

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

LOCATION: CIRM  
210 KING STREET  
SAN FRANCISCO, CALIFORNIA

DATE: APRIL 4, 2006  
12 P.M.

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

BRS FILE NO. : 75221

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

I N D E X

ITEM	DESCRIPTION	PAGE NO.
	CIRM STAFF PROGRESS REPORT	3
	CONSIDERATION OF REGULATIONS GOVERNING THE USE OF HUMAN TISSUE IN CIRM-FUNDED RESEARCH	6
	ADJOURNMENT	34

1                   STANDARDS WORKING GROUP TELECONFERENCE MEETING  
2                                   TUESDAY, APRIL 4, 2006

3  
4                   CHAIRMAN LO:   GEOFF, DO YOU WANT TO SORT OF  
5 GIVE US A STAFF PROGRESS REPORT ON SORT OF EVERYTHING  
6 THAT'S HAPPENING WITH THE ICOC AND CIRM.

7                   MR. LOMAX:   SURE.   I' LL DO A QUICK  
8 WALK-THROUGH THE PROGRESS.   ZACH ALREADY TOUCHED ON THE  
9 FACT THAT THE REGULATIONS, THEY WERE, OF COURSE, THE  
10 RECOMMENDED REGULATIONS THAT WERE PASSED OUT IN  
11 JANUARY, WERE APPROVED BY THE ICOC, AND I WOULD ADD  
12 VERY WELL RECEIVED BY THE ICOC.   AND BERNIE WAS A  
13 TREMENDOUS HELP IN REALLY ORIENTING THEM TO OUR WORK,  
14 AND WE'RE PLEASED ABOUT THAT.

15                   THEY WERE THEN WHAT WE CALL NOTICED IN THE  
16 CALIFORNIA REGULATORY REGISTER ON THE 17TH OF MARCH.  
17 THIS NOTICE FORMALLY INITIATES THE PUBLIC COMMENTING  
18 PERIOD.   WE ARE COMPILING COMMENTS AT THIS TIME.   THE  
19 MAJORITY OF OUR COMMENTS ARE COMMENTS THAT WE'VE  
20 ALREADY RECEIVED DURING OUR PROGRESS OVER THE PAST SIX  
21 MONTHS, WHICH YOU HAVE HAD SUMMARIZED.   I WOULD SAY THE  
22 COMMENTS TO DATE HAVE LARGELY -- WE HAVEN'T HAD ANY  
23 FORMAL COMMENTS, BUT WE HAVE HAD A NUMBER OF INQUIRIES  
24 FROM PARTICULARLY THE GRANTEE TYPES OF INSTITUTIONS WHO  
25 WOULD HAVE TO IMPLEMENT THE REGULATIONS INQUIRING ABOUT

1 THE REGULATIONS. SO WHAT WE ARE PLEASED ABOUT WITH  
2 THIS LINE OF COMMUNICATION IS THAT IT OFFERS THEM A  
3 CHANCE TO SORT OF ASK INTELLIGENT QUESTIONS, AND THEY  
4 WILL ULTIMATELY BE COMMENTING; BUT BY SORT OF ASKING US  
5 QUESTIONS ABOUT THE REGULATIONS IN ADVANCE, THAT SHOULD  
6 MEAN THAT THE ACTUAL COMMENTS WE GET ARE VERY FOCUSED  
7 AND VERY INFORMED AS OPPOSED TO KIND OF VERY BROAD. SO  
8 I'M VERY PLEASED ABOUT THAT LEVEL OF INTERACTION AND  
9 LOOKING FORWARD ULTIMATELY TO GETTING COMMENTS THAT  
10 WILL BE FOCUSED AND ALLOW US TO ADDRESS THEM.

11 THE PLAN WILL BE AS COMMENTS EMERGE, WHAT  
12 WE'D LIKE TO BE ABLE TO DO IS START TO PUT MATERIALS  
13 OUT, ADDITIONAL SUMMARY MATERIALS, SO THAT YOU WILL  
14 HAVE A CHANCE TO SEE THE FLAVOR OF WHAT'S BEING SAID  
15 AND CONSIDERED WELL IN ADVANCE OF THE MEETING WE HAVE  
16 SCHEDULED IN MARCH SO THAT WHEN WE SIT DOWN IN MARCH TO  
17 DISCUSS ISSUES AND POTENTIAL REVISIONS TO THE  
18 REGULATIONS, THAT YOU'RE NOT GETTING THEM COLD FOR THE  
19 FIRST TIME, BUT RATHER THERE'S BEEN SOME ABILITY --

20 DR. HALL: IN MAY.

21 MR. LOMAX: IN MAY. EXCUSE ME. I'M GETTING  
22 THE M MONTHS CONFUSED.

23 AS A REMINDER, ANY FORMAL MODIFICATIONS TO  
24 THE REGULATIONS WILL HAVE TO BE APPROVED AT THE MAY 5TH  
25 MEETING, AND THEN THERE'S AN ICOC MEETING SHORTLY

1       THEREAFTER.   SO THAT MAY 3D DATE IS PARTICULARLY  
2       IMPORTANT IN TERMS OF COMING TO CLOSURE ON THE OFFICE  
3       OF ADMINISTRATIVE LAW AND THE REGULATORY PROCESS FOR  
4       OUR FIRST ROUND OF REGULATIONS.

5               AS BERNIE INDICATED, WHAT WE'RE DISCUSSING  
6       TODAY ARE NOT AMENDMENTS TO THOSE REGULATIONS, RATHER  
7       IT WOULD BE A SEPARATE SUBMISSION THAT WOULD GO TO THE  
8       OFFICE OF ADMINISTRATIVE LAW.   IT WOULD REPEAT THIS  
9       PROCESS, SO WE'RE NOT CONSIDERING AMENDMENTS TO THOSE  
10       REGULATIONS TODAY.

11              CHAIRMAN LO:   GEOFF, THANKS.   CAN YOU REMIND  
12       US WHEN THE PUBLIC COMMENT PERIOD IS OFFICIALLY OVER?

13              MR. LOMAX:   IT'S OVER, I WANT TO SAY, THE  
14       FIRST OF MAY.   IT'S WITHIN A FEW DAYS OF OUR MAY 3D  
15       MEETING, SO I CAN CHECK THAT AND GET BACK TO YOU, BUT  
16       IT'S SOMEWHERE RIGHT AROUND THE BEGINNING OF MAY.

17              DR. KORDOWER:   JEFF KORDOWER.   SORRY I'M  
18       LATE.

19              CHAIRMAN LO:   HI, JEFF.   WELCOME.

20              JEFF, WE JUST WERE SORT OF GOING OVER SORT OF  
21       WHAT THE STATUS IS OF THE REGULATIONS THAT THE ICOC  
22       APPROVED AND OUR NOW PUBLIC COMMENT PERIOD THAT WILL BE  
23       TO MODIFY AND RESPOND TO PUBLIC COMMENTS AT OUR MAY 3D  
24       MEETING.   BUT NOW WHAT I'D LIKE TO DO IS TURN TO THE  
25       TOPICS OF THE DAY, WHICH, AS ZACH HALL MENTIONED, IS TO

1 PUT IN PLACE OR TO MAKE A, NOT A RECOMMENDATION, BUT TO  
2 GIVE A SENSE OF THE SWG TO THE ICOC REGARDING INTERIM  
3 REGULATIONS FOR FETAL TISSUE RESEARCH.

4 AND, AS ZACH MENTIONED, IT IS ANTICIPATED THE  
5 TRAINING GRANTS WE FUNDED WILL BE IMPORTANT TO HAVE IN  
6 PLACE SOME REGULATION FOR FETAL TISSUE RESEARCH, WHICH  
7 SOME OF THE GRANTEES -- THE TRAINEES MAY WANT TO WORK  
8 ON.

9 WHAT WE'RE PROPOSING IS THAT WE TODAY PASS AN  
10 INTERIM SET OF REGULATIONS THAT REALLY JUST SORT OF  
11 FORMALIZES EXISTING FEDERAL, STATE LAW AND REGULATIONS.  
12 THERE ARE OBVIOUSLY A LOT OF COMPLICATED ISSUES THAT  
13 REQUIRE MUCH MORE DISCUSSION THAT WE CAN'T DO TODAY,  
14 BUT WHAT THIS INTERIM REGULATION WILL DO IS KICK OFF  
15 THE REGULATORY PROCESS WITH A 270 -- IT WILL BE IN  
16 PLACE FOR 270 DAYS WHILE WE'LL HAVE A CHANCE DURING  
17 THAT PERIOD TO GO BACK, MODIFY, DEVELOP A FORMAL  
18 SUBMISSION FOR INTERIM REGULATIONS TO THE ICOC, WHICH  
19 WILL THEN GO TO A SEPARATE 45-DAY NOTICE PERIOD. THESE  
20 WILL BE SEPARATE THAN THE REGULATIONS ALREADY OUT FOR  
21 PUBLIC COMMENT. IS THAT CLEAR TO EVERYBODY?

