

BEFORE THE
NIH GUIDELINES RESPONSE TASK FORCE
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: AS INDICATED ON AGENDA

DATE: MAY 7, 2009
5:30 P.M.

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

BRS FILE NO.: 84473

BARRISTERS' REPORTING SERVICE

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CALL TO ORDER		3
ROLL CALL		3
CONSIDERATION OF RESPONSE TO NIH DRAFT GUIDELINES		5
PUBLIC COMMENT		48

BARRISTERS' REPORTING SERVICE

1 NIH GUIDELINES RESPONSE TASK FORCE OF THE ICOC

2 THURSDAY, MAY 7, 2009, 5:30 P.M.

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CHAIRMAN KLEIN: ALL RIGHT. GIVEN WE HAVE A SPECIFIC TIME SET HERE AND BEING SENSITIVE TO THE BOARD MEMBER AND THE PUBLIC TIME, I'D LIKE TO ASK IF GEOFF LOMAX COULD OPEN THIS BY A BASIC DISCUSSION OF THE DRAFT THAT HE HAS PREPARED IN DEALING WITH THE RECOMMENDATIONS OF THE INTERSTATE ALLIANCE, A SPECIFIC MEETING THAT HE ATTENDED INVOLVING THE MOST ACTIVE STATES IN THE UNITED STATES WITH EMBRYONIC STEM CELL PROGRAMS THAT ARE IN PROCESS.

MS. KING: BOB, BEFORE WE DO THAT, I'M JUST WONDERING, DID YOU WANT ME TO HOLD OFF ON TAKING ROLL UNTIL AFTER HE DOES THAT, OR DO YOU WANT TO DO THAT NOW?

CHAIRMAN KLEIN: GO AHEAD. I THOUGHT THAT YOU HAD INFORMALLY TAKEN THE ROLL, BUT LET'S DO IT FORMALLY.

MS. KING: FLOYD BLOOM.

DR. BLOOM: HERE.

MS. KING: SUSAN BRYANT.

DR. BRYANT: HERE.

MS. KING: MICHAEL FRIEDMAN.

BARRISTERS' REPORTING SERVICE

1 DR. FRIEDMAN: HERE.

2 MS. KING: BOB KLEIN.

3 CHAIRMAN KLEIN: PRESENT.

4 MS. KING: FRANCISCO PRIETO. JEANNIE
5 FONTANA FOR JOHN REED. I KNOW JEANNIE WAS HERE A
6 MOMENT AGO. WHO JUST JOINED?

7 ART TORRES.

8 MR. TORRES: HERE.

9 MS. KING: SO AS OF RIGHT NOW, WE DON'T
10 HAVE A QUORUM, BUT I THINK JEANNIE WILL GET BACK ON
11 THE LINE, AND WE'RE ALSO EXPECTING DR. PRIETO. AND
12 WHEN WE HAVE ONE OF THEM, WE WILL BE AT QUORUM, SO
13 I'LL TURN IT BACK OVER TO YOU.

14 MR. SHEEHY: MELISSA, YOU DIDN'T CALL MY
15 NAME.

16 MS. KING: JEFF SHEEHY. THANK YOU. I
17 KNEW THERE WAS SOMETHING FUNNY.

18 DR. FRIEDMAN: BOB, LET ME ASK YOU A
19 QUESTION IF I MAY. THE PURPOSE OF TODAY'S CALL IS
20 FOR DISCUSSION ABOUT THESE DRAFT GUIDELINES OR AN
21 ACTION ON THESE DRAFT GUIDELINES?

22 CHAIRMAN KLEIN: WELL, WHAT WE WANT TO DO,
23 DR. FRIEDMAN, IS HAVE A DISCUSSION. IF THE
24 DISCUSSION APPEARS TO HAVE A STRONG CONSENSUS, WE'LL
25 TAKE A VOTE. IF IT APPEARS PEOPLE ARE THINKING

BARRISTERS' REPORTING SERVICE

1 ABOUT THEM, NEED ADDITIONAL TIME, THIS DISCUSSION
2 WILL FORM A CONTRIBUTION FOR THE PUBLIC AND THE
3 MEMBERS TO THE BOARD MEETING ON THE 12TH.

4 DR. FRIEDMAN: THANK YOU.

5 CHAIRMAN KLEIN: SO WHO JUST JOINED?

6 DR. FONTANA: JEANNIE FONTANA. SORRY.
7 GOT DISCONNECTED, AND I'M HERE WITH TWO MEMBERS OF
8 THE PUBLIC.

9 MS. KING: THANK YOU. FOR THE RECORD,
10 JEANNIE FONTANA IS ON THE LINE. JUST A QUICK CHECK,
11 BETH, YOU'RE THERE AS WELL, RIGHT?

12 THE REPORTER: YES, I AM.

13 CHAIRMAN KLEIN: THANK YOU VERY MUCH,
14 MELISSA. SO GEOFF LOMAX, COULD YOU GIVE US A
15 SUMMARY OF YOUR CONCLUSION AND INPUT FROM THE
16 INTERSTATE ALLIANCE AND ALSO THE DRAFT
17 RECOMMENDATIONS TO DATE.

18 DR. LOMAX: THANK YOU, BOB. IN TERMS OF
19 SPECIFIC RECOMMENDATIONS OR SORT OF TOPIC AREAS, I'D
20 REFER THE GROUP TO ITEM 3, WHICH IS SORT OF OUR
21 SIX-PAGE DRAFT TO DATE WHERE WE'VE KIND OF GROUPED
22 THE ISSUES ACCORDING TO A SERIES OF BULLET POINTS.
23 AND ASSUMING YOU'VE ALL HAD A CHANCE TO TAKE A LOOK
24 AT THAT DRAFT, WHAT I THINK WOULD BE MOST EFFICIENT
25 FOR THE PURPOSES OF THIS CALL IS JUST TO RELATE THE

BARRISTERS' REPORTING SERVICE

1 MAJOR ITEMS FROM THE INTERSTATE ALLIANCE MEETING TO
2 ITEMS IN THIS DRAFT.

3 WHAT I'LL DO IS TRY TO DO THAT QUICKLY AND
4 SEE WHERE WE END UP. IF THAT'S SUFFICIENT, TURN IT
5 BACK OVER TO YOU. IF YOU FEEL THE NEED FOR ANY
6 ADDITIONS, LET ME KNOW, BUT I THINK I'LL DO THAT AS
7 A STARTING POINT BECAUSE I THINK IT SORT OF CAPTURES
8 MY SENSE OF THE ISSUE TO DATE.

9 A REMINDER FOR THOSE OF YOU WHO MAY NOT BE
10 FAMILIAR WITH THE INTERSTATE ALLIANCE ON STEM CELL
11 RESEARCH, IT'S A GROUP OF ALL THE MAJOR STATES WITH
12 FUNDING PROGRAMS. WE TRY TO MEET ABOUT TWICE A
13 YEAR. WE ALSO HAVE WISCONSIN WICELL IS PRESENT,
14 ISSCR, CANADA, AND THE UK. SO IT'S REALLY A GROUP
15 OF, I THINK, A LOT OF MAJOR ORGANIZATIONS THAT HAVE
16 A VERY KEEN INTEREST IN THE FIELD.

17 WE HAD THE OPPORTUNITY TO MEET WITH THE
18 NIH. THEY CAME TO OUR MEETING AND SORT OF WALKED US
19 THROUGH THE GUIDELINES, AND WE HAD A VERY ROBUST
20 DISCUSSION. IN TERMS OF SORT OF THE SPECIFIC ITEMS
21 THAT CAME UP, THEY INDICATED, AGAIN, SORT OF THE NIH
22 INDICATED, AGAIN, THEIR INTEREST IN BEING ABLE TO
23 MODIFY THE GUIDELINES, OR THEY INTENDED TO MODIFY
24 THE DRAFT IN RESPONSE TO COMMENTS, BUT CLEARLY
25 NEEDED TO HEAR FROM US IN THE FIELD.

BARRISTERS' REPORTING SERVICE

1 DURING THE DISCUSSION AND NOW RELATING TO
2 ITEM NO. 3, THE FIRST POINT THAT I WOULD SAY
3 RECEIVED A VERY CONSIDERABLE DISCUSSION IN FAIR
4 AMOUNT OF DETAIL WAS THE BULLET ITEM THAT SUGGESTS
5 THE NIH SHOULD TIGHTEN THE GUIDELINES BY LEVERAGING
6 THE ESTABLISHED IRB REVIEW PROCESS AS THE BASIS FOR
7 ACCEPTING STEM CELL LINES. THE POINT OF THAT
8 RECOMMENDATION WAS REALLY TO SUGGEST TO THE NIH THAT
9 THERE'S AN ESTABLISHED MECHANISM THROUGH THE
10 INSTITUTIONAL REVIEW BOARD PROCESS AND THE COMMON
11 RULE, AND THAT EVERY STATE PRESENT IN THE ROOM, BY
12 VIRTUE OF ADOPTING THE NATIONAL ACADEMIES
13 GUIDELINES, HAS USED THAT MECHANISM TO ENABLE THE
14 USE OF STEM CELL LINES, PARTICULARLY HISTORIC STEM
15 CELL LINES, BECAUSE THE NATIONAL ACADEMIES
16 GUIDELINES CITES THE COMMON RULE FOR ALL MATERIALS
17 THAT ARE DONATED TO RESEARCH.

18 THE GROUP ALSO HAD A LENGTHY DISCUSSION
19 AFTER THE MEETING AND HAS COME UP WITH A SET OF SORT
20 OF MEETING NOTES. AND THAT PARTICULAR POINT IS THE
21 MAJOR POINT IN THE SUMMARY NOTES FROM THE MEETING.
22 SO THERE WAS CONSENSUS AMONG THE PARTICIPANTS THAT
23 SUCH AN APPROACH WOULD BE VERY EFFECTIVE IN STRIKING
24 THAT BALANCE BETWEEN ETHICAL OVERSIGHT, CONSENT, AND
25 ALLOWING THE SORT OF OPTIMAL RESEARCH MATERIALS TO

BARRISTERS' REPORTING SERVICE

1 BE UTILIZED.

2 AGAIN, THE DISCUSSION -- THE CONCERN, THE
3 UNDERLYING CONCERN WITH THE CURRENT DRAFT IS THAT,
4 AS WRITTEN, IF YOU HAD AN APPROACH THAT SIMPLY
5 REQUIRED A VERY DETAILED SET OF CONSENT
6 REQUIREMENTS, AND YOU APPLY THAT, THAT A NUMBER OF
7 VALUABLE RESEARCH MATERIALS MAY BE DISQUALIFIED.
8 SO THAT WAS REALLY THE NO. 1 ITEM COMING FROM THE
9 INTERSTATE DISCUSSION.

10 TWO OTHER ITEMS THAT WERE NOTEWORTHY FROM
11 THAT DISCUSSION, AND, AGAIN, THEY'RE REFLECTED IN
12 THE DRAFT THAT WE PREPARED FOR YOU. THERE WAS VERY
13 STRONG CONSENSUS ON THE NEED FOR SOME TYPE OF
14 REGISTRY MECHANISM SUPPORTED BY NIH, AND THAT SEEMED
15 UNCONTROVERSIAL. AND THE NATIONAL INSTITUTES OF
16 HEALTH ALSO SEEMED VERY OPEN TO SOME SORT OF SUPPORT
17 MECHANISM.

18 SO THAT SEEMED SIMPLY TO BE AN ISSUE
19 WHERE, THROUGH PUBLIC COMMENT, IF THERE WAS SORT OF
20 ADDITIONAL ENDORSEMENT OF THAT APPROACH, THAT WOULD
21 BE HELPFUL.

22 THE GROUP ALSO DID AND THE MEMBER STATES
23 CAME UP WITH A STATEMENT INDICATING THAT WITHIN
24 THEIR STATE PROGRAMS, THEY ALLOW THE USE OF
25 PARTHENOGENIC LINES WHICH ARE NOT ELIGIBLE UNDER THE

BARRISTERS' REPORTING SERVICE

1 NIH DRAFT STANDARD. AND WHAT THE GROUP DID THERE
2 WAS CRAFT A STATEMENT SIMPLY INDICATING THE
3 SCIENTIFIC VALUE OF THOSE LINES SIMILAR -- WE
4 ACTUALLY BORROWED SOME OF THE LANGUAGE THAT WAS IN
5 ITEM NO. 3. WE SORT OF USED THAT AS A MODEL. SO
6 THAT WAS REALLY A STATEMENT TO SAY THAT STATES
7 CONTINUE TO AUTHORIZE THE USE OF THOSE LINES.

