

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

LOCATION: AS INDICATED ON THE AGENDA

DATE: OCTOBER 12, 2009
10 A.M.

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

BRS FILE NO.: 85795

BARRISTERS' REPORTING SERVICE

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ITEM	DESCRIPTION	PAGE NO.
CALL TO ORDER		3
ROLL CALL		4
CONSIDERATION OF REVISIONS FOR THE CIRM MES REGULATIONS		5

BARRISTERS' REPORTING SERVICE

1 MONDAY, OCTOBER 12, 2009

2 10:00 A.M.

3
4 CHAIRMAN LO: WHY DON'T WE GO AHEAD AND
5 START. WE HAVE A NUMBER OF PEOPLE FROM CIRM. WE
6 JUST FINISHED ANOTHER MEETING AND THEY'RE COMING IN,
7 INCLUDING BOB KLEIN. SO I'M GOING TO FIRST JUST
8 WELCOME EVERYBODY TO THIS SONG CALLED THE STANDARDS
9 WORKING GROUP OF CIRM. AND I WANT TO WISH EVERYONE
10 A HAPPY HOLIDAY, THE HOLIDAY FORMERLY KNOWN AS
11 COLUMBUS DAY, AND I GUESS IN SOME PARTS OF THE
12 COUNTRY IT'S STILL KNOWN AS COLUMBUS DAY. WHERE I
13 LIVE IN BERKELEY, IT'S INDIGENOUS PEOPLE'S DAY.
14 HAPPY HOLIDAY.

15 I DO ALSO WANT TO SAY CONGRATULATIONS TO
16 JANET ROWLEY, WHO HAS RECEIVED THE NATIONAL MERIT
17 MEDAL OF SCIENCE AND HER RECOGNITION OF REALLY A
18 LIFETIME OF WORK. JANET, WE'RE JUST VERY PROUD OF
19 YOU AS IS THE ENTIRE COUNTRY.

20 DR. ROWLEY: THANK YOU VERY MUCH. IT WAS
21 CERTAINLY A DELIGHT TO BE IN THE WHITE HOUSE, AND
22 I'M VERY HONORED AND SURPRISED BY IT ALL.

23 DR. LOMAX: COULD WE JUST DO A TECHNOLOGY
24 CHECK AT THIS POINT? THIS IS THE MEETING WE HAVE
25 BOTH THE MEMBERSHIP ON THE LINE AND WE HAVE A LINE

BARRISTERS' REPORTING SERVICE

1 OPEN FOR THE PUBLIC, AND WE HAVE BETH DOING
2 TRANSCRIPTION. SO IS EVERYONE ABLE TO HEAR THIS
3 MEETING?

4 DR. ROWLEY: AS LONG AS YOU DO THE
5 TALKING.

6 DR. LOMAX: NO PROBLEMS REPORTED, SO I'M
7 ASSUMING EVERYONE EITHER CAN'T HEAR US AT ALL OR IS
8 HEARING OKAY.

9 DR. CIBELLI: GEOFF, DO YOU WANT TO HAVE
10 THE ROLL CALL AND SEE WHO IS THERE?

11 DR. LOMAX: WE'RE GOING TO PROCEED WITH
12 THE ROLL CALL IN JUST A MOMENT. JUST WANTED TO
13 COVER THE PRELIMINARIES.

14 CHAIRMAN LO: GO AHEAD WITH ROLL CALL.

15 DR. LOMAX: TED PETERS.

16 DR. PETERS: HERE.

17 DR. LOMAX: JOSE CIBELLI.

18 DR. CIBELLI: HERE.

19 DR. LOMAX: DOROTHY ROBERTS.

20 DR. ROBERTS: HERE.

21 DR. LOMAX: JEFF SHEEHY.

22 MR. SHEEHY: HERE.

23 DR. LOMAX: BERNIE LO.

24 CHAIRMAN LO: HERE.

25 DR. LOMAX: JANET ROWLEY.

BARRISTERS' REPORTING SERVICE

1 DR. ROWLEY: HERE.

2 DR. LOMAX: ROBERT KLEIN.

3 MR. KLEIN: HERE.

4 DR. LOMAX: IS THERE ANYONE MISSING AT
5 THIS POINT THAT I'VE NOT CALLED WHO'S ON THE LINE?
6 OKAY.

7 SO AT THE MOMENT WE DO NOT HAVE A QUORUM,
8 BUT WE COULD DEVELOP A SENSE OF THE COMMITTEE.

9 CHAIRMAN LO: SO WHAT WE'RE GOING TO DO,
10 THEN, BECAUSE WE DON'T HAVE A QUORUM, IS DISCUSS THE
11 ISSUES AND TRY AND DEVELOP A SENSE OF THE COMMITTEE
12 THAT WE CAN TAKE BACK TO THE ICOC WHO, OF COURSE,
13 HAS THE AUTHORITY TO APPROVE GOING FORWARD THESE
14 REGULATIONS.

15 SO I'M GOING TO TURN IT OVER TO GEOFF, AND
16 I GUESS THERE'S A SLIDE SHOW THAT YOU HOPEFULLY HAVE
17 IN FRONT OF YOU, THOSE ON THE PHONE.

18 DR. LOMAX: THANK YOU, BERNIE. AGAIN, TO
19 PROVIDE A LITTLE BIT OF CONTEXT, THE AMENDMENTS
20 BEFORE YOU REALLY REFLECT, I HOPE APPROPRIATELY
21 REFLECT, THE SENSE OF THE COMMITTEE THAT WAS
22 DEVELOPED A COUPLE OF WEEKS AGO WHERE WE WERE ASKED
23 TO GO BACK AND DEVELOP REGULATORY LANGUAGE
24 CONSISTENT WITH THE POSITIONS DEVELOPED AT THE
25 MEETING IN SAN FRANCISCO. SO IDEALLY WHAT WE'RE

BARRISTERS' REPORTING SERVICE

1 DOING HERE IS REVIEWING THE LANGUAGE THAT'S
2 SUFFICIENT TO THEN GO TO THE ICOC.

3 AND I ALWAYS LIKE TO JUST REMIND PEOPLE OF
4 THE PROCESS. WHAT WE'RE TRYING TO DO HERE IS GET
5 LANGUAGE THAT THE ICOC CAN CONSIDER, AND HOPEFULLY
6 WITH ITS BLESSING WE WILL THEN MOVE FORWARD TO THE
7 PROCESS THROUGH THE OFFICE OF ADMINISTRATIVE LAW. I
8 MENTION THOSE TWO POINTS OF PROCESS BECAUSE IN EACH
9 OF THOSE POINTS IN THE PROCESS THERE ARE ADDITIONAL
10 OPPORTUNITIES FOR REVIEW AND PUBLIC COMMENT, AND, IN
11 ADDITION, THE OFFICE OF ADMINISTRATIVE LAW WILL BE
12 REVIEWING THIS LANGUAGE IN ACCORDANCE WITH ITS
13 MANDATES. SO IT'S GOING TO BE LOOKING AT IT AGAINST
14 A NUMBER OF CRITERIA IN TERMS OF APPROPRIATENESS AND
15 CONSISTENCY WITH WHAT'S EXPECTED UNDER CALIFORNIA
16 LAW.

17 SO WHAT WE'VE DONE IS WE'VE REALLY
18 ISOLATED SORT OF THREE CATEGORIES OF REVISIONS. AND
19 IF YOU GO TO THE SECOND SLIDE, I'LL FOCUS ON THE SET
20 OF REVISIONS THAT IMPACT THE ESCRO COMMITTEE REVIEW
21 AND NOTIFICATION REQUIREMENTS. AND WHAT I'VE DONE
22 IS PUT TOGETHER A SLIDE THAT HAS THAT KIND OF
23 TRAFFIC LIGHT PATTERN OF RED, YELLOW, AND GREEN.
24 AND WHAT'S ATTEMPTED TO DO THERE IS GIVE YOU A SENSE
25 OF THE SORT OF CATEGORIES THAT WE'VE -- WE'VE

BARRISTERS' REPORTING SERVICE

1 REVISED THE CATEGORIES IN A VERY, I THINK, A FAIRLY
2 MINOR WAY, BUT IT RESULTS IN A SORT OF CLEANER SET
3 OF CATEGORIES FOR SCRO REVIEW.

4 WHAT WE'VE DONE IS, FIRST OF ALL, IN
5 170(A), WE'VE MADE SOME SLIGHT CHANGES TO THE
6 LANGUAGE THERE PRIMARILY TO SAY ANY RESEARCH
7 INVOLVING THE PROCUREMENT, CREATION, OR USE OF HUMAN
8 GAMETES MAY NOT PROCEED WITHOUT THE FULL REVIEW OF A
9 SCRO COMMITTEE.

10 THIS TYPE OF RESEARCH HAS ALWAYS BEEN
11 SUBJECT TO FULL REVIEW AND APPROVAL. PART OF THE
12 DRIVING FORCE BEHIND THESE CHANGES WAS SORT OF
13 DISCUSSIONS ABOUT TO THE EXTENT YOU MIGHT BE USING
14 IPS RESEARCH TO POTENTIALLY GENERATE HUMAN GAMETES
15 OR HUMAN GAMETES AND -- WELL, PARTICULARLY IF YOU'RE
16 GENERATING HUMAN GAMETES FROM THOSE SOURCES. I
17 THINK THE PREVIOUS REGULATIONS CAPTURED THAT
18 CONTINGENCY; HOWEVER, THESE REVISIONS MAKE THAT
19 QUITE CLEAR, THAT ANY RESEARCH INVOLVING THE
20 DEVELOPMENT OF GAMETES IS SOMETHING THAT SHOULD HAVE
21 THE BENEFIT OF FULL COMMITTEE REVIEW.

22 WE'VE THEN MODIFIED SECTION B. IT'S
23 REALLY THE SAME CONSTRUCT: PROCUREMENT, CREATION,
24 OR USE OF HUMAN EMBRYOS. AND, AGAIN, THIS IS TAKING
25 INTO ACCOUNT THAT YOU CONCEIVABLY COULD CREATE

BARRISTERS' REPORTING SERVICE

1 EMBRYOS THROUGH SORT OF IVF -- I'M SORRY -- IPS-TYPE
2 PROCEDURES. AGAIN, JUST MAKING IT EXCEPTIONALLY
3 CLEAR THAT ANY WORK INVOLVING EITHER THE PROCUREMENT
4 OR USE OF EMBRYOS IS SUBJECT TO FULL REVIEW. AGAIN,
5 THE LEVEL OF REVIEW, THERE'S NO CHANGE THERE. IT'S
6 JUST MAKING CLEAR WHAT THAT CATEGORY CAPTURES.

7 CHAIRMAN LO: I THINK ONE OF THE THINGS
8 WE'RE TRYING TO DO IS MAKE SURE WE ARE NOT TIED TO
9 ANY SPECIFIC SCIENTIFIC TECHNOLOGY. THAT'S REALLY
10 SORT OF THE PURPOSE.

11 DR. LOMAX: THAT'S RIGHT. MAYBE PERHAPS
12 IT'S USEFUL TO TAKE ANY QUESTIONS THERE. AGAIN, I
13 PUT THOSE CATEGORIES AS SIMPLY CLARIFYING LANGUAGE
14 WITH NO CHANGE IN THE OVERALL REVIEW. I DON'T KNOW
15 IF THERE'S ANY QUESTIONS OR CONCERNS ABOUT ANY OF
16 THE ACCOMPANYING LANGUAGE.

17 DR. TROUNSON: UNDER A YOU CHANGED THE
18 CREATION OR USE OF HUMAN OOCYTES TO HUMAN GAMETES.
19 SO YOU'RE SAYING THE USE OF SPERM IN SOME PROCEDURE.
20 IT COULD BE AN IMMUNE PROCEDURE OR AN EXPERIMENT,
21 THAT YOU WOULD REQUIRE SCRO APPROVAL FOR THE USE
22 DONATED SPERM? THAT DOESN'T SEEM TO BE REALLY
23 NECESSARY. I'M NOT SURE WHY YOU CHANGED IT FROM
24 OOCYTES TO GAMETES UNLESS YOU WANTED TO INCLUDE
25 SPERM. I'M TRYING TO UNDERSTAND WHY SPERM HAS BEEN

BARRISTERS' REPORTING SERVICE

1 INCLUDED UNDER THAT.

2 DR. LOMAX: IT DOES GO BACK -- SO THE IDEA
3 WAS, YES, TO CAPTURE SPERM. AND, AGAIN, THE IDEA
4 PARTICULARLY THERE WAS THE NOTION THAT YOU MAY BE
5 ABLE TO, BASED ON THE RESEARCH, THAT PUBLICATION OF
6 PAPERS, THAT PEOPLE WERE USING IVF PROCEDURES TO, IN
7 FACT, GENERATE SPERM.

8 DR. TROUNSON: YOU ALSO SAY PROCUREMENT.

9 DR. LOMAX: THAT'S RIGHT.

10 DR. TROUNSON: SO IT'S NOT JUST THE
11 CREATION. SO IN ANY EXPERIMENT THAT REQUIRES YOU TO
12 MAKE USE OF SPERM OR SPERM PRODUCT, YOU HAVE TO GO
13 TO THE SCRO COMMITTEE. THAT'S UNUSUAL.

14 CHAIRMAN LO: I THINK WHAT ALAN IS DRIVING
15 AT, IF OUR CONCERN WAS TO MAKE THE CREATION OF SPERM
16 FALLS UNDER A, THEN MAYBE WE SHOULD NOT SAY -- YOU
17 MIGHT WANT TO THINK ABOUT SAYING PROCUREMENT,
18 CREATION, OR USE OF HUMAN OOCYTES OR THE CREATION OF
19 SPERM.

20 DR. TROUNSON: YOU COULD FORESEE A
21 TOLERANCE EXPERIMENT UTILIZING SPERM PRODUCT IN SOME
22 WAY THAT WOULDN'T REALLY REQUIRE YOU TO GO THROUGH A
23 SCRO PROCEDURE SO FAR AWAY FROM RETENTION.

24 MR. KLEIN: I THINK BERNIE'S WORDING
25 REALLY SOLVES THE PROBLEM.

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: ARE THERE ANY COMMENTS FROM
2 COMMITTEE MEMBERS ON THIS POINT?

