

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

LOCATION: TELECONFERENCE

DATE: FRIDAY, JULY 27, 2007  
12 P.M.

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

BRS FILE NO.: 79019

**BARRISTERS' REPORTING SERVICE**

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I N D E X

| ITEM              | DESCRIPTION  | PAGE NO. |
|-------------------|--|----------|
| CALL TO ORDER     |  | 3        |
| ROLL CALL         |  | 3        |
| CONSIDERATION OF: |  |          |
| A.                | USE OF CELL LINES DERIVED UNDER JAPANESE GUIDELINES    | 5        |
| B.                | LIMITATIONS ON PAYMENTS FOR CELLS                      | 78       |
| C.                | REQUIREMENTS FOR USE OF SOMATIC CELLS AND HUMAN TISSUE | 50       |
| ADJOURNMENT       |  | 88       |

**BARRISTERS' REPORTING SERVICE**

1 FRIDAY, JULY 27, 2007

2

3 CHAIRMAN LO: SO I GUESS I'D LIKE TO FORMALLY  
4 WELCOME EVERYBODY. IT'S A GORGEOUS DAY HERE IN SAN  
5 FRANCISCO. THERE'S A GIANTS GAME THIS EVENING AND FANS  
6 ACROSS THE STREET.

7 GEOFF, DO YOU WANT TO DO FORMAL ROLL CALL.

8 DR. LOMAX: SURE. I WILL GO THROUGH WHO I  
9 UNDERSTAND TO BE ON THE LINE; AND IF I MISSED ANYONE,  
10 COULD YOU PLEASE IDENTIFY YOURSELF?

11 MARCY FEIT.

12 MS. FEIT: HERE.

13 DR. LOMAX: JEFF SHEEHY.

14 MR. SHEEHY: HERE.

15 DR. LOMAX: ALTA CHARO.

16 MS. CHARO: HERE.

17 DR. LOMAX: BERNIE LO.

18 CHAIRMAN LO: HERE.

19 DR. LOMAX: PATRICIA KING.

20 MS. KING: HERE.

21 DR. LOMAX: TED PETERS.

22 DR. PETERS: HERE.

23 DR. LOMAX: JOSE CIBELLI.

24 DR. CIBELLI: HERE.

25 DR. LOMAX: KEVIN EGGAN.

## BARRISTERS' REPORTING SERVICE

1 DR. EGGAN: HERE.

2 DR. LOMAX: ROB TAYLOR.

3 DR. TAYLOR: HERE.

4 DID I MISS ANYONE? OKAY.

5 CHAIRMAN LO: ANY PUBLIC MEMBERS ON THE PHONE?  
6 IF SO, WELCOME, AND WOULD YOU LIKE TO IDENTIFY YOURSELF?

7 DR. LOMAX: WE DON'T. IN FACT, THE LINE IS NOT  
8 OPEN TO THE PUBLIC FOR THIS MEETING. THAT'S WHY WE HAVE  
9 IT AT THIS LOCATION, BUT IT'S GOOD. WE WANT TO KNOW IF  
10 THERE WERE PUBLIC MEMBERS ON THE CALL.

11 CHAIRMAN LO: WE HAVE SEVERAL PUBLIC MEMBERS  
12 HERE AS WELL AS SOME CIRM STAFF. YOU ARE ALLOWED TO EAT  
13 YOUR LUNCH.

14 DR. LOMAX: ONE ITEM, JUST TO UPDATE FOLKS ON,  
15 WE DIDN'T INTEND A FORMAL UPDATE, BUT WE RECEIVED NOTICE  
16 THIS WEEK THAT OUR FETAL TISSUE REGULATION, WHICH WE  
17 DISCUSSED EARLIER THIS YEAR IN APRIL, I BELIEVE, HAS BEEN  
18 APPROVED AND PASSED THE OFFICE OF ADMINISTRATIVE LAW. SO  
19 THAT IS GOOD NEWS. AND APPRECIATE EVERYONE'S HELP IN  
20 HELPING US DEVELOP THAT REGULATION.

21 WHAT I'VE BEEN ASKED TO DO FROM BERNIE IS TO  
22 INTRODUCE THE THREE ITEMS THAT ARE DESCRIBED IN THE  
23 BRIEFING MEMO AND THE SLIDES. WHAT I'M DOING AT THE  
24 PUBLIC SESSION HERE IS ESSENTIALLY READING OFF THE  
25 SLIDES.

## BARRISTERS' REPORTING SERVICE

1           CHAIRMAN LO:  HI.  WELCOME.  THIS IS BERNIE.  
2  WHO JUST JOINED?

3           DR. KIESSLING:  ANN KIESSLING.

4           DR. LOMAX:  SO WHAT WE'LL DO IS THE PROCEDURE  
5  FOR TODAY IS WE'D LIKE TO ADDRESS THE THREE ISSUES THAT  
6  ARE IDENTIFIED IN THE BRIEFING MEMO AND THE SLIDES.  WE'D  
7  LIKE TO GO THROUGH THEM ONE AT A TIME AND DEAL WITH EACH  
8  ITEM INDIVIDUALLY.  AND HOPEFULLY WE WILL GET THROUGH  
9  THAT IN THE ALLOTTED TIME OR SOME POINT LESS THAN THE  
10  ALLOTTED TIME.

11          CHAIRMAN LO:  ALWAYS GOOD TO HOPE FOR.

12          DR. LOMAX:  VERY GOOD.  ON THE SECOND SLIDE,  
13  WHICH LISTS THE ITEMS FOR CONSIDERATION, I'M NOW MOVING  
14  TO THE THIRD SLIDE, WHICH IS POINT ONE OR ISSUE NO. 1,  
15  THE JAPANESE GUIDELINES FOR STEM CELL RESEARCH.

16          BY WAY OF BACKGROUND, THE SENSE OF THE  
17  COMMITTEE IN OUR MAY MEETING WAS THAT STAFF SHOULD GO  
18  AHEAD AND REVIEW THE GUIDELINES FOR INCLUSION IN OUR  
19  REGULATIONS.  THE ATTACHMENT TO THE BRIEFING MEMO  
20  PROVIDES AN OVERVIEW OF THE COMPARABILITY OF THE  
21  GUIDELINES TO OUR REGULATIONS, AND WE ALSO WANTED TO  
22  POINT OUT THAT THE VALUE OF INCLUDING THE GUIDELINES  
23  WOULD INCREASE THE NUMBER OF CELL LINES AVAILABLE TO  
24  RESEARCHERS THAT COULD BE UTILIZED IN RESEARCH WITHOUT  
25  FURTHER REVIEW BY THE SCRO COMMITTEES, AND THAT THIS

## BARRISTERS' REPORTING SERVICE

1 POLICY SUPPORTS EFFORT TO PROMOTE INTERNATIONAL EXCHANGE  
2 AND COLLABORATION IN CIRM-FUNDED RESEARCH. THAT'S BOTH  
3 THE RATIONALE AND THE SORT OF POLICY DOCUMENTATION FOR  
4 MOVING FORWARD WITH THIS MODIFICATION.

5 CHAIRMAN LO: ANY DISCUSSION OF THIS ITEM?

6 DR. CIBELLI: JUST FOR MY INFORMATION, CAN YOU  
7 TELL ME HOW MANY CELL LINES WE'RE TALKING ABOUT HERE?

8 DR. LOMAX: MY UNDERSTANDING IS IT'S A FAIRLY  
9 MODEST NUMBER. I DON'T THINK IT'S ON THE ORDER OF FIVE  
10 CELL LINES. I DON'T THINK IT'S AN EXTENSIVE NUMBER AT  
11 THIS POINT, BUT I DON'T HAVE AN EXACT ANSWER TO THAT  
12 QUESTION.

13 DR. CIBELLI: THANK YOU.

14 DR. LOMAX: WHAT WE DO KNOW AND WHAT WE WERE  
15 INFORMED BY A DELEGATION FROM JAPAN IS THAT THEY ARE ALL  
16 LINES THAT HAVE BEEN DERIVED FROM EMBRYOS THAT WERE  
17 INTENDED FOR REPRODUCTIVE USE THAT WERE NO LONGER  
18 REQUIRED FOR THAT USE AND HAVE BEEN DONATED TO THE  
19 RESEARCH INSTITUTE FOR THE PURPOSE OF DERIVATION.

20 CHAIRMAN LO: YOU WANT TO SAY ANYTHING ABOUT  
21 THE CONSENT FOR THAT DONATION?

22 DR. LOMAX: AGAIN, IN THE PAST I'VE CIRCULATED  
23 THE ACTUAL LAW. THE CONSENT IN TERMS OF THE CONTENT OR  
24 THE SUBSTANCE OF THE CONSENT, IT IS VERY DETAILED. IT'S  
25 SOMEWHAT ANALOGOUS TO THE CONSENT THAT IS IN OUR

## BARRISTERS' REPORTING SERVICE

1 REGULATIONS IN THAT IT IS EXPLICIT IN TERMS OF WHAT THE  
2 FATE OF THE EMBRYO WILL BE AND POTENTIAL USES OF THE STEM  
3 CELL LINES. SO I THINK IT IS CERTAINLY ABOVE AND BEYOND  
4 SORT OF THE THRESHOLD OF THE BASIC CONSENT REQUIREMENT WE  
5 HAVE IN OUR REGULATIONS. AND UNDER THEIR LAW, THERE ARE  
6 A SERIES OF EXPLICIT STATEMENTS ABOUT STEM CELL RESEARCH  
7 AND HOW THE MATERIALS WILL BE USED IN THAT RESEARCH.

8 DID SOMEBODY ELSE JOIN ON THE CALL?

9 DR. PRIETO: FRANCISCO PRIETO.

10 CHAIRMAN LO: WELCOME. WE'RE TALKING ABOUT THE  
11 ITEM ON INCLUDING THE JAPANESE CELLS DERIVED UNDER THE  
12 JAPANESE GUIDELINES AS BEING DEEMED ACCEPTABLY DERIVED.

13 SO THE PROPOSAL FOR THE LANGUAGE IS TO ADD, FOR  
14 THE REGULATIONS, TO ADD ANOTHER ITEM UNDER THE LIST OF  
15 ACCEPTABLY DERIVED TO INCLUDE DERIVED IN ACCORDANCE WITH  
16 THE JAPANESE GUIDELINES FOR DERIVATION AND UTILIZATION OF  
17 HUMAN EMBRYONIC STEM CELLS. THAT'S ON PAGE 2 IN THE  
18 ITALICS. I WAS JUST READING THE LAST TWO LINES ON PAGE  
19 2, WHICH IS ACTUAL LANGUAGE THAT WOULD BE SUGGESTED TO  
20 INCLUDE THESE JAPANESE LINES LIKE THE CANADIAN AND UK.

21 DID SOMEONE JUST JOIN?

22 DR. ROWLEY: JANET ROWLEY. SORRY I'M LATE.

23 CHAIRMAN LO: HI, JANET. WELCOME. THIS IS  
24 BERNIE. GLAD TO HAVE YOU.

25 WE'RE TALKING ABOUT THE ITEM ON INCLUDING THE

## BARRISTERS' REPORTING SERVICE

1 JAPANESE EMBRYONIC STEM CELL LINES DERIVED UNDER THE  
2 JAPANESE GUIDELINES.

3 DR. PRIETO: ARE THERE ANY POTENTIAL OR ACTUAL  
4 OBJECTIONS TO THIS THAT WE'VE HEARD?

5 DR. LOMAX: WELL, WE NEITHER HEARD OBJECTION AT  
6 THE MAY MEETING. WE HAVE NOT PUT THE PROPOSAL OUT FOR  
7 ANY KIND OF FORMAL PUBLIC COMMENT PENDING THE DECISION BY  
8 THIS GROUP WHETHER WE MOVE FORWARD. IN THE EVENT WE MOVE  
9 FORWARD, IT WOULD GO OUT FOR FORMAL PUBLIC COMMENT  
10 THROUGH THE OFFICE OF ADMINISTRATIVE LAW PROCESS. AS OF  
11 NOW, NO; BUT WE HAVEN'T ACTIVELY SOUGHT PUBLIC COMMENT.  
12 THAT'S PART OF THE PURPOSE OF TODAY'S MEETING. I GUESS  
13 IT MIGHT BE AN APPROPRIATE TIME TO ASK IF ANY MEMBERS OF  
14 THE PUBLIC WOULD LIKE TO COMMENT ON THIS PROPOSAL.

15 CHAIRMAN LO: WE HAVE PUBLIC PEOPLE HERE IN SAN  
16 FRANCISCO. ANYONE FROM THE PUBLIC WANT TO MAKE A  
17 COMMENT? FOR THE RECORD, IF WE COULD HAVE YOU TALK RIGHT  
18 INTO THE MIC AND INTRODUCE YOURSELF, PLEASE.

19 MR. REED: DON REED. IN FAVOR OF  
20 INTERNATIONALISM, ALWAYS WAS GLAD THAT THESE LINES ARE  
21 SAID TO BE FAIRLY CONSERVATIVE AS THE GUIDELINES OF THE  
22 CANADIANS, AND JUST SEEMS LIKE A GOOD IDEA.

23 CHAIRMAN LO: ANY OTHER COMMENTS FROM ANYBODY  
24 ON THE COMMITTEE? THE WORKING GROUP?

25 DR. KIESSLING: HAVE WE SEEN A COPY OF THE

## BARRISTERS' REPORTING SERVICE

1 JAPANESE GUIDELINES? HAS THAT BEEN TRANSLATED FOR US?

2 DR. LOMAX: YES. THERE WAS A COPY INCLUDED IN  
3 THE PACKET OF MATERIALS FOR THE MAY MEETING, AND IT WAS  
4 INCLUDED THERE. AND IT WAS RECIRCULATED WITH THE  
5 ORIGINAL BRIEFING MEMO THAT SUMMARIZES -- WHAT STAFF WAS  
6 ASKED TO DO WAS CONTRAST THE GUIDELINES TO OUR EXISTING  
7 REGULATIONS TO IDENTIFY ANY NIH POINTS OF DIVERGENCE.  
8 AND, AGAIN, THEY WERE RESUBMITTED THERE. SO WE HAVE  
9 COPIES OF THOSE AND COULD RECIRCULATE THEM AGAIN IF YOU'D  
10 LIKE AS WELL.

11 DR. KIESSLING: NO, THAT'S OKAY.

12 DR. ROWLEY: WE DID GET IT IN MAY SO THAT WE  
13 HAD A CHANCE TO LOOK AT IT BEFORE THE MEETING AND DURING  
14 THE MEETING.

15 DR. KIESSLING: I REMEMBER THOSE.

16 DR. TAYLOR: I DON'T RECALL SEEING THIS OR,  
17 FRANKLY, EVEN LOOKING FOR IT, BUT IS VERY MUCH KNOWN  
18 ABOUT THE SCREENING OF PATIENTS FOR INFECTIOUS DISEASES  
19 IN THEIR IVF PROTOCOLS IN JAPAN? IS THAT SOMETHING  
20 THAT'S PART OF THIS POLICY? I'M KIND OF FLIPPING THROUGH  
21 IT, AND I DON'T SEE IT. DOES THAT RING A BELL FOR  
22 ANYONE?

23 DR. LOMAX: IT'S NOT AN ISSUE THAT WE DISCUSSED  
24 WITH THE DELEGATION THAT WAS HERE. BUT THEN, AGAIN, IT  
25 WASN'T SOMETHING THAT WE INQUIRED ABOUT. SO THE SHORT

## BARRISTERS' REPORTING SERVICE

1 ANSWER IS WE HAVE NOT INQUIRED AND DO NOT HAVE  
2 INFORMATION, BUT WE CERTAINLY, IF IT'S OF INTEREST TO THE  
3 WORKING GROUP, WE COULD SEEK INFORMATION. WE HAVE  
4 CONTACTS IN JAPAN WHO WE COULD ASK ABOUT THAT.

5 CHAIRMAN LO: AGAIN, TO PUT IT IN THE CONTEXT  
6 OF WHERE THIS IS IN THE REGULATIONS, IT'S IN THE SECTION  
7 OF SORT OF BEING ABLE TO USE CELL LINES DERIVED ELSEWHERE  
8 WITHOUT HAVING TO GO THROUGH A SEPARATE PROCESS FOR EACH  
9 LINE, THAT WE HAVE TAKEN SOME GROUPS OF CELLS, THOSE  
10 DERIVED IN THE UK, THOSE DERIVED IN ACCORDANCE WITH THE  
11 CANADIAN GUIDELINES, AND THEY MEET OUR STANDARDS  
12 PRIMARILY FOR CONSENT. AND SO THERE WOULD BE A SEPARATE  
13 ISSUE IF SOMEONE WOULD USE THEM FOR TRANSPLANTATION.

14 DR. TAYLOR: EXACTLY. FOR RESEARCH I DON'T  
15 HAVE ANY PROBLEMS WHATSOEVER.

16 DR. LOMAX: JUST TO ADD TO THAT, THOUGH, FOR  
17 CLARITY IS THAT THEY ALSO MEET OUR STANDARDS FOR PAYMENT  
18 AND OVERSIGHT AS WELL BECAUSE WE PAY SOME ATTENTION TO  
19 THE SERIES OF ISSUES THAT CONSTITUTE AN ACCEPTABLY  
20 DERIVED CELL LINE.

21 DR. ROWLEY: I THINK THE ONLY THING IS IT  
22 SEEMED TO ME THAT THEY COULD -- THE ISSUE OF TIME WAS A  
23 MATTER, THAT THEY CAN'T BE CULTURED MORE THAN 12 DAYS  
24 ACCORDING TO CALIFORNIA LAW, AND JAPANESE LAW WAS 14  
25 DAYS. I WOULDN'T THINK THAT WOULD INFLUENCE VERY MANY OF

## BARRISTERS' REPORTING SERVICE

1 THE CELL LINES, BUT THAT WAS A DIFFERENCE. I DON'T LOOK  
2 ON IT AS A CRITICAL DIFFERENCE.

3 DR. PRIETO: THAT WOULD BE AN ISSUE, I THINK,  
4 FOR US IF IT WERE DISCOVERED THAT SOME CELL LINES HAD  
5 BEEN DERIVED AFTER THE TWELFTH DAY, BUT HOW LIKELY IS  
6 THAT? I THOUGHT MOST CELL LINES WERE DERIVED WELL BEFORE  
7 THAT.

8 DR. LOMAX: AGAIN, WE COULD INQUIRE ABOUT THAT.  
9 I THINK MY SENSE IS AND MY UNDERSTANDING IS IT'S GENERAL  
10 PRACTICE TO DERIVE WELL BELOW THAT THRESHOLD. BUT,  
11 AGAIN, I WOULD HAVE TO SEEK ADDITIONAL INFORMATION TO  
12 GIVE AN ENTIRELY ACCURATE ANSWER TO THAT QUESTION.

13 DR. EGGAN: I THINK THE ANSWER TO THAT QUESTION  
14 AT THE MOMENT IS CLEARLY THAT THE TIMEFRAME SHOULDN'T BE  
15 A PROBLEM, BUT THERE ARE TWO NEW PAPERS THAT WERE JUST  
16 PUBLISHED IN *NATURE* IN THE LAST COUPLE OF WEEKS  
17 DESCRIBING A SORT OF EMBRYONIC STEM CELL DESCRIBED  
18 POSTIMPLANTATION MOUSE EMBRYOS THAT WOULD BE PAST THAT  
19 TIME OR RIGHT IN THE MIDDLE OF THAT SORT OF INTERVAL.  
20 AND SO I AM CONCERNED THAT PEOPLE ARE GOING TO START  
21 DERIVING AT AROUND THAT INTERVAL OF TIME, SO THERE COULD  
22 BE CONSEQUENCES. I THINK IT'D PROBABLY BE BEST TO TAKE A  
23 PROACTIVE APPROACH TO THIS.

24 DR. ROWLEY: MEANING SAYING THAT 12 DAYS WAS  
25 THE LIMIT?

## BARRISTERS' REPORTING SERVICE

1 DR. EGGAN: I THINK WE'D BE BETTER OFF KEEPING  
2 THE HORSES INSIDE THE BARN, IF YOU KNOW WHAT I MEAN, BY  
3 DOING SOMETHING LIKE THAT. IF THAT'S CALIFORNIA STATE  
4 LAW, THEN I THINK WE'D HAVE TO MODIFY THE LANGUAGE TO SAY  
5 SOMETHING ABOUT THAT IF THAT'S A CLEAR DIFFERENCE.

6 CHAIRMAN LO: I'M GOING TO HAVE TO ASK ONE OF  
7 OUR LEGAL EAGLES HERE TO COMMENT. SO NOW WE'RE TALKING  
8 ABOUT TWO DIFFERENT SECTIONS OF THE REGULATION. SO  
9 THERE'S ONE SECTION WHERE THE 12-DAY LIMIT IS INCLUDED,  
10 WHICH SAYS TO BE ELIGIBLE FOR CIRM -- ACTIVITIES NOT  
11 ELIGIBLE FOR CIRM FUNDING. SO IT'S 100030. THESE ARE  
12 THINGS THAT AREN'T ELIGIBLE FOR CIRM FUNDING, AND THE  
13 12-DAY LIMIT IS THERE.

14 SO I WOULD ASSUME THAT THAT WOULD BE IMPLIED TO  
15 ANYTHING THAT'S PROPOSED FOR CIRM FUNDING, WHETHER IT  
16 CAME FROM THE UK, CANADA, OR JAPAN; IS THAT CORRECT?

17 DR. LOMAX: WELL, I WILL PROVIDE AN ANSWER  
18 WHICH I THINK IS THE CORRECT ANSWER, BUT I WILL DEFER TO  
19 SCOTT SHOULD I MISSPEAK. GIVEN THAT WE DO NOT HAVE AN  
20 EXPLICIT STATEMENT IN OUR SECTION UNDER ACCEPTABLY  
21 DERIVED, IT WOULD NOT BE SORT OF LEGALLY BINDING TO APPLY  
22 THAT STANDARD WHICH WE IMPOSED ON CIRM-FUNDED RESEARCHERS  
23 TO ALL CELL LINES DERIVED ELSEWHERE. IT'S SIMPLY A  
24 DIFFERENT STANDARD.

25 ONE GOVERNS THE WORK THAT PEOPLE THAT WE FUND,

## BARRISTERS' REPORTING SERVICE

1 HOW THEY USE OUR FUNDING, WHAT THEY DO WITH IT. SINCE WE  
2 HAVE NOT EXPLICITLY STATED THAT IN THE SECTION UNDER  
3 ACCEPTABLY DERIVED, ONE CANNOT -- I DON'T THINK ONE WOULD  
4 BE LIABLE FOR WORKING WITH A CELL LINE THAT WAS DERIVED  
5 OUTSIDE THAT LIMIT BECAUSE IT'S NOT IN THAT SECTION.  
6 IT'S A REASONABLE INTERPRETATION, SCOTT, OR HAVE I  
7 MISSPOKEN THERE.

8 MR. TOCHER: NO, I THINK IT IS. I'LL HAVE TO  
9 DOUBLE-CHECK THE SPECIFIC PROVISION, BUT I BELIEVE THAT  
10 PROVISION OF 12 DAYS -- LET ME CHECK THE SPECIFIC  
11 PROVISION, BUT I BELIEVE THAT THE 12-DAY LIMIT THERE IS  
12 APPLICABLE TO LINES THAT ARE DERIVED WITH THE CIRM  
13 FUNDING. AND SO I THINK THAT AN ARGUMENT CAN BE MADE  
14 THAT THERE'S A DIFFERENCE BETWEEN LINES THAT ARE DERIVED  
15 WITH CIRM FUNDING VERSUS RESEARCH THAT USES DIFFERENT  
16 LINES THAT HAVE ALREADY BEEN DERIVED. WE PROBABLY HAVE A  
17 LITTLE MORE FLEXIBILITY.