8 AND LET ME -- I THINK I MAY JUST STOP
9 THERE BECAUSE, AGAIN, THERE'S ALREADY THREE MAJOR
10 ISSUES. AGAIN, VERY STRONG CONSENSUS AMONGST THE
11 GROUP, AND I ANTICIPATE A STATEMENT FROM THE
12 INTERSTATE GROUP COMING OUT SOMETIME TOMORROW.
13 WE'RE JUST TRYING TO MAKE SURE EVERYONE HAS HAD THE
14 OPPORTUNITY TO REVIEW THE DRAFT AND THEY FEEL
15 COMFORTABLE WITH ITS CONTENT.

16 CHAIRMAN KLEIN: AND I THINK THAT THE
17 DESIRE WAS TO HAVE AS MANY DIFFERENT SUBMISSIONS
18 AROUND THE COUNTRY THAT HAVE A MAJOR PORTION OF THAT
19 SUBMISSION TO BE CONSISTENT BECAUSE THERE'S A GREAT
20 DIFFICULTY IN MARSHALLING A COUNT FOR AND AGAINST
21 THE POSITION IF YOU HAVE NUMEROUS POSITIONS,
22 PARTICULARLY BECAUSE THE OPPOSITION POSITIONS,
23 HISTORICALLY AT LEAST, HAVE WORKED OFF OF A RIGID
24 TEMPLATE. SO YOU COULD SAY THERE'S 10,000 PEOPLE
25 THAT HAVE SENT IN THIS POSTCARD THAT FAVOR THIS

BARRISTERS' REPORTING SERVICE

1 PARTICULAR OPPOSITION POSITION. THERE IS A VALUE IN
2 TRYING TO ALIGN OURSELVES AS LONG AS ON THE
3 SCIENTIFIC MERIT WE AGREE WITH THE POSITION WITH A
4 POSITION WITH THE INTERSTATE ALLIANCE TO THE EXTENT
5 THAT WE AGREE. AND THEN TO THE EXTENT WE WANT TO
6 DIFFERENTIATE OUR POSITION, HAVING THAT IN A
7 SEPARATE BULLET POINT.

8 AS TO THE FIRST POINT THAT GEOFF LOMAX
9 RAISED, COULD I HAVE BOARD COMMENT ON THAT STARTING
10 WITH MAYBE JEFF SHEEHY IN SAN FRANCISCO.

11 MR. SHEEHY: WELL, I'M SUPPORTIVE OF THIS
12 APPROACH. IT SEEMS TO MAKE A LOT OF SENSE. I THINK
13 I'LL JUST LEAVE IT AT THAT. I WON'T TAKE TOO MUCH
14 TIME, BUT MAKES A TON OF SENSE TO ME.

15 CHAIRMAN KLEIN: OKAY. AND THEN GOING TO
16 SOUTHERN CALIFORNIA, DR. FRIEDMAN, DR. BRYANT, ANY
17 COMMENT?

18 DR. BRYANT: YES. THERE IS ONE COMMENT,
19 THAT THERE ARE SOME PRESIDENTIAL LINES THAT HAVE
20 NOT -- THERE'S NO EVIDENCE THAT THEY WENT THROUGH
21 IRB REVIEW AT ANY TIME. I'M NOT SURE THAT IT WOULD
22 BE WISE TO INCLUDE THOSE EVEN THOUGH WE WANT THE
23 ONES THAT ARE APPROVED ALREADY TO BE CONTINUED TO BE
24 USED.

25 CHAIRMAN KLEIN: RIGHT. DR. BLOOM.

BARRISTERS' REPORTING SERVICE

1 DR. BLOOM: I HAVE NO ADDITIONAL COMMENTS,
2 BOB. I DID RAISE WITH GEOFF OFF LINE THE ISSUE OF
3 DERIVATIVES, WHICH ARE NOT IN OUR CURRENT STATEMENT.

4 CHAIRMAN KLEIN: AND DR. FRIEDMAN.

5 DR. FRIEDMAN: I ENDORSE THE STATEMENTS
6 MADE PREVIOUSLY.

7 CHAIRMAN KLEIN: ALL RIGHT. AND DR.
8 FONTANA.

9 DR. FONTANA: I JUST WANTED TO CLARIFY
10 AGAIN, GEOFF, THE FEEDBACK THAT YOU GOT FROM THE NIH
11 THAT THEY WERE GOING TO APPROVE THE IDEA OF ALLOWING
12 THE IRB TO DETERMINE THE ELIGIBILITY OF THE LINES.

13 DR. LOMAX: WELL, IF YOU HAD THOSE
14 DISCUSSIONS WITH NIH, I THINK YOU HAVE TO READ
15 BETWEEN THE LINES A BIT. I THINK WHAT THEY WERE
16 INDICATING WAS A SORT OF OPENNESS TO THE APPROACH,
17 AND I DON'T KNOW IF -- THERE MAY BE OTHER FOLKS ON
18 THE CALL THAT HAVE HAD THE BENEFIT OF, YOU KNOW,
19 HEARING THE NIH DISCUSS THIS EARLY AND OFTEN. I
20 DON'T KNOW, FOR EXAMPLE, ALTA, DO YOU HAVE ANY
21 THOUGHTS ON THEIR SORT OF OVERALL SORT OF FEELING ON
22 THIS APPROACH?

23 DR. CHARO: GEOFF, AS YOU SUGGESTED, THEY
24 REALLY ARE NOT PERMITTED TO SAY ANYTHING AT THIS
25 POINT BECAUSE THEY'RE NOT ALLOWED TO HAVE MADE UP

BARRISTERS' REPORTING SERVICE

1 THEIR MINDS AT THIS POINT. THEY MUST WAIT UNTIL ALL
2 THE COMMENTS HAVE COME IN. BUT YOU'RE ABSOLUTELY
3 RIGHT. IN THE CONVERSATIONS THAT WERE TAKING PLACE
4 AROUND THE TABLE AND IN THE FORMAL PRESENTATION,
5 THEY MADE IT VERY CLEAR THAT THE DRAFT WAS TRULY A
6 DRAFT. IT WAS THEIR ATTEMPT TO CAPTURE AS MUCH AS
7 POSSIBLE ALL OF THE GUIDELINES AND REGULATIONS THAT
8 HAD BEEN WRITTEN IN THE INTERREGNUM WHERE WE HAD
9 RELATIVELY LITTLE FEDERAL FUNDING, AND THEY'VE
10 ALREADY COME TO REALIZE THAT THAT APPROACH, NOT ONLY
11 IS LOOKING BACKWARD INSTEAD OF FORWARD, BUT IT
12 FAILED TO TAKE ADVANTAGE OF THE FACT THAT NOW THAT
13 WE'RE ONCE AGAIN FEDERALLY FUNDING, WE CAN FULLY
14 EMBRACE THE FEDERAL SYSTEM RATHER THAN CREATING A
15 WHOLE NEW SYSTEM TO RUN PARALLEL TO IT.

16 SO IT STRUCK ME IN THEIR COMMENTS THAT
17 THEY ARE WILLING TO RETHINK THE VERY BASIC ASPECTS
18 OF THEIR APPROACH AND OPENS UP THE DOOR WIDE FOR
19 REALLY NORMALIZING THE RESEARCH WITHIN THE IRB
20 SYSTEM. WITH THE ONLY EXCEPTION BEING THAT WE WERE
21 TALKING THERE AROUND THE TABLE ABOUT HAVING IRB
22 APPROVAL EVEN FOR LINES WHERE THE DONOR MEDICAL
23 INFORMATION WAS NEVER COLLECTED, AND SO TECHNICALLY
24 WOULD HAVE BEEN EXEMPTED FROM HUMAN SUBJECTS
25 RESEARCH UNDER THE FEDERAL RULES.

BARRISTERS' REPORTING SERVICE

1 MS. KING: CHAIRMAN KLEIN, JUST BEFORE WE
2 MOVE POTENTIALLY TO PUBLIC COMMENT, I JUST WANTED TO
3 LET YOU KNOW, WHILE WE HAVE MEMBERS OF THE PUBLIC
4 JOINING FROM SEVERAL SITES, WE HAVE TWO SPECIFIC
5 MEMBERS OF THE PUBLIC THAT LET US KNOW THEY WOULD BE
6 JOINING. AND I WANTED YOU TO KNOW THEY'RE ON THE
7 LINE, AND THOSE ARE DR. MARTIN PERA FROM USC AND
8 DR. BERNARD LO FROM UCSF, WHO AS, I BELIEVE EVERYONE
9 ON THE CALL KNOWS, IS CHAIR OF OUR STANDARDS WORKING
10 GROUP.

11 CHAIRMAN KLEIN: CERTAINLY.

12 DR. FONTANA: I HAVE ONE MORE COMMENT.

13 CHAIRMAN KLEIN: THANK YOU, MELISSA.

14 DR. PERA, IF WE CAN, IF WE CAN HEAR FROM DR. LO.

15 DR. FONTANA: BOB, EXCUSE ME. I JUST HAD
16 ONE MORE COMMENT.

17 CHAIRMAN KLEIN: YES. GO AHEAD.

18 DR. FONTANA: UNDER THAT BULLET POINT, AND
19 I DON'T KNOW IF IT'S APPROPRIATE TO TALK ABOUT IT AT
20 THIS MOMENT, BUT IT IS UNDER THAT BULLET POINT WHERE
21 IT TALKS ABOUT FUTURE LINES DERIVED IN THE UNITED
22 STATES FROM BLASTOCYSTS CREATED AFTER JULY 2009
23 SHOULD CONFORM TO NIH GUIDELINES. MY QUESTION IS
24 THE DERIVATION OF THOSE BLASTOCYSTS. ARE WE GOING
25 TO CLARIFY THAT? ARE WE GOING TO KEEP IT GENERAL SO

BARRISTERS' REPORTING SERVICE

1 THAT WHATEVER BLASTOCYST IS CREATED AND IT CONFORMS
2 TO THE IRB CONSENT WILL BE APPROVED?

3 CHAIRMAN KLEIN: SO, DR. FONTANA, WHAT I'D
4 LIKE TO DO IS TAKE THAT UP UNDER A SEPARATE POINT,
5 WHICH IS GRANDFATHERING, BECAUSE AS TO THE STEM CELL
6 LINES AND TO BIOLOGICAL MATERIALS, IT APPEARS THAT
7 THERE IS A VERY SERIOUS QUESTION THAT UNLESS WE DO
8 GRANDFATHERING HERE, WE'RE TAKING A LARGE RISK THAT
9 THERE ARE DETAILS THROWN IN AT THE LAST MINUTE THAT
10 CREATES STANDARDS FOR THE IRB RETROACTIVELY THAT THE
11 IRB'S CANNOT MEET, AND THEN CREATES A MAJOR
12 SCIENTIFIC ROADBLOCK BECAUSE EVEN IF THEY CAN MEET
13 THE STANDARDS, IF THEY'RE REQUIRED TO GO THROUGH AND
14 RECONFIRM THEIR APPROVALS, WE WOULD HAVE A HUGE
15 WORKLOAD PUT ON THESE INSTITUTIONS AT A VERY SHORT
16 NOTICE. AND LINES WOULD HAVE TO CLEAR THEM TO BE
17 ELIGIBLE POTENTIALLY FOR STIMULUS FUNDING ON GRANTS
18 THAT HAVE ALREADY BEEN SUBMITTED.

19 DR. FONTANA: I UNDERSTAND ALL THAT. I
20 THINK THAT THAT'S WHAT WE'RE ADDRESSING IN THESE
21 GUIDELINES AND SUGGESTIONS, BUT I'M JUST ADDRESSING
22 ONE OF THE BULLET POINTS IN THERE THAT DOES ADDRESS
23 THE FUTURE BLASTOCYSTS. YOU MAY WANT TO TALK ABOUT
24 THAT IN A DIFFERENT PLACE, BUT IT IS IN THERE. AND
25 I WAS CURIOUS. IT'S KIND OF A GENERAL TERM, AND IS

BARRISTERS' REPORTING SERVICE

1 THAT SOMETHING THAT NEEDS ADDRESSING?

2 DR. PRIETO: YOU'RE TALKING ABOUT LIKE THE
3 SECOND TO LAST BULLET POINT?

4 DR. FONTANA: YES.

5 CHAIRMAN KLEIN: I SEE.

6 DR. PRIETO: YOU'RE TALKING ABOUT NEW CELL
7 LINES THAT WOULD BE CREATED FROM HERE FORWARD?

8 CHAIRMAN KLEIN: I SEE THE POINT YOU'RE
9 REFERRING TO, DR. FONTANA. LET US DO THIS, IF WE
10 CAN. THAT SHOULD STAND ON ITS OWN AS A SEPARATE
11 DISCUSSION POINT. IF WE COULD COVER THIS WITH A
12 CONTINUITY OF DISCUSSION, THIS FIRST APPROACH, AND
13 THEN WE'RE GOING TO GO TO GRANDFATHERING, AND THEN
14 WE CAN GO TO THAT POINT.