3 DR. ROWLEY: FINE WITH ME.

4 CHAIRMAN LO: GOOD.

5 MR. KLEIN: COULD I ASK ANOTHER GENERAL
6 COMMENT. WHEN IT SAYS ANY SOURCE, DOES THIS FULLY
7 INTERFACE WITH THE INTERNATIONAL -- THE ALTERNATIVE
8 INTERNATIONAL STANDARD? SO, FOR EXAMPLE, IF IT
9 MEETS THE UNITED KINGDOM STANDARD, THAT IT'S AN
10 ACCEPTABLE SOURCE TO US? I'M JUST ASKING THE
11 QUESTION. I DON'T KNOW THE ANSWER.

12 DR. LOMAX: THIS PARTICULAR SECTION
13 DOESN'T AT ALL DEAL WITH THE ACCEPTABILITY OR LACK
14 THEREOF OF THE MATERIALS. IT SIMPLY ADDRESSES THE
15 LEVEL OF REVIEW REQUIRED BY A COMMITTEE.

16 MR. KLEIN: WE'RE NOT CHANGING ANY OF THE
17 STANDARDS THAT ARE CURRENTLY IN PLACE AS TO
18 INTERNATIONAL SOURCES AND MATERIALS?

19 DR. LOMAX: NO.

20 CHAIRMAN LO: AS LONG AS THEY WERE DEEMED
21 ACCEPTABLE FOR CIRM USE.

22 MR. KLEIN: THANK YOU.

23 DR. LOMAX: SO THE ONE SECTION -- THIS IS,
24 I THINK, PARTICULARLY FOR THE BENEFIT OF THE
25 MEMBERSHIP THAT WASN'T AT THE MEETING IN SAN

BARRISTERS' REPORTING SERVICE

1 FRANCISCO, THE ONE SECTION WHERE I WANT TO ALERT YOU
2 TO A SLIGHT CHANGE IN THE SCOPE, IF YOU WILL, OF
3 WHAT IS SUBJECT TO SCRO COMMITTEE NOTIFICATION IS IN
4 THAT YELLOW BOX. THE PREVIOUS LANGUAGE SAID THAT
5 ANY RESEARCH INTENDED TO DERIVE A COVERED STEM CELL
6 LINE WOULD BE SUBJECT TO SCRO NOTIFICATION.

7 WHAT WE'VE DONE THERE IS WE'VE CHANGED
8 THAT REQUIREMENT SLIGHTLY TO SAY THAT IF YOU'RE
9 DOING ANY IN VITRO RESEARCH WITH IDENTIFIABLE
10 SOMATIC CELLS TO DO IPS DERIVATION OR YOU'RE WORKING
11 WITH IDENTIFIABLE HUMAN EMBRYONIC STEM CELLS, THAT
12 THE SCRO COMMITTEE SHOULD BE NOTIFIED.

13 SO WHAT WE'VE DONE CONCEPTUALLY IS WE'VE
14 CHANGED THE STANDARD SLIGHTLY TO SAY ANYTIME YOU'RE
15 WORKING WITH IDENTIFIABLE MATERIALS OF A PLURIPOTENT
16 NATURE, THE OVERSIGHT COMMITTEE AT LEAST NEEDS TO BE
17 AWARE OF IT. AND THIS RECOMMENDATION IS REALLY
18 CONSISTENT WITH THE LATEST REVISIONS OF THE NATIONAL
19 ACADEMIES GUIDELINES WHERE THEY INDICATE THAT IT
20 IS -- THERE'S A ROLE FOR THE SCRO COMMITTEE TO SORT
21 OF THINK ABOUT CONSENT IN TERMS OF ANY IDENTIFIABLE
22 MATERIALS. SO WE'VE SORT OF DRAWN THE LINE AS
23 IDENTIFIABILITY AS THE LINE THAT THEN TRIGGERS THE
24 SCRO NOTIFICATION. AND, AGAIN, THIS IS THE NOTION
25 THAT THE OVERSIGHT COMMITTEE MAY HAVE SOME USEFUL

BARRISTERS' REPORTING SERVICE

1 THINKING TO SHARE WITH THE IRB WITH REGARD TO
2 CONSENT.

3 MR. KLEIN: YOU SAID -- THIS SAYS
4 NONIDENTIFIABLE.

5 DR. LOMAX: SORRY. WHICH ONE ARE YOU
6 REFERRING TO, BOB?

7 MR. KLEIN: UNDER D.

8 DR. LOMAX: WE'RE GETTING TO D. WE'RE ON
9 C AT THE MOMENT. IF YOU ARE FOLLOWING -- THE OTHER
10 RESOURCE THAT SORT OF TRACKS THIS IS TABLE 1 THAT
11 WAS BOTH SENT TO THE MEMBERSHIP AND POSTED ON THE
12 WEB SITE. WE'RE ON ITEM C AT THE MOMENT.

13 IF THERE'S NO QUESTIONS OR COMMENTS ON
14 THAT, I THEN WANT TO MOVE TO ITEM D, WHICH IS THE
15 NONIDENTIFIABLE MATERIAL. AGAIN, BY WAY OF CONTEXT,
16 THIS WAS A DISCUSSION THAT DATES BACK TO DECEMBER OF
17 LAST YEAR WHERE THE SENSE OF THE COMMITTEE AT THAT
18 TIME WAS THAT IN VITRO RESEARCH WITH DEIDENTIFIED
19 MATERIALS WITH A LEVEL OF RESEARCH WHERE WE WERE
20 COMFORTABLE THERE WAS NO EXCEPTIONAL SORT OF ETHICAL
21 CONSIDERATIONS HERE. WE PREVIOUSLY HAD A SCRO
22 NOTIFICATION REQUIREMENT.

23 WHAT WE'VE RUN INTO IS WE DO HAVE A NUMBER
24 OF GRANTEES WITH ONE OR TWO RELATIVELY MODEST
25 GRANTS. THEY'RE DOING BASICALLY IPS WORK WITH

BARRISTERS' REPORTING SERVICE

1 ANONYMOUS DEIDENTIFIED CELLS. AND IT'S OUR
2 ASSESSMENT THAT WE CAN, THROUGH A STATEMENT OF
3 COMPLIANCE MECHANISM, GET THEM TO STATE THAT THEIR
4 MATERIALS MEET OUR EXISTING STANDARDS UNDER -- WE
5 HAVE A SET OF STANDARDS WHICH ALLOWS PEOPLE TO USE
6 DEIDENTIFIED MATERIALS THAT MEET THE FEDERAL
7 REQUIREMENTS, THAT YOU SHOULDN'T HAVE TO GO OUT AND
8 SHOP FOR A SCRO COMMITTEE JUST TO DO VERY BASIC IN
9 VITRO RESEARCH WITH ANONYMOUS CELLS.

10 SO IT'S GIVING THE GRANTEES A SECOND
11 OPTION TO SAY THESE MATERIALS MEET THE FEDERAL
12 STANDARDS AS DEVELOPED BY THE OFFICE OF HUMAN
13 RESEARCH PROTECTION. WE'RE NOT PUTTING THESE CELLS
14 INTO ANIMALS, WE'RE NOT PUTTING THESE CELLS INTO
15 PEOPLE, WE'RE NOT CREATING GAMETES OR EMBRYOS.
16 WE'RE SIMPLY TRYING TO WORK WITH SOMATIC CELLS.

17 OR, FOR EXAMPLE, WE'RE WORKING WITH HUMAN
18 EMBRYONIC STEM CELL LINES THAT ARE ANONYMOUS AND
19 THEY'RE ON THE NIH LIST, AND THAT WE ALLOW THAT
20 RESEARCH TO MOVE FORWARD WITHOUT NECESSITATING THE
21 CREATION OF AN OVERSIGHT COMMITTEE.

22 CHAIRMAN LO: AGAIN, TO PUT THIS IN
23 CONTEXT, THE FEDERAL REGULATIONS SAY THIS IS NOT
24 HUMAN SUBJECTS RESEARCH, DOESN'T HAVE TO GO BEFORE
25 AN IRB. WE ORIGINALLY SAID THE ESCRO AT LEAST HAS

BARRISTERS' REPORTING SERVICE

1 TO BE NOTIFIED. BUT THEN, AS GEOFF SAID, THERE ARE
2 GRANTEES THAT DO NOT HAVE A SCRO SET UP AND ARE
3 HAVING TO SET UP A SCRO JUST TO SATISFY THIS
4 REQUIREMENT WHEN, IN FACT, WE THINK THAT THE ETHICAL
5 CONCERNS ARE SO MODEST, THAT WE REALLY DON'T WANT
6 THEM SPENDING THEIR TIME AND ENERGY ON SETTING UP A
7 SCRO AND JUST DOING THE WORK.

8 SO WE'RE PROPOSING THAT A RESPONSIBLE
9 INSTITUTIONAL OFFICIAL BE ABLE TO CERTIFY OR GIVE A
10 STATEMENT THAT THEY'RE COMPLYING WITH THE REGULATORY
11 REQUIREMENTS WE'VE SET UP, BUT THEN THEY DON'T HAVE
12 TO HAVE CIRM ACTUALLY BE NOTIFIED. SO WE HOPE TO
13 REDUCE REGULATORY BURDENS THAT DON'T REALLY ADD
14 SUBSTANTIALLY TO PROTECTION OF DONORS OR THE
15 SAFEGUARDING OF ETHICAL CONCERNS.

16 DR. TROUNSON: I JUST WONDERED IF THE
17 INSTITUTIONAL OFFICIAL WOULD INCLUDE THE CEO OF A
18 COMPANY UNDER THE DEFINITION?

19 DR. LOMAX: WHAT WE DID IS WE TOOK THE
20 INSTITUTIONAL OFFICIAL LANGUAGE. IT'S ALREADY
21 INCORPORATED INTO THE REGULATIONS IN SECTION 10040.
22 IT SAYS, "EACH INSTITUTION SHALL ENSURE THAT THE
23 CHANCELLOR, CHIEF EXECUTIVE OFFICER, OR PERSONS WITH
24 FUNDING AUTHORITY DESIGNATES AN INSTITUTIONAL
25 OFFICIAL RESPONSIBLE FOR OVERSIGHT." SO IT'S A

BARRISTERS' REPORTING SERVICE

1 DESIGNATED PERSON THAT HAS SORT OF FULL
2 RESPONSIBILITY OVER THE GRANT AND LEGAL
3 RESPONSIBILITY.

4 SO WE'RE DRAWING OFF A REQUIREMENT THAT'S
5 IN A SEPARATE SET OF THE REGULATIONS; HENCE, WHY WE
6 CHOSE THAT TERMINOLOGY.

7 SO THAT CONCLUDES SORT OF THE SUMMARY OF
8 THE PROPOSED MODIFICATIONS ON THE OVERSIGHT SECTION
9 10070. I DON'T KNOW IF THERE'S ADDITIONAL QUESTIONS
10 THERE OR COMMENTS.

11 CHAIRMAN LO: ANYBODY ON THE PHONE HAVE A
12 QUESTION? IF NOT, GEOFF, YOU WANT TO GO TO THE NEXT
13 SECTION, WHICH IS 10080. SO WE HAVE ACCEPTABLY
14 DERIVED RESEARCH MATERIALS.

15 DR. LOMAX: DO YOU WANT TO PROVIDE ANY
16 BACKGROUND HERE, BERNIE?

17 CHAIRMAN LO: WHY DON'T YOU GO AHEAD.

18 DR. LOMAX: SO WHAT THE LANGUAGE IS -- THE
19 MODIFICATION IS INTENDED TO DO IN THIS SECTION, AND
20 THE KEY SECTION IS SECTION 10080(A)(2)(B), CAPITAL
21 B. AND WHAT WE'RE ATTEMPTING TO CAPTURE HERE IS THE
22 UNMODIFIED VERSION OF THESE REGULATIONS WOULD
23 PROHIBIT A GRANTEE FROM USING, I WANT TO EMPHASIZE
24 PARTICULARLY BOTH THE USE, USING A DERIVED CELL LINE
25 OR USING AN EMBRYO TO DERIVE A CELL LINE IF THAT

BARRISTERS' REPORTING SERVICE

1 EMBRYO CONTAINS PAID GAMETES. THE TYPICAL EXAMPLE,
2 THAT EMBRYO WAS CREATED AS A RESULT OF A PAID OOCYTE
3 DONOR. BUT THE PARTICULAR CIRCUMSTANCE WE'VE
4 FOCUSED ON IS THE CASE WHERE THE OOCYTE DONOR WAS
5 PAID IN AN IVF OR A REPRODUCTIVE CONTEXT. THE
6 EMBRYO HAS BEEN CREATED. IT IS AN EMBRYO THAT WAS
7 CREATED WITH THE INTENT TO BE USED IN A REPRODUCTIVE
8 CONTEXT, BUT AT SOME FUTURE POINT IN TIME, THE
9 COUPLE OR THE INDIVIDUAL WHO HAS DISPOSITIONAL
10 AUTHORITY OVER THAT EMBRYO NO LONGER NEEDS IT FOR
11 REPRODUCTION AND THEY'RE NOW MAKING A DECISION ABOUT
12 DISCARDING THE EMBRYO AND WHETHER THAT EMBRYO WOULD
13 BE ALLOWED IN FOR -- TWO POINTS. IF THAT WAS THE
14 CHAIN OF CIRCUMSTANCES AND SOMEBODY OUTSIDE OF CIRM
15 FUNDING DERIVED A HUMAN EMBRYONIC STEM CELL LINE,
16 WHETHER THOSE STEM CELL LINES WOULD BE ABLE TO BE
17 USED BY CIRM RESEARCHERS AS A RESULT OF THE FACT
18 THAT THERE WAS A PAID GAMETE INITIALLY THAT WENT
19 INTO IT. THE CURRENT REGULATIONS SAY NO BECAUSE THE
20 PREVIOUS LANGUAGE SAID DONORS OF HUMAN GAMETES DID
21 NOT RECEIVE VALUABLE CONSIDERATION, PERIOD.