18 CHAIRMAN LO: I GUESS THE QUESTION BACK TO THE  
19 WORKING GROUP IS DO WE WANT TO FORBID CIRM RESEARCHERS  
20 FROM USING LINES DERIVED ELSEWHERE THAT MEET ALL THE  
21 OTHER REQUIREMENTS IN TERMS OF CONSENT, OVERSIGHT, AND SO  
22 FORTH, BUT WOULD WE ALLOW LINES THAT GO PAST 12 DAYS, UP  
23 TO 14, OR DO WE WANT TO APPLY THE 12-DAY LIMIT? THAT  
24 SOUNDS LIKE IT'S NOT CLEARLY FORBIDDEN.

25 MR. TOCHER: RIGHT. OF COURSE, THE GROUP IS

## BARRISTERS' REPORTING SERVICE

1 FREE TO SCRIPT A REGULATION HOWEVER IT LIKES, SO IT CAN  
2 ALWAYS PLACE AN ADDITIONAL CONDITION. YOU CAN SAY YOU  
3 CAN USE IT IN ACCORDANCE WITH THE JAPANESE GUIDELINES AND  
4 WITH THE ADDITIONAL CAVEAT THAT IT'S DONE BEFORE 12 DAYS.

5 MS. CHARO: IT'S CERTAINLY A LITTLE HARD TO  
6 FOLLOW THIS WITHOUT ACTUALLY HAVING TEXT IN FRONT OF US,  
7 BUT MY UNDERSTANDING IS THE PURPOSE OF THE ORIGINAL  
8 12-DAY LIMIT WAS THAT IT WAS ABOUT NOT MAINTAINING A  
9 VIABLE HUMAN EMBRYO IN VITRO PAST 12 DAYS. AND THE  
10 CONCERN BEING THE SO-CALLED TRULY TEST TUBE BABY, WHICH  
11 WAS SCIENTIFICALLY IMPOSSIBLE, BUT PEOPLE WERE  
12 ANTICIPATING THIS. WHAT WOULD BE THE CONCERN HERE?  
13 WE'RE NOT TALKING ABOUT MAINTAINING A VIABLE HUMAN EMBRYO  
14 OUTSIDE THE BODY FOR MORE THAN 12 DAYS UNDER ANY NATIONAL  
15 SET OF RULES BECAUSE IT'S NOT POSSIBLE.

16 DR. TAYLOR: DIDN'T THIS HAVE MORE TO DO WITH  
17 SORT OF NEURAL TUBE DEVELOPMENT?

18 MS. CHARO: DID YOU ASK THAT TO ME?

19 DR. TAYLOR: MORE GENERALLY TO THE OTHER  
20 DEVELOPMENTAL BIOLOGISTS.

21 MS. CHARO: CERTAINLY THE 14-DAY LIMIT THAT THE  
22 WARNOCK COMMISSION CHOSE BACK IN THE '80S AND THEN WAS  
23 MIMICKED BY THE NIH EMBRYO RESEARCH PANEL WAS DESIGNED TO  
24 CAPTURE THE TIME DURING WHICH, YEAH, YOU BEGIN TO GET THE  
25 PRIMITIVE STREAK FORMING. BUT, AGAIN, IT WAS ABOUT

## BARRISTERS' REPORTING SERVICE

1 VIABLE HUMAN EMBRYOS. IT WAS ABOUT TRYING TO AVOID  
2 ENTERING THE REALM IN WHICH YOU NOW HAVE NO CLEAR  
3 DEMARCATIONS BETWEEN NONPERSON AND PERSON UNDER  
4 PERSONHOOD THEORIES, WHICH IS NOT TO SAY THE PRIMITIVE  
5 STREAK EQUALS PERSONHOOD. BEYOND THAT THERE'S NO CLEAR  
6 PLACE WHERE YOU CAN SAY HERE THERE IS AND HERE THERE IS  
7 NOT A PERSON.

8 DR. LOMAX: IF I COULD JUST OFFER ONE OTHER  
9 POINT JUST IN TERMS OF MECHANICS OF IMPLEMENTATION, THIS  
10 IS SOMETHING WE'VE SPENT A LOT OF TIME THROUGH THE  
11 EVALUATION INITIATIVE LEARNING ABOUT SORT OF HOW  
12 INSTITUTIONS ACTUALLY APPLY THESE REGULATIONS IS THAT IF  
13 YOU -- ONE NEEDS TO BE VERY SENSITIVE TO THE NUMBER OF  
14 REQUIREMENTS THAT REQUIRE POSITIVE VERIFICATION AT THE  
15 GRANTEE END BECAUSE, PARTICULARLY IN THE CASE OF FOREIGN  
16 LINES, WE'VE LEARNED IT'S THE ABILITY TO PROVIDE POSITIVE  
17 VERIFICATION TO WHATEVER OUR REQUIREMENTS ARE THAT, I  
18 THINK, CREATE THE MOST AMOUNT OF WORK FOR THE  
19 INSTITUTION.

20 SO I JUST WANT TO OFFER A WORD OF CAUTION, THAT  
21 ANY ADDITIONAL REQUIREMENTS THAT WE BRING INTO THE  
22 STANDARD FOR ACCEPTABLY DERIVED MAY POSE PROBLEMS IN  
23 TERMS OF THE ABILITY TO PROVIDE THOSE VERIFICATIONS. AND  
24 SO JUST WANT THE WORKING GROUP TO BE SENSITIVE TO THOSE.  
25 IT STARTS TO UNDERMINE THE INTENT OF THE PROVISION, WHICH

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1 IS TO FACILITATE EXCHANGE, NOT TO SUGGEST THAT THERE  
2 AREN'T CERTAIN STANDARDS FROM WHICH WE WOULD NOT WANT TO  
3 DEVIATE. THERE MAY BE OTHER ONES THAT JUST SORT OF  
4 ADMINISTRATIVELY CREATE SUCH A BURDEN, THAT THE STANDARD  
5 ITSELF BECOMES VERY DIFFICULT TO MAKE WORKABLE.

6 DR. PRIETO: GEOFF, WOULD A SPECIFIC PROVISIO  
7 ALONG THE LINES OF WHAT KEVIN SUGGESTED, THAT AN  
8 ACCEPTABLY DERIVED LINE DERIVED BEFORE THE 12TH DAY,  
9 WOULD ADDING THAT CONDITION PUT A SIGNIFICANT BURDEN UPON  
10 GRANTEES? AND WOULD THAT BE SUCH A DIFFICULT THING TO  
11 VERIFY?

12 DR. LOMAX: AGAIN, WE COULD POSE THAT QUESTION  
13 TO THE FOLKS THAT ARE IMPLEMENTING THESE REGULATIONS.  
14 BUT, YOU KNOW, I THINK, AGAIN, EVERY TIME YOU PUT IN A  
15 REQUIREMENT THAT IT'S INCUMBENT UPON THE GRANTEE TO MAKE  
16 A POSITIVE VERIFICATION BECAUSE IT BECOMES A COMPLIANCE  
17 AND LIABILITY ISSUE, THEN IT'S ANOTHER PIECE OF  
18 INFORMATION, WHICH, UNFORTUNATELY AT THIS POINT IN TIME,  
19 THE SYSTEM DOES NOT ROUTINELY CAPTURE.

20 EVEN ISSUES AROUND CONSENT, WE'VE HEARD VERY  
21 LONG DESCRIPTIONS ABOUT TIME AND ENERGY GOING IN TO  
22 VERIFY CONSENT, WHICH, AGAIN, EVERYONE BELIEVES IS TIME  
23 WELL SPENT. BUT, AGAIN, TO THE EXTENT WE CONTINUE TO  
24 LAYER IN THOSE REQUIREMENTS, IT DOES PRESENT CHALLENGES  
25 BASED ON THE INFORMATION I HAVE AT THIS TIME, AGAIN,

## BARRISTERS' REPORTING SERVICE

1 SIMPLY BECAUSE THERE ISN'T, TO MY KNOWLEDGE, SORT OF A  
2 LOT OF THIS INFORMATION ISN'T ROUTINELY COLLECTED.

3 AGAIN, WE COULD PROBE ON THAT AND SEE WHAT WE  
4 HEAR BACK. BUT MY SENSE WOULD BE BECAUSE WE HAVEN'T HAD  
5 A POSITIVE REQUIREMENT FOR THAT, WE WON'T KNOW THE ANSWER  
6 UNTIL WE PUT ONE IN PLACE AND THEN WE'LL FIND OUT WHAT  
7 THE ANSWER IS. IT'S REALLY HOW THIS WORKS. PEOPLE ARE  
8 RESPONDING TO THE REQUIREMENTS KIND OF RETROSPECTIVELY  
9 ONCE WE PUT THEM IN PLACE.

10 CHAIRMAN LO: LET ME TRY AND ASK A SLIGHTLY  
11 DIFFERENT WAY. WHAT IS THE POLICY REASON FOR ALLOWING  
12 CELLS TO BE USED THAT WERE DERIVED ELSEWHERE FROM DAY 13  
13 OR 14 OF CULTIVATION, EVEN THOUGH WE'RE NOT PERMITTING IT  
14 TO BE DONE UNDER CIRM FUNDING? CAN SOMEONE HELP US THINK  
15 THROUGH WHAT WOULD BE THE ARGUMENT AGAINST ALLOWING THAT  
16 OTHER THAN JUST APPARENT INCONSISTENCY? ARE THERE  
17 CERTAIN THINGS THAT WOULD HAPPEN DAY 13 OR 14 THAT WOULD  
18 IMPLICATE ETHICAL CONCERNS?

19 DR. CIBELLI: SCIENTIFICALLY I THINK THERE'S  
20 NONE. IT'S JUST A MATTER OF THE PERCEPTION OVERALL. I  
21 THINK ALTA, SHE PUT IT VERY WELL, NOT THAT YOU CAN  
22 EXPLAIN THE HISTORY OF THE 14 DAYS AGAIN, THAT PROBABLY  
23 WILL HELP US ALL UNDERSTAND.

24 MS. CHARO: I JUST THINK IT'S IMPORTANT THAT WE  
25 DON'T GET CAUGHT UP IN THE RULES WITHOUT REMEMBERING WHY

## BARRISTERS' REPORTING SERVICE

1 WE'RE PROPOSING THEM. AND THE MAIN CONCERN THAT HAD  
2 ORIGINALLY DRIVEN THIS ENTIRE NOTION OF A LIMIT ON THE  
3 NUMBER OF DAYS THAT YOU COULD MAINTAIN THINGS IN VITRO  
4 WAS THE SENSE THAT AT A CERTAIN POINT YOU'RE NO LONGER  
5 DEALING WITH AN ENTITY WHOSE MORAL STATUS WE COULD  
6 DIMINISH BY VIRTUE OF ITS BIOLOGICAL STRUCTURES. AND SO  
7 AMERICANS HAVE THIS KIND OF MIDDLE GROUND. AS THE  
8 ORGANISM GETS MORE DEVELOPED, THEY TEND TO ASCRIBE MORE  
9 MORAL STATUS. AND THE PRIMITIVE STREAK BEING ASSOCIATED  
10 WITH NEUROLOGICAL FUNCTION, EVEN IF IT IS NOT CURRENTLY  
11 FUNCTIONING, SEEM TO BE ASSOCIATED WITH PEOPLE BEGINNING  
12 TO THINK, OH, WELL, MAYBE NOW THIS IS AN ENTITY I OUGHT  
13 TO CARE ABOUT.

14 SINCCE IT DIDN'T MATTER BECAUSE NOBODY COULD  
15 MAINTAIN THESE ORGANISMS IN A LAB DISH BEYOND, WHAT,  
16 KEVIN, SIX OR SEVEN DAYS, THE WHOLE THING WAS REALLY  
17 QUITE A POLITIC SOLUTION, RIGHT? YOU'RE FORBIDDING  
18 SOMETHING THAT NOBODY CAN DO ANYWAY IN ORDER TO REASSURE  
19 PEOPLE THAT NOBODY WILL TRY TO DO IT.

20 MS. KING: I UNDERSTAND THE HISTORY OF THE  
21 14-DAY RULE, BUT WHAT I'M INTERESTED IN IS WHY THE  
22 CURRENT CIRM REGULATIONS SAY 12.

23 DR. PETERS: MAY I FOLLOW UP ON ALTA'S BEFORE  
24 WE TURN FROM 14 TO 12, PLEASE? THIS IS TED. CAN YOU  
25 HEAR ME?

## BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: PLEASE, GO AHEAD, TED.

2 DR. PETERS: THE ROMAN CATHOLIC HOUSE IS  
3 DIVIDED. THE DOMINANT VIEW COMES FROM THE VATICAN, BUT  
4 THERE ARE A MINORITY OF CREATIVE ROMAN CATHOLIC  
5 BIOETHICISTS WHO ARE QUITE CONCERNED ABOUT THE 14-DAY  
6 RULE BECAUSE WHEN THE PRIMITIVE STREAK OCCURS, YOU HAVE  
7 ESTABLISHED FOR THE FIRST TIME AN INDIVIDUAL. AND  
8 INDIVIDUATION IS VERY IMPORTANT IN CATHOLIC BIOETHICS.  
9 EVEN THOUGH THESE GUIDELINES ARE STRICTLY SECULAR IN  
10 CHARACTER, THEY ARE, IN PART, RESPONDING TO WHAT THE  
11 PUBLIC MIND IS.

12 I THINK, FINALLY, WHAT ALTA SAID AT THE END OF  
13 HER DISCOURSE THERE IS THAT IT DIDN'T SEEM TO MAKE MUCH  
14 DIFFERENCE SCIENTIFICALLY FOR THIS KIND OF RESEARCH. AND  
15 TO HAVE A 14-DAY RULE WOULD AT LEAST, WITHOUT  
16 ACKNOWLEDGING IT, SEEM TO RECOGNIZE THIS LINE OF RATHER  
17 SOPHISTICATED ETHICAL REASONING. I THINK WITH THAT  
18 OBSERVATION, I'M ONLY REINFORCING WHAT ALTA HAS ALREADY  
19 SAID.

20 MS. CHARO: YOU'RE QUIRE RIGHT, TED.

21 DR. PETERS: TO MOVE FROM 14 TO 12 DAYS IN THE  
22 CIRM GUIDELINES IS SOMETHING WE OUGHT TO WONDER ABOUT.  
23 IS IT NECESSARY TO GO BACK TO 12, AND I THOUGHT SOMEBODY  
24 HAD SAID AT ONE POINT IN OUR MEETINGS THAT THIS WAS JUST  
25 SORT OF AN EXTRA PRECAUTION TO CATCH THESE THINGS BEFORE

**BARRISTERS' REPORTING SERVICE**

1 THE PRIMITIVE STREAK HAD OCCURRED.

2 CHAIRMAN LO: ALSO, IT WAS LANGUAGE TAKEN FROM  
3 PROP 71, WHICH INCLUDED 12 DAYS EXPLICITLY AS OPPOSED TO  
4 14.

5 MS. KING: SO YOU THINK THE REASON -- I DON'T  
6 THINK I ATTENDED THAT MEETING. YOU THINK THE REASON FOR  
7 THE 12-DAY RULE IS ACTUALLY GOING BACK TO THE INITIATIVE?

8 DR. LOMAX: ABSOLUTELY.

9 CHAIRMAN LO: ABSOLUTELY. IT'S IN THE LANGUAGE  
10 IN THE INITIATIVE.

11 MS. KING: WHILE I UNDERSTAND ALL THE ARGUMENTS  
12 PEOPLE HAVE MADE ABOUT 14, THEN IT WOULD SEEM TO ME YOU  
13 NEED A FAIRLY STRONG LEGAL INTERPRETATION, NOT ETHICAL,  
14 LEGAL INTERPRETATION TO MAKE AN EXCEPTION FOR JAPANESE  
15 WHEN WE SAY 12 AND THE JAPANESE SAY 14. I UNDERSTAND ALL  
16 THE HISTORY AND ALL OF THAT, BUT A COUNTERHISTORY THAT  
17 SAYS THAT, IN TERMS OF THE INITIATIVE, THE 12 DAYS WAS  
18 MENTIONED, IT SEEMS TO ME THAT TO DEPART FROM THAT AS A  
19 REGULATORY MATTER REQUIRES A PRETTY STRONG LEGAL  
20 ARGUMENT.

21 CHAIRMAN LO: LET ME ASK SCOTT TO COMMENT HERE.

22 MR. TOCHER: THE PROVISION THAT I'M READING  
23 FROM IS FROM THE PROPOSITION. IT'S HEALTH AND SAFETY  
24 CODE SECTION 125290.35, AND SUBDIVISION B, NO. 6, TITLED  
25 "TIME LIMITS FOR OBTAINING CELLS." STANDARDS SETTING --

## BARRISTERS' REPORTING SERVICE

1     WHAT IT'S DICTATING IS THE ICOC SHALL ESTABLISH STANDARDS  
2     AS FOLLOWS.  AND THIS SUBDIVISION SAYS STANDARDS, SETTING  
3     A LIMIT ON THE TIME DURING WHICH CELLS MAY BE EXTRACTED  
4     FROM BLASTOCYSTS WHICH SHALL INITIALLY BE EIGHT TO 12  
5     DAYS AFTER CELL DIVISION BEGINS, NOT COUNTING ANY TIME  
6     DURING WHICH THE BLASTOCYST AND/OR CELLS HAVE BEEN STORED  
7     FROZEN.

8             DR. LOMAX:  AGAIN, I THINK THE IMPORTANT  
9     DISTINCTION, AND THIS IS WHY WE'VE FELT THERE'S SOME  
10    FLEXIBILITY WITH REGARD TO THIS PROVISION, IS THE  
11    LANGUAGE IN PROPOSITION 71 GOVERNS THE ACTIVITIES OF CIRM  
12    GRANTEES UTILIZING THE BLASTOCYSTS IN RESEARCH.  THE  
13    PROPOSITION DOES NOT EXPLICITLY ADDRESS THE USE OF CELL  
14    LINES DERIVED OUTSIDE OF THE CIRM FUNDING STREAM.  AND SO  
15    I'VE COVERED THIS WITH COUNSEL, BUT THAT IS A, I GUESS,  
16    FOR WANT OF A BETTER TERM, A REASONABLE DISTINCTION THAT  
17    CAN HAVE SOME FLEXIBILITY WITH REGARD TO OUTSIDE LINES  
18    VERSUS THE ACTUAL USE OF BLASTOCYSTS BY CIRM GRANTEES.

19            MS. KING:  MY CONCERN IS NOT AN ETHICAL ONE ON  
20    THIS POINT.  MY CONCERN IS THE FLEXIBILITY THAT YOU TALK  
21    ABOUT BECAUSE IT SEEMS TO ME THAT WHAT WE'RE SAYING IS  
22    THAT YOU CAN USE A JAPANESE LINE DERIVED IN A DIFFERENT  
23    WAY THAN A CIRM-FUNDED LINE AND THAT WOULD BE  
24    SUFFICIENT -- THAT WOULD BE ACCEPTABLE.  AND I DON'T KNOW  
25    WHAT ELSE WE CAN LOOK TO TO GET THAT KIND OF FLEXIBILITY.

## BARRISTERS' REPORTING SERVICE

1 I HEARD WHAT YOU SAID. THEY'RE IN TWO  
2 DIFFERENT SECTIONS, AND ONE GOVERNS OUR GRANTS, BUT I  
3 THOUGHT WE WERE EXPANDING LINES THAT COULD BE USED AS  
4 LONG AS THOSE LINES WERE CONSISTENT WITH OUR OWN  
5 STANDARDS FOR DERIVATION. SO FOR ME THAT'S A PROBLEM,  
6 BUT ANYBODY WOULD LIKE TO SPEAK TO IT.

7 DR. PRIETO: I WOULD. I'M CONCERNED THAT  
8 THERE'S SORT OF A, I GUESS, IT'S A POLITICAL AND A LEGAL  
9 ISSUE HERE. AND PARTICULARLY AT THE ICOC I THINK WE  
10 WOULD BE SENSITIVE TO THE PERCEPTION WE MIGHT CREATE THAT  
11 WE WERE PUSHING THE ENVELOPE, SO TO SPEAK, AND THE  
12 FALLOUT FROM THAT, WHICH COULD INCLUDE THAT THE LEGAL  
13 CHALLENGES THAT WE HAVE NOT EXACTLY BEEN STRANGERS TO,  
14 MIGHT BE REIGNITED, OR THIS WOULD BE AN OPPORTUNITY FOR  
15 SOMEONE TO SAY, WELL, YOU SAY THE LAW MEANS THIS, BUT WE  
16 SAY THE INITIATIVE MEANS THAT. AND THESE ARE GOING TO BE  
17 CIRM GRANTEES USING THESE CELL LINES; THEREFORE, IT'S  
18 CIRM-FUNDED RESEARCH, THEREFORE, YOUR 12-DAY LIMIT MUST  
19 APPLY, AND LET'S GO TO COURT FOR THE NEXT YEAR AND A HALF  
20 AND FIGHT ABOUT IT. I THINK THAT'S NOT A RESULT I'D BE  
21 EAGER TO SEE.

22 MR. SHEEHY: AND I THINK I AGREE WITH FRANCISCO  
23 AND PAT. AND AS I WAS LISTENING TO THE DISCUSSION AROUND  
24 THE SCIENCE, IT DOESN'T SEEM LIKE THAT THERE'RE LINES IN  
25 EXISTENCE, VERY LIKELY EXISTING LINES THAT HAVE BEEN

## BARRISTERS' REPORTING SERVICE

1 DERIVED PAST THAT 12TH DAY. SOUNDS LIKE THIS IS A  
2 PROSPECTIVE ISSUE. SO PART OF THE REASON FOR ACCEPTING  
3 ALL OF THESE OTHER VALIDATION MEASURES, WHETHER IT'S NIH  
4 OR THE UK STEM CELL BANK, IS TO ALLOW PEOPLE TO WORK WITH  
5 LINES THAT HAVE ALREADY BEEN ESTABLISHED.

6 SO I DO THINK THAT -- I MEAN WOULD THERE BE A  
7 LINE THAT EXISTS THAT'S BEEN ESTABLISHED THAT WAS CREATED  
8 AFTER 12 DAYS?

9 SO IF WE EXPLICITLY SAID THIS, I UNDERSTAND THE  
10 PAPERWORK ISSUE OF HAVING TO GO BACK AND VALIDATE THIS --

11 DR. WILLERSON: I'M SORRY TO BE LATE IN JOINING  
12 YOU.

13 MR. SHEEHY: IF WE KNOW IT HASN'T BEEN FEASIBLE  
14 BEFORE THIS POINT TO DO THIS, THEN I DON'T SEE WHY BEING  
15 EXPLICIT HERE ABOUT THE 12 DAYS, WHICH IS IN STATUTE,  
16 WHICH IS IN THE STATUTE, WOULD CREATE ANY UNNECESSARY  
17 BURDEN ON THE INSTITUTIONS GETTING OUR FUNDS. DOES THAT  
18 MAKE SENSE?

