

BEFORE THE
SCIENTIFIC AND MEDICAL ACCOUNTABILITY
STANDARDS WORKING GROUP
OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: THE LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA

DATE: MONDAY, JANUARY 30, 2006
TUESDAY, JANUARY 31, 2006

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1 LOS ANGELES, CALIFORNIA; MONDAY, JANUARY 30, 2006

2

3 CO-CHAIR LANSING: I THINK WE CAN GET
4 STARTED. FIRST OF ALL, I'D LIKE TO WELCOME ALL OF YOU
5 AND TELL YOU THAT OVER THE NEXT TWO DAYS, WE WILL BE
6 COMING TO A CLOSURE, AS MOST OF YOU KNOW, ON A
7 REGULATORY PACKAGE THAT WILL THEN BE SUBMITTED TO THE
8 ICOC. AND I HAVE TO SAY I BELIEVE THIS IS REALLY A
9 MILESTONE, AND IT'S REALLY A REMARKABLE ACHIEVEMENT.
10 AND I CAN'T HELP BUT REFLECT BACK ON WHEN WE ALL
11 STARTED TOGETHER AS A GROUP AND ALSO THE MEMBERS OF THE
12 PUBLIC THAT HAVE CONSISTENTLY BEEN HERE AND OBVIOUSLY
13 THE LEGISLATURE. ALL OF US HAVE WORKED TOGETHER. WE
14 WORKED TOGETHER TO FORM, WHICH I THINK YOU WILL SEE,
15 AND OBVIOUSLY THIS IS THE WORK OF THE NEXT TWO DAYS,
16 THE STRONGEST REGULATORY PACKAGE IN THE COUNTRY, IN THE
17 HISTORY OF THE COUNTRY.

18 WE DID JUST WHAT WE SAID WE WERE GOING TO DO.
19 WE TOOK THE NAS GUIDELINES AND WE DID NOT RUBBER-STAMP
20 THEM. WE DID NOT JUST SAY, WELL, THIS IS GOOD ENOUGH,
21 BUT WE WENT ABOVE AND BEYOND THAT AND WE IMPROVED THEM.

22 ON A PERSONAL LEVEL, I WANT TO SAY THAT IT
23 HAS BEEN A TRUE PRIVILEGE AND HONOR FOR ME TO WORK WITH
24 ALL OF YOU. AND I MEAN THE STANDARDS GROUP AND I ALSO
25 MEAN THE PUBLIC AND THE LEGISLATURE. AND NONE OF THIS

1 WOULD HAVE HAPPENED WITHOUT ALL THREE OF US WORKING
2 TOGETHER.

3 I FIRST WANT TO THANK THE MEMBERS OF THE
4 STANDARDS GROUP BECAUSE I AM VERY, VERY GRATEFUL TO ALL
5 OF THE WORK THAT YOU DID. AND I WANT TO REMIND
6 EVERYBODY WHAT A DISTINGUISHED GROUP WE HAVE ON THE
7 STANDARDS GROUP, ON OUR COMMITTEE, THE HIGHEST LEVEL OF
8 EXCELLENCE. AND JUST TO REMIND EVERYBODY, WE HAVE TWO
9 MEMBERS OF THE UNITED STATES NATIONAL BIOETHICS
10 ADVISORY COMMITTEE. WE HAVE TWO MEMBERS OF THE BLUE
11 RIBBON COMMITTEE THAT DEVELOPED THE NAS GUIDELINES FOR
12 EMBRYONIC STEM CELL RESEARCH. WE HAVE MEMBERS OF THE
13 INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF
14 SCIENCE, MEMBERS OF THE AMERICAN ACADEMY OF ARTS AND
15 SCIENCES, HOWARD HUGHES MEDICAL INSTITUTE FELLOWS, AND
16 OBVIOUSLY ICOC BOARD MEMBERS WHO ARE RECOGNIZED FOR
17 THEIR PATIENT ADVOCACY AND THEIR POLICY BUILDING.

18 IT'S AN EXTRAORDINARY GROUP, AND THE
19 ACCOMPLISHMENTS THAT THESE PEOPLE HAVE SPEAK FOR
20 THEMSELVES, BUT I ACTUALLY FOUND OUT THAT THE COMMITTEE
21 MEMBERS ALONE HAVE PRODUCED OVER 1,000 PEER-REVIEWED
22 MANUSCRIPTS IN THE AREAS OF THEIR RESEARCH. I THINK
23 THAT'S JUST AN ASTOUNDING STATISTIC. SO I WANT TO
24 THANK ALL OF YOU FOR YOUR COMMITMENT, FOR YOUR TIME,
25 FOR YOUR ENERGY, AND FOR YOUR PASSION.

1 THIS MEETING TODAY AND TOMORROW WILL
2 CULMINATE SEVEN MONTHS OF WORK. AND IT'S SEVEN MONTHS
3 OF WORK BY EVERY SINGLE MEMBER. THERE WASN'T A PERSON
4 WHO DIDN'T PARTICIPATE FULLY IN IT. JUST TO REMIND
5 YOU, WE HAD FIVE PUBLIC MEETINGS. AND EQUALLY AS
6 IMPRESSIVE TO ME IS THE COUNTLESS HOURS, WHICH I CAN'T
7 EVEN BEGIN TO ENUMERATE HOW MANY THERE WERE BETWEEN THE
8 MEETINGS, WHERE WE WENT THROUGH THE VARIOUS DRAFTS AND
9 OVER THE DRAFT AND OVER THE DRAFT, AND THAT'S IN
10 ADDITION TO ALL OF YOUR PROFESSIONAL RESPONSIBILITIES.
11 MOST OF YOU TRAVELED FROM OUT-OF-STATE, AND THAT ADDS
12 TO THE TIME THAT YOU ALSO SPENT.

13 AND I ALSO WANT TO THANK PARTICULARLY THE
14 ICOC MEMBERS WHO, IN ADDITION TO THIS, MANY OF US
15 PARTICIPATED IN MOST OF THE 57 PUBLIC MEETINGS THAT THE
16 ICOC HAD -- I SEE JEFF'S FACE -- FOR THE PAST 14
17 MONTHS. THIS DEDICATION AND THIS TIME WAS
18 EXTRAORDINARY. AND WITHOUT THIS, WE WOULD NOT HAVE
19 BEEN ABLE TO IMPROVE THE NAS GUIDELINES.

20 AGAIN, I REALLY WANT TO SAY WE ADOPTED
21 GUIDELINES ON AN INTERIM BASIS AND WE MADE THEM BETTER.
22 WE WENT BEYOND WHAT THE NAS GAVE US. BUT I ALSO WANT
23 TO REMIND ALL OF US THAT OUR WORK IS CONTINUAL, AND WE
24 ARE A CONTINUAL WORK IN PROGRESS. AND TODAY, IN MY
25 OPINION, NOT TODAY, I SHOULD SAY TOMORROW HOPEFULLY

1 WILL MARK THE END OF THE BEGINNING, THE END OF THE
2 FIRST PHASE OF WHAT WE'RE DOING, BUT OUR GROUP IS NOT
3 DISBANDING. OUR GROUP IS CONTINUING TO WORK. AS THE
4 SCIENCE TEACHES US NEW THINGS, AS THINGS EVOLVE, WE
5 WILL CONTINUE TO MAKE IMPROVEMENTS ON OUR POLICY.

6 I ALSO WANT TO THANK THE CALIFORNIA
7 LEGISLATURE BECAUSE THEY REALLY DID HELP US IN FORMING
8 OUR POLICY AND OUR DELIBERATIONS. AGAIN, YOU WILL SEE
9 WE ARE IN COMPLETE AGREEMENT ABOUT INFORMED CONSENT,
10 AND OBVIOUSLY WE REJECT HUMAN REPRODUCTIVE CLONING.
11 THE LEGISLATURE HAS BEEN A TREMENDOUS HELP TO US AND WE
12 ARE ALL VERY, VERY GRATEFUL FOR THEIR INPUT.

13 AND FINALLY I WANT TO THANK THE PUBLIC. A
14 LOT OF YOU ARE HERE TODAY, SOME OF YOU WE CORRESPONDED
15 WITH THROUGH E-MAIL. YOUR CONSISTENT MONITORING, YOUR
16 CONSISTENT INPUT, YOUR CONSISTENT ADVOCACY HAS LED US,
17 I BELIEVE, TO THESE POLICIES.

18 WE HAD THREE PUBLIC SESSIONS IN ADDITION TO
19 THE FIVE PUBLIC MEETINGS. AND THESE PUBLIC SESSIONS,
20 AND A LOT OF YOU HERE TODAY WERE PART OF THOSE, WERE
21 LIVELY. THERE WAS A GREAT DEAL OF DIALOGUE BETWEEN THE
22 MEMBERS OF THE GROUP AND THE PUBLIC. THE INPUT WAS
23 INVALUABLE, IT WAS TRANSPARENT, AND IT WAS INCLUSIVE.

24 AS I SAID, WE ALSO HAD FIVE PUBLIC MEETINGS,
25 AND THEN WE DID ALL OF THIS IN ADVANCE OF THE COMMENTS

1 THAT WE RECEIVED FROM THE FORMAL PUBLIC COMMENT PERIOD.
2 THOSE COMMENTS WE ALL RECEIVED, AND WE ALL, EVERY
3 SINGLE MEMBER OF THE GROUP, PAID ATTENTION TO, AND
4 AGAIN, I HAVE TO SAY THOSE INPUTS, AND I SPEAK ON
5 BEHALF OF ALL OF US, WERE INVALUABLE TO US IN MAKING
6 THE POLICY. SO FOR ME, WORKING WITH THE PUBLIC HAS
7 BEEN A TREMENDOUS HELP, AND I THINK I SPEAK FOR ALL US
8 IN SAYING THAT, AS WELL WORKING WITH THE LEGISLATURE
9 AND OBVIOUSLY WORKING WITH ALL OF YOU AND CONTINUING TO
10 WORK WITH ALL OF YOU, IT'S BEEN A TRUE PRIVILEGE IN MY
11 LIFE.

12 I ALSO THINK I WOULD BE REMISS IF I DIDN'T
13 SPEAK ON BEHALF ALL OF US HERE TODAY TO SAY HOW SAD AND
14 SHOCKED AND DISMAYED WE WERE AT WENT ON WITH DR. HWANG
15 IN KOREA AND THE FRAUD THAT WAS PERPETRATED THERE.
16 THIS DECEPTION NOT ONLY AFFECTED DR. HWANG, BUT IT ALSO
17 AFFECTED MANY OTHER PEOPLE WHO WERE HIS COLLABORATORS,
18 PEOPLE WHO DEPENDED ON HIM. AND ONE OF THOSE PEOPLE
19 WHO WAS AFFECTED WAS DR. JOSE CIBELLI, WHO WAS ONE OF
20 THE MANY CO-AUTHORS IN HIS FIRST SCIENCE PAPER IN THE
21 YEAR 2004.

22 BUT AS SOON AS DR. CIBELLI DISCOVERED THAT
23 SCIENTIFIC FRAUD WAS AN ISSUE, HE PERSONALLY ASKED FOR
24 AN INDEPENDENT INVESTIGATION AT MICHIGAN STATE
25 UNIVERSITY. HE ASKED FOR THIS. AND HE ASKED FOR THIS

1 TO DETERMINE WHETHER OR NOT HE HAD BEEN GUILTY OF ANY
2 WRONGDOING. AND AT THE SAME TIME DR. CIBELLI CONTACTED
3 US AT THE CIRM, AND HE INDICATED HIS DESIRE TO
4 VOLUNTARILY WITHDRAW FROM THE STANDARDS WORKING GROUP.
5 AND HE DID THIS BECAUSE HE DIDN'T WANT THIS ACTION IN
6 ANY WAY TO REFLECT ON OUR GROUP.

7 WE HAVE OBVIOUSLY ACCEPTED HIS WITHDRAWAL,
8 AND WE -- AND NONE OF US SHOULD DRAW JUDGMENT ON THIS
9 UNTIL WE KNOW THE FACTS AND UNTIL THE INVESTIGATION IS
10 COMPLETED. IT'S HIS WITHDRAWAL UNTIL THE INVESTIGATION
11 IS COMPLETED. BUT THAT RAISES THE QUESTION IS HOW DO
12 WE PROTECT OURSELVES AGAINST THE SAME THING HAPPENING
13 HERE? AND I HAVE TO SAY, ONCE AGAIN, THAT WE CAN ONLY
14 CONTROL OUR WORLD, BUT BY SETTING THESE STANDARDS,
15 WE'RE LEADING THE WORLD, AND WE HOPE THAT EVERYBODY
16 ELSE WILL ADOPT THESE STANDARDS, WHICH WILL GO A LONG
17 WAY IN STOPPING SUCH A SITUATION FROM HAPPENING AGAIN.

18 SO LET US REMIND OURSELVES OF WHAT WE HAVE
19 DONE TO PREVENT SOMETHING LIKE THIS FROM HAPPENING.
20 FIRST OF ALL, AS I SAID, WE STARTED WITH THE STRONG
21 ETHICAL GUIDELINES OF THE NAS, BUT WE IMPROVED THEM.
22 WE WENT BEYOND THEM. WE MADE THEM MORE STRINGENT, AND
23 WE DIDN'T JUST ACCEPT THEM AND RUBBER-STAMP THEM.

24 ADDITIONALLY, WE HAVE MORE LEVELS OF
25 OVERSIGHT. WE HAVE OUR DISTINGUISHED GROUP OF

1 OUT-OF-STATE RESEARCHERS WHO PRESENT AND OVERSEE
2 SCIENTIFIC PEER REVIEW; AND BECAUSE THEY'RE
3 OUT-OF-STATE, THERE IS NO CONFLICT OF INTEREST AND THEY
4 CAN REMAIN COMPLETELY OBJECTIVE. THEN AFTER THEY'VE
5 DONE THEIR PEER REVIEW, WHICH IS THE FIRST LEVEL OF
6 OVERSIGHT, IT GOES TO THE ICOC 29-MEMBER BOARD. AND
7 THAT BOARD REVIEWS IT. AND YOU WILL SEE THAT THAT
8 BOARD, EVEN IN OUR INITIAL GRANTING PROCESS, DOES NOT
9 JUST RUBBER-STAMP IT. IT CAN AGREE, IT CAN DISAGREE,
10 IT CAN QUESTION. SO THAT'S A SECOND LEVEL OF
11 OVERSIGHT.

12 AND THEN FINALLY, THE CIRM STAFF IS BOUND BY
13 OTHER GROUPS. WE DON'T EXIST IN A VACUUM, SO WE HAVE
14 THE CHECKS AND BALANCES OF THE SCIENTIFIC PEER REVIEW,
15 OF THE GRANTS ADMINISTRATION, OF INTELLECTUAL PROPERTY,
16 AND OUR OWN STANDARD GROUP. SO WE ARE NOT EXISTING IN
17 A VACUUM. THAT'S THE THIRD LEVEL OF OVERSIGHT. AND SO
18 BECAUSE OF THIS, I THINK WE'RE DOING EVERYTHING THAT IS
19 HUMANLY POSSIBLE TO PREVENT SOMETHING LIKE THIS FROM
20 HAPPENING. BUT AGAIN, I WANT TO SAY WE'RE A WORK IN
21 PROGRESS. SO WE CONTINUE, AS OTHER THINGS HAPPEN, TO
22 SEE IF WE NEED TO DO SOMETHING ELSE IN ADDITION.

23 FINALLY, I JUST WANT TO SAY AGAIN AN ENORMOUS
24 THANK YOU TO ALL OF YOU HERE TODAY IN THE PUBLIC, IN
25 THE LEGISLATURE, AND ON THE STANDARDS WORKING GROUP.

1 THE AMOUNT OF TIME, COMMITMENT, AND PASSION THAT YOU
2 HAVE GIVEN US IS EXTRAORDINARY; BUT, AGAIN, THIS IS
3 JUST THE END OF THE BEGINNING. OUR WORK CONTINUES.
4 IT'S A NEW FIELD, AND WE'RE CONSTANTLY GOING TO BE
5 ADAPTING AND CHANGING, BUT THIS FIRST STEP IS A
6 MONUMENTAL ONE.

7 SO WITH THAT SAID, I'D LIKE TO HAVE A ROLL
8 CALL.

9 MS. SHREVE: ALTA CHARO.

10 MS. CHARO: HERE.

11 MS. SHREVE: KEVIN EGGAN.

12 DR. EGGAN: HERE.

13 MS. SHREVE: MARCY FEIT. ANN KIESSLING.

14 DR. KIESSLING: HERE.

15 MS. SHREVE: PATRICIA KING.

16 DR. KING: BOB KLEIN. JEFFREY KORDOWER.

17 SHERRY LANSING.

18 CO-CHAIR LANSING: HERE.

19 MS. SHREVE: BERNARD LO.

20 CO-CHAIR LO: HERE.

21 MS. SHREVE: KENNETH OLDEN. TED PETERS.

22 MR. PETERS: HERE.

23 MS. SHREVE: FRANCISCO PRIETO.

24 DR. PRIETO: HERE.

25 MS. SHREVE: JANET ROWLEY. JEFF SHEEHY.

1 MR. SHEEHY: HERE.

2 MS. SHREVE: JON SHESTACK. ROBERT TAYLOR.

3 DR. TAYLOR: HERE.

4 MS. SHREVE: JOHN WAGNER.

5 DR. WAGNER: HERE.

6 MS. SHREVE: JAMES WILLERSON.

7 DR. WILLERSON: HERE.

8 MS. LANSING: THANK YOU. CAN I HAVE APPROVAL

9 OF THE MINUTES FROM THE OCTOBER 24TH MEETING?

10 DR. EGGAN: SO MOVED.

11 CO-CHAIR LANSING: SECOND?

12 MR. SHEEHY: SECOND.

13 CO-CHAIR LANSING: ANY OBJECTIONS? APPROVED.

14 APPROVAL OF THE MINUTES FROM THE DECEMBER 1, 2005,

15 MEETING.

16 DR. TAYLOR: SO MOVED.

17 CO-CHAIR LANSING: SECOND?

18 DR. KIESSLING: SECOND.

19 CO-CHAIR LANSING: ANY OBJECTIONS? MINUTES

20 ARE APPROVED.

21 AND NOW I'M GOING TO TURN IT OVER TO MY

22 ESTEEMED PARTNER, BERNIE LO.

23 CO-CHAIR LO: THANKS VERY MUCH, SHERRY.

24 THANK YOU VERY MUCH FOR YOUR OPENING COMMENTS. I WANT

25 TO START BY WELCOMING TWO PEOPLE. JOHN WAGNER WAS ON

1 OUR CONFERENCE CALL LAST TIME AS SORT OF A DISEMBODIED
2 VOICE FROM INDIANAPOLIS. IT'S GREAT TO SEE YOU HERE,
3 JOHN, IN PERSON. AND PATRICIA KING FROM GEORGETOWN
4 UNIVERSITY SCHOOL OF LAW IN WASHINGTON, D.C., IS HERE.
5 AND, PAT, IT'S ALWAYS A PLEASURE TO SEE YOU HERE AND
6 WELCOME TO CALIFORNIA.

7 TED PETERS IS ON THE CELL PHONE. TED, WE
8 KNOW IT'S HARD SORT OF COMMUNICATING BY CELL PHONE. SO
9 PLEASE LET US KNOW WHEN YOU WANT TO SAY SOMETHING, AND
10 WE'LL TRY AND KEEP YOU ACTIVE HERE. OKAY.

11 I WANT TO START WITH SOME INFORMATION FROM
12 OUR CIRM STAFF ON SEVERAL THINGS HAPPENING IN OTHER
13 PARTS OF THE CIRM FAMILY. AND GEOFF LOMAX IS GOING TO
14 BRING US UP TO DATE ON SOME IMPORTANT OTHER
15 DEVELOPMENTS.

16 MR. LOMAX: THANK YOU AND GOOD MORNING. I
17 WANT TO GIVE A QUICK PROGRESS REPORT THIS MORNING. THE
18 ITEMS I'D LIKE TO COVER ARE A SUMMARY OF OUR OUTREACH
19 WORK WHICH REFLECTS OUR EFFORT TO ENGAGE ALL
20 STAKEHOLDERS IN THE REGULATORY DEVELOPMENT PROCESS. SO
21 WE'LL GO THROUGH SOME OF THE ACTIVITIES THAT HAVE
22 OCCURRED SINCE THE DECEMBER MEETING, REVIEW THE
23 RULEMAKING TIMELINE BECAUSE WE'RE GOING TO NOW ENTER A
24 VERY FORMAL PHASE OF THE PROCESS FOR THESE REGULATIONS,
25 AND KEEP YOU UP TO DATE AND REMIND YOU ALL OF WHAT THAT

1 LOOKS LIKE.

2 AND I WANT TO, AGAIN, GIVE YOU A QUICK UPDATE
3 ON THE GRANTS ADMINISTRATION POLICY, WHICH ARLENE CHIU
4 DESCRIBED AT OUR LAST MEETING AND YOU HAD A FULL
5 BRIEFING ON, JUST TO BRING YOU UP TO SPEED ON THE
6 DEVELOPMENTS THERE, AN UPDATE ON THE CONFERENCE ON
7 OOCYTE DONATION, AND THEN JEFF SHEEHY WILL BE PROVIDING
8 YOU AN UPDATE ON THE WORK OF THE INTELLECTUAL PROPERTY
9 TASK FORCE, WHICH, AGAIN, YOU WERE BRIEFED ON MORE
10 FULLY AT THE LAST MEETING.

11 SO ON DECEMBER 14TH WE CONVENED A WORKSHOP
12 THAT WAS CO-SPONSORED BY THE OFFICE OF THE PRESIDENT OF
13 THE UNIVERSITY OF CALIFORNIA, AND IT WAS TO DISCUSS --
14 IT WAS TITLED "STEM CELL RESEARCH: ETHICAL OVERSIGHT
15 ISSUES." IT WAS A ONE-DAY MEETING AND, FIRST OF ALL,
16 WITH THE INTENTION OF DESCRIBING THIS PROCESS, THE
17 PROCESS OF DRAFTING THE REGULATIONS. AND MOST
18 IMPORTANTLY, WHAT WE WANTED TO DO IS HIGHLIGHT
19 IMPORTANT PROVISIONS WITHIN THE REGULATIONS,
20 PARTICULARLY THE PROVISIONS THAT WERE DISTINCT FROM THE
21 NATIONAL ACADEMIES DOCUMENT. I'D LIKE TO THANK OUR
22 CO-CHAIR, DR. BERNIE LO, FOR LEADING THE EFFORT IN THAT
23 REGARD.

24 DR. HALL: GEOFF, DO YOU WANT TO SAY WHO WAS
25 AT THE MEETING?

1 MR. LOMAX: WE WILL IN A SUBSEQUENT SLIDE.
2 THANK YOU.

3 AND THIS IS TO REALLY GO THROUGH THE GOALS
4 AND WHAT THE ATTENDEES WERE OFFERED. WE'LL GO THROUGH
5 THE ATTENDEE LIST IN JUST A MINUTE. WE WANTED TO THEN,
6 ONCE WE ORIENTED THE GROUP TO THE DRAFT, IS SOLICIT
7 FEEDBACK AND COMMENTS IN AN EFFORT, IF YOU WILL, TO
8 SORT OF GROUND TRUTH THE DOCUMENT. AGAIN, YOU WILL SEE
9 FROM THE ATTENDEE LIST WHY THAT POINT IS RELEVANT. AND
10 THEN FINALLY, IT PROVIDED AN OPPORTUNITY -- THE SECOND
11 HALF OF THE DAY PROVIDED AN OPPORTUNITY FOR THE
12 ATTENDEES TO TALK ABOUT THEIR EXPERIENCE IN TERMS OF
13 TRYING TO IMPLEMENT STEM CELL RESEARCH AT THEIR
14 INSTITUTIONS.

15 SO GO TO THE NEXT SLIDE. SO WE HAD 50
16 PARTICIPANTS FROM 25 RESEARCH INSTITUTIONS. AND THE
17 TYPICAL -- THIS SORT OF GIVES YOU A SENSE OF THE
18 ATTENDEES. IT WAS VICE CHANCELLORS FOR RESEARCH, STEM
19 CELL SCIENTISTS, IRB MEMBERS, AND MEMBERS FROM SOME
20 INSTITUTIONS THAT HAVE SET UP STEM CELL RESEARCH
21 OVERSIGHT COMMITTEES. WE HAD SOME OF THOSE MEMBERS.
22 AND PARTICIPANTS FROM THE LEGAL OFFICE.

23 SO AS YOU CAN SEE, IT WAS REALLY, IN TERMS OF
24 IMPLEMENTATION, OR THE TYPES OF INDIVIDUALS THAT WOULD
25 HAVE TO LOOK AT THE DOCUMENT WE HAVE BEFORE YOU AND PUT

1 THE RULES INTO PRACTICE AT AN INSTITUTION, IT WAS A
2 GOOD CROSS SECTION OF THOSE INDIVIDUALS.

3 SO IN TERMS OF THE DISCUSSION, I WILL DIRECT
4 YOUR ATTENTION. THERE IS A DOCUMENT IN THE PACKET
5 WHICH I'M GOING TO SUMMARIZE FAIRLY QUICKLY HERE, BUT
6 THERE'S A MORE DETAILED SORT OF DESCRIPTION OF SOME OF
7 THE QUESTIONS AND DISCUSSION ITEMS THAT CAME UP. AND
8 THAT DOCUMENT IS ALSO AVAILABLE TO THE PUBLIC. IT'S
9 INTENDED TO BE LITTLE BIT OF A SENSE OF THE BACK AND
10 FORTH THAT WENT ON AROUND CRITICAL ISSUES. FOR
11 EXAMPLE, THE NEED FOR THE STEM CELL RESEARCH OVERSIGHT
12 COMMITTEE, WHAT WAS THE SORT OF FUNDAMENTAL NEED THERE?
13 WHAT'S THE THINKING? AND A LOT OF DISCUSSION ABOUT WHY
14 IT'S IMPORTANT TO HAVE A UNIQUE BODY FOCUSED ON THE
15 SCIENTIFIC AND ETHICAL ASPECTS OF STEM CELL RESEARCH.

16 THERE WAS CONSIDERABLE DISCUSSION ABOUT HOW
17 TO BEST PROVIDE FOR THAT TYPE OF REVIEW. SO, FOR
18 EXAMPLE, THERE WAS A LOT OF QUESTIONS ABOUT WHAT TYPE
19 OF MEMBERSHIP WOULD ONE ENVISION IN A GROUP SUCH AS
20 THAT. AND, FOR EXAMPLE, THERE WERE INDIVIDUALS THERE
21 FROM INSTITUTIONS THAT WERE DESCRIBING THE TYPES OF
22 INDIVIDUALS AND THE TYPES OF EXPERTISE THEY HAD ON
23 THEIR COMMITTEES ALREADY, THE INSTITUTIONS THAT HAD
24 COMMITTEES. SO THAT WAS VERY HELPFUL BECAUSE THERE
25 WERE INSTITUTIONS IN THE AUDIENCE FOR ALL THIS WAS VERY

1 NEW TO THEM, SO THEY WERE GETTING THE BENEFIT OF
2 HEARING FROM OTHER INSTITUTIONS ABOUT HOW THEY HAD
3 POPULATED THESE COMMITTEES. SO IT WAS A VERY RICH
4 INFORMATION SHARING GOING ON.

5 SOME OF THE BEST PRACTICES FOR OBTAINING
6 INFORMED CONSENT, THERE WAS DISCUSSION THERE, A
7 FAMILIAR DISCUSSION, WHICH WE'VE HAVE HAD A NUMBER OF
8 TIMES AT THIS COMMITTEE. AND THERE WAS ALSO -- DR. LO
9 FACILITATED A VERY GOOD DISCUSSION ABOUT OUR OBJECTIVES
10 THAT WE WANT TO DEVELOP AND APPROACH FOR EVALUATING THE
11 EFFECTIVENESS OF INFORMED CONSENT, WHICH ULTIMATELY
12 SOME OF THAT LANGUAGE IS ENTERED INTO OUR DRAFT. AT
13 THIS WORKSHOP WE WERE ABLE TO INITIATE SOME OF THOSE
14 DISCUSSIONS WITH THE INSTITUTIONS WHERE PEOPLE COULD
15 TALK ABOUT THE PRACTICALITY OF EVALUATING CONSENT,
16 EVALUATING COMPREHENSION. SO, AGAIN, A RICH PART OF
17 THE DISCUSSION.

18 AGAIN, THIS IS A LITTLE BIT REDUNDANT, AND
19 IT'S REFLECTED IN THE MEMO YOU HAVE, FREQUENTLY CITED
20 ISSUES. THE NEED FOR INFORMED CONSENT, PROTECTIONS TO
21 PREVENT COERCION OF DONORS. AND THERE WERE, AGAIN, A
22 NUMBER OF QUESTIONS REGARDING THE ROLES AND
23 RESPONSIBILITY OF THE STEM CELL RESEARCH OVERSIGHT
24 COMMITTEE.

25 I WANT TO JUMP TO A SECOND TOPIC HERE JUST

1 QUICKLY. THE FACT THAT WE HAVE THE DOCUMENT BEFORE
2 YOU, WE THOUGHT IT WAS VALUABLE TO GET FEEDBACK FROM
3 SOME FOLKS OUTSIDE THE COMMITTEE NOW THAT WE'RE
4 ENTERING THE PHASE OF TRYING TO DEVELOP A FINAL
5 DOCUMENT. SO WE'VE HAD THE BENEFIT OF RICHARD HYNES
6 AND JONATHAN MORENO, WHO WERE THE CO-CHAIRS OF THE
7 NATIONAL ACADEMIES COMMITTEE, AGREE TO LOOK OVER THE
8 DOCUMENT AND PROVIDE FEEDBACK. OUR FORMER CO-CHAIR,
9 HARRIET RABB, HAS ALSO EXPRESSED A WILLINGNESS TO
10 REVIEW THE DOCUMENT AND HAS ACTUALLY PROVIDED A REVIEW
11 OF AN EARLIER DRAFT OF THIS DOCUMENT, AND HER COMMENTS
12 HAVE BEEN EXTRAORDINARILY HELPFUL.

13 I'M GOING TO SHIFT NOW BACK TO THE TIMELINE,
14 CHANGE GEARS, AND WANTED TO REMIND YOU ALL OF THE
15 PERIOD WE'RE ENTERING IN TERMS OF THE ADMINISTRATIVE
16 PROCESS FOR MOVING THIS DOCUMENT INTO FORMAL CALIFORNIA
17 REGULATION. SO WE NEED TO -- AT THE CLOSE OF THIS
18 MEETING ON TUESDAY, WE NEED TO MOVE FAIRLY QUICKLY AND
19 PREPARE A FINAL DRAFT FOR CONSIDERATION BY THE ICOC.
20 THE ICOC WILL BE MEETING ON FEBRUARY 10TH. IF APPROVED
21 BY THE ICOC, WE WILL THEN INITIATE APA OR
22 ADMINISTRATIVE PROCEDURES ACT, RULEMAKING, THE GOAL
23 BEING LATE FEBRUARY.

24 AND THEN WE ENTER A -- ONCE THAT PROCESS IS
25 INITIATED, WE WOULD ENTER A 45-DAY PUBLIC COMMENTING

1 PERIOD. SO, AGAIN, TO REITERATE, WE HAVE A NEW
2 OPPORTUNITY FOR INPUT, COMMENT. AND THIS IS A FORMAL
3 PUBLIC COMMENTING PERIOD, SO WE WILL BE COMPILING AND
4 THEN RESPONDING TO THOSE COMMENTS. AND WE ALSO LOOK
5 FORWARD TO ENGAGING THE WORKING GROUP IN THOSE
6 RESPONSES. SO YOU WILL ALL BE KEPT UP TO SPEED IN REAL
7 TIME IN TERMS OF THE PROGRESS OF THE PUBLIC COMMENT.

8 IF ALL GOES SMOOTHLY, WE WILL THEN SUBMIT A
9 PACKAGE TO THE OFFICE OF ADMINISTRATIVE LAW FOR REVIEW
10 IN MID-MAY. WHAT THEY'RE LOOKING FOR THERE IS THE
11 REGULATORY DOCUMENT, WHAT'S CALLED A STATEMENT OF
12 REASONS, WHICH DESCRIBES THE WHOLE BASIS FOR THE
13 DOCUMENT, WHERE THE AUTHORITY IS DERIVED, THE WHOLE
14 PROCESS FOR PUTTING IT TOGETHER, AND A REVIEW OF HOW
15 WE'VE ADDRESSED PUBLIC COMMENT. SO THEY'RE LOOKING FOR
16 A COMPLETE PACKAGE THAT SPELLS OUT ALL THE RHYME AND
17 REASON BEHIND WHAT WE'VE DONE.

18 WE WOULD HOPE THE OFFICE OF ADMINISTRATIVE
19 LAW WOULD COMPLETE THAT REVIEW BY LATE JUNE. IF THE
20 LATE JUNE APPROVAL CAME THROUGH, THE REGULATIONS WOULD
21 TAKE EFFECT MORE OR LESS AT THE END OF JULY. AND THAT
22 TIMELINE, IF YOU ALL REMEMBER FROM THE PREVIOUS MEETING
23 MATERIALS, WE HAVE IT ON A MAP WHERE IT'S KIND OF GOT
24 THE DATES AND THINGS. WE CAN MAKE A POINT OF
25 RECIRCULATING THAT SO YOU ALL CAN SEE THAT IN THAT KIND

1 OF GRAPHIC FORMAT AS WELL.

2 VERY QUICKLY TO NOW RETURN TO THE GRANTS
3 ADMINISTRATION POLICY, AT THE LAST MEETING, DR. ARLENE
4 CHIU DESCRIBED THE POLICY THAT WAS GOING TO BE BROUGHT
5 BEFORE THE ICOC AT ITS DECEMBER 6TH MEETING. THIS WAS
6 THE POLICY THAT IS INTENDED TO GOVERN THE TRAINING
7 GRANTS. SO IT'S THE INITIAL SET OF GRANTS
8 ADMINISTRATION PROCEDURES FOR THE INITIAL ROUND OF
9 GRANTS. THAT DOCUMENT WAS APPROVED. AND IF ANYONE
10 WOULD LIKE TO REFER TO THAT DOCUMENT, WE HAVE THE WEB
11 REFERENCE THERE.

12 THEY ARE IN THE PROCESS OF DEVELOPING A FINAL
13 POLICY THAT WOULD GOVERN ALL THE AWARDS. AND THE
14 GRANTS ADMINISTRATION TEAM IS DEVELOPING, I BELIEVE,
15 WHAT THEY CALL A POLICY STATEMENT, WHICH WILL BE
16 AVAILABLE IN ADVANCE OF THE FEBRUARY MEETING. AND THAT
17 POLICY STATEMENT WILL BE INTENDED TO UPDATE THE ICOC ON
18 THE STATUS OF THE FINAL GRANTS ADMINISTRATION POLICY.
19 AND IT'S NOT CLEAR AT THIS TIME WHETHER THE FINAL
20 DOCUMENT WILL BE AVAILABLE -- THE PROPOSED GRANTS
21 ADMINISTRATION POLICY WILL BE AVAILABLE FOR THE ICOC.

22 SCOTT, I DON'T KNOW, YOU'RE A LITTLE BIT
23 CLOSER TO THAT PROCESS. DO YOU HAVE ANY SENSE?

24 MR. TOCHER: WILL IT BE PUBLICLY AVAILABLE IN
25 ADVANCE?

1 MR. LOMAX: WILL THE FINAL DRAFT -- PROPOSED
2 FINAL POLICY BE AVAILABLE FOR THE FEBRUARY 10TH ICOC
3 MEETING?

4 MR. TOCHER: THAT'S WHAT WE'RE ANTICIPATING,
5 YES.

6 MR. LOMAX: SO THAT'S STILL THE GOAL?

7 MR. TOCHER: YES.

8 MR. LOMAX: SO WE HAVE A GOAL OF THE FINAL
9 GRANTS ADMINISTRATION POLICY TO BE AVAILABLE FOR
10 FEBRUARY 10TH.

11 I'D LIKE TO TURN THE FLOOR OVER DR. ZACH
12 HALL, IF HE COULD GIVE A QUICK UPDATE ON THE
13 ORGANIZATION PROCEEDING TOWARDS THE OOCYTE DONATION
14 CONFERENCE.

15 DR. HALL: THANKS, GEOFF. LET ME JUST SAY,
16 SO WE HAVE BEEN IN DISCUSSION ABOUT HAVING A CONFERENCE
17 FOR ASSESSMENT OF MEDICAL RISK FOR OOCYTE DONORS. THE
18 INTENT OF THIS WILL BE TO LOOK AT THE SCIENTIFIC DATA
19 TO FIND OUT WHAT WE KNOW ABOUT THE RISK, TO FIND OUT
20 WHAT DATA WE NEED, AND ALSO TO SEE IF THERE ARE
21 PROCEDURES THAT CAN BE USED THAT WILL REDUCE RISK FOR
22 EGG DONORS.

23 AND FOR THIS CONFERENCE, WHICH, AS FAR AS WE
24 CAN TELL, THERE HAS NOT BEEN SUCH A CONFERENCE
25 PREVIOUSLY. WE ARE SPONSORING THE CONFERENCE IN

1 COLLABORATION WITH THE SOCIETY FOR GYNECOLOGIC
2 INVESTIGATION, WHICH IS THE LEADING INTERNATIONAL
3 SOCIETY FOR RESEARCH IN OBSTETRICS AND GYNECOLOGY. AND
4 THE TWO OF US HAVE ASKED THE NATIONAL ACADEMIES AND THE
5 INSTITUTE OF MEDICINE IF THEY WOULD PUT THE CONFERENCE
6 ON FOR US. THEY WOULD CHOOSE THE SPEAKERS, ORGANIZE
7 THE EVENT, AND PROVIDE A SUMMARY OF THE MEETING. AND
8 THEY HAVE AGREED TO DO THAT.

9 WE ARE AT THE STAGE NOW OF SEEKING MONEY FOR
10 THE CONFERENCE. AS MANY OF YOU KNOW, WE'RE UNDER
11 RATHER STRAITENED FINANCIAL CIRCUMSTANCES. AND SO WE
12 ARE TRYING TO RAISE MONEY FROM OUTSIDE DONORS FOR A
13 SERIES OF SCIENTIFIC ACTIVITIES THAT WE WANT TO CARRY
14 OUT DURING THE YEAR OF WHICH THAT IS ONE. SO AS SOON
15 AS WE ARE ABLE TO SECURE THOSE FUNDS, THEN THE NATIONAL
16 ACADEMIES AND INSTITUTE OF MEDICINE WILL BEGIN WORK ON
17 THIS.

18 AT ANY RATE, WE THINK, AS I SAY, IT WILL BE A
19 VERY IMPORTANT CONFERENCE. WE WOULD LIKE TO HOLD IT AS
20 EARLY AS MAY, AND I THINK IT JUST DEPENDS ON HOW LONG
21 IT TAKES US TO PROVIDE THE FINANCIAL BACKING FOR IT,
22 BUT WE'RE QUITE EXCITED ABOUT IT.

23 DR. TAYLOR: I'M CURIOUS. HAVE YOU LOOKED
24 INTO R 15 FUNDING? THAT'S HOW THE BOARD CONFERENCES
25 ARE FUNDED. I THINK THAT'S THE RIGHT ALPHABET SOUP.

1 THE NIH WILL PROVIDE FUNDING FOR CONFERENCES.

2 DR. HALL: HADN'T OCCURRED TO ME UNDER THE
3 CIRCUMSTANCES THEY WOULD BE WILLING TO DO SO, BUT I
4 CERTAINLY WILL INVESTIGATE. THAT'S A GREAT IDEA.
5 THAT'S GOOD.

6 LET ME ADD ONE COMMENT, IF I MIGHT, GEOFF,
7 ABOUT THE MEETING THAT WE HAD WITH THE VARIOUS
8 INSTITUTIONAL REPRESENTATIVES BECAUSE IT'S VERY
9 IMPORTANT BECAUSE IT INDICATES THAT WE'RE INTERESTED
10 NOT ONLY IN FORMULATING A STRONG SET OF REGULATIONS,
11 WHICH WE CERTAINLY WILL DO. I'M CONFIDENT WHAT THIS
12 GROUP WILL DO IN THE NEXT COUPLE DAYS, BUT WE'RE ALSO
13 INTERESTED IN SEEING THOSE IMPLEMENTED IN THE MOST
14 EFFECTIVE AND CONSISTENT WAY. WE WILL CONTINUE -- THIS
15 IS THE FIRST OF WHAT WE HOPE WILL BE A SERIES OF
16 MEETINGS IN WHICH WE WORK WITH THE INSTITUTIONS TO BE
17 SURE THAT THE REGULATIONS ARE BEING WELL APPLIED AND
18 THAT THEY'RE BEING APPLIED, AS I SAY, IN A CONSISTENT
19 WAY. AND ALSO TO HELP THEM WHERE POSSIBLE DO THEIR JOB
20 IN THE BEST POSSIBLE WAY.

21 SO THAT WILL BE ONE OF OUR ACTIVITIES AT CIRM
22 GOING FORWARD. AND AS PROBLEMS ARISE IN THAT CONTEXT,
23 WE EXPECT WE MAY BRING THEM BACK TO THIS WORKING GROUP
24 IF SOMETHING NEW COMES UP AND SAY WE NEED YOUR HELP AND
25 ADVICE ON THIS. WHAT DO YOU RECOMMEND?

1 MR. LOMAX: I THINK WE'RE GOING TO TURN IT
2 OVER TO JEFF SHEEHY NOW, WHO IS GOING TO PROVIDE AN
3 UPDATE ON THE PROGRESS OF THE INTELLECTUAL PROPERTY
4 TASK FORCE.

5 MR. SHEEHY: FIRST, I JUST WANT TO THANK THE
6 MEMBERS OF THE TASK FORCE FOR THEIR HARD WORK. WE WERE
7 LED BY ED PENHOET, AND TWO OF THE MEMBERS ARE HERE,
8 WELL, THREE OF US COUNTING MYSELF, DR. PRIETO AND
9 SHERRY LANSING. AND IT WAS A REAL TESTAMENT TO THE
10 ICOC MODEL OF COMBINING PATIENT ADVOCATES, INDUSTRY,
11 AND ACADEMIC RESEARCH FOLKS. WE ACTUALLY CAME OUT, I
12 THINK, WITH A PRODUCT THAT SYNERGIZED THE ABILITIES OF
13 ALL THOSE THREE DIFFERENT VIEWPOINTS AND PRODUCED
14 SOMETHING THAT I THINK IS GOING TO NOT ONLY REALLY PUSH
15 THE BOUNDARIES, BUT IS GOING TO BE FEASIBLE.

16 I ALSO WOULD LIKE TO ACKNOWLEDGE THE
17 SIGNIFICANT AND IMPORTANT CONTRIBUTIONS OF OUTSIDE
18 ADVICE THAT WE RECEIVED, SPECIFICALLY SENATOR ORTIZ,
19 DEBORAH ORTIZ, CONDUCTED A HEARING THAT PROVIDED AN
20 ENORMOUS WEALTH OF INFORMATION TO US AS WE TRIED TO GO
21 FORWARD IN PRODUCING THIS. AND IT WAS ABSOLUTELY
22 INVALUABLE.

23 AND I ALSO WOULD LIKE TO ACKNOWLEDGE THE
24 FOUNDATION FOR TAXPAYER AND CONSUMERS RIGHTS. I THINK
25 JOHN SIMPSON IS HERE. THEY PRODUCED A REPORT WHICH IS

1 ALSO VERY INSTRUCTIVE. THIS IS A VERY COMPLICATED
2 AREA. AND PARTICIPATION OF THE PUBLIC AND THE
3 LEGISLATURE IN HELPING FORM THIS POLICY HAS BEEN OF
4 ENORMOUS BENEFIT.

5 SO WE'RE GOING TO START JUST A REAL QUICK
6 REVIEW OF THE PRINCIPLES UNDERLYING THE INTELLECTUAL
7 PROPERTY THAT UNDERLIE WHAT WE HAVE DRAFTED. FIRST, IN
8 TERMS OF OWNERSHIP, NONPROFIT GRANTEE OWNERSHIP,
9 ORGANIZATIONS WILL OWN THE RIGHTS TO INTELLECTUAL
10 PROPERTY. WE HAVE A STRONG POLICY IN PLACE TO SUPPORT
11 BROAD SHARING. WE STARTED OFF WITH THE PRINCIPLE OF
12 THE RESEARCH EXEMPTION SO THAT CIRM WOULDN'T HAVE TO
13 PAY TWICE FOR DISCOVERIES THAT WERE CREATED WITH OUR
14 FUNDING. LICENSING, WE ENCOURAGE COMMERCIALIZATION,
15 BUT WE ALSO WANTED TO HAVE ACCESS TO THERAPIES FOR
16 UNDERSERVED COMMUNITIES. AND WE ALSO WANTED TO HAVE A
17 BIAS TOWARDS NONEXCLUSIVE LICENSINGS. AND WE DID
18 RECOGNIZE THAT PER PROPOSITION 71 WE HAVE A BALANCING
19 ACT TO ENSURE THAT WHILE WE DO NOT WANT TO HAMPER
20 RESEARCH BY PUTTING AN ONEROUS BURDEN OF RETURN TO THE
21 STATE, WE DO HAVE AN OBLIGATION TO RETURN WHATEVER
22 PORTION WE CAN WITHIN A FEASIBLE LIMIT BACK TO THE
23 STATE.

24 AND IN TERMS OF MARCH-IN RIGHTS, WE STARTED
25 OFF FROM THE PREMISE THAT WE WOULD CLOSELY HUE TO THE

1 BAYH-DOLE LINE IN TERMS OF MARCH-IN RIGHTS. SO CIRM
2 WILL RETAIN MARCH-IN RIGHTS IN THE EVENT OF FAILURE TO
3 DEVELOP CIRM-FUNDED DISCOVERIES AND PUBLIC HEALTH AND
4 SAFETY REASONS.

5 SO THESE ARE THE PRINCIPLES THAT GUIDED OUR
6 FORMAL LANGUAGE. SO THE PRIMARY THEME OF THE POLICY IS
7 SHARING, AND THESE REGULATIONS WILL HAVE THE FORCE OF
8 LAW. THE FIRST DECISION IS THAT GRANTEES OWN AND
9 MANAGE INTELLECTUAL PROPERTY CREATED IN THE COURSE OF
10 CIRM-FUNDED RESEARCH.

11 THEN IN TERMS OF WHAT WILL HAPPEN WITH THE
12 REVENUES FROM CIRM-FUNDED INVENTIONS, GRANTEES WILL
13 SHARE REVENUES WITH INVENTORS IN ACCORDANCE WITH THEIR
14 ESTABLISHED POLICIES.

15 FURTHER, 25 PERCENT OF THE GRANTEE'S
16 ORGANIZATION'S SHARE OF REVENUES IN EXCESS OF \$500,000
17 WILL BE RETURNED TO THE STATE OF CALIFORNIA. OUR
18 SHARING REGULATIONS, FIRST, PUBLICATIONS, WE'RE ASKING
19 FOR A 500-WORD LAY ABSTRACT FOR EACH PUBLISHED
20 SCIENTIFIC ARTICLE.

21 DR. KIESSLING: WE'VE HAD A NUMBER OF
22 DISCUSSIONS ABOUT THE DIFFERENCE BETWEEN NONPROFIT
23 INSTITUTIONS GRANTED CIRM GRANTS AND BIOTECHNOLOGY
24 COMPANIES. ARE YOU TALKING NOW ONLY ABOUT
25 NOT-FOR-PROFIT LIKE UNIVERSITIES?

1 MR. SHEEHY: GOOD POINT. THIS IS ONE OF THE
2 POINTS THAT I TRIED TO EMPHASIZE. THIS IS THE FIRST
3 TIME I HAVEN'T OPENED WITH IT. WE HAVE CLEARLY
4 DELINEATED OUR APPROACH TOWARDS NONPROFIT ACADEMIC
5 RESEARCH INSTITUTIONS AND OTHER NONPROFIT RESEARCH
6 INSTITUTIONS AND WHAT OUR POLICY WILL BE FOR FOR-PROFIT
7 ENTITIES. THIS IS EXCLUSIVELY OUR POLICY FOR NONPROFIT
8 RESEARCH AND NONPROFIT ACADEMIC INSTITUTIONS.

9 TO STAY WITH PUBLICATIONS, I'LL COME TO THIS
10 IN A SECOND, WE ARE IN THE PROCESS OF -- WE DON'T HAVE
11 THIS FINALIZED. WE DO WANT TO CREATE SOME SORT OF BIAS
12 TOWARDS OPEN SOURCE. WE HAVE A POLICY STATEMENT. WE
13 HAVEN'T REALLY FINALIZED THE LANGUAGE, BUT WE DO WANT
14 TO TRY TO MAKE POSSIBLE THAT ANY PUBLICATION THAT IS
15 DONE WITH CIRM-FUNDED -- THAT CIRM FUNDS THE SCIENCE
16 BEHIND, THAT THAT WILL BE AVAILABLE TO THE GENERAL
17 PUBLIC AT SOME POINT AT NO COST, NOT JUST THE
18 ABSTRACTS.

19 NOW, IN TERMS OF SHARING REGULATIONS, AND I
20 HOPE THAT, BY THE WAY, WE COULD GET SOME FEEDBACK. I
21 THINK THIS IS THE PART WHERE, SINCE WE HAVE SEVERAL
22 WORKING SCIENTISTS, THEY MIGHT BE ABLE TO POINT OUT
23 POINTS WHERE IF THERE'S ANYTHING HERE THAT DOESN'T LOOK
24 LIKE IT'S GOING TO WORK, PLEASE LET US KNOW. BUT FOR
25 PUBLICATION-RELATED BIOMEDICAL MATERIALS, GRANTEES

1 SHALL SHARE BIOMEDICAL MATERIALS DESCRIBED IN PUBLISHED
2 SCIENTIFIC ARTICLES WITHIN 60 DAYS OF RECEIPT OF
3 REQUEST FOR RESEARCH PURPOSES AND WITHOUT BIAS AS TO
4 THE AFFILIATION OF THE REQUESTER. ALTERNATIVELY,
5 AUTHORS MAY PROVIDE REQUESTERS WITH INFORMATION ON HOW
6 TO RECONSTRUCT OR OBTAIN THE MATERIAL.

7 WE THINK WE'RE REALLY PUSHING THE ENVELOPE
8 HERE BY SENDING OUT A VERY, VERY STRONG PRINCIPLE THAT
9 WE EXPECT THE RESEARCH THAT WE FUND TO BE SHARED WITH
10 OTHER RESEARCHERS AROUND THE WORLD WITHOUT BIAS TO
11 ANYBODY.

12 DR. KIESSLING: DOES IT MATTER WHO'S FUNDING
13 THE REQUESTER?

14 MR. SHEEHY: NO.

15 DR. KIESSLING: THAT REQUESTER CAN BE A
16 FOR-PROFIT BIOTECH COMPANY?

17 MR. SHEEHY: YES.

18 MR. SHESTACK: AND MATERIALS BECOME
19 AVAILABLE -- SO IN ANY EVENT, NO MATERIALS ARE
20 AVAILABLE BEFORE PUBLICATION.

21 MR. SHEEHY: RIGHT.

22 DR. TAYLOR: THAT IS INTERESTING KIND OF
23 CHANGES. WE SET THE CLOCK IN OUR PREVIOUS DISCUSSION
24 WITH PUBLICATION. THE CLOCK IS NOW BEING SET ON THE
25 BASIS OF REQUEST.

1 MR. SHESTACK: NO. IT'S STILL PUBLICATION.

2 DR. TAYLOR: IT REQUIRES PUBLICATION. THE
3 CLOCK IS BEING SET WITH THE REQUEST.

4 DR. HALL: LET ME JUST DISTINGUISH TWO
5 THINGS. ONE IS THE STEM CELL BANK, DEPOSIT IN A STEM
6 CELL BANK. THE OTHER IS SOMEBODY WRITES TO YOU AND
7 SAYS WE'VE GOT AN ANTIBODY, SO YOU ARE NOT REQUIRED TO
8 PROVIDE IT, RIGHT, UNTIL AFTER PUBLICATION, BUT THE
9 CLOCK IS SET BY WHENEVER THEY REQUEST. I THINK OUR
10 DISCUSSION HERE WAS MOSTLY IN TERMS OF STEM CELL
11 BANKING.

12 MR. SHESTACK: THIS WOULD BE FOR AN ASSAY OR
13 ANTIBODY OR SOMETHING LIKE THAT.

14 MR. SHEEHY: MATERIALS ARE TO BE SHARED
15 WITHOUT COST. AND UNDER SUCH CIRCUMSTANCES WHERE
16 SIGNIFICANT EXPENSES ARE REQUIRED TO GENERATE THE
17 MATERIALS, THE GRANTEE CAN RECOVER THOSE EXPENSES AND
18 ONLY THOSE EXPENSES FROM THE REQUESTER WITH THE
19 APPROVAL OF THE CHIEF -- ARLENE. SPO, I CAN'T REMEMBER
20 WHAT THE P STANDS FOR. THE SCIENTIFIC OFFICER.

21 NOW, THIS IS, I THINK, ANOTHER INNOVATION IN
22 TERMS OF OUR RESEARCH EXEMPTION. CIRM-FUNDED PATENTED
23 INVENTIONS, GRANTEE ORGANIZATIONS SHALL MAKE THEIR
24 CIRM-FUNDED PATENTED INVENTIONS FREELY AVAILABLE FOR
25 FURTHER RESEARCH BY CALIFORNIA RESEARCH INSTITUTIONS.

1 THIS REQUIREMENT OF THE GRANTEE INSTITUTIONS EXTENDS
2 ALSO TO ANY LICENSEES OF CIRM-FUNDED INVENTIONS. AND
3 THIS ALSO IS NOT -- CALIFORNIA RESEARCH INSTITUTIONS IS
4 A VERY BROAD DESIGNATION AS DEFINED IN PROP 71, AND
5 THIS WOULD INCLUDE FOR-PROFIT ENTITIES AS WELL.

6 MR. SHESTACK: DO YOU MEAN AVAILABLE OR
7 AVAILABLE FOR FREE?

8 MR. SHEEHY: NO. THEY'RE AVAILABLE FOR FREE,
9 I THINK; IS THAT RIGHT?

10 MS. LANSING: YES. THAT'S THE WAY I
11 UNDERSTOOD.

12 MR. SHEEHY: I'M OFF A LITTLE TODAY. I
13 APOLOGIZE. I'M NOT QUITE AS LUCID AS USUAL. THERE IS
14 NOT A CHARGE FOR RESEARCH PURPOSES.

15 DR. HALL: IF THERE ARE EXPENSES INVOLVED IN
16 PRODUCING WHATEVER IT IS, THAT'S FAIR, BUT THERE'S NO
17 CHARGE OTHERWISE.

18 MS. CHARO: SO THE RESEARCH EXEMPTION, THE
19 RECREATION OF WHAT WAS OVERTURNED IN THE DUKE CASE,
20 RESEARCH EXEMPTION NOW APPLIES TO FOR-PROFIT BIOTECH
21 COMPANIES AS WELL.

22 MR. SHESTACK: THAT'S SORT OF WHAT I'M ASKING
23 ABOUT.

24 MS. CHARO: I JUST WANT TO BE CLEAR ABOUT
25 THAT BECAUSE TO MAKE IT AVAILABLE FOR FREE, AND THEN AS

1 ZACH SAYS, FOR RESEARCH WOULD MEAN THAT IT'S NOT JUST
2 THE NOT-FOR-PROFITS WE'RE TALKING ABOUT NOW. IT'S ALL
3 CALIFORNIA ENTITIES.

4 MR. SHEEHY: I'M NOT SURE WHICH END OF THE
5 PIPE YOU ARE TALKING ABOUT. YOU'RE ABOUT TALKING ABOUT
6 THE BY CALIFORNIA RESEARCH INSTITUTIONS. THAT'S WHERE,
7 I MEAN, THAT WE HAD THE BROADEST DEFINITION THAT'S
8 INCLUDED IN PROP 71.

9 MS. CHARO: UCSF PATENTS A DISCOVERY THAT WAS
10 MADE USING CIRM FUNDS. UCSF WILL NOW BE OBLIGATED TO
11 PROVIDE THAT PATENTED MATERIAL FOR FREE TO ANY
12 CALIFORNIA ENTITY, FOR-PROFIT OR NOT-FOR-PROFIT,
13 PROVIDED IT'S FOR A RESEARCH USE.

14 MR. SHEEHY: THAT'S MY UNDERSTANDING.

15 DR. HALL: YES. I THINK I WAS AWAY LAST WEEK
16 AND WASN'T AT THE MEETING. MY UNDERSTANDING IS THAT
17 THOSE ARE USUALLY ACCOMPANIED BY AN MTA THAT SAYS IF
18 THIS IS USED FOR ANY COMMERCIAL PURPOSES, THEN THAT'S
19 TOTALLY DIFFERENT.

20 MS. CHARO: TALKING ABOUT --

21 DR. HALL: YOU'RE FORBIDDEN TO USE IT FOR ANY
22 COMMERCIAL PURPOSES; BUT THEY WANT TO USE IT FOR THEIR
23 OWN RESEARCH, WE WILL PROVIDE.

24 MS. CHARO: RESEARCH EXEMPTION WILL APPLY TO
25 FOR-PROFIT INSTITUTIONS. I JUST WANT TO BE SURE I

1 UNDERSTAND WHAT IT IS.

2 MR. SHEEHY: WE KIND OF HAD A DISCUSSION OVER
3 THIS.

4 MS. LANSING: I THINK THAT'S RIGHT.

5 MR. SHEEHY: WE HAD A DISCUSSION.
6 UNFORTUNATELY I DON'T HAVE PROP 71 IN FRONT OF ME, BUT
7 MY UNDERSTANDING WAS CALIFORNIA RESEARCH INSTITUTIONS
8 WAS THE DEFINITION THAT IS FROM PROP 71, WHICH IS
9 INCLUSIVE OF FOR-PROFIT ENTITIES, BUT WE ARE LIMITING
10 IT TO A RESEARCH PURPOSE.

11 DR. WILLERSON: IN YOUR WRITTEN DOCUMENT, YOU
12 SHOULD MAKE THAT EXPLICIT. THIS SAME QUESTION IS GOING
13 TO COME UP OVER AND OVER AGAIN AS PEOPLE READ THIS.

14 MR. SHEEHY: BY THE WAY, YOU HAVE IN YOUR
15 PACKET THE DRAFT THAT HAS NOT BEEN UPDATED. SO WE HAVE
16 AN EARLIER ITERATION. IT'S NOT THE FINAL ITERATION.
17 AND THERE HAVE BEEN SOME ADVANCE -- THERE HAVE BEEN
18 SOME CHANGES THAT WE MADE AT THE LAST IP MEETING.

19 I WOULD ALSO NOTE THAT IT'S GOOD THAT WE HAVE
20 SCOTT HERE TO MAKE SURE. I THINK WE WILL HAVE A
21 DEFINITIONS PART.

22 DR. KIESSLING: JEFF, IS THERE A TIME LIMIT
23 TO THIS AS WELL?

24 MR. SHEEHY: NOT THAT I'M AWARE OF. IS THAT
25 SOMETHING WE SHOULD CONSIDER?

1 DR. KIESSLING: MAKING THE INVENTION
2 AVAILABLE WITHIN 60 DAYS.

3 MR. SHEEHY: THIS TIME, THE TIME LIMIT WAS
4 NOT DISCUSSED IN THE CONTEXT OF THIS PARTICULAR PIECE.
5 DO YOU THINK THAT THAT IS SOMETHING WE MIGHT NEED TO
6 CONSIDER TO PUT A CLOCK?

7 DR. HALL: SO MATERIALS ARE SOMETHING YOU
8 PROVIDE. BUT, IN GENERAL, INVENTIONS ARE OFTEN IDEAS
9 OR PROCEDURES. WHAT THIS MEANS IS THAT OTHERS ARE
10 ALLOWED TO USE THEM. THEY PRESUMABLY ARE --

11 DR. KIESSLING: YOU WANT TO PUT A TIME? WAIT
12 60 DAYS?

13 DR. HALL: WELL, YOU DON'T HAVE TO -- IF
14 YOU'RE THE INVENTOR, YOU DON'T HAVE TO NECESSARILY DO
15 ANYTHING. YOU DON'T HAVE TO SEND THEM ANYTHING OR DO
16 IT. JUST YOU'VE INVENTED A WAY TO DO SOMETHING, YOU
17 PUBLISH THE PROCEDURE, AND NOW YOU'VE PATENTED IT. AND
18 THEY SAY WE WANT TO USE THIS PROCEDURE FOR RESEARCH,
19 AND THEN YOU WORK IT OUT WITH THE TECH TRANSFER OFFICE
20 AND THEY WRITE AN MTA AND IT'S ALL NEGOTIATED BACK AND
21 FORTH, BUT YOU DON'T HAVE TO GIVE -- NECESSARILY HAVE
22 TO GIVE MATERIAL.

23 MR. SHESTACK: FROM A PROCEDURAL POINT OF
24 VIEW, ALL THESE --

25 DR. HALL: LET ME JUST SAY SOMETIMES IT DOES

1 TAKE TIME TO NEGOTIATE ISSUES LIKE CAN IT BE USED FOR
2 COMMERCIAL PRODUCTS AND OTHER -- IF ANY -- CAN'T BE
3 SUED, INDEMNIFICATION CLAUSES. THERE ARE THINGS TO
4 WORK OUT TO DO THIS, BUT, IN FACT, IT IS AVAILABLE.

5 MR. SHESTACK: ALL THESE STIPULATIONS WILL BE
6 BASICALLY WRITTEN INTO THE DISTRIBUTION OF THE GRANT --
7 GRANTING AGREEMENT. BASICALLY ANYBODY WHO TAKES CIRM'S
8 MONEY, ANY INSTITUTION IN CALIFORNIA, WOULD HAVE TO
9 AGREE IN ADVANCE TO THESE.

10 DR. HALL: RIGHT. THIS WILL BECOME PART OF
11 OUR GRANTS ADMINISTRATION POLICY THAT WE WILL PUT OUT.
12 THIS WILL BE A BIG CHUNK OF IT.

13 DR. KIESSLING: THE REASON I'M ASKING ABOUT
14 TIMING IS THAT A LIKELY SCENARIO HERE IS SOMEBODY
15 DEVELOPS A BETTER WAY TO REPROGRAM AN ADULT STEM CELL.
16 AND BEFORE -- AND THEN OTHER BUSINESS BECOMES --
17 SCIENTISTS HAVE BIG MOUTHS AND WE ALL KNOW ABOUT IT
18 BEFORE IT EVER GETS PUBLISHED OR ANYTHING. THERE ARE
19 SEVERAL GROUPS USING THIS METHOD. THIS IS A LIKELY
20 SCENARIO. AND THEN ONE GROUP PATENTS IT. THE GROUP
21 THAT DEVELOPED IT DECIDES TO PATENT IT. AND THERE'S
22 ALREADY NOW HALF A DOZEN OTHER GROUPS USING IT. WHAT
23 IS THE TIME FRAME? DO THEY HAVE TO STOP USING IT WHILE
24 SOME NEGOTIATION TAKES PLACE? THAT'S HOW THIS IS GOING
25 TO PLAY OUT.

1 DR. HALL: IT'S A COMPLICATED THING. YOU
2 FILE FOR A PATENT, AND IT TAKES SOME TIME FOR IT TO BE
3 ACTED ON. AND SO WHAT WOULD NORMALLY HAPPEN IS YOU
4 PUBLISH A PROCEDURE FOR DOING WHAT YOU DESCRIBE. AND
5 IF SOMEBODY WITH A COMPANY WANTS TO USE THAT, THEN
6 YOU --

7 DR. KIESSLING: SAY THEY'RE ALREADY USING IT.
8 THAT'S THE MOST LIKELY SCENARIO, I THINK.

9 DR. HALL: I DON'T KNOW THE MECHANICS OF
10 THAT. WE WOULD HAVE TO WALK THROUGH THAT AND SEE HOW
11 IT WORKS. I DON'T THINK A TIME -- I DON'T THINK THE
12 TIME LIMITATION IS USEFUL.

13 DR. TAYLOR: WILL THERE BE A PROVISION FOR
14 THE COSTS? LET'S TAKE THE EXAMPLE OF MORE OF A
15 REAGENT, YOU KNOW, A MONOCLONAL ANTIBODY OR A GROWTH
16 FACTOR LIGAND THAT ACTUALLY DOES THIS TRICK THAT
17 SOMEBODY DEVELOPS. THE COSTS OF PROVIDING THAT, FOR
18 MAKING IT AVAILABLE, WILL THAT BE SUBSUMED THROUGH
19 OTHER CIRM FUNDS, OR IS THAT PART OF THE PACKAGE?

20 LOTS OF INVESTIGATORS HAVE GOTTEN OVERWHELMED
21 WITH REQUESTS BEFORE YOU SELL IT OFF TO JACKSON LABS.

22 DR. HALL: SO YOU CAN PROVIDE IT AT COST.

23 MR. SHEEHY: THE COST CAN BE RECOVERED.

24 DR. HALL: IT COSTS US X AMOUNT OF MONEY TO
25 DO THIS. IF IT TURNS OUT TO BE HUGELY POPULAR, THEN

1 CIRM MIGHT SET UP SOME FACILITY TO DO THIS. WITH CELL
2 LINES WE HOPE THAT THIS WILL BE TAKEN CARE OF THROUGH A
3 BANK. BUT I THINK, AS HAS BEEN QUOTED HERE BEFORE, I
4 THINK BY KEVIN, DOUG MELTON SUPPOSEDLY HAS TWO
5 FULL-TIME TECHNICIANS DOING NOTHING BUT SENDING OUT
6 CELL LINES. AND HUGHES IS PAYING FOR THIS.

7 DR. EGGAN: HUGHES AND JDRF.

8 DR. HALL: THAT'S A SITUATION WHICH WE WOULD
9 HAPPILY DO THAT, BUT WHAT YOU CAN'T DO IS YOU CAN'T --
10 A UNIVERSITY CAN'T MAKE MONEY ON IT. THAT'S THE POINT.

11 MR. SHEEHY: THERE'S A LITTLE MISTAKE HERE,
12 THAT LAST SENTENCE. IN THE LICENSING REGULATIONS,
13 GRANTEE ORGANIZATIONS SHALL NEGOTIATE NONEXCLUSIVE
14 LICENSES OF CIRM-FUNDED INVENTIONS. ACTUALLY THE
15 SECOND CLAUSE IS SUPPOSED TO BE CONDITIONAL AND THE
16 WHENEVER POSSIBLE, THE FORMER LANGUAGE, IS MORE IF THE
17 SECOND PART HAS BEEN MET. UNLESS THE SECOND PART HAS
18 BEEN MET, THAT GRANTEE ORGANIZATIONS MAY NEGOTIATE MORE
19 EXCLUSIVE LICENSES FOR CIRM-FUNDED INVENTIONS RELEVANT
20 TO THERAPIES AND DIAGNOSTICS IF SUCH LICENSES ARE
21 NECESSARY TO PROVIDE ECONOMIC INCENTIVES REQUIRED TO
22 ENABLE COMMERCIAL DEVELOPMENT AND AVAILABILITY OF THE
23 INVENTION.

24 SO IT'S NOT SO MUCH WHENEVER POSSIBLE. IT'S
25 TO THE EXCLUSION OF THE SECOND PART THAT THEY CAN DO

1 EXCLUSIVE/NONEXCLUSIVE -- THEY CAN DO EXCLUSIVE
2 LICENSES. IS THAT CLEAR, OR DID I MUDDLE THAT SO BADLY
3 THAT NOBODY UNDERSTOOD?

4 WHAT WE'RE TRYING TO SAY HERE IS THAT WE
5 REALLY WANT NONEXCLUSIVE LICENSES UNLESS YOU ABSOLUTELY
6 HAVE TO HAVE AN EXCLUSIVE LICENSE IN ORDER TO DEVELOP
7 THE THERAPY OR DIAGNOSTIC. AND WE ASKED THEM TO MEET
8 THIS TEST BEFORE THEY DO AWARD AN EXCLUSIVE LICENSE.

9 IN TERMS OF ACCESS, LICENSEES WILL PROVIDE
10 THE LOWEST AVAILABLE U.S. PRICE FOR RESULTANT THERAPIES
11 AND DIAGNOSTICS TO PATIENTS COVERED BY STATE-SPONSORED
12 HEALTHCARE ACCESS PROGRAMS. SO THIS COULD BE MEDI-CAL,
13 THIS COULD BE HEALTHY FAMILIES. WE'RE STILL IN THE
14 PROCESS OF COMPILING WHAT THAT UNIVERSE IS.

15 AND THEN THE SECOND, WE WILL ASK LICENSEES TO
16 DEVELOP A PLAN FOR ACCESS TO RESULTANT THERAPIES AND
17 DIAGNOSTICS TO UNINSURED CALIFORNIA PATIENTS. GIVEN
18 THAT THE DIAGNOSTICS AND THERAPIES DON'T EXIST NOW, WE
19 CAN'T REALLY DEFINE WHAT THAT IS, BUT WE CAN ASK THEM
20 TO DEVELOP A PLAN.

21 MS. CHARO: JUST AGAIN, JUST FOR
22 CLARIFICATION, LICENSEES, THERE'S GOING TO BE A WHOLE
23 SERIES OF INDIVIDUALS AND COMPANIES THAT ARE GOING TO
24 BE MIDDLEMEN BEFORE YOU GET TO ANYBODY WHO IS ACTUALLY
25 PROVIDING THERAPY, RIGHT. AND THEN IF IT'S A

1 DRUG-BASED THERAPY, YOU HAVE A KIND OF PHARMACEUTICAL
2 MODEL WHERE YOU'RE SELLING A BUNCH OF PILLS, BUT HERE
3 WE MIGHT BE TALKING ABOUT CELL-BASED THERAPIES WHERE
4 IT'S A COMBINATION OF MATERIALS AND SURGEONS AND
5 HOSPITALS. I'M JUST A LITTLE BIT UNCLEAR AS TO EXACTLY
6 HOW THIS OPERATIONALIZES.

7 IT'S NOT THE SENTIMENT THAT I'M HAVING A
8 PROBLEM WITH. IT'S TRYING TO IMAGINE EXACTLY HOW THIS
9 PARTICULAR SECTION OPERATIONALIZES.

10 MR. SHEEHY: IT MAY BE A PROBLEM WITH -- THE
11 LANGUAGE DOES KIND OF OPEN THIS STUFF UP. WE DID HAVE
12 THAT DISCUSSION, AND IT WAS KIND OF CLEAR THAT YOU
13 COULDN'T REALLY REACH THROUGH AND SAY THAT THE SURGEON
14 WOULD THEN PROVIDE THE SERVICE. ONE CAN IMAGINE THAT
15 IF YOU DO HAVE A CELL-BASED THERAPY, THAT YOU WOULD
16 NEED A SURGEON TO GO IN, ESPECIALLY IF IT'S A
17 NEUROLOGICAL TYPE THING THAT WOULD BE DELIVERED, THAT
18 WE COULDN'T REACH THROUGH, BUT WE COULD ASK THAT THE
19 ACTUAL CELL-BASED PORTION OF IT THAT WAS DEVELOPED WITH
20 CIRM FUNDING WOULD BE PROVIDED TO THE STATE AT A
21 REASONABLE PRICE.

22 MS. CHARO: SO BIOLOGICS, INC. IS NOW THE
23 LAST LINK IN THE CHAIN OF LICENSEES, AND THEY'RE
24 PROVIDING THE CELLULAR MATERIAL THAT'S GOING TO BE
25 TRANSPLANTED, FOR EXAMPLE. AND THEY THEN ARE THE ONES

1 WHO ARE REALLY SUPPOSED TO BE NABBED BY THIS AND
2 CHARGED THE LOWEST AVAILABLE U.S. PRICE. IS THAT IT?

3 MR. SHEEHY: THAT IS THE INTENT. AND THE
4 LANGUAGE MAY NOT -- IF YOU HAVE --

5 MS. CHARO: NO, I CERTAINLY DON'T HAVE BETTER
6 LANGUAGE. I JUST WANT TO MAKE SURE -- I'M CATCHING UP
7 HERE AS TO WHAT YOU ALL HAVE BEEN DOING. I'M TRYING TO
8 UNDERSTAND ACCURATELY WHAT YOU'RE GETTING AT.

