AND PARTICIPATE IN THE

1 DEVELOPMENT OF THAT POLICY. WHILE WE KNOW THE SCIENCE 2 AND TECHNOLOGY COUNCIL ITSELF IS THE LEAD PARTICIPANT, 3 AT LEAST WE HAVE REPRESENTATIVES THERE THAT CAN RAISE 4 ISSUES OF IMPORTANCE.

5 AND DR. SUSAN BRYANT AND MICHAEL GOLDBERG 6 FROM THIS BOARD SERVE IN COOPERATION WITH THE 7 ASSEMBLY'S EFFORT TO MOVE FORWARD WITH A THOUGHTFUL --8 A THOUGHTFUL AND EXPERT REVIEW OF THE INTELLECTUAL 9 PROPERTY POLICY OF THE STATE, AND WE LOOK FORWARD AT 10 THIS BOARD TO HEARING THEIR RECOMMENDATIONS IN TRYING TO MOVE FORWARD WITH OUR INTELLECTUAL PROPERTY POLICY. 11 SO IT IS OUR INTENT TO REACH OUT AND COOPERATE WHENEVER 12 13 POSSIBLE WITH THE LEGISLATURE, AND WE APPLAUD THE 14 EFFORTS OF THE ASSEMBLY IN THEIR THOUGHTFUL AND 15 THOROUGH REVIEW AT AN EXPERT LEVEL OF INTELLECTUAL 16 PROPERTY POLICY.

WE DON'T UNDERSTAND THIS RUSH TO JUDGMENT IN THE ORTIZ BILL, WHICH IS ATTEMPTING TO PUT INTO PLACE AN ENTIRE POLICY ON INTELLECTUAL PROPERTY WITHOUT EVEN HEARING THE ASSEMBLY'S TASK FORCE INPUT, WHICH WE FIND TO BE VERY DISTURBING, AT LEAST I THINK FIND IT TO BE VERY DISTURBING.

23 WITHOUT GOING THROUGH THE INDIVIDUAL SECTIONS
24 OF THIS BILL COMPLETELY, I WOULD LIKE TO OPEN THIS TO
25 BOARD COMMENT FIRST ON THE PEER REVIEW POLICIES OF THE

SENATE CONSTITUTIONAL AMENDMENT 13. VERY SPECIFICALLY
 WE NEED TO DISCUSS WHAT THE SCA 13 LANGUAGE REALLY
 MEANS SO THAT THE PUBLIC UNDERSTANDS WHAT OUR ISSUES
 ARE WITH IT, HOW AMBIGUOUS -- DISCUSS HOW AMBIGUOUS
 LANGUAGE COULD CREATE AN ISSUE, AND WHAT MECHANISMS
 COULD BE CREATED TO INTERPRET OR IMPLEMENT THE
 LANGUAGE.

8 CERTAINLY IT IS OUR INTENT, AS I SAID, TO 9 FIND WAYS TO MAKE COOPERATION POSSIBLE WHILE POINTING 10 OUT THE EXTRAORDINARY PROBLEMS THAT THE CURRENT LANGUAGE WOULD PRODUCE. IN TERMS OF THE PEER REVIEW 11 12 LANGUAGE, I WOULD LIKE TO INDICATE THAT SENATOR ORTIZ HAS MADE AN AMENDMENT THAT SAYS THAT SHE WOULD ALLOW US 13 14 TO HAVE SCIENTIFIC PROPRIETARY INFORMATION REMAIN 15 CONFIDENTIAL; HOWEVER, THE ACTUAL CRITICISM OF THE 16 SCIENTISTS, THE RECORD, WHETHER THEY HAVE CAPACITY TO 17 REALLY MOVE FORWARD APPROPRIATELY ON A GRANT APPLICATION, WHETHER THEY HAVE THE KNOWLEDGE IN THE 18 19 SUBAREA, WHETHER THEIR STAFF IN THE INSTITUTION HAS THE 20 KNOWLEDGE TO PURSUE THIS, RIGHT NOW IN HER LANGUAGE IN 21 PEER REVIEW, SHE'S LEFT THAT ALL IN THE PUBLIC DOMAIN. 22 I THINK IT WOULD BE VERY HELPFUL TO HAVE SOME 23 BOARD DISCUSSION SPECIFICALLY POINTING OUT THE VALUE OF 24 PEER REVIEW. 25 ANY BOARD MEMBER WOULD LIKE TO DISCUSS THAT?

I KNOW THAT WE ALL HAVE DISCUSSED IT MANY TIMES, BUT
 FOR THE BENEFIT OF THE PUBLIC, THE VALUE OF HAVING THE
 REVIEW OF THE SCIENTISTS THEMSELVES AND THEIR PROPOSALS
 AS VERSUS JUST ANY PATENTABLE INFORMATION REMAIN
 PRIVATE AND CONFIDENTIAL.

6 MS. SAMUELSON: I'D LIKE TO RESPOND TO THAT, 7 BUT I THINK TAKING IT UP A LEVEL AND ALSO SIMPLY 8 SPEAKING AS A PATIENT AND VOTER, FIRST OF ALL. BECAUSE 9 BEING A MEMBER OF THIS COMMITTEE IS AN ENORMOUS HONOR 10 TO ME, BUT I'M ALSO A VOTER AND A PATIENT. AND I VOTED 11 FOR PROPOSITION 71, AND I CAN'T OVERSTATE THE IMMENSE 12 HOPE THAT THE PASSAGE OF THIS PROPOSITION GAVE ME.

13 I KNOW THIS -- THE TERMS OF THIS INITIATIVE 14 EXTREMELY WELL, AND IT PROMISES ME BREAKTHROUGH 15 THERAPIES FOR THE RELIEF OF PARKINSON'S DISEASE FAR 16 SOONER, I BELIEVE, THAN THEY WILL OTHERWISE BE 17 DELIVERED, AND THAT WILL MAKE THE DIFFERENCE OF IMMENSE SUFFERING AVOIDED AND PERHAPS IT WILL SAVE MY LIFE. 18 AND SO I TAKE THIS VERY SERIOUSLY. AND I 19 LOOK AT THIS SERIES OF PROVISIONS THAT ARE COVERED BY 20

SCA 13, WHICH I'M LOOKING AT PAGE 3 OF 4 IN OUR
MATERIALS. AND EVERY ONE OF THESE WERE TASKS THAT WERE
ASSIGNED TO US BY THE VOTERS TO UNDERTAKE. AND WE HAVE
BEEN WORKING AS HARD AS WE POSSIBLY CAN. WE HAVE BEEN
BRINGING IN EXPERTS FROM, NOT ONLY THE ENTIRE REACH OF

UNITED STATES OF AMERICA, BUT AROUND THE WORLD. 1 2 AND I LEARNED IN MY BRIEF TUTORIAL OF TWO DAYS IN IRVINE WHEN THE NATIONAL ACADEMIES CAME TO US 3 4 TO TUTOR US A BIT ON THE BREADTH OF ISSUES WE WERE GOING TO BE FACING. JUST SIMPLY ON PATENTS ALONE, I 5 6 LEARNED THAT THAT ISSUE IS COMPLETELY INTERTWINED WITH 7 THE ISSUE OF WHETHER OR AND HOW FAST WE WOULD GET CURES 8 BECAUSE IT'S INTERTWINED WITH THE INCENTIVES TO 9 SCIENTISTS, IS INTERTWINED WITH THE ISSUE OF DELIVERING 10 REVENUE BACK TO THE STATE OF CALIFORNIA, WHICH WE'RE GOING TO ENDEAVOR TO DO, AND WITH THE ISSUE OF PRICING, 11 AND THAT IT IS IMMENSELY COMPLICATED. 12 13 SO IT TOLD ME THAT WE'RE GOING TO HAVE AN 14 IMMENSELY DIFFICULT TASK HANDLING ALL OF THOSE WITH 15 DELIVERING A CURE AT THE FASTEST POSSIBLE SPEED, WHICH 16 IS OUR ULTIMATE MISSION, AND THAT WE WOULD NEED TO BRING IN THE EXPERTS FROM AROUND THE WORLD TO HELP US 17 DO THAT AND DO IT IN A VERY DELIBERATE, CAREFUL WAY. 18 THE THOUGHT THAT THIS TASK IS BEING LIFTED 19

OFF OF OUR PLATE IN WHATEVER WAY IT'S BEING DONE IS
WRONG. THE VOTERS GAVE IT TO US, AND WE'RE ENDEAVORING
TO WORK AS FAST AND AS HARD AS WE CAN AND AS
INTELLIGENTLY. SO NOT ONLY WOULD THIS UNDERMINE THIS
PROCESS, BUT IT IS RISKING THE LIFESAVING OPPORTUNITY
THAT PROPOSITION 71 PROVIDES US. AND I THINK IT VERY

1 WELL CAN CAUSE HARM THAT WILL BE MEASURED EASILY IN 2 EXTRA SUFFERING AND DEATHS. AND THAT MAY SOUND INFLAMMATORY, BUT I BELIEVE IT. AND I'M AFRAID THAT IT 3 4 WILL DO THAT, AND I BELIEVE THIS FROM THE BOTTOM OF MY 5 HEART, AND I'M SAYING THAT AS A PATIENT. 6 CHAIRMAN KLEIN: THANK YOU, JOAN. 7 DR. BIRGENEAU: BOB BIRGENEAU. SO HERE I 8 WILL SPEAK AS A LEADER OF ONE OUR PREMIERE PUBLIC 9 RESEARCH AND TEACHING UNIVERSITIES. OUR GREAT RESEARCH 10 AND TEACHING UNIVERSITIES IN THE UNITED STATES ARE --AND THE WHOLE SYSTEM IS GENUINELY THE ENVY OF THE 11 WORLD. AND A FUNDAMENTAL -- ONE OF THE FUNDAMENTAL 12 BASES OF THAT IS THE FACT THAT WE ARE ABLE TO MAKE VERY 13 STRICT JUDGMENTS BOTH ON THE PEOPLE WE APPOINT TO OUR 14 15 PERMANENT FACULTIES AND ON THE RESEARCH THEY DO, BOTH 16 DONE THROUGH THE PEER REVIEW PROCESS. 17 AND IN TURN, IN ORDER TO HAVE A VIABLE PEER REVIEW PROCESS, WE RELY ON PEERS BEING ABLE TO SAY 18 EXACTLY WHAT THEY THINK WITH -- IN A CANDID WAY WITHOUT 19 20 WORRY ABOUT THEIR VIEWS BEING PRESENTED PUBLICLY 21 BECAUSE, CLEARLY, IF THEY WERE PRESENTED PUBLICLY, THEN

22 VERY FEW PEOPLE WOULD BE WILLING TO GIVE US THE KIND OF23 CANDID INFORMATION THAT WE NEED.

24 THIS IS TRUE FOR RESEARCH, AND IT'S ALSO TRUE25 FOR APPOINTMENTS. IF WE WERE FORCED TO A SITUATION

1 WHERE ALL OF THE JUDGMENTS HAD TO BE DONE IN PUBLIC AND 2 WE WERE -- THEREFORE, WE HAD TO RELY ON OPINIONS EXPRESSED BY PEOPLE THAT WERE PART OF THE PUBLIC 3 4 RECORD, THEN VERY FEW PEOPLE WOULD BE WILLING TO GIVE US THE HONEST TRUTH. THE ONLY POSSIBILITY, THEN, IS 5 6 THAT THE CALIBER OF THE RESEARCH THAT WE'D BE CARRYING 7 OUT IN THE STEM CELL FIELD ON BEHALF OF THE PEOPLE OF 8 CALIFORNIA WOULD INEVITABLY BE COMPROMISED BECAUSE WE 9 COULD NO LONGER HAVE THE KIND OF INFORMATION THAT WE 10 NEED IN ORDER TO GUARANTEE THAT THESE DOLLARS WILL BE SPENT IN THE VERY BEST WAY POSSIBLE. 11 CHAIRMAN KLEIN: THANK YOU VERY MUCH, DR. 12 13 BIRGENEAU. DR. POMEROY. DR. POMEROY: WE'RE AT A CRITICAL JUNCTURE, I 14 15 THINK, AND THE DECISIONS THAT WE MAKE RIGHT NOW ABOUT 16 HOW WE DEAL WITH THESE ISSUES WILL SET A TONE, I THINK, FOR HOW WE DO BUSINESS AND HOW WE'RE PERCEIVED BY THE 17 PUBLIC. LIKE DR. BIRGENEAU, I AM AN EXTRAORDINARILY 18

STRONG SUPPORTER OF CONFIDENTIAL PEER REVIEW. I THINK
 IT'S ESSENTIAL TO THE ACADEMIC PROCESS. BUT I THINK
 THAT WE KNOW THAT IN ACADEMIA BECAUSE WE'VE SEEN IT.

22 RIGHT NOW THE PUBLIC DOES NOT PERCEIVE US AS
23 GRAPPLING APPROPRIATELY WITH THE CONFLICT OF INTEREST
24 RULES.

25

AND I THINK THAT AS A COMMITTEE WE HAVE A BIG

RESPONSIBILITY TO BE VERY INCLUSIVE IN OUR DISCUSSION
 OF THESE ISSUES. AS WE MOVE FORWARD, AND I THINK WE
 SHOULD REALLY CONCENTRATE ON MOVING FORWARD AND NOT
 GOING BACK ON HOW WE GOT TO THIS POINT BECAUSE THAT
 JUST SORT OF SOLIDIFIES US VERSUS THEM, AND I HOPE AS A
 COMMITTEE WE CAN SAY OUR GOAL IS TO GET ALL OF OUR
 CONSTITUENCIES INVOLVED IN THIS PROCESS.

8 WHEN THE PUBLIC AWARDED -- I KNOW YOU AGREE 9 WITH THIS, JOAN -- WHEN THE PUBLIC AWARDED US THIS 10 RESPONSIBILITY, THEY ASSUMED THAT WE WOULD TAKE IT VERY 11 SERIOUSLY AND INVOLVE INPUT FROM ALL DIFFERENT 12 PERSPECTIVES, NOT JUST ACADEMIA. AND I THINK THAT WE 13 ALL TAKE THAT RESPONSIBILITY VERY SERIOUSLY AS WELL.

14 SO AS WE DISCUSS THIS AND AS WE SORT OF THINK 15 ABOUT A RESOLUTION THAT WE MIGHT WANT TO PASS, I WOULD 16 HOPE THAT WE MIGHT MODIFY IT SOMEWHAT TO SAY SOMETHING LIKE IN ITS CURRENT FORM SCA 13 IS PROBLEMATIC FOR US, 17 BUT WE WOULD WANT TO WORK IN PUBLIC WITH ALL OF OUR 18 19 CONSTITUENCIES TO DEVISE THESE POLICIES AND THESE 20 PROCEDURES IN A WAY THAT IS UNDERSTANDABLE TO THE 21 PUBLIC AND ACCEPTABLE TO ALL THE CONSTITUENCIES IN A 22 MUCH MORE INCLUSIVE WAY, FRANKLY, THAN WE HAVE DONE UP 23 TO THIS POINT.

24 CHAIRMAN KLEIN: AND TO BE CLEAR, DR.25 POMEROY, THE RESOLUTION IS SPECIFICALLY INTENDED TO

COMMUNICATE THAT IN ITS CURRENT FORM BECAUSE WE WILL
 DEFINITELY CONTINUE TO REACH OUT TO FIND WAYS TO WORK
 WITH ALL CONSTITUENCIES AND SPECIFICALLY WITH SENATOR
 ORTIZ. WE KNOW THAT WHILE MR -- SOME OF THE COSPONSORS
 WERE ABSOLUTELY ADAMANT OPPOSITION TO PROPOSITION 71,
 SENATOR ORTIZ WAS A STRONG SUPPORTER. I DO BELIEVE WE
 SHARE GOALS. THE ISSUE IS THE CURRENT LANGUAGE.

8 DR. PRIETO: YES. I'D LIKE TO SAY, FIRST OF 9 ALL, I APPRECIATE COMMENTS LIKE THOSE JOAN AND DR. 10 BIRGENEAU MADE, AND THAT I COME AT THIS ALSO AS PATIENT ADVOCATE AND AS A PHYSICIAN WHO SEES PATIENTS EVERY DAY 11 SUFFERING FROM THESE CHRONIC DISEASES, SUFFERING AND 12 13 DYING BEFORE THEIR TIME FROM THESE CHRONIC DISEASES. 14 BUT I THINK IT'S PREMATURE FOR US TO TAKE A POSITION IN 15 OPPOSITION TO THIS BILL THAT, AS WE SAY IS NOT, AS IN 16 OUR UPDATE, IS NOT BASED OFFICIAL LANGUAGE, AND THAT 17 OFFICIAL LANGUAGE IS NOT AVAILABLE TO US AT THIS 18 WRITING.

19 I DON'T WANT TO SEE US DRAWING LINES IN THE 20 SAND THAT DON'T YET NEED TO BE DRAWN AND THAT MAY HURT 21 US IF THEY DRAW THEM NOW. I THINK IT'S IMPORTANT THAT 22 WE MAKE A DISTINCTION BETWEEN THE PEOPLE WHO ARE 23 INVOLVED IN THE LEGAL ACTION AGAINST US WHO ARE VERY 24 CLEARLY OPPONENTS OF THE RESEARCH, WHO WILL DO WHATEVER 25 THEY CAN TO POSTPONE IT AND DELAY IT AND STOP IT IF

THEY CAN, AND THOSE ARE WHO SUPPORTERS OF THIS RESEARCH
 AND HAVE SHOWN THAT THEY'RE SUPPORTERS OF THIS
 RESEARCH, BUT WHO PERHAPS DON'T TRUST US. AND I THINK
 IT'S IMPORTANT THAT WE DO EVERYTHING WE CAN TO EARN
 THEIR TRUST AND KEEP THEIR SUPPORT. AND I'D LIKE TO US
 MOVE FORWARD IN THAT VEIN AND STEP BACK FROM AN
 ADVERSARIAL POSTURE.

8 CHAIRMAN KLEIN: DR. PRIETO, I WOULD REMIND 9 YOU THAT WE HAVE FOLLOWED THAT POLICY TO DATE, AND WE 10 ARE BEING SCHEDULED OUT OF HEARINGS. THEY'RE BEING SCHEDULED SPECIFICALLY SO WE CANNOT ATTEND. WE ARE 11 VERY OPTIMISTIC ABOUT THE ABILITY TO ATTEND THE SENATE 12 APPROPRIATIONS COMMITTEE, AND WE ARE VERY THANKFUL TO 13 14 THE CHAIR OF THAT COMMITTEE FOR, IN FACT, NOT 15 SCHEDULING THAT HEARING TODAY SO THAT, IN FACT, WE 16 COULD ATTEND.

17 BUT LANGUAGE IN THE LEGISLATURE WILL CONTINUALLY CHANGE. WE ARE TAKING A POSITION BASED ON 18 THE LANGUAGE THAT WE HAVE. IF WE DON'T TAKE A POSITION 19 20 UNTIL WE HAVE LANGUAGE, WE WILL NEVER TAKE A POSITION. 21 SO WE HAVE TO TAKE A POSITION ON WHAT WE HAVE WHILE HOLDING OUT OPENLY THE DESIRE TO COOPERATE AND REACH 22 23 LANGUAGE THAT WILL WORK. BUT WE'RE OPPOSED BASED ON 24 THE LANGUAGE THAT WE HAVE, AND THAT'S THE BASIS OF 25 DR. BERG'S COMMENTS AS WELL.

1

## DR. SUSAN BRYANT.

2 DR. BRYANT: I WAS JUST WONDERING -- THERE IS -- I HAVE IN FRONT OF ME WHAT THE ACTUAL LANGUAGE 3 4 IS, AND SO IT HAS MADE SOME MOVE IN THE RIGHT DIRECTION. I'M JUST WONDERING IF IT WOULDN'T BE 5 6 PROFITABLE FOR US TO SUGGEST THE LANGUAGE THAT WOULD 7 COVER US SO THAT WE COULD DO THE KIND OF PEER REVIEW 8 THAT WE NEED BECAUSE I MEAN A SLIGHT TWEAKING OF THIS 9 MIGHT DO IT. I REALIZE THERE ARE OTHER ISSUES WITH 10 THIS PROPOSED AMENDMENT, BUT FOR THIS PARTICULAR ISSUE, IF A PROPOSED A REWRITE WERE ABLE TO BE PROMULGATED. 11 CHAIRMAN KLEIN: DR. BRYANT, WE HAVE MET WITH 12 13 SENATOR ORTIZ AND PROPOSED LANGUAGE AND DISCUSSED THE 14 IMPORTANCE OF PEER REVIEW, AND VARIOUS DELEGATIONS OF 15 SCIENTISTS HAVE MET WITH HER AND SUGGESTED HOW 16 IMPORTANT THE LANGUAGE WAS. AND IT IS -- THOSE HAVE ALL BEEN REBUFFED AS OF THIS DATE. SO THERE HAVE BEEN 17 NUMEROUS PERSONAL MEETINGS THAT HAVE OCCURRED TO TRY 18 19 AND POINT OUT HOW CRITICAL IT WAS, AND THEY HAVE BEEN 20 TURNED DOWN.

21 YES, DR. HENDERSON.

22 DR. HENDERSON: I WONDER IF THERE'S ANY OTHER 23 EXPERIENCE FROM ANYBODY ON THIS BOARD OR FROM DR. HALL 24 RELATED TO THIS LEGISLATION THAT WE COULD HEAR AT THIS 25 TIME. I'M ALSO UNCOMFORTABLE WITH TAKING A

1 CONFRONTATIONAL POSTURE IF IT ISN'T ABSOLUTELY

2 NECESSARY. IT SEEMS TO ME TO TAKE THIS COMMITTEE OFF IN THE WRONG DIRECTION AGAIN AND AWAY FROM OUR PRIMARY 3 4 WORK. I WONDER, DR. HALL, IF YOU'VE HAD ANY 5 DISCUSSIONS WITH SENATOR ORTIZ AND HOW YOU VIEW THIS. 6 DR. HALL: I HAVE NOT. I HAVE BEEN PLEASED 7 TO SEE THAT THE LANGUAGE HAS CHANGED SOMEWHAT. FROM MY 8 DISCUSSIONS THIS MORNING WITH VARIOUS MEMBERS OF THE 9 BOARD HERE, I'M QUITE DISCOURAGED ACTUALLY ABOUT OUR 10 ABILITY TO COME UP WITH SOMETHING THAT WE CAN LIVE WITH AND LET US GET ON WITH OUR WORK. 11

12 FROM MY POINT OF VIEW, WE ARE POISED TO MOVE 13 FORWARD, AND WE ARE BEING WEIGHTED DOWN WITH 14 REGULATIONS AND WITH REALLY A STRUGGLE THAT IS 15 UNNECESSARY AND IS ENORMOUSLY DISTRACTING FROM OUR REAL 16 MISSION. SO I LEAVE IT TO THOSE WHO ARE POLITICALLY 17 BETTER INFORMED, BUT I MUST SAY I'M QUITE DISCOURAGED 18 AT THE MOMENT.

