

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

LOCATION: WESTIN SAN FRANCISCO MARKET STREET
50 THIRD STREET
SAN FRANCISCO, CALIFORNIA

DATE: SEPTEMBER 18, 2009
9 A.M.

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

BRS FILE NO.: 85051

BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

1 SAN FRANCISCO, CALIFORNIA; FRIDAY, SEPTEMBER 18, 2009
2 9 A.M.

3
4 MS. LANSING: IN AN ATTEMPT TO START ON TIME,
5 IT'S 9 O'CLOCK. WE HAVE A LOT TO COVER TODAY, AND WE
6 DID PROMISE TO BE DONE BY THREE SINCE A LOT OF PEOPLE
7 HAVE PLANES TO CATCH. SO I WANT TO, ON BEHALF OF
8 BERNIE AND MYSELF, WELCOME ALL OF YOU AND, AGAIN, THANK
9 THE MEMBERS OF THE COMMITTEE WHO HAVE BEEN SO DILIGENT
10 AND SO OPEN TO SPEND SO MUCH TIME ON THIS COMMITTEE.
11 AND WE'RE EXTREMELY GRATEFUL TO ALL OF YOU.

12 ALSO WANT TO THANK THE MEMBERS OF THE PUBLIC
13 ALSO FOR THEIR COMMENTS AND FOR BEING WITH US. SOME OF
14 YOU HAVE BEEN HERE FROM THE VERY, VERY BEGINNING, AND
15 WE ARE VERY, VERY GRATEFUL TO THE COLLABORATION THAT WE
16 HAVE WITH YOU.

17 AS YOU REMEMBER WHEN WE FIRST STARTED AND WE
18 FIRST STARTED WITH OUR STANDARDS, WE SAID THAT THIS WAS
19 A WORK IN PROGRESS AND THAT WE WOULD BE CONSTANTLY
20 LOOKING AT WHAT WE HAD DONE, LOOKING AT WHERE THE
21 SCIENCE WAS, AND CONSTANTLY REEVALUATING IT. AND TODAY
22 IS AN EXAMPLE OF WHAT I WAS TALKING ABOUT BECAUSE TODAY
23 WE'RE GOING TO LOOK AT THE POSSIBLE MODIFICATION OF
24 SOME OF OUR REGULATIONS.

25 WHAT WE'RE GOING TO DISCUSS TODAY IS GOING TO

BARRISTERS' REPORTING SERVICE

1 BE FAMILIAR TO ALL OF YOU. IT'S OBVIOUSLY FAMILIAR TO
2 THE COMMITTEE, BUT IT'S GOING TO BE FAMILIAR TO ALL OF
3 YOU IN THE PUBLIC AS WELL BECAUSE WE ARE REVISITING
4 IRB'S THAT HAVE COME UP CONSTANTLY IN OUR MEETINGS AND
5 COME UP IN PUBLIC FORUMS AS WELL AS IN PUBLIC COMMENT.
6 WE'RE GOING TO RECONSIDER SOME OF THESE POLICIES THAT
7 YOU BROUGHT TO US AND THAT WE'VE DISCUSSED AMONG
8 OURSELVES. AND IT'S PARTICULARLY TIMELY THAT WE DO IT
9 TODAY BECAUSE THE NIH, AS YOU KNOW, HAS ISSUED ITS
10 GUIDELINES. THE WORLD HAS CHANGED WITH PRESIDENT OBAMA
11 SUPPORTING STEM CELL RESEARCH AND THE NIH ISSUING ITS
12 GUIDELINES.

13 THE ICOC DRAFTED ITS OWN COMMENTS TO THESE
14 GUIDELINES, AND WE TAKE THEM VERY, VERY SERIOUSLY. AND
15 THE BOARD OF THE ICOC HAS ASKED OUR STANDARDS COMMITTEE
16 TO CONSIDER BEING AS COMPATIBLE AS POSSIBLE TO THE NIH
17 GUIDELINES, ALWAYS MINDFUL, THOUGH, OF OUR OWN HIGH
18 STANDARDS. SO WE'RE NOT ASKING YOU TO COMPROMISE IN
19 ANY WAY OUR STANDARDS. AND OBVIOUSLY WE WANT TO
20 MAINTAIN OUR OWN INTEGRITY. BUT WE'D LIKE YOU TO LOOK
21 AT THE NIH GUIDELINES AND TO CONSIDER HOW WE CAN BE, IF
22 POSSIBLE, MORE COMPATIBLE.

23 FINALLY, I WOULD LIKE TO RECOGNIZE A NUMBER
24 OF INDIVIDUALS AND ORGANIZATIONS WHO CONTRIBUTED TO
25 TODAY'S MEETINGS. I'D LIKE TO THANK DR. LANA SKIRBALL

BARRISTERS' REPORTING SERVICE

1 AND DR. STORY LANDIS OF THE NIH AND THEIR STAFF WHO
2 WERE INSTRUMENTAL IN THE EFFORT TO ENACT EFFECTIVE
3 GUIDELINES AND CONTINUE TO SUPPORT THEIR
4 IMPLEMENTATION.

5 I'D ALSO LIKE TO THANK THE CALIFORNIA
6 DEPARTMENT OF PUBLIC HEALTH, I'D LIKE TO THANK THEIR
7 STAFF, AND I'D LIKE TO THANK PROFESSOR HANK GREELEY,
8 WHO CHAIRS THE STATE STEM CELL ADVISORY COMMITTEE. I
9 ALREADY THANKED DR. ROBERT KLITZMAN, WHO MADE THIS
10 INCREDIBLY LONG TRIP ON THE EVE OF ROSH HASHANAH, AND
11 IT WAS QUITE DIFFICULT FOR HIM TO DO SO. AND I FOUND
12 THE CONVERSATION ABOUT THE NEW YORK STEM CELL RULES
13 QUITE INFORMATIVE.

14 AND THEN, FINALLY, I WANT TO THANK ALL OF
15 YOU, ALL OF THE INSTITUTIONS, AND ALL OF THE PUBLIC WHO
16 HAVE COMMENTED SO OFTEN AND SO INTELLIGENTLY AND SO
17 PASSIONATELY ON OUR POLICY PROPOSALS. I'M GOING TO
18 LIMIT MY REMARKS BECAUSE I BELIEVE WE HAVE THE NIH ON
19 THE LINE, AND WE HAVE A VERY BUSY AGENDA. SO I'D LIKE
20 TO TURN IT OVER TO YOU NOW, BERNIE.

21 CHAIRMAN LO: THANKS VERY MUCH, SHERRY. AS A
22 BAY AREA NATIVE, I WANT TO GIVE A SPECIAL WELCOME TO
23 ALL OF YOU AND HOPE THAT YOU CAN APPRECIATE SOME OF
24 THIS WONDERFUL WEATHER WE'RE HAVING WHILE WE STILL HAVE
25 IT.

BARRISTERS' REPORTING SERVICE

1 I WANT TO ECHO SHERRY'S THANKS TO ALL THE
2 PEOPLE WHO HAVE HELPED US WITH THIS. I WANT TO, AGAIN,
3 IN TERMS OF CONTEXT, JUST SORT OF DRAW A LINE BETWEEN
4 LAST NIGHT, WHICH WAS REALLY SORT OF INFORMATION ONLY,
5 THAT THE ISSUES THAT ROBERT KLITZMAN TALKED ABOUT ARE
6 NOT THINGS THAT WE CAN ENACT IN CALIFORNIA, BUT IT WAS
7 JUST BACKGROUND.

8 ON THE OTHER HAND, THIS MORNING WE'RE GOING
9 TO START BY HEARING FROM TWO CHANGES IN POLICY THAT DO
10 AFFECT CIRM AND CIRM SCIENTISTS. SHERRY HAS ALREADY
11 ALLUDED TO THE NEW NIH GUIDELINES ON HUMAN EMBRYONIC
12 STEM CELL RESEARCH THAT HAVE BEEN ISSUED. AND I JUST
13 WANT TO REMIND EVERYONE THAT THESE WERE ISSUED IN
14 RESPONSE TO A DIRECTIVE FROM THE PRESIDENT, THE NEW
15 ADMINISTRATION, WHICH REALLY SIGNED A CHANGE IN MANY
16 WAYS FROM THE PREVIOUS POLICIES OF THE BUSH
17 ADMINISTRATION. AND I THINK IT REFLECTED TO A LARGE
18 EXTENT WIDE FEELINGS AMONG THE AMERICAN PEOPLE THAT
19 BARRIERS, INAPPROPRIATE BARRIERS, TO HUMAN EMBRYONIC
20 STEM CELL RESEARCH SHOULD BE IDENTIFIED AND, IF
21 POSSIBLE, REMOVED.

22 CLEARLY, CIRM SCIENTISTS ARE GOING TO BE
23 WORKING WITH NIH LINES. MANY CIRM SCIENTISTS WILL ALSO
24 WANT SIMULTANEOUS FUNDING FROM NIH. AND AS SHERRY
25 SAID, INsofar AS POSSIBLE, IF IT'S ETHICALLY

BARRISTERS' REPORTING SERVICE

1 APPROPRIATE, WE WOULD WANT OUR REGULATIONS TO HARMONIZE
2 WITH THE NIH GUIDELINES TO THE EXTENT THAT WE FEEL
3 COMFORTABLE DOING IT.

4 WE ALSO HAVE REGULATIONS IN CALIFORNIA FOR
5 STEM CELL RESEARCH THAT'S NOT SPONSORED BY CIRM. THE
6 COMMITTEE THAT HANK GREELEY CHAIRS FOR THE DEPARTMENT
7 OF PUBLIC HEALTH ADVISES ON THAT. AND, AGAIN, IT WOULD
8 ONLY MAKE SENSE FOR US TO SORT OF TRY AND BE CONSISTENT
9 WITH THOSE DPH GUIDELINES AS WELL. SO I THINK WE NEED
10 TO DAY THINK A LITTLE BIT ABOUT HOW WHAT WE'RE DOING
11 TIES IN WITH WHAT OTHER KEY REGULATORY OVERSIGHT
12 AGENCIES THAT AFFECT CALIFORNIA STEM CELL RESEARCHERS
13 ARE DOING.

14 SO, PAT, DO WE HAVE STORY LANDIS OR LANA
15 SKIRBALL ON THE LINE YET?

16 DR. LOMAX: I THINK WE DID HAVE SOMEONE JOIN.

17 CHAIRMAN LO: IS LANA SKIRBALL ON THE LINE?
18 IS ANYBODY ON THE LINE?

19 DR. WILLERSON: I AM, BERNIE. JIM WILLERSON.

20 CHAIRMAN LO: HI, DR. WILLERSON. WELCOME AND
21 THANK YOU FOR CALLING IN. WE UNDERSTAND YOU HAD A
22 PATIENT WHO REQUIRED YOUR CARE IN HOUSTON. WE
23 APPRECIATE YOUR JOINING US BY PHONE.

24 DR. WILLERSON: THANK YOU, BERNIE.

25 CHAIRMAN LO: IF WE DON'T HAVE LANA, GEOFF,

BARRISTERS' REPORTING SERVICE

1 DO YOU WANT TO START WITH THE STAFF REPORT.

2 DR. LOMAX: WHY DON'T WE, JUST FOR THE SAKE
3 OF THE RECORD, IT MIGHT BE HELPFUL JUST TO ACKNOWLEDGE
4 WHO IS CURRENTLY AT THE MEETING. AND I WOULD BE
5 HESITANT TO START THE STAFF REPORT; BUT IF WE HAVE TO
6 BECAUSE I IMAGINE NIH WILL BE JOINING US MOMENTARILY.

7 CHAIRMAN LO: WHY DON'T WE DO A FORMAL ROLL
8 CALL THEN.

9 DR. LOMAX: FRANCISCO PRIETO.

10 DR. PRIETO: HERE.

11 DR. LOMAX: ANN KIESSLING.

12 DR. KIESSLING: HERE.

13 DR. LOMAX: JOSE CIBELLI.

14 DR. CIBELLI: HERE.

15 DR. LOMAX: MARCY FEIT.

16 MS. FEIT: HERE.

17 DR. LOMAX: ALTA CHARO.

18 MS. CHARO: HERE.

19 DR. LOMAX: BERNIE LO.

20 CHAIRMAN LO: HERE.

21 DR. LOMAX: SHERRY LANSING.

22 MS. LANSING: HERE.

23 DR. LOMAX: JAMES WILLERSON.

24 DR. WILLERSON: HERE.

25 DR. LOMAX: JEFF SHEEHY. DOROTHY ROBERTS.

BARRISTERS' REPORTING SERVICE

1 DR. ROBERTS: HERE.

2 DR. LOMAX: ROBERT TAYLOR.

3 DR. TAYLOR: HERE.

4 DR. LOMAX: AND I BELIEVE THOSE ARE ALL THE
5 MEMBERS PRESENT.

6 WE COULD START THE STAFF REPORT IF YOU LIKE.
7 AGAIN, I IMAGINE NIH WILL BE JOINING US MOMENTARILY.

8 CHAIRMAN LO: WHY DON'T WE START WITH THE
9 UNDERSTANDING THAT WE'LL BREAK OFF WHEN LANA JOINS US
10 AND SHIFT GEARS.

11 DR. LOMAX: OKAY. AS WE TYPICALLY DO, I TAKE
12 A MOMENT TO BRING YOU UP TO DATE ON RECENT DEVELOPMENTS
13 SINCE OUR FEBRUARY MEETING. AND WE'VE HAD THE
14 OPPORTUNITY TO DEVELOP TWO REPORTS SINCE THAT MEETING.
15 THE FIRST REPORT IS THE WORKSHOP REPORT THAT, IF YOU
16 REMEMBER, AT THE FEBRUARY MEETING WE INCLUDED A
17 WORKSHOP AND A LONG DISCUSSION OF CLINICAL TRIALS
18 ISSUES. THAT REPORT HAS NOW BEEN POSTED. THE
19 APPENDICES FOR THOSE REPORTS INCLUDE ALL THE
20 PRESENTATIONS, SO THE REPORT ITSELF REALLY TRIES TO HIT
21 THE HIGHLIGHTS OF THE MEETING.

22 WE ALWAYS HAVE THE DETAILED RECORD OF THE
23 MEETING FOR EVERYTHING THAT WAS SAID, BUT THIS WAS AN
24 ATTEMPT TO REALLY CAPTURE HIGH POINTS FOR THE MEETING.
25 WE'VE HAD QUITE A BIT OF INTEREST IN THIS REPORT. IT'S

BARRISTERS' REPORTING SERVICE

1 BEEN A GOOD RESOURCE FOR STATES, AND A NUMBER OF
2 ACADEMICS HAVE ASKED TO HAVE COPIES. AND I THINK AS
3 ELONA MENTIONED YESTERDAY, WHEN SHE FIRST STARTED, THE
4 FIRST THING SHE ASKED ME IS WHAT HAVE YOU ALL BEEN
5 DOING IN THE AREA OF CLINICAL TRIALS? WHAT HAVE THE
6 DISCUSSIONS BEEN LIKE? AND IT WAS GREAT TO BE ABLE TO
7 OFFER HER THIS REPORT. AND I THINK, AS SHE INDICATED
8 YESTERDAY, IT WAS A USEFUL STARTING POINT FOR HER WORK,
9 WHICH HAS SUBSEQUENTLY LED TO THE COLLABORATION WITH
10 FDA WHICH SHE DESCRIBED YESTERDAY. SO THAT HAS PROVEN
11 TO BE, I HOPE, A USEFUL RESOURCE.

12 IN ADDITION, I'D LIKE TO MENTION WE HAD IN
13 JUNE 30TH, THE BEGINNING OF JULY OF THIS YEAR, WE PUT
14 TOGETHER A WORKSHOP FOR INSTITUTIONS THAT ARE IN THE
15 STEM CELL, THAT HAVE CIRM FUNDING, AND HAVE SET UP
16 OVERSIGHT AND COMPLIANCE PROGRAMS PURSUANT TO OUR
17 REGULATIONS. AND THE PURPOSE OF THIS WORKSHOP, IF YOU
18 REMEMBER, WE'VE HAD A NUMBER OF REPORTS THAT WE'VE
19 BROUGHT BACK TO YOU OVER THE YEARS. I'VE SORT OF
20 DESCRIBED A BROADER EVALUATION INITIATIVE THAT WE
21 MAINTAIN ON AN ONGOING BASIS. AND THE PURPOSE OF THIS
22 INITIATIVE IS REALLY TO HAVE A SORT OF FULL CIRCLE
23 FEEDBACK LOOP FOR OUR REGULATIONS AND OUR POLICIES.
24 AND IT'S REALLY BASED ON THE IDEA THAT GOOD POLICY
25 NEEDS AN EVIDENCE BASE, AND FROM THAT EVIDENCE BASE,

BARRISTERS' REPORTING SERVICE

1 THAT EVIDENCE AS A RESULT OF SORT OF CIRCULAR PROCESS
2 WHERE YOU REACH OUT TO THE PARTIES THAT ARE HAVING TO
3 DO DEAL WITH YOUR REGULATIONS, YOU LEARN FROM THAT, YOU
4 BRING IT BACK TO BODIES LIKE THIS, AND YOU CONTINUE TO
5 SORT OF EVALUATE.

6 SO THE WORKSHOP WAS, I THOUGHT, VERY
7 INFORMATIVE. THERE WERE 13 INSTITUTIONS PRESENT. WE
8 HAD THREE MEMBERS OF THE WORKING GROUP PARTICIPATE IN
9 THE WORKSHOP AS WELL. ANN AND ALTA WERE PRESENT AT THE
10 WORKSHOP, AND TED PETERS WAS THERE AS WELL. IT LED TO
11 SOME VERY LIVELY DISCUSSION. I THINK ONE OF THE THINGS
12 I REALLY TOOK AWAY FROM THE WORKSHOP THAT I THOUGHT WAS
13 VERY INTERESTING IS I THINK YOU MIGHT HAVE A SENSE, IF
14 YOU BRING TOGETHER A BUNCH OF GRANTEES AND REGULATED
15 PARTIES, THAT THEY MIGHT SORT OF GENERALLY WANT TO BE
16 MAKING THE CASE THAT LESS IS MORE, BUT IT WAS VERY
17 INTERESTING. THERE WERE A NUMBER OF INSTITUTIONS THAT
18 REALLY SPOKE TO WHAT THEY SAW AS THE VALUE OF
19 OVERSIGHT.

20 CHAIRMAN LO: HI. I JUST WANTED TO CHECK AND
21 SEE WHO JOINED THE CALL. IS THIS LANA?

22 MS. GABOIS: THIS IS ELLEN GABOIS FROM THE
23 NIH. LANA WILL BE CALLING IN SEPARATELY.

24 CHAIRMAN LO: OKAY. FINE. THANKS. WELCOME.
25 I JUST WANT TO MAKE SURE WE KNOW WHEN LANA JOINS US AND

BARRISTERS' REPORTING SERVICE

1 WE'LL BREAK OFF.

2 DR. LOMAX: I THINK A NUMBER OF INSTITUTIONS
3 REALLY SPOKE TO THE VALUE OF THE OVERSIGHT PROCESS,
4 PARTICULARLY THE STEM CELL RESEARCH OVERSIGHT
5 COMMITTEES. THERE WERE SOME EXTRAORDINARILY DETAILED
6 PRESENTATIONS ABOUT HOW THE INSTITUTIONS HAVE ACTUALLY
7 OPERATIONALIZED, IF YOU WILL, THE COMPLIANCE PROCESS
8 DOWN TO THE PARTICIPANTS SEEING VERY SPECIFIC DECISION
9 TREES AND FLOW CHARTS. IN ONE EXAMPLE ONE OF OUR
10 INSTITUTIONS DESCRIBED AN ELECTRONIC SYSTEM THAT REALLY
11 WALKS THE INVESTIGATORS THROUGH THE COMPLIANCE PROCESS.

12 SO THIS WAS ALL, I THINK, VERY REASSURING FOR
13 US IN THE SENSE THAT WE'RE REALLY SEEING IMPLEMENTATION
14 TAKE PLACE AND GETTING THE RESOURCES TO --

15 CHAIRMAN LO: LET ME JUST CHECK AND SEE. HI.
16 CAN THOSE OF YOU JUST JOINED, PLEASE TELL US WHO YOU
17 ARE.

18 DR. LANDIS: STORY LANDIS JUST JOINED.

19 CHAIRMAN LO: THANKS.

20 DR. LANDIS: LANA SKIRBALL WILL BE JOINING.
21 SHE IS ACTUALLY ILL AT HOME, BUT AGREED TO PARTICIPATE
22 IN THE CALL FROM HOME.

23 CHAIRMAN LO: WE'RE SORRY TO HEAR THAT. AS
24 SOON AS SHE JOINS, WE WILL BREAK OFF THE STAFF REPORT
25 WE'RE NOW DOING AND HAVE HER SPEAK TO US.

BARRISTERS' REPORTING SERVICE

1 DR. SKIRBALL: I'M HERE NOW. AND I'M SORRY.
2 I'M BARELY UNDERSTANDABLE, SO I'M GOING TO LET DR.
3 LANDIS DO THE SPEAKING TODAY, BUT I'LL HOP IN IF I NEED
4 TO. THANK YOU.

5 MS. CHARO: LANA, YOU SOUND TERRIBLE. WE'RE
6 SORRY TO HEAR YOU'RE SICK.

7 DR. SKIRBALL: AND YOU'RE VERY GLAD I'M NOT
8 THERE.

9 CHAIRMAN LO: LET ME JUST, FOR THOSE IN THE
10 ROOM, FORMALLY INTRODUCE LANA SKIRBALL, WHO'S THE
11 ASSOCIATE DIRECTOR OF NIH FOR SCIENCE POLICY, AND STORY
12 LANDIS IS THE DIRECTOR OF ONE OF THE INSTITUTES AT NIH,
13 NINDS, AND SHE IS TAKING THE SCIENTIFIC LEAD FOR STEM
14 CELL RESEARCH WITHIN NIH. AND SO WE WERE VERY MUCH
15 LOOKING FORWARD TO AN UPDATE ON THE NIH GUIDELINES FOR
16 HUMAN STEM CELL SEARCH THAT STORY'S GROUP HAS BEEN
17 WORKING VERY HARD ON AND WHICH ARE THE NATIONAL
18 GUIDELINES FOR ELIGIBILITY FOR NIH FUNDING FOR WORKING
19 WITH STEM CELL LINES DERIVED FROM EMBRYOS REMAINING
20 AFTER A WOMAN OR COUPLE IN IVF HAS COMPLETED THEIR
21 REPRODUCTIVE TREATMENT.

22 SO LET ME JUST TURN IT OVER TO LANA OR STORY,
23 AND WE LOOK FORWARD TO HEARING A LITTLE BIT ABOUT WHAT
24 YOU ARE DOING WITH THESE GUIDELINES WHICH HAVE BEEN
25 ISSUED IN REALLY QUITE REMARKABLE TIME.

BARRISTERS' REPORTING SERVICE

1 DR. LANDIS: AS I'M SURE YOU ALL KNOW, WE, AT
2 THE REQUEST OF THE PRESIDENT, HIS EXECUTIVE ORDER, WERE
3 ASKED TO DEVELOP GUIDELINES THAT WOULD DIRECT -- ARE
4 YOU ALL HEARING THE SAME ECHO THAT I AM?

5 MS. LANSING: NO. WE HEAR YOU PERFECTLY.

6 MS. LANDIS: WE WERE ASKED TO COME UP WITH
7 GUIDELINES THAT WOULD ALLOW NIH TO FUND A BROADER RANGE
8 OF RESEARCH USING HUMAN EMBRYONIC STEM CELLS THAT WOULD
9 BE BOTH RESPONSIBLE AND SCIENTIFICALLY WORTHY. AND SO
10 WE FOCUSED ON DEVELOPING A DRAFT SET OF GUIDELINES.
11 AND IN DOING THAT, A PRETTY LARGE TEAM AT NIH --

12 CHAIRMAN LO: STORY, CAN I INTERRUPT YOU A
13 MINUTE. SOMEONE MADE A SUGGESTION. IF ALL OF US IN
14 THE ROOM TURN OFF THE MICROPHONES AT OUR POSITIONS,
15 THAT MAY CUT DOWN THE ECHO THAT STORY AND LANA ARE
16 HEARING. WHILE STORY IS SPEAKING, LET'S KEEP THEM OFF
17 SO THAT SHE DOESN'T HEAR THIS ECHO THAT SHE'S BEEN
18 HEARING.

19 DR. LANDIS: SO WHEN WE BEGAN TO THINK ABOUT
20 PUTTING TOGETHER THE GUIDELINES, WE HAD THE ADVANTAGE
21 OF THE NIH GUIDELINES THAT HAD BEEN PUT TOGETHER IN
22 1999, BUT NEVER IMPLEMENTED AND THE ABILITY TO LOOK AT
23 THE NATIONAL ACADEMY OF SCIENCES GUIDELINES THAT WERE
24 PRODUCED IN 2005, REVISED IN 2007-2008, AND THE
25 INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH GUIDELINES

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1 AND OTHERS, INCLUDING THOSE THAT CIRM HAD PRODUCED.

2 AND I HAVE TO SAY, AS WE PUT TOGETHER THOSE
3 GUIDELINES, AS WE PUT TOGETHER THE DRAFT GUIDELINES, WE
4 HAD ASSUMED, I THINK QUITE REASONABLY, THAT
5 INVESTIGATORS WOULD HAVE BEEN ADHERING PRETTY CLOSELY
6 TO THOSE GUIDELINES THAT HAD COME OUT. AND SO THE
7 GUIDELINES -- INITIAL DRAFT GUIDELINES WERE, I THINK,
8 PRETTY PRESCRIPTIVE AND HAD CLEAR STATEMENTS ABOUT WHAT
9 THE INFORMED CONSENT PROCESS SHOULD LOOK LIKE AND OTHER
10 PRETTY DEFINED IDEAS ABOUT HOW THIS WOULD GO FORWARD.

11 WHEN WE OPENED UP THOSE DRAFT GUIDELINES FOR
12 COMMENTS, WE GOT 49,000 COMMENTS. AND MANY MEMBERS OF
13 THE TEAM AT NIH WENT THROUGH EVERY SINGLE ONE OF THOSE.
14 NOT EVERY PERSON ON THE TEAM WENT THROUGH EVERY
15 COMMENT, BUT A NUMBER OF THE PEOPLE WENT THROUGH THOSE
16 COMMENTS. AND WE PAID SPECIAL ATTENTION TO THOSE
17 COMMENTS THAT HAD SUBSTANTIVE NOTIONS ABOUT HOW OUR
18 GUIDELINES, OUR DRAFT GUIDELINES, COULD BE IMPROVED.
19 AND I THINK WE LEARNED AN INCREDIBLE AMOUNT FROM THE
20 COMMUNITY, BOTH THE PATIENT AND ADVOCACY COMMUNITIES
21 AND THE SCIENTIFIC COMMUNITIES AND PEOPLE WHO WERE
22 WORKING WITH STEM CELLS.

23 SO IT WAS A VERY USEFUL PROCESS. AS A
24 CONSEQUENCE OF THAT INPUT, WE MADE SEVERAL SIGNIFICANT
25 CHANGES TO OUR DRAFT GUIDELINES AS WE PUT TOGETHER THE

BARRISTERS' REPORTING SERVICE

1 FINAL GUIDELINES. ONE OF THE IMPORTANT CHANGES WAS
2 THAT WE HEARD FROM INVESTIGATORS AND INSTITUTIONS THAT
3 IT WOULD BE MOST USEFUL IF THERE WERE A SINGLE NIH
4 REGISTRY, A NEW REGISTRY, THAT WOULD LIST ALL THE LINES
5 THAT WERE AVAILABLE FOR NIH FUNDING. AND ONCE THAT
6 IDEA OF A REGISTRY BECAME A PART OF THE PLAN, IT ALSO
7 BECAME CLEAR THAT THERE WOULD HAVE TO BE CENTRAL REVIEW
8 BY NIH OF THE ELIGIBILITY OF LINES FOR NIH FUNDING.

9 AND WHILE PEOPLE HAD COMMENTED ABOUT THE
10 POSSIBILITY OF HAVING LOCAL IRB REVIEWS OR REVIEWS BY
11 ESCRO'S, AS SOON AS YOU HAVE A CENTRAL REGISTRY, AN NIH
12 REGISTRY, IT ALMOST REQUIRES THAT THERE BE CENTRAL
13 REVIEW.

14 AND THEN THE LAST MAJOR POINT WAS THAT IT
15 BECAME VERY CLEAR THAT WE NEEDED TO ADDRESS THE ISSUE
16 OF EMBRYOS DONATED BEFORE THESE GUIDELINES BECAME
17 EFFECTIVE AND THAT WE ALSO NEEDED TO ADDRESS THE ISSUE
18 OF DONATIONS FROM OTHER COUNTRIES.

19 SO THE FIRST HUMAN EMBRYONIC STEM CELL LINES
20 WERE CREATED IN 1998 BY JAMIE THOMSON, AND IT'S LIKELY,
21 ALTHOUGH WE DON'T KNOW THIS FOR SURE, THAT THE INFORMED
22 CONSENT PROCESSES AND THE PROCEDURES ASSOCIATED WITH
23 DONATION OF THE EMBRYOS FOR THOSE LINES AND LINES THAT
24 WERE -- EMBRYOS DONATED IN LINES THAT WERE CREATED
25 AFTER THAT WOULD HAVE BEEN RESPONSIBLE, THE DONATIONS

BARRISTERS' REPORTING SERVICE

1 AND THE GENERATION OF THE LINES, BUT THAT BECAUSE
2 THERE'S BEEN EVOLUTION OF INFORMED CONSENT PROCESSES
3 AND ACTUAL DOCUMENTS, THAT THOSE LINES, ALTHOUGH
4 RESPONSIBLY DERIVED, MIGHT WELL NOT MEET THE SPECIFICS
5 INCLUDED IN OUR GUIDELINES.

6 SO THAT MEANT THAT THERE WOULD BE AN
7 OPPORTUNITY FOR LINES GENERATED IN THE STATES BEFORE
8 THE GUIDELINES BECAME EFFECTIVE ON JULY 7TH TO BE
9 REVIEWED BY A SPECIAL WORKING GROUP OF THE ADVISORY
10 COMMITTEE TO THE DIRECTOR THAT WOULD LOOK AT THE
11 PROCESSES THAT WERE IN PLACE AND DETERMINE THAT THE
12 DONATION AND SUBSEQUENT DERIVATION WAS RESPONSIBLE.

13 WE ALSO RECOGNIZED THAT WE IN THE U.S. HAVE
14 NO AUTHORITY TO INSTRUCT INVESTIGATORS IN FOREIGN
15 COUNTRIES ABOUT THE PROCESSES OF DONATION AND THAT WE
16 NEEDED TO BE ABLE TO ENABLE RESEARCH TO BE FUNDED BY
17 NIH ON DONATIONS FROM FOREIGN COUNTRIES, AND SO
18 DONATIONS MADE BOTH BEFORE AND AFTER THE GUIDELINES
19 BECAME EFFECTIVE ON JULY 7TH COULD BE REVIEWED BY THIS
20 SPECIAL MECHANISM.

21 NOW, OUR EXPECTATION IS THAT NOW THAT THE
22 GUIDELINES ARE OUT, THAT ALL DONATIONS MADE IN THIS
23 COUNTRY OF EMBRYOS WILL MEET THE SPECIFICS OF THE
24 PROCEDURES THAT WE'VE INCLUDED IN THE GUIDELINES.

25 SO THE NEXT STEP OBVIOUSLY IS ENABLING

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1 INVESTIGATORS AND PEOPLE WHO ARE DERIVING HUMAN
2 EMBRYONIC STEM CELL LINES TO ACTUALLY GET THE APPROVAL
3 AND LISTING ON THE REGISTRY OF LINES. AND FOR THOSE OF
4 YOU WHO FOLLOW THIS, WE SEVERAL WEEKS AGO POSTED A WEB
5 SITE THAT OUTLINES THE PROCEDURES FOR SUBMITTING THE
6 INFORMATION ABOUT THE DONATIONS AND DERIVATION FOR
7 CONSIDERATION BY EITHER AN ADMINISTRATIVE REVIEW, IF
8 THEY MEET THE SPECIFICS OF SECTION 2(A), OR FOR REVIEW
9 BY THE WORKING GROUP OF THE ADVISORY COMMITTEE OF THE
10 DIRECTOR, AND THE PEOPLE WHO DERIVED OR ARE GOING TO
11 USE THE LINES IF THEY FEEL THAT THEY DON'T MEET THE
12 SPECIFIC REQUIREMENTS OF SECTION 2(A).

13 WE HOPE, PLAN THAT THE SITE WILL BE ACTIVE
14 VERY SOON AND THAT THE MEMBERS OF THE WORKING GROUP OF
15 THE ADVISORY COMMITTEE TO THE DIRECTOR WILL BE NAMED
16 SHORTLY. I CAN'T GIVE YOU A SPECIFIC DATE.

17 SO I'D BE WILLING TO TAKE QUESTIONS OR
18 COMMENTS. LANA, DO YOU WANT TO ADD ANYTHING?

19 CHAIRMAN LO: OKAY. THANKS VERY MUCH, STORY.
20 ANY QUESTIONS, COMMENTS FOR DR. LANDIS AND DR. SKIRBALL
21 FROM MEMBERS OF THE PANEL? OUR MICS HAVE BEEN TURNED
22 ON AGAIN, SO THERE MAY BE AN ECHO, BUT THAT'S THE ONLY
23 WAY THE PEOPLE ON THE CONFERENCE CAN HEAR WHAT WE SAY.
24 ANN KIESSLING. YOU WANT TO JUST INTRODUCE YOURSELF SO
25 THAT THEY KNOW WHO IS SPEAKING.

BARRISTERS' REPORTING SERVICE

1 DR. KIESSLING: THIS IS ANN KIESSLING. I'M A
2 MEMBER OF THE STANDARDS WORKING GROUP. THANK YOU VERY
3 MUCH FOR YOUR EXPLANATION, DR. LANDIS. ONE OF THE
4 THINGS THAT I'M WONDERING IS IF THE SCIENTISTS NOW
5 APPLY FOR NIH FUNDING FOR STEM CELL LINES THAT THEY
6 HAVE BEEN USING FOR SOME TIME THAT WERE POSTED ON THE
7 NIH REGISTRY, WHAT HAPPENS TO THOSE GRANT APPLICATIONS
8 BEFORE THIS WORKING GROUP IS CONVENED?

9 DR. LANDIS: SO THE DECISION WAS MADE THAT
10 ANY GRANT THAT WAS ALREADY FUNDED USING THE BUSH LINES,
11 THAT THAT WORK COULD CONTINUE UNTIL THE GRANT WAS
12 COMPLETED. FOR GRANTS THAT WOULD BE SUBMITTED TO USE
13 HUMAN EMBRYONIC STEM CELLS IN THE INTERIM BETWEEN THE
14 TIME THAT THE EXECUTIVE ORDER CAME OUT AND THIS NEW
15 POLICY IS FULLY IMPLEMENTED, WE ARE ALLOWING
16 INVESTIGATORS TO SUBMIT GRANTS AND FOR THOSE GRANTS TO
17 BE REVIEWED, BUT THE GRANTS WILL HAVE TO BE WRITTEN IN
18 SUCH A WAY THAT SPECIFIC LINES HAVE NOT BEEN
19 IDENTIFIED. AND THOSE LINES CAN THEN -- AND ONCE THE
20 REVIEW HAS HAPPENED AND THE DECISION HAS BEEN MADE TO
21 FUND, THE INVESTIGATORS WILL IN A JUST-IN-TIME FASHION
22 ADD SPECIFICS ON THE LINES THAT WILL BE STUDIED.

23 SO IT'S OBVIOUSLY REALLY IMPORTANT FOR PEOPLE
24 TO BE SUBMITTING LINES FOR CONSIDERATION, WHICH WE HOPE
25 THEY'LL BE ABLE TO DO SOON, AND FOR THOSE LINES TO BE

BARRISTERS' REPORTING SERVICE

1 CONSIDERED BY THE WORKING GROUP AND THEN
2 RECOMMENDATIONS BE MADE FROM THE WORKING GROUP TO THE
3 ADVISORY COMMITTEE, TO THE DIRECTOR, AND THEN TO THE
4 NIH DIRECTOR. WE ARE OPTIMISTIC THAT LINES WILL BE
5 IDENTIFIED AS ELIGIBLE IN THE NEXT SEVERAL MONTHS. SO
6 WE ARE ACCEPTING APPLICATIONS, THEY WILL BE REVIEWED,
7 BUT THE FUNDING -- AND THEY CAN BE FUNDED, BUT THE
8 FUNDS WILL BE RESTRICTED UNTIL LINES HAVE BEEN
9 IDENTIFIED.

10 DR. KIESSLING: THANK YOU. I HAVE ONE
11 FOLLOW-UP QUESTION. RIGHT NOW HOW MANY ONGOING NIH
12 PROJECTS DO YOU THINK THERE ARE THAT WERE APPROVED
13 PRIOR TO THE EXECUTIVE ORDER? HOW MANY ONGOING
14 PROJECTS DO YOU HAVE THAT ARE NIH FUNDED?

15 DR. LANDIS: I ACTUALLY DON'T HAVE THAT
16 NUMBER. I'M SORRY.

17 DR. KIESSLING: DO YOU GUESS IT'S TENS,
18 HUNDREDS, THOUSANDS?

19 DR. LANDIS: THE SIMPLEST -- THE NUMBER THAT
20 I CAN GIVE YOU IS LAST YEAR NIH FUNDED \$88 MILLION OF
21 HUMAN EMBRYONIC STEM CELL RESEARCH. AND THAT'S
22 PROBABLY REPRESENTING HUNDREDS OF GRANTS.

23 DR. KIESSLING: THANK YOU.

24 CHAIRMAN LO: ANY OTHER QUESTIONS OR COMMENTS
25 FOR DR. LANDIS? ALTA.

BARRISTERS' REPORTING SERVICE

1 MS. CHARO: THIS IS ALTA CHARO. IS THERE --
2 I REMEMBER YOU TALKING AT ONE OF THE PUBLIC SESSIONS
3 WITH THE NATIONAL ACADEMIES ABOUT HAVING SOME
4 LABORATORY KIND OF DO A TEST RUN THROUGH THIS PROCESS.
5 IS THAT STILL SOMETHING THAT YOU GUYS ARE PLANNING TO
6 DO?

7 DR. LANDIS: WE HAVE HAD A NUMBER -- SO THE
8 DIRECTIONS FOR HOW TO SUBMIT DONATED EMBRYOS AND LINES
9 FOR CONSIDERATION HAVE BEEN UP FOR SEVERAL WEEKS. AND
10 I AM SURE THAT INVESTIGATORS HAVE LOOKED AT THAT AND
11 BEGUN TO MARSHAL THEIR MATERIALS. WE'VE ALSO RUN DRY
12 RUNS ON THE SITE WITH PEOPLE WHO HAD ACCESS TO THE SITE
13 TO FIGURE OUT IF THERE WERE ANY GLITCHES IN THE WAY THE
14 SOFTWARE WOULD WORK. SO WE'RE LOOKING VERY CAREFULLY
15 AT THE SITE AND HOW IT WORKS AND ASSUME INVESTIGATORS
16 ARE DOING THAT AS WELL, PEOPLE WHO MIGHT ASK TO HAVE
17 LINES TO BE CONSIDERED.

18 MS. CHARO: THANKS.

19 CHAIRMAN LO: ROB TAYLOR.

20 DR. TAYLOR: YES. I'VE ACTUALLY GOT A
21 QUESTION ABOUT THE KIND OF INTERIM POLICY AND THE
22 JUST-IN-TIME MECHANISM. SO IT WOULD SEEM TO ME THAT
23 THE APPLICATIONS WOULD ALMOST HAVE TO BE SOMEWHAT
24 GENERIC IF IT ISN'T CERTAIN WHETHER A PARTICULAR STEM
25 CELL LINE WILL ULTIMATELY BE APPROVED. IS THAT FAIR TO

BARRISTERS' REPORTING SERVICE

1 SAY? AND HOW WILL YOU ACTUALLY SCIENTIFICALLY JUDGE A
2 PROJECT FOR WHICH A SPECIFIC STEM CELL LINE MIGHT NOT
3 BECOME AVAILABLE?

4 DR. LANDIS: THIS IS A VERY INTERESTING
5 QUESTION. THE REVIEW COMMITTEE -- SO I SHOULD BACK UP
6 AND SAY THAT REVIEWS WERE DONE ON GO GRANTS. THESE ARE
7 THE GRAND OPPORTUNITY GRANTS THAT WERE SUBMITTED IN
8 RESPONSE TO THE ARRA SOLICITATION THAT INCLUDED HUMAN
9 EMBRYONIC STEM CELLS. THEY WERE REVIEWED, THEY HAVE
10 BEEN SCORED, THERE ARE A NUMBER OF THEM THAT WILL BE
11 FUNDED. AND EVEN THOUGH THE SPECIFIC LINES THAT WOULD
12 BE UTILIZED CAN'T YET BE IDENTIFIED, AND THE PROCESS
13 THAT WILL HAPPEN IS THAT THOSE FUNDS WILL BE
14 RESTRICTED, EVEN THOUGH THE GRANT HAS BEEN AWARDED, THE
15 FUNDS WILL BE RESTRICTED UNTIL SPECIFIC LINES CAN BE
16 IDENTIFIED BECAUSE THEY'RE ON THE REGISTRY.

17 THERE WILL BE A REVIEW NEXT WEEK OF THE
18 CHALLENGE GRANTS, OVER A HUNDRED CHALLENGE GRANTS THAT
19 INCLUDED HUMAN EMBRYONIC STEM CELL RESEARCH. AND IN
20 BOTH OF THOSE CASES, THE REVIEW COMMITTEES WERE
21 INSTRUCTED TO NOT FOCUS ON THE SPECIFIC ATTRIBUTES OF
22 THE LINES THAT WOULD BE STUDIED.

23 NOW, I THINK FOR GENERIC BIOLOGY OF HUMAN
24 EMBRYONIC STEM CELLS, FOR COMPARISONS OF HUMAN
25 EMBRYONIC STEM CELLS AND INDUCED PLURIPOTENT STEM

BARRISTERS' REPORTING SERVICE

1 CELLS, WHICH IS OBVIOUSLY A VERY HOT SCIENTIFIC TOPIC,
2 THAT WILL WORK FINE. AS PEOPLE BEGIN TO REALIZE THAT
3 THEY COULD USE HUMAN EMBRYONIC STEM CELL LINES THAT
4 BEAR SPECIFIC HUMAN MUTATIONS, THAT OBVIOUSLY IS GOING
5 TO REQUIRE THE IDENTIFICATION OF THE SPECIFIC LINES AND
6 THE AWARENESS THAT THOSE LINES ACTUALLY EXIST.

7 BECAUSE OF THE TIMING OF THE EXECUTIVE ORDER,
8 I THINK PEOPLE ARE JUST NOW -- I ASSUME SCIENTISTS ARE
9 JUST NOW BEGINNING TO DEVISE EXPERIMENTAL STUDIES FOR
10 WHICH THEY WOULD WRITE GRANT APPLICATIONS AND WOULD BE
11 SUBMITTING THEM. IT IS AN AWKWARD INTERIM TIME, BUT I
12 THINK THAT THE BENEFIT, CLEAR BENEFIT OF HAVING AN
13 EXPANSION IN THE ABILITY OF SCIENTISTS TO USE
14 ADDITIONAL LINES, LINES CURRENTLY BEING DERIVED AND
15 WITH DISEASE MUTATIONS, SIGNIFICANTLY OUTWEIGHS THIS
16 AWKWARD INTERIM PERIOD.

17 CHAIRMAN LO: ANY OTHER QUESTIONS? STORY,
18 COULD I ASK YOU A QUESTION AND ASK YOU AS AN EMINENT
19 SCIENTIST TO JUST COMMENT A LITTLE BIT ON THE
20 DESIRABILITY OF HARMONIZATION BETWEEN NIH GUIDELINES
21 AND OTHER REGULATIONS SUCH AS CALIFORNIA REGULATIONS?
22 AND TO ALSO ADDRESS IT IN THE NEGATIVE, WHAT WOULD BE
23 THE IMPACT ON SCIENCE IF THERE WERE LINES THAT WERE
24 APPROVED FOR NIH FUNDING, BUT COULD NOT BE USED IN A
25 CERTAIN LABORATORY BECAUSE OF EITHER STATE REGULATIONS

BARRISTERS' REPORTING SERVICE

1 OR FUNDING RESTRICTIONS? IF YOU COULD HELP US
2 UNDERSTAND AS BACKGROUND, IT WOULD BE HELPFUL.

3 DR. LANDIS: TO BE PERFECTLY HONEST, THE
4 ISSUE OF HARMONIZATION IS ONE OF THE REASONS WHY WE
5 WENT TO A CENTRAL REVIEW AND A SINGLE NIH REGISTRY. WE
6 ENVISIONED IF THERE WERE APPROVAL OF LINES AT LOCAL
7 IRB'S, WHICH WAS A SUGGESTION MADE BY A NUMBER OF
8 PEOPLE IN THE COMMUNITY, AND CERTAINLY SOMETHING THAT
9 WE CONSIDERED BECAUSE IT WOULD BE WITHIN THE PURVIEW OF
10 IRB'S TO REVIEW THIS KIND OF RESEARCH, THE POSSIBILITY
11 THAT LINES MIGHT BE APPROVED BY IRB'S IN PENNSYLVANIA,
12 BUT NOT IN CALIFORNIA, OR IN CALIFORNIA, BUT NOT IN
13 ARKANSAS. SO WE RECOGNIZE THE NEED TO HAVE A
14 RELATIVELY UNIFORM SET OF GUIDELINES.

15 I ASSUME THAT EACH OF THE STATES IS NOW
16 LOOKING AT AND FUNDING ORGANIZATIONS IS LOOKING AT
17 THEIR GUIDELINES AND THE NIH GUIDELINES AND SEEING
18 WHERE THERE ARE DISCREPANCIES AND HOW THOSE
19 DISCREPANCIES MIGHT BE DEALT WITH.

20 CHAIRMAN LO: JUST A FOLLOW-UP. COULD YOU
21 SAY A LITTLE BIT ABOUT THE SCIENTIFIC VALUE IN HAVING
22 SOME DEGREE OF UNIFORMITY AND CONVERSELY HOW STEM CELL
23 SCIENCE MIGHT BE SET BACK BY LARGE DISCREPANCIES?

24 DR. LANDIS: WELL, WE'VE OBVIOUSLY SEEN FOR
25 THE PAST EIGHT, ALMOST NINE YEARS THE CONSEQUENCE OF

BARRISTERS' REPORTING SERVICE

1 DISCREPANCIES IN THAT NIH WAS ONLY ABLE TO FUND
2 RESEARCH ON 21 LINES; WHEREAS, A NUMBER OF STATES
3 SUPPORTED RESEARCH ON A MUCH BROADER RANGE. NOW, THE
4 FACT THAT THE STATES WERE ABLE TO DO THAT HAS MEANT
5 THAT THE SUPPORT OF STEM CELL RESEARCH HAS BEEN GREATER
6 THAN IT WOULD HAVE BEEN, AND STATES HAVE BEEN ABLE TO
7 CONTRIBUTE AS WELL AS PRIVATE ORGANIZATIONS IN A VERY
8 SUBSTANTIAL WAY.

9 SO I THINK ONE OF THE NEGATIVE CONSEQUENCES
10 HAS BEEN THE PERCEIVED REQUIREMENT OF SEPARATE
11 FACILITIES, DIFFICULTY IN COLLABORATIONS THAT MIGHT
12 EXIST BETWEEN PEOPLE IN STATES WHERE THERE WAS FUNDING
13 FOR LINES NOT ELIGIBLE FOR NIH VERSUS STATES WHERE ONLY
14 NIH-FUNDED LINES COULD BE STUDIED. I THINK TO THE
15 EXTENT THAT WE CAN HARMONIZE THE RULES AND REGULATIONS
16 AND THAT THERE'S CONSISTENCY, IT WILL CERTAINLY PROMOTE
17 MORE AND BETTER SCIENCE. AND I THINK AS WE GO FORWARD,
18 IT WILL BE VERY IMPORTANT TO LOOK AT THE CONSISTENCIES
19 AND INCONSISTENCIES.

20 MS. CHARO: STORY, THIS IS ALTA. JUST TO
21 EXPAND ON THAT A LITTLE BIT, ONE OF THE THINGS THAT HAD
22 CONCERNED THE NATIONAL ACADEMIES ALL THOSE YEARS AGO
23 WAS INTERCHANGEABILITY OF LINES AND PROSPECTS FOR
24 COLLABORATIVE RESEARCH. I SAW A NEWS BLIP THIS MORNING
25 ABOUT CIRM COLLABORATING WITH GERMANY, FOR EXAMPLE, ON

BARRISTERS' REPORTING SERVICE

1 RESEARCH. DO YOU HAVE ANY FURTHER THOUGHTS ABOUT THE
2 LEVEL OF INTERCHANGEABILITY THAT WE MIGHT BE ABLE TO
3 SEE BECAUSE OF THE NIH GUIDELINES OR WHAT KINDS OF
4 SPECIFIC CHANGES YOU NEED IN STATE AND NATIONAL RULES
5 TO MAKE THAT POSSIBLE?

6 DR. LANDIS: I THINK IT'S REALLY HARD IN THE
7 ABSTRACT TO CONSIDER THAT. I THINK IT WILL BE MUCH
8 MORE STRAIGHTFORWARD ONCE THE NIH PROCESS IS UNDER WAY
9 AND WE UNDERSTAND HOW THE WORKING GROUP OF THE ACD IS
10 GOING TO FUNCTION, WHAT LINES GET IDENTIFIED AS
11 ELIGIBLE AND WHICH LINES DON'T. AND AS YOU KNOW, IT'S
12 POSSIBLE FOR BOTH THE STATES AND THE NIH, IF IT'S
13 APPROPRIATE OR NECESSARY, AT LEAST FOR THE NIH TO
14 RELOOK AT OUR GUIDELINES.

15 MS. CHARO: THANK YOU.

16 CHAIRMAN LO: ANY OTHER COMMENTS OR QUESTIONS
17 FOR DR. LANDIS? STORY, I WANT TO THANK YOU ON BEHALF
18 OF THE COMMITTEE MEMBERS AND THE PUBLIC WHO'S IN THE
19 AUDIENCE, NOT JUST FOR THIS PRESENTATION, BUT FOR
20 REALLY THE LEADERSHIP THAT YOU AT NIH HAVE TAKEN SINCE
21 THE LAST ELECTIONS IN SORT OF MOVING STEM CELL RESEARCH
22 VERY QUICKLY AND VERY THOUGHTFULLY TO THE FOREFRONT OF
23 THE NIH AGENDA. WE LOOK FORWARD. I KNOW YOU AND YOUR
24 STAFF ARE WORKING VERY HARD, AND WE LOOK FORWARD TO
25 CONTINUED DEVELOPMENTS FROM NIH.

BARRISTERS' REPORTING SERVICE

1 AND, LANA, OUR BEST WISHES FOR YOUR SPEEDY
2 RECOVERY AND HOPE YOU GET A GOOD REST AND FEEL BETTER
3 SOON.

4 DR. LANDIS: ACTUALLY BEFORE WE HANG UP, I
5 WANT TO SAY THAT ALL THESE EFFORTS HAVE BEEN A
6 COLLABORATIVE EFFORT BETWEEN THE OFFICE OF SCIENCE
7 POLICY AT NIH HEADED BY LANA SKIRBALL, THE OFFICE OF
8 EXTRAMURAL RESEARCH HEADED BY SALLY ROCKE, AS WELL AS
9 THE SCIENTIFIC COMMUNITY AT NIH, AND THE COMMENTS THAT
10 WE GOT FROM THE BROAD SCIENTIFIC COMMUNITY AND ADVOCACY
11 COMMUNITY ABOUT CHANGES TO THE ORIGINAL DRAFT
12 GUIDELINES HAVE MADE IT POSSIBLE FOR US TO DO AS WELL
13 AS WE HAVE. SO THANK YOU.

14 CHAIRMAN LO: THANKS VERY MUCH.

15 DR. SKIRBALL: THANK YOU VERY MUCH. I WOULD
16 ADD ONE THING, THAT AS WE OPEN UP THE WEB SITE AND THE
17 ACD WORKING GROUP BEGINS ITS WORK, PLEASE UNDERSTAND
18 NIH IS STILL LISTENING. AND THERE IS A WEB SITE FOR
19 COMMENTS, AND WE'RE HAPPY TO CONTINUE TO ENGAGE IN
20 DIALOGUE WITH REGARD TO HOW WE'RE IMPLEMENTING THIS AND
21 ANY GLITCHES ALONG THE WAY, WHICH, GIVEN THE LAW OF
22 AVERAGES, THERE WILL BE. SO THANKS FOR YOUR PATIENCE
23 AND YOUR INTEREST.

24 CHAIRMAN LO: OKAY. THANKS AGAIN. WE
25 APPRECIATE YOUR JOINING US THIS MORNING.

BARRISTERS' REPORTING SERVICE

1 GEOFF, DO YOU WANT TO PICK UP AND GO BACK TO
2 SET UP THE REST OF OUR AGENDA THIS MORNING? I'M GOING
3 TO ASK GEOFF TO GIVE US SOME BACKGROUND INFORMATION ON
4 THE POSSIBLE REVISIONS TO THE GUIDELINES THAT ARE BEING
5 PROPOSED. AND WE'LL HAVE HIM GIVE SOME BACKGROUND, AND
6 THEN ASK HANK GREELEY TO TALK ABOUT THE CALIFORNIA
7 DEPARTMENT OF PUBLIC HEALTH ADVISORY COMMITTEE'S
8 PERSPECTIVE.

9 DR. LOMAX: THANK YOU. DR. WILLERSON, DO WE
10 STILL HAVE YOU ON THE LINE?

11 DR. WILLERSON: YES. I'M HERE.

12 DR. LOMAX: ARE WE COMING ACROSS CLEARLY?

13 DR. WILLERSON: YES. THANK YOU VERY MUCH.

14 DR. LOMAX: I WAS JUST SUMMARIZING AGAIN THE
15 WORKSHOP. I THINK THE TAKE-HOME MESSAGE THERE WAS THAT
16 THE INSTITUTIONS, PARTICULARLY THE PARTICIPATING
17 INSTITUTIONS, CERTAINLY PLACE A HIGH VALUE ON
18 COMPLIANCE. AND I THINK THE VALUE THEY PLACE ON IT IS
19 REFLECTED IN SORT OF WHAT THEY BROUGHT TO THE WORKSHOP
20 IN TERMS OF DEMONSTRATING THE SYSTEMS THEY HAVE IN
21 PLACE, THE PROCEDURES, THE STAFF. IT WAS VERY
22 REASSURING.

23 THE OTHER THING I WANT TO EMPHASIZE, IN PART
24 BECAUSE I HOPE IT SORT OF HELPS FLAVOR TODAY'S
25 DISCUSSIONS, IS THAT, IN ADDITION TO THESE WORKSHOPS,

BARRISTERS' REPORTING SERVICE

1 I'VE MENTIONED TO YOU BEFORE WE HAVE A VERY ACTIVE
2 PROGRAM OF REALLY GETTING OUT IN THE FIELD AND LOOKING
3 AT THE INSTITUTIONS ON-SITE AS WELL. WHEN DR. TROUNSON
4 CAME IN, THIS WAS HIS NO. 1 PRIORITY FOR ME WAS TO
5 INITIATE THIS NEW PROGRAM.

6 AND SO WE'VE, IN ADDITION TO THE WORKSHOPS
7 AND IN ADDITION TO ALL THE WORK WE DO IN ADVANCE OF
8 FUNDING A GRANT, WE ALSO GET OUT ON-SITE, ASK A LOT OF
9 TOUGH QUESTIONS, MAKE A LOT OF RECOMMENDATIONS, AND ARE
10 REALLY LOOKING VERY CAREFULLY AT WHAT INSTITUTIONS ARE
11 DOING. AND, YOU KNOW, WITH ALL DUE RESPECT TO MY
12 COLLEAGUES AT THE DEPARTMENT OF PUBLIC HEALTH AND EVEN
13 NIH, THE PUBLIC HEALTH -- MY COLLEAGUES AT DEPARTMENT
14 OF PUBLIC HEALTH DON'T HAVE THAT IN THEIR MANDATE TO DO
15 THAT. NIH IS A LARGE INSTITUTION AND DOESN'T HAVE THE
16 CAPACITY TO DO THAT.

17 I THINK THE LOOKS THAT THE INSTITUTIONS ARE
18 GETTING FROM CIRM IS SOMEWHAT DIFFERENT AND SOMEWHAT
19 NEW, AND THEY ARE REALIZING THAT WE'RE VERY SERIOUS
20 ABOUT, NOT JUST THE MEDICAL AND ETHICAL STANDARDS, BUT
21 OUR WHOLE RANGE OF REGULATIONS AND REQUIREMENTS. AND
22 THE COMPLIANCE VISITS ARE DESIGNED SORT OF TO CAPTURE
23 THAT. SO, FOR EXAMPLE, OUR IP POLICIES, OUR
24 PUBLICATIONS ARE FORWARDING, ETC., ETC.

25 SO I WANTED TO EMPHASIZE THAT BECAUSE I WANT

BARRISTERS' REPORTING SERVICE

1 TO REALLY EMPHASIZE THAT WE'RE TAKING A VERY ACTIVE
2 ROLE HERE THAT'S, I THINK, A BIT DIFFERENT. DID YOU
3 HAVE A QUESTION, DR. CIBELLI?