9 MR. SHEEHY: NO. WE RECOGNIZE THAT
10 THERE'S -- FRANKLY, WE ALSO RECOGNIZE THAT THERE'S A
11 PORTIONALITY ASPECT OF THIS AS WELL, THAT, YOU KNOW,
12 FUNDAMENTALLY THIS LOOKS LIKE THE ENTIRE THERAPY WILL
13 HAVE BEEN DEVELOPED WHOLLY WITH CIRM-FUNDED RESEARCH,
14 WHICH IS KIND OF HIGHLY UNLIKELY. SO THIS IS AN
15 INTENT, BUT OBVIOUSLY, GIVEN THAT THE THERAPIES AND
16 DIAGNOSTICS DON'T EXIST AT THIS TIME AND THAT THE
17 REALITY IS THAT THE POINT AT WHICH WE'RE FUNDING IS
18 MORE ON A BASIC LEVEL OF RESEARCH BECAUSE THIS DOES
19 APPLY ONLY TO NONPROFIT RESEARCH INSTITUTIONS, THAT
20 WE'RE NOT COMPLETELY SURE THAT -- THIS IS A GOOD
21 STARTING POINT. AND THIS WILL BE MORE APPLICABLE, I
22 THINK, AS AN ELEMENT THAT WILL COME INTO PLAY WHEN WE
23 START TO TALK ABOUT WHAT ARRANGEMENTS WE WANT TO HAVE
24 WITH COMMERCIAL ENTITIES BECAUSE THAT'S GOING TO BE
25 MUCH CLOSER TO THAT POINT.

1 DR. WAGNER: I HAVE A SIMILAR CONCERN WITH
2 REGARD TO THAT BULLET NO. 2 THERE WHERE WE TALK ABOUT
3 RESULTANT THERAPIES TO UNINSURED CALIFORNIA PATIENTS.
4 AND THE SENTIMENT IS REALLY AN ADMIRABLE ONE, AND NO
5 ONE WILL DISAGREE WITH THAT. HOWEVER, THE
6 PRACTICALITY, AND IN VIEW OF THE FACT THAT THIS IS WHAT
7 I DO, ALTHOUGH NOT IN CALIFORNIA, OF PROVIDING PHASE I
8 STUDIES THAT WOULD NOT BE INSURED OR ALLOWED BY WHETHER
9 IT BE MEDICAID, MEDICARE, OR ANY OTHER FORM OF THE WAY
10 YOU MIGHT PAY FOR SUCH THERAPY. REMEMBER THAT WHEN A
11 PATIENT COMES IN FOR THESE VERY POTENTIALLY HIGH RISK
12 THERAPIES THAT ARE "PHASE I," WHICH THEY WILL BE,
13 THEY'RE VERY SOPHISTICATED THERAPIES.

14 IN PRACTICALITY HOW WOULD THAT EVER OCCUR
15 BECAUSE THE FACT THAT NO ONE IS WILLING TO PAY FOR THE
16 COST OF THE CLINIC CARE OR THE COST OF THE INPATIENT
17 STAGE OR HOSPITAL WHICH ARE EXTRAORDINARILY EXPENSIVE.

18 SO ALTHOUGH I DON'T DISAGREE WITH THE BULLET
19 POINT, BUT YET FROM A PRACTICAL POINT OF VIEW, I WOULD
20 NEED SOME INSTRUCTION OF WHAT KIND OF PLAN YOU WERE
21 THINKING OF WHEN YOU SAY DEVELOP A PLAN. I DON'T KNOW
22 HOW TO BEGIN.

23 MR. SHEEHY: CAN I NOTE TWO ELEMENTS TO THAT?
24 FIRST OF ALL, WE DID ACKNOWLEDGE THAT -- AND
25 SPECIFICALLY WE DON'T ASK FOR THE PUBLICATION, BUT THAT

1 THE PLAN CAN BE A WORK IN PROGRESS, THAT WE DON'T ASK
2 THAT THE PLAN BE MADE AVAILABLE IN PUBLIC IN A PUBLIC
3 WAY UNTIL IT'S IN THE PHASE III SO THAT, YOU KNOW, THE
4 INSTITUTION AND THE LICENSEE CAN KIND OF START OFF WITH
5 A GENERALIZED FRAMEWORK. BUT OBVIOUSLY WE CAN
6 RECOGNIZE THAT IT MAKES NO SENSE TO TRY TO COME UP WITH
7 A PLAN FOR ACCESS BEFORE YOU'RE IN PHASE III. I THINK
8 A LOT OF PEOPLE START THINKING ABOUT THOSE ISSUES IN
9 PHASE III.

10 THE OTHER PART IS THAT THE PLAN IS GENERATED
11 BY THE LICENSEE. SO WE'RE ASKING THEM TO THINK ABOUT
12 THIS. I THINK A LOT OF COMPANIES ALREADY THINK ABOUT
13 THESE THINGS. AND SOME COMPANIES ARE REALLY TREMENDOUS
14 CITIZENS IN TERMS OF MAKING THEIR PRODUCTS ACCESSIBLE
15 TO PEOPLE WHO CAN'T PAY.

16 DR. WAGNER: JUST TO FOLLOW UP ON THAT, I
17 AGREE WITH YOU THAT PHASE III CERTAINLY MAKES IT EASIER
18 IN TERMS OF GETTING A THIRD-PARTY COVERAGE. ON THE
19 OTHER HAND, PHASE III WILL BE PROBABLY TEN YEARS BEYOND
20 THE BEGINNING OF THE INITIAL TRIALS, NO. 1, JUST SO
21 YOU'RE AWARE OF THAT.

22 SECONDLY, SOME OF THESE WILL NEVER GO TO
23 PHASE III BECAUSE OF THE TYPES OF DISEASES, THESE
24 ORPHAN DISEASES IN SOME CASES POTENTIALLY.

25 THE OTHER THING IS THAT, AGAIN, ALL I CAN SAY

1 IS THAT WHEN YOU THINK ABOUT PHASE I AND HOW IT BEGINS,
2 IS THAT MANY OF THESE WILL BE DONE AT THE UNIVERSITIES
3 THEMSELVES, AND THAT THERE WILL BE NO CORPORATE
4 SPONSOR. SO YOU HAVE TO KIND OF CONSIDER BOTH AVENUES
5 BECAUSE, AS YOU SAY, SOME WILL BE CORPORATE SPONSORS
6 AND THEY CAN HELP PAY OR DEFRAY SOME OF THE COST;
7 WHEREAS, OTHERS WILL NOT. IT'S GOING TO VARY.

8 DR. PRIETO: IF I CAN JUST SPEAK ABOUT SOME
9 OF THE DISCUSSION ON THE TASK FORCE. THE THINKING HERE
10 WAS THAT WE WOULD REQUIRE THE LICENSEES TO DEVELOP THIS
11 PLAN, IN PART, TO ENCOURAGE INNOVATION AND IMAGINATION,
12 OBLIGATE THEM TO COME BACK TO US WITH A PLAN THAT WOULD
13 WE WOULD THEN EVALUATE. WE THOUGHT WE'D GET MORE
14 IMAGINATIVE IDEAS THAT WAY.

15 MS. CHARO: THIS IS SIMPLY A COMMENT AIMED AT
16 THOSE OF YOU THAT ARE ON THE TASK FORCE BECAUSE I KNOW
17 YOU'RE GOING TO BE WATCHING THIS VERY CLOSELY. WHAT'S
18 BEING DISCUSSED HERE IS SOMETHING THAT OFFERS A
19 TREMENDOUS OPPORTUNITY TO LEARN ABOUT WHAT REALLY DOES
20 OR DOES NOT WORK IN THE IP AREA, WHICH HAS BEEN THE
21 SUBJECT OF A LOT OF CONTROVERSY. AND IN MANY
22 INDIVIDUAL STEPS ALONG THE WAY, THIS POLICY ACTUALLY
23 TAKES OUT THE ABILITY TO MAKE MONEY. AND THIS STEP
24 BEING PERHAPS ONE OF THE MOST SIGNIFICANT BECAUSE THE
25 BUSINESS PLANS THAT COMPANIES USE TO FIGURE OUT WHETHER

1 OR NOT IT'S WORTH THEIR WHILE TO MAKE THE INVESTMENT IN
2 THE CLINICAL TRIALS ARE PREMISED ON A PRICE POINT AS
3 WELL AS A MARKET. WHAT THIS DOES IS IT LOWERS THE
4 PRICE POINT.

5 SO THERE'S AN OPEN QUESTION ABOUT WHETHER OR
6 NOT THIS PLAN IS GOING TO UNDERMINE DEVELOPMENT OR
7 FACILITATE IT. AND THAT'S THE OPEN QUESTION EVERYBODY
8 HAS HAD ABOUT IP FOR THE LAST 25 YEARS.

9 ALL I'M SAYING IS SINCE WE'RE THINKING ABOUT
10 THIS FROM THE OUTSET AS A CONDITION OF RECEIVING PUBLIC
11 MONIES, IT'S ALSO AN OPPORTUNITY TO TRY TO CREATE A
12 PLAN OF INTERVIEWS TO CONSTANTLY BE DISCUSSING WITH THE
13 VARIOUS ACTORS HOW THIS IS AFFECTING THEIR ONGOING
14 DECISION-MAKING ABOUT FOR-PROFIT INSTITUTIONS
15 PARTNERING WITH UNIVERSITIES, BUT THEREBY BEING CAUGHT
16 UP IN THE CIRM RULES FOR FOR-PROFIT INSTITUTIONS
17 DECIDING WHETHER OR NOT TO INVEST IN CLINICAL TRIALS.
18 BECAUSE ESPECIALLY SINCE THIS IS AN AREA OF BIOLOGICS,
19 THE FDA APPROVAL PROCESS IS GOING TO BE PARTICULARLY
20 EXCRUCIATING.

21 I JUST WANT TO THROW OUT AS A SUGGESTION FOR
22 YOU ALL THAT IF YOU THINK OF THIS AS AN OPPORTUNITY FOR
23 KIND OF AN ONGOING STUDY THAT WILL NOT ONLY HELP TO
24 IMPROVE THIS POLICY AS TIME GOES ON, BUT ALSO ACTUALLY
25 DO THE ENTIRE COUNTRY A FAVOR AS IT DEBATES THE IP

1 POLICIES GENERALLY IN THE GENETICS AREA.

2 MR. SHEEHY: I THINK THAT'S A GREAT
3 SUGGESTION.

4 AND THEN IN TERMS OF MARCH-IN RIGHTS, WE HAVE
5 FAILURE TO DEVELOP INVENTIONS FOR PUBLIC USE, FAILURE
6 TO MEET REQUIREMENTS FOR PUBLIC USE, PUBLIC HEALTH AND
7 SAFETY NEEDS, WHICH ARE ALL BAYH-DOLE, AND THEN WE'VE
8 ADDED ONE FOR FAILURE TO MEET THE AGREED-UPON ACCESS
9 PLAN. BECAUSE WE ARE GIVING THE LICENSEES THE POWER TO
10 DETERMINE WHAT THEIR ACCESS PLAN IS, WE'RE NOT ASKING
11 THEM TO REVEAL IT UNTIL PHASE III. SO THAT WE DO ASK
12 THAT THEY TAKE THIS PROVISION SERIOUSLY AND THAT THEY
13 COME UP WITH SOMETHING THAT WILL WORK. THERE'S NO
14 CONTOURS TO WHAT THAT PLAN WILL BE, SO THEY HAVE
15 ENORMOUS FLEXIBILITY, BUT WE DO WANT THEM TO DO IT IF
16 THEY SAY THEY'RE GOING TO. WE DON'T WANT IT TO BE A PR
17 EXERCISE.

18 CO-CHAIR LO: JEFF, THANKS VERY MUCH. IT
19 STRIKES ME, AS I LISTEN TO YOUR PRESENTATION AND
20 QUESTIONS, THAT THIS IS AN EXAMPLE OF WHERE CIRM IS
21 REALLY PUSHING THE ENVELOPE, GOING BEYOND WHAT CURRENT
22 PRACTICE IS AND REALLY SETTING VERY HIGH ASPIRATIONAL
23 STANDARDS. AS MANY OF YOU IN THE COMMITTEE SAID, HOW
24 THIS GETS WORKED OUT IS GOING TO BE A CHALLENGE. AND
25 THIS IS THE FIRST STEP IN A LONG PROCESS, BUT I THINK

1 THE GOALS YOU'RE SETTING OUT OF INCREASED SHARING,
2 INCREASED ACCESS ARE CERTAINLY ONES THAT I THINK THE
3 MEMBERS OF THE COMMITTEE AGREE WITH AND I THINK THE
4 PUBLIC THINKS ARE VERY IMPORTANT.

5 I LOOK FORWARD TO WORKING WITH THE IP WORKING
6 GROUP AS DETAILS GET WORKED OUT. SOME OF THE PEOPLE
7 HERE HAVE A LOT OF EXPERIENCE IN HOW THIS ACTUALLY
8 WORKS OUT. THANKS VERY MUCH FOR THAT.

9 MR. SHEEHY: IF PEOPLE HAVE SPECIFIC
10 COMMENTS, WE ARE -- THIS IS NOT A FINALIZED POLICY YET.
11 SO WE WOULD DEFINITELY APPRECIATE FEEDBACK.

12 DR. WAGNER: I JUST WANT TO MAKE ONE COMMENT
13 THOUGH, AND THIS IS SPEAKING AS TO SOMEONE WHO HAS A
14 POTENTIAL -- LIKELY SOMEONE WHO IS A POTENTIAL USER.
15 AND THAT IS THAT I UNDERSTAND THE COMMENT ABOUT KEEPING
16 IT WIDE OPEN AND LETTING -- GETTING AS MUCH INPUT FROM
17 AS MANY PEOPLE AS POSSIBLE. AND YES, THIS WILL EVOLVE
18 OVER TIME, AND I UNDERSTAND ALL THAT STUFF.

19 THE PROBLEM IS THAT TO KNOW IT ALSO CAN BE AN
20 OBSTACLE, AN OBSTACLE THAT IS NOT SOMETHING THAT'S
21 NECESSARILY BAD, BUT YET AT THE SAME TIME THERE'S NO
22 CONSTRUCT BY WHICH I WOULD REALLY KNOW HOW TO BEGIN THE
23 PROCESS AND THEN MUCH LESS KNOW HOW IT'S GOING TO BE
24 REVIEWED.

25 AS YOU SAY, THE WALK-IN OR MARCH-IN RIGHTS,

1 THING IS I WOULD BE TRYING TO DEVELOP SOMETHING THAT I
2 HAVE NO PRECEDENT FOR DEVELOPING AND WHETHER OR NOT IT
3 WORKS OR NOT. I GUESS MY ONLY POINT IS THAT WHERE
4 POSSIBLE, AND MANY OF THE DISCUSSIONS THAT ARE PART OF
5 THIS WORKING GROUP'S SUBMISSION IS TO GIVE SOME
6 GUIDANCE IN THE WAY THAT'S NOT NECESSARILY A DIRECTIVE,
7 BUT AT LEAST SOME WAY OF BEGINNING THE PROCESS. AND
8 FURTHERMORE, IF I WERE THE IRB OR THE ESCRO, I NEED TO
9 HAVE SOME WAYS OF MEASURING WHAT IT IS, WHAT THE
10 COMMITTEE IS DESIRING OR WHAT THIS WHOLE INSTITUTION IS
11 DESIRING. SO I GUESS WHAT I'M TRYING TO SAY IS THAT
12 WHERE POSSIBLE TO GIVE EXAMPLES OR IDEAS JUST SO THAT
13 FROM A PRACTICAL POINT OF VIEW PEOPLE KNOW HOW TO BEGIN
14 THE PROCESS OF MAKING AN APPLICATION, FULFILLING THE
15 DESIRES OF THE COMMITTEE.

16 MR. SHEEHY: I WOULD REMARK. THE PLAN IS FOR
17 THE LICENSEES. SO THIS IS WHEN THEY LICENSE FROM A
18 UNIVERSITY. I MEAN REALISTICALLY WE WERE GIVEN THE
19 EXAMPLE OF STANFORD, WHICH OUT OF 400 PRODUCTS, ONLY
20 TWO HAVE REALLY BEEN PROFITABLE TO THE TUNE OF OVER
21 500,000. I THINK FOR THIS PARTICULAR ASPECT OF OUR
22 POLICY, THE SHARING IS PROBABLY MORE SIGNIFICANT
23 BECAUSE I DO THINK THAT THE PRODUCTS THAT COME OUT OF
24 THIS ARE PROBABLY GOING TO BE SO PATCHWORKED, THAT SOME
25 OF THESE AREN'T EVEN REALLY -- WHAT IF YOU ONLY HAVE 1

1 PERCENT THAT'S CIRM THAT'S ULTIMATELY FUNDING 5
2 PERCENT. SOME OF THESE ACCESS THINGS CLEARLY CAN'T
3 BECOME A BURDEN TO DEVELOPING THERAPY.

4 CO-CHAIR LO: IF I COULD JUST FOLLOW UP ON
5 JOHN'S COMMENT ABOUT THE NEED FOR GUIDANCE TO IRB'S AND
6 INVESTIGATORS AND LICENSEES. ONE MODEL YOU MIGHT THINK
7 ABOUT IS WHAT THIS GROUP DID BY SORT OF CONVENING A
8 MEETING WHERE PEOPLE COULD SHARE IDEAS, SHARE
9 APPROACHES, TRYING TO IDENTIFY BEST PRACTICES AND
10 PRACTICE TO AVOID. I THINK WE'RE TRYING TO BE
11 NONPRESCRIPTIVE AND SAYING YOU MUST DO THIS, THIS, AND
12 THAT. WE DON'T KNOW IF THAT WORKS, BUT IT'S ALSO SCARY
13 TO TELL PEOPLE WE HAVE THESE REGULATIONS THAT ARE
14 PRETTY BROAD AND OPEN-ENDED TO TRY, AND TO FIGURE OUT
15 WHAT DO I HAVE TO DO TO SATISFY THOSE IS ALWAYS A
16 CHALLENGE. I THINK THAT'S EXACTLY WHAT WE NEED TO DO
17 HERE BECAUSE WE DON'T KNOW YET.

18 DR. HALL: LET ME JUST SAY, BERNIE, THAT IN A
19 DIFFERENT WAY FROM THIS WORKING GROUP, THE TASK FORCE
20 ACTUALLY SOUGHT INPUT, ACTIVELY SOUGHT INPUT, FROM TECH
21 TRANSFER OFFICES BOTH CONNECTED WITH THE UNIVERSITY OF
22 CALIFORNIA AND OTHERS INSTITUTIONS. SO THE SAME GROUP
23 OF PEOPLE THAT JEFF DESCRIBED BEFORE ARE GENERALLY IN
24 UNIVERSITIES THOSE WHO ARE RESPONSIBLE FOR TECH
25 TRANSFER; THAT IS, VICE CHANCELLORS OR VICE CHANCELLORS

1 FOR RESEARCH. WE VERY MUCH INTEND TO HAVE A CONTINUING
2 RELATIONSHIP WITH OUR CONSTITUENTS TO MONITOR WHAT
3 THEY'RE DOING AND ALSO TO HELP THEM BOTH ACHIEVE THE
4 AIMS WE WANT AND TO WORK TOGETHER IN A COORDINATED WAY
5 FOR BEST PRACTICES ACROSS THE STATE. WE CERTAINLY WILL
6 DO THAT.

7 MR. SHEEHY: WE CAN ALL HOPE THAT BY THE TIME
8 WE ACTUALLY HAVE THERAPIES, WE HAVE SOME SORT OF
9 UNIVERSAL COVERAGE. THAT CONTRACTS, FRANKLY, GIVEN
10 WHAT'S GOING ON IN THIS COUNTRY WITH HEALTHCARE AND THE
11 TIMELINE FOR STEM CELL THERAPIES, I THINK WE'RE ON A
12 COLLISION COURSE, AND IT MAY BE A MOOT POINT.

13 CO-CHAIR LO: THANKS AGAIN, JEFF. I WANT TO
14 NOW TURN TO OUR NEXT AGENDA ITEM, NO. 7 ON THE AGENDA,
15 WHICH IS REALLY SORT OF THE MEAT OF THIS MEETING, WHICH
16 IS TO REVIEW THE DRAFT CIRM REGULATIONS. THERE'S A
17 HANDOUT. AND THOSE IN THE AUDIENCE, THERE'S COPIES ON
18 THE TABLE. THE ONES ON THE TABLE DO NOT HAVE THE
19 COLOR-CODED. WE COULDN'T GET COLOR XEROXING THIS
20 MORNING, BUT THE ONES THE COMMITTEE HAVE, WHICH IS
21 TITLED "DRAFT CALIFORNIA CODE OF REGULATIONS" IN A BOX
22 ON THE TOP AND RED HIGHLIGHTING ON THE FRONT PAGE.

23 WHAT WE WOULD LIKE TO DO TODAY AND TOMORROW
24 IS TO GO THROUGH THIS DRAFT AND REALLY TRY AND REACH
25 CLOSURE ON CERTAINLY THE IDEAS, THE SENTIMENT OF THIS.

1 THERE WILL BE SOME CHANGES TO THE ACTUAL LANGUAGE.
2 SCOTT TOCHER, OUR LEGAL CONSULTANT OR EXPERT IN
3 DRAFTING, WILL SIT DOWN AFTER THIS MEETING WITH STAFF
4 AND MAKE SURE THAT THE LANGUAGE WE HAVE IS ACCEPTABLE
5 TO THE OFFICE OF ADMINISTRATIVE LAW.

6 SO ON THE ONE HAND, WE DON'T WANT TO
7 WORDSMITH TOO MUCH; AND ON THE OTHER HAND, THERE ARE
8 GOING TO BE SOME TIMES WHEN THE WORDS ARE IMPORTANT.
9 BUT THE FINAL WALK-THROUGH, THE ACTUAL LANGUAGE WILL BE
10 CONTINGENT UPON WHAT WILL PASS OAL MUSTER.

11 WHAT I WOULD PROPOSE TO DO IS TO ACTUALLY GO
12 THROUGH THIS DRAFT SECTION BY SECTION. THERE ARE SEVEN
13 SECTIONS. SOME OF THEM ARE MORE COMPLICATED THAN
14 OTHERS. I THINK WE NEED TO SORT OF LOOK AT EACH
15 SECTION, ALSO HAVE A PICTURE OF THE WHOLE. THERE ARE A
16 COUPLE OF ISSUES THAT WE WILL HIGHLIGHT WHERE THERE'S
17 SOME NEW THINKING AND SOME UNRESOLVED ISSUES. I'D LIKE
18 TO MAKE SURE WE ADDRESS THOSE AND TRY AND REACH
19 CLOSURE.

20 WHAT I PROPOSE TO DO IS WE WALK THROUGH EACH
21 SECTION. AND THEN WITH EACH SECTION, I'M GOING TO
22 INVITE PUBLIC COMMENT AS WELL. WE DO WANT TO MAKE SURE
23 WE HAVE ADEQUATE PROVISIONS FOR PUBLIC COMMENTARY AND
24 QUESTIONS.

25 SO I'D LIKE TO START WITH CHAPTER -- SECTION

1 100000, SCOPE OF CHAPTER AND INTENT. AND THIS IS
2 REALLY TO JUST SORT OF ANCHOR US THAT WHAT WE'RE
3 TALKING ABOUT HERE IS INSTITUTIONS PERFORMING RESEARCH
4 FUNDED BY CIRM. AND SO WE'RE UNLIKE THE NAS
5 GUIDELINES. WE'RE REALLY RESTRICTING OURSELVES TO
6 RESEARCH WE FUND. TAKE A MINUTE. AND THEN ANY
7 QUESTIONS, SUGGESTIONS ON THAT.

8 DR. WAGNER: MAY I ASK A QUESTION? AND THAT
9 IS, THAT RELATED TO THIS, AS I'M READING THROUGH THE
10 DOCUMENT, AND I APOLOGIZE IF THIS HAS ALREADY BEEN
11 DISCUSSED PREVIOUSLY, BUT WHEN YOU INDICATE AN
12 INSTITUTION, DOES THAT MEAN ONLY INSTITUTIONS WITHIN
13 CALIFORNIA OR INSTITUTIONS IN CALIFORNIA THAT MAY HAVE
14 COLLABORATORS OUTSIDE THAT MAY BE PLAYING A ROLE INTO
15 THE PROJECT, BUT MAY BE OUTSIDE THE STATE?

16 CO-CHAIR LO: HELP ME, GEOFF. MY
17 UNDERSTANDING IS THIS APPLIES ONLY TO THE INSTITUTIONS
18 THAT RECEIVE CIRM FUNDING.

19 DR. WAGNER: BUT CIRM FUNDING MAY BE FOR A
20 PROJECT AT STANFORD, BUT THERE COULD BE
21 CO-INVESTIGATORS AT HARVARD.

22 MR. LOMAX: I'LL LOOK AT SCOTT. MY SHORT
23 ANSWER, BASED ON MY UNDERSTANDING, IT'S WHERE THE
24 GRANTS ADMINISTRATION POLICY BEGINS TO TAKE OVER AND
25 LAYS OUT IN MORE DETAIL SOME OF THOSE ARRANGEMENTS.

1 AND I WILL DEFER TO SCOTT AT THIS MOMENT TO ASK THE
2 QUESTION. TO WHAT EXTENT ARE THOSE RELATIONSHIPS
3 SPELLED OUT IN THE GRANTS ADMINISTRATION POLICY?

4 MR. TOCHER: I DON'T HAVE THE DRAFT GAP IN
5 FRONT OF ME. I WOULD JUST NOTE THAT IN THIS PARTICULAR
6 POLICY, THE TERM "INSTITUTION" IS DEFINED IN THE
7 FOLLOWING SECTION, WHICH ON THE DRAFT IS ON PAGE 10,
8 TWO LITTLE I, INDICATES THAT INSTITUTION MEANS ANY
9 PUBLIC OR PRIVATE ENTITY OR AGENCY, INCLUDING FEDERAL,
10 STATE, OR OTHER AGENCIES.

11 I'M NOT SURE IF THAT REACHES THE SCOPE THAT
12 YOU WERE TALKING ABOUT IN TERMS OF AFFILIATION IN YOUR
13 HYPOTHETICAL.

14 CO-CHAIR LO: IT SEEMS THAT SECOND PARAGRAPH
15 IN 100000 DOESN'T SAY IT'S ONLY THE STATE OF
16 CALIFORNIA. ANYONE DOING RESEARCH AS DEFINED UNDER THE
17 FEDERAL REGULATIONS CAN RECEIVE CIRM FUNDING. MY CUT,
18 TO ANSWER YOUR QUESTION, IT WOULD APPLY TO HARVARD AND
19 COLLABORATIONS. IS THAT YOUR UNDERSTANDING?

20 DR. HALL: I CAME IN LATE, BERNIE.

21 CO-CHAIR LO: JOHN WAGNER'S QUESTION WAS
22 WHETHER THESE REGULATIONS APPLY TO OUT-OF-STATE
23 INSTITUTIONS DOING RESEARCH IN COLLABORATION WITH THE
24 CALIFORNIA INSTITUTION FUNDED BY CIRM.

25 DR. WAGNER: THE REASON I ASK THAT QUESTION

1 IS BECAUSE, FOR EXAMPLE, MORE AND MORE FREQUENTLY TODAY
2 IT'S NOW MULTI-INSTITUTIONAL PROJECTS BECAUSE OF THE
3 SPECIFIC EXPERTISE, LET'S SAY DIABETES, FOR EXAMPLE.
4 SO IT MAY NOT BE SOMETHING THAT'S FOCUSED ONLY IN THE
5 STATE OF CALIFORNIA ALTHOUGH THE PRIMARY INSTITUTION
6 RECEIVING CIRM FUNDING COULD BE -- IS IN THE STATE OF
7 CALIFORNIA, BUT THEY HAVE COLLABORATORS. AND THE
8 REASON WHY THAT'S CRITICAL IS BECAUSE, AS WE REVIEW
9 SOME OF THESE THINGS, IT'S NOT GOING TO BE SO
10 STRAIGHTFORWARD IF WE'RE DEALING WITH OUT-OF-STATE
11 INSTITUTIONS.

12 DR. HALL: LET ME JUST SAY THAT NONE OF OUR
13 MONEY CAN GO OUT-OF-STATE EVEN VIA A SUBCONTRACT. SO
14 IT WOULD HAVE TO BE A CALIFORNIA INSTITUTION IN
15 COLLABORATION WITH SOMEBODY IN MINNESOTA WHO'S FUNDED
16 BY JDRF AS AN EXAMPLE. AND THEN I THINK WE WOULD HAVE
17 TO MAKE THE INSTITUTIONAL -- ESCRO GROUP WOULD HAVE TO
18 MAKE SOME JUDGMENT ABOUT WHETHER THERE WAS A PROBLEM
19 ABOUT PRACTICES. BUT I THINK THIS IS INTENDED FOR
20 PEOPLE WHOM WE FUND DIRECTLY, BUT IN SOME CASES WE MAKE
21 PROVISION, AND WE'LL DISCUSS THAT LATER, ABOUT WORK
22 DONE ELSEWHERE IF IT COMES DIRECTLY INTO THE STATE.
23 BUT I THINK WE -- I DON'T THINK WE CAN --

24 DR. WAGNER: IF THAT'S THE POLICY --

25 DR. HALL: IT'S A PROBLEM, BUT I THINK WE

1 CAN'T DRAFT THESE REGULATIONS SAYING THEY HAVE TO BE
2 APPLICABLE WORLDWIDE.

3 DR. WAGNER: IT MAKES IT A LITTLE BIT EASIER,
4 THEN, EVALUATING THIS IF WE'RE ONLY DEALING WITH JUST
5 IN STATE, ALTHOUGH THE BIGGER ISSUE IS IT THEN LIMITS
6 THE RESEARCH THAT CAN BE DONE. THAT'S A DIFFERENT
7 ISSUE.

8 DR. HALL: WE ARE LIMITED BY LAW. WE CAN
9 ONLY PAY FOR RESEARCH IN THE STATE, PERIOD.

10 CO-CHAIR LANSING: I HAVE A QUESTION BECAUSE
11 I'M CONFUSED. IF WE'RE TRYING TO SET THE STANDARDS FOR
12 THE COUNTRY, WHICH IS WHAT WE'RE TRYING TO DO, MAYBE
13 I'M OPENING A WHOLE THING. I JUST WANT TO ASK THIS.
14 WHEN WE -- ANYTHING THAT WE FUND HAS TO BE IN STATE,
15 BUT SHOULDN'T WE PARTNER, WHICH IS WHAT YOUR QUESTION
16 IS, DON'T WE WANT OUR PARTNERS TO HAVE THE SAME
17 STANDARDS, BE HELD TO THE EXACT SAME STANDARDS THAT
18 WE'RE HOLDING THE IN-STATE PEOPLE? I THINK WE DO.

19 DR. HALL: I THINK WE HAVE TO JUDGE IN EACH
20 CASE. THERE WILL BE SOME DIFFERENCES. NOBODY ELSE IS
21 GOING TO COME UP AND SAY, WELL, CALIFORNIA HAS DONE
22 THIS, SO WE'LL JUST ADOPT CALIFORNIA'S. EVERYBODY WILL
23 WANT TO DO THEIR OWN. THERE WILL BE SOME DIFFERENCES,
24 AND I THINK IN THOSE CASES WE JUST HAVE TO USE GOOD
25 JUDGMENT, AND THE ESCRO COMMITTEE WILL HAVE TO MAKE A

1 DECISION WHEN IT LOOKS AT THE APPLICATION. AND WHEN WE
2 DO, IT WILL COME IN PRESUMABLY SAYING THAT THEY'RE
3 GOING TO PARTNER. THROUGH OUR COMMITTEES WE WILL MAKE
4 SOME JUDGMENT ABOUT WHETHER THERE'S A POSSIBLE REAL
5 ISSUE HERE. IF THERE IS, WE WILL DEAL WITH IT. IF
6 NOT, IF IT'S A SMALL THING, I THINK WE'LL JUST USE OUR
7 COMMON SENSE. I DON'T THINK -- I DON'T SEE A WAY IN
8 WHICH WE CAN ANTICIPATE AND REGULATES ALL THOSE
9 POSSIBILITIES.

10 DR. WAGNER: BUT WHAT YOU'VE TOLD ME MAKES IT
11 EASIER TO REVIEW THE PROCEDURES.

12 DR. HALL: THINK OF IT AS WHAT WE FUND WITH
13 OUR MONEY.

14 CO-CHAIR LO: DID YOU WANT TO COMMENT?

15 DR. KIESSLING: I'M TRYING TO UNDERSTAND THE
16 PAGE 10. SO WE REFER FREQUENTLY TO DEFINITIONS AS
17 DEFINED BY CFR 46.102, WHICH IS THE FEDERAL GUIDELINES,
18 RIGHT.

19 MR. SHESTACK: WHAT DOES IT STAND FOR?

20 DR. KIESSLING: IT STANDS FOR FEDERAL
21 REGISTER -- IT'S A FEDERAL REGULATION. IT'D REALLY BE
22 NICE ACTUALLY IF WE HAD A COPY.

23 MR. LOMAX: WE HAVE A COPY AVAILABLE. THESE
24 ARE THE DEFINITIONS FROM WHAT'S REFERRED TO AS THE
25 FEDERAL COMMON RULE.

1 DR. KIESSLING: SO PAGE 10 IS FROM 45 CFR
2 PART 46.102, PAGE 10?

3 MR. LOMAX: CORRECT.

4 DR. KIESSLING: SO WHAT'S PAGE 11? WHAT IS
5 THE HEALTH AND SAFETY CODE? IS THAT CALIFORNIA'S
6 HEALTH AND SAFETY CODE?

7 MR. LOMAX: CORRECT. CALIFORNIA HEALTH AND
8 SAFETY CODE, WHICH IS REFERRED TO IN A DIFFERENT
9 SECTION OF THE DOCUMENT, SPECIFICALLY IN THE INFORMED
10 CONSENT REQUIREMENT. THE INTENT THERE WAS TO PROVIDE
11 YOU ALL WITH ANY REGULATORY LANGUAGE THAT IS
12 SIGNIFICANTLY CITED IN THIS DOCUMENT.

13 DR. KIESSLING: DOES THIS BASICALLY, SINCE I
14 HAVEN'T READ THIS, DOES THIS BASICALLY FOLLOW 45 CFR,
15 PART 46?

16 MR. LOMAX: YOU DO HAVE IN ONE OF THE
17 BRIEFING NOTES, THERE'S A TABLE WHICH COMPARES AND
18 CONTRASTS THE TWO REGULATIONS. AND WHAT YOU WILL SEE
19 IS THEY ARE CONSISTENT WITH ONE ANOTHER, AND CALIFORNIA
20 LAW BUILDS ADDITIONAL REQUIREMENTS INTO WHAT IS
21 REQUIRED UNDER THE COMMON RULE. AND THERE'S A TABLE
22 THAT DESCRIBES THOSE SPECIFIC PROVISIONS.

23 DR. KIESSLING: PART OF 45 CFR PART 46 IS
24 REQUIREMENTS FOR PEOPLE RECEIVING FEDERAL MONEY, RIGHT?

25 MR. LOMAX: CORRECT.

1 DR. KIESSLING: SO IT'S NOT ALL JUST THE
2 COMMON RULE. PART OF IT IS REGULATORY REQUIREMENTS IF
3 YOU RECEIVE FEDERAL DOLLARS.

4 CO-CHAIR LO: THE COMMON RULE APPLIES TO
5 INSTITUTIONS CONDUCTING RESEARCH WITH FEDERAL MONEY.
6 RESEARCH THAT WILL BE USED IN THE NEW DRUG IND TO THE
7 FDA. AND ALSO THE FEDERAL GOVERNMENT NEGOTIATES WITH
8 MANY UNIVERSITIES. IT'S A FEDERAL ASSURANCE THAT SAYS
9 IF YOU TAKE ANY FEDERAL MONEY, ALL RESEARCH CONDUCTED
10 IN THE INSTITUTION HAS TO BE GOVERNED BY THE COMMON
11 RULE. SO MOST RESEARCH INSTITUTIONS, EVERYTHING IS
12 DONE SUBJECT TO THE COMMON RULE.

13 DR. KIESSLING: COMMON RULE IS NOT AS
14 COMPREHENSIVE AS 45 CFR PART 46.

15 MS. CHARO: NO. THEY'RE THE SAME. 45 CFR
16 PART 46 IS THE COMMON RULE. THEY'RE IDENTICAL. THERE
17 ARE, IN ADDITION, IN THE CODE OF FEDERAL REGULATIONS,
18 THERE ARE SOME ADDITIONAL SUBPARTS WITH VERY
19 SPECIALIZED SECTIONS THAT APPLY TO PARTICULAR KINDS OF
20 RESEARCH, NOT ALL RESEARCH. FOR EXAMPLE, THE SECTIONS
21 ON RESEARCH FOR PREGNANT WOMEN, RESEARCH ON FETUSES,
22 RESEARCH ON PRISONERS, EDUCATIONAL SETTINGS, THOSE ARE
23 SPECIALIZED SECTIONS THAT ARE APPLICABLE IN SOME
24 SETTINGS WITH SOME FORMS OF FUNDING AND SOME
25 INSTITUTIONS AND NOT IN OTHERS. BUT THE GUTS OF THE

1 COMMON RULE IS ENTIRELY EMBODIED WITHIN 45 CFR 46.

2 DR. KIESSLING: I KNOW THAT. I JUST THOUGHT
3 IT WAS MORE EXPANSIVE THAN THE COMMON RULE.

4 MS. CHARO: 45 CFR? YES. THOSE ADDITIONAL
5 SUBPARTS IS WHAT YOU MIGHT HAVE IN MIND, AND THEY DON'T
6 ALWAYS APPLY TO EVERY KIND OF RESEARCH. IT REALLY
7 DEPENDS ON THE SOURCE OF FUNDING.

8 CO-CHAIR LO: TECHNICALLY THE COMMON RULE IS
9 SUBPART (A) OF 45 CFR 46 (B), (C), AND (D).

10 SO ANY QUESTIONS AND CONCERNS ABOUT 100000 ON
11 SCOPE? OKAY.

12 MOVING ON TO 100001, DEFINITIONS. IT SPILLS
13 OVER ONTO PAGE 2, (A) THROUGH (J). I WANT TO CALL YOUR
14 ATTENTION TO THE TWO ITEMS IN RED. FOR THOSE IN THE
15 PUBLIC, THAT'S (A), SECTION (A), THE DEFINITION OF
16 COVERED STEM CELL LINE, WHICH WE'LL TALK ABOUT FIRST,
17 AND THEN LATER ON SECTION (H).

18 SUBPART (A), WE REALIZE THAT THE NAS
19 GUIDELINES WERE DEALING ONLY WITH EMBRYONIC STEM CELLS.
20 THAT WAS THE CHARGE TO THAT NAS COMMITTEE. SINCE WE'RE
21 DEALING WITH ALL RESEARCH FUNDED BY CIRM, THERE WILL BE
22 STEM CELLS THAT ARE DERIVED IN OTHER WAYS. WE NEEDED
23 TO HAVE A DEFINITION, IF YOU WILL, OF WHAT STEM CELLS
24 WE'RE TALKING ABOUT.

25 WE ACTUALLY ARE PROPOSING THAT THE SECOND

1 DEFINITION, THE ONE ON THE TOP OF PAGE 2, BE ADOPTED AS
2 OUR DEFINITION. AND A NUMBER OF THE SCIENTISTS GAVE US
3 SOME VERY USEFUL ADVICE ON HOW TO DEFINE COVERED STEM
4 CELL LINES. IF YOU WANT TO TAKE A MINUTE, AND I'LL
5 JUST READ IT FROM THE TOP OF PAGE 2.

6 OUR DEFINITION IS A COVERED STEM CELL LINE
7 FOR PURPOSES OF THESE REGS IS A CULTURE-DERIVED, HUMAN
8 STEM CELL POPULATION. SO WHAT THIS MEANS IS THAT IT'S
9 NOT -- WE MEANT TO EXCLUDE THE INCIDENTAL STEM CELL
10 THAT MAY BE LURKING, FOR EXAMPLE, IN A CLUMP OF TUMOR
11 TISSUE THAT AN INVESTIGATOR MAY TRANSPLANT INTO AN
12 ANIMAL MODEL. THESE HAVE TO BE LAB-CULTURED CELLS.

13 SO IT'S A POPULATION WHICH IS CAPABLE OF,
14 ONE, SUSTAINED PROPAGATION IN CULTURE, SO IT'S
15 SELF-RENEWING; B, DIFFERENTIATION ALONG MULTIPLE CELL
16 LINEAGES. AND MULTIPLE, I GUESS, WOULD MEAN
17 MULTIPOTENT, BUT NOT NECESSARILY PLURIPOTENT OR
18 TOTIPOTENT. AND SELF-RENEWING TO PRODUCE DAUGHTER
19 CELLS WITH EQUIVALENT DEVELOPMENTAL POTENTIAL. THIS
20 DEFINITION INCLUDES BOTH EMBRYONIC AND NONEMBRYONIC
21 HUMAN STEM CELL LINES REGARDLESS OF THE TISSUE ORIGIN.
22 SO IT'S ANY STEM CELL REGARDLESS OF SOURCE OR MEANS OF
23 DERIVATION PROVIDED THAT IT'S MULTI -- IT IS CAPABLE OF
24 DIFFERENTIATING INTO MULTIPLE CELL LINES.

25 DR. KIESSLING: NOT NECESSARILY ENDODERM,

1 MESODERM, OR ECTODERM. DOESN'T HAVE TO DO ALL THREE OR
2 ANY OF THOSE.

3 CO-CHAIR LO: RIGHT. SO, FOR EXAMPLE, HELP
4 ME OUT, KEVIN AND JOHN, THIS WOULDN'T INCLUDE ADULT
5 STEM CELL LINES, WHICH MIGHT IN THE FUTURE BE SHOWN TO
6 BE CAPABLE OF DIFFERENTIATING, NOT JUST INTO NEURAL
7 PROGENITOR CELLS, BUT INTO OTHER TYPES OF CELLS, BUT
8 NOT NECESSARILY ALL THREE, ENDODERM, ECTODERM, AND
9 MESODERM.

10 DR. WAGNER: I THINK THAT THE VERY QUESTION,
11 WE HAVE TO MAKE IT CLEAR, THAT POINT NO. 2, WHAT
12 EXACTLY THAT WE MEAN BECAUSE WE LEFT IT OPEN-ENDED.
13 RIGHT NOW BY READING THIS, IT WOULD ALSO BE POTENTIALLY
14 EXPANDED BONE MARROW PROGENITORS THAT YOU COULD KEEP
15 FOR A PERIOD OF TIME.

16 DR. HALL: INTENDED TO INCLUDE SUCH CELLS.
17 IF SOMEBODY WAS ABLE TO SUCCESSFULLY CULTURE NEURAL OR
18 BONE MARROW PROGENITORS --

19 DR. WAGNER: NO. NO. NO. THIS IS JUST BONE
20 MARROW THAT CAN MAKE BONE MARROW.

21 DR. HALL: I UNDERSTAND. AND NEURAL THAT CAN
22 MAKE NEURAL. IF SOMEBODY IS ABLE TO SUCCESSFULLY
23 CULTURE THOSE, THEN THAT WOULD COME UNDER OUR
24 DEFINITIONS. IT'S INTENDED TO DO THAT.

25 NOW, IF YOU JUST TAKE BONE MARROW TRANSPLANT

1 THAT'S PRIMARY --

2 DR. WAGNER: NO. BUT YOU CAN DO EX VIVO
3 EXPANSION OF THE HEMATOPOETIC STEM CELL POPULATIONS --

4 DR. HALL: I UNDERSTAND. THAT'S MEANT TO BE
5 COVERED.

6 CO-CHAIR LO: WHAT THAT IMPLIES IN TERMS OF
7 WHAT THE ESCRO IS RESPONSIBLE FOR WE WILL COME TO
8 LATER. THE ESCRO CAN SAY THAT'S COVERED AND IT'S
9 COVERED TO THE EXTENT WE WANT INFORMATION TO DOCUMENT
10 THAT CONSENT WAS ORIGINALLY OBTAINED AND WE KEEP TRACK
11 OF IT. IT DOESN'T NECESSARILY MEAN A FULL REVIEW AS IT
12 WOULD FOR OTHER TYPES OF RESEARCH. SO THERE'S AN
13 INTERACTION BETWEEN THE DEFINITIONS AND WHAT THE
14 DEFINITION IMPLIES FOR WHAT THAT RESEARCHER NEEDS TO DO
15 WITH REGARD --

16 DR. EGGAN: TO RESTATE BERNIE'S POINT, ONE
17 COULD IMAGINE THAT AS TO IRB'S, THERE ARE EXPEDITED
18 TYPES OF REVIEWS AND THERE ARE FULL REVIEWS. SO THE
19 ESCRO MIGHT HAVE MORE POLICIES. SOMETHING LIKE EX VIVO
20 EXPANSION OF BONE MARROW POTENTIALLY WHERE IT COULD
21 INVOLVE DERIVATION OF EMBRYONIC STEM CELL LINE OR IT
22 MIGHT NOT BE.

23 DR. WAGNER: SO NONE OF THIS WOULD BE
24 EXPEDITED REVIEW FOR ANY REASON WHATSOEVER UNLESS
25 YOU'RE TALKING ABOUT WITHIN THE ESCRO, BUT NOT IN THE

1 IRB.

2 DR. EGGAN: I DO MEAN THE ESCRO. EXPEDITED
3 REVIEW BY THE ESCRO.

4 DR. WAGNER: HOWEVER, THIS ACTUALLY GETS
5 INTO, AGAIN, TALKING ABOUT OF A LYMPHOID STEM CELL THAT
6 IS ONLY GOING TO BE MAKING T-CELLS AND YOU CAN EXPAND
7 THEM IN CULTURE FOR A PERIOD OF TIME. DO YOU REALLY
8 WANT TO GET INTO THAT? THE ANSWER MAY BE YES. I'M
9 JUST ASKING THE QUESTION.

10 DR. HALL: YES. I THINK WE FEEL WE NEED TO
11 BE MORE INCLUSIVE RATHER THAN LESS HERE. THE POINT IS
12 IS THAT ONE OF THE CHARGES OF THE ESCRO IS THAT THEY BE
13 AWARE OF STEM CELL WORK THAT'S GOING ON IN THEIR
14 INSTITUTION. AND IF YOU RECALL, SO AN ESCRO MAY BE
15 ASKED TO SAY WE JUST NEED TO KNOW ABOUT THIS, BUT IT
16 DOESN'T NEED OUR FORMAL REVIEW. YOU'RE DOING
17 EXPERIMENTS IN VITRO, FOR EXAMPLE, THAT COULD BE TRUE.
18 OR TO SAY WE NEED TO REVIEW THIS, OR IT CAN SAY YOU'RE
19 ABSOLUTELY NOT PERMITTED TO DO THAT EXPERIMENT.

20 SO WE THINK IT'S IMPORTANT THAT THE ESCRO
21 KNOW ABOUT IT AND TO AT LEAST MAKE THAT JUDGMENT OF
22 WHETHER OR NOT IT'S NECESSARY TO REVIEW OR NOT. PART
23 OF THIS ARISES THROUGH XENOTRANSPLANTS. THAT IS, IN
24 FACT, A CASE CAME UP AT STANFORD WHERE I THINK ADULT
25 STEM CELLS, AS I RECALL --

1 DR. EGGAN: HERB WEISSMAN'S LAB TRANSFERRED
2 BRAIN CANCEROUS CELLS INTO A STEM CELL-LIKE POPULATION
3 FROM HUMAN PATIENTS INTO MICE. AND SOME PEOPLE FIND
4 THOSE EXPERIMENTS OBJECTIONABLE.

5 DR. HALL: WE WANT THEM REVIEWED.

6 DR. EGGAN: WE WANT THEM REVIEWED.

7 DR. HALL: SO THE POINT IS JUST TO MAKE SURE
8 THEY'RE ON THE RADAR SCREEN, AND THAT'S WHY THEY'RE
9 INCLUDED HERE BECAUSE I THINK WHAT WE DON'T WANT IS TO
10 HAVE WORK THAT IS NOT -- THAT THE INSTITUTION DOESN'T
11 SORT OF REGISTER STEM CELL WORK AND BE AWARE OF AND
12 MAKE THE JUDGMENT ABOUT WHETHER IT NEEDS A HIGH LEVEL
13 OF REVIEW OR NOT. SO IT'S INTENDED TO DO THAT.

14 DR. WAGNER: SO IT'S CLEAR, SO YOU'VE NOW
15 ADDED NOW AT LEAST A THIRD REVIEW BOARD AGENCY. FIRST
16 OFF YOU HAVE, FOR THE EXAMPLE YOU GAVE, THAT WOULD BE
17 THE CANCER CENTER REVIEW, WHICH WILL BE GUIDED BY THE
18 NCI, THEN YOU WOULD ALSO HAVE ONE THAT WOULD BE FROM
19 THE IRB, AND NOW ONE WOULD BE THE ESCRO. AND ONE OF
20 THE ISSUES WE ALREADY HAVE WITH THE CANCER CENTER
21 REVIEW BOARD VERSUS THE IRB IS THERE'S ALREADY
22 CONFLICTS. NOW WE'RE INCREASING THE CHANCE OF CONFLICT
23 BETWEEN THE DECISIONS OF EACH OF THE BOARDS.

24 SO FROM A PRACTICAL POINT OF VIEW, IT'S NOW
25 MUCH MORE LABORIOUS FOR THE INVESTIGATOR TO DO THE

1 RESEARCH THAT NEEDS TO BE DONE.

2 DR. HALL: WE'VE HAD QUITE A BIT OF
3 DISCUSSION ABOUT THAT, INCLUDING DISCUSSION WITH THE
4 INSTITUTIONS ABOUT HOW BEST TO HANDLE IT. WE CERTAINLY
5 ARE AWARE THAT IT DOES ADD AN EXTRA LAYER, BUT I THINK
6 WE FEEL THAT IN THE END IT IS IMPORTANT THAT IT BE
7 DONE. AND IF DOWN THE ROAD IT PROVES ONEROUS IN WAYS
8 THAT WE DON'T ANTICIPATE, WE CAN CERTAINLY CHANGE IT.
9 AS SHERRY SAYS, THIS IS A LIVING PROCESS HERE. BUT I
10 THINK IN THE BEGINNING, IN PARTICULAR, WE DON'T SEE A
11 GOOD ALTERNATIVE TO HAVING THAT LEVEL OF REVIEW JUST
12 BECAUSE OF THE SENSITIVITY OF STEM CELL RESEARCH.

13 DR. KIESSLING: I HAVE A QUESTION.

14 CO-CHAIR LO: I WANT TO KEEP AN ORDER HERE.
15 ALTA.

16 MS. CHARO: FIRST, JOHN, IT SOUNDS FROM
17 ZACH'S DESCRIPTION, THIS CONVERSATION WAS TAKING PLACE
18 LARGELY WHEN YOU AND I WERE TRYING TO CUT THROUGH THE
19 STATIC ON THE PHONE, WHICH IS WHY WE WEREN'T HERE FOR
20 IT. I WILL SAY I AM VERY SYMPATHETIC TO WHAT YOU'RE
21 DESCRIBING IS A PROBLEM OF OVERLAPPING AND CONFLICTING
22 REVIEWS. THERE'S AN ADDITIONAL ADVANTAGE THAT ZACH
23 HASN'T NECESSARILY MENTIONED YET.

24 EMBRYONIC STEM CELL RESEARCH HAS KIND OF
25 SUFFERED FROM A KIND OF RESEARCH EXCEPTIONALISM IN

1 WHICH ALL OF THE USUAL PROBLEMS OF RESEARCH HAVE BEEN
2 DISCUSSED AS IF THEY ONLY EXIST WITH REGARD TO
3 EMBRYONIC STEM CELL RESEARCH. INDEED, IN THIS AREA ALL
4 THESE AREAS OF RESEARCH HAVE THEIR OWN CHALLENGES. AND
5 IN MANY CASES THE CHALLENGES ARE THE SAME ACROSS
6 DIFFERENT TYPES. SO WHILE EMBRYONIC SOURCES MAY BE
7 PARTICULARLY CONTROVERSIAL IN TERMS OF THE INITIAL
8 DERIVATIONS, WHEN IT COMES TO THE ACTUAL LABORATORY
9 WORK AND THE INITIAL STAGES OF HUMAN EXPERIMENTATION,
10 IN MANY CASES, WHETHER IT'S AN EMBRYONIC SOURCE OR A
11 FETAL SOURCE OR AN ADULT SOURCE, SOME OF THE
12 UNCERTAINTIES ARE EXACTLY THE SAME. AND HAVING THE
13 ABILITY TO KIND OF INTEGRATE OUR OVERSIGHT ALLOWS US TO
14 BEGIN TO SEE THESE RISKS AND BENEFITS, I THINK, IN A
15 MORE SYNTHETIC WAY AS TO NOT KEEP SEPARATING ONE AREA
16 OF RESEARCH FROM OTHERS.

17 AND FINALLY, THESE OVERSIGHT ACTIVITIES, AS
18 YOU WERE TRYING TO SUGGEST, KEVIN, MIGHT TURN OUT TO BE
19 INDEED FAIRLY ABBREVIATED WHEN THE STAGE OF THE WORK IS
20 REALLY NONPROBLEMATIC. AND IT'S SIMPLY A MATTER OF
21 LETTING A BODY KNOW THAT SOMETHING IS GOING ON ON THE
22 CAMPUS AND BEGINNING TO HAVE A BIG PICTURE OF THE
23 RESEARCH PORTFOLIO OF THE CAMPUS.

24 DR. EGGAN: I STRONGLY ECHO BOTH ZACH AND
25 ALTA'S COMMENTS. AND I WOULD SAY AS A RESEARCHER WHO

1 HAS ENGAGED IN THIS TYPE OF OVERSIGHT PROCESS, HARVARD
2 NOW HAS AN ESCRO, THE PROCESS CAN BE MADE SIMPLER AS
3 LONG AS IT'S NOT DEMANDED THAT ONE REVIEW BE
4 SUBORDINATE TO ANOTHER, SO IT WOULDN'T A CATCH 22
5 SITUATION, WHICH IS OFTEN THE CASE IN CERTAIN REVIEW
6 PROCESSES. SO BY PLACING THE ESCRO IN PARALLEL RATHER
7 THAN SERIAL PROCESS, THIS PROBLEM YOU MENTIONED CAN
8 LARGELY BE ELIMINATED.

9 DR. KIESSLING: I WANT TO ASK JOHN. WHY DO
10 YOU THINK THE NCI PUT IN PLACE THE REQUIREMENT FOR
11 ADDITIONAL REVIEW ABOVE THE INSTITUTION'S IRB?

12 DR. WAGNER: AND I THINK FOR THE SIMILAR
13 REASON WHY WE'RE TALKING ABOUT ESCRO'S, BECAUSE THERE'S
14 SOME UNIQUE ASPECTS THAT, IN TERMS OF THE ETHICS, IN
15 TERMS OF THE STEM CELL BIOLOGY, THAT MAY NOT BE
16 AVAILABLE WITHIN AN IRB. IT PROVIDES A GREATER LEVEL
17 OF SCIENTIFIC REVIEW TO VERIFY THAT, INDEED, THIS IS
18 A -- THE PURPOSE OF THE NCI WAS TO HAVE THIS VERY HIGH
19 LEVEL SCIENTIFIC REVIEW FOR WHETHER IT BE BASIC OR
20 CLINICAL RESEARCH.

21 DR. HALL: I HAD SOME EXPERIENCE WITH THAT AS
22 VICE CHANCELLOR OF RESEARCH AT UCSF. LET'S TALK ABOUT
23 IT AT LUNCH.

24 DR. TAYLOR: IT'S MORE FUNDING BASED, I
25 THINK, JUST LIKE GCRC'S HAVE ANOTHER LEVEL. IRB'S

1 PROTECT THE PATIENT, BUT THE GCRC, THE NCI ARE ACTUALLY
2 REVIEWING THOSE PROTOCOLS FOR SCIENTIFIC.

3 DR. EGGAN: I'D LIKE TO MAKE ONE LAST COMMENT
4 TO CAP OFF THIS DISCUSSION. I THINK IT IS IMPORTANT TO
5 REALIZE THAT WITH THIS LEVEL OF OVERSIGHT, THAT IT DOES
6 IMPOSE RATHER ONEROUS RESPONSIBILITIES ON INVESTIGATORS
7 WHICH CAN BE INTIMIDATING TO SCIENTISTS WHO ARE NOT
8 USED TO NAVIGATING THESE SORTS OF ADMINISTRATIVE
9 WATERS. I THINK CIRM SHOULD PAY SPECIAL ATTENTION TO
10 THIS AND SHOULD PROMPTLY DISPENSE FUNDS FOR RESEARCH
11 FOR ADMINISTRATIVE SUPPORT TO THE SCIENTIST TO BE ABLE
12 TO AID THIS PROCESS.

13 CO-CHAIR LO: ANY OTHER COMMENTS? I ALSO
14 WANT TO CALL YOUR ATTENTION TO (H), THE NEW NAME FOR
15 THESE OVERSIGHT COMMITTEES. THEY USED BE ESCRO'S WITH
16 AN E. WE REALIZE THAT THEY'RE DOING MUCH MORE NOW THAN
17 JUST EMBRYONIC STEM CELLS, SO WE'RE NOW CALLING THEM
18 SCRO'S.

19 DR. PRIETO: I HAVE A SIMPLE QUESTION. I
20 WONDERED WHY IN THE SECOND DEFINITION THE WORDS
21 "THOUGHT TO BE" WERE DROPPED. THE FIRST ONE SAYS CELL
22 POPULATION THAT IS THOUGHT TO BE CAPABLE. LOOKS LIKE
23 WE WANTED TO SAY ONE WHICH IS CAPABLE.

24 CO-CHAIR LO: IT'S SECOND DEFINITION OF
25 COVERED STEM CELL LINE.

1 DR. HALL: I WOULD ASK WHAT'S THE PURPOSE
2 THOUGHT TO BE CAPABLE. I DON'T UNDERSTAND.

3 DR. PRIETO: WELL, I JUST WONDER --

4 DR. HALL: TO COULD CALL IT A BONA FIDE STEM
5 CELL LINE, ACTUALLY YOU NEED TO SHOW IT CAN PROPAGATE,
6 DIFFERENTIATE TO MULTIPLE LINEAGES. IF YOU DON'T DO
7 THAT, YOU HAVEN'T ESTABLISHED IT AS A STEM CELL LINE.
8 UNLESS I'M MISSING A POINT HERE, AND I MAY BE, I THINK
9 THIS IS THE PREFERABLE ONE.

10 MR. LOMAX: THERE WAS ALSO A TECHNICAL
11 CONSIDERATION THERE. I BELIEVE, I'LL HAVE TO CHECK MY
12 NOTES, I BELIEVE THAT RECOMMENDATION CAME ON BEHALF OF
13 THE GRANTS ADMINISTRATION TEAM. THIS IS JUST MORE
14 CONSISTENT WITH THEIR LANGUAGE. SO IT WAS A PURPOSE
15 FOR REGULATORY CONSISTENCY THERE. IT WASN'T
16 INTELLECTUAL DISSECTION OF WHAT IT MEANT. IT HELPS TO
17 HAVE THE LANGUAGE CONSISTENT THROUGHOUT THE
18 REGULATIONS.

19 DR. HALL: AS A FORMER ENGLISH MAJOR, CAN I
20 REQUEST THAT THE "WHICH" BE CHANGED TO "THAT"?

21 CO-CHAIR LO: RESTRICTIVE AND NONRESTRICTIVE
22 CLAUSE.

23 MR. LOMAX: A NOD TO OUR GRANTS
24 ADMINISTRATION TEAM, THAT EDIT WAS MADE LAST WEEK.
25 THEY JUST DIDN'T WANT TO REVISE THE DRAFT FOR THIS

1 MEETING. IT'S BEEN DONE.

2 CO-CHAIR LO: I WOULD INVITE PUBLIC COMMENTS
3 ON THESE FIRST TWO SECTIONS. ANYONE IN THE PUBLIC HAVE
4 A COMMENT OR QUESTION TO RAISE ON THESE FIRST TWO
5 SECTIONS. PLEASE INTRODUCE YOURSELF.

6 MR. TAYMOR: MY NAME IS KEN TAYMOR. ON
7 SECTION 1, FOLLOWED BY, I GUESS, FIVE ZEROS, THE LAST
8 SENTENCE OF THE FIRST PARAGRAPH STATES THAT IT'S THE
9 INTENT TO OPERATE IN COMPLIANCE WITH STATE AND NATIONAL
10 POLICIES TO PROTECT PATIENT SAFETY RIGHTS AND PRIVACY.
11 I HAD A CONCERN THAT IF THERE ARE EVOLVING NATIONAL
12 POLICIES, NOT LAWS, BUT POLICIES THAT MAY BE
13 INCONSISTENT WITH POLICIES THAT WE'RE DEVELOPING IN
14 CALIFORNIA, WHICH IS THE CASE NOW, THAT THIS COULD LEAD
15 TO A CLAIM THAT A RESEARCHER WAS IN COMPLIANCE WITH
16 CALIFORNIA LAW, BUT I WOULD CHANGE POLICIES TO LAW, OR
17 CONSIDER IT AT LEAST.

18 WITH RESPECT TO THE DEFINITIONS, I HAD A
19 QUESTION AS TO WHY, AND MAYBE YOU CAN EXPLAIN WHY YOU
20 HAVE COVERED STEM CELL LINE. IT SEEMS TO BE DIFFERENT
21 IN THE USE OF STEM CELL AND THE DEFINITION OF STEM
22 CELLS. YOU HAVE A DIFFERENTIATION ALONG MULTIPLE
23 LINEAGES IN THE STEM CELL LINE, THEN YOU HAVE
24 DIFFERENTIATION INTO MATURE CELLS WITH SPECIALIZED
25 FUNCTIONS IN THE DEFINITION OF STEM CELL. YOU HAVE

1 EQUIVALENT DEVELOPMENTAL POTENTIAL IN STEM CELL LINES,
2 BUT SELF-RENEWING TO PRODUCE DAUGHTER CELLS. I GUESS
3 IT'S -- SORRY -- SELF-RENEWAL IS ONE OR BOTH PROGENY
4 RETAIN THE UNDIFFERENTIATED STATE.

5 I THINK AT LEAST EITHER SOME EXPLANATION OF
6 THE MEANING OF THE DIFFERENCES OR SOME CLARIFICATION
7 THERE WOULD BE USEFUL.

8 AND FINALLY, IN TERMS -- I NOTICE GOING
9 FORWARD IN THE USE OF COVERED STEM CELL LINE, FOR
10 EXAMPLE, IN THE ETHICALLY DERIVED SECTION, YOU HAVE AN
11 (A). YOU TALK ABOUT HUMAN COVERED STEM CELL LINES;
12 (B), COVERED STEM CELL LINES, BUT NOT HUMAN; AND, (C),
13 YOU TALK ABOUT HUMAN, BUT IT'S NOT THE COVERED STEM
14 CELL LINES. SO I'M NOT SURE --

15 MS. CHARO: IN SECTION 4.

16 MR. TAYMOR: THIS IS 1 FOLLOWED BY FOUR ZEROS
17 AND A SEVEN. ACCEPTABLE RESEARCH METHODS.

18 CO-CHAIR LO: HE'S POINTING OUT --

19 MR. TAYMOR: IN TERMS OF HOW THESE ARE GOING
20 TO BE USED FORWARD WOULD BE HELPFUL.

21 FINALLY, STEMMING OFF THAT, WHEN YOU TALK
22 ABOUT HUMAN STEM CELLS, IF HUMAN WOULD INCLUDE A
23 CHIMERIC STEM CELL LINE THAT WAS HUMAN, AND, FOR
24 EXAMPLE, DISCUSSIONS IN THE UK WITH SCNT WORK WITH
25 HUMAN SOMATIC CELLS. WHETHER OR NOT -- I THINK IT

1 WOULD BE VERY HELPFUL TO THE COMMUNITY TO UNDERSTAND
2 WHETHER THOSE LINES WOULD BE COVERED OR NOT.

3 CO-CHAIR LO: SO THERE ARE A NUMBER OF --
4 MAKE SURE WE UNDERSTOOD THEM ALL. ONE IS TO TAKE
5 CONSISTENT (A) AND (J), WHICH WERE DRAFTED AT DIFFERENT
6 TIMES, AND MAKE SURE THAT -- I THINK WE MEAN THEM TO BE
7 IN PARALLEL, NOT TO HAVE DIFFERENCES THAT PEOPLE
8 SCRATCH THEIR HEADS ABOUT. SO I THINK THAT COULD BE A
9 DRAFTING PROBLEM.

10 HE ALSO WANTED US TO SEE HOW THE DEFINITIONS
11 IN 100001 PLAY OUT IN 100007 IS VERY IMPORTANT.

12 AND I GUESS THIS QUESTION -- SO THE QUESTION
13 WAS WHETHER WE'RE REALLY CLEAR ON COVERED STEM CELL
14 LINES, WHICH MY UNDERSTANDING ARE ALWAYS HUMAN. WE
15 NEED TO BE CLEAR ON THAT. AND THEN OTHER CATEGORIES
16 WHICH ARE TALKED ABOUT UNDER 100007.

17 AND THEN THE QUESTION OF CHIMERIC STEM CELL
18 LINES ALA THE UK WORK WITH NONHUMAN OOCYTES. THE
19 QUESTION IS WHETHER WE MEAN TO INCLUDE THAT IN OUR
20 DEFINITION OF STEM CELLS, WHICH I DON'T THINK WE'VE
21 EXPLICITLY DONE.

22 DR. EGGAN: ONE COULD ADD THE DEFINITION FOR
23 HUMAN STEM CELL. ONE CAN DEFINE WHAT IT MEANS TO BE
24 HUMAN IN A TWO- OR THREE-SENTENCE DEFINITION OR A
25 ONE-SENTENCE DEFINITION, I SUPPOSE.

1 CO-CHAIR LO: AND THAT WOULD INCLUDE THESE
2 CHIMERIC.

3 DR. EGGAN: I THINK THAT'S REASONABLE FOR US
4 TO DISCUSS. I THINK THAT'S A GOOD ONE.

5 DR. KIESSLING: IN THE PHRASE "COVERED STEM
6 CELL LINE," WE TALKED ABOUT THIS OVER THE PHONE. IT
7 SOUNDS AS THOUGH ZACH'S THINKING IS YOU WANTED TO BE
8 BROADER RATHER THAN NARROW. WHAT WOULD BE A STEM CELL
9 LINE THAT'S NOT COVERED?

10 CO-CHAIR LO: ONE THAT DOESN'T DIFFERENTIATE
11 INTO MULTIPLE CELL LINES, JUST ONE.

12 DR. HALL: I THINK WHAT THIS IS -- THIS IS A
13 DEFINITION. WHAT YOU ARE SAYING IS WHAT DO WE MEAN BY
14 CULTURE-DERIVED, HUMAN STEM CELL POPULATION. KEN
15 TAYMOR'S POINT IS THAT WE'VE LATER GONE AND DEFINED IT.
16 AT THE VERY LEAST THOSE OUGHT TO BE CONSISTENT. MAYBE
17 WE JUST NEED TO DEFINE IT ONCE. I THINK THIS IS
18 INTENDED TO BE A DEFINITION OF WHAT YOU MEAN.

19 DR. KIESSLING: ORIGINALLY WHEN WE HAD THIS
20 DISCUSSION, WE WERE TALKING ABOUT NOT TRYING TO INCLUDE
21 BONE MARROW TRANSPLANT WORK AND --

22 DR. HALL: BUT IF IT'S NOT -- AS WE JUST SAID
23 WITH JOHN'S COMMENT BEFORE, IF IT'S NOT PROPAGATED,
24 CULTURE IS A PURIFIED LINE, THEN IT'S NOT -- WE DON'T
25 NEED TO DO THAT.

1 DR. WAGNER: IT DOES. PART OF MY CONFUSION
2 WAS I LEFT OUT THE WORD "LINE" IN MY THINKING. THAT
3 KIND OF CHANGES THE WHOLE CHARACTER.

4 CO-CHAIR LO: YOU'RE MANIPULATING SOMEHOW IN
5 THE LABORATORY AS OPPOSED TO TAKING FROM THE DONOR AND
6 PUTTING IT IN THE --

7 CORRECT ME IF I'M WRONG, MY UNDERSTANDING OF
8 TWO WAS THAT IF YOU HAD A CELL THAT WAS SELF-RENEWING
9 AND SELF-PROPAGATING IN CULTURE, BUT ONLY COULD FORM
10 ONE TYPE OF CELL, MAKE A CARYOCYTE OR SOMETHING, THAT
11 WOULD NOT BE INCLUDED.

12 DR. WAGNER: I APOLOGIZE I LEFT THE WORD
13 "LINE."

14 DR. EGGAN: I THINK UNLESS WE'RE GOING TO
15 MOVE ON TO THIS ISSUE ABOUT WHAT IT MEANS TO BE HUMAN.

16 DR. HALL: YOU HAVE A SUGGESTED DEFINITION
17 THAT WOULD INCLUDE CHIMERIC?

18 DR. EGGAN: PART OF THE PROBLEM IS THAT IT'S
19 UNCLEAR. JUST TO FOCUS ON THIS ONE PARTICULAR ISSUE OF
20 NUCLEAR TRANSPLANTATION, I THINK IT'S AT THIS POINT
21 UNCLEAR EXACTLY WHAT THE COMPOSITION OF THIS MATERIAL
22 IS. ONE COULD SPECULATE VARIOUS COMPOSITIONS OF MATTER
23 AND TRY TO CAPTURE THOSE IN A DEFINITION, WHICH IS NOT
24 REASONABLE. ONE WOULD GUESS THAT THE NUCLEAR GENETIC
25 MATERIAL, SUCH AS A STEM CELL LINE, WOULD BE HUMAN IN

1 NATURE. SO REGARDLESS OF ITS MITOCHONDRIAL OR PROTEIN
2 COMPONENTS THAT MIGHT BE DERIVED FROM AN EGG OF ANOTHER
3 ANIMAL SPECIES, THIS WOULD BE CONSIDERED A HUMAN STEM
4 CELL LINE. LIKEWISE, THERE WILL BE MANY HUMAN STEM
5 CELL LINES THAT CAN MODIFIED BE THE ADDITION OF MOUSE
6 GENES THROUGH TRANSGENIC TECHNOLOGY WHICH MUST ALSO
7 BEING INCLUDED IN THIS TYPE OF DEFINITION.

8 CO-CHAIR LANSING: COULD I JUST ADD THAT TED
9 PETERS IS FINDING IT VERY DIFFICULT TO HEAR ALL OF US.
10 CAN WE TALK LOUDER AND MORE DIRECTLY INTO THE
11 MICROPHONE, PLEASE.

12 CO-CHAIR LO: GOOD POINT.

13 DR. HALL: WHAT ABOUT SOMETHING THAT NUCLEAR
14 GENETIC MATERIAL IS HUMAN OR LARGELY HUMAN?

15 DR. EGGAN: I THINK THAT WOULD BE A
16 REASONABLE STARTING POINT. WE SEEM TO BE SHIFTING
17 LANGUAGE HERE.

18 MS. CHARO: I DON'T KNOW. LIKE EVERYBODY
19 ELSE, I'M STILL THINKING IT OVER. WHEN WE GET INTO
20 NUCLEAR GENETIC MATERIALS HUMAN OR MOSTLY HUMAN, I'M
21 FLASHING ON THE PATENT OFFICE TRYING TO FIGURE OUT WHAT
22 PERCENTAGE HAS TO COME FROM HUMAN. AND ALSO I'M
23 FLASHING ON THE FACT THAT IN MANY CASES THERE'S NO
24 DISTINCTION BETWEEN HUMAN AND OTHER PRIMATE, FOR
25 EXAMPLE, OR HUMAN AND OTHER MAMMALIAN.

1 SO I'M WONDERING IF, RATHER, WE CLEARLY
2 DEFINE WHAT THE ENTITY IS. I'M NOT SURE. BUT I'M
3 THINKING OUT LOUD WHETHER WE'D BE BETTER OFF THINKING
4 IN TERMS SIMPLY OF WHAT THE SOURCES OF TISSUE WERE. SO
5 THAT WE MIGHT SAY COVERED STEM CELL LINES FOR THIS
6 REGULATION INCLUDE ANY STEM CELL LINES THAT WERE
7 ORIGINALLY DERIVED USING ANY TISSUE FROM A HUMAN DONOR.
8 AND THEN STOP THERE WITHOUT CHARACTERIZING HUMAN AND
9 NONHUMAN. AT THIS POINT IT MIGHT NO LONGER BE A HUMAN
10 LINE BY SOMEBODY'S STANDARDS.

11 BUT SINCE PART OF OUR GOAL HERE IS TO BE
12 FOCUSING ON THE ETHICS OF THE DONATION PROCESS, THE
13 DERIVATION PROCESS, ETC., IT GETS US OUT OF DEFINING
14 WHAT IT MEANS TO BE HUMAN.

15 DR. EGGAN: IT'S CRITICAL THAT NOT BE TOO
16 BROAD. FOR INSTANCE, I CAN ENVISION EXPERIMENTS WHERE
17 A DISEASED GENE IS ISOLATED FROM THE CELLS OF A DONOR
18 AND THEN THAT DISEASED GENE IS PUT INTO A MOUSE
19 EMBRYONIC STEM CELL LINE, AND THAT SHOULD NOT BE A
20 COVERED ENTITY.