22 DR. KORDOWER: NO, I GOT IT.

23 CHAIRMAN LO: GREAT. NOW, LET ME SORT OF  
24 START BY TRYING TO SET THE STAGE AND THEN PAT KING AND  
25 ALTA CHARO HAVE BOTH WORKED ON REGULATIONS REGARDING

1 THIS VERY ISSUE. AND I'M GOING TO SORT OF MAKE SURE TO  
2 DRAW ON THEIR EXPERTISE VERY HEAVILY.

3 IF WE LOOK AT CURRENT REGULATIONS, THE STATE  
4 AND FEDERAL LAW REALLY SORT OF ENUNCIATES TWO GENERAL  
5 PRINCIPLES. ONE IS THAT TO USE FETAL TISSUE FOR ANY  
6 KIND OF RESEARCH, YOU MUST OBTAIN INFORMED CONSENT FROM  
7 THE WOMAN PROVIDING THE FETAL TISSUE. AND THE SECOND  
8 ISSUE IS THAT THE CONSENT PROCESS FOR DONATING FOR  
9 RESEARCH MUST BE SEPARATE FROM THE CONSENT PROCESS TO  
10 UNDERGO A TERMINATION OF PREGNANCY.

11 DR. KORDOWER: AND SUBSEQUENT TO.

12 CHAIRMAN LO: RIGHT. SUBSEQUENT TO. THE  
13 IDEA IS THAT THE PROSPECT OF DONATING FOR RESEARCH  
14 SHOULD NOT BE ANY SORT OF INDUCEMENT TO A WOMAN TO  
15 TERMINATE PREGNANCY WHICH OTHERWISE WOULD WANT TO. AND  
16 THIS IS CODIFIED ACTUALLY IN FEDERAL LAW, THE NATIONAL  
17 ORGAN TRANSPLANT ACT. I THINK IT'S ALSO WELL  
18 ESTABLISHED IN A SORT OF ETHICS AS SORT OF A CONSENSUS.  
19 WHAT WE'RE PROPOSING IS THIS NEW SECTION 100085, USE OF  
20 FETAL TISSUE, WHICH TRIES TO SUMMARIZE AND CODIFY AS  
21 REGULATION THE RELEVANT PARTS OF EXISTING LAW AND  
22 REGULATIONS.

23 NOW, HAVING SAID THAT -- WE CAN GET TO THOSE  
24 DETAILS. BUT HAVING SAID THAT, THERE ARE A LOT OF  
25 OTHER ISSUES THAT ARE RAISED. AND PAT KING AND ROB

1 TAYLOR HAVE HAD, I THINK, A VERY, TO ME, ENLIGHTENING,  
2 ILLUMINATING DISCUSSION ON THE INTERNET AS TO A COUPLE  
3 OF OTHER ISSUES THAT TOUCH ON THIS FETAL TISSUE FOR  
4 RESEARCH. AND THOSE TWO ISSUES HAVE TO DO WITH CONSENT  
5 FROM THE FATHER OF THE FETUS TO USE THE MATERIALS FOR  
6 STEM CELL DERIVATION. THAT'S NOT CURRENTLY COVERED IN  
7 EXISTING LAW AND REGULATION. AND SECONDLY, THE ISSUE  
8 OF THE ROLE OF THE RESEARCHER IN PROCURING THE TISSUE  
9 LITERALLY IN THE DELIVERY ROOM -- OPERATING ROOM AS  
10 OPPOSED TO RELYING ON THIRD-PARTY PROCURERS.

11 THESE, I THINK, ARE ISSUES WE WILL NEED TO  
12 THINK THROUGH IN THE 270-DAY COMMENT PERIOD. AND AS I  
13 LOOK AHEAD TO WHAT WE EVENTUALLY RECOMMEND TO THE ICOC  
14 AS SORT OF DRAFT FINAL REGULATIONS, I THINK WE'LL WANT  
15 TO ADDRESS THEM. I DON'T THINK WE CAN SETTLE THAT  
16 TODAY, AND I DON'T THINK WE SHOULD BECAUSE WE WANT TO  
17 GET MUCH MORE PUBLIC COMMENT AND SORT OF THE REST OF  
18 THE COMMITTEE INVOLVED. I THOUGHT IF WE CAN AGREE ON  
19 SORT OF THE INTERIM REGULATIONS TO AT LEAST START THE  
20 DISCUSSION OF THE OTHER TWO ISSUES.

21 LET ME STOP HERE AND MAYBE INVITE PAT, ALTA,  
22 AND ROB, WHO HAVE ALREADY BEEN THINKING ABOUT THIS, TO  
23 STEP IN. PAT, DO YOU WANT TO START OUT AND HELP US PUT  
24 THIS IN CONTEXT?

25 MS. KING: WELL, I RAISED THE QUESTION OF



1       PROCUREMENT FOR THE FOLLOWING REASONS. I WANT TO MAKE  
2       IT CLEAR AT THE OUTSET THAT, AND THIS IS NOT -- IF  
3       ANYTHING, I'VE ALWAYS BEEN PRO CHOICE, SO I'M NOT  
4       RAISING THESE QUESTIONS BECAUSE I HAVE CONCERNS ABOUT  
5       ABORTION.

6                   WHEN I WORKED ON THE EFFORT THAT NIH MADE TO  
7       HAVE REGULATIONS FOR FETAL TISSUE, ONE OF THE QUESTIONS  
8       WAS PROCUREMENT. SOME RESEARCHERS EXPRESSED DISCOMFORT  
9       AT PROCURING DIRECTLY FROM PHYSICIANS WHO PERFORM  
10      ABORTIONS. AS A PRACTICAL MATTER, MOST ABORTIONS ARE  
11      PERFORMED IN ABORTION CLINICS. SO THERE WAS A LONG  
12      DISCUSSION ABOUT HAVING EITHER FOR-PROFIT OR NONPROFIT  
13      THIRD PARTIES THAT WERE IN THE PROCUREMENT CHAIN  
14      BETWEEN THE PHYSICIAN ATTENDING THE WOMAN AND THE  
15      RESEARCHER WHO WAS INTERESTED IN OBTAINING FETAL  
16      TISSUE.

17                   SOME OF THE EXPRESSIONS WERE A CONCERN ON THE  
18      RESEARCHER'S PART THAT THEY BE CONNECTED IN THE CHAIN  
19      WITH RESPECT TO THE ABORTION CLINIC. SO I RAISE THE  
20      QUESTION HERE WHETHER WE WANTED MORE -- A DEGREE OF  
21      SEPARATION BETWEEN THE PERSON PERFORMING THE ABORTION  
22      AND THE RESEARCHER WHO WAS IN NEED OF TISSUE. AND I  
23      RAISED IT FOR THAT REASON. WOULD IT BE BETTER OR  
24      PREFERABLE TO SEPARATE TO SOME EXTENT THE RESEARCH  
25      OPERATION FROM THE PROCUREMENT? SO THAT'S WHY I RAISED

1 THE QUESTION.

2 CHAIRMAN LO: GREAT. PAT, COULD I ALSO ASK  
3 YOU TO TAKE A STEP BACK AND THINKING IN TERMS OF  
4 INTERIM REGULATIONS RATHER THAN THE LONG-TERM  
5 RECOMMENDATION, WHETHER YOU WOULD AGREE THAT CONSENT  
6 FROM THE -- THAT THE TWO KEY POINTS WE SHOULD PUT IN  
7 FOR INTERIM REGULATIONS THAT SORT OF ARE CONSISTENT  
8 WITH EXISTING LEGAL REQUIREMENTS WOULD BE CONSENT FROM  
9 THE WOMAN AND NO TIMING, NO INDUCEMENT TO ABORTION,  
10 AND, THEREFORE, MAKING THE TIME -- SEPARATING THE  
11 TIMING OF CONSENT FOR DONATION TO RESEARCH FROM THE  
12 CONSENT FOR ABORTION? YOU THINK THOSE ARE THE KEY  
13 ELEMENTS THAT WE SHOULD PUT IN IN INTERIM REGS?

14 DR. KORDOWER: I THINK THERE'S AN ADDITIONAL  
15 REGULATION THAT WE SHOULD CONSIDER AND SHOULD BE IN  
16 THERE. WHEN WE DID OUR FETAL TRANSPLANTS FOR  
17 PARKINSON'S, WE WENT OVER THIS IN QUITE DETAIL. AND  
18 THE OTHER ISSUE IS NOT ONLY THE TIMING, BUT ALSO THAT  
19 THERE SHOULD BE NO ALTERATION IN THE PROCEDURE TO  
20 FACILITATE THE PROCUREMENT OF THE TISSUE.