19 CHAIRMAN KLEIN: I'D LIKE TO TALK ON -- CALL
20 ON JEFF SHEEHY, BUT FIRST I'D LIKE -- COULD OUR COUNSEL
21 GIVE AN EXAMPLE OF SOME OF THE OTHER LANGUAGE SO WE
22 HAVE AN OVERVIEW? IF THIS WERE ONE SECTION, IT WOULD
23 BE ONE PROBLEM. THE PROBLEM IS THERE ARE MINE FIELDS
24 IN ALL OF THE DIFFERENT PORTIONS OF THIS. AND, JAMES
25 HARRISON, COULD YOU PROVIDE SOME INSIGHT INTO SOME OF

1 THE LEGAL ISSUES JUST WITH LANGUAGE AND THE RISKS THAT 2 IT HAS? MS. SAMUELSON: POINT OF INFORMATION. IS IT 3 4 POSSIBLE THAT WE ALL GET A COPY OF THE BILL SO THAT WE WOULD HAVE IT IN FRONT OF US. AND THE FULL DRAFT IS 5 6 THERE. OKAY. 7 CHAIRMAN KLEIN: YOU HAVE IT IN YOUR BOOK. 8 DR. BRYANT: JOAN, IT'S THE LAST PIECE UNDER 9 TAB 8. 10 MR. HARRISON: LET ME GIVE YOU TWO EXAMPLES. IF YOU LOOK AT PAGE 3 OF 3, SECTION 9(A)(1), THIS IS A 11 PROVISION THAT READS: NOTWITHSTANDING SECTION 6, THE 12 13 CONTRACT AWARD, GRANT, LOAN OR OTHER ARRANGEMENT DOES NOT RESULT IN A GIFT OF PUBLIC FUNDS WITHIN THE MEANING 14 15 OF SECTION 6 OF ARTICLE 16. 16 SECTION 6 OF ARTICLE 16 OF THE STATE 17 CONSTITUTION PROHIBITS THE STATE FROM MAKING A GIFT OF PUBLIC FUNDS. THE GENERAL CASE LAW INTERPRETING THAT 18 PROVISION PROVIDES THAT IF AN EXPENDITURE SERVES A 19 20 PUBLIC PURPOSE, EVEN IF THERE'S SOME INCIDENTAL PRIVATE 21 BENEFIT, IT SATISFIES THE STATE CONSTITUTIONAL 22 STANDARD. 23 PROPOSITION 71 ITSELF DECLARED THAT 24 CONDUCTING STEM CELL RESEARCH IN CALIFORNIA SERVED A PUBLIC PURPOSE. WHAT THIS PROVISION APPEARS TO DO 25

1 WOULD BE TO REQUIRE THE ICOC TO MAKE A DETERMINATION 2 THAT EACH GRANT, LOAN, OR CONTRACT DOES NOT RESULT IN A GIFT OF PUBLIC FUNDS, SO IT RAISES A QUESTION ABOUT 3 4 WHAT STANDARD WOULD APPLY. IF THE PEOPLE IN ADOPTING PROPOSITION 71 HAVE ALREADY DECLARED THAT CONDUCTING 5 6 STEM CELL RESEARCH SERVES A PUBLIC PURPOSE, WHAT MORE 7 WOULD YOU NEED TO DEMONSTRATE IN ORDER TO SATISFY THIS 8 NEW CONSTITUTIONAL STANDARD? AND IT RAISES A QUESTION 9 ABOUT WHETHER IT COULD POTENTIALLY OPEN THE DOOR TO A 10 TAXPAYER ACTION, FOR EXAMPLE, WHO MIGHT FILE A LAWSUIT CHALLENGING A PARTICULAR GRANT OR LOAN TO A PRIVATE 11 INSTITUTION PERHAPS AS A GIFT OF PUBLIC FUNDS. 12 13 THE LANGUAGE IS VAGUE AND AMBIGUOUS. AND AS 14 WITH ALL VAGUE AND AMBIGUOUS LANGUAGE, PARTICULARLY 15 WHEN IT'S IN THE STATE CONSTITUTION, IT DOES RAISE THE 16 POSSIBILITY OF UNCERTAINTY AND LEGAL CHALLENGES. THE SECOND EXAMPLE IS ONE THAT'S NOT 17 REFLECTED IN THE CURRENT LANGUAGE, BUT IS APPARENTLY 18

GOING TO BE ADDED TODAY. AND THAT'S A PROVISION THAT 19 20 WOULD PROHIBIT MEMBERS OF THE BOARD FROM HAVING A 21 FINANCIAL INTEREST IN APPLICANTS FOR FUNDING AS WELL AS

23 RESEARCH. I THINK IT'S PROBABLY INTENDED TO BE LIMITED TO FINANCIAL INTEREST, MEANING INVESTMENTS, BUT THE 24 25 LANGUAGE REFERS TO THE POLITICAL REFORM ACT DEFINITION

ENTITIES THAT DO A SUBSTANTIAL AMOUNT OF STEM CELL

22

OF FINANCIAL INTEREST, WHICH INCLUDES A SOURCE OF
 INCOME OF \$500 OR MORE. IN OTHER WORDS, IF YOU RECEIVE
 \$500 OR MORE FROM AN APPLICANT FOR FUNDS, YOU WOULD BE
 PRECLUDED FROM SERVING ON THE BOARD.

5 NOW, THIS IS AGAIN --

б CHAIRMAN KLEIN: LET'S DRAW THAT OUT. THAT 7 MEANS THAT ANY MEMBER OF ANY RESEARCH INSTITUTION 8 THAT'S ON THIS BOARD WOULD BE KNOCKED OFF THE BOARD. MR. HARRISON: RIGHT. THE LANGUAGE MAY NOT 9 10 BE INTENTIONAL; AND, AS I SAID, THEY MAY WANT TO LIMIT IT OR THEY MAY MEAN TO LIMIT IT TO INVESTMENTS, BUT 11 THEY REFER TO FINANCIAL INTEREST UNDER THE POLITICAL 12 13 REFORM ACT, AND THE DEFINITION OF FINANCIAL INTEREST UNDER THE POLITICAL REFORM ACT IS QUITE BROAD. 14

15 SO THOSE ARE TWO ISSUES WHERE THE LANGUAGE, I
16 THINK, CREATES A GREAT DEAL OF UNCERTAINTY AND
17 AMBIGUITY.

DR. LEVEY: YES. I DON'T KNOW WHAT ALL THIS 18 DISCUSSION IS ABOUT. IN THE UC SYSTEM WE GET 19 20 CONTINUOUSLY CHALLENGED WITH LEGISLATION THAT IS 21 SOMETIMES ANTITHETICAL TO THE MISSION OF THE UC SYSTEM. 22 AND KEEPING THINGS RESPECTFUL, WHICH THEY DO, WE HAVE A 23 GOVERNMENT RELATIONS OFFICE THAT PUTS OUT ANALYSES OF 24 VARIOUS DOCUMENT -- VARIOUS PIECES OF LEGISLATION. AND 25 WE STAKE OUR POSITION FOR OR AGAINST. WE ALSO

DISSEMINATE OBVIOUSLY TO THE GOVERNOR AND OTHER KEY
 PERSONNEL. AND THAT'S THE POLITICAL PROCESS.

I DON'T THINK WE NEED TO BE OBSEQUIOUS TO
SENATOR ORTIZ. WE HAPPEN TO DISAGREE VERY STRONGLY
WITH WHAT SHE'S PUTTING OUT. IF WE DON'T STAND UP FOR
OURSELVES, WE'RE GOING TO END UP WITH SOME TERRIBLE
LEGISLATION.

8 SO I WOULD CERTAINLY STRONGLY SUGGEST THAT 9 THIS BOARD TAKE A VERY STRONG AND RESPECTFUL STANCE 10 WITH HER. AND I CONGRATULATE MR. KLEIN BECAUSE HE HAS GONE THE ENTIRE NINE YARDS IN TRYING TO MAKE VARIOUS 11 POINTS TO HER, AND HE'S ENUMERATED MANY WAYS IN WHICH 12 13 SHE HAS REBUFFED THESE OVERTURES. SO I WOULD HOPE 14 WE'RE NOT CONCERNED WITH ANYTHING OTHER THAN WE CAN 15 RESPECTFULLY DISAGREE WITH HER AND OPPOSE THE 16 LEGISLATION SHE'S SPONSORING.

17 CHAIRMAN KLEIN: JEFF SHEEHY. I'M SORRY. I

18 WAS GOING TO RECOGNIZE YOU.

MR. SHEEHY: LET ME JUST PUT SOME OF THIS IN
PERSPECTIVE. I'M THE APPOINTEE OF THE SENATE. I HAVE
SPOKEN TO PETER HANSEL, SENATOR ORTIZ' AIDE, AT LENGTH
NUMEROUS TIMES. I'VE MET WITH HIM IN SACRAMENTO. I'VE
OFFERED TO MEET WITH SENATOR ORTIZ AND TO GO UP TO
SACRAMENTO AND DO SO, AND SHE HAS NOT TAKEN ME UP ON
THAT OFFER. SHE HASN'T TAKEN ME UP ON ANY OFFER TO

CARRY ANYTHING BACK TO THIS BOARD AS A MEANS OF
 NEGOTIATION. THERE HAS BEEN NOT THE SCINTILLA OF
 COOPERATION WITH THIS BOARD.

4 AND I THINK THAT WE NEED TO SIT BACK AND ASK OURSELVES WHAT HAVE WE DONE WRONG. WHAT HAVE WE DONE 5 6 WRONG? WE HAVE CONDUCTED ALL OF OUR BUSINESS TO THE 7 THIS POINT IN PUBLIC. AND I AM PROUD OF MY SERVICE ON 8 HERE, ON THIS BOARD. I'M PROUD OF THE SERVICE OF THE 9 PEOPLE I'VE BEEN SERVING WITH. AND WE NEED TO STAND UP 10 AND SAY THAT TO THE PEOPLE OF CALIFORNIA. PEOPLE HAVE BEEN BEATING US UP, AND THERE'S NO JUST REASON FOR THIS 11 12 TO HAPPEN.

13 THIS BILL, LOOKING AT THIS BILL, IT IS A 14 DISASTER. AND IT IS BEING RUSHED TO THE BALLOT FOR 15 THIS NOVEMBER WITH HASTE THAT IS IRRESPONSIBLE. IT'S 16 POORLY DRAFTED. MEASURES IN THIS BILL, ESPECIALLY THE INTELLECTUAL PROPERTY PART, DO NOT BELONG IN THE 17 CALIFORNIA CONSTITUTION. WE ARE AMENDING THE 18 CONSTITUTION OF THIS -- SHE WANTS TO AMEND THE 19 20 CONSTITUTION OF THIS STATE. THIS IS HIGHLY 21 INAPPROPRIATE.

AND I HAVE TO SAY THERE IS A CRUELTY THAT IS ALMOST SAVAGE. AND I KNOW THAT SENATOR ORTIZ IS WELL-MEANING, BUT TO STEAL HOPE FROM PATIENTS AROUND THIS STATE, AND I'M NOT GOING TO SAY THAT WE'RE GOING

HAVE A CURE TOMORROW, BUT CURES ARE POSSIBLE. WE HAVE
 THIS MAJOR ADVANCE IN KOREA. AND PEOPLE'S SPIRITS ARE
 LIFTED. HOW DARE SHE STEAL HOPE FROM THE PATIENTS OF
 CALIFORNIA? HOW DARE SHE?

CHAIRMAN KLEIN: I WOULD LIKE TO POINT OUT 5 6 THAT JEFF SHEEHY AND DAVID SERRANO-SEWELL HAVE BEEN 7 LEADERSHIP ON THIS BOARD. IF YOU REMEMBER, AT LEAST 8 TWO BOARD MEMBERS AGO -- TWO BOARD MEETINGS AGO, THEY 9 BROUGHT UP THE CONCEPTUAL CHANGE TO OUR WORKING 10 POLICIES TO HAVE THE STANDARDS COMMITTEE BASIC POLICY BE, THAT THE STANDARDS WORKING GROUP WOULD BE OPEN WITH 11 MODIFICATIONS FOR PATIENT PRIVACY AND OTHER EXCEPTIONS 12 THAT WERE APPROPRIATE. AND THEY ARE WORKING WITH 13 COUNSEL TO BRING THAT BACK TO THE BOARD, BUT WE PUT 14 15 OURSELVES ON RECORD WITH THE VOTE TO MAKE THAT 16 BASICALLY AN OPEN PUBLIC HEARING ADVISORY GROUP. 17 AND IN THE AGENDA TODAY WE HAVE AN ITEM UNDER THE MEDICAL FACILITIES WORKING GROUP WHERE THEIR 18 RECOMMENDATION IS TO ADOPT THE SAME CONCEPT, THAT THE 19 FACILITIES WORKING GROUP WOULD BE AN OPEN HEARING 20 21 PROCESS OTHER THAN EXCEPTIONS LIKE NEGOTIATING OVER 22 LAND THAT WOULD BE ONGOING OR CONTRACT NEGOTIATIONS, 23 OTHER THINGS THAT NEED TO BE PROTECTED IN ORDER TO 24 PROTECT THE APPLICANT'S BEST OPPORTUNITY TO FULFILL 25 THEIR PROPOSALS.

1 SO THIS BOARD HAS MOVED FORWARD IN A VERY 2 THOUGHTFUL WAY THROUGH 29 PUBLIC HEARINGS IN THE LAST 22 WEEKS. IS THAT, I THINK, THE CURRENT COUNT? AN 3 4 INCREDIBLE AMOUNT OF OPENNESS. IN CREATING MORE OPENNESS AS WE PROCEEDED, AS EARLY AS FEBRUARY OF THIS 5 6 YEAR, THE END OF FEBRUARY OF THIS YEAR, I MET WITH 7 SENATOR ORTIZ AND PROVIDED HER A COPY OF A LETTER FROM 8 BRUCE ALBERTS OF THE NATIONAL ACADEMY POINTING OUT THE 9 NATIONAL ACADEMIES HAS A PART OF THEIR HEARINGS ON 10 STANDARDS THAT ARE OPEN, A PORTION THAT'S CONFIDENTIAL, AND LAYING THAT OUT, WHICH IS A LETTER THAT I HAVE 11 DISTRIBUTED ON OUR STAFF AS A MODEL AND TO MEMBERS ON 12 13 THIS BOARD AS A MODEL SO THAT SHE KNEW WE WERE WORKING 14 TOWARDS OPEN MEETINGS ON STANDARDS.

SO I WANT TO INDICATE THAT, A, I THINK DR.
LEVEY'S POSITION IS EXTREMELY WELL TAKEN. IT IS PART
OF THE PROCESS. THEY NEED TO KNOW IF WE'RE IN
OPPOSITION BASED ON ITS CURRENT POSITION. BUT WHILE WE
WILL CONTINUE TO WORK IN GOOD FAITH AND WE'LL CONTINUE
TO MAKE EVERY OVERTURE POSSIBLE BECAUSE WE KNOW WE HAVE
SHARED GOALS. YES. DAVID SERRANO-SEWELL.

22 MR. SERRANO-SEWELL: I'LL BE VERY BRIEF. 23 JOAN MAY HAVE ALREADY REFERRED TO IT AND EVERYONE IS 24 DOING THEIR PART IN SAYING THEIR THING. WE DID A 25 LITTLE THING IN THE CHRONICLE, "GIVE PATIENTS A

1 CHANCE." JEFF AND I AND JOAN ALL READ IT.

2 IF ENACTED AS PRESENTLY DRAFTED, AND WE'RE ALL SAYING AS PRESENTLY DRAFTED, THIS SCA 13 WILL 3 4 IMPAIR OUR EFFORTS TO FULFILL OUR STATUTORY MANDATE TO FIND CURES AND THERAPIES. THAT'S A CONCERN. 5 6 EVERY EFFORT, DR. HENDERSON, TO COMMUNICATE 7 TO THE SENATOR'S OFFICE, BACK CHANNELS, OFFICIAL 8 CHANNELS, WE'VE TRIED EVERYTHING BECAUSE WE WANT TO WORK WITH SENATOR ORTIZ. SHE'S OUR FRIEND. FRIENDS 9 10 WORK TOGETHER. AND THIS IS A POINT WHERE WE GOT TO SAY, OKAY, WE DISAGREE A LITTLE BIT. WE OPPOSE. 11 THAT'S THE WORD YOU USE. 12 13 IT DOESN'T MEAN WE'RE NOT -- HENCEFORTH WE'RE ENEMIES. IT JUST MEANS ON THIS PARTICULAR PIECE OF 14 15 LEGISLATION, WE'VE HEARD FROM DR. LEVEY, WE'VE HEARD 16 FROM DR. BIRGENEAU, WE KNOW WHAT THE ISSUES ARE. WHAT'S CONCERNING ME AT EVERY POINT IS THE CENTRAL 17 TENETS OF THIS SCA 13 REALLY HAVEN'T CHANGED. THERE'S 18 BEEN LITTLE AMENDMENTS HERE AND THERE TO MAKE IT A 19 20 LITTLE BIT BETTER, MAKE IT A LITTLE BIT MORE PALATABLE. 21 BUT WHEN IT COMES TO THE OPEN MEETINGS, THE INTELLECTUAL PROPERTY, AND THE CONFLICT OF INTEREST, 22 23 THE CONCERNS PERSIST AND REMAIN. WE'VE GOT TO MOVE FORWARD AND COMMUNICATE IN 24 25 A CLEAR MANNER TO THE LEGISLATURE WHERE THIS COMMITTEE

1 STANDS. IT SHOULD BE A UNANIMOUS VOTE.

2 DR. BALTIMORE: THERE'S SOMETHING I DON'T UNDERSTAND HERE. IF THIS WAS A PIECE OF LEGISLATION AT 3 4 THE NATIONAL LEVEL, AND THERE ARE LOTS OF -- WE SEE 5 LOTS OF LEGISLATION PROPOSED AT THE NATIONAL LEVEL 6 WHICH IS COUNTER TO THE INTERESTS OF THE SCIENTIFIC 7 COMMUNITY, OF SCIENTIFIC PROGRESS, OF THE UNIVERSITY 8 COMMUNITY. AND WE HAVE FRIENDS IN THE LEGISLATURE WHO 9 WILL CARRY THE WATER FOR AND OPPOSE THINGS WHICH JUST 10 DON'T MAKE SENSE. OFTEN THEY COME FROM PERFECTLY WELL MEANING PEOPLE WHO HAVE STRUCTURED A BILL WHOSE 11 12 IMPLICATIONS THEY DON'T REALLY FULLY UNDERSTAND, AND WE CAN BRING THE MUSCLE TO BEAR TO SEE THAT THAT 13 14 UNDERSTANDING COMES OUT. 15 WHY ARE WE FOCUSED ENTIRELY ON ORTIZ? WHERE 16 ARE OUR FRIENDS? IF WE HAVE NO FRIENDS, THEN THE SITUATION'S A LOT WORSE THAN JUST ONE PERSON WHO'S 17 CONCEIVED OF A MISCONCEIVED BILL. 18 CHAIRMAN KLEIN: DR. BALTIMORE, THERE ARE 19

20 INDIVIDUALS IN THE LEGISLATURE SUCH AS GENE MULLIN ON
21 THE ASSEMBLY SIDE WHO HAS, AS I SAID, VERY
22 CONSTRUCTIVELY MOVED FORWARD WITH ASSEMBLY CONCURRENT
23 RESOLUTION 252. AND NOW HAS ACR 24, WHICH IS FURTHER
24 MAKING IT CLEAR THAT THEY'RE LOOKING TO THE SCIENCE

25

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TECHNOLOGY COUNCIL FOR THE BIOMEDICAL AND INTELLECTUAL

1 PROPERTY POLICY THAT WE'RE WORKING WITH.

2 THERE'S ALSO NEGRETE MCLEOD, WHICH IS ANOTHER
3 ASSEMBLY CONCURRENT RESOLUTION NO. 1, WHICH WE'RE VERY
4 SUPPORTIVE OF.

5 SO THE -- BECAUSE DR. PAUL BERG HAD TIME 6 COMMITMENTS, WE HAVE STARTED ON THE ORTIZ LEGISLATION, 7 BUT THERE ARE A NUMBER OF OTHER LEGISLATORS THAT WE ARE 8 VERY SUPPORTIVE OF THE DIRECTION THAT THEY ARE 9 PROCEEDING IN.

10 THE ISSUE HAS ALSO BEEN THAT WHEN HEARINGS 11 ARE SCHEDULED ON DAYS THAT WE HAVE FULL PUBLIC HEARINGS 12 OURSELF AND WE CANNOT GET TO THE LEGISLATURE WITH OUR 13 WITNESSES AND THOSE DATES ARE CHANGED BY A MONTH AND 14 WE'RE GIVEN NOTICE LATE ON FRIDAY AFTERNOON, SO WE 15 CANNOT GET OUR MESSAGE OUT THERE AS TO WHY WE ARE 16 OPPOSED, IT MAKES IT EXTRAORDINARILY DIFFICULT.

17 WE HAVE ONE GOVERNMENT RELATIONS STAFF PERSON OUT OF OUR 15 STAFF MEMBERS, AND THAT INDIVIDUAL HAS 18 19 BEEN ALSO WORKING ON OTHER TASKS AS WE'VE GONE THROUGH 20 THE LAST 29 PUBLIC HEARINGS WITH OUR LIMITED STAFF. SO 21 BECAUSE WE HAVE SUCCESSFULLY AT THIS POINT AND AFTER 22 TODAY, HOPEFULLY, WILL HAVE COMPLETED THE PROCESS OF 23 SETTING UP OUR ADVISORY GROUPS, WITH GRANTS ADVISORY 24 GROUPS IN PLACE, STANDARDS IN PLACE, FACILITIES 25 ADVISORY GROUP IN PLACE, WE'VE SET UP ALL THE CONFLICT

OF INTEREST POSITIONS FOR THE VARIOUS ADVISORY GROUPS,
 WE WILL HAVE ADOPTED OUR MEDICAL AND ETHICAL STANDARDS
 IN PLACE.

4 WE HAVE PUT IN PLACE THE PREREQUISITES FOR MANY MEMBERS OF THE LEGISLATURE TO THEN SAY, LOOK, 5 THEY'RE NOT TALKING ABOUT DOING THIS. THEY HAVE DONE 6 7 IT. AND THEY HAVE SAID TO US, "COME TO US WHEN YOU 8 HAVE COMPLETED THIS TASK, AND WE WILL SUPPORT THIS 9 POSITION." SO WE HAVE BEEN WORKING AT AN EXTRAORDINARY 10 PACE TO ACCOMPLISH THE VERY TASKS THAT GIVE US THE CREDIBILITY BECAUSE WE ARE ON THE RECORD WITH THE 11 PIECES IN PLACE THAT MEET THE EXPECTATIONS OF THE 12 LEGISLATURE, AND GIVE THEM THE ASSURANCE THAT WE ARE, 13 IN FACT, CARRYING OUT THE MANDATE THAT THE PUBLIC GAVE 14 15 US. SO THE PREREQUISITES ARE THERE. AND BY END OF 16 TODAY TO, IN FACT, SAY, YES, YOU HAVE ACCOMPLISHED EVERYTHING WE ASKED AND EXPECTED. 17 IN FACT, IN SOME CASES EVEN THE NATIONAL 18

ACADEMIES HAVE REMARKABLY GIVEN THE NATIONAL ACADEMIES HAVE REMARKABLY GIVEN THE STATE OF CALIFORNIA THE CREDIT FOR SETTING THE HIGHEST STANDARD IN THE NATION FOR PROHIBITING COMPENSATION FOR EGG DONATION; BUT UNTIL WE GOT TO THE MEETING TODAY, WE HADN'T COMPLETED THAT PROCESS.

24 DR. PIZZO: FOLLOWING UP ON SOME OF THE25 COMMENTS THAT HAVE BEEN MADE BY JOAN AND JEFF AND

1 OTHERS, IT'S HARD TO IMAGINE THAT THIS GROUP COULD HAVE 2 BEEN WORKING MORE DILIGENTLY AND, I THINK, MORE EFFECTIVELY TO ACCOMPLISH THE VARIOUS TASKS THAT HAVE 3 4 BEEN BEFORE US. I CAN HARDLY LOOK BACK IN MY OWN PERSONAL EXPERIENCE TO THINK OF A TIME WHEN A GROUP OF 5 6 CITIZENS HAVE REALLY COME TOGETHER TO TRY AND DO 7 SOMETHING THAT THEY REALLY ARE DOING BECAUSE IT'S OF 8 VALUE TO THE CITIZENS, NOT ONLY OF THIS STATE, BUT THE 9 WORLD.

10 AND I WOULD ARGUE TWO THINGS. ONE IS THAT WE 11 TALK ABOUT PUBLIC TRUST, BUT IT REALLY NEEDS TO BE 12 BILATERAL. IT'S NOT ONLY THE FACT THAT WE'RE ASKING 13 AND SEEKING TO GAIN THE TRUST OF OUR COMMUNITY, BUT WE 14 ALSO SHOULD HOPE THAT OUR COMMUNITY, INCLUDING SENATOR 15 ORTIZ, HAVE TRUST IN US AS WELL. I THINK WE HAVE GIVEN 16 MUCH EVIDENCE FOR THAT.

