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

REGULAR MEETING

LOCATION:	LUXE HOTEL 11461 W. SUNSET BOULEVARD LOS ANGELES, CALIFORNIA
DATE:	FRIDAY, JULY 25, 2008 9 A.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
BRS FILE NO.:	81739

I N D E X

1072 SE BRISTOL STREET, COSTA MESA, CALIFORNIA 92626
1-800-622-6092 1-714-444-4100 EMAIL: DEPO@DEPO1.COM

LOS ANGELES, CALIFORNIA; FRIDAY, JULY 25, 2008

9 A.M.

CHAIRMAN LO: OKAY. I'D LIKE TO WELCOME EVERYBODY AND ASK PEOPLE TO GET SETTLED. IT TURNS OUT WE WILL NOT HAVE A QUORUM TODAY, SO WE ARE JUST GOING TO HAVE A DISCUSSION AND BE ADVISORY TO THE ICOC. BUT IT WILL BE IMPORTANT. THERE ARE A NUMBER OF ISSUES, IMPORTANT ISSUES TO DISCUSS.

I'M GOING TO ASK SHERRY TO START AND SORT OF FORMALLY GREET US. I FIRST WANT TO THANK YOU FOR THIS GORGEOUS WEATHER THAT YOU BROUGHT US IN LOS ANGELES.

CO-CHAIR LANSING: I WANT TO TAKE FULL RESPONSIBILITY FOR THE WEATHER. IT'S TOTALLY WITHIN MY CONTROL. SO THANK YOU.

I WANT TO WELCOME ALL OF YOU AND TELL YOU AGAIN WHAT AN HONOR IT IS FOR ME PERSONALLY TO SERVE ON THIS COMMITTEE, AND HOW GRATEFUL I AM TO ALL OF THE MEMBERS OF THIS COMMITTEE. I THANK YOU VERY, VERY, VERY MUCH FOR YOUR TIME. THIS IS OUR TWELFTH MEETING; AND AS I SAID WHEN WE FIRST STARTED THIS, THIS IS A CONTINUAL PROCESS THAT WILL GO ON IN ALL OF OUR LIFETIMES, I WOULD SAY, FOREVER UNTIL THE LAST DISEASE IS CONQUERED, DO YOU KNOW. AND WE ARE

A CONTINUAL WORK IN PROGRESS. WE WILL CONSTANTLY BE REEVALUATING WHERE WE ARE IN STEM CELL RESEARCH. I DON'T NEED TO TELL ALL OF YOU HOW FAST THE FIELD IS MOVING. AND IN ORDER TO KEEP UP WITH IT, WE CONSTANTLY HAVE TO LOOK AT THE DECISIONS WE'VE MADE AND QUESTION THEM IN THE LIGHT OF WHAT HAPPENS THROUGH SCIENCE.

WE ALSO WANT OUR POLICIES TO BE CONSISTENT. WE WANT OUR POLICIES TO BE CONSISTENT WITHIN OURSELVES OBVIOUSLY, BUT WE ALSO HAVE TO LOOK WHAT IS HAPPENING IN OTHER STATES AND WITH THE NATIONAL ACADEMY OF SCIENCE.

IN LIGHT OF THAT, WE DIRECTED OUR STAFF TO LISTEN TO THE CONSTITUENCIES WITHIN THE STATE TO HEAR WHAT THEY SAID AND TO REPORT BACK TO US. WE ALSO ASKED THEM TO LOOK AT WHAT'S HAPPENING IN THE NATIONAL AND INTERNATIONAL LEVEL IN THE FIELD OF SCIENCE, AND SOME OF THAT IS IN YOUR INFORMATION PACKETS.

AS YOU KNOW, WE TOOK A VERY CONSERVATIVE VIEW WHEN WE STARTED, AND WE FELT THAT WAS THE PRUDENT VIEW. NOW, IN OUR MEETING TODAY, WE WANT TO LOOK BACK AT SOME OF THOSE DECISIONS AND MAKE SURE THEY'RE RIGHT, MAKE SURE THEY'RE CORRECT, AND IF POSSIBLE REEVALUATE OR EVEN CHANGE SOME OF THEM.

IT'S GOING TO BE A HEALTHY DISCUSSION TODAY.

I ALSO WANT TO SAY, IN CLOSING, HOW GRATEFUL I AM TO ALL OF YOU IN THE PUBLIC. I FEEL AS IF I KNOW MOST OF YOU NOW, AND YOU'RE PART OF OUR TEAM. THIS IS A COLLABORATIVE EFFORT FOR ALL OF US TO DO THE BEST THAT WE CAN DO IN OUR AREA FOR THE PATIENTS TO LEAD TO THE CLOSEST CLINICAL TRIALS THAT WE CAN IMAGINE.

I ALSO WANT TO GIVE A SPECIAL THANK YOU TO PAT KING, WHO REGRETTABLY HAD TO RESIGN FROM OUR COMMITTEE DUE TO TIME AND TRAVEL CONSTRAINTS. WE'RE GRATEFUL FOR HER HELP, WE'RE GRATEFUL FOR EVERYTHING THAT SHE'S DONE, AND WE MISS HER.

SO, AGAIN, THANK YOU TO ALL OF YOU FOR COMING TODAY. THANK YOU TO THE PUBLIC WHO, AS I SAID, IS PART OF EVERYTHING THAT WE DO. THANK YOU ALL FOR YOUR TIME AND WELCOME. I LOOK FORWARD TO TODAY. THE TOPICS ARE INTERESTING, AND WE'RE GOING TO HAVE A LOT OF DETAILED DISCUSSION. THANKS AGAIN.

CHAIRMAN LO: THANKS, SHERRY. I JUST WANT TO, FIRST OF ALL, ADD MY OWN WELCOME AND THANKS TO THE COMMITTEE MEMBERS FOR THEIR HARD WORK AND CONTRIBUTING. I ALSO WANT TO, FIRST OF ALL, NOTE TO THANK PAT KING. PAT WAS APPOINTED TO THE GOVERNING

COMMITTEE AT HARVARD, WHICH IS AN ENORMOUS RESPONSIBILITY. IT'S TAKEN UP AN INCREDIBLE AMOUNT OF HER TIME. SHE FELT THAT, MUCH AS SHE ENJOYED THIS WORK AND THOUGHT IT WAS IMPORTANT, THAT TRAVELING FROM THE EAST COAST WAS JUST TOO MUCH. I REALLY WANT TO ACKNOWLEDGE HOW MUCH SHE'S HELPED US AND ALSO HELPED ME PERSONALLY TO THINK THROUGH THESE DIFFICULT ISSUES.

AS SHERRY SO NICELY SAID, I THINK OUR TASK TODAY IS TO SORT OF TAKE A LOOK AT OUR REGULATION WITH AN EYE TOWARDS THE EVOLVING SCIENCE, THE SCIENTIFIC NEEDS, AND WHAT'S GOING ON IN THE POLICY SPHERE IN OTHER STATES AND OTHER COUNTRIES AND THE NAS.

AS SHERRY ALWAYS REMINDS US, THESE REGULATIONS ARE MEANT TO BE DYNAMIC AND NOT STATIC, AND WE NEED TO SORT OF MAKE SURE WE'RE UP TO DATE. TODAY WE'LL BE TALKING ABOUT SOME ISSUES REGARDING THE USE OF HUMAN EMBRYONIC STEM CELL LINES AND THE DERIVATION OF NEW EMBRYONIC STEM CELL LINES AND WHETHER OUR CURRENT POLICIES, CURRENT REGULATIONS REALLY CAPTURE THE BEST APPROACH TO TAKE.

I WANT TO MAKE VERY CLEAR THAT WE'RE NOT GOING TO TALK TODAY ABOUT THE ISSUE OF OOCYTE DONATION SPECIFICALLY FOR RESEARCH OR PAYMENT FOR

OOCYTES IN THAT CONTEXT. THAT'S A MUCH -- IT'S A MUCH DIFFERENT ISSUE, I THINK, CONCEPTUALLY AS ONE WHERE PROP 71 HAS IMPORTANT THINGS TO SAY. SO ALTHOUGH THERE HAVE BEEN SOME REPORTS IN THE PRESS THAT WE WERE GOING TO DISCUSS THAT, WE SORT OF SAID THAT'S NOT OUR DISCUSSION. WE'RE TALKING ABOUT OOCYTES THAT HAVE EITHER BEEN DONATED FOR THE DERIVATION OF NEW STEM CELL LINES WHICH ARE BEING OFFERED TO STEM CELL RESEARCH.

NOW, WE HAVE A COUPLE OF OTHER THINGS WE'RE GOING TO DO. FIRST STAFF, GEOFF LOMAX, AGAIN, HE'S DONE A WONDERFUL JOB SORT OF PREPPING US FOR THIS, IS GOING TO GIVE US SOME BRIEF UPDATES JUST TO KEEP THOSE OF US ON THE SWG UP TO DATE ON THE SCIENTIFIC AND POLICY ISSUE. THE MAIN SUBSTANTIVE DISCUSSION WE'RE GOING TO DO TODAY IS THE UTILIZATION OF STEM CELL LINES AND EMBRYOS TO DERIVE EMBRYONIC STEM CELL LINES.

AND FINALLY, IF WE HAVE TIME, WE'RE GOING TO HEAR ABOUT THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH EFFORTS TO DEVELOP A SYSTEM TO TRACK OOCYTE DONATION. BUT LET ME JUST TURN IT OVER NOW TO GEOFF TO GIVE US THE, I GUESS, A FORMAL ROLL CALL AND STAFF REPORT.

DR. LOMAX: THANK YOU VERY MUCH, BERNIE

AND MEMBERS OF THE WORKING GROUP. QUICKLY, I'D LIKE TO DO A ROLL CALL.

ROBERT TAYLOR.

DR. TAYLOR: HERE.

DR. LOMAX: ANN KIESSLING.

DR. KIESSLING: HERE.

DR. LOMAX: FRANCISCO PRIETO.

DR. PRIETO: HERE.

DR. LOMAX: ALTA CHARO.

MS. CHARO: HERE.

DR. LOMAX: BERNIE LO.

CHAIRMAN LO: HERE.

DR. LOMAX: SHERRY LANSING.

CO-CHAIR LANSING: HERE.

DR. LOMAX: ROBERT KLEIN.

MR. KLEIN: HERE.

DR. LOMAX: MARCY FEIT.

MS. FEIT: HERE.

DR. LOMAX: JEFF SHEEHY.

MR. SHEEHY: HERE.

DR. LOMAX: JOSE CIBELLI.

DR. CIBELLI: HERE.

DR. LOMAX: THOSE ARE ALL THE MEMBERS PRESENT TODAY, AND, AGAIN, WE'RE NOT UNDER A QUORUM AND MAY WELL NOT BE FOR THE DAY.

WHAT I'D LIKE TO DO IS BRIEFLY UPDATE YOU ALL ON A NUMBER OF ITEMS THAT ARE ONGOING IN NATURE, AND THEY START WITH BRINGING YOU UP TO DATE ON THE MOST RECENT REGULATORY REVISIONS TO THE STANDARDS. A YEAR AGO YOU RECOMMENDED REVISIONS TO THREE SECTIONS OF THE REGULATIONS, AND I'VE BULLETED OUT THE SUBSTANTIAL REVISIONS. ONE, TO INCLUDE THE JAPANESE SUBSTEM CELL LINES DERIVED UNDER THE JAPANESE GUIDELINES AS ACCEPTABLY DERIVED. WE CLARIFIED LANGUAGE AROUND PAYMENTS FOR RESEARCH MATERIALS, AND WE SET A STANDARD TO ALLOW THE USE OF CERTAIN CELLS FOR IPS EXPERIMENTS. THESE ARE THE SO-CALLED ARCHIVED CELL LINES THAT WE WERE NOT ABLE TO GO BACK AND BRING UP -- GET THE LEVELS OF CONSENT THAT WOULD BE EXPECTED FOR MATERIALS PIPELINE TODAY.

SO THOSE REGULATIONS HAVE BECOME EFFECTIVE AS OF THE END OF JUNE. YOU HAVE A REVISED SET OF MATERIALS IN YOUR PACKET THAT REFLECT THE MOST RECENT CHANGES, AND THOSE MATERIALS ARE ALSO AT THE BACK OF THE ROOM IF MEMBERS OF THE PUBLIC WOULD LIKE TO TAKE A LOOK AT THEM.

THIS IS JUST A REFRESHER ON THE TIMELINE TO REMIND FOLKS OF THE PROCESS. ANY TIME WE GO THROUGH A REVISION OF THE REGULATIONS, YOU ALL MAKE RECOMMENDATION, THAT RECOMMENDATION WILL GO TO THE

ICOC. WE TYPICALLY HAVE A NUMBER OF ROUNDS OF PUBLIC COMMENT, AT LEAST ONE. IN THIS CASE WE HAD TWO CYCLES OF PUBLIC COMMENT. THE ICOC PROVIDED FINAL APPROVAL EARLY THIS YEAR, AND THE AOL REVIEW CONCLUDED, AGAIN, AT THE END OF MAY WITH A JUNE EFFECTIVE DATE.

I WANTED TO UPDATE YOU ON ANOTHER PROGRAMMATIC PIECE THAT WE'VE DEVELOPED AND ACTUALLY IMPLEMENTED IT AS OF THIS YEAR. WE INITIATED A PROGRAM OF SITE VISITS TO GRANTEE INSTITUTIONS TO REVIEW THEIR COMPLIANCE WITH THE REGULATIONS AND POLICIES THAT YOU ALL HAVE RECOMMENDED. THE SITE VISITS INCLUDE A REVIEW OF THE OVERALL PROCEDURES AND POLICIES, WHICH THE INSTITUTIONAL STEM CELL RESEARCH OVERSIGHT COMMITTEES OPERATE UNDER.

WE THEN LOOK VERY SPECIFICALLY AND WE LOOK AT APPLICATIONS AND PERFORM EFFECTIVELY AN AUDIT OF THOSE APPLICATIONS TO ENSURE THAT THE REQUIRED REVIEWS AND APPROVAL ARE IN ACCORDANCE WITH THE REGULATORY REQUIREMENTS. AND WE ALSO TALK TO THE PI'S ABOUT VARIOUS REPORTING REQUIREMENTS EXPECTED OF THEM, REPORTING REQUIREMENTS SUCH AS THE NEED TO REPORT PUBLICATIONS OR INTELLECTUAL PROPERTY DEVELOPMENTS.

WE ALSO TAKE A LOOK AT FINANCIAL RECORDS

TO ENSURE THAT SPECIFIC APPLICATIONS, THAT THE MONEY IS GOING WHERE IT'S SUPPOSED TO GO. A COLLEAGUE OF MINE, CYNTHIA SCHAFFER, LEADS THAT EFFORT, AND SHE'S DONE A TERRIFIC JOB THERE. IN ADDITION TO COMPLIANCE-RELATED ACTIVITIES, WE BUILD IN DURING THE SITE VISIT A SET OF INFORMATIONAL INTERVIEWS WITH THE STAFF AND THE PRINCIPAL INVESTIGATORS TO INFORM THE POLICY DELIBERATIONS YOU ALL ARE ENGAGED IN.

AND SOME OF THE COMMENTS YOU'VE GOT, FOR EXAMPLE, A LETTER FROM STANFORD UNIVERSITY IS REALLY A REFLECTION OF THAT INTERACTION TO SIT DOWN AND DISCUSS WITH THEM SOME OF THE VERY SPECIFIC ISSUES THAT YOU ALL ARE SEEKING INPUT ON. SO I THINK WE SORT OF ACCOMPLISHED TWO THINGS HERE. WE REALLY ENSURE A HIGH LEVEL OF COMPLIANCE AND REALLY SET EXPECTATIONS WITH REGARD TO THE INSTITUTIONS, AND WE GET QUALITY FEEDBACK FOR THE PURPOSES OF THESE MEETINGS.

JUST SOME VERY BRIEF COMMENTS BASED ON SOME INITIAL VISITS. WE DO BELIEVE THAT THE SITE VISITS WILL SUPPORT EFFECTIVE PROGRAM OVERSIGHT. IT'S VERY GOOD FOR THE INSTITUTIONS TO HEAR FROM US WHAT WE'RE EXPECTING THEM IN REGARDS TO THEIR REVIEWS AND APPROVALS. WE'VE ALSO BECOME AWARE THAT

WE THINK THERE ARE STEPS WE CAN TAKE INTERNALLY TO SET MORE STANDARDIZED DOCUMENTATION PROCEDURES FOR THEIR REVIEWS AND APPROVALS. SO WE'RE GOING TO BE WORKING ON THINGS LIKE A MODEL APPROVAL LETTER FOR STEM CELL RESEARCH OVERSIGHT COMMITTEE. AGAIN, THIS IS REALLY TO DEVELOP AS MUCH CONSISTENCY AS POSSIBLE IN THE APPROVAL PROCESS AND MORE SPECIFICALLY WITH DOCUMENTATION OF THAT PROCESS.

IN TERMS OF THE INTERVIEWS, AGAIN, THIS IS A COMMON THEME. I THINK WE SORT OF MENTIONED THIS AT THE LAST FOUR MEETINGS, BUT VERIFICATION OF ACCEPTABLY DERIVED CELL LINES CONTINUES TO REQUIRE A SUBSTANTIAL RESOURCE COMMITMENT ON THE PART OF INSTITUTIONS. AND THEY SORT OF CONTINUE TO SORT OF COMMENT THAT ANYTHING WE CAN DO TO DEVELOP A LIST OF SOME KIND OF MECHANISM THAT IDENTIFIES CELL LINES THAT ARE APPROPRIATE FOR USE IN RESEARCH, AND THAT LIST, PEOPLE COULD GO TO THAT LIST AS OPPOSED TO EVALUATING CELL LINES ON AN ONGOING BASIS. THAT WOULD BE A TREMENDOUS HELP.

AND FURTHER, CLEARLY, I THINK THIS IS A REFLECTION OF THE FACT THAT A LOT OF THE COMMITTEES AND A LOT OF PEOPLE OUT HERE REALLY LOOKING TO WHERE WE WANT TO GO WITH OUR RESEARCH. THEY REALLY SUGGESTED THE APPLICATION OF CELL THERAPIES, THAT

THE CLINICAL APPLICATION AND THE CLINICAL TRIALS IS A NEW TERRITORY THAT WILL REQUIRE GUIDANCE AND A LOT OF THOUGHT. SO PERHAPS THAT'S SOMETHING TO LOOK FORWARD TO IN THE FUTURE, BUT MORE EVEN IN THE NEAR FUTURE BECAUSE ALREADY PEOPLE ARE REALLY STARTING TO THINK SERIOUSLY ABOUT WHAT ABILITY THEY HAVE IN REGARDS TO CLINICAL TRIALS.

GIVEN THAT WE RECOGNIZE THIS PROBLEM OF CELL LINES AND WHAT CELL LINES ARE CONSIDERED ACCEPTABLY DERIVED AND THIS PROBLEM OF DOCUMENTATION OF CELL LINES, IN ADDITION TO SORT OF LISTING WHAT FOLKS HAVE TO SAY, WE HAVE BEGUN TO REACH OUT TO NATIONAL AND INTERNATIONAL PARTNERS TO CONSIDER HOW WE CAN SORT OF IMPROVE REGISTRY DATA TO SUPPORT THE DETERMINATION OF CELL LINES THAT ARE ACCEPTABLY DERIVED.

AND THERE ARE A NUMBER OF INITIATIVES OUT THERE, THE INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH, THE EUROPEAN REGISTRY, THE UNIVERSITY OF MASSACHUSETTS HAS BEGUN A REGISTRY EFFORT. THERE'S WORK AT THE UNIVERSITY OF WISCONSIN, THE UK STEM CELL BANK. THERE ARE A WHOLE SERIES OF EFFORTS OUT THERE TO SORT OF DO THIS WORK, SO I THINK OUR INITIAL THINKING WAS WE DON'T NEED ANOTHER EFFORT. WHAT WE NEED TO DO IS TO GET IN WITH SOME OF THE

INTERESTING EFFORTS AND SEE IF WE CAN'T FORGE SOME CONSENSUS AND SOME PRACTICES FOR DEVELOPING CONSISTENCY FOR CELL LINE DOCUMENTATION.

AND WE HAD A WHAT I WOULD SAY IS A VERY SUCCESSFUL MEETING THAT THE UNIVERSITY OF MASSACHUSETTS HOSTED WHERE WE ACTUALLY DEVELOPED A CONSENSUS STATEMENT WITH ALL THE PARTNERS PRESENT AND SOME OTHER INDIVIDUALS REALLY STATING SORT OF THE COMMITMENT, THAT WE NEED TO SORT OF MOVE FORWARD WITH AN EFFORT THAT IS SORT OF OPTIMAL AND THAT PEOPLE ARE THINKING TOGETHER. SO IT'S SORT OF THE FIRST STEPS, I HOPE, TOWARDS A BROADER APPROACH TO IMPROVING DATA, STANDARDIZATION AS WE'RE MOVING FORWARD IN A MORE RELAXED WAY. BUT IT'S A PRELIMINARY DEVELOPMENT THAT WE'VE BEEN -- I WOULD SAY IT WAS A VERY PROMISING SET OF MEETINGS, AND WE'LL KEEP YOU POSTED ON DEVELOPMENTS THERE.

I DID WANT TO JUST COME BACK TO THIS TABLE THAT WAS IN YOUR BRIEFING MATERIAL BECAUSE THIS WAS REALLY A FAIRLY SUBSTANTIAL PIECE OF FOLLOW-UP BASED ON THE REQUEST YOU ALL MADE IN THE LAST MEETING, WHICH WAS TO SURVEY THE LAY OF THE LAND WITH REGARD TO POLICIES RELATED TO THE USE OF CERTAIN TYPES OF CELL LINES OR THE USE OF EMBRYOS FOR THE DERIVATION OF CELL LINES. AND I WANT TO JUST TAKE A MOMENT TO

EXPLAIN WHAT'S BEHIND THIS TABLE.

FOR EVERY STATE LISTED THERE, WE HAVE BEEN IN DIRECT CONTACT WITH TYPICALLY THE ATTORNEY GENERAL'S OFFICE OR SOME LEGAL ENTITY WITHIN THE STATE THAT OVERSEAS THE REGULATIONS OR IS SORT OF THE FINAL PARTY TO INTERPRET THE REGULATIONS AT THE STATE LEVEL. AND WE DID THIS WORK THROUGH THE INTERSTATE ALLIANCE FOR STEM CELL RESEARCH, WHICH IS A COMMITTEE, WHICH IS A GROUP THAT I CO-CHAIR.

AND SO THESE FINDINGS IN TERMS OF WHAT'S REPRESENTED IN THIS CHART REALLY REPRESENTS THE COLLECTIVE WORK OF ALL THE STATES LISTED HERE AND THE NATIONAL ACADEMIES AND CANADA. SO JUST IF YOU HAVE ANY QUESTIONS ABOUT THE CONTENT, I'M HAPPY TO EXPAND ON IT. I HOPE THE TABLE WILL MAKE SENSE TO YOU ALL, BUT I DID WANT TO EMPHASIZE THE DILIGENCE THAT KIND OF WENT INTO THIS EFFORT BECAUSE IT WAS SUBSTANTIAL. AND WE HAVE, AGAIN, ADDITIONAL DOCUMENTATION BACK BEHIND ON THOSE DATA. ANYONE MORE INTERESTED IN THAT.

AND I THINK THAT'S ALL I HAVE. TURN IT OVER TO YOU.

CHAIRMAN LO: ANY QUESTIONS FOR GEOFF ABOUT THE UPDATE? OKAY. QUESTIONS FROM THE AUDIENCE.

WITH THAT, I'M GOING TO AGAIN TURN IT BACK TO GEOFF TO SORT OF HELP US GET STARTED ON THE ISSUES WE'RE GOING TO DISCUSS TODAY IN TERMS OF USING CELL LINES, FIRST USING HUMAN EMBRYONIC STEM CELL LINES DERIVED PRIOR TO THE EFFECTIVE DATE OF THE CIRM REGULATIONS, WHICH IS NOVEMBER 2006.

GEOFF'S PREPARED SOME SLIDES THAT I THINK WILL CLARIFY FOR US THE -- THERE ARE A LOT OF DIFFERENT ISSUES HERE. AND I THINK IT WOULD BE CONCEPTUALLY BETTER IF WE TRY TO SORT OF SEPARATE THEM OUT AND DEAL WITH THEM ONE AT A TIME AS OPPOSED TO ALTOGETHER. GEOFF HAS TRIED TO HELP US ANALYTICALLY THINK THROUGH THE DIFFERENT RELATED ISSUES.

DR. LOMAX: OKAY. AND JUST SO WE'RE ON ITEM 4 NOW. FOR THE BENEFIT OF THE MEMBERS OF THE AUDIENCE, WE HAVE A BRIEFING PAPER ON THIS ITEM, BRIEFING NARRATIVE AS WELL IF FOLKS WOULD LIKE TO FOLLOW ALONG.

THE ISSUE THAT WAS BROUGHT TO OUR ATTENTION IS THAT THERE'S --

CHAIRMAN LO: I'M SORRY. BEFORE YOU START, ON THE LAST PAGE OF YOUR BRIEFING, THE SLIDES --

DR. LOMAX: I DON'T KNOW IF WE HAVE --

CHAIRMAN LO: I'M SORRY. I MISSPOKE. THEY'RE NOT IN HERE YET.

DR. LOMAX: THE TROUBLE WITH OF SLIDES, THEY TEND TO GET DEVELOPED IN THE LAST 24 HOURS AFTER WE COPIED EVERYTHING ELSE FOR THE PACKET. I APOLOGIZE, BUT WE WILL MAKE THE SLIDES AVAILABLE. I HOPE WHAT'S ON THE SCREEN IS SUFFICIENT.

SO WOULD YOU LIKE ME TO WALK THROUGH THIS SLIDE, BERNIE?

CHAIRMAN LO: YEAH.

DR. LOMAX: OKAY. SO WHAT WE THOUGHT WOULD BE HELPFUL WAS TO TALK ABOUT, I GUESS, CONCEPTUALLY THE MATERIALS THAT I THINK ARE THE FOCUS OF TODAY'S DISCUSSION, WHICH A TYPICAL EXAMPLE WOULD BE YOU HAVE A SITUATION WHERE YOU'RE FORMING AN EMBRYO FOR -- WE'RE CALLING THEM IVF EMBRYOS, SO IT'S CREATED FOR INFERTILITY TREATMENT. IN SOME CASES YOU MAY HAVE ONE OR BOTH GAMETE DONORS ARE PAID IN THE CREATION OF THAT EMBRYO. AND THAT EMBRYO IS INTENDED TO GO TO AN IVF PATIENT FOR THE PURPOSES OF HAVING A CHILD.

AS WE'RE AWARE, THIS PROCESS HAS RESULTED IN A NUMBER OF STORED EMBRYOS THAT ARE NO LONGER REQUIRED FOR THE PATIENT FOR IVF PURPOSES. AND TYPICALLY THE PATIENT, THEN, HAS ONE OF THREE

OPTIONS FOR FINAL DISPOSITION OF THAT EMBRYO. IT COULD BE DONATED TO ANOTHER PATIENT, COULD BE DISCARDED, OR DONATED TO RESEARCH.

NOW, WHEN WE ORIGINALLY CRAFTED THE REGULATIONS, THIS ISSUE OF PAYMENT, WE DREW A SORT OF, I GUESS YOU WOULD SAY, A BRIGHT LINE IS ONE WAY OF CHARACTERIZING IT, AND SAID ANY CELL LINE THAT RESULTS FROM PAID GAMETE -- IF YOU'VE GOT A CELL LINE THAT'S CREATED FROM ONE OF THESE EMBRYOS WHERE THE PAID GAMETES IS CONTAINED IN THE EMBRYO, THEN WE WOULDN'T CONSIDER IT ACCEPTABLY DERIVED BY VIRTUE OF THE PAYMENT THAT WENT INTO THE INITIAL EMBRYO.

AND SO THE QUESTION -- THIS IS ONE EXAMPLE. AND SO THE QUESTION REALLY BEFORE YOU TODAY, ONE OF THE QUESTIONS BEFORE YOU TODAY, WILL BE DO WE WANT TO REEVALUATE THE CASE WHERE YOU'VE GOT A PAID EMBRYO AND IF THE CELL LINES ARE THEN -- YOU'VE GOT AN EMBRYO THAT'S CREATED FOR IVF, DO WE WANT TO REEVALUATE THAT POSITION AND ALLOW CELL LINES DERIVED FROM THESE EMBRYOS TO BE MADE AVAILABLE FOR RESEARCH. SO THAT'S ONE OF THE ISSUES.

NOW, BERNIE, THE PROBLEM WITH THIS SLIDE IS, WHICH WE STILL HAVEN'T ADDRESSED THE FIRST QUESTION, WHICH IS THE GRANDFATHERING OF LINES, SO

I'M DEFERRING TO YOU NOW. WHERE DO YOU WANT TO GO FROM HERE IN THE DISCUSSION?

CHAIRMAN LO: WHAT WE'RE TRYING TO DO HERE IS -- THE OTHER SITUATION WE WANT TO DISCUSS TODAY IS WHERE IN THE IVF CONTEXT THE GAMETE DONORS DONATED THEIR GAMETES FOR IVF AND GAVE CONSENT TO THAT, BUT THE RESEARCH DONATION WAS NOT MENTIONED TO DO THE GAMETE DONORS, AND NOW THEY MAY BE NO LONGER CONTACTED. THEY MAY BE ANONYMOUS OR THEY MAY HAVE INDICATED THEY DON'T WANT TO BE CONTACTED AGAIN. SO CONCEPTUALLY YOU HAVE EMBRYOS THAT WERE CREATED FROM GAMETES SPECIFICALLY FOR IVF CLINIC WORK THAT ENDED UP BEING FROZEN, NOT NEEDED BY THE WOMAN OR COUPLE IN IVF, AND NOW TYPICALLY YEARS AFTER THEY'VE COMPLETED THEIR INFERTILITY TREATMENT HAVE DECIDED THEY NO LONGER WANT TO KEEP THESE FROZEN EMBRYOS IN INDEFINITE STORAGE.

THEIR OPTIONS ARE TO EITHER DISCARD THEM, TO GIVE THEM TO ANOTHER WOMAN AND COUPLE FOR REPRODUCTIVE PURPOSES, OR A NUMBER OF THEM ARE SAYING ARE I'D LIKE TO DONATE THEM FOR RESEARCH IN SOME SPECIFIC STEM CELL RESEARCH. SO THE QUESTION IS IN THAT CONTEXT WHERE THE EMBRYOS WERE CREATED IN AN IVF CONTEXT WITH ALL THE APPROPRIATE CONSENT FOR IVF AND PERHAPS HUMAN GAMETE DONORS TYPICALLY AT A

TIME WHEN STEM CELL RESEARCH WAS NOT SOMETHING THAT PEOPLE WERE THINKING ABOUT. NOW DO WE ALLOW THOSE EMBRYOS TO BE USED FOR STEM CELL LINES DERIVED FROM IVF, EVEN THOUGH THEY DON'T MEET ALL THE REQUIREMENTS WE SUBSEQUENTLY SET UP IN NOVEMBER 2006 FOR CIRM-FUNDED DERIVATION OF NEW HES LINES.

SO I DON'T KNOW IF I'VE CONFUSED YOU. SHERRY, HELP US OUT.

CO-CHAIR LANSING: I DON'T NEED TO HELP YOU OUT SO MUCH AS I WANT TO CLARIFY MY UNDERSTANDING. AND I THINK I CAN PUT IT IN -- IT SEEMS TO ME THERE'S TWO GROUPS. MAYBE I'M WRONG. OKAY. SO LET ME JUST -- I KNOW IN THE FERTILITY -- A WOMAN GOES IN FOR FERTILITY TREATMENT, BUT IT'S ACTUALLY PERSONALIZED. AND SO, A, YOU CAN USE IT TO HAVE A CHILD; B, YOU'VE NOW DECIDED THAT YOU HAVE EXTRA ONES, AND SO YOU CAN USE THOSE TO HELP ANOTHER PATIENT WHO WANTS TO HAVE A CHILD. YOU CAN DISCARD THEM AND SAY I DON'T WANT ANYTHING ELSE DONE WITH THEM. I JUST WANT TO BE SURE I'M CORRECT. OR YOU CAN CHECK A BOX WHEN THAT BOX WAS AVAILABLE FOR RESEARCH, BUT NOT EVERYBODY HAD THAT BOX AVAILABLE; IS THAT CORRECT?

CHAIRMAN LO: WELL, BUT NOW AT THE TIME YOU SAID I'VE MADE UP MY MIND, I DON'T WANT TO KEEP

THEM IN STORAGE, THE IVF BANK WHERE YOU HAVE THEM FROZEN WILL SAY, BUT NOW YOU HAVE TO TELL US WHAT YOU WANT DONE. TODAY THEY'LL OFFER YOU THE CHOICE KEEP THEM FROZEN, GIVE THEM TO ANOTHER COUPLE FOR REPRODUCTIVE PURPOSES --

CO-CHAIR LANSING: OR RESEARCH.

CHAIRMAN LO: -- DISCARD OR --

CO-CHAIR LANSING: OKAY. AND THEY DON'T SPECIFY -- I JUST WANT TO BE CLEAR -- WHAT THAT RESEARCH IS BECAUSE YOU CAN'T. I MEAN THAT WOULD BE -- RIGHT?

CHAIRMAN LO: RIGHT. ALTHOUGH SOME -- AGAIN, IT DEPENDS ON, YOU KNOW, PEOPLE LIKE ROB THAT INVOLVED WITH IVF, ANN, I MEAN SOMETIMES THEY SAY JUST RESEARCH. OTHER TIMES NOW I THINK THEY SAY FOR STEM CELL RESEARCH IN PARTICULAR. SO THE COUPLE OR THE WOMAN IN IVF GENERALLY SAYS I WANT THESE TO GO SPECIFICALLY FOR STEM CELL RESEARCH. QUESTIONS THE GAMETE DONORS FROM YEARS AGO MAY NOT HAVE SAID THAT, AND NOW WE MAY NOT BE ABLE TO CONTACT THEM.

CO-CHAIR LANSING: OKAY. ISN'T IT -- AND THOSE GAMETE DONORS FROM BEFORE, I'M TALKING TEN YEARS AGO, DID THEY ACTUALLY HAVE A BOX THAT THEY COULD CHECK AT THAT TIME AND THEY GAVE THEM A RESEARCH OPTION? THE ANSWER IS NOT ALWAYS, RIGHT?

DR. TAYLOR: SOMETIMES. I MEAN WE HAVE RESEARCH BOXES. WE DIDN'T REALLY KNOW -- WE DIDN'T SPECIFY, FRANKLY, AND SOME PEOPLE MADE DIFFERENT DECISIONS ABOUT RESEARCH IN GENERAL VERSUS STEM CELL RESEARCH. BUT THOSE OPTIONS WERE THERE --

CO-CHAIR LANSING: THOSE OPTIONS WERE ALWAYS THERE TO CHECK THE RESEARCH BOX?

CHAIRMAN LO: BUT NOT IN ALL IVF CENTERS. I THINK ROB IS BEING MODEST. HE WAS SORT OF SETTING THE STAGE. AND, YOU KNOW, I WOULD SAY THE FARTHER BACK YOU GO IN TIME, THE MORE IVF CLINICS DIDN'T HAVE THAT OPTION FOR --

DR. KIESSLING: THE BIG DISTINCTION IS EGGS AND SPERM. THE EGG DONOR MORE FREQUENTLY HAVE THAT BOX TO CHECK THAN THE SPERM DONOR BECAUSE THE SPERM LINE HAS BEEN PURCHASED FROM A SPERM BANK, AND THOSE GUYS WERE ONLY ASKED ABOUT THEIR -- YOU KNOW, MOST SPERM DONORS HAVE NEVER CHECKED A RESEARCH BOX.

CO-CHAIR LANSING: SO DON'T WE THEN HAVE TWO POOLS? WE HAVE THE BOX OF PEOPLE THAT CHECKED IT FOR RESEARCH AND HOW WE DEAL WITH THAT, AND THE BOX THAT PEOPLE -- OF WHICH THERE NEVER WAS THAT OPTION. OKAY. SO NOW IF YOU TAKE THERE NEVER WAS THAT OPTION, I MEAN OBVIOUSLY IN ALL CASES YOU'RE GOING TO TRY AND FIND THE PEOPLE, BUT THAT'S NOT

GOING TO BE EASY. SO NOW YOU TAKE THE PEOPLE THAT CHECKED RESEARCH; AND THEN IF YOU'RE LUCKY IN A MORE SOPHISTICATED TIME, THERE WILL BE A RECOMMENDATION, I WOULD ASSUME FROM OUR GROUP, TO SAY YOU CHECK FOR RESEARCH OR YOU CHECK FOR STEM CELL RESEARCH OR YOU'RE NOT OBJECTING TO STEM CELL RESEARCH, WHATEVER WAY YOU WANT TO PUT IT.

BUT IF IT'S JUST IN GENERAL RESEARCH, THAT'S THE BIG POOL THAT WE HAVE TO DEAL WITH. AND, YOU KNOW, I KNOW WHERE I'M COMING OUT ON THIS BECAUSE RESEARCH IS RESEARCH, BUT I DON'T WANT TO SAY --

CHAIRMAN LO: SHERRY, THIS HAS BEEN A PROBLEM. LET ME JUST SORT OF CLARIFY -- TRY AND CLARIFY IT AGAIN. SO YOU'RE ASKING WHEREVER POSSIBLE WE SHOULD GO BACK AND SAY DO WE KNOW THAT THE -- WE ALWAYS KNOW THAT THE WOMAN AND COUPLE IN IVF TREATMENT HAVE CONSENTED TO DONATE FOR RESEARCH AND TYPICALLY FOR STEM CELL RESEARCH. WHEREVER POSSIBLE, WE GO BACK AND SAY DO WE KNOW THAT THE GAMETE DONORS ALSO APPROVED OF DONATING THIS TO STEM CELL RESEARCH? IF THEY DID, THEN THERE'S OBVIOUSLY NO ETHICAL PROBLEM.

CO-CHAIR LANSING: EXACTLY.

CHAIRMAN LO: IF THEY SOMEHOW SAID, NO, WE

ABSOLUTELY DON'T WANT IT --

CO-CHAIR LANSING: THEN THERE'S NO QUESTION EITHER.

DR. TROUNSON: BERNIE --

CHAIRMAN LO: LET ME JUST MAKE SURE I'VE GOT IT STRAIGHT. THE OTHER TWO CASES ARE WHERE THEY WERE NEVER ASKED AND WE DON'T KNOW, AND THEN THE OTHER CASE IS THEY CHECK RESEARCH IN GENERAL --

MS. LANSING: RESEARCH.

CHAIRMAN LO: -- BUT NO ONE THOUGHT OF STEM CELL RESEARCH.

CO-CHAIR LANSING: BUT RESEARCH IN GENERAL, I JUST WANT TO SAY THIS AS A PATIENT ADVOCATE, THAT'S HUGE. I MEAN IT'S A HUGE THING. AND THEN I DON'T THINK WE SHOULD BE PUNISHED ANY MORE THAN SOMEBODY ELSE SHOULD BE PUNISHED. SO I GUESS WHAT I'M TRYING TO SAY IS I CHECKED RESEARCH IN GENERAL, AND FOR SOME REASON I DON'T BELIEVE IN BREAST CANCER RESEARCH. I CAN'T IMAGINE ANYBODY SAYING THAT. NOBODY IS ASKING ME ABOUT SPECIFIC RESEARCH. AND SO WHY ARE WE -- I'M ACTUALLY NOW -- I WAS THE MOST CONSERVATIVE ON THIS ISSUE. I'M ACTUALLY SAYING WHY ARE WE HELD TO A HIGHER STANDARD THAN ANY OTHER KIND OF RESEARCH? I DON'T THINK WE SHOULD BE BECAUSE THEN YOU OPEN IT UP TO THE

PATIENT -- YOU NEVER GET ANYONE TO CHECK THE RESEARCH BOX BECAUSE I MEAN IF THEY DON'T BELIEVE IN BREAST CANCER RESEARCH, MAYBE I DON'T BELIEVE IN, YOU KNOW, MS RESEARCH. I DON'T KNOW.

CHAIRMAN LO: I THINK NOW WE'RE GOING TO GET SOME DISCUSSION. ALAN WANTED TO SAY SOMETHING AND BOB.

DR. TROUNSON: I THINK WHERE SHERRY IS TALKING ABOUT THERE'S SOME REASONABLE CLARITY. BUT THERE WAS A VIEW TEN YEARS AGO OR MORE THAT IF YOU DON'T HAND AN EGG TO ANOTHER COUPLE FOR FOSTERING A CHILD, SO THAT YOU DIDN'T -- THEREFORE, YOU KNOW, YOU WEREN'T REQUIRED TO MAKE THE DECISIONS AND NOW THE DISPOSITION OF EMBRYOS BECAUSE WHILE YOU'RE PROVIDING THE EGG OR THE SPERM, YOUR DECISION ABOUT WHETHER THAT SHOULD BE DISPOSED OF, THAT MEANT THAT SOMEBODY ELSE WAS TRANSFERRED TO THE RECIPIENT COUPLE. AND THAT WAS AT THE TIME A VIEW NOT UNIVERSALLY HELD, BUT IT WAS A COMMON VIEW, THAT YOU DIDN'T HAVE ANY BOXES TO PICK BESIDES DONATING TO THE OTHER COUPLE, RECIPIENT COUPLE. AND THE RECIPIENT COUPLE, AS YOU WOULD HAVE AS IF YOU HAVE AN ADOPTED CHILD, TO MAKE THE DECISIONS ON BEHALF OF THAT EMBRYO OR THOSE EMBRYOS FROM THEN ON.

AND YOU WOULDN'T GO BACK TO THE DONOR WHO

IN MANY INSTANCES WAS ANONYMOUS ANYWAY, WHO HAD PUT A BARRIER ABOUT GOING BACK TO THEM. SO THERE WAS A TIME WHERE ALL OF THESE THINGS WERE NOT SO CLEAR AS THEY ARE TODAY. AND WHEN, OF COURSE, WE GOT OUR GUIDELINES ESTABLISHED AT CIRM, IT'S BEEN VERY CLEAR. SO I THINK THAT'S A BIT OF A SITUATION, BUT WE'RE TALKING ABOUT TIME THAT WAS BEFORE NOW.

CHAIRMAN LO: AND LET ME AGAIN SORT OF ADD ON WHAT ALAN SAID, WHICH IS VERY IMPORTANT, THAT, IN FACT, IT WAS STANDARD PRACTICE IN A NUMBER OF IVF PRACTICES TO HAVE THE GAMETE DONORS SIGN BASICALLY A RELEASE FORM, SAYING I'M GOING TO GIVE THESE AWAY TO THE WOMAN OR COUPLE IN IVF, AND THEY CAN DO WHATEVER THEY WANT. THEY HAVE TOTAL AUTHORITY TO CONTROL THEM. SO IN A SENSE THEY SIGNED EVERYTHING OVER TO THE EMBRYO DONOR, BUT NOT ANYTHING SPECIFIC WITH THAT.

SO A NUMBER OF COMMENTS, WHICH IS GREAT, SO WE'RE GOING TO GO TO BOB AND THEN ALTA AND THEN FRANCISCO. AND ANYONE ELSE PUT YOUR HAND UP.

MR. KLEIN: SO JUST FOR THE FRAMEWORK OF THIS DISCUSSION, TIME STARTS WITH DR. TROUNSON'S DISCUSSION. THERE IS NO TIME IN THE DISCUSSION OF IVF PRIOR TO TROUNSON. SO TROUNSON IS OUR ULTIMATE HISTORIAN IN THIS REGARD SINCE IT'S HIS DISCOVERY

THAT RUNS IVF ON A GLOBAL SCALE. HE HAS THIS REMARKABLE WHOLE LOOK.

BUT MAYBE, DR. TROUNSON, YOU COULD CLARIFY FOR ME. I WAS UNDER THE IMPRESSION THAT EVEN IN VERY RECENT TIME, THAT SPERM DONORS, BECAUSE OF THEIR DESIRE TO BE TREATED ANONYMOUSLY AND, IN FACT, OFTEN NOT TO BE COMMUNICATED WITH, THAT EVEN IN -- THIS IS A CURRENT PROBLEM AS WELL AS A HISTORICAL PROBLEM WITH THE SPERM DONORS IS THAT WE HAVE DONORS WHO MAY BE PAID DONORS WHO JUST DON'T WANT TO BE COMMUNICATED WITH OR WE DON'T KNOW WHO THEY ARE.

IS THAT STILL A CURRENT PROBLEM? WHAT IS THE PRACTICE?

DR. TROUNSON: I THINK THAT'S NOT VERY COMMON ANYMORE. I THINK THE COMMUNITY HAS MOVED ON IN MATURITY IN THAT RESPECT, AND I THINK THERE IS -- THE COMMUNITY THINKS THERE IS AN APPROPRIATE WAY TO BANK IF EVERYTHING AGREES THAT YOU COULD GO BACK TO THE ORIGINAL DONOR BECAUSE THERE ARE SOME SITUATIONS WHERE THERE ARE OFFSPRING. THAT'S NOT UNIVERSAL, BOB, SO THERE'S A GREAT VARIETY, I THINK. AND SOME OF THE CONDITIONS THAT YOU DESCRIBE STILL EXIST. THEY DON'T EXIST ANY LONGER IN AUSTRALIA. YOU HAVE TO BE IDENTIFIABLE IN THE LONG TERM, BUT I UNDERSTAND IN THE U.S. IT'S VERY VARIED.

