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

REGULAR MEETING

LOCATION:	210 KING STREET 3D FLOOR SAN FRANCISCO, CALIFORNIA
DATE:	DECEMBER 12, 2008 9 A.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
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I N D E X

SAN FRANCISCO, CALIFORNIA; FRIDAY, DECEMBER 12, 2008

9 A.M.

DR. LOMAX: LET'S JUST LET BERNIE COME BACK INTO THE ROOM. GOOD MORNING, EVERYONE. THIS IS GEOFF LOMAX. SHOULD WE START THE TRANSCRIPTION AT THIS POINT.

OKAY. THIS IS THE DECEMBER 12, 2008, TELECONFERENCE MEETING OF THE MEDICAL AND ETHICAL STANDARDS WORKING GROUP. WHAT I CAN DO IS IT SOUNDS LIKE THERE ARE A FEW MORE PEOPLE ON THE LINE OR COMING IN. WHY DON'T I DO AN INITIAL ROLL CALL; AND THEN IF WE HEAR MORE PEOPLE COME IN, WE'LL ASK PEOPLE TO IDENTIFY THEMSELVES.

SHERRY LANSING.

MS. LANSING: HERE.

DR. LOMAX: FRANCISCO PRIETO. JEFF SHEEHY.

MR. SHEEHY: HERE.

DR. LOMAX: BERNARD LO.

CHAIRMAN LO: HERE.

DR. LOMAX: TED PETERS.

DR. PETERS: HERE.

DR. LOMAX: DOROTHY ROBERTS.

DR. ROBERTS: HERE.

DR. LOMAX: JOSE CIBELLI.

DR. CIBELLI: HERE.

DR. LOMAX: ANN KIESSLING.

DR. KIESSLING: HERE.

DR. LOMAX: JANET ROWLEY. JOHN WAGNER. JAMES WILLERSON.

DR. WILLERSON: HERE.

DR. LOMAX: IS THERE ANYONE I DIDN'T MENTION?

DR. TAYLOR: ROB TAYLOR IS HERE REMOTELY.

DR. LOMAX: OKAY. SORRY ABOUT THAT, ROB. MISSING YOU FROM MY LIST.

DR. TAYLOR: THAT'S ALL RIGHT.

CHAIRMAN LO: ANYONE ELSE? PAT, DO WE HAVE A QUORUM?

DR. LOMAX: WE ARE SHORT OF A QUORUM AT THE MOMENT.

CHAIRMAN LO: IF ANYONE BEEPS ON, I'LL HAVE TO SORT OF FIND OUT WHO THEY ARE.

OKAY. LET ME JUST FORMALLY WELCOME EVERYONE TO THE CALL. IT'S A BEAUTIFUL DAY HERE IN SAN FRANCISCO. AND, SHERRY, DO YOU WANT TO SAY SOME THINGS AS WELL TO WELCOME PEOPLE?

MS. LANSING: SOMEONE JUST JOINED. DID SOMEONE JOIN? SORRY. BERNIE.

CHAIRMAN LO: SHERRY, DO YOU WANT TO ADD ANYTHING?

MS. LANSING: NO. EVERYTHING JUST CLICKED OUT. IT WAS WEIRD. I FELT LIKE OTHER PEOPLE JUST JOINED IN BECAUSE I COULDN'T HEAR ANYTHING YOU SAID.

CHAIRMAN LO: SO AS WE'VE BEEN SAYING ALL ALONG, THIS FIELD MOVES FORWARD, AND WE HAVE TO SORT OF KEEP UP WITH EMERGING DEVELOPMENTS, BOTH SCIENTIFICALLY AND IN THE POLICY ARENA. AS WE'LL SEE, THE ISSUES THAT WE'D LIKE TO ADDRESS TODAY, USE OF SOMATIC CELLS TO DERIVE IPS CELLS, AND THEN GOING BACK TO THE ICOC WITH IDEAS AND SUGGESTIONS ABOUT EMBRYOS MADE WITH OOCYTES FROM PAID DONORS. THEY'RE BOTH SCIENTIFIC ISSUES AND ALSO SORT OF POLICY ISSUES WE NEED TO THINK THROUGH.

I WANT TO PARTICULARLY WELCOME DOROTHY ROBERTS TO OUR GROUP. DOROTHY IS THE -- I'M BLANKING ON THE NAME OF YOUR CHAIR.

PROFESSOR ROBERTS: KIRKLAND & ELLIS, A LAW FIRM IN CHICAGO.

CHAIRMAN LO: HAS A DISTINGUISHED NAMED PROFESSORSHIP AT NORTHWESTERN. AND DOROTHY HAS BOTH A STELLAR ACADEMIC RECORD AND A CAREER OF PUBLIC SERVICE. AND WE CERTAINLY WELCOME HER TO THE GROUP AND LOOK FORWARD TO WELCOMING HER IN PERSON AT THE

NEXT MEETING. BUT, DOROTHY, DELIGHTED TO HAVE YOU, AND WE LOOK FORWARD TO YOUR EXPERTISE AND YOUR GOOD IDEAS.

PROFESSOR ROBERTS: THANK YOU. IT'S GOOD TO BE PART OF THE GROUP.

CHAIRMAN LO: I JUST WANT TO REMIND EVERYONE TO MAKE PLANS TO COME TO OUR MEETING FEBRUARY 17TH, 18TH IN LOS ANGELES WHERE WE WILL DISCUSS A NUMBER OF ISSUES, AND WE'LL TALK MORE ABOUT THAT, BUT IT WILL BE IMPORTANT TO HAVE THIS FACE-TO-FACE MEETING.

ALSO, I WANT TO SORT OF TIP US OFF TO SOME ISSUES THAT I THINK WE SHOULD BE WORKING ON AS WE LOOK FORWARD TO THE NEW YEAR. MANY PEOPLE IN THE FIELD THINK THAT CLINICAL TRIALS OF STEM CELL THERAPIES WILL BE ON THE HORIZON FASTER THAN WE THINK. AND CIRM, WITH ALAN AND THE CIRM STRATEGIC PLAN, IS LOOKING TO BEING A MAJOR PLAYER IN SORT OF STIMULATING APPROPRIATE INNOVATIVE CLINICAL TRIALS.

AND SO I THINK IT WILL BE IMPORTANT FOR US TO HAVE THOUGHT ABOUT THOSE ISSUES TO KEEP AHEAD OF THE SCIENCE AS IT EMERGES. SO THIS, I THINK, WILL BECOME A PRIORITY FOR US, AND WE'LL BE HEARING MORE ABOUT THAT.

ALAN, DO YOU WANT TO SAY ANYTHING ABOUT

HOW YOU SEE? I PARTICULARLY WANT TO MAKE SURE THAT WHAT WE DO IN THE SWG REALLY FITS IN WITH THE SORT OF SCIENTIFIC AND STRATEGIC PLANS, THE EXCITING PLANS THAT CIRM IS DEVELOPING.

DR. TROUNSON: THANKS, BERNIE. WE WILL BE RELEASING AN RFA OR REQUEST FOR FUNDING IN THE AREA OF DISEASE TEAMS WHERE WE'RE EXPECTING THE APPLICANTS TO MAKE AN IND OR A SUBMISSION FOR A CLINICAL TRIAL WITHIN A FOUR-YEAR PERIOD. SOME OF THESE TEAMS MAY WELL MAKE IT INTO CLINICAL TRIAL BEFORE THAT TIME. AND WE NEED TO BE VERY COMFORTABLE WITH OUR VIEWS ABOUT THE CLINICAL TRIALS, AND THAT NEEDS TO BE IN CONCERT WITH, OF COURSE, THE MAJOR REGULATORY BODIES SUCH AS THE FDA, AND WE NEED TO CONSIDER THE SITUATION WITH NATIONAL STEM CELL RESEARCH SOCIETY AND PERHAPS EVEN IN OTHER INTERNATIONAL REGULATORY BODIES BECAUSE IT'S POSSIBLE THAT SOME OF THE CLINICAL TRIALS FOR THE WORK THAT WE'LL BE DOING WILL BE CONDUCTED IN OTHER STATES OR EVEN IN OTHER COUNTRIES.

SO I THINK THIS IS A PARTICULAR CHALLENGE FOR US TO HAVE HAD A PUBLIC DISCUSSION AND ALSO TO HAVE SOME INPUTS ON THE VIEWS WITH RESPECT TO THE REGULATORY AGENCIES AND THE RECOMMENDATIONS THAT ARE COMING FROM SOME OF THE SENIOR REPRESENTATIVE

BODIES.

CHAIRMAN LO: OKAY. SO AS ALAN ALLUDED TO, THE ISSCR, INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH, HAS JUST ISSUED DETAILED GUIDELINES FOR STEM CELL CLINICAL TRIALS. SO I THINK ONE THING WE'RE GOING TO NEED TO DO AS A COMMITTEE IS TO SORT OF FAMILIARIZE OURSELVES WITH THOSE, UNDERSTAND WHAT THEY'VE DONE, THE ISSUES THAT ARE LEFT TO BE DONE.

AND ALSO, AS ALAN SUGGESTED, THERE ARE REGULATORY SCHEMES IN PLACE. BOTH THE FDA AND OTHER COUNTRIES WILL HAVE REGULATIONS, AND ONE OF THE THINGS WE WANT TO DO HERE IS MAKE SURE GOOD SCIENCE GOES FORWARD WITH GOOD ETHICAL GUIDELINES, BUT NOT TO IMPOSE REGULATIONS THAT ARE EITHER UNNECESSARY OR INCONSISTENT WITH WHAT REGULATORY BODIES ON A NATIONAL SCHEME ARE DOING.

SO IT'S GOING TO BE IMPORTANT FOR US AS AN SWG TO SORT OF TAKE THE LEAD IN HELPING CIRM UNDERSTAND WHAT THE ISSUES ARE, WHERE EXISTING REGULATIONS HAVE BEEN COVERED, WHERE THERE ARE NEW THINGS ABOUT STEM CELL RESEARCH THAT MAY REQUIRE INVESTIGATORS TO PAY PARTICULAR ATTENTION BEYOND JUST THE MINIMUM REGULATIONS.

THIS WILL BE A FOCUS OF WHAT WE'LL BE DOING, AND I WILL WORK WITH GEOFF TO SORT OF HELP US

UNDERSTAND WHAT THESE ISSCR GUIDELINES ARE ALL ABOUT.

OKAY. SO THE TWO ISSUES THAT WE'D LIKE TO HANDLE, TO ADDRESS TODAY ARE SOMATIC CELLS AND PAYMENT -- I MEAN EMBRYONIC STEM CELLS DERIVED FROM OOCYTES WITH PAID DONORS. BUT BEFORE WE DO THAT, I WANT TO SORT OF ASK GEOFF TO GIVE US A STAFF REPORT ON A COUPLE OF THINGS THAT HAVE HAPPENED SINCE WE LAST WERE TOGETHER.

HAS ANYBODY JOINED THE CALL SINCE WE TOOK ROLL?

DR. PRIETO: YES. FRANCISCO PRIETO HERE.

CHAIRMAN LO: WELCOME, FRANCISCO. ANYONE ELSE? OKAY.

DR. LOMAX: THANK YOU, BERNIE. QUICKLY UPDATE YOU ON A FEW OF THE REGULATORY DEVELOPMENTS SINCE THE LAST TIME THIS GROUP MET. WE HAVE PUT FORWARD A REQUEST TO THE OFFICE OF ADMINISTRATIVE LAW TO FINALIZE WHAT I'LL REFER TO AS THE GRANDFATHERING RULE. THIS IS THE REGULATION THAT CREATED A MECHANISM FOR STEM CELL LINES DERIVED PRIOR TO NOVEMBER 2006. THIS IS THE DATE WHEN THE REGULATIONS TOOK EFFECT. IT CREATES A MECHANISM FOR APPLICANTS TO APPLY FOR LINES TO BE DESIGNATED AS ACCEPTABLE FOR CIRM-FUNDED RESEARCH. THERE ARE

LINES, WE SAW SOME EXAMPLES, WHERE THEY DON'T CONFORM TO THE PRECISE DETAILS OF OUR REGULATIONS, BUT THEY WERE CREATED PRIOR TO THE DATE OF THE REGULATIONS. SO THIS PROCESS ALLOWS US TO EVALUATE THEM ON A CASE-BY-CASE BASIS.

CURRENTLY THAT REGULATION EXISTS AS AN INTERIM REGULATION FOR A PERIOD OF 270 DAYS. AND WHAT GOING FORWARD WITH THE OFFICE OF ADMINISTRATIVE LAW ALLOWS US TO DO IS TURN THAT REGULATION INTO ONE THAT WILL MOVE FORWARD INDEFINITELY. SO WE'VE MOVED FORWARD ON THAT PROCESS. IT IS OPEN FOR PUBLIC COMMENT, SO WE HAVE COMMENTS COMING IN, AND WE'LL HAVE TO RESPOND TO THOSE ACCORDINGLY.

IN ADDITION, JUST TO REMIND FOLKS, WE HAVE BEEN IMPLEMENTING OUR COMPLIANCE PROGRAM. WE'VE DEVELOPED PROTOCOLS FOR EVALUATING COMPLIANCE WITH THE REGULATIONS AND ADMINISTRATIVE REQUIREMENTS. A BIG PIECE OF THAT IS GOING OUT AND LOOKING AT THE INSTITUTIONS, HOW THEY'VE ESTABLISHED OVERSIGHT COMMITTEES, AND LOOKING TO ENSURE -- WE GO IN AND LOOK FOR ASSURANCE THAT THEY ARE IMPLEMENTING, THE SCRO COMMITTEES, OUR REGULATIONS AS DESCRIBED.

AS OF DECEMBER 2008, WE'VE VISITED FIVE SITES WHICH REPRESENT 42 PERCENT OF CIRM FUNDING. WE'VE, IN GENERAL, FOUND SUBSTANTIAL COMPLIANCE WITH

THE REGULATIONS. WE HAVE IDENTIFIED SOME AREAS WHERE WE'VE SEEN ROOM FOR IMPROVEMENT, AND WE'VE COMMUNICATED THAT INFORMATION TO THE GRANTEES.

IN ADDITION, WE'RE USING THIS OPPORTUNITY TO DEVELOP A SERIES OF GUIDANCE DOCUMENTS AND TECHNICAL ASSISTANCE FACT SHEETS ON ISSUES; FOR EXAMPLE, LIKE WHAT THE IDEAL OVERSIGHT SCRO APPROVAL LETTER WOULD LOOK LIKE IN TERMS OF DOCUMENTING THE APPROVAL, THE TYPES OF CELL LINES APPROVED, ETC. SO IT'S REALLY GIVING US AN OPPORTUNITY TO INTERACT DIRECTLY WITH THE REGULATED COMMUNITY AND IDENTIFY WAYS IN WHICH WE CAN BE MOST EFFECTIVE IN TERMS OF REGULATIONS, ASSURANCE, AND DOCUMENTATION.

AND OUR GOAL IS TO VISIT ALL SITES WITH FUNDING GREATER THAN $5 MILLION BY THE FIRST HALF OF NEXT YEAR, AND WE'LL BE LOOKING FORWARD TO PROVIDING YOU WITH A FULL REPORT ONCE WE'VE COMPLETED OUR FIRST CYCLE.

CHAIRMAN LO: I JUST WANT TO ADD, IF I MAY, A NOTE TO THAT. UCSF WAS ACTUALLY ONE OF THE SITES THAT GEOFF VISITED. I ACTUALLY THINK THESE SITE VISITS ARE VERY IMPORTANT. THEY SERVE AN EDUCATIONAL PURPOSE TO MAKE SURE INSTITUTIONS REALLY UNDERSTAND WHAT THE CIRM REGULATIONS ARE ABOUT. I THINK IT ALSO SERVES A VERY IMPORTANT PURPOSE IN

TERMS OF ACCOUNTABILITY, THAT WHAT HAPPENED AT UCSF, AND I THINK THIS IS FAIR TO SAY, THAT THERE WERE DEFICIENCIES IN DOCUMENTATION OF OVERSIGHT THAT NEEDED TO BE CORRECTED BECAUSE I THINK, SINCE WE ARE A PUBLIC SOURCE OF FUNDING, IT'S IMPORTANT THAT WE BE ABLE TO DEMONSTRATE TO THE PUBLIC THAT ALL THE RESEARCH CARRIED OUT IS IN COMPLIANCE WITH THE REGULATIONS.

I THINK NOT HAVING GOOD DOCUMENTATION OF COMPLIANCE COULD RAISE PROBLEMS THAT THEN YOU HAVE TO DIG FURTHER INTO PRIMARY DATA SOURCES OF RECORDS WHICH IS ALWAYS MUCH MORE COMPLICATED. SO ALTHOUGH THESE THINGS MAY SEEM TO BE SORT OF BUREAUCRATIC, THEY'RE IMPORTANT TO DOCUMENT THAT WHAT'S DONE REALLY IS IN COMPLIANCE. I THINK GEOFF HAS DONE A VERY GOOD JOB SORT OF POINTING OUT TO INSTITUTIONS THE IMPORTANCE OF HAVING GOOD SYSTEMS OF NOT JUST OVERSIGHT, BUT ALSO DOCUMENTATION OF THE PROCESS.

DR. CIBELLI: CAN I ASK A QUESTION? THIS IS JOSE. GEOFF, DID YOU SEE ANY -- YOU SAID THERE WERE A FEW INSTITUTIONS THAT HAVE SOME ISSUES. OTHER THAN THE ONE THAT BERNIE JUST MENTIONED, STANFORD, HAVE YOU SEEN ANY COMMON ONES THAT MAY ACTUALLY BE SOMETHING THAT WE COULD IMPROVE IN TERMS OF CLARITY? THEY'RE ALL DIFFERENT FROM ALL THE

THINGS YOU'VE SEEN?

DR. LOMAX: I THINK BERNIE'S COMMENT REALLY CAPTURED THE FLAVOR OF IT. I THINK IT'S EXPECTATION WITH REGARD TO DOCUMENTATION. I WAS ACTUALLY QUITE IMPRESSED, AT LEAST IN THE GRANTS THAT WE LOOKED AT, WHERE, FOR EXAMPLE, WE WERE ASKING FOLKS THE COMMON AREA, WHICH IS COMMON TO ALMOST ALL THE GRANTS THAT INVOLVE HUMAN EMBRYONIC STEM CELL LINES, IS HOW DO THEY MAKE THE DETERMINATION THAT THE LINES WERE ACCEPTABLY DERIVED.

AND THERE WERE APPLICATIONS WHERE THE DOCUMENTATION WENT BACK TO SORT OF E-MAIL EXCHANGES BETWEEN THE PI AND COMMITTEE CHAIR, COMMITTEE ADMINISTRATOR, SORT OF SHOWING A BACK AND FORTH BETWEEN THE PROVIDER OF THE CELL LINES AND THE PI THAT REALLY CAPTURED THE PROVENANCE INFORMATION.

SO FIRST OFF, I SORT OF SAW VERY PROACTIVE WORK. BERNIE IS RIGHT. WHERE THERE WERE DEFICIENCIES, I THINK THEY WERE LESS IN TERMS OF, SAY, SOMETHING IN OUR STANDARDS WHICH SOMEONE CAN OR CANNOT COMPLY WITH, BUT MORE WHAT'S THE STANDARD OF EVIDENCE THAT WE REQUIRE TO BE ABLE TO SAY, YES, YOU'RE IN COMPLIANCE, YOU'RE NOT IN COMPLIANCE. AND THAT STANDARD REALLY DOES GET DOWN TO SOME OF THE

DETAILS, I THINK, OF PARTICULARLY THESE APPROVAL LETTERS THAT COME FROM THE OVERSIGHT COMMITTEE.

IF YOU READ THE REGULATIONS CAREFULLY, IT SAYS THE OVERSIGHT COMMITTEE SHALL ASSURE THAT SUCH-AND-SUCH AND SUCH-AND-SUCH HAS HAPPENED. AND THE COMMON THING I'M SEEING IS THOSE LETTERS, THERE IS ROOM FOR IMPROVEMENT IN THESE LETTERS. THE WORK IS BEING DONE. YOU CAN SORT OF SEE IT IN THE GRANTS FILES, YOU CAN SEE IT IN THE EXCHANGES BETWEEN EITHER THE PRINCIPAL INVESTIGATOR AND THE OVERSIGHT COMMITTEE OR EVEN THE PRINCIPAL INVESTIGATOR AND, SAY, THE SUPPLIER OF CELL LINES, THE SUPPLIERS OF EMBRYOS. IT'S THERE, BUT HOW TO TRANSLATE THAT WORK, WHICH BASICALLY EXISTS IN A BINDER OR FILE FOLDER, INTO A PIECE OF DOCUMENTATION THAT'S SORT OF CONSISTENT ACROSS THE GRANTEES.

