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

REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: JULY 24, 2013
10 A.M.

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

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I N D E X

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SAN FRANCISCO, CALIFORNIA; JULY 24, 2013

12 P.M.

DR. LOMAX: WHY DON'T WE START WITH ROLL. IT'S ONLY ONE PERSON WHO'S RESPONDED THAT I KNOW IS NOT HERE ON-SITE, BUT HOPEFULLY TED PETERS WILL BE ARRIVING SHORTLY.

SHERRY LANSING.

MS. LANSING: HERE.

DR. LOMAX: BERNARD LO.

CHAIRMAN LO: HERE.

DR. LOMAX: JEFF BODKIN.

DR. BODKIN: HERE.

DR. LOMAX: MARCY FEIT. TIM KAMP.

DR. KAMP: YES.

DR. LOMAX: ANN KIESSLING. KEN OLDEN. FRANCISCO PRIETO.

DR. PRIETO: HERE.

DR. LOMAX: TED PETERS.

DR. PETERS: TED PETERS IS HERE, YES, ON THE PHONE.

DR. LOMAX: OH, TERRIFIC. DOROTHY ROBERTS.

DR. ROBERTS: YES. I'M HERE ON THE PHONE.

DR. LOMAX: TERRIFIC.

JEFF SHEEHY.

MR. SHEEHY: HERE.

DR. LOMAX: PAT TAYLOR. ROBERT TAYLOR.

DR. TAYLOR: HERE.

DR. LOMAX: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

DR. LOMAX: JOHN WAGNER.

OKAY. WE MAY HAVE A COUPLE OF FOLKS JOINING US.

CHAIRMAN LO: OKAY. I WOULD BE INCLINED TO -- LET'S GO AHEAD AND START SINCE WE'RE A LITTLE BEHIND OUR ORIGINAL AGENDA.

I FIRST WANT TO JUST WELCOME EVERYBODY. THANK YOU FOR PARTICIPATING AND SORT OF INTERRUPTING YOUR SCHEDULE. THIS IS AN IMPORTANT ISSUE THAT OUR ADVICE WILL BE IMPORTANT FOR THE ICOC AS IT CONSIDERS IT. AND SO I WANT TO JUST SORT OF MOVE INTO IT AND FIRST START BY ASKING SHERRY TO SORT OF GIVE US A CONTEXT AND HISTORY HOW THIS FITS IN WITH WHAT THE SWG HAS DONE IN THE PAST. SHERRY.

MS. LANSING: SURE. THANK YOU, BERNIE. AND I TOO WANT TO WELCOME EVERYBODY AND TELL YOU HOW NICE IT IS TO HEAR SOME OF YOUR VOICES AGAIN. IT'S BEEN A LONG TIME SINCE I'VE SEEN YOU IN PERSON, BUT I REALLY APPRECIATE YOUR CONSISTENT INVOLVEMENT IN

THIS COMMITTEE AND YOUR CONSISTENT COMMITMENT TO IT.

I THINK, AS ALL OF YOU REMEMBER, WHEN WE FIRST FORMED THIS COMMITTEE, AND A LOT OF YOU WERE THERE IN THE BEGINNING, WE ALWAYS SAID THAT WE WERE A WORK IN PROGRESS, THAT WE WERE GOING TO MAKE RECOMMENDATIONS AND GUIDELINES, BUT THAT WE WERE GOING TO CONTINUALLY BE REVISITING THEM AS THE SCIENCE DEVELOPS AND AS THE PUBLIC VIEWS CHANGE ON THESE MATTERS.

AND TODAY IS SUCH AN EXAMPLE. I WANT TO REMIND ALL OF YOU THAT THROUGHOUT OUR HISTORY WE HAVE BEEN COMMITTED TO THE MEDICAL SAFETY OF WOMEN WHO ARE DONATING OOCYTES FOR RESEARCH. AND WE'VE BEEN COMMITTED TO THEIR INFORMED CONSENT TO PARTICIPATE OR NOT IN RESEARCH INVOLVING THESE DONATIONS. AND WE'VE ALSO BEEN COMMITTED TO AVOIDING ANY UNDUE FINANCIAL INDUCEMENTS TO RESEARCH SUBJECTS AND, IN FACT, WE HAVE NOT PAID THEM AT ALL. AND AFTER I'M DONE SPEAKING, BERNIE AND GEOFF WILL GO THROUGH ONCE AGAIN IN EVEN MORE DETAILS THE REGULATIONS AND GUIDELINES THAT HAVE IMPLEMENTED THIS COMMITMENT.

AND TODAY WE ARE NOT REALLY GOING TO RECOMMEND ANY SUBSTANTIAL CHANGES TO THAT COMMITMENT. BUT, AS I SAID EARLIER, WE'RE GOING TO

RECONSIDER SOME OF OUR RECOMMENDATIONS BECAUSE THE SCIENCE HAS CHANGED AND THE PUBLIC VIEW IN OTHER STATES HAS ALSO CHANGED AND ALSO BECAUSE WE HAVE A UNIQUE OPPORTUNITY TODAY TO ADVANCE THE SCIENCE.

SO TODAY WE'RE GOING TO LOOK AT THE DERIVATION OF LINES THROUGH SCNT AND WE'RE GOING TO LOOK AT THE BREAKTHROUGH IS BEING OFFERED TO US IN AN EXCITING OPPORTUNITY TO INFORM STEM CELL RESEARCH THAT'S TAKING PLACE IN CALIFORNIA. WE'RE GOING TO LOOK AT SOME OF THESE NEW LINES THAT HAVE THE POTENTIAL TO ADVANCE CIRM'S MISSION. AND DR. TROUNSON IS GOING TO TALK TO YOU TODAY ABOUT SOME OF THE SCIENTIFIC IMPLICATIONS THAT THESE NEW LINES WILL HAVE FOR US.

NOW, THIS SITUATION IS A UNIQUE ONE BECAUSE THESE LINES WERE DERIVED FROM OOCYTES FROM WOMEN WHO GAVE INFORMED CONSENT TO DERIVE THESE SCNT LINES FOR RESEARCH PURPOSES AND NOT TO ASSIST A WOMAN IN INFERTILITY TREATMENT. BUT THESE DONORS WERE PAID. AND THAT IS THE ONLY EXCEPTION THAT THE OREGON PROTOCOL IS DIFFERENT IN THE SENSE THAT THESE DONORS WERE PAID. BUT OTHER THAN THAT, THE WAY THAT THESE WOMEN GAVE THEIR INFORMED CONSENT, THE WAY THAT THEY DID REACH THEIR CONCLUSION MEETS AND IN SOME CASES ACTUALLY EXCEEDS, AND THIS IS VERY

IMPORTANT FOR YOU TO HEAR, ALL OF CIRM'S REQUIREMENTS.

NOW, PROP 71, WE ALL KNOW, FORBIDS CIRM FROM PAYING FOR ANY OOCYTE DONATIONS. SO I WANT TO BE CLEAR, AND THIS IS VERY IMPORTANT, THAT NO CIRM FUNDING WAS INVOLVED IN THESE LINES. SO THE ESSENTIAL QUESTION THAT WE ARE ASKING TODAY OR WE ARE CONSIDERING IS WHETHER CIRM FUNDS MAY BE USED FOR RESEARCH USING STEM CELL LINES WHICH WERE ALREADY DERIVED FROM WOMEN PAID AS PART OF DONATING THESE OOCYTES FOR RESEARCH.

I THINK THAT PRETTY MUCH SUMS IT UP. AND SO UNLESS THERE ARE ANY QUESTIONS, WHICH I KNOW THERE ARE GOING TO BE A LOT OF AND A LOT OF HEALTHY DISCUSSION, I'D LIKE TO TURN IT BACK TO YOU, BERNIE.

DR. LOMAX: WE HAVE YOU, SHERRY. HANG ON. BERNIE, ARE YOU ON THE LINE?

CHAIRMAN LO: SORRY. I HAD MY MUTE BUTTON ON.

MS. LANSING: WELL, I HOPE I EXPLAINED THE CONTEXT FOR IT.

CHAIRMAN LO: YOU WERE WONDERFUL.

MS. LANSING: NO, IT'S NOT WONDERFUL. BUT ANYWAY, THIS IS PART OF OUR CONTINUING PROCESS, AND I THINK WE'RE LOOKING FOR AN EXCEPTION. AND WE NEED

TO DISCUSS THIS THOROUGHLY. SO I'M NOW GOING TO TURN IT BACK TO YOU.

CHAIRMAN LO: OKAY. THANKS, SHERRY. LET ME JUST SAY SHERRY HAS, AS ALWAYS, VERY CLEARLY AND ELOQUENTLY SUMMARIZED SORT OF THE BIG PICTURE FOR US.

I WANT TO SORT OF DRILL DOWN A LITTLE BIT MORE AND SORT OF JUST TO KICK OFF OUR DISCUSSION, SORT OF HIGHLIGHT SOME OF THE ETHICAL ISSUES THAT HAVE BEEN RAISED ON THIS GENERAL ISSUE WHICH I THINK WILL BE PART OF OUR DELIBERATION TODAY.

AND, AS SHERRY SAID, WHAT'S IMPORTANT HERE IS THAT, IN LIGHT OF THE NEW SCIENTIFIC DEVELOPMENTS AND POLICY DEVELOPMENTS, ARE WE GOING TO RECOMMEND A CHANGE IN THE REGULATIONS WITH REGARD TO CIRM FUNDING. SO I'M NOT AS ELOQUENT AS SHERRY. I'M STILL NOT WEANED OFF POWERPOINT, SO I NEED TO DRAW UP A COUPLE OF POWERPOINT SLIDES. I JUST WANT TO GO THROUGH THEM AGAIN TO SORT OF SET A FRAMEWORK.

AND I THINK, GEOFF, THESE WERE ALL SENT OUT TO EVERYBODY AND HOPEFULLY YOU CAN LOOK AT THEM, BUT I'LL JUST TALK. AS SHERRY SAID, THERE ARE THREE ETHICAL CONCERNS THAT WE HAVE ADDRESSED IN THE PAST WITH REGARD TO DONATION OF GAMETES AND PARTICULARLY OOCYTES FOR STEM CELL RESEARCH. AND WE HAVE BEEN

COMMITTED AND WE'VE WRITTEN, I THINK, REGULATIONS OR RECOMMENDED REGULATIONS THAT ICOC HAS ADOPTED I THINK WE CAN REALLY BE VERY PROUD OF IN TERMS OF REALLY SETTING VERY HIGH STANDARDS FOR INFORMED CONSENT FOR OOCYTE DONATION, PROTECTION AGAINST UNDUE INFLUENCE FOR PAYMENT, AND PROTECTION ABOUT UNDUE MEDICAL RISKS FOR OOCYTE DONORS DONATING.

AS SHERRY HAS SAID, WE HAVE HAD A LONG, DEEP COMMITMENT TO THIS. AND I THINK IT'S REALLY IMPORTANT THAT IN THE PUBLIC DISCUSSION THAT'S GOING TO ENSUE WE BE VERY CLEAR THAT WE ARE UNWAVERING IN OUR STRONG COMMITMENT TO THESE THREE KIND OF BEDROCK ETHICAL PRINCIPLES.

I JUST WANT TO SAY THAT SOME OF THE CONCERNS ON THESE THREE ISSUES HAVE BEEN RAISED BY PEOPLE WHO ARE GENERALLY SUPPORTIVE OF HUMAN EMBRYONIC STEM CELL RESEARCH. SO THESE CONCERNS RUN BROAD IN THE COMMUNITY. I THINK WE NEED TO MAKE SURE WE ARE CLEAR AND THAT WE ARTICULATE TO THE ICOC AND THE PUBLIC OUR DEEP STANDING COMMITMENT TO ADDRESSING THESE CONCERNS.

NOW, IN THE NEXT SLIDE I SAY THERE ARE TWO OTHER ISSUES THAT COME UP WITH REGARD TO THESE LINES THAT GIVE PEOPLE SOME PAUSE. AND ONE IS THE CREATION OF EMBRYOS SPECIFICALLY FOR RESEARCH. MOST

OF THE WORK THAT, CORRECT ME IF I'M WRONG, GEOFF, BUT THE WORK WE HAVE FUNDED TO DATE IS FROM EMBRYONIC STEM CELL LINES DERIVED FROM EMBRYOS THAT ARE LEFT OVER WHEN A WOMAN HAS COMPLETED HER FAMILY PLANNING -- COMPLETED HER FAMILY AND WISHES TO DONATE THE FROZEN EMBRYOS TO RESEARCH AS OPPOSED TO OTHER OPTIONS THAT SHE HAS CONSIDERED AND GIVEN INFORMED CONSENT.

THIS IS CREATION OF EMBRYOS EXPRESSLY FOR RESEARCH AND THE EXPRESS INTENTION OF CARRYING OUT RESEARCH WITH THEM. AND THAT GIVES SOME PEOPLE PAUSE. WE NEED TO KIND OF UNDERSTAND THAT AND KEEP THAT IN MIND.

AND SECONDLY, THERE ARE PEOPLE WHO, FRANKLY, ARE VERY STRONGLY OPPOSED TO ALL HUMAN EMBRYONIC RESEARCH, WHO PROBABLY VOTED AGAINST PROP 71 AND HAVE NOT BEEN SUPPORTIVE OF THE FUNDING THAT WE'VE BEEN CARRYING OUT UNDER STATE AUSPICES, BUT ARE SAYING THAT THEY THINK THAT TO USE PUBLIC FUNDS TO CROSS THAT LINE TO SUPPORT RESEARCH ON LINES THAT WERE CREATED FROM EMBRYOS EXPRESSLY FOR RESEARCH IS AN OBJECTION. SO THAT'S KIND OF WHERE THE OPPOSITION, WHERE THE CONCERNS COME FROM. AND I THINK WE NEED TO REALLY MAKE SURE WE UNDERSTAND AND HAVE THOUGHT THOSE THROUGH AND ADDRESSED THEM.

NOW, THERE ARE A COUPLE OF QUESTIONS THAT WE NEED TO CONSIDER WITH REGARD TO WHAT LINES ARE ELIGIBLE FOR CIRM FUNDING. ONE IS, AS SHERRY SAID, WE'RE NOT PERMITTED UNDER PROP 71 TO ALLOW PAYMENT OF DONORS TO DONORS OF OOCYTES, PERIOD. AND, YOU KNOW, THERE'S SOME THOUGHT ABOUT CALIFORNIA LEGISLATURE; BUT AS SHERRY SAID, WE'RE NOT PAYING THE DONORS HERE. SOMEONE ELSE HAS PAID THEM WITH OTHER FUNDS, AND NOW WE'RE REALLY ASKING WHETHER THE LINES THAT ARE ALREADY IN EXISTENCE MAY BE USED BY CIRM INVESTIGATORS.

THE SECOND ISSUE IS, AGAIN, GOING BACK TO THE COMMITMENT THAT SHERRY REALLY EMPHASIZED, OUR COMMITMENT TO OTHER ETHICAL STANDARDS REGARDING THE DERIVATION OF STEM CELL LINES. IF THERE IS A LINE THAT A CIRM RESEARCHER IS PROPOSING TO USE, SHOULD THOSE LINES BE REQUIRED TO MEET THE MEDICAL AND ETHICAL STANDARDS IN PLACE, BEST PRACTICES, AT THE TIME OF DERIVATION? AND THAT WOULD INVOLVE CONSENT, PROTECTIONS AGAINST UNDUE INDUCEMENT, AND PROTECTIONS AGAINST UNDUE MEDICAL RISK TO THE WOMEN WHO ARE DONATING.

AND ONE OF THE QUESTIONS THAT'S BEEN RAISED IN THE PUBLIC DISCUSSION IS IS THERE AN INCENTIVE FOR THE PEOPLE DERIVING THESE LINES TO TRY

AND MAXIMIZE OR INCREASE THE YIELD OF OOCYTES AND OOCYTE RETRIEVAL BY THE WOMAN DONATING TO RESEARCH TO INCREASE THAT YIELD BEYOND WHAT WOULD BE SAFE, MEDICALLY ACCEPTABLE IN THE OOCYTE STIMULATION RETRIEVAL PROCESS.

AND THIS IS AN ISSUE, AGAIN, TO REMIND US, THAT CIRM COMMISSIONED AN INSTITUTE OF MEDICINE WORKSHOP AND THEN AFTER THAT COMMISSIONED A PANEL OF ART EXPERTS TO ACTUALLY RECOMMEND GUIDELINES THAT SHOULD BE FOLLOWED IN THE RETRIEVAL OF OOCYTES FOR RESEARCH. AND THAT'S BEEN PUBLISHED IN THE PEER-REVIEWED LITERATURE.

FINALLY, THERE'S AN ISSUE OF HOW MUCH DUE DILIGENCE AND REVIEW PROCESS SHOULD CIRM GO THROUGH, IF THERE IS APPROVAL THAT'S PERMITTED, BEFORE GRANTING APPROVAL. I WANT TO JUST REMIND US OF A SIMILAR ISSUE ON THE FEDERAL LEVEL. THE NIH MAY NOT PAY FOR THE DERIVATION OF STEM CELL LINES, BUT IT MAY SUPPORT RESEARCH ON LINES THAT HAVE ALREADY BEEN DERIVED UNDER APPROPRIATE ETHICAL AND MEDICAL STANDARDS.

AND THERE'S A COMMITTEE, THE NIH WORKING GROUP FOR HUMAN EMBRYONIC STEM CELL ELIGIBILITY REVIEW, INDEPENDENT OF EXPERTS OF THAT RECOMMEND TO THE ADVISORY COMMITTEE TO THE DIRECTOR OF NIH OF

WHETHER A PARTICULAR LINE SHOULD BE APPROVED OR NOT. AND JEFF BODKIN CHAIRS THAT COMMITTEE. I'M PRIVILEGED TO SERVE UNDER HIM AT THE NIH. AND JEFF MAY WANT TO SPEAK TO THIS, BUT I THINK THE LEVEL OF SCRUTINY BY THIS OUTSIDE PANEL IS VERY CAREFUL. WE REVIEW DOCUMENTS, GO BACK AND ASK QUESTIONS SO THAT WE REALLY MAKE SURE THAT THE NIH STANDARDS WITH REGARD TO INFORMED CONSENT OVERSIGHT, THE ABSENCE OF UNDUE INFLUENCE ARE MET BEFORE WE RECOMMEND TO THE DIRECTOR THAT NIH FUNDING BE PERMITTED.

SO THAT'S AN ADDITIONAL -- I GUESS I SHOULD JUST SAY THAT IT'S MY IMPRESSION THAT DR. COLLINS, THE NIH DIRECTOR, REALLY WAS VERY CLEAR THAT HE WANTED AN OUTSIDE EXPERT REVIEW OF WHETHER A PARTICULAR LINE MET THE GENERAL STANDARDS.

SO THAT'S JUST SOME ADDITIONAL BACKGROUND TO SORT OF HELP US FRAME THIS. AND UNLESS THERE ARE CLARIFICATION QUESTIONS, THESE ARE ISSUES WE'RE GOING TO DISCUSS IN THE REMAINDER OF THE CALL. I WANTED TO TURN IT OVER TO GEOFF TO TELL US ABOUT THESE LINES FROM OREGON HEALTH SERVICES UNIVERSITY DERIVING LINES THROUGH THE SOMATIC CELL NUCLEAR TRANSFER PROCESS, AND THEN WE'RE GOING TO HEAR ABOUT THE SCIENTIFIC VALUE OF -- POTENTIAL SCIENTIFIC VALUE FOR RESEARCH OF THESE LINES.

SO, GEOFF, MAY I TURN THIS OVER TO YOU?