MS. CHARO: IF I'M FOLLOWING THIS CORRECTLY, WE'VE ACTUALLY CHANGED THE DISCUSSION NOW FROM MUTUAL PAYMENT TO MUTUAL CONSENT, RIGHT? AND SO I'M GOING TO PUT ASIDE THE ISSUE OF PAYMENT FOR A MOMENT AND JUST WANT TO MENTION SOMETHING ABOUT HOW THE NATIONAL ACADEMIES CAME TO THE POSITION THEY CAME TO BECAUSE I KNOW THAT THAT WAS PART OF THE REGULATIONS HERE CAME TO BE WHERE THEY ARE.

THE NOTION HAD BEEN THAT, WHILE IT'S TRUE THAT MOST PEOPLE UNDERSTAND THE DONATION OF A GAMETE, EGG OR SPERM, ESSENTIALLY THE LEGAL ISSUE FOR CONTROL OVER IT, WE ALSO FOUND OURSELVES THINKING THAT MOST PEOPLE ENTER THAT ARRANGEMENT UNDER A CERTAIN SET OF ASSUMPTIONS. AND THOSE ASSUMPTIONS ARE BUILT AROUND THE NOTION THAT THIS IS FOR REPRODUCTIVE PURPOSES. AND THEN, OF COURSE, IT MAY FAIL AND THE EMBRYO MAY WIND UP DESTROYED OR NOT USED FOR A NUMBER OF REASONS, BUT THAT IT IS LIKELY, AT LEAST HISTORICALLY, THAT MOST PEOPLE DO NOT IMAGINE A TRANSFER OF THE EMBRYO TO RESEARCH AS A LIKELY OUTCOME.

AND SO BEING EXTREMELY CAUTIOUS, WE CHOSE TO PUT IN THE REQUIREMENT THAT THERE BE CONSENT FROM ALL UNDERLYING GAMETE DONORS SOLELY SO THAT THERE WAS A SENSE THAT THE ORIGINAL DECISION TO DONATE FOR

REPRODUCTIVE PURPOSES WAS DONE WITH COMPLETE -- WITH AN UNDERSTANDING OF THE COMPLETE RANGE OF OUTCOMES, BUT NOT NECESSARILY WITH A LIST OF PARTICULAR RESEARCH PROTOCOLS THAT MIGHT BE USED IN THE RESEARCH.

THAT SAID, I SHOULD AT LEAST PUT ON THE TABLE FOR YOU ALL THAT THAT HAS PROBABLY BEEN ONE OF THE TWO OR THREE MOST CHALLENGED GUIDELINES, RIGHT UP THERE WITH NONPAYMENT AND THE CREATION OF ESCRO'S TO BEGIN WITH AS OPPOSED TO USING IRB'S. AND JUST TO PROVE THAT CONFLICT OF INTEREST RULES ARE SOMETIMES OVERDONE WITH THE ASSUMPTION THAT AFFILIATIONS DETERMINE EVERYTHING, MY OWN INSTITUTION, AS I UNDERSTAND IT, IS PLANNING TO IGNORE THAT PARTICULAR GUIDELINE THAT I AND ANOTHER MEMBER OF MY INSTITUTION HELPED TO WRITE ON THE NATIONAL ACADEMY'S COMMITTEE.

SO I JUST WANT TO PUT THAT ON THE TABLE SO THAT PEOPLE APPRECIATE WHY THAT'S PUT IN, AND THAT IT'S NOT ABOUT THE SPECIFICS OF THE RESEARCH SO MUCH AS PEOPLE ENTERING THESE ARRANGEMENTS TO BE GAMETE DONORS WITH SOME APPRECIATION OF WHAT THEY'RE ACTUALLY GRANTING.

CHAIRMAN LO: FRANCISCO AND THEN ANN.

DR. PRIETO: I THINK THAT, YOU KNOW,

THERE'S QUESTIONS OBVIOUSLY LEGAL AND ETHICAL. AND THE LEGAL ONE SEEMS FAIRLY CLEAR-CUT, THAT YOU'VE RELINQUISHED CONTROL OVER THESE GAMETES PRESUMABLY WITH SOME SORT OF BLANKET RELEASE. AND, YOU KNOW, THERE IS NO LEGAL ISSUE OF REACHING BACK AND GETTING THEIR CONSENT. ETHICALLY I THINK WHAT WE HAVE TO DECIDE IS HOW ESSENTIAL IS IT TO GET THAT SORT OF APPROVAL.

I THINK IF THERE WAS A RESEARCH BOX CHECKED, THEN TO ME THAT OPENS UP THE WINDOW OF ACCEPTABILITY THAT, YOU KNOW, PEOPLE UNDERSTAND THAT VARIOUS THINGS ARE DONE IN RESEARCH. I DON'T THINK WE HAVE TO OR CAN GO BACK AND EXPLAIN TO PEOPLE. WE'D HAVE TO, YOU KNOW, TRAIN AT THE LEVEL OF A PH.D. TO UNDERSTAND ALL THE POTENTIAL RAMIFICATIONS OF THE RESEARCH. I DON'T THINK THAT WOULD EVER BE SOMETHING THAT WE'D LIKE. I THINK THE PEOPLE THAT CHECK THAT BOX, THEN THAT'S ACCEPTABLE.

CHAIRMAN LO: ANN AND THEN SHERRY.

DR. KIESSLING: I ACTUALLY WANT TO ASK ALTA A QUESTION WITH YOUR LAWYER HAT ON. I MEAN SETTING ASIDE THE ETHICAL ISSUES OF WHETHER SOME COLLEGE GUY IS DONATING SPERM FOR THE SPERM BANK, AND THE CALIFORNIA CRYO BANK IS THE ONE OF THE BIGGEST SPERM BANKS IN THE COUNTRY, WHOSE DONATIONS

ARE STILL ANONYMOUS. THERE'S TWO CHAPTERS IN BOSTON, I BELIEVE.

WHETHER OR NOT THAT PERSON ENVISIONS THAT AT SOME POINT IN TIME HIS GENETIC INFORMATION WOULD BE USED TO TREAT SPINAL CORD INJURY. I THINK THAT'S A DISCUSSION WE NEED TO HAVE AS A SEPARATE ISSUE.

BUT ONE OF THE LEGAL CONCERNS HERE, AND THIS IS NOW A LEGAL CONCERN, NOT AN ETHICAL CONCERN, HOW DOES THE RETROSPECTIVE WORK ON THAT? NOW, IF YOU ARE NOW -- AND THERE MUST BE EXAMPLES OF THIS IN TERMS OF A STANDARD FOR DOING HUMAN SUBJECTS RESEARCH THAT'S EMBRACED NOW AND LOOKING BACK AT WHEN DISCUSSING THING AT A PRIOR TIME.

SO IN OTHER WORDS, IF THIS COMES AS A COURT CHALLENGE, WHAT DO COURTS SAY ABOUT IF THE STANDARDS UNDER WHICH THIS MATERIAL WAS COLLECTED DO NOT AGREE WITH TODAY'S STANDARDS?

CHAIRMAN LO: THIS ACTUALLY IS GEOFF'S NEXT SLIDE. SO CAN WE HOLD AND THEN ALTA JUMP IN AFTER THIS BECAUSE GEOFF IS GOING TO TRY AND WALK US THROUGH THAT WITH ALTA'S HELP. SHERRY.

CO-CHAIR LANSING: WELL, I ACTUALLY WANT TO HEAR THE SLIDES, SO I'LL MAKE MY COMMENTS BRIEF. I ACTUALLY UNDERSTAND WHAT YOU ARE SAYING, ALTA, AND I AGREE WITH IT. BUT IF YOU -- IF WE ACCEPT THE

FACT THAT WE ARE A WORK IN PROGRESS, WE STARTED HERE ON THE SLATE OF CONSERVATIVISM AND WE HAVE THERE AND IT'S POSSIBLE. AND IT SEEMS TO ME A STEP TO TAKE WOULD BE TO SAY THAT ANYONE THAT CHECKED THE RESEARCH BOX, YOU KNOW, IS ACCEPTABLE BECAUSE WE'RE NOT GOING TO -- WE'RE NOT GOING TO SPECIFY WHAT KIND OF RESEARCH. I MEAN THAT WOULD BE IMPOSSIBLE TO DO. AND IF YOU CHECKED THAT BOX, THEN WHY SHOULD WE NOT BE ABLE TO USE THAT SINCE EVERYONE ELSE CAN? I MEAN WE'RE THEN ACTUALLY HOLDING OURSELVES TO A STANDARD NOW. THAT TO ME IS A STEP.

NOW, WHETHER OR NOT -- THEN THE NEXT STEP IS A MUCH BOLDER STEP AND A STEP THAT I WOULD SAY LET'S REVISIT IF WE NEED TO, AND I'M NOT RECOMMENDING IT TODAY, IS THEY NEVER CHECK THE RESEARCH BOX. AND THEN I THINK, YOU KNOW, YES, I WOULD SAY ALWAYS TRY AND FIND THE DONOR, ALWAYS TRY AND ASK THE QUESTIONS, AND I THINK AND GET PERMISSION, THEN LET'S NOT DO THAT TODAY.

CHAIRMAN LO: WELL, THE OTHER OPTION WOULD BE IF THERE WAS NO BOX FOR THEM TO CHECK WHEN THEY DONATED.

CO-CHAIR LANSING: THEN I THINK, AS MUCH AS, YOU KNOW, WISH WE COULD USE THEM ALL FOR RESEARCH, THEN I THINK THAT'S -- IF YOU CAN'T FIND

THEM, THEN I SAY THAT'S MAYBE TOO BIG A STEP TODAY.

CHAIRMAN LO: IF SOMEONE -- ROB.

DR. TAYLOR: YEAH. I'D ACTUALLY LIKE TO KIND OF STEP BACK TO THE QUESTION OF THE BOXES AND THE TIMELINE. SO TEN YEARS AGO IN A UNIVERSITY PROGRAM WHERE WE WERE DOING RESEARCH ON LOTS OF TISSUES THAT WERE MAINLY DERIVED FROM SURGICAL PROCEDURES OR BIOPSIES DONE IN THE OFFICE OR BLOOD SAMPLES THAT WERE BEING DRAWN ROUTINELY AS PART OF NORMAL CARE, WE HAD LOTS OF RESEARCH BOXES ON LOTS OF THINGS. SO I THINK IT WOULD BE FAIR TO SAY THAT IF WE GO BACK TEN YEARS AND WE LOOK AT THE POOL OF FROZEN EMBRYOS THAT ARE KIND OF SITTING AROUND, I WOULD HAVE TO ARGUE THAT THE BIGGEST COHORT IN A POOL PROBABLY HAVE NO INFORMATION ABOUT RESEARCH PROTOCOLS.

THERE'S A SMALLER SUBSET IN WHICH THERE WAS A BOX LIKE IN THE UC SAN FRANCISCO PROGRAM, LOTS OF OTHER UNIVERSITY PROGRAMS, I'M SURE, THAT HAD A RESEARCH BOX THAT WASN'T PARTICULARLY SPECIFIED, BUT IT WOULD ALLOW OTHERWISE DISCARDED MATERIAL TO BE USED FOR RESEARCH. AND THAT'S NOT GOING TO BE THE ENTIRE POPULATION OF THOSE FROZEN EMBRYOS, BUT IT'S GOING TO REPRESENT A SET.

AND IT'S GOING TO BE A MUCH, MUCH SMALLER

SET WHERE WE CAN TRACE IT BACK TO THE GAMETE DONORS, AND INFINITESIMALLY SMALLER GROUP, I WOULD ARGUE, BASED ON PARTICULARLY THE SPERM DONOR ISSUES, IN THIS COUNTRY AT LEAST, WHICH ARE ALMOST COMPLETELY ANONYMOUS AND UNTRACEABLE.

CO-CHAIR LANSING: BUT TEN YEARS AGO THERE WAS THIS BOX FOR RESEARCH, WHICH IS A START.

DR. TAYLOR: RIGHT.

CHAIRMAN LO: LET ME SORT OF PUT THIS IN A MUCH BIGGER CONTEXT, WHICH, AS ROB SUGGESTED, ALL THE TIME IN THE COURSE OF CLINICAL CARE, WE PHYSICIANS OBTAIN TISSUE AND IT'S STORED IN A REPOSITORY, BIOPSY SAMPLES FROM CANCER SURGERY, EXTRA TUBES OF BLOOD THAT MAY BE USED FOR (UNINTELLIGIBLE). AT A CERTAIN POINT WE ALLOW THOSE SPECIMENS TO BE USED FOR RESEARCH, BUT NOW IT'S SPECIFIC IN THE SENSE OF RESEARCH PROVIDING WE STRIP ALL IDENTIFIERS FROM THEM. AND THAT'S COMMONLY ACCEPTED. IN FACT, A LOT OF THE CANCER RESEARCH IS DONE WITH OLD PATHOLOGY SPECIMENS WHERE WE TAKE ALL THE PATIENT'S IDENTIFYING INFORMATION AND JUST TURN IT OVER TO THE RESEARCHER. AND FEDERAL REGULATIONS FOR HUMAN SUBJECTS RESEARCH EXPLICITLY ALLOWED THAT. SO ANONYMOUS TISSUE COLLECTED FOR CLINICAL PURPOSES LEFT OVER, NOT NEEDED FOR RESEARCH FOR CLINICAL WORK

MAY BE GIVEN TO RESEARCHERS WITHOUT EXPLICIT CONSENT --

CO-CHAIR LANSING: ANONYMOUSLY.

CHAIRMAN LO: -- ANONYMOUSLY. NOW, WHAT, AGAIN, I THINK SHERRY IS VERY RIGHT TO SAY, WE WANTED TO BE VERY CAUTIOUS ON THIS BECAUSE OF THE SENSE IT'S VIEWED AS EMBRYO RESEARCH WHERE WE KNOW THERE ARE PEOPLE IN THE POPULATION CAN SAY, WAIT A MINUTE, TAKING AWAY MY NAME DOESN'T MAKE IT ANY RIGHT.

CO-CHAIR LANSING: WHAT DO YOU SIGN WHEN YOU'RE AN ANONYMOUS TISSUE? MAYBE YOU SIGN AWAY YOUR RIGHTS. I DON'T KNOW.

CHAIRMAN LO: WELL, YOU SIGN AWAY YOUR RIGHTS WITH A GENERAL CONSENT TO COME TO THE HOSPITAL. NO ONE EVER READ IT BECAUSE IT'S JUST A PIECE OF PAPER. SO BASICALLY IT WAS, I THINK, AND ALTA CAN HELP ME OUT, BUT I THINK THE OTHER BACKGROUND IS THAT THIS SORT OF SPECIFIC CONSENT FOR RESEARCH FROM THESE REPRODUCTIVE TISSUES IS IN A SENSE AN EXCEPTION TO THE GENERAL RULE THAT ANONYMIZED TISSUE THAT'S ALREADY COLLECTED FOR CLINICAL PURPOSES USED FOR RESEARCH BECAUSE REPRODUCTIVE TISSUE IS A LITTLE MORE SENSITIVE AND BECAUSE EMBRYONIC STEM CELL RESEARCH MAY BE

ADDITIONALLY SENSITIVE.

AND I THINK THE NOTION WAS YOU WOULDN'T WANT SOMEONE TO COME BACK AND SAY, WELL, I REALLY WASN'T ASKED, BUT, YOU KNOW, HAD YOU ASKED, I WOULD HAVE THOUGHT NOW YOU'RE GOING TO DO RESEARCH ON INFERTILITY, WHICH I WOULD HAVE SUPPORTED, BUT -- SO THAT WAS -- ROB AND I CO-AUTHORED A PAPER IN 2004 WHICH ACTUALLY RECOMMENDED THAT WE GET SPECIFIC CONSENT TO USE THOSE EMBRYOS FROM BOTH AN EMBRYO DONOR AND THE GAMETE DONOR, BUT THAT WAS IN 2004. ALTA, HELP ME OUT.

MS. CHARO: YOU HAVE NO IDEA HOW MUCH I RESPECT YOUR OPINION ABOUT THIS, BUT I THINK THERE'S A LEGAL CONFUSION AT THE BASE OF IT WHICH MAKES THE ISSUE OF ANONYMITY NOT QUITE THE RIGHT ISSUE TO BE DISCUSSING HERE BECAUSE THERE ARE TWO THINGS THAT GO ON THAT DETERMINE HOW TO TREAT HUMAN TISSUE. ONE IS A PROPERTY ANALYSIS, MY DISPOSITIONAL AUTHORITY OVER THE TISSUE, AND THE SECOND IS HUMAN SUBJECTS PROTECTIONS.

NOW, IN THE CONTEXT OF ORDINARY SURGICAL WASTE, THE USUAL PROPERTY ANALYSIS IS THAT THAT TISSUE, WHATEVER MY PRIMARY INTEREST IN IT MIGHT BE, AND IT'S UNCLEAR IN MOST STATE LAW, WHATEVER THAT PROPERTY INTEREST IS, THE TISSUE HAS BEEN ABANDONED,

SO I NO LONGER HAVE A PROPERTY INTEREST THAT IS THE CONTROL, SO THE ONLY THING THAT'S LEFT ON THE TABLE IS PROTECTION OF MY INTEREST, WHICH IS WHERE ANONYMITY IS CONSIDERED SUFFICIENT, HUMAN SUBJECTS RULES NO LONGER APPLY.

HERE I THINK IT'S REALLY NOT THE SAME THING BECAUSE THE CONCERN ABOUT THE UNDERLYING GAMETE DONORS IS NOT SO MUCH WHETHER THEY ARE THE SUBJECT OF STUDY, WHICH WOULD TRIGGER HUMAN SUBJECTS RIGHTS, AND FOR WHICH ANONYMITY WOULD PROVIDE THE SOLUTION. I THINK THE QUESTION IS WHETHER OR NOT AT THE MOMENT THEY WERE ASKED TO DONATE GAMETES TO A COUPLE, THEY WOULD HAVE SAID, OH, I'D RATHER NOT HAD THEY KNOWN THAT RESEARCH WAS A POSSIBLE OUTCOME. IT'S WHETHER OR NOT THERE'S A MATERIAL MISUNDERSTANDING AS BETWEEN THE GAMETE DONORS AND THE RECIPIENTS ON THE POSSIBLE OUTCOMES THAT WOULD HAVE CHANGED THE TRANSACTION.

NOW, PROPERTY LAW ABOUT HUMAN TISSUE IN THE BODY AND OUTSIDE THE BODY, GAMETES, NONGAMETES, IS A MESS IN THE UNITED STATES. THERE ARE NO CLEAR NATIONAL RULES, AND EVEN WITHIN THE INDIVIDUAL STATES, THERE'S NO CLEAR ANALYSIS. BUT THE ONE THING I AM PRETTY CONFIDENT ABOUT IS THAT TO THE EXTENT THAT THERE'S ANY NOTION OF CONTROL, THAT IT

DOES REST UPON ACTUAL UNDERSTANDING OF THE MEANING OF THE TRANSACTION.

SO I DO THINK THAT, DESPITE THE ABSENCE OF HUMAN SUBJECTS RIGHTS IN THE ANONYMOUS CONTEXT, I DON'T THINK WE CAN COMPLETELY GET AROUND THE QUESTION OF WHETHER WE THINK, A, IT WOULD BE VERY LIKELY THAT PEOPLE WOULD DETERMINE THEIR WILLINGNESS TO DONATE GAMETES TO COUPLES BASED UPON WHETHER RESEARCH WAS ONE OF THE SEVERAL OUTCOMES THAT THEY WERE AWARE OF AND, SECOND, WHETHER, EVEN IF THEY KNEW THE OUTCOMES, THEY SOMEHOW HAD TO HAVE SOME INCREDIBLY ELABORATE LISTING OF ALL THE POSSIBLE OUTCOMES. I DON'T THINK WE CAN GET AWAY FROM EITHER OF THOSE QUESTIONS WITH HUMAN SUBJECTS RIGHTS.

CHAIRMAN LO: I WAS GOING TO SAY THAT THERE'S A BIGGER CONTEXT.

CO-CHAIR LANSING: I THINK -- I HAVE A QUESTION FOR YOU, ALAN. SINCE WE WANT TO DO WHAT IS ETHICAL, BUT WE ALSO WANT TO ADVANCE SCIENCE IN AN ETHICAL WAY, HOW BIG IS THIS POOL THAT WE'RE TALKING ABOUT OF PEOPLE THAT CHECKED THE RESEARCH BOX? YOU HAVE ANY IDEA? ARE WE ARGUING ABOUT SOMETHING WE DON'T NEED TO ARGUE ABOUT TODAY? I FEEL THAT PEOPLE, I COULD BE WRONG, AND MAYBE WE NEED TO DO A STRAW POLL, BUT I FEEL THAT IF YOU CHECKED THE

RESEARCH BOX, AND I'M ULTIMATELY WRONG, BUT I THINK MOST PEOPLE ARE SAYING YOU DON'T NEED -- WE'RE NOT GOING TO GO THROUGH A LIST OF WHAT THE RESEARCH IS. AND IF YOU CHECK THE RESEARCH BOX, THEN STEM CELL RESEARCH IS PART OF RESEARCH TOO.

BUT I'M ASKING YOU, FROM YOUR POINT OF VIEW AS A SCIENTIST, IS THAT A BIG ENOUGH POOL FOR US TO ADVANCE OUR WORK AT LEAST TODAY?

DR. TROUNSON: I THINK IT IS, SHERRY, WITHOUT TRYING TO REVISIT THE DECISION THAT THE COMMITTEE MADE SOME TIME AGO. ALL THE ORIGINAL LINES FROM ISRAEL THAT CONSTITUTED THE ORIGINAL EMBRYONIC STEM CELL LINES ALL FALL IN THIS CATEGORY. SO THEY WERE GRANDFATHERED IN ON THE BASIS THAT, YOU KNOW, IT WASN'T AVAILABLE. THAT CHOICE HADN'T BEEN -- WASN'T AVAILABLE AT THAT TIME AND NOT MADE AVAILABLE TO THOSE PATIENTS.

SO, NO. 1, IT IS, AS YOU GO BACK -- AS YOU GO FURTHER BACK ALL THE TIME, IT'S MORE AND MORE COMMON. AND SO THIS COULD BE A RATHER LARGE POOL OF MATERIAL THAT'S AVAILABLE.

TWO OTHER THINGS IS THAT SCIENTISTS HAVE BEEN USING THESE EMBRYOS TO FORM EMBRYONIC STEM CELLS. AND WE HAVE A SITUATION, FOR EXAMPLE, THAT'S WHY WE ARE PRESSING FOR A DISCUSSION ON THEM, THAT A

CELL LINE WAS -- A CELL LINE HAS BEEN MADE IN AN APPROPRIATE GMP WAY TO BE CLINICALLY ACCEPTABLE. IS THIS A BASIS FOR A WHOLE LOT OF RESEARCH WORK IN A GROUP OR A GROUP OF PEOPLE, AND IT'S NOT ACCEPTABLE UNDER OUR -- UNDER THESE DEFINITIONS BECAUSE THERE WAS A DONOR WAY BACK THAT DONATED THE EGG AND WHO DIDN'T GIVE ANY APPROVAL. THAT WAS SOME TIME AGO.

SO THERE ARE INDIVIDUAL SITUATIONS WHERE CELL LINES HAVE NOW BEEN DEVELOPED THAT ARE BEING USED TO STUDY AREAS OF IMPORTANCE. AND, IN FACT, THEY HAVE BEEN MADE CLINICALLY ACCEPTABLE OR, AS FAR AS WE CAN TELL, UNDER APPROPRIATE CONDITIONS THAT WOULD ACCEPT THEM BEING USEFULLY USED, BUT THEY DON'T QUALIFY UNDER OUR --

CO-CHAIR LANSING: BUT, ALAN, I JUST WANT TO MAKE SURE I UNDERSTOOD THIS ANSWER BECAUSE I AM A LAYPERSON. THE FIRST PART OF THE QUESTION, WHICH IS TO ME A MORE EASY ANSWER, IS THAT PEOPLE -- THAT YOU BELIEVE THERE'S A PRETTY BIG POOL THAT WOULD ADVANCE THE SCIENCE OF PEOPLE WHO KNOWINGLY CHECKED RESEARCH AS A POSSIBLE OPTION.

DR. TROUNSON: THERE'S A LARGE NUMBER OF EMBRYOS, AS I UNDERSTAND, IN THE U.S. WHERE THE BOX HAS BEEN CLEARLY.

CO-CHAIR LANSING: SO SAY THAT. THAT'S A

VERY IMPORTANT --

CHAIRMAN LO: YOU'RE SAYING THE BOX WAS CHECKED, NOT JUST BY THE PERSON WHO WANTED TO DONATE THE EMBRYO, BUT WAS ALSO CHECKED FOR RESEARCH BY THE GAMETE DONOR. THAT'S WHAT I WASN'T SURE OF.

DR. TROUNSON: WE DON'T HAVE THAT INFORMATION, I DON'T THINK, ANYWHERE AT HAND TO SAY WHAT PORTION OF THOSE THAT ARE. BUT THERE'S CERTAINLY, IF YOU GO BACK AND ASK IN EACH AND EVERY CASE, YOU WILL FIND SOME OF THOSE. BUT IT WILL BE -- IN THE CASE OF A DONATED EGG, THE FURTHER YOU GO BACK, THE LESS LIKELY THERE IS. AND EVEN NOW YOU WILL FIND IT, BUT IN THE CASE IT WAS A DONATED SPERM, AS ANN SAYS, IT'S STILL QUITE COMMON.

CO-CHAIR LANSING: THE DONATED EGG, THERE WILL BE -- BUT YOU THINK -- YOU SAID INITIALLY YOU THOUGHT THERE WAS A PRETTY BIG POOL OF RESEARCH CHECKED BOXES.

DR. TROUNSON: YES. YOU KNOW, I THINK OF RESEARCH CHECKED BOXES FOR EMBRYOS; BUT WHEN WE'RE TALKING ABOUT SORT OF DONATION OF EGGS TO FORM AN EMBRYO, THAT I CAN'T TELL. AND I DON'T THINK ANYONE HAS THAT --

CHAIRMAN LO: LET ME ASK SHERRY'S QUESTION A DIFFERENT WAY TO YOU AND ACTUALLY MARIE AS WELL.

IS THE POOL OF EMBRYOS FOR WHICH WE HAVE CONSENT FROM THE EMBRYO WOMAN OR COUPLE IN IVF PLUS A CHECK BOX ON BOTH GAMETE DONOR SUFFICIENT FOR SCIENTIFIC PURPOSES, OR IS THERE IMPORTANT SCIENCE THAT WOULD REQUIRE ADDITIONAL EMBRYOS USED -- TO USE IN RESEARCH WHERE WE HAVE CONSENT FROM THE DONOR COUPLE IN IVF, BUT WE ACTUALLY DON'T KNOW AT ALL WHAT THE OOCYTE OR GAMETE OR OOCYTE OR SPERM DONOR, THEY WEREN'T OFFERED A CHECK BOX? I GUESS THAT'S THE, I THINK, THE FOLLOW-ON TO SHERRY'S QUESTION.

DR. CSETE: SO FOR SCIENTIFIC PURPOSES, SOMETHING THAT HAS TO LEAVE THE LAB, THE ANSWER IS, YES, THERE'S SIGNIFICANT MATERIAL. I THINK EVERYONE WOULD AGREE TO THAT. HOWEVER, WHEN YOU GO FOR CLINICAL PURPOSES, WE NOW HAVE A SITUATION WHERE YOU CAN'T REPLACE A HUGE BODY OF BANKED MATERIAL BASED ON ONE CLINICAL LINE THAT SERVES AS THE MASTER BANK FOR A POTENTIAL CELL PRODUCT THAT'S VERY CLOSE TO GOING INTO PATIENTS. SO THAT'S WHY WE'RE HAVING THIS DISCUSSION.

I THINK PART OF YOUR QUESTION, SHERRY, I WANT TO TRY TO LEAD TO WHAT YOU SAID, WAS ARE THERE AVAILABLE MATERIALS THAT CAN SORT OF COVER THE NEED. AND I THINK, YES, THERE ARE FOR A NEED RESTRICTED TO A LABORATORY. BUT THERE'S A PARTICULAR CLINICAL

NEED FOR CONSIDERING SOME LINES THAT HAVE BEEN NOW EXTENSIVELY CHARACTERIZED AND BECOME THE BASIS FOR A NOMINAL THERAPY.

CO-CHAIR LANSING: HOW WOULD YOU EXPLAIN THAT SECOND PART?

DR. CSETE: THOSE ARE FEW. SO A COMMERCIAL ENTITY DECIDES TO MAKE A DIFFERENTIATED CELL PRODUCT FROM A HUMAN EMBRYONIC STEM CELL LINE. YOU'RE NOT GOING TO DO THAT FROM POOLS OF HUMAN EMBRYONIC STEM CELL LINES. YOU'RE GOING TO DO IT FROM ONE. AND THE EXPANSION OF THAT BANK THAT WILL SERVE AS THE SOURCE FOR THE CELLS FOR THERAPY IS UNIQUE TO THAT LINE BECAUSE THAT'S THE ONE THAT WAS PICKED, THAT'S THE ONE WHERE YEARS AND A HUGE AMOUNT OF EFFORT WENT INTO EXPANDING AND FREEZING THE SOURCE FOR THE FUTURE THERAPIES. AND THIS WAS ALL DONE PRIOR TO THE REGULATIONS.

CO-CHAIR LANSING: HOW DOES THAT -- HOW ARE WE AFFECTED BY THAT?

CHAIRMAN LO: LET ME -- SO THIS IS A SOMEWHAT DIFFERENT SITUATION, BUT MARIE'S COMMENT IS ACTUALLY A STEM CELL LINE THAT EXISTS, NOT AN EMBRYO --

CO-CHAIR LANSING: RIGHT.

CHAIRMAN LO: -- THAT WAS MADE AT LEAST

THROUGH AN EMBRYONIC STEM CELL LINE BEFORE 2005, AND ALSO, JUST TO SORT OF UNDERLINE THE REASON, WAS DONE UNDER GOOD MANUFACTURING PRACTICES. SO A LOT MORE ATTENTION TO STERILITY, QUALITY CONTROL, ALL THE THINGS THAT YOU DIDN'T WANT IN A STEM CELL LINE THAT MIGHT BE USED FOR TRANSPLANTATION. BUT TYPICALLY IF WE'RE JUST DOING IT IN THE LABORATORY TO DERIVE A STEM CELL LINE FOR SCIENTIFIC RESEARCH, YOU WOULDN'T GO THROUGH ALL THAT EXTRA EFFORT AND COST.

SO IT'S ONE PARTICULAR LINE THAT WAS ACTUALLY AN EXISTING LINE FROM EMBRYOS MADE INTO A LINE BEFORE NAS OR WE ISSUED GUIDELINES. AND BECAUSE IT WAS DONE UNDER THESE GOOD MANUFACTURING PRACTICES, IT'S DEEMED AS HIGHLY DESIRABLE FOR POTENTIAL TRANSPLANT. SO NOW A LOT OF PEOPLE ARE USING THIS ONE PARTICULAR LINE TRYING TO DIFFERENTIATE IT INTO A SPECIALIZED CELL, FOR EXAMPLE --

CO-CHAIR LANSING: I UNDERSTAND.

CHAIRMAN LO: -- TRYING TO GET AN ISLET CELL FOR TRANSPLANTATION.

CO-CHAIR LANSING: SO WHY CAN'T WE USE THAT? WHAT'S THE --

CHAIRMAN LO: WELL, THE PROBLEM WAS THAT WHEN YOU GO BACK TO HOW THAT LINE WAS DERIVED,

GRANTED, YOU DON'T KNOW THE YEAR, THEY HAD CONSENT FROM THE WOMAN IN IVF, THE COUPLE IN IVF, BUT ONE OF THE DONORS WAS ANONYMOUS. THEY DIDN'T KNOW WHETHER THAT DONOR WOULD HAVE APPROVED. THEY DID AT THE TIME BECAUSE AT THE TIME THEY DID IT, NO HAD MENTIONED GETTING CONSENT FROM OOCYTE OR SPERM DONORS FOR STEM CELL DERIVATION. THEY WENT AHEAD AND DID IT, WERE SUCCESSFUL, AND NOW IT'S BEING USED. AND THE QUESTION IS --

CO-CHAIR LANSING: THERE'S AN EXISTING STEM CELL LINE.

CHAIRMAN LO: IT'S AN EXISTING LINE WHICH IS DIFFERENT --

CO-CHAIR LANSING: SO IT'S BEEN DONE ALREADY, SO WE ARE NOT CULPABLE. IT'S BEEN DONE ALREADY, SO THAT'S AN EXISTING STEM CELL LINE, AND DO WE NOT USE IT THEN AGAIN, WE'D BE HELD TO A HIGHER STANDARD. THAT DOESN'T MAKE SENSE TO ME.

CHAIRMAN LO: SO THIS IS --

CO-CHAIR LANSING: I CAN'T UNDERSTAND THAT. I'M REALLY SORRY.

CHAIRMAN LO: THIS IS -- WE'VE GOT ALL THE ISSUES.

DR. TAYLOR: WITH ALL DUE RESPECT, I'VE GOT TO SAY THAT IF WE'RE GOING TO DEVELOP A STEM

CELL LINE AND GO THROUGH GMP PROCEDURES AND DO THIS WITH A CELL WE HAVE NO INFORMATION ABOUT WHO ARE THE GAMETE DONORS, I FIND THAT JUST HIGHLY IRRESPONSIBLE. GIVEN THE OPPORTUNITIES THAT WE HAVE, GIVEN THE OPPORTUNITIES THAT WE HAVE TO ACTUALLY KNOW AND DEVELOP CELLS AND KNOW WHAT THE GENETIC BACKGROUND IS, TO ME IT SEEMS CRAZY TO TAKE SOMETHING THAT WE ARE NEVER GOING TO HAVE ANY INFORMATION ABOUT AND DRIVE THAT CELL ALL THE WAY TO THE END SO THAT THAT BECOMES AN ATTRACTIVE CELL FOR PRODUCTION.

DR. CSETE: I WANT TO MAKE SURE THAT, YOU KNOW, THAT IT WASN'T DERIVED WITHOUT ANY INFORMATION. SO I'M JUST CONCERNED THAT IF WE'RE MAKING DECISIONS ABOUT NOT HAVING CONSENT FROM AN ANONYMOUS EGG DONOR, THAT THAT HAS IMPLICATIONS FOR THESE LINES. AND THERE WAS CONSENT. THERE IS CONSENT FROM SPERM DONOR, THE WOMAN WHO WAS THERE FOR REPRODUCTIVE PURPOSES, AND THERE'S NO CONTACT CLAUSE ON THE EGG DONOR, IRB APPROVAL CHECKED OFF, DONE WITH THE BEST OF THE INTENTIONS EVEN BEFORE THESE --

DR. TAYLOR: THERE ARE LOTS OF GREAT THINGS THEY CAN DO WITH THE CELLS. IT'S JUST THAT I DON'T PERSONALLY WANT THOSE CELLS TO TRANSPLANT IN

MY LIVER.

CHAIRMAN LO: WHAT YEAR WAS THAT DERIVED?

DR. LOMAX: MARCH -- LET ME JUST LOOK THROUGH. THE EMBRYO WAS CREATED IN 200- --

CHAIRMAN LO: WHAT WAS THE LINE?

DR. LOMAX: I BELIEVE IT'S A LINE THAT DIDN'T NEED TO BE -- THE EXTENSION OF THE LINE BEGAN IN MARCH 2005.

MR. KLEIN: AND, BERNIE, I'D LIKE TO COMMENT ON THIS. ROB, WITH DUE RESPECT, I HAVE A REAL PROBLEM WITH YOUR POSITION BECAUSE IF IT WAS LEGALLY DERIVED, AND THIS IS A FIELD THAT'S DEVELOPING, AND IN THE FIELD OF DIABETES SPECIFICALLY YOU'RE IMPACTING THAT I'M AWARE OF. IF YOU'VE GOT TO THE POINT YOU'VE GOT A GMP LINE THAT MEETS FDA REQUIREMENTS, THAT HAS PROPER CHARACTERIZATION, AND A TREMENDOUS AMOUNT OF RESEARCH HAS GONE INTO, AND YOU'RE GOING TO GO BACK AND SAY YOU DIDN'T HAVE A SPERM DONOR WHO DIDN'T -- WHO WANTED TO BE ANONYMOUS AND DIDN'T WANT TO BE CONTACTED, AND NOW TO IMPOSE AT THIS POINT AN OBLIGATION OF THAT PERSON HAVING CONSENTED, WHEN WE HAVE ALL THE OTHER PROTOCOLS BEING FOLLOWED, I THINK YOU'RE PUTTING A NEW STANDARD WITH FULL INFORMATION ABOVE THE IMPORTANCE OF THE PATIENT, WHICH VIOLATES

SOME BASIC VALUES OF MINE.

THE PATIENT HAS TO BE VALUED; THEIR LIFE HAS TO BE VALUED. WE CANNOT DEFAULT ON OUR OBLIGATIONS TO THE PATIENTS BECAUSE OF A SUPER ETHICAL PERSPECTIVE WE NOW HAVE THAT SOME SPERM DONOR FIVE YEARS AGO OR TEN YEARS AGO MAY HAVE WANTED TO, IF THEY HAD KNOWN AT THE TIME THEY GAVE UP CONTROL OF THAT SPERM, TO HAVE SOME FUTURE CONTROL.

SO I JUST DON'T -- I JUST DON'T AGREE IN TERMS OF ETHICAL VALUES, IN TERMS OF MORAL VALUES, OR IN TERMS OF LEGAL VALUES ON DEFAULTING OUT THAT TYPE OF LINE WHEN WE'RE SO DEPENDENT ON MOVING THERAPIES FOR PATIENTS WHO MAY BE GOING BLIND BECAUSE THEY HAVE A DISEASE OR LOSING THEIR KIDNEYS BECAUSE THEY HAVE A DISEASE. AND I THINK WE HAVE TO WEIGH THAT CONSIDERATION VERY SERIOUSLY.

DR. TAYLOR: I APPRECIATE WHAT YOU'RE SAYING. ACTUALLY MY ISSUES ARE NEITHER ETHICAL NOR MORAL. THEY'RE PURELY SCIENTIFIC AND INTELLECTUAL. IT SEEMS TO ME THAT IF WE'RE DEVELOPING CELLS FOR TRANSPLANTATION, I THINK IT'S BEST TO KNOW THE FAMILY HISTORY, AS MUCH DETAIL AS WE HAVE ABOUT THE INDIVIDUAL DONORS, AND TO HAVE DONORS WHO ARE WILLING TO SORT OF HAVE THAT INFORMATION COLLECTED.

SO IT'S REALLY NOT AN ETHICAL ISSUE. TO ME IT'S KIND OF A JUDGMENT ISSUE ABOUT WHAT CELL DO YOU KIND OF PUSH TO GATHER FIRST. AND IF IT WERE KIND OF COMING OUT OF MY LABORATORY, THAT WOULDN'T HAVE BEEN THE CELL LINE THAT I WOULD HAVE TRIED TO DRIVE TO THE END POINT.

NOW, IF YOU'RE TELLING ME THAT SORT OUT OF DESPERATION WE NEED TO USE WHATEVER IS AVAILABLE, THEN ONE HAS TO MAKE COMPROMISES. AND I THINK THE COMPROMISE WE'RE MAKING HERE, AGAIN FROM MY PERSPECTIVE, IS NOT REALLY A MORAL OR ETHICAL ONE. IT'S AN INFORMATIONAL ONE. THIS IS THE BEST ONE. IT'S LIKE SORT OF A BLOOD -- MISMATCHED BLOOD DONATION WHEN SOMEBODY'S EXSANGUINATED. YOU UTILIZE WHATEVER YOU'VE GOT.

MR. KLEIN: I CERTAINLY AGREE SCIENTIFICALLY WE WOULD PREFER TO HAVE THE MOST DETAILED INFORMATION POSSIBLE. IN THIS CASE MY UNDERSTANDING, IF YOU HAVE A VERY HIGH DEGREE OF INFORMATION, BUT AS TO THE SPERM DONOR AND THE DEGREE OF INFORMATION YOU HAVE, WHILE ANONYMOUS, AS TO HISTORY, I JUST DON'T HAVE THAT INFORMATION. YOU KNOW, I APPRECIATE THE CLARIFICATION, SO IT'S NOT AN ETHICAL OR MORAL DECISION. IT'S JUST A QUESTION OF SCIENTIFIC --

CHAIRMAN LO: SO I THINK IT FALLS TO SCIENCE BECAUSE THERE'S A CONCERN ABOUT SAFETY FOR THE TRANSPLANTED CELL.

MR. KLEIN: I UNDERSTAND.

DR. TAYLOR: I JUST KIND OF THINK IT WAS A BAD EXPERIMENT.

CHAIRMAN LO: SO A LOT OF PEOPLE ARE WANTING TO GET IN, SO LET ME JUST MAKE SURE. JEFF, MARCY, SHERRY. JEFF, YOU HAVEN'T HAD A CHANCE.

MR. SHEEHY: WELL, I GUESS WHAT I'M TRYING TO FOCUS ON IS KIND OF THE POINT BETWEEN BOB AND ROB. FOR WANT AFTER BETTER DESCRIPTION, I CALL IT UTILITY ARGUMENT. AND RATHER THAN TRYING TO REWRITE ALL OF OUR RULES, IS THERE A WAY TO CAPTURE JUST THIS -- YOU KNOW, THERE'S A LOT -- AND MAYBE WE CAN DO ONE-OFF EXCEPTIONS OR, YOU KNOW, THERE'S A LOT ABOUT THIS ONE PARTICULAR LINE THAT WE COULD DESCRIBE IN ORDER TO SAY THAT IT'S AN EXCEPTION. IT'S GMP, CERTAIN TYPES OF -- YOU KNOW, THERE'S ALL THESE OTHER UTILITY, WHAT IS IT GOING TO BE USED FOR, WHAT IT'S BEING USED FOR, THE GENERAL -- THE WAY IN WHICH IT'S KIND OF INVALIDATED FOR USE FOR ALL THESE OTHER FOLKS BESIDES US THAT COULD BE THE WAY TO CAPTURE THE ABILITY FOR OUR RESEARCHERS TO USE IT WITHOUT SUDDENLY SAYING ALL -- YOU KNOW, YOU

DON'T HAVE TO HAVE IDENTIFYING -- YOU DON'T HAVE TO BE ABLE TO GET IN CONTACT WITH EVERY GAMETE DONOR.

YOU KNOW, BECAUSE IT SEEMS LIKE WE'RE LETTING THE EXCEPTION DRAW THE RULES WHEN REALLY WE SHOULD WRITE A RULE FOR THE EXCEPTION. THAT'S MY POINT.

MS. FEIT: I JUST TEND TO AGREE WITH DR. TAYLOR'S COMMENTS BECAUSE I HAVE A SON WHO'S GOING BLIND OF DIABETES. HE'S STILL YOUNG. JUST HAD MAJOR EYE SURGERY. WE DON'T KNOW IF WE CAN SAVE HIS SIGHT, BUT I WOULD NOT WANT HIM INSTILLED WITH STEM CELLS COMPETING BEHIND. I MEAN CERTAINLY BEING BLIND AND LIVING ANOTHER 20 YEARS AS A BLIND PERSON IS A LIFE-ALTERING SITUATION FOR OTHER THINGS.

IN MEDICINE IT'S ALWAYS BEEN THE MANTRA DO NO HARM. AND SO I THINK YOU HAVE TO BE CAREFUL. YOU HAVE TO GET KNOWLEDGE, FOLLOW PROCESSES, WE HAVE TO ACKNOWLEDGE THE FACT THAT WE DON'T HAVE INFORMATION. THAT CAN MEAN SOMETHING. SO WE DO HAVE TO BE CAREFUL.

I THINK GOING BACK TO SHERRY'S COMMENTS, WHICH ARE VERY VALID, NOT UNDERSTANDING HOW MANY AND WHAT THE POOLS ARE AND WHAT THEY REPRESENT. MAYBE WHERE WE'RE GOING IS INTO AN ERA WHERE WE HAVE TO HAVE THAT KNOWLEDGE. AND WE HAVE TO KNOW, YOU KNOW,

HOW MANY OF THOSE EMBRYOS ARE AVAILABLE, WHAT IS THE CIRCUMSTANCE, ARE THEY DONATABLE, AND ARE THEY DONATABLE FOR GENERAL RESEARCH.

I ALSO AGREE THAT IF THEY SAID THEY COULD BE DONATED FOR GENERAL RESEARCH, AND WE HAVE ALL THE RIGHT SCIENTIFIC PROCESS INFORMATION, THAT WE SHOULDN'T THEN DISCRIMINATE. WE'RE A PART OF RESEARCH. WE SHOULD MOVE FORWARD.

CHAIRMAN LO: LET ME MAKE ONE COMMENT. I THINK THE LAST THREE OR FOUR SPEAKERS HAVE REALLY TOUCHED ON SOME IMPORTANT POINTS. I THINK IT'S POSSIBLE TO SEPARATE OUT THE SAFETY FOR POTENTIAL TRANSPLANT RECIPIENTS FROM THE QUESTION WHICH WE HAVE BEFORE US, WHICH IS REALLY SHOULD WE ALLOW CIRM-FUNDED RESEARCHERS TO WORK WITH THIS LINE. I THINK TO SOME EXTENT THE FDA CHARGE IS TO WHEN SOMEONE SAYS I WISH TO DO A CLINICAL TRIAL INVOLVING THIS CANDIDATE FOR THERAPY, THERE'S WHEN WE SHOULD LOOK AT THE POTENTIAL RISK TO THE PARTICIPANTS IN THAT CLINICAL TRIAL, WHICH IN THIS CASE I WOULD HOPE WE WOULD CONSIDER THIS NOTION OF DO WE HAVE ENOUGH INFORMATION ABOUT THE GAMETE DONOR.