19 DR. ROWLEY: CAN I JUST ASK A QUESTION OF OTHER  
20 THAN JAPAN, WHAT ARE THE TIME LIMITS OF UK AND CANADA?

21 DR. LOMAX: I WILL LOOK AT THAT.

22 DR. ROWLEY: BECAUSE IF IT'S JAPANESE, THEN  
23 THAT WOULD BE THE ONLY PLACE WHERE INVESTIGATORS WOULD  
24 HAVE TO SEE HOW OLD, IF YOU WILL, THE BLASTOCYST WAS AT  
25 THE TIME THAT CELLS WERE DERIVED, AND THAT MAY LIMIT THE

## BARRISTERS' REPORTING SERVICE

1 PROBLEM. I MORE OR LESS TAKE JEFF'S POINT OF VIEW, THAT  
2 THERE PROBABLY ISN'T ANY DIRECT BIOLOGICAL DIFFERENCE  
3 BETWEEN A 12-DAY AND A 14-DAY-OLD BLASTOCYST. AND SO YOU  
4 CAN SAY THAT WE'RE MAKING A LOT OF FUSS ABOUT NOTHING.  
5 AND I WAS ACTUALLY THE ONE WHO RAISED THE QUESTION OF 12  
6 AND 14 DAYS.

7 CHAIRMAN LO: LET ME TRY AND SEE IF I CAN PULL  
8 TOGETHER SOME THREADS OF THIS VERY INTERESTING, IMPORTANT  
9 DISCUSSION. LET ME GO BACK TO WHY THIS SECTION 10080 IS  
10 THERE IN THE FIRST PLACE. OUR LISTING CRITERIA FOR USE  
11 OF CELLS DERIVED NOT UNDER CIRM FUNDING, AND THERE ARE  
12 TWO WAYS TO BE ACCEPTABLE FOR CIRM-FUNDED RESEARCH. ONE  
13 IS THEY HAVE TO GO THROUGH A SERIES OF FIVE SEPARATE  
14 QUALIFICATIONS. THE OTHER OPTION IS TO SAY IF YOU'VE  
15 DERIVED UNDER THE AUSPICES OF THE NIH, UK, THE UK STEM  
16 CELL BANK, OR THE CANADIAN INSTITUTES, THOSE ARE DEEMED  
17 TO HAVE MET THOSE FIVE GUIDELINES. SO THE RESEARCHER  
18 DOESN'T HAVE TO GO AND LOOK THAT EACH CRITERIA IS MET,  
19 BUT IT WAS APPROVED UNDER ONE OF THESE OTHER AGENCIES.

20 THE NOTION WAS TO ADD OTHER COMPARABLE AGENCIES  
21 AS THEIR CELL LINES BEING DEEMED APPROPRIATE. NOW, I  
22 THINK THE 12-DAY VERSUS 14-DAY ISSUE SOUNDS LIKE THERE'S  
23 A LOT OF CONCERN ABOUT DEEMING IN LINES THAT, IN FACT,  
24 MAY HAVE GONE TO 13 OR 14 DAYS, NOT NECESSARILY FOR  
25 SCIENTIFIC OR EVEN ETHICAL REASONS AS MUCH AS PROVINCIAL

## BARRISTERS' REPORTING SERVICE

1 PUBLIC PERCEPTION REASONS AND THE THREAT OF TYING THINGS  
2 UP IN LAWSUIT.

3 SO ONE APPROACH WOULD BE TO AMEND 10080 EVEN  
4 FURTHER AND SAY THAT IF YOU'RE DEEMED -- IF YOU ARE GOING  
5 TO BE USED BY CIRM-FUNDED RESEARCHERS, WE WANT TO SAY  
6 SOMETHING ABOUT A 12-DAY LIMIT APPLYING TO ALL CELLS,  
7 WHETHER THEY'RE FROM JAPAN, THE UK, NIH, FOR THAT MATTER,  
8 OR UNDER INDIVIDUAL APPROVALS. AND THAT SEEMS TO ME ONE  
9 QUESTION.

10 THE OTHER QUESTION IS GIVEN -- I THINK NOW OUR  
11 CURRENT CONCERN IS TO WHAT THE UK AND CANADA SAY ABOUT 12  
12 VERSUS 14 VERSUS PRIMITIVE STREAK. ASSUMING THAT JAPAN  
13 IS SIMILAR TO THE UK AND CANADA AND EVERYTHING ELSE,  
14 THERE DOESN'T SEEM TO BE ANY REASON TO PUT A 12-DAY  
15 REQUIREMENT ON JAPAN, BUT NOT ON THE UK OR CANADA. SO IT  
16 STRIKES ME THAT WE MAY HAVE TWO DIFFERENT ISSUES THAT WE  
17 NEED TO ADDRESS, AND WE DON'T, I THINK, AT THIS POINT  
18 HAVE THE INFORMATION ON UK AND CANADA UNLESS GEOFF IS  
19 COMING UP WITH THEM RIGHT NOW ON HIS COMPUTER.

20 SO I DON'T KNOW IF WE WANT TO TAKE A SENSE OF  
21 THE COMMITTEE, THAT WE THINK CIRM RESEARCHERS, AT LEAST  
22 AT THIS POINT, SHOULD ONLY BE WORKING WITH LINES THAT  
23 HAVE NOT GONE BEYOND 12 DAYS OF DEVELOPMENT IN VITRO.  
24 LEAVE IT OPEN AT A LATER DATE TO COME BACK WITH A LINE  
25 THAT WENT TO 13 OR 14 DAYS AND TAKE IT UP FROM THERE.

## BARRISTERS' REPORTING SERVICE

1 MS. CHARO: I'M SO SORRY. I FEEL LIKE I'M  
2 MISSING SOMETHING, BUT YOU KEEP TALKING ABOUT LINES THAT  
3 HAVE BEEN MAINTAINED MORE THAN 12 DAYS. YOU REALLY MEAN  
4 EMBRYOS THAT WERE MAINTAINED.

5 CHAIRMAN LO: I MISSPOKE.

6 DR. CIBELLI: SHOULD WE MAKE A MOTION JUST TO  
7 SAY THAT AND KEEP GOING JUST TO TRY TO AVOID ANY  
8 CONFLICT, LIKE SOMEONE SAYING POTENTIAL LEGAL ISSUES. AT  
9 THE TIME THAT THERE'S AN URGENT NEED TO USE CELL LINES  
10 THAT ARE BEYOND 14 DAYS --

11 MS. KING: SORRY TO INTERRUPT. I JUST WANTED  
12 TO LET YOU KNOW I HAVE CHAIRMAN BOB KLEIN JOINING THE  
13 CALL.

14 CHAIRMAN LO: HI, BOB. WELCOME. DO WE HAVE  
15 ANYONE ELSE WHO JOINED AFTER WE STARTED?

16 DR. LOMAX: WAS IT DR. WILLERSON JOINING?

17 DR. TAYLOR: DR. WILLERSON DID JOIN. HE MIGHT  
18 HAVE DROPPED OFF AGAIN.

19 CHAIRMAN LO: FIRST, CAN I GET A SENSE OF THE  
20 COMMITTEE WHETHER WE THINK THE 12-DAY LIMIT AT THIS POINT  
21 IN IN-VIVO EMBRYO DEVELOPMENT SHOULD BE SOMETHING THAT  
22 APPLIES TO ANY LINE USED BY A CIRM RESEARCHER, NOT JUST  
23 CIRM-DERIVED LINES?

24 DR. CIBELLI: THIS IS JOSE. I JUST WANT TO  
25 FINISH WHAT I WAS TRYING TO SAY. THAT IN ORDER TO KEEP

## BARRISTERS' REPORTING SERVICE

1 MOVING IN THIS, UNLESS THERE IS AN URGENT NEED TO USE  
2 CELL LINES THAT HAVE BEEN DERIVED FROM EMBRYOS THAT HAVE  
3 BEEN CULTURED FROM DAY 13 FORWARD, I THINK WE JUST SAY  
4 THAT WE'RE GOING TO FUND THOSE THAT ARE DERIVED UP TO DAY  
5 12. AND THEN, OF COURSE, WE WOULD HAVE TO LEAVE THIS  
6 OPEN BECAUSE IN THE FUTURE I'M AFRAID WE'RE GOING TO HAVE  
7 TO REVISIT IT BECAUSE OF THE SCIENCE, AND ALSO THERE ARE  
8 OTHER COUNTRIES LIKE SWEDEN AND SPAIN WHERE THEY HAVE A  
9 DIFFERENT LIMIT.

10 CHAIRMAN LO: SO IT SOUNDS LIKE THAT'S  
11 SOMETHING -- WHAT DO YOU THINK OF THAT STRATEGY OF TODAY  
12 SAYING WE'LL TAKE THE 12-DAY LIMIT FROM PROP 71, BUT WE  
13 MAY NEED TO ADDRESS THAT AS THE SCIENCE DEVELOPS AND AS  
14 WE FIND OUT MORE ABOUT WHAT DIFFERENT COUNTRIES HAVE IN  
15 PLACE? AND JOSE HAS GIVEN US TWO MORE COUNTRIES TO LOOK  
16 AT.

17 DR. TAYLOR: MOST PRAGMATIC MYSELF. I LIKE  
18 THAT IDEA.

19 DR. EGGAN: I AGREE.

20 MS. KING: I AGREE TOO BECAUSE IF THE CASE  
21 BUILDS FOR GOING TO 14 DAYS, THEN THE CASE BUILDS FOR  
22 UNITED STATES OR CALIFORNIA TOO.

23 CHAIRMAN LO: I THINK WE WOULD NEED TO MAKE A  
24 STRONG ARGUMENT TO GO BEYOND 12 DAYS, BOTH A SCIENTIFIC  
25 ARGUMENT AND SORT OF A POLICY ARGUMENT THAT I DON'T THINK

## BARRISTERS' REPORTING SERVICE

1 WE'RE READY TO MAKE TODAY.

2 MR. KLEIN: LET ME ASK GEOFF LOMAX A QUESTION.

3 I DON'T HAVE A COPY OF THE INITIATIVE IN FRONT OF ME.

4 I'M ACTUALLY TRYING TO PULL ONE OUT. BUT I THINK THAT IT

5 ADDRESSES THAT OUR FUNDS CAN'T BE USED TO DERIVE IF IT'S

6 MORE THAN 12 DAYS.

7 DR. LOMAX: THAT'S CORRECT, BOB. AND WE --

8 THAT WAS MADE IN THE DELIBERATION, AND THAT DISTINCTION

9 BETWEEN USE OF OUR FUNDS VERSUS USE OF CELL LINES DERIVED

10 ELSEWHERE, SO YOU ARE CORRECT.

11 MR. KLEIN: SO LET'S NOT -- IF WE'RE CAREFUL

12 HERE, BECAUSE WE CURRENTLY HAVE THE ABILITY, AS LONG AS A

13 CELL LINE MEETS OTHER MEDICAL AND ETHICAL STANDARDS THAT

14 ARE OTHERWISE APPROVED, SINCE OUR FUNDS WEREN'T USED TO

15 DERIVE THOSE LINES, IF IT MEETS THOSE OTHER MEDICAL AND

16 ETHICAL STANDARDS, OUR SCIENTISTS COULD USE THOSE LINES.

17 THE 12 DAYS IS MEANT RESTRICTIVELY DEALING WITH LINES

18 DERIVED WITH THE USE OF OUR FUNDS.

19 CHAIRMAN LO: RIGHT. BOB, THIS MAY HAVE BEEN

20 DISCUSSED BEFORE YOU WERE ABLE TO JOIN US. THE CONCERN

21 WAS THAT THERE MIGHT BE A PUBLIC PERCEPTION THAT A

22 RESEARCHER COULD TAKE LINES DERIVED ELSEWHERE THAT WERE

23 CULTURED -- WHOSE EMBRYOS WERE CULTURED BEYOND 12 DAYS

24 AND USE THEM UNDER CIRM FUNDING, AND THAT THERE MIGHT BE

25 A PUBLIC PERCEPTION THAT SOMEHOW THE CLEAR LANGUAGE OF

## BARRISTERS' REPORTING SERVICE

1 PROP 71, THIS IS A PERCEPTION, SORT OF AN END RUN WAS  
2 BEING AROUND. AND THERE WAS CONCERN RAISED OF LITIGATION  
3 BY OPPONENTS OF EMBRYONIC STEM CELL RESEARCH LATCHING  
4 ONTO THIS APPARENT OR SEEMING --

5 MR. KLEIN: I WOULDN'T BUY THE LITIGATION  
6 ARGUMENT. AND IT'S IMPORTANT THAT WHEREVER OUR CELL  
7 LINES ARE DERIVED, THEY ARE UNDER OTHER MEDICAL AND  
8 ETHICAL STANDARDS WE FIND ACCEPTABLE, LIKE THE ONES IN  
9 ENGLAND, WHICH, OF COURSE, IS OUR CURRENT POLICY. I JUST  
10 WANT YOU TO OPERATE WITH ALL OF THE OPTIONS, AND I  
11 WOULDN'T BUY THE LITIGATION ARGUMENT BECAUSE OUR FUNDS  
12 WOULD NOT HAVE BEEN USED TO DERIVE THOSE LINES.

13 MS. KING: BERNIE, THIS IS PAT. I DIDN'T MAKE  
14 THE POINT ABOUT PUBLIC PERCEPTION. I THINK THAT YOU NEED  
15 A GOOD LEGAL ARGUMENT TO HAVE INTERPRETATION OF YOUR OWN  
16 REGULATIONS THAT SUPPORT A DISTINCTION BETWEEN  
17 CIRM-FUNDED RESEARCH LINES AND OTHER FUNDED RESEARCH  
18 LINES WHEN THEY'RE GOING TO BE USED BY CIRM-FUNDED  
19 RESEARCHERS.

20 CHAIRMAN LO: DISTINGUISH CIRM FUNDING FOR  
21 DERIVATION VERSUS CIRM FUNDING TO USE LINES DERIVED BY  
22 SOMEBODY ELSE.

23 MS. KING: RIGHT. AND ESPECIALLY BECAUSE IN  
24 THE LEGAL DOCUMENT THAT REALLY IS THE BACKBONE OF THE  
25 CREATION OF CIRM AND WHAT WE'RE DOING, THE 12 DAYS WAS

## BARRISTERS' REPORTING SERVICE

1 SPECIFICALLY MENTIONED, AS I UNDERSTAND IT.

2 MR. KLEIN: BUT, AGAIN, WHEN I WROTE THAT  
3 12-DAY LIMIT, IT WAS DEALING WITH OUR FUNDS SPECIFICALLY.  
4 BUT I AGREE WE NEED TO BE CLEAR ABOUT THE DISTINCTION  
5 WE'RE MAKING.

6 MS. KING: I UNDERSTAND THE DISTINCTION, BUT I  
7 DON'T KNOW HOW YOU CAN MAKE IT. ONCE YOU PUT 12 DAYS IN  
8 IN THE FOUNDING DOCUMENTS, I THINK THAT YOU'VE GOT TO  
9 CONFRONT THE FACT THAT THAT'S WHERE THE 12 DAYS IS  
10 DERIVED FROM. AND NOW TO SAY THAT WE HAVE A DISTINCTION  
11 BETWEEN LINES DERIVED FROM OUR RESEARCHERS AND LINES  
12 DERIVED ELSEWHERE, IT SEEMS TO ME THAT YOU OPEN THE  
13 PROSPECT OF CHANGING THE RULES TO SUIT YOU AS YOU MOVE  
14 THROUGH THIS PROCESS. AND SO THERE'S A PERCEPTION ISSUE  
15 HERE, BUT I THINK IN TERMS OF LAW, THAT YOU REALLY WANT  
16 TO HAVE A VERY STRONG ARGUMENT THAT WOULD SUPPORT  
17 DEVIATING WHEN LINES ARE COMING FROM ELSEWHERE.

18 MR. KLEIN: I WANT TO MAKE IT CLEAR THAT IN THE  
19 DEBATE THROUGHOUT THE STATE IN TERMS OF THIS 12 DAYS, WE  
20 WERE TALKING ABOUT DERIVING FUNDING -- LIMITATION ON OUR  
21 FUNDS BEING USED TO DERIVE LINES THAT WE WOULD FUND. IT  
22 WAS ALSO DISCUSSED IN THOSE DEBATES THAT THERE WERE STEM  
23 CELL LINES FROM AROUND THE WORLD, IN ENGLAND AND SWEDEN  
24 AND OTHER AREAS, THAT OUR RESEARCHERS WOULD ACCESS AS  
25 LONG AS THEY WERE MEETING WELL-DEVELOPED, THOUGHTFUL,

## BARRISTERS' REPORTING SERVICE

1 HIGHLY RESPECTED MEDICAL AND ETHICAL STANDARDS, AND THAT  
2 THOSE WERE DEVELOPED UNDER OTHER REGULATIONS.

3 SO IT ISN'T A CHANGE FROM WHAT WAS DEBATED IN  
4 THE STATE IN THE PASSAGE OF PROP 71 TO MAKE THIS  
5 DISTINCTION. I AGREE WITH YOU, AND OUR COUNSEL, I'LL ASK  
6 JAMES HARRISON TO WORK WITH GEOFF LOMAX TO LEGALLY REALLY  
7 WRITE OUT THE FUNDAMENTAL JUSTIFICATION AND HISTORY OF  
8 THAT SO WE HAVE A GOOD DOCUMENTARY FOUNDATION TO RELY ON.

9 CHAIRMAN LO: WE HAVE A COMMENT HERE IN SAN  
10 FRANCISCO.

11 MS. THOMPSON: THIS IS CHARIS THOMPSON. JUST A  
12 QUICK COMMENT, ALTHOUGH IT MAY BE MOOT AFTER THE LAST BIT  
13 OF THE CONVERSATION, BUT I THINK THAT THE 12-DAY LIMIT IS  
14 POPULAR. PEOPLE THINK THE 14 DAYS MEANINGFUL AND 12 DAYS  
15 GIVES YOU TWO DAYS GRACE, AND PEOPLE LIKE THAT.

16 RETURNING TO THE POINT THAT DR. LOMAX MADE  
17 ABOUT BURDEN OF COMPLIANCE ON GRANTING INSTITUTIONS, I  
18 THINK ONE THING THAT WOULD NEED TO BE WORKED OUT, IF YOU  
19 DID GO WITH THE 12-DAY FOR ALL LINES, WOULD BE HOW THAT  
20 INFORMATION IS COLLECTED, HOW YOU KNOW OF PLACES THAT IN  
21 THEIR OWN NATIONAL GUIDELINES ALLOW YOU TO DERIVE STEM  
22 CELL LINES UP TO 14 DAYS, HOW YOU KNOW WHETHER IT'S DONE  
23 BEFORE 12 DAYS OR NOT. I THINK IT WOULD BE REASONABLE TO  
24 PUT THE EMPHASIS ON THE COUNTRY OF ORIGIN OF THE STEM  
25 CELL LINES, PROVIDE THAT INFORMATION, BUT I THINK IT

## BARRISTERS' REPORTING SERVICE

1 WOULD HAVE TO BE TALKED ABOUT EXACTLY HOW THAT WAS DONE.  
2 MOST CLINICS, REPRODUCTIVE TECHNOLOGY CLINICS,  
3 WOULDN'T HAVE THAT INFORMATION, BUT IT MIGHT NOT BE  
4 PASSED ON TO NATIONAL REGISTRIES. IF YOU'RE GOING TO  
5 COLLECT IT AT THE PROVIDER SIDE, IT PROBABLY NEEDS TO BE  
6 TALKED ABOUT. THANK YOU.

7 MR. KLEIN: AND ADDITIONALLY, THE SECTION THAT  
8 THIS COMES FROM, I BELIEVE, IS 125290.35. AND IT'S ON  
9 TIME LIMITS FOR OBTAINING CELLS, WHICH IS SUBPAREN D,  
10 SMALL B IN PARENS, AND 6 IN PARENS. IT SAYS, STANDARDS,  
11 LIMIT ON THE TIME DURING WHICH CELLS MAY BE EXTRACTED  
12 FROM BLASTOCYSTS WHICH SHALL INITIALLY BE 8 TO 12 DAYS  
13 AFTER CELL DIVISION BEGINS, NOT COUNTING ANY TIME DURING  
14 WHICH THE BLASTOCYST AND/OR CELLS HAVE BEEN STORED  
15 FROZEN. YOU'VE GOT TO FIND OUT -- YOU'VE GOT TO BE  
16 CAREFUL ON HOW YOU LIMIT THIS. AND YOU SHOULD REALIZE  
17 THAT THE REASON WORD "INITIALLY" WAS IN THERE WAS OVER  
18 TIME THE SCIENCE MIGHT CHANGE. AND SO THERE'S ACTUALLY  
19 THE ABILITY FOR DISCRETION AS LONG AS IT'S WELL  
20 DOCUMENTED, THE STANDARDS WORKING GROUP PHILOSOPHICALLY  
21 THINKS IT OUT.

22 AND THE KEY HERE IS WE HAVE TO CONTINUE TO  
23 SERVE THE MISSION AS LONG AS IT'S MEDICALLY AND ETHICALLY  
24 THOUGHTFUL.

25 MR. SHEEHY: I JUST WANTED TO GO BACK. I

## BARRISTERS' REPORTING SERVICE

1       WONDER IF KEVIN CAN MAYBE ANSWER THIS. I JUST REALLY  
2       WANT TO COME BACK TO THE ISSUE OF ARE WE TALKING  
3       RETROSPECTIVELY OR PROSPECTIVELY? HOW MANY LINES OUT  
4       THERE WOULD THERE BE THAT WOULD HAVE BEEN DERIVED AFTER  
5       12 DAYS? IT SOUNDED LIKE IN SOME OF THE DISCUSSION THAT  
6       THAT WAS NOT FEASIBLE.

7               DR. EGGAN: WE'RE PROSPECTIVELY HERE, NOT  
8       RETROSPECTIVELY.

9               MR. SHEEHY: WHY WOULD WE NOT STAY WITH THE  
10       12-DAY STANDARD? IT SEEMS LIKE WE'RE MOVING.

11              DR. EGGAN: MY STATEMENT DID NOT SPEAK TO  
12       WHETHER OR NOT WE SHOULD OR SHOULD NOT STAY WITH THE  
13       12-DAY GUIDELINE. IT SIMPLY SAID THAT IF THERE'S A  
14       LOOPHOLE HERE -- I SIMPLY SAID IF THERE IS A POTENTIAL  
15       LOOPHOLE HERE, THAT WE SHOULD TRY TO CLOSE IT BECAUSE  
16       THERE IS NEW SCIENCE IN ANIMALS WHICH MAY DRIVE PEOPLE TO  
17       DERIVE DURING THIS TIMEFRAME IN A HUMAN SITUATION.

18              CHAIRMAN LO: LET ME MAKE A SUGGESTION.

19              DR. EGGAN: IS THAT CLEAR?

20              MR. SHEEHY: IT IS BECAUSE TRYING TO GO BACK TO  
21       WHERE WE WERE WHEN WE FIRST DID THIS, WE WERE REALLY  
22       TRYING IN MANY WAYS TO GRANDFATHER IN ALL THE THINGS THAT  
23       HAVE BEEN GOING ON AROUND THE WORLD BEFORE WE CAME INTO  
24       BEING AND NOT TRYING TO MAKE PEOPLE WHO ARE WORKING WITH  
25       LINES THAT HAVE ALREADY BEEN ESTABLISHED HAVE TO GO BACK

## BARRISTERS' REPORTING SERVICE

1 AND MAKE SURE THEY CONFORM TO OUR ETHICAL STANDARDS. AS  
2 THE FIELD AS A WHOLE IS STARTING TO GEL, GIVEN THAT WE'RE  
3 NOT TALKING ABOUT TELLING PEOPLE THEY CAN'T USE LINES  
4 THAT ALREADY EXIST, I DO THINK, GIVEN THAT PAT AND BOB  
5 DON'T SEEM TO NECESSARILY AGREE ON THIS, IT SOUNDS LIKE  
6 MAYBE BOB'S RIGHT. WE'D WIN THE LITIGATION, BUT I SURE  
7 WOULD NOT LIKE TO GO THROUGH IT, AND I DON'T THINK IT'S  
8 HELPFUL FOR THE FIELD TO CONTEMPLATE THAT.