21 CHAIRMAN LO: ABSOLUTELY. I THINK THAT'S  
22 ACTUALLY BOTH IN THE FEDERAL STATUTE AND OUR  
23 RECOMMENDATION. THAT'S RIGHT. THAT'S ABSOLUTELY KEY.

24 BUT, PAT, DO YOU THINK THOSE ARE THE -- WE'VE  
25 ACCURATELY SORT OF CAPTURED EXISTING LEGAL

1       REQUIREMENTS?

2                   MS. KING:   YES.   I HADN'T LOOKED AT IT FROM  
3       THAT POINT OF VIEW, BUT YOU SEEM TO HAVE, YES.

4                   CHAIRMAN LO:   ALTA, CAN WE ASK YOU TO STEP IN  
5       HERE FIRST ON THE ISSUE OF THE INTERIM REGULATIONS  
6       CAPTURING EXISTING LAW.   HAVE WE DONE THAT CORRECTLY?  
7       AND THEN ASK BOTH YOU AND ROB TO SORT OF GIVE US --  
8       SHARE YOUR THINKING ON THESE OTHER TWO ISSUES?

9                   MS. CHARO:   I BELIEVE THEY HAVE.   THE ONE  
10       THING THAT I'M NOT SURE, BUT I'M JUST NOT SURE IS I  
11       THOUGHT THAT THE FEDERAL REGULATIONS, PAT, SPECIFICALLY  
12       SAID NO DIRECTED DONATION FOR TRANSPLANTATION PURPOSES.

13                   MS. KING:   THEY DID.   AND I THOUGHT ABOUT  
14       THAT.   BUT WHEN I WAS GOING OVER -- THEY, IN FACT,  
15       STATE THAT.   THAT'S THE FIRST THING.   I WAS TRYING TO  
16       FIGURE OUT WHETHER WE WOULD HAVE DIRECT DONATION.   THAT  
17       WAS GOING TO BE ONE OF MY QUESTIONS.   WERE WE AT THE  
18       STAGE WHERE YOU COULD ACTUALLY DIRECT THAT THE RESEARCH  
19       BE DONE ON A CERTAIN PERSON?

20                   BUT I THINK ALTA IS RIGHT.   I KNOW SHE'S  
21       RIGHT ABOUT THE --

22                   MS. CHARO:   SO IN THAT CASE BASICALLY, SINCE  
23       WE'RE CONTROLLED BY FEDERAL LAW, THEN IT'S NOT A MATTER  
24       OF DEBATE ABOUT THE WISDOM OF IT.   I THINK WE SIMPLY  
25       NEED TO ACCEPT THAT IT IS REALITY.

1 CHAIRMAN LO: I THINK STRATEGICALLY IT WOULD  
2 BE GOOD TO ACTUALLY MAKE SURE OUR INTERIM REGS TRACK  
3 THE LANGUAGE. OTHERWISE PEOPLE WILL SAY WHY DID YOU  
4 LEAVE THAT PROVISION OUT? WERE YOU TRYING --

5 MS. CHARO: RIGHT. I'M SORRY I DIDN'T CATCH  
6 IT ANY EARLIER. IT SOMETIMES TAKES THREE VIEWINGS  
7 BEFORE YOU SEE IT. BUT WE SHOULD PROBABLY ADD THAT IN  
8 AND TAKE THE LANGUAGE -- LIFT THE LANGUAGE OUT OF THE  
9 FEDERAL RULES.

10 CHAIRMAN LO: THAT SOUNDS GOOD. ANYTHING  
11 ELSE, ALTA, IN TERMS OF THE PROPOSED INTERIM REGS THAT  
12 YOU WANT TO CALL OUR ATTENTION TO?

13 MS. CHARO: NO. I THANK YOU FOR HAVING HAD  
14 THE OPPORTUNITY TO LOOK AT THEM EARLIER, SO I'M FINE.

15 CHAIRMAN LO: THEN LET'S ASK YOUR THOUGHTS --  
16 WHY DON'T WE TRY AND SEPARATE THE INTERIM FROM SORT OF  
17 THE MORE COMPLICATED. LET ME JUST ASK, ROB, DO YOU  
18 HAVE ANY CONCERNS ABOUT THE INTERIM REGS THAT WERE  
19 PROPOSED AS THE NEW SECTION 100085?

20 DR. TAYLOR: NO, I DON'T. BUT I DO AGREE  
21 WITH ALTA, THAT NO DIRECTED DONATION SHOULD REALLY BE  
22 EMPHASIZED BECAUSE THIS COULD REALLY BE ABUSED BY  
23 SOMEBODY --

24 CHAIRMAN LO: ABSOLUTELY.

25 DR. TAYLOR: -- WANTING TO TREAT ONE OF THEIR

1 PREVIOUS CHILDREN OR SOMETHING.

2 CHAIRMAN LO: THAT WAS EXACTLY THE CONCERN.  
3 THAT WILL BE INCLUDED IN THE FEDERAL STATUTE.

4 ARE THERE ANY MEMBERS OF THE PUBLIC ON THE  
5 CALL? THIS IS ACTUALLY A PUBLIC MEETING. IF THERE  
6 ARE, IF ANYONE WANTS TO SPEAK UP. OKAY. I DON'T KNOW  
7 THAT ANYONE FROM THE PUBLIC IS ON THE CALL.

8 MR. LOMAX: THEY WOULD BE AT THIS SITE. THIS  
9 IS THE PUBLIC SITE.

10 CHAIRMAN LO: SO MAYBE WE COULD JUST STOP  
11 THERE AND ASK FOR A MOTION TO EXPRESS THE SENSE OF THIS  
12 SUBGROUP OF THE COMMITTEE TO THE ICOC FOR THEIR MEETING  
13 IN A COUPLE OF DAYS, THAT WE APPROVE -- THAT THEY  
14 APPROVE SECTION 100085 WITH THE EMENDATION THAT WE ADD  
15 THE CLAUSE THAT JEFF AND ROB AND ALTA TALKED ABOUT TO  
16 MAKE SURE WE TRACK VERY ACCURATELY THE EXISTING LAW.  
17 WOULD SOMEONE LIKE TO MOVE THAT?

18 DR. TAYLOR: BERNIE, I KIND OF HATE TO RAISE  
19 THE POINT. AT LEAST AS I'M READING IT HERE, IT HAS  
20 DONOR'S SIGNED STATEMENT. AND YOU MENTIONED IN YOUR  
21 KIND OF PREAMBLE THE SORT OF FATHER OF THE CONCEPTUS  
22 QUESTION. I PERSONALLY PREFER NOT TO HAVE TO GET INTO  
23 THAT, BUT MAYBE THIS IS THE TIME TO DO IT IF WE HAVE  
24 TO.

25 CHAIRMAN LO: LET'S DO -- LET'S TRY AND WORK

1 OUT THE INTERIM REGS.

2 DR. HALL: YOU DON'T HAVE TO AT THIS POINT,  
3 ROB. THE POINT WOULD BE TO POSTPONE DISCUSSION ON  
4 THOSE TWO ISSUES WHERE THERE WILL BE A LOT OF  
5 DISCUSSION ON EACH OF THEM.

6 DR. TAYLOR: THAT'S GREAT.

7 DR. HALL: JUST HAVE A MINIMAL INTERIM.

8 DR. TAYLOR: PERFECT.

9 CHAIRMAN LO: THAT'S WHAT I WAS HOPING FOR.

10 MS. KING: ROB, YOU DO HAVE A POINT. THAT  
11 IS, FOR THE PARENT ISSUE, ALL OF THE CURRENT REGS REFER  
12 TO DONOR BECAUSE THEY'RE PATTERNED ON THE FETAL TISSUE  
13 FEDERAL REGULATIONS. SO TO THE EXTENT THAT SOMEBODY  
14 MIGHT UNDERSTAND THAT AS PRECLUDING FATHERS, MAYBE IT'S  
15 NOT THE SAME KIND OF ISSUE AS THE ISSUE I RAISED. THE  
16 INTERIM REGULATIONS WOULD MAKE IT CLEAR THAT  
17 (INAUDIBLE) THAT NEED CONSENT.

18 CHAIRMAN LO: WELL, WE TOOK THE LANGUAGE  
19 ACTUALLY, AS PAT SAYS, FROM THE FEDERAL REGULATIONS,  
20 AND IT JUST TALKS ABOUT DONORS. IN CONTEXT, ALL  
21 THEY'RE TALKING ABOUT IS THE WOMAN UNDERGOING THE  
22 TERMINATION OF PREGNANCY OR HAVING A SPONTANEOUS  
23 MISCARRIAGE. BUT IT DOESN'T EXPLICITLY SAY THAT, SO  
24 THERE IS SOME AMBIGUITY, I SUPPOSE, BUT IT'S THE SAME  
25 AMBIGUITY THAT'S THERE NOW IN THE CURRENT FEDERAL REGS.