I DON'T KNOW WHAT THE -- THE FDA, THESE ARE CONFIDENTIAL DISCUSSIONS BETWEEN THE FDA AND THE INVESTIGATOR AND THE SPONSOR OF THE CLINICAL TRIAL.

SO I DON'T KNOW WHAT'S TRANSPIRED THERE, BUT I THINK WE SHOULD ALL KEEP IN MIND THE FDA, TO THE EXTENT IT DOES ITS CHARGE, IS SUPPOSED TO LOOK AT THIS QUESTION IN DETAIL WITH REGARD TO THE SPECIFIC PROTOCOLS. WE DON'T HAVE TO SETTLE THAT. IN FACT, WE CAN'T BECAUSE WE DON'T KNOW THE DETAILS.

DR. CSETE: THAT'S ABSOLUTELY RIGHT.

CHAIRMAN LO: IT'S NOT SOMETHING THAT'S --

DR. TROUNSON: IT'S NOT THAT THEY'RE GOING TO ISSUE GUIDELINES. THIS PARTICULAR ORGANIZATION HAS BEEN IN CONTACT WITH THE FDA, AND THEY HAVE BEEN CONTINUING TO DO WORK ON THE BASAL SET. IT IS VERY LIKELY THAT THAT COULD BE AGREED TO BY THE FDA. THEY'RE NOT CHARGED WITH SPECIFICALLY THE ETHICAL ISSUES, BUT BETTER THE MEDICAL RISKS IN SOME RESEARCH ASPECT. IN REALITY, NEARLY ALL THE RESEARCH HAS BEEN DONE ON STEM CELL LINES WHERE THERE'S ABSOLUTELY NO BACKGROUND KNOWLEDGE OR WILL THERE EVER BE ON THE GENOME AND DISEASE HISTORY.

SO I THINK IN A SENSE THAT, YOU KNOW, WE OUGHT TO IMPROVE THESE THINGS GOING FORWARD. MY OWN VIEW HERE IS IT'S NOT REALLY US, THE COMMITTEE SPECIFICALLY, CARTE BLANCHE TO DEVELOP NEW EMBRYONIC STEM CELL LINES FROM SUCH EMBRYOS, BUT HOPEFULLY

IT'S GRANDFATHERING IN SOMETHING THAT WAS DONE PRIOR TO THE ESTABLISHMENT OF OUR GUIDELINES BECAUSE IT SEEMS LIKE THAT IS SOMETHING THAT WE'VE DONE IN THE PAST, OR WE'VE AGREED TO IN THE PAST. AND IF THERE'S SUFFICIENT JUSTIFICATION TO DO THAT, I THINK IT WOULD BE EXTREMELY HELPFUL OR COULD BE EXTREMELY HELPFUL IN THE PARTICULAR INSTANCE THAT WE HAVE NOW.

CHAIRMAN LO: WE HAVE A LOT OF HANDS. SHERRY, AND THEN ANN --

CO-CHAIR LANSING: I'LL GO LAST SINCE I'VE TALKED A LOT.

CHAIRMAN LO: ANN.

DR. KIESSLING: I JUST WANTED TO MAKE A QUICK RESPONSE TO SHERRY'S QUESTION. ONLY ABOUT 15 PERCENT OF IVF CYCLES IN THE COUNTRY INVOLVE ANY DONATED GAMETES. SO 85 PERCENT OF IVF CYCLES IN THE COUNTRY ARE FROM THE COUPLE INVOLVED; IS THAT RIGHT?

DR. TAYLOR: (NODS.)

DR. KIESSLING: SO WE'RE TALKING ABOUT -- FROM THE EMBRYO WE'RE TALKING ABOUT MAYBE -- IT MIGHT BE MORE THAN 15 PERCENT OF EMBRYOS BECAUSE EGG DONORS TEND TO GENERATE MORE EMBRYOS, BUT WE'RE NOT TALKING ABOUT THAT PROBLEM RELATIVE TO THE ENTIRE FROZEN EMBRYO BANK. A RELATIVELY SMALL PERCENTAGE ARE DONATED.

CHAIRMAN LO: LET ME JUST, AGAIN, IF I COULD INTERRUPT FOR A MINUTE. BUT ALL OF THE 15 PERCENT OF EMBRYOS FROZEN IN IVF CLINICS THAT ARE FROM OOCYTE DONORS, ARE THERE SCIENTIFIC REASONS TO WANT TO USE THOSE TO DERIVE NEW EMBRYONIC STEM CELL LINES SINCE THE DONORS ARE YOUNGER AND MAY BE ABLE TO GET A MORE ROBUST LINE. THAT'S A QUESTION I DON'T KNOW THE ANSWER TO.

DR. TROUNSON: BERNIE, IT'S REALLY HARD TO ANSWER THAT QUESTION BECAUSE THERE MIGHT BE SOME SPECIAL REASON TO DO THAT. BUT THEN I THINK, AGAIN, WE CAN PICK A SPECIAL REASONS TO YOU. AS JEFF SAID, YOU KNOW, THAT THERE WOULD BE A REASON FOR DOING IT. FOR EXAMPLE, IF THERE WOULD BE A SPECIFIC GENOTYPE NOT AVAILABLE SOMEWHERE ELSE. ONE WOULD HAVE THOUGHT THAT MIGHT BE DIFFICULT.

BUT, YOU KNOW, I THINK THERE COULD BE REASONS. THE OTHER EXAMPLE FOR WHICH DR. CIBELLI WOULD BE AWARE IS IF AT TIMES WHEN YOU DEVELOP A SPECIAL STEM CELL LINE, SAY HOMOLOGOUS RECOMBINATION PROCEDURE THAT YOU INSERTED A REPORTER GENE INTO THESE CELLS. IT'S TAKEN FOUR YEARS TO DO IT. IT'S NOW A REAGENT AVAILABLE TO CALIFORNIA SCIENTISTS, BUT IT FALLS OUT UNDER THESE RULES BECAUSE THE DONOR WAS NOT -- COULD NOT GIVE APPROVAL. HERE WOULD BE

ANOTHER EXAMPLE FOR WHICH I THINK I'D WANT THE COMMITTEE TO CONSIDER THAT CAREFULLY BECAUSE FOUR YEARS OF WORK TO GET BACK TO THAT POINT IS AN AWFUL LONG TIME FOR AN IMPORTANT REAGENT.

CHAIRMAN LO: JOSE AND THEN ROB AND THEN ALTA.

DR. CIBELLI: FIRST THING I WOULD SAY IS THAT HAVING BEEN FACED WITH THIS, I THINK THAT SCIENCE WILL NEVER FINISH ANSWERING ALL THE QUESTIONS RELATED TO THE DERIVATION OF NEW STEM CELLS. SO WE ALSO NEED TO REALIZE IT'S BEEN 25 YEARS SINCE THE PERSON (INAUDIBLE). SO THIS IS GOING TO HAPPEN AND NEEDS TO HAPPEN.

THE OTHER QUESTION IS WHO HAS THE LEGAL AUTHORITY TO DECIDE THE FATE OF THAT EMBRYO? SO IF THE MALE IS DONATING HIS SPERM, AND AS ALAN WAS SAYING, THEN THOSE EMBRYOS ARE BASICALLY ADOPTED OR TAKEN BY THE COUPLE, IS THE COUPLE THE ONE THAT'S GOING TO DECIDE WHETHER WE'RE GOING GIVE THEM TO BE RESERVED, WHETHER THEY'VE TO BE DESTROYED, OR GOING INTO RESEARCH? I THINK THAT WE SHOULD STAY TO THE WISHES OF THE COUPLE. AND IF THE DONORS, IN FACT, ARE WILLING GIVE THOSE RIGHTS TO THE COUPLE, WHY WOULD WE GO BACK AND TRY TO CHANGE THEIR VIEWS?

DR. TAYLOR: LET'S SEE. I WAS JUST GOING

TO -- YOU KNOW, I SORT OF HESITATE TO SAY THIS BECAUSE WE'LL BE HERE FOREVER ON THE BASIS OF, BUT I DO BELIEVE THAT THERE'S RESEARCH AND THERE'S RESEARCH AND THERE'S RESEARCH AND THERE'S RESEARCH. I SORT OF -- IT'S UNFORTUNATE, BUT I BELIEVE THERE ARE A LOT OF LAYERS OF THINGS THAT WE MAY HAVE TO SUBCATEGORIZE IN TERMS OF THE DEGREE OF INFORMATION THAT WE HAVE BOTH KIND ON KIND OF A SCIENTIFIC BASIS AND ALSO POSSIBLY ON AN ETHICAL BASIS.

SO I DO BELIEVE THAT HOMOLOGOUS RECOMBINATION CELL LINES THAT WAS DERIVED COULD BE USEFUL FOR LABORATORY EXPERIMENTS TO LEARN LOTS AND LOTS AND LOTS OF THINGS AND SHOULD BE MADE AVAILABLE AS QUICKLY AS POSSIBLE. BUT WHAT I PERSONALLY FEEL IS THAT WHEN WE'RE TALKING ABOUT CELLS THAT ARE GOING TO BE PREPARED FOR CLINICAL INTERVENTIONS, THAT THOSE BE HELD TO THE VERY HIGHEST STANDARD, NOT JUST ETHICALLY, BUT PARTICULARLY SCIENTIFICALLY SO THAT WE KNOW AS MUCH ABOUT THOSE AS WE POSSIBLY CAN. AND SO IT MAY WELL BE THAT WE HAVE GRADED DEGREES OF CONSENT AND ASSENT.

AND, YOU KNOW, MY VIEW, AND I'M A SPERM DONOR WHO DIDN'T EVEN REALLY -- I HAD NEVER HEARD OF STEM CELLS, AND THOSE EMBRYOS WERE THEN LATER GIVEN FOR RESEARCH. I DON'T BELIEVE YOU'VE GOT TO GO BACK

AND GET THAT FOR SOMEBODY TO WORK ON STUFF IN THE LABORATORY. SO, YOU KNOW, AGAIN, I'M SORT OF SUGGESTING WE MIGHT HAVE AN INCREDIBLY COMPLEX MATRIX, AND THIS IS GOING TO BE A HUGE PAIN IN THE REAR TO GO THROUGH THIS POTENTIALLY, BUT I DO THINK IT'S WORTH THINKING ABOUT DIFFERENT DEGREES OF CONSENT, DIFFERENT DEGREES OF SORT OF SCIENTIFIC INFORMATION FOR DIFFERENT ULTIMATE PURPOSES.

AND WE'RE CLOSE NOW TO BEING ABLE TO SHOOT FOR THE MOON AND TO ACTUALLY DO WHAT WE WANT TO DO WITH THESE STEM CELLS. I'D JUST LIKE TO SEE THE VARIOUS CANDIDATES GET OUT THERE AND NOT HAVE SOMEBODY PUSH A PONY THAT THEY'VE INVESTED A LOT OF MONEY IN THAT MIGHT NOT BE THE BEST ONE TO RIDE DOWN THE ROAD.

MR. KLEIN: I THINK THAT WE HAVE TO RELY ON THE FDA BECAUSE THIS AREA OF SCIENCE IS CHANGING CONSTANTLY. I MEAN EVEN IN HUNTINGTON'S DISEASE AND MAYBE EIGHT DIFFERENT DISEASES, SOME PEOPLE WITH CERTAIN GENETIC CHARACTERISTICS YOU WOULD BELIEVE WITH HUNTINGTON'S DISEASE ARE FUNCTIONING NORMALLY AND SOME THAT HAVE THOSE CHARACTERISTICS THAT ARE REALLY TOTALLY DISABLED. THE SPEED OF GENETIC RESEARCH, THE SPEED OF BIOLOGICAL RESEARCH IS CHANGING OUR LEVELS OF KNOWLEDGE SO CONSTANTLY, THAT

THE PROBLEM IS THE OPTIMAL IS ALWAYS DIFFERENT. THE NEXT DAY IT'S GOING TO BE DIFFERENT FROM WHAT IT WAS THE DAY BEFORE.

AND I THINK WE NEED TO BELIEVE THAT THE FDA IS GOING TO BE EFFECTIVE IN FIGURING OUT WHAT IS A SCIENTIFICALLY ACCEPTABLE LINE FOR UTILITY PURPOSES BALANCED IN THE INITIATIVE. FOR ALS IT'S GOING TO BE DIFFERENT THAN IT IS POTENTIALLY FOR DIABETES. SO WE'RE GOING TO GET IN A LOT OF TROUBLE, I THINK, IF WE TRY AND CREATE SOME SCIENTIFIC STANDARDS THAT PREEMPT OUR SCIENTISTS FROM ACTUALLY REACHING EVERY DAY. AND WE NEED TO LOOK AT OUR CHARTER, WHICH HAS BEEN IS IT MORAL, IS IT ETHICAL, IS IT LEGAL. AND WE ALSO NEED TO REALIZE THAT OUR SCIENTISTS NEED TO WORK WITH THE SCIENTISTS FROM OTHER STATES.

THE OTHER CHART UP THERE THAT SHOWED US THAT EVERY OTHER STATE IN THE UNITED STATES THAT HAS NEEDED SCIENTISTS HAVE DECIDED THAT THESE LINES AS LONG AS THEY MEET THE OTHER STANDARDS, IF THEY HAD A SPERM DONOR WHO WAS PAID THAT IT WAS ACCEPTABLE. SO TO THE EXTENT THAT WE DON'T, ON THE BASIS OF INTEGRITY, SEE THAT THERE IS A MAJOR ETHICAL ISSUE, WE SHOULDN'T APPROVE IT. BUT IF WE THINK IT'S GOT ETHICS AND IT'S GOT MORALS, WE NEED TO APPROVE IT SO

OUR SCIENTISTS CAN ACTUALLY WORK WITH SCIENTISTS IN THESE OTHER STATES ON THESE LINES WHICH MAY BE IN MANY DISEASES VERY IMPORTANT TO THE ADVANCEMENT OF MEDICAL THERAPIES.

CHAIRMAN LO: ALTA.

MS. CHARO: I WANT TO IN SOME WAYS RETURN TO A QUESTION THAT ANN ASKED, BUT WAS NEVER ANSWERED ABOUT RETROACTIVE APPLICATION BECAUSE I THINK THERE ARE TWO VERY DIFFERENT DEBATES GOING ON. I FEEL LIKE OFTEN WE'RE CONFLATING THAT, AND I WANT TO FOCUS NOW ON THE ETHICS ISSUE ONLY, NOT THE SCIENTIFIC ISSUE.

CLEARLY WE HAVE AN OPTION OF DECIDING WE WANT TO HAVE THE TIGHTEST POSSIBLE STANDARDS FOR NEW DERIVATIONS GOING FORWARD, AND WE LIMIT THE RANGE OF EMBRYOS THAT CIRM GRANTEES MAY USE TO DIVIDE. AND THAT'S A CONSIDERED DECISION. YOU CAN GO EITHER WAY, BUT THAT'S ONE DISCUSSION ABOUT WHAT STANDARDS YOU WANT TO APPLY TO YOUR OWN GRANTEES FOR THE FUTURE GOING FORWARD.

IT'S A VERY DIFFERENT QUESTION ASKING WHETHER OR NOT YOUR GRANTEES CAN USE MATERIALS, NOT ONLY THAT WERE CREATED IN THE PAST, BUT THAT WERE CREATED BY OTHER PEOPLE IN OTHER JURISDICTIONS UNDER OTHER RULES. AND THIS GETS VERY TRICKY BECAUSE ON

THE ONE HAND, IF YOU DO WANT, NOT ONLY FOR THE SAKE OF CAPTIVE RESEARCH, BUT ALSO FOR THE SAKE OF RESPECT AND ACCOMMODATING AND AVOIDING A KIND OF CALIFORNIA ETHICAL IMPERIALISM, RIGHT, YOU WANT TO ACKNOWLEDGE THAT OTHER JURISDICTIONS MAY HAVE RULES THAT, ALTHOUGH THAT NOT THE SAME, ARE NONETHELESS REASONABLE WITHIN THE WORLD OF REASONABLE SENSE OF RULES, AND THAT THERE OUGHT TO BE THE ABILITY TO GO AHEAD AND USE THOSE LINES BECAUSE THEY WERE JUDGED TO BE REASONABLY DERIVED UNDER SOMEBODY'S ELSE'S NOTIONS OF REASONABLE, WHETHER IT'S THE UK HFEA OR IT'S THE AUSTRALIANS OR IT'S THE ISRAELIS OR WHATEVER.

THAT SAID, WE NONETHELESS ALSO, AND THE NATIONAL ACADEMIES DID THIS, JUST LIKE CIRM DID THIS, IDENTIFIED A FEW VERY FUNDAMENTAL CORE PRINCIPLES WHICH WERE NONNEGOTIABLE, FOR WHICH THERE WOULD BE AN ETHICAL IMPERIALISM, AN INSISTENCE ON CERTAIN THINGS. FOR EXAMPLE, AN INSISTENCE THAT THE EMBRYO, NOT THE GAMETE, BUT EMBRYO DONORS HAD GIVEN INFORMED CONSENT THAT THE EMBRYOS BE DIVERTED TO RESEARCH. THAT IT HAD BEEN DONE WITH SOME INDEPENDENT OVERSIGHT. THESE WERE NONNEGOTIABLES. THEY GO INTO THE DEFINITION OF SEPARATELY DERIVED.

SO IN SOME WAYS I THINK THE QUESTION THAT

WE MIGHT WANT TO FOCUS ON IS WHETHER OR NOT CONSENT FROM AN UNDERLYING OFTEN ANONYMOUS GAMETE DONOR IS ONE OF THOSE NONNEGOTIABLE FUNDAMENTALS THAT WE WILL INSIST UPON AS A CONDITION FOR THE USE OF LINES THAT WERE CREATED ELSEWHERE OR AT ANOTHER TIME VERSUS SAYING THAT THIS IS ONE OF THE ONES WHERE SO LONG AS IT WAS DONE IN A WAY THAT MET THE REQUIREMENTS AT THAT TIME IN THAT PLACE, WE WILL ACCEPT AS WITHIN THE REALM OF REASONABLE. AND FOCUSING ON THAT, I THINK, MAYBE NARROWS THE DISCUSSION A LITTLE BIT, NOT TO WHAT WOULD BE OPTIMAL, BUT TO WHAT IS SO CORE THAT WE WILL NOT YIELD ON IT EVEN IF THE LINES WERE LEGALLY DERIVED IN ANOTHER PLACE AND TIME.

CO-CHAIR LANSING: SO I JUST WANTED TO MAKE SURE THAT I'M HEARING THIS RIGHT BECAUSE I THINK WE'VE GOTTEN OFF AND CHANGED SLIGHTLY. I THINK WE'VE GOTTEN OFF ON WHAT OUR MISSION IS. OUR MISSION INITIALLY, THE QUESTION THAT WAS PUT BEFORE THE GROUP WAS WOULD WE REVISE OUR ETHICAL POLICY, THAT IF THERE WAS A PAYMENT FOR FERTILIZATION, WOULD WE NOW TAKE THOSE EMBRYOS FOR SCIENTIFIC RESEARCH. AND INITIALLY WE SAID NO. YOU KNOW, THAT WAS OUR VERY, VERY, VERY CONSERVATIVE STANCE, AND THAT STANCE WE ARE NOW REEVALUATING AND QUESTIONING WHETHER THAT IS TOO HIGH GIVEN THE INFORMATION THAT

WE'RE FINDING NATIONALLY AND INTERNATIONALLY, AND ALSO WHETHER IT'S HURTING US IN TERMS OF ADVANCING THE SCIENCE.

DR. TAYLOR: WE'RE BACK TO PAYMENT NOW, SO I'M KIND OF CONFUSED. REALLY THERE ARE TWO ISSUES.

CHAIRMAN LO: LET'S TRY --

CO-CHAIR LANSING: NOT PAYING FOR.

DR. LOMAX: I THINK FOR THE BENEFIT OF THE COMMITTEE AND THE AUDIENCE, PERHAPS I COULD JUST LAY OUT THE CONDITIONS, I THINK THE FACTS AROUND THE SPECIFIC EXAMPLE WHICH WE WANTED TO BRING TO YOUR ATTENTION AS AN EXAMPLE OF THE CATEGORY OF PROBLEM OR ISSUE WE'VE IDENTIFIED.

SO THIS DOES NOT ACTUALLY DEAL WITH PAYMENTS. IT IS THE CASE IN THIS PARTICULAR EXAMPLE, WHICH WAS DESCRIBED EARLIER BY THE SCIENTIFIC TEAM, OF AN EXISTING STEM CELL LINE THAT HAS CERTAIN SCIENTIFIC VALUE, WHICH IS DESCRIBED IN THE BRIEFING MEMO ON THIS TOPIC. THE TITLE OF THE MEMO IS "USE OF STEM CELL LINES DERIVED PRIOR TO THE EFFECTIVE DATE OF THE REGULATION."

SO IN THIS CASE IT IS AN EXISTING LINE. AND WHAT I'VE TRIED TO DO IN THIS VIEW GRAPH IS TO SUMMARIZE THE POLICY CONSIDERATIONS WHERE THERE'S A NARRATIVE IN THE BRIEFING MEMO. IF YOU WANT TO

EVALUATE THOSE LINES AGAINST OUR STANDARD FOR ACCEPTABLY DERIVED, THE ISSUE OF GAMETE DONOR CONSENT IS THE ISSUE WHERE THIS LINE DOES NOT MEET THE LETTER OF OUR STANDARD TODAY. BUT IF YOU WERE TO GO THROUGH THE ADDITIONAL CRITERIA, THERE WAS NO PAYMENT FOR THE GAMETE DONOR, IT WAS DONE UNDER IRB APPROVAL, AND THERE WAS NO REIMBURSEMENT FOR STORAGE.

SO THE FIRST QUESTION WE BROUGHT TO YOU TODAY WAS ACTUALLY NOT ABOUT PAYMENT PER SE. IT WAS ABOUT THE ACCEPTABILITY OF EXISTING LINES THAT WERE IN EXISTENCE PRIOR TO OUR REGULATIONS TAKING EFFECT. THEY WERE DERIVED OUTSIDE OF SORT OF THE CIRM UNIVERSE. AND IS THERE -- WE WANT TO CONSIDER SOME MECHANISM TO BRING A LOT OF THOSE MATERIALS TO ENTER INTO EXISTING CIRM GRANTS.

SO THAT'S THE SPECIFIC --

CO-CHAIR LANSING: WHEN YOU SAY EXISTING STEM CELL LINES --

DR. LOMAX: WELL, IT'S EXISTING STEM CELL LINES DERIVED PRIOR TO THE DATE OF OUR REGULATIONS. WE USED THAT AS A CUT POINT BECAUSE IT ADDRESSES THIS ISSUE OF WHETHER OR NOT YOU APPLY THE STANDARDS RETROACTIVELY OR NOT. AND I THINK THERE'S A SENTIMENT THAT YOU DON'T APPLY THINGS RETROACTIVELY,

BUT THAT'S ONE OF THE QUICK CONDITIONS. THE WAY THE STANDARDS ARE WRITTEN NOW, IF YOU WERE TO READ THEM AS WRITTEN, THEY DO APPLY RETROACTIVELY. THERE'S NO EXCEPTION FOR MATERIALS THAT WERE IN EXISTENCE PRIOR TO OUR STANDARDS. IT WAS THE POINT MR. KLEIN MADE EARLIER.

MR. KLEIN: SO, MADAM CHAIR, MAYBE WE COULD FOCUS ON THAT FIRST QUESTION ON EXISTING CELL LINES AND SEE IF THERE'S AN ABILITY TO HAVE A MOTION ON THAT, AND THEN DECIDE WHETHER WE GO TO THE MORE --

CO-CHAIR LANSING: THE SECOND.

DR. KIESSLING: THEN I'D LIKE AN ANSWER TO MY QUESTION FROM ALTA. ARE THERE EXAMPLES, LEGAL EXAMPLES, OF THINGS GOING FORWARD THAT ARE ACTUALLY WHERE TODAY'S STANDARDS ARE APPLIED RETROACTIVELY? I THINK THAT'S THE NUTS AND BOLTS OF WHAT YOU'RE ASKING. WHAT IS THE LIABILITY OF ACCEPTING SOMETHING DOES NOT MEET TODAY'S STANDARD, BUT IT WAS -- BECAUSE THE STANDARD DIDN'T EXIST WHEN THIS TOOK PLACE. THERE'S GOT TO BE EXAMPLES OF THAT IN THE MEDICAL RESEARCH.

MS. CHARO: I'M TRYING TO THINK OF SOMETHING. AND TAMAR WILL THINK OF AS WELL.

DR. TAYLOR: AN EXAMPLE COMES TO MIND IS

THE SPERM DONATION BEFORE THE TIME OF ROUTINE HIV SCREENING. SO, YOU KNOW, AT THE TIME THE HIV EPIDEMIC WAS REALLY STARTING TO BREAK OPEN, NOBODY REALLY NEW VERY MUCH. AND ACTUALLY WOMEN WERE IMPREGNATED FROM DONATED SPERM FROM DONORS WHO WERE NOT SCREENED, AND THERE WAS A BIG ISSUE ABOUT WHEN THAT SCREENING SHOULD HAVE OCCURRED OR WOMEN EXPOSED TO HIV POSITIVE OR SPERM IN HIV POSITIVE MEN. I JUST SORT REMEMBER THAT ISSUE.

MS. CHARO: WELL, THAT'S INTERESTING. I THINK WE'LL PROBABLY HAVE TO DOUBLE-CHECK ON THIS, BUT IT'S A GOOD EXAMPLE YOU BRING UP, ROB, BECAUSE THE FDA INSTITUTED REQUIREMENTS IN THE '90S, LATE '90S FOR THE SCREEN NOT ONLY FOR HIV, BUT FOR A VARIETY OF CONDITIONS, HEP C, HEP B, THINGS LIKE THAT. AND WHAT I DON'T REMEMBER WAS WHETHER OR NOT THOSE RULES WERE PROSPECTIVE ONLY FOR THE FUTURE RECRUITMENT OF SPERM DONORS OR WHETHER THEY EFFECTIVELY MADE IT -- THEY DISALLOWED THE USE OF ANY SEMEN THAT HAD BEEN COLLECTED PRIOR TO SCREENING PRACTICES. I'D BE SURPRISED IF THAT WERE THE CASE BECAUSE I DON'T REMEMBER THE SPERM BANKS PUTTING UP A HUGE FUSS, BUT IT COULD BE. AND I WOULD WANT TO CHECK IT BEFORE ASSUMING THAT THE FDA HAD ESSENTIALLY ALLOWED THE CONTINUED USE OF THE SEMEN

THAT WAS SCREENED UNDER THE OLD LAWS.

DR. CSETE: I THINK IT FELL UNDER THE SAME ISSUE AS STORED FRESH FROZEN PLASMA. ALL THAT STUFF WAS NOT ALLOWED.

MS. CHARO: SO ESSENTIALLY IT WAS THROWN OUT. IT WAS NO LONGER USABLE. BUT, OF COURSE, THESE WERE ALSO RULES THAT HAD TO DO WITH SAFETY AND NOT WITH -- TO CHANGE ETHICAL NORMS. YOU KNOW, ROB, IN MANY WAYS IT'S BEEN AROUND USE OF DATA FROM RESEARCH THAT IN THE PAST WAS DONE ON THE ASSUMPTION THAT IT WAS OKAY AND BY TODAY'S STANDARDS IS CONSIDERED APPALLING. SO OBVIOUSLY THE HOLOCAUST DATA WAS ONE EXAMPLE OF THAT DISCUSSION AND A MORE -- A LESS WELL-KNOWN ONE HAD TO DO WITH THE USE OF THE DATA FROM THE RADIATION EXPERIMENTS THAT THE DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF ENERGY DID IN THE '60S AND '70S.

AGAIN, IT KIND OF GOES BACK TO THE SAME THING I WAS TALKING ABOUT BEFORE, WHICH IS SOMETIMES WE WILL DISALLOW THE USE OF THE DATA BECAUSE THE PREVIOUSLY PERFORMED RESEARCH VIOLATED A STANDARD THAT WE NOW THINK OF AS SO FUNDAMENTAL, THAT YOU DO NOT WISH TO IN ANY WAY AFFILIATE YOURSELF WITH THAT BEHAVIOR. IN OTHER CASES YOU USE IT ON THE UNDERSTANDING THAT THERE'S NO WAY WHICH YOU ARE

FOSTERING THE CONTINUATION OF THAT BEHAVIOR BECAUSE WE'VE EVOLVED PAST THOSE PREVIOUS NORMS AND YOU TAKE WHAT YOU CAN.

SO I DON'T KNOW THAT THERE'S A SINGLE LEGAL RULE ABOUT IT. RETROACTIVE APPLICATION IS USUALLY A PROCESS QUESTION IN THE CONTEXT OF EITHER CRIMINAL JUSTICE OR OCCASIONALLY ASSESSING LIABILITY OF A PREVIOUS ACT THAT THIS RULE DOES.

MR. KLEIN: SO, MR. CHAIRMAN, JUST TO HAVE A FORMAL MOTION IN PLACE FOR OUR DISCUSSION, I WOULD LIKE TO KNOW HOW WE WOULD WORD A MOTION, AND MAYBE DR. CSETE COULD MAYBE INSTRUCT US ON THIS OR GEOFF.

DR. CSETE: BERNIE, YOU CAN HELP WITH THIS BECAUSE I THINK THE -- ONE SET OF WORDS DIDN'T COME UP IN THIS DISCUSSION THAT I THINK IS IMPORTANT TO COME UP IN THIS DISCUSSION IS THAT THE BEST EFFORTS OF THE ETHICAL STANDARDS AT THE TIME WERE FOLLOWED. AND SO JUST WHEN YOU FRAME YOUR MOTION, THINK ABOUT THAT AS PERHAPS A CONTEXT.

CHAIRMAN LO: I THINK THAT ACTUALLY GOES IN THE NEXT SLOT.

DR. LOMAX: AND JUST TO GIVE SOME CONTEXT TO MR. KLEIN'S COMMENT THERE, STAFF WERE APPROACHED ON THIS, AND I WANT TO ECHO SOMETHING JEFF SAID. WHAT WOULD YOU RECOMMEND IF YOU WERE GOING TO HANDLE

THIS IN A REGULATORY CONTEXT? AND, JEFF, YOU SUMMED IT UP VERY ARTICULATELY. OUR ASSESSMENT WAS THAT WE WERE NO LONGER AT A STAGE WHERE WE WANT TO CHANGE THE REGULATIONS FOR EVERY EXAMPLE. WE NEED SOME SORT OF A PROCESS.

SO WE CAME BACK AND SUGGESTED THAT FROM AN ADMINISTRATIVE, REGULATORY LENS THAT SOME TYPE OF PROCESS TO ADDRESS THIS AS OPPOSED TO CHANGING THE REGULATIONS WAS ADVISED BECAUSE OTHERWISE YOU DON'T HAVE REGULATIONS ANYMORE. YOU END UP WITH A SERIES OF PATHWAYS THAT LOSE SORT OF PARSIMONY. SO THE NEXT SLIDE WAS OUR SUGGESTION, WHICH WOULD BE SOME SORT OF PROCESS THAT WOULD ALLOW YOU TO EVALUATE THESE CRITERIA WHICH ARE REALLY THE DRIVING CRITERIA IN THE REGULATIONS. SO TURN IT OVER TO YOU, BERNIE.

MR. KLEIN: SO I ASKED THE QUESTION, BUT IT'S NOT BEEN ANSWERED.

CHAIRMAN LO: LET ME MAKE THE PROPOSAL, BOB, AS A STRAW. AGAIN, WE'RE NOT -- WE DON'T HAVE A QUORUM, SO THIS IS REALLY --

CO-CHAIR LANSING: WE CAN GO BACK.

CHAIRMAN LO: LET ME PROPOSE, IF I MAY, AND GEOFF YOU CAN GET THIS DOWN, THAT FOR HESC LINES THAT ALREADY BEEN DERIVED, OUR REGULATIONS EFFECTIVE IN NOVEMBER 2006 THAT ARE ALREADY DERIVED MAY BE

USED BY CIRM-FUNDED RESEARCHERS PROVIDED THAT, NO. 1, THAT THEY MET THE ETHICAL AND LEGAL STANDARDS IN PLACE AT THE TIME WHEN JURISDICTION WAS DERIVED. TWO, THAT THE -- SO THE ISSUES ARE CONSENT, IRB APPROVAL, AND SO FORTH.

SECOND, THAT THERE WAS CONSENT FROM THE DONOR COUPLE IN IVF WHO HAD A FROZEN EMBRYO TO DONATE THAT. AND I THINK WE'RE GOING TO HAVE TO SORT OF THINK THROUGH HOW MUCH CONSENT THAT WOULD TAKE. WHERE POSSIBLE --

MR. KLEIN: CONSENT CONSISTENT WITH STANDARDS OF CONSENT AT THE TIME.

CHAIRMAN LO: AT THE TIME. THAT'S RIGHT. AND THEN THERE MUST BE NO SORT OF INDICATION THAT THE GAMETE DONORS WOULD OBJECT TO THIS RESEARCH USE, SO THEY KNOW THE GAMETE DONOR OBJECTED.

ALSO, I WOULD SUGGEST WE HAVE THAT AN IRB OR EQUIVALENT APPROVE THE PROCESS BY WHICH THE MATERIALS WERE GIVEN TO THE RESEARCHERS AND THE DERIVATION. OKAY.

SO THAT'S, I THINK, THE GIST OF THAT. NOW, GEOFF HAS ALSO PROPOSED A PROCEDURE FOR HOW THAT'S DONE BECAUSE, AS YOU A NUMBER OF YOU HAVE SUGGESTED, WHAT'S LIKELY TO HAPPEN, THERE WILL BE SPECIFIC LINES THAT HAVE ACHIEVED THEIR USEFULNESS

OR SCIENTIFIC VALUE WHERE THERE WILL BE CERTAIN CIRCUMSTANCES THAT WE MAY NEED TO CONSIDER THIS ON A CASE-BY-CASE BASIS. AND GEOFF HAD SUGGESTED A PROCEDURE BY WHICH CIRM STAFF WITH ALAN TO MAKE A RECOMMENDATION TO THE ICOC WITH ADVICE AND INPUT FROM ONE OR TWO MEMBERS OF THE SWG. THAT'S A PROCEDURAL ISSUE OF HOW THAT ACTUALLY GETS DONE.

BUT IN TERMS OF THE SUBSTANCE, THAT'S HOW I FELT IN RESPONSE TO YOUR VERY -- TONE OF MY QUESTION.

MR. KLEIN: SO FOR PURPOSES OF THE DISCUSSION AT THIS POINT IN OUR MEETING, THAT IS THE QUESTION. AND ARE WE AT A POINT WHERE ON THIS NARROW ISSUE WE CAN ASK THE MEMBERS WHAT THEIR STRAW VOTE POSITION IS BECAUSE WE HAVE OTHER POSITIONS TO DISCUSS IN THIS MEETING.

CHAIRMAN LO: GEOFF, IF YOU COULD PUT THAT UP ON THE SCREEN AND READ IT, THAT WOULD BE GREAT.

DR. KIESSLING: SO, BERNIE, THE ONLY THING ABOUT THIS THAT TROUBLES ME IS THAT WHEN WAS THIS LINE DERIVED?

DR. CSETE: BEFORE THE NATIONAL ACADEMY GUIDELINES WERE PUBLISHED, JUST BEFORE ACTUALLY.

DR. KIESSLING: 2002?

CHAIRMAN LO: 2005.

DR. KIESSLING: SO ARE WE TO SAY THAT IN 2005 THE ETHICAL STANDARD IN THIS COUNTRY WAS THAT IT WAS ALL RIGHT TO DERIVE A STEM CELL LINE FROM AN EMBRYO FROM WHICH YOU DID NOT HAVE THE CONSENT OF BOTH GAMETE DONORS? I DON'T THINK THAT WAS THE ETHICAL STANDARD.

DR. CSETE: NO. THEY HAD THE CONSENT SO THAT THE -- THE EMBRYO WAS CREATED IN 2001. THEY HAD THE CONSENT OF THE COUPLE.

DR. KIESSLING: BUT NOT THE GAMETE DONORS?

DR. CSETE: NOT THE GAMETE DONORS.

MR. KLEIN: IT WAS 2001.

DR. KIESSLING: ARE WE SAYING THAT IN 2001 THE ETHICAL STANDARD IN THIS COUNTRY WAS THAT IT DID NOT MEET --

CHAIRMAN LO: WELL, I THINK THIS IS A NICE ILLUSTRATION OF IS THERE ARE ISSUES THAT HAVE TO DO WITH THE GENERAL POLICY, AND OTHERS HAVE BEEN LOOKING AT A SPECIFIC LINE. I GUESS I'D LIKE TO HAVE US TRY AND AGREE --

DR. KIESSLING: YOU KNOW, I'M HAPPY TO LOOK AT THE SPECIFIC LINE. I THINK THERE ARE COMPELLING ARGUMENTS ON THIS LINE. I DON'T WANT IT CONSTRUED THAT WE AGREE THAT THE ETHICAL STANDARD HAS ONLY EVOLVED IN THE LAST FIVE YEARS.

MS. CHARO: ANN, I WOULD SIMPLY NOTE THAT THE NIH ALLOWED FEDERAL MONEY TO BE USED ON THE LINES THAT WE NOW CALL THE PRESIDENTIAL LINES EVEN KNOWING THAT THERE WAS A LACK OF CLARITY ABOUT WHETHER THERE HAD BEEN AN ANONYMOUS DONOR OF GAMETES USED IN SOME OF THOSE EMBRYOS. FROM THE VERY BEGINNING THEY SAID THEY DIDN'T KNOW ONE WAY OR THE OTHER. SO IF ANYTHING, AT LEAST THE U.S. FEDERAL GOVERNMENT'S ETHICAL STANDARD WAS, WELL, IT DOESN'T MATTER ENOUGH THAT WE'RE GOING TO DISALLOW THINGS BASED ON THE FACT THAT WE CAN'T BE SURE THAT CONSENT WAS OBTAINED. THAT WAS THE FEDERAL GOVERNMENT'S POSITION. I DON'T KNOW IF THAT'S THE NORM.

CHAIRMAN LO: LET ME SUGGEST WE SEPARATE OUT THE GENERAL STANDARD OF HOW WE APPLY (UNINTELLIGIBLE) BECAUSE I DON'T WANT TO SAY RIGHT NOW IN THIS PARTICULAR CELL LINE WITHOUT SEEING MORE FACTS ABOUT THE CASE. I THINK IF WE CAN AGREE THAT HAVING THESE BE LEGAL, ETHICAL STANDARDS AT THE TIME, THEN I THINK IT'S A DIFFERENT -- IT'S A SECOND ORDER OF QUESTION. AT THAT PARTICULAR DAY IN TIME WAS IT THE LEGAL, ETHICAL STANDARD? AND YOU HAVE TO LOOK AT THE NIH POLICY, LOOK AT THE NAS POLICY, ROB TAYLOR AND OTHERS OF IN 2004 WAS LIKE. I MEAN THAT'S THE KIND OF A POINT IN A PARTICULAR CASE THAT

I DON'T THINK WE NEED TO DO TODAY.

WHAT WE CAN DO IS LAY OUT THE TIMELINE AND SAY WHO MAKES THAT DETERMINATION. I MEAN IF WE CAN AGREE --

DR. TAYLOR: LET'S CLARIFY THE TIME. 2001 IS WHEN IS THE EMBRYO WAS CREATED. 2005 IS WHEN THE CELL LINE WAS CREATED.

CHAIRMAN LO: SO I WOULD SAY IT HAD -- THAT WHEN THE LINE WAS DERIVED, SO IF HESC LINE WAS DERIVED, IT HAD TO BE BEFORE -- AGAIN, WE CAN ARGUE WHETHER IT'S OUR GUIDELINES OR THE NAS GUIDELINES, BUT WE ADOPTED THE NAS GUIDELINES AS TEMPORARY GUIDELINES AS SOON AS WE KNEW THEY EXISTED. BUT ONE OF THOSE CUTOFF DATES IS WHEN YOU HAVEN'T DERIVED THE LINE. THAT'S WHAT WE'RE TALKING ABOUT. WE CAN TALK ABOUT SOME OTHER CASES LATER, BUT LET'S TALK ABOUT DERIVING -- THE DERIVATION WAS DONE BEFORE THAT DATE. AND THE CRITERIA ARE IRB APPROVAL MEETING THE ETHICAL AND LEGAL STANDARDS AT THE TIME. AND NO CONTRADICTIONS -- AND CONSENT FROM THE EMBRYO DONOR AND NO CONTRADICTORY IDEA THAT THE -- AND NO INDICATION THAT THE GAMETE DONORS, IF ANY, WOULD HAVE OBJECTED TO THE RESEARCH.

WE'VE GOT TO GET THAT DOWN BECAUSE THIS IS THE SENSE THAT WE'RE GOING TO TRY AND ASK SHERRY AND

ROB AND JEFF AND MARCY TO TAKE BACK TO THE ICOC. IT'S REALLY OUR THINKING ON THIS TOPIC RATHER THAN A FORMAL VOTE.

MR. KLEIN: QUESTION FOR YOU. UP THERE THERE'S THIS KIND OF COMMENT ABOUT NO PAYMENT.

CHAIRMAN LO: YEAH. THAT'S WHY I WANT TO HAVE A NEW SLIDE FROM WHAT I WAS JUST TRYING TO SAY, AND THEN WE CAN MODIFY THAT. THAT WAS THE FIRST CUT.

MR. KLEIN: THIS ISSUE UP THERE I THINK WE SHOULD ELIMINATE. THE ISSUE OF PAYMENT FOR EMBRYO STORAGE SHOULDN'T BE THE CRITERIA. THAT'S IRRELEVANT TO THIS DISCUSSION.

DR. KIESSLING: PAYMENT OF ANY KIND IS IRRELEVANT TO THIS DISCUSSION.

MR. KLEIN: TO THIS DISCUSSION.

CHAIRMAN LO: OF THE DERIVED CELL LINES THE EXISTENCE BEFORE -- I GUESS -- IT STRIKES ME -- THERE'S AN ARGUMENT TO BE MADE FOR HAVING ALTA'S NAS GUIDELINES OF MAY 2005 --

MS. CHARO: APRIL.

CHAIRMAN LO: -- APRIL 2005 BE THE CUTOFF DATE. I FORGET, BOB, YOU'LL HAVE TO REMIND ME WHEN WE ADOPTED THOSE AS OUR INTERIM GUIDELINES.

MR. KLEIN: WE ADOPTED THOSE IN MAY OF

2005.

CHAIRMAN LO: IT WAS THE YEAR BEFORE -- A GOOD YEAR BEFORE OUR -- YEAR AND A HALF BEFORE OUR SWG GUIDELINE RECOMMENDATIONS WERE ACCEPTED BY ICOC.

OKAY. SO THESE WE'RE GOING TO TAKE OFF. WHY DON'T YOU JUST LOOK AT THAT AND SEE IF THAT'S THE SENSE OF OUR GROUP TO GO BACK TO THE ICOC.

MR. KLEIN: AS I UNDERSTAND IT, IN EVERY CASE, THE SCIENTIFIC STAFF IS GOING TO LOOK AT SPECIFIC LINES AND SPECIFIC STANDARDS. WE'RE NOT DOING THAT. WE DON'T HAVE ENOUGH YEARS IN OUR LIFE LEFT TO LOOK AT THAT, BUT SO WE'RE CREATING POLICY.

CHAIRMAN LO: POLICY. I DON'T KNOW IF IT'S WITHIN OUR AMBIT OR WHETHER IT WOULD BE HELPFUL TO MAKE A RECOMMENDATION TO CIRM LEADERSHIP AS TO WHAT THAT PROCESS SHOULD LOOK LIKE. OBVIOUSLY YOU NEED SCIENTIFIC INPUT, STAFF INPUT, ALAN, AND BOB, AND YOU MIGHT ALSO WANT ONE OR TWO MEMBERS OF THIS GROUP TO GIVE ETHICAL ADVICE ON WHAT, FOR EXAMPLE, IS LEGAL AT THE TIME. IT'S AN OPEN QUESTION TO WHAT EXTENT YOU WANT ANYONE FROM THIS GROUP INVOLVED IN THOSE CASE-BY-CASE DETERMINATIONS.

MR. KLEIN: ON A CASE-BY-CASE BASIS, IF WE COULD HAVE THE PRESIDENT HAVE THE ABILITY AND CHIEF SCIENTIFIC OFFICER HAVE THE ABILITY TO CONTACT A

MEMBER OF THIS GROUP, OR IF THERE'S A VERY SPECIALIZED QUESTION TO GO SOME OTHER PERSON OF SPECIALIZED INFORMATION. MY BELIEF IS THAT THEY WOULD GENERALLY ALWAYS COME TO THIS GROUP FOR INPUT, BUT I THINK WE SHOULD GIVE THE PRESIDENT AND CHIEF SCIENTIFIC OFFICER THE ABILITY TO ALSO DRAW INFORMATION FROM OUTSIDE.

CHAIRMAN LO: SO WE'RE NOT GOING TO MAKE THESE CASE-BY-CASE DETERMINATIONS AS A GROUP. WE'RE GOING TO SET THE GENERAL POLICY, AND IT'S GOING TO BE IMPLEMENTED BY THE PRESIDENT AND THE SCIENTIFIC OFFICER.

THOSE WHO ARE ON THE ICOC, JEFF, MARCY, SHERRY, ANY ADDITIONAL.