DR. PETERS: WHEN WE CAN RAISE OUR HANDS AND GET ON THE SEQUENCE LIST, THIS IS TED PETERS.

CHAIRMAN LO: YEAH. MAYBE WE SHOULD STOP HERE. I JUST WANT TO NOT DELVE INTO THE REAL MEAT OF THE ETHICS DISCUSSION TILL WE'VE HEARD ABOUT THESE PARTICULAR LINES. BUT IF THERE'S CLARIFICATION OF THE HISTORY AND THE BACKGROUND OR IF THERE ARE ETHICAL ISSUES, PLEASE RAISE THEM. TED, SO WHY DON'T WE CALL ON YOU NOW?

DR. PETERS: I'LL TRY TO KEEP THIS BRIEF. THANKS, BERNIE, TO YOU AND SHERRY FOR INTRODUCING THIS. THINKING SPECIFICALLY ABOUT SHERRY'S INTRODUCTION, IF I UNDERSTOOD IT CORRECTLY, THE HEALTH COMMITMENT THAT WE HAVE MADE FOR WOMEN DONORS WOULD BE BACKGROUND, AND THE FOREGROUND OR FOCUS WOULD BE THIS PARTICULAR CARE OF CELL LINES THAT HAVE INVOLVED MONEY TO THE DONORS.

AND THE QUESTION THAT I THINK YOU PARTIALLY ANSWERED, BERNIE, BUT I'D LIKE TO SEE IF IT'S ON SHERRY'S MIND, IS THAT PARTICULARLY THESE PARTICULAR LINES, WE WOULD ACTUALLY INCENTIVIZE OTHERS OUTSIDE CIRM TO PAY FOR LINES AND THEN TRY TO GET THEM APPROVED. AND IF THAT'S THE CASE, WOULD THAT IMPLY WE DON'T WANT TO CHANGE OUR STANDARDS?

AT MOST, WE WOULD SIMPLY MAKE AN EXCEPTION IN THIS CASE WITHOUT ANY CHANGE OF EXISTING STANDARDS. AM I UNDERSTANDING CORRECTLY AT LEAST AS SHERRY HAS LAID IT OUT?

CHAIRMAN LO: LET ME TAKE A FIRST CRACK AND THEN ASK SHERRY AND GEOFF. IS JAMES HARRISON ON THE CALL?

DR. LOMAX: PERHAPS, BERNIE, IF I UNDERSTAND CORRECTLY, IT WAS A QUESTION TO THE SUBSTANCE OF THE POLICY? IS THAT CORRECT?

CHAIRMAN LO: I THINK I WANT TO MAKE A DISTINCTION BETWEEN THE ETHICAL STANDARDS THAT WE HAVE HELD BY AND MADE RECOMMENDATIONS FOR THE ETHICAL --

MS. LANSING: I THINK I CAN ANSWER THIS.

CHAIRMAN LO: OKAY. SHERRY, WHY DON'T YOU GO AHEAD.

MS. LANSING: MAYBE I'M NOT UNDERSTANDING IT. WE ARE NOT RECOMMENDING ANY CHANGES TO CIRM'S POLICY IN THE STATE OF CALIFORNIA. BUT WE ARE THE MOST CONSERVATIVE OF ANYONE. NOW, I HAVE ALWAYS BEEN A BIG SUPPORTER OF OUR BEING THE MOST CONSERVATIVE BECAUSE WE WERE THE FIRST.

THE QUESTION IS, AND I AM FORMING MY OPINION LISTENING TO EVERYBODY, AND I DON'T WANT TO

RUSH THE MEETING, I WANT TO HEAR IT, BUT THE QUESTION IS OTHER STATES ARE DOING WHAT THEY'RE DOING. THEY'VE MADE THEIR RULES. THEY ARE PAYING FOR THESE WOMEN, BUT IN OREGON THEY FOLLOWED EVERY SINGLE RULE THAT CIRM HAS EXCEPT THEY PAID THEM. AND THERE'S ACTUALLY A BILL ON THE CALIFORNIA LEGISLATURE, WHETHER IT PASSES OR NOT AND IT'S IRRELEVANT FOR THIS DISCUSSION, WHERE THEY'RE RECOMMENDING PAYING WOMEN. BUT OUR STANDARDS, YOU KNOW, NO UNDUE PRESSURE, ALL THE THINGS THAT WE WORKED SO HARD ON, THIS OREGON LINE MET AND EVEN EXCEEDED.

SO THE QUESTION IS SINCE -- SOMEONE IS GOING TO EXPLAIN. I THOUGHT IT WAS ALAN TROUNSON IS GOING TO EXPLAIN WHY THIS LINE IS SO VITAL FOR RESEARCH. THE QUESTION IS DO WE MAKE AN EXCEPTION BECAUSE IT -- I DON'T WANT TO JUMP THIS, BUT I THINK WE'RE GOING TO HEAR -- HAS REMARKABLE SCIENTIFIC POTENTIAL, NOT TO CHANGE CIRM'S RULES, BUT TO TAKE A LINE FROM ANOTHER STATE THAT WAS DEVELOPED WHERE WOMEN WERE PAID, BUT ALL THE OTHER RULES ABOUT THEIR CHOICES WERE FOLLOWED OR EVEN EXCEEDED CIRM'S RULES. DID I SAY THAT CLEARLY FOR BERNIE AND FOR --

CHAIRMAN LO: THAT WAS VERY CLEAR. JAMES HARRISON, DO YOU WANT TO JUST GIVE US A TECHNICAL OF

LEGAL ISSUES ON WHAT WE'RE BEING ASKED TO DO HERE?

MR. HARRISON: LET ME JUST GET CLOSER TO THE PHONE, BERNIE. SO AS SHERRY AND BERNIE ARTICULATED EARLIER, IN 2006 CIRM ADOPTED A REGULATION THAT GOVERNS THE USE OF COVERED STEM CELL LINES AND THAT PROHIBITS USE OF A LINE DERIVED UNDER CIRCUMSTANCES WHERE THE DONOR WAS COMPENSATED. LET ME BE CLEAR THAT WE'RE NOT PROPOSING TO CHANGE IN ANY WAY THE PROHIBITION ON USE OF CIRM FUNDS TO COMPENSATE A DONOR.

WHAT WE'RE SUGGESTING FOR THE STANDARDS WORKING GROUP'S CONSIDERATION IS CREATING A PATHWAY OR A PROCESS FOR THE BOARD TO APPROVE USE OF A LINE DERIVED WITHOUT CIRM FUNDS WHERE THE DONOR WAS COMPENSATED.

SO THIS WOULD BE A PROCESS THAT WOULD ENTAIL THE SUBMISSION OF A PROPOSAL TO CIRM AND THAT WOULD IDENTIFY VARIOUS FACTORS FOR CONSIDERATION BY THE BOARD, WHICH WOULD ULTIMATELY MAKE A DETERMINATION WHETHER OR NOT TO APPROVE THE USE OF CIRM FUNDS ON SUCH LINES.

SO THAT'S THE POLICY PROPOSAL THAT'S BEFORE THE STANDARDS WORKING GROUP TODAY.

MS. LANSING: I WANT TO BE CLEAR, TED. THIS IS ALREADY BEING DONE. THEY'RE ALREADY PAYING.

SO THAT GENIE IN OTHER STATES ISN'T GOING TO GO BACK INTO THE BOTTLE.

DR. PETERS: YEAH. RIGHT.

MS. LANSING: AND THE QUESTION IS -- I MEAN I THINK I KNOW WHERE I COME OUT ON THIS, BUT THE QUESTION IS DO WE HAVE THE RIGHT TO USE THOSE LINES. I MEAN ARE WE RECOMMENDING THAT WE SHOULD USE THOSE LINES BECAUSE OF THEIR SCIENTIFIC -- I DON'T THINK WE'RE INCENTIVIZING OTHER PEOPLE TO DO THIS BECAUSE THEY'RE ALREADY DOING IT. AND WE'RE NOT CHANGING OUR RULES.

DR. PETERS: IS IT ON YOUR MIND THAT WE MIGHT INCENTIVIZE PEOPLE IN OTHER STATES TO COMPENSATE WOMEN DONORS THINKING THAT THEY COULD THEN SEND THOSE TO CIRM? I GATHER YOU'RE NOT WORRIED ABOUT THAT.

MS. LANSING: NO, I'M REALLY NOT BECAUSE I GUESS -- YOU KNOW, I WANTED TO WAIT FOR THE WHOLE DISCUSSION. BUT I DON'T THINK WE'RE INCENTIVIZING THEM BECAUSE IT'S ALREADY BEEN DONE. I MEAN IT'S ALREADY BEING DONE. WHAT PERCENTAGE OF STATES WHO ARE DOING STEM CELL RESEARCH ARE PAYING THE WOMEN? DO YOU KNOW THE ANSWER TO THAT, JAMES?

DR. LOMAX: WELL, OFFHAND WE HAVE REPORTS. WE KNOW OF THE NEW YORK PROGRAM WHICH PAYS AND PAYS

IF IT'S A STATE-FUNDED PROGRAM. SO IT'S A LITTLE BIT UNIQUE IN THAT REGARD. AND THEN THE OREGON PROGRAM WAS DONE WITH -- THE PROTOCOL IS ACTUALLY FUNDED THROUGH PRIVATE FUNDS, BUT YOU COULD SAY THERE WAS INDIRECT SUPPORT BECAUSE IT WAS DONE AT A STATE INSTITUTION. SO YOU HAVE TWO FORMAL PROGRAMS THAT WE'RE AWARE OF IN TWO STATES WHERE THERE IS SIGNIFICANT CAPACITY FOR STEM CELL SCIENCE.

MS. LANSING: SO, NO, I DON'T THINK WE'RE ENCOURAGING THEM. I THINK -- TWO THINGS DON'T BOTHER ME. I DON'T THINK WE'RE INCENTIVIZING IT. I HAVE TO BE VERY CLEAR. AND THE OTHER THING THAT REALLY DOESN'T BOTHER ME AS A WOMAN, THIS I HAVE TO SAY, IS THAT THESE WOMEN HAVE MADE THE CHOICE THAT THEY WANTED THEIR OOCYTES USED FOR RESEARCH RATHER THAN REPRODUCTIVE. AND ACTUALLY I THINK THAT'S A HEALTHY CHOICE. I MEAN YOU HAVE THE RIGHT TO DO WITH YOUR DONATION WHAT YOU WISH TO DO WITH IT. SO THAT DOESN'T BOTHER ME EITHER.

I DON'T WANT TO JUMP THE GUN, BUT I ALMOST FEEL IT'S IRRESPONSIBLE OF US NOT TO USE THESE LINES. IF I HEAR HOW VALUABLE THEY ARE, WHICH I HAD A LITTLE, YOU KNOW, BECAUSE OF CHAIRING THIS COMMITTEE, HAD A TINY LITTLE PREVIEW OF, AND I DON'T WANT TO JUMP THE MEETING. WE WILL BE BEHIND IN THE

SCIENCE THEN, AND THAT'S WHAT WE HAVE TO DO.

DR. PETERS: THANK YOU VERY MUCH, SHERRY. IT DOES CLARIFY IT. AND I'VE READ ABOUT THESE LINES IN *SCIENCE AND NATURE*. AND YES, INDEED, OF COURSE, IF IT'S THE BEST SCIENCE, WE WANT IT.

CHAIRMAN LO: OKAY. SO IT'S A GOOD JUMPING OFF POINT TO HAVE, FIRST, GEOFF TELL US ABOUT HOW THESE LINES IN OREGON WERE DERIVED. YOU MADE A SITE VISIT AND LOOKED VERY CAREFULLY AT THE CIRCUMSTANCES OF THE CONSENT AND RETRIEVAL, THE LEVEL OF PAYMENT, AND SO FORTH. AND THEN WE HAVE SOME PEOPLE WHO CAN ADDRESS THE SCIENTIFIC UNIQUENESS OF THESE LINES AND WHAT RESEARCH WITH THESE LINES MIGHT DO TO ADVANCE STEM CELL SCIENCE.

SO LET'S HOLD. I KNOW WE'RE GOING TO HAVE A VIGOROUS DISCUSSION, WHICH I LOOK FORWARD TO. I THINK THERE ARE PEOPLE IN THE AUDIENCE, RIGHT, THAT MAY ALSO WANT A PUBLIC COMMENT WE WANT, WE NEED TO GIVE TIME TO AND LISTEN TO. BUT LET'S MOVE AHEAD. GEOFF, IF YOU COULD TALK ABOUT WHAT YOU FOUND OUT ABOUT THE ACTUAL DERIVATION OF THESE LINES IN OREGON.

DR. LOMAX: THANK YOU, BERNIE. SO IN ADVANCE OF THIS MEETING, WE THOUGHT IT WOULD BE PRUDENT TO SUBJECT THE OREGON DERIVATION PROTOCOL TO

SORT OF OUR STANDARD PROTOCOL FOR GOING OUT AND EVALUATING COMPLIANCE WITH CIRM REGULATIONS. AND WE HAVE A LOT OF EXPERIENCE DOING COMPLIANCE VISITS. IT'S SOMETHING WE'VE DONE AT EVERY MAJOR GRANTEE INSTITUTION IN CALIFORNIA.

I'D LIKE TO ACKNOWLEDGE OREGON, WHO DOESN'T RECEIVE A DIME FROM CIRM, FOR VOLUNTARILY SUBJECTING ITSELF TO THE LEVEL OF INQUIRY BECAUSE WE DEMANDED A LOT FROM THEM BOTH IN WRITING AND IN TERMS OF PERSONNEL TIME ON OUR SITE VISIT.

SO TYPICALLY WHAT WE DO ON A SITE VISIT, FIRST OF ALL, WE LOOK AT THE GRANT AWARDS OR THE TYPE OF RESEARCH THAT'S BEING DONE AND IDENTIFY A SERIES OF POLICY AND COMPLIANCE QUESTIONS THAT APPLY TO THAT PARTICULAR RESEARCH. SO IN THIS CASE WE LOOKED AT THE CIRM STANDARDS WITH REGARD TO USE OF OOCYTES IN CIRM-FUNDED RESEARCH AND BUILT OUR EVALUATION CRITERIA AROUND THOSE REGULATORY REQUIREMENTS.

SO I'VE INCLUDED A SET OF SLIDES, AND THE RATIONALE BEHIND THOSE BULLET POINTS IS TO SORT OF CALL OUT SPECIFIC ITEMS THAT PERTAIN TO OUR REQUIREMENTS ON OOCYTE DONATION. SO IT'S LIMITED IN THAT SENSE, BUT OBVIOUSLY IT IS A BROADER SET OF COMPLIANCE ISSUES AS WELL THAT I'D BE HAPPY TO

ADDRESS, BUT I'LL FOCUS ON THE SPECIFIC REQUIREMENTS THAT PERTAIN TO OOCYTE DONATION AND STEM CELL RESEARCH.

SO THE ESCRO COMMITTEE AND CLINIC PERFORMING THE OOCYTE RETRIEVAL DID CONFORM TO ALL THE REQUIREMENTS WE WOULD EXPECT A CIRM GRANTEE TO COMPLY WITH. I THINK ONE POINT THAT REALLY STOOD OUT IS THAT THEY HAD A VERY COMPREHENSIVE PROCESS FOR INFORMING INTERESTED PARTICIPANTS IN THE RESEARCH PROTOCOL.

SO FIRST THEY WOULD SCREEN. THIS WAS A TELEPHONE SCREEN. AND ONCE THEY WERE THROUGH THE FIRST LEVEL OF SCREENING, PRIOR TO SIGNING UP FOR THE STUDY, THEY ARE REQUIRED TO ATTEND AN INFORMATION SEMINAR WHICH WAS HELD AT OREGON HEALTH SCIENCES. IT INCLUDED A SERIES OF PRESENTATIONS BY THE CLINICAL STAFF, RESEARCH STAFF. AND THAT WENT INTO DETAIL IN TERMS OF WHAT THE RESEARCH WAS INTENDED TO DO, HEALTH RISKS, THE VARIOUS SET OF ISSUES THAT ONE WOULD INCORPORATE INTO AN INFORMED CONSENT DOCUMENT, BUT IT WAS DONE IN A MULTIMEDIA GROUP PARTICIPATION FORMAT.

ONCE THAT SEMINAR WAS FINISHED, THE DONORS THEN WOULD LEAVE, WHICH GAVE THEM TIME TO DELIBERATE. THERE WAS ROUGHLY AT LEAST A ONE-WEEK

PERIOD PRIOR TO SOMEONE THEN COMING BACK AND BEING CONSENTED. SO THIS NOTION THAT INDIVIDUALS HAD SOME TIME TO REFLECT ON WHAT THEY WERE TOLD AND WHAT WAS INVOLVED IN THE RESEARCH PRIOR TO ACTUALLY SIGNING UP FOR THE RESEARCH.

THE INFORMED CONSENT DOCUMENTS, AGAIN, MATCH UP WITH BOTH THE NATIONAL ACADEMIES OF SCIENCES AND CIRM REQUIREMENTS. THE HEALTH RISK SECTIONS ARE EXTREMELY EXTENSIVE, AND THEY DOCUMENT -- EXTENSIVE IN THE SENSE THERE WERE, I BELIEVE, THREE PAGES OF INFORMATION AND VERY THOROUGH. THE DOCUMENT WAS DOMINATED BY INFORMATION ABOUT POTENTIAL RISKS ASSOCIATED WITH OOCYTE RETRIEVAL.

AND IN THE SORT OF DISCUSSION PART WITH OREGON HEALTH SCIENCES, THIS COMES BACK TO THE POINT SHERRY JUST RAISED, THERE WAS FAIRLY A SUBSET OF DONORS THAT WERE INTERESTED IN THE STUDY BECAUSE THEY EXPRESSED A PREFERENCE FOR RESEARCH DONATION OVER REPRODUCTIVE USE.

CHAIRMAN LO: GEOFF, COULD I INTERRUPT YOU A MINUTE JUST TO ASK FOR A FEW CLARIFYING POINTS?

DR. LOMAX: YES.

CHAIRMAN LO: FIRST, DID THESE WOMEN RESPOND ON THEIR OWN TO AN AD THAT WAS PLACED?

THESE WERE NOT WOMEN WHO OTHERWISE WERE COMING IN FOR DONATION FOR CLINICAL IVF?

AND SECONDLY, COULD YOU SAY A LITTLE ABOUT THE INFORMED CONSENT PROCESS? YOU MENTIONED THE CONSENT DOCUMENTS. TELL US A LITTLE BIT ABOUT THE WAY THAT THE ONE-ON-ONE DISCUSSIONS WERE HAD WITH THE POTENTIAL OOCYTE DONORS, WHO DID THAT. WAS THERE LOTS OF TIME FOR QUESTIONS AND THINGS LIKE THAT?

DR. LOMAX: SURE. SO THE RECRUITMENT REALLY DIDN'T DEVIATE IN ANY WAY FROM THE STANDARD RECRUITMENT MODES USED FOR IVF DONORS. SO IT WOULD BE THINGS LIKE ADS AND VARIOUS ADVERTISING MEDIA THAT ARE TYPICALLY USED. IT'S JUST THAT THEY WERE AWARE, THOUGH, THERE WAS OPTIONS. AND THEN IN THIS CASE RESEARCH WAS INCLUDED IN THE AD AS OPPOSED TO SIMPLY DONATING FOR REPRODUCTIVE USE. SO IN TERMS OF THE MODE OF ADVERTISING, IT WAS CONSISTENT WITH WHAT WOULD TYPICALLY BE DONE FOR IVF DONATION FOR REPRODUCTIVE PURPOSES.