21 MS. CHARO: OH, BOY.

22 DR. HALL: LET ME JUST TRY THIS. A
23 CULTURE-DERIVED, HUMAN STEM CELL POPULATION THAT HAS
24 BEEN DERIVED FROM HUMAN TISSUE AND IS CAPABLE. THE
25 DERIVED APPLIES TO THE CELL AND CELL POPULATION.

1 MS. CHARO: YEAH.

2 DR. EGGAN: I THINK WE'RE GOING TO HAVE TO
3 HUDDLE ON THIS ONE.

4 MS. CHARO: IT MAY BE EASIER ONCE WE ACTUALLY
5 SEE IT IN WRITING AND HAVE A CHANCE TO THINK ABOUT IT
6 AND PLAY IT AGAINST SITUATIONS.

7 CO-CHAIR LO: THEN WE CAN COME BACK TO IT AND
8 TRY AND DRAFT SOMETHING AND COME BACK TO IT LATER IN
9 THE DAY AFTER WE'VE HAD A CHANCE TO THINK ABOUT IT.

10 DR. EGGAN: ONE THING TO SAY, THOUGH, IT IS
11 CLEAR THE NATIONAL ACADEMY OF SCIENCE GUIDELINES
12 DIRECTLY ENDORSE AND SUPPORT THIS TYPE OF WORK.

13 MS. CHARO: IT'S NOT ABOUT FORBIDDING THE
14 WORK. IT'S TRYING TO FIGURE OUT WHETHER OR NOT IT
15 COMES UNDER THE ESCRO REVIEW.

16 DR. EGGAN: I WANTED TO SAY THAT POINT.

17 DR. KIESSLING: I'D LIKE TO FIDDLE WITH (I).
18 I'D LIKE TO FIDDLE WITH THE DEFINITION OF (I) WHERE IT
19 TALKS ABOUT THE NUCLEUS OF AN EGG IS GOING TO BE
20 REMOVED. THAT SHOULD BE CHANGED TO CHROMOSOMES. AS
21 LONG AS WE'RE DOING THIS, SHOULD JUST BE THE EGG'S
22 CHROMOSOMES ARE REMOVED.

23 DR. EGGAN: THIS IS IMPORTANT BECAUSE THE EGG
24 DOESN'T ACTUALLY CONTAIN A NUCLEUS AT THE TIME THAT
25 IT'S MANIPULATED.

1 DR. KIESSLING: SOME DO. SOME SPECIES DO.

2 CO-CHAIR LO: PUBLIC? ANYONE ELSE ON THE
3 COMMITTEE? SO IN (I) FROM EGGS IN WHICH CHROMOSOMES
4 HAVE BEEN REMOVED.

5 DR. KIESSLING: RIGHT.

6 MR. REED: I'M STRUGGLING TO FOLLOW YOU AT
7 THIS POINT. AND I'VE HEARD THAT THE CHINESE ARE TRYING
8 TO FIND A WAY NOT TO HAVE TO USE HUMAN EGGS AT ALL BY
9 USING RABBIT EGGS AND THEN THEY PUT THE SKIN CELL
10 INSIDE THAT. IS THERE ANYTHING THAT SEEMS A VALUABLE
11 POSSIBILITY TO ME. IS THERE ANYTHING IN THAT LANGUAGE
12 THAT WOULD PROHIBIT US FROM DOING THAT?

13 DR. HALL: THAT'S EXACTLY WHAT WE'RE TRYING
14 TO ADDRESS HERE.

15 CO-CHAIR LO: THIS IS JUST A DEFINITION OF
16 WHAT FALLS UNDER ESCRO OVERSIGHT. IT DOESN'T SAY
17 ANYTHING ABOUT WHETHER IT'S ETHICALLY PERMISSIBLE.
18 IT'S SOMETHING THAT NEEDS TO BE WORKED OUT BOTH IN THE
19 NEXT SECTION AND BY THE REGULATION.

20 DR. HALL: WE'RE SAYING THAT THAT WOULD BE
21 INCLUDED IN OUR DEFINITION.

22 MR. REED: I AM CONCERNED THAT THAT WOULD BE
23 PUT AT RISK.

24 DR. HALL: WE'RE NOT PROHIBITING ANYTHING
25 HERE. WE'RE JUST SAYING THAT IS INCLUDED IN WHAT WE

1 MEAN BY A STEM CELL. THANKS.

2 CO-CHAIR LO: OKAY.

3 MS. CHARO: JUST ALSO ON (I), THERE'S A
4 CROSSED-OUT PHRASE "OR ANOTHER CELL." CAN YOU REMIND
5 ME ABOUT THE ORIGIN OF THE PHRASE AND THE DECISION TO
6 CROSS IT OUT? I'M KIND OF CONFUSED NOW. OBVIOUSLY WE
7 ADDED AND THEN IT WAS TAKEN OUT.

8 DR. EGGAN: I THINK IT'S BECAUSE IT DIRECTLY
9 RELATES TO OUR LAB AND OTHERS DOING IT IN WHICH INSTEAD
10 OF TAKING AN OOCYTE AS THE SOURCE OF ACTIVITIES THAT
11 WOULD TURN BACK THE CLOCK ON A SOMATIC NUCLEUS, THE
12 NOTION IS THAT THERE MAY BE OTHER SOURCES. IN ADDITION
13 TO RABBIT OOCYTES, ONE COULD IMAGINE USING COMPONENTS
14 OF EMBRYONIC STEM CELLS THEMSELVES, SAY, AS A MEANS OF
15 CREATING EMBRYONIC STEM CELL LINES WHICH HAVE THE
16 GENETIC MAKEUP OF A PATIENT THEY'RE INTERESTED IN. I'M
17 SURE THAT'S WHAT THIS IS REFERRING TO.

18 NOW, THAT'S NOT SOMATIC CELL NUCLEAR
19 TRANSPLANTATION. THAT'S NOT THIS METHOD OF SCNT AS IT
20 HAS BECOME ACCEPTABLY KNOWN IN BOTH THE LAY AND
21 SCIENTIFIC PRESS. I'M SURE THAT'S ONE REASON WHY IT'S
22 REMOVED HERE, BUT THERE'S NO QUESTION THAT THOSE
23 CREATED BY THAT METHODOLOGY WOULD IMMEDIATELY FALL
24 UNDER COVERED STEM CELL LINES, SO, IN FACT, IT'S NOT
25 NECESSARY.

1 MS. CHARO: I SEE. SO IT DOESN'T REALLY
2 MATTER WHETHER YOU HAVE A DEFINITIONAL SECTION AND THE
3 DIFFERENT WAYS IN WHICH YOU COULD WIND UP WITH A
4 COVERED STEM CELL LINE. IT ONLY MATTERS THAT WE HAVE A
5 GOOD DEFINITION OF COVERED STEM CELL LINES.

6 DR. EGGAN: THAT'S RIGHT. SO BERNARD AND I
7 DISCUSSED THIS OVER THE PHONE AND CAME TO THAT
8 CONCLUSION.

9 DR. KIESSLING: I THINK I'M THE REASON IT'S
10 CROSSED OUT JUST FOR EXACTLY WHAT KEVIN SAID. YOU
11 DON'T HAVE TO DEFINE SOMATIC CELL NUCLEAR TRANSFER IF
12 YOU'RE MAKING A HYBRID CELL OF SOME KIND. SOMATIC CELL
13 NUCLEAR TRANSFER SPECIFICALLY HAS BEEN, AND I THINK
14 WE'RE VICTIMS HERE OF THE MEDIA, BUT IT SPECIFICALLY
15 RELATES TO TRANSFER OF THE SOMATIC CELL NUCLEUS INTO AN
16 EGG.

17 CO-CHAIR LO: HERE'S WHERE I THINK WE NEED TO
18 PAY ATTENTION AS WE GO THROUGH LATER SECTIONS. THE
19 IMPORTANCE OF THIS DEFINITION HAS TO DO WITH THE LEVEL
20 OF SCRO REVIEW. SO SCNT WE SINGLE OUT AS SAYING IT
21 MUST GO THROUGH A HIGH LEVEL ESCRO REVIEW. AND THE
22 QUESTION IS BY CROSSING OUT THE "OR OTHER CELL," DO WE
23 LOSE THAT DEGREE OF OVERSIGHT ON A CLASS OF EXPERIMENTS
24 WHICH USE DIFFERENT CELLS OTHER THAN OOCYTES?

25 DR. KIESSLING: NO, BECAUSE IT WOULD BE A

1 COVERED STEM CELL LINE.

2 MS. CHARO: SCNT TRIGGERED AN ENHANCED LEVEL
3 OF REVIEW.

4 CO-CHAIR LO: HIGH LEVEL OF REVIEW. SO WE
5 JUST NEED TO PAY ATTENTION.

6 DR. EGGAN: I WOULD ARGUE THIS FROM THE
7 OUTSET THAT FOR THE MOST PART THE ANSWER IS NO. THERE
8 IS AN ADDITIONAL CONCERN BECAUSE THOSE ADDITIONAL
9 CONCERNS FOR SCNT REALLY SURROUND THIS PIECE, AT LEAST
10 SOME LARGE NUMBER OF THESE LARGER CONCERNS SURROUND THE
11 USE OF WOMEN AS OOCYTE DONORS WHICH HAVE A COMPLETELY
12 SEPARATE INFORMED CONSENT AND MEDICAL ISSUES ASSOCIATED
13 WITH THEM AND I THINK MANY OF US FEEL DEMAND HIGHER
14 OVERSIGHT. THERE MAY BE OTHERS THAT WE SHOULD WATCH
15 OUT FOR AS WE GO ALONG THE WAY.

16 MS. CHARO: THAT WOULD, IN TURN, SUGGEST THAT
17 THE DEFINITIONS HERE COULD BE LIMITED TO HUMAN EGGS,
18 NOT TO EGGS FROM OTHER SPECIES. IF THE REAL CONCERN
19 ABOUT SCNT IS ABOUT DONOR WELFARE, HUMAN EGGS. OR IF
20 THE CONCERN IS ABOUT THE POTENTIAL FOR MISAPPROPRIATION
21 INTO REPRODUCTIVE USES, THEN, IN FACT, IT DOESN'T
22 MATTER WHETHER IT'S EGGS OR STEM CELLS OR ANY OTHER
23 KIND OF CELL INTO WHICH YOU'RE PLACING IT. IT'S THE
24 REPLICATION OF THE SOMATIC CELL GENOME. YOU'RE RIGHT.
25 WE'VE GOT TO KEEP VERY CLOSE TRACK OF THE PURPOSE OF

1 THE ENHANCED REVIEW.

2 DR. EGGAN: I THINK IF THERE ARE REPRODUCTIVE
3 ISSUES AND MEDICAL ISSUES WITH OOCYTE DONATION, THEN
4 SCNT USING HUMAN OOCYTES. IF THERE ARE QUESTIONS
5 SURROUNDING THE GENERAL USE OF THE STEM CELL LINES IN
6 ANIMAL EXPERIMENTS THAT RESULT BECAUSE THEY'RE SCNT
7 LINES AND ALSO ISSUES WHICH SURROUND THE DONATION OF
8 SOMATIC CELLS FOR SCNT RESEARCH, THOSE ARE THE SAME
9 REGARDLESS OF WHICH METHODOLOGY IS USED TO MAKE THE
10 CELL LINES FROM THOSE SOMATIC DONORS AND HAVE TO BE
11 WATCHED OUT FOR. SO I THINK THOSE ARE THE LINES THAT I
12 WOULD DRAW BETWEEN THESE TWO CLASSES OF CONCERNS.

13 CO-CHAIR LO: THERE MAY BE AN ADDITIONAL SET
14 OF CONCERNS IF YOU'RE USING NONHUMAN OOCYTES OR OTHER
15 CELLS INTO WHICH YOU PLACE THE SOMATIC CELL DNA.

16 DR. EGGAN: I THINK IT'S AT LEAST CLEAR THAT
17 ONE WOULD WANT THIS TO BE EXTREMELY CLEAR IN AN
18 INFORMED CONSENT DOCUMENT.

19 CO-CHAIR LO: I THINK LET'S JUST SORT OF MAKE
20 A MENTAL NOTE TO OURSELVES TO PAY ATTENTION TO WHERE
21 SCNT COMES UP LATER. MAYBE SOMEONE ON STAFF COULD SORT
22 OF DO, WHATEVER IT'S CALLED, A FIND IN THE DOCUMENT.
23 SEEK AND DESTROY. JUST TO MAKE SURE WE FIND IT. GOOD.

24 IF THERE ARE NO MORE COMMENTS, LET'S GO ON TO
25 SECTION 100002, ACTIVITIES NOT ELIGIBLE FOR CIRM

1 FUNDING.

2 ARE THERE ANY OTHER COMMENTS ON SECTION 1?

3 CO-CHAIR LANSING: FROM THE PUBLIC?

4 CO-CHAIR LO: THANK YOU.

5 DR. TAYLOR: ARE WE GOING TO TRY TO MAKE A
6 DECISION ABOUT (A), OR ARE WE MOVING ON?

7 CO-CHAIR LO: I THINK WHAT WE'RE SUGGESTING
8 IS WE PREFER THE SECOND ONE TO THE FIRST ONE.

9 MS. CHARO: THIS IS REALLY JUST A HEADS UP.
10 ON SUB-B IN THE DEFINITIONAL SECTION WHERE IT SAYS THAT
11 CERTAIN KINDS OF STEM CELLS ARE ETHICALLY DERIVED, I
12 HAD BEEN SUGGESTING THAT WE CHANGE THAT LANGUAGE TO
13 ACCEPTABLY DERIVED SO THAT WE'RE NOT IN A SENSE TRYING
14 TO DEFINE FOR THE WORLD WHAT IS ETHICAL AND NOT. LIMIT
15 OURSELVES TO WHAT IS ACCEPTABLE FOR CIRM FUNDING AND
16 WHAT IS NOT.

17 CO-CHAIR LO: THAT'S CONSISTENT WITH THE
18 HEADER IN 100007. WE SAY ACCEPTABLE. A MORE PRECISE
19 WORD.

20 LET'S MOVE ON TO 100002 THEN. WE HAVE FIVE
21 ACTIVITIES NOT ELIGIBLE FOR CIRM FUNDING. REPRODUCTIVE
22 USES OF SCNT. SO RIGHT HERE THE ISSUE IS, GOING BACK
23 TO WHAT KEVIN WAS DISCUSSING, DOES OUR DEFINITION OF
24 JUST A HUMAN OOCYTE FIT WITH WHAT WE'RE TRYING TO SAY
25 IN 100002? (B), A TIME LIMIT OF 12 DAYS OR THE

1 APPEARANCE OF THE PRIMITIVE STREAK, NOT COUNTING FROZEN
2 TIME.

3 (C) IS TRANSPLANTING COVERED HUMAN STEM
4 CELLS. THERE'S A TYPO IN THE FIRST LINE ON PAGE 2.
5 COVERED HUMAN STEM CELLS INTO NONHUMAN PRIMATE
6 BLASTOCYSTS.

7 AND THE FOURTH, INTRODUCTION OF COVERED STEM
8 CELLS, WHETHER HUMAN OR NONHUMAN, INTO HUMAN
9 BLASTOCYSTS.

10 SO, THERE, AGAIN, WE'RE NOW SAYING THAT WE
11 ARE TALKING ABOUT STEM CELLS THAT CAN BE EITHER HUMAN
12 OR NONHUMAN, WHICH MEANS THE DEFINITIONS OF STEM CELL
13 LINE AND STEM CELLS MIGHT BE DIFFERENT.

14 AND, FINALLY, (E), WE'RE PROHIBITING RESEARCH
15 RESULTING IN THE BREEDING OF ANY ANIMAL INTO WHICH
16 COVERED STEM CELLS HAVE BEEN INTRODUCED. THAT COULD
17 INCLUDE BOTH HUMAN AND NONHUMAN STEM CELLS.

18 DR. HALL: INFORMATION QUESTION. IN (I)
19 ABOVE, THE DEFINITION OF SCNT, WE DID NOT PUT THE WORD
20 "HUMAN" IN, RIGHT?

21 CO-CHAIR LO: WE DID NOT; IS THAT CORRECT?

22 DR. HALL: I THINK THAT'S THE RIGHT THING TO
23 DO, BUT I JUST WANTED TO BE SURE. HERE'S A SITUATION
24 WHERE EXACTLY ONE'S CONCERN FOR THE HUMAN OOCYTE.
25 DOESN'T MATTER WHICH SET YOU HAVE. IT'S A SLIGHTLY

1 DIFFERENT SET OF CONCERNS, BUT IT'S VERY RELEVANT.

2 CO-CHAIR LO: FOR (A), I GUESS I WANT TO GO
3 BACK TO -- I'M SORRY. WHY DON'T YOU GO AHEAD.

4 MS. CHARO: JUST ONE THAT'S KIND OF TECHNICAL
5 BEFORE WE GET INTO SUBSTANCE ON (D), THE INTRODUCTION
6 OF COVERED STEM CELLS, WHETHER HUMAN OR NONHUMAN, INTO
7 HUMAN BLASTOCYSTS. SINCE WE PREVIOUSLY DEFINED COVERED
8 STEM CELLS AS A CULTURE-DERIVED HUMAN STEM CELL
9 POPULATION, WE CAN'T HAVE THE INTRODUCTION OF A COVERED
10 STEM CELL THAT IS NONHUMAN BECAUSE THERE'S NO SUCH
11 THING AS A COVERED STEM CELL THAT'S NONHUMAN. SO WE
12 MAY WANT TO JUST DELETE THE REFERENCE TO NONHUMAN
13 ENTIRELY IN THIS SECTION.

14 I APPRECIATE THE REASON WHY IT'S THERE, BUT
15 IT'S NOT KIND OF LOGICAL ANY LONGER.

16 DR. KIESSLING: DO WE HAVE TO HAVE (C) AND
17 (D) AT ALL?

18 CO-CHAIR LO: THEY WERE IN THE NAS
19 GUIDELINES. THEY ARE, TO MANY PEOPLE, TYPES OF
20 RESEARCH WHICH IS EXTREMELY TROUBLING AND SHOULD NOT BE
21 CARRIED OUT, CERTAINLY NOT WITH PUBLIC FUNDS. I THINK
22 WHAT WE'RE TRYING TO DO IS SET THE OUTER BOUNDARIES OF
23 WHAT WE'RE WILLING TO FUND.

24 CO-CHAIR LANSING: I THINK IF WE DON'T HAVE,
25 THEN WE'LL LOOK LIKE --

1 DR. KIESSLING: I CAN THINK OF A NUMBER OF
2 EXPERIMENTS WHICH YOU WOULD LIKE TO TAKE ADVANTAGE OF
3 WATCHING WHAT HAPPENS TO HUMAN CELLS IN A MONKEY
4 BLASTOCYST FOR A DAY OR TWO. WHAT KINDS OF GENES GET
5 EXPRESSED. THERE'S A NUMBER OF TYPES OF EXPERIMENTS
6 THAT DON'T HAVE ANYTHING TO DO WITH TRYING TO CREATE A
7 CHIMERIC INDIVIDUAL, BUT HAVE A LOT TO DO WITH GENE
8 EXPRESSION AND CELL POTENTIAL AND CELL VIABILITY. AND
9 YOU'RE JUST GOING TO LOOK AT THEM FOR A DAY OR TWO IN
10 THE LAB.

11 I DON'T THINK YOU WANT TO NECESSARILY NEGATE
12 THOSE KINDS OF EXPERIMENTS. I THINK WHAT YOU WANT TO
13 NEGATE IS THE CONCEPT THAT YOU'RE CREATING AN
14 INDIVIDUAL THAT IS COMPOSED OF THESE TYPES OF CELLS.

15 DR. EGGAN: I THINK, FOR INSTANCE, ONE THING
16 THAT THESE SPECIFIC GUIDELINES DO NOT RULE OUT IS THE
17 POSSIBILITY OF PUTTING THESE CELLS INTO SOME ANIMAL
18 BLASTOCYST. IT'S VERY SPECIFIC ON THIS. AND THE NAS
19 GUIDELINES ARE VERY SPECIFIC ON THIS. I THINK IT'S
20 IMPORTANT TO REALIZE THAT THESE ARE GUIDELINES FOR NOW.
21 AND IT MAY BE SOMEDAY IMPORTANT TO DO THAT TYPE OF
22 EXPERIMENT, BUT NOW, I WOULD ARGUE, IS NOT THE TIME
23 BECAUSE NOW WE COULD, INSTEAD, DO EXPERIMENTS WHERE WE
24 SAY DO EXACTLY WHAT YOU'RE STATING BY PUTTING HUMAN
25 EMBRYONIC STEM CELLS INTO A MOUSE BLASTOCYST WHERE WE

1 FEEL, BASED ON THE BIOLOGY THAT WE KNOW THAT THE
2 LIKELIHOOD OF MEANINGFUL CHIMERA FORMING, EVEN IF THERE
3 WAS SOME MISAPPROPRIATION OF THAT EMBRYO OR TRANSFER OF
4 EMBRYO IN UTERUS, IT'S MINIMUM OR ZERO.

5 SO WE CAN GET A HINT OF WHAT THE ANSWER TO
6 THAT EXPERIMENT BY THIS TYPE OF EXPERIMENT FIRST. AND
7 THEN ONCE THE ANSWER IS KNOWN, IF IT'S THOUGHT THAT
8 THERE IS SOME VERY MEANINGFUL KNOWLEDGE THAT COULD BE
9 GAINED BY DOING THAT TYPE OF EXPERIMENT, THIS ISSUE
10 COULD BE REVISITED IN A THOUGHTFUL WAY.

11 CO-CHAIR LANSING: I AGREE.

12 MR. SHESTACK: THIS WOULD PERMIT --

13 MS. CHARO: WE DO EVERYTHING ANN IS
14 SUGGESTING WITH ANY MAMMAL EXCEPT A PRIMATE. SO WHAT
15 I'M NOT HEARING YET IS WHAT THE ADVANTAGE WOULD BE
16 DOING EXACTLY WHAT YOU OUTLINED IN A PRIMATE AS OPPOSED
17 TO A NONPRIMATE MAMMAL.

18 DR. KIESSLING: OH, LOTS. I CAN UNDERSTAND
19 (D). I CAN UNDERSTAND THAT WE'RE NOT READY FOR (D).
20 BUT I'M NOT SURE THAT THERE'S ANYTHING TO BE GAINED BY
21 (C) BECAUSE YOU'RE NOT GOING TO PUT -- I MEAN THERE'S
22 HEAVY RESTRICTIONS AGAINST PUTTING ANY OF THESE
23 BLASTOCYSTS BACK INTO A UTERUS. WHAT YOU REALLY WANT
24 TO DO IS RESTRICT WHAT YOU DO WITH THE CONSTRUCT, NOT
25 MAKING THE CONSTRUCT.

1 MS. CHARO: I'M STILL NOT SURE I UNDERSTAND
2 WHAT IT IS IN THAT ONE- OR TWO-DAY WINDOW THAT YOU ARE
3 DESCRIBING THAT CAN BE DONE WHEN YOU USE HUMAN-PRIMATE
4 COMBOS AS OPPOSED TO HUMAN-MAMMALIAN COMBOS.

5 DR. KIESSLING: THE MOUSE BLASTOCYST IS VERY
6 DIFFERENT FROM A PRIMATE BLASTOCYST.

7 DR. PETERS: CAN TED GET IN LINE TO SPEAK ON
8 THIS AT SOME POINT?

9 DR. KIESSLING: I'M SORRY?

10 DR. PETERS: FINISH YOUR CONVERSATION.

11 CO-CHAIR LO: WHY DON'T YOU DO IT NOW, TED.

12 DR. PETERS: I THINK I HEAR ANN SPEAKING, AND
13 I THINK I AGREE WITH HER. IT SEEMS TO ME THAT THE
14 INTRODUCTION OF STEM CELLS INTO PRIMATE BLASTOCYSTS IS
15 JUST GOING TO BE SOMETHING THE SCIENTISTS NEED TO DO.
16 I WOULD HATE TO SEE THAT PROSCRIBED. AND WITH THE
17 CAUTIONS THAT I THINK ANN THERE WAS SUGGESTING, THAT
18 MIGHT MEET THE NEEDS OF THOSE PEOPLE WHO ARE OBJECTING.

19 I'VE BEEN LOOKING INTO THE RECENT LITERATURE
20 ON THIS, AND I THINK THE OBJECTIONS TO CHIMERISM ARE
21 HISTORICAL IN CHARACTER. AND I DON'T BELIEVE THAT WE
22 SHOULD CAVE IN TO THAT BECAUSE I THINK THAT THE
23 SCIENTISTS ARE GOING TO NEED TO BE ABLE TO DO THIS KIND
24 OF EXPERIMENTAL RESEARCH.

25 DR. KIESSLING: THANK YOU, TED.

1 CO-CHAIR LANSING: NOT AS A SCIENTIST, I'M
2 VERY NERVOUS ABOUT TAKING ANYTHING OUT OF THE NAS
3 GUIDELINES. I'M REALLY HOPING THAT WHAT WE'RE GOING TO
4 DO IS MAKE THEM STRONGER. AND THIS IS JUST OUR FIRST
5 PASS. AND I'M NOT A SCIENTIST, ANN, SO I CAN'T REALLY
6 RESPOND TO IT, BUT WHAT I FEEL INSTINCTIVELY IS THAT WE
7 NEED TO MAKE THE NAS GUIDELINES, SINCE WE'RE THE FIRST
8 ONE THAT'S DOING THIS, STRONGER, MORE STRINGENT. AND,
9 YOU KNOW, SIX MONTHS FROM NOW, A YEAR FROM NOW,
10 WHATEVER, AS THE SCIENCE PROGRESSES, WE CAN ADAPT IT,
11 BUT I'M VERY NERVOUS ABOUT TAKING SOMETHING OUT.

12 DR. KIESSLING: IS THIS EXACTLY HOW IT'S
13 WORDED IN THE NAS GUIDELINES?

14 MS. CHARO: THIS JUST TRACKS THEM.

15 CO-CHAIR LO: THE NAS GUIDELINES DID PROHIBIT
16 INTRODUCING HUMAN STEM CELLS INTO A NONHUMAN PRIMATE
17 BLASTOCYST.

18 MS. CHARO: WE WENT AROUND ON THIS QUITE A
19 WHILE. IF YOU WANTED MORE BACKGROUND ON IT, THE PEOPLE
20 TO HAVE CALL IN AND TALK TO THE COMMITTEE HERE, I
21 THINK, WOULD BE JANET ROSSETT AND RICHARD HYNES BECAUSE
22 THEY REALLY WENT BACK AND FORTH ON JUST THIS POINT
23 ABOUT HOW CRUCIAL IT WAS AT THIS STAGE OF RESEARCH TO
24 BE DOING IT IN THE PRIMATE BLASTOCYST AS OPPOSED TO
25 OTHER MAMMALIAN BLASTOCYSTS. I'M YOU'RE STILL CURIOUS

1 ABOUT KEVIN'S RESPONSE.

2 SECOND, WHAT THE RISKS WERE IN TERMS OF NOT
3 BEING ABLE TO ADEQUATELY MANAGE THE RESEARCH BECAUSE I
4 THINK EVERYBODY UNDERSTOOD YOUR POINT AND AGREED WITH
5 IT, THAT IN THE END THAT THING THAT MATTERS IS THE
6 NONREPRODUCTIVE USES OF THESE CONSTRUCTS. EVERYBODY
7 AGREED WITH YOU ON THAT. AND THE QUESTION IS SIMPLY
8 HOW FAR BACK INTO THE RESEARCH PROCESS EVERYBODY WANTED
9 TO GO WITH A CHILLING EFFECT TO AVOID THAT OUTCOME.

10 DR. EGGAN: I WOULD JUST SAY, TO BETTER
11 OUTLINE THE EXPERIMENT WHICH ANN IS DESCRIBING, THERE
12 ARE QUESTIONS, PARTICULARLY WITH HUMAN EMBRYONIC STEM
13 CELLS, ABOUT THEIR GENERAL POTENCY TO BECOME A VARIETY
14 OF DIFFERENT CELL TYPES IN EMBRYOS. SO IT'S WELL
15 ESTABLISHED IN MOUSE, FOR INSTANCE, THAT MOUSE
16 EMBRYONIC STEM CELLS HAVE ONLY THE CAPACITY TO, AT
17 LEAST IN VIVO ONCE INJECTED INTO A BLASTCYST, GIVE RISE
18 TO TISSUES OF THE DEFINITIVE EMBRYO, WHICH IS TO SAY
19 THAT IF YOU BLAST THE PART OF THE EMBRYO WHICH, IF
20 ALLOWED TO DEVELOP, WOULD GO ON TO BECOME, SAY, A MOUSE
21 AND A CAGE RUNNING AROUND IT, BUT IT WOULD NOT BECOME A
22 YOKE SAC, THE AMNION, OR THE TROPHECTODERM, THE
23 PLACENTAL TISSUES OF THE MOUSE.

24 THIS IS NOT CLEAR FOR HUMAN EMBRYONIC STEM
25 CELLS, IF IT IS THE CASE, AND THERE ARE MANY THAT

1 BELIEVE THAT HUMAN EMBRYONIC STEM CELLS HAVE THE
2 CAPACITY TO, OF COURSE, NOT PROGRAM ALL OF THE
3 DEVELOPMENT OF A HUMAN EMBRYO BECAUSE THERE ARE SOME
4 THREE-DIMENSIONAL AND SPATIAL CONCERNS WITH DOING THAT,
5 BUT THEY CAN GIVE RISE TO ALL OF THESE DIFFERENT TYPES
6 OF CELLS WITHIN THE EMBRYO, INCLUDING TROPHECTODERMAL
7 CELLS.

8 SO THERE ARE SOME PEOPLE WHO BELIEVE
9 DIFFERENCES IN THE CAPACITY OF THESE CELLS TO
10 DIFFERENTIATE IN THESE TYPES OF EXPERIMENTS WHERE THE
11 CELLS WOULD BE INTRODUCED BACK INTO THE BLASTOCYSTS FOR
12 A SHORT AMOUNT OF TIME AND THEN WATCHED AND THEN SEE
13 WHICH BLASTOCYST THEY HONE TO OR GIVE RISE TO COULD
14 HELP CLARIFY THIS. BUT I THINK THAT THOSE EXPERIMENTS
15 COULD INITIALLY BE DONE IN NONPRIMATE BLASTOCYSTS. AND
16 WITH THE ANSWER IN HAND, WE COULD KNOW MORE ABOUT
17 WHETHER OR NOT IT'S GOING TO BE INFORMATIVE OR
18 NECESSARY TO DO IN A PRIMATE.

19 DR. HALL: SO YOUR CONCLUSION IS YOU THINK
20 IT'S BETTER AT THIS POINT TO LEAVE IT IN AND POSSIBLY
21 TAKE IT OUT LATER OR NOT?

22 DR. EGGAN: I THINK THE QUESTION IS JUST TO
23 WHAT EXTENT ARE WE COMMITTED TO REVISITING THIS ISSUE
24 IN A SERIOUS WAY AS RESEARCH CONTINUES. AND I THINK
25 THAT IF WE ARE, THEN I THINK IT'S NOT HARMFUL TO LEAVE

1 IT AS IS.

2 DR. PETERS: WHEN I HAVE A CHANCE, I'D LIKE
3 TO SPEAK TO THAT. I WOULD LIKE TO SEE (C) SIMPLY
4 DELETED; AND IF WE WANT TO REVISIT IT, LET'S PUT THE
5 BURDEN OF THOSE WHO WANT TO PUT IT IN THERE TO
6 DEMONSTRATE ITS NECESSITY.

7 CO-CHAIR LO: I THINK IT IS AN ISSUE OF WHICH
8 WAY THE PRESUMPTION GOES AND WHO BEARS THE BURDEN OF
9 ARGUMENT. IN THE BIGGER CONTEXT, THE CURRENT STANDARD
10 IS THE NAS GUIDELINES, WHICH WE ADOPTED. SO I THINK
11 THE BURDEN WOULD BE ON ANYONE PROPOSING CHANGES TO
12 THOSE GUIDELINES TO MAKE THE COMPELLING ARGUMENT THOSE
13 GUIDELINES NEED TO BE REVISED.

14 AND FAILING TO MAKE A PRETTY DETAILED AND
15 COMPELLING ARGUMENT WOULD LEAVE US OPEN TO SERIOUS
16 CRITICISMS FROM MEMBERS OF THE PUBLIC WHO JUST DON'T
17 UNDERSTAND THE REASONING. I THINK IF THERE ARE
18 COMPELLING SCIENTIFIC REASONS TO DO THESE EXPERIMENTS
19 AND THERE ARE ADEQUATE SAFEGUARDS IN PLACE, WE NEED TO
20 TALK ABOUT HOW MANY DAYS AND SO FORTH. AND I THINK
21 THERE IS, IN ADDITION TO REPRODUCTIVE ISSUES KEVIN
22 BROUGHT UP, IT STRIKES ME THERE ARE A LOT OF PEOPLE WHO
23 HAVE CONCERNS ABOUT INTERMINGLING THE SPECIES. AND
24 SOME PEOPLE MAY REJECT THOSE CONCERNS, BUT I THINK
25 THEY'RE QUITE WIDESPREAD, AND I THINK THEY NEED TO BE

1 ADDRESSED IN DETAIL BEFORE CHANGES ARE MADE.

2 I WOULD JUST BE CONCERNED ABOUT THIS IS NOT
3 THE TIME TO DO THAT. WE CAN COME BACK TO IT LATER, GET
4 MORE INFORMATION ABOUT WHAT KINDS OF EXPERIMENTS WE'RE
5 TALKING ABOUT, HAVE SOME REQUIREMENT FOR DOING THE WORK
6 FIRST IN NONPRIMATE, NONHUMAN SPECIES. I THINK THERE'S
7 A LOT OF THINGS THAT NEED TO BE THOUGHT THROUGH RATHER
8 THAN TRYING TO DO IT TODAY.

9 DR. PRIETO: I THINK IT WOULD BE MUCH MORE
10 DIFFICULT TO REINTRODUCE THE RESTRICTION LATER ON IF WE
11 REMOVED IT TODAY THAN IT WOULD BE TO LEAVE IT AS IS AND
12 REVISIT THE ISSUE AND DECIDE SIX MONTHS OR TWO YEARS
13 FROM NOW THAT, YES, THAT SHOULD BE REMOVED.

14 CO-CHAIR LANSING: AS THE SCIENCE PROGRESSES.

15 MS. CHARO: ONE OF THE THINGS THAT THE NAS
16 GUIDELINES HAVE IN THEM IS THE PHRASE "AT THIS TIME."
17 SO IT SAYS THAT THIS PARTICULAR RESEARCH SHOULD NOT BE
18 PERMITTED AT THIS TIME. AND THAT WAS CHOSEN VERY
19 DELIBERATELY TO ANTICIPATE THE NEED TO REVISIT THE NAS
20 GUIDELINES, HOWEVER, BEING ONLY GUIDELINES, AND NOT BE
21 SUBJECT TO ELABORATE ADMINISTRATIVE LAW RULES ABOUT HOW
22 ONE REVISES THINGS AND BEING COUPLED WITH THE PROPOSAL
23 FOR A NATIONAL BODY THAT ENGAGE IN THIS PERIODIC
24 REVIEW, WHICH HAS NOT YET BEEN SET UP, BUT IS STILL
25 UNDERWAY.

1 AND SO HERE THE DIFFERENCE IS THIS IS LESS
2 BROAD THAN THE NAS GUIDELINES. IT'S NOT SAYING CERTAIN
3 ACTIVITIES SHOULDN'T BE DONE. IT'S SIMPLY SAYING THAT
4 THEY SHOULDN'T BE FUNDED BY THIS PARTICULAR INSTITUTE.
5 IN THAT SENSE, THIS IS NARROWER. ON THE OTHER HAND,
6 THERE'S NOTHING IN HERE THAT TIME LIMITS THIS. I'M
7 LOOKING AT THE LANGUAGE AND SOMEBODY SAID THE QUESTION
8 IS -- MAYBE IT WAS TED ON THE PHONE -- HOW CONFIDENT
9 ARE WE ABOUT THE COMMITMENT TO REVISIT THIS AS THE
10 SCIENCE GOES.

11 SO I'M LOOKING AT THE LANGUAGE HERE AND I'M
12 LOOKING AT THE EXPERTISE ON HOW TO DRAFT IT IN
13 CALIFORNIA CODE AS TO WHETHER OR NOT ONE CAN WRITE
14 UNDER 100002 THE FOLLOWING ACTIVITIES ARE NOT ELIGIBLE
15 FOR CIRM FUNDING AT THIS TIME.

16 DR. KIESSLING: I DON'T THINK YOU WANT TO
17 MAKE IT THERE BECAUSE THAT INCLUDES (A), BUT YOU COULD
18 CERTAINLY ADD THAT PHRASE TO (C).

19 CO-CHAIR LANSING: AGAIN, I'M SPEAKING AS A
20 LAYPERSON. I THINK IT'S INHERENT IN EVERYTHING THAT
21 WE'VE DONE AS A GROUP THAT THIS GROUP IS COMING BACK
22 AGAIN. IF THIS SEEMS TO BE, AND I RESPECT IT, A VERY
23 IMPORTANT ISSUE, AND AS THE SCIENCE PROGRESSES, WE'RE
24 NOT DISBANDING. THIS IS WHERE -- THIS WHOLE DOCUMENT
25 IS AT THIS TIME. TO SINGLE OUT ONE PIECE OF IT, IT'S

1 THE WHOLE THING.

2 DR. KIESSLING: I UNDERSTOOD THAT IT'S VERY
3 DIFFICULT TO CHANGE THESE REGULATIONS ONCE THEY'RE IN
4 PLACE, THAT IT'S NOT A TRIVIAL UNDERTAKING.

5 MR. TOCHER: THE CHALLENGE OF AMENDING THE
6 REGS IS THE SAME PROCEDURE AS ADOPTING THEM. SO IT
7 WOULD BE A PERIOD OF A NOTICED MEETING THAT WOULD BE
8 HELD IN PUBLIC, PUBLIC INPUT, A 45-DAY WINDOW, AND THEN
9 A FINAL VOTE ON ANY SORT OF AMENDMENT. SO AMENDING IS
10 THE SAME AS ADOPTION. AND THERE'S NO -- I UNDERSTAND
11 THE POLICY POINT OF ADDING SUCH AS AT THIS TIME, IT'S A
12 SIGNAL, BUT IT DOESN'T HAVE ANY LEGAL SIGNIFICANCE.
13 EVERYTHING IN A REGULATION IS THE LAW AT THAT TIME
14 UNTIL IT'S AMENDED.

15 DR. EGGAN: I THINK IT'S STILL AN IMPORTANT
16 SIGNAL THAT WE CAN SEND.

17 CO-CHAIR LANSING: BUT IN MY MIND OUR WHOLE
18 DOCUMENT IS AT THIS TIME. I THINK, YOU KNOW, IT'S
19 BEHOLDEN ON US AT THE END OF THE MEETING AT 1 O'CLOCK
20 TOMORROW TO SET UP ANOTHER MEETING. THAT'S WHAT WE
21 INTENDED TO DO. AND ALL OF US WILL COME AGAIN. I
22 DOUBT THAT THIS WILL BE THE LAST ISSUE AS WE GO THROUGH
23 IT. DO YOU KNOW? AND IT WILL CONTINUE TO EVOLVE.

24 DR. WILLERSON: I WILL LET THE LADY GO FIRST.

25 MS. KING: I WAS JUST GOING TO ASK, SINCE I'M

1 NEW AT THIS, BUT IN THE STATEMENT OF REASONS PRECEDING
2 WHAT BECOMES REGULATION, ARE WE PRECLUDED FROM
3 EMPHASIZING THE INTENT? MAYBE WE SHOULD DO IT, TO
4 REVISIT THIS, NOT THIS PARTICULAR CASE, BUT TO REVISIT
5 WHENEVER THE SCIENCE MOVES FORWARD IN TERMS OF SENDING
6 A SIGNAL ABOUT WHAT THE GROUP INTENDS.

7 CO-CHAIR LO: THAT MAY BE THE PLACE TO DO IT
8 BECAUSE IT APPLIES TO ALL THE REGULATIONS, NOT JUST THE
9 ONE CLAUSE.

10 DR. WILLERSON: YOU COULD WRITE INTO A
11 PREAMBLE FOR THIS, ALL OF THIS IS SUBJECT TO REVIEW AND
12 CHANGE. WE REQUEST THE READERS' SUGGESTIONS,
13 SCIENTISTS' SUGGESTIONS OVER TIME. UNDOUBTEDLY SOME OF
14 THIS WILL CHANGE. THAT WOULD BE ONE WAY TO DO IT. I
15 THINK SHE HAS A GOOD POINT.

16 TOP OF PAGE 3, THE FIRST LINE. DID YOU HEAR
17 THE PREAMBLE PART OF THIS? I WOULD PUT INTO A PREAMBLE
18 THE GENERAL NOTION THAT THIS IS GOING TO BE REVIEWED
19 AND CAN BE CHANGED OVER TIME. AND IF WE INVITE
20 READERS', SCIENTISTS' SUGGESTIONS AS THE SCIENCE MOVES
21 FORWARD ABOUT AREAS THAT SHOULD BE REVIEWED BY THIS
22 COMMITTEE.

23 SECOND, TOP OF PAGE 3, IN ITEM (C) THERE'S
24 ANOTHER REDUNDANCY. IF WE'RE GOING TO DEFINE COVERED
25 STEM CELLS AS BEING HUMAN, THEN WE DON'T NEED TO SAY

1 COVERED STEM CELLS, HUMAN STEM CELL IN A NONHUMAN
2 PRIMATE BLASTOCYST. I THINK WE SHOULD DEFINE COVERED
3 STEM CELLS THE WAY SEVERAL HAVE SUGGESTED.

4 CO-CHAIR LO: ANY OTHER COMMENTS?

5 I WANT TO COME BACK TO ONE ISSUE THAT YOU
6 PERHAPS, KEVIN, RAISED, AND THAT'S (D). THE CURRENT
7 NAS GUIDELINES DO PROHIBIT EITHER HUMAN OR NONHUMAN
8 STEM CELLS, NOT PROHIBIT, BUT THEY OPPOSE TRANSPLANT
9 INTO -- EITHER HUMAN OR NONHUMAN STEM CELLS INTO HUMAN
10 BLASTOCYSTS. AND THERE WAS SOME DISCUSSION, WHICH I
11 WANT TO MAKE SURE WE FOLLOW UP ON, AS TO IN OUR SECTION
12 (D) WHETHER WE WANT TO PROHIBIT WITH CIRM FUNDING
13 INTRODUCING NONHUMAN STEM CELLS INTO HUMAN BLASTOCYSTS.

14 DR. KIESSLING: IF YOU'RE FOLLOWING THE NAS
15 GUIDELINES, THEN YOU MUST. ALL YOU WANT TO DO FOR (D)
16 IS GET RID OF THE WORD "COVERED."

17 CO-CHAIR LANSING: I AGREE.

18 CO-CHAIR LO: THAT'S GOOD. THANK YOU. OTHER
19 COMMENTS?

20 DR. EGGAN: I CAN'T THINK OF A COMPELLING
21 SCIENTIFIC REASON TO INTRODUCE NONHUMAN STEM CELLS INTO
22 A HUMAN BLASTOCYST.

23 CO-CHAIR LO: I WANT TO AT THIS TIME INVITE
24 MEMBERS OF THE PUBLIC TO COMMENT ON SECTION 100002,
25 WHAT WE'VE JUST BEEN DISCUSSING, (A) THROUGH (E).

1 THESE ARE SOME PRETTY IMPORTANT TOPICS.

2 MR. SIMPSON: MY NAME IS JOHN SIMPSON. I'M
3 WITH THE FOUNDATION FOR TAXPAYER AND CONSUMERS RIGHTS.
4 I JUST WANTED TO UNDERSCORE WHAT I UNDERSTOOD THE
5 CO-CHAIRMAN TO BE SAYING ABOUT HOW CRITICAL IT WOULD BE
6 THAT YOU STAY WITH THE NAS GUIDELINES AT THIS TIME,
7 PARTICULARLY FOR RESEARCH THAT'S PUBLICLY FUNDED. JUST
8 IT SEEMS TO ME ESSENTIAL THAT YOU DO THAT. IT DOESN'T
9 PRECLUDE OTHER THINGS GOING ON, AND IT CERTAINLY
10 DOESN'T PRECLUDE REVISITING IT AS THE SCIENCE IS
11 DEVELOPED, BUT I JUST THINK, FROM A POLICY POINT OF
12 VIEW AND EVEN FROM A PUBLIC RELATIONS POINT OF VIEW, IT
13 WOULD BE ESSENTIAL THAT YOU STICK WITH THOSE.

14 CO-CHAIR LO: THANK YOU. OTHER COMMENTS?
15 WE'VE GOT A NUMBER OF PEOPLE, SO WE'LL JUST GO IN TURN.

16 MR. REED: DON REED. I WONDER ABOUT THE
17 POSSIBILITY OF PUTTING AN ACTUAL TIME LIMIT ON
18 SOMETHING LIKE THIS. THIS SEEMS IMPORTANT. I THINK
19 WHAT IF WE HAVE, LIKE, SAY, BECAUSE OF CONCERNS, WE
20 CURRENTLY FAVOR A MORATORIUM ON FUNDING THIS RESEARCH,
21 BUT WANT TO COME BACK. I LIKE THE IDEA OF BEING CLEAR
22 THIS IS SOMETHING THAT WE'RE NOT BRANDING AS ILLEGAL
23 FOR ALL TIME.

24 CO-CHAIR LANSING: I'M TRYING TO SAY THERE'S
25 NO TIME LIMIT ON THIS COMMITTEE. SO WE'RE GOING TO

1 JUST KEEP DOING THIS ALL THE TIME. NOBODY LIKES WHEN I
2 SAY THAT. IT'S TRUE. THIS IS LIKE A LIFE'S WORK. THE
3 SCIENCE IS MOVING SO FAST.

4 MR. REED: I TOTALLY UNDERSTAND AND AGREE,
5 AND THAT'S ABSOLUTELY BEEN TRUE ALL THE WAY ALONG THE
6 LINE. AT THE SAME TIME I ALSO KNOW THAT ALL THESE
7 DIFFERENT STEPS THAT HAVE TO BE GONE THROUGH, THE TIME
8 RESTRAINTS. AND I JUST FEEL LIKE THIS IS GOING TO BE A
9 DOCUMENT THAT'S GOING TO BE LOOKED UPON AS WRITTEN IN
10 STONE. AND THOSE PEOPLE WHO DON'T LIKE US ARE GOING TO
11 FIND REASON TO ATTACK US NO MATTER WHAT. SO I THINK WE
12 OUGHT TO TRY AND MAKE IT BE AS RIGHT AS WE POSSIBLY CAN
13 RATHER THAN TRY AND ANTICIPATE THE OBJECTIONS AND CAVE
14 THEM FIRST.

15 MS. GREENFIELD: DEBORA GREENFIELD. I THINK
16 (A) IS VERY AMBIGUOUS. AND I WAS WONDERING IF THERE
17 WAS ANY MORE THOROUGHLY DETAILED DESCRIPTION OF
18 REPRODUCTIVE USES.

19 CO-CHAIR LO: THIS IS THE FIRST PROHIBITION.

20 MR. REYNOLDS: JESSE REYNOLDS. A FEW QUICK
21 POINTS. I'D LIKE TO REITERATE THE POINT MADE BY
22 MR. SIMPSON ABOUT BEING CONSISTENT WITH THE GUIDELINES
23 OF THE NATIONAL ACADEMIES BECAUSE, OF COURSE, PART OF
24 THE PROBLEM THAT'S BEING FACED RIGHT NOW IN THE FIELD
25 OF STEM CELL RESEARCH IS HAVING A PATCHWORK OF PRIVATE

1 FUNDING VERSUS WHAT'S AVAILABLE FOR FEDERAL FUNDING AND
2 SO FORTH. SO I'D ENCOURAGE YOU TO BE CONSISTENT WITH
3 THE FEDERAL POLICIES IN THE SAME WAY THAT THE IP POLICY
4 WAS TRYING TO BE CONSISTENT, BUT NOT NECESSARILY
5 FOLLOWED TO THE LETTER OF BAYH-DOLE.

6 SECOND, I'D LIKE TO SECOND THE POINT OF
7 MS. GREENFIELD ABOUT SOME CLARIFICATION ABOUT
8 REPRODUCTIVE PURPOSES.

9 AND FINALLY, ON POINT (B) HERE WITHIN THIS
10 SECTION, THE PHRASE "REGARDLESS OF DERIVATION METHOD"
11 HAS BEEN STRUCK OUT. AND WHAT THIS BRINGS UP IS THAT
12 THE PHRASE "EMBRYO" HAS NOT BEEN DEFINED. I CERTAINLY
13 DON'T MEAN TO OPEN THE WRONG CAN OF WORMS, BUT THE CAN
14 OF WORMS THAT I DO WANT TO ADDRESS IS WHETHER THE
15 PRODUCT OF SOMATIC CELL NUCLEAR TRANSFER IS AN EMBRYO.
16 SOME SCIENTISTS SAY YES AND SOME SCIENTISTS SAY NO. IN
17 ORDER TO CLARIFY REPRODUCTIVE USES, FOR EXAMPLE, YOU'LL
18 NEED TO DESCRIBE WHAT THE PRODUCT OF SCNT IS. THANK
19 YOU.

20 CO-CHAIR LO: YOUR COMMENTS ON (A) AND (B)
21 ARE LANGUAGE?

22 MR. REYNOLDS: YES.

23 MR. TAYMOR: KEN TAYMOR. YOU DON'T HAVE A
24 DEFINITION OF A COVERED STEM CELL. IT'S COVERED STEM
25 CELL LINES. SO YOU MAY WANT TO SAY STEM CELLS DERIVED

1 FROM THE COVERED STEM CELL LINES IN THOSE SECTIONS
2 WHERE YOU'VE USED THE TERM "COVERED STEM CELL" OR HAVE
3 A DEFINITION, PARTICULARLY IN LIGHT OF THE CONVERSATION
4 EARLIER THAT THERE'S A VERY IMPORTANT DISTINCTION
5 BETWEEN A STEM CELL AND A STEM CELL LINE.

6 AND FOLLOWING UP ON THIS QUESTION OF THE
7 REPRODUCTIVE USES, YOU HAVE IN (E) RESEARCH LEADING TO
8 BREEDING, IN A SENSE RESEARCH LEADING TO REPRODUCTIVE
9 USE. AND (A) YOU SPECIFICALLY IDENTIFY REPRODUCTIVE
10 USE. I THINK IT WOULD BE, AT LEAST IN ANSWERING THE
11 QUESTION ABOUT WHETHER REPRODUCTIVE USES OF SCNT SHOULD
12 BE MODIFIED, YOU READ IT IN LIGHT OF (E) AND HOW PEOPLE
13 IN THE FUTURE WHO ARE CRITICIZING THESE REGULATIONS IN
14 THE ABSTRACT MAY BE COMPARING THESE TWO ELEMENTS.

15 AND PARTICULARLY YOU DID RECEIVE THE -- CIRM
16 RECEIVED A LETTER EARLIER THIS YEAR ON THE QUESTION OF
17 WHETHER TRAINING GRANTS COULD BE TIED TO SOME TYPE OF
18 COMMITMENT FOR THE RECIPIENTS NOT TO ENGAGE IN ANY
19 REPRODUCTIVE USES -- FOR SCNT-TYPE REPRODUCTIVE USES.
20 I'M AGNOSTIC AS TO THAT QUESTION, BUT I THINK THAT THE
21 PUBLIC AT SOME POINT WARRANTS A RESPONSE.

22 CO-CHAIR LO: WE'VE HAD SEVERAL COMMENTS
23 REQUESTING THAT WE CLARIFY WHAT EXACTLY WE'RE
24 PROHIBITING WITH FUNDING IN TERMS OF REPRODUCTIVE USES.
25 AND THEY ALL SORT OF ARE RELATED AND FIT TOGETHER, AND

1 WE NEED TO TURN OUR ATTENTION.

2 DR. EGGAN: JUST TO CLARIFY ON THIS LAST
3 POINT, (A) AND (E) ARE DESIGNED IN PRINCIPLE TO
4 SAFEGUARD TWO DIFFERENT SORTS OF CONCERNS. ONE IS THE
5 CONCERN THAT SOMEONE WOULD USE SOMATIC CELL NUCLEAR
6 TRANSPLANTATION TO REPRODUCTIVELY CLONE A HUMAN BY
7 TAKING THAT BLASTOCYST AND PUTTING IT INTO A WOMAN'S
8 UTERUS AND CAUSING A CLONED CHILD TO BE BORN.

9 (E) IS A TOTALLY SEPARATE CONCERN, AND THAT
10 IS BECAUSE OF THE GENERALIZED POTENTIAL OF COVERED STEM
11 CELL LINES, THERE IS A FEAR THAT AFTER TRANSPLANT INTO
12 THE ANIMAL, THAT THOSE CELLS COULD GIVE RISE TO GAMETES
13 WITHIN THOSE ANIMALS. THAT IS, THAT THEY COULD, SAY,
14 FOR WHATEVER BIOLOGICAL PROPERTY, HOME TO THE OVARY OF
15 THE TESTES OF THOSE ANIMALS AND THERE MAKE EGG AND
16 SPERM. AND THEN AS HUMAN EGG AND SPERM IN THE CONTEXT
17 OF THAT ANIMAL OVARY, AS LOW AS THE SCIENTIFIC
18 PROBABILITY OF THAT BEING, THEY COULD BE RELEASED WITH
19 OTHER GAMETES, AND THEY COULD COME IN CONTACT WITH
20 OTHER ANIMAL GAMETES AFTER MATING. AND, AGAIN, AS LOW
21 AS THE PROBABILITY MIGHT BE OF CROSS FERTILIZATION,
22 THERE IS THE POSSIBILITY, ALBEIT AGAIN EXTREMELY LOW,
23 THAT ONE COULD MAKE A HYBRID HUMAN-ANIMAL CONCEPTUS.
24 THAT'S WHAT (E) IS SPECIFICALLY DESIGNED TO PROHIBIT,
25 AS I UNDERSTAND IT, IN THE WAY THIS DRAFTED.

1 I THINK THAT THEY'RE VERY DIFFERENT TYPES OF
2 CONCERNS, BUT BOTH WERE DECIDEDLY IMPORTANT BY THE NAS
3 GUIDELINES.

4 CO-CHAIR LO: I THINK THAT'S VERY CLEAR AND
5 VERY HELPFUL.

6 TO PICK UP ON WHAT YOU SAID WITH REGARD TO
7 (A), ONE OF THE SPECIFIC THINGS WE'RE CONCERNED ABOUT
8 IS ANY ATTEMPT TO TRANSFER A SCNT-PRODUCED CELL INTO A
9 WOMAN'S UTERUS.

10 DR. TAYLOR: HUMAN REPRODUCTIVE USES OF SCNT
11 AND WE SPECIFIED.

12 CO-CHAIR LO: I GUESS THE CONCERN WAS WHAT DO
13 WE MEAN BY REPRODUCTIVE USES. ARE WE REALLY TALKING
14 ABOUT IMPLANTATION OR PRIOR TO IMPLANTATION? IS THAT
15 WHAT WE'RE TRYING TO FORBID HERE?

16 MS. CHARO: WELL, TWO THINGS. ONE ON (A) AND
17 ONE ON (D). ON (A), WITHOUT HAVING THE TEXT OF THE
18 CALIFORNIA CONSTITUTIONAL LANGUAGE IN FRONT OF ME, IT'S
19 A LITTLE BIT HARD. AFTER A NUMBER OF CONGRESSIONAL
20 EFFORTS HAVE BEEN MADE TO INTRODUCE BILLS, CONSISTENTLY
21 THEY WIND UP FOCUSING ON A PROHIBITION ON THE TRANSFER
22 OF A HUMAN SCNT, QUOTE, EMBRYO INTO A UTERUS, WHETHER
23 HUMAN OR NONHUMAN UTERUS, BECAUSE THEY RECOGNIZE THAT
24 TRANSFER IS THE KEY POINT AT WHICH YOU MOVE FROM PURELY
25 LABORATORY EXPERIMENTS TO SOMETHING THAT HAS AT LEAST A

1 THEORETICAL RISK OF RESULTING IN A LIVE BIRTH.

2 AND SO WE COULD REWRITE THIS TO FOCUS ON
3 THAT, BUT WITH SOME CARE BECAUSE, AND THIS IS WHY I
4 MENTION (E) AS WELL, OFTEN THE LANGUAGE GETS A LITTLE
5 BIT MUDDY WHEN YOU TALK ABOUT THINGS THAT ARE INTENDED
6 TO. AND WE WANT TO AVOID THAT AND FOCUS ON THE ACTIONS
7 AS OPPOSED TO THE UNDERLYING INTENT BECAUSE WE CAN'T
8 READ SOMEBODY'S MIND. AND WE HAVE THE SAME PROBLEM, I
9 REALIZE, AS I'M READING AND READING THESE THINGS
10 CREEPING INTO (E), WHERE WE TALK ABOUT RESEARCH THAT'S
11 LEADING TO OR RESULTING IN THE BREEDING. THEY WANT TO
12 FOCUS MORE ON THE ACTIONS; THAT IS, RESEARCH THAT DOES
13 BREED OR WHATEVER LANGUAGE WE WANT TO FOCUS ON.

14 DR. HALL: BREEDING, START WITH BREEDING OF
15 ANY ANIMAL INTO WHICH COVERED STEM CELLS HAVE BEEN
16 INTRODUCED.

17 MS. CHARO: IT KEEPS IT NICE AND SIMPLE.

18 DR. EGGAN: IT DOES. AND I THINK IT'S
19 IMPORTANT TO NOTE HERE, AS A SCIENTIST, THAT THIS IS AN
20 AREA WHERE, AGAIN, LIKE IN (C) AND (D) OF THE SAME
21 SECTION, THIS IS AN AREA WHERE SCIENTISTS ARE
22 VOLUNTARILY GIVING UP GROUND WHICH COULD BE VERY
23 SCIENTIFICALLY VALUABLE IN EXCHANGE FOR PREVENTING THIS
24 SORT OF EXTREME RISK. FOR INSTANCE, THERE ARE ALMOST
25 CERTAINLY MANY HORMONALLY INDUCED EVENTS THAT WOULD

1 ALTER THE FUNCTION OF STEM CELLS WITHIN AN ANIMAL THAT
2 WE'LL NO LONGER BE ABLE TO OBSERVE, AT LEAST
3 TEMPORARILY, BECAUSE OF THIS PROHIBITION AGAINST
4 BREEDING, THE HORMONAL EFFECTS THAT PREGNANCY HAS ON A
5 FEMALE ANIMAL.

6 DR. KIESSLING: DOES ARTICLE 35, SECTION 3
7 CLARIFY (A)?

8 MR. LOMAX: YES, IT DOES. I CAN READ THAT
9 LANGUAGE SO WE HAVE IT FOR THE BENEFIT OF THE RECORD.
10 WE CAN REFERENCE HUMAN REPRODUCTIVE CLONING, AND IT'S
11 CONSISTENT WITH THE DESCRIPTION ALTA PROVIDED, WHICH IS
12 HUMAN REPRODUCTIVE CLONING MEANS THE PRACTICE OF
13 CREATING OR ATTEMPTING TO CREATE A HUMAN BEING BY
14 TRANSFERRING A NUCLEUS FROM THE HUMAN CELL INTO AN EGG
15 CELL FROM WHICH THE NUCLEUS HAS BEEN REMOVED FOR THE
16 PURPOSE OF IMPLANTING THE RESULTING PRODUCT IN A UTERUS
17 TO INITIATE PREGNANCY. THAT'S THE EXISTING DEFINITION,
18 WHICH, IF IT'S SATISFACTORY TO THE COMMITTEE, WE CAN
19 REFERENCE THROUGH CITATION AND NOT HAVING TO THEN
20 RESTATE.

21 CO-CHAIR LANSING: IT THINK THAT'S A GOOD
22 IDEA. I THINK IT'S A VERY GOOD IDEA.

23 CO-CHAIR LO: BECAUSE THIS IS SUCH AN
24 IMPORTANT POINT, CAN I ASK THOSE OF YOU IN THE PUBLIC
25 WHO BROUGHT THIS VERY SHARPLY TO OUR ATTENTION, WOULD

1 THAT LANGUAGE OF PROHIBITING THE TRANSFER INTO A UTERUS
2 ADDRESS YOUR CONCERNS ABOUT THE AMBIGUITY THAT'S NOW IN
3 THE LANGUAGE? A NUMBER OF YOU COMMENTED.

4 MR. REYNOLDS: YES. I THINK IT WOULD SATISFY
5 MY CONCERNS ABOUT THE REPRODUCTIVE USES, BUT THERE'S
6 STILL A SLIGHT LINGERING CONCERN WITHIN (B) ITSELF
7 ABOUT THE NUMBER OF DAYS THAT AN EMBRYO CAN BE CULTURED
8 IN VITRO. AND I JUST THINK IT NEEDS SOME CLARIFICATION
9 ABOUT WHETHER THAT APPLIES TO THE PRODUCT OF SCNT OR
10 NOT AS WELL. THAT'S A SMALLER CONCERN THAN CLARIFYING
11 REPRODUCTIVE CLONING. I THINK REFERRING TO THE
12 LANGUAGE IN PROP 71 IS APPROPRIATE.

13 CO-CHAIR LO: YOU ARGUE THAT THE PRODUCT OF
14 SCNT IS NOT AN EMBRYO, THEN THE 12-DAY LIMIT.

15 MR. REYNOLDS: EXACTLY. IF I WERE ASKED FOR
16 AN OPINION, I THINK THE STATEMENT IN (B) SHOULD APPLY
17 TO BOTH THE PRODUCT OF FERTILIZATION AND THE PRODUCT OF
18 SCNT.

19 DR. HALL: COULD WE USE THE TERM
20 "BLASTOCYST"?

21 MR. REYNOLDS: ONCE AGAIN, SOME SCIENTISTS --
22 I'VE HEARD A NUMBER OF SCIENTISTS SAY THAT THE PRODUCT
23 OF SCNT IS NOT A BLASTOCYST. IT'S NOT AN EMBRYO.

24 DR. HALL: I'VE NEVER HEARD ANYBODY SAY IT'S
25 NOT A BLASTOCYST.

1 MR. REYNOLDS: OKAY. I MIGHT BE WRONG. FOR
2 THE PURPOSES OF CLARITY, I ENCOURAGE YOU TO INCLUDE THE
3 PRODUCT OF SCNT.

4 MS. GREENFIELD: AND I WOULD ADD NOT JUST
5 HUMAN UTERUS, BUT ARTIFICIAL UTERUS.

6 CO-CHAIR LO: ANY UTERUS. GOOD POINT.

7 MR. REED: DR. KIESSLING HAS A TERM "OVASOME"
8 FOR THE PRODUCT OF SCNT. I THINK THAT'S ABSOLUTELY
9 PERFECT FOR WHAT WE'RE TALKING ABOUT. OVASOME, THERE'S
10 NO SPERM, THERE'S NO IMPLANTATION IN THE WOMB. IT'S
11 NOT AN EMBRYO. SO I THINK WE COULD GET AWAY FROM
12 EMBRYO COMPLETELY.

13 DR. HALL: I AGREE ABOUT THE TERM "EMBRYO,"
14 BUT I THINK THE POINT HERE IS BEYOND SCNT. IF YOU SAY
15 THE CULTURE IN VITRO OF ANY INTACT HUMAN BLASTOCYST
16 PRODUCED HOWEVER.

17 MR. REED: SO WE'RE JUST AVOIDING THE
18 IMPLANTATION.

19 DR. HALL: BY IVF OR BY SCNT, EITHER ONE.
20 THE POINT IS YOU DON'T TO CULTURE --

21 DR. EGGAN: THIS JUST HAS TO BE WORDED IN
22 SUCH A WAY THAT RECOGNIZES THAT THE BLASTOCYST STAGE OF
23 EMBRYO GENESIS, ALBEIT A MORPHOLOGICAL STAGE, WHICH
24 WOULD INCLUDE ALL THESE THINGS THAT WE'RE TALKING ABOUT
25 PRESUMABLY, IS A TRANSIENT ONE THAT THE EMBRYO WILL

1 PASS THROUGH, AND IT WILL NO LONGER BE A BLASTOCYST AT
2 THESE LATER STAGES OF DEVELOPMENT THAT WE'RE CONCERNED
3 ABOUT. IT WOULD BE IMPLANTING EMBRYOS UNDERGOING
4 THINGS LIKE GASTRULATION. IT WILL BE A PRIMITIVE
5 STREAK EMBRYO. IT WILL NO LONGER BE A BLASTOCYST. IF
6 YOU'RE GOING TO CRAFT THE LANGUAGE HINGING ON THAT
7 TERM, THAT HAS BEEN TAKEN INTO CONSIDERATION.

8 THIS IS AN IMPORTANT ISSUE BECAUSE, FOR
9 INSTANCE, THE LINCHPIN OF THE MASSACHUSETTS LEGISLATION
10 WHICH ALLOWS SCNT TO GO FORWARD RESTS ON THE DECISION
11 ON THE STATE LEGISLATURE, THAT INDEED THIS THING IS NOT
12 AN EMBRYO OF THE SAME SORT WHICH IS FORMED BY IN VITRO
13 FERTILIZATION.

14 DR. HALL: DO YOU HAVE A SUGGESTION FOR
15 LANGUAGE, KEVIN?

16 DR. KIESSLING: WHY COULDN'T YOU JUST INCLUDE
17 OR SCNT. THE CULTURE OF ANY INTACT HUMAN EMBRYO OR
18 PRODUCT OF SCNT. I WOULD LIKE TO HAVE THE TERM ADOPTED
19 THAT WE COINED SOME YEARS AGO BECAUSE DON THINKS IT'S A
20 VERY USEFUL TERM, BUT IT HASN'T BEEN ADOPTED YET. I
21 THINK, ALTHOUGH IT COULD BECOME A VERY USEFUL TERM, AND
22 I WOULD LIKE TO PROMOTE IT, IT ISN'T AT THE MOMENT.

23 MR. REED: MY THOUGHT IS THAT WHY NOT USE
24 SOMETHING THAT EXACTLY SUITS THE NEW REALITY? A
25 PRODUCT OF SCNT IS NOT AN EMBRYO. UNLESS YOU WANT TO

1 CALL A JET PLANE A CAR BECAUSE IT HAS WHEELS. THERE'S
2 SIMILARITIES, BUT IT'S NOT THE SAME THING. I THINK WE
3 NEED TO RECOGNIZE THAT DIFFERENCE.

4 DR. HALL: WHAT IF WE USE THE TERM "HUMAN
5 EMBRYO" OR PRODUCT OF SCNT?

6 DR. EGGAN: OR PARTHENOGENESIS OR
7 ANDROGENESIS. THESE ARE THE METHODOLOGIES THAT WE CAN
8 IMAGINE, I THINK.

9 MS. CHARO: YOU KNOW, I DO COMPLETELY
10 APPRECIATE WHY PEOPLE ARE SETTling ON THIS SOLUTION,
11 AND I'M NOT NECESSARILY OPPOSED TO IT, ALTHOUGH I THINK
12 WE DO NEED TO RECOGNIZE THAT BY PHRASING IT AS EMBRYO
13 OR PRODUCT OF SCNT, WE ARE IMPLICITLY ENDORSING THE
14 VIEW THAT THE PRODUCT OF SCNT IS NOT AN EMBRYO, WHICH
15 IS FINE. WE NEED TO RECOGNIZE THAT THAT'S WHAT WE'RE
16 STEPPING INTO, WHICH IS A KIND OF PUBLIC RELATIONS
17 MORASS.

18 BUT EVEN MORE SUBSTANTIVELY, THE REASON FOR
19 NOT CULTURING THESE ENTITIES IS IN LARGE PART BECAUSE
20 OF THE SENSE THAT THEY HAVE DEVELOPMENTAL POTENTIAL
21 UNDER CERTAIN CIRCUMSTANCES. AND IF, IN FACT, PRODUCT
22 OF SCNT AND THE PRODUCT OF ANDROGENESIS AND THE PRODUCT
23 OF PARTHENOGENESIS DOES NOT, IN FACT, DEVELOPMENT
24 POTENTIAL, AT A SUBSTANTIVE LEVEL THESE LIMITS DON'T
25 ACTUALLY MAKE A LOT OF SENSE FOR THESE ENTITIES.

1 POLITICALLY WE MAY NOT TO WANT GO THERE. IT MIGHT BE
2 MUCH SIMPLER, BUT IT'S AT LEAST HELPFUL TO RECOGNIZE IN
3 ONE'S MIND THE CONNECTION BETWEEN WHY YOU ARE MAKING A
4 PROHIBITION AND WHETHER OR NOT THAT PROHIBITION
5 ACTUALLY APPLIES IN THIS AREA.

6 DR. EGGAN: THE PROBLEM IS THAT WITH
7 PARTHENOGENESIS NOW AFTER MANIPULATION IN MOUSE AND
8 WITH SCNT, IT, FRANKLY, IS POSSIBLE TO MAKE AN ENTIRE
9 ANIMAL BY THESE METHODOLOGIES. IT IS, ANN. I
10 COMPLETELY AND CATEGORICALLY DISAGREE WITH YOU. THE
11 FACT OF THE MATTER IS THAT DOLLY WAS ALIVE AND WAS A
12 SHEEP. I THINK THIS IS GOING TO BE THE PUBLIC
13 RELATIONS NIGHTMARE THAT I THINK WE WOULD HAVE TO DEAL
14 WITH IF YOU CALL SCNT THING NOT CAPABLE OF BECOMING.

15 DR. KIESSLING: THAT'S DIFFERENT FROM A
16 PARTHENODE.

17 CO-CHAIR LO: I SUGGEST THAT WE USE SHERRY'S
18 AND ALTA'S CONCEPT OF AT THIS TIME AND WORK IN
19 PROGRESS. IF LATER THERE'S EVIDENCE THAT ANY OF THOSE
20 ENTITIES, IN FACT, DOES NOT HAVE DEVELOPMENTAL
21 POTENTIAL, SOLID SCIENTIFIC EVIDENCE, THAT WOULD GIVE
22 US WARRANT TO GO BACK AND READDRESS. AT THE CURRENT
23 TIME, GIVEN THE UNCERTAINTY AND AT LEAST THE SUGGESTION
24 THAT IN THE CASE OF SCNT THAT THERE IS FULL
25 DEVELOPMENTAL POTENTIAL, THAT WE KEEP THIS INTACT. AS

1 WITH EVERYTHING ELSE, THIS CAN ALWAYS BE REVISITED AS
2 THE SITUATION ARISES.

3 DR. PRIETO: WITHOUT THE ADDITIONAL LANGUAGE?

4 DR. WAGNER: THIS MAY SOUND STUPID, BUT UNDER
5 LETTER (B), DO WE HAVE TO USE THE WORD -- DO WE HAVE TO
6 PUT THE WORD IN THERE "INTACT"? AGAIN, LOOKING FOR
7 WAYS THAT PEOPLE MIGHT UTILIZE THIS AS AN OPT OUT OR AS
8 A WAY OF GETTING BEYOND THE INTENT OF THIS, ALTHOUGH
9 IT'S SORT OF SEMANTICS, BUT WHEN WE ACTUALLY DO CULTURE
10 OF EMBRYOS AND YOU ACTUALLY DO FREQUENTLY DISRUPT ONE
11 ZONE OF AN OOCYTE, WILL THAT EVER BE CONSIDERED A WAY
12 OF MAKING THAT NOT INTACT? WILL THAT SOMEHOW
13 INTERPRET --

14 DR. EGGAN: TO SPEAK TO THAT POINT, THE
15 EMBRYO IS GOING TO ESCAPE SHORTLY AFTER THAT ANYWAY.

16 DR. WAGNER: IT WILL. IT HAS TO.

17 DR. EGGAN: ALSO, I THINK IT'S IMPORTANT THAT
18 THIS INTACT IS KEY BECAUSE, FOR INSTANCE, PORTIONS OF
19 THE HUMAN EMBRYO ARE CULTURED ONWARDS FOR LONGER THAN
20 12 DAYS IN THE PROCESS OF DERIVING EMBRYONIC STEM CELL
21 LINES. THAT WORD IS CHOSEN AND PLACED THERE FOR A VERY
22 PARTICULAR REASON; THAT IS, TO ALLOW THE RESEARCH TO
23 HAPPEN.

24 CO-CHAIR LO: SO THE INNER CELL MASS IS A
25 NONINTACT PART OF AN EMBRYO.

1 DR. WAGNER: I WAS GOING TO LOOK AT IT THE
2 OTHER WAY AROUND, JUST TRYING TO MAKE SURE THAT SOMEHOW
3 IT'S NOT USED AGAINST WHAT THE INTENT OF THIS IS
4 SUPPOSED TO BE.

5 CO-CHAIR LO: ANY OTHER COMMENTS? SO, AGAIN,
6 I SUGGEST THAT WE ACTUALLY WRITE UP LANGUAGE FOR (A)
7 AND, AGAIN, COME BACK AND SEE IT WHEN WE HAVE ACTUAL
8 TEXT. SO WE GIVE GEOFF AND KATE AND STAFF SOME TASKS
9 TO DO.