MS. FEIT: I THINK JUST BASED ON -- WE'RE JUST TALKING ABOUT PROCESS ON EVALUATING THESE LINES AS WE MOVE FORWARD. WE'RE NOT TALKING ABOUT MAKING THOSE DETERMINATIONS. I THINK IT WILL HAVE TO INVOLVE SOLVING WHAT IS KNOWN ABOUT THEM, AND WHERE IT CAME FROM, WHEN IT WAS ESTABLISHED, WHAT WAS INVOLVED. AND THEN I THINK IN TERMS OF -- SO WE'RE JUST LOOKING AT PROCESS OF HOW THAT'S GOING TO HAPPEN AT THIS INSTITUTION.

CHAIRMAN LO: MORE THAN PROCESS. WE'RE SAYING GENERAL POLICY STANDARDS THAT WILL BE CARRIED

OUT ON A CASE-BY-CASE BASIS BY MARIE AND ALAN.

DR. CSETE: AND I'M EXPECTING THAT THIS IS A RARE EVENT.

MS. FEIT: I THINK THAT NEEDS TO BE STATED, THOUGH, IN THE PROCESS TO ENSURE THAT THE BOARD UNDERSTANDS THAT PROCESS.

CO-CHAIR LANSING: AND THAT THIS IS RARE. THAT THIS IS FOR THIS UNIQUE LINE. THIS IS NOT COMMON POLICY. THIS IS A RARE POLICY.

MR. KLEIN: I THINK THAT THE DERIVATIVE OF THAT, SHERRY, MAY BE GIVEN VERY LARGE NUMBERS OF LINES, WE CAN SEE IN THE PETITIONS FAIRLY FREQUENTLY IF ONE HAS 200 LINES, BUT YOU MIGHT SEE THEM COMING UP AT EVERY BOARD MEETING. AS LONG AS THERE'S A GOOD UTILITY FOR IT --

CO-CHAIR LANSING: THAT'S FINE.

MR. KLEIN: -- IT'S FINE.

CO-CHAIR LANSING: I THINK THAT'S GREAT.

CHAIRMAN LO: I WANT TO ASK ALAN TROUNSON AND MARIE CSETE TO SORT OF --

MR. SHEEHY: I JUST -- COULD I SEE THE WHOLE THING BECAUSE I'M NOT -- I JUST WANT -- I GET THESE CRITERIA AND THEN THE PROCESS.

CHAIRMAN LO: THE PROCESS WILL BE SEPARATE, SO YOU WANT TO TALK ABOUT THAT NOW?

MR. SHEEHY: AS LONG AS THERE'S A ROBUST PROCESS THAT VALIDATE THOSE CRITERIA. THIS PROCESS AS DESCRIBED HERE SEEMS FINE. AND THEN EFFECTIVE DATE WE'RE TALKING ABOUT IS MAY 2005 OR THE NOVEMBER 2006?

CHAIRMAN LO: I WOULD SAY MAY 2005, BUT THAT'S THE PLEASURE OF THE COMMITTEE. THAT'S WHEN WE FIRST PUT IN PLACE OUR INTERIM REGS.

MR. KLEIN: BY CHOOSING THAT DATE, YOU GET A GAP BECAUSE OUR REGS ARE MORE RESTRICTIVE THAN THE NATIONAL ACADEMY, SO YOU CREATE A GAP. SO I THINK YOU HAVE TO GO WITH WHEN OUR REGS WERE IN PLACE BECAUSE OTHERWISE YOU HAVE A SITUATION WHERE YOU'RE HOLDING THEM TO A HIGHER STANDARD THAT WASN'T IN PLACE IN 2005.

CHAIRMAN LO: AS FAR AS MY THOUGHTS WERE, THE NAS ISSUED ITS GUIDELINES IN MAY -- APRIL 2005. THOSE BECAME DE FACTO NATIONAL STANDARDS.

MR. KLEIN: RIGHT. SO IT WILL BE JUDGED AGAINST THOSE AT THAT TIME.

CHAIRMAN LO: AT THAT TIME.

MR. KLEIN: RIGHT. AND THE LATER DATE, THEN THERE'S OTHERS THAN WHEN OUR STANDARDS OCCURRED.

CHAIRMAN LO: SO LET'S LOOK AT THE

PROCESS. GEOFF, IF YOU'D GO TO NEXT SLIDE FOR PROCESS BECAUSE I THINK JEFF RIGHTLY WANTS US TO CONSIDER THEM BOTH TOGETHER AS A PAIR.

DR. KIESSLING: THE EFFECTIVE DATE IS 2005, MAY 2005.

CHAIRMAN LO: APRIL OF 2005. NO. NO. NO. THE EFFECTIVE --

MR. SHEEHY: IT IS NOVEMBER 2006.

CHAIRMAN LO: NOVEMBER 2006 FOR OUR REGULATIONS TO KICK IN EFFECT. OTHERWISE WE'RE GOING TO TIE IT ALL -- BOB, HAD THE NAS GUIDELINES --

DR. KIESSLING: WHAT IS THE EFFECTIVE DATE THEN?

CHAIRMAN LO: NOVEMBER 2006 WITH THE UNDERSTANDING, AS WE TURN THIS, IS AS OF APRIL 2005, THE NATIONAL STANDARD WAS THE NAS GUIDELINES.

DR. KIESSLING: WHAT'S THE EFFECTIVE DATE FOR --

CHAIRMAN LO: THIS IS -- THE PREVIOUS LINE, I THOUGHT WE WERE SAYING NOVEMBER 200- --

MR. SHEEHY: WE GOT TWO DIFFERENT THINGS.

DR. LOMAX: THIS IS A POINT OF CLARIFICATION, AND, ALTA, I'LL DEFER TO YOU ON THIS. MY UNDERSTANDING IS THAT THESE LINES WOULD NOT BE

DISQUALIFIED UNDER THE NATIONAL ACADEMY'S STANDARDS. SO IT'S NOT AN ISSUE UNTIL YOU GET TO NOVEMBER 2006 BECAUSE THE PREVAILING STANDARD OF THE TIME THAT WE ADOPTED AS INTERIM STANDARDS WERE THE NATIONAL ACADEMY STANDARDS. AND THESE LINES WOULD MEET THE NATIONAL ACADEMY STANDARDS.

MR. KLEIN: MORE FOCUSED, IN APRIL 2005, THEY HAVE TO MEET THE NATIONAL ACADEMY STANDARDS. IN 2006 THEY HAVE TO MEET OUR STANDARDS.

(SIMULTANEOUS DISCUSSION.)

MR. SHEEHY: SO WE HAVE TWO DIFFERENT DATELINES.

MS. PACHTER: THERE YOU WANT THE DATE THAT -- FOR PURPOSES OF ESTABLISHING A PROCESS, YOU WANT THE EFFECTIVE DATE OF OUR INTERIM REGULATIONS, THE CIRM INTERIM REGULATIONS.

DR. KIESSLING: THAT'S MAY 2005.

MR. SHEEHY: NO. THAT'S NOVEMBER 22 --

MS. PACHTER: NOVEMBER 2006.

MR. SHEEHY: YEAH.

MS. PACHTER: IT WAS THE NATIONAL ACADEMY'S GUIDELINES THAT WERE ADOPTED IN 2005.

DR. KIESSLING: WE ADOPTED THOSE, AND AREN'T THOSE THE CRITERIA THAT WE'RE TALKING ABOUT?

MR. SHEEHY: ANN, LET ME TRY TO DESCRIBE

IT TO YOU. ONE IS WHAT LINES DO WE WANT TO CONSIDER GRANDFATHERING, AND THOSE ARE THE ONES THAT WERE CREATED BEFORE OUR EFFECTIVE REGULATIONS IN NOVEMBER. THOSE LINES, THOUGH, WOULD HAVE TO BE, IF YOU LOOK AT THE LAST LINE, WOULD HAVE TO BE GOVERNED BY THE NAS STANDARDS IN THAT GAP.

MR. KLEIN: THAT'S RIGHT.

MR. SHEEHY: SO THE NAS STANDARDS ARE APPLICABLE TO THOSE LINES IF THEY WERE CREATED WHILE THE NAS GUIDELINES WERE AVAILABLE BECAUSE THAT WOULD HAVE BEEN THE PREVAILING ETHICAL-LEGAL STANDARD.

DR. KIESSLING: OKAY. SO --

MR. SHEEHY: BUT IN THE EVENT FOR OUR CONSIDERATION IN GRANDFATHERING, THE TOP LINE, THAT SHOULD BE NOVEMBER OF '06.

DR. KIESSLING: SO NOVEMBER. AND THEN IN PLACE AT THE TIME IS MAY OR APRIL 2005.

MR. SHEEHY: WELL, IT WOULD BE WHATEVER IS IN PLACE.

(SIMULTANEOUS DISCUSSION.)

CHAIRMAN LO: LET'S LOOK AT -- GEOFF HAD SOME SUGGESTIONS FOR PROCESS. SO THIS IS ACTUALLY A LITTLE DIFFERENT THAN WHAT BOB SAID. SO BASICALLY SOMEONE COMES TO CIRM AND SAYS WE'D LIKE YOU TO APPROVE THE USE OF THIS PARTICULAR CELL LINE BY A

CIRM-FUNDED RESEARCHER. SO CIRM STAFF MIGHT KNOW, THAT MEANS CHIEF SCIENTIFIC OFFICER, PRESIDENT, CEO, AND BOB SUGGESTED ACTUALLY THAT WE GIVE THE PRESIDENT AND CHIEF OPERATING OFFICER THE OPTION OF CONSULTING, NOT JUST ANYONE HERE ON THE SWG, BUT ALSO OUTSIDE EXPERTS. THIS WAS WRITTEN A LITTLE DIFFERENTLY. GOES TO THE ICOC WITH A RECOMMENDATION FROM STAFF AS TO WHAT ICOC SHOULD DO AND IT PROVIDES DOCUMENTATION.

THE ICOC CONSIDERS THAT IN ONE OF THEIR PUBLIC MEETINGS. SO THERE IS A PROCESS IN PLACE FOR PUBLIC COMMENT ON THIS AS WELL, BUT THE -- WE HAD THOUGHT THAT THE INITIAL DETERMINATION SHOULD BE DONE PRIMARILY BY CIRM STAFF FOR EFFICIENCY, CONSULTING WITH MEMBERS. I DON'T THINK SHERRY OR I HAVE A VESTED INTEREST IN ALWAYS BEING THE ONES BEING CONSULTED. I THINK --

CO-CHAIR LANSING: IT'S OUR PLACE TO GO BACK TO THE GROUP WHEN WE SEE SOME PROBLEMS.

CHAIRMAN LO: BOB AS WELL, BUT THERE COULD BE OTHER EXPERTS AROUND THE WORLD WHO MAY, IN FACT, BE CONSULTED.

MR. KLEIN: AND IT MAY HAVE BEEN DERIVED IN SOME OTHER --

MR. SHEEHY: I MIGHT CHANGE THAT WORD TO

"AND" AFTER SWG.

CHAIRMAN LO: I'M SORRY. MY OWN, IF THIS STATES AS CO-CHAIRS, IS THAT THEY COME AND IT'S A TECHNICAL POINT THAT ALTA OR ANN OR ROB WOULD KNOW, I WOULD SAY AT LEAST TALK TO THEM JUST TO BE SUFFICIENTLY INCLUSIVE. YOU'VE HEARD ABOUT GOING TO STANDARDS, GENERAL STANDARDS OF PROCESS WOULD BE LOOKED AT TOGETHER. AGAIN, THOSE OF YOU PLEASE SUGGEST ANY WAYS TO IMPROVE THIS.

ALAN, DOES THIS SEEM REASONABLE TO YOU AS WELL? AND THEN WE HAVE PUBLIC COMMENTS.

DR. TROUNSON: I THINK IT SEEMS PERFECTLY REASONABLE. IT'S REALLY COMING TO US AS AN ISSUE OF DELIVERY OUR MISSION. AND IF WE SEE THERE IS A PROBLEM US GOING FORWARD WITH SOME OF THE GRANTS, WHETHER WE COULD ACCEPT A GRANT. SO CLEARLY IT'S VERY PRAGMATIC FROM OUR POINT OF VIEW WE NEED GUIDANCE TO HELP US, SO WE WOULD BE QUITE PREPARED TO BRING IT CASE BY CASE. I DON'T EXPECT IT WOULD BE FREQUENT, BUT IT WOULD BE REALLY DIFFICULT TO ALWAYS PREDICT EXACTLY WHAT THE UNDERLYING REASONS WERE. AND IT WOULD GIVE US A CHANCE TO EXPLORE THOSE, SO WE WOULD FIND OUT WHETHER THERE WERE SUITABLE CELL LINES AVAILABLE AND THEN WHAT'S THE PRIMARY IMPEDIMENT.

I HAVE TO SAY TO YOU IN THIS PARTICULAR CASE, IT'S A VERY PRIMARY IMPEDIMENT FOR, AS BOB SAYS, DELIVERY TO THE PATIENTS BECAUSE THE REAL DERIVATION WOULD BE EXTRAORDINARILY COSTLY AND TIME-CONSUMING.

DR. CSETE: AND I JUST WANT TO ALLAY THE FEARS THAT OBVIOUSLY THE FDA'S CONSIDERATION FOR SAFETY WILL HAVE A HIGHER BAR. THE MEDICAL HISTORY IS UNKNOWN FROM WHEN ONE BIOLOGIC COMPONENT OF THIS. AND SO I WOULDN'T BE SURPRISED AT ALL IF THEY, FOR EXAMPLE, SAY WE'LL TAKE THIS (UNINTELLIGIBLE).

DR. TAYLOR: THAT MAY BE HELPFUL, BUT I STILL -- YOU HAVE MAYBE MORE FAITH IN THE FDA THAN I, ONE. TWO, MORE FAITH IN PRIMARY NUCLEOTIDE SEQUENCE THAN I.

CHAIRMAN LO: BUT, AGAIN, CERTAINLY THIS IS SOMETHING THAT IS SCIENTIFICALLY --

DR. CSETE: SO THE NORMAL DISEASES FOR WHICH THERE WOULD BE GENETIC TESTING IN AN IVF CLINIC SETTING.

MS. CHARO: I'M UNDERSTANDING THAT THIS IS NOW KIND OF AMORPHOUS GUIDANCE. WE'RE NOT DRAFTING REGULATIONS, CORRECT?

CHAIRMAN LO: YES, THAT IS CORRECT.

MS. CHARO: THEN WITH DUE RESPECT TO THE

STAFF, (UNINTELLIGIBLE) ONE MORE THING THAT THEY MIGHT DO, AND THAT IS TO TRY AND KEEP A FAIRLY GOOD RUNNING TALLY OF THE LINES AND THE REASONING BECAUSE I KNOW IT WILL BE IN A PUBLIC SESSION, I KNOW IT WILL BE TRANSPARENT, BUT AS SOON AS THE NIH GOES BACK INTO THE BUSINESS OF FUNDING EMBRYONIC STEM CELL RESEARCH, THEY WILL BE FACED WITH PRECISELY THIS QUESTION. IT WILL NOW BE 2009 OR MAYBE 2010, AND THERE IS MORE FUNDING, AND THE FIRST ISSUE IS GOING TO BE, NOW THAT WE'VE GOT OUR RULES FOR NEW DERIVATIONS -- I TAKE IT BACK. THEY'RE NOT GOING TO FUND THE DERIVATIONS. BUT THEY'LL STILL HAVE TO DECIDE WHAT THE STANDARDS ARE FOR THE LINES THAT THEY'RE WILLING TO FUND FOR USABILITY. AND SO TO SOME EXTENT, THIS CIRM EXPERIENCE CAN ACTUALLY HAVE A DRAMATIC EFFECT.

CO-CHAIR LANSING: IT'S A GREAT POINT. IT'S A GREAT POINT.

DR. TROUNSON: SO WE'RE PICKING THAT UP, AS GEOFF SAID, IN THE INFORMATION THAT WE'VE BEEN COMPILING IN ASSOCIATION WITH THE BANKING GROUPS.

MS. CHARO: OH, THAT'S GOOD.

DR. TROUNSON: AND THEN WE'LL BE TALKING ABOUT INCLUDING WHETHER THEY QUALIFY FOR USE OF THE CALIFORNIA; SO RATHER THAN WE CREATE SOMETHING THAT

IS THERE, WE'VE GOT GEOFF WORKING ON UTILIZING THE INFORMATION THAT'S PRESENTLY THERE THAT WE CAN THEN TAKE IN-HOUSE AND ANSWER THOSE QUESTIONS VERY PRECISELY.

CHAIRMAN LO: IF I COULD JUST EXPAND ON ALTA'S COMMENT. I THINK IT WAS VERY HELPFUL. IT WOULD ALSO BE EXTREMELY USEFUL TO SCRO'S AT INDIVIDUAL INSTITUTIONS, AND I THINK THEY WOULD REALLY APPRECIATE SORT OF THE SYNOPSIS OF THE REASONING THAT CIRM STAFF AND ICOC WENT THROUGH BECAUSE I WOULD ENVISION THE SCRO SAYING, OH, THESE GUYS REALLY LOOKED AT IT. HERE'S THEIR REPORT AND THEIR REASONING. RATHER THAN US GOING THROUGH ALL OF THIS, LET'S DEFER TO THEIR JUDGMENT.

MS. CHARO: THERE IS AN ESCRO LIST SERVE THAT THE NATIONAL ACADEMIES RUNS WHERE THEY SHARE INFORMATION AROUND IT. THAT WOULD BE A PERFECT PLACE ON A LINE-BY-LINE BASIS AFTER THE ICOC HAS MADE ITS DETERMINATIONS TO POST THE SYNOPSIS TO SHARE AROUND THE COUNTRY WHAT'S GOING ON HERE. IT DOESN'T CONTROL WHAT THEY'LL DO, BUT IS INFORMATIVE FOR EVERYBODY TO KNOW WHAT'S GOING ON.

CHAIRMAN LO: I JUST WANT TO OFFER AN OPPORTUNITY FOR ANYBODY IN THE PUBLIC ALSO TO COMMENT ON THIS. FOR THE RECORD STATE YOUR NAME.

MR. REED: I'M DON REED, CALIFORNIANS FOR CURES. KNOWING THE STRESS THE TIME ON THE ICOC, I WONDER IF THIS SHOULDN'T BE A MATTER THAT'S SET UP IN POLICY RATHER THAN FOR AN INDIVIDUAL PETITION. I THINK THIS IS GOING TO BE NOT JUST THIS ONE. I THINK THERE WILL BE OTHER -- A LOT MORE LINES LIKE THIS TO BE CONSIDERED. I THINK ONCE YOU ESTABLISH THE STANDARDS, IT SHOULD BE HANDLED INTERNALLY. IF THE NEW LINE MEETS THE STANDARDS, THEN IT SHOULD GO FORWARD. BUT IF IT HAS TO BE INDIVIDUALLY CONSIDERED BY THE ICOC, AND THEN MAYBE A LOT OF THESE COME ON, THAT COULD BE A LOT OF TIME INVOLVED.

CHAIRMAN LO: ANY OTHER COMMENTS?

MR. SIMPSON: JOHN SIMPSON FROM CONSUMER WATCHDOG. I UNFORTUNATELY FIND MYSELF DISAGREEING WITH MY FRIEND DON REED. I DO THINK THAT GOING BACK RETROACTIVELY, YOU CAN'T SET STANDARDS RETROACTIVELY BECAUSE EACH SITUATION IS DIFFERENT. THIS SEEMS TO ME THE PERFECT MIX OF THE RECOGNITION THAT THERE MAY BE VALUE THAT ETHICAL STANDARDS EVOLVE OVER THE TIME AND GIVES YOU A PROCESS TO DEAL WITH THESE SITUATIONS, I THINK, IS A VERY GOOD THING. I GUESS IT WILL END UP BEING AN AMORPHOUS RECOMMENDATION TO STAFF TO COME UP WITH REGS, WHICH WOULD THEN PRESUMABLY BE THE NEXT ICOC, AND THAT TO ME MAKES

SENSE. THANK YOU.

CHAIRMAN LO: SO I THINK IT'S FAIR TO SAY THAT I'M TAKING AN INFORMAL VOTE.

CO-CHAIR LANSING: WHY DON'T YOU JUST DO A STRAW POLL.

CHAIRMAN LO: LET'S DO A STRAW POLL. GEOFF, YOU WANT TO WALK US THROUGH A STRAW POLL TO GET THE SENSE OF THE GROUP TO THE ICOC. I GUESS WHY DON'T WE GO ON THE WHOLE PACKAGE.

DR. LOMAX: I THINK WE'RE GETTING A SENSE OF THE COMMITTEE TO -- THE PRIMARY SENSE OF THE COMMITTEE IS A DIRECTION FOR STAFF TO DEVELOP REGULATORY LANGUAGE THAT WOULD -- SORRY -- THE STAFF WOULD DEVISE A REGULATORY CONCEPT TO BE BROUGHT TO THE ICOC FOR A GRANDFATHERING CONCEPT CONSISTENT WITH THE ITEMS ON THIS SLIDE, THAT THERE WOULD BE AN EVALUATION OF THE INFORMED CONSENT, AN EVALUATION OF THE REVIEW OF THE PROTOCOL THAT GOVERN THE PROCUREMENT OF THE MATERIALS THAT WENT INTO THE STEM CELL LINE, AND AN EVALUATION OR DOCUMENTATION OF COMPLIANCE WITH PREVAILING ETHICAL AND LEGAL STANDARDS IN PLACE AT THE TIME OF THE DERIVATION.

SO THE SENSE OF THE COMMITTEE --

MR. KLEIN: YOU'RE LOOKING AT BOTH SLIDES.

CHAIRMAN LO: PLUS THE SECOND SLIDE.

DR. LOMAX: YES. I THINK HERE THIS IS SORT OF THE PARAMETERS OF WHAT I WOULD ENVISION A REGULATION --

CHAIRMAN LO: THIS BEING SORT OF THE IMPLEMENTATION NOT POLICY -- THAT'S TOO STRONG A WORD -- BUT PROCEDURES THAT WE WOULD -- I'M NOT SURE HOW TO FRAME THIS IN TERMS -- THIS IS OUR SENSE OF WHAT WE THINK CIRM AND STAFF SHOULD DO.

DR. LOMAX: I THINK THE FIRST SLIDE REFLECTS THE HIGH LEVEL POLICY, WHAT THE BOUNDARIES ARE FOR AN ANALYSIS THAT NEEDS TO GO TO THE ICOC. I THINK THE SECOND SLIDE MAY SPEAK TO A SLIGHTLY MORE GRANULAR LEVEL OF DETAIL, WHICH WOULDN'T NECESSARILY APPEAR IN THE REGULATORY LANGUAGE, BUT WOULD BE A SUPPORTING SORT OF PROTOCOL THAT BACKS UP THAT REGULATORY LANGUAGE.

MR. KLEIN: THEY WOULD BE ADOPTING PROCEDURES CONCURRENT WITH THE ADOPTION OF THE REGULATORY LANGUAGE.

DR. LOMAX: CORRECT. PROCEDURES VERSUS THE ENABLING REGULATION.

CO-CHAIR LANSING: WOULD YOU SAY THAT AGAIN?

DR. LOMAX: WE WANT TO START WITH THE FIRST ONE?

CHAIRMAN LO: WE'LL ADOPT BOTH TOGETHER BECAUSE JEFF RAISED THE POINT THAT STANDARDS, CRITERIA DON'T MAKE SENSE UNLESS WE UNDERSTAND THE PROCEDURE.

CO-CHAIR LANSING: ABSOLUTELY.

DR. LOMAX: SO THE STANDARD CRITERIA WOULD ENABLE AN ANALYSES WHERE STAFF -- THE DETERMINATION OF ACCEPTABLY DERIVED SHALL INCLUDE THE FOLLOWING PROCEDURES: CIRM RECEIVES DOCUMENTATION THAT THE ABOVE CRITERIA WERE SATISFIED IN THE PETITION TO USE THE HUMAN EMBRYONIC STEM CELL LINE FOR CIRM-FUNDED RESEARCH, CIRM STAFF IN CONSULTATION WITH THE CO-CHAIRS OF THE STANDARDS WORKING GROUP AND OTHER EXPERTS REVIEWS THE APPLICATION AND FORWARDS THE PETITION TO THE ICOC WITH A RECOMMENDATION FOR APPROVAL OR DISAPPROVAL, THE REVIEW OF THE APPLICATION SHOULD INCLUDE CONSIDERATION OF THE SCIENTIFIC SIGNIFICANCE OF THE STEM CELL LINE, AND THE ICOC WILL CONSIDER THE PETITION IN PUBLIC SESSION AFTER A PUBLIC POSTING OF THE PETITION.

CHAIRMAN LO: I'M JUST GOING TO WALK AROUND THE TABLE. DR. TAYLOR.

DR. TAYLOR: I'M IN FAVOR.

CHAIRMAN LO: DR. KIESSLING.

DR. KIESSLING: (INAUDIBLE.)

CHAIRMAN LO: DR. PRIETO.

DR. PRIETO: I'M IN FAVOR.

CHAIRMAN LO: PROFESSOR CHARO.

MS. CHARO: YES. I'M IN FAVOR.

CHAIRMAN LO: IN FAVOR. SO THAT'S OUR SENSE, AND THEN, SHERRY AND BOB, IF YOU COULD TAKE, AND MARCY AND JEFF, IF YOU COULD TAKE THIS BACK TO THE ICOC. I KEEP FORGETTING --

(SIMULTANEOUS DISCUSSION.)

CHAIRMAN LO: I'M PLAYING A DUAL ROLE. I SUGGEST WE REWARD OURSELVES WITH A BREAK. LET'S TAKE ABOUT A 15-MINUTE BREAK AND COME BACK.

(A RECESS WAS TAKEN.)

CHAIRMAN LO: I'D LIKE TO TRY AND GET STARTED BECAUSE WE HAVE SOME OTHER IMPORTANT AND FASCINATING ISSUES TO DEAL WITH. WHAT I WOULD LIKE TO DO, JUST SO THOSE OF YOU WHO WOULD LIKE TO SEE YOUR DAY PLANNED OUT, BEFORE LUNCH I WOULD LIKE TO HAVE AN OVERVIEW OF THE NEXT TOPIC FROM GEOFF. AND WE HAVE THREE PANELISTS TO PROVIDE KIND OF BACKGROUND INFORMATION FROM THREE VERY DIFFERENT PERSPECTIVES, COMPLEMENTARY AND IMPORTANT PERSPECTIVES, FOR US.

AND THEN I'M GOING TO -- THIS WILL BE MOSTLY INFORMATION BEFORE LUNCH. THEN AFTER LUNCH I

WANT US TO BE ABLE TO DELIBERATE ON THIS QUESTION OF USING EITHER STEM CELL LINES ALREADY CREATED THAT INVOLVE GAMETES DONATED FOR IVF PURPOSES FOR WHOM THE GAMETE DONORS WERE PAID. AND THE SECOND ISSUE IS FOR EMBRYOS THAT A WOMAN IN IVF WISHES TO DONATE FOR STEM CELL RESEARCH, BUT ONE OF THE GAMETE DONORS WAS COMPENSATED. SO THIS IS DIFFERENT THAN THE ISSUE WE TOOK BEFORE THE BREAK, BUT, AGAIN, THIS HAS COME UP.

SO GEOFF HAS PREPARED A COUPLE OF SLIDES TO JUST HELP WITH THIS ISSUE, DEFINE THE ISSUE AND PUT IT IN CONTEXT, AND THEN WE HAVE THREE PEOPLE WHO HAVE COME TO -- TWO PEOPLE HAVE ACTUALLY COME AND ONE ON THE CELL PHONE TO PROVIDE SOME BACKGROUND INFORMATION. SO, GEOFF, WHY DON'T YOU START. I'M GOING TO ASK US TO JUST SORT OF MAINLY BE IN A LISTENING MODE HERE AND THEN SAVE OUR DELIBERATIONS TILL AFTER LUNCH. GEOFF.

DR. LOMAX: OKAY. THANK YOU. SO THIS -- WE'RE NOW -- I'M GOING TO TRY TO PROVIDE A BRIEF BACKGROUND THAT'S CONSISTENT WITH THE BRIEFING MEMO TITLED "USE OF EMBRYOS CREATED FOR REPRODUCTIVE PURPOSES WITH PAID GAMETES." SO THIS SHOULD BE FAMILIAR BASED ON THIS MORNING'S DISCUSSION, BUT IT SORT OF SETS THE STAGE BECAUSE WE'RE DEALING WITH A

NUMBER OF SITUATIONS, ALL OF WHICH WE'D LIKE YOU TO AGAIN CONSIDER.

THE FIRST SITUATION WOULD BE AN EXISTING STEM CELL LINE THAT WAS CREATED FROM AN EMBRYO THAT WAS CONSTITUTED FROM ONE OR MORE PAID GAMETES. AND AGAIN, WHETHER APPLIED RETROACTIVELY OR NOT, BUT TO REMIND YOU THIS WOULD BE AN OUTSIDE LINE THAT WAS DERIVED FROM, LET'S JUST SAY, MASSACHUSETTS. THE ACCEPTABLY DERIVED STANDARD IN THE REGULATION WHICH GOVERNS WHETHER THAT STEM CELL LINE COULD OR COULD NOT BE USED BY A FUNDED RESEARCHER STIPULATES IN THE PROVISION THAT NO PAYMENT TO THE GAMETE DONORS COULD HAVE OCCURRED IN THE CREATION OF THAT EMBRYO. THEREFORE, THE ACTUAL LINE WOULD BE DISQUALIFIED FOR USE BY CIRM RESEARCHERS. SO IS THAT EXAMPLE CLEAR? MAKES SENSE?

SO THAT'S ONE SITUATION. THAT WAS QUESTION ONE, I BELIEVE, IN THE DOCUMENT THAT YOU WERE PROVIDED AS THE BACKGROUND DOCUMENT.

CHAIRMAN LO: GEOFF, IF I COULD JUST POINT OF CLARIFICATION. THESE ARE LINES THAT WERE DERIVED FROM EMBRYOS THAT WERE CREATED FOR IVF, NOT SPECIFICALLY FOR THE PURPOSE OF RESEARCH. SO THE WOMEN WHO DONATED OOCYTES RECEIVED COMPENSATION AS THEY OTHERWISE WOULD IN THE IVF PROCESS. THEY WERE

NOT, AS I UNDERSTAND IT, COMPENSATED TO THE SPECIFIC RESEARCH DONOR.

DR. LOMAX: THAT IS CORRECT. AND WE -- WE'VE COINED THE TERM IVF-EMBRYO IN THE BRIEFING MATERIALS TO TRY TO CAPTURE THAT DETAIL.

CHAIRMAN LO: SO THIS WAS A MISS -- THIS WAS SAID IN THE PRESS. WE'RE NOT TALKING ABOUT PAYING WOMEN TO COME AND GO THROUGH OOCYTE RETRIEVAL SPECIFICALLY FOR RESEARCH PURPOSES. WE'RE TALKING ABOUT WOMEN WHO ARE GOING THROUGH IVF DONATION.

DR. LOMAX: CORRECT. SO THE SECOND EXAMPLE, THIS GETS AT QUESTION THREE, AS IT CONCERNS THE UTILIZATION OF EMBRYOS THAT CONTAIN PAID GAMETES. SO AN EXAMPLE HERE MIGHT BE AN EMBRYO BANK, AND WE'LL HEAR ABOUT EMBRYO BANKING IN A FEW MINUTES, COMES INTO RECEIVERSHIP OF AN EMBRYO, IS NOW SITTING IN A BANK. AND IN THE PROCESS OF THAT EMBRYO GOING INTO THE BANK, ONE OF THE INDICATIONS SUPPORTING THAT -- ON ONE OF THE DOCUMENTATIONS I HAVE AVAILABLE IS AN INDICATION THAT A PAID DONOR PROVIDED ONE OR MORE OF THE GAMETES FOR THAT EMBRYO.

THE QUESTION, AGAIN, IT TRIGGERS THE SAME PROVISION IN THE STANDARD. IT'S ACTUALLY NOT TECHNICALLY CORRECT TO SAY ACCEPTABLY DERIVED. THERE'S ANOTHER PIECE OF THE REGULATION THAT SAYS

EMBRYOS -- ESSENTIALLY GAMETES IN EMBRYOS USED IN CIRM-FUNDED RESEARCH SHOULD NOT -- THERE SHOULD BE NO PAYMENT TO ANYONE DONATING FOR THAT.

MR. KLEIN: AND, GEOFF, WE'RE NOT TALKING ABOUT OTHER COUNTRIES' BANKS BECAUSE THOSE ARE GRANDFATHERED UNDER ANOTHER PROCESS OR IN THE UNITED STATES.

DR. LOMAX: NOW WE'RE TALKING ABOUT A SITUATION SPECIFICALLY WHERE ONE OF OUR GRANTEES IS PROPOSING TO DO A STEM CELL LINE DERIVATION, AND THE SOURCE MATERIAL FOR THAT DERIVATION WOULD BE AN EMBRYO. UNDER THE CURRENT REGULATIONS ONLY EMBRYOS FOR WHICH NONE OF THE GAMETE DONORS HAVE BEEN PAID IS ELIGIBLE TO BE USED IN DERIVATIONS. AND THE QUESTION BEFORE YOU ALL IS SHOULD THEY BE ABLE TO UTILIZE EMBRYOS FOR WHICH ONE OR MORE GAMETE DONORS HAVE BEEN PAID IF THE EMBRYO IS ORIGINALLY CREATED FOR THE SOLE PURPOSE OF IVF FOR REPRODUCTIVE USE.

MR. SHEEHY: DO WE KNOW WHEN THAT EMBRYO WAS CREATED? IS THAT PRIOR TO OUR REGULATIONS?

DR. LOMAX: THAT'S --

CHAIRMAN LO: THAT'S THE NEXT SLIDE.

DR. LOMAX: I TRIED TO -- I'M NOT SURE THIS SLIDE DOES ACTUALLY CAPTURE IT, BERNIE. THAT'S ANOTHER -- YOU MAY WANT TO -- I MIGHT SUGGEST YOU

KIND OF SORT OF AGAIN ADDRESS THESE QUESTIONS STEPWISE BECAUSE YOU HAVE SORT OF ANOTHER FACTOR WHICH IS TIMING, AND I SORT OF LOOK TO YOU ALL TO SORT OF THINK THAT THROUGH. IT'S ANOTHER VARIABLE IN A FAIRLY COMPLEX CHAIN OF CIRCUMSTANCES. I THINK SOME OF THE PANEL -- WE'VE BEEN ASKING THE PANEL. WE MIGHT BE ABLE TO SORT OF GET AT SOME OF THOSE QUESTIONS AS WELL WITH TIMING AND HOW MUCH WE KNOW ABOUT THEM.

MR. KLEIN: THE DATES ARE THE ACTUAL ISSUE.

MR. SHEEHY: THE ONLY POINT IS THAT FOR PURPOSE OF OUR REGULATIONS, YOU KNOW, IF THEY WERE MADE BEFORE OUR REGULATIONS WERE IN PLACE, HOW WOULD ANYBODY KNOW? BUT IF IT'S POST OUR REGULATIONS, THEN PEOPLE WOULD BE (INAUDIBLE).

DR. LOMAX: AGAIN, I THINK IN TERMS OF THE PANEL WE'VE CONVENED, THERE IS AN OPPORTUNITY TO HEAR A LITTLE BIT ABOUT HOW THAT IS ADDRESSED.

CHAIRMAN LO: IT'S AN IMPORTANT POINT. THAT'S ONE OF THE FEW THINGS WE NEED TO DISCUSS AFTER LUNCH. WHAT I WANT TO DO IS JUST LAY OUT FOR YOU, WHICH HAS BEEN HIGHLIGHTED IN THE FOURTH ONE, THE DATE AT WHICH THE EMBRYO WAS CREATED.

DR. TAYLOR: SO IS THE INTENT HERE TO LOOK

AT THIS AS AN EXCEPTION LIKE IN THE LAST DISCUSSION, OR IS THIS NOT VIEWED AS AN EXCEPTIONAL --

CHAIRMAN LO: RIGHT NOW WE'RE JUST TRYING TO LAY OUT SOME ISSUES FOR US TO CONSIDER. AND AFTER LUNCH WE NEED TO THINK THROUGH WHAT, IF ANYTHING, WE WISH TO DO TO MODIFY OUR CURRENT POLICY.

DR. LOMAX: THE SCOPE OF THESE ISSUES ARE A BIT BROADER THAN WHAT WE BROUGHT BEFORE YOU IN QUESTION ONE. AND SO WE HAD SORT OF A NARROW RECOMMENDATION. THIS IS AN ISSUE WHICH WE DON'T AT THIS TIME HAVE ANY FORMAL RECOMMENDATION. WE'RE TRYING TO FOLLOW THE SENSE OF THE COMMITTEE AND UNDERSTAND HOW TO MOVE FORWARD. SO THAT'S WHY WE TRIED TO SEPARATE IT.

SO I'M NOT SURE -- I'M WONDERING IF YOU THINK IT'S WORTH TRYING TO WALK THROUGH THIS SLIDE, OR DO YOU WANT THEN TO SORT OF BEGIN --

CHAIRMAN LO: MAYBE WE SHOULD TURN TO THE PANEL BECAUSE I THINK THEY HAVE A LOT OF IMPORTANT -- GO THROUGH -- YOU WANT TO GO THROUGH THIS SLIDE.

DR. LOMAX: WE'VE DONE THIS ONE. I JUST THOUGHT I'D GO BACK TO IT BECAUSE IT'S -- IT GIVES US SOMETHING TO LOOK AT. WE'VE DONE THIS ONE. THIS

IS THE EMBRYO EXAMPLE. NOW WE HAVE JEFF'S POINT TO BE SENSITIVE ABOUT TIMING AS WELL.

CHAIRMAN LO: SO DO YOU WANT TO, GEOFF, INTRODUCE THE PANEL. ANN, YOU HAD A QUESTION.

MR. KLEIN: IN INTRODUCING THE PANEL, COULD WE SEE HOW CLOSE SHERRY IS TO HER CONVERSATION? I THINK THIS PANEL IS VERY IMPORTANT. SO COULD SOMEONE JUST CHECK WHERE SHERRY IS?

CHAIRMAN LO: I THINK SHE HAD ANOTHER CALL SHE HAD TO TAKE AT 11:45.

MS. KING: RIGHT. IT WOULD BE STARTING IN ABOUT FIVE MINUTES.

DR. LOMAX: ONE MINUTE. WE'RE CHECKING ON HER.

(PAUSE IN PROCEEDINGS.)

MS. KING: DR. LO, IT'S GOING TO BE AT LEAST 15 OR 20 MINUTES.

CHAIRMAN LO: SO WHY DON'T YOU INTRODUCE ALL THREE PANELISTS FIRST, AND THEN WE'LL THEM GO IN ORDER.

DR. LOMAX: I THINK WE HAVE TWO PANELISTS AT THE MOMENT. SO FIRST, ONE OF THE -- SO WISHES OF THE COMMITTEE AT THE LAST MEETING WAS TO PROVIDE SORT OF MORE INSIGHT INTO THE ACTUAL PROCUREMENT PROCESS PARTICULARLY FOR EMBRYOS. SO WE CONTACTED

THE UCSF TISSUE BANK, AND DENISE BERNSTEIN IS GOING TO WALK US THROUGH THEIR PROCEDURES AND THEIR PROTOCOLS FOR OBTAINING MATERIALS THAT WOULD GO INTO THE BANK. AND THESE MATERIALS WOULD POTENTIALLY BE AVAILABLE FOR RESEARCH, PARTICULARLY DERIVATION RESEARCH.

WE ALSO INVITED DIANE MICHELSEN ALONG. SHE WORKS WITH INDIVIDUALS WHO ARE INVOLVED IN THE IVF PROCESS, AND SHE HAS SORT OF AN UNDERSTANDING OF SORT OF SOME OF THE ASPIRATIONS OF POTENTIAL DONORS, PARTICULARLY DONORS WHO MAY HAVE EMBRYOS THAT THEY WOULD LIKE TO GIVE TO RESEARCH, BUT BECAUSE OF THE REGULATIONS GOVERNING PAYMENTS AND OTHER RESTRICTIONS, SHE'S HAD FEEDBACK FROM DONORS AND BRINGS A LITTLE BIT OF A DONOR PERSPECTIVE IN TERMS OF HOW OUR REGULATIONS IMPACT SORT OF CALIFORNIANS. SO THOSE ARE TWO PERSPECTIVES.

WE HAVE SOME SCIENTISTS FROM STANFORD WHICH WE'RE TRYING TO GET ON THE PHONE, AND WE'VE ASKED THEM TO SORT OF EXPAND ON THE COMMENTS WHICH THEY'VE ALREADY PROVIDED IN WRITING, WHICH WERE SENT OUT TO YOU. AND THIS WILL DEAL MORE WITH THE SCIENTIFIC ASPECTS OF THE SCIENTIFIC UTILITY OF EMBRYOS. PARTICULARLY THIS QUESTION HAS COME UP ABOUT ARE THERE CHARACTERISTICS OF PAID IVF-EMBRYOS

THAT ARE SOMEWHAT DIFFERENT THAN THE OTHER 80 OR 75 PERCENT OF EMBRYOS. SO IT'S SORT OF A SPECTRUM OF VIEWS FROM SORT OF THE DONOR, THE SCIENTISTS, AND, AGAIN, TO ADDRESS A NUMBER OF QUESTIONS THAT YOU ALL RAISED IN THE MEETING IN FEBRUARY THIS YEAR.

MS. BERNSTEIN: SO THANK YOU FOR THE INVITATION. THIS IS A GREAT OPPORTUNITY FOR ME TO INTRODUCE THE CONSENTING PROCESS FOR UCSF'S TISSUE BANK. WE DO HAVE SOME DOCUMENTS THAT WERE EITHER E-MAILED TO YOU OR COPIED IN THE BACK REGARDING THE BANK. I MAY MAKE REFERENCE TO THESE OCCASIONALLY.

THIS IS THE FIRST STEP IN EMBRYONIC RESEARCH. IT'S CONSENTING AND OBTAINING EMBRYOS. SO THE PURPOSE OF OUR BANK IS TO PROVIDE THE RESEARCHERS WITH THE TISSUES THEY NEED, PROVIDING THE MAXIMUM USEFULNESS OF TISSUES, AND MATCHING THE SPECIFIC TISSUE QUALITY TO THE RESEARCH QUESTION.

WE CURRENTLY ARE PROVIDING EMBRYOS AND EGGS. WE OFFER THE DONORS LEVELS OF RESEARCH SO THAT THEY'RE COMFORTABLE CHOOSING A TYPE OF RESEARCH THAT IS DONE WITH THEIR EMBRYOS AND EGGS. WE ALSO DEIDENTIFY THE SPECIMENS SO THAT THE SCIENTIFIC RESEARCHER DOES NOT KNOW WHO THE DONOR IS. THEY DO NOT EVEN KNOW WHICH PROGRAM THEY COME FROM.

WE COMPLY WITH ALL THE RULES AND

REGULATIONS OF THESE AGENCIES AND THE CIRM AT THE TOP, OF COURSE.

SO I WAS TALKING ABOUT LEVELS OF RESEARCH. I'LL EXPLAIN THIS AS I EXPLAIN THIS TO PATIENTS ON THE PHONE THAT ARE DONORS IN PERSON OR ON THE PHONE. LEVEL ONE RESEARCH IS A GENERAL KIND OF RESEARCH. AND WHAT THAT IS IS ALLOWING THE RESEARCHERS IN ANY WAY THEY POSSIBLY CAN TO EXAMINE THE EMBRYOS OR EGGS. THAT COULD MEAN STAINING, DISSECTION, GROWING OUT EMBRYOS FOR TWO TO THREE DAYS TO TRY TO BETTER UNDERSTAND WHAT WOULD MAKE THEM NORMAL OR ABNORMAL, AND THEY CAN EXAMINE GENETIC PATTERNS. NO STEM CELLS ARE GROWN FROM LEVEL ONE EMBRYOS OR LEVEL ONE RESEARCH.

LEVEL TWO RESEARCH IS STEM CELL RESEARCH. IT'S ALLOWING THE RESEARCHERS TO ATTEMPT TO GROW, AND HOPEFULLY SUCCESSFULLY GROW, THOSE SPECIALIZED CELLS THAT REPAIR DAMAGED TISSUES. AND THAT DOES NOT REPLACE AN ORGAN THAT CAN BECOME A CELL SUPPORTING TYPE SUCH AS A HEART, BRAIN, SPINAL CORD CELL. IT'S IMPORTANT TO NOTE THAT THE DONOR'S DNA IS CONTAINED WITHIN THE STEM CELLS, AND THAT THOSE CELLS COULD BE OUT THERE FOR YEARS TO COME.

LEVEL THREE RESEARCH IS A MORE MANIPULATIVE FORM OF RESEARCH, AND ITS GOAL IS TO

CREATE A STEM CELL THAT MATCHES A SPECIFIC PERSON AS WELL AS A SPECIFIC ORGAN TYPE TO HOPEFULLY AVOID THE NEED FOR ANTIREJECTION MEDICATIONS. IT INVOLVES MOVING DNA FROM ONE CELL TO ANOTHER AND THEN GROWING OUT THOSE STEM CELLS. THE SCIENTIFIC TERM BEING STEM CELL NUCLEAR TRANSFER. ANOTHER TERM FOR THAT IS THERAPEUTIC CLONING, NOT TO BE CONFUSED WITH REPRODUCTIVE CLONING. WE'RE NOT TRYING TO CREATE ANOTHER BEING, BUT WE ARE TRYING TO CREATE CELLS THAT MATCH A PARTICULAR BEING.