17 I WOULD FURTHER ADD THAT WHILE WE LOOK AT OUR OWN WORK AND EFFORTS IN THIS REGARD, WE SHOULD 18 19 RECOGNIZE THAT THEY HAVE BEEN COMPLEMENTED BY THE KIND 20 OF INFORMATION THAT WE'VE RECEIVED FROM INDEPENDENT 21 SCIENTISTS AND PHYSICIANS ACROSS THIS COUNTRY. AS WE HAVE REACHED OUT AND TALKED TO INDIVIDUALS TO SERVE ON 22 23 THESE VARIOUS ADVISORY GROUPS, WE'VE HEARD A VERY 24 CONSISTENT BOTH SUPPORT FOR WHAT WE'RE DOING AND A 25 RECOGNITION THAT THE PROCESSES THAT HAVE BEEN PUT IN

1 PLACE ARE THE RIGHT ONES; AND, IN FACT, THAT IF THOSE 2 WERE ABANDONED, THAT THEY WOULD, IN FACT, NOT SERVE. SO IT SEEMS TO ME THAT WE NEED TO HAVE A 3 4 BROADER, PERHAPS, MORE OPEN DISCOURSE WITH THOSE 5 LEGISLATORS WHO MAY BE BEING PERSUADED THAT THE SENATOR 6 IS CORRECT. THEY VOTED PRETTY UNANIMOUSLY IN SUPPORT 7 OF TAKING THIS TO THE NEXT STEP. MAYBE OUR NEXT VISIT 8 AS A BOARD SHOULD BE TO SACRAMENTO TO MEET WITH THOSE 9 INDIVIDUALS AND MAKE OUR CASE BOTH STRONGLY AND OPENLY 10 BECAUSE I THINK WE CAN IN A VERY HONEST AND CLEAR WAY DO THAT. 11 CHAIRMAN KLEIN: I THINK THAT THAT'S 12 13 EXCELLENT. GAYLE WILSON. MS. WILSON: THE REASON THAT THEY'RE IN SUCH 14 15 A HURRY IN PUSHING THEIR MEETINGS AHEAD IS BECAUSE THEY 16 HAVE A JUNE 30TH DEADLINE IN ORDER TO HAVE THIS QUALIFY TO GO ON THE NOVEMBER BALLOT, IF THERE'S, IN FACT, A 17 SPECIAL ELECTION. EACH OF THE HOUSES, THE ASSEMBLY AND 18 THE SENATE, HAVE TO PASS THIS BY TWO-THIRDS. NOW, THAT 19 ISN'T EASY. HOWEVER, WE'RE CONCENTRATING ON SENATOR 20 21 ORTIZ. SHE'S GOTTEN IT OUT OF ONE COMMITTEE. SHE MAY GET IT OUT OF THE ANOTHER. WE EACH HAVE ASSEMBLY 22 23 PEOPLE AND STATE SENATORS WHO REPRESENT OUR DISTRICTS. WE SHOULD BE TALKING TO THEM BECAUSE THIS COULD EASILY 24

25 COME TO THEM FOR A VOTE. AND I DO THINK THAT THEY ARE

1 BEING PERSUADED BY PEOPLE WHO DON'T HAVE OUR BEST

2 INTERESTS AT HEART.

3 SO THERE ARE THINGS THAT WE CAN DO AND NOT 4 JUST WITH SENATOR ORTIZ, WHO'S OBVIOUSLY NOT GOING TO 5 MEET WITH US.

6 DR. PIZZO: CAN I JUST FOLLOW THAT? I THINK 7 THE INTERESTS THAT WE HAVE AT HEART ARE THE CITIZENS 8 AND PATIENTS OF CALIFORNIA AND THE NATION. AND I THINK 9 THAT'S THE MESSAGE THAT WE NEED TO GET ACROSS. I AGREE 10 WITH YOU THAT WE SHOULD BE ADVOCATING IN OUR LOCAL COMMUNITIES, BUT I DO THINK, MR. CHAIRMAN, THAT YOU 11 SHOULD LOOK AT THE PROSPECT OF WHETHER WE COULD AS A 12 13 BODY MAKE A VISIT TO SACRAMENTO AND MEET WITH THOSE WHO 14 ARE VOTING, I THINK, NOT IN THE INTERESTS OF THE 15 CITIZENRY BECAUSE THEY'RE NOT INFORMED ABOUT WHAT'S 16 HAPPENING, AND THAT WE SHOULD HAVE A DIALOGUE THAT 17 HELPS THEM TO BE BETTER ENGAGED IN MAKING AN INFORMED DECISION WITH US FOR THE CITIZENS OF CALIFORNIA. 18

19 CHAIRMAN KLEIN: I WOULD TAKE THAT SUGGESTION
20 AND HOPEFULLY COME BACK MAYBE AT THE JUNE 6TH MEETING
21 WITH A PROPOSAL TO TRY AND IMPLEMENT THAT SUGGESTION.
22 IT MAY BE THAT WE NEED TO DEFER OUR BUSINESS AGENDA FOR
23 JULY TO A LATER DATE TO PROVIDE US AN OPPORTUNITY -24 THE RELIEF FROM THE JULY MEETING SO WE HAVE THE
25 OPPORTUNITY INDIVIDUALLY TO MAKE VISITS TO SACRAMENTO

1 TO INDIVIDUALLY MEET WITH THE LEGISLATORS BECAUSE WE 2 SHOULDN'T BE SPEAKING WITH A SINGLE REPRESENTATIVE AND 3 A SINGLE VOICE. EVERY MEMBER ON THIS BOARD HAS 4 EXTRAORDINARY EXPERIENCE IN THE SEARCH FOR THERAPIES 5 AGAINST CHRONIC DISEASE. EVERY MEMBER ON THIS BOARD 6 HAS INDEPENDENT CREDIBILITY AND A VERY POWERFUL VOICE 7 THAT NEEDS TO BE INDIVIDUALLY EVALUATED.

8 JUNE 30TH IS THE QUALIFYING DEADLINE. AND 9 WHEN WE HAVE ASKED, IN TERMS OF THESE SCHEDULES THAT 10 HAVE BEEN MOVED FORWARD FOR 30 DAYS, THEY COULD HAVE 11 PURSUED THIS CONCURRENTLY IN THE ASSEMBLY AND THE 12 SENATE TO DEAL WITH THOSE DEADLINES AND STILL GIVING US 13 A WEEK OR TWO MORE TIME TO HAVE SUBSTANTIVE HEARINGS, 14 SO AT LEAST WE CAN BRING OUR WITNESSES TO BEAR.

BUT IN ANY CASE, WE WILL TRY AND BRING BACK A PROPOSAL FOR THE JUNE 6TH AGENDA TO ADDRESS THAT. JOAN SAMUELSON.

18 MS. SAMUELSON: CAN WE AFFORD TO WAIT UNTIL 19 JULY? I'M WONDERING IF WE SHOULDN'T JUST COMMIT OUR 20 JUNE MEETING -- I'M NOT REMEMBERING WHEN IT IS AT THE 21 MOMENT -- TO THIS TASK. GO TO SACRAMENTO AND SAY WE'RE 22 COMING, AND THAT WE WANT TO SIT DOWN WITH ANYONE IN THE 23 ASSEMBLY AND THE SENATE AND THE CONSTITUTIONAL 24 OFFICERS, FOR THAT MATTER, WHO WILL MEET WITH US. WE

25 WOULD LIKE TO TALK TO ALL OF THEM.

CHAIRMAN KLEIN: DR. WRIGHT, I BELIEVE, JUNE
 WAS SCHEDULED FOR SACRAMENTO -- IRVINE. WOULD IT BE
 POSSIBLE TO POTENTIALLY CONSIDER TRADING THAT DATE AND
 DOING A MEETING IN SACRAMENTO?

5 DR. BRYANT: OF COURSE, FOR THIS -- IT'S 6 IMPORTANT ENOUGH THAT WE NEED TO CONSIDER EVERY OPTION 7 THAT WE HAVE, AND I'M SURE THAT I WILL -- I'LL BE 8 APPROPRIATELY APOLOGETIC AT HOME AND MAKE SURE 9 EVERYTHING IS OKAY. DON'T WORRY.

10 CHAIRMAN KLEIN: VERY GOOD SUGGESTION. THANK
11 YOU.

DR. WRIGHT: I JUST AGREE WITH YOU, JOAN. I 12 THINK THAT'S A GREAT IDEA. AGAIN, REFLECTING OVER THE 13 14 COMMENTS OF THE GROUP, I HEAR THREE THEMES, AND THEY'RE 15 SORT OF CROSSCUTTING. THE FIRST I HEARD WAS TRUST, AND 16 TRUST WAS ESTABLISHED WITH SENATOR ORTIZ IN THE EARLY DAYS OF THIS PROPOSITION. AND WE WANT TO BUILD ON THAT 17 TRUST OR RENEW IT AND WE REAFFIRM THAT WE ARE ALL 18 WORKING FOR THE HEALTH OF NOT JUST THE CITIZENS OF 19 CALIFORNIA, BUT ACROSS THE WORLD. 20

SECONDLY, THE THEME I HEAR IS HOPE AND
OPTIMISM. AND I SPEAK NOT ONLY FOR DISEASES THAT HAVE
AFFECTED MY FAMILY; BUT IN MY JOB AS A CARDIOLOGIST,
EVERY DAY I MEET PEOPLE WHO WOULD BENEFIT FROM THIS
RESEARCH. AND MY CHARGE IS TO ADVOCATE FOR EVERYONE

WITH DISEASE, NOT JUST, OF COURSE, WITH HEART DISEASE.
 AND THIS WORK RENEWS MY OPTIMISM IN THE FUTURE OF
 HEALTHCARE, NOT JUST THE MEDICAL ASPECTS, BUT IN THE
 FUNDING AND THE BENEFITS THAT CAN RETURN AS A RESULT OF
 THIS RESEARCH. I AM ENERGIZED BY THE POTENTIAL THAT WE
 HAVE TO DO GOOD THINGS HERE, AND I DON'T WANT ANYTHING
 TO STEP IN THE WAY OF THAT.

8 AND THE THIRD THEME WAS MOST BEAUTIFULLY 9 ITERATED HERE BY JEFF, AND THAT IS RESPECT. AND IT'S 10 RESPECT FOR THE VOTES FROM THE STATE OF CALIFORNIA AND SUBSEQUENTLY THE RESPECT FOR THE WORK OF SENATOR ORTIZ 11 AND THE OTHER LEGISLATORS, BUT, THIRDLY, FOR THIS BOARD 12 13 AND FOR THE AMOUNT OF TIME THAT THESE EXPERTS AROUND 14 THE TABLE HAVE DEVOTED TO THE PROJECT. AND I THINK 15 SELF-RESPECT IS VERY IMPORTANT. AND AS A BOARD, I 16 THINK WE DO NEED TO GO TO SACRAMENTO AND HELP EDUCATE THOSE WHO HAVE NOT FULLY UNDERSTOOD THE IMPACT OF THIS 17 LEGISLATION AND MAKE OUR VOICES KNOWN. 18

19 CHAIRMAN KLEIN: THANK YOU.

20 MR. SHESTACK: PERHAPS I MISUNDERSTOOD, BUT I 21 THOUGHT THAT GAYLE WILSON WAS GIVING US A VERY SPECIFIC 22 MESSAGE, WHICH WAS THAT WE HAVE TO BE WORKING WITH OUR 23 REPRESENTATIVES IN DISTRICT, THAT IT'S A WASTE OF TIME 24 TO NOT -- IT'S NOT THE BEST USE OF OUR TIME TO TRY AND 25 CHANGE SENATOR ORTIZ' MIND, THAT IT IS A COMPLICATED

1 PROCESS THAT IS NOT SO EASY TO WIN FOR SENATOR ORTIZ. 2 I FEEL THAT YOU WERE GIVING US SOME VERY SPECIFIC POLITICAL ADVICE ON HOW TO HANDLE THIS SITUATION AND 3 4 HOW TO REACH OUT, HAVE -- FOR INSTANCE, LISTENING TO 5 YOU, I'M MOTIVATED TO ASK THE FAMILIES IN THE MENTAL 6 HEALTH COMMUNITY, FAMILIES AFFECTED BY AUTISM, 7 SCHIZOPHRENIA, OBSESSIVE COMPULSIVE DISORDER, ANYONE 8 WHO THINKS THIS IS POTENTIALLY IMPORTANT TO THEM NOT TO 9 GO TO SACRAMENTO, BUT TO GO TO THEIR DISTRICT AND TO 10 MEET THEIR REPRESENTATIVES, MEET THEIR SENATORS AND ASSEMBLYMEN AND TALK TO THEM ABOUT IT AND EXPLAIN IT. 11 I THOUGHT THAT YOU WERE GIVING US A SLIGHTLY 12 DIFFERENT MESSAGE THAN THE GROUP OF ALL OF -- WITH ALL 13 14 OUR IMMINENCE GOING TO SACRAMENTO. AM I INCORRECT? 15 MS. WILSON: NO, YOU'RE NOT INCORRECT. I 16 WILL TELL YOU THAT ALL POLITICS IS LOCAL. WE'D LIKE TO THINK THAT PEOPLE ARE LOOKING AT WHAT'S THE BEST FOR 17 THE STATE. BUT IF THEY SEE A LETTER OR A PHONE CALL 18 COMING FROM SOMEONE IN THEIR DISTRICT, NOT SOME OTHER 19 20 DISTRICT. I CAN GIVE YOU SOME EXPERIENCE WITH THAT 21 WHERE PEOPLE JUST PUSH INTO THE TRASH CAN ANY LETTER 22 FROM SOMEBODY OUTSIDE OF THEIR DISTRICT BECAUSE, HEY, 23 THEY'RE NOT GOING TO VOTE FOR THEM. I HOPE THERE'S A BIGGER VIEW THAN THAT, BUT IT STILL MEANS SOMETHING TO 24 25 HAVE PEOPLE FROM THEIR DISTRICT WEIGH IN ON THIS ISSUE.

1 CHAIRMAN KLEIN: THANK YOU VERY MUCH. THE 2 OTHER AREA THAT WE HAVEN'T TOUCHED ON DEEPLY HERE IS 3 THE INTELLECTUAL PROPERTY PROVISIONS THAT ARE IN THE 4 PROPOSED LANGUAGE SUGGEST THAT WE SHOULD SET ROYALTIES 5 AND PATENT REVENUE AT A LEVEL THAT WOULD RECOUP A 6 HUNDRED PERCENT OF THE COST OF THE RESEARCH FOR THE 7 STATE.

8 NOW, CERTAINLY DURING THE PROPOSITION 71 9 CAMPAIGN THAT WAS NEVER PUT FORWARD. IN FACT, THERE'S 10 A LEGAL RECORD OF WHAT WAS SUBMITTED TO THE LEGISLATIVE ANALYST, THAT WAS SUBMITTED TO EVERY CHAMBER OF 11 COMMERCE IN THE STATE, THAT WAS SUBMITTED, IN FACT, TO 12 13 EVERY CONSTITUTIONAL OFFICER THAT WAS USED IN THE 14 DEBATES. AND THOSE ARE ECONOMIC STUDIES DONE BY 15 DR. LAUREN BAKER OF STANFORD MEDICAL SCHOOL, A MEDICAL 16 ECONOMIST, AND THE ANALYSIS GROUP THAT DOES MEDICAL COST BENEFIT STUDIES THAT SUGGESTED THAT INTELLECTUAL 17 PROPERTY REVENUE WAS GOING TO BE A SMALL PART OF THE 18 PAYBACK TO THE STATE, THAT THE MAJOR BENEFIT TO THE 19 STATE WAS, IN FACT, POTENTIAL REDUCTION IN HUMAN 20 21 SUFFERING AND THE COST OF HEALTHCARE. AND MANY TIMES WE CITED THE FACT THAT THE 22

23 PROJECTIONS WERE THAT IF WE COULD GET A 2-PERCENT
24 ENHANCEMENT IN THE THERAPIES, EXISTING THERAPIES,
25 DEALING WITH FIVE OUT OF 70 OF THE CONDITIONS THAT WERE

INVOLVED, THAT THOSE REVENUES, COMBINED WITH THE NEW
 TAX REVENUES, WOULD PROVIDE A 236-PERCENT PAYBACK TO
 THE STATE. IT'S NOT REVENUE ACTUALLY. IT'S THE COST
 SAVINGS FROM HEALTHCARE IMPROVING BY 2 PERCENT; THAT
 IS, SOMEONE GETS OUT OF THE HOSPITAL 2 PERCENT EARLIER
 IN FIVE OUT OF 70 CONDITIONS.

7 THE HEALTHCARE COSTS FACING THIS STATE, \$14 8 BILLION INCREASING 8 TO 10 PERCENT A YEAR ARE SO 9 MASSIVE, THAT AT THE MARGIN, IF WE CAN JUST GET THE 10 KNOWLEDGE TO PROCEED TO THE POINT WHERE WE CAN GET INCREMENTAL IMPROVEMENTS IN THE THERAPIES, THOSE COST 11 SAVINGS WOULD BE BY FAR THE GREATEST CONTRIBUTION TO 12 13 THE STATE. WE CAN BE OPTIMISTIC AND HAVE HIGHER GOALS, 14 BUT ON A VERY CONSERVATIVE BASIS, THE ECONOMIC PAYBACKS 15 ARE DRIVEN BY COST SAVINGS TO THE STATE.

16 BUT I DON'T KNOW OF ANY PRECEDENT IN THE 17 NATION FOR ASSUMING YOU CAN SET ROYALTIES AT A LEVEL 18 THEY WOULD HAVE A HUNDRED PERCENT PAYBACK OF THE 19 SCIENTIFIC COSTS.

20 IN ADDITION, THE WAY THE LANGUAGE IS
21 STRUCTURED, WE BELIEVE OR I BELIEVE THAT IT CREATES A
22 PROBLEM FOR OUR BONDS AND, IN FACT, THAT THE BONDS
23 WOULD BECOME TAXABLE. WE ARE WAITING FOR BOND
24 COUNSEL'S OPINION ON THIS, BUT THE LANGUAGE RAISES SOME
25 VERY, VERY DIFFICULT PROBLEMS THAT WOULD INCREASE THE

1 COST TO THE STATE.

2 AS TO THE ISSUE RELATED TO THAT OF MAKING SURE THAT THESE THERAPIES ARE AVAILABLE TO EVERYONE IN 3 4 THE STATE, IT IS VERY IMPORTANT THAT THE PUBLIC 5 UNDERSTAND THAT THROUGH CLINICAL TRIALS, THE MEDICAL 6 STANDARDS ARE -- REQUIRE THAT CLINICAL TRIALS BE BLIND 7 AND THAT PEOPLE OF EVERY MEANS BE GIVEN ACCESS TO 8 CLINICAL TRIALS, AND THOSE CLINICAL TRIALS ARE PAID FOR 9 SO PEOPLE WOULD NOT BE SUBJECT TO BEING EXCLUDED FROM 10 CLINICAL TRIALS BECAUSE THEY DON'T HAVE THE ECONOMIC CAPACITY. 11

12 BUT DOWNSTREAM WHEN THERAPIES ARE AVAILABLE, 13 IT IS CERTAINLY IMPORTANT THAT COMPASSIONATE CARE BE 14 AVAILABLE. THE STATE HAS THE ABILITY, IN FACT, THE 15 LEGISLATURE HAS THE ABILITY TO SET ASIDE PART OF THE 16 INTELLECTUAL PROPERTY REVENUES FOR COMPASSIONATE CARE. THAT IS WITHIN THEIR DOMAIN AND THEIR CONTROL. AND BY 17 USING COMPASSIONATE CARE FROM THAT SIDE AND THAT 18 APPROACH, WE KNOW THAT THERE IS PRECEDENT FOR IT 19 20 WORKING AS A PART AND CONNECTED TO THE INTELLECTUAL 21 PROPERTY STANDARDS, THAT SHE WANTS TO DO A TIE-IN WHERE 22 YOU HAVE PRICE FIXING IN MEDICAL RESEARCH, WHICH HAS 23 BEEN A REAL PROBLEM.

AMONG OTHER ISSUES HERE, SHE'S APPROACHINGALL THE DISEASES AS IF THEY'RE THE SAME. AND THERE ARE

1 MANY DISEASES WITH SMALL POPULATIONS LIKE ALS OR MS OR 2 CYSTIC FIBROSIS WHERE IT'S DIFFICULT TO JUST GET PRIVATE COMPANIES TO ENTER THE FIELD AND MAKE IT 3 4 ECONOMICALLY FEASIBLE TO DEVELOP THERAPIES. AND TO TRY AND LATER, PRICE FIXING ON THAT TOP OF THAT WOULD 5 6 POTENTIALLY ELIMINATE THE ABILITY TO REALLY DEVELOP 7 THOSE THERAPIES AT ALL. THAT WOULD BE A DISSERVICE TO 8 THE PATIENTS. THAT WOULD BE A DISSERVICE TO THE 9 MISSION OF THE STATE.

10 SO WHILE THERE'S A VERY GOOD CONCEPT HERE 11 THAT WE NEED TO HAVE ADDRESSED, THE AFFORDABILITY FOR 12 PATIENTS OF LOWER INCOME, AND THAT CAN HAPPEN THROUGH 13 INTELLECTUAL PROPERTY REVENUE, PROVIDING COMPASSIONATE 14 CARE, THE OTHER APPROACH TO THIS SAME GOAL MAY, IN 15 FACT, DISABLE THE WHOLE ABILITY TO DEVELOP THERAPIES AT 16 ALL.

17 I THINK SOME OF THE MEMBERS OF THIS COMMITTEE 18 HAVE BEEN, IN FACT, EXPOSED TO THAT BACKGROUND IN TERMS 19 OF WHAT HAPPENS IF YOU TRY AND TAKE THE APPROACH THAT'S 20 OUTLINED IN THIS BILL WITH PRICE FIXING. DOES ANYONE 21 WANT TO COMMENT ON THAT ISSUE?

DR. BRYANT: I WOULD JUST COMMENT FROM
WORKING WITH THE CCST TO DEVELOP AN IP POLICY THAT IS
SUITABLE FOR STATE GRANTS, BUT ALSO PARTICULARLY
SUITABLE FOR CIRM, THERE ARE A LOT OF ISSUES THAT HAVE

BEEN DISCUSSED, MANY OF WHICH YOU MENTIONED. YOU KNOW,
 THE LAW THAT GOVERNS FEDERAL FUNDING FOR RESEARCH IS
 THE BAYH-DOLE ACT. AND THE BAYH-DOLE ACT HAS BEEN
 DEEMED EXTREMELY SUCCESSFUL IN BOTH PROMOTING, ALLOWING
 THE RESEARCH TO GO FORWARD, AND ALSO ENCOURAGING THE
 PRODUCTS OF THAT RESEARCH TO BE PICKED UP BY INDUSTRY
 AND DEVELOPED FURTHER.

8 AND IN THE BIOMEDICAL AREA, THERE IS A HUGE 9 GAP AFTER AN INVENTION IS DEVELOPED IN THE UNIVERSITY 10 BEFORE THAT PRODUCT IS READY TO BE APPLIED TO PEOPLE. AND THAT GAP CAN COST HUNDREDS OF MILLIONS OF DOLLARS. 11 SO THERE IS A VERY FINE BALANCING ACT THAT GOES ON HERE 12 13 THAT BAYH-DOLE HAS MANAGED TO CRAFT THAT ALLOWS 14 UNIVERSITIES TO DO THEIR RESEARCH AND INCENTIVIZES THEM 15 TO GET THAT RESEARCH -- THOSE RESEARCH PRODUCTS OUT 16 INTO THE COMMUNITY AND ALSO INCENTIVIZES THE START-UPS OR OTHER COMPANIES TO COME IN AND GET EXCLUSIVE 17 LICENSES TO THAT WORK SO THAT THEY CAN THEN MAKE THE 18 INVESTMENT. 19

20 AND THERE HAS BEEN ONE EXPERIMENT AT NIH 21 WHERE THEY TRIED FOR A PERIOD OF YEARS TO ENFORCE 22 REASONABLE PRICING ON PRODUCTS THAT WERE COMING OUT OF 23 THE INTERNAL NIH PROGRAM. WHAT IT DID WAS IT REDUCED 24 TO ALMOST ZERO THE NUMBER OF COMPANIES THAT WOULD COME 25 IN AND PICK UP ANY OF THE INVENTIONS BECAUSE THEY WERE

NOT WILLING TO PUT UP THIS HUGE INVESTMENT WITHOUT
 KNOWING AHEAD OF TIME WHAT THEIR OBLIGATIONS WOULD BE
 AND WHETHER THEY WOULD EVEN BE ABLE TO COVER THEIR
 COST.

5 SO I WOULD JUST SAY THAT IT'S AN EXTREMELY
6 COMPLICATED AREA WITH LOTS OF THINGS THAT COULD
7 UNBALANCE THE SITUATION.

8 ANOTHER ISSUE, OF COURSE, IS THE FACT THAT 9 DOWN THE LINE WE'RE HOPING THAT STATE AND FEDERAL FUNDS 10 WOULD BE POSSIBLE TO BE MIXED. I ASSUME WE'RE NOT STUCK WITH THE CURRENT SITUATION FOR VERY LONG. AND IF 11 WE DO HAVE THAT KIND OF SITUATION IN THE FUTURE, IN 12 ORDER TO HANDLE THE FUNDS AT AN INSTITUTIONAL LEVEL, IT 13 WILL BE VERY IMPORTANT THAT OUR POLICIES ARE CONSISTENT 14 WITH THE FEDERAL POLICIES. OTHERWISE IT WILL CREATE A 15 16 NIGHTMARE THAT MAYBE SOME INSTITUTIONS WON'T WANT TO EVEN PARTICIPATE UNDER THOSE CONDITIONS. THERE ARE 17 SEVERAL IMPORTANT ISSUES HERE. 18

19 CHAIRMAN KLEIN: I THINK DR. LOVE AND THEN20 DR. NOVA.

21 DR. LOVE: I JUST WANTED TO MAKE A COUPLE 22 COMMENTS ABOUT HOW I'M KIND OF FEELING LISTENING TO ALL 23 OF THIS. AND QUITE FRANKLY, I HAVE TO ADMIT I'M 24 FEELING VERY ANGRY AND VERY DISAPPOINTED. AND I THINK 25 THAT AS A GROUP, WE SHOULD FEEL COMFORTABLE EXPRESSING

1 THAT, NOT WITH THE INTENT OF BEING ADVERSARIAL, BUT 2 WITH THE INTENT OF BEING VERY CLEAR THAT THIS IS A VERY SERIOUS INITIATIVE THAT WE'VE ALL ENGAGED IN. AND I 3 4 THINK PEOPLE UP HERE HAVE TAKEN IT VERY SERIOUSLY, AND I THINK WE'RE VERY FOCUSED ON TRYING TO DO SOMETHING 5 6 THAT WILL HELP PATIENTS IN CALIFORNIA AND HELP PATIENTS 7 THROUGHOUT THE WORLD. AND LET'S FACE IT. THIS EFFORT 8 IS REALLY A PROBLEM FOR US, AND I THINK WE NEED TO BE 9 VERY CLEAR ABOUT BEING AGAINST IT, NOT AGAIN TO BE 10 ADVERSARIAL.