10 WE'RE WORRIED ABOUT THE PHYSICAL WELL-BEING
11 OF THE PUBLIC, THE WORKING GROUP MEMBERS, AND THE
12 PUBLIC IN TERMS OF LUNCH. AND LUNCH FOR WORKING GROUP
13 MEMBERS IS AT 12:15 ON THE UPPER PATIO OUTSIDE. IT'S
14 OUTSIDE, SO IT MIGHT BE BEST TO GET THERE AS SOON AS
15 POSSIBLE AT 12:15 SO THAT WE DON'T HAVE ANY SPOILAGE OF
16 PERISHABLE FOODS.

17 MEMBERS OF THE PUBLIC CAN GO TO THE HOTEL
18 RESTAURANT OR AN OUTSIDE EATERY. SO AT 12:15 YOU
19 ABSOLUTELY NEED TO PULL MY MICROPHONE. AT 12:15.

20 LET'S MOVE ON TO SECTION 100003,
21 INSTITUTIONAL ASSURANCES OF COMPLIANCE. AGAIN, WE'RE
22 PUTTING THE BURDEN ON THE INSTITUTION TO ACTUALLY
23 TECHNICALLY GET THE CIRM FUNDING, TO PROVIDE EVIDENCE
24 OF THEIR COMPLYING TO THE REQUIREMENTS IN THIS CHAPTER.
25 AND AT A MINIMUM WE'RE ASKING FOR (A), (B), (C), (D).

1 AN INSTITUTIONAL OFFICIAL TO BE RESPONSIBLE, DESIGNATE
2 AN ESCRO COMMITTEE, DESIGNATE AN IRB WHERE THAT'S
3 INVOLVED, AND, (E), ENSURE THAT CLINICAL PERSONNEL THAT
4 HAVE A CONSCIENTIOUS OBJECTION TO STEM CELL RESEARCH
5 NOT BE REQUIRED TO PARTICIPATE IN THE PROCUREMENT OF
6 BIOLOGICAL MATERIALS TO DERIVE STEM CELL LINES, BUT NOT
7 TO THE ACTUAL CARE OF THE DONOR RECIPIENT.

8 SO COMMENTS ON THIS SECTION FROM THE
9 COMMITTEE?

10 MR. SHEEHY: I JUST HAVE A QUESTION PROBABLY
11 FOR ZACH. WE DO HAVE A PLAN AT SOME POINT TO TRY TO
12 SET UP AN INSTITUTION, DESIGNATED INSTITUTIONAL ESCRO
13 SO THAT PER CIRM, AS WE DISCUSSED, THAT THERE MIGHT BE
14 ONE THAT WE DESIGNATED OR SET UP TO KIND OF CATCH. IF
15 SOMEONE DOESN'T HAVE AN ESCRO.

16 DR. HALL: YES. SO THEY --

17 MR. SHEEHY: THE POINT, AND WE TALKED ABOUT
18 THIS THE LAST TIME WE WERE IN LOS ANGELES, IS THAT
19 HAVING AN ESCRO SHOULD NOT BE A BARRIER TO ENTRY TO
20 PARTICIPATION IN STEM CELL RESEARCH, ESPECIALLY -- I
21 KNOW THIS IS INTO THE FUTURE, BUT A FOR-PROFIT ENTITY
22 WOULDN'T NECESSARILY SET UP AN ESCRO BEFORE YOU
23 COMPETED FOR A GRANT, AND YOU CAN'T COMPETE FOR A GRANT
24 UNLESS YOU HAD A ESCRO, SO IT'S THIS CATCH 22 SITUATION
25 OF HAVING TO GO TO THE EXPENSE OF SETTING UP AN ESCRO

1 WITHOUT HAVING RECEIVED A GRANT THAT WOULD MAKE THAT
2 ECONOMICALLY RATIONAL.

3 DR. HALL: SO IT'S POSSIBLE TO WORK OUT
4 ARRANGEMENTS WITH INSTITUTIONS THAT HAVE THEM, AND WE
5 ALLOW FOR THAT. WE ALLOW FOR INSTITUTIONS TO POOL
6 TOGETHER IF THEY WANT TO, BUT WE OURSELVES DO NOT WANT
7 TO BE IN THE ESCRO BUSINESS. I THINK WE DON'T HAVE THE
8 EXPERTISE. THAT PUTS US IN A WHOLE DIFFERENT CATEGORY,
9 AND I THINK MY OWN VIEW ALWAYS HAS BEEN THAT OUR JOB IS
10 TO COORDINATE, TO HELP. I DON'T THINK, JEFF, YOU
11 CORRECT ME AND BERNIE, BUT AT THE MEETING THAT WE
12 HEARD -- FOR-PROFITS MAY BE A DIFFERENT. THAT'S A
13 DIFFERENT SITUATION. BUT AT THE MEETING WE HEARD FOR
14 NONPROFIT RESEARCH INSTITUTIONS, I DON'T THINK WE HEARD
15 ANY DESIRE THAT WE SET UP AN ESCRO. DID YOU?

16 MR. LOMAX: NO. IT WAS ORIENTED -- THE
17 RESEARCH INSTITUTIONS WERE IN THE PROCESS, FOR THE MOST
18 PART, OF CONSIDERING OR LOOKING FOR GUIDANCE ON HOW TO
19 GO ABOUT SETTING THEM UP.

20 DR. HALL: I DON'T KNOW FOR A FOR-PROFIT
21 COMPANY HOW THAT WOULD WORK. I THINK THAT'S SOMETHING
22 WE'LL HAVE TO DEAL WITH, BUT I DON'T WANT FOR US TO BE
23 IN THE POSITION -- I MEAN THE ESCRO COMMITTEE IN A
24 CERTAIN SENSE IS RESPONSIBLE FOR ASSURING US THAT
25 THINGS ARE DONE IN THE RIGHT WAY. I THINK IT'S VERY

1 HARD FOR US TO ASSURE OURSELVES, PARTICULARLY ON BEHALF
2 OF A THIRD PARTY WHERE WE'RE NOT ON THE PREMISES, WE
3 DON'T KNOW, WE DON'T ANY INSTITUTIONAL AUTHORITY FROM
4 THEM EXCEPT ON THAT BASIS. SO I AM VERY LEERY OF THAT.
5 I HAVE YET TO SEE HOW IT WOULD WORK.

6 MR. SHEEHY: I THINK MY THOUGHT IS LESS THAT
7 WE SHOULD DIRECTLY SET ONE UP OURSELVES, BUT I DO SEE
8 THAT YOU CAN HAVE AN INSTITUTION THAT MIGHT ONLY BE
9 PLANNING TO APPLY FOR ONE GRANT, A SMALL INSTITUTION,
10 NOT ONE OF THE ONES -- OBVIOUSLY EVERYONE THAT CAME TO
11 THE STAKEHOLDER MEETING WERE PEOPLE THAT WERE EXPECTING
12 TO GET CIRM GRANTS. YOU COULD HAVE SOMEBODY AT AN
13 INSTITUTION THAT IS NOT EVEN ON THE RADAR THAT WOULD
14 WANT TO APPLY FOR A GRANT, BUT THE ESCRO REQUIREMENT
15 WOULD BE A BARRIER.

16 AND THIS MAY NOT BE THE PLACE TO ADDRESS IT,
17 BUT WE HAD DISCUSSED THIS AT A PREVIOUS MEETING, THAT
18 THERE BE SOME PROVISION THAT NOT HAVING AN ESCRO NOT BE
19 A BARRIER TO PARTICIPATION. THAT IT IS INCUMBENT ON US
20 AS CIRM TO MAKE SOME PROVISION, EVEN IF IT IS TO
21 CONTRACT OUT WITH AN EXISTING ESCRO AND HAVE SOME
22 ARRANGEMENT WHERE THEY FOR A FEE AGREE TO REVIEW GRANTS
23 FOR OTHER INSTITUTIONS THAT MAY WANT TO COMPETE.
24 I WOULD NOT LIKE THIS TO BE A BARRIER TO PARTICIPATION.

25 CO-CHAIR LO: KEVIN.

1 DR. EGGAN: I GUESS I JUST SIMPLY DON'T FEEL
2 LIKE IT'S THAT HIGH OF A BARRIER, PARTICULARLY SINCE WE
3 IN THIS GROUP MADE A VERY EXPLICIT STATEMENT THAT
4 INSTITUTIONS COULD SHARE AN ESCRO AND SO --

5 DR. HALL: ALMOST EVERY INSTITUTION THAT I
6 KNOW OR CAN THINK OF HAS A RELATION WITH OTHER
7 INSTITUTIONS THAT WOULD ALLOW THEM TO DO THAT.
8 CERTAINLY WHEN I WAS AT UCSF, SAN FRANCISCO DEPARTMENT
9 OF PUBLIC HEALTH, FOR EXAMPLE, WE HAD AN ARRANGEMENT
10 THAT WE WOULD HANDLE THEIR IRB. I GUESS IT WAS ALL IRB
11 WORK, BUT WE WOULD DO THAT. THOSE WERE RARE. THERE
12 WERE CONNECTIONS BETWEEN THE TWO GROUPS, WHICH, IN
13 FACT, I THINK IT WAS THROUGH THE AIDS GROUP, IF I'M NOT
14 MISTAKEN, WE DID THAT.

15 I THINK FOR ALMOST -- FOR MOST OF THE
16 FREESTANDING HOSPITALS, THEY HAVE RELATIONS WITH
17 UNIVERSITIES. AND IT WOULD BE -- WE JUST COULDN'T
18 THINK OF A PLACE, MAYBE A STATE COLLEGE.

19 MR. SHEEHY: ONE THING THAT COMES TO MIND.

20 DR. HALL: I THINK THEY HAVE AN ARRANGEMENT
21 THROUGH THE UNIVERSITY OF CALIFORNIA AND OTHER STATE
22 INSTITUTIONS.

23 DR. EGGAN: MAYBE THERE IS AN OPPORTUNITY FOR
24 A BURGEONING ENTREPRENEUR HERE TO SET UP AN ESCRO FOR
25 HIRE. THERE ARE ORGANIZATIONS LIKE WESTERN IRB WHICH

1 ARE WELL-KNOWN AND WELL-USED INSTITUTIONAL REVIEW
2 BOARDS THAT ARE USED FOR THE PROTECTION OF HUMAN
3 SUBJECTS. I GUESS IF ONE WOULD CONSIDER SOMETHING LIKE
4 A STAND-ALONE IN VITRO FERTILIZATION CLINIC, ONE COULD
5 IMAGINE A SIMILAR ORGANIZATION THAT WAS ESTABLISHED.
6 THE PROBLEM IS THAT THERE ARE FEDERAL GUIDELINES WHICH
7 STATE HOW IRB'S ARE SUPPOSED TO BEHAVE, WHICH HELPS TO
8 REGULATE COMPANIES LIKE WESTERN IRB.

9 I FEAR THERE'S SORT OF A POWER VACUUM THAT
10 MIGHT NOT BE APPROPRIATE IF THEY'RE DOING THIS ON THEIR
11 OWN.

12 DR. HALL: I DON'T KNOW ABOUT THAT PARTICULAR
13 COMPANY, BUT I THINK THAT'S -- WE DO NOT WANT TO
14 ENCOURAGE ESCRO'S FOR CONTRACT. I THINK THAT'S A REAL
15 PROBLEM UNLESS, AS YOU SAY, MAYBE WE'RE GOING TO
16 REGULATE THEM, BUT I THINK THAT REALLY DOES OPEN IS UP.

17 NOW, I THINK A COMPANY -- I DON'T KNOW IF
18 COMPANIES ARE ON YOUR MIND OR NOT, BUT COMPANIES EITHER
19 WOULD HAVE THE RESOURCES, OR IF THEY'RE COMMITTED TO
20 THE STEM CELL FIELD, THEY OUGHT TO HAVE AN ESCRO. IN
21 FACT, ACT DOES.

22 MR. SHEEHY: SO WE WOULD BE ABSOLUTELY -- AT
23 THE LOS ANGELES MEETING, A BIOTECH ENTREPRENEUR, IN
24 FACT, WAS RAISING THAT ISSUE FOR PRECISELY THIS REASON.
25 HE SAID WE WILL NOT SET UP AN ESCRO TO COMPETE FOR A

1 GRANT WE ARE NOT SURE WE COULD GET. THIS MAY BE A
2 LATER POINT BECAUSE I DON'T THINK WE'RE AT A POINT
3 WHERE WE'D BE FUNDING FOR-PROFITS, BUT I ALSO AM A
4 LITTLE BIT LEERY OF THE ESCRO BEING OUR PRIMARY
5 ENFORCEMENT MECHANISM IN THE HANDS OF INDUSTRY. I JUST
6 DON'T HAVE A HIGH DEGREE OF CONFIDENCE.

7 DR. HALL: SO I THINK IT WOULD BE THEIR -- I
8 THINK WE'D WANT TO INQUIRE ABOUT THAT. WE'D WANT TO
9 INQUIRE HOW IT WAS DONE, WHO WAS ON IT, AND HOW THEY
10 SET IT UP. I THINK THAT'S PERFECTLY LEGITIMATE. IT'S
11 ONE OF OUR REQUIREMENTS THAT THEY HAVE SUCH A
12 COMMITTEE, AND I THINK THAT IS WITHIN OUR PURVIEW, IN
13 ESSENCE, TO SAY THIS IS OR IS NOT AN ACCEPTABLE ESCRO.
14 OR IF WE HAVE CONCERNS ABOUT IT, I THINK THEN WE DO
15 STEP IN.

16 I DON'T KNOW -- I WOULD SAY THAT IF A COMPANY
17 WANTS TO DO THIS WORK AND IS NOT WILLING TO SET UP AN
18 ESCRO, I THINK THEY SHOULD THINK TWICE ABOUT WHETHER
19 THEY WANT TO DO IT. I'M NOT SURE THEY OUGHT TO BE
20 DOING IT.

21 MR. SHEEHY: THEY WANT TO DO THE WORK. THEY
22 CAN'T GET OUR FUNDING, WHICH IS NOT OUR MISSION. WE
23 WOULD BE BETTER OFF MAKING A MORE EXPANSIVE FRAMEWORK.

24 DR. HALL: ACT IS A SMALL BIOTECH COMPANY. I
25 KNOW THEY HAVE GONE TO GREAT PAINS TO SET UP AN ETHICS

1 COMMITTEE AND TO ARRANGE FOR AN ESCRO AND TO MEET ALL
2 THE REQUIREMENTS. AND I ACTUALLY DON'T KNOW ABOUT
3 GERON, BUT I THINK ANY -- MY SENSE IS IF WE'RE GOING TO
4 GIVE MONEY TO A COMPANY, THEN WE WANT TO BE CONVINCED
5 THAT THEY HAVE A BONA FIDE, HIGH QUALITY ESCRO. AND I
6 THINK THAT WE HAVE TO DO. I DON'T SEE ANY OTHER WAY
7 THAT WE CAN DO IT.

8 DR. KIESSLING: I SHARE JEFF'S CONCERNS ON
9 THIS. WE TALKED ABOUT THIS BEFORE. I DON'T KNOW
10 EXACTLY HOW TO DO IT. I UNDERSTAND WHAT YOU'RE SAYING,
11 BUT YOU DEFINITELY DON'T WANT THIS TO BE A BARRIER TO
12 ENTRY FOR THE RESEARCH. I THINK SMALL -- WHEN WE
13 TALKED ABOUT THIS BEFORE, IT WAS THE INVESTIGATOR AT,
14 SAY, A SMALL PRIVATE COLLEGE WHO HAS A REALLY GOOD IDEA
15 AND HIS INSTITUTION ISN'T GOING TO SET UP AN ESCRO
16 BECAUSE THE INSTITUTION AS A WHOLE IS NOT IN FAVOR OF
17 THE WORK. SO I THINK THERE'S SOME REAL CONCERNS ABOUT
18 MAKING AVAILABLE SOME LARGE CALIFORNIA INSTITUTION
19 THAT'S GOT TO BE ABLE TO OPEN UP ITS ARMS AND SAY IF
20 YOU NEED US, WE'RE HERE.

21 DR. HALL: THAT WOULD BE MY SUGGESTION, TO
22 MAKE A COLLABORATION WITH SOMEBODY AT AN INSTITUTION
23 THAT HAS AN ESCRO. AND I THINK IT'S JUST ESSENTIAL.
24 THE WORK IS GOING TO GO ON, THAT THE REGULATIONS NEED
25 TO BE IMPLEMENTED, AND WE NEED TO HAVE A GOOD COMMITTEE

1 IN PLACE AND ONE THAT WE'RE HAPPY WITH. I JUST THINK
2 ANYTHING LESS THAN THAT WE JUST ABSOLUTELY CANNOT DO.

3 I THINK OUR SERIOUSNESS ABOUT OUR REGULATIONS
4 DEPEND ON -- AS I SAID BEFORE, IT'S NOT JUST THAT WE
5 PRONOUNCE THE REGULATIONS AND SORT OF WASH OUR HANDS.
6 WE WANT TO BE ACTIVE AND WORK WITH PEOPLE TO BE SURE
7 THAT THEY'RE IMPLEMENTED AND THAT THEY'RE IMPLEMENTED
8 WELL AND THAT IT'S DONE IN A CONSISTENT WAY, AND THAT
9 THEY, AS I SAY, INSTITUTE BEST PRACTICES FOR PARTICULAR
10 WAYS OF HANDLING PROBLEMS. SO WE INTEND TO REMAIN
11 ACTIVE IN THIS AREA.

12 MY SENSE IS IF THERE IS SUCH AN INVESTIGATOR,
13 WE MIGHT TRY TO PUT THEM IN CONTACT WITH SOMEBODY, BUT
14 I THINK WE CAN'T TAKE RESPONSIBILITY FOR -- I REALIZE
15 IT'S NOT WHAT YOU WERE SAYING, BUT SOMEBODY HAS TO --
16 SOMEBODY WILL HAVE TO DO IT. HOWEVER IT WORKS OUT,
17 SOME BONA FIDE, GOOD, EXPERIENCED ESCRO COMMITTEE WILL
18 HAVE TO ACT ON IT, OR I THINK WE CAN'T ALLOW IT TO GO
19 FORWARD. THAT'S ALL THERE IS TO IT. THE STAKES ARE
20 BIGGER.

21 MR. SHEEHY: YOU REALLY HAVEN'T ADDRESSED THE
22 QUESTION. I DON'T KNOW IF THIS IS THE VENUE. THIS IS
23 ADEQUATE FOR THE TIME. WE CAN TALK ABOUT IT AT A
24 DIFFERENT TIME. I DON'T THINK THAT THE PROBLEM HAS
25 BEEN ADDRESSED, AND I DO THINK -- I DO WANT TO RETHINK

1 THIS WHEN WE GET CLOSER TO GIVING GRANTS TO FOR-PROFIT
2 ENTITIES BECAUSE I CAN THINK OF A WHOLE HOST OF REASONS
3 WHY I MIGHT HAVE CONFIDENCE IN A UNIVERSITY
4 ACADEMIC-BASED ESCRO AS A SELF-POLICING MECHANISM WHERE
5 I MIGHT NOT HAVE THE SAME CONFIDENCE IN THE INDUSTRY
6 SITUATION, ESPECIALLY GIVEN THE CONCERNS THAT WE HAVE
7 HERE.

8 OUR ONLY MECHANISM IS FUNDING TO ENFORCE
9 THIS. SO THEY JUST DON'T HAVE TO USE OUR FUNDS TO DO
10 THE STUFF WE DON'T WANT THEM TO DO, BUT THEY CAN STILL
11 DO IT.

12 DR. HALL: IN THE END WE CAN BE
13 RESPONSIBLE --

14 MR. SHEEHY: WE CAN USE OUR FUNDS TO GET THEM
15 TO THE WATER, SOMEBODY ELSE'S TO DRINK.

16 DR. HALL: WELL, WE'RE RESPONSIBLE FOR --
17 ONLY THING WE CAN BE SURE ABOUT HERE ARE THOSE THINGS
18 THAT WE FUND. THAT'S REALLY OUR RESPONSIBILITY.
19 OTHERWISE THINGS HAPPEN WE JUST SIMPLY DON'T HAVE
20 CONTROL OVER. AND I THINK IT GOES BEYOND OUR
21 RESPONSIBILITY TO TAKE CONTROL. I THINK WE SHOULD
22 DISCUSS FURTHER. I'M NOT ABSOLUTELY SURE I UNDERSTAND
23 ALL OF THE PARTS OF WHAT YOU'RE SAYING.

24 MR. SHEEHY: THERE ARE TWO DIFFERENT
25 CONCERNS. THEY ALL RELATE TO KIND OF NOT IN SOME WAY

1 HAVING CIRM HAVE SOME RELATIONSHIP WITH AN ESCRO WHERE
2 THAT ESCRO IS AVAILABLE. CIRM MAKES THAT ESCRO
3 AVAILABLE TO OTHER ENTITIES WHO MAY NOT HAVE AN ESCRO,
4 OR WE MAY NOT HAVE CONFIDENCE OR WHAT HAVE YOU. WE HAD
5 TALKED ABOUT -- THAT'S SOMETHING THAT CAN BE DONE ON A
6 CONTRACT BASIS.

7 DR. HALL: I THINK WE CAN SUGGEST IT, BUT I
8 DON'T THINK -- IF WE ARE GOING TO JUDGE THE ESCRO, WE
9 CAN'T AT THE SAME TIME HAVE IT BE ONE THAT WE'RE
10 RESPONSIBLE FOR. I THINK THE FIRST ROLE IS OURS, NOT
11 THE SECOND ONE.

12 MR. SHEEHY: I THINK YOU'RE PARSING THERE A
13 LITTLE BIT, BUT I THINK WE SHOULD MOVE ON.

14 CO-CHAIR LO: LET'S GET SOME OTHER PEOPLE IN
15 HERE.

16 DR. PRIETO: WE HAD DISCUSSED EARLIER AT
17 EARLIER MEETINGS THE CONCEPT OF A REGIONAL ESCRO AND
18 COOPERATION BETWEEN INSTITUTIONS. I JUST WONDER
19 WHETHER THERE MIGHT BE BUILT INTO SOMETHING LIKE THAT
20 AN ASSURANCE THAT WOULD GIVE OTHER RESEARCHERS ACCESS
21 TO SUCH AN ESCRO, THE TYPE OF RESEARCHERS THAT JEFF IS
22 TALKING ABOUT.

23 CO-CHAIR LO: WE EXPLICITLY ALLOW THAT IN THE
24 NEXT SECTION, 100005, WHERE WE SAY THAT AN INSTITUTION,
25 GROUP OF INSTITUTIONS, CIRM, OR OTHER STATE AGENCY MAY

1 CONVENE AN ESCRO. SO WE LEAVE IT OPEN THAT THAT'S
2 PERMISSIBLE WITHOUT REQUIRING IT IN A SUBSEQUENT
3 SECTION.

4 DR. PRIETO: WHICH DOESN'T GUARANTEE ACCESS.

5 CO-CHAIR LO: DOESN'T GUARANTEE ACCESS. IN
6 FACT, WE DON'T HAVE A WAY -- THERE'S NO WAY TO ENFORCE
7 THAT.

8 MR. SHEEHY: WHAT WOULD BE THE MOTIVATION TO
9 PROVIDE ACCESS TO A COMPETITOR FOR A GRANT?

10 DR. HALL: I THINK IT'S LIKE THAT FOR A LOT
11 OF ISSUES. I MEAN IF YOU HAVE AN INSTITUTION THAT
12 WANTS TO DO RESEARCH ON A CERTAIN LEVEL, THEY HAVE TO
13 HAVE A COMPLIANCE OFFICE, A RESEARCH COMPLIANCE
14 OFFICER. AND IF THEY DON'T, THEN THE INSTITUTION CAN'T
15 GO FORWARD. I MEAN THEY CAN'T DO FEDERAL WORK. SO
16 THERE'S A WHOLE -- IF AN INSTITUTION WANTS TO BE IN
17 THIS AREA, I THINK THEY HAVE TO FIGURE OUT A WAY TO
18 HANDLE THE REGULATORY REQUIREMENTS THAT GO ALONG BOTH
19 WITH OUR RESEARCH AND WITH FEDERAL RESEARCH. I THINK I
20 DON'T YET SEE A WAY IN WHICH WE CAN GUARANTEE ANYBODY
21 THAT THEY CAN'T DO IT. IT WOULD BE LIKE SAYING WE'RE
22 NOT GOING LET THEM APPLY AND STAND IN THE WAY OF DOING
23 RESEARCH. I DON'T SEE IT. I'M HAPPY TO CONTINUE THE
24 CONVERSATION.

25 CO-CHAIR LO: THIS SOUNDS LIKE AN ISSUE THAT

1 WE'RE NOT GOING TO RESOLVE TODAY, BUT CONTINUE TO
2 DISCUSS AND TRY AND ADDRESS THE CONCERNS JEFF'S BEEN
3 RAISING CONSISTENTLY.

4 ANY OTHER COMMENTS ON THIS SECTION ON
5 INSTITUTIONAL ASSURANCES FROM THE COMMITTEE MEMBERS?
6 PUBLIC PARTICIPANTS, ANY COMMENTS, SUGGESTIONS,
7 CONCERNS ON THIS SECTION?

8 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR
9 TAXPAYER AND CONSUMERS RIGHTS. I WAS VERY DELIGHTED TO
10 HEAR PRESIDENT HALL TALKING ABOUT THE NEED TO BE
11 CONSTANTLY INVOLVED IN THE PROCESS AND NOT WASH OUR
12 HANDS -- AND NOT HAVE CIRM WASH ITS HANDS OF WHAT
13 HAPPENS.

14 MY CONCERN WITH THIS IS THAT IT REQUIRES
15 SIMPLY AN ASSURANCE THAT THE RIGHT THINGS ARE BEING
16 DONE, AND IT DOESN'T SEEM TO HAVE A SORT OF PROACTIVE
17 WHAT HAPPENS IF IT'S NOT DONE. AND I WOULD THINK THERE
18 MIGHT NEED TO BE A LITTLE MORE TEETH PUT IN IT IF IT
19 WERE FOUND TO BE THE CASE THAT AN ESCRO DIDN'T MEET UP
20 WITH YOUR STANDARDS OR SOMETHING LIKE THAT. I'M NOT
21 QUITE SURE WHAT THE ENFORCEMENT MECHANISM WOULD BE.

22 DR. HALL: OH, VERY CLEAR. WE WOULD WITHHOLD
23 FUNDS FROM THAT INSTITUTION. NOT JUST THAT GRANT, BUT
24 IF WE THOUGHT THE ESCRO WAS NOT OPERATING, IF IT'S AN
25 ISOLATED CASE DEALING WITH ONE PERSON, THEN WE SAY,

1 OKAY, WE CAN STOP FUNDS TO THAT PERSON. THAT'S CLEARLY
2 WRITTEN IN OUR GRANTS ADMINISTRATION POLICY. IF THE
3 INSTITUTION DOESN'T HAVE AN ADEQUATE COMMITTEE, THIS IS
4 A BIG THREAT. WE THEN SAY, I'M SORRY. ALL YOUR FUNDS
5 ARE IN JEOPARDY UNTIL YOU STRAIGHTEN THIS OUT.

6 MR. SIMPSON: HOW WOULD YOU FIND THAT OUT IF
7 BASICALLY YOU'RE JUST RELYING ON THE ASSURANCE
8 PRESUMABLY IN SOME FORM THAT THEY'VE MET THE
9 REQUIREMENTS? WOULD THERE BE SOME PROVISION FOR
10 INVESTIGATION OR SPOT-CHECKS FROM TIME TO TIME OR, FOR
11 EXAMPLE, LIKE ME STANDING UP AND SAYING YOU OUGHT TO
12 LOOK AT THIS ONE?

13 DR. HALL: WE HAVE THE RIGHT TO GO IN AND
14 CHECK AND OBTAIN INFORMATION AT ANY TIME ABOUT THIS.
15 SO IF WE -- THE WAYS IN WHICH YOU TRADITIONALLY HEAR
16 ABOUT THIS WOULD BE EITHER THROUGH A WHISTLE-BLOWER OR
17 SOMEBODY COMES TO YOU AND SAYS THERE'S A PROBLEM. AND
18 THEN YOU CONTACT THE INSTITUTION AND WE SAY WE WANT TO
19 SEE THE RECORDS FOR THIS. HOW DID THIS WORK? LET'S
20 SEE THE RECORDS OF YOUR COMMITTEE. WE GO OVER THOSE
21 RECORDS.

22 I THINK THERE ARE PLENTY -- WE CERTAINLY HAVE
23 THE RIGHT AT ANY TIME TO STOP OR WITHHOLD FUNDS. IN
24 FACT, OUR WHOLE GRANTS ADMINISTRATION POLICY BASICALLY
25 SAYS HERE ARE THE THINGS YOU HAVE TO DO TO COMPLY WITH

1 OUR POLICIES; AND IF YOU DON'T, WE WILL SUSPEND OR
2 WITHHOLD FUNDS. SO PARTICULARLY FOR THESE
3 INSTITUTIONAL THINGS, THAT IS A VERY POWERFUL STICK.

4 MR. SIMPSON: THAT'S VERY ENCOURAGING TO HEAR
5 YOU SAY THAT, PARTICULARLY IN LIGHT OF WHAT'S HAPPENED
6 ON THE OTHER SIDE OF THE PACIFIC.

7 DR. HALL: OF COURSE, YES.

8 CO-CHAIR LO: JUST IF I COULD FOLLOW ON THAT,
9 THE NEXT SECTION WHICH WE WILL GET TO ACTUALLY HAS A
10 COMPLIANCE SECTION IN THESE REGULATIONS AS WELL AS THE
11 GRANTS ADMINISTRATION. SO IT IS IMPORTANT THAT WE MAKE
12 CLEAR WHAT THE CONSEQUENCES ARE IN THESE REGULATIONS
13 AND IN MORE DETAIL IN THE GRANTS ADMINISTRATION POLICY,
14 WHICH IS REALLY THE CONDITIONS OF THE FUNDING.

15 ANY OTHER PUBLIC COMMENTS? CAN WE TRY TO
16 KNOCK OFF ONE MORE SMALL ONE, 100004, COMPLIANCE, OR
17 SHOULD WE GO TO A BIGGER ONE.

18 NEXT SECTION, ALL CONDITIONS SET FORTH IN
19 THIS CHAPTER WILL BE COMPLIED WITH, WILL, MUST, SHALL
20 AS A CONDITION OF RELEASING RESEARCH FUNDS. FAILURE TO
21 COMPLY WITH THE TERMS SET FORTH IN THIS CHAPTER -- THAT
22 CHAPTER, I TAKE IT, INCLUDES THE WHOLE TEN PAGES --
23 CONSTITUTES GROUNDS FOR NONCONTINUATION OF EXISTING, OR
24 DISQUALIFICATION FOR FUTURE, CIRM FUNDING. AND THE
25 QUESTION MARK INSERTED IN RED IS DO WE ALSO WANT TO

1 TALK ABOUT REPAYMENT OF FUNDS ALREADY DISBURSED AS
2 OPPOSED TO STOPPING. COMMENTS?

3 DR. KIESSLING: IS THERE A PRECEDENT FOR
4 ASKING FOR REPAYMENT?

5 MS. CHARO: THERE IS NOW IN KOREA.

6 DR. HALL: CERTAINLY IN THE FEDERAL
7 GOVERNMENT THERE CAN BE. IF YOU HAVE A -- IF SOMEBODY
8 APPLIES FOR GRANT MONEY AND YOU HAVE, FOR EXAMPLE,
9 FRAUDULENTLY STATED, THE INSTITUTION HAS FRAUDULENTLY
10 MISSTATED SOMETHING THAT'S TRUE, NOT A RESEARCH RESULT,
11 BUT IF THEY SAY WE HAD A MEETING OF THIS COMMITTEE AND
12 IT NEVER MET, YOU CAN GO IN AND ASK FOR RETURN OF
13 FUNDS.

14 CO-CHAIR LANSING: IT'S IN THE FEDERAL. I
15 LIKE THAT.

16 MR. SHEEHY: YOU CAN ASK FOR UP TO THREE
17 TIMES BACK.

18 DR. KIESSLING: REALLY. IF THERE'S
19 PRECEDENT, GO FOR IT.

20 CO-CHAIR LANSING: I AGREE. LET'S TRY AND
21 GET IT.

22 MR. SHEEHY: I THINK THAT'S A GOOD IDEA. I
23 THINK THE ELEMENT OF FRAUD SHOULD BE -- I DON'T KNOW
24 WHAT THE LANGUAGE SHOULD BE, BUT IF SOMEBODY MAKES AN
25 ACCIDENT, I DON'T THINK WE SHOULD. IF SOMEBODY

1 KNOWINGLY FAILS TO COMPLY, I THINK WE SHOULD MIRROR
2 FEDERAL LANGUAGE ON THIS.

3 DR. HALL: SCOTT, WE'LL HAVE TO CHECK INTO
4 THIS, BUT I THINK IT'S JUST PART OF THE LEGAL CONTRACT
5 IF THEY -- IF THERE'S -- I DON'T KNOW WHAT IS REQUIRED
6 TO BE STATED THAT WE NEED TO DO THAT. I'M NOT SURE
7 ANYTHING IS, BUT LET'S CHECK THAT. CAN WE DO THAT? BE
8 SURE OF THAT.

9 MR. TOCHER: YOU'RE TALKING ABOUT THE
10 CONSEQUENCES AND WHAT THE RIGHTS OF CIRM WOULD BE AS A
11 RESULT OF FRAUD? SPELLING THAT OUT.

12 DR. HALL: NOT SCIENTIFIC FRAUD. THAT'S A
13 MORE COMPLICATED ISSUE. THAT'S HARD. LET'S NOT DEAL
14 WITH THAT RIGHT NOW. LET'S SUPPOSE AN INSTITUTION SAYS
15 WE HAVE AN ESCRO, FOR EXAMPLE, AND IT MET AND PASSED ON
16 THIS. AND THEN WE FIND OUT THAT, IN FACT, IT NEVER
17 MET, AND YET THEY SIGNED OFF ON IT. WE HAD ALREADY
18 GIVEN THEM THE MONEY. I THINK WE'D HAVE -- I'M ASKING.
19 DO WE HAVE LEGAL GROUNDS TO WALK IN AND SAY WE WANT OUR
20 MONEY BACK? YOU LIED.

21 MR. TOCHER: SURE, ABSOLUTELY.

22 DR. HALL: YOU DON'T HAVE TO STATE THAT IF
23 YOU DECEIVE US IN ANY WAY.

24 MR. TOCHER: NO. THE ADVANTAGE OF DOING SO
25 IS OBVIOUSLY IT REMOVES ANY SORT OF ARGUMENT FROM THE

1 TABLE THAT THEY CAN COME AND SAY, WELL, YOU KNOW,
2 THAT'S NOT SOMETHING WE SIGNED UP FOR AND HAVE THAT
3 SORT OF BACK AND FORTH.

4 DR. HALL: THE ONLY REASON I SAY IT IS TO
5 CRAFT LANGUAGE THAT ANTICIPATES EVERYTHING, THAT MAY BE
6 A BIT OF A CHALLENGE, AND YET DOES NOT, AS JEFF WAS
7 SAYING, IF IT'S SOMETHING THAT HAPPENS AND WE DON'T
8 INTEND IT, MAYBE THAT'S NOT -- I'M LOOKING FOR A WAY TO
9 NOT HAVE TO OURSELVES COME UP WITH THE --

10 MR. TOCHER: THERE'S A PROVISION THAT, AS YOU
11 MENTIONED A MOMENT AGO, IN THE GAP, THE OVERALL POLICY,
12 THAT LISTS IN A SECTION CALLED "FAILURE OF COMPLIANCE"
13 SORT OF THE WHOLE PANOPLY OF OPTIONS THAT ARE OPEN TO
14 CIRM FOR ANY TRANSGRESSION OF THE REQUIREMENTS. AND IT
15 REALLY IS EVERYTHING FROM PLEASE SUBMIT ADDITIONAL
16 PAPERWORK TO HALTING OF ALL FUNDS FOR THAT GRANT. AS
17 YOU MENTIONED, IF IT'S AN INSTITUTION, HALTING ALL THE
18 INSTITUTION'S GRANTS IF THERE'S A FAILURE EVEN AS TO
19 ONE IN COMPLIANCE. AND THEN RIGHT ON DOWN TO CIVIL
20 ACTION, IF NECESSARY, USING THE COURT SYSTEM.

21 CO-CHAIR LANSING: AND REPAYMENT OF FUNDS.

22 MR. TOCHER: REPAYMENT OF FUNDS, AS WELL, I
23 BELIEVE IS ONE OF THE CLAUSES IN THE DRAFT.

24 CO-CHAIR LANSING: IF SOMEONE FAILS TO COMPLY
25 IN SOME WAY, WE WANT TO GIVE THEM TIME TO COMPLY. IF

1 THEY ACTUALLY MAKE A MISTAKE OR NOT UNDERSTAND
2 SOMETHING, SO THAT DOESN'T GO AGAINST THEM.

3 MR. TOCHER: CORRECT, IT DOESN'T.

4 MR. SHEEHY: COULD WE CHECK THE FEDERAL MODEL
5 BECAUSE THE FEDERAL MODEL DOES HAVE A MULTIPLIER. YOU
6 CAN ASK FOR THREE TIMES THE AMOUNT OF THE GRANT AMOUNT
7 FOR FRAUD.

8 MR. TOCHER: I WOULD HAVE TO LOOK INTO THAT
9 ONLY BECAUSE THAT LOOKS LIKE IT MAY BE A FINE. AND I
10 WOULD JUST WANT TO CHECK TO MAKE SURE THAT WE HAVE THE
11 AUTHORITY TO IMPOSE FINES, WHICH IS USUALLY AN
12 ENFORCEMENT FUNCTION DESIGNATED TO AN AGENCY, WHICH IS
13 A UNIQUE QUESTION.

14 MR. SHEEHY: THIS IS A CONTRACT TERM.
15 ENFORCEMENT WOULD THEN TAKE PLACE THROUGH THE COURTS,
16 BUT THE REMEDY WOULD BE DAMAGES, TREBLE THE AMOUNT.

17 DR. HALL: LET ME JUST SAY, TO ELABORATE ON
18 WHAT SCOTT SAYS, WE INTEND TO COME OUT OF THIS -- WE'RE
19 PUTTING IN PLACE MEDICAL, ETHICAL STANDARDS, GRANTS
20 ADMINISTRATION POLICY, INTELLECTUAL PROPERTY POLICY,
21 ALL THESE THINGS, AND WE INTEND TO COME OUT OF THIS
22 WITH A VERY STRONG SYSTEM IN TERMS OF ENSURING
23 COMPLIANCE. THERE'S NO QUESTION ABOUT IT. AND THAT
24 WON'T -- THOSE PARTS OF IT WON'T COME UP SPECIFICALLY
25 HERE FOR EXTENSIVE DISCUSSION, BUT WILL BE BROUGHT UP

1 TO ICOC IN TERMS OF THE GRANTS ADMINISTRATION POLICY
2 CERTAINLY.

3 MR. SHEEHY: GIVEN THAT THIS IS PROBABLY THE
4 MOST IMPORTANT THING WE'RE ADOPTING, IT WOULD BE NICE
5 IF PEOPLE KNOWING IF THEY DON'T COMPLY WITH THIS, WE'LL
6 BE ABLE TO ADOPT THE STRICTEST FEDERAL MODEL AS OUR
7 MODEL IF AT ALL PRACTICAL. THAT'S ALL I'M ASKING IS
8 THAT WE INVESTIGATE AND CONSIDER IT BEFORE WE FINALIZE
9 THIS.

10 MS. FEIT: I REALLY THINK THAT REPAYMENT IS A
11 SERIOUS CONCERN. IF THERE'S FRAUD AND
12 MISREPRESENTATION, WE SHOULD PROTECT THE TAXPAYER
13 DOLLARS, AND WE SHOULD ASK FOR THAT TO BE RETURNED. I
14 THINK WE ARE OBLIGATED TO DEFINE UNDER WHAT CONDITIONS
15 REPAYMENT WOULD BE EXPECTED. MY EXPERIENCE IS THAT
16 WHEN AN INSTITUTION GIVES THAT MONEY, THEY WANT
17 REPAYMENT IF IT'S BEEN MISREPRESENTED, THERE'S BEEN A
18 TRUE FAILURE ON THE PART OF THE PROJECT. THEN YOU CAN
19 BE TIED UP IN LITIGATION FOR A VERY LONG PERIOD OF TIME
20 AND SPEND A LOT OF MONEY JUST ARGUING THE ISSUE. SO IF
21 YOU'RE CLEAR IN YOUR DOCUMENTS UNDER WHAT CIRCUMSTANCES
22 YOU WOULD EXPECT REPAYMENT, AND IT SHOULD BE SERIOUS
23 THINGS LIKE FRAUD AND MISREPRESENTATION, AND CERTAINLY
24 A COMPLETE PUBLIC RELATIONS PROBLEM WITH THE PROJECT
25 THAT JUST DIDN'T COMPLY THAT IS A DEFAMATION TO THE

1 WORK THAT CIRM WANTS TO DO CAN BE VERY DAMAGING.

2 WE SHOULD TAKE THE TIME TO THINK THROUGH THIS
3 PART OF IT BECAUSE I THINK REPAYMENT IS AN IMPORTANT
4 PART OF THAT CONDITION.

5 DR. HALL: WILL YOU MAKE -- I HOPE YOU'VE GOT
6 NOTES FOR THAT. THANK YOU.

7 CO-CHAIR LO: OTHER COMMENTS ON THIS SECTION?

8 DR. TAYLOR: I WAS JUST GOING TO SAY IT SEEMS
9 TO ME THAT IF THERE IS A PRECEDENT, IT'S PROBABLY
10 MEDICARE KINDS OF LITIGATION THAT WAS BROUGHT AGAINST A
11 NUMBER OF INSTITUTIONS OVER THE LAST COUPLE OF YEARS.
12 I DON'T KNOW OF ANY SITUATIONS. IT'S MORE
13 INVESTIGATIVE, SORT OF NIH DOING THAT, BUT CERTAINLY
14 MEDICARE HAS DONE A VERY GOOD JOB.

15 MR. SHEEHY: BERNIE AND I HAVE HEARD OF
16 EXAMPLES, BUT I DON'T THINK WE'RE AT LIBERTY TO DISCUSS
17 THEM.

18 CO-CHAIR LO: IT STRIKES ME THIS IS SOMETHING
19 WHERE IT'S PRETTY CLEAR THE GOAL WE'RE TRYING TO
20 ACHIEVE, WHICH IS TO PROTECT THE INVESTMENT THE PEOPLE
21 OF CALIFORNIA HAS MADE. AND SORT OF HOW WE DO THAT,
22 DRAFTING THE LANGUAGE, AND WHETHER IT BEST COMES HERE
23 OR GRANTS ADMINISTRATION POLICY, I THINK, WE NEED TO
24 SORT OUT. BUT AT THE VERY LEAST IN THE STATEMENT OF
25 REASONS WE SHOULD HAVE A STRONG STATEMENT OF THE

1 IMPORTANCE OF COMPLIANCE AND SERIOUSNESS OF THE
2 FAILURES.

3 PUBLIC COMMENT ON THIS, PLEASE. COME UP AND
4 INTRODUCE YOURSELF, PLEASE.

5 MS. FOGEL: SUSAN FOGEL WITH THE PRO CHOICE
6 ALLIANCE FOR RESPONSIBLE RESEARCH. I THINK THIS
7 COMPLIANCE SECTION IS -- I'M SORRY -- PATHETICALLY
8 THIN. THESE ARE REGULATIONS, AND THEY HAVE THE FORCE
9 OF LAW. AND IT SEEMS TO ME THAT THIS OUGHT TO BE A
10 REALLY BEEFY SECTION OF YOUR REGULATIONS, THAT THE
11 THINGS YOU HAVE IN YOUR GRANTS MANAGEMENT OUGHT TO BE
12 IN HERE. I AGREE THERE NEEDS TO BE CLARITY, AND
13 INSTITUTIONS NEED TO KNOW EXACTLY WHAT STANDARDS -- TO
14 WHICH STANDARDS THEY'RE BEING UPHELD.

15 BUT ESPECIALLY GIVEN THE LIMITATIONS OF CIRM
16 TO DO INSPECTIONS AND MONITORING JUST BECAUSE OF THE
17 LIMITATIONS ON THE SIZE OF THE STAFF, IT SEEMS TO ME
18 THAT THERE HAS TO BE REAL MEAT AND REAL TEETH HERE AND
19 REAL PENALTIES. BEYOND THIS, CERTAINLY PEOPLE SHOULD
20 BE REQUIRED TO COMPLY WITH ALL STATE AND FEDERAL LAWS.
21 IT'S SO MUCH BROADER THAN JUST COMPLYING WITH THIS
22 DOCUMENT. SO I JUST THINK THIS NEEDS A WHOLE NEW
23 LOOK-SEE.

24 THE OTHER THING I WANTED TO SAY ABOUT -- I'M
25 SORRY. THIS IS GOING BACK TO THE ESCRO ISSUES -- IS

1 ONE WAY OF RESOLVING SOME OF THE PROBLEMS OF HAVING TO
2 HAVE SOME KIND OF REGIONAL OR STATEWIDE ESCRO IS TO
3 ACTUALLY MAKE IT A GRANT, THAT CIRM COULD PUT OUT AN
4 RFA FOR SOMEONE TO SET UP A STATEWIDE OR REGIONAL
5 ESCRO. AND THAT WAY YOU WOULD AVOID THE CONFLICTS, DR.
6 HALL, YOU WERE SAYING ABOUT WE CAN'T POLICE OURSELVES.
7 YOU'D BE IN A POSITION OF POLICING IT, BUT SOMEONE ELSE
8 WOULD HAVE THE RESPONSIBILITY AND THE FUNDING TO MAKE
9 IT HAPPEN. SO THAT MIGHT BE ANOTHER APPROACH.

10 ANYWAY, I REALLY THINK THAT WE HAVE TO HAVE
11 VERY STRONG COMPLIANCE STANDARDS, AND THIS OUGHT TO BE
12 REVISITED. THANK YOU.

13 CO-CHAIR LO: THANK YOU.

14 MS. GREENFIELD: JUST ALONG WITH THAT, I WAS
15 WONDERING IF THERE WAS ANY WAY YOU COULD THINK, AND
16 UNDER THE APA I'M NOT SURE IF THERE IS ANYTHING IN
17 TERMS OF CITIZEN SUITS OR PRIVATE RIGHTS OF ACTIONS
18 ALONG WITH THE REGULATIONS.

19 CO-CHAIR LO: SORT OF THE KEY TEN PROCEDURES
20 IN THE FEDERAL.

21 MS. GREENFIELD: RIGHT.

22 MR. REYNOLDS: I'M ENCOURAGED THAT IT REALLY
23 SEEMS THAT YOU ARE SEEING WHAT ENFORCEMENT CAPABILITIES
24 YOU HAVE. OBVIOUSLY CIRM IS LARGELY LIMITED TO WITH
25 THE REMOVAL OF FUNDS AND THE REPAYMENT, POSSIBLY EVEN

1 CIVIL ACTION. WHAT I'M CONCERNED IS MISSING IS
2 OVERSIGHT OF THE ESCRO'S. AND A LOT OF WHAT'S ON MY
3 MIND HAS BEEN FROM WATCHING THE NEWS COMING FROM SOUTH
4 KOREA. THEY HAVE SORT OF A NATIONAL CENTRALIZED ESCRO,
5 AND IT SEEMS TO HAVE BEEN RUBBER-STAMPING ISSUES. AND
6 THE CHAIR OF THIS COMMITTEE HAD SERVED AS THE PRIVATE
7 LAWYER OF DR. HWANG. AND PROBLEMS THERE WERE UNCOVERED
8 BY -- THE ETHICAL BREACHES WERE UNCOVERED BY
9 INVESTIGATIVE JOURNALISTS WHO WERE REPORTING THIS NEWS
10 UNDER, NOT ONLY ADVERTISER BOYCOTTS, BUT SOME DEATH
11 THREATS.

12 SO THE ANALOGY HERE IN AMERICA WOULD BE A
13 SITUATION WHERE THE ESCRO'S WOULD HAVE CLOSE
14 INSTITUTIONAL AFFILIATIONS WITH THE INSTITUTION FOR
15 WHICH THEY'RE APPROVING RESEARCH. AND I'M JUST NOT
16 SEEING WHERE THERE IS AN OVERSIGHT MECHANISM. I DON'T
17 THINK WE WANT TO BE RELYING ON INVESTIGATIVE
18 JOURNALISTS AND WHISTLE-BLOWERS. WHERE CAN THE
19 BUILT-IN OVERSIGHT MECHANISM BE? I'M NOT SURE EXACTLY
20 WHAT THE ANSWER IS. IS IT A CENTRAL BODY? IS IT YOU?
21 IS IT THE ICOC? I THINK THERE'S A NUMBER OF
22 POSSIBILITIES.

23 DR. HALL: CAN I SAY SOMETHING IN RESPONSE?
24 INVESTIGATIVE JOURNALISTS GOT INVOLVED BECAUSE
25 SCIENTISTS REPORTED TO THEM THAT SOMETHING WAS AMISS.

1 I JUST WANTED TO MAKE THAT POINT. AND I THINK IT IS AN
2 INTERESTING QUESTION. IT MAY BE, FOR EXAMPLE, THAT IT
3 MIGHT BE USEFUL TO HAVE A CIRM PERSON SIT IN ON ESCRO
4 COMMITTEE MEETINGS AT INSTITUTIONS FROM TIME TO TIME IN
5 A SORT OF RANDOM AND UNANNOUNCED WAY. THAT WOULD BE
6 ONE POSSIBLE.

7 IT WILL BE IMPORTANT FOR US TO SET UP BOTH A
8 STRONG WORKING RELATIONSHIP WITH THE INSTITUTIONAL
9 ESCRO COMMITTEES, BUT ALSO MAKE CLEAR THAT WE HAVE
10 STRONG STANDARDS, AND WE ARE ABSOLUTELY DETERMINED TO
11 ENFORCE THOSE. AND SO I THINK THAT WILL BE A BIT OF A
12 LINE TO BALANCE. BUT I THINK THE IDEA OF HAVING
13 SOMETHING LIKE THAT MIGHT BE A GOOD IDEA.

14 I UNDERSTAND YOUR CONCERN. I THINK THE BEST
15 ANALOGY HERE IS WITH THE IRB COMMITTEES, WHICH BY AND
16 LARGE HAVE WORKED WELL. THERE HAVE BEEN SOME PROBLEMS
17 FROM TIME TO TIME, BUT IN GENERAL I THINK THAT'S BEEN A
18 GOOD MECHANISM. AND I THINK -- BUT I DO UNDERSTAND
19 YOUR CONCERNS.

20 MR. TAYMOR: I HAVE PERHAPS A DIFFERENT VIEW.
21 I THINK THAT THIS SECTION MAY BE TOO MUCH IN LIGHT OF
22 THE DESCRIPTIONS THAT YOU'VE GIVEN OF EXTENSIVE WORK ON
23 THE GRANTS ADMINISTRATION PROGRAM. I THINK YOU SHOULD
24 CONSIDER THE POSSIBILITY OF MISCHIEF THAT COMES FROM
25 THIS SIMPLE STATEMENT "ALL CONDITIONS WILL BE COMPLIED

1 WITH," AND I THINK PROBABLY SHALL IS MORE CORRECT, AS A
2 CONDITION OF FUNDING. THAT MEANS THAT THE VERY
3 DETAILED ADMINISTRATIVE PROCEDURES, APPEALS, ALL THE
4 WORK THAT'S OVER AT THE GRANTS ADMINISTRATION GROUP CAN
5 BE TRUMPED BY SOMEONE COMING IN AND BRINGING A SUIT
6 BASED ON THIS SECTION. IF YOU WOULD ELEVATE THAT IN
7 TERMS OF SOME TYPE OF PRIVATE RIGHT OF ACTION, I THINK
8 YOU COULD BE PLAYING VERY MUCH INTO THE HANDS OF PEOPLE
9 WHO HAVE BEEN SLOWING DOWN THE FUNDING OF CIRM, NOT SO
10 MUCH THIS BODY, BUT THE ICOC CONSIDERATION.

11 BUT I THINK IF THERE HAS BEEN THE TYPE OF
12 WORK THAT WE WOULD EXPECT FROM DR. HALL AND THE
13 EXPERIENCE THAT'S THERE, THE BACKGROUND, THIS SECTION
14 MAYBE JUST NEEDS TO REFER TO THAT AND SAY THE
15 ENFORCEMENT ADMINISTRATION AND SO FORTH WILL BE HANDLED
16 IN THAT SECTION AND NOT HAVE AN ENFORCEMENT SECTION AT
17 ALL IN HERE OTHER THAN SAYING WE HAVE ENFORCEMENT
18 SITUATED IN ANOTHER SECTION OF CIRM.

19 MR. REED: IS MY UNDERSTANDING CORRECT, THAT
20 THERE ARE ANNUAL REPORTS REQUIRED OF SCIENTISTS TO SAY
21 WHAT THEY'RE UP TO? IS THAT NOT A FORM OF OVERSIGHT AS
22 WELL?

23 DR. HALL: THAT'S A DIFFERENT KIND OF THING.
24 THAT REPORTS SCIENTIFIC PROGRESS, BUT THE INSTITUTIONS
25 HAVE TO REPORT AND MAKE A FINANCIAL REPORT. THE

1 SCIENTISTS HAVE TO MAKE A REPORT OF SCIENTIFIC
2 PROGRESS. THE QUESTION IS IF THERE WERE AN ESCRO, I
3 DON'T THINK THAT WOULD BE A VERY EFFICIENT WAY.

4 MR. REED: WHAT THE PUBLIC IS MOST CONCERNED
5 WITH, I THINK, IS WHAT THEY HEAR OUT OF KOREA. AND
6 THAT WAS FOUND BY SCIENTISTS LOOKING CLOSELY.

7 DR. HALL: IT'S VERY HARD TO -- IT'S VERY
8 HARD TO GUARANTEE THAT WHAT HAPPENED IN KOREA CAN'T
9 HAPPEN HERE IN THE FOLLOWING SENSE. THERE'S BEEN A
10 NUMBER -- DURING MY SCIENTIFIC CAREER, THERE HAVE BEEN
11 SEVERAL INCIDENTS OF FRAUD. AND IF YOU HAVE SOMEBODY
12 THAT'S SMART AND KNOWS THE FIELD AND IS DETERMINED TO
13 MAKE UP DATA, IT IS VERY HARD TO CATCH THEM UNLESS YOU
14 ARE SITTING RIGHT AT THEIR BENCH WATCHING THEM DO THEIR
15 WORK OR NOT DO THEIR WORK, AS THE CASE MAY BE. IN MANY
16 CASES THEY HAVE REAGENT BOTTLES, THEY BUSILY APPEAR TO
17 BE PIPETTING, THEY DO ALL, EVERYTHING GOES THROUGH, BUT
18 IN THE END THEY MAKE UP THE DATA. IT'S VERY HARD TO
19 STOP THAT FROM HAPPENING.

20 HOWEVER, ONCE IT HAPPENS, ALMOST INVARIABLY
21 PEOPLE GET CAUGHT. AND THE REASON IS THE MORE
22 IMPORTANT AND THE MORE VISIBLE THE WORK, SCIENTISTS
23 BUILD ON EACH OTHER'S WORK. THEY ASK FOR THE REAGENTS,
24 THEY ASK FOR THE CELLS, THEY TRY TO REPEAT THE RESULTS.
25 AND THE MORE EXCITING AND INTERESTING IT IS, THE

1 QUICKER THEY TRY TO DO THAT. SOON THEY FIND OUT THEY
2 CAN'T DO IT AND THE WHOLE THING COMES CRUMBLING DOWN.

3 MR. REED: TO THE BEST OF MY KNOWLEDGE, I DO
4 NOT KNOW OF ANY FIELD THAT DOES NOT HAVE CRIME IN IT.

5 DR. HALL: WELL --

6 MR. REED: I DON'T THINK THAT MAKES US
7 SPECIAL OR UNUSUAL THAT WE HAVE TO ADD SOMETHING.

8 DR. HALL: THERE ARE THOSE AND THEN OTHERS,
9 AND I THINK THE POINT IS THAT SCIENTISTS ARE HUMANS,
10 JUST LIKE JOURNALISTS AND JUST LIKE BUSINESS PEOPLE,
11 POLITICIANS, ANYBODY ELSE, AND THERE WILL ALWAYS BE A
12 FEW ABERRANT INDIVIDUALS. AND I THINK LET ME JUST
13 POINT OUT THERE IS A STRONG ELEMENT OF DELUSION IN
14 THIS, WHICH IS VERY ALMOST SAD. PEOPLE WHO DO THIS
15 REALLY DELUDE THEMSELVES. HOW IN THE WORLD THEY THINK
16 THEY'RE GOING TO GET AWAY WITH THIS IS JUST --
17 EVENTUALLY THEY'LL GET CAUGHT. THERE'S JUST NO TWO
18 WAYS ABOUT IT.

19 AND SO I THINK THE QUESTION IS HOW TO -- IT'S
20 VERY HARD TO STOP SOMETHING THIS CLEVER AND THIS ALMOST
21 CUNNING IN ITS PLANNING. BUT ONCE IT HAPPENS, THEN I
22 THINK THE MECHANISMS FOR FINDING IT AND DOING SOMETHING
23 ABOUT IT VERY QUICKLY, THAT WE CAN DO AND THAT WE
24 INTEND TO DO.

25 MR. REED: AND IT SEEMS TO ME EVERYBODY IS ON

1 THE SAME PAGE ON THIS. WE DON'T WANT FRAUD. AND IF
2 THEY TAKE MONEY UNDER UNFAIR PRETENSES, THEN THEY
3 SHOULD HAVE TO PAY IT BACK. THERE'S NO QUESTION ABOUT
4 THAT. IF THEY DO SOMETHING ACTIVELY DISHONEST, THEN
5 WHATEVER WEIGHT OF THE LAW IS APPLICABLE SHOULD BE
6 APPLIED. WE'RE ALL IN FAVOR OF HONESTY AND LET'S DO
7 IT, BUT I DON'T WANT US TO BE THINKING OF OURSELVES AS
8 A SCIENCE WHICH HAS ANYTHING TO BE ASHAMED OF. I'M
9 PROUD OF THE RECORD OF STEM CELL RESEARCH. I THINK WE
10 DO TREMENDOUS WORK, AND I THINK ONE ABERRANT INDIVIDUAL
11 DOES NOT STAIN THE WHOLE GROUP.

12 CO-CHAIR LO: MY PUBLIC HEALTH CONSCIENCE
13 SAYS THAT WE NEED TO GO UP FOR LUNCH. DR. WILLERSON
14 AND PROFESSOR CHARO BOTH HAD COMMENTS THEY WANTED TO
15 MAKE. WE'LL TAKE THOSE AND THEN TAKE A BREAK.

16 MS. CHARO: ONCE AGAIN, DEFERENCE TO THE
17 LADY. JUST VERY BRIEFLY. THE NIH DOES HAVE CRITERIA
18 FOR SUSPENSION AND TERMINATING OF AWARDS WITH
19 APPROPRIATE PENALTIES. PENALTIES DO NOT SPECIFICALLY
20 LAY OUT WHETHER OR NOT REPAYMENT IS INCLUDED, BUT THE
21 PENALTY SECTION DOES SAY EVERYTHING THAT'S AVAILABLE,
22 QUOTE, UNQUOTE, UNDER THE LAW. SO FURTHER
23 INVESTIGATION WITH THE OFFICE OF INSPECTOR GENERAL WILL
24 BE NECESSARY.

25 BUT IT OCCURRED TO ME AS I WAS FINDING THAT

1 LANGUAGE THAT THERE MIGHT BE ANOTHER SOURCE OF
2 AUTHORITY THAT'S CLOSER TO HOME.

3 CALIFORNIA ALREADY HAS A GRANTS PROGRAM FOR
4 CERTAIN SPECIFIC AREAS OF MEDICAL RESEARCH. AND ONE
5 CAN IMAGINE THAT IN THOSE ONGOING PROGRAMS, LIKE BREAST
6 CANCER AREA, THERE MIGHT ALREADY BE MECHANISMS FOR
7 MONITORING, AUDITING, REPORTING, AND A SERIES OF
8 PENALTIES ALONG WITH THE TRIGGERS FOR THE PENALTIES,
9 AND THE DUE PROCESS REQUIREMENTS. AND I WONDERED IF WE
10 MIGHT START BY LOOKING WITHIN CALIFORNIA STATE LAW
11 FIRST AND SEE IF WE CAN COME INTO COMPLIANCE WITH THAT,
12 SO AT LEAST THERE WOULD BE SOME KIND OF CONSISTENCY.

13 DR. HALL: EXCELLENT IDEA. WE'VE BEEN IN
14 TOUCH WITH THEM, BUT THE ONE PART THAT I AM ALMOST
15 ENTIRELY IGNORANT OF IS THE ENFORCEMENT PART. WE
16 CERTAINLY WILL FIND THAT OUT. THANK YOU.

17 DR. WILLERSON: I WAS GOING TO SAY SOMETHING
18 SIMILAR, AND I AGREE. BUT IRB'S LIVE UNDER THE THREAT
19 OF AUDITS FROM THE STATE, FEDERAL GOVERNMENT, AND THERE
20 ARE BIG PENALTIES IF THEY STRAY. AND LEADERS OF
21 INSTITUTIONS ARE VERY CONCERNED ABOUT THAT. I THINK
22 SCIENTISTS WILL CATCH SCIENTISTS THAT ARE COMMITTING
23 FRAUD, BUT I AM CONCERNED ABOUT THE OVERSIGHT OF THE
24 SCRO COMMITTEES. AND I THINK HAVING SOME KIND OF
25 AUDITING CAPABILITY THAT WE REPORT TO US PUT TOGETHER.

1 WE JUST HEARD A MECHANISM FOR IT.

2 CO-CHAIR LO: I THINK THERE WERE SOME GOOD
3 AND IMPORTANT IDEAS HERE. I SUGGEST WE ACTUALLY
4 ADJOURN TEMPORARILY FOR LUNCH, COME BACK WITH STOMACHS
5 FULL, AND MINDS READY TO WORK. 1:30.

6 (A RECESS WAS TAKEN.)

7 CO-CHAIR LO: I'D LIKE TO CALL US BACK TO
8 ORDER. WHILE WE'RE RECONGREGATING, A COUPLE OF
9 BUSINESS OR ADMINISTRATIVE REQUESTS. PEOPLE ARE HAVING
10 A REAL TOUGH TIME HEARING, SO CAN WE PLEASE GRAB THE
11 MIC AND SPEAK REAL CLOSE INTO IT AND SPEAK LOUDLY.

12 SECOND IS AN INCENTIVE. IF WE GET EVERYTHING
13 DONE, AT THE END OF THIS MEETING, KATE WILL TELL US
14 ABOUT PLANS FOR DINNER. BUT WE ONLY GET TO HEAR THAT
15 WHEN WE'RE DONE WITH OUR WORK.

16 THE THIRD THING IS ANOTHER REQUIREMENT, WHICH
17 IS JENNIFER HAS PUT ON EACH OF OUR PLACES A CIRM
18 CONFLICT OF INTEREST POLICY FOR STANDARDS WORKING GROUP
19 MEMBERS, NON-ICOC MEMBERS. AND WE NEED TO READ IT,
20 SIGN IT, AND FILL OUT THIS FORM DISCLOSING EVERYTHING.

21 NOW, JENNIFER, IS THIS DISCLOSURE JUST
22 CHANGES SINCE THE LAST ONE, OR IS IT COMPREHENSIVE? IS
23 IT CHANGES ONLY?

24 MS. SHREVE: THOSE DOCUMENTS HAVE CHANGED
25 SINCE THEY WERE -- THOSE DOCUMENTS HAVE CHANGED. THOSE

1 WERE SENT TO SOME -- YOU ALL SHOULD HAVE RECEIVED THEM
2 IN THE MAIL, BUT AGAIN WE WERE HAVING SOME DIFFICULTY
3 WITH OUR E-MAIL. SO I HAVE RECEIVED THEM BACK FROM
4 SOME OF YOU. SO THOSE THAT HAVE THOSE DOCUMENTS IN
5 FRONT OF YOU, THOSE HAVE BEEN REVISED SINCE YOU
6 ORIGINALLY SIGNED THEM IN MAY OR JUNE OF LAST YEAR, SO
7 WE ASK THAT YOU SIGN THOSE. THEY HAVE BEEN REVISED IN
8 AUGUST.

9 CO-CHAIR LO: THIS IS OUR OWN FINANCIAL
10 DISCLOSURE. DO WE HAVE TO FILL OUT ONLY ANY CHANGES
11 SINCE THE LAST TIME WE SIGNED THIS, OR DO WE HAVE TO
12 FILL OUR FROM SCRATCH?

13 MS. SHREVE: IT WOULD BE HELPFUL IF YOU DON'T
14 MIND FILLING IT OUT FROM SCRATCH SO THAT THAT REFLECTS
15 ALL THE INFORMATION THAT'S UP TO DATE.

16 CO-CHAIR LO: WHEN DO YOU WANT THESE BACK?
17 BY THE END OF THE MEETING?

18 MS. SHREVE: WHENEVER YOU'RE ABLE TO GIVE
19 THEM TO ME. IT WOULD GREAT BY THE END OF THE MEETING.

20 CO-CHAIR LO: SO WHAT I WOULD LIKE TO DO IS
21 CHANGE THE ORDER OF THE AGENDA. THERE ARE THREE
22 SECTIONS WHICH I THINK HAVE A LOT OF SUBSTANCE WHERE
23 THERE'S SOME ISSUES THAT WE NEED TO THINK THROUGH AND
24 REACH AGREEMENT ON. I'D LIKE TO TAKE THOSE OUT OF
25 ORDER BECAUSE BOTH ZACH HALL AND PAT KING WILL NOT BE

1 ABLE TO BE WITH US TOMORROW. PAT HAS TO TEACH AND ZACH
2 HAS A MEETING IN SACRAMENTO, AND THEY BOTH HAVE SOME
3 IDEAS ON SOME SECTIONS.

4 SO WHAT I WOULD LIKE TO DO IS TRY TO TURN TO
5 SECTIONS 100007, WHICH HAS TO DO WITH ACCEPTABLE
6 RESEARCH MATERIALS, 100008, WHICH HAS TO DO WITH
7 CONSENT, AND 100009, WHICH HAS TO DO WITH FAIRNESS AND
8 DIVERSITY, AND TRY AND COVER THOSE THIS AFTERNOON AT
9 THE LEAST WHILE WE STILL HAVE PAT AND ZACH HERE WITH
10 US.

11 LET'S FIRST START WITH 100007, ACCEPTABLE
12 RESEARCH MATERIALS. AND THIS IS A SECTION THAT, JUST
13 TO SORT OF SET IT IN CONCEPT, WE SEPARATE OUT THREE
14 DIFFERENT TYPES OF STEM CELL LINES. FIRST, (A), IS
15 STEM CELL LINES, COVERED STEM CELL LINES DERIVED WITH
16 CIRM FUNDING AFTER THESE REGULATIONS GO INTO EFFECT.
17 (B) IS COVERED STEM CELL LINES TO BE USED IN
18 CIRM-FUNDED RESEARCH, BUT THEY WERE DERIVED, THE STEM
19 CELL LINES WERE DERIVED WITHOUT CIRM FUNDING BEFORE THE
20 EFFECTIVE DATE OF THIS CHAPTER. AND (C) IS STEM CELL
21 LINES USED IN CIRM-FUNDED RESEARCH DERIVED -- I'M
22 SORRY. THIS ISN'T RIGHT, IS IT? (B) IS AFTER THE
23 EFFECTIVE DATE, AND (C) IS STEM CELL LINES DERIVED
24 WITHOUT CIRM FUNDING -- STEM CELL LINES DERIVED BEFORE
25 THESE REGULATIONS GO INTO EFFECT.

1 AND THERE ARE DIFFERENT, SOMEWHAT DIFFERENT,
2 REQUIREMENTS. AND ZACH HAD WHAT I THOUGHT WERE SOME
3 VERY IMPORTANT IDEAS ON MODIFYING THE DISCREPANCIES
4 BETWEEN THE FIRST TWO TYPES OF RESEARCH. ZACH, YOU
5 WANT TO START US OFF?

6 DR. HALL: YES. WE HAD A DISCUSSION LAST
7 TIME ABOUT THE REGULATIONS THAT SHOULD GOVERN STEM CELL
8 LINES THAT ARE NOT -- WHOSE DERIVATION WAS NOT PAID FOR
9 BY CIRM, BUT THAT CIRM-FUNDED INVESTIGATORS MIGHT WISH
10 TO USE. THAT IS, SOMEBODY MAY SAY I HAVE A PROJECT. I
11 WANT TO USE A STEM CELL LINE THAT IS PARTICULARLY
12 WELL-SUITED FOR THIS PROJECT, BUT IT'S OBTAINED FROM SO
13 AND SO, SO AND SO. THEY'VE AGREED TO GIVE IT TO ME.
14 HERE'S THE PAPERWORK. AND I'D LIKE TO DO THE WORK IN
15 MY LAB.

16 AND THE QUESTION IS WHAT RULES SHOULD GOVERN
17 THAT. SHOULD IT BE THE SAME RULES THAT GOVERN THE STEM
18 CELL LINES THAT ARE DERIVED UNDER CIRM FUNDING, OR
19 SHOULD WE MAKE ALLOWANCE FOR DIFFERENCES OF OPINION?
20 AND MY VIEW AT THE LAST MEETING WAS THAT, IN PART,
21 THROUGH THINGS THAT ANN AND OTHERS HAD SAID, THE VIEW
22 THAT THERE WAS AN ARGUMENT TO BE MADE FOR MODEST
23 REIMBURSEMENT, AND THAT ALTHOUGH WE CHOSE NOT TO DO IT,
24 IF SOMEBODY ELSE IN GOOD FAITH CHOSE TO DO THAT, THEN
25 IT SHOULD NOT PRECLUDE OUR INVESTIGATORS FROM WORKING

1 WITH THAT LINE.

2 BASICALLY IT WAS AN ARGUMENT THAT IS A
3 COMPLEX ISSUE, AND THERE ARE SEVERAL SORT OF POINTS OF
4 VIEW ON IT, AND THAT WE RECOGNIZE THAT OTHERS IN GOOD
5 FAITH AND AFTER THOUGHTFUL CONSIDERATION MIGHT COME TO
6 A CONCLUSION THAT WAS DIFFERENT FROM OURS. SO I URGE
7 THAT WE CONSIDER NOT EXCLUDING THOSE LINES.

8 AND I JUST, FOR WHAT IT'S WORTH, I WANTED TO
9 SAY THAT MY OWN VIEWS ON THIS HAVE CHANGED. I STILL
10 BELIEVE THAT WHAT I SAID WAS IMPORTANT, AND IT'S ONE OF
11 THE CONSIDERATIONS, BUT I ALSO THINK THAT AS WE ARE
12 REALLY THE FIRST IN THE COUNTRY TO PUT THESE INTO
13 REGULATIONS, THAT, IN FACT, WHAT WE DO WILL HAVE SOME
14 INFLUENCE ON OTHERS. AND THAT IF WE WERE TO ADOPT A
15 STRICT LINE ON THIS AND SAY THAT, IN FACT, WE WOULD NOT
16 FUND WORK ON LINES THAT HAD BEEN DERIVED WITH
17 COMPENSATION, THAT THAT ACTUALLY MIGHT INFLUENCE THE
18 BEHAVIOR OF OTHERS AND MIGHT WORK IN A GOOD WAY.

19 SO I JUST WANTED TO SAY THAT MY VIEWS ON THIS
20 HAVE SHIFTED, AND I THINK NOW IT WOULD BE BETTER TO
21 HAVE A UNIFORM POLICY, BOTH FOR THOSE LINES THAT ARE
22 DERIVED HERE AND FOR LINES THAT MIGHT BE DERIVED
23 ELSEWHERE, EVEN IF PEOPLE HAD GIVEN CAREFUL THOUGHT TO
24 IT. I THINK AFTER DISCUSSION WITH SEVERAL PEOPLE, I
25 THINK THAT RIGHT NOW THE NUMBER OF SUCH LINES IS

1 PROBABLY RELATIVELY SMALL. WE DON'T KNOW WHAT WILL
2 HAPPEN IN THE FUTURE, BUT THAT IF WE MAKE THE
3 STATEMENT, IT MIGHT ACTUALLY INFLUENCE OTHERS NOT TO
4 COMPENSATE SO THAT THEIR LINES MIGHT BE USED BY
5 CALIFORNIA RESEARCHERS.

6 SO THAT'S JUST AN OPINION I PUT OUT FOR YOUR
7 DISCUSSION AND CONSIDERATION. I THINK I WASN'T CLEAR
8 FROM THE LOOK ON JON'S FACE.