9 CHAIRMAN LO: LET ME MAKE A SUGGESTION. I  
10 THINK I'D LIKE TO TRY AND SEE IF YOU'RE WILLING TO  
11 SEPARATE TWO ISSUES. I'D LIKE TO SEPARATE OUT THE 12- TO  
12 14-DAY TIME LIMIT ON DEVELOPMENT OF EMBRYOS IN VITRO, AND  
13 TO SAY THAT WE NEED TO SORT OF STEP BACK A MINUTE, TRY  
14 AND UNDERSTAND WHAT THE SCIENTIFIC RATIONALE MIGHT BE IN  
15 THE FUTURE FOR CULTURING EMBRYOS BEYOND 12 DAYS. WE  
16 ALSO, I THINK, NEED TO LOOK AT WHAT THE CURRENT LEGAL  
17 LIMITS ARE IN OTHER COUNTRIES, PARTICULARLY UK, CANADA,  
18 JOSE, I THINK, MENTIONED SPAIN AND SWEDEN, AND TO SEE  
19 WHERE THE INTERNATIONAL STANDARDS ARE.

20 I THINK WE NEED TO COME BACK TO ANOTHER  
21 MEETING, I THINK EVENTUALLY TO THE ICOC, AND SAY IS THERE  
22 A CASE, BECAUSE THE SCIENCE IS CHANGED, TO GO BEYOND 12  
23 DAYS. I THINK WE NEED TO MAKE THAT CASE. I THINK BOTH  
24 PAT AND BOB SAID IT IN SOMEWHAT DIFFERENT WAYS, AND I  
25 DON'T THINK WE CAN DO THAT TODAY. SO I'D LIKE TO SORT OF

## BARRISTERS' REPORTING SERVICE

1 COMMISSION GEOFF AND OTHER CIRM STAFF TO TRY AND GATHER  
2 THAT INFORMATION FOR US SO WE CAN BE BETTER INFORMED, BUT  
3 NOT TO TRY AND SETTLE THAT TODAY.

4 SO I GUESS I WANT TO GET A SENSE FROM THE  
5 COMMITTEE -- I KNOW IT'S HARD ON THE PHONE -- AS TO HOW  
6 YOU WOULD FEEL ABOUT THAT BECAUSE IT'S A VERY IMPORTANT  
7 ISSUE THAT WE RAISE, AND I THINK WE NEED TO REALLY THINK  
8 THIS ONE THROUGH.

9 MS. KING: I'M COMFORTABLE WITH WHAT YOU  
10 PROPOSE.

11 DR. PRIETO: AS I AM, BERNIE.

12 MR. KLEIN: I AM AS WELL. THE TECHNICAL ISSUE  
13 THAT HAS BEEN RAISED ON LINES IS WHAT KIND OF DATABASE DO  
14 THEY HAVE THAT INDICATES EXACT NUMBER OF DAYS IN WHICH  
15 THE LINES WERE DERIVED IS AN INTERESTING ISSUE TO GET  
16 SOME CLARIFICATION ON.

17 CHAIRMAN LO: RIGHT. LET'S ADD THAT TO THE  
18 LIST OF DATA WE WANT GEOFF TO TRY AND COLLECT. SO I'M  
19 GOING TO TAKE THAT AS THE SENSE OF THE COMMITTEE.

20 NOW CAN WE GO BACK TO THE JAPANESE GUIDELINES,  
21 AND WE WANT TO PUT THEM ON THE SAME FOOTING AS THE UK AND  
22 CANADA. BOTH I THINK ARE GOING TO HAVE THIS 12 VERSUS  
23 14-DAY ISSUE TO BE DEALT WITH EVENTUALLY. BUT WE WANT TO  
24 SORT OF DEEM IN THE JAPANESE REGULATIONS AS BEING  
25 EQUIVALENT TO UK AND CANADA?

## BARRISTERS' REPORTING SERVICE

1 MR. KLEIN: EARLY ON IN THESE STANDARDS  
2 MEETINGS WE TALKED ABOUT, YOU KNOW, WHERE THERE WAS A  
3 FOREIGN COUNTRY WITH WELL-ESTABLISHED MEDICAL AND ETHICAL  
4 STANDARDS THOUGHTFULLY DERIVED THAT WE WOULD REASONABLY  
5 RECOGNIZE THAT BECAUSE THERE'S IMPORTANT RESEARCH AROUND  
6 THE WORLD THAT IS VITAL TO WHAT WE'RE DOING. AND WE WANT  
7 TO INCORPORATE REASONABLY AND THOUGHTFULLY AS MANY OF  
8 THOSE STANDARDS AS WE CAN.

9 SO I'D LIKE TO, FOR DISCUSSION PURPOSES, AT  
10 LEAST, I'D LIKE TO MAKE A MOTION THAT WE DO ADOPT THOSE  
11 JAPANESE STANDARDS.

12 CHAIRMAN LO: WE HAVE A MOTION. IF I CAN JUST  
13 MAKE A BRIEF COMMENT. BOB, AGAIN, BEFORE YOU CAME IN,  
14 GEOFF REMINDED US THAT THE EVIDENCE FOR THE JAPANESE  
15 GUIDELINES BEING CONSISTENT WITH THOSE GENERAL STANDARDS  
16 WAS PRESENTED IN THE MAY MEETING AND ALSO WAS SENT AROUND  
17 AGAIN WITH OUR BRIEFING BOOK.

18 SOMEONE LIKE TO SECOND BOB'S MOTION?

19 DR. CIBELLI: BEFORE WE DO THAT, CAN I ASK ALSO  
20 IF WE HAVE -- MAKE SURE WE DO HAVE A COPY OF THE CONSENT  
21 FORM THEY USE, OR AT LEAST HAVE THE COPY TRANSLATED.  
22 MAYBE WE CAN HAVE THAT SENT TO EACH ONE OF US. CONSENT  
23 FORM, AS YOU KNOW, AND OTHERS CAN TELL YOU, THEY CHANGE  
24 QUITE A BIT FROM ONE PLACE TO ANOTHER.

25 DR. LOMAX: JOSE, WHAT I COULD RECIRCULATE IS I

## BARRISTERS' REPORTING SERVICE

1 HAVE THE LEGAL REQUIREMENTS FOR CONSENT UNDER THE  
2 JAPANESE LAW. WE HAVE ACTUALLY NEVER ACTUALLY REVIEWED  
3 ACTUAL CONSENT FORMS. AND SO IF WHAT YOU ARE ASKING IS  
4 THE SORT OF STATUTORY REQUIREMENTS FOR CONSENT UNDER THE  
5 LAW, THAT HAS BEEN CIRCULATED, AND I WILL RECIRCULATE  
6 THAT.

7 DR. CIBELLI: NO. NO. I HAVE THAT. YOU SENT  
8 THAT EARLY IN MAY. IS THAT WHAT YOU ARE TALKING ABOUT?

9 DR. LOMAX: CORRECT.

10 DR. CIBELLI: I THINK MAY 8 OR APRIL 27 OR  
11 SOMETHING LIKE THAT. THOSE ARE OKAY. THOSE ARE THE  
12 GUIDELINES. I JUST WAS WONDERING IF WE DO HAVE TO ALSO  
13 HAVE THE CONSENT FORM THAT PEOPLE SIGN OR NOT.

14 CHAIRMAN LO: WHAT WE'VE DONE, TO MAKE SURE I  
15 HAVE THIS STRAIGHT, IS THAT WE'VE SAID THAT SINCE THESE  
16 OTHER COUNTRIES THAT WE'RE DEEMING IN HAVE SET UP THEIR  
17 OWN OVERSIGHT REGULATORY PROCESS, WE'RE IN A SENSE  
18 RELYING ON THEM TO MAKE SURE THE ACTUAL CONSENT FORMS ARE  
19 IN COMPLIANCE WITH THE LAW THEY HAVE. AND SO, FOR  
20 EXAMPLE, IF THE UK GUIDELINES, WE DON'T ACTUALLY ASK TO  
21 SEE THEIR ACTUAL CONSENT FORMS, WHICH, OF COURSE, IS WHAT  
22 ACTUALLY DRIVES THAT DISCUSSION, BUT WE'RE SAYING THAT WE  
23 TRUST HEATH IN THAT CASE TO ENSURE THAT THE ACTUAL  
24 CONSENT IS CONSISTENT WITH THE LEGAL REQUIREMENT.

25 SO IT'S MEANT, I THINK, TO MAKE IT A LITTLE

## BARRISTERS' REPORTING SERVICE

1 EASIER FOR RESEARCHERS TO USE THE LINES BY SAYING YOU  
2 DON'T ACTUALLY HAVE TO GET THE ACTUAL FORMS. YOU JUST  
3 HAVE TO SHOW US THAT THE STATUTORY AUTHORITY IN THAT  
4 COUNTRY APPROVED IT AS BEING CONSISTENT WITH THEIR OWN  
5 NATIONAL STANDARDS.

6 DR. CIBELLI: OKAY.

7 DR. WILLERSON: I'LL SECOND THE MOTION.

8 CHAIRMAN LO: JIM SECONDED THE MOTION.

9 WELCOME, BY THE WAY, JIM. I DON'T THINK WE SAID HELLO  
10 BEFORE.

11 MR. SHEEHY: SO I WILL NOT BE ABLE TO SUPPORT  
12 THIS MOTION UNLESS WE PUT IN SPECIFIC LANGUAGE TO  
13 INDICATE THE 12-DAY LIMIT AS BEING ABSURD BECAUSE I THINK  
14 IT'S -- WE'VE BEEN INFORMED ABOUT THIS ISSUE. THERE'S A  
15 DISCREPANCY BETWEEN 12 AND 14 DAYS. IT'S AN OPEN  
16 QUESTION. IT'S NOT CLEAR THAT PROP 71 -- HOW PROP 71,  
17 THE LANGUAGE IN PROP 71, APPLIES HERE. AND, YOU KNOW,  
18 THIS IS THE REASON WE HAD THE DISCUSSION IS BECAUSE OF  
19 THIS DISCREPANCY. AND THEN TO MAKE THE MOTION TO ADOPT  
20 THESE PENDING FURTHER INFORMATION WITHOUT SOME  
21 PLACEHOLDER LANGUAGE INDICATING THAT THEY WERE STILL  
22 OBSERVING THE STATUS QUO ANTE, WHICH IS THE 12-DAY RULE,  
23 IS NOT SOMETHING I CAN SUPPORT.

24 CHAIRMAN LO: OTHER COMMENTS?

25 MS. KING: I'D AGREE WITH JEFF.

**BARRISTERS' REPORTING SERVICE**

1 MS. FEIT: I AGREE WITH JEFF.

2 DR. PRIETO: WOULD A FRIENDLY AMENDMENT OR  
3 WOULD THE MAKER OF THE MOTION ACCEPT AN AMENDMENT TO PUT  
4 IN LANGUAGE TO THAT EFFECT?

5 MR. KLEIN: I THINK THERE WERE TWO PEOPLE  
6 TALKING AT ONCE.

7 DR. PETERS: PLEASE CLARIFY WHETHER THIS MOTION  
8 HAS A SECOND OR NOT.

9 DR. WILLERSON: IT IS A SECOND, BUT I WOULD  
10 AGREE WITH THE AMENDMENT.

11 DR. PETERS: I WOULD LIKE TO GET IN LINE AND  
12 ASK AN INFORMATION QUESTION WHEN THE TIME IS RIGHT.

13 CHAIRMAN LO: FRANCISCO IS OFFERING TO AMEND  
14 THE MOTION, AND I GUESS, BOB, WOULD THAT BE AMENDABLE TO  
15 YOU OR NOT?

16 MR. KLEIN: THERE WERE TWO PEOPLE TALKING WHEN  
17 FRANCISCO WAS TALKING, SO I COULDN'T QUITE HEAR WHAT HE  
18 WAS SAYING.

19 DR. PRIETO: MY SUGGESTION WAS ON AMENDMENT  
20 THAT WE INSERT, AS GEOFF SUGGESTED, PLACEHOLDER LANGUAGE  
21 TO STIPULATE THAT OUR INTENT WAS TO ABIDE BY THE 12-DAY  
22 LIMIT WHILE WE ARE INVESTIGATING STANDARDS, INTERNATIONAL  
23 STANDARDS, WITH REGARDS TO THIS IN JAPAN, ENGLAND,  
24 CANADA, AND ELSEWHERE.

25 CHAIRMAN LO: IF I COULD JUST MAKE A FRIENDLY,

**BARRISTERS' REPORTING SERVICE**

1 FRIENDLY AMENDMENT, PUT IN INVESTIGATING SCIENTIFIC  
2 BACKGROUND OR RATIONALE OR SOMETHING AS WELL AS THE  
3 STANDARDS.

4 DR. PRIETO: YES.

5 CHAIRMAN LO: BOB, IS THAT --

6 MR. KLEIN: LET ME UNDERSTAND THIS AS WELL.  
7 JEFF, IF THE ACTUAL LINES, IF THE EVIDENCE WERE THAT THEY  
8 DIDN'T HAVE IN JAPAN A 12-DAY LIMIT, BUT THE ACTUAL  
9 INFORMATION VERIFIED THAT THE LINE WAS DERIVED WITHIN 12  
10 DAYS, THEN IT WOULD STILL BE ACCEPTABLE. IS THAT YOUR  
11 THOUGHT?

12 MR. SHEEHY: YES. AND I THINK, AS KEVIN HAS  
13 SAID, WE'RE NOT TALKING ABOUT ANY LINES THAT EXIST RIGHT  
14 NOW. SO WE'RE TALKING ABOUT FUTURE LINES. SO I THINK  
15 PUTTING IN SOME SORT OF LANGUAGE INDICATING THAT WE'RE  
16 STILL MAINTAINING CONSISTENCY WITH PROP 71 WHILE WE LOOK  
17 AT WHERE THE SCIENCE IS AND GET A BETTER SENSE OF WHAT'S  
18 GOING ON MAKES A LOT OF SENSE.

19 MR. KLEIN: TO UNDERSTAND COMPLETELY, WHAT  
20 WE'RE SAYING IS AS TO ACCEPTANCE OF JAPANESE LINES THAT  
21 ARE ALREADY IN PLACE, TO THE EXTENT THAT THEY EXIST, THEY  
22 WOULD NOT BE HELD TO THIS NEW STANDARD. WE'RE TALKING  
23 ABOUT PROSPECTIVELY HOLDING THEM TO THE 12-DAY STANDARD.

24 MR. SHEEHY: AT LEAST BASED ON WHAT WE'VE HEARD  
25 FROM KEVIN, IT HAS NOT BEEN SCIENTIFICALLY POSSIBLE TO

## BARRISTERS' REPORTING SERVICE

1 DERIVE LINES PAST 12 DAYS. SO WE WOULDN'T -- THE LINES  
2 THAT ALREADY EXIST WOULD BE BY NATURE OF THE STATE OF  
3 SCIENCE NOT DERIVED AFTER 12 DAYS.

4 MR. KLEIN: SO WHAT I'M SAYING --

5 MR. SHEEHY: SO WE HAVE TO PUT IN LANGUAGE THAT  
6 SOMEHOW INDICATES SOME CONSISTENCY WITH THE 12-DAY RULE  
7 WHILE WE KIND OF FURTHER STUDY THIS ISSUE BECAUSE I DON'T  
8 WANT TO BE IN A POSITION WHERE WE'RE CHANGING THE 12-DAY  
9 RULE IN ORDER TO MAKE SOME SORT OF MATCH WITH WHAT THE  
10 JAPANESE RULES ARE WHEN THERE ARE NO LINES IN JAPAN THAT  
11 HAVE BEEN DERIVED AFTER 12 DAYS EVEN THOUGH THEY HAVE A  
12 14-DAY RULE.

13 MS. CHARO: MAY I SUGGEST ANOTHER APPROACH THAT  
14 MIGHT BE EVEN SIMPLER? SO GIVEN THAT RIGHT NOW THERE ARE  
15 NO LINES THAT COME FROM EMBRYOS THAT WERE MAINTAINED MORE  
16 THAN 12 DAYS, WHY NOT SIMPLY ADOPT THE JAPANESE  
17 GUIDELINES? THAT'S IT. ADOPT THEM. ON THE DAY WHEN  
18 THERE IS A SCIENTIFIC REPORT THAT IT IS POSSIBLE TO  
19 MAINTAIN AN EMBRYO FOR 13 DAYS, THAT'S THE DAY THAT THIS  
20 COMMITTEE NEEDS TO RECONVENE AND DECIDE WHETHER OR NOT  
21 THEY'RE GOING TO EITHER ALLOW FOR SOME DEGREE OF  
22 DIVERSITY AND ETHICAL POSITIONS AND ALLOW THE USE OF  
23 LINES THAT COME FROM EMBRYOS THAT WERE MAINTAINED FOR 13  
24 DAYS, OR IF IT IS NOW GOING TO IMPOSE REQUIREMENT NOT  
25 ONLY ON JAPAN, BUT EVERY OTHER COUNTRY THAT THE LINES

## BARRISTERS' REPORTING SERVICE

1 THAT WE ACCEPT MUST HAVE COME FROM EMBRYOS MAINTAINED  
2 ONLY 12 DAYS OR LESS. FOR THE MOMENT WE CAN JUST GO  
3 AHEAD AND ADOPT THE JAPANESE GUIDELINES. THERE'S NO  
4 PROBLEM.

5 MR. KLEIN: JEFF, WHAT'S YOUR THOUGHT ABOUT  
6 THAT?

7 MR. SHEEHY: WITH ALL DUE RESPECT, I'M NOT  
8 COMFORTABLE WITH THAT BECAUSE WE ARE CHANGING FROM  
9 SOMETHING THAT WAS PUT INTO STATUTE. AND THE REASON  
10 WE'RE DOING THIS IS THAT WE HAVE MOVED THE GOALPOST EVEN  
11 WE'RE THOUGH ACKNOWLEDGING THE GOALPOST HAS NOT BEEN  
12 MOVED SCIENTIFICALLY, WE HAVE MOVED THEM AS A MATTER OF  
13 OUR ETHICAL STANDARDS. AND SO IT'S NOT CLEAR TO ME THAT  
14 THE LEGAL ISSUES -- I STILL DON'T FEEL COMPLETELY  
15 COMFORTABLE WITH WHERE WE ARE WITH THE LEGAL ISSUES, AND  
16 I JUST DON'T -- WE STARTED THIS DISCUSSION BECAUSE WE  
17 DIDN'T -- IT'S JUST I'M NOT READY TO MOVE THE GOALPOST.

18 MS. CHARO: JEFF, LET ME JUST TRY ONE LAST  
19 THING TO SEE IF IT MIGHT MAKE YOU COMFORTABLE. IF NOT,  
20 IT DOESN'T MAKE YOU COMFORTABLE. BUT LAW DOESN'T EXIST  
21 IN A VACUUM. IT EXISTS AGAINST A BACKDROP OF FACTS. IF  
22 WE HAD RULES IN THE UNITED STATES THAT SAID NO INCEST  
23 BETWEEN COUSINS AND SIBLINGS AND MARTIANS, AND ANOTHER  
24 COUNTRY HAD A RULE THAT SAID NO INCEST BETWEEN COUSINS  
25 AND SIBLINGS, WE COULD CONSIDER THE SETS THE RULES

## BARRISTERS' REPORTING SERVICE

1 MUTUALLY CONSISTENT BECAUSE THERE ARE NO MARTIANS. AND  
2 RIGHT NOW THERE ARE NO EMBRYOS THAT ARE 13 DAYS OLD.

3 MR. KLEIN: JEFF, LET ME DO THIS. WHAT IF THE  
4 ACCEPTED AMENDMENT SAID THAT WE'RE ACCEPTING THE JAPANESE  
5 MEDICAL AND ETHICAL STANDARDS, BUT WITH THE EXCEPTION  
6 THAT AT SUCH TIME AS THE JAPANESE -- THERE ARE JAPANESE  
7 LINES THAT ARE DERIVED FOR MORE THAN 12 DAYS BEFORE THEY  
8 CAN BE USED, THIS COMMITTEE WOULD HAVE TO APPROVE THAT?

9 MR. SHEEHY: THAT'S A GOOD DIRECTION TO BE  
10 GOING. I'M VERY COMFORTABLE WITH THAT. I JUST DON'T  
11 WANT TO LEAVE THAT WINDOW OR THAT GAP.

12 MR. KLEIN: WOULD THAT BE ACCEPTABLE TO MY  
13 SECOND?

14 DR. WILLERSON: YES.

15 MR. KLEIN: JEFF, I WOULD AMEND MY MOTION AS  
16 STATED.

17 MS. KING: CAN I MAKE A POINT ABOUT THE COMMENT  
18 THAT JEFF JUST MADE? BASICALLY IN LISTENING TO THE  
19 AMENDMENTS, WE'RE TALKING IN LAWYER TERMS WHERE WE'RE  
20 GOING TO HAVE THE BURDEN OF GOING FORWARD. PUTTING THE  
21 PROVISION IN NOW MEANS THAT WE OUGHT TO BE LOOKING OUT  
22 FOR THIS AND INVESTIGATING IT NOW RATHER THAN WAITING OR  
23 FINDING OUT WHAT THE RULES WORLDWIDE ARE RATHER THAN  
24 WAITING FOR SOMEBODY TO GET TO THAT POINT AND THEN WE  
25 SCRAMBLE.

## BARRISTERS' REPORTING SERVICE

1 MR. KLEIN: I WOULD AGREE THAT WE SHOULD ASK  
2 GEOFF LOMAX TO INVESTIGATE THIS NOW SO THAT WE ARE  
3 EDUCATED WHEN THIS GOES FORWARD AND DON'T JUST BE  
4 REACTIVE.

5 MS. CHARO: KEEP IN MIND THIS IS GOING TO APPLY  
6 NOT ONLY TO JAPAN. THE BRITS HAVE A 14-DAY RULE, BUT  
7 WE'VE ALREADY ADOPTED THE BRITISH RULES WITHOUT HAVING  
8 THIS LONG DISCUSSION. SO THIS IS NOW GOING TO BE A  
9 CAVEAT, JEFF, THAT I'M SUSPECTING YOU'RE GOING TO WANT TO  
10 PLACE ON CANADA, UK, AS WELL AS JAPAN.

11 MR. KLEIN: AT THIS MOMENT I THINK WE'RE  
12 DEBATING, THOUGH, THE JAPAN. AND --

13 MS. CHARO: IT MAKES NO SENSE TO ONLY APPLY TO  
14 JAPAN IF THE BRITISH ALSO HAVE A 14-DAY RULE.

15 MR. KLEIN: THE ONLY MOTION THAT'S NOTICED FOR  
16 DISCUSSION TODAY IS DEALING WITH JAPAN.

17 DR. ROWLEY: THAT'S A LEGALISTIC WAY OF LOOKING  
18 AT IT. I AGREE, AND THAT'S WHY I ASKED THE QUESTION  
19 BECAUSE IT SEEMED TO ME THAT THE NATIONAL ACADEMY OF  
20 SCIENCES HAD A 14-DAY RULE, AND IT'S CALIFORNIA, IF YOU  
21 WILL PARDON ME, THAT'S DIFFERENT FROM THE REST OF THE  
22 WORLD.