22 WE'RE PROPOSING AMENDING THAT, SAYING FOR
23 EMBRYOS ORIGINALLY CREATED USING IN VITRO
24 FERTILIZATION FOR REPRODUCTIVE PURPOSES AND ARE NO
25 LONGER NEEDED FOR THIS PURPOSE, VALUABLE

BARRISTERS' REPORTING SERVICE

1 CONSIDERATION DOES NOT INCLUDE PAYMENTS TO THE
2 ORIGINAL GAMETE DONORS IN EXCESS OF PERMISSIBLE
3 EXPENSES.

4 I WILL COMMENT THAT A NUMBER OF PEOPLE
5 SORT OF WERE SORT OF SCRATCHING THEIR HEADS ABOUT
6 SORT OF THE GRAMMATICAL CONSTRUCTION OF THAT
7 SENTENCE, FEELING IT'S A BIT ODDLY WORDED. JUST TO
8 PROVIDE SOME CONTEXT, WE DECIDED TO EXTRACT THAT
9 LANGUAGE DIRECTLY FROM THE NIH GUIDELINES BECAUSE WE
10 FELT THAT THEY ALSO USE THAT LANGUAGE TO LIMIT THE
11 SCOPE OF EMBRYOS FOR RESEARCH TO EMBRYOS CREATED FOR
12 IVF. SO WHILE PERHAPS THE LANGUAGE ISN'T THE MOST
13 ELOQUENT, WE FELT IT HAS A PRECEDENT IN EXISTING
14 FEDERAL REGULATIONS. SO WE'RE SORT OF BALANCING
15 SORT OF OUR BEST TAKE ON WORDS ON PAPER AGAINST
16 ESTABLISHED FEDERAL PRECEDENT NOW AND FELT THAT, AS
17 A STARTING POINT, WE'D START WITH THE FEDERAL
18 LANGUAGE.

19 IS THERE ANY --

20 CHAIRMAN LO: QUESTIONS? COMMENTS?

21 DR. LOMAX: HOW DO YOU WANT TO HANDLE
22 PUBLIC COMMENT? DO YOU WANT TO TAKE IT AT THE END?

23 CHAIRMAN LO: WHY DON'T WE HAVE COMMENTS
24 FROM THE COMMITTEE FIRST, AND THEN WE'LL HAVE PUBLIC
25 COMMENTS. I KNOW THERE WERE PUBLIC CONCERNS RAISED.

BARRISTERS' REPORTING SERVICE

1 I WANT TO MAKE SURE --

2 DR. PETERS: IT'S APPROPRIATE, GIVEN OUR
3 COMMITMENT FOR SOME TIME NOW, TO FOLLOW NAS
4 GUIDELINES.

5 DR. LOMAX: THERE'S A REQUEST FROM THE
6 PUBLIC JUST TO -- THAT WAS TED PETERS JUST
7 SPEAKING -- TO MAKE SURE YOU IDENTIFY YOURSELF.
8 THAT HELPS THE TRANSCRIPTION AS WELL.

9 CHAIRMAN LO: ANY OTHER COMMENTS?
10 DOROTHY?

11 DR. ROBERTS: THIS IS DOROTHY ROBERTS. AT
12 THE MEETING IN SEPTEMBER WHEN THIS ISSUE WAS RAISED,
13 I RAISED THE CONFLICT OF INTEREST CONCERN BECAUSE
14 FOR ME TO APPROVE OF THIS REVISION, I WOULD WANT TO
15 SEE SOME BETTER ASSURANCE THAT THERE'S NO CONFLICT
16 OF INTEREST BETWEEN THE PHYSICIAN WHO WAS INVOLVED
17 IN ACQUIRING THE OOCYTES AND THE RESEARCHER WHO USES
18 THE EMBRYOS IN THE END. SO THE PHYSICIAN -- AND I
19 SHOULD ADD ACQUIRING THE OOCYTES WITH PAYMENT TO THE
20 PROVIDER AND THEN ENSURING NO CONFLICT OF INTEREST
21 BETWEEN THAT PHYSICIAN AND THE RESEARCHER WHO USES
22 THE EMBRYOS CREATED WITH THE OOCYTES.

23 SO AT THE MEETING BERNIE NOTED THAT THERE
24 WERE THREE POSSIBILITIES, THAT WE WOULD NOT CHANGE
25 THIS PROVISION AT ALL; SECOND, WE WOULD CHANGE IT AS

BARRISTERS' REPORTING SERVICE

1 IS PROPOSED NOW TO ALLOW FOR THE USE OF EMBRYOS
2 ORIGINALLY CREATED USING IN VITRO FERTILIZATION EVEN
3 THOUGH THE PROVIDER, THE GAMETE PROVIDER, WAS PAID;
4 AND THEN, THIRD, WAS TO CONDITION THIS REVISION ON
5 SOME STRENGTHENING OF THE CONFLICT OF INTEREST
6 PROVISIONS.

7 AND THE MOTION WAS MADE FOR THE SECOND
8 OPTION, AND WE NEVER -- I ABSTAINED BECAUSE I
9 THOUGHT WE SHOULD DISCUSS THE CONFLICT OF INTEREST
10 SOME MORE, BUT WE NEVER GOT TO IT. AND MAYBE THAT'S
11 PARTLY MY FAULT FOR NOT RAISING IT AGAIN. I THOUGHT
12 PERHAPS IT WOULD COME UP IN THE INFORMED CONSENT
13 DISCUSSION. BUT THAT DISCUSSION WENT PRETTY
14 QUICKLY, AND WE UNANIMOUSLY -- I GUESS IT WASN'T A
15 VOTE, BUT WE ALL AGREED THAT WE SHOULD MAINTAIN THE
16 INFORMED CONSENT PROVISION WITHOUT MODIFICATION.
17 AND WE NEVER GOT BACK TO THE CONFLICT OF INTEREST
18 ISSUE.

19 SO I CONTINUE TO BE CONCERNED ABOUT THAT.
20 I'VE LOOKED AT THE PROVISIONS AND I DON'T -- I JUST
21 DON'T SEE ANYWHERE ELSE IN THE REGULATIONS THAT
22 WOULD PROVIDE A WAY OF SEPARATING THE PHYSICIAN FROM
23 THE RESEARCHER. AND I'M CONCERNED THAT THERE IS THE
24 POSSIBILITY FOR A REAL CONFLICT OF INTEREST OR, IF
25 NOT THAT, THE APPEARANCE OF A CONFLICT OF INTEREST

BARRISTERS' REPORTING SERVICE

1 WHERE IT LOOKS AS IF THIS COULD BE A WAY AROUND THE
2 PAYMENT PROHIBITION.

3 SO I JUST WANT TO STATE THAT CONCERN AND
4 HAVE SOME FURTHER DISCUSSION ABOUT IT. FOR THOSE
5 WHO AREN'T CONCERNED ABOUT IT, I REALLY WOULD VALUE
6 SOMEONE POINTING TO ME IN THE REGULATIONS WHERE
7 THERE IS SUFFICIENT PROVISION TO AVOID A CONFLICT OF
8 INTEREST BETWEEN THE PHYSICIAN AND THE RESEARCHER.

9 MR. KLEIN: AS A POINT OF INFORMATION,
10 IT'S MY UNDERSTANDING, AND I MISSED THE PRIOR
11 MEETING, SO MY UNDERSTANDING MAY NOT BE COMPLETE,
12 THAT THIS FOLLOWS THE NATIONAL ACADEMY OF SCIENCE
13 AND NIH GUIDELINES. AND IT'S ALSO MY UNDERSTANDING
14 THAT THESE TYPES OF CONFLICTS ISSUES ARE BUILT INTO
15 A LOT OF REVIEW CRITERIA THAT GO INTO THIS PROCESS.

16 MS. DARNOVSKY: EXCUSE ME. I WONDER IF
17 THE PERSON SPEAKING COULD SPEAK UP A LITTLE BIT.
18 IT'S VERY DIFFICULT TO HEAR.

19 MR. KLEIN: SURE. THIS IS BOB KLEIN. AND
20 THE KEY HERE IS, IN TERMS OF OUR MISSION, IF WE'RE
21 GOING TO BE ABLE TO CONDUCT CRITICAL RESEARCH TO OUR
22 MISSION, IT IS IMPORTANT THAT WE GET CONSISTENCY
23 WITH THE NATIONAL ACADEMY OF SCIENCE AND THE NIH
24 WHEREVER WE REASONABLY CAN ACHIEVE THAT.

25 THERE'S AN ISSUE ABOUT WHETHER WE HAVE

BARRISTERS' REPORTING SERVICE

1 GOTTEN TO THE PERFECT POINT. ALL OF THESE DECISIONS
2 ARE BALANCING POINTS. AND IT WAS MY UNDERSTANDING
3 THAT REALLY THERE'S A LOT OF OTHER SCREENS IN THESE
4 PROCESSES THAT DEAL WITH ELIMINATING
5 UNREASONABLENESS, ELIMINATING CONFLICT. AND I WOULD
6 HOPE WE STAY AS CLOSE TO THE NATIONAL ACADEMY OF
7 SCIENCE AND THE NIH STANDARDS AS POSSIBLE SO WE CAN
8 CARRY OUT OUR PRIMARY MISSION HERE BECAUSE I THINK
9 THEY HAVE REASONABLY CONSIDERED THIS TYPE OF
10 QUESTION WHEN THEY GOT TO THEIR POLICY.

11 DR. ROBERTS: BUT THERE'S A DISTINCTION, A
12 SERIOUS DISTINCTION, WHICH IS THAT IN CALIFORNIA
13 PAYMENTS ARE PROHIBITED. SO WE ARE ALREADY TRYING
14 TO ACHIEVE A BALANCE BETWEEN THE INTEREST IN
15 FURTHERING THE RESEARCH AND THAT PROHIBITION BY
16 HAVING THIS PROPOSED REVISION WHICH WILL PERMIT THE
17 USE OF EMBRYOS THAT WERE CREATED WITH PAID OOCYTES.

18 SO THE PROVISION WE'RE CONSIDERING IS, AS
19 YOU KNOW YOU'RE SUGGESTING, A WAY OF TRYING TO HAVE
20 SOME BALANCE; BUT IN DOING THAT, I THINK WE STILL
21 HAVE TO BE CONCERNED ABOUT THE ORIGINAL PROHIBITION
22 AGAINST PAYMENT AND WHY THAT PROHIBITION EXISTS. I
23 THINK PART OF THAT HAS TO DO WITH CONFLICTS OF
24 INTEREST. SO I THINK BECAUSE OF THE PROHIBITION, WE
25 MIGHT BE MORE, I THINK WE SHOULD BE, MORE VIGILANT

BARRISTERS' REPORTING SERVICE

1 ABOUT IT THAN NIH WAS BECAUSE NIH IS NOT -- THEIR
2 POLICY ISN'T CONCERNED ABOUT PAYMENTS FOR OOCYTES.

3 DR. LOMAX: JUST ONE POINT OF CONTEXT. SO
4 WE DID, COMING OUT OF THE MEETING, DID TAKE OPTION
5 3. WE GAVE SOME THOUGHT TO IT. THE PRECEDENT WE'VE
6 HAD HISTORICALLY IN THE REGULATIONS IS IN THE AREA
7 OF WHEN CIRM IS FUNDING THE DERIVATION PROCESS,
8 WE'VE BEEN ABLE TO ADD ADDITIONAL LANGUAGE ON
9 CONFLICT OF INTEREST. WE SORT OF TALKED THIS
10 THROUGH. THE CHALLENGE WE KEPT RUNNING INTO IS
11 GETTING TO A POINT WHERE TO SORT OF EMULATE THAT
12 MODEL BEYOND THE RESEARCH WE FUND, WE WERE GETTING
13 INTO A REACH-THROUGH SCENARIO THAT WE FELT CREATED
14 PROBLEMS FOR US IN TERMS OF OUR AUTHORITY AND BASIC
15 PROBLEMS ABOUT WE SHOULDN'T BE REACHING THROUGH INTO
16 AN AREA THAT'S OUTSIDE OUR RESEARCH.

17 THAT DOESN'T SOLVE THE DILEMMA, BUT I JUST
18 WANTED TO SHARE THE SORT OF DUE DILIGENCE THAT WE
19 DID POST MEETING TO TRY TO CONSIDER HOW TO ADDRESS
20 THIS PROBLEM. AND THAT WAS THE SORT OF ROADBLOCK WE
21 RAN INTO FROM A KIND OF LEGAL REGULATORY SIDE OF
22 THINGS.

23 DR. ROBERTS: WHEN YOU SAY REACH-THROUGH,
24 YOU MEAN REACHING THROUGH TO THE PHYSICIAN WHO IS
25 ACQUIRING THE OOCYTES. IS THAT THE REACH-THROUGH

BARRISTERS' REPORTING SERVICE

1 YOU MEAN?

2 DR. LOMAX: THAT WE WOULD -- IT WOULD
3 BE -- THE PROVISIONS THAT EXIST ALREADY IN THE
4 REGULATIONS TALK ABOUT IN THE COURSE OF CIRM-FUNDED
5 RESEARCH, THE ATTENDING PHYSICIAN MAY NOT BE THE
6 INDIVIDUAL PERFORMING RESEARCH, THAT THERE'S
7 LANGUAGE LIKE THAT WHEN WE'RE ACTUALLY FUNDING THE
8 RETRIEVAL. AND THE POINT I WAS MAKING WAS LANGUAGE
9 LIKE THAT WOULD -- WE'D THEN SOMEHOW BE -- WE
10 CAN'T -- WE'RE NOT IN A POSITION TO IMPOSE THOSE
11 TYPES OF CONDITIONS ON IVF PRACTICE.

12 DR. ROBERTS: THAT'S WHAT I THOUGHT YOU
13 MEANT. I JUST WANTED TO CLARIFY THAT'S WHAT YOU
14 MEANT BY REACH-THROUGH.

15 DR. LOMAX: I DID WANT TO KIND OF
16 EMPHASIZE THE FOLLOW-UP OR AT LEAST WHERE OUR
17 THINKING GOT TO ON NO. 3 SUBSEQUENT TO THE LAST
18 MEETING.

19 DR. KIESSLING: HI. THIS IS ANN
20 KIESSLING. SORRY I'M LATE.

21 CHAIRMAN LO: WELCOME, ANN. SO I HAVE
22 JEFF SHEEHY AND THEN ELONA BAUM HERE IN THE ROOM.
23 ANYONE ON THE PHONE WANT TO SORT OF GET IN LINE FROM
24 THE COMMITTEE TO SPEAK TO THIS ISSUE?