4 DR. CIBELLI: IT JUST CAME OUT. WHAT IS THE
5 POWER THAT YOU HAVE TO ENFORCE THOSE THINGS? DO YOU
6 HAVE THE POWER TO SUSPEND THEIR GRANTS OR PUT THEM ON
7 HOLD?

8 DR. LOMAX: WELL, I'LL GIVE YOU ONE VERY
9 SPECIFIC EXAMPLE. RIGHT NOW I HAVE A NUMBER OF
10 QUESTIONS ABOUT A SPECIFIC APPROVAL WE'RE LOOKING AT
11 AND WHETHER THE APPROVAL THAT WE'VE SEEN IS CONSISTENT
12 WITH THE LEVEL OF REVIEW THAT WE WOULD EXPECT BASED ON
13 OUR STANDARDS. AND I'VE ASKED THAT THE GRANTS
14 ADMINISTRATION TEAM NOT MOVE FORWARD WITH THE FUNDING
15 OF THIS APPLICATION UNTIL I'VE INDICATED THAT I THINK
16 THE APPROVALS ARE SATISFACTORY. SO THAT'S ONE SPECIFIC
17 EXAMPLE, AND THERE ARE OTHER EXAMPLES LIKE THAT.

18 I MENTIONED THIS ALSO, AGAIN, THIS
19 INTERACTION, I THINK, FOR SOMEONE IN MY POSITION,
20 THERE'S ALWAYS THE -- IN THE BACK OF YOUR MIND, YOU'RE
21 ALWAYS CONCERNED ABOUT THIS NOTION OF KIND OF
22 REGULATORY CAPTURE, THAT YOU AS THE SORT OF REGULATOR
23 HAVE A CLOSE RELATIONSHIP WITH THE INSTITUTIONS THAT
24 YOU'RE REGULATING. AND I THINK THAT'S SOMETHING -- I'M
25 SENSITIVE TO THAT BECAUSE I FEEL MY ROLE WITH THIS

BARRISTERS' REPORTING SERVICE

1 WORKING GROUP HAS EVOLVED OVER TIME. WHEN I FIRST
2 STARTED THIS JOB, IT WAS SORT OF A BLANK SLATE AND WE
3 WENT THROUGH A SET OF REGULATIONS. AND I DO FEEL THAT
4 OVER TIME MY ROLE HAS EVOLVED A BIT TO WHERE AT TIMES I
5 FEEL LIKE I HAVE A LITTLE BIT MORE OF AN ADVOCACY HAT
6 ON FOR SOME OF THE POLICIES.

7 I WANT YOU ALL TO BE VERY AWARE THAT I'M
8 SENSITIVE TO THAT, BUT I'M SENSITIVE TO IT FROM THE
9 PERSPECTIVE THAT I HAVE COME TO THE FIRM BELIEF THROUGH
10 THIS PROCESS, THROUGH THIS EVALUATION, THAT THE BEST
11 WAY TO GET GOOD COMPLIANCE IS TO GET GOOD REGULATION.
12 AND GOOD REGULATION IS REGULATIONS THAT PEOPLE
13 UNDERSTAND, THEY CAN IMPLEMENT, AND THEY CAN IMPLEMENT
14 EFFECTIVELY.

15 SO I WANT TO ACKNOWLEDGE THAT NOW BECAUSE I
16 THINK IT'S IMPORTANT FOR ME TO KIND OF PUT THAT OUT
17 THERE, AND IT SORT OF SPEAKS TO MY EVOLVING ROLE WITH
18 YOU ALL.

19 MOVING FORWARD, AGAIN, WE'VE HAD THE
20 PRESENTATION FROM THE NIH. I ALSO WANT TO HIGHLIGHT
21 THE NIH MENTIONED THE FEEDBACK THEY RECEIVED FROM THE
22 COMMUNITY. ONE OF THE REPORTS THAT WE HAD AN
23 OPPORTUNITY TO BE INVOLVED WITH WAS THE REPORT FROM THE
24 INTERSTATE ALLIANCE. AND WE CIRCULATED THIS ALL OF
25 YOU, I BELIEVE, IN JUNE. AND THIS DOCUMENT, I MUST

BARRISTERS' REPORTING SERVICE

1 SAY, WAS A REALLY WONDERFUL PIECE OF WORK TO BE
2 INVOLVED WITH BECAUSE IF YOU WERE ABLE TO REVIEW THE
3 REPORT, I THINK THERE WERE 15 INSTITUTIONS SORT OF
4 NATIONALLY, INCLUDING INSTITUTIONS LIKE HARVARD
5 UNIVERSITY, WISCONSIN, NEW YORK, THE VARIOUS STATES
6 WITH STEM CELL PROGRAMS, AND WHAT WAS REALLY A PLEASURE
7 ABOUT THIS WORK WAS THAT WE ALL GOT ON BOARD AND PUT
8 OUR NAME ON A SINGLE DOCUMENT WITH A VERY NARROW SET OF
9 RECOMMENDATIONS. AND IT WAS REALLY, I THINK,
10 INTERESTING THAT REALLY IT SPEAKS, I THINK, TO WHAT'S
11 GOING ON IN THE FIELD OF STEM CELL RESEARCH AND THE
12 FIELD OF STEM CELL POLICY THAT YOU COULD GET SUCH A
13 DIVERSE GROUP OF VERY HIGH LEVEL ORGANIZATIONS AND
14 STATES TO REALLY SIGN ON TO A SINGLE SET OF
15 RECOMMENDATIONS THAT WERE QUITE SPECIFIC. AND, AGAIN,
16 I THINK THE FINAL NIH GUIDELINES REALLY DO REFLECT THE
17 RECOMMENDATIONS OF THIS REPORT.

18 SO, AGAIN, IT'S JUST ANOTHER SIDE OF KIND OF
19 WHAT WE'RE TRYING TO DO IN THE FIELD IN TERMS OF THE
20 NATIONAL AND INTERNATIONAL NETWORKING. AND, AGAIN, IF
21 YOU HAVEN'T HAD A CHANCE TO SORT OF LOOK THROUGH THIS
22 DOCUMENT, I REALLY ENCOURAGE YOU TO GO BACK AND TAKE A
23 LOOK. IT WAS A PLEASURE TO WORK WITH, AND IT WAS
24 SOMETHING I THINK YOU DON'T OFTEN SEE IN SORT OF THE
25 POLICYMAKING PROCESS TO HAVE SO MANY ORGANIZATIONS COME

BARRISTERS' REPORTING SERVICE

1 TOGETHER IN SUCH A FOCUSED WAY.

2 WITH THAT BY WAY OF BACKGROUND IN TERMS OF
3 THINGS WE'VE BEEN UP TO, I DID WANT TO TAKE A LITTLE
4 BIT OF TIME TO COME BACK DOWN TO THE PROCESS THAT HAS
5 SORT OF BROUGHT US HERE TODAY. AS SHERRY MENTIONED, I
6 THINK IT DOES SEEM LIKE SOMETIMES WE'RE CIRCLING BACK
7 TO A SIMILAR SET OF ISSUES AND WE ARE. I JUST WANT TO
8 REMIND EVERYONE WHY WE DO THAT, BECAUSE IT'S THE LAW OF
9 MAKING REGULATION THAT SORT OF BRINGS US TO THIS POINT.
10 SO I JUST WANT TO SHOW TWO OR THREE SLIDES THAT QUICKLY
11 SORT OF REMIND US OF THE PROCESS THAT WE'VE BEEN
12 FOLLOWING TO DATE.

13 IF YOU CAN THINK BACK TO JULY OF 2008, THAT
14 WAS A MEETING IN LOS ANGELES, THAT WAS THE FIRST TIME
15 WE DISCUSSED ONE OF THE ISSUES THAT WILL COME BEFORE US
16 TODAY, THE ISSUE OF UTILIZATION OF THE EMBRYOS FOR
17 WHICH GAMETE DONORS HAVE BEEN PAID. AND WE HAD A
18 DISCUSSION ABOUT THAT. WE PUT FORWARD A POLICY. THE
19 POLICY WAS IMPLEMENTED IN THE FORM OF AN INTERIM
20 REGULATION. I THINK, IF YOU ALL MAY RECALL, WE HAVE
21 THE AUTHORITY TO PUT FORTH INTERIM REGULATIONS WHICH
22 ARE IN EFFECT FOR 270 DAYS. SO WE DID THAT. THE ICOC
23 APPROVED THAT REGULATION, BUT THAT REGULATION ACTUALLY
24 HAD A DROP-DEAD DATE IN JULY 2009. AND SO WE ARE NOW
25 IN A POSITION WHERE THAT REGULATION HAS IN A SENSE

BARRISTERS' REPORTING SERVICE

1 EXPIRED.

2 WHAT WE DID DO WAS IN MAY 2009, IN
3 ANTICIPATION OF THE REGULATION EXPIRING, WE SUBMITTED
4 TO OAL A SET OF AMENDMENTS THAT WOULD HAVE ALLOWED THE
5 REGULATION TO CARRY FORWARD TO SOME POINT IN JULY.
6 NOW, WHAT'S HAPPENED IS WE'VE RUN INTO A SET OF PUBLIC
7 COMMENTS IN ADDITION TO THE MEETING, SO WE RAN INTO FAR
8 MORE COMMENTS AND ISSUES THAN WE SORT OF HAD
9 ANTICIPATED. THEY DIDN'T COME UP IN THE INTERIM
10 PROCESS, AND SO WE'VE IN A SENSE HAD TO WAIT TO CONVENE
11 YOU ALL TO REALLY GO THROUGH THOSE PUBLIC COMMENTS ON
12 THAT PARTICULAR POLICY.

13 IN ADDITION, IF YOU MAY RECALL, IN DECEMBER
14 OF 2009, WE HAD A SET OF DISCUSSIONS ABOUT OVERSIGHT
15 STANDARDS AND USE OF SOMATIC CELLS. AND I THINK THE
16 GENERAL NATURE OF THAT CONVERSATION WAS THERE'S A SET
17 OF EXPERIMENTS INVOLVING SOMATIC CELLS AND DEIDENTIFIED
18 MATERIALS FOR WHICH WE ARE COMFORTABLE WITH, AND THAT
19 WE WANTED TO SORT OF TWEAK OUR OVERSIGHT REQUIREMENTS A
20 BIT, ALLOW THE USE OF CERTAIN MATERIALS THAT COMPLY TO
21 FEDERAL STANDARDS. SO WHAT WE DID IS WE INITIATED THAT
22 PROCESS ABOUT SIMULTANEOUSLY WITH THE MAY REVISIONS.

23 AGAIN, WE'VE RECEIVED SOME COMMENTS ON THIS
24 SET OF REGULATIONS AS WELL, SO WHAT WE'RE BRINGING TO
25 YOU TODAY REALLY IS THE CULMINATION OF THE DECEMBER

BARRISTERS' REPORTING SERVICE

1 RULES THAT WE STARTED THE END OF LAST YEAR, THE JULY
2 RULE EXPIRING, AND THEN LAYERED INTO THAT THE NIH
3 GUIDELINES, WHICH, AGAIN, AS SHERRY HAD NOTED, THERE
4 CERTAINLY ARE SOME ASPIRATIONAL STATEMENTS FROM THE
5 BOARD TO SAY, YOU KNOW, WHILE YOU'RE HERE, PLEASE THINK
6 ABOUT THIS ISSUE OF NIH AND CONSISTENCY AND
7 COMPATIBILITY BECAUSE THAT'S REALLY WHAT PROPOSITION 71
8 SORT OF SIGNALS TO US TO BE THINKING ABOUT AS SORT OF
9 RAISING THE FIELD IN GENERAL. SO IT'S REALLY THE
10 CULMINATION OF A NUMBER OF THINGS THAT SORT OF PLACED
11 US INTO THIS DISCUSSION RIGHT HERE IN SEPTEMBER.

12 SO MOVING FORWARD, IDEALLY WE WOULD BE ABLE
13 TO ADDRESS THE PUBLIC COMMENTS AT THIS MEETING. WE
14 WOULD PRESENT EITHER AT THE OCTOBER OR DECEMBER MEETING
15 A SET OF POLICY RECOMMENDATIONS TO THE BOARD, AND THE
16 BOARD WOULD CONSIDER THOSE RECOMMENDATIONS. WE WOULD
17 INITIATE ANOTHER ROUND OF RULEMAKING THAT WOULD, AGAIN,
18 BE OPEN TO PUBLIC COMMENT AT SOME POINT DOWNSTREAM,
19 EITHER STARTING TOWARDS THE END OF THE YEAR OR STARTING
20 NEXT YEAR DEPENDING ON HOW QUICKLY WE CAN TRANSLATE
21 THIS MEETING INTO A PRESENTATION TO THE BOARD AND
22 INITIATE THE OFFICE OF ADMINISTRATIVE LAW PROCESS.

23 SO THIS IS HOW WE GOT TO WHERE WE ARE TODAY.
24 I DON'T KNOW IF THERE'S ANY QUESTIONS AT THIS POINT IN
25 TERMS OF THE PROCESS. OTHERWISE, WE CAN MOVE TO THE

BARRISTERS' REPORTING SERVICE

1 SUBSTANCE.

2 CHAIRMAN LO: LET'S HEAR ABOUT THE SUBSTANCE
3 OF THE PUBLIC COMMENTS AND THE ISSUES THAT THEY RAISE
4 THAT WE NEED TO CONSIDER TODAY.

5 DR. LOMAX: SO WHAT WE'VE DONE HERE IS WE'VE
6 TRIED TO PUT TOGETHER THREE BINS, IF YOU WILL, I THINK
7 THREE BINS OF CONSIDERATION. NOW, ALL THESE ISSUES DO
8 INTERRELATE SOMEWHAT; BUT I THINK FOR THE PURPOSES OF A
9 DISCUSSION, THESE BREAKOUTS WILL WORK, I HOPE. SO THE
10 FIRST SET OF ISSUES CONCERN OVERSIGHT REQUIREMENTS OF
11 THE STEM CELL RESEARCH OVERSIGHT COMMITTEE.

12 AND THE TENOR OF THE COMMENTS IS THINGS LIKE
13 THE REGULATIONS SHOULD DRAW UPON EXISTING REVIEW
14 PROCEDURES TO THE EXTENT POSSIBLE. THERE'S SOME SORT
15 OF DISCUSSION IN THE BACKGROUND PAPER. I THINK WHAT
16 THE COMMENTERS ARE SAYING THERE IS TO THE EXTENT WE
17 HAVE EXISTING POLICY AND GUIDELINES, TALK ABOUT THINGS
18 LIKE EXPEDITED REVIEW. IT'S JUST REALLY WORDS ON
19 PAPER. TO DRAW ON SOME OF THAT MODEL LANGUAGE AND
20 INCORPORATE THAT EITHER THROUGH REGULATION OR GUIDANCE
21 SO THAT PEOPLE ARE CLEAR WHAT'S OKAY.

22 WHAT PEOPLE TEND TO BE REACTING TO IS A
23 NUMBER OF POINTS IN THE REGULATION, WE TALK ABOUT
24 NOTIFICATION, AND THEY SAY WHAT DOES NOTIFICATION MEAN?
25 I DON'T TAKE THIS TO BE A VERY DIFFICULT ISSUE AT A

BARRISTERS' REPORTING SERVICE

1 SORT OF POLICY LEVEL. WE JUST NEED TO SORT OF CLARIFY
2 THERE'S MANY WAYS TO NOTIFY, AND HERE'S ALL THE THINGS
3 THAT ARE ACCEPTABLE.

4 THEY ALSO WANT US TO -- THIS ONE IS A MORE
5 SUBSTANTIVE POINT IS TO CLARIFY RESEARCH THAT DOES NOT
6 REQUIRE THE SAME LEVEL OF SCRUTINY AS GAMETE, EMBRYO,
7 AND HUMAN SUBJECTS WORK. REALLY WHAT'S BEING SAID
8 THERE IS, AND THIS IS REALLY FOLLOW-ON TO THE DECEMBER
9 MEETING THAT WE HAD, THE DECEMBER DISCUSSION, IS THAT
10 THE REGULATIONS SEEM TO BE MOVING IN A DIRECTION WHERE
11 THERE ARE CERTAIN TYPES OF RESEARCH, RESEARCH, FOR
12 EXAMPLE, LIKE DEIDENTIFIED SOMATIC CELLS, MATERIALS
13 THAT ARE COVERED UNDER FEDERAL REGULATIONS, BUT DON'T
14 HAVE ANY HUMAN SUBJECTS IMPLICATIONS, THEY'RE NOT BEING
15 PUT INTO ANIMALS, NOTHING EXTRAORDINARY IS BEING DONE
16 WITH THEM. CLARIFY -- GIVE US A BRIGHT LINE OF WHAT
17 SEPARATES THE IMPORTANT STUFF FROM THE STUFF WE NEED TO
18 PAY MORE ATTENTION TO. AGAIN, THE SPECIFIC PROPOSALS
19 YOU HAVE BEFORE YOU TRY TO KIND OF SHARPEN THAT LINE.

20 AND, AGAIN, PERHAPS PROFESSOR GREELEY CAN
21 COMMENT ON THIS. I THINK THIS IS EXACTLY THE DIRECTION
22 THAT THE STATE DEPARTMENT OF HEALTH IS TAKING WITH
23 THEIR GUIDELINES IS TO REALLY CLARIFY WHERE WE WANT TO
24 DRAW THE LINES, WHEN WE WANT TO START INVOLVING STEM
25 CELL RESEARCH OVERSIGHT COMMITTEES IN LOOKING AT

BARRISTERS' REPORTING SERVICE

1 PROPOSALS, AND WHEN IT'S REALLY COVERED THROUGH
2 EXISTING GUIDELINES AND REGULATIONS. SO THAT'S WHAT
3 THIS TOPIC IS ABOUT.

4 THE SECOND TOPIC IS THE DONOR COMPENSATION
5 ISSUE. I DON'T NECESSARILY WANT TO GO THROUGH EVERY
6 BULLET. FOLKS CAN READ THEM. IT'S BEEN WELL DEVELOPED
7 IN THE BACKGROUND MATERIALS. BASICALLY THE ISSUE THAT
8 WE RECEIVED THE MOST PUBLIC COMMENT ON, YOU HAVE
9 COMMENTS, IT WAS A VERY LONG DISCUSSION AT THE WORKSHOP
10 ON WHETHER IT IS -- THIS ISSUE OF WHETHER THERE NEEDS
11 TO BE A CUTOFF DATE FOR THE UTILIZATION OF EMBRYOS IN
12 CIRM-FUNDED RESEARCH, SPECIFICALLY EMBRYOS THAT CONTAIN
13 PAID OOCYTES, BUT WERE ORIGINALLY CREATED FOR
14 REPRODUCTIVE USE AND ARE NO LONGER REQUIRED FOR THAT
15 PURPOSE. THAT'S, AGAIN, A CONVERSATION I THINK WE'RE
16 ALL FAMILIAR WITH, AND IT'S ONE THAT CONTINUES TO
17 CREATE THE MOST DISCUSSION IN BOTH PUBLIC COMMENT AND
18 IN THE FORUMS.

19 AND THE FINAL ONE -- IT'S NOT ON THE SLIDE
20 HERE. I'VE GOT SOME MORE DETAILED SLIDES ON THIS THIRD
21 POINT LATER. THERE'S AN ISSUE AROUND CLARIFICATION OF
22 WHAT CONSTITUTES APPROPRIATE CONSENT FOR RESEARCH
23 EMBRYOS -- SORRY -- FOR EMBRYOS THAT WOULD BE DONATED
24 TO RESEARCH. AND THE SPECIFIC EXAMPLE IS WHEN A COUPLE
25 WHO IS INTENDING TO DONATE TO RESEARCH AN EMBRYO WHERE

BARRISTERS' REPORTING SERVICE

1 ONE OF THE GAMETES, TYPICALLY THE OOCYTE, WAS DONATED
2 BY A THIRD-PARTY DONOR, PAID OR OTHERWISE, WHAT IS THE
3 LEVEL OF CONSENT OR DISCLOSURE THAT NEEDS TO BE GIVEN
4 TO THE THIRD-PARTY DONOR IN ORDER FOR US TO ALLOW THE
5 USE OF THAT EMBRYO IN RESEARCH?

6 NOW, WE'VE, AGAIN, HAD A LOT OF DISCUSSION
7 ABOUT THAT. THE RECORD REFLECTS THAT WE ACCEPT A
8 CERTAIN LEVEL OF DISCLOSURE, BUT OUR CONVERSATION IS A
9 BIT FUZZY. WE TALK ABOUT DISCLOSURE AS APPROPRIATE UP
10 TO A CERTAIN POINT, AND THAT IT'S A LITTLE BIT UNCLEAR
11 WHAT WE MEAN AFTER THAT. AND THE SORT OF QUESTIONS
12 WE'RE GETTING IS WHAT'S YOUR POLICY MOVING FORWARD?
13 AGAIN, I THINK WE CAN SORT OF GET INTO THAT IN MORE
14 DETAIL WHEN WE GET TO THAT SPECIFIC POINT. BUT IT'S A
15 VERY SOPHISTICATED QUESTION, AND, AGAIN, I THINK IT
16 REFLECTS THE FACT THAT THE FOLKS WHO ARE TRYING TO
17 IMPLEMENT THESE REGULATIONS ARE LOOKING AT THEM
18 EXTRAORDINARILY CAREFULLY AND REALLY TRYING TO
19 UNDERSTAND EXACTLY WHAT WE MEAN IN EACH AND EVERY CASE.

20 SO THOSE ARE REALLY THE THREE TOPICS OVERALL.
21 BERNIE, I SORT OF LEAVE IT TO YOU TO SORT OF CONSIDER
22 HOW YOU'D LIKE TO MOVE THROUGH THEM. WHILE THERE'S
23 SORT OF NUMERIC ORDER, CERTAINLY YOU ALL SHOULD DECIDE
24 HOW BEST TO SORT OF MOVE THROUGH THESE SETS OF ISSUES.

25 CHAIRMAN LO: GEOFF, FIRST, THANK YOU FOR

BARRISTERS' REPORTING SERVICE

1 SORT OF LAYING OUT IN BROAD TERMS THE THREE ISSUES I
2 THINK WE HAVE TO DEAL WITH. AND, AGAIN, TO REITERATE
3 WHAT GEOFF SAID, WE DISCUSSED THIS AT OUR LAST MEETING.
4 WE MADE RECOMMENDATIONS TO THE ICOC. AND WE'RE NOW
5 ASKED, IN LIGHT OF BOTH THE PUBLIC COMMENTS THAT WE
6 RECEIVED, WHICH WE WILL GO INTO IN MORE DETAIL, AS WELL
7 AS OTHER THINGS THAT HAVE HAPPENED WITH REGARD, FOR
8 EXAMPLE, TO THE NEW NIH GUIDELINES WHICH WERE ISSUED
9 SUBSEQUENT TO OUR LAST MEETING, TO THINK AGAIN ABOUT
10 THESE ISSUES.

11 AS WE'VE DONE ALL ALONG, WE'VE SAID THAT THIS
12 IS A MOVING TARGET, TO USE SHERRY'S ANALOGY, THAT WE
13 ALWAYS WANT TO SORT OF BE WILLING TO READDRESS ISSUES
14 WE'VE TALKED ABOUT BEFORE AND TO CONSIDER NEW
15 INFORMATION, NEW ARGUMENTS, NEW IDEAS. AND THAT'S WHAT
16 WE'RE GOING TO DO TODAY AS PART OF THE REGULATORY
17 PROCESS THAT WE ARE COMMITTED TO, SORT OF MAKING
18 RECOMMENDATIONS, HAVING REGULATIONS BE PROPOSED, AND
19 THEN HAVING A PUBLIC COMMENT PERIOD WHERE THE PUBLIC IS
20 INVITED AND ENCOURAGED TO COMMENT. AND THEN IT'S OUR
21 JOB NOW TO SORT OF THINK ABOUT THOSE COMMENTS AND TO
22 ADDRESS THEM, RESPOND TO THEM, AND, IF NECESSARY,
23 REVISE THE RECOMMENDATIONS BACK TO THE ICOC.

24 MS. LANSING: I JUST WANT TO PUT IT IN A
25 LITTLE CONTEXT ALSO IN ADDITION TO WHAT YOU SAID,

BARRISTERS' REPORTING SERVICE

1 BERNIE. WE WERE THE FIRST ONE THERE. AND BECAUSE WE
2 WERE THE FIRST ONE THERE, WE WERE VERY MINDFUL OF THAT
3 AND ALWAYS ERRED ON THE SIDE OF THE EXTREME
4 CONSERVATIVE SITUATION. I THINK THAT WAS CORRECT. I'M
5 NOT SUGGESTING IN ANY WAY WE COMPROMISE OR CHANGE OUR
6 STANDARD OF INTEGRITY BECAUSE I THINK THAT IS EXTREMELY
7 IMPORTANT.

8 I ALSO WANT TO PUT IT IN THE CONTEXT THAT THE
9 WORLD IS MOVING, THE NIH HAS MOVED, AND I DON'T WANT US
10 TO BE THE MOST DIFFICULT STATE TO DO OUR RESEARCH
11 EITHER. SO, AGAIN, I THINK AS WE EVALUATE THESE
12 THINGS, WE ALWAYS SAID AS THE SCIENCE MOVED AHEAD, AS
13 THE WORLD MOVED AHEAD, AS OTHER GOVERNMENTS MOVED
14 AHEAD, WE WOULD BE MINDFUL OF THAT AND REEVALUATE.
15 AGAIN, I HAVEN'T REACHED ANY CONCLUSION ON ANY OF THESE
16 ISSUES, BUT WE WERE THE FIRST AND SO WE MADE CERTAIN
17 DECISIONS. AND NOW I DON'T WANT US TO BE THE MOST
18 DIFFICULT PLACE TO DO THE RESEARCH.

19 CHAIRMAN LO: OKAY. SO ANY QUESTIONS? JOSE.

20 DR. CIBELLI: GEOFF, DO YOU HAVE ANY IDEA,
21 FOR EXAMPLE, NO. 2, DONOR COMPENSATION, HOW MANY
22 PROPOSALS WE'VE GOTTEN FOR PEOPLE TRYING TO DO RESEARCH
23 WITH EMBRYOS IN WHICH THE OOCYTE DONOR HAS BEEN PAID
24 AND THEN THE EMBRYOS BEING DONATED? IS THIS REALLY --
25 WHAT IS THE MAGNITUDE OF THE PROBLEM?

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: IT'S A GOOD QUESTION. I CAN'T
2 OFFER YOU A VERY GOOD ANSWER AT THE PROPOSAL LEVEL.
3 WHAT I CAN TELL YOU IS THAT MORE THAN ONE MAJOR
4 ACADEMIC CENTER THAT HAS AN IVF FACILITY AS PART OF THE
5 ACADEMIC CENTER, SO LET'S JUST SAY TWO, TWO HAVE
6 INDICATED THAT THEY HAVE A NUMBER OF EMBRYOS OR THEY
7 HAVE EMBRYOS AT THE MOMENT THAT ACTUALLY QUALIFY IF WE
8 WERE TO AT LEAST MAINTAIN OUR 2008 STANDARD. AGAIN,
9 THE RULES EXPIRED, SO THEY HAVE SORT OF EMBRYOS IN
10 LIMBO, IF YOU WILL, BECAUSE WE DON'T HAVE ANY POLICY.
11 AND WHAT I'M TOLD IS A SUBSTANTIAL NUMBER. I CAN'T
12 TELL YOU WHAT A SUBSTANTIAL NUMBER IS, BUT THEY'RE
13 THERE.

14 AGAIN, TYPICALLY MY UNDERSTANDING OF THE
15 PROCESS IS WITHIN THE SORT OF ORGANIZATIONS WE'RE
16 FUNDING, THERE TENDS TO BE A SORT OF FACILITY, A BANK,
17 A TISSUE BANK --

18 (INTERRUPTION IN PROCEEDINGS.)

19 CHAIRMAN LO: COULD I ASK THOSE OF YOU IN
20 AUDIENCE TO AT LEAST TURN YOUR CELL PHONES TO SILENT
21 RING SO THEY VIBRATE OR SOMETHING AND NOT TO DISRUPT
22 THE MEETING LIKE THAT.

23 DR. LOMAX: THEY HAVE A BANK, TISSUE BANK,
24 WHERE THEY'RE COLLECTING MATERIALS FROM ALL SORTS OF --
25 THERE TENDS TO BE REPRODUCTIVE TISSUE BANKS AND THEY'RE

BARRISTERS' REPORTING SERVICE

1 A BIT DIFFERENT THAN THE GENERIC CELL BANKS. AND
2 THEY'RE COLLECTING MATERIALS GENERALLY. AND SO ONE OF
3 THE THINGS THEY'RE LOOKING AT, THEN, IS, YOU KNOW,
4 GIVEN THAT CIRM-FUNDED RESEARCH IS ONE SORT OF OUTPUT
5 FOR THOSE MATERIALS, THEY'RE OBVIOUSLY LOOKING AT OUR
6 REGULATIONS VERY CAREFULLY. SO THE TWO INSTITUTIONS
7 INDICATE SORT OF TWO KIND OF GENERAL ISSUES THAT COME
8 UP.

9 ONE IS THAT, YES, WE'VE GOT MATERIALS IN
10 LIMBO THAT AT LEAST THEY WERE SORT OF PRE-2008. WE'D
11 LIKE THE OPPORTUNITY TO CONTINUE TO USE THEM. SO WE
12 NEED SOME TYPE OF REVISION TO THIS STANDARD.

13 THE SECOND POINT THAT COMES UP IS WE'VE
14 GOTTEN A LITTLE BIT OF A TENSION BETWEEN YOUR SORT OF
15 ARTICULATED DESIRE, YOU BEING CIRM, TO SORT OF DO THE
16 BEST JOB POSSIBLE ON CONSENT AND THE UNCERTAINTY AS TO
17 WHETHER, WELL, IF WE GO AHEAD AND TRY TO CONSENT NOW
18 PROSPECTIVELY, SORT OF INTERACTIONS THAT ARE GOING ON
19 BETWEEN SORT OF DONORS AND COUPLES SORT OF POST, NOW,
20 2009 FORWARD, IT CREATES AN AWKWARD SITUATION BECAUSE
21 WE CAN SORT OF CONSENT IN A WAY THAT'S SORT OF MORE
22 COMPATIBLE WITH YOUR SORT OF REGULATIONS OR IN SOME
23 WAYS TOTALLY EXACTLY LIKE THE REGULATIONS, BUT IT'S
24 AWKWARD TO SORT OF TRY TO GET THE PEOPLE WHO ACTUALLY
25 INTERACT WITH THE DONORS TO IMPLEMENT SOMETHING IF

BARRISTERS' REPORTING SERVICE

1 THERE'S NO SORT OF CERTAINTY THAT WHEN THAT TIME COMES
2 THAT THERE MAY WANT TO BE A DONATION, THAT WE WOULD
3 HAVE THE OPPORTUNITY TO EVEN USE THE MATERIALS. IT
4 SORT OF MAKES FOR AN AWKWARD CONSENT PROCESS.

5 SO THOSE ARE THE POINTS THAT ARE RAISED. BUT
6 IN TERMS OF ANY KIND OF QUANTITATIVE ASPECT TO THAT,
7 I'VE FOUND THAT, IN GENERAL, PEOPLE ARE NOT VERY
8 FORTHCOMING WITH NUMBERS. AND I DON'T KNOW IF THAT
9 REFLECTS EITHER TRYING TO PERSUADE ME OF SOMETHING
10 THAT'S MUCH SMALLER IN MAGNITUDE THAN IS REALITY OR
11 JUST A GENERAL FEELING THAT PEOPLE TEND TO SORT OF NOT
12 DISCLOSE NUMBERS OF THINGS VERY READILY. I DON'T KNOW
13 WHAT THE ANSWER IS.

14 DR. CIBELLI: ONE WAY OF GETTING BACK TO THE
15 NUMBERS, I'VE LEARNED, AND YOU SHOULD TELL ME IF I'M
16 RIGHT OR WRONG WITH THIS, BUT IT'S USUALLY 10 PERCENT
17 OF WHAT THE CLINIC IS. NUMBER OF CYCLES THEY PRODUCE
18 IS WHAT YOU EXPECT TO SEE, NUMBERS OF EMBRYOS AS
19 DONATED A YEAR.

20 DR. LOMAX: YES. ONE CLINIC IN PARTICULAR
21 THAT HAS BEEN VOCAL ON THIS AREA INDICATES THAT THEY --
22 THE POINT THEY SAID IS BE AWARE OF NATIONAL AVERAGES
23 BECAUSE WE TEND TO HAVE A FAIRLY LARGE PATIENT
24 POPULATION THAT'S DOING THIS IN THE SAME SEX COUPLE
25 COMMUNITY. SO I THINK WE ALSO HAVE THE CAUTION OF SORT

BARRISTERS' REPORTING SERVICE

1 OF PUTTING OUT A CERTAIN GROUP AND TYPE. THAT'S NOT
2 THE POINT. THE POINT IS THAT THE NUMBERS HAVE TO BE
3 BALANCED AGAINST WHAT'S THE POPULATION THAT'S
4 APPROACHING THAT COMMUNITY FOR SERVICES, AND THAT CAN
5 SKEW THE PERCENTAGES. AGAIN, 10 PERCENT IS AN AVERAGE.
6 THE NUMBER THAT WAS PROVIDED TO ME WAS MORE LIKE 20, 25
7 PERCENT. THAT'S WHAT THEY'RE DEALING WITH. SO IT'S
8 ABOUT A QUARTER OF THEIR STOCK.

9 DR. TAYLOR: I THINK THAT'S RIGHT FOR CERTAIN
10 PRACTICES. PROBABLY BE AS HIGH AS 25 PERCENT. FOR
11 CERTAIN PRACTICES IN CERTAIN COMMUNITIES, AND
12 PARTICULARLY THE PROGRAMS THAT HAVE A BIG REPUTATION
13 FOR DOING DONOR, THAT THE NUMBERS CAN BE QUITE A BIT
14 HIGHER THAN THAT.

15 CHAIRMAN LO: IF I COULD JUST ADD A POINT OF
16 INFORMATION. SO THIS WAS RAISED AT AN NAS MEETING
17 WHICH STORY LANDIS ATTENDED. WHEN ASKED THAT, THE DATA
18 ARE THAT THE MOST UP-TO-DATE DATA FROM CDC SAYS THAT IN
19 2006 12 PERCENT OF ART CYCLES USED DONOR OOCYTES ON
20 NATIONAL AVERAGE AND 3.5 PERCENT USED ANONYMOUS SPERM
21 DONORS. AS HAS ALREADY BEEN SAID, THAT'S AN AVERAGE,
22 AND THERE'S SOME CLINICS HAVE MUCH HIGHER.

23 THE OTHER POINT THAT SOME STEM CELL
24 SCIENTISTS RAISE IS THAT THEY CLAIM THAT EMBRYOS FROM
25 OOCYTE DONORS WHO ARE YOUNG AND HEALTHY AS OPPOSED TO

BARRISTERS' REPORTING SERVICE

1 OLDER WOMEN OR WOMEN WHO HAVE INFERTILITY PROBLEMS
2 DONATING OOCYTES THEMSELVES FOR THEIR OWN REPRODUCTION,
3 THE THOUGHT IS THAT THEY MAY BE MORE EFFECTIVE AT
4 GENERATING NEW HUMAN EMBRYONIC STEM CELL LINES. I
5 DON'T HAVE DATA ON THAT, BUT A NUMBER OF HUMAN STEM
6 CELL SCIENTISTS HAVE SAID THAT.

7 SO THAT'S I THINK -- YOU'RE RIGHT. WE SHOULD
8 BE EVIDENCE BASED AS BEST WE CAN, AND I THINK THAT'S
9 THE BEST DATA WE HAVE ON THAT. ALTA AND FRANCISCO
10 AFTER THAT.

11 MS. CHARO: I THINK ALSO PERTINENT TO THIS
12 DISCUSSION IS A LURKING PROBLEM. WE'RE NOT DEALING
13 ONLY WITH CALIFORNIA INSTITUTIONS THAT ARE ANTICIPATING
14 THE NEED TO CONFORM TO CIRM REGULATIONS. THERE ARE
15 LINES DERIVED ALL OVER THE COUNTRY AND ALL OVER THE
16 WORLD WITH VERY LITTLE ATTENTION TO CIRM REGULATIONS.
17 AND THERE IS SIMPLY AN ABSENCE OF KNOWLEDGE FOR MANY
18 EMBRYOS AS TO WHETHER OR NOT A DONOR GAMETE WAS USED.
19 SO IT'S NOT THAT YOU KNOW THIS ONE WAS AND THIS ONE
20 WASN'T MADE WITH A DONOR GAMETE. YOU SIMPLY CAN'T
21 DISTINGUISH THEM IN MANY PLACES, AND THE LINES THAT
22 RESULT, THEREFORE, CANNOT BE CATALOGUED AS HAVING COME
23 FROM AN EMBRYO WITH OR WITHOUT DONOR GAMETES.

24 SO THAT UNCERTAINTY IS GOING TO DOG MANY
25 LINES THAT CALIFORNIA GRANTEES MIGHT WANT TO USE AS

BARRISTERS' REPORTING SERVICE

1 PART OF THEIR OWN RESEARCH OR AS PART OF A
2 COLLABORATIVE EFFORT.

3 DR. WILLERSON: JIM WILLERSON.

4 CHAIRMAN LO: JIM, WHY DON'T YOU GO AHEAD,
5 PLEASE.

6 DR. WILLERSON: IT WOULD BE VERY NICE TO BE
7 ABLE TO TEST THE FUNCTIONAL CAPABILITY OF THESE
8 EMBRYONIC CELLS. IF YOU LOOK AT ADULT STEM CELLS,
9 CARDIAC STEM CELLS, WE FOUND AND SO HAVE OTHERS THAT
10 AGING PEOPLE, PARTICULARLY IF THEY HAVE CERTAIN
11 ILLNESSES, THEIR ADULT STEM CELLS CANNOT REPRODUCE
12 THEMSELVES IN CULTURE, AND THEY DON'T HELP A HUMAN
13 HEART WHEN THEY'RE PUT INTO IT.

14 ON THE OTHER HAND, THEY CAN REPRODUCE
15 THEMSELVES IN CULTURE, FORM COLONIES, AND THEY DO HELP
16 THE HUMAN HEART, AT LEAST CD34 POSITIVE AND MESENCHYMAL
17 CELLS DO. SO IT WOULD BE REALLY NICE, THINKING ABOUT
18 YOUNGER AND OLDER WOMEN DONORS, IF THERE WERE A WAY TO
19 TEST THE FUNCTIONALITY OF THOSE CELLS BEFORE THEY WERE
20 USED. I THINK IT WOULD BE IMPORTANT; AND IF WE DON'T
21 HAVE THE WAYS TO DO IT, WE NEED TO DEVELOP THEM.

22 CHAIRMAN LO: I HAVE A NUMBER OF OTHER PEOPLE
23 WITH COMMENTS. I HAVE FRANCISCO, JEFF, AND MY ENTIRE
24 LEFT FIELD OF VISION.

25 DR. TAYLOR: THE ENTIRE LEFT WING.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: I SAID LEFT FIELD OF VISION TO
2 BE PRECISE.

3 DR. PRIETO: FIRST OF ALL, A QUESTION FOR MY
4 CLARIFICATION. WE'RE TALKING ABOUT THE PROPORTION OF
5 IVF EMBRYOS IN WHICH OOCYTES ARE DONATED AS OPPOSED TO
6 THOSE WHERE THE OOCYTE COMES FROM THE WOMAN AND THE
7 COUPLE?

8 DR. LOMAX: YES.

9 DR. PRIETO: AND THEN IN THE SITUATION OF
10 DONOR OOCYTES, HOW COMMON IS IT FOR THERE TO BE ANY OF
11 THOSE EMBRYOS WHERE THE DONOR WAS NOT COMPENSATED? I
12 WOULD THINK THAT WOULD BE --

13 DR. LOMAX: THERE ARE OCCASIONAL EXAMPLES
14 WHERE FAMILY MEMBERS WILL PROVIDE FOR THE COUPLE IN
15 FERTILITY TREATMENT ON AN UNCOMPENSATED BASIS. BUT
16 YOU'RE RIGHT, THE OVERARCHING -- THE MAJORITY OF CASES
17 WE'RE TALKING ABOUT THE COMPENSATED DONOR.

18 DR. PRIETO: DO WE HAVE ANY IDEA OF NUMBERS?

19 DR. LOMAX: AGAIN, THE NATIONAL AVERAGE, AS
20 WAS CITED, WAS 10 TO 12 PERCENT. THOSE ARE THE
21 FIGURES. THE FEEDBACK I'VE BEEN GIVEN IS THAT IT CAN
22 BE UPWARD OF 20, 25 PERCENT AT CERTAIN CALIFORNIA-BASED
23 INSTITUTIONS, WHICH IS NOT INCONSISTENT WITH THE
24 FIGURES, I THINK, FOR THE TYPE OF DEMOGRAPHIC YOU WOULD
25 SEE IN A PLACE LIKE LOS ANGELES OR SAN FRANCISCO.

BARRISTERS' REPORTING SERVICE

1 DR. PRIETO: TWENTY, 25 PERCENT VOLUNTARY,
2 UNCOMPENSATED?

3 DR. LOMAX: NOW WE'RE TALKING ABOUT -- JUST
4 TO BE CLEAR, OF EMBRYOS THAT ARE CURRENTLY IN TISSUE
5 BANKS, THE INDIVIDUALS THAT HAD DISPOSITIONAL AUTHORITY
6 OF THOSE EMBRYOS HAVE DONATED THEM TO THE BANK
7 GENERALLY FOR RESEARCH, I THINK IN ALMOST ALL CASES FOR
8 RESEARCH, AND THE BANKS ARE IN POSSESSION OF THOSE
9 EMBRYOS, THEY'RE SORT OF IN A POSITION TO BE USED IN
10 RESEARCH.

11 THE QUESTION BEFORE US OR WE'RE BEING ASKED
12 IS CAN WE USE THEM? OR YOU NEED TO EVALUATE
13 REGULATIONS WHETHER WE CAN -- WILL YOU ALLOW US TO USE
14 THEM MOVING FORWARD?

15 DR. PRIETO: I GUESS WHAT I'M WONDERING IS
16 WHAT PROPORTION OR PERCENTAGE OF THOSE EXIST WHERE
17 THERE WAS NO COMPENSATION INVOLVED?

18 DR. LOMAX: PRESUMABLY IT WOULD BE THE OTHER
19 75 PERCENT. I DON'T KNOW.

20 MS. LANSING: SEVENTY-FIVE PERCENT WERE NOT
21 COMPENSATED?

22 DR. TAYLOR: NO. NO. NO. I WOULD JUST
23 SUGGEST THAT PROBABLY ABOUT 25 PERCENT ARE COMING FROM
24 DONOR IN A LOT OF PRACTICES, YOU KNOW, IN CALIFORNIA.
25 AND --

BARRISTERS' REPORTING SERVICE

1 DR. PRIETO: YOU MEAN UNCOMPENSATED DONORS.

2 DR. TAYLOR: NO. I'M JUST TALKING ABOUT
3 DONOR IN GENERAL. AND I WOULD IMAGINE LESS THAN 5
4 PERCENT ARE COMING FROM A FAMILY MEMBER, UNCOMPENSATED
5 DONOR, AND THE OTHER 75 PERCENT ARE COUPLES UNDERGOING
6 FERTILIZATION OF THEIR OWN GAMETES. THAT'S HOW I WOULD
7 GENERALLY BREAK THE NUMBERS DOWN.

8 CHAIRMAN LO: SO LET'S GO THAT WAY AND THEN
9 WE'LL COME BACK THIS WAY. JEFF, YOU'RE NEXT.

10 MR. SHEEHY: JUST A POINT OF CLARIFICATION OF
11 WHAT WE'RE TALKING ABOUT BECAUSE I GOT A LITTLE
12 CONFUSED WITH ALTA'S COMMENTS. WE'RE TALKING ABOUT
13 DERIVATION OF NEW LINES. WE ACTUALLY, IF A LINE WAS
14 APPROVED BY THE NIH OR THE UK OR ANOTHER PLACE, WE'VE
15 ALREADY SAID THAT THOSE WILL BE ACCEPTABLY DERIVED.
16 PEOPLE CAN WORK ON THOSE LINES, RIGHT?

17 DR. LOMAX: IF THEY WERE APPROVED BY
18 ANOTHER --

19 MR. SHEEHY: SO WHEN THE NIH HAS IT'S
20 REGISTRY, EVERYTHING THAT'S ON THERE WILL BE
21 AUTOMATICALLY APPROVED FOR USE BY --

22 DR. LOMAX: THE CURRENT LANGUAGE OF OUR
23 REGULATIONS INDICATE THAT NIH-APPROVED LINES ARE
24 ACCEPTABLE FOR CIRM-FUNDED RESEARCH. THE POINT WHERE
25 ALTA'S CLARIFICATION COMES INTO PLAY IS OUR STANDARD

BARRISTERS' REPORTING SERVICE

1 FOR ACCEPTABLY DERIVED, HOWEVER. SO THIS WOULD BE ANY
2 LINE THAT WAS DERIVED ELSEWHERE AND DOESN'T FIT INTO
3 ONE OF THOSE WHAT WE'RE CALLING AUTHORIZED AUTHORITY,
4 NIH, THE UK BANK. THAT STANDARD STILL SAYS THE
5 ORIGINAL GAMETE DONOR COULDN'T HAVE BEEN PAID. SO IT'S
6 A SUBTLE, BUT IMPORTANT POINT.

7 WE ACTUALLY AT TWO POINTS IN OUR PROCESS
8 CURRENTLY WOULD PRECLUDE THE USE OF HUMAN EMBRYONIC
9 STEM CELL LINES FROM THE EMBRYOS WE'RE TALKING ABOUT
10 WITH THE PAID GAMETES. IT WOULD BE BOTH THE DERIVATION
11 AND THE USE. SO IT'S A LITTLE BIT OF A SUBTLE POINT.
12 I'M GLAD ALTA RAISED IT, BUT THERE'S ACTUALLY TWO
13 CHECKPOINTS IN OUR REGULATION THAT AT THE MOMENT
14 REPRESENT BARRIERS TO USE OF THOSE MATERIALS.

15 MR. SHEEHY: AGAIN, I'M JUST TRYING TO BE
16 CLEAR BECAUSE -- AND I'M LESS CONCERNED ABOUT THIS
17 ISSUE BECAUSE PROBABLY, AS I MENTIONED TO YOU, I'M
18 RELAXED ON THIS, BUT MORE ON THE DONOR CONSENT, WHICH I
19 THINK -- I'M CONFUSED BECAUSE WE DON'T APPLY BOTH
20 STANDARDS. WE ONLY APPLY ONE. SO IF THE NIH HAS PUT
21 IT ON ITS REGISTRY, EVEN IF THOSE WERE PAID FOR, THE
22 OOCYTES, THAT WOULD BE ACCEPTABLY DERIVED FOR USE BY
23 OUR RESEARCHERS --

24 DR. LOMAX: CORRECT.

25 MR. SHEEHY: -- IN RESEARCH, RIGHT?

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: SO WE'RE INCONSISTENT?

2 MR. SHEEHY: NO, WE ARE CONSISTENT.

3 MS. CHARO: IF I CAN CLARIFY, JEFF, OKAY. IT
4 IS TRUE THAT FOR A NAKED LINE COMING WITHOUT THE
5 IMPRIMATUR OF ANY GOVERNMENT STAMP OF APPROVAL, THAT
6 OUR STANDARDS SAY THAT IT CANNOT COME FROM AN EMBRYO
7 THAT HAS WITHIN IT, UNDERLINED, A PAID GAMETE DONOR;
8 BUT THAT, YES, IF IT WAS ON THE STEM CELL REGISTRY AT
9 THE UK, APPROVED BY THE NIH, THEN WE IGNORE THAT, AND
10 WE SAY, WELL, THEIR IMPRIMATUR IS GOOD ENOUGH.

11 THE PROBLEM IS THAT THE NIH IS NOT GOING TO
12 HAVE MANY LINES ON ITS REGISTRY VERY QUICKLY. THEIR
13 APPROACH IS GOING TO BE TO WAIT FOR EACH INDIVIDUAL
14 INVESTIGATOR TO COME UP WITH A GRANT PROPOSAL AND
15 SPECIFY THE LINE THE LABORATORY PLANS TO USE. AND ONLY
16 THEN WILL THEIR COMMITTEE, THEIR WORKING GROUP,
17 ACTUALLY LOOK AT THAT LINE AND DETERMINE IF THEY'RE
18 WILLING TO PUT IT ON THEIR REGISTRY.

19 SO FOR THE NEXT X NUMBER OF YEARS, THERE'S
20 GOING TO BE FEW LINES ON THE NIH REGISTRY. AND ANY
21 TIME A CIRM GRANTEE WANTS TO WORK WITH A LINE COMING
22 FROM ANOTHER LABORATORY WITH CIRM MONEY WHERE NO NIH
23 MONEY HAS BEEN IMPLICATED, NO GRANT PROPOSAL IS GOING
24 TO THE NIH, WE WILL NOT HAVE THE ADVANTAGE OF THE NIH
25 STAMP OF APPROVAL. AND WE WILL BE STUCK WITH OUR OTHER

BARRISTERS' REPORTING SERVICE

1 PROVISIONS, WHICH SAYS NO UNDERLYING PAID DONORS EVEN
2 IF IT WAS DONE IN A REPRODUCTIVE CONTEXT.

3 MR. SHEEHY: DO WE THEN -- BECAUSE I SEE THE
4 DONOR CONSENT AND THE DONOR COMPENSATION BEING LINKED.
5 THESE ARE TWO PLACES, AND SO THERE'S AN INCONSISTENCY
6 IN STAFF RECOMMENDATION BECAUSE THEY RECOMMEND THAT
7 WE -- AND I ACTUALLY AGREE WITH THE STAFF POSITION.
8 THEY RECOMMEND THAT WE HARMONIZE ON THE DONOR
9 COMPENSATION, BUT THAT WE CONTINUE TO HAVE THIS HIGHER
10 STANDARD ON DONOR CONSENT. THAT'S WHY I'M KIND OF
11 CONFUSED. AND I ACTUALLY THINK I WOULD APPROVE BECAUSE
12 OF THE DISCUSSION WE HAD -- ROB HAS ALWAYS BEEN VERY
13 ARTICULATE ABOUT THE NEED FOR THE VERY FINEST LINES FOR
14 GOING INTO THE CLINIC. WE WANT DONOR CONSENT BECAUSE
15 WE WOULD WANT TO BE ABLE TO GO BACK. WE DON'T KNOW
16 WHAT'S GOING TO BE REQUIRED FOR A CLINICAL LINE, AND
17 DONOR CONSENT JUST SEEMS PROSPECTIVELY A BETTER WAY TO
18 GO FORWARD.

19 SO, AGAIN, I GET CONFUSED WHEN WE START
20 TALKING ABOUT HARMONIZING WITH THE NIH BECAUSE AT THE
21 END OF THE DAY, WE'RE GOING TO TAKE WHATEVER THE NIH
22 SAYS IS OKAY NO MATTER WHAT BECAUSE WE HAVE THIS RULE
23 THAT SAYS NIH -- WHAT IS IT -- NIH, THE UK, CANADIANS,
24 THE JAPANESE ARE ALL --

25 MS. CHARO: AND THE NIH IS SILENT ON THE

BARRISTERS' REPORTING SERVICE

1 ISSUE OF UNDERLYING GAMETE DONOR CONSENT OR
2 COMPENSATION.

3 MS. LANSING: CAN I JUST ASK A QUESTION? SO
4 BECAUSE THEY'RE SILENT, IS THEIR SILENCE IN A WAY, DO
5 WE ASSUME OR DO WE NOT ASSUME THAT THEY WILL BE
6 COMPLIANT IN TAKING LINES WHERE PEOPLE DIDN'T SIGN
7 CONSENT AND WHERE THEY DIDN'T -- THAN WHERE THEY GOT
8 PAID?

9 CHAIRMAN LO: LET ME TRY AND CLARIFY. AGAIN,
10 THIS IS A WORK IN PROGRESS. THE NIH COMMITTEE THAT
11 WILL -- THE GUIDELINES ARE OUT, BUT THE COMMITTEE
12 THAT'S GOING TO ADJUDICATE TOUGH CASES FOLLOWING THOSE
13 GUIDELINES HAS NOT BEEN OFFICIALLY NAMED. SO JUST TO
14 BACK UP, SO WE'RE ALL CLEAR, WE HAVE, AS GEOFF HAS
15 POINTED OUT, WE HAVE SEVERAL WAYS THAT A STEM CELL LINE
16 CAN BE APPROVED FOR CIRM FUNDING. YOU ONLY HAVE TO
17 SATISFY ONE OF THEM. SO, A, YOU CAN BE APPROVED BY ONE
18 OF THESE OTHER ORGANIZATIONS LIKE NIH, LIKE HEEFA.
19 SECOND, YOU CAN MEET OUR EXPLICIT STANDARDS, WHICH
20 WE'VE TALKED ABOUT.

21 NOW, THE NIH GUIDELINES CURRENTLY DO NOT
22 REQUIRE THIRD-PARTY CONSENT FOR EMBRYOS -- IF AN EMBRYO
23 THAT'S REMAINING AFTER -- THAT WAS CREATED FOR IVF, BUT
24 IS NO LONGER NEEDED IN IVF AND IS DONATED BY THE COUPLE
25 OR PATIENT IN IVF FOR RESEARCH, THEY DO NOT REQUIRE

BARRISTERS' REPORTING SERVICE

1 THIRD-PARTY CONSENT. THEY SAY THAT SINCE THE GAMETE
2 DONOR SIGNED AN AUTHORIZATION OF DISPOSITION GRANTING
3 THE IVF PATIENT DISPOSITIONAL RIGHTS OVER THE EMBRYO
4 CREATED WITH THEIR GAMETE, THEY SAY THAT'S GOOD ENOUGH
5 FOR THEM. AND MY UNDERSTANDING IS ALMOST ALL THESE
6 LINES HAVE SUCH KIND OF DISPOSITIONS, THOUGHT TO HAVE
7 SUCH DISPOSITIONAL AUTHORITY FROM THE GAMETE DONOR.

8 THE NIH GUIDELINES DO NOT TALK AT ALL ABOUT
9 COMPENSATION TO THIRD-PARTY GAMETE DONORS. SO IT'S NOT
10 A CRITERIA THAT WOULD BE USED BECAUSE IT'S NOT IN THE
11 GUIDELINES.

12 MS. LANSING: THEREFORE, WE --

13 CHAIRMAN LO: WE'RE STRICTER.

14 MS. LANSING: -- ARE TOUGHER. AND WE'RE
15 INCONSISTENT UNLESS I'M NOT UNDERSTANDING THIS RIGHT.
16 WE'RE INCONSISTENT BECAUSE IF WE HAVE IN OUR BYLAWS
17 THAT WE TAKE THE NIH LINES, AND IF THE NIH LINES ARE
18 TAKING LINES FROM PEOPLE THAT GOT PAID MONEY AND DIDN'T
19 SIGN CONSENT, THEN I DON'T UNDERSTAND WHY WE WOULDN'T
20 MAKE OURSELVES CONSISTENT.

21 MR. SHEEHY: WELL, I MEAN BECAUSE THOSE NIH
22 LINES WE CAN USE. I'LL GIVE YOU A HYPOTHETICAL.

23 MS. LANSING: YEAH, BUT WE'RE CONFLICTING
24 OURSELVES.

25 MR. SHEEHY: NO, WE'RE NOT BECAUSE WE'RE

BARRISTERS' REPORTING SERVICE

1 ALREADY DEFERRING TO THE NIH AS A HIGHER AUTHORITY. SO
2 FOR ME PERSONALLY THE POLICY ISSUE COMES TO DERIVING
3 NEW LINES. SO WHEN WE TALK ABOUT GETTING INFORMED
4 CONSENT FROM GAMETE DONORS, THAT GOES TO THE QUALITY OF
5 THE LINES THAT WE'RE GOING TO BE FUNDING TO CREATE. IN
6 GENERAL, SOMEONE COULD GO AND CREATE A LINE IN
7 CALIFORNIA WITH A PAID OOCYTE DONOR FOR THE EMBRYO THAT
8 WAS CREATED FOR REPRODUCTIVE PURPOSES WITH NO DONOR
9 CONSENT, NO GAMETE DONOR CONSENT, GET APPROVAL BY THE
10 NIH FOR USE, GET ON THEIR LIST, AND THAT LINE WOULD BE
11 ELIGIBLE FOR USE BY OUR RESEARCHERS EVEN THOUGH IF THEY
12 HAD NOT GOTTEN THE NIH -- IF THEY HAD GOTTEN ON THE NIH
13 LIST, THEY WOULD NOT BE ELIGIBLE FOR OUR FUNDING.