SO THAT'S, I THINK, REALLY THE FOCUS. I WOULD SUGGEST AT THIS POINT IT'S A BIT MORE OF AN ADMINISTRATIVE TASK AT OUR END IN SORT OF SORTING THAT OUT, BUT THERE ARE VERY PRESSING ISSUES FOR THE WORKING GROUP.

HOWEVER, WITH THAT SAID, I HAVE SUMMARIZED THE INTERVIEWS THAT ARE PART OF THIS PROTOCOL, AND THEY'RE ATTACHED TO THE BRIEFING PACKET. AND WITHIN THAT SET OF INTERVIEW SUMMARIES, THERE MAY BE ISSUES

IN THERE THAT I'M MISSING, WHICH A SHARPER EYE MAY THINK ARE ISSUES THAT ARE RIGHT FOR THE WORKING GROUP TO CONSIDER. SO I WOULD ALSO DIRECT YOU TO THAT DOCUMENT AND SUGGEST THERE MAY BE ISSUES SORT OF EMBEDDED IN THERE THAT WE SHOULD THINK ABOUT. SO THAT HAS BEEN PROVIDED TO YOU ALL. AND AS THIS PROCESS MOVES FORWARD, THAT DOCUMENT WILL BE UPDATED AS MORE INTERVIEWS ARE CONDUCTED. SO WE SORT OF CONTINUE TO SEE THAT AS A MECHANISM FOR IDENTIFYING SORT OF NEW ISSUES THAT ELEVATE TO THE LEVEL OF STANDARDS WORKING GROUP OR ICOC.

CHAIRMAN LO: OKAY. THANKS, GEOFF. IF THERE ARE NO OTHER QUESTIONS OR COMMENTS, I'D LIKE TO MOVE ON. I THINK NOW WE'RE ON AGENDA ITEM NO. 4, REGULATORY AND POLICY CONSIDERATIONS. FIRST, JUST AS CONTEXT, AS WE'VE SAID ALL ALONG, THIS IS A FIELD THAT'S EXCITING, IT'S MOVING FORWARD, AND WE NEED TO MAKE SURE THE REGULATIONS AND THE ETHICAL CONSIDERATIONS ARE KEEPING UP WITH THE SCIENCE AND NATIONAL DEVELOPMENTS.

AND THERE ARE A NUMBER OF NATIONAL DEVELOPMENTS. THE NATIONAL ACADEMY OF SCIENCES ISSUED UPDATES TO ITS GUIDELINES THIS SPRING. THAT INCLUDED BRINGING THESE INDUCED PLURIPOTENTIAL CELLS INTO THE RECOMMENDATIONS THAT THEY HAD MADE.

THERE'S CERTAINLY AN EXPECTATION THAT THERE MAY BE CHANGES ON THE FEDERAL LEVEL FROM NIH IN THE NEW ADMINISTRATION. WE'LL HAVE TO SEE HOW THAT WORKS OUT.

BUT I THINK THERE ARE TWO ISSUES THAT REALLY ARE THE MEAT OF OUR AGENDA TODAY. 4(A) IS SOMATIC CELLS AND IPS LINES AND 4(B) IS IVF EMBRYOS FROM PAID DONORS. I'M GOING TO FOLLOW THE AGENDA AND HAVE US START WITH 4(A), SOMATIC CELLS. AND I THINK THE BEST WAY TO DO THIS IS TO TURN TO THE SLIDES THAT GEOFF SENT BY E-MAIL. THERE ARE A SET OF EIGHT POWERPOINT SLIDES. I'M SORRY. I FORGET WHAT THEY WERE ENTITLED JUST SO PEOPLE --

DR. LOMAX: I THINK IT SAYS POWERPOINT VIEW GRAPHS FOR 12/02 MEETING. IT'S THE ONLY POWERPOINT THAT WAS INCLUDED IN THE SET OF BACKGROUND MATERIALS YOU RECEIVED.

DR. PRIETO: GEOFF, IT BEGINS WITH THE FIRST SLIDE IS CURRENT CIRM STANDARDS FOR SCRO OVERSIGHT, PAYMENT?

CHAIRMAN LO: ABSOLUTELY. THOSE ARE THE ONES.

DR. LOMAX: NOW THAT I MENTION IT, IT MIGHT HAVE BEEN IN PDF FORMAT.

DR. PRIETO: MINE IS IN A PDF FORMAT.

CHAIRMAN LO: THANKS FOR THIS CORRECTION. GEOFF, DO YOU WANT TO WALK US THROUGH THE FIRST TWO SLIDES. I THINK THEY'RE SORT OF THE FIRST SLIDES THAT VISUALLY HELP US TO UNDERSTAND WHAT THE ISSUES ARE FOR SOMATIC CELL DONATION FOR IPS DERIVATION.

DR. LOMAX: THESE SLIDES ARE INTENDED TO GIVE YOU A SENSE, IF YOU WILL, OF THE SCOPING OF OUR REGULATIONS. SO WHEN WE INITIALLY SAT DOWN AND DEVELOPED THE STANDARDS FOR OVERSIGHT, PAYMENTS, AND CONSENT, WE SORT OF DREW A CIRCLE WHERE WE SAY ALL EMBRYOS, GAMETES, OR SOMATIC CELLS USED IN CIRM-FUNDED RESEARCH. THAT'S THE UNIVERSE OF MATERIAL WE CAPTURED, WHICH IS REALLY A BIT BROADER THAN WHAT THE NATIONAL ACADEMIES DID. THEIR UNIVERSE FOCUSED LARGELY ON EMBRYOS AND GAMETES WITH SOME SUBSEQUENT UPDATES THAT DO ADDRESS ISSUES RELATED TO SOMATIC CELLS.

SO WHEN YOU LOOK AT OUR STANDARDS FOR SORT OF THE OVERSIGHT COMMITTEE FOR PAYMENTS AND FOR CONSENT, CURRENTLY WE TREAT ALL THOSE MATERIALS AS EQUAL. AND OUR REGULATIONS ARE FAIRLY AGGRESSIVE IN TERMS OF CONSENT, PAYMENT, AND OVERSIGHT IN ALL THOSE AREAS.

NOW, LET ME JUST STOP THERE AND JUST ASK. SO IS THAT POINT -- DO PEOPLE UNDERSTAND THAT POINT?

DOES THIS SLIDE SORT OF EFFECTIVELY SORT OF CONVEY THAT?

PROFESSOR ROBERTS: I THINK SO.

DR. LOMAX: SO LET ME TURN TO THE SECOND SLIDE, WHICH IS TITLED "PROPOSED MODIFICATION." AND THIS IS PROPOSED MODIFICATION OF STANDARDS FOR OVERSIGHT, PAYMENTS, AND CONSENT.

SO THIS GIVES YOU SORT OF A CONCEPTUAL VIEW OF WHAT THIS PACKAGE OF AMENDMENTS WOULD ACCOMPLISH IF ALL THE RECOMMENDATIONS WERE ADOPTED IN WHOLE. WHAT WE'D EFFECTIVELY BE DOING IS APPLYING THE SORT OF MOST AGGRESSIVE STANDARDS TO EMBRYOS AND GAMETES, AND THAT'S MORE OR LESS CONSISTENT WITH THE NATIONAL ACADEMIES. BUT FOR THE SOMATIC CELL PORTION OF THE WORK, WE WOULD BE SORT OF CARVING OUT, SPECIFICALLY FOR IN VITRO WORK AND LABORATORY WORK INVOLVING SOMATIC CELLS, THERE WOULD BE -- RATHER THAN PROVIDING A FULL REVIEW, FOR EXAMPLE, OF A PROPOSED STUDY, AN ADMINISTRATIVE NOTIFICATION OF THE OVERSIGHT COMMITTEE PER SE DOING SOME WORK WHERE THERE MIGHT BE REPROGRAMMING INVOLVING, LET'S JUST SAY, A BLOOD SAMPLE. THIS IS THE EXAMPLE THAT ACTUALLY CAME OUT OF THE WORK I MENTIONED EARLIER.

THE CASE EXAMPLE WAS ONE WHERE WE HAVE A

BANK THAT ROUTINELY COLLECTS BLOOD SAMPLES FROM PATIENTS WITH HIV. THE PATIENTS DO CONSENT, GIVE A GENERAL RESEARCH CONSENT FOR THE USE OF THOSE MATERIALS IN RESEARCH, AND THEN THEY'RE BANKED. SO THERE'S AN INVESTIGATOR THAT'S INTERESTED IN BEING ABLE TO ROUTINELY GO BACK AND FORTH TO THAT BANK TO PULL BLOOD SAMPLES OF DIFFERING IMMUNOLOGICAL CHARACTERISTICS FOR LABORATORY WORK.

SO WHAT THIS WOULD SAY IS FOR THAT TYPE OF RELATIONSHIP OR THAT TYPE OF STUDY, A NOTIFICATION IS APPROPRIATE. AND THEN THE OTHER SIDE OF IT ON THE CONSENT SIDE, YOU KNOW, AGAIN, THERE'S A LITTLE BIT OF -- THERE'S AN ISSUE ON THE CONSENT SIDE BECAUSE WE SAY IF YOU'RE DOING RESEARCH THAT'S DESIGNED OR INTENDED TO CREATE BASICALLY A PLURIPOTENT STEM CELL LINE, THEN OUR CONSENT STANDARD COMES INTO EFFECT. AND OUR CONSENT STANDARD IS VERY DETAILED.

IN THE EXAMPLE I'M GIVING --

CHAIRMAN LO: COULD I BREAK IN FOR A MINUTE AND JUST SORT OF TAKE A STEP BACKWARD AND SAY WHY DO WE THINK DONATING SOMATIC CELLS FOR RESEARCH IS DIFFERENT THAN DONATING GAMETES OR EMBRYOS? AND WHY, THEREFORE, WE MIGHT HAVE A DIFFERENT REGULATORY SCHEME? I THINK WE HAVE TO GO BACK AND REMEMBER

THAT RESEARCH WITH GAMETES AND EMBRYOS IS SENSITIVE FOR A LOT OF REASONS. MANY PEOPLE HAVE PUT A SPECIAL SIGNIFICANCE ON THOSE CELLS COMPARED TO BLOOD CELLS, SKIN CELLS THAT ARE TO BE USED FOR IPS. THE METHOD OF OBTAINING THOSE CELLS IS MEDICALLY RISKIER.

IF YOU HAVE A WOMAN WHO'S UNDERGOING OOCYTE DONATION, THERE ARE, AS WE HAVE TALKED IN THIS GROUP BEFORE, THERE ARE MEDICAL RISKS IN THAT WHICH AREN'T THE CASE WHEN YOU'RE DONATING A BLOOD SAMPLE OR EVEN DONATING A SKIN BIOPSY. THERE ARE RISKS, BUT THEY'RE VERY, VERY LOWER AND LESS FREQUENT COMPARED TO THE RISKS OF OOCYTE DONATION.

THERE ALSO ARE CONCERNS ABOUT THE CONSENT PROCESS ITSELF, GIVEN THAT CONSENT FOR DONATION OF OOCYTES FOR GAMETES AND EMBRYOS IS TIED IN WITH REPRODUCTIVE USE WHICH, AGAIN, HAS SPECIAL SIGNIFICANCE. THERE HAVE BEEN CONCERNS RAISED ABOUT WHETHER WOMEN ARE REALLY GIVEN THE INFORMATION THEY NEED.

SO ALL THOSE WERE CONSIDERATIONS THAT LED, NOT JUST US, BUT THE NATIONAL ACADEMIES AND OTHER STATES AS WELL TO SAY FOR DONATION OF EMBRYOS AND GAMETES FOR STEM CELL RESEARCH, WE NEED TO BE SURE THAT THE RISKS ARE ACCEPTABLE AND MINIMIZED AND THAT

THE CONSENT PROCESS IS RIGOROUS.

DR. PRIETO: SOME OF THOSE CONCERNS I RECOGNIZE, PARTICULARLY THE RISKS, APPLY FOR WOMEN, BUT NOT FOR MEN WHEN YOU'RE TALKING ABOUT GAMETES. BUT I THINK ISN'T PART OF THE ETHICAL CONCERN THE REGENERATIVE OR THE INHERENT REGENERATIVE/PROCREATIVE POTENTIAL OF THOSE CELLS AS OPPOSED TO OTHER CELLS AS OPPOSED TO SOMATIC CELLS AND, OF COURSE, THEN THE SORT OF RELATED ISSUE NOW THAT SCIENCE IS BLURRING OR MAY BE ERASING THAT DISTINCTION?

CHAIRMAN LO: WELL, LET ME -- I THINK YOU'RE ABSOLUTELY RIGHT, FRANCISCO, THAT THERE WERE MANY REASONS WHY PEOPLE SAID LET'S BE PARTICULARLY CAREFUL ABOUT CONSENT, PAYMENT, AND OVERSIGHT IN THE CONTEXT OF USING OOCYTES AND EMBRYOS FOR STEM CELL RESEARCH. AND I THINK WE DID THAT.

THE QUESTION NOW IS INCREASINGLY THERE'S TREMENDOUS SCIENTIFIC INTEREST IN DERIVING THESE INDUCED PLURIPOTENTIAL CELLS FROM SKIN BIOPSIES OR IN SOME CASES BLOOD SAMPLES BECAUSE THEY ALLOW THE INVESTIGATOR TO DERIVE A STEM CELL LINE THAT'S GENETICALLY IDENTICAL TO THE DONOR. SO THAT MAY HAVE A STEM CELL LINE EXPRESSING A PARTICULAR CLINICAL PHENOTYPE, A CONDITION -- GEORGE DALY DID

THIS AT HARVARD WITH A NUMBER OF LINES WITH THE DEGENERATIVE DISEASES SO THE SCIENTISTS COULD STUDY THEM.

AND SO I THINK, GIVEN THE SCIENTIFIC INTEREST, IT'S IMPORTANT TO MAKE SURE THAT WE HAVE THE RIGHT SET OF GUIDELINES FOR THIS NEW TYPE OF RESEARCH.

THE OTHER FACTOR THAT'S MISSING IS THAT THERE ARE REGULATIONS ON DONATION OF STORED BLOOD OR BIOPSY SAMPLES FOR RESEARCH THAT'S COVERED UNDER EXISTING FEDERAL REGULATION. CONSENT IS REQUIRED, BUT NOT IN THE LEVEL OF DETAIL THAT WE HAD REQUIRED FOR OOCYTES. AND ALSO THERE'S A PROVISION IN THE FEDERAL REGULATIONS WHICH MANY RESEARCHERS TAKE ADVANTAGE OF, WHICH IS TO USE EXISTING SAMPLES THAT ARE ANONYMIZED, STRIPPED OF ALL IDENTIFIERS, SO THEY'RE SAMPLES THAT ARE LEFT OVER FROM CLINICAL USAGE, A TUBE OF BLOOD THAT'S LEFT OVER, A BIOPSY SPECIMEN THAT'S NOT NEEDED FOR CLINICAL PURPOSES, OR A SPECIMEN THAT WAS OBTAINED IN ANOTHER RESEARCH PROJECT, BUT WASN'T FULLY USED. THOSE EXISTING SAMPLES CAN BE USED FOR OTHER RESEARCH IF THEY'RE ANONYMIZED UNDER FEDERAL REGULATIONS.

IN FACT, THE FIRST IPS LINES DERIVED WERE ALL DONE WITH COMMERCIALLY AVAILABLE SOMATIC CELLS

THAT WERE ANONYMIZED, AND THERE WAS NO SPECIFIC CONSENT GIVEN BY THOSE DONORS FOR DERIVATION OF STEM CELLS. SO THE IDEA IS THAT IF WE APPLY THE FULL DETAILED CONSENT THAT WE'RE REQUIRING FOR DONORS OF OOCYTES TO HAVE TO GIVE SPECIFIC CONSENT FOR DERIVATION OF A STEM CELL LINE, THAT WOULD REMOVE A LOT OF EXISTING TISSUE WHICH SCIENTISTS, WHETHER WITH CIRM FUNDING OR WITHOUT, WOULD FIND VALUE IN USING.

SO THAT I'M JUST SAYING THAT THE CONTEXT IS THAT WE HAVE VERY STRONG OVERSIGHT AND REQUIREMENTS FOR BOTH REVIEW, PAYMENT, AND CONSENT FOR EMBRYOS AND GAMETES. THE QUESTION I THINK WE'RE DEALING WITH IS DO WE MOVE FOR THE SOMATIC CELLS FOR IPS TO A LEVEL OF OVERSIGHT AND CONSENT THAT'S MORE CONSISTENT WITH WHAT'S DONE WITH USING THESE CELLS FOR OTHER TYPES OF RESEARCH?

YOU CAN TAKE THESE CELLS AND PUT OTHER GENES INTO THEM IN THE LAB WITHOUT GOING THROUGH THE DETAILED OVERSIGHT THAT IS REQUIRED FOR GAMETES UNDER OUR REQUIREMENTS. AND SO SCIENTISTS IN THE LAB ARE SAYING, WELL, WHAT'S SO DIFFERENT ABOUT THESE TWO OR THREE GENES I'M INSERTING THAT MAKE IT DIFFERENT FROM OTHER WORK THAT IS GOING ON IN THE LAB NEXT DOOR WHERE I DON'T NEED TO GET SUCH

ELABORATE CONSENT?

DR. LOMAX: COULD I JUST MAKE ONE CLARIFICATION THERE, BERNIE, JUST BECAUSE THERE WERE ACTUALLY TWO ISSUES THERE. I APOLOGIZE FOR BEING SO DETAIL ORIENTED, BUT THAT'S MY JOB.

WE DID IN TERMS OF THE ANONYMOUS LINES, IF YOU WILL RECALL, LINES THAT HAVE BEEN ANONYMIZED WE DID ACTUALLY APPROVE FOR USE IF THEY MET THE FEDERAL STANDARD. THAT WAS IN A MEMO WE DID BACK IN 2007.

THIS PARTICULAR EXAMPLE, WHAT'S CAUGHT UP -- AND THE EXAMPLE GIVEN WITH THE HIV PATIENTS, THE SAMPLES ARE ACTUALLY NOT ANONYMOUS. THAT'S A CRITICAL POINT. SO WE ARE DEALING WITH A -- CONCEPTUALLY WE HAVE MOVED THE ANONYMOUS CELL ISSUE. THIS WOULD BE A CASE WHERE THEY'RE CONSENTED MATERIALS, BUT THERE MAY BE -- IN THIS CASE THERE'S MEDICAL HISTORY ATTACHED, WHICH IS VERY IMPORTANT FOR THE RESEARCH. SO WE ARE DEALING WITH A SLIGHTLY DIFFERENT EXAMPLE HERE. I JUST DIDN'T WANT THOSE TWO ISSUES --

CHAIRMAN LO: ABSOLUTELY. BUT IT'S CONSENT FOR GENERAL RESEARCH, NOT CONSENT SPECIFICALLY TO DERIVE IPS LINES THAT WOULD BE USED TO CHARACTERIZE THEM IN BASIC LABORATORY RESEARCH. SO WE'RE SAYING THAT FOR WORK THAT'S INSERTING

GENES, CHARACTERIZING CELLS, INJECTING THEM IN ANIMALS TO SHOW THAT THEY FUNCTION PROPERLY AS PLURIPOTENT CELLS, THOSE ARE ALL THINGS THAT WE WOULD SUGGEST BE DONE UNDER -- BE PERMITTED UNDER A GENERAL CONSENT. WE WOULD DRAW THE LINE AT OTHER TYPES OF MORE SENSITIVE DOWNSTREAM RESEARCH.

TED PETERS HAD A COMMENT AND THEN SOMEONE ELSE ON THE PHONE AS WELL. WHY DON'T WE TAKE TED FIRST. I'M SORRY. WHO JUST SPOKE? I CAN'T RECOGNIZE YOUR VOICE.

MR. SHEEHY: JEFF SHEEHY. I'M A LITTLE SCRATCHY TODAY.

CHAIRMAN LO: I HOPE YOU'RE FEELING BETTER, JEFF. LET'S DO TED FIRST AND THEN TURN TO JEFF.

