

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
OF THE
SCIENTIFIC AND MEDICAL ACCOUNTABILITY
STANDARDS WORKING GROUP

LOCATION: GRAND HYATT HOTEL
PLAZA BALLROOM EAST
345 STOCKTON STREET
SAN FRANCISCO, CALIFORNIA

DATE: WEDNESDAY, JULY 6, 2005
10 A.M.

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

BRS FILE NO.: 72823

I N D E X

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CONSIDERATION OF THE NAS GUIDELINES		012

1 SAN FRANCISCO, CALIFORNIA; WEDNESDAY, JULY 6, 2005

2

3 CO-CHAIR LANSING: CAN I CALL THIS MEETING TO
4 ORDER, PLEASE. EVERYONE COME TO THEIR SEATS. HI. I'D
5 LIKE TO WELCOME ALL OF YOU HERE TODAY. MY NAME IS
6 SHERRY LANSING, AND ON BEHALF OF MY CO-CHAIR, HARRIET
7 RABB, AND ZACH HALL, I'D LIKE TO WELCOME ALL OF YOU
8 HERE TODAY. AS I MET ALL OF YOU AND AS I READ ABOUT
9 ALL OF YOU, I HAVE TO SAY I AM IN AWE OF THIS
10 DISTINGUISHED GROUP OF PEOPLE WHO HAVE COME TOGETHER TO
11 WORK SO HARD FOR OUR STEM CELL ISSUES. I REALLY WANT
12 TO THANK ALL OF YOU FOR TAKING TIME OUT OF YOUR
13 INCREDIBLY BUSY SCHEDULES TO BE HERE TODAY.

14 THE TASK THAT WE HAVE BEFORE US IS AN
15 INCREDIBLY IMPORTANT ONE. AND I FEEL, AS I THINK ALL
16 OF YOU DO, THAT THE WORLD IS WATCHING US AS WE
17 DELIBERATE ON THE ISSUES BEFORE US. AND I FEEL MORE
18 THAN EVER THAT WHAT WE DO HERE TODAY WILL SERVE AS A
19 ROLE MODEL FOR EVERYONE ELSE WHO PURSUES THIS. SO,
20 AGAIN, I CANNOT THANK YOU ENOUGH FOR BEING HERE TODAY,
21 FOR GIVING US OF YOUR TIME. AND I ALSO WANTED TO SAY
22 THAT WE MUST REALIZE THAT WHAT WE'RE DOING HERE TODAY
23 IS ONE STEP IN THE PROCESS. THIS IS A LIVING,
24 BREATHING ORGANISM, AND WE ARE GOING TO DO WORK HERE
25 TODAY AND WE'RE GOING TO DO WORK THROUGHOUT THE YEARS,

1 AND WE RESERVE THE RIGHT TO MODIFY WHAT WE DO, TO LOOK
2 AT IT AGAIN AND AGAIN, AND TO REEVALUATE IT.

3 SO WITHOUT ANY MORE TO DO, I JUST WANT TO
4 THANK YOU AGAIN. AND I'D LIKE TO OFFICIALLY CALL THE
5 MEETING TO ORDER AND ASK KATE SHREVE TO DO THE ROLL
6 CALL FOR US. ZACH, I'M HAPPY IF YOU DO IT.

7 DR. HALL: I JUST WANT TO WELCOME THE WORKING
8 GROUP ON BEHALF OF THE CALIFORNIA INSTITUTE FOR
9 REGENERATIVE MEDICINE AND ALSO WELCOME THE PUBLIC TO
10 THE FIRST MEETING OF THE SCIENTIFIC AND MEDICAL
11 ACCOUNTABILITY STANDARDS WORKING GROUP. AS YOU KNOW,
12 THE STANDARDS WORKING GROUP IS ONE OF THREE GROUPS
13 ESTABLISHED BY PROPOSITION 71 TO AID THE INSTITUTE IN
14 SUPPORTING STEM CELL RESEARCH, WORKING TOWARD THERAPIES
15 FOR DISEASE IN CALIFORNIA.

16 THE OTHER WORKING GROUPS, GRANTS REVIEW AND
17 FACILITIES, ARE CONCERNED WITH OUR GRANT-MAKING
18 ACTIVITIES. THE STANDARDS WORKING GROUP SERVES A
19 DIFFERENT FUNCTION, THAT OF ESTABLISHING THE
20 SCIENTIFIC, MEDICAL, AND ETHICAL GUIDELINES BY WHICH
21 THE RESEARCH SPONSORED BY CIRM IS CARRIED OUT. THE
22 RECOMMENDATIONS THAT YOU MAKE TO THE ICOC WILL ENSURE
23 THAT STEM CELL RESEARCH IN CALIFORNIA WILL BE CARRIED
24 OUT ACCORDING TO THE VERY HIGHEST STANDARDS.

25 FOR ANOTHER REASON TODAY, AS SHERRY HAS

1 MENTIONED, THE MEETING TODAY IS VERY SPECIAL FOR THE
2 INSTITUTE. IT'S A RED LETTER DAY, IF YOU WILL. WE
3 HAVE BEEN ENGAGED IN A LONG PERIOD IN WHICH THE ICOC
4 AND THE CIRM, INDEPENDENT CITIZENS' OVERSIGHT
5 COMMITTEE, AND THE CALIFORNIA INSTITUTE FOR
6 REGENERATIVE MEDICINE HAVE BEEN ENGAGED ALMOST
7 EXCLUSIVELY IN MATTERS OF PREPARATION. THIS MEETING
8 MARKS THE BEGINNING OF OUR REAL WORK.

9 OVER THE LAST SIX MONTHS WE HAVE SELECTED AN
10 INTERIM PRESIDENT, WE HAVE CHOSEN A PERMANENT SITE, WE
11 HAVE SELECTED THE MEMBERS OF OUR THREE WORKING GROUPS,
12 WE HAVE ESTABLISHED INTERIM CONFLICT OF INTEREST
13 POLICIES, WE HAVE ENGAGED IN FRUITFUL DISCUSSION WITH
14 THE LEGISLATURE, WE HAVE ESTABLISHED INTERIM STANDARDS,
15 WE HAVE BEGUN TO HIRE STAFF, AND WE HAVE WRITTEN AND
16 ISSUED OUR FIRST RFA FOR TRAINING GRANTS.

17 THE APPLICATIONS FOR THAT RFA CAME IN ON JULY
18 1ST, JUST THIS LAST WEEKEND. AND IN AUGUST IN OUR
19 GRANTS WORKING GROUP WILL MEET TO CONSIDER AND EVALUATE
20 THOSE GRANTS. BUT BEFORE WE'RE ABLE TO AWARD ANY
21 GRANTS, WE MUST ESTABLISH THE GUIDELINES BY WHICH THEIR
22 WORK WILL BE DONE. AS YOU WILL HEAR A FEW MINUTES
23 LATER, THIS WILL BE A LENGTHY PROCESS TO BE CARRIED OUT
24 WITH DUE CONSIDERATION AND WITH STRONG INPUT FROM THE
25 PUBLIC. BECAUSE DOING THE WORK ETHICALLY, HOWEVER, IS

1 ONE OF THE CORE VALUES OF PROPOSITION 71, IT SEEMS TO
2 ME VERY APPROPRIATE THAT OUR WORK BEGINS WITH A MEETING
3 OF THE STANDARDS WORKING GROUP.

4 WE ARE DELIGHTED TO HAVE SUCH A DISTINGUISHED
5 GROUP ADVISE US ON THE COMPLEX ISSUES THAT SURROUND
6 STEM CELL RESEARCH AND THERAPY, AND WE LOOK FORWARD TO
7 YOUR DELIBERATIONS. THANK YOU VERY MUCH.

8 CO-CHAIR LANSING: THANK YOU, ZACH, AS
9 ALWAYS. NOW, KATE, YOU WANT TO DO THE ROLL CALL.

10 MS. SHREVE: ALTA CHARO.

11 MS. CHARO: HERE.

12 MS. SHREVE: JOSE CIBELLI.

13 DR. CIBELLI: HERE.

14 MS. SHREVE: KEVIN EGGAN.

15 DR. EGGAN: HERE.

16 MS. SHREVE: ANN KIESSLING.

17 DR. KIESSLING: HERE.

18 MS. SHREVE: ROBERT KLEIN.

19 MR. KLEIN: HERE.

20 MS. SHREVE: JEFFREY KORDOWER.

21 DR. KORDOWER: HERE.

22 MS. SHREVE: SHERRY LANSING.

23 CO-CHAIR LANSING: HERE.

24 MS. SHREVE: BERNARD LO.

25 DR. LO: HERE.

1 MS. SHREVE: KENNETH OLDEN. THEODORE PETERS.
2 MR. PETERS: HERE.
3 MS. SHREVE: FRANCISCO PRIETO.
4 DR. PRIETO: HERE.
5 MS. SHREVE: HARRIET RABB.
6 CO-CHAIR RABB: HERE.
7 MS. SHREVE: JANET ROWLEY.
8 DR. ROWLEY: HERE.
9 MS. SHREVE: JEFF SHEEHY.
10 MR. SHEEHY: HERE.
11 MS. SHREVE: JONATHAN SHESTACK.
12 MR. SHESTACK: HERE.
13 MS. SHREVE: ROBERT TAYLOR.
14 DR. TAYLOR: HERE.
15 MS. SHREVE: JAMES WILLERSON.
16 DR. WILLERSON: HERE.
17 CO-CHAIR LANSING: THANK YOU. NOW I'D LIKE
18 TO TURN THE MEETING BACK TO ZACH AND JAMES HARRISON.
19 DR. HALL: LET ME STAND UP HERE BECAUSE I
20 HAVE A COUPLE SLIDES. THE ROOM IS LAID OUT SO IT'S NOT
21 POSSIBLE TO LOOK AT THE AUDIENCE AND THE COMMITTEE,
22 WORKING GROUP, AT THE SAME TIME. WE'LL DO THE BEST WE
23 CAN.
24 WHAT I WANTED TO DO WAS TO JUST TALK BRIEFLY
25 ABOUT WHAT THE CHARGE TO THE COMMITTEE -- FOR THE

1 WORKING GROUP IS. AND I SHOULD SAY AT THE OUTSET THAT
2 WE WERE HELPED IN THIS BY THE GOOD EFFORTS OF OUR KEN
3 TAYMORE, WHO ON A PRO BONO BASIS, HELPED US THINK ABOUT
4 BOTH SOME MATTERS OF THE CHARGE TO THE COMMITTEE AND
5 ALSO ON MATTERS OF OUR PUBLIC MEETING POLICY.

6 SO THIS NOW IS REALLY DIRECTLY FROM
7 PROPOSITION 71 WHERE THE ISSUE IS ADDRESSED IN TWO
8 PLACES. AND I JUST WANTED TO GO THROUGH THIS. I'M
9 SURE ALL OF YOU HAVE SEEN THIS OR LOOKED AT PARTS OF
10 IT, BUT JUST AS A REMINDER AT THE BEGINNING OF THE
11 FORMAL CHARGE TO THE COMMITTEE FROM THE PROPOSITION.

12 SO THE STANDARDS WORKING GROUP GIVES ADVICE
13 AND RECOMMENDATIONS TO THE ICOC ON SCIENTIFIC, MEDICAL,
14 AND ETHICAL STANDARDS, ON MEDICAL, SOCIOECONOMIC, AND
15 FINANCIAL STANDARDS FOR ASPECTS OF CLINICAL TRIALS AND
16 THERAPY, FOR OVERSIGHT, CONTINUING OVERSIGHT OF FUNDED
17 RESEARCH, FOR RELEVANT ETHICAL AND REGULATORY ISSUES,
18 AND FINALLY FOR THE RULES AND PROCEDURES FOR THE
19 STANDARDS WORKING GROUP OPERATIONS. AND I'LL COME BACK
20 TO THAT IN JUST A MOMENT.

21 AMONG THE TOPICS THAT THE WORKING GROUP IS
22 ASKED TO CONSIDER BY THE PROPOSITION ARE MATTERS OF
23 INFORMED CONSENT, CONTROLS ON RESEARCH INVOLVING
24 HUMANS, PROHIBITION ON COMPENSATION, ASSURING
25 COMPLIANCE WITH PATIENT PRIVACY LAWS, LIMITATIONS ON

1 PAYMENT FOR CELLS, AND TIME LIMITS FOR OBTAINING CELLS.

2 NOW, THIS, THEN, IS THE FORMAL CHARGE. IF
3 YOU REMEMBER FROM THE LAST SLIDE, ONE OF THE ITEMS IS
4 THE QUESTION OF RULES AND PROCEDURES FOR THE STANDARDS
5 WORKING GROUP'S OPERATION. ACCORDING TO PROPOSITION
6 71, THE WORKING GROUPS, ALL WORKING GROUPS, WERE EXEMPT
7 FROM THE BAGLEY-KEENE OPEN MEETING LAW IN CALIFORNIA.
8 HOWEVER, AFTER DISCUSSION BY THE ICOC AND DISCUSSION
9 WITH THE PUBLIC, WE DECIDED AT OUR MAY MEETING -- I'M
10 SORRY -- WE DECIDED AT THE APRIL ICOC MEETING TO
11 CONSIDER THE MATTER OF MAKING THE MEETINGS OF THIS
12 WORKING GROUP PUBLIC MEETINGS. AND KEN TAYMORE, WHO I
13 SEE HAS JUST WALKED IN THE ROOM, WAS VERY HELPFUL TO
14 US. AND ON THE BASIS OF WORK THAT HE DID AND THEN
15 HARRIET RABB FOLLOWED UP ON, WE THEN EVOLVED A POLICY,
16 WHICH YOU SHOULD HAVE IN YOUR FOLDER, FOR PUBLIC
17 MEETINGS, WHICH I THOUGHT I HAD IN MY HAND, BUT I
18 DON'T.

19 AT ANY RATE, THE GIST OF THAT IS THAT THE
20 MEETINGS OF THIS COMMITTEE WILL BE PUBLIC, HENCE YOU
21 SEE THE PUBLIC GATHERED IN FRONT OF US, THOSE MEMBERS
22 WHO ARE INTERESTED AND WISH TO ATTEND. AND THERE ARE
23 THEN LISTS OF SEVERAL POINTS THAT HAVE TO DO WITH THIS,
24 AND SO WHAT I WOULD LIKE TO -- HARRIET, IF I COULD JUST
25 BORROW YOUR COPY. I'M SORRY. I'LL JUST QUICKLY READ

1 THESE.

2 SO THERE WILL BE A PROCESS ABOUT WHICH WE
3 WILL DISCUSS WITH JAMES HARRISON LATER THAT WE WILL GO
4 THROUGH. BUT IN ANY CASE, THE WORKING GROUP WILL
5 GATHER AND ANALYZE INFORMATION, WILL REACH DECISION
6 POINTS ON PROPOSED STANDARDS, PREPARE DRAFT AND FINAL
7 RECOMMENDATIONS, AND FORWARD THESE RECOMMENDATIONS TO
8 THE ICOC. THE WORKING GROUP WILL GIVE PUBLIC NOTICE OF
9 MEETINGS IN A TIMELY MANNER AND POST PROPOSED MEETING
10 AGENDAS, HOLD PUBLIC MEETINGS, AND PROVIDE PUBLIC
11 COMMENT PERIOD DURING EACH MEETING, HOLD MEETINGS WHICH
12 MEMBERS OF THE PUBLIC WILL BE ENCOURAGED TO ATTEND AND
13 AT WHICH THEY MAY COMMENT ON DRAFT FINDINGS AND
14 RECOMMENDATIONS, TAKE PUBLIC VOTES OF THE WORKING GROUP
15 MEMBERS ON DECISIONS AND RECOMMENDATIONS TO THE ICOC,
16 POST PUBLICLY THE WORKING GROUP'S FINAL RECOMMENDATIONS
17 AND MINORITY AND INDIVIDUAL OPINIONS TO BE FORWARDED TO
18 THE ICOC ON MATTERS THAT EMERGE OUT OF THE FOREGOING
19 PROCESS, AND, FINALLY, MEET IN CONFIDENTIAL SESSION
20 ONLY IF NEEDED; E.G., TO REVIEW A COMPLAINT REGARDING
21 INVESTIGATORS OR AN INSTITUTION'S COMPLIANCE WITH
22 MEDICAL OR ETHICAL STANDARDS ADOPTED BY THE ICOC WITH
23 ANY FINAL ACTION TO BE TAKEN IN A PUBLIC MEETING.

24 SO ONE OF THE TASKS THAT I WOULD LIKE TO ASK
25 OF YOU TODAY IS THAT YOU, IN FACT, CONSIDER THIS

1 PROPOSAL WHICH HAS BEEN APPROVED BY THE ICOC; BUT IF
2 YOU WISH TO CHANGE IT, YOU CERTAINLY MAY DO SO. IN ANY
3 CASE, I THINK WE WOULD LIKE SOME FORMAL STATEMENT FROM
4 YOU ABOUT IT. YOU CAN DO THAT NOW OR LATER AS THE
5 CO-CHAIRS CHOOSE.

6 CO-CHAIR LANSING: I THINK WE SHOULD DO IT
7 NOW BECAUSE IT'S BEFORE US. IT'S ALWAYS BETTER TO DO
8 SOMETHING NOW. I THINK THAT I SPEAK FOR MYSELF, AND
9 I'D LIKE TO GET EVERYBODY ELSE'S OPINION. I THINK THIS
10 IS VERY GOOD. I THINK THAT WE SHOULD CONDUCT THESE
11 MEETINGS WITH THE PUBLIC, AS WE ARE DOING TODAY, AND
12 I'D LIKE ANY COMMENTS FROM ANYBODY WHO HERE HAS ANY
13 COMMENTS.

14 MR. KLEIN: SHERRY, BOB KLEIN. I WOULD JUST
15 RECOGNIZE THAT IT IS JEFF SHEEHY AND DAVID
16 SERRANO-SEWELL THAT LED US INTO THIS PROCESS OF GETTING
17 TO OUR OPEN MEETING FORMAT. AND WE ALSO HAD THE
18 BENEFIT OF LOOKING AT THE OPEN MEETING FORMAT ADOPTED
19 BY THE NATIONAL ACADEMIES, WHICH IS IN FEDERAL STATUTE,
20 AS A MODEL FOR HOW OPEN MEETINGS COULD PROCEED. AND I
21 BELIEVE OUR MEETINGS ARE, IN FACT, MORE OPEN THAN THE
22 NATIONAL ACADEMY IN THE SENSE THAT THEY HAVE MAYBE SOME
23 BROADER CONFIDENTIALITY PROVISIONS AND BROADER CLOSED
24 MEETING PROVISIONS THAN WE HAVE AT THIS TIME, BUT IT'S
25 CERTAINLY A GREAT EXAMPLE FOR CALIFORNIA TO FOLLOW.

1 CO-CHAIR LANSING: THANK YOU, BOB, AND THANK
2 YOU, JEFF AND DAVID.

3 CO-CHAIR RABB: I HAVE ONE COMMENT TO MAKE.
4 IN TALKING ABOUT THE PUBLIC'S PARTICIPATION, IT'S BEEN
5 OUR ASSUMPTION, BUT IT HASN'T BEEN EXPLICIT, AND I
6 THINK IT SHOULD BE EXPLICIT, THAT NOT ONLY WILL THE
7 PUBLIC BE ASKED TO COMMENT AT MEETINGS AND GIVEN THE
8 OPPORTUNITY TO COMMENT, BUT I THINK WE HAVE A
9 COMMITMENT THAT NO VOTE SHALL BE TAKEN UNTIL AFTER
10 PUBLIC COMMENT ON THE MATTER TO BE DISCUSSED AND
11 DECIDED.

12 AND SINCE WE INTEND TO DO THAT, I THINK WE
13 OUGHT TO BE EXPLICIT ABOUT IT. SO I PROPOSE THAT WE
14 AMEND OUR PROPOSED MEETING PROCEDURES TO THAT EXTENT,
15 THAT THE SECOND BULLET, PROVIDE PUBLIC COMMENT PERIOD
16 DURING EACH MEETING, THAT WE EXPLICITLY STATE NO VOTE
17 WILL BE TAKEN WITHOUT OPPORTUNITY FOR PUBLIC COMMENT.

18 MR. KLEIN: IF THAT'S A MOTION, I'D SECOND
19 THAT.

20 CO-CHAIR LANSING: ALL IN FAVOR. ANY
21 OPPOSED? PASSES UNANIMOUSLY.

22 ZACH, YOU HAVE MORE COMMENTS AND JAMES
23 HARRISON.

24 DR. HALL: LET ME JUST -- I'M JUST GOING TO
25 SPEAK FROM HERE IF THAT'S OKAY. SO JUST TO INTRODUCE

1 THE NEXT TOPIC HERE BRIEFLY, AND I WILL TURN IT OVER TO
2 JAMES, THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
3 ADOPTED AT ITS MEETING ON MAY 23D THE NATIONAL
4 ACADEMIES' GUIDELINES FOR RESEARCH ON HUMAN EMBRYONIC
5 STEM CELLS AS THE INTERIM STANDARDS BY WHICH RESEARCH
6 ON HUMAN EMBRYONIC STEM CELLS SPONSORED BY THE
7 CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE WOULD BE
8 GUIDED.

9 AS IT TURNS OUT, BY ADOPTING THOSE INTERIM
10 STANDARDS, WE SET IN MOTION BY CALIFORNIA LAW AN
11 EXTENSIVE TRAIN OF EVENTS, AND I WILL TURN IT OVER TO
12 JAMES HARRISON TO EXPLAIN THOSE -- WHAT THOSE ARE.

13 MR. HALPERN: POINT OF ORDER, MADAM CHAIR.

14 CO-CHAIR LANSING: SURE.

15 MR. HALPERN: THERE WAS NO -- I THOUGHT THERE
16 WAS A VOTE ON THE AMENDMENT, AND I WOULD LIKE TO
17 ADDRESS SOME OF THE OTHER PROVISIONS OF THIS OPEN
18 MEETING PROCEDURE AND PROPOSE SOME OTHER AMENDMENTS.

19 CO-CHAIR LANSING: I THINK THAT'S FINE. I
20 THINK WE VOTED ON THE WHOLE THING AND THE AMENDMENT,
21 BUT I WELCOME EVERYTHING THAT YOU HAVE TO SAY.

22 MR. HALPERN: THANK YOU, MADAM CHAIR. IN A
23 CERTAIN SENSE I'M TRYING TO EMBODY MS. RABB'S
24 SUGGESTION THAT WE HAVE A PUBLIC OPPORTUNITY TO COMMENT
25 BEFORE EACH VOTE.

1 CO-CHAIR LANSING: I GOT IT. SURE.

2 MR. HALPERN: FOR THOSE OF YOU FROM OUTSIDE
3 THE STATE, THE ISSUE OF OPEN MEETINGS IN CALIFORNIA IS
4 AN EXTREMELY IMPORTANT ISSUE. THE SAME DAY THAT PROP
5 71 WAS ADOPTED ANOTHER PROPOSITION CALLED PROP 59 WAS
6 ADOPTED, AND ITS PURPOSE WAS TO ASSURE OPEN MEETINGS
7 AND TO RAISE TO CONSTITUTIONAL STATUS THE OPEN MEETINGS
8 POLICY. THIS MAY SEEM A PECULIARITY OF CALIFORNIANS,
9 BUT IT'S SOMETHING WE CARE ABOUT A GREAT DEAL.

10 IN CONNECTION WITH PROP 59, THIS WAS HOW THE
11 BALLOT WAS PRESENTED TO THE VOTERS. IT WILL ALLOW THE
12 PUBLIC TO SEE AND UNDERSTAND THE DELIBERATIVE PROCESS
13 THROUGH WHICH DECISIONS ARE MADE. THAT'S THE -- THAT
14 IS CONSTITUTIONAL POLICY IN CALIFORNIA, AND IT'S
15 EMBODIED IN THE BAGLEY-KEENE ACT, WHICH IS AN ACT WHICH
16 HAS GONE THROUGH YEARS AND YEARS OF INTERPRETATION IN
17 THE COURTS AND ADMINISTRATIVE AGENCIES.

18 I WOULD LIKE TO TRY TO BRING SOME OF THAT
19 LORE INTO THIS ACT. FOR EXAMPLE, PARAGRAPH 1 STATES,
20 "PUBLIC NOTICE WILL BE GIVEN IN A TIMELY MANNER." THE
21 LAW IN THIS STATE IS PUBLIC NOTICE OF MEETINGS SHALL BE
22 GIVEN TEN DAYS IN ADVANCE. I THINK THAT THE COMMITTEE
23 OUGHT TO ADOPT THAT, AND SO I WOULD URGE YOU TO
24 CONSIDER, IF A MEMBER OF THE COMMITTEE AGREED WITH ME,
25 AN AMENDMENT WHICH PUT IN THE TEN-DAY LIMIT.

1 I MIGHT ALSO SAY THAT I AM OFFERING THESE
2 COMMENTS ON MY OWN BEHALF AS A PERSONAL PUBLIC INTEREST
3 LAWYER WITH A LONG-STANDING AND CONTINUING INTEREST IN
4 THE PROCESSES OF THE ICOC AND ALSO ON BEHALF OF AN
5 ORGANIZATION CALLED CALIFORNIANS AWARE AND ITS
6 EXECUTIVE DIRECTOR, TERRY FRANK. CALIFORNIANS AWARE IS
7 THE NO. 1 OPEN MEETINGS LAW NONPROFIT ORGANIZATION
8 LOCATED IN SACRAMENTO. SO I SPEAK FOR HIM WHEN I
9 SUGGEST THIS TEN-DAY NOTICE.

10 I THINK WE SHOULD ALSO BE SPECIFIC --

11 CO-CHAIR LANSING: SORRY. I WAS ASKING A
12 QUESTION ABOUT THE TEN DAYS. PLEASE, I DID NOT MEAN TO
13 BE RUDE.

14 MR. HALPERN: IN THAT SAME PARAGRAPH, I WOULD
15 SUGGEST THAT WHERE IT SAYS THAT THEY WILL BE POSTED,
16 THAT IT SHOULD SAY THEY WOULD BE POSTED ON THE CIRM
17 WEBSITE, AN EXCELLENT RESOURCE THAT THE PUBLIC HAS
18 GOTTEN USED TO CONSULTING REGULARLY.

19 A THIRD, IT SAYS AN AGENDA -- A PROPOSED
20 AGENDA WILL BE POSTED, IMPLYING THAT THE AGENDA MIGHT
21 BE CHANGED. THE LAW IN THIS STATE -- I UNDERSTAND THE
22 LAW DOESN'T APPLY TO THIS COMMITTEE, BUT I THINK WHERE
23 THE LAW MAKES SENSE AND EMBODIES EFFECTIVE PUBLIC
24 POLICY, IT SHOULD BE INCORPORATED. THE AGENDA, WHEN
25 IT'S PUBLISHED TEN DAYS IN ADVANCE, BECOMES THE AGENDA

1 FOR THE MEETING. NEW ITEMS CANNOT BE ADDED, ITEMS
2 CANNOT BE SUBTRACTED.

3 AND LASTLY, WITH REGARD TO THE FIRST
4 PARAGRAPH, I WANT TO SUGGEST THAT ANY DOCUMENTS TO BE
5 DISCUSSED AT THE MEETING SHOULD BE POSTED TEN DAYS IN
6 ADVANCE SO THAT PUBLIC PARTICIPATION CAN BE WELL
7 INFORMED, AND PEOPLE HAVE AN OPPORTUNITY TO UNDERSTAND
8 WHAT IS BEING CONSIDERED.

9 MADAM CHAIR, I HAVE OTHER COMMENTS ON OTHER
10 ITEMS WHICH I HOPE THE COMMITTEE WILL CONSIDER -- THE
11 WORKING GROUP WILL CONSIDER BEFORE HOLDING THE FINAL
12 VOTE.

13 CO-CHAIR LANSING: SHALL WE HEAR -- WHAT I AM
14 TRYING TO -- AGAIN, AS I SAID, THIS IS A GROUP THAT'S
15 GOING TO EVOLVE AND CHANGE, AND WHAT WE'RE REALLY
16 TRYING TO DO TODAY WAS TO SAY THAT WE INTENDED TO HAVE
17 THE MEETINGS IN PUBLIC. I TAKE YOUR POINTS, AND I
18 THINK VERY THEY'RE VALID, AND I'D REALLY LIKE TO HEAR
19 WHAT, JAMES, IF YOU HAVE SOME REACTION TO SOME OF THEM
20 AND WHAT PROBLEMS YOU FORESEE THAT THEY MIGHT PRESENT.

21 MR. HARRISON: CURRENTLY THE POLICY THAT WAS
22 ADOPTED BY THE ICOC, WHICH THIS COMMITTEE IS -- THIS
23 WORKING GROUP IS NOW CONSIDERING PROVIDES FOR A TIMELY
24 NOTICE. MR. HALPERN HAS SUGGESTED THAT TIMELY NOTICE
25 ESSENTIALLY BE DEFINED AS TEN DAYS, WHICH IS THE

1 STANDARD UNDER THE BAGLEY-KEENE ACT. SO I DON'T THINK
2 THAT PRESENTS ANY PARTICULAR PROBLEMS OTHER THAN THAT
3 IF FOR SOME REASON THE COMMITTEE NEEDS TO CONVENE ON AN
4 EMERGENCY BASIS, IT SHOULD CONSIDER A POLICY THAT WOULD
5 PERMIT IT TO DO SO ON A CERTAIN VOTE AND UNDER CERTAIN
6 CIRCUMSTANCES.

7 CO-CHAIR LANSING: WHAT ABOUT -- I DON'T
8 ANTICIPATE ANY PROBLEMS WITH POSTING IT ON THE WEBSITE.
9 WHAT ABOUT NOT BEING ABLE TO CHANGE THE AGENDA? THAT'S
10 THE ONE THAT GOT ME A LITTLE NERVOUS BECAUSE WE DON'T
11 KNOW, AS EMERGENCY THINGS COME UP, THAT WE MIGHT NOT
12 WANT TO ADJUST CERTAIN ISSUES.

13 MR. HARRISON: THAT'S ANOTHER COMMENT I
14 WANTED TO MAKE. WHAT MR. HALPERN HAS SUGGESTED IS THAT
15 THE AGENDA AS PUBLISHED TEN DAYS IN ADVANCE WOULD BE
16 THE FINAL AGENDA AND WOULD NOT BE SUBJECT TO CHANGE.
17 SO ANOTHER THING YOU MIGHT WANT TO CONSIDER IS WHETHER
18 TO ADOPT SOME PROCEDURES, IF YOU ARE INCLINED TO ACCEPT
19 MR. HALPERN'S PROPOSAL, THAT WOULD ALLOW THE WORKING
20 GROUP TO ADD ITEMS TO THE AGENDA UNDER CERTAIN
21 CIRCUMSTANCES.

22 CO-CHAIR LANSING: DO I HAVE ANY OTHER
23 COMMENTS?

24 DR. KIESSLING: COULD THE SPEAKER PLEASE
25 IDENTIFY HIMSELF?

1 MR. HALPERN: EXCUSE ME. I'M SORRY. I'VE
2 BEEN INVOLVED IN THE ICOC PROCESS SO LONG. I
3 APOLOGIZE. MY NAME IS CHARLES HALPERN. I'M AN
4 INDEPENDENT PUBLIC INTEREST LAWYER LIVING IN BERKELEY.
5 DR. PHILIP LEE AND I HAVE TOGETHER FILED A PETITION
6 WITH THE ICOC URGING THEM, AMONG OTHER THINGS, TO OPEN
7 THESE PROCESSES MORE FULLY TO PUBLIC PARTICIPATION.

8 DR. KIESSLING: THANK YOU.

9 MS. CHARO: REGARDING THE DISTRIBUTION OF
10 MATERIALS TO BE DISCUSSED AT THE MEETING, I SUSPECT
11 MANY PEOPLE AROUND THE TABLE HAVE PARTICIPATED IN A LOT
12 OF PUBLIC BODIES. IT'S BEEN MY EXPERIENCE THAT NO
13 MATTER HOW HARD THE STAFF WORK, THEY SOMETIMES DON'T
14 FINISH THE MATERIALS UNTIL THE VERY LAST MINUTE. AND
15 IT WOULD BE SUCH A SHAME IF MEETINGS HAD TO BE CANCELED
16 ON A ROUTINE BASIS AND MONEY SPENT FOR AIRFARES AND
17 HOTELS AND LOSSES IF WE AREN'T ALLOWED TO DISCUSS THE
18 MATERIALS.

19 I HAVE BEEN AT MANY SETTINGS AT WHICH THE
20 UNDERSTANDING WAS THAT YOU CAN DISCUSS ANYTHING AT THE
21 TABLE THAT WASN'T ACTUALLY PREPARED AND READY FOR THE
22 AUDIENCE TO ALSO PICK UP AND READ. AND THIS WAY IT WAS
23 NOT A SITUATION IN WHICH PEOPLE IN THE AUDIENCE WEREN'T
24 ABLE TO SEE THE DOCUMENT UNDER DISCUSSION AND FELT THAT
25 THEY HAD NO IDEA WHAT PARAGRAPH OR PAGE, BUT IT ALSO

1 GAVE THE COMMITTEE SOME FLEXIBILITY WITH AN INTENT TO
2 GET IT OUT AS EARLY AS POSSIBLE WITH SOME FLEXIBILITY.

3 CO-CHAIR LANSING: ACTUALLY I KNOW HARRIET
4 HAD THE SAME REACTION.

5 CO-CHAIR RABB: I JUST WANTED TO SAY HOW YOU
6 HELP US THINK ABOUT THIS BECAUSE WE'VE ALL HAD THIS
7 EXPERIENCE. THE EXPERIENCE OF IF THINGS IN THE WORLD
8 CHANGE, EVERYBODY IS ALREADY PLANNING TO BE HERE, HOW
9 WOULD YOU HELP US THINK ABOUT WHAT CONSTITUTED A FAIR
10 BASIS FOR EXPANDING A CONVERSATION OR MAKING SURE THAT
11 AVAILABLE MATERIALS WERE IN EVERYONE'S HAND EVEN IF
12 THEY WEREN'T OUT TEN DAYS BEFORE?

13 MR. HALPERN: WELL, I HAVE TWO REACTIONS TO
14 THAT, MADAM CHAIR. FIRST, IF THERE'S SOME SORT OF
15 EMERGENCY PROVISION AND THAT THE CHAIRS CAN, ON THE
16 BASIS OF SOME UNANTICIPATED EMERGENCY, CAN ADD AN ITEM
17 TO THE AGENDA OR MAKE SOME ADJUSTMENT OR SOMETHING,
18 PERHAPS EVEN HAVE AN EMERGENCY PROVISION WITH REGARD TO
19 THE TEN-DAY NOTICE REQUIREMENT. SO I THINK THAT --
20 THIS WOULD ESTABLISH THE NORMS SUBJECT TO THE CHAIR,
21 THE CO-CHAIRS, MAKING A FINDING THAT THERE'S AN
22 EMERGENCY SITUATION.

23 BUT AS TO THE PROBLEMS OF STAFF OVERLOAD, I
24 SPENT -- I'VE SPENT MOST OF MY LIFE MANAGING BOARD
25 PROCESSES IN NONPROFIT ORGANIZATIONS AND ONE PUBLIC LAW

1 SCHOOL. AND WE ALWAYS HAD DEADLINES AND DISCIPLINE OF
2 CIRCULATING BOARD BOOKS. ALL WE'RE TALKING ABOUT NOW
3 IS WHAT GOES OUT IN THE BOARD BOOKS TEN DAYS IN ADVANCE
4 ALSO GETS POSTED ON THE WEBSITE TEN DAYS IN ADVANCE.
5 AND THAT WAS -- WHEN I WAS RUNNING THE NATHAN CUMMINGS
6 FOUNDATION, THAT WAS ALWAYS A DISCIPLINE THAT I, QUITE
7 FRANKLY, CAME TO WELCOME. AND I WOULD URGE THAT ON
8 STAFF HERE BECAUSE IN THIS STATE IT'S BACKED UP BY PROP
9 59, WHICH IS, AGAIN, I WANT TO EMPHASIZE, A THIRD AGAIN
10 OF THE CALIFORNIA VOTERS, A THIRD MORE THAN THOSE WHO
11 SUPPORTED PROP 71, SUPPORTED PROP 59. THIS IS A VERY
12 POWERFUL POLICY IN THIS STATE.

13 CO-CHAIR LANSING: THANK YOU.

14 MR. REED: I'M DON REED, CALIFORNIANS FOR
15 CURE. I WOULD LIKE TO ASK THAT WHATEVER CONSIDERATION
16 IS GIVEN TO THE VALID COMMENTS BEING MADE THAT THIS NOT
17 BE WRITTEN IN STONE, THAT IT BE A GOAL TO BE STRIVED
18 TOWARD RATHER THAN AN INFLEXIBLE GUIDELINE. IT'S VERY
19 HARD TO GET EVERYBODY HERE TOGETHER ON ONE DAY. ALSO,
20 BIG THINGS HAPPEN. WE JUST HAD A SUPREME COURT
21 NOMINATION OPEN UP, WHICH COULD SWAY THE BALANCE OF THE
22 SUPREME COURT, WHICH COULD CONCEIVABLY THREATEN MUCH OF
23 OUR RESEARCH. I THINK WE HAVE TO HAVE THE FLEXIBILITY
24 TO BE ABLE TO DEAL WITH WHATEVER COMES UP. THANK YOU.

25 CO-CHAIR LANSING: THANK YOU VERY MUCH.

1 MR. SHESTACK: MR. HALPERN, IS THIS -- WOULD
2 YOU PROPOSE THAT THIS GROUP VOTE ON THIS SUGGESTION
3 TODAY?

4 CO-CHAIR LANSING: YES, MR. HALPERN.

5 MR. HALPERN: AGAIN, WHAT WE'RE TALKING
6 ABOUT --

7 MR. SHESTACK: JUST ANSWER THE QUESTION
8 BECAUSE I'M TRYING TO UNDERSTAND THE PROCESS.

9 MR. HALPERN: I'M NOT ON THE WITNESS STAND,
10 MR. SHESTACK.

11 MR. SHESTACK: ARE YOU ASKING FOR
12 FLEXIBILITY -- TO NOT HAVE ANY FLEXIBILITY? YOU HAVE A
13 SUGGESTION. THIS GROUP MIGHT WANT TO CONSIDER THIS
14 SUGGESTION, BUT IT SEEMS LIKE WE WOULDN'T BE ALLOWED TO
15 BECAUSE IT WASN'T ON THE AGENDA.

16 MR. HALPERN: CAN I PUT THIS INTO PROCEDURAL
17 CONTEXT? THIS ITEM -- THIS DRAFT IS ON THE AGENDA. SO
18 WHAT I'M PROPOSING IS CERTAINLY BEFORE THE COMMITTEE.
19 BUT NOT -- LET ME JUST, MADAM CHAIR, PUT THIS IN
20 CONTEXT.

21 WHAT THIS COMMITTEE IS BEING ASKED TO DO AT
22 THIS POINT IS NOT TO ADOPT THESE PROCEDURES, BUT TO
23 ADOPT THESE PROCEDURES AS A RECOMMENDATION TO GO BACK
24 TO THE ICOC --

25 CO-CHAIR LANSING: CORRECT.

1 MR. HALPERN: -- WHICH HAS THE FINAL VOTE.
2 AND ITS AGENDA FOR ITS JULY 12TH MEETING IS BROAD
3 ENOUGH SO THAT THE RECOMMENDATIONS COMING FROM THIS
4 COMMITTEE CAN APPROPRIATELY BE CONSIDERED.

5 MR. SHESTACK: LET ME JUST REALLY, AS AN
6 INDIVIDUAL WHO IS A VOLUNTEER, WHO HAS TO -- WHO HAS AN
7 EIGHT-YEAR TERM, WHO HAS TO ATTEND THREE, SOMETIMES
8 FOUR MEETINGS A MONTH, THAT THESE -- THAT HAVING A
9 POLICY WHERE THERE'S NO FLEXIBILITY IN AGENDA ITEMS IS
10 A BIG AND ONEROUS IMPOSITION, AND I FEEL DOES NOT ALLOW
11 ME TO SERVE WELL ON THE COMMITTEE, DOES NOT ALLOW ME TO
12 REPRESENT THE COMMUNITY FROM WHICH I ADVOCATE, AND IS
13 SETTING UP UNNECESSARY HURDLES GIVEN THE POINT THAT YOU
14 MADE, THAT THIS IS IN ANY EVENT THE ITEMS THAT APPEAR
15 ON OUR AGENDA ARE ULTIMATELY BROUGHT TO THE ICOC FOR A
16 FULL VOTE AND RATIFICATION. SO THERE ARE MANY, MANY
17 FENCES THAT HAVE BEEN BUILT IN, AND I DON'T SEE A
18 GREATER PURPOSE SERVED IN BUILDING ANY ADDITIONAL ONES.

19 CO-CHAIR LANSING: I WOULD JUST LIKE TO SAY
20 THAT -- FIRST OF ALL, I WANT TO SAY ONCE AGAIN THAT WE
21 REALLY, REALLY DO VALUE YOUR COMMENTS. AND I'VE BEEN
22 SPEAKING TO CHARLES SINCE WE STARTED THIS, AND HE'S
23 BEEN A TREMENDOUS WATCHDOG FOR US AT THE ICOC. BUT I
24 ALSO WANT TO SAY THAT THE ISSUES THAT YOU'RE RAISING, I
25 WANT TO GO BACK AND REMIND EVERYBODY THAT WE HAVE TAKEN

1 A HUGE STEP BECAUSE THESE MEETINGS ARE NOW PUBLIC AND
2 THEY WERE NOT -- THEY DID NOT HAVE TO BE. I THINK THAT
3 THE POINTS THAT YOU ARE RAISING, MANY OF THEM ARE VERY
4 VALID, AND I THINK THEY ARE A GOLD STANDARD THAT
5 EVERYONE WOULD ASPIRE TO, BUT SOME OF THEM MAY NOT BE
6 FEASIBLE BECAUSE OF ALL THE ISSUES THAT WE RAISED.

7 I THINK TEN DAYS NOTICE FOR ALL OF US IS
8 GREAT, MAY NOT BE ABLE TO HAPPEN ALL THE TIME BECAUSE,
9 AS YOU SAID, THERE MAY BE EMERGENCIES. CERTAINLY
10 POSTING IT ON THE WEBSITE IS FINE. GETTING AN AGENDA
11 THAT YOU CAN NEVER CHANGE PRESENTS A LOT OF PROBLEMS, I
12 THINK, FROM MY PERSONAL LEVEL AND OTHER PEOPLE'S
13 BECAUSE THE WORLD IS MOVING SO FAST. IT'S NICE IF WE
14 CAN DO IT.

15 HAVING SAID THAT, WHAT I WOULD LIKE TO
16 SUGGEST IS THAT WE EXAMINE ALL OF THE ITEMS THAT YOU
17 HAVE BROUGHT UP, THAT WE HAVE, YOU KNOW, A SMALL STAFF
18 GROUP DO IT WITH YOU, JAMES, AND SOME OF THE PEOPLE,
19 AND THEN MAKE A RECOMMENDATION BACK TO THIS GROUP AND
20 THEN BACK TO THE ICOC, TAKING INTO SERIOUS
21 CONSIDERATION WHAT YOU HAVE MENTIONED. SOME OF IT, YOU
22 KNOW, WE'LL JUST HAVE TO EVALUATE WHAT WE GIVE AND WHAT
23 WE LOSE. AND I'D LIKE TO HEAR MORE OF IT AT THAT TIME
24 AS WELL IF THAT'S OKAY WITH YOU.

25 MR. HALPERN: THAT SOUNDS FINE TO ME, MADAM

1 CHAIR, PROVIDED THAT THE PROCESS THAT THE STAFF
2 UNDERTAKES IS ONE THAT IS AN OPEN PROCESS, WHICH NOT
3 ONLY I, BUT MR. FRANK FROM CALIFORNIANS AWARE AND OTHER
4 MEMBERS OF THE INTERESTED PUBLIC, ALSO HAVE AN
5 OPPORTUNITY TO PARTICIPATE.

6 THERE ARE A NUMBER OF OTHER POINTS THAT I
7 WOULD LIKE TO MAKE TOO. I DON'T KNOW WHETHER YOU WANT
8 TO HEAR THEM NOW OR WHETHER YOU WANT TO REFER THE WHOLE
9 MATTER TO THE STAFF.

10 CO-CHAIR LANSING: I'M NOT TRYING TO BE
11 DISRESPECTFUL BECAUSE I DO WANT TO HEAR THEM ALL, AND I
12 DO WANT TO BE PART OF THE STAFF THAT WORKS ON IT, BUT I
13 THINK IT'S BETTER BECAUSE I THINK IT'S GOING TO OPEN UP
14 SO MANY OTHER ISSUES, THAT WE ACCEPT THE FACT THAT
15 TODAY WE HAVE MADE THESE MEETINGS OPEN TO THE PUBLIC,
16 WHICH IS SOMETHING THAT WE DID NOT HAVE TO DO, BUT WE
17 WANT TO DO AND WELCOME DOING. NOW LET'S SEE HOW WE CAN
18 REFINE THIS TO MAKE IT EVEN BETTER, YOU KNOW, WITHOUT
19 LETTING US GET LOST IN SOMETHING THAT BECOMES A
20 BUREAUCRATIC NIGHTMARE. AND SO I WOULD LIKE TO REFER
21 IT TO THE STAFF AND HAVE YOU AND ANYONE ELSE THAT
22 PARTICIPATES AS WELL AS ALL OF US HERE.

23 MR. HALPERN: MAY I JUST CLARIFY WHAT THE
24 PROCESS YOU'RE SUGGESTING IS, MADAM CHAIR. ARE YOU
25 SUGGESTING THAT THIS PROPOSED MEETING PROCEDURES

1 DOCUMENT AMENDED, AS MRS. RABB HAS SUGGESTED, THAT THIS
2 DOCUMENT WILL BE TABLED FOR LATER CONSIDERATION BY THIS
3 COMMITTEE, AND THEN THE COMMITTEE WILL MAKE A
4 RECOMMENDATION?

5 CO-CHAIR LANSING: NO. I AM PROPOSING --
6 SORRY -- THIS IS THE FIRST TIME SOMEONE COULDN'T HEAR
7 MY VOICE OVER A MIC. I AM PROPOSING THAT WE HAVE
8 PASSED THIS RESOLUTION, WHICH WE HAVE ALREADY DONE,
9 WHICH DOES NOT MEAN THAT WE CANNOT MODIFY IT AND ADD
10 THE ITEMS THAT YOU ARE TALKING ABOUT BECAUSE THIS IS
11 JUST THE BEGINNING. AND I AM PROPOSING THAT WE TOOK A
12 VOTE, AND THAT IN THE INTERIM, WE'RE GOING TO HAVE A
13 SMALL STAFF THAT'S GOING TO GET MORE INPUT FROM YOU
14 THAT WE'RE ALL GOING TO WORK ON. AND WE ARE GOING TO
15 THEN SEE IF WE WANT TO MODIFY IT IN THE WAYS THAT YOU
16 SUGGESTED AND IN THE OTHER WAYS, BUT I CAN'T RESCIND
17 THE VOTE THAT WE ALREADY TOOK.

18 WHAT YOU ARE ASKING FOR IS AN EXPANSION OF
19 WHAT WE TOOK. THERE'S NOTHING THAT WE VOTED ON THAT
20 YOU'RE AGAINST, BUT YOU WANT MORE FROM WHAT I'M
21 HEARING.

22 MR. HALPERN: MY HOPE IS THAT THE WORKING
23 GROUP IS GOING TO BE A GENUINELY DELIBERATIVE BODY, AND
24 IT'S GOING TO PASS ON RECOMMENDATIONS TO THE ICOC THAT
25 REFLECT REAL DELIBERATION. AND QUITE FRANKLY, FIRST OF

1 ALL, THE VOTE THAT WAS TAKEN BEFORE HAD PERMITTED NO
2 DISCUSSION AT ALL, NO COMMENT FROM THE PUBLIC, WHICH I
3 THINK IS A MISTAKE. AND SECOND, I THINK IF YOU ARE
4 GOING TO REFER IT TO STAFF, THAT THERE BE SOME KIND OF
5 DEADLINE SO THAT THE STAFF WILL REPORT BACK TO THE
6 COMMITTEE AND THE COMMITTEE WILL ACT IN A MORE
7 DELIBERATIVE FASHION, NOT NECESSARILY IN-PERSON
8 MEETING. COULD BE A TELEPHONE MEETING. BUT, SAY,
9 WITHIN 30 DAYS THERE WILL BE A REVIEW OF POSSIBLE
10 AMENDMENTS.

11 DR. HALL: I'M VERY WORRIED ABOUT COMMITMENTS
12 OF STAFF. WE RIGHT NOW ARE STILL GEARING UP. WE ARE
13 TRYING TO HIRE THE LIAISON FOR THIS COMMITTEE RIGHT
14 NOW. WE HAVE NOT HIRED SUCH A PERSON. AND THE DEMANDS
15 ON STAFF TIME FOR SUPPORTING THESE MEETINGS,
16 PARTICULARLY THE BAGLEY-KEENE STYLE MEETINGS THAT
17 MR. HALPERN DESCRIBES AS GOLD STANDARD, THE STAFF TIME
18 FOR THOSE IS ENORMOUS. MUCH OF THE STAFF OF CIRM RIGHT
19 NOW HAS BEEN SUPPORTING THOSE PUBLIC MEETINGS. SO JUST
20 A WORD OF CAUTION ABOUT WHAT YOU ARE ASKING THE STAFF
21 TO DO HERE ON A QUICK TIME SCALE BECAUSE I THINK IT'S
22 GOING TO BE VERY DIFFICULT.

23 CO-CHAIR LANSING: I THINK THE BEST WE CAN
24 SAY, AND THIS IS SORT OF IRONIC, AND I DO REALLY
25 RESPECT WHAT YOU'RE SAYING, YOU KNOW, BUT IT'S SORT OF

1 IONIC BECAUSE WE ARE DOING SOMETHING THAT WE DIDN'T
2 HAVE TO DO. WE'RE TRYING TO OPEN THE MEETINGS UP TO
3 THE PUBLIC AND WE'RE ALL HERE DOING THAT, AND THAT
4 WASN'T PART OF WHAT WE HAD TO DO.

5 NOW, HAVING SAID THAT, YOU'RE RAISING VERY
6 VALID POINTS, BUT OTHER PEOPLE ARE ALSO RAISING POINTS,
7 AND I, QUITE HONESTLY, DON'T KNOW THE ANSWER, NOR
8 SHOULD I BECAUSE THERE HASN'T BEEN AN OPEN DISCUSSION
9 THAT WE NEED TO HAVE TO REALLY EXAMINE WHAT WE GIVE AND
10 WHAT WE LOSE. OTHER PEOPLE ARE RAISING CONCERNS. I
11 THINK THE BEST THAT I CAN SAY IS WE'RE GOING TO MOVE
12 FORWARD WITH WHAT WE HAVE NOW, AND WE ARE GOING TO
13 CONTINUE TO TALK TO YOU, WITH JAMES, WITH MYSELF, WITH
14 OTHER PEOPLE AND TRY TO COME TO A SOLUTION THAT MAKES
15 EVERYBODY HAPPY AND DOESN'T HURT US IN THE PROCESS.

16 DR. HALL: CAN I MAKE ONE --

17 CO-CHAIR LANSING: AND DO IT AS QUICKLY AS WE
18 POSSIBLY CAN.

19 DR. HALL: -- STATEMENT, PLEASE, THAT IT
20 SEEMS TO ME THAT ONE WAY TO THINK ABOUT TRYING TO
21 PLEASE WHAT MR. HALPERN WANTS WITH THE VERY REAL
22 DEMANDS ON THE COMMITTEE, ON THE STAFF, ON THE WORKING
23 GROUP MEMBERS, AS MR. SHESTACK SAID, IS THAT I THINK
24 THE REAL PRINCIPLE IS THAT AS SOON AS ANY MATERIAL IS
25 READY FOR THE COMMITTEE, IT ALSO SHOULD BE MADE AT THE

1 SAME TIME AVAILABLE TO THE PUBLIC.

2 CO-CHAIR LANSING: ABSOLUTELY. ABSOLUTELY.

3 DR. HALL: THAT IS, THERE'S NO -- IT'S NOT
4 THAT THE COMMITTEE AND THE PUBLIC ARE BEING TREATED
5 DIFFERENTLY. AND IF THERE'S A CHANGE IN AGENDA, IT
6 WOULD BE POSTED IMMEDIATELY AS SOON AS THE CHANGE IS
7 MADE SO THAT IT LEAVES US FLEXIBILITY AND YET TREATS
8 THE WORKING GROUP AND THE PUBLIC EXACTLY THE SAME WAY
9 IN TERMS OF ACCESS TO INFORMATION. IF THAT COULD BE
10 THE GUIDING PRINCIPLE, I THINK IT WOULD BE VERY
11 HELPFUL.

12 CO-CHAIR LANSING: WE COULD SAY TODAY THAT
13 WHENEVER POSSIBLE, WE'RE GOING TO TRY AND GIVE TEN DAYS
14 NOTICE. WE CAN SAY TODAY THAT WHEN WE GET THE
15 INFORMATION, THE PUBLIC IS GOING TO GET THE
16 INFORMATION. WE CAN SAY TODAY WE'RE GOING TO POST IT
17 ON THE WEBSITE, BUT I DON'T KNOW THAT THAT'S ENOUGH FOR
18 YOU. IS THAT ENOUGH FOR YOU TODAY? AND THEN YOU WANT
19 TO HAVE FURTHER DISCUSSIONS?

20 MR. HALPERN: THAT'S ENOUGH WITH REGARD TO
21 PARAGRAPH 1. I THINK IT'S TERRIFIC. THE FACT IS THERE
22 ARE -- I THINK THERE ARE SOME -- AND MR. FRANK AGREES
23 WITH ME -- THERE ARE SOME VERY SERIOUS DEFICIENCIES
24 WITH THIS POLICY. MUCH AS WE WELCOME THE DISTANCE THAT
25 THE ICOC HAS COME IN EVEN PROPOSING THIS MUCH, WE

1 WELCOME THAT AND WE ACKNOWLEDGE IT, BUT THERE ARE
2 RELATIVELY MODEST THINGS WHICH ARE SO DISCORDANT, SO
3 OUT OF TUNE WITH CALIFORNIA PRACTICE AND EXPECTATIONS,
4 THAT I THINK THAT THIS WORKING GROUP COULD RELATIVELY
5 EASILY CORRECT THEM.

6 CO-CHAIR LANSING: THEN WE HAVE TO GO BACK TO
7 WHAT I SAID. I THINK WE NEED TO MOVE ON, AND AGAIN,
8 HAVE A SMALL GROUP THAT TRIES TO CORRECT THEM THAT
9 DOESN'T HARM THE WORKING GROUP AND ALSO GIVES YOU
10 SATISFACTION BECAUSE OTHERWISE WE WILL SPEND THE NEXT
11 FIVE HOURS DOING THAT. AND I THINK THAT WOULD BE A
12 MISTAKE TO DO TODAY.

13 MR. KLEIN: MADAM CHAIRMAN, I THINK THAT THE
14 BOARD WOULD BE RECEPTIVE TO, IN FACT, AUGMENT STAFF
15 WITH CONTRACT STAFF, IF NECESSARY, TO MAKE SURE THAT
16 THERE IS SUPPORT TO WORK WITH THIS COMMITTEE AND THE
17 TEAM TO EVALUATE THIS PROCESS.

18 CO-CHAIR LANSING: I THINK WE NEED TO GET A
19 SMALL GROUP TOGETHER, WHICH WE WILL DISCUSS WITH YOU,
20 MAKE SURE THAT YOU ARE SATISFIED WITH IT, A SMALL GROUP
21 OF US. I AGREE WITH YOU. IT WILL NOT BE HARD TO SOLVE
22 THIS BECAUSE I THINK WE'RE ALL REASONABLE PEOPLE WHO
23 WANT THE SAME THING. SO WITH YOUR COMPLIANCE, I'D LIKE
24 TO MOVE ON, REFER THIS TO A SMALLER GROUP, AND TAKE
25 EVERYTHING THAT YOU'VE SAID SO FAR AND MORE TO COME

1 INTO SERIOUS CONSIDERATION.

2 MR. KLEIN: AND, MADAM CHAIR, TO PROVIDE
3 MR. HALPERN AND THE PUBLIC ASSURANCE WHERE THIS WORKING
4 GROUP STANDS, WITH THE BENEFIT OF THESE PUBLIC COMMENTS
5 AND TO CLARIFY THAT IN THE CONTEXT OF THE PUBLIC
6 COMMENTS, THAT THE BOARD DID WANT TO MOVE FORWARD WITH
7 THE INITIAL AMENDMENT AND MATTERS AS ADOPTED MIGHT WANT
8 TO JUST HAVE A MOTION TO ADOPT THE ENTIRE RESOLUTION AS
9 AMENDED WITH THE BENEFIT OF THE PUBLIC COMMENT SO THAT
10 PROCEDURALLY WE CAN FOLLOW THAT FORMAT.

11 CO-CHAIR LANSING: ALL RIGHT.

12 MR. KLEIN: AND I WOULD MAKE THAT MOTION IF
13 THERE WERE A SECOND.

14 CO-CHAIR LANSING: SECOND. ALL IN FAVOR.

15 MR. SHEEHY: CAN I MAKE A COMMENT? CAN WE
16 JUST TAKE INTO ACCOUNT YOUR COMMENT THAT WE MAKE ALL
17 THE MATERIALS AVAILABLE TO THE PUBLIC AS SOON AS WE GET
18 THEM? YOU SUGGESTED THAT IN TERMS OF AGENDAS AND OTHER
19 MATERIALS THAT WE HAVE. THERE'S NOT GOING TO BE
20 ANYTHING IN HERE TO MAKE THOSE AVAILABLE TO THE PUBLIC
21 WHEN WE GET THEM.

22 CO-CHAIR LANSING: I THINK -- YOU WANT TO
23 MAKE THAT PART OF OUR --

24 MR. SHEEHY: SURE.

25 CO-CHAIR LANSING: I HAVE NO PROBLEMS.

1 MR. KLEIN: I WOULD AGREE TO THAT AS A
2 FRIENDLY AMENDMENT.

3 CO-CHAIR LANSING: ALL IN FAVOR. SO, AGAIN,
4 I JUST WANT TO PUT THIS IN PERSPECTIVE. WE REALLY WANT
5 THIS TO BE OPEN TO THE PUBLIC. WE ARE DOING THIS
6 VOLUNTARILY, AND WE'RE TRYING TO SATISFY EVERYONE. SO
7 WE'VE NOW AMENDED OUR INITIAL THING BECAUSE OF YOUR
8 HELP, MR. HALPERN, AND WE WILL CONTINUE TO AMEND IT AND
9 GET TO A SOLUTION THAT MAKES EVERYBODY HAPPY, AND WE
10 WILL DO IT IN AS TIMELY A FASHION AS POSSIBLE. AND WE
11 WILL GET A SUBGROUP TOGETHER TO DO SO.

12 MR. HARRISON: AS DR. HALL EXPLAINED, THIS
13 WORKING GROUP IS CHARGED WITH RECOMMENDING SCIENTIFIC,
14 MEDICAL, AND ETHICAL STANDARDS TO THE ICOC FOR ITS
15 CONSIDERATION. I WANT TO SPEND A FEW MINUTES GIVING
16 YOU A LITTLE BIT OF BACKGROUND ABOUT THE PROCESS AND
17 THE LAW ITSELF. IN ORDER TO EXPEDITE FUNDING FOR STEM
18 CELL RESEARCH, PROP 71 AUTHORIZES THE ICOC TO ADOPT
19 INTERIM STANDARDS TO GOVERN RESEARCH FUNDED BY THE
20 INSTITUTE. THESE INTERIM STANDARDS ARE AKIN TO
21 EMERGENCY REGULATIONS UNDER CALIFORNIA LAW. BUT, YOU
22 KNOW, LIKE EMERGENCY REGULATIONS, WHICH EXPIRE AFTER
23 120 DAYS, THE INTERIM STANDARDS ADOPTED BY THE ICOC
24 REMAIN IN EFFECT FOR UP TO 270 DAYS, WHICH ALLOWS MORE
25 TIME FOR PUBLIC COMMENT AND CONSIDERATION BEFORE THE

1 ICOC ADOPTS PERMANENT STANDARDS BASED UPON THE
2 RECOMMENDATIONS OF THIS WORKING GROUP.

3 UNDER PROP 71 THE PERMANENT STANDARDS MUST BE
4 ADOPTED IN ACCORDANCE WITH THE CALIFORNIA
5 ADMINISTRATIVE PROCEDURE ACT. AND LET ME BRIEFLY
6 DESCRIBE WHAT THAT ENTAILS. THE APA REQUIRES THE CIRM
7 TO PUBLISH INTERIM STANDARDS IN THE CALIFORNIA
8 REGULATORY NOTICE REGISTRY. IN ADDITION, THE APA
9 REQUIRES THE CIRM TO PERMIT A MINIMUM OF 45 DAYS FOR
10 PUBLIC COMMENT. THE CIRM IS REQUIRED TO RESPOND TO
11 PUBLIC COMMENTS AND, IF NECESSARY, DRAFT MODIFICATIONS
12 TO THE STANDARDS IN RESPONSE TO THOSE PUBLIC COMMENTS.

13 IF SUBSTANTIAL, BUT RELATED CHANGES ARE MADE,
14 THE CIRM MUST ALLOW AN ADDITIONAL 15 DAYS FOR PUBLIC
15 COMMENTS ON THOSE CHANGES. MAJOR CHANGES MAY TRIGGER A
16 NEW 45-DAY PUBLIC COMMENT PERIOD.

17 ONCE THE FINAL STANDARDS ARE APPROVED BY THE
18 ICOC, AFTER BEING RECOMMENDED BY THIS WORKING GROUP,
19 THEY WILL BE SUBMITTED TO THE OFFICE OF ADMINISTRATIVE
20 LAW FOR REVIEW. THE OAL REVIEWS THE STANDARDS BASED ON
21 SIX DIFFERENT CRITERIA:

22 FIRST IS AUTHORITY; THAT IS, WHETHER THE
23 AGENCY HAS STATUTORY AUTHORITY TO ADOPT THE REGULATION.

24 THE SECOND IS REFERENCE; THAT IS, THE
25 IDENTIFICATION OF THE STATUTE THAT THE REGULATION IS

1 INTENDED TO IMPLEMENT.

2 THE THIRD CRITERIA IS CONSISTENCY, WHETHER
3 THE REGULATION IS IN HARMONY WITH THE STATUTE UPON
4 WHICH IT'S BASED AND ANY OTHER COURT DECISIONS OR LAWS.

5 THE FOURTH CRITERIA IS CLARITY, WHETHER THE
6 REGULATION IS WRITTEN SO THAT THE MEANING OF THE
7 REGULATION IS EASILY UNDERSTOOD BY THOSE PERSONS
8 DIRECTLY AFFECTED BY IT.

9 FIFTH, NONDUPLICATION, WHETHER THE REGULATION
10 SERVES THE SAME PURPOSE AS ANOTHER STATUTE OR
11 REGULATION.

12 AND THE FINAL CRITERIA IS NECESSITY, WHETHER
13 THE RECORD DEMONSTRATES BY SUBSTANTIAL EVIDENCE THE
14 NEED FOR THE REGULATION TO EFFECTUATE THE PURPOSE OF
15 THE STATUTE.

16 THOSE ARE THE SIX CRITERIA UPON WHICH THE OAL
17 WILL REVIEW THE STANDARDS RECOMMENDED BY THIS WORKING
18 GROUP AND APPROVED BY THE ICOC. THE OFFICE OF
19 ADMINISTRATIVE LAW HAS 30 WORKING DAYS IN WHICH TO
20 UNDERTAKE THAT PROCESS. AS DR. HALL NOTED EARLIER, THE
21 ICOC IS REQUIRED TO ADOPT STANDARDS BEFORE RESEARCH CAN
22 BE CONDUCTED. FORTUNATELY FOR THE ICOC, THE NATIONAL
23 ACADEMY OF SCIENCES HAS DEVOTED SUBSTANTIAL TIME AND
24 RESOURCES TO DEVELOP STANDARDS FOR HUMAN EMBRYONIC STEM
25 CELL RESEARCH. BECAUSE OF THE STRENGTH OF THESE

1 GUIDELINES AND THE NEED TO PUT THE STANDARDS IN PLACE
2 BEFORE GRANTS CAN BE AWARDED, THE ICOC HAS ADOPTED THE
3 NATIONAL ACADEMY OF SCIENCES GUIDELINES ON HUMAN
4 EMBRYONIC STEM CELL RESEARCH AS ITS INTERIM STANDARDS.
5 THE ICOC ADOPTED THESE STANDARDS AT ITS MAY 23D, 2005,
6 MEETING, AND THEY WILL REMAIN IN EFFECT UNTIL FEBRUARY
7 16 -- FEBRUARY 16, 2006.

8 OVER THE COURSE OF THE NEXT SEVERAL MONTHS,
9 THE CIRM STAFF, ALONG WITH THIS WORKING GROUP, WILL
10 ELICIT PUBLIC COMMENT AND HOLD PUBLIC MEETINGS
11 CONCERNING THESE INTERIM STANDARDS. THESE COMMENTS
12 WILL BE SUMMARIZED AND PRESENTED TO THIS WORKING GROUP
13 FOR ITS CONSIDERATION AT ITS NEXT MEETING. AND THIS
14 WORKING GROUP WILL THEN CONSIDER THE COMMENTS AND
15 PROPOSE ANY MODIFICATIONS TO THE ICOC, WHICH WILL
16 ULTIMATELY MAKE THE FINAL DETERMINATION ON THE
17 STANDARDS.

18 I'D BE HAPPY TO ANSWER ANY QUESTIONS YOU
19 HAVE, BUT THAT'S A GENERAL OUTLINE OF THE PROCESS.

20 MR. KLEIN: JAMES, I THINK THE STATEMENT, AS
21 I INTERPRET IT, IS THEY'LL REMAIN IN EFFECT UNTIL
22 FEBRUARY UNLESS OTHERWISE SUPERSEDED BY FINAL STANDARDS
23 AS PROCESSED THROUGH THIS COMMITTEE AND THE BOARD. IS
24 THAT A CORRECT STATEMENT?

25 MR. HARRISON: THAT'S CORRECT. IF THIS

1 COMMITTEE WERE TO APPROVE THE -- TO RECOMMEND STANDARDS
2 TO THE ICOC AND THE ICOC WERE TO APPROVE THOSE
3 PERMANENT STANDARDS AND THE OAL WERE TO APPROVE THEM,
4 THEN THEY GO INTO EFFECT IMMEDIATELY, AND THE INTERIM
5 STANDARDS WOULD EXPIRE.

6 MR. KLEIN: AND THE NEXT ITEM RELATES TO THE
7 VALUE OF THE STANDARDS IN TERMS OF OUR RESEARCH
8 INTERFACE WITH OTHER STATES. DR. HALL, MAYBE YOU COULD
9 COMMENT. AS CALIFORNIA BEING THE FIRST STATE IN THE
10 COUNTRY TO ADOPT THESE STANDARDS, IF WE'RE ABLE IN
11 CALIFORNIA TO PASS RESEARCH MATERIALS, BIOLOGICAL
12 RESEARCH MATERIALS, BACK AND FORTH BETWEEN OTHER
13 STATES, MAYBE YOU CAN COMMENT ON THE CRITICAL VALUE OF
14 HAVING CONSISTENCY IN STANDARDS BETWEEN STATES AND THE
15 IMPORTANCE PERHAPS OF GETTING INPUT FROM OTHER STATES
16 AS WE GO FORWARD. AND IF WE AMEND THESE SIGNIFICANT
17 STANDARDS ON INFORMED CONSENT, WHAT THAT WILL MEAN IN
18 TERMS OF OUR ABILITY TO PASS MATERIALS BACK AND FORTH
19 WITH OTHER STATES ALSO DOING RESEARCH CONCURRENTLY.
20 AND SHOULD WE HAVE A PROCESS, MORE FORMAL PROCESS,
21 WHERE WE GET INTERRELATIONSHIPS OR INPUT FROM OTHER
22 STATES, IF THEY ARE, FOR EXAMPLE, CONSIDERING OTHER
23 MODIFICATIONS OF THESE STANDARDS.

24 DR. HALL: TWO POINTS. ONE IS I THINK
25 EVERYBODY UNDERSTANDS THE DESIRABILITY OF HAVING FREE

1 EXCHANGE OF MATERIALS IN THE SCIENTIFIC COMMUNITY.
2 IT'S TREMENDOUSLY IMPORTANT, AND I THINK IT'S A SERIOUS
3 ISSUE GOING FORWARD.

4 SECOND, I THINK ONE OF THE ADVANTAGES OF
5 HAVING A SET OF NATIONAL STANDARDS AS PROMULGATED BY
6 THE NATIONAL ACADEMIES IS JUST SO THAT THERE IS A SORT
7 OF UMBRELLA SET OF STANDARDS THAT MANY DIFFERENT STATES
8 CAN ADHERE TO. I THINK IF WE END UP HAVING TO
9 NEGOTIATE WITH MANY DIFFERENT STATES TO MAKE SURE OUR
10 STANDARDS ARE THE SAME AS THEIRS. I THINK ONE THING
11 THAT THE WORKING GROUP MAY WISH TO CONSIDER AS IT GOES
12 FORWARD IS JUST HOW TO HANDLE QUESTIONS OF DIFFERENCES
13 IN STANDARDS.

14 IN THE NATIONAL ACADEMY GUIDELINES, AS I
15 RECALL, ONE OF THE TASKS ASSIGNED TO THE ESCRO
16 COMMITTEES AT THE INSTITUTIONS IS TO DEAL WITH THAT
17 PROBLEM; THAT IS, WHERE THERE ARE DIFFERENCES BETWEEN,
18 SAY, THE WHAT THE KOREAN STANDARDS USED AND WHAT WAS
19 USED IN THE UNITED STATES FOR HOW TO ADJUDICATE THOSE.

20 I THINK WHETHER THE EXACT ROLE THAT CIRM
21 OUGHT TO PLAY IN THAT, I THINK OUR AIM SHOULD BE TO TRY
22 TO DO WHAT WE CAN WHILE MAINTAINING HIGH STANDARDS AT
23 THE SAME TIME TO FACILITATE AND NOT IMPEDE EXCHANGE,
24 BUT TO FACILITATE THE FREE FLOW OF SCIENTIFIC
25 INFORMATION AND MATERIALS EXCEPT IN UNREASONABLE CASES.