14 SO WE DO DEFER TO A HIGHER STANDARD. SO FOR
15 ME PART OF IT IS THE POLICY ISSUE REALLY GOES TO THE
16 CREATION OF THE EMBRYOS. WHAT KIND OF STANDARD DO WE
17 WANT TO SET BECAUSE THE NIH IS GOING TO, I THINK,
18 SUPERSEDE US. WHEN YOU THINK ABOUT IT FROM THE LONGEST
19 POLICYMAKING BECAUSE, YOU KNOW, IT TAKES FOREVER TO GET
20 THESE REGS INTO LAW. THE LONGEST VIEW IS THAT THE NIH
21 IS GOING TO SUPERSEDE US ON THIS, PUT LINES ON THE
22 REGISTRY. OUR RESEARCHERS WILL BE ABLE TO USE ALL
23 THOSE LINES. BUT WHAT WE CAN DO THE NIH CANNOT DO IS
24 CREATE NEW LINES.

25 SO THOSE PLACES WHERE OUR RULES MIGHT IMPACT

BARRISTERS' REPORTING SERVICE

1 THE CREATION OF A NEW LINE IS WHERE -- TO MY MIND, I
2 THINK WE NEED TO BE SENSITIVE TO THE IMPACT OF THE
3 RULE. AND THAT'S WHY DONOR CONSENT FOR ME BECOMES AN
4 IMPORTANT ISSUE BECAUSE THAT, AT LEAST FROM A
5 SCIENTIFIC POINT OF VIEW, SEEMS TO BE SOMETHING THAT
6 MIGHT ACTUALLY IMPROVE THE QUALITY OF LINES THAT WE USE
7 IN A CLINIC OR MAKE FOR BETTER CLINICAL GRADE LINES.
8 WHEREAS, THIS ISSUE, I THINK, IS NOT ONE THAT -- THIS
9 IS ONE WHERE I THINK CONFORMITY PERSONALLY MAKES A LOT
10 OF SENSE BECAUSE WHY WOULD WE ENCOURAGE SOMEBODY TO GO
11 AND -- YOU KNOW, THEY CAN JUST GAME THE SYSTEM. THEY
12 CAN JUST GET ON THE NIH LIST AND NOT ON OURS. IT
13 SHOULDN'T MAKE ANY REAL DIFFERENCE TO US AS LONG AS
14 WE'RE CERTAIN THAT THE EMBRYO WAS CREATED FOR
15 REPRODUCTIVE USE. IT SHOULDN'T REALLY MATTER TO US AT
16 THIS POINT WHETHER THE OOCYTES WERE PAID FOR.

17 MS. LANSING: I AGREE WITH THAT. I WANT TO
18 LISTEN TO EVERYBODY ELSE.

19 DR. LOMAX: JUST SO YOU'RE AWARE. YOU ARE
20 CORRECT, THOUGH. OUR STANDARD IS HIGHER IN THE AREA OF
21 USE OF EMBRYOS. YOU MUST HAVE AT LEAST WHAT YOU ALL
22 REFERRED TO AS SORT OF DISCLOSURE OF RESEARCH TO USE AN
23 EMBRYO FOR CIRM-FUNDED RESEARCH. THE SCENARIO JEFF
24 LAYS OUT IS CORRECT. ONCE YOU GET DOWN TO THE LEVEL OF
25 THE STEM CELL LINE, IT COULD WORK ITS WAY INTO THE

BARRISTERS' REPORTING SERVICE

1 SYSTEM, BUT WE HAVE A HIGHER STANDARD FOR THE
2 UTILIZATION OF EMBRYOS. AND THERE'S NOTHING ON THE
3 TABLE THAT WOULD CHANGE THAT IN THIS DISCUSSION.

4 CHAIRMAN LO: SO I THINK IT IS IMPORTANT.
5 THIS IS A COMPLICATED ISSUE, AND IT'S NOT AN EASY
6 ISSUE. IT'S A DIFFICULT ISSUE. SO I THINK IT'S
7 IMPORTANT THAT WE TRY AND EACH SORT OF WRAP OUR HANDS
8 AROUND THIS.

9 DR. KIESSLING: I JUST WANT TO KIND OF BACK
10 UP WHAT JEFF SAID FOR EVERYBODY'S UNDERSTANDING. I
11 THINK THE ISSUES OF COMPENSATING THE OOCYTE DONORS IS
12 NOT -- THAT SHOULD JUST GO AWAY. I MEAN THAT'S A BIG
13 PROBLEM IN CALIFORNIA AND NEEDS TO BE DISCUSSED. YOU
14 GOT TO REMEMBER THAT ALMOST ALL SPERM DONORS ARE
15 COMPENSATED. BUT THE BIG ISSUE HERE, THE BIG DEVIATION
16 FROM THE NEW NIH GUIDELINES IS EXACTLY WHAT YOU'RE
17 TALKING ABOUT. THEY ARE NO LONGER REQUIRING THE
18 INFORMED CONSENT OF THE GAMETE DONORS. AND I THINK
19 THAT'S THE ISSUE THAT NEEDS TO BE DISCUSSED. AND
20 WHETHER OR NOT THE OOCYTE DONOR WAS COMPENSATED IS
21 LESS, IS BELOW THAT BAR FOR THIS GROUP BECAUSE THIS
22 GROUP HAS DISCUSSED EXTENSIVELY THE CONCEPT OF DOES
23 THIS SPERM DONOR -- AND I WANT TO SORT OF DEFEND THE
24 SPERM DONORS HERE TOO -- DOES THIS SPERM DONOR REALIZE
25 THAT HIS SPERM WAS GOING TO BE USED TO DERIVE A LINE OF

BARRISTERS' REPORTING SERVICE

1 STEM CELLS? I THINK THAT'S THE ISSUE THAT NEEDS TO BE
2 DISCUSSED BY THIS GROUP BECAUSE WE SPENT A LONG TIME
3 WORRYING ABOUT THAT.

4 CHAIRMAN LO: LET ME SEE IF THIS PROCEDURAL
5 SUGGESTION WORKS. THERE'S DIFFERENT ISSUES, WHICH, AS
6 JEFF POINTED OUT, ARE INTERLINKED BUT SOMEWHAT
7 SEPARATE. I WOULD SUGGEST WE SORT OF TACKLE THEM ONE
8 AT A TIME RATHER THAN ALTOGETHER. I WOULD SUGGEST THAT
9 WE FIRST TALK ABOUT DONOR COMPENSATION BECAUSE I'M
10 HEARING SOME PEOPLE SAY THAT'S A LESS -- IT'S NOT EASY,
11 BUT IT'S LESS COMPLICATED THAN THE DONOR CONSENT. AND
12 I WOULD SUGGEST WE JUST MOVE THE SCRO OVERSIGHT TO
13 LATER IN THE MEETING BECAUSE I THINK THE TWO BIG ISSUES
14 ARE DONOR COMPENSATION AND DONOR CONSENT.

15 AND I THINK WHAT WE NEED TO DO BEFORE WE
16 TACKLE DONOR COMPENSATION IS ACTUALLY HAVE A LITTLE
17 MORE BACKGROUND, WHICH GEOFF HAS PREPARED, TO MAKE SURE
18 WE UNDERSTAND THE COMMENTS THAT WERE MADE THAT WE NEED
19 TO CONSIDER AND RESPOND TO.

20 AND THEN, HANK, IS IT OKAY WITH YOU IF WE
21 SORT OF HAVE YOU COME IN AFTER WE'VE HAD A DISCUSSION,
22 OR DID YOU WANT TO SAY SOMETHING AT THE ONSET? YOU
23 HAVE TO TEACH THIS AFTERNOON. WHEN DO WE LOSE YOU? I
24 WANT TO MAKE SURE WE GET INPUT FROM YOU.

25 MR. GREELEY: AFTER LUNCH.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: EITHER WE HAVE A VERY LATE
2 LUNCH, OR WE NEED TO MAKE SURE WE GIVE HANK TIME TO
3 INTERACT WITH US BEFORE HE HAS TO GO BACK. GEOFF, DO
4 YOU WANT TO MOVE AHEAD TO THE DONOR COMPENSATION ISSUE?

5 DR. LOMAX: I HAVE THIS SLIDE. I THINK YOU
6 ALL HAVE TALKED YOURSELF INTO A VERY GOOD PLACE. I'M
7 ALWAYS LEERY OF STARTING TO TALK AGAIN AND MOVE YOU OUT
8 OF THAT PLACE. SO I'M HAPPY TO DO THAT IF YOU THINK
9 IT'S NECESSARY. AGAIN, THESE WERE VERY MUCH DETAILED
10 IN THE BRIEFING MATERIALS AND YOU HAVE THE SLIDE. SO
11 IF YOU'D LIKE ME TO CONTINUE, I'M HAPPY TO DO SO, BUT
12 I'M NOT SURE I ADD MUCH VALUE AT THIS POINT. WHAT ARE
13 YOUR THOUGHTS?

14 DR. CIBELLI: BEFORE WE MOVE AWAY FROM THIS,
15 THE NEW NIH GUIDELINES, CAN YOU DERIVE NEW LINES WITH
16 EMBRYOS IN WHICH THE DONOR OF THE OOCYTE WAS NOT
17 NOTIFIED? WE'RE TALKING ABOUT ALL LINES THAT WERE
18 DERIVED AND NOW THEY CAN BE REGISTERED?

19 DR. LOMAX: AGAIN, THAT POINT WAS JUST MADE.

20 DR. KIESSLING: SO THE NIH HAS TAKEN THE
21 POSITION, WHICH IS NOT A POSITION THAT'S BEEN TAKEN BY
22 ALL ESCRO COMMITTEES, I WILL TELL YOU, THEY'VE TAKEN
23 THE POSITION THAT THE COUPLE UNDERGOING THE FERTILITY
24 TREATMENT OWN THE EMBRYOS, PERIOD. AND THAT THE ONLY
25 CONSENT FOR USE OF THOSE -- FOR CELL LINES DERIVED FROM

BARRISTERS' REPORTING SERVICE

1 THESE EMBRYOS COMES FROM THE COUPLE. GAMETE DONORS DO
2 NOT HAVE TO BE CONSENTED WITH RESPECT TO DERIVING STEM
3 CELL LINES FROM THE EMBRYOS FOR WHICH THEY DONATED
4 THEIR GAMETES. THAT'S A BIG DIVERSION FROM A LOT OF
5 ESCRO COMMITTEES AROUND THE COUNTRY.

6 DR. LOMAX: WHAT I WILL DO IS, AGAIN, I DON'T
7 FEEL THE NEED TO NECESSARILY GO THROUGH ALL THESE
8 SLIDES, BUT I'LL JUST TOUCH ON THE ONES THAT PUT
9 ADDITIONAL MATERIAL OUT THERE FOR YOUR CONSIDERATION
10 THAT WAS PROVIDED TO US TO SORT OF ROUND OUT YOUR
11 DELIBERATION. AGAIN, THE CUTOFF DATE WAS THE MAJOR
12 ISSUE IN THE COMMENT PERIOD.

13 THERE WAS ALSO A NUMBER OF COMMENTS AND THERE
14 WAS A MEMO LAID OUT TO YOU ALL JUST TALKING ABOUT
15 VARIOUS CALIFORNIA LAWS THAT REALLY ARE INTENDED BOTH
16 IN THE WAY THEY'RE WRITTEN, AND IF YOU TRACK THE RECORD
17 OF THOSE LAWS, TO GIVE PEOPLE CLEAR INFORMATION ABOUT
18 THE ABILITY TO DONATE MATERIALS TO RESEARCH. SO
19 THERE'S KIND OF A BASIS IN LAW.

20 CHAIRMAN LO: PEOPLE BEING WHO? EMBRYO?

21 DR. LOMAX: LET ME PUT IT UP. SO, FOR
22 EXAMPLE, AND THIS IS PART OF THE CALIFORNIA PENAL CODE,
23 SO WE'RE BEYOND GUIDELINES HERE. WE'RE EVEN BEYOND
24 CIRM. THIS IS A PART OF THE LAW THAT YOU CAN -- THERE
25 ARE VERY SERIOUS CONSEQUENCES FOR NOT FOLLOWING THAT

BARRISTERS' REPORTING SERVICE

1 PART OF THE LAW.

2 SO THERE ARE -- IT WAS POINTED OUT THAT
3 CALIFORNIA LAW HAS A VERY STRONG DISCLOSURE
4 REQUIREMENT. SO THIS IS MATERIAL THAT MUST BE TOLD TO
5 ANYONE IF YOU INTEND TO SORT OF GIVE THEIR MATERIALS
6 OVER TO RESEARCH, AND I'VE HIGHLIGHTED THE KEY POINTS
7 IN RED. AND THIS LAW WAS TOUCHED UPON AT THE JULY
8 MEETING LAST YEAR BY ONE OF THE PRESENTERS. AND I JUST
9 WANT TO GO BACK TO THE RECORD, AGAIN, TO GIVE YOU A
10 LITTLE BIT OF AN INDICATION OF WHAT SHE SAID. I THINK
11 IT'S -- AGAIN, THIS IS A LITTLE BIT CLOSER TO CONSENT,
12 BUT IT RELATES TO THE CONTEXT WHERE YOU HAVE A PAID
13 DONOR.

14 SHE INDICATED THAT 90 PERCENT OF THE
15 CONTRACTS THAT SHE CREATED THROUGH HER PRACTICE HAVE A
16 CLEAR STATEMENT ABOUT DONATION FOR RESEARCH. SO,
17 AGAIN, YOU CAN SEE THE BROADER TEXT. SO I THINK I
18 REALIZE --

19 CHAIRMAN LO: GEOFF, LET'S TRY AND STICK TO
20 THE PAYMENT ISSUE. WE'RE GOING TO GET TO THIS WITH
21 CONSENT. BUT IN TERMS OF PAYMENT, ARE YOU SAYING THAT
22 THERE ARE EXISTING CALIFORNIA LAWS AND POLICIES TO
23 ENCOURAGE OR TO PROMOTE THE USE OF EMBRYOS FOR RESEARCH
24 THAT WERE GENERATED IN IVF PRACTICES USING PAID GAMETE
25 DONORS?

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: YES. THERE'S CERTAINLY
2 REQUIREMENTS TO DISCLOSE THAT.

3 CHAIRMAN LO: IN TERMS OF -- I WANT TO
4 SEPARATE THE PAYMENT ISSUE FROM DISCLOSURE. DO ANY OF
5 THESE LAWS TALK ABOUT PAID DONORS?

6 DR. LOMAX: ANY DONOR OF BIOLOGICAL MATERIAL.
7 SO THAT'S ANOTHER PIECE OF THE SORT OF POLICY CONTEXT
8 IN WHICH THIS OPERATES.

9 MS. CHARO: I WANT TO TRY JUST TO RUN DOWN
10 LIKE THREE OR FOUR POINTS JUST TO MAKE SURE I'VE GOT
11 THEM STRAIGHT. FIRST, CALIFORNIA LAW DOES NOT PROHIBIT
12 THE USE OF A STEM CELL LINE THAT COMES FROM AN EMBRYO
13 ORIGINALLY MADE FOR REPRODUCTIVE PURPOSES WITH GAMETE
14 DONORS WHO WERE PAID FOR THEIR SPERM OR THEIR EGGS,
15 CORRECT? DOES NOT PROHIBIT IT.

16 SECOND, BECAUSE THESE PAYMENTS WERE MADE FOR
17 EMBRYOS THAT WERE BEING CREATED FOR REPRODUCTIVE
18 PURPOSES, THESE GAMETE DONORS, SPERM OR OVA, WERE IN NO
19 WAY BEING INDUCED TO DONATE SPECIFICALLY FOR RESEARCH,
20 CORRECT?

21 DR. LOMAX: CORRECT.

22 MS. CHARO: WHATEVER THEY DID -- OKAY.

23 THIRD, WE HAVE NO POLICY CURRENTLY UNDER CIRM
24 REGULATIONS BECAUSE OUR POLICY, WHATEVER IT WAS,
25 EXPIRED?

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: CORRECT.

2 MS. CHARO: SO CURRENTLY OUR GRANTEES CAN USE
3 LINES THAT COME FROM EMBRYOS MADE FOR REPRODUCTIVE
4 PURPOSES WHOSE UNDERLYING GAMETE DONORS MAY HAVE BEEN
5 PAID?

6 DR. LOMAX: NO. IT'S THE OPPOSITE.

7 MS. CHARO: CAN'T BE USED. THE PRESUMPTION
8 IS CAN'T BE USED UNLESS SPECIFICALLY. THANK YOU. SEE,
9 I NEEDED THAT CLARIFICATION. THANK YOU.

10 DR. ROBERTS: WELL, I WANTED TO COMMENT ON
11 SOME OF THE REASONS THAT COMMENTATORS GAVE FOR ALLOWING
12 FOR USE OF EMBRYOS THAT WERE CREATED WITH PAID GAMETES.
13 SO ONE OF THE MAIN ISSUES IS WHETHER OR NOT THAT AUGUST
14 2008 DATE IS ARBITRARY AND MAKES THE GAMETES MORE OR
15 LESS ETHICAL. AND I THINK THAT THAT -- I DON'T THINK
16 THE ISSUE IS ARE THEY ETHICAL OR NOT. I THINK THE
17 QUESTION IS WHAT WAS THE PURPOSE OF THAT DATE, AND IS
18 IT ARBITRARY?

19 I THINK THE REASON FOR THAT DATE WAS THAT
20 THERE WAS NO IMPACT THAT CIRM COULD HAVE ON THE
21 DONATION OF GAMETES PRIOR TO THAT PERIOD. THEY WERE
22 ALREADY -- IT WAS ALREADY DONE. AND SO THE QUESTION
23 WAS, WELL, GOING FORWARD, WHAT WILL BE THE IMPACT OF
24 OUR POLICY? AND I THINK -- SO THAT'S THE REASON FOR
25 THEM. IT'S NOT ARBITRARY. THERE'S A REASON. IT'S

BARRISTERS' REPORTING SERVICE

1 AFTER THAT DATE, WE COULD HAVE SOME IMPACT ON THE
2 ETHICAL NATURE OF THE DONATION OF GAMETES AND THEIR USE
3 IN RESEARCH. I JUST DON'T FIND THAT ARGUMENT VERY
4 PERSUASIVE.

5 NOW, DOES THAT DATE MAKE A DIFFERENCE THOUGH?
6 THAT'S OUR QUESTION. DOES IT MAKE A DIFFERENCE? WELL,
7 I THINK, AS MANY HAVE SAID, IT DOESN'T REALLY MAKE A
8 DIFFERENCE IN TERMS OF WHETHER OR NOT, AS ALTA JUST
9 SAID, THESE WOMEN ARE BEING GIVEN EXTRA INDUCEMENT TO
10 DONATE EGGS FOR RESEARCH BECAUSE THEY'RE NOT DONATING
11 THEIR EGGS FOR RESEARCH. THEY'RE DONATING THEIR EGGS
12 FOR REPRODUCTIVE PURPOSES, AND THAT'S WHAT THEY'RE PAID
13 FOR. SO I THINK THAT ARGUMENT DOES MAKE SENSE.

14 BUT ON THE OTHER HAND, IS THERE A CONFLICT, A
15 POTENTIAL CONFLICT OF INTEREST THAT WOULD PUT SOME KIND
16 OF PRESSURE ON WOMEN WHO WERE DONATING THEIR EGGS FOR
17 REPRODUCTIVE PURPOSES TO PERHAPS DONATE MORE EGGS THAN
18 THEY WOULD HAVE IF SOMEONE INVOLVED DIDN'T HAVE
19 RESEARCH IN MIND? THAT CONFLICT OF INTEREST, I THINK,
20 IS STILL THERE.

21 SO RELATING TO THE FIRST POINT ABOUT IS THERE
22 SOME EXTRA RISK FOR COMPENSATION, I THINK IT WOULD
23 BE -- I AGREE WITH SOME OTHER MEMBERS OF THE PANEL,
24 THAT WE COULD DISPENSE WITH THE AUGUST 28TH DATE. NOW,
25 THE PROBLEM I HAVE, THOUGH, IS THAT THAT'S NOT WHAT THE

BARRISTERS' REPORTING SERVICE

1 RECOMMENDATION WAS. THE RECOMMENDATION DIDN'T SAY
2 DELETE THE AUGUST 28TH DATE. IT HAS THIS VERY BROAD
3 LANGUAGE OF ADDING TO THE RULES ABOUT ACCEPTABLE
4 RESEARCH MATERIALS, THAT THE LIMIT OF THE PAYMENT
5 RESTRICTION WOULD BE TO THE DONATION OF OOCYTES
6 PROVIDED SPECIFICALLY FOR RESEARCH PURPOSES.

7 AND I WOULD JUST SUGGEST THAT WE STRIKE THAT,
8 THAT THAT'S NOT GOOD LANGUAGE TO EVEN CONSIDER, BECAUSE
9 THAT WOULD BE -- THERE'S NOTHING IN THIS PROVISION, THE
10 ACCEPTABLE RESEARCH, IT'S ON PAGES 4 AND 5 OF THE
11 YELLOW, THE REGULATIONS, THERE'S NOTHING IN THAT THAT
12 PERTAINS JUST TO REPRODUCTIVE PURPOSES. THIS IS JUST
13 THE GENERAL PROVISION OF WHAT ARE ACCEPTABLE RESEARCH
14 MATERIALS.

15 AND SO IF WE ADDED TO (A)(2)(B) THAT THIS
16 LIMIT ON PAYMENT ONLY PERTAINS TO OOCYTES PROVIDED
17 SPECIFICALLY FOR RESEARCH PURPOSES, IT WOULD BE A
18 GENERAL LIMIT ON THIS RULE, WHICH IS REQUIRED BY
19 PROPOSITION 71 OF NOT PAYING FOR RESEARCH MATERIALS.

20 AND THE PROBLEM -- I THINK THE PROBLEM IS,
21 WHAT DOES IT MEAN PROVIDED SPECIFICALLY FOR RESEARCH
22 PURPOSES? HOW IS THAT DIFFERENT FROM PROVIDED FOR
23 RESEARCH PURPOSES? ALL I CAN INTERPRET THAT TO MEAN IS
24 THAT SPECIFICALLY WOULD BE GENERALLY INTERPRETED AS
25 ONLY FOR RESEARCH PURPOSES. SO, THEREFORE, YOU COULD

BARRISTERS' REPORTING SERVICE

1 HAVE OOCYTES THAT WERE DONATED FOR BOTH RESEARCH AND
2 REPRODUCTIVE PURPOSES EXEMPTED FROM THE PAYMENT
3 RESTRICTION. I THINK THAT WOULD BE A LOGICAL
4 INTERPRETATION OF THIS LANGUAGE.

5 SO I DON'T THINK WE SHOULD USE THAT LANGUAGE.
6 IF WE'RE GOING TO TAKE OUT THE AUGUST 28TH -- AUGUST
7 13, 2008, CUTOFF, THEN WHY DON'T WE JUST DO THAT? SO
8 IN OTHER WORDS, WHAT WE DID BEFORE -- I'M SAYING WE. I
9 WASN'T ON THE COMMITTEE THEN -- BUT WHAT YOU, COUNSEL,
10 SAY WE DID BEFORE WAS ADD A NARROW EXEMPTION IN 100090
11 ON PAGE 6. FOR EMBRYOS CREATED ON OR BEFORE AUGUST
12 13TH, VALUABLE CONSIDERATION DOES NOT INCLUDE PAYMENTS
13 TO GAMETE DONORS IN EXCESS OF PERMISSIBLE EXPENSES
14 PROVIDED THE EMBRYO WAS ORIGINALLY CREATED FOR
15 REPRODUCTIVE PURPOSES.

16 SO INSTEAD OF THIS BROAD LANGUAGE THAT WOULD
17 PERTAIN TO ANY OOCYTES THAT WEREN'T PROVIDED
18 SPECIFICALLY FOR RESEARCH PURPOSES, IT WOULD BE JUST A
19 NARROW EXEMPTION FOR EMBRYOS ORIGINALLY CREATED FOR
20 REPRODUCTIVE PURPOSES. SO I'M JUST SUGGESTING THAT IF
21 THAT'S -- IF WE AGREE THAT WE ARE GOING TO ALLOW LINES
22 TO BE DERIVED FROM EMBRYOS THAT USED PAID GAMETES FOR
23 REPRODUCTIVE PURPOSES, IT SHOULD BE A NARROW EXCEPTION
24 LIKE WAS DONE BEFORE EXCEPT THERE WOULDN'T BE THE
25 AUGUST 13TH DATE, WHICH I AGREE TO SOME EXTENT DOESN'T

BARRISTERS' REPORTING SERVICE

1 MAKE SENSE TO KEEP.

2 BUT ON THE OTHER HAND, JUST TO MAKE ONE MORE
3 POINT. THAT'S MY SUGGESTION FOR DEALING WITH THE ISSUE
4 OF COMPENSATION, THE EXTRA RISK CREATED BY
5 COMPENSATION.

6 NOW, THAT, THOUGH, DOES NOT DEAL WITH THE
7 CONFLICT OF INTEREST ISSUE. I THINK ALTA MADE A
8 HELPFUL STATEMENT, I THINK, AT THE JULY MEETING WHERE
9 YOU SAID, WELL, THAT HAS TO DO WITH THE IMPACT OF
10 COMPENSATION ON THE RESEARCHERS AND THE DOCTORS, NOT
11 THE GAMETE DONOR. AND I THINK THAT IS ANOTHER ISSUE,
12 THE CONFLICT OF INTEREST, WHICH IT WOULD STILL EXIST,
13 AND I DON'T THINK WE SHOULD IGNORE IT. AND SO I WOULD
14 HOPE THAT IF WE DO LIFT THE CURRENT RESTRICTION ON
15 EMBRYOS WITH PAID GAMETE DONORS AFTER AUGUST 13, 2008,
16 THAT WE WOULD STILL THINK ABOUT OR PUT IN PLACE
17 PROTECTIONS AGAINST A POTENTIAL CONFLICT OF INTEREST IN
18 OBTAINING THESE OOCYTES, PAID OOCYTES, THAT NOW
19 EVERYONE KNOWS CAN BE USED, THE EMBRYOS, FOR RESEARCH
20 PURPOSES.

21 DR. LOMAX: BERNIE, CAN I JUST OFFER ONE
22 BECAUSE IT'S A VERY IMPORTANT POINT. I JUST WANT TO
23 DIRECT YOUR ATTENTION TO THE DOCUMENT IN THE PROCESS.
24 VERY MUCH THE INTENT THERE, I MENTIONED A NUMBER OF
25 TIMES IN THE BRIEFING DOCUMENT, IS THAT THAT RESEARCH

BARRISTERS' REPORTING SERVICE

1 PURPOSE LANGUAGE WAS JUST BORROWED FROM THE NATIONAL
2 ACADEMIES. AND IT'S JUST GENUINELY INTENDED TO BE A
3 CONCEPTUAL PLACEHOLDER.

4 I DO WANT TO EMPHASIZE ONE ITEM, AND IT'S IN
5 NO. 2. IT'S ALSO THE POINT THAT CIRM SHOULD NOT
6 RESTRICT THE USE OF CELLS PROCURED UNDER IRB-APPROVED
7 PROTOCOLS. IF YOU GO BACK, REMEMBER THAT DECEMBER 9TH
8 MEETING, WE WERE IN THE MIDST OF THAT DISCUSSION AND
9 SOME QUESTIONS WERE RAISED BY THE SCOPE OF THE PAYMENT
10 RESTRICTION. I THINK, PROFESSOR ROBERTS, YOU RAISED
11 THAT POINT. AND SO I NOTE -- JAMES HARRISON IS HERE.
12 SO WE STOPPED AT THAT POINT AND SAID WE NEED TO GO BACK
13 AND CONSIDER THE SCOPE OF THAT RESTRICTION. AND SO
14 WHAT THAT LANGUAGE IS INTENDED TO DO WAS CAPTURE THE
15 VERY SPECIFIC SITUATION WHERE YOU'VE GOT A PAID -- NO
16 PAID OOCYTE GOING INTO CIRM-FUNDED RESEARCH. AGAIN,
17 CONCEPTUAL PLACEHOLDER.

18 CLEARLY WHATEVER THE FINAL LANGUAGE IS, IT
19 NEEDS TO BE AMPLIFIED IN A WAY THAT'S SATISFACTORY.
20 BUT IT IS AN INTENT THERE, AND I NEED TO BE VERY CLEAR
21 ABOUT THIS, IS TO ALSO NOT RESTRICT THE USE OF OTHER
22 CELLS FOR WHICH THERE HAVE BEEN MODEST PAYMENTS.

23 I KNOW JAMES HARRISON IS PREPARED TO SORT OF
24 DISCUSS THIS POINT FURTHER, BUT IT WAS THE ISSUE THAT,
25 AGAIN, ON THE DECEMBER 12TH MEETING SORT OF WAS A

BARRISTERS' REPORTING SERVICE

1 STOPPING POINT FOR OUR CONVERSATION. AND TO THE EXTENT
2 WE NEED TO PICK THAT UP AS WELL, I KNOW JAMES HARRISON
3 IS PREPARED TO DO THAT. I JUST WANT TO BE CLEAR WHY
4 THE SCOPE HERE IS WHY IT WAS RECOMMENDED THE WAY IT WAS
5 RECOMMENDED AND PARTICULARLY WHAT POINT. IT'S AT ITEM
6 NO. 2. IT'S THE OTHER CELLS THAT WE'RE ALSO TRYING TO
7 ADDRESS THERE.

8 CHAIRMAN LO: LET ME SEE IF I HAVE CLEAR WHAT
9 I THINK WE'VE JUST HEARD.

10 DOROTHY, I THINK, MADE A NUMBER OF POINTS,
11 ONE OF WHICH WAS THAT WE SHOULD CRAFT OUR LANGUAGE
12 NARROWLY TO ACHIEVE THE PURPOSE WE'RE INTENDING TO
13 ACHIEVE AND NOT STATE IT IN OVERLY BROAD TERMS THAT
14 MIGHT HAVE UNINTENDED EFFECTS EITHER GOOD OR BAD. AND
15 HER SPECIFIC RECOMMENDATION ON THIS ISSUE OF PAYMENT TO
16 OOCYTE DONORS IN THE IVF CONTEXT AND THEIR EMBRYOS
17 BEING ACCEPTABLE FOR USE WHEN DONATED BY THE GAMETE
18 DONOR -- THE EMBRYO DONOR, SHE SUGGESTED WE USE THE
19 LANGUAGE WE CRAFTED THE LAST TIME IN 10090(A), WHICH IS
20 ON PAGE 6 OF THE YELLOW SHEETS, AND JUST DELETE THE
21 DATE OF AUGUST 2008 AND SAY SOMETHING ALONG THE LINES
22 THAT FOR EMBRYOS CREATED FOR REPRODUCTIVE PURPOSES,
23 ORIGINALLY CREATED FOR REPRODUCTIVE PURPOSES, VALUABLE
24 CONSIDERATION DOES NOT INCLUDE PAYMENT TO GAMETE DONORS
25 IN EXCESS OF PERMISSIBLE EXPENSES.

BARRISTERS' REPORTING SERVICE

1 SHE ALSO WENT ON TO SAY, BUT SHE HAS SOME
2 CONCERNS ABOUT POTENTIAL CONFLICTS OF INTEREST WHERE
3 THE IVF TREATING PHYSICIAN MAY HAVE RESEARCH EMBRYOS IN
4 MIND DOWN THE ROAD AND MAY TAKE ADVANTAGE -- MAY PUT
5 THE WOMAN AT EXCESS MEDICAL RISK OVER AND BEYOND WHAT
6 SHE WOULD HAVE EXPERIENCED HAD SHE JUST BEEN DONATING
7 SOLELY IN THE IVF CONTEXT WITH NO THOUGHT OF FUTURE
8 USE, TO MAYBE SQUEEZE A FEW EXTRA OOCYTES OUT. AND SHE
9 SUGGESTED WE TRY AND ADDRESS THAT CONFLICT OF INTEREST
10 ISSUE SEPARATELY, BUT SHE WOULD LIKE THEM AS A PACKAGE.

11 SO THEN I HEARD GEOFF SAY THERE'S ANOTHER
12 COMPENSATION ISSUE WHICH HAS TO DO WITH COMPENSATING
13 SOMATIC CELL DONORS 25, \$50 FOR A SKIN BIOPSY THAT'S
14 USED FOR IPS CELLS. DO WE WANT TO SAY FOR THAT
15 PARTICULAR PURPOSE, WE DO NOT WANT -- THAT WE WANT TO
16 ADDRESS THAT ISSUE, WHETHER THAT IS PERMISSIBLE BECAUSE
17 MANY IPS LINES ARE PAYING THEIR SOMATIC CELL DONORS.

18 I WOULD SUGGEST WE SEPARATE THAT OUT AND COME
19 BACK TO IT LATER BECAUSE I THINK THIS OOCYTE
20 COMPENSATION IN THE IVF CONTEXT IS SOMETHING THAT WE
21 SHOULD SOLVE. I GUESS I FIRST WANT TO GET A SENSE OF
22 THE COMMITTEE AS TO WHETHER YOU LIKE DOROTHY'S GENERAL
23 IDEA OF TAILORING NARROWLY ALLOWING -- INTERPRETING
24 VALUABLE CONSIDERATION NOT TO INCLUDE PAYMENT TO GAMETE
25 DONORS IN THE REPRODUCTIVE CONTEXT COUPLED WITH A AS

BARRISTERS' REPORTING SERVICE

1 YET TO BE DETERMINED REQUIREMENT LIMITING, AS DOROTHY
2 PUT IT, CONFLICTS OF INTEREST ON THE PART OF THE
3 TREATING IVF PHYSICIAN. WE HAVE TO THINK ABOUT HOW WE
4 MIGHT CRAFT THAT. IS THAT ACCEPTABLE, SORT OF
5 DISPENSING WITH THE AUGUST 2008 CUTOFF IN A NARROW WAY,
6 BUT ADDRESSING THIS ISSUE OF PROTECTING WOMEN BY
7 ADDRESSING CONFLICTS OF INTEREST?

8 MS. LANSING: WE WOULD THEN TAKE -- I GET SO
9 CONFUSED -- WE WOULD THEN TAKE THINGS WHERE PEOPLE HAD
10 BEEN PAID FOR IT, BUT WE NOW -- SO WE WOULD LIMIT.

11 DR. ROBERTS: IN THE IVF CONTEXT ONLY THOUGH.

12 MS. LANSING: YES. WE WOULD LIFT THE BAN AND
13 MAKE IT FOREVER FORWARD. AND NOW THE QUESTION IS HOW
14 DO WE PROTECT THE WOMAN FROM BEING EXPLOITED IN SOME
15 WAY BY THE TREATING PHYSICIAN.

16 CHAIRMAN LO: I MUST SAY --

17 MS. LANSING: I THINK THERE'S WAYS.

18 CHAIRMAN LO: LET ME JUST AGAIN IN CONTEXT,
19 WE HAVE ALWAYS BEEN MINDFUL OF PROTECTING WOMEN IN A
20 NUMBER OF WAYS, ONE OF WHICH IS PROTECTING THEM FROM
21 MEDICAL RISKS, ESPECIALLY IF THEY'RE UNDUE OR EXCESSIVE
22 MEDICAL RISKS IN LIGHT OF THE POTENTIAL BENEFITS. WE
23 ALSO PROTECT THEM IN OTHER WAYS BY TRYING TO RESPECT
24 THEIR DECISION MAKING ABILITY TO MAKE DIFFICULT
25 DECISIONS FOR THEMSELVES. SO WE'VE TRIED TO BE MINDFUL

BARRISTERS' REPORTING SERVICE

1 OF PROTECTING WOMEN IN OUR REGULATIONS. I THINK THAT'S
2 SOMETHING WE SHOULD CONTINUE TO DO BECAUSE I THINK IT'S
3 IMPORTANT.

4 DR. TAYLOR: BERNIE, DO WE REALLY WANT TO
5 SEPARATE THOSE TWO THINGS? I APOLOGIZE, BUT I WOULD
6 SORT OF ARGUE THAT THE SOMATIC CELLS, I JUST AS SOON
7 SEE THAT DISCUSSION IN THE SAME DISCUSSION HERE. THE
8 OOCYTE AND GAMETE ISSUE IS HUGER THAN THE OTHER.

9 CHAIRMAN LO: I'D LIKE TO SEPARATE THEM
10 BECAUSE YOU DO NOT HAVE THE SAME CONCERNS ABOUT RISK
11 WHEN YOU'RE DONATING SOMATIC CELLS. YOU'RE TALKING
12 ABOUT TAKING A SKIN BIOPSY, WHICH IS DONE IN MANY OTHER
13 RESEARCH CONTEXTS AND PAID FOR. IT'S NOT HIGHLY RISKY.
14 IT'S NOT NEARLY AS RISKY WHEN THINGS GO WRONG AS OOCYTE
15 DONATION.

16 DR. TAYLOR: I GUESS IT KIND OF DEPENDS ON
17 WHERE THE DISCUSSION IS GOING TO GO.

18 MS. CHARO: BEFORE WE EVEN MOVE ON TO THE
19 ISSUE OF CONFLICT OF INTEREST, WHETHER THERE IS ONE, IF
20 THERE IS ONE, HOW ONE HANDLES IT, ON A HYPER TECHNICAL
21 DRAFTING MATTER, WHICH IS GOING TO BE INCREDIBLY
22 TEDIOUS FOR ALL OF US, I THINK WE RUN INTO A BIT OF A
23 PROBLEM. WE TAKE YOUR SUGGESTION, DOROTHY, AND WE
24 SIMPLY DELETE THE DATE WHERE IT APPEARS, BUT THAT
25 SECTION APPLIES ONLY TO THE DERIVATION OF NEW LINES.

BARRISTERS' REPORTING SERVICE

1 WE ALSO HAVE TO BE WORRYING ABOUT WHETHER OR
2 NOT WE CAN HAVE OUR GRANTEES USE LINES THAT COME FROM
3 ELSEWHERE. THAT BRINGS UP THE ISSUE OF ACCEPTABLY
4 DERIVED. IF WE GO BACK TO THE ACCEPTABLY DERIVED
5 SECTION, YOU HAVE TO MEET ONE OF THREE SETS OF RULES.
6 THE FIRST ONE BEING IT'S BEEN GIVEN THE GOOD
7 HOUSEKEEPING STAMP OF APPROVAL. THE THIRD IS WHERE
8 IT'S NONIDENTIFIABLE. BUT IN THE MIDDLE IS THE ONE
9 WITH ALL THE DETAILED RULES ABOUT ACCEPTABLY DERIVED.
10 AND IN THAT YOU FIND BURIED IN THERE THAT DONORS OF
11 GAMETES, EMBRYOS, SOMATIC CELLS, OR TISSUE DID NOT
12 RECEIVE VALUABLE CONSIDERATION. SO THAT'S GOING TO
13 TAKE SOME VERY CAREFUL REDRAFTING TO TEASE OUT BECAUSE
14 YOU STILL DON'T WANT THE EMBRYOS TO BE BOUGHT AND SOLD.
15 SO JUST AS AN ASIDE, WE CAN'T DO THIS UNTIL WE AT LEAST
16 KNOW THAT WE'VE GOT TO DO SOME VERY NUANCED DRAFTING TO
17 PULL THIS OFF.

18 CHAIRMAN LO: MAKE SURE WE'RE ALL LOOKING AT
19 THE SAME PAGE.

20 MS. CHARO: I'M SORRY. THAT'S PAGE 5, AND
21 IT'S SECTION -- I HATE THE NUMBERING -- 100080(A)(2) --
22 SMALL A, NO. 2, CAPITAL B. COULD IT BE MORE CONFUSING?
23 I DON'T THINK SO.

24 CHAIRMAN LO: IF YOU JUST PICK UP THE PAPER
25 THAT'S YELLOW, ON PAGE 5, IT'S RIGHT HERE.

BARRISTERS' REPORTING SERVICE

1 MS. CHARO: IT'S LIKE MIDDLE OF THE LEFT-HAND
2 COLUMN, RIGHT.

3 CHAIRMAN LO: ALTA, THAT'S --

4 MS. CHARO: I DON'T THINK WE NEED TO REDRAFT
5 IT AS A GROUP BECAUSE THAT'S A NIGHTMARE, BUT I JUST
6 WANT TO MAKE SURE WE PUT THAT ON THE LIST.

7 CHAIRMAN LO: COULD WE SAY OUR ATTENTION HERE
8 IS TO PUT IN THERE A NARROWLY WRITTEN REVISION TO B
9 THAT SAYS, IN THE CONTEXT OF GAMETES BEING DONATED IN
10 THE IVF CONTEXT TO FORM EMBRYOS FOR REPRODUCTION,
11 VALUABLE CONSIDERATION DOES NOT INCLUDE THOSE,
12 SOMETHING LIKE THAT.

13 MS. CHARO: I WANTED IT ON THE RECORD BECAUSE
14 IT WASN'T REALLY CLEAR. OF COURSE, I DON'T THINK
15 THERE'S ANYTHING I WANT MORE THAN YET ANOTHER SUB, SUB,
16 SUB, SUBSECTION FOR THIS SET OF REGULATIONS. I'M
17 DELIGHTED AT THE PROSPECT.

18 DR. LOMAX: JUST TO REMIND YOU ON A
19 PROCEDURAL BASIS THAT WE HAVE A LONG HISTORY OF, PRIOR
20 TO INITIATING ANY PROCESS, IS CIRCULATING BACK TO THE
21 COMMITTEE MEMBERS ANY PROPOSED LANGUAGE AND OPPORTUNITY
22 TO COMMENT. SO WE DO THAT BECAUSE IT IS AWKWARD IF WE
23 TRY TO CRAFT LANGUAGE IN THE RECORD, AND THEN WE MAKE A
24 MISTAKE. SO WE HAVE MULTIPLE OPPORTUNITIES DOWNSTREAM
25 TO THINK ABOUT THE WORDING WITH YOU AND THE PUBLIC.

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: JUST BECAUSE I'M THE LAYPERSON,
2 BUT THE SENSE OF THE GROUP, AND I DON'T SEE ANY
3 RESISTANCE, IS THAT IF SOMEBODY WAS PAID FOR
4 REPRODUCTIVE PURPOSES AND ONLY FOR REPRODUCTIVE
5 PURPOSES, WE WOULD BE ABLE TO USE THE MATERIAL, WHICH
6 IS SOMETHING THAT THERE WOULD BE NO RESTRICTION ON
7 DATES.

8 DR. KIESSLING: THAT SORT OF SIDESTEPS WHAT
9 WAS THIS DONOR'S CONSENT? WHAT WAS HER CONSENT
10 PROCESS? WELL, I THINK THAT'S ACTUALLY PART OF
11 PROTECTING HER. I THINK THAT'S NOT A SEPARATE ISSUE.
12 I THINK THAT'S PROBABLY THE OVERARCHING ISSUE, WHETHER
13 OR NOT SHE WAS PAID.

14 CHAIRMAN LO: LET'S TRY AND MOVE ON TO THAT.
15 LET ME GET WHETHER IT'S THE SENSE OF THE COMMITTEE,
16 BECAUSE WE HAVE ACTUALLY TWO OPTIONS HERE. I THINK ONE
17 IS TO SORT OF CHARGE STAFF WITH DRAFTING LANGUAGE,
18 REGULATORY LANGUAGE, THAT WILL ACHIEVE DOROTHY'S STATED
19 GOAL OF PERMITTING EMBRYOS THAT WERE DERIVED IN THE IVF
20 CONTEXT USING THIRD-PARTY GAMETE DONORS THAT WERE PAID,
21 TO ALLOW THAT WITHOUT ANY REFERENCE TO A CUTOFF DATE.
22 HER PROPOSAL WAS PROVIDED THAT WE ALSO HAVE SOME
23 PROVISION TO ADDRESS CONFLICTS OF INTEREST. WE COULD
24 ALSO HAVE A SUBSTITUTE OPTION WHICH IS TO REMOVE THE
25 CUTOFF DATE WITH NO REFERENCE TO CONFLICTS OF INTEREST.

BARRISTERS' REPORTING SERVICE

1 SO THOSE ARE TWO OPTIONS WE SHOULD AT LEAST
2 THINK ABOUT. ALL THAT SUBJECT, AS ANN HAS RIGHTLY
3 POINTED OUT, THOSE LINES STILL HAVE TO MEET WHATEVER WE
4 DECIDE IS APPROPRIATE CONSENT FROM THE GAMETE DONORS.

5 MS. LANSING: BUT THOSE ARE THREE THINGS. WE
6 WERE DISCUSSING NO. 1. WE HAVE TWO MORE TO DISCUSS.

7 DR. KIESSLING: I THINK THE APPROPRIATE
8 CONSENT ISSUE IS FAR MORE OVERARCHING.

9 CHAIRMAN LO: WHAT I'M PROPOSING IS TRY AND
10 MOVE ON TO THAT BY GETTING A SENSE OF WHERE WE STAND ON
11 THE COMPENSATION ASSUMING --

12 MS. LANSING: WE DIDN'T AGREE WITH THIS LAST
13 TIME. WE HAD A VERY NARROW CUTOFF DATE. SO AS SMALL
14 AS IT MAY SEEM, IT'S HUGE FOR OUR GROUP.

15 CHAIRMAN LO: ONE THING IS DOES ANYBODY
16 OBJECT IN PRINCIPLE TO REMOVING THE AUGUST 2008 CUTOFF
17 DATE NO MATTER WHAT ELSE WE DO ON THE COMMITTEE? OKAY.

18 BEFORE I GET PUBLIC COMMENT, THEN I WANT TO
19 SEE HOW MANY OF YOU FEEL THAT YOUR AGREEMENT WITH THAT
20 IS CONTINGENT ON OUR DOING SOMETHING TO ADDRESS THE
21 CONFLICT OF INTEREST ISSUE THAT DOROTHY RAISED? NO.
22 WE'RE NOT UNANIMOUS THERE. OF COURSE, WE WERE ALL
23 AGREEING THAT YOU STILL HAVE TO GET APPROPRIATE
24 CONSENT, WHATEVER WE DECIDE THAT IS FROM THE GAMETE
25 DONOR.

BARRISTERS' REPORTING SERVICE

1 SO LET'S TALK A LITTLE ABOUT THE CONFLICT OF
2 INTEREST IDEA AS TO WHETHER THAT'S GOING TO PROVIDE --

3 DR. KIESSLING: HAVE WE AGREED THAT WE NEED
4 TO GET -- THAT THE GAMETE DONORS NEEDED TO HAVE
5 CONSENTED TO --

6 MS. CHARO: NO. THAT'S GOING TO BE THE NEXT
7 STEP.

8 CHAIRMAN LO: SO THE OPTION HERE --

9 MS. CHARO: WE'RE GOING FROM NARROW TO BROAD.

10 CHAIRMAN LO: ASSUMING THAT WE AGREE ON
11 CONSENT, WHICH IS OUR NEXT STEP, THE PAYMENT PER SE TO
12 THE GAMETE DONOR IN THE REPRODUCTIVE CONTEXT WOULD NOT
13 DISQUALIFY AN EMBRYO OR HESC LINE FROM BEING USED. SO
14 I'M TRYING TO DO THIS RELATIVELY -- A VERY IMPORTANT
15 THING, BUT IT'S LESS COMPLICATED THAN THE CONSENT.

16 MS. FEIT: DO WE NEED TO MENTION THAT THE
17 PAYMENT NEEDS TO MEET THE ACCEPTABLE GUIDELINES THAT WE
18 HEARD ABOUT YESTERDAY? THERE WAS AMOUNTS OF MONEY THAT
19 WERE SAID WERE SORT OF INDUSTRY STANDARDS FOR PAYMENT.
20 IS IT NECESSARY FOR US TO IDENTIFY IT THAT PRECISELY?

21 MS. LANSING: I'M ACTUALLY LESS CONCERNED
22 ABOUT THAT BECAUSE THAT WAS PURELY FOR REPRODUCTIVE
23 ISSUES. AND SO I DON'T KNOW THAT THAT'S OUR ISSUE.
24 WHAT I'M CONCERNED ABOUT IS WHAT DOROTHY BROUGHT UP,
25 THAT SOME PHYSICIAN OR CLINICIAN COULD SAY, WELL, I'M

BARRISTERS' REPORTING SERVICE

1 GOING TO GET MORE THAN I NEED, PUTTING THE WOMAN AT
2 HARM. AND EVEN WITH INFORMED CONSENT, I DON'T THINK
3 THE PATIENT WOULD KNOW THAT THAT WAS REALLY GOING ON.
4 THEY WOULDN'T KNOW WHAT IS MORE.

5 AND SO IT SEEMS TO ME, AND ACTUALLY, YOU
6 KNOW, BERNIE, YOU AND I TALKED ABOUT THIS, SO I DON'T
7 WANT TO TAKE IT. WHEN WE TALKED ABOUT IT, IT SEEMED TO
8 ME THAT THERE WAS A RELATIVELY CLEAR WAY TO PROTECT
9 THAT, WHICH IS THAT THE CLINICIAN WHO WAS DEALING WITH
10 THE REPRODUCTIVE RIGHTS CAN IN NO WAY USE ANY OF THE
11 MATERIAL FOR RESEARCH. SO, THEREFORE, THEY WOULD HAVE
12 NO MOTIVATION TO DO THAT. SO THEY CAN'T USE IT.

13 DR. CIBELLI: DECOUPLING THE PHYSICIAN FROM
14 THE --

15 MS. LANSING: YEAH. THE PHYSICIAN IS THE
16 REPRODUCTIVE PHYSICIAN, AND SOMEBODY WHO WANTS TO DO
17 RESEARCH ON STEM CELLS OR SOMETHING CANNOT BE --

18 DR. CIBELLI: BUT THESE ARE BIG CLINICS.
19 THIS IS USUALLY A TEAM EFFORT. IT'S GOING TO BE
20 COMPLICATED, I THINK.

21 DR. TAYLOR: I THINK LOGISTICALLY THAT'S
22 GOING TO BE REALLY HARD TO PULL OFF. LOGISTICALLY TO
23 COMPLETELY SEPARATE THE CLINICAL MANAGEMENT OF THE
24 PATIENT FROM THE KIND OF INSTITUTIONAL AND RESEARCH
25 INTERESTS OF AN ACADEMIC CENTER, I THINK, ARE GOING TO

BARRISTERS' REPORTING SERVICE

1 BE ALMOST IMPOSSIBLE TO FULLY DISSOCIATE UNLESS YOU
2 SORT OF SEND SOMEONE ACROSS TOWN. I DON'T SEE IT
3 HAPPENING IN A VERY EFFECTIVE WAY. THE TRUTH IS TO
4 MAKE ONE OF THESE PROGRAMS WORK, YOU HAVE TO HAVE
5 SCIENTISTS THAT ARE INTERESTED IN DEVELOPING THE CELLS
6 AND CLINICIANS WHO ARE WILLING TO SORT OF USE THE
7 PATIENT POPULATION OR TO HELP THE PATIENT POPULATION
8 WANT TO SORT OF MAKE A CONTRIBUTION. I THINK THAT'S
9 GOING TO BE HARD TO DISSOCIATE.

10 DR. ROBERTS: IT SOUNDS ALMOST AS IF THE VERY
11 SOURCE OF THE CONFLICT MEANS THAT YOU CAN'T ADDRESS THE
12 CONFLICT. THAT'S WHY THERE IS A POTENTIAL CONFLICT,
13 BECAUSE THE IVF DOCTORS AND THE RESEARCHERS ARE SO
14 OFTEN WORKING TOGETHER. BUT SO DO YOU THINK IT'S
15 IMPOSSIBLE TO ADDRESS THE CONFLICT THEN?

16 DR. TAYLOR: I THINK THAT THE --

17 DR. ROBERTS: OR THE CONFLICT ISN'T A SERIOUS
18 CONCERN?

19 DR. TAYLOR: I THINK THE CONFLICT HAS TO BE
20 SORT OF MITIGATED AND MINIMIZED. I THINK THAT IT
21 ACTUALLY RESULTS IN POOR PATIENT CARE TO GET AROUND IT
22 COMPLETELY BECAUSE YOU HAVE KIND OF DISSOCIATED
23 INTERESTS.

24 MS. LANSING: ARE THERE STANDARD MEDICAL
25 PRACTICES THAT APPLY THAT IF YOU WENT BEYOND A CERTAIN

BARRISTERS' REPORTING SERVICE

1 NUMBER, YOU WOULD BE VIOLATING THOSE RULES?

2 DR. TAYLOR: THERE AREN'T THE STRICTEST
3 REGULATIONS. THERE ARE SORT OF GUIDELINES AND
4 RECOMMENDATIONS, BUT NOT REALLY COMPLETELY STRICT
5 LIMITS, I WOULD SAY. AND THOSE ARE THINGS THAT, AGAIN,
6 I THINK MOST PHYSICIANS, RESPONSIBLE PHYSICIANS WANT TO
7 KIND OF HAVE SOME FLEXIBILITY IN GIVEN SITUATIONS.

8 MS. CHARO: A COUPLE OF THINGS. FIRST, I
9 WANT TO NOTE THAT THIS QUESTION ABOUT CONFLICT OF
10 INTEREST AROSE IN THE CONTEXT OF YOUR DISCUSSION ABOUT
11 AN UNDERLYING PAID GAMETE DONOR, BUT NOW WE'RE TALKING
12 ABOUT IT IN A MORE GENERAL FASHION HAVING TO DO WITH
13 ANY PROCESS BY WHICH THERE IS A GAMETE RETRIEVAL. I
14 SENSE YOUR CONCERN IS MORE ABOUT OOCYTE RETRIEVAL THAN
15 SPERM.

16 REGARDLESS OF WHETHER SOMEBODY IS HAVING
17 OOCYTES RETRIEVED FOR HER OWN USE OR SHE'S HAVING THEM
18 RETRIEVED IN ORDER TO HAVE THEM GIVEN TO SOMEBODY ELSE,
19 BECAUSE IF YOUR CONCERN IS THAT THE CLINICAL PHYSICIAN
20 HAS IN HIS OR HER MIND SOME NOTION THAT IF WE GET A FEW
21 MORE EGGS WITH A BIGGER STIMULATION, WE MAY HAVE SOME
22 LEFTOVERS FOR RESEARCH, IT DOESN'T SEEM TO ME OBVIOUS
23 THAT IT MATTERS WHETHER OR NOT THE UNDERLYING OOCYTE
24 DONOR WAS PAID OR NOT.

25 THE SECOND, I THINK, MORE GENERAL COMMENT

BARRISTERS' REPORTING SERVICE

1 THOUGH --

2 MS. LANSING: THAT'S A VERY GOOD POINT.

3 MS. CHARO: -- IS ONE THAT GOES TO KIND OF
4 THE SETS OF PRESUMPTIONS WITH WHICH WE APPROACH THE
5 FIELD. WE HAVE NO EVIDENCE BEFORE US OF ANY ACTUAL
6 ABUSES, SO WE'RE TALKING ABOUT A HYPOTHETICAL
7 POSSIBILITY. I THINK WE'RE OPERATING OFF OF OUR
8 INSTINCTS ABOUT WHETHER OR NOT THIS IS SOMETHING THAT
9 IS AT LEAST REASONABLY LIKELY TO OCCUR, SO WE WANT TO
10 PUT IN PREVENTIVE MEASURES EVEN IF MAKE THE PROCESS OF
11 OBTAINING EMBRYOS FOR RESEARCH MORE DIFFICULT, OR SOME
12 APPROACHING IT WITH A HIGHER DEGREE OF TRUST IN THE
13 CLINICAL SETTING AND A KIND OF SENSE THAT UNLESS WE SEE
14 EVIDENCE OF A REAL PROBLEM, WE'RE NOT GOING TO DO
15 ANYTHING THAT MIGHT CAUSE PROBLEMS.

16 SO I THINK WE NEED TO RECOGNIZE WE'RE TALKING
17 OFF OF KIND OF INSTINCTUAL STUFF. AND IF WE EXPECT
18 THAT OUR CLINICAL PEOPLE CAN GIVE US ANY MORE ACTUAL
19 EMPIRICAL INFORMATION, I THINK IT WOULD BE A WELCOME
20 ADDITION TO THE DISCUSSION.

21 DR. ROBERTS: I WOULD BE HAPPY TO HEAR MORE
22 INFORMATION.

23 MS. LANSING: WHAT YOU SAID TO ME IS WHAT
24 MADE MY MIND FEEL COMFORTABLE, WHICH IS WHETHER THEY'RE
25 PAID OR NOT PAID, THE RISK IS STILL THERE. AND THAT TO

BARRISTERS' REPORTING SERVICE

1 ME --

2 MS. CHARO: I THINK WE NEED TO BE
3 DISCUSSING -- I MEAN THIS IS GOING TO BE A GENERAL
4 CONCERN ABOUT CONFLICTS.

5 THE THIRD IS SIMPLY TO NOTE, BY WAY OF
6 INFORMATION, THAT THIS CONCERN ABOUT CONFLICT IS NOT
7 ONE THAT HAS ARISEN ONLY IN THIS GROUP. IT'S ARISEN
8 ELSEWHERE. AND WHAT YOU WILL FIND IF YOU LOOK AT THE
9 NATIONAL ACADEMY GUIDELINES AND IF YOU LOOK AT THE NEW
10 NIH GUIDELINES IS A KIND OF COMPROMISE APPROACH IN
11 WHICH YOU TEND TO SEE LANGUAGE THAT SAYS IN EFFECT. IT
12 WOULD BE OPTIMAL. IF THE PERSON WHO'S INVOLVED IN THE
13 CLINICAL CARE OF THE PATIENT IS NOT THE SAME PERSON WHO
14 HAS IN ANY WAY AN INTEREST IN WHETHER OR NOT ANY
15 RESULTING EMBRYOS ULTIMATELY GET DONATED, BUT WE CAN'T
16 GUARANTEE THIS.