AND I DO HAVE SOME NUMBERS THAT I BROUGHT WITH ME REGARDING HOW MANY PEOPLE CHOOSE THESE DIFFERENT LEVELS OF RESEARCH AND ALSO THE EGG DONORS WHO WE CONSENT AND WHAT THEY SELECT.

SO WHO ARE THE DONORS? THERE ARE SEVEN DONOR GROUPS, AND, YES, SEVEN CONSENTING PACKETS FOR EACH OF THESE GROUPS. AND THE PERSON'S DNA CONTRIBUTION DIRECTS US TO THE CORRECT PACKET. THERE ARE THREE GROUPS THAT DONATE FRESH TISSUES AND THERE ARE FOUR GROUPS THAT DONATE FROZEN TISSUES.

THOSE THAT DONATE FRESH TISSUES ARE FROM THE UCSF IVF PRACTICE, AND THAT WOULD BE YOUR STANDARD IVF PATIENT. UCSF EGG DONORS, KNOWN, WERE ANONYMOUS, PAID OR UNPAID, AND UCSF SPERM DONORS KNOWN, PAID, OR UNPAID. I JUST HAVE TO SAY THAT THE

SPERM DONOR GROUP, IT'S AN EXTREMELY RARE THAT WE GET A CONSENT FROM THEM. THE BANKS DO NOT GET THAT RESEARCH CLAUSE PUT IN THEIR CONTRACT, AND WE'VE NEVER HAD A DONATION FROM AN ANONYMOUS SPERM DONOR.

WE COLLECT CONSENTS FROM ALL DONORS THAT ARE IN THE PRACTICE WHETHER THEY'RE PAID OR UNPAID, BUT WE ONLY DISTRIBUTE MATERIALS OF UNPAID DONORS. WE DO NOT DISTRIBUTE THOSE FROM PAID DONORS.

THE NEXT GROUP ARE PEOPLE THAT DONATE FROZEN MATERIALS, AND IT'S PRIMARILY EMBRYOS. AND THESE ARE PEOPLE THAT NO LONGER NEED, NO LONGER WANT THEIR FROZEN TISSUES ANYMORE. IT'S PRIMARILY PEOPLE WHO HAVE COMPLETED THEIR FAMILIES. SOMETIMES IT'S DIVORCE. SOMETIMES IT'S DEATH. AND THE FROZEN GROUPS CONSIST OF THOSE WHO ARE DONATING FROZEN EMBRYOS, EGG DONORS WHO CONTRIBUTED TO THE CREATION OF FROZEN EMBRYOS, SPERM DONORS WHO CONTRIBUTED TO THE CREATION OF FROZEN EMBRYOS, AND DONORS OF FROZEN EGGS. THESE ARE USUALLY WOMEN WHO ARE GOING THROUGH CANCER TREATMENT AND HAVE CHOSEN TO FREEZE THEIR EGGS PRIOR TO CHEMOTHERAPY AND HOPING TO PRESERVE THEIR FUTURE FERTILITY.

SO THE CONSENTING OF THE FRESH TISSUE DONORS, AT UCSF THE PATIENTS PRIOR TO THEIR IVF CYCLE GET A LARGE NUMBER OF DOCUMENTS AND INCLUDE

MULTIPLE CONSENTS. ONE OF THOSE IS A GROUP OR OUR PACKET OF CONSENTS FOR TISSUE DONATION FOR THE TISSUE BANK. THIS IS FOR GENERAL IVF PATIENTS AND THE EGG DONORS.

PRIOR TO THEM STARTING TREATMENT, THEY SIT DOWN WITH A NURSE COORDINATOR OR RESEARCH COORDINATOR, AND THE LEVELS OF RESEARCH ARE DISCUSSED WITH THEM. THEY ARE OFFERED LEVELS ONE, TWO, AND THREE. THEY ARE ALSO OFFERED TO DECLINE. SO THERE'S A DECLINE BOX AND THEY CAN JUST CHECK THAT OFF. AND THEN THESE PARTIES PUT THE CONSENT FORM IN AN ENVELOPE, A SEALED ENVELOPE, AND IT COMES TO ME.

PRIOR TO THE IVF TREATMENT FOR THE ACTUAL RETRIEVAL, I MEET WITH THEM AND GO THROUGH A CIRM VERIFICATION FORM. THERE ARE SEVEN POINTS ON THAT FORM THAT WE MAKE SURE THEY UNDERSTAND, AND I HAVE A COPY OF THAT AS WELL. IT GIVES THEM THE OPPORTUNITY TO CLARIFY ANY QUESTIONS THEY MIGHT HAVE AND TO CHANGE THEIR MIND IF THEY WISH.

IN ORDER TO PREVENT CLINICAL BIAS, PHYSICIANS AND EMBRYOLOGISTS ARE NOT PERMITTED TO KNOW IF THEIR PATIENTS HAVE CONSENTED TO DONATE TO THE TISSUE BANK.

NOW, THE CONSENTING OF FROZEN TISSUE

DONORS, FIRST OF ALL, THOSE DONORS COME FROM MOSTLY OUTSIDE PROGRAMS THROUGHOUT THE UNITED STATES, AND THEY CONTACT US BY GETTING INFORMATION FROM THEIR IVF PROGRAM OR FROM THE INTERNET, BUT FROM THEIR IVF PROGRAMS PRIMARILY. THEY GET A BROCHURE WHICH SOME OF YOU HAVE COPIES OF, AND IT TELLS THEM HOW TO CONTACT US. WHEN THEY FIRST CALL ME, I ASK THEM ELIGIBILITY QUESTIONS. THE FIRST QUESTION BEING DID YOU USE DONOR GAMETES AND EXPLAINING WHAT THAT MEANS. AND I'LL GET INTO THAT A LITTLE BIT MORE LATER.

THE OTHER ISSUE IS WHAT STATE WERE YOU EMBRYOS CREATED. WE WILL NOT ACCEPT EMBRYOS FROM STATES THAT BAN EMBRYONIC RESEARCH.

I MAIL THE CONSENT PACKET OUT TO THEM AND ASK THAT BOTH PARTNERS READ THROUGH IT. AND THEN I HAVE TO SPEAK WITH THEM BY PHONE TO REVIEW THE CONSENT FORM PRIOR TO THEM MAILING IT BACK. WE DO NOT CONSIDER A RETURNED CONSENT BY PHONE ONLY VALID. I GO THROUGH THE LEVELS OF CONSENT, PERSONAL HEALTH INFORMATION CONSENT WHICH IS UNIQUE TO UNIVERSITY OF CALIFORNIA, REVIEW THE CIRM FORM. AND IF THEY HAVE TIME AND IF THEY'RE WILLING, I GO THROUGH A HEALTH QUESTIONNAIRE WITH EACH PARTNER.

AFTER THE CONSENTS ARE COMPLETE, I REVIEW

THEM TO MAKE SURE ALL THE LINES ARE FILLED IN, PRETTY COMPULSIVE ABOUT THAT, AND THEN I NOTIFY THE IVF PROGRAM AND MAKE ARRANGEMENTS FOR THOSE EMBRYOS TO BE SHIPPED TO UCSF. IF A KNOWN GAMETE DONOR WAS USED, IT'S THE RESPONSIBILITY OF THE RECIPIENT COUPLE TO CONTACT THAT DONOR AND ASK HER TO CONTACT ME. I CANNOT PURSUE THE DONOR. ONCE THE DONOR CONTACTS ME, I MAIL HER A PACKET AND I DO THE SAME THING WITH HER, REVIEWING THE FULL CONSENT, AND THEN SHE CAN MAIL IT BACK TO ME.

THE CONSENTING PROCESS IS A COSTLY ENDEAVOR. THERE'S ADMINISTRATIVE COST, SCIENTIFIC COST, STAFFING, PAPER, MAILING, SHIPPING, STORAGE, DATA MANAGEMENT, WHICH IS HUGE, AND DEIDENTIFYING. INDEPENDENT RESEARCH GRANTS COVER A MINIMUM OF A HUNDRED DOLLARS PER EMBRYO. THE IRONY IS THAT THE RESEARCH FUNDING THAT IS PROVIDED FOR THE STUDIES THAT REQUIRE THE USE OF THE EMBRYOS, BUT FUNDING HAS NOT BEEN MADE AVAILABLE TO SUPPORT THE SOURCE OF THE MATERIALS. AND AS I'VE INDICATED, THEY'RE EXPENSIVE.

FUTURE CONTACT, ALL DONORS ARE ASKED IF WE CAN CONTACT THEM AT SOME FUTURE POINT. IT COULD BE FIVE TO TEN YEARS FROM NOW. IT'S 2008 AND WE DON'T KNOW WHAT 2012 OR 2018 IS GOING TO BRING. SO THEY

CAN DECLINE OR THEY CAN AGREE. BOTH PARTIES NEED TO AGREE. THE TWO REASONS WE WOULD DO THAT IS IF A RESEARCHER FOUND SOME INFORMATION THAT COULD BE USEFUL TO THEM IN THEIR FUTURE HEALTHCARE DECISIONS OR FOR THEIR CHILDREN. OR IF STEM CELLS WERE CREATED AND THEY COULD BE USED THERAPEUTICALLY, WE ARE ASSUMING THAT THE FOOD AND DRUG ADMINISTRATION IS GOING TO ASK US TO CONTACT THESE DONORS AND ASK IF THERE'S BEEN ANY UPDATE IN THEIR HEALTH HISTORY. SO THEY GIVE US WHAT THEY WOULD ESTIMATE TO BE THEIR FUTURE CONTACT INFORMATION, AND IT'S USUALLY CELL PHONES AND E-MAILS, AND WE GO WITH THAT. WE ALSO ANTICIPATE THAT WE WOULD UTILIZE THE ETHICS COMMITTEE TO MAKE SURE THAT WE ARE INDEED PASSING ALONG USEFUL INFORMATION.

NOW, THERE ARE SOME ALTERNATIVES TO THE TISSUE BANK CONSENTS. I'M GOING TO START AT THE BOTTOM OF THE CONSENT FOR CRYOPRESERVATION. THAT IS A FORM THAT ALL IVF PROGRAMS USE PRIOR TO FREEZING EMBRYOS, AND THEY OFFER CERTAIN LIFE SITUATIONS AND THEN OPTIONS FOR DISPOSITION. THE LIFE SITUATIONS MIGHT BE IF THIS PARTNER DIES OR THAT PARTNER DIES, IF THERE'S A DIVORCE. IF THEY DONATED THE EMBRYOS AND NOBODY CAN FIND THEM IN, SAY, FIVE YEARS TO MAKE THE PAYMENT UNDER YEARLY PAYMENT, THEY CAN DETERMINE

WHERE THOSE EMBRYOS WOULD GO IN THOSE SITUATIONS, AND THAT COULD BE DONATION TO RESEARCH, DONATE TO ANOTHER COUPLE, DONATE TO THE OTHER PARTY, DISCARD.

ANOTHER GROUP WOULD BE FORTUNATELY A SMALL GROUP, BUT WE STILL HAVE HAD THEM, IS CONSENT VIA THEIR WILL. AND MOST PEOPLE DON'T THINK THAT FAR AHEAD WHEN THEY HAVE FROZEN EMBRYOS, BUT SOME PEOPLE WILL PUT INTO THEIR WILL WHAT THEY WOULD LIKE DONE WITH THESE FROZEN EMBRYOS. AND IF THAT OPTION IS RESEARCH, THEN WE CAN ACCEPT THAT WILL AS CONSENT.

MR. KLEIN: IF I CAN ASK YOU A QUESTION HERE, A LEGALISTIC QUESTION. THE WORD "ONLY" FOLLOWS THE WORD "RESEARCH" UNDER LEVEL ONE RESEARCH. SO THESE FORMS ARE LIMITED TO LEVEL ONE RESEARCH ONLY. THAT MEANS THAT THEY ONLY DISCUSS GENERAL MEDICAL RESEARCH. IT DOESN'T MEAN THAT THEY SAY -- THE FORM DOESN'T SAY THAT YOU CAN ONLY DO RESEARCH WHICH IS NOT SCNT AND NOT STEM CELL RESEARCH.

MS. BERNSTEIN: NO. IT DOESN'T CLARIFY IT ON THE FORMS. IT JUST -- IF THEY SAY RESEARCH AND THEY DON'T CLARIFY STEM CELL RESEARCH --

MR. KLEIN: I WAS ONLY TRYING TO ACUTELY GET TO THE FUNCTIONALITY OF THE MODIFIER.

MS. BERNSTEIN: YEAH. YEAH. MAYBE I

SHOULDN'T HAVE PUT MY ONLY IN ANOTHER SPOT.

WE CAN ACCEPT CONSENT FROM A GAMETE DONOR CONTRACT. WHEN SOMEBODY SIGNS WITH THEIR AGENCY, THEY SOMETIMES WILL SAY THAT THE RECIPIENT COUPLE CAN CHOOSE TO DONATE THOSE EMBRYOS TO RESEARCH. IF WE CAN GET A COPY OF THAT SIGNED CONSENT, THAT IS CONSIDERED CONSENT FOR TISSUE BANK RESEARCH. THE OTHER ONE IS CONSENT BY DISPOSITION FORM. AND THIS IS NOW UNIQUE TO ONLY TWO GROUPS, UC SAN FRANCISCO IVF PROGRAM AND A PRIVATE STORAGE FACILITY IN NORTHERN NEVADA. THEY HAVE THE OPTION OF KEEPING THE EMBRYOS IN STORAGE OR DONATING THEM TO ANOTHER COUPLE OR DONATING TO RESEARCH OR TO DISCARD. AND IF THEY DONATE TO RESEARCH, THEN THOSE CAN COME DIRECTLY TO US.

AGAIN, THE LIMITATION IS THAT IT'S FOR LEVEL ONE RESEARCH ONLY. AND ALSO THIS GROUP CANNOT HAVE FUTURE CONTACT.

THE ADVANTAGES TO THE TISSUE DONORS ARE THAT IT'S A SATISFYING OPTION. MOST PEOPLE WILL SAY WE'RE NOT JUST THROWING THEM AWAY. THE OTHER THING IS THAT THEY HAVE A DESIRE, STRONG DESIRE, TO HELP OTHERS. THE MEDIA HAS BEEN VERY HELPFUL IN MOST CASES OF ADVERTISING FOR STEM CELL RESEARCH AND HOW IT CAN HELP. SOMETIMES THEY'RE A LITTLE OPTIMISTIC,

BUT GENERALLY SPEAKING IT HELPS.

THEY'RE OFFERED THE LEVELS OF RESEARCH, AND THIS GIVES THEM THE OPTION TO CHOOSE A LEVEL THAT THEY'RE COMFORTABLE WITH AND THAT THEY HAVE CONTROL OVER THE DECISION ABOUT WHERE THEIR EMBRYOS ARE GOING. AND THEY ARE VERY GLAD TO HAVE THE SEPARATION OF THE FIREWALL, IF YOU WILL, FROM SEPARATING DONORS FROM THE RESEARCHERS.

THE ADVANTAGES TO THE RESEARCHERS ARE CONSISTENT WITH CONSENTING. AND THE COLLECTION OF TISSUES IS ONGOING, AND THEY DON'T HAVE TO START AND STOP THE RECRUITMENT WITH EACH PROTOCOL. IF THE STUDY STOPS IN APRIL AND THEY START A NEW PROTOCOL IN OCTOBER, THEY DON'T NEED TO RESTART THE RECRUITING PROCESS BECAUSE WE, AS THE TISSUE BANK, ARE JUST COLLECTING EMBRYOS ALL ALONG THE WAY. TISSUE BANK HANDLES ALL CONSENTING ISSUES, REGULATIONS, THE COMMITTEES, AND THE SCIENTIFIC RESEARCHERS, OF COURSE, HAVE TO DO SOME OF THIS ON THEIR OWN IN THEIR OWN PROTOCOLS, BUT THEY DON'T HAVE TO HANDLE ANY OF THAT CONSENTING.

AND IT DECREASES THEIR RECRUITMENT COSTS. STAFF AND TIME AND DOCUMENTS, AS I MENTIONED EARLIER, SOMEBODY HAS TO PICK THAT UP, AND THAT IS THE TISSUE BANK. WE DO NOT GET CIRM FUNDS.

WHAT DISAPPOINTS OR ANGERS POTENTIAL DONORS, I HAD TO PUT THIS SLIDE HERE BECAUSE OF MY INTERACTIONS WITH THE DONORS. THE INDIVIDUAL STATE LAWS BANNING RESEARCH, IT'S HARD TO TAKE. IT, I BELIEVE, IS A CLASS FOUR FELONY IN LOUISIANA TO DESTROY AN EMBRYO. THERE ARE SOME STATES THAT HAVE PENDING LEGISLATION. UCSF DEPARTMENT OF LEGAL AFFAIRS CHECKS THE LAWS IN EACH STATE, AND WE TELL THE PERSON YES OR NO WE CAN OR CANNOT ACCEPT FROM YOUR STATE. I DO HAVE A SHORT LIST OF WHICH STATES ARE LEGAL AND WHICH ONES AREN'T.

THE RISK IS TO THE DONOR AND TO THE PHYSICIAN. UCSF HAS NO RISK IN ACCEPTING THESE EMBRYOS, BUT WE DON'T WANT TO VIOLATE THE PATIENTS IF WE VIOLATED, THEIR CONFIDENTIALITY BE VIOLATED IN THE STATE THAT THEY LIVE IN.

SOME OF THEM HAVE EVEN OFFERED TO SHIP THEIR EMBRYOS TO ANOTHER STATE AND THEN ASK US TO SHIP THEM IN FROM THAT STATE. AND THAT'S WHY WE ASK THEM WHAT STATE WERE THEY CREATED BECAUSE THEY WILL SHIP THEM TO TEXAS AND THEN TRY TO SHIP THEM TO US. TEXAS IS A LEGAL STATE.

NOW, OUR CONSENTING PROCESS IS TEDIOUS AND IT'S DIFFICULT. AND WHEN YOU SEE THE SIZE OF OUR PACKETS AND YOU KNOW THE NUMBER OF PHONE CALLS THAT

HAVE TO HAPPEN, YOU WILL SEE WHY. SOME PEOPLE WILL JUST SAY, YOU KNOW WHAT, IT'S JUST EASIER TO DISCARD AND WE WILL. THOSE WHO SAY IT'S EASIER TO DISCARD AND STILL DONATE, THOSE ARE PEOPLE THAT ARE MOTIVATED.

NOW, THE GAMETE DONOR RESTRICTIONS IS THE HOTTEST ISSUE THAT I DEAL WITH ON ANY GIVEN DAY. A RECIPIENT COUPLE WILL CALL ME, AND I HAVE TO ASK THEM CAN I GET CONSENT FROM THIS DONOR. IF I CANNOT GET CONSENT FROM THE DONOR, THEN IT'S ALL OVER. I HAVE TO TELL THEM I'M SORRY I CAN'T ACCEPT YOUR DONATION. THEY DON'T UNDERSTAND WHY THIS IS THE CASE WHEN THEIR DONOR CONTRACT STATES THAT I TURN OVER ALL RIGHTS TO THE RECIPIENT COUPLE. I ASSUME THAT DIANE CAN PROBABLY CLARIFY THIS, BUT ALL RIGHTS MEANS THAT THEY CAN DISPOSE OF THEM OR THEY CAN DONATE THEM TO ANOTHER COUPLE OR THEY CAN DO WHATEVER THEY WANT WITH THEM, BUT THEY CAN'T DO RESEARCH. AND SO I ALWAYS TELL THE AGENCIES WE'RE LOOKING FOR THE MAGIC WORD "RESEARCH" IN THE CONTRACT.

SO WE SHARE THIS DISAPPOINTMENT IN A BIG WAY. OUR CONCERN IS NOT ONLY THE NUMBER OF EMBRYOS IN THE BANK, BUT THE QUALITY OF THOSE EMBRYOS IN THE BANK. CERTAINLY ACCEPTING EMBRYOS FROM YOUNGER

DONORS IS PREFERABLE AND ENHANCES THE RESEARCH OUTCOMES.

SO IN CONCLUSION, THE DETAILED CONSENTING PROCESS IS VALUABLE TO THE RESEARCHERS AND THE DONORS. BY HAVING A CONSISTENT CONSENTING PROCESS, WE'RE MAKING CERTAIN THAT RESEARCHERS ARE RECEIVING TISSUES FROM DONORS WHO HAVE PROVIDED TRULY INFORMED CONSENT AND THAT SOCIETY WILL BENEFIT FROM THE WORK OF THIS RESEARCH TEAM, AND THIS TEAM IS THE TISSUE BANK AND THE SCIENTIFIC RESEARCHERS AND THE DONORS. SO I'M SURE I'VE RAISED MORE QUESTIONS THAN I HAVE ANSWERS, BUT I THANK YOU FOR YOUR TIME.

CHAIRMAN LO: OKAY. THANKS VERY MUCH. QUICK QUESTIONS. WE HAVE THREE PEOPLE ON THE LINE IN THE CLINIC WHO WANT TO MAKE A PRESENTATION. SO WE'LL HOLD THESE. WHY DON'T WE GET BACK TO THE QUESTIONS TO DENISE.

HELLO, PALO ALTO. ANYBODY THERE? NO ONE IS THERE. ALL RIGHT. ASK YOUR QUESTION, JOSE.

DR. CIBELLI: CAN I ASK YOU A QUESTION PLEASE?

MS. BERNSTEIN: YES. I'M SORRY.

DR. CIBELLI: HAVE YOU ATTEMPTED TO GET THOSE FORMS SIGNED FOR PEOPLE WHO HAVE DONATED OOCYTES FOR A SINGLE (INAUDIBLE)?

MS. BERNSTEIN: YES.

DR. CIBELLI: HOW DIFFICULT, HOW EASY? DO PEOPLE DONATE JUST FOR (INAUDIBLE) REASONS?

MS. BERNSTEIN: FIRST OF ALL, THE PEOPLE THAT APPROACH ME WHO ARE DONATING FROZEN SPECIMENS ARE ALREADY MOTIVATED AND THEY'RE EASY TO GET CONSENT FROM. THE FRESH CYCLES ARE A LITTLE TOUGHER BECAUSE THESE PEOPLE ARE IN ACTIVE TREATMENT, AND THE MAIN TRUST ISSUES ARE THEY'RE OVERWHELMED. AND SO I THINK AT UCSF ABOUT 50 PERCENT OF PEOPLE WHO ARE GOING THROUGH ACTIVE TREATMENT CHOOSE TO DONATE TO RESEARCH. I DO HAVE NUMBERS, THOUGH, ON THE EGG DONORS THAT I APPROACH.

CHAIRMAN LO: I'M SORRY, DENISE. DID YOU TALK ABOUT 50 PERCENT OF WOMEN UNDERGOING TREATMENT AGREE TO BE DONORS, AND WHAT ARE THEY DONATING?

MS. BERNSTEIN: OH, TO DONATE TISSUE --

CHAIRMAN LO: TISSUE, BUT NOT --

MS. BERNSTEIN: -- TO THE TISSUE BANK. SO IT WOULD BE EGGS THAT ARE IMMATURE, EGGS THAT DON'T FERTILIZE, OR DON'T FERTILIZE NORMALLY OR ABNORMALLY GROWING EMBRYOS OR THOSE THAT CAN'T BE --

CHAIRMAN LO: NOT FRESH OOCYTES THAT ARE NORMAL MORPHOLOGY WHERE YOU SEND THEM TO SCNT.

MS. BERNSTEIN: I REALLY THINK OF US AS

HAVING TWO BANKS, SO THERE REALLY ARE TWO SEPARATE GROUPS.

DR. CIBELLI: THIS GOES BACK TO THE PREVIOUS DISCUSSION THAT WE HAD IN TERMS OF HOW WE SEE HOW HARD IT WILL BE TO GET OOCYTES DONATED FOR SCNT. OF THOSE YOU APPROACH, HOW MANY OF THOSE ACTUALLY DONATED GOOD QUALITY OOCYTES FOR SCNT?

MS. BERNSTEIN: GOOD QUALITY, I CAN'T TELL YOU THAT. MAYBE I'LL JUST GO THROUGH THIS GROUP OF NUMBERS.

THERE WERE 228 CYCLES THAT WERE DONATED TO US IN THE FROZEN BANK. SO THE FROZEN EMBRYOS. OF THOSE 107 WERE LEVEL ONE ONLY; BUT IF YOU PULL OFF THE 90 THAT CONSENTED BY DISPOSITION FORM ONLY, THAT LEAVES YOU WITH 17. THOSE THAT CONSENTED BY DISPOSITION FORM AUTOMATICALLY ARE LEVEL ONE.

LEVEL TWO RESEARCH, WHICH IS STEM CELL RESEARCH, IS 30. AND LEVEL ONE, TWO, THREE, ALL BUT STEM CELL NUCLEAR TRANSFER FINDING ONE. SO VAST MAJORITY GO THROUGH ALL THIS RESEARCH, ONE, TWO, AND THREE.

CHAIRMAN LO: DR. CIBELLI HAS A QUESTION.

DR. CIBELLI: (32:34 TRACK 3) MY QUESTION IS WHAT IS THE PRACTICAL TERMS AT UCSF FOR SOMEONE THAT WANTED FRESH, WELL, NOT FRESH, BUT GOOD QUALITY

OOCYTES EVEN THOUGH I COULD TAKE SOME FROZEN, I CAN USE THOSE TOO. HOW PRACTICAL IS THAT? IS IT PRECLUSIVE OR BOTH ARE TRYING TO DO THAT? AND BEFORE WE GO INTO TOO MUCH DETAIL IN THAT, I WOULD WANT TO KNOW IF IT'S FEASIBLE.

MS. BERNSTEIN: IT CAN HAPPEN ON THE FROZEN, YOU'D PROBABLY GET BETTER QUALITY SPECIMEN AND, YES, YOU CAN GET LEVEL THREE EMBRYOS. WE CAN FOLLOW ABOUT 30 TO 40 IN A WEEK. FRESH EMBRYOS THAT WE GET, WE'VE HAD --

DR. CIBELLI: YOU SAY EMBRYOS. I'M ASKING YOU ABOUT OOCYTES.

MS. BERNSTEIN: OOCYTES. I'M SORRY. WE HAVEN'T DONE THAT IN A WHILE.

CHAIRMAN LO: AGAIN, THIS IS NOT QUITE WHAT WE WANT TO TALK ABOUT, THOUGH, AN IMPORTANT TOPIC, BUT I THINK THE ANSWER IS THEY AREN'T.

DR. CIBELLI: SINCE WE HAVE HER HERE.

MS. BERNSTEIN: I DON'T HAVE THE STATISTICS IN FRONT OF ME ON OOCYTES. I HAVE THEM AS THEY RELATE TO THE DONORS, BUT I DON'T HAVE DISTRIBUTION. BUT I WOULD GUESS THAT WE GAVE OUT MAYBE 10 TO 12 OOCYTES PER WEEK WHEN WE WERE GIVING THOSE OUT. THEY WERE FRESH ONLY. THEY WERE NOT FROZEN. AND THEY WERE PRIMARILY M1'S THAT WERE NOT

MATURE ENOUGH. IF THAT'S WHAT YOU WERE LOOKING FOR.

DR. CIBELLI: IF YOU HAVE THE OPPORTUNITY (INAUDIBLE).

MS. BERNSTEIN: I MIGHT ACTUALLY RECOMMEND THAT OUR REPRODUCTIVE BIOLOGIST DO THAT.

MR. KLEIN: JUST TO CLARIFY, YOU SAY THEY WERE M1S THAT WERE IMMATURE.

MS. BERNSTEIN: YEAH.

MR. KLEIN: SO THEY'RE NOT -- THEY'RE NOT THE HIGH QUALITY DESIGNEE FOR SCNT?

CHAIRMAN LO: SO I WANT TO MAKE SURE WE DON'T -- BECAUSE THE ISSUE WE WANTED TO SORT OF ADDRESS FOR THE CIRM LEADERSHIP WAS REALLY THE EXISTING STEM CELL LINES AND EMBRYOS TO BE USED FOR THE DERIVATION OF NEW LINES. SO I WANT MAKE SURE WE GET TO THOSE BECAUSE THE OOCYTE DONATIONS ARE A WHOLE DIFFERENT ISSUE AND AN IMPORTANT ONE, BUT I THINK NOT WHAT I UNDERSTOOD WE WANTED TO DO TODAY.

NOW, WE HAVE ANOTHER STANFORD. DENISE, CAN WE -- I'M SORRY. DIANE, CAN WE TURN TO YOU AND HAVE YOU TALK.

MS. MICHELSEN: SURE. THANKS FOR HAVING ME. MY NAME IS DIANE MICHELSEN. I AM AN ATTORNEY AND MY PRACTICE IS IN LAFAYETTE, AND AS PART OF THIS PRACTICE, WE HAVE A DONATION PROGRAM, AND SURROGACY

DONATION PROGRAMS. WE WRITE CONTRACTS FOR PEOPLE DEALING WITH ASSISTED REPRODUCTION, AND WE REVIEW CONTRACTS FOR PEOPLE THAT ARE INVOLVED IN ASSISTED REPRODUCTION. AND THAT COULD BE EMBRYO DONATION, IT COULD BE OVUM DONATION, IT COULD BE SPERM DONATION, IT COULD BE REDONATION, ANY OF THAT.

SO I SPEAK WITH A LOT OF PEOPLE FROM ACROSS THE UNITED STATES AND CANADA. IN TERMS OF CREDENTIALS, I HAVE BEEN PRESIDENT OF THE AMERICAN ACADEMY OF ADOPTION ATTORNEYS, AND I HAVE BEEN HEAD OF THEIR ASSISTED REPRODUCTION COMMITTEE, AND I HAVE BEEN PRESIDENT OF THE ACADEMY OF HEALTH AND ADOPTION. SO I'VE BEEN ACTIVE IN THE FIELD FOR OVER 25 YEARS, AND I'VE BEEN WATCHING YOU ALL.

ONE OF THE WAYS I GOT INVOLVED WITH THIS IS WHEN IT FIRST CAME TO MY ATTENTION THAT DONATIONS FROM PAID GAMETE DONORS INVALIDATED THE POSSIBILITY OF RESEARCH. I STARTED REALIZING THAT ALL OF THE DISPENSATIONS THAT WE HAD BEEN PUTTING IN CONTRACTS FOR PAID GAMETE DONORS WERE GOING TO BE NOT ABLE TO BE FOLLOWED. AND I WAS KIND OF CONCERNED ON BEHALF OF MY CLIENTS, AND THAT IS REALLY HOW I GOT IN TOUCH WITH GEOFF.

THERE ARE AN AMAZING NUMBER OF PEOPLE WHO CREATE EMBRYOS; AND THEN WHEN THEIR EMBRYOS ARE --

THEY HAVE COMPLETED THEIR FAMILY AND THEIR EMBRYOS HAVE BEEN FROZEN FOR A PERIOD OF YEARS, AND THEY DECIDE THEN THAT THEY WOULD LIKE TO DO SOMETHING WITH THIS BECAUSE THEY WOULD LIKE TO REALLY HELP OTHER PEOPLE WHO HAVE FERTILITY PROBLEMS. AND IF THEY CAN GO FOR OTHER TYPES OF RESEARCH, THEY'RE ALL VERY DELIGHTED TO DO THAT. IT COSTS THEM A LOT OF MONEY TO CREATE THE EMBRYOS, AND THEY WOULD LIKE NOT TO JUST THAW THEM AND TOSS THEM.

SO MANY OF THESE PEOPLE, I WOULD SAY MOST OF THESE PEOPLE ARE NOT INVOLVED IN DONATING EMBRYOS TO ANOTHER COUPLE. THEY DO NOT WANT A FULL SIBLING OF THEIR CHILD TO BE RAISED BY ANOTHER COUPLE WHERE THEY HAVE NO CONTACT OR NO CONTROL. AND SO THE RESEARCH IS THEIR DESIRED OUTCOME.

I SEE PROBABLY, I WOULD SAY, 90 PERCENT OF THE CONTRACTS WE EITHER CREATE OR REVIEW HAVE DONATIONS FOR RESEARCH, AND THEY'RE DONE WITH PAID DONORS. THE CHARACTERISTICS OF THE PAID DONORS, AND THIS IS WHY PEOPLE I'M WORKING WITH TEND USE THE PAID DONORS, IS THEY'RE YOUNGER. THEY'RE USUALLY 18 TO 34. THEY HAVE A VERY CLEAN HEALTH HISTORY, AND PART OF THAT IS THEY ARE YOUNGER. BUT THEIR FAMILY HEALTH HISTORY TENDS TO BE PRETTY CLEAN, AT LEAST THE REPORTED FAMILY HEALTH HISTORY TENDS TO BE

CLEAN. THEY'RE BODY MASS INDEX IS USUALLY LESS THAN 26. AND THEN ALL OF THE ASRM GUIDELINES ARE FOLLOWED IN TERMS OF TATTOOS AND ACUPUNCTURE AND BLOOD DONATIONS AND SUCH.

THE VAST MAJORITY OF THESE DONORS ARE ANONYMOUS TO THE RECIPIENTS. THAT IS NOT TO SAY THAT THE PROGRAM DOESN'T HAVE INFORMATION AS TO WHO'S WHO. BUT AT THE MOMENT THERE IS NO ABSOLUTE REGISTRY, SO THE ABILITY TO GO BACK AND CONTACT DONORS IS NOT AS REALLY COMPLETE BECAUSE WHAT HAPPENS IS SOME OF THE PROGRAMS, THEY GO OUT OF BUSINESS AND THEIR RECORDS ARE GONE.

THE CONTRACTS WE CREATE GENERALLY HAVE A CLAUSE THAT SAYS THE DONOR IS DONATING SPECIFICALLY TO MR. AND MRS. XYZ, AND OFTEN WE'LL WRITE THESE ANONYMOUSLY, NOT MY PREFERENCE, BY THE WAY, AND THEY'RE DONATING THEM FOR THEIR OWN USE. AND THEY ARE ALSO ALLOWING ANY UNUSED DONATIONS TO BE UTILIZED FOR RESEARCH PURPOSES. THEY ARE NOT DOING A BLANKET DONATION THAT ALLOWS MR. AND MRS. XYZ TO DONATE TO ANOTHER COUPLE.

AND THERE IS INDEED A STATUTE IN CALIFORNIA THAT SAYS DONORS NEED TO KNOW WHAT THE DISPOSITION OF THEIR GENETIC MATERIAL IS. SO IT'S SOMETHING I INTERPRET A LITTLE MORE TIGHTLY THAN

SOME OF THE OTHER PROGRAMS. SOME OF THE PROGRAMS BELIEVE IF THE DONORS SIGN A BLANKET DONATION PERMISSION SLIP, THAT ANYTHING CAN HAPPEN. I DON'T. I DON'T THINK THAT'S THE APPROPRIATE INTERPRETATION AND WOULD RATHER ERR ON THE SIDE OF CAUTION.

SO --

MR. KLEIN: COULD WE GET A CLARIFICATION ABOUT WHAT SHE JUST SAID.

MS. MICHELSEN: YES.

MR. KLEIN: SO IF THEY SIGN THIS DONATION, YOUR INTERPRETATION --

MS. MICHELSEN: SIGNED ADMISSION.

MR. KLEIN: IN CALIFORNIA THERE'S A LAW THAT SAYS THAT SOMEONE WHO DONATES HAS TO KNOW WHAT THE ULTIMATE DISPOSITION IS?

MS. MICHELSEN: THEY HAVE TO BE DONATING FOR A PARTICULAR PURPOSE.

MR. KLEIN: AND THE FORMS THAT YOU USE INCLUDE RESEARCH OR DO NOT?

MS. MICHELSEN: TYPICALLY THEY DO.

MR. KLEIN: THEY INCLUDE --

MS. MICHELSEN: BUT THAT'S PART OF MY DONOR CONTRACT, THAT THE DONOR ALLOW RESEARCH.

MR. KLEIN: OKAY. THANK YOU.

MS. LANSING: BUT NOT THE SPECIFIC KIND OF

RESEARCH. THAT'S AN IMPORTANT DISTINCTION.

MS. MICHELSEN: YOU HAD ASKED ABOUT GOOD QUALITY EMBRYOS OR GOOD QUALITY EGGS IS REALLY WHAT YOU ASKED. LET ME JUST TALK ABOUT GOOD QUALITY EMBRYOS AND THEN GO BACK TO EGGS JUST FOR A BRIEF MOMENT.

TYPICALLY WHAT WILL HAPPEN IS FRESH EMBRYOS OF THE BEST QUALITY ARE THOSE THAT ARE USED FIRST, AND THEN THE NEXT ARE FROZEN FOR SECONDARY USE. WHAT IS HAPPENING WITH MANY OF THE IVF PROGRAMS NOW IS THEY ARE JUST FREEZING. THEY'RE NOT BRINGING IT OUT FRESH. AND PART OF THAT IS FOR CYCLE ADJUSTMENT. BUT MANY OF THE PROGRAMS THAT I'VE BEEN TALKING TO HAVE NOT SEEN STATISTICS THAT MANDATE THAT THE EMBRYOS HAD TO BE FRESH.

SO WHAT I'M SEEING IS MORE PEOPLE HAVE FROZEN EMBRYOS RATHER THAN FRESH, AND THAT MAY HAVE IMPLICATIONS FOR RESEARCH. ALMOST ALWAYS PEOPLE WILL NOT DONATE FRESH EMBRYOS BECAUSE THEY DO NOT KNOW IF THEIR FAMILIES ARE GOING TO BE COMPLETED OR IF THE PREGNANCY WILL TAKE. AND IF THE EMBRYOS ARE OF ANY GOOD QUALITY AT ALL, THEY WANT TO PRESERVE THE ABILITY TO REINSERT THEM.

IT'S VERY SIMILAR ON FRESH EGGS BECAUSE THEY MAY HARVEST 20 EGGS, AND THEY'RE ALMOST ALWAYS

GOING TO WANT TO FERTILIZE ALL OF THE EGGS TO SEE WHAT GRADE EMBRYOS COME OUT. TWENTY EGGS, YOU MAY GET OUT OF THAT FOUR EXCELLENT EMBRYOS, YOU MAY GET NONE, YOU MAY GET 20. BUT ALMOST EVERY PROGRAM WE'VE WORKED WITH, AND I CAN SAY EVERY PROGRAM I'VE WORKED WITH, FERTILIZES ALL OF THE EGGS THAT ARE ANY DECENT QUALITY. SO THAT KIND OF MAKES YOUR QUESTION, BUT THAT'S PROBABLY NOT GOING TO HAPPEN.

THAT'S MY COMMENTS. AND I'M OPEN FOR ANY QUESTIONS.

CHAIRMAN LO: QUESTIONS FOR EITHER DENISE OR DIANE?

MR. KLEIN: SO LET ME ASK THIS QUESTION. YOU'RE SAYING THAT IN CALIFORNIA A SPERM DONOR WOULD BE COVERED BY THE LAW YOU CITED AS WELL?

MS. MICHELSEN: YES.

MR. KLEIN: SO YOU HAVE TO HAVE A RESEARCH AUTHORIZATION IN THE FORM.

MS. MICHELSEN: YES.

MR. KLEIN: NOW, IS THAT TRUE IN MASSACHUSETTS?

MS. LANSING: WISCONSIN.

MS. MICHELSEN: I CAN'T SPEAK TO THAT. I DON'T KNOW.

MS. LANSING: DOES SOMEBODY KNOW THE

ANSWER TO THAT? WE'VE BEEN TALKING ABOUT THIS BECAUSE THAT'S THE REAL ISSUE, ISN'T IT? I MEAN THE SPERM DONOR. AM I WRONG?

MR. KLEIN: MOST FREQUENTLY.

MS. LANSING: MOST FREQUENTLY. I'M JUST ASKING BECAUSE IT -- AM I WRONG -- BECAUSE IT SEEMS LIKE IN CALIFORNIA WE'RE NOT GOING TO HAVE THAT PROBLEM, BUT IF WE WANT TO USE OTHER LINES -- MY REAL QUESTION IS, TO COME BACK TO THIS, NO ONE CAN SEEM TO ANSWER WHAT THE POOL IS WHERE YOU HAD A CONSENT TO RESEARCH FROM BOTH THE SPERM AND THE EGG DONOR. WHAT'S THAT POOL? IS THAT POOL BIG ENOUGH? AND THEN, B, FOR OUT-OF-STATE, WHAT HAPPENS IN WISCONSIN OR PLACES WHERE WE COULD HAVE SOME VERY GOOD LINES?

MR. KLEIN: MAYBE WE CAN ASK ANN. WE'RE CONFERRING -- SHERRY AND I BOTH ARE CONFERRING IN SOME OF THIS DISCUSSION, THAT IN MASSACHUSETTS WE'RE REALLY TALKING ABOUT THERE IS RESEARCH ON OOCYTES, BUT THE PROBLEM IS THERE IS CONSENT ON OOCYTES. BUT IF -- TO THE EXTENT THAT THERE'S CONSENT ISSUES, IS THE CONSENT ISSUE GENERALLY WITH THE SPERM DONOR?

DR. KIESSLING: YOU KNOW, I REALLY -- I THINK SO. IT'S MY IMPRESSION THAT SPERM DONORS DO NOT VERY OFTEN SIGN A RESEARCH FORM. BUT YOU'RE

SAYING THAT IN CALIFORNIA SOMEBODY GOING INTO DONATING SPERM FOR FERTILITY AT A SPERM BANK, HE'S GOING TO BE PAID, WHAT, $250 OR $300. HE SIGNS A FORM THAT SAYS THAT THE EMBRYO MAY BE USED FOR RESEARCH PURPOSES?

MS. MICHELSEN: I CAN'T ABSOLUTELY SAY ONE WAY OR ANOTHER. I DON'T KNOW. I WORK MOSTLY WITH EGGS. I VERY RARELY WILL WORK WITH SPERM FROM SPERM BANKS.

MR. KLEIN: BUT THE POINT, ANN, IS THAT SHE INDICATED THERE WAS A STATUTE IN CALIFORNIA THAT CONCERNS THE BIOLOGICAL MATERIAL. AND IF THE STATUTE COVERS SPERM, THEN WE CAN ONLY MAKE A DECISION WHERE THE SPERM DONOR HAS GIVEN CONSENT.

DR. KIESSLING: IS THAT --

MS. MICHELSEN: YOU NEED A COPY OF THAT STATUTE.

MS. LANSING: YES.

MS. MICHELSEN: AND WHEN WE BREAK FOR LUNCH, I WILL SEE IF I CAN GET ONE.

MS. LANSING: IT SEEMS TO ME THAT WHAT WE'RE TALKING ABOUT IS, UNLESS I'M READING THIS WRONG, IF SOMEBODY IS GIVING YOU CONSENT, AN EGG AND A SPERM DONOR, TO USE IT FOR RESEARCH, WE'RE ALL SAYING THEY DON'T WANT TO SPECIFY WHAT THAT RESEARCH

IS, THAT WE WOULDN'T DO THAT. NOW THE QUESTION IS YOU ONLY HAVE THE EGG DONOR GIVING YOU CONSENT, AND SO HOW DO YOU TRACK BACK TO THE SPERM DONOR ESPECIALLY IF YOU CAN'T TRACK IT? AND ARE WE HURTING OURSELVES?

CHAIRMAN LO: THE OTHER ISSUE MEMBERS WANTED TO TALK ABOUT THIS SESSION IS THE PAYMENT ISSUE. SO THE OTHER ISSUE IS THE OOCYTE DONORS. EXCEPT IN A RARE CASE WHERE IT'S A RELATIVE OR CLOSE FRIEND ARE PAID THE STANDARD AMOUNT FOR OOCYTE RETRIEVAL FOR IVF, AND THAT WHAT WE NOW HAVE IS AFTER THE WOMAN GOES THROUGH RETRIEVAL, THE COUPLE OR WOMAN IN IVF GOES THROUGH THEIR FERTILITY TREATMENT AND DECIDE THAT THEY'VE COMPLETED THEIR FAMILY, THEY DON'T WANT TO DONATE THEM TO ANOTHER COUPLE FOR REPRODUCTION, RATHER THAN DISCARD THEM, THEY WOULD LIKE TO DONATE TO RESEARCH. BUT THE QUESTION OF THE PAYMENT ISSUE, CONSENT IS ONE PROBLEM OF PAYMENT. IT'S ANOTHER PROBLEM DISQUALIFYING THAT EMBRYO OR A LINE THAT'S ALREADY DERIVED FROM SUCH AN EMBRYO.

MS. LANSING: I MEAN I WAS THE MOST CONSERVATIVE ON THIS, AND I'VE COME FULL CIRCLE, NOT FULL CIRCLE, BUT I'VE COME TO (INAUDIBLE). BECAUSE, YOU KNOW, WHAT, DID WE START TWO YEARS AGO? IT'S

TWO YEARS LATER, AND ONE IS ENTITLED TO REEVALUATE AND QUESTION AS THE SCIENCE MOVES AHEAD. AND IT JUST SEEMS TO ME THAT TO HOLD OUR RESEARCH TO A HIGHER STANDARD THAN ANY OTHER RESEARCH THAT IS DONE, YOU KNOW, IN THE UNITED STATES SEEMS TO ME DISCRIMINATION AGAINST THE STEM CELL RESEARCH, WHICH I DON'T THINK IS CORRECT.

CHAIRMAN LO: DENISE WANTED TO SAY SOMETHING, AND THEN WE HAVE A LOT OF QUESTIONS.

MS. BERNSTEIN: I WAS JUST GOING TO SAY WHEN THE DONOR SIGNS THEIR CONTRACT, THAT THEY DO WANT RESEARCH SUCH AS AN EGG DONOR OR A SPERM DONOR, WE DO NEED TO RECEIVE A COPY OF THAT CONTRACT AS THE CONSENT, AND THE SPERM BANKS WILL NOT RELEASE THAT. THEY STILL WANT TO KEEP THE ANONYMITY OF THE DONOR, SO HAVING THEM SIGN A CONSENT SAYING THAT IT'S OKAY TO DO RESEARCH IS NOT REALLY USEFUL AT ALL. WE CAN'T ACCEPT THAT.