9 MR. SHESTACK: I JUST -- IT'S THE LAST TIME
10 I'LL BRING THIS UP. WE ALWAYS HAVE THIS STANDARD, THAT
11 IT IS UNETHICAL THAT REIMBURSEMENT IS -- FOR EGG
12 DONATION IS --

13 DR. HALL: IT'S IN THE PROPOSITION FROM THE
14 BEGINNING HARDWIRED.

15 MR. SHESTACK: RIGHT. BUT THERE ARE OTHER
16 ETHICAL STANDARDS ABOUT THIS, WHICH IS WHY I REALLY
17 DON'T AGREE WITH TAKING THIS HARD LINE. I ACTUALLY
18 THINK THAT WHAT WE HAVE IN OUR LEGISLATION IS
19 UNETHICAL. I THINK IT ACTUALLY -- I THINK THE POSITION
20 THAT WOMEN SHOULDN'T BE COMPENSATED IS THE MOST
21 UNETHICAL OF ALL THE POSITIONS THAT ACTUALLY DRIVES
22 THIS DIFFERENT KIND OF DESPERATION INTO DONATION. AND
23 SO I ACTUALLY REALLY DON'T WANT -- I WOULD PREFER US
24 NOT TAKING A HARD LINE ON THAT, IF IT WERE POSSIBLE
25 THAT SOMEONE COULD UNDERSTAND THE SUBTLETIES.

1 THE LINE WE HAVE NOW IS THAT, NO, BUT
2 ACTUALLY THE ONLY PEOPLE WHO DONATE ARE PEOPLE WHO --
3 THEY'RE NOT DRIVEN BY FINANCIAL REASONS, BUT THEY'RE
4 USUALLY DRIVEN BY A DIFFERENT KIND OF PERSONAL
5 DESPERATION OR OVERPROMISING FROM THE SCIENTIFIC
6 ESTABLISHMENT. IT ACTUALLY SEEMS MORE UNETHICAL TO ME.
7 I JUST WANTED TO PUT IT OUT THERE ONE MORE TIME.

8 DR. PRIETO: OR I WOULD HOPE AND BELIEVE THAT
9 THIS WILL COME TO SOMETHING, THAT A CONCERN BECAUSE OF
10 THEIR OWN PERSONAL OR FAMILY EXPERIENCE THAT THEY WANT
11 TO PUSH THE RESEARCH FORWARD. I THINK THERE ARE PLENTY
12 OF PEOPLE LIKE THAT. I THINK ANN MADE THAT POINT A
13 COUPLE OF MEETINGS AGO.

14 QUESTION I HAVE ABOUT WHAT'S BEING DONE IN
15 THE UK, DON'T THEY ALSO PROHIBIT COMPENSATION?

16 MS. CHARO: YES, THEY DO PROHIBIT, BUT --

17 DR. PRIETO: BUT ALLOW REIMBURSEMENT.

18 MS. CHARO: CORRECT.

19 DR. PRIETO: AND I WOULD ARGUE CERTAINLY FOR
20 DEFINING REIMBURSEMENT GENEROUSLY, BUT STILL DRAWING
21 THAT LINE BETWEEN THAT AND PAYMENT.

22 CO-CHAIR LO: FRANCISCO, YOU WOULD SUPPORT
23 HAVING IT BOTH FOR LINES DERIVED WITH CIRM FUNDING AND
24 CIRM USE OF LINES DERIVED WITH OTHER SOURCES OF
25 FUNDING?

1 DR. PRIETO: YES.

2 DR. HALL: SO WE HAVE A STATEMENT IN
3 PROPOSITION 71 THAT, AS I SAY, HAS BEEN IN FROM THE
4 BEGINNING, AND THAT OBVIOUSLY WILL GOVERN WHAT WE DO.
5 AND SO I DO THINK THERE ARE ARGUMENTS ON BOTH SIDES,
6 AND I UNDERSTAND SOME OF THE SUBTLE POINTS THAT YOU
7 MAKE, JON.

8 MR. SHESTACK: I'M JUST MAKING A REAL POLITIC
9 ARGUMENT.

10 DR. HALL: WE ARE IN THE VANGUARD HERE. AND
11 IT MAY BE -- I GUESS WHAT I REALLY STARTED THINKING
12 ABOUT WAS SO HOW MANY LINES ARE OUT THERE THAT WE MIGHT
13 BE DEPRIVING CALIFORNIA INVESTIGATORS OF. IT TURNS
14 OUT, AS FAR AS I CAN TELL, THERE ARE NOT VERY MANY.
15 AND IT MAY BE, BY US DOING THIS, THAT WE CAN INFLUENCE
16 OTHERS TO DO IT. AND IF OVER TIME ANOTHER POSITION
17 DEVELOPS THAT TAKES INTO ACCOUNT SOME OF THE SUBTLETIES
18 THAT YOU MENTIONED, I THINK THAT IS POSSIBLE. BUT I
19 THINK FOR THE MOMENT I THINK THE RIGHT THING TO DO, MY
20 OWN VIEW, IS TO TRY TO NOT HAVE A DIFFERENCE BETWEEN
21 THE TWO, BUT SIMPLY SAY THIS IS THE WAY WE THINK IT
22 OUGHT TO BE DONE. AND I THINK IT MAY INFLUENCE THE WAY
23 IT'S DONE GENERALLY. I DON'T KNOW. THAT'S MY.

24 CO-CHAIR LO: OTHER THOUGHTS BY COMMITTEE
25 MEMBERS ON THIS TOPIC?

1 DR. PETERS: WELL, I'D LIKE TO HEAR ANN SPEAK
2 TO THIS. WHEN WE HAVE HAD THE SUBGROUP DISCUSSION OF
3 THESE MATTERS, IT SEEMED THAT ANN WAS IN POSSESSION OF
4 A GREAT DEAL OF DATA THAT WOULD SUGGEST THINKING OF
5 THESE WOMEN AS IN DESPERATION IS REALLY NOT ACCURATE.
6 THERE IS, ON THE BASIS OF OUR CURRENT KNOWLEDGE, GOING
7 TO BE AN ADEQUATE SUPPLY OF WOMEN WHO WOULD BE WILLING
8 TO PARTICIPATE BECAUSE OF THEIR WILLINGNESS TO
9 CONTRIBUTE TO SCIENTIFIC RESEARCH, AND THAT THE
10 COMPENSATION FOR EXPENSES IS A FAIR WAY OF TREATING
11 THIS WITHOUT OPENING DOORS TO OTHER KINDS OF PROBLEMS
12 THAT MAKING THEM SALABLE WOULD LEAD TO.

13 BUT LET ME JUST SAY THAT I DON'T CLAIM TO BE
14 AN EXPERT ON THIS, AND I FEEL THAT I'VE LEARNED A LOT
15 FROM WHAT ANN HAS WRITTEN AND SAID ABOUT THIS.

16 DR. KIESSLING: I THINK I'LL REITERATE MY
17 POSITION ON THIS BECAUSE I'VE NOW HAD TO DO IT MANY
18 TIMES IN THE LAST TWO WEEKS FOR NEWSPAPER REPORTERS.
19 SO I JUST AS WELL DO IT FOR THIS COMMITTEE.

20 THE OVERWHELMING IMPORTANT THING TO CONSIDER
21 ABOUT THE EGG DONORS IS NOT SO MUCH WHETHER THEY'RE
22 COMPENSATED FOR THEIR LOST WORK EFFORT AS WHETHER OR
23 NOT THEY ARE FULLY INFORMED. THE CONSENT PROCESS
24 SHOULD BE THE PRIMARY CONCERN FOR RECRUITING EGG
25 DONORS. AND THE CONSENT PROCESS HAS TO HAVE SEVERAL

1 ASPECTS TO IT. THEY HAVE TO KNOW THEIR RISKS, THEY
2 ABSOLUTELY HAVE TO UNDERSTAND THE SCIENCE, AND THEY
3 HAVE TO KNOW EXACTLY WHAT'S GOING TO HAPPEN WITH THEIR
4 EGG DONATION IN TERMS OF WHETHER OR NOT IT HAS ANY HOPE
5 OF BENEFITING THEM OR THE PERSON THAT THEY'RE HOPING TO
6 BENEFIT.

7 SO THE OTHER ASPECT OF WHETHER THEY ACTUALLY
8 GET COMPENSATED FOR THEIR TIME OR NOT IS TRIVIAL
9 COMPARED TO THE COST OF THE PROCESS AS A WHOLE. ONE
10 EGG DONOR CYCLE FOR RESEARCH IN OUR EXPERIENCE COSTS
11 ABOUT \$25,000. SO TO COMPENSATE A DONOR FOR SOME
12 REASONABLE AMOUNT OF OFFSET OF HER LOST WORK TIME,
13 WHICH COULD BE 150 TO 200 HOURS, AMOUNTS TO A VERY
14 SMALL PERCENTAGE OF THE TOTAL COST OF THE CYCLE. IT IS
15 NOT GOING TO REALLY INFLUENCE WHETHER OR NOT SHE'S
16 DOING THIS OF HER OWN FREE WILL. SO IT'S REALLY HER
17 INFORMED CONSENT PROCESS THAT'S FAR MORE IMPORTANT THAN
18 WHAT THIS WOMAN GETS COMPENSATED OR NOT.

19 HAVING SAID THAT, WHAT WE HAVE EXPERIENCED IS
20 THAT THE WOMEN WHO WOULD LIKE TO DONATE EGGS FOR STEM
21 CELL RESEARCH BECAUSE THEY BELIEVE IT'S GOING TO BE
22 HELPFUL GENERALLY TO SOMEONE IN THEIR FAMILY, MANY OF
23 THOSE WOMEN CAN ONLY DO IT IF THEY ARE COMPENSATED FOR
24 LOST WORK. SO TO NOT COMPENSATE SOMEONE FOR THE TIME
25 THAT SHE'S GOING TO HAVE TO SPEND DOING THIS MEANS

1 YOU'RE LIMITING THE NUMBERS OF WOMEN WHO CAN ACTUALLY
2 CONTRIBUTE.

3 TO OPEN THIS POSSIBILITY UP FOR ALL WOMEN ALL
4 OVER WHO WOULD LIKE TO HELP OUT, YOU ARE GOING TO HAVE
5 TO COMPENSATE THEM FOR LOST WORK EFFORT. IF YOU DON'T
6 DO THAT, YOU'RE STILL GOING TO HAVE PLENTY OF EGG
7 DONORS. IT'S NOT GOING TO BE THE BROAD SECTION THAT
8 YOU COULD GET OF YOU COMPENSATED THEM FOR THE TIME
9 SPENT IN THE CLINIC.

10 DR. PETERS: WELL, WOULD THAT LEAD TO SOME
11 KIND OF COMPROMISE FORMULATION BECAUSE OF VERY SPECIFIC
12 COMPENSATION FOR EXPENSES THAT'S DIFFERENT THAN BLANKET
13 COMPENSATION OR PAYMENT, WHICH COULD LEAD TO THE
14 PROBLEMS OF INDUCEMENT?

15 DR. KIESSLING: I THINK THE BIGGER PROBLEM OF
16 INDUCEMENT IS NOT FULLY -- IS FOR THE WOMAN TO NOT
17 FULLY UNDERSTAND WHAT THE LIMITATIONS TO THE SCIENCE
18 ARE RIGHT NOW AND TO EXACTLY WHAT HER RISKS ARE IN
19 PARTICIPATING.

20 DR. PRIETO: AREN'T LOST WAGES SOMETHING THAT
21 WE CAN CONSIDER, THAT WE CAN DEFINE AS AN EXPENSE? IT
22 IS AN EXPENSE FOR MOST PEOPLE. I HAVE TO GIVE UP TIME
23 FROM WORK, THAT'S AN EXPENSE.

24 DR. TAYLOR: I WAS JUST GOING TO SAY THAT ANN
25 HAS MADE A REALLY IMPORTANT POINT HERE. I THINK THAT

1 THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE
2 CALCULATED THAT THERE'S ABOUT 60 HOURS PER EGG DONOR
3 INVOLVED IN THE CONSENTING FOR CLINICAL EGG DONATION.
4 AND FOR PROTOCOL LIKE THIS, I'M NOT SURPRISED THAT THAT
5 NUMBER IS DOUBLED IN YOUR EXPERIENCE, SO A HUNDRED TO
6 120 HOURS OF INVESTED TIME TO ACTUALLY GET THROUGH THIS
7 PROCESS. WHEN YOU START UNDERSTANDING THAT LEVEL OF
8 COMPLEXITY, THEN SOME TYPE OF REIMBURSEMENT FOR LOST
9 PRODUCTIVITY SEEMS APPROPRIATE TO ME.

10 MS. FEIT: I THINK MY CONCERN WOULD BE ONLY
11 WHO'S GOING TO DEFINE WORK, WHAT TYPE OF WORK. IS THIS
12 SOMEBODY WHO STAYS HOME AND SAYS I HAVE A PARENT, A
13 DOG, AND I HAVE TO TAKE CARE OF THEM, AND SO THAT'S
14 LOSS OF TIME. WE GET INTO A LITTLE BIT OF A SLIPPERY
15 SLOPE AROUND THAT DEFINITION AND HOW THEY SHOULD BE
16 COMPENSATED BECAUSE NOT EVERYBODY IS EQUAL IN THAT
17 ARENA.

18 SO I THINK I WOULD BE CONCERNED. IS CIRM IN
19 A POSITION TO BE ABLE TO OVERSEE THAT AND MAKE SURE
20 THAT IT'S REASONABLE? SO I JUST HAVE SOME CONCERNS. I
21 THINK ANN'S COMMENT ABOUT THE ESSENCE OF THE DONOR IS
22 REALLY THE CONSENT AND THE FULL EDUCATION AND
23 UNDERSTANDING OF WHAT THE RISKS ARE. AND I THINK IT'S
24 APPROPRIATE THAT EXPENSES AND LOSSES OF ANY KIND OCCUR
25 DURING THE TIME, I RECOGNIZE, AND SHOULD BE ABLE TO BE

1 QUANTIFIED READILY. SO THAT WOULD BE MY ONLY COMMENT.

2 DR. HALL: LET ME JUST MAKE A SUGGESTION. WE
3 HAVE IN PROPOSITION 71 THE STATEMENT THAT REIMBURSEMENT
4 IS APPROPRIATE; WHEREAS, COMPENSATION IS NOT. AND I
5 THINK WE SHOULD DO TWO THINGS. FIRST OF ALL, I'M
6 SUGGESTING THAT WE HAVE IT UNIFORM BETWEEN THE TWO. I
7 THINK THAT'S THE ISSUE THAT I WAS SAYING THAT I THINK
8 WE CAN HAVE INFLUENCE.

9 THE SECOND IS WHETHER WE SHOULD GET INTO ALL
10 THE NUTS AND BOLTS OF SAYING WHAT APPROPRIATE
11 REIMBURSEMENT WAS. I'M NOT SURE. AND MAYBE WHAT WE
12 SHOULD DO IS LEAVE THAT FOR INDIVIDUAL STUDIES,
13 INDIVIDUAL PEOPLE WHO ARE GOING TO DO THIS, AND THAT
14 CAN BE WORKED OUT WITH IRB'S AND WITH ESCRO'S WHO HAVE
15 EXPERIENCE WITH THIS IN OTHER CONTEXTS. THEY WILL HAVE
16 A NUMBER OF THINGS LIKE THIS IN OTHER KINDS OF CLINICAL
17 AND OTHER STUDIES.

18 I THINK IF WE MAKE CLEAR THE GENERAL
19 PRINCIPLES THAT WE THINK SHOULD BE FOLLOWED AND LEAVE
20 THOSE DETAILS TO BE WORKED OUT BY THE INDIVIDUAL
21 INVESTIGATOR PROPOSING, AND THEN TO BE APPROVED BY
22 ESCRO OR THE IRB, THAT WOULD BE MY PREFERENCE. AND TO
23 FOCUS FOR THIS COMMITTEE ON MAKING THE STATEMENT THAT'S
24 IN PROPOSITION 71 ALSO APPLY TO THE DERIVATION OF ANY
25 CELL LINES USED BY CIRM-FUNDED INVESTIGATORS.

1 DR. PRIETO: I THINK THE LINE NEEDS TO FALL
2 BETWEEN THE DIFFERENCE BETWEEN DANGLING A CHECK IN
3 FRONT OF SOMEONE AS AN INDUCEMENT TO SAY WE WILL GIVE
4 YOU \$5,000 OR WHATEVER AMOUNT TO COME FORWARD VERSUS WE
5 WILL COVER YOUR EXPENSES AND INCLUDING LOST WAGES FOR
6 PER DIEM, BUT SOME FIXED AMOUNT. I THINK THAT THERE'S
7 A CRUCIAL DIFFERENCE THERE.

8 DR. EGGAN: I WANT TO ECHO ZACH'S COMMENTS.
9 I THINK IT PROBABLY IS BEST FOR NOW TO LEAVE THIS IN
10 MORE GENERAL TERMS BECAUSE I THINK IT IS CLEAR THAT THE
11 STATUTE STATES THAT WE CANNOT -- SHOULD NOT COMPENSATE
12 THESE WOMEN. AND I THINK THAT THAT'S WHAT'S CRITICAL
13 FOR COERCION THAT WE'RE ALL WORRIED ABOUT. FUNDAMENTAL
14 CONCERN IS THAT WOMEN WITHOUT INFORMED CONSENT WILL BE
15 COERCED INTO DONATING THEIR OOCYTES AND MAKE A BAD
16 DECISION IN EXCHANGE FOR MONEY. AS LONG AS THERE IS
17 NOT STRONG INAPPROPRIATE COMPENSATION, BUT ONLY
18 REIMBURSEMENT, THAT IS, IT BE IMPORTANT THAT IT BE A
19 ZERO-SUM GAME FOR THOSE WOMEN THAT ARE INVOLVED IN THE
20 PROCEDURE.

21 AND SO I THINK IT'S STILL NOT CLEAR TO US,
22 AND IT'S GOING TO BE A LENGTHY DECISION AROUND THIS
23 TABLE AS TO WHAT THAT MEANS. I THINK IT IS IMPORTANT
24 THAT IRB'S AND OTHER GROUPS DO HAVE A LOT OF EXPERIENCE
25 WITH DEALING WITH THAT EXACT ISSUE OF WHAT IS THE

1 PROPER AMOUNT TO REIMBURSE PEOPLE FOR PARTICIPATION IN
2 HUMAN SUBJECTS RESEARCH, AND THAT TO SOME EXTENT NOT
3 DEFER THE EXPERTISE, BUT ENGAGE IT. I THINK THIS IS
4 PROBABLY THE BEST THAT WE CAN DO FOR NOW.

5 CO-CHAIR LO: OTHER THOUGHTS, COMMENTS?
6 GEOFF, WILL YOU REMIND US WHAT PROPOSITION 71 SAYS?

7 MR. LOMAX: HEADING HERE IS "PROHIBITIONS ON
8 COMPENSATION." STANDARDS PROHIBITING COMPENSATION TO
9 RESEARCH DONORS OR PARTICIPANTS WHILE PERMITTING
10 REIMBURSEMENT OF EXPENSES. AND THEN THERE'S A SECOND
11 SECTION WHICH IS LIMITATION ON PAYMENTS FOR CELLS.
12 STANDARDS LIMITING PAYMENTS FOR THE PURCHASE OF STEM
13 CELLS OR STEM CELL LINES TO REASONABLE PAYMENTS FOR
14 REMOVAL, PROCESSING, DISPOSAL. SO THAT'S SORT OF
15 TRANSACTION COST, BUT THE SPECIFIC SECTION IS QUITE
16 SHORT IN TERMS OF THE, AGAIN, I'LL REPEAT, STANDARDS
17 PROHIBITING COMPENSATION TO RESEARCH DONORS OR
18 PARTICIPANTS WHILE PERMITTING REIMBURSEMENT OF
19 EXPENSES.

20 WHAT STILL REMAINS UNDEFINED IS THE TERM
21 "EXPENSES," LOOKING AT SCOTT FOR AN ANSWER THERE.

22 MR. TOCHER: OBVIOUSLY IT'S NOT DEFINED IN
23 THE ACT WHAT A PERMISSIBLE EXPENSE IS. THAT'S WITHIN
24 THE PURVIEW OF CIRM TO DEFINE, OR, IF IT SO CHOOSES, TO
25 LET AN ESCRO OR IRB WORK THAT OUT IN PRACTICE.

1 FROM A REGULATORY APPROACH, SOMETIMES IT'S
2 GOOD TO TRY TO ANTICIPATE WHERE YOU THINK THE REGULATED
3 COMMUNITY WILL NEED ASSISTANCE. AND SO TO SAVE
4 HEADACHE AND TIME, YOU TRY TO ANTICIPATE THAT AND WORK
5 THAT INTO A REGULATION QUESTIONS YOU KNOW THAT WILL
6 COME UP REPEATEDLY.

7 ON THE OTHER HAND, IT'S ALSO AS EQUALLY
8 EFFECTIVE SOMETIMES TO SORT OF LET THINGS PLAY OUT, AS
9 YOU'VE HEARD TODAY, TO SEE WHAT THE EXPERIENCE IS. AND
10 YOU WILL SEE SOMETIMES DIFFERENT APPROACHES LEAD TO A
11 SOLUTION THAT YOU WANT TO ADOPT AT A LATER TIME.

12 DR. EGGAN: MIGHT BE HELPFUL IF WE'RE
13 DEFINING EXPENSE TO JUST REASONABLE DEFINITIONS FROM
14 THE DICTIONARIES. JUST FROM THE DICTIONARY ON MY
15 MACINTOSH COMPUTER, EXPENSE, NOUN, THE COST REQUIRED
16 FOR SOMETHING, THE MONEY SPENT ON SOMETHING. THAT'S
17 ONE DEFINITION. IT CAN ALSO BE THE COST INCURRED IN
18 THE PERFORMANCE OF ONE'S JOB OR SPECIFIC TASK,
19 ESPECIALLY ONE UNDERTAKEN FOR ANOTHER PERSON. OR A
20 THING ON WHICH ONE IS REQUIRED TO SPEND MONEY.

21 I THINK THAT IN A WAY THE SECOND ONE IS
22 PROBABLY THE MOST APT HERE. I THINK IT DOES LEAVE SOME
23 ROOM OPEN. I THINK IT DOES, BY THAT DEFINITION, LIMIT
24 WHAT REIMBURSEMENT MEANS. I THINK IT DEFINITELY IS A
25 SLIGHTLY RESTRICTING DEFINITION. THAT'S THE WAY I READ

1 IT.

2 CO-CHAIR LO: ALTA.

3 MS. CHARO: KEVIN AND I ARE THINKING ALONG
4 THE SAME LINES. WHAT I WAS SCRAMBLING FOR HERE, BUT
5 DIDN'T FIND YET, IS WHETHER OR NOT IN THE AREA OF ORGAN
6 DONATION THERE IS A STANDING DEFINITION BECAUSE WHAT
7 WE'RE TALKING ABOUT IS MOVING EGG DONATION INTO KIND OF
8 AN ORGAN DONATION MODEL. YOU DON'T PAY FOR ORGANS BY
9 AND LARGE. THERE'S NO NATIONAL RULE ON THE PAYMENT FOR
10 GAMETES, BUT THIS IS ESSENTIALLY SAYING, FOR CIRM
11 PURPOSES, THERE WILL BE NO PAYMENT FOR GAMETES. IF WE
12 CAN FIND SOMETHING THAT'S BEEN OPERATIONALIZED FOR
13 YEARS, AT LEAST WE'D HAVE A BODY OF PRECEDENT. AND
14 ALSO I THINK IT WOULD BE A DEFENSIBLE WAY OF GOING
15 ABOUT IT INSTEAD OF MAKING IT UP FROM WHOLE CLOTH.

16 UNOS MIGHT BE A USEFUL SOURCE OF INFORMATION.

17 DR. KIESSLING: I'D LIKE TO SPEAK TO THAT
18 BECAUSE, ALTHOUGH IN SOME WAYS, ALTA, EGG DONATION IS
19 SIMILAR TO KIDNEY DONATION, IN OTHER WAYS IT'S VERY
20 DIFFERENT. I THINK THAT LUMPING THOSE TWO IN THE SAME
21 POT HAS ACTUALLY CAUSED SOME CONFUSION BECAUSE WHAT
22 WE'RE ASKING THESE WOMEN TO DO IS PARTICIPATE AS NORMAL
23 HUMAN SUBJECTS IN A RESEARCH PROTOCOL. I THINK THAT'S
24 VERY DIFFERENT FROM DONATING AN ORGAN TO SAVE SOMEONE'S
25 LIFE, A. I DON'T THINK THOSE TWO SHOULD REALLY BE

1 LUMPED TOGETHER. THE MORE I THINK IT ABOUT IT, THE
2 MORE I THINK THEY'RE DIFFERENT.

3 WE HAVE A ZERO TOLERANCE FOR RISK FOR WOMEN
4 GOING THROUGH EGG DONATION. THEY SHOULD HAVE NO
5 MEDICAL ISSUE. THEIR MEDICAL RISKS SHOULD ABSOLUTELY
6 BE MINIMIZED, AND I THINK YOU'RE WILLING TO ACCEPT SOME
7 MEDICAL RISK FOR SOMEBODY WHO'S DONATING A KIDNEY TO
8 SAVE SOMEBODY'S LIFE.

9 MS. CHARO: IF I MAY, ANN, JUST TO BE CLEAR,
10 I WASN'T SUGGESTING THAT ANALOGY BE EXTENDED TO
11 ANYTHING HAVING TO DO WITH THE WAY IN WHICH WE RECRUIT,
12 INFORM, OR THE TOLERANCE FOR RISK THAT WE HAVE. I WAS
13 TALKING ONLY ABOUT THE DEFINITION OF REIMBURSABLE
14 EXPENSES.

15 DR. KIESSLING: RIGHT. AND AS FAR AS I KNOW,
16 ALL NORMAL HUMAN SUBJECTS ARE COMPENSATED FOR THEIR
17 RESEARCH TIME. AND SO THAT IS USUALLY DEFINED AT THE
18 LEVEL OF INSTITUTIONAL REVIEW. IF YOU WANT TO PAY
19 SOMEBODY \$25 TO DONATE BLOOD FOR YOUR PLATELET STUDY,
20 THE INSTITUTIONAL REVIEW BOARD DECIDES IF THAT'S TOO
21 MUCH, TOO LITTLE, WHATEVER. SO COMPENSATING PEOPLE FOR
22 NORMAL HUMAN SUBJECTS RESEARCH IS SORT OF MORE
23 STANDARD.

24 MS. CHARO: ANN, I APPRECIATE THAT, BUT WE'RE
25 NOT GOING TO PAY PEOPLE FOR THEIR RESEARCH

1 PARTICIPATION HERE. THAT'S OFF THE TABLE BECAUSE OF
2 PROP 71. IT'S JUST OFF THE TABLE. SO WHAT WE'RE
3 TALKING ABOUT IS WHAT IS A REIMBURSABLE EXPENSE.

4 DR. HALL: REIMBURSED.

5 MS. CHARO: WE'RE NOT TALKING ABOUT PAYMENT/
6 COMPENSATION. THAT'S NOT PERMISSIBLE.

7 DR. KIESSLING: BUT THE NORMAL HUMAN SUBJECTS
8 COMPENSATION IS USUALLY FOR TIME AND EFFORT.

9 MS. CHARO: IT DOESN'T MATTER WHAT IT IS FOR
10 HUMAN SUBJECTS ORDINARILY BECAUSE WE CAN'T BORROW THAT
11 SINCE WE'RE NOT ALLOWED TO COMPENSATE WOMEN FOR
12 PARTICIPATING HERE. WHAT WE ARE ALLOWED TO DO IS
13 REIMBURSE THEM. AND WE'RE TRYING TO UNDERSTAND WHAT IS
14 A REIMBURSABLE EXPENSE. ALL I'M SUGGESTING IS THAT
15 THERE ARE OTHER PLACES THAT ALSO DO NOT COMPENSATE
16 PEOPLE. UNOS IS AN EXAMPLE WHERE THEY, NONETHELESS,
17 REIMBURSE THEM FOR EXPENSES FROM WHICH WE MIGHT GET
18 SOME GUIDANCE.

19 UNFORTUNATELY WHETHER -- I'M NOT GOING TO
20 ENGAGE IN ARGUING ABOUT WHETHER IT'S ETHICAL TO PAY
21 PEOPLE TO GIVE EGGS BECAUSE THE ISSUE HAS BEEN TAKEN
22 AWAY FROM US BY PROPOSITION 71. I'M NOT TRYING TO
23 DEFEND OR CRITIQUE THE RULE THAT WE CAN'T PAY THEM.
24 I'M JUST SAYING WE CAN'T EVEN DISCUSS IT, RIGHT.

25 MS. FEIT: IN TERMS OF ORGAN DONATION, THE

1 REASON THAT WE HAVE STANDARDS THAT ARE SO STRICT ABOUT
2 ANY FORM OF MONEY GOING TO FAMILIES OR INDIVIDUALS FOR
3 AN ORGAN OF ANY KIND IS BECAUSE IT'S REALLY ADDRESSING
4 THE HUMAN NATURE OUT THERE IN THE BIG WORLD. AND THE
5 HUMAN NATURE AND WHERE IT WAS GOING BEFORE THESE
6 NATIONAL STANDARDS AND REGULATIONS WERE PUT IN IS THAT
7 THERE WERE PEOPLE WHO WERE TRYING TO BUY THEM AND
8 TRYING TO CIRCUMVENT PROCESS, GOOD, MEDICAL, SCIENTIFIC
9 PROCESS THAT WAS PUT OUT THERE UNDER GOOD, ETHICAL,
10 MEANINGFUL INTENT, AND IT DIDN'T WORK BECAUSE THERE WAS
11 A HUGE BLACK MARKET FOR ORGANS THAT HAD STARTED TO BE
12 CREATED.

13 I THINK EVERYBODY IS RIGHT HERE IN WHAT
14 THEY'RE SAYING. ANN'S RIGHT IN TERMS OF THAT WHOLE
15 RESEARCH PROCESS, BUT WHAT WE'RE REALLY TRYING TO DO IS
16 PROTECT PEOPLE AND TO MAKE SURE THAT THE PROCESS THAT
17 WE HAVE FOR DONATION HAS THE HIGHEST STANDARDS. AND IF
18 THERE IS AN OTHER LIKE REPRESENTATION OF LEARNING AND
19 UNDERSTANDING AND EXPERIENCE THAT WENT ON, THEN
20 CERTAINLY ORGAN DONATION WAS OF THEM BECAUSE THAT IS
21 WHERE IT WAS GOING IS THAT THERE WAS A BLACK MARKET FOR
22 IT INTERNATIONALLY, AND SOMETHING HAD TO BE DONE TO
23 STABILIZE IT AND MAKE SURE THAT THERE WAS REAL CLEAR
24 INTENT OF HOW ORGANS ARE DONATED AND WHO SHOULD GET
25 THEM AND WHEN THEY SHOULD GET THEM BECAUSE THAT WAS THE

1 OTHER ISSUE.

2 I THINK THAT'S WHAT WE'RE TRYING TO CREATE
3 HERE IS THAT PROTECTION. IT'S NOT REALLY TO CHALLENGE
4 THE RESEARCH PROCESS OR TO SAY THAT THE COMPENSATION
5 SHOULD BE THERE OR SHOULDN'T BE THERE.

6 CO-CHAIR LO: OTHER COMMENTS?

7 MS. KING: I'VE FORGOT. WHAT DO THE FEDERAL
8 RULES DO? THEY DISTINGUISH BETWEEN COMPENSATION AND
9 REIMBURSEMENT. WHAT GUIDELINES ARE THERE?

10 MS. CHARO: THEY DON'T. THAT'S THE PROBLEM.
11 OHRP HAS NEVER PUT OUT REALLY GOOD GUIDELINES ON WHAT
12 CONSTITUTES A REIMBURSABLE EXPENSE.

13 CO-CHAIR LO: AS I HEAR THIS DISCUSSION,
14 THERE ARE TWO DIFFERENT ISSUES. ONE IS DO WE HAVE THE
15 SAME STANDARDS FOR CIRM-FUNDED DERIVATION AS FOR STEM
16 CELL LINES DERIVED WITHOUT CIRM FUNDING, DERIVATION
17 THAT CIRM FUNDS WISH TO USE. AND ZACH HAS PROPOSED
18 THAT THEY BE.

19 AND THE SECOND QUESTION IS WHAT WE WANT TO
20 SAY ABOUT COMPENSATION AND REIMBURSEMENT WITHIN THE
21 BOUNDS OF THE LIMITS PROPOSITION 71 SETS FOR US.

22 DR. EGGAN: I WOULD PROPOSE ESSENTIALLY, AND
23 BASED ON ANOTHER READING OF A DEFINITION FROM THE
24 DICTIONARY, WHICH I SHOULD HAVE DONE BEFORE, WHICH IS
25 WHAT DOES IT MEAN TO BE REIMBURSED. IT MEANS TO REPAY,

1 PARENTHESES, A PERSON WHO SPENT OR LOST MONEY. I THINK
2 THAT'S PRETTY CLEAR WITH RESPECT TO THESE ISSUES WHICH
3 WE'RE DISCUSSING.

4 SO I WOULD SAY THAT I THINK THAT ESSENTIALLY
5 DEFERRING TO THE IRB'S ON THIS ISSUE, WHO ARE GOING TO
6 HAVE STRONGLY VESTED INTERESTS FOR THEIR OWN
7 INSTITUTIONS TO MAKE SURE THAT THERE IS NOT A HINT OF
8 COERCION IN THIS REGARD, IS GOING TO BE A STRONG WAY TO
9 GO WITH, I THINK, THE STRONG COMMITMENT FROM THIS GROUP
10 THAT IF WE FEEL LIKE THERE'S WRONGDOING, THAT IT SEEMS
11 THAT WE HAVE THE MANDATE TO INTERVENE.

12 CO-CHAIR LANSING: I AGREE WITH THAT. I
13 THINK ALL WE CAN DO IS SET THE BROAD STANDARDS, AND
14 THEN WE HAVE TO SAY -- MAYBE WE CAN SAY IN HERE THAT
15 THE IRB IS THE ONE THAT IS GOING TO DETERMINE THE
16 LEGITIMACY OF AN EXPENSE OR NOT THE LEGITIMACY OF AN
17 EXPENSE. AND THEN IT BRINGS BACK SOMETHING TO THE
18 GOVERNANCE COMMITTEE AND GRANTS COMMITTEES, WHICH IS
19 SETTING UP A MECHANISM WHERE THEY MONITOR THIS OR WE
20 WANT THEM TO MONITOR FRAUD, WE WANT TO MONITOR THIS.
21 AND YOU SAID THIS GOES BACK TO THE COMMITTEE WHETHER WE
22 SET UP SPOT-CHECK OR SET UP A SUBCOMMITTEE THAT
23 SPOT-CHECKS EVERY THREE WEEKS ON SOMETHING.

24 DR. WAGNER: I JUST WANT TO MAKE ONE COMMENT.
25 THE CONVERSATION AS IT GOES FORWARD, I GUESS ONE THING

1 WE OUGHT TO MAKE SURE OF AND WE'RE TRYING TO STRUGGLE
2 WITH IS HOW DO WE NOT END UP EXCLUDING THE DIVERSE
3 POPULATION THAT WE WANT TO INCLUDE, AND ARE WE TAKING A
4 RISK IN THAT WAY.

5 SECONDLY, WHAT ARE WE GOING TO DO IF WE ALLOW
6 THE IRB'S TO DETERMINE WHAT IS THE APPROPRIATE COST AND
7 TIME, WHATEVER IT IS? WHAT WE DO IF THERE IS
8 SIGNIFICANT DIFFERENCES BETWEEN DIFFERENT IRB'S? FOR
9 EXAMPLE, AT STANFORD THEY COME UP WITH ONE WAY AND THEN
10 AT UCSF THEY COME UP WITH ANOTHER WAY. AND I THINK
11 WHAT WAS DISCUSSED EARLIER IS THAT IF WE CAN, WE MIGHT
12 GIVE THEM AS MUCH GUIDELINE AS WE CAN SO THAT WE
13 HOPEFULLY REDUCE AT LEAST SIGNIFICANT DIFFERENCES
14 BETWEEN GROUPS. AS YOU SAY, IT CAN COME BACK AND MAYBE
15 WE'LL LEARN OVER TIME. BUT IN ANY EVENT, IT WOULD BE A
16 CONCERN IS IF YOU GET SOME TYPE OF REIMBURSEMENT OF
17 \$2,000 AT UCSF AND 500 AT STANFORD OR SOMETHING LIKE
18 THAT.

19 MS. KING: FIRST, MY OWN SENSE IS THE
20 QUICKEST THING THAT CAN DERAIL A STEM CELL PROGRAM
21 TODAY IS TO HAVE A CONTROVERSY OVER PAYMENTS MADE TO
22 PEOPLE WHO DONATE. THAT SAID, AND I REALLY MEAN THAT.
23 ALL YOU NEED IS A BAD JUDGMENT IN THIS AREA SO THAT YOU
24 HAVE MAJOR CRISIS. SO WHAT I PROPOSE IS THAT WE FOLLOW
25 WHAT'S BEEN OUTLINED HERE AND LEAVE IT TO THE REVIEWING

1 COMMITTEES, BUT THAT WE HAVE A REQUIREMENT THAT
2 REVIEWING COMMITTEES BE ABLE TO DOCUMENT THE RATIONALE
3 FOR THE FIGURES THAT THEY HAVE SELECTED.

4 SO IN THE EVENT THAT THERE IS SOME CONCERN OR
5 DISAGREEMENT ABOUT THIS, WE CAN AT LEAST START WITH
6 WHAT WAS THE ORIGINAL RATIONALE FOR THE AMOUNTS AGREED
7 TO. AND THEY CAN VARY. CONCEIVABLY IT WILL BE THAT
8 COMMITTEES WOULD REACH DIFFERENT AMOUNTS IN THEIR
9 DELIBERATIONS. BUT IF THEY DOCUMENT THEIR RATIONALE,
10 AT LEAST IN TERMS OF FUTURE REVIEW OF THE PROGRAM, YOU
11 WOULD AT LEAST SEE THE RANGE OF WHAT IRB'S OR ALL THE
12 COMMITTEES CONSIDERED. AND WE CAN MAKE THAT PART OF
13 THE REGULATION, I WOULD THINK, RIGHT?

14 MR. TOCHER: RIGHT.

15 DR. HALL: WE ACTUALLY HAVE A WAY OF
16 MONITORING THAT, PAT, AND THAT IS THE FOLLOWING. SO
17 WHAT HAPPENS IS SOMEBODY WANTS TO DO A STUDY. THEY PUT
18 TOGETHER AN APPLICATION TO US, AND THAT APPLICATION,
19 WHICH DOCUMENTS ALL OF THIS, MUST GO THROUGH THE ESCRO
20 AND THE IRB. IT THEN COMES TO OUR SCIENCE REVIEW
21 COMMITTEE. AT THAT POINT WE SEE THE APPLICATION, AND
22 WE CAN EITHER SEE OR ASK FOR HOW THAT IS DETERMINED.
23 WE CAN PUT THAT IN THE RFA. SO THEN WE HAVE ON RECORD
24 IF WE SEE SOMETHING AT THAT STAGE, LONG BEFORE THE
25 GRANT HAS BEEN AWARDED, THAT SEEMS OUT OF LINE TO US OR

1 THAT SEEMS NOT IN KEEPING WITH THE POLICY WE HAVE, THEN
2 I THINK BEFORE WE EVER AGREE TO FUND THAT GRANT, WE CAN
3 GO BACK AND SAY, LOOK, YOU'VE GOT TO WORK ON THIS.
4 THIS IS NOT ACCEPTABLE.

5 MY POINT IS EVEN BEFORE ANYTHING HAPPENS, WE
6 HAVE A WAY OF TRACKING IT AND FOLLOWING IT BECAUSE IT
7 WILL HAVE TO GO THROUGH THOSE COMMITTEES. I THINK
8 THAT'S A MECHANISM WE CAN EASILY IMPLEMENT.

9 MS. KING: IS IT CURRENTLY REQUIRED THAT YOU
10 SUBMIT THIS INFORMATION IN THE RFA?

11 DR. HALL: WELL, WE HAVE NOT WRITTEN AN RFA
12 FOR DERIVATION OF CELL LINES.

13 MS. KING: WHAT WE WANT TO DO IS TO SOMEHOW
14 AT THIS COMMITTEE LEVEL MAKE SURE THAT THAT REQUEST
15 GETS IN SINCE IT'S NOT WITHIN -- I DON'T KNOW HOW TO DO
16 THIS.

17 DR. HALL: I DON'T KNOW THAT IT NEEDS TO BE
18 IN REGULATIONS. WHAT DO YOU THINK, SCOTT? WHAT'S THE
19 RIGHT WAY TO DO THAT? YOU COULD PASS IT AS A
20 RESOLUTION BY THIS COMMITTEE, WHICH WE CAN TAKE TO THE
21 ICOC, THAT THIS WOULD BE PART OF THE RFA THAT CALLED
22 FOR EGG DONATION.

23 MR. TOCHER: RIGHT. YOU COULD PUT LANGUAGE
24 IN THAT SIMPLY SAYS THAT --

25 DR. HALL: THIS IS INTENDED TO US, NOT TO OUR

1 GRANTEE INSTITUTIONS. THIS IS A MESSAGE TO CIRM.

2 MS. KING: I JUST DON'T WANT IT TO FALL
3 BETWEEN THE CRACKS.

4 MR. TOCHER: THE ICOC WILL PUT IT IN AN RFA.

5 DR. HALL: THE RFA WILL INSTRUCT CIRM TO PUT
6 THAT INTO THE RESOLUTION, TO PUT THAT INTO ANY RFA FOR
7 EGG DONATION THAT WE REQUIRE ON THE APPLICATION.

8 MR. TOCHER: THE GRANTEE POTENTIALLY, THE
9 APPLICANT.

10 DR. HALL: HOW THEY INTEND TO CALCULATE
11 COMPENSATION OR REIMBURSEMENT.

12 DR. PRIETO: DO WE HAVE A MOTION?

13 CO-CHAIR LO: I'M SORRY, SCOTT. WOULD YOU
14 RECOMMEND DOING IT AS A PART OF THESE REGULATIONS OR AS
15 RESOLUTION?

16 MR. TOCHER: SOME OF THIS HAS BEEN ADDRESSED
17 WHEN WE TALK ABOUT THE APPLICATION PROCESS IN THE GAP.
18 AND SO THE ACTUAL FINE-TUNING OF PRECISELY THE
19 PLACEMENT OF THAT REQUIREMENT MAY TURN OUT TO BE THE
20 GAP AS OPPOSED TO THE PARTICULAR DOCUMENT YOU'RE
21 LOOKING AT NOW SIMPLY BECAUSE THERE'S A PROCEDURES
22 THERE FOR APPLICATIONS.

23 DR. HALL: LET ME ASK FOR A CLEAR-CUT
24 RESOLUTION FROM THIS GROUP THAT WE PUT THAT IN THE
25 GRANTS ADMINISTRATION POLICY. I THINK THAT WOULD BE

1 VERY HELPFUL. AND THEN WE REPORT THAT TO ICOC TO
2 APPROVE THAT AS WELL. I DON'T THINK THERE'S ANY DOUBT.

3 MY POINT IS TWO THINGS. I WANT IT ON RECORD,
4 AND I WANT IT ON THE RECORD TO US THAT'S AN INSTRUCTION
5 TO US. AND I THINK I DON'T -- I THINK IT'S VERY GOOD
6 TO HAVE IT MADE EXPLICITLY AND DIRECTLY AND PUBLICLY TO
7 CIRM TO DO THAT, SO THAT'S PART OF OUR REQUIREMENT FOR
8 HOW WE OPERATE. AND PUT IT IN THE GAP.

9 CO-CHAIR LO: THIS IS A VERY IMPORTANT ISSUE.
10 I WOULD LIKE TO PAUSE HERE FOR A MINUTE AND GET PUBLIC
11 COMMENT, IF I MAY.

12 MS. FEIT: ZACH, WOULDN'T YOU WANT, THOUGH,
13 AS A MATTER OF RECORD -- BECAUSE IT'S SUCH AN IMPORTANT
14 ISSUE AND WE'VE COME TO A CONSENSUS IN THIS WORKING
15 GROUP, DON'T YOU THINK IT'S A MATTER OF RECORD THAT WE
16 SHOULD AT LEAST HAVE A FORMAL RECOMMENDATION AND
17 AGREEMENT ON RECORD FROM THIS GROUP?

18 DR. HALL: THAT'S WHAT I ASKED FOR.

19 CO-CHAIR LO: BEFORE WE DO THAT, I WANT TO
20 MAKE SURE WE HAVE PUBLIC COMMENT.

21 MS. CHARO: IT'S A COMBINATION OF THINGS. WE
22 WANT TO SET THE PARAMETERS, AND THEN WE WANT SOME
23 REPORT FROM THE IRB'S ON HOW THEY'RE IMPLEMENTING, BUT
24 WE ALSO HAVEN'T YET COME TO COMPLETE CONSENSUS ON THE
25 PARAMETERS. WE WERE TALKING ABOUT DEFINITION AND LOST

1 WAGES.

2 JUST FOR THE SAKE OF LETTING YOU KNOW, UNDER
3 THE NATIONAL ORGAN TRANSPLANTATION ACT, WHICH
4 SPECIFICALLY PROHIBITS THE PURCHASING OF ORGANS, RIGHT,
5 AND THEY SAY BASICALLY PURCHASING MEANS GIVING WHAT THE
6 LAW CALLS VALUABLE CONSIDERATION, HERE ARE THE THINGS
7 THAT ARE NOT VALUABLE CONSIDERATION. HERE ARE THE
8 THINGS YOU CAN GIVE.

9 THE REASONABLE COSTS ASSOCIATED WITH THE
10 REMOVAL, TRANSPORTATION, IMPLANTATION, PROCESSING,
11 PRESERVATION, QUALITY CONTROL, AND STORAGE OF A HUMAN
12 ORGAN, OR THE EXPENSES OF TRAVEL, HOUSING, AND LOST
13 WAGES INCURRED BY THE DONOR.

14 SEE, NOW SHE'S HAPPY. NOW SHE'S HAPPY THAT
15 I'M LOOKING FOR PRECEDENT SOMEPLACE ELSE. OH, YOU
16 FICKLE WOMAN, YOU.

17 DR. KIESSLING: I'M JUST CONCERNED ABOUT THE
18 COMPARISON WITH KIDNEY DONATION. THAT'S GREAT, ALTA.

19 CO-CHAIR LO: THANK YOU, ALTA. I THINK WE'RE
20 GOING TO HAVE A LOT OF PUBLIC COMMENT, SO I REALLY WANT
21 TO MAKE SURE WE HEAR THESE.

22 MR. REED: THIS IS VERY FRESH TO ME BECAUSE
23 MY BROTHER IS GOING TO BE GIVING BONE MARROW TO MY
24 SISTER FOR HER CANCER NEEDS. NOW, HE CAN FINANCIALLY
25 AFFORD TO FLY DOWN AND TO MISS A LITTLE TIME FROM WORK,

1 AND IT'S NOT GOING TO BE AS MUCH AS THE PEOPLE WHO WILL
2 BE DONATING EGGS. NOBODY WANTS TO MAKE A PROFIT. I
3 THINK THAT'S CLEAR, BUT WE DO WANT TO MAKE IT POSSIBLE.

4 I WONDER, THEREFOR, IF WE COULD HAVE
5 SOMETHING IN HERE, SOME GUIDELINE THAT MINIMAL
6 REIMBURSEMENT WOULD BE ALLOWED. WE HAVE MINIMUM WAGE
7 IN CALIFORNIA. IT COULD BE MINIMAL REIMBURSEMENT TO
8 MAKE IT POSSIBLE BECAUSE THIS IS A SACRIFICE. WE WANT
9 TO MAKE IT POSSIBLE. WE DON'T WANT ANYBODY TO BE
10 BLOCKED FROM DOING THIS FOR FINANCIAL REASONS.

11 DR. HALL: PROPOSITION 71 PROHIBITS.

12 MR. REED: IT SAYS COMPENSATION, BUT WE'RE
13 TALKING ABOUT EXPENSES HERE.

14 DR. HALL: MINIMAL COMPENSATION.

15 MR. REED: MINIMAL REIMBURSEMENT, WHATEVER
16 PHRASE WE WANT TO USE, BUT IT'S MONEY LOST. AND IF IT
17 WAS MINIMAL REIMBURSEMENT, I THINK THAT WOULD BE TWO
18 GOOD WORDS.

19 ALSO, I THINK WE SHOULD PUT SOMETHING ON THE
20 RECORD RATHER THAN LEAVE IT UP TO THE IRB'S. THINK
21 ABOUT IT. IF YOU WANT AN EXCUSE TO SUE US, THEY CAN
22 SAY, OH, THEY'RE ALREADY IN OPPOSITION TO THEIR OWN
23 BILL. THEY'RE ALREADY ALLOWING PEOPLE TO HAVE THEIR
24 FREE WILL TO PAY THEM WHATEVER THEY WANT. I THINK WE
25 NEED TO COME ON RECORD FOR THIS.

1 DR. PRICE: I'M ROBERT PRICE. I'M THE
2 ASSOCIATE VICE CHANCELLOR FOR RESEARCH AT UC BERKELEY.
3 I REALLY WANT TO URGE YOU TO TAKE A POSITION THAT COULD
4 BE A GUIDANCE POSITION ON HOW YOU DEFINE REIMBURSEMENT
5 AND NOT LEAVE IT UP TO THE IRB'S WITHOUT ANY GUIDANCE
6 FROM YOU AS TO WHETHER THE COVERING OF LOST WAGES IS AN
7 APPROPRIATE REIMBURSABLE EXPENSE.

8 IT'S ONE THING TO DESCRIBE WHAT YOU ARE
9 DOING; BUT IF YOU DON'T KNOW IF IT'S IN VIOLATION OF
10 THE STANDARDS, WHICH ARE THEN THREATENING, OF COURSE,
11 TO WITHDRAW OR TO FINE OR TO PENALIZE THE INSTITUTION
12 FOR DOING AFTER THE FACT, YOU PUT US IN AN IMPOSSIBLE
13 POSITION. YOU CAN'T PASS THE BUCK TO THE SECONDARY
14 SOURCE OF REVIEW AND THEN AFTER THE FACT SAY, NO, TOO
15 BAD. YOU'RE PAYING SOMEBODY --

16 DR. HALL: LET ME STEP IN HERE BECAUSE I
17 THINK THAT'S NOT -- THE PROCEDURE I JUST DESCRIBED IS
18 WE WOULD HAVE A CHANCE TO SEE YOUR PLANS, THE LEVEL OF
19 REVIEW. AND IF THEY ARE, WE FEEL, IN VIOLATION OF WHAT
20 WE INTENDED, THEN BEFORE WE EVER GIVE YOU THE MONEY, WE
21 WOULD COME TO YOU AND SAY I'M SORRY. THIS ISN'T GOING
22 TO WORK. HERE'S WHY.

23 DR. PRICE: THEN YOU WOULD HAVE TO -- FOR
24 EACH ONE OF THESE REVIEWS, WOULDN'T THE STANDARDS GROUP
25 HAVE TO COME TOGETHER AND DECIDE WHETHER IT'S

1 APPROPRIATE OR NOT?

2 DR. HALL: NO. I THINK MOST CASES,
3 PRESUMABLY EVERYBODY -- SO CERTAINLY INSTITUTIONS,
4 PARTICULARLY THOSE WITH LARGE CLINICAL PROGRAMS OR
5 CLINICAL PROGRAMS, ARE VERY FAMILIAR WITH THIS. AND SO
6 THEY WILL QUICKLY FIGURE OUT AND COME TO A POLICY ON
7 THIS, AND IT WILL GET SORTED OUT VERY QUICKLY. I THINK
8 EVERYBODY WILL UNDERSTAND. THEY'LL ALSO WORK WITH THE
9 VICE CHANCELLORS, THAT COMMITTEE WE WERE TALKING ABOUT
10 BEFORE. SO IT'S NOT THE CASE THAT WE'RE GOING TO LET
11 YOU GET OUT ON A LIMB AND THEN SAW THE LIMB OFF.
12 THAT'S NOT THE POINT.

13 THE WHOLE POINT OF WHAT I SAID WAS WE WILL
14 HAVE A CHANCE TO MONITOR THIS AT A VERY EARLY STAGE
15 BEFORE ANY ACTION IS TAKEN, BEFORE YOU GET ANY MONEY IF
16 WE THINK YOU'RE OFF ON THE WRONG TRACK.

17 DR. PRICE: FINE. THAT'S ONE ISSUE, BUT IT
18 SEEMS TO ME THE FUNDAMENTAL ISSUE IS WHETHER OR NOT
19 LOST WAGES CAN BE COVERED AS A REIMBURSABLE EXPENSE.
20 THAT IS A FUNDAMENTAL QUESTION.

21 CO-CHAIR LO: WHAT I HEAR YOU SAYING IS YOU
22 WANT US IN THE STANDARDS TO CLARIFY THAT RATHER THAN
23 SAYING, OKAY, IRB'S.

24 DR. PRICE: FIGURE IT OUT YOURSELF WHEN YOU
25 DON'T KNOW WHAT YOU'RE THINKING.

1 CO-CHAIR LO: THAT'S FAIR.

2 DR. EGGAN: I THINK IT'S FAIR, BUT I THINK
3 IT'S ALSO JUST AS FAIR TO SAY THAT IRB'S HAVE SOME
4 JURISDICTION AND WISDOM ON THEIR OWN. AND IT'S IN SOME
5 WAYS CONDESCENDING OF US TO SAY THAT THEY DON'T HAVE
6 ANY ABILITY TO REACH DECISIONS.

7 DR. TAYLOR: I LIKE THAT TOO. THAT WAS THE
8 POINT WHAT I WAS GOING TO MAKE. THEY ACTUALLY DO LIKE
9 TO BE ABLE TO INDEPENDENTLY WITHIN THEIR OWN
10 CONSTRAINTS TO MAINTAIN EQUITABLE COMPENSATION.

11 MS. CHARO: HAVING SERVED ON AN IRB FOR MANY,
12 MANY YEARS, I'M SENSITIVE TO THIS POINT. BUT THERE'S A
13 DIFFERENCE BETWEEN AN IRB BEING TOLD WHAT CATEGORY OF
14 EXPENSES ARE PERMITTED, QUESTION OF LOST WAGES IS A
15 CATEGORICAL QUESTION, VERSUS WHERE THE GUIDANCE SAYS
16 REASONABLE REIMBURSEMENT FOR TRAVEL AND HOUSING. AND
17 THE QUESTION IS UP TO THE IRB WHAT'S REASONABLE FOR
18 TRAVEL. DOES IT MEAN THAT THEY HAVE TO TAKE THE
19 CHEAPEST POSSIBLE, OR CAN THEY TAKE ANYTHING IN COACH?
20 IS IT THE MOTEL 6 OR IS IT THE LOCAL HYATT OR IS IT THE
21 FOUR SEASONS? THAT'S A LEVEL OF DISCRETION I FEEL
22 COMFORTABLE LEAVING TO THE IRB.

23 BUT CATEGORICALLY WHETHER LOST WAGES ARE
24 INCLUDED OR NOT, IT SEEMS TO ME TO BE A DIFFERENT KIND
25 OF QUESTION. IT'S EXACTLY WHY I WAS DESPERATELY

1 LOOKING FOR SOME PERSUASIVE PRECEDENT IN OTHER SETTINGS
2 TO TRY TO ACCOMPLISH THE SAME THING, WHICH IS TO MAKE
3 SURE PEOPLE DO NOT WIND UP WORSE OFF FINANCIALLY BY
4 VIRTUE OF HAVING BEEN A SAMARITAN AND A VOLUNTEER, AND
5 AT THE SAME TIME TO PREVENT THEM MARKETING SOMETHING
6 FROM DEVELOPING. I WAS LOOKING FOR THE NATIONAL ORGAN
7 TRANSPLANTATION ACT.

8 CO-CHAIR LANSING: CAN YOU READ THAT AGAIN?

9 MS. CHARO: IT EXCLUDES FROM THE TERM
10 "VALUABLE CONSIDERATION," YOU CAN'T GIVE VALUABLE
11 CONSIDERATION, BASICALLY THAT'S PAYMENT, RIGHT, CAN'T
12 GIVE PAYMENT. SO THE TERM "VALUABLE CONSIDERATION"
13 DOES NOT INCLUDE REASONABLE PAYMENTS ASSOCIATED WITH
14 THE REMOVAL, TRANSPORTATION, IMPLANTATION, PROCESSING,
15 PRESERVATION, QUALITY CONTROL, AND STORAGE OF A HUMAN
16 ORGAN -- THAT WOULD HAVE TO BE ADAPTED SLIGHTLY FOR
17 STEM CELL LINES -- OR THE EXPENSES OF TRAVEL, HOUSING,
18 AND LOST WAGES INCURRED BY THE DONOR OF A HUMAN ORGAN
19 IN CONNECTION. SO IT BASICALLY SAYS YOU CAN BE
20 REIMBURSED FOR THE TRAVEL COST, THE HOUSING COST, AND
21 YOU CAN BE REIMBURSED FOR LOST WAGES. RIGHT.

22 AND THE THING THAT'S OMITTED HERE THAT I
23 THINK IS PROBABLY IMPLICIT AND YOU MIGHT WANT TO MAKE
24 EXPLICIT WHEN YOU WROTE THESE THINGS WOULD BE THAT YOU
25 CAN ALSO REIMBURSE THE DONOR FOR ANY MEDICAL EXPENSES

1 THAT ARE INCURRED IN CONJUNCTION WITH PROVIDING THE
2 DONATION. PRESUMABLY THESE THINGS ARE ALL GOING TO BE
3 DONE FOR FREE, BUT ONE CAN IMAGINE SOME INCIDENTAL
4 MEDICAL EXPENSES SOMEBODY MIGHT INCUR THAT YOU ALSO
5 WANT TO MAKE REIMBURSABLE.

6 DR. HALL: IF YOU ARE GOING TO SPECIFY
7 CATEGORIES, YOU SURELY WANT TO INCLUDE CHILDCARE.

8 MS. CHARO: THAT IS NOT LISTED, BUT WE HAVE
9 THE OPTION.

10 DR. HALL: I'M SUGGESTING THAT. IF WE END UP
11 DOING THAT.

12 MS. CHARO: THIS IS THE BEGINNING OF A MODEL
13 WHERE YOU WANTED TO SET OUT THE CATEGORIES OF
14 REIMBURSABLE EXPENSES.

15 CO-CHAIR LANSING: CAN I ASK A QUESTION? IF
16 WE DID THIS -- I'M CONFUSED NOW. IF WE DID THIS, ARE
17 WE SUGGESTING THAT WE WOULD SAY TO THE IRB THESE ARE
18 THE TYPE OF CATEGORIES THAT ARE ACCEPTABLE FOR
19 REIMBURSEMENT, AND WE LEAVE IT UP TO YOU TO DECIDE WHAT
20 TO DO WITH THOSE CATEGORIES?

21 MS. CHARO: YES. THEY WOULD HAVE TO THEN
22 DECIDE WHETHER OR NOT TO REIMBURSE THE FOUR SEASONS OR
23 MOTEL 6.

24 CO-CHAIR LANSING: AND THEY COULD SAY -- IN
25 OTHER WORDS, IT'S OKAY IF YOU REIMBURSE THEM FOR ALL OF

1 THESE; BUT IF THEY DECIDED THAT THEY DIDN'T REIMBURSE
2 THEM FOR ALL OF THESE, THAT WOULD BE AT THEIR
3 DISCRETION.

4 MS. CHARO: PRESUMABLY. THIS IS PERMISSIBLE,
5 NOT MANDATORY.

6 CO-CHAIR LANSING: THAT'S WHAT I WOULD WANT
7 TO BE SURE OF.

8 CO-CHAIR LO: I'M SURE THAT WE'RE GOING TO
9 HAVE A LOT OF COMMENTS, AND I WANT TO MAKE SURE WE HEAR
10 THEM.

11 MR. REYNOLDS: MY COMMENT'S ACTUALLY ABOUT
12 THE CONSISTENCY OF THE STANDARDS ACROSS THE LINES THAT
13 ARE DERIVED WITH CIRM FUNDING AND THOSE THAT ARE
14 ELIGIBLE TO BE WORKED ON THE CIRM FUNDING AFTER THEY'RE
15 DERIVED THROUGH OTHER SOURCES, AS WELL AS CONSISTENCY
16 WITH THE RECOMMENDATIONS OF THE NATIONAL ACADEMIES. I
17 THINK IT'S IMPORTANT TO, AS I MENTIONED EARLIER, TO
18 AVOID A PATCHWORK OF STANDARDS. I THINK IT'S
19 PARTICULARLY IMPORTANT THAT THAT HOLD TRUE WITH THE --
20 THERE'S ONLY FOUR OR SO MEDICAL AND ETHICAL STANDARDS
21 THAT ARE ACTUALLY SPELLED OUT WITHIN PROPOSITION 71,
22 ONE OF WHICH IS THE COMPENSATION AND REIMBURSEMENT
23 LANGUAGE, AND THE OTHER ONES ARE THE 12-DAY LIMIT, I
24 BELIEVE, ON THE CULTURING OF BLASTOCYSTS AND THERE'S A
25 COUPLE MORE.

1 I THINK THAT THOSE WERE ADVERTISED TO THE
2 VOTERS. THAT, I THINK, CAN BE INTERPRETED AS BEING
3 PART OF THE INTENTIONS OF THE VOTERS, AND THAT SHOULD
4 BE CARRIED FORTH WITH ALL THE RESEARCH THAT IS FUNDED
5 THROUGH CIRM REGARDLESS OF THE SOURCE OF THE
6 DERIVATION. I THINK OTHERWISE IT WOULD BE BUILDING UP
7 A LOOPHOLE, SO IT SOUNDS LIKE IN THAT REGARD YOU'RE ON
8 THE RIGHT TRACK. THANK YOU.

9 MS. FOGEL: I ALSO WANT TO ECHO THAT. I
10 THINK THE GUIDELINES AS THEY WERE WRITTEN HAD AN
11 EXCEPTION THAT SWALLOWED THE RULE. THERE'S A HUGE
12 INCENTIVE JUST TO GO GET YOUR EGGS SOMEWHERE ELSE, SO
13 THANK YOU FOR DOING THAT.

14 I WANT TO ADDRESS THE EXPENSES ISSUE. WE ALL
15 HAVE THE SAME GOAL, WHICH IS NOT TO CREATE A MARKET IN
16 EGGS, NOT TO HAVE LOW-INCOME WOMEN OR YOUNG WOMEN FEEL
17 COERCED BY THE MONEY, THE CARROT OUT THERE. AND WHAT
18 I'D LIKE US NOT TO DO IS THROW A LOT OF MONEY AT WOMEN
19 AND CALL IT REIMBURSEMENT. I THINK THE INTENT OF THE
20 PROPOSITION WAS VERY CLEAR. AND THE NATIONAL ACADEMIES
21 LANGUAGE EVEN SAYS DIRECT EXPENSES.

22 THE IDEA IS THAT, YOU KNOW, THINK ABOUT A
23 LOW-INCOME WOMAN MAYBE WHO DOESN'T HAVE A JOB OR MAKES
24 MINIMUM WAGE, SO SHE GETS SIX BUCKS AND A LAWYER GETS A
25 FEW THOUSAND DOLLARS. IT WOULD OPEN UP A WHOLE -- ALL

1 KINDS OF LEVELS OF DISPARITIES, DISINCENTIVES TO SCREEN
2 OUT HIGH EARNING WOMEN AND SCREEN IN LOW EARNING WOMEN
3 TO MAKE YOUR COST LOWER. AND I REALLY THINK WE NEED TO
4 STAY AWAY FROM WAGES. DIRECT EXPENSES, TRAVEL, WOMAN
5 HAS TO PAY CHILDCARE, SURE, IT'S A DIRECT EXPENSE.
6 TRANSPORTATION, IT'S A DIRECT EXPENSE. BUT I THINK
7 IT'S YOUR JOB TO SET THESE HIGH STANDARDS AND NOT TO
8 LEAVE IT LOOSEY-GOOSEY. I ACTUALLY AGREE WITH THE
9 RESEARCHER. IT OUGHT TO BE CLEAR. AND I THINK THAT
10 OPENING UP TO LOST WAGES REALLY DOES OPEN UP A CAN OF
11 WORMS THAT WE DON'T WANT TO HAVE IF WE REALLY HAVE A
12 GOAL OF PROTECTING WOMEN.

13 CO-CHAIR LANSING: COULD I ASK YOU A QUESTION
14 THOUGH BECAUSE THIS IS LIKE A REALLY IMPORTANT ISSUE TO
15 ME. I INITIALLY SORT OF AGREED WITH YOU, BUT NOW I'M
16 NOT SURE I DO. I WANT TO JUST HAVE A DIALOGUE FOR A
17 SECOND. WHAT I'M REALLY CONCERNED ABOUT WHEN WE GET TO
18 THE END IS TRYING TO HAVE A DIVERSE POOL. AND IN ORDER
19 TO HAVE A DIVERSE POOL, I'M REALLY LESS WORRIED THAT
20 THE LAWYER -- WITH ALL DUE RESPECT TO THE LAWYERS IN
21 THIS ROOM -- I'M REALLY LESS WORRIED THAT THE LAWYER
22 WHO'S EARNING A THOUSAND DOLLARS IS GOING TO ASK FOR
23 REIMBURSEMENT OF HER EXPENSES, AND I'M WORRIED THAT A
24 WOMAN WHO REALLY WANTS TO DO SOMETHING AND IS EARNING A
25 MINIMUM WAGE WILL NOT BE ABLE TO AFFORD TO NOT WORK FOR

1 A DAY.

2 AND SO WHAT I'M TRYING TO FIGURE OUT IS HOW
3 YOU DO THAT BECAUSE INITIALLY I ACTUALLY DID AGREE WITH
4 YOU, AND I THOUGHT, NO, WE SHOULDN'T DO ANYTHING FOR
5 WAGES. HOW ARE YOU GOING TO GET THIS DIVERSE
6 POPULATION?

7 MS. FOGEL: I DON'T THINK WE SHOULD BE
8 CONFUSING RACE WITH ECONOMICS IN THE FIRST PLACE. SO
9 DIVERSITY --

10 CO-CHAIR LANSING: I'M NOT. LET ME FOR THE
11 RECORD STATE THAT IS NOT WHAT I MEANT BY DIVERSITY
12 EITHER. YOU WANT A DIVERSE POOL OF PEOPLE. SO WHAT
13 I'M TRYING TO SAY IS HOW ARE YOU GOING TO PROTECT
14 SOMEBODY WHO CANNOT AFFORD TO MISS A DAY OF WORK?

15 MS. FOGEL: PERHAPS SHE SHOULDN'T BE DONATING
16 HER EGGS. WELL, I MEAN IF SHE WANTS TO, SHE WILL, BUT
17 I'M NOT SURE THAT CREATING A WHOLE PACKAGE OF
18 REIMBURSEMENT THAT BECOMES EQUATED WITH COMPENSATION IS
19 JUST BEING CALLED SOMETHING ELSE. I THINK THAT'S JUST
20 AS PROBLEMATIC. I THINK THE INTENT WAS THERE WILL BE
21 WOMEN WHO WANT TO DO THIS. HOPEFULLY, THERE WILL BE
22 WOMEN ACROSS THE SPECTRUM WHO WILL WANT TO DO THIS.
23 BUT I THINK THAT OPENING UP LOST WAGES CREATES
24 DISPARITIES THAT WE'RE TRYING NOT TO CREATE.

25 DR. EGGAN: I DO WANT TO ASK THIS ONE POINT,

1 AND ALSO IT DIRECTLY REFERS TO WHAT SHERRY WAS SAYING.
2 THAT IS, ALTA, PLEASE CHIME IN WHEN I GET THIS WRONG,
3 WHICH I MAY, BUT AS I UNDERSTAND IT, THERE ARE LAWS
4 WHICH, FEDERAL LAWS, WHICH GUIDE REGULATION OF HUMAN
5 SUBJECTS RESEARCH. AND THEY MANDATE THAT CITIZENS OF
6 THIS COUNTRY SHOULD HAVE AN EQUAL OPPORTUNITY TO
7 PARTICIPATE IN HUMAN SUBJECTS RESEARCH. AND THAT'S
8 WHAT SHERRY MEANS BY DIVERSITY.

9 MS. FOGEL: AND THAT'S RIGHT.

10 DR. EGGAN: AND THAT IS WHY IT'S IMPORTANT TO
11 REIMBURSE PEOPLE FOR THEIR PARTICIPATION BECAUSE IT
12 SHOULD BE POSSIBLE FOR A WOMAN WHO IS OF LOW INCOME WHO
13 HAS A RELATIVE WHO SUFFERS FROM A DEBILITATING DISEASE
14 WHO WANTS TO PARTICIPATE IN SOME SORT OF RESEARCH TO BE
15 ABLE TO DO THAT. SHE SHOULD NOT BE DENIED THAT
16 OPPORTUNITY BECAUSE SHE CAN'T AFFORD TO MISS A DAY OF
17 WORK.

18 MS. FOGEL: I DON'T DISAGREE WITH YOU. I DID
19 NOT MEAN WHAT IT SOUNDED LIKE I SAID, BUT I DO FEEL
20 THAT THERE IS -- THE LOST WAGES ISSUES ACROSS CLASSES
21 DOES CREATE SOME DISPARITIES THAT HAVE TO BE ADDRESSED.

22 MS. CHARO: HOW CREATE --

23 CO-CHAIR LO: ONE AT A TIME. ARE YOU
24 FINISHED?

25 MS. FOGEL: I HAD ONE OTHER POINT THAT'S NOT

1 ADDRESSED HERE. I DON'T WANT TO INTERRUPT THIS, SO CAN
2 I JUST COME BACK AND MAKE THAT POINT?

3 CO-CHAIR LANSING: I THINK WHAT WE'RE ALL
4 SAYING, AND I KNOW YOU, SUSAN, IS EXACTLY THE SAME
5 THING. WE WANT EVERYONE TO HAVE THE EQUAL OPPORTUNITY
6 OF ANY RACE, RELIGION, NATIONALITY TO PARTICIPATE IN
7 THESE CLINICAL TRIALS OR DONATION. AND WE'RE ALL
8 AGREED ON THAT.

9 SO NOW, JUST SAYING IN THE SPIRIT OF OUR
10 COOPERATION WHICH WE'VE HAD OVER MANY MONTHS, THE REAL
11 QUESTION THAT I'M RAISING IS HOW DO WE ACHIEVE THAT FOR
12 SOMEBODY WHO CANNOT AFFORD TO MISS A DAY OF WORK? AND
13 THAT OPENS UP SOMETHING I HAD NEVER THOUGHT ABOUT. I
14 DON'T HAVE THE ANSWER TO THAT.

15 CO-CHAIR LO: THIS HAS SPARKED A LOT OF
16 COMMENTS. I WANT TO GET PAT AND THEN ALTA AND THEN
17 KEVIN.

18 MS. KING: FIRST OF ALL, IT SEEMS TO ME WE'RE
19 TALKING ABOUT THIS IN PIECES IN ISOLATION. I CAN SEE
20 THAT BOTH OF YOU ARE SAYING SOMETHING THAT I WOULD
21 ACCEPT AS RIGHT. THE PROBLEM IS EQUAL OPPORTUNITY TO
22 PARTICIPATE. AND ONCE YOU START TALKING ABOUT LOST
23 WAGES AND DIFFERENCES AND DISPARITIES IN WAGES, YOU
24 FUDGE TOGETHER REIMBURSEMENT COMPENSATION. THERE IS NO
25 DOUBT THAT THE FIRST PROGRAM THAT GETS REPORTED FOR

1 THREE OR \$4,000 TO A WOMAN, EASY GIVEN THE HOURS THAT
2 I'VE HEARD TODAY, AND LOST WAGES IS GOING TO BE ON THE
3 FRONT PAGE OF ALL YOUR NEWSPAPERS TALKING ABOUT HOW BAD
4 THIS PROGRAM IS.

5 THE JURY SYSTEM ACTUALLY HAD TO DEVISE A WAY
6 TO CUT THROUGH DIFFERENCES IN INCOME WHILE AFFORDING
7 EQUAL PROTECTION. I DON'T KNOW IF YOU WANT TO GO
8 THERE. THE WAY THEY DO IT IS YOU REIMBURSE FOR WAGES,
9 BUT AT A SET FEE. AND THAT IS YOU CANNOT GO BEYOND IT,
10 BUT IT ALLOWS POOR PEOPLE TO SERVE AS JURORS TO SOME
11 EXTENT, AND IT DOES NOT, AT LEAST MY JURY SYSTEM, IT
12 DOES NOT ALLOW ANY COMPENSATION IF YOUR EMPLOYER IS
13 WILLING TO DONATE THE TIME TO YOUR PARTICIPATION AS A
14 CIVIC LEADER.