17 SO THEY TEND TO SOFTEN THE LANGUAGE BY SAYING
18 WHERE PRACTICABLE, WHERE POSSIBLE, RIGHT, WHERE
19 REASONABLY MANAGEABLE, AND SO THEY CREATE THIS KIND OF
20 NOTION OF AN OPTIMAL PRACTICE, BUT IT MAY NOT OCCUR,
21 AND THAT DOESN'T MEAN THAT IT'S AN UNETHICAL PRACTICE
22 IF IT DOESN'T OCCUR. SO I WANT US TO JUST KEEP IN MIND
23 THAT IF WE'RE TALKING ABOUT HARMONIZATION, AS WE WERE
24 EARLIER, THERE MAY BE SOME MODELS WE CAN LOOK TO THAT
25 WILL GET US AWAY FROM WHAT OTHERWISE MAY BECOME A VERY

BARRISTERS' REPORTING SERVICE

1 HARD CONFLICT ABOUT WHAT TO DO HERE.

2 DR. ROBERTS: WE ACTUALLY HAVE SOME OF THOSE
3 REQUIREMENTS ALREADY IN THE REGULATIONS IN 100095,
4 ADDITIONAL REQUIREMENTS FOR CIRM-FUNDED RESEARCH
5 INVOLVING OOCYTES. AND THERE'S THE REQUIREMENT D, THE
6 PHYSICIAN ATTENDING TO ANY DONOR AND THE PRINCIPAL
7 INVESTIGATOR SHOULD NOT BE THE SAME PERSON UNLESS
8 EXCEPTIONAL CIRCUMSTANCES EXIST. I'M JUST NOW LOOKING
9 AT THIS. I HAVEN'T THOUGHT THROUGH HOW THEY RELATE,
10 BUT CIRM HAS ALREADY THOUGHT ABOUT THIS.

11 MS. CHARO: THIS IS A LITTLE BIT NARROWER
12 THAN WHAT THE NATIONAL ACADEMIES AND THE NIH DID. THIS
13 WAS, OF COURSE, ABOUT OOCYTE DONATION FOR RESEARCH
14 WHERE THERE WAS A HEIGHTENED PUBLIC SENSITIVITY. AND
15 THIS IS A LITTLE NARROWER BECAUSE IT'S ALL ABOUT
16 GETTING SPECIFIC IRB APPROVAL. AND THERE IT'S MORE --
17 IT'S DEFINITELY LOOSIER GOOSIER, BUT I THINK IT GOES
18 BACK AGAIN TO OUR SETS OF PRESUMPTIONS.

19 DR. LOMAX: THE SPECIFIC FRAME THERE, THOUGH,
20 IS IT'S RESEARCH -- IT'S WHEN WE ARE FUNDING THE ACTUAL
21 PROCUREMENT. SO IT GIVES US A FAR GREATER ABILITY TO
22 MANDATE THAT PROCESS IN A MORE STRUCTURED WAY.

23 DR. ROBERTS: I WASN'T NECESSARILY SAYING TO
24 APPLY THIS TO THIS SITUATION, BUT JUST THAT CIRM HAD
25 THOUGHT ABOUT THIS ISSUE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: I'M MINDFUL -- I'VE BEEN
2 REMINDING THAT WE NEED TO TRY AND MOVE ON PARTICULARLY
3 BECAUSE WE WANT TO ACCOMMODATE HANK GREELEY BEFORE
4 LUNCH. SO I'M HEARING THAT WE'RE STRUGGLING WITH THIS
5 NOTION OF HOW TO TRANSLATE OUR INTUITIONS ABOUT THE
6 POSSIBLE CONFLICTS OF INTEREST INTO REGULATORY
7 LANGUAGE, PARTICULARLY GIVEN THAT THERE ARE TWO VERY
8 DIFFICULT SITUATIONS. ONE IS IN UNIVERSITY PRACTICE
9 WHERE YOU HAVE SOME CONTROL OVER WHAT'S GOING ON IN THE
10 PRACTICE, BUT MANY OF THESE EMBRYOS COME FROM PRIVATE
11 IVF PRACTICES THAT ARE REALLY NOT UNDER THE PURVIEW OF
12 AN ACADEMIC CENTER, BUT THEY SAY, YOU KNOW, WE'VE GOT
13 THESE EMBRYOS AND OUR PATIENTS WOULD LIKE TO DONATE
14 THEM. THERE'S NO WAY WE CAN GO BACK, ANYBODY CAN GO
15 BACK, EITHER CIRM OR THE HESC RESEARCHER, GO BACK TO
16 THAT PRACTICE AND SAY, WELL, SHOW US HOW YOU PROTECT --
17 HOW YOU NOT PUT WOMEN AT UNDUE RISK IN THE PROCEDURE.
18 YOU END UP PUTTING IN REQUIREMENTS THAT END UP
19 DISQUALIFYING A LOT OF POTENTIAL MATERIALS JUST BECAUSE
20 YOU CAN'T VERIFY ONE WAY OR THE OTHER.

21 DR. KIESSLING: I STILL THINK THAT PROTECTING
22 THE DONOR, WHETHER SHE'S PAID OR NOT PAID OR KNOWN OR
23 UNKNOWN, IS BASED IN THE CONSENT FORM THAT SHE SIGNS.
24 SO THIS IS ALL ABOUT INFORMED CONSENT FOR EGG DONATION.
25 THAT'S WHAT'S GOING TO PROTECT HER. SHE HAS TO BE

BARRISTERS' REPORTING SERVICE

1 FULLY AWARE OF WHAT THE RISKS ARE, WHATEVER. SO THE
2 COMMUNICATION BETWEEN THE EGG DONOR AND THE CLINICIAN
3 TAKING CARE OF HER IS WHAT PROTECTS HER FROM UNDUE
4 HORMONE STIMULATION. DON'T YOU AGREE, ROB? I THINK
5 THAT'S THE CONVERSATION. SO IT'S BASED IN WHAT SHE
6 KNOWS AND WHAT SHE SIGNS IS WHAT PROTECTS HER.

7 CHAIRMAN LO: SO I'M GETTING A SENSE THAT WE
8 NEED TO MOVE ON TO CONSENT. BEFORE WE DO THAT, LET ME
9 JUST ASK HANK GREELEY IF HE HAS SOMETHING HE'D LIKE TO
10 SAY ON THIS ISSUE, EITHER ON THIS ISSUE OF PAYMENT IN
11 THE IVF CONTEXT FOR EMBRYOS THAT ARE SUBSEQUENTLY USED
12 IN RESEARCH OR JUST MORE GENERALLY ABOUT NARROW
13 REGULATIONS, WHATEVER. AND THEN I THINK WE NEED TO GET
14 SOME PUBLIC COMMENTS AS WELL.

15 DR. CIBELLI: ARE WE GOING TO HAVE A MOTION?

16 CHAIRMAN LO: NOT QUITE YET. I THINK I'M
17 HEARING THAT WE NEED TO DO MORE WORK ON THE CONFLICT OF
18 INTEREST, BUT I ALSO HEAR THAT WE WANT TO MOVE ON TO
19 CONSENT BECAUSE SOME PEOPLE THINK THAT'S MORE
20 IMPORTANT. I THINK AT THIS POINT WE'RE JUST TALKING
21 ABOUT SORT OF GENERAL APPROACHES AS OPPOSED TO A
22 SPECIFIC MOTION.

23 DR. CIBELLI: I THINK PEOPLE FEEL QUITE
24 DIFFERENTLY IN TERMS OF THE CONFLICT OF INTEREST.

25 CHAIRMAN LO: LET'S HEAR FROM HANK AND THEN

BARRISTERS' REPORTING SERVICE

1 THE PUBLIC, AND THEN JOSE IS CALLING FOR A FORMAL VOTE
2 ON CONFLICT.

3 MR. GREELEY: WELL, THANKS FOR ASKING ME TO
4 BE HERE. I THINK I'M ACTUALLY MAYBE THE FIRST
5 REPRESENTATIVE OF THE PUBLIC. I AM THE CHAIR OF THE
6 ADVISORY COMMITTEE ON HUMAN STEM CELL RESEARCH AT THE
7 DEPARTMENT OF PUBLIC HEALTH, STATE OF CALIFORNIA. I'M
8 ALSO A MEMBER OF STANFORD'S EMBRYONIC STEM CELL
9 RESEARCH OVERSIGHT COMMITTEE, BUT I'M NOT HERE
10 OFFICIALLY IN EITHER OF THOSE CAPACITIES. WHAT I HAVE
11 TO SAY IS NOT THE OFFICIAL POSITION OF THE DEPARTMENT
12 OF PUBLIC HEALTH OR THE ADVISORY COMMITTEE OR THE
13 STANFORD SCRO.

14 I DO WANT TO THOUGH STRESS ONE OF THE QUIRKS
15 OF THE CALIFORNIA SYSTEM, THAT CIRM PROVIDES
16 REGULATIONS BINDING ON ALL CIRM GRANTEES, BUT AT THE
17 SAME TIME THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH IS
18 REQUIRED BY CALIFORNIA STATUTE TO PROVIDE GUIDELINES
19 THAT ARE TO BIND CALIFORNIA ENTITIES DOING STEM CELL
20 RESEARCH THAT AREN'T GETTING CIRM FUNDING.

21 NOW, THAT STRIKES ME AS KIND OF ODD. IT IS
22 AN ARTIFACT OF THE DIFFERENT WAYS IN WHICH CALIFORNIA
23 HAS CHOSEN TO REGULATE STEM CELL RESEARCH, PROP 71
24 CREATING CIRM, A VARIETY OF STATE STATUTES CREATING THE
25 AUTHORITY UNDER THE DEPARTMENT OF PUBLIC HEALTH. IT'S

BARRISTERS' REPORTING SERVICE

1 NOT NECESSARILY SILLY. THE STATE IN ITS ROLE AS FUNDER
2 OF RESEARCH MIGHT WELL WANT TO DO THINGS THAT THE STATE
3 IN ITS ROLE AS REGULATOR OF PRIVATELY FUNDED OR
4 OTHERWISE FUNDED RESEARCH MIGHT NOT WANT TO DO. BUT IT
5 DOES CREATE KIND OF A TENSION IN TERMS OF HAVING TWO
6 DIFFERENT REGULATORY BODIES FOR RESEARCHERS IN
7 CALIFORNIA.

8 WE HAVE TRIED TO COPE WITH THIS OVER THE
9 YEARS. AND I THINK WE'VE BEEN IN THE -- THE ADVISORY
10 COMMITTEE HAS BEEN IN BEING PERHAPS EVEN LONGER THAN
11 YOUR WORKING GROUP HAS, CERTAINLY ABOUT AS LONG. WE'VE
12 TRIED TO COPE WITH THIS OVER THE YEARS BY COORDINATING
13 OUR ACTIVITIES. THIS HAS BEEN AIDED IMMEASURABLY BY
14 THE FACT THAT DR. LO IS ON THE CALIFORNIA ADVISORY
15 COMMITTEE AS WELL AS ON YOUR WORKING GROUP AND THAT DR.
16 LOMAX HAS COME TO ALL OR ALMOST ALL OF OUR COMMITTEE
17 MEETINGS. SO WE'VE TRIED TO KEEP ABREAST OF WHAT YOU
18 GUYS ARE DOING, AND WE'VE TRIED OUR BEST, GIVEN --
19 WE'VE TRIED OUR BEST TO HAVE OUR GUIDELINES CONSISTENT
20 WITH THE CIRM REGULATIONS.

21 WE JUST NOTE ONE REASON THIS IS ESPECIALLY
22 IMPORTANT IS MANY CALIFORNIA RESEARCHERS DOING
23 PARTICULAR RESEARCH PROJECTS HAVE FUNDING BOTH FROM
24 CIRM AND NOT FROM CIRM. AND AS A RESULT, IN THE SAME
25 LAB, SOMETIMES ON THE VERY SAME PROJECT, THEY ARE

BARRISTERS' REPORTING SERVICE

1 SUBJECT BOTH TO YOUR REGULATIONS AND TO OUR GUIDELINES.
2 IT'S REALLY IMPORTANT AS A RESULT THAT RESEARCHERS BE
3 ABLE TO MEET BOTH THOSE REQUIREMENTS.

4 SO I THINK IT'S IMPORTANT FOR US TO KEEP IN
5 MIND THE NEED FOR US TO COORDINATE CLOSELY IN OUR
6 VARIOUS ACTIVITIES.

7 WE HAVE GONE THROUGH A NUMBER OF DIFFERENT
8 REVISIONS OF OUR GUIDELINES OVER TIME. AND I THINK
9 IT'S NOT A COINCIDENCE THAT SOME OF THE REVISIONS
10 YOU'RE TALKING ABOUT ARE REVISIONS THAT WE HAVE
11 RECENTLY GONE THROUGH BOTH BECAUSE OF THE INTERACTION
12 BETWEEN THE COMMITTEES AND BECAUSE THEY'VE BEEN INDUCED
13 BY THE SAME KIND OF CHANGES IN THE SCIENCE AND IN THE
14 WORLD. OUR LAST SET OF REVISIONS IS CURRENTLY OUT FOR
15 COMMENT OR WILL SOON BE OUT FOR COMMENT. IT IS OUT FOR
16 COMMENT AT THIS POINT AND WILL EVENTUALLY, I THINK,
17 BECOME FINAL, AND WE'VE ADDRESSED A NUMBER OF THE
18 ISSUES THAT YOU'RE ADDRESSING.

19 WE MADE THOSE REVISIONS BEFORE THE NIH
20 GUIDELINES WERE FINAL. I DON'T THINK I'M BEEPING.

21 CHAIRMAN LO: I THINK PEOPLE ARE GOING OFF
22 THE PHONE LINE.

23 MR. GREELEY: COMING ON TO HEAR ME, SURELY.
24 NOT GOING OFF.

25 CHAIRMAN LO: YOUR FAMILY, ALL YOUR COUSINS

BARRISTERS' REPORTING SERVICE

1 ARE TURNING OFF.

2 MR. GREELEY: SO IT WAS BEFORE THE
3 FINALIZATION OF THE NIH GUIDELINES, ALTHOUGH I'M NOT
4 SURE THE NIH GUIDELINES, CERTAINLY IT'S SOMETHING WE'LL
5 TAKE INTO CONSIDERATION IN OUR NEXT SET OF MEETINGS.
6 I'M NOT SURE IT WILL MAKE MUCH DIFFERENCE TO US.

7 IN TERMS OF THE SUBSTANTIVE THINGS YOU GUYS
8 ARE LOOKING AT, WE HAVE ALREADY MADE PROPOSALS TO
9 REVISE THE REGULATION, THE DEFINITION. WE'RE DOING IT
10 THROUGH REDEFINING WHAT CELL LINES WE'RE COVERING AND
11 WHAT CELLS WE'RE COVERING TO LIMIT THE DEGREE OF
12 OVERSIGHT NECESSARY FOR THE CREATION OF INDUCED
13 PLURIPOTENT STEM CELLS. WE ALSO HAVE MADE CHANGES ON
14 THE COMPENSATION ISSUE WHERE WE HAVE BASICALLY SAID,
15 WITHOUT ANY LIMIT OF TIME, THAT AS LONG AS THE DONORS
16 WERE NOT PAID, WERE NOT GIVEN VALUABLE CONSIDERATION
17 FOR RESEARCH USES, THAT THE LINES ARE FINE FROM OUR
18 PERSPECTIVE.

19 SO RATHER THAN SAY THEY WERE GIVEN VALUABLE
20 CONSIDERATION FOR REPRODUCTIVE USES, WE'RE SAYING THEY
21 WEREN'T GIVEN VALUABLE CONSIDERATION FOR RESEARCH USES.
22 I SUPPOSE IN THEORY THERE IS SOME OTHER USE FOR WHICH
23 THERE MIGHT HAVE BEEN VALUABLE CONSIDERATION THAT'S
24 NEITHER A REPRODUCTIVE USE NOR RESEARCH USE. I DON'T
25 KNOW WHAT THAT USE WOULD BE. BUT IF SO, THEN OUR

BARRISTERS' REPORTING SERVICE

1 REGULATIONS, THE WAY WE'VE WRITTEN IT, WOULD ALLOW IT.
2 IF ONE DEFINED IT AS NOT BEING PAID FOR REPRODUCTIVE
3 USE, YOU WOULDN'T ALLOW IT.

4 FINALLY, ON THE DONATION ISSUE, ON THE
5 CONSENT ISSUE, WE'VE MAINTAINED A PRETTY STRONG LINE ON
6 CONSENT. WE CONTINUE TO REQUIRE CONSENT. WE THINK
7 IT'S IMPORTANT. WE THINK IT'S CONSISTENT WITH THE
8 SPIRIT, AT LEAST, OF A VARIETY OF CALIFORNIA STATUTES,
9 STATUTES THAT TO SOME EXTENT APPLY TO THE PEOPLE UNDER
10 OUR JURISDICTION, BUT DON'T NECESSARILY APPLY TO CIRM
11 AND THE GRANTEES UNDER CIRM JURISDICTION, SUCH AS
12 SB 1260 AND ITS STRONG CONSENT REQUIREMENTS FOR OOCYTE
13 DONATION, BUT WE FEEL VERY STRONGLY THAT DONOR CONSENT
14 CONTINUES TO BE IMPORTANT.

15 IF YOUR COMMITTEE OR IF CIRM WERE TO TAKE A
16 DIFFERENT POSITION, WE WOULD, OF COURSE, CONSIDER
17 WHETHER WE SHOULD CHANGE THAT IN THE INTEREST OF
18 COORDINATION BETWEEN THE TWO REGULATORY SCHEMES, BUT I
19 DON'T KNOW WHERE WE WOULD COME OUT ON IT.

20 I GUESS WHAT I REALLY WANT TO SAY IS THESE
21 ISSUES ARE EXTREMELY COMPLICATED BECAUSE OF THE
22 INTERSECTION OF A NUMBER OF DIFFERENT JURISDICTIONS AND
23 REGULATORY SCHEMES, INCLUDING THE INTERSECTION OF TWO
24 DIFFERENT REGULATORY SCHEMES WITHIN CALIFORNIA. WE MAY
25 BE SOMEWHAT LIMITED BY CALIFORNIA STATUTES THAT DON'T

BARRISTERS' REPORTING SERVICE

1 AFFECT YOU, AND YET YOUR GRANTEES MAY BE LIMITED BY OUR
2 GUIDELINES, EVEN THOUGH CIRM ITSELF MAY NOT BE LIMITED
3 BY THOSE STATUES BY THE FACT THAT THEY'LL HAVE TO
4 SATISFY BOTH SETS OF GUIDELINES IF THEY'RE GETTING SOME
5 NON-CIRM MONEY ALONG WITH THEIR CIRM MONEY.

6 I THINK THE NIH IS ANOTHER KETTLE OF FISH;
7 BUT TO THE EXTENT THAT ITS REQUIREMENTS ARE LAXER THAN
8 THE CALIFORNIA REQUIREMENTS, IT SHOULDN'T CREATE THIS
9 KIND OF CONFLICT THAT WE SEE.

10 SO THIS IS ONE OF THE MORE -- I'VE BEEN
11 AROUND DOING THIS SORT OF STUFF FOR A LONG TIME. THIS
12 WHOLE AREA OF STEM CELL REGULATION, PARTICULARLY IN
13 CALIFORNIA, IS ONE OF THE MORE HEADACHE INDUCING AREAS
14 THAT I HAVE DEALT WITH. ITS COMPLEXITY IN A NUMBER OF
15 INTERLOCKING JURISDICTIONS HAS MADE IT A HEADACHE, I
16 THINK, FOR ALL INVOLVED. I CONGRATULATE YOUR WORKING
17 GROUP ON THE GOOD WORK YOU'VE DONE IN THE PAST, BUT I
18 THINK YOU NEED TO PROCEED CAREFULLY AND THOUGHTFULLY,
19 AS OBVIOUSLY YOU ARE, AND WE NEED TO MAKE SURE THAT OUR
20 TWO DIFFERENT REGULATORY SCHEMES CONTINUE TO BE AS
21 MUTUALLY CONSISTENT AS THE STATUTES ALLOW THEM. I
22 THINK THAT'S ALL I HAVE TO SAY.

23 CHAIRMAN LO: HANK, THANKS VERY MUCH. I WANT
24 TO JUST SEE IF I'VE HEARD YOU RIGHT BECAUSE I ALWAYS
25 HAVE TROUBLE FOLLOWING THE COMPLICATED CHAINS OF

BARRISTERS' REPORTING SERVICE

1 REASONING.

2 MR. GREELEY: YOU JUST HAVE TROUBLE FOLLOWING
3 ME.

4 CHAIRMAN LO: NO. NO. LAW PROFESSORS HAVE A
5 CHAIN OF THOUGHT THAT'S MUCH LONGER THAN MY MEDICAL
6 BRAIN ALLOWS. YOU'RE SAYING THAT YOU, AS AN
7 INDIVIDUAL, AND TO THE EXTENT THAT THIS MAY BE SHARED
8 BY DPH, FEEL VERY STRONGLY THAT CONSENT FROM
9 THIRD-PARTY DONORS IS VERY IMPORTANT. AND
10 NOTWITHSTANDING THE NIH CURRENT POSITION, YOU'RE NOT
11 PERSUADED TO GIVE UP THAT STRONG INTEREST IN CONSENT
12 FROM THIRD-PARTY GAMETE DONORS. NONETHELESS, DPH HAS
13 ALREADY ALLOWED FOR THE REGULATIONS FOR THE RESEARCH IT
14 REGULATES PAYMENT TO THIRD-PARTY GAMETES TO BE ALLOWED
15 IN THE REPRODUCTIVE CONTEXT BY CONSTRUING IT AS AS LONG
16 AS YOU AREN'T PROVIDING VALUABLE CONSIDERATION FOR
17 RESEARCH PURPOSES.

18 SO THAT CURRENTLY A RESEARCHER IN CALIFORNIA
19 WHO HAS NON-CIRM FUNDING WOULD BE ALLOWED TO USE
20 EMBRYOS FROM IVF PRACTICES WHERE THE THIRD-PARTY GAMETE
21 DONOR WAS PAID FOR THE IVF EVEN THOUGH UNDER CIRM
22 REGULATIONS CURRENTLY THAT WOULD NOT BE PERMISSIBLE FOR
23 CIRM-FUNDED RESEARCH.

24 MR. GREELEY: WITH ONE CAVEAT, I BELIEVE
25 THAT'S RIGHT. I'M NOT THE LAWYER FOR DPH ON THIS, BUT

BARRISTERS' REPORTING SERVICE

1 I THINK THAT'S RIGHT WITH THE EXCEPTION THAT SO FAR
2 THESE CHANGES ARE OUR PROPOSED CHANGES OUT FOR COMMENT
3 IN OUR GUIDELINES. AND THE DPH GUIDELINES, THEY HAVE
4 NOT YET BEEN ADOPTED. AND SO THE ACTUAL GOVERNING
5 GUIDELINES WON'T CHANGE UNLESS OR UNTIL THEY HAVE BEEN
6 ADOPTED.

7 ON THE ISSUE OF CONSENT, IT IS MY PERSONAL
8 VIEW THAT CONSENT CONTINUES TO BE VERY IMPORTANT. I'M
9 NOT SPEAKING FOR THE COMMITTEE OR FOR DPH THERE. IT IS
10 MY SENSE, AS THE CHAIR OF THE COMMITTEE, THAT THAT VIEW
11 IS WIDELY SHARED WITHIN OUR COMMITTEE, BUT THAT'S MY
12 GUESS ABOUT HOW PEOPLE FEEL.

13 CHAIRMAN LO: JUST TO FOLLOW UP AGAIN --

14 MR. GREELEY: I'M SORRY, BERNIE. BEFORE I
15 LOSE MY TRAIN OF THOUGHT, I SHOULD POINT OUT OUR MOST
16 RECENT REVISIONS DO PROVIDE THAT SOME CELL LINES CAN BE
17 USED FOR RESEARCH IN CALIFORNIA IF THE CONSENT IS NOT
18 UP TO THE STANDARDS WE OTHERWISE REQUIRE. IF THE CELL
19 LINES WERE CREATED BEFORE APRIL SOMETHING 2005, YET
20 ANOTHER APPARENTLY ARBITRARY DATE, BUT IT'S THE NAS
21 REPORT DATE -- I SEE PROFESSOR CHARO GRIMACING.

22 MS. CHARO: BEMOANING THE STATE OF THE LEGAL
23 WORLD.

24 MR. GREELEY: GESTICULATING WITH HER FACE.
25 IN ADDITION, THAT THE SCRO, THAT AN INDIVIDUAL SCRO

BARRISTERS' REPORTING SERVICE

1 CONFRONTING THAT CELL LINE MAKE A FINDING THAT THERE IS
2 SOME IMPORTANT, SCIENTIFICALLY IMPORTANT, REASON FOR IT
3 TO BE USED. SO WE DON'T REQUIRE CONSENT IN ALL
4 CIRCUMSTANCES; BUT FOR ANY CELL LINES CREATED SINCE
5 APRIL 2005, WE DO REQUIRE THAT CONSENT OR AT LEAST
6 THAT'S OUR CURRENT POSITION.

7 CHAIRMAN LO: AND COULD I ASK YOU TO GIVE US
8 YOUR PERSONAL VIEW ON THE CONFLICT OF INTEREST ISSUE?
9 OBVIOUSLY DPH DID NOT COUPLE ITS ALLOWING PAYMENTS IN
10 THE IVF CONTEXT TO THIRD-PARTY GAMETE DONORS, DID NOT
11 REQUIRE THAT TO BE COUPLED WITH ANY PROVISIONS ABOUT
12 CONFLICTS OF INTEREST. DO YOU WANT TO JUST ADDRESS
13 THAT?

14 MR. GREELEY: IT IS NOT CLEAR TO ME HOW
15 REALISTIC OR SERIOUS A CONFLICT OF INTEREST THIS IS
16 WHEN ONE IS DEALING WITH THE CLINICIAN, PHYSICIAN WHO
17 HAS A PATIENT AND PHYSICIAN-PATIENT -- AND OBLIGATIONS,
18 BOTH LEGAL AND ETHICAL, TO THAT PATIENT IN A CONTEXT
19 WHERE BOTH THE PHYSICIAN AND THE PATIENT ARE LIKELY TO
20 WANT TO TRY TO MAXIMIZE FOR REPRODUCTIVE PURPOSES THE
21 NUMBER OF OOCYTES COLLECTED. AND I AGREE. I THINK
22 IT'S VERY HARD FOR ME TO IMAGINE THIS IS MUCH OF A
23 DIFFICULT ISSUE WITH RESPECT TO SPERM DONATION. WE'RE
24 REALLY TALKING ABOUT OOCYTE DONATION HERE.

25 SO THE PHYSICIAN AND THE PATIENT -- WELL, THE

BARRISTERS' REPORTING SERVICE

1 PHYSICIAN IS LIKELY TO WANT TO MAXIMIZE FOR CLINICAL
2 PURPOSES, CONSISTENT WITH THE SUBJECT'S HEALTH, THE
3 NUMBER OF OOCYTES COLLECTED. IT'S DIFFICULT FOR ME TO
4 SEE AS A REALISTIC MATTER MUCH ADDITIONAL INCENTIVE TO
5 RISK THE SUBJECT'S HEALTH AND THE PHYSICIAN'S
6 MALPRACTICE INSURANCE FOR THE PURPOSE OF GETTING SOME
7 CONSIDERABLE OOCYTES THAT MIGHT ULTIMATELY BE USED FOR
8 RESEARCH. IT'S NOT TO SAY THAT IT COULDN'T HAPPEN, BUT
9 I THINK THE POSSIBILITIES ARE FAINT.

10 I WOULD ALSO NOTE THAT WITH RESPECT TO OOCYTE
11 DONATION IN CALIFORNIA OR ANY OOCYTE RETRIEVAL IN
12 CALIFORNIA EXCEPT, ARGUABLY, SOME THAT MIGHT BE
13 DIRECTLY FUNDED BY CIRM GRANTS, IF CIRM WERE TO DO
14 THAT, THE ODD CONNECTION BETWEEN PROP 71 AND OTHER
15 STATE STATUTES. SB 1260 HAS EXTREMELY DETAILED
16 DISCLOSURE AND SUBSTANTIVE LIMITATIONS ON THE PROCESS
17 OF OOCYTE DONATION THAT I THINK MAKE CALIFORNIA A
18 LEADER IN THE PROTECTION OF WOMEN WHO ARE UNDERGOING
19 THE OOCYTE HARVEST PROCESS. NOW, THAT WOULDN'T
20 NECESSARILY APPLY, OF COURSE, TO CELL LINES CREATED
21 FROM OOCYTES THAT WERE HARVESTED OUTSIDE THE STATE OF
22 CALIFORNIA. BUT WITHIN CALIFORNIA, CALIFORNIA
23 SUBSTANTIVE LAW HAS VERY STRONG PROTECTIONS IN PLACE
24 WITH RESPECT TO OOCYTE RETRIEVAL.

25 SO FUNDAMENTALLY I COULD BE CONVINCED, BUT

BARRISTERS' REPORTING SERVICE

1 I'M OPEN TO -- IF I WERE ON YOUR COMMITTEE, I WOULD NO
2 DOUBT BE OPEN TO ARGUMENT. BUT IT DOESN'T STRIKE ME
3 THAT THE CONFLICT OF INTEREST ISSUE SHOULD BE A LARGE
4 CONCERN.

5 CHAIRMAN LO: HANK, THANK YOU. JUST TO
6 CLARIFY. WHEN YOU TALK ABOUT SB 1260 AND ITS
7 PROTECTIONS, CAN YOU JUST STATE FOR THE RECORD, THAT'S
8 IN THE CONTEXT OF DONATING OOCYTES FOR RESEARCH
9 PURPOSES OR DONATING OOCYTES FOR REPRODUCTIVE PURPOSES?

10 MR. GREELEY: IT IS FOR -- LET ME SEE IF I'VE
11 GOT IT ON MY COMPUTER. MY RECOLLECTION IS THAT IT IS
12 DONATING FOR RESEARCH PURPOSES.

13 CHAIRMAN LO: THAT WAS MY RECOLLECTION.

14 MR. GREELEY: BUT I THINK IT MIGHT APPLY TO A
15 DUAL PURPOSE DONATION, THOUGH I'M NOT SURE.

16 CHAIRMAN LO: AGAIN, WE'RE TALKING HERE ABOUT
17 NOT OOCYTE SHARING AND NOT OOCYTE DONATION DIRECTLY TO
18 RESEARCHERS, BUT OOCYTES IN THE IVF CONTEXT USED TO
19 CREATE EMBRYOS FOR REPRODUCTIVE PURPOSES SUBSEQUENTLY
20 NOT NEEDED AND DONATED TO RESEARCH.

21 MR. GREELEY: SB 1260 THEN MIGHT NOT APPLY,
22 BUT THEN THE DOCTOR-PATIENT RELATIONSHIP CONTINUES TO
23 BE, I THINK, BOTH AN ETHICAL, LEGAL, AND, MY SENSE FROM
24 THE PHYSICIANS I KNOW, A GENUINE CONSTRAINT ON THE
25 DEGREE TO WHICH THEY WILL OVERSTRESS AND RISK THE

BARRISTERS' REPORTING SERVICE

1 HEALTH OF THE PEOPLE WITH WHOM THEY HAVE A
2 DOCTOR-PATIENT RELATIONSHIP.

3 CHAIRMAN LO: THANK YOU. I'M GOING TO
4 ACTUALLY NOW ASK IF THERE ARE ANY PUBLIC COMMENTS.
5 AND, AGAIN, ON THIS ISSUE OF PAYMENT TO GAMETE DONORS
6 IN THE CONTEXT OF IVF AND THEN THE EMBRYOS RESULTING
7 FROM THOSE GAMETES WERE CREATED FOR REPRODUCTIVE
8 PURPOSES BUT SUBSEQUENTLY NOT NEEDED AND THEN DONATED
9 TO RESEARCHERS. PUBLIC COMMENTS ON THIS.

10 COULD YOU COME TO THE MIC AND ALSO PLEASE
11 INTRODUCE YOURSELF FOR THE RECORD.

12 DR. EGAN: HI, BERNIE. I WONDER BEFORE THE
13 PUBLIC COMMENT, THIS IS KEVIN, I'VE BEEN QUIETLY ON THE
14 PHONE FOR A LITTLE WHILE, WHETHER OR NOT I MIGHT BE
15 ABLE TO SAY SOMETHING.

16 CHAIRMAN LO: WELCOME, KEVIN. THANKS FOR
17 JOINING US.

18 DR. EGAN: I APOLOGIZE FOR JOINING LATE, BUT
19 I TEACH AN INTRODUCTORY STEM CELL BIOLOGY COURSE TO
20 HARVARD SOPHOMORES FROM 1:00 UNTIL 2:00 OR 2:30 EVERY
21 MONDAY, WEDNESDAY, AND FRIDAY, AND THIS IS THE FIRST I
22 COULD JOIN THE CALL. SO MY APOLOGIES FOR COMING IN
23 LATE. AND I'LL ALSO APOLOGIZE IF I HAPPEN TO REPEAT
24 ANYTHING THAT WAS STATED BEFORE. AND JUST BRIEFLY
25 SHARE OUR OWN EXPERIENCE WITH EMBRYO DONATION FOR STEM

BARRISTERS' REPORTING SERVICE

1 CELL RESEARCH AT HARVARD.

2 SO WE'VE GOT AN ONGOING PROGRAM OF EMBRYO
3 DONATION FOR STEM CELL DERIVATION AND RESEARCH FOR
4 ABOUT THE LAST EIGHT YEARS NOW AT HARVARD UNIVERSITY.
5 MORE THAN A THOUSAND PATIENT COUPLES HAVE DONATED THEIR
6 EMBRYOS THROUGH THAT PROTOCOL OVER THOSE YEARS. IT'S A
7 VERY SUCCESSFUL PROGRAM WHICH OBTAINS DONATED EMBRYOS
8 FROM DOZENS OF IN VITRO FERTILIZATION CLINICS AROUND
9 THE COUNTRY AND INCLUDING IN CALIFORNIA.

10 AND I WOULD SAY THAT THE STATUS OF THAT
11 PROTOCOL AT THE MOMENT IS THAT WE HAVE NOT BEEN ABLE TO
12 THUS FAR ACCEPT EMBRYOS THAT HAVE COME FROM ANONYMOUS,
13 COMPENSATED GAMETE DONORS THAT PARTICIPATED IN OOCYTE
14 DONATION SPECIFICALLY FOR THE PURPOSE OF ASSISTED
15 REPRODUCTION. AND THIS HAS BEEN, I WOULD SAY, A
16 CONFUSING AND DISAPPOINTING ISSUE FOR MANY, MANY
17 COUPLES WHO UNDERGO ASSISTED REPRODUCTION USING A
18 COMPENSATED EGG DONOR WHO'S ANONYMOUS TO THEM.

19 WHEN THEY FIND THAT THEY CANNOT PARTICIPATE
20 IN STEM CELL RESEARCH, BECAUSE OF THESE TWO ISSUES OF
21 NEEDING TO RETURN BACK TO THE ANONYMOUS DONOR FOR THEIR
22 CONSENT WHO'S OFTEN NOT AVAILABLE OR THE INDIVIDUALS
23 WHO HAVE RECRUITED THAT INDIVIDUAL LOOK TO GO BACK TO
24 THEM TO OBTAIN CONSENT, AND ALSO BECAUSE OF THE ISSUE
25 OF COMPENSATION IN SOME CASES. ONE REASON WHY THIS IS

BARRISTERS' REPORTING SERVICE

1 CONFUSING TO THOSE INDIVIDUALS IS THAT THEY FEEL THAT
2 THESE EMBRYOS WERE THEIRS, AND THEY ARE THEIRS TO DO
3 WHATEVER THEY WISH WITH.

4 AND I'LL JUST REMIND YOU THAT ALTHOUGH THERE
5 MAY BE SOME DOCTORS THAT WOULD EXPRESS THEIR CONCERN
6 ABOUT PERHAPS IF THERE WERE MULTIPLE DOWNSTREAM
7 APPLICATIONS FOR EMBRYOS, THAT THERE WOULD BE A
8 MOTIVATION TO OVERSTIMULATE WOMEN WHO ARE EGG DONORS,
9 THERE'S ALREADY QUITE A SIGNIFICANT IMPETUS FOR
10 STIMULATING THOSE WOMEN TO REASONABLE EFFECT TO MAKE
11 SURE THAT THERE ARE ENOUGH OOCYTES TO SATISFY THE
12 REPRODUCTIVE NEEDS OF THE WOMAN WHO'S RECEIVING THOSE
13 EGGS AS A DONATION. SO THERE ARE JUST AS MANY, I WOULD
14 SAY, OR MORE IVF CLINICIANS THAT I INTERACT WHICH FIND
15 THAT THIS ISSUE OF SOME OF THEIR PATIENTS NOT BEING
16 ABLE TO UTILIZE A KEY DISPOSITION OF THEIR EMBRYOS WHEN
17 THEY'RE READY TO DISCARD THEM IS EVEN MORE OF A
18 PROBLEM.

19 SO I'M TRYING TO SORT OF ILLUSTRATE THAT THIS
20 IS AN ISSUE THAT CUTS BOTH WAYS. AND I CAN TELL YOU
21 THAT WE HEAR QUITE A LOT OF COMPLAINTS, BOTH FROM IVF
22 CLINICS AND FROM PATIENT COUPLES. WHEN THEY FIND THAT
23 THEY CAN'T PARTICIPATE IN STEM CELL RESEARCH, IT'S AN
24 ENORMOUS DISAPPOINTMENT TO THEM.

25 CHAIRMAN LO: OKAY. THANKS, KEVIN. WE'RE

BARRISTERS' REPORTING SERVICE

1 GOING TO MOVE ON TO PUBLIC COMMENTS. AND, AGAIN, JUST
2 ASK EVERYONE TO PLEASE INTRODUCE YOURSELF FOR THE
3 RECORD AND SPEAK DIRECTLY INTO THE MICROPHONE.

4 MS. SMITH-CROWLEY: GOOD MORNING. THANK YOU.
5 I DON'T EVEN HAVE TO SPEAK ALL THAT DIRECTLY INTO IT.
6 I'M SHANNON SMITH-CROWLEY, AND I'M REPRESENTING THE
7 AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE.

8 I THINK THERE'S A PIECE HERE THAT'S NOT
9 REALLY BEEN TALKED ABOUT MUCH THAT, IF YOU CONSIDER, IT
10 MAY ALLAY A LOT OF YOUR CONCERNS ABOUT CONFLICTS OF
11 INTEREST, AND THAT'S THE RECIPIENT COUPLE. THE
12 RECIPIENT COUPLE IS THE ONE -- ARE THE PEOPLE THAT ARE
13 COMPENSATING THE DONOR. IT IS NOT AN OUTSIDE ENTITY,
14 IT IS NOT A RESEARCH ORGANIZATION. IT'S OUT OF THEIR
15 POCKET. AND THIS IS IN ADDITION TO THE FEES FOR THE
16 SERVICE THAT THE RECIPIENT COUPLE IS GOING TO HAVE FOR
17 THEIR OWN CARE, MUCH OF WHICH IS NOT COVERED BY
18 INSURANCE. SO THERE'S A SIGNIFICANT COST INVOLVED WITH
19 THIS. THEIR MOTIVATION IS GOING TO BE REPRODUCTION.

20 THE OTHER ISSUE IS IN TERMS OF THE
21 HYPERSTIMULATION AND THE EXCESSIVE USE OF MEDICATIONS
22 TO GET EVEN MORE EGGS IS NOW THAT WE KNOW ABOUT
23 HYPERSTIMULATION SYNDROME, IF THEY'RE BEGINNING TO SEE
24 SIGNS OF THAT, WHAT HAPPENS IS THEY STOP THE CYCLE.
25 AND THE WOMAN WHO'S GOING THROUGH THE PROCESS GETS PAID

BARRISTERS' REPORTING SERVICE

1 REGARDLESS BY THE RECIPIENT COUPLE. YOU'RE GOING TO
2 HAVE ONE PISSED OFF RECIPIENT COUPLE IF THEY HAVE TO
3 STOP THAT CYCLE AND START A WHOLE NEW CYCLE AGAIN AND
4 PAYING FOR A WHOLE NEW CYCLE.

5 SO I DON'T THINK THAT THE PHYSICIAN IS GOING
6 TO HAVE THE MOTIVATION TO OVERSTIMULATE THE WOMAN. IN
7 FACT, I THINK YOU'RE GOING TO HAVE MULTIPLE REASONS WHY
8 THE PHYSICIAN'S GOING TO HAVE TO TAKE EXTREME CARE AND
9 OPERATE WITHIN THE STANDARD OF CARE. SO I THINK THAT
10 THAT WILL HELP ALLAY SOME OF YOUR CONCERNS.

11 CHAIRMAN LO: THANKS VERY MUCH. WE HAVE
12 PROBABLY SOME OTHER PEOPLE IN THE AUDIENCE WHO'D LIKE
13 TO COMMENT.

14 DR. BEASON: THANK YOU. MY NAME IS DIANE
15 BEASON. I'M A MEDICAL SOCIOLOGIST. I'M A PROFESSOR AT
16 CAL STATE EAST BAY, AND I HAVE BEEN INTERVIEWING
17 STUDENTS WHO ARE INCREASINGLY BEING PRESSURED BY THEIR
18 FINANCIAL SITUATIONS TO SELL THEIR EGGS. I'VE BEEN
19 DOING THIS FOR A COUPLE OF YEARS. I'M ALSO A MEMBER OF
20 A NETWORK OF FACULTY MEMBERS, UNIVERSITY PROFESSORS,
21 WHO ARE ALSO INCREASINGLY CONFRONTING THE EXPERIENCES
22 OR BEING INFORMED BY THE EXPERIENCES OF OUR STUDENTS.

23 AND SO SPEAKING WITH YOU TODAY, I AM MOST
24 CONCERNED ABOUT THAT 12 PERCENT. ONLY 12 PERCENT OF
25 THE EMBRYOS THAT YOU'RE DISCUSSING TODAY ARE CREATED BY

BARRISTERS' REPORTING SERVICE

1 DONOR EGGS. BUT IT IS THOSE DONORS WITH WHOM I HAVE
2 THE MOST FAMILIARITY AND THE GREATEST CONCERN. AND I
3 WONDER -- I ALSO HAVE A FEW QUESTIONS.

4 FOR ONE THING, WHEN -- LET ME TELL YOU A
5 LITTLE BIT ABOUT MY EXPERIENCE. I'M SURE YOU ALL KNOW
6 THAT THERE IS NO REGISTRY THAT FOLLOWS DONORS OR EVEN
7 WOMEN WHO HAVE IVF. SO THE DATA THAT YOU ARE
8 APPARENTLY DRAWING ON, SUCH AS THAT PREPARED BY THE
9 IOM-CIRM PANEL, HAS BEEN PRODUCED BY PEOPLE WHO HAVE A
10 CONFLICT OF INTEREST. MOST OF THEM ARE EXPERTS IN THE
11 FIELD. THEY'RE ALSO THE MOST CONSCIENTIOUS, THE MOST
12 RESPONSIBLE IN THE FIELD BECAUSE MOST OF THEM ARE
13 AFFILIATED WITH UNIVERSITIES.

14 BUT STUDENTS I HAVE INTERVIEWED -- FIRST OF
15 ALL, I WANT TO COMMENT THAT I'VE TALKED TO A NUMBER OF
16 STUDENTS WHO HAVE BEEN IN ACUTE DISTRESS, OBVIOUS SIGNS
17 OF OVARIAN HYPERSTIMULATION SYNDROME, AND DOCTORS DO
18 NOT NECESSARILY COAST THEM OR STOP THEM BECAUSE THERE
19 IS ALREADY TREMENDOUS PRESSURE FOR THOSE EGGS. SO I'M
20 NOT SURE YOU ALL UNDERSTAND THE TREMENDOUS PRESSURE
21 THAT DOCTORS FEEL TO GET MORE EGGS, AT LEAST FROM WHAT
22 THE STUDENTS TELL ME.

23 I'VE TALKED TO STUDENTS WHO HAVE HAD -- I
24 KNOW THAT THE IOM REPORT TALKS ABOUT MAYBE TEN TO
25 TWELVE EGGS. I'VE TALKED TO -- I'VE INTERVIEWED A

BARRISTERS' REPORTING SERVICE

1 NUMBER OF STUDENTS WHO HAVE 36 EGGS, 42 EGGS, EVEN ONE
2 WITH 72 EGGS TAKEN FROM THEM. AND SOME OF THEM NOW
3 HAVE CANCER, EARLY ONSET BREAST CANCER. ONE OF THE
4 MOTHERS OF A FORMER DONOR WHO DIED, JENNIFER SCHNEIDER,
5 A PHYSICIAN, IS CONCERNED. HER DAUGHTER DIED OF COLON
6 CANCER. WE HAVE NO -- I WOULD THINK IF YOU WERE
7 INTERESTED IN GETTING EMBRYOS CREATED WITH DONATED
8 GAMETES, AT LEAST YOU WOULD TRY TO HELP PUT IN PLACE
9 SOME KIND OF REGISTRY SO THAT INFORMED CONSENT IS MORE
10 THAN A SHAM.

11 I'LL TELL YOU, A LOT IF THESE GIRLS AREN'T
12 GETTING CONSENT FORMS UNTIL THEIR LEGS ARE UP IN THE
13 STIRRUP. THEY ARE GETTING THESE HORMONES IN THE MAIL.
14 THEY SIGN UP ONLINE, THEY GET THEM IN THE MAIL, THEY'RE
15 TOLD TO GO TO THEIR DOCTOR TO GET CLEARED. AND WHEN
16 THEY TRY TO FIND OUT WHAT THE RISKS ARE EARLY ON, THEY
17 SAID, WELL, BECAUSE MOST OF THESE PEOPLE DOING THIS ARE
18 UNLICENSED BROKERS, SOME OF THEM FORMER EGG DONORS
19 THEMSELVES WHO DON'T WANT TO GO THROUGH THE PROCESS
20 AGAIN, BUT WOULD RATHER HAVE SOMEBODY ELSE DO IT, SO
21 THEY PUT OUT A SHINGLE. THERE'S NO REGULATION.

22 I DON'T SEE HOW YOU CAN CONSIDER THESE
23 QUESTIONS SERIOUSLY BY BRACKETING THE EXPERIENCE OF EGG
24 DONORS THE WAY IT HAS BEEN BRACKETED BY PEOPLE WHO ARE
25 MAKING A LIVING AND APPARENTLY, ACCORDING TO *NEW YORK*

BARRISTERS' REPORTING SERVICE

1 *TIMES*, ARE THE MOST HIGHEST PAID MEDICAL SPECIALISTS IN
2 THE COUNTRY.

3 SO I HARDLY KNOW WHERE TO BEGIN. I GUESS
4 I'LL JUST CLOSE BY SAYING THAT I THINK YOU HAVE A
5 RESPONSIBILITY, AS EVERYBODY IN THIS FIELD DOES, AND I
6 APPRECIATE THAT YOU ARE BEING SO CONSCIENTIOUS ABOUT
7 IT, TO AVOID EVEN THE APPEARANCE OF CONFLICT OF
8 INTEREST BECAUSE THE LAW CANNOT SEE INTO THE MINDS OF
9 EVERY RESEARCHER. IT IS IMPOSSIBLE. AND AS HAS BEEN
10 POINTED OUT, MANY OF THESE PEOPLE SUPPLYING EGGS ARE
11 NOT RESEARCHERS.

12 SO, ANYWAY, I APPRECIATE THAT YOU'RE LOOKING
13 INTO THIS AS DEEPLY AS YOU ARE, AND I HOPE THAT YOU
14 WILL CREATE SOME KIND OF FORUM SO THAT WE CAN GET
15 BETTER INFORMATION ABOUT THESE EGG DONORS' EXPERIENCES.
16 I CAN'T GET THEM TO TALK TO THE PRESS BECAUSE THEY FEEL
17 LIKE RAPE VICTIMS. THEY'RE ASHAMED OF WHAT THEY'VE
18 DONE. THEY DON'T HAVE MEDICAL INSURANCE, SO THEY DON'T
19 WANT TO COME OUT WITH ALL THE TREMENDOUS PROBLEMS THAT
20 HAVE NEVER BEEN STUDIED, LIKE TREMENDOUS MOOD PROBLEMS.
21 DO YOU KNOW WHAT MANIPULATION OF THE ENDOCRINE SYSTEM
22 DOES TO YOUR EMOTIONS, TO PMS, TO THINGS LIKE THAT LONG
23 INTO THE FUTURE, TO UNCONTROLLABLE WEIGHT GAIN
24 PROBLEMS, ALL KINDS OF THINGS THAT WERE NEVER EVER
25 BROACHED IN THE IOM REPORT?

BARRISTERS' REPORTING SERVICE

1 SO PLEASE, PLEASE, IF YOU CARE ABOUT
2 PROTECTING WOMEN'S HEALTH, HELP US TO GET SOME KIND OF
3 REGISTRY GOING, SOME KIND OF PUBLIC DIALOGUE ON THIS
4 ISSUE SO THAT YOU AT LEAST CAN HAVE INFORMED CONSENT
5 FOR THE DECISIONS THAT YOU MAKE. THANK YOU.

6 CHAIRMAN LO: THANK YOU.

7 MR. REED: DON REED, PATIENT ADVOCATE. FROM
8 THE VERY BEGINNING WHEN THE DECISION WAS MADE NOT TO
9 ALLOW PAYMENT FOR A WOMAN'S EGGS, I FEEL THAT THE ICOC
10 AND THE CIRM HAS BENT OVER BACKWARD TO TRY TO BE OPEN
11 AND SENSITIVE AND CAUTIOUS ABOUT THE WOMEN WHO ARE SO
12 IMPORTANT.

13 ALSO, THE PATIENTS ARE SO IMPORTANT, AND
14 THEIR LIVES MATTER TOO. THE WOMEN WHO HAVE CHOSEN TO
15 DONATE THEIR EGGS FOR REPRODUCTION ARE PAID FOR THAT.
16 I HAVE NEVER FULLY UNDERSTOOD WHY IT'S OKAY FOR
17 EVERYBODY IN THE OPERATING ROOM TO BE PAID EXCEPT FOR
18 THE WOMAN. I REALLY -- THAT IS THE LAW THAT ICOC PUT
19 INTO BEING, AND WE ERRED ON THE SIDE OF CAUTION. AND
20 THAT'S WHAT WE HAVE.

21 MY QUESTION IS IF WE ARE TRYING TO HARMONIZE
22 WITH THE NIH, I WONDER IF WE REALLY NEED TO TRY AND
23 COME UP WITH SOMETHING WHICH COULD NARROWLY DEFINE IT.
24 INSTEAD, I WONDER IF IT WOULD BE POSSIBLE TO JUST SAY
25 THAT WE SUPPORT THE NIH'S STANCE ON THIS ISSUE AND

BARRISTERS' REPORTING SERVICE

1 LEAVE IT AT THAT.

2 CHAIRMAN LO: ANY OTHER PUBLIC COMMENTS?

3 MS. CHARO: CAN WE ASK QUESTIONS OF ANY OF
4 THE PEOPLE?

5 CHAIRMAN LO: IF YOU HAVE QUESTIONS, BY ALL
6 MEANS. JUST SAY WHO YOU'RE DIRECTING THE QUESTION TO.

7 MS. CHARO: IT GOES ALL THE WAY BACK TO HANK
8 GREELEY, SO WHY DON'T YOU CONTINUE AND THEN WE'LL PICK
9 UP QUESTIONS AT THE END FOR EVERYBODY.

10 MR. REYNOLDS: WE'RE ALREADY ON SUCH A
11 TANGENT. LET'S CONTINUE. THANK YOU FOR THE
12 OPPORTUNITY TO SPEAK. MY NAME IS JESSE REYNOLDS WITH
13 THE CENTER FOR GENETICS AND SOCIETY.

14 I WOULD FIRST LIKE TO THANK THE STAFF FOR
15 GETTING THE BACKGROUND MATERIALS AVAILABLE TO THE
16 PUBLIC SO EARLY, AS WELL AS REPLYING PROMPTLY TO A
17 LETTER THAT I SENT ADDRESSING SOME CONCERNS IN THOSE
18 BACKGROUND MATERIALS. I'D LIKE TO POINT OUT THAT THAT
19 LETTER EXPRESSED CONCERNS ABOUT THE LANGUAGE THAT WAS
20 IN THE BACKGROUND MATERIALS, WHICH IS VERY DIFFERENT
21 THAN THE DIRECTION THE CONVERSATION TODAY HAS BEEN.
22 I'M VERY ENCOURAGED BY THAT DIRECTION OF THIS
23 CONVERSATION, TO LIMIT THE DISCUSSION AT HAND TO THE
24 USE OF EMBRYOS THAT WERE CREATED IN REPRODUCTIVE
25 CONTEXT USING PAID GAMETES.

BARRISTERS' REPORTING SERVICE

1 HOWEVER, I'M ALSO ENCOURAGED, THOUGH, BY
2 ADDRESSING THE ISSUE OF CONFLICTS OF INTEREST. I THINK
3 THAT THERE IS A REAL POTENTIAL HERE FOR CONFLICTS OF
4 INTEREST. I THINK, HOWEVER, IT'S A MANAGEABLE PROBLEM.
5 SOME STARTING POINTS AS, PROFESSOR ROBERTS POINTED OUT,
6 ARE CONTAINED ELSEWHERE IN YOUR REGULATIONS CONCERNING
7 SOME OTHER SITUATIONS OF PROVIDING GAMETES.

8 I WOULD AGREE WITH WHAT DR. CHARO BROUGHT UP,
9 THAT THIS SITUATION CAN ALSO APPLY TO COUPLES, WOMEN
10 PARTICULARLY, PROVIDING EGGS FOR THEIR OWN USE. THAT'S
11 NOT RULED OUT. I CAN IMAGINE THAT THE POTENTIAL FOR
12 CONFLICT OF INTEREST IS GREATER WHEN YOU HAVE ONE WOMAN
13 PROVIDING EGGS FOR ANOTHER COUPLE OR WOMAN'S USE.

14 WHERE I MIGHT DISAGREE WITH DR. CHARO IS HER
15 DOWNPLAYING OF THE REALITY OF THE POTENTIAL OF THESE
16 CONFLICTS OF INTEREST. THERE ARE -- THERE'S ENOUGH
17 INSTANCES OF MALFEASANCE IN THE ART INDUSTRY THAT WE
18 SHOULD ERR ON THE SIDE OF CAUTION. FOR EXAMPLE, JUST
19 THIS WEEK THERE WERE NEWS ARTICLES ABOUT A SETTLEMENT
20 BEING REACHED IN A LONG-STANDING SITUATION AT THE
21 FERTILITY CLINIC ASSOCIATED WITH THE UNIVERSITY OF
22 CALIFORNIA IRVINE WHERE SOME GAMETES AND EMBRYOS WERE
23 USED FOR PURPOSES NOT INTENDED BY THEIR PROVIDERS, AND
24 IT ENDED UP WITH THE CLINICIAN FLEEING THE COUNTRY AND
25 A MULTIMILLION DOLLAR SETTLEMENT.

BARRISTERS' REPORTING SERVICE

1 SO I'LL LEAVE IT AT THAT, AND I LOOK FORWARD
2 TO THE DRAFT LANGUAGE AND COMMENTING ON IT. THANK YOU.

3 CHAIRMAN LO: THANK YOU. ANY OTHER COMMENTS
4 FROM THE PUBLIC?

5 MS. STEVENS: I'M TINA STEVENS. I'M FACULTY
6 MEMBER AT SAN FRANCISCO STATE UNIVERSITY AND A
7 CO-FOUNDER OF THE ALLIANCE FOR HUMANE BIOTECHNOLOGY.
8 PART OF WHAT WE DO IS TALK TO YOUNG WOMEN ON COLLEGE
9 CAMPUSES, AND SO WE HAVE THE BENEFIT OF LEARNING FROM
10 THEM AS MUCH AS WHAT THEY LEARN FROM US.

11 AND I JUST WANTED TO SHARE WITH YOU SOMETHING
12 INTERESTING THAT WE LEARNED THAT PERTAINS TO THE ISSUE
13 OF HOW YOUNG WOMEN ARE UNDERSTANDING INFORMED CONSENT,
14 WHAT KIND OF INFORMATION ARE THEY GETTING, AND HOW ARE
15 THEY UNDERSTANDING IT, AND HOW SOON ARE THEY GETTING
16 IT. MANY OF THE WOMEN WE TALK TO SAY THAT WHEN THEY
17 SEE THE EGG BROKER ADS IN THE COLLEGE NEWSPAPERS,
18 THEY'RE THINKING GOES, WELL, I HAVE ONE EGG A MONTH.
19 WHY CAN'T OTHER PEOPLE WHO ARE INFERTILE AND DESPERATE
20 HAVE THAT EGG? IN OTHER WORDS, THEY THINK THAT THEY'RE
21 GOING TO BE GIVING AWAY ONE EGG. AND IT'S ONLY AFTER
22 THEY'VE SPENT THE MONEY IN THEIR HEAD AND THEY'RE WELL
23 INTO THE PROCESS DO THEY UNDERSTAND THAT THEY'RE GOING
24 TO BE HYPERSTIMULATED.

25 SO I THINK THAT THERE IS -- I REALLY DON'T

BARRISTERS' REPORTING SERVICE

1 WANT TO GO ON. I JUST WANT TO POINT OUT THAT THERE MAY
2 BE A GAP BETWEEN THE IMAGINED EGG DONOR AND WHAT WE'RE
3 LEARNING SORT OF IN THE FIELD. AND THAT'S SOMETHING
4 THAT PERHAPS CAN BE CONSIDERED AS REGULATIONS ARE MADE.
5 THANK YOU.