WE'RE ABLE TO -- AGAIN, AND AGAIN I WANT TO ACKNOWLEDGE THE TIME AND EFFORT PUT IN BY THE OREGON GROUP. SO THE INDIVIDUALS THAT PERFORMED THE CONSENT WERE THERE. I MEAN SOME OF THE POINTS I'M JUST SORT OF REFLECTING ON THESE FROM MEMORY. I

THINK ON AVERAGE THE CONSENT PROCESS COULD EASILY TAKE ABOUT AN HOUR, BUT I PROBABLY SHOULD GO BACK AND CONFIRM THAT WITH THEM, BUT THAT WAS THE SENSE I HAD FROM OUR DISCUSSIONS WITH THE CONSENTERS.

THERE WAS AMPLE TIME FOR QUESTIONS; BUT, AGAIN, THE INDICATION -- A LOT OF QUESTIONS WERE ASKED IN ADVANCE IN THE INFORMATIONAL SESSION AS WELL. AND AFTER THE INFORMATIONAL SESSION, THEY WERE GIVEN INFORMATION PACKETS. SO MY UNDERSTANDING IS THE CONSENT PROCESS, WHILE THEY WENT THROUGH THE FORM, IT WAS REALLY -- MY SENSE WAS IT WAS DOMINATED BY THE OPPORTUNITY TO SORT OF ASK CLARIFYING QUESTIONS AS WELL AS REALLY GO THROUGH THE CONSENT FORM AS ONE TYPICALLY WOULD IN A CONSENT PROCESS. OTHER THAN THAT, I'D HESITATE TO SAY A LOT MORE WITHOUT KIND OF GOING BACK AND -- BY THE WAY, I JUST WANT TO LET YOU KNOW THE OREGON GROUP HAD HOPED TO BE ON THIS CALL, BUT THE PERSON WHO WAS GOING TO REPRESENT THEM IS ALSO IN CLINIC TODAY. SO SHE MAY --

DR. AMATO: GEOFF.

DR. LOMAX: YEAH.

DR. AMATO: THIS IS PAULA AMATO. I'M SORRY. I DIDN'T KNOW IF YOU KNEW I WAS ON THE LINE.

DR. LOMAX: I DIDN'T.

DR. AMATO: FOR THE LAST FEW MINUTES. SORRY.

DR. LOMAX: SURE. DID I CHARACTERIZE THAT ACCURATELY, AND WOULD YOU LIKE TO ADD ANYTHING TO THE DESCRIPTION I GAVE?

DR. AMATO: THE ONLY THING I WOULD ADD IS WE DID ADVERTISE SEPARATELY FOR THE RESEARCH DONORS AND THE CLINICAL DONORS. SO SIMILAR-TYPE ADS, BUT IN DIFFERENT PLACES. WE HAVE A RESEARCH WEB SITE AND THEN WE HAVE A CLINICAL IVF WEB SITE. SO PEOPLE THAT RESPONDED WERE RESPONDING TO THE RESEARCH DONATION ADS.

DR. LOMAX: SO THE POINT IS THEY WEREN'T COMBINED. IT WAS THE SAME MODE OF ADVERTISING, BUT A CLEAR DISTINCTION BETWEEN RESEARCH AND IVF.

DR. AMATO: CORRECT. CORRECT. AND THEN THE CONSENT PROCESS, I'M THE ONE WHO GAVE THE INFORMATIONAL SEMINAR ALONG WITH THE RESEARCH STAFF. AND THEN THE INDIVIDUAL CONSENTING WAS DONE BY ONE OF THE RESEARCH STAFF AND THEN MYSELF AS WELL PAGE BY PAGE. YEAH, IT TAKES ABOUT HALF AN HOUR, 45 MINUTES TO GO THROUGH THE DOCUMENT IN DETAIL.

CHAIRMAN LO: I APPRECIATE, DR. AMATO, YOU BEING ON THE CALL. THERE MAY WELL BE QUESTIONS LATER FOR YOU.

DR. AMATO: OKAY. SURE. I AM SEEING PATIENTS, AS GEOFF MENTIONED, SO I MIGHT HAVE TO POP OFF, BUT I CAN BE ON FOR THE NEXT FEW MINUTES.

CHAIRMAN LO: GEOFF, WHY DON'T WE DO THIS. WHY DON'T WE SIT AND LET YOU FINISH YOUR PRESENTATION, AND MAYBE WE COULD ASK QUESTIONS SPECIFICALLY OF DR. AMATO IF THERE ARE QUESTIONS INVOLVING WHAT THE PROCESS WAS AT OHIC.

DR. LOMAX: AND I'LL TRY TO GO QUICKLY THROUGH THIS. SO LET ME JUST DO THAT; AND THEN IF THERE'S QUESTIONS, PLEASE COME BACK WITH THEM.

I THINK THE IMPORTANT -- AND THIS IS DOCUMENTED BOTH IN THE JOURNAL PAPER AND WE REVIEWED THIS DURING THE SITE VISIT. WE PUT OUT VERY, I THINK, CONSERVATIVE GUIDELINES FOR OOCYTE DONATION. THESE ARE QUANTITATIVE GUIDELINES IN TERMS OF THE ACTUAL CLINICAL PROTOCOL. THOSE GUIDELINES WERE MET OR EXCEEDED IN THIS PROTOCOL.

IN ADDITION, SOMETHING THAT WAS, I THINK, VERY IMPORTANT IN THE CIRM REQUIREMENTS WAS THAT THERE WAS A MECHANISM IN PLACE TO AVOID ANY OUT-OF-POCKET EXPENSE TO DONORS IN THE EVENT OF ANY MEDICAL COMPLICATION. IN THIS CASE THE OREGON HEALTH SCIENCES TEAM PURCHASED INDIVIDUAL INSURANCE POLICIES FOR THE DONOR AT NO COST TO THEM IN THE

EVENT OF A COMPLICATION. AND THAT WOULD BE TO AVOID ANY OUT-OF-POCKET EXPENSES.

AGAIN, THE INFORMED CONSENT WAS EXTENSIVE. AND, AGAIN, I JUST HAVE TO -- I WILL SORT OF ONCE AGAIN STATE THAT THE TEAMS WERE EXTREMELY RESPONSIVE TO A LOT OF PRODDING AND PROBING AND A LOT OF QUESTIONS. AND I JUST HAVE TO ACKNOWLEDGE THAT BECAUSE HAVING A LOT OF EXPERIENCE ON SITES AT DIFFERENT RESEARCH INSTITUTIONS, IT WAS AN EXCEPTIONAL TEAM, AND THEY WERE EXCEPTIONALLY THOROUGH AND RESPONSIVE.

CHAIRMAN LO: GEOFF, LET ME JUST SAY, TO CLARIFY FOR THE STANDARDS WORKING GROUP, THAT WE'RE NOT BEING ASKED TO RECOMMEND APPROVAL OF THIS PARTICULAR LINE. WE'RE BEING ASKED IF WE WISH TO RECOMMEND A PROCESS BY WHICH CIRM MAY ALLOW LINES LIKE THIS TO BE USED IN CIRM-FUNDED RESEARCH PROJECTS. BUT WE'RE USING THIS AS EXAMPLE, SO TO SPEAK, A TEST CASE, TO SEE WHAT KINDS OF CONCERNS MIGHT COME OUT. BUT WE'RE NOT BEING ASKED TO APPROVE THIS PARTICULAR LINE. IS THAT CORRECT, JAMES AND GEOFF?

MR. HARRISON: YOU STATED IT CORRECTLY, BERNIE.

CHAIRMAN LO: OKAY. GREAT. SO SINCE DR.

AMATO IS INTERRUPTING HER DAY, DO ANY OF THE SWG MEMBERS HAVE A QUESTION FOR HER THAT WOULD HELP US UNDERSTAND WHAT PROCEDURES WE MIGHT WISH TO RECOMMEND?

MR. HARRISON: BERNIE, I THINK JEFF SHEEHY HAS A QUESTION.

CHAIRMAN LO: JEFF, PLEASE. I CAN'T TELL WHO'S GOT THEIR HAND UP.

MR. SHEEHY: CAN YOU HEAR ME?

CHAIRMAN LO: IF YOU COULD GET CLOSE TO THE PHONE, JEFF, THAT WOULD BE EVEN BETTER. SORRY.

MR. SHEEHY: I REALLY HAVE TWO QUESTIONS. SO IF THERE'S AN INSURANCE POLICY THAT'S PURCHASED, HOW LONG IS THAT ACTIVE? WAS THAT JUST FOR THE COURSE OF THE RESEARCH, OR DOES THAT COVER A PERIOD OF YEARS?

AND THEN THE SECOND QUESTION IS WHAT KIND OF LONG-TERM FOLLOW-UP IN TERMS OF HEALTH OUTCOMES? IS THERE A RESEARCH -- YOU KNOW, ARE THEY GOING TO BE FOLLOWED UP -- IS THERE A LARGER RESEARCH PROJECT? I THINK THIS IS SOMETHING WE'VE BEEN TALKING ABOUT SINCE THIS ISSUE CAME UP AND BEEN BEFORE US. IS THERE ANY KIND OF LONG-TERM LOOK AT WHAT THE HEALTH OUTCOMES ARE FOR DOING THESE TYPES OF DONATIONS FOR THESE PATIENTS, PARTICIPANTS? SO

THOSE ARE MY TWO QUESTIONS.

CHAIRMAN LO: THANKS, JEFF. DR. AMATO.

DR. AMATO: SURE. FIRST, I'D LIKE TO SAY I APPRECIATE THE INVITATION TO BE ON THE CALL AND THE OPPORTUNITY TO ANSWER QUESTIONS.

SO REGARDING YOUR FIRST QUESTION REGARDING THE MEDICAL INSURANCE POLICY, THAT IS TERM LIMITED AND IT JUST COVERS SORT OF ADVERSE EVENTS RELATED TO THE CYCLE AND UP TO, I BELIEVE IT'S, 30 DAYS POST. SO SHORT, BUT IT COVERS THE CYCLE.

THE SECOND QUESTION, WE PERSONALLY DON'T HAVE ANY LONG-TERM RESEARCH PROJECT TO LOOK AT LONG-TERM OUTCOMES. WE CERTAINLY HAVE ALL THE CONTACT INFORMATION OBVIOUSLY OF THESE DONORS, SO THAT'S CERTAINLY SOMETHING WE COULD DO. I THINK IT'S A GREAT IDEA. THERE'S BEEN SOME RESEARCH ON LONG-TERM FOLLOW-UP OF FERTILITY DONORS, AND WE EXPECT THE OUTCOMES TO BE SIMILAR, ALTHOUGH THERE COULD BE DIFFERENCES. SO I THINK THAT'S AN INTERESTING POINT. AT THE MOMENT WE DON'T HAVE ANY PLANS OR APPROVED PROTOCOL TO DO THAT, BUT IT'S SOMETHING WE MAY DO IN THE FUTURE.

MS. LANSING: AND WHAT WERE THE LONG-TERM HEALTH OUTCOMES ON FERTILITY DONORS?

DR. AMATO: MOSTLY THEY WERE -- SO THESE

WERE MOSTLY SURVEY STUDIES AND LOOKED AT PSYCHOLOGICAL RISKS MOSTLY. THEY WERE, YOU KNOW, DO YOU REGRET YOUR DONATION? HOW DO YOU FEEL ABOUT IT? AND AS FAR AS FERTILITY DONORS, MOST OF THAT DATA, AND, AGAIN, IT'S LIMITED, BUT MOST OF THAT DATA IS REASSURING THAT PEOPLE WERE HAPPY WITH THEIR DECISION THAT THEY MADE SEVERAL YEARS PRIOR.

CHAIRMAN LO: DR. AMATO OR GEOFF, MAYBE YOU COULD CLARIFY. IN TERMS OF THE RECOMMENDATIONS OF THE CIRM WORKING GROUP ON ALL OF THESE DONATIONS, WHAT WAS THE NATURE OF THE INSURANCE THAT WAS RECOMMENDED TO IMPLEMENT THE CIRM STANDARD THAT THIS GROUP RECOMMENDED THAT THERE BE INSURANCE? AND IS THIS COMPARABLE TO THE INSURANCE THAT OOCYTE DONORS HAVE AVAILABLE TO BE GIVEN IF THEY'RE DONATING IN THE CONTEXT OF INFERTILITY?

DR. LOMAX: SO OUR STANDARD -- WE HAD -- I KNOW A NUMBER OF THE MEMBERS WEREN'T PRESENT AT THAT TIME, SO JUST AS A QUICK REFRESHER. WE HAD CONSIDERABLE DISCUSSION OF THIS POINT. THE TERM OF THE INSURANCE THAT WAS SOMETHING WAS AN ISSUE. AND AS A RESULT, OUR STANDARD READS DIRECT AND PROXIMATE. SO --

CHAIRMAN LO: COMPLICATION.

DR. LOMAX: YEAH. SO I WOULD INTERPRET

THAT TO BE THAT THE OREGON APPROACH WAS SUBSTANTIALLY SIMILAR TO OUR REGULATORY REQUIREMENT BECAUSE THIS NOTION OF DIRECT AND PROXIMATE IS TRYING TO CAPTURE ACUTE HEALTH OUTCOMES THAT WOULD HAPPEN IN THE COURSE OF THE OOCYTE RETRIEVAL PROCESS. THAT'S CERTAINLY -- I THINK THE RECORD OF THE STANDARDS WORKING GROUP REFLECTS THAT INTENT AS WELL.

CHAIRMAN LO: ANY OTHER QUESTIONS FOR DR. AMATO? GEOFF, YOU CAN JUST KEEP SENDING ME E-MAILS OF WHO WANTS TO SPEAK. I GUESS ALSO MAYBE THOSE OF YOU ON THE PHONE WHO WANT TO SPEAK COULD SEND ME AN E-MAIL.

DR. ROBERTS: OKAY. CAN YOU HEAR ME? THIS IS DOROTHY.

CHAIRMAN LO: YES, PLEASE.

DR. ROBERTS: OKAY. SO I HAVE A COUPLE QUESTIONS. ONE RELATES TO WHAT JEFF WAS JUST ASKING ABOUT IN TERMS OF LONG-TERM FOLLOW-UP. I MEAN MY UNDERSTANDING IS THAT THERE AREN'T STUDIES OF LONG-TERM HEALTH RISKS TO OOCYTE DONORS. AND I WONDERED IF THAT INFORMATION WAS PART OF THE INFORMED CONSENT PROCESS. IN OTHER WORDS, LETTING DONORS KNOW THAT WE DON'T KNOW FOR SURE WHAT THE HEALTH RISKS ARE. AND I THINK THAT SHOULD BE PART

OF OUR CONSIDERATION IN THINKING ABOUT AN EXCEPTION TO THE POLICY.

AND THEN THE OTHER QUESTION I HAD WAS ABOUT THE NUMBER OF EGGS THAT WERE RETRIEVED FROM THE DONORS AND WHETHER IT IS THE CASE THAT THERE WERE AT LEAST ONE WOMAN, IF NOT MORE, FOR WHOM MORE THAN 20 EGGS WERE RETRIEVED.

DR. AMATO: OKAY. THIS IS DR. AMATO AGAIN. I'LL ANSWER YOUR SECOND QUESTION FIRST. I DON'T REMEMBER OFF THE TOP OF MY HEAD IF THERE WAS ANYBODY THAT YIELDED MORE THAN 20 EGGS. THERE MAY HAVE BEEN, BUT THAT'S SOMETHING, YOU KNOW, WE CAN'T CONTROL. I THINK OUR STIMULATION PROTOCOL WAS CONSISTENT WITH CLINICAL GUIDELINES AND THE PAPER THAT WAS PUBLISHED REGARDING GUIDELINES FOR STEM CELL RESEARCH. IN SOME CASES THERE MAY HAVE BEEN MORE EGGS. BUT CERTAINLY FROM A SAFETY POINT OF VIEW, IF YOU HAVE TO RETRIEVE ALL THE FOLLICLES, THAT DECREASES YOUR RISK OF OVARIAN STIMULATION. SO WE WOULD NEVER LEAVE FOLLICLES BEHIND IF THEY HAPPEN TO DEVELOP.

THE FIRST QUESTION WAS REGARDING LONG-TERM RISKS. WE DID TELL THEM THAT, YES, THERE MAY BE RISKS THAT WE'RE NOT AWARE OF. AS FAR AS WE KNOW, THERE AREN'T ANY LONG-TERM RISKS. WE DISCUSS --

SEVERAL YEARS AGO THERE WAS SOME QUESTION ABOUT WHETHER FERTILITY MEDICATIONS WERE ASSOCIATED WITH OVARIAN CANCER AND WE TALK ABOUT THAT. BUT --

MS. LANSING: CAN YOU JUST TELL ME, BECAUSE I'M JUST CURIOUS, WHAT WAS THE CONCLUSION? IS IT NOT DEFINITIVE?

DR. AMA: REGARDING OVARIAN CANCER?

MS. LANSING: YES.

DR. AMATO: IT WAS NOT DEFINITIVE, CORRECT. THERE'S SEVERAL STUDIES OUT THERE, AND WE DON'T BELIEVE THAT THERE IS AN INCREASED RISK, BUT IT ALWAYS COMES UP IN THE CONSENT PROCESS.

MS. LANSING: BUT YOU DO TELL THE WOMEN THAT WE DON'T KNOW.

DR. AMATO: ABSOLUTELY.

MS. LANSING: OKAY. THAT WAS MY QUESTION.

DR. AMATO: SAME WITH PSYCHOLOGICAL RISK. I MEAN, AGAIN, THERE'S LIMITED DATA, BUT NOT A LOT OF DATA.

CHAIRMAN LO: DR. AMATO, IF I COULD PRESS ON THIS BECAUSE I THINK THIS IS IMPORTANT. SO MY UNDERSTANDING, AND I'M NOT A REPRODUCTIVE ENDOCRINOLOGIST OR EVEN AN OB-GYN, IS THAT THE RECOMMENDATIONS ARE TO MONITOR THE NUMBER OF FOLLICLES DEVELOPING AND TO ADJUST -- BY ULTRASOUND

AND TO ADJUST THE LEVEL OF STIMULATION DOWNWARD IF THERE APPEARS TO BE TOO MANY FOLLICLES DEVELOPING AND TO TERMINATE THE CYCLE IF YOU THINK THERE'S A RISK OF, I DON'T KNOW, PREMATURE RUPTURE. IS THAT ACCURATE?

DR. TROUNSON: YEAH. BERNIE, DAVID ADAMSON IS HERE IN TOWN. DAVE ADAMSON IS THE PAST PRESIDENT OF THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE. HE'S HERE WITH US AND MIGHT LIKE TO MAKE A COMMENT ON THOSE THINGS BECAUSE HE'S BEEN INSTRUMENTAL IN FOLLOWING ALL OF THESE ISSUES, OF COURSE, AS HEAD OF THE AMERICAN SOCIETY.

CHAIRMAN LO: IF I COULD MAYBE ASK DR. AMATO FIRST. AND THEN, DR. AMATO, IF I MAY, MAY I ASK A QUESTION. WHEN ONE READS THE PUBLIC DISCUSSION, THERE ARE ALSO CONCERNS THAT WOMEN MAY HAVE IMPAIRMENT OF FERTILITY AS A RESULT OF DONATING OOCYTES EVEN IN THE REPRODUCTIVE CONTEXT. WAS THAT DISCUSSED DURING THE CONSENT PROCESS?

AND AFTER THAT, I WOULD BE GRATEFUL TO ALSO CALL ON DR. ADAMSON.