25 MR. SHEEHY: FIRST, I JUST WANT TO GET,

BARRISTERS' REPORTING SERVICE

1 LIKE AT THE LAST MEETING, SEPARATE OUT THE NIH
2 ISSUE, THE PRIOR PROVISION 10080. ANYTHING THAT'S
3 ACCEPTABLY DERIVED BY THE NIH IS APPROVED FOR
4 FUNDING BY US. SO WE DON'T HAVE TO CONFORM TO NIH
5 STANDARDS. OUR CHARGE IS REALLY TO THINK ABOUT WHAT
6 WE WANT FOR OUR OWN STANDARDS INDEPENDENT OF THAT.

7 SO WHAT THE NIH DOES REALLY SHOULD NOT OR
8 DOESN'T DO, SHOULDN'T REALLY BE A MAJOR
9 CONSIDERATION BECAUSE ALL NIH LINES ARE
10 AUTOMATICALLY APPROVED FOR USE WITH OUR FUNDING
11 ANYWAY.

12 BUT I WANTED TO GET TO DOROTHY'S POINT.
13 AND FOR ME, AND I GUESS FOR ME THIS IS REALLY
14 RESOLVED WITH THE INFORMED CONSENT ISSUE. THAT'S
15 WHERE I FELT LIKE THE SAFEGUARD WAS. I DO KIND OF
16 TAKE GEOFF'S POINT ABOUT REACH-THROUGH. AND IT'S
17 HARD FOR ME TO IMAGINE THE SCENARIOS THAT WE'RE
18 TALKING ABOUT. I TRY TO ALWAYS THINK ABOUT
19 WORST-CASE SCENARIOS. YOU'RE TALKING ABOUT THE USE
20 OF A PAID OOCYTE DONOR TO PRODUCE EMBRYOS FOR
21 REPRODUCTIVE PURPOSES. THAT SEEMS TO BE A
22 COMPLETELY SEPARATE DECISION, THAT REALLY I HAVEN'T
23 SEEN ANY COMPELLING EVIDENCE THAT PEOPLE WOULD
24 SOMEHOW INDUCE MORE OOCYTE PRODUCTION IN THAT DONOR
25 IN ORDER TO PRODUCE MORE EMBRYOS AND HOPE THAT MORE

BARRISTERS' REPORTING SERVICE

1 EMBRYOS WOULD THEN PRODUCE FOR RESEARCH. IT'S HARD
2 FOR ME TO SEE EITHER THE APPEARANCE OF THE PEOPLE
3 RESPONSIBLE FOR THOSE EMBRYOS WANTING TO CREATE
4 NEEDLESSLY EXTRA EMBRYOS.

5 I THINK THERE'S ALREADY A BIAS. AND
6 THERE'S ACTUALLY AN EXCELLENT SERIES OF ARTICLES
7 BEING RUN IN THE *NEW YORK TIMES* ON SOME OF THE
8 PROBLEMS AROUND IVF. AND ULTIMATELY I THINK THE
9 BIGGEST, THE STRONGEST PRESSURE, FRANKLY, FOR
10 GETTING EXTRA OOCYTES OR PRODUCING EXTRA EMBRYOS IS
11 THE FACT THAT NOBODY PAYS FOR THIS. AND THIS IS ALL
12 COMING OUT OF PEOPLE'S SECOND MORTGAGES OR OTHER
13 KIND OF DURESS. I DON'T REALLY THINK -- AND, AGAIN,
14 HAVING KNOWN PEOPLE WHO HAVE GONE THROUGH IVF, I
15 DON'T THINK PEOPLE ARE THINKING ABOUT THE
16 DISPOSITION OF THE EMBRYOS, GETTING MORE EMBRYOS SO
17 THEY CAN GIVE THEM TO RESEARCH. I THINK REALLY IT'S
18 SUCH A DIFFICULT TIME FOR PARENTS AT THAT POINT THAT
19 THEY'RE REALLY FOCUSED ON REPRODUCTIVE SUCCESS. AND
20 AT END OF THE DAY, ONCE THAT'S BEEN ACCOMPLISHED, IF
21 THERE ARE EXCESS EMBRYOS, THEN THERE'S KIND OF THIS
22 OTHER CONSIDERATION THAT COMES IN.

23 AND I'M NOT CERTAIN THAT THERE IS A REAL
24 STRONG PROBABILITY OF SOME KIND OF CONFLICT OF
25 INTEREST TAKING PLACE IN THAT SCENARIO. I DO THINK

BARRISTERS' REPORTING SERVICE

1 THAT THOSE PARENTS, THEIR SINGLE-MINDED GOAL IS TO
2 REALLY HAVE A HEALTHY CHILD AND TO HAVE A SUCCESSFUL
3 PREGNANCY.

4 SO I DON'T THINK -- THE ONE THING I WAS
5 REALLY CONCERNED ABOUT IS THAT WE DIDN'T SOMEHOW
6 THROW OUT INFORMED CONSENT FROM THE ORIGINAL GAMETE
7 DONORS WHICH I THINK IS STILL A STRONG CONSIDERATION
8 FOR US.

9 I'M HAVING TROUBLE REALLY SEEING THE
10 CONFLICT OF INTEREST. I DON'T SEE RESEARCHERS GOING
11 INTO IVF CLINICS TRYING TO GET EMBRYOS FOR PEOPLE
12 WHO ARE TRYING TO CONCEIVE. I MEAN I DON'T THINK
13 ANY ETHICAL IVF CLINIC WOULD ALLOW THAT. I THINK IT
14 JUST SOUNDS INCREDIBLY MESSY AND REALLY A BIT
15 BURDENSOME ON THESE FAMILIES. I DON'T THINK WE'RE
16 HEADED THAT WAY. MAYBE I'M WRONG.

17 MS. BAUM: I JUST WANTED TO POINT OUT
18 SOMETHING THAT'S VERY OBVIOUS, THE FACT THAT
19 SUBSECTION C TALKS ABOUT THE FACT THAT IT WILL BE
20 OVERSEEN BY AN IRB. SO THAT ADDS SORT OF ANOTHER
21 LAYER OF PROTECTION AGAINST THESE CONFLICTS OF
22 INTEREST.

23 CHAIRMAN LO: PRESUMABLY THE IRB IS
24 CHARGED WITH LOOKING AT POTENTIAL CONFLICTS OF
25 INTEREST, GIVING MORE ATTENTION TO THAT IN THE LAST

BARRISTERS' REPORTING SERVICE

1 NUMBER OF YEARS. ALAN, DID YOU WANT --

2 DR. TROUNSON: NO. I THINK THE POINTS ARE
3 RELEVANT. HAVING BEEN IN IVF FOR A LONG TIME, SO
4 LONG, 30 OR 40 YEARS, AND I'D AGREE WITH JEFF. IT'S
5 NOT AN ISSUE FOR THE PATIENT. IT COMES LONG AFTER
6 ALL OF THAT WHEN PEOPLE HAVE SATISFIED THEIR
7 REPRODUCTIVE NEEDS ONE WAY OR ANOTHER. I ACTUALLY
8 DON'T REALLY SEE THAT THERE'S A MAJOR CONFLICT OF
9 INTEREST THERE.

10 CHAIRMAN LO: ANY OTHER COMMITTEE MEMBERS
11 WANT TO TALK TO THE TOPIC?

12 MS. DARNOVSKY: EXCUSE ME. THIS IS MARCY
13 DARNOVSKY. IT'S VERY DIFFICULT TO HEAR SOME OF THE
14 COMMENTS. IF PEOPLE COULD SPEAK RIGHT INTO THE
15 MICROPHONE, I THINK IT WOULD HELP A LOT.

16 CHAIRMAN LO: THANKS. WE'LL TRY AND
17 REMIND EVERYONE. ANYONE ELSE ON THE PHONE FROM THE
18 COMMITTEE? IF NOT, ARE THERE COMMENTS FROM THE
19 PUBLIC WHO WOULD LIKE TO TALK TO THIS ISSUE? FROM
20 THE PUBLIC, ANYONE WANT TO TALK TO THIS ISSUE?

21 MS. SMITH-CROWLEY: THIS IS SHANNON
22 SMITH-CROWLEY, REPRESENTING THE AMERICAN SOCIETY FOR
23 REPRODUCTIVE MEDICINE. AND I JUST WANTED TO
24 REITERATE WHAT WAS BEING SAID ABOUT THAT THESE ARE
25 EMBRYOS THAT ARE CREATED FOR FERTILITY, AND THAT IF

BARRISTERS' REPORTING SERVICE

1 AN OOCYTE DONOR IS USED, IT'S THE COUPLE THAT IS
2 PAYING FOR THIS. AND THE WHOLE FOCUS IS FERTILITY.
3 BUT THAT WHEN IT COMES TO -- ONE OF THE HARDEST
4 THINGS ABOUT IVF IS THE WHOLE ISSUE OF WHAT DO YOU
5 DO WITH THE SURPLUS EMBRYOS. AND ACTUALLY VERY FEW
6 OF THE COUPLES FEEL COMFORTABLE WITH DONATING THE
7 SURPLUS EMBRYOS TO ANOTHER COUPLE AND HAVE THEIR OWN
8 GENETIC CHILD OUT THERE. AND A SIGNIFICANT NUMBER
9 OF THEM REALLY JUST FEEL LIKE IT WOULD BE -- THEY
10 WENT THROUGH ALL OF THIS EFFORT TO CREATE THESE
11 EMBRYOS, AND THEY WOULD LIKE TO NOT HAVE THEM JUST
12 BE DISPOSED OF AS MEDICAL WASTE.

13 SO I THINK IN TERMS OF THE CONFLICTS OF
14 INTEREST, YOU'VE GOT COMPLETELY DIFFERENT ISSUES
15 THAT THE PARTIES HAVE. AND IT'S THE COUPLE PAYING
16 THE DONOR, NOT ANY RESEARCHER.

17 CHAIRMAN LO: OTHER COMMENTS FROM THE
18 PUBLIC?

19 MR. REED: THIS IS DON REED. I'VE FOR A
20 LONG TIME BEEN CONCERNED THAT WE CANNOT PAY THE
21 DONORS, AND I REALIZE THAT'S IN LAW. WE HAVE TO
22 ACCEPT THAT. BUT WE ARE ALREADY OPERATING, BECAUSE
23 OF THAT, WITH ONE HAND TIED BEHIND OUR BACK. I'D
24 JUST BE EXTREMELY CAUTIOUS OF ANY FURTHER
25 RESTRICTIONS OR BARRIERS TO MAKE IT POSSIBLE FOR

BARRISTERS' REPORTING SERVICE

1 COUPLES TO DONATE. SO THAT WOULD BE MY THOUGHT.

2 CHAIRMAN LO: OTHER PUBLIC COMMENTS?

3 DR. PECKMAN: THIS IS STEVE PECKMAN FROM
4 UCLA. I'D LIKE TO VOICE MY SUPPORT OF THE PERSON
5 FROM THE SOCIETY OF REPRODUCTIVE CLINICIANS. ALSO,
6 I'D LIKE TO REMIND THE STANDARDS WORKING GROUP THAT
7 THERE ARE CURRENTLY RULES IN PLACE IN YOUR
8 REGULATIONS REGARDING CONFLICTS OF INTEREST AND
9 PAYMENT OF OOCYTE DONORS UNDER 100095(D) AND (E).
10 AND THAT FOR THOSE PEOPLE WHO ARE TRYING TO GET
11 OOCYTES DIRECTLY FOR RESEARCH, THOSE CONFLICTS OF
12 INTEREST THAT MS. ROBERTS WAS DISCUSSING ARE
13 ADDRESSED IN THE REGULATIONS.

14 NOW, WHAT WE'RE CLEARLY TALKING ABOUT HERE
15 IS AFTER-THE-FACT STORED EMBRYOS WHICH THE DONORS
16 WERE ALREADY PAID FOR CLINICAL PURPOSES. AND THESE
17 ARE TWO VERY DIFFERENT THINGS. THANK YOU.

18 MS. FOGEL: I WANT TO RAISE JUST A COUPLE
19 OF ISSUES. FIRST OF ALL, I JUST WANT TO TELL YOU
20 OUR POSITION ON THIS IS THAT SINCE 88 PERCENT OF
21 EMBRYOS THAT ARE CREATED DON'T USE PAID GAMETES, AND
22 WE'D LIKE TO RECOMMEND MORE OF AN OPT-IN RATHER THAN
23 AN OPT-OUT SCENARIO. IN OTHER WORDS, I UNDERSTAND
24 THE ISSUES ABOUT HARMONIZATION OR WHEN IT'S
25 IMPOSSIBLE TO ASCERTAIN WHETHER OR NOT THE EGG

BARRISTERS' REPORTING SERVICE

1 PROVIDER WAS PAID WHEN YOU'RE DEALING WITH A LINE
2 THAT'S ALREADY BEEN ESTABLISHED.

3 IT SEEMS TO ME, NO. 1, GIVEN THE FACT THAT
4 IN THE UNITED STATES 34 PERCENT OF FERTILITY
5 TREATMENTS ARE DONE IN CALIFORNIA, AND MOST OF OUR
6 MAJOR UNIVERSITIES HAVE FERTILITY CLINICS, AND THERE
7 IS -- THERE COULD BE A WAY OF REALLY NARROWING THIS
8 EXCEPTION BECAUSE IT SHOULD BE AN EXCEPTION, NOT THE
9 RULE. THAT'S OUR FIRST POINT.

10 AND I THINK, AS CAME UP AT THE LAST
11 MEETING, THE PERCEPTION THAT EMBRYOS CREATED WITH
12 YOUNGER EGGS ARE BETTER, THERE ISN'T ANY DATA ON
13 THAT, AS WAS REPORTED IN THE LAST MEETING. SO WE
14 DON'T EVEN KNOW IF THIS IS A REASON TO OPEN THIS UP
15 TO PAYMENT.