1 DR. TAYLOR: THAT'S GREAT.

2 MS. CHARO: IN TERMS OF HOW WE TACKLE THIS  
3 LATER ON, KNOWING HOW THIS IS ALMOST RADIOACTIVE  
4 BECAUSE OF THE SENSE IN WHICH EVERY DECISION IS A  
5 SIGNAL ABOUT ATTITUDES ABOUT THE ROLE OF MEN IN  
6 ABORTION DECISIONS, WE DO HAVE A SAFETY VALVE, WHICH IS  
7 THAT, INDEPENDENT OF WHETHER IT'S FETAL TISSUE OR  
8 EMBRYOS OR SOMATIC CELLS OR ANYTHING, WE HAVE THE  
9 ABILITY TO SIMPLY SAY THAT WHERE CELL LINES ARE BEING  
10 DEVELOPED THAT HAVE GENETIC INFORMATION THAT REVEALS  
11 SOMETHING ABOUT AN INDIVIDUAL, THEN THOSE INDIVIDUALS  
12 ARE GOING TO BE THE ONES WE SAY HAVE THE RIGHT TO  
13 CONSENT TO THE USE OF THE TISSUE OR NOT. SO,  
14 THEREFORE, IN THAT CASE, YOU KNOW, A MALE PROGENITOR,  
15 AND I'M NOT EVEN GOING TO USE THE WORD "FATHER" HERE  
16 BEFORE YOU HAVE A BABY, IS SOMEBODY WHOSE PERSONAL  
17 INFORMATION IS IMPLICATED IN THE CELL LINES DEVELOPED  
18 FROM FETAL TISSUE. ON THAT BASIS ALONE, LIKE OTHER  
19 PEOPLE THAT WE'VE ATTENDED TO, MAY BE DESERVING OF AN  
20 OPPORTUNITY TO REFUSE CONSENT FOR USE OF THE TISSUE.

21 AND WE CAN TACKLE IT THERE JUST LIKE WE  
22 TACKLED THE ISSUE OF THE ANONYMOUS SPERM DONOR THAT  
23 CAN'T BE RECONTACTED WHOSE MATERIALS WERE USED IN AN  
24 EMBRYO THAT'S NOW BEING DONATED.

25 CHAIRMAN LO: I WOULD SUGGEST THAT WE

1 RECOGNIZE THIS AS AN ISSUE WE WANT TO ADDRESS, BUT NOT  
2 TRY AND DO IT IN THE INTERIM REGS IF THAT'S OKAY WITH  
3 EVERYBODY.

4 MR. LOMAX: FOR THE BENEFIT OF THE RECORD, IF  
5 FOLKS, AGAIN, COULD JUST TRY TO INTRODUCE THEMSELVES.

6 CHAIRMAN LO: SO WITH THAT IN MIND, CAN WE  
7 ENTERTAIN A MOTION TO APPROVE 100085 AS -- NOT APPROVE,  
8 TO HOPE ICOC ADOPTS 100085 WITH THE EMENDATION --  
9 ADDITION THAT PAT, ALTA, AND JEFF RAISED? JUST A SENSE  
10 OF THE COMMITTEE, NOT SORT OF A FORMAL.

11 MS. KING: I'LL SO MOVE.

12 DR. KORDOWER: SECOND.

13 CHAIRMAN LO: THAT WAS JEFF. ALL THOSE IN  
14 FAVOR. (ALL SAY AYE.) ANY OPPOSED? OKAY. SO IT'S A  
15 UNANIMOUS SENSE OF OUR CONFERENCE CALL THAT THE ICOC  
16 ADOPT THESE REGULATIONS.

17 NOW, WITH THAT IN PLACE, LET'S SPEND SOME  
18 TIME ADDRESSING WHAT I THINK ARE TOUGHER AND MORE  
19 COMPLICATED, IN SOME SENSE MORE INTERESTING ISSUES.  
20 ALTA, DO YOU WANT -- PAT HAD STARTED TO SORT OF HELP US  
21 THINK THROUGH THOSE ISSUES. DO YOU WANT TO ALSO MAKE  
22 SOME COMMENTS HERE, AND THEN I'LL TURN TO BOTH JEFF AND  
23 ROB AS WELL WITH REGARD TO THE ROLE OF THE PATERNAL  
24 PROGENITOR AS WELL AS THE USE OF THIRD PARTIES FOR  
25 PROCUREMENT OF FETAL TISSUE FOR RESEARCH.



1 MS. CHARO: I THINK I JUST MADE MY COMMENTS  
2 ABOUT THE MALE PROGENITOR, SO I'LL LEAVE IT TO PAT TO  
3 TALK ABOUT THE THIRD PARTIES.

4 CHAIRMAN LO: PAT DID SO AT THE BEGINNING.  
5 DO YOU WANT ADD ANYTHING TO THAT, PAT?

6 MS. KING: ARE WE GOING TO DISCUSS THE TWO  
7 ISSUES SEPARATELY, SERIATIM, OR DO YOU WANT ME TO PITCH  
8 IN ON THE POINT NOW RAISED BY I'LL JUST SAY FATHERS  
9 SINCE WE SAY MOTHERS.

10 CHAIRMAN LO: SINCE WE'RE NOT ATTEMPTING TO  
11 REACH CLOSURE ON THESE TWO ISSUES, MAYBE WE JUST -- WHY  
12 DON'T YOU CONTINUE TO SAY WHAT YOU WANTED TO SAY ABOUT  
13 THE FATHER, MALE PROGENITOR ISSUE AS WELL?

14 MS. KING: THIS IS JUST BY WAY OF HISTORY,  
15 SORT OF A FACTUAL BACKGROUND. THE FEDERAL REGULATIONS  
16 ON RESEARCH ON THE FETUS AS DISTINCT FROM FETAL TISSUE  
17 REGULATIONS DO HAVE PROVISIONS ABOUT THE ROLE OF  
18 FATHER, WHICH I COULD GO PULL DOWN DURING THE COURSE OF  
19 THE CONVERSATION MAYBE AND READ THEM. THE FETAL TISSUE  
20 TRANSPLANTATION COMMITTEE DID NOT RECOMMEND A ROLE FOR  
21 FATHERS. I THINK WE DID NOT RECOMMEND IT BECAUSE WE  
22 THOUGHT OF THIS AS AN ABORTION DECISION TOTALLY, AND WE  
23 SAW THAT AS ONLY THE RIGHT OF THE MOTHER.

24 NOW, THAT DOESN'T -- I'M NOT TRYING TO  
25 SUGGEST THAT THE NATIONAL COMMISSION WAS RIGHT AND THE

1 FETAL TISSUE -- I SERVED ON BOTH.

2 CHAIRMAN LO: YOU'VE HAD YOUR HANDS ALL OVER  
3 THIS ISSUE.

4 MS. KING: AND THE FETAL TISSUE WAS WRONG. I  
5 JUST WANTED TO PUT THE HISTORY OUT. I WOULD THINK THAT  
6 IN TODAY'S REALM VERSUS 30 ODD YEARS AGO THAT WE  
7 (INAUDIBLE) THE ISSUE WOULD BE NOT THE GENETIC  
8 COMPOSITION OF THE TISSUE. IT WOULD BE WHETHER THE  
9 FATHER OR THE PROGENITOR OF (INAUDIBLE) CONSCIENCE  
10 OBJECTIONS TO FETAL TISSUE BEING USED IN THIS FASHION.  
11 SO MAYBE THE DISCUSSION SHOULD CENTER AROUND WHETHER  
12 THAT'S REALLY THE MOTHER'S QUESTION NOW THAT SHE HAS A  
13 RIGHT TO MAKE THIS.

14 DR. KORDOWER: I THINK OF IT FROM A DIFFERENT  
15 PERSPECTIVE. AND THAT IS, ONE THING WE'RE SURE OF IS  
16 WHO THE MOTHER IS. BUT SOMEONE CLAIMING TO BE THE  
17 FATHER MAY NOT BE SO. AND SO WOULD THE DELAY IN  
18 DECIDING WHETHER SOMEONE ACTUALLY IS THE FATHER CAUSE  
19 US TO LOSE THE OPPORTUNITY TO USE THAT TISSUE IN  
20 RESEARCH? HELLO.

21 CHAIRMAN LO: I THINK WE'RE TRYING TO ABSORB  
22 THAT. IT'S AN IMPORTANT COMMENT. JEFF, WHAT ARE YOUR  
23 THOUGHTS ON -- I GUESS THE SITUATION THAT WOULD SORT OF  
24 RAISE THE MOST CONCERNS WOULD BE A SITUATION WHERE THE  
25 FATHER OR MALE PROGENITOR LATER ON SAID, WELL, I DON'T

1 HAVE A PROBLEM WITH THE ABORTION. THAT WAS HER  
2 DECISION AND SHE MADE IT AND THAT'S FINE, BUT I DO HAVE  
3 A PROBLEM WITH THE STEM CELL RESEARCH THAT'S BEING  
4 PROPOSED BEING DONE WITH CELLS THAT PARTLY CARRY HALF  
5 OF THE DNA THAT COMES FROM ME.