MS. MICHELSEN: CAN YOU ACCEPT IT IF THE NAMES ARE REDACTED AND THE BANK SWEARS UNDER PENALTY OF PERJURY THAT THIS IS A TRUE COPY OF THEIR RELEASE AND THAT TAKES US TO DONOR 8235?

DR. TAYLOR: THERE'S ZERO FINANCIAL INCENTIVE FOR THEM TO PROVIDE THAT.

MS. MICHELSEN: YES.

MS. BERNSTEIN: WE HAVE HAD ZERO SUCCESS WORKING WITH THE SPERM BANK.

MR. KLEIN: THIS IS A VERY IMPORTANT POINT THAT DENISE JUST MADE, SHERRY. EVEN THOUGH THE SPERM BANK, THEY GET THE RESEARCH FORMS SIGNED, BECAUSE OF THE REQUIREMENT FOR ANONYMITY, THE SPERM BANK CAN'T GIVE THAT FORM TO UCSF. SO IT DOESN'T DO THEM ANY GOOD BECAUSE THEY CAN'T DELIVER THAT CONSENT FORM. SO IT MAY BE SITTING THERE WITH CONSENT, BUT THEY CAN'T EVEN GET THE CONSENT OVER TO UCSF SO THEY CAN USE THE LINE.

CHAIRMAN LO: DIANE, YOU HAD SOMETHING.

MS. MICHELSEN: THIS IS JUST A PIECE OF CLARIFICATION THAT WOULD BE REALLY HELPFUL TO ME. THE PURPOSE OF YOUR REGULATIONS ABOUT NOT ACCEPTING EMBRYOS IF THERE WAS A PAYMENT TO THE GAMETE DONOR IS WHAT?

MR. KLEIN: THE PURPOSE IS NOT TO INDUCE THE GAMETE DONOR TO SELL EGGS FOR RESEARCH.

MS. LANSING: AND I DON'T THINK WE WANT TO CHANGE THAT. IN OTHER WORDS, SOMEONE WHO IS SPECIFICALLY COMING IN TO DONATE -- I FEEL VERY STRONGLY ABOUT THIS. IT'S IN OUR STATUTE. WE CAN'T CHANGE IT -- SOMEONE SPECIFICALLY COMING IN TO DONATE THEIR EGGS FOR STEM CELL RESEARCH, PERIOD,

THERE IS NO PAYMENT.

MS. MICHELSEN: THEREIN IS PERHAPS THE CRUX THAT YOU CAN WORK WITH, SPECIFICALLY GETTING PAID FOR RESEARCH PURPOSES, BECAUSE THE DONORS THAT I'M TALKING ABOUT, THEY'RE NOT GETTING PAID AT ALL FOR RESEARCH PURPOSES. IT HAS NOTHING TO DO --

MS. LANSING: THAT'S CORRECT.

MS. MICHELSEN: MAYBE THIS --

MS. LANSING: THAT'S WHY I CHANGED MY OPINION.

MS. MICHELSEN: MAYBE THE STATUTE IS ALREADY BROAD THE WAY IT'S WRITTEN, AND IT COULD BE REWRITTEN TO PROTECT THAT WHICH YOU WANT PROTECTED.

MS. LANSING: YOU ARE GIVING US -- WE HAVE TO GET EVERYBODY'S OPINION, BUT WE STARTED TWO YEARS AGO WITH THE MOST CONSERVATIVE. AND SO WE STARTED AT ONE POINT, AND NOW WE'RE JUST MOVING A LITTLE BIT AS WE ARE BECOMING MORE EDUCATED. AND YOU'RE QUITE RIGHT. THEY WERE PAID FOR IVF AND THAT'S IT, AND THEY CHECKED A BOX THAT SAID RESEARCH. AND SO FOR US NOT TO BE ABLE TO USE IT IN AN EQUAL OPPORTUNITY RESEARCH WAY I THINK IS PUNITIVE TO US.

CHAIRMAN LO: A NUMBER OF PEOPLE. FRANCISCO HAS BEEN VERY PATIENT AND ALTA AND WHO ELSE, BOB.

DR. PRIETO: MY FEELING ON PAYMENT LIKE SHERRY IS ALL PUT -- CONSENT SEEMS PRETTY BASIC, AND I GUESS I REALLY DON'T -- YOU KNOW, BOB HAS PUT THAT THE CONSENT FORM CAN'T BE TRANSFERRED OVER. I DON'T REALLY UNDERSTAND WHY THAT WOULD BE UNDER THE TERMS THAT YOU LAID OUT WITH THE NAMES REDACTED AND SO ON. I MEAN IT DOESN'T SEEM TO ME THAT SPERM DONORS ARE THAT HARD TO RECRUIT, AND IT'S HARD FOR ME TO BELIEVE THAT IN 2008 THE STANDARD IS, NOT KNOWING THAT THIS RESEARCH IS OUT THERE, TO GET SOME SORT OF CONSENT THAT YOUR GENETIC MATERIAL MAY BE USED FOR RESEARCH. HOW HARD IS THAT?

MR. KLEIN: THE ISSUE IS THE CONSENT FORM WHEN SIGNED HAS THE NAME.

DR. PRIETO: SO YOU REDACT THE NAME, YOU CODE IT SO THAT YOU ANONYMIZE IT, YOU ISOLATE THE RESEARCHER FROM THAT INFORMATION.

MR. KLEIN: MAYBE WE SHOULD JUST ASK WHAT WOULD BE PRACTICAL BECAUSE WHAT MAY BE PRACTICAL IS THAT THE SPERM BANK PROVIDES JUST AN ACKNOWLEDGEMENT THAT THIS MATERIAL CAN BE USED FOR RESEARCH.

DR. PRIETO: SURE. AND UNDER PENALTY OF PERJURY WE OBTAINED THE APPROPRIATE CONSENTS.

MR. KLEIN: DOES THAT WORK, DENISE?

DR. PRIETO: BUT THAT SHOULD BE THE

STANDARD.

MS. BERNSTEIN: I'D HAVE TO LOOK BACK AT THAT. IT WOULD CERTAINLY BE DIFFERENT FROM WHAT WE DID FOR THE EGG DONORS, AND IT WOULD BE PUTTING ANOTHER PARTY IN THE CONSENTING PROCESS. IN OTHER WORDS, THE SPERM BANK WOULD BE SAYING, NO, WE SWEAR THIS IS THIS PERSON.

MR. KLEIN: AND I THINK THE POINT WAS MADE BY DR. TAYLOR, THEY DON'T HAVE ANY ECONOMIC INCENTIVE TO SWEAR UNDER PENALTY OF PERJURY AND THEN GET SUED.

DR. PRIETO: BUT THEY DON'T HAVE A DISINCENTIVE.

MR. KLEIN: BECAUSE SOMEONE CHANGED THEIR MIND OR SOMETHING. WHAT WE ARE -- ARE WE CORRECTLY UNDERSTANDING THAT THE OOCYTE CONSENTS ARE FAIRLY STRAIGHTFORWARD? THE REAL PROBLEM HERE IS THE SPERM CONSENTS?

MS. BERNSTEIN: THE OOCYTES ARE NOT TOTALLY CLEAR BECAUSE THE ONES WHO CONSENT AT UCSF SIGN THEIR REAL NAME, THEY CHOOSE THE LEVEL OF RESEARCH THEY'RE COMFORTABLE WITH, AND THEY'RE VERY, VERY CLEAN. WE EVEN FIND OUT IF THEY ARE PAID OR UNPAID. BUT IF SOMEBODY CALLS ME FROM NEW YORK AND HAS AN ANONYMOUS GAMETE DONOR AND THEY HAVE NO WAY

OF FINDING THEM AND THE PROGRAM IS NOT GOING TO TELL US WHO THEY ARE, THEN THE WHOLE PROCESS STOPS RIGHT THERE. AND THAT'S A COMMON OCCURRENCE.

MS. MICHELSEN: SO THOSE ARE PEOPLE THAT WANT TO DONATE THEIR EMBRYOS WHICH ARE --

DR. PRIETO: THESE ARE ALL RELATIVE.

MR. KLEIN: DID DR. CSETE WANT TO MAKE A COMMENT? I MEAN IS THERE A GROUP WITHIN THIS LARGER GROUP WHERE WE HAVE AN EASIER ISSUE WITH THE OOCYTES?

DR. CSETE: I'M JUST GOING TO MAKE IT MORE COMPLICATED. I JUST WANT EVERYBODY TO KEEP IN THE BACK OF THEIR MIND THAT THERE ARE POTENTIALLY INHERENTLY COERCIBLE POPULATIONS WHO CAN'T AFFORD IVF, AND THE CONSENT PROCESS FOR -- HAS TO BE VERY CAREFULLY DONE TO NOT MAKE THE DONATION FOR RESEARCH COERCIVE.

MR. KLEIN: THAT'S A SEPARATE ISSUE HERE BEFORE US. THESE PEOPLE ARE IVF AND THEY'RE NOT CONSIDERED RESEARCH.

DR. CSETE: HAS TO BE CLEANLY SEPARATED.

CHAIRMAN LO: A LOT OF PEOPLE ARE TRYING TO GET IN ON THIS. ALTA, FRANCISCO, ROB, JEFF SHEEHY. ALTA. AND THEN THE OTHER CONSTRAINT WE HAVE, WE LOST THE STANFORD PARTY, BUT WE PROMISED

PAT BECKER THAT WE'RE GOING TO ADJOURN FOR LUNCH AT 12:45, WHICH IS ABOUT 20 MINUTES.

MS. CHARO: I'M GOING TO RETURN TO THE ISSUE OF PAYMENT FOR A MOMENT BECAUSE I THOUGHT WE HAD KIND OF DISCUSSED CONSENT BEFORE THE BREAK. I FIND IT HELPFUL IN THESE DISCUSSIONS TO GO BACK TO THE ORIGINAL PURPOSE OF THE RULES IN ORDER TO EXAMINE THEM WHETHER THE VARIATIONS MAKE SENSE.

SO AS I UNDERSTAND IT, THE ORIGINAL REASON THAT WE AGREED TO PROHIBIT PAYMENT BEYOND THE REIMBURSEMENT OF OUT-OF-POCKET EXPENSES WAS TO ALLAY ANY FEAR, JUSTIFIED OR UNJUSTIFIED, THAT THE OFFER OF PAYMENT WOULD INDUCE WOMEN TO UNDERGO AN OVULATION PROCEDURE THAT THEY MIGHT OTHERWISE NOT HAVE UNDERGONE. AND SO THE IDEA WAS NOT TO ENCOURAGE OR INCENTIVIZE IN ANY WAY ANY ADDITIONAL RISK.

WHEN I LOOK AT THE USE OF EMBRYOS OR LINES FROM EMBRYOS THAT WERE MADE WITH EGG DONORS WHO PARTICIPATED SOLELY FOR REPRODUCTIVE PURPOSES, THEY MAY OR MAY NOT HAVE BEEN PAID. USUALLY THEY ARE. THEY TOOK ON CERTAIN RISKS IN EXCHANGE FOR PAYMENT IN A REPRODUCTIVE CONTEXT. OUR USE OF THOSE EMBRYOS OR THOSE LINES AT THIS POINT I CAN'T SEE WOULD EITHER INCREASE THE RISK TO THOSE WOMEN BECAUSE THEY

ARE NO LONGER PRESENTED WITH ANY MEDICAL INTERVENTIONS, NOR DO I REALISTICALLY THINK IT INCENTIVIZES WOMEN TO PARTICIPATE IN REPRODUCTIVE DONATIONS THAT THEY MIGHT OTHERWISE HAVE AVOIDED. RIGHT?

SO IN THIS SENSE I FIND THAT THE EXTENSION OF THE PROHIBITION ON PAID GAMETES TO THE USE OF EMBRYOS THAT WERE MADE ORIGINALLY IN A REPRODUCTIVE CONTEXT DOESN'T NECESSARILY FULFILL THE ORIGINAL PURPOSE OF CONTRIBUTING PAYMENT. I WILL SAY, THAT SAID, I WILL ACKNOWLEDGE THAT THERE'S IRONY HERE BECAUSE, IF ANYTHING, THE PAYMENTS IN THE REPRODUCTIVE CONTEXT ARE THE ONES THAT UPSET PEOPLE THE MOST AND WHERE THE AMOUNTS ARE UNREGULATED AND WITH LITTLE OR NO OVERSIGHT, AND WHERE THERE ARE CONCERNS ABOUT UNDUE INDUCEMENT ARE PROBABLY MOST SIGNIFICANT RATHER THAN THE RESEARCH CONTEXT. BUT WE DON'T GET TO REGULATE REPRODUCTIVE PRACTICES IN IVF CLINICS, SO WE DON'T GET A CHANCE TO REACH OUT AND SAY YOU SHOULDN'T PAY THEM THERE. MAYBE YOU SHOULD BE PAYING THEM IN THE RESEARCH CONTEXT.

SO WITHIN THE LIMITED JURISDICTION THAT WE HAVE, I DON'T SEE THE PROHIBITIONS, THE MOST CONSERVATIVE EXTENSIONS OF THE PROHIBITIONS, ACTUALLY SERVES THE UNDERLYING PURPOSE FOR WHICH THE

RULE THAT NONPAYMENT WAS WRITTEN.

CHAIRMAN LO: ROB.

DR. TAYLOR: ACTUALLY I WAS GOING TO -- I REALLY LIKE YOUR COMMENTS, ALTA, ON THAT POINT. I AGREE COMPLETELY.

I WANT TO COME BACK TO THE SPERM CONSENT ISSUE JUST TO MAKE THE COMMENT THAT THERE ARE PROBABLY ABOUT FIVE CRYOBANKS AROUND THE COUNTRY THAT I WOULD GUESSTIMATE ARE RESPONSIBLE FOR AT LEAST 70 PERCENT OF THE DONATED SPERM CYCLES. AND WHILE -- SO IT MAY BE -- YOU KNOW, ONE STRATEGY MIGHT BE TO TRY TO GET TO THOSE BANKS AND TRY TO MAKE THIS DONATION PROCESS ACTUALLY WORK FROM THAT LEVEL. SO IT'S VERY DIFFERENT, AND THE REASON THE OOCYTE DONATION AND SPERM DONATION ARE SO DIFFERENT IN THIS REGARD IS THAT OOCYTE DONATION ESSENTIALLY HAS TO BE DONE FRESH, AND IT'S BEEN REGULATED BY SORT OF LOCAL INDIVIDUALS WHO SORT OF RECRUIT AND DEVELOP THAT PROCESS. IT'S NOT CONSOLIDATED LIKE SOME OF THESE CRYOBANKS.

SO MAYBE IF WE WANTED TO GO AFTER THE SPERM ISSUE, CALIFORNIA CRYOBANK, FAIRFAX CRYOBANK, NEW ENGLAND CENTER, CHECK OFF A LIST TO KIND OF GO AFTER AND FIGURE OUT IS THERE A MECHANISM THAT WE CAN SORT OF DEVELOP SOMETHING THAT WOULD INCENT THEM

TO ACTUALLY WANT TO PARTICIPATE AND GET THE INFORMATION TO THE INVESTIGATORS.

MS. BERNSTEIN: I THINK IT WOULD HAVE TO HAPPEN AT THIS LEVEL, AT YOUR LEVEL.

DR. TAYLOR: YEAH. MAYBE IT CAN BE DONE AT THE STATUTORY LEVEL; BUT AT THE VERY LEAST, I WOULD THINK WE'D ONLY HAVE TO MAKE FIVE OR SIX PHONE CALLS TO GET THE MAJORITY OF THE ACTION.

CHAIRMAN LO: JEFF.

MR. SHEEHY: I DO HAVE A QUESTION, BUT I DO WANT TO COMMENT. I MEAN I STILL GO BACK TO THE ORIGINAL POINT OF NOT USING -- IN THE PREVIOUS DISCUSSION, EVEN IF YOU GET CONSENT, DOES THAT MEAN THAT PERSON IS GOING TO BE WILLING TO BE CONTACTED FOR A FULL MEDICAL HISTORY?

DR. TAYLOR: DOWN THE LINE.

MR. SHEEHY: SO I JUST -- YOU KNOW, IT DOESN'T SEEM LIKE THE SPERM DONATION PRESENTS A GREAT DEAL -- THAT THERE'S A LOT WORKING ON THE CREATION OF THE EMBRYOS AND I MAY BE WRONG.

MS. MICHELSEN: THERE'S CERTAINLY LESS SPERM DONATION INVOLVED IN CREATION OF EMBRYOS BECAUSE THE SUCCESS IN IVF GENERALLY IS CONNECTED TO THE AGE OF THE EGG, MUCH LESS SO WITH THE AGE OF THE SPERM. SO SOMEONE AGES OUT PRETTY QUICKLY AS A

WOMAN. AS A MAN AND A COUPLE, ASSUMING YOU HAVE A HETEROSEXUAL COUPLE, NOT NEARLY AS SIGNIFICANT.

MR. SHEEHY: SO IF 50 PERCENT DONATE AN EGG, THEN I WOULD SUSPECT THAT THE NUMBER WHO HAVE DONATED SPERM -- WE'RE NOT TALKING ABOUT --

THE SECOND POINT I WANTED TO GET TO WAS IF WE DID GRANDFATHER THESE IN, I MEAN IF WE DID DECIDE THAT THIS WAS OKAY, I MEAN I GET WHAT YOU'RE SAYING. SO ONE CAN IMAGINE A SCENARIO WHERE IT MIGHT BE -- SOMEONE MIGHT CONSIDER IT VALUABLE TO CREATE AN EMBRYO JUST FOR RESEARCH, YOU KNOW. OR YOU CAN THINK OF SOMEONE WHO HAD A CONDITION, AND YOU COULD SAY, YOU KNOW, A FAMILY HISTORY OR SOMETHING, AND ACTUALLY -- ONCE YOU START PAYING, YOU KNOW, I JUST WORRY ABOUT IF WE START TO DRAW THAT LINE AT A TIME -- YOU KNOW, THERE ARE GENETIC CHARACTERISTICS THAT MAY INDUCE PEOPLE TO -- YOU KNOW, WE'RE NOT TALKING ABOUT A WELL-REGULATED INDUSTRY WHERE SOMEONE COULDN'T GO AND CREATE AN EMBRYO WITH A PAID DONOR WITH THE THOUGHT IN THEIR MIND THAT THEY'RE GOING TO -- THEY DON'T REALLY WANT TO DO REPRODUCTION. THEY WANT IT TO JUST DONATE THIS FOR RESEARCH.

I MEAN WE CAN IMAGINE SCENARIOS, EVEN YOU, KNOW, YOU HAD A CONDITION OF ALZHEIMER'S, YOU HAD A

HISTORY OF ALZHEIMER'S, YOU WANTED TO CREATE A DISEASE MODEL.

MS. CHARO: OF COURSE, ANY SET OF RULES, ANY SET OF RULES, THERE ARE THOSE PEOPLE THAT ARE DELIBERATELY GOING TO TRY TO CIRCUMVENT THEM. SO THAT, THEN, JUST GETS TO THE QUESTION OF HOW YOU WANT TO WRITE THE RULES. YOU WANT TO WRITE THEM AS A GENERAL SET OF RULES FOR THE WAY YOU THINK THE SYSTEM OUGHT TO BE, OR YOU'RE WRITING THEM DEFENSIVELY AGAINST EVERY POSSIBLE VIOLATION OF SOCIAL LEGAL NORMS.

AND THAT IS A VERY -- IT DEPENDS HOW SCARED YOU ARE OF THAT SCENARIO WHETHER OR NOT YOU'RE GOING TO WRITE THE RULES TO ANTICIPATE FAIRLY UNLIKELY EVENTS.

MR. SHEEHY: WELL, WE'RE NOT REALLY. WE'RE ENFORCING WRITING RULES WITH THE FORCE OF LAW IN THE CALIFORNIA CONSTITUTION. SO IT'S A LITTLE BIT DIFFERENT WHERE THE PAID OOCYTE ISSUE IS BECAUSE WE'RE NOT JUST SIMPLY WRITING RULES TO TRY TO COVER -- IF IT WERE JUST RULEMAKING, I'D AGREED WITH YOU. BUT WE'RE ACTUALLY WRITING RULES TO ENFORCE THE LAW.

MS. CHARO: I UNDERSTAND. WHAT YOU'RE SUGGESTING IS THAT I WANT RESEARCH TO PROCEED ON MY

PARTICULAR DISEASE OR I WANT TISSUE CREATED ULTIMATELY FOR MY OWN TRANSPLANT, WHICH WOULD PRESUME THAT THE FDA IS NOT GOING TO BE APPROVING IT. I'M GOING TO GO TO MY IVF CLINIC, CLAIM I WANT EMBRYOS FOR REPRODUCTIVE PURPOSES, OBTAIN AN EGG DONOR THROUGH PAYMENT, HAVE THE EMBRYOS MADE, HAVE TO AT LEAST GO THROUGH AT LEAST ONE CYCLE OF IMPLANTATION TO CONVINCE THE IVF CLINIC I WAS SERIOUS, AND THEN WITH THE REMAINING EMBRYOS NOW DONATE THEM TO RESEARCH, AND HOPE THEY WILL ACTUALLY REBOUND TO MY BENEFIT.

MR. SHEEHY: WELL, I DON'T WANT TO CREATE SCENARIOS. I'M JUST MAKING THE POINT. BUT, YOU KNOW, THIS IS A NEW IDEA, AND I'M NOT TRYING TO THINK OF EITHER THE WORST-CASE SCENARIOS OR THE BEST-CASE SCENARIOS. I JUST CAN IMAGINE THAT THERE WOULD BE A SCENARIO, YOU KNOW, ESPECIALLY SINCE WE HAVE ALL THE STEM CELL RESEARCH GOING ON.

BUT MY OTHER QUESTION WAS I WAS REALLY INTRIGUED BY SOMETHING YOU SAID. SO WHEN PEOPLE -- WHEN PEOPLE GO THROUGH IVF, THEY FERTILIZE ALL THE EGGS GENERALLY IN YOUR EXPERIENCE?

MS. MICHELSEN: UNLESS THE EGGS ARE IMMATURE OR ARE BLIGHTED, THEY FERTILIZE ANY VIABLE EGG.

DR. TAYLOR: THAT MIGHT CHANGE AS WE GET BETTER AT FREEZING EGGS. OUR SUCCESS RATES ARE IMPROVING NOW WITH FREEZING EGGS, BUT WE'RE SO MUCH BETTER, MORE SUCCESSFUL AT FREEZING EMBRYOS, THAT THE IDEA WAS TO CREATE AS MANY EMBRYOS AS WE COULD AND THEN FREEZE THE EXTRA EMBRYOS RATHER THAN --

MR. SHEEHY: YOU ALSO DON'T KNOW WHAT -- YOU DON'T KNOW WHEN THE FIRST EGG THAT IS -- THE FIRST EMBRYO IS CREATED WITH (INAUDIBLE) AND THE TWENTIETH EMBRYO IS CREATED.

DR. KIESSLING: NOT FOR A COUPLE OF DAYS.

DR. TAYLOR: YOU CAN LOOK AT THEM AFTER A COUPLE OF DAYS BEFORE YOU DECIDE WHICH ONES LOOK THE BEST.

MR. SHEEHY: SO THE LOGIC IS HAVING EXCESS EMBRYO -- EXCESS OOCYTES GOING TO RESEARCH.

DR. TAYLOR: WE MAY SEE MORE OF IT IN THE FUTURE, I THINK, AS WE GET BETTER AT FREEZING EGGS, BUT IT'S STILL --

MR. SHEEHY: SO WE WOULDN'T AT THIS KIND OF IVF PROCESS WITH THE EXCESS EGGS.

MR. KLEIN: THE OTHER SIDE OF THIS, JEFF, IS MY UNDERSTANDING IS THAT --

MR. SHEEHY: THIS IS FOR ANOTHER DAY.

MR. KLEIN: FOR YOUR POINT, MY

UNDERSTANDING IS --

MR. SHEEHY: I DON'T NECESSARILY WANT DISCUSSION TODAY.

MR. KLEIN: -- IS THAT WOMEN ARE ONLY GOING TO GO THROUGH SO MANY OF THESE IMPLANTATIONS OF EGGS, AND AT EIGHT OR TEN THEY MAY BE ESSENTIALLY LIMITED OUT, JUST NOT GOING TO GO THROUGH THIS.

MR. SHEEHY: IT SEEMS LIKE THE REPRODUCTIVE CONSENTS, WE'RE GOING TO FERTILIZE ALL THE EGGS.

DR. TROUNSON: JEFF, I DON'T THINK THAT'S NECESSARILY CORRECT.

MR. SHEEHY: I'M WORKING WITHIN WHAT IS COMMON PRACTICE AS DESCRIBED. AND THIS IS NOT A DISCUSSION FOR TODAY, BUT WE NEED TO BRING IT UP AGAIN.

DR. TROUNSON: BUT I THINK WHAT YOU SAID WASN'T NECESSARILY CORRECT. YOU NEED TO HAVE LINES (INAUDIBLE).

CHAIRMAN LO: I THINK THIS IS ACTUALLY A GOOD TIME TO BREAK FOR LUNCH. LET ME JUST SAY THAT -- BECAUSE I THINK AFTER LUNCH WE HAVE TO KNOW WHAT DO WE WANT TO DO.

MS. LANSING: WE ALSO NEED TO SEE WHAT -- IF WE CAN GET -- THE --

CHAIRMAN LO: THE STANFORD PEOPLE, I GUESS, ARE NOT AVAILABLE. THEY HUNG UP.

MS. BECKER: I'M STILL WORKING ON IT.

CHAIRMAN LO: OKAY. THEY WERE GOING TO ADD, WHICH MAYBE WE CAN GET AFTER LUNCH FROM OUR SCIENTISTS, IS SORT OF WHAT ARE WE LOSING IN TERMS OF RESEARCH BY FOREGOING THESE LINES, HESC LINES CREATED FROM -- ALREADY IN EXISTENCE CREATED WITH OLD FAMILY HEALTH INFORMATION OR GIVING UP THE USE OF DERIVING NEW LINES WITH EXISTING EMBRYOS FOR WHICH THE DONORS (INAUDIBLE). THAT'S THE OTHER PART OF THIS. WHAT ARE WE LOSING SCIENTIFICALLY? AND, YOU KNOW, MAYBE I COULD ASK, BECAUSE THE STANFORD PEOPLE, I DON'T THINK, ARE GOING TO BE AVAILABLE, MAYBE ASK ALAN OR MARIE AND THE SCIENTISTS ON OUR PANEL TO HELP THOSE OF US WHO AREN'T REPRODUCTIVE STEM CELL SCIENTISTS TO UNDERSTAND.

MEANWHILE SHALL WE BREAK FOR LUNCH? I WOULD LIKE US BACK AT 1:30. IS THAT OKAY? BECAUSE WE ALSO HAVE MEMBERS FROM THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH WHO WANT TO TELL US ABOUT THEIR REPORTING REQUIREMENTS.

(A RECESS WAS TAKEN.)

CHAIRMAN LO: I'D LIKE TO RECONVENE. BEFORE OUR LUNCH BREAK WE HEARD SOME VERY IMPORTANT,

VERY INTERESTING INFORMATION FROM OUR TWO GUEST SPEAKERS. AND THERE WAS A LOT OF DISCUSSION OVER LUNCH, AND WHAT SHERRY AND I WOULD LIKE TO TRY TO DO AS CO-CHAIRS -- I REALLY HAVE TO TIP MY HAT TO SHERRY -- IS TO TRY AND SORT OF PUT OUT SOME SAMPLE LANGUAGE THAT WE MAY BE ABLE TO REFINE AND THEN AGREE ON.

SO JUST TO PUT THE CONTEXT, THERE ARE EMBRYOS THAT ARE CREATED WITH THE INTENTION OF BEING USED IN IVF PROGRAMS. OFTEN THESE ARE FROM YOUNGER WOMEN DONORS, AND SO THERE MAY BE SOME SCIENTIFIC (UNINTELLIGIBLE). BUT AS IS TYPICAL IN IVF PRACTICE, MOST OF THESE IVF-EMBRYOS HAD PAYMENTS TO DONORS, GAMETE DONORS, THAT RECEIVED THE ACTUAL OUT-OF-THE POCKET EXPENSES. AND YEARS AFTER THEY WERE DONATED WHEN THE WOMAN, COUPLE IN IVF HAS COMPLETED THEIR TREATMENT, THAT WOMAN MAY WANT TO DONATE THEM FOR RESEARCH, SPECIFICALLY STEM CELL RESEARCH, AFTER MAKING A DECISION NOT TO KEEP THEM FROZEN OR TO DONATE THEM TO ANOTHER COUPLE FOR FERTILITY.

AND WHAT WE'RE TRYING TO DO IS SEE ARE THERE SOME OF THOSE OR SOME OF THE CIRM POLICIES AND REGULATIONS RESTRICTING SOME OF THE DONATIONS IN A WAY THAT IS UNNECESSARY FROM THE POINT OF VIEW OF

PROTECTING THE INTERESTS AND THE SAFETY OF THE DONOR WOMEN AS WELL AS THE WOMEN OR COUPLE IN IVF. SO I'M PROPOSING THIS AS SOMETHING WE NEED TO DISCUSS, MODIFY AS THE NEED BE.

FIRST, THE USE OF HUMAN EMBRYONIC STEM CELL LINES DERIVED FROM EMBRYOS DONATED AFTER THE WOMAN IN IVF HAS COMPLETED FERTILITY TREATMENT TO SAY THAT THESE MAY BE USED IN CIRM-FUNDED RESEARCH EVEN THOUGH THE GAMETE DONOR RECEIVED, AND THE LANGUAGE IS NOT GOOD, SO I'M OPEN TO SUGGESTION, SO I'M TRYING TO GET THE THOUGHT DOWN, EVEN THOUGH THE GAMETE DONOR RECEIVED PAYMENT IN EXCESS OF EXPENSES PROVIDED THAT SEVERAL THINGS. ONE, THAT CONSENT FOR RESEARCH USE HAS BEEN OBTAINED FROM AND PROVIDED BY THE EMBRYO DONOR AS WELL AS BOTH GAMETE DONORS. WE UNDERSTAND WE'RE GOING TO LOSE SOME EMBRYO LINES BECAUSE THE GAMETE DONORS DIDN'T CHECK OFF THAT BOX. AND IRB HAS TO APPROVE THE RESEARCH PROTOCOL.

AND THEN I THINK THERE WERE CONCERNS THAT A NUMBER OF PEOPLE EXPRESSED OF ARE WE MAKING SURE WE'RE PROTECTING AGAINST THE POSSIBILITY THAT THIS WOULD BE -- THIS EXCEPTION OR THIS CHANGE WOULD BE EXPLOITED BY PEOPLE TO THE DETRIMENT OF WOMEN DONATING OOCYTES.

SO SOME OF THE CONCERNS THAT ONE MIGHT

HAVE ARE THAT, FOR EXAMPLE, HAVE BEEN PRESSURED TO HAVE A MORE INTENSE INDUCTION CYCLE, RETRIEVAL CYCLE TO SORT OF RETRIEVE 25 OOCYTES RATHER THAN 15. OBVIOUSLY THAT WAS WHERE THE WOMEN DONATING OOCYTES HAVE GREATER RISK. WE HEARD THAT FROM THE NAS PANEL THAT LINDA GUIDICE CHAIRED.

AND THE OTHER CONCERN THAT WAS RAISED WAS THAT, WELL, MAYBE PEOPLE WOULD SAY THAT THEY WERE GOING TO USE THESE -- THEY'RE INTENDING TO USE THESE EMBRYOS FOR FERTILITY; AND THEN AFTER THEY'RE DERIVED, OH, ACTUALLY I CHANGED MY MIND. I DON'T WANT TO HAVE CHILDREN ANYMORE. LET'S GIVE THEM ALL TO SCIENCE, SORT OF AS A MAYBE NOT SO TRANSPARENT -- I DON'T KNOW IF BAIT AND SWITCH IS TOO STRONG A TERM -- BUT SORT OF LESS THAN FORTHRIGHT.

SO, AGAIN, I THINK WE DON'T WANT TO -- WE WANT TO MAKE SURE WE'RE PROVIDING, IT SEEMS TO ME AT LEAST PERSONALLY, ADEQUATE PROTECTION TO THE WOMEN DONATING OOCYTES INVOLVED IN FERTILITY TREATMENT. AND THAT'S WHY I HAVE THOSE LAST TWO BULLETS WAS TO SUGGEST THAT WE PROTECT AGAINST -- WE'RE TRYING TO PROTECT AGAINST EMBRYOS THAT REALLY WERE INTENDED FOR RESEARCH ALL ALONG, SO THEY HADN'T BEEN USED FOR AT LEAST ONE IVF CYCLE. I THINK WE MAY WANT TO THINK -- I DIDN'T HAVE TIME TO THINK THIS THROUGH --

IF WE NEED OTHER PROTECTIONS PROTECTING AGAINST SORT OF (UNINTELLIGIBLE).

BUT I THINK THE INTENTION IS TO ALLOW THESE TO BE USED BECAUSE OF THE RESEARCH VALUE AND BECAUSE OF THE WISH OF MANY OF THE WOMEN IN IVF AFTER TREATMENT TO DONATE THEM TO RESEARCH, BUT WE ALSO I THINK WANT TO MAKE SURE WE DON'T DO SO MUCH THAT WE ACCEPT EMBRYOS WHERE THERE WAS A RISK.

NOW, LET ME JUST SAY THIS IS NOW FOR BOTH THE LINES THAT ARE ALREADY DEVELOPED IN EXISTENCE, BUT ALSO LOOKING TO THE FUTURE. SO I THINK THAT'S THE OTHER THING WE TALKED ABOUT BEFORE LUNCH. WE JUST HAVE TO GRANDFATHER THEM AND SEPARATE THAT OFF FROM A FUTURE USE. THAT'S ANOTHER POSSIBILITY THAT'S BEEN SUGGESTED.

I WANTED TO LAY THIS OUT AND JUST HAVE PEOPLE KIND OF ANALYZE. I THINK THERE'S GOING TO BE PEOPLE FROM THE PUBLIC WHO WILL DEFINITELY WANT TO COMMENT, AND WE WANT TO HEAR THOSE COMMENTS AS WELL.

LET ME JUST START ON THE COMMITTEE. THIS IS VERY ROUGH AND OPEN FOR MODIFICATION. ANN.

DR. KIESSLING: WHY DID YOU NOT INCLUDE ESCRO?

CHAIRMAN LO: THAT'S FINE. IRB AND ESCRO OR ESCRO. SHOULD BE IRB/ESCRO.

DR. LOMAX: WELL, WE DO NEED TO BE A BIT CAREFUL BECAUSE THE PRIOR APPROVALS IN THE CURRENT SITUATION WITH THE REGULATIONS DEPEND ON THE UTILIZATION OF A COVERED STEM CELL LINE.

MR. KLEIN: WELL, IT WOULD BE IRB OR ESCRO AS APPLICABLE.

DR. LO: YEAH. SOMETHING LIKE THAT.

DR. LOMAX: YEAH.

CHAIRMAN LO: WE DON'T WANT TO AVOID ESCRO REVIEW IF IT WOULD OTHERWISE BE ASKED FOR. THAT'S AN IMPORTANT CORRECTION.

DR. CIBELLI: QUESTION. IT IS A LITTLE BIT PROBLEMATIC TO ALLOW THIS TO TAKE PLACE IN THE FUTURE. I MEAN WE SHOULD TALK ABOUT THE PAST. I'M WONDERING IF YOU HAVE STATISTICS HOW MANY EMBRYOS CAN BE THERE. HOW MANY WERE APPROVED, HUGE, JUST IN CALIFORNIA.

CHAIRMAN LO: THAT'S A GOOD QUESTION.

DR. CIBELLI: I THINK WITH THOSE STATISTICS, WE SHOULD BE ABLE TO GET THEM (UNINTELLIGIBLE). PROBABLY IS NOT AFTER 2007, BUT YOU WOULD BE ABLE TO GET 2005 IN CALIFORNIA.

CHAIRMAN LO: I DON'T KNOW THAT. I DON'T KNOW IF ANYONE HERE HAS THAT DATA.

MS. LANSING: WE HAVE IT?

CHAIRMAN LO: WHY DON'T YOU JUST, AGAIN, FOR THE RECORD, STEVE.

DR. PECKMAN: IT'S STEVE PECKMAN, UCLA. I DON'T HAVE ANY EXACT DATA ON THAT, BUT I CAN GIVE YOU ANECDOTAL DATA OF WHAT WE'VE EXPERIENCED AT UCLA, WHICH IS 50 PERCENT OF THE PEOPLE WHO HAVE CONTACTED US ABOUT EMBRYO DONATION FOR STEM CELL RESEARCH, EMBRYOS CREATED FOR CLINICAL IVF PURPOSES, 50 PERCENT OF THOSE INQUIRIES, NOT ANY ADVERTISING, JUST PEOPLE PROACTIVELY CONTACTING US AT OUR INSTITUTION, 50 PERCENT OF THOSE ARE MADE WITH DONATED OOCYTES FROM THOSE DONORS. THAT'S HUNDREDS OF POTENTIAL EMBRYOS AT ONE INSTITUTION THAT CANNOT BE USED CURRENTLY BECAUSE THE OOCYTES HAVE BEEN PAID FOR FOR CLINICAL PURPOSES.

CHAIRMAN LO: DENISE, DO YOU WANT MAKE A COMMENT ABOUT UCSF'S EXPERIENCE AGAIN WITH PEOPLE WANTING TO -- CONTACTING YOU TO DONATE, PEOPLE DONATING LEFT-OVER EMBRYOS AFTER IVF?

MS. BERNSTEIN: I DON'T HAVE THE SAME NUMBERS AT ALL. I DON'T HAVE EVEN NUMBERS AT ALL, BUT THE PROGRAMS THAT REFER PEOPLE TO US KIND OF WEED OUT THE PEOPLE THAT HAVE USED DONOR GAMETES AHEAD OF TIME SO THAT I'M NOT THE PERSON GIVING THE BAD NEWS, THEY ARE, WHICH I APPRECIATE. SO IT DOES.

IT HAPPENS FREQUENTLY, AND THEY HAVE THE MOST TO DONATE. THEY HAVE THE MOST NUMBER OF EMBRYOS TO DONATE.

CHAIRMAN LO: MIKE KALICHMAN WAS HERE BEFORE. ANY THOUGHTS FROM UCSD?

MR. KALICHMAN: WE DON'T HAVE ANY EXPERIENCE ON THEM.

CHAIRMAN LO: BUT STEVE PECKMAN SAYS THAT THIS IS A MAJOR --

DR. PECKMAN: SO FOR US IT'S A SUBSTANTIAL ISSUE REGARDING STEM CELL RESEARCH AND THE DERIVATION OF NEW STEM CELL LINES.

MS. CHARO: BUT, STEVE, LET ME ASK. NOW THAT WE'VE BEEN ALERTED BY DIANE AT LEAST IN THE UNKNOWN CALIFORNIA STATUTE, THAT INDEPENDENTLY REQUIRES ABSOLUTELY THAT THERE BE CONSENT FROM BOTH SPERM AND EGG DONORS BEFORE THEIR MATERIALS CAN BE DIVERTED INTO ANYTHING. WOULD THERE BE ANY SUBSTANTIAL DIFFERENCE IN THE NUMBER OF EMBRYOS THAT HAVE TO BE REJECTED IF WE WERE TO -- IF THE RULE ABOUT PAID GAMETE DONORS HAD CHANGED SINCE THE CONSENT ISSUE WOULD STILL HAVE TO BE HANDLED?

DR. PECKMAN: RIGHT. I THINK THAT'S AN IMPORTANT QUESTION. I WAS THINKING ABOUT THAT DURING HER TALK, AND THOUGH I'M NOT GOING TO

QUESTION ANYONE'S LEGAL EXPERTISE HERE TODAY, IT WOULD BE MY OPINION THAT WE GET A LEGAL OPINION ON THAT AND REVIEW THE ACTUAL STATUTE. I KNOW WHAT SHE'S TALKING ABOUT. I DON'T REMEMBER THE EXACT WORDING OF THE STATUTE, AND I DON'T REMEMBER IT BEING THAT EXCLUSIVE.

THAT BEING SAID, IF THERE ARE -- LET'S SAY THAT 75 PERCENT OF THAT 50 PERCENT THAT CAN'T DONATE NOW ACTUALLY HAVE CHECKED THE BOX ON THE FORM THAT SAYS RESEARCH, AND IF WE SAY THAT RESEARCH IS SUFFICIENT ENOUGH CONSENT, AND IF WE REMOVE THE RESTRICTION ABOUT PAYMENT FOR IVF CLINICAL PURPOSES, THEN WE'VE EXPONENTIALLY INCREASED THE NUMBER OF EMBRYOS THAT ARE AVAILABLE TO DERIVE STEM CELL LINES.

AND SO THE ISSUE HERE FOR US HAS NOT BEEN THE FACT THAT ONE OF THE DONORS WERE UNKNOWN BECAUSE ACTUALLY THE MAJORITY OF THE CASES OF PATIENTS WHO HAVE CONTACTED US ACTUALLY KNEW THE DONORS BECAUSE THERE HAD BEEN A RELATIONSHIP SET UP, WHICH I'M ASSUMING HAPPENS OFTEN, BUT THAT THERE WAS AN ISSUE ABOUT RESEARCH THAT HAD ALREADY BEEN ADDRESSED.

NOW, LET'S SAY THAT THE STATUTE ISN'T WHAT WE THINK IT IS TODAY AND IT'S LESS RESTRICTIVE. THEN I THINK THE IMPORTANT QUESTION IS OWNERSHIP.

THAT WAS SOMETHING THAT MR. CIBELLI TALKED ABOUT THIS MORNING, WHICH IS IF THE OWNERSHIP OF THE RESULTING EMBRYO REVERTS TO THE PEOPLE WHO REQUESTED THE CREATION OF THAT EMBRYO, WHAT FURTHER INTEREST DOES THE GAMETE DONOR HAVE IN THAT IN TERMS OF CONSENT FOR THAT GAMETE AND THE USE OF IT?

AND THE SAME THING THAT IF YOU SELL ME AN OBJECT, ALTA, FOR X PURPOSE, AND I BUY IT AND I WANT TO USE IT FOR ANOTHER PURPOSE THAN WHAT YOU SOLD IT TO ME FOR, AM I BARRED LEGALLY FROM USING IT FOR THAT OTHER PURPOSE?

MS. CHARO: TRUST ME, STEVE, THAT THAT QUESTION IS MORE COMPLICATED THAN IT SOUNDS.

CHAIRMAN LO: I WANT TO SORT OF GET BACK TO SORT OF THE QUESTION -- THANKS, STEVE. THAT'S VERY HELPFUL. I THINK IN ALL HONESTY DIANE MICHELSEN WAS TRYING TO GIVE US TEXT OF THE LAW. I THINK WE NEED TO REFER THIS TO TAMAR AND HER STAFF TO SORT OF SEE HOW THIS IMPACTS. BUT JUST NOTE THAT ONE OF THE THINGS THAT WAS SUGGESTED WE AGREE ON IS THAT BOTH GAMETE DONORS, ANY GAMETE DONORS IN THIS EMBRYO FOR IVF HAD TO HAVE GIVEN CONSENT FOR RESEARCH AT LEAST IN A GENERAL SENSE, AS SHERRY HAS POINTED OUT. BUT THEN WE HAD A LOT OF COMMENTS HERE, AND I JUST WANT SHERRY AND LET'S JUST GO

AROUND.

MS. LANSING: I THINK, YOU KNOW, AT LUNCH WE ACTUALLY -- WE WERE TALKING. AND I THINK, UNLESS I'M MISUNDERSTANDING IT, WE CAN FIND OUT WITH A STRAW VOTE, THERE IS REAL CONSENSUS THAT WE STAY FOCUSED ON OUR ISSUE WITH ONE POSSIBLE -- ONE THAT CAN POSSIBLY BE WORKED OUT. I THINK THERE'S A REAL CONSENSUS THAT IF SOMEONE RECEIVED PAYMENT FOR IVF TREATMENT AND ACTUALLY WENT THROUGH SOME FORM OF THE TREATMENT AND CHECKED -- AND BOTH OF THE SPERM AND THE EGG DONOR BOTH CHECKED THE RESEARCH BOX, THAT THEN THAT WOULD BE ACCEPTABLE. THAT'S A BIG MOVE FOR US. I MEAN THAT'S SOMETHING THAT WE DIDN'T DO.

THE QUESTION THAT HAS COME UP FROM THE PUBLIC AND FROM SOME OF US, WHICH I THINK WE NEED MORE WORK ON, WHICH IS NOT THE GRANDFATHER PART, BUT THE MOVING FORWARD PART. AND WE NEED TO PUT UP THE PROTECTIONS DOWN THERE, MAKE SURE THAT THERE'S NO ABUSE OF THIS, THAT SOME, YOU KNOW, FERTILITY EXPERT WOULD WANT TO -- I HOPE THIS IS MERELY A FANTASY -- WOULD RISK ENDANGERING THE WOMAN'S HEALTH TO GET MORE EGGS THAT COULD BE USED.

AND THAT'S THE OTHER PROTECTIONS PART THAT WE WANT TO PROTECT AGAINST SO WE CAN MOVE FORWARD IN THE FUTURE SO THERE IS NO ABUSE OF THIS. AND I

THINK THAT'S THE LANGUAGE THAT WE DON'T YET HAVE.

