

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

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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

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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

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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

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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,

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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

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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,

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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 PROVISIO 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 COMMERCIALLY 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 COMMERCIALLY 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