6 HOW WOULD YOU RESPOND? HOW DO YOU THINK WE  
7 SHOULD THINK THROUGH THAT SITUATION?

8 DR. KORDOWER: IT'S A TOUGH QUESTION. I  
9 GUESS IF THEY DON'T OBJECT TO THE ABORTION. I MEAN I'M  
10 NOT SURE HOW TO ANSWER THAT QUESTION. IF THEY DON'T  
11 GET THE ABORTION, DO THEY THEN HAVE THE RIGHT TO OBJECT  
12 TO THE USE OF THE TISSUE AFTER THE ABORTION?

13 MS. CHARO: THEY'RE SEPARATE ISSUES.  
14 OBJECTING TO THE ABORTION HAS IMPLICATIONS FOR  
15 CONTROLLING SOMEBODY ELSE'S ABILITY TO DETERMINE WHAT  
16 HAPPENS TO HER BODY. ONCE THE FETAL CADAVER IS OUTSIDE  
17 OF HER BODY, THE LEGAL INTERESTS SHE HAS ARE QUITE  
18 DIFFERENT AND ARE MUCH MORE LIKELY TO BE BALANCED  
19 AGAINST THE INTERESTS OF ANOTHER PROGENITOR, BUT THIS  
20 IS A HOTLY CONTESTED AREA.

21 DR. KORDOWER: I DON'T KNOW IS MY ANSWER.

22 CHAIRMAN LO: ROB, YOU'VE DONE RESEARCH  
23 RELATED TO THIS AREA. WHAT ARE YOUR THOUGHTS ON THIS?

24 DR. TAYLOR: I GUESS IT'S A TOUGH QUESTION.  
25 I WOULD SAY THAT THERE'S KIND OF A PRAGMATIC

1 PERSPECTIVE AND THEN THERE'S PERHAPS A PURELY ETHICAL  
2 ONE. AND IN THE PURE ETHICAL ENVIRONMENT, IT WOULD BE  
3 WONDERFUL TO HAVE EVERYBODY'S SORT OF KNOWN PATERNITY,  
4 INVOLVED PATERNITY, AND CONSENT OR NOT FROM THAT  
5 PARTNER. BUT UNFORTUNATELY, I THINK, ON THE PRACTICAL  
6 SIDE OF THIS, THE WOMEN THAT ARE CHOOSING TO TERMINATE  
7 PREGNANCIES, IN GENERAL, ARE NOT IN A KIND OF FORMALLY  
8 COUPLED OR WELL-COUPLED RELATIONSHIP. OFTENTIMES I  
9 THINK THEY'RE MAKING THESE DECISIONS WITHOUT THE  
10 CONSENT OF THE MALE PROGENITOR, AND I THINK THAT THE  
11 REALITY OF MAKING THAT COME TOGETHER IS GOING TO BE  
12 EXTREMELY DIFFICULT, AND IT LEADS TO THE POSSIBLE  
13 INTRUSION, I THINK, INTO THE DECISION FOR THE ABORTION.

14 SO I USUALLY DON'T LIKE SEPARATING THE THINGS  
15 SO MUCH THAT WAY, BUT THIS IS ONE WHERE I'M HAVING  
16 TROUBLE SEEING WHERE VENN DIAGRAMS OVERLAP A WHOLE LOT.

17 CHAIRMAN LO: IT'S COMPLICATED, TO BE SURE.  
18 ALTA RAISED THE POINT OF KIND OF CONSISTENCY WITH OTHER  
19 SITUATIONS, SUCH AS THE ANONYMOUS SPERM DONOR IN  
20 EMBRYONIC STEM CELL LINES. HOW DO THE REST OF YOU FEEL  
21 ABOUT THAT LINE OF THINKING?

22 I THINK, PAT, YOU CUT OUT A LITTLE BIT ON THE  
23 PHONE LINE, BUT I THINK WHAT I HEARD IS THAT YOU HAD  
24 ACTUALLY A DIFFERENT APPROACH THAN WHAT ALTA WAS  
25 SUGGESTING.

1 MS. KING: NO. I DIDN'T HAVE A DIFFERENT  
2 APPROACH BECAUSE I ACTUALLY HAVEN'T MADE UP MY MIND. I  
3 WAS JUST GIVING HISTORICAL BACKGROUND, BUT I HAVE AN  
4 ADDITIONAL THOUGHT BASED ON SOMETHING I JUST HEARD.

5 I DO THINK THAT, GIVEN THE FACT THAT YOU CAN  
6 HAVE AN ABORTION WITHOUT THE HUSBAND'S CONSENT, AND  
7 THAT'S A CONSTITUTIONAL DECISION, AND THAT IS SORT OF  
8 GROUNDED IN THE IDEA THAT WOMEN WILL HAVE REASONS THAT  
9 THEY WILL NOT WANT THE MALE WITH WHOM THEY HAVE HAD  
10 SEXUAL INTERCOURSE TO KNOW THAT THEY'RE HAVING AN  
11 ABORTION, THAT THESE DECISIONS SHOULD BE LEFT UP TO THE  
12 WOMAN. I THINK THAT ON THAT BASIS, IF YOU ASK FOR  
13 CONSENT FROM BOTH WITH RESPECT TO THE REMAINS, YOU  
14 UNDERMINE OR UNDERCUT THE WOMAN'S ABILITY TO BE ABLE TO  
15 CARRY OUT A PREGNANCY TERMINATION IN SAFETY FOR HER,  
16 BOTH IN PRIVACY TERMS AND ACTUALLY IN SAFETY TERMS.

17 SO I GUESS I COME DOWN ON THE SIDE THAT WE  
18 SHOULDN'T HAVE CONSENT OF THE FATHER.

19 CHAIRMAN LO: LET ME THROW IN YET ANOTHER  
20 CONSIDERATION BECAUSE I THINK THIS IS SO COMPLICATED.  
21 AND THAT'S IF WE HAVE A STEM CELL LINE DERIVED FROM  
22 FETAL TISSUE THAT WE ARE GOING TO USE IN A  
23 TRANSPLANTATION CLINICAL TRIAL, IT IS LIKELY, IT SEEMS  
24 TO ME, THAT WE WOULD WANT TO HAVE SOME SCREENING OF  
25 THAT TISSUE IN TERMS OF GENETIC DISEASES AS WELL AS

1 INFECTIOUS DISEASES, AND WHETHER YOU WOULD NEED TO HAVE  
2 SOME, AT LEAST, FAMILY HISTORY AND MEDICAL HISTORY OF  
3 THE FATHER TO PROVIDE SOME ASSURANCE THAT THERE'S NOT A  
4 FAMILIAL HISTORY OF CANCER IN THE DNA POSSIBLY FROM  
5 THAT PROGENITOR.

6 DR. KORDOWER: I CAN TELL YOU FROM OUR FETAL  
7 TRANSPLANT FILES WE DID NOT DO THAT. WE DID INFECTIOUS  
8 SCREENING, BUT THERE WAS NO GENETIC SCREENING.

9 CHAIRMAN LO: OKAY. OKAY. DO YOU WANT TO  
10 TRY -- YOU WERE SHAKING YOUR HEAD.

11 DR. CHIU: I JUST WANTED TO AGREE WITH THE  
12 LAST COMMENT, THAT BECAUSE OF ANONYMITY, IT WOULD BE  
13 VERY HARD TO TRACK INFORMATION ON LINEAGE AND ON  
14 DISEASES THAT THE FAMILY MIGHT HAVE. THAT WOULD ALSO  
15 BE ENCROACHING ON THE PRIVACY OF THE FAMILY MEMBERS.  
16 SO IT WOULD BE VERY DIFFICULT TO TRACK THAT IN ORDER TO  
17 DEVELOP THE LINE. MY UNDERSTANDING NOW IS IF YOU  
18 DEVELOP CULTURES OR LINES DERIVED FROM FETAL TISSUE,  
19 YOU CAN TEST FOR ALL THE COMPONENTS THAT THE FDA HAS  
20 ASKED FOR, BUT YOU DO NOT TRACK. UNLESS YOU CAN DO IT  
21 GENETICALLY BASED ON TISSUE, YOU DO NOT TRACK BASED ON  
22 FAMILY.

23 DR. TAYLOR: THEN DOES THAT ALSO LET THE  
24 WOMAN HERSELF, THE DONOR, OFF THE HOOK IN TERMS OF  
25 PROVIDING GENETIC INFORMATION?