JUST TO PUT SOME OF THIS INTO CONTEXT AND 11 RESPOND TO BOB'S SPECIFIC OUESTION ABOUT INTELLECTUAL 12 13 PROPERTY AND ROLES ASSOCIATED WITH THAT, JUST LAST WEEK I MET WITH A GROUP OF VENTURE CAPITALISTS IN THE BAY 14 15 AREA. AND QUITE FRANKLY, ONE OF THEIR CONCERNS RIGHT 16 NOW IS HOW LONG IT WOULD TAKE TO GET A RETURN BY INVESTING IN COMPANIES ENGAGED IN STEM CELL RESEARCH. 17 AND FOR US TO TACK A BURDEN ONTO THAT EFFORT, I THINK, 18 WILL GREATLY DISSUADE AN EFFORT AND WILL CRIPPLE THE 19 20 WHOLE PROCESS OF WHAT WE'RE TRYING TO GENERATE HERE IN 21 TERMS OF MAKING THERAPIES AVAILABLE FOR PATIENTS. 22 JUST TO PUT SOMETHING INTO CONTEXT FOR 23 PEOPLE, \$3 BILLION IS A LOT OF MONEY, BUT \$3 BILLION IS 24 NOWHERE NEAR THE KIND OF MONEY THAT'S GOING TO BE 25 REQUIRED TO MAKE THERAPIES ACTUALLY AVAILABLE. I SPEND

1 MY CAREER IN A COMPANY. AND JUST TO GIVE PEOPLE SOME 2 IDEA, IT PROBABLY TAKES SOMEWHERE BETWEEN 750 MILLION TO A BILLION DOLLARS TO MAKE ONE SUCCESSFUL COMPANY IN 3 4 BIOTECHNOLOGY, ONE COMPANY. WE EXPECT THIS AREA, I WOULD EXPECT THIS TO BE AN AREA WHERE THERE WILL 5 6 LITERALLY BE HUNDREDS OF COMPANIES GENERATED. SO WE'RE 7 TALKING ULTIMATELY ABOUT HUNDREDS OF BILLIONS OF 8 DOLLARS INVESTED TO MAKE THIS GO FORWARD.

9 SO, AGAIN, I WOULD JUST END ON THE POINT OF 10 SAYING I THINK THIS GROUP SHOULD TAKE A VERY FIRM POSITION OF BEING AGAINST THE LEGISLATION. WE 11 SHOULDN'T BE ASHAMED OF THAT. I THINK WE SHOULD 12 13 CONTINUE TO EXPRESS OUR WILLINGNESS TO BE OPEN AND TO 14 WORK WITH SENATOR ORTIZ; BUT, AGAIN, I WOULD BE 15 DISCOURAGED BASED ON WHAT WE'VE SEEN SO FAR IN TERMS OF 16 HER WILLINGNESS TO WORK WITH THIS GROUP.

17 DR. NOVA: THAT WAS VERY WELL SUMMARIZED BY DR. LOVE EXACTLY WHAT I WAS GOING TO SAY. COMING FROM 18 19 INDUSTRY, WE HAVE A DIFFERENT PERCEPTION ABOUT 20 INTELLECTUAL PROPERTY. AND I COMPLETELY AGREE THAT IF 21 WE DO NOT FOLLOW THESE GUIDELINES LIKE YOU HAVE JUST 22 SAID, THAT WE WILL KILL THE INDUSTRY BECAUSE WITHOUT 23 THE VENTURE CAPITALIST SUPPORT IN THE END, JUST LIKE 24 DR. BRIAN AS ALLUDED TO, THIS WILL GO TO THE NEXT STEP 25 AND WILL NOT BECOME A REALITY. WE HAVE TO LOOK TO IT

DOWN THE LINE, AND I THINK WE SHOULD BE VERY AGGRESSIVE
 AND VERY STRONG ON THIS ISSUE. AND I SUPPORT IT
 COMPLETELY. THANK YOU.

4 CHAIRMAN KLEIN: DR. LEVEY.

5 DR. LEVEY: I WOULD JUST LIKE A COUPLE OF 6 SUGGESTIONS. ONE, WHEN WE DO WRITE OUR LETTER, IT'D 7 PROBABLY BE NICE -- BOB, YOU HAVE YOUR NETWORK OF 8 SUPPORTERS. I KNOW SOME OF THEM WERE IN LOS ANGELES. 9 BE NICE TO COPY THEM ON THESE LETTERS AND ASK THEM TO 10 WRITE LETTERS AS WELL AS IF THEY WERE IN AGREEMENT WITH 11 OUR POSITION.

12 AND THE SECOND THING IS I THINK WE NEED SOME 13 ADVICE FROM GOVERNMENT RELATIONS EXPERTS BECAUSE I KNOW 14 WHEN THE UC GOES TO SACRAMENTO, THESE ARE REALLY 15 WELL-PLANNED OUT VISITS BECAUSE IT'S NOT EASY TO SET 16 VISITS UP. SO BEFORE WE PLAN SUCH A VISIT, IT MAY NOT 17 BE SUCCESSFUL BECAUSE WE'RE TALKING TWO WEEKS FROM NOW AND IT MAY NOT BE APPROPRIATE TIME TO ACTUALLY MAKE 18 THOSE KINDS OF VISITS. I THINK WE NEED SOME ADVICE, 19 20 AND I'M SURE PEOPLE LIKE STEVE ARDIDDE (PHONETIC) IN 21 THE UC SYSTEM WOULD BE MORE THAN HAPPY TO GIVE YOU 22 ADVICE.

CHAIRMAN KLEIN: I THANK YOU. I'D LIKE TO
POINT OUT WE ARE WORKING IN CONJUNCTION WITH THE
VARIOUS RESEARCH INSTITUTIONS, THE UNIVERSITIES, THEIR

1 GOVERNMENT RELATIONS PEOPLE, PATIENT GROUPS, THEIR 2 GOVERNMENT RELATIONS REPRESENTATIVES. AND I AM PERSONALLY GOING TO SACRAMENTO BEFORE OUR MEETING ON 3 4 THURSDAY TO SPECIFICALLY MEET WITH SENATOR ORTIZ. AND 5 I HAVE AN APPOINTMENT SET UP TO TRY AND MAKE IT CLEAR 6 WE'RE OPPOSED BASED ON THE CURRENT LANGUAGE, BUT WE'D 7 LIKE TO FIND A WAY TO GET LANGUAGE THAT ACTUALLY DOES 8 WORK.

9 DR. HOLMES: MR. CHAIR, I'D LIKE TO SAY 10 PERSONALLY I'M VERY SUPPORTIVE OF THE DISCUSSION WE'VE HAD TODAY. I'M PARTICULARLY ENTHUSIASTIC ABOUT 11 APPROACHING THE WIDE RANGE OF INDIVIDUALS ON THIS. AND 12 13 REALLY I HAVE A QUESTION, AND MAYBE LEGAL COUNSEL COULD 14 HELP ME WITH THIS, THAT THERE ARE FIVE OF US ON THIS 15 BOARD WHO ARE APPOINTEES VIA OUR ROLES IN THE 16 UNIVERSITY OF CALIFORNIA. AND I BELIEVE THERE ARE SPECIFIC PROHIBITIONS ABOUT PEOPLE WHO ARE EMPLOYEES OF 17 THE UNIVERSITY DIRECTLY LOBBYING FOR SPECIFIC 18 LEGISLATION. AND WHAT I WOULD NOT LIKE TO HAVE HAPPEN 19 IS THAT SOMEHOW MY VOICE GOT MUTED. I'M ENTHUSIASTIC 20 21 ABOUT THIS, BUT WERE IT TO BE SOMEHOW LEGISLATED WE 22 COULDN'T HAVE A VOICE, I WOULDN'T WANT IT TO BE A 23 NEGATIVE VOTE ON OUR PART, BUT ONE THAT, AT LEAST PERSONALLY, I WAS ON RECORD AS SAYING I SUPPORTED THIS. 24 25 AND I DON'T KNOW, JAMES, IF YOU COULD HELP US

1 OR NOT, BUT I THINK THERE ARE SOME PROHIBITIONS ABOUT 2 SPECIFIC LEGISLATION AND WHAT WE CAN SAY. MR. HARRISON: I DON'T KNOW THE ANSWER TO 3 4 THAT QUESTION, BUT I WILL RESEARCH IT AND GET BACK TO 5 YOU. 6 DR. BRYANT: SO I'VE ALREADY WRITTEN TO MY 7 LOCAL REPRESENTATIVES, SO I'M ALREADY IN TROUBLE. 8 MR. HARRISON: I'LL CALL YOU FIRST. 9 CHAIRMAN KLEIN: WE WILL IMMEDIATELY EMBARK 10 ON THIS. WE'RE USING THE RESOURCES OF A SIGNIFICANT GROUP OF PEOPLE. UNTIL, FRANKLY, THIS LAST WEEK, WE'VE 11 BEEN TIED DOWN BY INCREDIBLE TIME PRESSURES DEALING 12 WITH THE SITE SEARCH AND ALL OF THESE COMMITTEE 13 FORMATIONS AND OTHER PROCESSES. EVERY ONE OF THOSE 28 14 15 OR 29 HEARINGS TOOK A HUGE AMOUNT OF TIME. AND GIVEN 16 THE EXTRAORDINARILY LIMITED STAFF, IT HAS BEEN A REAL 17 CHALLENGE. I'D LIKE TO ASK BEFORE -- WE'RE GOING TO 18 BREAK FOR LUNCH AND EXECUTIVE SESSION, BUT I'D LIKE TO 19 20 ASK IS THERE COMMENT FROM THE PUBLIC ON THE ORTIZ 21 LEGISLATION? MR. REED: I THINK AS SOMEBODY WHO HAS PUSHED 22 23 A LAW THROUGH THE DIFFERENT STEPS, I THINK A COUPLE 24 THINGS ARE IMPORTANT. NO. 1, THE COMMITTEE HEARINGS

25 ARE IRREVOCABLE STEPS. THOSE CANNOT BE UNDONE. THE

FACT THAT WE WERE UNABLE TO MAKE AN EFFECTIVE PRESENCE
 AT THE LAST ONE IS HUGELY SIGNIFICANT, AND WE MUST FIND
 WAYS TO SPEAK AND BE HEARD AT THE FUTURE ONES.

4 SECONDLY, THIS IS BEING PROPOSED AS A TINKERING IN SOMETHING THAT'S WONDERFUL, MINOR 5 6 TINKERING TO MAKE SURE IT RUNS RIGHT. IT'S IMPORTANT 7 THAT WE RECOGNIZE AS HOW SHE IS THOUGHT OF. SHE IS 8 THOUGHT OF AS PERSON WHO KNOWS THE WHOLE SHOOTING 9 MATCH. IF SHE THINKS IT'S THAT WAY, THE ONLY THING 10 THAT WILL MAKE HER -- WILL STOP HER IS A STRONG OPPOSITION. WE CAN BE AS POLITE AS WE WANT; BUT IF 11 12 WE'RE NOT CLEAR AND BLUNT AND OUTSPOKEN, SHE'LL WIN BECAUSE THE PEOPLE IN THERE, FIRST OF ALL, THEY LIKE 13 14 POWER. THEY LIKE OVERSIGHT. THEY WANT THE CONTROL. 15 IT'S IN THEIR NATURE TO CONTROL. AND IF SHE, THE 16 EXPERT, WHOM THEY KNOW WAS SUPPORTIVE, IF SHE SAYS CONTROL IS NEEDED, THEIR FIRST INSTINCT IS GOING TO BE 17 TO GO WITH HER. 18

SECONDLY, THIS IS RADICAL. THIS GOES
 COMPLETELY AGAINST THE PRESENT SETUP FOR PEER REVIEW.
 HIV/AIDS, BREAST CANCER, TOBACCO-RELATED ILLNESSES,
 THESE ALL HAVE PRIVATE PEER REVIEW BOARDS. THIS IS
 RADICALLY DIFFERENT.

24 SECONDLY -- THIRDLY, THE ATTEMPT TO MAKE THIS
 25 AFFORDABLE HAS BEEN TRIED BEFORE. THE NIH TRIED IT,

1 AND THERE'S A GOOD STUDY WHICH SHOWS THAT IT WAS AN 2 UTTER DISASTER. WHAT PEOPLE FINALLY CAME TO REALIZE IS BEFORE WE CAN HAVE AFFORDABLE COMPUTERS, WE MUST HAVE 3 4 COMPUTERS. THE GREATER GOOD IS THE BENEFIT OF THIS, NOT THE SMALL INDIVIDUAL TINKERING, WHICH WILL SLOW THE 5 6 WHOLE THING DOWN, LIKE A MONKEY WRENCH THROWN INTO A 7 FINE-TUNED MACHINE STOP US, SO WE HAVE TO FIGHT. WE 8 CANNOT SIT BACK AND WATCH, WAIT FOR OTHERS. WE ARE 9 ALSO INDIVIDUALS. YOU ARE OUR LEADERS. AND THERE MAY 10 BE SOME SMALL TECHNICAL CONSTRAINTS, BUT STRETCH THEM TO THE LIMIT. YOU'RE ALSO INDIVIDUAL CITIZENS, AND YOU 11 ARE THE EXPERTS. AND IF YOU DON'T SPEAK UP FOR US, 12 13 WE'RE NOT GOING TO BE SPOKEN UP FOR WELL. THANK YOU. 14 CHAIRMAN KLEIN: I WOULD LIKE TO SAY THAT 15 PERSONALLY IT'S MY HOPE THAT WITH THE VOICES OF MEMBERS 16 OF THIS BOARD AND THE INSTITUTIONS AND SCIENTISTS THAT THEY REPRESENT AND THE PATIENT GROUPS THEY REPRESENT 17 COMMUNICATED TO SENATOR ORTIZ, IT'S STILL MY HOPE, 18 GIVEN THAT SHE'S FOR THE SAME GOALS THAT, IN FACT, THE 19 LANGUAGE WILL BE CHANGED AND WE WILL BE ABLE TO WORK 20 21 TOGETHER, BUT I DO BELIEVE IT'S EXTREMELY IMPORTANT TO 22 COMMUNICATE THAT THE CURRENT LANGUAGE IS A DISASTER. 23 IT JUST -- IT'S THE WAY THE PROCESS IS DONE. 24 ANY ADDITIONAL PUBLIC COMMENT? I DON'T WANT

25 TO CALL FOR A VOTE ON THE RESOLUTION WHICH ADDRESSES

1 SEVERAL DIFFERENT PIECES OF LEGISLATION. I'D JUST LIKE 2 A VOTE ON AN OPPOSITION POSITION ON SCA 13 BEFORE WE ADJOURN FOR LUNCH. 3 4 MR. SERRANO-SEWELL: SO MOVED. CHAIRMAN KLEIN: IT'S BEEN MOVED. 5 6 DR. LEVEY: SECOND. 7 CHAIRMAN KLEIN: SECONDED. THIS IS JUST A 8 VOTE ON AN OPPOSITION POSITION TO SENATE CONSTITUTIONAL

9 AMENDMENT 13. IT WAS MOVED BY DAVID SERRANO-SEWELL AND10 SECONDED BY DR. LEVEY.

11 DR. KESSLER: CAN I JUST ASK WHAT AN

12 OPPOSITION POSITION MEANS?

25

13 CHAIRMAN KLEIN: IT MEANS THAT WE ARE OPPOSED
14 TO THE CURRENT LANGUAGE OF THIS BILL. IT MEANS THAT WE
15 ARE OPPOSED TO IT PASSING WITH THE CURRENT LANGUAGE.

16 DR. KESSLER: OUR JOB, CORRECT ME IF I'M
17 WRONG, AND MAYBE COUNSEL CAN HELP, IT GOES TO THE POINT
18 OF WHAT, AS STATE OFFICIALS, WE SHOULD BE DOING.

MY SENSE IS IT IS ALWAYS SAFE HARBOR IF WE
ARE EDUCATING. I THINK WHERE THE LINE IS IS WE CANNOT
LOBBY. I THINK THAT IS THE -- I LEAVE IT TO YOU TO GET
BACK WHETHER -- TAKING POSITIONS ON CERTAIN BILLS, IS
THAT LOBBYING OR IS THAT EDUCATION AND WHAT DOES THE
LAW SAY?

MR. HARRISON: YOU AS A BOARD CAN TAKE A

POSITION ON THIS LEGISLATION. THERE'S NO QUESTION
 ABOUT THAT. SO YOU CAN ADOPT A POSITION EITHER TO
 SUPPORT OR OPPOSE A PIECE OF LEGISLATION.

4 STATE AGENCIES ALSO ENGAGE IN LOBBYING 5 EFFORTS TO MAKE SURE THE INTERESTS ARE SERVED AT THE 6 LEGISLATURE. WHETHER PARTICULAR MEMBERS OF THIS BOARD 7 CAN ENGAGE IN LOBBYING, IF YOU ARE A UC OFFICIAL, IS 8 SOMETHING I NEED TO LOOK INTO. THE BOARD CAN TAKE A 9 POSITION ON LEGISLATION.

10 CHAIRMAN KLEIN: IT'S A VERY CLEAR POSITION, AS YOU SAY. STATE -- EVERY STATE DEPARTMENT, 11 DEPARTMENT OF HEALTH, DEPARTMENT OF HOUSING, HAS 12 13 POSITIONS OPPOSED TO A BILL IN FAVOR OF OTHER BILLS, CONCERN ON OTHER BILLS. THIS IS THE STANDARD PRACTICE. 14 DR. BALTIMORE: I WONDER WHETHER -- LET ME 15 16 START OFF FROM WHERE I COME FROM HERE. I THINK THAT 17 THIS LEGISLATION WILL MAKE IT IMPOSSIBLE FOR CALIFORNIA SCIENTISTS TO PLAY A CONSTRUCTIVE ROLE IN THE 18 DEVELOPMENT OF EITHER THE KNOWLEDGE OR THE THERAPIES 19 20 THAT CAN COME FROM STEM CELLS. 21 GIVEN THAT PERSPECTIVE, I THINK WHAT WE SHOULD SAY IS THAT IT IS OUR CONSIDERED OPINION THIS 22 23 LEGISLATION WILL MAKE IT IMPOSSIBLE FOR THE SCIENTISTS 24 OF THE STATE OF CALIFORNIA TO PLAY A CONSTRUCTIVE ROLE

25 IN THIS RESEARCH.

CHAIRMAN KLEIN: WITH ITS CURRENT LANGUAGE.
 DR. BALTIMORE: WITH ITS CURRENTS LANGUAGE.
 NOT JUST SAY WE'RE IN OPPOSITION.

4 CHAIRMAN KLEIN: DO YOU ACCEPT THAT --MR. SERRANO-SEWELL: I AGREE. WE CAN GO ON 5 6 AND SAY NOT IN ADDITION TO THE SCIENTISTS, AS YOU SAID, 7 DR. BALTIMORE. IT WILL MAKE IT ABSOLUTELY IMPOSSIBLE 8 FOR THEM TO CONDUCT AND DO THEIR JOB AS THEY'RE TRAINED 9 TO DO. WE COULD ALSO SAY, COMMA, AND DELAY CURES AND 10 THERAPIES AND, COMMA, I MEAN WE CAN JUST GO ON AND ON. CHAIRMAN KLEIN: LET'S KEEP --11 MR. SERRANO-SEWELL: AS WITH -- I'M SORRY, 12 CHAIRMAN KLEIN. I ACCEPT HIS FRIENDLY AMENDMENT. 13 14 CHAIRMAN KLEIN: AND, DR. BALTIMORE, DO YOU 15 ACCEPT THE -- SUGGESTION IS THAT WE -- FROM THE MAKER 16 OF THE MOTION THAT WE ALSO SAY AND DELAY CRITICALLY 17 NEEDED MEDICAL THERAPIES. DR. BALTIMORE: YES. 18 DR. POMEROY: ONCE AGAIN, I HAVE SOME 19 CONCERNS ABOUT VOTING ON A MOTION THAT SEEMS SORT OF 20

21 NEBULOUS AND NOT WRITTEN OUT. I'M WONDERING IF OVER 22 LUNCH WE COULD WRITE WHAT WE'RE VOTING ON SO THAT WE 23 KNOW. BECAUSE I DO THINK WE NEED TO BE VERY CAREFUL 24 ABOUT MAKING A SIMPLISTIC MOTION THAT DOESN'T EMPHASIZE 25 THAT WE BELIEVE IN CONFLICT OF INTEREST RULES, WE

BELIEVE IN WORKING TOGETHER. AND OBVIOUSLY, YOU KNOW,
 THIS LANGUAGE IS PROBLEMATIC, BUT I'M NOT SURE THAT THE
 MOTION RIGHT NOW CAPTURES THE FULL SPECTRUM OF THE
 DISCUSSION THAT WE'VE HAD THIS MORNING.

5 DR. PIZZO: CAN WE HEAR THE MOTION? 6 CHAIRMAN KLEIN: THERE WILL BE A LATER 7 DISCUSSION OF A RESOLUTION THAT GOES INTO GREATER 8 DETAIL. WE'RE JUST TRYING TO ADDRESS SCA 13, BUT THE 9 STAFF CAN WORK WITH YOU IN ADDRESSING THESE ISSUES; 10 BUT, FOR EXAMPLE, THE CONFLICT OF INTEREST PROVISIONS IS A COMPLICATED COMMUNICATION BECAUSE THE DESIRE --11 THE FIRST DESIRE OF THE AUTHOR WAS TO APPLY THE 12 NATIONAL INSTITUTES OF HEALTH EMPLOYEE CONFLICT 13 14 STANDARDS TO PEER REVIEW.

15 THE NEW POSITION THAT HAS BEEN TAKEN BY THE 16 AUTHOR IS TO APPLY THE EMPLOYEE STANDARDS FOR THE 17 CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE TO THE 18 PEER REVIEW.

19DR. POMEROY: I'VE READ THIS VERY CAREFULLY.20I'M NOT ARGUING ABOUT THE DETAILS OF THE WORDING. WHAT21I'M SAYING IS A SIMPLISTIC MOTION CAN GET PERCEIVED AS22US SAYING WE DON'T SUPPORT THE BASIC CONCEPTS. AND I23WOULD JUST LIKE TO KNOW THE MOTION THAT WE'RE VOTING24ON.

25 CHAIRMAN KLEIN: IT'S MY -- IF I COULD FOR A

MINUTE, DR. KESSLER. WHY DON'T WE TRY DURING LUNCH TO
 WRITE SOMETHING OUT AND BRING IT BACK.

DR. KESSLER: CAN I ALSO UNDERSTAND, JUST AS 3 4 A MATTER OF PROCEDURE, WHEN A STATE AGENCY SENDS TO THE LEGISLATURE, AS YOU SAID, ITS VIEWS ON LEGISLATION AND 5 6 IT CAN OPPOSE, I ASSUME IT'S NOT A SENTENCE OR TWO. I 7 ASSUME -- WHAT'S THE STANDARD WAY -- I ASSUME IT IS 8 DONE IN A THOUGHTFUL DOCUMENT, ARTICULATING THE 9 SUBSTANTIVE ISSUES THE AGENCY HAS. 10 MR. HARRISON: I THINK THE PRACTICE VARIES, BUT MANY AGENCIES ADOPT RESOLUTIONS THAT SET OUT THEIR 11 POSITION AND EXPLAIN WHY THEY'RE TAKING THAT POSITION. 12 13 DR. KESSLER: SO I GUESS THE QUESTION IS, I WOULD JUST ASK AGAIN, SUPPORTING MY COLLEAGUE, THAT 14 15 ANYTHING WE SAY NEEDS TO BE DONE THOUGHTFULLY 16 EXPLAINING WHY WE'RE DOING WHAT WE'RE DOING. WE JUST HAD TWO HOURS OF EXCELLENT DISCUSSION ABOUT THE ISSUES 17 HERE. AND IT'S VERY IMPORTANT THAT THOSE BE CAPTURED 18 19 IN OUR VIEWS. 20 CHAIRMAN KLEIN: DR. KESSLER, THE DESIRE WAS 21 TO TAKE A PRELIMINARY POSITION. AND THEN WE DO HAVE A WRITTEN RESOLUTION TO CONSIDER WHICH WE'RE GOING TO 22 23 COME BACK TO.

24 DR. KESSLER: I DON'T UNDERSTAND WHY WE'RE25 DOING TWO THINGS.

1 DR. HENDERSON: CAN I JUST ASK ABOUT THE 2 LETTER THAT WAS SENT. VERY EARLY ON YOU REFERRED TO A LETTER FROM PRESIDENTS SAMPLE, BALTIMORE, AND OTHERS. 3 4 IF WE HAD THAT LETTER AND WE COULD ENDORSE IT AS A COMMITTEE, WOULD THAT BE A FAIRLY STRAIGHTFORWARD WAY 5 6 OF SHOWING OUR SUPPORT? 7 CHAIRMAN KLEIN: THAT LETTER EXPRESSES 8 CONCERNS AND FOCUSES, FOR EXAMPLE, ON PEER REVIEW, BUT 9 IT DOESN'T FOCUS IN-DEPTH ON INTELLECTUAL PROPERTY AND 10 OTHER ISSUES. WE HAVE THAT LETTER, AND WE CAN BRING THAT BACK FOR CONSIDERATION FOR INCORPORATING 11 PROVISIONS IN IT. 12 WHAT I WOULD SUGGEST IS LET'S -- AS THE 13 CHAIRMAN, I'D LIKE TO FOLLOW DR. POMEROY'S SUGGESTION 14 15 AND HAVE THE STAFF TRY AND WORK ON SOMETHING DURING 16 LUNCH. 17 MR. SERRANO-SEWELL: CHAIRMAN KLEIN, I THINK THAT'S AN EXCELLENT SUGGESTION. HOWEVER, IT WOULD BE 18 MY PREFERENCE, AND I'M GOING TO DEFER WHAT MY 19 20 PREFERENCE IS TO LEADERSHIP, BUT I WANT TO SAY ON THE 21 RECORD WE CAN HAVE A DISCUSSION, WE CAN HAVE STAFF WRITE A NICE FLOWERY THING. AT THE END OF THE DAY, 22 23 EITHER YOU SUPPORT SOMETHING OR YOU OPPOSE IT. TO ME 24 THE MOST SIMPLISTIC MOTION WOULD BE THE ONE THAT THE 25 CHAIRMAN HAS SUGGESTED, AND THAT IS TO SIMPLY VOTE ON

PRELIMINARILY WHETHER WE SUPPORT OR OPPOSE SCA 13.
 LET'S GO TO LUNCH. LET'S WRITE A NICE SENTENCE. OKAY.
 THIS IS AN IMPORTANT ISSUE AND WE'VE GOT TO
 GO ON RECORD.