CHAIRMAN-LO: SHERRY, LET ME SORT OF -- I MADE THIS SLIDE VERY RUSHED. BUT SO THIS REALLY IS BIFURCATED. AND ONE IS STEM CELL LINES ALREADY IN EXISTENCE AS OF NOVEMBER 2006, SO SORT OF THE GRANDFATHERING. YOU KNOW, WE'RE NOT -- YOU KNOW, THAT'S ONE ISSUE. WE MAY JUST WANT TO SAY, FOR EXAMPLE, WITH JUST THESE BULLETS WE'RE GOING TO ALLOW EXISTING --

MS. LANSING: WE HAVE UNANIMOUS CONSENT ON THAT.

CHAIRMAN LO: RIGHT.

MS. LANSING: I THINK.

CHAIRMAN LO: THEN GOING FORWARD INTO THE FUTURE WHERE THE ISSUE OF ADDITIONAL PROTECTIONS FOR THE WOMAN DONATING OOCYTES AND PERHAPS ALSO THE WOMEN IN IVF TREATMENT, I THINK WE NEED TO BE SENSITIVE TO THEM. AND THEN THE QUESTION IS WHAT ARE THE APPROPRIATE PROTECTIONS THAT ONE MIGHT WANT TO CONDITION HERE FOR GOING FORWARD TO ENSURE THAT PROTECTION.

SO ONE WAY TO SPLIT IT IS TO SAY DO WE AGREE ON GRANDFATHERING; AND IF WE DO, THAT'S A BIG STEP.

MS. LANSING: THAT'S A GOOD WAY TO DO IT.

AND THEN MAYBE GO TO STAFF AND ASK FOR WHAT OTHER PROTECTIONS WE WOULD NEED TO MOVE FORWARD IN THE FUTURE TO PROTECT AGAINST ANY --

CHAIRMAN LO: AND I'D ALSO LIKE TO GET OBVIOUSLY SOME PUBLIC COMMENT ON THIS AS WELL.

MR. KLEIN: WAIT A MINUTE. FOR GRANDFATHERING, AREN'T YOU TALKING ABOUT THE WRONG DATE BECAUSE IF WE ADOPT THIS --

MS. LANSING: FROM TODAY FORWARD.

MR. KLEIN: THE EMBRYOS ARE ALREADY IN EXISTENCE.

MS. LANSING: I AGREE. THE DATE OF THIS MEETING, GRANT EVERYTHING BACKWARDS.

CHAIRMAN LO: OR THE DATE OF THE ADOPTION.

MR. KLEIN: IT'S NOT STEM CELL LINES IN EXISTENCE. IF THE EMBRYOS ARE ALREADY IN EXISTENCE --

CHAIRMAN LO: THAT WAS THE NEXT -- GEOFF, IF YOU CAN SHOW THE NEXT SLIDE, I HAD A COMPARABLE SUGGESTION, AGAIN TRYING TO SEPARATE OUT WHICH -- THERE'S NO TITLE -- USE OF IVF-EMBRYOS. I THINK -- SO BOB IS SAYING, YOU KNOW, WE'RE TALKING ABOUT STEM CELL LINES. WE'RE ALSO TALKING ABOUT EMBRYOS THAT EXIST AS OF EITHER TODAY OR THE DAY THE ICOC OFFICIALLY ADOPTS IT --

MR. KLEIN: RIGHT.

CHAIRMAN LO: -- GRANDFATHERING THAT. IF WE CAN ALL AGREE ON THAT, THE GRANDFATHERING OF EITHER THE LINES OR EMBRYOS, THAT WOULD BE A BIG STEP.

MS. LANSING: CAN I JUST -- I'M SORRY. I THINK THAT'S, YOU KNOW, AS WE TALK TO, YOU KNOW -- MARCY, I'D LOVE FOR YOU TO SPEAK.

DR. DARNOVSKEY: I'D LOVE TO.

MS. LANSING: BECAUSE I THINK THIS IS A BIG DEAL, AND I THINK WHAT WE REALLY WANT TO DO IS MOVE FORWARD IN THE MOST POSITIVE WAY WITH OUR PARTNERSHIP WITH THE PUBLIC AND NEW STANDARDS SO THAT WE CAN PRESENT IT TO THE ICOC. I THINK IF TODAY WE SAY, I KNOW, JEFF, YOU HAD SOME CONCERNS AS WELL, AND I THINK IF WE SAY AS OF WHATEVER IS ADOPTED, EVERYTHING IS GRANDFATHERED IN, AND NOW WE'RE GOING TO LOOK TO THE FUTURE AND ASK STAFF TO COME BACK WITH SOME PROTECTIONS AND HAVE ANOTHER MEETING TO TALK -- TO SEE IF WE CAN COME UP WITH SUFFICIENT PROTECTIONS SO THAT THERE CAN BE NO ABUSES MOVING FORWARD.

CHAIRMAN LO: OKAY. SO A NUMBER OF PEOPLE -- I CAN'T TELL IF SOME OF YOU ARE JUST STRETCHING. ROB HAD HIS HAND UP. MARCY. SHE'S

STRETCHING. JEFF, I KNOW AT LUNCH WE HAD A VERY INTERESTING CONVERSATION I'D LIKE YOU TO ADDRESS IF YOU WANT. AND THEN I'M ASK TO GET THE AUDIENCE INVOLVED.

DR. TAYLOR: YEAH. I WAS JUST GOING TO SAY I THINK THAT'S A WONDERFUL SUGGESTION. AND IT'S LIKELY THAT THAT'S GOING TO OPEN UP A LOT OF MATERIAL THAT, EVEN IF GOING FORWARD SOMEHOW THERE'S A BLOCK TO EVER SORT OF CHANGING THE ESTABLISHED POLICY AS WE KNOW IT, WE'D STILL BE MAKING A HUGE CONTRIBUTION BECAUSE I THINK THERE'S A LOT OF STUFF IN THE BANK CURRENTLY THAT CAN ACTUALLY BE UTILIZED NOW. SO I WOULD CERTAINLY SUPPORT THAT.

CHAIRMAN LO: JEFF SHEEHY.

MR. SHEEHY: YEAH. I THINK -- I REALLY THINK THAT THIS PROTECTS US, AT LEAST THIS FIRST PHASE, BECAUSE THOSE EMBRYOS WOULD NOT HAVE BEEN CREATED UNDER ANY INFLUENCE FROM US. AND SO THAT'S THE REAL -- THEY WERE CREATED FOR A COMPLETELY DIFFERENT PURPOSE, NONE OF OUR POLICIES HAD ANY IMPACT ON THEIR CREATION, SO I DON'T FEEL ANY SENSE OF UNEASE OR DISCOMFORT THAT IN ANY WAY WE VIOLATED, AS ALTA WAS TALKING ABOUT, YOU KNOW, THOSE BRIGHT LINES, THOSE CORE PRINCIPLES THAT UNDERLIE A POLICY. I DON'T THINK WE'RE IN ANY WAY INCONSISTENT WITH ANY

STATE LAWS OR ANYTHING LIKE THAT.

AND IF WE CAN PUT THE ADEQUATE PROTECTIONS, WE SHOULD LET STAFF STUDY AND SEE IF THERE'S A WAY WE CAN TALK ABOUT GOING FORWARD. BUT IT WOULD AT LEAST TAKE CARE OF, I THINK, PARTIALLY WHY FOLKS EXAMPLE ARE HERE, STANFORD, THESE EMBRYOS ARE GOING TO NO GOOD USE. IT'S IMPORTANT TO THE PARENTS, RIGHT, THAT'S WHAT IT IS IS PARENTS, TO HAVE SOMETHING GOOD COME OUT OF THIS, NOT JUST TO HAVE THEM DESTROYED AND JUST SIT IN THE FREEZER.

CHAIRMAN LO: DENISE AND THEN MARCY I'M GOING TO ASK YOU TO SPEAK.

MS. BERNSTEIN: WHEN YOU SAY THAT THESE WOULD GO TO RESEARCH, ARE YOU GOING TO BE DIFFERENTIATING TYPES OF RESEARCH, OR IT CAN ALL GO TO STEM CELL RESEARCH AND YOU CAN PROPAGATE CELLS AND DNA OUT THERE?

CHAIRMAN LO: WE'RE NOT GOING TO USE THE FINE-GRAINED CONSENT THAT YOU'VE PUT IN PLACE, AND WE STILL NOW SAYING GOING FORWARD WE WOULD WANT THAT. THAT'S PART OF WHAT WE NEED TO WORK OUT.

MS. BERNSTEIN: SO IT WOULD JUST BE EVERYTHING.

CHAIRMAN LO: WHAT'S HAPPENED IN THE PAST, WE'RE SAYING RATHER THAN THAW AND DISCARD THESE

EMBRYOS, WITH THESE PROVISIONS, IF THEY'RE ALREADY IN EXISTENCE AS OF TODAY, WE'D ALLOW THEIR USE FOR RESEARCH.

MS. BERNSTEIN: STEM CELL RESEARCH.

CHAIRMAN LO: GOING FORWARD, I THINK A NUMBER OF YOU HAVE SAID I'M COMFORTABLE WITH LOOKING BACKWARDS, HAVING ALREADY BEEN CREATED, WE'RE NOT GOING --

MR. KLEIN: GOING FORWARD THE PROBLEM IS NOT EVERY PLACE IS A UNIVERSITY, NOT EVERY PLACE IS THIS GOING TO HAPPEN ALL THIS VERIFICATION, SO LET'S LEAVE THAT FOR A FUTURE DISCUSSION. BUT ON AN HISTORIC BASIS, GENERAL RESEARCH IS RESEARCH.

CHAIRMAN LO: AND, AGAIN, JUST FOR THE RECORD.

DR. DARNOVSKEY: I'M MARCY DARNOVSKEY, CENTER FOR GENETICS AND SOCIETY. AND I APPRECIATE YOUR SOLICITING MY INPUT ON THIS.

YOU KNOW, WE'VE ALWAYS SAID THAT WE ARE SUPPORTIVE OF EMBRYONIC STEM CELL RESEARCH USING LEFT-OVER IVF-EMBRYOS, AND SO I AM COMFORTABLE WITH THE GRANDFATHERING ISSUE. LOOKING BACKWARDS, AS SEVERAL PEOPLE HAVE SAID, THOSE EMBRYOS WERE CREATED FOR A PARTICULAR PURPOSE, THEY'RE THERE, WHY SHOULD THEY GO TO WASTE? THE PEOPLE WHOSE GAMETES THEY ARE

AND PEOPLE WHOSE EMBRYOS THEY ARE WANT THEM TO BE USED FOR RESEARCH, GREAT. BUT I THINK IT'S REALLY VERY DIFFERENT TO THINK ABOUT GOING FORWARD. --

THAT'S WHEN YOU GET INTO THE SITUATION WHERE YOU GET ALL SORTS OF CONFLICTS OF INTEREST, ALL SORTS OF COMPETING INCENTIVES OF PRACTITIONERS. YOU KNOW, I DON'T THINK IT'S JUST A FANTASY, UNFORTUNATELY, THAT PEOPLE WOULD EITHER CONSCIOUSLY OR UNCONSCIOUSLY FEEL THAT, YOU KNOW, JUST A LITTLE MORE OF THIS HORMONE, WE GET A FEW MORE EGGS, WE REALLY WANT THEM. AND WHAT WE SEE TO DATE IN THE ATTEMPTS TO ACQUIRE EGGS FOR SCNT RESEARCH IS THAT JUST BECAUSE OF THE NATURE OF THESE FIELDS, THE IVF PRACTITIONERS AND THE STEM CELL RESEARCHERS ARE VERY CLOSE TO EACH OTHER, SOMETIMES NOT FREQUENTLY, YOU KNOW, THE SAME INSTITUTION, SOMETIMES ON A DIFFERENT FLOOR OF THE SAME BUILDING. AND IT'S A SITUATION WHERE I THINK IT'S REALLY DIFFICULT TO SEPARATE PEOPLE EVEN INSIDE THEMSELVES, EVEN PEOPLE OF GREAT INTEGRITY, TO SEPARATE THEIR DESIRE AND DUTY OF CARE TO THE WOMAN WHO COMES IN TO PROVIDE EGGS AND THEIR DESIRE AND THEIR, YOU KNOW, SENSE OF DUTY TO THE PERSON WHO'S UNDERGOING THE IVF TREATMENT AND ALSO THEIR DESIRE AND MAYBE, AS THEY SEE IT, THEIR DUTY TO ADVANCING THE RESEARCH.

AND I THINK THAT PUTS THESE PEOPLE IN A VERY DIFFICULT SITUATION, AND IT PUTS THE WOMEN WHO ARE PROVIDING THE EGGS AT RISK. SO THAT, I THINK, MAKES THE GOING FORWARD, THE PROSPECTIVE, ALLOWING THE USE OF IVF-EMBRYOS WITH PAID GAMETES IN A PROSPECTIVE WAY, I THINK THERE IS A VERY BRIGHT LINE CONCEPTUALLY, LOGICALLY, ETHICALLY, MAYBE LEGALLY BETWEEN THE GRANDFATHERING AND THE MOVING FORWARD.

CHAIRMAN LO: THERE'S A NUMBER OF COMMENTS.

MS. LANSING: I JUST WANTED TO THANK YOU, MARCY, BECAUSE I THINK ACTUALLY WE HAD AN OPPORTUNITY TO TALK. AND I THINK YOUR INPUT WAS INVALUABLE.

DR. DARNOVSKEY: THANK YOU.

MS. LANSING: AND I THINK THAT IT'S GREAT THAT WE HAVE CONSENSUS, I THINK, I HOPE I'M NOT SPEAKING OUT OF TURN, AROUND THE GRANDFATHERING BECAUSE WE ALWAYS WANT TO MOVE FORWARD WITH CONSENSUS WITH YOU AS OUR PARTNER. AND I HOPE, BECAUSE I THINK YOUR INPUT WAS REALLY GOOD, I HOPE THAT YOU WILL WORK WITH US IN SEEING IF THERE'S A POSSIBILITY TO HAVE ENOUGH PROTECTIONS THAT WE CAN LOOK TO THE FUTURE AS WELL.

CHAIRMAN LO: LET ME ASK ALTA, AND THEN WE

HAVE SOME OTHER PUBLIC COMMENT.

MS. CHARO: WELL, FIRST, SINCE IN MOST CASES WE'RE TALKING ABOUT PAID EGG DONORS, NOT SPERM DONORS, I WOULD SUGGEST WE START TALKING ABOUT GRANDMOTHERING AS OPPOSED TO GRANDFATHERING.

LISTENING CLOSELY, I REALIZE THAT THERE ARE TWO DIFFERENT SETS OF CONCERNS IN THE CONTEXT OF THE PROSPECTIVE RULE THAT WE WOULD ALLOW CIRM GRANTEES TO DERIVE FROM EMBRYOS THAT INCLUDE WITH THEM GAMETES FROM A PAID DONOR. AND THE FIRST, WHICH IS WHAT I THOUGHT WE WERE GOING TO BE WORRIED ABOUT, WAS THAT SOMEHOW THIS WAS GOING TO ENCOURAGE WOMEN TO BECOME PAID GAMETE DONORS IN THE REPRODUCTIVE CONTEXT WHEN THEY OTHERWISE MIGHT NOT DO IT. AND THAT REALLY DID WORRY ME A BIT BECAUSE THAT'S EXACTLY THE LOGIC THAT HAD BEEN USED BY THE H. W. BUSH AND W. BUSH ADMINISTRATIONS WHEN IT CAME TO THE RULES ABOUT, FIRST, FETAL TISSUE RESEARCH IN THE '80S AND THEN ABOUT EMBRYONIC STEM CELL RESEARCH AT ALL IN THE 2000S. THAT IS, THAT THE PROSPECT OF RESEARCH OUT THERE SOMEWHERE IN THE WORLD AS AN AVENUE FOR DISCARDED PRODUCTS TO GO WOULD SOMEHOW ENCOURAGE PARTICIPATION.

AND THAT WAS A LINE THAT MOST OF US HAD REJECTED AS UNREALISTIC, AND I'M GLAD THAT THAT'S

ACTUALLY NOT, I THINK, FROM WHAT I'M HEARING, THE FOCUS OF CONCERN HERE.

BUT MARCY RAISED A TOTALLY SEPARATE CONCERN, WHICH I ACTUALLY HADN'T REALLY THOUGHT ABOUT, WHICH IS THE POTENTIAL EFFECT, NOT ON THE WOMAN, BUT ON THE PEOPLE SURROUNDING THE WOMAN. AND ON THAT SCORE, IT IS INTERESTING, THOUGH, TO GO BACK TO THE OLD FETAL TISSUE RULES BECAUSE THAT WAS ALSO A CONCERN, THAT THE MODE OF ABORTION, TIMING, METHOD, ETC., MIGHT BE ALTERED TO MAKE THE FETAL TISSUE FROM THE ABORTUS MORE USABLE TO RESEARCH. AND THAT THIS WOULD HAVE AN ADVERSE EFFECT ON THE QUALITY OF THE MEDICAL CARE GIVEN TO THE WOMAN UNDERGOING ABORTION.

AND AS A RESULT, IN THE FEDERAL REGULATIONS, THEY WRITE IN A RULE THAT SAYS IF YOU ARE GOING TO USE THIS TISSUE, AND THESE RULES STILL PERSIST EVEN NOW IN THE W. BUSH ADMINISTRATION, IF YOU ARE GOING TO USE THIS TISSUE, YOU HAVE TO TESTIFY NOT ONLY TO THE FACT THAT THE WOMAN WASN'T PAID TO INDUCE HER TO HAVE AN ABORTION, BUT THAT THE METHOD OF ABORTION WAS NOT ALTERED. AND TO PROVE THAT, YOU HAVE TO SHOW THAT THE METHOD OF ABORTION WAS CHOSEN BEFORE SHE WAS APPROACHED FOR HER CONSENT TO RELINQUISH THE PRODUCTS OF ABORTION TO RESEARCH.

IN OTHER WORDS, YOU SEPARATE OUT FOR BOTH THE WOMAN'S THINKING AND THE CARRIER'S THINKING, RIGHT, THE PROSPECT OF RESEARCH AS THEY'RE COMING TO AN AGREEMENT ON HOW TO PROCEED.

IT MAY NOT BE COMPLETELY TRANSFERABLE INSTANTLY, AND I DO TAKE THE POINT ABOUT THE COLLABORATIONS THAT GO ON, ESPECIALLY AS WE'RE MOVING TO GMP QUALITY RESEARCH WHERE YOU ACTUALLY NEED THE IVF DOCS AND THE RESEARCHERS TO BE IN FAIRLY CLOSE PROXIMITY IN ORDER TO MANAGE THE PHYSICAL ENVIRONMENT. I KNOW UP IN NEWCASTLE THEY HAVE BEEN DOING THIS. BUT IT DOES SEEM TO BE AN AVENUE OF ENDEAVOR THAT MIGHT LEAD TO THE KIND OF PROTECTIONS THAT WE'D LIKE TO SEE WITHOUT NECESSARILY HAVING TO ABSOLUTELY PREVENT THE USE OF SUCH EMBRYOS BECAUSE NOW AT LEAST WE'RE FOCUSED ON WHAT WE'RE WORRIED ABOUT, AND WE'VE GOT SOME MODELS OF HOW TO GUARD AGAINST ANY INCIDENTAL ABUSES EVEN BY PEOPLE OF GOOD INTENTION.

CHAIRMAN LO: OTHER PUBLIC -- SEVERAL PUBLIC COMMENTS. LET'S DO ONE AT A TIME. AGAIN, PLEASE INTRODUCE YOURSELF FOR THE RECORD.

MS. SMITH-CROWLEY: SHANNON SMITH-CROWLEY, REPRESENTING THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE. I WAS VERY PLEASED TO HEAR

DR. DARNOVSKEY'S AGREEMENT AS TO THE GRANDMOTHERING OF THE EMBRYOS USING PAID GAMETES. AND I WOULD LIKE TO SAY THAT WE WILL DO EVERYTHING IN OUR POWER TO WORK TO FIND A SOLUTION TO HELP PUT SOME PROTECTIONS IN PLACE. AND I THINK THE ISSUES THAT WERE BROUGHT UP WERE EXTREMELY VALID, AND I HOPE WE CAN ADDRESS THEM, ESPECIALLY LOOKING AT THE HISTORICAL REFERENCES IN TERMS OF SOME THINGS SUCH AS THE FETAL TISSUE THAT THE OB-GYN'S HAVE HAD TO DEAL WITH MORE MANY YEARS. THANK YOU.

MR. REED: IT'S ALWAYS A PLEASURE TO HEAR THE AMAZINGLY ELEVATED LEVEL OF DISCOURSE THAT GOES ON HERE. I WISH SOME OF OUR OPPONENTS IN THE PRESS WOULD COME TO OUR MEETINGS AND HEAR WHAT IS ACTUALLY SAID.

TO GO TO A VERY SMALL DETAIL, I'M CONCERNED ABOUT THE FIRST SENTENCE, EMBRYOS DONATED AFTER A WOMAN IN IVF HAS COMPLETED FERTILITY TREATMENT. DOES THAT MEAN AFTER SHE HAS COMPLETED AN IVF CYCLE, OR COULD THAT BE CONSTRUED AS WHEN SHE IS BEYOND REPRODUCTIVE AGE? IS THAT SOMETHING THAT COULD BRING US BACK DIFFICULTIES IN THE FUTURE, OR COULD THERE BE HAS COMPLETED AN INFERTILITY TREATMENT CYCLE, SOMETHING LIKE THAT?

DR. PECKMAN: FAMILY PLANNING IS

COMPLETED.

MS. CHARO: I THINK THE INTENT IS PROBABLY AT THE POINT AT WHICH SHE NO LONGER PLANS TO USE ANY REMAINING EMBRYOS. WHETHER SHE'S AT REPRODUCTIVE AGE OR NOT, SHE'S DECIDED SHE'S GOING TO CONCLUDE HER IVF EFFORTS.

MR. KLEIN: A WOMAN'S CHOICE. IT'S THE WOMAN'S CHOICE.

MR. REED: RIGHT. I DON'T QUESTION THE INTENT. I JUST QUESTION COULD THIS BE USED AGAINST US IN ANY WAY?

DR. TAYLOR: REPRODUCTIVE AGE IS PRETTY BROAD NOW, SO I DON'T THINK WE WANT TO TRY TO DEFINE THAT.

CHAIRMAN LO: WE HAVE THE LUXURY TO BE ADVISORY TO THE ICOC.

MS. LANSING: WHEN SHE DECIDES SHE NO LONGER WANTS.

CHAIRMAN LO: THAT'S A GOOD POINT.

MR. KLEIN: DID SOMEONE GET SHERRY'S COMMENT THERE?

MS. LANSING: WHEN SHE DECIDES THAT SHE NO LONGER WANTS THEM.

DR. LOMAX: THIS IS IN THE RECORD.

MR. KLEIN: WE HAVE A TRANSCRIPT FROM THE

RECORDING.

DR. LOMAX: SHERRY'S COMMENT IS ACTUALLY CONSISTENT WITH OUR EXISTING BODY OF REGULATION, WHICH INDICATES THAT THESE DECISIONS ARE BY THE WOMAN. SO IT'S CONSISTENT WITH OUR EXISTING LANGUAGE. WHEN WE COME BACK TO YOU, WHICH I WOULD SUGGEST THAT -- I ENVISION ON THIS ITEM A PROCESS WHERE PERHAPS WE WOULD COME BACK TO THE WORKING GROUP FIRST BECAUSE THIS IS VERY GOOD DIRECTION, BUT UNLIKE THE FIRST ITEM THAT HAD SUFFICIENT --

MR. KLEIN: GEOFF, I THINK THIS IS THE DIRECTION TO THE ICOC. WE'RE GOING TO DEAL WITH IT AT THE ICOC.

MS. LANSING: IF YOU CAN -- WITH ALL DUE RESPECT, BOB, IF YOU CAN GIVE US SOME WRITTEN POINTS TO KIND OF HELP US IN OUR DIRECTION, WE DON'T OBJECT TO THAT. THE MORE SPECIFIC YOU CAN HELP US BE FOR THE ICOC.

DR. LOMAX: I THINK THE POINT IS WE NEED TO REALLY KIND OF GO BACK INTO THE REGULATIONS GIVEN THE SENSE OF THE COMMITTEE TODAY AND UNDERSTAND SORT OF WHERE THE POINTS OF -- WHERE WE CAN ACTUALLY BRING THIS IN. SO THE DETAILS OF THE LANGUAGE WE NEED TO DEVELOP, BUT WITHIN THE CONTEXT OF EXISTING REGULATIONS. AND ON THIS PARTICULAR ITEM --

MS. LANSING: THIS IS JUST --

CHAIRMAN LO: LET ME -- I THINK THERE NEED TO BE MORE COMMENTS AND DISCUSSION ON THE PANEL. STEVE, WHY DON'T YOU GO AHEAD.

DR. PECKMAN: STEVE PECKMAN, UCLA. FIRST OF ALL, I'D LIKE TO SECOND ALTA'S COMMENTS ABOUT SEPARATING OUT THE IVF TREATMENT FROM THE DONATION FOR RESEARCH WITH OOCYTE -- CLINICAL OOCYTE DONORS, AND THAT WE SHOULDN'T WHOLE CLOTH DISMISS THE IDEA THAT COUPLES OR INDIVIDUALS CREATING EMBRYOS WITH DONATED OOCYTES, THAT THOSE NEED TO BE REMOVED OFF THE TABLE IN THE FUTURE BECAUSE THERE MAY BE APPEARANCE -- BECAUSE THERE MAY BE QUESTIONS WE HAVE, BUT RATHER ENSURE THAT THOSE QUESTIONS ARE ADDRESSED AND MAKE THOSE EMBRYOS AVAILABLE IN THE FUTURE WITH THOSE QUESTIONS ADDRESSED. THAT'S THE MAIN POINT I ACTUALLY CAME HERE TO MAKE TODAY, SO I'M GLAD THAT ALTA MADE IT FOR ME.

I WANT TO GO BACK TO THE DISCUSSION THAT HAPPENED BEFORE LUNCH REGARDING SPERM DONORS AND INFORMED CONSENT. I DON'T KNOW OF ANY ACADEMIC MEDICAL CENTER IN CALIFORNIA THAT REQUIRES WHEN TISSUES ARE BEING SHARED THAT THEY RECEIVE AN ACTUAL SIGNED CONSENT FORM FROM THE DONOR. WHAT THEY REQUEST IS THE CONSENT FORM THAT'S USED WHICH THEY

HAVE OBTAINED INFORMED CONSENT, AN ATTESTATION BY THE PROVIDER THAT IT HAS BEEN USED APPROPRIATELY, AND THAT NO ONE ASKS TO SEE THE ACTUAL SIGNED DOCUMENT. I THINK THAT'S A RED HERRING THAT SHOULD BE TAKEN OFF THE TABLE COMPLETELY.

BUT THE MAIN POINT HERE TODAY IS TO ENCOURAGE YOU TO CONSIDER THE USE BOTH RETROSPECTIVELY AND PROSPECTIVELY OF EMBRYOS THAT ARE CREATED WITH PAID DONORS FOR CLINICAL REASONS, THAT THOSE BE ALLOWED TO BE USED FOR RESEARCH EVEN THOUGH THOSE DONORS WERE PAID FOR CLINICAL PURPOSES BECAUSE, AS YOU DISCUSSED EARLIER, INTENT OF THE RESTRICTION WAS TO ADDRESS UNDUE INFLUENCE ON THE OOCYTE DONOR. AND THERE'S CLEARLY NO UNDUE INFLUENCE ON THE OOCYTE DONOR WHO IS CONTRIBUTING THE OOCYTE FOR FERTILITY PURPOSES, AND THAT THE RESEARCH COMES FOLLOWING THOSE DECISIONS AND IS ACTUALLY NOT RELATED TO THAT IVF PROCESS AT ALL. AND WE NEED TO SEPARATE THOSE ASPECTS OUT. THANK YOU.

CHAIRMAN LO: THANK YOU.

MR. KLEIN: SO, MR. CHAIRMAN, IF THE INSTITUTIONS LIKE UCLA HAVE BEEN ALIGNED UPON THE PROVIDING -- ATTESTING TO THE FACT THAT CONSENT IS THERE, IT'S NOT OUR INTENT TO ASK THEM TO ACTUALLY

SUBMIT THE FORM; IS THAT CORRECT, WITH THE GRANDFATHERED EMBRYOS THAT REALLY EXIST IN PRACTICES?

DR. PECKMAN: I THINK WHAT YOU WANT -- WHAT YOU WANT TO SEE IS THE SAMPLE FORM THAT'S BEING USED, NOT THE ACTUAL SIGNED DOCUMENT.

MR. KLEIN: YEAH. THAT MAKES SENSE.

CHAIRMAN LO: I THINK, AGAIN, WHAT WE'RE TRYING TO DO IS HAVE A FAIRLY VIABLE POLICY RECOMMENDATION WITH THE ICOC. I THINK SOME OF THESE DETAILS, I'LL BE SHRINKING THEM. WE WON'T BE ABLE TO DO THAT TODAY. I THINK THAT'S SOMETHING WE'D LIKE FRANKLY THE ICOC STAFF SORT OF DO.

MR. SIMPSON: JOHN SIMPSON FROM CONSUMER WATCHDOG. I JUST WANTED TO AGREE THAT THE GRANDMOTHERING AND THE GRANDFATHERING AND GRANDPERSONING IS ABSOLUTELY THE RIGHT THING TO DO. I ALSO WANTED TO AGREE WITH THE PREVIOUS SPEAKER, THAT I DO ALSO THINK THAT IF COUPLES ARE IN A POSITION AND THEY ARE COMPLETED WITH THEIR IVF CYCLE, THAT THEY OUGHT TO BE ABLE TO GIVE DONATION OF THE EMBRYOS NO MATTER HOW THEY WERE OBTAINED ORIGINALLY.

SO I THINK YOU NEED TO PUT TREMENDOUS EMPHASIS ON THE PROSPECTIVE ASPECT OF THIS BECAUSE I

THINK WHAT YOU WILL END UP DOING HERE, IF YOU LET IT DRAG ON, YOU'RE GOING TO HAVE A VERY BIFURCATED GROUP OF PEOPLE, PEOPLE WHO KNOW THAT THEIR EMBRYOS WERE DONATED, AND THERE WILL BE A FRUSTRATED GROUP THAT WOULD LIKE TO BE DONATING THEM, BUT DON'T UNDERSTAND WHY THEY CAN'T. SO I WOULD ENCOURAGE APPROPRIATE DELIVERY OF THE CASE IN MOVING FORWARD TO FIGURE OUT TO MAKE THIS WORK IN THE FUTURE.

CHAIRMAN LO: I THINK, AGAIN, THE PROSPECTIVE IS SOMETHING WE'RE GOING HAVE TO COME BACK TO. WE'RE GOING TO WORK WITH THOSE PEOPLE.

JOSE, YOU'VE BEEN VERY PATIENT.

DR. CIBELLI: YEAH. I HAPPEN TO HAVE MY COMPUTER WITH 2004 CDC REPORT. AND DID A QUICK SEARCH. I THINK IT'S IMPORTANT JUST THE MAGNITUDE OF THE ISSUE. I'M NOT AN EXPERT, BUT I READ THE NUMBERS TO YOU. SO IN 2004 THEY WERE DOING OVER 127,877 CYCLES. AND OF THOSE, 58,175 WERE DONOR EGGS. THAT'S ABOUT 12 PERCENT ON THE WHOLE CYCLES IN THE U.S. I DON'T KNOW IF THAT GIVES SOME PERSPECTIVE OR IT'S RELATED TO THIS OR NOT.

CHAIRMAN LO: DOES THAT GIVE STATISTICS FOR THE NUMBER OF CYCLES WITH DONATED SPERM?

DR. CIBELLI: I COULDN'T FIND IT.

CHAIRMAN LO: COULDN'T FIND IT. THAT'S

SOMETHING I'M GOING TO ASK STAFF TO LOOK AT. THANK YOU. IT'S GREAT TO SEE THE INTERNET AT WORK.

MS. MICHELSEN: IN HEARING THE CONCERNS AS TO HOW YOU OFFER PROTECTION, PERHAPS ONE OF THE THINGS THE COMMITTEE MIGHT DO IS DRAFT A CONSENT FORM THAT HAS THE PIECES YOU WANT TO MAKE SURE THAT PEOPLE HAVE ADHERED TO AND REQUIRE, FOR EXAMPLE, THAT THIS CONSENT FORM BE SIGNED NO SOONER THAN AFTER THE IVF PROCEDURE. AND THAT WAY IT'S VERY CLEAR THAT THE PROCEDURE TOOK PLACE PRIOR TO THE CONCEPT OF DONATION. AND THEN YOU CAN ADD IN YOUR OTHER PROTECTIONS ON THE CONSENT FORM, AND POSSIBLY THEN YOU CAN MANDATE THIS CONSENT FORM BE SIGNED BY THE VARIOUS IVF CLINICS AND SO FORTH THAT MAY BE DOING THESE PROCEDURES. SO THAT'S AN IDEA.

CHAIRMAN LO: GREAT. I THINK, AGAIN, MY SENSE IS WE'RE GOING TO NEED TO THINK MORE ABOUT THE PROSPECTIVE. I'D LIKE TO KIND OF REACH CLOSURE HERE. SO, GEOFF, IF YOU COULD CHANGE THIS, THAT THIS REALLY -- THIS -- WHY DON'T YOU PUT BACK ON THE SLIDE.

IS IT THE SENSE OF THIS MEETING THAT TO WE GO TO THE ICOC AND SAY THAT WITH REGARD TO BOTH EXISTING STEM CELL LINES AND EMBRYOS ALREADY IN EXISTENCE AS OF THE CUTOFF DATE WE MENTIONED TODAY

OR AT THE ICOC MEETING, THAT THEY BE ALLOWED TO BE USED SUBJECT TO THESE, BUT RATHER THAN THE LAST BULLET, THIS IS REALLY FOR ONES ALREADY IN EXISTENCE, THAT WE'RE GOING TO TODAY JUST PICK UP ON THAT IF WE CAN AND COME BACK AT THE NEXT MEETING TO PROPOSE PROTECTIONS.

MR. KLEIN: AND THE SLIDE DOESN'T ACTUALLY SAY EMBRYOS ALREADY IN EXISTENCE AS OF THE DATE OF OUR ADOPTION, BUT WE COULD ADD A BULLET POINT.

MS. LANSING: THIS WOULD APPLY TO ANY EMBRYOS --

CHAIRMAN LO: EMBRYOS AND LINES.

MS. LANSING: -- IN THE PAST UP TO THE DATE OF THE ADOPTION.

MR. KLEIN: THAT'S RIGHT.

CHAIRMAN LO: GEOFF WILL --

MS. LANSING: AND WE'RE GOING TO THEN COME BACK. OUR NEXT SUBJECT OF OUR NEXT MEETING IS HOW WE MOVE FORWARD IN THE FUTURE.

CHAIRMAN LO: SO, MARCY, YOU HAD A COMMENT? FOR THE RECORD.

DR. DARNOVSKEY: FOR THE RECORD, MARCY DARNOVSKEY, CENTER FOR GENETICS AND SOCIETY. I JUST WANT TO CONNECT SOME DOTS HERE. ONE ABOUT THE -- I'M NOT CONVINCED THERE'S A WAY TO ADEQUATELY

PROTECT WOMEN PROVIDING EGGS DOING IT IN THE FUTURE AT ALL. AND I THINK ONE OF THE THINGS THAT HAS TO BE CONSIDERED IS DO YOU REALLY NEED THIS? YOU KNOW, YOU HAVE A 85, MAYBE 80 PERCENT OF EMBRYOS THAT DON'T HAVE PAID GAMETES IN THEM AT ALL. NOW WE'RE SAYING THE ONES THAT ALREADY EXIST ARE GOING TO BE ALLOWED. THAT'S A WHOLE -- AS DR. TAYLOR SAID, WE HAVE A WHOLE NOTHER SUPPLY OF MATERIAL.

SO I THINK WE'RE IN A DIFFERENT MEETING SITUATION THAN WE WERE FIVE MINUTES AGO BY A LOT. AND THAT REALLY RECOGNIZING THAT NUMBER, THAT IT'S ONLY 12 PERCENT OF THE CYCLES, FOLKS, YOU KNOW, WE'RE NOT TALKING ABOUT THAT MANY, SO I THINK THAT DISCUSSION HAS TO REALLY --

CHAIRMAN LO: THE WHOLE PROSPECTIVE ISSUE IS WE NEED TO COME BACK TO THAT.

MS. LANSING: WE NEED TO REALLY DISCUSS IT, YOU KNOW, AND SEE WHAT --

CHAIRMAN LO: WHAT I WOULD LIKE TO -- DENISE. IS THIS ON THE RETROSPECTIVE BECAUSE I WANT --

MS. BERNSTEIN: THIS IS JUST VERY QUICKLY ON THE COMMENT. I JUST THINK THAT THE EMBRYOS THAT ARE FROZEN, THAT HAVE BEEN FROZEN FROM THE DONOR GAMETES, IT'S NOT JUST A QUANTITY ISSUE. THOSE

EMBRYOS ARE PROBABLY SCIENTIFICALLY SOUND.

CHAIRMAN LO: WE'RE GOING TO HAVE TO -- WE'RE UNABLE TO GET THE STANFORD SCIENTISTS, BUT I THINK THAT'S PART OF THE DISCUSSION. WHAT WOULD BE THE GAIN SCIENTIFICALLY IF WE COULD USE THESE EMBRYOS GOING FORWARD? WHAT'S THE MAGNITUDE OF THAT POTENTIAL CASE?

MS. LANSING: AND HOW DO WE PROTECT? AND SO I THINK, TO PUT THIS IN PERSPECTIVE, YOU KNOW, AFTER TWO YEARS, YOU KNOW, OF EACH OF US HAVING DIFFERING OPINIONS TO WHAT, I HOPE, I THINK WILL PROBABLY BE A CONSENSUS WITH OUR GROUP AND OUR ADVOCATES IN THE PUBLIC, THIS IS A BIG STEP FOR US. AND NOW WE'RE GOING TO A LOT OF DISCUSSION, A LOT OF INPUT FROM EVERY SIDES TO SEE IF THERE IS A WAY TO MOVE FORWARD IN THE FUTURE, THE BENEFITS, THE DOWNSIDE, AND WE CAN ANALYZE IT.

CHAIRMAN LO: WHAT I WOULD PROPOSE WE DO NOW IS TO ACTUALLY TAKE AN ADVISORY ROLL CALL VOTE TO THE ICOC AND SEE IF IT IS THE SENSE OF THIS COMMITTEE TODAY TO RECOMMEND TO THE ICOC THIS GRANDPARENTING IN OF THESE EMBRYOS AND EXISTING STEM CELL LINES USING PAID GAMETES SUBJECT TO THESE CONDITIONS.

OKAY. GEOFF, YOU WANT TO READ THE ROLL.

DR. LOMAX: ARE WE CLEAR -- DO WE NEED TO --

MR. KLEIN: YEAH.

DR. LOMAX: -- FURTHER ELUCIDATE THE MOTION? OKAY. SO THE RECORD REFLECTS WHAT WE'RE VOTING ON, AND WE CAN JUST GO FORWARD AND VOTE. AND FOR ANY REASON -- WELL, LET'S JUST MOVE FORWARD WITH THE VOTE.

ROBERT TAYLOR.

DR. TAYLOR: YEAH. I'M FOR GRANDMOTHERING.

DR. LOMAX: ANN KIESSLING.

DR. KIESSLING: I AM A GRANDMOTHER.

DR. LOMAX: FRANCISCO PRIETO.

DR. PRIETO: I SUPPORT GRANDMOTHERS.

DR. LOMAX: ALTA CHARO.

MR. KLEIN: FOR THE RECORD, WE REALLY SHOULD -- WE NEED THE VOTE.

DR. KIESSLING: YES.

DR. PRIETO: YES.

MS. CHARO: YES. AND IF I'M EVER LUCKY ENOUGH TO HAVE CHILDREN, I'M LIKELY TO BE A GRANDMOTHER.

CHAIRMAN LO: I'M JUST GOING TO SAY YES.

MS. LANSING: I'M GOING TO SAY YES IN

FAVOR. YES. I CAN'T RESIST THIS. I HOPE SOMEDAY TO BE A GRANDMOTHER IN FAVOR OF ALL GRANDMOTHERS.

MR. KLEIN: YES.

MS. FEIT: YES.

MR. SHEEHY: YES.

DR. CIBELLI: IN FAVOR OF THIS.

CHAIRMAN LO: WELL, THANK YOU VERY MUCH. I THINK THIS IS AN IMPORTANT STEP.

(APPLAUSE.)

MS. LANSING: JUST LET ME SAY WHAT I LIKE ABOUT THIS IS THAT, YOU KNOW, HAVING WORKED WITH THIS GROUP FOR TWO YEARS, HAVING WORKED WITH THE PUBLIC, IT SHOWS THAT WE REALLY ARE A WORK IN PROGRESS, THAT WE'RE CONSTANTLY LOOKING AT WHAT'S HAPPENING, WE'RE CONSTANTLY EVALUATING, REEVALUATING, AND TRYING TO DO THE BEST FOR THE PATIENT AND FOR THE SCIENCE. I THINK THIS IS REALLY QUITE EXCITING.

DR. TROUNSON: BERNIE AND SHERRY AND COMMITTEE, REALLY DO APPRECIATE THE CLARITY OF THE PROPOSAL AND THE ABILITY FOR US TO MOVE ALONG IN THESE STEPS. SMALL AS THEY MIGHT BE, THEY'RE VERY SIGNIFICANT IN US ACHIEVING OUR MISSION. SO THANK YOU VERY, VERY MUCH.

MS. LANSING: THANK YOU.

CHAIRMAN LO: AND NOW I'D LIKE TO ACTUALLY MOVE US FORWARD TO THE NEXT AGENDA ITEM. IT'S ACTUALLY A REPORT FROM THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, WHICH, AS YOU KNOW, IS RESPONSIBLE FOR THE OVERSIGHT OF ALL STEM CELL RESEARCH IN CALIFORNIA NOT FUNDED BY CIRM, AND THEY'VE ACTUALLY BEEN WORKING VERY HARD ON REPORTING REQUIREMENTS FOR OOCYTE DONATION. SO WE ARE VERY THANKFUL TO SHABBIR COMING FROM SACRAMENTO TODAY.

MR. AHMAD: FIRST OF ALL, I WANT TO THANK YOU AND THE WORK GROUP WILLING TO GIVE THE DEPARTMENT THE OPPORTUNITY TO SHARE THE REQUIREMENTS OF REPORTING FOR THE HUMAN EMBRYONIC STEM CELL RESEARCH AS WELL AS ASSISTED OOCYTE PRODUCTION FOR RESEARCH FROM THIS COMMITTEE.

AND I ALSO WANT TO ENCOURAGE THAT THERE SHOULD BE MORE AND MORE COLLABORATION BETWEEN CIRM AND THE DEPARTMENT OF THE PUBLIC HEALTH IN TERMS OF THE STEM CELL RESEARCH BECAUSE I WAS IN FRONT OF ONE SENATE BUDGET SUBCOMMITTEE, AND THE QUESTION WAS ASKED HOW YOU INTERACT WITH EACH OTHER ON STEM CELL RESEARCH. AND I THANK DR. GEOFF LOMAX TO INITIATE THAT PROCESS AND ATTENDING THE ADVISORY COMMITTEE MEETINGS FROM DEPARTMENT OF PUBLIC HEALTH. AND THIS IS ANOTHER EXAMPLE THAT WE ARE COLLABORATING ON

THESE ISSUES.

FROM THE OUTSET I WANT TO THANK THE ADVISORY COMMITTEE, ESPECIALLY THE CHAIR, PROFESSOR GREELEY, DR. RUBEN, THE CO-CHAIR OF THE ADVISORY COMMITTEE, DR. MAGNUS, DR. LO, THE OTHER COMMITTEE MEMBERS WHO PROVIDED GREAT INPUT, ADVICE, GUIDANCE, RECOMMENDATIONS, AND THEIR VOLUNTARY TIME TO DEVELOP THE GUIDELINES AS WELL AS THESE REPORTING FORMS, WHICH I WANT TO DISCUSS WITH YOU.

ALSO WANT TO THANK THE PUBLIC PARTICIPATION IN THIS PROCESS. WE RECEIVED VERY EXCELLENT SUGGESTIONS, VERY CONSTRUCTIVE CRITIQUE AND COMMENTS AND CONCERN WHILE WE WERE GOING THROUGH THE DEVELOPMENT OF THESE REPORTING FORMS. AND, OF COURSE, THE STAFF OF THE DEPARTMENT OF PUBLIC HEALTH, AS WELL AS DEPARTMENT OF PUBLIC HEALTH LEGAL AND PRIVACY OFFICERS WHO PARTICIPATED IN THE PROCESS.

SO WHAT I'M GOING TO DO IS JUST REFRESH OUR MEMORIES, GIVING YOU SOME OF THE STATUTORY MANDATES BY WHICH THESE REPORTING REQUIREMENTS ARE THERE, AND THEN GO OVER THAT JUST BRIEFLY WHAT PROCESS WE FOLLOWED TO DEVELOP THESE REPORTING FORMS, AND THEN GIVE A BRIEF DESCRIPTION OF THE FORMS AND THE NEXT STEPS.

THESE HEALTH AND SAFETY CODES, THEY WERE ENACTED THROUGH BILL SB 1260. ALL OF YOU KNOW SENATOR ORTIZ INTRODUCED THE BILL, AND IT WAS SIGNED INTO POLICY BY THE GOVERNOR. AND THERE ARE SOME REQUIREMENTS FROM SCRO COMMITTEES, FROM IRB, FROM DEPARTMENT OF PUBLIC HEALTH, IN DEVELOPING THE REVIEW REPORT FOR THE LEGISLATURE.