1 DR. CHIU: THAT IS MY UNDERSTANDING.

2 CHAIRMAN LO: SO LET'S TRY AND THINK THROUGH.  
3 I'M GOING TO PUSH ON THIS BECAUSE I THINK THIS IS SO  
4 COMPLICATED. LET'S AGAIN CLOSE THE CASE -- ROB, I  
5 DON'T KNOW IF YOU WERE INVOLVED. THIS CAME OUT OF UC A  
6 COUPLE YEARS AGO AND THE IVF PROGRAM. IN THE  
7 INFERTILITY CONTEXT, NOT THE TRANSPLANTATION CONTEXT, A  
8 YOUNG WOMAN HAD DONATED AN OOCYTE TO AN INFERTILE  
9 COUPLE. THEY HAD A CHILD. AND THEN SUBSEQUENT TO THAT  
10 DONATION, A STRONG FAMILY HISTORY OF A GENETIC CANCER  
11 DEVELOPED IN THE FAMILY OF THE EGG DONOR. AND THERE  
12 WERE CONCERNS ABOUT WHETHER -- SHE ACTUALLY CAME FORTH  
13 AND WANTED TO DISCLOSE THAT TO THE PARENTS BECAUSE OF  
14 THE SCREENING IMPLICATIONS. AND SO THERE IS THE  
15 POSSIBILITY -- AT THAT POINT THERE WAS NO MUTATION, DNA  
16 MUTATION THAT HAD BEEN IDENTIFIED, BUT IT WAS PRETTY  
17 CLEAR FROM THE GENETICIST WHO THOUGHT IT WAS A STRONG,  
18 DOMINANT TRAIT.

19 SO THE ISSUE WOULD BE THAT THERE MAY BE  
20 FAMILY HISTORIES OF CANCER THAT CANNOT BE PICKED UP BY  
21 SCREENING, BUT COULD BE PICKED UP BY A SIMPLE FAMILY  
22 HISTORY. AND NOW THE QUESTION WOULD BE IN TERMS OF  
23 LOOKING NOW AT THE RISKS TO TRANSPLANT RECIPIENTS,  
24 WHICH IS A DIFFERENT ISSUE, IT SEEMS TO ME, THAN  
25 CONFIDENTIALITY OF THE DONOR, TO WHAT EXTENT WE NEED TO

1 FOLD THAT IN.

2 ANYONE WANTS TO SPEAK, BUT I WANT TO GET ROB  
3 AND JEFF.

4 DR. CHIU: MAY I JUST RELAY A CASE THAT I  
5 RECALL THAT WAS DISCUSSED AT THE NIH. AND THAT WAS  
6 THAT SOMEBODY HAD SENT OUT A FORM FOR, I BELIEVE, A  
7 PATIENT TO INDICATE THE FAMILIAL HISTORY OF  
8 (UNINTELLIGIBLE) OR DISEASES OF THAT SORT. AND SHE  
9 NOTED IN AND DREW THE FAMILY TREE, FATHER, AN UNCLE,  
10 ETC., AND SENT IT IN. AND THERE WAS A VERY STRONG CASE  
11 MADE THAT (INAUDIBLE) OBJECTED TO IT. HIS PROFESSION,  
12 HE WAS PILOT, FOR EXAMPLE, AND THAT WOULD AFFECT HIS  
13 ABILITY TO HIS WORK AND HIS EMPLOYER, AND IT WAS A  
14 BREACH OF HIS PRIVACY, THAT SHE -- IN ASKING HER TO  
15 PROVIDE SUCH INFORMATION, IT WAS STEPPING INTO HIS  
16 PRIVACY. SO I RECALL THAT AS SOMETHING THAT IS NOT  
17 REALLY LOOKED UPON FAVORABLY NOW. YOU CAN'T DO IT  
18 WITHOUT GIVING OUT INFORMATION ABOUT OTHER PEOPLE.

19 CHAIRMAN LO: THIS IS WHAT MAKES GENETIC  
20 INFORMATION TOUGH. CAN I GET THE COMMENTS FROM THE  
21 REST OF YOU ON THIS? AGAIN, THIS IS JUST A KICKOFF OF  
22 WHAT'S GOING TO BE A SERIES OF DISCUSSIONS, BUT ANY OF  
23 THOSE ON THE PHONE WANT TO CHIME IN ON THIS?

24 DR. TAYLOR: I GUESS I'M TRYING, AGAIN, TO  
25 THINK A LITTLE BIT ABOUT THE LIKELIHOOD OF ESTABLISHING



1 USEFUL STEM CELL LINES FOR THERAPEUTIC USES FROM FETAL  
2 TISSUE. IT HAS SOME FINITE AND RELATIVELY SMALL NUMBER  
3 ATTACHED TO IT. THE NUMBER OF OTHER TYPES OF FETAL  
4 TISSUE EXPERIMENTS THAT COULD BE UNDERTAKEN FOR WHICH  
5 THE PEDIGREES, I THINK, ARE SUBSTANTIALLY LESS  
6 IMPORTANT IS A MUCH LARGER NUMBER. AND I'M JUST A  
7 LITTLE BIT CONCERNED THAT IF WE HOLD EVERYONE TO A --  
8 I'M TRYING TO FIGURE OUT HOW WE CAN MAYBE HAVE  
9 DIFFERENT STANDARDS OF INFORMATION FOR THE TYPES OF  
10 EXPERIMENTS THAT ARE PROPOSED TO BE DONE WITH CELLS  
11 DERIVED FROM FETAL TISSUE. BECAUSE I DO AGREE THAT  
12 INSOFAR AS THE INDIVIDUALS CAN BE PROTECTED FROM UNDUE  
13 INSURANCE KINDS OF INVOLVEMENT, THAT HAVING AS MUCH  
14 INFORMATION ABOUT THOSE TISSUES FOR CANCER RISK AND  
15 OTHER THINGS FOR A LONG-TERM TRANSPLANTATION IS GOING  
16 TO BE CRITICAL AND IMPORTANT TO THE SAFETY OF THE  
17 PUBLIC.

18 ON THE OTHER HAND, I THINK IF WE HOLD  
19 EVERYONE TO THAT STANDARD, THERE ARE GOING TO BE A LOT  
20 OF PEOPLE THAT TURN DOWN THE OPPORTUNITY TO DONATE, AND  
21 THE PIPELINE TO GIVE FETAL TISSUE FOR RESEARCH IN  
22 GENERAL COULD GET PRETTY MUCH DRIED UP.

23 CHAIRMAN LO: OTHERS? JEFF, YOU'VE WORKED IN  
24 THIS AREA. WHAT ARE YOUR THOUGHTS HERE?

25 DR. KORDOWER: YOU ASKING ME?

1 CHAIRMAN LO: YEAH. YOU'RE THE ONE WITH A  
2 LOT OF HANDS-ON EXPERIENCE IN TERMS --

3 DR. KORDOWER: I'M WONDERING HOW WE'RE  
4 DEFINING FAMILY HISTORY, FIRST OF ALL. AND IF YOU LOOK  
5 HARD ENOUGH, YOU'RE LIKELY TO FIND A FAMILY HISTORY OF  
6 SOMETHING FOR EVERY DONOR YOU LOOK FOR, YOU HAVE THE  
7 POTENTIAL OF GETTING. AND I THINK EVERYTHING HAS A  
8 CERTAIN AMOUNT OF RISK. CERTAINLY WE WANT TO MINIMIZE  
9 THAT RISK, IF POSSIBLE, BUT I THINK YOU'RE OPENING UP A  
10 CAN OF WORMS HERE THAT YOU CAN'T CLOSE. BUT UNLESS YOU  
11 HAVE A DISEASE THAT IS -- FIRST OF ALL, EVEN HAVING AN  
12 ENHANCED RISK OF CANCER PER SE DOESN'T MEAN YOU ARE  
13 GETTING CANCER. AND I THINK YOU'RE OPENING UP A CAN OF  
14 WORMS HERE THAT IS GOING TO BE VERY DIFFICULT TO DEFINE  
15 AND TO MAKE, THEN, DONATION A PRACTICAL AND USEFUL  
16 RESOURCE.

17 CHAIRMAN LO: PAT AND ALTA, DO YOU WANT TO  
18 HELP US THINK THROUGH THE ISSUE OF CONFIDENTIALITY  
19 VERSUS PROTECTION OF TRANSPLANT RECIPIENTS?