DR. AMATO: SO WE FOLLOWED CLINICAL PROTOCOLS AND WE CERTAINLY TURN DOWN THE DOSE AS WE PROGRESS WITH THE STIMULATION. IF WE WERE REALLY WORRIED ABOUT SOMEBODY, WE WOULD ON OCCASION CANCEL

THE CYCLE, BUT WE NEVER HAD TO DO THAT. THERE WERE NOT ADVERSE EVENTS WITH THIS COHORT OF DONORS THAT PARTICIPATED IN THE SCNT TRIAL.

AND THEN THE OTHER QUESTION?

CHAIRMAN LO: CONCERNS ABOUT LONG-TERM FERTILITY.

DR. AMATO: RIGHT. SO THERE ARE NO KNOWN LONG-TERM EFFECTS ON FERTILITY BARRING ANY MAJOR COMPLICATIONS. SO OBVIOUSLY IF THERE'S SEVERE INFECTION AS A RESULT OF THE PROCEDURE OR HEMORRHAGE RESULTING IN LOSS OF AN OVARY OR SOMETHING LIKE THAT, BUT THOSE CASES ARE VERY EXCEPTIONAL. OTHERWISE, FROM WHAT WE KNOW, DONATING DOES NOT AFFECT FUTURE FERTILITY.

CHAIRMAN LO: AND WAS THAT DISCUSSED IN THE INFORMATION SESSION?

DR. AMATO: YES.

CHAIRMAN LO: OKAY. THAT'S VERY HELPFUL.

DR. ADAMSON, YOU'RE AN EXPERT IN FERTILITY. ANYTHING YOU WOULD WANT TO ADD TO THE DISCUSSION HERE?

DR. ADAMSON: THANK YOU VERY MUCH FOR GIVING ME THE OPPORTUNITY TO MAKE A COMMENT. I WOULD AGREE ACTUALLY WITH WHAT DR. AMATO SAID. JUST TO PUT SOME PERSPECTIVE ON THIS, THERE HAVE BEEN

PROBABLY OVER 20 MILLION CYCLES OF EGG RETRIEVALS PERFORMED GLOBALLY, OVER 20 MILLION. I KNOW THIS BECAUSE I'M CHAIR OF THE INTERNATIONAL COMMITTEE MONITORING ART, WHICH PUBLISHES ANNUALLY THE GLOBAL RESULTS OF IVF.

AND SO IT'S TRUE THAT THERE ARE NO 25-YEAR-LONG STUDIES WITH A MILLION PATIENTS, BUT THERE'S 20 MILLION PATIENTS WITH EXPERIENCE, AND THERE HAVE NOT BEEN LONG-TERM RISKS THAT HAVE BEEN IDENTIFIED. THERE HAVE BEEN A NUMBER OF STUDIES THAT HAVE BEEN DONE, BUT IT'S DIFFICULT TO PROVE A NEGATIVE. SO THESE STUDIES HAVE NOT BEEN ABLE TO PROVE THAT THERE ARE NO RISKS, BUT THEY HAVE NOT IDENTIFIED RISKS EITHER. AND THIS INCLUDES RISKS OF OVARIAN CANCER, WHICH WERE INITIALLY SUGGESTED OVER 20 YEARS AGO, BUT APPROXIMATELY A DOZEN STUDIES SINCE THEN HAVE NOT BEEN ABLE TO DOCUMENT AN INCREASED RISK OF OVARIAN CANCER. WITH SOME DRUGS, NOT THE DRUGS USED IN IVF, WITH POLESINE (PHONETIC) THERE MAY BE AN INCREASED RISK, A SMALL INCREASED RISK, OF BORDERLINE OVARIAN TUMORS, BUT THESE ARE NOT THE DRUGS USED WITH IVF.

PSYCHOLOGICAL LONG-TERM RISKS, CANCER RISKS, AND FUTURE FERTILITY RISKS HAVE BEEN ASSESSED, AND IT'S NOT BEEN DEMONSTRATED TO SHOW ANY

INCREASED RISK. SO, AGAIN, CAN'T APPROVE A NEGATIVE EASILY, BUT 20 MILLION CYCLES OVER BETTER THAN A QUARTER CENTURY WOULD SUGGEST THAT THERE ARE EITHER NOT SIGNIFICANT RISKS OR EXTREMELY RARE RISKS.

THE SCANDINAVIAN COUNTRIES NOW ARE PERFORMING LONG-TERM FOLLOW-UP STUDIES AND WE'RE STARTING TO GET BETTER DATA ON THE HEALTH OF BOTH BABIES FOR FERTILITY PATIENTS AND OF MOTHERS WHO HAVE DONE THIS. THERE ARE ALSO SOME STUDIES STARTING IN THE U.S. TO LOOK AT LONG-TERM FOLLOW-UP. AND HERE IN CALIFORNIA THERE HAVE BEEN SOME INITIATIVES. WE'RE BEGINNING TO TRY TO IDENTIFY A LONG-TERM REGISTRY IN CALIFORNIA. THERE ARE MANY ISSUES OBVIOUSLY, INCLUDING COST, CONFIDENTIALITY, ETC. SO I WOULD AGREE WITH DR. AMATO'S COMMENTS.

I WOULD ALSO STATE THAT I THINK IN ALL REPUTABLE PROGRAMS, THE PATIENTS ARE DEFINITELY INFORMED OF THE LACK OF 10-, 20-YEAR STUDIES. AND IN ADDITION, I WOULD REALLY EMPHASIZE THAT IN THE RESEARCH SITUATION, IT IS VERY EASY AND, I BELIEVE, APPROPRIATE TO PUT PROTOCOLS IN PLACE WHICH WILL ABSOLUTELY MINIMIZE THE RISK OF OVARIAN HYPERSTIMULATION OR INFECTION OR OTHER COMPLICATIONS, LIKE CAREFUL PATIENT SELECTION AND CAREFUL USE OF PROTOCOLS. AND I THINK THESE ARE NOT

ONLY POSSIBLE, BUT I THINK VERY IMPORTANT IN THE RESEARCH STUDIES. THANK YOU.

CHAIRMAN LO: THANK YOU VERY MUCH. I DIDN'T HAVE A CHANCE PREVIOUSLY. THANK YOU FOR MAKING YOURSELF AVAILABLE TO ANSWER THE QUESTIONS TO HELP US.

DR. LOMAX: BERNIE, WE HAVE ONE QUESTION HERE IN SAN FRANCISCO.

CHAIRMAN LO: IF YOU COULD SEND ME A LIST, GEOFF, OF PEOPLE BECAUSE I HAVE IN ORDER JEFF BODKIN AND ROB TAYLOR HAD QUESTIONS THEY WANTED TO POSE OVER THE PHONE, AND THEN I TAKE IT THERE ARE PEOPLE THERE WHO HAVE QUESTIONS AS WELL. JEFF, YOU WANT TO GO NEXT?

DR. BODKIN: SURE. THANKS. AND I WANTED TO GET BACK TO THE COMPENSATION ISSUE IF THAT'S ALL RIGHT.

CHAIRMAN LO: PLEASE.

DR. BODKIN: I WANT TO SAY AT THE BEGINNING I'M VERY IMPRESSED WITH THE THOUGHTFULNESS AND CARE FOR THIS WHOLE DISCUSSION. SO VERY MUCH APPRECIATE THAT.

SO IN TERMS OF THE COMPENSATION POLICY, WE'RE, I THINK, USING THAT TERM FAIRLY BROADLY. AND IN THIS DOMAIN RESEARCH FOLKS HAVE COMPENSATION OF A

VARIETY OF DIFFERENT TYPES. YOU CAN BE COMPENSATED FOR YOUR ART EXPENSES THAT YOU PAID OUT OF POCKET TO COME TO THE CENTER AND EAT LUNCH AND THOSE SORT OF THINGS. THERE'S COMPENSATION FOR TIME AND EFFORT. AND THEN THERE CAN BE JUST PLAIN INCENTIVE PAYMENTS TO ENCOURAGE FOLKS TO COME IN.

AND DOES THE CALIFORNIA PROHIBITION AGAINST COMPENSATION INCLUDE ALL OF THOSE TYPES OF COMPENSATION?

DR. LOMAX: CALIFORNIA PROHIBITION IS AGAINST -- I THINK, BERNIE, YOU CHARACTERIZE IT AS THE POCKETBOOK SHALL BE NO LIGHTER POLICY. AND THE CALIFORNIA APPROACH WOULD BE THAT ANY COST INCURRED -- I SHOULDN'T SAY CALIFORNIA. I SHOULD SAY CIRM'S APPROACH IS THAT ANY COST INCURRED BY THE PARTICIPANT FOR PARTICIPATION IN THE PROTOCOL WOULD BE SUBJECT TO REIMBURSEMENT, BUT NO ADDITIONAL AMOUNT OF MONEY BEYOND OUT-OF-POCKET EXPENSES COULD BE PROVIDED TO THE DONOR OR AS AN INCENTIVE TO PARTICIPATE.

CHAIRMAN LO: IF CIRM WERE PAYING THE DONOR. SO IT'S ONLY THINGS THAT YOU SPENT YOUR OWN MONEY ON.

OTHER QUESTIONS, GEOFF?

DR. BODKIN: AND JUST TO FOLLOW UP, WE

HAVEN'T BEEN TOLD HOW MUCH THE COMPENSATION WAS IN THE PARTICULAR CASE THAT WE'RE USING AS AN EXAMPLE HERE. IS THAT APPROPRIATE TO LET US KNOW?

CHAIRMAN LO: ABSOLUTELY. DR. AMATO, WOULD YOU BE WILLING TO ANSWER THAT?

DR. AMATO: I'M COMFORTABLE SHARING THAT. THAT'S $5,000 PER DONATION.

CHAIRMAN LO: OKAY.

DR. LOMAX: THAT WAS IN THE PAPER, SO THEY WERE VERY CANDID ABOUT THAT. AND THAT IS, DR. AMATO, I BELIEVE, CONSISTENT WITH AN IVF REIMBURSEMENT AS WELL?

DR. AMATO: CORRECT. I'M SORRY. I HAVE TO SIGN OFF TO GO SEE PATIENTS, BUT WERE THERE ANY OTHER QUESTIONS?

CHAIRMAN LO: ARE THERE OTHER QUESTIONS SPECIFICALLY FOR DR. AMATO BEFORE SHE NEEDS TO GET BACK TO HER CLINIC?

DR. TAYLOR: MINE IS, BERNIE.

CHAIRMAN LO: OKAY. THAT'S ROB?

DR. TAYLOR: HI, PAULA. HOW ARE YOU?

DR. AMATO: HEY, ROB. WELL, THANKS.

DR. TAYLOR: ALL RIGHT. GOOD TO HEAR YOUR VOICE.

DR. AMATO: LIKEWISE.

DR. TAYLOR: HERE'S A QUESTION. SO MY UNDERSTANDING OF THE TACHIBANA PAPER WAS THAT ALL OF THE SUCCESSFUL CELLS CAME FROM ANTAGONIST CYCLES. AND ARE YOU CONSIDERING CHANGING THE PROTOCOL, WHICH WOULD, FRANKLY, MAKE IT A SAFER PROTOCOL, I WOULD BELIEVE, BASED ON THAT RESULT? OR AM I MISINTERPRETING THAT RESULT?

DR. AMATO: YOU KNOW, WE DID MAKE THAT STATEMENT. I THINK THE NUMBERS ARE SMALL, SO AT THIS POINT WHETHER WE USE ANTAGONIST OR AN AGONIST IS BASED ON A NUMBER OF FACTORS, INCLUDING PATIENT'S AGE AND THEIR ACTUAL FOLLICLE COUNT AND AMH LEVEL. WE HAVEN'T CHANGED OUR POLICY ABOUT THAT.

THE NUMBERS -- THE DATA WAS INTERESTING IN THAT REGARD, BUT WE FELT THAT THE NUMBERS WERE TOO SMALL TO BE REALLY DEFINITIVE ABOUT THAT.

DR. TAYLOR: THAT SEEMS PRUDENT. WELL, WHEN WE MADE OUR RECOMMENDATIONS IN 2010, WE DIDN'T MAKE ANY RECOMMENDATIONS ABOUT HOW THE CYCLE SHOULD BE SUPPRESSED, BUT IT LOOKS INTERESTING. OKAY. THANK YOU.

DR. AMATO: OKAY.

CHAIRMAN LO: ANY OTHER QUESTIONS FOR DR. AMATO? OKAY.

CAN I JUST ASK ONE OTHER QUALIFICATION,

DR. AMATO?

DR. AMATO: SURE.

CHAIRMAN LO: SO THE PAYMENT OF $5,000, COULD YOU JUST CONFIRM THAT THIS WAS NOT CONTINGENT ON THE NUMBER OF OOCYTES RETRIEVED, THAT THAT WAS FOR GOING THROUGH THE CYCLE. YOU SAID IF THERE HAD BEEN NO OOCYTES, THEY WOULDN'T RECEIVE THE PAYMENT.

DR. AMATO: ABSOLUTELY. ABSOLUTELY. THERE WAS A PRORATED SCALE. SO IF, FOR EXAMPLE, THE CYCLE WAS CANCELED FOR SOME REASON PRIOR TO RETRIEVAL, THEN THEY WOULD HAVE RECEIVED LESS, YOU KNOW, CALCULATED UP TO THEIR PARTICIPATION TO THAT POINT. BUT THE MAJORITY OF PATIENTS THAT COMPLETED THE CYCLE, THEY ALL RECEIVED THE SAME AMOUNT REGARDLESS OF THE NUMBER OF EGGS THAT THEY YIELDED.

CHAIRMAN LO: THEN ASSUMING THERE ARE NO FURTHER QUESTIONS FOR DR. AMATO, I WANT TO THANK YOU AGAIN FOR BEING AVAILABLE. IF THERE'S ANY OTHER ISSUES, I'D LIKE TO BE ABLE TO CONTACT YOU.

DR. LOMAX: BERNIE, WE HAVE ONE QUESTION FROM THE PUBLIC.

CHAIRMAN LO: WITH REGARD TO DR. AMATO'S --

DR. LOMAX: YEAH. YES.

CHAIRMAN LO: INTRODUCE YOURSELF FOR THE

RECORD.

MS. STEVENS: THANK YOU. I'M TINA STEVENS FOR THE ALLIANCE --

CHAIRMAN LO: COULD YOU COME CLOSER TO THE PHONE? THOSE ON THE PHONE ARE REALLY HAVING TROUBLE HEARING.

MS. STEVENS: I'M TINA STEVENS WITH THE ALLIANCE FOR HUMAN BIOTECHNOLOGY. AND MY QUESTION IS ON THE ADS DISEASE, ON THE DONOR ADS, CALIFORNIA HAS A REQUIREMENT THAT DONOR -- THAT ADS TO DONORS MENTION RISKS. AND MY QUESTION IS DID THE ADS DISEASE FOR DONORS MENTION RISKS?

DR. AMATO: YOU KNOW, I'D HAVE TO GO BACK AND LOOK AT THEM, BUT I DON'T BELIEVE SO. I THINK THE RISKS WERE DISCUSSED DEFINITELY IN THE INFORMATION SEMINAR AND ON THE CONSENT FORM, BUT NOT NECESSARILY IN THE ADS.

CHAIRMAN LO: WOULD THEY BE DISCUSSED FROM A TELEPHONE SCREENING STANDPOINT?

DR. AMATO: NO, NOT NECESSARILY, NO, UNTIL THEY CAME TO THE INFORMATION SEMINAR.

CHAIRMAN LO: THANK YOU. OKAY. THANKS AGAIN.

DR. AMATO: OKAY. THANK YOU, EVERYBODY. BYE-BYE.

CHAIRMAN LO: ARE THERE OTHER QUESTIONS PERHAPS -- WELL, LET'S HOLD DR. ADAMSON BECAUSE HE HAS MORE GENERAL COMMENTS HE MAY WISH TO MAKE, BUT --

MR. SHEEHY: I HAD A QUESTION FOR DR. ADAMSON.

CHAIRMAN LO: I'M SORRY.

DR. LOMAX: JEFF SHEEHY HAS A QUESTION.

CHAIRMAN LO: OKAY.

MR. SHEEHY: I HAVE QUESTIONS FOR DR. ADAMSON. IF HE WAS GOING TO PRESENT, I THOUGHT I MIGHT ASK HIM A COUPLE OF QUESTIONS. YOU WANT TO WAIT FOR THAT, BERNIE?

CHAIRMAN LO: YEAH. WHY DON'T WE WAIT FOR THAT, IF THAT'S OKAY, BUT I'LL MAKE SURE THAT YOU HAVE FIRST QUESTION.

MS. LANSING: AND CAN I JUST ADD ONE THING, WHICH IS AN UNFORTUNATE THING. WE'RE GOING LOSE OUR QUORUM AT 11:45. SO I THINK WE JUST HAVE LIKE 45 MINUTES UNFORTUNATELY.

CHAIRMAN LO: OKAY. SO WE'LL THINK AND WE'LL MAKE LIKE WE'RE IN NEW YORK AND THINK QUICKLY, TALK QUICKLY.

MS. LANSING: SORRY. I JUST GOT THAT INFORMATION.

DR. LOMAX: SO, BERNIE, WOULD YOU LIKE TO MOVE TO THE SCIENTIFIC PIECE AT THIS POINT?

CHAIRMAN LO: I WOULD. ALAN, IF YOU COULD WALK US THROUGH THE SCIENTIFIC VALUE OF THESE LINES AND ACTUALLY OTHER LINES THAT MAY BE DERIVED BY THIS PROCESS? AGAIN, KEEPING SHERRY'S INSIGHT IN MIND, IF WE COULD REALLY TRY AND MAKE THIS AS CONCISE AS POSSIBLE WITH THE INFORMATION YOU WANT TO CONVEY.

DR. LOMAX: JUST FOR QUORUM AND FOR THE RECORD, JOHN WAGNER HAS JOINED THE CALL.

CHAIRMAN LO: OKAY. GOOD.

DR. TROUNSON: SO THANK YOU, BERNIE. WHAT I'LL TRY AND DO IS MAKE SURE THAT I DON'T SPEAK IN TOO MUCH JARGON ABOUT THE SCIENCE PART OF IT. THE GROUP MADE FOUR EMBRYONIC STEM CELL LINES IN THEIR STUDIES, AND THOSE FOUR EMBRYONIC STEM CELL LINES WERE MADE BY SOMATIC CELL NUCLEAR TRANSFER. SO WHAT'S CALLED A CLONING PROCEDURE, BUT IT'S A WAY OF REMOVING THE NUCLEUS FROM THE EGG CELL AND THEN INTRODUCING THE NUCLEUS OF A CELL FROM A PATIENT OR THE CELL LINE.

THEY FOLLOWED IT UP TO LOOK AT REPLICATION, AND THEY LOOKED AT USING 20 EGGS FROM TWO PATIENTS AND USED THE NUCLEAR CELL FROM A PATIENT WITH A DISEASE CONDITION, I THINK IT'S

CALLED LYON'S DISEASE, AND THEY WERE ALSO VERY SUCCESSFUL. THEY ESTABLISHED TWO CELL LINES FROM THAT CONDITION.

SO I UNDERSTAND THAT THE SCIENTISTS IN CALIFORNIA ARE INTERESTED PARTICULARLY IN THE FOUR EMBRYONIC STEM CELL LINES THAT WERE MADE FROM NORMAL CELL TYPES.