1 CO-CHAIR LANSING: ANY OTHER COMMENTS? ANY
2 PUBLIC COMMENT?

3 DR. CIBELLI: I THINK WE HAVE AN OPPORTUNITY
4 TO REVIEW THE -- WE HAVE AN OPPORTUNITY TO REVIEW THE
5 NATIONAL ACADEMY GUIDELINES. ARE WE GOING TO HAVE AN
6 OPPORTUNITY TO REALLY COMMENT ON THEM AND SEE IF IT'S
7 GOOD TO DO OR NOT?

8 CO-CHAIR LANSING: YES.

9 DR. CIBELLI: WHEN IS IT GOING TO HAPPEN?

10 MR. SHESTACK: IT SEEMS LIKE AGENDA ITEM 5
11 ACTUALLY, AND IT SEEMED LIKE WE JUMPED FOUR AND GOT
12 INTO A DISCUSSION ON RELATIVE MERITS OF NAS GUIDELINES
13 AND STATE-BY-STATE GUIDELINES.

14 CO-CHAIR LANSING: IT IS ITEM NO. 5.

15 MR. SHESTACK: RIGHT. AND IT SEEMED LIKE WE
16 KIND OF STARTED DISCUSSING IT BEFORE NO. 4.

17 DR. PRIETO: I THINK WE'RE STILL ON NO. 4.
18 WE'RE TALKING ABOUT THE ROLE OF THIS COMMITTEE IN
19 FINDING THOSE GUIDELINES AND MODIFYING THEM RATHER THAN
20 THE GUIDELINES THEMSELVES.

21 DR. HALL: I'M A LITTLE CONFUSED MYSELF. I
22 THINK WHAT HAPPENED IS I THINK MR. HALPERN'S COMMENT
23 PULLED US BACK TO THE PREVIOUS ISSUE QUITE CORRECTLY;
24 BUT THAT WHEN I MADE MY COMMENTS AND THEN FOLLOWED BY
25 JAMES, I THINK THAT WAS INTENDED TO BE THE INTRODUCTION

1 FOR PART FIVE. WE DIDN'T IDENTIFY IT AS SUCH, BUT JUST
2 TO STATE WHERE WE ARE AT THE PRESENT MOMENT; THAT IS,
3 WE HAD ADOPTED THESE STANDARDS, AND THEN JAMES HARRISON
4 DESCRIBING FOR US THE PROCEDURES THAT WE WOULD USE
5 GOING FORWARD. DURING THAT PERIOD OF TIME,
6 DR. CIBELLI, THAT THE WORKING GROUP WOULD HAVE A CHANCE
7 TO DISCUSS AMONG ITSELF AND TO HEAR FROM THE PUBLIC
8 VARIOUS ASPECTS OF THE NATIONAL ACADEMY STANDARDS.

9 MR. SHESTACK: SO, IN FACT, WE ARE STILL ON
10 AGENDA ITEM 4; IS THAT CORRECT?

11 CO-CHAIR LANSING: I THOUGHT WE WERE ON
12 AGENDA ITEM 4, BUT WE GOT A LITTLE BIT INTO FIVE. JUST
13 TO MAKE SURE THE PUBLIC HAS A CHANCE, LET ME JUST OPEN
14 IT TO PUBLIC COMMENT AND OFFICIALLY GO TO AGENDA 5.
15 PUBLIC COMMENT ON MY SHEET IS AFTER THIS.

16 MR. SHESTACK: THE CONSIDERATION OF THE
17 CHARGE, IS THE CHARGE WE PUT -- ARE WE BEING ASKED TO
18 SORT OF ACKNOWLEDGE WE UNDERSTAND THE CHARGE OF THE
19 COMMITTEE?

20 CO-CHAIR LANSING: ARE THERE ANY QUESTIONS
21 FROM THE GROUP ON THE CONSIDERATION OF THE CHARGE?

22 DR. PRIETO: I THINK THE CHARGE IS DEFINED BY
23 THE INITIATIVE AND WHAT PRESIDENT HALL HAS SET UP
24 BEFORE US. I DON'T THINK WE NEED TO VOTE ON THAT.

25 CO-CHAIR LANSING: NO, THERE'S NOTHING TO

1 VOTE ON. JUST ANY QUESTIONS. NOW, ON MY THING THAT
2 EVERYBODY HAS, IN THE SPIRIT OF THE PUBLIC, I'M ASKING
3 IF THERE'S ANY PUBLIC COMMENT SO FAR ON ANYTHING ELSE?
4 THAT UNDERSTOOD --

5 MR. SHESTACK: I'M SORRY. I DO HAVE SOME
6 QUESTIONS ABOUT THE CHARGE BECAUSE THERE ARE -- FOR
7 INSTANCE, THE WORKING GROUP, THERE WERE MANY
8 DISCUSSIONS ON THE PROPER DEFINITION OF THE CHARGE OF
9 THE COMMITTEE WAS. FOR INSTANCE, THIS CAME UP
10 EXTENSIVELY WHEN WE WERE SETTING THE CRITERIA FOR
11 MEMBERS OF THIS COMMITTEE. THEY HAVE EXPERTISE --

12 MR. KLEIN: JON, I THINK THAT THE PUBLIC IS
13 SAYING THAT IF YOU MOVE THE -- IF YOU'RE CLOSER TO THE
14 MIC, WE CAN HEAR YOU.

15 MR. SHESTACK: THERE WAS DISCUSSION ON WHAT
16 EXACTLY THE CHARGE MIGHT BE. FOR INSTANCE, WHEN WE
17 WERE DISCUSSING QUALIFICATIONS OF COMMITTEE MEMBERS,
18 THERE WAS A SET OF CATEGORIES, SOME WERE WHETHER THEY
19 HAD EXPERIENCE, FOR INSTANCE, ON THE CLINICAL TRIALS,
20 WHETHER THEY HAD EXPERIENCE IN RESEARCH CREATION AND
21 BANKING, DIVERSITY, ALL SORTS OF THINGS.

22 AND I WANTED TO PUT BACK UP THE DEFINITION SO
23 WE UNDERSTAND WE HAVE A STRICT DEFINITION. THERE WERE
24 ALSO DISCUSSIONS THAT I DON'T KNOW THE RESULT, FOR
25 INSTANCE, WHETHER OR NOT THIS COMMITTEE WOULD BE THE

1 APPROPRIATE COMMITTEE, FOR INSTANCE, TO OFFER AN
2 ETHICAL POINT OF VIEW ON SOME OF THE FINANCIAL ISSUES,
3 SOME OF THE ISSUES THAT HAVE TO DO WITH PATENTING
4 BIOMATERIALS WITH WIDE DISTRIBUTION. AND SO I DO THINK
5 THAT WE SHOULD TAKE THE OPPORTUNITY.

6 THE WORKING GROUP MAYBE WASN'T THE RIGHT --
7 THE SUBCOMMITTEE WASN'T THE RIGHT PLACE TO DO IT, BUT
8 THIS IS THE WORKING GROUP THAT WILL BE HERE FOR A YEAR,
9 SO I WOULD LIKE TO CLARIFY, IF ONLY FOR MYSELF, WHETHER
10 OR NOT --

11 CO-CHAIR LANSING: I UNDERSTAND WHAT YOU ARE
12 SAYING.

13 MR. SHESTACK: I WISH I HAD ACCESS,
14 UNFORTUNATELY I DON'T, TO THE MINUTES OF SOME OF THOSE
15 PREVIOUS WORKING GROUPS.

16 CO-CHAIR LANSING: I THINK THAT YOU LISTED
17 THE CONSIDERATION OF A CHARGE THAT DID HAVE PATENT IN
18 IT, AS I REMEMBER.

19 DR. HALL: WHAT WAS ON THE POWERPOINT, AND I
20 CAN EASILY PUT IT BACK UP IF YOU WOULD LIKE, IS TAKEN
21 ALMOST DIRECTLY, COURTESY OF KEN TAYMORE, DIRECTLY FROM
22 PROPOSITION 71. THESE ARE NOT ITEMS TO BE VOTED ON BY
23 THE WORKING GROUP, BUT IT IS --

24 CO-CHAIR LANSING: IT'S A CLARIFICATION FOR
25 JONATHAN.

1 DR. HALL: THE QUESTION YOU RAISED, JON --

2 MR. SHESTACK: YOU WERE AT THESE MEETINGS,
3 AND I THINK THE GROUP HAD A LOT OF DISCUSSION OVER
4 THERE IS DEFINITION BY THE LAW OF THAT -- FROM THE LAW
5 AND THEN THERE IS ITS INTERPRETATION. THE GROUP IS
6 SOMEWHAT -- THE SUBCOMMITTEE IS GIVING IT A SOMEWHAT
7 BROAD INTERPRETATION, MY RECOLLECTION, OF WHAT THEY
8 THOUGHT WOULD BE APPROPRIATE FOR THIS WORKING GROUP TO
9 BE ABLE TO TOUCH UPON TO ADVISE THE FULL ICOC.

10 DR. HALL: WE CAN PUT THOSE BACK UP ON THE
11 SCREEN.

12 CO-CHAIR LANSING: I THINK JON WOULD LIKE
13 THAT.

14 MR. SHEEHY: I THINK ONE OF THE -- YEAH. ONE
15 OF THE ISSUES THAT WE HAD QUITE A BIT OF DISCUSSION ON
16 WAS WHETHER OR NOT INTELLECTUAL PROPERTY GUIDELINES
17 WOULD COME THROUGH THIS COMMITTEE. I DO NOTICE WITHIN
18 THE FEDERAL GUIDELINES THAT WE HAVE IN FRONT OF US --
19 NATIONAL ACADEMY, I'M SORRY -- THEY DO MENTION SOME
20 INTELLECTUAL PROPERTY RELATED ISSUES. THERE IS CONCERN
21 WITH ADEQUATE BENEFIT TO THE PUBLIC. THERE'S A PART IN
22 HERE ON INTELLECTUAL PROPERTY POLICIES. AND SO I THINK
23 IT'S REALLY UNCLEAR AS TO WHETHER OR NOT THIS COMMITTEE
24 HAS THAT CHARGE. AND I DON'T KNOW IF THIS IS WHERE WE
25 WANT TO DECIDE THAT.

1 CO-CHAIR LANSING: FIRST OF ALL, IF YOU
2 LOOK -- WANT TO PUT UP THE SLIDE. LET ME JUST MAKE
3 SOMETHING CLEAR BECAUSE MAYBE THIS IS WHAT YOU GUYS ARE
4 GETTING CONFUSED ABOUT. WE'RE ADOPTING THE INTERIM NAS
5 GUIDELINES, BUT THAT'S NOT ALL WE'RE DOING. WE'RE
6 GOING TO EVALUATE THEM AND LOOK AT THEM, AND THOSE ARE
7 NOT NECESSARILY GOING TO BE OUR GUIDELINES. AND OUR
8 CHARGE DID GET IN HERE. I REMEMBER IT DID GET INTO
9 PATENT AND IT DID GET INTO ALL THE INTELLECTUAL
10 PROPERTY ISSUES.

11 DR. HALL: MADAM CHAIR, CAN I MAKE A COMMENT
12 ON THAT? THERE ARE TWO ITEMS THAT ARE MENTIONED IN THE
13 PROPOSITION, INTELLECTUAL PROPERTY AND CONFLICT OF
14 INTEREST. AND MAYBE JAMES HARRISON WOULD COMMENT ON
15 THOSE BECAUSE THOSE ARE, AS I UNDERSTAND IT, CONSIDERED
16 NOT TO BE WITHIN THE PURVIEW OF THIS COMMITTEE, BUT
17 WILL BE TAKEN UP ELSEWHERE.

18 CO-CHAIR LANSING: THEN I'M WRONG BECAUSE I
19 THOUGHT THERE WAS SOMETHING UP HERE THAT SAID THAT. SO
20 PLEASE CORRECT ME THEN.

21 DR. KIESSLING: EXCUSE ME. CAN I ASK A
22 QUESTION?

23 CO-CHAIR LANSING: SURE.

24 DR. KIESSLING: COULD MR. HARRISON PLEASE
25 DEFINE WHO YOU ARE?

1 MR. HARRISON: I'M SPECIAL COUNSEL TO THE
2 CIRM.

3 DR. KIESSLING: THANK YOU.

4 CO-CHAIR LANSING: THANK YOU. AND AGAIN,
5 THAT'S MY FAULT. SO I APOLOGIZE. AGAIN, IF EVERYONE
6 BEFORE ON THIS FIRST MEETING WILL JUST SAY WHO THEY
7 ARE, IT PROBABLY WOULD BE VERY HELPFUL FOR EVERYBODY.

8 MR. HARRISON: THE ACT REFERS TO THE WORKING
9 GROUP TAKING INTO ACCOUNT STANDARDS FOR MEDICAL,
10 SOCIOECONOMIC, AND FINANCIAL ASPECTS OF CLINICAL
11 TRIALS. AND I THINK THE REFERENCE TO FINANCIAL ASPECTS
12 OF CLINICAL TRIALS WAS INTENDED TO GO TO THINGS LIKE
13 STANDARDS FOR COMPENSATION FOR DONORS AND PARTICIPANTS
14 AS OPPOSED TO THE FINANCIAL ASPECTS RELATING TO
15 PATENTS.

16 IT'S TRUE THAT THE ICOC IS REQUIRED TO ADOPT
17 STANDARDS FOR ROYALTIES. AND ONE OF THE THINGS THAT
18 WAS DISCUSSED IN THE SEARCH SUBCOMMITTEE WAS HAVING
19 THIS WORKING GROUP, WHILE NOT UNDERTAKING SOLE
20 RESPONSIBILITY FOR DEVELOPING INTELLECTUAL PROPERTY
21 STANDARDS, HAVING THIS WORKING GROUP, NONETHELESS, BE
22 CONSULTED ABOUT THESE STANDARDS FOR ANY INPUT THAT IT
23 MIGHT HAVE THROUGH WHATEVER MECHANISM THE ICOC SETS UP
24 TO CONSIDER THOSE ISSUES.

25 CO-CHAIR LANSING: WHAT WORKING GROUP IS

1 DEALING WITH THIS?

2 MR. HARRISON: THERE ARE NO WORKING GROUPS
3 THAT ARE ASSIGNED TO CONSIDER THE INTELLECTUAL PROPERTY
4 STANDARDS. THAT'S SOMETHING THAT THE ICOC COULD DECIDE
5 AS A BODY OR COULD APPOINT A SUBCOMMITTEE TO CONSIDER.

6 DR. HALL: POINT ABOUT IT NOT BEING A
7 REGULATION THAT HAS TO FOLLOW -- FALLS UNDER THE
8 ADMINISTRATIVE PROCEDURES ACT, I MAY HAVE
9 MISUNDERSTOOD, I THOUGHT THAT WAS THE POINT BEING MADE
10 TO ME AT ONE POINT ABOUT IP AND CONFLICT OF INTEREST,
11 THAT THOSE WERE NOT.

12 MR. HARRISON: NO, THAT'S NOT NECESSARILY THE
13 CASE. IT'S JUST THEY ARE NOT -- THEY DON'T FALL
14 EXCLUSIVELY WITHIN THE JURISDICTION OF THIS WORKING
15 GROUP. THE ICOC MAY MAKE A DECISION TO CONSULT THIS
16 WORKING GROUP ON THOSE ISSUES AS THE SEARCH
17 SUBCOMMITTEE SUGGESTED DURING ITS MEETINGS.

18 MR. SHEEHY: I'D JUST LIKE TO NOTE THAT WE'VE
19 ADOPTED THESE GUIDELINES, AND THESE GUIDELINES SAY
20 BESIDES THE EXCELLENT SCIENTIFIC WORK WE HAVE
21 ACCOMPLISHED, THE INSTITUTIONS INVOLVED IN HUMAN
22 EMBRYONIC STEM CELL RESEARCH SHALL... IN DEVISING
23 HEALTHCARE SYSTEMS THAT WILL MAKE THE LONG-TERM
24 BENEFITS OF THIS WORK WIDELY AVAILABLE.

25 WE'VE ALREADY STEPPED INTO IT, AND THIS

1 COMMITTEE CHARGE HAS THAT CHARGE DEALING WITH THOSE
2 ISSUES.

3 DR. EGGAN: I THINK THAT THE GUIDELINES
4 SUGGEST THAT THE INSTITUTIONS WHICH ARE INVOLVED IN
5 THIS RESEARCH WITHIN THE UNIVERSITIES AND THE ENTITIES
6 WHICH CARRY OUT THE RESEARCH, NOT THIS GROUP, HAVE THAT
7 CHARGE; IS THAT CORRECT?

8 MR. KLEIN: I WOULD JUST LIKE TO SAY THAT
9 FROM THE INTENT OF THE INITIATIVE ITSELF, THAT IT'S
10 PERFECTLY CONSISTENT WITH WHAT SHERRY LANSING IS
11 SAYING, WHAT JEFF SHEEHY IS SAYING, WHAT JON SHESTACK
12 IS SAYING, THAT THIS WORKING GROUP COULD QUITE
13 APPROPRIATELY ADDRESS THIS INTELLECTUAL PROPERTY, AS
14 HAS BEEN DISCUSSED BEFORE, AS BEING SOMETHING THAT
15 WOULD BE DISCUSSED. IT DOESN'T NECESSARILY DEAL WITH
16 THE CONTRACT PROVISIONS, BUT IN TERMS OF THE POLICY AS
17 IT RELATES TO OUR STANDARDS, THIS IS, AS JEFF QUITE
18 PROPERLY POINTS OUT, IS SOMETHING REFERENCED IN THE
19 NATIONAL ACADEMY STANDARDS AND, THEREFORE, NATURALLY
20 COME UP WITHIN THE CONTEXT OF THIS DISCUSSION.

21 AND ECONOMIC CRITERIA, THE MEDICAL,
22 SOCIOECONOMIC, AND FINANCIAL STANDARDS CERTAINLY WOULD
23 EMBRACE THE SPECTRUM THAT IS BEING DISCUSSED HERE BY
24 JON SHESTACK AND JEFF AND SHERRY LANSING. I THINK
25 THAT'S QUITE PROPERLY BEEN REFLECTED IN BOARD

1 DISCUSSIONS WHICH SHERRY AND THE OTHER TWO BOARD
2 MEMBERS ARE PICKING UP ON.

3 CO-CHAIR LANSING: I'M NOT HALLUCINATING. I
4 THINK WHAT WE HAVE THE RIGHT TO DO, AGAIN, AS A LIVING
5 BODY IS WHEN WE GET INTO THE GUIDELINES, TO DETERMINE
6 IF WE WISH TO DO THAT, WHICH I ASSUMED WE WERE, BUT
7 MAYBE EVERYBODY ELSE WOULD FEEL THAT WAY, AND THEN TO
8 EVALUATE WHICH ISSUES WE WISH TO TACKLE.

9 MR. SHEEHY: I GUESS MY POINT IS THAT I THINK
10 OTHER PARTS OF THE ICOC WILL BE LOOKING AT THE
11 INTELLECTUAL PROPERTY ISSUE, AND I JUST THINK THAT WE
12 OUGHT TO MAKE SURE THAT THOSE ISSUES LAND HERE BECAUSE
13 WE DO -- FIRST OF ALL, BECAUSE WE HAVE ETHICISTS HERE.
14 AND I THINK THAT IT WOULD BE A GREAT IDEA TO GET A
15 WEIGH-IN FROM ETHICISTS ON ANY INTELLECTUAL PROPERTY OR
16 ACCESS TO THERAPIES ISSUES.

17 CO-CHAIR LANSING: I THINK YOU'RE SENSING
18 THAT THAT PROBABLY IS THE WISH OF EVERYBODY HERE, AND
19 IT IS POSSIBLE FOR US TO DO THAT, AM I CORRECT, IF WE
20 WISH TO? SO THOSE -- I THINK THAT'S PROBABLY WHAT
21 WE'RE GOING TO DO WHEN WE GET TO THAT PART OF IT.

22 MR. SHESTACK: SOME OF THESE THINGS
23 WOULDN'T -- WE'RE GOING TO REVIEW THE NAS GUIDELINES
24 REALLY LINE BY LINE, BUT SOME OF THESE THINGS WOULDN'T
25 NATURALLY COME UP. THERE ARE OTHER BIGGER, BOLDER

1 HEADLINES THAT NATURALLY --

2 CO-CHAIR LANSING: BUT WE HAVE THE RIGHT TO
3 ADD THAT IF WE WISH TO.

4 MR. SHESTACK: BUT I THINK THAT -- I AGREE
5 WITH JEFF SHEEHY, THAT THIS IS AN APPROPRIATE PLACE TO
6 GET AN OPINION AND RECOMMENDATIONS TO THE ICOC FROM
7 ETHICISTS AS WELL AS SCIENTISTS AND ADVOCATES ON
8 ETHICAL IMPLICATIONS OF SOME OF THE INTELLECTUAL
9 PROPERTY ISSUES, AND I WOULD ALSO LIKE TO ADD
10 PARTICULARLY ON BANK -- ON RESOURCE CREATION AND CELL
11 LINE BANKING, WHICH PERSONALLY I CONSIDER SORT OF AN
12 ETHICAL OBLIGATION OF AN INSTITUTE LIKE THE CIRM, AND I
13 WOULD HOPE THAT IF WE MADE THAT RECOMMENDATION, THAT
14 RECOMMENDATION WOULD BE CARRIED TO THE ICOC AND TO THE
15 GRANTS WORKING GROUP AS PART OF THEIR CONSIDERATION
16 PROCESS.

17 CO-CHAIR LANSING: ANY OTHER?

18 MS. CHARO: SPEAKING AS ONE OF THE SUPPOSED
19 ETHICISTS HERE, I JUST WANT TO NOTE THAT WHEN WE
20 FINALLY GET TO THE POINT OF DISCUSSING THE SUBSTANCE OF
21 THE NAS GUIDELINES AND TALKING ABOUT WHETHER OR NOT
22 THEY MAKE SENSE FOR THIS FUNDING AGENCY, THE ISSUES
23 AROUND FINANCE AND WHO GETS IT AND WHO GETS THE BENEFIT
24 WILL INEVITABLY COME UP IN SOME WAYS BECAUSE THOSE ARE
25 THE BENEFITS OF THE RESEARCH THAT HAVE TO BE MEASURED

1 AGAINST THE RISK. SO TO THE EXTENT THAT WE'RE TALKING
2 ABOUT RISK BENEFIT IT COMES IN.

3 BUT QUESTIONS ABOUT PATENT POLICY AT THE
4 FEDERAL LEVEL, ABOUT PATENT POLICY AT THE INSTITUTIONAL
5 LEVEL OFTEN REQUIRES EXPERTISE THAT GOES FAR BEYOND THE
6 EXPERTISE FOUND ON THIS COMMITTEE BECAUSE THE ISSUES
7 HAVE STRONG, NOT ONLY LEGAL UNDERPINNINGS, BUT ECONOMIC
8 UNDERPINNINGS AND CONTRACT UNDERPINNINGS BECAUSE OF
9 EXISTING AGREEMENTS. AND SO TACKLING THAT TOPIC
10 SEPARATELY AND INDEPENDENTLY MIGHT FEEL SATISFYING, BUT
11 MIGHT NOT BE AS CONSTRUCTIVE AS WE WOULD HOPE BECAUSE
12 WE WOULDN'T HAVE ALL THE RIGHT PEOPLE IN PLACE. MAYBE
13 THAT'S EXACTLY THE KIND OF TOPIC THAT NEEDS AN
14 INTERWORKING GROUP COLLECTION OF FOLKS WHO CAN BRING
15 THE VARIOUS PERSPECTIVES TOGETHER IN A SETTING WHERE
16 YOU'VE GOT ALL THE RIGHT TALENT AT THE TABLE.

17 CO-CHAIR LANSING: WHAT I'M CONFUSED, AND
18 THEN I WANT TO CONTINUE THE DISCUSSION IS -- AND MAYBE,
19 AGAIN, I'M CONFUSED, SO NOW YOU GUYS CAN HELP ME. WHEN
20 WE GET TO THE SUBSTANCE OF THE NAS GUIDELINES, WE'RE
21 GOING TO GO THROUGH EVERY SINGLE THING, AND WE'RE GOING
22 TO AS A GROUP HAVE LOTS OF CONVERSATION. THIS IS NOT
23 FIVE MINUTES. THIS IS GOING TO BE DAYS, AND IT'S GOING
24 TO BE HOURS, AND WE'RE GOING TO DISSECT EVERYTHING.
25 AND AT THAT TIME I WAS ALWAYS UNDER THE ASSUMPTION THAT

1 WE WOULD DECIDE WHETHER OR NOT WE WANTED TO ADD THIS
2 ISSUE, MODIFY IT, TAKE IT OFF THE TABLE, WHATEVER, BUT
3 WE WOULD DO IT AS A WORKING GROUP.

4 I FEEL, QUITE HONESTLY, WE'RE GETTING A
5 LITTLE BIT AHEAD OF OURSELVES BECAUSE WE HAVE TO START
6 AND REALLY GO FROM THE BEGINNING THROUGH EVERYTHING
7 AND --

8 MR. SHESTACK: THE CONFUSION MAY REALLY BE AN
9 ISSUE THAT IS ONLY SALIENT FOR JEFF AND MYSELF BECAUSE
10 I THINK WE ARE THE ONLY TWO PEOPLE WHO ARE ON THIS
11 COMMITTEE WHO ARE ACTUALLY ALSO ON THE WORKING GROUP --
12 THE SUBCOMMITTEE WHERE MANY OF THESE ISSUES WERE
13 DISCUSSED OUTSIDE -- WHETHER OR NOT THEY BELONG IN THE
14 PURVIEW OF THE COMMITTEE OUTSIDE OF THE REVIEW OF THE
15 NAS GUIDELINES. AND SO SINCE THIS IS THE FIRST
16 MEETING, I JUST BRING UP ISSUES THAT CONCERN ME TO PUT
17 THEM IN THE AIR. I DON'T EXPECT THAT THEY NEED TO BE
18 DEALT WITH SPECIFICALLY NOW, BUT THEY'RE IN THE AIR AND
19 THEY WILL SET A STAGE FOR THAT, NOT ONLY WITHIN THE
20 DISCUSSION OF THE NAS GUIDELINES.

21 CO-CHAIR LANSING: THEY WILL BE DISCUSSED
22 WHEN WE GET TO THE GUIDELINES. I HOPE YOU WILL BRING
23 THEM UP SO WE CAN EXPLORE THEM.

24 DR. LO: I JUST WANT TO SAY THAT THESE ARE
25 EXTREMELY IMPORTANT ISSUES, AND THAT I THINK IT WOULD

1 BE VERY USEFUL FOR US TO CONSIDER THEM. I WOULD DEFER
2 TO THE CHAIRS' SENSE OF HOW THE MEETING SHOULD FLOW AND
3 BE ORGANIZED. WHEN THE TIME COMES, I WOULD CALL ON
4 JEFF SHEEHY AND JON SHESTACK TO MAKE SURE THAT THESE
5 ISSUES GET RAISED AND DISCUSSED FULLY.

6 CO-CHAIR LANSING: LET ME JUST SAY AGAIN IN
7 THE SPIRIT OF ALL OF US, WHAT'S GOING TO HAPPEN IS
8 WE'RE GOING TO GO THROUGH EACH THING. AND I ENCOURAGE
9 EVERYBODY HERE AS WELL AS THE PUBLIC TO SAY, WAIT A
10 MINUTE. WHAT ABOUT THIS OTHER ISSUE, YOU KNOW, THAT
11 YOU DIDN'T DISCUSS? AND THEN WE WILL DISCUSS WHETHER
12 OR NOT WE WANT TO DISCUSS IT.

13 ANY OTHER COMMENTS?

14 DR. KIESSLING: IN THE INTEREST OF TIME, IT
15 WOULD BE A BIG HELP TO ME IF SOMEONE WOULD GIVE US A
16 VERY -- I KNOW THAT PROPOSITION 71 CALLS FOR THREE
17 WORKING GROUPS. AND AS I GO THROUGH THE PROPOSITION,
18 AS I'VE GONE THROUGH OUR CHARGE, IT ISN'T REALLY CLEAR
19 TO ME WHAT IS THE CHARGE TO EACH OF THOSE THREE WORKING
20 GROUPS AND WHERE THE OVERLAP IS. I THINK SOME OF THIS
21 DISCUSSION IS THAT THERE'S SOME OVERLAP BETWEEN WHAT
22 OUR CHARGE IS AND WHAT THE OTHER TWO WORKING GROUPS'
23 CHARGES ARE. SINCE THAT'S NOT CLEAR TO ME, IF SOMEBODY
24 COULD GIVE ME A TWO-MINUTE SYNOPSIS OF THE WORKING
25 GROUPS.

1 CO-CHAIR LANSING: WE'LL GIVE IT TO YOU RIGHT
2 NOW.

3 MR. HARRISON: YOU ARE CORRECT. THERE ARE
4 THREE WORKING GROUPS. THE STANDARDS WORKING GROUP, DR.
5 HALL HAS DESCRIBED THE CHARGE OF THIS WORKING GROUP.
6 THE OTHER TWO WORKING GROUPS ARE THE GRANTS REVIEW
7 WORKING GROUP, WHICH IS CHARGED WITH DEVELOPING
8 CRITERIA AND STANDARDS FOR THE EVALUATION AND AWARD OF
9 GRANTS AND LOANS AND THEN FOR UNDERTAKING SCIENTIFIC
10 EVALUATION OF APPLICATIONS AND FOR MAKING
11 RECOMMENDATIONS TO THE ICOC REGARDING THE AWARD OF
12 GRANTS AND LOANS.

13 THE THIRD WORKING GROUP IS THE FACILITIES
14 WORKING GROUP, WHICH IS CHARGED, AGAIN, WITH DEVELOPING
15 CRITERIA AND STANDARDS FOR THE EVALUATION AND AWARD OF
16 GRANTS FOR THE CONSTRUCTION OF FACILITIES IN WHICH TO
17 CONDUCT STEM CELL RESEARCH, FOR EVALUATING FACILITIES'
18 APPLICATIONS IN CONSULTATION WITH THE GRANTS REVIEW
19 WORKING GROUP TO DETERMINE THE LEVEL OF SCIENCE THAT IS
20 BEING PROPOSED TO BE CONDUCTED IN A FACILITY, AND
21 ULTIMATELY FOR MAKING RECOMMENDATIONS TO THE ICOC FOR
22 THE AWARD OF THE FACILITIES GRANTS AND LOANS.

23 THAT IN A NUTSHELL ENCOMPASSES THE ROLE OF
24 THE THREE DIFFERENT WORKING GROUPS.

25 DR. KIESSLING: WHERE DO YOU SEE THE OVERLAP?

1 MR. HARRISON: I THINK THE PRIMARY OVERLAP
2 IS, AT LEAST IN TERMS OF INTELLECTUAL PROPERTY ISSUES,
3 SINCE WE'VE JUST BEEN DISCUSSING THOSE, THERE ARE TWO
4 COMPONENTS I THINK, AS ALTA CHARO MENTIONED. ONE IS
5 THE INTELLECTUAL PROPERTY AGREEMENTS THEMSELVES WHICH
6 WILL ULTIMATELY BE PART OF THE GRANT AGREEMENTS. AND
7 THE GRANTS REVIEW WORKING GROUP, AS I MENTIONED, IS
8 CHARGED WITH DEVELOPING THE STANDARDS AND CRITERIA FOR
9 THE EVALUATION OF GRANTS. I DON'T THINK THAT WILL
10 NECESSARILY GET INTO THE INTELLECTUAL PROPERTY ISSUES,
11 BUT THERE MAY BE SOME OVERLAP.

12 THE PRIMARY OVERLAP, I THINK, IS WITH THE
13 FACILITIES WORKING GROUP AND GRANTS REVIEW WORKING
14 GROUP SINCE BOTH WILL HAVE TO EVALUATE THE SCIENCE;
15 AND, THEREFORE, THERE WILL BE A LOT OF COMMUNICATION
16 BETWEEN THE TWO OF THEM.

17 DR. KIESSLING: DO YOU SEE THIS WORKING GROUP
18 AS BEING ADVISORY TO THE SCIENCE REVIEW GROUP?

19 MR. HARRISON: NO. THIS WORKING GROUP IS
20 ADVISORY TO THE ICOC WHICH ULTIMATELY WILL MAKE THE
21 FINAL DETERMINATION ON STANDARDS.

22 MR. KLEIN: A COMMENT ON THAT ANSWER BECAUSE
23 IMPLICITLY WHILE YOU'RE ADVISING THE ICOC, YOU ARE
24 ADVISING THE GRANTS WORKING GROUP. AND THERE CERTAINLY
25 CAN BE SUBSTANTIAL OVERLAP BETWEEN STANDARDS AND THE

1 GRANT REVIEW. I WROTE THESE PROVISIONS, FOR EXAMPLE,
2 THAT CLEARLY CONTEMPLATED THAT WITH ALS AND OTHER VERY
3 FAST-CLOCK DISEASES, THE PATIENT ADVOCACY GROUPS MIGHT
4 ASK FOR RESPONSIBLE PROVISIONS TO ACCELERATE TRIALS FOR
5 THOSE GROUPS ON DIFFERENT STANDARDS THAT AFFECT OTHER
6 DISEASES THAT HAVE MORE STABLE DEVELOPMENT PROCESSES.

7 SO THERE CAN BE A SUBSTANTIAL OVERLAP AND A
8 SUBSTANTIAL DIRECTIVE FUNCTION HERE OF THIS COMMITTEE
9 AS RELATES TO THE GRANTS COMMITTEE.

10 CO-CHAIR LANSING: ANY OTHER QUESTIONS?
11 PUBLIC COMMENT?

12 MR. HALPERN: THANK YOU, MADAM CHAIR. I JUST
13 WANT TO DRAW ATTENTION TO THE LAST BULLET POINT, NOT
14 THE MOST GLAMOROUS PART OF THE CHARGE TO THIS WORKING
15 GROUP, BUT ONE THAT'S EXTREMELY IMPORTANT.

16 THE PROP 71 ITSELF STATES, "EACH WORKING
17 GROUP SHALL RECOMMEND TO ICOC RULES, PROCEDURES, AND
18 PRACTICES FOR THAT WORKING GROUP." AND I WANT TO
19 ENCOURAGE THIS WORKING GROUP TO TAKE THAT PART OF THE
20 CHARGE VERY SERIOUSLY. AND WHETHER IT SETS UP A
21 SUBCOMMITTEE TO WORK WITH STAFF ON WHAT KIND OF BYLAWS,
22 PROCEDURES, AND RULES IT ADOPTS, BUT THAT HAS TO
23 ORIGINATE IN THE WORKING GROUP, AND ITS RECOMMENDATION
24 HAS TO GO UP TO THE ICOC FOR CONSIDERATION. I JUST
25 WANT TO MAKE SURE THAT THE KIND OF FOUNDATIONAL NUTS

1 AND BOLTS CONSIDERATION DOESN'T SLIP THROUGH THE
2 CRACKS.

3 CO-CHAIR LANSING: THANK YOU. NOW WE ARE
4 OFFICIALLY ON FIVE, SOME OF WHICH WE HAVE ALREADY DONE.
5 I THINK WE ALREADY DID 5(A). AM I CORRECT IN THAT, OR
6 DO YOU WANT TO ADD ANYTHING, ZACH AND JAMES?

7 DR. HALL: NO.

8 CO-CHAIR LANSING: AND NOW I TURN IT OVER TO
9 HARRIET TO DISCUSS THE PUBLIC COMMENT PROCESS, SOME OF
10 WHICH WE'VE ALSO ALREADY DONE.

11 CO-CHAIR RABB: MAYBE IF YOU WILL INDULGE ME
12 FOR A COUPLE OF MINUTES JUST TO LAY A FOUNDATION FOR
13 WHAT I THINK WE'RE GOING TO DO NEXT AND HOW I THINK WE
14 MIGHT DO IT, EVEN IF IT MEANS TALKING A BIT. MAYBE WE
15 CAN GET CLARITY.

16 I THINK IT'S CONTROL BOOTH AND NOT MINE.

17 AT ITS MAY MEETING THE ICOC ADOPTED AS THE
18 INTERIM REGULATIONS FOR THE STATE OF CALIFORNIA THE
19 RECOMMENDATIONS OF THE NATIONAL ACADEMY OF SCIENCE.
20 THOSE RECOMMENDATIONS APPEAR ON SIX PAGES OF BOLDFACED
21 TYPE. IF YOU PRINTED THE NAS GUIDELINES DOWN FROM
22 PAGES 107 THROUGH 112, THERE WAS BEFORE THOSE
23 GUIDELINES IN THE NAS PUBLICATION A VERY LONG, VERY
24 GOOD, VERY INTERESTING REPORT, BUT THAT REPORT HAS NOT
25 BEEN ADOPTED AS THE GUIDELINES. THAT REPORT IS

1 INFORMATION AND BACKGROUND.

2 SO AS WE PROCEED TODAY, WHAT WE WILL BE
3 TALKING ABOUT ARE THE INTERIM GUIDELINES THE IC ADOPTED
4 FOR THIS STATE, AND THOSE GUIDELINES ARE ON THE SIX
5 PAGES, PAGES 107 THROUGH 112, IF YOU PRINTED THIS DOWN
6 FROM THE WEB, OF THE NAS REPORT.

7 I ASSUME WE CAN MAKE COPIES OF THOSE IF
8 ANYBODY DIDN'T HAVE THOSE PAGES, BUT THOSE ARE THE ONES
9 THAT WE'RE GOING TO BE TALKING ABOUT AND LOOKING AT,
10 AND THOSE ARE THE ONES THAT UNTIL THE ICOC ADOPTS FINAL
11 REGS, IT IS THOSE SIX PAGES AND WHAT'S WRITTEN ON THEM
12 THAT ARE INTERIM REGS.

13 IT'S CLEAR FROM LOOKING AT THOSE
14 RECOMMENDATIONS, WHICH ARE FOR US NOW REGULATIONS,
15 INTERIM REGULATIONS, THAT THEY ARE INAPPROPRIATE AS
16 FINAL REGULATIONS IN ONE WAY FOR CERTAIN AND IN ANOTHER
17 WAY PERHAPS DEPENDING ON WHAT HAPPENS AS A RESULT OF
18 OUR DELIBERATIONS. THE FIRST RESPECT IN WHICH THEY ARE
19 NOT APPROPRIATE AS REGULATIONS IS THAT THEY SPEAK
20 GENERALLY ABOUT ASPIRATIONS AND ABOUT WAYS OF THINKING
21 ABOUT THINGS AND EVEN, FOR EXAMPLE, DESCRIBE HOW THINGS
22 ARE DONE IN ANOTHER COUNTRY. THAT'S NOT STANDARD
23 REGULATION TALK. SO WHAT WE'LL HAVE TO DO IS, AT THE
24 VERY LEAST, TURN THESE RECOMMENDATIONS INTO OPERATIONAL
25 GUIDELINES. AND THAT MEANS TURNING THEM INTO

1 REGULATORY LANGUAGE.

2 AS JAMES DESCRIBED, WE'LL WORK ON SOME OF
3 THAT HERE, AND THE LAWYERS AND THE OFFICE OF
4 ADMINISTRATIVE LAW WILL WORK ON THE REST OF IT TO MAKE
5 IT INTO A PROPER FORM.

6 BUT THE OTHER RESPECT IN WHICH THOSE
7 GUIDELINES MAY BE AMENDED, MAY BE AMENDED, BY THE ICOC
8 ON RECOMMENDATION FOR US OR BEYOND OR IN ADDITION TO
9 OUR RECOMMENDATIONS WILL BE ON THE CONTENT OF THE
10 RECOMMENDATIONS AS THEY ARE NOW IN EFFECT INTERIM REGS.
11 AND FOR THAT WE ARE VERY MUCH IN NEED OF AND COMMITTED
12 TO AS OUR MAIN ORDER OF BUSINESS, IN ADDITION TO MAKING
13 SURE THAT WE DO OUR BUSINESS WELL AND APPROPRIATELY AS
14 A MATTER OF PROCEDURE, OUR MAIN ORDER OF BUSINESS WILL
15 BE TALKING AMONG THE WORKING GROUP IN PUBLIC MEETINGS
16 AND HEARING FROM THE PUBLIC, BOTH IN MEETINGS AND ON
17 OUR WEBSITE THAT I WOULD LIKE TO PROPOSE AND DESCRIBE,
18 THE VIEWS OF THE PEOPLE ABOUT WHAT WILL BECOME A
19 RECOMMENDATION TO THE ICOC.

20 IF YOU WILL INDULGE ME A LITTLE BIT MORE, I'D
21 LIKE TO TALK ABOUT HOW THAT PROCESS MIGHT WORK, THE
22 PROCESS OF THINKING ABOUT THESE INTERIM REGS, THESE
23 INTERIM GUIDELINES.

24 WE'RE GOING TO BEGIN THE DISCUSSION OF THESE
25 INTERIM GUIDELINES TODAY. AND AFTER I MAKE THE

1 DESCRIPTION OF WHAT I HOPE WILL HAPPEN, WE WILL, I
2 HOPE, ADOPT A MODE OF OPERATING THAT IS SOMETHING LIKE
3 WHAT I HOPE TO PROPOSE TO YOU AND THINK WILL WORK FOR
4 US. DISCUSSION OF THE GUIDELINES WILL BEGIN TODAY, NOW
5 ESSENTIALLY.

6 IN ORDER TO MEET OUR LEGAL REQUIREMENTS FOR
7 PUBLIC NOTICE AND COMMENT, ON JULY 22D, WE CAN HAVE A
8 DOCUMENT READY TO GO UP ON THE WEBSITE WHERE THE PUBLIC
9 COULD MAKE COMMENTS. THAT WEBSITE IS
10 GUIDELINES@CIRM.CA.GOV.

11 OUR INTERIM REGS WILL BE POSTED ON THAT
12 GUIDELINE -- ON THAT WEBSITE AS OF JULY 22D. ALL
13 COMMENTS TO THAT WEBSITE AS OF JULY 22D, AS WELL AS ALL
14 COMMENTS MADE TO ANY MEETING OF THE MEMBERS OF THIS
15 WORKING GROUP WILL BECOME PART OF THE FORMAL RECORD OF
16 OUR RECOMMENDATIONS TO THE ICOC.

17 THE WEBSITE ITSELF WILL OFFER INSTRUCTIONS TO
18 PEOPLE ON HOW TO COMMENT, HOW TO POST THEIR COMMENTS,
19 AND THE COMMENTS WILL BE SUMMARIZED AND MADE AVAILABLE
20 TO THE PUBLIC ON ANOTHER WEBSITE, THE CIRM WEBSITE,
21 WHICH WE TALKED ABOUT THIS MORNING WHERE MEETING
22 NOTICES GET POSTED AND AGENDAS AND DOCUMENTS WILL GET
23 POSTED. THAT WEBSITE, JUST TO BE CLEAR, IS
24 WWW.CIRM.CA.GOV.

25 NOW, THE WEBSITE TO WHICH PEOPLE WILL POST

1 THEIR COMMENTS WILL BE AVAILABLE FOR PEOPLE TO LOOK AT
2 JULY THE 11TH. WE JUST WON'T HAVE THE CAPACITY TO
3 GUARANTEE THE NECESSARY FORMALITIES TO MAKE COMMENTS
4 PART OF THE FORMAL RECORD BEFORE JULY 22D. BUT IF YOU
5 WANT TO GO AND LOOK AT THE GUIDELINES WEBSITE, IT WILL
6 BE AVAILABLE STARTING SOMETIME NEXT WEEK AS SOON AS THE
7 WEBMASTERS CAN GET IT UP.

8 THE FORMAL COMMENT PERIOD WILL RUN FROM JULY
9 22D TO SEPTEMBER 5TH. THIS PERIOD OF TIME HAS BEEN
10 DESIGNATED IN COLLABORATION WITH THE STATE'S OFFICE OF
11 ADMINISTRATIVE LAW, AND THE BENEFIT OF THE
12 COLLABORATION HAS BEEN THAT WE KNOW THAT WE WON'T GO
13 THROUGH AS A CITIZENRY OR A WORKING GROUP A PROCESS
14 THAT ENDS UP RUNNING AFOUL OF A LEGAL PROBLEM. SO
15 HAVING SET THIS TIME IN COLLABORATION WITH THE STATE'S
16 ADMINISTRATIVE LAW OFFICE, WE ARE ASSURED AS LAWYERS
17 CAN ASSURE ANYBODY THAT WHAT WE DO WILL AT LEAST NOT BE
18 SUBJECT TO CHALLENGE FROM THE STATE FOR ANY LEGAL
19 MISSTEP.

20 THIS IS A GOOD REASSURANCE, AND THE STAFF IS
21 VERY MUCH TO BE CONGRATULATED FOR WORKING THROUGH WITH
22 THE OAL THIS PROCESS, SO THE PUBLIC NOW KNOWS THEIR
23 COMMENTS WILL COUNT AND SO WILL OUR PUBLIC MEETINGS AND
24 SO WILL OUR PUBLIC PROCESSES.

25 THE URL ITSELF, THE WEBSITE, WOULD NOT BE

1 INTERACTIVE. IT'S TOO DIFFICULT APPARENTLY TO MAKE IT
2 INTERACTIVE. BUT IN ORDER TO MAKE SURE THAT PEOPLE WHO
3 ARE POSTING THEIR COMMENTS DON'T FEEL THAT THEY ARE
4 SPEAKING INTO A DARK BOX, THE STAFF HAS TAKEN A
5 COMMITMENT TO HELP US BY SUMMARIZING COMMENTS, THE
6 ASPIRATION IS ONCE A WEEK, AND POSTING THE SUMMARIES OF
7 COMMENTS ON THE CIRM WEBSITE SO PEOPLE HAVE A SENSE OF
8 WHAT THE PUBLIC IS SPEAKING TO AND HAVE A SENSE OF
9 THINGS THAT, EVEN IF THEY READ THE RECOMMENDATIONS
10 THEMSELVES AND DIDN'T SEE AN ISSUE EMBEDDED IN THEM, IF
11 THEY NOW SEE WHAT THE SUMMARY LOOKS LIKE, PERHAPS IT
12 WILL PROMPT PEOPLE'S THINKING. AND WE THOUGHT THAT
13 MAYBE HAVING THE SUMMARY WOULD BE AN IMPORTANT ASSIST
14 TO THE PUBLIC IN WORKING THROUGH THE ISSUES THEY MIGHT
15 WANT TO COMMENT ON.

16 THE CIRM IS ALSO GOING TO HOLD OUR WORKING
17 GROUPS -- IT'S ALSO GOING TO HOLD TWO MEETINGS AT WHICH
18 PEOPLE CAN MAKE COMMENTS IF THEY ELECT TO DO THAT IN
19 PERSON RATHER THAN ON THE WEB OR IN ADDITION TO ANY
20 COMMENTS THEY WANT TO MAKE ON THE WEB. AUGUST IS NOT
21 AN EASY TIME TO GET PEOPLE TOGETHER. SO WITH PRIOR
22 APOLOGIES FOR NOT HAVING A VERY FULLY STAFFED WORKING
23 GROUP, AT LEAST AT THESE TWO MEETINGS WHERE THE ONLY
24 OBJECTIVE REALLY WILL BE TO TAKE PUBLIC COMMENTS FROM
25 PEOPLE WHO WANT TO USE THAT MODE OF SPEAKING. ONE WILL

1 BE ON AUGUST THE 10TH IN SAN FRANCISCO. AND I THINK,
2 IF I REMEMBER CORRECTLY, IT'S AT THE CIVIC CENTER. THE
3 OTHER WILL BE ON AUGUST THE 25TH IN LOS ANGELES AT THE
4 MAIN BRANCH OF THE PUBLIC LIBRARY. SOME BUT NOT ALL
5 MEMBERS OF THE WORKING GROUP WILL BE AT EACH OF THOSE.

6 AND THE COMMENTS MADE THERE, LIKE THE
7 COMMENTS MADE TO THE WEBSITE, WILL BECOME PART OF THE
8 FORMAL RECORD OF THE REGULATION AS IT MOVES FORWARD.

9 IN ADDITION, THERE WILL BE TRANSCRIPTS MADE
10 OF EACH OF THE PUBLIC MEETINGS OF THE FULL WORKING
11 GROUP, WHICH ITSELF, AGAIN, WILL BECOME, THOSE
12 TRANSCRIPTS THEMSELVES, WILL BECOME PART OF THE RECORD.

13 ALL OF THESE COMMENTS AND TRANSCRIPTS WILL BE
14 MADE AVAILABLE AS PART OF THE PUBLIC RECORD AND
15 PROVIDED TO THE CALIFORNIA OFFICE OF ADMINISTRATIVE
16 LAW. THE RECOMMENDATIONS THAT FLOW OUT OF THESE PUBLIC
17 COMMENTS IN OUR DELIBERATIONS WILL THEN BE MADE BY US
18 TO THE ICOC WHERE THE PROCESS THAT JAMES DESCRIBED
19 EARLIER WOULD UNFOLD THROUGH A SERIES OF TIME FRAMES TO
20 GET WORK DONE SO THAT BY FEBRUARY 16TH, AT OUR OUTSIDE
21 DATE, THE STATE HAS FINAL REGULATIONS TO OPERATE UNDER.

22 THE USE OF THE TERM "FINAL" DOESN'T MEAN VERY
23 LAST, NEVER AGAIN LOOKED AT BECAUSE, AS SHERRY HAS
24 SAID, EXPERIENCE WILL BE HELPFUL TO US, IT WILL TEACH
25 US THINGS, AND IT WILL HELP TO BOTH RECONSIDER ANY

1 ASPECTS OF THIS ADOPTION THAT REQUIRE RECONSIDERATION,
2 BUT ALSO THIS SET OF GUIDELINES, THIS FIRST SET OF
3 REGULATIONS, ADDRESSES OBVIOUSLY A PIECE OF OUR AGENDA,
4 A PIECE OF WHAT WE NEED TO DO, BUT MAY NOT ADDRESS
5 EVERYTHING WE WANT TO DO. AND SO THERE WILL BE
6 ITERATIONS OF THIS GUIDELINE, REITERATIONS OF THE
7 GUIDELINE, AND NEW THINGS FOR US TO THINK ABOUT,
8 INCLUDING SOME OF THE THINGS THAT WERE DISCUSSED JUST
9 PREVIOUS TO THIS SET OF COMMENTS.

10 SO WHAT WOULD I LIKE TO DO IS MOVE THAT WE
11 ADOPT THIS PROCEDURE, HAVING A MOTION BEFORE US FOR
12 DISCUSSION, DISCUSS THIS PROCEDURE, BOTH THE WORKING
13 GROUP AND THE PUBLIC; AND IF WE'RE SATISFIED WITH IT OR
14 AS WE AMEND IT, ADOPT IT AS THE WAY WE'RE GOING TO GO
15 FORWARD TO TAKE PUBLIC COMMENTS ON WHAT ARE NOW THESE
16 INTERIM GUIDELINES MOVING TOWARD A FINAL RECOMMENDATION
17 TO THE ICOC.

18 CO-CHAIR LANSING: THAT WAS AN EXCELLENT
19 PRESENTATION. KATE SHREVE HAD A POINT OF
20 CLARIFICATION.

21 MS. SHREVE: I JUST WANTED TO OFFER ONE PIECE
22 OF ADMINISTRATIVE CLARIFICATION, WHICH IS THAT THE
23 WEBSITE ON WHICH THE REGULATIONS SUMMARY COMMENT AND
24 INSTRUCTIONS FOR POSTING WILL BE AT WWW.CIRM.CA.GOV.
25 AND E-MAILED COMMENT CAN BE SENT TO

1 GUIDELINES@CIRM.CA.GOV.

2 CO-CHAIR RABB: THANK YOU.

3 DR. KIESSLING: DO WE HAVE A COPY IN OUR
4 INFORMATION OF WHAT YOU JUST SAID?

5 CO-CHAIR RABB: I WROTE IT FOR MYSELF, BUT I
6 CAN MAKE IT AVAILABLE. WE CAN MAKE IT AVAILABLE JUST
7 BY, AMONG OTHER THINGS, TRYING TO RETYPE THIS OR
8 PHOTOCOPY IT QUICKLY.

9 CO-CHAIR LANSING: WE CAN GET THIS TO YOU
10 PRETTY EASY.

11 MR. KLEIN: SO DURING THE LUNCH BREAK, MAYBE
12 A COPY OF THAT COULD BE MADE AND DISTRIBUTED TO ALL THE
13 MEMBERS.

14 DR. KIESSLING: I'M STILL TRYING TO FIGURE
15 OUT IS WHAT YOU'RE PROPOSING SIMPLY A PROCEDURE THAT
16 THIS WORKING GROUP WILL ADOPT? ARE YOU PROPOSING A
17 GUIDELINE OR BYLAW?

18 CO-CHAIR RABB: IT'S JUST A PROCEDURE FOR HOW
19 WE WOULD ACCEPT AND MANAGE THE PROCESS OF DELIBERATION
20 AND PUBLIC INPUT.

21 DR. KIESSLING: SO THIS IS A PROCEDURE FOR A
22 SPECIFIC TASK?

23 CO-CHAIR LANSING: THIS IS A PROCEDURE FOR US
24 TO GET OUR GUIDELINES TOGETHER. WE HAVEN'T GOTTEN INTO
25 THE GUIDELINES AT ALL. SO THIS IS JUST A PROCEDURE BY

1 WHICH THE PUBLIC WILL BE PART OF IT, AND OUR WORKING
2 DATE SO THAT WE HAVE OUR DATES IN ADVANCE.

3 MR. KLEIN: TO UNDERSTAND THIS, THIS IS A
4 PROCEDURE FOR DEALING WITH THE NATIONAL ACADEMY MEDICAL
5 AND ETHICAL STANDARDS, BUT WE COULD HAVE SEPARATE
6 PROCEDURES FOR SEPARATE SUBTOPICS THAT WOULD GO ON A
7 DIFFERENT TIME LINE INSTEAD; IS THAT A CORRECT
8 STATEMENT?

9 CO-CHAIR RABB: I DON'T KNOW. I'M
10 INTERESTED -- DR. KIESSLING HAS A QUESTION.

11 DR. KIESSLING: WELL, I DON'T WANT TO MAKE
12 THIS ANY MORE ADMINISTRATIVELY BURDENSOME THAN IT IS,
13 BUT I DON'T KNOW THAT THIS WORKING GROUP HAS ANY
14 BYLAWS. AND IF WE DO HAVE BYLAWS WHERE WE HAVE SOME
15 KIND OF WRITTEN DOCUMENTATION AS TO HOW WE ARE TO
16 PROCEED WITH EACH OF THESE TASKS BEFORE US, I'M NOT
17 AWARE OF THEM.

18 DR. HALL: WE ARE IN THE PROCESS OF DRAWING
19 UP BYLAWS. WE HAVE A DRAFT, BUT UNFORTUNATELY NOT
20 READY FOR THIS MEETING.

21 DR. KIESSLING: THAT'S OKAY.

22 DR. HALL: HOWEVER, THE PROCESS THAT YOU'VE
23 HEARD IS DRIVEN NOT BY INTERNAL BYLAWS REALLY, BUT BY,
24 AS I UNDERSTAND IT, THE ADMINISTRATIVE PROCEDURES ACT
25 OF CALIFORNIA. WHAT THIS GROUP IS DOING IS MAKING A

1 REGULATION UNDER THAT ACT. AND WHAT YOU'VE JUST HEARD
2 HAS BEEN TAILORED TO FIT THAT PROCESS REQUIRED BY LAW
3 ALONG WITH THE TIME LINE THAT WE HAVE, WHICH IS THAT
4 THE INTERIM STANDARDS EXPIRE, UNLESS OTHERWISE ACTED
5 ON, BY FEBRUARY. SO THAT'S WHAT'S DRIVING IT. THAT
6 WILL NOT BE IN THE BYLAWS.

7 DR. KIESSLING: I'M VERY WELL AWARE OF THE
8 PRESSURES, AND I'M ALL FOR THIS, BUT I'M TRYING TO
9 UNDERSTAND WHETHER THIS FITS INTO IT. SOMEBODY HAS
10 MENTIONED SEVERAL TIMES THIS MORNING THAT THERE IS
11 ALREADY AN OFFICE IN PLACE IN CALIFORNIA THAT COVERS
12 ADMINISTRATIVE -- SOMEBODY HELP ME WITH THIS.

13 MR. KLEIN: ADMINISTRATIVE LAW.

14 DR. KIESSLING: IS THERE SOME BODY OF BYLAWS
15 OR SOME REGULATIONS OR WHATEVER IN THAT OFFICE THAT CAN
16 SIMPLY BE ADOPTED BY THIS WORKING GROUP?

17 CO-CHAIR RABB: THE OFFICE OF ADMINISTRATIVE
18 LAW IS THE OFFICE OF THE STATE OF CALIFORNIA THAT
19 MANAGES THE DEVELOPMENT OF REGULATIONS FOR THE WHOLE
20 STATE GOVERNMENT. IT IS NOT SPECIFIC TO OUR PROCESS
21 HERE.

22 DR. KIESSLING: WE HAVE TO DO SOMETHING
23 DIFFERENT.

24 CO-CHAIR RABB: WELL, IT'S NOT DIFFERENT SO
25 MUCH AS WHAT WE'RE TRYING TO DO IS FIT WITHIN THE

1 REQUIREMENTS OF THE OAL, OFFICE OF ADMINISTRATIVE LAW,
2 SO THAT THE PROCESS WE DO IS LEGALLY SOUND AND CAN
3 YIELD ULTIMATELY ENFORCEABLE REGULATIONS FOR THE STATE
4 OF CALIFORNIA.

5 DR. KIESSLING: WE HEARD A NUMBER OF CONCERNS
6 THIS MORNING ABOUT THE FACT THAT WHAT KINDS OF
7 PROCEDURES ARE GOING TO BE ADOPTED HERE. AND I'VE
8 ACTUALLY WONDERED THAT MYSELF. SO WE'LL JUST WAIT FOR
9 THE BYLAWS TO COME THROUGH.

10 CO-CHAIR RABB: I THINK IT'S FAIR TO SAY
11 THOSE BYLAWS ARE MORE -- ARE GOING TO BE A BROADER SET
12 OF GUIDANCES ABOUT HOW WE OPERATE, THINGS LIKE QUORUMS
13 AND VOTES AND CONVERSATION. THAT'S WHAT'S GOING TO BE
14 IN THOSE BROADER GUIDELINES AS A CHARTER FOR THIS
15 GROUP. AND WHAT WE'RE TALKING ABOUT NOW, BECAUSE I
16 THINK THERE'S A SENSE OF THE NEED TO GET UNDERWAY TO
17 MEET THE 200 -- THERE'S A 270-DAY WINDOW FROM THE
18 INTERIM GUIDELINES ACCEPTANCE TO THE END. SO THIS IS
19 REALLY A STRATEGY THAT WE'RE PROPOSING THAT WILL HELP
20 US MEET THE STATE LAW REQUIREMENTS, BUT IT IS IN NO WAY
21 THE CHARTER FOR THIS GROUP'S WAY OF PROCEEDING.

22 DR. HALL: JUST A NOTE. WE ARE A STATE
23 AGENCY, AND AS SUCH NEED TO FOLLOW THE GUIDELINES FOR A
24 STATE GOVERNMENT. AND THAT'S WHAT WE'RE TRYING TO FIT
25 INTO HERE.

1 DR. KIESSLING: WELL, THE CIRM IS A STATE
2 AGENCY, BUT THIS WORKING GROUP IS NOT, CORRECT?

3 DR. HALL: THE WORKING GROUP IS A -- HOW TO
4 PUT IT -- IS AN ADVISORY GROUP TO THE ICOC, BUT IT'S
5 ALSO DESCRIBED AS PART OF THE CIRM.

6 DR. KIESSLING: SO IT'S NOT CLEAR.

7 DR. HALL: SO I GUESS THAT'S RIGHT.

8 CO-CHAIR LANSING: JAMES, WE'RE FOLLOWING THE
9 BYLAWS OF THE STATE AGENCY AS WE PROCEED, RIGHT?

10 DR. KIESSLING: SOMEWHERE WE HAVE SOME KIND
11 OF MATERIAL THAT MAKES IT VERY CLEAR THAT THIS GROUP IS
12 NOT A STATE AGENCY.

13 CO-CHAIR LANSING: BUT WE HAVE TO FILE --
14 JAMES.

15 MR. HARRISON: LET ME SEE IF I CAN CLARIFY
16 THIS. THE MEMBERS OF THIS WORKING GROUP ARE NOT STATE
17 OFFICIALS OR STATE EMPLOYEES; AND, THEREFORE, YOU
18 PERSONALLY ARE NOT GOVERNED, FOR EXAMPLE, BY THE STATE
19 POLITICAL REFORM ACT, NOR IS THIS BODY AS A WHOLE,
20 BECAUSE IT'S PURELY ADVISORY IN NATURE, REQUIRED TO
21 COMPLY WITH THE BAGLEY-KEENE ACT. NONETHELESS, IT IS
22 AN ADVISORY BODY TO A STATE AGENCY, AND THE STATE
23 AGENCY IS ULTIMATELY CHARGED WITH ADOPTING THESE
24 STANDARDS AS REGULATIONS CONSISTENT WITH THE
25 ADMINISTRATIVE PROCEDURE ACT, WHICH IS WHY WE'RE TRYING

1 TO MELD THE PROCESS OF THIS WORKING GROUP INTO THE
2 STATE LAW FRAMEWORK.

3 DR. KIESSLING: THANK YOU. I UNDERSTAND.

4 CO-CHAIR RABB: I'D LIKE TO HAVE COMMENTS
5 FROM THE WORKING GROUP AND FROM THE PUBLIC, IF YOU HAVE
6 THEM, ABOUT THE PROPOSED WAY OF DEVELOPING INPUT.

7 DR. HALL: IS THERE A MOTION?

8 CO-CHAIR RABB: I THINK WHAT WE OUGHT TO DO
9 IS START WITH A MOTION TO ADOPT A PROCESS THAT WE CAN
10 THEN TALK ABOUT THAT PROCESS AND HEAR FROM PEOPLE.

11 DR. PETERS: COULD WE HAVE THE MOTION READ,
12 PLEASE?

13 CO-CHAIR RABB: WELL, I SUPPOSE THE MOTION
14 WOULD BE THAT WE ADOPT THE PROCEDURE JUST DESCRIBED,
15 WHICH IS TO SAY THAT WE WILL HAVE COMMENT AT THIS
16 WORKING GROUP MEETING AND OTHER WORKING GROUP MEETINGS
17 FROM THE PUBLIC WHO WISH TO EXPRESS THEMSELVES IN THOSE
18 FORUMS. THOSE COMMENTS WILL BE TRANSCRIBED. WE WILL
19 ALSO RECEIVE COMMENT ON THE WEBSITE ESTABLISHED FOR
20 THAT PURPOSE. THAT WEBSITE IS NOT AN INTERACTIVE
21 WEBSITE. SO THE COMMENTS WILL ALL BE RECEIVED AND
22 RECORDED.

23 BUT IN ORDER TO GIVE PEOPLE A SENSE, AN
24 INTERACTIVE SENSE OF WHAT'S HAPPENING, THE STAFF WILL,
25 WE HOPE ONCE A WEEK, PROPOSE AND POST A SUMMARY OF THE

1 COMMENTS RECEIVED ON THE WEB SO THAT PEOPLE KNOW THE
2 DIRECTION THAT COMMENTS MAY BE TAKING. THAT ULTIMATELY
3 ALL THOSE COMMENTS WILL COME BACK TO THIS WORKING GROUP
4 AND TO THE PUBLIC IN THE FORM OF MATERIAL ON WHICH
5 FINAL DECISIONS WOULD BE MADE HERE ON RECOMMENDATIONS
6 TO BE MADE TO THE ICOC. AND THAT, CONSISTENT WITH
7 STATE LAW REQUIREMENTS, THE FORMAL RECORD WOULD REFLECT
8 ALL OF THE COMMENTS THAT WERE RECEIVED AND COMMENTS
9 THAT WERE MADE, INCLUDING THE TRANSCRIPTS AND THE
10 WRITINGS THAT WE'VE GOTTEN FROM THE PUBLIC.

11 DR. KIESSLING: IS THAT THE MOTION?

12 CO-CHAIR RABB: YES.

13 MR. HARRISON: COULD I JUST ADD ONE THING FOR
14 CLARIFICATION? THE CIRM IS REQUIRED AS PART OF THIS
15 PROCESS TO RESPOND TO THOSE PUBLIC COMMENTS. THAT WILL
16 ALSO BE PART OF THE PUBLIC RECORD.

17 DR. LO: HARRIET, IF I COULD ADD SOMETHING TO
18 MAKE MORE EXPLICIT, THAT THERE WILL ALSO BE TWO PUBLIC
19 HEARINGS SOLELY FOR THE PURPOSE OF ELICITING PUBLIC
20 COMMENT.

21 CO-CHAIR RABB: YES. YES. THOSE ARE TWO OF
22 THE WORKING GROUP MEETINGS I WAS THINKING ABOUT.

23 DR. PETERS: DO WE NEED A SECOND?

24 MR. SHEEHY: SECOND.

25 CO-CHAIR RABB: DID WE GET A MOTION? DR.

1 PETERS, WAS THAT YOUR MOTION?

2 DR. PRIETO: IF THE CHAIR CANNOT MAKE A
3 MOTION, I'LL MAKE THE MOTION.

4 CO-CHAIR RABB: DR. PRIETO YOU MOVE.

5 MR. SHEEHY: I'LL SECOND THE MOTION.

6 CO-CHAIR RABB: THANK YOU VERY MUCH.

7 MR. HALPERN: I'D LIKE TO CLARIFY ONE THING
8 ABOUT THE MOTION, WHICH I THINK IS IN GENERAL. THE
9 PROCESS IS AN EXCELLENT ONE, AND I THINK IT VERY
10 THOUGHTFULLY INCORPORATES THE DELIBERATIONS BY THE
11 WORKING GROUP AND ALSO AN OPPORTUNITY FOR PUBLIC TO BE
12 HEARD.

13 THE ONE IMPORTANT QUESTION I HAVE IS ABOUT
14 WHAT'S GOING TO BE POSTED ON JULY 22D. MY HOPE IS THAT
15 DURING THE REMAINDER OF THIS MEETING, THE NAS
16 GUIDELINES WILL BE REVIEWED AND AMENDED AND DISCUSSED,
17 AND WHAT'S POSTED ON JULY 22D REFLECTS THE INPUT OF
18 THIS GROUP, WHICH WILL THEN PASS AS A RECOMMENDATION
19 FOR THE JULY 12TH MEETING OF THE ICOC. SO WE WON'T
20 HAVE THESE NAS GUIDELINES, WHICH REALLY ARE NOT
21 GUIDELINES, AS YOU SAID BEFORE. SOME OF THEM ARE MORE
22 LIKE PHILOSOPHICAL ESSAYS; BUT, IN FACT, WHAT GETS
23 POSTED ON JULY 22D WILL BE A SET OF INTERIM GUIDELINES
24 WHICH CAN THEN BE MODIFIED IN LIGHT OF THE DISCUSSION.

25 CO-CHAIR RABB: I THINK THAT'S NOT POSSIBLE.

1 I THINK THAT'S NOT POSSIBLE BECAUSE THE ADMINISTRATIVE
2 LAW PROCESS, I BELIEVE, REQUIRE THE ICOC TO ADOPT WHAT
3 ARE RIGHT NOW FORMALLY INTERIM GUIDELINES. AND IT IS
4 THOSE INTERIM GUIDELINES ON WHICH THE PUBLIC COMMENTS.
5 AND MAKING CHANGES AT MEETINGS THAT HAPPEN WOULD BE
6 LIKE MAKING CHANGES AS A RESULT OF COMMENTS THAT COME
7 IN OVER THE WEB. AND IT IS NOT, IT SEEMS TO ME, EITHER
8 CONSISTENT WITH THE OAL PROCESS OR WITH GIVING THE
9 PUBLIC A FAIR CHANCE TO PARTICIPATE THAT GUIDELINES
10 COULD GET CHANGED WITHOUT THEIR KNOWLEDGE THAT THAT WAS
11 GOING TO HAPPEN.

12 WHAT WE WERE PROPOSING TO DO IS TO DISCUSS
13 THE GUIDELINES HERE, TO RECEIVE FURTHER INPUT FROM
14 OTHER PUBLIC COMMENT, AND DELIBERATION OVER TIME.
15 CHANGING GUIDELINES ON THE BASIS OF SOME PARTIAL PUBLIC
16 COMMENT OR SOME PARTIAL DELIBERATION SEEMS BOTH
17 DIFFICULT FOR THE PUBLIC TO KEEP UP WITH, HASTY BECAUSE
18 IT DOESN'T ALLOW FOR MUCH DELIBERATION AND REFLECTION,
19 AND PROBABLY, ALTHOUGH I'M NO EXPERT ON CALIFORNIA LAW,
20 NOT CONSISTENT WITH THE ADMINISTRATIVE LAW PROCESS, BUT
21 YOU SHOULD SPEAK, AND THEN MAYBE JAMES WILL HELP US.

22 MR. HALPERN: COULD I SPEAK TO THAT?

23 CO-CHAIR RABB: SURE.

24 MR. HALPERN: THERE ARE SOME RESPECTS IN
25 WHICH THE NAS DOCUMENT, ADMIRABLE AS IT IS, SIMPLY

1 DOESN'T FUNCTION AS A REGULATION. THE MOST OBVIOUS
2 ONES, FIRST OF ALL, SECTION 5.0 ABOUT BANKING AND
3 DISTRIBUTION, WHICH IS JUST AN ESSAY. IT'S NOT A
4 GUIDELINE. HERE IT TAKES THIS CRITICALLY IMPORTANT
5 ISSUE AND SAYS THESE ARE THINGS THAT SOMEONE OUGHT TO
6 GIVE THOUGHT TO. YOU MIGHT TAKE A LOOK AT THE U.K.
7 EXAMPLE.

8 THE OTHER THING THAT JUMPS OUT AT ONE IS THE
9 REQUIREMENT THAT THERE BE -- THAT NO CELLS BE HARVESTED
10 FROM AN EMBRYO THAT IS OLDER THAN 14 DAYS OLD. THAT'S
11 INCONSISTENT WITH PROP 71, WHICH SETS A LIMIT OF 8 TO
12 12 DAYS.

13 SO THE QUESTION IS HOW CAN A REGULATION BE
14 ADOPTED THAT'S INCONSISTENT WITH PROP 71 ITSELF, BASIC
15 CHARTER OF THE ENTIRE ENTERPRISE? SO IT SEEMS TO ME
16 THAT SOME EFFORT HAS TO BE MADE TO TAKE THE RAW
17 MATERIAL OF NAS AND TURN IT INTO PROCEDURES.

18 AS FOR THE NOTICE TO THE PUBLIC, THAT ISSUE
19 WAS -- I THOUGHT THAT'S WHAT WE WERE COMING HERE TO
20 DISCUSS. IT SAID THE NAS GUIDELINES ARE UNDER
21 DISCUSSION, SO THERE'S AMPLE NOTICE. NO ONE WILL BE
22 SURPRISED.