16 THE SECOND ISSUE IS IF WE ARE GOING TO
17 OPEN IT UP TO PAYMENT, THEN THERE OUGHT TO BE SOME
18 VERY NARROW AND CLEAR CONFLICT OF INTEREST RULES.
19 THE RULES THAT DR. PECKMAN JUST REFERRED TO ONLY
20 PERTAIN TO OOCYTES. THEY DON'T PERTAIN TO EMBRYOS.
21 SO YOU DON'T HAVE ANY CONFLICT OF INTEREST RULES
22 HERE. IT SEEMS TO ME THAT WHAT WE WANT TO DO IS WE
23 WANT TO RECOGNIZE THAT THE TRENDS IN INFERTILITY
24 TREATMENT ARE TO CREATE FEWER EMBRYOS, GIVE WOMEN
25 LESSER DOSES OF DRUGS, ALL OF THAT. CERTAINLY IN

BARRISTERS' REPORTING SERVICE

1 THE UK, THE STANDARD IN PARIS IS MOVING TOWARDS
2 IMPLANTING ONE EMBRYO AT A TIME. IN THE UNITED
3 STATES THE TREND IS MOVING TO, I THINK, NO MORE THAN
4 TWO GENERALLY.

5 SO ALL OF THIS CREATES INCENTIVES FOR
6 FEWER EMBRYOS TO BE CREATED. AND WHAT WE DON'T WANT
7 TO DO IS CREATE A DISINCENTIVE TO FOLLOWING THOSE
8 RULES THAT ARE ALL ABOUT THE PATIENT'S HEALTH. IT'S
9 ABOUT THE WOMAN WHO'S PROVIDING THE EGGS HEALTH, AND
10 IT'S ABOUT THE CHILDREN WHO ARE BORN, AS THESE
11 ARTICLES IN THE *NEW YORK TIMES* ARE SHOWING, THAT WE
12 WANT TO HAVE MORE HEALTHY BIRTHS. WE'RE ALL ON THE
13 SAME PAGE WITH THAT.

14 SO WE THINK THAT THERE OUGHT TO BE, NO. 1,
15 SOME KIND OF CONTROL IN TERMS OF TIME. IF WE'RE
16 TALKING ABOUT EMBRYOS THAT ARE NO LONGER NEEDED FOR
17 REPRODUCTIVE PURPOSES, THEN I REALIZE YOU ALL THINK
18 THAT THE AUGUST DATE WAS ARBITRARY, BUT WHY DON'T WE
19 SAY THAT THE EMBRYOS HAVE TO HAVE BEEN CREATED MORE
20 THAN X YEARS AGO OR X TIME AGO SO THAT WE'RE REALLY
21 MAKING SURE THAT THERE WASN'T AN INCENTIVE TO CREATE
22 MORE EMBRYOS THAN WERE NEEDED?

23 SECOND OF ALL, THERE REALLY NEEDS TO BE A
24 FIREWALL BETWEEN THE FERTILITY CLINIC AND THE
25 RESEARCHER. THERE ARE JUST TOO MANY OPPORTUNITIES

BARRISTERS' REPORTING SERVICE

1 BECAUSE OF EVEN SHARED SPACE THAT FOR SOME -- MOST
2 FERTILITY DOCTORS ARE OF THE HIGHEST STANDARDS, I'M
3 SURE. BUT THERE DEFINITELY ARE OPPORTUNITIES FOR
4 CREATING A CONFLICT OF INTEREST IF THERE ISN'T A
5 FIREWALL BETWEEN THEM.

6 SO WE THINK THAT THESE REGULATIONS AS
7 PROPOSED ARE JUST INADEQUATE AND NEED TO BE REVISED
8 TO REALLY MAKE SURE THAT WE'RE CREATING SAFE
9 CONDITIONS FOR THE WOMEN AND THE PATIENTS AND THE
10 CHILDREN IN TERMS OF WHAT'S GOING ON IN THE IVF AND
11 THE RELATIONSHIP TO RESEARCH.

12 MR. SHEEHY: COULD I ASK A QUICK QUESTION
13 OF SUSAN? GENERALLY, SUSAN, I'VE TAKEN YOUR
14 CONCERNS VERY SERIOUSLY. I HAVE TROUBLE. WHAT IS
15 GOING TO BE THE INDUCEMENT TO THE PARENTS TO DO
16 SOMETHING?

17 MS. FOGEL: IT'S NOT THE PARENT. YOU'RE
18 RIGHT. THERE'S NO INDUCEMENT TO THE PARENT, BUT
19 WE'RE NOT TALKING ABOUT A CONFLICT OF INTEREST OF
20 THE POTENTIAL PARENT. WE'RE TALKING ABOUT THE
21 CONFLICT OF INTEREST BETWEEN THE FERTILITY DOC AND
22 THE RESEARCH. SO THE FERTILITY DOC KNOWS THAT X
23 RESEARCH IS GOING ON AND MAYBE DOESN'T BREAK THE
24 STANDARD, VIOLATE THE STANDARD OF CARE, BUT ERRS IN
25 ONE DIRECTION OR ANOTHER KNOWING THAT THERE WILL

BARRISTERS' REPORTING SERVICE

1 THEN BE EMBRYOS LEFT OVER, SO TO SPEAK, FOR
2 RESEARCH.

3 WE KNOW THAT THERE ARE MANY PEOPLE, I
4 THINK THERE'S A NEW STUDY THAT SHOWS THAT 60 PERCENT
5 OF FERTILITY PATIENTS WOULD LIKE TO PROVIDE EMBRYOS
6 FOR RESEARCH. SO WE KNOW THAT FOLKS WANT TO DO
7 THAT, BUT WE WANT TO MAKE SURE THAT IT'S DONE IN A
8 WAY THAT WE DON'T HAVE A DOC CREATING EMBRYOS FOR
9 RESEARCH AND WHEN DOES THE PATIENT KNOW? THE
10 PATIENT DOESN'T KNOW HOW MANY EMBRYOS SHOULD BE
11 CREATED. ESPECIALLY WE KNOW THAT PATIENTS THAT COME
12 INTO IVF CLINICS FOR THE MOST PART DESPERATELY WANT
13 A BIOLOGICAL CHILD, AND THE DOCTOR SAYS WE'RE GOING
14 TO USE THIS DOSE OF HORMONE, THE DOCTOR SAYS WE'RE
15 GOING TO CREATE THIS MANY EMBRYOS. THE PATIENT IS
16 NOT IN ANY POSITION TO JUDGE WHETHER THAT'S
17 APPROPRIATE OR NOT. AND SO WE HAVE TO MAKE SURE
18 THERE ARE GOOD STANDARDS IN PLACE THAT PREVENT THAT
19 FROM HAPPENING.

20 CHAIRMAN LO: IF I MAY SAY SOMETHING. I
21 THINK YOU'RE CITING A STUDY BY ANNIE DRABKIN MYERLY
22 (PHONETIC), A COLLEAGUE AT DUKE. SHE PUBLISHED TWO
23 STUDIES, ONE IN *SCIENCE* AND ONE IN *JAMA*. IT'S
24 IMPORTANT TO REALIZE THAT THOSE STUDIES WERE DONE
25 WITH WOMEN WHO HAD FROZEN EMBRYOS. THEY WERE DONE

BARRISTERS' REPORTING SERVICE

1 WITH WOMEN WHO HAD COMPLETED THEIR INFERTILITY
2 TREATMENT. AND ONE STRIKING FINDING WAS THESE WOMEN
3 FOUND THE DECISION OF DISPOSITION TO BE INCREDIBLY
4 DIFFICULT. THEY WERE AMBIVALENT. THEY FELT TORN
5 BETWEEN FEELING THIS WAS SOMETHING TERRIBLY
6 IMPORTANT, BUT ALSO NOT WANTING TO EITHER DISCARD
7 THEM OR TO GIVE THEM TO ANOTHER WOMAN OR COUPLE FOR
8 THEIR REPRODUCTIVE PURPOSES.

9 SO THESE ARE NOT WOMEN STARTING THE IVF
10 PROCESS. THESE ARE WOMEN AT THE END OF THE PROCESS.
11 I THINK IT'S IMPORTANT THAT WE SAY THAT THE DATA ON
12 THE WOMEN WHO HAVE COMPLETED IVF MAY OR MAY NOT
13 APPLY TO WOMEN WHO ARE JUST STARTING THE IVF
14 PROCESS. I THINK IT'S REALLY AN OPEN QUESTION AS TO
15 WHETHER THEY'RE REALLY THINKING OF HELPING STEM CELL
16 RESEARCHERS AS OPPOSED TO HELPING TO CREATE THE
17 FAMILY THEY SO DESPERATELY WANT. I WANTED TO MAKE
18 SURE WE HAD THAT CORRECT.

19 MR. SHEEHY: I GUESS I'M JUST TRYING TO --
20 I MEAN YOU'RE TALKING ABOUT A PHYSICIAN. THE PEOPLE
21 WHO HAVE THE POWER IN THAT SITUATION ARE THE PARENTS
22 WHO ARE TRYING TO CREATE THE EMBRYO. AND I GUESS
23 YOU ARE ASKING US TO REGULATE THE FERTILITY DOCTOR
24 WHOSE SOLE PURPOSE AT THIS POINT IS TO ASSIST THEM
25 IN HAVING A CHILD. AND FOR US TO REACH THROUGH

BARRISTERS' REPORTING SERVICE

1 IS -- I GUESS I JUST DON'T SEE ANY PLAUSIBLE WAY. I
2 THINK THERE ARE IRB'S THAT EXIST FOR THAT, YOU KNOW.
3 AND MAYBE TALK TO MS. CROWLEY ABOUT OTHER
4 LEGISLATION THAT MAY BE NEEDED TO REGULATE IVF
5 CLINICS.

6 OUR PURPOSE IS IT'S REALLY HARD FOR ME TO
7 SEE, UNLESS THERE'S SOME MONEY CHANGING HANDS, WHICH
8 IS CLEARLY ILLEGAL, RIGHT, UNDER ALMOST ANYBODY'S
9 REGULATORY ENVIRONMENT, UNLESS THERE'S MONEY GOING
10 FROM THE RESEARCHER TO THE IVF DOCTOR TO GET EXTRA
11 EMBRYOS, UNLESS SOMEBODY IS GIVING EXTRA MONEY TO
12 THE PARENTS OR DISCOUNTING THEIR IVF, WHICH ALL
13 THESE THINGS ARE NOT PERMISSIBLE, UNLESS SOMETHING
14 IMPERMISSIBLE IS HAPPENING, THEN IT'S HARD FOR ME TO
15 REALLY SEE WHAT THE INDUCEMENT IS -- HOW -- FIRST OF
16 ALL, I THINK THE PARENTS ARE GOING TO COME IN AND
17 THEY'RE GOING TO CREATE AN EMBRYO. IT'S EXPENSIVE.
18 WHETHER THEY'RE HAVING TO PAY THE SURROGATE OR, YOU
19 KNOW, WHETHER THEY'RE PRODUCING EGGS THEMSELVES,
20 THESE ARE EXPENSIVE PROCEDURES. YOU'RE NOT GOING TO
21 COME IN AND SAY I'M ONLY GOING TO FERTILIZE TWO EGGS
22 FROM THIS SURROGATE AFTER I'VE JUST PAID, WHAT,
23 \$8,000 AND I'VE PAID ALL THIS MONEY OUT OF MY OWN
24 POCKET TO OBTAIN THESE OOCYTES FOR THIS PURPOSE.
25 YOU'RE PROBABLY GOING TO CREATE SOME EXCESS EMBRYOS

BARRISTERS' REPORTING SERVICE

1 IN CASE YOUR PROCEDURE DOESN'T WORK.

2 SO I THINK THERE'S ALREADY BUILT IN A
3 CERTAIN BIAS TOWARDS EXCESS EMBRYO CREATION. AND
4 IT'S HARD FOR ME TO SEE THIS OTHER RESEARCH
5 CONSIDERATION SUDDENLY EMERGING AT THAT POINT
6 OUTSIDE OF SOME ALREADY ILLEGAL, IMPERMISSIBLE
7 INDUCEMENT THAT WOULDN'T BE ALLOWED UNDER ANY SCHEME
8 WHETHER IT'S THE FEDERAL SCHEME OR OUR SCHEME.
9 THAT'S WHERE I HAD SOME UNDERSTANDING WHY WE NEED TO
10 PUT IN ANOTHER --

11 MS. FOGEL: CAN I JUST ADD ONE MORE THING
12 AND THEN I KNOW OTHER PEOPLE HAVE THINGS. AT THE
13 VERY, VERY LEAST, IT SEEMS TO ME THAT THE PROVISION
14 IN 10095 THAT INVOLVES OOCYTES SHOULD BE APPLIED TO
15 EMBRYOS. SO IT SAYS THAT THE CLINIC HAS TO BE A
16 MEMBER OF THE SOCIETY FOR ASSISTED REPRODUCTIVE
17 TECHNOLOGY. THESE ARE EXISTING REGULATIONS. THAT
18 THE PROCUREMENT SHALL NOT KNOWINGLY COMPROMISE
19 OPTIMAL REPRODUCTIVE SUCCESS OF THE WOMAN IN A
20 FERTILITY TREATMENT. THAT THE PHYSICIAN ATTENDING
21 AND THE PRINCIPAL INVESTIGATOR SHOULD NOT BE THE
22 SAME PERSON. YOU'VE ALREADY GOT SOME CONFLICT OF
23 INTEREST PROTECTIONS IN PLACE AROUND OOCYTES. WHY
24 WOULD YOU NOT AT THE VERY LEAST EXTEND THOSE TO
25 EMBRYOS?