6 CHAIRMAN LO: THANK YOU. MAY I JUST SAY TO
7 PROFESSOR STEVENS, PROFESSOR BEASON, IF YOU HAVE
8 WRITTEN MATERIALS YOU'D LIKE TO SHARE WITH US ABOUT
9 YOUR INTERVIEWS AND EXPERIENCES WITH EGG DONORS, I
10 THINK WE'D BE VERY INTERESTED.

11 ANY OTHER PUBLIC COMMENTS?

12 MR. TEMPSKE: GOOD MORNING. MY NAME IS TOM
13 TEMPSKE. I'M HERE IN A PERSONAL AND INDIVIDUAL
14 CAPACITY ON MY FURLOUGH DAY FOR THE STATE OF
15 CALIFORNIA. I WORK WITH THE CALIFORNIA DEPARTMENT OF
16 PUBLIC HEALTH. I'M IN LABORATORY FIELD SERVICES. WE
17 REGULATE TISSUE BANKS IN THE STATE OF CALIFORNIA. AND
18 MY CURRENT POSITION IS PROGRAM MANAGER OF CLINICAL
19 LABORATORY COMPLAINTS AND REGULATORY COMPLIANCE.

20 I AM HERE TO GATHER INFORMATION. I ACCEPTED
21 AN INVITATION LAST WEEK TO GIVE A TALK IN JANUARY AT
22 THE INTERNATIONAL CONFERENCE OF STEM CELL, WORLD STEM
23 CELL CONFERENCE. AND I HAVE TO SAY THAT THE MEETING
24 LAST NIGHT AND TODAY HAS MADE MY PRESENTATION MUCH MORE
25 COMPLEX. I WAS GOING TO BE TALKING ABOUT GOVERNMENT

BARRISTERS' REPORTING SERVICE

1 REGULATIONS, STRAIGHT-UP GOVERNMENT REGULATION, WHAT
2 ARE LAWS, HCTP'S AND CALIFORNIA STATE TISSUE BANK LAWS.
3 AND I'M GOING TO -- I CAN SEE THAT THERE'S A LOT MORE
4 INFORMATION THAT I'M GOING TO HAVE TO BRING INTO IT
5 THAT I HADN'T REALIZED WHEN I ACCEPTED THE INVITATION.

6 HOWEVER, I SPENT YEARS REGULATING IVF
7 CLINICS, AND SO I'VE HAD A LOOK AT MANY, MANY IVF
8 CLINICS IN THE STATE OF CALIFORNIA. AND SO THAT KIND
9 OF GIVES -- THAT'S MY BACKGROUND IN THE FIELD, AS WELL
10 AS COURSES IN EMBRYOLOGY AND WHATNOT, BUT, ANYWAY, THAT
11 INFORMS MY OPINION.

12 I WANTED TO COMMENT ON PAID DONORS. I THINK
13 THAT PAYING DONORS CAN BE -- IS VERY IMPORTANT AND I
14 SUPPORT IT WHOLEHEARTEDLY. AND THE REASON IS THAT, AS
15 WAS POINTED OUT EARLIER, PEOPLE WHO ARE SEEKING
16 FERTILITY TREATMENT ARE PEOPLE WHO HAVE HAD PROBLEMS.
17 AND PAID DONORS TEND TO BE YOUNGER AND HEALTHY, THEY'RE
18 EVALUATED MEDICALLY TO ENSURE THAT THEY'RE YOUNGER AND
19 HEALTHY. AND YOUNGER DONORS, IF THERE ARE INDIVIDUALS,
20 IF THERE ARE WOMEN WHO POSSESS CERTAIN TRAITS THAT
21 WOULD BE USEFUL FOR STEM CELL RESEARCH, I THINK THAT
22 EVERY HONEST AND ETHICAL AND REASONABLE ACCOMMODATION
23 SHOULD BE ABLE TO BE OFFERED TO THEM IN ORDER TO GET
24 THEM TO DONATE TO SUPPORT RESEARCH.

25 I THINK THE PROBLEM WITH THE LAST EIGHT YEARS

BARRISTERS' REPORTING SERVICE

1 AND THE GUIDELINES, THE PROSCRIPTIONS ON NIH FUNDING
2 SET US BACK SO FAR. AND I THINK THAT WE WANT TO BE AS
3 LEAST RESTRICTIVE AS WE CAN. AND I THINK THAT AS LONG
4 AS THERE IS INFORMED CONSENT, ADEQUATE INFORMED
5 CONSENT, AND THEY'RE EVALUATED AND IT'S ENSURED THAT
6 THEY'RE NOT BEING COERCED OR WHATEVER, I THINK THAT
7 PAYMENT IS APPROPRIATE.

8 AND IN THAT LINE ALSO, OVARIAN
9 HYPERSTIMULATION BEING TALKED ABOUT, I'VE HAD A LITTLE
10 BIT OF EXPERIENCE WITH PATIENTS UNDERGOING THAT. AND
11 ALL I CAN SAY IS IF YOU HAVEN'T HAD ANY EXPERIENCED
12 OBSERVATIONS, IT'S TERRIBLE. AND I COULD SEE WHERE
13 SOMEBODY WOULD REALLY WANT TO DONATE, BUT TO HAVE TO GO
14 THROUGH THAT, YOU KNOW, I THINK THEY DESERVE TO BE
15 PAID, FRANKLY.

16 SO THAT'S WHAT I HAVE TO SAY ABOUT THE PAID
17 DONORS. AND WITH RESPECT TO INFORMED CONSENT, I'VE
18 LOOKED AT MANY CONTRACTS FROM TISSUE BANKS FOR
19 ANONYMOUS DONORS AND DIRECTED DONORS. AND THE INFORMED
20 CONSENT THAT TISSUE BANKS IN CALIFORNIA REQUIRE IN
21 ORDER TO DONATE GAMETES ARE VERY COMPREHENSIVE. AND
22 THEY SIGN AWAY -- IN THESE INFORMED CONSENTS TO
23 DONATION, THEY SIGN AWAY BASICALLY ALL OF THEIR RIGHTS.
24 I MEAN THEY'RE VERY COMPREHENSIVE.

25 NOW, I WOULD SAY THAT ONE ASPECT, THOUGH, TO

BARRISTERS' REPORTING SERVICE

1 KEEP IN MIND, WHEN THEY'RE SIGNING AWAY ALL THEIR
2 RIGHTS, IS THAT THERE ARE POSSIBLY OR POTENTIALLY
3 PEOPLE WHO ARE WILLING TO SIGN AWAY ALL THEIR RIGHTS,
4 BUT THEY HAVE A PERSONAL OR RELIGIOUS OBJECTION TO
5 HUMAN EMBRYONIC STEM CELL RESEARCH. AND SO MY OWN
6 FEELING IS OR MY OWN OPINION IS THAT THE INFORMED
7 CONSENTS AS GENERALLY USED IN THE STATE NOW ARE
8 PROBABLY ADEQUATE IF THERE WAS ALSO A SENTENCE THAT
9 SAID YOUR CELLS MAY ALSO BE USED FOR EMBRYONIC STEM
10 CELL RESEARCH SO THAT THEY KNOW STRAIGHT UP THAT WHILE
11 THEY'RE SIGNING AWAY ALL THEIR PROPERTY RIGHTS,
12 INHERITANCE RIGHTS, ETC., ETC., THEY'RE ALSO
13 SURRENDERING THEIR RIGHT TO PREVENT THEIR CELLS FROM
14 BEING USED FOR EMBRYONIC STEM CELL RESEARCH. AND IF
15 THEY HAVE A RELIGIOUS PROBLEM WITH THAT, IT'S TAKEN
16 CARE OF. SO THAT'S ALL I HAVE TO SAY. THANK YOU.

17 CHAIRMAN LO: THANKS VERY MUCH. I WANT TO
18 SORT OF MAKE A PROCEDURAL PROPOSAL TO THE COMMITTEE AND
19 SEE IF THIS IS AGREEABLE TO YOU.

20 MS. SMITH-CROWLEY: SHANNON SMITH-CROWLEY,
21 AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE.
22 CONSIDERING PROFESSOR BEASON'S COMMENT, I FELT THAT I
23 NEED TO SAY SOMETHING ON THE RECORD ON BEHALF OF MY
24 CLIENTS WHO ARE THE FERTILITY PHYSICIANS.

25 WHAT SHE WAS DESCRIBING IS IN NO WAY THE

BARRISTERS' REPORTING SERVICE

1 STANDARD OF CARE, THAT WOMEN ARE NOT GETTING INFORMED
2 CONSENT UNTIL THEIR FEET ARE IN THE STIRRUPS, THEY
3 SHOULD BE GETTING HORMONES THROUGH THE MAIL WITHOUT
4 CONSULTATION OF A PHYSICIAN, AND GOING THROUGH A
5 BROKER. IF BROKERS ARE PRACTICING MEDICINE WITHOUT A
6 PHYSICIAN, THEY SHOULD BE TURNED INTO THE STATE. IF
7 THE PHYSICIAN IS VIOLATING THE STANDARD OF CARE, THEY
8 SHOULD BE TURNED INTO THE MEDICAL BOARD. IF THERE IS A
9 VIOLATION OF STANDARD OF CARE, THERE ARE SEVERAL
10 REMEDIES. AND I BELIEVE THAT THE PHYSICIANS ARE ACTING
11 ETHICALLY, AND I TAKE GREAT UMBRAGE TO MANY OF HER
12 COMMENTS AND WISH THAT SHE WOULD DIRECT THEM TO US SO
13 THAT WE CAN DEAL WITH THEM. THANK YOU.

14 CHAIRMAN LO: THANK YOU. SO LET ME SORT OF
15 HAVE A PROCEDURAL SUGGESTION FOR THE COMMITTEE. IT'S
16 NOW TEN OF TWELVE AND LUNCH IS IMPORTANT. I WOULD
17 SUGGEST THE FOLLOWING: THAT WE TAKE A VOTE OF THE
18 COMMITTEE ON SORT OF THREE OPTIONS THAT I'VE HEARD FOR
19 DEALING WITH THE PAYMENT TO GAMETE DONORS IN THE
20 CONTEXT OF IVF TO GET A SENSE OF WHERE THE COMMITTEE
21 IS.

22 I THINK WE DO NEED TO START TO ADDRESS THE
23 CONSENT ISSUE, WHICH A NUMBER OF PEOPLE ON THE
24 COMMITTEE HAVE REALLY IDENTIFIED AS BEING A KEY ISSUE.
25 AND I WILL LEAVE IT UP TO YOUR PLEASURE WHETHER YOU

BARRISTERS' REPORTING SERVICE

1 WANT TO EAT FIRST AND COME BACK WITH A FULL STOMACH TO
2 ADDRESS THAT ISSUE OR IF YOU WANT TO START ADDRESSING
3 IT AND THEN TAKE A LUNCH BREAK IN ABOUT 30, 40 MINUTES.
4 I'M FIRST ASKING YOU FOR A VOTE ON WHEN YOU WANT LUNCH,
5 AND SECONDLY I'LL ASK YOU FOR A VOTE.

6 MS. LANSING: WE WOULD TAKE THE VOTE BEFORE
7 LUNCH NO MATTER WHAT.

8 CHAIRMAN LO: LET'S TAKE THE VOTE BEFORE
9 LUNCH. WE CAN DO THE VOTE ON THE OPTIONS FOR PAYMENT
10 AND THEN VOTE ON WHETHER YOU WANT TO HAVE LUNCH.

11 MS. LANSING: LET'S VOTE AND THEN VOTE ON
12 WHEN WE WANT TO HAVE LUNCH.

13 CHAIRMAN LO: SO I SEE THREE OPTIONS THAT
14 I'VE HEARD TODAY FOR THE ISSUE OF PAYMENT TO GAMETE
15 DONORS IN THE IVF CONTEXT AND THEN EMBRYOS FROM THOSE
16 DONORS BEING USED FOR CIRM-FUNDED RESEARCH OR THE HESC
17 LINES BEING USED FOR CIRM-FUNDED RESEARCH.

18 ONE IS THAT WE RETAIN OR WE REINSTATE WHAT WE
19 VOTED ON LAST TIME, WHICH IS TO SAY THAT THERE'S A LINE
20 OF AUGUST 2008, AND THAT WE'RE GOING TO ALLOW PAYMENTS
21 BEFORE THAT DATE, BUT NOT AFTER THAT DATE. JUST TO BE
22 COMPLETE.

23 SECOND OPTION IS TO SAY, NO, WE'RE GOING TO
24 NARROWLY REVISE THE REGULATIONS TO ALLOW PAYMENT IN THE
25 INFERTILITY CONTEXT TO BE MADE TO THOSE GAMETE DONORS

BARRISTERS' REPORTING SERVICE

1 AND TO ALLOW THE SUBSEQUENT EMBRYOS AFTER COMPLETION OF
2 IVF TREATMENT TO BE USED FOR HESC RESEARCH FUNDED BY
3 CIRM.

4 AND A THIRD OPTION IS -- AND THAT SECOND
5 OPTION HAS NO DATE OF A CUTOFF.

6 AND THE THIRD OPTION IS TO HAVE THE SAME
7 PROPOSITION AS TWO WITH NO CUTOFF DATE, BUT TO COUPLE
8 THAT WITH SOMETHING WHICH WE YET HAVE TO DEVISE THAT
9 ADDRESSES THE CONFLICT OF INTEREST ISSUE ON THE PART OF
10 THE TREATING PHYSICIAN. I THINK THOSE ARE MUTUALLY
11 EXCLUSIVE.

12 MS. LANSING: THEY ARE. ALL OF THAT GOES
13 WITH INFORMED CONSENT AS IT IS NOW, ALL THREE OF THOSE
14 THINGS.

15 CHAIRMAN LO: IN ADDITION, THAT'S JUST ONE OF
16 SEVERAL SORT OF REQUIREMENTS THAT NEED TO BE MET, AND
17 INFORMED CONSENT IS ANOTHER REQUIREMENT THAT WE'LL
18 DISCUSS.

19 MS. LANSING: SO I WOULD LIKE TO MOVE AND SEE
20 HOW MANY VOTES WE GET THAT NO. 2, I GUESS, IS WHERE
21 WE -- I CAN'T SAY IT AS WELL YOU SAID. WHERE IF IT WAS
22 USED FOR REPRODUCTIVE SERVICES AND THERE WAS PAYMENT,
23 IT IS ACCEPTABLE TO US. THERE'S NO -- WE'RE NOT
24 DEALING WITH ANY CONFLICT WITH THE PHYSICIANS AND WE'RE
25 REMOVING ANY DATES.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: JAMES. I'M SORRY. ONE OF OUR
2 LEGAL ADVISORS, WHAT AM I PERMITTED TO CALL FOR A VOTE
3 FOR HERE? IS THIS A SENSE OF THE COMMITTEE? IS IT A
4 VOTE? DO WE HAVE TO WRITE OUT THE TEXT?

5 MR. HARRISON: I THINK SHERRY HAS MADE A
6 MOTION. IF IT'S SECONDED, YOU CAN HAVE A VOTE.

7 DR. LOMAX: I BELIEVE WE'RE CURRENTLY NOT
8 UNDER A QUORUM, SO THIS WOULD BE A SENSE OF THE
9 COMMITTEE VOTE.

10 CHAIRMAN LO: SENSE OF THE COMMITTEE. SO
11 SHERRY MADE A MOTION.

12 MS. LANSING: JEFF SECONDED IT.

13 CHAIRMAN LO: JEFF SECONDED.

14 MS. LANSING: SO NOW YOU NEED A ROLL CALL.

15 CHAIRMAN LO: I THINK WE'VE DISCUSSED THIS,
16 SO I WOULD JUST LIKE TO CALL THE QUESTION. AND LET'S
17 PROCEED TO A ROLL CALL OF WHO IS HERE JUST FOR THE
18 RECORD.

19 MS. LANSING: IT'S JUST A SENSE OF THE
20 COMMITTEE.

21 CHAIRMAN LO: IT'S A SENSE BECAUSE I THINK
22 WE'RE UNDER QUORUM.

23 DR. LOMAX: FRANCISCO PRIETO.

24 DR. PRIETO: YES.

25 DR. LOMAX: ANN KIESSLING.

BARRISTERS' REPORTING SERVICE

1 DR. KIESSLING: ABSTAIN.
2 DR. LOMAX: JOSE CIBELLI.
3 DR. CIBELLI: YES.
4 DR. LOMAX: ALTA CHARO.
5 MS. CHARO: YES.
6 DR. LOMAX: BERNIE LO.
7 CHAIRMAN LO: YES.
8 DR. LOMAX: SHERRY LANSING.
9 MS. LANSING: YES.
10 DR. LOMAX: JEFF SHEEHY.
11 MR. SHEEHY: YES.
12 DR. LOMAX: DOROTHY ROBERTS.
13 DR. ROBERTS: ABSTAIN UNTIL WE DISCUSS
14 CONSENT.
15 DR. LOMAX: ROBERT TAYLOR.
16 DR. TAYLOR: YES.
17 DR. EGAN: HEY, WHAT ABOUT ME?
18 DR. WILLERSON: JIM WILLERSON, YES.
19 CHAIRMAN LO: JIM FIRST.
20 DR. WILLERSON: YES.
21 CHAIRMAN LO: AND KEVIN EGAN.
22 DR. EGAN: YES.
23 CHAIRMAN LO: ANY OTHER COMMITTEE MEMBERS ON
24 THE PHONE WE DON'T KNOW ABOUT? THANK YOU VERY MUCH.
25 DO WE HAVE A QUORUM?

BARRISTERS' REPORTING SERVICE

1 MS. LANSING: I THINK WE ARE.

2 CHAIRMAN LO: WE'RE SHORT ONE.

3 MS. LANSING: NOW I WOULD LIKE TO MAKE A
4 SECOND MOTION. I VOTE THAT WE ADJOURN FOR LUNCH, EAT
5 FOR A HALF HOUR, AND COME BACK AND TALK ABOUT CONSENT,
6 WHICH IS A HEAVY ISSUE.

7 CHAIRMAN LO: OKAY. FORTIFY YOURSELVES, BUT
8 DON'T EAT SO MUCH THAT YOU GET SOPORIFIC. SOMEONE WANT
9 TO SECOND THAT?

10 MS. CHARO: SECOND.

11 CHAIRMAN LO: HOW MANY WANT TO GO EAT LUNCH?
12 OKAY. YOU CAN'T FIGHT THE STOMACHS. THANK YOU,
13 SHERRY.

14 (A RECESS WAS TAKEN.)

15 CHAIRMAN LO: I'D LIKE TO WELCOME EVERYONE
16 BACK TO THE AFTERNOON SESSION, WHICH I'D LIKE TO CALL
17 TO ORDER. I WANT TO PUT EVERYONE ON NOTICE THAT
18 NEITHER OF YOUR CO-CHAIRS WAS WELL FED, SO WE'RE SORT
19 OF MEAN AND SURLY. WHAT THAT MEANS IS WE'RE GOING TO
20 REALLY TRY AND FINISH ON TIME AND KEEP US MOVING
21 BECAUSE WE HAVE A LOT OF IMPORTANT THINGS TO DISCUSS.
22 I WAS JUSTIFYING TRYING TO KEEP US ON SCHEDULE BECAUSE
23 WE HAVE A NUMBER OF ISSUES.

24 I ASKED GEOFF TO SORT OF JUST LAY OUT FOR US
25 IN LIST FORM THE DIFFERENT ISSUES WE'RE GOING TO TRY

BARRISTERS' REPORTING SERVICE

1 AND DEAL WITH THIS AFTERNOON.

2 DR. LOMAX: IN ORDER TO NOT COMPLICATE
3 THINGS, I SIMPLY TOOK A SLIDE THAT IS IN YOUR PACKET
4 AND PUT A LINE THROUGH ITEMS WE HAVE COMPLETED. NOW,
5 THAT MAY LOOK INTIMIDATING BECAUSE WE'VE DEALT WITH ONE
6 OF FIVE, BUT I THINK IT MAY BE MANAGEABLE BECAUSE A
7 COUPLE OF THOSE, I THINK, ARE FAIRLY STRAIGHTFORWARD.
8 WHERE YOU ARE NOW, I BELIEVE, IS YOUR ISSUE OF CONSENT,
9 WHICH RELATES TO ITEM 3, AND THE PAYMENT ISSUE WHICH WE
10 RAISED EARLIER.

11 CHAIRMAN LO: I JUST WANT TO ADD ONE OTHER
12 ISSUE WHICH SURFACED THIS MORNING, BUT IT'S NOT ON YOUR
13 LIST, WHICH IS PAYMENT TO DONORS OF SOMATIC CELLS USED
14 FOR IPS DERIVATION, EITHER PAYMENT WITH CIRM FUNDING OR
15 CIRM RESEARCHERS USING IPS LINES CREATED WITH SUCH PAID
16 SOMATIC CELLS.

17 DR. LOMAX: JUST FOR THE RECORD, THAT ITEM IS
18 CAPTURED IN THIS BULLET, ALTHOUGH IT MAY BE SOMEWHAT
19 OPAQUE. IT'S THE TOP BULLET ON ITEM 2, DONOR
20 COMPENSATION. SO IT'S SOMATIC CELLS PROCURED UNDER
21 IRB-APPROVED PROTOCOLS, AND THAT RELATES TO A
22 CONVERSATION YOU ALL HAD IN DECEMBER, WHICH IS EXACTLY
23 THAT ISSUE, THE USE OF SOMATIC CELLS IN IPS EXPERIMENTS
24 FOR WHICH YOU MAY HAVE HAD A PAID SOMATIC CELL DONOR.

25 CHAIRMAN LO: SO WITH THAT, LET'S MOVE AHEAD

BARRISTERS' REPORTING SERVICE

1 TO DONOR CONSENT, WHICH I THINK IS AN IMPORTANT AND
2 COMPLEX ISSUE. AND I'M GOING TO ASK GEOFF TO WALK US
3 THROUGH SOME OF THE DETAILS ON THAT.

4 DR. LOMAX: OKAY. THANK YOU. SO --

5 CHAIRMAN LO: WHAT WE'RE TALKING ABOUT HERE
6 IS DONORS OF THIRD-PARTY GAMETES USED IN THE IVF
7 CONTEXT TO CREATE EMBRYOS THAT WERE SUBSEQUENTLY NOT
8 NEEDED FOR REPRODUCTION AND THEN DONATED BY THE WOMAN
9 OR COUPLE IN IVF FOR STEM CELL RESEARCH. AND THE
10 QUESTION -- THOSE EMBRYO DONORS HAVE TO GIVE INFORMED
11 CONSENT THAT'S QUITE LAID OUT. OUR QUESTION IS WHAT
12 ABOUT THE -- WHAT DO THE THIRD-PARTY GAMETE DONORS WHO
13 ARE WAY BACK IN THE IVF PROCESS AND OOCYTE RETRIEVAL
14 PROCESS, NOT AT THE TIME THE FROZEN EMBRYOS ARE
15 ACTUALLY GIVEN TO RESEARCHERS.

16 DR. LOMAX: IN THIS CASE WE'VE BEEN ASKED IN
17 PART TO CLARIFY WHAT OUR STANDARD IS BECAUSE, IF YOU
18 MAY RECALL IN PAST MEETINGS, CERTAINLY FOR THE OLDER
19 MATERIALS, YOU'VE ALLUDED TO KIND OF, IF YOU WILL, SORT
20 OF A CHECK BOX APPROACH, THAT THERE WAS SOME DISCLOSURE
21 OF RESEARCH USE FOR AN EMBRYO. AND THE QUESTION'S COME
22 UP: IS THAT STANDARD SUFFICIENT MOVING FORWARD
23 PROSPECTIVELY?

24 AND THE INFORMATION YOU HAVE THAT WAS
25 PRESENTED IN JULY OF LAST YEAR IS THAT DONORS ARE

BARRISTERS' REPORTING SERVICE

1 TYPICALLY NOTIFIED FOR A RESEARCH USE OPTION, BUT
2 THEY'RE NOT FORMALLY CONSENTED AS WE UNDERSTAND CONSENT
3 UNDER THE FEDERAL COMMON RULE. THEY'RE NOT CONSENTED
4 IN THE COMMON RULE CONTEXT.

5 YOU RECEIVED COMMENTS FROM ONE PARTICIPANT
6 THAT THE VAST MAJORITY OF HER CONTRACTS, AND SHE USED
7 THE FIGURE 90 PERCENT, INCLUDE A DISCLOSURE CLAUSE,
8 THAT THE FINAL -- IF THE EMBRYO IS NOT USED FOR
9 REPRODUCTIVE PURPOSES, IT MAY ULTIMATELY BE DESTROYED.
10 AND IT GIVES A LIST OF THINGS, AND AS PART OF THAT, IT
11 INCLUDES RESEARCH, IN SOME CASES STEM CELL RESEARCH.

12 THERE WAS A BIT OF DISCUSSION THERE. BUT SHE
13 WAS MAKING THE POINT THAT HER CONTRACTS CLEARLY LAID
14 OUT RESEARCH. AND SHE INDICATED IN PART BECAUSE IN
15 CALIFORNIA THE LAW I CITED PREVIOUSLY IS VERY STRICT,
16 AND THAT'S HOW THEY'VE TAKEN TO INTERPRET IT. THEY
17 NEED TO DO MAXIMUM DISCLOSURE.

18 SO A KEY QUESTION FOR YOU ALL IS DOES A
19 DISCLOSURE SATISFY WHAT WE COMMONLY OFTEN SAY IS
20 CONSENT? AND THAT'S WHAT WE'RE ASKING YOU ALL TO
21 CLARIFY FOR THIS PARTICULAR.

22 MS. LANSING: JUST A DISCLOSURE THAT JUST
23 SAYS IT MAY BE, NOT CHECKING A BOX THAT SAYS I AGREE,
24 RIGHT?

25 DR. LOMAX: MY UNDERSTANDING IS IT'S THEY'RE

BARRISTERS' REPORTING SERVICE

1 SIGNING A DOCUMENT THAT INCLUDES THAT LANGUAGE. I
2 DON'T HAVE THE OTHER INFORMATION AVAILABLE TO SORT OF
3 CHARACTERIZE SORT OF THE NATURE OF WHETHER SOMETHING
4 IS -- HOW IT'S HANDLED, HOW THE DONOR ACTUALLY SORT OF
5 INTERACTS WITH THAT DOCUMENT.

6 CHAIRMAN LO: JUST TO SORT OF FOLLOW UP WITH
7 SHERRY'S COMMENT, YOU CAN THINK ABOUT A LIST OF
8 OPTIONS. AND ONE OPTION IS THAT THESE THIRD-PARTY
9 GAMETE DONORS HAVE TO PROVIDE A SEPARATE CONSENT FORM
10 FOR RESEARCH. SECOND OPTION IS THAT THEY SIGN
11 SOMETHING THAT INCLUDES A CHECK BOX THAT SAYS AMONG THE
12 THINGS TO BE DONE WITH MY MATERIALS IS DONATION OF
13 EMBRYOS -- RESULTING EMBRYOS FOR RESEARCH. NEXT
14 POSSIBILITY IS THEY SIGN A FORM THAT IN THE BODY OF THE
15 FORM SAYS A LOT OF THINGS. BY SIGNING AWAY
16 DISPOSITIONAL RIGHTS TO THE WOMAN OR COUPLE IN IVF,
17 YOU'RE SIGNING AWAY A LOT OF STUFF, INCLUDING
18 VISITATION RIGHTS, PARENTING RIGHTS, AND THE RIGHT TO
19 HAVE THAT EMBRYO GIVEN TO ANOTHER COUPLE FOR
20 REPRODUCTIVE PURPOSES OTHER THAN THE PERSON YOU DONATE
21 TO OR RESEARCH. AND YOU SIGN THE WHOLE DOCUMENT, AND
22 YOU DON'T REALLY KNOW THAT YOU ACTUALLY LOOKED AT EACH
23 OF THE PROVISIONS.

24 MS. LANSING: WHAT'S CURRENTLY IN IT? DOES
25 IT SAY ALL THOSE THINGS ALREADY?

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: WELL, IT VARIES FROM PROGRAM TO
2 PROGRAM. THERE'S NO STANDARDIZATION.

3 AND THE FINAL THING IS YOU JUST SIGN A FORM
4 SAYING I GIVE UP ALL RIGHTS WHATSOEVER TO THE RESULTING
5 EMBRYOS, AND THE OWNER CAN DO WHATEVER SHE OR THEY
6 WANT. SO THERE'S A GRADATION OF SORT OF HOW EXPLICITLY
7 DOES THE GAMETE DONOR HAVE TO SAY YES AND RESEARCH IS A
8 SPECIFIC THING I AGREE TO.

9 DR. KIESSLING: WITH RESPECT TO THIS CONSENT,
10 DO WE NEED TO DISTINGUISH OOCYTE DONORS FROM SPERM
11 DONORS, OR SHOULD THEY HAVE SIGNED THE SAME CONSENT
12 FORM?

13 CHAIRMAN LO: IT'S A QUESTION.

14 DR. KIESSLING: AND DOES THAT CONSENT FORM --
15 SHOULD THAT CONSENT FORM BE DIFFERENT FROM THE CONSENT
16 FORM SIGNED BY COUPLES GOING THROUGH INFERTILITY
17 TREATMENT WITH THEIR OWN GAMETES TO DONATE THOSE
18 EMBRYOS FOR RESEARCH?

19 CHAIRMAN LO: WELL, I GUESS THERE'S SOME
20 PRACTICAL ISSUES THAT WE NEED TO ADDRESS HERE. FIRST
21 OF ALL.

22 (INTERRUPTION IN PROCEEDINGS.)

23 MS. CHARO: I'M SORRY. THAT'S NOT EVEN MY
24 RING. DO I HAVE SOMEBODY ELSE'S PHONE?

25 CHAIRMAN LO: YOU'VE JUST WON THE LOTTERY,

BARRISTERS' REPORTING SERVICE

1 ALTA.

2 SO TO GET BACK TO ANN'S QUESTION, ONE OF THE
3 PROBLEMS WITH USING EMBRYOS ORIGINALLY CREATED FOR
4 REPRODUCTIVE PURPOSES BUT LATER FOUND NOT TO BE USED
5 AND ARE GIVEN TO STEM CELL RESEARCH AS OPPOSED TO BEING
6 DESTROYED IS THAT THE INTERACTION WITH THE GAMETE DONOR
7 HAPPENED LONG BEFORE RESEARCH WAS CONTEMPLATED. AND
8 THAT IN SOME CASES GAMETE DONORS HAVE SAID, YOU KNOW,
9 "I'VE DONE WHAT I SAID I WOULD DO. I GAVE YOU GAMETES.
10 I DON'T WANT TO BE CONTACTED AGAIN. I DON'T WANT TO BE
11 BOTHERED. YOU DO WHATEVER YOU WANT WITH THEM." SO YOU
12 CAN'T GO BACK AND RECONTACT THEM IN SOME CASES, MANY
13 CASES.

14 WITH THE WOMAN OR COUPLE IN IVF WHO THEN
15 DECIDES TO DONATE THE FROZEN EMBRYOS, IF SHE IS THE
16 ACTUAL GAMETE DONOR, AT THAT TIME YOU SORT OF HAVE HER
17 AGREEMENT THAT, YES, THEY'RE MY GAMETES, THEY'RE MY
18 EMBRYOS, AND I WANT TO GIVE THEM TO RESEARCH. AND THAT
19 THERE NEEDS TO BE A RECONFIRMATION OF CONSENT FROM THE
20 EMBRYO DONOR, AT LEAST THE NIH GUIDELINES, AT THE TIME
21 THE DONATION IS MADE.

22 SO THAT'S THE JUSTIFICATION. WE'RE SAYING
23 WE'RE GOING TO TREAT EMBRYO DONORS AND GAMETE DONORS
24 DIFFERENTLY BECAUSE OF JUST THE PRACTICALITIES OF CAN
25 WE GET BACK IN TOUCH WITH THEM.

BARRISTERS' REPORTING SERVICE

1 DR. KIESSLING: IS THAT THE BEST THING TO DO?
2 SO THERE'S THE PAST AND THEN THERE'S WHAT YOU'D LIKE TO
3 DO GOING FORWARD, RIGHT?

4 CHAIRMAN LO: IN TERMS OF OUR POLICY.

5 MS. LANSING: IT'S OUR POLICY. WE CAN'T
6 CHANGE EVERYBODY ELSE'S POLICY. IT'S WHAT WE WANT.

7 DR. KIESSLING: WE'VE TALKED ABOUT THIS ISSUE
8 A LOT AND HAVE ALWAYS DECIDED TO COME DOWN ON THE SIDE
9 THAT THE GAMETE DONORS NEEDED TO HAVE CONSENTED AT
10 LEAST FOR RESEARCH PURPOSES, I BELIEVE.

11 MS. LANSING: THAT'S WHY I'M A LITTLE
12 CONFUSED IS EXACTLY WHAT YOU'RE SAYING. SO WE'VE
13 ALWAYS SAID THEY HAD TO CONSENT IN SOME WAY FOR
14 RESEARCH, BUT IT ISN'T UP TO US. WE CAN SAY BEST
15 PRACTICES WOULD BE, BUT IT ISN'T UP TO US TO TELL EVERY
16 REPRODUCTIVE SERVICE THAT IT CAN'T BE IN THE BODY, THAT
17 IT HAS TO BE A SPECIAL THIS OR HAS TO BE THAT. WE
18 COULD SAY BEST PRACTICES, OF COURSE, WOULD BE THAT YOU
19 WOULD ACTUALLY IDENTIFY RESEARCH AS A POSSIBILITY, AND
20 IT WOULD NOT BE IN THE BODY SO THAT PEOPLE READ IT.

21 BUT I DON'T -- IF THEY SIGN THE PIECE OF
22 PAPER AND IT'S IN THE BODY, I HAVE TO HOPE THAT
23 SOMEBODY TOLD THEM WHAT WAS IN THE BODY. THAT DOESN'T
24 MEAN THEY DID. I HAVE TO HOPE. QUITE HONESTLY, THEY
25 MIGHT NOT HAVE EVER THOUGHT ABOUT STEM CELL RESEARCH.

BARRISTERS' REPORTING SERVICE

1 THEY MIGHT HAVE THOUGHT ABOUT OTHER RESEARCH. BUT ONCE
2 YOU SAY RESEARCH, NO MATTER WHAT -- IT'S NOT -- WE'RE
3 NOT GOVERNING REPRODUCTIVE SERVICES. SO WHATEVER THEY
4 DO HAS TO BE, I THINK, GOOD ENOUGH FOR US. I THINK WE
5 COULD ADAPT BEST PRACTICES, BUT I DON'T THINK WE SHOULD
6 HOLD THAT TO OUR STANDARD OF CONSENT. IF THEY SAID
7 IT'S OKAY FOR RESEARCH, THEN I THINK WE HAVE TO ACCEPT
8 IT.

9 DR. LOMAX: IT'S A FAIRLY NUANCED POINT.
10 WHAT WE'RE ASKING OF YOU IS JUST TO CLARIFY WHAT, I
11 THINK, CAN BE INTERPRETED AS THE EXISTING POLICY, THAT
12 THE DISCLOSURE, THE WORDS THAT THIS ONE OPTION IS
13 RESEARCH IS SUFFICIENT. THE POINT OF CONFUSION ARISES
14 IS LITERALLY THE REGULATIONS SAY CONSENT. SO JUST THE
15 TERM "CONSENT" DOES INTRODUCE SOME CONFUSION TO FOLKS
16 THAT ARE TAKING OUR REGULATIONS SERIOUSLY, AS WE WANT
17 THEM TO DO. AND THE QUESTION BECOMES DO YOU MEAN,
18 LIKE, INFORMED CONSENT UNDER THE COMMON RULE, OR DO YOU
19 MEAN WHAT I'M REFERRING TO AS DISCLOSURE BECAUSE
20 THEY'RE DIFFERENT.

21 A CONSENT UNDER THE COMMON RULE WOULD BE AN
22 IRB-APPROVED PROTOCOL, WHICH JUST ISN'T HAPPENING.
23 DISCLOSURE WOULD BE YOU'VE BEEN NOTIFIED IN A DOCUMENT
24 OF THIS POTENTIAL OUTCOME OF YOUR MATERIAL, AND YOU'VE
25 SIGNED THE DOCUMENT AND SAID THAT YOU WERE OKAY WITH

BARRISTERS' REPORTING SERVICE

1 THAT.

2 MS. LANSING: THREE YEARS LATER, YOU KNOW,
3 WHERE WE ARE TODAY, WHENEVER WE STARTED, THAT WOULD BE
4 GOOD ENOUGH FOR ME TODAY. I WOULD NOT SAY THAT'S BEST
5 PRACTICES. I WOULD SAY WE WOULD ENCOURAGE PEOPLE, WE
6 WOULD ENCOURAGE REPRODUCTIVE SERVICES TO DO BETTER THAN
7 THAT, BUT IT'S NOT OUR BUSINESS. WE CAN ONLY
8 ENCOURAGE.

9 DR. PRIETO: I THINK I WOULD AGREE WITH
10 SHERRY THERE. I FEEL WE SHOULD STIPULATE THAT
11 DISCLOSURE IS REQUIRED AND THAT BEST PRACTICE WOULD BE
12 TO ACTUALLY CONSENT PEOPLE, BUT WE CAN'T REGULATE THAT
13 KIND OF MEDICAL PRACTICE.

14 MS. LANSING: JUST TO ADD --

15 DR. PRIETO: I'M NOT SURE HOW MUCH INCENTIVE
16 WE EVEN PROVIDE.

17 MS. LANSING: DISCLOSURE MIGHT BE -- THE WORD
18 COULD BE INTERPRETED MANY WAYS. SOMETIMES YOU JUST
19 GIVE SOMEONE A PIECE OF PAPER AND SAY HERE SIGN IT.
20 AND ANOTHER FORM OF DISCLOSURE SAYS THIS IS POINT A,
21 THIS IS WHAT YOU'RE SIGNING; THIS IS POINT B. THAT'S
22 GOOD DISCLOSURE, DO YOU KNOW, BUT I DON'T THINK WE CAN
23 REGULATE THAT.

24 CHAIRMAN LO: I NOTICE A LOT OF THE PEOPLE.
25 I JUST WANT TO EMPHASIZE THAT UNDER THE CURRENT NIH

BARRISTERS' REPORTING SERVICE

1 GUIDELINES, THERE'S NO NEED FOR DISCLOSURE. YOUR FACT
2 THAT YOU SIGNED OVER DISPOSITIONAL RIGHTS AS A
3 THIRD-PARTY GAMETE DONOR TO THE IVF PATIENT, FROM THE
4 NIH POINT OF VIEW, THAT'S SUFFICIENT FOR THE EMBRYO
5 RECIPIENT TO DONATE THAT EMBRYO TO RESEARCHERS.

6 DR. PRIETO: SO IF WE'VE ALREADY SAID THAT
7 LINES PRODUCED UNDER NIH GUIDELINES ARE ACCEPTABLE TO
8 US, HAVE WE BY DEFAULT MADE THAT OUR STANDARD?

9 DR. LOMAX: NO, BECAUSE THIS LANGUAGE WOULD
10 COVER THE UTILIZATION OF HUMAN EMBRYOS BY OUR GRANTEES.
11 SO WE WOULD STILL BE HOLDING OUR GRANTEES TO A HIGHER
12 STANDARD FOR ANY HUMAN EMBRYO UTILIZATION. ANY
13 RESEARCH ON EMBRYOS OR DERIVATION OF STEM CELL LINES
14 DONE BY OUR GRANTEES WOULD HAVE TO CONFORM TO THIS
15 HIGHER STANDARD OF CONSENT.

16 MS. LANSING: THEY COULDN'T GET THE NIH
17 LINES?

18 DR. LOMAX: ONCE THE LINES ARE DERIVED, OUR
19 REGULATIONS CURRENTLY WOULD ALLOW THEIR UTILIZATION.

20 DR. PRIETO: THIS WOULD ONLY APPLY FOR LINES
21 THEY WERE DERIVING?

22 DR. LOMAX: WOULD APPLY TO ANY EMBRYOS THEY
23 WERE --

24 DR. PRIETO: FROM WHICH THEY WERE DERIVING A
25 LINE.

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: -- WOULD USE IN FUNDED RESEARCH.
2 PRESUMABLY IT'S A DERIVATION, YES, BUT IT COULD BE
3 OTHER --

4 DR. TROUNSON: MR. CHAIR, IT'S AN IMPORTANT
5 POINT BECAUSE IF WE'RE TRYING TO HARMONIZE, IF WE'RE IN
6 CONFLICT WITH NIH, THEN WE'RE GOING TO CREATE A
7 SITUATION THAT WE HAD BEFORE. SO WE NEED TO BE CERTAIN
8 THAT WE WANT TO HAVE A HIGHER STANDARD AND THE
9 CONSEQUENCES OF THAT BECAUSE THAT WOULD MEAN THAT YOU
10 WOULD HAVE SEPARATE FACILITIES AND BE VERY SEPARATE
11 ABOUT YOUR PROCESSES IF YOU'RE A RESEARCHER.

12 MS. LANSING: SO, ALAN, CAN YOU EXPLAIN WHAT
13 YOU -- SO YOU WOULD RECOMMEND THAT WE NOT EVEN HAVE
14 DISCLOSURE, THEN, IN ORDER TO BE HARMONIOUS WITH THE
15 NIH?

16 DR. TROUNSON: I'M THINKING, SHERRY, THAT
17 IT'S PRETTY IMPORTANT IF WE CAN GET AS CLOSE AS
18 POSSIBLE TO HARMONIZATION BECAUSE WE HAD THE
19 DISHARMONIZATION BEFORE, WHICH CREATED ALL THESE OTHER
20 PROBLEMS. AND WE DON'T -- IF WE CAN AVOID THAT
21 LARGELY, I THINK THAT WOULD BE THE PREFERABLE
22 SITUATION. BUT YOU'VE GOT TO BE COMFORTABLE THAT THE
23 REGULATIONS BY THE NIH ARE ACCEPTABLE TO YOU AS A
24 COMMITTEE.

25 SO ALL I'M POINTING OUT IS PLEASE TREAT IT

BARRISTERS' REPORTING SERVICE

1 WITH A LOT OF THOUGHT BECAUSE WE DON'T TO WANT TO
2 RECREATE --

3 MS. LANSING: I JUST HAVE ONE QUESTION, THEN
4 I'LL YIELD THE FLOOR AND I WON'T TALK ANYMORE. THE
5 REASON I'M CONFUSED AND THE REASON THAT I THINK JEFF
6 GOT -- WHEN HE SAID IT, WE SAID WE WOULD TAKE ALL NIH
7 LINES WERE ACCEPTABLE, RIGHT? RIGHT. SO I REALIZE
8 THAT WE HAVE AN INCONSISTENCY WITHIN OUR POLICY BECAUSE
9 WE SAID WE'D ACCEPT ALL NIH LINES. SO THESE ARE ONLY
10 LINES THAT WE CREATE OURSELVES, FROM WHAT I UNDERSTAND.
11 WE'RE TOUGHER ON THOSE LINES.

12 MS. CHARO: I APOLOGIZE FOR MAKING THIS EVEN
13 MORE CONFUSING. IF I GOT THIS WRONG, I'D BE HAPPY TO
14 BE CORRECTED. GO BACK AGAIN TO WHAT IS ACCEPTABLY
15 DERIVED. I UNDERSTAND WE CAN PUT WHATEVER REQUIREMENTS
16 WE WANT ON OUR GRANTEES WHO ARE GOING TO DERIVE A NEW
17 LINE. NO PROBLEM. BUT WHEN WE'RE TALKING ABOUT THE
18 GRANTEES SAYING I WANT TO USE A LINE THAT COMES FROM
19 MINNESOTA, HOW DO YOU KNOW IF THE GRANTEE CAN WORK WITH
20 IT? IT EITHER HAS TO BE A LINE THAT WAS BLESSED BY
21 NIH, THE UK, THE JAPANESE, THE CANADIANS, OR IT HAS TO
22 BE ONE OF THESE LINES THAT COMES FROM AN UNIDENTIFIED
23 SOMATIC CELL, OR, THIRD, IT HAS TO MEET OUR SPECIFIC
24 RULES ON ACCEPTABLY DERIVED.

25 AND THOSE SPECIFIC RULES INCLUDE DONORS OF

BARRISTERS' REPORTING SERVICE

1 HUMAN GAMETES, EMBRYOS, SOMATIC CELLS, OR TISSUE, GAVE
2 VOLUNTARY AND INFORMED CONSENT. THIS MEANS THAT A LINE
3 THAT COMES FROM -- A LINE THAT EXISTS ALREADY THAT HAS
4 NOT BEEN BLESSED CANNOT BE USED UNLESS, IN FACT, THERE
5 IS INFORMED CONSENT FROM ALL THE UNDERLYING GAMETE
6 DONORS AS THE REGULATIONS NOW STAND. WE CAN CHANGE
7 THEM; BUT AS THEY NOW STAND, WE REALLY ARE.

8 MS. LANSING: WE CAN USE NIH LINES THEN.

9 MS. CHARO: THAT'S RIGHT. YOU CAN EITHER USE
10 THE NIH LINES, WHICH WILL NOT NECESSARILY HAVE CONSENT.

11 MS. LANSING: THEY WON'T. LET'S ASSUME FOR
12 ARGUMENT SAKE THEY DON'T.

13 MS. CHARO: OR YOU CAN USE LINES WHERE YOU
14 ABSOLUTELY DO HAVE CONSENT, WHETHER THEY COME FROM
15 ABROAD OR THEY'RE DERIVED HERE. BUT THE POINT IS NOT
16 LIKE IT'S JUST LINES THAT WE DERIVED HAVE ONE SET OF
17 RULES AND ALL THE OTHER LINES HAVE AN EASIER SET
18 BECAUSE THEY'RE NIH BLESSED. THERE'S GOING TO BE A
19 CATEGORY IN BETWEEN. THEY'RE NOT NIH BLESSED AND
20 THEY'RE NOT DERIVED HERE. THEY ARE A THIRD CATEGORY.
21 THEY'RE LINES THAT THE NIH HASN'T REVIEWED, THE UK
22 HASN'T REVIEWED, BUT THEY EXIST AND OUR RESEARCHERS
23 WANT TO USE THEM. SO WE NEED TO CONFRONT THAT AND
24 DECIDE WHETHER WE WANT INFORMED CONSENT TO BE THE
25 STANDARD FOR THOSE LINES.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: SO I THINK WE NEED -- THIS IS
2 COMPLICATED. I THINK WE NEED TO KEEP STRAIGHT OUR
3 REQUIREMENTS FOR THE DERIVATION OF NEW EMBRYONIC STEM
4 CELL LINES FROM EMBRYOS LEFTOVER FROM IVF RESEARCH,
5 WHICH THE NIH WILL NOT FUND, VERSUS CIRM RESEARCHERS
6 USING EXISTING LINES DERIVED EITHER BY THEMSELVES OR
7 SOMEONE ELSE. AND WHAT ALTA IS TALKING ABOUT IS THAT
8 THERE ARE THREE WAYS YOU CAN HAVE PERMISSION AS A CIRM
9 RESEARCHER TO USE AN EXISTING STEM CELL LINE. ONE OF
10 THEM IS IT'S APPROVED BY NIH OR UK.

11 MS. LANSING: AND THEY CAN BE PAID FOR AND
12 NOT HAVE INFORMED CONSENT AND WE ACCEPT THEM.

13 CHAIRMAN LO: OR IF SOMEHOW YOU DIDN'T GO TO
14 THE NIH, BUT YOU DECIDED -- THEN YOU HAVE TO MEET A
15 SECOND SORT OF OPTION UNDER THAT. AS ALTA POINTS OUT,
16 THAT DOES REQUIRE INFORMED CONSENT FOR GAMETE DONORS.
17 SO --

18 MS. LANSING: OR DISCLOSURE IF WE DECIDE
19 DISCLOSURE.

20 MS. CHARO: HOWEVER WE DEFINE INFORMED
21 CONSENT.

22 MS. LANSING: SO WE'RE LEANING, I THINK, FROM
23 WHAT I CAN TELL, INFORMED CONSENT TO INCLUDE
24 DISCLOSURE. THAT'S WHAT I THINK EVERYBODY IS SAYING.
25 NOW THE QUESTION IS WHY ARE WE HOLDING THOSE LINES TO A

BARRISTERS' REPORTING SERVICE

1 HIGHER STANDARD THAN THE NIH?

2 MS. CHARO: EXACTLY. HOLDING NEW DERIVATIONS
3 TO A DIFFERENT STANDARD IS A LITTLE EASIER TO
4 UNDERSTAND. BUT WHEN YOU'RE TALKING ABOUT IMPORTING
5 LINES FROM ELSEWHERE, WHY WOULD WE HAVE A DIFFERENT
6 STANDARD FOR THE IMPORTATION OF NIH-APPROVED LINES
7 VERSUS THE IMPORTATION OF A LINE NOT APPROVED BY NIH
8 BUT, IN FACT, DERIVED AND MANAGED IN EXACTLY THE SAME
9 WAY AS THE NIH LINES? THAT'S THE DISCUSSION THAT I
10 THINK WE'RE UP TO.

11 MS. LANSING: I HAVE TO ASK YOU A QUESTION
12 BECAUSE I AM A LAYPERSON. THEN I'LL SHUT UP TOO.
13 SORRY. I SAID I WOULDN'T TALK ANYMORE AND I DID.

14 ARE THESE NEW LINES, LET'S SAY THE MINNESOTA
15 LINE, I'M JUST PICKING A STATE FOR NO REASON, ARE THEY
16 NOT AS GOOD AS THE NIH? DOES THE NIH DO BETTER WORK?
17 IS THERE ANY REASON TO ASSUME THAT IT WOULD BE
18 COMPROMISED IN ANY WAY?

19 MS. CHARO: THE NIH REGISTRY, THAT'S GOING TO
20 BE WHAT WE CONSTITUTE APPROVED LINES. IT'S GOING TO BE
21 MADE UP IN THE FOLLOWING WAY: NIH WILL RECEIVE GRANT
22 PROPOSALS. THE INVESTIGATORS WILL PROPOSE TO USE A
23 LINE, LINE H 53. AND THAT'S WHEN THIS COMMITTEE THAT
24 NIH IS CREATING IS GOING TO DECIDE IF H 53 IS
25 ACCEPTABLE OR NOT. IF THEY DO, H 53 GOES ON THE

BARRISTERS' REPORTING SERVICE

1 REGISTRY. NOW, THERE MAY BE 300 OTHER LINES THAT WOULD
2 BE EQUALLY ELIGIBLE, BUT NOBODY HAS PROPOSED THEM. AND
3 NIH IS NOT GOING TO GO OUT AND LOOK FOR THEM AND LIST
4 THEM.

5 SO THERE'S GOING TO BE HUNDREDS OF LINES THAT
6 ARE NOT NIH APPROVED IN THE SENSE OF BEING PUT ON THE
7 REGISTRY EVEN THOUGH THEY COULD BE.

8 MS. LANSING: SO YOU COULD SAY, AND THEN I'M
9 DONE, YOU CAN SAY THERE'S TWO WAYS. THERE'S THE NIH
10 APPROVED, WHICH WE ALREADY HAVE IN OUR BYLAWS, AND ANY
11 OTHER LINES THAT MEET THOSE STANDARDS OF NIH, AND THEN
12 YOU CAN STILL KEEP THE MORE RIDGED INFORMED CONSENT FOR
13 THE NEW LINES THAT WE PAY FOR IN THIS STATE.

14 MS. CHARO: THAT IS CERTAINLY AN OPTION.
15 ABSOLUTELY.

16 MS. LANSING: THEN WE WOULD, I THINK, MAYBE
17 HAVE THE MIDDLE GROUND.

18 CHAIRMAN LO: LET ME JUST SAY, AGAIN TO
19 CLARIFY. I'M SORRY WE DIDN'T ASK STORY THIS. MY
20 UNDERSTANDING IS THE NIH WILL HAVE A REGISTRY OF
21 EXISTING LINES AND THAT SOMEONE HAS TO ASK THE NIH TO
22 APPROVE A LINE. IT CAN EITHER BE SOMEONE APPLYING TO
23 NIH FOR A GRANT OR IT CAN BE SOMEONE WHO'S GOT A STEM
24 CELL LINE THAT WAS DERIVED IN THEIR LABORATORY SAYS,
25 YOU KNOW, OTHER PEOPLE ARE GOING TO USE THIS. IT'S A

BARRISTERS' REPORTING SERVICE

1 LOT EASIER FOR ME TO SUBMIT THE PAPERWORK BECAUSE IT'S
2 A FAIR AMOUNT OF PAPERWORK.

3 THE NIH IS INTENDING FOR THERE TO BE A DUAL
4 REVIEW PROCESS. ONE IS REVIEW BY NIH STAFF WHERE
5 SOMETHING CLEARLY MEETS ALL THE NIH REQUIREMENTS.
6 THEY'RE NOT GOING TO HAVE TO WAIT FOR A COMMITTEE TO
7 GET TOGETHER. THEY'RE JUST GOING TO HAVE IT APPROVED
8 BY THE APPROPRIATE NIH OFFICIAL. THEY ANTICIPATE A LOT
9 OF THESE LINES WILL DO THAT. FOR INSTANCE, AS LONG AS
10 THEY HAVE AN AUTHORIZATION FROM THE GAMETE DONOR SAYING
11 I RENOUNCE, I GIVE OVER TO THE PATIENT IN IVF ALL
12 RIGHTS, PERIOD, THEN THAT PIECE OF PAPER, THEY'RE GOING
13 TO SAY FINE. THAT CONDITION IS CHECKED OF.

14 THE COMMITTEE IS ONLY GOING TO HAVE TO MEET
15 TO DISCUSS THE LINES WHERE IT ISN'T REALLY CLEAR, BASED
16 ON THE EVIDENCE, THERE NEEDS TO BE SOME INTERPRETATION.
17 SO THEY'RE HOPING THIS PROCESS WILL BE RELATIVELY
18 EFFICIENT. IT DOES HAVE THE ADVANTAGE OF SOMEONE
19 ACTUALLY SAID SHOW US THE DOCUMENTATION, LET US LOOK AT
20 IT CHECKED OFF SO THAT IT'S NOT A SELF-DECLARATION THAT
21 WE MET THE GUIDELINES. IT'S NIH SAYING YOU GAVE US
22 INFORMATION; BASED ON THAT, WE APPROVE -- WE AGREE THAT
23 YOU MET OUR GUIDELINES AND, THEREFORE, APPROVE.

24 MS. LANSING: THE ONLY THING WE WANT TO BE
25 SURE IS THAT WE'RE NOT GETTING BAD LINES THAT WILL THEN

BARRISTERS' REPORTING SERVICE

1 AFFECT OUR RESEARCH.

2 CHAIRMAN LO: BAD IN THE SCIENTIFIC SENSE?

3 MS. LANSING: YES. THAT THE NIH BLESSED
4 THESE LINES WITH A GOLD STANDARD AND I JUST WANT TO BE
5 SURE.

6 CHAIRMAN LO: NIH IS NOT SAYING ANYTHING
7 ABOUT THE SCIENTIFIC MERIT OF THE LINE. ALL THEY'RE
8 SAYING IS THAT THEY'RE APPROVED IN TERMS OF THE ETHICS
9 OF BEING CONSISTENT WITH PRESIDENT OBAMA'S EXECUTIVE
10 ORDER. PRESUMABLY THE SCIENTIFIC REVIEW BY THE CAPS
11 PEER REVIEWERS WOULD SAY, THAT LINE JUST ISN'T ANY GOOD
12 FOR THIS BECAUSE IT'S GOT EITHER THIS MUTATION OR
13 DOESN'T GROW THAT WAY. I WOULD TRUST THAT ALAN'S
14 SCIENTIFIC REVIEW --

15 DR. TAYLOR: I THINK SHERRY'S POINT IS ONE
16 THAT YOU SHOULDN'T BECAUSE I THINK THAT'S THE MOST
17 IMPORTANT LONG-TERM POINT ACTUALLY IS EXACTLY THE
18 QUALITY CONTROL ISSUE THAT SHERRY IS RAISING NOW.
19 REALLY, WHAT WE'RE DOING IS WE'RE CREATING TWO
20 STANDARDS. WE'RE CREATING AN NIH STANDARD OF CELLS AND
21 WE'RE CREATING A CIRM STANDARD OF CELLS. AND IF I WERE
22 A CALIFORNIA STEM CELL INVESTIGATOR AND I WANTED TO GET
23 TO THE NEXT STEP, I WOULD TAKE THE MOST EXPEDITIOUS
24 ROUTE, WHICH IS TO USE THE BACK DOOR THROUGH THE NIH TO
25 GET CELLS THAT ARE KIND OF OUT THERE.

BARRISTERS' REPORTING SERVICE

1 SO I WOULD SAY THAT FOR THERAPEUTIC
2 APPLICATION, AND MAYBE I'M HOLDING TOO HIGH A STANDARD
3 HERE, I WOULD WANT TO KNOW THAT WE HAVE THE VERY BEST
4 CELLS THAT CAME FROM GAMETE DONORS THAT HAD DISCLOSED
5 ABOUT WHETHER THEY HAD A HISTORY OF GENETIC DISEASES OR
6 HERITABLE KINDS OF ISSUES. AND THAT WHEN YOU GO TO
7 MAKE A THERAPEUTIC STEM CELL LINE, YOU'RE ACTUALLY
8 DEALING WITH SOMETHING THAT YOU HAVE PERMISSION TO GO
9 BACK AND TRACE AND DO ALL THINGS.