23 FINALLY, THE ICOC IS AUTHORIZED AND REQUIRED
24 TO ACT FOLLOWING, A QUOTE FROM THE STATUTE, IT'S
25 SUPPOSED TO ACT AFTER THE RECOMMENDATIONS OF THE

1 WORKING GROUPS IN MAKING ITS DECISIONS -- I'M
2 SKIPPING -- ADOPTING REGULATORY STANDARDS. SO THE
3 TEXTURE OF PROP 71 ANTICIPATES THAT THIS WORKING GROUP
4 WILL MAKE ITS RECOMMENDATIONS, AND THE ICOC WILL THEN
5 TAKE ACTION TAKING INTO ACCOUNT THOSE RECOMMENDATIONS.

6 WELL, WHEN THEY ACTED IN MAY, THEY DIDN'T
7 HAVE THE RECOMMENDATIONS OF THIS GROUP. WHEN THEY MEET
8 IN JULY, THEY CAN HAVE THE RECOMMENDATIONS OF THE
9 GROUP, WHICH WOULD PERMIT THEM TO THEN ACT IN THE
10 FASHION THAT PROP 71 ANTICIPATES.

11 CO-CHAIR RABB: IF I MAY -- I HEAR YOU. MAY
12 I SAY, REMIND EVERYBODY AGAIN, WHILE YOU MAKE REFERENCE
13 TO SECTION 5.0 AS AN ESSAY, SECTION 5.0 IS NOT ON THE
14 SIX PAGES. IT'S IN THE REPORT. THE REPORT, WHILE
15 HELPFUL, IS NOT -- IS NOT A PART OF THE RECOMMENDATIONS
16 AND IS NOT A PART OF THE INTERIM GUIDELINES.

17 NOW, YOUR POINT IS STILL RELEVANT BECAUSE
18 THERE ARE ASPECTS OF THE RECOMMENDATIONS THAT ARE
19 HORTATORY AND ENCOURAGE DOING THINGS IN CERTAIN
20 FASHIONS. AND IT IS TRUE, AS I SAID AT THE OUTSET,
21 THIS IS NOT REGULATORY LANGUAGE. AND ONE OF THE
22 AMENDMENTS WE'RE GOING TO HAVE TO MAKE IS TO TURN THIS
23 LANGUAGE INTO FORMAL REGULATORY TEXT. THAT'S
24 ABSOLUTELY UNDERSTOOD. BUT WE NEED TO KEEP FOCUSED ON
25 THE SIX SINGLE-SPACED PAGES OF BOLD TEXT THAT ARE THE

1 CURRENT INTERIM GUIDELINES.

2 MR. SHESTACK: ARE THE SIX PAGES IN OUR
3 NOTEBOOKS?

4 DR. PRIETO: THEY'RE IN OUR BINDER.

5 MR. HALPERN: I'M VERY CONFUSED. I DIDN'T
6 SAY 6.0. I SAID 5.0, WHICH IS BANKING AND DISTRIBUTION
7 OF HES CELL LINES WHICH --

8 CO-CHAIR RABB: WHICH RECOMMENDATION ARE YOU
9 LOOKING AT?

10 DR. LO: HARRIET, THERE ARE TWO DIFFERENT
11 DOCUMENTS.

12 DR. EGGAN: APPENDIX A OF THE NATIONAL
13 ACADEMY OF SCIENCE GUIDELINES ARE THE INTERIM
14 GUIDELINES.

15 DR. KIESSLING: IT STARTS ON PAGE 107.

16 DR. LO: IT'S NOT WHAT MR. HALPERN HAS. HE
17 HAS PAGES 80 TO 88.

18 MR. HALPERN: I GOT THIS OFF THE WEBSITE, OFF
19 THE CIRM WEBSITE. SO I DON'T EVEN KNOW WHAT'S BEING
20 RECOMMENDED.

21 DR. PRIETO: THIS IS ALSO IN THE MATERIALS.
22 I THINK WHAT YOU ARE REFERRING TO ARE THE SUMMARY OF
23 GUIDELINES, AND WHAT WE'RE REFERRING TO IN OUR BINDER,
24 AT LEAST, IS APPENDIX A AND IT IS PAGED AS --

25 MR. SHESTACK: COMPILATION AND

1 RECOMMENDATIONS.

2 CO-CHAIR LANSING: APPENDIX A.

3 MR. HALPERN: WHAT I HAVE SAYS AT THE TOP
4 "NATIONAL ACADEMIES GUIDELINES FOR RESEARCH ON HUMAN
5 EMBRYONIC STEM CELLS."

6 DR. CIBELLI: I WAS JUST WONDERING IF WE CAN
7 JUST BRING ORDER TO THIS DISCUSSION. THIS CAN GO ON
8 FOREVER. SO CAN WE JUST GO INTO THE NATIONAL ACADEMIES
9 GUIDELINES ONE BY ONE AND DISCUSS ISSUES, IF THERE ARE
10 ANY, THAT PEOPLE WANT TO JUST CHANGE OR ADOPT, AND MAKE
11 A MOTION FOR IT, AND GO TO THE NEXT AND SO FORTH?

12 CO-CHAIR RABB: THE ONLY REASON I THINK WE
13 NEED TO STOP AND DEAL WITH THE PROCEDURAL IS BECAUSE WE
14 HAVE A MOTION ON THE FLOOR TO ADOPT THE PROCEDURE ABOUT
15 HOW WE'RE GOING TO TAKE COMMENTS FROM THE PUBLIC AND
16 HOW WE'RE GOING TO DELIBERATE.

17 DR. CIBELLI: RIGHT NOW THE COMMENTS FROM THE
18 PUBLIC ARE VERY SPECIFIC TO THE GUIDELINES, BOTH THE
19 NATIONAL ACADEMY. I JUST THINK THIS IS NEVER ENDING.

20 CO-CHAIR RABB: NO. I JUST MEANT THAT CAN
21 WE --

22 MR. SHESTACK: CALL THE QUESTION ON THE
23 MOTION THAT'S ON THE TABLE.

24 CO-CHAIR RABB: ABOUT HOW WE'LL TAKE PUBLIC
25 COMMENT AND ABOUT THE URL'S AND SO FORTH. IF WE DID

1 THAT, THEN IT WOULD BE MY -- WHAT I'D LIKE TO DO, THEN,
2 IS INTRODUCE A WAY OF THINKING ABOUT THESE GUIDELINES
3 THAT CURRENTLY HAVE BEEN ADOPTED BY THE ICOC, AND THEN
4 GET TO IT ON THE MERITS. SO, JONATHAN, YOU CALLED --

5 MR. SHESTACK: CALL THE QUESTION THAT'S ON
6 THE TABLE, WHICH IS THE PROCEDURE OUTLINED BY THE
7 CHAIRWOMAN ON PUBLIC REVIEW FOR THIS ONGOING PROCESS.
8 THERE WERE SOME DATES SPECIFIED. AND IT SEEMS A
9 REASONABLE THING. THERE HAS BEEN PUBLIC COMMENT ON IT,
10 I BELIEVE. COULD WE VOTE ON THAT?

11 CO-CHAIR RABB: DO I HEAR ANY OTHER COMMENT
12 BEFORE WE GO TO THAT VOTE? THEN I THINK WE ARE READY
13 TO GO THAT TO VOTE. ARE THERE -- ALL IN FAVOR OF
14 ADOPTING THE RECOMMENDATION, THE MOTION THAT WAS MADE
15 EARLIER, PLEASE SIGNIFY. ALL THOSE WHO ARE OPPOSED TO
16 DOING SO.

17 HEARING NO OBJECTION, WHAT I WOULD LIKE TO
18 DO, AND I'M HOPING THAT EVERYBODY HAS THE SAME
19 MATERIAL, EVEN IF IT'S DENOMINATED IN A DIFFERENT
20 FORM -- LET'S STOP FOR A MINUTE. MAYBE WHAT WE SHOULD
21 DO IS WHAT IF WE TAKE A FIVE-MINUTE COMFORT BREAK FOR
22 EVERYBODY, MAKE OURSELVES COMFORTABLE, THEN EVERYBODY
23 HAS THE SAME PIECES OF PAPER TO TALK ABOUT, AT LEAST
24 THE SAME TEXT, AND TAKE A QUICK BREAK FOR COMFORT
25 PURPOSES AND --

1 MR. SHESTACK: THE TEXT THAT YOU WERE ASKING
2 AND WE ARE ALL REFERRING TO IS APPENDIX A. IT'S
3 UNDER --

4 MS. CHARO: IT'S CALLED "COMPILATION OF
5 RECOMMENDATIONS."

6 MR. SHESTACK: IT'S IN MOST PEOPLE'S BOOKS.
7 I JUST WANT TO MAKE SURE THAT WE ARE REFERRING TO THE
8 SAME DOCUMENT.

9 CO-CHAIR RABB: WE NEED TO MAKE SURE THAT THE
10 PUBLIC HAS EXACTLY THE SAME TEXT. LET'S CALL IT FIVE
11 MINUTES.

12 (A RECESS WAS TAKEN.)

13 CO-CHAIR LANSING: CAN I CALL THE MEETING TO
14 ORDER THEN? I'M GOING TO TURN THE MEETING BACK TO
15 HARRIET, BUT I JUST WANT TO REMIND EVERYBODY ONCE AGAIN
16 THAT WE ARE A COMMITTEE THAT HAS 270 WORKING DAYS TO GO
17 AHEAD, BUT IN THE NEXT SIX HOURS, WE HOPE TO ACCOMPLISH
18 QUITE A BIT. AND WE ARE GOING TO GO THROUGH THE ITEMS,
19 THE RECOMMENDATIONS INITIALLY, WHICH HARRIET IS GOING
20 TO CHAIR, WE ARE GOING TO HAVE A WORKING SESSION AMONG
21 OURSELVES TO EVALUATE THESE RECOMMENDATIONS, TO HAVE
22 COMMENT ON THEM. AND, AGAIN, THIS IS THE BEGINNING. I
23 REALLY WANT EVERYBODY TO UNDERSTAND THIS. WE CAN ADD
24 MUCH MORE TO ANY OF THESE RECOMMENDATIONS, WE CAN
25 CHALLENGE THEM. AND AS ONE OF MY COLLEAGUE JUST SAID,

1 IT IS ENABLING US TO BEGIN AND FOR US TO ADD TO. SO
2 THANK YOU VERY MUCH.

3 I ALSO WANT TO SAY AT THE END OF THAT, WE
4 WILL THEN BE OPEN AND WELCOME TO MORE PUBLIC COMMENT,
5 TO SEE WHAT OTHER ISSUES WE MAY HAVE NEGLECTED TO
6 ADDRESS. SO WITH THAT, I TURN IT OVER TO HARRIET.

7 DR. EGGAN: MADAM CHAIR, AS A POINT OF
8 CLARIFICATION, I THINK IT'S IMPORTANT TO KNOW PRECISELY
9 WHICH DOCUMENT THE ICOC ADOPTED AS THE INTERIM REGS.

10 CO-CHAIR LANSING: HARRIET IS GOING TO GET
11 INTO THAT.

12 CO-CHAIR RABB: APPARENTLY WHAT HAPPENED WAS
13 THAT THE DOCUMENT DENOMINATED GUIDELINES AS WELL AS THE
14 APPENDIX A SUMMARY RECOMMENDATIONS WERE BOTH BEFORE THE
15 ICOC. AND SO WE CAN CHOOSE, FOR EASE OF DISCUSSION, TO
16 FOCUS ON WHICHEVER TEXT WILL HELP TO DIRECT OUR
17 CONVERSATION MOST SPECIFICALLY. AND ALL THAT PAPER IS
18 BEING REPRODUCED RIGHT NOW SO THAT EVERYBODY IN THE
19 ROOM HAS IT IN FRONT OF HIM OR HER, ALL OF US THE SAME
20 PIECES OF PAPER, BUT ALL IF IT WAS BEFORE THE ICOC, AS
21 I UNDERSTAND IT.

22 DR. PRIETO: AS A POINT OF CLARIFICATION, I'D
23 LIKE TO BRING UP MY UNDERSTANDING, THAT AT THE ICOC WE
24 DID ADOPT THE GUIDELINES. AND THAT THE GUIDELINES
25 INCLUDE WHAT WE'RE REFERRING TO AS APPENDIX A, WHICH IS

1 A COMPILATION OF RECOMMENDATIONS. THAT'S THE TEXT, I
2 THINK, THE PUBLIC HAS JUST BEEN GIVEN NOW.

3 CO-CHAIR RABB: I THINK THAT'S HELPFUL. WHAT
4 WE HOPED TO DO WAS SPEND AT LEAST THREE-QUARTERS OF AN
5 HOUR NOW ON WHAT BROUGHT US HERE, ALL OF US HERE, WHICH
6 IS THE GUIDELINES THAT ARE CURRENTLY THE INTERIM
7 REGULATIONS FOR THE STATE.

8 TWO OF THE MEMBERS HERE -- WELL, LET ME BEGIN
9 BY SAYING THAT THE GUIDELINES ESSENTIALLY FALL INTO
10 FOUR CATEGORIES, ALTHOUGH THERE'S NOTHING FORMAL AND
11 LIMITING ABOUT THIS. THE FOUR CATEGORIES ARE
12 RECOMMENDATIONS ABOUT EMBRYONIC STEM CELL RESEARCH
13 OVERSIGHT COMMITTEES, ESCRO'S; REVIEW BY BOARDS AND
14 OTHER THAN ESCRO'S AND PROCESSES THAT WOULD INCLUDE
15 INSTITUTIONAL REVIEW BOARDS AND INSTITUTIONAL ANIMAL
16 CARE AND USE COMMITTEE BOARDS AND OTHER OF THE REVIEW
17 ENTITIES THAT ARE TYPICALLY INVOLVED IN BASIC AND
18 CLINICAL RESEARCH; A SET OF GUIDELINES ABOUT DONATION
19 OF TISSUE AND HOW THOSE DONATIONS SHOULD PROPERLY BE
20 MADE AND WHAT DOCUMENTATION THERE SHOULD BE THAT WILL
21 GUIDE REVIEW AND TRACKING OF THE RESEARCH; AND,
22 FINALLY, BANKING, EITHER FORMAL BANKING OR BANKING BY
23 AN INDIVIDUAL WHO IS RECEIVING AND MAINTAINING SETS OF
24 STEM CELL LINES.

25 TWO OF THE MEMBERS OF THIS WORKING GROUP WERE

1 INVOLVED IN THE CREATION OF THE NAS GUIDELINES,
2 DR. JANET ROWLEY AND ALTA CHARO, WHO IS A DOCTOR OF
3 JURISPRUDENCE, BUT WE DON'T GET TO CALL EACH OTHER
4 DOCTOR. I'VE ASKED BOTH OF THEM TO SAY A FEW WORDS
5 ABOUT TWO OF THE TOPICS THAT FROM MY EXPERIENCE IN MY
6 RESEARCH INSTITUTION I KNOW HAVE BEEN TOPICS THAT HAVE
7 GENERATED CONSIDERABLE DISCUSSION. I OFFER THESE TWO
8 UP, ONE IS ABOUT WOMEN AND THE DONATION OF OOCYTES, THE
9 OTHER IS ABOUT WHAT'S CALLED IN THE NAS GUIDELINES
10 CHIMERIC RESEARCH, BOTH BECAUSE THEY'RE TOPICS THAT I
11 THINK THE PUBLIC IS INTERESTED IN AND ALSO BECAUSE I
12 WANTED FOR MYSELF AND I HOPE FOR ALL OF US TO BE CLEAR
13 THAT WE'RE NOT -- THAT WE'RE GOING TO ADDRESS THE HARD
14 ISSUES, THAT THERE IS NOTHING WE CAN'T TALK ABOUT HERE,
15 AND THAT LOTS OF THINGS MAY BE HARD FOR DIFFERENT
16 PEOPLE ON DIFFERENT GROUNDS. THEY'RE ALL GOING TO BE
17 OF INTEREST TO US.

18 I'D ASKED OUR COLLEAGUES TO SPEAK BRIEFLY,
19 WHICH IS TO SAY UNDER TEN MINUTES, ON THE TOPICS THAT
20 I'VE DESCRIBED. DR. ROWLEY ON THE QUESTIONS OF
21 OOCYTES. COLLEAGUES OF OURS HERE WHO HAVE IVF
22 EXPERIENCE WILL BE ABLE TO COMMENT.

23 AND THE OBJECTIVE HERE IS NOT TO TALK SO MUCH
24 ABOUT WHERE WE OUGHT TO END UP, BUT WHERE WE START.
25 SINCE AT LEAST ONE GOAL OF THIS WORKING GROUP, FROM MY

1 PERSPECTIVE, OUGHT TO BE TO MAKE SURE THAT THE PUBLIC
2 HAS THE FACTUAL INFORMATION ON THE BASIS OF WHICH TO
3 MAKE UP THEIR OWN MINDS, THAT WITHOUT GOOD INFORMATION
4 ABOUT THE SCIENCE, GOOD GUIDELINES WILL NOT FOLLOW. OR
5 THE REVERSE BEING TRUE, GOOD INFORMATION IS LIKELY TO
6 GENERATE GOOD DECISIONS. SO I WANTED TO START HERE
7 WITH SOME DISCUSSION THAT I THINK WILL PROVIDE FOR ALL
8 OF US GOOD INFORMATION.

9 DR. ROWLEY, IF YOU WOULD HELP US FOR THE NEXT
10 FEW MINUTES, AND THEN WE WILL TAKE COMMENT FROM
11 COLLEAGUES, PARTICULARLY THOSE OF YOU WHO HAVE
12 EXPERTISE IN THIS AREA, AND THEN MOVE ON. OPEN THE
13 WHOLE DISCUSSION UP, THEN, OF ALL THESE GUIDELINES TO
14 MEMBERS OF THIS WORKING GROUP WHO WANT TO ADDRESS ANY
15 ONE OF THEM OR MORE OF THEM, ALL OF IT WILL BE ON THE
16 TABLE. IT WILL BE THE BEGINNING. THERE WILL BE MORE
17 TO FOLLOW. DR. ROWLEY.

18 DR. ROWLEY: THANK YOU. WELL, I'M EXTREMELY
19 PLEASED TO BE ASKED TO PARTICIPATE IN THIS PROCESS IN
20 CALIFORNIA BECAUSE, AS HARRIET HAS ALREADY SAID, WHEN
21 WE WERE DEVELOPING THE NAS GUIDELINES, IT WAS HOPED
22 THAT THEY WOULD ACTUALLY FORM A BASIS OR A FRAMEWORK
23 FOR DISCUSSIONS, MOST SPECIFICALLY IN DIFFERENT
24 INSTITUTIONS AND DIFFERENT STATES. SO HAVING WORKED IN
25 THEORY, IT'S NOW NICE TO SEE THE NEXT STEP MOVING

1 TOWARD PRACTICE.

2 I WANT TO BEGIN MY COMMENTS WITH SOME MORE
3 GENERAL OBSERVATIONS AS WELL. THE NAS GUIDELINES WERE
4 FRAMED IN THE CONTEXT OF SEVERAL CRITICAL
5 CONSIDERATIONS. FIRST, THE GENERATION AND USE OF HUMAN
6 EMBRYOS FOR RESEARCH OR THERAPY IS A MOST CONTENTIOUS
7 ISSUE IN AMERICAN SOCIETY. SO IT'S ESSENTIAL THAT ALL
8 SCIENTISTS AND OTHERS INVOLVED IN THE PROCESS ACT IN
9 THE MOST ETHICALLY APPROPRIATE MANNER.

10 SECONDLY, ALTHOUGH MANY COUNTRIES HAVE
11 NATIONAL GUIDELINES, WE MUST RECOGNIZE THAT THE U.S.
12 DOES NOT HAVE ANY NATIONAL GUIDELINES. AS MORE
13 SCIENTISTS AND INSTITUTIONS ARE BEING INVOLVED IN THIS
14 RESEARCH, THERE IS AN URGENT NEED FOR SOME GUIDELINES
15 THAT CAN BE ADOPTED BY AS MANY PARTICIPANTS AS
16 POSSIBLE. AS SHERRY HAS ALREADY SAID, CALIFORNIA IS IN
17 ONE SENSE LEADING THE WAY IN TRANSLATING THE GUIDELINES
18 THAT WERE WRITTEN TO SPECIFIC REGULATIONS.

19 BUT FINALLY, THIS IS A RAPIDLY MOVING FIELD
20 WITH DISCOVERIES BOTH TECHNICAL AND BIOLOGICAL
21 CONSTANTLY BEING MADE. SO ANY GUIDELINES MUST INCLUDE
22 THE ABILITY FOR CONTINUAL REVISION AS CHANGING NEEDS
23 AND PROBLEMS DICTATE.

24 I ALSO WANT TO ACKNOWLEDGE THAT MEMBERS OF
25 THE NATIONAL ACADEMY WORKING GROUP ACCEPTED THE TWO

1 PREVIOUS NAS REPORTS ON HUMAN EMBRYONIC STEM CELLS THAT
2 RECOMMENDED, A, THAT REPRODUCTIVE CLONING BE BANNED AND
3 THAT, B, RESEARCH ON HUMAN EMBRYONIC STEM CELLS PROCEED
4 AS RAPIDLY AND ETHICALLY AS POSSIBLE WITHIN THE
5 ACCEPTED GUIDELINES. SO OUR WORKING GROUP IN THE NAS
6 HAD NO DISCUSSION ABOUT WHETHER RESEARCH SHOULD
7 PROCEED. IT WAS, RATHER, TO DEVELOP A SET OF
8 GUIDELINES THAT MET THE CONDITIONS THAT I'VE JUST
9 OUTLINED.

10 NOW, WITH REGARD TO OOCYTE DONATION AND THE
11 POTENTIAL RISKS FOR THE DONOR, THIS IS A COMPLEX
12 MEDICAL PROBLEM. AND IN A SENSE I'M AN INADEQUATE
13 COMMENTATOR ON THIS, BUT FORTUNATELY THERE ARE A NUMBER
14 OF MEMBERS OF THE COMMITTEE, DR. TAYLOR, DR. KIESSLING
15 AMONG THEM, WHO CAN COMMENT ON WHAT I SAY. I THINK
16 IT'S IMPORTANT TO PUT THIS ASPECT IN SOME PERSPECTIVE
17 AS WELL.

18 INDUCTION OF OVULATION BY GONADOTROPINS WAS
19 FIRST USED IN 1958, AND REALLY BECAME COMMON WITH THE
20 EXPANSION IN IN VITRO FERTILIZATION IN THE '80S. AND
21 FOR IVF THE GOAL IS TO INDUCE THE MATURATION OF
22 MULTIPLE OVARIAN FOLLICLES, AS MANY AS POSSIBLE,
23 SIMULTANEOUSLY RATHER THAN AS OCCURS NATURALLY, ONE
24 WITH EACH MENSTRUAL CYCLE. SO VARIOUS HORMONES,
25 NATURAL OR SYNTHETIC, ARE USED USUALLY IN COMBINATION

1 AND SEQUENTIALLY TO ACHIEVE THE GOAL OF MATURATION OF
2 MULTIPLE FOLLICLES.

3 DIFFERENT HORMONES ARE ASSOCIATED WITH
4 DIFFERENT INCIDENCE OR SEVERITY OF OVARIAN
5 HYPERSTIMULATION SYNDROME, OHSS, AND THAT APPEARS RIGHT
6 NOW TO BE THE MOST CRITICAL RISK FOR OOCYTE DONORS. AT
7 THE SAME TIME, DESPITE THE FACT THAT THERE ARE A NUMBER
8 OF SURVEYS AND REVIEWS OF PATIENTS AND THE FREQUENCY OF
9 THESE DIFFERENT ASPECTS OF THE SYNDROME, DATA ARE HARD
10 TO COME BY. AND THERE HAVE BEEN SEVERAL REPORTS FROM
11 THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, ONE IN
12 NOVEMBER OF 2003, AND THE OTHER JUNE 30, 2005.

13 IT SEEMS THAT THE HIGHEST INCIDENCE OF THE
14 MOST SEVERE COMPLICATIONS OCCURS WITH PREGNANCY, MOST
15 ESPECIALLY MULTIPLE PREGNANCIES, WHICH MAY OCCUR IN UP
16 TO 50 PERCENT OF THE PATIENTS. NOW, THIS IS CLEARLY
17 NOT AN ISSUE FOR DONORS OF OOCYTES FOR RESEARCH
18 BECAUSE, AS PART OF THE PROCESS, THEY AREN'T THEMSELVES
19 GOING TO BECOME PREGNANT. THOUGH I SHOULD NOTE THAT
20 ONE COMPLICATION OF OOCYTE DONATION CAN BE UNEXPECTED
21 PREGNANCY BECAUSE DONORS MUST DISCONTINUE THE USE OF
22 HORMONAL CONTRACEPTIVES DURING THE PROCESS. SO THAT'S
23 SOMETHING TO BE CONSIDERED.

24 OVULATION IS MANDATORY FOR OHSS TO OCCUR, AND
25 THERE'S A LAG OF ABOUT THREE TO SIX DAYS BEFORE

1 SYMPTOMS DO OCCUR. THE SYNDROME IS DUE TO THE
2 ENLARGEMENT OF THE OVARIES AND A SHIFT OF FLUID FROM
3 THE VASCULAR SYSTEM TO OTHER COMPARTMENTS, INCLUDING
4 ASCITES, WHICH IS FLUID IN THE PERITONEAL CAVITY DUE TO
5 INCREASED CAPILLARY PERMEABILITY. CURRENT RESEARCH
6 SUGGESTS THAT THIS IS DUE TO INCREASED LEVELS OF A
7 PROTEIN CALLED VEG-F, VASCULAR ENDOTHELIAL GROWTH
8 FACTOR, WHICH APPEARS TO PLAY AN IMPORTANT ROLE IN
9 FOLLICULAR GROWTH AND CORPUS LUTEUM FUNCTION. SOME OF
10 THE HORMONES USED TO INDUCE OVULATION ALSO SIMULATE THE
11 VEG-F EXPRESSION. AND VEG-F LEVELS CORRELATE WITH THE
12 SEVERITY OF OHSS, THOUGH THERE ARE MULTIPLE OTHER
13 FACTORS THAT ARE INVOLVED.

14 THERE IS A RECENT PAPER THAT WAS PUBLISHED IN
15 HUMAN REPRODUCTION FROM DR. ORVIETO, WHO SUGGESTS THAT
16 YOU CAN ELIMINATE SEVERE OVARIAN HYPERSTIMULATION BY A
17 NUMBER OF STRATEGIES. AND, AGAIN, I WANT TO EMPHASIZE
18 THIS SHOULD NOT BE A PROBLEM WITH OOCYTE DONATION, THAT
19 IS, THE SEVERE FORM, BECAUSE UNDER THE BEST OF
20 CIRCUMSTANCES, THEY SHOULD NOT BE -- THEY SHOULDN'T
21 BECOME PREGNANT, AND THAT'S ONE OF THE THINGS THAT
22 TRIGGERS IT.

23 I THINK THE ETHICAL ISSUES ARE CLEARLY
24 OUTLINED BY DAVID MAGNUS AND MILDRED CHO IN THEIR
25 COMMENTARY IN THE RECENT REPORT FROM SOUTH -- THEIR

1 COMMENTARY ON THE RECENT REPORT FROM SOUTH KOREA, WHICH
2 APPEARED IN SCIENCE JUNE 17TH. THEY HIGHLIGHT THE
3 PROBLEMS OF INTERNATIONAL COLLABORATION WHERE COUNTRIES
4 HAVE DIFFERENT RULES. SO TO THE EXTENT THAT
5 INSTITUTIONS IN THE UNITED STATES CAN ALL ADOPT COMMON
6 RULES, IT MAKES SHARING OF CELL LINES VERY MUCH EASIER.
7 AND I THINK THAT SHOULD BE ONE OF THE THINGS THAT WE
8 SHOULD STRIVE FOR.

9 THE SECOND ISSUE IS THE NONMEDICAL OOCYTE
10 DONATION, WHICH IS VERY DIFFERENT IN TERMS OF RISK THAN
11 SPERM DONATION, AND, THEREFORE, THEY REQUIRE SOME
12 DIFFERENCES IN COMPENSATION.

13 AND I THINK THAT THERE ARE A NUMBER OF
14 PROBLEMS AS WELL. A THIRD PROBLEM THEY'VE MENTIONED IS
15 OVERSELLING OF THE TECHNOLOGY. AND WE ALL KNOW THE
16 STATUS OF GENE THERAPY, AND SO WE HAVE TO BE CONCERNED
17 THAT WE NOT OVEREMPHASIZE THE CONTRIBUTIONS THAT THIS
18 MAKES. BUT I THINK ALSO ONE HAS TO RECOGNIZE THE FACT
19 THAT SINGAPORE, CHINA, SOUTH KOREA ARE POURING MILLIONS
20 OF DOLLARS INTO THIS RESEARCH MAKES IT LIKELY THAT WE
21 ARE GOING TO BEGIN USING STEM CELLS FOR THERAPY MUCH,
22 MUCH SOONER THAN WE MIGHT ANTICIPATE.

23 MY OWN VIEW IS THAT IT'S DIFFICULT TO STRIKE
24 A BALANCE BETWEEN THE NEED TO RECOGNIZE THE EFFORT AND
25 THE INCONVENIENCE THAT WOMEN WOULD SUFFER AS OOCYTE

1 DONORS AGAINST THE CONCERN THAT YOU ARE ENCOURAGING
2 THEM TO DONATE, PARTICULARLY POOR WOMEN, TO DONATE.
3 AND THIS IS A BALANCE THAT'S MAYBE DIFFICULT TO
4 ACHIEVE.

5 ONE ALSO HAS TO CONSIDER THE REPORT FROM
6 SOUTH KOREA, THAT THE MOST EFFECTIVE OOCYTES IN TERMS
7 OF DEVELOPING STEM CELL LINES FROM SOMATIC CELL NUCLEAR
8 TRANSFER WERE OOCYTES DONATED BY WOMEN UNDER 30 YEARS
9 OF AGE. AND SO, AGAIN, THIS MAY BE A MORE VULNERABLE
10 GROUP IN TERMS OF EITHER FINANCIAL INCENTIVES OR
11 SUSCEPTIBILITY TO PRESSURE FROM OTHERS.

12 I ALSO THINK THAT WE HAVE TO RECOGNIZE, AS I
13 SAID, THESE ARE RAPIDLY MOVING TIMES, AND THERE ARE A
14 NUMBER OF RECENT REPORTS FROM SCIENTISTS, AND OTHERS
15 CAN PROBABLY COMMENT ON THIS IN MORE DEPTH THAN I, URI
16 VALINSKY (PHONETIC) HAS INDICATED THAT HE'S USED CELLS
17 FROM EARLY EMBRYOS, AND HAS BEEN SUCCESSFUL IN
18 DEVELOPING STEM CELL LINES USING SCNT.

19 DR. LANZA HAS SAID IN THE MEDIA THAT HE CAN
20 TAKE ONE CELL OR A BLASTOMERE FROM AN EIGHT-CELL EMBRYO
21 IN THE MOUSE, CO-CULTURE IT WITH ES CELLS AND MAKE THE
22 BLASTOMERE APPEAR TO BE LIKE -- HAVE FEATURES OF
23 EMBRYONIC STEM CELLS WITH A SUCCESS RATE OF 25 TO 30
24 PERCENT.

25 SO THERE IS EVIDENCE THAT MAYBE THIS PROBLEM

1 OF OOCYTE DONATION MAY DISAPPEAR DUE TO TECHNICAL
2 ADVANCES; BUT AT THE PRESENT TIME, I THINK IT IS A
3 SERIOUS ISSUE.

4 CO-CHAIR RABB: DR. KIESSLING, DR. TAYLOR,
5 AND THEN OTHERS IF WE CAN OPEN IT UP TO THINK ABOUT --
6 MORE ABOUT THIS EXPERIENCE OF OOCYTE DONATION.

7 DR. TAYLOR: ALL RIGHT. MY NAME IS ROB
8 TAYLOR. I'M A PROFESSOR AT EMORY UNIVERSITY IN THE
9 DEPARTMENT OF GYNECOLOGY AND OBSTETRICS, PREVIOUSLY
10 HERE AT UC SAN FRANCISCO.

11 I GUESS I THINK IN TERMS OF THINKING ABOUT
12 WHAT DR. ROWLEY HAS DESCRIBED THE RISKS TO WOMEN WHO
13 ARE OOCYTE -- POTENTIAL OOCYTE OR EGG DONORS, I THINK
14 IT'S PROBABLY IMPORTANT TO KIND OF THINK ABOUT THOSE
15 AND PUT THAT INTO THE PERSPECTIVE OF STEM CELL
16 DEVELOPMENT, AND ALSO REALLY MOSTLY THE DATA THAT WE
17 HAVE ARE FROM WOMEN WHO ARE DONATING OOCYTES FOR OTHER
18 COUPLES ACTUALLY FOR PROCREATIVE REASONS, FOR
19 FERTILITY, INFERTILITY PROBLEMS IN OTHER COUPLES, AND
20 THAT'S REALLY WHERE WE'VE GOT OUR EXPERIENCE WITH THE
21 COMPLICATIONS OF THESE EGG DONORS' EXPERIENCE.

22 SO I THINK IT'S CORRECT TO POINT OUT THERE
23 ARE SOME SORT OF ACUTE AND THEN MORE CHRONIC, I THINK,
24 RISKS THAT WOMEN WHO ARE UNDERGOING EGG RETRIEVAL
25 EXPERIENCE. THE ACUTE RISKS PROBABLY IN ORDER OF

1 FREQUENCY, I WOULD SAY, WOULD BE PAIN, WHICH IS
2 GENERALLY MILD AND TOLERABLE, BUT IT'S CERTAINLY THE
3 MOST COMMON. I THINK BEYOND THAT THE RISK OF BLEEDING,
4 WHICH PROBABLY OCCURS TO SOME EXTENT IN ALL WOMEN
5 UNDERGOING OOCYTE PUNCTURE. IN THE VAST MAJORITY OF
6 THE CASES, THIS IS NOT THREATENING IN ANY KIND OF A
7 WAY, BUT CAN BE IN CERTAIN RARE CIRCUMSTANCES.

8 THE RISK OF OVARIAN HYPERSTIMULATION
9 SYNDROME, AS HAS BEEN DESCRIBED, WE BELIEVE THAT THAT
10 OCCURS IN THE SEVERE FORM IN WOMEN UNDERGOING EGG
11 RETRIEVAL IN ABOUT 1 PERCENT OF WOMEN THAT ARE HAVING
12 THAT PROCEDURE, BUT IT SHOULD BE NOTED, AS DR. ROWLEY
13 POINTED OUT, THAT IT'S REALLY PREGNANCY AND THE
14 PREGNANCY INDUCED HORMONES OF EARLY IMPLANTATION, THE
15 HUMAN CHORIONIC GONADOTROPINS MADE BY THE GROWING AND
16 INVADING BLASTOCYST, THAT, IN FACT, STIMULATES THAT
17 OVARIAN HYPERSTIMULATION SYNDROME. SO IN A WOMAN WHO'S
18 GIVING EGGS AND NOT RECEIVING BACK THE EMBRYO, THERE'S
19 NOT THAT STIMULUS TO SORT OF DRIVE THE HYPERSTIMULATION
20 SYNDROME.

21 CLINICALLY WE TEND TO CATEGORIZE THAT AS
22 BEING MILD, MODERATE, OR SEVERE. IN SEVERE CASES THE
23 OVARIES TYPICALLY ARE ENLARGED TO GREATER THAN 10
24 CENTIMETERS IN DIAMETER, OVERALL DIAMETER. AGAIN, IT'S
25 QUITE AN UNUSUAL SITUATION, BUT IT TYPICALLY OCCURS IN

1 WOMEN WITH OTHER ENDOCRINE KINDS OF PROBLEMS, MOST
2 COMMONLY POLYCYSTIC OVARIAN SYNDROME. THOSE ARE
3 PERHAPS NOT THE BEST INDIVIDUALS TO RECRUIT POTENTIALLY
4 FOR EGG DONATION IF ONE WANTED TO TRY TO MITIGATE THAT
5 RISK.

6 THERE'S A RISK OF INFECTION WITH EGG PUNCTURE
7 AND OOCYTE RETRIEVAL, AGAIN VERY LOW RISK. AND
8 FINALLY, THE RISK OF PREGNANCY, AS WAS NOTED, IN WOMEN
9 WHO DON'T WANT TO BECOME PREGNANT OR ARE JUST DONATING
10 EGGS, AND BARRIER CONTRACEPTION AND ABSTINENCE ARE THE
11 BEST WAY TO AVOID THAT.

12 THERE'S SOME OF THE MORE CHRONIC RISKS OF EGG
13 DONATION THAT I THINK WE'RE NOT VERY FAMILIAR WITH
14 CURRENTLY, BUT ARE SORT OF THEORETICAL POSSIBILITIES IN
15 THE FUTURE. ONE WOULD BE A CONCERN ABOUT OOCYTE
16 DEPLETION IN YOUNG WOMEN, AND MIGHT THEIR ULTIMATE
17 REPRODUCTIVE CAPACITY BE COMPROMISED BY HAVING GONE
18 THROUGH PROCEDURES EARLIER IN THEIR LIFE WHERE THEY'VE
19 ACTUALLY DONATED EGGS. AND THERE'S SOME EVIDENCE,
20 ALTHOUGH IT'S NOT VERY STRONG AND TENDS TO REQUIRE
21 MONTHS AND MONTHS AND MONTHS OF STIMULATION AS TO BE
22 UNUSUAL IN AN EGG DONOR IN THIS SETTING WHERE IT SEEMS
23 LIKE HYPERSTIMULATING THE OVARIES, PARTICULARLY IN
24 FERTILE WOMEN, MAY INCREASE THEIR RISK OF DEVELOPING
25 OVARIAN CANCERS. THAT'S NOT BEEN SUBSTANTIATED YET,

1 BUT IT'S BEEN A KIND OF THEORETICAL CONCERN.

2 SO IN MY VIEW, THOSE ARE REALLY THE
3 SHORT-TERM AND LONG-TERM RISKS THAT WE SHOULD CONSIDER
4 IN WOMEN WHO ARE THINKING ABOUT EGG DONATION FOR THE
5 PURPOSE OF STEM CELL RESEARCH.

6 CO-CHAIR RABB: THANK YOU VERY MUCH.
7 DR. KIESSLING.

8 DR. KIESSLING: I SORT OF DIDN'T REALIZE WE
9 WERE GOING TO GET INTO THIS TOPIC THIS MORNING, BUT MY
10 EXPERIENCE WITH ORGANIZING, AND WE PROBABLY HAVE THE
11 ONLY ORGANIZED EGG DONOR PROGRAM FOR STEM CELL RESEARCH
12 IN THE -- MAYBE IN THE WORLD, FOR ALL I KNOW. MY
13 EXPERIENCE BEGAN WITH THIS ABOUT FIVE YEARS AGO WHEN
14 DR. CIBELLI KNOCKED ON MY DOOR AND SAID, "WE'RE WAITING
15 TO DO THIS. HOW ARE WE GOING TO DO IT?"

16 AND WE HAVE -- WE SPENT TWO OR THREE YEARS,
17 THEN, DEVELOPING GUIDELINES TO AVOID THE COMPLICATIONS
18 THAT BOTH DR. TAYLOR AND DR. ROWLEY HAVE TALKED ABOUT.
19 AND I WOULD BE HAPPY TO GO THROUGH THAT WITH THIS GROUP
20 IN AN ORGANIZED FASHION. I ACTUALLY HAVE THOSE
21 GUIDELINES AND THE PROGRAM PRETTY WELL ORGANIZED IN A
22 POWERPOINT PRESENTATION. IT'S UP IN MY HOTEL ROOM, SO
23 I WOULD HAVE TO DO THAT AFTER LUNCH. I WOULD BE HAPPY
24 TO DO THAT.

25 I THINK AS AN OVERARCHING CONSIDERATION ABOUT

1 THIS, HOWEVER, THERE ARE TWO OR THREE THINGS THAT DON'T
2 ALWAYS COME UP FIRST. AND I THINK THE MOST IMPORTANT
3 THING TO REMEMBER IS THAT THE HOPE BY EVERYONE INVOLVED
4 IS THAT WE WON'T NEED HUMAN EGGS VERY LONG. SO THE
5 CONCEPT OF THE SPECTER OF RECRUITING, AND FOR SOME
6 REASON THIS IS ALWAYS POOR WOMEN DONATING THEIR EGGS
7 FOR MONEY, IS SOMETHING THAT REALLY SHOULD BE SET
8 ASIDE. I DON'T THINK THAT'S GOING TO HAPPEN. I DON'T
9 THINK THAT'S THE GOAL. I DON'T THINK THAT'S THE
10 OUTCOME. SO THIS SHOULD BE REGARDED AS AN INTERIM
11 RESEARCH PROJECT THAT NEEDS TO BE SOLVED BY USING
12 SOMETHING OTHER THAN EGGS FROM WOMEN.

13 AND I THINK EVEN THE GREATER CONCERN IS TO
14 HOLD OUT THE HOPE TO WOMEN THAT IF THEY SIMPLY DONATE
15 THEIR EGGS, THEIR CHILD WHO HAS TYPE 1 DIABETES IS
16 GOING TO BE OKAY. THIS TO ME IS THE FAR GREATER
17 CONCERN FOR WOMEN GOING THROUGH THIS THAN ANY KIND OF
18 FINANCIAL CONSIDERATION.

19 SO WOMEN DO LOTS OF THINGS. THEY MAKE
20 LIFELONG COMMITMENTS EVERY TIME WE HAVE A CHILD.
21 THEY'RE VERY WILLING TO BECOME OVERCOMMITTED TO
22 DONATING. MONEY IS A MINOR PLAYER IN THIS EXPERIENCE.
23 AND SO I WOULD VERY MUCH LIKE TO HAVE THE COMPENSATION
24 OF DONORS BE COMPLETELY SET ASIDE. THAT'S NOT AN
25 ISSUE. ALL MEDICAL RESEARCH FOR PEOPLE WHO ARE HEALTHY

1 HUMAN SUBJECTS BE COMPENSATED. IT ISN'T A MATTER OF
2 SHOULD THEY BE COMPENSATED OR NOT. IF THIS COMMITTEE
3 IS CONCERNED ABOUT IT, THERE SHOULD BE GUIDELINES FOR
4 IT.

5 IF YOU'RE ASKED TO FILL OUT A QUESTIONNAIRE
6 ABOUT WHAT YOU HAD FOR LUNCH EVERY FRIDAY, YOU'RE
7 COMPENSATED FOR THAT. IF YOU GIVE PLATELETS TO THE
8 PEOPLE DOWN THE HALL, YOU ARE GOING TO GET \$25 FOR
9 DOING IT. SO ALL NORMAL HEALTHY SUBJECTS THAT UNDERGO
10 ANY KIND OF RESEARCH, BIOMEDICAL RESEARCH, IN THIS
11 COUNTRY ARE COMPENSATED FOR THEIR TIME. AND SO THAT
12 NEEDS TO BE SOMETHING THAT'S CONSIDERED AND WORKED INTO
13 THE GUIDELINES FOR THE WOMEN DONORS.

14 HAVING SAID THAT, I DON'T MEAN TO TRIVIALIZE
15 THE EFFORT THAT WOMEN GO THROUGH. AND I WOULD REALLY
16 LIKE TO DEFER UNTIL MAYBE AFTER LUNCH WHEN I CAN SPEND
17 TEN MINUTES TO MAKE SURE THAT THE GUIDELINES THAT ARE
18 IN PLACE THAT SEEM TO HAVE BEEN SUCCESSFUL ARE REALLY
19 WELL UNDERSTOOD TO THIS GROUP. WOULD THAT BE OKAY?

20 CO-CHAIR RABB: TERRIFIC. COME BACK TO THIS.
21 I WANT TO OPEN TO THE WORKING GROUP. AND ALTA HAS GOT
22 A HAND UP AND SO DOES JONATHAN, SO DOES KEVIN, AND SO
23 DOES BERNIE. OKAY. WHY DON'T WE START THAT WAY. AND
24 IN ORDER TO GIVE EVERYBODY A CHANCE TO SPEAK, I JUST
25 ASK EVERYBODY TO BE --

1 DR. KIESSLING: WOULD YOU LIKE ME TO GO GET
2 MY COMPUTER AT THIS TIME? WOULD IT BE BEST TO GO
3 THROUGH IT RIGHT NOW?

4 DR. EGGAN: MAYBE DURING LUNCH. I THINK IT'S
5 BEST IF SHE'S HERE FOR OUR COMMENTS.

6 CO-CHAIR RABB: I DO NOT WANT YOU TO MISS
7 WHAT WE'RE SAYING. ALTA.

8 MS. CHARO: JUST ONE COMMENT ABOUT THE DEGREE
9 TO WHICH THE ISSUES OF COMPENSATION IS NOT ON THE
10 TABLE. BUT AT LEAST WHEN WE WORKED ON THE NATIONAL
11 ACADEMIES' REPORT, IT WAS OUR UNDERSTANDING THAT PROP
12 71 HAD PRETTY MUCH STATED WHETHER OR NOT PROP 71-FUNDED
13 RESEARCH COULD INVOLVE COMPENSATION FOR EGG DONORS, AND
14 THAT THE ANSWER WAS NO. AND, INDEED, OUR UNDERSTANDING
15 OF THAT WAS SO STRONG, THAT IT ACTUALLY DROVE THE
16 DISCUSSION WITHIN THE NATIONAL ACADEMIES GROUP, SINCE
17 AS HARRIET -- AS JANET HAD SAID, ONE OF THE GOALS OF
18 THE NATIONAL ACADEMIES COMMITTEE WAS TO CREATE
19 STANDARDS THAT WOULD BE INTERCHANGEABLE AMONG STATES.
20 SINCE PROP 71 AT THE TIME WAS THOUGHT TO BE LIKELY TO
21 BE THE DRIVING FORCE FINANCIALLY IN THE RESEARCH,
22 HAVING BASICALLY PROHIBITED COMPENSATION FOR THE PROP
23 71-SPONSORED RESEARCH, THE ONLY WAY TO MAXIMIZE
24 INTERCHANGEABILITY AMONG STATES WAS TO FOLLOW
25 CALIFORNIA'S LEAD.

1 AND SO I WAS UNDER THE IMPRESSION THAT REALLY
2 THAT PARTICULAR ISSUE IS KIND OF BEYOND ANY DISCUSSION
3 AT THIS STAGE.

4 DR. KIESSLING: I THINK IT'S A MATTER OF
5 DEFINING WHAT THE WORD "COMPENSATION" MEANS.

6 MR. SHESTACK: NO COMPENSATION IS ALLOWED.

7 DR. PRIETO: COULD I ASK BOB TO COMMENT ON
8 THAT?

9 MR. KLEIN: YES. PROP 71, AS I WROTE IT,
10 DOES NOT PERMIT COMPENSATION TO EGG DONORS EITHER
11 DIRECTLY OR ANY INDIRECT COMPENSATION TO THEM. THERE
12 IS A SEPARATE STATE LAW THAT WAS ON THE BOOKS THAT
13 DEALT WITH COMPENSATION AND PROHIBITED COMPENSATION IN
14 CALIFORNIA. AND TO MAKE IT CLEAR THAT WE WERE NOT
15 CREATING A MORE PERMISSIVE STANDARD UNDER PROP 71,
16 SINCE IT HAS THE ABILITY TO SET ITS OWN STANDARDS, I
17 MADE IT EXPLICIT THAT WE COULD NOT HAVE COMPENSATION
18 FOR THE DONORS DIRECTLY OR INDIRECTLY.

19 DR. EGGAN: AS A POINT OF CLARIFICATION, IT
20 DOES DIRECTLY ALLOW REIMBURSEMENT.

21 MR. KLEIN: IT DOES PROVIDE FOR REIMBURSEMENT
22 OF MEDICAL PROCEDURES, YES.

23 MS. CHARO: OF OUT-OF-POCKET EXPENSES, BUT
24 NOT OPPORTUNITY COSTS.

25 DR. EGGAN: IS THAT DIRECTLY PROSCRIBED IN

1 THE PROPOSITION?

2 MR. KLEIN: YES, IT IS.

3 DR. KIESSLING: THIS COMPENSATION DISCUSSION
4 BECOMES MUCH CLEARER WHEN YOU GO THROUGH THIS IN A MORE
5 ORGANIZED WAY. RATHER THAN DEBATE WHETHER -- WHAT
6 EXACTLY IT IS, I THINK IT WOULD BE HELPFUL.

7 CO-CHAIR RABB: LET'S HOLD THE COMPENSATION
8 ASPECTS OF THIS, BUT I HAVE NOW JONATHAN, KEVIN, AND
9 JOSE IN THAT ORDER.

10 MR. SHESTACK: I JUST HAVE SOME QUESTIONS
11 THAT PERHAPS DR. KIESSLING COULD ANSWER AT SOME POINT,
12 WHICH IS I'M TRYING TO UNDERSTAND -- I UNDERSTAND THE
13 GOAL IS TO HOPEFULLY DIRECT RESEARCH AND HAVE RESEARCH
14 BE SUCCESSFUL SO THAT OOCYTE DONATION THE WAY IT'S
15 CURRENTLY DONE IS NOT NECESSARY. BUT WHAT DO PEOPLE
16 WHO KNOW A LOT ABOUT THIS ANTICIPATE ACTUALLY THE
17 DEMAND FOR DONATED OOCYTES TO BE UP UNTIL THAT DAY, SO
18 WE HAVE A SENSE OF HOW MANY PEOPLE WE'RE TALKING ABOUT?
19 AND MY ONLY EXPERIENCE REALLY WITH DONATION OF
20 BIOMATERIALS COMES FROM MY EXPERIENCE IN AUTISM WHERE
21 WE HAVE AFFECTED FAMILY MEMBERS WHO ARE OFTEN GUARDIANS
22 OF VULNERABLE A POPULATION, BUT THEY DECIDE TO MAKE A
23 DNA -- A BLOOD DONATION. AND THEY AREN'T EXPECTING
24 DIRECT GAIN OR EVEN INDIRECT GAIN, BUT THEY HAVE A
25 DIRECT INTEREST IN THE ISSUE.

1 AND COULD YOU EXPLAIN FOR ME WHERE IS IT THAT
2 WE GET WOMEN WHO ARE MAKING STRICTLY A RESEARCH
3 DONATION OF OOCYTES? AND WHAT IS THAT WORLD LIKE? I
4 JUST DON'T KNOW IT. I WANT TO GET A SENSE OF IT.

5 DR. KIESSLING: WE'RE CONTACTED IF NOT DAILY,
6 MANY TIMES A WEEK BY WOMEN WHO ARE SIMPLY HAPPY TO
7 DONATE THEIR EGGS TO HELP. AND THEY EITHER HAVE A
8 PERSONAL FAMILY MEMBER. THERE IS NOT NOW, NOR WILL
9 THERE BE IN THE FORESEEABLE FUTURE A LIMIT TO THE
10 NUMBERS OF WOMEN WHO WOULD LOVE TO HELP. SO THERE IS
11 NO -- COMPENSATION TO THESE WOMEN IT NOT -- THERE IS NO
12 INDUCEMENT NEEDED. WOMEN ARE SIMPLY HAPPY TO HELP, AND
13 THERE'S A LOT OF THEM, SO THAT'S NOT AN ISSUE.

14 IN TERMS OF HOW MANY WE'RE GOING TO NEED TO
15 GET THE RESEARCH DONE, I'M GOING TO DEFER THE LAST HALF
16 OF THAT ANSWER TO DR. CIBELLI, WHO'S REALLY THOUGHT
17 ABOUT THIS A LOT MORE THAN I HAVE IN TERMS OF NUMBERS.
18 HE ONLY TALKS ABOUT HOW MANY EGGS HE'D LIKE. BUT THE
19 PROBLEM IS THAT WE DON'T KNOW HOW LONG IT'S GOING TO
20 TAKE TO REPLACE THE EGG.

21 IF WE COULD REPLACE THE EGG TOMORROW, WE
22 WOULD. WE SIMPLY DON'T KNOW WHAT THE EGG ACTUALLY DOES
23 AT THE MOLECULAR LEVEL, THAT WE CAN'T SEEM TO FIGURE
24 OUT HOW TO DO IN THE LAB YET. AND THE MORE RESOURCES
25 ARE Poured INTO THE CREATION OF, QUOTE, AN ARTIFICIAL

1 EGG, WHETHER IT COMES FROM EXISTING STEM CELL LINES,
2 WHETHER IT COMES FROM SOMETHING ELSE, IS GOING TO LIMIT
3 THE NUMBERS OF WOMEN THAT WE'RE GOING TO HAVE TO ASK TO
4 GO DONATE THEIR EGGS. I THINK JOSE HAS A MUCH BETTER
5 SENSE OF THAT THAN I DO.

6 CO-CHAIR RABB: DR. CIBELLI, CAN YOU MAYBE
7 HELP US OUT HERE, AND THEN WE'LL MOVE ON TO THE OTHER
8 QUESTION.

9 DR. CIBELLI: SO THE TECHNICAL ANSWER TO THE
10 QUESTION WOULD BE THAT IF WE TAKE THE KOREAN WORK AT
11 FACE VALUE, SO WE CAN ALL REPLICATE WHAT THEY'VE DONE,
12 THAT MEANS ONE WOMAN PER CELL LINE. IF WE THINK ABOUT
13 ALL THE -- SO THE APPLICATION THAT I SEE RIGHT NOW IS
14 JUST TO UNDERSTAND DISEASE, NOT TO TREAT A PATIENT.
15 OKAY? SO IF YOU TAKE, LET'S SAY, TEN DIFFERENT
16 DISEASES, IT WOULD BE NICE TO HAVE AT LEAST 10 OR 20
17 DIFFERENT CELL LINES FROM DIFFERENT PATIENTS WHO
18 CARRIES THE DISEASE. SO DO THE MATH. WE'RE TALKING
19 ABOUT MAYBE SOMEWHERE BETWEEN A HUNDRED TO 500 WOMEN.

20 BUT THE PROBLEM IS THAT THE KOREAN RESULTS
21 WILL BE VERY HARD TO REPLICATE. I CAN TELL YOU THAT --
22 I'M NOT SAYING THAT IT'S NOT REAL. WHAT I'M SAYING IS
23 THEY'RE SO AHEAD OF US IN TERMS OF EXPERTISE AND
24 DEXTERITY IN THE MICROSCOPE, THAT IT WILL BE HARD TO
25 GET TO THEIR LEVEL OF EFFICIENCY.

1 SO I WOULD -- IF I HAD TO GUESS, JUST A
2 GUESS, I WOULD SAY MORE THAN A THOUSAND WOMEN WILL HAVE
3 TO BE ACQUIRED.

4 NOW I'M GOING TO MAKE A POINT, THE REASON WHY
5 I RAISED MY HAND. WE'RE ALL -- SO FOR CLARIFICATION,
6 WE'RE TALKING ABOUT THE NATIONAL ACADEMIES 3.B, WOMEN
7 SHOULD BE -- A WOMAN SHOULD BE REIMBURSED ONLY FOR
8 DIRECT EXPENSES. SO I HAVE TO FIRST CONGRATULATE. I
9 DON'T KNOW WHY YOU GUYS PUT YOURSELF IN THE POSITION
10 WHERE YOU CANNOT COMPENSATE FOR TIME AND EFFORT.
11 THAT'S SOMETHING THAT YOU ARE GOING TO COME TO REGRET.
12 BECAUSE AT SOME POINT YOU ARE GOING TO HAVE TO
13 RECOGNIZE THAT THIS IS SOMETHING THAT IS VERY PRECIOUS
14 FOR THE SCIENTIFIC COMMUNITY. AND SOMETIME YOU HAVE TO
15 COMPENSATE FOR IT. I'M NOT SAYING IT SHOULD BE THE
16 INCENTIVE TO GET THE OOCYTES, BUT WE'RE GOING TO NEED
17 THEM.

18 AND SO AS A SCIENTIST MYSELF, I CAN TELL YOU
19 THAT IT WILL BE HARD. SO I WOULD JUST LEAVE THAT OPEN,
20 AND THAT'S MY OPINION, PERSONAL OPINION.

21 CO-CHAIR LANSING: I HAVE A QUESTION. AND,
22 AGAIN, THIS IS A LAY PERSON. WOMEN GO THROUGH THIS FOR
23 FERTILITY ALL THE TIME. AND THERE'S, AS I UNDERSTAND
24 IT, A GREAT MANY EGGS THAT AREN'T USED, THAT WOULD BE
25 DESTROYED, AND THEY WOULD BE, AM I CORRECT IN ASSUMING,

1 GOOD EGGS FOR OUR RESEARCH?

2 DR. CIBELLI: YOU COULD FIND THIS IS A VERY
3 COMPLICATED PROCEDURE. THIS IS SOMETHING THAT THE EGG
4 IS NOT PREPARED TO HANDLE NEEDLES AND MICROSCOPES AND
5 BEING OUT OF THE HUMAN BEING FOR SO LONG. SO YOU WANT
6 TO HAVE TO -- YOU WANT TO START WITH THE BEST MATERIAL
7 YOU CAN GET. SO YOU DON'T WANT TO USE MATERIAL THAT
8 HAS BEEN LEFT OVER AND JUST MATERIALS THAT ARE NOT GOOD
9 FOR IVF. SO IF THE SPERM WAS NOT ABLE TO TAKE CARE OF
10 THAT EGG, THE CHANCES FOR US TO GET IT TO DO SOMETHING
11 WILL BE SLIM.

12 CO-CHAIR LANSING: I'M VERY CONFUSED.

13 DR. KIESSLING: DR. CIBELLI, I THINK, IS
14 RESPONDING TO WOULD YOU USE EGGS THAT FAIL TO
15 FERTILIZE. THE ANSWER TO YOUR QUESTION IS REALLY, AND
16 THERE'S TWO ASPECTS OF THIS, AND WE THOUGHT ABOUT THIS
17 A LOT. FIRST OF ALL, OUR GOVERNMENT CONVENED TWO
18 COMMITTEES OVER THE COURSE OF THE LAST 10 OR 15 YEARS
19 TO LOOK AT THIS. SHOULD YOU ASK WOMEN WHO ARE GOING
20 THROUGH INFERTILITY PROCEDURES TO DONATE EGGS FOR
21 RESEARCH? AND THE ANSWER IS, ACCORDING TO ONE
22 COMMITTEE, ABSOLUTELY NOT, AND ACCORDING TO ANOTHER
23 COMMITTEE, YES. SO THE GOVERNMENT HAS REALLY LOOKED AT
24 THIS AND NOT COME UP WITH ANY PARTICULAR CONSENSUS, AS
25 NEAR AS I CAN TELL.

1 THE PROBLEM BECOMES ONE OF THIS WOMAN IS NOW
2 TRYING DESPERATELY TO GET HER FAMILY ORGANIZED. DO YOU
3 LOAD HER UP NOW WITH PERMISSION TO USE SOME OF THOSE,
4 QUOTE, LEFTOVER EGGS FOR STEM CELL RESEARCH? THAT'S
5 REALLY HARD. AND IT'S HARD ENOUGH TO ASK PATIENTS
6 GOING THROUGH THIS, AND DR. TAYLOR CAN SPEAK TO THIS,
7 TO TRY TO FIGURE OUT WHAT THEY WANT TO DO WITH EMBRYOS
8 THAT ARE FROZEN NOW THAT THEY ALREADY HAVE THEIR TWO OR
9 THREE. BUT TO UP FRONT BEFORE SHE GOES THROUGH THE
10 PROCEDURE ASK HER IF SHE WOULD BE WILLING TO TAKE OFF
11 TWO OR THREE EGGS TO DO RESEARCH ON AND NOT FERTILIZE
12 THEM SO THAT YOU CAN GIVE THEM TO SOMEBODY TO DO A
13 PROJECT. AND THE PROBLEM IS THERE'S A TIME CONSTRAINT
14 HERE UNTIL WE LEARN HOW TO CRYOPRESERVE THEM. SO YOU
15 CAN'T DO AN EXPERIMENT EASILY WITH TWO OR THREE EGGS.
16 YOU HAVE TO TIME THE NUMBER OF WOMEN. TO DO RESEARCH
17 YOU NEED A GROUP OF EGGS, A COHORT, SO THAT YOU CAN
18 ACTUALLY GET THE WORK DONE.

19 SO TO LOAD SOMEBODY GOING THROUGH A FERTILITY
20 PROCEDURE WITH THAT KIND OF BURDEN FOR THE RESEARCH
21 BECOMES REALLY AN ISSUE OF INFORMED CONSENT AND WHAT
22 THEY CAN REALLY UNDERSTAND ABOUT WHAT THEY'RE DOING.

23 CO-CHAIR LANSING: AGAIN, I JUST HAVE TO
24 UNDERSTAND THIS. SO THERE ARE NOT -- THERE ARE NOT
25 LEFTOVER EGGS?

1 DR. KIESSLING: THERE ARE VERY RARELY, QUOTE,
2 LEFTOVER EGGS UNLESS YOU'VE GOT A PROGRAM ORGANIZED.
3 AND THERE ARE SOME OF THESE IN ENGLAND, AND THERE ARE
4 PROGRAMS IN ENGLAND THAT HAVE ALWAYS ASKED PATIENTS TO
5 DONATE TWO OR THREE EGGS TO RESEARCH. THE CONCEPT OF
6 LEFTOVER EGGS IS ONLY IF FOR RELIGIOUS REASONS SOMEBODY
7 WILL NOT CRYOPRESERVE EMBRYOS, DOESN'T WANT TO RISK
8 DESTROYING AN EMBRYO, THEN ONLY A LIMITED OF NUMBER OF
9 EGGS ARE FERTILIZED.

10 MR. SHESTACK: SHE'S NOT ASKING ABOUT -- I
11 BELIEVE YOU ARE NOT ASKING ABOUT FERTILIZED EGGS ON A
12 PROSPECTIVE BASIS.

13 DR. KIESSLING: NO. SHE'S ASKING ABOUT
14 LEFTOVER EGGS.

15 MR. SHESTACK: THE DONATION AS OPPOSED TO
16 USEFUL EGGS.

17 MS. CHARO: BASICALLY SOMEBODY PRODUCES 17
18 EGGS. ORDINARILY THERE'S NOTHING LEFT OVER BECAUSE
19 EVERY ONE OF THEM IS POTENTIALLY USEFUL FOR FERTILITY
20 TREATMENT. SO THERE'S NO SUCH THING AS A LEFTOVER EGG
21 UNLESS SHE VOLUNTARILY FOR OTHER REASONS DECIDES NOT TO
22 TRY TO FERTILIZE THEM ALL.

23 DR. ROWLEY: THAT ISN'T SO. SHERMAN ELIAS
24 SAYS HE HAS FREEZERS FULL OF LEFTOVER OOCYTES. AND THE
25 POINT THAT KEVIN MADE WAS THAT, AND DR. CIBELLI, IS

1 THAT YOU WANT TO START WITH THE BEST POSSIBLE SOURCE OF
2 MATERIAL. AND WE HAVE NO EXPERIENCE AS FAR AS I'M
3 AWARE OF USING FROZEN OOCYTES TO TRY TO THEN DO SCNT.

4 DR. KIESSLING: FROZEN OOCYTES ARE ACTUALLY
5 NOT THAT COMMON. THERE ARE SOME PROGRAMS THAT ARE
6 PRETTY GOOD AT IT, AND HOPEFULLY THAT WILL GET BETTER.

7 DR. ROWLEY: WELL, HE HAS SEVERAL THOUSAND.

8 MS. CHARO: AREN'T THOSE FAILED TO FERTILIZE
9 EGGS? THE EGG WAS EXPOSED TO SEMEN?

10 DR. ROWLEY: ACCORDING TO SHERMAN, THESE ARE
11 NEVER EXPOSED TO SEMEN.

12 CO-CHAIR LANSING: I READ SOMETHING LIKE
13 THAT. THAT'S WHY I WAS SO CONFUSED. WHAT MY QUESTION
14 IS FOR THE GROUP IS IS THIS NOT A VERY GOOD SOURCE FOR
15 US TO ACCESS. AND I DON'T KNOW THE ANSWER, BUT THAT
16 WAS MY QUESTION.

17 CO-CHAIR RABB: CAN WE MOVE ON ON THE LIST
18 AND WE'LL COME BACK TO PEOPLE WHO HAVE ALREADY SPOKEN.

19 DR. EGGAN: I WANT TO COMMENT ON A COUPLE OF
20 THESE THINGS. FIRST OF ALL, I DEFER TO ANN ON THIS,
21 BUT MY UNDERSTANDING IS THAT OOCYTE FREEZING IS STILL A
22 DIFFICULT PROCEDURE, ONE THAT IS NOT WELL ESTABLISHED
23 AT MANY IVF CLINICS. IT IS TRUE THAT OPTIMIZING OOCYTE
24 FREEZING AND DEVELOPING THAT TECHNOLOGY IS INDEED A
25 VERY DESIRABLE THING TO DO. AND IT WOULD ALLEVIATE

1 MANY OF THE CONSTRAINTS THAT ARE PLACED ON THIS
2 RESEARCH AND ON, INDEED, WOMEN'S REPRODUCTIVE HEALTH IN
3 GENERAL.

4 AND SO I WOULD ARGUE THAT IS SOMETHING THAT
5 THIS IS INSTITUTE SHOULD STRONGLY CONSIDER SUPPORTING
6 DIRECTLY.

7 NOW, THAT BEING SAID, AS TO THE DEMAND FOR
8 OOCYTES AND OTHER ALTERNATIVES, I THINK IT IS SOMETHING
9 THAT SCIENTISTS SHOULD AND INDEED NEED TO CONSIDER AND
10 SOMETHING MY LAB IS CONSIDERING. FOR THE MOMENT WE
11 HAVE TO OPERATE UNDER THE ASSUMPTION THAT THOSE
12 POSSIBILITIES AS ALTERNATIVES MAY NOT COME. AND SO WE
13 NEED TO CONSIDER HOW TO MOVE FORWARD WITHIN THE
14 FUNCTIONAL FRAMEWORK THAT WE KNOW TO EXIST; NAMELY,
15 DERIVATION OF EMBRYONIC STEM CELL LINES FROM STARTED
16 EMBRYOS AND BY NUCLEAR TRANSPLANTATION BY THE METHODS
17 THAT HAVE BEEN ESTABLISHED BY THE SOUTH KOREANS NOW.

18 AS TO REIMBURSEMENT COMPENSATION, I THINK
19 THAT CLEARLY THERE CAN BE NO COMPENSATION BASED ON THE
20 PROPOSITION 71, BUT THAT REIMBURSEMENT FOR EXPENSES, AS
21 I SEE IT, READS HERE DIRECTLY IN THE LANGUAGE, IT CAN
22 BE BROADLY INTERPRETED. AND THERE'S SOME FLEXIBILITY
23 THERE, AND THAT'S SOMETHING THAT WE SHOULD DISCUSS. I
24 THINK IT'S IMPORTANT TO SAY, ALTHOUGH I AGREE WITH ANN,
25 THAT PRIMARILY THAT WOMEN CHOOSE TO DONATE BECAUSE THEY

1 BELIEVE IN THE RESEARCH AND WANT TO HELP, THAT I
2 BELIEVE THERE'S BEEN SOME QUESTION IN THE PRESS, AT
3 LEAST FROM THE U.K., AS TO THE AVAILABILITY OF OOCYTE
4 DONORS IN AN ENVIRONMENT WHERE THERE IS NO
5 COMPENSATION, WHICH IS ESSENTIALLY WHAT EXISTS NOW IN
6 THE UNITED KINGDOM VERSUS REPRODUCTION AND IS WHAT WE
7 ARE PROPOSING HERE FOR RESEARCH.

8 SO I THINK IT IS STILL A VERY OPEN QUESTION
9 AS TO WHETHER OR NOT WOMEN WILL DONATE WITHOUT
10 COMPENSATION, AND THAT'S SOMETHING THAT WE NEED TO
11 CONSIDER. AND I WOULD HESITATE TO -- I THINK IT'S
12 INDEED IMPORTANT THAT IF WE'RE DEDICATED TO MOVING THIS
13 RESEARCH FORWARD, THAT WE LEAVE SOME FLEXIBILITY AS TO
14 WHAT WE'RE GOING TO DEFINE AS REIMBURSEMENT OPEN SO
15 THAT THAT CAN BE EXPANDED IF, INDEED, NO ONE WILL
16 PRESENT THEMSELVES.

17 LASTLY, I AGREE STRONGLY WITH ANN, THAT
18 FAILED TO FERTILIZE EMBRYOS ARE INDEED A TROUBLING
19 SOURCE OF MATERIAL, BOTH WITH RESPECT TO THE ULTIMATE
20 SUCCESS OF THE RESEARCH AND TO PUTTING THE CLINICIAN
21 AND THE PATIENT WHO'S UNDERGOING ASSISTED REPRODUCTION
22 IN A DIFFICULT SITUATION, ONE THAT WOULD BE
23 UNDESIRABLE, I BELIEVE.

24 CO-CHAIR RABB: CAN I ASK YOU. YOU SAID
25 FAILED TO FERTILIZE EMBRYOS. DID YOU MISSPEAK?

1 DR. EGGAN: FAILED TO FERTILIZE OOCYTES.
2 YES.

3 DR. LO: FIRST I WANT TO THANK OUR SCIENTIFIC
4 COLLEAGUES FOR HELPING TO START TO UNDERSTAND THE
5 TECHNICAL BACKGROUND, WHICH I THINK IS CRUCIAL. I HAVE
6 SOME QUESTIONS FOR ROB TAYLOR ABOUT THE RISKS OF OOCYTE
7 DONATION, BUT I WANTED TO TRY AND ADDRESS SHERRY'S
8 QUESTION BECAUSE THIS COMES UP A LOT IN PUBLIC
9 DISCUSSION. WHY DO WE USE SORT OF OOCYTES THAT AREN'T
10 NEEDED.

11 AND THE PROBLEM IS YOU ONLY -- FOR THE
12 OOCYTES THAT ARE FRESH OOCYTES THAT AREN'T PROBLEMATIC
13 IN TERMS OF BEING EXPOSED TO SPERM, AND YOU ONLY KNOW
14 AFTER THE FACT, AFTER THE WOMAN HAS COMPLETED HER
15 FAMILY, THAT SHE MIGHT NOT HAVE NEEDED THEM. SO
16 STATISTICALLY IF YOU RETRIEVE 12, 15 OOCYTES, YOU WOULD
17 SAY STATISTICALLY YOU'RE NOT GOING TO NEED ALL THOSE
18 FOR YOUR FAMILY. BUT WITH ANY INDIVIDUAL IVF PATIENT,
19 YOU DON'T KNOW THAT TILL SHE'S FINISHED. AND SO YOU'RE
20 ASKING A WOMAN TO MAKE A TERRIBLE CHOICE IN TERMS OF
21 PUTTING IN SECOND PLACE HER PRIMARY DESIRE TO HAVE AS
22 MANY CHILDREN AS SHE WANTS WHEN SHE MAY LATER ON REGRET
23 HAVING GIVEN AWAY TWO OR THREE OOCYTES.