DR. PETERS: WOULD ONE IMPLICATION, BERNIE, BE IF WE SEPARATE OUT THE SOMATIC CELLS FROM THE MORE ETHICALLY SENSITIVE EMBRYOS AND GAMETES, ARE WE INDIRECTLY, THEN, ENCOURAGING IPS AND OTHER FORMS OF RESEARCH BY PUTTING FEWER HURDLES IN THE WAY OF THOSE RESEARCHERS? IS THAT PART OF THE MOTIVE FOR THIS SEGREGATION?

CHAIRMAN LO: I'M NOT SURE IT'S PART OF A MOTIVE, BUT IT MAY WELL HAVE THAT EFFECT. IT'S ACTUALLY HAVING THAT EFFECT ON SCIENTISTS. ALAN,

CORRECT ME IF I'M WRONG, BUT SCIENTISTS ARE SAYING, LOOK, I CAN DO THIS. IT'S A LOT EASIER TO DO IN THE LABORATORY, AND THESE CELLS HAVE PROPERTIES THAT ARE VERY VALUABLE TO UNDERSTANDING DISEASE. I THINK THE IMPETUS ISN'T COMING FROM US. IT'S COMING FROM THE SCIENTISTS WHO SAY THESE ARE REALLY EXCITING TYPES OF RESEARCH THAT CAN BE DONE. AND PLEASE DON'T HOLD IT UP IN WAYS THAT DON'T REALLY PROTECT DONORS OR PROTECT OTHER VALUES THAT ARE IMPORTANT.

PROFESSOR ROBERTS: CAN I JUST ASK A QUESTION ABOUT THE QUESTION?

CHAIRMAN LO: ABSOLUTELY.

PROFESSOR ROBERTS: BECAUSE EVEN THOUGH THE IMPETUS IS COMING FROM THE RESEARCHERS, WE MIGHT, IN CONSIDERING THIS, THINK, WELL, IF THERE ARE FEWER HURDLES FOR RESEARCH ON SOMATIC CELLS THAT MAY HAVE AN IMPACT ON THE DEMAND FOR GAMETES, IS THAT -- I THOUGHT MAYBE THAT WAS PART OF THE THOUGHT BEHIND THE QUESTION, AT LEAST IT WAS A THOUGHT I HAD IN LOOKING.

CHAIRMAN LO: I'M GOING TO DEFER TO ALAN TO SPEAK ON THE SCIENTIFIC ISSUES.

DR. TROUNSON: I DIDN'T REALLY UNDERSTAND THAT, AND I APOLOGIZE FOR THAT. THE IPS CELLS THEMSELVES DON'T REALLY INVOLVE ANY GAMETES.

PROFESSOR ROBERTS: RIGHT. SO I'M SAYING IF THERE WERE MORE OF THOSE -- ARE THESE TWO COMPLETELY SEPARATE SOURCES FOR CELLS, OR MIGHT THERE BE SOME RELATIONSHIP BETWEEN THE SUPPLY OF EACH ONE?

DR. TROUNSON: I DON'T THINK SO EXCEPT WHERE MAYBE THE SCIENTISTS MIGHT BELIEVE THAT IT'S MORE PRUDENT AND MORE WORTHWHILE TO STUDY IPS CELLS RATHER THAN EMBRYONIC STEM CELLS OR, FOR EXAMPLE, PERHAPS CLOSER RELATIONSHIP MIGHT BE RATHER THAN DOING NUCLEAR TRANSFER, THE SCNT PROCEDURE, TO DERIVE PATIENT-SPECIFIC EMBRYONIC STEM CELLS. THERE MAY WELL BE A SHIFT IN THE INTEREST OF SCIENTISTS TO WORK WITH IPS CELLS RATHER THAN NUCLEAR TRANSFER PROCEDURE.

THAT WOULD HAVE A KNOCK-ON EFFECT OF NOT REALLY MAKING -- OF BASICALLY SAYING THAT THERE'S LESS INTEREST IN DERIVING NUCLEAR TRANSFER CELLS AND, HENCE, OBTAINING OOCYTES FOR THAT PURPOSE.

PROFESSOR ROBERTS: THAT WAS MY THOUGHT.

DR. TROUNSON: I THINK THAT IS PROBABLY WHAT IS CURRENTLY GOING ON, ALTHOUGH THERE'S STILL MANY LABORATORIES THAT ARE COMMITTED TO NUCLEAR TRANSFER, AND THERE'S MANY SCIENTISTS WHO REMAIN VERY MUCH SUPPORTIVE OF THAT AREA.

JOSE CIBELLI, MANY SCIENTISTS OUT THERE HAVE VERY STRONG INTEREST IN THIS AREA. SO, YOU KNOW, I THINK WHILE IT'S PROBABLY TRUE FOR THE VOLUME OF RESEARCH, I THINK THERE ARE MANY LABORATORIES THAT STILL REMAIN INTERESTED IN THE SOMATIC CELL NUCLEAR TRANSFER.

CHAIRMAN LO: JEFF SHEEHY, I KNOW YOU WANTED TO MAKE A COMMENT.

MR. SHEEHY: I HAD A QUESTION. I THINK THIS IS PROBABLY A GENERIC QUESTION FOR EVERY ISSUE, FRANKLY, GOING FORWARD. GIVEN THE RECENT ELECTION, I FEEL LIKE THAT WE FUNDAMENTALLY HAVE CHANGED IN TERMS OF PERSPECTIVE IN OUR REGULATIONS, IN OUR REGULATORY OUTLOOK IN THAT WE'RE NO LONGER KIND OF OFF ON AN ISLAND CREATING RULES BY OURSELVES WITH SOME GUIDANCE FROM THE NATIONAL ACADEMIES, BUT WE'RE REALLY IN A POSITION WITH THE FEDERAL GOVERNMENT COMING INTO THIS SPACE.

HOW DOES THIS CONTEXTUALIZE WITHIN -- I'M NOT VERY ARTICULATE TODAY BECAUSE I'M SUFFERING FROM THIS HEAD COLD.

I'M TRYING TO GET A SENSE OF THE NATIONAL CONTEXT. ARE WE MERGING TOWARD A NATIONAL STANDARD IF WE CHANGE THIS? ARE WE GETTING AHEAD OF A NATIONAL? ARE WE STRICTER? ARE WE LAXER?

IT SEEMS TO ME OUR GOAL OUGHT TO BE TO TRY TO BLEND IN WITH WHAT WILL BE EVENTUALLY A REGULATORY CONTEXT THAT'S GOING TO BE NATIONAL AND DIRECTED MORE FROM WASHINGTON. AND I THINK SOME OF THE ONUS ON US IS GOING TO BE RELIEVED WITHIN THE NEXT SIX MONTHS TO A YEAR. I MAY BE WRONG IN THAT ASSESSMENT.

MS. LANSING: CAN I ADD TO WHAT JEFF IS SAYING? THIS IS SHERRY.

CHAIRMAN LO: PLEASE.

MS. LANSING: I THINK, UNLESS WE'RE READING THE OBAMA ADMINISTRATION WRONG, THERE'S GOING TO BE A CHANGE IN POLICY. SO I DON'T WANT US JUST TO BLEND IN. I WANT US TO SENSE WHAT IT IS AND, IF NECESSARY, TO LEAD BECAUSE I'M NOT SURE THEY KNOW WHAT THEY'RE GOING TO BE DOING YET. SO I DON'T WANT US TO GET TOO FAR AHEAD OF THE CURVE, BUT THE QUESTION IS DO WE HAVE ANY INDICATION OF WHAT THEY'RE GOING TO DO, IF THERE'S A PROBLEM WITH WHAT THEY'RE GOING DO. CAN WE BE EFFECTIVE IN TRYING TO ADVOCATE AS WELL?

CHAIRMAN LO: WELL, LET ME TRY AND ANSWER THAT. IT'S ALWAYS A DIFFICULT THING TO SORT OF PREDICT THE FUTURE.

MS. LANSING: EXACTLY.

CHAIRMAN LO: VERY MANY PEOPLE HAVE HOPES ON WHAT THE NEW ADMINISTRATION WILL DO, AND IT REMAINS TO BE SEEN. TOM DASCHLE WAS JUST APPOINTED SECRETARY OF HHS. THE NEW NIH DIRECTOR HAS YET TO BE APPOINTED. SO THERE'S QUESTIONS. I KNOW ALTA CHARO IS ACTUALLY INVOLVED IN THE TRANSITION TEAM EFFORTS.

LET ME SAY, THOUGH, OBAMA, DURING THE CAMPAIGN, PROMISED THAT HE WOULD ALLOW NIH FUNDING FOR DERIVATION OF NEW STEM CELL LINES FROM FROZEN OOCYTES THAT WOULD OTHERWISE BE DESTROYED. SO IT'S A LOOSENING OF THE BUSH STRICTURE. NOW, THAT'S JUST NIH FUNDING.

NOW, WHETHER THE AMOUNT AND THE BUDGET FOR THAT AND HOW THAT WILL GO THROUGH REMAINS TO BE SEEN, IF HE DOES IT. THAT CAN BE DONE BY EXECUTIVE ORDER.

TO ISSUE REGULATIONS THROUGH HHS IS ACTUALLY QUITE A LENGTHY PROCESS AND WOULD NOT HAPPEN SOON. SO I THINK THAT EVEN IF THEY WANTED TO DO CHANGES, IT WOULD REQUIRE A MUCH LENGTHIER PROCESS THAN WE COULD PERHAPS DO ON SOME OF THESE ISSUES.

SO I THINK THAT IT PROBABLY WOULD BE IMPORTANT FOR US TO ACT, CERTAINLY TO TRY AND BE

ABREAST OF WHAT'S LIKELY TO HAPPEN; BUT, AGAIN, ALAN AND HIS STAFF ARE GOING TO BE REVIEWING GRANTS, ASKING FOR FUNDING IN THE NEXT CYCLE. WE HAVE TO MAKE SURE THAT THE REGULATIONS IN PLACE ARE APPROPRIATE FOR THE TYPES OF RESEARCH THAT THEY'RE ASKING FOR AND APPLICATIONS THAT THEY'RE RECEIVING. SO I THINK WE NEED TO BE COORDINATED, BUT I DON'T THINK WE CAN WAIT UNTIL --

MS. LANSING: I GOT IT. THANK YOU, BERNIE. THAT REALLY CLARIFIES IT.

CHAIRMAN LO: DOES THAT HELP, JEFF?

MR. SHEEHY: YES, IT DOES.

MS. LANSING: IT REALLY DOES. IT CLARIFIES IT A LOT.

MR. SHEEHY: I LIKE THE TERM "COORDINATED." I THINK IT GIVES ME A GOOD SENSE OF HOW WE'RE GOING TO PROCEED.

CHAIRMAN LO: I THINK WE WOULD CERTAINLY TAKE IT ON OURSELVES TO SORT OF MAKE CONTACT WITH THE POINT PERSON. I'M NOT SURE IT WOULD BE IN THE NEW ADMINISTRATION OR AT NIH BECAUSE NIH WOULD NOT BE REDOING THE REGULATIONS. THAT WOULD BE SOMEPLACE ELSE IN HHS. SO THERE'S GOING TO BE -- NOW, WHAT FDA MAY DO MAY ALSO CHANGE AS WELL.

DR. PRIETO: I JUST QUESTION WHETHER

ANYONE HAS MADE CONTACT WITH ALTA TO TALK TO HER ABOUT THESE ISSUES.

CHAIRMAN LO: WE'VE TRIED. ALTA IS IN OVER HER, WHATEVER, EARS, THE TOP OF HER HEAD WORKING ON TRYING TO FILL SLOTS. SO I THINK WE -- YOU KNOW, THEY'RE DEALING WITH CABINET OFFICIALS NOW. WE'RE TALKING ABOUT PEOPLE SEVERAL LAYERS BELOW. THIS WILL TAKE SOME TIME TO SORT OUT.

DR. TROUNSON: BERNIE, I THINK IN THE FIRST INSTANCE, I WILL REFER TO THE NATIONAL ACADEMIES GUIDELINES ALMOST CERTAINLY, YOU KNOW, TO PROVIDE THEM WITH INSTRUCTION ABOUT HOW THEY WOULD DEVELOP ANY OTHER FURTHER REGULATION. AND THAT'S WHAT WE'VE BEEN CONNECTED TO.

I THINK WHAT PEOPLE HAVEN'T DONE IS REALLY THOUGHT TOO FAR INTO THIS IPS CELL AREA. AND I THINK THE PROPOSAL THAT'S ON THE TABLE IS IMPORTANT. IT'S ALSO IMPORTANT TO CONSIDER THE CONTEXT OF THE RESEARCH, THAT WE NEED TO BE CAREFUL HERE BECAUSE IT IS CERTAINLY POSSIBLE IN THEORY TO BE ABLE TO DERIVE GAMETES AND POSSIBLY EMBRYOS FROM IPS CELLS.

SO IN THAT CONTEXT, I THINK WE NEED TO PUT A DOT MARK OVER THE RESEARCH CONTEXT AND BRING THAT BACK INTO OUR MAINFRAME IN ORDER TO COMPLETE THE CIRCLE.

CHAIRMAN LO: ABSOLUTELY. I WANT TO JUST UNDERSCORE THE POINT ALAN JUST MADE ABOUT WE'RE TALKING ABOUT, IN GEOFF'S NO. 2, THE FIRST STEP IN OBTAINING SOMATIC CELLS FOR DERIVATION OF IPS LINES AND DOING BASIC LABORATORY WORK. THERE IS DOWNSTREAM RESEARCH THAT STARTS TO GET SENSITIVE; NAMELY, IF THESE ARE TRULY PLURIPOTENT CELLS, THESE IPS CELLS, IT MAY BE POSSIBLE TO TRANSFORM THEM INTO GAMETES, OOCYTES AND SPERM, OKAY, AND WITH THOSE GAMETES TO CREATE AN EMBRYO.

NOW, THAT WE'RE NOT SAYING SHOULD BE ALLOWED UNDER A GENERAL RESEARCH CONCERN. ALAN VERY APPROPRIATELY POINTED OUT THERE'S A LINE THERE WE'RE TRYING TO DRAW, BUT WE'RE TALKING ABOUT THE SORT OF UPSTREAM WHAT I WOULD CALL FUNDAMENTAL BASIC LAB RESEARCH TO SORT OF REPROGRAM A SOMATIC CELL TO A PLURIPOTENT CELL AND DEMONSTRATE PLURIPOTENTIALITY AND SORT OF DRIVE THEM INTO BETA ISLET CELLS, NEURAL CELLS, WHICH ARE THE FOCUS OF MANY OF THESE DISEASE TEAMS THAT CIRM IS SETTING UP.

I ALSO WANT TO JUST CLARIFY ANOTHER COMMENT ALAN MADE. NAS, NATIONAL ACADEMY OF SCIENCES, AGAIN WILL PLAY A ROLE. THEY HAVE AN ONGOING COMMITTEE, AND THEY PRESUMABLY WILL MAKE ANOTHER REPORT IN 2009. AGAIN, MUCH AS I LOVE NAS

AND I'M ON THE COUNCIL ON IOM, THEY HAVE A PEER REVIEW CONSENSUS PROCESS, SO ANY REPORT THEY MAKE GOES THROUGH A VERY LONG PROCESS. AND, AGAIN, THEY'RE NOT AS NIMBLE OR FLEXIBLE AS PERHAPS WE MIGHT BE.

SO I THINK, AGAIN, WE NEED TO BE MINDFUL OF WHAT ALL THESE PEOPLE ARE DOING, SORT OF BE COORDINATED AND HOPEFULLY IN HARMONY WITH THEM. BUT THEY HAVE ACTUALLY LOOKED TO US, I THINK I CAN SAY THIS IN ALL MODESTY, TO SORT OF SET THE LEAD. IF YOU LOOK AT, FOR INSTANCE, THE HIGH STANDARDS FOR CONSENT FOR OOCYTE DONATION FOR DERIVATION OF EMBRYONIC STEM CELL LINES, THAT WAS REALLY TAKEN AFTER IDEAS THAT CAME OUT OF CALIFORNIA.

ANY OTHER QUESTIONS? I DON'T KNOW IF THERE'S ANYONE ELSE ON THE PHONE WHO HAD A COMMENT ABOUT SORT OF THE IPS VERSUS EMBRYONIC STEM CELLS.

DR. TAYLOR: I JUST WANTED TO KIND OF REITERATE A COUPLE OF THE POINTS THAT CAME UP AND TO AGAIN TRY TO PUT THIS IN PERSPECTIVE. SO I REALLY APPRECIATE GEOFF'S KIND OF CLARIFYING THE ANONYMIZED DIFFERENCE HERE BECAUSE, TO BE HONEST, REALLY THE POWER OF THE IPS SYSTEM IS NOT ANONYMIZED. THE ADVANTAGE THERE IS TO REALLY TAKE THE DISEASE-SPECIFIC OR SPECIFIC CHARACTERISTICS OF THE

INDIVIDUAL THAT THOSE CELLS COME FROM. SO I THINK THAT WE'VE GOT TO THINK ABOUT THAT IN THAT RESPECT, THAT, AGAIN, SORT OF KNOWING SOMETHING ABOUT THESE CASES IS WHAT'S GOING TO MAKE THOSE CELLS WORTHWHILE.

AND THE OTHER PART IS REALLY, AND I'M ACTUALLY IN FAVOR OF THIS, BUT I DO THINK THAT IN THE CONTEXT OF WHAT WE'RE SUGGESTING, IF YOU CAN USE ARCHIVED CELLS THAT WERE COLLECTED ON A GENERAL CONSENT, AND WE ACTUALLY ARE USING A LOWER LEVEL ETHICAL STRINGENCY THAN WE DO FOR KIND OF STRAIGHTFORWARD DNA STUDIES NOW WHERE WE REQUIRE MUCH MORE CLARITY ABOUT WHAT THE INDIVIDUALS CONSENTED FOR. SO GIVEN SOME OF THE SENSITIVITIES ABOUT WHERE THESE CELLS COULD POTENTIALLY GO, I JUST THINK WE MIGHT WANT TO BE A LITTLE BIT CAREFUL ABOUT SETTING A STANDARD THAT'S ACTUALLY LOWER THAN THAT FOR SNP ANALYSIS.

CHAIRMAN LO: LET ME SORT OF TRY AND FOLLOW UP ON THAT TWO WAYS. FIRST, I THINK ANONYMIZED DOESN'T MEAN YOU CAN'T HAVE VERY RICH CLINICAL INFORMATION ABOUT THE PHENOTYPIC CLINICAL INFORMATION ABOUT THE PERSON FROM WHOM THE CELLS CAME.

DR. TAYLOR: GOING FORWARD, I THINK THAT'S

TRUE. RETROSPECTIVELY I WOULD QUESTION THAT.

CHAIRMAN LO: WELL, REMEMBER, THE WAY, FOR EXAMPLE, CANCER CENTERS WORK AND PATHOLOGY DEPARTMENTS IS THAT THE UNIVERSITY OR THE PATHOLOGY LAB HAS IDENTIFIED CELLS AND ACCESS TO RECORDS. WHAT THEY GIVE TO RESEARCHERS STRIPS OFF THE 19 HIPAA IDENTIFIERS, GIVES YOU THE CLINICAL INFORMATION AND THE SAMPLE AND A CODE NUMBER, 001, 002. AND GENERALLY THERE'S AN AGREEMENT BETWEEN THE BANK AND THE RESEARCHER THAT THE RESEARCHER DOESN'T GET THE CODE.

NOW, THERE ARE ISSUES THAT NEED TO GET WORKED OUT ABOUT IF YOU DISCOVER FOREIGN GENETIC MUTATIONS, BUT I JUST WANT TO EMPHASIZE YOU CAN HAVE RICH PHENOTYPICAL CLINICAL MATERIAL ACCOMPANYING A CELL WITHOUT KNOWING THE IDENTITY OF THE DONOR.

SECOND POINT, ROB RAISES A GOOD POINT IN THAT STANDARDS ARE CHANGING FOR CONSENT IN OTHER AREAS. AND CERTAINLY FOR GENOMEWIDE ASSOCIATION STUDIES OR WHOLE GENOME SEQUENCING, NIH, FOR EXAMPLE, IS VERY CONCERNED NOW ABOUT WHAT KIND OF CONSENT DO YOU NEED FOR THESE TYPES OF TECHNIQUES. CURRENTLY IT IS STILL THE REGULATION THAT YOU MAY DO THIS UNDER GENERAL CONSENT TO RESEARCH.