15 DR. FONTANA: EVEN THOUGH IT COULD FALL
16 UNDER THIS BECAUSE IF WE ARE SUGGESTING THAT THE NIH
17 SHOULD USE ESTABLISHED IRB'S WITH ADDITIONAL ITEMS
18 AND CONSENT FORMS FOR FUTURE LINES, IT FALLS UNDER
19 THAT BULLET POINT.

20 CHAIRMAN KLEIN: IT DOES. I'M JUST TRYING
21 TO SEGREGATE IT OUT TO GET, FIRST, COMMENTS ON THE
22 IRB APPROACH.

23 DR. FONTANA: OKAY. I SUPPORT THE IRB
24 APPROACH.

25 CHAIRMAN KLEIN: OKAY. AND DR. LO.

BARRISTERS' REPORTING SERVICE

1 DR. LO: THANKS, BOB. I REALLY THINK IT'S
2 IMPORTANT FOR CIRM TO BE A STRONG VOICE HERE. I
3 PARTICULARLY SECOND GEOFF'S IDEA OF MOBILIZING OTHER
4 STAKEHOLDERS WHO ARE FUNDING RESEARCH AND SUPPORTING
5 RESEARCH BECAUSE THERE WILL BE TREMENDOUS INPUT FROM
6 THE OPPONENTS OF STEM CELL RESEARCH.

7 I HAVE TWO SUGGESTIONS. ONE, I THINK IT
8 WOULD BE IMPORTANT TO GIVE SPECIFIC EXAMPLES OF THE
9 SCIENTIFIC ROADBLOCKS THAT ARE LIKELY TO OCCUR IF
10 THE DRAFT GUIDELINES ARE ENACTED AND HOW THAT WILL
11 TRANSLATE INTO LOST OPPORTUNITY FOR SOCIETY AS A
12 WHOLE AND THE NATION IN PARTICULAR.

13 AND SECOND, I THINK IT WOULD BE IMPORTANT
14 TO TRY AND EMPHASIZE THE POINT THAT BRINGING
15 EMBRYONIC STEM CELL RESEARCH UNDER THE COMMON RULE
16 AND IRB OVERSIGHT IS NOT A WEAKENING OF ETHICAL
17 REVIEW, WHICH IS, I'M SURE, HOW IT WILL BE PORTRAYED
18 BY THE OPPONENTS OF STEM CELL RESEARCH. BUT THAT,
19 IN FACT, PROVIDES RIGOROUS REVIEW THAT'S ALSO
20 EFFICIENT.

21 CHAIRMAN KLEIN: OKAY. SO I APPRECIATE
22 THOSE COMMENTS. AND FOR THE PUBLIC, I WOULD SAY
23 THAT FOR THE -- HOPEFULLY FOR THE MEETING OF THE
24 BOARD ON THE 12TH AND CERTAINLY SHORTLY FOLLOWING
25 THAT, IF NOT BY THE 12TH, THE STAFF IS ALSO

BARRISTERS' REPORTING SERVICE

1 DEVELOPING A CHART LISTING ALL THE CELL LINES THAT
2 WE KNOW OF AND THE DISEASES THEY SPECIFICALLY RELATE
3 TO SO IT CAN BE CLEAR WHAT THE SCIENTIFIC STAKES
4 HERE OF MEDICAL RESEARCH IN PROGRESS THAT ADDRESSES
5 SPECIFIC DISEASES. IT'S IMPORTANT FOR THE PUBLIC TO
6 UNDERSTAND, IN TERMS OF CONCRETE RELATIONSHIP TO
7 MEDICAL RESEARCH, WHAT'S AT STAKE.

8 BUT, DR. LO, COULD YOU WORK WITH GEOFF
9 LOMAX ON SOME EXAMPLES OF THESE SCIENTIFIC
10 ROADBLOCKS? I THINK THAT WOULD REALLY HELP INFORM
11 THE DEBATE ON THE 12TH.

12 DR. LO: I'D BE GLAD TO, BOB. I THINK
13 SOME OF THE SCIENTISTS ON THE ICOC ARE PROBABLY MUCH
14 BETTER QUALIFIED THAN I TO WORK WITH THEM, BUT I'D
15 BE GLAD TO HELP.

16 CHAIRMAN KLEIN: MAYBE YOU AND GEOFF COULD
17 IDENTIFY SOME SCIENTISTS TO BORROW EXAMPLES FROM
18 BECAUSE I THINK IT WOULD BE A VERY VALUABLE
19 EXERCISE.

20 DR. LO: SURE. I'M ALWAYS DELIGHTED TO
21 WORK WITH GEOFF.

22 CHAIRMAN KLEIN: DR. PERA.

23 DR. PERA: CHAIRMAN, I SUPPORT THE IRB
24 APPROACH. I DO HAVE A FEW COMMENTS ON THE DOCUMENT
25 AS IT REFERS TO MATERIAL IN TISSUE BANKS THAT'S BEEN

BARRISTERS' REPORTING SERVICE

1 CONSENTED. BUT I GUESS YOU WANT TO TALK ABOUT THAT
2 LATER.

3 CHAIRMAN KLEIN: IF WE COULD. SO I WILL
4 MAKE IT NOTE TO COME BACK TO YOU, DR. PERA.

5 DR. BRYANT: I HAVE A MEMBER OF THE PUBLIC
6 HERE AT IRVINE WHO IS THE CHAIR OF OUR ESCRO
7 COMMITTEE, AND HE HAS A COMMENT IF NOW IS THE TIME.

8 CHAIRMAN KLEIN: I THINK THAT WOULD BE
9 APPROPRIATE. THANK YOU, DR. BRYANT. DR. SYD GOLUB,
10 SYDNEY.

11 DR. GOLUB: THANK YOU. THIS ISSUE WAS, IN
12 FACT, DISCUSSED BY THE UCI STEM CELL RESEARCH
13 OVERSIGHT COMMITTEE THIS MORNING IN AN EXTENSIVE
14 DISCUSSION DEVOTED TO OUR DESIRE TO SEND IN OUR
15 RESPONSES TO THE DRAFT GUIDELINES. WE MADE SEVERAL
16 POINTS THAT I'D LIKE TO TRANSMIT.

17 FIRST OF ALL, WE STRONGLY SUPPORT THE CIRM
18 APPROACH, WHICH WE THINK IS LARGELY RIGHT ON TARGET.
19 THERE ARE SOME CONCERNS ABOUT THE PRESIDENTIAL LINES
20 IN THAT THERE ARE A SMALL NUMBER THAT ARE RATHER
21 PROBLEMATIC AND DON'T MEET THE CRITERIA THEY SET OUT
22 AT THE TIME -- THEY APPARENTLY DON'T MEET THE
23 CRITERIA SET OUT AT THE TIME THAT THEY WERE ACCEPTED
24 INTO THAT REGISTRY. AND GRANDFATHERING ALL OF THEM,
25 THOSE THAT WERE APPROPRIATELY REVIEWED AT THE TIME

BARRISTERS' REPORTING SERVICE

1 OF THE DONATION AND THOSE THAT WERE APPARENTLY NOT,
2 LINKS US TO SOME ETHICALLY DOUBTFUL MATERIAL.

3 I THINK THAT THE CRITERIA SET OUT FOR
4 NONPRESIDENTIAL LINES IS FINE, AND IT PROBABLY OUGHT
5 TO BE UNIVERSALLY APPLIED TO ALL. IF THAT MEANS
6 SACRIFICING TWO OR THREE CELL LINES, SO BE IT; BUT
7 TO LINK OURSELVES TO LINES THAT WE KNOW TO BE
8 PROBLEMATIC IS A POLITICALLY DOUBTFUL THING TO DO.

9 THE OTHER THING MY COMMITTEE URGED IS SOME
10 MENTION SOMEPLACE OF THE ROLES OF THE STEM CELL
11 RESEARCH OVERSIGHT COMMITTEES IN THE MONITORING
12 PROCESS AND THEIR CONTRIBUTIONS ENVISIONED BY THE
13 NATIONAL ACADEMY REPORT. THANK YOU.

14 CHAIRMAN KLEIN: THANK YOU VERY MUCH.
15 DEFINITELY WE GAIN TREMENDOUSLY BY HAVING SOMEONE
16 WHO RUNS ONE OF THESE COMMITTEES MAKE A DIRECT
17 CONTRIBUTION.

18 DR. LOMAX: CAN I JUST MAKE ONE COMMENT
19 ONLY BECAUSE WE DID DIRECT A SPECIFIC COMMENT IN
20 THIS REGARD?

21 CHAIRMAN KLEIN: GO AHEAD, GEOFF.

22 DR. LOMAX: THE ONE PROBLEM WITH AN
23 EXPLICIT REFERENCE TO THE STEM CELL RESEARCH
24 OVERSIGHT COMMITTEE IS THAT THOSE COMMITTEES ARE
25 CURRENTLY NOT RECOGNIZED IN ANY FEDERAL STATUTE OR

BARRISTERS' REPORTING SERVICE

1 REGULATION. AND WE WENT FURTHER TO ASK THE NIH DO
2 THEY HAVE THE ABILITY TO CITE THE COMMITTEE IF A
3 STATE HAS ESTABLISHED IT IN A STATE STATUTE. AND ON
4 THAT COUNT, THEY ALSO INDICATED THAT THEY COULD NOT.

5 SO THE PROBLEM OR THE BARRIER TO YOUR
6 POINT TWO THAT WE'VE IDENTIFIED IS A FUNDAMENTAL
7 BARRIER OF SIMPLY AN INABILITY TO RECOGNIZE THAT
8 ENTITY. SO IT'S HARD TO THEN COME UP WITH A COMMENT
9 THAT SOMEHOW RECOGNIZES THEM IN ANY SORT OF FORMAL
10 WAY. THAT'S THE BARRIER THERE.

11 DR. GOLUB: ONE COULD RECOGNIZE THE NEED
12 FOR CONTINUING OVERSIGHT, AND THAT WOULD AT LEAST
13 INDIRECTLY DO IT.

14 DR. LOMAX: CORRECT. IT CAN BE DONE
15 INDIRECTLY, BUT -- IT'S EXACTLY RIGHT. THERE COULD
16 BE INDIRECT REFERENCE TO SOME TYPE OF OVERSIGHT
17 MECHANISM. THAT'S RIGHT.

18 CHAIRMAN KLEIN: OKAY. AND IS ELONA ON?

19 MS. BAUM: I AM.

20 CHAIRMAN KLEIN: ELONA, IF YOU AND IAN AND
21 JAMES CAN LOOK AT THE ISSUE OF WHETHER FEDERAL
22 GOVERNMENT HAS THE ABILITY TO REFERENCE AND
23 RECOGNIZE STATE LAW AND REGULATIONS. IT'S DIFFICULT
24 FOR ME TO UNDERSTAND WHY THEY CANNOT DO THAT, BUT I
25 DON'T WANT TO -- THERE'S NO WAY TO PREJUDGE THE AREA

BARRISTERS' REPORTING SERVICE

1 WITHOUT RESEARCH.

2 MS. KING: CHAIRMAN KLEIN, JUST FOR THE
3 RECORD, YOU MIGHT WANT TO NOTE, AND ALSO FOR MEMBERS
4 OF THE PUBLIC THAT MAY NOT KNOW, WHO ELONA IS.

5 CHAIRMAN KLEIN: ELONA IS OUR NEW GENERAL
6 COUNSEL. THANK YOU.

7 I'D LIKE TO ON THIS IRB ISSUE GO FROM
8 NORTH TO SOUTH AND ASK EITHER AT JEFF SHEEHY'S
9 PUBLICLY NOTICED SITE OR AT THE AGENCY ARE THERE
10 PUBLIC COMMENTS?