24 CO-CHAIR LANSING: I REALLY READ THIS IN THE
25 PRESS, AND IT GOES TO WANT JANET SAID, THAT THERE WAS A

1 LOT OF THESE AROUND, FOR WANT OF A BETTER WORD.

2 DR. LO: A LOT OF THESE BEING?

3 CO-CHAIR LANSING: EGGS THAT --

4 MR. SHESTACK: FERTILIZED EMBRYOS FROM WOMEN
5 WHO HAVE ALREADY HAD --

6 DR. LO: OOCYTES THAT THEY CHOOSE NOT TO
7 EXPOSE THEM TO SPERM BECAUSE YOU WANT TO BE ABLE TO USE
8 THEM POTENTIALLY FOR RESEARCH. NOW --

9 CO-CHAIR LANSING: IN BANKS.

10 DR. LO: PROFESSOR ROWLEY SAYS THAT THERE'S
11 ONE OB-GYN WHO SAYS, YES, IN HIS STANCE, HE CAN DO
12 THAT; BUT WHETHER OR NOT THAT'S POSSIBLE ON THE
13 WIDESPREAD BASIS, HOW EFFECTIVE THOSE OOCYTES ARE WHEN
14 THEY'RE UNTHAWED. IT'S NOT LIKE FROZEN SPERM BECAUSE,
15 MY UNDERSTANDING IS THE INTRACELLULAR WATER CONTENT IS
16 HIGH. IT'S ACTUALLY A TECHNICAL PROBLEM TO FREEZE AND
17 UNFREEZE OOCYTES.

18 I THINK THAT AT THIS POINT IT'S A POSSIBLE
19 TECHNIQUE, BUT I DON'T THINK WE COULD SAY THAT --

20 DR. EGGAN: WE NEED TO CLARIFY THAT. AS I
21 UNDERSTAND, THERE ARE NO WELL-ESTABLISHED,
22 WELL-DISTRIBUTED METHODS TO CREATE THE UNFERTILIZED EGG
23 WHICH IS WHAT ONE NEEDS FOR NUCLEAR TRANSPLANTATION.
24 SO ALTHOUGH SOME SMALL NUMBER MAY HAVE LIMITED SUCCESS
25 WITH THIS, AND THE ONE DR. ROWLEY IS REFERRING TO, IT

1 IS NOT ESTABLISHED, AND IT WOULD BE DESIRABLE TO HAVE
2 ESTABLISHED.

3 IN CONTRAST, ONCE THE EMBRYO IS FERTILIZED,
4 ONCE THE OOCYTE IS FERTILIZED AND BECOMES AN EMBRYO,
5 THERE ARE ULTRASTRUCTURAL CHANGES WHICH OCCUR TO THOSE
6 CELLS WHICH NOW ALLOW IT TO BE FROZEN. SO THERE ARE
7 MANY TENS OF THOUSANDS, IF NOT MORE, FROZEN EMBRYOS
8 THAT ARE BEING HELD FOR WOMEN'S REPRODUCTION WHICH ARE,
9 AGAIN, A SOURCE OF STEM CELL LINES THAT ARE BEING USED.
10 THOSE CANNOT BE USED FOR NUCLEAR TRANSPLANTATION, THOSE
11 FROZEN EMBRYOS. ONLY OOCYTES WHICH HAVE BEEN
12 UNFERTILIZED WOULD BE USABLE FOR NUCLEAR
13 TRANSPLANTATION.

14 DR. ROWLEY: I JUST WANT TO CLARIFY THAT MY
15 QUOTING SHERMAN, AND ONE SHOULD CERTAINLY GO BACK AND
16 MAKE SURE THAT MY RECOLLECTIONS ARE ACCURATE, THESE ARE
17 UNFERTILIZED OOCYTES THAT ARE FROZEN. SO THEY MAY WE
18 WELL TOTALLY INCAPABLE OF BEING THAWED AND THEN THE
19 NUCLEUS EXTRUDED AND REPLACED WITH A DONOR NUCLEUS.
20 AND SINCE TO MY KNOWLEDGE NONE OF THAT HAS BEEN DONE,
21 IT'S AN UNANSWERED QUESTION.

22 CO-CHAIR LANSING: I UNDERSTAND.

23 DR. LO: CAN I ASK ROB TAYLOR THIS QUESTION.
24 I THINK I WOULD AGREE WITH DR. EGGAN, BUT AT THE
25 CURRENT TIME WE HAVE TO SAY THAT IF WE'RE GOING TO

1 PROCEED WITH SOMATIC CELL NUCLEAR TRANSFER FOR RESEARCH
2 PURPOSES, THE MOST FEASIBLE SOURCE OF BIOLOGICAL
3 MATERIALS ARE FRESH OOCYTES DONATED FOR THE PURPOSES OF
4 RESEARCH. AND OBVIOUSLY THERE'S BEEN CONCERNS RAISED
5 IN CALIFORNIA. SENATOR ORTIZ, FOR EXAMPLE, RAISED
6 CONCERNS ABOUT THE SAFETY OF THAT PROCEDURE.

7 SO I WANTED TO ASK ROB TAYLOR AND THE OTHERS
8 ON THE COMMITTEE WITH THE SCIENTIFIC BACKGROUND A
9 COUPLE OF QUESTIONS AND TRY AND QUANTIFY. FIRST, IN
10 TERMS OF SHORT-TERM RISKS, IS THE RISK OF SEVERE
11 HYPEROVULATION SYNDROME RELATED TO THE DOSAGE OF
12 HORMONAL MANIPULATION? SO THE CONCERN, I THINK, IS
13 THAT IN AN EFFORT TO KIND OF RETRIEVE AS MANY OOCYTES
14 AS POSSIBLE FOR THE PURPOSE OF, I GUESS, RESEARCH OR
15 FERTILITY TREATMENT, THE TREATING PHYSICIAN WILL
16 MANIPULATE THE HORMONAL CYCLE IN A WAY THAT MAXIMIZES
17 THE YIELD. DOES THAT MAXIMIZATION ACTUALLY INCREASE
18 THE RISK, WHICH YOU QUOTE AS 1 PERCENT, OR SOMETHING
19 HIGHER? SO THAT'S MY FIRST QUESTION.

20 THE SECOND QUESTION IS THE LONG-TERM SIDE
21 EFFECTS, AND THAT'S ALSO BEEN RAISED IN THE POPULAR
22 PRESS. AND YOU MENTION A POSSIBILITY OF OOCYTE
23 DEPLETION, WHICH POTENTIALLY, I SUPPOSE, COULD LEAD TO
24 INFERTILITY IN THE YOUNG WOMAN WHO'S DONATING. THERE
25 HAVE ALSO BEEN CONCERNS RAISED IN THE POPULAR PRESS

1 ABOUT POSSIBILITY OF OVARIAN CANCER OR OTHER CANCERS
2 DUE TO THIS HORMONAL MANIPULATION. WHAT IS THE
3 EVIDENCE AT THIS POINT OF ANY ASSOCIATION BETWEEN
4 OOCYTE DONATION, HORMONAL MANIPULATION, AND LONG-TERM
5 CANCER?

6 DR. TAYLOR: I'M VERY PLEASED TO ANSWER YOUR
7 FIRST QUESTION. THE SECOND ONE I'M NOT SO HAPPY ABOUT,
8 BUT THANKS, BERNIE. IN TERMS OF THE FIRST QUESTION,
9 ACTUALLY I THINK FOR ANY PRACTICING CLINICIAN DOING
10 REPRODUCTIVE MEDICINE, FRANKLY, THE BEST PATIENT
11 POPULATION TO AVOID OVARIAN HYPERSTIMULATION SYNDROME
12 WOULD BE AN EGG DONOR IN WHICH YOU WERE REALLY TRYING
13 TO GENERATE A CERTAIN NUMBER OF EGGS FOR RESEARCH
14 PURPOSES. I THINK YOU'RE RIGHT. IT'S NOT A CLEAR
15 LINEAR DOSE RESPONSE EFFECT, BUT THE MORE HORMONAL
16 STIMULATION, TYPICALLY THE HIGHER THE ESTRADIOL LEVEL,
17 ESTRADIOL AS WELL AS OTHER PROBABLY LOCAL OVARIAN
18 FACTORS, ACTIVATE THE VEG-F GENE PROMOTER. IT'S PRETTY
19 WELL DEFINED. THERE ARE ESTROGEN RESPONSIVE ELEMENTS
20 ON THAT GENE. WE KNOW SORT OF HOW THAT GENE GETS
21 TURNED ON. AND THE MORE TURNED ON IT IS, THE GREATER
22 THE RISK OF VASCULAR PERMEABILITY IN THE SEVERE OHSS
23 SYNDROME.

24 SO, AGAIN, IN A GROUP OF WOMEN WHO AREN'T
25 GOING TO BECOME PREGNANT AND IN WHOM YOU'RE NOT REALLY

1 PUSHING THE OVARY SO HARD TO GET LOTS OF EMBRYOS FOR
2 FERTILITY PURPOSES, I THINK YOU WOULD BE IN A POSITION
3 TO BE ABLE TO BACK OFF QUITE A BIT AND COME UP WITH
4 PROTOCOLS, CLINICAL PROTOCOLS, THAT WOULD REALLY LIMIT
5 THE RISK OF THAT PARTICULAR COMPLICATION. AND SOME OF
6 THE OTHER THINGS, WHETHER IN TORSION OR TWISTING OF THE
7 OVARY AND BLEEDING, WHICH PROBABLY IS RELATED TO THE
8 NUMBER OF PUNCTURES IN THE OVARY, AGAIN, YOU CAN LIMIT
9 ALL OF THOSE BY REDUCING THE NUMBER OF OOCYTES AND
10 FOLLICLES THAT YOU STIMULATE AND THE AMOUNT OF TRAUMA
11 THAT THE OVARY RECEIVES. SO I THINK THAT THOSE RISKS
12 COULD EASILY BE MITIGATED, MORE EASILY MITIGATED IN
13 WOMEN UNDERGOING STIMULATION FOR EGG DONATION FOR
14 RESEARCH PURPOSES. AND, FRANKLY, WE CAN DO IN COUPLES
15 THAT ARE REALLY PUTTING EVERYTHING THEY'VE GOT INTO,
16 YOU KNOW, THEIR SAVINGS SO THAT THEY CAN ACTUALLY HAVE
17 A CHILD THAT THEY'VE BEEN UNABLE TO HAVE THROUGH MORE
18 NATURAL MEANS. SO I THINK THAT THAT SEEMS LIKE QUITE A
19 SOLUBLE PROBLEM.

20 THE QUESTIONS ABOUT -- I GUESS I WOULD LIKE
21 TO MAKE ONE COMMENT ABOUT THE COMPENSATION ISSUE THAT'S
22 BEEN RAISED. I THINK THAT WE MAY HAVE TROUBLE GOING
23 FORWARD AND BEING VERY SUCCESSFUL GETTING IRB APPROVAL,
24 INSTITUTIONAL REVIEW BOARD APPROVAL, TO ALLOW WOMEN TO
25 UNDERGO EGG DONATION WITHOUT SOME FORM OF COMPENSATION.

1 I THINK THAT AT LEAST IN THE ACADEMIC INSTITUTIONS IN
2 WHICH I'VE OPERATED, IT WOULD BE DIFFICULT TO CONVINCING
3 OUR REVIEW BOARDS THAT NO TYPE OF COMPENSATION WOULD
4 OFFSET THE RISKS THAT THOSE WOMEN MIGHT BE TAKING.

5 SO I THINK THAT IF WE MAKE OUR REGULATIONS
6 TOO STRICT IN THAT REGARD, WE MIGHT REALLY LIMIT THE
7 NUMBER OF WOMEN WHO WANT TO VOLUNTEER, BUT MAY NOT
8 ACTUALLY BE ALLOWED TO DO SO BECAUSE OF THE
9 INSTITUTIONAL REVIEW BOARD.

10 IN TERMS OF THE LONGER-TERM RISKS THAT BERNIE
11 BROUGHT UP, AGAIN, THESE ARE REALLY VERY THEORETICAL.
12 WOMEN ARE BORN WITH PROBABLY 400,000 EGGS OF WHICH THEY
13 WILL OVULATE 400 IN A LIFETIME. SO THERE ARE LOTS OF
14 EXTRA EGGS. IT'S UNLIKELY THAT WE'RE DEPLETING A
15 NUMBER OF THOSE, BUT THERE'S BEEN SOME RECENT
16 LITERATURE, AT LEAST IN ANIMAL MODELS, THAT EGGS MIGHT,
17 IN FACT, BE REPLICATING WITHIN THE OVARY EVEN AFTER
18 BIRTH, SOMETHING THAT WE DIDN'T BELIEVE SEVERAL YEARS
19 AGO. AND THAT MAYBE SOME OF THE HORMONAL MEDICATIONS
20 THAT WE USE TO CONTROL THE NUMBER OF EGGS IN THE
21 COORDINATION OR SYNCHRONIZATION OF EGG GROWTH IN WOMEN
22 WHO ARE BEING HYPERSTIMULATED MIGHT, IN FACT, HAVE
23 EFFECTS, PARTICULARLY GENE ANTAGONISTS. THERE'S A
24 RECENT PAPER THAT SUGGESTS, AT LEAST IN A MOUSE MODEL,
25 THAT THOSE DRUGS MIGHT ACTUALLY REDUCE THE TOTAL NUMBER

1 OF EGGS IN THE OVARY.

2 SO I THINK THAT THERE ARE SOME REASONS EITHER
3 THROUGH TRAUMA OR THROUGH SOME HORMONAL MEDICATIONS WE
4 THINK ABOUT USING THAT WE MIGHT, IN FACT, HAVE EFFECTS
5 ON THE LONG-TERM NUMBER OF EGGS WITHIN THE OVARY.
6 WHETHER THAT WILL BRING ON EARLY MENOPAUSE OR
7 INFERTILITY DOWN THE ROAD, THERE'S NO EVIDENCE OF THAT.
8 IT'S A THEORETICAL QUESTION.

9 AND FINALLY, THE QUESTION ABOUT OVARIAN
10 CANCER, THERE IS A CLEAR ASSOCIATION BETWEEN LONG-TERM
11 INFERTILITY AND AN INCREASED RISK OF OVARIAN CANCER.
12 AND BECAUSE WOMEN WITH LONG-TERM INFERTILITY HAVE
13 RECEIVED A LOT OF INFERTILITY DRUGS AND OVULATION
14 STIMULATED DRUGS THAT ASSOCIATION HAS BEEN COUPLED, BUT
15 THERE'S NOT REALLY A VERY STRONG EPIDEMIOLOGIC OR LAB
16 CHEMICAL MECHANISTIC EVIDENCE TO SUPPORT THAT
17 ASSOCIATION. SO I THINK THE JURY IS STILL OUT A LITTLE
18 BIT. THERE'S SOME DATA ON EITHER SIDE THAT SUGGESTS
19 THAT THE RISK MAY BE SLIGHTLY INCREASED, BUT, AGAIN,
20 THESE ARE PROBABLY WOMEN WHO HAVE RECEIVED MULTIPLE
21 EPISODES OF OVARIAN STIMULATION. I THINK IN THIS
22 SETTING, IT'S REALLY NOT A SERIOUS CONCERN.

23 CO-CHAIR RABB: HERE'S WHAT I WOULD LIKE TO
24 DO. JANET HAS ASKED TO RESPOND TO ROBERT. FRANCISCO
25 IS OUR LAST SPEAKER ON MY LIST. I THINK WHAT WE OUGHT

1 TO DO IS HEAR FROM BOTH OF THEM, TAKE A BREAK FOR
2 LUNCH. WE'RE TORN BETWEEN WANTING TO HAVE A LONG LUNCH
3 BECAUSE EVERYBODY IS HERE PROVIDED FOR, BUT YOU ALL ARE
4 NOT. YOU ALL IN THE PUBLIC ARE NOT. ON THE OTHER
5 HAND, EVEN THOUGH IT MIGHT BE MORE CONVENIENT TO YOU TO
6 TAKE A LONG LUNCH BREAK, WE HOPE YOU'LL COME BACK
7 QUICKLY SO THAT WE CAN GET STARTED AGAIN. AND HOPE
8 THAT LET'S SAY 30 MINUTES IN THE HOPE THAT WE CAN GET
9 GOING BY FORTY. BRING FOOD BACK IF YOU CAN SO THAT WE
10 HAVE MORE TIME TO KEEP GOING.

11 JANET AND THEN FRANCISCO, AND THEN WE'LL TAKE
12 A BREAK. AND AT WHATEVER TIME WE TAKE THE BREAK, AFTER
13 30 MINUTES, LET'S TRY AND COME BACK.

14 DR. ROWLEY: I WANT TO MAKE TWO POINTS. ONE
15 IS TO FOLLOW UP ON WHAT JOSE ALLUDED TO IN PASSING,
16 THAT THE KOREANS HAVE REALLY SPENT A GREAT DEAL OF TIME
17 AND EFFORT, OBVIOUSLY UNDER THE LEADERSHIP OF
18 DR. WHANG, IN DEVELOPING THE TECHNOLOGY OF OOCYTE
19 RETRIEVAL, REMOVAL OF THE NUCLEUS, REPLACEMENT WITH THE
20 DONOR NUCLEUS IN WAYS THAT NOBODY ELSE CAN MATCH. AT
21 LEAST THAT'S MY UNDERSTANDING.

22 AND I THINK THE ONE THING THAT CALIFORNIA CAN
23 DO IS TO TRY TO EITHER, THROUGH LOTS OF TRAINING OR
24 COLLABORATION, REALLY DEVELOP THESE KINDS OF SKILLS IN
25 AMERICA. WE'RE PAYING A HIGH PRICE FOR OUR

1 INEFFICIENCY.

2 THE SECOND POINT, THE AMERICAN SOCIETY FOR
3 REPRODUCTIVE MEDICINE, JUNE 30, 2005, AND I DON'T KNOW
4 WHERE THIS IS PUBLISHED, BUT THEY SENT IT TO ME, HAS A
5 TWO-PAGE DOCUMENT ON COMPLICATIONS OF OVARIAN
6 HYPERSTIMULATION. AND AMONGST THE LONG-TERM
7 COMPLICATIONS THEY DISCUSS IS CANCER. AND THERE IS ONE
8 REPORT BY A DR. BRINTON THAT INDICATED THERE MIGHT BE
9 AN INCREASE IN BREAST AND GYNECOLOGIC TUMORS, BUT
10 THAT'S BEEN CRITICIZED BECAUSE HE HAD VERY FEW
11 SUBJECTS. SO VEN ET AL., WHICH IS PUBLISHED IN THE
12 LANCET 1999, CONCLUDED FROM A RETROSPECTIVE ANALYSIS OF
13 A COHORT OF 29,700 SUBJECTS THAT WOMEN EXPOSED TO
14 FERTILITY DRUGS HAD A TRANSIENT, BUT NOT AN OVERALL
15 INCREASE IN BREAST OR UTERINE CANCER.

16 SO THEY COME TO THE CONCLUSION THAT, WHILE
17 THERE IS NEED FOR FURTHER MONITORING, IT DOES NOT
18 APPEAR AT THE PRESENT TIME THAT OVARIAN, BREAST, AND
19 ENDOMETRIAL CANCER ARE INCREASED AS A CONSEQUENCE OF
20 OVARIAN HYPERSTIMULATION.

21 DR. PRIETO: I HAVE QUESTIONS FOR DR. TAYLOR,
22 DR. KIESSLING, I THINK, AND ALSO MAYBE ONE MORE GENERAL
23 QUESTION. ONE WAS WHETHER OVARIAN HYPERSTIMULATION
24 SYNDROME EVER OCCURS IN THE ABSENCE OF PREGNANCY? I
25 DON'T KNOW THE ANSWER TO THAT.

1 I HAD ANOTHER QUESTION ABOUT OVARIAN CANCER
2 WHICH I THINK HAS BEEN ADDRESSED ALREADY. AND THE
3 OTHER MORE GENERAL ONE REGARDING COMPENSATION OR
4 REIMBURSEMENT, MAYBE THAT'S A SEMANTIC DISCUSSION, BUT
5 I WONDER WHETHER IT ISN'T UNREASONABLE TO EXPECT
6 INSTITUTIONS TO INCLUDE AS PART OF REIMBURSEMENT
7 MEDICAL TREATMENT FOR ANY AND ALL COMPLICATIONS OF THE
8 MEDICAL PROCEDURES THAT WE UNDERTAKE INVOLVED IN OOCYTE
9 DONATION.

10 DR. EGGAN: I CAN COMMENT DIRECTLY ON THAT AS
11 WE'RE IN THE PROCESS OF DESIGNING STUDIES TO REPLICATE
12 THE WORK AT HARVARD UNIVERSITY AND IN LONG DISCUSSIONS
13 WITH OUR OWN ESL OVERSIGHT COMMITTEE, AS WELL AS OUR
14 IRB, AND IT'S CLEAR THAT SORT OF INSURANCE IS GOING TO
15 BE A CRITICAL COMPONENT IN THIS, THAT ALL OOCYTE
16 DONORS, INDEED, IN MY OPINION, AND OUR IRB'S OPINION,
17 SHOULD BE INSURED AND COVERED FOR THE COURSE OF THEIR
18 PARTICIPATION IN SUPEROVULATION AND OOCYTE DONATION AND
19 RETRIEVAL.

20 DR. PRIETO: SO THAT IS BECOMING THE
21 STANDARD, BUT DOES IT INCLUDE TREATMENT ON INTO THE
22 FUTURE SHOULD COMPLICATIONS ARISE?

23 DR. EGGAN: THIS WOULD -- NO, NOT IN THE LONG
24 TERM. IN THE SHORT TERM, YES. SO CERTAINLY FOR THE
25 NEXT TWO WEEKS OR WHATEVER THE STANDARD AMOUNT IS WHERE

1 WE CAN ALLEVIATE THE CONCERNS ABOUT OVARIAN
2 HYPERSTIMULATION SYNDROME, YEAH. THESE MORE UNCERTAIN
3 CONCERNS ABOUT LONG-TERMS EFFECTS AT THE MOMENT, NO.

4 DR. PRIETO: I WONDER WHETHER WE SHOULDN'T --
5 PERHAPS IT WILL COME UP AT THE ICOC ALSO, BUT IF WE ARE
6 NOT ABLE TO PROVIDE COMPENSATION DIRECTLY AS
7 COMPENSATION, WHETHER ENHANCED REIMBURSEMENT, IF YOU
8 WILL, IS ANOTHER MECHANISM FOR MAKING SURE THAT WOMEN
9 WHO DO DONATE DON'T PUT THEMSELVES AT ANY RISK OR ANY
10 FUTURE JEOPARDY, PARTICULARLY CONSIDERING THE STATUS OF
11 HEALTH INSURANCE IN OUR COUNTRY TODAY.

12 CO-CHAIR RABB: I THINK THAT IS A REALLY
13 INTERESTING, BUT VERY BIG CONVERSATION. AND I THINK WE
14 OUGHT TO HOLD ONTO THAT. I THINK IT'S GOING TO COME
15 BACK IN OTHER WAYS AS WE GO THROUGH THESE GUIDELINES.

16 CO-CHAIR LANSING: I KNOW WE'RE GOING TO
17 BREAK FOR LUNCH. BUT CAN I JUST ASK JAMES IF HE CAN
18 TELL US BECAUSE WE'RE OPERATING WITH A LAW THAT WE
19 PASSED, AND AS I UNDERSTOOD IT, WE WERE NOT ABLE TO
20 COMPENSATE DONORS. AND I JUST WANT TO KNOW, AND YOU
21 DON'T HAVE TO ANSWER IT RIGHT NOW, BUT IF YOU COULD
22 TELL US WHAT LEEWAY WE HAVE, IF ANY.

23 MR. HARRISON: LET ME JUST READ TO YOU THE
24 PRECISE LANGUAGE SO EVERYONE HAS IT IN MIND. THE ICOC
25 IS REQUIRED TO ADOPT STANDARDS, INCLUDING STANDARDS

1 PROHIBITING COMPENSATION TO RESEARCH DONORS OR
2 PARTICIPANTS WHILE PERMITTING REIMBURSEMENT OF
3 EXPENSES. SO I THINK THE AREA WHERE YOU HAVE SOME
4 LATITUDE IN TERMS OF DEFINING WHAT'S COVERED IS
5 REIMBURSEMENT OF EXPENSES AND WHAT EXPENSES ENTAILS.

6 CO-CHAIR RABB: I HAVE 1:15 ON MY CLOCK,
7 WHATEVER YOU'VE GOT ON YOURS, 30 MINUTES FROM NOW
8 PLEASE RECONVENE. THE MEMBERS OF THE WORKING GROUP
9 ARE, FOR CONVENIENCE SAKE, ASKED TO GO BACK TO WHERE WE
10 MET THIS MORNING DOWN THE HALL. LET'S DO THAT AND BE
11 BACK IN HALF HOUR.

12 (A RECESS WAS TAKEN.)

13 CO-CHAIR RABB: CAN WE CONVENE AGAIN PLEASE
14 AND GET STARTED. HERE'S WHAT WE PROPOSE TO DO AT THIS
15 POINT. ANN CAN GIVE US WHAT IS ABOUT SOMETHING JUST
16 UNDER A TEN-MINUTE POWERPOINT PRESENTATION ABOUT THE
17 WAY THAT THEY'VE ENJOYED A PROCESS AT THE CLINIC SHE'S
18 ASSOCIATED WITH. AT THE END OF THAT, I THINK WE ARE
19 GOING TO MOVE AWAY FROM THE QUESTION OF OOCYTE DONATION
20 UNLESS THERE'S DIRECT FOLLOW-UP FROM THE WORKING GROUP
21 FOR ANN. ANN HAS OFFERED TO MAKE THE TRANSPARENCIES
22 AVAILABLE AS AN EXHIBIT SO THE TRANSCRIBER DOESN'T HAVE
23 TO TRY TO DESCRIBE THE PICTURES THAT WE'RE GOING TO
24 SEE, AND SO THAT WOULD BE AVAILABLE TO ALL OF US FOR
25 THE TRANSCRIPT.

1 DR. KIESSLING: CAN I E-MAIL THESE TO YOU?

2 CO-CHAIR RABB: ANN, THANK YOU FOR DOING THIS
3 ON I WOULD SAY SHORT NOTICE, BUT IT WAS NO NOTICE.

4 DR. KIESSLING: I WANT TO JUST MAKE SURE THAT
5 EVERYBODY IN THIS ROOM UNDERSTANDS WHAT IT'S LIKE TO GO
6 THROUGH AN EGG DONATION. I WANT TO GO QUICKLY THROUGH
7 THE PROGRAM THAT WE SET UP. AND THIS IS A VERY SMALL,
8 PRIVATE FOUNDATION IN MASSACHUSETTS WHICH IS HANDLING
9 THIS. AND AS I MENTIONED TO A NUMBER OF PEOPLE IN THIS
10 ROOM, WE'VE DONE IT FOR SEVERAL YEARS TRYING TO STAY
11 BELOW THE RADAR SCREEN SO THAT WE CAN KEEP THE WORK
12 GOING FORWARD WITHOUT CALLING A LOT OF ATTENTION TO IT.

13 WE STARTED THIS AND WHEN -- BY WAY OF
14 INTRODUCTION, IT'S IMPORTANT, I THINK, TO UNDERSTAND
15 THAT I STARTED THE FIRST IVF LAB IN OREGON IN THE
16 EARLY '80S, SO I'VE BEEN ASSOCIATED WITH ASSISTED
17 REPRODUCTION FOR MOST OF MY LIFE AND GOT OUT OF IT SOME
18 YEARS AGO TO FOCUS MORE ON ACADEMICS AND RESEARCH THAN
19 THE CLINICAL PART. BECAUSE OF THAT HAD RUN A SEMINAR
20 PROGRAM IN BOSTON FOR MANY YEARS CALLED EGG GROUP. AND
21 ONE OF THE PARTICIPANTS IN EGG GROUP FROM TIME TO TIME,
22 IT WAS DESIGNED FOR STUDENTS ALL THROUGH THE BOSTON
23 AREA, WAS JOSE CIBELLI. SO WHEN JOSE GOT TO THE POINT
24 IN HIS CAREER WHEN IT WAS TIME TO TRY TO FIGURE OUT HOW
25 TO ORGANIZE A HUMAN EGG DONOR PROGRAM, HE CAME AND WE

1 TALKED ABOUT IT. AND I THINK HIS THESIS ADVISOR
2 APPROACHED ME FIRST. SO THIS ACTUALLY -- THIS
3 DISCUSSION STARTED IN THE LATE ABOUT '99 OR 2000.

4 THE VERY FIRST THING WE REALIZED WE HAD TO DO
5 WAS PULL TOGETHER AN ETHICS ADVISORY BOARD, AND WE WERE
6 VERY LUCKY AND WE WERE ABLE TO GET SOMEBODY NAMED RON
7 GREEN, WHO WAS CHAIRMAN OF RELIGIOUS STUDIES AT
8 DARTMOUTH COLLEGE, TO CHAIR THIS BOARD FOR US. RON WAS
9 WONDERFUL. HE WAS ON THE PRESIDENT'S EMBRYO RESEARCH
10 PANEL IN 1994. HE HAS A VERY HIGH REGARD FOR THE WORK
11 AND KNOWS THE ETHICAL ISSUES, AND WE WERE VERY LUCKY TO
12 HAVE HIM.

13 NOW, THE CHARGE BEFORE THE BOARD AT THIS TIME
14 WAS BEFORE WE DID EXPERIMENT ONE, WE WANTED TO DESIGN
15 WHAT WE FELT AT THE TIME WAS THE GOLD STANDARD FOR
16 HUMAN EGG DONATION FOR STEM CELL RESEARCH. THAT WAS
17 THE GOAL. NOT TO TRY TO FIGURE OUT HOW TO GET HUMAN
18 EGGS, BUT TO ACTUALLY DESIGN A PROGRAM FOR WOMEN TO
19 DONATE EGGS SPECIFICALLY FOR STEM CELL RESEARCH.

20 AND, OF COURSE, THE QUESTION, THE FIRST
21 QUESTION, IS SHOULD WOMEN BE ASKED TO DO THIS. AND THE
22 ANSWER WE DECIDED WAS YES AS LONG AS ALL THE GUIDELINES
23 FOR FULLY INFORMED CONSENT WERE FOLLOWED AND THE DONOR
24 WAS DETERMINED TO BE PHYSICALLY AND MENTALLY CAPABLE OF
25 EGG DONATION. THOSE WERE THE GUIDELINES.

1 WE ALSO WONDERED WHO SHOULD DONATE. AND THIS
2 PARTICULAR BOARD DECIDED THAT IT SHOULD BE WOMEN
3 BETWEEN THE AGES OF 21 AND 35. THAT AGE RANGE HAS NOW
4 BEEN REDUCED TO 34 MOSTLY BECAUSE IT TAKES THEM A LONG
5 TIME TO GET THROUGH THE SCREENING PROCESS WITH AT LEAST
6 ONE BIOLOGIC CHILD. THERE WERE LOTS OF DISCUSSIONS
7 ABOUT WHY THESE WOMEN SHOULD BE MOTHERS BEFORE THEY
8 DONATED EGGS. I WON'T GO INTO THAT NOW; BUT IF YOU
9 HAVE QUESTIONS ABOUT THAT, I CAN GO THROUGH THE LOGIC.
10 THIS CERTAINLY CAN BE DEBATED. THAT'S WHAT THE
11 STANDARD IS NOW.

12 AND SHOULD THEY BE COMPENSATED? THIS WAS A
13 QUESTION THAT WE ASKED TOO, SHOULD WE BE COMPENSATED.
14 LOCAL COMPENSATION FOR WOMEN DONATING EGGS FOR A
15 FERTILITY PROGRAM IS IN PLACE IN ALMOST EVERY PLACE IN
16 THE COUNTRY. THE CONCERN WAS IF YOU DIDN'T COMPENSATE
17 DONORS TO DONATE EGGS, WOULD YOU GET ANY, OR WOULD THEY
18 ALL DONATE EGGS FOR INFERTILITY PROGRAMS. THAT TURNED
19 OUT TO ACTUALLY BE A NONISSUE BECAUSE IT TURNS OUT THAT
20 THE WOMEN WHO WANTED TO DONATE EGGS FOR STEM CELL
21 RESEARCH BY AND LARGE WOULD NEVER CONSIDER DONATING
22 EGGS FOR FERTILITY PROGRAMS. IT'S A DIFFERENT GROUP OF
23 PEOPLE.

24 SO WE DECIDED THEY SHOULD BE COMPENSATED FOR
25 THEIR TIME, FOR THEIR TRAVEL, AND FOR THEIR CHILD CARE

1 EXPENSES BECAUSE WE WANT -- WE ASKED THEM TO BE
2 MOTHERS, SO THEY HAD TO FIND BABYSITTERS.

3 HOW SHOULD THEY BE RECRUITED? AND WHAT WE
4 DECIDED TO DO WAS TO SIMPLY MAKE THIS AS TRANSPARENT AS
5 POSSIBLE. WE PUT AN AD IN THE BOSTON GLOBE. AND THIS
6 IS WHAT THE AD READ, AND WE PLACED THIS AD IN SEPTEMBER
7 OF 2000. AND WE DECIDED IT DOESN'T GET ANY MORE
8 TRANSPARENT THAN THIS. THIS IS EXACTLY WHAT WE WERE
9 ASKING WOMEN TO DO. AND BASICALLY WHAT HAPPENED IN
10 RESPONSE TO THIS AD, WE WERE PREPARED FOR THE PHONE TO
11 START RINGING OFF THE HOOK AND TO BE PICKETED.
12 BASICALLY WHAT HAPPENED WAS THIS AD WAS NOTHING.

13 SO WE DECIDED MAYBE NOBODY READS THE GLOBE.
14 AND WE ENDED NOT GETTING VERY MANY. WE DIDN'T GET ANY
15 REPORTERS. WE DIDN'T GET VERY MANY DONORS FROM THIS
16 AD. WHAT WE DID DISCOVER IS THAT IF YOU WANT YOUR
17 DONORS TO BE MOMS, YOU NEED TO ADVERTISE IN LOCAL
18 COMMUNITY PAPERS OR PARENTS NEWSPAPERS OR SOMETHING.
19 THIS IS HOW LONG WE'VE BEEN DOING THIS.

20 NOW, THE BIGGEST QUESTION WAS HOW SHOULD YOU
21 EVALUATE THE DONORS TO MAKE SURE THIS WAS SAFE FOR
22 THEM? IT WAS ONE THING TO WANT EGGS. IT WAS ANOTHER
23 THING TO MAKE SURE THAT NOTHING THAT HAPPENED TO THESE
24 WOMEN WAS NOT SAFE. AND IN THE END, HERE'S WHAT THE
25 DONORS HAVE TO GO THROUGH AT THIS TIME.

1 THEY GO THROUGH, FIRST OF ALL, A
2 PSYCHOLOGICAL SCREENING, AND THIS TURNED TO TAKE A TEAM
3 OF PSYCHOLOGISTS WHO DID ANSWER ADS IN THE GLOBE. AND
4 THEY PUT TOGETHER A WHOLE SCREENING PROCESS. THEY TAKE
5 A COUPLE OF PEN AND PAPER TESTS, INCLUDING THE
6 MINNESOTA MULTIPHASIC PERSONALITY INDEX, SOMETHING ELSE
7 WHICH IS CALLED SEL 90 WHICH RECORDS A QUEUED STRESS.
8 THEY ARE -- THESE TESTS ARE SENT FOR SCORING. IN
9 MINNESOTA THEY COME BACK, THEY IDENTIFY MAJOR
10 PATHOLOGY. THEY'RE THEN SCREENED BY A PSYCHOLOGIST,
11 AND THAT SCREENING PROCESS TAKES, I DON'T KNOW, A
12 COUPLE OF HOURS. THE PSYCHOLOGIST THEN COMES BACK WITH
13 THE REPORT, SO WE GET A COUPLE OF PAGE REPORT FROM THE
14 PSYCHOLOGIST JUST TOUCHING ON WHETHER THIS PERSON HAS
15 TIME TO DO THIS, WHETHER HER SITUATION CURRENTLY GIVES
16 HER A STRESS FREE PERIOD OF TIME THAT SHE CAN ACTUALLY
17 MANAGE THIS. AND IF THEY HAVE ANY HISTORY OF ANY KIND
18 OF REAL, NOT NECESSARILY EMOTIONAL STRESS BECAUSE
19 EVERYBODY HAS THAT, BUT A REAL HISTORY OF ANYTHING LIKE
20 POSTPARTUM DEPRESSION, ANYTHING LIKE THAT. THEY'RE
21 COUNSELED THIS IS NOT A GREAT IDEA FOR THEM. SO ANY
22 KIND OF HISTORY OF SCHIZOPHRENIA OR MAJOR MENTAL
23 ILLNESS IS SCREENED OUT.

24 IF THEY GET THROUGH THAT, THE DONORS ARE ALL
25 TOLD THAT THEY HAVE TO KEEP THIS PROCESS GOING. NOBODY

1 IS GOING TO CALL THEM TO REMIND THEM WHAT THEY HAVE TO
2 DO NEXT. THAT PROCESS BY ITSELF SCREENS OUT PEOPLE WHO
3 ARE NOT TOTALLY INTERESTED IN BEING DEDICATED. ONCE
4 THEY GET THROUGH ALL THE SCREENING PROCESS AND
5 PSYCHOLOGIST SAYS, OKAY, THIS WOMAN CAN HANDLE THE
6 STRESS OF THIS, THEY THEN GO TO A GYNECOLOGIST, A
7 REPRODUCTIVE ENDOCRINE PERSON, AND THEY'RE SCREENED.
8 THEY HAVE TO GO THROUGH A BATTERY OF TESTS. THEY'RE
9 TESTED FOR EVERY INFECTIOUS DISEASE YOU CAN THINK OF,
10 BIG HORMONE PROFILE, ROUTINE THINGS LIKE PAP SMEARS.
11 IT'S A MAJOR PHYSICAL WORK-UP.

12 AND THEN IF THERE'S NOTHING FOUND THERE, IF
13 THEY ACTUALLY COME UP WITH AN ABNORMAL PAP SMEAR OR
14 SOMETHING, THEY'RE NOT NECESSARILY CANCELED, BUT THEY
15 HAVE TO GET THAT RESOLVED. ANY PHYSICAL ISSUE HAS TO
16 BE RESOLVED BEFORE THEY CAN GO FORWARD. THEN AT THE
17 VERY END, IF NOBODY FINDS ANY PARTICULAR REASON WHY
18 THIS ISN'T A GOOD TIME IN THIS WOMAN'S LIFE FOR HER TO
19 GO AHEAD AND GET INVOLVED IN THIS RESEARCH PROJECT,
20 SHE'S THEN SCREENED BY SOMEBODY THAT WE CALL AN
21 INDEPENDENT STUDY MONITOR.

22 THE BIGGEST CONCERN I HAD WHEN WE STARTED
23 THIS WAS THAT WOMEN WOULD VOLUNTEER TO DO THIS OUT OF
24 PRESSURE FROM THE FAMILY BECAUSE SOME FAMILY MEMBER HAS
25 SOME KIND OF A DISEASE THAT THIS MIGHT HELP. AND

1 THERE'S BEEN A NUMBER OF REPORTS THAT THAT'S WHY PEOPLE
2 DONATE KIDNEYS. SO WE WERE VERY WORRIED THAT THAT
3 WOULD BE THE ISSUE.

4 THE STUDY MONITOR, HER JOB IS TO MAKE SURE --
5 THIS IS A PERSON WE FOUND AS AN ATTORNEY NURSE THAT HAD
6 A MAJOR INFERTILITY PROBLEM, SO SHE UNDERSTANDS WHAT
7 THE DONORS HAVE BEEN THROUGH PHYSICALLY AND
8 EMOTIONALLY, AND SHE ALSO UNDERSTANDS WHAT THE LAWS ARE
9 IN MASSACHUSETTS. HER JOB IS TO MAKE SURE THAT THIS
10 DONOR UNDERSTANDS THE BIOLOGY, HAS NOBODY COERCING HER
11 IN THE BACKGROUND, REALLY UNDERSTANDS WHAT SHE'S DOING,
12 AND IS DOING THIS OF HER OWN FREE WILL.

13 NOW, HOW SHOULD WE PAY FOR THE COST OF THE
14 DONOR PROGRAM? ORIGINALLY IT WAS PAID -- WE FINALLY
15 CAME TO THE FACT THAT IT NEEDS TO BE ALL ORGANIZED
16 THROUGH A PUBLIC NOT-FOR-PROFIT ENTITY, WHICH THE ONE
17 THAT WE'RE USING NOW IS CALLED BEDFORD RESEARCH
18 FOUNDATION. IT ACTUALLY DOES HAVE A WEBSITE. SO THAT
19 ALL OF THE -- ANY FINANCIAL TRANSACTIONS INVOLVED IN
20 THIS ARE ALL PUBLIC INFORMATION. SO THAT'S HOW IT'S
21 MANAGED.

22 LET ME GO BACK. LET ME GO BACK A LITTLE BIT
23 TO THE COMPENSATION ISSUE. AS THEY GO THROUGH -- NOW,
24 SO EACH TIME INVOLVED, IF THE DONOR COMES IN TO TAKE A
25 TEST AND HAS TO BE SCREENED, THERE IS A LEVEL OF

1 COMPENSATION ASSOCIATED WITH THAT, JUST AS IF SHE'D
2 BEEN ASKED TO BE SCREENED IN AN OBESITY CLINIC FOR HOW
3 MUCH SHE WANTED TO WEIGH. IT'S A VERY STANDARD HUMAN
4 SUBJECTS KIND OF LEVEL. IF SHE GETS THROUGH THAT, THEN
5 IT'S TWO OR \$300 FOR EACH OF THESE PHASES, IF SHE GETS
6 THROUGH THAT AND IT'S DETERMINED THAT SHE IS NO LONGER
7 ELIGIBLE TO GO FORWARD, SHE IS COMPENSATED FOR THAT
8 PIECE OF IT. AS SHE GOES THROUGH EACH OF THESE STEPS
9 OF THE PROGRAM, HER COMPENSATION MATCHES WHAT YOU WOULD
10 PAY ANY HUMAN SUBJECTS RESEARCH FOR NORMAL HUMAN
11 SUBJECT IN ANY RESEARCH PROGRAM IN THE COUNTRY.

12 WHETHER YOU WANT TO CALL THAT PAYMENT FOR
13 DONATION OR NOT, I DON'T KNOW. IT IS CERTAINLY
14 SIMPLY -- IN THE WAY IT'S HANDLED, IT'S CERTAINLY
15 COMPENSATION FOR HER TIME. SAME THING IS TRUE HERE.
16 THE COMPENSATION ASSOCIATED WITH GOING THROUGH AN EGG
17 DONATION PROCESS, IF YOU GO THROUGH ALL THE TIME
18 INVOLVED, IN OUR PROGRAM WE'VE ADDED IT UP. IT SEEMS
19 TO BE ABOUT 40 TO 50 HOURS OF HER TIME THAT SHE HAS TO
20 SPEND DOING ALL THE MONITORING TO MAKE SURE THAT SHE'S
21 NOT OVERRESPONDING TO THE HORMONES. IF SHE IS
22 OVERRESPONDING TO THE HORMONES, THEN THAT CYCLE IS
23 SIMPLY CANCELED. IF YOU ADD UP ALL THE COSTS FOR
24 PUTTING A DONOR THROUGH THE CYCLE, AND THE DONOR MAKES
25 ALL THE STEPS, THE COST OF THE CYCLE PER DONOR IS ABOUT

1 \$25,000, WHICH IS ABOUT WHAT IT IS IN AN INFERTILITY
2 PROGRAM FOR THE INFERTILITY DONOR. OF THAT \$25,000
3 COST, MOST OF IT IS HORMONE MEDICAL TEAM AND THE
4 SCREENING PROCESS. A DONOR THAT GOES ALL THE WAY
5 THROUGH IS COMPENSATED ON THE AVERAGE OF ABOUT \$4,000
6 FOR ALL OF THE PHASES. SO HER COMPENSATION IS TINY
7 RELATIVE TO THE COMPENSATION OF THE WHOLE PROJECT
8 ITSELF.

9 I CAN ANSWER QUESTIONS IF YOU WANT TO TAKE
10 TIME. I THINK HARRIET WOULD LIKE TO GET ON WITH THE
11 NEXT DEBATE.

12 CO-CHAIR RABB: ONLY BECAUSE -- AND FOR
13 PEOPLE WHO HAVE QUESTIONS, CERTAINLY WHEN WE COME TO
14 THE PUBLIC COMMENT TIME, I WILL INVITE YOU TO RAISE THE
15 QUESTIONS YOU'VE GOT. LET'S SEE HOW MUCH WE CAN GET ON
16 THE TABLE FOR EVERYBODY TO DISCUSS ALL THE GUIDELINES.

17 OUR OTHER MEMBER OF THIS WORKING GROUP WHO
18 WAS PART OF THE NAS GUIDELINES PROCESS IS ALTA CHARO,
19 AND I ASKED ALTA TO PICK UP ANOTHER NONCONTROVERSIAL
20 TOPIC. THAT OTHER NONCONTROVERSIAL TOPIC IS CHIMERIC
21 RESEARCH. I'M KIDDING. IT'S AT LEAST AS CONTROVERSIAL
22 AS THIS ONE IS. AND MAYBE IF SHE RAISES IT FOR US AND
23 GIVES US A LITTLE BACKGROUND, WE CAN DISCUSS THAT. AND
24 THEN WHAT I'D LIKE TO DO IS OPEN IT TO ALL THE MEMBERS
25 OF THE WORKING GROUP TO RAISE ANY PART OF ANY THE

1 GUIDELINES FROM ESCRO'S TO CONSENT FORMS TO BANKING AND
2 EVERYTHING IN BETWEEN.

3 SO WE GO THROUGH THE CHIMERIC FIRST. WE'LL
4 OPEN FOR THE REST AFTER.

5 MS. CHARO: THESE REMARKS WILL BE INCREDIBLY
6 BRIEF BECAUSE I'M NOT A TRAINED SCIENTIST. BASICALLY
7 THE NATIONAL ACADEMIES DID RECOGNIZE THAT THERE WERE
8 LOTS OF ETHICAL ISSUES HAVING TO DO WITH THE DERIVATION
9 OF EMBRYONIC STEM CELL LINES. THE NATIONAL ACADEMIES
10 DID RECOGNIZE THERE WERE LOTS OF ETHICAL ISSUES
11 ASSOCIATED WITH DERIVING NEW LINES, WHICH INVOLVES
12 COLLECTING MATERIALS, NOT JUST EGGS, WHICH IS GOING TO
13 BE RELATIVELY RARELY NEEDED, BUT JUST OBTAINING NEW
14 SURPLUS EMBRYOS THAT ARE BEING DONATED BY COUPLES IN
15 CLINICS.

16 BUT THE ACADEMIES ALSO RECOGNIZED THAT BEYOND
17 DERIVING NEW LINES, THERE WAS A WORLD OF RESEARCH THAT
18 WAS GOING ON IN THE LABORATORIES THAT HAD NOT YET
19 GOTTEN MUCH ATTENTION. AND SO REALLY THIS REPORT
20 FOCUSES, I THINK, THE FIRST SUSTAINED ATTENTION ON
21 ETHICAL ISSUES HAVING TO DO WITH WHAT WE CALL THE
22 PRECLINICAL RESEARCH PHASE. THAT IS, THE PHASE OF
23 RESEARCH THAT INVOLVES LAB WORK AND ANIMAL WORK JUST
24 PRIOR TO TRYING TO GO INTO HUMAN TRIALS. SO IT'S KIND
25 OF A TRANSLATIONAL AREA OF RESEARCH.

1 AND ONE OF THE THINGS THAT JUMPED OUT
2 IMMEDIATELY WAS THAT CERTAIN ASPECTS OF THIS
3 TRANSLATIONAL WORK ARE GOING TO REQUIRE THAT HUMAN
4 MATERIALS BE EXPOSED TO NONHUMAN MATERIALS IN ORDER TO
5 OBTAIN INFORMATION NECESSARY FOR MOVING ALONG
6 ULTIMATELY INTO HUMAN TRIALS.

7 LET ME FIRST DISTINGUISH BETWEEN THE VARIOUS
8 KINDS OF HUMAN, NONHUMAN COMBINATIONS. PEOPLE WERE ALL
9 TALKING ABOUT THE SAME THING. WE WEREN'T TALKING ABOUT
10 HYBRIDS WHERE YOU TAKE SPERM FROM ONE SPECIES AND AN
11 EGG FROM ANOTHER SPECIES AND CROSS FERTILIZE AND CREATE
12 AN ENTIRELY NEW COMBINATION, USUALLY A STERILE ANIMAL.
13 WHAT WE ARE TALKING ABOUT ARE ENTITIES THAT HAVE TWO
14 DIFFERENT SPECIES TISSUES COMBINED IN SOME FASHION.
15 AND IT'S SOMETHING THAT WE DO ALREADY AS A ROUTINE
16 MATTER IN LABORATORIES, AND THIS WAS AN IMPORTANT PART
17 OF THE CONTEXT.

18 WE HAVE MICE WHO HAVE HUMAN SKIN GRAFTED ONTO
19 THEM FOR VARIOUS RESEARCH PURPOSES HAVING TO DO WITH
20 EXAMINING HUMAN SKIN. WE DO IN THE CLINICAL CONTEXT
21 HAVE PIG VALVES THAT ARE IMPLANTED IN HUMAN BEINGS'
22 HEARTS WHEN THEY'VE GOT VALVE DISEASE. SO WE'RE
23 FAMILIAR WITH THE IDEA OF HUMAN, NONHUMAN COMBINATIONS,
24 BUT WE RECOGNIZED ALSO THAT IT HAS A KIND OF ALARMING
25 SOUND WHEN DISCUSSED WITHOUT CONTEXT. AND EVEN ITS OWN

1 NAME, THE CHIMERA NAME, COMES FROM GREEK MYTHOLOGY
2 WHERE USUALLY THERE'S SOME KIND OF MONSTER IN THE
3 IMAGINATION, HEAD OF ONE SPECIES AND THE BODY OF
4 ANOTHER. SO THE POTENTIAL FOR PUBLIC MISUNDERSTANDING
5 WAS VAST. AND FOR THAT REASON ALONE, IT MIGHT MAKE
6 SENSE TO HAVE A PARTICULARLY CAREFUL OVERSIGHT IN THIS
7 AREA, LET ALONE FOR MORE SUBSTANTIVE REASONS ABOUT WHAT
8 WE DON'T KNOW AND WHAT WE DO KNOW ABOUT THE RESEARCH.

9 NOW, THE ACADEMIES' COMMITTEE TRIED TO GO
10 THROUGH THE REASONS WHY YOU WOULD NEED TO HAVE CHIMERAS
11 IN RESEARCH. AND IT CAME UP WITH A VARIETY OF THEM,
12 WHICH I WANT TO OUTLINE VERY BRIEFLY. THE FIRST WAS TO
13 ACTUALLY TEST YOUR ABILITY TO DIFFERENTIATE HUMAN
14 EMBRYONIC STEM CELLS DOWN THE LINEAGE OF INTEREST. AND
15 SO, FOR EXAMPLE, YOU WANT TO MAKE NORMAL TISSUE, YOU'VE
16 GOT TO BE ABLE TO DIFFERENTIATE THE EMBRYONIC STEM
17 CELLS, AND SOMETIMES THIS IS GOING TO BE DONE BEST IN
18 SITU IN A NONHUMAN SYSTEM, A CHICKEN EGG, FOR EXAMPLE.

19 SECOND, IF YOU'VE GROWN TISSUE FROM HUMAN
20 EMBRYONIC STEM CELLS THAT YOU IMAGINE IN THE FUTURE
21 MIGHT BE THE BASIS OF TISSUE TRANSPLANTATION, YOU'RE
22 CERTAINLY NOT GOING TO WANT TO HAVE YOUR VERY FIRST
23 EFFORT AT TRANSPLANTATION BE WITH A HUMAN BEING. SO
24 WHAT YOU'RE GOING TO WANT TO DO IS YOU'RE GOING TO GROW
25 SOME TISSUE, AND THEN YOU'RE GOING TO GRAFT IT INTO A

1 NONHUMAN ANIMAL AND SEE IF YOU CAN LEARN HOW TO GRAFT
2 IT PROPERLY. OFTEN THE GRAFTS HAVE TO BE
3 THREE-DIMENSIONAL STRUCTURES. SO IT'S NONTRIVIAL
4 FIGURING OUT HOW TO CONSTRUCT THE ACTUAL TISSUE IN ALL
5 THREE DIMENSIONS THAT WILL CORRECTLY LATCH ONTO THE
6 TISSUE WITHIN THE BODY OF THE ANIMAL. AND LOOKING AT
7 THIS AND TESTING IT REPEATEDLY IS THE WAY TO MOVE
8 SAFELY TOWARD DOING IT WITH HUMANS.

9 NEXT, BECAUSE OF YOU WERE GOING TO BE
10 TRANSPLANTING TISSUE, YOU WANT TO BE SURE THAT THE
11 TISSUE IS MADE UP OF DIFFERENTIATED CELLS; THAT IS,
12 THEY NOW ALL ARE NEURONAL OR CARDIAC MUSCLE OR WHATEVER
13 AND THEY DON'T HAVE ANY REMAINING UNDIFFERENTIATED
14 CELLS THAT MIGHT BECOME UNPREDICTABLE FORMS OF TISSUE
15 NOW LOCATED IN THE WRONG PART OF THE BODY. THIS IS
16 ALSO RELATED VERY MUCH TO CONCERNS ABOUT TUMOR
17 FORMATION. THE FDA, INDEED, HAD SIGNALLED THAT THAT WAS
18 GOING TO BE A VERY IMPORTANT AREA OF FOCUS FOR THEIR
19 ATTENTION BEFORE THEY APPROVE ANY HUMAN TRIALS; THAT
20 IS, PROOF THAT YOU WERE NOT GOING TO BE RISKING
21 UNDIFFERENTIATED CELL TRANSPLANT. SO TESTING OUT IN
22 ANIMALS THE TISSUE THAT YOU TRANSPLANT ALLOWS YOU TO
23 ASSESS SIMULTANEOUSLY YOUR ABILITY TO DETECT
24 UNDIFFERENTIATED CELLS IN THE TISSUE THAT YOU'RE
25 DEVELOPING AND ALSO HOW A VERY SMALL NUMBER OF

1 UNDIFFERENTIATED CELLS WILL REACT IN VIVO IN A LIVE
2 SYSTEM.

3 AND, FINALLY, YOU WANT TO LOOK AT WHAT
4 HAPPENS ONCE THE TISSUE IS GRAFTED AND MAKE SURE YOU
5 UNDERSTAND HOW IT TENDS TO GROW. DOES IT GROW ONLY IN
6 THE RIGHT PLACES, OR ARE YOU RISKING HAVING MIGRATION
7 TO UNINTENDED AREAS OF THE BODY WHERE THE TISSUE MIGHT
8 ACTUALLY CAUSE INJURY RATHER THAN BE THERAPEUTIC.

9 NOW, EACH OF THESE ARE IMPORTANT PRECLINICAL
10 RESEARCH STEPS, AND EACH SEEM TO BE EXACTLY THE KIND OF
11 STEPS THAT THE FDA REQUIRES BEFORE YOU CAN MOVE INTO
12 HUMAN TRIALS. THEY, IN TURN, RAISE VERY SPECIAL
13 QUESTIONS ABOUT THE SAFETY. THESE RAISE VERY SPECIAL
14 QUESTIONS ABOUT THE SAFETY AND ETHICS OF THE RESEARCH.

15 FROM A PUBLIC SAFETY POINT OF VIEW, ANY TIME
16 YOU HAVE HUMAN AND NONHUMAN MATERIAL COMING INTO
17 CONTACT, YOU RISK HAVING NEW VIRAL MUTATIONS. SO
18 THERE'S ATTENTION TO WHETHER OR NOT THE PARTICULAR
19 RESEARCH THAT YOU ARE DOING RAISES THIS CONCERN OR NOT
20 BECAUSE NOT EVERY EXPERIMENT WILL. WE DO WANT TO PAY
21 ATTENTION TO THAT.

22 AND THIS IS, BY THE WAY, ONE OF THE REASONS
23 WHY WE WERE ALSO PAYING ATTENTION TO EXISTING FEDERAL
24 REQUIREMENTS FOR RESEARCH OVERSIGHT. AND IN THIS CASE
25 THINGS LIKE INSTITUTIONAL BIOSAFETY COMMITTEES FORM A

1 POTENTIAL SOURCE OF AUTHORITY HERE. THEY ALSO FORM A
2 SOURCE OF AUTHORITY WHEN YOU DO EXPERIMENTS THAT
3 INVOLVE ENGINEERING YOUR EMBRYONIC STEM CELLS, EVEN IF
4 IT'S A SIMPLE THING AS PUTTING IN A FLORESCENT TRAIT SO
5 YOU'RE MORE EASILY ABLE TO TRACE THE TRANSPLANTED
6 TISSUE FROM THE UNTRANSPLANTED TISSUE. THE
7 INSTITUTIONAL BIOSAFETY COMMITTEES EXIST ALREADY AS PER
8 FEDERAL REQUIREMENTS TO OVERSEE PUBLIC SAFETY ASPECTS
9 OF THE WORK.

10 SECOND, IF YOU ARE COMBINING HUMAN AND
11 NONHUMAN MATERIAL AND YOU'RE USING A LIVE ANIMAL
12 SYSTEM, A LIVE MOUSE, FOR EXAMPLE, YOU'VE GOT ANIMAL
13 WELFARE ISSUES TO WORRY ABOUT. THOSE TWO ARE COVERED
14 BY FEDERAL LAW. IF YOU ARE WORRIED THAT YOUR
15 PARTICULAR FORM OF RESEARCH IS GOING TO BE HARMFUL,
16 IT'S GOING TO BE PAINFUL, THIS KIND OF QUESTION IS
17 HANDLED AT THE INSTITUTIONAL LEVEL BY THE INSTITUTIONAL
18 ANIMAL CARE USE COMMITTEE, IACUC. SO THAT TOO WAS
19 IDENTIFIED BY THE ACADEMIES AS AN ELEMENT ALREADY IN
20 PLACE FOR OVERSIGHT OF THIS KIND OF RESEARCH, ALTHOUGH
21 WE DID ACKNOWLEDGE THAT THE IACUC'S HAVE PROBABLY NOT
22 YET BEEN CONFRONTED WITH RESEARCH QUITE LIKE THIS.

23 THIRD, THOUGH, I THINK THIS IS WHERE THE REAL
24 FOCUS WAS, THAT THERE'S SOME UNCERTAINTY ABOUT THE
25 RESULTS AND WHAT THEY MEAN. FOR EXAMPLE, IF YOU TAKE

1 HUMAN EMBRYONIC STEM CELLS AND MAKE TISSUE THAT IS
2 GOING TO BE TRANSPLANTED INTO THE ADULT ORGANS OF AN
3 ANIMAL. FOR EXAMPLE, YOU WANT TO TRANSPLANT INTO A
4 LIVE BORN SHEEP AND YOU WANT TO TRANSPLANT INTO THE
5 SHEEP KIDNEY, IT TENDS NOT TO RAISE THAT MANY CONCERNS
6 BECAUSE IT'S ALREADY WELL-DEVELOPED TISSUE AND THE
7 CHANCES OF RANDOM MIGRATION BEYOND THE ORGAN SEEM TO BE
8 LOWER. AND HERE WE UNDERSTOOD THAT YOU STILL MIGHT
9 WANT TO HAVE CLOSE ATTENTION TO THE EXACT STAGE OF THE
10 ANIMAL'S DEVELOPMENT INTO WHICH YOU'RE PUTTING YOUR
11 TISSUE AND YOUR EXACT DEGREE OF CONFIDENCE THAT IT'S
12 FULLY DIFFERENTIATED TISSUE.

13 SO WE RECOMMENDED KIND OF AN AD HOC REVIEW OF
14 SUCH EXPERIMENTS. THAT IS, EVERY TIME YOU WANT TO PUT
15 HUMAN EMBRYONIC STEM CELL DERIVED TISSUE INTO A
16 NONHUMAN ANIMAL, WHATEVER STAGE OF DEVELOPMENT, THAT
17 YOU HAVE A CONSULTATION WITH THE LOCAL INSTITUTIONAL
18 OVERSIGHT BOARD, WHICH WE HAVE NOT DISCUSSED YET, BUT
19 IS PROPOSED IN THE ACADEMIES' REPORT, WHERE THEY CAN
20 TAKE A CLOSE LOOK AT WHETHER OR NOT THERE IS A RISK OF
21 ANY KIND OF UNINTENDED MIGRATION OF TISSUE TO A
22 DIFFERENT PART OF THE ANIMAL'S BODY OR WHETHER THE
23 PARTICULAR ORGAN SYSTEM IS ONE THAT RAISES SPECIAL
24 CONCERNS. KIDNEYS DON'T REALLY, BUT BRAIN CERTAINLY
25 DOES.

1 ON THE OTHER HAND, IF YOU WERE TO TAKE
2 EMBRYONIC STEM CELLS AND PUT THEM INTO THE EARLY EMBRYO
3 OF AN ANIMAL AT THE BLASTOCYST STAGE, TAKE HUMAN
4 EMBRYONIC STEM CELL AND YOU COMBINE IT WITH THE 64-CELL
5 SHEEP EMBRYO, FOR EXAMPLE, AND ALLOW THAT SHEEP EMBRYO
6 THEN TO DEVELOP THROUGH FETAL STAGES AND INTO LIVE
7 BIRTH, WHAT YOU'D EXPECT IS THAT THE HUMAN EMBRYONIC
8 STEM CELL WOULD NOW CREATE TISSUE THAT DISPERSES
9 THROUGHOUT THE SHEEP'S BODY. IT WOULD DISPERSE NOT
10 ONLY INTO THE KIDNEY AND THE HEART AND THE LIVER, BUT
11 IT WOULD ALSO DISPERSE INTO THE BRAIN AND INTO THE
12 GAMETES.

13 BECAUSE WE DON'T REALLY UNDERSTAND COMPLETELY
14 THE IMPLICATIONS OF HAVING HUMAN MATERIAL MIXED SO
15 THOROUGHLY WITH NONHUMAN MATERIAL, PARTICULARLY IN
16 THINGS LIKE THE NEUROLOGICAL SYSTEM, WE DON'T
17 UNDERSTAND IT IN TERMS OF THE EXPERIENCE OF THE ANIMAL,
18 ITS SENSORY CAPACITIES, HOW WE WOULD ASSESS ANIMAL
19 WELFARE UNDER THOSE CIRCUMSTANCES, FOR EXAMPLE, THIS
20 WAS MARKED OUT FOR SPECIAL ATTENTION. IT'S WHY WE
21 WANTED THE AD HOC CASE-BY-CASE REVIEW OF THIS RESEARCH
22 WE THOUGHT WAS NECESSARY SO THAT THE INSTITUTIONAL
23 OVERSIGHT BOARDS CAN WORK WITH INVESTIGATORS TO SEE IF
24 THERE'S ANY WAY TO ACCOMPLISH THEIR GOALS THAT DON'T
25 RAISE THESE QUESTIONS OF UNCERTAINTY, TO IDENTIFY AREAS

1 OF RESEARCH THAT MIGHT NEED TO BE DONE FIRST TO REDUCE
2 THE AREAS OF UNCERTAINTY, ETC.

3 FINALLY, THERE WAS A RECOMMENDATION FOR A
4 VERY LIMITED NUMBER OF EXPERIMENTS THAT SIMPLY
5 SHOULDN'T BE DONE AT ALL BECAUSE THE UNCERTAINTY WAS
6 TOO GREAT AT THIS POINT TO RISK IT. AND THE ONE THAT
7 WAS SPECIFICALLY MENTIONED WAS TAKING HUMAN EMBRYONIC
8 STEM CELLS AND PUTTING THEM INTO A PRIMATE EMBRYO.
9 BECAUSE HERE THE SENSE WAS THAT THE NEUROLOGICAL
10 SYSTEMS OF OUR NEAREST PRIMATE COUSINS WERE
11 SUFFICIENTLY CLOSE TO OURS, THAT OUR CONCERNS ABOUT THE
12 KIND OF SENSORY CAPACITIES OF THE RESULTING BRAIN THAT
13 HAS FULLY MERGED HUMAN AND NONHUMAN PRIMATE MATERIAL
14 WAS VERY DIFFICULT TO ASSESS AND VERY PROBLEMATIC.

15 SO WE COUNSELED THAT THIS SHOULD NOT BE DONE
16 AT ALL AT THIS TIME TILL THE DAY COMES WHEN WE'D REALLY
17 BE ABLE TO UNDERSTAND WHAT IN THE WORLD WE'RE CREATING.

18 THERE WERE A FEW OTHER VERY SPECIFIC KINDS OF
19 PROHIBITIONS, BUT THEY REALLY WERE NOT DIRECTED AT THE
20 CHIMERAS EXCEPT TO SAY THAT UNDER ALL CIRCUMSTANCES
21 THERE WAS THE SUGGESTION THAT THE CHIMERIC ANIMALS NOT
22 BREED AGAINST THE EXTREMELY REMOTE CHANCE OF GAMETIC
23 CHANGE.

24 AND THAT IS IN -- THAT'S THE SUBSTANCE OF
25 THIS PARTICULAR AREA. IT SUPPLEMENTS, BUT DOES NOT

1 SUBSTITUTE FOR FEDERAL GUIDELINES THAT ARE ALREADY IN
2 PLACE.

3 CO-CHAIR RABB: WHEN YOU READ IT, IT WILL
4 COME BY MORE SLOWLY THAN YOU JUST HEARD IT. I THINK
5 YOU WILL FIND THERE'S A WEALTH OF INFORMATION THERE TO
6 THINK ABOUT AND TO HELP US DECIDE HOW THE RESEARCH THAT
7 CALIFORNIA IS GOING TO FUND THESE GUIDELINES SUIT THIS
8 FUNDING AGENCY, THE ICOC, AND HOW PEOPLE OF THE STATE
9 ARE GOING TO FEEL ABOUT THEM.

10 DR. PETERS: MAY I ASK TWO QUESTIONS OF ALTA?

11 CO-CHAIR RABB: OF COURSE.

12 MS. CHARO: AND JANET BECAUSE SHE WAS ON THE
13 COMMITTEE TOO.

14 DR. ROWLEY: ALTA'S DONE SUCH A GREAT JOB.

15 DR. PETERS: THANKS. FOR EITHER ONE OF YOU.
16 THE FIRST QUESTION HAS TO DO WITH HOW PRECISE DID THE
17 PEOPLE YOU WORK WITH USE THE WORD "CHIMERA"? DOES IT
18 REFER TO A CELL THAT MIGHT HAVE SOME GENES INTRODUCED
19 FROM A SECOND SPECIES? DOES IT REFER TO A SINGLE CELL
20 THAT WOULD HAVE MORE THAN THE NORMAL NUMBER OF
21 CHROMOSOMES, SOME REPRESENTING TWO DIFFERENT SPECIES?
22 DOES IT REFER TO A SINGLE TISSUE IN WHICH THE CELL OF
23 ONE SPECIES SITS SIDE BY SIDE WITH A CELL OF ANOTHER
24 TISSUE? DOES IT REFER TO ALL OF THOSE? AND IS THE
25 WORD "CHIMERA" SHARPLY DISTINGUISHED FROM

1 XENOTRANSPLANTATION? COULD YOU JUST SAY SOMETHING
2 ABOUT HOW THAT VOCABULARY WORKS?

3 MS. CHARO: I CAN TELL YOU EXACTLY WHAT
4 DEFINITION WE WORKED FROM, BUT I CANNOT GUARANTEE THAT
5 ALL PEOPLE WORKED FROM THE SAME DEFINITION. AND I
6 AGREE WITH YOU THAT WORD HAS BEEN USED FOR MANY
7 PURPOSES. WE DEFINED CHIMERA IN THE GLOSSARY FOR THIS
8 REPORT'S PURPOSES AS AN ORGANISM COMPOSED OF CELLS
9 DERIVED FROM AT LEAST TWO GENETICALLY DIFFERENT CELL
10 TYPES. THE CELLS COULD BE FROM THE SAME OR SEPARATE
11 SPECIES. THAT WOULD MEAN THAT, FOR EXAMPLE, YOUR
12 HYPOTHETICALS ABOUT A CELL THAT HAS ALTERED DNA OR
13 ADDITIONAL CHROMOSOMES WOULD NOT BE COVERED. THIS IS
14 ABOUT CELL-CELL COMBINATIONS AND NOT ABOUT
15 INTRACELLULAR CHANGES.

16 BUT I COMPLETELY UNDERSTAND WHY SOME PEOPLE
17 WHO WERE LOOKING AT GENETICALLY ENGINEERED ORGANISMS
18 COULD EASILY FIND THEMSELVES REFERRING TO THOSE
19 ORGANISMS AS CHIMERAS IF THE ENGINEERING INVOLVED
20 INTRODUCTION OF A DIFFERENT SPECIES TRAIT.

21 DR. PETERS: THANK YOU VERY MUCH. THAT
22 HELPS.

23 SECOND QUESTION. WAS THERE MUCH IN THE WAY
24 OF A PHILOSOPHICAL DISCUSSION BEHIND THIS THAT YOU
25 HAVEN'T REPORTED? I NOTICED IN READING THROUGH THE

1 RECOMMENDATIONS THE RECOMMENDATION THAT WE NOT ALLOW
2 CHIMERAS TO BREED. AND THEN I WAS SORT OF BACKING IT
3 UP, I HEARD YOU ENUNCIATE THE SAFETY ARGUMENT, WHICH I
4 UNDERSTAND, BUT WHEN YOU GOT TO THINGS SUCH AS WHAT
5 WOULD HAPPEN IN THE BRAIN OF A CHIMERIC ANIMAL, OTHER
6 THAN THE SAFETY ARGUMENT, WAS THERE MUCH CONCERN ABOUT
7 ANTHROPOLOGY, THE HUMAN NATURE? DID THESE THINGS COME
8 UP, OR WAS THIS JUST STRICTLY PRECAUTIONARY WITHOUT
9 NECESSARILY A PHILOSOPHICAL ARGUMENT?