SO LET ME JUST SAY THAT IN THE LABORATORIES IN CALIFORNIA THERE ARE THREE MAJOR LABORATORIES WHICH ARE THE LEADING EPIGENOMICS LABORATORIES IN THE COUNTRY. THERE'S THE BING REN AND JOE ECKER LABORATORY AT THE LUDWIG & SALK IN LA JOLLA. AND THEY HAVE INCREDIBLE PUBLICATIONS WHICH ARE WAY OUT BEYOND 800 CITATIONS. SO THEY ARE THE LEADING LABORATORY IN THE WORLD IN THIS AREA OF EPIGENETICS.

JEANNIE LORING, WHO'S ALSO ON THE PHONE FROM SCRIPPS, IS ANOTHER ONE OF THESE THREE LABORATORIES. AND I THINK SHE'S ON THE TELEPHONE. THEY'RE INTERESTED IN LOOKING AT EPIGENETICS OF CELL LINES. AND, AGAIN, HER STUDIES ARE EXTREMELY WELL CITED, ABOVE 500, I THINK.

AND THEN FINALLY KATHERINE PLANT FROM THE UNIVERSITY OF CALIFORNIA IN LOS ANGELES IS AN EXPERT IN EPIGENETICS. SHE'S A RELATIVELY YOUNG PERSON,

AND SHE'S PROBABLY THE LEADING YOUNG SCIENTIST, I SUSPECT, IN THE WORLD IN EPIGENETICS AND GENOMICS. AND AGAIN, HER PAPERS ARE RECEIVING CITATIONS, ABOUT 500.

SO THESE ARE THE CONCENTRATION OF SCIENTISTS PARTICULARLY INTERESTED IN THESE CELLS. I'VE ALSO HAD CONTACT FROM SCIENTISTS AT UCSF, THE UNIVERSITY OF CALIFORNIA SAN DIEGO, AND UP AT STANFORD.

NOW, WHAT ARE THE QUESTIONS BEING RAISED BY THIS AND WHY ARE THEY SO INTERESTED? FIRST OF ALL, LET ME JUST GO QUICKLY THROUGH THESE THINGS AND THEN, IF YOU LIKE, YOU CAN ASK ME QUESTIONS TO AMPLIFY.

FIRST OF ALL, WE DON'T REALLY KNOW WHAT THE ABILITY OF THESE CELL TYPES ARE TO FORM DIFFERENTIATED CELL TYPES. PRESENTLY HUMAN EMBRYONIC STEM CELLS ARE MORE ROBUST, QUESTIONABLY BETTER THAN IPS CELLS, AT DERIVING SOME OF THE DERIVATIVES: HEART CELLS, LUNG CELLS, LIVER CELLS, FOR EXAMPLE. NOW, WE DON'T KNOW WHETHER THE SCNT CELL LINES PERFORM MORE LIKE EMBRYONIC STEM CELLS OR MORE LIKE IPS CELLS IN THAT REGARD.

SECONDLY, IPS CELLS SHOW SOME INSTABILITY IN LONG-TERM CULTURE. YOU'VE GOT TO MULTIPLY IPS

CELLS QUITE DRAMATICALLY FOR THE USE BECAUSE YOU START WITH ONE SINGLE CLONE AND YOU NEED TO MULTIPLY THEM. THEY TEND TO BE UNSTABLE IN CULTURE AND MORE UNSTABLE THAN EMBRYONIC STEM CELLS. BUT THE QUESTION IS WHAT DO SCNT STEM CELL LINES, DO THEY BEHAVE THE SAME OR BETTER? IT'S A GOOD QUESTION.

THIRDLY, THE ISSUE OF EPIGENETIC MEMORY, THAT IS, THE MEMORY OF THE CELL TYPE THAT WAS USED FOR THE DONATION. IN IPS CELLS THE EPIGENETIC MEMORY REMAINS AND CAN BE QUITE SIGNIFICANT. AND, OF COURSE, EMBRYONIC STEM CELLS DON'T HAVE THAT EPIGENETIC MEMORY. SO THEY'RE RATHER DIFFERENT. BUT THE QUESTION IS WHAT HAPPENS IN SCNT CELL LINES? DO THEY HAVE AN EPIGENETIC MEMORY THAT COULD CAUSE A PROBLEM? IT IS POSSIBLE THAT THEY DO? BUT IS IT TO THE SAME EXTENT AS IPS CELLS IS THE QUESTION THERE.

AND REMEMBER THE WAY IN WHICH IPS CELLS WERE ORIGINALLY DERIVED, THE WORK WAS BASED ON EMBRYONIC STEM CELLS, FIGURING OUT THE TRANSCRIPTION FACTORS THAT WERE CRITICAL FOR PLURIPOTENTIALITY, THE ABILITY TO BECOME CELLS THAT CAN GROW INTO ANY CELL TYPE. SO WITHOUT EMBRYONIC STEM CELLS WE WOULDN'T HAVE IPS CELLS.

AND THEN THERE WAS A VIEW BEFORE THIS TECHNIQUE WAS SUCCESSFUL THAT IPS CELLS WOULD

DEVELOP WITHOUT THE NECESSITY FOR SCNT. THAT'S NOT THE MAJORITY VIEW OF SCIENCE. THERE ARE SOME SCIENTISTS WHO BELIEVE THAT, BUT THEY'RE WAY IN THE MINORITY. THE INTEREST IS TO TRY AND UNDERSTAND WHETHER THIS OTHER CELL TYPE IS BETTER OR IS WORSE.

NOW, ONE OF THE OTHER ISSUES, WHICH IS A PRETTY MAJOR MATTER AND IT'S UNRESOLVED AT PRESENT, IS THE SOURCE OF THE STUDIES BY KATHRIN PLATH IS X CHROMOSOME INACTIVATION. AND WHAT HAPPENS WITH IPS CELLS IS QUITE DIFFERENT FROM EMBRYONIC STEM CELLS. WHAT YOU NEED TO DO WHEN YOU BECOME A PLURIPOTENTIAL STEM CELL IS TO ACTIVATE BOTH X CHROMOSOMES.

IN THE DEVELOPED STATE, ONE OF THOSE X CHROMOSOMES HAS TO BE TURNED OFF, AND IT'S TURNED OFF BY THE XIST GENE. AND SO THE XIST GENE COATS ONE OF THE X CHROMOSOMES. SO IN ALL FEMALE CELLS, ONE X CHROMOSOME NEEDS TO BE TURNED OFF. OTHERWISE YOU HAVE A GENE DOSAGE ISSUE, WHICH IS DANGEROUS.

AND SO WHAT HAPPENS WITH HUMAN IPS CELLS IS THAT THEY DON'T REALLY INACTIVATE THIS X CHROMOSOME IN THE SAME WAY EMBRYONIC STEM CELLS DO. AND IT'S A QUESTION HERE, WHICH IS WHAT KATHERINE IS ASKING, IS WOULD THE OOCYTE HAVE THE MACHINERY THERE TO DO THAT; WHEREAS, THE TRANSCRIPTION FACTORS ARE NOT SET UP TO DO THAT. SO IS THERE A DIFFERENCE

HERE BETWEEN THE SOMATIC CELL NUCLEAR TRANSFER AND THE IPS CELLS?

NOW, THE WHOLE QUESTION OF THIS IS IS THIS BASIC SCIENCE REALLY MOVING TOWARD SAYING, WELL, IF WE CAN SHOW THAT THE IPS CELLS ARE, IN FACT, EQUIVALENT TO SCNT CELLS, THEN THERE'S NO REASON TO DO SCNT. RIGHT? SO THEY ACTUALLY CAN BE AS NORMAL. THERE'S NO REAL POINT. SO IN THE END THIS IS WORKING TOWARDS THE SOLUTION OF, I THINK, FOR HAVING THE CONFIDENCE TO BE ABLE TO DEVELOP IPS CELLS.

NOW, A THIRD -- ON THE NEXT PAGE, ONE OF THE IMPORTANT THINGS IS TO BE ABLE TO COMPARE IPS CELLS AND SCNT CELLS FROM THE SAME PATIENT. SO DR. MITALIPOV AND HIS COLLEAGUES ARE ACTUALLY MAKING IPS -- HAVE MADE IPS CELLS FROM THE CELLS THAT WERE MADE FROM THE SCNT. SO THEY'RE PREPARED TO MAKE THEM AVAILABLE, AND THERE'S NO ISSUE, AS FAR AS WE KNOW, FOR IPS CELLS MADE IN THAT WAY. AND SO THE CALIFORNIA SCIENTISTS, IF INTERESTED, WOULD GET BOTH, AND THEY WOULD GET A SIDE-BY-SIDE COMPARISON FROM THE SAME PATIENT. SO THAT'S AS GOOD A CONTROL AS YOU CAN ACTUALLY GET.

EQUIVALENCE IN DRUG SCREENS, WE DON'T KNOW THE ANSWER TO THAT, WHETHER THESE NEW CELLS WILL BE ANY BETTER THAN IPS CELLS OR NOT, BUT IT'S A

QUESTION BEING ASKED BY SOME SCIENTISTS.

NOW, THE NEW EFFICIENT REPROGRAMMING FACTORS, AS I SAID, WE HAD EMBRYONIC STEM CELLS WHICH POINT TO THE TRANSCRIPTION FACTORS WE NEEDED FOR MAKING IPS CELLS. NOW, THE NUCLEAR TRANSFER PROCEDURE IS MUCH MORE EFFICIENT THAN IPS AND IT'S MUCH SHORTER. SO YOU GET REPROGRAMMING OF THE NUCLEUS WITHIN TWO DAYS OR PROBABLY WITHIN 24 HOURS. AND THIS IS WORK WHICH HAS REALLY BEEN DONE BY JOHN GURDON, WHO WON THE NOBEL PRIZE ALONG WITH SHINYA YAMANAKA.

SO THEY'RE INTERESTED IN IDENTIFYING THE REPROGRAMMING FACTORS THAT ARE IN THE OOCYTE. AND IF THOSE FACTORS THAT COULD BE UTILIZED TO MAKE IPS CELLS MORE EFFICIENT AND MORE EFFECTIVE, THEN WE WOULD GET A BOUNCE-UP, IF YOU LIKE, A BIG BOUNCE-UP IN OUR CAPACITY FOR IPS CELLS. SO THAT'S AN OPPORTUNITY FOR WHICH WE SHOULD TAKE THAT FOR THESE CELLS.

SO FINALLY, THE CLINICAL ISSUES WHERE THIS TECHNIQUE MIGHT INVOLVE EVENTUALLY, FIRST OF ALL, IN MITOCHONDRIAL DISEASE, IF YOU HAVE MITOCHONDRIAL DISEASE, THESE ARE MUTATIONS IN THE DNA IN YOUR MITOCHONDRIA. AND THESE DISEASES CAN BE REALLY QUITE DREADFUL. SO THERE'S AN OPPORTUNITY HERE FOR

USING SCNT TO CORRECT THAT BECAUSE IF YOU PUT THE NUCLEUS OF THE DONOR CELL FROM A PATIENT WHO HAS THAT DISEASE INTO AN OOCYTE, THEN YOU WILL AVOID THE TRANSMISSION OF THAT MITOCHONDRIAL GENETIC DISORDER.

SO THERE IS INTEREST BOTH IN THE UK AND IN THE U.S. FOR USING THIS CLINICALLY FOR THAT PROCEDURE. BUT YOU CAN ALSO MAKE, IF YOU LIKE, EMBRYONIC STEM CELLS FOR THOSE PATIENTS THAT DO NOT HAVE THAT MITOCHONDRIAL DISEASE. SO THEY MAY BE IMPORTANT FOR HELPING THESE PATIENTS IN DUE COURSE IN TRANSPLANTATION. SO TO BE ABLE TO MAKE GENOMICALLY THESE CELLS WITHOUT A MUTATION THAT'S CAUSING THE DISEASE.

THEN FINALLY, DO THESE SCNT CELLS DIFFER FROM ES CELLS OR IPS CELLS IN THE DETECTION BY IMMUNE SURVEILLANCE? WE DON'T REALLY KNOW THE ANSWER TO THIS. BOTH ES, EMBRYONIC STEM CELLS, AND IPS CELLS CAN BE RECOGNIZED BY THE BODY AND CAN BE REJECTED. THEY'RE REJECTED ON DIFFERENT MECHANISMS. EMBRYONIC STEM CELLS ARE ALLOGENEIC, SO THEY'RE REJECTED BECAUSE THEY'RE A DIFFERENT GENOTYPE. AND THE IPS CELLS ARE REJECTED BECAUSE THEY'RE SIMILAR. SO WHAT HAPPENS IS THAT THOSE CELLS ARE TAKEN OUT BY NATURAL KILLER CELLS, AND SO WE KNOW THAT THERE ARE ISSUES ON THE IMMUNE SYSTEM FOR BOTH OF THOSE CELLS,

WHICH MAY GET RESOLVED IN LONG-TERM STUDIES. AND WE DON'T KNOW WHETHER THE SCNT CELLS WOULD BE DIFFERENT OR THE SAME AS EITHER EMBRYONIC STEM CELLS, OR THEY SHOULD BE MORE LIKE IPS CELLS, WHETHER THEY HAVE SOME ADVANTAGE IN TRANSPLANTATION.

SO THOSE ARE THE ISSUES, BERNIE. I HOPE I HAVEN'T BEEN TOO TECHNICAL IN THAT REGARD, AND I'M CLEARLY OPEN TO ANSWERING ANY QUESTIONS.

CHAIRMAN LO: ALAN, THANK YOU VERY MUCH. I'M GOING TO -- I'M NOT IN THE ROOM. I TAKE IT THERE ARE A LOT OF QUESTIONS AND THERE ARE QUESTIONS FROM THE PUBLIC, COMMENTS FROM THE PUBLIC. I WANT TO KIND OF MOVE US AHEAD. THERE ARE ALSO A NUMBER OF COMMENTS, QUESTIONS FROM THE SWG.

AND AGAIN, JUST TO FRAME THIS, I THINK WE'RE REALLY TALKING ABOUT ARE WE GOING TO RECOMMEND A PROCESS, A PROCEDURE, BY WHICH CIRM MAY FUND RESEARCH ON STEM CELL LINES DERIVED FROM DONORS WHO WERE PAID TO DONATE THEIR OOCYTES. WE'RE NOT BEING ASKED TO APPROVE THE OREGON LINE, BUT REALLY THE QUESTIONS ARE ARE THERE CONCERNS THAT WOULD EITHER LEAD SOME MEMBERS OF THE SWG TO SAY, NO, I DON'T THINK CIRM SHOULD EVER FUND RESEARCH ON THOSE LINES EVEN THOUGH WE'RE NOT PAYING FOR THE ORIGINAL DONATION? OR, ALSO, ARE THERE CONCERNS THAT WOULD

NEED TO BE ADDRESSED IN SOME SORT OF REVIEW PROCESS BEFORE CIRM WOULD BE ABLE TO APPROVE ANY PARTICULAR LINES.

SO I HAVE, JUST SO I KNOW, ON MY LIST DOROTHY, FRANCISCO. JEFF SHEEHY, I WASN'T SURE IF YOU HAD ANOTHER QUESTION. IF THERE ARE OTHER MEMBERS OF THE SWG WHO HAVE QUESTIONS, PLEASE LET ME KNOW.

DR. LORING: CAN I INTERRUPT? THIS IS JEANNIE LORING. I JUST WANTED YOU TO KNOW THAT I'M ON THE LINE.

CHAIRMAN LO: HI. I'M SORRY. I CAN'T RECOGNIZE YOUR VOICE.

DR. LORING: THIS IS JEANNIE LORING. I'M ONE OF THE SCIENTISTS THAT ALAN MENTIONED, AND I'M HERE TO ANSWER QUESTIONS ABOUT THE SCIENCE.

CHAIRMAN LO: I'M NOT GOING TO ASK YOU TO GIVE A PRESENTATION, BUT MY SENSE IS THAT MANY OF THE QUESTIONS THAT ARE GOING TO BE RAISED ARE NOT SCIENTIFIC IN NATURE, BUT WE MAY CALL ON YOU IF YOU'RE WILLING IN RESPONSE TO A PARTICULAR QUESTION.

DR. LORING: THAT'S FINE. I DON'T HAVE A PRESENTATION ANYWAY. I WAS JUST HERE TO ANSWER QUESTIONS.

DR. LOMAX: BERNIE, WE HAVE A NUMBER OF

MEMBERS OF THE PUBLIC THAT WOULD LIKE TO ASK QUESTIONS. IF THE QUESTIONS ARE LIMITED FROM THE WORKING GROUP, WE COULD GO THROUGH THEM QUICKLY AND THEN MOVE TO PUBLIC COMMENT, OR JUST FOR THE BENEFIT OF THE WORKING GROUP, WE COULD TAKE QUESTIONS NOW. WHAT'S YOUR PLEASURE?

CHAIRMAN LO: I WOULD PREFER TO HAVE THE PEOPLE WHO HAVE INDICATED TO ME ALREADY THEY WANT TO FROM THE WORKING GROUP. SO IT'S DOROTHY, FRANCISCO, AND I'M NOT SURE IF JEFF HAS ANOTHER QUESTION. DOROTHY, YOU WANT TO GO NEXT, PLEASE?

DR. ROBERTS: YEAH. MY QUESTION ACTUALLY GOES ALL THE WAY BACK TO SHERRY'S PRESENTATION AND SORT OF THE ORIENTATION OF OUR DISCUSSION BECAUSE IT SEEMS THAT THE DISCUSSION IS STARTING FROM THE PREMISE THAT NOTHING ABOUT CIRM POLICY IS GOING TO CHANGE. AND MY UNDERSTANDING, EVEN FROM THE JULY 1ST MEMO THAT WE GOT FROM CIRM, IS THAT THE POLICY IS TO EXTEND THE PROHIBITION ON CIRM FUNDS BEING PAID FOR COMPENSATION EVEN TO RESEARCH THAT WAS -- OR COMPENSATION THAT WAS NOT PAID BY CIRM.

SO IN OTHER WORDS, WE ARE BEING ASKED TO CHANGE THE POLICY. I MEAN THE MEMO SAYS IN 2006 THIS INTERPRETATION WAS EXTENDED TO EXCLUDE FROM USE IN CIRM-FUNDED RESEARCH ANY STEM CELL LINE WHERE

RESEARCH DONORS WERE FINANCIALLY COMPENSATED EVEN IF THE DERIVATION WAS DONE WITHOUT THE USE OF CIRM FUNDS.

SO WHEN I APPROACHED THIS, MY SENSE IS THE CURRENT POLICY IS NOT TO ALLOW -- FOR CIRM FUNDS NOT TO GO TO RESEARCH WHERE DONORS WERE COMPENSATED REGARDLESS OF WHETHER IT WAS WITH CIRM FUNDS OR NOT. AND THEN MY QUESTION IS WHAT HAS CHANGED THAT WOULD LEAD ME TO WANT TO CHANGE THIS POLICY? AND I JUST HAVEN'T HEARD WHAT HAS CHANGED. IT SEEMS TO ME WHATEVER THE CONCERNS WERE, AND I THINK THERE WERE CONCERNS ABOUT WOMEN'S HEALTH THAT LED TO THAT, CONCERNS THAT ARE RAISED IN THE ARTICLE WE GOT FOR POST-OOCYTE DONATION GUIDELINES THAT GEOFF LOMAX AND ROBERT TAYLOR CO-AUTHORED. THOSE CONCERNS SEEM TO ME TO STILL BE PRESENT, THE CONCERNS ABOUT THE HEALTH AND CONCERNS ABOUT UNDUE INDUCEMENT.