11 MR. SHEEHY: NO PUBLIC COMMENTS HERE, BOB.

12 CHAIRMAN KLEIN: AT THE AGENCY, ARE THERE
13 PUBLIC COMMENTS ON THE IRB ISSUE?

14 MS. KING: NONE ON THE ISSUE. YOU MIGHT
15 WANT TO JUST CIRCLE UP TO DR. PRIETO, WHO'S UP IN
16 SACRAMENTO.

17 CHAIRMAN KLEIN: DR. PRIETO, I DIDN'T HEAR
18 THAT YOU HAD JOINED.

19 DR. PRIETO: NO PUBLIC COMMENTS HERE.

20 CHAIRMAN KLEIN: DO YOU HAVE A COMMENT,
21 DR. PRIETO?

22 DR. PRIETO: NO. I THINK I ECHO WHAT
23 PEOPLE HAVE BEEN SAYING. NOTHING MORE RIGHT NOW.

24 CHAIRMAN KLEIN: OKAY. THANK YOU. THERE
25 ARE -- THERE'S NO PUBLIC ATTENDING AT MY PUBLICLY

BARRISTERS' REPORTING SERVICE

1 NOTICED OFFICE. DR. FRIEDMAN.

2 DR. FRIEDMAN: NO MEMBER OF THE PUBLIC
3 HERE.

4 CHAIRMAN KLEIN: DR. FONTANA.

5 UNIDENTIFIED SPEAKER: SHE STEPPED OUT,
6 BUT THERE'S NO COMMENT HERE.

7 CHAIRMAN KLEIN: DR. BRYANT.

8 DR. BRYANT: NO FURTHER COMMENTS HERE.

9 CHAIRMAN KLEIN: DR. BLOOM.

10 DR. BLOOM: NO PUBLIC HERE, BOB.

11 CHAIRMAN KLEIN: I'D LIKE TO MOVE TO THE
12 NEXT DISCUSSION, WHICH IS A DERIVATIVE OF THE FIRST
13 DISCUSSION, AND ADDRESS SPECIFICALLY THE ISSUE OF
14 GRANDFATHERING. AND THEN WE'RE GOING TO MOVE TO
15 JEANNIE FONTANA'S ISSUE GOING FORWARD. AND THAT IS
16 THAT IF WE WERE TO ACCEPT AN IRB STANDARD, ONE OF
17 THE POLITICAL RISKS IS WITH THE TREMENDOUS AMOUNT OF
18 POLITICAL PRESSURE AND ORGANIZED OPPOSITION, IT
19 WOULD BE VERY DIFFICULT IF, IN FACT, THE IRB'S WERE
20 FORCED TO GO BACK THROUGH SOMETHING THAT WAS
21 PREVIOUSLY APPROVED AND/OR ACCEPT A SET OF NEW
22 STANDARDS RETROACTIVELY.

23 SO I'D LIKE TO HAVE A DISCUSSION ON THE
24 THEME THAT WE WOULD GRANDFATHER THOSE PAST IRB AND
25 STATE-APPROVED LINES THAT HAD BEEN DEVELOPED --

BARRISTERS' REPORTING SERVICE

1 WHERE THE STATE-APPROVED STANDARDS HAD BEEN
2 DEVELOPED WITH PUBLIC HEARINGS FOR THOSE STANDARDS.
3 SO AS TO THE ISSUE OF GRANDFATHERING AS A PROTECTION
4 AGAINST VERY MINUTE DETAILED RETAILING OF PRIOR
5 ACTIONS OF THE IRB THAT WOULD BE DIFFICULT TO DEAL
6 WITH INDIVIDUALLY IN A MASSIVE WAY BECAUSE OF THE
7 NUMBER OF IRB'S INVOLVED IN THE COUNTRY AND THE
8 NUMBER OF LINES INVOLVED, WHAT IS THE PLEASURE OF
9 THE COMMITTEE FROM THAT APPROACH? JEFF.

10 MR. SHEEHY: I'M SUPPORTIVE.

11 CHAIRMAN KLEIN: OKAY. LET ME GO TO
12 FRANCISCO PRIETO IN SACRAMENTO.

13 DR. PRIETO: I WOULD SUPPORT THAT.

14 CHAIRMAN KLEIN: AND DR. FRIEDMAN. NOT ON
15 FOR THE MOMENT. DR. BRYANT.

16 DR. BRYANT: YES, I AGREE.

17 CHAIRMAN KLEIN: DR. BLOOM.

18 DR. BLOOM: I AGREE, BUT WE DON'T WANT TO
19 FORGET THE POINT RAISED BY DR. GOLUB ABOUT SOME OF
20 THOSE LINES THAT WERE INAPPROPRIATELY.

21 CHAIRMAN KLEIN: THOSE, AS I UNDERSTAND
22 IT, WERE NOT IRB APPROVED. IS THAT TRUE, DR. GOLUB?

23 DR. GOLUB: YES. AT LEAST THAT'S THE
24 FINDING OF A VERY INTERESTING PAPER THAT WAS
25 PUBLISHED ABOUT THE NIH REGISTRY LINES.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: SO WHAT WE WOULD NEED TO
2 DO IS, GEOFF LOMAX, IS BE CAREFUL TO TALK ABOUT
3 GRANDFATHERING ON IRB STANDARDS AND STATE AGENCY
4 STANDARDS AND ESSENTIALLY, I THINK, REFERENCE TO THE
5 ISSCR AND THE NATIONAL ACADEMY STANDARDS AS
6 APPROPRIATE IN THOSE TIME PERIODS.

7 DR. PRIETO: BOB, COULD THERE BE SOME
8 WORDING SAYING THAT, YOU KNOW, SOMETHING TO THE
9 EFFECT THAT IF ADHERENCE TO THOSE STANDARDS HAD BEEN
10 VERIFIED?

11 CHAIRMAN KLEIN: LET'S TRY AND GET GEOFF
12 LOMAX AND THE LAWYERS TO WORK ON THE WORDING, BUT
13 WHAT WE'RE TRYING TO DO IN THIS MEETING IS TO TRY
14 AND GET THE CONCEPT. BUT LET'S --

15 DR. FONTANA: I SUPPORT THE CONCEPT. AND
16 I ALSO SUPPORT FRANCISCO'S STATEMENT BECAUSE I THINK
17 IT APPEALS TO THE CONCERN THAT LINES WERE MADE UNDER
18 THE HIGHEST REGULATION CONSENT AT THE TIME. HENCE,
19 GOING FORWARD, WE'RE GOING TO EVEN DO IT WITH A
20 HIGHER STANDARD. AND THEN ALSO POINTING OUT THAT
21 WE'VE ALREADY SPENT \$761 MILLION ON LINES THAT ARE
22 ESTABLISHED WITH THE GUIDELINES IN PLACE.

23 MS. KING: ELONA WOULD LIKE TO MAKE A
24 COMMENT ON THAT.

25 MS. BAUM: HI. I JUST WANTED TO SAY TO

BARRISTERS' REPORTING SERVICE

1 THE EXTENT THAT WE'RE REQUIRING VERIFICATION THAT
2 THE IRB VERIFICATION WITH COMPLIANCE WITH OTHER
3 REGULATIONS, SUCH AS THE NAS, I THINK WHAT WE'RE
4 DOING IS SORT OF UNRAVELING THE WHOLE IMPACT OF THE
5 GRANDFATHERING. AND YOU COULD END UP HAVING TO DO A
6 VERY THOROUGH REVIEW AGAIN.

7 CHAIRMAN KLEIN: I THINK THAT I WAS
8 REFERRING TO STATE STANDARDS DEVELOPED IN REFERENCE
9 TO THE NATIONAL ACADEMY STANDARDS SUBSTANTIVELY IN
10 REFERENCE TO IT BECAUSE THERE CAN BE SOME
11 MODIFICATIONS AND ISSCR -- AND/OR ISSCR STANDARDS.
12 IN TERMS OF THE IRB'S, IF THEY HAVE APPROVED
13 CONSISTENT WITH THE STANDARDS THAT WERE APPLICABLE
14 AT THE TIME, I WOULD THINK THAT THAT GRANDFATHERING
15 SHOULD BE DONE. AND CONSISTENCY OF THE IRB
16 DOCUMENTATION ACROSS THIS COUNTRY HAS HISTORICALLY
17 BEEN VERY GOOD.

18 SO I DON'T THINK, DR. PRIETO, YOU'RE
19 TRYING TO RETROACTIVELY APPLY NATIONAL ACADEMY
20 STANDARDS --

21 DR. PRIETO: NO. NO. NO.

22 CHAIRMAN KLEIN: -- AT IRB MEETING.

23 DR. PRIETO: NO. JUST THAT WE VERIFY THAT
24 THEY WERE CONSISTENT WITH THE STANDARDS IN PLACE AT
25 THE TIME, THAT REASONABLE PROCEDURES WERE FOLLOWED.

BARRISTERS' REPORTING SERVICE

1 I MEAN I DON'T WANT TO ADD ANOTHER LAYER OF REVIEW
2 AND UNNECESSARY DOCUMENTATION ON THIS. QUESTIONS
3 HAVE BEEN RAISED ABOUT WHETHER STANDARDS WERE
4 FOLLOWED. I, AS JEANNIE SAID, WANT TO MAKE SURE
5 THAT WE'RE VERY CLEAR THAT WE BELIEVE THAT THE
6 HIGHEST STANDARDS APPLICABLE AND CURRENT AT THE TIME
7 SHOULD BE FOLLOWED, AND WE WANT HIGHER STANDARDS
8 THAN THAT GOING FORWARD.

9 CHAIRMAN KLEIN: OKAY. ADDITIONAL
10 COMMENTS ON THE GRANDFATHERING? I THINK WE
11 HAVEN'T --

12 DR. FONTANA: CAN WE CLARIFY? WHEN YOU
13 SAID GRANDFATHERING, I'M SORRY, DID YOU SAY THE
14 PRESIDENTIAL LINES OR ALL LINES?

15 CHAIRMAN KLEIN: ALL LINES THAT HAVE GONE
16 THROUGH AN IRB AND/OR HAVE BEEN APPROVED BY A STATE
17 AGENCY DEVELOPED STANDARDS THROUGH PUBLIC HEARINGS
18 AND CONSISTENT WITH NATIONAL ACADEMY OR ISSCR
19 GUIDELINES.

20 DR. FONTANA: WOULD WE NOW INCLUDE
21 PARTHENOS, OR WOULD WE JUST SAY ALL LINES THAT WERE
22 DERIVED UNDER THE APPROVED IRB PROTOCOL?

23 CHAIRMAN KLEIN: THE APPROACH -- ONE
24 APPROACH IS TO SAY ALL LINES, BUT WE HAVE THAT AS A
25 SEPARATE ITEM WE'RE GOING TO TOUCH ON. LET'S

BARRISTERS' REPORTING SERVICE

1 ADDRESS IT AT THAT POINT.

2 DR. FONTANA: OKAY.

3 CHAIRMAN KLEIN: I'D LIKE TO ASK FOR
4 PUBLIC COMMENT ON THE GRANDFATHERING APPROACH WITH
5 THE SUGGESTED GENERAL STANDARD CONCEPTUALLY. I'D
6 LIKE TO START THIS TIME FROM THE SOUTH. DR. BLOOM,
7 IS ANYONE WITH YOU?

8 DR. BLOOM: NO ONE HERE.

9 CHAIRMAN KLEIN: DR. BRYANT.

10 DR. BRYANT: NO COMMENTS.

11 CHAIRMAN KLEIN: DR. FRIEDMAN.

12 DR. FRIEDMAN: NO ONE HERE, BUT LET ME
13 JUST SAY, BECAUSE I COULDN'T GET THE MUTE BUTTON OFF
14 IN TIME, WHILE WE WANT TO BE VERY ATTENTIVE TO NOT
15 MAKING EXTRA WORK FOR PEOPLE, I THINK IT'S
16 CRITICALLY IMPORTANT AS WE ESTABLISH THE FRAMEWORK
17 FOR EVERYTHING GOING FORWARD THAT WE BE METICULOUSLY
18 CAREFUL AND PERHAPS EVEN OVERCAREFUL BECAUSE THIS IS
19 THE ONE CHANCE WE HAVE TO BRING EVERYTHING UP TO A
20 CERTAIN LEVEL. HOW THAT TRANSLATES, I'M NOT
21 COMPLETELY CLEAR, AND I'M STILL TRYING TO THINK THAT
22 THROUGH IN MY OWN MIND. BUT I WOULDN'T LET EXTRA
23 EFFORT DISSUADE ME NECESSARILY FROM ASKING FOR
24 CERTAIN DOCUMENTATION NOW, CERTAIN REVIEW NOW JUST
25 BECAUSE THIS IS OUR ONE CHANCE TO GET EVERYTHING

BARRISTERS' REPORTING SERVICE

1 RIGHT.

2 CHAIRMAN KLEIN: IN TERMS OF EXTRA EFFORT
3 AND BEING CAREFUL WITH THAT ISSUE SO AS NOT TO
4 DERAIL THE SCIENCE, ON ONE SINGLE LINE THAT WENT
5 THROUGH OUR COMMITTEE THAT WASN'T GRANDFATHERED AND
6 WAS CREATED PRIOR TO SPECIFIC DATES, IT TOOK OVER
7 150 HOURS OF OUR STAFF AND OVER 150 HOURS OF THE
8 INSTITUTION'S STAFF FOR A SINGLE LINE JUST ON
9 DOCUMENTATION. IT TURNED OUT THAT DOCUMENTATION WAS
10 THERE, BUT IT WAS EXTRAORDINARILY TIME-CONSUMING
11 FINDING DOCUMENTATION THAT WENT BACK SEVEN OR EIGHT
12 YEARS.