NOW, PEOPLE HAVE SAID A BEST PRACTICE

WOULD BE TO HAVE HIGHER STANDARDS. AGAIN, I THINK ONE OF THE THINGS WE'RE SAYING IS THAT IF ALL YOU ARE GOING TO DO IN THE INITIAL DERIVATION OF IPS CELLS IS EITHER INSERT THREE GENES OR ACTUALLY NOW TO TRY AND FIND TRANSCRIPTION FACTORS THAT DON'T INVOLVE GENETIC MANIPULATIONS OF SOMATIC CELLS, THAT'S NOT IN THE ARGUMENT AT LEAST OF MANY RESEARCHERS VERY DIFFERENT FROM WHAT PEOPLE DO NOW ALL THE TIME IN LABORATORIES FOR PURPOSES OTHER THAN STEM CELL DERIVATION.

AND SO THEY'RE SAYING EVEN THOUGH THEY END UP WITH A PLURIPOTENT CELL, THE TYPES OF THINGS YOU'RE DOING DON'T DIFFER IN KIND. SO THAT'S, I THINK, ROB, YOU SORT OF PUT YOUR FINGER ON AN IMPORTANT ISSUE.

WHAT KIND OF CONSENT WOULD WE BE COMFORTABLE WITH FOR THOSE INITIAL STAGES OF OBTAINING THE SAMPLE OF THE SOMATIC CELL SAMPLE AND DOING THE BASIC FUNDAMENTAL LABORATORY WORK?

PROFESSOR ROBERTS: I HAVE SOME QUESTIONS TO FOLLOW UP ON THAT. JUST FOLLOWING UP ON THAT ISSUE OF CONSENT, ARE WE GOING TO MAKE A DISTINCTION BETWEEN THE CELLS THAT ALREADY EXIST IN BLOOD BANKS OR WHEREVER AND THOSE THAT ARE COLLECTED PROSPECTIVELY? BECAUSE A LOT OF THIS DEBATE OR THE

ARGUMENT TO HAVE A DIFFERENT STANDARD FOR SOMATIC CELLS IS THAT ALL THESE SAMPLES ALREADY EXIST AND CAN'T BE USED FOR STEM CELL RESEARCH.

BUT THEN THERE'S A SEPARATE ISSUE, IT SEEMS, WITH, OKAY, NOW, PROSPECTIVELY WILL IT BE TREATED THE SAME WAY AS WHERE THERE ISN'T THIS PROBLEM OF NOT BEING ABLE TO USE WHAT ALREADY EXISTS? BECAUSE, OF COURSE, SINCE THE CONSENTS -- THERE WAS JUST GENERAL CONSENT TAKEN FOR THE SAMPLES THAT ALREADY EXIST. THERE'S NOTHING YOU CAN DO ABOUT CONSENT, BUT PROSPECTIVELY THERE COULD BE A DIFFERENT CONSENT STANDARD FOR THESE NONEMBRYONIC SAMPLES.

SO ARE WE JUST TALKING ABOUT EXISTING SAMPLES OR PROSPECTIVE ONES?

CHAIRMAN LO: DOROTHY, THAT'S AN EXCELLENT POINT AND SUGGESTION. IN FACT, AT UCSF WHAT WE'VE DONE IS MADE THAT DISTINCTION AND SAID THAT IF YOU ARE GOING TO COLLECT FRESH MATERIALS STARTING FROM SEVERAL MONTHS AGO, THAT WE WOULD REQUIRE YOU TO ASK FOR CONSENT FOR DERIVATION OF SOMATIC -- FOR THE IPS LINE. SO IF YOU'RE COLLECTING FRESH MATERIALS, I THINK GENERALLY THE STANDARD IS YOU HAVE TO EXPLAIN WHAT YOU ARE DOING, HAVE IN MIND TO DO, AND THEN YOU MAY ALSO ASK FOR PERMISSION TO USE IT FOR OTHER

TYPES OF RESEARCH WITH LEFT-OVER SPECIMENS. THAT'S AN IMPORTANT AND VALUABLE DISTINCTION THAT'S BEEN MADE IN OTHER CONTEXT.

PROFESSOR ROBERTS: WELL, I THINK IF THERE ARE CONCERNS ABOUT THE CONSENT BEING ADEQUATE, I THINK THAT'S A DISTINCTION THAT MAYBE WE SHOULD MAKE BECAUSE THAT WOULD OBVIOUSLY ALLOW US TO THINK MORE CAREFULLY ABOUT CONSENT PROSPECTIVELY.

ANOTHER, THIS IS ALSO RELATED, IS WHILE THERE MAY NOT BE SO MUCH CONCERN ABOUT THIS BASIC RESEARCH AND JUST USING THE GENERAL CONSENT FOR THAT, AS SOMEONE JUST POINTED OUT, I CAN'T REMEMBER IF IT WAS BERNIE OR GEOFF, THERE ARE THESE LATER POTENTIAL USES THAT I THINK WE AND ALSO THE DONORS MIGHT BE MORE CONCERNED ABOUT WITH CREATING EMBRYOS. AND EVEN THOUGH WE COULD SAY THAT THIS SOMATIC CELL RESEARCH IS QUALITATIVELY DIFFERENT FROM USING GAMETES, SO WE MAKE A DISTINCTION BETWEEN THE TWO, IF THERE'S A POTENTIAL TO CREATE EMBRYOS, SOME OF THE DISTINCTION, I THINK, DISAPPEARS. AND I THINK, YOU KNOW, IF I WERE A DONOR, I WOULD WANT TO KNOW ABOUT THOSE POTENTIAL OR PROBLEMATIC USES OF MY MATERIAL.

AND SO, FIRST, I WONDER IF THE POTENTIAL FOR THAT SHOULD SOMEHOW BE TAKEN INTO ACCOUNT BOTH

IN CONSENT, BUT ALSO IN THE SCOPE OF THE REVIEW. I JUST WASN'T CLEAR IN WHAT WOULD TRIGGER THE FULL REVIEW. IN THE MATERIALS WE GOT, IT SAID THAT TRANSFER TO HUMANS OR ANIMALS WOULD STILL REQUIRE FULL REVIEW. BUT ARE THOSE THE ONLY -- WOULD THAT ALSO COVER CREATION OF EMBRYOS FROM THE IPS RESEARCH?

CHAIRMAN LO: LET ME JUST TRY AND RESPOND TO DOROTHY, AND THEN TED PETERS WANTS TO COMMENT AS WELL. DOROTHY, I THINK, HAS RAISED SOME VERY IMPORTANT POINTS. LET ME TRY AND REFRAME THEM A BIT.

PROFESSOR ROBERTS: YES, PLEASE. I'M SURE YOU CAN DO IT BETTER THAN I CAN.

CHAIRMAN LO: THERE ARE SOME TYPES OF RESEARCH USING IPS CELLS DERIVED FROM SOMATIC CELLS, DOWNSTREAM RESEARCH, THAT I THINK IS MORE SENSITIVE AND ARGUABLY WOULD REQUIRE HIGHER, STRICTER, MORE ROBUST CONSENT AND STRICTER OVERSIGHT. AND ON THE THIRD SLIDE -- AND DOROTHY ASKED THE QUESTION, SO IF WE'RE SAYING THAT THERE'S STEM CELL RESEARCH INVOLVING OOCYTES AND EMBRYOS, THERE'S IPS RESEARCH, THEN THERE'S SOME IPS RESEARCH THAT IS A LITTLE MORE SENSITIVE. A NUMBER OF TYPES OF RESEARCH MIGHT WELL FALL IN THAT CATEGORY.

ONE IS DOWNSTREAM RESEARCH FROM PLURIPOTENT IPS CELLS THAT DERIVES GAMETES AND PARTICULARLY EMBRYOS. REMEMBER THE SHARP LINE THAT HAS BEEN DRAWN BY CERTAINLY OPPONENTS OF EMBRYONIC STEM CELL RESEARCH IS THAT IN THEIR VIEW, MANY OF THEM, HUMAN LIFE, QUOTE, BEGINS AT CONCEPTION, UNQUOTE, WHICH IS FERTILIZATION. SO THE EMBRYO IS GIVEN EVEN MORE MORAL SIGNIFICANCE IN THEIR VIEW THAN OOCYTES. SO THAT KIND OF RESEARCH, REPRODUCTIVE RESEARCH.

SECOND COULD WELL BE TRANSPLANTATION INTO ANOTHER HUMAN BEING NOT THE ORIGINAL SOMATIC CELL DONOR. WE CAN PERHAPS TALK ABOUT THAT.

AND THIRD DOROTHY POINTED OUT IS NONCLINICAL RESEARCH INVOLVING THE TRANSPLANTATION OF STEM CELLS OR DIRECT STEM CELL DERIVATIVES INTO ANIMALS, PARTICULARLY YOU'RE DOING NEUROLOGICAL -- NEUROPRECURSOR CELLS, HUMAN PRECURSORS. SO THERE ARE CERTAIN TYPES OF RESEARCH THAT MIGHT, AS DOROTHY POINTED OUT, BOTH REQUIRE EXPANDED CONSENT AND STRICTER OVERSIGHT.

AND ON SLIDE 3 ON THE SECOND PAGE OF YOUR PDF, WE'VE SORT OF SUGGESTED THAT THOSE BE SUBJECT TO STRICTER OVERSIGHT. SO THAT THE GRAPH YOU SAW ON SLIDE 2 IS SORT OF THE GENERAL CASE, BUT THEN WE

HAVE THESE SPECIAL SITUATIONS OF STRICTER OVERSIGHT AND MORE ROBUST CONSENT.

GEOFF, IS THAT A FAIR SUMMARY OF JUST SORT OF NOT THE DETAILS AGAIN, BUT THE BIG PICTURE OF HOW WE'RE IN A SENSE SAYING THAT A LOT OF IPS RESEARCH WITH SOMATIC CELLS DOESN'T REQUIRE THE SAME LEVEL OF EITHER CONSENT OR OVERSIGHT, BUT SOME TYPES OF WORK YOU MAY DO WITH THOSE CELLS HAS TO REQUIRE MORE SPECIFIC CONSENT AND GET FULL SCRO REVIEW OR IRB REVIEW?

DR. LOMAX: THAT'S RIGHT. I THINK IN TERMS OF WHAT WOULD CHANGE HERE AS ANOTHER WAY OF LOOKING AT IT, THE ONLY THING WORTH RECOMMENDING A CHANGE ON WOULD BE THE CONDITIONS IN WHICH THE WHAT WE'RE CALLING OUR IN VITRO STANDARD, THE CONDITION IN WHICH MATERIALS COULD BE USED FOR IN VITRO RESEARCH, WHICH, IF YOU REMEMBER IN THE REGULATIONS, WE HAVE THESE CATEGORIES OF THINGS, USE OF OOCYTES, USE OF EMBRYOS, WORK TO DERIVE STEM CELL LINES, IN VITRO RESEARCH. WE'RE TRYING TO CREATE A CARVE-OUT TO BE MORE FLEXIBLE ON THE IN VITRO SIDE WITHOUT IMPACTING EITHER WORK THAT INTENDS TO CREATE AN EMBRYO, INTENDS TO DERIVE GAMETES, AND THAT'S ENTIRELY CONSISTENT WITH THE NATIONAL ACADEMY.

I WISH WE COULD HAVE ACTUALLY -- WHAT WILL

HAPPEN IS, REMEMBER THE STAGE OF THIS PROCESS IS WE THEN HAVE TO PROPOSE FURTHER LANGUAGE WHICH WOULD BE SUBJECT TO A VERY EXTENSIVE REVIEW. WE HAVE A SORT OF SECOND STEP HERE WHERE WE COULD SORT OF COMMENT ON THE ACTUAL LANGUAGE. CLEARLY THAT WAS THE INTENT.

ONE OTHER THING THAT DID COME UP, BECAUSE THIS CAME OUT IN THE BACKGROUND RESEARCH, AND IT'S REALLY TRYING TO BE RESPONSIVE TO PROFESSOR ROBERTS' FIRST POINT, IS THAT WHILE IT'S ON THE CONSENT, THE PROSPECTIVE CONSENT, WHICH IS THE WAY IT WAS PRESENTED BY A NUMBER OF INSTITUTIONS, WAS WHILE WE'D LIKE TO BELIEVE EVERYONE IS MOVING FORWARD WITH KEEN SENSITIVITY TO THE EXACT DETAILS OF WHAT CIRM WOULD LIKE TO SEE, THERE ARE A NUMBER OF ESTABLISHED BANKS FOR ANY NUMBER OF DISEASES, CANCER, HIV, THAT THESE ARE LONG ESTABLISHED BANKS THAT HAVE BEEN COLLECTING MATERIALS. AND THEY FEEL THEY HAVE A SORT OF ROBUST CONSENT PROCESS. THEY HAVE THE ABILITY TO RECONTACT A NUMBER OF DONORS, BUT IT'S JUST NOT FEASIBLE TO INCORPORATE EVERY SPECIFIC THAT WE INCORPORATE INTO OUR CONSENT.

BECAUSE I RAISED THAT POINT, WHAT ABOUT PROSPECTIVELY COULDN'T YOU DO THIS. IT'S JUST THE IDEA THAT STEM CELL RESEARCH IS SORT OF ONE CATEGORY

OF RESEARCH AMONG AN ARRAY OF RESEARCH. AND TRYING TO GET EVERYONE TO ADOPT OUR STANDARD IS, THEY FELT, NOT PRACTICAL. SO THAT WAS THE COMMENT. I'LL LEAVE IT TO YOU ALL TO SORT OF JUDGE THE EFFICACY OF THAT, BUT THAT POINT WAS RAISED WITH THE INSTITUTIONS THAT I WAS ABLE TO SURVEY.

CHAIRMAN LO: LET ME JUST, AGAIN, WE NEVER GOT TO YOU, TED. LET ME GO TO TED. WHAT I'VE BEEN DOING IS RESPONDING TO PEOPLE, AND POOR TED HAS BEEN PATIENTLY WAITING.

DR. PETERS: I'D LIKE TO RESPOND TO DOROTHY AND THE BRIEF REMARK OF FRANCISCO EARLIER ABOUT SEPARATING SOMATIC CELLS FROM EMBRYOS AND GAMETES. WHEN BERNIE OPENED THIS DISCUSSION, HE SAID THAT EMBRYOS AND GAMETES ARE ETHICALLY SENSITIVE AREAS, BUT FOR DIFFERENT REASONS. AND LET ME JUST TRY TO TEASE OUT WHAT I THINK THAT THEY MIGHT BE.

IN THE CASE OF THE DESTRUCTION OF HUMAN EMBRYONIC STEM CELLS, WITH THE DESTRUCTION OF THE BLASTOCYST TO OBTAIN THEM, YOU'VE GOT THE VATICAN, YOU'VE THE AMERICAN EVANGELICALS WHO BELIEVE THAT ONCE THE EGG IS FERTILIZED, THAT YOU'RE COMMITTING AN ABORTION WHEN YOU DO THAT. THAT'S WHAT MAKES EMBRYONIC STEM CELL RESEARCH ETHICALLY SENSITIVE.

WHEN IT COMES TO GAMETE RETRIEVAL, IT'S THE OOCYTE RETRIEVAL ISSUE. ROMAN CATHOLICS ARE UNCONCERNED ABOUT THE MORAL STATUS OF THE GAMETES. THEY ARE ABOUT THE EMBRYOS, BUT NOT ABOUT THE GAMETES.

NOW, WHAT IS ON THE HORIZON WITH IPS AS WELL AS EXPERIMENTS IN PARTHENOGENESIS AND CYTOPLASMIC REPROGRAMMING IS THE POSSIBILITY OF CREATING AN EMBRYO BYPASSING THE GAMETES IN THE FIRST PLACE. SO THE QUESTION WOULD BE IS THAT ETHICALLY SENSITIVE? MY ANSWER IS NO.

RECENTLY, WHEN THE IPS EXPERIMENTS WERE ANNOUNCED, RICHARD DORFLINGER, WHO IS A SPOKESPERSON FOR THE NATIONAL CONFERENCE OF ROMAN CATHOLIC BISHOPS, SAID HE SAW NO MORAL DIFFICULTIES IN THIS AT ALL, EVEN WITH THE PROSPECT THAT RESEARCH DOWN THE LINE MIGHT PRODUCE EMBRYOS IN THIS FASHION.

NOW, IT'S MY OWN JUDGMENT THAT FATHER DORFLINGER UNDERESTIMATES THE THEOLOGICAL AND ETHICAL SIGNIFICANCE OF WHAT IT IS WE'RE TALKING ABOUT. BUT THE GOOD NEWS FOR US IS THAT I THINK IT MAKES REASONABLE THE PROPOSAL THAT GEOFF AND BERNIE ARE GIVING, THAT WE COULD, AT LEAST FOR THE TIME BEING IN THE NEAR FUTURE, REMOVE SOMATIC CELL RESEARCH FROM THE SAME CATEGORY THAT WE HAVE FOR

EMBRYOS AND GAMETES.

DR. TROUNSON: THE ONE THING, BERNIE, THAT DOESN'T SEEM TO STRIKE ME QUITE RIGHT HERE IS THE WORDS "GAMETES AND BLASTOCYSTS." NO. 1, I THINK IT'S MORE ABOUT EMBRYOS, AS WE'VE JUST HEARD. SO BLASTOCYST IS A STAGE WELL AND TRULY DOWNSTREAM. SO YOU SHOULD USE THE WORD "EMBRYOS."

BUT I ACTUALLY DON'T SEE WHY RESEARCH ON THE STUDY OF IPS CELLS IN GAMETES WOULD ACTUALLY PRODUCE ANY GENUINE DIFFICULTY. THE PROBLEM IS KNOWING WHERE IN THE SPACE YOU'VE GOT A GAMETE BECAUSE YOU GO DOWN THE GERM CELL, AND THEN YOU'VE GOT A WHOLE SORT OF SEQUENCE OF EVENTS, AND THEN SUDDENLY YOU ARE ARRIVING AT SOMETHING THAT'S A DIFFICULTY.

I ESSENTIALLY THINK THE REAL PROBLEM IS THE PRODUCTION OF AN EMBRYO OR THE TRANSPLANTATION OF THE GAMETES. SO YOU'VE GOT IT VERY ADEQUATELY COVERED IF YOU ACCEPT BOTH THE EMBRYO AND THE TRANSPLANTATION AS REQUIRING YOU TO GET A HIGHER LEVEL OF DEMAND IN TERMS OF A CONSENT FROM YOUR SCRO COMMITTEES OR WHATEVER.

CHAIRMAN LO: OR FROM THE DONOR. SO THERE ARE TWO ISSUES HERE. WHAT LEVEL OF REVIEW AND WHAT LEVEL OF CONSENT YOU WANT FROM THE DONOR. OKAY.

I'M HEARING A FAIR AMOUNT OF AGREEMENT THAT -- ACTUALLY I DON'T THINK THIS IS SPECIFIC TO IPS CELLS, BUT IF YOU'RE DOING -- I GUESS LET ME JUST SAY. IF YOU HAVE AN IPS CELL AND YOU'RE DOING RESEARCH TO CREATE AN EMBRYO FROM GAMETES DERIVED FROM IPS CELL, THAT THAT REQUIRES STRICTER STANDARDS OF BOTH CONSENT AND OVERSIGHT. AND I THINK HAVING HEARD OBJECTION TO THE IDEA THAT IF YOU'RE GOING TO DO ALLOGENEIC TRANSPLANTATION INTO ANOTHER HUMAN BEING, THAT ALSO SHOULD REQUIRE HIGHER STANDARDS.

DR. TROUNSON: OR ANIMALS.

CHAIRMAN LO: OR ANIMALS. OKAY. SO THAT WHAT WE'RE SAYING -- I THINK WE MAY NEED TO HAVE SOME DISCUSSION AROUND GAMETES, ALTHOUGH THE LAST COUPLE PEOPLE SAID THAT IF YOU'RE GOING TO DRAW A LINE, IT SHOULD BE AT EMBRYOS RATHER THAN AT GAMETES. BUT THEN ABSENT THOSE SORT OF CASES, IF YOU ARE JUST DERIVING THE CELLS OR CHARACTERIZING ITS PROPERTIES AND IDENTIFYING MARKERS AND THINGS LIKE THAT, THAT THOSE WOULD ONLY REQUIRE NOTIFYING THE SCRO AND HAVING CONSENT FROM THE ORIGINAL SOMATIC CELL DONOR FOR JUST GENERAL RESEARCH.