5 DR. HALL: IT SEEMS TO ME THAT WE'RE TALKING 6 ABOUT TWO THINGS. TWO JOBS NEED TO BE DONE. I THINK 7 ONE IS TO ADDRESS IN A SUBSTANTIVE AND THOUGHTFUL AND 8 CAREFUL WAY THE ISSUES RAISED IN THE BILL. THOSE 9 ARGUMENTS ARE COMPLICATED. THEY'RE NOT EASY TO 10 UNDERSTAND. I THINK WE SHOULD DO IT.

11 SECOND THING WE NEED TO DO, WHICH I ALSO 12 THINK WE NEED TO DO, IS TO SAY VERY CLEARLY THAT THE 13 CONSEQUENCES OF PASSING THIS LEGISLATION AS WRITTEN 14 WILL CRIPPLE US, WILL STOP US IN OUR TRACKS. I THINK 15 THE POINT IS NOT TO ARGUE, SAY THIS IS HOW WE'D LIKE IT 16 DONE, BUT SIMPLY TO SAY HERE ARE THE CONSEQUENCES OF 17 WHAT HAPPENS IF THIS BILL GOES THROUGH.

DR. BALTIMORE: THAT'S EXACTLY RIGHT. THIS 18 IS A SHOT OVER THE BOW. WE'RE TRYING TO TELL THE 19 20 LEGISLATURE THAT THERE ARE BIG ISSUES HERE, THAT THEY 21 NEED TO TAKE TIME TO THINK ABOUT THEM, AND THAT IT IS OUR CONSIDERED OPINION THAT THIS IS TOTALLY 22 23 COUNTERPRODUCTIVE. AND I DON'T THINK WE HAVE TO EXPLAIN EVERYTHING IN THIS PARTICULAR MOTION. I DO 24 25 THINK WE ULTIMATELY HAVE TO EXPLAIN EVERYTHING TO

PEOPLE WHO ARE INTERESTED IN IT. BUT THAT, AS ZACH
 SAYS, IS A TOME.

CHAIRMAN KLEIN: IN FACT, WE PREVIOUSLY 3 4 PREPARED ABOUT 50 PAGES OF DOCUMENTATION AND LETTERS FROM UNIVERSITY AND ASSOCIATIONS OPPOSED TO THIS, AND 5 6 OTHER GROUPS' COMMENTS. BUT -- SO WE WILL DEFINITELY 7 EXPRESS IN GREAT DETAIL, INCLUDING STATEMENTS FROM THE 8 LAWYERS, ABOUT THE TECHNICAL ISSUES OF THIS. WE'RE 9 TRYING TO CAPTURE THE FUNDAMENTAL CONCEPTS SO WE HAVE A 10 CLEAN, UNDERSTANDABLE MESSAGE THAT THIS WILL CRIPPLE THE INITIATIVE AS WRITTEN. 11 MR. SHEEHY: I JUST KIND OF LIKE TO GET 12

13 THINGS DONE. I HAVE A LITTLE BIT OF A BIAS, AND I 14 THOUGHT THE MOTION AS PROPOSED WAS OUTSTANDING WITH THE 15 ADDITION OF DR. BALTIMORE'S COMMENTS. I WONDER IF WE 16 COULD JUST HAVE THAT READ BACK AND TAKE A VOTE.

DR. BALTIMORE: I THINK THAT'S THE PROBLEM. 17 THE PROBLEM IS EVEN TWO SENTENCES WE DON'T HAVE 18 STRAIGHT. CLAIRE IS ABSOLUTELY RIGHT. WE OUGHT TO 19 20 HAVE IT DOWN ON PAPER. IT OUGHT TO BE GENERAL 21 PROCEDURES FOR THIS COMMISSION, WHATEVER WE ARE, THAT WE ALWAYS DO THAT. AND, IN FACT, ONE OF THE PROBLEMS 22 23 THAT WE'VE HAD ALL ALONG IS THAT WE DON'T HAVE A RECORD 24 OF MOTIONS THAT ARE MADE. THEY'RE BEING MADE SORT OF 25 AD HOC WITH FOOTNOTES AND THE WAY PEOPLE ORDINARILY

TALK. AND THEN SOMEBODY ADDS ON A LITTLE BIT. SOMEHOW
 WE NEED TO CAPTURE MOTIONS IN A FORM IN WHICH WE KNOW
 WHAT WE'RE VOTING ON.

4 CHAIRMAN KLEIN: IF I SUGGEST THAT DURING THE LUNCH BREAK IF THE MEMBERS OF THE BOARD WOULD READ THE 5 6 RESOLUTION THAT ADDRESSES STATE LEGISLATION STARTING AT 7 THE BOTTOM OF PAGE 2 AND GOING THROUGH PAGE 3 OVER TO 8 PAGE 4. IT'S ON TAB 8, WHICH IS VERY SPECIFIC 9 LANGUAGE. I DID NOT WANT TO VOTE ON THIS RESOLUTION 10 YET BECAUSE WE HAVE NOT ADDRESSED THE OTHER ITEMS OF THIS LEGISLATION WHICH WE'RE SUGGESTING WE SUPPORT. SO 11 WE HAVE IT IN WRITING, BUT I'D LIKE TO MAKE SURE THAT 12 13 THE COMMITTEE HAS A CHANCE TO READ THIS. AND THIS IS 14 AVAILABLE TO THE PUBLIC OUTSIDE AS CONTEMPLATED 15 LANGUAGE. WE WERE JUST DOING THIS IN STEPS, BUT WE 16 WILL ADDRESS IT AT LUNCH.

DR. KESSLER: COULD YOU JUST EXPLAIN THE
DIFFERENCE BETWEEN THIS RESOLUTION AND WHAT YOU'RE
ASKING FOR?

20 CHAIRMAN KLEIN: YES. THE INTENT WAS TO 21 INITIALLY TAKE A VOTE ON WHETHER WE WERE OPPOSED, AND 22 THEN IN A SECOND STEP ARTICULATE SPECIFICALLY THE 23 THOUGHT BEHIND. THAT THE INTENT WAS TO INCORPORATE 24 THAT IN THE RESOLUTION THAT SHOWED THE LEGISLATURE VERY 25 CLEARLY THAT WE WERE ALSO VERY SUPPORTIVE OF A NUMBER

OF OTHER THINGS THE LEGISLATURE WAS DOING. THAT WAS
 THE ORIGINAL INTENT. WE CAN DISCUSS THAT AS WE
 RECONVENE AFTER LUNCH.

BUT WE THANK THE PUBLIC AND WE WILL BE
ADJOURNING FOR ABOUT AN HOUR AND 15 MINUTES. THANK
YOU.

7 (A RECESS WAS TAKEN.)

8 CHAIRMAN KLEIN: RECONVENE PLEASE. CAN 9 I HAVE THE MIC, PLEASE. ALL RIGHT. IF I CAN HAVE THE 10 MIC ON, PLEASE. I WANT TO FOCUS HERE VERY QUICKLY ON CRITICAL ITEMS. WE HAVE SCA 13 POSITION. WE HAVE A 11 CONFLICTS PROVISION DEALING WITH THE FACILITIES GROUP 12 CONFLICTS POLICY, AND WE HAVE A REPORT FROM THE 13 FACILITIES GROUP THAT WILL CONCEPTUALLY MAKE THAT AN 14 15 OPEN MEETING WITH THE STAFF AND THE ATTORNEYS THAT NEED 16 TO PROCEED TO DEFINE FOR US WHAT THE EXCEPTIONS WOULD 17 BE TO THAT OPEN MEETING POSITION.

18 ON SCA 13 COULD I HAVE THE PROPOSED LANGUAGE19 ON THE SCREEN, PLEASE.

OKAY. CAN I HAVE BOARD DISCUSSION ON THIS
LANGUAGE, PLEASE. WHAT WE'RE TRYING TO DO HERE IS
DISTILL SO IT'S A VERY UNDERSTANDABLE AND SHORT MESSAGE
ABOUT OUR CURRENT POSITION CLEARLY WITH INTENT TO WORK
WITH THE AUTHOR AND THE LEGISLATURE IN BOTH HOUSES TO
TRY AND DEVELOP SOME CONSENSUS.

1 DR. PENHOET: JUST ONE SUGGESTION. I THINK, 2 ALL DEFERENCE TO DR. BALTIMORE, USE OF A WORD LIKE "IMPOSSIBLE" LEAVES US OPEN TO CHALLENGES BECAUSE IT 3 4 MIGHT NOT BE IMPOSSIBLE. SO I WOULD SUBSTITUTE SOMETHING LIKE EXTREMELY DIFFICULT OR SIMILAR A WORD. 5 6 MR. GOLDBERG: ON BEHALF OF DR. BIRGENEAU, HE 7 SECONDS THAT COMMENT. 8 CHAIRMAN KLEIN: HOW ABOUT EXTRAORDINARILY 9 DIFFICULT? 10 DR. BALTIMORE: AS YOU WISH. MS. SAMUELSON: I'M AFRAID I HAVE TO 11 DISAGREE. I THINK WE REVIEWED IT AND WE DECIDED IT WAS 12 IMPOSSIBLE. IT WOULD DERAIL THE ABILITY TO DO WHAT WE 13 HAVE TO DO. IF ALL THE MEMBERS OF THE PEER REVIEW TEAM 14 15 QUIT, THAT MAKES IT IMPOSSIBLE FOR THEM TO DO THEIR 16 JOBS. WE HAVE TO BE STRONG ABOUT IT AND CLEAR. 17 MR. SHESTACK: YOU COULD SAY EXTREMELY DIFFICULT, AND THEN SAY -- COME BACK AND SAY WE ARE 18 STRONGLY OPPOSED TO SCA 13, WHICH IT DOESN'T ACTUALLY 19 20 SAY. YOU DON'T ACTUALLY SAY THAT THE GROUP IS OPPOSED. 21 AND I WOULD -- IF WE'RE ADDING ADDITIONAL WORDS, I 22 WOULD JUST GET RID OF THE SECOND SENTENCE, WHICH MAKES THE THING A LITTLE TOO LONG. JUST SAY WE WANT TO WORK 23 24 WITH YOU, CONFLICT OF INTEREST IS IMPORTANT TO US, BUT 25 THIS BILL IS REALLY TERRIBLE. THAT'S -- THOSE ARE THE

1 THOUGHTS.

2 DR. BRYANT: I THINK WE HAVE MORE PROBLEMS THAN CONFLICT OF INTEREST, SO I WOULD LIKE A SENTENCE 3 4 THAT SAYS THAT WE ARE CONCERNED ABOUT THE PROVISIONS THAT RELATE TO OPEN REVIEWS OF GRANTS, CONFLICT OF 5 6 INTEREST, AND INTELLECTUAL PROPERTY, SOMETHING LIKE 7 THAT. THOSE ARE THE THREE BASIC AREAS. 8 CHAIRMAN KLEIN: LET'S MAKE THIS SPECIFIC 9 BECAUSE WE'VE GOT TO MOVE VERY QUICKLY HERE. IS 10 COMMITTED TO WORKING WITH THE LEGISLATORS TO ADVANCE STEM CELL RESEARCH, TO ENSURE TRANSPARENCY, CONFLICT OF 11 12 INTEREST, TO PROVIDE AN OUTSTANDING PEER REVIEW SYSTEM, TO PROVIDE AN OUTSTANDING PEER REVIEW SYSTEM, AND TO 13 PROVIDE A STRONG AND EFFECTIVE PROTECTION FOR THE STATE 14 15 FOR INTELLECTUAL PROPERTY. 16 DR. BRYANT: YES. CHAIRMAN KLEIN: CAN WE PUT THAT INTO THE 17 TEXT. AFTER CONFLICT OF INTEREST, WE WOULD ADD THE 18 LANGUAGE SPECIFICALLY --19 20 DR. BRYANT: AND AN APPROPRIATE INTELLECTUAL 21 PROPERTY PROVISION. 22 DR. HALL: STRONG AND EFFECTIVE. 23 CHAIRMAN KLEIN: STRONG AND EFFECTIVE PEER 24 REVIEW SYSTEM -- INTELLECTUAL PROPERTY SYSTEM TO 25 PROTECT THE INTERESTS OF THE STATE OF CALIFORNIA AND

1 ITS CITIZENS. STRONG AND EFFECTIVE INTELLECTUAL 2 PROPERTY SYSTEM TO PROTECT -- PROVIDE A STRONG AND EFFECTIVE INTELLECTUAL PROPERTY PROGRAM TO PROTECT THE 3 4 INTERESTS OF THE STATE OF CALIFORNIA AND ITS CITIZENS. NOW, I DON'T BELIEVE WE'LL EVER HAVE A 5 6 COMPLETELY PERFECT DOCUMENT; BUT IF WE COULD ALL WORK 7 WITH THIS, HOW IMPORTANT IS IT TO SUBSTITUTE OUT THE 8 WORD "IMPOSSIBLE" BECAUSE I THINK THAT DR. BALTIMORE 9 WAS QUITE CORRECT. IF WE DON'T HAVE A PEER REVIEW 10 SYSTEM, WE DON'T HAVE A PROGRAM. AND THE CURRENT INTELLECTUAL PROPERTY SYSTEM IS IMPOSSIBLE TO 11 12 IMPLEMENT. DR. HALL: NOT POSSIBLE, INFINITESIMALLY --13 DR. BRYANT: HOW ABOUT EXTREMELY DIFFICULT, 14 15 IF NOT IMPOSSIBLE? 16 CHAIRMAN KLEIN: HOW ABOUT THAT? EXTREMELY 17 DIFFICULT, IF NOT IMPOSSIBLE. (SIMULTANEOUS DISCUSSION.) 18 MR. SHEEHY: I REALLY WOULD LIKE TO STAY WITH 19 IMPOSSIBLE. I REALLY FEEL PRETTY STRONGLY WE SHOULD 20 21 STAY WITH IMPOSSIBLE. I MEAN, YOU KNOW, FOR THOSE OF 22 US WHO ARE WAITING FOR THESE CURES, IT'S IMPOSSIBLE. 23 CHAIRMAN KLEIN: LET US DO THIS IF WE CAN, JEFF. CAN WE TAKE PUBLIC COMMENT ON THIS LANGUAGE 24 25 WHILE THEY'RE MECHANICALLY WORKING THROUGH IT? IS

1 THERE ANY PUBLIC COMMENT THAT IS REALLY ESSENTIAL HERE? 2 UNIDENTIFIED SPEAKER: WHY DON'T YOU SUBSTITUTE THE WORD "PREVENT" FOR IMPOSSIBLE? 3 4 DR. REED: FOR THE COURT REPORTER, I WOULD LIKE THE FIRST SENTENCE TO BE A STATEMENT OF PURPOSE. 5 6 THIS LEAVES IT TO THE VERY BOTTOM. SOMETHING LIKE THE 7 ICOC OPPOSES SCA 13 AT THE VERY BEGINNING, AND THEN PUT 8 YOUR POINTS. AS IT IS NOW, IT LOOKS LIKE YOU'RE 9 SUPPORTING IT UNTIL YOU GET TO THE VERY LAST. 10 CHAIRMAN KLEIN: I THINK THAT'S AN EXCELLENT SUGGESTION. SO THE INDEPENDENT -- WE DON'T USE 11 ACRONYMS HERE. THE INDEPENDENT CITIZENS OVERSIGHT 12 COMMITTEE OPPOSES SCA 13. AND THE NEXT SENTENCE WOULD 13 BE MODIFIED TO START WITH WE ARE COMMITTED. 14 15 DR. PIZZO: OR THE ICOC IS COMMITTED. 16 DR. FONTANA: AND STRONGLY OPPOSES. CHAIRMAN KLEIN: WE NEED TO -- ARE THERE 17 ADDITIONAL PUBLIC COMMENTS? OKAY. SEEING NO 18 ADDITIONAL PUBLIC COMMENTS, I'D LIKE TO FOCUS HERE ON 19 20 THE BOARD. I'M GOING TO START AT THIS CORNER, GO DOWN, 21 AND WE'RE GOING TO END AT THAT CORNER, AND THEN WE'RE 22 GOING TO ASK IF WE CAN CALL THE QUESTION. ANY 23 ADDITIONAL COMMENTS OR CHANGES? 24 DR. BRYANT: WE DIDN'T MAKE THE PREVENT 25 CHANGE.

MS. SAMUELSON: IF WE JUST WANT TO APPROVE IT 1 2 TO GET GOING, THAT'S FINE, BUT I THINK WE COULD VASTLY SHORTEN IT BY IN THE SECOND SENTENCE BY SAYING WE'RE 3 4 COMMITTED TO WORKING WITH THE LEGISLATURE TO SUCCESSFULLY ACHIEVE THE GOALS OF PROPOSITION 71. AND 5 6 THEN GO DOWN TO THE LAST SENTENCE AND SAY SCA 13 WILL 7 MAKE IT EXTREMELY DIFFICULT, IF NOT IMPOSSIBLE, FOR 8 SCIENTISTS TO DO THEIR JOBS, AND IT WILL DELAY 9 CRITICALLY NEEDED MEDICAL THERAPIES. I THINK THAT SAYS 10 IT ALL WITHOUT GETTING INTO THE DETAILS. CHAIRMAN KLEIN: THERE ARE SOME INDIVIDUALS 11 THAT PREVIOUSLY RAISED THE POINT THAT THEY WOULD LIKE 12 13 TO MENTION THESE ITEMS. DR. LEVEY: IT'S GOOD TO DO THAT BECAUSE IT 14 REALLY THEN TAKES ON THE ESSENCE OF CIRM. 15 16 DR. PIZZO: WHILE I USUALLY AGREE WITH JOAN, I THINK THAT IT WOULD BE MORE POWERFUL TO ACTUALLY SAY 17 WHAT WE'RE TAKING ON. 18 CHAIRMAN KLEIN: OKAY. I'D LIKE TO SEE IF WE 19 CAN -- DO WE HAVE A SPECIFIC MOTION THAT ADOPTS THE 20 21 LANGUAGE AS IT NOW EXISTS? 22 MR. SERRANO-SEWELL: SO MOVED. DR. LEVEY: SECOND. WE DO STILL HAVE A 23 24 MOTION ON THE TABLE. 25 CHAIRMAN KLEIN: THE MOTION ON THE TABLE WAS

1 MADE BY DAVID SERRANO-SEWELL AND SECONDED BY DR. LEVEY. 2 SO THIS IS AN AMENDED MOTION. WE CAN, IN FACT, FORESHORTEN THIS PROCESS BY ASKING THE MAKER OF THE 3 4 ORIGINAL MOTION AND THE AMENDED MOTION IF THEY ACCEPT THIS AMENDED LANGUAGE. DAVID SERRANO-SEWELL, DO YOU 5 6 ACCEPT THE AMENDED LANGUAGE? 7 MR. SERRANO-SEWELL: I DO. 8 DR. LEVEY: YES. 9 CHAIRMAN KLEIN: THE AMENDED LANGUAGE BEING 10 ACCEPTED BY THE MAKER OF THE MOTION AND THE SECOND, WE CAN NOW GO DIRECTLY TO VOTE ON THE MOTION. 11 (THE AMENDED LANGUAGE FOR THE MOTION IS 12 13 HEREIN INCORPORATED AS FOLLOWS:) "THE INDEPENDENT CITIZENS' OVERSIGHT 14 15 COMMITTEE OPPOSES SCA 13. WE ARE COMMITTED TO WORKING 16 WITH THE LEGISLATURE TO ADVANCE STEM CELL RESEARCH, TO 17 ENSURE TRANSPARENCY, TO PREVENT CONFLICTS OF INTEREST, TO PROVIDE AN OUTSTANDING PEER REVIEW SYSTEM, TO 18 19 PROVIDE A STRONG AND EFFECTIVE INTELLECTUAL PROPERTY 20 PROGRAM TO PROTECT THE INTERESTS OF THE STATE OF 21 CALIFORNIA AND ITS CITIZENS, AND WE BELIEVE WE HAVE PUT STANDARDS AND POLICIES IN PLACE TO ACHIEVE THESE 22 23 OBJECTIVES. THE ICOC ALSO SHARES THE GOAL THAT 24 THERAPIES AND CURES DEVELOPED THROUGH RESEARCH FUNDED 25 BY PROPOSITION 71 BE MADE AVAILABLE TO ALL MEMBERS OF

THE CALIFORNIA PUBLIC. AS CURRENTLY DRAFTED, HOWEVER, 1 2 SCA 13 WILL MAKE IT EXTREMELY DIFFICULT, IF NOT IMPOSSIBLE, FOR SCIENTISTS TO DO THEIR JOBS, AND IT 3 4 WILL DELAY CRITICALLY NEEDED MEDICAL THERAPIES." 5 CHAIRMAN KLEIN: ALL IN FAVOR. OPPOSED. IT 6 UNANIMOUSLY PASSES. 7 THANK YOU. WE HAVE COUPLE OF CRITICAL ITEMS 8 THAT I THINK WE CAN HANDLE IN -- DOCTOR, IF WE COULD WAIT JUST ONE MOMENT HERE. WHERE ARE WE ON OUR COUNT 9 10 ON OUR QUORUM? THANK YOU, DOCTOR. IS THAT CONFIRMED? WE DO HAVE A QUORUM. 11 12 OKAY. I'D LIKE TO MOVE IMMEDIATELY TO THE ITEM ON 13 THE AGENDA THAT DEALS WITH THE CONFLICT OF INTEREST FOR 14 15 THE FACILITIES COMMITTEE, ITEM 10. DR. ZACH HALL, 16 WOULD YOU PLEASE PRESENT THIS ITEM. 17 DR. HALL: I THINK YOU ALL HAVE IN FRONT OF YOU A COPY OF AGENDA ITEM NO. 10, I HOPE SO, CIRM 18 CONFLICT OF INTEREST POLICY FOR FACILITIES WORKING 19 20 GROUP MEMBERS. 21 THIS IS A POLICY THAT WAS DRAWN UP REALLY TO BE AN ADAPTATION OF THE POLICY THAT WE USED FOR OUR 22 23 GRANTS REVIEW WORKING GROUP TO MAKE APPROPRIATE FOR THE 24 FACILITIES WORKING GROUP MEMBERS. SO IT'S VERY

25 SIMILAR. IT DEFINES WHAT'S MEANT BY FINANCIAL CONFLICT

OF INTEREST, WHICH IS EITHER THAT THE REVIEWER OR CLOSE
 FAMILY MEMBER IS AN EMPLOYEE OF ANY CONSTRUCTION
 DEVELOPMENT ENTITY ON THE APPLICATION UNDER ACTIVE
 CONSIDERATION FOR EMPLOYMENT WHO STANDS TO RECEIVE A
 FINANCIAL BENEFIT OR HAS RECEIVED OR COULD RECEIVE A
 FINANCIAL BENEFIT OF ANY TYPE UNRELATED TO THE PROPOSAL
 OVER \$5,000 A YEAR.

8 IT ALSO DEFINES A PROFESSIONAL CONFLICT OF 9 INTEREST. IF THE REVIEWER AND A PROJECT DIRECTOR OR 10 MANAGER OF AN APPLICATION ARE ENGAGED IN OR PLAN TO BE ENGAGED IN A JOINT PROJECT. IT THEN TALKS ABOUT THE 11 PROCEDURES THAT WILL BE USED, WHICH ARE SIMILAR TO 12 13 THOSE THAT WE HAVE DISCUSSED FOR GRANTS REVIEW. THAT 14 IS, REVIEWERS ARE REQUIRED TO STATE IF THEY HAVE A 15 CONFLICT OF INTEREST. THEY WILL NOT THEN PARTICIPATE 16 IN THAT APPLICATION IF THEY DO, AND THEY MUST SIGN A STATEMENT AT THE END UNDER PENALTY OF PERJURY STATING 17 THAT THEY WERE NOT INVOLVED IN CONFLICT OF INTEREST. 18 19 AND THEN THERE ARE A SERIES OF DEFINITIONS.