10 SHOULD EVERYBODY THAT DOES AN INVESTIGATION
11 HERE IN THE STATE OF CALIFORNIA HAVE TO GO THROUGH ALL
12 THOSE HOOPS? NO. BUT I'M A LITTLE BIT AFRAID THAT IF
13 WE KIND OF CREATE TWO STANDARDS, THAT WE'RE GOING TO
14 COMPLETELY CUT OFF THE GENERATION OF THOSE REALLY HIGH
15 QUALITY STEM CELLS THAT PROBABLY SHOULD COME FROM YOUNG
16 DONORS, AS WAS KIND OF POINTED OUT BOTH BY THOMAS, I
17 THINK YOU SAID YOUR NAME WAS -- I MIGHT HAVE GOTTEN IT
18 WRONG -- AS WELL AS JIM WILLERSON MADE THE POINT THAT
19 SORT OF OLDER PEOPLE DON'T HAVE SUCH CELLS.

20 CHAIRMAN LO: WE ALSO HAVE TO BE CLEAR THAT
21 THERE'S NOTHING IN THE NIH GUIDELINES THAT REQUIRES YOU
22 TO HAVE THE ABILITY TO GO BACK TO EITHER GET A FULL
23 GENETIC FAMILY HISTORY FROM THE GAMETE DONOR. ALL
24 THEY'RE SAYING IS DID YOU SIGN DISPOSITIONAL RIGHTS TO
25 THE WOMAN. AGAIN, I THINK WE NEED TO DISTINGUISH, I

BARRISTERS' REPORTING SERVICE

1 THINK, SCIENTIFIC APPROPRIATENESS FOR THE GIVEN LINE TO
2 BE USED IN CERTAIN RESEARCH, WHICH I DON'T THINK WE CAN
3 DECIDE, VERSUS ARE THERE BASIC ETHICAL CONSIDERATIONS
4 THAT NO MATTER HOW GOOD THE LINE WAS, IF YOU DIDN'T GET
5 SOME PERMISSION FROM THE EMBRYO DONOR AND GAMETE DONOR,
6 WE WOULD BE UNCOMFORTABLE USING. I THINK WE NEED TO
7 NOT TRY AND HAVE SCIENTIFIC STANDARDS IN THE CONTEXT
8 WHERE IT ISN'T GOING TO BE POSSIBLE. THERE'S A LOT OF
9 PEOPLE. I'M GOING TO KEEP QUIET TOO. JEFF AND THEN
10 JOSE.

11 MR. SHEEHY: I GUESS, AGAIN, I GET CONFUSED
12 BECAUSE, NO. 1, WE'RE DEALING WITH A HYPOTHETICAL ABOUT
13 LINES THAT WERE CREATED SOMEWHERE THAT DON'T HAVE ANY
14 VALIDATION, BUT THAT IS NOT SOMETHING WE'VE EXPERIENCED
15 IN THE CONTEXT OF OUR WORKING GROUP. SO PEOPLE AREN'T
16 COMING UP WITH THESE MINNESOTA LINES WITH THIS
17 MYSTERIOUS INFORMED CONSENT PROVENANCE. THEY'RE COMING
18 UP WITH LINES THAT THEIR SCRO'S HAVE IDENTIFIED AS
19 MEETING OUR STANDARDS.

20 SO I DON'T KNOW WHY WE SHOULD CHANGE OUR
21 RULES TO MEET THAT STANDARD. AND I DON'T KNOW, GIVEN
22 THAT THE NIH CANNOT FUND DERIVATION OF ANY NEW LINES,
23 RIGHT, DICKEY WICKER, WHY WOULD WE PUT IN PLACE TWO
24 DIFFERENT STANDARDS? WE'D HAVE ONE FOR DERIVATION,
25 WHICH I THINK THERE'S STRONG SCIENTIFIC REASONS TO HAVE

BARRISTERS' REPORTING SERVICE

1 ALL THE INFORMED CONSENT PROVISIONS, NOT THE LEAST OF
2 WHICH IS IT ALLOWS US TO GO BACK AND CONTACT THE DONORS
3 AND MAKE SURE. THOSE ARE LIKELY TO BE THE FINEST
4 CLINICAL LINES, I SUSPECT, IN THE LONG RUN.

5 SO I DON'T KNOW WHY WE WANT TO CREATE --
6 WE'RE GOING TO HAVE WHAT THE NIH APPROVES, WHICH WILL
7 GET IN, AND WE HAVE OUR STANDARDS WHICH APPLY TO
8 ANYTHING THAT'S IN CALIFORNIA OR ELSEWHERE THAT MEETS
9 OUR STANDARDS. WHY DO WE NEED TO CREATE A THIRD
10 CATEGORY OF THINGS THAT NEITHER MEET OUR STANDARDS NOR
11 HAVE BEEN APPROVED BY THE NIH AND SAY WE NEED TO USE
12 THOSE WHEN NOBODY HAS COME AND ASKED US? I DON'T KNOW
13 WHY WE'RE CHANGING ANYTHING. I THINK OUR RULES ARE
14 FINE.

15 WAS THAT NOT THE STAFF'S RECOMMENDATION, JUST
16 TO LEAVE THINGS AS THEY ARE? I AGREE THAT THE NIH IS
17 GOING FOR A LAXER STANDARD. THEY HAVE A DIFFERENT
18 POLICY APPROACH TO DOING IT, BUT WE DON'T HAVE TO HAVE
19 ANY RELATIONSHIP TO THAT BECAUSE IT WILL NOT PREVENT
20 ANYONE FROM EVER WORKING ON ONE OF THOSE NIH LINES ONCE
21 THEY'RE PUT INTO THE REGISTRY. AND, FRANKLY,
22 ENCOURAGING PEOPLE TO GO THROUGH SOME SORT OF ETHICAL
23 REVIEW FOR THEIR LINE, WHETHER IT'S OUR REVIEW
24 ACCORDING TO OUR STANDARD OR WHATEVER THE NIH SETS UP,
25 JUST TRYING TO PUSH PEOPLE DOWN SOME PATHWAY SEEMS TO

BARRISTERS' REPORTING SERVICE

1 ME TO BE ADVANTAGEOUS FOR THE FIELD.

2 I DO THINK THAT THE SCIENTIFIC CONSIDERATIONS
3 WILL START TO COME IN; BUT, FRANKLY, I THINK PEOPLE ARE
4 GOING TO BE LOOKING AT THE FDA MORE THAN NIH FOR WHAT
5 IS A GOOD LINE BECAUSE IT'S GOING TO BE THE LINES THAT
6 ARE FURTHEST DOWN THE FDA. THE MORE DOCUMENTATION THE
7 FDA HAS ON A LINE IS REALLY GOING TO BE COMPELLING
8 THERAPEUTIC REASONS. EVEN IF YOU HAVE THE MOST
9 FANTASTIC LINE, IF YOU'VE GOT A LINE THAT'S ALREADY
10 CLOSE TO AN IND AND HAS GOTTEN ALL THIS DATA FILED WITH
11 THE FDA, PEOPLE WILL SAY TAKE THIS, YOU CAN USE IT IN A
12 CLINICAL TRIAL. I THINK THAT THAT'S GOING TO BE MORE
13 COMPELLING THAN ALL THESE OTHER SCIENTIFIC REASONS.
14 THAT'S ACTUALLY PROBABLY WHAT'S GOING TO DRIVE IT MORE
15 THAN SOME INDEPENDENT SCIENTIST LOOKING AT THIS AND
16 SAYING, OH, THIS IS THE BEST LINE OF ALL. IT'S GOING
17 TO BE THOSE FOLKS WHO ARE TAKING THEIR LINES FIRST TO
18 THE FDA AND GETTING FURTHEREST DOWN THE ROAD WITH IT, I
19 SUSPECT.

20 DR. LOMAX: COULD I JUST RESPOND TO JEFF? HE
21 IS CORRECT. AND ALTA'S ANALYSIS WAS A CORRECT ANALYSIS
22 FROM KIND OF LOOKING HOLISTICALLY AT THE REGULATIONS.
23 BUT THE REASON WE BROUGHT THE MORE NARROW ISSUE OF WHAT
24 IS NOTIFICATION SUFFICIENT IS BECAUSE YOU ARE CORRECT.
25 THE ISSUES THAT WERE BROUGHT UP IN PUBLIC COMMENT

BARRISTERS' REPORTING SERVICE

1 PERTAIN TO, AGAIN, THE USE OF EMBRYOS IN FUNDED
2 RESEARCH AND THAT WE COULD MAINTAIN THAT CONSENT
3 STANDARD WHILE STILL ALLOWING ACCESS TO NIH LINES
4 BECAUSE OUR REGULATIONS CURRENTLY ALLOW THAT.

5 ALTA IS CORRECT. THERE'S STILL THE -- ISSUE
6 SHE RAISED STILL STANDS, BUT WE ACTUALLY DID NOT
7 RECEIVE PUBLIC COMMENT REQUESTING THAT WE ADDRESS THAT.
8 SO IT'S KIND OF HANGING OUT THERE AS WHATEVER IT IS, AN
9 INCONSISTENCY OR WHATEVER ELSE.

10 JUST TO RESPOND TO YOUR STATEMENT, WHICH I
11 TOOK AS A QUESTION. THAT'S THE GENESIS HERE.

12 DR. CIBELLI: I HAVE SEVERAL COMMENTS. JUST
13 TO KEEP IT SHORT. NEVER UNDERESTIMATE THE CREATIVITY
14 OR THE CAPACITY FOR A SCIENTIST TO COME UP WITH NEW
15 QUESTIONS. I'M SURE THOSE WILL BE HAPPENING SOON. SO
16 YOU WILL HAVE THE NEED FOR NEW CELL LINES FROM MULTIPLE
17 SOURCES. AND MY QUESTION GOES BACK TO WHAT ALAN
18 TROUNSON WAS SAYING BEFORE. HOW ARE WE GOING TO ALLOW
19 A SCIENTIST TO RUN EXPERIMENTS, LET'S SAY, TO COMPARE
20 THE IMPRINTING PROFILE OF 50 DIFFERENT CELL LINES WHEN
21 THE FUNDING IS COMING FROM DIFFERENT PLACES?

22 SO IF YOU HAVE CELL LINES THAT ARE COMING
23 FROM -- I MEAN IF YOU HAVE TO DERIVE CELL LINES, FOR
24 EXAMPLE, WE WERE TRYING TO MAKE AN EXPERIMENT WITH CELL
25 LINES OF PASSAGE TWO. SO THE ONLY OPTION YOU HAVE

BARRISTERS' REPORTING SERVICE

1 THERE IS TO DERIVE YOUR OWN CELL LINE. SO HOW WOULD
2 YOU DO THAT? IT'S COMPLICATED. YOU HAVE TO SEPARATE
3 ALL THE EQUIPMENT. YOU HAVE TO SEPARATE ALL THE
4 REAGENTS. THE LOGISTICS OF THAT, I DON'T KNOW HOW A
5 SCIENTIST WILL BE ABLE TO DO IT.

6 THIS IS MORE LIKE TO ALAN. WHEN YOU WERE
7 SAYING THAT YOU HAVE TO KEEP SEPARATE, IF WE WERE TO DO
8 SOMETHING DIFFERENT FROM NIH, DO YOU HAVE TO KEEP TRACK
9 OF YOUR REAGENTS?

10 MR. SHEEHY: NO. AS LONG AS IT'S APPROVED BY
11 NIH, OUR RULES ALLOW IT.

12 DR. TROUNSON: JEFF'S RIGHT. IF IT'S ALLOWED
13 UNDER THE NIH, THEN WE CAN DO IT. I THINK THE SUBTLETY
14 THERE IS THAT IT WILL BE OKAY BECAUSE WE GRANDFATHERED
15 THEM IN BASICALLY, AS I UNDERSTAND IT, FROM NIH AND
16 FROM OTHER PLACES. SO THOSE RULES WILL BE SLIGHTLY
17 DIFFERENT THAN THE ONES THAT ARE USED TO DERIVE
18 EMBRYONIC STEM CELL LINES IN CALIFORNIA. SO I THINK
19 IT'S OKAY UNDER THAT SCENARIO.

20 I JUST DIDN'T WANT TO PRODUCE A SCENARIO
21 WHICH WAS LIKE THE PREVIOUS TIME, BUT I DON'T THINK IT
22 DOES IF WE'VE GRANDFATHERED. IF WE CONTINUE TO
23 GRANDFATHER IN ON A PROSPECTIVE BASIS NIH LINES SO THAT
24 THEY'RE NOT DIFFERENT BECAUSE WE MAY BE -- IF THEY WERE
25 DIFFERENT, THEN WE MAY HAVE TO FACE THE SITUATION THAT

BARRISTERS' REPORTING SERVICE

1 WE ENFORCE THE SEPARATION OF THE CELL LINES.

2 DR. CIBELLI: I THINK THE IMPORTANT POINT IS
3 WHAT JEFF WAS SAYING, THAT CURRENTLY, BECAUSE OF THE
4 APPROPRIATION BILL, THE NIH MONEY CANNOT BE USED TO
5 CREATE NEW LINES. SO --

6 DR. TROUNSON: WELL, BUT IF THEY'RE AGREED
7 PROSPECTIVELY TO BE INCLUSIVE, IT'S NOT
8 RETROSPECTIVE -- I'M SORRY. WE AGREED TO INCORPORATE
9 NIH LINES AS THEY COME IN TO BE AGREED TO, SO IN A
10 PROSPECTIVE WAY, THEN IT WILL WORK. BECAUSE THEY'VE
11 GOT TO DO ALL OF THEIR LINES AGAIN, AS I UNDERSTAND IT.
12 SO IT WILL TAKE SOME TIME FOR THEM TO AGREE. THOSE
13 LINES, SOME OF THOSE MIGHT BE GMP-DERIVED LINES FOR
14 WHICH CALIFORNIANS MIGHT NEED TO USE IT. ON THE OTHER
15 HAND, WE MAY BE DERIVING GMP ES CELL LINES UNDER THE
16 CODE WHICH WE'VE AGREED TO.

17 I THINK IT'S ALL RIGHT IF WE AGREE THAT
18 WHATEVER THE NIH DOES REGISTER IS OKAY FOR OUR
19 SCIENTISTS TO USE.

20 MR. SHEEHY: WE HAD THAT EXPLICIT. WE HAVE
21 IDENTIFIED OTHER REGULATORS WHOSE BY-PRODUCTS, SO TO
22 SPEAK, WE AUTOMATICALLY ACCEPT, NO QUESTIONS ASKED,
23 NIH, UK, JAPAN, CANADA.

24 I ALSO, AGAIN, SO THAT WE'RE NOT NECESSARILY
25 THINKING WE'RE LOSING MATERIALS, I DID THINK WE PUT IN

BARRISTERS' REPORTING SERVICE

1 AN APPEAL PROCESS FOR LINES THAT DON'T NECESSARILY MEET
2 OUR STANDARDS. SO IF A RESEARCHER DOES IDENTIFY A LINE
3 THAT HASN'T BEEN APPROVED BY THE NIH, THAT ISN'T
4 ACCORDING TO OUR STANDARDS, AND YET THE PRESIDENT -- I
5 THINK THE PRESIDENT HAS THE STARTING POINT. I'M NOT
6 SURE WHAT OUR TRIGGER WAS, BUT I THINK THE PRESIDENT.
7 SO IF YOU MAKE THE CASE TO ALAN THAT WE NEED THIS LINE,
8 WE'VE DONE IT ALREADY, I THINK, FOR ONE LINE, HAVEN'T
9 WE? WE'VE ALREADY APPROVED A LINE FOR RESEARCH --

10 DR. LOMAX: YES, THAT'S CORRECT.

11 MR. SHEEHY: -- THAT DID NOT HAVE BOTH GAMETE
12 DONORS CONSENTED, SO WE DO HAVE A PROCESS. SO THAT
13 KIND OF GIVES US A HISTORY, IF YOU WANT TO BE EVIDENCE
14 BASED, ON WHAT THE NECESSITY IS FOR INCLUDING LINES
15 THAT DON'T MEET OUR STANDARDS. WHAT HAS BEEN THE
16 DEMAND FROM THE SCIENTISTS DOING THE RESEARCH FOR LINES
17 THAT DON'T MEET OUR STANDARDS? SO FAR WE HAVE ONE
18 CASE. AND THAT PRESUMABLY SHOULD DIMINISH BECAUSE IT
19 SHOULD INCENTIVIZE SCIENTISTS TO GET THE NIH -- TO BE
20 ON THE NIH REGISTRY. ESPECIALLY IF THESE ARE CLINICAL
21 GRADE LINES, THEY'RE GOING TO WANT THOSE TO BE AS
22 WIDELY AVAILABLE.

23 I THINK THIS WAS, IN FACT, A CLINICAL GRADE
24 LINE. IF YOU'RE PRODUCING A LINE THAT CAN BE USED THAT
25 HAS ALL THIS FDA STUFF GOING FORWARD, YOU'RE GOING TO

BARRISTERS' REPORTING SERVICE

1 WANT TO GET IT OUT TO AS MANY HANDS AS POSSIBLE. IT'S
2 IN THEIR INTEREST, AND WHY WOULDN'T YOU TAKE THE
3 PROACTIVE STEP OF GOING TO THE NIH AND SAYING PLEASE
4 PUT OUR LINE ON THE REGISTRY. THIS IS WHAT WE'VE DONE.
5 THIS IS WHERE ARE. AND THEY ACTUALLY DON'T HAVE THE
6 REQUIREMENT FOR CONSENT FOR GAMETE DONORS, WHICH WOULD
7 BE FAIRLY STRAIGHTFORWARD.

8 MS. CHARO: FIRST, I'M GOING TO MAKE
9 ABSOLUTELY NO COMMENT THAT EVEN REMOTELY RELATES TO THE
10 FDA.

11 I THINK PERFECTLY REASONABLE PEOPLE CAN
12 DISAGREE ABOUT WHETHER OR NOT YOU WANT TO MAINTAIN THIS
13 REQUIREMENT FOR THE CONSENT OF THE UNDERLYING GAMETE
14 DONORS WHO GAVE ORIGINALLY IN A REPRODUCTIVE CONTEXT.
15 I UNDERSTAND WHERE THE IMPETUS FOR THIS CAME FROM. IN
16 FACT, THE NATIONAL ACADEMIES COMMITTEE CAME TO THE SAME
17 CONCLUSION. A LOT OF IT HAD TO DO WITH THE SENSE THAT
18 THIS WAS A VERY CONTROVERSIAL AND SENSITIVE FIELD, AND
19 THAT CERTAINLY FED INTO THE DISCUSSION ABOUT WHICH WAY
20 TO GO ON SOMETHING WHERE THE LAW GIVES NO CLEAR
21 DIRECTION BECAUSE THE LAWS OF THE 50 STATES ON THE
22 PROPERTY STATUS OF GAMETES THAT ARE BEING DONATED IS
23 VERY UNCLEAR, BUT MOSTLY IT DOESN'T APPEAR THAT THERE'S
24 ANY LEGAL OBLIGATION TO GET THEIR CONSENT. SO WE ARE
25 TALKING ETHICS, NOT LAW.

BARRISTERS' REPORTING SERVICE

1 BUT I DID WANT TO, JUST FOR THE SAKE OF THE
2 DISCUSSION, NOTE THAT TO REQUIRE THE CONSENT OF AN
3 ANONYMOUS GAMETE DONOR, THAT IS, SOMEBODY WHOSE
4 IDENTITY IS NO LONGER KNOWN, WOULD BE TO DRAW -- IT
5 WOULD BE TO HAVE A POLICY THAT'S DIFFERENT THAN THE ONE
6 WE GENERALLY USE FOR TISSUE-BASED RESEARCH IN OTHER
7 CONTEXTS. IF I AM A SURGICAL PATIENT AND I RELEASE MY
8 TISSUE, EVEN IF IT'S FOR A SPECIFIC PURPOSE, I RELEASE
9 MY TISSUE FOR BREAST CANCER RESEARCH, AND IT'S PUT INTO
10 A TISSUE BANK, AND SUBSEQUENTLY IT IS DEIDENTIFIED,
11 THAT TISSUE CAN NOW BE USED FOR ANYTHING, ANYTHING.
12 DOESN'T MATTER THAT IT HAS NOTHING TO DO WITH BREAST
13 CANCER RESEARCH.

14 SO THAT'S HOW WE TREAT TISSUE-BASED RESEARCH
15 IN THE UNITED STATES UNDER THE FEDERAL HUMAN SUBJECTS
16 REGULATIONS THAT APPLY IN A VARIETY OF CONTEXTS.

17 NOW, THERE'S LOTS OF GOOD REASONS WHY YOU
18 MIGHT WANT TO TREAT SPERM AND EGGS DIFFERENTLY THAN ANY
19 OTHER KIND OF TISSUE. I THINK DOROTHY MADE THAT POINT
20 YESTERDAY, LAST NIGHT, OR THIS MORNING. SO I REALLY DO
21 MEAN THAT REASONABLE PEOPLE CAN DISAGREE, BUT I DID
22 WANT TO JUST MAKE SURE WE APPRECIATE THE CONTEXT IN
23 WHICH THIS REQUIREMENT IS BEING MADE IN A WAY THAT'S
24 DIFFERENT FROM WHAT IS BEING DONE FOR OTHER TISSUES AND
25 JUST MAKE SURE THAT THE DECISION IS CONSCIOUS, IF

BARRISTERS' REPORTING SERVICE

1 THAT'S THE DECISION THE COMMITTEE COMES TO.

2 CHAIRMAN LO: IF I CAN JUST PICK UP ALTA'S
3 POINT. THE ARGUMENT FOR TREATING MATERIALS DERIVED
4 FROM DONATED GAMETES, THIRD-PARTY GAMETES, DIFFERENTLY
5 THAN, SAY, CANCER TISSUE REMOVED AT SURGERY IS THAT WE
6 DON'T BOTHER -- WE DON'T THINK IT'S IMPORTANT TO GET
7 EXPLICIT CONSENT FROM THE CANCER PATIENT TO DONATE
8 LEFTOVER TISSUE BECAUSE THE ASSUMPTION IS IF THEY WERE
9 ASKED, NO ONE WOULD OBJECT. AND IT JUST WOULD BE A
10 DISPROPORTIONATE BURDEN ON RESEARCHERS TO SAY, WELL,
11 YOU CAN'T USE THIS TISSUE EVEN THOUGH WE DON'T THINK
12 THE PERSON WOULD OBJECT BECAUSE YOU DON'T HAVE THE
13 RIGHT PIECE OF PAPER.

14 NOW, THE PROBLEM, THE CONCERN IS THAT IN THE
15 REPRODUCTIVE AREA, IT'S NOT JUST -- WE CLEARLY KNOW
16 THAT SOME WOMEN IN IVF DO NOT WANT TO DONATE THEIR
17 LEFTOVER TISSUE EVEN IF ANONYMIZED BECAUSE IT HAS
18 SPECIAL SIGNIFICANCE TO THEM. NOW, QUESTION IS DO
19 GAMETE DONORS, PARTICULARLY OOCYTE DONORS, CONSIDER
20 EMBRYOS MADE FROM THEIR GAMETES TO BE DIFFERENT THAN,
21 SAY, CANCER TISSUE REMOVED IN SURGERY? AND WE DON'T
22 REALLY HAVE A LOT OF EVIDENCE ON THAT.

23 THERE'S BEEN ONE STUDY THAT CLAIMS, AN
24 EARLIER STUDY, THAT SAID THAT 25 PERCENT OF OOCYTE
25 DONORS SAID "NO, NO. NOW THAT YOU'VE ASKED ME, I WAS

BARRISTERS' REPORTING SERVICE

1 VERY, VERY WILLING AND EAGER TO GIVE MY TISSUE TO HELP
2 ANOTHER WOMAN OR FAMILY GET A CHILD, BUT I REALLY DO
3 NOT WANT MY MATERIALS USED FOR RESEARCH PURPOSES,
4 PARTICULARLY STEM CELL RESEARCH." SO IT'S SORT OF A
5 RESPECT FOR THE WISHES OF THE GAMETE DONORS. IF YOU
6 DIDN'T ASK THEM AND THEY SAID DO WHATEVER YOU WANT, WAS
7 IT REALLY AN ETHICALLY ROBUST RENUNCIATION OF RIGHTS?

8 I THINK THAT'S THE QUESTION. I THINK WHAT I
9 HEAR PEOPLE SAYING IS THAT IF WE'RE DERIVING A NEW STEM
10 CELL LINE FROM AN EMBRYO AND PAYING FOR IT WITH CIRM
11 MONEY, WE WANT TO HAVE SOME ASSURANCE THAT WHEN THE
12 WOMAN -- WE'RE REALLY TALKING ABOUT OOCYTE DONORS --
13 SIGNED OVER DISPOSITIONAL RIGHTS, THEY WERE AT LEAST
14 INFORMED THAT RESEARCH WAS ONE OF THE OPTIONS, AND THEY
15 SHOULD HAVE BEEN PUT ON NOTICE TO OBJECT IF THAT'S NOT
16 WHAT THEY WANTED.

17 SO I GUESS THERE'S A RESPECT FOR PEOPLE WHO
18 MAY NOT HAVE KNOWN AND WEREN'T EXPLICITLY ASKED.

19 DR. ROBERTS: YEAH. I THINK I AGREE WITH
20 BERNIE THAT THOSE TWO PURPOSES, DONATING FOR
21 REPRODUCTIVE USE AND DONATING FOR RESEARCH, ARE VERY
22 DIFFERENT PURPOSES. SOME PEOPLE MAY NOT THINK THEY'RE
23 THAT DIFFERENT, BUT SOME PEOPLE MAY THINK THEY'RE
24 EXTREMELY DIFFERENT. I'LL QUOTE ONE OF MY COLLEAGUES
25 AT NORTHWESTERN MEDICAL SCHOOL, A BIOETHICIST THERE,

BARRISTERS' REPORTING SERVICE

1 KATIE WATSON, WHOSE RULE OF THUMB ON CONSENT IS IF YOU
2 THINK NOTIFYING A PATIENT WILL MAKE A DIFFERENCE TO HER
3 DECISION, THAT'S WHEN YOU NEED TO HAVE IT. AND SO IF
4 WE THINK THAT NOTIFYING AN EGG DONOR OR, TO TAKE ANN'S
5 POINT, A SPERM DONOR, THAT THEIR DONATION WILL GO TO
6 RESEARCH WILL MAKE A DIFFERENCE IN THEIR DECISION,
7 THAT'S EXACTLY -- THAT'S NOT WHEN YOU DON'T GIVE THEM
8 CONSENT BECAUSE YOU'RE AFRAID IT WILL MAKE A
9 DIFFERENCE. THAT'S EXACTLY WHEN YOU NEED TO GET
10 CONSENT. OR IN THIS CASE PERHAPS DISCLOSURE.

11 I THINK IT REALLY COULD MAKE A DIFFERENCE TO
12 SOME DONORS. ONE OF THE COMMENTATORS MENTIONED IT
13 COULD MAKE A DIFFERENCE FOR RELIGIOUS REASONS OR OTHER
14 KINDS OF REASONS AS WELL. AND SO I THINK IT'S
15 IMPORTANT FOR THAT REASON.

16 CHAIRMAN LO: OTHER COMMENTS?

17 DR. CIBELLI: ONE FINAL CLARIFICATION. SO
18 THEN IF WE GO THAT ROAD, THERE WILL NOT BE ANY, I
19 GUESS, ROADBLOCK FOR A SCIENTIST TO BE ABLE -- ACTUALLY
20 IS IT GOING TO BE MORE DIFFICULT FOR THE SCIENTIST TO
21 WORK WITH CIRM MONEY OR ANY KIND OF OTHER FUNDING? I
22 DON'T SEE ANY PROBLEM.

23 DR. LOMAX: WE'VE NOT BEEN MADE AWARE OF ANY
24 BARRIERS. AS WE MOVE FORWARD IN REGULATIONS, WE ALWAYS
25 TAKE THE TIME TO ASK. SO THAT'S WHERE -- I DON'T HAVE

BARRISTERS' REPORTING SERVICE

1 ANYTHING TO ADD SUBSTANTIVELY, BUT JUST THE POINT THAT,
2 AGAIN, THE ACCEPTABLY DERIVED STANDARD DOES INTRODUCE A
3 KIND OF INCONSISTENCY, IF YOU WANT, BUT WE WEREN'T SORT
4 OF BEING TOLD IT'S SUCH A PROBLEM, WE ABSOLUTELY NEED
5 TO FIX IT AT THIS MEETING. SO THAT'S WHERE WE STAND.
6 WE JUST DON'T HAVE -- LIKE I SAY, CERTAINLY I'M TAKING
7 FROM THIS CONVERSATION THE IDEA THAT WE NEED TO GO OUT
8 NOW AND WE CAN EVALUATE THIS, BUT WE DON'T HAVE
9 EVIDENCE THAT WE'RE BEING OVERLY RESTRICTED IN A WAY
10 THAT'S COMPROMISING OUR ABILITY TO CONDUCT THE
11 RESEARCH.

12 CHAIRMAN LO: WE HAVE HEARD --

13 MR. SHEEHY: DON'T WE HAVE A METRIC ALREADY
14 BASED ON APPLICATIONS RECEIVED AND REQUESTS FOR LINES
15 THAT ARE NOT -- SO AS WE KNOW, WE'VE ONLY HAD ONE
16 REQUEST TO USE A LINE THAT HASN'T BEEN DERIVED
17 ACCORDING TO OUR STANDARDS. I DON'T EVEN THINK WE NEED
18 TO NECESSARILY GO OUT. WE HAVE A VERY CLEAR METRIC
19 THAT EXISTS.

20 CHAIRMAN LO: AND IT WAS APPROVED.

21 MR. SHEEHY: WE COULD GO OUT AND DO FURTHER
22 LEGWORK.

23 CHAIRMAN LO: MY UNDERSTANDING IS THAT LINE
24 WAS APPROVED BECAUSE THE SCIENTIFIC BENEFITS OF USING
25 THAT LINE AS A UNIQUE LINE WERE VERY IMPORTANT. AND

BARRISTERS' REPORTING SERVICE

1 THERE'S A WEIGHING OF THE SCIENTIFIC BENEFIT OF THE
2 RESEARCH VERSUS JUST NOT KNOWING WHAT ONE OF THE GAMETE
3 DONORS, ONE OF THE TWO GAMETE DONORS, WOULD HAVE
4 WANTED.

5 MS. LANSING: I'M VERY AWARE OF WHAT ALTA IS
6 SAYING, AND THERE'S A CERTAIN INCONSISTENCY IN WHAT
7 WE'RE DOING, AND I UNDERSTAND IT. BUT WE'VE COME --
8 AGAIN, WE'RE GOING TO MEET AGAIN. YOU KNOW WHAT I'M
9 SAYING? IT WAS SORT OF DUE PROCESS, AND MAYBE WE GO
10 SLOWER, DO YOU KNOW, JUST THAT'S THE WAY THIS HAS BEEN
11 SET UP AND THERE'S SO MUCH CONTROVERSY SURROUNDING IT
12 IN OUR STATE, THOUGH LESS NOW WITH OBAMA'S NEW
13 REGULATIONS.

14 I THINK THAT THE FACT THAT WE'VE TAKEN OFF
15 THAT DATE, DO YOU KNOW, REMOVING, YOU KNOW, WHEN WE CAN
16 USE PEOPLE THAT WERE PAID FOR REPRODUCTIVE SERVICES, I
17 THINK THAT'S A BIG STEP FOR US. AND I THINK IF WE, IN
18 MY OPINION AT LEAST, MAKE DISCLOSURE GOOD ENOUGH, I
19 THINK THAT'S ALSO A BIG STEP FOR TODAY. AND THEN I
20 THINK WE SHOULD SEE, JOSE, IF, IN FACT, WHAT WE BELIEVE
21 TO BE TRUE, THAT WE'RE NOT HURTING ANY OF OUR
22 RESEARCHERS. IF WE START TO GET COMPLAINTS, THEN WE
23 HAVE TO REEVALUATE IT AGAIN AND COME BACK TO THE ISSUE
24 BECAUSE THERE IS THAT MIDDLE GROUND THAT ALTA SO
25 ELOQUENTLY POINTED OUT AND SEE HOW MANY REQUESTS WE

BARRISTERS' REPORTING SERVICE

1 HAVE FOR THAT MIDDLE GROUND.

2 CHAIRMAN LO: SO TRYING TO SORT OF TAKE WHAT
3 I THINK I'M HEARING, I WANT TO DIRECT US BACK TO, IT
4 WOULD BE PAGE 6 OF YOUR YELLOW PAGES, THE LEFT COLUMN,
5 100090, SPECIAL CONSIDERATION FOR CIRM-FUNDED
6 DERIVATION OF NEW EMBRYONIC STEM CELL LINES. WE WANT
7 TO LOOK AT B. THE CONCERN IS THE SCRO COMMITTEE MUST
8 CONFIRM THE DONORS OF, AND THAT APPARENTLY WOULD
9 INCLUDE GAMETE DONORS, THIRD-PARTY GAMETE DONORS,
10 PROVIDED VOLUNTARY INFORMED CONSENT IN ACCORDANCE WITH
11 CODE OF CALIFORNIA REGS, TITLE 17.

12 WHAT I THINK THE PROPOSAL I'M HEARING IS THAT
13 WE REQUIRE VOLUNTARY INFORMED CONSENT FROM THE EMBRYO
14 DONORS; BUT FOR THE THIRD-PARTY GAMETE DONORS, IF THERE
15 ARE, WE'RE SAYING THAT WHAT WE'RE ASKING IS THAT THEY
16 SIGNED OVER DISPOSITIONAL RIGHTS TO THE WOMAN OR COUPLE
17 IN IVF AND, MOREOVER, THAT BEFORE DOING SO, THEY WERE
18 NOTIFIED THAT ONE OF THE OPTIONS THAT THAT IVF PATIENT
19 COULD DO WITH LEFTOVER EMBRYOS WAS TO DONATE FOR
20 RESEARCH. AND PRESUMABLY THEY ALSO SAY AND THEY COULD
21 DO OTHER THINGS, SUCH AS DESTROY THEM AND GIVE THEM TO
22 A THIRD. SO IT'S LESS STRICT THAN INFORMED CONSENT,
23 WHICH SEEMS TO HAVE ALL THESE IMPLICATIONS OF A
24 SEPARATE CONSENT FORM, IRB APPROVAL.

25 MS. LANSING: THIS IS JUST DISCLOSURE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: THIS JUST DISCLOSURE PLUS
2 SIGNING OVER TO THE COUPLE, WOMAN IN IVF, YOU DO WHAT
3 YOU WANT. THEY'RE NOW YOURS.

4 DR. KIESSLING: SO WE'RE GOING TO CHANGE OUR
5 GUIDELINES?

6 CHAIRMAN LO: I THINK IT'S A PROPOSAL THAT
7 WOULD COME OUT OF WHAT GEOFF HEARD AT THIS MEETING,
8 THAT PEOPLE WERE SAYING ARE YOU REALLY MEANING REAL
9 INFORMED CONSENT FROM GAMETE DONORS WHO SIGNED OVER
10 THEIR RIGHT, THEIR DISPOSITIONAL AUTHORITY TO THE
11 EMBRYO TO THE PATIENT, AND THAT HAPPENED A LONG TIME
12 AGO.

13 DR. LOMAX: I WOULDN'T CHARACTERIZE IT AS A
14 CHANGE. AGAIN, YOU ALL DID ARTICULATE A POSITION
15 CONSISTENT WITH WHAT BERNIE JUST ARTICULATED, AND THAT
16 GOES BACK TO THE JULY MEETING. WITHIN THAT THERE IS
17 SOME -- AS I SAID IN MY OPENING REMARKS, WHAT'S NOT
18 CLEAR FROM THE RECORD, YOU CAN CUT IT BOTH WAYS. AND
19 THIS IS WHAT WE'RE ASKING FOR CLARIFICATION ON. DOES
20 THAT NOTIFICATION STANDARD SORT OF MOVE FORWARD
21 FOREVER, OR DID IT SORT OF END AT SOME MYSTERIOUS POINT
22 IN TIME? WHAT WE'VE SORT OF -- WHAT'S BEEN SUGGESTED
23 TO US IS THE MOVING FORWARD OF A STANDARD THAT
24 RECOGNIZES NOTIFICATION AS REQUIRED BY CALIFORNIA LAW
25 WOULD BE SOMETHING THAT IS SORT OF COMPATIBLE WITH, YOU

BARRISTERS' REPORTING SERVICE

1 KNOW, SORT OF WHAT'S REALITY, I GUESS IS THE BEST WAY
2 TO PUT IT. THIS IS KIND OF THE STANDARD OF CARE WE'RE
3 LIVING WITHIN, AND IS THAT OKAY? SO THAT'S WHAT WE'RE
4 ASKING YOU TO CLARIFY.

5 MS. LANSING: IT'S MORE OF A CLARIFICATION.

6 DR. KIESSLING: BUT IN OUR GUIDELINES, IT
7 SAYS THE DONORS OF HUMAN GAMETES, EMBRYOS, SOMATIC
8 CELLS, OR TISSUE GAVE VOLUNTARY AND INFORMED CONSENT.

9 DR. LOMAX: THAT'S RIGHT. SO IN THAT CASE
10 WE'RE ALWAYS TALKING ABOUT THE PERSON WHO'S DONATING
11 THE ACTUAL EMBRYO; BUT AS WE'VE BEEN DISCUSSING ALL
12 DAY, WHAT ABOUT THOSE CIRCUMSTANCES --

13 DR. KIESSLING: IT SAYS GAMETES.

14 CHAIRMAN LO: QUESTION IS DO WE WANT TO
15 CHANGE THAT, AS WAS SUGGESTED BY SOME OF THE COMMENTS
16 IN THIS PUBLIC MEETING.

17 DR. CIBELLI: SO THE CHANGE WOULD BE TO
18 CHANGE THE CONSENT FORM AND AT LEAST REQUIRE THE DONOR
19 TO KNOW WHERE THIS GAMETE -- HOW THE GAMETE IS GOING TO
20 BE USED, OR IF THEY'RE GOING TO MAKE EMBRYONIC STEM
21 CELLS, YOU SHOULD KNOW OR HE SHOULD KNOW.

22 DR. KIESSLING: THAT'S WHAT WE HAVE NOW.

23 DR. CIBELLI: NOW, THE QUESTION IS MANY OF
24 THE EMBRYOS THAT ARE FROZEN, AND THEY'RE PROBABLY GOING
25 TO BE THE FIRST ONES THAT ARE GOING TO COME UP FOR CIRM

BARRISTERS' REPORTING SERVICE

1 FOR NEW LINES, ARE OLD. WHAT HAPPENS IF YOU CANNOT
2 LOCATE THE DONOR?

3 CHAIRMAN LO: MY UNDERSTANDING IS WHAT
4 TYPICALLY HAPPENS IS YOU HAVE A PIECE OF PAPER FROM THE
5 THIRD-PARTY GAMETE DONOR THAT SAYS I RENOUNCE ALL
6 RIGHTS TO MY MATERIALS AND THE EMBRYOS YOU MIGHT CREATE
7 WITH THEM, AND WHATEVER THE WOMAN, COUPLE IN IVF WANTS
8 TO DO IS FINE WITH ME. SO WE'RE NOT TECHNICALLY DOING
9 ANYTHING ON THE BOARD THERE DIFFERENT THAN WHAT THEY
10 AGREED TO, BUT WE'RE NOT CLEAR THAT THEY UNDERSTOOD ONE
11 OF THE THINGS THEY'RE AGREEING TO WAS RESEARCH. SO
12 IT'S ACTUALLY STRONGER, THE DISCLOSURE PART WILL BE
13 STRONGER THAN WHAT'S IN THE CALIFORNIA PENAL CODE, BUT
14 IT WOULDN'T NECESSARILY BE INFORMED CONSENT WHICH,
15 FIRST OF ALL, TO SOME SAYS, WELL, THAT MEANS YOU HAD TO
16 HAVE GOTTEN IRB APPROVAL. IS THAT WHAT YOU MEAN HERE?
17 DOES IT MEAN A SEPARATE CONSENT FORM ON A DIFFERENT
18 PIECE OF PAPER? DOES IT MEAN A LOT MORE INFORMATION
19 ABOUT WHAT ARE THE RISKS AND BENEFITS OF DONATING TO
20 STEM CELL RESEARCH OR OTHER RESEARCH?

21 THE TERM "INFORMED CONSENT" FOR SORT OF
22 PEOPLE INVOLVED WITH HUMAN RESEARCH OVERSIGHT OR HUMAN
23 RESEARCH PROTECTION HAS A WHOLE LOT OF THINGS ON IT.
24 THAT MAY BE WHAT WE WANT OR IT MAY NOT BE WHAT WE WANT.
25 I THINK THAT'S THE ISSUE WE NEED TO TRY AND TACKLE

BARRISTERS' REPORTING SERVICE

1 HEAD-ON. THE NIH SAID ALL YOU NEED IS JUST DO WHAT YOU
2 WANT WITH THEM. ONE PROPOSAL IS WE NEED TO DO A LITTLE
3 MORE THAN THAT AND SAY DO WHAT YOU WANT WITH THEM, AND
4 SOMEWHERE YOU TELL THE THIRD-PARTY GAMETE DONOR AMONG
5 THE THINGS THAT MIGHT BE DONE IS RESEARCH.

6 DR. CIBELLI: I STILL DON'T HAVE AN ANSWER.
7 WHAT DO YOU TELL THE RESEARCHER? YOU GIVE THIS PIECE
8 OF PAPER, GO BACK TO THE DONOR, AND ASK FOR THEM TO
9 SIGN THAT SHE ALLOWS THE EMBRYO TO BE USED FOR
10 RESEARCH, OR THE EMBRYO THAT WAS PRODUCED WITH HER
11 OOCYTE?

12 CHAIRMAN LO: NO. I THINK THAT -- I THINK
13 WHAT WE'RE HEARING, GEOFF, CORRECT ME IF I'M WRONG, IS
14 THAT MANY RESEARCHERS SAY THERE'S NO WAY YOU CAN DO
15 THAT.

16 DR. CIBELLI: SO THEN THAT EMBRYO CAN'T BE
17 USED.

18 CHAIRMAN LO: THAT EMBRYO CAN'T BE USED
19 BECAUSE WE DON'T HAVE -- ALL WE HAVE IS A PIECE OF
20 PAPER SAYING I GIVE THE RIGHTS TO THIS EMBRYO, BUT IT
21 DOESN'T EXPLICITLY SAY RESEARCH. SO THAT'S WHERE
22 PEOPLE ARE GETTING --

23 DR. KIESSLING: BUT SOME CONSENT FORMS
24 PROBABLY DO SAY RESEARCH.

25 CHAIRMAN LO: SOME DO. THAT'S GREAT. I

BARRISTERS' REPORTING SERVICE

1 THINK WE WOULD HOPE THAT MORE OF THEM DO.

2 DR. KIESSLING: THE BIGGER CONCERN IS WHAT DO
3 THE SPERM DONOR CONSENT FORMS SAY. I WAS JUST LOOKING
4 ON CALIFORNIA CRYOBANK'S SITE, AND THEY USED TO HAVE
5 THEIR CONSENT FORM POSTED. I CAN'T FIND IT ON THEIR
6 SITE ANYMORE. BUT I DON'T KNOW WHAT THE SPERM DONATION
7 SITES SAY FOR THEIR CONSENT FORM. I WOULD ACTUALLY
8 LIKE TO SEE A COUPLE OF THOSE.

9 MS. CHARO: THE OTHER THING IS TO PAY CLOSE
10 ATTENTION TO THOSE THAT SAY ANYTHING, WHETHER THEY SAY
11 RESEARCH OR STEM CELL RESEARCH, BECAUSE AS SOON AS YOU
12 MAKE IT SAY STEM CELL RESEARCH IN PARTICULAR, IT'S MUCH
13 NARROWER AS OPPOSED TO RESEARCH, WHICH IS A MORE
14 CATEGORICAL NONPRODUCTIVE USE, WHICH GOES BACK TO YOUR
15 QUESTION OF WHAT IT IS THAT YOU THINK WOULD CHANGE
16 PEOPLE'S MINDS.

17 DR. ROBERTS: EXACTLY. SHERRY RAISED THAT AT
18 THE BEGINNING, THAT WHEN WE SAY DISCLOSURE, WHAT HAS TO
19 BE DISCLOSED? DOES IT HAVE TO BE AS NARROW AS STEM
20 CELL RESEARCH, OR IS RESEARCH SUFFICIENT?

21 DR. KIESSLING: WHAT I THINK WE HAVE TO
22 DECIDE IS IF WE WANT TO STAY WITH OUR PRESENT LANGUAGE,
23 WHICH I STILL THINK IS FINE. I THINK THE DONORS OF
24 HUMAN GAMETES, SOMATIC CELLS, OR TISSUES SHOULD HAVE
25 GIVEN VOLUNTARY AND INFORMED CONSENT. AND IF A

BARRISTERS' REPORTING SERVICE

1 SITUATION ARISES WHERE SOMETHING THAT SEEMS
2 PARTICULARLY VALUABLE IS MISSING SOME OF THAT, THAT CAN
3 ALWAYS BE A SEPARATE CONSIDERATION. BUT I THINK THIS
4 GIVES SOME GUIDANCE TO ESCRO COMMITTEES AS TO WHAT WE
5 THINK IS THE BEST RESEARCH STANDARD GOING FORWARD.

6 THE PROBLEM IS WHAT DO WE MEAN BY VOLUNTARY
7 AND INFORMED CONSENT. AND I DON'T KNOW IF WE NEED TO
8 REDEFINE THAT, IF WE NEED TO MAKE IT CLEARER THAN THAT,
9 BUT IT CERTAINLY -- I'M VERY MUCH IN FAVOR OF STAYING
10 WITH WHAT WE HAVE. I THOUGHT IT NEEDED TO BE DISCUSSED
11 BECAUSE IT'S DIFFERENT FROM WHAT NIH HAS DECIDED, BUT I
12 THINK THAT FOR WHAT WE HAVE, THIS IS IT. I JUST DON'T
13 KNOW IF OUT THERE IN THE WORKING PLACE THEY NEED
14 CLARITY ON WHAT VOLUNTARY AND INFORMED CONSENT MEANS IN
15 THIS CONTEXT.

16 CHAIRMAN LO: LET ME TRY AND ARTICULATE. NIH
17 DOES NOT SAY ANYTHING ABOUT THIS BECAUSE NIH CANNOT
18 FUND DERIVATION RESEARCH, SO THEY HAVE NO POLICY ON IF
19 WHAT YOU NEED TO DO IF YOU'RE DERIVING A NEW STEM CELL
20 LINE FROM AN EMBRYO LEFTOVER FROM IVF, WHAT NEEDS TO BE
21 DONE. THEY DO HAVE RULES ONCE YOU GET THE LINE WHAT
22 YOU NEED DONE, WHAT YOU NEED TO HAVE DONE TO ALLOW
23 FUNDING FOR THAT LINE.

24 MY UNDERSTANDING FROM WHAT GEOFF PRESENTED IS
25 THAT, IN FACT, SOME RESEARCHERS AND RESEARCH

BARRISTERS' REPORTING SERVICE

1 INSTITUTIONS ARE SAYING THERE IS A PROBLEM WITH THE
2 INFORMED -- NO ONE IS OBJECTING TO INFORMED CONSENT
3 FROM THE EMBRYO DONORS. BUT WHAT THEY'RE SAYING IS WE
4 DON'T KNOW WHAT YOU MEAN BY INFORMED CONSENT FROM
5 GAMETE DONORS. AND IF WE INTERPRET IT TO BE THE KIND
6 OF INFORMED CONSENT WE REQUIRE FOR HUMAN SUBJECTS
7 RESEARCH, THAT DISQUALIFIES A LOT OF PEOPLE FROM
8 DONATING THEIR EMBRYOS TO US BECAUSE THEY DON'T HAVE
9 THAT DOCUMENTATION. AND IT'S NOT REALISTIC TO ASK THEM
10 TO GO BACK AND TRY AND FIND THE GAMETE DONORS. SO,
11 GEOFF, IS THAT ACCURATE?

12 DR. LOMAX: THAT IS ACCURATE. THE ONLY THING
13 I WOULD ADD TO THAT STATEMENT IS THEY ARE IN POSSESSION
14 OF OR THEY HAVE THE ABILITY TO OBTAIN FROM THE EMBRYO
15 PROVIDER A STATEMENT OR A CERTIFICATION OR EVEN A BLANK
16 DOCUMENT THAT SAYS THIS IS THE -- THE ORIGINAL GAMETE
17 DONOR WAS NOTIFIED. AND, AGAIN, WHAT'S TYPICALLY
18 DRIVING THAT NOTIFICATION IS THE LAWYERLY
19 INTERPRETATION OF THIS SECTION OF THE CALIFORNIA PENAL
20 CODE WHICH REQUIRES THIS LEVEL OF DISCLOSURE.

21 SO AS I MENTIONED A FEW TIMES, PEOPLE ARE
22 OPERATING WITHIN THAT CONTEXT. AND THE QUESTION REALLY
23 BEFORE YOU ALL IS IS THAT CONTEXT SUFFICIENT IN THE
24 MORE NARROW CIRCUMSTANCE WHERE THE EMBRYO WAS CREATED
25 THROUGH THIS THIRD-PARTY RELATIONSHIP.

BARRISTERS' REPORTING SERVICE

1 MS. CHARO: YOU KNOW, IT STRIKES ME THAT ONE
2 OF THE CHALLENGES IN THIS AREA IS THE DISCONNECT
3 BETWEEN WHO IT IS THAT HAS TO ACTUALLY MAKE SURE SUCH
4 PAPERWORK IS -- ENSURE THAT IT'S PROVIDED AND THOSE
5 THAT ACTUALLY HAVE TO GET THE LINES. THAT IS, THE
6 INVESTIGATORS ARE NOT THE ONES IN THE CLINIC WHO ARE
7 DEALING WITH COUPLES, THEY'RE NOT THE ONES AT THE SPERM
8 BANKS THAT ARE DEALING WITH DONORS. SO ONE OF THE
9 QUESTIONS THAT I ASK MYSELF IS HOW, IF AT ALL, THESE
10 REGULATIONS WILL ACTUALLY INFLUENCE THE PRACTICE IN THE
11 CLINICAL SETTING IN ORDER TO INCENTIVIZE THE CHANGE IN
12 PRACTICE THAT WOULD MAKE MORE EMBRYOS, MORE GAMETES
13 COLLECTED IN A WAY THAT WOULD MEET THESE RULES.

14 AND I'M WRESTLING WITH THAT BECAUSE, FOR ONE
15 THING, IT'S NOT AS IF THE INFORMATION FLOW IS PERFECT.
16 THE CLINICAL PRACTICES DON'T NECESSARILY HAVE AN
17 INTEREST IN CHANGING THEIR PRACTICE FOR THE SAKE OF
18 SOME UNKNOWN FUTURE INVESTIGATOR. AND THE SECOND IS,
19 ESPECIALLY IN LIGHT OF THE FACT THAT THE NIH IS NOT
20 GOING TO REQUIRE THIS FOR THE LINES THAT THEY WILL LET
21 THEIR GRANTEES USE, THERE'LL BE LOTS OF PEOPLE WHO CAN
22 USE LOTS OF LINES THAT COME FROM LOTS OF EMBRYOS THAT
23 HAD DONATED GAMETES THAT DON'T MEET THESE KINDS OF
24 RULES.

25 SO THE ABILITY OF THE CIRM FUNDING TO BE A

BARRISTERS' REPORTING SERVICE

1 DRIVER OF CLINICAL PRACTICE CHANGES SO THAT THESE
2 PRACTICES CAN MAKE SURE THEIR EMBRYOS ARE SOMEHOW
3 USABLE IN CALIFORNIA RESEARCH IS WEAKENED BY THE FACT
4 THAT FOR EVERYBODY, IF THEY'RE USING NIH MONEY, IT'S
5 IRRELEVANT. SO THAT'S NOT AN ARGUMENT AGAINST THIS SO
6 MUCH LIKE LET'S BE AWARE OF HOW MUCH WE MIGHT ACTUALLY
7 ACCOMPLISH BY IMPOSING THESE RULES.

8 MR. SHEEHY: AGAIN, THAT ALMOST TAKES ME THE
9 OPPOSITE DIRECTION, WHICH PUTS THE ONUS ON US TO
10 ACTUALLY SAY WHAT DO WE THINK IS ETHICAL. THE FACT
11 THAT PEOPLE DON'T HAVE TO COMPLY WITH OUR RULES MEANS
12 THAT WE'RE NOT REALLY FORESTALLING THE ABILITY TO USE
13 THOSE EMBRYOS. THEY CAN FIND OTHER FUNDING TO DO IT
14 AND THEN GET THAT LINE REGISTERED BY THE NIH.

15 SO WHAT IT REALLY SAYS TO ME IS THAT, I THINK
16 THIS WAS BROUGHT UP VERY EARLY IN THIS DISCUSSION, THIS
17 IS AN ETHICAL DISCUSSION. IT'S NOT ABOUT
18 FUNCTIONALITY. IT'S NOT ABOUT THE SCIENCE. IT'S
19 REALLY WHAT WE BELIEVE IS APPROPRIATE FOR THAT MAN OR
20 WOMAN WHO MADE THAT DONATION, YOU KNOW, WHAT KIND OF
21 INFORMATION THEY HAD WHEN THEY MADE THAT DONATION AND
22 WHAT ABILITY THEY HAD TO MAKE A DECISION ON THE FINAL
23 DISPOSITION OF THAT MATERIAL. AND, YOU KNOW, WE CAN
24 DEBATE WHETHER GAMETES ARE SPECIAL MATERIAL
25 INDIVIDUALLY, BUT I DO THINK WE WOULD HAVE TO

BARRISTERS' REPORTING SERVICE

1 ACKNOWLEDGE THAT FOR SOME INDIVIDUALS IN OUR SOCIETY
2 GAMETES, WHETHER OVA OR SPERM, ARE ACCORDED INCREDIBLE
3 SIGNIFICANCE.

4 SO I THINK WE REALLY NEED TO THINK ABOUT
5 PURELY, WHICH IS HOW WE APPROACHED, I THINK, WHEN WE
6 FIRST MADE THIS RULE, WE REALLY LOOKED AT IT IN A
7 VACUUM AND WE ASKED OURSELVES WHAT IS ETHICAL, AND WE
8 REALLY TRIED TO LOOK AT IT FROM THE PERSPECTIVE OF THE
9 DONEES FOR GAMETES.

10 CHAIRMAN LO: LET ME TRY AND MOVE US ALONG
11 HERE. SO LET'S, AGAIN, FIRST JUST LOOK AT THE ISSUE OF
12 REQUIREMENTS FOR CIRM-FUNDED DERIVATION OF NEW HESC
13 LINES. I THOUGHT I HEARD MOST PEOPLE SAYING THAT WE
14 ARE GOING TO ALLOW EXISTING LINES ON THE NIH REGISTRY
15 TO BE USED BY CIRM RESEARCHERS IN ACCORDANCE WITH THE
16 CURRENT REGULATIONS. BUT WE WANTED -- THE QUESTION
17 WE'RE POSED IS DO WE WANT TO CLARIFY OR POSSIBLY MODIFY
18 THE REQUIREMENTS FOR CIRM-FUNDED DERIVATION OF NEW
19 EMBRYONIC STEM CELL LINES, WHICH THE NIH CANNOT FUND,
20 WILL NOT FUND.

21 AND SO I THINK THE ISSUE WE NEED TO CONSIDER
22 IS DO WE LEAVE IT AS THE THIRD-PARTY GAMETE DONORS NEED
23 TO HAVE PROVIDED VOLUNTARY INFORMED CONSENT? AND
24 APPRECIATING THAT FROM WHAT GEOFF AND OTHERS HAVE SAID
25 IT'S NOT GOING TO -- WE HAVE HAD NO EXAMPLES OF PEOPLE

BARRISTERS' REPORTING SERVICE

1 COMING TO US SAYING WE WANT TO DERIVE A NEW HESC LINE
2 FROM AN EMBRYO THAT DOESN'T MEET THIS, AND HERE'S THE
3 COMPELLING SCIENTIFIC REASON. PRESUMABLY THEY COULD DO
4 THAT, BUT WE HAVEN'T HAD THAT COME UP YET. OR WE COULD
5 MOVE THE OTHER WAY AND SAY FOR THE THIRD-PARTY GAMETE
6 DONOR, LET'S CLARIFY OR TRY AND DISPEL SOME OF THE
7 CONFUSION THAT IS OUT THERE AMONG RESEARCHERS AND
8 RESEARCH INSTITUTIONS ABOUT WHAT KIND OF PERMISSION
9 FROM THE THIRD-PARTY GAMETE DONORS IS NEEDED.

10 ONE OF THE OPTIONS ON THE TABLE IS TO SAY WE
11 DON'T MEAN INFORMED CONSENT IN THE SENSE OF GOING TO AN
12 IRB AND HAVING A SEPARATE PIECE OF PAPER, BUT WE WANT
13 DISCLOSURE, AND WE TALKED ABOUT DISCLOSURE THAT
14 RESEARCH IS ONE OF THE OPTIONS OR STEM CELL RESEARCH IS
15 ONE OF THE OPTIONS, PLUS SIGNING OVER DISPOSITIONAL
16 RIGHTS WITH THE IMPLICIT PRESUMPTION THAT THEY HAD BEEN
17 GIVEN THE OPPORTUNITY TO BE AWARE OF WHAT THEY WERE
18 SIGNING THE PAPER TO. IS THAT A FAIR, GEOFF, STATEMENT
19 OF WHERE I THINK WE ARE?