15 CO-CHAIR LANSING: IF YOU DON'T HAVE A JOB,
16 WHAT WE WOULD NOT WANT TO DO, BECAUSE YOU SAID THIS, IF
17 YOU DON'T HAVE A JOB, YOU STILL GET A FLAT FEE.

18 MS. KING: WHEN I GO TO SERVE ON A JURY, I
19 GET A \$2 FEE BECAUSE MY EMPLOYER PAYS FOR MY TIME. SO
20 THERE MUST BE SOME MINIMUM WAGE. THAT'S THE WAY YOU
21 BALANCE OUT QUESTIONS OF, AT LEAST I SEE, OF EQUAL
22 PARTICIPATION, BUT NOT WANTING TO BE CAUGHT UP IN THE
23 INEQUALITIES OF SALARIES.

24 SO THIS GETS TO BE A COMPLICATED REGULATION
25 IF YOU GO DOWN THIS ROAD. THAT'S THE OTHER SIDE OF NOT

1 GOING DOWN THE ROAD WE ORIGINALLY TALKED ABOUT ABOUT
2 IRB'S. AND THAT IS THAT YOU NEED NOW SOME STANDARD
3 THAT YOU WILL HOLD EVERYBODY TO, THAT HITS THE LINE
4 THAT ALLOWS PARTICIPATION, BUT DOESN'T END UP PAYING
5 REALLY HUGE AMOUNTS OF MONEY TO PEOPLE TO BE DONORS.

6 CO-CHAIR LO: PAT, IF I CAN JUST PARAPHRASE,
7 YOUR IDEA ELIMINATES THE DISPARITIES WHERE ONE WOMAN
8 GETS REIMBURSED OR PAID A GREATER DOLLAR AMOUNT THAN
9 ANOTHER ONE WITH A DIFFERENT KIND OF JOB. SO IT
10 ELIMINATES DISCREPANCY ISSUES. IT DOESN'T ELIMINATE
11 OBJECTIONS BASED ON -- IT STILL SOUNDS TOO CLOSE TO
12 PAYING, BUYING, SELLING, WHICH SOME PEOPLE OBJECT TO,
13 BUT IT ADDRESSES ONE SET OF CONCERNS.

14 MS. KING: I THINK IT ADDRESSES BOTH. HER
15 FIRST STATEMENT -- I'M SORRY. I DON'T KNOW WHO YOU
16 ARE. HER FIRST STATEMENT WAS THAT, AND THIS ALWAYS
17 OCCURS, DIFFERENCES IN INCOME WILL PRODUCE DIFFERENT
18 SUMS. SO THE OTHER CONSIDERATION IS HOW LARGE A SUM
19 CAN THE STEM CELL PROGRAM IN CALIFORNIA TAKE WITHOUT
20 BEING CALLED COMPENSATION BY THE BACK DOOR. AND SO MY
21 PROPOSAL, AT LEAST IF YOU MOVE IN THAT DIRECTION -- I
22 ACTUALLY FAVORED THE FIRST DIRECTION FIRS -- LET THE
23 IRB DO IT; BUT IF YOU'RE NOT IN AGREEMENT WITH THAT,
24 THEN AT LEAST MY PROPOSAL WOULD SAY WE KNOW WHAT LOST
25 WAGES MAXIMUMS ARE GOING TO COME IN. IT'S NOT GOING TO

1 BE A SHOCK TO ANYBODY, AND IT WILL BE A PART OF WHAT'S
2 ACCEPTED. AND I THINK IT WILL BE VIEWED AS
3 REIMBURSEMENT UNDER THOSE CIRCUMSTANCES, NOT AS
4 COMPENSATION. AND THERE'S A DIFFERENCE. IT'S VERY
5 IMPORTANT TO KEEP THE TERMS SEPARATE.

6 CO-CHAIR LO: IF I CAN JUST INTERJECT AN
7 ACTUAL MATTER. AT UCSF OUR IRB HAS IN ITS MIND AN
8 HOURLY WAGE RATE, WHICH IS NOT EXORBITANT, WHAT YOU
9 NEED TO LIVE ON IN SAN FRANCISCO, AROUND 15 TO \$20 AN
10 HOUR. EVERYBODY GETS THAT AMOUNT FOR PARTICIPATION IN
11 THE RESEARCH REGARDLESS OF THE ACTUAL INCOME THEY WOULD
12 HAVE TAKEN HOME HAD THEY GONE TO WORK. SO IT DOES
13 ELIMINATE THOSE DISPARITIES.

14 CO-CHAIR LANSING: WHAT IF THEY'RE A COLLEGE
15 STUDENT? WHAT IF THEY HAVE NO JOB?

16 CO-CHAIR LO: THEY GET THAT.

17 MS. CHARO: I FEEL LIKE I AM COMPLETELY
18 MISSING SOMETHING HERE. I THOUGHT WE WERE TALKING
19 ABOUT LOST WAGES. AND SUDDENLY IT'S TURNED INTO
20 SOMETHING THAT SOUNDS LIKE PAYMENT. IF SOMEBODY HAS
21 ACTUALLY LOST A THOUSAND DOLLARS AND YOU GIVE HER BACK
22 A THOUSAND DOLLARS, SHE'S BACK TO A NO GAIN, NO LOSS
23 SITUATION. SOMEBODY'S ONLY LOST \$10 AND YOU GIVE HER
24 BACK \$10, SHE'S BACK TO A NO LOSS, NO GAIN SITUATION.
25 SO THE DISPARITY DOESN'T EXIST ONCE THE REIMBURSEMENT

1 HAS BEEN COMPLETED. THERE'S NO DISPARITY AT THE END IF
2 EVERYBODY COMES OUT NO BETTER OFF AND NO WORSE OFF THAN
3 THEY WERE.

4 SO I AM REALLY TRULY BEFUDDLED BY THE
5 IMPLICATION THAT'S BEEN RUNNING THROUGH THIS
6 DISCUSSION, THAT REIMBURSING SOMEBODY FOR A SIZABLE
7 LOSS SOMEHOW OPERATES AS AN INCENTIVE OR A REWARD AS
8 OPPOSED TO SIMPLY PUTTING THEM BACK TO WHERE THEY WERE.

9 CO-CHAIR LANSING: NO. NO. WHAT I THINK
10 WE'RE ALL SAYING IS THAT THE PROGRAM WHEN DECIDING HOW
11 MUCH IT'S GOING TO REIMBURSE ONE PERSON FOR A THOUSAND
12 DOLLARS AND ONE PERSON FOR \$50, THEY'RE PROBABLY GOING
13 TO CHOOSE THE PERSON FOR \$50. IN OTHER WORDS, THAT'S
14 THE FEAR.

15 MS. CHARO: IS THAT THE FEAR? THAT'S THE
16 FIRST TIME I'VE HEARD ANYBODY SAY THAT. THAT'S
17 ACTUALLY AN INTERESTING LINE OF INQUIRY, BUT I NEVER
18 HEARD ANYBODY SUGGEST ANYTHING QUITE LIKE THAT.

19 CO-CHAIR LANSING: THAT'S THE WAY I
20 UNDERSTAND THE FEAR. CORRECT ME.

21 MS. FOGEL: THAT IS ONE OF THE CONCERNS, YES,
22 THAT THE CHEAPEST WOMEN WILL BE BROUGHT INTO EGG
23 EXTRACTION, AND THAT'S NOT WHAT WE'RE TRYING TO
24 ACCOMPLISH. IT'S SOMETHING WE'RE TRYING TO PROTECT
25 AGAINST.

1 CO-CHAIR LANSING: MY CONCERN WAS -- AND
2 INITIALLY THAT'S WHY WE WEREN'T GOING TO REIMBURSE.

3 MS. CHARO: SO PART OF THE GROUP HERE WAS
4 WORRIED THAT THE REIMBURSEMENT LIMITS WERE NEEDED IN
5 ORDER TO ENSURE THAT POOR WOMEN WERE ABLE TO DONATE,
6 BUT NOW YOU'RE SAYING THAT THE REAL PROBLEM IS THAT
7 WHAT YOU'RE TRYING TO DO IS ENSURE THAT RICH WOMEN WILL
8 BE DONATING AS WELL AS POOR WOMEN BY MAKING SURE THAT
9 NOBODY GETS REIMBURSED A WHOLE LOT.

10 MR. SHESTACK: IT WAS A PUBLIC RELATIONS
11 ISSUE. SOMEONE WHO EARNED A THOUSAND DOLLARS A DAY
12 GAVE UP FIVE DAYS, AND IN YOUR ANNUAL REPORT IT SAID
13 YOU PAID SOMEBODY \$5,000 AS OPPOSED TO IF YOU PAID
14 SOMEBODY \$500.

15 MS. CHARO: NOW, THAT'S THE FIRST THING I
16 UNDERSTOOD.

17 MR. SHESTACK: BAD FOR US. THAT, I THINK, IS
18 BASICALLY THE CRUX OF THE SECOND PART OF THE ARGUMENT.

19 CO-CHAIR LANSING: THAT'S THE SECOND PART OF
20 IT.

21 DR. EGGAN: THIS IS NOT A PRINCIPLE PROBLEM.
22 THIS IS A PROCEDURAL PROBLEM. RIGHT. THE PRINCIPLES
23 WE CAN ALL AGREE ON. AND SO, FOR INSTANCE, THERE ARE
24 WAYS THAT THAT SORT OF MISENROLLING IN HUMAN SUBJECTS
25 RESEARCH CAN BE DONE. THAT IS SIMPLY WOMEN COME, THEY

1 GIVE THEIR INFORMED CONSENT, AND THEN THERE IS NO
2 PRORATED COMPENSATION FOR LOST WAGES. AT THE END OF
3 THEIR PARTICIPATION, THEY PRESENT THEIR PAY STUBS FROM,
4 SAY, THEIR MOST RECENT PAY PERIOD TO THE RESEARCH
5 ADMINISTRATOR, AND THEY ARE REIMBURSED AT AN
6 APPROPRIATE AMOUNT FOR THAT AMOUNT OF TIME THAT THEY
7 PARTICIPATED IN THEIR SUBJECTS.

8 I THINK IF WE'RE SAYING THAT WOMEN -- BY
9 SAYING THAT WOMEN WILL BE REIMBURSED, WE ARE SAYING
10 THERE WILL BE NO PRORATED, PRO FORMA AMOUNT OF MONEY
11 THAT WILL BE GIVEN TO THESE WOMEN BECAUSE THAT IS
12 COMPENSATION OR IT COULD BE PERCEIVED AS THAT. THERE
13 NEEDS TO BE DOCUMENTED REIMBURSEMENT OF THESE WOMEN FOR
14 EVERY ASPECT OF THAT WHICH THEY ARE GIVEN. THAT'S
15 WHAT'S GOING TO HELP PREVENT, TO SOME EXTENT, THESE
16 SORTS OF PROBLEMS THAT YOU'RE TALKING ABOUT.

17 I HAVE ONE MORE THING I WANT TO SAY BEFORE
18 GOING ON. THE CONCERN IS THAT IT'S GOING TO BE THAT
19 WOMEN -- THE REAL CONCERN IS THAT WOMEN WERE PAID
20 \$5,000 EACH TO DONATE THEIR EGGS. THAT'S THE REAL
21 PROBLEM. TO SOME EXTENT, IF A WOMAN IS REIMBURSED A
22 CERTAIN AMOUNT OF MONEY, THAT'S WHAT IT IS. I THINK WE
23 SHOULD BE HONEST ABOUT THAT, AND WE SHOULD ALL BE
24 WILLING TO TALK TO PEOPLE IN THE PRESS TO EDUCATE THAT
25 THIS ISSUE IS REALLY A CONCERN. I KNOW THIS IS HARD,

1 AND I KNOW THAT THERE'S A PUBLIC RELATIONS ISSUE HERE.

2 WHILE I HAVE THE FLOOR, I WANT TO DO ONE MORE
3 THING, THAT IS, READ THE DEFINITION OF COMPENSATION
4 BECAUSE IT'S SUBSTANTIALLY DIFFERENT FROM
5 REIMBURSEMENT. THAT IS, SOMETHING, TYPICALLY MONEY,
6 AWARDED TO SOMEONE AS A RECOMPENSE FOR INJURY OR
7 SUFFERING. THAT'S ONE DEFINITION. OR THE MONEY
8 RECEIVED BY AN EMPLOYEE FROM AN EMPLOYER AS A SALARY OR
9 WAGE. SO THIS GETS BACK TO THE ZERO-SUM GAME ASPECT OF
10 WHAT WE'RE TALKING ABOUT.

11 MS. KING: IF I WERE A POOR WOMAN WHO EARNED
12 MINIMUM WAGE, AND YOU ASKED ME TO BE A DONOR, AND WHEN
13 I CAME IN, YOU SAID I'M GOING TO GIVE YOU WHAT YOUR
14 MINIMUM WAGE IS. AND THEN I WAS SITTING IN THE SAME
15 ROOM WITH A WOMAN WHO HAD COME IN AND SHE TOO IS
16 DONATING FOR THE SAME REASON I'M DONATING. WE HAVE
17 DIABETES IN MY FAMILY. I CARE ABOUT WHAT CAN HAPPEN.
18 AND I SAY HOW MUCH ARE YOU GOING TO GET? AND SHE SAYS,
19 "OH, MY DAILY SALARY IS \$500 AN HOUR." THAT'S WHAT I'M
20 GOING TO GET IN THIS PROGRAM. I WOULD SAY -- I CAN'T
21 TELL WHAT I WOULD SAY. IT WOULD BE LET ME GET OUT OF
22 AS FAST AS I CAN GET OUT OF HERE BECAUSE THESE ARE --
23 THERE ARE MANY ARGUMENTS IN THE ROOM.

24 ONE OF THE ARGUMENTS IS REINFORCING THE
25 INEQUALITIES THAT ALREADY EXIST IN THIS SOCIETY WITH A

1 RESEARCH PROGRAM. THAT'S ONE ISSUE. A SECOND ISSUE IS
2 IN PRESERVING, FOR ME, IT'S PRESERVING INTEGRITY OF
3 WHAT YOU ARE TRYING TO DO AND KEEP IT ON TRACK AND NOT
4 ALLOW IT TO BE SIDETRACKED BY THINGS YOU CAN'T CONTROL
5 ONCE IT GETS GOING. BIG SUMS OF MONEY IS ONE WAY TO DO
6 THAT. I CAN GIVE YOU SOME OTHER REASONS TOO, BUT THERE
7 ARE NOT ANY ONE, TWO, OR THREE REASONS. THIS IS A
8 SENSITIVE ISSUE FOR A REASON.

9 LOST WAGES DOES, IN FACT, CARRY YOU INTO THAT
10 LINE BETWEEN COMPENSATION AND REIMBURSEMENT. I READ
11 THE DICTIONARY DEFINITION. I HEARD YOU GIVE THE
12 DICTIONARY DEFINITION. YOU'RE MAINTAINING IN YOUR MIND
13 THIS IS WHAT I EARN; THEREFORE, THIS IS WHAT I CAN
14 COMMAND. IT'S A PERFECTLY DECENT REASON. THAT'S
15 WHAT'S REFLECTED IN THE DICTIONARY. FOR THE REST OF
16 THE PEOPLE IN THE WORLD OR PEOPLE WHO PARTICIPATE, IT
17 BECOMES WHAT IS THE WORK THAT I AM DOING.

18 CO-CHAIR LANSING: THIS IS REALLY AN
19 IMPORTANT ISSUE. AND I THANK SUSAN FOR BRINGING IT UP
20 BECAUSE WE ARE ALL IN AGREEMENT THAT WE WANT EQUAL
21 OPPORTUNITY FOR EVERYBODY, AND TO DONATE THE EGGS, IF
22 THEY CHOOSE TO IN ANY WAY. I'M COMING AROUND. I'LL
23 TAKE A FUNNY EXAMPLE OF SOMEONE EARNING AN EXCESSIVE
24 AMOUNT OF MONEY EVERY DAY AND WHO DECIDES THAT THEY
25 WANT TO DO IT. WE MAYBE COULD NOT REIMBURSE WHAT THEIR

1 LOST WAGES WERE. THERE ARE PEOPLE WHO EARN GREAT DEALS
2 OF MONEY.

3 SIMILARLY, ON THE OTHER END OF THE TWO
4 EXTREMES, SOMEBODY WHO CAN'T AFFORD TO MISS A DAY OF
5 WORK BECAUSE THEY SIMPLY CAN'T AFFORD THE LOST WAGE AND
6 REALLY CARES. SO I'M COMING TO THIS JURY SYSTEM IDEA
7 THAT YOU GAVE, WHICH IS THAT THERE IS SOME -- THERE'S A
8 MAXIMUM THAT YOU CAN GET AS A, QUOTE, LOST WAGE, A
9 MAXIMUM AS A LOST WAGE. AND, THEREFORE, YOU HAVE TO DO
10 A JOB, OTHERWISE YOU DON'T HAVE A LOST WAGE. SO THAT
11 TAKES CARE OF COLLEGE STUDENTS OR ANYBODY WHO THINKS
12 THAT THEY WANT TO MAKE MONEY ON THIS. IT'S A MAXIMUM
13 AND IT'S A FLAT THING SO THAT THERE ISN'T AN INEQUALITY
14 IN THAT ROOM, WHICH I AGREE WITH YOU ON. I THINK THIS
15 IS REALLY WORTHY OF US REALLY SERIOUSLY GOING THROUGH.

16 MS. FOGEL: I DON'T KNOW IF I HEARD YOU
17 CORRECTLY. IF YOU DON'T HAVE A JOB, WHAT HAPPENS TO
18 YOU?

19 CO-CHAIR LANSING: YOU HAVE NO LOST WAGE.
20 THAT MUST MAINTAIN.

21 DR. KIESSLING: CAN I JUST INTERJECT ONE
22 QUICK COMMENT?

23 CO-CHAIR LO: I WANT TO TRY AND KEEP AN ORDER
24 HERE. ALTA AND THEN ANN.

25 MS. CHARO: PAT, YOUR CONVERSATION THAT YOU

1 POSIT IS FRUSTRATING BECAUSE IT'S -- ALTHOUGH I
2 COMPLETELY BELIEVE THAT THE CONVERSATION YOU'RE
3 RECOUNTING MIGHT TAKE PLACE, IT'S PREMISED ON A
4 MISUNDERSTANDING. WHAT WE'RE TALKING ABOUT IS
5 OUT-OF-POCKET LOSSES. IT'S NOT WHAT I CAN COMMAND, AND
6 IT'S NOT WHAT I CAN EARN. IT'S WHAT I AM OUT OF
7 POCKET. IF I HAD TO TRAVEL A HUNDRED MILES, THEN
8 THEY'RE GOING GIVE ME MORE MONEY FOR THE TICKET THAT I
9 HAD TO PAY THAN SOMEBODY WHO ONLY HAD TO WALK ACROSS
10 THE STREET.

11 CO-CHAIR LO: WE'RE TALKING ABOUT LOST WAGES.

12 MS. CHARO: I UNDERSTAND THAT, SHERRY, BUT
13 I'M SAYING THAT IN EITHER CASE WE'RE TALKING ABOUT AN
14 OUT-OF-POCKET COST. IF I DON'T SHOW UP TO WORK AND I
15 TAKE LEAVE WITHOUT PAY FOR THAT DAY, I AM OUT OF POCKET
16 FOR THAT AMOUNT OF MONEY, AND THEY'RE GOING TO PUT BACK
17 INTO MY POCKET EXACTLY THE AMOUNT I WAS OUT OF POCKET,
18 NO MORE, NO LESS. SO IT IS NOT ABOUT -- IT ALL
19 SOUNDS -- THE WAY WE'RE DISCUSSING IT, IT SOUNDS AS IF
20 SOMEHOW I'M GETTING SOME BONUS FOR HAVING DONATED, AND
21 THERE'S NO BONUS.

22 CO-CHAIR LANSING: WHAT IF IT'S A CEO OF A
23 COMPANY? THEY'RE OUT OF POCKET THOSE LOST WAGES FOR
24 THE DAY, BUT YOU CAN'T REIMBURSE THEM. I THINK YOU
25 HAVE TO HAVE A MAXIMUM OF LOST WAGES.

1 DR. EGGAN: AGAIN, THIS IS ONE REASON WHY
2 IT'S HELPFUL TO LEAVE -- TO AGAIN DEFINE THESE AREAS OF
3 REIMBURSEMENT AND LEAVE SOMETHING UP TO THE IRB TO HELP
4 WITH. TO SOME EXTENT, IT MAY BE THAT THE INVESTIGATOR
5 DOES HAVE THE AMOUNT OF MONEY AND THEY DO FEEL THAT
6 THAT'S RIGHT, AND THEY COULD BASICALLY DO THAT.

7 CO-CHAIR LO: I'M GOING TO BE REALLY MEAN AND
8 TRY AND GO IN ORDER. ANN, AND THEN MARCY. ANYONE
9 ELSE?

10 DR. KIESSLING: I JUST WANT TO INTERJECT THE
11 COMMENT THAT I'M SURE THIS COMMITTEE IS GOING TO
12 APPRECIATE HOW DELIGHTED I AM THAT WE'VE GONE FROM THE
13 CONCEPT OF ABSOLUTELY NO REIMBURSEMENT FOR LOST WAGES
14 TO HOW MUCH.

15 MS. FEIT: WE'VE STATED A COUPLE OF
16 INCONSISTENCIES HERE THAT ARE REALLY IN DIRECT CONFLICT
17 WITH WHAT WE REALLY WANT TO HAVE HAPPEN. I'VE HEARD
18 JUST IN THIS CONVERSATION THAT WOMEN -- A POOR WOMAN
19 WHO HAS A FAMILY HISTORY OF DIABETES OR, LET'S SAY,
20 SOME OTHER NEUROLOGICAL DISEASE WANTS TO DONATE TO HELP
21 FIND A CURE FOR HER LOVED ONES. SO SHE'S ALREADY
22 MAKING A MORAL AND ETHICAL DECISION TO HELP HER FAMILY.
23 HAS NOTHING TO DO WITH HER ECONOMIC STATUS AND WANTS TO
24 BE PART OF THE RESEARCH.

25 SO I THINK WE'RE SELLING THAT INDIVIDUAL A

1 LITTLE SHORT BY ALL OF A SUDDEN STARTING TO WHITTLE
2 DOWN INTO SOME ECONOMICS. I THINK WE GET ON A SLIPPERY
3 SLOPE OF I DON'T THINK WE'RE EVER GOING TO SOLVE THIS.
4 I THINK WE COULD BE HERE TOMORROW NIGHT AND STILL BE
5 ARGUING THE ISSUE OF HOW MUCH TO PAY SOMEBODY FOR LOST
6 WAGES.

7 MY DAUGHTER WHO'S A STAY-AT-HOME MOM WOULD
8 CHALLENGE THE QUESTION JUST BECAUSE SHE DOESN'T GET A
9 PAYCHECK, THAT SHE ISN'T WORTH SOMETHING AND HASN'T
10 LOST SOMETHING. SO WE GET INTO THAT REAL SLIPPERY
11 SLOPE. I THINK, FIRST OF ALL, WOMEN WHO WANT TO DO
12 THIS MAKE THAT FIRST MORAL AND ETHICAL DECISION THAT
13 THEY HAVE A REASON TO WANT TO PARTICIPATE. AND I DON'T
14 THINK IT HAS TO DO WITH ECONOMIC STATUS. IT HAS TO DO
15 WITH THEIR OWN FEELING ABOUT WHAT THEY WANT TO DO.
16 THEN THE INFORMED CONSENT COMES THROUGH.

17 I THINK, THOUGH, IT IS APPROPRIATE THAT THEY
18 SHOULD NOT INCUR A \$1500 LAB BILL BECAUSE THEY HAD TO
19 HAVE LAB TESTS. IT'S APPROPRIATE THAT THEY BE
20 REIMBURSED FOR REASONABLE EXPENSES GOING THROUGH THE
21 PROCESS, BUT I THINK WHEN WE TRY TO CIRCUMVENT THAT
22 INITIAL FEELING, I WANT TO BE PART OF THIS RESEARCH,
23 REGARDLESS OF WHO THEY ARE, THEN WE PUT IN A
24 DISCRIMINATORY BEGINNING IN THE WHOLE PROCESS. AND I
25 WOULD SAY WE SHOULD NOT EVEN GO THERE. THAT WE SHOULD

1 SAY REASONABLE EXPENSES THAT WERE INCURRED DURING THIS
2 PROCESS. I THINK THERE ARE MEDICAL EXPENSES. THERE'S
3 LABS, THERE'S RADIOLOGY, THERE ARE TREATMENTS. AND SO
4 THOSE SHOULD BE THE MOST IMPORTANT.

5 I THINK IF THAT WERE ME, THAT'S WHAT I WOULD
6 BE THINKING OF. I DON'T WANT TO GET A \$10,000 BILL
7 FROM A CLINIC OR A HOSPITAL BECAUSE I WANTED TO HELP
8 CURE PARKINSON'S DISEASE. THAT WOULD NOT BE A GOOD
9 THING. BUT I THINK IF I MADE THE DECISION, I ALSO MADE
10 THE DECISION TO TAKE THE TIME TO PARTICIPATE IN IT.
11 AND I THINK WHEN WE TRY TO GET IN FRONT OF THAT MORAL,
12 ETHICAL DECISION THAT THEY HAVE MADE, WE'VE SOLD THEM
13 SHORT.

14 CO-CHAIR LO: MORE PUBLIC COMMENT?

15 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR
16 TAXPAYER AND CONSUMER RIGHTS. I MYSELF AM COMPLETELY
17 AGNOSTIC AS TO WHETHER IT'S APPROPRIATE TO BE ABLE TO
18 OFFER MONEY OR NOT OFFER MONEY TO A DONOR. I'M FOCUSED
19 MUCH MORE ON THE POLICY THAT WAS PASSED BY THE VOTERS.
20 IT SEEMS TO ME THAT YOU ARE CONSTRAINED EXPLICITLY BY
21 WHAT'S IN PROPOSITION 7, WHICH IS THAT YOU CAN ONLY
22 HAVE REIMBURSEMENT. AND TO ME REIMBURSEMENT MEANS OUT
23 OF POCKET. AND WE CAN SIT AROUND ABOUT MIGHT BE, WHAT
24 COULD BE, WHAT IF, BUT IT SEEMS TO ME YOU HAVE A LAW
25 THAT YOU HAVE AN OBLIGATION TO MEET. AND THAT'S SIMPLY

1 THAT REIMBURSEMENT STANDARD, WHICH THEN RAISES THE
2 SECOND QUESTION OF THE LANGUAGE IN POINT (B), I GUESS,
3 FOR THE RESEARCH WITH NON-CIRM-FUNDED STEM CELL LINES
4 WHERE YOU ARE TALKING ABOUT REASONABLE COMPENSATION.

5 AND I DON'T SEE HOW YOU CAN DO THAT. IT
6 SEEMS TO ME THE ONLY THING YOU'RE ALLOWED TO DO IS COME
7 UP WITH CATEGORIES ABOUT WHAT IS APPROPRIATE
8 REIMBURSEMENT. AND I WOULD UNDERSTAND THAT TO MEAN OUT
9 OF POCKET.

10 CO-CHAIR LO: IF I COULD JUST ASK YOU TO TRY
11 AND BE VERY CLEAR. SO ON THIS ISSUE OF LOST WAGES,
12 WOULD YOU ALLOW THAT AS REIMBURSEMENT OR NOT?

13 MR. SIMPSON: MY UNDERSTANDING IS THAT IF YOU
14 COULD PRESENT A PAY STUB THAT SHOWED WHAT YOUR LOST
15 WAGES WERE, YOU WOULD BE ABLE TO BE ENTITLED TO BE
16 REIMBURSED FOR IT. THAT WOULD BE MY UNDERSTANDING.

17 CO-CHAIR LO: ANY LIMIT ON THE ABSOLUTE
18 DOLLAR AMOUNT THAT SHOULD BE REIMBURSED IF YOU WERE A
19 VERY HIGH PAID INDIVIDUAL?

20 MR. SIMPSON: IT WOULD SEEM TO ME THAT YOU
21 ARE ENTITLED TO GET YOUR REIMBURSEMENT FOR WHATEVER IT
22 IS. NOW, THAT MAY NOT BE WHAT IS THE MOST DESIRABLE
23 SOCIAL GOAL, BUT THE WAY TO REMEDY THAT WOULD SEEM TO
24 ME TO BE ADDRESS IT IN THE ORIGINAL PROPOSITION 71,
25 WHICH I THINK TAKES YOU DOWN THE ROAD OF A VERY

1 CONVOLUTED PROCESS. I THINK, TO A GREAT EXTENT, YOU
2 ARE HAVING TO DEAL WITH WHAT THE PEOPLE WHO WERE FOR
3 PROPOSITION 71 IN THE BEGINNING PRESENTED TO THE VOTERS
4 AND PROMISED TO THE VOTERS AND WHAT THE VOTERS ACTED
5 ON. AND I'M AFRAID IT'S REIMBURSEMENT IN THIS CASE.

6 CO-CHAIR LO: JUST AS A POINT OF INFORMATION,
7 AT THE MEETING THE LAST TIME IN LOS ANGELES, WE WERE
8 REMINDED THAT WHAT CONTROLS HERE IS ACTUAL LANGUAGE OF
9 THE PROPOSITION, NOT THE INTENT NECESSARILY OF THE
10 PEOPLE WHO WROTE IT. SO IT GETS BACK TO PRINCIPLES OF
11 STATUTORY INTERPRETATION.

12 LISTENING TO THIS, THIS IS A TOUGH QUESTION.
13 AND IT'S TOUGH BECAUSE THERE ARE SEVERAL ETHICAL
14 PRINCIPLES THAT WE ALL BELIEVE VERY STRONGLY IN. THESE
15 ARE ALL PULLING IN DIFFERENT DIRECTIONS. SO I'VE HEARD
16 A NUMBER OF THEM THAT DIFFERING PEOPLE HAVE IDENTIFIED.
17 ONE IS EQUAL OPPORTUNITY FOR PEOPLE TO PARTICIPATE IN
18 RESEARCH. SECOND IS NOT TO MAKE PEOPLE WORSE OFF FROM
19 HAVING PARTICIPATED THAN THEY WOULD HAVE BEEN HAD THEY
20 NOT PARTICIPATED.

21 BUT PULLING IN OTHER DIRECTIONS ARE THIS
22 NOTION THAT PEOPLE SHOULD RECEIVE EQUAL AMOUNTS OF
23 MONEY FOR THE SAME TASK ACCOMPLISHED.

24 AND FINALLY, THAT YOU DON'T WANT TO REINFORCE
25 SOCIAL, ECONOMIC, OTHER INEQUALITIES THAT ALREADY

1 EXIST. DEPENDING ON WHICH OF THOSE YOU BELIEVE MOST
2 STRONGLY IN, WE COULD COME TO VERY DIFFERENT
3 CONCLUSIONS.

4 LET ME TRY AND SEE IF WE CAN GET SOME
5 AGREEMENT HERE. FIRST, I THINK I'VE HEARD THAT WE ALL
6 AGREE THAT OUT OF -- THAT REASONABLE -- REIMBURSEMENT
7 FOR REASONABLE EXPENSES SHOULD BE PERMITTED, AS IS, IN
8 FACT, PERMISSIBLE UNDER PROP 71, AND THAT WE SHOULD
9 PROHIBIT COMPENSATION, HOWEVER WE DRAW THAT LINE, BUT
10 THAT WE CLEARLY WANT TO TRY AND ADHERE TO PROP 71 AND
11 ALLOW THE REIMBURSEMENT.

12 SO AS A GENERAL PRINCIPLE, IS THAT SOMETHING
13 WE CAN AGREE, SORT OF LEAVING OUT PAYMENT AND
14 INCENTIVES. SO WE WOULD PERMIT REIMBURSEMENT. THEN
15 THE QUESTION IS -- FIRST OF ALL, DO WE ALL AGREE WE
16 SHOULD PUT IN REIMBURSEMENT FOR REASONABLE EXPENSES?
17 ANYBODY NOT AGREE WITH THAT?

18 THEN THE QUESTION IS DO WE INCLUDE UNDER
19 REIMBURSEMENT LOST WAGES, SORT OF USING THE LANGUAGE
20 THAT ALTA FOUND FOR US FROM THE NATIONAL --

21 DR. PETERS: COULD TED GET IN LINE?

22 CO-CHAIR LO: SO THAT'S THE NEXT THRESHOLD.

23 DR. PETERS: I LIKE WHAT I THINK WAS ALTA'S
24 PHRASE, NO LOSS, NO GAIN. IF THAT COULD BE AN
25 OVERRIDING PRINCIPLE, THEN PERHAPS THE GRANTEE WHO'S

1 ACTUALLY DEALING WITH THE EGG DONOR COULD DETERMINE
2 WHAT COUNTS AND WHAT DOESN'T COUNT AS LONG AS THE NO
3 LOSS, NO GAIN PRINCIPLE HOLDS. THAT'S ALL. THANKS.

4 CO-CHAIR LO: WITH THIS ISSUE OF DO WE WANT
5 TO INCLUDE LOST WAGES, DOCUMENTABLE LOST WAGES, AS PART
6 OF AN ALLOWABLE REIMBURSEMENT?

7 MS. KING: THE ROAD YOU'RE GOING DOWN SEEMS
8 TO ASSUME THAT WE ARE ALL IN AGREEMENT THAT THIS
9 COMMITTEE SHOULD SO SPECIFY IN REGULATIONS. I SAID
10 SEVERAL TIMES I THOUGHT THE ROAD THAT WE WERE GOING
11 DOWN FIRST WAS THE ROAD THAT MADE SENSE TO ME, WHICH
12 PARALLELED WHAT WE CURRENTLY DO UNDER THE FEDERAL REGS,
13 WHICH IS THAT IRB'S, THE REVIEWING AUTHORITIES, HAVE TO
14 MAKE DECISIONS ABOUT WHAT THEY WILL DO, AND THAT WE
15 MAINTAIN SOME DOCUMENTATION. SO YOU'RE TAKING US DOWN
16 A DIFFERENT ROAD. DOES THAT MEAN THAT WE REVERSE THAT?

17 CO-CHAIR LO: NO. NO. THAT COULD BE AN
18 OPTION. WE CAN SAY AS A GENERAL STATEMENT WE PERMIT
19 REIMBURSEMENT FOR REASONABLE EXPENSES. WE PROHIBIT
20 COMPENSATION, AND WE SAY TO THE IRB, YOU NEED TO FIGURE
21 THAT OUT, AND YOU NEED TO EXPLAIN YOUR RATIONALE TO US.
22 RESEARCHERS NEED TO SUBMIT A RATIONALE FOR ANY
23 REIMBURSEMENT TO THE GRANTS WORKING GROUP WHEN THEY
24 REVIEW IT.

25 CO-CHAIR LANSING: ALTA, WHEN YOU READ THE

1 ORGAN TRANSPLANT THING, YOU HAD A WHOLE LIST OF THINGS
2 WHICH WERE ACCEPTABLE REIMBURSABLE EXPENSES, THAT THEY
3 WERE NOT MANDATORY, SO THEY DID NOT HAVE TO REIMBURSE
4 FOR THEM. AND I THINK IF WE DO THAT, THEN WE'VE
5 COVERED EVERYTHING THAT WE WANT TO COVER BECAUSE THEN
6 WHEN WE GET TO THE SECTION ON LOST WAGES, THE
7 INDIVIDUAL GROUP COULD SAY WE'RE CAPPING IT OR WE'RE
8 NOT REIMBURSING IT. WE LEAVE IT UP TO THEM TO DECIDE,
9 BUT WE PUT IT IN THE LONG LIST THAT YOU READ. I WOULD
10 BE COMFORTABLE WITH THAT.

11 MS. FEIT: CATEGORIES TO BE CONSIDERED.

12 CO-CHAIR LANSING: EXACTLY.

13 CO-CHAIR LO: CONSIDERED, BUT NOT LIMITED TO;
14 SHALL INCLUDE, BUT ARE NOT LIMITED TO REASONABLE
15 EXPENSES.

16 MS. CHARO: CATEGORIES FOR WHICH
17 REIMBURSEMENT IS PERMITTED, BUT NOT REQUIRED.

18 MR. TOCHER: JUST PERMISSIBLE EXPENSES.

19 MS. CHARO: CATEGORIES FOR WHICH
20 REIMBURSEMENT IS PERMITTED, BUT NOT REQUIRED INCLUDE,
21 BUT ARE NOT LIMITED TO.

22 DR. PRIETO: ALTA, YOU'RE NOT AN ATTORNEY,
23 ARE YOU?

24 CO-CHAIR LO: THAT'S ONE. AND TIED WITH THAT
25 IS ZACH'S ORIGINAL PROPOSAL, THAT WHEN A GRANT IS

1 SUBMITTED THAT PROVIDES REIMBURSEMENTS, THERE NEEDS TO
2 BE AN EXPLANATION FROM THE PI SUBMITTING THE GRANT FOR
3 HOW THEY CALCULATE REIMBURSEMENT. SORT OF INSTRUCT THE
4 GRANTS WORKING GROUP TO --

5 DR. HALL: I WOULD LIKE A SEPARATE
6 RESOLUTION, IF POSSIBLE, INDEPENDENT OF THE RESOLUTION
7 ABOUT YOUR DOCUMENT, WHICH IS SOMETHING THAT DIRECTS US
8 TO DO THAT. I THINK THAT WOULD BE VERY GOOD.

9 CO-CHAIR LO: WITH THE UNDERSTANDING THAT
10 THESE WOULD COME AS A PACKAGE.

11 CAN WE TALK NOW ABOUT ALTA'S PROPOSAL, SHERRY
12 AND ALTA'S PROPOSAL IN RESPONSE TO PAT'S COMMENT, THAT
13 WE SAY THAT REIMBURSEMENT MAY BE PERMITTED --
14 REIMBURSEMENT IS PERMISSIBLE FOR REASONABLE EXPENSES
15 THAT INCLUDE, BUT ARE NOT LIMITED TO THE FOLLOWING
16 CATEGORIES. LANGUAGE ISN'T QUITE RIGHT.

17 DR. HALL: PLUS CHILDCARE.

18 MS. CHARO: THE LIST THAT WE HAD WAS TRAVEL,
19 HOUSING, ACTUAL -- HOW ABOUT ACTUAL LOST WAGES,
20 CHILDCARE, MEDICAL EXPENSES. I DON'T THINK I REMEMBER
21 ANYTHING ELSE.

22 DR. EGGAN: INCLUDING HEALTH INSURANCE
23 PROBABLY. PROBABLY HEALTH INSURANCE SHOULD BE PROVIDED
24 BY THE ACTUAL STUDY; BUT IF IT'S NOT, THESE WOMEN NEED
25 HEALTH INSURANCE DURING THIS.

1 MS. CHARO: MEDICAL EXPENSES. AND WE'LL
2 FIGURE OUT THE LANGUAGE. HEALTH INSURANCE PREMIUMS OR
3 SOMETHING LIKE THAT. IT MAY BE SEPARATE, BUT JUST TO
4 MAKE SURE PEOPLE ARE ENROLLED.

5 CO-CHAIR LO: DISCUSSION ON THAT? I DON'T
6 KNOW WHETHER THE SILENCE IS ASSENT.

7 DR. PRIETO: DO WE HAVE A MOTION? THIS IS A
8 MOTION TO THE CIRM, A SENSE OF THIS COMMITTEE.

9 CO-CHAIR LO: I THOUGHT THIS PART IS GOING IN
10 THE REGULATIONS.

11 DR. KIESSLING: WHERE IS IT GOING TO GO?

12 CO-CHAIR LO: THIS WOULD GO INTO
13 100007(A)(2), RIGHT.

14 MS. CHARO: SAY THAT AGAIN.

15 CO-CHAIR LO: 100007, PAGE 5, SECTION (A),
16 NO. 2, VERY LAST PROVISION ON THE PAGE.

17 MR. TOCHER: LET ME ALSO POINT OUT THERE
18 WOULD NEED TO BE A CORRESPONDING CHANGE IN THE
19 DEFINITIONS SECTION, 01 SECTION, LOOKS LIKE,
20 SUBDIVISION (C) BECAUSE EXPENSES ARE DEFINED THERE.

21 CO-CHAIR LO: DIRECTLY INCURRED EXPENSES AS A
22 RESULT.

23 MR. TOCHER: IN FACT, THAT MIGHT BE THE IDEAL
24 PLACE TO PUT IT.

25 CO-CHAIR LO: EXPENSES THAT ARE PERMISSIBLE

1 MAY INCLUDE -- THAT ARE PERMISSIBLE, BUT ARE NOT
2 REQUIRED, MAY INCLUDE, BUT ARE NOT LIMITED TO.

3 MS. CHARO: THAT ACTUALLY SIMPLIFIES IT. YOU
4 CHANGE THE DEFINITION OF EXPENSES, AND THEN YOU GO BACK
5 DOWN TO THE WAY 07 IS NOW WRITTEN. IT SAYS THEY MAY BE
6 REIMBURSED FOR EXPENSES. IT DOESN'T SAY THAT THEY MUST
7 BE. IT ACTUALLY SIMPLIFIES EVERYTHING.

8 MR. TOCHER: I WOULD DRAW THAT YOU COULD USE
9 THE EXISTING DEFINITION THERE, AND THEN AT THE END OF
10 THE PERIOD, BEGIN THIS SENTENCE THAT YOU ARE
11 STRUCTURING NOW TO SAY PERMISSIBLE REIMBURSABLE
12 EXPENSES THAT MAY BE REIMBURSED INCLUDE, BUT ARE NOT
13 LIMITED TO, CHILDCARE, TRAVEL, HOUSING, MEDICAL
14 EXPENSES --

15 CO-CHAIR LO: ACTUAL LOST WAGES.

16 MR. TOCHER: -- AND ACTUAL LOST WAGES.

17 CO-CHAIR LO: WE HAVE LANGUAGE. DO WE AGREE
18 ON THAT OR NOT?

19 DR. KIESSLING: WE'RE GOING TO CHANGE THE
20 DEFINITION UNDER 1(C), 1(A)(C).

21 CO-CHAIR LO: NO. NOW WE'RE GOING BACK TO
22 PAGE 2, THE DEFINITION OF EXPENSES, PERIOD, AND A NEW
23 SENTENCE. EXPENSES THAT MAY BE, BUT ARE NOT REQUIRED
24 TO BE REIMBURSED, INCLUDE, BUT ARE NOT LIMITED TO,
25 TRAVEL, HOUSING, FOOD, CHILDCARE, ACTUAL LOST WAGES,

1 MEDICAL EXPENSES.

2 DR. KIESSLING: WHAT'S THE ACTUAL?

3 CO-CHAIR LO: ACTUAL LOST WAGES. IF YOU
4 PRODUCE YOUR PAY STUB AND SAY THIS IS PERMISSIBLE, SO
5 THE IRB CAN CONSIDER IT. WE'RE NOT SAYING YOU HAVE TO
6 REIMBURSE. THEY MAY CAP IT IF THEY WANT.

7 MS. KING: I'M NOT GOING TO OPPOSE.

8 CO-CHAIR LO: WE NEED TO SORT OF TRY AND SEE
9 IF THERE'S AGREEMENT. IF THERE'S NOT --

10 DR. KIESSLING: I THINK THE WORD "ACTUAL" IS
11 A PROBLEM.

12 MS. CHARO: IT'S ADDED FOR EMPHASIS BECAUSE
13 IN OTHER AREAS WHERE PEOPLE CALCULATE THEIR LOSSES,
14 THEY OFTEN GET A LITTLE BIT MORE KIND OF HYPOTHETICAL
15 ABOUT THEIR LOSSES, LOST OPPORTUNITY, I WASN'T ABLE TO
16 DAY TRADE TODAY, OR I MIGHT HAVE GOTTEN THAT JOB. IF I
17 HAD, IT WOULD HAVE BEEN -- IT'S MORE EMPHASIS THAN
18 ANYTHING ELSE, AND IT DOES HAVE SOME REDUNDANCY TO IT.
19 I AGREE WITH YOU. QUESTION IS WHETHER IT ADDS A
20 MESSAGE THAT WE WANT TO ADD THERE.

21 DR. KIESSLING: THE SPIRIT IS RIGHT.

22 CO-CHAIR LO: DOES SOMEONE WANT TO MAKE THAT
23 AS A MOTION?

24 MS. CHARO: I SO MOVE.

25 DR. EGGAN: SECOND.

1 DR. HALL: SOMEBODY GOING TO READ IT?

2 CO-CHAIR LO: ALTA WILL READ IT.

3 MS. CHARO: WE'RE MOVING THAT THE
4 REGULATION -- THE DEFINITION OF PERMISSIBLE EXPENSES IN
5 THE DEFINITIONAL SECTION NOW BE AMENDED TO READ THAT
6 THEY INCLUDE, BUT ARE NOT LIMITED TO PERMISSIBLE
7 EXPENSES. PERMISSIBLE EXPENSES ARE DEFINED AS THE
8 NECESSARY AND REASONABLE COSTS INCURRED OR EXPENDED AS
9 A RESULT OF DONATION AND MAY INCLUDE, BUT ARE NOT
10 LIMITED TO, CHILDCARE, TRAVEL, HOUSING, MEDICAL
11 EXPENSES, HEALTH INSURANCE EXPENSES, AND ACTUAL LOST
12 WAGES.

13 CO-CHAIR LO: AND MEALS.

14 MS. CHARO: MEALS, PER DIEM.

15 IN SECTION 100007 IN SUBSECTION (A)(2), IT
16 WILL THEN SAY THAT INDIVIDUALS MAY BE REIMBURSED FOR
17 PERMISSIBLE EXPENSES, THUS INCORPORATING THE
18 DEFINITIONAL SECTION.

19 CO-CHAIR LANSING: AND IT'S NOT MANDATORY.

20 MS. CHARO: IT SAYS MAY BE REIMBURSED. IT
21 WILL NOT BE MANDATORY, AS DETERMINED BY AN IRB, WHICH
22 GIVES THE IRB THE RESPONSIBILITY OF FIGURING OUT WHAT
23 IS A REASONABLE AND NECESSARY EXPENSE THAT HAS, IN
24 FACT, BEEN INCURRED AS A RESULT OF THE DONATION
25 PROCESS. THE IRB'S ARE, OF COURSE, FREE, IF THEY

1 DECIDE TO GO FOR A PROTOCOL WITH NO REIMBURSEMENT OR
2 ONLY PARTIAL REIMBURSEMENT OR A CAP ON REIMBURSEMENT,
3 AND THAT COULD VARY FROM LOCALE TO LOCALE.

4 CO-CHAIR LO: DISCUSSION? PUBLIC COMMENT?

5 DR. WAGNER: SO NOW PUTTING ON THE HAT OF I'M
6 THE INVESTIGATOR AND I'M NOW TRYING TO WRITE MY
7 APPLICATION TO CIRM IN TERMS OF TRYING -- PUTTING IN
8 THE SECTION THERE IN MY BUDGET AND A BUDGET
9 JUSTIFICATION. NOW NOT KNOWING EXACTLY HOW THE IRB
10 WILL EVENTUALLY WORD THIS, BUT I COULD GO TO THE IRB IN
11 ADVANCE AND ASK THEM FOR THAT.

12 SO THEN I AM AT ONE INSTITUTION AND MY IRB
13 SAYS, YES, WE'RE GOING TO PAY THEM THEIR EXPENSES FOR
14 XYZ. THAT COULD VARY FROM ONE INDIVIDUAL TO THE NEXT.
15 IT'S GOING TO MAKE IT DIFFICULT TO COME UP WITH A
16 BUDGET NOT KNOWING IN ADVANCE WHAT THAT VARIATION IS
17 GOING TO BE. I'M JUST TRYING TO THINK OF THE PRACTICAL
18 THINGS. AGAIN, MAYBE THERE ARE WAYS AROUND IT. MAYBE
19 WE DON'T WANT TO GET INTO THOSE DETAILS; BUT AS WE
20 THINK ABOUT THAT, THERE IS THE POTENTIAL FOR THE
21 EXTREMES THAT WE'VE ALL TALKED ABOUT.

22 IT'S JUST A MATTER OF IS THIS SOMETHING THAT
23 IS -- THAT THIS GROUP CAN SUSTAIN IN TERMS OF THE
24 FUNDING THAT MIGHT BE REQUESTED. MAYBE THE ANSWER IS
25 WE'LL SEE HOW IT COMES.

1 CO-CHAIR LO: MY GUESS IS THAT THERE'S
2 PROBABLY GOING TO BE A DISCUSSION BETWEEN THE
3 INVESTIGATOR AND THE INSTITUTIONAL IRB. THE IRB MAY
4 SAY WE HAVE A POLICY FOR OTHER TYPES OF LOST WAGES,
5 REIMBURSEMENT OF LOST WAGES, AND IT NEEDS TO BE
6 CONSISTENT. AND CIRM MAY COME BACK AND SAY YOU PUT IN
7 A MILLION DOLLARS HERE FOR DONATION BECAUSE YOU THINK
8 YOU KNOW WHO'S GOING TO BE LINING UP TO DONATE.

9 DR. HALL: CEDARS-SINAI HAS HIGH-PRICED
10 ACTORS AND ACTRESSES LINING UP TO DONATE. WE'LL HAVE
11 TO DEAL WITH THAT.

12 MS. CHARO: THEY'VE GOT MORE LOW-PRICE ACTORS
13 AND ACTRESSES ACTUALLY.

14 CO-CHAIR LO: COMMENTS FROM THE PUBLIC ON
15 THIS?

16 MR. TAYMOR: IN LISTENING TO THIS
17 CONVERSATION, THE PUBLIC RELATIONS QUESTION WAS RAISED.
18 AND I DO THINK THAT, FROM LOOKING AT THE STATUTE, AS A
19 LAWYER, THIS IS AN AGGRESSIVE READING OF REIMBURSEMENT,
20 WHICH YOU MAY BE CHALLENGED ON. I THINK THAT WHERE YOU
21 ARE DEALING WITH PUBLIC RELATIONS, AND TO THE EXTENT
22 THAT, AS RESEARCHERS, YOU FEEL THAT THE HARVESTING OF
23 OOCYTES FROM A DIVERSE POPULATION IS NECESSARY IN ORDER
24 TO EFFECTIVELY CONDUCT THIS RESEARCH, IT WOULD BE VERY
25 BENEFICIAL TO THE PUBLIC DEBATE THAT IS ONGOING AND

1 LIKELY TO ENSUE THAT THERE BE SOME EVIDENCE-BASED
2 DECISION-MAKING GOING ON.

3 TO THE EXTENT THAT THE EVIDENCE IS AVAILABLE
4 NOW -- I KNOW DR. KIESSLING PROVIDED A VERY INTERESTING
5 REPORT EARLIER ON. I'M SURE OTHERS AT THE TABLE HAVE
6 OTHER PIECES OF EVIDENCE -- THAT COULD BE FOLDED INTO
7 THE STATEMENT OF REASONS. I THINK IT WOULD BE VERY
8 HELPFUL TO SUPPORT THE CONCLUSIONS THAT ARE BEING
9 REACHED TODAY. AND THAT OUT OF THE CONFERENCE YOU'RE
10 HOSTING AND MAYBE GOING FORWARD, YOU MAY THINK OF SOME
11 FUNDING BECAUSE THIS WILL BE AN ONGOING DEBATE, AND
12 EVIDENCE WILL UNFOLD AS YOUR POLICIES ARE IN PRACTICE.

13 DR. EGGAN: I THINK IT'S IMPORTANT TO SAY
14 THAT I DON'T KNOW OF ANY EVIDENCE WHICH SUGGESTS,
15 ALTHOUGH ANN COULD CORRECT ME ON THIS, THAT THERE IS A
16 NEED TO GET OOCYTES FROM A RACIALLY DIVERSE GROUP OF
17 WOMEN IS THE IMPLICATION OF THE STATEMENT THAT YOU ARE
18 MAKING. WE NEED DIVERSITY IN THE PEOPLES THAT ARE
19 DONATING THEIR EGGS. THE COMMITMENT TO DIVERSITY IS
20 THE COMMITMENT TO EQUAL OPPORTUNITY TO PARTICIPATE IN
21 HUMAN SUBJECTS RESEARCH AS MANDATED BY FEDERAL
22 LEGISLATION. THAT IS -- THAT'S THE RESPONSIBILITY OF
23 THIS GROUP, AND THAT'S WHAT EVERYONE IS TRYING TO LIVE
24 UP TO. AND I THINK NOTHING MORE AND NOTHING LESS THAN
25 THAT.

1 SO I THINK THAT THE KEY IS, AS ALTA KEEPS
2 SAYING OVER AND OVER AND OVER AGAIN, IS AT LEAST AS WE
3 ARE TRYING TO INTERPRET IT AND BELIEVE IT SHOULD BE
4 INTERPRETED, THAT REIMBURSEMENT MEANS A ZERO-SUM GAME
5 FOR PARTICIPATION. THAT IS, ONCE MORE TO REITERATE
6 WHAT YOU SAID, THAT WOMEN WHO PARTICIPATE SHOULD BE NO
7 BETTER OR WORSE OFF FOR HAVING DONE THIS. SO I DON'T
8 SEE IT AS BEING AN AGGRESSIVE READING OF THE WORD
9 "REIMBURSEMENT" AT ALL, BUT THE FRANK AND EARNEST
10 ATTEMPT TO LIVE UP TO THE SPIRIT OF THAT WORK.

11 CO-CHAIR LO: OTHER PUBLIC COMMENT? OKAY.
12 FURTHER DISCUSSION ON THE COMMITTEE? CALL THE
13 QUESTION.

14 DR. ROWLEY: QUESTION.

15 CO-CHAIR LO: THANK YOU. OKAY. SO DO WE ALL
16 KNOW THE PROPOSITIONS WE'RE CONSIDERING? HOW MANY ARE
17 IN FAVOR OF THAT FORMULATION? KEEP YOUR HANDS UP. SO
18 IT'S 11.

19 DR. TAYLOR: I DON'T REALLY KNOW. I'VE HAD A
20 PHONE IN MY EAR, AND I DON'T KNOW QUITE WHAT THE -- I'M
21 THE ONLY ONE IN THE ROOM WHO --

22 MS. KING: YOU ABSTAIN IS WHAT YOU DO IF YOU
23 DON'T WANT TO VOTE YES OR NO.

24 CO-CHAIR LO: MY UNDERSTANDING OF WHAT THIS
25 IS IS WE'RE AMENDING THE DEFINITION OF REIMBURSEMENT TO

1 SAY THAT PERMISSIBLE REIMBURSEMENT MAY INCLUDE THE
2 FOLLOWING CATEGORIES, BUT IS NOT LIMITED TO, TRAVEL,
3 MEALS, CHILDCARE, MEDICAL CARE, HEALTH INSURANCE, AND
4 LOST WAGES. AS KEVIN SAYS, THE IDEA BEING TO SORT OF
5 MAKE PEOPLE FINANCIALLY NEUTRAL AFTER HAVING
6 PARTICIPATED COMPARED TO WHEN BEFORE THEY PARTICIPATED.

7 PAT ABSTAINED?

8 MS. KING: YES.

9 MR. TOCHER: THERE'S A VOTE ON THE PHONE.

10 DR. PETERS: YES, I'M.

11 CO-CHAIR LO: WE DIDN'T GET YOUR VOTE.

12 DR. PETERS: MY VOTE IS THUMBS UP. YOU CAN'T
13 SEE MY THUMB, BUT IT'S GOING UP.

14 LET ME ALSO MENTION THAT IN A MOMENT OR SO,
15 I'M GOING TO NEED TO DUCK OFF THE PHONE. SO LET ME SAY
16 IT'S BEEN NICE PARTICIPATING AND WISH YOU WELL. I
17 WON'T BE ABLE TO PARTICIPATE TOMORROW MORNING.

18 CO-CHAIR LO: WE'LL MISS YOU, TED. THANKS
19 VERY MUCH FOR PHONING IN.

20 WELL, NOW WE'RE NOWHERE NEAR DONE BECAUSE THE
21 QUESTION NOW IS -- WE AMENDED (A). WE AMENDED THE
22 DEFINITION OF 100001. WE AMENDED (A). THERE'S A
23 QUESTION OF WHAT TO DO --

24 MS. FOGEL: I'M SORRY. COULD I HAVE THE
25 SECOND HALF OF MY PUBLIC COMMENT ON THAT?

1 NOW, YOU'VE INCLUDED MEDICAL INSURANCE AND
2 MEDICAL PAYMENTS, WHICH IS, OF COURSE, USEFUL FOR WOMEN
3 WHO ACTUALLY HAVE INSURANCE OR WHO HAVE A REGULAR
4 SOURCE OF HEALTHCARE AND CAN AFFORD TO PAY OUT OF
5 POCKET TO BE REIMBURSED, BUT IT REALLY DOESN'T HELP
6 ANYBODY ELSE.

7 WE'D LIKE TO RECOMMEND A NO. 5 AS PART OF
8 WHAT NEEDS TO BE -- A NEW NO. 5 UNDER (A), WHAT NEEDS
9 TO BE INCLUDED IS THAT ANY NECESSARY MEDICAL CARE
10 REQUIRED BY THE OOCYTE DONOR AS A RESULT OF THE
11 DONATION PROCESS BE PROVIDED BY THE RESEARCH
12 INSTITUTION. SO THAT THEY'RE REQUIRED TO COVER AND PAY
13 FOR AND PROVIDE ANY MEDICAL CARE SHE MIGHT NEED AS A
14 DIRECT RESULT.

15 CO-CHAIR LO: COULD I ASK YOU A QUESTION AS
16 TO WHETHER THESE EXPENSES ARE RESTRICTED IN TIME AT
17 ALL?

18 MS. FOGEL: DIRECT RESULT.

19 CO-CHAIR LO: DIRECT RESULT.

20 MS. FOGEL: WE APPRECIATE THE LONG-TERM
21 ISSUES HERE, BUT WE DO THINK THAT TO THE EXTENT THAT
22 ANY ADVERSE HEALTH OUTCOME IS DIRECTLY RELATED TO THE
23 EGG EXTRACTION PROCESS, THAT HER MEDICAL CARE NEEDS TO
24 BE TAKEN CARE OF, NOT JUST FOR HER TO BE LEFT ON HER
25 OWN TO GO FIGURE IT OUT, AND THEN HOW TO BE REIMBURSED

1 FOR IT.

2 CO-CHAIR LO: OKAY. THIS IS AN IMPORTANT
3 CONSIDERATION.

4 DR. EGGAN: I THINK BOTH ANN AND I, HER HAND
5 IS KIND OF UP THERE TOO, WE CAN PROBABLY SHARE OUR
6 LIMITED EXPERIENCE IN TRYING TO DESIGN THESE TYPES OF
7 CLINICAL PROCEDURES.

8 I THINK IT -- FIRST OF ALL, IF WOMEN WERE
9 ASKED TO PAY FOR ANY PORTION OF THIS PROCEDURE, SIMPLY
10 NO ONE WOULD VOLUNTEER BECAUSE IT'S EXTREMELY
11 EXPENSIVE, AS ANN SAYS. I THINK THAT BALLPARK NUMBER
12 IS, FRANKLY, ABOUT RIGHT. AND SO IT'S GOING TO COST --
13 THE CLINICAL EXPENSE ASSOCIATED WITH THIS IS GOING TO
14 BE ON THE ORDER OF TEN AND \$20,000, DEPENDING ON HOW
15 PRECISELY IT'S DONE. TO EXPECT ANY WOMAN TO PAY THAT
16 IS GOING TO BE OUTRAGEOUS.

17 IT IS ALSO TRUE THAT THERE ARE SIDE EFFECTS,
18 POTENTIAL SIDE EFFECTS, WHICH ARE ASSOCIATED WITH THIS
19 PROCEDURE. AND AGAIN, THESE ARE SIDE EFFECTS THAT I
20 WOULD DESCRIBE AS -- SIDE EFFECTS CAN BE SEVERE, BUT
21 THE RISKS ARE SMALL. AND SO AS IT TURNS OUT, THERE IS
22 IN THE UNITED STATES A BOILERPLATE HEALTH INSURANCE
23 POLICY FOR WOMEN THAT UNDERGO OOCYTE DONATION OR
24 REPRODUCTION. IT'S PRECISELY THE SAME MEDICAL
25 PROCEDURE THAT THESE WOMEN WILL NEED TO UNDERGO, AND SO

1 THAT BOILERPLATE HEALTH INSURANCE POLICY COULD APPLY AS
2 WELL, AND IN PRACTICE ARGUABLY SHOULD.

3 MS. CHARO: THIS IS SOMETHING THAT WOMEN
4 GOING FOR IVF WILL PURCHASE SEPARATE FROM THEIR
5 EXISTING INSURANCE?

6 DR. EGGAN: WELL, THE BEST MODEL IS A WOMAN
7 WHO IS DONATING EGGS FOR ANOTHER WOMAN'S REPRODUCTION,
8 WHICH IS ESSENTIALLY PRECISELY WHAT'S HAPPENING HERE.
9 INSTEAD OF THOSE EGGS BEING GIVEN TO ANOTHER WOMAN'S
10 REPRODUCTION, THEY'RE GIVEN TO RESEARCH. THAT WOMAN
11 HAS A HEALTH INSURANCE POLICY THAT SHE TAKES OUT AS
12 PART OF THAT PROCEDURE DEDICATED TO THAT TIME DURING
13 HER PROCEDURE. AND THE ASPECTS OF IT ARE COMPLETELY
14 PRESCRIBED BY THE INSURANCE COMPANY. YOU MAY HAVE MORE
15 EXPERIENCE WITH IT THAN I DO.

16 DR. TAYLOR: I CAN'T RECALL THE NAME OF
17 HIS -- I THINK THERE'S SEVERAL COMPANIES OUT, BUT
18 ACTUALLY HE'S A FRIEND OF MINE WHO STARTED ONE OF THE
19 FIRST ONES BASICALLY. SO HE UNDERWRITES THESE
20 POLICIES. I'M NOT SURE WHERE HIS FUNDING CAME FROM,
21 AND THEY'RE SPECIFICALLY FOR EGG DONORS.

22 DR. KIESSLING: IT'S ABOUT A THREE- TO
23 SIX-WEEK POLICY COVERAGE.

24 CO-CHAIR LO: IT'S FOR SHORT-TERM, IMMEDIATE
25 COMPLICATIONS OF THE OOCYTE RETRIEVAL PROCESS.

1 DR. KIESSLING: THAT'S RIGHT. STANDARD
2 PRACTICE FOR OOCYTE DONATION. THE PROBLEM WITH IT IS
3 THAT THESE PARTICULAR INSURANCE COMPANIES WOULD
4 RATHER -- THEY FIRST WANT TO KNOW IF THE PERSON
5 DONATING EGGS HAS A POLICY. SO YOU HAVE TO BE KIND OF
6 CAREFUL HOW YOU DEAL WITH THESE PEOPLE BECAUSE IF SHE
7 HAS A POLICY, THEY WANT YOU USE THAT FIRST, WHICH IS
8 NOT ACCEPTABLE. THERE'S CERTAINLY INSURANCE COVERAGE
9 FOR THIS PROCESS, AND IT'S NOT TERRIBLY EXPENSIVE, AND
10 IT'S VERY WELL ESTABLISHED.

11 CO-CHAIR LO: PRESUMING THE INSTITUTION COULD
12 PURCHASE THIS.

13 DR. KIESSLING: OR THE PROJECT CAN PURCHASE
14 IT.

15 MS. CHARO: QUESTION. YOU ANSWERED THE FIRST
16 ONE, WHICH IS WHETHER IT'S DESIGNED TO BE PRIMARY OR
17 SECONDARY. THAT NEEDS ATTENTION.

18 SECOND IS THE RISKS ARE LOW, BUT REAL. ABOUT
19 1 IN 20 WOMEN WILL HAVE AT LEAST SOME SYMPTOMS OF
20 HYPERSTIMULATION SYNDROME, MAYBE MORE THAN THAT. THEN
21 THERE'S A PERCENTAGE OF THOSE, AND I'VE NEVER BEEN ABLE
22 TO GET A GOOD FIGURE ON THIS, WHO THEN GO ON TO A MORE
23 SEVERE VERSION THAT NEEDS HOSPITALIZATION, ETC. WHAT
24 DO WE KNOW ABOUT THE ACTUAL TIME FRAME? YOU SAID THREE
25 TO SIX WEEKS, BUT WHAT'S THE REAL TIME FRAME FOR THESE

1 ADVERSE EVENTS SO THAT WE HAVE A GOOD UNDERSTANDING?

2 DR. TAYLOR: AGAIN, I THINK IT DEPENDS A
3 LITTLE BIT WHAT YOU CALL SIDE EFFECTS AND HOW MILD IS
4 MILD. I MEAN ALMOST ALL WOMEN ARE GOING TO HAVE SOME
5 ABDOMINAL FULLNESS AND OVARIAN DISCOMFORT AND A LITTLE
6 BIT OF NAUSEA WHICH ARE VERY COMMON WITH ANY TYPE OF
7 OVARIAN STIMULATION. THE TIME COURSE IN A NORMAL IVF
8 CYCLE IS TYPICALLY FOUR TO SEVEN WEEKS INTO THE
9 PROCEDURE. THAT'S BECAUSE THEY BECOME PREGNANT AND
10 THEY'RE MAKING THEIR OWN HCG. SO FOR AN EGG DONOR,
11 YOU'RE NOT GOING TO SEE THAT SORT OF SECOND PHASE OF
12 RISK, WHICH IS ACTUALLY THE MORE LIKELY PHASE IN WHICH
13 SYMPTOMS ARE TO OCCUR. EGG DONORS WILL ACTUALLY AVOID
14 THAT PHASE OF IT BECAUSE THEY'RE NOT BECOMING PREGNANT.

15 I THINK IT'S BEEN SORT OF ESTIMATED THAT
16 SOMEWHERE BETWEEN ONE AND 50,000, AND ONE IN 500,000
17 WOMEN MIGHT HAVE REALLY ANY SORT OF A LIFE THREATENING.
18 THE EVENTS ARE SO RARE, THAT IT'S KIND OF HARD TO GET A
19 GOOD DENOMINATOR ON THAT. AND THOSE WOULD BE
20 THROMBOSIS AND STROKE AND THINGS LIKE THAT AND THOSE
21 SORT OF SERIOUS THINGS. THOSE ARE THE KINDS OF
22 NUMBERS, I GUESS, WE'RE TALKING ABOUT.

23 CO-CHAIR LO: WHEN DO THOSE COMPLICATIONS
24 OCCUR RELATIVE TO THE OOCYTE RETRIEVAL CYCLE IF SOMEONE
25 HAS A STROKE A YEAR OUT, FIVE YEARS OUT, TEN YEARS OUT?

1 DR. TAYLOR: AGAIN, THOSE ARE USUALLY IN THE
2 ONE-MONTH TO TWO-MONTH WINDOW OF TIME. AGAIN,
3 TYPICALLY ASSOCIATED WITH PREGNANCY AND VASCULAR --

4 CO-CHAIR LO: FOR THE DONORS WHO DON'T GET
5 PREGNANT.

6 DR. TAYLOR: AFTER ABOUT THREE WEEKS.

7 DR. EGGAN: I'D LIKE TO INTERJECT, I'M GOING
8 TO DEFER TO GREATER EXPERTISE HERE, BUT COUPLE OF
9 COMMENTS TO ADD TO THAT. OF COURSE, THESE WOMEN ARE
10 GOING TO BE UNDERGOING ALMOST DAILY MONITORING OF THEIR
11 ESTRADIOL LEVELS DURING THIS PROCEDURE. AND THERE IS,
12 FOR INSTANCE, NO REASON THAT IRB'S COULDN'T STATE THAT
13 PERHAPS THAT THE MAXIMUM LEVELS OF ESTRADIOL FOR THESE
14 WOMEN SHOULDN'T BE LOWER THAN THE MAXIMUM ESTRADIOL
15 LEVELS FOR WOMEN WHO PARTICIPATE IN THE PRODUCTIVE EGG
16 DONATION. AND IT IS THOUGHT, AND I THINK STRONGLY
17 BELIEVED, THAT BY LOWERING THAT MAXIMUM ESTRADIOL
18 LEVEL, YOU CAN HELP TO AMELIORATE SOME OF THESE SIDE
19 EFFECTS IN THE PROCEDURE. THAT'S ONE IMPORTANT THING
20 TO SAY.

21 ANOTHER THING THAT'S IMPORTANT TO SAY IS THAT
22 PROBABLY ONE OF THE GREATEST RISKS FOR THESE WOMEN
23 AFTER UNDERGOING OOCYTE DONATION IS UNINTENDED
24 PREGNANCY. VERY SPECIFICALLY WE SHOULD POINT OUT THAT
25 THAT'S AN ISSUE THAT'S A SIDE EFFECT AND SHOULD BE

1 INSURED FOR BECAUSE IF AN OOCYTE OR TWO ARE MISSED AND
2 THAT WOMAN DOES NOT FOLLOW THROUGH WITH CONTRACEPTION
3 AFTER EGG DONATION AND SHE BECOMES PREGNANT, AND THAT
4 WOULD CERTAINLY, IN PRINCIPLE, BE AN UNINTENDED SIDE
5 EFFECT OF THE PROCEDURE WHICH SOME PEOPLE AREN'T
6 WATCHING OUT FOR.

7 DR. HALL: LET ME SAY THAT IN AND AROUND
8 THESE ISSUES, AND FOR THE ESTRADIOL ISSUE THAT YOU
9 MENTIONED, THIS IS PRECISELY THE KIND OF INFORMATION
10 THAT WE WOULD LIKE TO GET OUT OF OUR CONFERENCE WHICH
11 WE'RE PLANNING. AND OUR HOPE IS THAT THAT WILL INFORM
12 US AND HELP US IN OFFERING ADVICE AND GUIDELINES FOR
13 PEOPLE DOING THIS WORK IN CALIFORNIA.

14 DR. TAYLOR: THE EXPERIENCE THAT WE HAVE IS
15 REALLY WITH EGG DONORS WHO ARE UNDERGOING STIMULATION
16 FOR THE CLINICAL THERAPY, AND OUR GOALS IN THAT SETTING
17 ARE SOMEWHAT DIFFERENT THAN WHAT WE'RE TRYING TO
18 ACCOMPLISH HERE. SO PUSHING TO GET MORE OOCYTES
19 TYPICALLY FOR WOMEN WHO HAVE -- COUPLES WHO HAVE
20 INFERTILITY PROBLEMS WHERE THEY MIGHT NEED MORE EGGS
21 AND WE MIGHT WANT TO TRANSFER MORE EMBRYOS BACK INTO AN
22 ENVIRONMENT THAT'S NOT NECESSARILY NORMAL OR
23 PHYSIOLOGIC. SO I WOULD SAY THAT THE ESTRADIOL LEVELS
24 WE TRY TO ACHIEVE FOR A DONOR CYCLE MIGHT BE DIFFERENT
25 OR LIKELY TO BE HIGHER THAN WHAT YOU WOULD TRY TO

1 ACHIEVE IN A DONATION CYCLE FOR THE PURPOSE OF STEM
2 CELL RESEARCH.

3 SO I THINK WE COULD MITIGATE A LOT OF THESE
4 RISKS BECAUSE OF THE OUTCOME WE'RE LOOKING FOR.

5 CO-CHAIR LO: OTHER COMMENTS? SO I'M HEARING
6 NO OBJECTIONS TO THE IDEA OF REQUIRING INSTITUTIONS TO
7 COVER REASONABLE MEDICAL EXPENSES FOR THE SHORT-TERM
8 PERIOD AFTER OOCYTE RETRIEVAL. IN FACT, THERE'S A
9 PRECEDENT FOR DOING SO IN TERMS OF COMMERCIALY
10 AVAILABLE INSURANCE FOR OOCYTE DONORS, SO THERE'S SOME
11 ACTUARIAL THINGS WORKED OUT.

12 ONE QUESTION THAT WAS RAISED, BUT WE HAVEN'T
13 REALLY ADDRESSED, IS WHETHER THIS SHOULD BE PRIMARY
14 COVERAGE OR SECONDARY COVERAGE, WHETHER THE WOMAN'S
15 EXPENSES SHOULD BE PAID BY THE INSTITUTION WITHOUT
16 TRYING TO GET THE MONEY FROM THE INSURER, WHICH COULD
17 INVOLVE COPAYS, DEDUCTIBLES, UNINSURABILITY IF SHE HAS
18 TO PURCHASE INSURANCE. THERE ARE REASONS FOR TRYING TO
19 SAY THAT PAYMENT -- THIS SHOULD BE PROVIDED WHETHER OR
20 NOT THE WOMAN HAS INSURANCE.