THAT BEING SAID, I WOULD SORT OF -- I WOULD PERSONALLY, BUT I DON'T KNOW HOW THE REST OF YOU FEEL, SUPPORT DOROTHY'S ARGUMENT. IF YOU'RE

GOING TO GET FRESH SOMATIC CELLS TO DERIVE NEW IPS LINES, YOU OUGHT TO GO THROUGH A FAIRLY THOROUGH CONSENT PROCESS RATHER THAN JUST GETTING THE MINIMAL PROCESS.

AND THE ARGUMENT I WOULD MAKE IS BECAUSE YOU DON'T KNOW WHAT PEOPLE MIGHT WANT TO DO WITH THOSE LINES DOWNSTREAM. THAT WHEN YOU JUST GET THE SOMATIC CELLS, YOU DON'T KNOW IF YOU ARE GOING TO BE SUCCESSFUL DERIVING AN IPS LINE. IF YOU DO DERIVE THE LINE, MY IMPRESSION IS THAT YOU DON'T KNOW WHETHER IT'S GOING TO BE A LINE THAT'S EASY TO GROW, THAT DOESN'T MUTATE OR DIE, OR YOU DON'T KNOW WHETHER PEOPLE ARE ACTUALLY GOING TO BE ABLE DERIVE IT INTO MORE A SPECIALIZED LINE. BUT IF IT HAS THOSE PROPERTIES, OTHER SCIENTISTS ARE GOING TO WANT TO DO RESEARCH YOU WEREN'T PLANNING TO DO PERSONALLY.

IT STRIKES ME IT WOULD BE A SHAME, BECAUSE YOU DIDN'T SORT OF DO A PRETTY THOROUGH CONSENT PROCESS UP FRONT, THAT LATER RESEARCHERS WOULD BE ENABLE TO USE THOSE LINES BECAUSE YOU DID NOT ASK ABOUT THESE. I AT LEAST WANT TO JUST THROW THAT OUT AS A SUGGESTION.

DR. TROUNSON: AGAIN, IF YOU USE THAT ARGUMENT, BERNIE, WHY WOULDN'T IT BE IMPORTANT

PERHAPS TO BE ABLE TO GO BACK TO THE DONOR? YOU KNOW, IF IT WAS A PROPENSITY FOR A DISEASE THAT DIDN'T SHOW UP TILL LATER IN LIFE, IT MIGHT BE QUITE IMPORTANT TO BE ABLE TO DO THAT. HENCE, THE NEED TO BE ABLE TO HAVE THAT AS SOME SORT OF CONSENT MIGHT ALSO BE IMPORTANT.

CHAIRMAN LO: ABSOLUTELY. AGAIN, THAT'S WHAT WE'VE DONE AT UCSF. WE'VE SAID WHAT WE'D LIKE TO SEE IDEALLY IS AN EXPLANATION THAT ALL THESE MIGHT BE DONE. DO YOU AGREE TO SOME OF THESE MORE SENSITIVE, AND THEN MAY WE RECONTACT YOU EITHER IF NEW INFORMATION COMES UP IN YOUR HISTORY THAT WE WANT TO KNOW ABOUT. THERE'S ALWAYS THE POTENTIAL WE MAY FIND SOMETHING THAT MAY BE OF CLINICAL IMPORTANCE TO YOU. BUT ALSO, THAT IF SOMEONE PROPOSES RESEARCH THAT WE HADN'T THOUGHT OF, BUT MIGHT BE SENSITIVE, WE WOULDN'T WANT TO DO THAT WITHOUT GETTING BACK IN TOUCH.

LET ME SAY ONE OTHER THING. THE OTHER REASON THAT THIS IS A DIFFERENT APPROACH THAN WHAT'S BEEN LEGISLATIVELY ENACTED IN CALIFORNIA IS THAT THERE ARE CALIFORNIA LAWS SPECIFYING, AND ACTUALLY SOME ARE A RECOMMENDATION, SPECIFYING WHAT MUST BE SAID TO A DONOR. AND I THINK ONE OF THE PROBLEMS WITH ACTUALLY SPECIFYING YOU MUST SAY XYZ AND ABC IS

THAT THAT CHANGES AS THE NATURE OF THE SCIENCE CHANGES AND WE UNDERSTAND MORE WHAT PEOPLE ARE CONCERNED ABOUT.

SO, AGAIN, I WANT TO REMIND YOU THAT WE HAVE TRIED NOT TO BE PRESCRIPTIVE IN OUR REGULATIONS, BUT TO SAY THESE ARE THE GOALS WE WANT TO ACCOMPLISH AND LEAVE FLEXIBILITY OF SORT OF HOW YOU ACTUALLY FULFILL THOSE GOALS. AND TO THE EXTENT THAT, I THINK, THAT'S BEEN IMPORTANT IN A RAPIDLY MOVING FIELD, I WOULD URGE US TO SORT OF THINK ABOUT USING SORT OF GOAL-ORIENTED REGULATIONS RATHER THAN VERY PRESCRIPTIVE REGULATIONS.

I CUT SOMEONE OFF.

DR. PRIETO: JUST A QUESTION ABOUT THE ISSUE OF RECONTACT. I UNDERSTAND SITUATIONS WHERE THAT MIGHT BE DESIRABLE, BUT WHAT ARE THE IMPLICATIONS IF THE RECONTACT TURNS OUT TO BE IMPOSSIBLE?

CHAIRMAN LO: RIGHT. I THINK --

DR. PRIETO: YOU KNOW, THE PERSON IS UNAVAILABLE.

CHAIRMAN LO: RIGHT. OR DECIDES NOT TO WANT TO TALK TO YOU. THEY CHANGED THEIR MIND. ABSOLUTELY.

DR. PRIETO: OR HAS PASSED AWAY. MAYBE

THAT SORT OF REMOVES SOME ISSUES, BUT CERTAINLY THE OTHERS.

CHAIRMAN LO: THIS IS -- NO MATTER WHICH OPTION WE TAKE, THERE ARE ALWAYS COMPLICATIONS WHERE THINGS DON'T QUITE WORK OUT THE WAY YOU WOULD HOPE. AND THEN THAT'S, I THINK, SOMETHING THAT THE SCRO, THE IRB WILL HAVE TO SORT OF MAKE A DECISION ON WITHIN A FRAMEWORK OF WHATEVER REGULATIONS AND GUIDELINES ARE OUT THERE.

DR. TAYLOR: ACTUALLY I THINK THE POINTS ARE REALLY IMPORTANT NOW. I'D JUST LIKE TO EMPHASIZE THAT THEY'RE NOT ONLY THEORETICAL. AT OUR LAST MEETING, I THOUGHT WHAT WAS A RELATIVELY HEATED DISCUSSION WAS OVER THE FACT THAT A STEM CELL LINE THAT MIGHT BE AVAILABLE FOR CLINICAL TRIALS REALLY HAD BEEN OBTAINED UNDER SORT OF IN A SITUATION WHERE WE REALLY DIDN'T HAVE VERY MUCH CLINICAL INFORMATION AT ALL ABOUT WHERE CELLS CAME FROM.

SO I THINK WE REALLY WANT TO -- I CERTAINLY DON'T WANT TO STIFLE THE SCIENCE GOING FORWARD, BUT I DON'T WANT TO INHIBIT OUR ABILITY TO HAVE REALLY USEFUL THINGS THAT WE WOULD GET IF WE DID IT RIGHT KIND OF THE FIRST TIME.

I THINK IT IS IMPORTANT TO REALLY THINK THROUGH THIS TO MAKE SURE THAT THE CONSENT IS IN

PLACE SO THAT WE CAN GO BACK AND GET THE INFORMATION IF THE CELLS REALLY TURN OUT TO BE VALUABLE. WHEN YOU WERE TALKING ABOUT THE POLITICS AS WELL, AND I GUESS KIND OF PARAPHRASING YOGI BERRA, PREDICTION IS DIFFICULT PARTICULARLY ABOUT THE FUTURE.

CHAIRMAN LO: YOGI IS QUITE A GUY. YES. AGAIN, I THINK THE VERY HELPFUL DISTINCTION, I THINK IT WAS DOROTHY THAT POINTED OUT TO US, THAT WE NEED TO THINK DIFFERENTLY ABOUT EXISTING MATERIALS WHERE WE CAN'T GO BACK AND CONTACT VERSUS FRESH MATERIALS WE MAY WANT TO GATHER PROSPECTIVELY IN THE FUTURE WHERE THERE WILL BE SOME INTERACTION WITH THE DONOR OF THE CELLS AROUND THE TIME OF DONATION.

DR. LOMAX: CAN I ASK YOU A QUESTION ABOUT THAT, BERNIE, AND THIS IS ALSO DIRECTED TOWARDS PROFESSOR ROBERTS. ONE WAY TO THINK ABOUT THAT SCENARIO, SO I'M TRYING TO BE SENSITIVE TO THE PROBLEM WE'RE TRYING TO FIX, AND IF THE POLICY DOESN'T ADDRESS THE PROBLEM, THEN WE DON'T NEED A NEW POLICY.

WOULD IT BE REASONABLE -- IT SEEMED THAT THE CRITICAL STEP IN THE SCENARIO YOU DESCRIBE WAS THE INTENT TO SORT OF REDISTRIBUTE OR OTHERWISE CREATE A CELL LINE THAT WOULD BECOME READILY AVAILABLE TO RESEARCHERS. BECAUSE THE PROBLEM THAT

WAS IDENTIFIED WAS THE INABILITY TO TAKE BANKED MATERIALS AND DO SORT OF RAPID SCREENING, SORT THROUGH, SAY, A SELECTION OF CELLS FOR THE PURPOSE OF THEN MOVING FORWARD AND MOVING IN A DIRECTION. AND IF THE CONSENT HAS TO BE DONE ALL IN ADVANCE, THEN YOU STILL DON'T HAVE THAT OPTION OF KIND OF THAT RAPID SCREENING.

BUT SAY THE SCENARIO IS AN INVESTIGATOR PERFORMS THAT RAPID SCREENING WITH MATERIALS THAT ARE IDENTIFIABLE, THERE IS AN OPPORTUNITY TO GO BACK TO THE DONOR. IF THE NEXT STEP IS THAT THERE'S A PARTICULAR CELL LINE THAT HAS SOME EXTRAORDINARY CLINICAL OR SCIENTIFIC POTENTIAL THAT ALSO THEY'D WANT TO DISTRIBUTE AS A DERIVED LINE, THEN THEY'VE SORT OF GONE THROUGH THE STAGE OF IDENTIFYING THE OPTIMAL MATERIAL, AND THEN THERE'S A REAL -- IT'S NOT THAT DIFFICULT TO THEN RECONTACT AND RECONSENT.

SO THE POINT I'M TRYING TO MAKE IS COULD YOU DO THE BASIC WORK TO DO IDENTIFICATION, THE BASIC RESEARCH WITH A GENERAL CONSENT? AND THEN IF YOU BUMPED UP TO THE LEVEL THAT WOULD TAKE IT TO WHERE I THINK YOU WERE INDICATING WHERE IT WOULD BE PUT OUT THERE AND POTENTIALLY AVAILABLE BROADLY, THAT THAT'S WHEN THE HIGHER LEVEL OF CONSENT WOULD BE REQUIRED.

SO THE STANDARD WOULD READ SOMETHING TO THE EFFECT THAT LINES INTENDED FOR SUBSEQUENT BANKING AND/OR DISTRIBUTION, ETC., SHALL. YOU KNOW, SO, AGAIN, WE'RE STILL PROVIDING THAT OPPORTUNITY FOR THE RAPID SCREENING, THE GOING TO THE BANKS AND DO THE VERY BASIC RESEARCH. IS THAT CONSISTENT WITH YOUR COMMENTS?

CHAIRMAN LO: LET ME SORT OF TRY AND DRAW A DISTINCTION BETWEEN SCREENING OF EXISTING SOMATIC CELLS IN SOMEBODY'S PATHOLOGY BANK OR CANCER CENTER BANK VERSUS SCREENING OF EXISTING IPS CELLS. SO, AGAIN, I THINK WHAT WE'RE SAYING IS THERE ARE DIFFERENT TYPES OF IPS RESEARCH. AND SOME OF THE UP-FRONT BASIC RESEARCH JUST TO DERIVE, CHARACTERIZE, AND PROVE ITS PLURIPOTENT, THAT TO US DOESN'T SEEM TO IMPLICATE THE SAME KIND OF HEIGHTENED ETHICAL SENSITIVITY AND CONCERN.

BUT THEN ONCE YOU HAVE DERIVED THAT LINE, AND YOU SAY, WOW, THIS IS A PRETTY GOOD LINE, LET'S SORT OF SHARE WITH OTHER RESEARCHERS, LET'S DO OTHER THINGS, THEN THERE ARE CERTAIN THINGS THAT ARE DOWNSTREAM RESEARCH THAT WOULD SAY, BOY, IF YOU ARE GOING TO DO THAT, WE'RE NOT COMFORTABLE WITH SORT OF JUST A GENERAL CONSENT. WE WOULD WANT YOU TO HAVE GOTTEN MORE SPECIFIC.

ALAN HAS PROPOSED THAT, WELL, YOU JUST GO BACK TO PEOPLE AND SAY, "WELL, WE'VE DERIVED A LINE. THANK YOU VERY MUCH. NOW THERE ARE OTHER THINGS WE'D LIKE TO DO." THAT'S ONE MODEL.

THE OTHER MODEL IS TO TRY AND DO MORE OF THAT CONSENT UP FRONT. BUT I THINK WHAT WE'RE SAYING IS YOU MAY END UP IN A SITUATION WHERE YOU GET THE MATERIALS, THE SOMATIC CELLS, UNDER A GENERAL CONSENT, DERIVE A LINE, IT'S GANGBUSTERS, IT'S TERRIFIC, YOU NOW WANT TO DO LOTS OF OTHER THINGS. YOU TRY AND RECONTACT THE PERSON. I THINK IT WAS FRANCISCO. YOU CAN'T FIND THEM. THEY'VE MOVED AWAY. THEN YOU MAY BE PRECLUDED FROM USING THOSE LINES WHICH MAY HAVE VERY DESIRABLE SCIENTIFIC PROPERTIES FOR RESEARCH.

THAT'S THE DILEMMA WE FOUND OURSELVES IN AT UCSF. WE SAID LET'S TRY AND AVOID THAT BECAUSE THAT WOULD BE AWFUL, TO HAVE A LINE THAT'S REALLY VALUABLE AND SAY, WELL, IT'S REALLY GOT GREAT SCIENTIFIC PROPERTIES, BUT WE JUST DIDN'T ASK THAT, AND NOW WE CAN'T CONTACT THEM. SO WE SAID WHY DON'T WE TRY AND DO MORE OF THAT. THERE'S ALWAYS A TENSION BETWEEN TRYING TO ANTICIPATE WHAT YOU MIGHT WANT TO DO VERSUS HAVING SOMETHING COME UP THAT YOU DIDN'T ANTICIPATE.

BUT IT'S NOT UNWORKABLE TO SPEND EXTRA WHATEVER IT IS AMOUNT OF TIME UP FRONT WITH YOUR DONOR AND SAY IF THIS WERE TO WORK, THESE ARE SOME THINGS WE MIGHT WANT TO THINK ABOUT. WOULD YOU AGREE TO BE RECONTACTED? AND WOULD YOU AGREE TO THESE OTHER TYPES OF RESEARCH? SO, AGAIN, I THINK WE HAVE TO DIFFERENTIATE BETWEEN REGULATION AND SUGGESTIONS. WE MAY SAY AS A REGULATION, YOU MAY DO THIS TYPE OF RESEARCH WITH THIS TYPE OF CONSENT AND OVERSIGHT, BUT YOU MAY NOT DO THIS TYPE OF RESEARCH. THEN IT'S UP TO THE RESEARCHER TO MAKE THAT CALL WHETHER THEY WANT TO SPEND MORE TIME UP FRONT WITH THE CONSENT OR GO BACK LATER.

I DON'T THINK WE SHOULD BE PRESCRIBING YOU MUST DO ALL THESE THINGS FOR SOMETHING THAT MAY OR MAY NOT HAPPEN IN THE FUTURE. SO I THINK THE WAY IT'S LAID OUT HERE IS IF YOU'RE GOING TO DO CERTAIN TYPES OF RESEARCH WITH SOMATIC CELLS AND IPS CELLS, THESE ARE THE TYPES OF CONSENT YOU MUST HAVE AND THIS IS THE TYPE OF OVERSIGHT. WE MAY SUGGEST AS GUIDANCE OR NOT EVEN GUIDANCE, SORT OF A RECOMMENDATION HOW TO DO WHAT THEY MIGHT WANT TO DO, BUT THAT WILL EVOLVE. DIFFERENT RESEARCHERS WILL WORK OUT IN DIFFERENT WAYS, AND THEY MAY COME UP WITH BETTER IDEAS THAN WE CAN DO RIGHT NOW.

ANY OTHER COMMENTS FROM THOSE OF YOU ON THE PHONE? IT'S A PUBLIC MEETING, AND SO THERE'S SOME PEOPLE, I THINK, WHO WANT TO COMMENT, AND I'M GOING TO SORT OF OPEN THAT UP. ACTUALLY, MARCY, I'M GOING TO ASK YOU TO COME TO THE FRONT AND SPEAK INTO THE WHATEVER, THE PHONE, SO PEOPLE CAN HEAR YOU. FOR THE RECORD IDENTIFY YOURSELF, PLEASE.

DR. DARNOVSKY: THIS IS MARCY DARNOVSKY FROM THE CENTER FOR GENETICS AND SOCIETY. SO IT SEEMED LIKE THE DISCUSSION APPROACHED CONSIDERING SOME OF THE MUCH MORE ETHICALLY SENSITIVE DOWNSTREAM USES. AND I DON'T KNOW IF THIS IS THE APPROPRIATE VENUE FOR RAISING THEM. TED PETERS DID. AND I THOUGHT SINCE YOU DID, IT WOULD BE A GOOD THING TO PUT ON THE RECORD THAT THE CREATION OF GAMETES, EMBRYOS, BLASTOCYSTS OUT OF IPS CELLS, I THINK, WOULD RAISE VERY, VERY DEEP CONCERNS FOR A LOT OF PEOPLE, INCLUDING THOSE WHO SUPPORT EMBRYONIC STEM CELL RESEARCH, SUPPORT EMBRYO DESTRUCTIVE RESEARCH, AND SO ON.

SO YOU'VE HEARD FROM ME A LOT WHEN I'VE RAISED CONCERNS ABOUT THE ACQUISITION OF EGGS FROM WOMEN. AND THIS IS A DIFFERENT CONCERN ABOUT THE USE OF POTENTIALLY -- THE USE OF GAMETES OR BLASTOCYSTS, EMBRYOS FOR REPRODUCTIVE PURPOSES. AND

THAT SEEMS TO ME A VERY, VERY BRIGHT LINE THAT, AS FAR AS I KNOW, NOBODY IS CONTEMPLATING -- NO SCIENTISTS ARE CONTEMPLATING DOING THAT RIGHT NOW, AND I HOPE THAT REMAINS THE CASE.

BUT, YOU KNOW, IS IT TOO SOON TO BE RAISING THAT? I WOULD NOT LIKE THERE TO BE SOMETHING THAT, FOR EXAMPLE, THAT SOME PROVISION IN A CONSENT FORM, WE MAY USE CELL LINES DERIVED FROM YOUR TISSUE TO DO XYZ AND CREATE GENETICALLY MODIFIED BABIES. I WOULD NOT LIKE TO SEE THAT IN THE CONSENT FORM BECAUSE THAT BEGINS TO INTRODUCE THE POSSIBILITY THAT SOMEBODY THINKS THAT'S OKAY. AND THERE WOULD BE A WHOLE LOT OF PEOPLE WHO DON'T.