SO THEN MY NEXT QUESTION WOULD BE, OKAY, IS THERE SOME PROCEDURE THAT'S GOING TO BE IN PLACE THAT WOULD MAKE SURE THAT THOSE CONCERNS ARE NOT PRESENT IN ANY CIRM FUNDING THAT'S GOING TO RESEARCH USING LINES DERIVED FROM EGGS FOR WHICH WOMEN WERE COMPENSATED. AND THE PROCEDURE I SEE IS JUST SO FLIMSY -- WE DON'T HAVE ANY INFORMATION. THE QUESTION IS WILL IT ADVANCE CIRM'S MISSION.

WELL, THAT DOESN'T EVEN ASK WHETHER OR NOT WOMEN'S HEALTH IS GOING TO BE TAKEN INTO ACCOUNT. BERNIE, WHEN YOU TALKED ABOUT THE NIH WORKING GROUP AND ABOUT THE SCRUTINY INVOLVED THERE, I JUST -- I NEED MORE ASSURANCE THAT THAT KIND OF SCRUTINY IS GOING TO BE PART OF WHAT WE'RE BEING ASKED TO APPROVE TODAY.

SO THOSE ARE MY QUESTIONS. I UNDERSTAND WHAT ALAN WAS SAYING. I ABSOLUTELY UNDERSTAND THAT SCIENTISTS ARE VERY INTERESTED IN THESE PARTICULAR LINES; BUT LIKE BERNIE JUST SAID, WE'RE NOT BEING ASKED TO APPROVE THIS PARTICULAR RESEARCH USING THESE LINES. WE'RE BEING ASKED TO CHANGE THE POLICY I THINK PRETTY DRAMATICALLY TO ALLOW FOR CIRM FUNDS TO GO FOR RESEARCH USING EGGS THAT WERE PAID FOR.

MS. LANSING: WELL, CAN I JUST TAKE A SHOT AT SOME OF THIS, BERNIE?

DR. ROBERTS: YEAH, PLEASE.

CHAIRMAN LO: PLEASE, SHERRY.

MS. LANSING: I THOUGHT I WAS CLEAR, BUT I APOLOGIZE IF IT WASN'T. OUR FUNDING PER SE, WE'RE NOT GOING TO PAY PER SE IN CALIFORNIA FOR ANY DONATION. SO WE'RE NOT CHANGING OUR POLICY, BUT WE ARE ASKING FOR AN EXCEPTION. AND THE EXCEPTION IS WHEN THE WOMEN HAVE BEEN -- I DON'T KNOW WHAT THE

RIGHT WORD IS -- INFORMED IN THE SAME MANNER THAT WE DO IN TERMS OF HEALTH RISKS, IN TERMS OF PSYCHOLOGICAL RISKS, IN TERMS OF THE PROCESS, THE LINES THAT WE'RE SUGGESTING THAT THEY'VE GONE THROUGH ALL THAT PROCESS, WE'RE ASKING TO USE THOSE LINES, FOR EXAMPLE, IN OREGON WHERE THESE WOMEN HAVE IN ADDITION BEEN PAID.

DR. ROBERTS: I DON'T MEAN TO CUT YOU OFF, SHERRY. IT'S JUST THAT BECAUSE OF THE SHORTNESS OF TIME. I UNDERSTAND THAT. WHAT I'M SAYING IS CIRM POLICY ISN'T JUST NOT TO PAY WOMEN DIRECTLY. THE CURRENT POLICY EXTENDS THAT SINCE 2006. I'M READING PAGE 1.

MS. LANSING: WE'RE ASKING FOR THE EXCEPTION. AND WE'RE ASKING FOR THE EXCEPTION.

DR. ROBERTS: RIGHT. WHICH IS A CHANGE IN CIRM POLICY. THAT'S THE ONLY POINT I'M MAKING.

MS. LANSING: OKAY.

DR. ROBERTS: SEE WHAT I'M SAYING? OKAY.

CHAIRMAN LO: OKAY. WHETHER WE CALL IT AN EXCEPTION OR A CHANGE IN POLICY, UNDER CURRENT CIRM REGULATION, THE LINES THAT WE'RE TALKING ABOUT FROM OREGON OR ANY OTHERS LIKE IT WHERE DONORS HAVE BEEN PAID COULD NOT TODAY BE USED BY A CIRM-FUNDED RESEARCHER IN CIRM-FUNDED RESEARCH. AND THE

QUESTION THAT DOROTHY IS POSING IS WE ARE, ARE WE NOT, BEING ASKED TO MAKE SOME RECOMMENDATION THAT WOULD ALLOW THOSE LINES TO BE FUNDED TO ALLOW RESEARCHERS USING THOSE LINES BE FUNDED. I TAKE IT DOROTHY IS SAYING THAT'S THE CHANGE FROM WHAT CAN BE DONE TODAY.

MS. LANSING: AND DOROTHY IS SAYING THAT AND WE'RE NOT DISAGREEING, BUT WHAT I'M SAYING IN THE BEGINNING WAS WE ALWAYS SAID WE WOULD RELOOK AT OUR POLICIES. WE ALWAYS SAID WE WOULD ADAPT AS THE SCIENCE AND THE PUBLIC EVOLVE, AND I THINK WE'RE AT THAT POINT NOW.

CHAIRMAN LO: DOROTHY, JUST TO MAKE SURE WE UNDERSTAND, THE SECOND POINT SHE MADE IS THAT ONE OF THE PROCEDURES UNDER THIS EXCEPTION OR CHANGE THAT WE'RE BEING ASKED TO MAKE THAT WOULD PROVIDE ASSURANCE THAT CONCERNS ABOUT MEDICAL RISK, UNDUE INFLUENCE, AND INFORMED CONSENT HAS BEEN ADDRESSED WITH ANY PARTICULAR LINE.

DR. ROBERTS: RIGHT.

CHAIRMAN LO: SO I HAVE FRANCISCO NEXT ON THE LIST.

DR. PRIETO: SO ACTUALLY DOROTHY BROUGHT UP A LOT OF WHAT I WANTED TO ASK ABOUT, WHICH IS -- I KIND OF WAS HOPING GEOFF WOULD COMMENT A LITTLE

MORE ON THE PREVIOUS DISCUSSIONS WE HAD USING OTHER CELL LINES, NOT NECESSARILY THESE SCNT LINES, THAT HAD BEEN DERIVED FROM PAID DONORS BUT WHERE THE CELL LINE PROPOSED FOR USE IN CALIFORNIA WAS DOWNSTREAM FROM THAT PROCESS. THAT SEEMS TO ME THE CRUX OF THE QUESTION HERE. IS THE NEED FOR THESE CELLS OR THE INFORMATION THAT WE CAN GET FROM THEM SO COMPELLING AS TO MAKE US WANT TO CHANGE THAT POLICY OR MAKE AN EXEMPTION FROM THAT POLICY?

AS FAR AS THE PROCESS FOR MAKING THE EXCEPTION, I'M PRETTY SATISFIED THAT THE PROPOSAL, THE 100082, HAS A LOT OF SAFEGUARDS, BUT DO WE WANT TO CROSS THIS LINE? AND GEOFF, MAYBE YOU COULD COMMENT ON THAT.

DR. LOMAX: LET ME TRY. FIRST OF ALL, THE PURPOSE OF GOING THROUGH THE OREGON EXERCISE WAS TO GIVE A CONCRETE ILLUSTRATION OF WHAT THE REVIEW PROCEDURE WOULD LOOK LIKE. AND I WOULD POINT OUT I THINK THIS WAS AN UNPRECEDENTED LEVEL OF SCRUTINY AND EVALUATION.

IN TERMS OF -- I DON'T WANT TO SPEAK OUT OF TURN HERE. A COUPLE OF THINGS THAT HAVE CHANGED, I MEAN IN 2006 THE BASIS -- SCNT WAS A CONCEPTUAL CURIOSITY WITH A HIGH DEGREE OF UNCERTAINTY ABOUT EVEN HOW MANY OOCYTES WOULD BE NECESSARY. AND I

THINK THE STANDARDS WORKING GROUP RECOMMENDED THE RIGHT DECISION AT THAT TIME. THEY'RE NO LONGER A CONCEPTUAL CURIOSITY. AND IN ADDITION, WE WERE CONCERNED ABOUT OUR LEADERSHIP ROLE IN THE POLICY ENVIRONMENT AT THAT TIME. AND SO, AGAIN, I THINK WE MADE THE RIGHT CHOICE. SUBSEQUENT TO THAT TIME, THE POLICY ENVIRONMENT HAS CHANGED AND OTHERS HAVE CHOSEN A DIFFERENT POLICY OUTCOME.

SO THOSE WERE SOME OF THE THINGS I TRIED TO HIGHLIGHT MAYBE IN TOO MUCH OF A BULLETED WAY IN THE MEMO, BUT THAT'S, I THINK, THE CONTEXT IN WHICH WE APPROACHED THIS DECISION. FOR EXAMPLE, WHEN NEW YORK STEM CELL FOUNDATION ANNOUNCED SCNT LINES ABOUT A YEAR AND A HALF, TWO YEARS AGO, WE DIDN'T -- WE SORT OF LOOKED AT IT THROUGH THE SCIENTIFIC LENS AND SAID THIS IS NOT NECESSARY. SO I THINK IT TRULY IS THE SCIENTIFIC IMPERATIVE AT THIS STAGE, WHICH IS WHY WE'RE ASKING YOU TO RECONSIDER THIS. THAT'S SORT OF THE FUNDAMENTAL CHANGE.

DR. TROUNSON: I THINK FRANCISCO IS ALSO ASKING YOU, GEOFF, WHETHER WE EVER USED ANY DONOR EGGS FROM A DONOR THAT HAVE GONE TO A RECIPIENT PATIENT THAT DIDN'T USE THEM, EITHER EMBRYONIC STEM CELLS IN THE PAST.

DR. LOMAX: THE CASES WE HAVE -- WE

AUTHORIZED IN 2007, I BELIEVE, THE USE OF EMBRYOS FROM IVF FROM WHICH THE OOCYTE DONOR TO THAT EMBRYO WOULD HAVE BEEN PAID PROVIDED THE ORIGINAL REASON FOR THE CREATION OF THE EMBRYO WAS FOR REPRODUCTIVE PURPOSES. SO THERE IS A POLICY PRECEDENT OF UTILIZING MATERIALS WHERE PAYMENT HAS COME INTO THE FOLD, YES.

DR. PRIETO: THAT WAS A QUESTION IN MY MIND. I THOUGHT THAT SOMETHING LIKE THAT (UNINTELLIGIBLE).

DR. LOMAX: I APOLOGIZE.

CHAIRMAN LO: I'M MINDFUL OF THE TIME AND THE NUMBER OF PEOPLE WHO, I TAKE IT IN THE ROOM, WANT TO ASK QUESTIONS. IS THERE ANYONE ELSE ON THE CIRM SWG THAT HASN'T ASKED A QUESTION YET THAT WANTS TO RAISE A QUESTION? IF NOT, I WOULD LIKE TO GET SOME PUBLIC COMMENT.

CHAIRMAN THOMAS: BERNIE, IT'S J.T. I DON'T HAVE A QUESTION, BUT I DO WANT TO MAKE A STATEMENT AT THE APPROPRIATE TIME IN RESPONSE TO A NUMBER OF THE COMMENTS.

CHAIRMAN LO: OKAY. I WOULD LIKE TO --

MR. SHEEHY: BERNIE, AM I STILL ON THE LIST?

CHAIRMAN LO: JEFF, YEAH. LET'S GIVE YOU

ANOTHER QUESTION. I KNOW DOROTHY HAD SOME FURTHER QUESTIONS. I WANTED TO GET OTHER VOICES INTO THIS CONVERSATION.

MR. SHEEHY: FIRST OF ALL, I WANT TO SAY I DON'T THINK WE HAVE TO DO THIS TODAY. IT'S VERY SHORT AND HASTY. BUT, YOU KNOW, I REMEMBER 2006. RIGHT? AND WE WERE GUIDED BY THE LAW THAT'S IN THE CALIFORNIA CONSTITUTION, WHICH IS PROP 71, WHICH HAS NOT CHANGED. AND THE IMPETUS FOR THAT BEING IN PROP 71 WERE HEALTH CONCERNS. AND I HAVEN'T SEEN ANYTHING RELATED TO HEALTH CONCERNS IN THIS PRESENTATION.

AND I'M CONFUSED BECAUSE THE SCIENTIFIC NECESSITY WAS GREATER -- IT WAS HEART WRENCHING FOR ME IN 2006 WHEN WE WERE TALKING ABOUT -- BEFORE WE HAD IPS CELLS, WHEN WE WERE TALKING ABOUT BEING ABLE TO MODEL DISEASE, AND WE WERE TALKING ABOUT THE THERAPEUTIC POSSIBILITY OF THESE CELLS. NOW THE SCIENTIFIC NECESSITY IS PARAFFIN STUDIES, WHICH A WHOLE SEVERAL ORDERS OF MAGNITUDE LESS THAN THE SCIENTIFIC NECESSITY THAT WE FACED IN 2006, YET WE MADE OUR CHOICE THEN BASED ON THE LAW.

SO I HAVE A LOT OF TROUBLE UNDERSTANDING HOW WE CAN UNDO PROP 71 WHEN WE HAVEN'T EVEN GOTTEN ANY INFORMATION RELATED TO THE HEALTH RISKS THAT

MADE PROP 71 CONTAIN THAT PROHIBITION THAT WAS SPECIFICALLY IN OOCYTE DONATION.

MY ONLY CONCERN IS THAT I KEEP HEARING BECAUSE OTHER PEOPLE ARE DOING IT. WELL, I HAVE AN EIGHT-YEAR-OLD. I HEAR THAT EVERY DAY. IT'S NOT A GOOD REASON. WE HAVE A LAW, YOU KNOW. WE SHOULD FOLLOW OUR LAW. AND I'M VERY UNCOMFORTABLE WITH THE SPEED, THE HASTE, THE ABSOLUTE UTTER LACK OF INFORMATION ABOUT HEALTH RISKS, WHICH HAS ALWAYS BEEN THE MAIN DRIVER FOR THIS, NOT THE SCIENTIFIC NEED, THE HEALTH CONCERNS. AND WE HAVE GOTTEN NOTHING TODAY. AND I JUST FEEL VERY UNCOMFORTABLE WITH THIS WHOLE PROCESS.

CHAIRMAN LO: JEFF RAISES A VERY STRONG SUGGESTION THAT THIS IS NOT SOMETHING WE SHOULD TRY TO MAKE A RECOMMENDATION ON THIS PHONE CALL AND THAT WE NEED A FULLER, LONGER DISCUSSION. SO I THINK THAT'S SOMETHING REALLY TO KEEP IN MIND.

I DO THINK IT'S IMPORTANT TO HEAR FROM PEOPLE IN THE PUBLIC WHO HAVE COME TO THE MEETING WITH QUESTIONS OR COMMENTS IN MIND.

MR. TORRES: BERNIE, THIS IS ART TORRES. I THINK DR. ADAMSON HAD A RESPONSE TO JEFF, AND THEN MAYBE WE CAN GO TO PUBLIC COMMENT.

CHAIRMAN LO: OKAY. I'M REALLY CONCERNED

ABOUT WHETHER EVEN A VERY -- WHETHER WE REALLY NEED MORE TIME, I GUESS. I DON'T HAVE A SENSE OF HOW MANY PEOPLE IN THE ROOM WANT TO ASK QUESTIONS. WE'RE NOW 11:36. SO HOW MANY PEOPLE ARE THERE IN THE ROOM THAT WANT --

DR. LOMAX: SEVEN OR EIGHT.

DR. FEIGAL: THREE WANT TO ASK QUESTIONS.

CHAIRMAN LO: SEVEN OR EIGHT. OKAY. DR. ADAMSON, CAN YOU GIVE A BRIEF RESPONSE TO JEFF SHEEHY? AND THEN I REALLY DO WANT TO HEAR FROM MEMBERS OF THE PUBLIC.

DR. ADAMSON: I OBVIOUSLY RECOGNIZE THIS IS A VERY DIFFICULT ISSUE. I WOULD MAKE THE COMMENTS THAT AFTER 30 PLUS YEARS OF IVF AND 20 MILLION EGG RETRIEVALS, AND SINCE 2006 THERE ARE MULTIPLE PUBLICATIONS, SOME OF WHICH I'D BE HAPPY TO SHARE, AND MULTIPLE ASSESSMENTS BY AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, OTHER PROFESSIONAL GLOBAL ORGANIZATIONS THAT WOULD SUGGEST THAT THERE ARE NO -- DESPITE A LOT OF WORK, THERE'S BEEN NO DEFINED FINDING OF SERIOUS LONG-TERM HEALTH RISKS.

MR. SHEEHY: CAN I ASK A COUPLE OF QUESTIONS?

DR. ADAMSON: LET ME JUST FINISH.

CHAIRMAN LO: I'M REALLY CONCERNED ABOUT

TIME. THAT'S A QUESTION WE'RE NOT GOING TO RESOLVE TODAY, AND I LIKE JEFF'S SUGGESTION --

(SIMULTANEOUS DISCUSSION.)

CHAIRMAN LO: -- THE CONCERN ABOUT MEDICAL RISK AND TO LOOK MORE CLOSELY AT THE DATA.

MR. SHEEHY: IF SOMEONE GOES AHEAD AND GETS PREGNANT, THAT MITIGATES SOME OF THE RISK OF BEING A DONOR? I DON'T UNDERSTAND.

DR. ADAMSON: IF I CAN JUST MAKE ONE COMMENT. THE NOBEL PRIZE WAS GIVEN TO BOB EDWARDS. AND BASED ON COMMENTS FROM CARL NEGRIN, WHO'S A VERY HIGHLY REGARDED SWEDISH RESEARCHER AND FRIEND OF MINE, ONE OF THE REASONS THAT THEY FINALLY GAVE BOB EDWARDS THE NOBEL PRIZE PROBABLY 10, 15 YEARS AFTER THEY SHOULD HAVE IS THEY WERE WAITING TO SEE IF THEY FELT THAT IVF WOULD BE A SAFE TECHNOLOGY. AND THAT'S FROM CARL NEGRIN IN STOCKHOLM, SWEDEN. THEY'VE TALKED WITH PEOPLE ON THE COMMITTEE.

NOW, THAT'S OBVIOUSLY NOT HARD EVIDENCE; BUT, AGAIN, TO PROVE THAT SOMETHING WILL BE SAFE IN 50 OR 60 YEARS OBVIOUSLY ISN'T EVER GOING TO BE POSSIBLE IN OUR LIFETIMES. AND I THINK IT'S A BALANCE OF BENEFITS AND HARMS.

CHAIRMAN LO: IT'S VERY HARD TO PROVE.

JEFF, CAN WE GIVE OTHER -- I THINK YOU'VE

MADE POINTS VERY STRONG. ARE THERE OTHER PEOPLE IN THE ROOM FROM THE PUBLIC THAT I THINK I WOULD LIKE TO HEAR FROM?

DR. LOMAX: YEAH. WE'LL MOVE TO PUBLIC COMMENT AND REMIND FOLKS THAT IT'S A THREE-MINUTE PUBLIC COMMENT AND THAT IS -- WHY DON'T WE JUST HAVE FOLKS JUST COME UP TO THE MICROPHONE.

CHAIRMAN LO: AND PLEASE INTRODUCE YOURSELF TO US FOR THE RECORD.

MR. REED: THIS IS DON REED. I UNDERSTAND THE CONCERNS ABOUT THE LONG-TERM HEALTH POSSIBILITIES OF RISK. BUT I ALSO KNOW THAT THERE ARE PEOPLE WHO ARE SUFFERING RIGHT NOW, AND THAT'S NOT THEORETICAL AT ALL. THAT'S REAL. I'VE BEEN WAITING FOR SCNT TO BE ALLOWED FOR MANY, MANY YEARS, EVER SINCE BEFORE PRESIDENT GERALD FORD CAME OUT IN FAVOR OF IT. IT'S JUST -- I FEEL IT'S A TREMENDOUS LEAP FORWARD, AND I'VE JUST BEEN WAITING SO HARD FOR THIS. I THINK WE HAVE TO FIND A WAY TO DO IT. THANK YOU.