20 DR. TAYLOR: APPARENTLY NOT.

21 CHAIRMAN LO: ALTA, ARE YOU STILL THERE? WE  
22 MAY HAVE LOST THEM.

23 MR. LOMAX: ALTA MIGHT HAVE HAD TO LEAVE THE  
24 CALL.

25 MS. KING: YOU HAVEN'T LOST ME. I JUST DON'T

1 KNOW WHAT TO SAY. I LIKE -- I DON'T KNOW A LOT ABOUT  
2 THE SCIENCE. I LIKED THE IDEA OF NOT TRYING TO HAVE  
3 ONE RULE THAT MIGHT COVER ALL POSSIBILITIES, ESPECIALLY  
4 AS THE RESEARCH DEVELOPS. AND THAT MAYBE WE NEED SOME  
5 GRADUATED WAY OF LOOKING AT THIS, BUT I CAN'T THINK OF  
6 A GRADUATED WAY. I MEAN IT WOULD BE POSSIBLE, OF  
7 COURSE, IF THERE WERE A WILLING FATHER WHO WAS THERE AS  
8 WELL WITH RESPECT TO THE TISSUE TO GET THE KIND OF  
9 INFORMATION WE'VE BEEN TALKING ABOUT FROM BOTH PARTIES.  
10 MAYBE WE HAVE TO SET SOME GENERAL GUIDELINES AND ALLOW  
11 THE REVIEWING BODY, BASED ON THE NATURE OF THE  
12 RESEARCH, I GUESS, IN THE FUTURE GET INFORMATION FROM  
13 BOTH THE MOTHER AND THE FATHER, SO THEY WOULD BE IN A  
14 POSITION TO EVALUATE WHETHER IT MAKES SENSE TO DO THAT  
15 GIVEN THE TYPE OF RESEARCH.

16 I'M COMPLETELY BEFUDDLED. IT'S REALLY TOUGH.

17 CHAIRMAN LO: I THINK THIS IS GOING TO BE  
18 TOUGH TO WORK OUT FOR OUR SORT OF FINAL RECOMMENDATION.  
19 I THOUGHT WE COULD JUST SORT OF GET THE DISCUSSION  
20 JUMP-STARTED.

21 ROB, IN THE E-MAIL DISCUSSIONS WE'VE HAD, YOU  
22 MADE SOME, I THOUGHT, WERE VERY, VERY GOOD COMMENTS ON  
23 THE ISSUE OF THIRD-PARTY INVOLVEMENT IN THE PROCUREMENT  
24 OF FETAL TISSUE FOR RESEARCH AND SORT OF MADE SOME  
25 POINTS IN FAVOR OF THE RESEARCHER BEING INVOLVED IN THE

1 OPERATING ROOM IN TERMS OF THE QUALITY, THE FRESHNESS  
2 OF THE TISSUE. DO YOU WANT TO SORT OF SAY THAT? AND  
3 I'D LIKE TO GET JEFF'S COMMENTS AS WELL BECAUSE IT'S  
4 SOMETHING I KNOW HE HAS EXPERIENCE WITH.

5 DR. TAYLOR: LET ME START BY I ABSOLUTELY  
6 RESPECT PAT'S KIND OF CONCERNS ABOUT BOTH PROTECTION OF  
7 INVESTIGATORS FROM POSSIBLE BACKLASH OF BEING INVOLVED  
8 IN AN ABORTION CLINIC ENVIRONMENT. BUT I GUESS AS  
9 SOMEBODY WHO'S DONE SOME OF THIS RESEARCH IN THE PAST  
10 AND REALLY ALL OF MY WORK IS KIND OF BASED ON PRIMARY  
11 HUMAN TISSUE TYPES OF INVESTIGATIONS, I CERTAINLY HAVE  
12 A BIAS TO WANTING TO BE THERE BOTH TO CONSENT THE  
13 PATIENTS, TO SORT OF HAVE DIRECT CONTACT WITH THEM, TO  
14 INFORM THEM WHAT MY RESEARCH PROTOCOLS ARE ALL ABOUT,  
15 TO BE ABLE TO ADDRESS QUESTIONS THAT THEY HAVE. AND I  
16 THINK THAT THOSE ARE PROBABLY EVEN GREATER IN THE STEM  
17 CELL AREA. AND THAT ACTUALLY REQUIRES A CERTAIN AMOUNT  
18 OF CONTACT WITH THE SUBJECT. AND TO BE PRESENT AT THE  
19 TIME THAT THE PROCEDURE IS DONE AND AS IMMEDIATELY  
20 AVAILABLE AS POSSIBLE SO THAT THE TISSUE CAN BE HANDLED  
21 IN THE MOST EXPEDITIOUS WAY TO PROTECT RNA AND PROTEIN  
22 FROM DEGRADATION AND TO MAKE SURE THAT THAT TISSUE KIND  
23 OF GETS INTO THE RIGHT FIXATIVE OR FROZEN OR HOWEVER  
24 IT'S GOING TO BE PREPARED. AND TO RELY ON A SORT OF  
25 THIRD PARTY TO PROVIDE THOSE SERVICES, CONSENTING AS

1 WELL AS TISSUE HANDLING, I'VE JUST NEVER PERSONALLY  
2 BEEN COMFORTABLE WITH HAVING THAT DEGREE OF SEPARATION.

3 DR. KORDOWER: WE ACTUALLY DID IT THAT WAY.  
4 WE INVOKED THE COLLABORATION OF THE PEOPLE AT THE  
5 ABORTION CLINIC. THEY HANDLED ALL THE CONSENT. THEY  
6 HANDLED THE PROCUREMENT OF THE TISSUE. THEY WERE  
7 TRAINED BY OUR GROUP IN TERMS OF HOW TO HANDLE THE  
8 TISSUE ONCE IT WAS PROCURED, WHAT KIND OF MEDIUM TO PUT  
9 IT IN, HOW TO STORE IT. AND ONCE THE TISSUE IS  
10 PROCURED, SOMEONE FROM OUR LAB GROUP WENT AND GOT IT,  
11 BROUGHT IT BACK TO OUR LABORATORY FOR FURTHER  
12 DISSECTION. I GUESS IT COULD WORK EITHER WAY.

13 MS. KING: I THINK THERE ARE TWO DIFFERENT  
14 ISSUES HERE AND WE SHOULD CLARIFY THEM. HISTORICALLY  
15 WHENEVER WE'VE DONE ORGAN OR TISSUE TRANSPLANTATION, AT  
16 LEAST THAT I'M AWARE OF, WE WANTED A SEPARATION BETWEEN  
17 THE PERSON PROCURING THE ORGAN OR TISSUE AND WHERE IT  
18 WOULD GO AFTER IT WAS PROCURED. I THINK THIS GOES BACK  
19 TO KIDNEY TRANSPLANTS. SO THE LATTER DESCRIPTION THAT  
20 I JUST HEARD WOULD BE IN ACCORD WITH THAT HISTORY.

21 WHAT ROB DESCRIBED, I THINK, WOULD NOT  
22 BECAUSE HE DESCRIBED IT AS WANTING TO PARTICIPATE IN  
23 CONSENT OF THE PATIENT, WANTING TO BE PRESENT. SO I  
24 THINK WE HAVE TWO DIFFERENT SITUATIONS.

25 ONE OF THE REASONS FOR THE ORIGINAL

1 SEPARATION RULE -- THIS DOESN'T INVOLVE THIRD PARTIES  
2 NOW. I HAVEN'T GOTTEN TO THAT. ONE OF THE REASONS FOR  
3 THE ORIGINAL SEPARATION RULE WAS THE PROTECTION FOR THE  
4 DONOR, THAT YOU WOULD STILL WORRY ABOUT COERCION OR  
5 INDUCEMENT IF YOU HAD BOTH THE PARTY WHO'S GOING TO  
6 RECEIVE AND THE PARTY WHO WAS GOING TO DONATE HANDLED  
7 BY THE SAME PERSON. SO I WOULD THINK THAT THAT'S ONE  
8 SET OF ISSUES.

9 THE OTHER SET OF ISSUES IS WOULD YOU HAVE A  
10 THIRD-PARTY PERSON. SO I HAVEN'T GOTTEN TO THAT, JUST  
11 LISTENING TO THE TWO OF YOU TALK ABOUT WHAT YOUR  
12 PRACTICES ARE.

13 DR. KORDOWER: MAYBE I'M MISUNDERSTANDING  
14 WHAT WE MEAN BY THIRD PARTY.

15 MS. KING: A THIRD PARTY IS THAT THERE'S AN  
16 INTERMEDIARY BETWEEN THE PERSON OBTAINING THE TISSUE  
17 AND THE PERSON WHO WANTS TO USE IT. IN OTHER WORDS,  
18 YOU CAN HAVE A NONPROFIT INTERMEDIARY THAT --

19 DR. KORDOWER: I SEE. OKAY. I GOT IT.

20 CHAIRMAN LO: PAT, DID YOU WANT TO SAY MORE  
21 ABOUT THE THIRD-PARTY ISSUE AT THIS POINT JUST TO SORT  
22 OF, AGAIN, GET THE ISSUES OUT?