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: BECAUSE THESE EMBRYOS ARE NOT
2 BEING CREATED FOR RESEARCH. AND THESE REGULATIONS
3 APPLY TO OOCYTES WHO ARE BEING OBTAINED FOR
4 RESEARCH. THOSE EMBRYOS THAT ARE BEING PRODUCED
5 HAVE NO RELATIONSHIP TO RESEARCH WHEN THEY'RE BEING
6 PRODUCED. THAT'S THE PROBLEM. THAT'S THE PROBLEM I
7 HAVE UNDERSTANDING IS HOW WE CAN GO THROUGH AND SAY
8 YOU'RE CREATING EMBRYOS THAT HAVE NOTHING TO DO WITH
9 RESEARCH, NOTHING TO DO WITH CIRM BUSINESS. YOU'RE
10 CREATING EMBRYOS BECAUSE YOU WANT -- YOU'RE UNABLE
11 TO -- BECAUSE YOU HAVE TO GO THROUGH IVF. I CAN'T
12 FIND THE RIGHT LANGUAGE. BECAUSE YOU'RE GOING
13 THROUGH IVF, SOMEHOW YOU HAVE TO CONFORM TO OUR
14 RESEARCH REGULATIONS WHEN I THINK IN A LOT OF
15 PEOPLE'S MIND RESEARCH IS NOT REALLY WHAT'S GOING ON
16 IN THEIR HEAD. THEY'RE THINKING WE WANT TO HAVE A
17 KID. IT'S EXPENSIVE. WE'RE GOING THROUGH A LOT OF
18 TROUBLE. I THINK PEOPLE ARE VERY EMOTIONAL. A LOT
19 OF EMOTIONAL THINGS ARE GOING ON WITH FOLKS AT THAT
20 TIME, AND I DON'T THINK THAT THEY'RE REALLY THINKING
21 ABOUT RESEARCH.

22 SO I GUESS -- I UNDERSTAND THAT IT MIGHT
23 BE HELPFUL TO HAVE US REGULATE THE IVF CLINIC, BUT I
24 DON'T KNOW IF THAT'S REALLY SOMETHING THAT'S
25 FEASIBLE FOR US TO DO OR EVEN NECESSARILY

BARRISTERS' REPORTING SERVICE

1 APPROPRIATE.

2 MS. DARNOVSKY: THIS IS MARCY DARNOVSKY
3 FROM THE CENTER FOR GENETICS AND SOCIETY. I THINK
4 THERE MIGHT BE SOME -- I GUESS WE'RE SEEING IT
5 DIFFERENTLY. WE'VE ALWAYS SUPPORTED THE USE OF
6 EXCESS IVF EMBRYOS FOR STEM CELL RESEARCH, AND WE
7 WANT TO MAKE SURE THAT THOSE ARE AVAILABLE.
8 INITIALLY WE WERE CONFUSED ABOUT WHY THIS FOCUS ON
9 THE PAID GAMETE EMBRYOS SINCE THEY WERE SUCH A SMALL
10 PERCENTAGE, 10 TO 12 PERCENT, OF THE EXCESS EMBRYOS
11 THAT WOULD BE AVAILABLE FOR STEM CELL RESEARCH.
12 THEN WE STARTED TO THINK, WELL, THERE IS THIS FOCUS
13 ON THAT SMALL SUBSET OF EMBRYOS AND REALIZED THAT
14 THOSE ARE THEN, ALTHOUGH, AS SUSAN POINTS OUT, WE
15 HAVE NOT SEEN ANY EVIDENCE THAT THOSE EMBRYOS
16 CREATED WITH PAID GAMETES ARE BETTER FOR RESEARCH.
17 THAT DOES SEEM TO HAVE THE SENTIMENT OF A LOT OF
18 RESEARCHERS.

19 SO THAT RESEARCHERS ARE GOING TO BE
20 FOCUSED ON THAT 10 PERCENT. THEY'RE GOING TO WANT
21 ESPECIALLY THE IVF EMBRYOS THAT WERE CREATED WITH
22 PAID GAMETE DONORS. AND THOSE ARE THE WOMEN THAT
23 WE'VE BEEN FEELING THAT THEIR INTERESTS HAVE NOT
24 BEEN CENTRAL ENOUGH IN THE CONCERNS OF PEOPLE WHO
25 ARE THINKING THIS THROUGH.

BARRISTERS' REPORTING SERVICE

1 SO IN THE SCENARIO THAT YOU'RE DESCRIBING,
2 JEFF, IT'S NOT THE PARENTS AT ALL. IT'S REALLY THE
3 DOCTORS; AND IT'S DOCTORS WHO BECAUSE OF, AS SUSAN
4 POINTS OUT, OF THEIR PROXIMITY OFTEN IN THEIR
5 OFFICES AND IN THEIR INSTITUTIONS TO STEM CELL
6 RESEARCHERS, THOSE ARE THE PEOPLE WHO WE'RE
7 CONCERNED ABOUT CONFLICT OF INTEREST. AND IT
8 DOESN'T HAVE TO BE SOMEONE WHO'S DOING SOMETHING
9 ILLEGAL, AND IT DOESN'T HAVE TO BE SOMEONE WHO'S
10 DOING SOMETHING WITH THE INTENTION OF -- WITH THE
11 CONSCIOUS INTENTION EVEN OF PROVIDING -- GETTING
12 EXTRA EGGS OUT OF THIS EGG DONOR SO THAT WE CAN HAVE
13 MORE EMBRYOS. WE KNOW FROM STUDIES OF INCIDENCES ON
14 DOCTORS THAT YOU CAN GET LUNCH BROUGHT IN FOR YOUR
15 ADMINISTRATIVE STAFF, AND THAT THAT INFLUENCES
16 DOCTOR'S PRESCRIPTION WRITING BEHAVIORS.

17 SO DON'T YOU THINK THAT WHERE WE HAVE IVF
18 DOCTORS WHO ARE COLLEAGUES OF STEM CELL RESEARCHERS,
19 THAT EVEN UNCONSCIOUSLY THAT MIGHT INFLUENCE THEIR
20 BEHAVIORS? AND THE BEHAVIOR THAT WE'RE TALKING
21 ABOUT HERE IS JUST A LITTLE BIT EXTRA OF THE
22 STIMULATING HORMONE OR A LITTLE BIT MORE RELUCTANCE
23 TO BACK OFF OF A CYCLE WHEN MAYBE IT'S A CALL.
24 WE'RE NOT ASKING FOR A REACH-THROUGH TO REGULATE
25 FERTILITY. THAT'S A SEPARATE QUESTION AND A

BARRISTERS' REPORTING SERVICE

1 SEPARATE DEBATE.

2 WHAT WE'RE SAYING IS THAT THESE ARE THE
3 CIRCUMSTANCES UNDER WHICH WE'RE TALKING ABOUT MAKING
4 IVF EMBRYOS AVAILABLE FOR STEM CELL RESEARCH. AND
5 WE HAVE TO BE -- IT SEEMS TO ME WE SHOULD BE
6 COGNIZANT OF THE CONDITIONS THAT PERTAIN TO THE
7 CREATION OF THAT PARTICULAR SUBSET OF EMBRYOS. AND
8 IF THERE IS A POTENTIAL THERE FOR CONFLICT OF
9 INTEREST, PUT SOME RULES IN PLACE, PUT SOME
10 PROTECTIONS IN PLACE SO THAT WE AVOID IT.

11 MR. SHEEHY: AGAIN, IT COMES TO A
12 PRACTICALITY THING. I DON'T SEE ANY WAY FEASIBLE
13 FOR US TO PUT IN PLACE RULES THAT APPLY TO A
14 SITUATION WHICH IS ONLY REPRODUCTIVE IN CONTEXT AND
15 HAS NO RESEARCH COMPONENT. AND I THINK -- I KNOW
16 WHAT YOU'RE INTERESTED IN. IT SEEMS TO ME THAT
17 YOU'RE REALLY WORRIED ABOUT PEOPLE PROVIDING MORE
18 HORMONE TO WOMEN WHO ARE DONATING OOCYTES. AND I
19 STILL BELIEVE THAT THE GREATEST BIAS FOR PROVIDING
20 MORE HORMONES IS GOING TO COME FROM THE PARENTS
21 BECAUSE THESE ARE THE PROCEDURES. THE SINGLE BEST
22 THING THAT CAN BE DONE TO ENSURE THAT PEOPLE
23 DON'T -- THERE'S NOT ALL THIS PRESSURE ON EVERYBODY
24 INVOLVED IN THIS FOR REPRODUCTIVE SUCCESS. AND IT
25 MIGHT BE IN THE HEALTHCARE REFORM ACT PAYMENT FOR

BARRISTERS' REPORTING SERVICE

1 REPRODUCTIVE IVF PROCEDURES. I DON'T SEE -- I JUST
2 DON'T -- IT'S HARD FOR ME TO VISUALIZE HOW THIS
3 RESEARCH CONSIDERATION IS GOING TO GO ALL THE WAY
4 DOWN TO THE FERTILITY DOC WITH THE OOCYTE DONOR.

5 HE'S GOING TO SAY I'M GOING TO GIVE HER
6 MORE -- I'M GOING TO GET HER TO PRODUCE MORE EGGS SO
7 I CAN CREATE MORE EMBRYOS SO I CAN HAVE MORE LEFT
8 OVER FOR RESEARCH. I'M HAVING A LOT OF TROUBLE, A,
9 REALLY VISUALIZING THAT HAPPENING ANY MORE THAN
10 ANYBODY ELSE MIGHT BE A BAD ACTOR AND THINGS THAT WE
11 CAN'T CONTROL; AND, B, UNDERSTANDING HOW WE CAN
12 REGULATE THAT WHEN WE CAN REALLY ONLY TALK ABOUT
13 WHAT WE FUND. AND THE RESEARCH DONATION QUESTION IS
14 NOT THE ISSUE THAT'S GOING ON. THIS IS NOT A
15 RESEARCH QUESTION.

16 AND I JUST I THINK YOU CAN -- IT DOESN'T
17 TAKE LONG TO FIND THINGS THAT ARE NOT NECESSARILY
18 ALWAYS RIGHT IN REPRODUCTIVE IVF SETTINGS. THIS IS
19 NOT TO SAY THAT MOST PEOPLE ARE NOT GOOD ACTORS
20 DOING THEIR BEST, BUT YOU CAN ALWAYS FIND THESE
21 THINGS. ULTIMATELY IT'S NOT UP TO US TO REGULATE
22 THAT FIELD. THAT'S NOT OUR WRIT. I JUST DON'T SEE
23 THE RESEARCH CONSIDERATION BECOMING PARAMOUNT IN THE
24 CREATION OF THESE EMBRYOS.

25 DR. ROBERTS: LET ME SEE IF I CAN JUST ADD

BARRISTERS' REPORTING SERVICE

1 ONE MORE THOUGHT TO THIS, JEFF, BECAUSE I THINK
2 YOU'RE STILL MISSING WHAT THE PURPOSE OF
3 STRENGTHENING THE CONFLICT OF INTEREST REQUIREMENTS
4 OR HAVING THEM APPLY THEM TO EMBRYOS WOULD MEAN.
5 IT'S NOT REGULATING THE IVF PHYSICIAN. IT'S MAKING
6 SURE THAT THE REVISION WE ARE PUTTING INTO PLACE
7 DOESN'T HAVE AN IMPACT ON WHAT THE IVF DOCTORS WHO
8 MAY BE IN CLOSE RELATION IN SOME RESEARCH
9 INSTITUTIONS TO THE RESEARCHERS ARE DOING.

10 AND SO IT'S -- BY HAVING A PROVISION LIKE
11 THE ONES THAT WE ALREADY HAVE THAT APPLY TO OOCYTES,
12 IT WOULD BE A DETERRENT AGAINST SOME INFLUENCE ON
13 THE IVF DOCTORS TO CREATE MORE EMBRYOS. IT'S NOT AS
14 IF WE'RE REGULATING THEM, BUT HAVING PROVISIONS THAT
15 WOULD LIMIT WHICH EMBRYOS WOULD BE ACCEPTABLE SO
16 THAT THERE ARE ONLY EMBRYOS THAT WERE CREATED WHERE
17 THERE WAS NO CONFLICT OF INTEREST WOULD HAVE A
18 DETERRENT EFFECT ON THE IVF DOCTORS ENGAGING OR
19 BEING INFLUENCED BY A CONFLICT OF INTEREST. IT'S
20 NOT A DIRECT REGULATION OF THEM. IT'S A REGULATION
21 OF WHICH ARE ACCEPTABLE EMBRYOS FOR USE IN STEM CELL
22 RESEARCH.

23 DR. KIESSLING: THIS IS ANN KIESSLING.
24 WHAT YOU'RE TALKING ABOUT, THOUGH, IS NOT GOING TO
25 BE LIMITED TO EGG DONORS, AND I THINK THAT'S WHAT

BARRISTERS' REPORTING SERVICE

1 WE'RE TALKING ABOUT NOW. WHAT YOU'RE TALKING ABOUT
2 WOULD BE LIMITED TO THE GENERAL PRACTICE OF IVF.

3 DR. TROUNSON: BERNIE, I FIND THIS A BIT
4 DISTRESSING BECAUSE YOU'RE NOT REALLY INVOLVING THE
5 IVF DOCS IN THIS DISCUSSION. I ACTUALLY DON'T THINK
6 I KNOW OF A DOCTOR THAT WOULD EXCESSIVELY GIVE
7 HORMONE TO PATIENTS, PARTICULARLY YOUNG PATIENTS WHO
8 ARE GOING TO BE DONORS, BECAUSE IT'S A REAL RISK TO
9 THOSE PATIENTS. YOU DON'T PUT YOUR PATIENT AT RISK
10 BY GIVING THEM EXCESS HORMONE. BASICALLY YOU TREAT
11 THOSE DONORS, YOU KNOW, AS CAREFULLY AS POSSIBLE TO
12 OBTAIN A COHORT OF EMBRYOS THAT COULD HELP THE
13 INFERTILE PATIENT. YOU DO IT WITH A GREAT DEAL OF
14 CARE.

15 THERE IS NO CONSIDERATION, I THINK, EVER
16 FOR GIVING ANY ADDITIONAL GONADOTROPHIN TO THESE
17 TYPES OF PATIENTS. IT WOULD RISK THEIR LIVES. I
18 DON'T THINK UNDER ANY CIRCUMSTANCE I CAN IMAGINE
19 ANYONE DOING IT. YOU'RE NOT GIVING MONEY FOR IT.
20 THE WHOLE THING IS BASED ON -- I DON'T KNOW WHAT
21 IT'S BASED ON. YOU'RE NOT GOING TO BE REWARDED FOR
22 DOING IT. YOU'RE NOT GOING TO BE PART OF ANY PAPERS
23 THAT COME OUT OF IT BECAUSE YOU'RE SO DISTANT.
24 YOU'VE NEVER BEEN INCLUDED ON A PUBLICATION, NOT
25 RECEIVED MONEY. IT JUST SEEMS VERY STRANGE THAT

BARRISTERS' REPORTING SERVICE

1 THIS IS HIGHLIGHTED HERE FOR A GROUP OF PEOPLE WHO
2 REALLY ARE WORKING ON BEHALF OF THEIR PATIENTS
3 RATHER THAN WORKING ON BEHALF OF RESEARCH. IT'S
4 JUST NOT A REALISTIC -- IT'S NOT A REAL PARTICULAR
5 DRIVER. I DON'T THINK IT IS. AND I DON'T THINK YOU
6 COULD EVER FIND A CLINICIAN WHO WOULD OPERATE IN
7 THAT WAY. IT'S JUST NOT FEASIBLE.