13 DR. FRIEDMAN: AND I DO APPRECIATE THAT,
14 BOB. AND THAT'S WHY I'M TRYING TO STRIKE A BALANCED
15 POSITION, BUT I JUST -- AND I UNDERSTAND THAT I MAY
16 BE IN THE MINORITY HERE, AND THAT'S JUST FINE. I
17 JUST THINK WE SHOULDN'T LET -- I'VE ALREADY SAID IT.
18 I WON'T REPEAT. PLEASE, GO RIGHT AHEAD.

19 CHAIRMAN KLEIN: I THINK WE'RE GOING TO BE
20 VERY SENSITIVE TO THE FACT THAT SETTING AN IRB
21 STANDARD AND THEIR HISTORICAL PERFORMANCE ON STRICT
22 ADHERENCE TO PROTOCOL AND ETHICS, HOPEFULLY WE HAVE
23 A REASONABLE BALANCE IF THEY'VE PREVIOUSLY CERTIFIED
24 AND APPROVED A LINE. CERTAINLY THAT'S GOING TO BE
25 AN ONGOING DISCUSSION HERE WE CAN CARRY FORWARD TO

BARRISTERS' REPORTING SERVICE

1 THE NEXT MEETING.

2 I'D LIKE TO SEE, JEANNIE FONTANA, IS THERE
3 ANY PUBLIC COMMENT FROM YOUR SITE?

4 DR. FONTANA: NOT AT THIS MOMENT.

5 CHAIRMAN KLEIN: AND, DR. PERA, DID YOU
6 HAVE ANY COMMENTS?

7 DR. PERA: FULLY SUPPORTIVE OF THE
8 GRANDFATHERING APPROACH. IT'S REALLY ESSENTIAL FOR
9 THE SCIENCE TO PROCEED FORWARD.

10 CHAIRMAN KLEIN? AND, DR. LO. I DON'T
11 HEAR DR. LO FOR THE MOMENT. WE'LL COME BACK.

12 DR. LO: NO COMMENT. SORRY.

13 CHAIRMAN KLEIN: THANK YOU, DR. LO. AND
14 ARE THERE ADDITIONAL SITES? SAN FRANCISCO,
15 ADDITIONAL COMMENTS AT THE CIRM OFFICE?

16 MS. KING: WE DO HAVE ONE HERE, DON REED.

17 MR. REED: JUST TO MAKE SURE I UNDERSTAND.
18 IS IT CORRECT THAT PRESIDENTIALLY APPROVED LINES AND
19 THE IRB LINES WOULD -- OUR POSITION WOULD BE THAT
20 THEY WOULD BE ELIGIBLE FOR FUNDING?

21 CHAIRMAN KLEIN: WELL, WE'RE TAKING A
22 POSITION. AT THE MOMENT WE'VE SUGGESTED THAT THEY
23 BE IRB OR STATE AGENCY APPROVED LINES, AND THAT
24 MEANS THAT THERE ARE A COUPLE OF PRESIDENTIAL LINES,
25 IT'S MY UNDERSTANDING, THAT MAY HAVE AN ISSUE

BARRISTERS' REPORTING SERVICE

1 ASSOCIATED WITH THEM. DO WE KNOW WHETHER THE VOLUME
2 OF SCIENTIFIC RESEARCH THAT'S DEPENDENT, IF WE COULD
3 TALK TO DR. BRYANT.

4 DR. BRYANT: YES. I HAVEN'T SEEN THE
5 PAPER, BUT I THINK DR. GOLUB CAN COMMENT ON THAT.

6 DR. GOLUB: THERE'S CONCERN ABOUT RANGING
7 FROM MINOR CONCERNS TO MAJOR CONCERNS. THE ONES
8 THAT HAVE DRAWN THE MOST ATTENTION ARE THREE CELL
9 LINES FROM BRESAGEN COMPANY. OTHER THAN THAT, I
10 DON'T THINK THERE'S ANY THAT WOULDN'T MEET THE
11 STANDARD WE'RE TALKING ABOUT. THERE MAY BE ONE OR
12 TWO OTHERS, BUT THEY WENT BACK AND RECONSENTED THE
13 DONORS ON THOSE. SO I THINK REALLY LIMITED TO THOSE
14 TWO OR THREE CELL LINES.

15 DR. LOMAX: BOB, FOR THE BENEFIT OF THE
16 COMMITTEE, WE'VE LOOKED AT -- IN AS MUCH DETAIL AS
17 WE CAN, WE'VE LOOKED AT CELL LINES APPROVED BY
18 OVERSIGHT COMMITTEES FOR USE BY OUR GRANTEES IN
19 FUNDED RESEARCH, AND THERE IS CURRENTLY NONE OF THE
20 THREE LINES THAT ARE IN USE OR HAVE BEEN APPROVED
21 FOR USE BY OUR GRANTEES. AND WE HAVE NO INDICATION
22 THAT ANY OF OUR GRANTEES ARE ACTUALLY USING THOSE
23 LINES.

24 CHAIRMAN KLEIN: THAT'S VERY HELPFUL. IF
25 YOU COULD PASS THAT ON IN THE BOARD CALL, THAT WOULD

BARRISTERS' REPORTING SERVICE

1 BE IMPORTANT.

2 DR. CHARO: BOB, CAN YOU TAKE PUBLIC
3 COMMENT FROM OUT OF STATE?

4 CHAIRMAN KLEIN: DR. CHARO. AND I REMIND
5 EVERYONE THAT DR. CHARO WAS ORIGINALLY RETAINED BY
6 THIS AGENCY AS WE WENT THROUGH OUR MEDICAL AND
7 ETHICAL STANDARDS PROCESS. SO DR. CHARO IS AN
8 OUTSIDE EXPERT AS VERSUS A PUBLIC MEMBER. IF YOU
9 COULD PROVIDE INPUT.

10 DR. CHARO: THANK YOU. AND I APPRECIATE
11 THAT HAVING WORKED ON THE ETHICS STANDARD GROUPS ALL
12 THESE YEARS, I ALSO FEEL SOME LOYALTY TO CIRM. I
13 WANT TO JUST MAKE ONE COMMENT ABOUT THE LANGUAGE
14 THAT WE'RE USING. PEOPLE OFTEN INTERPRET THE PHRASE
15 "GRANDFATHERING" TO MEAN THAT WE'RE LOOKING
16 BACKWARDS AND WE'RE TAKING THINGS THAT DON'T MEET
17 TODAY'S STANDARDS AND WE'RE LETTING THEM IN.

18 I JUST WANT TO EMPHASIZE SOMETHING THAT
19 BERNIE SAID, THAT GEOFF SAID, AND THAT IS WE'RE
20 TALKING ABOUT HAVING EXACTLY THE SAME STANDARDS FOR
21 LINES THAT WERE MADE YESTERDAY OR TOMORROW. THE IRB
22 STANDARDS HAVE NOT CHANGED IN THE LAST TEN YEARS.
23 THEY'VE ALWAYS BEEN THE SAME EIGHT ELEMENTS OF
24 INFORMED CONSENT THAT ARE LISTED IN THE FEDERAL
25 REGULATIONS. IRB'S HAVE BEEN INTERPRETING THEM FOR

BARRISTERS' REPORTING SERVICE

1 YEARS, BUT NEITHER THE NATIONAL ACADEMY GUIDELINES
2 OR THE ISSCR GUIDELINES, NONE OF THOSE HAVE CHANGED
3 THE STANDARD BY WHICH IRB'S REVIEW WHETHER OR NOT
4 DONORS HAVE PROPERLY GIVEN INFORMED AND VOLUNTARY'
5 CONSENT FOR THEIR EMBRYOS TO BE RELINQUISHED TO
6 RESEARCH.

7 SO ONE NEED NOT TALK ABOUT GRANDFATHERING
8 THE OLDER IRB'S RULES. ALL ONE HAS TO SAY IS IF A
9 LINE WAS APPROVED BY OR IS APPROVED BY AN IRB, THEN
10 THE LINE CAN BE ASSURED TO NIH. AN IRB IS FREE, IF
11 THEY HAVE CONCERNS ABOUT A LINE THAT THEY ONCE
12 APPROVED OR THAT SOMEBODY ELSE APPROVED, THEY'RE
13 FREE TO GO BACK AND SAY WE WANT TO LOOK AT IT AGAIN,
14 BUT THEY WOULDN'T BE REQUIRED TO.

15 CHAIRMAN KLEIN: THERE'S TWO THINGS, ALTA.
16 ONE IS THAT ON A TECHNICAL BASIS, WHILE AS TO IRB'S,
17 THAT'S TRUE. OBVIOUSLY STATE AGENCIES NEED TO BE
18 GRANDFATHERED. BUT SECONDLY, AS TO THE IRB'S, IT'S
19 IMPORTANT THAT WE RAISE THE POINT THAT YOU JUST
20 RAISED IN THE BOARD SESSION. BY HAVING
21 GRANDFATHERING, WHICH MEMBERS OF CONGRESS
22 UNDERSTAND, IT'S A SIMPLE CONCEPT. BY
23 GRANDFATHERING WHAT'S ALREADY BEEN THROUGH IRB'S,
24 THE CONCEPT IS THAT WE'RE NOT GOING TO CHANGE THE
25 GAME ON IRB'S RETROACTIVELY. AND THAT IS SOMETHING

BARRISTERS' REPORTING SERVICE

1 THAT THERE'S BEEN AND WILL BE A GREAT DEAL OF PUBLIC
2 PRESSURE TO DO FROM THE OPPOSITION, WHICH IS TO SAY,
3 WELL, IRB'S CAN BE USED, BUT WE'RE GOING TO CHANGE
4 THE STANDARDS THEY SHOULD HAVE USED IN APPROVING
5 THEM.

6 DR. CHARO: THE POINT IS -- I THINK THE
7 POINT OF WHAT WAS GOING ON AT THE ISSCR -- IASCR WAS
8 THAT WE SHOULD RESIST THAT PRESSURE. WE SHOULD
9 RESIST ANY TEMPTATION TO WRITE SPECIAL, DETAILED
10 RULES ABOUT THE NATURE OF THE CONSENT, AND WE SIMPLY
11 ASK THE IRB'S TO APPLY THE FAIRLY COMPREHENSIVE
12 STANDARDS THAT ARE ALREADY IN PLACE FOR CONSENTING
13 FOR THE RELEASE OF TISSUE FOR RESEARCH MATERIAL, AND
14 FOR IRB'S TO ALLOW THEIR INVESTIGATORS TO GET TISSUE
15 FROM TISSUE BANKS. ALL OF THAT IS IN PLACE. AND
16 WHY WOULD WE WANT TO INVITE THAT TO BE CHANGED?

17 CHAIRMAN KLEIN: WE DON'T WANT TO INVITE
18 IT TO BE CHANGED, BUT THE POINT IS THAT IF, IN FACT,
19 THAT POSITION IS FULLY ACCEPTED, WE DON'T NEED
20 GRANDFATHERING AS TO THE IRB'S. WE STILL NEED
21 GRANDFATHERING AS TO STATE AGENCIES. BUT IF TO THE
22 EXTENT ANYONE WANTS TO RAISE THE ISSUE OF TRYING TO
23 CHANGE THE IRB STANDARDS RETROACTIVELY OR
24 PROSPECTIVELY, AT A MINIMUM WE WANT TO HAVE A REALLY
25 STRONG POSITION ON GRANDFATHERING ALL OF THE

BARRISTERS' REPORTING SERVICE

1 HISTORIC POSITIONS, WHICH YOU SAY HAVE BEEN QUITE
2 STRICT AND CONSISTENT FOR A DECADE.

3 DR. FONTANA: I JUST HAVE A QUESTION. ARE
4 WE BEING REDUNDANT THERE? IF WE MADE AN AGREEMENT
5 THAT WE ALL APPROVE THAT WE SHOULD ALLOW THE IRB'S
6 TO DETERMINE THE ELIGIBILITY OF LINES, AND AS ALTA
7 POINTED OUT, THERE ARE WELL-ESTABLISHED PROTOCOLS
8 FOR THAT, IS IT NECESSARY TO ADD THAT WE NEED TO
9 GRANDFATHER THEM IN?