20 SO I THINK IT'S FAIRLY STRAIGHTFORWARD BASED 21 ON WHAT WE'VE DONE PREVIOUSLY. IT SETS THE STAGE NOW 22 FOR US TO APPROACH PROPOSED MEMBERS OF THAT WORKING 23 GROUP TO SEE IF THEY'RE WILLING TO SERVE UNDER THE 24 TERMS OF THIS CONFLICT OF INTEREST AGREEMENT. 25 CHAIRMAN KLEIN: AND, DR. HALL, WAS THIS

INTRODUCED JUST FOR DISCUSSION PREVIOUSLY? AS A MATTER
 OF RECORD, I'M JUST ASKING.

3 DR. HALL: NO. I DON'T THINK IT DID. I
4 DON'T THINK IT EVER CAME UP.

5 CHAIRMAN KLEIN: THANK YOU. THIS WOULD 6 COMPLETE THE CONFLICTS POLICIES FOR EACH OF THE WORKING 7 GROUPS. AND IT IS EFFECTIVELY A VERY IMPORTANT 8 CONTRIBUTION TO THAT PROCESS.

9 ADDITIONALLY, WE'RE ABOUT TO CONSIDER THE 10 APPOINTMENT OF THESE MEMBERS, AND IT'S VERY IMPORTANT THEY HAVE CLEAR UNDERSTANDING OF THE CONFLICTS POLICY. 11 THE -- DR. HALL HAS SPENT A SIGNIFICANT 12 AMOUNT OF TIME DEVELOPING THIS. AND I WOULD ASK FOR 13 BOARD COMMENT ON THIS. AND I WOULD LIKE TO LET THE 14 15 BOARD KNOW WE ALSO HAVE ON OUR AGENDA IMMEDIATELY AFTER 16 THIS THE APPOINTMENTS OF MEMBERS OF THE FACILITIES 17 COMMITTEE, WHICH WE'RE GOING TO TRY AND GET TO. WE HAVE DR. LEVEY WHO HAS TO LEAVE IN ABOUT 15 OR 20 18 19 MINUTES. 20 DR. HENDERSON: I MOVE APPROVAL OF THIS

21 CONFLICT OF INTEREST POLICY FOR THE FACILITIES GROUP.22 MS. SAMUELSON: SECOND.

23 CHAIRMAN KLEIN: THERE'S A MOTION AND A
24 SECOND. I'D LIKE TO ASK ARE THERE PUBLIC COMMENTS ON
25 THIS PROPOSED POLICY? JESSE REYNOLDS.

1 MR. REYNOLDS: THANKS FOR THE OPPORTUNITY TO 2 SPEAK. AGAIN, FOR THE RECORD, MY NAME IS JESSE REYNOLDS WITH THE CENTER FOR GENETICS IN SOCIETY. 3 4 AND I HAVE TWO THOUGHTS ON THIS CONFLICT OF INTEREST POLICY. I THINK THE SECOND ONE IS MORE OF A 5 6 QUESTION THOUGH. MY FIRST THOUGHT IS I FEEL IT 7 CAPTURES, UNFORTUNATELY, SOME OF THE INADEQUACIES THAT 8 WERE IN THE ADOPTED CONFLICT OF INTEREST POLICIES FOR 9 THE OTHER TWO WORKING GROUPS. AND ONE OF IT IS THAT BY 10 HAVING NO PREVIOUS DISCLOSURE REQUIREMENTS, WHAT IT AMOUNTS TO IS A SELF-RECUSAL POLICY, AND THAT IT WOULD 11 BE IMPOSSIBLE FOR ANYONE TO MONITOR THE IMPLEMENTATION 12 13 OF THIS CONFLICTS POLICY.

AND SECOND, WHAT IT BORROWS, UNFORTUNATELY, 14 15 FROM THE CONFLICTS OF INTEREST POLICY FOR THE STANDARDS 16 WORKING GROUP IS AN EXCEPTION. AND THERE ON THE BACK IT SAYS IF SOMEONE REALLY HAS THE EXPERTISE THAT WE 17 WANT, WE WILL MAKE AN EXCEPTION AROUND THE CONFLICTS 18 POLICY. AND I THINK THAT THAT MIGHT RESULT -- THAT 19 20 WHEN PUSH COMES TO SHOVE, THERE'S NO REAL SUBSTANCE TO 21 SUCH A CONFLICTS POLICY.

22 MY QUESTION, THOUGH, IS THAT PREVIOUSLY WE 23 WERE TOLD THAT THESE OPEN MEETINGS POLICIES AND THE 24 CONFLICT OF INTEREST POLICIES WERE INTERIM AND THAT 25 THERE WOULD BE A PERIOD OF PUBLIC HEARINGS TO REVISE

THESE. AND I WOULD LIKE TO KNOW IF THAT IS, IN FACT,
 STILL THE CASE.

CHAIRMAN KLEIN: THE INTENT IS TO HAVE A 3 4 GOOD, SOLID CONFLICTS POLICY, MR. REYNOLDS, TO PROVIDE A GOOD STARTING POINT. AND I WOULD ASK, DR. HALL, AS 5 6 SOON AS WE TAKE AN ACTION ON THIS AND THE FOLLOWING 7 ITEM, TO PROVIDE A COMPLETE RESPONSE TO MR. REYNOLDS, I 8 THINK IT'S IMPORTANT FOR THE PUBLIC TO THEN REVISIT THE 9 ISSUE OF HOW THE PEER REVIEW GROUP WILL HAVE A 10 DISCLOSURE POLICY UNDER THE NIH MODEL, AND THAT IN TERMS OF MR. REYNOLDS' POSITION, WE HAVE A LATER 11 HEARING, PUBLIC HEARING, THAT'S GOING TO ADDRESS THIS 12 13 ISSUE.

I THINK YOUR POINT ABOUT DISCLOSURES IN 14 15 ADVANCE IS A VERY GOOD ONE. AS YOU KNOW, I HAVE 16 PERSONALLY WRITTEN A LETTER TO THE BOARD SAYING I WILL NOT HOLD ANY INTEREST IN ANY ENTITY THAT WILL EVER DO 17 ANY OF THE CONSTRUCTION, HAVE ANY ECONOMIC INTEREST IN 18 ANY BUILDING. OF COURSE, FACILITIES CAN ONLY BE BUILT 19 20 FOR NONPROFIT INSTITUTIONS. BUT I BELIEVE THAT THIS 21 DISCLOSURE POINT THAT YOU BRING UP IS INCORPORATED IN OUR GRANT COMMITTEE POLICY, BUT WE WILL HAVE A SPECIFIC 22 23 PUBLIC HEARING. AND I WILL AGENDIZE THAT SPECIFIC ITEM FOR DISCUSSION IN THAT PUBLIC HEARING. 2.4

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DR. HALL: LET ME
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DR. HALL: LET ME JUST ADDRESS THAT ISSUE

BECAUSE IT'S COME UP. IT IS -- LET ME POINT OUT THAT
 IT IS THE RESPONSIBILITY OF THE CIRM STAFF TO ENSURE
 THAT ALL OF THE REVIEWS ARE FAIR AND FREE OF CONFLICT
 OF INTEREST. THIS IS PART OF OUR JOB. IT'S WHAT
 THE STAFF PEOPLE THAT WE HIRE AS REVIEWERS WILL BE
 CHARGED WITH DOING.

7 IN ORDER TO CARRY THAT OUT EFFECTIVELY, WE 8 WILL ASK EACH MEMBER OF THE WORKING GROUP TO TELL US 9 WHAT INVESTMENTS, WHAT COMPANIES THEY ARE INVESTED IN 10 THAT WOULD FALL IN THE RANGE AS DESCRIBED HERE. WE DO NOT NEED TO KNOW HOW MUCH IT IS. WE SIMPLY NEED TO 11 KNOW IF THEY HAVE THOSE CONFLICTS. WE WILL ASK THEM 12 EACH YEAR OR SOME PERIOD OF TIME TO UPDATE THAT, AND 13 THEN WE WILL USE THAT IN ALERTING THEM THAT -- WE WILL 14 15 SAY YOU HAVE A CONFLICT OF INTEREST HERE. WE HAVE AN 16 APPLICATION FOR SUCH-AND-SUCH COMPANY, YOU'VE LISTED IT. SO WE DO NOT INTEND TO MAKE THOSE PUBLIC RECORDS 17 AS THESE ARE NOT EMPLOYEES, BUT ARE CONSULTANTS. 18

SO WE WILL HAVE THE RECORDS. WE WILL USE
THEM. IT'S THE WAY WE WILL HELP THE MEMBERS OF THESE
WORKING GROUPS AVOID CONFLICT OF INTEREST SITUATIONS,
BUT THEY WILL NOT BE PUBLIC DOCUMENTS.

23 CHAIRMAN KLEIN: JAMES HARRISON, WOULD YOU
24 SPECIFICALLY JUST INFORM THE BOARD AND PUBLIC QUICKLY
25 ABOUT THE PROVISION IN THE INITIATIVE ITSELF THAT

PROHIBITS ANYONE WHO WOULD BE ON THIS FACILITIES
 COMMITTEE FROM, IN FACT, HAVING ANY INTEREST, ECONOMIC
 INTEREST, IN A COMPANY THAT WOULD BUILD FACILITIES OF
 THIS TYPE?

5 MR. HARRISON: YES. THE ACT PROVIDES IN 6 SECTION 125290.65 (A)(2) THAT MEMBERS OF THE WORKING 7 GROUP -- OF THE FACILITIES WORKING GROUP SHALL BE 8 PROHIBITED FROM RECEIVING COMPENSATION FROM ANY 9 CONSTRUCTION OR DEVELOPMENT ENTITY PROVIDING 10 SPECIALIZED SERVICES FOR MEDICAL RESEARCH FACILITIES. CHAIRMAN KLEIN: AND I BELIEVE THAT WHEN WE 11 AGENDIZE THIS, MR. REYNOLDS, WE SHOULD PROBABLY 12 DIRECTLY ADDRESS THAT PORTION OF THE INITIATIVE AND TRY 13 AND CARRY IT OUT WITH SOME DISCLOSURE PROVISIONS. VERY 14 15 HELPFUL SUGGESTION. 16 MS. SAMUELSON: MAY I CALL THE QUESTION. 17 CHAIRMAN KLEIN: CALL THE QUESTION. AND WHO WAS THE PERSON WHO MADE THE MOTION? 18 DR. HENDERSON: I MADE THE MOTION. 19 20 CHAIRMAN KLEIN: ANYTHING THAT HAS OCCURRED 21 IN THE DISCUSSION THAT WOULD CAUSE YOU TO MODIFY THE 22 MOTION? 23 DR. HENDERSON: NO. 24 CHAIRMAN KLEIN: THANK YOU FOR THE CONFIRMATION. ALL IN FAVOR. OPPOSED? THANK YOU. 25

1 THE -- DR. FRIEDMAN IS -- BECAUSE HE IS NOT 2 HERE TODAY, I JUST RECEIVED A MESSAGE THAT HE WOULD LIKE TO BE INVOLVED IN PRESENTING THE CANDIDATES TO THE 3 4 BOARD; IS THAT CORRECT, MELISSA KING? BUT THERE IS A COMPONENT OF THE DECISIONS OF THAT GROUP THAT COULD 5 MOVE FORWARD TODAY. AND THAT COMPONENT IS THAT A VERY 6 7 SPECIFIC DISCUSSION TOOK PLACE VERY SIMILAR TO THE 8 DISCUSSION THAT HAPPENED AT THIS BOARD WHERE JEFF 9 SHEEHY AND DAVID SERRANO-SEWELL SUGGESTED FOR THE 10 STANDARDS COMMITTEE THAT WE HAVE AN OPEN PUBLIC HEARING POLICY, THAT WE WOULD HAVE THAT POLICY HAVE EXCEPTIONS 11 FOR SPECIFIC ITEMS, IN THE CASE OF STANDARDS COMMITTEE, 12 13 FOR EXAMPLE, INCLUDING PATIENT PRIVACY AND OTHER SPECIFIC EXCEPTIONS THAT WERE CRITICAL TO THE MISSION 14 15 OF THE INSTITUTE.

16 SO IN TERMS OF THE SPECIAL SUBCOMMITTEE OF THE BOARD, I'D LIKE TO ASK THE MEMBERS OF THE COMMITTEE 17 THAT ARE HERE IN ADDITION TO MYSELF, DO WE FEEL 18 CONFIDENT THAT WE HAD, I BELIEVE, A UNANIMOUS CONSENSUS 19 20 ON THIS ISSUE SO THAT IT WOULD APPEAR TO ME THAT WE 21 COULD MOVE FORWARD WITH THAT ITEM TODAY AT THE BOARD 22 WHERE WE SPECIFICALLY WOULD ADOPT IN CONCEPT, ASK THE 23 COUNSEL TO COME BACK WITH SPECIFIC LANGUAGE TO THIS BOARD TO IMPLEMENT A CONCEPT WHERE THE FACILITIES 2.4 25 HEARINGS WERE GENERALLY OPEN WITH EXCEPTIONS,

1 INCLUDING, AS DR. FRIEDMAN LAID OUT, SCIENTIFIC INPUT 2 THAT RELATED TO THE SCIENTIFIC CAPACITY OF AN INSTITUTION TO UTILIZE THIS GRANT OR GRANTS, THE 3 4 CERTAIN TRADITIONAL EXCEPTIONS SUCH AS NEGOTIATING REAL ESTATE TERMS AND CONTRACTS AND OTHER POTENTIAL 5 6 EXCEPTIONS THAT ARE EXPECTED TO BE WITHIN THE PURVIEW 7 OF THAT COMMITTEE AND WOULD NECESSARILY BE COMPROMISED 8 IF THEY WEREN'T DONE IN A CONFIDENTIAL HEARING. OF 9 COURSE, ALWAYS WITH RESULTS REPORTED IN AN ADVISORY 10 CAPACITY TO THIS BOARD, WHERE ALL FINAL DECISIONS HAVE TO BE MADE. 11 DR. TED LOVE, DO YOU THINK THAT THAT 12 13 CONSENSUS IS WELL ESTABLISHED IN THE COMMITTEE? DR. LOVE: I AGREE THAT IT WAS, AND I 14 15 ACTUALLY THOUGHT THAT DON REED TOWARD THE END OF OUR 16 MEETING MADE A COMMENT THAT KIND OF DESCRIBED THAT THE 17 PROCESS OF -- DESCRIBING HOW WE WOULD APPROACH OUR BUSINESS, THE CRITERIA THAT WE AGREED UPON WOULD ALL BE 18 19 TRANSPARENT, BUT THE ACTUAL REVIEW PROCESS WHERE 20 SPECIFICS ARE BEING DISCUSSED, INDIVIDUALS ARE BEING 21 DISCUSSED, THAT WOULD BE HELD IN PRIVATE. AND THEN THE 22 OUTPUT WOULD ALL COME BACK TO THE PUBLIC AS WELL. 23 SO BASICALLY KIND OF A BOOKEND PROCESS THAT

24 WOULD BE PUBLIC WITH THE INTERNAL PROCESS BEING

25 PRIVATE.

1 CHAIRMAN KLEIN: ALL RIGHT. 2 DR. LOVE: I DIDN'T SAY IT QUITE AS WELL AS MR. REED SAYS IT. 3 4 CHAIRMAN KLEIN: MR. REED IS SO DEDICATED THAT HE PARTICIPATES IN MANY -- AS A MEMBER OF THE 5 6 PUBLIC IN MANY OF THESE SUBCOMMITTEE MEETINGS. 7 ADDITIONAL BOARD COMMENTS? GAYLE WILSON. 8 MS. WILSON: NO. I AGREE WITH WHAT HE HAD TO 9 SAY. WE'RE DEFERRING THE POINT OF BRINGING UP THE 10 NAMES OF THE ONES WE SELECTED. CHAIRMAN KLEIN: IT WAS MY UNDERSTANDING THAT 11 THE NAMES WERE GOING TO BE BROUGHT UP TODAY, BUT 12 13 DR. FRIEDMAN IS NOT HERE. MS. WILSON: SO THAT WILL BE DONE IN JUNE? 14 CHAIRMAN KLEIN: IT WILL BE DONE IN 15 16 APPROXIMATELY TWO WEEKS AT THE JUNE MEETING. 17 MS. KING: JUST TO REMIND THE SUBCOMMITTEE THAT THE TIME LINE THAT WE APPROVED A COUPLE MONTHS AGO 18 19 WAS ACTUALLY TO BRING FORTH OUR CANDIDATES AT THE JUNE 20 6TH MEETING, AND THAT'S WHAT WE'RE PLANNING TO DO 21 SPECIFICALLY BECAUSE DR. FRIEDMAN WOULD NOT BE AT THIS 22 MEETING. 23 CHAIRMAN KLEIN: THANK YOU VERY MUCH. THAT'S 24 VERY HELPFUL. 25 DR. PIZZO: MR. CHAIRMAN, COULD YOU CLARIFY

1 WHAT WE'RE NOW GOING TO DO AT THE JUNE 6TH MEETING? WE 2 HAD DISCUSSION EARLIER TODAY ABOUT A VARIANCE OF PLAN. IS THAT -- HOW ARE WE THINKING ABOUT THE JUNE 6TH 3 4 MEETING? 5 CHAIRMAN KLEIN: I'D BE HAPPY TO, BUT IF WE 6 COULD FINISH THIS ITEM FIRST. 7 DR. PIZZO: BY ALL MEANS. CHAIRMAN KLEIN: THANK YOU. ADDITIONAL 8 9 PUBLIC -- FIRST OF ALL, IS THERE A MOTION TO ADOPT THIS 10 CONCEPT IN CONCEPT FOR THE ATTORNEYS TO DEVELOP THE LANGUAGE AND BRING IT BACK TO THIS COMMITTEE AS 11 12 DISCUSSED? DR. HOLMES: SO MOVED. 13 CHAIRMAN KLEIN: MOVED BY DR. HOLMES. 14 DR. LOVE: SECOND. VARIETY OF SECONDS. 15 16 CHAIRMAN KLEIN: SECOND BY DR. LOVE. THAT IS THE MOTION ON THE TABLE. IS THERE 17 OTHER BOARD COMMENT BEFORE WE GO TO PUBLIC COMMENT? 18 PUBLIC COMMENT. 19 20 I THINK THE PURPOSE OF THIS IS TO MAKE IT 21 VERY CLEAR THAT SYSTEMATICALLY WE'RE MOVING IN THE DIRECTION OF PROVIDING OPENNESS WHEREVER WE CAN WHERE 22 23 IT DOESN'T COMPROMISE THE CRITICAL MISSION OF THE 24 INSTITUTE. 25 NO ADDITIONAL PUBLIC COMMENT, I WOULD LIKE TO

ASK FOR THE VOTE. ALL IN FAVOR. OPPOSED. 1 2 THE FACILITIES COMMITTEE HAS GREAT WILL IN FORCE HERE. IT'S HIGHLY RESPECTED. WE NEED TO 3 4 COMMUNICATE THAT TO DR. FRIEDMAN. 5 DR. HOLMES: HIS ABSENCE... 6 CHAIRMAN KLEIN: IN TERMS OF OUR QUORUM, DO 7 WE HAVE A TRAVEL POLICY WE TO NEED COVER VERY QUICKLY? 8 MR. BARNES: IT'S NOT A DECISION. IT'S JUST 9 AN INFORMATION ITEM. 10 CHAIRMAN KLEIN: IS THERE ANY OTHER DECISION ITEM THAT WE HAVE? 11 THERE'S A VOTE THIS WEEK ON FEDERAL 12 LEGISLATION THAT --13 (OVERLAPPING DISCUSSION ABOUT QUORUM.) 14 CHAIRMAN KLEIN: ITEM 13. I BELIEVE THAT 15 16 DR. KESSLER WANTED ZACH HALL TO PRESENT THAT. LET'S 17 PROCEED WITH THAT, AND THEN WE'RE GOING TO PROCEED WITH THE FEDERAL ISSUE. 18 DR. HALL: SO AS YOU REMEMBER, WE DISCUSSED 19 20 THIS ACTUALLY AT GREAT LENGTH LAST TIME, AND ALSO WHAT 21 DR. PIZZO REFERRED TO VERY ELOQUENTLY AS AN ANTECEDENT ISSUE. AND THAT IS A QUESTION OF WHETHER MEMBERS OF 22 23 THE STANDARDS WORKING GROUP, A, NEED TO BE 24 CALIFORNIANS --25 CHAIRMAN KLEIN: DR. LEVEY, I THINK WE NEED

1 YOU JUST FOR THIS ONE MOMENT.

2 DR. HALL: THIRTY SECONDS, JERRY. I'LL TALK 3 A LITTLE FASTER.

4 CHAIRMAN KLEIN: WE'D ALSO LIKE TO GET A 5 RECORD REAL QUICKLY. WHERE IS JEFF? DR. HALL.

6 DR. HALL: SO THE ISSUE WAS WHETHER MEMBERS 7 OF THE STANDARDS WORKING GROUP COULD APPLY FOR A GRANT 8 OR NOT. AND THAT COMES IN TWO FORMS; THAT IS, I GUESS 9 THE THREE POSITIONS ARE TO SAY THAT THEY'RE WELCOME TO 10 BE ON GRANTS, ONE EXTREME POSITION. THE OTHER IS THEY 11 SHOULD NOT BE ON A GRANT. OR THE INTERMEDIATE POSITION 12 IS THEY SHOULD NOT BE PRINCIPAL INVESTIGATOR ON A

13 GRANT.

14 AND WE HAD TWO PROPOSED MEMBERS FOR WHICH 15 THERE WAS A POTENTIAL CONFLICT, AND ONE OF THEM DID NOT 16 WISH TO HAVE THEIR NAME BROUGHT FORTH UNTIL THE POLICY 17 WAS CLARIFIED. SO WE NEED TO MAKE A DECISION ON THIS. MY SUGGESTION IS WE HAD A VERY LENGTHY 18 DISCUSSION ON IT LAST TIME. SO I HOPE THAT WE COULD 19 HAVE A FAIRLY BRIEF DISCUSSION ON IT THIS TIME. I 20 21 THINK THE ISSUES WERE THE ISSUE FOR PROHIBITION IS 22 THAT -- WELL, LET ME DO IT THE OTHER WAY AROUND. THE 23 ISSUE FOR INCLUDING THEM, AS WAS MENTIONED, I THINK, BY JON SHESTACK, AND THAT IS THAT THEY ARE NOT INVOLVED IN 24

25 GRANTS REVIEW AND DON'T HAVE THE SAME KIND OF CONFLICT

1 OF INTEREST.

2 THE OTHER VIEW TO PUT IT IS THAT EVEN THOUGH THEY MAY NOT BE DIRECTLY INVOLVED, THERE MAY BE A 3 4 PERCEPTION OF CONFLICT OF INTEREST. AND I THINK IT'S THOSE TWO ISSUES THAT EVERYONE NEEDS TO WEIGH AND MAKE 5 6 SOME SORT OF DECISION ABOUT. 7 DR. PENHOET: CLARIFY THE INTERMEDIATE 8 POSITION AGAIN, PLEASE. 9 DR. HALL: INTERMEDIATE POSITION IS THAT 10 PEOPLE ON THE COMMITTEE WOULD NOT BE ABLE TO APPLY FOR A GRANT AS PRINCIPAL INVESTIGATOR OR TO RECEIVE MONEY 11 FROM THE GRANT, EMPLOYED BY THE GRANT. I THINK THIS IS 12 THE SAME ONE WE HAVE, IN ONE OTHER CASE, PERHAPS FOR 13 14 THE ICOC, AS I RECALL. BUT, FOR EXAMPLE, WE HAVE IN 15 OUR TRAINING GRANTS RFA, WE HAVE STATED THAT EVERYBODY

16 THAT HAS A TRAINING GRANT PROGRAM MUST HAVE A COURSE ON 17 THE ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF STEM CELL RESEARCH. AND, FOR EXAMPLE, YOU COULD IMAGINE A 18 SITUATION UNDER WHICH SOMEBODY ON OUR ETHICS STANDARDS 19 20 COMMITTEE WHO IS AN ETHICIST MIGHT BE A PARTICIPANT OR 21 MIGHT ACTUALLY TEACH OR ORGANIZE SUCH A COURSE WHICH WOULD NOT BE -- THEY WOULDN'T RUN THE TRAINING PROGRAM, 22 23 BUT THEY WOULD CONTRIBUTE TO IT IN THAT WAY.

LET ME JUST SAY, IN GENERAL, THAT WE WILLFACE THIS ISSUE LATER OF WHETHER OR NOT AND HOW TO

1 TREAT THIS VERY IMPORTANT AREA OF THE ETHICAL 2 IMPLICATIONS OF STEM CELL RESEARCH. AND ONE PREVALENT IDEA IS THAT THIS IS BEST DONE NOT BY GIVING GRANTS 3 4 SPECIFICALLY FOR THE AREAS OR THESE QUESTIONS, BUT HAVING THEM AS PART OF OTHER GRANTS. THAT IS, TO HAVE 5 6 THE ETHICAL AND SOCIAL -- THE ETHICISTS AND POLICY 7 PEOPLE WORKING WITH SCIENTISTS IN ORDER TO WORK ON 8 THESE ISSUES AND HAVE THEM AS PART OF LARGER GRANTS. 9 I'M SORRY THAT'S NOT VERY WELL PUT, BUT AT ANY RATE 10 MAYBE YOU CAN --

CHAIRMAN KLEIN: WE DID DISCUSS THE ISSUE AT 11 LENGTH IN THE LAST MEETING. DR. KESSLER ASKED US TO 12 13 BRING IT BACK SINCE WE HAD A SIGNIFICANT LENGTH OF TIME TO TALK ABOUT IT. HE FELT IT WAS AN IMPORTANT POINT TO 14 15 ALLOW THE ETHICISTS, WHO ARE SOME OF THE BEST IN THE 16 COUNTRY, TO REALLY PARTICIPATE IN SOME OF THESE COURSES THAT ARE GOING TO BE TAUGHT AND DESIGNING SOME OF THESE 17 COURSES THAT WOULD REALLY ADVANCE THE STANDARDS AROUND 18 THE COUNTRY AND IN CALIFORNIA. BUT IT'S OPEN TO THE 19 20 BOARD. WHAT'S THE BOARD'S PLEASURE? ANY BOARD 21 COMMENTS? DR. MURPHY.