8 CHAIRMAN LO: ANY OTHER COMMENTS FROM
9 OTHER MEMBERS OF THE WORKING GROUP ON THE CALL?

10 DR. CIBELLI: I HAVE MORE QUESTION FOR
11 GEOFF. DO WE HAVE -- YOU DO HAVE -- I GUESS I WANT
12 TO ASK YOU TO REITERATE THINGS THAT YOU SAID IN THE
13 MEETING. YOU DO HAVE WAYS OF ENFORCING CIRM
14 POLICIES AS SOON AS WE FIND OUT THAT SOMETHING IS
15 GRAY AND SOME PEOPLE ARE NOT TAKING CARE OF THE
16 REGULATIONS THAT THEY SHOULD BE, RIGHT?

17 DR. LOMAX: WE HAVE ACTIVELY GONE OUT AND
18 IN A SENSE, I USE THE WORD "AUDIT," BUT I DON'T KNOW
19 IF IT WOULD QUALIFY AS A BONA FIDE AUDIT. WE'VE
20 GONE OUT AND REVIEWED PROCEDURES AND POLICIES OF OUR
21 GRANTEE INSTITUTIONS WITH REGARD TO OVERSIGHT AND
22 REVIEW OF FUNDED RESEARCH. AND A DRIVING CRITERION
23 FOR SORT OF WHAT WOULD TRIGGER A REVIEW AND
24 EVALUATION WOULD BE SOMETHING THAT, IF YOU GO BACK
25 TO THAT SLIDE WHERE WE HAD THE RED, YELLOW, GREEN

BARRISTERS' REPORTING SERVICE

1 TRAFFIC LIGHT ANALOGY, WE HONE IN ON ACTIVITIES THAT
2 WOULD FALL INTO THAT RED ZONE ACTIVITIES WHERE WE'D
3 WANT TO GIVE THE HIGHEST REVIEW.

4 SO I THINK THE BEST WAY, THE EXTENT I CAN
5 SORT OF REITERATE WHAT WAS SAID AT THAT MEETING, TO
6 THE EXTENT THERE ARE ACTIVITIES GOING ON BY OUR
7 GRANTEES THAT FALL INTO THAT SPACE, WE PRIORITIZE
8 THOSE FROM A COMPLIANCE EVALUATION PERSPECTIVE.

9 CHAIRMAN LO: THESE WOULD BE OUR GRANTEES,
10 NOT IVF PRACTICE.

11 DR. LOMAX: CORRECT. ALTHOUGH WE WOULD IN
12 THE CASE OF A GRANTEE DOING A DERIVATION, WE WOULD
13 ASK QUESTIONS ABOUT THE ACTUAL PROCUREMENT OF
14 EMBRYOS, THE CONSENT PROCESS. AGAIN, THAT'S
15 SOMEWHAT INDIRECT. I DON'T WANT TO SUGGEST IT
16 DIRECTLY ADDRESSES THE SORT OF SET OF CONSIDERATIONS
17 BEING RAISED BY SOME MEMBERS OF THE PUBLIC AND THE
18 WORKING GROUP, BUT IT GIVES YOU A BIT OF A SENSE OF
19 OUR ROLE. AND THAT, AGAIN, IS A UNIQUE ROLE THAT IS
20 NEITHER -- TO MY KNOWLEDGE, THE STATE DOESN'T HAVE
21 THE RESOURCES TO CARRY THAT OUT IN ITS OTHER
22 PROGRAMS, SO THAT'S A UNIQUE CIRM FUNCTION.

23 DR. CIBELLI: THANK YOU.

24 CHAIRMAN LO: BUT YOU COULD ASK THE
25 INVESTIGATOR THAT'S FUNDED BY CIRM WHETHER THEY HAVE

BARRISTERS' REPORTING SERVICE

1 FINANCIAL ARRANGEMENTS WITH THE -- WHETHER THE
2 PEOPLE IN THE IVF CLINIC HAVE A STAKE. YOU CAN'T
3 TALK TO -- IT SEEMS TO ME TO BE VERY HARD TO GO BACK
4 TO THE IVF CLINIC AND SAY WE WANT TO ASK THESE
5 QUESTIONS.

6 DR. LOMAX: THAT'S CORRECT. WE COULD ASK
7 QUESTIONS, OR THROUGH ADMINISTRATIVE MECHANISMS, WE
8 COULD PROBE ON ISSUES IN THE CONTEXT WHERE THEY'RE
9 USING EMBRYOS.

10 I WANT TO REMIND FOLKS THAT THERE'S SORT
11 OF TWO ISSUES HERE. IT'S THE ACCEPTABLY DERIVED
12 STANDARD WHICH GOVERNS THE USE OF DERIVED STEM CELL
13 LINES. THAT ONE, I THINK, IS VERY CHALLENGING TO
14 SORT OF SORT OUT HOW TO IMPACT. BUT THE USE OF
15 EMBRYOS TO DO DERIVATION, WE HAVE -- AGAIN, WE'VE
16 ASKED MORE QUESTIONS, WE HAVE MORE OF AN ABILITY TO
17 PROBE IN THAT SPACE.

18 CHAIRMAN LO: ANY OTHER QUESTIONS,
19 COMMENTS FROM MEMBERS OF THE COMMITTEE?

20 MS. STAYN: BERNIE, WILL YOU TAKE ANOTHER
21 PUBLIC COMMENT?

22 CHAIRMAN LO: OH, ABSOLUTELY.

23 MS. STAYN: SUSAN STAYN FROM STANFORD
24 UNIVERSITY. I WANTED TO VOICE SUPPORT FOR THE
25 PROPOSED REVISION. I ALSO WANTED TO ADDRESS A

BARRISTERS' REPORTING SERVICE

1 QUESTION THAT CAME UP EITHER BY THE COMMITTEE OR IN
2 PUBLIC COMMENT ABOUT MEDICAL OR SCIENTIFIC EVIDENCE
3 OF THE VALUE OF THESE EMBRYOS THAT WERE MADE WITH
4 PAID GAMETES.

5 OF COURSE, RESEARCH INSTITUTIONS' HANDS
6 HAVE BEEN TIED BECAUSE WE HAVEN'T BEEN ABLE TO USE
7 THOSE EMBRYOS IN CIRM-FUNDED RESEARCH BECAUSE OF THE
8 EXISTING RESTRICTION. BUT I WANTED TO, AS A POINT
9 OF INFORMATION, MENTION TO THE COMMITTEE THAT
10 STANFORD UNIVERSITY DID SUBMIT COMMENTS ABOUT A YEAR
11 AGO AT A TIME WHEN THIS REGULATION WAS BEING
12 CONSIDERED FOR OTHER REASONS. AND WE DID POINT TO
13 THE REASON THAT OUR SCIENTISTS AND OUR IVF CLINICIAN
14 RESEARCHERS DO WANT TO DO RESEARCH ON THESE EMBRYOS.

15 AND SO THAT IS IN THE RECORD. IT'S FROM
16 ABOUT DECEMBER OF 2008, AND IT WAS A LETTER MADE
17 DURING THE PUBLIC COMMENT PERIOD SUBMITTED BY
18 STANFORD UNIVERSITY.

19 I WOULD ALSO LIKE TO REITERATE THE PRIOR
20 COMMENT MADE BY ASRM ABOUT THE SEPARATION OF THE
21 PAYMENT TO EGG DONORS FROM ANY PAYMENT BEING MADE BY
22 THE RESEARCH INSTITUTION OR THE IVF PHYSICIAN. IT'S
23 COMPLETELY SEPARATE FROM THE RESEARCH INSTITUTION
24 AND THE RESEARCHERS.

25 AND LASTLY, I JUST WANTED TO MENTION AS A

BARRISTERS' REPORTING SERVICE

1 POINT OF INFORMATION FOR SOME OF THE RECENT PUBLIC
2 COMMENTS THAT STATE LAW REQUIRES IVF DOCTORS TO
3 OFFER PATIENTS ALL DISPOSITIONAL OPTIONS INCLUDING
4 DONATION TO RESEARCH. THERE'S NO CATEGORICAL
5 EXCLUSION FOR COUPLES WHO HAVE HAD TO USE GAMETES
6 AND HAVE HAD TO PAY FOR THEM TO CREATE EMBRYOS FOR
7 THEIR REPRODUCTIVE PURPOSES.

8 SO IVF PHYSICIANS DO HAVE TO OFFER ALL
9 DISPOSITIONAL CHOICES INCLUDING DONATION TO
10 RESEARCH. AND SO WE FELT AT THE GROUND LEVEL THAT
11 IT'S UNFAIR TO NOT BE ABLE TO OFFER CERTAIN COUPLES
12 THE OPTION TO DONATE TO RESEARCH WHEN THOSE EMBRYOS
13 COULD BE QUITE SCIENTIFICALLY VALUABLE AND, AGAIN,
14 COUPLES ARE VOLUNTARILY PROVIDING CONSENT TO DO SO.

15 CHAIRMAN LO: SO I WANT TO TRY -- A NUMBER
16 OF YOU ON THE CALL HAVEN'T SPOKEN. I'M TRYING TO
17 GET A SENSE OF WHERE YOU ALL STAND. SO I INVITE ANY
18 OF YOU ON THE COMMITTEE WHO HAVEN'T YET ADDRESSED
19 THIS ISSUE JUST TO SORT OF LET US KNOW YOUR
20 THOUGHTS. TED AND JANET, I DON'T KNOW IF YOU WANT
21 TO SORT OF OFFER YOUR --

22 DR. PETERS: I'M JUST SAYING THIS IS TED.
23 I DON'T NEED TO ADD ANYTHING HERE.

24 DR. ROWLEY: THIS IS JANET. AND I GUESS I
25 DO REFLECT SOME OF THE CONCERNS THAT, AND POSSIBLY

BARRISTERS' REPORTING SERVICE

1 THIS IS COLORED BY MY EXPERIENCE WITH THE ACADEMY
2 COMMITTEE QUITE SOME TIME AGO, WE CAN'T MAKE A
3 PERFECT WORLD NOW. AND THERE ARE GOING TO BE SOME
4 AREAS WHICH WITH EXPERIENCE WE MAY FIND THAT WE NEED
5 TO CHANGE THIS OR TAKE INTO ACCOUNT FACTORS THAT WE
6 HAD IGNORED BEFORE.

7 AND IN AN IMPERFECT WORLD, I THINK THAT WE
8 AS IMPERFECT PEOPLE ARE GOING TO COME UP WITH
9 REGULATIONS THAT WILL HAVE SOME FLAWS, BUT I THINK
10 THAT THERE'S BEEN EXTENSIVE DISCUSSION ON THIS. THE
11 CONCERNS OF MANY PEOPLE HAVE BEEN HEARD, AND I THINK
12 THAT WE JUST HAVE TO GET ON WITH IT, OR WE WILL BE
13 SPENDING THE NEXT SOME MONTHS ARGUING THESE SAME
14 POINTS YET AGAIN.

15 CHAIRMAN LO: ANY OTHER THOUGHTS ON THIS
16 FROM THE COMMITTEE MEMBERS?

17 SO I'M GOING TO SORT OF SEE IF I CAN MOVE
18 US ALONG HERE AND OFFER -- IT SEEMS TO ME WE HAVE A
19 COUPLE OF OPTIONS. ONE IS TO ADOPT THE PROPOSED
20 CHANGES AS WAS PRESENTED TO YOU IN SORT OF THE
21 BRIEFING MATERIALS RECEIVED. THE OTHER IS TO, IN
22 ADDITION TO THAT, ADD ON SOME PROVISIONS TO DIRECT
23 CONFLICTS OF INTEREST -- TO TRY AND EXCLUDE
24 CONFLICTS OF INTEREST BETWEEN THE IVF PHYSICIAN AND
25 THE RESEARCHER.

BARRISTERS' REPORTING SERVICE

1 I THINK IF WE WANTED TO DO THAT, IT'S NOT
2 CLEAR TO ME HOW WE WOULD WRITE THOSE BECAUSE, AS
3 GEOFF POINTED OUT, WE HAVE TWO DISTINCT SITUATIONS
4 HERE. ONE IS AN EXISTING STEM CELL LINE THAT WAS
5 CREATED SOME TIME AGO BY SOMEBODY ELSEWHERE WHERE WE
6 ARE ACTUALLY NOT GOING TO KNOW. IT'S GOING TO BE
7 PRETTY HARD TO FIND THE INFORMATION ABOUT THE IVF
8 PRACTICE THAT SUPPLIED THE EMBRYOS.

9 I THINK THE OTHER IS FOR CIRM-FUNDED
10 RESEARCH TO DERIVE A NEW EMBRYONIC STEM CELL LINE
11 WHERE WE'RE ACTUALLY GIVING MONEY TO A CIRM-FUNDED
12 RESEARCHER, WE ACTUALLY, I THINK, CAN. IN THAT
13 SITUATION IT WOULD BE FEASIBLE IF WE SO DESIRED TO
14 SORT OF FIND OUT MORE INFORMATION ABOUT THE
15 RELATIONSHIP.

16 BUT I GUESS I NEED TO GET A SENSE OF THE
17 COMMITTEE WHETHER WE WANT TO SORT OF PURSUE TRYING
18 TO THINK ABOUT CONFLICT OF INTEREST REQUIREMENTS.
19 AND IF SO, I THINK WE NEED TO, AS ALAN SAID, REALLY
20 TALK TO IVF PRACTICES AND CIRM RESEARCHERS WHO ARE
21 INTERESTED IN DERIVING LINES AND SEE WHAT'S FEASIBLE
22 TO DO BECAUSE WE DON'T WANT TO WRITE REQUIREMENTS
23 THAT ARE GOING TO BE VERY DIFFICULT TO ACTUALLY
24 FOLLOW THROUGH IN PRACTICE.