10 CHAIRMAN KLEIN: WELL, THE ISSUE IS THAT
11 THERE ARE INDIVIDUALS THAT MAY TRY AND CHANGE THE
12 STANDARDS FOR THE IRB'S PROSPECTIVELY, WHICH, OF
13 COURSE, IS A SEPARATE ISSUE THAT, MY UNDERSTANDING,
14 IS NOT ACCEPTABLE. BUT NO. 2 IS TO THE EXTENT THAT
15 SOMEONE WANTS TO TRY AND CHANGE THE -- CHANGE THE
16 STANDARDS RETROSPECTIVELY, OUR POSITION WOULD BE TO
17 GRANDFATHER. IF NO ONE WANTS TO TRY AND CHANGE
18 THESE STANDARDS, FINE. THEY STAND AS THEY ARE. WE
19 DON'T NEED TO GRANDFATHER.

20 THE ISSUE IS, JEANNIE, ON A POLITICAL
21 BASIS, THE CONCEPT OF GRANDFATHERING IS SOMETHING
22 THAT IS UNDERSTOOD FAIRLY CLEANLY.

23 DR. FONTANA: I APPRECIATE ALTA'S COMMENT
24 ON THAT THOUGH, WHAT IT IMPLIES, AND WOULD LIKE TO
25 JUST TAKE HER COMMENTS INTO CONSIDERATION.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: WELL, I THINK THAT THAT'S
2 THE PURPOSE OF THIS MEETING. SO WE SHOULD
3 DEFINITELY DO THAT. BUT SO, JEANNIE, IF THEY CAME
4 IN AND SUGGESTED THAT THE IRB STANDARDS BE CHANGED,
5 AND THERE WASN'T AN ABILITY TO WIN ON THE IRB
6 STANDARDS BEING CHANGED, AT THAT POINT WOULD YOU, IN
7 FACT, REQUEST THAT AT LEAST THEY GRANDFATHER THE
8 PRIOR CONSISTENT RECORD OF THE IRB'S?

9 DR. FONTANA: YES.

10 CHAIRMAN KLEIN: THAT'S THE POINT.

11 DR. FONTANA: OKAY.

12 CHAIRMAN KLEIN: OKAY. SO WE'VE COVERED
13 THOSE ISSUES. I WANT TO, JEANNIE, GO NOW TO THE
14 ISSUE YOU PREVIOUSLY RAISED. COULD YOU PRESENT THAT
15 ITEM?

16 DR. FONTANA: YOU HAVE IT ON GEOFF AND
17 YOUR NICE DRAFT. I BELIEVE IT'S ON PAGE 2. PAGE 3
18 ON THE ITEM NO. 3, AND THERE'S A BULLET POINT. YOU
19 HAD BROUGHT UP -- IT COMES UNDER THE BOLDED BULLET
20 POINT ON PAGE 2 IS THE NIH SHOULD TIGHTEN THE
21 GUIDELINES BY LEVERAGING THE ESTABLISHED IRB REVIEW
22 PROCESS ON THE BASIS OF ACCEPTABILITY PRE-JULY 1.
23 AND THEN THERE'S A NUMBER OF LITTLE BULLET POINTS
24 UNDER THAT. WHEN YOU GO ON PAGE 3 ABOVE ONE OF
25 THOSE BULLET POINTS, IT SAYS, FUTURE LINES DERIVED

BARRISTERS' REPORTING SERVICE

1 IN THE UNITED STATES FROM BLASTOCYSTS, AND THIS IS
2 UNDERLINED, CREATED AFTER JULY 2009 SHOULD CONFORM
3 TO NIH GUIDELINES.

4 AND MY QUESTION IS ALL LINES SHOULD
5 CONFORM TO NIH GUIDELINES AT THAT TIME, RIGHT? AND
6 THEN ARE WE GOING TO DEFINE BLASTOCYSTS, WHERE DID
7 THEY COME FROM, OR ARE WE JUST GOING TO SAY
8 BLASTOCYSTS, AND THEN WE DON'T HAVE TO WORRY ABOUT
9 THE PARTHENOS, THE SCNT, THE BGG, ALL THE DIFFERENT
10 FORMS OF GETTING A BLASTOCYST.

11 DR. PRIETO: JEANNIE, WHAT IF THEIR
12 GUIDELINES SPECIFICALLY EXCLUDE SOME OF THOSE
13 CATEGORIES?

14 DR. FONTANA: THAT'S WHY I'M ASKING. ARE
15 WE SPECIFICALLY NOT INCLUDING IT? WE'RE BEING
16 GENERAL? OR ON PURPOSE? I GUESS THAT'S MY
17 QUESTION.

18 CHAIRMAN KLEIN: GEOFF, YOU WANT TO
19 COMMENT, PLEASE?

20 DR. LOMAX: SURE. AS ALWAYS, JEANNIE, YOU
21 PUT WORDS ON PAPER, AND THEY MEAN ONE THING TO THE
22 AUTHOR, AND THEY COULD MEAN MANY OTHER THINGS TO THE
23 READER. I THINK THE ONLY -- THE DRIVING FORCE
24 BEHIND THAT STATEMENT WAS JUST TO SORT OF PLANT THE
25 SEED FOR THE IDEA THAT IF THERE WAS GOING TO BE SOME

BARRISTERS' REPORTING SERVICE

1 SORT OF MODIFICATION TO WHAT CONSTITUTES INFORMED
2 CONSENT AND THERE WERE EITHER SOME SORT OF GUIDANCE
3 OR GUIDELINES ON KIND OF WHAT THE, QUOTE, UNQUOTE,
4 MAGIC WORDS WERE, THAT IT WOULD SEEM REASONABLE TO
5 APPLY THAT PROSPECTIVELY AS OPPOSED TO
6 RETROSPECTIVELY.

7 SO IT WAS SIMPLY JUST TO THROW OUT A POINT
8 THAT IF THERE IS GOING TO BE SOME
9 RECONCEPTUALIZATION OF WHAT EXACTLY NEEDS TO BE TOLD
10 TO A DONOR, IT'S FAIRLY COMMON IN PUBLIC POLICY THAT
11 ONE SORT -- WHEN ONE IS SORT OF BUILDING A MORE
12 AGGRESSIVE STANDARD, THAT ONE APPLIES IT AFTER A
13 DATE AND TIME THAT ALLOWS PEOPLE TO COMPLY, AND IT
14 DOESN'T REACH BACK AND DISQUALIFY MATERIALS THAT ARE
15 OTHERWISE ACCEPTABLE.

16 THAT WAS REALLY THE ONLY -- THE USE OF THE
17 TERM "BLASTOCYST" WAS JUST THERE BECAUSE IT WAS --
18 WANTED TO SORT OF ALSO MENTION THAT IF YOU LIMIT IT
19 TO EVERYTHING THAT'S CREATED AT THAT DATE, YOU HAVE
20 NO CHANCE OF LOSING BLASTOCYSTS THAT MAY HAVE BEEN
21 CREATED A BIT EARLIER AND ALREADY DONATED.

22 DR. FONTANA: I GUESS I SUPPORT THE
23 PRINCIPLE OF GOING FORWARD. THERE'S ALMOST A
24 UNIVERSAL CONSENT FORM BECAUSE THERE MAY BE, AND I
25 CAN'T FORESEE THE FUTURE, BUT THERE MAY BE SOME NEW

BARRISTERS' REPORTING SERVICE

1 WAY THAT COMES UP THAT SHOULD FALL UNDER A UNIVERSAL
2 CONSENT FORM. AND RIGHT NOW WE'VE JUST FOCUSED ON
3 CONSENTING FOR DISCARDED EMBRYOS FROM IVF CLINICS.
4 COULD WE COME UP WITH -- IT SEEMS LIKE THESE
5 GUIDELINES HAVE BEEN TRYING TO BE MORE ETHICAL TO
6 THE DONOR TO GIVE THEM DIFFERENT OPTIONS AND SO
7 FORTH, BUT CAN WE ALSO MAYBE ADDRESS BEING A LITTLE
8 MORE INCLUSIVE OF AND RAISING THE BAR WITH
9 GUIDELINES AND STANDARDS OF ALL FORMS OF DERIVATION
10 OF CELL LINES?

11 CHAIRMAN KLEIN: SO YOU RAISE TWO POINTS,
12 JEANNIE. ONE IS, IN QUOTES, THE UNIVERSAL CONSENT
13 FORM. AND IS IT, IN FACT, UNIVERSAL, OR IS IT
14 UNIFORM IN THE UNITED STATES, AND IT MIGHT BE
15 DIFFERENT IN AUSTRALIA, UNITED KINGDOM, GERMANY,
16 FRANCE, CANADA? THE ISSCR, I THINK, REFERS TO
17 SOMETHING THAT IS APPROPRIATE CONSENT CONFORMING TO
18 THE STANDARDS PUBLICLY DEVELOPED IN THOSE COUNTRIES.
19 THAT'S ONE ISSUE.

20 THE OTHER ISSUE IS YOU WANT TO BE
21 INCLUSIVE FOR BLASTOCYSTS DERIVED FROM ALL
22 TECHNIQUES.

23 DR. FONTANA: I JUST RAISE THE QUESTION:
24 DO WE WANT TO DEFINE IT, OR ARE WE PURPOSELY BEING
25 GENERAL?

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: JUST SO YOU KNOW, WHEN WE
2 DEVELOPED THESE REGULATIONS, THIS DRAFT, WE ONLY
3 SPOKE TO WHAT WAS -- TRYING TO SPEAK WHAT WAS IN THE
4 SCOPE OF THE DRAFT GUIDELINES. AND SINCE THE DRAFT
5 GUIDELINES WERE REFERRING SPECIFICALLY TO
6 BLASTOCYSTS CREATED FOR REPRODUCTIVE PURPOSES, BUT
7 NO LONGER NEEDED FOR THOSE PURPOSES, ALL REFERENCES
8 TO THOSE TERMS WERE SORT OF LIMITED TO THAT SCOPE.
9 SO IT DOESN'T ANSWER THE QUESTION, DOESN'T RESOLVE
10 THE QUESTION, BUT JUST TO BE CLEAR ALL THE WAY
11 THROUGH, THAT'S HOW WE SORT OF THOUGHT ABOUT IT IN
12 TERMS OF OFFERING YOU A FRAMEWORK FOR COMMENTING.

13 DR. FONTANA: I APPRECIATE THAT, BUT MAYBE
14 IT CAN BE ADDRESSED IN THE NEXT BULLET WHERE YOU
15 TALK ABOUT PARTHENO LINES. I APPRECIATE WORKING
16 WITHIN THE FRAMEWORK AND MOVING FORWARD.

17 CHAIRMAN KLEIN: OKAY. WOULD BOARD
18 MEMBERS LIKE TO COMMENT ON DR. FONTANA'S POINT? ALL
19 RIGHT. IS THERE PUBLIC COMMENT ON DR. FONTANA'S
20 POINT? ALL RIGHT. THANK YOU, DR. FONTANA, FOR
21 MAKING THE POINT.

22 GEOFF, PLEASE CONSIDER THAT POINT IN YOUR
23 REPORT TO THE BOARD. I WOULD LIKE TO GO TO DR. PERA
24 WHO HAD A SPECIFIC POINT HE WANTED TO RELATE TO ON
25 TISSUE BANKS.

BARRISTERS' REPORTING SERVICE

1 DR. PERA: YES. THE DOCUMENT REFERS TO
2 MATERIAL IN TISSUE BANKS THAT MAY HAVE ALREADY BEEN
3 CONSENTED. AND THE AIM IS NOT TO AVOID ELIMINATING
4 THAT MATERIAL FROM FUTURE RESEARCH USE.

5 TWO POINTS. FIRST OF ALL, I SUSPECT THAT
6 MUCH OF THE RELEVANT MATERIAL IS NOT ACTUALLY FROZEN
7 AT THE BLASTOCYST STAGE OF DEVELOPMENT. SO THE USE
8 OF THE TERM "BLASTOCYST" MIGHT BE PREFERABLE TO
9 REFER TO EMBRYOS.