21 DR. TAYLOR: PRACTICALLY SPEAKING, WE USUALLY
22 LOOK FOR THE BEST KIND OF COVERAGE FOR AN INDIVIDUAL.
23 THIS IS A DIFFERENT SITUATION. SO I WOULD TEND TO
24 BELIEVE THAT THIS SHOULD FORM THE BASIS OF PRIMARY
25 COVERAGE RATHER THAN RELY ON THAT INDIVIDUAL'S POSSIBLY

1 BETTER POLICY TO COVER SOME.

2 MS. CHARO: ALTHOUGH I DON'T DISAGREE WITH
3 WHAT ROB IS SAYING, THERE IS A POINT AT WHICH WE MIGHT
4 BE GETTING A LITTLE OVERLY DETAILED. THE REAL REASON
5 WHY YOU DON'T WANT SOMEBODY'S PRIMARY CARRIER TO HAVE
6 TO PICK UP THESE ADVERSE EVENTS IS BECAUSE WE FEAR
7 THEIR PREMIUMS WILL GO UP OR THERE'S SOME OTHER KIND OF
8 ADVERSE EFFECT ON THEM, BUT THOSE ADVERSE EFFECTS DON'T
9 EXIST WHEN YOU'RE PART OF A GROUP POLICY. SO PEOPLE'S
10 SITUATIONS ARE GOING TO VARY. SOMEBODY WHO IS PART OF
11 A SMALL GROUP POLICY OR SOMEBODY WHO'S GOT AN
12 INDIVIDUAL POLICY HAS GOT MUCH MORE AT STAKE IN KEEPING
13 THEIR INSURER OUT OF THIS THAN SOMEBODY WHO, LIKE ME,
14 IS EMPLOYED THROUGH A LARGE GROUP WHICH CONSTITUTES ALL
15 STATE EMPLOYEES. IT DOESN'T REALLY MATTER WHICH OF MY
16 INSURERS PICK UP THE COVERAGE BECAUSE NONE OF THEM CAN
17 GET RID OF ME NO MATTER HOW MUCH THEY WANT TO.

18 I'M WONDERING IF WE WANT TO MAKE SURE THAT WE
19 LEAVE A LITTLE BIT OF ROOM IN HERE FOR INDIVIDUAL
20 SITUATIONS. WE HAVE SOME PEOPLE THEIR PRIMARY CARRIER
21 RIGHT NOW IS A VERY EXPENSIVE BLUES-TYPE POLICY WITH
22 COMPLETE FREEDOM OF CHOICE WITH REGARD TO DOCTOR AND
23 FACILITY. I THINK A PRIMARY INSURANCE POLICY OUGHT TO
24 BE MADE AVAILABLE TO THEM SO THAT THEY CAN AVOID USING
25 THEIR OWN INSURER IF THEY'D LIKE TO, BUT I DON'T KNOW

1 THAT WE'VE GOT TO REQUIRE THAT IT BE AN EXCLUSIVE
2 OPTION.

3 DR. KIESSLING: IT NEVER OCCURRED TO ME TO
4 HAVE AN INSURANCE COMPANY PAY FOR A RESEARCH PROJECT,
5 BUT AREN'T THERE GUIDELINES FOR THAT ANYWAY?

6 MS. CHARO: IT'S NOT THE INSURANCE COMPANY
7 PAYING FOR IT. WE'RE TALKING ABOUT WHAT IT IS THAT THE
8 INVESTIGATORS HAVE TO PURCHASE ON BEHALF OF THE
9 PARTICIPANTS. SO WHAT I'M SAYING IS THAT RATHER THAN
10 SAYING INVESTIGATORS CAN ONLY PURCHASE INSURANCE
11 POLICIES THAT GUARANTEE THAT THEY'LL BE THE PRIMARY --
12 THAT THEY'LL PROVIDE PRIMARY COVERAGE, I'M SAYING
13 PROVIDED THEY CAN MAKE SURE THAT SUCH A POLICY IS
14 AVAILABLE TO THOSE WHO WANT IT. THERE MAY BE SOME
15 PEOPLE FOR WHOM IT JUST DOESN'T MATTER.

16 DR. KIESSLING: I THINK THE EXISTING DONOR
17 POLICIES ARE -- THEY'RE SECONDARY ONLY IF THERE IS A
18 PRIMARY. IF THERE'S NO PRIMARY, THEY'RE IT.

19 MS. CHARO: I GUESS I'M STILL NOT BEING
20 CLEAR. THERE ARE SOME PEOPLE WHO HAVE AN INSURANCE
21 POLICY, BUT WOULD NOT WANT THEIR CURRENT INSURER TO BE
22 THE PRIMARY BECAUSE, FOR EXAMPLE, THEY'RE PART OF A
23 SMALL GROUP OR THEY'VE GOT AN INDIVIDUAL POLICY.
24 THEY'RE AT HIGHER RISK OF PREMIUM CHANGES AND DROPS AND
25 SUCH. FOR THOSE PEOPLE, EITHER WE ASK THAT THERE BE A

1 DONOR INSURANCE POLICY AVAILABLE TO THEM THAT OFFERS
2 PRIMARY COVERAGE, OR THEY JUST HAVE TO BE CAREFULLY
3 COUNSELED ABOUT THE INSURANCE IMPLICATIONS IF THEY
4 DECIDE NOT TO PARTICIPATE IF THEY FEEL LIKE THERE'S TOO
5 MUCH OF A RISK.

6 DR. TAYLOR: I THINK THIS IS REALLY AN
7 EXCELLENT IDEA, BUT IT'S GOING TO SET AN INTERESTING
8 PRECEDENT FOR A LOT OF -- ON IRB'S WE DISCUSS A LOT
9 SOME OF THESE ISSUES ABOUT WHO'S GOING TO COVER, AND
10 I'VE NEVER HEARD -- IT'S ONLY BECAUSE I HAPPEN TO KNOW
11 THAT THESE DONOR INSURANCE PROGRAMS ARE OUT THERE FOR
12 CLINICAL PURPOSES, BUT I'VE NEVER REALLY HEARD OF
13 ANYBODY SUGGESTING THAT A STUDY ACTUALLY PARTIALLY
14 INSURE THE PATIENT FOR COMPLICATIONS THAT MIGHT BE
15 INCURRED. SO I THINK THIS IS A GOOD DISCUSSION.
16 INTERESTING TO SEE HOW THIS PLAYS OUT.

17 CO-CHAIR LO: WELL, AGAIN, THERE'S DIFFERENT
18 WAYS OF PHRASING THIS. ONE IS TO PLACE RESPONSIBILITY
19 ON THE RESEARCH INSTITUTION TO PROVIDE FREE COVERAGE
20 FOR THESE KINDS OF COMPLICATIONS. AND ONE WAY THEY DO
21 THAT IS TO PURCHASE SOME SORT -- THEY MAY SELF-INSURE.
22 UC SYSTEMWIDE HAS TRIED TO HAVE A POLICY IN PLACE, AND
23 THEY'RE PUTTING IT UP TO EACH INDIVIDUAL CAMPUS TO
24 FIGURE OUT HOW TO DO IT. THEY'LL ALL BE SELF-INSURED.

25 THE NOTION IS THAT SOMEONE HAS TO TAKE

1 RESPONSIBILITY FOR PAYING, AND IT'S PROBABLY THE
2 RESEARCH INSTITUTION THAT NEEDS TO DO THAT.

3 MR. SHEEHY: JUST ONE POINT. I THINK YOU MAY
4 REMEMBER THIS. WE DO HAVE TO MAKE SURE THAT THIS
5 INSURANCE POLICY IS IN SOME WAY LIMITED SO THAT IT
6 DOESN'T IN AND OF ITSELF BECOME AN INDUCEMENT.

7 DR. TAYLOR: THAT'S THE WAY IT IS FOR THESE
8 CLINICAL DONOR PROGRAMS.

9 CO-CHAIR LO: ANY OTHER -- SO ARE WE ALL IN
10 AGREEMENT THAT REQUIRING INSTITUTIONS TO PROVIDE FREE
11 COVERAGE BY SOME MEANS FOR THESE KINDS OF SHORT-TERM
12 MEDICAL EXPENSES?

13 ANY PUBLIC COMMENT ON THAT?

14 MS. FOGEL: I GUESS I JUST WANT TO MAKE --
15 THANK YOU. I THINK THIS IS GREAT. I JUST WANT TO MAKE
16 SURE THAT WHAT YOUR -- ALL THIS TALK ABOUT INSURANCE
17 POLICIES, THAT THE CARE THAT IS PROVIDED IS NOT NOW
18 DETERMINED BY WHAT THE INSURER IS WILLING TO OFFER.
19 I'M NOT FAMILIAR WITH THESE POLICIES AT ALL. THEY MAY
20 CHANGE OVER TIME. THE PRINCIPLE, THE REGULATION, HAS
21 TO BE THAT THE INSTITUTION IS RESPONSIBLE FOR THE
22 MEDICAL CARE. HOW THEY DECIDE TO COVER OR PROVIDE THAT
23 MEDICAL CARE SHOULD BE LEFT TO THE IRB. THAT'S ALL.

24 CO-CHAIR LANSING: WE'RE GIVING THAT AS AN
25 OPTION. IT'S A GOOD POINT THOUGH.

1 CO-CHAIR LO: CAN WE TRY --

2 MS. KING: YOU NEED A RESOLUTION OF THE
3 DOCUMENTATION OF THE EXPENSES FOR IRB'S.

4 CO-CHAIR LO: RIGHT. RIGHT. SO I WILL BE
5 GLAD TO HEAR A MOTION FROM THIS GROUP EXPRESSING TO THE
6 GRANTS WORKING GROUP THAT THEY INCLUDE IN THEIR --

7 DR. HALL: CIRM STAFF. WE WRITE THE RFA.
8 IT'S A RESOLUTION TO CIRM, REQUESTING THAT ANY RFA
9 DEALING WITH EGG DONATION INCLUDE A SPECIFICATION OF
10 REASONABLE REIMBURSEMENT WILL BE DETERMINED.

11 MS. KING: SECOND.

12 CO-CHAIR LO: DISCUSSION? ALL IN FAVOR. I
13 WANT TO DO THIS FORMALLY. THIS ONE IS UNANIMOUS. SO
14 IT'S UNANIMOUS FROM THIS --

15 MR. TOCHER: BERNIE, ON THE PHONE.

16 CO-CHAIR LO: HE'S GONE. HE SIGNED OFF.

17 YOU NEED A BREAK? WE'LL TAKE A BRIEF
18 FIVE-MINUTE BREAK AND THEN COME BACK.

19 (A RECESS WAS TAKEN.)

20 CO-CHAIR LO: CAN WE RECONVENE, PLEASE.
21 WE'RE MAKING GOOD PROGRESS, AND WE STILL HAVE A WAYS TO
22 GO. I'D LIKE TO FORGE AHEAD. THERE'S AN INCENTIVE
23 HERE, THE FASTER WE FINISH, THE SOONER WE HEAR ABOUT
24 DINNER TONIGHT, AND THE SOONER WE CAN GO HOME TOMORROW.

25 I TOLD MY DAUGHTER THIS WAS NOT UNLIKE HER

1 HOMEWORK, THAT WE STAY IN THE ROOM UNTIL WE GET IT
2 DONE. WITH THAT BREAK, LET'S TRY AND COME BACK.

3 WE LEFT AT THE BREAK UNRESOLVED ONE OF THE
4 ISSUES WE ORIGINALLY STARTED WITH, WHICH IS ON PAGE 6
5 OF SECTION (D), THIS COVERED STEM CELL LINES WHICH ARE
6 DERIVED WITHOUT CIRM FUNDING, WHETHER WE WOULD ALLOW
7 ANY DIFFERENT REIMBURSEMENT CRITERIA OUTSIDE OF THE
8 CIRM FUNDING FOR CIRM FUNDING.

9 WHAT WE'VE DONE, JUST TO REMIND OURSELVES, IS
10 TO SAY THAT REIMBURSEMENT UNDER (A) CAN INCLUDE, MAY
11 INCLUDE REASONABLE EXPENSES FOR LOST WAGES. THE
12 QUESTION IN (B)(3) IS WHETHER WE WOULD ALLOW PAYMENT
13 BEYOND THAT, WHICH NOW WE'RE USING LANGUAGE OF
14 REASONABLE COMPENSATION, OR DO WE WANT, AS ZACH
15 SUGGESTED ORIGINALLY, TO MAKE (B)(3) CONSISTENT WITH
16 (A)(2)? CORRECT? THOUGHTS ON THAT.

17 DR. KIESSLING: I'M SORRY. I'M LOST WITH THE
18 NUMBERS.

19 CO-CHAIR LO: PAGE 6, THE MIDDLE PART OF THE
20 PAGE OF THE HEADER (B) OUT IN THE MARGIN. SO THAT'S
21 NOW STEM CELL RESEARCH USING LINES NOT DERIVED WITH
22 CIRM FUNDING. AS WRITTEN, NO. 3 UNDER THAT ALLOWS
23 PAYMENT BEYOND REASONABLE COMPENSATION. AND THE
24 QUESTION IS DO WE WANT TO AMEND THAT TO MAKE IT MORE
25 CONSISTENT WITH WHAT WE JUST DID FOR SUBPART (A), WHICH

1 IS CIRM-FUNDED DERIVATION.

2 THE ARGUMENT ZACH MADE AT THE BEGINNING WAS
3 TO HAVE THE SAME STANDARD APPLY WHETHER IT WAS DERIVED
4 WITH CIRM FUNDING OR OTHER FUNDING. SO THAT, FOR
5 EXAMPLE, WOULD EXCLUDE ACT STEM CELL LINES, WHICH I
6 UNDERSTAND ARE -- THEY'VE PAID SOME OF THEIR DONORS
7 BEYOND -- NOT USING A CALCULATION OF LOST WAGES AND
8 REASONABLE EXPENSES. THOSE WILL BE NOT BE ELIGIBLE,
9 UNDER ZACH'S PROPOSED AMENDMENT, WOULD NOT BE ELIGIBLE
10 FOR CIRM-FUNDED RESEARCHERS TO USE.

11 MR. SHEEHY: CAN I GET SOME BACKGROUND? IF
12 YOU'RE GOING TO THROW OUT ACT, I DON'T KNOW WHAT THAT
13 MEANS.

14 DR. ROWLEY: ADVANCED CELL TECHNOLOGY.

15 DR. HALL: IT'S A COMPANY IN WORCESTER,
16 MASSACHUSETTS, THAT ACTUALLY IS CONTEMPLATING
17 ESTABLISHING A BRANCH IN CALIFORNIA.

18 DR. KIESSLING: THEY DON'T HAVE ANY STEM CELL
19 LINES ANYWAY.

20 DR. HALL: IS THAT RIGHT? I'M NOT SURE OF
21 THAT ACTUALLY. THEY DID DO --

22 MR. SHEEHY: IT'S A GOOD ONE TO KIND OF
23 ELUCIDATE AND KIND OF DRAW OUT THE PROBLEM BECAUSE
24 ASSUMING THAT THEY DID -- IT DRAWS OUT THE PROBLEM.
25 ASSUMING THAT THEY DID HAVE STEM CELL LINES, AND WHAT

1 WOULD BE THE IMPORTANCE? WHAT WOULD BE A DETERMINATION
2 THAT IS IN ACCORDANCE WITH POLICY GOVERNING THAT
3 INSTITUTION IN THEIR OWN PARTICULAR INSTANCE? DO YOU
4 SEE WHAT I MEAN? THE TEST HERE. THE QUESTION IS
5 WHETHER WE BALANCE WITH CIRM OR WE ALLOW A DIFFERENT
6 STANDARD. I CAN SEE IF IT WERE GOVERNMENTAL, LIKE IT
7 WAS UK, WE MIGHT SAY, WELL, THERE'S AN ETHICAL STANDARD
8 IN THE UK. BUT IF IT'S ACT AND IT'S IN ACCORDANCE WITH
9 THE GUIDELINES THAT THEY'RE OPERATING UNDER, I DON'T
10 KNOW THAT THAT'S -- IT MAY BE ARGUMENT FOR ZACH'S
11 INITIAL THING, BUT IT'S A GOOD SCENARIO. AT LEAST THIS
12 LANGUAGE IS TOO BROAD, IT SEEMS LIKE, ON THE FACE OF
13 IT.

14 DR. PRIETO: I THINK IT IS AN ARGUMENT FOR
15 WHAT ZACH SAID EARLIER, THAT IF WE WANT OUR STANDARDS
16 TO BE REALLY MEANINGFUL, THEN WE WANT THEM TO APPLY
17 CONSISTENTLY.

18 DR. EGGAN: I WOULD STRONGLY SUPPORT THAT
19 NOTION. I THINK IT REALLY DOES SEND A MESSAGE THAT
20 WOULD UNDERMINE THE DISCUSSION WE JUST HAD, THAT ONE
21 COULD GO OUTSIDE THE SYSTEM AND DERIVE STEM CELL LINES
22 AND THEN IMPORT THEM BACK IN. I THINK WE HAVE TO DO
23 SOMETHING LIKE THIS. WE HAVE TO SAY THIS IS WHAT WE
24 BELIEVE IN, AND THIS IS WHAT WE WILL ADHERE TO.

25 NOW, SINCE THERE'S THE POINT THAT WAS JUST

1 RAISED ABOUT BEING ABLE TO INTERFACE WITH OTHER
2 GOVERNMENTAL ORGANIZATIONS IN BEING TO RECONCILE THAT
3 THIS IS THE OPINIONS BETWEEN THEM, BUT I THINK THAT IT
4 SEEMS LIKE THESE VARIOUS COMPANIES, INSTITUTIONS LIKE
5 OURSELVES, LIKE THE NATIONAL ACADEMY OF SCIENCES, LIKE
6 HUMAN EMBRYO AND FERTILIZATION AUTHORITY ARE COMING TO
7 RATHER SIMILAR POINTS OF VIEW ON THIS ISSUE, SO AT
8 LEAST FOR THE TIME BEING. SO I THINK THAT IF THESE
9 SORTS OF THINGS DID ARISE AS PRINCIPAL DIFFERENCES IN
10 OPINION, THAT THEY COULD BE REVISITED. WE SHOULD BE
11 COMMITTED TO THAT, BUT FOR NOW I THINK IT'S GOING TO BE
12 IMPORTANT THAT WE MAKE A STRONG STATEMENT AND BE
13 CONSISTENT TO IT.

14 DR. ROWLEY: I THINK THAT MAYBE FOR -- IT'S
15 NOT CLARITY, AT LEAST FOR COMPATIBILITY WITH THE
16 EARLIER RESOLUTION, REASONABLE COMPENSATION SHOULD BE
17 CHANGED TO REASONABLE REIMBURSEMENT IN BOTH SENTENCES 1
18 AND 2.

19 DR. HALL: I WOULD SUGGEST IS IT POSSIBLE
20 JUST TO IMPORT WHATEVER WE PUT IN 2 IN (A) TO THE OTHER
21 PLACE. AND I ALSO NOTICED THAT NO. 1 IN (A) IN NO. 2
22 IN (B) EXPRESS THE SAME, BUT ARE SLIGHTLY DIFFERENTLY
23 WORDED. I THINK IN THE INTEREST OF WHAT ONE OF THE
24 PUBLIC SPEAKERS SAID EARLIER ABOUT THE -- THAT'S
25 RIGHT -- THE DIFFICULTIES OF HAVING DUPLICATIVE WORDING

1 THAT'S NOT QUITE THE SAME OPENS THE DOOR. SO I THINK
2 WE SHOULD STANDARDIZE THOSE TWO.

3 CO-CHAIR LO: THIS WILL BE PART OF THE
4 CLEANUP THAT SCOTT WILL DO FOR US IN THE NEXT COUPLE OF
5 DAYS.

6 DR. HALL: I THINK ONE CAN GET THE PRINCIPLE.

7 CO-CHAIR LO: I HEAR PRETTY MUCH AGREEMENT ON
8 THAT. ANYONE IN THE PUBLIC WANT TO COMMENT ON THIS
9 NOTION OF MAKING SIMILAR STANDARDS INDEPENDENT OF THE
10 FUNDING OF THE DERIVATION?

11 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR
12 TAXPAYER AND CONSUMER RIGHTS. I JUST WANT TO COMMEND
13 THAT APPROACH. IT SEEMS TO ME THAT YOU ABSOLUTELY HAVE
14 TO DO THAT. AND IF YOU HAVE HIGH STANDARDS FOR CIRM,
15 IF YOU LEFT IT THE WAY IT WAS, IT WOULD HAVE BEEN A
16 BACK DOOR FOR MUCH LOWER STANDARDS TO SNEAK THROUGH.
17 SO I REALLY THINK YOU ARE DOING THE RIGHT THING HERE
18 AND COMMEND YOU FOR THAT.

19 CO-CHAIR LO: THANK YOU. YES.

20 MS. GREENFIELD: JUST AS A POINT OF
21 CLARIFICATION, DOES THIS MEAN THAT YOU ARE SKIPPING
22 OVER POINTS 3 OR 4 ON THE ORIGINAL? ARE THOSE STILL
23 OPEN FOR PUBLIC COMMENTS ON (A)(3) AND (4)?

24 CO-CHAIR LO: YEAH. PLEASE.

25 MS. GREENFIELD: SO WE CAN HAVE COMMENTS ON

1 (3) AND (4). IT OCCURS TO ME THAT IT'S SORT OF READING
2 MORE LIKE SORT OF AGAIN SORT OF NEBULOUS LANGUAGE AS
3 OPPOSED TO LIKE STRICT REGULATORY LANGUAGE. SHALL NOT
4 COMPROMISE THE OPTIMAL REPRODUCTIVE SUCCESS OF THE
5 WOMAN IN FERTILITY TREATMENT. MY QUESTION WOULD BE
6 HOW? WHAT ARE YOU SUGGESTING THAT WE DO SO THAT IT'S
7 NOT COMPROMISED? THAT WOULD BE FOR NO. 3.

8 AND IN NO. 4, AGAIN, THE IRB APPROVAL OF AN
9 EXEMPTION. I DON'T THINK YOU'RE GIVING ANY GUIDANCE AS
10 TO WHAT YOU THINK MIGHT SUGGEST AN EXEMPTION FOR THIS
11 PARTICULAR REGULATION. THANK YOU.

12 CO-CHAIR LO: OTHER COMMENTS FROM THE PUBLIC?

13 MS. FOGEL: I HAVE TO APOLOGIZE BECAUSE I
14 STEPPED OUT OF THE ROOM. MAYBE I MISSED SOMETHING.
15 BUT I THOUGHT THAT WE WERE -- THAT YOU VOTED OR HAD
16 CONSENSUS THAT ALL RESEARCH THAT WAS FUNDED BY CIRM HAD
17 TO USE EGGS THAT MET ALL THESE HIGH STANDARDS WHETHER
18 OR NOT, RIGHT, AND SO YOU DIDN'T ENCOURAGE SOMEBODY TO
19 GO CREATE AN EGG FACTORY OVER HERE. SO WHY WOULD YOU
20 NOT COLLAPSE (A) AND (B), AND THEN HAVE JUST ONE LIST
21 OF CRITERIA THAT MADE IT CONSISTENT?

22 MR. LOMAX: IN FACT, THAT'S A -- WE RECOGNIZE
23 THAT POINT. NOW WE'VE DEVELOPED AN EQUIVALENT
24 STANDARD, AND THAT'S ACTUALLY HOW IT APPEARS WE WILL IN
25 THE REDRAFT SIMPLY COLLAPSE THAT INTO A SINGLE STANDARD

1 DEALING WITH CELL LINES DERIVED AFTER THE EFFECTIVE
2 DATE OF THE CHAPTER.

3 MS. FOGEL: THANK YOU.

4 CO-CHAIR LO: DOES THE COMMITTEE WANT TO TAKE
5 UP THIS ISSUE OF (3) AND (4) AT THE TOP OF THE PAGE AS
6 TO NOT BEING SPECIFIC ENOUGH FOR REGULATIONS? AND WHAT
7 WE DO YOU MEAN BY NOT COMPROMISING OPTIMAL REPRODUCTIVE
8 SUCCESS?

9 DR. HALL: I WOULD JUST REMIND PEOPLE WE HAD
10 QUITE A LONG DISCUSSION ON THIS AT A PREVIOUS MEETING,
11 AND I THINK THE ISSUE -- I THINK TED, WHO MAY STILL BE
12 ONLINE. HE'S OFF. AT ANY RATE, THE QUESTION THAT --
13 WE GOT INVOLVED IN A LOT OF DETAILS, AND THE QUESTION
14 WAS WHAT WAS THE PRINCIPLE IN ALL THIS. AND THAT IS
15 THAT REPRODUCTIVE SUCCESS NOT BE COMPROMISED. AND I
16 THINK OUR SENSE WAS THAT PEOPLE WHO WERE GIVING EGGS
17 FOR REPRODUCTION SHOULD NOT TO ASKED TO GIVE PART OF
18 THEM, FOR EXAMPLE, FOR RESEARCH.

19 AND THE TECHNICAL PART OF THIS IS THAT YOU
20 CAN STORE FERTILIZED EGGS, BUT YOU CAN'T STORE
21 UNFERTILIZED OOCYTES. YOU DON'T KNOW THAT THE
22 PREGNANCY IS SUCCESSFUL AT THE TIME YOU'RE ASKED TO
23 DONATE OOCYTES. AND THERE WERE SEVERAL OTHER SPECIFIC
24 EXAMPLES THAT CAME UP. WE SPENT, MY GUESS IS, PROBABLY
25 TWO HOURS TALKING ABOUT THIS, SO THERE WAS LOTS OF

1 GRANULAR DETAIL IN THAT, BUT THE GENERAL PRINCIPLE THAT
2 EMERGED IS THAT YOU SHOULD NOT DO ANYTHING TO
3 JEOPARDIZE REPRODUCTIVE SUCCESS.

4 MS. GREENFIELD: I READ THE MINUTES OF THE
5 MEETING, SO I'M WELL AWARE OF THE DISCUSSION, BUT IT
6 JUST OCCURS TO ME THAT IN THE PRINCIPLE HOW IS THAT
7 TRANSLATED? AND I REALLY THINK THERE'S A NECESSITY TO
8 TRANSLATE THE PRINCIPLE INTO WORKING RULES AND
9 STANDARDS.

10 DR. HALL: THERE IS A POSSIBILITY HERE, WHICH
11 WE DISCUSSED, AND THAT IS THAT EGG DONATION FOR
12 RESEARCH SHOULD BE SEPARATED FROM EGG DONATION FOR
13 REPRODUCTION, PERIOD.

14 MS. GREENFIELD: THAT'S A GOOD SUGGESTION.

15 DR. HALL: MAYBE THAT IS A SIMPLER AND MORE
16 DIRECT WAY.

17 MS. GREENFIELD: IN OTHER WORDS, YOU HAVE
18 SITUATIONS LIKE -- IT'S ALMOST LIKE IN CONTRADICTION
19 BECAUSE YOU ARE TALKING ABOUT LESS HORMONES BEING GIVEN
20 FOR RESEARCH PURPOSES THAN FOR REPRODUCTIVE PURPOSES.
21 SO HOW DO YOU DO THAT IF YOU'RE NOT COMPROMISING THE
22 FERTILITY CHANCES?

23 CO-CHAIR LO: THERE IS SOME FACTUAL
24 INFORMATION FROM THE UK WE NEED TO PUT IN HERE. THE UK
25 ALLOWS WHAT THEY CALL OOCYTE SHARING FOR ACTUALLY WHAT

1 I WOULD CONSIDER CONSIDERATION. SO THE QUESTION IS IF
2 WE SAY YOU CAN'T DERIVE OOCYTES -- YOU CAN'T TAKE
3 OOCYTES FROM AN OUTSIDE SOURCE AND USE THEM FOR STEM
4 CELL LINES, THAT WOULD CLOSE OFF THE UK LINES. THAT'S
5 ONE OF THE REASONS WHY, AND THEY ACTUALLY CLAIM IT
6 DOESN'T COMPROMISE A WOMAN'S REPRODUCTIVE SUCCESS OF
7 THE WOMAN IN IVF. THEY ACTUALLY HAVE SOME DATA FOR
8 THAT. THAT'S WHY WE MAY WANT TO STAY AWAY FROM GETTING
9 TOO PRESCRIPTIVE.

10 DR. EGGAN: THERE'S ALSO THIS ISSUE OF
11 WHETHER OR NOT THESE SO-CALLED FAILED TO FERTILIZE
12 OOCYTES ARE USEFUL MATERIAL FROM SOMATIC CELL NUCLEAR
13 TRANSPLANTATION. AND THAT'S -- I DON'T WANT TO OPEN UP
14 THAT ENTIRE DISCUSSION AGAIN, BUT THIS IS ANOTHER THING
15 THAT WE CONSIDERED AT LENGTH LAST TIME IN WHICH, I
16 THINK, WE AGREED, AFTER SOME DISCUSSION, THAT UNDER THE
17 PROPER CIRCUMSTANCES MIGHT BE ACCEPTABLE MATERIAL AND
18 COULD BE ACQUIRED WITH A PROPER INFORMED CONSENT.

19 I THINK THERE ARE PROBLEMS WITH SEPARATING
20 THOSE THINGS ENTIRELY FROM ONE ANOTHER.

21 CO-CHAIR LO: MIGHT HAVE UNINTENDED
22 CONSEQUENCES.

23 MR. SHEEHY: I'M JUST TRYING TO UNDERSTAND
24 THIS. SO IN (3) WE'RE SAYING THAT A WOMAN CAN GO IN TO
25 PROVIDE -- FOR (3) A WOMAN CAN GO IN TO PROVIDE OOCYTES

1 FOR ANOTHER WOMAN IN AN INFERTILITY CLINIC AND DECIDE
2 TO DIVERT SOME OF THOSE TO RESEARCH OR NOT.

3 A WOMAN CAN GO IN TO DONATE OOCYTES TO
4 ANOTHER WOMAN FOR INFERTILITY, AND THEN COULD SAY I
5 WANT SOME OF THOSE TO GO FOR RESEARCH. THAT'S WHAT (3)
6 ALLOWS, RIGHT?

7 DR. ROWLEY: OR SHE'S DOING IT FOR HERSELF.

8 MR. SHEEHY: I'M TRYING TO MAKE A SPECIFIC
9 POINT BECAUSE IF SHE'S DONATING FOR ANOTHER WOMAN,
10 SHE'S GOING TO BE COMPENSATED.

11 DR. PRIETO: IN THIS COUNTRY UNDER CURRENT
12 PROTOCOLS.

13 MR. SHEEHY: ALMOST CERTAINLY WILL BE
14 COMPENSATED. I DON'T SEE HOW THAT'S CONSISTENT WITH
15 WHAT WE'VE ALREADY ADOPTED.

16 DR. EGGAN: WOMEN AREN'T COMPENSATED FOR EGG
17 DONATION UNDER ANY CIRCUMSTANCES IN THE UNITED KINGDOM,
18 EVEN FOR ANOTHER WOMAN'S REPRODUCTION, PERIOD. SO
19 THERE'S ONLY REIMBURSEMENT IN THE UNITED KINGDOM. IT'S
20 A ZERO-SUM GAME FOR THE ENTIRE ENTERPRISE. THAT'S AN
21 IMPORTANT FIRST THING TO SAY.

22 SECOND, THERE ARE MANY DOCTORS THAT WOULD NOT
23 BE COMFORTABLE WITH THE SCHEME THAT YOU JUST DESCRIBED,
24 FROM MY CONVERSATIONS WITH IVF DOCTORS, BECAUSE THERE'S
25 THIS SORT OF GENERALLY IT'S THE WOMAN WHO IS HAVING HER

1 REPRODUCTION ASSISTED WHO PAYS FOR THE DONOR CYCLE OF
2 THAT EGG DONOR. SORT OF IN A FACTO SENSE, THOSE
3 DONOR'S EGGS ARE HERS; AND SINCE SHE NEEDS EVERY EGG
4 THAT SHE CAN GET TO TRY TO BECOME PREGNANT, IN
5 PRINCIPLE, CREATES AN UNCOMFORTABLE SITUATION FOR THE
6 CLINICIAN THEN TO RELEASE SOME OF THOSE EGGS FOR
7 SCIENCE, RIGHT.

8 SO I THINK THAT'S A COMPLICATED PLACE TO GO,
9 BUT I THINK IT'S DESIGNED TO -- I DON'T THINK IT'S
10 DESIGNED SPECIFICALLY TO ENABLE WHAT YOU'RE DESCRIBING
11 OF THESE OTHER THINGS THAT WE'VE TALKED ABOUT AT
12 LENGTH, LIKE FAILED TO FERTILIZE OOCYTES, ETC.

13 DR. HALL: FOR BETTER OR FOR WORSE, I THINK
14 NO. 3 WAS CRAFTED TO SAY -- TO TRY TO NOT GET INTO EACH
15 OF THE SPECIFIC SITUATIONS THAT MIGHT ARISE OR TO
16 ANTICIPATE THEM, BUT TO GIVE IRB'S A PRINCIPLE BY WHICH
17 TO JUDGE WHATEVER SPECIFIC SITUATION WAS AT HAND.

18 MR. SHEEHY: I'M TRYING TO UNDERSTAND (3),
19 AND (3) MAKES ME -- YOU KNOW, I DON'T GO ALONG WITH
20 PEOPLE THINK IT'S OKAY. IT'S HARD FOR ME TO
21 UNDERSTAND, BUT IT'S SOMEONE'S CHOICE. SOMEONE WHO IS
22 UNDERGOING INFERTILITY TREATMENTS IN ORDER TO PRODUCE
23 EGGS FOR HERSELF. SHE MAY DECIDE THAT SHE WANTS TO
24 DIVERT SOME FOR RESEARCH. I THINK THAT THAT'S REALLY
25 DIFFICULT TO MANAGE ETHICALLY, BUT I CAN KIND OF

1 UNDERSTAND.

2 I CANNOT UNDERSTAND HOW WE CAN PRESUME TO
3 MANAGE THE ENVIRONMENT WHERE A WOMAN IS GETTING PAID TO
4 PRODUCE EGGS FOR ANOTHER WOMAN, AND THAT SHE CAN DIVERT
5 SOME OF THOSE TO RESEARCH, AND WE CAN SAY SHE'S NOT
6 BEING COMPENSATED FOR PRODUCING EGGS.

7 DR. HALL: I DON'T THINK IT WAS INTENDED TO
8 PERMIT THAT BECAUSE SHE WOULD BE COMPENSATED. I THINK
9 THAT'S CORRECT. I THINK WHAT WE'VE HEARD IS THAT IN
10 THE UK, THAT IT'S POSSIBLE TO DO THAT, AND WOMEN DO
11 THAT WITHOUT COMPENSATION; ISN'T THAT RIGHT?

12 MR. SHEEHY: WHAT'S THAT HAVE TO DO -- I'M
13 SORRY. MAYBE I'M BEING DENSE.

14 MS. KING: CAN I ASK YOU A QUESTION?
15 HISTORICALLY IN DEALING WITH SOME OF THESE ISSUES AND
16 ETHICS, WE'VE SOUGHT TO HAVE SEPARATION OF THE CLINICAL
17 ARENA FROM THE RESEARCH ARENA. TISSUE TRANSPLANTATION
18 RESEARCH, WHEN WE WENT THROUGH THOSE RULES. THAT'S
19 TRUE IN ORGAN DONATION.

20 MY FIRST QUESTION WOULD BE WHAT'S THE
21 ARGUMENT FOR NOT HAVING COMPLETE SEPARATION HERE?

22 DR. EGGAN: FOR INSTANCE, I WILL PROVIDE THIS
23 JUST SPECIFIC ACTIVITY, WHICH HAS BEEN WIDELY DISCUSSED
24 IN THIS FIELD OF SOMATIC CELL NUCLEAR TRANSPLANTATION
25 RESEARCH, WHICH IS, FRANKLY, WHAT WE'RE MOSTLY TALKING

1 ABOUT HERE. IN FACT, ALL OF THE SCNT PROTOCOLS
2 APPROVED BY THE HUMAN EMBRYO AND FERTILIZATION
3 AUTHORITY IN THE UNITED KINGDOM USE OOCYTES WHICH ARE,
4 QUOTE, UNQUOTE, LEFT OVER AFTER INFERTILITY TREATMENT.
5 THESE ARE EMBRYOS WHICH 24 TO 48 HOURS LATER AFTER
6 FERTILIZATION FAILED FERTILIZE -- SORRY. OOCYTES.
7 PARDON ME. THESE ARE FAILED TO FERTILIZE OOCYTES THAT
8 WOULD HAVE BEEN DISCARDED, BUT INSTEAD ARE THEN USED
9 FOR RESEARCH. SO THIS IS A CLEAR EXAMPLE OF A CASE
10 WHERE THERE IS SOME OBVIOUS OVERLAP OF TWO THINGS AND
11 SOME -- BUT THE ARGUMENT WOULD BE THIS COULD BE DONE
12 UNDER SUCH A STRUCTURE THAT IT WOULD IN NO WAY
13 INTERFERE WITH THAT WOMAN'S OWN REPRODUCTION.

14 MS. KING: I UNDERSTAND ABOUT THE UNITED
15 KINGDOM, BUT SINCE THEY OPERATE ON A SYSTEM THAT ALLOWS
16 NO COMPENSATION FOR DONORS AND WE DON'T IN THE UNITED
17 STATES, WHAT I'M TRYING TO FIGURE OUT IS HOW TO MAKE
18 THE TRANSLATION TO THE UNITED STATES AND STILL BE
19 CONSISTENT.

20 DR. EGGAN: BUT NO. 3 IS NOT ABOUT
21 COMPENSATION OR REIMBURSEMENT. IT'S ABOUT ENSURING
22 THAT MATERIAL WHICH IS GOING FOR A WOMAN'S REPRODUCTIVE
23 PURPOSES IS NOT INAPPROPRIATELY DIVERTED AWAY FROM
24 THAT. I THINK THAT'S A CRITICAL DIFFERENCE. AND
25 THAT'S WHAT NO. 3 IS ABOUT.

1 SO, FOR INSTANCE, IN THIS CASE ONE COULD BE
2 CONCERNED THAT THIS SPECIFIC INSTANCE THAT I DESCRIBED
3 TO YOU PLACES THE DOCTOR OR THE EMBRYOLOGIST WHO'S
4 MAKING THE DECISION ABOUT WHETHER OR NOT AN OOCYTE HAS
5 FAILED TO FERTILIZE IN A DIFFICULT SITUATION WITH
6 RESPECT TO THEIR PATIENT-DOCTOR RELATIONSHIP. SO, FOR
7 INSTANCE, IF THERE WAS ANY PERCEPTION THAT THAT DOCTOR
8 WAS MISAPPROPRIATING SOME OF THEIR OOCYTES FOR
9 RESEARCH, MAYBE INTENTIONALLY PUTTING THEM INTO A
10 SITUATION WHERE THEY WOULDN'T BE OPTIMALLY FERTILIZED,
11 THEN THAT COULD BE A DIFFICULT SITUATION.

12 SO IT'S BASICALLY SENDING A SIGNAL TO IRB'S
13 TO SAY WATCH OUT FOR THIS. FOR INSTANCE, IN THIS CASE
14 WATCH OUT FOR THIS CONCERN ABOUT THE RELATIONSHIP
15 BETWEEN THE DOCTOR AND THE SCIENTIST AND THE DOCTOR AND
16 THE PATIENT. AND, FOR INSTANCE, PERHAPS COME UP WITH
17 SOME CODED METHODOLOGY, LIKE WE DISCUSSED IN THE LAST
18 MEETING, TO ENSURE THAT THERE'S NO PROBLEM. SO SAY,
19 FOR INSTANCE, FOR THE EMBRYOLOGIST TO MAKE THE DECISION
20 ABOUT WHICH OOCYTES FAILED TO FERTILIZE BEFORE THEY
21 KNEW THAT THAT PARTICULAR WOMAN WAS GOING TO BE A DE
22 FACTO EGG DONOR. THIS WOULD THEN IMMUNIZE THAT CLINIC
23 FROM THIS CONCERN.

24 THAT'S THE SIGNAL THAT NO. 3 IS DESIGNED TO
25 SEND; BUT, OF COURSE, ONE COULD PERHAPS IMAGINE OTHER

1 TYPES OF CASES WHERE THIS WOULD APPLY AND OTHER
2 SITUATIONS AS WAS DISCUSSED AS THIS SORT OF EGG POOLING
3 THAT'S GOING ON IN THE UNITED KINGDOM. SO WE WANT TO
4 ACCOUNT FOR THAT WITH GENERAL LANGUAGE.

5 MR. SHEEHY: NOT TO GO BACK TO REUSE THE
6 METAPHOR, BUT NOT ONLY -- IT SEEMS TO ME THAT WE NOT
7 ONLY BROUGHT SOMEBODY TO THE WATER, BUT WE'RE
8 ENCOURAGING THEM TO DRINK. IF WE HAVE SOMEBODY IN
9 THERE THAT'S BEEN COMPENSATED TO DONATE OOCYTES, AND,
10 YOU KNOW, WE HAVE THE OPPORTUNITY TO DIVERT SOME OF
11 THOSE TO RESEARCH, I THINK THAT THE -- I MEAN
12 PRESUMABLY THE REASON THAT PERSON HAS UNDERGONE THIS
13 PROCEDURE TO GENERATE OOCYTES IS FOR COMPENSATION,
14 RIGHT. THEY'RE DOING IT IN ORDER TO BE COMPENSATED IN
15 ORDER TO PRODUCE OOCYTES FOR REPRODUCTION FOR ANOTHER
16 WOMAN.

17 AND SO WE'RE JUST GOING TO SAY THAT THERE'S
18 SOME BY-PRODUCT OF THIS THAT CAN BE DIVERTED TO
19 RESEARCH, BUT SHE'S STILL BEEN COMPENSATED TO GO
20 THROUGH THE PROCEDURE.

21 DR. HALL: THAT'S FORBIDDEN. BY COMPENSATION
22 RULES, THAT'S FORBIDDEN; ISN'T THAT CORRECT? THAT'S
23 FORBIDDEN BY COMPENSATION RULES.

24 MS. CHARO: I THINK I FINALLY FIGURED OUT
25 WHAT IT IS YOU'RE WORRIED ABOUT. IT SEEMS LIKE AN

1 UNLIKELY SCENARIO, BUT YOU'RE RIGHT, IT'S POSSIBLE.
2 IMAGINE YOU'VE GOT MARY IS INFERTILE. SHE ADVERTISES
3 IN THE STANFORD NEWSPAPER, AND SHE GETS SOME
4 UNDERGRADUATE TO PROVIDE EGGS FOR A FEE.
5 UNDERGRADUATE, WE'LL CALL HER MARTHA, RIGHT. AND
6 MARTHA IS GOING TO GET PAID \$20,000, AND MARTHA AGREES
7 TO DO THIS FOR INFERTILE MARY ON THE CONDITION THAT
8 INFERTILE MARY GETS THE FIRST EIGHT EGGS THAT ARE
9 PRODUCED, BUT ANY SURPLUS ABOVE EIGHT WE'RE GOING TO
10 DONATE TO RESEARCH.

11 MR. SHEEHY: MAYBE THE IVF CLINIC SAYS TO
12 MARY THAT WE'LL DISCOUNT YOUR PROCEDURE IF YOU CAN --
13 YOUR PROCEDURE WILL BE CHEAPER IF MARTHA WILL LET US
14 HAVE SOME --

15 MS. CHARO: THAT'S ACTUALLY FORBIDDEN
16 ELSEWHERE.

17 DR. EGGAN: THIS WOULD BE FORBIDDEN UNDER NAS
18 GUIDELINES. I'M PRETTY SURE --

19 MS. CHARO: I APPRECIATE -- FORGET ABOUT THE
20 IVF CLINIC. I APPRECIATE THE CONCERNS THAT ANY PERSON
21 WHO'S PROVIDING EGGS IN A DUAL CAPACITY AS BOTH A PAID
22 PROVIDER FOR SOMEBODY ELSE'S FERTILITY TREATMENT AND AN
23 UNPAID DONOR FOR RESEARCH PURPOSES IS NOW AN UNTENABLE
24 POSITION BECAUSE ALTHOUGH TECHNICALLY THEY'RE NOT
25 GETTING PAID TO PROVIDE EGGS FOR RESEARCH, THE FACT

1 THAT THEY'RE SIMULTANEOUSLY THERE IN A PAID CAPACITY
2 MUDDIES THE WATER. IT MIGHT BE THAT THE SIMPLEST WAY
3 TO DO THIS, RIGHT, IN SOME WAYS IT'S IMPLICIT HERE
4 BECAUSE HERE IT SUGGESTS THAT YOU'RE NOT ALLOWED TO
5 DIVERT ANY OF THE EGGS BECAUSE IT WOULD UNDERMINE
6 MARY'S OPTIMAL REPRODUCTIVE SUCCESS TO PEEL OFF THE
7 EXTRA EGGS BECAUSE YOU NEVER KNOW HOW MANY YOU'RE GOING
8 TO NEED IN ORDER TO GET A REQUISITE NUMBER OF EMBRYOS.
9 IF WE NEED TO MAKE IT CLEARER THAN THAT, WE CAN MAKE IT
10 CLEARER THAN THAT.

11 YOU CANNOT OBTAIN EGGS FROM A DONOR WHO IS
12 SIMULTANEOUSLY BEING PAID TO PROVIDE THEM FOR ANOTHER
13 PURPOSE.

14 CO-CHAIR LO: WHAT WOULD YOU DO WITH THE
15 POSSIBILITY OF THE FAILED TO FERTILIZE OOCYTES?

16 MS. CHARO: WE CAN TALK ABOUT UNFERTILIZED
17 OOCYTES, AND THAT WAY WE CAN PRESERVE WHAT KEVIN IS
18 CONCERNED ABOUT HERE, WHICH IS A COMPLETELY SEPARATE
19 SITUATION HAVING TO DO WITH FAILED TO FERTILIZE OOCYTES
20 THAT ARE NOW USELESS FOR REPRODUCTIVE PURPOSES BUT
21 POTENTIALLY VALUABLE FOR RESEARCH PURPOSES.

22 MS. FEIT: I THINK KEVIN IS GOING BEYOND
23 THAT. IF I LISTEN TO HIM, HE'S SAYING THIS WOMAN, NO.
24 1, HAS ALREADY RECEIVED MONEY. SHE GOT \$20,000. SO
25 WHETHER SHE PRODUCED SIX EGGS FOR SOMEBODY TO GET

1 PREGNANT OR GAVE TWO AWAY, THE ACT ALONE SHE WAS
2 COMPENSATED. HOW ARE WE GOING TO GET AROUND THE FACT
3 THAT SOMEBODY RAISES THE POINT YOU GOT THESE OOCYTES
4 FROM SOMEBODY WHO RECEIVED COMPENSATION. SHE GOT A
5 \$20,000 CHECK FROM MARY, AND MARTHA IS NOW SAYING,
6 OKAY, WELL, I GOT A FEW EXTRA. YOU CAN HAVE THEM. SHE
7 WAS COMPENSATED. SO HOW ARE WE GOING TO DEAL WITH
8 THAT?

9 I HEAR WHAT YOU ARE SAYING. WE CAN FURTHER
10 PROTECT THE PERSON FROM THE REPRODUCTIVE PIECE OF IT,
11 BUT I THINK THAT'S WHAT KEVIN WAS SAYING OR JEFF WAS
12 SAYING IN THE FIRST PLACE IS THAT, WAIT A MINUTE, WE'VE
13 GOT COMPENSATION HERE. HOW CAN WE GO DOWN THIS PATH?

14 MR. SHEEHY: ESPECIALLY SINCE IVF CLINICS ARE
15 VERY HIGHLY REGULATED, IF MY MEMORY SERVES ME RIGHT.

16 DR. EGGAN: AGAIN, JUST TO REITERATE, THIS IS
17 NOT A PROBLEM BECAUSE THOSE EGGS CANNOT BE CONSIDERED
18 FOR USE BECAUSE THAT DONOR WAS COMPENSATED REGARDLESS
19 OF WHEN, HOW, OR AT WHAT TIME THEY WERE USED FOR
20 REPRODUCTION. THERE'S NO WAY THAT THAT WOMAN -- IN
21 THIS CASE THERE'S NO WAY THAT THAT WOMAN'S EGGS CAN BE
22 USED FOR SOMATIC CELL NUCLEAR TRANSPLANTATION
23 EXPERIMENT IN THIS STATE BY LAW.

24 CO-CHAIR LANSING: THAT'S CORRECT.

25 DR. EGGAN: THERE IS NO WAY. SO MY

1 HYPOTHETICAL SITUATION ONLY ARISES IF WOMEN WHO ARE
2 UNDERGOING, SAY, SUPER OVULATION FOR THEIR OWN
3 REPRODUCTIVE NEEDS IN THE COURSE OF THEIR IVF CYCLE, OR
4 IF THEY HAVE A SISTER THAT DOES IT FOR FREE. AND THEN
5 IT'S A TOTALLY DIFFERENT BALL GAME, AND THEN YOU NEED
6 NO. 3.

7 (OVERLAPPING DISCUSSION.)

8 DR. TAYLOR: THERE ARE --

9 DR. EGGAN: I THOUGHT I WAS CLEAR.

10 THE REPORTER: ONE AT A TIME, PLEASE.

11 CO-CHAIR LO: ONE AT A TIME, PLEASE.

12 MS. KING: WHY CAN'T WE PUT, TO MAKE IT CLEAR
13 THEN, IN (3) OBTAIN FROM A WOMAN WHO HAS NOT BEEN PAID
14 TO REINFORCE? A LOT OF THE CONFUSION IS REALLY COMING
15 FROM THE FACT THAT THIS LOOKS SEPARATE AND DISTINCT
16 FROM THE NONCOMPENSATION. I UNDERSTOOD YOUR EXAMPLE
17 PERFECTLY WELL, BUT IF WE'RE SITTING HERE ARGUING ABOUT
18 IT, SO WILL THE IRB. SO WHY DON'T WE JUST MAKE IT
19 CLEAR THAT WE'RE APPLYING TO THE NONCOMPENSATING WOMAN
20 OR A SISTER ESSENTIALLY?

21 DR. PRIETO: ISN'T THAT ALREADY IN OUR
22 REGULATIONS?

23 CO-CHAIR LO: PAT'S POINT IS THAT IT'S SORT
24 OF THERE, BUT WE LOST TRACK OF IT WHEN WE WERE TALKING
25 ABOUT (3), SO WHY NOT JUST REPEAT IT SO THAT ANY OTHER

1 READER WILL SAY, AH, THEY'RE NOT ALLOWING THE STANFORD
2 UNDERGRADUATE TO WALK OFF WITH MONEY.

3 DR. HALL: THAT WOULD TAKE CARE OF JEFF'S
4 CONCERN.

5 CO-CHAIR LO: THAT WOULD ADDRESS JEFF'S
6 CONCERN. YOU CANNOT BE PAID FOR OOCYTES THAT END UP IN
7 RESEARCH.

8 DR. HALL: IF OOCYTES ARE REQUIRED FOR
9 DERIVATION OR OBTAINED FROM A WOMAN WHO HAS NOT BEEN
10 PAID FOR PROVIDING OOCYTES FOR RESEARCH AND FERTILITY
11 TREATMENT. JUST PUT THAT IN.

12 MS. KING: BECAUSE IT WOULD GO TO ANY
13 VOLUNTEER. THERE ARE SOME VOLUNTEERS OUT THERE.

14 MR. SHEEHY: I DON'T WANT TO DO ANYTHING TO
15 INTERFERE WITH SOMEONE VOLUNTEERING. IN FACT, I WOULD
16 PROBABLY -- I WOULD AGREE WITH THE SCHOOL OF THOUGHT
17 THAT THINKS IT'S MOST ETHICAL TO PAY WOMEN FOR
18 UNDERGOING THESE PROCEDURES. I DON'T WANT TO GET US
19 INTO A POSITION WHERE WE'RE GETTING THERE BY THE BACK
20 DOOR. WHEN I READ THIS, IT FELT --

21 CO-CHAIR LO: POINT TAKEN. KEVIN, I WANT TO
22 COME BACK TO YOUR HYPOTHETICAL PROTOCOL OF TAKING
23 FAILED TO FERTILIZE OOCYTES AND USING THEM FOR
24 RESEARCH. IS THAT -- I GUESS IT'S FOR THE GROUP. ARE
25 WE ALLOWING THAT? IF A WOMAN IS PAID TO DONATE OOCYTES

1 IN IVF, AND THOSE OOCYTES FAILED TO FERTILIZE, CAN
2 THOSE OOCYTES THAT FAILED TO FERTILIZE BE USED? NO.
3 ALL RIGHT.

4 MS. KING: WE'RE JUST GOING TO MAKE IT CLEAR
5 SO THAT NOBODY ELSE HAS THE SAME PROBLEM.

6 CO-CHAIR LO: SO MAYBE A COVER STATEMENT IN
7 THE STATEMENT OF REASONS.

8 DR. TAYLOR: AREN'T WE STILL LEFT WITH THESE
9 POINTS (3) AND (4), WHICH ARE REALLY PRINCIPLES TO TRY
10 TO PROTECT TO THE REPRODUCTIVE OUTCOMES OF PATIENTS?
11 AND THEY REALLY ARE RARE, BUT CIRCUMSTANCES, AND ONE
12 THAT WE HAD IN OUR CLINIC NOT TOO LONG AGO WAS THE
13 HUSBAND WAS UNABLE TO GENERATE A SPERM SAMPLE WITHIN
14 THE 24- TO 48-HOUR PERIOD THAT IT WAS REQUIRED DUE TO
15 STRESS OR WHATEVER. WE HAD A DONOR'S EGGS THAT --
16 AGAIN, IF SHE HAD BEEN COMPENSATED IT WOULD BE CLEARLY
17 VERBOTEN, BUT IF SHE'S NOT COMPENSATED, WHAT HAPPENS IN
18 THAT SITUATION OR IN THE SITUATION THAT YOU DESCRIBE?

19 DR. EGGAN: THOSE ARE FAILED TO FERTILIZE
20 EGGS.

21 CO-CHAIR LO: THIS ALLOWS THOSE UNUSUAL
22 SITUATIONS --

23 DR. TAYLOR: TO BE USEFUL.

24 DR. HALL: AS WE TALK THIS THROUGH, WE SEE
25 THE WISDOM OF THE PARTICULAR LANGUAGE.

1 CO-CHAIR LO: THAT'S WHY WE WROTE IT THIS
2 WAY.

3 DR. EGGAN: WE SPENT LIKE TWO AND A HALF
4 HOURS AT THE MEETING IN THE DEEP DARK CAVE IN SAN
5 FRANCISCO.

6 MR. LOMAX: IF I COULD REMIND KEVIN EGGAN OF
7 THIS ONE OTHER EXAMPLE THAT I THINK YOU ALL
8 SPECIFICALLY CITED, WHICH WAS A PREIMPLANTATION GENETIC
9 DIAGNOSIS WHERE YOU MIGHT WANT TO TAKE OFF THE DISEASED
10 LINES BECAUSE THE PERSON GOING THROUGH THE
11 PREIMPLANTATION.

12 CO-CHAIR LO: SAVE THIS ALL FOR PREAMBLE.
13 LET'S TRY AND MOVE ON. PAT, WHOM I DID NOT ASK TO SAY
14 THAT, SAID THE MAGIC TWO WORDS, INFORMED CONSENT.
15 SHE GETS AN EXTRA WHATEVER AT DINNER. I'LL PAY FOR IT.
16 WE NOW TURN TO PAGE 7 AND 8. I WOULD ACTUALLY LIKE US
17 TO START ON INFORMED CONSENT.

18 MR. TAYMOR: I HAD A GLOBAL QUESTION, WHICH
19 PERHAPS YOU HAD ADDRESSED ON SECTION 100007. THAT'S
20 HOW DEFINITIVE IS THE DECISION OF THE ESCRO COMMITTEE?
21 IN EACH OF THESE (A), (B), (C), NOW TO BE (A) AND (B),
22 CERTAIN STEPS MUST BE -- CAN BE TAKEN ONLY IF THE ESCRO
23 COMMITTEE MUST DETERMINE ALL THE FOLLOWING OR EITHER OF
24 THE FOLLOWING REQUIREMENTS HAVE BEEN MADE.

25 IF THE ESCRO COMMITTEE MAKES THOSE

1 DETERMINATIONS, WHO GETS TO LOOK AT THEM AND SAY THEY
2 WERE WRONG? I THINK IT WOULD BE VERY HELPFUL IN
3 ANTICIPATION OF ANY CHALLENGES TO MAKE IT CLEAR WHAT'S
4 THE STANDARD OF REVIEW OF THE ESCRO COMMITTEE'S
5 DECISION, CLEAR AND CONVINCING EVIDENCE, SOME TYPE
6 OF -- IT'S PRESUMPTIVELY CORRECT.

7 I IMAGINE FROM YOUR EXPERIENCE, WORKING WITH
8 IRB'S IN THE RESEARCH FIELD, THAT THIS IS ALL -- YOU
9 KNOW EXACTLY WHAT THE STANDARD IS AND HOW IT WORKS, BUT
10 I DIDN'T SEE IT LAID OUT IN HERE. THESE STANDARDS ARE
11 A SELF-CONTAINED UNIT. AND IF SOMEONE COMES ALONG AND
12 SAYS, WELL, THE ESCRO COMMITTEE DETERMINED THIS, BUT
13 THEY WERE WRONG, CAN THEY TAKE THAT TO COURT. IF THEY
14 DO, WHAT DOES THE COURT DO BECAUSE I DON'T THINK YOU
15 WANT A COURT TO MAKE A NEW REVIEW.

16 MS. CHARO: I'M JUST NOT SURE I COMPLETELY
17 APPRECIATE YOUR POINT. LET'S GO BACK TO HOW IRB'S
18 OPERATE, FOR EXAMPLE. WITH IRB'S THERE IS NO STANDARD
19 OF REVIEW OR STANDARD OF PROOF THAT IS LAID OUT
20 ANYWHERE IN THE FEDERAL REGULATIONS. SO IRB
21 DETERMINATIONS ARE FINAL. THERE ARE INFORMAL APPEAL
22 MECHANISMS WITHIN THE INSTITUTION IF THE INVESTIGATORS
23 AREN'T HAPPY. AND THERE ARE PERIODIC AUDITS BY THE
24 FEDERAL GOVERNMENT OF THE IRB'S, WHICH CAN REVEAL THAT
25 THERE IS INADEQUATE DOCUMENTATION TO SUPPORT

1 DETERMINATIONS AND CAN RESULT IN AN IRB LOSING ITS
2 CERTIFICATION.

3 THE ANALOGOUS SITUATION HERE WOULD BE THAT
4 CIRM CAN DECLINE TO FUND ANY RESEARCH THAT IS RELYING
5 UPON A PARTICULAR ESCRO'S SIGN-OFF IF THE ESCRO ITSELF
6 IS FOUND TO BE DEFICIENT. SO HELP ME UNDERSTAND WHAT
7 PRECISELY YOU WANT.

8 MR. TAYMOR: THAT WOULD BE -- THAT WOULD SEEM
9 TO ME TO BE A STANDARD, AND THAT WOULD ARTICULATE A
10 STANDARD. THE DETERMINATION OF THE ESCRO HAS BEEN
11 CORRECT WITH RESPECT TO THESE GRANT FUNDS OR WITH
12 RESPECT TO THE DERIVATION OF THE CELL LINES SO THAT A
13 PLAINTIFF COULDN'T COME IN INDEPENDENTLY AND SAY, YES,
14 THE ESCRO MADE THIS DETERMINATION, BUT THEY WERE WRONG;
15 AND, THEREFORE, CIRM IS NOW FUNDING THIS GRANT OR IT'S
16 FUNDING THIS RESEARCH OR IT'S USING THESE CELL LINES
17 THAT'S IN VIOLATION OF ITS REGULATIONS. CIRM IS
18 OPERATING IN VIOLATION OF ITS REGULATIONS. WE WANT
19 YOU, THE COURT, TO TAKE A LOOK AT THIS, AND YOU WILL
20 SEE, IF YOU LOOK AT THIS, COURT, YOU WILL SEE THAT THE
21 OOCYTE -- THAT THERE WAS DONATION OR THERE WAS NOT --
22 THERE WAS COMPENSATION, NOT JUST REIMBURSEMENT.

23 MS. CHARO: YOU ARE TRYING TO GET
24 CLARIFICATION ON WHETHER OR NOT ESSENTIALLY THERE CAN
25 BE A CITIZEN SUIT STANDING FOR A RANDOM CITIZEN CLAIM

1 THAT CIRM HAS MISSENT ITS FUNDS BY GIVING IT TO
2 GRANTEES WHOSE REVIEWS WERE INADEQUATE UNDER THE
3 APPLICABLE ESCRO.

4 MR. TAYMOR: THAT WOULD CERTAINLY BE ONE OF
5 THE STANDARDS. YOU'RE TALKING ABOUT THE REVIEWS ARE
6 INADEQUATE, WHICH MAY GO TO THE PROCEDURES OF THE
7 REVIEWS, OR IT MAY BE THAT THE DETERMINATION WAS WRONG.
8 SO THERE ARE TWO TYPES OF SUITS THAT COULD FLOW FROM
9 THAT. ONE IS PROCEDURALLY THERE WAS AN INADEQUACY IN
10 THE REVIEW SUBSTANTIVELY, THE FINDING WAS WRONG.

11 DR. HALL: POSE AN ALTERNATIVE. WHAT ARE YOU
12 DRIVING AT HERE?

13 MR. TAYMOR: I WOULD PROPOSE THAT THE IRB'S
14 DETERMINATION IS CONCLUSIVE UNLESS THERE'S SOME FINDING
15 OF CLEAR AND CONVINCING EVIDENCE OR SOME HIGH LEVEL
16 STANDARD THAT WOULD HAVE TO BE DEMONSTRATED, OR THAT AS
17 LONG AS THE IRB HAS -- UNLESS CIRM DECERTIFIES THE IRB
18 THAT THE DETERMINATIONS WORK. I'D JUST LIKE TO KEEP IT
19 WITHIN CIRM.

20 MS. CHARO: YOU MEAN THE ESCRO, NOT THE IRB.

21 MR. TAYMOR: THE ESCRO. I JUST WOULD SUGGEST
22 THAT CIRM'S FUNDING WILL BE MORE EFFICIENT IF YOU CAN
23 KEEP IT -- THE DECISION WITHIN CIRM.

24 MS. CHARO: WHAT YOU ARE TALKING ABOUT IS NOT
25 SO MUCH THE STANDARD. THAT'S THE SECOND QUESTION.

1 IT'S THE STANDING; THAT IS, WHO CAN COMPLAIN AND IN
2 WHAT VENUE? I'M NOT SURE THAT'S WITHIN OUR PURVIEW
3 HERE. I DON'T KNOW WHO HAS CONTROL OF THAT. THAT
4 STRIKES ME AS CONTROLLED BY OTHER PARTS OF CALIFORNIA
5 LAW. THIS MAY BE --

6 MR. TAYMOR: THE STANDING WOULD, BUT THE
7 LEVEL OF REVIEW COULD BE BY THE ADMINISTRATIVE AGENCY.
8 IT COULD SET ITS OWN STANDARD -- ITS OWN LEVEL OF
9 REVIEW.

10 MS. CHARO: I GUESS --

11 CO-CHAIR LO: ARE YOU SUGGESTING IF SOMEWHERE
12 CIRM HAD SOME GUIDELINES OR STANDARDS AS TO WHAT
13 HAPPENS WHEN SOMEONE STEPS FORTH AND SAYS THIS RESEARCH
14 IS UNETHICAL BECAUSE EITHER THE PROCEDURES OR THE
15 SUBSTANCE OF THE REGULATIONS WERE VIOLATED, YOU WANT TO
16 KEEP THAT WITHIN A CIRM APPEALS PROCESS.

17 MR. TAYMOR: AS MUCH AS YOU POSSIBLY CAN. AS
18 MUCH AS THE LAW IS POSSIBLY GOING TO ALLOW YOU TO DO
19 IT, TO KEEP IT AT HOME.

20 DR. HALL: I DON'T UNDERSTAND. THEN CIRM
21 GETS SUED.

22 MR. TAYMOR: CIRM WOULD ALWAYS BE SUED.

23 DR. HALL: SO YOU JUST MOVE UP. I DON'T GET
24 THE --

25 MR. TAYMOR: BECAUSE THERE'S A PRINCIPLE IN

1 LAW, WHICH IS IF THE ADMINISTRATIVE AGENCY, AND
2 PROBABLY THIS IS NOT THE BODY TO BE SPENDING THIS TIME.

3 DR. HALL: WHY DON'T DISCUSS THIS WITH SCOTT
4 LATER.

5 CO-CHAIR LO: IT'S AN IMPORTANT POINT.

6 MR. TAYMOR: I AGREE.

7 MR. REYNOLDS: I HOPE THIS IS THE RIGHT
8 OPPORTUNITY TO MAKE A QUICK COMMENT I HAVE ABOUT 100007
9 (A)(4) ABOUT PROVIDING -- BEFORE WE MOVE ON TO INFORMED
10 CONSENT.

11 TWO QUICK POINTS. THE INTENT OF THIS SEEMS
12 TO BE TO TRY TO SET UP SOME TYPE OF A FIREWALL BETWEEN
13 THE RESEARCHER AND THE EGG RETRIEVER, I THINK, IS THE
14 TERM USED HERE. I'M A LITTLE CONCERNED THAT SIMPLY NOT
15 HAVING IT AS THE SAME PERSON MIGHT NOT BE EFFECTIVE
16 ENOUGH. WHAT IF THEY'RE COLLEAGUES IN THE SAME LAB?
17 WHAT IF THE EGG RETRIEVER WORKS FOR THE RESEARCHER?
18 WHAT IF THEY'RE AT THE SAME INSTITUTION? AND I WOULD
19 ENCOURAGE YOU TO ADOPT A SITUATION WHERE THEY'RE
20 ACTUALLY AT SEPARATE INSTITUTIONS.

21 AND SECOND, THERE IS THE PROVISION FOR AN
22 EXCEPTION TO BE PROVIDED BY THE IRB. PERHAPS IT MIGHT
23 BE BETTER TO CLARIFY UNDER WHAT CASES SUCH AN EXEMPTION
24 MIGHT BE PROVIDED. THANKS.

25 CO-CHAIR LO: COMMENTS ON THAT LAST ONE?

1 DR. KIESSLING: I WOULD LIKE TO ASK BEFORE
2 YOU SIT DOWN, WHAT ARE YOU TRYING TO ACCOMPLISH BY
3 SEPARATING THE CLINICAL TEAM FROM THE DONOR? NOT THAT
4 I'M OPPOSED TO IT, BUT WHAT IS YOUR PURPOSE IN THAT
5 SEPARATION?

6 MR. REYNOLDS: I THINK SOME -- I THINK
7 THERE'S A LEGITIMATE CONCERN THAT THE CLINICIAN WHO IS
8 PERFORMING THE EGG EXTRACTION MIGHT HAVE AN INCENTIVE,
9 LET'S SAY, TO DERIVE MORE EGGS PER CYCLE, PER EGG
10 EXTRACTION BECAUSE HE OR SHE HAS AN AFFILIATION OR AN
11 EMPLOYMENT RELATIONSHIP WITH THE RESEARCHER. AND SO
12 HAVING SOME SORT OF INSTITUTIONAL FIREWALL MIGHT
13 PREVENT THIS CLINICIAN FROM SERVING TWO MASTERS, SO TO
14 SPEAK.

15 DR. KIESSLING: WHAT YOU'RE HOPING FOR IS
16 ADDED PROTECTION FOR THE DONOR.

17 MR. REYNOLDS: THAT'S THE END POINT.

18 DR. KIESSLING: THAT CAN BE BUILT INTO THE
19 STUDY PROTOCOL.

20 MR. REYNOLDS: OKAY. IN WHAT WAY?

21 DR. KIESSLING: JUST SIMPLY GUIDELINES IN THE
22 STUDY PROTOCOL AS TO EXACTLY HOW THE DONORS WILL BE
23 MONITORED AND CARED FOR AND PROTECTED AGAINST ANY KIND
24 OF -- BECAUSE PUTTING IN TWO SEPARATE INSTITUTIONS
25 ISN'T NECESSARILY GOING TO SOLVE THAT. WHAT YOU REALLY

1 WANT ARE GUIDELINES TO PROTECT THE DONORS.

2 DR. EGGAN: THIS IS THE EXACT PURVIEW OF THE
3 IRB. THIS IS THE FEDERALLY MANDATED PURPOSE OF THE
4 IRB, TO PROTECT THIS HUMAN SUBJECT. WE HAVE TO RELY ON
5 THEIR ABILITY TO DO THIS, OR THE ENTIRE ENTERPRISE IS
6 IMPOSSIBLE.

7 I THINK THIS EXACT POINT, THAT THE IRB TAKE
8 THE RESPONSIBILITY TO REVIEW THESE PROTOCOLS IN DEPTH
9 AND TO SOLICIT OUTSIDE EXPERT HELP IF THEY FEEL THAT
10 THEY ARE NOT THEMSELVES EXPERT ENOUGH TO DEAL WITH
11 THEM. WE HAVE TO EXPECT THAT IRB'S WILL DO THIS
12 BECAUSE, AS ANN SAYS, WE CAN PRESCRIBE ALL THE THINGS
13 THAT WE WANT; BUT IF THEY'RE NOT RESPONSIBLE, THEN
14 THESE WOMEN WILL NOT BE SAFE. SO I THINK WE HAVE TO
15 TRUST THAT THEY WILL DO THAT.

16 MS. GREENFIELD: IF I COULD COMMENT ON THAT.
17 IT SEEMS TO ME THAT THE DIFFERENCE, THOUGH, THAT THIS
18 IS A STATE-CREATED AGENCY THAT'S IN CHARGE OF
19 FORMULATING THOSE REGULATIONS TO PROTECT DONORS. AND
20 THAT'S, TO ME, A BIG DISTINCTION IN THAT THIS AGENCY IS
21 SPECIFICALLY CREATED AND PROMISED THE VOTERS OF
22 CALIFORNIA THAT THEY WOULD CREATE THE ETHICAL STANDARDS
23 AND NOT HAVE IT BE DELEGATED TO AN IRB.

24 DR. EGGAN: I BELIEVE THAT WE ARE MANDATED TO
25 TAKE CARE OF SCIENTIFIC STANDARDS AND MEDICAL

1 ACCOUNTABILITY. AND THAT YOU ARE CORRECT. WE ARE
2 RESPONSIBLE FOR THE ETHICAL STANDARDS AND GUIDELINES BY
3 WHICH CIRM FUNCTIONS. BUT WE ARE NOT ALL DOCTORS,
4 ALTHOUGH SOME OF US ARE, AND ALTHOUGH WE ARE SIMILAR IN
5 MAKEUP TO AN INSTITUTIONAL REVIEW BOARD, WE ARE NOT.
6 WE ARE NOT A COMMITTEE ON THE PROTECTION OF HUMAN
7 SUBJECTS IN RESEARCH. AND THERE ARE MANY OF THOSE, AND
8 THERE ARE THESE AT EACH ONE OF THESE INSTITUTIONS. AND
9 CERTAINLY ANY ONE OF THESE PROTOCOLS, WHICH IS GOING TO
10 GO UP BEFORE CIRM FUNDING, CERTAINLY WILL HAVE TO HAVE
11 THE APPROVAL OF THE INSTITUTIONAL REVIEW BOARD. THAT'S
12 PRECISELY WHAT THAT BOARD IS FOR.

13 I THINK THAT YOU'RE RIGHT, IT IS CLEAR THAT
14 WE DO HAVE A VERY SPECIFIC MANDATE TO GUIDE THIS
15 RESEARCH AND TO HELP DO THIS. IT'S NOT -- I DON'T
16 THINK THAT'S OUR JOB.

17 MS. KING: I CAN'T RESIST. YOU CONVINCED ME
18 BEFORE ABOUT WHY NO WALL OF SEPARATION. BUT EVEN THE
19 FEDERAL GOVERNMENT HAS FOUND IT NECESSARY AT TIMES IN
20 THIS RESEARCH PROGRAM TO ISSUE RULES ABOVE THE IRB, AND
21 SOMETIMES THAT INVOLVES SEPARATION. SO I DON'T WANT TO
22 OVERSTATE THE CASE. I THINK THAT THE EXAMPLE THAT YOU
23 OFFERED LAST TIME, WHICH DEALT WITH A NARROW SET OF
24 CIRCUMSTANCES, WAS AN ARGUMENT FOR NOT MAINTAINING A
25 RIGID SEPARATION. AND I THINK THAT'S A GOOD

1 JUSTIFICATION, BUT THERE ARE DANGERS, AS THERE ALWAYS
2 ARE, WHEN YOU DON'T MAINTAIN RIGID SEPARATION.

3 SO I JUST WANT TO TRY TO MAKE THAT CLEAR,
4 THAT THERE'S A SCIENCE REASON HERE WHY YOU MIGHT WANT
5 TO DO SOMETHING DIFFERENTLY THAN WE HAVE HISTORICALLY
6 DONE WHEN WE HAVE HAD TOUGH RESEARCH PROTECTION ISSUES.

7 CO-CHAIR LO: ALSO, IT STRIKES ME AS A BIGGER
8 ISSUE, AND THAT'S PHYSICIANS FULFILLING DUAL ROLES AND
9 CAUSING AT LEAST THE PERCEPTION OF CONFLICTS OF
10 INTEREST AND QUESTIONS ABOUT LOYALTY TO A PATIENT
11 VERSUS SOMETHING ELSE.