CHAIRMAN LO: LET ME, AGAIN, I THINK THIS IS HELPFUL. LET ME TRY AND RAISE TWO QUESTIONS. ONE IS THERE'S A CONTINUUM OF WORK, RIGHT, AND LET ME JUST SAY, FIRST, THERE IS GOING TO BE INTEREST IN USING IPS, I THINK, USING IPS CELLS FOR REPRODUCTIVE PURPOSES. IF YOU THINK ABOUT PEOPLE LIVING WITH CANCER WHO, BECAUSE OF THEIR CHEMO OR RADIATION THERAPY NO LONGER CAN PRODUCE GAMETES ON THEIR OWN, THEY MAY WANT VERY MUCH, AFTER THEY'VE SORT OF GONE THROUGH THEIR TREATMENT AND BEEN DISEASE FREE FOR FIVE, TEN YEARS AND CONSIDERED CURED OF THEIR DISEASE, TO SAY, GEE, I WOULD LIKE TO HAVE CHILDREN

THAT ARE GENETICALLY RELATED TO ME.

RIGHT NOW THE WAY THAT'S HANDLED IS THAT PEOPLE ARE ASKED TO -- MEN ARE ASKED TO BANK SPERM; BUT FOR WOMEN, BECAUSE OOCYTE RETRIEVAL AND FREEZING IS NOT AS SIMPLE OR EFFECTIVE, IT'S REALLY NOT AN OPTION. WHEREAS, WHAT YOU SAID ALLOWS AN OPTION, YOU KNOW, THIS IS WAY DOWNSTREAM WHERE WE TAKE A BIOPSY OF YOUR SKIN, GIVE IT TO SOMEONE'S LABORATORY, AND THEY TURN IT INTO AN IPS LINE, AND THEN DERIVE IT INTO AN OOCYTE. AND THEN IN IVF WE MIGHT -- I THINK THAT WOULD BE ATTRACTIVE TO PEOPLE FOR THAT PURPOSE, AT LEAST SOME PEOPLE.

SO I THINK THERE WOULD BE INTEREST IN DOING THAT. SO IF YOU -- YOU CAN THINK OF OTHER SCENARIOS WHERE PEOPLE WOULD SAY, OH, MY GOSH, THAT'S AWFUL OF PEOPLE TO THINK ABOUT WHATEVER.

DIFFERENT STEPS ON THE PROCESS. I THINK WE'VE SORT OF SAID THERE'S A CLEAR LINE THAT MANY DIFFERENT SORT OF FAITH TRADITIONS HAVE DRAWN BETWEEN CREATION OF AN EMBRYO, A TOTALLY POTENT ENTITY, THAT THAT HAS ENORMOUS MORAL SIGNIFICANCE, AND THAT REQUIRES VERY HIGH LEVEL. THEN GOING BACKWARDS IS CREATING THE GAMETE, BUT NOT USING IT FOR FERTILIZATION. WHAT'S THE SIGNIFICANCE OF THAT? THE PREVIOUS RESEARCH, SORT OF THE MORE BASIC

RESEARCH, TO SORT OF DERIVE IT INTO SORT OF A GERM CELL PRECURSOR. SO I THINK THERE'S CLEARLY A LINE THAT EVERYONE AGREES ON. THEN WE NEED TO SORT OF THEN SAY HOW MUCH FURTHER BACK DOES THAT GO?

DR. TROUNSON: IT WAS CERTAINLY THE CASE THAT YOU COULD IMAGINE THAT YOU COULD DERIVE GERM CELLS. GIVEN THE CURRENT TECHNOLOGY, THERE MAY WELL BE INTEREST, FOR EXAMPLE, IN MEN WHO HAVE NO SPERM TO BE ABLE TO RECEIVE THEIR GERM CELLS BACK AND REALLY TEST IT SO THAT THEY WOULD ACTUALLY PRODUCE SPERM. YOU KNOW, YOU CAN WELL IMAGINE THAT THEY WOULD WANT TO RECOVER FERTILITY. IT'S THEIR OWN CELLS. IT'S THEIR OWN FERTILITY.

IT'S CERTAINLY THE CASE THAT IN THE REPRODUCTIVE AREA, THERE WILL BE CERTAINLY INTEREST IN THAT.

DR. PETERS: THE REASON THAT UP UNTIL THIS POINT EMBRYOS HAVE BEEN ETHICALLY SENSITIVE AND GAMETES HAVE BEEN ETHICALLY SENSITIVE, I THINK, IS PROBABLY GOING TO BE DIFFERENT THAN WHY IT IS THAT THE PRODUCTION OF TOTALLY PLURIPOTENT CELLS FROM IPS OR OTHER SORTS OF THINGS WILL COME TO THE FORE. SO COULD YOU STATE, IN YOUR JUDGMENT, EXACTLY WHY WE WOULD HAVE AN ETHICAL CONCERN BECAUSE I SUSPECT IT'S GOING TO BE DIFFERENT FROM THE VATICAN'S ETHICAL

CONCERN UP UNTIL THIS POINT.

SO WHAT WOULD YOUR CONCERN BE IF WE DO MAKE BABIES FROM IPS EXPERIMENTS?

DR. DARNOVSKY: OUR CONCERN WOULD BE THAT THAT WOULD BE A PATH TOWARD GENETIC ENHANCEMENT OF FUTURE GENERATIONS WITH ALL THE ATTENDING SOCIAL CONSEQUENTIALITY OF THAT THAT, YOU KNOW, POTENTIALLY OPENS UP INTO EUGENIC SCENARIOS USING THIS KIND OF TECHNOLOGY.

CHAIRMAN LO: MAY I ALSO ASK, MARCY, IF YOU WOULD TO SORT OF SAY SOMETHING ABOUT WHY YOU DREW THE LINE AT PRODUCING GAMETES RATHER THAN PRODUCING EMBRYOS?

DR. DARNOVSKY: TO THE EXTENT THAT IT WOULD BE POSSIBLE TO INTRODUCE THOSE SORTS OF GENETIC SO-CALLED ENHANCEMENTS FOR REPRODUCTIVE PURPOSES. I'M IMAGINING THAT YOU COULD DO THAT IN GAMETES AS WELL AS IN EARLY STAGE EMBRYOS.

CHAIRMAN LO: BUT IF IT WAS POSSIBLE TO DRAW A BRIGHT LINE BETWEEN SAYING YOU CAN DO THE RESEARCH, BUT YOU CAN'T PRODUCE THE EMBRYO, WHICH THEN COULD BE IMPLANTED. SO THE QUESTION IS, YOU WANT, IF YOU WANT TO STOP THE ULTIMATE OUTCOME, HOW FAR BACK. THOSE --

DR. DARNOVSKY: THESE THINGS, BECAUSE OF

THIS NOW PROSPECT OF PRODUCING PLURIPOTENT AND EVENTUALLY TOTIPOTENT CELLS USING THE CELL REPROGRAMMING METHODS, IT BLURS SOME OF THESE LINES THAT USED TO BE BRIGHTER.

CHAIRMAN LO: AND YOUR CONCERN WITH GENETIC ENGINEERING, EVEN IF THE ONLY GENETIC MODIFICATIONS YOU MADE WERE TO MAKE THE SOMATIC CELL PLURIPOTENT AS OPPOSED TO THROWING IN A GENE FOR BETTER MEMORY AND LESS SLEEP AND --

DR. DARNOVSKY: THOSE ARE THE THINGS -- THE LATTER IS WHAT OUR CONCERN IS, THE ABILITY TO MAKE STEM CELLS WITHOUT HAVING TO -- DISEASE-SPECIFIC OR PATIENT-SPECIFIC STEM CELLS WITHOUT HAVING TO TAKE ON ALL THE PROBLEMS AND DIFFICULTIES AND RISKS OF EXTRACTING EGGS FROM WOMEN. THAT'S VERY ATTRACTIVE OBVIOUSLY.

DR. TROUNSON: I THINK IT MIGHT BE THE BRIGHT LINE THAT I THINK IS THE ONE TO MAKE SURE THAT IF YOU ARE GOING TO ACTUALLY TRANSPLANT ANY OF THIS MATERIAL, ANY OF IT, THAT YOU ACTUALLY GO TO A MUCH DETAILED, MUCH HIGHER LEVEL, WHICH WOULD BRING FORTH THESE KIND OF THINGS BECAUSE I MEAN I THINK, AS YOU SAY, MOST PEOPLE WOULDN'T BE SUPPORTIVE OF ANY KIND OF ENHANCEMENT. BUT THEY MIGHT THINK ABOUT THE CORRECTION OF HUNTINGTON'S DISEASE, OR SOMETHING

LIKE THIS MAY BRING A BIT OF A DIFFERENT THOUGHT.

CHAIRMAN LO: OR THALASSEMIA, WHICH IS A SINGLE MUTATION.

DR. TROUNSON: I THINK THERE'S SUCH INCREDIBLE RISKS IN ALL OF THAT, THAT YOU WOULD HAVE TO HAVE A VERY DETAILED AND PROPER EXAMINATION OF THE WHOLE PERSPECTIVE SO THAT ANY KIND OF TRANSPLANT ACTUALLY HAS TO BE, AND I INCLUDE ANIMALS BECAUSE YOU COULD MAKE THEM IN ANIMALS. I THINK THAT NEEDS TO BE CONSIDERED AS WELL. AND I ALSO THINK IN THE FORMATION OF AN EMBRYO IN THE LABORATORY BRINGS THE SAME KIND OF BRIGHT LINE.

DR. DARNOVSKY: THERE'S DOWNSTREAM AND THERE'S WAY, WAY DOWNSTREAM. I THINK THE DOWNSTREAM TRANSPLANTATION FOR CLINICAL USES, THAT'S ALREADY FOR VERY DIFFERENT REASONS A CONCERN THAT WE'RE TALKING ABOUT HERE. THE WAY, WAY DOWNSTREAM I DIDN'T KNOW IF IT MADE SENSE TO RAISE IT, BUT I DECIDED DO IT BECAUSE YOU DID, TED.

CHAIRMAN LO: ONE OF THE THINGS WE'RE TRYING TO DO HERE IS TO SEE THE BIG PICTURE. THANK YOU. THERE'S SOMEONE ON THE PHONE WANTED TO COMMENT.

DR. PRIETO: I REALLY APPRECIATED ALAN'S COMMENTS, AND PARTICULARLY THE MENTION OF

HUNTINGTON'S DISEASE. AND I GUESS I'D WANT, IS IT MARCY, TO COMMENT ON THAT SPECIFIC SITUATION BECAUSE I CAN IMAGINE THAT THERE ARE FAMILIES AND INDIVIDUALS VERY INTERESTED IN FERTILITY WHO, IF THE POSSIBILITY OF MAKING THAT MODIFICATION EXISTED, WOULD BE VERY INTERESTED. AND I JUST WANTED TO HEAR HER COMMENTS.

DR. DARNOVSKY: YEAH. THAT RAISES A REALLY DIFFICULT DILEMMA BECAUSE THE BLURRINESS, THE INHERENT BLURRINESS OF THE LINE BETWEEN THERAPEUTIC AND ENHANCEMENT USES REALLY PUTS US IN A SITUATION WHERE IT'S NOT AS EASY TO MAKE POLICY TO PREVENT THE OUTCOMES THAT YOU WANT TO PREVENT. SO I DON'T THINK WE CAN SOLVE THAT HERE.

BUT ARGUABLY -- WELL, I DON'T THINK WE CAN SOLVE THAT RIGHT NOW, BUT I THINK PUTTING IT ON THE TABLE AND SAYING WE WOULD LIKE TO MAKE POLICY THAT PRECLUDES GENETIC ENHANCEMENT OF FUTURE GENERATIONS USING THESE TECHNOLOGIES IS A GOOD THING AS A GOAL THAT WE HAVE TO WORK TOWARDS.

DR. PRIETO: IS THIS GENETIC ENHANCEMENT, OR IS THIS THERAPEUTIC?

DR. DARNOVSKY: THAT'S THE CONCERN. THAT'S THE BLURRINESS THAT RAISES THE DILEMMA.

CHAIRMAN LO: SO LET ME TRY AND SEE WHERE

I THINK WE ARE AFTER THIS DISCUSSION AND THE ISSUES THAT WERE RAISED WITH ICOC AND GEOFF IDENTIFIED.

SO I THINK WHAT WE'RE TRYING TO DO NOW IS IDENTIFY A SET OF RESEARCH INVOLVING DONATION OF SOMATIC CELLS, DERIVATION OF IPS LINES FOR WHICH WE WOULD WANT TO NOT REQUIRE THE STRICT STANDARDS OF OVERSIGHT AND CONSENT THAT WE NOW HAVE IN PLACE UNDER THE CURRENT REGULATIONS. WHAT I'M GOING TO SUGGEST IS THAT THE TYPES OF RESEARCH WE'RE TRYING TO TALK ABOUT ARE NOT THE CONTROVERSIAL RESEARCH OR THE NEAR CONTROVERSIAL RESEARCH, BUT THE SORT OF MUCH MORE BASIC, WHICH I HOPE IS NOT CONTROVERSIAL, DONATION OF SOMATIC CELLS FOR THE PURPOSE OF DERIVING IPS LINES OR THE USE OF EXISTING SOMATIC CELLS. AND THE DERIVATION WOULD MEAN THE CHARACTERIZATION OF THE LINE BY EXAMINING OF ITS NEUROMARKERS AND PROPERTIES AND ESTABLISHING PROOF OF PLURIPOTENCY.

NOW, I DO SORT OF HAVE TO RAISE THE ISSUE THAT ONE OF THE CLASSIC TESTS OF PLURIPOTENCY IS IF YOU INJECT INTO A MOUSE, DO YOU DERIVE A TERATOMA THAT SHOWS ALL THREE EMBRYONIC. RIGHT NOW YOU'RE ALREADY TALKING ABOUT PUTTING THINGS INTO ANIMALS. THAT, IT STRIKES ME, YOU MAY WANT TO SAY, WE MAY WANT TO SAY DOES NOT REQUIRE FULL SCRO REVIEW.

THE NAS HAS ACTUALLY RECOMMENDED THAT ONLY REQUIRES SCRO NOTIFICATION, THAT YOU SAY TO YOUR SCRO THIS IS WHAT WE'RE PROPOSING TO DO. WE'RE TELLING YOU WE'RE GOING TO DO THAT, BUT UNDER NAS GUIDELINES, YOU DON'T EVEN HAVE TO LOOK AT IT, REVIEW IT IN DETAIL BECAUSE THAT'S ALL WE'RE DOING. THAT'S ONE PROPOSAL.

SO THERE'S THREE DIFFERENT VARIABLES HERE. WHAT KIND OF RESEARCH ARE WE TALKING ABOUT? SECONDLY, WHAT ARE WE GOING TO DO WITH REGARD TO OVERSIGHT REVIEW? AND THIRD IS WHAT KIND OF CONSENT ARE WE GOING TO REQUIRE?

AND, AGAIN, SO THE QUESTION NOW IS WHETHER WE ALLOW THIS TYPE OF WORK TO PROCEED WITH IDENTIFIABLE MATERIALS UNDER JUST A GENERAL CONSENT TO RESEARCH AS OPPOSED TO A MORE SPECIFIC CONSENT FOR DERIVATION OF STEM CELLS WHICH MAY INVOLVE ALL THE FOLLOWING. IT'S NOT TO SAY YOU COULD DO MORE IF YOU WANTED, BUT YOU DON'T HAVE TO DO THAT MUCH DETAIL AND CONSENT TO ALLOW JUST THIS TYPE OF RESEARCH. WE'LL TALK ABOUT PAYMENT IN A MINUTE BECAUSE WE HAVEN'T TALKED ABOUT THAT YET. IS THAT, GEOFF, WHAT I THINK --

DR. LOMAX: YES, EXACTLY. THOSE ARE THE CATEGORIES. AND YOU'VE DONE A NICE JOB, BERNIE, OF

KIND OF ILLUSTRATING THE INTERACTION. THAT'S WHY WE'VE CONSTRUCTED THOSE THREE CATEGORIES OR WHY WE SORT OF HIGHLIGHTED THOSE THREE CATEGORIES THAT EXIST IN THE REGULATIONS. I THINK YOU SUMMED IT UP NICELY.

CHAIRMAN LO: WE DON'T WANT TO CALL IT IN VITRO RESEARCH BECAUSE WE WANT TO LEAVE OUT OF THIS IN VITRO FERTILIZATION, RIGHT? SO I THINK THAT'S NOT --

DR. LOMAX: JUST TO SAY, I APPRECIATE THE PREVIOUS DISCUSSION, BUT IN MY MIND, AS I WAS SORT OF TICKING THROUGH EVERY ONE OF THOSE POINTS, I DON'T SEE ANY GAP IN OUR REGULATIONS THAT DOESN'T APPLY OUR MOST STRICT STANDARDS ON THOSE TYPES OF ACTIVITIES, CREATION OF EMBRYOS, THE IMPLANTATION OF EMBRYOS. UNLESS I'M MISSING SOMETHING, AND I'D BE HAPPY TO SORT OF RECEIVE THAT.

CHAIRMAN LO: WE WANT TO WRITE THIS -- THIS IS A REVISION TO OUR CURRENT VERY STRICT STANDARDS. WE WANT TO MAKE SURE WE'RE NOT ALLOWING AS AN EXCEPTION STUFF THAT WE DIDN'T MEAN TO ACCEPT. SO THAT'S WHY I'M WORRIED ABOUT USING IN VITRO TO CHARACTERIZE THIS TYPE OF RESEARCH.

I'M ALSO, I MUST SAY, CONCERNED ABOUT THE INJECTION TO ANIMALS BECAUSE TO ME THERE'S A --

WELL, YOU KNOW, I'M JUST ME, BUT I THINK THERE ARE MORE PEOPLE WHO ARE CONCERNED ABOUT INJECTING HUMAN NEURAL PRECURSORS CELLS INTO NONHUMAN ANIMALS, PARTICULARLY PRIMATES, THAN INJECTING -- I MEAN BECAUSE RIGHT NOW THIS IS WHAT PEOPLE DO WITH EMBRYONIC STEM CELLS. THEY INJECT THEM INTO MICE TO FORM TERATOMAS. SO I THINK WHOLESALE BANNING OF ALL TRANSPLANTATION TO ANIMALS WOULD SET BACK STEM CELL BASIC SCIENCE IN WAYS THAT'S INCONSISTENT WITH WHAT'S DONE IN LABORATORIES NOW, WHICH I THINK WE DON'T WANT TO DO. WE DON'T WANT TO MAKE IT HARDER TO DO THIS WHEN THEY'RE DOING THE EXACT SAME THING THAT RESEARCHERS USING ES LINES ARE DOING.

DR. TAYLOR: I ACTUALLY THINK THAT CREATING TERATOMAS IS ALMOST PART OF THE DEFINITION OF THE IPS CELL.

CHAIRMAN LO: RIGHT.

DR. TAYLOR: WE DON'T REALLY WANT TO PREVENT THAT.

CHAIRMAN LO: THAT'S WHY I WAS SAYING TRANSPLANTATION TO ANIMALS, IF WE PUT THAT IN, BECAUSE WE'RE THINKING ABOUT THE HUMAN NEURO MOUSE, WOULD INADVERTENTLY EXCLUDE THESE KINDS OF TERATOMA EXPERIMENTS, WHICH I THINK WE DON'T WANT TO DO.

DR. LOMAX: JUST TO REMIND YOU ALL, THE

WAY WE DID ADDRESS THAT IS IT'S THE LANGUAGE WHICH ACKNOWLEDGES THE STATE OF THE SCIENCE IS THAT THOSE EXPERIMENTS ARE INTEGRAL TO DETERMINING PLURIPOTENCY, AND THEN THE REGULATIONS REQUIRE THAT THOSE ANIMALS BASICALLY MUST BE DESTROYED. THEY'RE NOT ALLOWED TO BREED. SO THAT'S HOW IT'S SORT OF HANDLED BOTH IN OUR REGULATION AND THE NATIONAL ACADEMIES. IT'S THAT ONCE THAT EXPERIMENT IS DONE, THOSE ANIMALS ARE DESTROYED.

CHAIRMAN LO: MAYBE YOU COULD HELP ME, GEOFF. WHAT'S THE LANGUAGE WITH THE NAS GUIDELINES ON THIS? WHAT ARE THEY PUTTING IN AS THE EXCLUSION?

DR. LOMAX: LET ME SEE IF I CAN GO BACK HERE. THE LANGUAGE IS IN THE FOOTNOTE OF SLIDE 2, AND I CAN GIVE YOU THE MORE -- I'LL JUST TURN TO THE NATIONAL ACADEMIES DOCUMENT TO MAKE SURE.