23 MR. KLEIN: THAT IS TRUE, AND THAT'S ONE REASON  
24 THAT THE STATUTE ITSELF SAYS INITIALLY. BUT WHAT WE -- I  
25 HAVE A MOTION THAT'S PENDING ON JAPAN BECAUSE THAT'S WHAT

## BARRISTERS' REPORTING SERVICE

1 WAS NOTICED AND THAT'S WHAT WE CAN DEAL WITH, WHICH IS  
2 NOT TO SAY WE SHOULDN'T GET A MAJOR REVIEW OF THIS  
3 INFORMATION AND BRING IT BACK TO THIS COMMITTEE.

4 CHAIRMAN LO: LET ME SORT OF INTERRUPT AS CHAIR  
5 AND SEE IF I CAN TRY AND PUT US BACK ON COMMON GROUND. I  
6 THINK WE'RE ALL CONCERNED ABOUT NEEDING TO THINK THROUGH  
7 AND GET MORE INFORMATION ON THE 12 TO 14 DAYS. THERE  
8 ACTUALLY IS NO URGENCY TO APPROVE THE JAPANESE LINES  
9 TODAY. THERE'S NOT ANY RESEARCHER SAYING WE'RE HOLDING  
10 BACK RESEARCH. I THINK THERE CLEARLY MAY BE IN THE  
11 FUTURE, BUT THERE'S NO CURRENT CIRM-FUNDED RESEARCH.

12 SO I THINK THIS IS AN ISSUE THAT WE MAY WANT TO  
13 DEFER AND COME BACK TO. IT'S, FRANKLY, TURNED OUT TO BE  
14 MUCH MORE COMPLICATED THAN WE HAD ORIGINALLY ANTICIPATED,  
15 BUT IT'S GOOD BECAUSE WE'VE RAISED SOME IMPORTANT ISSUES.  
16 BUT I'M WONDERING, IN LIGHT OF SOME OF THE OTHER AGENDA  
17 ITEMS, WHICH I THINK ARE A LITTLE MORE TIME URGENT,  
18 WHETHER WE WANT TO IN A SENSE TABLE THIS DISCUSSION UNTIL  
19 WE HAVE HAD A CHANCE TO BOTH GET MORE INFORMATION ABOUT  
20 THE SCIENCE AND ABOUT THE INTERNATIONAL GUIDELINES, ALSO  
21 THINK A LITTLE BIT MORE ABOUT SORT OF EQUITY BETWEEN THE  
22 NEW SET OF -- BETWEEN JAPAN, UK, AND CANADA BECAUSE I  
23 THINK THE 12- TO 14-DAY DISCREPANCY WOULD APPLY ACROSS  
24 THE BOARD.

25 I'M JUST SAYING THAT IT MAY NOT BE THE BEST USE

## BARRISTERS' REPORTING SERVICE

1 OF OUR TIME TODAY TO TRY AND PUSH MORE ON THIS. IT'S  
2 MUCH MORE COMPLICATED THAN I HAD ANTICIPATED SETTING OUT  
3 THE AGENDA.

4 MR. KLEIN: BERNIE, SINCE WE HAVE A MOTION AND  
5 A SECOND, AND IT APPEARS THAT JEFF SHEEHY BELIEVES THAT,  
6 AS AMENDED, THAT IT'S ACCEPTABLE TO HIM, AND GIVEN THAT  
7 WE DON'T KNOW WHAT ALL THE RESEARCHERS IN CALIFORNIA ARE  
8 WORKING ON AND GIVEN THAT THERE IS SOME VERY IMPORTANT  
9 JAPANESE RESEARCH GOING ON, WHY NOT TAKE A VOTE ON THIS  
10 MOTION? WE'RE GOING TO HAVE TO COME BACK TO THE SUBJECT  
11 AT A DIFFERENT TIME ANYWAY, BUT WHY NOT TAKE A VOTE ON  
12 THIS MOTION?

13 CHAIRMAN LO: LET'S DO THAT AND SETTLE IT. ANY  
14 FURTHER DISCUSSION ON THE MOTION?

15 DR. PETERS: WHAT IS THE MOTION? IS IT  
16 COMPREHENSIVE, OR DEALING ONLY WITH THE 12-DAY RULE?

17 MR. KLEIN: IT'S ONLY DEALING -- IT IS TO  
18 APPROVE THE JAPANESE MEDICAL AND ETHICAL -- THE LINES  
19 DERIVED UNDER THE JAPANESE MEDICAL AND ETHICAL STANDARDS  
20 WITH THE EXCEPTION THAT AT SUCH TIME AS THERE ARE LINES  
21 IN JAPAN DERIVED THAT ARE MORE THAN 12 DAYS, IT WILL HAVE  
22 TO COME BACK TO THIS COMMITTEE FOR CONSIDERATION OF  
23 WHETHER THOSE LINES CAN BE USED.

24 DR. PETERS: GOOD. DOES THIS MOTION COVER  
25 SECTION B AS WE RECEIVED IT IN THE AGENDA BECAUSE I WOULD

**BARRISTERS' REPORTING SERVICE**

1       LIKE TO ASK ABOUT THAT?

2                   CHAIRMAN LO:  TED, CAN YOU CLARIFY WHAT YOU ARE  
3       REFERRING TO UNDER B?

4                   DR. PETERS:  100080, SECTION B, SUBSECTION 1, I  
5       WOULD LIKE TO ASK ABOUT --

6                   CHAIRMAN LO:  NO.  THAT'S A WHOLE ANOTHER  
7       DISCUSSION WHICH I ACTUALLY WOULD LIKE TO GET TO BECAUSE  
8       THAT'S URGENT.  THAT JUST COVERS IN YOUR PAGE -- IT'S  
9       10080(A)(5), THAT BLUE TWO-LINER.

10                  DR. PETERS:  OKAY.  I'LL WAIT THEN.  I'D LIKE  
11       TO ASK BOB ABOUT THAT WHEN WE GET TO IT.

12                  CHAIRMAN LO:  LET ME TRY AND DO SOME TRAFFIC  
13       HERE.

14                  MR. TOCHER:  I JUST WANTED TO BACK UP BERNIE'S  
15       OBSERVATION.  SORT OF WHAT REALLY WHAT WE'RE DOING HERE  
16       TODAY IS THAT YOU'RE NOT DECIDING TO AMEND THE REGULATION  
17       EFFECTIVE TODAY OR EVEN 30 DAYS FROM NOW.  THIS IS A  
18       RECOMMENDATION THAT WILL GO, THEN, TO THE ICOC TO  
19       INITIATE THE AMENDMENT PROCESS TO INCLUDE THE JAPANESE  
20       GUIDELINES.  SO THERE IS STILL, I THINK, PLENTY OF TIME  
21       TO GET THE INPUT THAT YOU WANT AND NEED IN ORDER TO COME  
22       TO A FINAL DECISION, NOT ONLY AS TO THE JAPANESE  
23       GUIDELINES, BUT ALSO AS TO THE OTHERS IF YOU CHOOSE TO GO  
24       DOWN THAT ROAD.

25                  CHAIRMAN LO:  AND THERE WILL BE AMPLE TIME FOR

## BARRISTERS' REPORTING SERVICE

1 PUBLIC COMMENT AND DISCUSSION. WE HAVE A PUBLIC COMMENT  
2 HERE IN SAN FRANCISCO.

3 MS. THOMPSON: CHARIS THOMPSON AGAIN FROM SAN  
4 FRANCISCO. I WONDER IF NOW WOULD BE THE TIME, IN LIGHT  
5 OF THE 12- AND 14-DAY AND ALSO IN LIGHT OF THE GROWING  
6 LIST OF 100080 BETWEEN THE ENUMERATED ITEMS IN A TO  
7 CHANGE THE LANGUAGE -- TO BEGIN DISCUSSING CHANGING THE  
8 LANGUAGE TO INCLUDE ALL ETHICALLY DERIVED LINES FROM  
9 AROUND THE WORLD SO THAT YOU DON'T HAVE TO ADD A LINE  
10 ITEM FOR EVERY SPECIFIC COUNTRY, AND AT THE SAME TIME YOU  
11 COULD STIPULATE AS YOU LIKE ABOUT THE 12-DAY LIMIT.  
12 PRESUMABLY SWEDEN, SINGAPORE, ALL SORTS OF PLACES ARE  
13 GOING TO BE FOLLOWING THIS VERY SOON, AND IT WILL BEGIN  
14 TO LOOK VERY BURDENSOME TO APPROVE EACH COUNTRY  
15 INDIVIDUALLY, AS WELL AS CAPRICIOUS IF SOME ARE LEFT OUT.  
16 THANK YOU.

17 CHAIRMAN LO: OKAY. IS THERE A CALL FOR THE  
18 QUESTION?

19 DR. PRIETO: CALL THE QUESTION.

20 CHAIRMAN LO: THANK YOU, FRANCISCO.

21 DR. LOMAX: I'M GOING TO DO A ROLL CALL VOTE  
22 JUST TO MAKE SURE WE STILL HAVE A QUORUM.

23 MARCY FEIT.

24 MS. FEIT: I WANT TO ABSTAIN FOR NOW.

25 DR. LOMAX: ROBERT KLEIN.

## BARRISTERS' REPORTING SERVICE

1 UNIDENTIFIED SPEAKER: ROBERT KLEIN HAD TO STEP  
2 OUT OF THE OFFICE TO SPEAK WITH THE SPEAKER OF THE HOUSE,  
3 BUT HE VOTES AYE.

4 DR. LOMAX: FRANCISCO PRIETO.

5 DR. PRIETO: AYE.

6 DR. LOMAX: JEFF SHEEHY.

7 MR. SHEEHY: YES.

8 DR. LOMAX: ALTA CHARO.

9 MS. CHARO: NAY.

10 DR. LOMAX: BERNIE LO.

11 CHAIRMAN LO: AYE.

12 DR. LOMAX: PATRICIA KING.

13 MS. KING: NAY.

14 DR. LOMAX: TED PETERS.

15 DR. PETERS: AYE.

16 DR. LOMAX: JOSE CIBELLI.

17 DR. CIBELLI: AYE.

18 DR. LOMAX: KEVIN EGGAN.

19 DR. EGGAN: AYE.

20 DR. LOMAX: ANN KIESSLING.

21 DR. KIESSLING: AYE.

22 DR. LOMAX: JEFFREY KORDOWER. KEN OLDEN.

23 JANET ROWLEY.

24 DR. ROWLEY: AYE.

25 DR. LOMAX: ROBERT TAYLOR.

## BARRISTERS' REPORTING SERVICE

1 DR. TAYLOR: AYE.

2 DR. LOMAX: JOHN WAGNER. JAMES WILLERSON.

3 DR. WILLERSON: AYE.

4 CHAIRMAN LO: IS THAT ACTUALLY A QUORUM?

5 THAT'S ACTUALLY A QUORUM, SO IT'S A FORMAL VOTE. AND WE  
6 RECOMMEND THIS TO THE ICOC ON THEIR AUGUST 8TH MEETING  
7 FOR THEIR CONSIDERATION TO START THE AOL REGULATORY  
8 PROCESS.

9 MR. TOCHER: I'LL CHECK TO MAKE SURE THAT  
10 THAT'S ON THE AGENDA, BUT, YES, IT WILL GO TO ICOC TO  
11 INITIATE THE AMENDMENT PROCESS.

12 CHAIRMAN LO: GOOD. THANK YOU. THIS WAS AN  
13 IMPORTANT ISSUE AND ONE WE'RE GOING TO COME BACK TO.

14 THE SECOND ISSUE -- LET ME JUST ASK, GEOFF,  
15 WHICH IS THE MOST PRESSING QUESTION?

16 DR. LOMAX: I THINK THE C IS THE MOST PRESSING  
17 ISSUE.

18 CHAIRMAN LO: I'D LIKE TO INVERT THE AGENDA AND  
19 TALK ABOUT ITEM C, WHICH IS THE USE OF SOMATIC CELLS,  
20 EXISTING SOMATIC CELLS FOR SOMATIC CELL REPROGRAMMING.  
21 SO THESE ARE ATTEMPTS TO DERIVE STEM CELL LINES USING  
22 THIS NEW REPROGRAMMING TECHNIQUE THAT WAS DESCRIBED AND  
23 JUST RECENTLY VERIFIED OF INSERTING GENES INTO THE  
24 SOMATIC CELLS WHICH TURN THEM INTO PLURIPOTENT CELLS. SO  
25 THIS DOES NOT INVOLVE EMBRYOS, AND A LOT OF RESEARCHERS

## BARRISTERS' REPORTING SERVICE

1 ARE ACTUALLY QUITE EAGER TO TRY AND DEVELOP THIS  
2 TECHNIQUE IN HUMANS AS OPPOSED TO THE MOUSE LINES THAT  
3 HAVE BEEN DERIVED. AND THERE ACTUALLY IS -- IS IT PUBLIC  
4 KNOWLEDGE THAT THERE'S A CIRM GRANT?

5 DR. LOMAX: WELL, THERE ARE --

6 CHAIRMAN LO: THERE'S A LOT OF INTEREST IN  
7 CALIFORNIA IN SORT OF OBTAINING CIRM FUNDING TO DO THIS  
8 KIND OF REPROGRAMMING WORK TO DERIVE PLURIPOTENT LINES.  
9 AND THERE IS AN AMBIGUITY AND POTENTIAL INCONSISTENCY IN  
10 WHAT OUR CURRENT REGULATIONS ARE. THAT'S WHAT'S SORT OF  
11 PUSHING THIS 10080(B) SUGGESTION.

12 I'M GOING TO -- THAT'S JUST BACKGROUND. I'M  
13 GOING TO TURN TO GEOFF TO SORT OF WALK US THROUGH THE  
14 POLICY BACKGROUND ON IT.

15 DR. LOMAX: I'M WALKING THROUGH -- IN THE  
16 PUBLIC MEETING, WE HAVE SLIDES TITLED, NO. 3, "USE OF  
17 SOMATIC CELLS IN HUMAN TISSUE." THE CURRENT LANGUAGE IN  
18 THE CIRM REGULATIONS DOES REQUIRE EXACT CIRM CONSENT  
19 REQUIREMENTS FOR THE USE OF SOMATIC CELLS, AND THOSE ARE  
20 THE DETAILED CONSENT REQUIREMENTS WHICH WE APPLY TO USE  
21 OF EMBRYOS, SCNT, ETC.

22 BY VIRTUE OF CONSENT REQUIREMENTS, IT CREATES  
23 LIMITS ON THE USE OF SOMATIC CELLS COLLECTED BEFORE THE  
24 EFFECTIVE DATE OF THE REGULATIONS BECAUSE THEY WERE  
25 COLLECTED UNDER -- THEY WEREN'T COLLECTED WHEN THIS

## BARRISTERS' REPORTING SERVICE

1 STANDARD EXISTED.

2 AS BERNIE INDICATED, WE HAVE HAD INQUIRIES FROM  
3 INSTITUTIONS SUGGESTING THAT SOME EXISTING SOMATIC CELL  
4 LINES ARE ATTRACTIVE MAINLY BECAUSE THEY ARE  
5 SCIENTIFICALLY WELL CHARACTERIZED, AND THAT MAKES THEM  
6 ATTRACTIVE FOR REPROGRAMMING STUDIES.

7 I'M NOW IN THE PUBLIC MEETING JUST SHOWING THE  
8 EXISTING REGULATORY LANGUAGE, WHICH IS THE NEXT SLIDE,  
9 AND JUST TO HIGHLIGHT THE PROVISION WHICH IS IN SECTION  
10 100090, WHICH BRINGS SOMATIC CELL LINES UNDER THE CONSENT  
11 REQUIREMENTS. THE REASON THEY, AGAIN, GET BROUGHT INTO  
12 THIS, TAKEN INTO THE EXACT CONSENT REQUIREMENTS OF CIRM,  
13 IS BECAUSE THE RESEARCH IS INTENDED TO DERIVE A COVERED  
14 STEM CELL LINE.

15 I AM NOW GOING TO SORT OF VERY QUICKLY MOVE  
16 THROUGH A SET OF SORT OF GRAPHICS JUST TO REITERATE THE  
17 POINT.

18 CHAIRMAN LO: PAGE 4 IN THE HANDOUT.

19 DR. LOMAX: AGAIN, THE CURRENT CONSENT  
20 REQUIREMENTS FOR DONORS OF GAMETES, EMBRYOS, OR SOMATIC  
21 CELL, OR HUMAN TISSUE ALL GET -- THEY ALL FALL UNDER THE  
22 CIRM SPECIFIC CONSENT REQUIREMENTS, WHICH ARE ILLUSTRATED  
23 IN THE BLUE BOXES. MOVING AGAIN TO THE SLIDE WITH THE  
24 SAME TITLE, I'M JUST SORT OF REFORMATTING THAT  
25 INFORMATION INTO A FOUR-BY-TWO TABLE TO SHOW THE

## BARRISTERS' REPORTING SERVICE

1 MATERIALS COVERED BY THE CURRENT REQUIREMENTS.

2 STAFF WAS ASKED TO CONSIDER LANGUAGE THAT WOULD  
3 MAKE AVAILABLE FOR RESEARCH SOMATIC CELLS UNDER -- MAKE  
4 AVAILABLE SOMATIC CELLS THAT WOULD ALLOW THEM TO BE USED  
5 IN RESEARCH RECOGNIZING THAT THEY CANNOT CONFORM  
6 RETROACTIVELY TO THE CONSENT REQUIREMENTS.

7 CHAIRMAN LO: JUST, AGAIN, TO BE REALLY CLEAR  
8 ON THIS. WE'RE TALKING ABOUT SOMATIC CELLS USED FOR THE  
9 REPROGRAMMING BY GENETIC INSERTION OF FOUR OR SIX,  
10 HOWEVER MANY, GENES, NOT SOMATIC CELLS THAT MIGHT BE USED  
11 FOR SCNT EXPERIMENTS.

12 DR. LOMAX: CORRECT. SO IT IS TITLED "FLEXIBLE  
13 OPTION FOR USE OF SOMATIC CELLS," AND WE HAVE DEVELOPED  
14 LANGUAGE THAT WOULD ALLOW THE USE OF THOSE MATERIALS  
15 CONSISTENT WITH EXISTING FEDERAL GUIDELINES FOR THE USE  
16 OF HUMAN CELLS AND TISSUES.

17 IN CONSULTATION WITH THE CHAIR, WE ALSO THOUGHT  
18 IT WAS IMPORTANT TO THINK THROUGH A LONGER-TERM  
19 PERSPECTIVE. SO THE NEXT SLIDE, WHICH IS TITLED  
20 "FLEXIBLE OPTION WITH BASIC RESEARCH LIMITATION," IS  
21 DESIGNED TO SORT OF PROVIDE THE LONG VIEW, IF YOU WILL,  
22 FOR THE WORKING GROUP WHERE IT IS QUITE FEASIBLE, GIVEN  
23 THE EXISTING CIRM REGULATIONS, TO LIMIT THE USE OF THOSE  
24 MATERIALS TO DERIVATION RESEARCH WHICH IS IN VITRO. SO  
25 THE POINT BEING THAT THERE WAS CONCERN THAT IF YOU ARE

## BARRISTERS' REPORTING SERVICE

1 DOING TRANSPLANTATION RESEARCH, TRANSPLANTING CELLS INTO  
2 HUMANS, THAT THERE WAS A SENSE THAT YOU WOULD THEN WANT A  
3 MORE AGGRESSIVE LEVEL OF CONSENT TO APPLY; NAMELY, THE  
4 CIRM CONSENT OR THE CONSENT UNDER THE ACCEPTABLY DERIVED  
5 STANDARDS.

6 SO WE HAVE NOT ACTUALLY PRESENTED LANGUAGE IN  
7 THE RECOMMENDED LANGUAGE TODAY THAT WOULD ACCOMPLISH THE  
8 CONSENT REQUIREMENT FOR HUMAN TRANSPLANTATION, BUT SIMPLY  
9 TO ILLUSTRATE THAT DOWNSTREAM THAT'S AN OPTION THAT'S  
10 QUITE FEASIBLE GIVEN THE EXISTING FRAMEWORK OF THE  
11 MEDICAL AND ETHICAL STANDARDS REGULATIONS.

12 CHAIRMAN LO: JUST LET ME MAKE SURE WE SORT OF  
13 HAVE THE BACKGROUND HERE. THE BACKGROUND IS THAT THE  
14 CURRENT FEDERAL -- THERE'S CURRENT FEDERAL REGULATION OR  
15 GUIDELINES FROM THE OFFICE OF HUMAN RESEARCH PROTECTIONS  
16 ON THE USE OF EXISTING CELLS OR TISSUE THAT A RESEARCHER  
17 WANTS TO USE FOR OTHER EXPERIMENTS. AND THEY CAN BE USED  
18 EITHER UNDER A GENERAL CONSENT FOR RESEARCH SO THAT  
19 SOMEONE MAY HAVE, WHEN THEY ENTERED A HOSPITAL, SIGNED A  
20 GENERAL FORM SAYING ANYTHING LEFT OVER FROM SURGERY CAN  
21 BE USED IN RESEARCH, BUT THERE ALSO IS A PROVISION TO  
22 TAKE EXISTING CELLS AND MATERIAL OBTAINED FOR ANOTHER  
23 PURPOSE AND TO ANONYMIZE IT, TO STRIP ALL IDENTIFIERS,  
24 AND THEN IT'S NO LONGER ACTUALLY CONSIDERED HUMAN  
25 SUBJECTS RESEARCH, AND YOU DON'T NEED CONSENT FOR THOSE

## BARRISTERS' REPORTING SERVICE

1 ANONYMIZED EXISTING LINES.

2 AND MANY OF THESE LINES ARE ACTUALLY NOW  
3 AVAILABLE COMMERCIALY. THEY'RE FIBROBLAST LINES  
4 AVAILABLE COMMERCIALY. SOME OF THEM WERE DERIVED WITH  
5 GENERAL CONSENT. SOME WERE JUST DERIVED FROM TISSUE THAT  
6 HAPPENED TO BE AVAILABLE AND WORKED WITH. AND THESE ARE  
7 WIDELY USED BY RESEARCHERS, AND A NUMBER OF RESEARCHERS  
8 HAVE SAID THAT THEY ARE LINES THEY ARE CURRENTLY WORKING  
9 WITH OF THIS NATURE THAT THEY WOULD LIKE TO NOW USE FOR  
10 SOMATIC CELL REPROGRAMMING THROUGH INSERTION OF GENES.

11 AND IT'S WHETHER THE MUCH MORE STRINGENT  
12 CONSENT REQUIREMENTS THAT GEOFF SHOWED US UNDER 100090,  
13 BUT WOULD PRECLUDE THE USE OF THOSE EXISTING LINES EVEN  
14 THOUGH THEY WOULD BE CURRENTLY PERMITTED UNDER FEDERAL  
15 REGULATIONS AS INTERPRETED BY OHRP.

16 SO THE RESEARCHERS ARE SAYING LET US USE THEM  
17 AS WE WOULD FOR ANY OTHER PURPOSE IN THE LABORATORY OR  
18 FOR ANIMAL EXPERIMENTS AS WELL.