CHAIRMAN LO: THANKS. NEXT COMMENT PLEASE.

MS. DARNOVSKY: HI. THIS IS MARCY DARNOVSKY. I'M EXECUTIVE DIRECTOR OF THE CENTER FOR GENETICS AND SOCIETY. SO WE'VE BEEN FOLLOWING THIS

ISSUE FOR MANY YEARS. WE'VE BEEN CONCERNED ABOUT THE HEALTH RISKS TO WOMEN FOR MANY YEARS. WE'VE BEEN CONCERNED ABOUT THE LACK OF FOLLOW-UP STUDIES. FOR TEN YEARS WE'VE BEEN ASKING FOR THESE STUDIES TO BE DONE. THEY HAVEN'T BEEN DONE. WE NEED A REGISTRY. WE NEED TO TRACK PEOPLE WHO UNDERGO EGG RETRIEVAL UNDER DIFFERENT PROTOCOLS WHO THEN GET PREGNANT OR WHO THEN DO NOT GET PREGNANT. WE DON'T HAVE THAT INFORMATION. AND SO THE WHOLE POSSIBILITY OF GIVING INFORMED CONSENT FOR WOMEN IS A CHALLENGE.

THERE ARE SO MANY OF THE ASSERTIONS OF FACT AND INTERPRETATION THAT HAVE BEEN MADE AT THIS MEETING SO FAR THAT I THINK REQUIRE SOME REALLY SUBSTANTIAL DISCUSSION. AND I KNOW THAT -- SOME OF THEM ARE IN THE MEMO THAT WE DID DISTRIBUTE, I HOPE ALL OF YOU HAVE IT, THAT WE PREPARED LOOKING AT THE PUBLICLY AVAILABLE DOCUMENTS.

BUT I THINK IN MY REMAINING 90 SECONDS WHAT I WANT TO SAY IS THERE'S SEVEN MINUTES LEFT BEFORE A QUORUM IS NOT POSSIBLE AT THIS MEETING, AND I WOULD LIKE TO SECOND OR -- I GUESS I'M NOT A MEMBER, SO I CAN'T DO THAT. I WOULD LIKE TO SAY THAT IT DOESN'T MAKE ANY SENSE TO MAKE A DECISION. THERE'S BEEN NO, ZERO, DISCUSSION OF WHAT THE NEW PROCEDURE WOULD ENTAIL, OF WHAT IT WOULD MEAN FOR

THE ICOC TO APPROVE A PARTICULAR CELL LINE FOR USE, WHAT KIND OF SCRUTINY WOULD BE GIVEN, WHO WOULD GIVE THAT SCRUTINY, WHAT INFORMATION WOULD THE ICOC RECEIVE? AND I THINK WITHOUT AT LEAST THAT KIND OF DISCUSSION OF WHAT THIS NEW PROCEDURE WOULD ENTAIL, THIS COMMITTEE, I CAN'T SEE HOW YOU COULD MAKE AN INFORMED DECISION ABOUT WHAT'S IN FRONT OF YOU.

WE'VE HEARD A LOT ABOUT THE OREGON STUDY. THERE'S A LOT OF THINGS I WOULD LIKE TO KNOW AND ASK THAT AREN'T IN THE PUBLICLY AVAILABLE DOCUMENTS ABOUT THE OREGON STUDY. YOU'RE NOT BEING ASKED TO APPROVE THAT CELL LINE. AND THAT -- THE WAY THAT THIS HAS BEEN PRESENTED IS AN EXCEPTION THAT'S SWALLOWING THE RULE. I MEAN YOU DON'T EVEN SEE THE RULE. WHAT IS THE PROCEDURE BEING SUGGESTED HERE? WHAT WOULD BE THE ROLE OF THE STANDARDS WORKING GROUP GOING FORWARD?

SO THAT'S WHAT I'LL STOP WITH.

CHAIRMAN LO: THANK YOU VERY MUCH FOR THOSE COMMENTS AND SUGGESTIONS.

DR. LOMAX: BERNIE, WE HAVE A QUORUM TILL THE TOP OF THE HOUR, BY THE WAY, JUST SO YOU'RE AWARE.

CHAIRMAN LO: OKAY. HOW MANY MORE PEOPLE?

DR. LOMAX: FOUR.

CHAIRMAN LO: PLEASE, IF THE NEXT SPEAKER COULD COME FORWARD, WE'RE INTERESTED IN HEARING YOUR THOUGHTS.

MS. BEESON: I'M DIANE BEESON. I'M A PROFESSOR EMERITUS OF SOCIOLOGY. I'M A MEDICAL SOCIOLOGIST, WHICH MEANS I SPENT MY CAREER -- AND I'M ALSO ASSOCIATE DIRECTOR OF ALLIANCE FOR HUMANE BIOTECHNOLOGY. AND BEING A MEDICAL SOCIOLOGIST MEANS THAT I'VE SPENT MY CAREER LOOKING AT THE SOCIAL CONSEQUENCES OF NEW MEDICAL TECHNOLOGIES.

AND I APPRECIATE THAT YOU'VE EXTENDED THE TIME BEYOND THE 12 MINUTES THAT WAS LEFT FOR PUBLIC COMMENT BECAUSE OF IF YOU ARE CONSIDERING ADOPTING A PROCESS AND YOU'RE SINCERE ABOUT YOUR CONCERN ABOUT NOT PUTTING WOMEN UNDER MEDICAL RISK AS A RESULT OF THE RESEARCH THAT YOU WOULD LIKE TO DO, I WOULD LIKE TO ASK YOU WHY YOU ARE NOT INSISTING ON MORE THAN 30 DAYS MEDICAL COVERAGE FOR WOMEN WHO BECOME EGG DONORS.

I WOULD THINK THAT GIVEN THE HISTORY OF OVERZEALOUS USE OF HORMONES ON WOMEN'S BODIES, STARTING WITH THE DES DISASTER AND THROUGH HRT RESEARCH WHERE ONLY AFTER DECADES OF ACTIVISM BY WOMEN HEALTH ADVOCATES DID THE APPROPRIATE CLINICAL TRIALS GET PUT INTO PLACE TO SHOW THE DAMAGE THAT

WAS BEING DONE. THIS INFORMATION HAS NEVER COME FROM THE INDUSTRY SPOKESPEOPLE THAT YOU INVITE HERE WHO HAVE CONFLICTS OF INTEREST.

YOU ARE ASKING WOMEN TO UNDERGO DRAMATIC MANIPULATION OF THEIR ENDOCRINE SYSTEMS, AND I PERSONALLY -- ANYBODY WHO SPEAKS TO STUDENTS OR WOMEN SEES MANY, MANY SCORES OF CASES OF WOMEN WHO HAVE BEEN HARMED BY THIS PROCESS AND NO STUDIES. THE ONLY STUDIES THAT HAVE BEEN DONE EVEN ON THE WOMEN UNDERGOING IVF ARE CANCER STUDIES. AND THERE ARE TEN STUDIES THAT SHOW INCREASED CANCER RISK, STUDIES THAT SHOW MAYBE NOT SUCH INCREASED CANCER RISK ALMOST WITHOUT EXCEPTION ACKNOWLEDGE THE TIME SPENT FOR THOSE STUDIES IS INADEQUATE TO COME TO ANY CONCLUSION. WHY IS NOBODY STUDYING.

I MEAN I INTERVIEWED A WOMAN COUPLE WEEKS AGO HAD TO HAVE A HYSTERECTOMY AT 40. MANY OF THESE WOMEN'S MENSTRUAL CYCLES NEVER EVER READJUST, AND YOU CERTAINLY WOULDN'T KNOW THAT WITHIN 30 DAYS. THERE ARE TREMENDOUS MOOD DISORDERS BEING CREATED AND MANY OTHER KINDS OF PROBLEMS. SO THIS 30-DAY MEDICAL COVERAGE IS LUDICROUS, AND IT SHOWS A REAL CONTEMPT FOR THE HEALTH OF WOMEN. AND I THINK THE REPRESENTATION OF CIRM HERE IS AT STAKE.

I WOULD BE VERY PROUD OF AND I THINK WE

CAN BE PROUD OF THE HIGHER STANDARDS THAT WE'VE HAD IN CALIFORNIA, AND I CERTAINLY HOPE THAT IF YOU ARE GOING TO CONSIDER A CHANGE IN PROCESS, YOU WILL INVITE SOME OF THE MANY CRITICS, WOMEN'S HEALTH ADVOCATES TO HELP EDUCATE MOST OF YOU MALES WHO ARE MAKING THIS DECISION ABOUT THE COMPLICATIONS OF WOMEN'S BODIES. THANK YOU.

CHAIRMAN LO: THANK YOU FOR YOUR COMMENTS. COULD I ASK THE NEXT SPEAKER TO COME FORWARD PLEASE.

MS. SCHEPER-HUGHES: YES. I'M PROFESSOR NANCY SCHEPER-HUGHES, AND I'M A PROFESSOR OF MEDICAL ANTHROPOLOGY WHERE I DIRECT PH.D. STUDIES, BOTH M.D. AND PH.D. STUDENTS. AND I'M ALSO THE DIRECTOR OF OREGON'S WATCH, WHICH HAS LOOKED INTO TISSUES AS WELL. I HAVE SOME QUESTIONS. MAYBE I'LL REPEAT A COUPLE POINTS.

NO. 1 IS CANCER REMAINS THE LARGEST SINGLE KILLER OF YOUNG WOMEN. FOR A CENTURY RESEARCH HAS LINKED EXOGENOUS AND ENDOGENOUS HORMONES TO CANCER. WE KNOW BEYOND A DOUBT THAT HORMONES CAUSE AND FEED CANCER. SO WE DO KNOW THAT. BUT I'M CONCERNED ABOUT THE KIND OF CONSENT, THE NATURE OF THE INFORMED CONSENT, BECAUSE WHAT I GATHERED FROM THE OREGON STORY IS THAT IT'S RUN BY THE RESEARCH INSTITUTES THEMSELVES.

NOW, FROM MY YEARS OF WORKING WITH PAID KIDNEY DONORS, THE CONSEQUENCES WERE HIDDEN IN PART BECAUSE THERE WAS NO DONOR ADVOCATE, THERE WAS NO FOLLOW-UP, THERE WAS NO REGISTRY OF DONORS. SINCE WE HAVE HAD THAT, THE TRANSPLANT PROFESSION HAS HAD TO ACCEPT THAT THEY DID NOT KNOW WHAT THE CONSEQUENCES, MEDICAL, PSYCHOLOGICAL, SOCIAL, AND SO FORTH WERE OF THIS. SO TO ASK -- THIS NUDGING THAT GOES ON IN CONSENT, WHEN THE UNIVERSITY OF CALIFORNIA IN 2010 TRIED TO GET DNA -- YOU KNOW, GIVE YOUR GENES TO BERKELEY PROJECT, YOU KNOW, THIS WAS PASSED BY THE UNIVERSITY'S HUMAN SUBJECTS PROTECTION. IT WAS EXPEDITED.

SO I'D WANT TO KNOW FOR SURE, YOU KNOW, HOW THE CONSENT IS BEING GARNERED BECAUSE NOW IN TRANSPLANT WE HAVE A MANDATED INDEPENDENT DONOR ADVOCATE, AND THOSE DONOR ADVOCATES GO AFTER WHERE THERE ARE LAPSES IN THE SCIENTIFIC KNOWLEDGE IN THE LONG TERM. AND I AGREE. I'LL JUST USE THE WORD IT'S LUDICROUS TO HAVE THE SHORT-TERM 30. WE'RE NOT TALKING ABOUT SHORT-TERM CONSEQUENCES. THOSE ARE READILY OBVIOUS. WE'RE TALKING ABOUT CANCER AND POSSIBLY INFERTILITY.

CHAIRMAN LO: THANK YOU VERY MUCH.

MS. FOGEL: HI. THANK YOU. I'M SUSAN

FOGEL. I'M THE CO-FOUNDER OF THE PRO-CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH. I'M A PUBLIC INTEREST LAWYER. AND I DON'T WANT TO BE REDUNDANT, SO I SUPPORT MUCH OF WHAT HAS ALREADY BEEN SAID.

I DO WANT TO POINT OUT, IN ADDITION TO OUR SERIOUS CONCERNS ABOUT WOMEN'S HEALTH AND THAT THERE IS NOTHING -- WE KEEP HEARING THIS IS NOT A CHANGE, A SUBSTANTIAL CHANGE IN POLICY. THIS IS A SUBSTANTIAL CHANGE IN POLICY. AND IT REALLY FEELS LIKE ANOTHER PUSH TO FIND A LOOPHOLE TO GET AROUND A PROHIBITION THAT'S IN THE LAW, NO. 1.

NO. 2, AND I THINK THAT TED PETERS SAID IT EARLIER, THAT THIS REALLY FEELS LIKE THIS DOES INCENTIVIZE PEOPLE NOT BOUND BY CIRM RULES PAY WOMEN, THEN YOU GET TO USE THOSE LINES, AND WE ARE JUST CREATING A MARKET IN WOMEN'S EGGS WITHOUT REAL REGARD FOR WOMEN'S HEALTH.

SECOND OF ALL, THE PURPOSE OF A REGULATION IS TO GIVE SPECIFICITY, CONCRETE GUIDANCE AROUND A LAW. THIS PROPOSED REGULATION, FIRST OF ALL, ISN'T SUPPORTED BY THE LAW. AND SECOND OF ALL, THE IDEA OF A REGULATION THAT IS ULTIMATELY DETERMINED BY ADVANCING CIRM'S MISSION, WHAT DOES THAT EVEN MEAN? MISSION STATEMENTS ARE VERY BROAD, AND THE IDEA THAT THERE IS NO PUBLIC PROCESS IN THIS, THERE'S NO

PROTECTION FOR WOMEN'S HEALTH, YOU KNOW, THERE IS -- THE INSTITUTE OF MEDICINE REPORT THAT YOU COMMISSIONED WAS VERY CLEAR THAT THE STUDIES ARE LIMITED, ARE SMALL, THEY'RE OFTEN CLINIC SPECIFIC. AND THE IDEA TO TAKE A VERY SMALL NUMBER OF SCIENTISTS, TO TAKE A VERY SMALL NUMBER OF STUDIES AND THEN SAY THERE'S NO EVIDENCE OF LONG-TERM EFFECT, WELL, WE HAVEN'T STUDIED IT. SO WE DON'T KNOW ABOUT LONG-TERM EFFECTS.

THERE IS ONE REGISTRY NOW IN THE UNITED STATES AT DARTMOUTH. THEY'RE HAVING A TERRIBLE TIME GETTING CLINICS TO ACTUALLY REFER WOMEN INTO THAT STUDY. IT'S GOING TO BE SOME TIME BEFORE WE HAVE ANY CONCRETE INFORMATION. I THINK IT'S IRRESPONSIBLE, FIRST OF ALL, IRRESPONSIBLE OF THE STANDARDS WORKING GROUP. STANDARDS WORKING GROUP, YOU ARE RESPONSIBLE. YOU HAVE AN OBLIGATION UNDER THE LAW TO BE DEVELOPING CLEAR ETHICAL AND MEDICAL STANDARDS IN 11 MINUTES TO RUSH THIS THROUGH ON A VOTE WHEN YOU HAVE SO LITTLE INFORMATION, NO. 1. AND NO. 2, THIS NEEDS TO GO -- EVEN IF YOU WERE TO MAKE SOME SMALL EXCEPTION, WHICH WE DON'T SUPPORT, THIS NEEDS TO GO BACK TO THE DRAWING BOARD FOR A VERY CONCRETE POLICY. THANK YOU.

CHAIRMAN LO: THANK YOU. ARE THERE OTHER

PEOPLE IN THE ROOM WHO HAVE BEEN WAITING?

MR. TORRES: YES.

MS. STEVENS: HI, DR. LO. THIS IS TINA STEVENS AGAIN FROM THE ALLIANCE FOR HUMANE BIOTECHNOLOGY. AND I JUST WANTED THE STANDARDS WORKING GROUP TO KNOW THAT, IN ADDITION TO THE GROUPS THAT ARE REPRESENTED HERE TODAY, AHB, CENTER FOR GENETICS IN SOCIETY, PRO-CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH, OUR BODIES OURSELVES, ORGANS WATCH, THAT THE LIST OF ORGANIZATIONS THAT ARE CONCERNED BY THE INCREASING MARKET IN WOMEN'S EGGS IS GROWING. THEY NOW INCLUDE BLACK WOMEN'S HEALTH IMPERATIVE, BREAST CANCER ACTION, CANCER PREVENTION AND TREATMENT FIRMS, COUNCIL FOR RESPONSIBILE RESEARCH, NATIONAL WOMEN'S HEALTH NETWORK, WE ARE EGG DONORS, AND I MUST SAY THE LIST GOES ON. IT'S A LIST OF THE COALITION OF THE WATCHFUL, AND WE WILL BE VERY INTERESTED IN FINDING OUT WHAT THE STANDARDS WORKING GROUP WILL BE DOING TODAY. THANK YOU.

CHAIRMAN LO: THANK YOU. SO WE'VE HEARD A LOT OF --

MS. TOBER: I HAVE SOME THINGS I'D LIKE TO SAY. MY NAME IS DIANE TOBER. I'M A MEDICAL ANTHROPOLOGIST. I'M ALSO ASSOCIATE EXECUTIVE DIRECTOR FOR THE CENTER FOR GENETICS AND SOCIETY.

AND ONE OF THE THINGS THAT CONCERNS ME IS REALLY THIS ISSUE OF RESEARCH. IF WE LOOK AT WHAT'S BEEN DONE IN NEW YORK, FOR EXAMPLE, NOW WE HAVE A SYSTEM IN NEW YORK PAYING WOMEN FOR THEIR EGGS FOR RESEARCH. I'VE SCOURED THE INTERNET. I'VE SCOURED GOOGLE SCHOLAR. I'VE SCOURED ALL KINDS OF PLACES TO -- DATABASES LOOKING FOR THE RESULTS, TRYING TO FIND THE DEMOGRAPHICS OF WOMEN, TRYING TO FIND THE COMPLICATIONS THAT WOMEN MIGHT HAVE BEEN EXPERIENCING. THAT RESEARCH, THAT INFORMATION IS NOT AVAILABLE ANYWHERE. SO WE HAVE NO IDEA WHAT'S GOING ON IN NEW YORK. WE HAVE NO IDEA HOW MANY WOMEN ARE BEING USED TO RETRIEVE THEIR EGGS FOR RESEARCH. WE HAVE NO IDEA OF THE NUMBER OF EGGS PER CYCLE, THE NUMBER OF WOMEN, THE NUMBER OF CYCLES THAT WOMEN GO THROUGH, NONE OF IT.

THEN I ALSO LOOKED AT THE OREGON REPORT, THE RESEARCH THAT CAME OUT ABOUT A LITTLE OVER A MONTH AGO. AND AS I WAS READING THROUGH THAT, I ALSO OBSERVED THAT THERE WERE NO WOMEN. THERE WERE EGGS THAT WERE BEING RESEARCHED, THERE WERE STEM CELL LINES, BUT THERE WERE NO WOMEN. THERE WAS NO INFORMATION REPORTED ON THE DEMOGRAPHICS OF THE WOMEN. THERE WAS NO INFORMATION REPORTED ON THE NUMBER OF EGGS RETRIEVED PER CYCLE, PER WOMAN, OR

THE NUMBER OF CYCLES THAT WOMEN WENT THROUGH, OR THE NUMBER OF WOMEN THAT EXPERIENCED COMPLICATIONS.