10 MS. CHARO: NO. THEY DID COME UP, AND THERE
11 IS AN ABBREVIATED DISCUSSION IN THE REPORT. I THINK
12 BERNIE LO MENTIONED DURING THE BREAK THAT HE WAS STRUCK
13 BY THE FACT THAT THE REPORT KIND OF GETS DOWN TO BRASS
14 TACKS WITHOUT RUNNING THROUGH REASONING IN MANY PLACES,
15 AND IT DISADVANTAGES US BECAUSE WE DIDN'T SPELL
16 EVERYTHING OUT.

17 THAT DISCUSSION CAME UP IN TWO CONTEXTS. ONE
18 HAD TO DO WITH ANIMAL WELFARE. THE OTHER HAD TO DO
19 WITH WHAT IS COMMONLY REFERRED TO AS SPECIES INTEGRITY
20 ARGUMENTS. AND I THINK YOU CAN HEAR IN THE INITIAL
21 COMMENTS I MADE THE ANIMAL WELFARE CONCERNS. BECAUSE,
22 ALTHOUGH WE HAVE GOOD REASON TO BELIEVE THAT A MOUSE
23 WITH HUMAN MATERIAL PROBABLY DOESN'T HAVE THE
24 ARCHITECTURE TO SUBSTANTIALLY CHANGE ITS EXPERIENCE OF
25 MOUSENESS, WHEN YOU'RE DEALING WITH CROSS SPECIES

1 COMBINATIONS WITH OUR PRIMATE COUSINS WHERE THE
2 ARCHITECTURE IS NOT THE SAME, BUT HAS SOME
3 SIMILARITIES, THERE WAS A CONCERN ABOUT OUR ABILITY TO
4 UNDERSTAND WHAT MIGHT RESULT BECAUSE NOW YOU HAVE
5 SIMILARITY BOTH OF TISSUE AND ARCHITECTURE.

6 ON THE SECOND SET OF DISCUSSIONS HAVING TO DO
7 WITH THE NOTION OF WHETHER OR NOT THERE'S SOMETHING
8 INTRINSICALLY OFFPUTTING ABOUT CREATING ORGANISMS THAT
9 HAVE CHARACTERISTICS OF MORE THAN ONE SPECIES, WE FOUND
10 OURSELVES RAPIDLY RECOGNIZING WHAT IS RECOGNIZED IN THE
11 WORLD OF BIOLOGY, BUT NOT ALWAYS RECOGNIZED IN THE
12 WORLD OF KIND OF POPULAR UNDERSTANDINGS ABOUT BIOLOGY,
13 AND THAT IS THE NOTION OF SPECIES IS REALLY VERY FUZZY.
14 AND THAT, FIRST OF ALL, THE TAXONOMY BY WHICH WE DEFINE
15 SPECIES IS RATHER ARBITRARY.

16 AND WE SAT AND LISTENED TO SOME VERY
17 INTERESTING DISCUSSIONS THAT HAVE SUGGESTED THAT IT'S
18 ACTUALLY QUITE ANTIQUATED AND NEEDS TO BE RADICALLY
19 REVISED IN ORDER TO BETTER REPRESENT THE GENUINE
20 RELATIONSHIPS AMONG DIFFERENT SPECIES.

21 SO THERE'S A KIND OF ARTIFICIALITY. IT'S NOT
22 NECESSARILY KIND OF INTRINSIC TO THE NATURE OF THE
23 WORLD THAT OUR SPECIES BE DIVIDED PRECISELY THE WAY
24 THEY ARE ON THESE NICE LITTLE CHARTS THAT COME FROM
25 EUROPE SEVERAL HUNDRED YEARS AGO. AND THE SECOND THING

1 IS THAT NO MATTER HOW YOU DIVIDE IT UP, THAT THERE IS A
2 GREAT DEAL OF BLURRINESS. THERE ARE GROUPS OF ANIMALS
3 THAT ARE DEFINED AS SEPARATE SPECIES BECAUSE THEY DON'T
4 INTERBREED, BUT THE LACK OF INTERBREEDING IS MORE
5 BEHAVIORAL AND ENVIRONMENTAL THAN IT IS BECAUSE THERE'S
6 AN INTRINSIC OBSTACLE TO INTERBREEDING. SO BREEDING
7 DOESN'T BECOME A PERFECT KIND OF EXPLANATION.

8 YOU GO TO VISUAL, IT LOOKS -- YOU KNOW, AS
9 YOU EXAMINE IT, THE CLOSER YOU GET TO IT, THE LESS
10 CLEAR IT BECOMES AND THE MORE DIFFICULT IT IS TO ARGUE
11 THAT THERE'S SOMETHING INHERENTLY WRONG IN BREAKING
12 THROUGH BOUNDARIES THAT IN SOME WAYS ARE NOT GENUINE
13 BOUNDARIES. THEY ARE LINES WE HAVE DRAWN FOR
14 CONVENIENCE AND NOW ARE SAYING AREN'T ALWAYS CONVENIENT
15 FOR ALL PURPOSES.

16 DR. ROWLEY: I JUST WANT TO MAKE TWO MORE
17 POINTS. ALTA HAS DONE A MARVELOUS JOB.

18 IN RESPONSE TO YOUR SECOND QUESTION, WE DID
19 DISCUSS THIS, AS ALTA HAS ALREADY ALLUDED TO. I THINK
20 IT'S IMPORTANT TO NOTE THIS, AGAIN, IS WHY WE THOUGHT
21 AN ESCRO COMMITTEE, EMBRYONIC STEM CELL RESEARCH
22 OVERSIGHT COMMITTEE, WAS REALLY IMPORTANT BECAUSE WE
23 THOUGHT THAT SOME OF THIS DEPENDED ON, A, THE
24 SCIENTIFIC QUESTION THAT WAS BEING ASKED; B, WAS THIS
25 THE ONLY WAY TO ANSWER IT, AND A MATTER OF PROPORTION

1 SO THAT IF YOU HAD AN ANIMAL, EVEN A FETUS, WHERE YOU
2 WERE GOING TO INJECT A FEW HUMAN EMBRYONIC STEM CELLS
3 TO DIFFERENTIATE IT TOWARD NEURONAL FEATURES OR
4 DOPAMINE PRODUCING CELLS, YOU WANTED TO SEE IF THEY
5 COULD RESCUE AN ANIMAL THAT HAD BEEN TREATED TO DEVELOP
6 PARKINSON'S, THEN THIS WAS ONE KIND OF THING.

7 IF YOU WERE GOING TO SEE THAT YOU INJECTED A
8 WHOLE LOT OF CELLS AND WERE JUST WONDERING WHERE THEY
9 WENT IN THE BRAIN AND WHAT THEY DID, THAT MIGHT RAISE
10 MORE QUESTIONS. AND THAT THE INVESTIGATOR AND THE
11 ESCRO SHOULD REALLY WORK THESE ISSUES OUT AS TO WHAT IS
12 A REASONABLE WAY TO DO IT. AND, AGAIN, IF AT ALL
13 POSSIBLE, ONE WOULD APPROPRIATELY TRY SOME OF THESE
14 THINGS WITH PRIMATE CELLS TO SEE WHAT HAPPENED IN THE
15 EXPERIMENTAL SITUATION, AND THEN MOVE TO HUMAN CELLS,
16 DEPENDING ON THE ANSWER.

17 CO-CHAIR RABB: OTHER MEMBERS OF THE WORKING
18 GROUP ON THIS QUESTION OF CHIMERIC RESEARCH?

19 DR. KORDOWER: JUST A QUICK POINT ON THE LAST
20 COMMENT. LET ME -- A LOT OF REASONS WHY PEOPLE DON'T
21 USE PRIMATE CELLS TO INJECT INTO PRIMATES IS THEY'RE A
22 LOT MORE DIFFICULT TO GET. THE BREEDING OF MONKEYS TO
23 INJECT INTO MONKEYS IS A VERY DIFFICULT TASK AND ONE
24 THAT A LOT OF PLACES AREN'T SET UP TO DO.

25 DR. PRIETO: POINT OF INFORMATION. WE DO

1 HAVE AT LEAST ONE MAJOR PRIMATE RESEARCH CENTER
2 ASSOCIATED WITH THE UNIVERSITY OF CALIFORNIA. SO SOME
3 OF THESE ISSUES ARE GOING TO COME UP, AND I'M SURE
4 THERE WILL BE PROPOSALS TO DO CERTAIN TYPES OF STEM
5 CELL RESEARCH AT THE CENTER.

6 DR. KORDOWER: TRUE, BUT WHATEVER YOU FIND
7 FROM PRIMATE TO PRIMATE EVENTUALLY HAVE TO BE
8 REPLICATED IN THE HUMAN, SO IT ALMOST SEEMS LIKE IN
9 SOME REGARDS AN APPROPRIATE STEP.

10 DR. PRIETO: THE POINT WAS MADE THAT THERE'S
11 SOME THINGS THAT SHOULD WE WANT TO TRY IN OTHER
12 SPECIES.

13 DR. KORDOWER: I AGREE WITH THAT. I'M NOT
14 SURE THAT THE PRIMATE IS THE RIGHT SPECIES TO TRY THAT.

15 MS. CHARO: THIS WAS EXACTLY THE KIND OF
16 CONVERSATION THAT WAS GOING ON, AND IT ACTUALLY LETS US
17 REITERATE JANET'S POINT, THAT THE INVESTIGATOR WHO
18 COMES FORWARD WITH AN IDEA WHO'S ASKED TO GO TO AN
19 ESCRO FIRST WILL BE ASKED TO DISCUSS WITH PEOPLE WHY HE
20 NEEDS TO DO IT THE PARTICULAR WAY WE WANTS TO DO IT AND
21 ARE THERE ALTERNATIVES. COULD YOU, FOR EXAMPLE, DO
22 THIS WITH PRIMATE ES CELLS INTO A NONPRIMATE SPECIES AS
23 THE FIRST STEP BEFORE YOU USE HUMAN CELLS? COULD YOU
24 USE A PRIMATE ES CELLS INTO PRIMATES FIRST, AND THE
25 ANSWER MAY BE ABOUT THE LOCAL AVAILABILITY OF PRIMATES,

1 OR IT MIGHT BE THAT ANIMAL WELFARE, AND IT MIGHT BE,
2 NO, ACTUALLY THAT'S A GOOD IDEA. WE SHOULD DO IT.

3 VERY HARD TO GIVE FIXED CATEGORIES AHEAD OF
4 TIME FOR EVERY POSSIBLE AREA OF RESEARCH AS OPPOSED TO
5 THIS KIND OF CONVERSATIONAL APPROACH. AT LEAST THAT
6 WAS WHAT STRUCK US.

7 DR. EGGAN: IF I MIGHT INTERJECT, THIS IS A
8 BROADER SUBJECT OF CONVERSATION FOR THIS GROUP, TO WHAT
9 EXTENT THIS WORKING GROUP WANTS TO MICROMANAGE THESE
10 BIG ISSUES AND THE EXTENT TO WHICH THIS GROUP WANTS TO
11 PUT THE POWER TO MAKE THESE DECISIONS IN INSTITUTIONAL
12 HANDS IS AN IMPORTANT ISSUE THAT WE SHOULD DISCUSS.

13 CO-CHAIR RABB: KEVIN, ARE YOU MOVING US TO
14 THE DISCUSSION OF ESCRO'S AND OTHER OVERSIGHT BODIES?

15 DR. EGGAN: I THINK THAT MIGHT NOT BE A BAD
16 THING TO DO.

17 CO-CHAIR RABB: WHY DON'T YOU START US WITH
18 THE PROPOSITION YOU WANT US TO CONSIDER.

19 DR. EGGAN: I THINK THAT, INDEED, AN
20 IMPORTANT PROPOSITION WOULD BE THAT THIS GROUP DEMAND
21 THAT INSTITUTIONS WHICH ARE INVOLVED IN HUMAN EMBRYONIC
22 STEM CELL RESEARCH HAVE AN ES CELL OVERSIGHT COMMITTEE.
23 AND I THINK ONE THING THAT WE COULD RECOMMEND IS WHAT
24 THE CONSTITUENCY OF SUCH A COMMITTEE WOULD BE AND HOW
25 IT SHOULD ACT AND WHAT ITS JURISDICTION WITHIN THAT

1 INSTITUTION IS.

2 MR. KLEIN: KEVIN, ONE OF THE ISSUES THAT HAS
3 COME OUT PREVIOUSLY AT OUR BOARD IS POTENTIALLY SOME
4 INSTITUTIONS ARE NOT LARGE ENOUGH TO HAVE THEIR OWN
5 COMMITTEE, BUT A COLLABORATIVE COMMITTEE IN THE GENERAL
6 REGION WHERE THEY'RE LOCATED. AND DO YOU SEE ANY
7 PROBLEM WITH THAT AS BEING AN EFFECTIVE WAY TO BRING
8 THE EXPERTISE TOGETHER?

9 DR. EGGAN: IT SEEMS REASONABLE. I WOULDN'T
10 SEE ANY PARTICULAR PROBLEM TO THAT AS LONG AS IT WAS
11 CLEAR WHO THEY WERE ANSWERING TO, AND THAT THEY WOULD
12 BE BOUND TO THE DECISION OF THAT GROUP.

13 DR. ROWLEY: THAT WAS ACTUALLY DISCUSSED AT
14 THE ACADEMY, AND THAT WAS THE SOLUTION FOR SMALL
15 INSTITUTIONS WAS TO HAVE REGIONAL OR WHATEVER. IT WAS
16 THOUGHT THAT TO HAVE A SINGLE NATIONAL ESCRO COMMITTEE,
17 PARTICULARLY AT THIS POINT IN TIME, WHEN WE'RE ALL
18 TRYING TO SEARCH FOR ANSWERS, WOULD JUST BE TOO
19 UNWIELDY. WE DO WANT AN OPPORTUNITY FOR THERE TO BE
20 MORE CONVERSATION BETWEEN THE ESCRO COMMITTEE, THE
21 INVESTIGATOR, NOT NECESSARILY A SINGLE INCIDENT, BUT
22 SEVERAL MEETINGS, WHERE YOU TRY TO DEAL WITH THESE
23 ISSUES. SO I THINK THAT A REGIONAL OR CALIFORNIA,
24 THOUGH CALIFORNIA IS SO BIG, YOU'D CERTAINLY PROBABLY
25 WANT SEVERAL.

1 DR. EGGAN: IF I MIGHT RESPOND. I WOULD JUST
2 SAY THAT ALMOST EVERY INSTITUTION, EVEN A SMALL ONE,
3 HAS ITS OWN UNIQUE INSTITUTIONAL ISSUES. AND, INDEED,
4 IT MAY BE A MORE MANEUVERABLE, WORKABLE SYSTEM FOR AN
5 INVESTIGATOR TO BE ABLE TO DEAL WITH A GROUP OF PEOPLE
6 THAT HAS INTIMATE KNOWLEDGE OF THEIR INSTITUTION AND
7 THE OTHER PROCEDURAL ISSUES LIKE IRB ISSUES WHICH ARE
8 UNIQUE TO THEIR OWN INSTITUTION, WHICH MAY OR MAY NOT
9 BE RELEVANT TO A REGIONAL SCALE. SO ALTHOUGH I AGREE
10 THE NEED FOR THIS ESCRO GROUP MAY DEMAND RESOURCES FROM
11 EVEN SMALL INSTITUTIONS, I CAN SEE HOW THERE WOULD BE
12 DESIRE TO HAVE LARGER, BROADER SCALE OVERSIGHT. I'M
13 AFRAID THAT THE FURTHER YOU PULL THAT GROUP AWAY FROM
14 THE INSTITUTION, THE MORE UNWIELDY THAT GROUP WILL BE
15 WITH RESPECT TO THE INVESTIGATOR. AND I THINK THAT
16 THAT'S GOING TO BE ONE OF THE IMPORTANT THINGS HERE IS
17 TO TRY TO KEEP THIS REASONABLE.

18 CO-CHAIR RABB: FOR THE MEMBERS OF THE PUBLIC
19 WHO MAY NOT HAVE ACTUALLY FASTENED ONTO THIS YET, THE
20 EMBRYO STEM CELL OVERSIGHT COMMITTEE WOULD BE TASKED
21 WITH, ESCRO, WILL BE TASKED WITH REVIEWING INDIVIDUAL
22 PROTOCOLS TO ENGAGE IN THE KIND OF CONVERSATION THAT
23 THE COLLEAGUES HERE HAVE SPOKEN ABOUT. SO WHEN YOU'RE
24 THINKING ABOUT HOW THIS SHOULD BE SITUATED, WHO SHOULD
25 BE MAKING THESE REVIEWS, WHAT THEIR INSTITUTIONAL

1 LOYALTIES ARE, WHAT THEIR INSTITUTIONAL INDEPENDENCE
2 IS, WHAT THEIR CAPACITY FOR DISTANCE IS, WHAT THEIR
3 CAPACITY FOR GENUINE UNDERSTANDING AT THE SAME TIME IS,
4 THAT'S WHAT THE REST OF THIS CONVERSATION, AT LEAST FOR
5 A PERIOD OF TIME, WILL BE ABOUT.

6 I HAVE JOSE, SHERRY, I HAVE FRANCISCO AND BOB
7 AND JANET.

8 DR. CIBELLI: SO I WANTED TO KNOW IF THE
9 NATIONAL ACADEMIES ACTUALLY WANTS TO DO THIS ESCRO IS
10 SOMETHING THAT YOU HAVE TO GET APPROVAL BEFORE YOU
11 FUND --

12 CO-CHAIR RABB: I DIDN'T HEAR YOU, THE LAST
13 PART.

14 DR. CIBELLI: SO IT'S SOMETHING THAT WHEN YOU
15 WRITE A GRANT, YOU DON'T HAVE AN IACUC APPROVED
16 PROTOCOL, YOU DON'T GET FUNDS. WOULD THAT BE THE
17 AUTHORITY THAT YOU GIVE TO THE ESCRO GROUPS, THEN, TO
18 HAVE THE INVESTIGATOR TO HAVE TO HAVE A PROTOCOL RUN BY
19 AND APPROVED BY THE ESCRO GROUP AND THEN FUNDS ARE
20 RELEASED? OTHERWISE IT'S JUST AN ACADEMIC EXERCISE AND
21 DOESN'T HAVE ANY POWER.

22 DR. ROWLEY: WELL, I THINK THE ANSWER FROM
23 THE ACADEMIES' POINT OF VIEW WAS THAT THIS SHOULD BE
24 DONE EARLY ON IN THE PROCESS TO BE SURE THAT THE
25 SCIENCE HAD SOME ETHICAL AND SCIENTIFIC MERIT TO IT AND

1 THAT THIS WASN'T ALREADY BEING DONE IN SIX OTHER PLACES
2 OR SOMEBODY ELSE HAD ALREADY PUBLISHED THIS IDENTICAL
3 RESEARCH. SO THAT THE ESCRO IS SUPPOSED TO BE A BOARD
4 OF REALLY WELL -- EXPERTS IN ALL OF THE AREAS THAT ARE
5 REPRESENTED HERE.

6 MS. CHARO: DR. CIBELLI, JUST TO ANSWER YOUR
7 QUESTION QUITE DIRECTLY IN TERMS OF ENFORCEMENT. THERE
8 ARE TWO MECHANISMS OR TEETH THAT ARE ANTICIPATED. FROM
9 THE INSTITUTIONAL POINT OF VIEW, IT'S THE USUAL
10 MECHANISM YOU HAVE FOR REGULATING THE FACULTY, RIGHT.
11 YOU TELL YOUR FACULTY THESE ARE THE RULES; AND IF THEY
12 DON'T FOLLOW THEM, THEN THE INSTITUTION SETS ITS OWN
13 DISCIPLINARY MEASURES.

14 FOR FUNDERS IT IS UP TO FUNDERS WHETHER THEY
15 WANT TO MAKE REVIEW BY AN ESCRO A CONDITION FOR
16 RECEIVING FUNDING. IN ADDITION, JOURNALS, JUST LIKE
17 THEY DO NOW, COULD DECIDE THERE'S A CONDITION OF
18 PUBLICATION. EACH ENTITY IS IN A DIFFERENT PART OF THE
19 FOOD CHAIN FOR THE RESEARCH AND IT'S A DIFFERENT
20 MECHANISM AT THEIR FINGERTIPS.

21 DR. CIBELLI: WELL, I THINK IT'S OUR ROLE
22 HERE TO RECOMMEND WHETHER IT'S GOING TO BE SOMETHING
23 THAT WE HAVE TO EMPOWER OR NOT.

24 MS. CHARO: EXACTLY. THIS GROUP COULD DECIDE
25 WHETHER OR NOT GOING TO AN ESCRO IS A CONDITION FOR

1 RECEIVING PROP 71 FUNDING.

2 DR. HALL: CAN I JUST ADDRESS THIS QUICKLY
3 OUT OF ORDER? IT SEEMS TO ME -- KEVIN MENTIONED ONE
4 THING, AND THAT IS THAT I THINK INSTITUTIONS THAT
5 SUBMIT GRANTS TO US SHOULD HAVE AN ESCRO OR AFFILIATION
6 WITH AN ESCRO. THAT SHOULD BE A CONDITION.

7 NO. 2, I THINK THAT THE ESCRO, LOCAL ESCRO
8 COMMITTEE, SHOULD HAVE SIGNED OFF ON IT BEFORE WE
9 ACCEPT THE APPLICATION EXCEPT UNDER UNUSUAL
10 CIRCUMSTANCES.

11 AND I THINK THERE IS THE SAME KIND OF TENSION
12 HERE THAT ONE OFTEN FINDS IN IRB'S. THAT IS, IS THEIR
13 INTENT TO MAKE SURE THAT THE PATIENT -- HUMAN SUBJECTS
14 PROTECTION IS IN PLACE VERSUS JUDGING THE SCIENCE.
15 THAT'S OFTEN A DIFFICULT TENSION BECAUSE IT'S VERY HARD
16 FOR AN IRB TO BE EXPERT IN EVERY AREA. IN A CERTAIN
17 SENSE, I THINK YOU HAVE TO ASK THAT QUESTION. IN THE
18 OTHER SENSE IT IS OUR JOB AS CIRM TO SAY IS THIS A GOOD
19 EXPERIMENT? HAS IT BEEN WELL PLANNED? HOW DOES IT FIT
20 IN? ALL THE REST KIND OF PEER REVIEW THAT COMES OUT
21 HERE.

22 I THINK IT WILL INEVITABLY BE JUDGED AT BOTH
23 LEVELS, BOTH AT THE INSTITUTIONAL AND HERE, AND THERE
24 IS THAT SORT OF TENSION ALWAYS.

25 CO-CHAIR RABB: LET'S GO BACK. I HAD A

1 FEELING JOSE HAD NOT FINISHED WHAT HE WANTED TO SAY OR
2 WHAT HE WANTED TO ASK. AND IF YOU HAD A VIEW ABOUT THE
3 QUESTION THAT YOU GENEROUSLY ASKED OTHERS TO SPEAK TO,
4 I'D BE INTERESTED TO HEAR YOUR VIEWS.

5 DR. CIBELLI: I WOULD SAY THAT MONEY TALKS.
6 SO IF YOU CAN TIE THE ESCRO APPROVAL TO THE RELEASE OF
7 THE FUNDS, THAT'S THE ONLY WAY YOU CAN ENFORCE IT.

8 CO-CHAIR RABB: GOT IT. SHERRY, YOU HAD A
9 QUESTION.

10 CO-CHAIR LANSING: I'M JUST CONFUSED. YOU
11 ARE GOING TO HAVE AN OVERALL -- I JUST DON'T UNDERSTAND
12 IT. YOU'RE GOING TO HAVE AN OVERALL INDEPENDENT
13 OVERSIGHT COMMITTEE, SO TO SPEAK. YOU'RE GOING TO HAVE
14 LOCAL ESCRO'S, WHICH MEANS THAT PEOPLE ARE GOING TO BE
15 DOING RESEARCH IN ONE PART OF THE STATE THAT THEY
16 COULDN'T DO IN ANOTHER PART OF THE STATE?

17 MS. CHARO: IT IS STILL A QUESTION WHETHER OR
18 NOT ESCRO'S WILL BE UNIQUE TO EACH INSTITUTION OR
19 INSTITUTIONS WOULD LIKE TO BAND TOGETHER TO SHARE ONE
20 FOR A REGION, FOR A CITY. OR YOU COULD CHOOSE TO HAVE
21 ONE THAT OPERATES FOR ALL PROP-71 FUNDED RESEARCH.
22 THESE ARE ALL OPTIONS.

23 I THINK KEVIN WAS ALREADY BEGINNING TO
24 OUTLINE SOME OF THE PROS AND CONS THAT HAVE BEEN
25 IDENTIFIED IN THE IRB WORLD OF LOCAL VERSUS CENTRALIZED

1 REVIEW.

2 CO-CHAIR LANSING: I DID UNDERSTAND IT. WHAT
3 I'M AFRAID OF IS THAT WE'RE ONE STATE. WE VOTED FOR
4 SOMETHING AS ONE GROUP. AND IF WE STARTED HAVING, YOU
5 KNOW, IN SOUTHERN CALIFORNIA YOU COULD DO THIS, IN
6 NORTHERN CALIFORNIA YOU COULD DO THIS, I JUST THINK IT
7 WOULD CREATE A KIND OF UNNECESSARY TENSION UNLESS I
8 JUST DON'T UNDERSTAND IT.

9 DR. PRIETO: I THINK MY UNDERSTANDING IS THAT
10 THE ESCRO IN A SENSE WOULD BE A PRELIMINARY STEP. WE
11 WOULD EXPECT BEFORE PROPOSALS WERE BROUGHT FORWARD TO
12 US AND THAT IN A WAY WE WOULD BE DELEGATING SOME OF THE
13 ENFORCEMENT OF GUIDELINES TO ESCRO'S. THAT IS, WE
14 WOULD EXPECT THAT YOU WOULD HAVE TAKEN CARE OF A, B,
15 AND C AT YOUR INSTITUTIONAL LEVEL OR PERHAPS WITHIN THE
16 GROUPS OF INSTITUTIONS. I THINK THE OTHER -- ACTUALLY
17 THE POINT I WANTED TO MAKE IN FAVOR PERHAPS OF GROUPS
18 OF INSTITUTIONS DOING THIS IS THAT ONE ADVANTAGE WE
19 MIGHT SEE WOULD BE INSULATING THE ESCRO FROM
20 INSTITUTIONAL PRESSURES, WHICH PARTICULARLY IN A SMALL
21 INSTITUTION MIGHT BE CONSIDERABLE.

22 DR. CIBELLI: I GUESS WE AS COMMITTEE, WE
23 HAVE TO DECIDE IF ESCRO'S ARE A GOOD IDEA FOR
24 CALIFORNIA OR NOT AND THEN MOVE FORWARD. I DON'T KNOW,
25 ALTA, YOU DIDN'T SUMMARIZE WHAT THE ROLE OF THE ESCRO

1 WOULD BE. VERY GENERAL, BUT I'D LIKE TO KNOW MORE
2 SPECIFICS.

3 MS. CHARO: SURE. YOU'RE RIGHT. THE
4 STANDARDS THAT YOU CHOOSE ARE RELATED TO WHO'S
5 ENFORCING THEM. THE ESCRO IS IMAGINED AS A KIND OF
6 GENERALIZED BODY THAT SERVES THE FOLLOWING FUNCTIONS:
7 IT IS THE PLACE YOU GO IF YOU WANT TO DERIVE NEW LINES
8 BECAUSE YOU HAVE TO EXPLAIN WHY IT IS THAT THE OLD
9 LINES ARE NOT ADEQUATE. THIS WAS A WAY TO MAKE SURE
10 THAT EMBRYOS -- WE'RE TALKING MORE GENERALLY NOT ABOUT
11 EGG DONATION, JUST EMBRYOS -- ARE NOT DESTROYED FOR
12 FRIVOLOUS REASONS. AND THIS IS A GENUINE GESTURE OF
13 RESPECT FOR THE DEPTH OF THE DEBATE AROUND THE SUBJECT.

14 SECOND, THEY EXIST TO DO AD HOC REVIEW OF
15 THOSE LABORATORY EXPERIMENTS THAT RAISE SPECIAL
16 CONCERNS. AND THAT'S WHY WE WENT THROUGH THE
17 DISCUSSION ABOUT CHIMERAS, WHICH WAS IDENTIFIED. THE
18 SECOND AREA OF POTENTIAL SPECIAL CONCERN HAS TO DO WITH
19 CELL LINES THAT STILL HAVE IDENTIFIERS THAT LINK BACK
20 TO THE ORIGINAL DONORS. THAT'S MORE COMPLICATED. I
21 WON'T GO INTO DEPTH BECAUSE IT HAS IMPLICATIONS FOR IRB
22 REVIEW AND HIPAA REVIEW, ETC., BUT THAT WAS ANOTHER ONE
23 THAT WAS IDENTIFIED AS APPROPRIATE FOR SPECIAL ESCRO
24 ATTENTION. IF YOU'RE GOING TO USE IDENTIFYING LINES,
25 PLEASE COME TO US AND CHAT.

1 THIRD, THE ESCRO WAS A PLACE WHERE YOU WOULD
2 SLOWLY ACCUMULATE EXPERIENCE IN RECOGNIZING THE
3 EXPERIMENTS THAT SEEMED TO FALL WITHIN THE CRACKS OF
4 ALL THESE THINGS AND BEGIN TO FIGURE OUT WHERE YOU'RE
5 GOING TO NEED TO REVISE OR EXTEND THESE EXISTING SETS
6 OF STANDARDS.

7 AND FINALLY, IT'S THE BODY THAT WILL ACTUALLY
8 SAY NO TO A VERY LIMITED RANGE OF EXPERIMENTS, SUCH AS
9 THE USE OF NEW ES CELLS IN A NONHUMAN PRIMATE
10 BLASTOCYST.

11 THOSE WERE ITS GENERAL FUNCTIONS. IT WAS
12 ALSO ANTICIPATED THAT IT MIGHT POSSIBLY SERVE AS A
13 FORUM FOR FURTHER PUBLIC DISCUSSION, DEBATE,
14 CONFERENCES, ETC. THAT WAS NOT ITS PRIMARY PURPOSE.

15 PLEASE UNDERSTAND IT'S NOT SUPPOSED TO BE
16 THERE AS A KIND OF PEER REVIEW COMMITTEE LOOKING AT THE
17 VALUE OF YOUR SCIENCE INDEPENDENT OF THE SPECIFIC
18 QUESTION BEFORE THEM, WHICH IS WHY DO YOU NEED TO
19 DERIVE NEW LINES INSTEAD OF USING AN OLD ONE, OR WHY DO
20 YOU NEED TO USE AN IDENTIFIED LINE INSTEAD OF AN
21 UNIDENTIFIED LINE. SO THEY'RE SUPPOSED TO BE LIKE A
22 SUPER NSF OR SUPER NIH.

23 THE QUESTIONS ABOUT SCIENTIFIC MERIT COME UP
24 ONLY WHEN THEY'RE TIED DIRECTLY TO THE QUESTION ABOUT
25 WHETHER OR NOT THE EXPERIMENT ITSELF IS JUSTIFIED FOR

1 THIS ONE.

2 DR. ROWLEY: THERE WERE A COUPLE OF OTHER
3 ISSUES FOR ESCRO'S. ONE IS AS MORE AND MORE
4 INSTITUTIONS OR INVESTIGATORS IN INSTITUTIONS IMPORT
5 CELL LINES FROM OUTSIDE, YOU WANT TO BE SURE THAT THESE
6 HAVE ACTUALLY BEEN OBTAINED WITH APPROPRIATE DONOR
7 CONSENT AND THAT YOU REALLY KNOW THAT THERE WAS
8 INFORMED, VOLUNTARY DONATION OF ALL OF THE INVOLVED
9 INDIVIDUALS. AND SO THE ESCRO WOULD BE THE GROUP
10 WITHIN AN INSTITUTION THAT WOULD MONITOR OUTSIDE CELL
11 LINES BEFORE THEY WERE IMPORTED.

12 AND ALSO, WE THOUGHT THE ESCRO COULD SERVE AS
13 A REGISTRY FOR CELL LINES IN AN INSTITUTION, THOSE THAT
14 WERE DEVELOPED IN AN INSTITUTION, THOSE THAT WERE
15 IMPORTED FROM OTHER INSTITUTIONS, AND THE INVESTIGATORS
16 WHO WERE INVOLVED. SO IF SOMEBODY, FOR INSTANCE, IN
17 CALIFORNIA, IF A LEGISLATOR GOES TO UCSF AND SAYS HOW
18 MANY CELL LINES DO YOU HAVE AND WHO'S DOING WHAT, THE
19 ESCRO WOULD BE THE REGISTRY WHERE THIS INFORMATION
20 WOULD BE AVAILABLE.

21 AND I THINK AS MORE CELL LINES ARE AVAILABLE,
22 AS THEY COME FROM MANY DISPARATE SOURCES WITH MANY
23 DIFFERENT FORMS OF CONSENT, IT'S GOING TO BE EXTREMELY
24 IMPORTANT THAT EACH INSTITUTION FOR ITS OWN PROTECTION
25 HAVE THESE MECHANISMS WELL IN PLACE.

1 CO-CHAIR RABB: I'M GOING TO PUT JOSE AND
2 SHERRY BACK ON THE LIST, BUT WE HAVE HAD PATIENT
3 WAITING BY FRANCISCO, BOB, JANET, AND BERNIE.

4 DR. PRIETO: THANK YOU.

5 CO-CHAIR RABB: YOU'RE DONE? YOUR TURN.

6 MR. KLEIN: THREE QUICK COMMENTS. KEVIN MADE
7 THE POINT QUITE PROPERLY THAT SOME OF THESE
8 INSTITUTIONS ARE SO LARGE ON THEIR OWN, THEY DON'T
9 REALLY NEED TO BE IN A REGIONAL AGGREGATION. AND WHAT
10 WAS DISCUSSED WAS AN OPTION EITHER TO ACT, IF THEY MET
11 CERTAIN STANDARDS, TO EITHER ACT THROUGH THEIR
12 INSTITUTIONAL GROUP OR THROUGH AN AGGREGATION OF
13 SEVERAL INSTITUTIONS SO THAT WE DON'T ENCUMBER AN
14 ALREADY HIGHLY COMPETENT, FULLY SCOPED INSTITUTIONAL
15 REVIEW PROCESS WITH ANOTHER REQUIREMENT TO JOIN IN WITH
16 OTHER INSTITUTIONS.

17 SECONDLY, WE HAVE IMPORTANT ISSUES HERE THAT
18 WE MADE IT CLEAR IN ADOPTING THESE GUIDELINES, THAT
19 WE'RE ADOPTING THEM PROSPECTIVELY BECAUSE WE CERTAINLY
20 HAVE CELL LINES THAT WERE DERIVED POTENTIALLY WITH
21 COMPENSATION. AND IT WAS OUR INTENT IN DEALING WITH
22 THE ISSUE OF OUR STANDARDS, THAT SOME OF OUR STANDARDS
23 MAY WELL BE STATE SPECIFIC AS, FOR EXAMPLE, THE
24 COMPENSATION ISSUE. BUT THAT DOESN'T STOP OUR
25 RESEARCHERS FROM USING BIOLOGICAL MATERIALS FROM OTHER

1 STATES, WHICH IS AN ISSUE WE NEED TO ADDRESS.

2 AND CERTAINLY THE NEXT LAYER OF THAT IS THAT
3 THERE ARE STANDARDS AND CULTURAL DIFFERENCES BETWEEN
4 COUNTRIES. AND WHAT IS OUR POSITION AS TO MATERIAL
5 FROM INDIA OR SINGAPORE OR CHINA OR KOREA WHERE
6 DIFFERENT STANDARDS, QUITE APPROPRIATE AND THOUGHTFULLY
7 PUBLICLY REVIEWED IN THEIR COUNTRY, MAY HAVE BEEN
8 ADOPTED. AND WILL WE RESPECT THEIR CULTURE AND THEIR
9 STANDARDS AND THEIR PROCESS SO THAT OUR RESEARCHERS CAN
10 BENEFIT FROM THAT?

11 THOSE ARE ISSUES HOPEFULLY WE WILL GET TO
12 HERE AT SOME POINT, BUT IT CERTAINLY SHOULD BE WITHIN
13 THE SCOPE OF WHAT WE DISCUSS. IT COULD BE THAT WE
14 ALLOW THESE INSTITUTIONAL ESCRO'S TO DEAL WITH THOSE
15 ISSUES. IT COULD BE THAT WE SET STANDARDS ON THE STATE
16 BASIS.

17 CO-CHAIR RABB: JANET, I HAD YOU NEXT.

18 DR. ROWLEY: WELL, I JUST WANTED TO MAKE TWO
19 OTHER POINTS. ONE, WE DID TRY TO DEFINE AND
20 DISTINGUISH THE FUNCTIONS OF THE IRB AND THE ESCRO,
21 SAYING THAT THE IRB WAS THE PLACE WITHIN AN INSTITUTION
22 WHERE THE -- WHICH REVIEWED PATIENT CONSENT FORMS AND
23 MADE SURE THAT ALL OF THE APPROPRIATE GUIDELINES FOR
24 DERIVING ANY EXPERIMENT USING GAMETES OR CELLS OR
25 EMBRYOS WAS APPROPRIATELY DONE. SO THAT WAS THE

1 FUNCTION OF THE IRB, WHICH IS WHAT IT IS RIGHT NOW IN
2 TERMS OF HUMAN PROTECTION AND ALSO BOTH INSTITUTIONALLY
3 AND LEGALLY THEY'RE RESPONSIBLE FOR REVIEWING THAT,
4 THINKING THAT THE ESCRO IS GOING TO DEAL WITH OTHER
5 ISSUES THAT WERE IMPORTANT.

6 IN THE ACADEMY REPORT WE DID ALSO RECOGNIZE
7 THAT DIFFERENT ESCRO'S ARE GOING TO COME TO DIFFERENT
8 ANSWERS ON THE SAME QUESTION AND THOUGHT THAT IT WOULD
9 BE IMPORTANT TO TRY TO SEE IF IT WAS POSSIBLE TO
10 DEVELOP, SAY, A NATIONAL OVERSIGHT BODY WHERE ESCRO
11 MEMBERS COULD COME OR WHERE THESE ISSUES COULD BE
12 RAISED FOR LARGER DISCUSSION, HOPING FOR CONSISTENCY
13 BECAUSE THE LAST THING THAT WE NEED IN THIS AREA IS TO
14 HAVE A CANNIBALIZATION OR VULCANIZATION OF RESEARCH
15 ACROSS THE COUNTRY.

16 SO IT WAS ENVISIONED THAT WE WOULD HAVE SOME
17 LARGER GROUP. CERTAINLY WITHIN CALIFORNIA, IF YOU HAVE
18 TWO DOZEN ESCRO'S, YOU COULD CERTAINLY SET UP SOME SORT
19 OF A FORUM WHERE PEOPLE JUST GET TOGETHER AND SAY THIS
20 IS THE PROBLEM WE'RE HAVING. THIS IS OUR ANSWER.
21 WHAT'S YOUR ANSWER? WHY? AND DISCUSS IT.

22 CO-CHAIR RABB: ONE OF THE THINGS THAT YOU
23 MIGHT BE DISCUSSING WOULD BE SOME FORM OF FUNDING THAT
24 WOULD FACILITATE MEETINGS IF THERE ARE INSTITUTIONAL
25 ESCRO'S AS OPPOSED TO REGIONAL OR STATE, ONE STATEWIDE,

1 THAT WOULD FACILITATE MEETINGS AMONG ESCRO MEMBERS FOR
2 SOME PERIOD OF TIME UNTIL THERE IS A SORT OF
3 JURISPRUDENCE OF THE ESCRO'S THAT EVERYBODY UNDERSTOOD.
4 SO THINK ABOUT A FUNDING AGENCY FOR CIRM.

5 MR. KLEIN: MADAM CHAIR, COULD DR. HALL
6 COMMENT ON THE POTENTIAL ROLE OF THE NATIONAL ACADEMIES
7 IN THIS PROCESS?

8 DR. HALL: LET ME CHEAT AND TAKE ADVANTAGE OF
9 BEING RECOGNIZED TO MAKE SEVERAL POINTS, WHICH THAT
10 WILL BE ONE. I WANT TO COME BACK TO SHERRY'S POINT. I
11 THINK IT'S A VERY IMPORTANT ROLE THE COMMITTEE WILL
12 PLAY.

13 FIRST OF ALL, WE'RE FAMILIAR WITH MANY OF
14 THESE PROBLEMS FROM IRB'S WHERE EACH INSTITUTION HAS
15 THEIR OWN IRB, BUT ONE DIFFICULTY CERTAINLY, AS A
16 FORMER ADMINISTRATOR THAT I FOUND, WAS THAT -- LET ME
17 BACK IT UP AND PUT IT ANOTHER WAY. I THINK THE CIRM
18 CAN PLAY A VERY USEFUL ROLE IN TRYING TO MAKE SURE THAT
19 THERE ARE NO BARRIERS BETWEEN ESCRO'S. AND I KNOW
20 TRYING TO GET STANFORD AND USCF TO SIGN AN AGREEMENT
21 THAT THEY WOULD EACH RECOGNIZE THE OTHER'S IRB APPROVAL
22 FOR COLLABORATIVE RESEARCH TOOK PROBABLY THREE YEARS TO
23 NEGOTIATE. I THINK IF WE COULD PLAY A ROLE IN THAT, I
24 THINK IT COULD BE VERY USEFUL IN TRYING TO SET THOSE
25 STANDARDS.

1 THE OTHER THING IS THAT I THINK THE CIRM ALSO
2 IS A VERY NATURAL PLACE. WE MIGHT BE THE ONE TO CALL
3 THE MEETINGS OF THE CHAIRS OF THE ESCRO COMMITTEES
4 THROUGHOUT THE STATE TO DISCUSS COMMON PROBLEMS AND
5 SORT OF KEEP EVERYBODY IN TOUCH WITH EACH OTHER. I
6 THINK THAT'S VERY IMPORTANT AS WELL.

7 FINALLY, ON THE NATIONAL ACADEMY QUESTION
8 WHICH I WAS ASKED, I SENT A LETTER ON BEHALF OF CIRM
9 SUGGESTING THAT THE NATIONAL ACADEMY BE THE APPROPRIATE
10 PLACE FOR THAT NATIONAL COMMITTEE. AS JANET AND ALTA
11 KNOW AND PERHAPS OTHERS AS WELL, ALTHOUGH THEY
12 RECOMMENDED THAT THERE BE A NATIONAL COMMITTEE, IT WAS
13 NOT CLEAR WHERE IT SHOULD BE. ALTHOUGH I KNOW THERE IS
14 SOME DISCUSSION ABOUT THIS, IT SEEMS FOR THE MOMENT
15 THAT THE NATIONAL ACADEMY IS THE BEST PLACE, LET ME PUT
16 IT THAT WAY. AND SO WE HOPE THAT WHAT WE DO IN
17 CALIFORNIA WILL ALSO THROUGH THAT COMMITTEE BE
18 COORDINATED WITH OTHER EFFORTS IN OTHER STATES.

19 CO-CHAIR RABB: I HAVE BERNIE, JOSE, SHERRY,
20 AND ANN.

21 DR. LO: THERE ARE ALWAYS A NUMBER OF ISSUES
22 TO COME UP WHENEVER ONE TALKS ABOUT RESEARCH OVERSIGHT.
23 AS I TRY AND ABSORB WHAT ALTA AND JANET HAVE TOLD US
24 ABOUT THE NAS REPORT, IT SEEMS TO ME WE CAN THINK ABOUT
25 WHAT ARE THE FUNCTIONS THAT WE ARE SUPPOSED TO FULFILL.

1 AND IT STRIKES ME THEY'RE VERY HETEROGENEOUS. SOME
2 REALLY ARE POLICY ISSUES, IT STRIKES ME. WHAT'S
3 INSTITUTIONAL POLICY GOING TO BE. SOME OF IT IS
4 RECORDKEEPING OF THE REGISTRY, AND SOME IS, I THINK, A
5 CASE-BY-CASE, PROTOCOL-BY-PROTOCOL ANALYSIS OF THE
6 TOUGH ISSUES.

7 AND I GUESS ONCE I LOOK AT FUNCTIONS, I
8 ALWAYS ASK WHAT'S THE BEST PERSON OR BEST GROUP OR THE
9 BEST PROCEDURE FOR CARRYING OUT THAT FUNCTION. IT
10 ISN'T CLEAR TO ME THAT THE SAME GROUP SHOULD BE THE ONE
11 DOING ALL THOSE DIFFERENT THINGS. SO I'D LIKE TO SORT
12 OF THINK THROUGH A BIT MORE SORT OF THE FUNCTIONS THIS
13 IS SUPPOSED FULFILL AND WHETHER THAT'S THE RIGHT
14 STRUCTURE.

15 I ALSO THINK WE NEED TO LOOK AT WHAT ARE THE
16 BENEFITS AND BURDENS OF ANY ADDITIONAL OVERSIGHT THAT
17 WE CREATE. ALREADY THERE'S A LOT OF OVERSIGHT.
18 THERE'S OVERLAPPING OVERSIGHT. AND I GUESS THE
19 QUESTION IS WOULD THE ADDITIONAL OVERSIGHT THAT ANY NEW
20 BODY WOULD GIVE, IS IT WORTH IT? WHAT DO WE GAIN FROM
21 IT? AND WHAT ARE THE POTENTIAL BURDENS IN TERMS OF
22 COST DELAYS, INCONSISTENCY, OR WHATEVER?

23 AND I THINK THAT'S A TRICKY QUESTION BECAUSE
24 SOME OVERLAP IS USEFUL, AND TOO MUCH OVERLAP IS
25 STIFLING. SO, AGAIN, AS I LOOK AT SOME OF THE THINGS,

1 THESE FUNCTIONS, IT STRIKES ME THAT SOME OF THESE
2 TASKS, FOR INSTANCE, IS IT REALLY JUSTIFIED TO DERIVE A
3 NEW CELL LINE? DO WE REALLY NEED THIS NEW CELL LINE?
4 DO WE REALLY NEED TO DO THIS ANIMAL STUDY THAT RAISES
5 SPECIAL CONCERNS? COULD YOU USE AN ALTERNATIVE DESIGN
6 THAT'S NOT QUITE AS ETHICALLY TROUBLESOME?

7 IT STRIKES ME THAT THOSE JUDGMENTS REQUIRE
8 IN-DEPTH SCIENTIFIC REVIEW AS WELL AS ETHICAL ANALYSIS.
9 AND A LOT OF THE GRANTS THAT WE SEND OUT TO NIH, WHICH
10 ARE EXTENSIVELY FOR SCIENTIFIC REASONS, ACTUALLY COME
11 BACK WITH A LOT OF ETHICAL CRITICISM. WE'VE DONE A
12 NUMBER OF GRANTS THAT COME BACK SAYING SCIENTIFICALLY
13 WE THINK IT'S OKAY, BUT WE THINK IT'S UNACCEPTABLE FOR
14 ETHICS BECAUSE OF SUBJECTS CONCERNS, CONSENT ISSUES,
15 AND THE LIKE. SO I GUESS I THINK WE ALL SEEM TO THINK
16 ABOUT TO WHAT EXTENT DO WE WANT THE CIRM REVIEW
17 PROCESS, WHICH STRIKES ME WE'RE GOING TO DO THE REALLY
18 IN-DEPTH, VERY CRITICAL SCIENTIFIC ANALYSIS, DO WE ALSO
19 WANT THEM TO BE ABLE TO OR TO EXPECT THEM TO MAKE SOME
20 JUDGMENT ABOUT SOME OF THE ISSUES ALTA LAID OUT IN
21 TERMS OF THE JUSTIFICATION FOR NEW LINES, DERIVING NEW
22 STEM CELL LINES?

23 SO I THINK, YOU KNOW, IT'S HARD TO GET AROUND
24 THIS BECAUSE THE PROTOCOLS ARE GOING TO BE DIFFERENT,
25 BUT WE CAN MAKE MISTAKE BY HAVING TOO MUCH NEW

1 OVERSIGHT AS WELL AS TOO LITTLE OVERSIGHT.

2 I WANTED TO JUST ADD ANOTHER QUESTION WHICH
3 IS THE CONCERN SINCE HEALTH ISSUES REQUIRE A LOT OF
4 EXPERTISE, AND IT'S NOT CLEAR TO ME HOW MANY PEOPLE
5 THERE ARE IN THE STATE AND COUNTRY THAT REALLY WOULD BE
6 THE KINDS OF EXPERTS YOU WANT. AS I LOOK AROUND THIS
7 TABLE, THIS IS A GREAT COMMITTEE. I'VE LEARNED SO MUCH
8 FROM MY COLLEAGUES. HOW MANY OTHER PEOPLE ARE LIKE
9 THAT THAT COULD POPULATE ALL THE ESCRO'S AROUND
10 INSTITUTIONS? AND THERE NEEDS TO BE SOME WAY OF SORT
11 OF LEARNING FROM CASES THAT OTHER ESCRO'S AND
12 INSTITUTIONS HAVE FACED.

13 BOB KLEIN OR ZACH OR SOMEBODY MADE THE
14 SUGGESTION THAT YOU WANT TO GET THE CHAIRS OF THESE
15 ESCRO'S TOGETHER TO TALK ABOUT THEIR TOP CASES AND
16 THINK THEM THROUGH. I THINK THAT'S CERTAINLY
17 IMPORTANT, BUT ALSO IT STRIKES ME THAT THE COMMON LAW
18 WORKS BY SORT OF ASKING THE JUDGE OR THE APPELLATE
19 COURT TO WRITE AN OPINION THAT LAYS OUT THE ARGUMENTS,
20 WHAT THEY CONSIDERED, WHY THEY DECIDED ONE WAY OR THE
21 OTHER. IRB'S DON'T HAVE TO DO THAT. I DON'T KNOW IF
22 ESCRO'S ARE GOING TO BE ASKED TO DO THAT, BUT IT
23 STRIKES ME THE KIND OF LAYING OUT THE DATA, THE
24 ARGUMENTS OF HOW YOU PUT THEM TOGETHER WOULD BE VERY
25 USEFUL TO SORT OF HELP THE NEXT ESCRO DEAL WITH THAT.

1 AND IF THERE'S A WAY OF LEAVING THAT KIND OF HISTORY OF
2 DELIBERATIONS IN PLACE THAT ANOTHER INVESTIGATOR, IRB,
3 ESCRO COULD GO TO THAT WOULD BE VERY USEFUL. PERHAPS
4 CIRM COULD PLAY SOME ROLE IN THAT.

5 CO-CHAIR RABB: VERY INTERESTING. I HAVE
6 JOSE, SHERRY, AND KEVIN.

7 DR. CIBELLI: JUST QUICKLY TO SAY THAT
8 SOMEONE MENTIONED THAT BEFORE THE PROPOSAL IS SUBMITTED
9 TO THE CIRM FOR FUNDING, THEY SHOULD HAVE AN ESCRO.
10 EVEN IF WE DECIDE THAT ESCRO IS THE WAY TO GO, APPROVAL
11 LETTER OR SOMETHING OF THAT NATURE, THAT WOULD TAKE
12 FOREVER. I WOULD SAY THAT THEY SHOULD JUST SEND THE
13 PROPOSAL PENDING APPROVAL FROM THE ESCRO.

14 CO-CHAIR RABB: IT COULD BE LIKE WHAT WE DO
15 AT NIH ON CONFLICT OF INTEREST. YOU TELL THEM YOU'VE
16 GOT A CONFLICT, BUT YOU CAN'T SPEND THE MONEY UNTIL
17 YOU'VE MANAGED IT. SAME KIND OF SYSTEM YOU -- YOU
18 REPORT THAT YOU'RE GOING TO GO AND GET YOUR FUNDING,
19 BUT YOU CAN'T SPEND IT UNTIL YOU FINISH THE PROCESS.

20 DR. TAYLOR: A JUST-IN-TIME PROCESS.

21 CO-CHAIR RABB: SHERRY.

22 CO-CHAIR LANSING: I'VE BEEN LISTENING VERY
23 CAREFULLY, AND A LOT OF MY CONCERNS HAVE BEEN
24 ADDRESSED, BUT JUST WANT TO KIND OF VOICE AGAIN WHAT
25 I'M WORRIED ABOUT. I THINK THERE IS A NEED FOR AN

1 OVERALL ESCRO FOR THE STATE. DO YOU KNOW? I MEAN WE
2 ARE ONE STATE. WE VOTED THIS BILL THROUGH AS A BODY.
3 AND I DON'T MIND LOCAL ESCRO'S THAT IMPLEMENT THE WILL
4 OF THE OVERALL ESCRO, BUT WHAT I'M TERRIFIED OF, I HAVE
5 TO SAY, AND JANET ALLUDED TO IT, IS AN INCONSISTENCY
6 AMONG THE STATES. I'M JUST TERRIFIED THAT ONE GROUP
7 WILL SAY THIS IS OKAY AND ANOTHER GROUP WILL SAY THIS
8 IS OKAY, AND IT'S KIND OF A COMPETITION BETWEEN
9 INSTITUTIONS THAT IS AN UNHEALTHY COMPETITION.

10 AND I THINK WE'RE ENTERING A NEW FIELD, AND I
11 THINK THAT WE NEED CONSISTENCY. NOW, WE CAN CHANGE OUR
12 VIEWS ON CERTAIN THINGS AS WE GO ALONG, BUT I THINK
13 INITIALLY WE NEED TO START OUT WITH AN OVERALL POLICY.

14 MR. SHESTACK: DID YOU SAY WITHIN THE STATES
15 OR BETWEEN STATES?

16 CO-CHAIR LANSING: WITHIN THE STATE. RIGHT
17 NOW THAT'S ALL THAT I CAN DEAL WITH IS THE STATE.
18 OTHER STATES CAN HAVE THEIR OWN POLICIES, BUT WE HAVE
19 TO HAVE CONSISTENCIES WITHIN OUR STATE AND WITHIN OUR
20 INSTITUTIONS.

21 DR. HALL: THAT'S THE JOB OF THIS WORKING
22 GROUP, TO PLAY EXACTLY THAT ROLE.

23 CO-CHAIR LANSING: THAT'S ALL I'M SAYING. I
24 GET NERVOUS. I'M JUST LISTENING. I GET NERVOUS, AND
25 THAT'S WHAT I WAS INITIALLY SAYING. WITH LOCAL ESCRO'S

1 MAKING UP THEIR OWN POLICY RATHER THAN IMPLEMENTING AN
2 OVERALL POLICY.

3 DR. CIBELLI: SO YOUR QUESTION IS WHETHER
4 WE'RE GOING DELEGATE THAT TO THE LOCAL ESCRO'S, OR THIS
5 IS GOING TO BE THE ROLE OF THIS COMMITTEE.

6 CO-CHAIR LANSING: I THINK IT SHOULD BE THE
7 ROLE OF THIS GROUP. I THINK WE SHOULD HAVE AN
8 OVERALL -- EITHER IT'S JUST THIS GROUP --

9 DR. CIBELLI: HOW MANY MEETINGS A YEAR YOU
10 ARE THINKING ABOUT?

11 CO-CHAIR LANSING: WHAT?

12 DR. CIBELLI: HOW MANY MEETINGS WILL YOU BE
13 HAVING?

14 CO-CHAIR RABB: WHY DON'T WE TAKE THIS UP IN
15 TURN.

16 CO-CHAIR LANSING: ALL I WANT TO DO IS --
17 THAT'S FINE -- I JUST AM TERRIFIED THAT WITHIN THIS
18 STATE, AND THAT'S ALL I'M CONCERNED ABOUT AT THE
19 MOMENT, THAT WE'RE GOING TO HAVE DIFFERENT POLICIES FOR
20 DIFFERENT INSTITUTIONS WHICH WOULD LEAD TO A HIGHLY
21 UNHEALTHY THING; WHEREAS, I THINK WE HAVE A
22 RESPONSIBILITY TO HAVE AN OVERALL ESCRO, BUT MAYBE
23 LOCAL ONES THAT IMPLEMENT IT BECAUSE YOU'RE SAYING
24 ABOUT RECORDING CERTAIN THINGS AND STUFF LIKE THAT.

25 CO-CHAIR RABB: I THINK EVERYBODY WANTS TO

1 RESPOND TO THIS PARTICULAR POINT, SO STAYING ON THIS
2 POINT, LET'S DO IT IN THE ORDER OF ANN, KEVIN, ALTA,
3 AND FRANCISCO.

4 DR. KIESSLING: I ACTUALLY WANTED TO MAKE AN
5 ARGUMENT THAT CALIFORNIA DOES NOT NEED AN ESCRO. I
6 THINK THAT THIS GUIDELINE WAS PUT IN PLACE BY THE
7 NATIONAL ACADEMY TO MAKE UP FOR DEFICITS THAT ARE IN
8 THE IRB'S. AND THIS IS REMINISCENT OF THE OLD
9 RECOMBINANT DNA COMMITTEES THAT USED TO EXIST WHEN WE
10 DIDN'T UNDERSTAND RECOMBINANT DNA, AND YOU HAD TO HAVE
11 YOUR RESEARCH REVIEWED BY THEM.

12 BUT CALIFORNIA HAS IN PLACE AN INSTITUTE.
13 MASSACHUSETTS IS GOING TO NEED AN ESCRO BECAUSE WE
14 DON'T HAVE AN OVERARCHING BODY. BUT YOU HAVE AN
15 OVERARCHING BODY THAT'S GOING TO REVIEW THESE PROPOSALS
16 AS THEY COME TO YOU. AND I'M NOT SURE THAT IN
17 CALIFORNIA THAT ISN'T GOING TO SERVE THE PURPOSE THAT
18 THE NATIONAL ACADEMY MEANT. THE NATIONAL ACADEMY
19 WANTED SOMEBODY -- SOME EXPERTISE IN PLACE THAT HAD TO
20 DO WITH STEM CELLS. YOU'VE CREATED THAT ENTITY.

21 SO IT SEEMS TO ME AS THOUGH IN CALIFORNIA THE
22 PEOPLE WHO ARE REVIEWING THE GRANT APPLICATIONS
23 THEMSELVES ARE GOING TO BE THE ONES QUALIFIED TO SERVE
24 THIS FUNCTION.

25 CO-CHAIR LANSING: WE'LL HAVE CONSISTENT

1 RULES. THIS GROUP IS GOING TO COME UP WITH GUIDELINES,
2 ETC.

3 DR. KIESSLING: THAT DOESN'T REPLACE THE IRB.
4 INSTITUTION IS GOING TO HAVE TO HAVE SOME KIND OF IRB
5 REVIEW. WHETHER OR NOT THE QUESTIONS THAT YOU ARE
6 ASKING ABOUT THE STEM CELL SPECIFIC PART OF THE
7 PROJECT, IT SEEMS TO ME LIKE YOU'RE GOING TO HAVE THE
8 EXPERTISE ON YOUR COMMITTEE.

9 DR. EGGAN: THIS REMINDS ME OF THAT SCENE IN
10 JERRY MAGUIRE AND DECIDING WHO GETS RUN WHAT EVENT. WE
11 ARE THE COMMITTEE.

12 CO-CHAIR LANSING: I DIDN'T PRODUCE IT. LET
13 ME FOR THE RECORD, I WAS AT FOX. I DON'T WANT TO TAKE
14 CREDIT.

15 DR. EGGAN: I THINK THAT AT LEAST FOR THAT
16 RESEARCH WHICH IS FUNDED BY THE CIRM, WE HAVE -- THIS
17 GROUP COULD SORT OF REASONABLY ASK AT LEAST A GROUP
18 THAT DOES, AS YOU SUGGEST, PUBLISH WHAT SHOULD BE THE
19 MINIMAL CONSTRAINTS. AND IF INSTITUTIONS WANT TO
20 INSTILL ADDITIONAL CONSTRAINTS, THEN THEY SHOULD FEEL
21 FREE TO DO THAT. IT DOESN'T SEEM LIKE THIS GROUP WOULD
22 HAVE JURISDICTION OVER THOSE THAT OPERATE OUTSIDE
23 FUNDING FROM CIRM.

24 WHAT I BELIEVE WE HAVE THE OPPORTUNITY TO DO
25 IS TO IMPOSE THAT THOSE INSTITUTIONS WHICH WANT CIRM

1 FUNDING ESTABLISH THEIR OWN ESCRO'S, AND THAT THOSE
2 ESCRO'S WILL, OF COURSE, ALSO THEN HAVE JURISDICTION
3 WITHIN THOSE INSTITUTIONS OVER THAT FUNDING, OVER THAT
4 SPONSORED RESEARCH, OR RESEARCH IN GENERAL WHICH IS NOT
5 OBTAINED OR FUNDED THROUGH THE CIRM. SO THIS IS AN
6 OPPORTUNITY, I THINK, THAT WE HAVE TO ESSENTIALLY SET
7 THE REGULATORY STATUS IN CALIFORNIA FOR ALL
8 INSTITUTIONS THAT SORT OF WANT TO PARTICIPATE IN THE
9 CIRM. THAT IS WHY IT WOULD BE A GOOD THING TO IMPOSE.

10 NOW, WHY IS THERE A SPECIFIC NEED FOR
11 ESCRO'S, WHICH ARE, I AGREE WITH THIS GENERAL CONCERN,
12 AS A SCIENTIST, I, OF COURSE, HAVE GREAT CONCERN ABOUT
13 BEING OVERMANAGED OR BE SUBJECT TO TOO MUCH OVERSIGHT
14 OR REGULATION. THUS FAR WE'VE BEEN VERY LUCKY, AND OUR
15 ESCRO HAS BEEN A VERY FAST ACTING AND PRUDENT BODY.

16 HAVING SAID THAT, I'D LIKE TO POINT OUT THIS
17 IS ONE REASON WHY I THINK IT'S IMPORTANT TO HAVE SUCH A
18 GROUP. SO CLEARLY ISSUES SURROUNDING DESTRUCTION OF
19 EMBRYOS ARE WEIGHTY, ETHICAL, AND MORAL ISSUES. ONE
20 OPINION WOULD BE THAT THIS, OF COURSE, UNDER THE
21 PURVIEW OF A HUMAN SUBJECTS COMMITTEE, WHICH IS
22 DESIGNED FOR PROTECTION OF HUMAN SUBJECTS. IF A HUMAN
23 SUBJECTS COMMITTEE WERE TO DECIDE THAT A HUMAN
24 PREIMPLANTATION EMBRYO WAS A HUMAN SUBJECT, THEN I IN
25 CHARGE WOULD HAVE TO PROTECT THAT ENTITY AND WOULD HAVE

1 TO DISALLOW IN A SENSE, I THINK ONE COULD SAY, THAT
2 SORT OF RESEARCH.

3 SO ESSENTIALLY IT COULD BE A QUESTION IN --
4 YOU'RE SCOWLING OVER THERE, ALTA, BUT I THINK THERE ARE
5 SOME PEOPLE WHICH ARE HESITANT FOR A HUMAN SUBJECTS
6 COMMITTEE TO REVIEW STEM CELL RESEARCH BECAUSE IN A
7 SENSE IT PLACES THAT -- THERE ARE THOSE THAT FEEL THAT
8 EMBRYO BECOMES A HUMAN SUBJECT, AND SO THEN, THEREFORE,
9 IT WOULD BE WRONG FOR THAT GROUP TO DECIDE TO DESTROY
10 IT. SO BY PUTTING THOSE SORTS OF DECISIONS AS TO WHAT
11 SORT OF HUMAN EMBRYO RESEARCH CAN HAPPEN IN THIS OTHER
12 GROUP, IT CREATES A NEW CLASS OF REGULATION AND HELPS
13 TO CLARIFY THOSE CONCERNS.

14 I WOULD ARGUE AS A SCIENTIST THAT'S INVOLVED
15 IN THAT TYPE OF RESEARCH, I THINK IT'S IMPORTANT FOR
16 THE RESEARCH TO GO TO BOTH GROUPS, THE HUMAN SUBJECTS
17 COMMITTEE, TO DECIDE WHETHER OR NOT THERE IS A HUMAN
18 SUBJECT INVOLVED IN THIS STUDY AND MAKING A DECISION
19 ONE WAY OR ANOTHER. THAT'S WHY IT IS IMPORTANT TO HAVE
20 THIS OTHER GROUP.

21 CO-CHAIR RABB: I THINK WE HEARD FROM JANET
22 AND BERNIE, IF I'M PLACING THOUGHTS IN THE RIGHT PLACE,
23 THAT APART FROM THE QUESTION OF HUMAN SUBJECTS
24 PROTECTION WHEN THE EMBRYO IS THE FOCUS, AS YOU'RE
25 DESCRIBING IT, KEVIN, THAT OTHERS HAVE SAID THAT THE

1 TYPICAL ROLE OF AN IRB IS TO THINK ABOUT WHETHER PROPER
2 CONSENT HAD BEEN GIVEN ALL ALONG THE WAY. AND THAT
3 COULD STILL, COULD STILL BE THE QUESTION FOR AN IRB
4 SINCE YOU HAVE TO LOOK AT CONSENT BY EMBRYO AND GAMETE
5 DONORS TO DETERMINE THAT THOSE CONSENTS WERE
6 APPROPRIATE.

7 DR. EGGAN: ABSOLUTELY.

8 CO-CHAIR RABB: SO THAT WOULD BE -- THAT WAS
9 SORT OF THE CARVE-OUT FROM WHAT YOU SUGGESTED THAT ARE
10 ON COMMENTS ALSO MENTIONED. ALTA, FRANCISCO, BOB.

11 MS. CHARO: SOME THOUGHTS IN RESPONSE TO
12 KEVIN AND TO ANN. KEVIN, THE IRB'S ARE CREATURES OF
13 FEDERAL LAW AND REGULATION. AND THE FEDERAL
14 REGULATIONS ARE EXTREMELY CLEAR THAT A HUMAN SUBJECT IS
15 NOT AN EMBRYO. NOW, THE BUSH ADMINISTRATION HAS AN
16 ADVISORY COMMITTEE.

17 DR. ROWLEY: YOU HAVE THOSE REVERSED.

18 MS. CHARO: EMBRYO IS NOT A HUMAN SUBJECT.
19 SORRY. THE BUSH ADMINISTRATION HAS BEEN LOOKING AT
20 THIS QUESTION FOR SEVERAL YEARS, AND THEY MAY CHANGE
21 THOSE REGULATIONS. BUT FOR THE MOMENT, THE IRB'S DO
22 NOT HAVE THE DISCRETION TO DECIDE THAT AN EMBRYO IS A
23 HUMAN SUBJECT AND THAT, THEREFORE, ALL RESEARCH ON
24 EMBRYOS FALLS WITHIN THEIR JURISDICTION. THAT'S SIMPLY
25 NOT PERMITTED TO THEM UNDER FEDERAL REGULATION.

1 THEY ARE, HOWEVER, SUPPOSED TO LOOK THAT THE
2 PROCESS BY WHICH LIVE-BORN PEOPLE ARE GIVING BIOLOGICAL
3 MATERIALS, INCLUDING THEIR EMBRYOS, FOR RESEARCH
4 PURPOSES. SO THE FOCUS OF ATTENTION IS NOT ON THE,
5 QUOTE, UNQUOTE, PROTECTION OF THE EMBRYO WHICH
6 PRESUPPOSES THE NOTION ABOUT INSURANCE ON THE EMBRYO.
7 THAT GETS INTO A WHOLE OTHER SET OF DEBATES.

8 THEIR FOCUS IS ON THE ADULTS, HOW IT IS THAT
9 WE RECRUIT THEM, HOW IT IS THAT WE ADVISE THEM, HOW IT
10 IS THAT THEY RELEASE THE MATERIALS, WHETHER IT'S EGGS,
11 SPERMS, SOMATIC CELLS, OR EMBRYOS. AND THAT ALSO
12 INCLUDES ISSUES ABOUT MEDICAL CONFIDENTIALITY THAT ARE
13 PART OF THEIR PURVIEW.

14 I THINK THE REASON WHY THERE'S BEEN
15 RESISTANCE TO IRB'S REVIEWING STEM CELL RESEARCH IS NOT
16 BECAUSE OF TURNING AN EMBRYO INTO A HUMAN SUBJECT IN
17 PEOPLE'S MINDS. IT'S BECAUSE THEY HAVE ABSOLUTELY NO
18 BUSINESS REVIEWING BASIC LAB RESEARCH THAT DOESN'T
19 INVOLVE HUMAN SUBJECTS. THEY DON'T HAVE THE EXPERTISE,
20 AND THEY DON'T HAVE THE LEGAL JURISDICTION. AND THE
21 ESCRO'S WERE SUGGESTED AS A WAY TO FILL THAT GAP, AND
22 IT'S A TRADITIONAL GAP. WE DON'T USUALLY REGULATE LAB
23 SCIENCE UNLESS IT INVOLVES AN ANIMAL OR GENETIC
24 ENGINEERING, ETC. SO THIS IS ALREADY KIND OF SUPER
25 AUDITORY IN AN EFFORT TO ADDRESS THE SPECIAL

1 CHARACTERISTICS, WHICH GOES BACK TO YOUR COMMENT ABOUT
2 THE RECOMBINANT DNA MODEL. THAT'S EXACTLY THE MODEL.

3 I THINK YOU'RE ABSOLUTELY RIGHT. CIRM COULD
4 DECIDE THAT IT WANTS TO CONSTRUCT ITS OWN ESCRO, WHICH
5 WILL FUNCTION FOR ALL CIRM-FUNDED RESEARCH, AND
6 INSTITUTIONS WILL BE FREE TO MAKE OR NOT MAKE THEIR OWN
7 LOCAL ESCRO'S AND TO HANDLE OTHER RESEARCH, WHATEVER,
8 BUT IT CERTAINLY CAN BE DONE. IT'S A LOT OF WORK. ONE
9 OF THE ADVANTAGES OF A LOCAL ESCRO SYSTEM IS THAT THIS
10 GROUP ONLY HAS TO SAY HERE ARE THE CORE PRINCIPLES. WE
11 WON'T ACCEPT -- WE WON'T ACCEPT FOR FUNDING ANY
12 PROPOSALS THAT FAIL TO MEET THESE BASIC CORE PRINCIPLES
13 AND THAT IT MAY BE INFORMED CONSENT THAT INCLUDES THESE
14 SIX ELEMENTS OR IT MIGHT BE NO COMPENSATION, WHATEVER
15 IT IS, AND THEY'D BE THE SAME CORE ELEMENTS YOU'D USE
16 IN DETERMINING IF SOUTH KOREA OR SINGAPORE'S REVIEW
17 SYSTEM IS WHAT WE CALL SUBSTANTIALLY EQUIVALENT AND,
18 THEREFORE, LINES FROM THOSE AREAS WOULD BE FREELY
19 ACCEPTED AND USED IN THE LABORATORIES HERE.