19 DR. PRIETO: FOR DERIVATION RESEARCH, BERNIE?

20 CHAIRMAN LO: YES. NOW TRYING TO DERIVE THEM.  
21 NO ONE HAS YET DERIVED THESE IN HUMANS, BUT THERE ARE A  
22 LOT OF PEOPLE EAGER TO TRY AND DERIVE A PLURIPOTENT CELL  
23 LINE FROM SOMATIC CELLS. ARLENE CHIU HAS A COMMENT.

24 DR. CHIU: JUST FOR CLARIFICATION, I'M SEEING  
25 THIS SLIDE FOR THE FIRST TIME, AND I NOTICE IT SAYS,

## BARRISTERS' REPORTING SERVICE

1 QUOTE, TO DERIVE NEW HUMAN STEM CELL LINES. IT DOESN'T  
2 SAY PLURIPOTENT. IT SHOULD SAY. I JUST WANTED THAT  
3 CLARIFICATION BECAUSE I DON'T SEE THAT WORD UP HERE, AND  
4 OTHERWISE IT WILL BE A VERY BROAD SWATH.

5 CHAIRMAN LO: AMEND THOSE SLIDES. ALL THESE  
6 TWO- AND THREE-COLOR SLIDES GEOFF GAVE US, THEY ALL  
7 SHOULD SAY DERIVE NEW HUMAN PLURIPOTENT STEM CELL LINES,  
8 GOING BACK TO PAGE 4 OR 5, 6 AS WELL.

9 DR. LOMAX: I APOLOGIZE.

10 CHAIRMAN LO: ALL OUR DISCUSSION, BY THE WAY,  
11 IS ON THE USE OF SOMATIC CELLS FOR REPROGRAMMING TO  
12 DERIVE PLURIPOTENT.

13 DR. LOMAX: I JUST WANTED TO APOLOGIZE FOR THE  
14 OMISSION IN THE SLIDES, BUT THERE WAS ALSO DRAFT LANGUAGE  
15 CIRCULATED, AND THAT LANGUAGE IS CLEAR IN THAT IT IS  
16 REFERRING TO COVERED STEM CELL LINES, WHICH ARE, IN FACT,  
17 PLURIPOTENT HUMAN STEM CELL LINES. SO THERE'S A SLIGHT  
18 DISCONNECT BETWEEN THE SUMMARY MATERIAL AND THE LANGUAGE  
19 CIRCULATED, BUT THE LANGUAGE DOES REFLECT THE DISTINCTION  
20 THAT DR. CHIU JUST POINTED OUT.

21 CHAIRMAN LO: COULD I JUST SORT OF GET THIS  
22 DISCUSSION GOING. COULD I FIRST ASK SOME OF OUR  
23 SCIENTISTS, KEVIN AND JOSE, YOU ARE STILL ON THE CALL?  
24 COULD YOU JUST SAY A LITTLE BIT WHY THIS IS IMPORTANT TO  
25 SCIENTISTS TO BE ABLE TO USE THESE EXISTING LINES WHERE

## BARRISTERS' REPORTING SERVICE

1 THE CONSENT IS MAYBE PRETTY HARD TO -- IT MAY BE VERY  
2 HARD TO KNOW WHAT KIND OF CONSENT WAS OBTAINED, BUT  
3 THEY'RE COMMERCIALY AVAILABLE, PUBLICLY AVAILABLE.

4 DR. EGGAN: I CAN TAKE ONE SHOT AT IT. THERE  
5 ARE A VARIETY OF HUMAN PRIMARY CELL LINES WHICH RESIDE IN  
6 THE AMERICAN-TYPE CULTURE COLLECTION WHICH HAVE BEEN USED  
7 BY LABORATORY SCIENTISTS FOR AS LONG AS A DECADE NOW IN  
8 CANCER STUDIES AND IN TRANSGENIC CULTURE EXPERIMENTS.  
9 AND I THINK IT'S PRETTY CLEAR THAT, AS A RESULT OF THOSE  
10 EXPERIMENTS, THERE'S A LARGE RESOURCE IN THE SCIENTIFIC  
11 COMMUNITY OF THOSE MODIFIED CELLS WHICH MAY BE STARTING  
12 POINTS FOR THESE TYPES OF EXPERIMENTS.

13 I THINK THAT'S ONE COMPELLING SORT OF  
14 UTILITARIAN ARGUMENT OF WHY YOU'D WANT TO BE ABLE TO  
15 ACCESS THIS MATERIAL.

16 CHAIRMAN LO: JOSE CIBELLI HAS HAD TO LEAVE THE  
17 CONFERENCE. THERE ARE A NUMBER -- IN SAN FRANCISCO THERE  
18 ARE A NUMBER OF SCIENTISTS IN THE AUDIENCE, EITHER FROM  
19 CIRM OR THE PUBLIC. ANY OF THEM WANT TO COMMENT ON THE  
20 SCIENTIFIC USEFULNESS OF BEING ABLE TO USE THESE EXISTING  
21 LINES TO TRY AND DERIVE PLURIPOTENT CELLS THROUGH THIS  
22 REPROGRAMMING, NOT THROUGH SCNT?

23 MR. KLEIN: THIS IS BOB KLEIN. I'M BACK. I  
24 APOLOGIZE. IS ARLENE THERE?

25 DR. CHIU: I'M NOT A BENCH SCIENTIST ANYMORE,

## BARRISTERS' REPORTING SERVICE

1 AND SO WHAT I'M SAYING IS JUST EXTRAPOLATION. BUT IT  
2 SEEMS TO ME MANY OF THESE LINES HAVE BEEN USED IN A  
3 VARIETY OF EXPERIMENTS, ARE WELL DOCUMENTED, HAVE A  
4 HISTORY OF USE, ANY ABNORMALITIES MAY HAVE BEEN NOTED BY  
5 PEOPLE OVER MANY PASSAGES; AND, THEREFORE, THAT'S ONE  
6 POINT.

7 A SECOND POINT IS THAT THEY ARE READILY  
8 AVAILABLE COMMERCIALY. AND SO I WOULD -- I CAN SEE  
9 INVESTIGATORS IN THE EARLY PHASES OF DOING THIS WORK  
10 DRAWN TO USE THESE TYPES OF LINES BOTH FOR CONVENIENCE  
11 AND FOR HISTORICAL BACKGROUND.

12 SOME OF THESE LINES MAY NOT HAVE THE CONSENT  
13 FORMS, ALL THE CONSENT FORMS THAT WE ARE NOW THINKING OF  
14 THAT WOULD BE REQUIRED. WHAT THIS MEANS IS IF THEY DON'T  
15 HAVE THE APPROPRIATE CONSENT, THEY MAY NOT BE ABLE TO USE  
16 SOME OF THESE LINES. RESEARCHERS MAY HAVE TO DERIVE NEW  
17 LINES WITHOUT MUCH HISTORY, SPEND A YEAR OR SO PACKAGING  
18 THEM AND CHECKING THEIR GROW PROPERTIES BEFORE THEY CAN  
19 START THE REPROGRAMMING STUDIES. HOW IMPORTANT OR NOT  
20 THESE ASPECTS ARE, I CANNOT SPEAK DIRECTLY. I'M HOPING  
21 SOME BENCH SCIENTISTS WITH MORE EXPERIENCE CAN ADDRESS  
22 THESE, BUT THAT WOULD BE A CONCERN IN THE COMMUNITY.  
23 THANK YOU.

24 CHAIRMAN LO: WOULD ANYONE ELSE --

25 DR. KIESSLING: WHY WOULD -- WHAT IS THE

## BARRISTERS' REPORTING SERVICE

1 CONCERN ABOUT USING EXISTING LINES? IS IT SIMPLY WITH  
2 THE CONSENT FORMS THAT WERE USED TO GIVE PERMISSION TO  
3 USE THOSE LINES FOR RESEARCH? IS THAT YOUR CONCERN, THAT  
4 THEY MAY NOT HAVE THE APPROPRIATE CONSENT FORMS?

5 CHAIRMAN LO: RIGHT. THE CONCERN IS THAT SOME  
6 OF THESE LINES THAT MAY NOT HAVE EVER BEEN CONSENTED,  
7 THAT THEY WERE USED THROUGH THIS ANONYMIZATION SORT OF  
8 PROVISION. AND THE OTHER ISSUE IS THAT IF SOME LINES,  
9 THE CONSENT WOULD HAVE BEEN A VERY GENERAL CONSENT  
10 BECAUSE THE CONSENT WAS OBTAINED QUITE SOME AGO, MANY  
11 YEARS AGO, WHEN THIS OBVIOUSLY WAS NOT IN ANYBODY'S MIND.

12 SO THE ISSUE IS IS THERE A CONCERN ABOUT TAKING  
13 SOMEONE'S SOMATIC CELLS AND TURNING THEM INTO A  
14 PLURIPOTENT LINE OR AT LEAST TRYING TO TURN THEM INTO A  
15 PLURIPOTENT LINE WITHOUT THEIR EXPLICIT CONSENT? IS  
16 THERE SOMETHING DIFFERENT ABOUT TRYING TO DERIVE A  
17 PLURIPOTENT LINE THAT GIVES YOU ETHICAL CONCERNS THAT  
18 WOULD NOT BE PRESENT IN TERMS OF THE OTHER TYPES OF  
19 RESEARCH THAT ARE TYPICALLY DONE OR WERE IN THE MIND OF  
20 THE DONOR OR THE PERSON OBTAINING CONSENT?

21 DR. KIESSLING: AND THE ALTERNATIVE WOULD BE TO  
22 REQUIRE THAT THE SCIENTIST DERIVE THE LINES NEW WITH THE  
23 APPROPRIATE CONSENT.

24 CHAIRMAN LO: RIGHT. WITH A DIFFERENT CONSENT,  
25 WITH ALL THE LIMITATIONS THAT WOULD INCLUDE ON USING

## BARRISTERS' REPORTING SERVICE

1 EXISTING LINES. GEOFF LOMAX HAS SORT OF TALKED TO ATC  
2 ABOUT THE CONSENTS, AND IT'S VERY VARIABLE. THEY  
3 ACTUALLY DON'T AT THEIR FINGERTIPS KNOW EXACTLY WHAT KIND  
4 OF CONSENT WAS OBTAINED. SO IT'S NOT AS IF YOU CAN TO GO  
5 TO A CATALOG AND SAY I WANT A FIBROBLAST LINE WITH A  
6 CERTAIN TYPE OF CONSENT.

7 DR. KIESSLING: I UNDERSTAND THAT. BUT IF YOU  
8 DON'T REQUIRE THE INVESTIGATOR TO PROVIDE SOME HISTORY  
9 ABOUT THE LINES THEY CHOOSE TO USE, THEN THE ALTERNATIVE  
10 IS TO SIMPLY ALLOW BLANKET USE OF LINES THAT EXIST NOW?  
11 I THINK THE PROBLEM IS GOING TO BE, EVEN IF YOU DECIDE  
12 THAT HISTORICAL LINES THAT HAVE BEEN IN CULTURE FOR 25  
13 YEARS, THAT PERHAPS THAT CONSENT FORM IS NO LONGER  
14 RELEVANT, I DON'T KNOW HOW YOU ARE GOING TO CHOOSE THOSE  
15 OVER LINES THAT HAVE MAYBE ONLY BEEN IN EXISTENCE FOR  
16 FIVE OR SIX YEARS AND MIGHT BE PASSED FROM LAB TO LAB.

17 MR. KLEIN: ANN, THIS IS BOB KLEIN, IF I CAN  
18 UNDERSTAND WHAT YOU'RE SAYING HERE. THE INTENT HERE, AS  
19 I UNDERSTOOD IT, IS THAT THERE ARE FIBROBLAST LINES THAT  
20 HAVE YEARS OF HISTORY AND EXTREMELY DETAILED  
21 CHARACTERIZATION ON GENE EXPRESSION, AND THE USE OF THOSE  
22 LINES THAT ARE COMMERCIALY AVAILABLE CAN REALLY  
23 ACCELERATE RESEARCH. AND SO IS THERE A WAY TO GET TO  
24 THIS GOAL THAT WOULD MAKE YOU COMFORTABLE?

25 DR. KIESSLING: I'M ACTUALLY NOT UNCOM- -- THE

## BARRISTERS' REPORTING SERVICE

1 ONLY THING I'M UNCOMFORTABLE WITH IS TRYING TO MAKE SOME  
2 KIND OF BLANKET DECISION ABOUT, QUOTE, ALL EXISTING CELL  
3 LINES. I THINK THAT'S GOING TO BE VERY DIFFICULT. THE  
4 NUMBERS OF HUMAN FIBROBLASTS THAT ARE COMMERCIALY  
5 AVAILABLE THAT ARE NOT ALREADY TRANSFORMED THAT ARE  
6 NORMAL FIBROBLASTS IS REALLY NOT VERY MANY. SO I THINK  
7 ANY INVESTIGATOR, IF THEY WANT TO CHOOSE A HUMAN  
8 FIBROBLAST CELL LINE, AND IN PRINCIPLE IT CAN USE THIS  
9 RESEARCH, THEN I THINK THE INVESTIGATOR NEEDS TO KIND OF  
10 LOOK INTO EXACTLY WHAT THE HISTORY OF THAT LINE IS. I  
11 THINK TO TRY TO SAY, OKAY, WELL, EVERYTHING THAT'S ON  
12 FILE WITH THE ATCC OR EVERYTHING THAT'S ON FILE WITH  
13 ROSWELL PARK MEMORIAL'S LIBRARY OR ANYTHING, I THINK  
14 THAT'S GOING TO BE VERY DIFFICULT TO DO.

15 DR. OLSON: THIS DR. PATRICIA OLSON WITH THE  
16 CIRM. I GUESS I JUST WANTED TO MAKE ONE COMMENT. I  
17 THINK THE OTHER CONSIDERATION IS CONSISTENCY WITH FEDERAL  
18 GUIDELINES. AND SO THE FEDERAL GOVERNMENT HAS NOT  
19 BASICALLY ALLOWED THIS, AND SO PEOPLE OUTSIDE OF  
20 CALIFORNIA WOULD BE ALLOWED TO ACQUIRE THESE LINES, DO  
21 THIS RESEARCH, YET UNDER OUR CURRENT GUIDELINES, PEOPLE  
22 WITHIN CALIFORNIA, AND THIS ACTUALLY INCLUDES SOME OF OUR  
23 APPROVED APPLICATIONS, WE CANNOT ALLOW THEM TO START THIS  
24 RESEARCH GIVEN THE CURRENT GUIDELINES. SO THAT'S WHY WE  
25 HAVE BROUGHT THIS UP AND ARE ASKING YOU TO ADDRESS.

## BARRISTERS' REPORTING SERVICE

1           CHAIRMAN LO: SO IT'S REALLY THEY CAN'T DO IT  
2 WITH CIRM FUNDING.

3           DR. OLSON: RIGHT. THAT'S WHAT I MEAN WITH  
4 CIRM FUNDING.

5           DR. TAYLOR: MY QUESTION IS A LITTLE BIT  
6 DIFFERENT, BUT IT HAS TO DO WITH WHY THE PROVISO ABOUT  
7 SCNT AT THIS POINT? I THINK ORIGINALLY WE FELT THAT THAT  
8 TYPE OF AN EXPERIMENT WOULD NEVER WORK, THAT IT DID NOT  
9 MAKE ANY SENSE TO TRANSFER A NUCLEUS INTO A FULLY  
10 DIFFERENTIATED CELL. BUT TO ME THE DIFFERENCE BETWEEN  
11 TRANSFECTING OR TRANSFERRING FOUR TO EIGHT GENES VERSUS  
12 AN ENTIRE NUCLEUS ISN'T PARTICULARLY SENSIBLE FROM, I  
13 GUESS, A SCIENTIFIC PERSPECTIVE. SO WHY IS THAT STILL  
14 BEING EXCLUDED?

15           ACTUALLY I THINK I'M COMFORTABLE WITH WHERE  
16 YOU'RE TRYING TO GO WITH THIS BECAUSE THERE MAY BE WAYS  
17 OF WORKING OUT NUCLEAR TRANSFER INTO DIFFERENTIATED CELLS  
18 THAT ACTUALLY WILL ALLOW THAT CELL TO BE REPROGRAMMED.  
19 WHY ARE YOU EXCLUDING THAT?

20           CHAIRMAN LO: I GUESS IT GOES BACK TO THE  
21 QUESTION THAT WE HAVEN'T REALLY DIRECTLY ADDRESSED. SO  
22 WHAT ABOUT VARIOUS ASPECTS OF DERIVING PLURIPOTENT STEM  
23 CELL LINES MIGHT RAISE ETHICAL CONCERNS? IT STRIKES ME  
24 THERE MAY BE PEOPLE WHO WOULD NOT WANT THEIR SOMATIC CELL  
25 USED TO CREATE AN EMBRYO THAT WOULD THEN BE USED TO

## BARRISTERS' REPORTING SERVICE

1 CREATE A PLURIPOTENT LINE THROUGH SCNT OR ACTUALLY EVEN  
2 USING -- WELL, USING SCNT. BUT AS LONG AS YOU DON'T  
3 CREATE AN EMBRYO, BUT DERIVE A PLURIPOTENT LINE BY SOME  
4 OTHER TECHNIQUE, THAT IS FINE AND PLEASE GO AHEAD AND DO  
5 IT. SO --

6 DR. PETERS: I THINK WE NEED TO LOOK INTO THE  
7 FUTURE A LITTLE BIT, AND IT'S POSSIBLE THAT THE LINE  
8 BETWEEN PLURIPOTENT AND TOTIPOTENT STEM CELLS MAY  
9 EVENTUALLY GET A RAISE, THAT IF WE WERE TO TEMPORARILY  
10 THINK THAT CYTOPLASMIC REPROGRAMMING COULD AVOID SOME OF  
11 THE ETHICAL ISSUES THAT ARE CONNECTED WITH TOTIPOTENT  
12 CELLS, I THINK WE'RE NOT LOOKING FAR ENOUGH INTO THE  
13 FUTURE. SO I DO THINK THE QUESTION ABOUT THE  
14 RELATIONSHIP TO NUCLEAR TRANSFER AND OTHER KINDS OF  
15 TECHNIQUES THAT COULD PROVIDE TOTIPOTENT CELLS AS WELL AS  
16 PLURIPOTENT CELLS REALLY SHOULD SORT OF STAY ON THE TABLE  
17 FOR DISCUSSION.

18 CHAIRMAN LO: ONE OF THE THINGS WE WANT TO DO  
19 IS TO SAY THAT RIGHT NOW WE'RE TRYING TO SEE WHETHER OR  
20 NOT THESE TECHNIQUES THAT ARE DESCRIBED AS SUCCESSFUL IN  
21 MICE, WHY IT SHOULD WORK IN HUMANS. SO THAT RIGHT NOW  
22 WHAT SCIENTISTS WANT TO DO IS SIMPLY WORK IN THE LAB TO  
23 TRY AND DERIVE THESE LINES AND THEN DO EXPERIMENTS  
24 INJECTING LINES IN ANIMALS TO DEMONSTRATE THEY'RE  
25 PLURIPOTENT AND THEN HOPEFULLY TO SHOW THEY CAN DERIVE

## BARRISTERS' REPORTING SERVICE

1     THEM ALONG A CERTAIN DIFFERENTIATION PATH. WE CAN  
2     APPROVE THAT RESEARCH AND LEAVE FOR ANOTHER TIME  
3     QUESTIONS ABOUT IF THE PLURIPOTENT LINES ACTUALLY EXIST,  
4     MAYBE IF THEY'RE TOTIPOTENT, ARE THERE ADDITIONAL ISSUES  
5     WE WANT TO RAISE THEN IN POLICY.

6             BUT WHAT'S DRIVING THIS DISCUSSION IS THE  
7     SCIENTISTS' EAGARNESS TO SAY LET US AT LEAST GET STARTED.  
8     THIS MAY NOT WORK AT ALL, BUT IT DOES SEEM PROMISING. AT  
9     LEAST GIVE US PERMISSION TO DO THE BASIC IN-VITRO WORK,  
10    PLUS THE NONHUMAN ANIMAL WORK, TO DEMONSTRATE THAT WE CAN  
11    DERIVE THESE LINES. THEN IF WE CAN DO THAT, THEN  
12    OBVIOUSLY THERE ARE A WHOLE HOST OF EXPERIMENTS AND A  
13    WHOLE HOST OF POLICY QUESTIONS.

14            MY CONCERN IS I DON'T THINK WE WILL RESOLVE ALL  
15    THOSE QUESTIONS TODAY, BUT I'M TRYING TO SEE IF WE CAN AT  
16    LEAST AGREE THAT -- RAISE A QUESTION OF CAN WE AGREE TO  
17    ALLOW THE USE OF EXISTING COMMERCIALY AVAILABLE LINES.

18            DR. PETERS: BERNIE, I THINK THE BURDEN OF  
19    PROOF SHOULD BE COMING FROM THE OPPOSITE DIRECTION. THAT  
20    IS TO SAY, WHY TRANSFERRING AN ENTIRE NUCLEUS IS GOING TO  
21    BE A PROBLEM BECAUSE ONE OF THE GOALS OF CERTAIN  
22    RESEARCHERS IS TO PROVIDE HISTOCOMPATIBLE CELL LINES,  
23    PATIENT-SPECIFIC CELL LINES. AND SO THESE INITIAL  
24    EXPERIMENTS, WHICH SIMPLY TRIGGER CYTOPLASMIC  
25    REPROGRAMMING, ARE REALLY THE FIRST STEP IN A LONG SERIES

## BARRISTERS' REPORTING SERVICE

1 IN WHICH WE HOPE TO EVENTUALLY PROVIDE PATIENT-SPECIFIC  
2 CELL LINES.

3 OUR GUIDELINE SHOULD ANTICIPATE THAT. AND IF I  
4 INTERPRET WHAT YOU SAID CORRECTLY, IT SOUNDS LIKE WE'RE  
5 GOING TO PERMIT RESEARCH THAT WILL FALL SHORT OF THAT  
6 RATHER THAN TO ENCOURAGE ACHIEVEMENT OF THE LONGER RANGE  
7 GOAL.

8 DR. LOMAX: CAN I MAKE ONE CLARIFYING  
9 STATEMENT. I JUST WANT THE POLICY HISTORY HERE TO BE  
10 CLEAR, AND ALSO YOU CAN CORRECT ME IF I'M MAKING A  
11 MISSTATEMENT HERE. BUT THE ORIGINAL POLICY DECISION OF  
12 THE -- RECOMMENDATION OF THIS GROUP AND THEN THE ICOC  
13 AFFIRMED WAS TO ADOPT THE NATIONAL ACADEMIES' GUIDELINES.  
14 THOSE GUIDELINES WERE THEN FOLDED IN AS REGULATION.

15 NOW, MY RECOLLECTION, AND I BELIEVE I'M  
16 SPEAKING ACCURATELY HERE, IS THAT THE NATIONAL -- THE  
17 CONSENT REQUIREMENTS FOR SCNT ARE A RECOMMENDATION WITHIN  
18 THE NATIONAL ACADEMIES' GUIDELINES. SO JUST AS A MATTER  
19 OF SORT OF POLICY, WE MADE A CONSCIOUS DECISION TO ADOPT  
20 THEM. AND SO THAT'S WHERE THAT CAME IN. THAT ISSUE ON  
21 SOMATIC CELLS WAS SOMETHING THAT CAME IN LATER THROUGH  
22 THE ULTIMATE REDRAFTING AND FINALIZATION OF THE CIRM  
23 GUIDELINES. AND ACTUALLY IN REVIEW OF THE RECORD, IT WAS  
24 A LITTLE BIT -- IT'S NOT CLEAR EXACTLY WHERE THAT  
25 REQUIREMENT CAME FROM, BUT I WON'T GO INTO MORE DETAIL.