12 I'D ASK ALTA TO SORT OF LOOK AT HOW WE DEAL
13 IN THE TRANSPLANTATION SITUATION WITH TRYING TO
14 SEPARATE THE DOCTORS WHO ARE MAKING THE DETERMINATION
15 OF BRAIN DEATH FOR CADAVERIC TRANSPLANTATION OF THE
16 DOCTORS DOING THE TRANSPLANTATION. SO TRYING TO
17 SEPARATE THOSE ROLES SO THERE ISN'T A CONFUSION OR
18 PERCEPTION.

19 DR. EGGAN: I TAKE THE LAST COMMENT VERY MUCH
20 TO HEART, AND I COULD NOT AGREE MORE, WHICH IS WHY I
21 FEEL LIKE WE ARE INDEED DOING THINGS LIKE THAT. SO I
22 THINK RECOMBINANT DNA, ONE COULD ARGUE, RAISED
23 DIFFERENT, BUT OUTSTANDING ISSUES WHICH HADN'T BEEN
24 ADDRESSED BEFORE. SO WITH RESPECT TO GENE THERAPY, NIH
25 INSTITUTED THE RAC, AND ALSO IT WAS DEMANDED THAT EACH

1 HOME INSTITUTION FOUND A COMMITTEE ON MICROBIOLOGICAL
2 SAFETY TO ENSURE THAT THESE THINGS WERE ESPECIALLY
3 COVERED.

4 AND LIKEWISE, I THINK THIS GROUP HAS, UNDER
5 THE NATIONAL ACADEMY GUIDELINES, SUGGESTED THAT
6 INSTITUTIONS FORM ESCRO'S TO ALSO REVIEW THESE VERY
7 SPECIFIC INSTANCES. SO I THINK THAT THERE HAS BEEN AN
8 EARNEST AND TRUE ATTEMPT TO BE ABLE TO LAY OUT
9 ADDITIONAL OVERSIGHT TO TRY TO COVER EXACTLY THESE
10 SORTS OF ISSUES THAT SORT OF ARISE IN ONE OF THESE
11 MICROCOSMS THAT WE'RE TRYING TO ADDRESS.

12 CO-CHAIR LO: LET ME MAKE THE SUGGESTION, I'M
13 GOING TO ASK YOU TO DO THIS, TO THINK ABOUT IF THE
14 LANGUAGE IN (4) IS -- I THINK THE SENTIMENT OF TRYING
15 TO HAVE A SEPARATION, BUT NOT TO THE POINT THAT IT
16 MAKES IMPOSSIBLE VALUABLE SCIENTIFIC RESEARCH WHERE
17 THERE IS NO REAL ETHICAL PROBLEM SUBJECT TO IRB
18 APPROVAL.

19 ONE OF THE COMMENTS WAS IS THE SEPARATION OF
20 ATTENDING PHYSICIAN FROM RESEARCHER THE ONLY PROTECTION
21 WE WANT TO HAVE THERE? LET'S COME BACK TO THAT. I
22 THINK THERE'S A POINT WORTH NOTING.

23 I WOULD NOW LIKE TO TURN TO PAGE 7 AND
24 INFORMED CONSENT, AND START THIS SECTION BECAUSE PAT
25 AND ZACH WON'T BE HERE TOMORROW. JUST TO PUT THIS IN

1 CONTEXT, WHAT WE'VE TRIED TO DO WITH INFORMED CONSENT
2 IS TO SAY THIS IS VERY IMPORTANT. AND ALTHOUGH PROP 71
3 EXEMPTED CIRM FROM A LOT OF THE EXISTING FEDERAL AND
4 STATE LAWS AND REGULATIONS, THE FIRST PART BEFORE THE
5 (A), THAT PARAGRAPH SAYS WE'RE VOLUNTARILY SAYING
6 CIRM-FUNDED RESEARCHERS MUST COMPLY WITH FEDERAL AND
7 STATE LAWS AND REGULATIONS.

8 NOW, BEYOND THAT, WE ALSO WANTED TO SAY
9 CIRM-FUNDED RESEARCHERS MUST BE IN ADHERENCE TO THE NAS
10 GUIDELINES. AND IN ADDITION TO THE PROVISIONS OF
11 SENATOR ORTIZ' BILL S 322, THE FEDERAL AND STATE LAWS
12 AND REGULATIONS WE DECIDED TO CITE BY LEGAL CITATION.
13 AND THE ARGUMENT THAT WAS GIVEN TO US WAS THAT THOSE
14 ARE AMENDED. THE AMENDMENTS ARE PART OF THE CIRM
15 REGULATIONS. WHERE IF WE SPELL THEM ALL OUT, IF THEY
16 GOT AMENDED, THE AMENDMENTS WOULD NOT APPLY TO US.

17 THIS IS ON -- GEOFF IS POINTING OUT A TABLE
18 THAT'S IN THE BRIEFING BOOK OR JUST YOUR BOOK.

19 MR. LOMAX: IT'S IN THE BRIEFING NOTES AT NO.
20 3.

21 CO-CHAIR LO: SO THERE'S A TABLE THAT LOOKS
22 LIKE THIS THAT SHOWS YOU SORT OF WHAT THESE DIFFERENT
23 LAWS DO AND HOW THEY DIFFER.

24 BUT THE POINT IS THAT THE FIRST PARAGRAPH
25 SAYS WE'RE GOING TO FOLLOW APPLICABLE STATE AND FEDERAL

1 LAW AND REGULATION. (A) SAYS WE'RE GOING TO GO EVEN
2 BEYOND THAT AND FOLLOW NAS GUIDELINES AND A BILL THAT
3 WAS PASSED BY BOTH THE SENATE AND ASSEMBLY, BUT VETOED,
4 BUT IS GOING TO BE REINTRODUCED. WE WANT CIRM
5 RESEARCHERS TO FOLLOW THOSE, SO WE ACTUALLY ARE LISTING
6 UNDER (A), WHICH GOES THAT WHOLE PAGE, THOSE KINDS OF
7 PROVISIONS.

8 THEN IF YOU TURN TO PAGE 8, WE ACTUALLY
9 THOUGHT THAT EVEN BEYOND ALL THOSE EXISTING LAWS AND
10 REGULATIONS, EXISTING GUIDELINES AND PROPOSED BILLS, WE
11 STILL HAD OTHER THINGS THAT WE THOUGHT WE NEED TO
12 INCLUDE IN THE CONSENT PROCESS. IN PARTICULAR, WE WERE
13 VERY CONCERNED ABOUT MAKING SURE WOMEN DONATING OOCYTES
14 FOR THIS TYPE OF RESEARCH UNDERSTOOD THE KEY ISSUES,
15 NOT THAT THEY WERE GIVEN REAMS AND REAMS OF PAPER OR
16 TOLD ABOUT THINGS, BUT ACTUALLY THEY UNDERSTOOD IT.

17 I THINK THIS GOES BACK TO THE POINT ANN
18 KIESSLING RAISED THAT WHAT'S REALLY IMPORTANT TO
19 PROTECT WOMEN WHO ARE DONATING OOCYTES IS THAT THE
20 CONSENT PROCESS BE REALLY INFORMED AND IN A SENSE BE
21 MORE RIGOROUS. THIS IS MORE RIGOROUS THAN THE CONSENT
22 PROCEDURES FOR MOST RESEARCH CARRIED OUT BY U.S.
23 INSTITUTIONS.

24 THAT'S SORT OF THE BIG PICTURE WE'RE TRYING
25 TO PUT, THAT WE'RE INCORPORATING EXISTING LAWS, WE'RE

1 GOING BEYOND THAT TO INCORPORATE REGULATIONS OF
2 PROPOSED BILLS, AND STILL GOING BEYOND THAT. AND IT'S
3 A LITTLE BIT CUMBERSOME IN TERMS OF AS YOU READ IT
4 THROUGH, BUT I HOPE THAT EXPLAINS WHY IT APPEARS IN THE
5 FORM IT DOES, SOME CITATION.

6 SO WITH THAT, LET'S TOSS THIS OPEN AND GET
7 STARTED WITH THIS DISCUSSION.

8 CO-CHAIR LANSING: I JUST WANT TO SAY I'M
9 ACTUALLY PLEASED THAT IT IS SO LONG, AND IT HAS GOT
10 EVERYTHING DOWN THERE BECAUSE I'D RATHER HAVE MORE
11 INFORMATION IN THIS CASE THAN LESS.

12 I GUESS THE QUESTION IS IS THERE ANYTHING IN
13 THIS THAT BOTHERS ANYBODY THAT THEY THINK IS CONFUSING
14 OR ANYTHING WE OMITTED?

15 MS. KING: IT HAS TO BE CONFORMED TO THE
16 CHANGES WE'VE MADE DURING TODAY'S DISCUSSION, FOR
17 EXAMPLE.

18 CO-CHAIR LO: RIGHT.

19 DR. KIESSLING: I'M SORRY. WHICH ONE?

20 MS. KING: COMPENSATION, FOR EXAMPLE, HAS TO
21 BE CHANGED TO CONFORM TO WHAT WE DECIDED EARLIER. SO I
22 SAID THAT SOMEBODY NEEDS TO GO THROUGH IT AND CONFORM
23 IT TO ALL THE DECISIONS THAT WERE MADE TODAY TO MAKE
24 SURE THEY'RE OKAY.

25 MR. TOCHER: I JUST WANTED TO MAKE A QUICK,

1 SMALL CLARIFICATION. WHEN WE'RE REFERRING TO THE --
2 HERE IN SECTION 08, WHEN REFERRING TO THE CODE OF
3 FEDERAL REGULATIONS, THEY ACTUALLY DON'T AUTOMATICALLY
4 UPDATE SORT OF BY VIRTUE OF THE FACT THAT YOU ARE
5 SIMPLY REFERRING TO THEM IN THE FEDERAL PART. OFFICE
6 OF ADMINISTRATIVE LAW DOESN'T LIKE THE NOTION OF
7 ACTUALLY FARMING REG ADOPTION AND CHANGES.

8 SO WHAT WOULD HAPPEN IS WE WOULD HAVE TO
9 INDICATE THE EFFECTIVE DATE OF THIS PARTICULAR FEDERAL
10 REGULATION THAT WE'RE SPEAKING OF, AND THEN WE COULD
11 JUST REFER TO IT WITHOUT HAVING TO CITE THE ENTIRE
12 SUBSTANCE OF THAT PARTICULAR FEDERAL REGULATION.

13 ANY CORRESPONDING CHANGES TO THE FEDERAL
14 REGULATION AFTER THAT WOULD NOT BE INCORPORATED
15 AUTOMATICALLY, BUT WOULD HAVE TO BE ADOPTED BY
16 AMENDMENT TO OUR REGULATION.

17 CO-CHAIR LO: THANK YOU. MAYBE I CAN POINT
18 OUT SOME OF THE PLACES WHERE WE MADE CHANGES FROM
19 EXISTING GUIDELINES, PARTICULARLY THE NAS GUIDELINES.

20 IN (A)(2) WHERE WE TALK ABOUT RECONTACT WITH
21 DONORS, THE NAS GUIDELINES FOCUS PRIMARILY ON RECONTACT
22 TO PROVIDE DONOR'S INFORMATION RESEARCHERS MIGHT HAVE
23 GAINED THAT MIGHT BE OF VALUE TO THE DONORS. WE'VE
24 ADDED HERE INFORMATION -- THE POSSIBILITY OR THE
25 LIKELIHOOD ACTUALLY THAT RESEARCHERS MAY WANT TO

1 RECONTACT DONORS PRIOR TO TRANSPLANTATION FOR UPDATING
2 SCREENING AND HEALTH HISTORY AND THE LIKE. THAT'S IN
3 ADDITION TO WHAT THE NAS HAD SAID IN THE SPIRIT OF
4 LETTING THE DONORS KNOW THAT THEY MIGHT BE RECONTACTED
5 FOR THE PURPOSE OF PROTECTING TRANSPLANT RECIPIENTS.

6 ANOTHER CHANGE IS --

7 DR. WAGNER: CAN I ASK A QUESTION JUST TO
8 ADD? AM I TO PRESUME, THOUGH, THAT WE WOULD GIVE THEM
9 AN OPT OUT SO THEY CAN SPECIFICALLY CHECK OFF A BOX
10 THAT SAYS, NO, I DO NOT WANT TO BE RECONTACTED? SO ON
11 ONE HAND, I UNDERSTAND THAT YOU'RE PUTTING THIS IN SO
12 THAT YOU'RE SAYING, YOU KNOW, WE'RE ASKING YOU TO BE
13 RECONTACTED, BUT AT THE SAME TIME THEY COULD ALSO
14 SAY -- WE HAVE TO GIVE THEM THE OPPORTUNITY OF SAYING,
15 NO, I DON'T WANT TO BE RECONTACTED.

16 MR. SHESTACK: I THINK THEY'RE BEING ASKED TO
17 DO AN OPT IN. AREN'T YOU ASKING THEM TO SPECIFICALLY
18 SAY THEY'RE WILLING TO BE RECONTACTED, NOT THAT THEY
19 MIGHT BE?

20 CO-CHAIR LO: WELL, WHAT'S WRITTEN HERE IN
21 (2) IS THEY MAY BE RECONTACTED ONLY IF THEY CONSENTED
22 TO CONTACT UP FRONT.

23 MR. SHESTACK: SPECIFICALLY TO OPT IN IN THE
24 BEGINNING.

25 CO-CHAIR LO: RIGHT. RIGHT. THERE'S NOTHING

1 TO PREVENT A RESEARCHER SAYING I DON'T WANT TO HAVE TO
2 RECONTACT THEM, AND THEN WE HAVE PROVISIONS IN THIS (A)
3 TO SAY YOU DON'T HAVE TO PUT IT IN IF IT'S NOT PART OF
4 YOUR PROTOCOL.

5 DR. WAGNER: I'M REALLY CONCERNED ABOUT THE
6 DONOR SAYING I DON'T WANT TO BE RECONTACTED.

7 CO-CHAIR LO: RIGHT. RIGHT. RIGHT.

8 ANOTHER DIFFERENCE IS NO. 9, WHICH WE ADDED,
9 AGAIN, BECAUSE OF CONCERNS ABOUT THE COMMERCIAL ASPECTS
10 OF STEM CELL RESEARCH THAT WILL BE REQUIRED TO BRING
11 THE PRODUCT TO MARKET TO DISCLOSE TO DONORS THE
12 POSSIBILITY THAT THE RESULTS MAY HAVE COMMERCIAL
13 POTENTIAL, AND THAT THE DONORS THEMSELVES WILL NOT
14 RECEIVE ANY FINANCIAL OR OTHER BENEFITS FROM FUTURE
15 COMMERCIAL DEVELOPMENT. JUST SO THEY UNDERSTOOD THAT
16 ASPECT OF WHAT THEY WERE DOING.

17 THE NEXT PAGE, PAGE 8(B), WHICH IS IN RED
18 PRINT FOR SOME PEOPLE AND BLACK FOR OTHERS, THAT,
19 AGAIN, WE'VE ADDED TO BE MORE SPECIFIC ABOUT WHAT KINDS
20 OF RISKS FROM OOCYTE DONATION NEEDED TO BE DISCLOSED TO
21 OOCYTE DONORS. WE TALKED ABOUT FORESEEABLE RISK, AND
22 WE SPECIFICALLY MENTION THAT THEY NEED TO BE INFORMED
23 ABOUT HYPERSTIMULATION, BLEEDING, INFECTION, AND
24 ANESTHESIA RISKS, BUT NOT LIMITED TO THOSE.

25 AGAIN, RESPONDING TO CONCERNS THAT WOMEN

1 UNDERGOING THESE PROCEDURES REALLY NEEDED TO HAVE
2 INFORMATION ABOUT THOSE RISKS, AND WE COME BACK LATER
3 AND SAID THEY ALSO NEEDED TO DEMONSTRATE THEY
4 UNDERSTOOD THOSE RISKS.

5 DR. WAGNER: CAN I JUST ASK A QUESTION THEN?
6 BECAUSE YOU'VE SPECIFICALLY INDICATED SOME RISKS LIKE
7 OVARIAN HYPERSTIMULATION, BLEEDING, INFECTION,
8 ANESTHESIA, DO YOU NOT PUT IN THE RISK OF MULTIPLE
9 PREGNANCY? OBVIOUSLY IF YOU ONLY REMOVE A PORTION OF
10 THE OOCYTES, THERE'S ANOTHER RISK OF PREGNANCY SHOULD
11 THEY NOT USE APPROPRIATE BIRTH CONTROL.

12 DR. KIESSLING: THAT'S AN INTERESTING POINT.
13 I THINK ROB AND I WOULD AGREE WITH THAT TOO. I THINK
14 ROB WOULD AGREE WITH THAT TOO. THE RISK OF MULTIPLE
15 PREGNANCY IS REAL FOR THESE GIRLS.

16 DR. TAYLOR: WE HAVE TALKED ABOUT IT A LITTLE
17 BIT HERE TODAY TOO THAT PREGNANCY IS A RISK FOR DONORS
18 WHO AREN'T REALLY USING AN ASSIDUOUS KIND OF
19 CONTRACEPTIVE METHOD BECAUSE THEY ARE LIKELY TO HAVE
20 REMAINING OOCYTES, SO WE SHOULD PROBABLY INCLUDE THAT
21 AS ONE OF THE RISKS.

22 CO-CHAIR LO: GOOD POINT. ANYTHING ELSE?

23 MS. CHARO: NOT ON THIS ONE, BUT ON (D).

24 CO-CHAIR LO: LET'S GO TO (D).

25 MS. CHARO: ASSUMING YOU'RE DONE WITH (B) AND

1 (C).

2 CO-CHAIR LO: UP TO THE COMMITTEE IF ANYBODY
3 HAS COMMENTS.

4 MS. CHARO: ON (D) I NOTE THAT IT SAYS THE
5 UMBILICAL CORD BLOOD OR THE PLACENTA, CONSENT SHALL BE
6 OBTAINED FROM A BRACKETED KNOWN BIOLOGICAL PARENT. I
7 WAS WONDERING WHY BIOLOGICAL PARENT AS OPPOSED TO
8 INTENDED REARING PARENT. I CAN IMAGINE WE'D WANT THE
9 BIOLOGICAL PARENT. QUESTION IS WHETHER OR NOT THEY
10 WERE WILLING TO RENOUNCE ANY POSSIBILITY OF HAVING THAT
11 UMBILICAL CORD BLOOD USEFUL FOR THEMSELVES, IF THEY
12 THINK IT WOULD BE, AS OPPOSED TO INTENDED REARING
13 PARENT WHERE IT'S PROTECTING THE INTERESTS OF THE
14 CHILD, OR IF IT WAS JUST A KIND OF UNINTENDED
15 CONFLATION OF KNOWN BIOLOGICAL WITH INTENT TO REAR,
16 WHICH IS FREQUENTLY, BUT NOT ALWAYS, THE SAME SET OF
17 PEOPLE.

18 CO-CHAIR LO: I THINK THERE IS AN ARGUMENT
19 THAT WE NEED TO CONSIDER. SO WHETHER WE SHOULD ALSO
20 GET CONSENT FROM THE REARING PARENTS FOR THE REASONS
21 YOU STATED. THE OTHER REASON FOR ASKING CONSENT FOR
22 BIOLOGICAL PARENTS IS TO BE PARALLEL TO WHAT WE'VE SAID
23 ABOUT DONATION OF GAMETES FOR EMBRYONIC STEM CELL
24 LINES, THAT IF YOU WERE TO CREATE A STEM CELL LINE
25 WHICH INVOLVES YOUR DNA BEING PROPAGATED AND CULTURED

1 AND POSSIBLY TRANSPLANTED, YOU SHOULD KNOW ABOUT THAT
2 AND CONSENT TO IT.

3 MS. CHARO: OF COURSE, NOW IT'S LITTLE A
4 DIFFERENT, ISN'T IT?

5 DR. TAYLOR: THERE IS THE OPPORTUNITY FOR
6 SOME THERAPEUTIC, IN THIS PARTICULAR SETTING THERAPY OF
7 THAT FETUS, WHICH PRESUMABLY WOULD INVOLVE CONSENT OF
8 THE REARING PARENTS. I CAN SEE THAT COMPLEXITY, BUT I
9 DON'T THINK WE REALLY --

10 MS. KING: SHOULDN'T THE REGULATORY TERM BE
11 LEGAL PARENT?

12 MR. TOCHER: OR GUARDIAN.

13 MS. KING: LEGAL PARENT OR GUARDIAN, AND THEN
14 SUCH OTHERS BECAUSE NONE OF THE CONSENT IS GOING TO BE
15 VALID UNLESS IT'S THE LEGAL PARENT.

16 MS. CHARO: YEAH. YEAH.

17 MS. KING: AND THAT MAY BE BIOLOGICAL, IT MAY
18 BE INTENDED, SO YOU MAY WANT ADDITIONAL LANGUAGE THAT
19 SAYS AND OTHERS AS REQUIRED OR SOMETHING LIKE THAT, BUT
20 LEGAL HAS TO BE OPERATIVE HERE.

21 CO-CHAIR LO: LEGAL.

22 DR. WILLERSON: JUST ANOTHER COMPLEXITY.
23 THOSE TISSUES BELONG TO THE MOTHER. WHEN YOU WORRY
24 ABOUT TREATING A CHILD WITH CELLS ISOLATED FROM THAT, I
25 AGREE THE MOTHER AND THE FATHER BOTH HAVE A ROLE, IF

1 IT'S GOING TO OCCUR IN A SHORT PERIOD OF TIME. LATER
2 THE CHILD MAKES THAT DECISION, IT SEEMS TO ME. BUT THE
3 TISSUES REALLY BELONG TO THE MOTHER. THEY DON'T BELONG
4 TO THE FATHER.

5 DR. EGGAN: I THINK THAT'S A GOOD POINT.
6 WHAT IS THE PRECEDENCE FOR THAT? ARE THESE THE
7 MOTHER'S?

8 MS. CHARO: YOU DON'T REALLY WANT TO GO NEAR
9 THE TOPIC OF HOW STATE LAW AND PROPERTY LAW TREAT HUMAN
10 TISSUE. IT'S A MORASS.

11 DR. TAYLOR: WE WEREN'T REALLY THINKING ABOUT
12 IT FROM THIS PERSPECTIVE. I THINK WE WERE LOOKING FOR
13 KIND OF THE BIOLOGICAL SOURCE OF THE CELLS WHEN WE
14 CRAFTED THIS LANGUAGE. WHEN YOU THINK ABOUT THE
15 APPLICATION OF THOSE CELLS --

16 DR. WILLERSON: WHAT I'D LIKE TO DO IS NOT
17 LIMIT THIS POSSIBILITY IF THE FATHER'S NOT AVAILABLE.
18 WE DON'T KNOW WHO THE FATHER IS. HE'S NOT AVAILABLE.

19 CO-CHAIR LO: HE DOESN'T WANT TO LIMIT
20 RESEARCH IF THE FATHER IS NOT AVAILABLE.

21 DR. WILLERSON: I'M JUST SAYING FATHERS IN
22 THESE TIMES SOMETIMES AREN'T AVAILABLE FOR ONE REASON
23 OR ANOTHER. AND I'D HATE TO SEE THIS BE PRECLUDED BY
24 NOT BEING ABLE TO GET A FATHER'S PERMISSION ABOUT
25 SOMETHING THAT REALLY IS THE MOTHER'S.

1 MS. CHARO: THERE'S A VERY ACTIVE DISCUSSION
2 ABOUT UMBILICAL CORD BLOOD COLLECTION THAT WE MIGHT
3 WELL BE ADVISED TO TAP INTO BEFORE WRITING DE NOVO A
4 SET OF RULES ABOUT WHICH PEOPLE HAVE TO GIVE CONSENT
5 AND WHEN THEY HAVE TO GIVE CONSENT, ETC., ETC. I'M
6 JUST WONDERING IF THERE'S A WAY TO RAPIDLY IDENTIFY
7 THOSE EVOLVING STANDARDS AND PERHAPS CROSS REFERENCE
8 THEM BECAUSE REALLY THERE ARE PEOPLE THAT HAVE WORKED
9 ON THIS FOR QUITE A WHILE NOW IN THE CONTEXT OF
10 NATIONAL CORD BLOOD BANKS AND SUCH.

11 DR. WAGNER: MAY I ADDRESS THIS SINCE I'M ON
12 ONE. I CAN TELL YOU THAT WE ONLY ASK FOR THE MOTHER'S
13 CONSENT. IT'S ALL THAT'S REQUIRED. SO THE IOM PANEL
14 MET. ALTHOUGH THERE ARE CERTAIN CIRCUMSTANCES WHERE
15 THE FATHER'S CONSENT MIGHT BE REQUESTED, FOR ALL
16 INTENTS AND PURPOSES, IT'S ONLY THE MOTHER'S THAT'S
17 ACTUALLY REQUIRED.

18 CO-CHAIR LO: JOHN, DID THAT PANEL CONSIDER
19 THE POSSIBILITY OF DERIVATION OF STEM CELL LINES AS
20 OPPOSED TO STEM CELL TRANSPLANTATION?

21 DR. WAGNER: IT WAS CERTAINLY NOT THE FOCUS
22 OF THE GROUP. IT WAS REALLY THE CREATION OF A NATIONAL
23 INVENTORY OF CORD BLOOD; HOWEVER, IT WAS PART OF THE
24 DISCUSSION. HOWEVER, WE CAN GO BACK AND I CAN GO BACK
25 AND ACTUALLY LOOK AT THE ACTUAL CHAPTERS THAT

1 SPECIFICALLY ADDRESS THE STEM CELL LINES AND SEE
2 WHETHER OR NOT THERE'S SOMETHING DIFFERENT THERE
3 BECAUSE I MIGHT NOT BE RECALLING IT, BUT IT'S EASY
4 ACCESS. IT'S READILY AVAILABLE.

5 CO-CHAIR LO: THE PROPOSAL IS THAT WE, IN A
6 SENSE, TABLE THIS AND COME BACK WITH MORE INFORMATION
7 RATHER THAN TRYING TO DO IT ALL OURSELVES DE NOVO WHEN
8 OTHERS HAVE THOUGHT LONG AND HARD ABOUT THIS.

9 DR. WILLERSON: GET LEGAL OPINION TOO.

10 MS. KING: YOU KNOW, WHAT YOU WANT TO DO IS
11 SEPARATE THE TWO THINGS OUT. WHAT YOU WANT TO DO IS
12 SEPARATE THE TWO ISSUES OUT, DERIVATION AND POSSIBILITY
13 OF FUTURE USE, BECAUSE ONE OF THE THINGS WE DO KNOW IS
14 THAT WHEN WE REQUIRE DIFFERENT CONSENTS BECAUSE FOR
15 FUTURE APPLICATION, THEN IT IS RELEVANT TO TALK ABOUT
16 THE FATHER IF THE FATHER IS AVAILABLE, FOR EXAMPLE,
17 BECAUSE THAT'S GOT TO BE PARENTS, HOWEVER THE STATE
18 DEFINES THE LEGAL PARENTS, AND IF THE FATHER IS
19 AVAILABLE. BUT DERIVATION, IT'S LIKE USING FETAL
20 TISSUE. YOU GO TO THE MOTHER. THAT'S WHY THE MOTHER.
21 BUT THERE MAY BE VARIATION. YOU SHOULD JUST FIND OUT
22 WHAT THEY'RE DOING IN CORD BLOOD. YOU NEED TO KNOW
23 CALIFORNIA LAW BECAUSE I ASSUME THAT THIS -- YEAH, YOU
24 HAVE TO KNOW -- YOU WANT TO BE IN CONFORMITY WITH
25 CALIFORNIA LAW, DON'T YOU?

1 CO-CHAIR LO: HOPE SO.

2 MS. KING: SO THE REAL ISSUE IS TO FIND OUT
3 HOW CALIFORNIA DEALS WITH SOME OF THESE ISSUES, BUT
4 SEPARATE THE TWO ISSUES OUT. THEY CAN DIFFER.

5 CO-CHAIR LO: SO THIS MAY BE SOMETHING WE
6 NEED TO PUT A PLACEHOLDER AND AN ASTERISK AND COME BACK
7 AND PROBABLY NOT TRY AND RESOLVE IT TODAY AND TOMORROW.

8 OKAY. (F) IN RED IN SOME VERSIONS, GIVEN
9 THAT WE DON'T WANT TO DO THINGS WITH PEOPLE'S CELLS IN
10 THE FUTURE THAT THEY WOULDN'T HAVE AGREED TO, BUT THAT
11 WE CAN'T ACTUALLY PREDICT ALL OF THE THINGS THAT
12 RESEARCHERS MAY WANT TO DO IN THE FUTURE WITH STEM CELL
13 LINES, WE PUT IN (F) TO EXPLICITLY GIVE PERMISSION TO
14 RESEARCHERS TO SAY WE DON'T REALLY KNOW ALL THE THINGS
15 THAT MIGHT BE DONE WITH CELLS IF WE'RE SUCCESSFUL IN
16 DERIVING A STEM CELL LINE. WE WANT TO RESTRICT
17 DONATION OF BIOLOGICAL MATERIALS USED TO DERIVE THOSE
18 LINES. PEOPLE ARE COMFORTABLE SAYING ANYTHING THAT'S
19 APPROVED BY A SCIENTIFIC PANEL, ETHICAL REVIEW PANEL, I
20 WOULD CONSENT TO USE IN THE FUTURE AND NOT TRY AND SAY
21 I WOULD ALLOW THIS, BUT NOT THAT AND SO FORTH.

22 THAT'S, AGAIN, SOMETHING NEW AND ACTUALLY
23 GOES BEYOND WHAT'S IN CURRENT GUIDELINES, SO I WANT TO
24 PARTICULARLY CALL YOUR ATTENTION TO THAT AND MAKE SURE
25 THAT PEOPLE AGREE WITH THAT.

1 MR. SHESTACK: BASICALLY WHAT YOU ARE SAYING
2 HERE IS THAT YOU CAN'T PICK OR CHOOSE ANYTHING ON THIS
3 MENU. IF YOU ARE GOING TO SIGN, YOU'RE SIGNING ALL OF
4 IT. IT'S SORT OF ANOTHER WAY OF SAYING IT.

5 CO-CHAIR LANSING: YOU DO PICK OR CHOOSE.

6 MR. SHESTACK: WHAT YOU ARE SAYING IS WE
7 DON'T HAVE TO USE YOU. IF YOU DON'T AGREE TO UNLIMITED
8 USE OF YOUR CELLS NOW AND IN THE FUTURE, YOU WON'T BE
9 IN THIS STUDY.

10 CO-CHAIR LO: IT DEPENDS ON THE NATURE OF THE
11 STUDY. THERE MAY BE SOME STUDIES WHERE, IN FACT,
12 PEOPLE SAY I ONLY WANT IT USED FOR THIS STUDY AND
13 NOTHING ELSE. THE RESEARCHER SAYS, YES, GIVEN THE
14 STUDY, THAT'S REASONABLE.

15 I GUESS THE CONCERN IS IF YOU ARE DERIVING
16 STEM CELL LINES WHERE YOU CAN PREDICT AS A RESEARCHER
17 WHAT OTHER PEOPLE WANT TO DO IN THE FUTURE WITH THOSE
18 STEM CELL LINES. WILL IT BE FEASIBLE OR REALISTIC TO
19 TELL DONORS THAT IF YOU DON'T WANT THEM USED FOR THIS
20 PURPOSE AND THAT PURPOSE, WE CAN SORT OF PREVENT THAT
21 FROM HAPPENING IN THE FUTURE. A LOT OF RESEARCHERS
22 HAVE SAID --

23 MR. SHESTACK: NO, IT'S NOT FEASIBLE. I JUST
24 WANT TO MAKE SURE THAT YOU UNDERSTAND WHAT YOU'RE
25 ACTUALLY SAYING HERE TO PEOPLE. IT'S NOT PARTICULARLY

1 FRIENDLY. IT'S VERY PRACTICAL, BUT IT'S NOT THAT
2 FRIENDLY. IT'S JUST LIKE YOU HAVE HERE SOMETHING ABOUT
3 COMMERCIAL USE. WHAT A BETTER THING TO PUT IN THE
4 CONSENT FORM IS YOUR CELL LINES WILL BE USED BY
5 PHARMACEUTICAL COMPANIES. IT ACTUALLY BE PUT IN THE
6 AFFIRMATIVE IN THE BEGINNING BECAUSE YOU WILL FIND
7 PEOPLE OFTEN DON'T WANT IT, AND THEY NEED TO UNDERSTAND
8 THAT IT'S NOT JUST COMMERCIAL USE. YOU HAVE TO
9 ACTUALLY SAY WHAT IT IS, THAT A PHARMACEUTICAL COMPANY
10 WILL EVENTUALLY HAVE YOUR CELL LINE OR PRODUCTS FROM
11 YOUR CELL LINE. AND IF YOU WANT TO AVOID PEOPLE
12 AFTERWARDS SAYING, GETTING INTO A BEEF WITH YOU AND
13 SAYING THEY DIDN'T UNDERSTAND, ASKING THAT THEIR CELL
14 LINES BE TAKEN OUT OF CIRCULATION, YOU MIGHT WANT TO
15 EVEN BE A LITTLE BIT MORE CLEAR ABOUT IT.

16 CO-CHAIR LANSING: I'M CONFUSED. I THINK I
17 UNDERSTOOD IT.

18 MR. SHESTACK: I WAS JUST --

19 CO-CHAIR LO: JON IS SAYING WE MAY WANT TO BE
20 MORE DIRECT.

21 MR. SHESTACK: I THINK YOU WANT TO BE MORE
22 SPECIFIC.

23 CO-CHAIR LANSING: YOU'RE GETTING INFORMED
24 CONSENT. YOU'RE SAYING I WANT MY CELL LINES TO GO TO
25 THIS, OR I DON'T WANT MY CELL LINES TO GO TO THAT,

1 WHICH IS FINE, ISN'T IT?

2 MS. KING: BUT THIS SAYS THAT RESEARCHERS
3 MAY -- ARE PERMITTED TO CREATE -- HAVE A RESEARCH
4 PROJECT WHERE WHEN WE FIRST DO THEIR INFORMED CONSENT
5 FORM, IT SAYS YOU'RE AGREEING TO ALL FUTURE USES, OR
6 YOU WON'T BE SELECTED AS A SUBJECT.

7 CO-CHAIR LANSING: OF THAT ONE RESEARCH
8 PROJECT, NOT ALL RESEARCH PROJECTS.

9 MS. KING: FOR THAT ONE PROJECT.

10 DR. HALL: YOU CAN BE.

11 CO-CHAIR LANSING: YOU CAN DO THAT. SOMEONE
12 CAN SAY I'M COMFORTABLE WITH THAT. I WANT TO DO THAT,
13 AND OTHER PEOPLE WILL SAY NO.

14 MR. SHESTACK: IN MANY CASES SOMEONE IS GOING
15 TO BE CONSENTING FOR DONATION OF BIOMATERIALS THAT WILL
16 END UP BEING PERHAPS PART OF A RESOURCE CREATED LATER
17 WHERE THEY WILL BE USED FOR INNUMERABLE THINGS.

18 DR. HALL: WE HOPE.

19 CO-CHAIR LANSING: WE HOPE. THEY DON'T HAVE
20 TO. THEY CAN LIMIT IT.

21 DR. HALL: THEN THEY GO TO ANOTHER PROJECT.

22 MR. SHESTACK: OKAY.

23 MS. KING: ONE OF THE INTERESTING QUESTIONS
24 IS WILL THEY GO TO OTHER PROJECTS BECAUSE INCREASINGLY
25 ANYBODY WHO WORKS WITH TISSUES ONLY WANTS A PERSON TO

1 AGREE TO EVERYTHING IN THE FUTURE. THAT'S REALLY WHAT
2 THE ISSUE IS. THE ISSUE IS IF YOU WERE A RESEARCHER,
3 WHY WOULD YOU EVER HAVE A PROJECT THAT ALLOWED PEOPLE
4 TO OPT IN, OPT OUT ALONG CERTAIN LINES? SO I DON'T
5 KNOW WHETHER I OPPOSE IT OR NOT, BUT THE ISSUE IS, IN
6 EFFECT, WE CAN BE SURE THAT FUTURE RESEARCH PROJECTS
7 FOR THE MOST PART HAVE THIS KIND OF REQUIREMENT. I SEE
8 IT ALL THE TIME. THIS IS WHAT'S HAPPENING ON THE
9 CANCER GENOME RESEARCH. THEY WANT THE CONSENT TO LAST
10 FOREVER, AND THEY DON'T EVEN WANT TO CREATE PROJECTS
11 REALLY WHERE YOU DON'T HAVE THAT PROVISION BECAUSE IT'S
12 THE SAFEST THING FOR A RESEARCHER TO DO.

13 CO-CHAIR LANSING: BUT IF YOU DON'T HAVE IT,
14 THEN YOU DON'T HAVE A TRANSPARENT PROJECT. YOU DON'T
15 HAVE A REAL INFORMED CONSENT IF YOU DON'T HAVE A PERSON
16 HAVING THEIR CHOICE AS TO WHETHER OR NOT THEY WANT IT
17 TO GO TO ANYTHING.

18 MS. KING: WELL --

19 CO-CHAIR LO: I THINK ONE THING THAT'S
20 CERTAINLY CLEAR HERE IS THAT, FOR EXAMPLE, YOU LOOK AT
21 STEM CELL LINES THAT ARE NOW IN USE. MY GUESS IS THAT
22 WHEN MATERIALS WERE DONATED FOR THOSE EMBRYONIC STEM
23 CELL LINES, NO ONE WENT TO THE PEOPLE AND SAID ONE OF
24 THE THINGS WE MIGHT DO LATER IS TAKE STEM CELLS DERIVED
25 FROM YOUR EMBRYO AND TRANSPLANT THEM INTO NONHUMAN

1 PRIMATES FOR THE FOLLOWING REASONS. THEY MAY HAVE OR
2 THEY MAY NOT HAVE, BUT IT'S POSSIBLE THAT A DONOR WOULD
3 SAY, IT NEVER OCCURRED TO ME THAT'S WHAT THEY WERE
4 GOING TO DO. ACTUALLY I HAVE VERY STRONG FEELINGS
5 ABOUT THAT, AND I NEVER WOULD HAVE CONSENTED HAD YOU
6 TOLD ME AT THE TIME.

7 SO, FIRST, YOU CAN'T TELL THEM EVERYTHING
8 THAT'S GOING TO HAPPEN. SO, LIKE, IT'S A WAY OF
9 PROTECTING PEOPLE FROM SAYING LATER THEY DIDN'T TELL ME
10 ABOUT THAT PARTICULAR USE, AND IT REALLY BOTHERS ME
11 THAT MY CELLS MIGHT HAVE BEEN USED FOR THAT PURPOSE.
12 THERE IS THAT TENSION.

13 MR. SHESTACK: THAT'S RIGHT. BUT YOU SHOULD
14 ACTUALLY SPELL IT OUT. IT'S JUST LIKE IN A DRUG AD NOW
15 WHERE YOU'VE GOT THE HAPPY COUPLE, AND THEN YOU'VE GOT
16 20 MINUTES OF, LIKE, EVERYTHING TERRIBLE THAT CAN
17 HAPPEN. BASICALLY SPELL IT OUT. YOUR PRODUCTS WILL BE
18 USED BY A PHARMACEUTICAL COMPANY. THIS MAY HAPPEN.
19 THAT MAY HAPPEN. IF YOU DON'T WANT TO DO IT, AND WE'RE
20 NEVER GOING BACK TO YOU, SO IF YOU DON'T WANT IT, DON'T
21 DO IT NOW. ACTUALLY DO IT IN PLAIN ENGLISH ONCE.

22 MS. KING: BUT IN CONNECTION WITH THIS
23 PROVISION, I THINK WHAT I HEAR YOU SAYING IS THAT ONCE
24 YOU GIVE RESEARCHERS PERMISSION, YOU NEED TO TELL THE
25 RESEARCHER THE LIMITS OF THE PERMISSION. AND ONE OF

1 THE THINGS THAT YOU WANT LINKED TO ALL FUTURE USES IS
2 SOMETHING THAT SAYS THIS MEANS THAT YOU MIGHT BE USED
3 IN THE FUTURE FOR THESE THINGS THAT WE CAN FORESEE NOW.
4 THAT'S THE THRUST OF IT.

5 MR. SHESTACK: YEAH.

6 MS. KING: BECAUSE WHAT HE'S SAYING IS YOU
7 DON'T KNOW WHAT YOU'RE GIVING -- IF YOU GO TO A
8 SUBJECT, YOU DON'T -- THE SUBJECT DOESN'T KNOW WHAT
9 THEY'RE GIVING UP UNLESS YOU GIVE THEM SOME EXAMPLES OF
10 WHAT FUTURE USES ARE.

11 DR. HALL: THE WHOLE POINT OF IT IS IT'S
12 IMPOSSIBLE TO MAKE, FIRST OF ALL, AN EXHAUSTIVE LIST
13 EVEN FOR WHAT WE DO KNOW. SECOND, TO IMAGINE WHAT
14 WOULD HAPPEN LATER ON.

15 MS. KING: WE DO HAVE SOME IDEAS.

16 DR. HALL: IF YOU START DOWN THE TRAIL, IT
17 SEEMS TO ME IT'S MUCH WORSE. THEN THEY CAN SAY, WELL,
18 YOU TOLD ME ABOUT THIS, THIS, AND THIS, BUT YOU DIDN'T
19 TELL ME ABOUT THAT.

20 MS. KING: ALL YOU HAVE TO DO IS SAY THESE
21 ARE THE KINDS OF EXAMPLES. WE KNOW WHAT FUTURE USES
22 ARE, AND I THINK WHAT I'M HEARING IS PATIENTS -- PEOPLE
23 WHO COME IN TO DONATE COME IN FOR THEIR OWN REASONS.
24 THEY DON'T NECESSARILY KNOW WHAT FUTURE USES, AND THEY
25 MAY NOT EVEN OBJECT ACTUALLY, BUT THEY PROBABLY DON'T

1 REALLY HAVE AN UNDERSTANDING OF YOU MAY END UP IN
2 MULTIPLE STUDIES IN THE FUTURE. YOU MAY END UP IN
3 STUDIES AND TYPES OF RESEARCH THAT WE CAN'T EVEN
4 ANTICIPATE. EVEN THAT'S USEFUL INFORMATION. WE WON'T
5 KNOW WHAT IT IS.

6 I THINK THAT'S THE THRUST OF WHAT YOU'RE
7 SAYING, THAT IN SOME WAYS PEOPLE ARE NOT REALLY
8 INFORMED BECAUSE THEY HAVEN'T A CLUE ABOUT WHAT FUTURE
9 USES RAISES.

10 CO-CHAIR LO: ALTA AND THEN FRANCISCO.

11 MS. CHARO: PAT, I WONDER IF WE CAN ENCOURAGE
12 YOU TO TAKE THIS ANOTHER STEP BECAUSE IF WE GO BACK TO
13 PAGE 7, MANY OF THE THINGS THAT YOU'VE JUST MENTIONED
14 ACTUALLY ARE ALREADY THERE. SO THERE HAS BEEN AN
15 ATTEMPT TO ANTICIPATE THOSE THINGS THAT WE KNOW ALREADY
16 TEND TO BE SORE SPOTS WITH PEOPLE. AND I TAKE JON'S
17 POINT, THE POSSIBILITY THAT THERE MIGHT BE COMMERCIAL
18 TENSION MIGHT BE REWRITTEN MORE VIVIDLY AS THIS
19 POSSIBILITY THAT SOMEBODY ELSE, INCLUDING A
20 PHARMACEUTICAL COMPANY, MIGHT MAKE MONEY OFF THIS.
21 THAT WAS ABOUT MAKING IT MORE VIVID.

22 TOPICALLY IT ALREADY SAYS THAT PEOPLE NEED TO
23 BE INFORMED THAT IT MAY INVOLVE GENETIC MANIPULATION,
24 THAT IT MIGHT INVOLVE --

25 MR. SHESTACK: TRANSPLANTATION.

1 MS. CHARO: -- INTO ANIMALS, THAT THERE MAY
2 BE STUDIES THAT CAN'T BE DESCRIBED AT THIS TIME. SO
3 GIVEN THIS LIST AND GIVEN THE POSSIBILITY THAT MAYBE WE
4 NEED TO MAKE THE LIST MORE VIVID, ARE THERE TOPICS, ARE
5 THERE PARTICULAR KINDS OF TOPICS THAT YOU CAN IMAGINE
6 NEED TO BE ADDED TO THE LIST THAT WE KNOW ARE POTENTIAL
7 SORE SPOTS FOR PEOPLE AND WE WANT TO GIVE THEM FAIR
8 WARNING.

9 MS. KING: NO. I WOULD GO IN A DIFFERENT
10 DIRECTION. RESEARCHERS WILL KNOW FROM THE VERY
11 BEGINNING THAT THEY'RE GOING TO REQUIRE THAT EVERYBODY,
12 IF THIS PERMISSIBLE, THAT EVERYBODY AGREE TO ALL FUTURE
13 USES. RIGHT. THEY WILL KNOW WHEN THEY SET OUT THE
14 PROJECT THAT'S WHAT THEY'RE GOING TO DO, I ASSUME.

15 MS. CHARO: SURE. NOT ALL RESEARCHERS ARE
16 GOING TO DO THAT. A LOT OF THEM.

17 MS. KING: I JUST WANT A RESEARCHER IN DOING
18 INFORMED CONSENT WHO DECIDES TO GO THIS OPTION BE SURE
19 TO SPELL OUT ALL FUTURE USES. I'M TALKING ABOUT A
20 PROCESS POINT. IF YOU'RE A RESEARCHER AND YOU KNEW YOU
21 ONLY WANTED TO USE SUBJECTS FOR ALL FUTURE USES, WHAT
22 WOULD YOU DO?

23 MR. SHESTACK: I DON'T UNDERSTAND PART OF
24 (F).

25 CO-CHAIR LO: THE POINT OF (F) -- LET ME TRY

1 AND PROVIDE SOME BACKGROUND. (A), PAT AND JON, TRIES
2 TO DO THE CONSENT TO DONORS. WE TRY AND SAY YOU NEED
3 TO BE TOLD THE FOLLOWING THINGS. AND I TAKE JON'S
4 POINT, THAT SOME OF THE THINGS IN THAT (1) THROUGH (9)
5 NEEDED TO BE STATED MORE CLEARLY, PLAIN ENGLISH.

6 (F) WAS PUT IN TO ADDRESS RESEARCHERS'
7 CONCERNS WHO CAME TO US AND SAID, LOOK, IT LOOKS LIKE
8 YOU'RE GIVING PEOPLE THE OPPORTUNITY TO OPT OUT, WHICH
9 WE THINK IS IMPORTANT, BUT THEN THAT MEANS I CAN'T USE
10 THEIR STEM CELLS BECAUSE I DON'T KNOW WHAT I'M GOING TO
11 END UP DOING. (F) WAS REALLY MEANT TO REASSURE
12 RESEARCHERS THAT IF THEY CHOSE TO LIMIT PEOPLE AND
13 DONORS AND MATERIALS IN THEIR STUDIES TO THOSE WHO
14 AGREED TO A BROAD RANGE OF FUTURE AND AS YET
15 UNSPECIFIED USES, THAT WOULD BE PERMISSIBLE.

16 DR. HALL: IF YOU ARE SUCCESSFUL IN DERIVING
17 A CELL LINE, IT'S GOING TO BE SHIPPED AROUND THE WORLD.
18 AND PEOPLE WILL USE IT FOR ALL SORTS OF DISEASES AND
19 ALL SORTS OF WAYS POSSIBLE. THAT'S THE MOST -- THAT'S
20 WHAT WE HOPE FOR IS A LINE THAT'S SO SUCCESSFUL, THAT
21 EVERYBODY WILL WANT TO USE IT. AND IT JUST --

22 MS. KING: THIS IS NOT A SCIENTIST ISSUE.
23 THIS IS AN INFORMED CONSENT ISSUE TO ME. AND THIS
24 PARAGRAPH STUCK HERE BY ITSELF IN REGULATORY LANGUAGE
25 NEEDS SOME WORDS THAT SAYS --

1 DR. HALL: SUCH AS.

2 MS. KING: IT MAY BE REFERRED BACK TO ALL THE
3 PROVISIONS BEFORE, THAT THE DIRECTION TO THE RESEARCHER
4 SHOULD NOT BE ALLOWED TO HANG BY ITSELF. THAT'S
5 BASICALLY WHAT MY OBJECTION IS. AND THAT IS, UNLESS
6 YOU AGREE -- THAT YOU MAY ONLY HAVE IN YOUR GROUP THOSE
7 WHO'VE AGREED TO ALL FUTURE USES. BUT ALL THOSE FUTURE
8 USES HAVE BEEN DISCLOSED BECAUSE IF YOU KNOW --

9 CO-CHAIR LANSING: WE CAN'T. DON'T KNOW WHAT
10 THEY ARE.

11 MS. KING: THAT'S EXACTLY RIGHT.

12 CO-CHAIR LO: TO THE EXTENT WE CAN DISCLOSE.
13 THERE ARE OTHERS WE CAN'T EVEN TELL YOU ABOUT. I THINK
14 PAT'S SAYING THAT THE RESEARCHER, YOU HAVE TO REFER
15 BACK TO (A)(1) THROUGH (9).

16 MS. KING: PART OF IT IS PLACEMENT. AND THAT
17 IS, THAT YOU MIGHT BE DISCLOSING ALL THESE USES SO THAT
18 PEOPLE CAN OPT OUT FROM ONE OR TWO. YOU MIGHT BE
19 DISCLOSING ALL THOSE USES BECAUSE YOU WANT TO ELIMINATE
20 THOSE PEOPLE ALTOGETHER.

21 CO-CHAIR LO: OBJECT TO ANYTHING. IT'S A
22 PLACEMENT IN CONTEXT ISSUE. THAT'S HELPFUL.

23 DR. PRIETO: JUST A COMMENT ON THAT. I THINK
24 THIS IS JUST AN ISSUE OF FULLY INFORMED CONSENT. AND I
25 THINK YOU COULD USE THE LEGAL LANGUAGE OF INCLUDING,

1 BUT NOT LIMITED TO THOSE REFERENCED IN (A). BUT THEN I
2 THINK THE OTHER ISSUE ABOUT INFORMED CONSENT, I DON'T
3 KNOW IF WE NEED TO ADDRESS IT IN THIS LANGUAGE OR WHERE
4 WE WOULD ADDRESS IT, BUT THAT I'M VERY CONCERNED THAT
5 IT MUST BE IN PLAIN ENGLISH AT A LEVEL THAT'S
6 UNDERSTANDABLE TO THE PARTICIPANTS BECAUSE THAT'S A
7 GREAT FAILING OF INFORMED CONSENT IN GENERAL OR WHAT WE
8 NOW CALL INFORMED CONSENT.

9 I'VE BEEN EXPOSED TO A LITTLE OF THIS JUST IN
10 PRACTICE AND IN MY GROUP AND MY HOSPITAL, AND MUCH OF
11 THIS IS WRITTEN BY ATTORNEYS SOMETIMES, IT SEEMS, FOR
12 THE UNDERSTANDING OF PEOPLE WITH A SIMILAR LEVEL OF
13 EDUCATION, BUT IS NOT REALLY APPROACHABLE OR
14 UNDERSTANDABLE BY THE PEOPLE WHO HAVE TO GIVE THE
15 CONSENT.

16 CO-CHAIR LO: I THINK THAT'S INCLUDED IN THAT
17 FIRST PARAGRAPH, BUT NOT EXPLICITLY IN TERMS OF BOTH
18 CLEAR LANGUAGE AND IN A LANGUAGE UNDERSTANDABLE TO THE
19 RESEARCH PARTICIPANT.

20 DR. PRIETO: I THINK THAT'S THE KEY POINT.

21 CO-CHAIR LANSING: THEN IF YOU GET TO THE
22 END, YOU HAVE TO GO HOME AND THINK ABOUT IT.

23 DR. PRIETO: WE HAVE TO HAVE A WAY OF
24 ASSESSING THEIR UNDERSTANDING.

25 CO-CHAIR LO: WORTH PULLING THAT OUT

1 EXPLICITLY. THAT IS SO IMPORTANT. THAT'S GOOD.

2 CAN I CALL YOUR ATTENTION TO (G) BEFORE WE
3 TRY AND ADJOURN. (G) IS, AGAIN, GOING WAY BEYOND WHAT
4 THE CUSTOMARY STANDARD PRACTICE IS TO SAY THAT IN
5 ADDITION TO DISCLOSING ALL THIS INFORMATION, YOU HAVE
6 TO HAVE A PROCESS THAT YOUR IRB OR ESCRO APPROVED TO
7 ASCERTAIN WHETHER THE SUBJECT HAS ACTUALLY UNDERSTOOD
8 AT A MINIMUM THE FOLLOWING POINTS. WE'RE ASKING DID
9 THEY REALLY UNDERSTAND ALL THE STUFF THAT WE DISCLOSED.

10 SO IT'S BOTH AN INNOVATION OF SOME SORT. YOU
11 HAVE TO HAVE SOME PROCEDURE IN PLACE. AND THEN, OF
12 COURSE, THERE'S ALWAYS THE QUESTION OF WHAT THINGS ARE
13 YOU GOING TO ASK THEM ABOUT THAT THEY NEED TO KNOW. WE
14 TRIED TO REALLY GET SORT OF THE NINE THINGS THAT WE
15 THOUGHT WERE THE ESSENTIALS. AND THOSE MAY OR MAY NOT
16 BE THE RIGHT NINE. THAT'S WORTH A CAREFUL LOOK, PAT,
17 SINCE YOU WEREN'T INVOLVED IN THE ORIGINAL.

18 MS. KING: MAYBE IT WOULD BE BETTER TO, IN
19 TERMS OF HOW TO REALLY MAKE THIS INFORMED, IS TO HAVE
20 THE ISSUE OF FUTURE USES IN THE COMPREHENSION SECTION.
21 IT MIGHT BE, IN TERMS OF HOW -- FROM AN INFORMED
22 CONSENT PERSPECTIVE, WHAT I CALL THE COMPREHENSION
23 SECTION, THAT THE ONE THING YOU REALLY WANT THEM TO
24 COMPREHEND IS ALL FUTURE USES.

25 CO-CHAIR LO: THE INTENT. THAT'S ESSENTIAL.

1 THAT WAS HELPFUL. OTHER CONCERNS ABOUT ANYTHING ON
2 THIS PAGE?

3 MR. SHEEHY: I THINK THIS WAS WHERE
4 JONATHAN'S POINT MIGHT NEED TO BE ABOUT COMMERCIAL
5 POTENTIAL, THE POINT THAT HE WAS ALLUDING TO, THAT
6 PEOPLE MIGHT WANT TO ASK FOR COMPREHENSION.

7 CO-CHAIR LO: SO THAT WOULD BE ANOTHER POINT
8 ABOUT THE COMMERCIAL --

9 MR. SHEEHY: I PUT IT OUT THERE.

10 MR. SHESTACK: MY CONCERN ACTUALLY WAS FOR
11 PROTECTION -- WAS IN A WAY FOR THE EASY LIFE OF THE
12 RESEARCHER. I JUST FOUND OUR OWN SIMPLE EXPERIENCE
13 WITH A GENE BANK WAS WE DIDN'T REALLY WRITE IT
14 SPECIFICALLY ENOUGH THAT PHARMACEUTICAL COMPANIES WERE
15 GOING TO SOMETIMES ACCESS THIS DNA. WE SORT OF SAID
16 MULTIPLE USERS AND MANY ACADEMIC INSTITUTIONS, AND WE
17 DIDN'T ACTUALLY SAY PHARMA AND BIOTECH. THEN WE HAD
18 SEVERAL INSTANCES WHERE FAMILIES DECIDED THEY DIDN'T
19 LIKE PHARMACEUTICAL COMPANIES ANYMORE, WHATEVER IT WAS,
20 AND THEY SAID YOU HAVE TO WITHDRAW OUR FAMILIES FROM
21 THE COLLECTION. WE SAID, WELL, YOU CONSENTED, AND THEY
22 SAID WE DIDN'T UNDERSTAND WHAT WE CONSENTED TO, AND SO
23 WE WITHDRAW THEIR FAMILIES FROM THE COLLECTION.

24 WE HAD TO SEND NOTICES, AND WE DID EVERYTHING
25 WE HAD TO DO. BUT IN RETROSPECT, WE COULD HAVE

1 ACTUALLY BEEN REALLY SPECIFIC AND KNOWN THAT THIS IS A
2 HOT BUTTON ISSUE FOR SOME FAMILIES AND MADE IT EASIER,
3 BETTER FOR THEM AND EASIER ON OURSELVES BY JUST REALLY
4 SAYING AS CLEARLY AS POSSIBLE PHARMA, THE BAD GUYS, OR
5 NOT, WHATEVER YOU THINK, BUT SAY IT.

6 DR. PRIETO: NOT EVEN PHARMA, AND NOT EVEN
7 USING WORDS LIKE COMMERCIAL DEVELOPMENT, BUT SOMEONE
8 MAY MAKE MONEY OFF OF AN INVENTION THAT WILL BE DERIVED
9 IN SOME WAY FROM YOUR CELLS AND YOU WILL NOT
10 PARTICIPATE IN THIS.

11 (SIMULTANEOUS DISCUSSION.)

12 DR. PRIETO: AND IT MAY BE 50 YEARS FROM NOW
13 OR 500, BUT THIS IS A POSSIBILITY.

14 CO-CHAIR LO: I THINK WHAT I HEAR JON SAYING,
15 AND I THINK IT'S A VERY IMPORTANT POINT, IT'S SORT OF
16 THERE, BUT IT'S NOT THERE LANGUAGE WHERE IT HITS PEOPLE
17 AND SAYS, OH, THAT'S WHAT YOU MEAN.

18 ANY SPECIFIC SUGGESTIONS, JON, AND THOSE OF
19 YOU, KEVIN, THOSE WHO HAVE ACTUALLY HAD EXPERIENCE
20 GETTING CONSENT TO SHARPEN THIS WOULD BE HELPFUL.
21 OBVIOUSLY THE IRB IS GOING TO BE GOING OVER THE ACTUAL
22 CONSENT DOCUMENT AND THE PROCEDURE FOR ASSESSING
23 COMPREHENSION. BUT ANYTHING WE CAN DO TO MAKE IT
24 CLEARER, I THINK, WOULD DEFINITELY BE A GOOD POINT.

25 DR. KIESSLING: THIS REALLY DEPENDS ON WHOSE

1 LAWYERS YOU ARE TALKING TO, HOW THEY WANT THIS WORDED.
2 THIS IS REALLY HARD, I THINK. IN THE CONCEPT THAT THE
3 DONORS SIMPLY GIVE UP ALL RIGHTS TO THEIR EGGS AND
4 WHATEVER THEIR EGGS MAY DERIVE SEEMS TO BE THE
5 CLEAREST.

6 CO-CHAIR LO: GIVING UP ALL RIGHTS IS
7 DIFFERENT THAN SAYING A PHARMACEUTICAL COMPANY IS GOING
8 TO MAKE MONEY OFF YOUR EGG.

9 DR. KIESSLING: THAT'S USUALLY PART OF IT.
10 YOUR EGGS MAY BE USED IN COMMERCIAL DEVELOPMENT, AND
11 YOU HAVE NO RIGHTS TO THOSE. THERE'S PROBLEMS WITH
12 ASKING PEOPLE TO GIVE UP ALL THEIR RIGHTS.

13 CO-CHAIR LO: AGAIN, I THINK WE WANT TO MAKE
14 THIS COMPREHENSIBLE TO THE SUBJECTS AND NOT MAKE THE
15 LAWYERS NECESSARILY HAPPY.

16 WE'RE GOING TO NEED TO COME BACK TO THIS
17 TOMORROW. I WANT TO GIVE THE PUBLIC A CHANCE TO WEIGH
18 IN ON THIS CONSENT SECTION, WHICH I THINK IS VERY
19 IMPORTANT.

20 MR. REED: I USED TO WRITE SCIENCE ARTICLES
21 FOR *HIGHLIGHTS FOR CHILDREN*, A CHILDREN'S SCIENCE
22 MAGAZINE YEARS AGO. I WOULD SUGGEST YOU START OFF WITH
23 THE BASIC CONCERN AND JUST SAY, AS WITH A BLOOD
24 DONATION, YOU WILL NOT BE ABLE TO KNOW WHAT HAPPENS TO
25 THE CELLS THAT YOU DONATE. WE HOPE THAT SOMETHING GOOD

1 WILL COME OF IT. HERE ARE SOME POSSIBILITIES AND LEAVE
2 IT AT THAT.

3 SOMETHING ELSE TO CONSIDER IS THE WAY THE UK
4 DOES IT, WHICH IS THEY TEACH AN ACTUAL COURSE AND GIVE
5 PEOPLE AN ACTUAL TEST AT THE END OF IT SO THEY CAN
6 NEVER SAY I DID NOT UNDERSTAND.

7 CO-CHAIR LO: THE TEST IS -- WE'RE NOT GIVING
8 THE COURSE AT CIRM, BUT WE'RE SAYING IN A SENSE THE
9 INVESTIGATOR HAS TO HAVE THE IRB APPROVE OF THE TEST OF
10 COMPREHENSION.

11 MR. REED: NO, A TEST FOR THE PERSON WHO
12 DONATES THEIR EGGS.

13 CO-CHAIR LO: THAT'S WHAT WE'RE SAYING.
14 THAT'S WHAT (G) IS ABOUT. IT'S A TEST FOR THE RESEARCH
15 DONORS.

16 MS. GREENFIELD: FOR (B) ON THE RISKS, AS A
17 WOMAN WHO UNDERWENT IVF TWICE, I FEEL LIKE THE RISKS
18 ARE SUBTLY WRITTEN TO ASSUME OR HAVE A PRESUMPTION OF
19 OVARIAN STIMULATION. AND I WOULD LIKE YOU GUYS TO
20 CONSIDER THE IDEA OF ADDING THE FACT THAT NATURAL
21 RETRIEVAL IS POSSIBLE. I WAS NEVER GIVEN THAT OPTION.
22 I WAS NEVER TOLD OF IT. AND I THINK IT WOULD BE A
23 MAJOR STEP FORWARD TO INCLUDE IN THE CONSENT THE IDEA
24 THAT YOU DO NOT HAVE TO UNDERGO OVARIAN
25 HYPERSTIMULATION. THAT'S ONE POINT.

1 MY SECOND POINT IS AS TO MR. SHESTACK'S
2 ADMONITION, THERE IS A EUROPEAN MODEL FOR CONSENT
3 THAT'S SAYS AN INVENTION IS BASED ON BIOLOGICAL
4 MATERIAL OF HUMAN ORIGIN; OR IF IT USES SUCH MATERIAL,
5 THE PERSON FROM WHOSE BODY THE MATERIAL IS TAKEN MUST
6 HAVE HAD AN OPPORTUNITY OF EXPRESSING FREE AND INFORMED
7 CONSENT THERETO IN ACCORDANCE WITH NATIONAL LAW.

8 SOMEWHERE IN BETWEEN, YOU KNOW, IT WILL BE
9 COMMERCIALIZED AND YOUR BODY WILL MAKE SOMEBODY ELSE
10 VERY WEALTHY. MAYBE THERE'S SOME MIDDLE GROUND. THANK
11 YOU.

12 MS. FOGEL: I HAVE A COUPLE OF THINGS. FIRST
13 OF ALL, UNDER DISCLOSURES, I THINK THAT THERE NEEDS TO
14 BE DISCLOSURE OF THE RELATIONSHIP BETWEEN THE PHYSICIAN
15 AND THE RESEARCH -- WHOEVER THE RESEARCHER IS. WE DID
16 COMMENT ON HOW EARLIER THAT RELATIONSHIP IS DRAWN SO
17 VERY NARROWLY, IT'S JUST THEY CAN'T BE THE SAME PERSON,
18 AND THERE CAN BE AN EXEMPTION AS YOU ADOPTED IT. SO IT
19 SEEMS TO US THAT WHATEVER THAT RELATIONSHIP IS OUGHT TO
20 BE DISCLOSED WHEN WE'RE TALKING ABOUT EGG EXTRACTION.

21 I WAS CURIOUS WHY -- THE NATIONAL ACADEMIES
22 GUIDELINES SUGGEST THAT WOMEN SHOULD BE ABLE TO HAVE
23 SOMETHING TO SAY ABOUT HOW THEIR EGGS ARE GOING TO BE
24 USED, BUT (F) AS YOU'VE DEBATED --

25 DR. HALL: SAYS YOU MAY DO THAT.

1 MS. FOGEL: I KNOW. ALL RIGHT. YOU MAY.
2 THEY'RE GUIDELINES. IT ALL SAYS MAY.

3 DR. HALL: NO. NO.

4 MS. FOGEL: OF COURSE, (F) AS YOU -- WE HAVE
5 CONCERNS TOO THAT (F) JUST KIND OF SWALLOWS THAT. THAT
6 DOESN'T REALLY ENCOURAGE RESEARCHERS TO OFFER THOSE
7 OPTIONS TO PATIENTS.

8 MS. CHARO: IF I MAY CORRECT, I SERVED ON
9 THAT COMMITTEE. SO THAT WAS A MAY BECAUSE WE
10 ABSOLUTELY ANTICIPATED THAT RESEARCHERS WOULD NOT BE IN
11 A POSITION AT ALL TIMES TO ADEQUATELY PREDICT WHAT THE
12 STUDIES WERE GOING TO BE AND, THEREFORE, WOULD HAVE TO
13 MAKE A CHOICE BETWEEN LIMITING THE USEFULNESS OF STEM
14 CELL LINES INDEFINITELY INTO THE FUTURE WITH ALL THE
15 RECORDKEEPING COMPLICATIONS AS THEY'RE MOVED AROUND THE
16 COUNTRY OR HAVING STEM CELL LINES DONATED ONLY WITH
17 OPEN-ENDED PERMISSION. SO THERE IS NO IMPLICATION IN
18 THE NATIONAL ACADEMY GUIDELINES THAT THERE WAS AN
19 ATTEMPT TO DISCOURAGE THE CREATION OF OPEN-ENDED STEM
20 CELL LINES. IT WAS THERE BECAUSE SOME RESEARCHERS WILL
21 WANT TO OPT FOR THAT, AND OTHERS ON OTHER OCCASIONS MAY
22 WANT TO CREATE STEM CELL LINES WITH LIMITED USEFULNESS.

23 MS. FOGEL: I WAS THINKING PERHAPS IT COULD
24 BE LIKE A TWO-TIERED WHERE THE EMPHASIS IS ON OFFERING
25 THAT OPTION, AND THEN THIS IS THE FALLBACK AS OPPOSED

1 TO IT BEING THE OPTION WE FIGURE EVERYONE IS GOING TO
2 CHOOSE.

3 MS. CHARO: REALISTICALLY, THE PROCESS OF
4 TRYING TO MAINTAIN A COMPREHENSIVE CATALOG OF
5 CONDITIONS FOR EACH LINE IS DAUNTING. AND RIGHT NOW A
6 LOT OF THE COMPLAINTS THAT CURRENTLY EXIST IN THE
7 ACADEMIC COMMUNITY ABOUT THE LICENSING FROM WISCONSIN
8 TO OTHER UNIVERSITIES STEMS EXACTLY, NO PUN INTENDED,
9 FROM THAT EXACTLY THAT PHENOMENON. WHEN THE ORIGINAL
10 LINES THAT JIM THOMPSON DEVELOPED WERE DERIVED, THEY
11 WERE DERIVED IN ACCORDANCE WITH A PROTOCOL IN WHICH THE
12 ORIGINAL DONORS WERE MADE CERTAIN PROMISES ABOUT WHAT
13 THE LINES WOULD BE USED FOR, WHAT THEY WOULD NOT BE
14 USED FOR. AND IT TURNED OUT THAT THAT NOW IS DOGGING
15 US, HOW MANY YEARS LATER, BECAUSE NOW, INSTEAD OF BEING
16 ABLE TO BE FAIRLY EASYGOING ABOUT OTHER UNIVERSITIES
17 USING THOSE LINES FOR PURE RESEARCH AND PUSHING THE
18 FIELD FORWARD, EVERY UNIVERSITY IS SUBJECT TO A
19 LICENSING AGREEMENT.

20 AND INVESTIGATORS IN KEVIN'S LAB CAN'T MOVE
21 THOSE LINES TO A LAB DOWN THE HALL WITHOUT ANOTHER
22 LICENSE OR ANOTHER NEGOTIATION SPECIFICALLY BECAUSE
23 YOU'VE GOT TO MAKE SURE EVERY USER IS AWARE OF THE
24 ORIGINAL CONDITIONS THAT WERE PLACED ON THOSE LINES BY
25 THE ORIGINAL DONORS.

1 SO WE'VE LEARNED FROM EXPERIENCE HOW
2 INCREDIBLY ONEROUS IT IS. AND FOR THAT REASON, THERE
3 WAS NEVER, AT LEAST IN TERMS OF HOW WE CHARACTERIZED
4 THE NATIONAL ACADEMY EFFORT, THERE WAS NEVER AN INTENT
5 TO MAKE LIMITATIONS ON LINES THE NORM OR THE PREFERRED
6 METHOD.

7 MS. FOGEL: I THINK THERE'S A DISAGREEMENT ON
8 WHERE THAT POWER SHOULD BE. I DON'T WANT TO BELABOR
9 IT. IT'S DAUNTING TO RESEARCHERS, BUT IT'S EMPOWERING
10 TO THE PEOPLE WHOSE GENETIC MATERIAL IN A WHOLE RANGE
11 OF ARENAS IS ASKED FOR. I DON'T WANT TO BELABOR THE
12 POINT, BUT IT'S ONLY DAUNTING DEPENDING ON WHICH SIDE
13 YOU SIT.

14 MR. SHESTACK: I THOUGHT THE REASON THAT
15 PEOPLE HAD TO GO BACK AND APPLY AND GET MULTIPLE
16 LICENSES WAS SO THAT THE UNIVERSITY OF WISCONSIN COULD
17 GET MULTIPLE PAYMENTS. WHAT IS ACTUALLY --

18 MS. CHARO: HONESTLY, IT'S LIKE A LITTLE EH,
19 EH, EH AT WISCONSIN. THEY DON'T MAKE THEIR MONEY BACK
20 ON THE PAYMENT, SO IT'S NOT ABOUT THE MONEY. THERE
21 WERE PROMISES MADE ABOUT NO XENOTRANSPLANT. NO
22 CHIMERAS, NO XENOTRANSPLANT. AT THE TIME NOBODY
23 THOUGHT IT WOULD BE.

24 CO-CHAIR LO: I THINK THAT'S THE WHOLE POINT.

25 MS. CHARO: AND THAT'S EXACTLY THE WHOLE

1 POINT.

2 MS. FOGEL: IN (B), IN TERMS OF THE RISKS,
3 WHILE YOU TALK ABOUT THE RISKS OF OVARIAN
4 HYPERSTIMULATION SYNDROME, THOSE ARE THE HYPER
5 STIMULATING DRUGS. THERE'S NOTHING ABOUT THE RISKS OF
6 THE DRUGS USED TO SHUT DOWN THE OVARIES, AND THAT ALSO
7 OUGHT TO BE INCLUDED, BOTH SHORT-TERM AND LONG-TERM
8 RISKS.

9 IN (D), JUST A LITTLE THING THAT SAYS CALLS
10 INSTEAD OF CELLS.

11 AND UNDER (G) --

12 CO-CHAIR LO: I'M SORRY. THE LAST STATEMENT,
13 WHERE IS THAT?

14 MS. FOGEL: UNDER -- I'M SORRY. I'M A NERDY
15 EDITOR. UNDER (D), IT SAYS AS TO WHETHER THE DONATED
16 CALLS MAY BE AVAILABLE INSTEAD OF CELLS.

17 UNDER (G), SINCE YOU DID ADOPT A
18 RECOMMENDATION THAT HEALTHCARE BE PROVIDED, THAT OUGHT
19 TO BE PART OF THE INFORMATION THAT'S GIVEN TO THE EGG
20 DONOR SO THAT SHE KNOWS THAT ANY HEALTH RISKS WILL BE
21 COVERED. THANK YOU.

22 CO-CHAIR LO: ANY OTHER PUBLIC COMMENTS?
23 OKAY. IS JENNIFER HERE? I UNDERSTAND THERE WERE SOME
24 SUGGESTIONS FOR DINNER FOR THIS HARDWORKING CREW AS TO
25 WHEN AND WHERE AND HOW TO GET THERE. SO I WOULD BE

1 GLAD TO HEAR A MOTION TO ADJOURN.

2 MS. CHARO: SO MOVED.

3 CO-CHAIR LO: HEARING NO OBJECTION, THIS
4 MEETING IS ADJOURNED. THANK YOU VERY MUCH BOTH TO THE
5 MEMBERS OF THE SWG AND TO THE PUBLIC FOR THEIR
6 COMMENTS. AND HERE IS JENNIFER TO TELL US ABOUT FOOD.

7 (THE MEETING WAS THEN CONCLUDED AT 05:14
8 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUPS OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

THE LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA
ON
MONDAY, JANUARY 30, 2006

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

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