20 SO YOU COULD LIMIT YOURSELF TO THAT KIND OF
21 CORE, AND THEN THERE WOULD BE SOME DEGREE OF
22 EMBROIDERY, SHERRY, AT THE LEVEL OF THE IMPLEMENTATION
23 AS THEY INTERPRET THE MICROINTERPRETATION OF EACH WORD,
24 OR YOU COULD CONSTRUCT YOUR OWN ESCRO SOUP TO NUTS. IT
25 DOES IT ALL. IT'S A TREMENDOUS COMMITMENT OF RESOURCES

1 TO DO THAT.

2 CO-CHAIR LANSING: YOU'RE SAYING TO ME THAT
3 WOULD BE INCONSISTENCY. THERE WOULD JUST BE SOME
4 VARIATION OF INCONSISTENCY.

5 MS. CHARO: THERE'S A CORE CONSISTENCY, AND
6 THEN THERE'S SOME VARIATION AROUND THE STATE WHICH
7 WOULD, IF BERNIE'S SUGGESTION WERE FOLLOWED,
8 PERIODICALLY BEGIN TO SHRINK AS PEOPLE DISCUSS WITH ONE
9 ANOTHER HOW THEY ADDRESS THESE THINGS. DID YOU FIND
10 THAT THE SOUTH KOREA SYSTEM WAS SUBSTANTIALLY
11 EQUIVALENT? DID YOU FIND THAT PUTTING THIS PARTICULAR
12 KIND OF TISSUE INTO THAT PARTICULAR SHEEP IN THIS
13 PARTICULAR ORGAN AT THAT PARTICULAR STAGE OF
14 DEVELOPMENT WAS A GOOD IDEA OR A BAD IDEA? AND THE
15 AREAS OF DIFFERENCE MIGHT SHRINK.

16 CO-CHAIR LANSING: I GOT IT. THANK YOU.

17 CO-CHAIR RABB: FRANCISCO, BOB KLEIN, BOB
18 TAYLOR, ANN.

19 DR. PRIETO: I'M JUST RESPONDING TO SHERRY'S
20 COMMENT AND TO THE QUESTION THAT ANN BROUGHT UP.
21 TRYING TO BE AWARE OF THE FACT THAT UNDER PROP 71 WE'RE
22 LIMITED IN THE AMOUNT OF STAFF THAT CIRM IS ALLOWED TO
23 HAVE, A GRAND TOTAL OF 50, AND THAT CANNOT BE EXCEEDED,
24 AND THE AMOUNT OF THE PUBLIC MONEY THAT WE'RE GOING TO
25 SPEND ON THIS, I THINK FOR CONSISTENCY SAKE, WE WOULD

1 WANT TO HAVE ESCRO'S FOLLOWING CONSISTENT GUIDELINES.
2 WE WANT TO SET THOSE OUT AS THIS COMMITTEE, BUT I'M NOT
3 SURE THAT WE WANT THE CIRM OR THE WORKING GROUPS TO BE
4 THE ESCRO AND TO DO ALL OF THAT WORK IF WE CAN DELEGATE
5 SOME OF THAT WORK AND JUST ENSURE THAT IT'S DONE
6 ACCORDING TO THE TERM THAT WE SET OUT.

7 CO-CHAIR LANSING: THAT IS ACTUALLY WHAT I
8 WAS SAYING.

9 DR. PRIETO: WE DON'T WANT VARIATION.

10 CO-CHAIR LANSING: I THINK NOW WE'RE ALL
11 GETTING TO THE SAME PLACE.

12 DR. PRIETO: AND IT ALSO GETS BACK TO THE
13 POINT I MADE EARLIER ABOUT THAT THIS DOESN'T
14 NECESSARILY NEED TO BE INDIVIDUAL INSTITUTIONS. IT MAY
15 BE GROUPS OF INSTITUTIONS, OR WE MAY ALLOW THAT OPTION.
16 BUT I THINK IT WOULD BE IN OUR INTEREST TO DELEGATE
17 SOME OF THIS RESPONSIBILITY.

18 MR. KLEIN: JUST FOLLOWING ON WITH
19 FRANCISCO'S POINT, THIS IS NOT JUST A COST BENEFIT
20 ANALYSIS BECAUSE WE HAVE AN ABSOLUTE CAP OF 3 PERCENT
21 GENERAL OVERHEAD, 3 PERCENT FOR RESEARCH OVERSIGHT. SO
22 IT'S AN ABSOLUTE TRADE-OFF WITHIN THE CAP OF FUNCTIONS
23 AND UTILITY OF THOSE FUNCTIONS THAT CAN BE PERFORMED.

24 AND CERTAINLY I THINK, TO GO TO SHERRY'S
25 POINT, IF WE HAVE A CORE, AS MANY OF US HAVE MENTIONED,

1 THAT PROVIDES CONSISTENCY ON A STATEWIDE BASIS, WE
2 STILL HAVE TO RECOGNIZE THAT BETWEEN NORTHERN AND
3 SOUTHERN CALIFORNIA, JUST ANALOGIZE FOR A MOMENT, THERE
4 MAY BE A DIFFERENCE IN INTERPRETATION OF WHAT A CLASS A
5 SITE MIGHT BE. SO THERE WILL BE CONSISTENCY IN
6 STANDARDS, BUT THERE STILL CAN BE VALID INTERPRETATION
7 DIFFERENCES THAT ARE INSTITUTIONALLY BASED AND WITHIN
8 THEIR CULTURE AND PRACTICES BE VERY DEFENSIBLE.

9 MR. SHESTACK: DOES THAT MEAN YOU CAN SHOP
10 FOR AN ESCRO, OR WOULD YOU BE BOUND BY YOUR REGION'S
11 ESCRO?

12 MR. KLEIN: DR. HALL.

13 DR. HALL: YOU HAVE TO SAY -- EACH
14 INSTITUTION WOULD HAVE ONE, AND YOU HAVE TO APPLY TO
15 YOUR INSTITUTION FOR THE ESCRO.

16 LET ME JUST SAY THAT ONE ARGUMENT FOR HAVING
17 LOCAL ONES WAS ALLUDED TO EARLIER, MAYBE NOT MADE
18 EXPLICIT. ANYTHING THAT'S CENTRALIZED RAPIDLY BECOMES
19 LESS RESPONSIVE TO INDIVIDUAL INVESTIGATORS. CERTAINLY
20 FROM THE INVESTIGATOR'S POINT OF VIEW, ABILITY TO HAVE
21 A LOCAL COMMITTEE THAT IS ACCOUNTABLE TO THE
22 ADMINISTRATION LOCALLY AND RESPONSIVE IN TERMS OF
23 TIMELINESS AND IN TERMS OF CONSISTENCY AND ALL THESE
24 OTHER THINGS, RESPONSIVE TO THE LOCAL SCIENTIFIC
25 COMMUNITY, I THINK, IS VERY, VERY IMPORTANT. AND I

1 THINK, AGAIN, THE MORE DISTANT, THE LESS RESPONSIVE.

2 SO MY OWN VIEW IS THE WAY THIS DISCUSSION IS
3 GOING IT SEEMS TO ME TO BE A VERY GOOD ONE.

4 CO-CHAIR LANSING: I THINK WE'RE ALL SORT OF
5 GETTING TO THE SAME PLACE. I'M THE ONE THAT WAS THE
6 MOST CONCERNED. I THINK WE'RE ALL SORT OF SAYING,
7 OKAY, WE'LL ESTABLISH THESE BROAD RULES, AND THEN WE'RE
8 GOING TO HAVE LOCAL THINGS THAT ARE GOING TO IMPLEMENT
9 THEM AND INTERPRET THEM. I UNDERSTAND THAT THERE WILL
10 BE SOME VARIATION, BUT THERE WILL STILL BE AN OVERALL
11 CONSISTENCY. THAT WOULD MAKE ME COMFORTABLE.

12 DR. TAYLOR: WITH ALL DUE RESPECT TO YOU,
13 ALTA, I DON'T THINK WE SHOULD TRY TO DISTANCE OURSELVES
14 TOO FAR FROM THE IRB. IT WAS REALLY THE MANDATE OF THE
15 PROPOSITION 71, IN MY OPINION, TO USE THIS KIND OF
16 TECHNOLOGY TO REALLY BRING HEALTHCARE PRODUCTS TO THE
17 PEOPLE OF CALIFORNIA. SO I HAVE A LITTLE BIT OF A
18 NIGHTMARISH SCENARIO TO DESCRIBE TO YOU.

19 IF I WERE AN INVESTIGATOR AT UCSF USING ONE
20 OF THE ESTABLISHED HUMAN EMBRYONIC STEM CELL LINES THAT
21 ARE APPROVED ALREADY BY THE BUSH ADMINISTRATION, AND I
22 WANTED TO DEVELOP PROTOCOL TO TREAT TYPE 1 DIABETES, I
23 WOULD GO THROUGH THE FOLLOWING REDUNDANT PROCESSES OF
24 OVERSIGHT. THIS IS GOING TO HAPPEN. I HAVE TO GO TO
25 NIH HUMAN EMBRYONIC STEM CELL COMMITTEE TO GET

1 APPROVAL, I'D HAVE TO GO THROUGH MY NIH STUDY SECTION
2 TO GET APPROVAL, I WOULD THEN HAVE TO GO THROUGH MY
3 UCSF IRB, THEN GO THROUGH THE UCSF ESCRO, AND THEN I'D
4 GO TO THE UCSF GCRC TO GET PERMISSION TO DO THE STUDY.
5 THESE WOULD ARE ALL BE LAYERS --

6 MS. CHARO: WAIT. WHY ARE YOU GOING TO THE
7 IRB? ARE YOU ACTUALLY DOING HUMAN TRIALS, OR ARE YOU
8 DOING LAB WORK?

9 DR. TAYLOR: I'M DOING HUMAN TRIALS.

10 DR. ROWLEY: YOU CAN'T USE THE BUSH LINES FOR
11 HUMAN TRIALS.

12 MS. CHARO: EVEN IF YOU COULD, AT THAT POINT
13 THE ESCRO IS NOW -- THE ESCRO IS ABOUT LAB WORK. IT IS
14 NOT ABOUT HUMAN CLINICAL TRIALS. HUMAN CLINICAL TRIALS
15 IS BACK TO THE IRB. THE ESCRO IS ABOUT LABORATORY
16 WORK. IT'S ABOUT THE PRECLINICAL PHASE, NOT THE
17 CLINICAL PHASE OF RESEARCH.

18 DR. TAYLOR: WELL, TO GET TO THE -- I MEAN
19 YOU'VE GOT TO GO THROUGH THE ESCRO. SO YOU'RE JUST
20 SAYING THAT ONCE WE HAVE -- LET'S SAY WE'VE GOT A CELL
21 LINE AND WE'VE GROWN THE HUMAN FEEDERS AND IT'S READY
22 FOR CLINICAL USE. THAT'S OUTSIDE OF THE ESCRO?

23 MS. CHARO: YEAH. THE ESCRO IS THERE FOR THE
24 PRECLINICAL WORK. AT THE TIME WHEN YOU COMPLETE YOUR
25 CLINICAL WORK AND THE FDA SAYS YOU'RE ALLOWED TO GO

1 FORWARD, AND THAT'S NOW BACK TO THE HUMAN SUBJECTS LAB.
2 THE ESCRO IS THE IN-BETWEEN WORLD. IT'S IN BETWEEN.
3 THE IRB COMES IN AT THE BEGINNING WHEN YOU'RE
4 COLLECTING EMBRYOS, COLLECTING EGGS, COLLECTING SPERM,
5 THEN THE IRB GOES AWAY, AND THE ESCRO STANDS THERE FOR
6 THE LABORATORY ANIMAL PHASES ALONG WITH THE ANIMAL CARE
7 COMMITTEES. AND THEN WHEN YOU'RE READY TO GO INTO
8 HUMAN TRIALS, THE ESCRO GOES AWAY AND THE IRB COMES
9 BACK.

10 MR. SHESTACK: BUT THERE WOULD BE A STAGE
11 WHERE YOU WOULD HAVE TO SUBMIT YOUR WORK IN THAT
12 PRECLINICAL STAGE TO BOTH AN IRB AND AN ESCRO.

13 MS. CHARO: WHY WOULD YOU GO TO AN IRB FOR
14 THE PRECLINICAL WORK?

15 MR. SHESTACK: WELL, IF YOUR STUDY INCLUDED
16 RECRUITING. IF YOU WERE A SOUP-TO-NUTS SHOP AND YOUR
17 STUDY INCLUDED RECRUITMENT OF HUMAN SUBJECTS, AND THEN
18 DISEASE-SPECIFIC HUMAN SUBJECTS, AND THEN LAB WORK ON
19 THEM.

20 DR. TAYLOR: OR EVEN VOLUNTEERS.

21 MS. CHARO: I DON'T UNDERSTAND.

22 MR. SHESTACK: YOU'RE RIGHT. YOU MIGHT
23 HAVE -- A PARTICULAR LAB MIGHT HAVE TO DO PAPERWORK
24 WITH AN IRB AND AN ESCRO.

25 MS. CHARO: I'M NOT SURE I UNDERSTAND THE

1 EXAMPLE. WE IDENTIFIED ONE WHERE THAT MIGHT COME UP,
2 AND THAT'S WHERE YOU USE IDENTIFIED CELL LINES. BUT I
3 DON'T UNDERSTAND WHERE IN THE PRECLINICAL WORK THAT
4 DOESN'T INVOLVE HUMAN SUBJECTS WHERE ELSE YOU WOULD
5 FIND THE IRB IS IMPLICATED.

6 CO-CHAIR RABB: WAIT.

7 MS. CHARO: BUT THAT'S -- BUT THE ESCRO IS
8 NOT INVOLVED IN THAT. THE IDEA WAS KIND OF A SERIES OF
9 TRADE-OFFS, HAND-OFFS. IRB THAT HANDED OFF TO ESCRO
10 THAT HANDED OFF BACK TO IRB, NOT PARALLEL REGULATION.

11 CO-CHAIR RABB: LET'S SEE IF WE CAN STICK
12 WITH THIS ISSUE. ANN HAS BEEN PATIENT AND, I THINK,
13 WANTED TO RESPOND ON THIS QUESTION AS WELL.

14 DR. KIESSLING: HOW ARE PROJECTS GOING TO BE
15 FUNDED? THEY'RE GOING TO BE REVIEWED BY OUR PARTNER
16 COMMITTEE, RIGHT? I DON'T SEE WHY YOU NEED A LAYER OF
17 PEER REVIEW ON TOP OF THAT.

18 THE WAY IT WORKS NOW AT THE NIH, TO GO
19 THROUGH THE NIH, IS THAT THE JOB THAT YOU ARE ASKING AN
20 ESCRO TO DO HERE, WHICH MOST STATES DON'T HAVE AN
21 ALTERNATIVE. THEY'RE GOING TO HAVE DO THIS.
22 CALIFORNIA HAS AN ALTERNATIVE. YOU HAVE IN PLACE A
23 FUNDING ORGANIZATION THAT'S GOING TO HAVE FULLY
24 QUALIFIED SCIENTISTS ON IT THAT ARE GOING TO REVIEW THE
25 PROJECT FOR EVERYTHING THAT THIS ESCRO IS GOING TO

1 REVIEW IT FOR. RIGHT? AND AT THAT LEVEL, IF IT
2 DOESN'T PASS MUSTER, IT'S NOT GOING TO GET FUNDED.

3 NOW, IF YOU WANT TO PASS A GUIDELINE THAT
4 COVERS ALL TYPES OF FUNDING OUTSIDE OF CIRM FUNDING,
5 THEN WE HAVE TO DISCUSS AN ESCRO BECAUSE OTHER FUNDING
6 AGENCIES MAY NOT HAVE THIS EXPERTISE. BUT YOUR FUNDING
7 AGENCY AND YOUR FUNDING MECHANISM, TO REQUIRE THE
8 CREATION OF ESCRO'S AROUND THE STATE IS SIMPLY GOING TO
9 DUPLICATE THAT LEVEL OF EXPERTISE AND OVERSIGHT. IF
10 THE WORK ISN'T JUSTIFIED, THEY DON'T NEED TO DO THIS
11 THIS WAY, YOU'RE NOT GOING TO GIVE IT ANY MONEY.

12 CO-CHAIR RABB: I GUESS THE QUESTION WOULD BE
13 IF WE WOULD EXPECT THE GRANTS WORKING GROUP TO
14 DETERMINE WHAT QUESTIONS AN INVESTIGATOR HAS TO ANSWER
15 TO ETHICALLY JUSTIFY THE WORK AS WELL AS SCIENTIFICALLY
16 PROVIDE A PROTOCOL THAT'S WORTH FUNDING.

17 DR. KIESSLING: THAT'S WHY IT'S JUST A
18 DUPLICATION OF EFFORT. THAT'S WHAT -- YOU SEE WHAT I'M
19 SAYING, RIGHT? RIGHT NOW IF I PROPOSE A PROJECT TO
20 NIH, THAT SOMEBODY THERE SAYS, OH, NO. THIS ISN'T
21 SCIENTIFICALLY SOUND OR IT DOESN'T MEET THESE
22 GUIDELINES, WHATEVER, IT BOUNCES BACK.

23 CO-CHAIR RABB: WHAT YOU'RE IMAGINING, THEN,
24 WOULD BE THIS GROUP WOULD ESTABLISH THE CORE
25 PRINCIPLES. THEY WOULD BECOME A PART OF THE REVIEW BY

1 THE GRANTS GROUP.

2 DR. KIESSLING: OR YOUR GRANTS GROUP WOULD
3 INCORPORATE THE ESCRO CONCEPT AS PART OF ITS REVIEW.

4 CO-CHAIR RABB: BUT WHO'S GOING TO BE -- IN
5 YOUR VISION, WHO'S DECIDING WHAT THOSE CORE PRINCIPLES
6 WILL BE THAT ETHICALLY ESTABLISH BOUNDARIES FOR
7 CALIFORNIA FUNDING? WILL IT BE THIS ORGANIZATION?

8 DR. KIESSLING: THAT'S A DISCUSSION SEPARATE
9 FROM CREATING A NEW COMMITTEE.

10 CO-CHAIR RABB: WELL --

11 DR. KIESSLING: I'M REALLY TROUBLED BY THAT
12 FACT THAT YOU ALREADY HAVE MORE STRUCTURE IN YOUR STATE
13 THAN ANYPLACE ELSE IN THE WORLD, AND YOU HAVE EACH
14 INSTITUTION IN CALIFORNIA THAT'S GOING TO DO THIS HAS
15 IN PLACE A VERY QUALIFIED IRB TO HANDLE THAT PART OF
16 IT. YOU ARE GOING TO HAVE A FUNDING MECHANISM THAT'S
17 GOING TO HAVE ANOTHER LAYER OF EXPERT AND PEER REVIEW.
18 YOU DON'T NEED ANOTHER LAYER ON TOP OF THAT.

19 NOW, IF YOU WANT TO INCORPORATE INTO THOSE
20 PEER REVIEW GUIDELINES ALL OF THE ESCRO CONCERNS LAID
21 OUT BY JANET AND ALTA, THAT'S, I THINK, A SEPARATE
22 DISCUSSION FROM DECIDING WHETHER OR NOT YOU ARE GOING
23 TO CREATE A WHOLE NEW SET OF COMMITTEES AROUND THIS
24 TABLE.

25 CO-CHAIR RABB: KEVIN.

1 DR. EGGAN: FIRST OF ALL, WE HAVE NO
2 JURISDICTION OVER DECIDING WHETHER OR NOT EVERYONE IN
3 THE STATE OF CALIFORNIA SHOULD BE SUBJECT TO SOME
4 ESCRO. WE CERTAINLY DO HAVE THE ABILITY TO ENFORCE
5 INSTITUTIONAL ESCRO'S ON THOSE WHO WANT CIRM FUNDING.
6 THAT SEEMS LIKE A REASONABLE THING TO DO.

7 AND ALSO, I KNOW IT'S PENDING WHAT THESE
8 ESCRO'S SHOULD BE DEFINED AS; BUT AS I READ THE NIH
9 GUIDELINES, I SEE THE ESCRO AS A BROADBASED GROUP WHO
10 SHOULD BE KNOWLEDGEABLE IN GENERAL ABOUT THE NATURE OF
11 ALL STEM CELL RESEARCH, HUMAN EMBRYONIC STEM CELL
12 RESEARCH GOING ON IN AN INSTITUTION. AND SO IT SEEMS
13 TO ME THAT THAT THEN, THEREFORE, NEEDS TO BE A GROUP
14 WHICH IS INVOLVED AT MOST EVERY STEP IN THE RESEARCH.

15 SO ALTHOUGH I UNDERSTAND WHAT YOU ARE SAYING,
16 THERE MAY BE TIMES WHEN THE ESCRO IS THE ONLY ONE
17 THAT'S MAKING A DECISION ON A PARTICULAR THING BECAUSE
18 THERE WILL BE TYPES OF RESEARCH WHICH INVOLVE ESL'S
19 WHICH ARE OUTSIDE THE IRB.

20 BUT IT SEEMS LIKE ALMOST ANY IRB DECISION
21 THAT WAS MADE CONCERNING ES CELL RESEARCH SHOULD ALSO
22 BE REVIEWED BY AN ESCRO. FOR INSTANCE, DERIVATION OF
23 NEW ES CELL LINES WOULD PROBABLY NECESSITATE IRB REVIEW
24 FOR DONATION OF GAMETES OR EMBRYOS BECAUSE THE HUMAN
25 SUBJECTS IN QUESTION THERE ARE THE DONORS, AND SO THEY

1 NEED TO BE CONSENTED, AND THAT'S THE PURVIEW OF THE
2 IRB.

3 NOW, IT WOULD ALSO BE IN THE PURVIEW OF THE
4 ESCRO BECAUSE IT NEEDS TO BE DECIDED WHETHER OR NOT
5 THESE ARE ETHICALLY REASONABLE AND IMPORTANT
6 EXPERIMENTS TO DO WITH RESPECT TO EMBRYONIC STEM CELL
7 BIOLOGY.

8 DR. KIESSLING: AND YOU DON'T THINK THAT
9 WOULD BE DONE BY THE GRANTS GROUP?

10 DR. EGGAN: NO, I DO NOT. AND AS A
11 SCIENTIST, ACTUALLY, I THINK IT'S IMPORTANT THAT EVERY
12 INSTITUTION BE ABLE TO ANSWER TO GREATER OUTSIDE
13 CRITICISM WHAT'S GOING ON WITH EMBRYONIC STEM CELLS IN
14 THEIR PARTICULAR INSTITUTION. AND ACTUALLY AS A
15 SCIENTIST, I FEEL GREAT PROTECTION THAT THERE IS A
16 GROUP OF THOUGHTFUL PEOPLE THAT ARE NOT DIRECTLY
17 RELATED TO ME, AND WHICH ARE NOT DIRECTLY RELATED TO
18 FUNDING THE RESEARCH WHO HAVE THOUGHT DEEPLY ABOUT
19 THESE TOPICS AND COULD ANSWER TO OUTSIDE CRITICS.

20 BUT THE KEY THING IS THAT THAT BE MADE BY A
21 VIABLE GROUP, A GROUP THAT CAN ACT SWIFTLY AND THAT CAN
22 ACT TO PROTECT, TO THINK ABOUT, AND TO SUPPORT THE
23 SCIENTISTS THAT ARE DOING THE RESEARCH.

24 CO-CHAIR RABB: ZACH, DID YOU WANT TO WEIGH
25 IN?

1 DR. HALL: WELL, JUST TO ECHO WHAT KEVIN JUST
2 SAID. FROM MY OWN PERSPECTIVE AS AN INSTITUTIONAL
3 ADMINISTRATOR, I THINK INSTITUTIONS DO HAVE A
4 RESPONSIBILITY TO KNOW WHAT RESEARCH IS GOING ON IN
5 THEIR INSTITUTIONS TO BE ABLE TO ANSWER TO THE PUBLIC.
6 AND I THINK ONE OF THE ROLES OF THE ESCRO AS DEFINED
7 HERE IS TO ACTUALLY KNOW WHO'S DOING WHAT IN THE
8 INSTITUTION. THEY GO ON TO GIVE, AS YOU MAY RECALL,
9 THREE LEVELS OF THINGS THAT MAY NEED TO BE REVIEWED BY
10 THE ESCRO COMMITTEE, MAY NOT BE, OR THINGS THAT ARE
11 ABSOLUTELY IMPERMISSIBLE. AND IT SEEMS TO ME THAT THAT
12 JUDGMENT NEEDS TO BE MADE LOCALLY ACCORDING TO THE
13 RULES THAT WE SET UP.

14 I WAS JUST THINKING. I DON'T THINK WE HAVE
15 ANYBODY ON OUR PANEL FROM STANFORD, AND I CAN'T SPEAK
16 ABOUT THIS FIRSTHAND, BUT I DO KNOW THAT IRV WEISSMAN
17 HAS BEEN INVOLVED IN EXPERIMENTS IN WHICH HE'S, MY
18 UNDERSTANDING, PUT HUMAN -- IS PUTTING HUMAN STEM CELLS
19 INTO MICE BRAINS, AND HAS FOUND OUT ACTUALLY EXTREMELY
20 INTERESTING THINGS ABOUT HOW THEY BEHAVE. THEY MIGRATE
21 TO SITES OF INJURY. AND STANFORD WENT THROUGH QUITE A
22 LENGTHY PROCEDURE, ACCORDING TO MY UNDERSTANDING,
23 DISCUSSING THESE EXPERIMENTS, DEBATING THEM, AND
24 DECIDING THAT IT WAS ALL RIGHT FOR THEM TO DO THAT. I
25 THINK THAT'S RESPONSIBLE INSTITUTIONAL BEHAVIOR. I

1 THINK STANFORD SHOULD BE DOING THAT.

2 DR. KIESSLING: THAT WAS PROBABLY THE ANIMAL
3 COMMITTEE. IT WAS PROBABLY THE IACUC.

4 MS. CHARO: NO. IT WAS A SPECIALLY
5 CONSTRUCTED ETHICS COMMITTEE.

6 DR. HALL: SPECIAL COMMITTEE. I THINK THE
7 POINT ABOUT THE LABORATORY RESEARCH WHICH, AS SEVERAL
8 PEOPLE SAID, DOESN'T ORDINARILY COME UNDER THIS KIND OF
9 SCRUTINY IS TO ACKNOWLEDGE THE SPECIALNESS OF THIS KIND
10 OF RESEARCH. I MEAN WE ARE ALL COMMITTED TO ENGAGING
11 IN IT, BUT I THINK WE ALSO ARE COMMITTED TO A SENSE OF
12 DEEP RESPONSIBILITY ABOUT DOING THIS KIND OF RESEARCH.
13 AND IT SEEMS TO ME THAT THE ESCRO COMMITTEES ARE ONE
14 EXPRESSION OF THAT, BUT TO LOOK AT WHATEVER IS BEING
15 DONE AND SAY IS THIS APPROPRIATE? WE NEED TO KNOW WHAT
16 OUR INVESTIGATORS ARE DOING. AND IF THERE ARE CERTAIN
17 LINES THEY CAN'T CROSS AND OTHERS WE NEED TO THINK
18 ABOUT AND THEN OTHERS ARE OKAY.

19 DR. KIESSLING: I THINK THAT THAT CAN BE
20 ACCOMPLISHED WITHOUT CREATING A WHOLE SEPARATE
21 ADMINISTRATIVE BODY.

22 CO-CHAIR RABB: WE'RE IN A POSITION OF HAVING
23 NO NAMES ON THE LIST. WE CAN CONTINUE TO TALK ABOUT
24 THIS ASPECT OF THE GUIDELINES THAT HAVE BEEN ADOPTED
25 AND THAT WE'RE REVIEWING. WE CAN TURN TO ANOTHER PIECE

1 OF IT. NAMES ON THE LIST, JANET AND FRANCISCO.

2 DR. ROWLEY: I THINK THAT WE SHOULD -- WE
3 OBVIOUSLY HAVE A DIFFERENCE OF OPINION IN THE GROUP. I
4 THINK WE SHOULDN'T JUST LEAVE IT HANGING WITHOUT COMING
5 TO SOME SENSE OF SIX PEOPLE ARE IN FAVOR OF THIS AND
6 FOUR IN FAVOR OF THAT, AND TWO ARE ABSTAINING OR MORE
7 DISCUSSION. I THINK I'M GOING TO BE IN KEVIN'S CAMP
8 HERE BECAUSE I THINK THAT THIS IS SOMETHING -- IT'S
9 BEEN RAISED BEFORE, AND WE CERTAINLY WERE COGNIZANT OF
10 IT IN THE NATIONAL ACADEMY COMMITTEE ABOUT THE
11 EXPERIENCE WITH THE RAC THAT SERVED SCIENTISTS
12 EXTREMELY WELL, ANOTHER LAYER OF REVIEW, BUT FOR AN
13 AREA THAT WAS VERY SENSITIVE.

14 AND WE DID A GOOD JOB, AND I THINK WE THOUGHT
15 THAT THE EMBRYONIC STEM CELLS, HUMAN EMBRYONIC STEM
16 CELLS ARE SUCH A SENSITIVE ISSUE THAT WE SHOULD BEND
17 OVER BACKWARDS TO SHOW THAT WE REALLY ARE DOING THIS IN
18 A RESPONSIBLE FASHION BECAUSE I'M CONTINUALLY
19 CONFRONTED ON THE PRESIDENT'S COUNCIL THAT SCIENTISTS
20 WANT NO RESTRAINTS, THEY JUST WANT TO DO WHATEVER THEY
21 DAMN WELL PLEASE AND GO RIGHT AHEAD.

22 DR. KIESSLING: KEVIN AND I WILL TELL YOU
23 THAT'S NOT TRUE.

24 DR. ROWLEY: BUT THAT'S THE GENERAL
25 PERCEPTION OF A CERTAIN PORTION OF THE POPULATION, AND

1 ESCRO'S ARE ONE PROTECTION AGAINST THAT PORTION OF THE
2 POPULATION.

3 DR. KIESSLING: CAN YOU REMIND ME? WHAT
4 HAPPENED TO RECOMBINANT DNA REVIEW? WE DON'T DO IT
5 ANYMORE. WAS THAT SOMETHING THAT WAS PUT IN PLACE
6 ANNUALLY?

7 DR. ROWLEY: WELL, ACTUALLY YOU SEE THERE IS
8 A RAC COMMITTEE AT NIH WHICH NOW IS LOOKING AT GENE
9 THERAPY. SO THEY'RE REVIEWING -- ANY PROPOSALS FOR
10 GENE THERAPY IN HUMANS IS REVIEWED BY A COMMITTEE, AND
11 IT'S ACTUALLY SOMEBODY -- TED FRIEDMAN, I THINK, FROM
12 CALIFORNIA.

13 DR. KIESSLING: NOT LOCAL COMMITTEES ANYMORE.

14 DR. EGGAN: THERE ARE LOCAL COMMITTEES.
15 THERE ARE LOCAL COMMITTEES THAT REVIEW -- ALL
16 RECOMBINANT DNA IS REVIEWED BY A LOCAL BIOSAFETY
17 COMMITTEE. EVERY TIME I PUT PRB 22 INTO A BACTERIA, I
18 HAVE TO HAVE PERMISSION.

19 CO-CHAIR RABB: LET ME INTERRUPT FOR A
20 MINUTE. BERNIE SERVES ON THE RECOMBINANT DNA ADVISORY
21 COMMITTEE, SO MAYBE BERNIE CAN TALK ABOUT THE
22 EXPERIENCE. AND IF YOU HAD EXPERIENCE OVER TIME ABOUT
23 HOW THE ROLE OF THE RAC HAS CHANGED, MAYBE THAT WOULD
24 BE HELPFUL TO EVERYBODY IN THINKING ABOUT WHAT COULD
25 HAPPEN HERE. JEFF, YOU ON IT AS WELL?

1 DR. KORDOWER: I'VE BEEN THROUGH IT. I JUST
2 WENT THROUGH IT.

3 CO-CHAIR RABB: BERNIE AND JEFFREY AND
4 FRANCISCO. LET'S SEE WHETHER THAT HELPS US TO THINK
5 THROUGH WHAT WE MIGHT BE CONTEMPLATING.

6 DR. LO: I ACTUALLY JUST FINISHED MY TERM ON
7 THE RAC, SO I'M ACTUALLY LOOKING BACK AT IT. I THINK
8 IT OFFERS SOME INTERESTING SORT OF HISTORICAL
9 ANALOGIES. ITS ROLE HAS CHANGED OVER TIME. IT STARTED
10 AROUND THE TIME CONCERNS ABOUT RECOMBINANT DNA, THE
11 ASILOMAR CONFERENCE. ITS ROLE REALLY CHANGED
12 DRAMATICALLY AFTER THE JESSE GELSINGER CASE OF GENE
13 TRANSFER FOR ORNITHINE TRANSCARBAMYLASE DEFICIENCY. HE
14 ACTUALLY VOLUNTEERED.

15 APPARENTLY ALL GENE TRANSFER PROTOCOLS IN
16 HUMANS THAT ARE EITHER FUNDED BY NIH OR WERE AN
17 NIH-FUNDED INSTITUTION DERIVED THE VECTOR THAT'S BEING
18 USED IN THE TRIAL HAVE TO BE REVIEWED BY THE RAC IN
19 ADDITION TO LOCAL IRB AND LOCAL BIOSAFETY REVIEW
20 COMMITTEES. IT'S VOLUNTARY FOR PEOPLE WITH COMPLETELY
21 PRIVATE FUNDING.

22 DR. KORDOWER CAN SPEAK TO THE INVESTIGATOR'S
23 PERSPECTIVE. THERE CERTAINLY HAVE BEEN CONCERNS THAT
24 IT'S A DELAY IN THE PROCESS, THAT IT'S NOT REALLY
25 RESPONSIVE TO THE TIMETABLE THAT PROTOCOL DEVELOPERS

1 ARE ON. ON THE OTHER HAND, HAVING SAT ON THE RAC, I
2 THINK IT GIVES A LEVEL REVIEW, BOTH SCIENTIFIC AND SORT
3 OF ETHICS, THAT SOMETIMES IS NOT AVAILABLE LOCALLY.
4 AGAIN, THE DIFFERENCE BETWEEN THE PROTOCOLS WE SAW ON
5 THE RAC AND WHAT CIRM WAS SEEING WAS THAT OFTEN THESE
6 PROTOCOLS DID NOT UNDERGO NIH-TYPE PEER REVIEW OR
7 CIRM-TYPE PEER REVIEW FOR SCIENTIFIC MERIT. SO OFTEN
8 MANY OF THE CONCERNS RAISED ARE SCIENTIFIC QUESTIONS
9 ABOUT WHY THIS VECTOR, WHY STUDY THIS GROUP, WHETHER
10 YOU'RE USING THE RIGHT END POINTS, ARE YOU ASSESSING
11 FOR SAFETY ADEQUATELY.

12 AND A LOT OF THE CONCERNS THAT ARE RAISED
13 HAVE TO DO WITH SUGGESTIONS TO TRY AND REDUCE THE RISKS
14 TO PARTICIPANTS WHO ARE RECEIVING THE GENE TRANSFER IN
15 PHASE I OR PHASE I, OR PHASE I-II PROTOCOLS.

16 I THINK, AGAIN, THERE'S ALWAYS THIS CONCERN
17 THAT IS WHAT YOU'RE GETTING WORTH THE TIME AND THE
18 EFFORT AND THE ENERGY. PART OF THAT WAS DRIVEN BY THE
19 PUBLIC CONCERNS AFTER CLEARLY -- A CASE HAD CLEARLY
20 RAISED CONCERNS ABOUT THE ADEQUACY OF BOTH THE
21 SCIENTIFIC AND THE ETHICAL REVIEW THAT ONE TAKES. SO
22 IT'S A RESPONSIVE SYSTEM TO ONE CASE THAT HAD A
23 TERRIBLE OUTCOME AS FAR AS EVERYONE WAS CONCERNED.

24 THERE CERTAINLY ARE INVESTIGATORS, AGAIN I
25 WOULD DEFER TO JEFFREY, WHO BELIEVE THAT NOW IT'S SORT

1 OF A BURDEN ON INVESTIGATORS THAT SLOWS UP THEIR
2 PROCESS. WHETHER THEY THINK THAT THE SUGGESTIONS MADE
3 BY THE RAC ARE GOOD OR NOT, I CAN'T SAY. CERTAINLY
4 THERE'S A CRITICISM THAT'S BEEN MADE THAT SOME OF THE
5 SCIENTISTS ON THE COMMITTEE RAISED QUESTIONS WHICH ARE
6 SORT OF ACADEMIC OR END QUESTIONS THAT HAVE TO DO WITH
7 MORE MECHANISMS OF ACTION AND BIOLOGICAL MECHANISMS AS
8 OPPOSED TO THE CLINICAL SAFETY AND EFFICACY QUESTIONS
9 THAT A TRIAL IS DESIGNED TO IMPLEMENT. ALL THE TIME
10 QUESTIONS OF WHY DON'T YOU USE A DIFFERENT VECTOR, A
11 DIFFERENT AGENT, AND IT JUST TAKES SO LONG TO GO
12 THROUGH THE PROCEDURE OF GETTING THE FDA TO APPROVE
13 SOMETHING THAT'S GOING TO BE USED IN THE CLINICAL
14 TRIAL.

15 BUT I THINK THE INVESTIGATOR'S PERSPECTIVE IS
16 AN IMPORTANT ONE, AS WOULD BE A PUBLIC PERSPECTIVE AS
17 TO WHETHER THIS HELPS -- I MEAN ONE OF THE REASONS FOR
18 THE RAC EXPLICITLY IS TO TRY AND INCREASE PUBLIC TRUST
19 THAT THIS RESEARCH IS BEING RESPONSIBLY DONE, IT GETS
20 BACK TO DR. ROWLEY'S QUESTION, PARTICULAR
21 RESPONSIVENESS BECAUSE THE PUBLIC RAISED VERY SERIOUS
22 QUESTIONS ABOUT THE ADEQUACY OF SELF-OVERSIGHT BY
23 SCIENTISTS.

24 DR. KIESSLING: WHY WOULD YOU BE GETTING
25 PROPOSALS THAT WERE NOT PEER REVIEWED FIRST?

1 DR. LO: BECAUSE SOMETIMES WITH TOTALLY
2 PRIVATE FUNDING THE INVESTIGATOR JUST GETS A GRANT, NOT
3 A GRANT, I GUESS IT'S AN ENDOWMENT, UNRESTRICTED
4 ENDOWMENT FROM A SPONSOR OR FROM A BIOTECH COMPANY THAT
5 IS DEVELOPING PRODUCT, AND IT HAS NOT UNDERGONE
6 NIH-TYPE PEER REVIEW OR THE TYPE OF CIRM PEER REVIEW OF
7 THE SCIENTIFIC WORK.

8 DR. KIESSLING: SO THIS IS PARTICULARLY OF
9 VALUE IF THERE'S NO LEVEL OF PEER REVIEW.

10 DR. LO: WELL, AGAIN, IT DEPENDS ON WHOSE
11 PERSPECTIVE. FROM THE PERSPECTIVE OF THE SCIENCE, THE
12 PERSPECTIVE OF RAC MEMBERS, IT'S A CHANCE TO REALLY
13 ENGAGE IN IN-DEPTH DISCUSSION. NOT ALL PROTOCOLS, BY
14 THE WAY, GET DISCUSSED IN-DEPTH. IF IT'S SIMILAR TO A
15 PROTOCOL, IF IT DOESN'T PRESENT ANY NOVEL SCIENTIFIC OR
16 ETHICAL CONCERNS OR IS SIMILAR TO A PREVIOUSLY APPROVED
17 PROTOCOL, THERE'S SUBMISSION, BUT THEN THE FORMAL
18 PUBLIC REVIEW IS WAIVED.

19 DR. KORDOWER: I'VE BEEN PART OF THE RAC --
20 AN APPLICANT TO THE RAC AS PART OF A COMPANY CALLED
21 CEREGENE, WHICH IS NOW IN PHASE I CLINICAL TRIALS FOR
22 GENE TRANSFER OF A PRODUCT CALLED NURTURING USING THE
23 AV TECHNOLOGY IN PATIENTS WITH PARKINSON'S DISEASE.

24 AND WHAT WAS KIND OF ODD FOR US IS THAT WE
25 HAD TO GO THROUGH THE RAC AFTER ALREADY RECEIVING FDA

1 APPROVAL. SO IT WAS KIND OF, FIRST OF ALL, THE CART
2 WAS ALREADY IN FRONT OF THE HORSE. SO WE FELT THAT IT
3 WAS A LITTLE BIT REDUNDANT. I THINK THE PROCESS WAS
4 NOT ALL THAT HELPFUL. AND WE FELT THAT IT DID DELAY,
5 POTENTIALLY DELAY SIGNIFICANTLY OUR CHANCE OF GOING
6 INTO THE CLINIC. THANKFULLY OUR REVIEW WAS A
7 RELATIVELY POSITIVE ONE. THE HOOPS WE HAD TO JUMP
8 THROUGH WE WERE ABLE TO DO IN A RELATIVELY SHORT PERIOD
9 OF TIME, SO IT DIDN'T DELAY OUR TRIAL ALL THAT MUCH.

10 BUT THERE ARE OTHERS WHO I KNOW FELT THAT IT
11 DELAYED THEM SIGNIFICANTLY AND DELAYED BRINGING IN
12 FDA-APPROVED PROTOCOL TO THE CLINIC FOR PATIENTS THAT
13 DESPERATELY NEED NOVEL THERAPIES THAT MIGHT BE HELPED
14 BY GENE THERAPY A SIGNIFICANT PERIOD OF TIME.

15 SO IT WAS FROM AN ACADEMIC POINT OF VIEW, IT
16 WAS A VERY RIGOROUS INVESTIGATIVE DAY. BUT IN TERMS OF
17 BRINGING NOVEL THERAPIES TO THE CLINIC, WE FOUND IT TO
18 BE A BIT COUNTERPRODUCTIVE.

19 CO-CHAIR RABB: FRANCISCO.

20 DR. PRIETO: I THINK I WOULD HAVE TO COME
21 DOWN ON THE SIDE OF SUPPORTING ESCRO'S AT INSTITUTIONS
22 OR GROUPS OF INSTITUTIONS. I THINK THAT ALTHOUGH THE
23 CIRM MAY HAVE A PROCESS IN PLACE FOR THE WORKING GROUPS
24 THAT WOULD ALLOW US TO PERFORM THIS FUNCTION OURSELVES,
25 THIS WILL BE PERHAPS THE PREEMINENT FUNDING SOURCE FOR

1 MUCH OF THIS RESEARCH IN CALIFORNIA, BUT IT WILL BE NOT
2 THE ONLY ONE. I THINK, AS ZACH POINTED OUT, IT DOES
3 PROVIDE PROTECTION FOR THE RESEARCHER AND FOR THE
4 INSTITUTION AS WELL TO HAVE THIS IN PLACE AND TO BE
5 ABLE TO BUILD CONFIDENCE AMONG THE PUBLIC THAT, YES, IN
6 FACT, WE HAVE REVIEWED THIS AND REVIEWED IT AT SEVERAL
7 LEVELS.

8 THAT SAID, I THINK IT WOULDN'T BE
9 UNREASONABLE FOR US TO PUT IN SOME SORT OF STIPULATION
10 THAT THIS KIND OF REVIEW SHOULD BE TIMELY AND PERHAPS
11 EVEN PUT A CRITERIA FOR THAT.

12 BUT I WONDERED WHETHER WE AREN'T READY TO
13 ENTERTAIN A MOTION THAT WE ADOPT RECOMMENDATION NO. 1.

14 CO-CHAIR RABB: WHAT I'D LIKE TO DO IS,
15 ROBERT HAD HIS HAND UP, HEAR ROBERT, AND THEN LET'S
16 OPEN TO THE PUBLIC FOR EVERYTHING WE'VE TALKED ABOUT SO
17 FAR HAVING TO DO WITH THE GUIDELINES, AFTER WHICH WE
18 CAN EITHER DECIDE WHETHER WE'RE READY TO DECIDE
19 SOMETHING OR TAKE A BREAK AND THEN COME BACK, HAVING
20 HAD A CHANCE TO SPEND FIVE MINUTES THINKING ABOUT IT
21 AND GET A DRINK OF WATER OR WHATEVER AND GO FROM THERE.

22 JEFF, YOU WANT TO MAKE A COMMENT ON THE
23 PROCESS?

24 MR. SHEEHY: YES. ONE THING THAT IS REALLY
25 UNCLEAR TO ME IN ALL THIS DISCUSSION IS HOW THIS IS

1 GOING TO HELP THE ICOC FULFILL ITS FUNCTIONS. YOU
2 KNOW, I SEE THAT THIS IS A NEW REGULATORY STEP, BUT WE
3 STILL HAVE ULTIMATE RESPONSIBILITY. SO ARE WE NOT
4 GOING TO BE MAKING DECISIONS ON THE ETHICAL CONDITIONS
5 UNDER WHICH THESE GRANTS ARE GIVEN OUT AT SOME POINT?
6 OR ARE WE ABDICATING THAT RESPONSIBILITY TO THESE
7 COMMITTEES THAT ARE GOING TO BE AT AN INSTITUTIONAL
8 LEVEL? I DON'T KNOW IF WE HAVE THE AUTHORITY TO DO
9 THAT, TO BE HONEST, IN STATUTE.

10 AND IT'S JUST -- YOU KNOW, I THINK IT WOULD
11 BE A GREAT IDEA IF THE INSTITUTIONS SET UP THESE
12 ESCRO'S BECAUSE WE'RE NOT THE RIGHT REGULATORY AGENCY
13 FOR STEM CELL RESEARCH IN CALIFORNIA, NOR SHOULD WE
14 PRETEND THAT WE ARE. BUT I THINK BEFORE WE SEND OUT A
15 GRANT, BEFORE WE APPROVE A GRANT, WE SHOULD KNOW THAT
16 IT FULFILLS OUR ETHICAL CONDITIONS AND IT FULFILLS THE
17 SCIENTIFIC CONDITIONS THAT WE'VE DISCUSSED THAT COULD
18 BE PART OF THE ESCRO REVIEW. AND I THINK IF WE
19 APPROVED A GRANT AND IT WAS DELAYED, ESPECIALLY WITH
20 SOMETHING THAT HAD HUGE POTENTIAL, I THINK I WOULD BE
21 VERY UNHAPPY AS A PATIENT WAITING FOR SOME BENEFIT FROM
22 THAT THERAPY.

23 SO IT'S JUST VERY UNCLEAR HOW THESE ESCRO'S
24 FIT WITHIN THE CONTEXT OF OUR PROCESSES AND HELP OUR
25 PROCESS. I MEAN ARE WE STIPULATING THAT THESE ARE

1 GOING TO BE ENFORCEMENT BODIES FOR POLICIES THAT WE SET
2 UP? AND HOW DO WE ENSURE THAT THE ENFORCEMENT TAKES
3 PLACE? IT'S JUST VERY UNCLEAR HOW THIS FITS IN WITH
4 OUR STATUTORY DUTIES.

5 CO-CHAIR RABB: LET'S TAKE PUBLIC COMMENT
6 FROM NOW UNTIL IT'S TIME FOR A BREAK AND STRETCH A BIT,
7 THINK A MINUTE, AND THEN COME BACK AND TALK ABOUT WHAT
8 WE DO NEXT. PLEASE, WE INVITE MEMBERS OF THE PUBLIC TO
9 PLEASE COME TO THE MIC AND HAVE YOUR SAY. AND IT WOULD
10 BE BEST IF YOU WOULD -- WE'VE TALKED FOR A LONG TIME,
11 BUT IF YOU COULD AT LEAST YOUR ORIGINAL COMMENTS, THREE
12 MINUTES, AND THEN WE'LL MOVE ALONG TO MAKE SURE
13 EVERYBODY WHO WANTS TO SPEAK GETS THE CHANCE TO DO SO.
14 WE WILL COME BACK FOR MORE PUBLIC COMMENT BEFORE THE
15 MEETING ADJOURNS.

16 MR. REED: DON REED. I WAS VERY IMPRESSED BY
17 THE BRITISH APPROACH TO INFORMED CONSENT FOR THE EGG
18 DONORS. THEY DIDN'T HAVE THE EDUCATIONAL CLASSES AND
19 TELLING A PERSON ALL IN ONE DAY. THEY HAD IT OVER
20 SEVERAL DAYS SO THAT NO ONE COULD SAY THEY DIDN'T FULLY
21 UNDERSTAND. ALSO, THEY TESTED THE INDIVIDUAL, SO THEY
22 HAD TO PROVE THAT THEY KNEW EXACTLY WHAT'S GOING ON, SO
23 THEY COULD NEVER SAY I WAS MISLED, DIDN'T UNDERSTAND.

24 ALSO, I LIKE THE IDEA OF GIVING THEM SOME
25 REIMBURSEMENT FOR THEIR TIME BECAUSE THEY ARE DOING

1 SOMETHING NICE AND WONDERFUL. AND THEY'RE GOING
2 THROUGH A LOT OF HASSLE. I SEE NOTHING WRONG WITH
3 THAT. WE HAVE TO FULFILL OUR BARGAIN WITH CALIFORNIA,
4 BUT I THINK THAT THERE'S ENOUGH FLEXIBILITY IN THERE TO
5 REIMBURSE THEM FOR THEIR TIME.

6 ALSO, SOMETHING RELATED THAT THE BRITISH ALSO
7 DO THAT I WAS IMPRESSED WITH IS THAT THEY HAVE
8 INFORMATIONAL PACKETS WHICH ARE SENT OUT TO SCHOOLS.
9 AND I KNOW THAT SCIENCE TEACHERS ARE ANXIOUS. AS A
10 17-YEAR TEACHER MYSELF, SCIENCE TEACHERS LIKE TO HAVE
11 INFORMATION TO SHARE WITH THEIR CLASSES. I WOULD THINK
12 IT WOULD BE VERY HELPFUL IF WE COULD DO SOMETHING ALONG
13 THOSE LINES AND SHARE WITH OUR SCHOOLS WHAT'S HAPPENING
14 HERE.

15 CO-CHAIR RABB: THANK YOU.

16 MR. REYNOLDS: THANKS FOR GIVING ME THE
17 OPPORTUNITY. MY NAME IS JESSE REYNOLDS. I'M FROM THE
18 CENTER FOR GENETICS IN SOCIETY. AND I HAVE A FEW
19 POINTS HERE, AND I'LL TRY TO BE AS BRIEF AS POSSIBLE.

20 BACKING UP A LITTLE BIT TO THE EGG ISSUE THAT
21 WAS DISCUSSED EARLIER TODAY, THERE ARE THREE THINGS
22 THAT I THINK DESERVE A LITTLE BIT OF EXTRA ATTENTION AT
23 SOME POINT IN TIME. MR. REED BROUGHT UP THE ISSUE OF
24 INFORMED CONSENT. THIS IS REALLY CRITICAL. THERE'S --
25 WHAT I'D HATE TO SEE HAPPEN IS THAT THE NATURE OF

1 INFORMED CONSENT THAT'S APPLIED TO EGG PROVIDING FOR
2 REPRODUCTIVE PURPOSES JUST BE REPRODUCED AND PUT OVER
3 TO PROVIDING EGGS FOR RESEARCH, I THINK THAT DR.
4 KIESSLING BROUGHT UP A LOT OF INTERESTING IDEAS ABOUT
5 HOW'S SHE'S BEEN WORKING ON THAT.

6 SECOND, DR. PRIETO BROUGHT UP A LITTLE BIT
7 ABOUT WHO WOULD BEAR THE COST OF SHORT- AND LONG-TERM
8 HEALTH CONSEQUENCES. I THINK THIS IS A VERY SERIOUS
9 MATTER THAT DESERVES MORE INVESTIGATION, SOME IDEA OF
10 SOME SORT OF FINANCIAL TRUST OR A LONG-TERM INSURANCE
11 PROGRAM OR SOMETHING SHOULD BE WORKED OUT SO THAT THE
12 WOMEN WHO ARE BEING KIND ENOUGH TO PROVIDE THESE EGGS
13 FOR THE RESEARCH DON'T PAY PRICES FURTHER DOWN THE
14 ROAD.

15 THIRD POINT ON THE EGGS IS WE FEEL THAT THERE
16 NEEDS TO BE A SEPARATION, DEGREE OF INDEPENDENCE THAT
17 THOSE DOCTORS WHO ARE PERFORMING THE EGG EXTRACTION AND
18 PROVIDING THE INFORMATION FOR THE INFORMED CONSENT
19 PROCEDURE BE ONE STEP REMOVED FROM THE RESEARCH ITSELF.
20 SO THERE'S NOT A POSITION WHERE THEY HAVE AN INCENTIVE
21 TO GET MORE AND MORE EGGS, THAT THE DOCTOR DOESN'T HAVE
22 AN INCENTIVE AND A POTENTIAL CONFLICT.

23 FINALLY, ONE POINT ON THIS VERY DIFFICULT
24 QUESTION, AND I DON'T KNOW EXACTLY WHERE I COME DOWN ON
25 THIS ON THE ESCRO ISSUE ABOUT WHO HAS THE AUTHORITY AND

1 IS IT CENTRAL OR IS IT DECENTRALIZED. AND I HEARD A
2 LOT OF VERY GOOD IDEAS. BUT WHAT I DO KNOW IS THAT
3 THERE NEEDS TO BE A LAYER WHERE THERE IS REAL AUTHORITY
4 THAT'S INDEPENDENT. THAT'S A LITTLE TRICKY BECAUSE THE
5 INSTITUTIONAL BODIES, SIMILAR TO THE IRB'S, SEEM TO
6 HAVE A BIAS TOWARD SUPPORTING THEIR OWN INSTITUTIONS,
7 AND THEY'RE UNLIKELY TO HAVE REAL TEETH TO THEIR OWN
8 COLLEAGUES, OR AT THE VERY LEAST IT WILL BE MORE
9 DIFFICULT. BUT AT THE SAME TIME, THERE ARE THESE
10 SHORTCOMINGS WITH CENTRALIZED BODIES AND WHETHER THE
11 WORKING GROUP HERE IN FRONT OF US HAS THE AUTHORITY TO
12 BE THAT REGULATORY AGENCY. SO I'M NOT SURE EXACTLY
13 WHERE THAT MIDDLE GROUND IS, BUT THERE IS A NECESSITY
14 TO HAVE SOMETHING WITH TEETH.

15 DR. ROWLEY: CAN I JUST POINT OUT TO YOU THAT
16 RECOMMENDATION 14, WHICH IS CURRENTLY IN FORCE IN
17 CALIFORNIA, DOES DEAL WITH THE SEPARATION OF THE
18 DECISION FOR EGG DONATION AND FOR PEOPLE WHO ARE
19 RESPONSIBLE FOR THAT FROM THOSE WHO ARE INVOLVED IN
20 RESEARCH. SO THAT'S ALREADY INCORPORATED INTO
21 CALIFORNIA.

22 MR. REYNOLDS: RIGHT. MY CONCERN IS THAT,
23 THAT SAID, IF I RECALL RIGHT, THE LANGUAGE AROUND THAT
24 WAS A LITTLE BIT LOOSE, LIKE WHENEVER IT IS POSSIBLE OR
25 PRACTICABLE. WHENEVER IT'S PRACTICABLE TO HAVE THAT.

1 I FEEL THAT THIS IS AN IMPORTANT ENOUGH ISSUE THAT IT
2 SHOULD BE UNIFORMLY ENFORCED.

3 CO-CHAIR RABB: POINT TAKEN.

4 MR. HALPERN: I WANT TO THANK THE MEMBERS OF
5 THE COMMITTEE FOR A REALLY ILLUMINATING DISCUSSION.
6 I'VE BEEN COMING TO A LOT OF PROP 71 MEETINGS, AND THIS
7 HAS BEEN THE MOST SUBSTANTIVE AND MOST SERIOUS.

8 I WANT TO SPEAK BRIEFLY TO DR. ROWLEY'S
9 RECOMMENDATION. AND THAT IS THAT THIS BE PUT TO A
10 VOTE. I THINK IT'S PARTICULARLY IMPORTANT BECAUSE THE
11 NAS DOCUMENT THAT'S BEEN LAID BEFORE YOU TAKES A
12 POSITION, WHICH IS THAT EVERY INSTITUTION MUST HAVE AN
13 ESCRO. THAT'S THE POSITION PRESENTED, AND THAT THERE'S
14 NO CENTRALIZED AUTHORITY AT ALL. THERE'S NOT EVEN A
15 SYSTEM FOR REPORTING EACH ESCRO'S DECISION CENTRALLY.
16 SO I THINK IT REALLY IS IMPORTANT TO TRY TO CULL THE
17 DISCUSSION AND SET PRINCIPLES AND STANDARDS.

18 I ALSO AGREE COMPLETELY WITH MS. LANSING'S
19 VIEW, THAT A LACK OF UNIFORMITY IN THE STATE WILL
20 UNDERMINE PUBLIC CONFIDENCE IN THIS PROCESS. AND I AM
21 CONFIDENT THAT WHEN YOU'RE DEALING WITH DIFFICULT
22 QUESTIONS, FOR EXAMPLE, CHIMERIC RESEARCH, YOU ARE
23 GOING TO END UP WITH DIFFERENT RESULTS IN DIFFERENT
24 INSTITUTIONS. AND YOU ARE GOING TO BE ALL OVER THE
25 LAW, AND THAT IS NOT A DESIRABLE SITUATION, NOT EVEN

1 FOR THE NEXT SEVEN MONTHS BEFORE THE FINAL STANDARDS
2 ARE ADOPTED.

3 FOR EXAMPLE, WHAT 1.2(B) IN THE GUIDELINES,
4 WHICH IS ALSO REFLECTED IN THE APPENDIX B, IT SAYS THAT
5 CERTAIN KINDS OF STEM CELL -- CHIMERIC RESEARCH SHOULD
6 HAVE ADDITIONAL REVIEW AND APPROVAL, BUT IT DOESN'T SAY
7 WHO IT IS OR WHAT THE STANDARD SHOULD BE. THIS BRINGS
8 UP ANOTHER POINT THAT HAS NOT YET BEEN TOUCHED ON IN
9 THE DISCUSSION. THAT IS THE FACT THAT THIS STANDARD
10 HERE IS NOT SIMPLY GOING TO APPLY TO ACADEMIC
11 INSTITUTIONS WHICH HAVE A WELL-KNOWN AND HONORED
12 HISTORY IN THIS AREA, IT ALSO APPLIES TO PRIVATE
13 CORPORATIONS.

14 SO WHATEVER DOUBTS WE MAY HAVE ABOUT ESCRO'S
15 AND THEIR INDEPENDENCE, ONCE YOU PUT IT INSIDE GERON
16 WHERE THE PEOPLE ON THE COMMITTEE ARE GERON EMPLOYEES,
17 GERON MANAGEMENT IS HANDLING THE WHOLE THING, ONE
18 WONDERS WHETHER THE ESCRO IS GOING TO HAVE THE KIND OF
19 ROBUST INDEPENDENCE THAT I THINK IS IMPORTANT FOR IT TO
20 EXERCISE THE SORT OF REVIEW THAT'S ANTICIPATED HERE.

21 SO BASED ON THE CONVERSATION I'VE HEARD, IT
22 SEEMS TO ME THAT RATHER THAN SIMPLY REQUIRE THAT EACH
23 INSTITUTION SHOULD HAVE ITS OWN, IT SHOULD SAY EITHER
24 THAT IT SHOULD HAVE ITS OWN OR SOME KIND OF REGIONAL
25 ESCRO SYSTEM. IT SHOULD ADDITIONALLY SAY THAT ALL

1 DECISIONS MADE BY AN ESCRO SHOULD BE REPORTED CENTRALLY
2 TO THIS WORKING GROUP AND TO CIRM, AND IN PARTICULAR
3 ANY APPROVALS OF CHIMERIC RESEARCH OF THE TYPE OUTLINED
4 IN 1.2(B) OUGHT TO BE DESCRIBED IN DETAIL TO THIS
5 GROUP. AND THIS GROUP SHOULD SIGN OFF BEFORE THE
6 RESEARCH PROCEEDS.

7 AND LASTLY, THIS POINT HAS BEEN MADE BY
8 SEVERAL SPEAKERS, AND I JUST WANT TO ENDORSE IT. AND
9 THAT IS THE IDEA THAT THIS SYSTEM WITH THE ESCRO'S IN
10 PLACE AND WITH THE SET OF LIMITATIONS SHOULD APPLY TO
11 ALL GRANTEE ORGANIZATIONS INSOFAR AS THEY'RE INVOLVED
12 IN STEM CELL RESEARCH. WE'RE NOT, IN OTHER WORDS,
13 TALKING ONLY ABOUT A SYSTEM WHICH WOULD BE APPLIED TO
14 THE CIRM MONEY, BUT THEY CAN JUST IGNORE THEIR ESCRO'S
15 AND THINGS FOR PROJECTS FUNDED FROM OTHER SOURCES. IT
16 SHOULD BE CLEAR WHEN AN INSTITUTION TAKES CIRM MONEY,
17 THEY ARE COMMITTING THEMSELVES IN ALL OF THEIR STEM
18 CELL RESEARCH AND ALL THEIR STEM CELL ACTIVITIES,
19 TRAININGS AS WELL AS RESEARCH, TO FOLLOW THE STANDARDS
20 SET OUT AND PROSCRIBED BY THE CIRM.

21 CO-CHAIR RABB: ARE THERE OTHER PUBLIC
22 COMMENTS? FRANCISCO WANTS TO REMARK. I AM ESPECIALLY
23 INTERESTED IN COMING BACK TO SOME OF THE THINGS THAT
24 YOU ALL SPOKE ABOUT. BUT AFTER FRANCISCO, MAYBE WE CAN
25 TAKE A BRIEF BREAK FOR COMFORT PURPOSES AND THEN COME

1 BACK AND SEE IF OUR HEADS ARE CLEAR ABOUT HOW WE SHOULD
2 PROCEED FOR THE REST OF THE AFTERNOON. FRANCISCO.

3 DR. PRIETO: I JUST WANTED TO RESPOND TO WHAT
4 MR. HALPERN SAID. I THINK THAT ULTIMATELY THE ICOC, ON
5 BEHALF OF THE BOARD OF THE CIRM, WHICH IS THE FUNDING
6 INSTITUTION, IS ULTIMATELY RESPONSIBLE. WE DO BEAR
7 THAT RESPONSIBILITY. I DO NOT THINK THAT WE CAN REALLY
8 ENFORCE OUR STANDARDS ON BEHALF OF OTHER FUNDERS, BUT I
9 THINK CERTAINLY WE WOULD BE LOOKING AT THAT IF PEOPLE
10 WERE IGNORING THEM.

11 AND I JUST -- I THINK THAT SOME OF HIS
12 COMMENTS AND SUGGESTIONS WERE REALLY VERY GOOD ONES. I
13 THINK THAT ADDING THE STIPULATION THAT THE FINDINGS OF
14 THE ESCRO SHOULD BE REPORTED TO THE CIRM, I THINK
15 PERHAPS WE ASSUMED THAT, BUT THERE'S NO PROBLEM IN MY
16 VIEW WITH MAKING THAT EXPLICIT.

17 AND I WOULD WANT TO MODIFY THE RECOMMENDATION
18 TO SAY THAT, THE FIRST SENTENCE OF THE FIRST
19 RECOMMENDATION, THAT EACH INSTITUTION OR GROUP OF
20 INSTITUTIONS TO ALLOW FOR THAT FLEXIBILITY,
21 PARTICULARLY FOR SMALL INSTITUTIONS, AS I MENTIONED.

22 I WOULD ALSO JUST, AGAIN, RESPOND.
23 MR. HALPERN POINTED OUT THAT THE RECOMMENDATION FROM
24 THE ACADEMIES DOES STIPULATE THAT THE COMMITTEE SHOULD
25 INCLUDE REPRESENTATIVES OF THE PUBLIC AND PERSONS WITH

1 THE DIFFERENT EXPERTISE THAT'S LAID OUT THERE. I THINK
2 ALMOST BY DEFINITION WITHIN A PRIVATE CORPORATION THEY
3 WOULD HAVE TO GO OUTSIDE THEMSELVES IF THEY WERE
4 ESTABLISHING THEIR OWN ESCRO IN ORDER TO GET THAT KIND
5 OF EXPERTISE.

6 CO-CHAIR RABB: OKAY. MUCH TO DIGEST. LET'S
7 TAKE TEN MINUTES AND COME BACK TO CONTINUE.

8 (A RECESS WAS TAKEN.)

9 CO-CHAIR RABB: THERE HAVE BEEN MANY, MANY
10 BENEFITS TO THIS PUBLIC SESSION, ONE OF WHICH HAS
11 OCCASIONED THIS OVERLONG BREAK, DURING WHICH WE
12 DISCUSSED A MATTER THAT CAME TO OUR ATTENTION WITH A
13 SORT OF LASER-LIKE CLARITY THAT WE HAD NOT HAD BEFORE.
14 AND THAT IS, AS IT BECAME EVIDENT THROUGH THE PUBLIC'S
15 PARTICIPATION, THAT WHILE THE ICOC HAD ADOPTED THE NAS
16 GUIDELINES, WE HAD NOT PREPARED SPECIFIC DRAFT
17 REGULATORY LANGUAGE THAT WOULD ENHANCE THE ABILITY OF
18 THE PUBLIC TO RESPOND, NOT ONLY TO THE CONCEPTS IN THE
19 TEXT, BUT TO A TEXT ITSELF BECAUSE, AS WE KNOW, WORDS
20 MATTER.

21 AND IT HAS BEEN PROPOSED THAT WE TAKE A STEP
22 TO TAKE TIME AND TURN THE NAS GUIDELINES, NOT TO CHANGE
23 THEM, BUT TO TURN THEM INTO REGULATORY LANGUAGE TO
24 ENHANCE THE CAPACITY OF EVERYONE TO UNDERSTAND THE
25 BASELINE SO THAT THEY CAN RESPOND, NOT ONLY TO TEXT --

1 TO CONTENT -- NOT ONLY TO CONTENT, BUT TO THE LANGUAGE
2 AND THE WORDS THAT ARE BEING PUT OUT FOR PEOPLE TO
3 THINK ABOUT.

4 THE CIRM COLLEAGUES, THE STAFF, HAVE
5 UNDERTAKEN TO MAKE THAT DRAFTING CHANGE, WHICH IS
6 DESIGNED TO SUSTAIN THE CONCEPTS OF THE GUIDELINES, NOT
7 TO AMEND THEM, NOT TO AMEND THEM, BUT TO PRESENT TO THE
8 ICOC TEXT, WORDS, FORMAT THAT HONORS THE CHOICE THEY'VE
9 MADE TO ADOPT THESE GUIDELINES WHILE AT THE SAME TIME
10 SATISFYING WHAT MAY BE STRICT LEGAL REQUIREMENTS, THAT
11 WE GO FROM A DRAFT REGULATION TO A FINAL REGULATION
12 WITH THE MAXIMUM CLARITY POSSIBLE.

13 NOW, THAT MAY HAVE AN EFFECT ON THE TIMING OF
14 THE PUBLIC COMMENT, WHICH WE SAID THIS MORNING BEFORE
15 WE HAD THIS CONVERSATION ABOUT THE TEXT HERE IN THIS
16 MEETING, THAT ON JULY 22D THERE WOULD BE A WEBSITE,
17 FORMAL COMMENT, YADA, YADA. AND IT MAY AFFECT THE
18 TIMING OF WHEN WE GET UP ON THE WEB BECAUSE THE ICOC
19 WILL HAVE TO HAVE THE OPPORTUNITY, AS IT SHOULD HAVE,
20 TO REVIEW THIS DRAFT TO BE CERTAIN THAT WHAT WAS DONE
21 IS NOT A CHANGE IN WHAT THE IC WANTED TO ADOPT. IT IS
22 A CHANGE IN THE WORDS AND TEXT THAT REFLECT THAT
23 ADOPTION.

24 OTHERS WHO HAVE SPOKEN ABOUT THIS DURING THE
25 BREAK MAYBE WANT TO HAVE SOMETHING TO SAY. ROBERT, YOU

1 DO.

2 MR. KLEIN: IF I CAN ASK TWO QUESTIONS.
3 FIRST, DR. HALL, TO MAXIMIZE THE PUBLIC'S INPUT, I
4 ASSUME WE CAN STILL PUT THE GUIDELINES THAT WE HAVE UP
5 ON THE WEB, HAVE THEM UP ON THE WEB, AND HAVE INPUT SO
6 WHILE REGULATORY LANGUAGE IS BEING DEVELOPED, WE CAN
7 GET THE BENEFIT OF THE PUBLIC INPUT ON THE SAME
8 TIMETABLE.

9 DR. HALL: BASED ON THE CURRENT LANGUAGE,
10 JUST AS WE'D HAD A DISCUSSION HERE TODAY.

11 MR. KLEIN: WHILE THE PROCESS IS GOING ON, IF
12 THAT'S ACCEPTABLE TO THE CHAIR.

13 CO-CHAIR RABB: I'M SURE IT IS. THE ONE
14 THING THAT I THINK WE OUGHT TO HAVE GOOD LEGAL ADVICE
15 ABOUT, AND THIS COULD ALSO GO UP ON THE WEBSITE, EITHER
16 THE CIRM GENERAL OR THE GUIDELINES -- I'M GOING TO COME
17 BACK TO YOU, I PROMISE. THAT WHAT WE NEED GOOD LEGAL
18 ADVICE ABOUT IS HOW TO INCORPORATE ALL COMMENTS,
19 WHETHER PRIOR TO THE NEXT ICOC MEETING OR AFTER THE
20 ICOC ADOPTS REGULATORY LANGUAGE, HOW TO MAKE SURE THAT
21 ALL THE COMMENTS BECOME A PART OF THE PUBLIC RECORD
22 BECAUSE THAT WILL BE CRITICAL, THAT PEOPLE DON'T
23 SOMEHOW THINK THAT BECAUSE WE RESPONDED NOW, THEY'RE
24 ALL RIGHT.

25 MR. KLEIN: AND THE SECOND QUESTION GOES TO

1 COUNSEL. IS THE CORRECT MECHANISM TO ACCOMPLISH THIS
2 FOR US AS A GROUP TO VOTE TO RECOMMEND BACK TO THE ICOC
3 THAT THEY DIRECT US TO ACCOMPLISH THIS SO THAT THEY
4 WOULD EFFECTIVELY READOPT THESE WITH THE RESOLUTION
5 DIRECTING THAT THE REGULATORY LANGUAGE BE CREATED FOR
6 CLARITY AND BE REPORTED BACK TO THE ICOC ON A SPECIFIC
7 DATE?