## BARRISTERS' REPORTING SERVICE

1 MR. KLEIN: GEOFF, THE NATIONAL ACADEMY  
2 GUIDELINES, WOULD THEY BE -- THE WAY THEY'RE CONSTRUCTED  
3 AS TO CONSENT, THEY WOULD GIVE US PROBLEM AS TO THE  
4 COMMERCIALY AVAILABLE LINES WE'RE DISCUSSING?

5 DR. LOMAX: NO. NO. I WAS TRYING TO ANSWER  
6 ROB'S QUESTION INITIALLY ABOUT WHY SCNT VERSUS ANOTHER  
7 METHOD, AND SIMPLY FOR SCNT, THE NATIONAL ACADEMIES'  
8 GUIDELINES RECOMMENDS CONSENT FROM ALL DONORS OF GAMETES  
9 OR NUCLEAR DNA FOR THE PROCESS.

10 MR. KLEIN: AND, DR. OLSON, IF I COULD ASK YOU.  
11 IF WE JUST DID THIS IN A TWO-STEP PROCESS, FIRST  
12 ADDRESSING WHAT BERNIE RAISED AS FOCUSING ON THESE  
13 COMMERCIALY AVAILABLE LINES, WOULD THAT ALLOW THE  
14 RESEARCH THAT CIRM HAS ALREADY AGREED TO FUND TO GO  
15 FORWARD?

16 DR. OLSON: I THINK THE QUESTION HERE IS WOULD  
17 WE CONSIDER ALLOWING SOMATIC CELL LINES FOR REPROGRAMMING  
18 STUDIES, NOT FOR SCNT STUDIES. SO IT WOULD ALLOW SOME OF  
19 THE CIRM-APPROVED RESEARCH. THERE ARE OTHERS WHERE,  
20 AGAIN, THE ISSUE IS SCNT.

21 MR. KLEIN: SO IN ORDER TO COVER CIRM-APPROVED  
22 RESEARCH, WE WOULD HAVE TO ADDRESS BOTH THE SCNT.

23 DR. OLSON: AS GEOFF HAS RIGHTLY POINTED OUT,  
24 THE NATIONAL ACADEMY GUIDELINES REGARDING REPROGRAMMING,  
25 IT DOES NOT SPEAK TO THE ISSUE OF CONSENT FOR THE DONOR.

## BARRISTERS' REPORTING SERVICE

1 IT'S NOT A DONOR HERE. IT DOES NOT SPEAK TO THE ISSUE OF  
2 CONSENT FOR THE SOMATIC CELL THAT IS TO BE -- CELL LINE  
3 THAT IS TO BE REPROGRAMMED; WHEREAS, IT DOES IN THE CASE  
4 OF A DONOR SOMATIC CELL NUCLEUS. SO SINCE THIS  
5 COMMITTEE, I'M SURE, HAS SPENT A LOT OF TIME THINKING  
6 ABOUT THE SCNT WITH DONOR NUCLEI, BUT I THINK MAYBE -- I  
7 THINK IN OUR DISCUSSIONS HAVE REALIZED THAT THIS  
8 REPROGRAMMING WAS NOT ADEQUATELY -- OR WAS NOT  
9 CONTEMPLATED AND, THEREFORE, DISCUSSED, WE HAVE BROUGHT  
10 THIS TO YOUR ATTENTION AT THIS POINT TO TRY AND ADDRESS  
11 WHAT WE CONSIDER AT LEAST TO BE THE EASIER ISSUE BECAUSE  
12 WE'RE ASKING YOU TO THINK ABOUT CONSISTENCY WITH ACTUAL  
13 FEDERAL POLICY.

14 DR. KIESSLING: JUST TO MAKE SURE THAT  
15 EVERYBODY UNDERSTANDS, IT REALLY DOESN'T TAKE VERY LONG  
16 TO DERIVE A NEW LINE OF HUMAN FIBROBLASTS. THAT'S NOT  
17 VERY DIFFICULT TO DO. THAT CAN BE DONE WITHIN A MONTH.

18 MR. KLEIN: WHAT ABOUT THE ISSUE OF THE HISTORY  
19 OF THE USE OF THAT LINE AND THE HISTORY OF -- THE  
20 HISTORIC CONTROLS OF THE EXPERIMENTS THAT HAVE GONE  
21 BEFORE ON THAT LINE? IS THERE ANY VALUE TO THAT?

22 DR. KIESSLING: THERE IS, BOB, BUT THAT'S  
23 SOMETHING THAT THE INVESTIGATOR CAN JUSTIFY. A VERY  
24 SIMPLE WAY TO DO THIS IS TO ASK THE INVESTIGATOR TO  
25 JUSTIFY THE NEED FOR USE OF AN EXISTING CELL LINE. THERE

## BARRISTERS' REPORTING SERVICE

1 ARE THOUSANDS OF EXISTING CELL LINES.

2 DR. ROWLEY: OF FIBROBLAST, HUMAN, NORMAL?

3 DR. KIESSLING: NO, NOT OF FIBROBLASTS, BUT YOU  
4 ARE GOING TO FIND A NUMBER OF PEOPLE WHO ARE GOING TO BE  
5 HARD-PRESSED TO DEFINE A FIBROBLAST CELL LINE.

6 DR. ROWLEY: THE CELL THAT DOESN'T GROW IN  
7 SUSPENSION, THAT MAINTAINS ITS KARYOTYPE OVER A PERIOD OF  
8 TIME AS WELL AS OTHER FEATURES? I THINK I WOULD TAKE  
9 EXCEPTION TO ANN'S STATEMENT THAT, A, THERE ARE THOUSANDS  
10 AND, B, THAT IT CAN HAPPEN, YOU KNOW, VERY EASILY BECAUSE  
11 THAT'S BEEN ONE OF THE PROBLEMS OF PEOPLE SETTING UP  
12 HUMAN CELL LINES IS -- FIBROBLAST CELL LINES IS THAT  
13 HUMAN FIBROBLASTS ARE NOT LIKE MOUSE OR OTHER ANIMALS,  
14 AND THEY ARE HARD TO GROW AND TO GROW OVER A LONG PERIOD  
15 OF TIME AND HAVE THEM MAINTAIN A NORMAL PHENOTYPE.

16 DR. KIESSLING: THAT'S NOT OUR EXPERIENCE.

17 DR. TAYLOR: I DO THIS FOR A LIVING. I  
18 ACTUALLY AGREE WITH JANET, THAT THEY'RE NOT ALL THAT  
19 EASY. BUT THE TRUTH OF THE MATTER IS I'M MORE IMPRESSED  
20 WITH THE DIFFERENCES THAT PEOPLE SEE WHEN THEY SHARE  
21 CELLS AND SOME OF THE SIMILARITIES. BOB, WHILE I RESPECT  
22 THE IDEA THAT YOU'D THINK THAT A CELL LINE USED IN ONE  
23 LAB AND ANOTHER LAB WOULD HAVE A FAIR AMOUNT OF  
24 CONSISTENCY OF THE RESULTS, I DON'T THINK THAT THAT'S  
25 ALWAYS THE CASE. SO I DON'T KNOW THAT SOME OF THOSE

## BARRISTERS' REPORTING SERVICE

1 BENEFITS NECESSARILY WILL BE DERIVED AS WE KIND OF GO  
2 FORWARD.

3 CHAIRMAN LO: ROB, LET ME ASK YOU TO CLARIFY.  
4 ARE YOU SAYING THAT EVEN THOUGH YOU ARE WORKING WITH A  
5 LINE THAT A LOT OF OTHER SCIENTISTS HAVE WORKED WITH, AND  
6 IT'S EASY TO OBTAIN, YOU CANNOT NECESSARILY ASSUME THAT  
7 THE PROPERTIES DESCRIBED IN OTHER LABS OR PREVIOUS  
8 PUBLICATIONS APPLY TO THE CLUMP OF CELLS YOU HAVE IN YOUR  
9 LAB, AND YOU HAVE TO KIND OF REDO ALL THOSE  
10 CHARACTERIZATION EXPERIMENTS?

11 DR. TAYLOR: I THINK THAT'S PARTICULARLY TRUE  
12 IN TERMS OF STEROID RECEPTOR RESPONSES, WHICH TEND TO BE  
13 LOST IN CULTURE. CERTAINLY YOU WANT SOMETHING THAT'S  
14 KARYOTYPICALLY STABLE, BUT THE PHENOTYPE ISN'T ALWAYS AS  
15 SORT OF REPRODUCIBLE AS YOU MIGHT LIKE.

16 MR. KLEIN: WITH HUMAN FIBROBLAST, IS THAT TRUE  
17 OR DOES IT --

18 DR. TAYLOR: I ONLY DO HUMAN FIBROBLASTS  
19 ACTUALLY.

20 DR. EGGAN: I JUST WANT TO RETURN TO THE  
21 ORIGINAL POINT THAT I MADE, BECAUSE IT IS SIGNIFICANT,  
22 WITH RESPECT TO TIME AND RESOURCES, AND THAT IS THAT  
23 ALTHOUGH THESE POINTS ARE TRUE ABOUT THE CHANGING NATURE  
24 OF HUMAN FIBROBLASTS IN CULTURE, THERE ARE HUMAN  
25 FIBROBLASTIC CELL LINES WHICH HAVE BEEN ALREADY

## BARRISTERS' REPORTING SERVICE

1 GENETICALLY MODIFIED BY EITHER TRANSFECTION OR VIRAL  
2 TRANSDUCTION THAT MAY ALREADY CARRY GENES WHICH ARE  
3 IMPORTANT FOR REPROGRAMMING. FOR INSTANCE, BOB  
4 WEINBERG'S LAB AT MIT STUDIES THE MOLECULAR MECHANISMS  
5 THAT ARE REQUIRED FOR TRANSFORMATION OF A NORMAL CELL  
6 INTO A CANCER CELL, AND THEY DO THIS THROUGH A SIMILAR  
7 APPROACH, BY TAKING GENIC FACTORS AND INTRODUCING THEM  
8 INTO SKIN CELLS.

9 IT MAY BE THAT MANY OF THOSE ARE PREEXISTING  
10 RESOURCES WHICH WOULD BE INVALUABLE TO THOSE TRYING TO  
11 STUDY REPROGRAMMING. MANY OF THOSE CELL LINES TOOK YEARS  
12 TO CREATE, AND IT WOULD BE A SUBSTANTIAL WASTE OF  
13 RESOURCES TO HAVE TO REMAKE THEM.

14 MR. KLEIN: SO WHAT THAT DOES, KEVIN, HOW WOULD  
15 YOU PROPOSE A MOTION THAT WOULD CAPTURE WHAT IS INTENDED  
16 AND WE CAN SEE WHAT THE SENSE OF THE COMMITTEE IS?

17 DR. EGGAN: TALK ABOUT BEING PUT ON THE HOT  
18 SEAT. WHY DON'T I THINK ABOUT THAT FOR A MINUTE WHILE  
19 THE DISCUSSION GOES ON.

20 CHAIRMAN LO: YOU CAN LOOK ON PAGES 6 OR 7  
21 WHERE STAFF HAS VERY HELPFULLY OR THE BLUE MATERIALS ON  
22 PAGE 1 OF THE DRAFT LANGUAGE, WHICH IS SUGGESTED  
23 LANGUAGE. KEVIN, FEEL FREE TO LOOK AT THAT AND CRAFT.

24 I THINK WHAT IS MOST IMPORTANT IS WE GET A  
25 SENSE OF WHAT WE'RE TRYING TO DO. THE ACTUAL CRAFTING OF

## BARRISTERS' REPORTING SERVICE

1 LANGUAGE WILL TAKE SOME TIME, AND I THINK STAFF AND LEGAL  
2 COUNSEL ARE GOING TO HAVE TO HELP US WITH THAT. WHAT WE  
3 NEED TO DO IS SORT OF GET A SENSE OF WHAT WE WOULD LIKE  
4 TO ACCOMPLISH.

5 FURTHER COMMENTS IN THE ROOM HERE IN SAN  
6 FRANCISCO? I'M GOING TO CALL ON SOME OF THE PEOPLE HERE  
7 AND THEN GO BACK TO THE PHONE LINES.

8 MS. JAMES: JAN JAMES FROM STANFORD UNIVERSITY.  
9 OUR SCIENTISTS ARE TURNING OVER IN HORROR THAT I'M  
10 SPEAKING FOR THEM, BUT JUST A BRIEF COMMENT. ONE OF THE  
11 ISSUES HERE IS WHETHER THIS APPROACH IS NECESSARY OR NOT.  
12 AND I WOULD JUST SAY FROM THE STANDPOINT OF OUR FACULTY,  
13 THEY'VE EXPRESSED A DESIRE TO HAVE THE OPTION. IF  
14 THERE'S NO OTHER REASON TO RESTRICT THIS RESEARCH, AND  
15 THUS FAR I HAVEN'T NOTED THAT THERE WAS A MORAL OBJECTION  
16 OR ETHICAL OBJECTION TO DOING SO IN THE REPROGRAMMING,  
17 THAT IT IS IMPORTANT THAT THEY BE ABLE TO DESIGN THE  
18 SCIENCE. AND OBVIOUSLY WHEN IT IS REVIEWED, THE  
19 SCIENTIFIC QUESTIONS WILL BE ASKED IN THAT SETTING. BUT  
20 THEY WOULD LIKE TO HAVE THAT FLEXIBILITY AND, FRANKLY,  
21 DIDN'T UNDERSTAND WHY IT WAS LIMITED.

22 SO WE'VE HAD A LOT OF CONVERSATIONS, AND THEY  
23 VERY STRONGLY FEEL THAT THEY WOULD LIKE THE FLEXIBILITY  
24 TO BE ABLE TO USE THESE EXISTING LINES AND COMPARE THEM  
25 WITH NEWLY DERIVED LINES.

## BARRISTERS' REPORTING SERVICE

1                   CHAIRMAN LO:  COULD I JUST ASK SINCE YOU'VE  
2                   SPOKEN A LOT TO YOUR SCIENTISTS.  WOULD THEY MAKE ANY  
3                   DISTINCTION BETWEEN IN-VITRO WORK TO DERIVE PLURIPOTENT  
4                   LINES, ANIMAL STUDIES TO CHARACTERIZE AND VERIFY THEY'RE  
5                   PLURIPOTENT, WOULD FURTHER DOWNSTREAM USES, ARE THEY  
6                   SAYING THAT THEY SHOULD BE ABLE TO DO JUST THE FIRST TWO  
7                   STEPS OR SORT OF ALL DOWNSTREAM WITH LINES THAT HAVE  
8                   CONSENT, BUT WERE JUST ANONYMIZED AND USED IN ACCORDANCE  
9                   WITH THE --

10                  MS. JAMES:  I PROBABLY SHOULD NOT GO TO THE  
11                  THIRD STEP WITHOUT SPEAKING TO THEM.  I KNOW THAT THE  
12                  FIRST TWO FALL WITHIN THE AREA --

13                  CHAIRMAN LO:  SO THEY WANT VERY MUCH TO DO THE  
14                  FIRST TWO STEPS OF RESEARCH WITH LINES THAT THEY CAN WORK  
15                  WITH FOR OTHER PURPOSES.

16                  MS. JAMES:  THEY DO.  THEY WANT TO BE ABLE TO  
17                  DO BOTH.

18                  MR. REED:  DON REED.  AS A LAYMAN, I DON'T  
19                  PRETEND TO UNDERSTAND A LOT OF WHAT'S BEEN SAID.  BUT THE  
20                  ONLY THING THAT DOES STRIKE ME AS VITAL IS THAT WE DON'T  
21                  CUT OURSELVES OFF FROM ANY KNOWLEDGE WHICH PREEXISTS, BUT  
22                  JUST HASN'T BEEN DOCUMENTED ONTO THE NEW STANDARDS THAT  
23                  WERE COMING UP.  I THINK THERE'S A LOT OF SCIENCE THAT  
24                  GOES WAY, WAY, WAY BACK TO HANDWRITTEN DRAWINGS OF THE  
25                  NERVES, WHICH IS STILL VALUABLE, BUT IT'S JUST NOT

## BARRISTERS' REPORTING SERVICE

1 DOCUMENTED THE SAME WAY THAT WE DO. SO I WOULD JUST HOPE  
2 THAT WE DON'T TIE OUR HANDS FROM OBTAINING KNOWLEDGE THAT  
3 IS VALUABLE THAT'S NOT DOCUMENTED THE SAME WAY THAT WE DO  
4 IT NOW. THANK YOU.

5 CHAIRMAN LO: OTHER COMMENTS FROM THE  
6 COMMITTEE?

7 MR. KLEIN: IS THERE IN THE SUGGESTED LANGUAGE,  
8 AND I DON'T HAPPEN TO HAVE THE BLUE SHEET, A SUGGESTED  
9 MOTION THAT COULD BE READ TO TEST THE COMMITTEE'S  
10 AGREEMENT WITH IT?

11 CHAIRMAN LO: LET ME TAKE -- LET ME THROW OUT A  
12 STRAW MOTION, WHICH IS TO ALLOW CIRM-FUNDED RESEARCHERS  
13 TO USE EXISTING HUMAN CELLS, TISSUES, OR CELL LINES THAT  
14 ARE CONSISTENT WITH THE CURRENT OHRP REGULATIONS FOR USE  
15 WITH -- FOR RESEARCH WITH EXISTING TISSUES FOR THE  
16 PURPOSES OF IN-VITRO WORK AND NONHUMAN ANIMAL WORK TO  
17 ATTEMPT TO DERIVE PLURIPOTENT STEM CELL LINES.

18 DR. EGGAN: I SECOND THAT MOTION.

19 DR. KIESSLING: AS PART OF THE DISCUSSION OF  
20 THIS MOTION, WILL THIS THEN BECOME AN ESCRO ISSUE?

21 CHAIRMAN LO: IN A SENSE, RIGHT. I THINK WE  
22 WOULD ASSUME THAT THE LOCAL STEM CELL RESEARCH OVERSIGHT  
23 COMMITTEE WILL HAVE TO VERIFY THAT THE OHRP GUIDANCE  
24 REQUIREMENTS WERE MET IN TERMS OF THE PROPER  
25 ANONYMIZATION OF THE LINES. THAT'S SOMETHING THEY NOW DO

## BARRISTERS' REPORTING SERVICE

1 FOR OTHER TYPES OF RESEARCH WITH EXISTING LINES AND  
2 EXISTING DATA AS WELL, SO IT'S WELL WITHIN THE PURVIEW OF  
3 IRB'S AND SCRO'S.

4 DR. LOMAX: THAT'S CORRECT. LET ME JUST  
5 CLARIFY THE POINT BERNIE JUST MADE. PART OF OUR RESEARCH  
6 WAS IN LOOKING INTO THIS ISSUE THERE IS ALREADY ROUTINELY  
7 EXCHANGED DOCUMENTATION IN THIS AREA THAT IS ROUTINELY  
8 REQUESTED BY IRB'S, AND THE DOCUMENTATION IS CRAFTED IN  
9 SUCH A WAY TO GIVE ASSURANCE THAT THE OHRP GUIDELINES ARE  
10 IN COMPLIANCE WITH THE MATERIALS IN QUESTION. THAT IS A  
11 VERY ROUTINIZED SYSTEM WITHIN THE EXISTING COMMERCIAL  
12 CELL PROCUREMENT SYSTEM.

13 DR. OLSON: I JUST WANTED TO ADD THAT UNDER THE  
14 GUIDELINES ESSENTIALLY PUT FORTH BY THIS COMMITTEE, THE  
15 DERIVATION OF PLURIPOTENT COVERED STEM CELL LINES DOES  
16 FALL UNDER THE ESCRO COMMITTEE. THIS APPLIES.

17 DR. KIESSLING: IT SEEMS TO ME LIKE THAT'S THE  
18 BASIC ISSUE HERE. IF WE ARE SEEING THE MODIFICATION TO  
19 THE CELL LINES TO BECOME PLURIPOTENT, IF WE ARE THEN  
20 PUTTING THAT RESEARCH IN THE LAP OF THE STEM CELL  
21 RESEARCH OVERSIGHT COMMITTEES RATHER THAN THE IRB.

22 CHAIRMAN LO: WE'VE TRIED TO BE FLEXIBLE SAYING  
23 THE IRB AND THE SCRO SHOULD WORK TOGETHER TO SORT OF  
24 PROVIDE COORDINATED OVERSIGHT, BUT LEAVING IT UP TO EACH  
25 INDIVIDUAL INSTITUTION. GEOFF HAS ACTUALLY TALKED A LOT

## BARRISTERS' REPORTING SERVICE

1 WITH SCRO'S AND IRB'S AND INSTITUTIONS AND MIGHT BE ABLE  
2 TO COMMENT ON HOW THEY WOULD BE ABLE TO HANDLE.

3 DR. LOMAX: AGAIN, I THINK WHAT WE'VE LEARNED  
4 IN CALIFORNIA IS THAT THEY ARE CLEARLY -- THE  
5 INSTITUTIONS CLEARLY HAVE ADOPTED THE REGULATIONS. THE  
6 CIRM FUNDING HAS FORCED A NUMBER OF THESE ISSUES THROUGH.  
7 THAT'S, IN FACT, HOW THEY CAME TO OUR ATTENTION. AND  
8 WHAT WE'RE SEEING IN SORT OF DISCUSSION WITH THE  
9 INSTITUTIONS IS THERE'S A VERY CLEAR COORDINATION THERE.  
10 CERTAINLY HUMAN SUBJECTS ISSUES, IF THERE WERE HUMAN  
11 SUBJECTS ISSUES, THEY WOULD BE HANDLED JOINTLY BY THE IRB  
12 AND THE SCRO. AND TO THE EXTENT HUMAN SUBJECTS ISSUES  
13 MAY NOT EXIST, THERE'S CERTAINLY SCRO OVERSIGHT OR  
14 APPROVAL FOR THE VAST MAJORITY OF THE OTHER RESEARCH  
15 GOING ON.

16 CHAIRMAN LO: OTHER COMMENTS, THOUGHTS,  
17 REACTIONS? EVERYBODY LEFT AND GONE TO THE BASEBALL GAME?  
18 OKAY. THERE'S A MOTION AND A SECOND. WOULD SOMEONE LIKE  
19 TO CALL THE QUESTION?

20 MR. KLEIN: LET'S CALL THE QUESTION.

21 CHAIRMAN LO: PUBLIC COMMENT. OKAY. GEOFF,  
22 WOULD YOU LIKE TO DO A ROLL CALL.

23 MS. FEIT: COULD WE HAVE A RESTATEMENT OF THE  
24 MOTION PLEASE BEFORE WE VOTE?

25 CHAIRMAN LO: I THINK THE MOTION IS TO ALLOW

## BARRISTERS' REPORTING SERVICE

1 CIRM-FUNDED RESEARCHERS TO USE EXISTING CELLS, TISSUES,  
2 AND CELL LINES THAT ARE IN COMPLIANCE WITH THE CURRENT  
3 OHRP GUIDELINES FOR RESEARCH WITH EXISTING CELLS,  
4 TISSUES, AND LINES WITH THE INTENTION OF CREATING A  
5 PLURIPOTENT STEM CELL LINE PROVIDED THAT WHEN THEY'RE  
6 CARRYING OUT IN-VITRO RESEARCH AND NONHUMAN ANIMAL  
7 RESEARCH, TO DERIVE AND VERIFY THOSE LINES. I THINK  
8 THAT'S THE MOTION. OKAY.