CHAIRMAN LO: THEY WERE TALKING ABOUT HUMAN TRANSPLANTATION, AND WE'VE SORT OF SAID, WELL, HOW ABOUT INJECTING HUMAN CELLS INTO ANIMALS. THERE ARE PEOPLE --

DR. TROUNSON: BERNIE, I THINK YOU NEED TO BE CAREFUL HERE BECAUSE I WAS TALKING ABOUT THE INJECTION OF GAMETES INTO ANIMALS SPECIFICALLY. BECAUSE I THINK A LOT OF FUNCTIONALITY REQUIRES THAT YOU ACTUALLY INSERT IT INTO SOME ANIMAL TISSUE TO

FIGURE OUT WHETHER IT ACTUALLY WORKS, WHETHER IT FUNCTIONS. THAT'S PART OF THE PROOF OF CONCEPT NECESSARY FOR YOU EVER TO MOVE TO THE HUMAN.

CHAIRMAN LO: YOU WOULDN'T WANT -- IT WOULD BE AWFUL TO ALLOW THAT AND TO SORT OF INJECT A DERIVED LINE INTO A HUMAN BEFORE YOU'VE SHOWN IN ANIMALS THAT IT DOESN'T DIFFERENTIATE INTO SOMETHING YOU DON'T WANT.

SO WE COULD -- AGAIN, I THINK THE OTHER WAY TO DO IT IS TO SAY THERE'S ANOTHER LINE WE DON'T ALLOW PEOPLE USING THESE TYPES OF REVIEW AND CONSENT TO DO REPRODUCTIVE RESEARCH TRANSPLANTATION TO OTHER HUMAN BEINGS. I THINK THOSE ARE THE THINGS WE MEANT TO EXCLUDE.

MY OWN SENSE IS THAT WE SHOULD SORT OF ALLOW -- WRITE THE EXCEPTION TO ALLOW WHAT WE WANT TO ALLOW, AND THEN LEAVE SORT OF A GRAY ZONE UNADDRESSED HERE BECAUSE THEY WOULD NOW FALL UNDER THE MORE RIGOROUS REVIEW AND THE MORE RIGOROUS CONSENT. WE'RE NOW CARVING OUT AN EXCEPTION FROM THE VERY, VERY HIGH STANDARDS OF CONSENT AND REVIEW.

DR. TROUNSON: JUST NEED TO SORT OF RECOGNIZE THAT IF YOU ACTUALLY PUT, SAY, GERM CELLS INTO A MOUSE, HUMAN GERM CELLS, YOU MIGHT END UP WITH HUMAN SPERM. SO THAT, I THINK, WOULD PUT A

FLAG UP IN THE SYSTEM; WHEREAS, LOOKING AT FUNCTIONALITY OF NEURAL CELLS EVEN IN THE BRAIN IN AN IMMUNE-COMPROMISED MOUSE IS REALLY SORT OF INCREDIBLY ROUTINE AND REQUIRED. SO I THINK THE DEVICE NEEDS TO RUN WITH THE AREA WHERE THE COMMUNITY IS SENSITIVE ABOUT THIS.

DR. LOMAX: WAY THE NATIONAL ACADEMIES CAPTURED THIS, AND IT IS CAPTURED IN THAT FOOTNOTE ON THE SECOND SLIDE, IS THAT THEY DRAW THE LINE OF DERIVE A PRODUCT FOR HUMAN TRANSPLANTATION, WHICH I THINK IS A VERY CLEVER WAY OF DOING IT BECAUSE IT'S NOT LIMITING IT TO THE CELLS YOU DERIVE, BUT ANY SUBSEQUENT DOWNSTREAM PRODUCT INTENDED TO BE TRANSPLANTED TO A HUMAN. SO I THINK THAT CONSTRUCT IS SOMETHING WE CAN WORK WITHIN TO ENSURE THAT THE SCOPE HERE IS VERY NARROW, VERY DISCRETE, AND CONSISTENT WITH WHAT YOU'VE OUTLINED. THAT'S HOW THE NATIONAL ACADEMIES ADDRESSED IT.

CHAIRMAN LO: YEAH, BUT THEY DIDN'T -- DID THEY ADDRESS THE ISSUE OF TAKING A PLURIPOTENT LINE, TRYING TO DERIVE GAMETES, AND THEN FERTILIZE THEM?

DR. LOMAX: YES. THEY TALK ABOUT FUNDED RESEARCH DESIGNED OR EXPECTED TO YIELD GAMETES OR BLASTOCYSTS OR DERIVE A PRODUCT FOR HUMAN TRANSPLANTATION. SO THEY TRIED TO HIT EACH OF THOSE

CATEGORIES.

CHAIRMAN LO: THEY'RE SAYING THAT IS NOT FORBIDDEN. IT JUST HAS TO HAVE FULL SCRO REVIEW.

DR. LOMAX: THAT BUMPS UP TO THE ELEVATED TOP STANDARD, HOWEVER YOU WANT TO DESCRIBE IT, YES.

CHAIRMAN LO: SO THAT LEAVES OPEN THE QUESTION OF WHETHER SOME OF THAT RESEARCH IS -- THE NAS DOES HAVE KINDS OF RESEARCH WHICH ARE NOT APPROVABLE, AND THOSE WOULD NOT AUTOMATICALLY.

AGAIN, I THINK THAT IF WE'RE SAYING THAT WE HAVE VERY STRICT STANDARDS EXISTING AND WE'RE TRYING TO CARVE OUT AN EXCEPTION TO THAT, AND THE CARVE-OUT WOULD BE DONATION OF SOMATIC CELLS, DERIVATION OF IPS LINE, I'M NOT QUITE SURE WHAT OTHER LANGUAGE, CHARACTERIZATION AND PROOF OF PLURIPOTENCY, BUT ALSO, AS ALAN POINTED OUT, IF YOU THEN DERIVE A DERIVATIVE OF A PLURIPOTENT LINE, YOU WANT TO SHOW THAT IT ACTUALLY IS THE LINEAGE YOU THOUGHT IT WAS AND DOES HAVE THE PROPERTIES OF THAT LINE. SO IT GOES A LITTLE BEYOND THAT.

SO I THINK WE NEED TO -- I GUESS I'M TRYING NOW TO STRUGGLE WITH DO WE HAVE THE CONCEPT IN PLACE. I GUESS I'M GOING TO TURN IT BACK TO THE COMMITTEE. A NUMBER OF YOU HAVE GIVEN VERY THOUGHTFUL COMMENTS. ARE YOU COMFORTABLE WITH THAT

AS THE DIRECTION WE'RE GOING? SO DOROTHY, TED, OTHERS WHO HAVE JOINED IN ON THIS, JEFF SHEEHY, NAME THEM ALL. LET ME GET YOUR THOUGHTS ON THIS AFTER OUR DISCUSSION. TED.

DR. PETERS: THUMBS UP.

CHAIRMAN LO: DOROTHY, DOES THIS --

PROFESSOR ROBERTS: I'M COMFORTABLE WITH IT JUST -- SO FAR WE'VE JUST TALKED ABOUT -- WE'RE SORT OF FOCUSING ON THE SCRO REVIEW. I'M COMFORTABLE AS LONG AS THE EXCEPTION IS VERY CLEARLY STATED. YOU KNOW, I THINK THAT SINCE WE'RE TALKING ABOUT AN EXCEPTION, IT SHOULD BE VERY CLEAR WHAT THE EXCEPTION APPLIES TO.

CHAIRMAN LO: OKAY.

PROFESSOR ROBERTS: AND THE WAY IT SEEMS TO BE WORDED NOW IS THERE'S THE ASTERISK FOR WHAT THE EXCEPTION WOULD NOT APPLY TO, BUT I WOULD WANT TO MAKE SURE THERE'S NO GRAY AREA IN BETWEEN, AND IT'S CLEAR THAT THE EXCEPTION ONLY APPLIES TO THIS SPECIFIC ACTIVITY.

CHAIRMAN LO: SO IF I MAY TRY AND SEE IF I UNDERSTAND YOU. WHAT YOU'RE SAYING IS WE ACTUALLY SPECIFY WHAT THE EXCEPTION IS TO THE HEIGHTENED CONSENT AND OVERVIEW SO THAT IF IT'S IN THE GRAY ZONE, IT WILL REQUIRE FULL SCRO REVIEW AND FULL

ROBUST CONSENT.

PROFESSOR ROBERTS: I THINK THAT'S GENERALLY THE BEST WAY TO TREAT AN EXCEPTION. IT'S CLEAR WHAT ACTIVITY THE EXCEPTION APPLIES TO.

DR. LOMAX: JUST TO MAKE A NOTE PROCEDURALLY, BECAUSE I THINK THAT'S AN EXCELLENT COMMENT FOR US. BUT TO REMIND EVERYONE OF THE PROCESS HERE, WE TYPICALLY KIND OF GET A CONCEPTUAL DECISION ABOUT SORT OF HOW WE WANT TO MOVE AN AMENDMENT. WE THEN ARE OBLIGATED TO SORT OF SPELL THAT OUT IN VERY PRECISE LANGUAGE, AND THEN WE HAVE TYPICALLY A VERY ROBUST PUBLIC COMMENT PERIOD AND OPPORTUNITY FOR REVIEW BY THE WORKING GROUP AS WELL WHERE WE'LL HAVE TO COME BACK. AND WE INEVITABLY WILL ALWAYS HAVE TO MAKE MODIFICATIONS.

SO SORT OF THE NEXT STEP IS THAT, I THINK, THE NEXT LEVEL OF ANALYSIS YOU EXPECT. I JUST WANTED TO EMPHASIZE THAT WE'RE KIND OF IN STAGE ONE OF THE PROCESS WHERE WE SORT OF GET A CONCEPTUAL IN OR OUT OF A PARTICULAR POLICY. AND THEN I THINK THROUGH THE SUBSEQUENT STEPS, WE HAVE A VERY ROBUST PROCESS SORT OF TO PERFORM THAT EVALUATION AND SEE WHERE IT ENDS UP.

PROFESSOR ROBERTS: OKAY. SO LET ME REFRAME THAT SINCE I'M SURE THERE WILL BE THESE

FURTHER STEPS THAT WILL -- THAT CLARIFY THE EXCEPTION. BROADLY SPEAKING, I AGREE WITH THE NEED FOR AN EXCEPTION FOR SOMATIC CELLS AS WE'VE DISCUSSED.

CHAIRMAN LO: OKAY. THANKS, DOROTHY.

DR. CIBELLI: CAN I ADD SOMETHING? I HAVE A -- WELL, IT'S SOMETHING THAT WE HAVE TO CONTEMPLATE IN RESEARCH. MANY OF THE GREAT DISCOVERIES HAPPEN BY CHANCE. SO WHAT IF SOMEONE IS USING THE CELLS TO PRODUCE OTHER SOMATIC CELLS, AND ALL OF A SUDDEN YOU START GETTING GERM CELLS IN YOUR PLATE OR OOCYTES OR SPERM OR ANY GAMETES? WHAT WOULD YOU DO IN THAT CASE? WILL THE CONSENT BE DIFFERENT?

CHAIRMAN LO: WELL, AGAIN, I THINK WHAT WE'RE ESTABLISHING HERE IS AN EXCEPTION, BUT THERE'S NOTHING -- JUST BECAUSE OF THAT, A RESEARCHER MAY SAY, YOU KNOW, TO TAKE INTO ACCOUNT, I'M GOING TO GET REALLY FULL CONSENT OR AT LEAST CONSENT TO GO BACK AND RECONTACT THEM TO SAY SOMETHING CAME UP THAT WE WEREN'T ANTICIPATING, BUT WE'D LIKE TO PURSUE IT. WE DIDN'T REALLY ASK YOU ABOUT THAT, BUT WE WANTED TO GET YOUR PERMISSION TO DO THIS NEW LINE OF EXPERIMENTS.

MS. LANSING: YOU'RE ESTABLISHING THE

MINIMUM THAT YOU CAN DO.

CHAIRMAN LO: WE'RE ESTABLISHING THE MINIMUM. MY OWN SENSE, BUT I'M NOT A RESEARCHER HERE, IS THAT, YOU KNOW, PEOPLE MAY SAY WE'RE GOING TO DO MUCH MORE THAN MINIMUM BECAUSE IT WILL MAKE OUR LIFE EASIER FOR US LATER ON OR FOR OTHER RESEARCHERS. BUT THAT'S GOING BEYOND WHAT WE'RE DOING HERE, JUST AS CARVING OUT, AS DOROTHY PUT IT, A NARROW EXCEPTION.

DR. TROUNSON: THAT WAS THE VIEW THAT I HAD, THAT YOU SHOULDN'T -- IF YOU'RE JUST TRYING TO DERIVE CELLS IN THE LABORATORY, IF YOU HAPPEN TO GO DOWN THE GERM CELL LINEAGE AND END UP WITH SOMETHING THAT IS A PRE-GAMETE, YOU WOULDN'T BE IN AWFUL DIFFICULTY. I REALLY THINK THAT THE BIG PROBLEM COMES IF YOU JOIN THE GAMETES IN ANY WAY TOGETHER AND, HENCE, THE EMBRYO, OR IF YOU TRANSFER THOSE CELLS TO AN ANIMAL AND PRODUCE GAMETES. SO MY CONCERNS WERE, I THINK, IN LINE WITH WHAT YOU WERE WORRIED ABOUT.

DR. CIBELLI: THANK YOU.

CHAIRMAN LO: SO WHAT I'VE PUT UP ON THE BOARD HERE, I KNOW THE REST OF YOU CAN'T SEE IT, IS WHAT WE'RE TALKING ABOUT IS DONATION OF SOMATIC CELLS, DERIVATION OF AN IPS LINE, CHARACTERIZATION

OF THE CELLS IN THAT LINE, ESTABLISHING PROOF OF PLURIPOTENCY. AND IF YOU THEN DERIVE A SPECIALIZED CELL LINE, SUCH AS A BETA CELL TO PRODUCE INSULIN OR A CARDIOMYOCYTE, THAT YOU CAN CARRY OUT THE EXPERIMENTS TO PROVE THAT YOU'VE ACTUALLY DERIVED THAT SPECIAL LINE, WHICH MAY INVOLVE, AS ALAN HAS POINTED OUT, INJECTION INTO ANIMALS TO PROVE THAT THE LINEAGE HAS REALLY BEEN DRIVEN THE WAY YOU HOPED IT WOULD BE. BUT WE WOULD SAY NOT IF YOU'RE INTENTIONALLY TRYING TO DERIVE GAMETES CAN YOU USE THE SORT OF LIGHTER REVIEW AND THE LESS DETAILED CONSENT.

SO, AGAIN, THIS IS PRETTY NARROW, BUT WE'RE -- I THINK WHAT I'D LIKE TO DO IS SAY DERIVE THE CELLS, USE THINGS PEOPLE ARE HOPING FOR, CURES FOR DIABETES, TREATMENTS FOR DIABETES, NEUROLOGICAL DEGENERATIVE DISEASES, HEART DISEASE, ALL THE OTHER THINGS. DO THE WORK THAT YOU NEED TO DO TO ESTABLISH THAT WE'RE READY TO START THINKING ABOUT DOING HUMAN RESEARCH.

COMMENTS FIRST FROM THE COMMITTEE AND THEN THERE MAY BE SOME MORE PUBLIC COMMENT. ANYONE ELSE ON THE COMMITTEE WANT TO COMMENT ON THIS?

MS. LANSING: JUST TO SAY THAT I'M COMFORTABLE WITH IT BECAUSE I DO THINK IT'S THE

MINIMUM, AND I DO KNOW THAT IT'S GOING TO BE INTENSELY SCRUTINIZED.

CHAIRMAN LO: I GUESS, AS GEOFF SAID, WE'RE GOING TO TRY -- SO THIS IS NOW JUST GETTING THE CONCEPT. WE NEED TO VOTE ON HAVING THE CONCEPT, GEOFF?

DR. LOMAX: I'D LIKE TO REVISIT THE ROLL CALL BECAUSE LAST TIME I CHECKED, WE WERE AT 12 MEMBERS. AND IF WE'RE AT 13 MEMBERS, IT PUTS US PAST A THRESHOLD OF WHETHER THIS IS A FORMAL RECOMMENDATION OF THE WORKING GROUP OR SENSE OF THE COMMITTEE. WE CAN DO THAT, BUT WE MIGHT AS WELL WAIT UNTIL YOU WANT TO CALL THE QUESTION. I ALERT YOU TO THE FACT THAT YOU DID WANT TO DISCUSS THE ISSUES OF PAYMENTS, WHICH YOU STILL HAVEN'T ADDRESSED.

CHAIRMAN LO: THAT'S WHAT I WAS GOING TO GET TO. SO NOW, ASSUMING WE HAVE A SENSE OF THE COMMITTEE THAT WE'RE GOING TO AGREE FOR THIS NARROW SET OF RESEARCH TO HAVE AN EXCEPTION TO REVIEW AND CONCEPT, LET'S TALK ABOUT PAYMENT.

THERE WERE MANY, MANY OBJECTIONS TO THE IDEA OF PAYING FOR EMBRYOS OR ESPECIALLY OOCYTES TO DERIVE HUMAN EMBRYONIC STEM CELL LINES. IN FACT, THERE'S A PROHIBITION IN PROP 71 ABOUT PAYMENT FOR

OOCYTES FOR THAT PURPOSE. THERE ARE MANY REASONS WHICH WE SORT OF ALLUDED TO AT THE BEGINNING OF THE SESSION AS TO WHY THAT IS, THE SENSITIVITY, THE RISK, THE CONCERNS ABOUT EXPLOITATION OF WOMEN, COMMODIFICATION OF REPRODUCTIVE TISSUE, ETC.

HOWEVER, THE FACT OF LIFE IS IF A PERSON UNDERGOES A SKIN BIOPSY FOR RESEARCH PURPOSES, TYPICALLY, OR NOT TYPICALLY, IT'S NOT UNCOMMON FOR THEM TO BE PAID SOME AMOUNT OF MONEY, 10, 25, PERHAPS EVEN $50 AS IT IS FOR OTHER TYPES OF RESEARCH PARTICIPATION, USUALLY NOT PAID FOR JUST DONATION OF BLOOD. AND SO THE QUESTION IS SHOULD WE PERMIT PAYMENTS APPROVED BY THE LOCAL IRB TO BE MADE FOR PEOPLE DONATING SOMATIC CELLS FOR THESE TYPES OF NARROW RESEARCH?

DR. TROUNSON: BERNIE, IN ADDITION, ONE OF THE MORE RECENT PUBLICATIONS HAS SUGGESTED THAT LIVER CELLS ARE MUCH EASIER TO REPROGRAM. AND TAKING A LIVER BIOPSY IS A LITTLE DIFFERENT THAN TAKING A SKIN BIOPSY, AND I CAN WELL IMAGINE THAT THERE WOULD BE SOME COMPENSATION FOR THAT.

CHAIRMAN LO: AGAIN, TYPICALLY THAT'S IN THE SEVERAL HUNDRED DOLLARS. IN OUR INSTITUTION, INVASIVE PROCEDURE LIKE LIVER BIOPSY IS 300 OR 500 OR MORE DOLLARS. SO, AGAIN, WE JUST HAVE TO SAY

THAT THERE'S A PRACTICE THAT'S OVERSEEN, REVIEWED BY IRB'S, AND PERMITTED FOR PAYMENT. AND SO, AGAIN, WE HAVE THIS INTERACTION.

ONE QUESTION IS DO WE ALLOW PAYMENT, APPROPRIATE PAYMENT THAT'S NOT AN UNDUE INDUCEMENT? IF WE DO ALLOW PAYMENT, THEN THAT'S GOING TO INTERACT WITH BOTH THE REVIEW AND THE CONSENT. CLEARLY FOR A LIVER BIOPSY, YOU'RE GOING TO HAVE A MUCH MORE DETAILED CONSENT ABOUT THE RISKS OF LIVER BIOPSY. AND I WOULD THINK A LIVER BIOPSY IS GOING TO BE NOT SCRO NOTIFICATION, BUT IRB REVIEW BECAUSE THAT'S AN INVASIVE PROCEDURE. SO IT DOESN'T NECESSARILY SUPERSEDE PROTECTIONS CURRENTLY IN PLACE, BUT WE SHOULD BE CLEAR THAT NOTIFYING THE SCRO, BECAUSE THERE ARE NO STEM CELL-SPECIFIC ETHICAL CONCERNS, DOESN'T WAIVE IRB CONCERNS ABOUT HUMAN SUBJECTS PROTECTION IN TERMS OF RISK TO THE DONOR.