25 MR. KLEIN: BERNIE, I SUGGEST THAT YOU

BARRISTERS' REPORTING SERVICE

1 TAKE A STRAW POLL JUST ON ADOPTING IT AS WRITTEN.
2 AND THEN IF THAT DOESN'T SHOW A MAJORITY, THEN YOU
3 CAN MOVE ON TO THE SECOND ISSUE.

4 CHAIRMAN LO: WHY DON'T WE DO THAT. WE DO
5 NOT HAVE A QUORUM.

6 MR. KLEIN: THE ADJUSTED LANGUAGE THAT
7 ALAN TROUNSON ADDED, WE ALREADY ADDRESSED THAT.

8 CHAIRMAN LO: MY SENSE IS THAT WE SORT OF
9 AGREED ON 170. I THINK IT'S 180 WE'VE HAD
10 DISCUSSION. I'D JUST LIKE TO TAKE THAT POSITION, GO
11 THROUGH AND SORT OF TAKE A POLL AS TO WHETHER WE
12 WOULD SUPPORT THE REVISIONS TO 10080 AS IN THE
13 BRIEFING MATERIALS. IF NOT, THEN I THINK WE HAVE
14 OTHER ISSUES TO ADDRESS. DO YOU WANT TO JUST GO
15 THROUGH THE ROLL CALL, GEOFF, BECAUSE I CAN'T CALL
16 FOR A SHOW OF HANDS.

17 DR. LOMAX: TED PETERS.

18 DR. PETERS: THE FIRST OPTION WITHOUT
19 PURSUING THE CONFLICT OF INTEREST ADDITION.

20 CHAIRMAN LO: APPROVE AS PRESENTED.

21 DR. PETERS: APPROVE AS PRESENTED.

22 DR. LOMAX: JOSE CIBELLI.

23 DR. CIBELLI: APPROVE AS PRESENTED.

24 DR. LOMAX: DOROTHY ROBERTS.

25 DR. ROBERTS: I WOULD PREFER TO HAVE

BARRISTERS' REPORTING SERVICE

1 FURTHER CONSIDERATION OF CONFLICT OF INTEREST.

2 DR. LOMAX: JEFF SHEEHY.

3 MR. SHEEHY: APPROVE AS PRESENTED.

4 DR. LOMAX: BERNIE LO.

5 CHAIRMAN LO: APPROVE AS PRESENTED.

6 DR. LOMAX: JANET ROWLEY.

7 DR. ROWLEY: APPROVE AS PRESENTED.

8 DR. LOMAX: ANN KIESSLING.

9 DR. KIESSLING: APPROVE AS PRESENTED.

10 DR. LOMAX: BOB KLEIN.

11 MR. KLEIN: APPROVE AS PRESENTED.

12 CHAIRMAN LO: I THINK IT'S THE SENSE OF
13 THE COMMITTEE THAT WE SHOULD APPROVE THIS. I THINK
14 WHEN WE GO TO THE ICOC, I THINK I WILL OR WHOEVER
15 PRESENTS THIS WILL SAY THAT THERE WERE CONCERNS
16 RAISED ABOUT CONFLICTS OF INTEREST AND THE COMMITTEE
17 THOUGHT ABOUT IT. AND THERE WILL BE OPPORTUNITY FOR
18 PUBLIC INPUT THERE AS WELL SO THAT THE ICOC WILL BE
19 ABLE TO MAKE THEIR DELIBERATIONS WITH THIS.

20 I THINK THIS IS AN IMPORTANT -- CONFLICT
21 OF INTEREST IS AN IMPORTANT ISSUE. I THINK IT'S
22 IMPORTANT THAT WE THOUGHT ABOUT IT AND DISCUSSED IT.

23 GEOFF, WE HAVE ONE MORE PROVISION, 10090.

24 DR. LOMAX: LET ME MOVE ON. THIS IS THE
25 NEXT SLIDE. BY WAY OF CONTEXT, THERE'S TWO THINGS

BARRISTERS' REPORTING SERVICE

1 GOING ON IN THIS PROVISION. FIRST OF ALL, THIS
2 SECTION HAS BEEN REDRAFTED IN PART BECAUSE WE WERE
3 ALREADY IN THE PROCESS OF SUBMITTING REVISIONS TO
4 THE OFFICE OF ADMINISTRATIVE LAW. AND SO WE'RE
5 RESPONDING TO THE PREVIOUS PUBLIC COMMENTS.

6 THEN IN ADDITION, THE KEY PROVISION WAS
7 DURING THE LAST MEETING, IT CAME UP IN DISCUSSION
8 THAT THERE WAS A CONCERN THAT IF WE ALLOWED -- LET
9 ME BACK TRACK A LITTLE BIT HERE.

10 WE HAD A DISCUSSION ABOUT THE
11 APPROPRIATENESS OF CIRM GRANTEEES USING MATERIALS,
12 AND IN THIS CASE THE DRIVER FOR THE CONVERSATION
13 WERE SOMATIC CELLS, MATERIALS THAT ARE ROUTINELY
14 COLLECTED IN RESEARCH WHERE THERE'S AN IRB-APPROVED
15 PROCUREMENT PROTOCOL AND THE DONOR MAY RECEIVE SOME
16 MODEST SUM OF MONEY, WHICH IS TYPICALLY IN THE SORT
17 OF 25 TO \$50 RANGE, FOR SHOWING UP AND GIVING SKIN
18 CELLS OR CHEEK CELLS OR SOME MATERIAL LIKE THAT.

19 OUR REGULATIONS EXPLICITLY PROHIBITED
20 EITHER THE USE OF ANY MATERIAL, WHETHER IT'S A
21 GAMETE, EMBRYO, OR SOMATIC SELL, WHERE THE DONOR
22 RECEIVED ANY PAYMENT REGARDLESS OF WHO DID THE
23 PAYING. THERE WAS A DISCUSSION AT THE MEETING WHERE
24 PEOPLE FELT IT WAS REASONABLE TO ALLOW THE USE OF
25 MATERIALS WHERE THERE HAD BEEN MODEST IRB-APPROVED

BARRISTERS' REPORTING SERVICE

1 PAYMENTS OR I SHOULD SAY IRB-APPROVED PAYMENTS.
2 MODEST IS A SUBJECTIVE TERM. HOWEVER, THERE WAS
3 CONCERN AMONG THE WORKING GROUP THAT BY DOING SO, IT
4 MAY OPEN CIRM UP TO LEGAL CHALLENGES BASED ON
5 LANGUAGE IN PROP 71 THAT PRECLUDES ANY PAYMENT OF
6 DONORS.

7 SO WHAT WE DISCUSSED AT THE MEETING WAS
8 ADDING A PROVISION, AND IT'S REFLECTED IN 190(B),
9 PARDON THE FIRST TYPO THERE, WHERE WE SAY CIRM FUNDS
10 MAY NOT BE USED TO PROVIDE VALUABLE CONSIDERATION TO
11 DONORS OF GAMETES, EMBRYOS, SOMATIC CELLS, OR
12 TISSUES. AND THE THINKING HERE IS THAT MOST OF THE
13 MATERIALS THAT ALREADY EXIST IN BANKS OR IN TISSUE
14 BANKS IN PARTICULAR, THE PROCUREMENT WASN'T DONE BY
15 CIRM ANYWAY. SO THIS PAYMENT RESTRICTION IS
16 REASONABLE BECAUSE WHAT IT SAYS IS DON'T USE CIRM
17 FUNDS, BUT YOU'RE FREE TO USE MATERIALS THAT ALREADY
18 EXIST IN ESTABLISHED TISSUE BANKS.

19 AND AGAIN, THIS PAYMENT ISSUE, WHICH CAN
20 BE VERY DIFFICULT TO ASCERTAIN FOR HISTORICALLY
21 BANKED MATERIALS, IS ONE THAT ISN'T A BARRIER TO
22 SORT OF BASIC RESEARCH, IN PARTICULAR IPS RESEARCH
23 WHERE THIS WAS TENDING TO SORT OF DRIVE THIS ISSUE.

24 SO THAT'S THE KEY CHANGE THAT SORT OF
25 COUPLES -- THAT SORT OF COUPLES US WITH THE MEETING

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1 OF LAST SEPTEMBER.

2 CHAIRMAN LO: SO JUST AS A NONLAWYER TO
3 MAKE SURE I UNDERSTAND THIS, IN 10090 ALL THE
4 PROVISIONS OF A WHERE YOU TALK ABOUT EMBRYOS AND
5 GAMETES, EXCEPT FOR 3, WHICH IS SOMATIC CELLS, B
6 SAYS YOU CAN'T USE CIRM FUNDING, BUT IT LEAVES OPEN
7 THAT OTHER SOURCES OF FUNDING MAY HAVE PROVIDED
8 PAYMENTS TO DONORS; IS THAT CORRECT?

9 DR. LOMAX: CORRECT.

10 CHAIRMAN LO: SUBJECT TO THE RESTRICTIONS
11 IN A.

12 DR. LOMAX: CORRECT.

13 CHAIRMAN LO: ANY COMMENT FROM MEMBERS OF
14 THE COMMITTEE? IT'S A TECHNICAL CLARIFICATION.

15 DR. LOMAX: IT WASN'T JUST TECHNICAL. IT
16 WAS A WAY OF MAINTAINING -- IT WAS KIND OF SPLIT --
17 I DON'T KNOW THE BEST WAY TO CHARACTERIZE IT, BUT
18 IT'S SUBSTANTIVE IN THE SENSE THAT IT STILL
19 MAINTAINS THE PAYMENT RESTRICTION WITH REGARDS TO
20 CIRM-FUNDED RESEARCH.

21 CHAIRMAN LO: ANY COMMENTS FROM THE
22 COMMITTEE? QUESTIONS? ANY PUBLIC QUESTIONS OR
23 COMMENTS ON 10090?

24 MS. FOGEL: HOW THIS SQUARES WITH THE
25 ACTUAL PROP 71 STATUTE BECAUSE IT SAYS NO

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1 COMPENSATION TO RESEARCH DONORS. SO I MEAN I
2 JUST -- I GUESS I JUST DON'T UNDERSTAND HOW THAT
3 FITS.

4 MR. KLEIN: THIS IS BOB KLEIN. THE
5 PROPOSED LANGUAGE HERE IS IT SAYS NONE OF OUR FUNDS
6 ARE GOING TO BE USED FOR COMPENSATION.

7 I'D ALSO ADDITIONALLY LIKE TO JUST SAY
8 HISTORICALLY THAT THE STANDARDS WE HAVE ARE MUCH
9 MORE RESTRICTIVE THAN THE INITIATIVE IN THE FIRST
10 PLACE. THE INITIATIVE PROVIDES FOR REIMBURSEMENTS,
11 AND THERE'S A NUMBER OF THINGS THAT ARE BEING
12 DISCUSSED HERE, LIKE EXPENSES TO THE SPERM DONOR FOR
13 GETTING TO THE PLACE TO DONATE. THAT IS CLEARLY A
14 REIMBURSEMENT. IT'S NOT COMPENSATION IN THE FIRST
15 PLACE. BUT VERY CLEARLY, THIS LEGALLY IS CREATING A
16 VERY SAFE POSITION WHICH IS OUR FUNDS FROM THIS
17 INITIATIVE ARE NOT USED FOR THIS PURPOSE.

18 CHAIRMAN LO: ANY COMMENT FROM OUR LEGAL
19 COUNSEL, JAMES? ANY OTHER PUBLIC COMMENT, QUESTION?

20 MS. DARNOVSKY: I MAY HAVE MISSED SOME
21 PREVIOUS DISCUSSIONS A FEW MINUTES AGO. WOULD THIS
22 THEN PERMIT, IN THE CASE OF EGGS, PAYMENT BEYOND
23 REIMBURSEMENT FOR EGGS AS LONG AS IT WAS NOT DONE
24 WITH CIRM FUNDS, BUT COULD THEN BE USED FOR
25 RESEARCHERS? THAT'S NOT THE INTENT HERE, IS IT?

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1 DR. LOMAX: NO. THE WAY THAT'S COVERED,
2 MARCY, THIS IS IN ADDITION TO THE STANDARDS IN
3 10080, WHICH EXPLICITLY PROHIBITS THE PAYMENT OF
4 DONORS OF OOCYTES. THESE ARE ADDITIONAL
5 REQUIREMENTS THAT LAYER ON TOP OF 180. WE REFERENCE
6 SECTION 180 IN PART A WHERE IT SAYS, IN ADDITION TO
7 THE REQUIREMENTS OF CIRM REGULATIONS SECTION 10080,
8 SUBDIVISION, ETC., ETC. WHAT THAT'S SAYING IS THESE
9 ALL NOW STACK ON TOP OF THOSE SET OF REQUIREMENTS.

10 MS. DARNOVSKY: THANK YOU.

11 CHAIRMAN LO: ANY OTHER COMMENTS? SO AM I
12 FAIR IN DECLARING IT'S A SENSE OF THE COMMITTEE THAT
13 WE WILL RECOMMEND TO THE ICOC TO ADOPT LANGUAGE FOR
14 10090? QUESTIONS, COMMENTS FROM THE COMMITTEE?
15 OKAY.

16 SO WITH THAT, I WANT TO THANK YOU ALL FOR
17 ATTENDING AND SORT OF GIVING YOUR THOUGHTS IN
18 CONSIDERATION OF THESE IMPORTANT TOPICS.

19 MR. REED: THIS IS DON REED. I JUST
20 RECEIVED AN E-MAIL FROM JACQUELINE KINNEY OF SENATOR
21 ROMERO'S OFFICE AND SAID THAT THE GOVERNOR JUST
22 SIGNED SENATE BILL 471, THE EDUCATION BILL, INTO
23 LAW.

24 CHAIRMAN LO: GOOD. THANK YOU. OKAY.
25 HEARING NO FURTHER COMMENTS, QUESTIONS, I WANT TO

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1 THANK YOU ALL AND DECLARE THE MEETING ADJOURNED.

2 THANKS VERY MUCH.

3 (THE MEETING WAS THEN CONCLUDED AT
4 11:27 A.M.)

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BARRISTERS' REPORTING SERVICE

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON OCTOBER 12, 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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