20 DR. LOMAX: YES. YOUR FINAL STATEMENT IS
21 SORT OF CONSISTENT WITH SORT OF WHERE YOU ARE, TO THE
22 EXTENT YOU'RE BEING PETITIONED BY OUR GRANTEES TO
23 CLARIFY, THEY'VE ARTICULATED A DESIRE TO UTILIZE A
24 SUBSTANTIALLY SIMILAR MECHANISM TO SUPPORT DERIVATION
25 OF STEM CELL LINES, THEY'VE INDICATED THAT'S FEASIBLE.

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1 CHAIRMAN LO: SO I'M GOING -- WE DO NEED TO
2 GET PUBLIC COMMENT AND INPUT ON THIS. AND I WOULD
3 EXPECT THERE ARE A NUMBER OF PEOPLE IN THE AUDIENCE WHO
4 REALLY HAVE IMPORTANT THINGS THEY WANT TO SAY. SO IF
5 IT'S ALL RIGHT WITH THE COMMITTEE, I'M GOING TO SORT OF
6 ASK NOW FOR PEOPLE IN THE AUDIENCE WHO WISH TO ADDRESS
7 THIS ISSUE OF CIRM-FUNDED DERIVATION OF NEW EMBRYONIC
8 STEM CELL LINES FROM EMBRYOS CREATED FROM GAMETES FROM
9 THIRD-PARTY DONORS.

10 DR. LOMAX: BERNIE, JUST TO BE PRECISE, COULD
11 WE SAY UTILIZATION OF EMBRYOS?

12 CHAIRMAN LO: UTILIZATION OF EMBRYOS.

13 DR. LOMAX: NO NEED TO NARROW THE SCOPE HERE.

14 CHAIRMAN LO: I EXPECT THERE ARE SOME PEOPLE
15 IN THE AUDIENCE WHO WANT TO COMMENT ON THIS. NO? I
16 DON'T KNOW WHAT THAT MEANS. IT MAY MEAN THEY GOT A
17 REALLY GOOD DINNER, LUNCH.

18 MS. LANSING: I THINK THAT MEANS WE'RE ALL
19 MOVING IN THE SAME DIRECTION.

20 CHAIRMAN LO: SO --

21 MR. TEMPSKE: TOM TEMPSKE. I JUST WANT TO
22 REITERATE, I THINK I MADE THE POINT EARLIER, THAT I
23 THINK THAT IN LOOKING FORWARD, THAT WE REALLY DO WANT
24 TO EMPHASIZE OPENING THE DOORS AS MUCH AS WE CAN. I
25 THINK THAT NOT PUTTING ALL THESE RESTRICTIONS THAT MAY

BARRISTERS' REPORTING SERVICE

1 THEORETICALLY BE POSSIBLE, YOU KNOW, WE STAY AWAY FROM
2 THAT. PART OF YOUR DISCUSSION WHERE, FOR INSTANCE, FOR
3 THE DOCUMENTATION, SAY YOU'RE CIRM APPROVED OR YOU'RE
4 NIH APPROVED, THERE HAVE BEEN -- I'VE SEEN IN MY OWN
5 EXPERIENCE FORGED DOCUMENTS. WE COULD KEEP GOING ON
6 AND ON ABOUT ALL THE THINGS THAT ARE THEORETICALLY
7 POSSIBLE, BUT I THINK THAT BY KEEPING THE RESTRICTIONS
8 AS MINIMAL AS WE CAN, JUST KIND OF USING A COMMON SENSE
9 APPROACH, I THINK, WOULD BE PREFERABLE. THANK YOU.

10 CHAIRMAN LO: THANK YOU. DO WE NEED TO GET
11 HIM FOR THE RECORD?

12 THE REPORTER: I HAVE IT.

13 CHAIRMAN LO: ANYONE ELSE WISHING TO COMMENT?
14 WOULD SOMEONE ON THE COMMITTEE, THEN, LIKE TO MAKE A
15 MOTION THAT WE CAN CONSIDER WITH REGARD TO THIS?

16 DR. KIESSLING: I MOVE THAT WE KEEP THE
17 LANGUAGE AS IT IS.

18 CHAIRMAN LO: SECOND.

19 DR. ROBERTS: I'LL SECOND THAT.

20 CHAIRMAN LO: OKAY. DO WE NEED TO ASCERTAIN
21 WHO IS ON THE PHONE?

22 DR. ROBERTS: MAYBE WE NEED DISCUSSION ON HOW
23 WE'RE GOING TO DEAL WITH THIS DISCLOSURE AS OPPOSED TO
24 INFORMED CONSENT.

25 MS. LANSING: KEEPING THE LANGUAGE AS IT IS

BARRISTERS' REPORTING SERVICE

1 WOULDNT INCLUDE DISCLOSURE.

2 MR. SHEEHY: IT DOES INCLUDE DISCLOSURE.
3 DISCLOSURE IS A WEAKER STANDARD THAN WHAT WE CURRENTLY
4 HAVE.

5 DR. KIESSLING: WHAT WE CURRENTLY HAVE IS A
6 SLIGHTLY HIGHER STANDARD. THEY NEED TO HAVE INFORMED
7 CONSENT.

8 MS. LANSING: SO YOU'RE MOVING, JUST SO I
9 UNDERSTAND, THAT WE NOT INCLUDE DISCLOSURE.

10 DR. KIESSLING: IT WOULD INCLUDE DISCLOSURE.

11 CHAIRMAN LO: HIGH LEVEL OF DISCLOSURE THAT
12 INFORMED CONSENT IMPLIES.

13 DR. KIESSLING: I THINK WE SHOULD KEEP OUR
14 LANGUAGE -- WE'VE TALKED ABOUT THIS A LOT. AND I THINK
15 THIS IS AN APPROPRIATE BALANCE FOR WHAT'S REALISTIC AND
16 WHAT'S NOT REALISTIC.

17 MS. LANSING: WOULD IT INCLUDE DISCLOSURE?

18 CHAIRMAN LO: YES. IN FACT, MORE THAN JUST
19 SAYING RESEARCH IS ONE OF THE THINGS YOU COULD DO.
20 PRESUMABLY YOU WOULD SAY EVEN MORE THAN THAT ABOUT WHAT
21 KINDS OF RESEARCH, WHAT'S THE RISK AND BENEFITS.

22 MS. LANSING: I'M CONFUSED. I'M SORRY.

23 DR. ROBERTS: I DO HAVE A QUESTION THEN
24 BECAUSE IF WHAT WE'RE DOING IS SAYING WE'LL KEEP THE
25 LANGUAGE THE WAY IT IS, BUT THAT MEANS JUST DISCLOSURE,

BARRISTERS' REPORTING SERVICE

1 THEN THAT WILL APPLY TO EVERY SITUATION WHERE THERE ARE
2 DONORS OF HUMAN GAMETES, NOT JUST IN THE REPRODUCTIVE
3 CONTEXT. SO IF WE'RE GOING TO DO THAT, THEN I THINK WE
4 DO NEED TO SAY SOMETHING ABOUT THE CONTEXT WHERE
5 DISCLOSURE ALONE IS SUFFICIENT. BECAUSE IF YOU HAVE
6 DONORS, IF YOU HAVE DONORS, EGG DONORS, WHO ARE
7 DONATING NOT FOR PAYMENT, BUT DONATING THEIR EGGS FOR
8 STEM CELL RESEARCH, DON'T YOU NEED INFORMED CONSENT,
9 NOT JUST DISCLOSURE? SO WE DON'T WANT TO BE HEARD
10 TODAY SAYING THAT THIS LANGUAGE MEANS FOR EVERY CASE OF
11 DONATION OF HUMAN GAMETES THAT VOLUNTARY AND INFORMED
12 CONSENT MEANS JUST DISCLOSURE BECAUSE THAT DOES AWAY
13 WITH INFORMED CONSENT FOR ALL THESE OTHER AREAS.

14 CHAIRMAN LO: YOU'RE ABSOLUTELY RIGHT. THE
15 ALTERNATIVE PROPOSAL TO ANN'S SUGGESTION WOULD BE TO
16 SAY, AND YOU'RE ABSOLUTELY RIGHT, DOROTHY, IN THE
17 SPECIFIC CIRCUMSTANCE OF A GAMETE DONOR DONATING
18 EMBRYOS FOR REPRODUCTIVE PURPOSES IN ART AND THE EMBRYO
19 SUBSEQUENTLY IS NOT NEEDED FOR ART AND THE EMBRYO --
20 THE WOMAN IN ART DECIDED TO DONATE FOR RESEARCH, WHAT
21 WE WOULD REQUIRE, RATHER THAN FULL INFORMED, DETAILED
22 CONSENT, IS AUTHORIZATION OF DISPOSITIONAL RIGHTS TO
23 THE WOMAN, COUPLE IN IVF TREATMENT PLUS SOME EVIDENCE
24 THAT THEY WERE TOLD OR NOTIFIED OR DISCLOSED THAT
25 RESEARCH WAS ONE OF THE OPTIONS THAT THE IVF PATIENT

BARRISTERS' REPORTING SERVICE

1 COULD CHOOSE WITH LEFTOVER EMBRYOS.

2 SO YOU'RE RIGHT. IT'S THE NARROW SITUATION.

3 DR. ROBERTS: IT'S AN INTERPRETATION OF
4 INFORMED -- THAT'S WHY I AGREE WITH ANN THAT WE COULD
5 KEEP THIS LANGUAGE, BUT WE NEED SOME KIND OF
6 INTERPRETATION OF IT JUST IN THE CASE OF EMBRYOS
7 CREATED IN IVF.

8 DR. KIESSLING: I DON'T AGREE WITH THAT. I
9 REALLY THINK THAT THERE SHOULD BE INFORMED CONSENT. I
10 THINK THE GAMETE DONORS SHOULD HAVE INFORMED CONSENT.
11 THE DISCLOSURE IS A CONVERSATION I HAVEN'T ENTERED
12 INTO. I REALLY THINK THE WAY IT STANDS NOW IS THE WAY
13 IT SHOULD BE. I DON'T THINK THERE SHOULD BE ANY
14 DISTINCTION BETWEEN DONATING SPERM FOR STEM CELL
15 RESEARCH, DONATING SKIN BIOPSY FOR STEM CELL RESEARCH,
16 OR DONATING EMBRYOS FOR STEM CELL RESEARCH. I THINK IT
17 SHOULD BE ALL THE SAME.

18 AND IF THERE'S A SPECIFIC CASE IN WHICH
19 SOMETHING SEEMS REALLY UNUSUAL AND INCREDIBLY VALUABLE,
20 THAT CAN BE CONSIDERED. BUT I THINK THAT THE INFORMED
21 CONSENT PROCESS SHOULD APPLY TO EVERYTHING THAT WE'RE
22 DOING.

23 DR. ROBERTS: I THINK WE NEED TO BE VERY
24 CLEAR THAT IF WE VOTE TO KEEP THIS, THAT IT DOESN'T
25 INCLUDE ALL THIS DISCUSSION WE HAD ABOUT DISCLOSURE. I

BARRISTERS' REPORTING SERVICE

1 DON'T THINK THAT EVERYONE IS CLEAR ABOUT THIS.

2 MS. LANSING: THAT'S WHY I ASKED THE
3 QUESTION. SO THAT'S WHY I ASKED IT, AND YOU SAID IT
4 DOES INCLUDE DISCLOSURE, BUT I DON'T THINK IT DOES.

5 MR. SHEEHY: IT DOES INCLUDE. DISCLOSURE IS
6 A WEAKER STANDARD. AND THE QUESTION BEFORE US IS
7 WHETHER WE KEEP THE LANGUAGE WE HAVE, WHICH IS A TERM
8 OF ART. INFORMED CONSENT, I THINK, IS A TERM OF ART
9 WITHIN THE ETHICAL COMMUNITY. YOU KNOW WHAT IT MEANS.
10 AND THEY'RE ASKING US TO BRING THAT DOWN TO A LOWER
11 STANDARD, WHICH IS DISCLOSURE.

12 WE HAVE A MOTION ON THE FLOOR, WHICH I
13 SUPPORT AND YOU HAVE SECONDED, TO STAY WITH OUR
14 LANGUAGE, WHICH HAS INFORMED -- WHICH IS INFORMED
15 CONSENT, A HIGHER STANDARD. AND I WOULD JUST ADD IF
16 THIS WAS SUCH A COMPELLING CASE, SO IMPORTANT, WE WOULD
17 HAVE AN ENORMOUS AMOUNT OF PUBLIC TESTIMONY TELLING US
18 TO CHANGE IT. I HAVE HEARD SEVERAL TIMES PEOPLE COME
19 AND SAY THAT WE CREATED A LOT OF PROBLEMS ON THE DONOR
20 COMPENSATION ISSUE. SO THAT SEEMED TO ME TO BE A LIVE
21 ISSUE. WE GOT SOME PUBLIC COMMENTS THAT SAID WE DON'T
22 KNOW WHAT INFORMED CONSENT MEANS, WHICH I THINK IS KIND
23 OF A STRAW MAN BECAUSE I DO THINK WE KNOW WHAT INFORMED
24 CONSENT MEANS. AND THEY'VE ASKED US TO GO TO A LOWER
25 STANDARD.

BARRISTERS' REPORTING SERVICE

1 I'M NOT PREPARED TO GO TO A LOWER STANDARD.
2 I THINK WE'VE DONE FINE UP TO THIS POINT WITH THIS HIGH
3 STANDARD OF INFORMED CONSENT. I THINK PEOPLE KNOW WHAT
4 IT MEANS. I THINK WE SHOULD STAY THERE.

5 DR. LOMAX: CAN I JUST CLARIFY THOUGH. YOU
6 DID AT THE JULY MEETING ACTUALLY HAVE A DISCUSSION
7 ABOUT THIS, AND THE ACTUAL CONFUSION THAT WAS TAKEN
8 FROM THAT MEETING, THE UNDERSTANDING WAS THAT A CERTAIN
9 SORT OF CHECKOFF WAS SUFFICIENT AT A SORT OF PRIOR
10 POINT IN TIME. AND THE POINT IN TIME, IT APPEARS FROM
11 THE RECORD, WAS PRIOR TO THE PROMULGATION OF THESE
12 REGULATIONS. THE QUESTION WAS THEN IS THAT ACCEPTABLE
13 MOVING FORWARD?

14 SO IF WHAT YOU'RE SAYING NOW IS IT WOULD
15 ACTUALLY -- YOU'RE NOW SUGGESTING THAT IT WOULD
16 ACTUALLY BE ERASING THAT SORT OF PRIOR CONVERSATION.
17 AGAIN, THIS IS JUST WHAT WAS DISCUSSED.

18 MS. LANSING: IN OTHER WORDS, I THOUGHT THE
19 QUESTION WAS, AND MAYBE I'M COMPLETELY LOST, I THOUGHT
20 THE QUESTION THAT WE WERE SUPPOSED TO DECIDE TODAY WAS
21 IS DISCLOSURE IN ALL ITS MANY FORMS, SOMETIMES IN SOME
22 AGENCIES THEY HAND YOU 20 PAGES AND I'M SURE THEY DON'T
23 TELL YOU ANYTHING, AND SOMETIMES THEY GO THROUGH IT
24 STEP BY STEP BY STEP, BUT THAT IT ISN'T OUR
25 RESPONSIBILITY TO MONITOR IT. IS DISCLOSURE PART OF

BARRISTERS' REPORTING SERVICE

1 INFORMED CONSENT, OR DO YOU HAVE TO CHECK A BOX THAT
2 SAYS FOR RESEARCH, OR DO YOU HAVE TO CHECK A BOX THAT
3 SAYS FOR STEM CELL RESEARCH? RIGHT? ISN'T THAT THE
4 QUESTION?

5 CHAIRMAN LO: LET ME TRY AND CLARIFY AND SEE
6 IF I GET THIS RIGHT. SO THERE ARE TWO THINGS YOU NEED.
7 FIRST OF ALL, YOU NEED AUTHORIZATION OR PERMISSION OR
8 SOMETHING WHERE SOMEONE SAYS YOU CAN DO WHAT YOU WANT.

9 MS. LANSING: YES.

10 CHAIRMAN LO: WHAT WE'RE SAYING IS THAT'S
11 OKAY IF COUPLED WITH PROVIDING INFORMATION WHERE YOU
12 SAY THAT ONE OF THE THINGS THAT COULD BE DONE IS
13 RESEARCH. NOW, SOME PEOPLE THINK INFORMED CONSENT IS
14 ACTUALLY A LOT MORE, THAT YOU STILL HAVE TO GET
15 PERMISSION, AUTHORIZATION, BUT IT'S A DIFFERENT PROCESS
16 WHERE IT MAY BE A SEPARATE PIECE OF PAPER. YOU MAY
17 HAVE TO GET SOMEONE, AN IRB OR SOMEONE, TO REVIEW THAT.
18 BUT THE LEVEL OF DISCLOSURE IN INFORMED CONSENT IS MUCH
19 MORE DETAILED THAN SAYING, OH, RESEARCH IS ONE OF THE
20 THINGS THEY COULD DO.

21 GENERALLY IT'S THOUGHT THAT IN AN INFORMED
22 CONSENT DISCUSSION, YOU HAVE TO GIVE ALL THE OTHER
23 OPTIONS AND TALK ABOUT THE PROS AND CONS OF EACH
24 OPTION. SO IT'S MUCH MORE THAN SORT OF JUST HANDING
25 SOMEONE AN INFORMATION SHEET THAT SAYS AFTER YOU ARE

BARRISTERS' REPORTING SERVICE

1 DONE WITH YOUR DONATION, THE EMBRYOS ARE MADE AND IT
2 MAY BE THEY'RE NOT NEEDED FOR THIS COUPLE OR THIS
3 WOMAN'S IVF TREATMENT. HERE'S SOME THINGS THAT MIGHT
4 BE DONE, DESTRUCTION AND DISCARDED, DONATION TO ANOTHER
5 COUPLE, WHAT THAT INVOLVES, PROS AND CONS. IF THIS
6 HAPPENS, YOU MAY FEEL REGRET. INFORMED CONSENT
7 TYPICALLY GOES THROUGH ALL THE OPTIONS AND THE PROS AND
8 CONS. SO THAT'S --

9 MS. LANSING: DISCLOSURE --

10 CHAIRMAN LO: DISCLOSURE, I THINK, CAN BE, AS
11 YOU SAID --

12 MS. LANSING: IT'S IN THERE SOMEWHERE. AND I
13 THINK DISCLOSURE IS ENOUGH. SO I WOULD THEN BE NOT --
14 IT'S A DIFFERENT THING THAN WHAT YOU'RE SAYING.

15 DR. KIESSLING: SHERRY, I THINK THAT WE'VE
16 TALKED ABOUT THIS A LOT, AND I THINK THAT THE INDUSTRY
17 IS GOING TO BE BETTER OFF IF WE MAINTAIN THE LANGUAGE
18 WE HAVE. I THINK THE WHOLE AREA OF RESEARCH IS GOING
19 TO BE BETTER. IF THERE IS A SPECIAL CASE IN WHICH
20 SOMETHING NEEDS TO BE DONE AND THESE RULES ARE TOO
21 STRINGENT, WE CAN CONSIDER THAT, AS HAS BEEN DONE
22 ALREADY. RIGHT? THERE'S AN EXAMPLE OF THAT.

23 DR. LOMAX: WE SHOULD BE CAREFUL. WE ARE
24 CROSSING OUR EXAMPLES. AND I JUST WANT TO CLARIFY
25 HERE. AGAIN, THIS IS THE USE OF EMBRYOS, AND, AGAIN,

BARRISTERS' REPORTING SERVICE

1 SPEAKING FOR SORT OF THE PETITIONER, WHAT THEY'RE
2 SAYING IS THERE'S JUST A SET OF EMBRYOS. IF DISCLOSURE
3 IS NOT GOOD ENOUGH, WE'RE NOT GOING TO CONSIDER THEM IN
4 CIRM-FUNDED RESEARCH. THE EXEMPTION WAS FOR A DERIVED
5 STEM CELL LINE. AGAIN, WE HAVE TO BE CAREFUL.

6 DR. KIESSLING: IF IT TURNS OUT THAT THERE'S
7 SOME SPECIFIC EMBRYOS WHO WOULD BE SPECIFICALLY
8 VALUABLE TO DERIVE STEM CELL LINES FROM AND THIS CAN'T
9 BE FOLLOWED EXACTLY, THAT COULD BE CONSIDERED.

10 DR. LOMAX: WE DO NOT HAVE A PROCESS FOR
11 THAT. WE HAVE TO BE CLEAR. WE ONLY HAVE A PROCESS FOR
12 EMBRYONIC STEM CELL LINES. THOSE EMBRYOS WILL NOT BE
13 CONSIDERED. THEY PROBABLY WOULDN'T BRING THE PETITION.

14 DR. KIESSLING: WELL, I THINK IF IT WERE A
15 COMPELLING ENOUGH CASE, AN ESCRO COMMITTEE WOULD GET A
16 PETITION.

17 DR. LOMAX: WE DON'T HAVE A PROCESS.

18 CHAIRMAN LO: THERE'S NO PROVISION IN OUR
19 REGULATIONS TO ALLOW A PETITION TO USE AN EMBRYO THAT
20 DOESN'T MEET OUR STANDARDS AS OPPOSED TO USING A STEM
21 CELL LINE THAT DOESN'T MEET OUR REQUIREMENTS.

22 DR. KIESSLING: MAYBE THAT'S SOMETHING THAT
23 WE COULD ADD.

24 MR. SHEEHY: AGAIN, I JUST AM NOT SEEING THE
25 NECESSITY OF THIS. IT JUST COMES -- IT SEEMS TO ME

BARRISTERS' REPORTING SERVICE

1 THAT THE QUESTION IS WE HAVE THESE EMBRYOS, WE WANT TO
2 BE ABLE TO USE THEM, BUT WE DON'T NECESSARILY HAVE TO
3 USE THESE PARTICULAR ONES. AND THE FACT THAT THEY HAVE
4 LESS WELL-DEVELOPED PROVENANCE DOESN'T MAKE THEM MORE
5 ATTRACTIVE TO ME PERSONALLY. I WOULD -- I STILL THINK
6 THAT THIS IS FUNDAMENTALLY AN ETHICAL QUESTION. WE
7 KEEP GETTING INTO THE UTILITY QUESTION, AND I DON'T
8 THINK THE UTILITY QUESTION IS ON THE TABLE BECAUSE WE
9 DON'T HAVE ANY CONCRETE EXAMPLES OF EMBRYOS THAT ARE
10 NOT BEING USED, RESEARCH THAT'S NOT BEING DONE BECAUSE
11 OF THIS RULE.

12 WE'VE HAD A NEW CELL LINE RFA. PEOPLE DERIVE
13 NEW LINES WITHIN THE CONTEXT OF THE RFA. WE GOT AT
14 LEAST THREE AND A HALF YEARS OF ACTUALLY FUNDING
15 RESEARCH. AND SO NO ONE HAS COMPLAINED ABOUT THIS
16 STANDARD OTHER THAN RIGHT NOW. WHAT THEY WANT TO DO IS
17 LOWER THE STANDARD.

18 AND THEN I WOULD COME BACK TO WHAT WE DID
19 EARLIER ON DONOR COMPENSATION, AND ACTUALLY THOSE ARE
20 PROBABLY THE EMBRYOS THAT PEOPLE REALLY WANT THEIR
21 HANDS ON THAT ARE NEWER, HAVE BETTER PROVENANCE. AND
22 SO I DON'T SEE THAT THE UTILITY QUESTION IS EVEN ON THE
23 TABLE. THIS IS REALLY AN ETHICAL QUESTION. I BELIEVE
24 THAT, FROM WHAT WE'VE HEARD, THE 25 PERCENT OF PEOPLE
25 WHO, WHEN THEY HEARD IT WAS STEM CELL RESEARCH, THAT

BARRISTERS' REPORTING SERVICE

1 GAVE THEM PAUSE, YOU KNOW, THE EXAMPLE OF THE STUDY YOU
2 CITED. AND THEN YOUR POINT, DR. ROBERTS' POINT, THAT
3 BECAUSE PEOPLE MIGHT NOT LIKE SOMETHING IS THE REASON
4 TO ADHERE TO A STRICTER STANDARD, NOT TO RELAX IT.

5 I THINK I TOTALLY SUPPORT THIS MOTION. I
6 THINK WE SHOULD STAY WHERE WE ARE, AND I THINK WE'RE
7 FINE.

8 DR. LOMAX: YOU DO POINT OUT A CRITICAL
9 INTERACTION THERE. YOU HAVE TO BE VERY AWARE OF THIS.
10 BECAUSE WE HAD THE PROHIBITION ON THE UTILIZATION OF
11 DONOR COMPENSATION, THERE WAS SORT OF TWO ROADBLOCKS.
12 WHAT WE'RE TALKING ABOUT ARE EMBRYOS FOR WHICH THERE
13 HAS BEEN A THIRD-PARTY DONOR, WHICH MEANS THERE'S BEEN
14 COMPENSATION, AND THERE'S BEEN DISCLOSURE, NOT FULLY
15 INFORMED CONSENT. BECAUSE WE ALWAYS HAD THE BARRIER OF
16 PAYMENT, IT WAS SORT OF A NONISSUE BECAUSE THEY WERE
17 OFF THE TABLE ANYWAY.

18 SO, AGAIN, THE GENESIS OF THIS WAS, WELL,
19 WE'RE PLEASED IF YOU ARE GOING TO RECONSIDER PAYMENT.
20 IT WASN'T. IT WAS, OKAY, WE'RE PLEASED THAT YOU
21 ALLOWED THE PRE-2008 -- YOU'RE ALLOWING SOME OF THESE
22 MATERIALS IN, BUT NOW THAT YOU'RE ALLOWING THEM IN, CAN
23 YOU PLEASE DESCRIBE FOR US WHAT DOES CONSENT MEAN.

24 NOW THAT WE'VE SORT OF ACCEPTED THE USE OF
25 THE EMBRYOS WITH THE PAID GAMETES, THIS QUESTION

BARRISTERS' REPORTING SERVICE

1 BECOMES EVEN MORE GERMANE BECAUSE THE QUESTION IS STILL
2 THERE, AND THE CONDITIONS ARE THE ONES WHERE YOU HAVE
3 THE PAID EGGS IN THE EMBRYO. SO THIS IS WHY THIS
4 PROBLEM BECOMES MORE ACUTE.

5 MR. SHEEHY: I SEE, BUT THAT DOESN'T CHANGE
6 THE FUNDAMENTAL ETHICAL QUESTION, WHICH IS WHAT IF WE
7 WANT TO ASSUME --

8 DR. LOMAX: I'M JUST TRYING TO ADDRESS WHAT
9 CHANGES.

10 MR. SHEEHY: I UNDERSTAND THAT, BUT WE STILL
11 HAVE TO SOMEHOW MAKE SOME ESTIMATION OURSELVES ABOUT
12 WHAT WE THINK IS APPROPRIATE FOR THOSE GAMETE DONORS,
13 AND WHETHER WE THINK THAT WE CAN GO TO THIS LOWER
14 STANDARD AND THAT SOMEHOW THAT WILL ENSURE THAT ALL OF
15 THOSE GAMETE DONORS ACTUALLY TRULY DID CONSENT IN SOME
16 WAY TO HAVING THESE MATERIALS USED FOR STEM CELL
17 RESEARCH.

18 DR. LOMAX: I WAS TRYING TO ADDRESS THE
19 SCIENTIFIC SIDE OF IT THERE.

20 MS. LANSING: BUT YOU'LL NEVER BE ABLE TO
21 TRACE THE THIRD-PARTY ONES. WE'RE TALKING ABOUT THE
22 THIRD PARTY, RIGHT? I DO UNDERSTAND INFORMED CONSENT
23 WITH THE REPRODUCTIVE PARTNERS. WHAT WE'RE TALKING
24 ABOUT IS THE THIRD-PARTY ONES THAT YOU CAN NEVER TRACE
25 BACK. WE'LL NEVER BE ABLE TO FIND THEM, AND I DON'T

BARRISTERS' REPORTING SERVICE

1 UNDERSTAND -- I'M ASSUMING THEY SIGNED A PIECE OF PAPER
2 THAT GAVE AWAY EITHER ALL THEIR RIGHTS OR AGREED TO
3 RESEARCH AS WELL AS THE USE FOR REPRODUCTION.

4 MR. SHEEHY: YOU WOULD BE COMFORTABLE WITH
5 YOUR DNA WHEN YOU HAD A PROFOUND MORAL --

6 MS. LANSING: A SIGNED PIECE OF PAPER.

7 MR. SHEEHY: A PROFOUND MORAL OBJECTION TO
8 STEM CELL RESEARCH, YOU WOULD BE COMFORTABLE.

9 MS. LANSING: IF I HAD A PROFOUND MORAL
10 OBJECTION TO STEM CELL RESEARCH, I WOULD HAVE PUT IN
11 THE PIECE OF PAPER EXCEPT FOR STEM CELL RESEARCH.

12 MR. SHEEHY: I DON'T THINK THAT'S WHAT PEOPLE
13 WENT IN THERE TO DO. THEY WENT IN THERE TO HELP A
14 WOMAN CONCEIVE. AND THEY SIGNED A PIECE OF PAPER.
15 YOU'RE TALKING ABOUT INSTANCES AND WHY THIS IS
16 RELEVANT, INSTANCES WHERE THE PAPER DID NOT SAY STEM
17 CELL RESEARCH.

18 MS. LANSING: BUT IT SAID RESEARCH.

19 MR. SHEEHY: IT SAID RESEARCH. AND SO YOU
20 THINK IT'S OKAY THAT WHERE WE KNOW THAT PEOPLE HAVE
21 PROFOUND --

22 MS. LANSING: ARE ALL RIGHT.

23 MR. SHEEHY: -- MORAL OBJECTIONS TO STEM CELL
24 RESEARCH, THAT WE JUST SAY, YOU KNOW, THAT'S OKAY.

25 MS. LANSING: I THINK THEY SIGNED AWAY THEIR

BARRISTERS' REPORTING SERVICE

1 RIGHTS.

2 CHAIRMAN LO: BY THE WAY, THIS MAY BE AN
3 ISSUE --

4 MR. SHEEHY: I THINK IT'S A PHILOSOPHICAL AND
5 ETHICAL QUESTION. THIS IS THE LEVEL WE SHOULD BE
6 DISCUSSING IT.

7 MS. LANSING: I THINK THEY SIGNED AWAY THEIR
8 RIGHTS.

9 CHAIRMAN LO: THIS MAY BE AN ISSUE WHERE AT
10 THE END OF THE DAY, WE DON'T COME TO UNANIMITY. I
11 WOULD LIKE TO TRY AND MOVE THIS ALONG BECAUSE WE'VE
12 TALKED ABOUT IT A LOT. I THINK THERE MAY WELL BE
13 DIFFERENT POSITIONS ON THIS COMMITTEE. ALTA, YOU HAD
14 SOMETHING TO SAY, AND THEN I DO WANT TO TRY AND MOVE
15 ON.

16 MS. CHARO: IN THE VEIN OF TRYING TO MOVE
17 TOWARD BEING ABLE TO VOTE ON THE MOTION, WHICH IS STILL
18 ON THE TABLE, WHICH WAS THE MOTION TO LEAVE THE
19 LANGUAGE AS IT IS, JUST A COUPLE OF THOUGHTS.

20 FIRST, I DO THINK THAT UTILITY HAS TO BE PART
21 OF THE CALCULATION BECAUSE, FOR ONE THING, THE REASON
22 WE'RE ALLOWING IN THE USE OF LINES FROM NIH, I THINK,
23 IS LARGELY BECAUSE OF UTILITY. WE DON'T WANT TO GO
24 WITHOUT ALL OF THEM. IN OTHER CONTEXTS, WE'VE
25 UNDERSTOOD THAT UTILITY IS AN ISSUE LURKING IN THE

BARRISTERS' REPORTING SERVICE

1 BACKGROUND.

2 BUT I APPRECIATE YOUR POINT THAT, BY AND
3 LARGE, IT'S REALLY AT THE END OF THE DAY ABOUT RESPECT,
4 AND DOROTHY'S POINT ABOUT EACH ONE OF US ASKING WHAT DO
5 YOU THINK IT IS THAT IS SUFFICIENT TO GIVE SOMEBODY THE
6 SIGNAL THAT THEY NEED IN ORDER TO BE ABLE TO SAY, OH, I
7 NEED TO THINK ABOUT THIS, I NEED TO DISCUSS THIS, I
8 NEED TO OBJECT TO THIS; IN OTHER WORDS, WHAT IS IT THAT
9 YOU NEED TO GIVE TO PEOPLE SO THAT THEY ACTUALLY ARE
10 AWARE THAT THERE'S A CHOICE TO BE MADE? AND CLEARLY
11 FOR SOME PEOPLE THEY'RE GOING TO SAY, YOU KNOW, UNLESS
12 THERE'S A REALLY STRONG, VERY DIRECT SIGNAL, LIKE IT
13 SAYS, STEM CELL RESEARCH, MOST FOLKS ARE LIKELY TO NOT
14 NOTICE AND NOT REALIZE; AND IF THEY HAD REALIZED, THEY
15 MIGHT HAVE DONE SOMETHING DIFFERENT.

16 I THINK, SHERRY, YOU PROBABLY READ EVERYTHING
17 THAT YOU SIGN. AND SO FOR YOU, IF IT JUST SIGNALS THAT
18 THERE'S ANY USE OTHER THAN REPRODUCTION, IT'S ENOUGH TO
19 TRIGGER, OH, WELL, WHAT IS THAT? DO I LIKE THOSE? DO
20 I NOT? PEOPLE ARE GOING TO VARY. THAT, I THINK, IS
21 PART OF WHAT WE'RE VOTING ON IS OUR INSTINCTS ABOUT
22 PEOPLE. IT CAN'T BE A HUNDRED PERCENT, BUT YOU WANT IT
23 TO BE LARGELY.

24 ALSO, THOUGH, I WANTED TO SAY ONE LAST THING,
25 AND THAT IS THAT ON THIS QUESTION OF HOW THESE TERMS

BARRISTERS' REPORTING SERVICE

1 ARE UNDERSTOOD, EVEN IF THERE'S SOME ADVANTAGE TO
2 DISCLOSURE IN YOUR MIND BECAUSE IT ALLOWS FOR MORE
3 UTILITY, IN THEORY, MORE LINES THAT CAN BE USED OUT OF
4 THE EMBRYOS THAT ARE OUT THERE, IT HAS A DISADVANTAGE,
5 WHICH IS THAT THE WORD "DISCLOSURE" IS NOT A FAMILIAR
6 ONE. AND EVERY COMMITTEE IS GOING TO HAVE TO FIGURE
7 OUT WHAT IT MEANS TO THEM. INFORMED CONSENT, FOR ALL
8 THAT IT'S A PAIN IN THE NECK, IS, IN FACT, AS, I THINK
9 JEFF SAID, A TERM OF ART. AND PEOPLE REALLY DO HAVE A
10 LOT OF EXPERIENCE APPLYING IT, PARTICULARLY IN THE
11 HUMAN SUBJECTS CONTEXT. SOME OF THOSE ELEMENTS OF
12 CONSENT DON'T APPLY HERE, LIKE YOUR CLINICAL CARE WON'T
13 BE AFFECTED, BUT A LOT OF THE OTHER ONES DO. BERNIE
14 RAN THROUGH SOME OF THEM.

15 SO EVEN THOUGH IT'S A STRICTER STANDARD AND
16 IT WILL CUT OUT MORE EMBRYOS THAT WILL BE MADE
17 INELIGIBLE FOR USE IN DERIVATIONS BY CIRM GRANTEES, IT
18 MAY NOT NECESSARILY BE LESS EFFICIENT TO RETAIN THE
19 CURRENT LANGUAGE BECAUSE PEOPLE ON THE VARIOUS
20 COMMITTEES WILL PROBABLY BE ABLE TO INTERPRET IT MORE
21 QUICKLY AND MORE CONFIDENTLY. JUST, ONCE AGAIN, TRYING
22 TO SET THINGS UP FOR OUR DECISION.

23 MS. LANSING: THE NIH LINES, EVEN IF THEY
24 SAY --

25 MS. CHARO: THAT'S UNAFFECTED. THAT'S WHY I

BARRISTERS' REPORTING SERVICE

1 THINK EVERYBODY'S NOTION HERE ABOUT PRINCIPLES THAT
2 THEY'RE STANDING ON HAS YIELDED TO SOME DEGREE OF
3 UTILITY.

4 MS. LANSING: YES. THAT'S WHAT I'M SAYING.

5 MR. SHEEHY: I DISAGREE WITH THE NIH BEING A
6 QUESTION OF UTILITY. THIS IS A QUESTION OF REGULATORY
7 OVERREACH. SO WE DEFER TO OTHER REGULATORY AGENCIES
8 NOT BEING OMNIPOTENT, THAT INCLUDING THE FEDERAL
9 GOVERNMENT, THE FEDERAL GOVERNMENT OF THE UK, THE
10 FEDERAL GOVERNMENT OF CANADA, AND THE FEDERAL
11 GOVERNMENT IN JAPAN. WE CANNOT REGULATE THOSE FOLKS,
12 YET WE HAVE TO RECOGNIZE THAT THERE'S STRONG ETHICAL
13 PRINCIPLES UNDERLYING THOSE GOVERNMENTS AND THOSE
14 NATIONS. SO THAT WAS THE PRINCIPLE UNDER WHICH WE'VE
15 ALLOWED THOSE REGULATORY REGIMES TO BE ACCEPTABLE FOR
16 USE BY US, NOT UNDER ANY UTILITY ARGUMENT, BUT VERY
17 SIMPLY BECAUSE THE ROBUSTNESS OF THOSE PARTICULAR
18 POLITICAL CULTURES AND POLITICAL ARRANGEMENTS, SO IT'S
19 NOT A UTILITY QUESTION TO ME. IT'S REALLY A REGULATORY
20 ISSUE. DO WE TRUST THOSE REGULATORS, DO WE TRUST THOSE
21 NATIONS TO PUT IN PLACE STRONG SAFEGUARDS FOR THIS TYPE
22 OF RESEARCH WITHOUT HAVING TO MAKE INDEPENDENT
23 JUDGMENTS ON EVERY ASPECT OF THE REGULATORY REGIMES
24 THEY PUT IN PLACE?

25 MS. LANSING: JEFF, THEY HAVEN'T RULED ON

BARRISTERS' REPORTING SERVICE

1 THIS YET IS WHAT I'M HEARING, RIGHT?

2 MS. CHARO: WHO? NIH IS NOT GOING TO INSIST
3 ON CONSENT OF ANY SORT OR DISCLOSURE OF ANY SORT.

4 CHAIRMAN LO: FROM THIRD-PARTY GAMETE DONORS.

5 MS. CHARO: FROM THIRD-PARTY GAMETE DONORS.

6 MS. LANSING: SO THEN BUT THEY WILL FROM THE
7 OTHERS. SO, THEREFORE, WHAT I GUESS I'M SAYING IS WHEN
8 WE GET TO THE MORAL IMPERATIVE OF IT, THEN TECHNICALLY,
9 AND I DON'T ADVOCATE THIS, IF WE WERE MORALLY REALLY
10 CONSISTENT AND GREAT INTEGRITY, WE WOULDN'T TAKE THOSE
11 LINES EITHER. I HATE TO SAY THAT. I DON'T WANT THAT.
12 I THINK THAT WOULD BE RIDICULOUS.

13 MS. CHARO: IT'S JUST A WAY OF MAKING SURE
14 THAT NONE OF US FEEL LIKE WE CAN BE TOTALLY PURE HERE
15 TO SOME OPTIMAL NOTION.

16 MS. LANSING: WE ARE TAKING LINES -- THE
17 QUESTION THAT YOU ASKED ABOUT THE DNA, THE QUESTION
18 THAT YOU ASKED ME ABOUT THE DNA, THE NIH WILL BE FILLED
19 WITH THOSE LINES THAT WE TAKE WHERE PEOPLE HAD NO IDEA
20 WHERE THEIR DNA --

21 MR. SHEEHY: AGAIN, WE DON'T LIVE IN A WORLD
22 OF MORAL ABSOLUTES. WE'RE NOT BEING ASKED TO MAKE
23 GREATER JUDGMENTS. WE ARE BEING ASKED ONLY TO ANSWER
24 THE QUESTION THAT WE CAN ANSWER.

25 CHAIRMAN LO: I THINK THIS IS SOMETHING WE'RE

BARRISTERS' REPORTING SERVICE

1 NOT GOING TO HAVE A UNANIMOUS VOTE. I THINK IT WOULD
2 BE USEFUL, AND THIS IS NOT A BINDING VOTE, THIS IS A
3 SENSE OF THE COMMITTEE BECAUSE WE DON'T HAVE A QUORUM.
4 IT WILL GO TO THE ICOC WHERE JEFF AND SHERRY SIT AND
5 FRANCISCO. IT WOULD BE USEFUL, I THINK, TO GET A SENSE
6 OF THIS COMMITTEE. SO WE HAVE A MOTION MADE AND
7 SECONDED, ANN'S MOTION, THAT WE LEAVE THE LANGUAGE AS
8 IS. SO NO CHANGE. WE'VE THOUGHT ABOUT IT AND WE'VE
9 DECIDED WE LIKE IT THE WAY IT IS. SO IT'S A SIMPLE
10 MOTION. GEOFF, CALL THE ROLL.

11 DR. LOMAX: BERNIE, WE SHOULD ASK ONE
12 QUESTION OF COUNSEL. IS THERE ANYTHING -- WE'VE SAID
13 WE'RE LEAVING IT, BUT WE'VE ALSO DISCUSSED THAT, ONE
14 COMMENT WAS MADE WAS THAT THERE'S SOME KIND OF
15 DISCRETIONARY ELEMENT IN THE EXISTING LANGUAGE THAT IS
16 INTERPRETED -- THAT SOMEONE HAS TO INTERPRET WHAT
17 CONSENT MEANS. MY QUESTION IS WAS THERE ANYTHING IN
18 THIS DISCUSSION THAT IN A WAY SORT OF CHANGED THAT
19 STANDARD BECAUSE THERE WAS IN THIS DISCUSSION SOME
20 REFERENCE TO WHAT THAT STANDARD SHOULD BE. SO I'M A
21 LITTLE BIT CONFUSED ON HOW TO PROCEED.

22 DR. TAYLOR: I DON'T THINK SO. I THOUGHT
23 THERE WAS MORE AMBIGUITY IN DISCLOSURE THAN THERE WAS
24 IN CONSENT.

25 DR. LOMAX: WHEN WE SAY REQUIRING INFORMED

BARRISTERS' REPORTING SERVICE

1 CONSENT, WE DON'T HAVE A PRESCRIPTIVE CONSENT STANDARD
2 OTHER THAN WHAT'S IN WHAT WE REQUIRE OF OUR GRANTEES.

3 CHAIRMAN LO: NO. I THINK WHAT THE PLAIN
4 LANGUAGE TO ME SAYS, WE DEFER TO THE INDIVIDUAL SCRO TO
5 DECIDE WHAT INFORMED CONSENT WAS, AND WE RESPECT THEIR
6 DECISION.

7 DR. LOMAX: OKAY. THAT'S WHAT I NEEDED. I
8 JUST WANTED TO UNDERSTAND CLEARLY, SO WE HAVEN'T --

9 CHAIRMAN LO: MAKE SURE ELONA AGREES WITH US.

10 MS. BAUM: I WOULD JUST SAY THAT INFORMED
11 CONSENT IS A TERM OF ART THAT ALL OF INDUSTRY
12 UNDERSTAND, AND I DON'T THINK THAT THE CONVERSATION HAS
13 CHANGED THAT.

14 DR. LOMAX: OKAY.

15 CHAIRMAN LO: CALL THE ROLL AND LET'S SEE
16 WHERE WE STAND.

17 DR. LOMAX: FRANCISCO PRIETO.

18 DR. PRIETO: AYE.

19 DR. LOMAX: ANN KIESSLING.

20 DR. KIESSLING: YES.

21 DR. LOMAX: JOSE CIBELLI.

22 DR. CIBELLI: YES.

23 DR. LOMAX: ALTA CHARO.

24 MS. CHARO: ABSTAIN.

25 DR. LOMAX: BERNIE LO.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: YES.
2 DR. LOMAX: SHERRY LANSING.
3 MS. LANSING: WELL, I GUESS NO.
4 DR. LOMAX: JEFF SHEEHY.
5 MR. SHEEHY: YES.
6 DR. LOMAX: DOROTHY ROBERTS.
7 DR. ROBERTS: YES.
8 DR. LOMAX: ROBERT TAYLOR.
9 DR. TAYLOR: YES.
10 DR. LOMAX: ARE THERE ANY MEMBERS ON THE
11 PHONE?
12 DR. WILLERSON: JIM WILLERSON, YES.
13 DR. LOMAX: THANK YOU.
14 MS. LANSING: I WANT TO SAY THIS. I
15 EXPRESSED MYSELF, BUT THIS WAS SUCH AN OVERWHELMING
16 SUPPORT OF IT, THAT THEN I'M COMFORTABLE WITH IT. I
17 THINK IT WAS A HEALTHY DISCUSSION. AND SO I THINK THIS
18 IS OUR RECOMMENDATION THEN. WHAT I WOULD JUST LIKE IS
19 TO MONITOR THIS AND TO REVISIT IT AND SEE IF IT DOES US
20 ANY HARM IN GETTING LINES.
21 MR. SHEEHY: IF IT DOESN'T WORK, WE'LL HEAR
22 FROM PEOPLE.
23 CHAIRMAN LO: I THINK THAT'S UNDERSTOOD.
24 MS. LANSING: I VOTE YES. NO. SERIOUSLY.
25 THIS IS GOOD ENOUGH FOR ME.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN LO: LET'S TAKE A BIG DEEP BREATH,
2 AND WE'RE GOING TO TAKE A VIRTUAL BREAK, BUT NOT A REAL
3 BREAK. PLEASE COME RIGHT BACK BECAUSE I DO WANT TO GET
4 US OUT OF HERE BY THREE. PEOPLE HAVE PLANES TO CATCH,
5 AND THERE ARE TWO OTHER ITEMS WE NEED TO ADDRESS.

6 (A RECESS WAS TAKEN.)

7 DR. LOMAX: COULD WE GET STARTED?

8 CHAIRMAN LO: OKAY. I'D LIKE TO CALL US BACK
9 TO ORDER HERE. WE DO HAVE BUSINESS, AND WE HAVE A FIRM
10 3 O'CLOCK TERMINATION TIME. SO I'M GOING TO ASK PEOPLE
11 TO CUT SHORT THEIR CONVERSATION, INCLUDING MY ESTEEMED
12 CO-CHAIR. OKAY. SO THANK YOU. I HOPE EVERYONE
13 ENJOYED THEIR BREAK.

14 WE DO HAVE A COUPLE OF ISSUES TO ADDRESS, AND
15 WE DO HAVE A FIRM 3 O'CLOCK. FIRST, I WANT TO SAY I
16 THOUGHT THE DISCUSSION WE HAD, AS ALWAYS HERE, WAS
17 WIDERANGING, THOUGHTFUL, UNINHIBITED, WHICH IS, I
18 THINK, WHAT WE NEED TO DO. AND, AGAIN, I JUST WANT TO
19 UNDERLINE THAT EVERYTHING WE DO IS PREMISED ON THE IDEA
20 THAT WE'RE OPEN TO RECONSIDER IN THE LIGHT OF NEW
21 EVIDENCE, NEW SCIENTIFIC DEVELOPMENTS, AND NEW POLICY
22 CHANGES ELSEWHERE. SO WHAT WE'RE SAYING TODAY HOLDS
23 FOR TODAY, AND WE HAVE AN OPEN MIND FOR THE FUTURE.

24 THERE ARE A COUPLE OF SPECIFIC ISSUES THAT WE
25 HOPE ARE LESS COMPLICATED AND LESS CONTROVERSIAL, BUT

BARRISTERS' REPORTING SERVICE

1 DO, ACCORDING TO THE PUBLIC COMMENTS RECEIVED, POSE
2 SOME CONCERNS TO MEMBERS OF THE PUBLIC WHO COME. SO
3 I'M GOING TO ASK GEOFF TO WALK US THROUGH THOSE AND
4 ALSO SUGGEST SPECIFIC RECOMMENDATIONS THAT WE MIGHT
5 WANT TO MAKE.

6 DR. LOMAX: I HOPE THIS IS THE ONE THAT MAYBE
7 WE CAN MOVE THROUGH QUICKLY. SO THIS IS TABLE 2 IN THE
8 BRIEFING DOCUMENTS THAT I'VE JUST POPPED UP HERE. AND
9 THERE'S A COUPLE OF THINGS TO POINT OUT TO TRY TO
10 EXPLAIN WHAT THE SUGGESTION IS HERE. TWO THINGS. THE
11 FIRST THING IS JUST SORT OF WE THINK THERE'S A MORE
12 PARSIMONIOUS WAY TO ALIGN OUR CATEGORIES, OUR RESEARCH
13 CATEGORIES, JUST TO MAKE CLEAR WHAT SHOULD BE SUBJECT
14 TO OVERSIGHT COMMITTEE REVIEW AND OVERSIGHT.

15 SO IF YOU LOOK AT THE LEFT-HAND COLUMN, WHICH
16 IS OUR CURRENT REGULATIONS, PARTICULAR ATTENTION GIVEN
17 TO B AND C. IF YOU ACTUALLY NOTICE THERE, IT'S
18 RESEARCH INVOLVING HUMAN EMBRYOS; AND THEN C TALKS
19 ABOUT RESEARCH WITH THE AIM TO DERIVE A COVERED STEM
20 CELL LINE FROM HUMAN GAMETES, EMBRYOS, OR PRODUCTS OF
21 SCNT. IT'S ALWAYS HELPFUL IN THESE SORTS OF DOCUMENTS
22 TO TRY TO HAVE SOME MUTUALLY EXCLUSIVE CATEGORIES.

23 IN BOTH CASES THERE'S -- THE OTHER POINT IN
24 PARTICULAR IS WE REALLY WANT ANY HUMAN EMBRYO WORK TO
25 UNDERGO A FULL REVIEW BY THE SCRO COMMITTEE. SO WHAT

BARRISTERS' REPORTING SERVICE

1 WE ALSO HAD IS, BESIDES HAVING TWO CATEGORIES THAT HAD
2 SOME OVERLAP, THERE WAS ALSO A LITTLE BIT OF A
3 DIFFERENT STANDARD. ONE WAS A NOTIFICATION STANDARD
4 AND ONE WAS A FULL REVIEW STANDARD.

5 NOW, THIS IS IN LINE WITH WHAT THE CALIFORNIA
6 DEPARTMENT OF PUBLIC HEALTH IS DOING WITH THEIR
7 DOCUMENTS. THEY REALLY WANTED TO MAKE SURE THEY REALLY
8 FOCUSED ON GAMETE AND EMBRYO RESEARCH RECEIVING THE
9 FULL ATTENTION AND APPROVAL OF THE SCRO COMMITTEE. IN
10 ADDITION, SORT OF TYING BACK TO LAST NIGHT'S
11 DISCUSSION, THAT THERE MAY BE A RESEARCH THAT COULD
12 INVOLVE THE ACTUAL CREATION OF GAMETES. WE THOUGHT IT
13 WAS HELPFUL TO CLARIFY THAT THAT TYPE OF WORK TOO
14 SHOULD BE SUBJECT TO FULL REVIEW BY AN OVERSIGHT
15 COMMITTEE.

16 SO WHAT'S PROPOSED IS TO MAKE VERY CLEAR
17 CATEGORIES, THIS IS NOW THAT MIDDLE PROPOSED REVISIONS,
18 IS RESEARCH INVOLVING THE CREATION OR USE OF HUMAN
19 GAMETES, FULL SCRO REVIEW. AGAIN, THERE'S NO CHANGE IN
20 THE POLICY, BUT THE CATEGORY IS HOPEFULLY CRYSTAL
21 CLEAR. SO IF YOU ARE PROPOSING TO EVEN GENERATE
22 GAMETES THROUGH IPS, YOU WOULD BE COVERED UNDER THIS
23 STANDARD. AND THEN, AGAIN, A PARALLEL SORT OF
24 CONSTRUCTION, CREATION OR USE OF HUMAN BLASTOCYSTS,
25 INCLUDING SCNT, FULL REVIEW. AGAIN, NO CHANGE IN THE

BARRISTERS' REPORTING SERVICE

1 SUBSTANTIVE STANDARD, BUT THE CATEGORY WOULD BE
2 EXCEPTIONALLY CLEAR.

3 SO THAT COVERS SORT OF THE TOP TWO
4 CATEGORIES, AGAIN, KIND OF CHANGING LANGUAGE, BUT
5 THERE'S NO CHANGE TO THE REVIEW STANDARD.

6 NOW, THE SECTIONS IN GRAY THERE ARE SUBTLE
7 CHANGES IN THE REVIEW STANDARD, BUT THEY'RE CHANGES
8 THAT I BELIEVE ARE ENTIRELY CONSISTENT WITH THE
9 DISCUSSION WE HAD IN DECEMBER ABOUT TRYING TO ALLOW
10 CERTAIN RESEARCH, PARTICULARLY RESEARCH INVOLVING
11 SOMATIC CELLS, PARTICULARLY THE ANONYMOUS SOMATIC CELLS
12 WHERE THERE'S NO HUMAN SUBJECTS ISSUES, THAT THAT
13 RESEARCH COULD PROCEED IN A MANNER THAT WAS MORE
14 FLEXIBLE AND DIDN'T NECESSARILY INVOLVE THE SCRO
15 COMMITTEE IN EVERY CASE.

16 SO THE CATEGORY C, AGAIN, IT'S SOMEWHAT
17 PARALLEL TO THE PREVIOUS STANDARD WHERE WE TALKED ABOUT
18 RESEARCH WITH THE AIM TO DERIVE A COVERED STEM CELL
19 LINE, WHICH IS EFFECTIVELY NOW AN IPS CATEGORY, BUT THE
20 SCOPE OF THE STANDARD, WHICH IS A NOTIFICATION STANDARD
21 TO THE OVERSIGHT COMMITTEE, WOULD BE LIMITED TO HUMAN
22 SUBJECTS RESEARCH INVOLVING SOMATIC CELLS. WHAT THAT
23 DOES, IT'S CONSISTENT WITH WHAT WE DISCUSSED IN
24 DECEMBER. IT MEANS THAT THE WORK INVOLVING ANONYMOUS
25 CELLS AND REPROGRAMMING OF CELLS THAT DON'T HAVE HUMAN

BARRISTERS' REPORTING SERVICE

1 SUBJECTS IMPLICATIONS SORT OF WOULD FALL INTO A
2 SEPARATE SORT OF CATEGORY.

3 THE NOTIFICATION STANDARD, THE IDEA THERE IS
4 FOR HUMAN SUBJECTS RESEARCH INVOLVING SORT OF
5 DEVELOPMENT OF PLURIPOTENT CELLS, WE WANT THE SCRO TO
6 BE ON NOTICE OF THIS TYPE OF WORK. THIS IS THE KIND OF
7 ISSUE THEY SHOULD BE THINKING ABOUT. I THINK IT'S IN
8 THE SPIRIT OF THE NATIONAL ACADEMIES GUIDELINES, THEIR
9 REVISIONS, WHERE THEY DON'T NECESSARILY -- THEY DON'T
10 SPECIFICALLY CALL FOR NOTIFICATION OF THE OVERSIGHT
11 COMMITTEE, BUT THEY TALK ABOUT THE FACT THAT WHEN YOU
12 HAVE IDENTIFIABLE MATERIALS, THERE MAY BE UNIQUE
13 CONCERNS THAT NEED TO BE THOUGHT ABOUT IN TERMS OF THE
14 SCRO MAY WANT TO CONSULT, FOR EXAMPLE, WITH THE IRB. I
15 THINK IT'S REALLY IN THE SPIRIT OF THE NATIONAL
16 ACADEMIES RECOMMENDATIONS, BUT IT'S A LITTLE BIT MORE
17 HARDWIRED. WE TALK ABOUT NOTIFICATION, WHICH MEANS
18 THERE NEEDS TO BE A DIRECT COMMUNICATION TO THE
19 OVERSIGHT COMMITTEE THAT THIS WORK IS GOING ON. IS
20 THAT CLEAR SO FAR?

21 CHAIRMAN LO: LET ME JUST TRY AND PARAPHRASE
22 TO MAKE SURE WE UNDERSTAND. THE THRUST OF THIS NUMBER
23 C IS TO HAVE LESS REGULATORY BURDEN ON RESEARCHERS WHO
24 ARE USING ANONYMIZED OR DEIDENTIFIED SOMATIC CELLS LEFT
25 OVER FROM CLINICAL CARE OR ANOTHER RESEARCH PROJECT,

BARRISTERS' REPORTING SERVICE

1 DEIDENTIFIED, TO TRY TO CREATE A NEW PLURIPOTENT STEM
2 CELL OR STEM CELL LINE. THIS IS NOT CONSIDERED HUMAN
3 SUBJECTS RESEARCH UNDER LONG-STANDING FEDERAL
4 REGULATIONS. IF EXISTING TISSUE IS USED IN RESEARCH
5 AND IS NOT IDENTIFIABLE, THE IRB -- IT'S NOT HUMAN
6 SUBJECTS RESEARCH AND IT FALLS OUTSIDE OUR IRB PURVIEW.
7 SO IT'S BRINGING THIS TYPE OF RESEARCH BACK TO A PAR OF
8 OVERSIGHT WITH OTHER TYPES OF RESEARCH WITH EXISTING
9 ANONYMIZED TISSUE.