10 THE SECOND POINT IS THAT YOU REFER TO
11 BLASTOCYSTS OR PREFERABLY EMBRYOS THAT HAVE BEEN
12 DONATED FOR RESEARCH WHEN YOU'RE TALKING ABOUT THE
13 CONSENT. AND I GUESS THAT IN MOST CASES WE WOULD
14 HAVE TO HAVE SPECIFIC CONSENT TO DERIVE A CELL LINE.
15 AND IF YOU DIDN'T, YOU WOULD HAVE TO GO BACK AND
16 RECONSENT THE PATIENT. SO I KIND OF FEEL THAT'S
17 SOMETHING THAT MIGHT REQUIRE CLARIFICATION.

18 CHAIRMAN KLEIN: ALL RIGHT. DR. PERA, ON
19 PAGE 3 AT THE BOTTOM BELOW THE LAST -- BEFORE THE
20 LAST -- THE PARAGRAPH BEFORE THE LAST BOLD BULLET
21 POINT, IT TALKS ABOUT ISSCR ADDRESSING INTERNATIONAL
22 STANDARDS AND THE NEED TO EMBRACE CELL LINES DERIVED
23 OUTSIDE THE U.S. AS LONG AS SUCH DERIVATIVES WERE
24 DONE IN ACCORDANCE WITH ETHICALLY RESPONSIBLE
25 NATIONAL LAWS OF THAT COUNTRY OF THE DERIVATION.

BARRISTERS' REPORTING SERVICE

1 COULD YOU ADDRESS THAT POINT ON THE
2 IMPORTANCE OF THOSE LINES?

3 DR. PERA: YES. THERE ARE MANY LINES FROM
4 OUTSIDE OF THE UNITED STATES THAT HAVE BEEN DERIVED
5 THAT ARE VERY, VERY USEFUL INDEED. AND I THINK IT
6 WOULD BE VERY, VERY IMPORTANT NOT TO EXCLUDE THEM.

7 CHAIRMAN KLEIN: ARE THERE BOARD COMMENTS
8 ON THAT POINT?

9 DR. FONTANA: WE ALL AGREE HERE, THAT WE
10 THINK IT'S GREAT TO HAVE THE INTERNATIONAL COMMUNITY
11 BE A PART OF THESE GUIDELINES.

12 CHAIRMAN KLEIN: AND IS THERE OTHER BOARD
13 COMMENT?

14 DR. BRYANT: I AGREE. I THINK AS LONG AS
15 THEY WERE ESTABLISHED, APPROVED LINES AND SO FORTH,
16 I THINK THAT'S OKAY. AND ACTUALLY IT'S IMPORTANT
17 BECAUSE, AS DR. PERA POINTED OUT, THERE'S A LOT OF
18 IMPORTANT RESEARCH THAT'S BEEN DONE ON THOSE LINES.

19 CHAIRMAN KLEIN: ALL RIGHT. IS THERE
20 PUBLIC COMMENT ON THAT POINT?

21 DR. FONTANA: WE HAVE ONE PUBLIC COMMENT
22 HERE, BOB.

23 MR. ALDRIDGE: THIS IS KEN ALDRIDGE. THE
24 ONE COMMENT I WOULD HAVE ON IT, WHICH I THINK YOU'RE
25 ALLUDING TO, IS THAT WE SHOULD ALLOW LINES THAT COME

BARRISTERS' REPORTING SERVICE

1 IN FROM FOREIGN SOURCES. SOMEWHERE IN HERE THERE
2 WAS A REFERENCE TO SPECIFIC COUNTRY PROTOCOLS. ONE
3 OF THE THINGS THAT I THINK WE MAY FIND IS THAT
4 INDIVIDUALS OR RESEARCHERS ARE OPERATING IN
5 COUNTRIES THAT MAY NOT HAVE WELL-DEFINED PROTOCOLS,
6 BUT ARE THEMSELVES OPERATING AND REQUIRING CONSENTS
7 THAT MEET INTERNATIONAL AND U.S. STANDARDS. WE
8 DON'T WANT TO INADVERTENTLY EXCLUDE THOSE.

9 CHAIRMAN KLEIN: RIGHT. I THINK THAT THIS
10 BULLET POINT TALKS ABOUT SHOULD ALLOW IRB'S TO
11 RECOGNIZE THOSE LINES AS LONG AS THEY WERE DERIVED
12 IN ACCORDANCE WITH ETHICALLY RESPONSIBLE NATIONAL
13 LAWS OF THAT COUNTRY. AND WHAT YOU ARE SAYING IS
14 THE COUNTRY MAY NOT HAVE THOSE NATIONAL LAWS, BUT
15 YOU'RE SUGGESTING WE PUT IN THE WORDS "OR EQUIVALENT
16 INTERNATIONAL STANDARDS."

17 MR. ALDRIDGE: YES, THAT'S RIGHT.

18 CHAIRMAN KLEIN: GEOFF, WOULD YOU TAKE
19 NOTE OF THAT COMMENT, PLEASE?

20 DR. LOMAX: HAVE DONE. THANK YOU.

21 CHAIRMAN KLEIN: THANK YOU. I WOULD LIKE
22 AT THIS POINT TO ASK IF THERE IS ANY BOARD MEMBER
23 THAT WOULD LIKE TO SPECIFICALLY RAISE AN ADDITIONAL
24 POINT IN THESE DISCUSSIONS? AND THANK YOU, GEOFF,
25 FOR PREPARING THESE VERY WELL-ORGANIZED COMMENTS

BARRISTERS' REPORTING SERVICE

1 THAT ARE VERY EFFECTIVE IN PROMOTING PUBLIC
2 DISCUSSION AND STUDY AS WELL AS BOARD STUDY BEFORE
3 OUR BOARD MEETING.

4 MS. KING: GEOFF WAS ATTEMPTING TO GIVE A
5 SHOUT OUT TO ELONA FOR WORKING WITH HIM ON THAT.
6 AND DON GIBBONS.

7 CHAIRMAN KLEIN: THANK YOU, ELONA AND DON
8 GIBBONS.

9 DR. FONTANA: BOB, DID WE EVER TALK ABOUT
10 THE PARTHENOS?

11 CHAIRMAN KLEIN: YOU HAVE THE FLOOR, DR.
12 FONTANA.

13 DR. FONTANA: WELL, I THINK THERE WAS A
14 SPECIFIC LINE ITEM ADDRESSING THE PARTHENOS, THOSE
15 LINES THAT HAVE ALREADY BEEN ESTABLISHED. AND I
16 THINK THAT THEY'RE DESERVING QUALIFYING FOR
17 GRANDFATHERING IN IF WE NEED TO PULL THEM OUT AS A
18 SEPARATE LINE ITEM AS LONG AS THEY TOO HAVE FOLLOWED
19 THE PROPER IRB GUIDELINES THAT WE HAVE SET.

20 AND THEN I WOULD LIKE TO MAKE A PRINCIPLED
21 STATEMENT BY SAYING THAT I THINK, IN ADDITION TO THE
22 PARTHENOS, THAT ALTHOUGH THERE ARE NOT SCNT CELL
23 LINES DERIVED YET OR EVEN INTERSPECIES NUCLEAR
24 TRANSFER CELL LINES DERIVED YET, THERE MOST
25 CERTAINLY WILL BE SHORTLY. AND WOULDN'T IT BE

BARRISTERS' REPORTING SERVICE

1 PRUDENT TO INCLUDE THAT IN THESE GUIDELINES?

2 CHAIRMAN KLEIN: JEANNIE, I WANT TO NOT
3 HAVE THAT PARTICULAR DISCUSSION AT THE MOMENT
4 BECAUSE I WANT TO MAKE CERTAIN THAT ON SCNT, THAT WE
5 SCREEN FOR ANY ISSUES WITH THIS DISCUSSION. BUT IF
6 WE WANT TO -- CAN WE TALK ABOUT PARTHENOGENESIS
7 LINES, WHICH IS THE TOPIC YOU ORIGINALLY BROUGHT UP?

8 DR. FONTANA: YOU KNOW, I UNDERSTAND THE
9 POLITICS BEHIND OR THE EMOTION BEHIND THE SCNT, BUT
10 I ALSO WOULD LIKE TO RAISE THE POINT OF WE CAN STAND
11 ON PRINCIPLE TOO.

12 CHAIRMAN KLEIN: BUT, JEANNIE, I DON'T
13 THINK YOU ARE THE BOARD MEMBER THAT MIGHT WANT TO
14 ADDRESS THAT TOPIC BECAUSE YOU'VE BEEN VERY INVOLVED
15 IN TRYING TO ADVANCE THIS AREA OF SCIENCE.

16 DR. FONTANA: THAT'S ALL THE MORE REASON
17 WHY I SHOULD BRING IT UP. I KNOW IT.

18 CHAIRMAN KLEIN: I'D JUST LIKE YOU TO
19 CLEAR WITH ELONA TO MAKE CERTAIN THAT WE DON'T RUN
20 INTO CONFLICTS IN THAT DISCUSSION.

21 DR. FONTANA: THAT'S FINE. I'M HAPPY, BUT
22 I'M REALLY NOT SPEAKING FROM A CONFLICT BECAUSE I'M
23 FEELING LIKE ALL LINES, AS LONG AS THEY ARE
24 ESTABLISHED WITH THE ACCEPTABLE IRB AND CONSENT
25 FORMS, SHOULD BE CONSIDERED FOR FUTURE NIH FUNDING.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: AS A GENERAL STATEMENT, I
2 THINK THAT'S QUITE APPROPRIATE.

3 DR. FONTANA: AND THAT'S MY COMMENT.

4 CHAIRMAN KLEIN: THANK YOU.

5 DR. FONTANA: WE HAVE PUBLIC COMMENT.

6 MR. ALDRIDGE: THIS IS KEN ALDRIDGE AGAIN.
7 I JUST WANTED TO POINT OUT SOMETHING IN THE LANGUAGE
8 ON YOUR BULLET POINT RELATING TO PARTHENOS. IT SAYS
9 ESTABLISHED CELL LINES CREATED, ETC., AND THEN IT
10 SAYS ALLOW THE USE OF SUCH LINES. I SUSPECT THE
11 INTENT IS NOT TO EXCLUDE FUTURE LINES THAT MIGHT BE
12 DEVELOPED, BUT I'M CONCERNED THAT THE LANGUAGE MIGHT
13 HAVE THAT RESULT.

14 CHAIRMAN KLEIN: COULD YOU STATE THAT
15 AGAIN A LITTLE LOUDER?

16 MR. ALDRIDGE: IN YOUR BULLET POINT
17 RELATING TO PARTHENOS, THE GUIDELINES SAY
18 ESTABLISHED HESC CELL LINES CREATED FROM
19 PARTHENOGENESIS, ETC., AND THEN IT SAYS ALLOW THE
20 USE OF SUCH LINES, WHICH IMPLIES OR I'M CONCERNED
21 SOMEONE MIGHT INTERPRET IT TO MEAN THAT ONLY
22 PREEXISTING PARTHENO LINES COULD BE USED. WHEREAS,
23 IT'S A NEW SCIENCE, AND THERE ARE UNDOUBTEDLY GOING
24 TO BE MANY PARTHENO LINES MADE THROUGHOUT THE WORLD.

25 DR. LOMAX: POINT WELL TAKEN.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN KLEIN: OKAY. THANK YOU.

2 ADDITIONAL SPECIFIC POINTS, PLEASE. ANY BOARD
3 MEMBER WANT TO RAISE A SPECIFIC POINT?

4 DR. BLOOM: I WANTED TO RAISE AN ISSUE AT
5 LEAST FOR MOMENTARY DISCUSSION THAT I PICKED UP FROM
6 THE CHAIRMAN OF THE STEM CELL RESEARCH OVERSIGHT
7 COMMITTEE LAST NIGHT AT A MEETING WE HAD IN SAN
8 DIEGO CONCERNING THE LACK OF AN NIH DEFINITION FOR
9 DERIVATIVES OF FEDERALLY FUNDED STEM CELL LINES.

10 AND WHEN I MENTIONED THAT TO GEOFF, HE HAD
11 SOME EXPERIENCE WITH IT. AND PERHAPS HE COULD STATE
12 WHAT HIS VIEWS WOULD BE.

13 DR. LOMAX: WELL, THE QUESTION, AS I
14 UNDERSTOOD IT, IS HOW DOES THE FEDERAL -- HOW WOULD
15 NIH VIEW DERIVATIVE NONPLURIPOTENT PRODUCTS FROM
16 HUMAN PLURIPOTENT STEM CELL LINES. WHEN WE SAY
17 DERIVATIVE, IS THAT WHAT WE UNDERSTAND A DERIVATIVE
18 TO BE?