THE INFORMATION THAT IS RECEIVED WE RECEIVED THROUGH THESE FORMS FROM SCRO'S, IRB'S, AND RESEARCHERS. THE HEALTH AND SAFETY CODE 125119(A)(1), ALL RESEARCH PROJECTS INVOLVING THE DERIVATION OF USE OF HUMAN EMBRYONIC STEM CELLS SHALL BE REVIEWED AND APPROVED BY A STEM CELL RESEARCH OVERSIGHT COMMITTEE PRIOR TO BEING UNDERTAKEN. AND (B), NOT LESS THAN ONCE PER YEAR A STEM CELL RESEARCH OVERSIGHT COMMITTEE SHALL CONDUCT CONTINUING REVIEW OF HUMAN EMBRYONIC STEM CELL RESEARCH PROJECTS REVIEWED AND APPROVED UNDER THIS SECTION.

AND THEN THE COMMITTEE IS REQUIRED TO REPORT TO THE DEPARTMENT ANNUALLY ON THE NUMBER OF HUMAN STEM CELL RESEARCH PROJECTS AND THE STATUS AND DISPOSITION OF EACH. AND I HIGHLIGHTED THE WORD "EACH" IN THIS CODE BECAUSE THERE WAS A LOT OF DISCUSSION ON WHETHER THERE SHOULD BE A REQUIREMENT

FOR REPORTING ON AN INDIVIDUAL PROJECT OR THERE SHOULD BE (UNINTELLIGIBLE) COMING FROM SCRO COMMITTEES OR FROM IRB'S OR RESEARCHERS. BUT WE SAID IN THE SPIRIT OF THE LAW, THAT WE NEED THE INFORMATION ON EACH OF THESE PROJECTS.

125119.3(B), EACH STEM CELL RESEARCH OVERSIGHT COMMITTEE SHALL ALSO REPORT TO THE DEPARTMENT REGARDING UNANTICIPATED PROBLEMS, UNFORESEEN ISSUES, OR SERIOUS CONTINUING INVESTIGATOR NONCOMPLIANCE. SO IT'S NOT ONLY THE WRITTEN STATUS DISPOSITION OF THE PROJECT, BUT ANY ISSUES RELATED TO THOSE PROJECTS NEEDS TO BE FORWARDED TO THE DEPARTMENT.

THE DEPARTMENT SHALL AT LEAST -- NOW, THIS IS THE RESPONSIBILITY OF THE DEPARTMENT -- SHALL AT LEAST ANNUALLY REVIEW THESE REPORTS AND WHAT HAS BEEN LEARNED OF DATA AND MAY USE THE INFORMATION COMING OUT OF THESE FORMS AND REPORTS MAY REVISE THE GUIDELINES DEVELOPED PURSUANT TO THE SECTION 125118 AS IT DEEMS NECESSARY TO THE ADVISORY COMMITTEE AND THE PUBLIC PARTICIPATION.

THE B PART, THE DEPARTMENT SHALL PROVIDE A BIENNIAL REVIEW. WE ARE REQUIRED TO DEVELOP A REPORT, A REVIEW REPORT FOR THE LEGISLATURE ON ALL THE HUMAN EMBRYONIC STEM CELL RESEARCH ACTIVITY

WHICH IS NOT FULLY FUNDED BY CIRM. SO THIS IS THE RESEARCH THAT IS BEING DONE WITH THE FUNDS FROM NON-CIRM RESOURCES.

MR. KLEIN: COULD I ASK A QUESTION ON THAT?

MR. AHMAD: SURE.

MR. KLEIN: WHEN YOU SAY NOT FULLY FUNDED BY CIRM, IF IT'S FUNDED IN PART BY ANOTHER STATE SOURCE, BUT IF THE BALANCE OF THE FUNDING IS FROM PRIVATE OR NIH, IF IT'S A CIRM-SPONSORED GRANT, THEY WOULD BE UNDER CIRM REGULATIONS.

MR. AHMAD: IF THE FUNDING, AT LEAST WHAT OUR LEGAL COUNSEL HAS INTERPRETED, THAT IF THERE ARE ANY DOLLARS TO THE RESEARCH THAT ARE COMING FROM NON-CIRM RESOURCE, THEN WHETHER IT'S NIH, WHETHER IT IS A STATE FUNDING, WHETHER THERE IS A FOUNDATION, PRIVATE DONATION, PRIVATE FUNDING, THEN THESE REPORTING REQUIREMENTS WOULD APPLY.

MR. KLEIN: OKAY. BUT WHAT'S VERY IMPORTANT HERE IS THAT WE HAVE OUR COUNSEL TALK TOGETHER BECAUSE ON A CONSTITUTIONAL AND A STATUTORY BASIS, OUR LEGAL POSITION IS THAT IF IT'S A CIRM-SPONSORED GRANT, IF THERE'S NIH DOLLARS, IF THERE'S ANY OTHER SOURCE'S FUNDING PART OF IT, IT'S A CIRM-SPONSORED GRANT, COMES UNDER CIRM

JURISDICTION. SO IT IS VERY HELPFUL TO HAVE YOU HERE SO WE GET THIS COORDINATED BECAUSE THIS IS A VERY IMPORTANT LEGAL DECISION FOR US. WE CAN'T HAVE TWO DIFFERENT STANDARDS APPLYING TO THE SAME RESEARCH. AND IF IT'S A CIRM GRANT, IT'S OUR LEGAL POSITION THAT IT IS EXCLUSIVELY THE JURISDICTION OF CIRM'S REGULATORY REGIME.

MR. AHMAD: I THINK WE NEED TO WORK ON THAT. THIS IS BEYOND MY OPINION AT THIS MOMENT, AND THE ISSUE SHOULD BE DISCUSSED WITH THE DEPARTMENT LEGAL ADVICE AND OPINION.

MR. KLEIN: SO WE REALLY APPRECIATE YOU GETTING THERE SO WE CAN SOLVE THESE PROBLEMS EARLY AND HAVE GREAT COORDINATION, SO THIS IS VERY HELPFUL.

MR. AHMAD: OKAY GREAT. I WILL FOLLOW UP WITH DR. LOMAX, WHO WILL CONTINUE ON THAT ISSUE.

SO THE IRB REQUIREMENTS, THIS IS JUST REFRESHING YOU ALL FOR REMEMBERING, WRITTEN SUMMARY OF HEALTH RISKS, INFORMED CONSENT REQUIREMENTS, POSTPROCEDURE MEDICAL EXAMINATION, AND COVERAGE OF MEDICAL EXPENSES, THOSE THINGS TO BE APPROVED AND COVERED BY THE IRB ON ASSISTED OOCYTE PRODUCTION.

NOW, THE COMPONENTS OF THE WRITTEN RECORD OF SUBJECTS AND OOCYTES, A RESEARCH PROGRAM OR

PROJECT, THERE HAS BEEN A LOT OF DISCUSSION WHO SHOULD REPORT THIS FOR ASSISTED OOCYTE PRODUCTION. THE LAW SAYS THAT IT IS THE RESEARCH PROJECT OR THE PROGRAM. WE HAVE GOTTEN THE OPINION THAT IT SHOULD BE OKAY BECAUSE IF SCRO HAS GONE THROUGH THE RESEARCH PROJECT, THE SCRO COMMITTEES CAN REPORT ON THE ASSISTED OOCYTE PRODUCTION.

AND WHAT IS NEEDED IN THAT REPORT IS THE DEMOGRAPHICS OF THE SUBJECT, WHICH SAYS INCLUDING, BUT NOT LIMITED TO, THEIR AGE, RACE, PRIMARY LANGUAGE, ETHNICITY, INCOME BRACKET, EDUCATION LEVEL, AND THE FIRST THREE DIGITS OF THE ZIP CODE OF THE CURRENT RESIDENCE. SO THESE ARE SOME OF THE VARIABLES WHICH WE INCLUDED IN THE REPORTING FORMS.

SECOND, INFORMATION REGARDING EVERY OOCYTE, AGAIN, HERE THE WORD "EVERY" IS VERY IMPORTANT, THAT HAS BEEN DONATED OR USED. THIS RECORD SHOULD BE SUFFICIENT TO DETERMINE THE PROVENANCE AND THE DISPOSITION OF THOSE MATERIALS.

NUMBER THIRD, A RECORD OF ALL ADVERSE HEALTH OUTCOMES, INCLUDING, BUT NOT LIMITED TO, INCIDENCES AND DEGREES OF SEVERITY RESULTING FROM THE ASSISTED OOCYTE PRODUCTION OR ANY ALTERNATIVE METHOD OF OOCYTE RETRIEVAL.

SUBJECT PRIVACY PROVISIONS, THE HEALTH AND

SAFETY CODE 125342(B)(1), THE INFORMATION INCLUDED IN THE WRITTEN RECORD PURSUANT TO SUBDIVISION A SHALL NOT DISCLOSE PERSONALLY IDENTIFIABLE INFORMATION ABOUT SUBJECTS, AND SHALL BE CONFIDENTIAL, AND IS DEEMED PROTECTED BY SUBJECT PRIVACY PROVISIONS OF LAW.

THIS INFORMATION SHALL BE REPORTED TO THE STATE DEPARTMENT OF HEALTH SERVICES, NOW STATE DEPENDENT OF PUBLIC HEALTH, WHICH SHALL AGGREGATE THE DATA, SHALL AGGREGATE THE DATA AND MAKE IT PUBLICLY AVAILABLE, AND THE DEPARTMENT SHALL PROVIDE PUBLIC ACCESS TO THIS INFORMATION THROUGH THE CALIFORNIA PUBLIC RECORDS ACT. AND THIS IS SECTION 8 OF WHAT 1260 SAYS, THAT THIS ACT SHALL NOT BE CONSTRUED TO AMEND PROPOSITION 71 APPROVED BY THE VOTERS AT THE NOVEMBER 2, 2004, GENERAL ELECTION.

THIS IS JUST A SUMMARY, BUT I HAVE SAID THERE ARE SOME REQUIREMENTS FROM DEPARTMENT OF PUBLIC HEALTH, SOME FROM IRB, SOME FROM SCRO COMMITTEES, AND SOME FROM THE RESEARCHERS OF THE RESEARCH PROGRAMS.

THE PROCESS WE WENT THROUGH TO DEVELOP THESE TWO REPORTING FORMS WAS QUITE EXTENSIVE. THE FORMS WERE DRAFTED BASED ON INTERPRETATION OF THE STATUTES, AND THE DEPARTMENT OF PUBLIC HEALTH HUMAN

STEM CELL RESEARCH ADVISORY COMMITTEE MEETING WENT TO WORK ON THAT DRAFT, AND THERE WAS DISCUSSION OF THE REVISION OF THE FORMS. THERE WAS A SECOND COMMITTEE MEETING ON DECEMBER 2007 THAT ALSO INCLUDED THE PUBLIC COMMENTS, AND THE FORMS ARE FURTHER REVISED.

THE PUBLIC COMMENT PERIOD FROM DECEMBER TO JANUARY, WE RECEIVED MANY COMMENTS FROM UC, FROM STANFORD, FROM OTHER STAKEHOLDERS, AND WE HAD A GREAT DISCUSSION BACK AND FORTH WITH THOSE WHO PROVIDED US THE COMMENTS. AND THOSE COMMENTS WERE VERY SERIOUSLY CONSIDERED BY THE DEPARTMENT IN DEVELOPING THE FINAL FORM PROVIDED BY THE COMMITTEE.

THE FINAL REVIEW WAS GIVEN BY THE LEGAL SERVICES FROM THE DEPARTMENT, AND THE FORMS WERE BETA TESTED AT LEAST FROM TWO SITES. AND I WANT TO ACKNOWLEDGE DR. MARTINEZ-MASA FROM UCLA AS WELL AS DR. DAVID MAGNUS, WHO AT LEAST GAVE US SOME INPUT LIKE HOW FRIENDLY THESE FORMS ARE IN FILLING, WHAT ARE THE ISSUES, AND THEN MINOR REVISIONS WERE MADE BASED ON THEIR COMMENTS. AND FORMS WERE FINALIZED AND POSTED TWO OR THREE MONTHS AGO ON OUR WEBSITE.

SO THERE ARE TWO FORMS THAT HAVE BEEN DEVELOPED. ONE IS FROM THE -- THAT WOULD BE REPORTED BY THE SCRO COMMITTEE TO THE DEPARTMENT,

AND THE SECOND FORM -- AND THE FIRST FORM IS BASICALLY FOR HUMAN EMBRYONIC STEM CELL RESEARCH. AND THE SECOND FORM THAT IS RESEARCH INVOLVING OOCYTE RETRIEVAL. AND THAT HAS TO BE -- THE REPORT -- THE FORM NEED TO BE FILLED BY THE RESEARCH PROGRAM, RESEARCHER, OR THE SCRO COMMITTEE.

THE FORMS, WE HAVE THE HANDOUTS. I DON'T KNOW IF YOU HAVE WITH YOU AT THIS MOMENT. WE PUT SOME FORMS THAT WERE HERE. WE PROVIDED QUITE DETAILED INSTRUCTIONS LIKE WHAT IS THE STATUTORY AUTHORITY, REPORTING PERIOD BECAUSE THESE PROVISIONS WERE ENACTED FROM JANUARY 2007, AND THAT'S THE STARTING TIME FOR THE REPORTING ON STEM CELL RESEARCH PROJECTS, AS WELL AS ASSISTED OOCYTE PRODUCTION.

THE FIRST CYCLE OF REPORTING IS 18 MONTHS, AND THEN IT WOULD BE ON THE YEARLY BASIS FROM JULY 1ST TO JUNE 30TH EVERY YEAR. DUE DATE FOR THE FIRST REPORTING CYCLE IS AUGUST 1ST, AND WE HAVE RECEIVED AT LEAST FIVE OR SIX FORMS FILLED BY VARIOUS SCRO COMMITTEES AND INSTITUTIONS. THE FORMS HAVE SPECIAL EXCEL FEATURES. THEY'RE VERY USER FRIENDLY, AND THEY HAVE DROP MENUS, AND THERE ARE COMMENTS INCLUDED FOR THE DETAILS PROVIDED TO THE RESEARCHERS AND THE SCRO COMMITTEE MEMBERS SO THAT THERE ARE

DETAILS AVAILABLE. AND THE COMPLETE FORMS ARE SUBMITTED THROUGH THE STEM CELL@CDPH.CA.GOV ELECTRONICALLY.

THIS IS JUST ONE SNAPSHOT ON THE FORM 1. AND IT'S JUST RESEARCH PROTOCOL, I.D.; AND THEN IF YOU SEE NO. 3, THIS RESEARCH PROJECT INVOLVES, LIKE, RESEARCH OF HUMAN EMBRYONIC STEM CELL RESEARCH IN VITRO, IN VIVO, CREATION/DERIVATION OF HUMAN EMBRYONIC STEM CELLS OR CELL LINES, USE OF HUMAN OOCYTES FOR HESC RESEARCH, USE OF HUMAN EMBRYOS FOR HESC RESEARCH. SO THIS IS JUST A DESCRIPTION WHAT INVOLVES IN THE RESEARCH PROJECT.

AND EACH -- NOT EACH -- WHEREVER THERE IS A FORMAL DESCRIPTION NEEDED OR INSTRUCTIONS OR INFORMATION NEEDED, WE EMBEDDED COMMENTS FOR THAT PARTICULAR CELL.

SO THIS IS THE SECOND PAGE OF FORM 2 -- FORM 1.

THIS IS THE FORM 2, WHICH IS RESEARCH INVOLVING OOCYTE RETRIEVAL. AND THIS IS ON THE HORMONE TREATMENT (OOCYTE PRODUCTION/OVARIAN STIMULATION). AND WHAT IS --

MS. CHARO: SHOULD WE ASK A QUESTION WHILE YOU'RE GOING FORWARD? SO WHO'S FILLING OUT THIS FORM? IS IT THE STEM CELL PI, OR IS IT THE IVF DOC?

MR. AHMAD: THESE WOULD BE THE FORM FIRST WOULD BE FILLED BY THE SCRO COMMITTEE.

MS. CHARO: OKAY.

MR. AHMAD: THAT'S THE REQUIREMENT. THE STATUTE SAYING FOR FORM 2, WHICH IS FOR AOP, THAT SHOULD BE FILLED BY THE RESEARCH PROGRAM OR RESEARCHER.

MS. CHARO: BUT THE RESEARCHER WOULDN'T NECESSARILY BE ABLE TO ANSWER THESE QUESTIONS. SO NOW THE RESEARCHER HAS TO GO BACK TO THE ORIGINAL CLINIC, RIGHT?

MR. AHMAD: RIGHT. SO THERE HAS BEEN A LOT OF DISCUSSION ON THAT, AND THE ADVISORY COMMITTEE HAD A RECOMMENDATION THAT MAYBE THIS INFORMATION IS COMING, THE SCRO MAY -- AND SCRO MAYBE CAN'T FILL THESE FORMS, SO THAT'S A RECOMMENDATION WE ARE GOING WITH THE ADVISORY COMMITTEE.

AND AS THE STATUTE SAYS, THAT WHAT ARE THE UNTOWARD EFFECTS OF AOP, WHETHER THEY'RE MODERATE OR SEVERE, AND IF THERE ARE SOME SURGICAL OR CLINICAL INDICATIONS FOR OOCYTE RETRIEVAL LIKE VAGINAL BLEEDING, INTRA-ABDOMINAL BLEEDING, INTESTINAL INJURIES, INFLAMMATION, ALL THOSE.

SO JUST TO GIVE YOU -- SUMMARIZE, WE

STARTED WITH VERY ELABORATE REQUIREMENTS BASED ON JUST INITIAL EFFORT; BUT AFTER MULTIPLE REVISIONS AND REVIEWS AND PUBLIC COMMENTS, WE TRIED TO HAVE A BALANCE BY WHICH THERE IS IMPLEMENTATION OF THESE STATUTES, BUT AT THE SAME TIME IT DOES NOT IMPEDE ANY RESEARCH. WE WERE VERY MUCH CAREFUL ABOUT THAT ISSUE, THAT WE DO NOT OVERBURDEN.

AGAIN AND AGAIN IN THE PUBLIC COMMENTS, THE ISSUE CAME OF THE BURDEN OF IT, THAT WE DO NOT IMPOSE THROUGH THESE STATUTES ON THE SCRO COMMITTEES OR ON THE RESEARCHERS BECAUSE OF MULTIPLE LAYERS OF REPORTING BY THESE CLINICIANS OR THESE COMMITTEES OR MEMBERS. SO WE KEPT IT TO THE MINIMUM WHAT IS REQUIRED BY LAW THAT WAS INCLUDED.

SO I WOULD END WITH THAT. THESE FORMS, THIS IS THE FIRST YEAR. AND WE WOULD LEARN FROM THE PROCESS. IF THERE ARE SOME DIFFICULTIES OR THERE ARE FURTHER COMMENTS OF CONCERN FROM THE RESEARCHERS, SCRO COMMITTEES, I THINK THAT WE WILL COLLECT THOSE, WE WILL PUT FORWARD IN FRONT OF THE ADVISORY COMMITTEE. AND IF THERE IS A NEED TO REVISE THESE FORMS FURTHER, WE WILL -- WE ARE OPEN TO THAT. AND WE ARE ALSO STARTING THE PROCESS BY WHICH THESE FORMS WOULD BE PROMULGATED THROUGH REGULATIONS.

MS. CHARO: MR. CHAIR, ANOTHER QUESTION ABOUT THE REPORTING. SO I'M GOING TO PRESUME THAT ALL OF THE WOMEN WHO ARE BEING RECRUITED TO DONATE OOCYTES UNDER THIS SYSTEM ARE CONSENTING TO HAVE ALL OF THIS MEDICAL INFORMATION FORWARDED ONTO INVESTIGATORS, TO STATE COMMITTEES, AND OTHER BODIES RIGHT. SO I GUESS THE FIRST QUESTION IS HOW IS THE MEDICAL CONFIDENTIALITY MANAGED?

AND SECOND, IS THIS INFORMATION ACTUALLY PUT INTO HER MEDICAL RECORD, WHICH WOULD RAISE QUESTIONS ABOUT PREEXISTING CONDITION REPORTING TO INSURANCE COMPANIES AND SUCH? I KNOW WE'RE CONCERNED ABOUT THE MEDICAL RISKS OF OOCYTE DONATION, BUT IN SOME WAYS THE FINANCIAL RISKS MIGHT ACTUALLY EXCEED THE MEDICAL RISKS.

MR. KLEIN: I THINK THIS IS A VERY IMPORTANT ISSUE THAT DR. CHARO IS RAISING. WE'VE BEEN TRYING TO BE VERY CAREFUL ABOUT HIPAA. WE'VE BEEN TRYING TO BE VERY CAREFUL ABOUT NOT PREJUDICING THE MEDICAL RECORD OF THE WOMAN THAT'S INVOLVED. AND HAVING THIS LEVEL OF DETAIL DISTRIBUTED TO ANOTHER INSTITUTIONAL LEVEL IS A REAL RISK ISSUE FOR THE WOMEN INVOLVED. SO THIS RAISES A CONCERN.

MR. AHMAD: WE WENT TO OUR LEGAL AS WELL AS OUR PRIVACY OFFICIALS, AND THEY ARE -- THEY'RE

COMFORTABLE THAT THIS INFORMATION COMING TO THE DEPARTMENT. BUT THROUGH THE STATUTE, DEPARTMENT IS REQUIRED TO MAKE EVERY EFFORT TO NOT RELEASE ANY IDENTIFIABLE INFORMATION. RATHER, THE FORWARDING OF THE (UNINTELLIGIBLE) THAT WOULD BE PROVIDED TO THE LEGISLATURE OR TO THE PUBLIC, THAT WOULD BE AGGREGATE DATA, AND THE DEPARTMENT WILL TAKE EVERY -- MAKE EVERY EFFORT TO NOT INCLUDE ANY IDENTIFIABLE INFORMATION REGARDING THE INSTITUTION OR RESEARCHER OR THE SUBJECT WHO IS DONATING EGG FOR RESEARCH PURPOSES.

AND I SEE THAT THERE IS ALWAYS A POSSIBILITY, BUT THE WAY WE ARE PROVIDING THIS INFORMATION, LIKE, THROUGH ELECTRONIC SUBMISSION DIRECTLY TO THE DEPARTMENT WAS ONE WAY OF SAFEGUARDING INFORMATION COMING FROM SCRO COMMITTEES TO THE DEPARTMENT, YES.

MR. KLEIN: SO DOES THE PUBLIC INFORMATION ACT GIVE ACCESS TO INFORMATION IN THE ESCRO COMMITTEE IN CALIFORNIA THROUGH THE PUBLIC RECORDS ACT?

MR. AHMAD: I CANNOT SPEAK TO THAT, BUT I CAN --

MR. KLEIN: THE REASON I'M RAISING THAT QUESTION IS AT THE ESCRO ON SPECIFIC GRANTS, IF YOU

HAVE THAT DETAILED INFORMATION, YOU COULD POTENTIALLY THEN RELATE IT BACK TO THE PERSON.

MR. AHMAD: I SEE YOUR POINT. I THINK THAT'S WHAT'S CONCERNING TO LEGAL COUNSEL, THIS ISSUE.

MR. KLEIN: AND, MR. CHAIRMAN, MAYBE THE RESEARCH INSTITUTIONS THAT ARE HERE COULD COMMENT ON THIS.

CHAIRMAN LO: OKAY. ALTHOUGH THESE ARE REALLY STATE REGULATIONS, I'D RATHER THEY BE RAISED AT A STATE MEETING.

MR. KLEIN: WELL, THEY'RE GOING TAKING THE POSITION CURRENTLY THAT THEY APPLY TO ANY GRANT THAT WE DON'T FUND FULLY, WHICH, WHILE WE CLEARLY DISAGREE WITH THAT POSITION, I'D LIKE TO UNDERSTAND WHAT THE RESEARCH INSTITUTIONS FEEL ABOUT THE ISSUES RAISED BY DR. CHARO WITH THE PRIVACY ISSUES AND PROTECT HER CONDITIONS, MEDICAL RECORDS AND OTHER COMPLICATIONS DISPLAYED FROM THE DATA. I THINK WE HAVE SOME RESEARCH INSTITUTIONS HERE.

CHAIRMAN LO: UCLA, UCSF, UCSD.

DR. PECKMAN: ON BEHALF OF UCLA, WE'D SAY THAT CALIFORNIA DEPARTMENT OF PUBLIC HEALTH HAS COME A LONG WAY IN THIS PROCESS AND CAREFULLY CONSIDERED COMMENTS FROM US AND UC SAN DIEGO AND STANFORD

UNIVERSITY. ALL THREE ACADEMIC CENTERS VOICED GREAT CONCERNS ABOUT THE CONFIDENTIALITY OF PATIENTS IN THIS REPORTING PROCESS. SO THE FORMS ARE WHAT WE'VE BEEN ASKED TO COMPLETE BY STATE LAW BY THE DATE PROVIDED, AND WE'LL COMPLY WITH THE LAW.

I'LL SAY THIS ABOUT PUBLIC RECORDS ACT, WHICH IS, AS IT RELATES TO IRB'S, IT DOES NOT COMPEL THE IRB'S TO PROVIDE IDENTIFIABLE INFORMATION ABOUT SUBJECTS. SO I WOULD ASSUME THAT THAT COULD BE EXTRAPOLATED TO SCRO'S AS WELL. BUT WE HAVE BEEN VERY CONCERNED ABOUT THE IDENTIFIERS REQUESTED IN THAT REPORTING, SO THE PORTION OF ZIP CODE, OTHER ELEMENTS, ALL COMBINED WITH CERTAIN AREAS WITHIN THE STATE COULD CERTAINLY LEAD TO IDENTIFYING POTENTIAL PATIENTS OR PATIENTS WHO HAVE PARTICIPATED IN OOCYTE PRODUCTION FOR RESEARCH. AND WE ASKED FOR AN INDEPENDENT ASSESSMENT OF THOSE IDENTIFIERS AND WHETHER THEY COULD BE ATTACHED TO SPECIFIC INDIVIDUALS, AND WE HAVEN'T RECEIVED RESPONSE ON THAT COMMENT.

MR. KLEIN: THANK YOU.

CHAIRMAN LO: THERE IS A WAY, BY THE WAY, OF ASKING -- YOU KNOW, UNDER HIPAA THERE'S A WAY OF GETTING A BIOSTATISTICAL CONSULTATION ON THE LIKELIHOOD OF REIDENTIFYING FROM IDENTIFIERS. AND

IT SEEMS TO ME GIVEN THE IMPORTANCE OF CONFIDENTIALITY, THIS IS AN EXTREMELY PERSONAL, PRIVATE SENSITIVE ISSUE, THAT I THINK THE COMMENTS THAT PROFESSOR CHARO, PRESIDENT KLEIN, AND OTHERS HAVE RAISED IS REALLY IMPORTANT. IT'S PSYCHOSOCIAL. IT'S REALLY A RISK TO SOMEONE.

DR. KIESSLING: THIS IS AN EXTRAORDINARY AMOUNT OF INFORMATION TO BE REPORTING TO A STATE AGENCY ABOUT A RESEARCH PROJECT. AND I'M WONDERING IF -- AND I'M NOT FAMILIAR WITH THE CALIFORNIA SYSTEM. DOES CALIFORNIA AS A STATE GRANT RESEARCH GRANTS IN ANY OTHER AREA OF RESEARCH? DOES CALIFORNIA HAVE A BREAST CANCER FUNDING PROGRAM? DOES IT HAVE A PROSTATE CANCER FUNDING PROGRAM?

DR. PECKMAN: UNIVERSITY OF CALIFORNIA DOES.

DR. KIESSLING: WHAT OTHER STATE --

MS. CHARO: I THINK THE STATE ACTUALLY DOES HAVE A BREAST CANCER RESEARCH PROJECT.

MR. AHMAD: THERE ARE STATE PROGRAMS WHO FUND RESEARCH, BUT ON THE STEM CELL --

DR. KIESSLING: NO. NO. NO. THE STATE PROGRAMS THAT FUND RESEARCH ON --

MR. AHMAD: LIKE OFFICE OF AIDS PROBABLY THROUGH THE UC COLLABORATION PERFORMED RESEARCH.

DR. KIESSLING: WHAT KINDS OF REPORTING REQUIREMENTS DOES THE DEPARTMENT OF PUBLIC HEALTH ASK OF THOSE PROGRAMS? DOES IT EVEN APPROACH THIS LEVEL OF DETAIL?

MR. AHMAD: IN THIS SPECIAL CASE, THIS IS, OF COURSE, THE ACTIONS, WHAT IS IN THE STATUTE, WE HAVE TO FOLLOW. THEY MAY NOT BE STATUTE FOR THE RESEARCH, LET'S SAY, FOR STATE-FUNDED CANCER RESEARCH OR STATE-FUNDED AIDS RESEARCH, BUT IN THIS SPECIFIC CASE, WE ARE GIVEN THE RESPONSIBILITY BY LAW TO HAVE THAT INFORMATION. AND THOSE VARIABLES WHICH WE ARE ASKING, THEY ARE ACTUALLY SPECIFIED IN THE LAW.

DR. KIESSLING: BUT, NOW, IS THIS STATUTE? IS THIS PROPOSITION 71? IS THAT THE STATUTE YOU'RE REFERRING TO?

MR. AHMAD: THIS IS STATE HEALTH AND SAFETY CODE, YES.

DR. KIESSLING: AND SO THAT STATUTE APPLIES SPECIFICALLY TO STEM CELL RESEARCH?

MR. AHMAD: YES. YES.

DR. KIESSLING: SO THIS IS A NEW LEVEL PF REPORTING REQUIRED OF STEM CELL RESEARCH THAT'S DIFFERENT FROM ALL OTHER STATE-FUNDED RESEARCH ACTIVITIES. YOU HAVE AN EXPLANATION FOR THAT?

MR. KLEIN: DR. KIESSLING, THIS IS -- THAT ACT SAYS SPECIFICALLY NOT TO AMEND, MODIFY, OR CHANGE ANY PORTION OF PROP 71. SO IT IS NOT INTENDED TO CHANGE WHAT WE THINK IS EXCLUSIVE JURISDICTION WHERE ANY OF OUR RESEARCH FUNDS ARE CONTROLLED. BUT I'M JUST NOW LEARNING THAT THERE IS A DIFFERENT LEGAL OPINION OUT THERE WHICH WOULD BE REALLY PROBLEMATIC BECAUSE IT WOULD MEAN OUR GRANTEES WOULD HAVE TO RESPOND TO MULTIPLE STANDARDS, WHICH, OF COURSE, DOESN'T WORK. SO WE'RE GOING TO HAVE TO RESOLVE THIS ON AN EXPEDITED BASIS.

DR. KIESSLING: THIS IS JUST AN EXTRAORDINARY AMOUNT OF INFORMATION THAT NEEDS TO BE REPORTED. I'M UNFAMILIAR WITH THE STATUTE THAT YOU'RE TALKING ABOUT. I WOULD BE VERY INTERESTED IN THE MOTIVATION BEHIND IT.

CHAIRMAN LO: THE PUBLIC MOTIVATION FOR THAT WAS TO PROTECT WOMEN WHO ARE DONATING OOCYTES FOR RESEARCH, STEM CELL RESEARCH.

DR. TAYLOR: BERNIE AND SHERRY AND BOB, I WOULD SUSPECT THAT THERE MAY BE SOME INTELLECTUAL PROPERTY ISSUES ASSOCIATED WITH THIS AS WELL. YOU KNOW, THE PRIVACY ISSUES ARE PARAMOUNT, BUT I THINK THIS COULD ALSO SORT OF HAVE A CHILLING EFFECT AROUND SOME OTHER ASPECTS OF WHAT WE'RE TRYING TO

ACCOMPLISH.

CHAIRMAN LO: I WANT TO THANK DR. AHMAD FOR COMING AND UPDATING US ON THE REPORTING REQUIREMENTS. PUBLIC COMMENTS. AND IF THERE ARE COMMENTS -- I WANT TO KEEP THE COMMENTS FOCUSED ON THE CIRM ASPECT BECAUSE THERE'S OBVIOUSLY A LOT OF DISCUSSION WITH DEPENDENT OF PUBLIC HEALTH. THANK YOU VERY MUCH.

MR. KALICHMAN: MIKE KALICHMAN, UC SAN DIEGO. JUST A BRIEF COMMENT. I AGREE WITH EVERYTHING STEVE PECKMAN SAID, AS I ALMOST ALWAYS DO. BUT RELATIVE TO CIRM, PARTICULARLY BECAUSE THIS PARTICULAR REQUIREMENT OVERLAPS CIRM FUNDING, I WANT TO PERHAPS ENCOURAGE CIRM TO THINK ABOUT SUGGESTING OTHER WAYS THAT STATE REQUIREMENT CAN BE MET. WHAT WE SEE IN THIS KIND OF INVASIVE QUESTIONING IS AN ATTEMPT TO GET INFORMATION THAT MIGHT BE USEFUL, BUT IT LOOKS MORE LIKE A RESEARCH PROJECT. THIS IS PART OF THE COMMENTS I SENT INTO THE STATE. LOOKS MORE LIKE A RESEARCH PROJECT THAT NEEDS TO BE DESIGNED PROPERLY THAN A PROJECT THAT WILL BE USEFUL FOR HELPING THE STATE UNDERSTAND WHAT'S HAPPENING. AND THERE MIGHT BE OTHER WAYS TO GET THIS INFORMATION INSTEAD OF ASKING INSTITUTIONS TO REVEAL WHAT IS CLEARLY PRETTY INVASIVE INFORMATION.

I HAVE ALMOST NO DOUBT AT ALL THAT WHAT WE HAVE HERE IS IDENTIFIABLE INFORMATION IN MANY CASES THAT YOU COULD TRACK BACK TO AN INDIVIDUAL. THIS IS A PERSONAL COMMENT CONCERNING UC SAN DIEGO BECAUSE WE ARE NOT YET DEALING WITH OOCYTE DONATION IN OUR RESEARCH PROJECTS.

CHAIRMAN LO: THANKS.

MR. AHMAD: I JUST WANT TO ADD ONE COMMENT. DR. LO INDICATED THAT WE NEED TO CONSULT SOME BIOSTATISTICIAN. IT'S OUR INTENT AT THIS MOMENT, IF THERE IS A NUMBER OF -- ESPECIALLY ON THE IRB, IF THERE ARE REPORTS LESS THAN FIVE, FIVE OR LESS THAN FIVE, WE WOULD NOT AGGREGATE THE DATA, AND THAT WE WILL NOT REPORT IT BECAUSE OF THE POSSIBILITY OF IDENTIFYING THE INDIVIDUAL. IF IT IS BEYOND THAT NUMBER, NOW, FIVE IS THE ONE USED BY BIOSTATISTICIANS. IF A CELL HAS, LET'S SAY, AN INDIVIDUAL OF FOUR, THREE, TWO, THAT CELL IS MASKED AND THAT INFORMATION IS NOT PROVIDED. THAT'S THE PRACTICE.

SO WE ARE LOOKING INTO WHAT SHOULD BE THE MINIMUM NUMBER UNDER WHICH THAT AGGREGATION OF THE DATA WOULD NOT BE DONE AND WOULD NOT BE REPORTED. SO WE DID NOT DETERMINE THAT NUMBER YET, BUT THAT IS SUBJECT TO DISCUSSION AT THE ADVISORY COMMITTEE.

CHAIRMAN LO: ALTA.

MS. CHARO: WELL, FOCUSING ON CIRM FOR WHICH THE INFORMATION IS BEING DEVELOPED SO THAT, NOT THAT YOUR PROGRAM IS CONCERNED, BUT CIRM ITSELF IS VERY INTERESTED IN UNDERSTANDING AT ALL TIMES THE MOST UP-TO-DATE INFORMATION ABOUT RISKS ASSOCIATED WITH HYPERSTIMULATION.

ONE THING THAT I WORRY ABOUT IS THAT IT'S STILL SUCH AN INFREQUENT ACTIVITY IN THE CONTEXT OF RESEARCH, THAT EVEN WITH ALL OF THIS INFORMATION, THERE WILL NOT BE A DATA COLLECTION LARGE ENOUGH FROM WHICH ONE COULD DRAW STATISTICALLY SIGNIFICANT CONCLUSIONS. AND ALTHOUGH I HAVE NO CONTROL OVER HOW THE STATE PROCEEDS, IT DOES STRIKE ME THAT IN THE FUTURE, IF PEOPLE WERE RETHINKING THIS, AN ALTERNATIVE WAY OF GENERATING VALUABLE INFORMATION IS TO WORK THROUGH THE FDA'S ADVERSE EVENT REPORTING SYSTEM, WHICH ALREADY EXISTS AND WHERE THE FDA IS NOW FINALLY FRESHLY FOCUSED ON POSTMARKETING SURVEILLANCE, TO WORK WITH THE PHYSICIANS WHO ARE LEADERS OF THE IVF CLINICS THROUGHOUT THE STATE TO MORE COMPLETELY TRACK AND REPORT ADVERSE EVENTS ASSOCIATED WITH THE DRUGS THAT THEY'RE USING.

THAT DATA COULD INCLUDE CLINICAL STIMULATIONS AS WELL AS RESEARCH-ORIENTED ONES MIGHT

GENERATE ENOUGH DATA THAT IT WOULD BE USEFUL FOR CIRM AS WELL AS BEING, INCIDENTALLY, USEFUL FOR THE DRUG MANUFACTURERS, THE FDA, AND THE INFERTILITY COMMUNITY IN GENERAL.

SO I UNDERSTAND THAT THIS IS A SEPARATE EFFORT, BUT I DO FIND MYSELF WONDERING IF IT WOULD BE CAPABLE OF GENERATING ENOUGH INFORMATION THAT'S USABLE TO ACCOMPLISH ALL THE PURPOSES TO WHICH CIRM WOULD LIKE TO PUT IT.

DR. TAYLOR: YOU'RE RIGHT. YOU'D HAVE A DENOMINATOR AS WELL AS A NUMERATOR WITH THAT APPROACH.

MR. KLEIN: AND, BERNIE, I'D JUST LIKE TO INDICATE MY COMMENTS WERE IN THE CONTEXT OF, A, CLEARLY A HUGE AMOUNT OF EFFORT HAS BEEN PUT INTO THIS, VERY THOUGHTFUL EFFORT, VERY SENSITIVE EFFORT. THE ISSUE IS THAT THERE MAY BE A LEVEL WHERE THE GOALS OF THIS REPORTING FLY IN THE FACE OF OTHER POLICIES THAT YOU HAVE NOT BEEN DIRECTED TO NECESSARILY WEIGH. WE ARE WEIGHING THOSE POLICIES, AND WE NEED TO SIT DOWN WITH YOU BECAUSE YOU'RE TRYING TO DO A FABULOUS JOB FOR THE STATE. WE'RE TRYING TO DO A FABULOUS JOB FOR THE STATE. AND WE HAVE THE SAME GOALS, SO WE REALLY NEED TO SIT DOWN TOGETHER.

MR. AHMAD: I THINK THAT THAT'S A VERY GOOD SUGGESTION THAT WE CAN HAVE BOTH THE STANDARDS SUBGROUP OR FROM HERE SOME MEMBERS AND WORKING WITH THE DEPARTMENT OF PUBLIC HEALTH ADVISORY COMMITTEE MEMBERS AND SORT OUT SOME OF THE ISSUES WHICH ARE MUTUALLY IMPEDING RESEARCH OR THEY ARE PROBLEMATIC OR THEY NEED TO BE ADDRESSED FOR THE PURPOSE OF LEGAL REASONS OR SOME OTHER REASON, PRIVACY REASONS. AND, OF COURSE, ANY RECOMMENDATIONS COMING FROM A JOINT EFFORT WOULD BE SUBJECT TO PUBLIC COMMENTS, PUBLIC PARTICIPATION, AND PUBLIC INPUT. I THINK THAT'S A GOOD IDEA.

DR. CSETE: I'D JUST LIKE TO SAY SOMETHING THAT IN OUR INTEREST IN FACILITATING RESEARCH, YOU DON'T WANT TO OVERBURDEN THE SCRO COMMITTEES WHO ARE UNPAID VOLUNTEERS WITH INFORMATION THAT'S NOT GOING TO HAVE A LOT OF UTILITY. SO I THINK IN THE THOUGHT PROCESSES THAT GO INTO THIS, SIMPLIFICATION SHOULD BE A BIG PART OF THE FOCUS.

DR. PECKMAN: I KNOW YOU WANT TO WRAP THIS UP, BUT WITH THE SUGGESTION OF GROUPING TOGETHER CIRM AND CALIFORNIA DEPARTMENT OF PUBLIC HEALTH ADVISORY COMMITTEES TO LOOK AT THIS EFFORT MORE IN-DEPTH, I WOULD STRONGLY SUGGEST, I THINK I CAN SPEAK ON BEHALF OF SAN DIEGO AND STANFORD, THAT YOU

INCLUDE MEMBERS ON THOSE -- ON THAT COMMITTEE WHO ACTUALLY DO THE WORK AND ARE INVOLVED ON THE GROUND LEVEL WHO CAN PROVIDE SOME INSIGHT INTO THE PLANNING PROCESS.

MR. KLEIN: AND FOR THE RECORD, IF YOU COULD JUST REPEAT FOR THE TRANSCRIPTED RECORD YOUR NAME AND YOUR ASSOCIATION.

DR. PECKMAN: STEVE PECKMAN, UCLA.

CHAIRMAN LO: WE CAN SEE YOU, BUT THE --

DR. PECKMAN: I UNDERSTAND.

CHAIRMAN LO: WITH THAT, THANK YOU AGAIN TO THE CALIFORNIA DEPARTMENT OF HEALTH.

I ACTUALLY WANT TO CONGRATULATE THE SWG ON WHAT I THOUGHT WAS A VERY STIMULATING AND, I THINK, PRODUCTIVE MEETING. I THINK WE GOT THROUGH SOME DIFFICULT ISSUES AND SORT OF MADE SOME VERY THOUGHTFUL DECISIONS AND ALSO HAVE THINGS FOR THE FUTURE. I THINK WE GAVE OURSELVES CHALLENGES WHICH GEOFF AND STAFF WILL HELP US TO ADDRESS IN THE FUTURE. I WANTED TO THANK YOU ALL FOR YOUR THOUGHTFULNESS.

AND I WILL BE GLAD TO ENTERTAIN A MOTION TO ADJOURN.

MS. LANSING: WELL, I MOVE WE ADJOURN. AND I ALSO WANT TO THANK BERNIE. YOUR LEADERSHIP IS

ALWAYS EXTRAORDINARY, AND THE THOUGHTFUL AND COLLABORATIVE WAY YOU BUILD CONSENSUS IS JUST REMARKABLE AND FUN TO PARTICIPATE IN.

I ALSO WANT TO THANK ALL THE MEMBERS OF COMMITTEE FOR THE COUNTLESS HOURS THAT THEY SPENT HERE AND THE THOUGHTFUL AND COLLEGIAL WAY WE ALL WORK TOGETHER. AND THE MEMBERS OF THE PUBLIC, WHO ONCE AGAIN, PROVE THAT YOUR INPUT WAS TERRIFIC IN GETTING US TO ADDRESS AN ISSUE THAT WE HAD QUITE HONESTLY NOT TAKEN SUFFICIENT THOUGHT.

MR. KLEIN: AND, SHERRY, I THINK THAT THIS WHOLE WORKING GROUP WAS DRAWN TOGETHER WITH PAT BECKER DOING ALL THE LOGISTICS, COORDINATION BRINGING THIS EXTRAORDINARY GROUP TOGETHER, AND THE PATIENT INTERFACE, WHICH I THINK MELISSA HAS BEEN SUPPORTING MATERIALS TO GET ALL OF US AS PATIENT ADVOCATES UP TO SPEED AS WE WENT FORWARD. SO WE REALLY OWE A GREAT DEAL OF THANKS TO THE STAFF ALONG WITH TAMAR PACHTER, MARIE CSETE, ALAN TROUNSON. BUT WE ALSO, I DON'T THINK, HAVE GIVEN A HAND OF APPLAUSE TO OUR SPECIAL GUESTS WHO PROVIDED THEIR TESTIMONY THROUGH TODAY AND THAT MIGHT BE APPROPRIATE.

(APPLAUSE.)

CHAIRMAN LO: BEFORE WE DO THAT, I ALSO

WANTED TO THANK GEOFF LOMAX FOR HIS VERY THOUGHTFUL ANALYSIS. AND ACTUALLY SHERRY IS FAR TOO MODEST. I MEAN SHE'S REALLY BEEN THE ONE TO SORT OF GET THE ISSUES -- SHE HAS THAT WONDERFUL WAY TO SORT OF DRILL DOWN TO THE CORE ISSUES AND REALLY GET PEOPLE TO ARTICULATE THEIR CONCERNS AND THEN ADDRESS THEM IN A WAY. I JUST THINK IT'S MARVELOUS TO WORK WITH YOU, SHERRY. SO WITH THAT DO I HAVE A SECOND?

MS. FEIT: SECOND.

CHAIRMAN LO: SECOND. THANK YOU, EVERYONE. SAFE TRAVELS HOME.

(THE MEETING WAS THEN ADJOURNED AT 3:09 P.M.)

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 INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

LUXE HOTEL
11461 W. SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA
ON
FRIDAY, JULY 25, 2008

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE DIGITALLY RECORDED AND THEN 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 BRISTOL STREET
SUITE 100
COSTA MESA, CALIFORNIA
(714) 444-4100