10 WE'RE WEAKENING OUR REQUIREMENT, BUT WE'RE
11 NOT WEAKENING ANY SUBSTANTIVE PROTECTIONS THAT THE
12 FEDERAL HUMAN SUBJECTS REGULATIONS GIVE TO DONORS OF
13 ANONYMIZED TISSUE. THEY SAY IT'S ANONYMIZED. THERE
14 REALLY AREN'T ANY HUMAN SUBJECTS ETHICAL CONCERNS.

15 DR. LOMAX: I WOULDN'T SAY WEAKENING BECAUSE,
16 I THINK, AGAIN, WE HAD THIS DISCUSSION IN DECEMBER, AND
17 YOU APPROVED SORT OF IT'S OKAY TO USE ANONYMIZED
18 MATERIALS.

19 CHAIRMAN LO: WE'RE NOT REQUIRING
20 NOTIFICATION, WHICH IS PAPERWORK.

21 DR. LOMAX: YES, EXACTLY. BUT IF IT'S HUMAN
22 SUBJECTS RESEARCH, IF THE MATERIALS ARE IDENTIFIABLE,
23 WE THEN WANT THE NOTIFICATION TO THE OVERSIGHT
24 COMMITTEE. THAT, AGAIN, I THINK IS IN THE SPIRIT OF
25 WHAT THE NATIONAL ACADEMIES HAS ARTICULATED, INDICATING

BARRISTERS' REPORTING SERVICE

1 THAT THERE MAY BE SPECIAL CONSIDERATIONS FOR HUMAN
2 SUBJECTS RESEARCH.

3 NOW, OTHER THAN THAT, THERE'S ONLY ONE SUBTLE
4 DIFFERENCE THAT I'D LIKE TO EXPLAIN THAT IS
5 SUBSTANTIVE, AND IT SORT OF, AGAIN, IS A RESULT OF
6 PUBLIC COMMENTS IN THE WORKSHOP. SO IN CATEGORY D,
7 WHICH IS THE ANONYMIZED MATERIALS THAT MEET FEDERAL
8 GUIDELINES THAT ARE COMPLETELY ANONYMOUS, NO HUMAN
9 SUBJECTS IMPLICATION. LET'S SAY YOU WANT TO DO
10 REPROGRAMMING WORK ON THOSE MATERIALS. THE PRIOR
11 THINKING WAS YOU SHOULD NOTIFY THE STEM CELL RESEARCH
12 OVERSIGHT COMMITTEE.

13 THE QUESTION COMES UP: WHAT IF YOU DON'T
14 HAVE -- WHAT IF YOU'RE A GRANTEE AND YOU DON'T HAVE A
15 STEM CELL RESEARCH OVERSIGHT COMMITTEE? DO WE WANT TO
16 SORT OF PUSH PEOPLE TO EITHER CONTRACT WITH SOME
17 THIRD-PARTY COMMITTEE OR CONSTITUTE A COMMITTEE FOR
18 RESEARCH THAT IS, FOR ALL INTENT AND PURPOSES, I THINK
19 YOU'VE ALREADY INDICATED, NOT CONTROVERSIAL, NOT SORT
20 OF RUNNING INTO ETHICAL PROBLEMS, SO WHAT WE WOULD LIKE
21 TO CARVE OUT IS A NEW CATEGORY THAT A DESIGNATED
22 INSTITUTIONAL OFFICIAL CAN PROVIDE US WITH A STATEMENT
23 THAT SAYS THESE MATERIALS CONFORM TO WHATEVER FEDERAL
24 REQUIREMENT.

25 BECAUSE OTHERWISE WE WOULD HAVE A GRANTEE,

BARRISTERS' REPORTING SERVICE

1 SAY, WITH ONE GRANT THAT ALL THEY'RE DOING IS, SAY,
2 TAKING AN NIH REGISTRY LINE AND DIFFERENTIATING IT AND
3 SEEING HOW IT BEHAVES IN AN IN VITRO SYSTEM. DO WE
4 REALLY WANT THEM GOING OUT AND TRYING TO CONVENE A SCRO
5 COMMITTEE TO NOTIFY ABOUT THAT WORK? AND I THINK IT'S
6 HARD TO IMAGINE WHY WE'D WANT TO PUT THEM THROUGH THAT.
7 COULDN'T WE LIVE WITH AN ASSURANCE, THE TYPE OF
8 ASSURANCE WE DO ALL THE TIME WHEN WE CUT FOLKS A CHECK,
9 COULDN'T WE GET THAT INSTITUTIONAL OFFICIAL TO VERIFY
10 THAT THEY'RE USING COMPLIANT MATERIALS?

11 SO THAT'S THE ONE SORT OF SUBSTANTIVE CHANGE
12 THAT REALLY VARIES FROM OUR PRIOR DISCUSSIONS.

13 CHAIRMAN LO: OKAY. DISCUSSION? DO WE NEED
14 CLARIFICATION OF JUST THE GRAY MATTER STUFF HERE?

15 DR. PRIETO: I THINK I NEED A LITTLE
16 CLARIFICATION. IT JUST SEEMS TO ME THE ORIGINAL
17 MEANING OF C DOESN'T SEEM TO BE INCLUDED IN THE NEW
18 WORDING. AND IS THAT RESEARCH COVERED ELSEWHERE? AM I
19 JUST MISSING THAT? THE RESEARCH WITH THE AIM TO DERIVE
20 OR CREATE A COVERED STEM CELL LINE FROM HUMAN GAMETES,
21 EMBRYOS, OR PRODUCTS OF SCNT, AND NOW WE'RE JUST SAYING
22 NOTHING ABOUT THAT?

23 DR. LOMAX: THOSE CONDITIONS WOULD BE COVERED
24 EITHER IN A OR B, AND IT'S THE SAME LEVEL OF REVIEW.
25 IT'S JUST CREATING CLEARER CATEGORIES.

BARRISTERS' REPORTING SERVICE

1 DR. PRIETO: OH, OKAY.

2 DR. LOMAX: FOR C I DIDN'T WANT TO CHANGE THE
3 BRIEFING DOCUMENT BECAUSE IT WAS ALREADY UP ONLINE. ON
4 THE SLIDES I HAVE HERE, ALSO RECOMMENDING FOR C, NOT
5 ONLY INVOLVING HUMAN SOMATIC CELLS, BUT ALSO
6 IDENTIFIABLE HUMAN EMBRYONIC STEM CELLS AS WELL. SO IT
7 WOULD BE ANY IDENTIFIABLE MATERIAL THAT HAS HUMAN
8 SUBJECTS CONSIDERATION, THE SCRO SHOULD BE NOTIFIED OF
9 THAT WORK FOR REASONS I ALREADY ARTICULATED IN C.

10 DR. PRIETO: YOU KNOW, B REFERS TO CREATION
11 OR USE OF HUMAN BLASTOCYSTS OR EMBRYOS, JUST DOESN'T
12 SPECIFICALLY TALK ABOUT CREATION OF CELL LINES. MAYBE
13 THAT'S A FINE POINT.

14 DR. LOMAX: IF WE NEED THAT CLARIFICATION, I
15 THINK ANY CELL LINE -- ANY HUMAN EMBRYONIC STEM CELL
16 LINE WOULD INVOLVE THE USE OF HUMAN EMBRYOS OR
17 BLASTOCYSTS; BUT IF FOR SOME REASON WE NEED TO CLARIFY
18 THAT, IT'S INTENDED TO BE CAPTURED IN THAT CATEGORY.

19 CHAIRMAN LO: ANY OTHER QUESTIONS ABOUT C OR
20 D OR POINTS OF CLARIFICATION?

21 MS. CHARO: THIS IS NOT SO MUCH -- JUST AS A
22 COMMENT. I HAVE NO OBJECTION IN PRINCIPLE TO ANY OF
23 THESE THINGS, BUT I'M FINDING IT VERY HARD TO IMAGINE
24 WHAT THEY WOULD LOOK LIKE UNTIL I SEE THEM WRITTEN
25 BECAUSE WE'VE ALREADY SEEN HOW ORGANIZATIONAL CHANGES

BARRISTERS' REPORTING SERVICE

1 OFTEN HAVE UNINTENDED CONSEQUENCES WHEN YOU READ REALLY
2 CLOSELY.

3 JUST A QUESTION. ARE WE SUPPOSED TO BE
4 VOTING ON THESE TODAY OR SIMPLY REACTING TO THE
5 CONCEPTS AND THEN LATER THERE WILL BE A PRESENTATION OF
6 THE ACTUAL NEW VERSION?

7 DR. LOMAX: WE COULD PROVIDE YOU WITH A
8 VERSION OF IT. IF WE WERE TO DO THAT AND YOU WANTED TO
9 APPROVE THE PROPOSED LANGUAGE, WE WOULD HAVE TO CONVENE
10 A TELEPHONE MEETING OF THAT NATURE.

11 CHAIRMAN LO: WE'RE GOING TO HAVE TO CONVENE
12 A TELEPHONE MEETING BECAUSE WE CHARGED STAFF WITH
13 WRITING LANGUAGE TO SORT OF SORT OUT WHAT WE VOTED ON
14 BEFORE LUNCH. SO WE CAN ADD -- I THINK WHAT I'M ASKING
15 FOR NOW IS AN AGREEMENT IN PRINCIPLE TO GO TO THIS
16 IDEA, AND WE WILL SEE THE EXACT LANGUAGE IN CONTEXT.

17 MS. CHARO: THANKS.

18 CHAIRMAN LO: ALTA IS RIGHT. I THINK THAT
19 WILL JUST BE ANOTHER ITEM ON THIS CALL.

20 DR. LOMAX: THAT'S FINE. IF WE'VE DETERMINED
21 WE'RE GOING TO HAVE THAT MEETING, THEN, YES,
22 ABSOLUTELY.

23 CHAIRMAN LO: I THINK WE HAVE TO HAVE A
24 MEETING BECAUSE WE VOTED ON SOMETHING THAT HAS TO HAVE
25 LANGUAGE WRITTEN BY YOU AND STAFF.

BARRISTERS' REPORTING SERVICE

1 ANY OTHER DISCUSSION OF THIS POINT, C AND D?
2 SO, AGAIN, THIS IS JUST CLARIFYING THE LEVEL OF
3 DOCUMENTATION OF OVERSIGHT THAT'S --

4 MS. LANSING: I MOVE APPROVAL OF THE GIST,
5 THE IDEAS IN C AND D.

6 CHAIRMAN LO: SECOND?

7 MR. SHEEHY: SECOND.

8 CHAIRMAN LO: JEFF SECONDS. ANY PUBLIC
9 DISCUSSION? ANY COMMENTS FROM THE PUBLIC ON THIS?
10 OKAY. DO YOU WANT TO CALL THE ROLL.

11 DR. LOMAX: DO WE NEED A ROLL CALL VOTE?

12 CHAIRMAN LO: ALL THOSE IN FAVOR JUST PUT
13 YOUR HANDS UP. IS DR. WILLERSON STILL ON THE PHONE?

14 DR. LOMAX: IT'S UNANIMOUS.

15 DR. WILLERSON: I'M HERE.

16 CHAIRMAN LO: I DON'T KNOW IF YOU CAN SEE
17 THESE SLIDES. YOU CAN'T SEE THE SLIDES. DO YOU KNOW
18 WHAT WE'RE VOTING ON, JIM, OR DO YOU NEED TO DEFER? DO
19 YOU NEED TO ABSTAIN BECAUSE IT'S NOT CLEAR? WE'LL COME
20 BACK TO THAT IN A SUBSEQUENT CONFERENCE CALL. THIS IS
21 JUST A SORT OF PROOF OF CONCEPT APPROVAL. ANYONE
22 OBJECT TO THIS? OKAY. GREAT.

23 AND THEN LET'S MOVE ON, GEOFF, TO THE ISSUE
24 OF PAYMENT FOR DONORS OF SOMATIC CELLS USED IN IPS
25 RESEARCH.

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: SO, AGAIN, THE CONTEXT HERE WAS
2 WE WERE IN A DISCUSSION IN MAYBE THE DECEMBER MEETING
3 WHERE WE HAD ADDRESSED A NUMBER OF ISSUES RELATED TO
4 SOMATIC CELLS. AND THE FINAL ISSUE OF DISCUSSION THERE
5 WAS IS IT ACCEPTABLE FOR SOMATIC CELLS WHERE THERE HAVE
6 BEEN IRB-APPROVED PAYMENTS TO BE USED IN CIRM-FUNDED
7 RESEARCH. AND IT WAS POINTED OUT THAT THE WAY THE
8 LANGUAGE IS CURRENTLY DRAFTED, THE PAYMENT PROVISIONS
9 APPLY BROADLY TO ALL MATERIALS USED IN RESEARCH.

10 SO THE QUESTION THAT CAME UP AT THAT POINT IN
11 TIME WAS WE'D NEED TO ADEQUATELY ADDRESS THE SCOPE OF
12 THE PAYMENT RESTRICTIONS IN PROP 71 IN ORDER FOR YOU
13 ALL TO MAKE A DECISION ON THIS POINT. AND THAT WAS A
14 POINT OF UNCERTAINTY. SO WHAT I'VE DONE IS ASKED JAMES
15 HARRISON TO SORT OF DO THAT AND SORT OF SAY THIS WAS
16 THE SORT OF POINT OF UNCERTAINTY. WE COULDN'T RESOLVE
17 IT AT THAT TIME.

18 CHAIRMAN LO: JAMES, BEFORE YOU DO THAT, LET
19 ME JUST TRY AND PUT THIS IN CONTEXT. SO I THINK
20 THERE'S CLEAR AGREEMENT THAT IN PROP 71 THE INTENTION
21 OF THE PUBLIC, THE VOTERS, BECAUSE OF THE WAY THIS WAS
22 PRESENTED TO THEM, IS THAT THAT PROPOSITION BANNED THE
23 PAYMENT BEYOND REASONABLE EXPENSES TO OOCYTE DONORS AND
24 EMBRYO DONORS, THAT THIS WAS FELT TO BE SUCH A NEW
25 TOPIC, THAT WE WERE TAKING A LEAD, IT WAS STILL

BARRISTERS' REPORTING SERVICE

1 SENSITIVE, AND WE SAID WE DO NOT WANT PAYMENT BEYOND
2 EXPENSES FOR OOCYTES, GAMETES, AND EMBRYOS. WE DIDN'T
3 WANT ANY WHIFF.

4 NOW, SUBSEQUENT AND WHEN WE SORT OF WROTE THE
5 REGULATIONS, WE SAID, WELL, WE WERE THINKING MORE OF
6 SOMATIC CELLS BEING USED FOR SCNT, WHICH, AGAIN, IS
7 EXPRESSLY PERMITTED AS A CONSTITUTIONAL RIGHT UNDER
8 PROP 71, BUT, AGAIN, WE WANTED TO MAKE SURE THERE WAS
9 NO FINANCIAL INDUCEMENT. SINCE THAT TIME, AS WE ALL
10 KNOW, SOMATIC CELLS ARE USED IN STEM CELL RESEARCH FOR
11 IPS CELLS WHICH DO NOT INVOKE THE SAME KINDS OF ETHICAL
12 CONCERNS BECAUSE THEY'RE NOT REPRODUCTIVE TISSUE THAT
13 EMBRYONIC STEM CELL RESEARCH OR DONATION OF GAMETES AND
14 EMBRYOS DOES.

15 NOW, IN POINT OF FACT, WHAT HAPPENS WHEN
16 PEOPLE TRY AND DERIVE A NEW IPS LINE FROM SOMATIC CELLS
17 IS THEY GET A SKIN BIOPSY FROM A RESEARCH SUBJECT. AND
18 IT'S QUITE COMMON WHENEVER YOU GET A SKIN BIOPSY FOR
19 RESEARCH TO MAKE A NOMINAL PAYMENT, USUALLY ABOUT \$50,
20 FOR TIME AND INCONVENIENCE. IT'S NOT A RISKY
21 PROCEDURE. NOW, THERE'S TRANSIENT PAIN, AND IT JUST
22 DOES NOT INVOKE THE KINDS OF MEDICAL RISKS THAT WE WERE
23 TALKING ABOUT WITH OOCYTE DONATION. SO THE QUESTION IS
24 DO WE REALLY MEAN TO FORBID PAYMENTS TO DONORS OF SKIN
25 BIOPSIES FOR IPS CELLS WHEN IT'S DONE WITHOUT CIRM

BARRISTERS' REPORTING SERVICE

1 FUNDING IN OTHER VENUES FOR IPS CELL DERIVATION?

2 MS. LANSING: IT'S JUST THE SKIN BIOPSY. IT
3 HAS NOTHING TO DO WITH REPRODUCTION.

4 CHAIRMAN LO: IT HAS NOTHING AT ALL TO DO
5 WITH REPRODUCTION.

6 MS. LANSING: AND IT'S \$50.

7 CHAIRMAN LO: IT'S OF THAT ORDER OF
8 MAGNITUDE, SOMETIMES 25. I DON'T KNOW IF IT'S MUCH
9 MORE THAN THAT.

10 MS. LANSING: SO THAT WOULD GO UNDER
11 REASONABLE EXPENSES LIKE WE HAD APPROVED BEFORE.

12 CHAIRMAN LO: SEE, WE'VE ALWAYS TALKED ABOUT
13 REASONABLE OUT-OF-POCKET EXPENSES OR IF YOU COULD
14 DEMONSTRATE A RECEIPT. NOW WE'RE SAYING THAT FOR THIS
15 AMOUNT, WE DON'T THINK -- WE THINK IT SHOULD BE TREATED
16 LIKE ALL OTHER PAYMENTS FOR DONATION OF TISSUE IN
17 RESEARCH. IF YOU DONATE A SKIN BIOPSY TO A DERMATOLOGY
18 RESEARCH PROJECT, YOU'RE PAID THAT AMOUNT. I THINK
19 THAT'S THE BACKGROUND HERE.

20 AND THERE ARE TWO ISSUES. ONE, DO WE THINK
21 MORALLY IT'S ETHICALLY THE APPROPRIATE THING TO DO, TO
22 ALLOW THAT KIND OF PAYMENT FOR THESE KINDS OF CELLS FOR
23 IPS? AND, SECONDLY, DOES THAT RUN AFOUL OF PROP 71?
24 SO I'VE ASKED OUR LEGAL EXPERTS, JAMES HARRISON AND
25 ELONA BAUM, TO COMMENT ON THAT. JAMES, YOU WERE GOING

BARRISTERS' REPORTING SERVICE

1 TO COMMENT.

2 MR. HARRISON: THANKS, BERNIE. LET ME JUST
3 TRY TO FRAME THE LEGAL ISSUE FOR YOU. PROP 71 REQUIRES
4 THE ICOC, BASED ON THE ADVICE OF THIS GROUP, TO ADOPT
5 STANDARDS PROHIBITING COMPENSATION TO RESEARCH DONORS.
6 THAT'S THE LANGUAGE THAT'S USED. IT INCLUDES AN
7 EXCEPTION FOR REIMBURSEMENT FOR EXPENSES. THOUGH THE
8 LANGUAGE ON ITS FACE APPEARS BROAD, AS BERNIE SAID, THE
9 INTENT AND THE FOCUS OF THE PROP 71 CAMPAIGN WAS ON
10 PROHIBITION -- WAS ON PROTECTING AGAINST UNDUE
11 INDUCEMENT TO EGG DONORS.

12 IN FACT, OPPONENTS OF PROP 71 IN THEIR BALLOT
13 ARGUMENTS RAISED THE SPECTER OF WOMEN BEING COERCED TO
14 DONATE EGGS. THOUSANDS OF WOMEN MAY BE SUBJECTED TO
15 THE SUBSTANTIAL RISKS OF HIGH DOSE HORMONES AND EGG
16 EXTRACTION PROCEDURES JUST FOR THE PURPOSES OF
17 RESEARCH. THAT'S WHAT THE VOTERS WERE FOCUSED ON.
18 THAT'S WHAT THE ARGUMENTS WERE FOCUSED ON.

19 AS BERNIE SAID, SOMATIC CELLS DIDN'T ENTER
20 INTO THE DEBATE. NONETHELESS, WE DO HAVE THIS BROAD
21 LANGUAGE WHICH RAISES A QUESTION ABOUT THE SCOPE OF
22 YOUR AUTHORITY. AND I THINK IT'S IMPORTANT TO KEEP A
23 COUPLE OF TOOLS OF STATUTORY CONSTRUCTION IN MIND, AND
24 ALTA WILL BE FAMILIAR WITH THESE. THE PRIMARY --

25 CHAIRMAN LO: AND DOROTHY AS WELL.

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: AND DOROTHY AS WELL. THE
2 PRIMARY GOAL OF STATUTORY CONSTRUCTION IS TO EFFECTUATE
3 THE INTENT OF THE ENACTING BODY, IN THIS CASE
4 CALIFORNIA VOTERS. AND AS WE'VE PREVIOUSLY STATED, THE
5 SPECIFIC INTENT OF THIS PROVISION WAS REALLY NOT
6 DIRECTED IN ANY WAY TO SOMATIC CELL DONORS.

7 SECOND, BECAUSE THE LAW VESTED DISCRETION IN
8 CIRM AND SPECIFICALLY IN THE ICOC, BASED ON
9 RECOMMENDATIONS FROM THIS GROUP, THE COURTS ACCORD A
10 LARGE DEGREE OF DEFERENCE TO THE AGENCY'S
11 INTERPRETATION OF A STATUTE THAT IT'S CHARGED WITH
12 IMPLEMENTING, AND PARTICULARLY IN A CASE LIKE THIS,
13 WHERE IT SETS A VERY BROAD STANDARD AND THEN REQUIRES
14 YOU TO FLESH IT OUT.

15 SO I THINK THAT PERMITS SOME ROOM FOR
16 INTERPRETATION. AND WHEN YOU CONSIDER SOMATIC CELL
17 DONORS AND HOW THEY FIT WITHIN THE CONTEXT OF WHAT THE
18 LAW WAS INTENDED TO PROTECT AGAINST, WE DON'T HAVE AN
19 UNDUE INDUCEMENT ISSUE BECAUSE WE'RE TALKING ABOUT A
20 MODEST PAYMENT. WE HAVE APPROPRIATE SAFEGUARDS IN
21 PLACE BECAUSE IT'S A SUM THAT'S APPROVED BY AN IRB OR A
22 SCRO. AND IT REALLY IN SOME WAYS IS BETTER
23 CHARACTERIZED AS REIMBURSEMENT FOR THE TIME AND
24 INCONVENIENCE OF THE DONOR RATHER THAN STRICTLY AS
25 COMPENSATION. IT'S DISSIMILAR IN THAT SENSE FROM

BARRISTERS' REPORTING SERVICE

1 COMPENSATION THAT IS PAID TO GAMETE DONORS FOR
2 REPRODUCTIVE PURPOSES.

3 SO FROM THAT STANDPOINT, IF YOU LOOK AT THE
4 PURPOSE OF PROP 71, IT REALLY WASN'T INTENDED TO
5 ADDRESS THIS DE MINIMIS COMPENSATION TO SOMATIC CELL
6 DONORS. FOR THAT REASON, WE BELIEVE YOU HAVE SOME
7 LATITUDE IN CONSTRUING THE LAW AND PROPOSING A STANDARD
8 THAT EXCLUDES THIS DE MINIMIS IRB-APPROVED COMPENSATION
9 TO SOMATIC CELL DONORS.

10 MS. CHARO: WHAT SECTION WAS IT AGAIN OF PROP
11 71?

12 MR. HARRISON: SECTION 125290.35(B)(3), AND
13 IT SAYS SPECIFICALLY -- LET ME READ IT TO YOU.

14 CHAIRMAN LO: DID YOU GET THAT, ALTA?

15 MR. HARRISON: IT DIRECTS THE ICOC TO, QUOTE,
16 ADOPT STANDARDS PROHIBITING COMPENSATION TO RESEARCH
17 DONORS OR PARTICIPANTS WHILE PERMITTING REIMBURSEMENT
18 OF EXPENSES. SO THE LANGUAGE ITSELF IS VERY BROAD.

19 MS. LANSING: MY ONLY QUESTION IS --
20 PHILOSOPHICALLY I'M COMPLETELY COMFORTABLE WITH GIVING
21 ANYONE WHO DOES THIS \$50, AND I DON'T THINK IT VIOLATES
22 THE SPIRIT AS YOU'VE OUTLINED IT. BUT HAVING SAID
23 THAT, I JUST WONDER, SINCE THERE ARE STILL A LOT OF
24 PEOPLE OUT THERE THAT WOULD LIKE TO GIVE US ANOTHER
25 LAWSUIT, THAT FOR THIS, IS IT WORTH IT, AND ARE WE

BARRISTERS' REPORTING SERVICE

1 GOING TO BE OPEN TO ANOTHER LAWSUIT? IN OTHER WORDS,
2 IF THAT'S -- THAT'S MY QUESTION. BECAUSE WE'RE GOING
3 TO BE OPEN TO ANOTHER LAWSUIT, IT'S GOING TO TAKE A LOT
4 OF THE TIME AND ENERGY, I WOULD SAY WHAT'S THE POINT?
5 I'M SORRY THAT OUR LANGUAGE WAS SO BROAD, BUT NO ONE IS
6 GOING TO NOT DO IT BECAUSE THEY DIDN'T GET THE \$50.

7 MR. HARRISON: THAT'S CERTAINLY A RISK, AND
8 IT ALWAYS IS IN ANYTHING THIS AGENCY DOES. I WILL SAY
9 THAT IF YOU LOOK AT THE INTEREST OF THE OPPONENTS OF
10 THE CIRM, AND SPECIFICALLY THE PLAINTIFFS WHO FILED
11 LITIGATION AGAINST THE AGENCY, THEY WERE PRIMARILY
12 CONCERNED WITH THE USE OF EMBRYOS FOR RESEARCH PURPOSES
13 AND WITH SCNT. SO IN SOME SENSE THE DERIVATION OF
14 LINES FROM SOMATIC CELLS, FROM A MORAL PERSPECTIVE,
15 USING THAT TERM RELATIVELY FROM THEIR POINT OF VIEW, IT
16 PRESENTS FEWER CONCERNS. SO IN THAT --

17 MS. LANSING: I WONDER ABOUT THE LEGIS- -- I
18 MEAN WE HAVE A LOT OF PEOPLE IN THE STATE THAT ARE NOT
19 OUR FRIENDS, AND WILL THEY INTERPRET THIS AS, OH, THEY
20 VIOLATED THEIR RULES?

21 MR. SHEEHY: IF YOU REMEMBER, WHEN THERE WAS
22 LEGISLATION, THE STIPULATION THAT WAS PUT IN THERE BY
23 THE REPUBLICAN CAUCUS WAS TO TREAT PRECISELY THIS TYPE
24 OF RESEARCH AS IDENTICAL. WE HAVE A BIAS TOWARDS
25 EMBRYONIC STEM CELL RESEARCH. THEIR POLICY INTEREST AT

BARRISTERS' REPORTING SERVICE

1 THAT TIME WAS TO ACTUALLY PROMOTE INDUCED PLURIPOTENT
2 SOMATIC CELL RESEARCH AND TRIED TO GIVE EQUIVALENCY TO
3 EMBRYONIC STEM CELL RESEARCH WITHIN PROP 71. THAT WAS
4 THE ONLY CHANGE THAT THEY REALLY WANTED TO MAKE TO IT.

5 SO IT WOULD BE -- THEY COULD POTENTIALLY SUE
6 US NOT TO DO IPS RESEARCH, BUT THEY'RE ALL RUNNING
7 AROUND THE COUNTRY SAYING WE DON'T NEED TO DO EMBRYONIC
8 STEM CELL BECAUSE WE CAN DO IPS RESEARCH. SO THEY
9 WOULD BE KIND OF CUTTING OFF THEIR LEGS.

10 MS. LANSING: COULD THEY USE THIS? I'M JUST
11 TRYING TO PLAY -- I'M FOR THIS. I'M JUST TRYING TO
12 PLAY DEFENSIVE. COULD THEY USE THIS AND SAY, AHA, THIS
13 AUGUST BOARD WE WANT TO GET RID OF ANYWAYS VIOLATED THE
14 LAW, YOU KNOW, AND NOW WE'RE GOING TO GET AN INJUNCTION
15 TO STOP THINGS THAT PEOPLE DO?

16 CHAIRMAN LO: MAY I MAKE A SUGGESTION, THAT
17 WE TRY AND SEPARATE OUT WHETHER WE THINK IT'S THE
18 MORALLY CORRECT THING TO DO FROM THE PRAGMATIC
19 IMPLICATIONS OF WILL THIS CAUSE TROUBLE FROM LAWSUITS
20 BROUGHT AGAINST CIRM. AND MAYBE OUR RECOMMENDATION TO
21 THE ICOC, WHICH IS, I THINK, IN A BETTER POSITION TO
22 ASSESS THE OVERALL SORT OF PICTURE, THAT WE THINK IT'S
23 THE ETHICALLY APPROPRIATE THING TO DO. THERE WERE
24 CONCERNS RAISED THAT THIS COULD OPEN THE DOOR TO A
25 LAWSUIT THAT COULD TIE UP CIRM FUNDING, STAFF,

BARRISTERS' REPORTING SERVICE

1 RESOURCES, AND THAT WE WOULD DEFER TO THE ICOC'S
2 JUDGMENT AS TO WHETHER THEY WANTED TO CHANGE THIS.

3 MS. LANSING: TAKE THE RISK.

4 CHAIRMAN LO: THE OTHER THING I DON'T KNOW IS
5 WHETHER IF THEY PASS THIS AND THERE'S A LAWSUIT, THEY
6 CAN JUST TURN RIGHT AROUND AND SAY WE'RE GOING TO
7 CANCEL THE PAYMENTS.

8 MS. LANSING: THEY COULD ACCUSE -- YOU'RE THE
9 LAWYER, BUT THEY COULD ACCUSE US OF VIOLATING THE
10 PROPOSITION AND THROW US ALL OUT ON THE BASIS OF THAT.
11 THAT COULD BE THE LAWSUIT. THESE PEOPLE, YOU KNOW,
12 JUST LIKE THEY ACCUSED US OF CONFLICT OF INTEREST,
13 WHATEVER.

14 MR. HARRISON: THEY COULD CERTAINLY MAKE
15 WHATEVER ALLEGATIONS THEY WANT. I THINK A SPECIFIC
16 LAWSUIT WOULD GO TO A CHALLENGE TO THIS PARTICULAR
17 REGULATION. IT WOULD PROBABLY BE DIFFICULT FOR THEM TO
18 MOUNT A MORE ALL INCLUSIVE CHALLENGE GIVEN THE FACT
19 THAT THE COURTS HAVE ALREADY REJECTED MANY OF THOSE
20 THAT THEY MIGHT RAISE. BUT THAT DOESN'T MINIMIZE THE
21 POSSIBILITY THAT THERE IS ALWAYS SOME RISK OF
22 LITIGATION.

23 MS. LANSING: SO THIS IS MY LAST SENTENCE,
24 BUT FOR \$50, I THINK NO ONE WON'T DO IT. THEY DO IT
25 JUST TO GET THE \$50. AND SITTING, AS SOME OF US DO, ON

BARRISTERS' REPORTING SERVICE

1 THE BOARD OF CIRM, I DON'T WANT ANY MORE DISTRACTIONS
2 BECAUSE WE'VE GOT ENOUGH OF THEM, SO I WOULD TREAD VERY
3 CAUTIOUSLY.

4 DR. TROUNSON: I THINK YOU'RE MAKING A FAIR
5 POINT, SHERRY. IF WE INVEST HUNDREDS OF THOUSANDS OF
6 DOLLARS OR MILLIONS OF DOLLARS IN DEVELOPING OF THIS
7 CELL LINE FROM SUCH A PATIENT, YOU KNOW, THAT WAS
8 DERIVED FROM SUCH A PATIENT WHERE THERE WAS A PAYMENT
9 AND THEN WE WERE CAUGHT UP WITH HAVING TO, YOU KNOW, GO
10 BACK AND REDO IT ALL BECAUSE OF SOMEONE'S INSANITY IN
11 THE COURTS, IT WOULD BE A REAL PROBLEM. SO I THINK MY
12 OWN VIEW WOULD BE TO TRY AND RESPECT AS CLOSELY THE
13 LAW, IDENTIFYING THAT, YOU KNOW, IF WE HAD OUR RATHERS,
14 WE WOULD PREFER TO HAVE SOME ALTERATION TO THE WORDING.
15 BUT I THINK THAT'S MOST UNLIKELY TO OCCUR.

16 CHAIRMAN LO: LET ME AGAIN, IN THE INTEREST,
17 I THINK -- WELL, LET ME SEE IF WE CAN SORT OF GET SOME
18 CLOSURE ON THIS. ONE OPTION IS TO SAY WE JUST LEAVE
19 THINGS AS IS AND SAY WE'RE NOT GOING TO PAY SOMATIC
20 CELL DONORS. SECOND OPTION IS TO REPORT BACK TO THE
21 ICOC WE THINK THERE ARE ETHICAL REASONS FOR PAYING, BUT
22 WE'RE VERY CONCERNED ABOUT THE POTENTIAL OF A LAWSUIT
23 AND THE RISK TO TYING UP CIRM RESOURCES AND TIME IF
24 THAT WERE TO TAKE PLACE EVEN IF THE LAWSUIT HAD NO
25 MERIT.

BARRISTERS' REPORTING SERVICE

1 DR. LOMAX: BERNIE, I APOLOGIZE. IT'S
2 PROBABLY I'M GUILTY OF COMPRESSING MY COMMENTS. THIS
3 SITUATION IS NOT NECESSARILY THE CASE WHERE IT'S CIRM
4 GRANTEES PAYING POTENTIAL DONORS. AGAIN, IF YOU GO
5 BACK TO THE CONVERSATION, IT'S ABOUT ANY SOMATIC CELLS
6 IN A BANK THAT WERE PAID FOR ON ANY LEVEL. SO YOU CAN
7 ACTUALLY SEPARATE THE CIRM PAYMENT, IF YOU LIKE, IN
8 YOUR THINKING. IT'S ANY PAYMENT. IT'S ANALOGOUS TO
9 THE OOCYTE SITUATION. SO IT'S NOT NECESSARILY CIRM --

10 CHAIRMAN LO: THAT'S VERY DIFFERENT.

11 MS. LANSING: THEREFORE, WE COULD SAY WE
12 ACCEPT THEM, BUT CIRM CAN'T IN AND OF ITSELF INITIATE
13 PAYMENT FOR THEM.

14 DR. PRIETO: PAYMENT OTHER THAN COMPENSATION
15 FOR TIME LOST, EXPENSES, ETC.

16 MS. CHARO: I'M ALMOST SCARED TO RAISE THE
17 QUESTION, BUT I WANT TO TALK FOR A MOMENT JUST ABOUT
18 UTILITY BECAUSE THERE'S NO ETHICAL OBJECTION TO GIVING
19 PEOPLE 25 OR \$50 FOR A SKIN BIOPSY, BUT NEITHER IS
20 THERE AN ETHICAL REQUIREMENT THAT WE DO SO. IT'S
21 TOTALLY DISCRETIONARY.

22 SO THE QUESTION I WOULD HAVE IS HOW BIG A
23 LOSS IS IT IF ONE DID NOT USE ANY OF THE TISSUES IN
24 THOSE BANKS? FOR ONE THING, WE'VE GOT SOME HINTS IN
25 THE RESEARCH RECENTLY THAT FIBROBLASTS FROM SKIN MAY

BARRISTERS' REPORTING SERVICE

1 TURN OUT NOT TO BE THE BEST TISSUES FROM WHICH TO DO
2 IPS WORK. I THINK ACTUALLY I'M SITTING ON A GOLD MINE
3 HERE BECAUSE I THINK THEY SAID THAT FAT CELLS MIGHT BE
4 BETTER. AND SO IT MIGHT BE THAT I'M GOING TO PAY THEM
5 TO DO THE LIPO AND THEN LET THEM HAVE ALL THE CELLS.

6 DR. TAYLOR: FIFTEEN, WE'LL GIVE YOU FIFTEEN
7 BUCKS.

8 MS. CHARO: SECOND, THERE'S LOTS AND LOTS OF
9 SURGICAL WASTE FOR WHICH NO PAYMENT WAS EVER MADE THAT
10 GOES INTO BANKS. IT'S COMPLETELY ANONYMOUS. SO MY
11 QUESTION IS WHAT IS THE LOSS EVEN IF WE DON'T USE
12 BANKED TISSUES FOR WHICH THERE WAS ANY KIND OF PAYMENT?
13 IS IT A BIG DEAL? BECAUSE IF IT'S NOT A BIG DEAL, THEN
14 SHERRY'S CONCERN THAT ANY AMOUNT OF HASSLE FACTOR IS
15 JUST A DISTRACTION COMES BACK INTO PLAY.

16 DR. PRIETO: I WONDER IF THIS DOESN'T
17 ACTUALLY DECREASE. IN A SENSE THE OPPONENTS MAY THINK,
18 AH, IF THEY'RE USING MORE -- FUNDING MORE IPS RESEARCH
19 THAN WE WANT, TO PUT WORDS INTO THEIR MOUTH, THESE
20 GUYS, THEY'RE SEEING THE WISDOM OF OUR WAYS, THEIR
21 WAYS, AND WOULD LEAVE US ALONE.

22 CHAIRMAN LO: LET ME DRAW OUT A SCENARIO
23 WHICH I THINK MAY WELL HAPPEN. THAT SOMEONE WITHOUT
24 CIRM MONEY DERIVES AN IPS CELL LINE FROM A PAID SOMATIC
25 CELL DONOR, WHATEVER SORT, DOES IT UNDER GOOD CLINICAL

BARRISTERS' REPORTING SERVICE

1 PRACTICE CONDITIONS SO THAT IT WOULD SORT OF MEET AT
2 LEAST CURRENT OR PROJECTED STANDARDS OF THE FDA, UNDER
3 STERILE CONDITIONS, A LOT OF SORT OF ATTENTION TO THE
4 QUALITY CONTROL. AND THEN A CIRM RESEARCHER WRITES A
5 GRANT TO SAY I WANT TO TAKE THAT UNDIFFERENTIATED IPS
6 CELL LINE AND DRIVE IT INTO PANCREATIC BETA ISLET
7 CELLS, WHATEVER CELLS, THAT CAN BE TRANSLATED INTO A
8 SPECIFIC DISEASE, AND THAT MAY BE THE ONLY OR ONE OF
9 THE FEW GOOD CLINICAL PRACTICE QUALITY LINES. AND TO
10 REDO THAT FROM SCRATCH FROM A NONPAID DONOR MIGHT BE AN
11 ISSUE.

12 SO I THINK THAT'S THE SCENARIO THAT I WOULD
13 IMAGINE, ALAN. I DON'T KNOW IF YOU HAVE ANY OTHER
14 SCENARIOS IN MIND WHERE IT COULD SET BACK THE
15 SCIENTIFIC AGENDA NOT TO USE AN IPS LINE SOMEONE ELSE
16 DERIVED WITHOUT CIRM FUNDING FROM A PAID SOMATIC CELL
17 DONOR.

18 DR. TAYLOR: BERNIE, I AGREE, BUT I THINK
19 SHERRY'S REALLY GOT A GOOD POINT. AND, JIM, LET ME
20 KIND OF CLARIFY THIS. YOU SAY THAT THERE'S A PARALLEL
21 REALLY BETWEEN OOCYTE DONORS AND THIS POLICY; BUT IN
22 REALITY, IF I UNDERSTAND IT RIGHT, WE ALREADY HAVE A
23 POLICY FOR SOMATIC CELLS IN PROP 71. THAT WAS SOMATIC
24 CELLS AS, YOU KNOW, SOMATIC CELLS AS DONORS OF NUCLEI,
25 BUT THERE'S ALREADY WORDING THAT SAYS THAT WE'RE NOT

BARRISTERS' REPORTING SERVICE

1 GOING TO COMPENSATE FOR SOMATIC CELLS. SO TO COME BACK
2 AND SAY WE'RE NOW GOING TO COMPENSATE FOR SOMATIC CELLS
3 FOR IPS, I WOULD SAY THAT THE LOGIC OF THIS IS REALLY
4 KIND OF FLAWED EVEN THOUGH I COMPLETELY AGREE WITH WHAT
5 EVERYBODY IS SAYING ABOUT THE ETHICS.

6 MR. HARRISON: LET ME JUST CLARIFY ONE THING.
7 THERE'S NO WORDING IN PROP 71 THAT REFERS SPECIFICALLY
8 TO COMPENSATION FOR SOMATIC CELL DONORS. THE LANGUAGE
9 THAT WE'RE TALKING ABOUT IS LANGUAGE THAT WAS ADOPTED
10 BY THE ICOC, BASED ON RECOMMENDATIONS FROM THIS GROUP,
11 IN INTERPRETING THE PROVISION THAT PROHIBITS --
12 REQUIRES THE BOARD TO ADOPT STANDARDS PROHIBITING
13 COMPENSATION TO RESEARCH DONORS. SO IT'S A
14 REGULATION --

15 DR. TAYLOR: WITHIN ICOC, BUT NOT WITHIN THE
16 LAW.

17 MR. HARRISON: CORRECT.

18 DR. TAYLOR: SO I GUESS THAT MAKES IT A
19 LITTLE BIT LESS FRAGILE.

20 MR. HARRISON: IT DOES.

21 CHAIRMAN LO: AGAIN, I'M VERY MINDFUL OF NOT
22 SORT OF TRYING TO LEAD UNWITTINGLY CIRM INTO LAWSUITS
23 THEY DON'T WANT TO HAVE TO BE INVOLVED IN. IF SOMEONE
24 MAKES A PROPOSAL FOR CIRM FUNDING FROM THE KIND OF LINE
25 I DESCRIBED, COULD WE THEN REVISIT THIS WITH SORT OF A

BARRISTERS' REPORTING SERVICE

1 REAL NEED TO CHANGE AND TRY AND ENACT EMERGENCY INTERIM
2 GUIDELINES? IS THAT AN OPTION, GEOFF, ELONA, ALAN,
3 THAT'S FEASIBLE?

4 DR. LOMAX: ONE OF THE POINTS THAT CAME UP,
5 AND IT SPEAKS TO THE STATEMENT ALTA MADE PREVIOUSLY, IS
6 UNFORTUNATELY IT'S THE ABILITY OF THE GRANTEE TO
7 OPERATE -- THEY WOULD LIKE TO OPERATE WITH A HUNDRED
8 PERCENT CERTAINTY AND THEY NEVER CAN. THE TROUBLE WITH
9 A LOT OF MATERIAL IN TISSUE BANKS THAT'S BEEN
10 ANONYMIZED IN PARTICULAR, IT'S ALL OUR TRAINING
11 PROGRAMS, THEY CAN NEVER ACTUALLY MAKE A DETERMINATION
12 ON THAT MATERIAL. SO AS LONG AS WE HAVE A RULE THAT
13 SAYS SOME OF THAT MATERIAL MAY NOT BE ALLOWED IF IT
14 MEETS CERTAIN CONDITIONS AND THEY CANNOT VERIFY THOSE
15 CONDITIONS, WE INTRODUCE A LEVEL OF UNCERTAINTY WHICH
16 IS NOT IDEAL FOR THE GRANTEES, PARTICULARLY THE
17 GRANTEES WE'RE PUSHING TO BE AS COMPLIANT AS POSSIBLE.

18 SO THE QUESTION SORT OF COMES IN A WAY IF
19 THIS IS NOT SERVING A PURPOSE, BUT IS ONLY SERVING TO
20 INTRODUCE UNCERTAINTY, CAN WE LIVE WITHOUT IT? THAT'S
21 KIND OF WHERE IT'S COMING FROM. SO WE CAN'T ANSWER
22 YOUR QUESTION, ALTA, BECAUSE THE NATURE OF SO MANY OF
23 THESE MATERIALS IS THAT SOME OF THEM ARE 15, 20 YEARS
24 OLD AND THEY'RE VERY WELL ESTABLISHED IN THE SCIENTIFIC
25 LITERATURE, AND NO ONE CAN REALLY GO BACK AND MAKE THAT

BARRISTERS' REPORTING SERVICE

1 DETERMINATION.

2 SO WE'RE ALREADY INTRODUCING A LEVEL OF
3 UNCERTAINTY WHICH IS NOT COMFORTABLE FOR THOSE WHO
4 WE'RE SIMULTANEOUSLY PUSHING TO BE AS CLEAN AS
5 POSSIBLE. SO THAT'S THE TENSION. YOU KNOW, IF WE CAN
6 RESOLVE THAT, IT HELPS EVERYONE. I DON'T WANT TO TRY
7 TO --

8 CHAIRMAN LO: I THINK THE NEW ISSUE THAT
9 SHERRY RAISED IS THE RISK OF MOVING TO REDUCE THAT
10 UNCERTAINTY AND OPENING UP THE DOOR TO A LAWSUIT THAT
11 COULD BE QUITE DAMAGING.

12 DR. LOMAX: IF YOU HAVE THE OPTION BETWEEN
13 THE CIRM-FUNDED -- AGAIN, I THINK THE REAL PROBLEM IS
14 THEY DON'T NEED CIRM MONEY TO GET THESE MATERIALS. I
15 DON'T THINK THAT'S THE PROBLEM. IT'S THE UNCERTAINTY
16 ASSOCIATED WITH THE WELL-ESTABLISHED STOCKS OF
17 MATERIALS THAT ARE OUT THERE THAT NO ONE CAN PIN DOWN
18 IN TERMS OF THEIR STATUS.

19 CHAIRMAN LO: I GUESS WHAT I WANT TO ASK ALAN
20 IS IS THERE REALLY CUTTING EDGE SCIENCE THAT WE WOULD
21 FOREGO BY SAYING YOU CANNOT USE CELLS THAT WERE PAID
22 FOR?

23 DR. TROUNSON: WELL, IT'S VERY DIFFICULT TO
24 KNOW, BERNIE, TO BE HONEST. BUT WHAT NORMALLY HAPPENS
25 IS THAT DEVELOPMENTS WILL COME FROM A SPECIFIC AREA.

BARRISTERS' REPORTING SERVICE

1 PERHAPS WE DON'T HAVE VERY MUCH SAY IN THE ORIGINS, AND
2 THESE CELLS GET DEVELOPED INTO SOMETHING WHICH BECOMES,
3 LET'S SAY, REGULATORY APPROVED OR APPROVED IN THE
4 PROCESSES; AND, HENCE, A LOT OF BENEFIT IS ACTUALLY
5 ACCRUED IN THEIR DEVELOPMENT TO THAT POINT FOR WHICH
6 YOU MIGHT NOT WANT TO GO BACK TO THE ORIGINS TO REDO.

7 SO I THINK THERE IS A STRONG POSSIBILITY THAT
8 WE COULD END UP WITH SUCH A SITUATION REALLY JUST BY
9 CIRCUMSTANCE BECAUSE THAT'S THE WAY THINGS HAPPEN IN
10 THIS AREA.

11 DR. TAYLOR: I WOULD JUST LIKE TO SAY THAT I
12 SPEND MY LIFE GROWING PRIMARY CELL CULTURES. THAT'S
13 WHAT MY CAREER HAS KIND OF BEEN BASED ON. ANY SORT OF
14 HUMAN CELL LINE OR CELL CULTURE THAT YOU CAN BRING FROM
15 A PRIMARY SKIN BIOPSY AND CARRY FOR 15 YEARS, I
16 GUARANTEE YOU THAT THAT'S CARRYING ENOUGH CHROMOSOMAL
17 ABNORMALITIES THAT YOU REALLY WOULDN'T WANT TO USE IT
18 FOR VERY MUCH OF ANYTHING. IN FACT, AFTER ABOUT SIX
19 PASSAGES, THESE THINGS BECOME FAIRLY UNSTABLE.

20 SO I'M NOT REALLY SO CONCERNED THAT THERE IS
21 GOING TO BE SUCH A GREAT SORT OF WEALTH OF MATERIAL AND
22 STUFF THAT'S BEEN AROUND THAT LONG, AND WE MIGHT BE
23 BETTER SERVED BY ACTUALLY STARTING FRESH.

24 DR. TROUNSON: THE EXPERIENCE WITH EMBRYONIC
25 STEM CELLS, ROUND ABOUT 90 OR 95 PERCENT OF ALL THE

BARRISTERS' REPORTING SERVICE

1 RESEARCH WORK IS DONE WITH TWO EMBRYONIC STEM CELL
2 LINES. AND SO THERE'S AN ENORMOUS INVESTMENT IN
3 KNOWLEDGE ABOUT THOSE LINES. AND, FOR EXAMPLE, THEY'RE
4 THE LINES THAT GERON ARE USING FOR THEIR TRIAL. SO WE
5 COULD -- I'M JUST SUGGESTING THAT, OF COURSE, IT'S NOT
6 THAT HARD TO DERIVE IT, BUT IF YOU'VE GOT SO FAR DOWN A
7 PIPELINE WITH LOTS AND LOTS OF TESTING, IT'S NOT THE
8 CELL LINE THAT'S THE ISSUE. IT'S EVERYTHING THAT'S
9 ACCUMULATED WITH IT, THE EXPERIENCE, THE TEST RESULTS.
10 AND THESE ARE THE REALLY, YOU KNOW, VERY EXPENSIVE
11 THINGS THAT YOU HAVE TO GO TO THE REGULATORY BODIES
12 WITH. AND MAYBE THE INVESTMENT INCLUDES \$50 RIGHT AT
13 THE BEGINNING WHICH SOME PERSON, YOU KNOW, WOULD WANT
14 TO SORT OF PULL THE RUG ON. THAT'S THE PRIMARY ISSUE,
15 I THINK, THAT YOU COULDN'T BE INVOLVED BECAUSE OF SOME
16 SILLINESS ABOUT A VERY EARLY PREPAYMENT FOR ACCESS TO
17 THE TISSUE.

18 SO I REMAIN A LITTLE CONCERNED ABOUT THIS,
19 BUT I RECOGNIZE WE'RE KIND OF A BIT CAUGHT REALLY
20 THROUGH THE FRAMEWORK OF WHAT'S WRITTEN. I THINK WHAT
21 MIGHT BE HELPFUL IS IF THIS GROUP WAS ABLE TO INTERPRET
22 THAT FOR THE POINT OF VIEW OF A VIEW TO THE ICOC THAT
23 WAS NOT MEANT TO INCLUDE SUCH CELLS, AND SO THAT MIGHT
24 BE HELPFUL SOMEWHERE ALONG THE LINE.

25 CHAIRMAN LO: LET ME MAKE A PROPOSAL BECAUSE

BARRISTERS' REPORTING SERVICE

1 I THINK THE TIME IS WINDING DOWN. I WOULD SUGGEST THAT
2 WE, FIRST OF ALL, SAY THAT WE DO NOT WANT CIRM FUNDING
3 TO BE USED TO PAY DONORS OF SOMATIC CELLS, BUT THAT WE
4 THINK THERE ARE NO ETHICAL OBJECTIONS TO CIRM
5 RESEARCHERS USING IPS LINES IN EXISTENCE THAT WERE
6 DERIVED FROM SOMATIC CELL DONORS WHO WERE PAID FOR
7 THEIR DONATION PROVIDED THAT WAS OVERSEEN BY AN IRB
8 THAT --

9 MS. LANSING: MUCH LIKE WE DO WITH THE
10 REPRODUCTION.

11 CHAIRMAN LO: RIGHT. BUT EVEN THOUGH WE SEE
12 NO MORAL, ETHICAL OBJECTIONS, WE DO WANT TO EXPRESS OUR
13 CONCERN TO THE ICOC, NOT THAT THE INTERPRETATION THAT
14 JAMES HAS GIVEN IS INCORRECT, BUT THAT SOME PARTIES IN
15 THE STATE MAY VIEW THIS AS AN OPPORTUNITY TO BRING A
16 LAWSUIT THAT EVEN THOUGH --

17 MS. LANSING: AS LONG AS -- I DON'T THINK
18 THAT ONE DOES BECAUSE THEN WE'D BE LIABLE WITH THE
19 REPRODUCTIVE GROUP AS WELL, SO I THINK WE'RE OKAY, AS
20 LONG AS WE'RE NOT DOING IT.

21 CHAIRMAN LO: OKAY. DO YOU WANT TO --
22 SOMEONE WANT TO SECOND A MOTION JUST TO SAY THAT, NO,
23 THERE ARE NO ETHICAL OBJECTIONS TO CIRM RESEARCHERS
24 USING CIRM FUNDING TO WORK ON AN IPS LINE DERIVED FROM
25 A DONOR WHO WAS PAID FOR THE DONATION OF THE SOMATIC

BARRISTERS' REPORTING SERVICE

1 CELL UNDER THE OVERSIGHT OF AN IRB, BUT THAT CIRM
2 FUNDING COULD NOT BE USED FOR THAT PAYMENT TO DERIVE A
3 NEW LINE, PERIOD?

4 DR. WILLERSON: SECOND.

5 CHAIRMAN LO: SOMEBODY SAID SECOND.

6 DISCUSSION? THANKS, JIM. ANY PUBLIC DISCUSSION?

7 OKAY. ROLL CALL. JIM, LET'S START WITH YOU, AYE OR
8 NAY?

9 DR. WILLERSON: AYE.

10 CHAIRMAN LO: FRANCISCO.

11 DR. PRIETO: YES.

12 DR. KIESSLING: YES.

13 DR. CIBELLI: YES.

14 DR. CHARO: YES.

15 CHAIRMAN LO: YES.

16 MR. SHEEHY: YES.

17 MS. LANSING: YES.

18 MS. ROBERTS: YES.

19 DR. TAYLOR: YES.

20 CHAIRMAN LO: THAT'S UNANIMOUS. LET ME SAY
21 THAT WE ARE ALMOST EXACTLY ON TIME. SHERRY WILL GET
22 HER FLIGHT. I WANT TO THANK ALL OF YOU FOR NOT JUST
23 COMING AND GIVING US A CHANCE TO GET TOGETHER, BUT
24 REALLY, AGAIN, FOR YOUR THOUGHTFULNESS AND DEDICATION
25 AND YOUR WILLINGNESS TO SORT OF STEP UP TO THE PLATE

BARRISTERS' REPORTING SERVICE

1 AND ADDRESS SOME TOUGH ISSUES. SO THANKS AGAIN. HAVE
2 A SAFE TRIP HOME.

3 DR. LOMAX: CAN I MAKE ONE APPEAL, AND THANK
4 YOU ALL. WE WILL WANT TO TRY TO GET THIS PHONE MEETING
5 SCHEDULED IN AS QUICKLY AS POSSIBLE. WE'RE OPERATING
6 ON VERY UNUSUAL CIRCUMSTANCE OF HAVING REGULATIONS THAT
7 ARE EXPIRED AND THINGS WE REALLY NEED TO MOVE THROUGH
8 THE OAL PROCESS. WHEN YOU GET THAT E-MAIL FROM PAT
9 BECKER, PLEASE, PLEASE, PLEASE GET BACK TO HER AS
10 QUICKLY AS POSSIBLE. AND WE'LL DO EVERYTHING WE CAN TO
11 BE AS COMPLETE AND CLEAR AS POSSIBLE IN TERMS OF HOW
12 WE'VE TAKEN THE ASPIRATIONS OF THIS MEETING AND PUT IT
13 INTO WORDS.

14 MS. LANSING: I WANT TO THANK ALL OF YOU
15 ALSO, NOT JUST FOR THE DEDICATION AND THE TIME AND THE
16 INTENSITY OF THE DISCUSSION, BUT ALSO BECAUSE IT
17 HAPPENS TO BE FUN AS WELL. SO THANK YOU.

18 CHAIRMAN LO: LET ME JUST ADD MY THANKS TO
19 GEOFF.

20 MS. LANSING: A FUN GROUP.

21 CHAIRMAN LO: LET ME JUST ADD MY THANKS TO
22 GEOFF LOMAX, WHO STAFFS THIS COMMITTEE AND HAS REALLY
23 DONE THE YEOMAN'S WORK SORT OF GATHERING.

24 MS. LANSING: AND TO YOU, BERNIE, OUR
25 INCREDIBLE LEADER.

BARRISTERS' REPORTING SERVICE

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(APPLAUSE.)

CHAIRMAN LO: I JUST SIT HERE AND WORK SIDE
BY SIDE.

DR. TROUNSON: AND THANK ALTA. I THINK THIS
MIGHT BE HER LAST MEETING.

MS. CHARO: MY LAST MEETING. LOVED YOU ALL.
BYE.

CHAIRMAN LO: THANKS TO ALTA AND THANKS TO
HER FOR TAKING OVER AN IMPORTANT POSITION AT FDA. AND
WE WISH HER ALL THE BEST OF LUCK IN SORT OF MAKING IT A
BETTER COUNTRY FOR US. THANK YOU.

(THE MEETING WAS THEN CONCLUDED AT 03:04 P.M)

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 PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

WESTIN SAN FRANCISCO MARKET STREET
50 THIRD STREET
SAN FRANCISCO, CALIFORNIA
ON
SEPTEMBER 18, 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.

BETH C. DRAIN, CSR 7152
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