22 DR. MURPHY: MR. CHAIRMAN, LAST TIME TOO,
23 ZACH, WE DECIDED THAT CALIFORNIANS COULD BE ON THE
24 STANDARDS COMMITTEE.

25 DR. HALL: THAT ISSUE WAS DECIDED.

1 DR. MURPHY: IT IS REALLY CONSISTENT IF WE 2 HAD THE POLICY THAT SOMEONE COULD BENEFIT FROM THESE GRANTS WITHOUT BEING A PI ON THE GRANT. 3 4 CHAIRMAN KLEIN: OKAY. 5 DR. PENHOET: I'M GOING TO MAKE THE MOTION 6 THAT WE ADOPT THE INTERMEDIATE PROPOSAL WHICH IS THEY 7 CANNOT BE A PI, NOR BENEFIT FINANCIALLY DIRECTLY, BUT 8 CAN BE A MEMBER OF A GRANT. 9 DR. PIZZO: SECOND. 10 CHAIRMAN KLEIN: MOTION IS MADE AND SECONDED. ANY ADDITIONAL BOARD DISCUSSION? ANY COMMENTS FROM THE 11 PUBLIC? SEEING NO COMMENTS FROM THE PUBLIC, WE'D LIKE 12 то --13 MS. SAMUELSON: CALL THE QUESTION. 14 CHAIRMAN KLEIN: -- CALL THE QUESTION. ALL 15 16 IN FAVOR. OPPOSED. AND VERY QUICKLY, JUST TO GET ON THE RECORD 17 VERY QUICKLY, DAVID, THE CASTLE-DEGETTE BILL ON THE 18 FEDERAL LEVEL THAT WOULD EXPAND THE PRESIDENTIAL LINES, 19 20 SPECTER-HARKIN IN THE SENATE UP THIS WEEK. IS THERE A 21 MOTION THAT WE CAN MAKE TO SUPPORT THAT BILL? 22 (MOVED BY MULTIPLE MEMBERS.) 23 DR. PRIETO: SECOND. CHAIRMAN KLEIN: DAVID. DR. PRIETO SECOND. 24 25 ANY BOARD DISCUSSION?

1 MS. SAMUELSON: THIS ISN'T A FLIPPANT ACTION. 2 WE'VE ALL STUDIED THIS VERY CAREFULLY, AND WE KNOW YOU'VE STUDIED IT ON AN ENCYCLOPAEDIC LEVEL, AND I 3 4 THINK IT'S IMPORTANT WE TAKE A POSITION. 5 CHAIRMAN KLEIN: GAYLE WILSON AND I WENT TO 6 WASHINGTON, D.C., MET WITH CASTLE AND DEGETTE AND MET 7 WITH SEVERAL MEMBERS OF THE CALIFORNIA DELEGATION. 8 THIS IS SOMETHING THAT'S BEEN IN THE PROCESS FOR 9 MONTHS. AND I WOULD TELL YOU THAT GAYLE WILSON IS 10 EXTRAORDINARILY EFFECTIVE IN WASHINGTON, D.C., AND THE GOVERNOR'S OFFICE IS EXTRAORDINARILY HELPFUL AND 11 COMMITTED AND EFFECTIVE IN HELPING US WITH THIS. 12 MS. SAMUELSON: CALL THE QUESTION. 13 CHAIRMAN KLEIN: CALL THE QUESTION. ANY 14 15 PUBLIC COMMENT ON THIS? NO. 16 MS. WILSON: I'D LIKE TO MAKE ONE COMMENT. 17 IT MAY BE UP TOMORROW, AND THERE ARE CALIFORNIANS WHO ARE NOT GOING TO VOTE FOR THIS. SO NOW IS THE TIME TO 18 19 WEIGH IN. 20 DR. PIZZO: I SPOKE WITH TWO OF THEM ON MY 21 WAY HERE TODAY. AND ONE OF THEM, ISSA, IS STILL 22 UNCLEAR, AND THE SECOND IS RADANOVICH --23 CHAIRMAN KLEIN: CAN WE DO THIS AND THE 24 COORDINATION AFTER -- DR. LEVEY. I WANT TO DO THIS. 25 WE'LL TALK ABOUT COORDINATION AFTER WE HAVE HAD THE

VOTE. I'D LIKE TO CALL THE QUESTION. ALL IN FAVOR.
 OPPOSED.

THANK YOU, DR. LEVEY. 3 4 (APPLAUSE.) CHAIRMAN KLEIN: OKAY. IN TERMS OF 5 6 COORDINATION, THIS IS VERY IMPORTANT. GAYLE WILSON 7 PRESENTS AN EXTREMELY IMPORTANT POINT HERE. GAYLE, 8 COULD YOU CONTINUE SPEAKING TO THIS ISSUE. 9 MS. WILSON: THERE ARE -- KIRK KLEINSCHMIDT 10 IS VERY CONVERSANT WITH WHICH DISTRICTS VOTED FOR PROP 71, WHAT THE VOTES ARE IN THE HOUSE PARTICULARLY. AND 11

13 AGAINST THIS. AND IF THEY ARE IN YOUR DISTRICT OR YOU 14 ARE IN THEIR DISTRICT, NOW IS THE TIME TO CALL THEM.

THERE ARE DEFINITELY SOME CALIFORNIANS WHO WILL VOTE

15 DR. BRYANT: CAN WE KNOW WHO THEY ARE?

12

16 MS. WILSON: KIRK WILL BE ABLE TO TELL YOU.
17 I KNOW WHO SOME OF THEM ARE. IF I WERE YOU, I WOULD
18 JUST ASK KIRK LATER. HE CAN TELL YOU.

CHAIRMAN KLEIN: KIRK, COULD YOU JUST TAKE
 THE MIC AND TELL US WHO THE POSSIBLE YESES ARE WHO ARE
 NOT YET IN THE YES COLUMN? I POINT OUT THERE'S BEEN AN
 EXTRAORDINARY INCREASE IN THE NUMBER OF CALIFORNIANS
 VOTING YES SINCE PROPOSITION 71 PASSED.

24 MR. KLEINSCHMIDT: THE MEMBERS FROM25 CALIFORNIA THAT I'VE BEEN TOLD ARE IMPORTANT PEOPLE TO

1 COMMUNICATE POSITIONS WITH ARE CONGRESSMAN LEWIS,

2 CONGRESSMAN CUNNINGHAM, CONGRESSMAN DREIER, CONGRESSMAN3 MCKEON, AND CONGRESSMAN ISSA.

4 DR. PIZZO: YOU THINK THEY'RE VOTING --5 MR. KLEINSCHMIDT: I'VE JUST BEEN TOLD THAT 6 THEY'RE GETTING A LOT OF PRESSURE, AND SO IT'S JUST 7 IMPORTANT TO COMMUNICATE WITH THEM.

8 DR. PIZZO: I SPOKE WITH ISSA'S OFFICE ON THE 9 WAY HERE, AND HE HAS NOT MADE UP HIS MIND YET. WASN'T 10 CLEAR WHERE HE IS. BUT ON THE OTHER HAND, RADANOVICH, 11 I SPOKE WITH HIS STAFFER AS WELL, AND THEY SAID THAT 12 HE'S ABSOLUTELY AGAINST IT ON RELIGIOUS GROUNDS, SO I 13 DON'T KNOW WHAT WE CAN DO THERE.

CHAIRMAN KLEIN: RADANOVICH. IF WE COULD DO 14 15 THIS, KIRK, IF YOU COULD SEND E-MAILS TO THE BOARD 16 MEMBERS FOR THEIR INFORMATION ON THESE MEMBERS AND 17 THEIR CONTACT INFORMATION SO THEY CAN MAKE AN INDEPENDENT DECISION WHO THEY COULD REACH OUT TO AND IF 18 THEY COULD DO SO IMMEDIATELY. THE VOTE COUNT IN THE 19 20 HOUSE WAS APPROXIMATELY 230 BEFORE THE PRESIDENT'S 21 THREATENED VETO, WITH 201 CO-SPONSORS AND MORE THAN 50 VOTE COUNT IN THE SENATE FOR THIS. 22

23 THE INDIVIDUALS THAT ARE ON THE FENCE HERE
24 NEED TO KNOW THAT WE'RE VERY STRONGLY SUPPORTIVE OF
25 THEM AND WILL BACK THEM UP. GAYLE WILSON AND I SAW

DAVID DREIER, CONGRESSMAN DAVID DREIER'S STAFF IN
 WASHINGTON, D.C. THEY WERE QUITE SUPPORTIVE. IN FACT,
 I BELIEVE WERE QUITE HELPFUL ACTUALLY IN GETTING THE
 RULES COMMITTEE TO AGREE TO BRING THIS TO A VOTE. SO
 IF HIS VOTE IS NOT KNOWN AT THIS POINT, IT'S BECAUSE
 HE'S UNDER EXTRAORDINARY PRESSURE, BUT HE DID SUPPORT
 PROPOSITION 71 PUBLICLY.

8 ADDITIONALLY, GAYLE WILSON, MAYBE YOU COULD 9 REPORT HOW JERRY LEWIS CONVEYED HIS SUPPORT OF OUR 10 POSITION IN THE PHONE CALL WHILE WE WERE IN CONGRESSMAN 11 DREIER'S OFFICE.

MS. WILSON: WELL, I DON'T SPECIFICALLYREMEMBER THAT.

14 CHAIRMAN KLEIN: WITHOUT QUOTING HIM, BECAUSE
15 I CAN'T REALLY QUOTE HIM EITHER, GAYLE, IS THAT --

16 MS. WILSON: HE WAS ON THE FLOOR. THAT'S 17 RIGHT.

18 CHAIRMAN KLEIN: HE WAS ON THE FLOOR, AND HE
19 HAD HIS STAFF CALL TO SAY THAT HE WAS COMPLETELY BEHIND
20 WHAT WE WERE DOING WITH PROP 71.

21 NOW, THIS IS MUCH MORE RESTRICTIVE THAN PROP 22 71 BECAUSE CASTLE-DEGETTE ONLY DEALS WITH EXPANDING THE 23 LINES THROUGH ACCESS IN VITRO FERTILIZATION, CELLS THAT 24 ARE DIVIDED FOR LESS THAN 14 DAYS, THERE'S INFORMED 25 CONSENT, AND THEY WOULD OTHERWISE BE THROWN AWAY. SO

1 IT'S VERY RESTRICTIVE.

2 DR. PIZZO: BOB, DO YOU HAVE A SENSE -- LET'S ASSUME OPTIMISTICALLY THAT IT PASSES IN THE HOUSE AND 3 4 THEN IN THE SENATE AS WELL AND THAT THE PRESIDENT THEN VETOES IT. DO YOU HAVE A SENSE, GAYLE, WHAT THE VOTES 5 6 ARE LIKELY IN TERMS OF OVERTURNING THE VETO. 7 MS. WILSON: I'D BE SURPRISED IF THEY COULD 8 OVERTURN THE VETO. 9 DR. PIZZO: THAT'S MY SENSE BECAUSE IT'S 10 RIGHT TOO CLOSE. MS. WILSON: I THINK THE MOMENTUM IS STILL ON 11 OUR SIDE JUST TO HAVE A VOTE THAT PASSES. 12 DR. PIZZO: AT LEAST GET THE VOTE PASSED 13 WOULD BE A REALLY IMPORTANT START. 14 15 CHAIRMAN KLEIN: I THINK GETTING A VOTE TO 16 PASS IT IS A VERY IMPORTANT MESSAGE FOR THE COUNTRY. AND SO ANYTHING WE CAN EACH INDIVIDUALLY DO TO ADVANCE 17 THAT AGENDA WOULD BE VERY HELPFUL. 18 WHILE, KIRK, YOU'RE THERE, PERHAPS YOU COULD 19 ALSO JUST COVER THE OTHER FEDERAL. SENATOR ORRIN 20 21 HATCH, AS WE ALL KNOW, IS A LEADING PRO LIFE 22 REPUBLICAN, AND SENATOR FEINSTEIN AUTHORED AND CONTINUE 23 TO AUTHOR THIS YEAR A BILL TO PROHIBIT HUMAN PRODUCTIVE 24 CLONING. AND WHY DON'T YOU COVER THAT BILL AS WELL AS 25 CONGRESSWOMAN --

1 MR. KLEINSCHMIDT: IT'S IN THE PACKET THAT 2 YOU RECEIVED FOR THIS MEETING. HR 1822 IS BY 3 CONGRESSMAN MARY BONO, AND THE COMPANION BILL IN THE 4 SENATE IS SENATE BILL 876 BY SENATORS HATCH AND 5 FEINSTEIN. AS BOB JUST MENTIONED, THIS WOULD PROHIBIT 6 REPRODUCTIVE CLONING, BUT PERMIT THERAPEUTIC CLONING OR 7 SCNT.

8 THE OTHER PIECE THAT WE'RE FOLLOWING CLOSELY 9 IS HR 1357 BY CONGRESSMAN WELDON AND SENATE BILL 658 BY 10 SENATOR BROWNBACH. AND THIS PARTICULAR PIECE OF 11 LEGISLATION WOULD BAN BOTH REPRODUCTIVE AS WELL AS 12 THERAPEUTIC CLONING. AND THE HOUSE VERSION OF THIS 13 MEASURE HAS PASSED IN TWO PREVIOUS CONGRESSES.

DR. PIZZO: JUST ONE, MAYBE IT'S A MINOR 14 15 COMMENT, BUT I THINK IT'S RELEVANT. AND THAT IS, WHEN 16 THE TERM "THERAPEUTIC CLONING" IS USED, IT HAS A 17 NEGATIVE IMPACT ON INDIVIDUALS SUPPORTING IT. AND SO I THINK ALL THE SURVEYS THAT HAVE BEEN DONE DEMONSTRATE 18 THAT IF WE CAN REFER TO THIS BY SOME OTHER NAME, AND 19 20 THE APPROPRIATE NAME IS SOMATIC CELL NUCLEAR TRANSFER 21 AT THIS POINT, THAT ACTUALLY RENDERS A MORE FAVORABLE VIEW. I THINK THAT'S WHERE WE COME AT ODDS WITH THE 22 23 ADMINISTRATION THAT CLEARLY PREFERS TO USE THE CLONING 24 TERM BECAUSE IT EVOKES PUBLIC FEAR.

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25 DR. PRIETO: I THINK THAT'S A VERY GOOD
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POINT, THAT WE NEED TO TALK IN TERMS OF, AS I THINK DR.
 PIZZO ALSO SAID EARLIER TODAY, THIS IS THE CREATION OF
 PATIENT-SPECIFIC CELL LINES AND DISEASE-SPECIFIC CELL
 LINES TO BRING US A STEP CLOSER TO CURES. AND USE THAT
 SORT OF TERMINOLOGY BECAUSE THAT IS WHAT WE'RE TALKING
 ABOUT.

7 DR. HALL: IF WE'RE TRYING TO BE SIMPLER, I 8 THINK JUST NUCLEAR TRANSFER IS OFTEN USED. I THINK IN 9 THE NATIONAL ACADEMIES REPORT THEY TRIED TO DO THAT. 10 DR. PIZZO: THAT WOULD BE A VERY GOOD THING, 11 ZACH, AS WELL. I THINK ANYTHING THAT AVOIDS THE TERM 12 "CLONING" IS A GOOD THING. AND I KNOW DR. BERG WAS

HERE EARLIER TODAY. HE AND I HAVE HAD MANY DEBATES ABOUT THIS, BUT HE, I THINK, NOW AGREES THAT NOT USING CLONING IS A GOOD IDEA.

16 DR. PRIETO: I STILL THINK IT'S IMPORTANT 17 THAT THIS BE UNDERSTANDABLE TO THE PUBLIC BECAUSE 18 PUBLIC SUPPORT FOR THIS ENTERPRISE -- AND ALTHOUGH 19 NUCLEAR TRANSFER IS ACCURATE, I DON'T THINK THAT MEANS 20 MUCH TO THE LAY PUBLIC; WHEREAS, PATIENT-SPECIFIC CELL 21 LINES AND DISEASE-SPECIFIC CELL LINES MEANS SOMETHING 22 THAT I THINK PEOPLE CAN UNDERSTAND.

23DR. PIZZO:THAT'S A GOOD TERM EXACTLY.I24AGREE.

25 CHAIRMAN KLEIN: I THINK IT'S ALSO VERY

1 IMPORTANT TO RECOUNT A DISCUSSION WE HAD WITH 2 CONGRESSMAN CASTLE WHERE IN SUGGESTING TO HIM THAT IN CALIFORNIA PEOPLE WERE QUITE RECEPTIVE DURING THE 3 4 CAMPAIGN TO UNDERSTANDING THIS IN THE CONTEXT THAT THIS IS A SOLID AREA OF FAMILY VALUES WHERE FAMILIES 5 6 HISTORICALLY HAVE BEEN GIVEN THE RIGHT TO ACCESS AND TO 7 HAVE THE COUNTRY DEVELOP THE BEST MEDICAL TECHNOLOGIES 8 AND THERAPIES FOR THEIR CHILDREN, THEIR AGING PARENTS, 9 AND THEIR SPOUSES. AND TO PROHIBIT THIS DEVELOPMENT OF 10 THESE THERAPIES IS TO REALLY PROHIBIT PARENTS FROM HAVING THE CHOICE OF ACCESSING THERAPIES FOR THEIR 11 CHILDREN, TO PROHIBIT PARENTS FROM ACCESS OF THERAPIES 12 13 FOR THEIR AGING PARENTS.

14 IT'S REALLY A GOVERNMENT INTERVENTION IN THE 15 RIGHTS OF THE FAMILY TO GET THE BEST HEALTHCARE IN THIS 16 NATION. AND IT'S TAKING AWAY RIGHTS THAT HAVE BEEN 17 SACROSANCT AND HELD BY THE FAMILY FOR A VERY LONG TIME 18 IN THIS COUNTRY.

SO WITH MANY LIBERTARIANS IN THIS COUNTRY,
THEY REJECT THIS PROHIBITION ON THE GROUNDS THAT IT
DENIES THE CHOICE OF THE FAMILY, AND IT PUTS GOVERNMENT
IN THE PLACE OF MAKING THAT DECISION INSTEAD OF
ALLOWING THE FAMILY ITS FUNDAMENTAL RIGHTS TO TAKE CARE
OF THEIR CHILDREN AND THEIR PARENTS.

25 THAT SEEMS TO HAVE A GREAT RESONANCE, AND I

1 THINK, GAYLE, HAD A GREAT RESONANCE IN WASHINGTON.

2 DR. PRIETO: I DON'T THINK IT SHOULD ESCAPE 3 ANYONE'S ATTENTION EITHER THAT THE SOUTH KOREANS 4 LAUNCHED SPUTNIK IN THIS ARENA LAST WEEK.

5 CHAIRMAN KLEIN: ALL RIGHT. KIRK, COULD YOU, 6 WHILE YOU'RE HERE, INFORMATIONALLY ALSO GO THROUGH AND 7 JUST GIVE US A QUICK UPDATE ON THE OTHER STATE 8 LEGISLATION THAT, IN FACT, THE STAFF RECOMMENDATION IS 9 TO BE QUITE SUPPORTIVE OF?

10 MR. KLEINSCHMIDT: SURE. COUPLE OF THEM WERE MENTIONED EARLIER. ASSEMBLY CONCURRENT RESOLUTION 1 IS 11 12 SPONSORED BY ASSEMBLYWOMAN NEGRETE MCLEOD OF L.A., AND THIS WOULD BASICALLY PUT THE LEGISLATURE ON RECORD 13 14 ENCOURAGING US TO, INDEED, PASS STRONG CONFLICT OF 15 INTEREST POLICIES AND TO REPORT OUR FINDING FOR OUR 16 POLICIES TO THE LEGISLATURE BY JULY 1ST. AND WITH THE BOARD'S ACTION TODAY, YOU, IN FACT, HAVE MADE THAT 17 DEADLINE AND WILL BE ABLE TO REPORT ALL THE POLICIES 18 THAT WE'VE PASSED TO DATE. THAT ONE HAS PASSED THE 19 20 SENATE -- I'M SORRY -- ASSEMBLY AND IS IN THE SENATE 21 HEALTH AT THE CURRENT TIME.

ASSEMBLY CONCURRENT RESOLUTION 24 BY
ASSEMBLYMAN GENE MULLIN IS AN EXPANSION OF ASSEMBLY
CONCURRENT RESOLUTION 252, WHICH IS THE ONE THAT SUE
BRYANT AND MICHAEL GOLDBERG ARE PARTICIPATING WITH,

WHICH IS TO ASK THIS COMMITTEE TO COME UP WITH BEST
 PRACTICES POLICY TO TREAT INTELLECTUAL POLICY DEVELOPED
 FROM STATE FUNDS.

4 THE OTHER BILLS THAT WE ARE WATCHING CLOSELY, THERE'S A COUPLE OF THEM THAT WE'RE NOT ENCOURAGING YOU 5 6 TO TAKE POSITIONS ON TODAY, BUT SENATE BILL 18 BY 7 SENATOR DEBORAH ORTIZ. THIS MEASURE HAS A NUMBER OF DIFFERENT THINGS. THE PROVISION THAT'S FOCUSED ON THE 8 9 WORK OF THE INSTITUTE HAS TO DO WITH A STATE AUDIT THAT 10 WOULD BE REQUIRED TO BE COMPLETED AS CURRENTLY WRITTEN BY THE END OF JUNE OF 2006. AND THEN THERE WOULD BE 11 12 SUBSEQUENT AUDITS IN THE NEXT THREE YEARS.

13 IT ALSO HAS SOME LANGUAGE HAVING TO DO WITH
14 PROHIBITION OF COMPENSATION FOR ANY EGG DONOR AND
15 DETAILS WHAT THAT POLICY WOULD BE, AS WELL AS DETAILS
16 OF INFORMED CONSENT PROVISIONS FOR ANY POTENTIAL EGG
17 DONOR.

CHAIRMAN KLEIN: LET ME JUST SUGGEST THAT THE 18 19 ISSUES WITH INFORMED CONSENT ARE ONLY TO MAKE IT CLEAR 20 THAT THERE'S NO INTENTION TO PROHIBIT THE AVAILABILITY 21 OF PRIOR LINES THAT MAY HAVE BEEN DEVELOPED UNDER DIFFERENT INFORMED CONSENT PROVISIONS. THERE'S SOME 22 23 VERY TECHNICAL ISSUES TO MAKE SURE WE DON'T CREATE LEGAL PROBLEMS FOR RESEARCH DEALING WITH BIOLOGICAL 24 25 MATERIALS THAT MAY HAVE ORIGINATED IN CALIFORNIA BEFORE

1 THESE NEW MEDICAL STANDARDS WERE IN PLACE.

2 STILL THE NIH INFORMED CONSENT REGULATIONS
3 WERE ALREADY IN PLACE. SO THE VERY HIGH STANDARD WAS
4 THERE. WE'VE JUST ENHANCED THAT STANDARD.

5 THE ADDITIONAL PROVISION IN THAT BILL IS THAT 6 SHE -- ONE COULD READ IT TO UNDERSTAND THAT WE'RE BEING 7 ASKED TO UNDERTAKE A CANCER STUDY OF HYPEROVULATION 8 DRUGS. THE CONSULTANT FOR SENATOR MIGDEN AND SENATOR 9 MIGDEN HAVE INDICATED TO US THEY DO NOT READ IT THAT 10 WAY AND WOULD CLARIFY IT IN COMMITTEE, THAT WE'RE ENCOURAGED TO DO A STUDY, BUT WE'RE NOT REQUIRED TO 11 UNDERTAKE A STUDY. AND WE HAVE CERTAINLY EXPRESSED THE 12 FACT THAT IT'S NOT THE MISSION OF THIS INSTITUTE TO 13 14 UNDERTAKE BROAD-SCALE MEDICAL STUDIES IN THIS AREA. 15 WE HAVE A VERY FOCUSED MISSION, AND THE 16 DEPARTMENT OF HEALTH IN THE STATE MIGHT BE A MORE APPROPRIATE PLACE TO UNDERTAKE THE STUDY. NATIONAL 17 CANCER INSTITUTE HAS UNDERTAKEN THE STUDY ON A VERY 18 BROAD SCALE. AND, KIRK, COULD YOU GIVE US THE CITATION 19 OF THAT, AND WE CAN PUT THAT STUDY UP ON OUR WEBSITE. 20 21 MR. KLEINSCHMIDT: I HAVE IT OVER THERE, BUT I DON'T HAVE IT WITH ME AT THE PODIUM. 22 23 CHAIRMAN KLEIN: WE CAN PUT THAT CITATION UP

ON OUR WEBSITE AND E-MAIL THE INFORMATION TO EVERYONE.NATIONAL CANCER INSTITUTE HAS UNDERTAKEN THAT STUDY.