SO IT SEEMS TO ME IT'S EXTREMELY IRRESPONSIBLE TO BE PROPOSING TO GO FORWARD WITH PROMOTING THIS KIND OF RESEARCH AND GETTING ON BOARD WITH THE PAYMENT OF EGGS FOR RESEARCH AND INADVERTENTLY CHANGING POLICY, LIKE MY COLLEAGUE JUST SAID, WITH THE LOOPHOLES WITHOUT HAVING ANY SOLID INFORMATION AS TO WHERE THE WOMEN ARE, WHO THEY ARE, AND HOW THEY'RE BEING RECRUITED, HOW THEY'RE BEING UTILIZED, AND WHAT'S HAPPENING WITH THEIR BODIES. THANK YOU.

CHAIRMAN LO: THANK YOU. LET ME TRY AND SUMMARIZE WHAT I HEARD. THERE WERE A LOT OF CONCERNS THAT WERE RAISED BOTH BY MEMBERS OF OUR WORKING GROUP AND BY THE PUBLIC ABOUT, FIRST, WHAT THE PROPOSAL UNDER DISCUSSION IS, CONCERNS ABOUT LACK OF SPECIFICITY, ABOUT NEEDING MORE INFORMATION ABOUT THE PROCESS, ABOUT THE STANDARD OF ADVANCE THE MISSION OF CIRM, AND SO FORTH.

THERE CONTINUE TO BE CONCERNS RAISED ABOUT THE ISSUES THAT WE HAVE BEEN TALKING ABOUT FOR YEARS, WHICH ARE RISKS OF OOCYTE DONATION EVEN UNDER BEST PRACTICE PROTOCOLS AND THE DIFFICULTIES OF GETTING DATA ON LONG TERM ARE. CONCERNS ABOUT THE

NATURE OF THE CONSENT PROCESS, WHICH WE HEARD ABOUT IN THIS STUDY. AND THIRD, THE CONCERNS ABOUT UNDUE INFLUENCE AND PERHAPS CERTAIN PEOPLE BEING -- CERTAIN DONORS BEING PARTICULARLY AT RISK FOR BEING VULNERABLE.

IT SEEMS TO ME WE HAVE A COUPLE OF OPTIONS. ONE IS TO SAY THIS IS SUCH AN IMPORTANT ISSUE THAT WE NEED TO HAVE MORE DELIBERATION, MORE DISCUSSION, AND BASICALLY TABLE TAKING ACTION ON THE CURRENT PROPOSAL.

SECOND OPTION IS TO SAY -- TO JUST REJECT THE PROPOSAL AT HAND.

THIRD IS TO TRY AND AMEND IT, WHICH I WOULD NOT RECOMMEND AMENDING SOMETHING IN A COUPLE OF MINUTES.

I GUESS THE FOURTH OPTION IS TO APPROVE IT AS -- TO RECOMMEND THAT THE ICOC CONSIDER IT AS IT STANDS.

THERE ARE A COUPLE MEMBERS OF THE SWG WHO HAVE NOT YET SPOKEN OR MAY WISH TO SPEAK ON OUR NEXT STEPS. IF I READ WHAT THE DISCUSSION I HEARD RIGHT IS I THINK DOROTHY ROBERTS AND JEFF SHEEHY WOULD CERTAINLY NOT BE -- WOULD NOT AGREE WITH MAKING A POSITIVE RECOMMENDATION, BUT PERHAPS WOULD BE OPEN TO A MEETING, AND I WOULD SAY IT PROBABLY SHOULD BE

A FACE-TO-FACE MEETING WHERE WE CAN REALLY DISCUSS THIS IN MORE DETAIL. AND PERHAPS IF WE AGREE TO MOVE FORWARD, TO SORT OF SUGGEST DIFFERENT LANGUAGE, INCLUDING LOTS MORE PROCEDURES.

BUT THERE ARE A NUMBER OF PEOPLE ON THE COMMITTEE WE HAVEN'T HEARD FROM ON WHERE TO GO FORWARD, AND I'D LIKE TO ASK THEM TO SPEAK.

DR. WAGNER: BERNIE, THIS IS JOHN WAGNER. CAN I SPEAK?

CHAIRMAN LO: JOHN, PLEASE. ABSOLUTELY.

DR. WAGNER: SINCE MANY OF THESE SAME DISCUSSIONS OCCURRED -- HAVE OCCURRED PREVIOUSLY IN OTHER FORA, AND ONE OF THE THINGS THAT WAS DISCUSSED IN OTHER FORA WAS IN THIS PARTICULAR CASE, AND YOU CAN TELL ME IF I'M WRONG, BUT IT'S NOT THE STEM CELL LINE ITSELF THAT'S BEEN CREATED THAT'S THE ISSUE. THE LINE ITSELF IS NOT THE PROBLEM. IT'S SIMPLY THE DERIVATION OF THIS LINE FROM A PAID EGG DONOR; IS THAT CORRECT?

MS. LANSING: CORRECT.

DR. WAGNER: SO THE ISSUE THAT COMES BACK IS, YOU KNOW, IT ALL COMES DOWN TO WHETHER OR NOT, YOU KNOW, PEOPLE, I THINK, DO THEY FEEL THAT THIS IS SOME FORM OF COERCION OR HAVE WE SOMEHOW HURT THIS INDIVIDUAL. THAT SEEMS TO BE THE DISCUSSION. IS

THAT IT?

CHAIRMAN LO: THAT'S THE KEY ISSUE. I THINK GOING FORWARD IN TERMS OF THE CHANGE WE'RE MAKING IS TO ALLOW THIS EXCEPTION.

DR. WAGNER: I JUST WANT TO MAKE SURE THERE WERE NO OTHER ISSUES BESIDES THOSE TWO.

CHAIRMAN LO: I THINK THERE ARE OTHER ENTITIES --

(SIMULTANEOUS DISCUSSION.)

MR. SHEEHY: IT'S A MATTER OF LAW.

CHAIRMAN LO: I THINK THERE ARE PEOPLE WHO SAY THEY'RE SO CONCERNED ABOUT THE DONATION OF OOCYTES, CERTAINLY IN A RESEARCH CONTEXT, THAT THEY HAVE CONCERNS ABOUT THE SAFETY AND THE RISK AND THE NATURE OF THE CONSENT, WHETHER OR NOT THERE'S PAYMENT INVOLVED. THAT'S NOT WHAT THIS -- THAT MAY BE RELEVANT TO A PARTICULAR LINE.

DR. WAGNER: I THINK IT COMES DOWN TO ME. SO THE LINES THAT ALREADY EXIST, IT'S ALREADY DONE. OKAY. AND I THINK -- SO NOTHING WE SAY OR DO TODAY CHANGES THAT FACT. THE LINE EXISTS, AND THE QUESTION IS CAN WE USE THOSE LINES SIMPLY BECAUSE THEY EXIST? WHAT I THINK THE FEAR IS IS THAT BY USING THOSE LINES, THAT SOMEHOW WE ARE GOING TO SUGGEST THAT OTHERS CONTINUE OR EXPAND THEIR USE OR

DEVELOPMENT OF SUCH LINES. THE LINE ITSELF ALREADY EXISTS. IT DOESN'T CHANGE ANYTHING FOR THOSE PARTICULAR EGG DONORS. AND THE QUESTION IS WHETHER OR NOT WE CAN USE THAT.

BUT I GUESS THE WAY IT COMES DOWN FROM AN ETHICAL POINT OF VIEW, AND YOU'RE THE EXPERT HERE AMONG THE EXPERTS HERE, IS SAYING USE OF THAT CELL LINE ITSELF THAT ALREADY EXISTS DOESN'T CHANGE ANYTHING AT THIS POINT IN TERMS OF THAT PARTICULAR DONOR. BUT THE QUESTION, I GUESS, TO YOU AS A BIOETHICIST IS HOW DO WE USE THAT? IF YOU CONSIDER THE DERIVATION UNETHICAL, IF THAT'S THE CASE, IF THE DERIVATION IS UNETHICAL OF THAT OOCYTE DONOR BECAUSE WE PAID THEM, YOU KNOW, CAN YOU USE MATERIAL THAT WAS DERIVED IN THAT WAY?

AND THERE'S A WHOLE LITERATURE ON THE USE OF INFORMATION OR MATERIAL. DOES THAT HELP US AT ALL? THAT'S DERIVED, QUOTE, IN AN ETHICAL WAY? I'M NOT SAYING THAT'S MY OPINION, BUT I'M JUST SAYING THAT'S CERTAINLY WHAT'S BEING DEBATED HERE.

MS. LANSING: CAN I JUST ADD TWO THINGS TO THIS?

CHAIRMAN LO: SHERRY, GO AHEAD. AND THEN I HAVE --

MS. LANSING: I'M AFRAID OUR ANSWER IS

GOING TO BE SELF-EXPLANATORY, THAT WE NEED MORE DISCUSSION BECAUSE WE ONLY HAVE FIVE MINUTES LEFT. BUT I JUST WANT TO ADD TWO THINGS. AS A PERSON WHO REPRESENTS THE CANCER COMMUNITY, I AM VERY AWARE OF THE STUDIES THAT HAVE BEEN ON WHETHER THEY HAVE BEEN COMPLETE ENOUGH OR NOT, BUT THAT RISK EXISTS WHETHER WOMEN ARE PAID OR NOT. I MEAN IT'S THE SAME RISK TO YOUR HEALTH WHETHER YOU WERE PAID OR NOT. AND I REALLY DO BELIEVE THAT OUR SYSTEM IN PLACE DOES WARN WOMEN OF THESE POTENTIAL HEALTH RISKS WHICH WE DON'T KNOW YET ENOUGH ABOUT. AND WHETHER WE SHOULD AS CIRM INVEST OUR MONEY IN DOING RESEARCH INTO THAT IS A QUESTION.

I JUST WANT TO POSE, YOU KNOW, AS WE CONTINUE TO THINK ABOUT THIS ISSUE, WHICH IS WHAT I THINK IS WHAT'S GOING TO HAPPEN, THAT THERE'S ALSO AN OBLIGATION THAT WE HAVE TO THE, AND I THINK IT WAS MR. REED WHO SAID THIS AS A PATIENT ADVOCATE, TO THE MILLIONS OF PEOPLE WHO ARE COUNTING ON US TO FIND LINES THAT WILL HELP US WITH OUR RESEARCH TO CURE DISEASES. AND SO I THINK THAT HOLDING ONTO POLICY THAT WE'VE HAD FOR MANY, MANY YEARS AND NOT BEING OPEN TO AT LEAST DISCUSSING OR AMENDING WAYS TO LOOK AT WHAT'S GOING ON, NOT JUST IN OUR STATE, BUT IN THE WORLD AND WILL CONTINUE TO GO ON, IS

ALMOST IRRESPONSIBLE TO THE PEOPLE WHO ARE SICK.

CHAIRMAN LO: ARE THERE OTHER MATTERS --

CHAIRMAN THOMAS: BERNIE, THIS IS J.T. I JUST WANTED TO ADDRESS ONE ISSUE, WHICH IS THE QUESTION OF HOW THIS ADVANCES CIRM'S MISSION. I'LL GO BACK TO AN ANALOGY THAT I FREQUENTLY INVOKE IN SPEECHES, WHICH IS THAT OF THE MINERS WHO WERE TRAPPED IN CHILE TWO OR THREE YEARS AGO, WHERE YOU'VE GOT PEOPLE DOWN THERE AND YOU HAD THREE HOLES BEING BORED IN THE HOPES THAT ONE OF THEM AT LEAST WOULD REACH THE CAVE AND THE MINERS WOULD BE SAVED.

WHAT WE ARE DOING IS DIRECTLY ANALOGOUS WHERE THE PATIENTS ARE THE MINERS IN THE CAVE, AND WE ARE TRYING TO TAKE ADVANTAGE OF ALL TECHNOLOGIES THAT GIVE US THE HOPE THAT AT LEAST ONE OF THEM WILL GET ACROSS THE FINISH LINE OR IN THAT CASE SUCCEED IN GETTING TO THE CAVE AND FREEING THE MINERS.

IN THE COURSE OF FUNDING THAT WE HAVE, WE HAVE FUNDING FOR EMBRYONIC STEM CELL RESEARCH FOR ADULT STEM CELL RESEARCH, FOR IPS, TRANSDIFFERENTIATION. SCNT IS UNQUESTIONABLY ANOTHER ARROW IN THE QUIVER THAT COULD ADD AN ADDITIONAL HOLE BEING BORED TOWARDS PATIENT ADVOCATE RECOVERY. AND I THINK THAT, FOLLOWING ON WHAT SHERRY SAYS, THAT IS SOMETHING THAT DIRECTLY

ADVANCES CIRM'S MISSION. IT DIRECTLY SPEAKS TO THE PATIENTS OUT THERE.

AND TO THE EXTENT -- THERE HAVE BEEN A LOT OF GOOD POINTS RAISED HERE TODAY, THAT WE CAN SUFFICIENTLY ADDRESS THE ETHICAL ISSUES IN CONNECTION TO THIS, I THINK IT BEHOOVES US TO FIND A WAY TO TAKE ADVANTAGE OF THIS TECHNOLOGY IF WE CAN BECAUSE IT WILL UNDOUBTEDLY LEAD TO AN ENTIRE NEW AVENUE THAT WILL YIELD PROFOUND SCIENTIFIC RESULTS THAT ADVANCES WHAT CIRM IS ALL ABOUT.

CHAIRMAN LO: THANK YOU, JON. I'M GOING TAKE THE PREROGATIVE OF CHAIRING THE MEETING OVER THE PHONE TO SUGGEST THAT WE SHOULD SCHEDULE ANOTHER MEETING. AND AS I SAID PRIOR, I'D LIKE THAT TO BE A FACE-TO-FACE MEETING TO REALLY DISCUSS THIS ISSUE IN MORE DETAIL AND MORE DEPTH AND WITH MORE TIME. I THINK MY OWN SENSE, AND I'M GOING TO ASK THE REST OF THE SWG IF THEY AGREE, IS THAT WE'RE NOT PREPARED TO CERTAINLY TO APPROVE OR AMEND WHAT STAFF VERY THOUGHTFULLY DREW UP BECAUSE THERE'S A LOT OF ISSUES WE NEED TO READDRESS, THINK THROUGH, GET MORE INFORMATION.

AND I GUESS I WOULD BE OPEN TO SOMEONE MAKING A MOTION THAT WE ACKNOWLEDGE THE IMPORTANCE OF THIS TOPIC, THE POTENTIAL SCIENTIFIC UTILITY AND

THE CONCERNS THAT HAVE BEEN RAISED BOTH HERE AND OUTSIDE THE MEETING ABOUT ETHICAL CONCERNS AND ABOUT PROCEDURES WHICH MIGHT SUFFICE TO ADDRESS THOSE CONCERNS FOR A PARTICULAR LINE. AND THAT WE RECOMMEND THE ICOC WAIT TILL WE HAVE A MEETING WHERE WE CAN EXPLORE THIS IN MORE DEPTH.

MS. LANSING: I'LL MAKE THAT MOTION AND JUST HAVE A FRIENDLY AMENDMENT TO IT.

CHAIRMAN LO: ABSOLUTELY.

MS. LANSING: THAT THE TIMELINESS OF THIS, THAT THE MEETING BE -- HOW DO I SAY THIS? -- DONE AS QUICKLY AS POSSIBLE BECAUSE WE ARE MINDFUL OF HOW IMPORTANT THE SCIENCE POTENTIALLY COULD BE AND THAT THE MEETING BE IN PERSON.

MR. SHEEHY: COULD I OFFER ANOTHER FRIENDLY AMENDMENT? THAT THERE BE INCLUDED IN THIS DISCUSSION HEALTH INFORMATION THAT IS NOT FROM CONFLICTED OR SELF-INTERESTED PARTIES SO WE GET INDEPENDENT HEALTH INFORMATION THAT IS SPECIFICALLY RELATED TO THE HEALTH RISKS TO INDIVIDUALS, NOT JUST WHO GO THROUGH THESE PROCEDURES IN ORDER TO HAVE CHILDREN, BUT FOR PEOPLE WHO ACTUALLY GO THROUGH THESE PROCEDURES TO DONATE, AND THAT WE COLLECT ALL THE AVAILABLE INFORMATION ON HEALTH OUTCOMES THAT WE CAN FOR THAT.

CHAIRMAN LO: THAT WAS JEFF SHEEHY, RIGHT? I HEARD A COUPLE VOICES. ANY OTHER AMENDMENTS TO THIS SUGGESTION? DOES SOMEONE WANT TO SECOND THAT?

DR. KAMP: THIS IS TIM KAMP. I'LL SECOND.

CHAIRMAN LO: OKAY. THANK YOU, TIM. SORRY WE DIDN'T HAVE A CHANCE TO HEAR MORE FROM YOU, BUT I LOOK FORWARD TO IT.

SO, GEOFF, CAN WE TAKE A VOTE ON THIS?

DR. LOMAX: YES. WE SHOULD DO A VOICE VOTE SINCE THIS IS A TELECONFERENCE.

SHERRY LANSING.

MS. LANSING: YES.

DR. LOMAX: BERNIE LO.

CHAIRMAN LO: AYE.

DR. LOMAX: JEFFREY BODKIN.

DR. BODKIN: AYE.

DR. LOMAX: MARCY FEIT. TIM KAMP.

DR. KAMP: YES.

DR. LOMAX: FRANCISCO PRIETO. TED PETERS.

DR. PETERS: YES.

DR. LOMAX: DOROTHY ROBERTS.

DR. ROBERTS: YES.

DR. LOMAX: JEFF SHEEHY.

MR. SHEEHY: YES.

DR. LOMAX: PAT TAYLOR. ROBERT TAYLOR.

DR. TAYLOR: YES.

DR. LOMAX: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

DR. LOMAX: JOHN WAGNER.

DR. WAGNER: YES.

CHAIRMAN LO: WELL, WITH THAT, FIRST, I WANT TO THANK STAFF FOR HELPING PROVIDE ALL THE INFORMATION. THANK THE MEMBERS OF THE SWG FOR NOT ONLY PARTICIPATING, BUT FOR ASKING GOOD QUESTIONS, MAKING THOUGHTFUL COMMENTS, AND PROVIDING GOOD ADVICE. AND I WANT TO THANK THE MEMBERS OF THE PUBLIC FOR THEIR INTEREST AND THEIR PARTICIPATION AND THEIR WANTING TO HAVE US TAKE THE BENEFIT OF THEIR THINKING.

SO, GEOFF, I WILL WORK WITH YOU TO TRY AND SCHEDULE THIS TO TRY AND ACCOMMODATE EVERYONE'S SCHEDULE AND TO SORT OF FIND A TIME THAT AS MANY OF THE BOARD AS POSSIBLE CAN ATTEND. I THINK IT DOES NEED TO BE FACE TO FACE, AND WE'LL WORK ON THIS AND PROVIDE AS SOUND AND THOUGHTFUL ADVICE AS WE CAN SO THE ICOC CAN REALLY ADDRESS THIS ISSUE.

MS. LANSING: THANK YOU VERY MUCH FOR YOUR EXCELLENT LEADERSHIP, BERNIE.

CHAIRMAN LO: THANK YOU, SHERRY.

(THE MEETING WAS THEN CONCLUDED AT 2 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 TELEPHONIC 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 ON JULY 24, 2013, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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