23 MS. KING: I THINK I REALLY SAID THE  
24 THIRD-PARTY QUESTION IS, FOR ME, IN THESE TIMES, WITH  
25 STEM CELL RESEARCH ALREADY BEING CONTROVERSIAL, THAT

1 THIS IS GOING TO MAKE IT EVEN MORE SO. IF RESEARCHERS  
2 DON'T FEEL THAT THIS IS A PROBLEM, I'M NOT GOING TO  
3 CONTINUE TO RAISE IT IF THEY FEEL COMFORTABLE ABOUT THE  
4 THIRD-PARTY PROBLEM.

5 I DON'T THINK THAT WHAT ROB DESCRIBED,  
6 HOWEVER, I WOULDN'T BE COMFORTABLE WITH THAT. AND THAT  
7 IS DIRECT INVOLVEMENT IN PROCUREMENT OF THE TISSUE  
8 WORKING WITH PEOPLE DIRECTLY IN THE ABORTION CLINIC.  
9 SO I UNDERSTAND HIS REASONS FOR WANTING TO DO SO. I  
10 JUST THINK THAT RAISES -- IT RAISES A DIFFERENT ISSUE  
11 FOR ME. IT'S NOT A QUESTION OF TRYING TO PROTECT THE  
12 RESEARCHER. IT'S A QUESTION OF NOW TRYING TO PROTECT  
13 THE WOMAN UNDERGOING ABORTION.

14 CHAIRMAN LO: ROB, IS THERE A WAY OF  
15 SEPARATING, I GUESS, THE ABORTION PROCEDURE WITH THE  
16 HANDLING OF THE TISSUE IMMEDIATELY AFTERWARDS? I'M  
17 TRYING TO -- WHAT EXACTLY IS THE EXTENT OF YOUR  
18 INVOLVEMENT? I GUESS IF IT DOESN'T AFFECT THE WAY THE  
19 ABORTION PROCEDURE IS HANDLED, BUT IT'S REALLY A MATTER  
20 OF RECEIVING THE TISSUE AFTER THE ABORTION IS  
21 COMPLETED, I'M WONDERING IF THAT WOULD ADDRESS PAT'S  
22 CONCERNS OR, PAT, IT'S REALLY JUST A SORT OF THE  
23 PRESENCE HOVERING AROUND THE ABORTION CLINIC THAT SORT  
24 OF CAUSES PAT'S CONCERN.

25 DR. TAYLOR: I SENSE THAT ACTUALLY PAT DOES

1 RAISE KIND OF THE COERCION CONCERN THAT POTENTIALLY IS  
2 GREATER WHEN THERE'S A TRULY INTERESTED PARTY. I  
3 JUST -- IT'S REALLY JUST KIND OF BASED ON MY OWN  
4 EXPERIENCE IN KIND OF ESTABLISHING COLLABORATIVE  
5 RELATIONSHIPS RATHER THAN MORE INDIRECT ONES, THAT  
6 THERE ARE TIMES WHEN IT'S UNCLEAR -- THE CLINICIAN  
7 OBVIOUSLY WHO'S DOING THE PROCEDURE SHOULD ALWAYS BE  
8 MAKING THE RIGHT CHOICES FOR THAT SUBJECT, THE PATIENT.  
9 AND IF YOU THINK YOU'RE DOING AN ABORTION, YOU DO A D&C  
10 AND YOU DON'T SEE ANYTHING THAT REALLY LOOKS LIKE  
11 TISSUE THERE, THEN THERE'S A RISK THAT THAT WOMAN COULD  
12 HAVE AN ECTOPIC PREGNANCY, A TUBAL PREGNANCY, AND  
13 THAT'S SOMETHING THAT SOMEONE -- I THINK EVERYBODY  
14 NEEDS TO BE AWARE OF AND THEY WANT TO MAKE SURE THAT --  
15 I'M NOT SURE THAT A THIRD PARTY WOULD NECESSARILY  
16 RECOGNIZE THAT PARTS OF THE TISSUE THAT WERE SUPPOSED  
17 TO BE THERE MIGHT NOT BE.

18 MAYBE JEFF HAS HAD MORE EXPERIENCE FARMING  
19 OUT SOME OF THIS AND FEELS COMFORTABLE WITH IT. MAYBE  
20 I'M A LITTLE BIT TOO PARANOID MYSELF ABOUT THE WAY I DO  
21 THINGS. I DO UNDERSTAND PAT'S CONCERN ABOUT MAYBE IT'S  
22 A MORE COERCIVE ATMOSPHERE IF THE INVESTIGATORS  
23 THEMSELVES ARE THERE OBTAINING CONSENT.

24 AGAIN, MY OPINION IS IS THAT THE MOST  
25 INFORMED PERSON SHOULD BE OBTAINING CONSENT AND



1 ANSWERING QUESTIONS, BUT THAT'S JUST AN OPINION.

2 DR. KORDOWER: JUST FOR CLARITY, WHEN WE DID  
3 OUR STUDIES, THE PERSON OBTAINING THE TISSUE WAS THE  
4 PERSON WHO HAD PREVIOUSLY BEEN DOING THE ABORTIONS AND  
5 STILL DOING THE ABORTIONS AT THE CLINIC. IT WASN'T  
6 THAT WE BROUGHT IN A THIRD PERSON FOR EXPERIMENTAL  
7 PURPOSES WHO WAS, AGAIN, THE PERSON WHO WAS DOING IT  
8 NORMALLY. AND, AGAIN, NOT TO CHANGE ANY OF THE  
9 PROCEDURES ONE IOTA.

10 CHAIRMAN LO: WELL, THIS IS AN IMPORTANT AND  
11 COMPLICATED ISSUE. MY SENSE IS THAT WE'RE CERTAINLY  
12 NOT GOING TO SETTLE IT TODAY. I DOUBT THAT WE'LL GET  
13 TO IT IN MAY BECAUSE WE'LL HAVE SO MANY OTHER THINGS ON  
14 THE AGENDA. BUT I THINK, ASSUMING THAT THE ICOC PASSES  
15 INTERIM REGULATIONS, THEN WE HAVE A 270-DAY PERIOD  
16 WHERE I THINK WE DO NEED TO DELIBERATE ABOUT THIS TO  
17 TRY AND ADDRESS THESE ISSUES IN A PUBLIC MEETING AND  
18 MAKE RECOMMENDATIONS THAT WOULD THEN BE SENT BACK TO  
19 THE ICOC AND GO THROUGH THIS 45-DAY COMMENT PERIOD.

20 I THINK AT LEAST WE'RE NOW, I THINK, WELL ON  
21 THE ROAD TO IDENTIFYING WHAT THE PERTINENT  
22 CONSIDERATIONS ARE. I DON'T THINK WE'VE WORKED OUT  
23 KIND OF HOW TO SORT THEM OUT, BUT I THINK IT'S A GOOD  
24 START.

25 MS. KING: THIS IS PAT. I'M GOING TO GO

1 LEAVE BECAUSE I'M TEACHING.

2 CHAIRMAN LO: OKAY. THANK YOU, PAT. AND WE  
3 WILL BE BACK TO YOU ON THIS ISSUE. THAT IS --

4 MS. KING: THANK ALL OF YOU BECAUSE EVERYBODY  
5 GOT ME TO THINK ABOUT IT SOME MORE.

6 CHAIRMAN LO: GOOD. I THINK THAT'S THE WHOLE  
7 POINT OF WHAT WE NEED TO DO IS ALL THINK ABOUT IT.  
8 WE'VE GOT DIFFERENT PERSPECTIVES WHICH ARE VERY USEFUL,  
9 AND HOPEFULLY WE CAN COME TOGETHER AND MAKE SOME  
10 CONSENSUS GUIDELINES.

11 SO THANKS, PAT, AND THANKS, JEFF AND ROB, AS  
12 WELL. AND, AGAIN, I THINK YOUR THOUGHTS ARE CRUCIAL  
13 BECAUSE YOU'VE BEEN INVOLVED WITH RESEARCH WITH FETAL  
14 TISSUE. AND I THINK WE HAVE TO SORT OF KEEP THAT  
15 UNDERSTANDING OF WHAT ACTUALLY GOES ON AND WHAT'S  
16 POSSIBLE. BUT THANKS AGAIN. AND THEN WE WILL PASS OUR  
17 SENSE OF THE COMMITTEE ON THE ICOC AND THEN BE IN TOUCH  
18 WITH YOU AGAIN BEFORE THE MAY MEETING. THANKS.

19 HOPE THE WEATHER IS BETTER AT YOUR PLACE THAN  
20 IT IS FOR US. THANKS.

21 (THE MEETING WAS THEN CONCLUDED AT 12:58  
22 P. M. )

23

24


25

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 TELEPHONICALLY AS INDICATED BELOW

210 KING STREET  
SAN FRANCISCO, CALIFORNIA  
ON  
APRIL 4, 2006

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  
BARRISTER' S REPORTING SERVICE  
1072 S. E. BRISTOL STREET  
SUITE 100  
SANTA ANA HEIGHTS, CALIFORNIA  
(714) 444-4100