9 DR. LOMAX: MARCY FEIT.

10 MS. FEIT: YES.

11 DR. LOMAX: ROBERT KLEIN.

12 MR. KLEIN: YES.

13 DR. LOMAX: FRANCISCO PRIETO.

14 DR. PRIETO: YES.

15 DR. LOMAX: JEFF SHEEHY.

16 MR. SHEEHY: YES.

17 DR. LOMAX: ALTA CHARO. BERNIE LO.

18 CHAIRMAN LO: YES.

19 DR. LOMAX: PATRICIA KING.

20 MS. KING: YES.

21 DR. LOMAX: TED PETERS.

22 DR. PETERS: YES.

23 DR. LOMAX: I BELIEVE, JOSE CIBELLI, ARE YOU ON  
24 THE LINE?

25 CHAIRMAN LO: HE'S LEFT.

## BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: KEVIN EGGAN.

2 DR. EGGAN: YES.

3 DR. LOMAX: ANN KIESSLING.

4 DR. KIESSLING: YES.

5 DR. LOMAX: JANET ROWLEY.

6 DR. ROWLEY: YES.

7 DR. LOMAX: ROBERT TAYLOR.

8 DR. TAYLOR: YES.

9 DR. LOMAX: JOHN WAGNER. JAMES WILLERSON.

10 DR. WILLERSON: YES.

11 MS. CHARO: AND ALTA IS HERE AND SAID YES.

12 CHAIRMAN LO: THANK YOU, ALTA. YOU'RE THE  
13 QUORUM.

14 MS. CHARO: I STEPPED OUT FOR TWO SECS.

15 CHAIRMAN LO: WE HAVE A QUORUM.

16 DR. TAYLOR: THAT MUST BE A FIRST, A UNANIMOUS  
17 VOTE.

18 CHAIRMAN LO: WE'VE DONE A LOT OF THOSE. OKAY.

19 WITH THAT, CAN WE TAKE A BIG, DEEP BREATH AND TAKE A  
20 VIRTUAL STRETCH AND VIRTUAL BREAK, BUT NOT ACTUALLY A  
21 PHYSICAL BREAK? AND I'M AFRAID IF WE HAVE A BREAK,  
22 PEOPLE ARE JUST GOING TO DISAPPEAR. CAN WE GO BACK,  
23 THEN, TO ITEM B, WHICH IS PAYMENT FOR COMMERCIALY  
24 AVAILABLE CELLS.

25 DR. CHIU: I'M SORRY. BEFORE YOU MOVE ON, HAVE

## BARRISTERS' REPORTING SERVICE

1 YOU DECIDED ON THE LANGUAGE?

2 CHAIRMAN LO: I THINK I'M SAYING WE'RE GOING TO  
3 HAVE STAFF WORK ON CRAFTING LANGUAGE RATHER THAN TRYING  
4 TO DO IT HERE. IT'S TOO COMPLICATED FOR US TO DO.  
5 AGAIN, CALLING, ON GEOFF AND SCOTT AND THEIR EXPERTISE  
6 AND OTHER CIRM STAFF EXPERTISE.

7 DR. LOMAX: WE WILL CONTINUE TO DEVELOP  
8 LANGUAGE CONSISTENT WITH THAT ASPIRATION.

9 CHAIRMAN LO: WE'LL PASS THAT AROUND FOR  
10 COMMENT AS WELL. BUT WE DO WANT TO ADDRESS ANOTHER ISSUE  
11 WHICH HAS TO COME UP WHICH HAS TO DO WITH PAYMENT FOR  
12 COMMERCIALLY AVAILABLE CELLS, SO CELLS AND LINES AND  
13 TISSUES. I WANT TO AGAIN SAY THAT WE'RE NOT TALKING  
14 ABOUT PAYMENT TO THE DONORS OF CELLS, WHICH HAS BEEN, I  
15 THINK, DISCUSSED AND COVERED IN THE GUIDELINES, BUT WE'RE  
16 TALKING ABOUT WHAT HAS BEEN POINTED OUT AS AN APPARENT  
17 INCONSISTENCY OR AMBIGUITY IN PAYMENTS TO THIRD PARTIES.

18 AND, GEOFF, IF YOU COULD WALK US THROUGH THAT,  
19 PLEASE.

20 DR. LOMAX: AGAIN, I HOPE THIS IS REASONABLY  
21 CLEAR IN THE BRIEFING MEMO THAT WAS SENT AROUND. IT'S  
22 ITEM NO. 2, LIMITATIONS ON PAYMENTS FOR CELLS AND  
23 EXCLUDING COVERED STEM CELL LINES AND DONOR MATERIALS.  
24 BUT THE CURRENT LANGUAGE IN THE REGULATIONS IS SOMEWHAT  
25 DUPLICATIVE WITH PROPOSITION 71, WHICH IS THE ENABLING

## BARRISTERS' REPORTING SERVICE

1 LAW. AND PROPOSITION 71 DOES CONTAIN LANGUAGE WITH  
2 REGARD TO PAYMENT FOR COMMERCIALLY AVAILABLE CELLS. AND,  
3 AGAIN, I THINK WE CRAFTED A SET OF REGULATORY LANGUAGE  
4 UNAWARE THAT THIS LANGUAGE IS IN PLACE, AND I'LL  
5 ATTRIBUTE THAT TO STAFF OVERSIGHT. AND, AGAIN, TO  
6 EMPHASIZE THAT WHAT WE'VE PROVIDED IN THE BRIEFING MEMO  
7 IS REVISED LANGUAGE. ESSENTIALLY THE REVISED LANGUAGE IS  
8 TO JUST CITE BACK TO PROPOSITION 71. IN FACT, COUNSEL  
9 HAS SUGGESTED GIVEN THAT'S ALREADY IN PROPOSITION 71, WE  
10 MAY NOT EVEN HAVE TO CITE BACK TO IT, BUT WE HAVE THE  
11 OPTION OF REFERENCING THE PROP 71 LANGUAGE.

12 AND THE LANGUAGE SORT OF DESCRIBES THE TYPES OF  
13 PAYMENTS THAT WOULD BE ALLOWED FOR, AGAIN, COMMERCIAL  
14 CELL LINES, AND THIS IS ONLY FOR THIRD-PARTY  
15 TRANSACTIONS. AND THIS PROVISION WOULD IN NO WAY IMPACT  
16 EXISTING REQUIREMENTS GOVERNING THE RESTRICTIONS ON  
17 PAYMENTS TO HUMAN SUBJECTS OR OTHER DONORS OF MATERIALS;  
18 FOR EXAMPLE, COUPLES THAT WOULD BE DONATING EMBRYOS, SAY,  
19 TO STEM CELL RESEARCH. SO IT'S CLEARLY IN THE ARENA OF  
20 THIRD-PARTY TRANSACTIONS FOR CELLS.

21 CHAIRMAN LO: SO IN SUMMARY, WHAT WE'RE TRYING  
22 TO DO IS MAKE SURE THAT IT'S CLEAR THAT THE LANGUAGE THAT  
23 WAS IN PROP 71, ACTUALLY QUITE CLEAR IN PROP 71, IS WHAT  
24 CARRIES OVER TO THESE THIRD-PARTY TRANSACTIONS IN THE  
25 REGULATIONS.

**BARRISTERS' REPORTING SERVICE**

1 DR. LOMAX: I GUESS TO ADD ONE OTHER FOOTNOTE  
2 THERE, AGAIN, THESE ISSUES ARE SORT OF TECHNICAL ISSUES  
3 THAT ARE COMING TO OUR ATTENTION AS A RESULT OF  
4 INSTITUTIONS PERFORMING THEIR OBLIGATED REVIEWS NOW THAT  
5 THE FUNDING IS OUT. AND THIS, AGAIN, WAS SIMPLY  
6 IDENTIFIED AS SOMETHING THAT WAS PRESENTING SOME  
7 CONFUSION AND AMBIGUITY.

8 (INTERRUPTION IN PROCEEDINGS DUE TO  
9 TELEPHONE INTERFERENCE. THE FOLLOWING WAS THEN HEARD IN  
10 OPEN SESSION:)

11 DR. LOMAX: GIVEN THE INTERRUPTION, IT WOULD BE  
12 USEFUL WE SHOULD DO ROLL AGAIN JUST SO WE KNOW WHO IS ON  
13 THE CALL. I WILL GO THROUGH THE ROLL, AND THEN RENAME  
14 PEOPLE.

15 MARCY FEIT.

16 MS. FEIT: HERE.

17 DR. LOMAX: ROBERT KLEIN. FRANCISCO PRIETO.

18 DR. PRIETO: HERE.

19 DR. LOMAX: JEFF SHEEHY.

20 MR. SHEEHY: HERE.

21 UNIDENTIFIED SPEAKER: I'VE GOT DR. WILLERSON  
22 AGAIN.

23 DR. LOMAX: DR. WILLERSON ON. ALTA CHARO.

24 MS. CHARO: HERE.

25 DR. LOMAX: PATRICIA KING.

## BARRISTERS' REPORTING SERVICE

1 MS. KING: HERE.

2 DR. LOMAX: TED PETERS.

3 DR. PETERS: HERE.

4 DR. LOMAX: KEVIN EGGAN.

5 DR. EGGAN: HERE.

6 DR. LOMAX: ANN KIESSLING. JANET ROWLEY.

7 DR. ROWLEY: HERE.

8 DR. LOMAX: ROBERT TAYLOR. ROBERT KLEIN.

9 DR. KIESSLING: ANN KIESSLING.

10 DR. LOMAX: ANN KIESSLING. ROBERT TAYLOR.

11 DR. TAYLOR: HERE.

12 DR. WILLERSON: DR. WILLERSON IS HERE TOO.

13 MS. KING: WE'RE TAKING A BREAK?

14 DR. WILLERSON: YES.

15 (A RECESS WAS TAKEN.)

16 CHAIRMAN LO: WELCOME BACK, EVERYBODY.

17 DR. LOMAX: WE DID A ROLL CALL. I BELIEVE WE  
18 NOW HAVE EVERYONE BACK ON THE LINE. WE DO EVERYONE BACK  
19 ON THE LINE BECAUSE BOB KLEIN JOINED US.

20 CHAIRMAN LO: SO SORRY ABOUT THAT INTERRUPTION.  
21 EVERYBODY ACTUALLY STILL THERE?

22 SO I DON'T KNOW, BOB. MAYBE YOU COULD START US  
23 OFF BECAUSE I THINK PROP 71 IS REALLY CLEAR ON THIS  
24 ISSUE, AND SOMEHOW WHEN WE DRAFTED REGULATIONS, WE LOST  
25 THAT CLARITY. BUT I THINK WHAT WE'RE TRYING TO DO IS GO

## BARRISTERS' REPORTING SERVICE

1 BACK TO THE REQUIREMENTS THAT WERE VERY CLEARLY STATED IN  
2 PROP 71 AND SORT OF MAKE OUR REGULATIONS IN HARMONY WITH  
3 THAT PROPOSITION.

4 MR. KLEIN: WELL, JUST DISCLOSING A BIAS, I  
5 CLEARLY PREFER THE LANGUAGE IN PROP 71. IN ANY CASE, I  
6 THINK THAT THE CONCERN HERE IS THAT WITH PROP 71 SETTING  
7 OUT A VERY CLEAR STANDARD, WHEN THE LATER RECOMMENDATION  
8 OCCURRED, SINCE IT DIDN'T DISCUSS PERMITTING REQUIRED  
9 PAYMENT FOR MEDICAL OR SCIENTIFIC TECHNOLOGIES OR  
10 PROCESSES OR LICENSING FEES OR, YOU KNOW, LEGAL COSTS, IT  
11 COULD BE SAID THAT YOU INTENDED WITH THE NEW  
12 RECOMMENDATION TO EXCLUDE THOSE THINGS THAT WERE IN PROP  
13 71. I DON'T THINK THAT WAS THE INTENT.

14 CHAIRMAN LO: ABSOLUTELY. THAT WAS AN  
15 OVERSIGHT. YOU PUT YOUR FINGER ON THE KIND OF QUESTIONS  
16 THAT HAVE BEEN RAISED THAT WE WOULD LIKE TO DISPEL BY  
17 GOING BACK TO PROP 71 LANGUAGE.

18 MR. KLEIN: SO IF WE JUST LEAVE THE PROP 71  
19 LANGUAGE THERE AND ELIMINATE THE NEW LANGUAGE OR AS IN  
20 THE MODEL LANGUAGE THAT'S BEEN SUGGESTED, IT'S A VERY  
21 SIMPLE STATEMENT THAT THEN CROSS-REFERENCES PROP 71, I  
22 THINK THAT ACCOMPLISHES THE GOAL WITHOUT ANY UNINTENDED  
23 CONSEQUENCES.

24 CHAIRMAN LO: RIGHT. EXACTLY. AS YOU SAID,  
25 THE MODEL LANGUAGE ON PAGE 4, AS I UNDERSTAND IT, AND

## BARRISTERS' REPORTING SERVICE

1 I'LL DEFER TO GEOFF AND SCOTT, IS THAT JUST SAY LOOK AT  
2 PROP 71. THAT'S WHAT THE REGULATION IS.

3 DR. LOMAX: FOR IT TO BE CLEAR, THE ONE THING  
4 THE MODEL LANGUAGE DOES DO IS IT'S SLIGHTLY EXPANSIVE IN  
5 THE SENSE THAT PROP 71 LANGUAGE WAS IN REFERENCE TO STEM  
6 CELL LINES OR STEM CELLS; WHEREAS, THAT LANGUAGE, THE  
7 SCOPE WOULD BE STEM CELL LINES, GAMETES, EMBRYOS, SOMATIC  
8 CELLS, OR HUMAN TISSUES. SO IT JUST APPLIES A CONSISTENT  
9 STANDARD TO ESSENTIALLY THE SCOPE OF MATERIALS THAT ONE  
10 WOULD USE IN THESE TYPES OF EXPERIMENTS.

11 IN THAT SENSE THAT'S THE ONLY SORT OF  
12 DISCRETION NOW THAT'S BEING EXERCISED IS EXPANSION OF THE  
13 REQUIREMENT TO A SLIGHTLY LARGER UNIVERSE OF MATERIALS.

14 DR. TAYLOR: BERNIE AND GEOFF, THIS IS ROB  
15 TAYLOR. JUST SORT OF A CLARIFICATION. IS IT CLEAR THAT  
16 THESE COSTS HAVE BEEN BUDGETED IN THE GRANT APPLICATION  
17 IN A WAY THAT A SCIENTIFIC REVIEW CAN TAKE THAT INTO  
18 ACCOUNT? I CAN IMAGINE SOME FAIRLY HIGH CHARGES MOUNTING  
19 FOR THINGS. I JUST WANTED TO BE SURE THAT IT STIPULATED  
20 THAT THOSE ARE APPROVED IN THE SORT OF GRANT APPROVAL AND  
21 BUDGET APPROVAL PROCESS.

22 MR. KLEIN: THAT'S A SEPARATE -- I THINK THAT  
23 GOES TO GRANT ADMINISTRATION POLICY, IF I UNDERSTAND THE  
24 COMMENT.

25 DR. TAYLOR: I GUESS WHAT I'M TRYING TO AVOID

## BARRISTERS' REPORTING SERVICE

1 IS SOME EXORBITANT FEE.

2 MR. KLEIN: THE GRANT ADMINISTRATION POLICIES  
3 WOULD SET LIMITATIONS ON REASONABLENESS. THAT'S UNDER A  
4 SEPARATE SET OF CONTROLS THAT ARE IN PLACE.

5 DR. TAYLOR: AGAIN, FROM A GENERAL GRANTING  
6 POLICY ISSUE, I WOULD HATE TO SEE A LOT OF REBUDGETING OF  
7 FUNDS FROM CIRM GOING TO PAY FOR LEGAL FEES FOR OBTAINING  
8 A PARTICULAR STEM CELL THAT WASN'T KIND OF PREAPPROVED  
9 DURING THE REVIEW PROCESS.

10 DR. OLSON: THIS IS PAT OLSON FROM CIRM. WE DO  
11 ASK FOR BUDGET JUSTIFICATIONS FOR A BUDGET AS IT IS  
12 PRESENTED. THE REVIEWERS DO LOOK AT THAT. I ALSO THINK  
13 THAT AS FAR AS PAYMENTS FOR LINES AND SUCH, THAT, YOU  
14 KNOW, PEOPLE ARE AWARE OF SORT OF THE NORMAL COSTS. WHEN  
15 WE REVIEW THE BUDGET AS PART OF THE ADMINISTRATIVE REVIEW  
16 FOR APPROVED APPLICATIONS, WE DO LOOK AT COST. SO I  
17 THINK THERE ARE SEVERAL LEVELS, AND ANY UNREASONABLE OR  
18 VERY HIGH COSTS ARE NOTICED AND FLAGGED FOR AT LEAST  
19 DISCUSSION.

20 CHAIRMAN LO: ANY FURTHER DISCUSSION? ANY  
21 PUBLIC COMMENT HERE IN SAN FRANCISCO? IF NOT, I'D LOVE  
22 TO ENTERTAIN A MOTION TO CALL THE QUESTION.

23 MR. KLEIN: I DON'T THINK WE HAVE A FORMAL  
24 MOTION ON THE TABLE.

25 CHAIRMAN LO: CAN'T CALL THE QUESTION UNLESS

**BARRISTERS' REPORTING SERVICE**

1 SOMEONE GIVES ME A MOTION.

2 MR. KLEIN: BUT I WOULD MAKE A FORMAL MOTION WE  
3 ADOPT THE MODEL LANGUAGE ON PAGE 4.

4 CHAIRMAN LO: OKAY. A SECOND?

5 MR. SHEEHY: SECOND.

6 CHAIRMAN LO: JEFF SECONDS. OKAY.

7 DR. LOMAX: COULD I JUST CLARIFY, BOB, THAT IT  
8 WOULD BE EITHER THE MODEL LANGUAGE OR THE LANGUAGE THAT  
9 WOULD ACCOMPLISH THE SAME. THIS IS A SCOPE ISSUE BECAUSE  
10 WE HAVE HAD A COMMENT FROM COUNSEL THAT ADDITIONAL  
11 LANGUAGE MAY NOT BE REQUIRED -- WELL, IT WOULDN'T TO  
12 EXPAND THE SCOPE. I'LL LEAVE IT AT THAT. I THINK WE'VE  
13 GOT THE RIGHT.

14 MR. KLEIN: THE MOTION WOULD BE THE MODEL  
15 LANGUAGE WITH PROPER MODIFICATIONS BY COUNSEL.

16 CHAIRMAN LO: I THINK THAT'S ALWAYS UNDERSTOOD  
17 WHEN OUR COMMITTEE TRIES TO DRAFT REGULATIONS. WE ALWAYS  
18 DEFER TO OUR EXPERT COUNSEL. OKAY. I DON'T THINK  
19 THERE'S ANY DISCUSSION, SO I'D BE GLAD TO HEAR A CALL.

20 MR. KLEIN: WHAT ABOUT THE PUBLIC?

21 CHAIRMAN LO: I ASKED THE PUBLIC, BUT IF THEY  
22 WOULD NOW LIKE TO SPEAK UP. NO. THEY'RE ALL --

23 MR. LOMAX: MARCY FEIT.

24 MS. FEIT: YES.

25 DR. LOMAX: ROBERT KLEIN.

## BARRISTERS' REPORTING SERVICE

1 MR. KLEIN: YES.

2 DR. LOMAX: FRANCISCO PRIETO.

3 DR. PRIETO: YES.

4 DR. LOMAX: JEFF SHEEHY.

5 MR. SHEEHY: YES.

6 DR. LOMAX: ALTA CHARO.

7 MS. CHARO: YES.

8 DR. LOMAX: BERNIE LO.

9 CHAIRMAN LO: AYE.

10 DR. LOMAX: PATRICIA KING.

11 MS. KING: YES.

12 DR. LOMAX: TED PETERS.

13 DR. PETERS: YES.

14 DR. LOMAX: KEVIN EGGAN.

15 DR. EGGAN: YES.

16 DR. LOMAX: ANN KIESSLING.

17 DR. LOMAX: OKAY. WE'LL HOLD THAT OPEN AND

18 COME BACK. JANET ROWLEY.

19 DR. ROWLEY: YES.

20 DR. LOMAX: ROBERT TAYLOR.

21 DR. TAYLOR: YES.

22 DR. LOMAX: JOHN WAGNER. JAMES WILLERSON.

23 DR. WILLERSON: YES.

24 DR. LOMAX: IS ANN KIESSLING ON THE LINE?

25 CHAIRMAN LO: WE HAVE A QUORUM? WE HAVE A

## BARRISTERS' REPORTING SERVICE

1 UNANIMOUS SENSE OF THE COMMITTEE WHICH WE'LL CONVEY TO  
2 THE ICOC.

3 OKAY. ANY FURTHER BUSINESS?

4 MR. KLEIN: BERNIE, YOU MIGHT WANT TO JUST HOLD  
5 THE VOTE OPEN FOR ANN WHO MIGHT BE OFF THE LINE FOR A  
6 MOMENT.

7 CHAIRMAN LO: THAT'S A GOOD SUGGESTION. OTHER  
8 COMMENTS?

9 I WOULD JUST LIKE TO SAY FIRST I WANT TO THANK  
10 YOU ALL. THIS IS A VERY IMPORTANT AND USEFUL MEETING.

11 DR. PETERS: THANK YOU, BERNIE, FOR YOUR  
12 LEADERSHIP.

13 CHAIRMAN LO: I'M FOLLOWING HERE, TRYING TO  
14 KEEP UP. WE WILL CONVEY TO THE ICOC FOR THEIR  
15 DELIBERATIONS, AND OBVIOUSLY SOME OF OUR MEMBERS ARE ON  
16 THE ICOC AND WILL HELP IN THAT DISCUSSION. WE HAVE CUT  
17 OUT FOR OURSELVES A TASK THAT GEOFF AND OTHER STAFF ARE  
18 GOING TO HELP US THROUGH WITH UNDERSTANDING THIS 12  
19 VERSUS 14 DAYS BOTH SCIENTIFICALLY AND POLICIES AROUND  
20 THE COUNTRY. I THINK THIS IS ONE THAT WE DO WANT TO STAY  
21 AHEAD OF, AND WE DO WANT TO ALSO MAKE SURE THAT WHATEVER  
22 POLICY WE EVENTUALLY ENACT APPLIES ACROSS THE BOARD TO  
23 ALL CELL LINES, ALTHOUGH TODAY WE JUST TALKED ABOUT  
24 JAPAN.

25 I WANT TO THANK YOU ALL AND WISH ALL OF YOU WHO

**BARRISTERS' REPORTING SERVICE**

1 HAVE NOT HAD YOUR SUMMER VACATION A WONDERFUL VACATION.  
2 AND THOSE LIKE PAT WHO ARE JUST BACK FROM SUMMER VACATION  
3 HOPING IT DOESN'T WEAR OFF TOO SOON.

4 MS. KING: RIGHT.

5 CHAIRMAN LO: ANY OTHER COMMENTS? IF NOT, I'D  
6 LOVE TO HEAR A MOTION TO ADJOURN. SO I WILL TAKE IT WE  
7 ARE ADJOURNING AND INVITE EVERYONE TO COME VISIT SAN  
8 FRANCISCO AS SOON AS YOU CAN.

9 (THE MEETING WAS THEN CONCLUDED AT 02:20  
10 P.M.)

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## BARRISTERS' REPORTING SERVICE

### 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 TELEPHONIC PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDEICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW ON JULY 27, 2007, 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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