19 DR. BLOOM: YES.

20 DR. LOMAX: SO MY SORT OF SHORTHAND
21 ANSWER, WHICH IS AN ANSWER I'VE GIVEN A NUMBER OF
22 TIMES WHEN THIS QUESTION HAS BEEN RAISED BY OUR
23 GRANTEES, IS THAT IN OUR REGULATIONS, IF THEY
24 COVER -- THE DEFINITION OF A COVERED STEM CELL LINE,
25 WITHIN THAT DEFINITION IT'S LIMITED TO THE

BARRISTERS' REPORTING SERVICE

1 PLURIPOTENT ASPECT OF THE LINE IS CRITICAL. AND IF
2 THE MATERIAL IS NO LONGER PLURIPOTENT, IT REALLY
3 FALLS OUTSIDE THE SCOPE OF OUR REGULATIONS. SO WE
4 HAVE -- SO IN A SENSE, THE RESPONSE I OFFER TO THE
5 GRANTEE IS YOU'RE NOT OBLIGATED TO PERFORM A
6 PARTICULAR TYPE OF EVALUATION ON A DERIVATIVE
7 PRODUCT. IT'S OUTSIDE THE SCOPE OF OUR REGULATIONS.

8 THAT'S NOT A VERY HELPFUL ANSWER IF YOU'RE
9 TRYING TO UNDERSTAND WHAT NIH'S POSITION IS ON
10 DERIVATIVES. AND AT THAT POINT IT GETS TO THE SORT
11 OF LIMITS OF MY UNDERSTANDING, AND IT'S SORT OF THE
12 BEST I CAN DO. I DON'T THINK WE HAVE A CLEAR
13 UNDERSTANDING OF DERIVATIVES. I KNOW IT'S AN ISSUE
14 THAT HAS BEEN DISCUSSED FAIRLY EXTENSIVELY AMONGST
15 OUR GRANTEE INSTITUTIONS, AND IT MAY BE A QUESTION
16 WHERE WE WANT TO SORT OF REACH OUT AND SORT OF
17 SURVEY THEIR COLLECTIVE WISDOM AT THIS TIME IF WE
18 WANTED A MORE ROBUST ANSWER TO THAT QUESTION IN
19 TERMS OF NIH.

20 CHAIRMAN KLEIN: ALTA, DO YOU HAVE A
21 COMMENT ON THAT?

22 DR. CHARO: AS I RECALL, THE ISSUE WAS
23 REALLY HAVING TO DO WITH ELIGIBILITY FOR NIH FUNDS.

24 DR. BLOOM: THAT'S CORRECT, YES.

25 DR. CHARO: THAT WAS ALSO IN THE CONTEXT

BARRISTERS' REPORTING SERVICE

1 OF THE PREVIOUS ADMINISTRATION WHERE INTERPRETATIONS
2 WERE A LITTLE HARD TO COME BY, AND EVERYBODY WAS
3 VERY CONSERVATIVE. BUT FROM WHAT I CAN TELL IN THE
4 CONVERSATIONS I'VE HEARD, THEY'RE TALKING SOLELY
5 ABOUT PLURIPOTENT CELLS BECAUSE THEY'RE TALKING
6 SOLELY ABOUT HUMAN EMBRYONIC STEM CELLS AND NOTHING
7 BUT HUMAN EMBRYONIC STEM CELLS. AND A MULTIPOTENT
8 CELL IS NO LONGER A HUMAN EMBRYONIC STEM CELL.
9 OBVIOUSLY IT NEEDS TO BE CONFIRMED WITH THEM, BUT
10 THE POLITICS, I THINK, OF THE INTERPRETIVE CONFUSION
11 HAS CHANGED.

12 CHAIRMAN KLEIN: GEOFF, COULD YOU AND ALTA
13 BEFORE THE BOARD MEETING PLEASE CLARIFY ON THIS
14 POINT AND REPORT?

15 DR. LOMAX: I MAY DO A BIT OF RECRUITING
16 ON THAT FRONT, BUT WE'VE GOT GOOD BACKUP AROUND
17 HERE.

18 CHAIRMAN KLEIN: WE APPRECIATE THAT. ALL
19 RIGHT. SO ADDITIONAL POINTS FROM THE BOARD?
20 ADDITIONAL POINTS FROM THE PUBLIC?

21 MS. KING: WE HAVE TWO HERE AT THE CIRM IN
22 SAN FRANCISCO. WE'RE GOING TO START WITH JESSE
23 REYNOLDS.

24 MR. REYNOLDS: THANKS FOR THE OPPORTUNITY
25 TO SPEAK. I WANT TO JUMP BACK A MOMENT TO THE

BARRISTERS' REPORTING SERVICE

1 PARTHENOS QUESTION. I DIDN'T FEEL I HAD AN
2 OPPORTUNITY TO JUMP IN THEN. I COULD HAVE BEEN
3 MISTAKEN. I HAVE SORT OF FIRST A GENERAL COMMENT
4 AND OBSERVATION, AND SECOND A QUESTION ABOUT
5 CLARIFICATION.

6 AND MY GENERAL OBSERVATION IS THAT I'M
7 SOMEWHAT STRUCK BY THE INCLUSION OF THAT BULLET ITEM
8 IN THE LIST IN THAT IT'S THE ONE THAT I SUPPOSE
9 RAISES AN ISSUE THAT'S QUALITATIVELY DIFFERENT;
10 WHEREAS, THE OTHER BULLETS POINTS ARE ABOUT ISSUES
11 LIKE CLARIFICATION AND GRANDFATHERING AROUND ISSUES
12 OF CONSENT AND BANKING AND REGISTRIES.

13 PARTHENOS IS A SORT OF A QUALITATIVELY
14 DIFFERENT CATEGORY OF STEM CELL LINE. THAT'S MY
15 OBSERVATION.

16 AND MY QUESTION IS FOR CLARIFICATION, AND
17 THAT'S THAT THE LANGUAGE IN THE UNDERLINED SECTION
18 THERE AT THE END OF THAT BULLET POINT THERE AT THE
19 TOP OF PAGE 4 IS A LITTLE UNCLEAR. AND THE QUESTION
20 FROM MR. ALDRIDGE TRYING TO CLARIFY THAT, I THINK I
21 ENDED UP MORE CONFUSED. IS THIS A REQUEST FOR A --
22 ASKING FOR PARTHENOGENIC LINES UP A PARTICULAR DATE
23 TO BE ELIGIBLE FOR FUNDING, OR ALL PARTHENO LINES
24 EVEN PROSPECTIVELY ALSO TO BE ELIGIBLE FOR FUNDING?

25 CHAIRMAN KLEIN: ALL RIGHT. GEOFF, YOU

BARRISTERS' REPORTING SERVICE

1 WANT TO ADDRESS THAT, PLEASE?

2 DR. LOMAX: INCORPORATING THE PREVIOUS
3 QUESTION AND COMMENT WHICH WE RECEIVED, I UNDERSTOOD
4 THE ANSWER TO BE IT WOULD BE ALL LINES IN EXISTENCE
5 OR FUTURE LINES PROVIDED THEY WERE DERIVED
6 EFFECTIVELY WITH THE IRB APPROVAL WE'VE BEEN
7 DESCRIBING, BUT THE OVERSIGHT AND APPROVAL WHICH HAS
8 BEEN THE CONSISTENT THREAD THROUGHOUT THIS ENTIRE
9 CONVERSATION. SO IT WOULD BE CURRENT AND FUTURE --

10 CHAIRMAN KLEIN: OKAY.

11 DR. LOMAX: -- BASED ON THE LEAD FROM YOU
12 ALL IN TERMS OF THIS DISCUSSION.

13 CHAIRMAN KLEIN: ALL RIGHT. ANY OTHER
14 ADDITIONAL BOARD COMMENT ON THAT ANSWER? THANK YOU.
15 ANY ADDITIONAL POINTS FROM THE PUBLIC?

16 MS. KING: WE DO HAVE ONE MORE HERE. THIS
17 IS DON REED.

18 MR. REED: YES. TWO THINGS. FIRST OFF, I
19 FEEL A SENSE OF FRUSTRATION ABOUT SCNT. I DON'T
20 LIKE THE IDEA OF IT BEING SINGLED OUT AS IF IT IS
21 SOMEHOW A NEGATIVE THING. I WONDER IF IT WOULD BE
22 POSSIBLE FOR JUST A PHRASE, BECAUSE I CAN SEE
23 OPPOSITION IMMEDIATELY STATE BY STATE COMING OUT
24 WITH LAWS AGAINST IT, AND WHAT IF THERE'S SOMETHING
25 VALUABLE WE JUST HAVEN'T FOUND OUT? SO MY THOUGHT

BARRISTERS' REPORTING SERVICE

1 WOULD BE IF WE CAN POSSIBLY PUT SOMETHING IN THAT
2 THIS SHOULD NOT BE CONSTRUED AS A NEGATIVE ABOUT
3 SCNT, JUST THAT IT'S NOT FUNDABLE AT THE MOMENT.
4 I'M NOT SURE HOW TO SAY THAT.

5 SECONDLY, SOMETHING THAT HASN'T COME UP AT
6 ALL IS THE NEED FOR GENERAL STATEMENTS OF SUPPORT
7 FROM EVERYONE ABOUT JUST THE GENERAL IDEA OF FUNDING
8 EMBRYONIC STEM CELL RESEARCH. I SAY THAT AS SOMEONE
9 WHO HAS MY COMPUTER SET UP SO I GET A LOT OF E-MAILS
10 FROM OPPOSITION AROUND THE WORLD. AND IT'S
11 SYSTEMATIC. ANYBODY THAT DOUBTS THAT SHOULD JUST GO
12 TO THE U.S. CONFERENCE OF CATHOLIC BISHOPS WEBSITE,
13 WHICH IS CALLED STEM CELL ACTION PLAN. AND THERE
14 ARE MASSIVE ATTEMPTS TO DISCREDIT THE RESEARCH WHICH
15 IS GOING TO BE COMING OUT, WHICH IS COMING OUT NOW.
16 SO I THINK PEOPLE, IF THEY SUPPORT THE RESEARCH AT
17 ALL, THEY NEED TO FILL OUT THAT LITTLE COMMENT BOX
18 AND GET INVOLVED HERE.

19 I WONDER IF YOU GUYS MIGHT HAVE SOME
20 COMMENTS ON THAT.

21 CHAIRMAN KLEIN: LET'S DO THIS. WE ARE
22 APPROXIMATELY TEN MINUTES OVER, DON. APPRECIATE
23 YOUR COMMENTS AS ALWAYS. YOU MIGHT SUPPLY TO THE
24 STAFF THE MATERIALS FROM THE CATHOLIC BISHOPS
25 ORGANIZATION. IT'S OPPOSITIONAL MATERIAL, BUT IT

BARRISTERS' REPORTING SERVICE

1 SHOULD BE AVAILABLE TO THE BOARD SO THEY CAN SEE
2 WHAT THE OPPOSITIONAL POSITION IS. AND I THINK
3 BEING A PUBLIC SUBMISSION, HOPEFULLY A NUMBER OF THE
4 SCIENTIFIC ORGANIZATIONS IN THE STATE WILL RECOGNIZE
5 THAT IF THEIR VIEWS ARE GOING TO BE HEARD, THEY NEED
6 TO BE AS ORGANIZED AS THE OPPOSITION IS REFLECTED BY
7 MATERIALS THAT YOU ARE REFERRING TO THAT I'VE
8 PREVIOUSLY SEEN.

9 I'D LIKE TO KEEP THIS ON TIME. I THINK
10 WE'VE HAD A VERY INFORMATIONAL MEETING. THANK
11 GEOFF, ELONA, DON GIBBONS, MELISSA. MELISSA ALWAYS
12 PULLS THESE MEETINGS TOGETHER. AND ALL THE BOARD
13 MEMBERS AND THE PUBLIC FOR ATTENDING. AND WE WILL
14 CONTINUE TO PROVIDE MATERIALS AS THEY BECOME
15 AVAILABLE. SO THANK YOU VERY MUCH.

16 MS. KING: THANKS, EVERYBODY.

17 (THE MEETING WAS THEN CONCLUDED AT
18 06:41 P.M)

19
20
21
22
23
24
25

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 NIH GUIDELINES RESPONSE TASK FORCE TO THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING ON MAY 7, 2009, 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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