1 THE BASIC CONCLUSIONS OF THAT STUDY IS THAT WHILE WOMEN 2 WHO HAVE FERTILITY ISSUES OR CHALLENGES SEEM TO HAVE SOME GENETIC CONNECTION TO A STRONGER PROCLIVITY FOR 3 4 CANCER, BUT THERE IS NO STATISTICAL DIFFERENCE BETWEEN 5 THOSE WHO HAVE CANCER AND UNDERGO IN VITRO 6 FERTILIZATION AND THOSE WHO HAVE CANCER AND DON'T 7 UNDERGO IN VITRO FERTILIZATION. IS THAT CORRECT, DR. 8 HENDERSON? DR. HENDERSON: THAT'S CORRECT. 9 10 CHAIRMAN KLEIN: IT'S ENCOURAGING AND I PROPERLY RESTATED FROM MEMORY ONE OF MANY SCIENTIFIC 11 STUDIES. IT'S VERY IMPORTANT FOR PEOPLE TO REALIZE A 12 VERY THOUGHTFUL STUDY HAS BEEN UNDERTAKEN BY THE 13 NATIONAL CANCER INSTITUTE ON THIS VERY SUBJECT. AND SO 14 THE QUESTION IS WHY IS IT THAT THAT STUDY IS 15 16 INADEQUATE. THE PRODUCTIVE RIGHTS ORGANIZATIONS IN 17 THIS COUNTRY BELIEVE THAT THAT STUDY IS, IN FACT, ADEQUATE, BUT THAT IS NOT WITHIN OUR MISSION STATEMENT. 18 19 IT'S A DIFFERENT MISSION STATEMENT. 20 MR. KLEINSCHMIDT: LAST COMMENT ABOUT SB 18 21 IS THAT THERE IS A PROVISION REQUESTING US TO DO -- I SHOULD SAY ENCOURAGING THE ICOC TO REVIEW EXISTING 22 23 STUDIES CONCERNING THE HEALTH RISKS AND BENEFITS OF 24 OVARIAN STIMULATION DRUGS FOR ASSISTED OOCYTE

25 PRODUCTION AND IDENTIFY GAPS IN CURRENT KNOWLEDGE BASED

ON THE HEALTH RISKS AND BENEFITS TO AND TO TAKE FURTHER
 RESEARCH AS NECESSARY. SO THE INTERPRETATION IS THAT
 IT'S INTENT LANGUAGE USING THIS WORD "EXPECTATION,"
 IT'S A BIT OF CONCERN.

DR. HENDERSON: I SHOULD JUST SAY FOR 5 6 EVERYBODY'S INTEREST THAT THERE'S A VERY LARGE POOLING 7 STUDY OF OVARIAN CANCER CASES GOING ON IN THE U.K. AND 8 THE UNITED STATES NOW TAKING TOGETHER SEVERAL THOUSAND 9 CASES OF OVARIAN CANCER AND MATCHED CONTROLS WHERE THIS 10 SUBJECT, THAT IS, THE ROLE, POTENTIAL ROLE, OF STIMULATING DRUGS, IS BEING INVESTIGATED AGAIN. AND 11 THAT REPORT, I THINK, IS DUE OUT WITHIN THREE TO SIX 12 13 MONTHS.

14 CHAIRMAN KLEIN: IT WOULD BE VERY HELPFUL,
15 DR. HENDERSON, IF WE COULD BRING THAT ON THURSDAY WITH
16 US TO THE HEARING, THE CITATIONS TO THAT REPORT.

17 KIRK, I THINK WE'VE ADEQUATELY COVERED THE
18 SUBJECT. AND KIRK HAS AN EXTRAORDINARY JOB TO DO WITH
19 FEDERAL AND STATE LEGISLATION MOVING CONCURRENTLY UNDER
20 TREMENDOUS PRESSURE.

I EXPECT TO BE DEDICATING A HUGE PORTION OF
MY OWN TIME TO THIS IN THE COMING 60 DAYS AS WELL.
KIRK, ANY OTHER ITEMS THAT WE NEED TO COVER?
MR. KLEINSCHMIDT: THAT'S IT. THERE IS A
RESOLUTION IN YOUR MATERIALS REGARDING THE STATE

1 LEGISLATION.

2 CHAIRMAN KLEIN: WHAT WE ATTEMPTED TO DO IS BREAK OUT THE MOST IMPORTANT PART OF THAT RESOLUTION, 3 4 AND WE CAN LOOK FORWARD POTENTIALLY TO PASSING A MORE FORMAL RESOLUTION THAT COVERS ALL THE REST OF THE STATE 5 6 LEGISLATION AT THE NEXT MEETING, BUT WE GOT THROUGH THE 7 ACTION RELATED TO SCA 13, WHICH IS THE IMMEDIATE ITEM 8 ON WHICH AN OPPOSITION STATEMENT WAS NEEDED. 9 ON SB 18 WE DID NOT RECOMMEND OPPOSITION, 10 RATHER CONCERN, WHICH WE CAN EXPRESS WITHOUT A RESOLUTION. I THANK YOU VERY MUCH. 11 IS THERE -- IF THE BOARD PLEASES, I WOULD 12 13 TAKE PUBLIC COMMENT AND COMPLETE THIS MEETING. PUBLIC 14 COMMENT? YES. MS. MEADE: THANK YOU. MY NAME IS ANN MEADE, 15 16 AND I'M AN INTERESTED MEMBER OF THE PUBLIC. I'VE BEEN LISTENING TO THE DISCUSSION OF THE LEGISLATION, STATE 17 AND FEDERAL, AND REALIZING I'VE BEEN FOLLOWING THIS 18 WITH GREAT INTEREST IN THE PAPERS, BUT IT'S HARD TO 19 20 KNOW THE IMPORT OF THE LEGISLATION AND WHAT TO DO. 21 YOU'VE GOT A HUGE POPULAR BASE OF SUPPORT IN 22 THIS STATE, BUT PEOPLE DON'T REALLY UNDERSTAND WHAT THE 23 ISSUES ARE. IT'S HARD TO UNDERSTAND IT IN THE PRESS. I WONDERED IF, SHORT OF ADVOCACY, THIS IS KIND OF A 24 25 QUESTION FOR THE COUNSEL, IF YOU COULD PUT SOMETHING

LIKE THE LEGISLATIVE ANALYSIS ON YOUR WEBSITE JUST FOR
 STARTERS OR -- AND EVEN MORE SO, IS THERE ANY MORE
 ACTIVE WAY TO REACH OUT TO THE PUBLIC, AGAIN SHORT OF
 ADVOCACY, BUT OF LETTING THE PEOPLE THAT VOTED FOR THIS
 KNOW THAT THERE IS A NEED FOR PUBLIC ACTION, FOR
 EXAMPLE, AND HOW TO UNDERSTAND THE ISSUES, HOW TO
 INTERPRET THEM? THANK YOU.

8 CHAIRMAN KLEIN: THANK YOU VERY MUCH. JAMES 9 HARRISON, MAYBE YOU COULD SKETCH FOR US THE BROAD 10 DIMENSION OF PUBLIC EDUCATION THAT WE CAN PARTICIPATE 11 IN AND WHAT THE GUIDELINES WOULD BE.

12 MR. HARRISON: THE INSTITUTE CAN CLEARLY PUT 13 ANALYSIS OF THIS LEGISLATION ON ITS WEBSITE IN AN 14 EFFORT TO EDUCATE THE PUBLIC, AS WELL AS MAKE IT CLEAR 15 TO THE PUBLIC THE POSITIONS THAT ITS TAKEN TODAY ON THE 16 VARIOUS PIECES OF LEGISLATION.

17 THE LINE TENDS TO BE DRAWN AT EFFORTS
18 DIRECTED AT THE GRASS ROOTS LEVEL, TO VOTERS, TO HAVE
19 THEM THEN CONTACT THEIR LEGISLATORS.

20 CHAIRMAN KLEIN: MY UNDERSTANDING IS THAT THE 21 INSTITUTE CAN RESPOND TO ORGANIZATIONS' REQUESTS FOR 22 INFORMATION AND EXPLANATIONS OF OUR POSITIONS SO THAT 23 THE CALIFORNIA MEDICAL ASSOCIATION, THE NATIONAL 24 MEDICAL ASSOCIATION, THE GOLDEN STATE MEDICAL

ASSOCIATION, FOR EXAMPLE, WHO WERE SUPPORTERS, CAN

25

UNDERSTAND WHAT OUR POSITION IS AND WHY WE'VE TAKEN THE
 POSITION; IS THAT CORRECT?

MR. HARRISON: THAT'S CORRECT. 3 4 CHAIRMAN KLEIN: AND THAT ALSO OBVIOUSLY INVOLVES PATIENT ADVOCACY ORGANIZATIONS AND 5 6 INSTITUTIONS. MR. REYNOLDS. 7 MR. REYNOLDS: THANK YOU. REGARDLESS OF THE 8 FATE OF THE SB 18, I ENCOURAGE THE INSTITUTE AND THE 9 BOARD MEMBERS TO TAKE A SERIOUS LOOK AT THE VARIOUS 10 DATA ON THE EFFECTS OF HYPER-STIMULATING DRUGS ON THE LONG-TERM HEALTH EFFECTS ON WOMEN. MY UNDERSTANDING, 11 AND I'M SPEAKING SECONDHAND, AS MY COLLEAGUES WHO 12 AREN'T PRESENT ARE THE EXPERTS ON THIS, IS THAT THERE'S 13 NOT CONSENSUS IN THE REPRODUCTIVE HEALTH FIELD ABOUT 14 15 THE LONG-TERM HEALTH EFFECTS OF THESE DRUGS. I WOULD 16 BE GLAD TO OFFER TO GET TOGETHER SOME DATA AND 17 SCIENTIFIC STUDIES AND FORWARD THAT TO YOU FOR YOUR 18 REVIEW. CHAIRMAN KLEIN: THAT WOULD BE HELPFUL. AND 19 20 WE WILL FORWARD TO YOU THE STUDIES THAT DR. HENDERSON 21 IS REFERENCING SO THAT YOU CAN MONITOR THOSE AS WELL. 22 BE INTERESTED IN YOUR VIEW OF THEIR OUTCOME. IT MAY 23 SUBSTANTIALLY ADD TO THE INFORMATION AVAILABLE.

24 MR. REYNOLDS: YES.

25 CHAIRMAN KLEIN: ADDITIONAL PUBLIC COMMENT?

1 MR. SCHUPPENHAUER: JUST A COMMENT ON THE 2 CANCER IMPACT OF USING HORMONES OUT OF THE IN VITRO FERTILIZATION SET, THAT SCIENTIFIC DISCUSSION HAS BEEN 3 4 FAIRLY CONTENTIOUS. WANT TO GO BACK INTO THE END OF THE '90S. SOME OF THE RESEARCH WAS ACTUALLY DONE OUT 5 6 OF THE INSTITUTE OF ROBERT GALLO. AND WHEN I MENTION 7 THAT NAME, YOU WILL UNDERSTAND THAT THERE WAS A LOT OF 8 DEGREE OF SUSPECT ABOUT THE IMPACT, FOR INSTANCE, HCG, 9 THE IMPACT OF HCG ON VARIOUS CANCER FORMS THAT CAN GO 10 BOTH WAYS.

IF YOU GO BACK TO THE LITERATURE, THERE'S NOT
 A VERY SIMPLE DISCUSSION AND NOT VERY SIMPLE RESEARCH
 IN THERE; AND BECAUSE OF THE INVOLVEMENT OF DR. GALLO,
 A LOT OF THE RESEARCH WAS CONTENDED, ETC.

15 THE MAJOR POINT THAT I WANTED TO MAKE WAS 16 THAT JUST FROM AN OUTSIDER'S PERSPECTIVE WHEN I'M LOOKING AT THE POSITIONS YOU'RE TAKING, I THINK ONE OF 17 THE KEY REASONS WHY THE PROP 71 IS IMPORTANT FOR THE 18 STATE OF CALIFORNIA IS AN ECONOMIC REASON. AND I'M 19 20 REALLY MISSING THE ECONOMIC IMPACT OF \$3 BILLION BEING 21 SPENT, WHAT THAT MEANS FOR CALIFORNIA ON A GLOBAL 22 SCALE.

23 WE'RE TALKING ABOUT ETHICAL VALUES AND WE'RE
24 TALKING ABOUT ALL SORTS OF OTHER THINGS, BUT I THINK IT
25 IS VERY, VERY IMPORTANT FOR THE PUBLIC TO UNDERSTAND

1 THAT THE U.S. IS ALREADY BEHIND IN TERMS OF STEM CELL 2 RESEARCH. AND IF CALIFORNIA IS NOT CATCHING UP AND WE'RE LOSING ANYTHING THAT STATE OF CALIFORNIA HAS ON 3 4 THE ECONOMIC SIDE, YOU ARE AWARE OF THE \$50 MILLION 5 THAT WERE SPENT IN -- OR GRANTED IN NEW YORK JUST 6 YESTERDAY. AND THE CLEAR AND ONLY REASON WAS IN ORDER 7 TO MAKE NEW YORK UNIVERSITIES COMPETITIVE FROM A 8 SCIENTIFIC AND BUSINESS PERSPECTIVE. THANKS VERY MUCH. 9 CHAIRMAN KLEIN: THANK YOU. ANY ADDITIONAL PUBLIC COMMENT? MOTION TO ADJOURN? WALTER BARNES 10 INDICATES THAT HE HAS AN INFORMATIONAL ITEM TO PUT 11 12 FORWARD.

MR. BARNES: I'LL KEEP IT VERY SHORT. AT THE
LAST MEETING I MENTIONED TO ALL OF YOU THAT THERE WERE
MEMOS COMING OUT ON PER DIEM AND ON TRAVEL EXPENSES.
THESE ARE TO REFLECT THE POLICIES THAT YOU ADOPTED AT
THE APRIL MEETING. THOSE MEMOS ARE OUT NOW. THERE'S A
COPY OF THEM UNDER TAB 14 IN YOUR NOTEBOOKS.

WE'VE ALSO SEPARATELY SENT OUT TO YOU
ENROLLMENT FORMS SO THAT THAT THOSE OF YOU THAT WISH TO
RECEIVE PER DIEM CAN FILL THEM OUT AND BE ENTERED INTO
THE PAYROLLING SYSTEM SO THAT WE CAN BEGIN PAYING
THOSE. I'VE BEEN GETTING BOTH THE ENROLLMENT FORMS AS
WELL AS THOSE WHO HAVE INDICATED THAT THEY WANT TO
WAIVE IT AND GETTING THAT INFORMATION IN, SO I SHOULD

1 BE ABLE TO START PUTTING THAT STUFF INTO THE SYSTEM 2 THIS WEEK. SO YOU SHOULD BE STARTING TO GET REIMBURSEMENTS FROM THOSE PROBABLY WITHIN A TWO-WEEK 3 4 PERIOD. AND THEN AS YOU SUBMIT THEM ON A MONTHLY BASIS OR WEEKLY BASIS, AS THE CASE MAY BE, WE'LL GET THEM OUT 5 6 ТОО. 7 ANYWAY, THE OTHER THING IS THAT BOTH CLAIM 8 FORMS, THE TRAVEL EXPENSE CLAIM FORM AND THE PER DIEM 9 CLAIM FORM, ARE NOW ON THE WEBSITE, THE CIRM WEBSITE. 10 YOU LOOK FOR ADMINISTRATIVE INFORMATION, AND IT ALLOWS YOU TO FILL AND PRINT, SO YOU CAN ENTER IN ALL THE 11 INFORMATION ON BOTH FORMS, PRINT IT OUT, SIGN IT, 12 ATTACH ALL YOUR RECEIPTS, AND SEND IT IN. SO HOPEFULLY 13 14 THAT WILL BE A LITTLE EASIER THAN TRYING TO SEARCH

15 THROUGH THE GENERAL SERVICES WEBSITE FOR IT.

16 AND OBVIOUSLY, AS ALWAYS, IF YOU HAVE ANY
17 QUESTIONS, MY PHONE NUMBER IS ON THERE. GIVE ME A
18 CALL.

19DR. HENDERSON: I JUST WONDERED, DR. HALL, IF20YOU'VE HAD -- YOU HAD AN OPEN ITEM HERE FOR A REPORT21WITH NO DOCUMENTS. AND I WONDERED IF THERE WAS22ANYTHING ELSE AT THIS TIME.23CHAIRMAN KLEIN: THE REPORT THAT HE MADE

ADDRESSED THE CONFLICTS PROVISIONS.

25 DR. HALL: PRESIDENT'S REPORT, I DON'T KNOW

1 IF YOU WANT TO DO THAT AT THIS LATE DATE OR NOT. 2 CHAIRMAN KLEIN: IT'S THE PLEASURE --DR. HALL: HAPPY TO DO SO IF YOU WANT. 3 4 DR. HENDERSON: I JUST WANTED TO GIVE YOU THE 5 OPPORTUNITY. 6 CHAIRMAN KLEIN: WHY DON'T WE HEAR --7 DR. HALL: THERE IS ONE ITEM I WOULD LIKE TO 8 BRING TO THE ATTENTION OF THE COMMITTEE. SO FIRST IS 9 JUST TO LET YOU KNOW THAT IN THE -- WITH ALL THE 10 POLITICAL FIRESTORMS FLYING OVERHEAD, WE HAVE BEEN BUSY UNDERNEATH WITH OUR SCIENTIFIC ACTIVITIES. WE WERE 11 VERY PROUD TO ISSUE OUR FIRST RFA A WEEK AGO FRIDAY. 12 13 (APPLAUSE.) DR. HALL: WE HAVE BEGUN INTERVIEWS. AND 14 MARY MAXON AND ARLENE CHIU DID A FABULOUS JOB IN 15 16 GETTING THAT OUT. 17 WE HAVE INTERVIEWS FOR OUR SCIENTIFIC PROGRAM REVIEW OFFICERS. WE ARE BEGINNING THAT. WE ARE 18 SCHEDULING THE FIRST MEETING OF THE GRANTS REVIEWS AND 19 20 STANDARDS WORKING GROUP. WE'VE POSTED A JOB FOR THE 21 SENIOR STAFF OFFICER FOR THE STANDARDS WORKING GROUP, AND WE HAVE BEEN HARD AT WORK FINALIZING THE SCIENTIFIC 22 23 AND ADMINISTRATIVE PROGRAM FOR THE BUILDOUT OF THE NEW 24 HEADQUARTERS. 25 NOW, THE ONE THING I REALLY WANTED TO MENTION

1 TO YOU IS I HAVE TALKED BEFORE ABOUT A SCIENTIFIC 2 PRIORITIES MEETING WHOSE PURPOSE IS TO IDENTIFY 3 SCIENTIFIC MEDICAL OPPORTUNITIES AND BARRIERS TO 4 PROGRESS AND TO IDENTIFY WAYS IN WHICH SPECIFIC 5 INITIATIVES BY CIRM MIGHT ADVANCE THE FIELD. AND THE 6 RECOMMENDATIONS FROM THIS COMMITTEE WILL BE THE BASIS 7 FOR OUR OWN STRATEGIC PLANNING.

8 WE WANT TO INVITE BOTH CALIFORNIA SCIENTISTS 9 AND INTERNATIONAL EXPERTS. WE WILL HAVE SESSIONS THAT 10 ARE OPEN TO THE PUBLIC, AND WE HOPE THESE SESSIONS WILL 11 SERVE AS AN EDUCATIONAL AS WELL AS SCIENTIFIC PURPOSE.

12 WE ARE NOW IN DISCUSSION ABOUT A DATE, AND WE 13 ARE HOPING TO HAVE A MEETING IN LATE SEPTEMBER. WE DO 14 HAVE A DISTINGUISHED PLANNING COMMITTEE FOR THIS 15 MEETING, AND I WANTED TO LET YOU KNOW THAT. IT'S AN 16 INTERNATIONAL GROUP. WE HAVE PETER ANDREWS FROM 17 UNIVERSITY OF EDINBURGH, WHO'S ONE OF THE LEADING STEM CELL RESEARCHERS IN BRITAIN; WE HAVE GEORGE DALEY, 18 HARVARD MEDICAL SCHOOL; IAN DUNCAN FROM UNIVERSITY OF 19 WISCONSIN; RUSTY GAGE FROM THE SALK INSTITUTE; MYSELF, 20 21 DOUG MELTON FROM HARVARD; ED PENHOET AND JANET WRIGHT ON THE ICOC. 22

23 WE WILL BE MEETING SOON, AND OUR PURPOSE WILL 24 BE TO GO OVER THE FORMAT TO DECIDE ON THE TOPICS THAT 25 WE WANT TO ADDRESS AND TO CHOOSE THE SPEAKERS. OUR

1 INTENT IS TO HAVE ROUGHLY FIVE SESSIONS THAT WILL EACH 2 BE FOCUSED ON A PARTICULAR TOPIC. WE WILL HAVE TWO OR 3 THREE SPEAKERS WHOM WE WILL IMPLORE NOT TO GIVE THEIR 4 USUAL SCIENTIFIC SEMINARS, BUT TO BASICALLY GIVE US AN 5 ASSESSMENT OF WHERE WE ARE WITH RESPECT TO THAT 6 PARTICULAR TOPIC, WHAT OPPORTUNITIES THERE ARE, WHAT 7 CHALLENGES THERE ARE, AND WHAT WE MIGHT DO.

8 I STAND CORRECTED. PETER ANDREWS IS AT SHEFFIELD, NOT EDINBURGH. I BEG YOUR PARDON, PETER. 9 10 AT ANY RATE, AND THEN WE WILL HAVE A SUMMING-UP MEETING IN WHICH WE WILL ASK EACH OF THESE 11 12 SESSIONS -- FOR EACH SESSION WE'LL HAVE SEVERAL 13 SPEAKERS, WE'LL HAVE A PERIOD OF DISCUSSION, AND THEN 14 WE'LL ASK THE SPEAKERS AND PANEL MEMBERS TO COME UP 15 WITH SEVERAL RECOMMENDATIONS FOR THE CIRM. WE WILL 16 HAVE A SUMMARY OF THAT AT THE END OF THE MEETING. ALL 17 THIS WILL BE OPEN TO THE PUBLIC. WE HOPE TO ATTRACT SCIENTISTS FROM ACROSS CALIFORNIA TO COME TO THE 18 MEETING, AS WELL AS I HOPE ALL OF YOU CAN BE THERE, IF 19

20 YOU HAVE THE TIME INTERSPERSED WITH ALL THE OTHER

21 MEETINGS. I THINK IT WILL BE AN EXCITING EVENT FOR US.

22 IT WILL BE SORT OF A FIRST STEP IN OUR PLANNING

23 PROCESS. THANK YOU VERY MUCH.

24 CHAIRMAN KLEIN: WITH THAT, I'D LIKE TO CALL25 THE MEETING AS ADJOURNED.

1 MS. KING: WE JUST HAVE ONE BRIEF 2 ANNOUNCEMENT FROM WES WEINERT THE TECH MUSEUM. MR. WEINERT: I JUST WANTED TO SAY ON BEHALF 3 4 OF THE TECH MUSEUM, THANK YOU SO MUCH FOR COMING AND 5 SHARING YOUR KNOWLEDGE WITH OUR -- WITHIN OUR BUILDING. 6 WE APOLOGIZE, BUT WE CELEBRATE THE ENERGY OF THE 7 THOUSAND ODD SCHOOL KIDS THAT WERE OUTSIDE THE DOORS 8 TODAY. JUST WHAT A JOY IT WAS TO WORK WITH MELISSA AND 9 JENNIFER. 10 AND IF ANYBODY HERE IS INTERESTED, WE HAVE REALLY, I THINK, A VERY INCREDIBLE GALLERY ON GENETICS. 11 AND GREG BROWN, ONE OF OUR SENIOR STAFF AND VP OF 12 13 ENGINEERING AND TECHNOLOGY, WOULD LIKE FOR ANYBODY 14 WANTING TO JUST A THREE- TO FIVE-MINUTE TOUR OF THAT 15 GALLERY. IT WILL BE VERY BRIEF AND JUST UP THE STAIRS. 16 GREG IS JUST RIGHT HERE. SO AGAIN, THANK YOU SO MUCH. WE HOPE TO HAVE YOU FOLKS COME BACK AGAIN. 17 CHAIRMAN KLEIN: AS I UNDERSTOOD IT, WE ARE 18 19 GOING TO RESCHEDULE THAT MEETING IN JUNE FOR 20 SACRAMENTO, SAME DAY, SO THAT WE CAN, IN FACT, BE 21 THERE. IN ADDITION, GAYLE WILSON HAS POINTED OUT WE 22 NEED TO ALL REACH OUT WITHIN OUR OWN AREAS. AND JAMES 23 HARRISON WILL PROVIDE SOME GUIDANCE ON WHAT IS APPROPRIATE FOR THE DIFFERENT INSTITUTIONAL MEMBERS. 24

25 THANK YOU VERY MUCH. MEETING IS ADJOURNED.

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