8 MR. HARRISON: YES. I THINK IF YOU ENVISION
9 THE PROCESS IN THIS WAY. WHAT THIS WORKING GROUP WOULD
10 DO WOULD BE TO ADOPT A MOTION ASKING THE ICOC TO DIRECT
11 THE WORKING GROUP TO DEVELOP PRECISE REGULATORY
12 LANGUAGE FOR PROPOSAL TO THE ICOC TO ADOPT AS INTERIM
13 STANDARDS. ONCE THE ICOC CONSIDERED THAT PRECISE
14 LANGUAGE AND ADOPTED IT, THAT WOULD TRIGGER THE FORMAL
15 RULEMAKING PROCESS UNDER THE ADMINISTRATIVE PROCEDURE
16 ACT. SO IN A SENSE WE'D HAVE TWO LEVELS OF PUBLIC
17 COMMENT. WE HAVE A LEVEL OF PUBLIC COMMENT ASSOCIATED
18 WITH THE DEVELOPMENT OF THE PRECISE REGULATORY
19 LANGUAGE, AND THEN WE'D HAVE A FORMAL OPPORTUNITY
20 DURING THE RULEMAKING PROCESS FOR FURTHER PUBLIC
21 COMMENT ON THAT LANGUAGE.

22 MR. KLEIN: SO TO CLARIFY THAT, MY
23 UNDERSTANDING IS THAT ESSENTIALLY THE PUBLIC'S TIME
24 PERIOD FOR COMMENT IS GOING TO RUN AFTER WE HAVE THIS
25 PRECISE REGULATORY PERIOD, WHICH IS WHAT THE CHAIR WAS

1 REFERRING TO, IS THAT BY US RECOMMENDING THIS TO THE
2 ICOC AND ASKING THEM TO DO THIS, IT GIVES US THE
3 ABILITY TO GET MORE PRECISE LANGUAGE.

4 NOW, THERE'S SOME SECTIONS, AS MR. HALPERN'S
5 POINTED OUT, WHERE THE STEM CELL BANK, WHERE THE WORLD
6 IS DEVELOPING LANGUAGE. SO WE WON'T HAVE -- WE'LL
7 STILL HAVE SOME FAIRLY CONCEPTUAL REGULATORY LANGUAGE
8 BECAUSE IT'S THE STATE OF THE ART, STATE OF THE
9 SCIENCE. BUT ON OTHER SECTIONS, WE CAN, WHILE KEEPING
10 THE SAME MODEL -- AS THE CHAIR HAS INDICATED, WE'RE NOT
11 CHANGING THE MODEL FOR OUR REGULATORY STANDARDS. WE'RE
12 CREATING A PROCESS WHERE WE HAVE MORE PRECISE LANGUAGE,
13 AS THE CHAIR HAS SAID, TO PROVIDE THE GREATEST CLARITY
14 TO THE PUBLIC DURING THE PUBLIC COMMENTARY PERIOD; IS
15 THAT CORRECT?

16 MR. HARRISON: YES. IN OTHER WORDS, THE
17 PUBLIC COULD CERTAINLY COMMENT ON THE LANGUAGE DURING
18 THIS PERIOD WHILE THE STANDARDS WORKING GROUP IS
19 CONSIDERING THE PRECISE LANGUAGE. AND WHEN THE
20 STANDARDS WORKING GROUP IS PRESENTED WITH THAT
21 LANGUAGE, THERE WOULD OBVIOUSLY BE ANOTHER OPPORTUNITY
22 FOR PUBLIC COMMENT AT THAT MEETING. THE STANDARDS
23 WORKING GROUP WOULD THEN RECOMMEND LANGUAGE TO THE ICOC
24 FOR ITS CONSIDERATION AND ADOPTION AS INTERIM
25 STANDARDS, AND THEN WE WOULD BEGIN A FORMAL RULEMAKING

1 PROCESS WHERE THERE WOULD BE OPPORTUNITY FOR PUBLIC
2 COMMENT AND FURTHER MODIFICATION, IF NECESSARY.

3 CO-CHAIR RABB: WE HAVE TED, ZACH, KEVIN,
4 PUBLIC.

5 DR. PETERS: TO WHAT DOES THIS TRANSLATION
6 INTO REGULATORY LANGUAGE APPLY? ALL OF THE NAS
7 RECOMMENDATIONS OR ONLY THOSE HAVING TO DO WITH PUBLIC
8 PARTICIPATION?

9 CO-CHAIR RABB: MY UNDERSTANDING IS THAT THE
10 DRAFTING AND REFORMATTING WOULD APPLY TO THE WHOLE NAS
11 GUIDELINES PROCESS AND NOT JUST THE PUBLIC
12 PARTICIPATION.

13 DR. PETERS: WELL, I SEE A PROBLEM. MAY I?

14 CO-CHAIR RABB: OF COURSE.

15 DR. PETERS: I THINK THE MAIN PROBLEM IS I
16 THINK IT'S UNNECESSARY WORK. AND THE SECOND ONE IS I
17 WONDER WHY WE WOULD WANT TO VOLUNTEER TO DO THIS IF, AS
18 I UNDERSTOOD WHAT WAS SAID EARLIER, THE ICOC ON MAY 23D
19 ADOPTED THIS AS THE INTERIM GUIDELINES. THAT IS THEIR
20 DECISION. AND THEY STAND AS ALREADY APPROVED AS THE
21 INTERIM GUIDELINES. WE HERE TODAY HAVE NOT YET BEEN
22 ASKED WHETHER OR NOT THIS COMMITTEE AGREES OR
23 DISAGREES, SO WE DON'T EVEN KNOW AS TO WHETHER OR NOT
24 WE DO. WE WOULDN'T NEED TO AGREE OR DISAGREE.

25 IF WE ARE IN THE PROCESS OF FORMULATING WHAT

1 WE BELIEVE TO BE OUR STANDARDS, WE'LL PROBABLY DO IT
2 ONE ITEM AT A TIME, AND EACH ONE CAN BE FORMULATED IN
3 REGULATORY LANGUAGE. THERE'S NO REASON FOR US TO DO
4 THE WORK OF THE ICOC AND HAVE IT DELAY US FROM DOING
5 THE WORK THAT WE'VE BEEN COMMISSIONED TO DO, IT SEEMS
6 TO ME. IF I'M UNDERSTANDING THE SITUATION CORRECTLY,
7 OR IF I'M MISUNDERSTANDING, I APOLOGIZE.

8 CO-CHAIR RABB: I HAVE ZACH, KEVIN, AND THEN
9 PUBLIC.

10 DR. HALL: I WAS JUST GOING TO MAKE THE POINT
11 THAT MAY BE RELEVANT TO THAT, AND THAT IS DOING IT THIS
12 WAY HAS THE ADDITIONAL ADVANTAGE THAT PROPOSITION 71
13 ACTUALLY SAYS THAT THE WORKING GROUP SHOULD RECOMMEND
14 TO THE ICOC. AND WE WENT AHEAD AND ADOPTED THE INTERIM
15 STANDARDS IN OUR EAGERNESS TO GET GOING. THIS IS IN A
16 WAY SORT OF ADDRESSING THAT PROCEDURAL NICETY AS WELL
17 IN DOING IT THE OTHER WAY. SO THEN WE'RE STRICTLY
18 ACCORDING TO PROPOSITION 71, AND WE START WITH THE NAS
19 STANDARDS AND REGULATORY LANGUAGE, WHICH WE CAN THEN,
20 AS THE CHAIR SAID.

21 CO-CHAIR RABB: JAMES, WHY DON'T YOU ADD ON
22 TO THAT JUST TO RESPOND TO TED.

23 MR. HARRISON: I JUST WANTED TO RESPOND
24 SPECIFICALLY TO YOUR QUESTION. THE STAFF WILL
25 UNDERTAKE THE TASK OF PUTTING THE GUIDELINES INTO

1 REGULATORY LANGUAGE. AND THAT'S A REQUIREMENT OF
2 CALIFORNIA LAW. THIS -- THE CHARGE OF THIS WORKING
3 GROUP WILL NOT CHANGE. IT WILL STILL BE CONSIDERING
4 THE SUBSTANCE OF THE GUIDELINES AND WHETHER OR NOT
5 MODIFICATION SHOULD BE RECOMMENDED TO THE ICOC. IT'S
6 JUST THAT WE'LL IN A SENSE REVERSE THE PROCESS. WE'LL
7 NOW START WITH SOME REGULATORY, SOME PRECISE REGULATORY
8 LANGUAGE, BUT YOUR CHARGE WILL BE TO CONSIDER THAT
9 LANGUAGE AND THE CONCEPTS AND TO MAKE ANY
10 RECOMMENDATIONS FOR CHANGES TO THE ICOC FOR ITS
11 APPROVAL AS INTERIM STANDARDS IN SEPTEMBER, AND THEN
12 THE FORMAL RULEMAKING PROCESS WILL BEGIN.

13 DR. EGGAN: THAT'S JUST WHAT I WANTED TO
14 CLARIFY IS TO SAY THAT, AGAIN, THIS WOULD BE IN THE
15 SPIRIT OF FORMALLY ENACTING FROM OUR PERSPECTIVE THAT
16 THIS IS A REASONABLE STARTING PLACE. AND THAT
17 ESSENTIALLY ONCE THAT STARTING PLACE IN A REGULATORY
18 LANGUAGE IS DEFINED, IT WILL BE EASY FOR US TO GO --
19 EASIER, I SHOULD SAY, TO GO BACK AND CHANGE THOSE
20 ACTUAL WORDS -- I THINK THAT'S WHAT YOU WERE DRIVING AT
21 IN YOUR COMMENT -- INTO WHAT WE AS A GROUP FEEL SHOULD
22 BE THE DRAFT FINAL RULES.

23 AND, AGAIN, I WOULD EVEN SAY THAT THERE MAY
24 BE NO FINAL RULES. THIS IS GOING TO BE A -- THERE WILL
25 BE CONSTANT CHANGE PERHAPS TO THIS OVER TIME AS THE

1 LANDSCAPE CHANGES.

2 CO-CHAIR RABB: LET'S HEAR FROM THE PUBLIC,
3 AND THEN WE CAN COME BACK, AND THOSE OF US WHO HAVEN'T
4 SAID ANYTHING YET WHO WANT TO WILL BE INVITED TO.

5 MR. HALPERN: I THINK THIS IS A STEP FORWARD.
6 MAY NOT FEEL LIKE A STEP FORWARD, BUT I REALLY THINK IT
7 IS BECAUSE, AS ZACH SAYS, THIS IS PUTTING US BACK INTO
8 THE ORDER THAT PROP 71 INDICATED. IT'S NOT THAT THIS
9 WORKING GROUP IS TAKING OVER AN ICOC TASK. IT IS DOING
10 PRECISELY WHAT PROP 71 ANTICIPATED THAT THIS WORKING
11 GROUP WOULD DO. THAT'S ONE GOOD THING.

12 I THINK MUCH OF THE MATERIAL IN THE NAS
13 GUIDELINES CAN BE EASILY TURNED INTO REGULATORY
14 LANGUAGE. ONE SIMPLE TASK THAT YOU CAN DO AT A
15 COMPUTER KEYBOARD IS TO TAKE EVERY TIME IT SAYS SHOULD,
16 WHICH IS KIND OF ADVISORY LANGUAGE, AND PUT IN SHALL,
17 SO IT BECOMES THE LANGUAGE OF REGULATION. THAT'S EASY.

18 THERE ARE THINGS IN HERE, THOUGH, THAT SIMPLY
19 CAN'T BE TRANSLATED IN THAT FASHION. ONE BEING THIS
20 ENTIRE SUBJECT OF BANKING AND DISTRIBUTION WHERE IT
21 DOESN'T OFFER ANYTHING EXCEPT, YOU KNOW, THAT THERE'S
22 INTERESTING STUFF. AND THEN THERE'S SOME THINGS WHICH
23 I THINK ARE SO CLEARLY INAPPROPRIATE IN CALIFORNIA,
24 THAT IT DOESN'T MAKE SENSE TO OFFER THEM JUST BECAUSE
25 THE NAS HAS SAID IT. LIKE, FOR EXAMPLE, THIS 14-DAY

1 LIMITATION ON HARVESTING CELLS WHEN WE IN CALIFORNIA
2 HAVE AN 8- TO 12-DAY LIMITATION. AND SINCE THAT'S IN
3 STATUTE, IT SHOULD GOVERN.

4 SO MY HOPE WOULD BE, AND I THINK THE MOST
5 EXPEDITIOUS WAY TO PROCEED WOULD BE JUST WHAT YOU ARE
6 SUGGESTING. THERE'S NO NEED TO WAIT FOR THE ICOC TO
7 DELEGATE TO THIS WORKING GROUP WHAT PROP 71 HAS ALREADY
8 DELEGATED TO THIS WORKING GROUP. AND BUT RATHER THAN
9 JUST HAVE THE STAFF ON ITS OWN DO THIS AS IF IT WERE
10 SIMPLY A MINISTERIAL TASK, MY HOPE WOULD BE THAT A
11 SUBCOMMITTEE OF THIS WORKING GROUP WOULD WORK WITH THE
12 STAFF, WHERE IT'S POSSIBLE TO SIMPLY TRANSLATE IT INTO
13 THE LANGUAGE OF REGULATORY REGULATION, DO THAT. AND
14 WHERE IT'S NOT, EITHER TO RECOMMEND SOMETHING TO THE
15 WORKING GROUP OR TO JUST FRAME AN ISSUE FOR THE WORKING
16 GROUP TO CONSIDER. THAT MEANS THAT I THINK YOU WILL BE
17 ABLE TO MOVE THINGS AHEAD MORE EXPEDITIOUSLY, WHICH I
18 THINK IS WHAT EVERYBODY IN THIS ROOM WANTS TO SEE
19 HAPPEN.

20 CO-CHAIR RABB: I THINK THAT SUGGESTION, LIKE
21 ALL THE OTHERS, IS GOING TO HAVE TO SIT WITH ALL OF US
22 FOR A PERIOD OF TIME AFTER THIS MEETING BECAUSE
23 UNINTENDED CONSEQUENCES WOULD BE A COMPLICATION THAT
24 NONE OF US WANT, BUT I HEAR YOU AND I UNDERSTAND
25 EVERYBODY DOES. WE HAVE ANOTHER.

1 MS. AURITI: I'M ELLEN AURITI FROM THE
2 UNIVERSITY OF CALIFORNIA. I'M NOT SURE WHERE THIS FITS
3 INTO YOUR AGENDA IN CONSIDERING INDIVIDUAL
4 RECOMMENDATIONS OF THE NAS GUIDELINES AND WHAT THIS
5 WORK GROUP MAY OR MAY NOT RECOMMEND AS ALTERATIONS, BUT
6 IT WOULD BE HELPFUL TO US TO HAVE SOME CLARIFICATION AS
7 TO WHAT THE INTENT IS IN ADOPTING THE NAS GUIDELINES
8 WITH RESPECT TO THE RECOMMENDATION THAT CONSENT BE
9 OBTAINED FROM ALL GAMETE DONORS AT THE TIME OF DONATION
10 FOR BLASTOCYSTS THAT ARE USED IN EMBRYO -- IN STEM CELL
11 RESEARCH.

12 IT'S UNCLEAR WHETHER THE INTENT IS THAT
13 INSTITUTIONS WOULD NOT BE ABLE TO MAKE USE OF EXISTING
14 STEM CELL LINES AND RESEARCH THAT'S FUNDED BY CIRM. IT
15 WOULD BE VERY HELPFUL TO HAVE SOME CLARIFICATION FROM
16 THIS GROUP. AS CHAIRMAN KLEIN SAID EARLIER, THAT THE
17 INTENT WAS THAT THE ADOPTION WOULD BE PROSPECTIVE. AND
18 I KNOW THAT MAYBE ALTA CHARO OR DR. ROWLEY COULD
19 COMMENT ON WHAT THE NAS INTENT WAS IN PUTTING FORTH
20 THAT RECOMMENDATION. THANK YOU.

21 CO-CHAIR RABB: ONE OF THE WAYS OF DEALING
22 WITH THE FINAL REG WILL BE THAT WE -- THAT THE TEXT
23 SHOULD BE -- WITHIN THE FOUR CORNERS OF THE TEXT, THAT
24 KIND OF CLARITY SHOULD BE OFFERED SO THAT IT'S NOT
25 NECESSARY TO HEAR WHAT THE INTENT OF THE DRAFTERS WAS.

1 YOUR POINT IS VERY WELL TAKEN, THAT THAT'S AN ISSUE
2 WE'RE GOING TO HAVE TO DEAL WITH SO THAT THE TEXT
3 ITSELF MAKES VERY CLEAR WHAT'S COVERED AND WHAT'S NOT.
4 AND THIS PARTICULAR ISSUE IS A GOOD ONE.

5 OTHER PUBLIC. THIS IS NOT ALL IN. THE
6 PUBLIC CAN SPEAK UP AGAIN. ROBERT.

7 MR. KLEIN: VERY SPECIFICALLY RESPOND TO YOUR
8 POINT. THE GUIDELINES ACTUALLY WERE ADOPTED WITH
9 ESSENTIALLY A PREAMBLE THAT SPECIFIED THAT IT WAS
10 PROSPECTIVE ONLY. WHAT WE NEED TO DO IS WE RECONSIDER
11 THESE AGAIN AT THE NEXT MEETING, HAVE STAFF PROVIDE US
12 WITH THAT PREAMBLE THAT MADE IT VERY CLEAR IT WAS
13 INCORPORATED IN OUR ADOPTION AND THAT IT BE
14 PROSPECTIVE.

15 ADDITIONALLY, IN THAT ADOPTION I BELIEVE THAT
16 IT DID REFERENCE THAT THE 14 DAYS WOULD BE LIMITED TO
17 12 DAYS. AS REFERENCED HERE THE INITIATIVE LIMITS IT
18 UNDER THE PROP 71 STANDARD TO 12 DAYS. BUT THOSE
19 POINTS WOULD BE INCORPORATED AS THE VERY SPECIFIC
20 LANGUAGE THAT WAS REFERRED AS A MODEL TO THIS COMMITTEE
21 IN THE LANGUAGE THAT IS TO BE ADOPTED.

22 BUT I THINK PROCEDURALLY TO FOLLOW STEP BY
23 STEP IN THE TRACKS OF PROP 71, AS DR. HALL HAS SAID,
24 THAT IN GETTING THIS CLARIFIED LANGUAGE, AND AS
25 MR. HALPERN POINTS OUT, MUCH OF IT CAN BE A VERY SIMPLE

1 AMENDMENT JUST TO GET THIS MOVING WITH CLARITY FROM A
2 SHOULD TO A SHALL TO MORE REGULATORY POSTURE IN THE
3 LANGUAGE. BUT IN THE LANGUAGE THAT DEALS WITH STEM
4 CELL BANKS AND OTHER ISSUES, IT'S POSSIBLE -- LIKE TO
5 HEAR SOME DISCUSSION FROM COLLEAGUES ON THIS BOARD
6 ABOUT HOW WE ACTUALLY ADDRESS THE STEM CELL BANK. THAT
7 IS A VERY EVOLVING TOPIC, REQUIRES A LOT OF BRAIN
8 POWER, IT'S NOT BEEN WELL SETTLED INTERNATIONALLY OR
9 NATIONALLY, ALTHOUGH THERE'S SOME VERY GOOD MODELS IN
10 DIFFERENT COUNTRIES.

11 DR. HALL, DO YOU HAVE A SPECIFIC
12 RECOMMENDATION ABOUT HOW WE SHOULD ADDRESS THAT
13 SPECIFIC SECTION?

14 DR. HALL: YOU HAVE SOMETHING URGENT? LOOKS
15 LIKE YOU ARE SEIZED WITH --

16 DR. PETERS: I FIND THE AGENDA RIGHT NOW
17 CONFUSED. ARE WE TALKING ABOUT A PROCEDURAL MATTER?
18 IF I UNDERSTOOD THE ORIGINAL MOTION, IT WAS TO SIMPLY
19 TRANSLATE THIS EXISTING DOCUMENT WITHOUT ANY CHANGES
20 INTO REGULATORY LANGUAGE IN ORDER TO DO A FAVOR TO THE
21 ICOC AND TO PERMIT US TO HAVE A BASELINE FOR OUR OWN
22 REFORMULATIONS. NOW WHAT I HEAR IS A SUBSTANTIVE
23 DISCUSSION WHICH RETURNS US TO THE MAIN AGENDA THAT WE
24 SHOULD BE TAKING UP OVER THE NEXT 270 DAYS.

25 AND AT ANY RATE, WHERE ARE WE, MADAM

1 CHAIRMAN?

2 CO-CHAIR RABB: YES.

3 CO-CHAIR LANSING: WELL, I AGREE WITH YOU,
4 TED. I JUST WANT TO HAVE A POINT OF CLARIFICATION
5 BECAUSE I THINK IT'S REALLY IMPORTANT. WHAT I
6 UNDERSTAND IS THAT THE ICOC ADOPTED A SET OF GUIDELINES
7 WHICH HAD AN APPENDIX A IN IT, WHICH IS BASICALLY A
8 SUMMARY OF THOSE GUIDELINES, WHICH FOR PEOPLE LIKE
9 MYSELF IS HELPFUL TO READ.

10 NOW, WHAT WE ARE ATTEMPTING TO DO IS JUST TO
11 TRANSLATE THAT INTO LEGAL LANGUAGE. BUT IF WE START
12 CHANGING IT, THEN WE'RE DOING THE NEXT STEP BECAUSE
13 WHAT I THOUGHT WE WERE GOING TO DO IS TAKE THIS, AS TED
14 SAID, TAKE THIS WITH THE APPENDIX AND WITH THE
15 GUIDELINES AND NOW TRANSLATE IT INTO LEGAL LANGUAGE,
16 WHICH WOULD GIVE US A BASELINE TO LOOK AT. AND THEN TO
17 MAKE ALL THE CHANGES THAT WE WANT TO WHEN WE CAME TO,
18 FOR EXAMPLE, BANKS, WHICH THERE IS NO CLARITY, WE WOULD
19 JUST HAVE TO BE THIS IS AN ISSUE WE'RE GOING TO DEAL
20 WITH OR WHATEVER LANGUAGE YOU WANT TO PUT IT IN
21 LEGALLY.

22 MY QUESTION TO YOU, AND I HAVE NO PROBLEM
23 WITH THIS INTERIM STAGE BECAUSE IT WILL GIVE US A
24 BASELINE TO WORK FROM AS WE CONTINUE THESE DISCUSSIONS
25 AND GIVE US IN A FUNNY WAY A HEAD START BECAUSE WE'LL

1 BE DOING THE PROCESS IS HOW I LOOK AT IT. WE'LL BE
2 GETTING A HEAD START ON THE PROCESS AND CHANGING
3 EVENTUALLY, BUT NOT IN THE FIRST STAGE, THE SHOULD TO
4 SHOULD OR THE SHOULD TO SHOULD, WHATEVER.

5 MY QUESTION IS HOW LONG IS IT GOING TO TAKE
6 BEFORE WE'LL HAVE THIS BASELINE TO LOOK AT --

7 DR. HALL: AS I UNDERSTAND --

8 CO-CHAIR LANSING: -- IN ORDER FOR IT TO BE
9 HELPFUL TO US?

10 DR. HALL: YES. THERE IS A MEETING OF THIS
11 WORKING GROUP SCHEDULED FOR AUGUST 30TH; IS THAT RIGHT?

12 CO-CHAIR RABB: I DON'T KNOW.

13 DR. HALL: THERE IS. AUGUST WHATEVER THAT
14 DATE IS.

15 CO-CHAIR LANSING: APPROXIMATELY.

16 DR. HALL: IN THE SPIRIT OF OUR DISCUSSION
17 THIS MORNING, WE WILL DO EVERYTHING WE CAN TO HAVE THAT
18 VERSION READY TEN DAYS BEFORE THE DATE OF THE MEETING.
19 I CANNOT PROMISE THAT WE'LL BE ABLE TO DO THAT, BUT WE
20 WILL CERTAINLY WORK VERY HARD TO DO THAT.

21 SO JUST -- DOES THAT ANSWER YOUR QUESTION?

22 CO-CHAIR LANSING: YES. BECAUSE I THINK IT'S
23 EXTREMELY IMPORTANT, AS TED ALSO SAID, THAT THIS JUST
24 BE A FACTUAL AND LEGAL TRANSLATION OF THE GUIDELINES
25 AND APPENDIX A, FOR WANT OF A BETTER WORD, WHICH IS A

1 SUMMARY OF THE GUIDELINES.

2 DR. HALL: SO DR. PETERS IS QUITE RIGHT. WE
3 HAVE TWO THINGS GOING ON HERE. ONE IS THE BEGINNING OF
4 A RESOLUTION THAT JAMES ASKED FOR, AND THE OTHER IS
5 WHAT I SEE AS PART OF AN ONGOING DISCUSSION WITH NO
6 ACTION TO BE TAKEN TODAY, BUT TO CONTINUE -- I THINK
7 SHERRY PUT IT NICELY -- A HEAD START; THAT IS, THERE
8 ARE LOTS OF ISSUES TO BE DISCUSSED. WE HAVE LOTS OF
9 OPINIONS TO GET, BOTH FROM THIS GROUP AND FROM THE
10 COMMITTEE. THAT'S GOING TO TAKE SOME TIME, AND SO WE
11 SHOULD GO AHEAD AND DO THAT.

12 CO-CHAIR LANSING: SO WE'RE DOING A PROCESS
13 BY WHICH WE'RE STARTING THE LEGAL LANGUAGE PROCESS,
14 WHICH WILL MAKE IT EASIER FOR US WHEN WE MODIFY IT AND
15 ADD TO IT.

16 DR. HALL: YES. AND WE WILL GO AHEAD AND
17 BEGIN TO RECEIVE COMMENT, NOT AS PART OF THE OFFICIAL
18 45-DAY PERIOD, BUT WE WILL GO AHEAD AND BEGIN TO
19 RECEIVE COMMENT ON THE WEBSITE, AS SOON AS WE CAN GET
20 IT UP, ON NATIONAL ACADEMY GUIDELINES. AND WHEN OUR
21 NEW VERSION IS READY, WE WILL PUT THAT UP ALSO.

22 DR. EGGAN: AS WAS POINTED OUT IN PUBLIC
23 DISCUSSION, WOULD IT NOT BE APPROPRIATE TO MODIFY THOSE
24 GUIDELINES SO THAT THEY ARE APPROPRIATE PURSUANT TO THE
25 PREEXISTING?

1 CO-CHAIR LANSING: NOT YET.

2 DR. EGGAN: CAN THE ICOC APPROVE THEM IF THEY
3 GO AGAINST WHAT PROPOSITION 71 SAYS TO BE TRUE? SHOULD
4 THEY BE MODIFIED, FOR INSTANCE, THIS ISSUE ABOUT TIMING
5 OF WHEN THE EMBRYO ARE DESTROYED? IN THOSE PLACES
6 WHERE THERE ARE CLEAR FACTUAL DIFFERENCES BETWEEN WHAT
7 IS IN THE GUIDELINES AND WHAT IS ALLOWABLE BY LAW,
8 INDEED, IT SEEMS THAT MUST BE CHANGED. AND IF WE CAN
9 ALL AGREE TO ACCEPT THOSE CHANGES THAT ARE ALREADY
10 ACTED UPON.

11 MR. KLEIN: AS A POINT OF ORDER, IT WAS
12 ADOPTED WITH PROSPECTIVE LANGUAGE. WE HAVE TO
13 INCORPORATE THE LANGUAGE AS A PREAMBLE THAT IT'S
14 PROSPECTIVE IF WE'RE GOING TO -- IF WE'RE GOING TO
15 TRANSLATE INTO REGULATIONS WHAT WAS ADOPTED.

16 DR. KIESSLING: DO WE HAVE A COPY OF THAT
17 PREAMBLE?

18 MR. KLEIN: WE HAVE IT IN THE TRANSCRIPTS
19 THAT SHOULD BE MADE AVAILABLE TO ALL OF US.

20 CO-CHAIR LANSING: OUR LEGAL SCHOLARS COULD
21 GET A JUMP ON IT AND HAVE IT BE THERE, AND THEN GET A
22 JUMP AND SAY, NO, THIS ONE IS NOT LEGAL. SO WE'RE
23 TRYING TO GET AHEAD OF IT SO THAT WE CAN GET SOME OF
24 THE LEGAL WORK DONE SO THAT WE WON'T BE SCRAMBLING ON
25 DAY 270 WHATEVER IT IS.

1 DR. HALL: I DON'T WANT TO LET THE MOTION --
2 WE DON'T HAVE A MOTION, BUT JAMES SUGGESTED THAT THE
3 WORKING GROUP -- I'LL LET YOU.

4 MR. HARRISON: WHAT I HAD SUGGESTED IS THAT
5 THE WORKING GROUP ADOPT A MOTION ASKING THE ICOC TO
6 DIRECT THE WORKING GROUP TO PROPOSE SPECIFIC LANGUAGE,
7 WHICH STAFF WILL DRAFT, AND ANY OTHER RECOMMENDED
8 CHANGES THAT THIS WORKING GROUP WANTS TO MAKE TO THE
9 STANDARDS THEMSELVES FOR THE ICOC'S CONSIDERATION AS
10 INTERIM STANDARDS AT ITS SEPTEMBER 9TH MEETING, AND
11 COMMENCE THE FORMAL RULEMAKING PROCESS AFTER THE ICOC
12 HAS ADOPTED THOSE INTERIM STANDARDS.

13 CO-CHAIR RABB: WILL YOU ACCEPT AN AMENDMENT
14 TO YOUR PROPOSAL?

15 MR. HARRISON: IT'S NOT MINE, SO, YES, I'D BE
16 HAPPY TO.

17 CO-CHAIR RABB: IT SEEMS TO ME THAT WE --
18 EVERYTHING WAS FINE EXCEPT THAT WE SHOULD PUT THE NAS
19 GUIDELINES INTO REGULATORY FORMAT. THAT SEEMS FINE TO
20 ME. I WAS NOT COMFORTABLE WITH "AND MAKE ANY OTHER
21 CHANGES WE WANT TO MAKE." AND THE REASON I'M NOT
22 COMFORTABLE WITH THAT IS FOR THE REASONS THAT TED AND
23 OTHERS HAVE SPOKEN ABOUT AND A NEED TO HAVE MUCH MORE
24 DELIBERATION. PERHAPS WE COULD SAY AND TO MAKE ANY
25 CHANGES THAT ARE NECESSARY TO CONFORM THE REGULATION AS

1 PROPOSED TO THE LAW OF THE STATE. AND THAT WILL MAKE
2 ONLY, SO AS FAR AS I CAN SEE, A CHANGE IN THE 14 DAYS,
3 WHICH IS PROPOSED AS THE PERIOD OF TIME WITHIN WHICH
4 YOU CAN DERIVE STEM CELLS FROM THE BLASTOCYST, TO
5 CONFORM TO STATE LAW, WHICH IS 8 TO 12 DAYS. SO THAT
6 IT WILL BE VERY CLEAR THAT NO JUDGMENT HAS BEEN TAKEN
7 HERE ON THE BASIS OF WHAT IS SO FAR A LIMITED
8 OPPORTUNITY FOR THE PUBLIC AND FOR US TO THINK ABOUT.

9 DR. HALL: I PRESUME THAT AS PART OF THIS
10 PROCESS, PART OF THE JOB WOULD BE TO STATE THEM AS CIRM
11 STANDARDS; IS THAT CORRECT? THAT IS TO SAY, THE
12 INTERIM STANDARDS FOR CIRM.

13 CO-CHAIR RABB: YES.

14 DR. HALL: RATHER THAN CONTINUALLY DOING
15 NATIONAL ACADEMY. FURTHER THE WORDING SO THAT THEY ARE
16 OUR STANDARDS.

17 CO-CHAIR RABB: THEY WILL BE OURS. OKAY.

18 CO-CHAIR LANSING: THAT'S THE ONLY CHANGE
19 WE'RE GOING TO MAKE IS THAT ONE CHANGE.

20 CO-CHAIR RABB: UNLESS THERE'S SOME OTHER
21 THAT JAMES DISCOVERS THAT AS A MATTER OF LAW REQUIRE
22 ALTERATION FOR CONSISTENCY WITH CURRENT STATE LAW.

23 MR. KLEIN: MADAM CHAIRMAN, DO YOU HAVE --
24 DID YOU MEAN TO EXCLUDE -- DO YOU HAVE A PROBLEM WITH
25 THE OTHER LANGUAGE THAT CIRM PREVIOUSLY ADOPTED IN

1 ADOPTING THESE, MAKING THEM PROSPECTIVE?

2 CO-CHAIR RABB: I THINK WHAT WE SHOULD DO
3 IS -- WELL, LET'S THINK ABOUT THAT. I GUESS THE
4 QUESTION, BECAUSE YA'LL COULD DO THAT AGAIN IF YOU
5 WANTED TO. I DON'T KNOW WHETHER THAT IS THE KIND OF
6 SUBSTANTIVE CHANGE THAT PEOPLE HERE WOULD THINK WE
7 DIDN'T HAVE ENOUGH TIME TO TALK ABOUT.

8 DR. KIESSLING: WE DON'T HAVE A COPY OF
9 THOSE.

10 CO-CHAIR RABB: I THINK WE NEED TO THINK
11 ABOUT IT. OBVIOUSLY THEY'RE AT LIBERTY TO GIVE US
12 DIRECTION.

13 MR. KLEIN: THAT'S FINE. THAT'S TRUE. IN
14 TAKING THE MOTION, WE COULD AT THE ICOC, THEN, READOPT
15 THE PROSPECTIVE PROVISIONS, IN FACT, WITH THE PRECISE
16 LANGUAGE. THAT WOULD BE GOOD.

17 CO-CHAIR RABB: OKAY.

18 DR. PETERS: I DON'T WANT TO HOLD UP THE
19 PROCESS, BUT I'M STILL UNEASY WITH THIS MOTION BECAUSE
20 I THINK IT'S CONFUSING WHAT NAS DID WITH WHAT IS OUR
21 RESPONSIBILITY. AND IT SEEMS TO ME THAT IF THIS IS
22 ONLY A TRANSLATION OF THE NAS DOCUMENT, AND IF WE'RE
23 COMPELLED TO MAKE CHANGES ON BEHALF OF CALIFORNIA STATE
24 LAW, COULD WE PUT IN A FOOTNOTE OR SOMETHING LIKE THAT?
25 THIS GROUP WILL NOT HAVE A CHANCE AT OWNERSHIP OVER

1 THIS TEXT. THIS TEXT WILL BE PUBLISHED BEFORE WE CAN
2 DISCUSS IT AND OWN IT.

3 SO IT SEEMS TO ME THAT IF THIS TEXT IS
4 ACKNOWLEDGED AS THE NAS GUIDELINES, WHICH ON MAY 23D
5 WERE APPROVED BY THE ICOC AS THE INTERIM GUIDELINES,
6 THAT'S WHAT IT IS. AND IF WE WOULD LIKE TO HELP BY
7 SHOWING POINTS AT WHICH CALIFORNIA LAW NEEDS TO BE
8 INVOKED, THAT WILL BE FINE. BUT THIS IS NOT OUR
9 DOCUMENT YET. OUR DOCUMENT IS STILL SOMETHING THAT
10 COMES IN THE FUTURE.

11 DR. LO: I'M TRYING TO GO BACK TO SHERRY'S
12 POINT, WHICH I THOUGHT WAS VERY HELPFUL, IN TRYING TO
13 MOVE THE WHOLE PROCESS FORWARD. I GUESS I'M BEGINNING
14 TO LOSE TRACK OF SORT OF THE LEGAL SUBTLETIES HERE. I
15 WILL DEFER TO THOSE WHO ARE MORE KNOWLEDGEABLE.

16 BUT I GUESS ONE THING THAT, AS I'M THINKING
17 OF THE TIMES I'VE TRIED TO LOOK AT INTERIM GUIDELINES
18 IN THE FEDERAL REGISTER, TRYING TO MAKE SENSE OF THEM,
19 SOMETIMES I FIND IT HELPFUL, FOR PURPOSES OF
20 STIMULATING DISCUSSION, TO HIGHLIGHT ISSUES THAT THERE
21 WERE PARTICULARLY RELEVANT COMMENTS ON. SO THAT IF
22 THERE ARE ISSUES LIKE THE STEM CELL BANK WHERE WE CAN
23 SAY WE REALIZE THAT'S WHAT'S IN THESE GUIDELINES, WHICH
24 WERE JUST TAKEN OVER AND TRANSLATED FROM THE NAS
25 PROBABLY, AREN'T GOING TO BE A FINAL GUIDE. WE REALLY

1 WELCOME COMMENTS ON THOSE ISSUES.

2 THEN WE CAN IN A SENSE FOLLOW TED'S
3 SUGGESTION, WHICH IS DOING A STRAIGHT LITERAL
4 TRANSLATION, BUT ALSO TRY AND STIMULATE THE DISCUSSION
5 BY POINTING OUT THINGS THAT WE'RE ALL CERTAINLY GOING
6 TO CHANGE TO CONFORM TO CALIFORNIA LAW, BUT ALSO ISSUES
7 WHERE WE REALLY WANT TO. I THINK THAT'S WHERE WE WANT
8 TO GET TO THE TOUGH ISSUES.

9 MR. KLEIN: MADAM CHAIR, DO YOU NEED A SECOND
10 TO YOUR MOTION?

11 CO-CHAIR RABB: THAT WAS MY QUESTION.

12 MR. KLEIN: I WOULD SECOND YOUR MOTION.

13 CO-CHAIR RABB: DO PEOPLE FEEL FULLY INFORMED
14 ABOUT WHAT WE'RE PLANNING TO DO, THE TRANSLATION, WHICH
15 WILL BE, AS JAMES DESCRIBED IT, WITH THE FRIENDLY
16 AMENDMENT, THAT WE MAKE ALTERATIONS TO WHAT'S BEFORE US
17 ONLY TO THE EXTENT NECESSARY TO CONFORM TO STATE LAW.

18 IS THERE ANY OTHER PUBLIC COMMENT?

19 MR. REED: I THINK THIS IS VALUABLE BECAUSE
20 IT WILL GIVE US A CLEAR UNDERSTANDING OF EXACTLY WHAT
21 WE'RE WORKING WITH. WE'RE NOT SAYING WE AGREE OR
22 DISAGREE WITH EVERYTHING. WE ARE JUST SAYING THIS IS
23 EXACTLY WHAT WOULD HAPPEN, SO WE CAN SEE. THERE'S A
24 BIG DIFFERENCE BETWEEN SHOULD AND SHALL. IF IT SAID
25 SHALL, THEN WE HAVE TO DO IT. SO I THINK THIS IS JUST

1 A CLARIFICATION, AND IT'S PROBABLY A NECESSARY STEP.

2 CO-CHAIR RABB: THANKS. OTHER MORE PUBLIC
3 COMMENT? OTHER MORE WORKING GROUP COMMENT?

4 DR. PRIETO: MADAM CHAIR, ARE WE GOING TO
5 ADDRESS THE ISSUE OF BANKING OR WE DEFER THAT FOR OUR
6 NEXT MEETING? I DON'T SEE HOW THAT TRANSLATES INTO THE
7 REGULATORY LANGUAGE.

8 CO-CHAIR RABB: I THINK IT'S GOING TO BE
9 DIFFICULT. ON THE OTHER HAND, FOR US TO START
10 DRAFTING -- FOR US TO MAKE DECISIONS NOW THAT GET
11 TRANSLATED BY THE STAFF INTO A DRAFT NOW FOR
12 PRESENTATION TO THE ICOC, IT SEEMS TO ME A PROBLEM.
13 NOT A LARGER PROBLEM, JUST A DIFFERENT PROBLEM FROM THE
14 PROBLEM OF HAVING TO TRY TO TRANSLATE WHAT IS NOW THINK
15 PIECES ON BANKING INTO REGULATORY LANGUAGE.

16 I'M INTERESTED IN HEARING WHAT OTHERS HAVE TO
17 SAY ABOUT WHICH OF THOSE EVILS IS THE LESSER BECAUSE
18 NEITHER OF THEM PRESENTS A PERFECT ALTERNATIVE.

19 DR. ROWLEY: WELL, I HAVE TO CONFESS THAT I
20 AM THE AUTHOR OF RECOMMENDATION 23, WHICH IS THE
21 BANKING RECOMMENDATION. AND, IN FACT, THIS IS DRAFTED
22 MORE OR LESS FOLLOWING U.K. BANKING GUIDELINES. SO
23 THAT IF ANYBODY GOES BACK AND READS THE U.K. BANKING
24 GUIDELINES WILL SEE THAT ALL OR MOST OF THE IMPORTANT
25 POINTS ARE INCLUDED HERE.

1 NOW, I RECOGNIZE THIS WAS WRITTEN TO TRY TO
2 MAKE SURE THAT ALL OF THE THINGS THAT WERE BROUGHT OUT
3 IN THE U.K. FORM WERE ALSO CONSIDERED AS WE ESTABLISHED
4 SOME KIND OF A CENTRAL TISSUE BANK, WHICH IS WHAT THE
5 UNITED KINGDOM HAS, THAT WE FOLLOWED THE STEPS THAT
6 THEY HAD THOUGHT WERE IMPORTANT. AND ACTUALLY THIS WAS
7 DISCUSSED AT THE ACADEMY. I WON'T SAY IN GREAT DETAIL,
8 BUT IT WAS AGREED THAT THESE WERE IMPORTANT
9 CONSIDERATIONS, THAT ANY KIND OF CENTRALIZED BANK
10 SHOULD HAVE IN PLACE, IF THEY ARE GOING TO ACCEPT CELL
11 LINES FROM OTHER SOURCES, AND IF THEY ARE GOING TO BE
12 DISTRIBUTING CELL LINES FROM VARIOUS SOURCES, THESE ARE
13 THE ISSUES THAT THEY SHOULD CONSIDER.

14 MR. KLEIN: I WOULD THINK THAT THIS COULD BE
15 CONVERTED BY THE STAFF INTO REGULATORY LANGUAGE. SO
16 WHILE IT DOESN'T REFER IN REGULATORY FORM TO U.K. STEM
17 CELL BANK, YOU COULD SAY INSTITUTIONS ENGAGED IN HUMAN
18 EMBRYONIC STEM CELL RESEARCH SHALL SEEK MECHANISMS FOR
19 ESTABLISHING CENTRAL REPOSITORIES. GOING ON
20 MR. HALPERN'S POINT, WE CAN VERY EFFICIENTLY, TERSELY
21 CONVERT THIS INTO PRELIMINARY REGULATORY LANGUAGE WHICH
22 LATER WILL BE DISCUSSED IN GREAT DEPTH BY THIS GROUP.

23 DR. PRIETO: WHICH INCORPORATES SOME FORM OF
24 THE LANGUAGE IN RECOMMENDATION 23.

25 MR. KLEIN: YEAH. IT WOULD BE TAKING WHAT'S

1 ON PAGE -- THE ANSWER IS YES, BUT IT'S PAGE 85 AS
2 5.05.1.

3 DR. PRIETO: BUT THE LANGUAGE IN THE
4 GUIDELINES IS VERY GENERAL, AND 23 SEEMS MORE SPECIFIC.

5 MR. KLEIN: YES.

6 CO-CHAIR RABB: YEAH. THE ANSWER IS WHEN YOU
7 LOOK AT 23, IT'S A WAY OF EXPLICATING MORE PARTICULARLY
8 WHAT THE GUIDELINES THEMSELVES WERE INTENDING TO
9 RECOMMEND.

10 SHALL WE HAVE A VOTE ON THIS? ARE WE
11 PREPARED TO SAY THAT WE APPROVE THE NOTION OF
12 CREATING --

13 MR. KLEIN: CALL FOR THE QUESTION.

14 CO-CHAIR RABB: -- APPROVE THE NOTION OF
15 MAKING THIS TRANSLATION INTO REGULATORY LANGUAGE AS
16 DESCRIBED QUITE A FEW TIMES BEFORE. ALL THOSE IN
17 FAVOR. OPPOSED? GOOD. THANKS.

18 AND FOR THOSE OF YOU WHO HAVE QUESTIONS ABOUT
19 IT, YOUR FORBEARANCE AND KINDNESS TO LET US GO THROUGH
20 THIS EXERCISE ARE GREATLY APPRECIATED.

21 ARE THERE OTHER SUBSTANTIVE TOPICS WITHIN THE
22 GUIDELINES THAT ARE ON THE MINDS OF ANY MEMBER OF THE
23 WORKING GROUP THAT YOU WANT TO RAISE?

24 MS. CHARO: IT'S NOT A SEPARATE ISSUE. IT'S
25 JUST A KIND OF FOR-THE-RECORD THING BECAUSE OF A

1 QUESTION. QUESTION WAS ASKED ABOUT THE NAS INTENTIONS
2 ABOUT EXISTING LINES. REGARDLESS OF WHAT THEIR
3 INTENTIONS ARE OR ARE NOT, THE ACTIONS OF THE ICOC
4 SUPERSEDE. JUST FOR CLARITY, ONCE A REPORT'S
5 COMPLETED, IT'S COMPLETED AND NOBODY IS ALLOWED TO
6 SPEAK FOR THE COMMITTEE. IT'S THE TEXT. AND SO THE
7 TEXT IS SILENT ON THIS POINT, WHICH MEANS PEOPLE WHO
8 WANT TO ADOPT THESE RECOMMENDATIONS, THEY'RE FREE TO
9 ADOPT THEM WITH OR WITHOUT RETROACTIVE APPLICATION TO
10 THE EXISTING LINES. THERE'S NOTHING IN THERE THAT
11 TALKS ABOUT A SITUATION AND TRIES TO PREJUDGE IT.

12 CO-CHAIR RABB: WE HAVE A MEMBER OF THE
13 WORKING GROUP WHO'S BEEN -- I'M SORRY, BERNIE. ON A
14 DIFFERENT QUESTION. WE HAVE A MEMBER OF THE WORKING
15 GROUP WHO'S BEEN ON THE TELEPHONE WITH US ALL DAY.
16 DR. GENE WILLERSON WHO'S IN HOUSTON, TEXAS.

17 DR. WILLERSON, DID YOU SURVIVE? ARE YOU
18 THERE?

19 DR. WILLERSON: I AM HERE. I'VE ENJOYED IT.
20 I'M SORRY I WAS WASN'T THERE IN PERSON, BUT I THINK
21 YOU'VE DONE A GREAT JOB ALL DAY LONG.

22 CO-CHAIR RABB: WELL, I WANTED TO ASK YOU IF
23 THERE WAS ANY PART OF TODAY'S PROCEEDINGS OR THOSE YET
24 TO COME THAT YOU WOULD LIKE TO SPEAK TO?

25 DR. WILLERSON: I LOOK FORWARD TO BEING WITH

1 YOU PHYSICALLY NEXT TIME, AND I'LL BE A LITTLE MORE
2 VOCAL. BUT I THANK YOU. I DON'T HAVE A CONCERN FOR
3 FROM WHAT'S OCCURRED TODAY.

4 CO-CHAIR RABB: WELL, WE APPRECIATE YOUR
5 PATIENCE. IT'S HARDER TO BE IN THE MEETING WHEN YOU'RE
6 NOT PHYSICALLY THERE. AND YOUR ATTENTION IS VERY
7 GREATLY APPRECIATED.

8 DR. WILLERSON: THANK YOU VERY MUCH.

9 CO-CHAIR RABB: BERNIE, DO YOU WANT TO COME
10 BACK TO SOMETHING?

11 DR. LO: YEAH. I GUESS PART OF IT IS A
12 QUESTION FOR THE CHAIRS AS SORT OF WHAT YOU ENVISAGE US
13 DOING BETWEEN NOW AND ADJOURNMENT AND TRYING TO THINK
14 AHEAD TO HOW WE CAN SORT OF START THE PROCESS OF REALLY
15 TACKLING THE SUBSTANTIVE ISSUES. SO I'M WONDERING IF
16 IT MIGHT -- I WANT TO SUGGEST THAT WE TRY AND JUST
17 IDENTIFY A SERIES OF TOPICS AND NOT TRY AND DISCUSS
18 THEM, BUT JUST SAYING HERE'S A TOPIC WE REALLY NEED TO
19 PAY ATTENTION TO.

20 CO-CHAIR RABB: PERFECT.

21 DR. LO: BUT THEN ALSO TO THINK ABOUT HOW
22 WE'RE GOING TO GO ABOUT DELIBERATING ABOUT THIS. SOME
23 OF THESE TOPICS THERE'S BACKGROUND INFORMATION THAT I
24 CERTAINLY WOULD FIND VERY HELPFUL. WHAT ARE
25 INSTITUTIONS DOING AND OTHER COUNTRIES DOING WITH

1 REGARD TO STEM CELL BANKS? SO IS THERE A WAY OF TRYING
2 TO GATHER INFORMATION THAT WOULD BE USEFUL ON THESE
3 PARTICULAR TOPICS, BOTH TO US AND TO THE PUBLIC, AND IS
4 THERE EVEN A WAY OF -- I DON'T KNOW HOW THE STAFF
5 FEELS, BUT WHETHER THERE'S ANY WAY OF TRYING TO HAVE
6 STAFF, NOT ONLY ASSEMBLE THAT MATERIAL, BUT TO TRY AND
7 PREPARE SORT OF A COVERING WHITE PAPER TO SAY THESE ARE
8 THE ISSUES THAT COME OUT THAT WE OUGHT TO AT LEAST
9 THINK ABOUT.

10 CO-CHAIR LANSING: I HAVE A SUGGESTION
11 BECAUSE I ACTUALLY WAS STRUGGLING MYSELF -- I'M SORRY.
12 I HAVE A SUGGESTION, WHICH IS I'M STRUGGLING WITH THE
13 ORGANIZATIONAL WAY THAT WE MOVE FORWARD. AND SINCE AS
14 MUCH AS I THINK WE WOULD ALL LIKE TO BE ABLE TO BE IN
15 PERSON, WE PROBABLY WON'T BE ABLE TO, BUT WE ARE
16 ALLOWED TO HAVE OPEN CONFERENCE CALLS. SO I WONDER IF
17 WE COULD DO THREE THINGS. FIRST, IDENTIFY THE ISSUES
18 THAT ARE IMPORTANT TO US AND WRITE THEM DOWN ON A PIECE
19 OF PAPER. THEN PERHAPS ASSIGN A PERSON WHO WOULD IN
20 THE SUBCOMMITTEE BE RESPONSIBLE FOR GATHERING A LOT OF
21 INFORMATION AND GETTING IT TO ALL OF US. AND THEN
22 SCHEDULE A VIDEO CONFERENCE, PHONE CONFERENCE CALL OPEN
23 TO THE PUBLIC IN WHICH WE DISCUSS EACH OF THESE ISSUES
24 BEFORE WE MEET AGAIN IN OUR BIG GROUP, WHICH WE'RE
25 AIMING FOR APPROXIMATELY AUGUST 30TH, I BELIEVE, BUT WE

1 HAVE NOT SET THAT DAY. AND THEN WE WOULD HAVE DONE A
2 LOT OF THE LEGWORK IN BETWEEN. WE'D HAVE ONE PERSON
3 GUIDING IT RATHER THAN ALL OF US KIND OF RUNNING
4 AROUND, YOU KNOW, LOOKING.

5 CO-CHAIR RABB: OTHER THOUGHTS?

6 DR. CIBELLI: IS THAT A MOTION?

7 DR. PETERS: THANK YOU. I APPRECIATE WHAT
8 BOTH YOU AND BERNIE HAVE JUST SAID HERE. I THINK OUR
9 DEFAULT POSITION FOR PROCEEDING IS TO TAKE APPENDIX A
10 AND SIMPLY GO THROUGH THE NAS RECOMMENDATIONS. ON THE
11 OTHER HAND, I DON'T THINK WE SHOULD BE LIMITED BY THE
12 SCOPE OF WHAT NAS DID. WE ARE GOING TO HAVE OUR OWN
13 NEEDS AND APPROPRIATIONS HERE.

14 IN ADDITION TO THAT, I THINK WE SHOULD
15 INVESTIGATE THE BACKGROUND FOR SOME OF THESE
16 RECOMMENDATIONS TO SEE IF WE HAVE A CONSENSUS TO SEE
17 WHETHER OR NOT THE APPLICATIONS ARE GOING TO BE THE
18 SAME. LET ME JUST THROW OUT TWO ITEMS THAT I HAVE
19 CONCERN FOR THAT I WOULD LIKE TO SEE GO ON THIS LIST.

20 ONE IS THE QUESTION AS TO WHETHER OR NOT
21 GRANTS SHOULD BE -- THAT GRANT AWARDS SHOULD GIVE HIGH
22 PREFERENCE TO NEW RESEARCH THAT TAKES INTO ACCOUNT THE
23 PRESENT STATE OF THE PREVIOUS RESEARCH SO THAT WE
24 MINIMIZE THE DUPLICATION OF EXISTING KNOWLEDGE. AND
25 THAT WILL REQUIRE SIGNIFICANT INVESTIGATION INTO WHAT

1 KNOWLEDGE ALREADY EXISTS SO THAT WE'RE GOING TO BE
2 FUNDING ONLY THINGS THAT ARE GOING TO MOVE THE FIELD
3 RATHER THAN TO BUILD UP LABORATORIES THAT WOULD BUY
4 EQUIPMENT AND FACILITIES THAT WOULD, WHAT, ENHANCE THE
5 ASSETS OF THE INSTITUTION, BUT WOULDN'T NECESSARILY
6 ACCOMPLISH AS QUICKLY AS POSSIBLE WHAT THE GOALS ARE.

7 IT SEEMS TO ME I WOULD LIKE TO HAVE A
8 DISCUSSION OF THAT GIVEN THAT THIS IS AN AREA OF
9 SCIENCE WHICH HAS SOME URGENCY.

10 SIMILARLY, I APPRECIATED THE DISCUSSION OF
11 CHIMERISM. I THINK THAT, AS ALTA WAS SAYING, THAT
12 SCIENTIFICALLY THE IDEA OF SPECIES INTEGRITY IS
13 PROBABLY NOT GOING TO BE A PROBLEM. AND I WOULD HOPE
14 THAT THE GROUP WOULD WANT TO DISCUSS THAT
15 PHILOSOPHICALLY AND ASK OURSELVES WE WANT TO COPY NAS
16 ON THIS. WHAT IS IT THAT PRESENT RESEARCHERS IN
17 CALIFORNIA ARE ALREADY DOING IN THE AREA OF CHIMERISM?
18 WOULD WE BE UNNECESSARILY HANDCUFFING THEM IF WE WERE
19 TO FOLLOW THIS GUIDELINE? I THINK WE NEED TO SEARCH
20 THAT KIND OF THING OUT.

21 AT ANY RATE, THOSE ARE A COUPLE OF ITEMS THAT
22 I WOULD LIKE TO SEE US DISCUSS IN AN UNHURRIED FASHION
23 WHEN THE TIME COMES.

24 CO-CHAIR RABB: KEVIN HAD A HAND UP.

25 DR. EGGAN: TO THE FIRST POINT I WOULD SIMPLY

1 STATE THAT I BELIEVE THAT FIRST ISSUE WHICH YOU
2 DISCUSSED IS SIMPLY NOT THE PURVIEW OF THIS GROUP, AND
3 THAT THAT IS THE DECISION OF ONE OF THE OTHER WORKING
4 GROUPS; NAMELY, THE GRANT REVIEW WORKING GROUP. THAT
5 ESSENTIALLY IT IS TO SOME EXTENT OUR DECISION ABOUT
6 WHAT SORT OF RESEARCH CAN BE DONE AND IN WHAT WAY IT'S
7 DONE, NOT WHO DOES IT OR WHAT SPECIFICALLY IS DONE.
8 AND SO I WOULD THINK THAT THAT KNOWLEDGE AS TO WHAT
9 EXISTS, WHAT HAS ALREADY BEEN UNDERTAKEN, WHAT IS
10 ALREADY DEEMED KNOWN FALLS TO THOSE SCIENTIFIC EXPERTS
11 WHO WILL REVIEW THE GRANTS AND SCORE THEM BOTH ON THE
12 BASIS OF NOVELTY.

13 DR. PETERS: I WOULD JUST SAY IT'S AN ETHICAL
14 ISSUE AS TO HOW TAXPAYERS' MONEY GETS SPENT AS TO
15 WHETHER OR NOT THE FIELD IS GOING TO MOVE QUICKLY
16 BECAUSE OF OUR FUNDING, OR WHETHER OR NOT IT MAY GO
17 SLUGGISHLY BECAUSE THE FUNDING GETS USED TO SUPPORT THE
18 EXPANSION OF INSTITUTIONS.

19 CO-CHAIR RABB: KEVIN, DID YOU WANT TO SAY
20 MORE ABOUT PUTTING MORE OTHER TOPICS ON THE TABLE
21 BECAUSE I'M SORT OF INTERESTED IN A LITTLE BRAINSTORM
22 HERE TO SEE WHAT WE CAN GET GOING? ZACH, YOU HAD A
23 COMMENT?

24 DR. HALL: DR. PETERS, INVITE HIM TO ATTEND
25 AS A MEMBER OF THE PUBLIC THE DISCUSSION ABOUT CRITERIA

1 THAT WILL TAKE PLACE AT THE GRANTS WORKING GROUP AUGUST
2 3D AND 4TH. WE'LL BE GLAD TO HAVE YOU PARTICIPATE IN
3 THAT. WE WILL ALSO HAVE SOME DISCUSSION AT THE ICOC
4 MEETING ON JULY 12TH OF THE CRITERIA FOR GRANTS. I
5 THINK THAT WOULD BE THE APPROPRIATE PLACE.

6 THE OTHER ISSUE IS THAT WE ARE PLANNING A
7 SCIENTIFIC MEETING OCTOBER 1ST AND 2D THAT WILL
8 BASICALLY DO JUST WHAT YOU SUGGEST; AND THAT IS, ASK A
9 NUMBER OF PEOPLE FROM AROUND THE WORLD TO COME IN AND
10 TELL US WHAT'S THE STATE OF OUR KNOWLEDGE IN A
11 PARTICULAR PLACE, WHAT ARE THE SCIENTIFIC
12 OPPORTUNITIES, WHAT ARE THE ROADBLOCKS, AND WHAT SHOULD
13 CIRM BEING DOING TO MOVE THIS STEM CELL RESEARCH AHEAD
14 IN AN IMPORTANT WAY.

15 SO THANK YOU FOR YOUR COMMENTS, AND I HOPE
16 YOU WILL PARTICIPATE IN THE DISCUSSION IN THESE OTHER
17 VENUES.

18 CO-CHAIR RABB: BERNIE, GIVE US SOME
19 THOUGHTS.

20 DR. LO: I HAVE A VERY LITERAL MIND, SO I'M
21 GOING TO GIVE YOU A LIST OF POTENTIAL TOPICS AS PER
22 SHERRY'S SUGGESTION. ONE IS BANKING OF STEM CELLS AND
23 STEM CELL REGISTRIES. NO. 2, INFORMED CONSENT PROCESS
24 FOR DONORS' MATERIAL USED TO DERIVE NEW STEM CELL
25 LINES. NO. 3, PAYMENT TO DONORS UNDER THE TERMS OF

1 PROP 71. AND COMPENSATION FOR INJURIES SUFFERED BY
2 DONORS AS A RESULT OF PARTICIPATING IN RESEARCH, ALSO
3 DONORS WHO SUFFER HYPEROVULATION SYNDROME.

4 I THINK THE CHIMERA ISSUE THAT DR. PETERS
5 ALLUDED TO IS AN IMPORTANT ONE. I THINK THE GRANT
6 PARENTING ISSUES OF WHAT DO WE DO WITH STEM CELL LINES
7 DERIVED BEFORE THESE REGULATIONS GO INTO EFFECT IS
8 SOMETHING THAT THERE'S A PUBLIC COMMENT ON THAT. AND
9 FINALLY, THIS ISSUE OF INTERNATIONAL COLLABORATION. I
10 GUESS I WOULD DEFER TO MY SCIENTIFIC COLLEAGUES FOR
11 THIS. IT'S LIKELY TO BE AN ISSUE FOR SOMEONE WHO WANTS
12 TO WORK WITH A LINE THAT, FOR INSTANCE, WAS DERIVED IN
13 SOUTH KOREA OR SINGAPORE AND USE THEM IN, FOR EXAMPLE,
14 CLINICAL TRIALS HERE. AND HOW WOULD WE JUDGE THE
15 STANDARDS UNDER WHICH THAT RESEARCH WAS DONE, SORT OF
16 THE EQUIVALENT OF WHAT WE WANT TO DO IN THIS COUNTRY.

17 ON A NUMBER OF THESE IT STRIKES ME THERE'S
18 SOME BACKGROUND INFORMATION THAT WOULD BE EXTREMELY
19 HELPFUL TO US. TO THE EXTENT THAT A DISCUSSION WITH
20 SOME COMMITTEE MEMBER WORKING WITH STAFF TO KIND OF PUT
21 TOGETHER A NICE JUICY BRIEFING BOOK FOR US.

22 CO-CHAIR RABB: I'M INTERESTED IN ADDING TO
23 ONE OF THE THINGS YOU RAISED, BUT IN PERIL OF THINKING
24 SOMEONE IS GOING TO ASK ME TO DO THE BACKGROUND
25 BRIEFING. I SUPPOSE THAT'S TRUE FOR ALL OF US BECAUSE

1 WE TALK ABOUT STAFF AS IF THERE WERE PEOPLE. AND STAFF
2 IS PRETTY MUCH SITTING IN THIS ROOM. IN THE VARIOUS
3 MEETINGS THAT ZACH IS TALKING ABOUT, OUR MEETING STAFF,
4 THE STAFF IS GOING TO HAVE TO PULL TOGETHER. SO LET'S
5 SEE WHAT ELSE WE CAN GET ON THE LIST AND THEN THINK
6 ABOUT WHETHER PEOPLE WANT TO COME BACK TO THINKING
7 ABOUT HOW WE'RE GOING TO DO THE STAFFING.

8 LET ME JUST ADD TO ONE OF BERNIE'S -- A
9 WRINKLE IN ONE OF BERNIE'S SUGGESTIONS AND THEN COME TO
10 YOU, JOSE, AND, I GUESS, KEVIN, YOU HAD YOUR HAND UP
11 AGAIN.

12 ON THE QUESTION OF PROVIDING COMPENSATION TO
13 PERSONS INJURED BY PARTICIPATION IN A CIRM-FUNDED
14 RESEARCH, IT'S A HARD ISSUE. THE DEFENSE DEPARTMENT
15 RAISED THIS QUESTION FOR DEFENSE DEPARTMENT GRANTS IN
16 ABOUT 2001 AND 2002. I DON'T KNOW OF ANY OTHER PART OF
17 THE FEDERAL GOVERNMENT THAT HAS TAKEN A POSITION THAT
18 THAT SHOULD BE AN ELEMENT OF FEDERAL REGS.

19 ONE OF THE THINGS THAT I'VE LOOKED AT FOR MY
20 OWN INSTITUTION IS WHETHER ANY OF THE INSTITUTIONS'
21 MALPRACTICE INSURANCE, PRODUCT LIABILITY INSURANCE,
22 LIABILITY INSURANCE, ORDINARY NEGLIGENCE INSURANCE
23 WOULD COVER INJURIES TO PERSONS WHO AS A RESULT OF
24 PARTICIPATING IN RESEARCH SUFFER AN INJURY. LEAVE
25 ASIDE THE QUESTION AT ANY GREAT SCOPE OF PSYCHOLOGICAL

1 DAMAGE DONE TO SOMEONE WHO THOUGHT AT AN EARLY AGE SHE
2 WANTED TO PARTICIPATE, LET'S SAY, AS AN OOCYTE DONOR
3 WHO DISCOVERS LATER THAT SHE IS HAVING EMOTIONAL
4 REACTION TEN YEARS LATER TO WHAT SHE'S DONE, WHO MIGHT
5 COME BACK TO CLAIM DAMAGES. I DO NOT DENIGRATE THIS
6 POSSIBILITY. I'M NOT TRYING TO FIND AN EXTREME
7 EXAMPLE. I THINK THIS IS A POSSIBLE, A GENUINE
8 POSSIBLE.

9 IT'S NOT CLEAR TO ME HOW ONE WOULD QUANTIFY
10 THE AMOUNT OR KIND OF SERVICES THAT MIGHT BE REQUIRED
11 TO COMPENSATE PEOPLE FOR INJURIES, EVEN IF YOU DRAFT
12 THE LANGUAGE NARROWLY, ARISING OUT OF THE RESEARCH IF
13 WHAT WE WANT IS TO COVER COMPENSATION REQUIRED AS A
14 RESULT OF AN IMMEDIATE, OBSERVABLE INJURY. AND IT'S
15 NOT CLEAR TO ME THAT THERE IS ANY INSURANCE THAT AN
16 INSTITUTION CAN BUY. WE'VE CHECKED WITH OUR CARRIERS.
17 WE'RE NOT SURE THAT THERE'S ANY INSURANCE THAT CAN BE
18 BOUGHT THAT WOULD COVER THAT KIND OF LIABILITY.

19 AND IF THERE IS NO INSURANCE AND IF THE RISK
20 IS VERY HARD TO QUANTIFY, EVEN IF AN INSTITUTION SET
21 ASIDE SOME PORTION OF ITS RESEARCH GRANT AS A TRUST
22 THAT IS HELD FOR THIS PURPOSE, WHEN ALL THE OTHER GRANT
23 MONEY HAS BEEN SPENT, IT IS NOT CLEAR HOW ANYBODY WOULD
24 DECIDE HOW MUCH OF THE GRANT MONEY NEEDED TO BE HELD
25 ASIDE FOR THIS PURPOSE AND FOR HOW LONG AND WHAT WOULD

1 QUALIFY. I THINK THESE ARE THINGS WE NEED TO THINK
2 ABOUT BECAUSE I HEAR THE SENTIMENT, I CAN'T SAY AROUND
3 THE TABLE, BUT CERTAINLY FROM MEMBERS AND FROM THE
4 PUBLIC WHO WANT TO THINK ABOUT THIS. AND I THINK WE
5 NEED INFORMATION. I THINK WE NEED TO UNDERSTAND WHAT'S
6 POSSIBLE GIVEN CURRENT FORMS OF LIABILITY COVERAGE AND
7 WHAT WE MIGHT WANT TO RECOMMEND BE DESIGNED. BECAUSE
8 IF THERE'S -- IF THERE IS A WAY OUT THERE TO COVER
9 THESE LIABILITIES, IT WOULD CHANGE VERY MUCH THE WAY
10 THIS ORGANIZATION WOULD THINK ABOUT A SHALL OR A MUST
11 AND ON WHAT TIME FRAME.

12 ANYWAY, I HOPE WE CAN GET INFORMATION ABOUT,
13 AMONG OTHER THINGS, INSURANCE, WHICH IS VERY HARD TO
14 COME BY.

15 MR. SHESTACK: IT'S MIREED IN OTHER
16 CONTROVERSY THESE DAYS. THERE IS ONE FEDERAL MODEL
17 WHICH IS THE VACCINE COMPENSATION TRUST FUND WHERE
18 THERE IS A FORMULATION. IT'S CONTRIBUTION BY
19 MANUFACTURERS AND ACTUALLY BY CONSUMERS, IN THIS CASE,
20 WHICH IS PROBABLY NOT THE PROPER WAY TO DO IT, BUT
21 THERE IS A FORMULATION. THERE IS MONEY HELD IN TRUST.
22 TO DATE NONE OF IT HAS EVER BEEN SPENT, BUT IT IS THERE
23 IN TRUST FOR COMPENSATION.

24 CO-CHAIR RABB: ACTUALLY THE VACCINE COMP
25 PROGRAM DOES PAY OUT. BUT YOUR POINT IS A REALLY

1 INTERESTING ONE, THAT IF WE WANTED TO THINK ABOUT CIRM,
2 THE STATE OF CALIFORNIA CREATING A COMP MODEL THAT'S
3 MORE LIKE A WORKERS' COMP RATHER THAN LIKE KIND OF
4 INJURY AND FOLLOWED BY LIABILITY IMPOSED BY JURIES AT
5 THE END OF LONG LITIGATIONS. IT'S A REALLY INTERESTING
6 MODEL TO THINK ABOUT, AND THAT WOULD BE --

7 MR. SHESTACK: I APOLOGIZE. THEY HAVE PAID
8 OUT. THEY HAVEN'T PAID OUT, FOR INSTANCE, IN AUTISM
9 CLAIMS. THEY HAVE PAID OUT AND IT'S A FULLY FUNDED
10 FUND.

11 CO-CHAIR RABB: IT'S A VERY USEFUL INSIGHT.

12 DR. CIBELLI: MAYBE ALTA WANTED TO ADD TO
13 THIS.

14 MS. CHARO: ON THE COMPENSATION THING.
15 THANKS, JOSE. I'LL BE VERY QUICK. I WANT TO POINT OUT
16 THAT THIS QUESTION ABOUT COMPENSATION FOLLOWING INJURY
17 DURING RESEARCH PARTICIPATION IS NOT A NEW QUESTION.
18 IT'S DOGGED THE RESEARCH FIELD FOR 35 YEARS. IT'S BEEN
19 EXAMINED REPEATEDLY. THERE ARE SOME VERY DIFFICULT
20 PROBLEMS IN IDENTIFYING INJURIES THAT ARE, IN FACT,
21 LINKED TO THE RESEARCH PARTICIPATION VERSUS INJURIES
22 THAT HAVE TO DO WITH UNDERLYING CONDITIONS OR
23 COMORBIDITIES OR OTHER FACTORS. THERE ARE TREMENDOUS
24 DIFFICULTIES IN FIGURING OUT THE DIFFERENCE BETWEEN AN
25 EVENT THAT'S CLOSELY ASSOCIATED IN TIME AND ONE THAT'S

1 DISTANT IN TIME, FIGURING OUT WHETHER OR NOT A DISTANT
2 IN TIME EVENT IS ACTUALLY RELATED TO PARTICIPATION.

3 I JUST WANTED TO EMPHASIZE THIS IS NOT
4 SOMETHING THAT IS NECESSARILY BEST SOLVED FOR ONE
5 RESEARCH PROTOCOL. AND IT IS SOMETHING WHERE QUESTIONS
6 ABOUT THE VACCINE COMPENSATION PROGRAM AND OTHER KINDS
7 OF WORKERS' COMP PROGRAMS, ETC., HAVE ALL BEEN EXAMINED
8 AS POTENTIAL SYSTEMIC SOLUTIONS. I KNOW THAT THE
9 REPORT THAT BERNIE, FOR EXAMPLE, PARTICIPATED IN FROM
10 THE NATIONAL BIOETHICS ADVISORY COMMISSION HAS A
11 SECTION ON THIS, SUMMARIZES SOME OF THE EXISTING
12 THINKING.

13 JUST A CAUTIONARY NOTE. IT BEGAN TO SOUND AS
14 THOUGH PEOPLE WANTED TO CREATE A WHOLE NEW KIND OF
15 MEGACOMPENSATION SCHEME AROUND THIS ONE AREA, WHICH IS
16 EGG DONATION, WHICH WOULD ACTUALLY NOT NECESSARILY BE
17 THE MOST SENSIBLE KIND OF RESEARCH PARTICIPATION WITH
18 WHICH TO START. YOU REALLY WANT TO FOCUS ON
19 COMPENSATION FOR INJURY.

20 CO-CHAIR RABB: I WOULD SAY THAT AS TO THIS
21 PARTICULAR ISSUE, WHAT WOULD BE VERY HELPFUL IS IF WE
22 COULD PUT UP ON OUR URL, FROM MEMBERS OF THIS GROUP WHO
23 HAVE HAD REASON TO KNOW ABOUT THIS TOPIC, SOME
24 CITATIONS TO ARTICLES OR INFORMATION THAT PEOPLE COULD
25 READ. WE HAVE TO START AGAIN WITH A BASE OF

1 INFORMATION RATHER THAN THINKING ABOUT JUMPING STRAIGHT
2 TO LET'S CREATE A PROGRAM. AND I THINK THE
3 INFORMATION -- THERE'S LOT OF INFORMATION THAT PEOPLE
4 ARE DESCRIBING. AND IF WE COULD HAVE SOME OF THAT ON
5 OUR WEBSITE, IT WOULD BE VERY HELPFUL TO EVERYBODY IN
6 THINKING ABOUT WHETHER IT GIVES US A BASIS FOR THINKING
7 WE SHOULD TRY TO CREATE SOMETHING, OR WHETHER WE STILL
8 CAN GIVE THIS MORE THOUGHT. KEVIN.

9 DR. EGGAN: ANOTHER THING THAT WOULD BE
10 USEFUL TO DISCUSS IS ACTUALLY TO REHASH THE DISCUSSION
11 WE HAD EARLIER ABOUT RECOMMENDING SOURCES OF OOCYTES
12 FOR NUCLEAR TRANSPLANTATION EXPERIMENTS, ACTUALLY
13 MAKING SPECIFIC RECOMMENDATIONS ABOUT WHAT CURRENTLY
14 CAN BE DONE, WHAT WE SHOULD SUPPORT IN THE LONG TERM,
15 WHAT WE THINK IS REASONABLE. FOR INSTANCE, WEIGHING IN
16 ON THINGS WE DISCUSSED EARLIER ABOUT FAILED TO
17 FERTILIZE OOCYTES AND WHETHER OR NOT THEY ARE AN
18 ETHICALLY AND BIOLOGICALLY CHALLENGED SOURCE OF
19 MATERIAL, WHETHER OR NOT, INDEED, WHAT WE WOULD
20 RECOMMEND IS THAT THERE BE DEDICATED DONATION FOR
21 RESEARCH, ETC., ETC., AND TO DISCUSS THAT AND TO
22 PROBABLY GENERATE SOME SORT OF POSITION ON THAT IN
23 GENERAL.

24 CO-CHAIR RABB: JOSE.

25 DR. CIBELLI: TWO MORE THINGS FOR THE LIST.

1 AND I THINK, DR. LO, YOU MADE VERY GOOD ADDITIONS TO
2 THAT LIST. MINE ARE GOING TO BE MINOR. I WAS
3 SURPRISED TODAY THAT SOME MEMBERS OF THE COMMITTEE WERE
4 A LITTLE BIT CONFUSED ABOUT THE POTENTIAL USE OF THE
5 CELLS, THE IMMEDIATE USE OF THE -- I'M TALKING ABOUT
6 EMBRYONIC STEM CELLS. AND THERE'S NO DOUBT THAT THE
7 IMMEDIATE USE WILL BE TO UNDERSTAND DISEASE. BEFORE
8 TREATING ANYTHING, WE GOT BE ABLE TO UNDERSTAND
9 DISEASE. SO I GUESS THAT'S THE MAIN THING THAT WE
10 CAN -- I THINK THE BEST THINGS WE CAN DO RIGHT NOW
11 ABOUT THE SOMATIC CELL NUCLEAR TRANSFER IS TAKE CELLS
12 FROM PEOPLE THAT ARE SICK AND TURN THEM INTO EMBRYONIC
13 STEM CELLS, AND THEN TRY TO MAKE DISEASE AND DEVELOP
14 NEW TREATMENTS FOR THAT.

15 SO ON THAT I THINK ONE THING WE HAVE TO
16 PONDER IS WE MAY HAVE TO TAKE CELLS FROM BABIES OR FROM
17 LITTLE CHILDREN THAT MAY NOT MAKE IT TO BE ADULTS TO
18 THE POINT WE CAN MAKE A DECISION WHETHER THEY WANT TO
19 DONATE THEIR SOMATIC CELLS OR NOT.

20 AND THEN ANOTHER ONE THAT I DON'T KNOW IS
21 RELEVANT TO THIS GROUP OR MAYBE THE GRANTS GROUP. I'M
22 NOT SURE WE HAVE A REAL IDEA OF THE CURRENT EMBRYONIC
23 STEM CELL LINES THAT WE HAVE AVAILABLE. WHAT IS THE
24 ETHNIC BACKGROUND OF THOSE CELL LINES? SO THE WHOLE
25 ISSUE OF MINORITIES REPRESENTED ON THE -- WHAT EMBRYOS

1 ARE WE GOING TO BE USING. DO WE HAVE ENOUGH BLACKS?
2 WE KNOW THAT AFRICAN AMERICANS SUFFER FROM PARTICULAR
3 DISEASES THAT CAUCASIANS DON'T SUFFER AND VICE VERSA.
4 SAME THING FOR HISPANICS OR ASIANS.

5 SO TWO THINGS ARE CHILDREN THAT CAN DONATE
6 THEIR SOMATIC CELLS TO UNDERSTAND DISEASE BEFORE THEY
7 CAN MAKE A DECISION WHETHER THEY WANT TO DO IT OR NOT,
8 AND THEN MINORITIES.

9 DR. EGGAN: AND AS AN EXTENSION OF THAT,
10 THERE'S A GENERAL -- I WOULD JUST GENERALIZE JOSE'S
11 COMMENT TO ALL INDIVIDUALS WHO WOULD HAVE TROUBLE
12 GIVING INFORMED CONSENT. FOR INSTANCE, IT WOULD BE
13 VERY DESIRABLE TO HAVE SOMATIC CELL LINES AS DONORS
14 FROM PATIENTS WITH ALZHEIMER'S DISEASE AND OTHER -- OR
15 A VARIETY OF CONDITIONS THAT WOULD CHALLENGE THAT
16 INDIVIDUAL TO BE ABLE TO GIVE THEIR OWN INFORMED
17 CONSENT, AND SO WHAT WOULD BE THE PROCESS FOR THOSE
18 INDIVIDUALS.

19 CO-CHAIR LANSING: AS A FINAL THING AND TO BE
20 A LITTLE MUNDANE, WE ALSO HAVE TO EVALUATE ALL OF THE
21 GUIDELINES THAT WE'RE GIVING. I GUESS THERE'S 23
22 GUIDELINES, WHATEVER, THAT WILL BE TRANSLATED INTO
23 LEGAL LANGUAGE. AND, HARRIET, YOU HAD BROKEN THEM UP
24 INTO LIKE FOUR DIFFERENT THINGS. SO THERE'S STILL THE
25 ESCRO THING. WE HAVE DONATION. I THINK THE BANKING

1 CELL LINES HAVE BEEN TAKEN CARE OF, BUT I THINK WE HAVE
2 TO ACTUALLY HAVE AN OPINION ON EACH ONE OF THESE
3 THINGS. SO MAYBE WE CAN HAVE THESE FOUR CLUMPS THAT
4 YOU HAD ORGANIZED INITIALLY.

5 CO-CHAIR RABB: AND THE FOUR HEADINGS THAT I
6 HAVE BEEN WORKING UNDER WERE ESCRO'S AND EVERYTHING
7 HAVING TO DO WITH THEM. WHILE WE TALKED A LOT ABOUT
8 THAT, WE OBVIOUSLY HAVE TO COME TO CONCLUSIONS OVER
9 TIME WHEN WE'RE READY TO MAKE RECOMMENDATIONS. REVIEW
10 BOARDS LIKE IACUC'S AND IRB'S, AND WE TALKED SOME ABOUT
11 THAT TODAY. WHEN IS THERE REDUNDANCY THAT'S HEALTHY,
12 PRODUCTIVE REDUNDANCY, AND WHEN IS IT JUST A PAIN IN
13 THE NECK?

14 THE THIRD WAS DONATION AND EVERYTHING HAVING
15 TO DO WITH IT. WE SPENT MOST OF OUR TIME ON OOCYTES.
16 WE DIDN'T TALK ABOUT THE PROBLEM OF A MAN WHO WANTS TO
17 DONATE SPERM, IS HAPPY TO DONATE SPERM, IS HAPPY TO SAY
18 AT THE TIME OF ORIGINAL DONATION YOU CAN USE THIS FOR
19 ANYTHING. YOU DON'T NEED TO COME BACK AND SEE ME.
20 YES, I UNDERSTAND THAT IT CAN BE USED IN A CHIMERIC
21 EXPERIMENT. IT COULD BE USED IN XENO EXPERIMENTS OF
22 ANY KIND. IT COULD BE USED FOR ALL KINDS OF THINGS,
23 TRANSPLANTATION, ETC., BUT DON'T BOTHER ME BY COMING
24 BACK. I'M PREPARED TO TELL YOU RIGHT NOW WHATEVER YOU
25 WANT USE IT.

1 AND IT'S AN ISSUE WE OUGHT TO COME BACK TO,
2 WHETHER SPERM DONATION AND EGG DONATION ARE
3 SUFFICIENTLY DIFFERENT -- WELL, WHETHER SPERM DONATION
4 IS SUFFICIENTLY DIFFERENT FROM OOCYTE AND EMBRYO
5 DONATION TO WHERE MAYBE WE WOULD THINK ABOUT TREATING
6 THEM DIFFERENTLY. IT'S A THING TO COME BACK. I DON'T
7 KNOW THAT WE WOULD. IT'S A POSSIBILITY.

8 AND THEN THE BANKING QUESTIONS, BANKING. FOR
9 THOSE INSTITUTIONS THAT ARE MAKING THEIR OWN CELL
10 LINES, THAT ARE DERIVING THEIR OWN CELL LINES, WHAT
11 KINDS, THEY'RE NOT EXACTLY BANKS, BUT THEY WILL HAVE
12 CELL LINES THEY'RE GOING TO BE PROVIDING TO OTHER
13 INVESTIGATORS. AND SOME OF THEM, IF THEY'RE LUCKY,
14 WILL HAVE NUMEROUS CELL LINES THAT THEY'VE DERIVED THAT
15 THEY'LL BE PROVIDING TO OTHER INVESTIGATORS. WHAT ARE
16 THEIR OBLIGATIONS?

17 MR. SHESTACK: QUESTION IS WHAT ARE THE
18 OBLIGATIONS THAT PEOPLE, WHETHER OR NOT CIRM WANTS TO
19 SET STRONG OBLIGATIONS FOR ANYBODY THAT FUNDS ON
20 RELEASE OF BIOMATERIALS, DATA, AND PERHAPS CELL LINES
21 THAT GO INTO THE GENERAL POOL, WHETHER THAT IS, FOR
22 INSTANCE, A PRECONDITION OF FUNDING.

23 CO-CHAIR RABB: EXACTLY. REPOSITORY
24 QUESTIONS IN GENERAL.

25 MR. SHESTACK: THE OTHER THING, SOMETHING

1 CAME UP EARLIER IN THE MEETING, I DON'T KNOW IF IT
2 NEEDS TO BE ADDRESSED IN THIS FORMAT, IS I THINK NOW
3 THAT WE HAVE A LOT OF SCIENTISTS WORKING WITH US, AND
4 FOR THE PUBLIC UNDERSTANDING AS WELL AS ADVOCATE
5 UNDERSTANDING, WHAT IS THE RELATIVE POTENTIAL THAT
6 SCIENTISTS FEEL FOR DISCOVERY FROM THE SCNT PROCESS,
7 WHICH REQUIRES OOCYTE DONATION, WHICH WILL HAVE --
8 HARDER TO DO, MUCH MORE EXPENSIVE VERSUS THE CASE OF
9 DISCARDABLE FERTILIZED EMBRYOS. WHAT IS THE ACTUAL --
10 WHERE IS OUR GROUP DECIDING -- PLACING ITS BETS BECAUSE
11 IT IS SOMETHING THAT THE PUBLIC NEEDS TO UNDERSTAND
12 FROM A STRATEGIC POINT OF VIEW. AND I THINK THERE'S
13 CONFUSION ON IT.

14 DR. EGGAN: I'D BE VERY HAPPY TO SPEAK
15 DIRECTLY TO THIS POINT. I THINK I CAN GIVE YOU ONE
16 EXAMPLE THAT EXEMPLIFIES WHY SCNT IS SO IMPORTANT, AND
17 IT IS DIRECTLY RELEVANT. SO RIGHT NOW THERE ARE MANY
18 DISEASES WHICH WE KNOW HAVE STRONG GENETIC COMPONENTS.
19 AUTISM IS ONE OF THEM. WE ALSO KNOW THIS IS TRUE FOR
20 DIABETES. WE KNOW IT IS TRUE FOR PARKINSON'S DISEASE
21 AND ALZHEIMER'S. BUT IT'S MANY GENES WORKING TOGETHER
22 TO CAUSE THESE DISEASE PHENOTYPES. AS I SAID, WE DON'T
23 KNOW THE IDENTITY OF. THEREFORE, IT IS DIFFICULT OR
24 IMPOSSIBLE TO ENGINEER A CELL LINE OR AN ANIMAL TO
25 MODEL THESE DISEASES.

1 THE ONLY WAY THAT WE KNOW THAT THE GENES ARE
2 TOGETHER IN THE RIGHT PLACE TO CAUSE THE DISEASE ARE
3 WHEN THE PATIENT MANIFESTS THE PHENOTYPE. SCNT OFFERS
4 US AN OPPORTUNITY TO RETROSPECTIVELY CAPTURE THAT
5 GENOTYPE AND TURN IT INTO A MODEL. FOR INSTANCE, FROM
6 DISCARDED IVF EMBRYOS, IT WOULD BE IMPOSSIBLE TO SAY A
7 PRIORI THAT ANY EMBRYO OR ANY ES CELL LINE HAD THE
8 PROPER GENOTYPE TO MANIFEST DISEASE. BY TAKING SKIN
9 CELLS FROM A PATIENT THAT HAS THAT DISEASE, WE KNOW ALL
10 THE GENES THAT ARE REQUIRED FOR THAT DISEASE ARE
11 PRESENT. WE CAN MAKE THE ES CELL LINE. AND THEN NOW
12 WE HAVE AN INEXHAUSTIBLE SOURCE OF MATERIAL OF THAT
13 GENOTYPE TO DIFFERENTIATE INTO THE AFFECTED CELL TYPE
14 AND TO OBSERVE THE DEVELOPMENT OF THAT DISEASE OVER AND
15 OVER AND OVER AGAIN IN THE LAB. THIS A VERY POWERFUL
16 AND GENERALIZABLE APPROACH TO THE STUDY OF ANY GENETIC
17 DISEASE. THAT'S WHY WE NEED SCNT.

18 DR. TAYLOR: I SORT OF HESITATE TO BRING THIS
19 UP THIS LATE, BUT ONE OF THE THINGS THAT ISN'T
20 ADDRESSED IN THE NAS GUIDELINES, AND I THINK THAT YOU
21 ALLUDED TO IS THE VERY THORNY ISSUE, AND AGAIN MAYBE
22 I'M GOING TO BE ACCUSED OF TRYING TO JUMP AHEAD TOO FAR
23 TO THE THERAPEUTIC USE OF THESE CELLS, WHICH
24 ADMITTEDLY, AND I COMPLETELY AGREE WITH JOSE, IS NOT
25 GOING TO BE THE FIRST OR PROBABLY SECOND OR EVEN THIRD

1 THING THAT WE DO, AND THE EXPERIMENTS THAT KEVIN
2 DESCRIBES ALSO ATTAINABLE, I THINK, IMMEDIATELY, BUT WE
3 ARE MANDATED, I THINK, TO BE LOOKING DOWN THE ROAD TO
4 THE THERAPY AT LEAST. AND THAT IS GOING TO REQUIRE OUR
5 ABILITY TO TRACK DONORS ESSENTIALLY AD INFINITUM TO
6 FOLLOW UP THEIR HEALTHCARE AND HEALTH PROBLEM
7 DEVELOPMENTS.

8 AND THE ISSUES, THE ETHICAL ISSUES
9 SURROUNDING THAT ARE GOING TO BE ABSOLUTELY HUGE. I
10 WOULD SUBMIT THAT ANYBODY THAT DONATES CELLS THAT WILL
11 EVER POTENTIALLY BE USED THERAPEUTICALLY, WE'RE GOING
12 TO HAVE TO ABLE TO TRACK THOSE PEOPLE ULTIMATELY INTO
13 THEIR OLDER AGE TO MAKE SURE THAT THEY DIDN'T DEVELOP
14 PARKINSON'S OR DIDN'T DEVELOP SOME OTHER DISORDER.

15 SO THOSE KINDS OF ISSUES I DON'T THINK HAVE
16 EVER BEEN ADDRESSED IN AN ETHICS PROCESS, BUT IN MY
17 VIEW ARE THE THORNIEST ONES THAT WE WILL NEED TO DEAL
18 WITH HERE. OBVIOUSLY I DON'T THINK ANYBODY WANTS TO
19 DISCUSS THIS RIGHT NOW, BUT IT'S SOMETHING EVERYBODY
20 HAS TO BE THINKING ABOUT GOING FORWARD.

21 DR. ROWLEY: I SHOULD SAY THAT THERE IS A
22 REQUIREMENT BOTH IN THE U.K. AND THE EUROPEAN UNION
23 THAT ALL DONORS BE TRACKABLE. AND THAT WAS IMPLIED IN
24 A WAY IN THE BANKING RECOMMENDATIONS, THAT YOU BE ABLE
25 TO TRACK THE DONOR. NOW, IT WAS NEVER SPELLED OUT, OF

1 COURSE, AS TO EXACTLY HOW YOU TRACK THE DONOR. THE
2 THRUST IN BRITAIN AND, I THINK, ALSO IN THE EUROPEAN
3 UNION WAS RATHER THAN BEING ABLE TO FIND OUT WHAT BAD
4 THINGS HAPPEN TO THE DONOR, IT WAS MORE THAT AS
5 INVESTIGATORS USING THEIR CELL LINES MAKE DISCOVERIES
6 THAT HAVE GENETIC IMPLICATIONS FOR THE DONOR, WHAT IS
7 THE REQUIREMENT OF THAT INVESTIGATOR TO TELL SOMEONE
8 WHO THEN GOES AND TELLS THE PHYSICIAN OF THE DONOR WHO
9 THEN HAS TO DECIDE WHETHER THEY TELL THE DONOR.

10 THAT WAS THE TRAIN, BUT IT IS OBVIOUSLY A
11 TWO-WAY STREET. I THINK YOU'RE QUITE RIGHT THAT WE
12 SHOULD BE THINKING ABOUT THOSE ISSUES BECAUSE THEY ARE
13 CERTAINLY GOING TO COME UP IN THE FUTURE. AND WE MIGHT
14 JUST AS WELL BE PREPARED FOR THEM.

15 MS. CHARO: JUST A QUICK SUPPLEMENT. THE FDA
16 ALREADY REQUIRES THAT TRACKING FOR DONOR TISSUE
17 TRANSPLANT.

18 DR. EGGAN: AND HIPAA SPEAKS TO THIS TOO.
19 THE NEW HIPAA REGULATIONS SPEAK TO HOW THIS MUST BE
20 ADMINISTRATED TOO.

21 MS. CHARO: THAT HAS TO DO WITH THE MEDICAL
22 RECORDS. BUT IN TERMS OF THE DONOR -- MAINTENANCE OF
23 TRACKING FOR THE DONORS, THE FDA HAS THAT, BUT,
24 CORRECT, THERE'S AN INTERPLAY ABOUT HOW IN THE HECK DO
25 YOU GET INTO THE MEDICAL RECORDS TO DO THE TRACKING.

1 MR. SHESTACK: THIS BECOMES PART OF YOUR
2 INITIAL SCREENING AND CONSENT PROCESS. IT'S NOT --

3 DR. TAYLOR: IT SEEMS TO ME THAT COUPLES OR
4 INDIVIDUALS WILL CONSENT TO CERTAIN PROCEDURES, AND
5 THAT WILL LIMIT HOW THOSE CELLS GET USED. SO NOT
6 EVERYBODY HAS TO SIGN THE SAME FORM AND AGREE TO THE
7 SAME.

8 CO-CHAIR RABB: I HAVE THE FEELING THAT
9 THERE'S MORE THAT WE COULD ADD TO THE LIST, BOTH
10 BECAUSE THERE ARE MORE THINGS THAT ARE INTERESTING AND
11 BECAUSE WE DON'T WANT TO STOP ADDING BECAUSE ONCE WE
12 STOP ADDING, WE HAVE TO MAKE ASSIGNMENTS. BUT WE'RE
13 GETTING TO THE END OF THE MEETING, AND I THINK WE OUGHT
14 TO THINK ABOUT HOW WE'RE GOING TO PRODUCE FOR OURSELVES
15 THE KIND OF INFORMATION THAT WE'RE ALL SAYING WE NEED
16 IN ORDER TO DISCUSS THESE TOPICS. SO LET'S TURN TO THE
17 QUESTION OF WHAT WE CAN DO.

18 AND I THINK THE STATEMENT "ASK THE STAFF TO
19 PROVIDE" SHOULD BE THE LAST THING WE TRY TO SAY. SO
20 LET'S SEE WHAT WE CAN SAY WITHOUT SAYING THAT ABOUT HOW
21 WE CAN PROVIDE INFORMATION.

22 CO-CHAIR LANSING: I WOULD LIKE TO GO BACK TO
23 MY EARLY SUGGESTION, WHICH IS THAT EITHER HERE NOW WE
24 VOLUNTEER FOR DIFFERENT AREAS THAT WE FEEL WE WOULD
25 LIKE TO TAKE THE LEAD IN, OR, YOU KNOW, HARRIET AND I

1 AND THE STAFF WILL HAVE TO ASSIGN PEOPLE THINGS BECAUSE
2 I DON'T KNOW HOW ELSE TO DO THIS. DO YOU KNOW? I
3 DON'T THINK WE CAN REALLY RELY ON THE STAFF BECAUSE
4 IT'S NOT FAIR. I THINK WE HAVE TO RELY ON OURSELVES
5 AND OUR OWN INDIVIDUAL STAFF OR NOT. AND THEN I THINK
6 WHAT WE HAVE TO DO IS TAKE IT UPON OURSELVES BETWEEN
7 NOW AND OUR NEXT MEETING TO SCHEDULE CONFERENCE CALLS
8 THAT ARE OPEN TO THE PUBLIC TO EXPLORE THE ISSUE SO
9 THAT WE HAVE A RECOMMENDATION WHEN WE MEET AGAIN AUGUST
10 30TH AND WE DISCUSS, ONCE AGAIN, WITH THE FULL GROUP.

11 I DON'T KNOW HOW ELSE TO DO IT BECAUSE WE
12 HAVE TO HAVE A DIVISION OF LABOR. WE CAN'T RELY ON ONE
13 OR TWO PEOPLE TO DO THE WHOLE THING. I THINK WE HAVE
14 TO SUBDIVIDE IT ACCORDING TO OUR OWN INTEREST, OUR OWN
15 EXPERTISE.

16 DR. KIESSLING: WHY DON'T YOU GO THROUGH THE
17 LIST AND ASK FOR VOLUNTEERS?

18 CO-CHAIR RABB: I MADE AN INFORMAL LIST. SO
19 LET'S IF ANYBODY ELSE DID TOO, PLEASE CORRECT ME IF I
20 GET IT WRONG. ONE OF THE QUESTIONS THAT WAS RAISED
21 TWICE WAS ABOUT THE RESEARCH BEING DONE IN CALIFORNIA
22 ON CHIMERISM. I THINK CERTAINLY EVERYBODY COULD BE
23 GIVEN COPIES OF ARTICLES BY DR. WEISSMAN. THAT WOULD
24 BE AN EXAMPLE. IT WON'T BE EXHAUSTIVE, BUT IT COULD
25 GIVE PEOPLE A SENSE OF THE KIND OF RESEARCH. AND

1 MAYBE, TED, THAT WOULD BE RESPONSIVE TO YOUR REQUEST.

2 DR. HALL: I THINK HANK GREELEY AT STANFORD
3 WOULD PROBABLY KNOW. HE'S AN ETHICIST IN THE LAW
4 SCHOOL AT STANFORD AND I THINK IS ON THE COMMITTEE THAT
5 DEALT WITH THAT. AND I THINK WOULD KNOW, NOT JUST IRV
6 WEISSMAN, BUT PERHAPS OTHER EXAMPLES. HE MIGHT BE A
7 RESOURCE.

8 DR. EGGAN: THE BROADER ISSUE, WHICH IS TO
9 WHAT EXTENT SHOULD WE SOLICIT OPINIONS FROM PEOPLE AND
10 HAVE THEM TESTIFY AT THIS WORKING GROUP.

11 CO-CHAIR RABB: GOOD EFFORT TO GET US
12 DIVERTED FROM MAKING ASSIGNMENTS, KEVIN. BUT I THINK
13 IT IS AN INTERESTING QUESTION, AND I THINK THERE MAY BE
14 SOME THINGS THAT REQUIRE VOICE-TO-VOICE EFFORT AND NOT
15 STAFF SWATTING IT UP OR US SWATTING IT UP.

16 BUT, ZACH, HAVING SAID WHAT YOU DID, HOW DO
17 WE GO ABOUT GETTING THAT KIND OF INFORMATION FROM THE
18 RESEARCHER AT STANFORD, THE INVESTIGATOR AT STANFORD?

19 DR. HALL: WELL, I DON'T KNOW. ONE OF US --

20 CO-CHAIR LANSING: I'M NOT TRYING TO BE
21 DIFFICULT, AND I HAVE THE LEAST KNOWLEDGE OF ANYONE
22 HERE.

23 DR. HALL: BERNIE HAS VOLUNTEERED TO CALL --

24 DR. LO: I THINK WHY DON'T WE DO TO A DEFAULT
25 SYSTEM WHERE WE INVEST OUR CO-CHAIRS WITH THE POWER TO

1 ASSIGN PEOPLE, THAT WE CAN MAKE KNOWN TO THE CHAIRS OUR
2 PREFERENCES, AND WE'LL TRY AND HONOR THEM. WE NEED TO
3 HAVE SOME MARCHING ORDERS LAID OUT AS TO WHO DOES WHAT,
4 WHEN YOU WANT THE INITIAL SORT OF BRIEFING BOOK.

5 DR. KIESSLING: JUST DO IT.

6 CO-CHAIR RABB: MAKE KNOWN YOUR PREFERENCES
7 NOW. BERNIE, WHAT ARE YOUR PREFERENCES?

8 DR. LO: INFORMED CONSENT.

9 CO-CHAIR RABB: INFORMED CONSENT. OKAY.
10 OTHER PEOPLE, WHAT WOULD YOU SAY IF THIS WERE OUR CALL
11 TO YOU?

12 DR. CIBELLI: WHAT IS THE DUTY? I JUST DON'T
13 KNOW --

14 CO-CHAIR LANSING: CAN I JUST MAKE IT CLEAR
15 WHAT WE'RE DOING BECAUSE I THINK WE'RE SORT OF
16 CONFUSED. WE HAVE TWO THINGS THAT WE HAVE TO DO. WE
17 HAVE TO EVALUATE THE NAS GUIDELINES. WE LITERALLY HAVE
18 TO YES, NO, OR WE'RE MODIFYING IT. SO, HARRIET, YOU
19 HAD A WONDERFUL CLUMP OF FIVE THAT WERE LIKE BASICALLY
20 THE SAME, AND THERE WERE TWO THAT WERE THE SAME. YOU
21 KNOW WHAT I MEAN? SO WE HAVE TO DIVIDE THOSE UP, AND
22 SOMEBODY AMONG US HAS TO SAY I'M GOING TO BE
23 RESPONSIBLE FOR THAT. I'M GOING TO ORGANIZE A
24 CONFERENCE CALL WITH AS MANY PEOPLE AS CAN ATTEND. AND
25 I'M GOING TO MAKE THE RECOMMENDATIONS THAT WE AGREE, WE

1 DON'T AGREE, WE MODIFIED IT THIS WAY.

2 THEN WE HAVE THE INDIVIDUAL THINGS THAT WERE
3 BROUGHT UP THAT AREN'T IN THE NAS GUIDELINES. AND SOME
4 OF THEM OVERLAP, AND WE HAVE TO BY AUGUST 30TH HAVE A
5 POINT OF VIEW ON ALL OF THIS. IT'S A LOT. WE MAY TO
6 WANT NOT TO ATTEMPT --

7 DR. HALL: EXCUSE ME, SHERRY. WITH OUR NEW
8 PROCEDURES, WE HAVE BEYOND. WE HAVE AUGUST 30TH PLUS
9 45 DAYS. WE DO HAVE A LITTLE MORE TIME FOR THE
10 REVISIONS, BUT YES.

11 CO-CHAIR LANSING: WELL, WE HAVE TO HAVE A
12 POINT OF VIEW BY THEN. WE DON'T HAVE TO HAVE ALL THIS
13 DONE.

14 CO-CHAIR RABB: WHAT YOU'RE SAYING, SHERRY,
15 IS THAT EVEN THOUGH NOBODY PUT ESCRO'S ON THE LIST,
16 WE'RE GOING TO HAVE TO DEAL WITH THE QUESTION OF HOW WE
17 WANT TO COME OUT ON ESCRO'S. BUT I HAD THOUGHT THAT
18 RATHER THAN MOVING TO DECIDING WHERE WE WANT TO BE,
19 THAT FOR THE NEXT SHORT PERIOD OF TIME, WE'RE GOING TO
20 GATHER INFORMATION THAT WOULD SO INFORM US ON THE
21 TOPICS WE'RE GOING TO HAVE DEAL WITH, THAT IF WE HAD
22 THE INFORMATION, WE COULD THEREAFTER DECIDE WHERE WE
23 WANT TO BE.

24 CO-CHAIR LANSING: AGAIN, I DON'T WANT TO BE
25 DIFFICULT. MAYBE I'M, YOU KNOW, JUST APPLYING THE

1 WRONG CONCEPT TO IT, BUT I'M DEALING WITH AUGUST 30TH.
2 THAT'S THE ONLY THING I KNOW FOR SURE. WHAT I'M SAYING
3 IS TODAY IS JULY 6TH. SO BETWEEN JULY 6TH AND PERHAPS
4 IT'S AUGUST 30TH, IT MAY BE AUGUST 29TH, IT MAY BE
5 SEPTEMBER 1ST WHEN THIS BIG GROUP MEETS AGAIN. I
6 THOUGHT THAT THE BEST USE OF OUR TIME WAS FOR THE NEXT
7 SEVEN WEEKS, THAT WE WOULD DIVIDE THE WORK UP, AND EACH
8 OF US OR TEAMS OF US WOULD BE ASSIGNED TO DIFFERENT
9 THINGS. WE WOULD THEN ORGANIZE INFORMED CONSENT.
10 OKAY. BERNIE WOULD SAY, OKAY, I'M SENDING OUT THE
11 PAPERWORK AND ON SUCH-AND-SUCH A DAY I'M HAVING A
12 CONFERENCE CALL, YOU ALL PHONE INTO THIS NUMBER, AND WE
13 TALK ABOUT IT.

14 AND THAT SUBGROUP COMES TO SOME SORT OF
15 CONCLUSION, NOT MAYBE IN THE FIRST CALL, BUT IN THE
16 SECOND OR THE THIRD CALL THAT THEY BRING BACK TO US ON
17 AUGUST 30TH THAT THEN WE CAN DISCUSS AND AGREE. IF WE
18 WERE ON THAT PHONE CALL, THEN WE ACTUALLY WILL BE ABLE
19 TO GO THROUGH THAT ISSUE RATHER QUICKLY.

20 DR. CIBELLI: I THINK WE ALL HAVE TO BE
21 INFORMED OF WHAT ARE THE CHOICES.

22 CO-CHAIR LANSING: WE WOULD BE.

23 DR. CIBELLI: YOU'RE SAYING THAT WE'RE GIVING
24 RECOMMENDATION. YOU'RE SAYING THAT WE'RE GOING TO BE
25 GIVING A RECOMMENDATION THAT THE SUBCOMMITTEE --

1 CO-CHAIR LANSING: NO. I'M SAYING SOMETHING
2 DIFFERENT. AGAIN, POKE HOLES IN THIS. I'M JUST TRYING
3 TO FIGURE OUT HOW WE GET OUR WORK DONE, AND I DON'T
4 KNOW THAT THIS IS THE BEST SUGGESTION AT ALL. BUT
5 LET'S TAKE INFORMED CONSENT BECAUSE WE HAVE A VOLUNTEER
6 FOR THAT. SO NOW ALL THAT INFORMATION THAT BERNIE
7 FINDS OUT GOES TO EVERYBODY. HE SCHEDULES A VIDEO
8 CONFERENCE CALL BECAUSE WE'LL NEVER ALL GET HERE TEN
9 TIMES BETWEEN NOW AND AUGUST 30TH. AND THAT'S FINE.
10 IF WE HAVE A VIDEO -- IF WE HAVE A CONFERENCE CALL ON
11 THE PHONE WHICH EVERYONE ATTENDS. IF YOU CAN'T ATTEND,
12 THAT'S UNDERSTANDABLE.

13 DR. CIBELLI: THAT'S DIFFERENT FROM WHAT YOU
14 WERE SAYING BEFORE.

15 CO-CHAIR LANSING: NO. THAT'S WHAT I WAS
16 SAYING. AND THEN THAT GROUP DISCUSSES IT, AND IT CAN
17 BE ALL OF US. IF SOMEONE MISSES IT, THEY MISS IT. I'M
18 NOT SUGGESTING THAT EVERYONE WILL HAVE EQUAL INTEREST
19 OR NECESSARILY WANT TO BE ON THE PHONE FOR ALL TEN
20 ISSUES. THAT'S UP TO YOU. BUT YOU CERTAINLY WILL BE
21 ABLE TO BE ON THE PHONE FOR ALL TEN ISSUES. THAT
22 GROUP, ALL OF US OR AS MANY OF US AS WISH TO
23 PARTICIPATE WOULD THEN COME TO SOME CONCLUSIONS. IF
24 IT'S ALL OF US, IT WOULD BE EASY BECAUSE THEN WE WOULD
25 KNOW THAT YOU HAD UNANIMOUS CONSENT. IF SOMEONE MISSED

1 IT AND AT OUR NEXT BIG GROUP WANTS TO QUESTION IT, THEN
2 THEY CAN QUESTION IT.

3 DR. EGGAN: THAT'S WHERE I HESITATE. I THINK
4 IT'S REACH SOME CONCLUSIONS. I'M NOT SURE THAT I'M
5 COMFORTABLE WITH THAT STATEMENT. I THINK IT'S VERY
6 REASONABLE THAT THERE BE A BIG CONFERENCE CALL THAT AT
7 THAT OPPORTUNITY THAT POINTS OF INFORMATION ARE RAISED
8 AND THINGS ARE DISCUSSED AT LENGTH, BUT I THINK IT
9 WOULD BE INAPPROPRIATE FOR SOME SMALLER GROUP TO COME
10 TO SOME CONCLUSION THAT THEN THE OTHER PART OF THE
11 GROUP WOULD HAVE TO ANSWER TO, AND ANYTHING LESS
12 THAN -- NOW, IF WE AS A GROUP DECIDE THAT EACH ONE OF
13 THESE THINGS ARE FORMAL MEETINGS OF THIS WORKING GROUP,
14 THEN THAT'S FINE.

15 CO-CHAIR LANSING: THAT'S SORT OF WHAT I WAS
16 SAYING.

17 DR. HALL: THAT CREATES PROBLEMS WITH OUR
18 COMMITMENT, HOWEVER, TO HAVING PUBLIC DECISION-MAKING.

19 MR. SHESTACK: ALSO THE OTHER THING THAT,
20 SHERRY, IS THAT WHY NOT NECESSARILY HAVE, FOR INSTANCE,
21 ETHICISTS REPRESENTED ON EVERY TOPIC. WHEREAS, IF WE
22 HAD -- WHEN IT COMES TO THE CENTRAL ROOM, YOU CAN BE
23 THAT SURE THAT WE WILL HAVE ETHICISTS HERE REPRESENTING
24 WHO COULD SPEAK TO EVERY TOPIC.

25 CO-CHAIR LANSING: SO HERE'S MY QUESTION. I

1 GET IT. LET ME ASK YOU A QUESTION. ON AUGUST 30TH,
2 AND I'M NOT TRYING TO BE DIFFICULT, I'M REALLY JUST
3 TRYING TO MAKE SURE WE GET OUR WORK DONE, ON AUGUST
4 30TH, WHICH I UNDERSTAND MAYBE WE'RE GOING TO HAVE MORE
5 TIME, BUT RIGHT NOW WE TECHNICALLY DON'T, SO I'M GOING
6 TO USE THAT AS THE DATE. ON AUGUST 30TH NOW WE'RE
7 GOING TO HAVE THIS LONG LIST, THAT WE'RE ALL GOING TO
8 BE AS INFORMED AS WE WISH TO BE, AND HOPEFULLY ALL OF
9 US WILL HAVE BEEN ON EVERY CALL. DO YOU REALLY BELIEVE
10 THAT IN THAT DAY, MAYBE WE NEED TWO DAYS, THAT WE'LL BE
11 ABLE TO GO THROUGH EVERYTHING AND GET IT ALL DONE?
12 THAT'S MY QUESTION.

13 DR. ROWLEY: LET ME JUST THAT SAY THAT THIS
14 IS OBVIOUSLY A PROBLEM THAT WE FACED IN THE ACADEMY
15 WRITING THESE THINGS. AND, IN FACT, WE DID DIVIDE IT
16 UP SO THAT THE DIFFERENT MEMBERS OF THE WORKING GROUP
17 WERE RESPONSIBLE FOR DIFFERENT CHAPTERS. AND, IN FACT,
18 THE RECOMMENDATIONS ARE IDENTIFIED BY CHAPTERS. SO THE
19 CHAPTER ON THE ETHICS WAS MAINLY WRITTEN BY THE VARIOUS
20 ETHICISTS DISCUSSING THINGS. THEY HAD CONFERENCE
21 CALLS. ALL OF THAT WAS THEN TRANSLATED, FIRSTLY, TO
22 THE PERSON WHO WAS INVOLVED IN THE ACTUAL WRITING WAS A
23 STAFF PERSON, BUT ALL OF THAT CAME BACK TO EVERYONE ON
24 THE WORKING GROUP, WHO THEN SAID I THINK THIS IS FINE.
25 I DON'T LIKE THAT. OR WHY DID YOU DO IT THIS WAY OR

1 WHY DID YOU DO IT THAT WAY. SO IT'S IN AN ONGOING
2 PROCESS, PARTLY CONFERENCE CALL AND THEN PARTLY E-MAILS
3 SO THAT YOU COULD SEE WHAT WAS GOING ON AND WHERE YOU
4 HAD QUESTIONS AND WHERE YOU DIDN'T. AND I THINK THAT'S
5 THE ONLY WAY TO GET THIS DONE IN THAT TIME FRAME.

6 CO-CHAIR LANSING: I AGREE. IT'S NOT A
7 VIOLATION OF THE PUBLIC BECAUSE THE PUBLIC IS WELCOME
8 TO ANY CONFERENCE CALL. IT'S OPEN TO EVERYBODY.
9 THAT'S THE WAY WE'VE DONE IT THE REST OF THE ICOC. YOU
10 JUST PHONE IN.

11 DR. KIESSLING: BUT THAT'S NOT MAKING THE
12 DECISIONS. KEVIN IS JUST WORRIED ABOUT DECISIONS BEING
13 MADE.

14 DR. HALL: DRAFTING LANGUAGE.

15 CO-CHAIR LANSING: I DIDN'T SAY DECISIONS. I
16 SAID RECOMMENDATION. I SAID RECOMMENDATION. I SAID
17 EXACTLY WHAT JANET IS SAYING, BUT SHE SAID IT BETTER.

18 DR. EGGAN: WHAT JANET SAID IS GREAT.

19 CO-CHAIR LANSING: I AGREE. THANK YOU,
20 JANET. THANK YOU. I SAID RECOMMENDATIONS. THANK YOU,
21 JANET.

22 DR. WILLERSON: ONE WAY TO DO THIS WOULD BE
23 TO LIST ALL OF THESE TOPICS, SEND THEM TO US, AND
24 REQUIRE THAT EACH ONE OF US PICK ONE. AND MAYBE
25 THERE'S SOME MORE THAN ONE WOULD WANT TO WORK ON, AND

1 THEY COULD DO IT TOGETHER. THAT WOULD GIVE US A CHANCE
2 TO LOOK AT IT THOUGHTFULLY AT A TIME WE'RE PROBABLY NOT
3 AS TIRED AS WE ARE RIGHT NOW.

4 CO-CHAIR RABB: ONE OF THE THINGS WE HAVE TO
5 REALIZE IS THAT WE'VE PUT ON THIS LIST THINGS TO THINK
6 ABOUT THAT AREN'T NOW, IN SOME INSTANCES, IN THE
7 GUIDELINES THAT WE'RE GOING TO PREPARE AT ALL. AND
8 SHERRY KEEPS BRINGING US BACK APPROPRIATELY TO TWO
9 THINGS THAT ARE UP FOR CONSIDERATION. ONE IS WHAT ARE
10 WE GOING TO DO TO TRY TO MOVE OURSELVES TOWARD THINKING
11 ABOUT WHERE WE'D LIKE TO GO ON THE THINGS THAT ARE
12 ALREADY -- THAT WILL BE IN THE DRAFT REGULATION, LIKE
13 ESCRO'S, WHICH NEVER MADE THEIR WAY, BY THE WAY, BACK
14 ONTO OUR LIST OF THINGS WE'D LIKE TO THINK ABOUT.

15 AND THEN WHAT WE DO ABOUT THE THINGS THAT ARE
16 ON OUR LIST, THE THINGS WE WANT TO THINK ABOUT WHICH GO
17 BEYOND ANYTHING THAT'S EITHER EXPLICIT OR IN SOME
18 INSTANCES EVEN IMPLICIT IN WHAT ARE GOING TO BE OUR
19 GUIDELINE RECOMMENDATIONS.

20 CO-CHAIR LANSING: I HAVE ANOTHER SUGGESTION.
21 LET'S YOU AND I WITH A COUPLE OF STAFF MAKE THIS LONG
22 LIST, WHICH HAS ESCRO'S ON IT, AND WHICH HAS EVERYTHING
23 THAT WE'RE SUPPOSED TO DO. THAT WILL GET E-MAILED TO
24 YOU OR FAXED TO YOU BY, YOU KNOW, 48 HOURS FROM NOW.

25 CO-CHAIR RABB: NO. NO.

1 CO-CHAIR LANSING: SOON. AS SOON AS HUMANLY
2 POSSIBLE. YOU WILL ALL X THE ONES, YOU CAN X AS MANY
3 AS YOU WANT THAT YOU WANT TO PARTICIPATE IN, BUT YOU
4 CAN'T NOT X SOMETHING. DO YOU KNOW WHAT I'M SAYING?
5 AND THEN IF THERE'S A BLANK NEXT TO SOMETHING, IF IT IS
6 A BLANK NEXT TO SOMETHING IN THE NAS GUIDELINES, YOU
7 AND I WITH ZACH WILL ASSIGN IT TO SOMEBODY. IF THERE'S
8 A BLANK NEXT TO ONE OF THE NEW ONES, WE WILL ASSUME
9 THAT THERE'S NOT ENOUGH INTEREST AT THIS TIME TO PURSUE
10 THAT ISSUE. AND SINCE WE'RE A GROUP THAT'S GOING TO BE
11 MEETING FOR THE NEXT TEN YEARS, WE WILL FIND TIME TO
12 BRING IT UP AGAIN.

13 DOES THAT MEET WITH EVERYBODY'S APPROVAL?

14 DR. HALL: LET ME JUST COMMENT. I'VE HEARD
15 TWO SLIGHTLY DIFFERENT THINGS FROM OUR TWO CO-CHAIRS.
16 AND THAT IS, WHAT I HEARD FROM HARRIET WAS MAINLY
17 INFORMATION GATHERING; THAT IS, ASSIGNING PEOPLE TO BE
18 RESPONSIBLE FOR GATHERING INFORMATION, RELEVANT
19 INFORMATION. AND WHAT I HEAR FROM YOU IS MORE THE
20 DRAFTING. AND SO MAYBE THOSE CAN BE COMBINED BY HAVING
21 A POINT PERSON FOR EACH ONE FOR EACH TOPIC ON THE LIST.
22 WE WOULD HAVE THAT RESPONSIBILITY FOR TRYING TO GATHER
23 SOME RELEVANT INFORMATION, IF NECESSARY. THAT IS, IF
24 SOMEBODY NEEDS TO CALL HANK GREELEY, THEN THAT PERSON
25 WOULD TAKE THE RESPONSIBILITY BEFORE THE PHONE CALL OF

1 TRYING TO GATHER THAT INFORMATION OR PUTTING AN
2 ARTICLE --

3 CO-CHAIR LANSING: BUT YOU WON'T BE ABLE TO
4 HAVE A DISCUSSION WITHOUT BACKGROUND INFORMATION. SO
5 I'M ASSUMING THAT YOU'RE GOING TO DO BOTH.

6 DR. HALL: I JUST WANT TO MAKE SURE SOMEBODY
7 IS ASSIGNED THAT RESPONSIBILITY.

8 CO-CHAIR LANSING: I'M LOOKING TO SET UP
9 SUBCOMMITTEES TO DEAL WITH ALL OF THESE ISSUES AMONG
10 OURSELVES, AND EACH SUBCOMMITTEE WILL DECIDE WHO IS THE
11 HEAD PERSON FOR THE SUBCOMMITTEE. AND THEN YOU WILL
12 DECIDE WHAT INFORMATION YOU NEED. SOME COMMITTEES HAVE
13 15 PEOPLE ON IT. SOME COMMITTEES ONLY HAVE FOUR.
14 DEPEND ON WHAT WE GET. AND WE'LL DECIDE WHAT
15 BACKGROUND INFORMATION. IT'S BASICALLY WHAT JANET
16 SAID. ALL YOU WILL DO IS MAKE A RECOMMENDATION. I'M
17 NOT SUGGESTING THAT IT BE A LEGAL RECOMMENDATION. AND
18 TO TAKE KEVIN'S POINT, IT'S NOT BINDING. IT'S SIMPLY A
19 RECOMMENDATION SO THAT WHEN WE COME BACK HERE ON AUGUST
20 30TH, WE'LL HAVE A PLATFORM TO DISCUSS THINGS.

21 DR. HALL: CAN I JUST SAY THAT OUR FIRST
22 RESPONSIBILITY, I ASSUME, ON AUGUST 30TH, THE FIRST
23 RESPONSIBILITY OF THIS WORKING GROUP WILL BE TO
24 CONSIDER OUR NEWLY CRAFTED TRANSLATION, RIGHT?

25 CO-CHAIR LANSING: WELL --

1 DR. HALL: SO THAT WE START WITH THAT, AND
2 THEN WE WILL GO FORWARD. I'M NOT TRYING TO DERAIL
3 THIS, BUT SIMPLY TO SAY THAT WE DO HAVE SOME TIME. WE
4 START WITH THAT. AND THEN I THINK WE'LL BE ABLE TO
5 CONSIDER SOME OF THESE TOPICS. WE DON'T HAVE TO GET
6 EVERYTHING DONE BY AUGUST 30TH MEETING. THAT'S MY
7 POINT. WE WILL CONTINUE ACTUALLY TO COLLECT
8 INFORMATION FROM THE PUBLIC AT THAT MEETING AND THROUGH
9 SOME 45 DAYS AFTERWARDS.

10 CO-CHAIR LANSING: SO POINT OF CLARIFICATION.
11 ALL WE NEED TO DO ON AUGUST 30TH IS GET THE NATIONAL
12 ACADEMY OF SCIENCE DONE; IS THAT CORRECT?

13 DR. HALL: WELL, AND THEN TO START AND
14 CONTINUE THE DIALOGUE ABOUT THESE VARIOUS ISSUES THAT
15 ARE BEING BROUGHT UP. I DON'T THINK -- I THINK IT'S
16 GREAT TO GET STARTED ON THIS, BUT I THINK TO THINK THAT
17 WE'RE GOING TO HAVE TO DEVELOP A POSITION, GATHER
18 INFORMATION, DEVELOP A POSITION ON EACH ONE OF THESE
19 POINTS BETWEEN NOW AND THEN IS, I THINK, NOT REALISTIC,
20 AND I THINK IS ASKING -- I'M NOT SURE THAT WOULD WORK.

21 DR. ROWLEY: LET ME JUST INTERJECT HERE AT
22 THE RISK OF EITHER GETTING MYSELF INTO WORK, WHICH I
23 KNOW I WON'T BE ABLE TO DO, OR MAKING ENEMIES OF ALL OF
24 THE STAFF OF THE NATIONAL ACADEMY OF SCIENCES. BUT I
25 PROBABLY HAVE, AND ALTA PROBABLY HAS, TWO FEET OF

1 PAPER.

2 MS. CHARO: YOU'VE STILL GOT THAT?

3 DR. ROWLEY: I NEVER THROW ANYTHING AWAY,
4 MUCH TO MY HUSBAND'S DISTRESS.

5 MS. CHARO: I'M GLAD YOU STILL HAVE IT. IT'S
6 GONE.

7 DR. ROWLEY: BUT THEY SENT US ALL SORTS OF
8 THINGS. JUST AS A POINT OF EXAMPLE, THE U.K.
9 GUIDELINES, I HAVE 6 INCHES OF PAPER COMING FROM THE
10 UNITED KINGDOM ON ALL SORTS OF STUFF THAT WERE USED TO
11 WRITE THOSE REPORTS. SO SOMEBODY HAS IN ONE SENSE
12 ACCUMULATED A LOT OF WHAT SHERRY IS ASKING FOR. AS I
13 SAY, I DON'T WANT TO PUT MYSELF IN THE POSITION OF
14 GOING THROUGH MY TWO FEET OF PAPER TO SEE WHAT'S
15 RELEVANT TO EACH ONE OF THE RECOMMENDATIONS, BUT IT MAY
16 BE THAT BETWEEN MYSELF, KATHY HARRIS, WHO IS THE AUTHOR
17 OF THE TEXT, SCRUTINIZED WORD BY WORD BY 24 PEOPLE, BUT
18 SHE IS THE AUTHOR, AND SHE PROBABLY HAS SOME OF THE
19 STUFF. MAYBE WE CAN MAKE THIS A LITTLE BIT LESS
20 PAINFUL A PROCESS BY DRAWING ON RESOURCES AND TEXT AND
21 REFERENCES THAT WE ALREADY HAVE ACCUMULATED.

22 MS. CHARO: I CAN SAY THIS WITH THE GREATEST
23 RESPECT FOR EVERYBODY HERE, BUT I'M BEGINNING TO WORRY
24 THAT THIS IS MAYBE NOT THE BEST PATH. AS I'M LISTENING
25 TO WHAT WE HAVE IMPLEMENTED, ESPECIALLY THE THOUGHT OF

1 DISTRIBUTING THE -- 2 FEET IS PROBABLY AN
2 UNDERESTIMATE, JANET, OF MATERIALS. IT DOES SEEM TO ME
3 THAT THE NAS RECOMMENDATIONS ARE NOT TO BE ADOPTED
4 WHOLESALE, BUT THEY FORM AN OUTLINE THAT FORMS THE
5 BASIS FOR DISCUSSION. AND ALTHOUGH IT DID SEEM TO MAKE
6 IT TEDIOUS AND MUNDANE TO SAY LET'S START WITH
7 RECOMMENDATION 1 AND MOVE ON TO NO. 2, IT DOESN'T SEEM
8 TEDIOUS AND MUNDANE TO SAY HERE ARE THE FOUR
9 RECOMMENDATIONS THAT HAVE TO DO WITH HOW TO RECRUIT
10 DONORS, AND LET'S LOOK AT THAT AND LET'S DECIDE WHAT DO
11 WE LIKE, WHAT DO WE NOT LIKE AS A MATTER OF PRINCIPLE,
12 WHERE WE'VE GOT REGULATORY LANGUAGE, WHERE DO WE THINK
13 THE LANGUAGE DOES OR DOES NOT CAPTURE WHAT WE AGREE
14 WITH? WHERE IS THERE SOMETHING THAT'S NOT CAPTURED
15 THAT WE THINK SHOULD BE CAPTURED.

16 IN THE COURSE OF THAT DISCUSSION, WE
17 CAREFULLY MAKE LISTS OF ANY PIECE OF INFORMATION THAT
18 WE NEED TO COME TO A CONCLUSION THAT WE DON'T YET HAVE.

19 IF IT WERE ABOUT THE RECRUITMENT AND INFORMED
20 CONSENT, AND WE WERE GOING THROUGH THE NAS MATERIALS AS
21 A STARTING POINT, SOMEBODY MIGHT SAY, YOU KNOW, I DON'T
22 FEEL LIKE I'VE GOT ENOUGH DOCUMENTATION ON THE RANGE OF
23 LONG-TERM RISKS TO BE ABLE TO DECIDE WHAT KIND OF
24 CONSENT PROCESS IS NEEDED BEFORE SOMEBODY CAN SAY YEA
25 OR NAY. NOW IT'S ON OUR LIST, BUT IT'S SO MUCH MORE

1 FOCUSED. AS WE'RE LISTENING TO THIS SERIES OF TOPICS
2 AND THIS SERIES OF WHITE PAPERS AND THE RESEARCH, IT'S
3 ALMOST LIKE REDOING THE HIPAA REPORT, THE CANADIAN
4 REPORT, THE NAS REPORT, THE SINGAPORE REPORT. I JUST
5 FEAR WE'RE GOING TO TURN INTO A REPORT WRITING GROUP
6 INSTEAD OF ONE THAT ACTUALLY LOOKS AT THE LANGUAGE AND
7 SAYS HOW DOES IT HAVE TO BE TWEAKED IN ORDER TO BE
8 IMPLEMENTED.

9 CO-CHAIR LANSING: SO ARE YOU COMFORTABLE --
10 AGAIN, I COME BACK TO -- I'M GOING TO NOW JUST DEAL
11 WITH THE NAS BECAUSE THAT'S WHAT YOU'RE SAYING WE HAVE
12 TO DEAL WITH. I'M GOING TO TAKE ALL THE OTHER THINGS
13 THAT PEOPLE BROUGHT UP AND JUST TABLE THAT FOR A
14 SECOND. YOU HAD DIVIDED, I THOUGHT, VERY INTELLIGENTLY
15 THE NAS INTO LIKE FOUR GROUPS WHICH WE TALKED ABOUT.
16 ARE YOU COMFORTABLE WITH FOUR SUBCOMMITTEES, SO TO
17 SPEAK, HEADED BY ONE PERSON, THAT IN THIS TIME BETWEEN
18 NOW AND THE 30TH LOOKS AT THESE FOUR THINGS, WE CAN ALL
19 PARTICIPATE IN THEM AS MUCH AS WE WISH TO OR NOT, BUT
20 THERE WILL BE FOUR PEOPLE THAT ARE RUNNING EACH OF
21 THESE, AND SUPPLY AS MUCH AS INFORMATION AS SOMEBODY
22 ASKS FOR. YOU KNOW, LIKE SOMEONE SAYS, WELL, I DON'T
23 UNDERSTAND THIS. CAN I HAVE THIS PAPER TO LOOK AT IT
24 ETHICALLY? AND THEN THAT GROUP COMES BACK WITH THE
25 TWEAKS THAT ARE MERELY RECOMMENDATIONS SO THAT THEN

1 WHEN WE MEET AGAIN ON THE 30TH, WE HAVE SOMETHING TO GO
2 BY.

3 AND THEN AFTER THAT IS DONE, WE OPEN IT UP TO
4 THESE OTHER ISSUES THAT ARE NOT PART OF THE NAS
5 GUIDELINES, AND WE OPEN IT UP TO THESE OTHER ISSUES,
6 AND THAT IS PART OF OUR EVOLVING PROCESS AS AN
7 ORGANIZATIONAL GROUP.

8 CO-CHAIR RABB: TO MAKE IT MORE CONCRETE OR
9 AT LEAST DOWN THE WEEDS, MY DIVISION WAS
10 RECOMMENDATIONS 1 THROUGH 5 FORM ONE CLUSTER OF ISSUES
11 HAVING TO DO WITH ESCRO'S, 8 THROUGH 12 ARE ABOUT
12 REVIEW BOARDS AND OTHER RELATED PROCESSES, 13 THROUGH
13 21 HAD TO DO WITH DONATION, AND 22 AND 23 HAD TO DO
14 WITH BANKING. THAT'S OBVIOUSLY A ROUGH CUT, AND THERE
15 ARE NUMBERS MISSING, AND SOME OF THEM OVERLAP.

16 CO-CHAIR LANSING: BUT IT'S A PRETTY GOOD
17 CUT. IT'S A PRETTY GOOD CUT. SO COULD WE -- DOES THAT
18 MAKE SENSE? AND THEN AFTER WE SOLVE THE NAS ON OR
19 ABOUT THE 30TH, WHENEVER IT IS, THEN WE WILL SEE WHAT
20 OTHER ISSUES THAT ARE ON THAT LIST AND CONTINUE TO
21 ALLOW, AND WE'LL TACKLE THEM ONE AT TIME IN THE MONTHS
22 AND YEARS AHEAD.

23 MR. KLEIN: INFORMATIONALLY, JAMES HARRISON,
24 WE ONLY NEED TO DEAL ON AUGUST 30TH WITH THAT PORTION
25 OF THE NATIONAL ACADEMY THAT WE CAN REFINE. WE CAN

1 KEEP THE OTHER AS JUST INTERIM REGULATION AND WITH MORE
2 TIME TO DO REFINEMENTS ON THE BALANCE. OR DO WE NEED
3 ALL OF THE CHANGES TO THE NATIONAL ACADEMY PORTION
4 DONE?

5 MR. HARRISON: UNDER THE MOTION THAT YOU
6 ADOPTED IN YOUR REQUEST TO THE ICOC, ESSENTIALLY WHAT
7 YOU'VE ASKED THE ICOC TO DO IS TO CHARGE YOU WITH THE
8 RESPONSIBILITY TO PRESENT PRECISE REGULATORY LANGUAGE
9 TO THE ICOC FOR ITS CONSIDERATION ON SEPTEMBER 9TH.
10 STAFF WILL DRAFT THAT AND MAKES CHANGES TO CONFORM THE
11 GUIDELINES TO CALIFORNIA LAW. AT THAT POINT IN TIME,
12 WE WOULD ANTICIPATE THAT THE ICOC WOULD ADOPT THAT
13 REGULATORY LANGUAGE AS ITS INTERIM STANDARDS. IT'S AT
14 THAT POINT IN TIME THAT THE FORMAL RULEMAKING PROCESS
15 WOULD START, AND WE WOULD HOPE TO HAVE THE FULL 270
16 DAYS IN WHICH TO ENGAGE IN THAT PROCESS TO --

17 MR. KLEIN: WE ONLY NEED TO DO THOSE
18 MODIFICATIONS ON AUGUST 30TH ON THE NATIONAL ACADEMY
19 PROVISIONS THAT WE ALL FEEL VERY COMFORTABLE WITH.

20 DR. HALL: THAT HAS TO BE DONE, BUT IN
21 ADDITION, MY ASSUMPTION IS THAT THAT'S NOT GOING TO
22 TAKE VERY LONG. THAT WILL NOT TAKE ALL DAY.

23 MR. KLEIN: I UNDERSTAND.

24 DR. HALL: AND THEN THE REST OF THE DAY I
25 THINK ONE CAN BEGIN AND SAY, OKAY, THAT'S OUR INTERIM

1 STANDARD. NOW LET'S BEGIN THE PROCESS OF EXAMINING
2 THESE VARIOUS ISSUES THAT ARE IN THE NATIONAL ACADEMY
3 STANDARD, AND LET'S PICK UP THE ONES THAT WE WANT TO
4 LOOK AT. PICK IT UP, LOOK AT IT. IF WE'RE READY TO
5 MAKE A DECISION, WE CAN. IF WE WANT TO WAIT FOR MORE
6 PUBLIC COMMENT, IF WE WANT TO DO WHATEVER WE CAN, WE
7 CAN DO THAT. MY POINT IS THEN YOU START PICKING THEM
8 UP ONE BY ONE.

9 MR. KLEIN: I WAS ONLY TRYING TO SAY THE
10 ESSENTIAL TASK FROM THE DESIRE.

11 CO-CHAIR LANSING: I THINK WE CAN OPERATE OFF
12 OF THE DESIRED TASK BECAUSE I MEAN I THINK WE MAY NOT
13 ACHIEVE IT, BUT YOU'VE BROKEN IT DOWN INTO FOUR REALLY
14 CLEAR THINGS. AND WE MAY NOT GET IT ALL DONE, BUT
15 THEN, AGAIN, WE MIGHT BECAUSE THE NATIONAL ACADEMY OF
16 SCIENCE IS VERY SMART IN WHAT THEY DID. WE'RE GOING TO
17 TWEAK IT. WE'RE GOING TO CHANGE SOME OF IT. NOW --
18 AND THEN WE'RE GOING TO OPEN IT UP TO OTHER ISSUES, BUT
19 I THINK -- I THINK, YOU KNOW, WE HAVE SEVEN WEEKS IN
20 WHICH WE CAN REALLY START TO LOOK AT THESE THINGS, AND
21 I THINK WE SHOULD.

22 CO-CHAIR RABB: WELL, I WOULD JUST REFERENCE
23 ALL OF THIS BACK WHEN WE READ THE TRANSCRIPT TO WHAT IT
24 IS WE ACTUALLY VOTED FOR AND MAKE SURE THAT WE HAVE NOT
25 COMMITTED TO MAKING A BUNCH OF CHANGES THAT WHEN WE HAD

1 EVERYBODY IN THE ROOM, WE SAID WE WEREN'T GOING TO MAKE
2 SUBSTANTIVE CHANGES EXCEPT TO CONFORM TO STATE LAW. I
3 THINK THAT'S WHERE WE OUGHT TO BE GOING INTO
4 PRESENTATION OF THE NEW DRAFT IN PROPER TEXT FORM.

5 WE HAVE WORLD ENOUGH IN TIME, STARTING WITH
6 THE PROCESS WE'RE DESCRIBING, OF DIVIDING OUR
7 GUIDELINES UP AND APPROACHING THEM IN GROUPS TO DO WHAT
8 WE WANT TO DO OVER THE 270 OR SOME PART OF THE 270 DAYS
9 THEREAFTER IN THE ROOM WITH THE PUBLIC TO THINK ABOUT
10 HOW WE'RE GOING TO MAKE OUR FINAL RECOMMENDATIONS.

11 DR. HALL: MAY I SUGGEST. SOMEBODY HAD
12 SUGGESTED THAT THE THREE OF US BASICALLY ASSIGN THOSE
13 AREAS. AND I SUGGEST, IN THE INTEREST OF TIME AND
14 CLARITY, THAT WE JUST ADOPT A SORT OF NONDICTATORSHIP
15 HERE, AND PEOPLE WANT TO E-MAIL WHAT THEIR PREFERENCES
16 ARE, PLEASE DO SO. WE TRY TO NOT WORK IT OUT HERE IN
17 THE COMMITTEE. IT'S LATE IN THE DAY. LET'S JUST DO IT
18 AND WE CAN DO IT FAIRLY QUICKLY.

19 CO-CHAIR LANSING: CAN I JUST MAKE A POINT OF
20 CLARIFICATION JUST SO WE ALL UNDERSTAND. I THINK WE'RE
21 IN AGREEMENT. WE HAVE DECIDED TWO THINGS TODAY. WE
22 HAD A MOTION THAT SAID THAT WHAT WE WERE GOING TO DO IS
23 TAKE THE NATIONAL ACADEMY OF SCIENCE AND TRANSLATE IT
24 LITERALLY INTO LEGAL LANGUAGE WITH THE EXCEPTION OF THE
25 ONE POINT THAT WE KNOW OF, MAYBE THERE WILL BE ANOTHER,

1 THAT WAS AGAINST THE CALIFORNIA LAW. THAT'S GOING TO
2 BE DONE. WE'RE NOT THE ONES THAT ARE DOING THAT
3 LEGALLY. JAMES, YOU'RE DOING IT. OKAY.

4 OUR GROUP NOW HAS FOUR COMPARTMENTS OF THE
5 NATIONAL ACADEMY OF SCIENCE, ESCRO, REVIEW BOARDS, AND
6 PROCESSES, DONATION, AND BANKING CELL LINES. THOSE ARE
7 FOUR SUBCOMMITTEES TO ANALYZE THE NATIONAL ACADEMY OF
8 SCIENCE BODIES.

9 WE WILL GET E-MAIL, GET FAXES, AND WE WILL
10 SAY OUR PREFERENCES TO WHICH ONE OF THESE, ALL OF THESE
11 WE WISH TO PARTICIPATE IN. WE WILL START TO HAVE
12 CONFERENCE CALLS. WE WILL START TO GET INFORMATION,
13 AND WE WILL START TO SEE HOW WE FEEL ABOUT THESE 23
14 BASIC PARTS OF THE NATIONAL ACADEMY OF SCIENCE, AND
15 COME BACK ON AUGUST 30TH AND DISCUSS THEM. IS THAT
16 CLEAR?

17 DR. HALL: YES, THAT'S RIGHT. BUT WE DON'T
18 NEED TO MAKE DECISIONS ON THEM NECESSARILY. THAT'S
19 FINE. THAT'S THE ONLY POINT. AND WE HAVE COMMITTED
20 OURSELVES TO THE PROCESS OF PUBLIC HEARING AND OF
21 ACTUALLY GETTING BOTH.

22 DR. EGGAN: SO THE ONLY ACTION THAT WE'LL
23 HAVE TO DO ON THAT DAY IS TO APPROVE THE REWRITING TO
24 BE SENT TO THE ICOC.

25 DR. HALL: START THE OTHER.

1 CO-CHAIR LANSING: IT IS CONCEIVABLE THAT
2 SOME OF THESE ISSUES THAT, AS WE START, WE APPROVE THE
3 LANGUAGE SHOULD TAKE --

4 DR. HALL: WE'VE COMMITTED TO A PUBLIC
5 PROCESS OF TAKING INFORMATION, AND WE DO NOT WANT TO
6 SHORT-CIRCUIT THAT. SO WE START WITH THAT, WE START
7 OUR DISCUSSIONS, BUT I THINK WE WILL THEN CONTINUE WITH
8 THE WEBSITE, AS HARRIET DESCRIBED EARLIER, TAKE THE
9 COMMENTS BY E-MAIL. WE NEED TO PLAN AGAIN ABOUT OUR
10 POSSIBILITY OF HAVING PUBLIC HEARINGS WHERE PEOPLE JUST
11 COME AND COMMENT. BUT WE RECEIVE ALL OF THAT, AND THEN
12 JUST AS YOU SAID THAT BECOMES PART OF THE MATERIAL THAT
13 WE WORK WITH IN ADDITION TO THE WORK OF THIS WORKING
14 GROUP.

15 CO-CHAIR RABB: SO WE MAY CHANGE SOME DATES
16 OF VARIOUS PLANNED PUBLIC PARTICIPATION, THE CONCEPT
17 THAT WE ADOPTED EARLIER, THE NOTION OF IT, NEW DATES
18 PUT IN, PROCEED TO. I THINK IT'S FAIR TO SAY THAT
19 PEOPLE HAVE BEEN INCREDIBLY PATIENT, FORTHCOMING, AND
20 HELPFUL. WE HAVE ANOTHER PUBLIC COMMENT BEFORE WE COME
21 TO A CLOSE.

22 MR. REED: THIS IS NOT SOMETHING THAT
23 REQUIRES IMMEDIATE ACTION, BUT I THINK IT'S SOMETHING
24 THAT SHOULD BE THOUGHT OF. EVERYBODY HERE BEGINS WITH
25 A STRONG SENSE OF WHAT WE'RE DOING IS ETHICALLY RIGHT,

1 BUT THERE'S OPPOSITION OUT THERE WHICH FEELS OTHERWISE.
2 I THINK WE NEED A STATEMENT ON THE ETHICAL RIGHTNESS OF
3 WHAT WE'RE DOING. IT'S GOING TO COME UP AGAIN AND
4 AGAIN AND AGAIN. JUST IN READING THE TRANSCRIPT OF THE
5 HR 810 BATTLE. AND THE WORK THAT WE LOVE IS BEING
6 CALLED THE CULTURE OF DEATH, BEING CALLED BABY KILLERS,
7 ALL THIS TRASH.

8 I THINK WE NEED A STATEMENT OF THE ETHICAL
9 BEAUTY AND THE RIGHTNESS OF WHAT WE'RE DOING. I THINK
10 THIS IS THE COMMITTEE THAT SHOULD COME UP WITH IT. SO
11 AT SOME POINT IN TIME, THIS IS GOING TO BE PART OF THE
12 SUPREME COURT DECISION. IT'S GOING TO BE IN HR 810.
13 IT MAY COME UP AROUND THAT AGAIN AND AGAIN. WE NEED
14 SOMETHING THAT CAN BE QUOTED, SOMETHING ON THE ETHICAL
15 RIGHTNESS AND THE BEAUTY OF WHAT THIS IS ALL ABOUT.
16 THANK YOU.

17 CO-CHAIR RABB: TO THE MEMBERS OF THE PUBLIC
18 WHO HAVE STUCK IT OUT UNTIL THE VERY LAST HOUR, AND TO
19 ALL THE MEMBERS OF THE COMMITTEE, ENORMOUS THANKS FOR
20 EVERYBODY'S PARTICIPATION, PATIENCE, AND WILLINGNESS TO
21 PARTICIPATE TO BE PART OF THE DISCUSSION.

22 DR. PETERS: THANKS TO OUR LEADERS FOR
23 SHEPHERDING THIS.

24 (APPLAUSE.)

25 DR. EGGAN: I MOVE TO ADJOURN THE MEETING.

1 CO-CHAIR RABB: DO WE HEAR ANY OPPOSITION?

2 CO-CHAIR LANSING: I WAS GOING TO OFFICIALLY
3 ASK IF THERE WAS OTHER BUSINESS THAT YOU'D LIKE TO
4 DISCUSS.

5 CO-CHAIR RABB: THE MEETING IS ADJOURNED AND
6 THANK YOU ALL.

7 DR. HALL: I JUST WANT TO SAY THANKS FOR A
8 GREAT START TO OUR ACTIVITIES HERE AT CIRM.

9 (THE MEETING WAS THEN ADJOURNED AT 06:18
10 P.M.)

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