SO I GUESS THE ONE QUESTION IS THRESHOLD. ARE WE GOING TO SAY THAT SOME APPROPRIATE COMPENSATION IS PERMITTED? BECAUSE IF NOT, THAT WOULD BE A CHANGE FROM WHAT'S TYPICALLY DONE WITH THESE KINDS OF BIOPSIES. FOLKS ON THE COMMITTEE, WHAT DO YOU THINK? SOME OF YOU ACTUALLY COLLECT TISSUE. JAMES WILLERSON IS STILL ON THE PHONE, I

KNOW WHAT THE PRACTICE YOU USUALLY DO IS. ANYBODY ON THE PHONE WANT TO COMMENT ON PAYMENT TO DONORS?

PROFESSOR ROBERTS: AGAIN, I WONDER, AND WE DIDN'T REALLY CONCLUSIVELY DECIDE ANYTHING ABOUT THIS FOR THE PRIOR ISSUES, BUT IF THERE SHOULD BE A DISTINCTION BETWEEN MATERIAL THAT ALREADY EXISTS WHERE DONORS WERE PAID THESE MODEST PAYMENTS, ALTHOUGH IT SEEMS TO BE MORE I'M LEARNING NOW WITH LIVER BIOPSIES, AND PROSPECTIVELY BECAUSE I DO THINK WE HAVE TO TAKE INTO ACCOUNT THAT PROPOSITION 71 SAYS THAT THERE SHOULD NOT BE PAYMENT.

MS. LANSING: IT'S PROHIBITED.

PROFESSOR ROBERTS: PROHIBITED, EXACTLY. LET'S PUT IT MORE STRONGLY. IT'S PROHIBITED. SO WE WOULD -- IF WE GO DOWN THIS PATH, WE WOULD BE SAYING THAT, CONTRARY TO THE PROHIBITION IN PROPOSITION 71, PROSPECTIVELY DONORS COULD BE -- YOU KNOW, IT'S OKAY FOR DONORS TO BE PAID EVEN AMOUNTS NOW WE'RE SAYING UP TO $500. I THINK WE -- I THINK THAT POSES A PROBLEM THAT WE NEED TO DISCUSS VERY CAREFULLY. I DON'T THINK IT'S -- I DON'T THINK IT'S RIGHT TO JUST CALL IT A NOMINAL PAYMENT THAT DOESN'T POSE ANY PROBLEM WITH --

DR. PETERS: IS IT RELEVANT TO DISTINGUISH DONOR PAYMENTS WITH OR WITHOUT PROP 71 MONEY SO

THESE GRANDFATHERED PAID DONORS STILL WOULD NOT BE PAID WITH PROPOSITION 71 MONEY?

CHAIRMAN LO: LET ME ALSO, DOROTHY, ASK YOU. THERE ARE LEGAL ISSUES IN THAT WE ARE BOUND BY PROP 71. I GUESS THE OTHER ISSUES ARE ETHICAL ISSUES. ARE THERE ETHICAL CONCERNS EVEN IN THE ABSENCE OF PROP 71 YOU WOULD HAVE ABOUT PAYING SOMATIC CELL DONORS FOR THEIR TISSUE?

PROFESSOR ROBERTS: WELL, I THINK EVEN THOUGH IT DOESN'T RISE PERHAPS TO THE LEVEL OF CONCERN OR THE SAME KIND OF CONCERN AS WITH GAMETE DONORS, THERE STILL IS, AGAIN, ESPECIALLY IF WE'RE TALKING -- EVEN WITH PAYMENTS OF $50, BUT CERTAINLY WITH 300 AND $500, THAT IS AN INDUCEMENT FOR SOMEONE WHO IS IN DESPERATE NEED OF MONEY TO DONATE THEIR TISSUE. SO, AGAIN, I THINK IT DOES RAISE THE SAME KIND OF ETHICAL CONCERN EVEN THOUGH IT'S AT A DIFFERENT LEVEL THAN WITH EGG DONATION.

DR. KIESSLING: BERNIE, CAN SOMEBODY CLARIFY FOR ME? DOES PROP 71 SPECIFICALLY TALK ABOUT ANY KIND OF DONATION?

CHAIRMAN LO: LET ME -- I JUST LOOKED UP PROP 71. AND IT SAYS THE ICOC SHALL ESTABLISH STANDARDS AS FOLLOWS: NO. 3, PROHIBITION OF COMPENSATION. STANDARDS PROHIBITING COMPENSATION TO

RESEARCH DONORS OR PARTICIPANTS WHILE PERMITTING REIMBURSEMENT OF EXPENSES. SO IT DOESN'T SAY OOCYTE DONORS OR EMBRYONIC DONORS. IT SAYS RESEARCH DONORS.

PROFESSOR ROBERTS: YEAH. THAT WAS MY UNDERSTANDING. IT COVERS ANY KIND OF DONATION IN CONNECTION WITH THIS RESEARCH EXCEPT -- AND THEN THERE'S THE ISSUE OF NON-CIRM MONEY BEING PAID. AGAIN, THAT SAME BASIC QUESTION I WAS RAISING BEFORE OF ARE WE TALKING ABOUT TISSUE THAT ALREADY EXISTS OR PERHAPS WILL BE CREATED FOR OTHER KINDS OF RESEARCH, OR TO TISSUE THAT IS PAID FOR WITH CIRM MONEY PROSPECTIVELY? I THINK AT THIS POINT THE MATERIALS WE RECEIVED DIDN'T MAKE THAT DISTINCTION.

DR. LOMAX: THAT'S CORRECT. ACTUALLY THAT'S AN EXCELLENT DISTINCTION. I'LL TAKE FULL CREDIT FOR THAT OVERSIGHT. AND I APPRECIATE THE COMMENT, AND I THINK WE SHOULD GET AN OPINION THERE.

THE MATERIALS WERE INTENDED TO ADDRESS, JUST LIKE THE PREVIOUS SESSION, THE PROCEDURES RELATED TO EXISTING BANKING EFFORTS. SO IT WASN'T CONTEMPLATED THAT IT WAS CIRM FUNDS. BUT NONETHELESS, IT'S AN EXCELLENT QUESTION. I THINK WE SHOULD, YOU KNOW, GET AN OPINION ON THAT.

BUT TO CLARIFY KIND OF THE GENESIS OF THE

QUESTION, BUT THANK YOU FOR POINTING THAT OUT BECAUSE IT WAS AN OVERSIGHT, AND MY APOLOGIES ON THAT FRONT.

CHAIRMAN LO: SO IT STRIKES ME THAT DOROTHY'S VERY HELPFUL DISTINCTION BETWEEN PROSPECTIVELY COLLECTED RESEARCH MATERIALS AND ALREADY EXISTING RESEARCH MATERIALS MIGHT BE USEFUL. IT SEEMS TO ME THAT, AGAIN, I'M NOT A LAWYER OR A LAW PROFESSOR, BUT THE CLEAR LANGUAGE OF THE PROP 71 SEEMS TO SAY TO ME YOU CAN'T PAY COMPENSATION TO RESEARCH DONORS BEYOND EXPENSES. AND I THINK THAT IT WOULD BE HARD TO SORT OF ARGUE THAT GOING FORWARD.

I THINK WE MAY MAKE THE ARGUMENT THAT IF THEY'VE ALREADY BEEN PAID IN THE PAST AND THE MATERIAL IS ALREADY EXISTING, AS WE'VE DONE WITH IVF OOCYTES THAT WERE PAID FOR AND ARE NOW FROZEN AND OTHERWISE TO BE DESTROYED, THAT THERE'S NO WAY THAT ALLOWING THOSE TO BE USED FOR RESEARCH IN ANY WAY WAS AN UNDUE INFLUENCE ON THE ORIGINAL DECISION OR HAD PEOPLE TAKING ON RISKS THEY OTHERWISE WOULDN'T HAVE TAKEN ON.

SO I THINK IT'S ONE THING TO SAY WE'LL GRANDPARENT IN EXISTING MATERIALS AS AN EXCEPTION TO THE PROHIBITION ON CONSENT. THAT MAY BE VERY

DIFFERENT THAN SAYING GOING FORWARD WE'RE GOING TO ALLOW PAYMENTS. NOBODY EVEN SAID $5 NOMINAL FOR A SKIN BIOPSY IS A LOT DIFFERENT THAN $500 FOR A LIVER BIOPSY, WHICH IS MUCH RISKIER.

GEOFF, I DON'T KNOW IF IT MAKES SENSE TO SAY THAT THE DOLLAR ISSUE SHOULD BE AN EXEMPTION ONLY FOR -- EXEMPTION FROM THE PROHIBITION OF PAYMENT ONLY FOR EXISTING MATERIALS IN EXISTENCE AT THE TIME THE RESEARCH WAS BEING PROPOSED AS OPPOSED TO PROSPECTIVELY COLLECTING NEW RESEARCH MATERIALS. THIS WOULD RAISE PROBLEMS WITH THE LIVER BIOPSY.

DR. TAYLOR: WHY CAN'T WE JUST GO BACK TO THE GRANDFATHERING CLAUSE THAT GEOFF KIND OF REPORTED AT THE BEGINNING? IT SEEMS TO ME THAT THERE'S A POINT IN TIME, AND WE DON'T REALLY HAVE TO PUT A DOLLAR AMOUNT AT ALL. WE CAN SAY -- I HEAR WHERE THE CONVERSATION IS GOING TO GO BECAUSE REALLY FROZEN LIVER CELLS DON'T REALLY GROW OUT THE WAY YOU CAN GET LEUKOCYTES TO GROW. SO SOME OF THE SAMPLES THAT WERE COLLECTED IN THE PAST MIGHT NOT BE PARTICULARLY HELPFUL.

BUT I DO THINK THAT WE'RE IN TROUBLE AS WE'VE BEEN ALL ALONG KIND OF GOING FORWARD GIVEN THE WAY THE LAW WAS WRITTEN, BUT IT SEEMS TO ME THAT THE GRANDFATHER CLAUSE THAT YOU ALREADY HAVE IN PLACE

MIGHT COVER THIS.

CHAIRMAN LO: I THINK THAT'S RIGHT. GRANDFATHERING IS CONCEPTUALLY DIFFERENT THAN PROSPECTIVELY COLLECTING MATERIALS. WITH PROSPECTIVELY COLLECTED MATERIALS, IT STRIKES ME, THERE AGAIN, WE MAY WANT TO DISTINGUISH DIFFERENT CIRCUMSTANCES. ONE IS THAT CIRM ACTUALLY IS -- A CIRM-FUNDED RESEARCHER IS ACTUALLY CARRYING OUT THE RESEARCH TO DERIVE, CHARACTERIZE THESE IPS CELLS, AND TO CREATE A SPECIALIZED LINEAGE.

THE OTHER ISSUE IS IS A CIRM RESEARCHER GOING TO BE ALLOWED TO USE LINES THAT SOMEONE ELSE DERIVED WITHOUT CIRM FUNDING, BUT WAS DONE UNDER OTHER AUSPICES THAT PERMIT THE LIVER DONOR, BIOPSY DONOR, TO BE PAID IN ACCORDANCE WITH IRB APPROVAL, AND NOW CIRM RESEARCHER SAYING THIS IS THE BEST LINE OUT THERE. THIS REALLY IS A TERRIFIC LINE. I'D LIKE TO USE IT. THERE'S NO CIRM MONEY INVOLVED, BUT IS IT AN ACCEPTABLY DERIVED LINE, GEOFF, IN OUR STANDARDS? THAT STRIKES ME AS YET ANOTHER SITUATION WE'RE GOING TO HAVE TO THINK ABOUT.

I WOULD SUGGEST RIGHT NOW ARE WE AGREED, IS THERE FEELING FOR ALLOWING GRANDFATHERING OF PAYMENT APPROVED BY AN IRB FOR MATERIALS ALREADY IN EXISTENCE AT THE TIME THE IPS RESEARCH IS BEING

CONTEMPLATED? SO IT'S A GRANDFATHERING CLAUSE, AND THE RATIONALE FOR IT WOULD BE THE DONATION AND THE RISK HAVE ALREADY TAKEN PLACE, THERE CAN BE NO UNDUE INDUCEMENT TO SOMETHING THAT'S ALREADY HAPPENED IN TIME.

DR. LOMAX: TO JUST SORT OF INTERJECT, WITH ALL DUE RESPECT, IF THE DETERMINATION, THOUGH, IS IS IT ANY PAYMENT WHATSOEVER OR PAYMENT WITH CIRM FUNDS, UNTIL WE RESOLVE -- THAT QUESTION SEEMS, AND PROFESSOR ROBERTS, I'M DEFERRING TO YOU HERE FOR JUDGMENT, WOULDN'T THAT QUESTION SORT OF TRUMP, IF YOU WILL, ANY SORT OF TEMPORAL ASPECT OF WHEN THE LINES WERE ACQUIRED? I'M JUST TRYING TO THINK SORT OF IN TERMS OF ORDER OF OPERATION BECAUSE WE MAY NOT BE ABLE TO RESOLVE THIS TODAY IF THAT'S THE OVERARCHING QUESTION.

MS. LANSING: I THOUGHT IF THE LINES, MAYBE I'M MISUNDERSTANDING THIS AND CONFUSING THIS AS A LAYPERSON, BUT SOMETHING WAS DONE BEFORE THE PROPOSITION WAS PASSED, THEN THEY WERE SAFE. WE'RE ALREADY USING THOSE, AREN'T WE?

DR. TAYLOR: THAT'S THE RIGHT INTERPRETATION, I THINK.

PROFESSOR ROBERTS: YEAH.

MS. LANSING: NOBODY COULD HAVE BEEN BE

DOING IT FOR MONEY BECAUSE THERE WAS NO PROPOSITION THEN.

DR. PRIETO: WE COULDN'T VERY WELL IMPOSE OUR STANDARDS ON PEOPLE WHO WERE DOING SOMETHING BEFORE WE EXISTED.

MS. LANSING: SO THAT'S OKAY BECAUSE NOBODY COULD HAVE BEEN EXPLOITED.

PROFESSOR ROBERTS: RIGHT. I THINK I AGREE. THAT'S MY INTERPRETATION AS WELL. BUT WAS THERE ANOTHER QUESTION ABOUT, EVEN IF THAT'S TRUE, IF THAT'S STILL --

DR. LOMAX: IT WAS A QUESTION THAT TED PETERS RAISED ABOUT IS THERE A DISTINCTION BETWEEN THE PAYMENT SOURCE, IF YOU WILL, CIRM FUNDS VERSUS FUNDS UNRELATED.

PROFESSOR ROBERTS: I THINK THAT QUESTION THEN IS RAISED BY RESEARCH -- BY USING CELLS THAT WERE COLLECTED AFTER THE REGULATION BECAUSE THEN THE QUESTION IS DOES IT MATTER IF CIRM MONEY WAS USED TO PAY FOR THE MATERIAL THAT WAS USED IN THE RESEARCH.

DR. PRIETO: QUESTION. WOULDN'T THIS, I DON'T KNOW, EVEN INADVERTENTLY SET UP A SITUATION WHERE WE WOULD PERHAPS INDUCE RESEARCHERS TO COMPARTMENTALIZE CERTAIN ACTIVITIES JUST TO GET AROUND THAT KIND OF RESTRICTION?

PROFESSOR ROBERTS: YES. I AGREE. I THINK IT'S --

DR. PRIETO: SO THAT DOESN'T ANSWER ANY ETHICAL CONCERNS IF THEY DO THAT.

DR. TAYLOR: I DON'T THINK THE PROP 71 LAW SAYS ANYTHING ABOUT THEY CAN'T BE PAID WITH CIRM MONEY. THEY SAY THEY CAN'T BE PAID.

PROFESSOR ROBERTS: EXACTLY. I AGREE. I WASN'T ENDORSING THAT DISTINCTION. I WAS JUST INTERPRETING THE DISTINCTION, BUT I THINK -- OR RESTATING IT. TO ME IT'S THE PAYMENT OF MONEY FOR THE DONATION IS THE ISSUE, WHETHER IT'S WITH CIRM MONEY OR NOT, BUT A CIRM-FUNDED RESEARCHER USING MATERIAL THAT WAS PAID FOR IS THE PROBLEM.

MS. LANSING: BUT NOT BEFORE THE BILL WAS PASSED.

PROFESSOR ROBERTS: YES. YES. I THINK -- MY SENSE IS WE'RE AGREEING.

DR. PRIETO: I THINK WE AGREE.

PROFESSOR ROBERTS: I AGREE WITH THAT AS WELL. I'M REALLY CONCERNED ABOUT THIS PROSPECTIVE.

DR. TROUNSON: ONE THING THAT'S GOING TO HAPPEN, OF COURSE, AS FAR AS I CAN SEE, IS THAT YOU REALLY WON'T HAVE DONORS COMING IN TO DONATE LIVER TISSUE BECAUSE, YOU KNOW, WHO WOULD DO IT. IT'S THE

SAME CATEGORY AS DONATING EGGS WITHOUT ANY COMPENSATION WHEN ONE WANTS TO DO IT.

WHAT I THINK IS A BIT OF A CONCERN IS THAT WHAT WILL HAPPEN IS THAT THE PATIENTS WILL DO IT. YOU KNOW, YOU'LL ACTUALLY ENCOURAGE PEOPLE WHO'VE GOT DISEASES WHO ARE PROBABLY -- WHO COULD EVEN BE QUITE SICK TO COME IN AND DONATE THE MATERIAL BECAUSE IN THE INTEREST OF GETTING THE FIELD WORKING. SO I THINK WE JUST NEED TO BE THOUGHTFUL ABOUT THAT. IF THAT IS THE PRACTICAL OUTCOME, IT MIGHT BE SOMETHING THAT WE COULD REGRET.

PROFESSOR ROBERTS: BUT THAT ISSUE WAS DECIDED BY THE VOTERS OF CALIFORNIA WHEN THEY VOTED FOR PROP 71 WITH THIS RESTRICTION IN IT.

MR. SHEEHY: ONE THING TO PUT INTO PERSPECTIVE ABOUT PROP 71 IS THAT NO ONE IMAGINED IPS, SO I DON'T THINK ANYONE REALLY IMAGINED THAT SOMATIC CELLS WERE AT STAKE. SO PEOPLE WERE THINKING OF PRIMARILY OOCYTES, I THINK, WAS THE CONSIDERATION IF YOU ARE LOOKING AT LEGISLATIVE INTENT AND WHAT PEOPLE THOUGHT THEY WERE VOTING FOR.

CAN I JUST GET AS A BACKGROUND, AND I THINK -- ISN'T THERE ALREADY -- WHAT IS THE STATE, NOT TALKING ABOUT IPS, NOT TALKING ABOUT STEM CELL RESEARCH, WHAT TYPES OF MATERIALS -- WHAT IS THE

STATE OF RESEARCH NOW? ARE THERE CERTAIN MATERIALS THAT PEOPLE ARE GENERALLY PAID TO DONATE FOR RESEARCH OF WHICH NO ONE HAS ANY SPECIFIC CONCERNS AND THAT THESE ARE KIND OF DONE THROUGH THE SOME SORT OF ROUTINE IRB REGULATORY PROCESS? I JUST DON'T KNOW WHAT HAPPENS. JUST FORGET ABOUT STEM CELL RESEARCH. ARE PEOPLE DONATING SOMATIC CELLS FOR PAYMENT IN OTHER CONTEXTS?

CHAIRMAN LO: ABSOLUTELY. EVEN LIVER CELLS. THERE'S RESEARCH GOING ON WHERE PEOPLE DONATE -- WELL, DONATE MAY NOT BE THE RIGHT WORD BECAUSE THEY'RE OFTEN COMPENSATED. BUT SKIN CELLS, BUT LIVER CELLS, BONE MARROW BIOPSIES, ALL KINDS OF CELLS, AND TYPICALLY WHAT SCIENTISTS HAVE FOUND IS THAT WITHOUT SOME SORT OF COMPENSATION, YOU JUST DON'T GET PEOPLE DONATING. AND THIS IS ALL OVERSEEN BY THE IRB. SO THE IRB REVIEWS THE PROTOCOL, IT'S A FULL PROTOCOL REVIEW, AND THEY HAVE TO REVIEW IT WITH THE VIEW OF WHETHER THE AMOUNT OF PAYMENT IS AN UNDUE INFLUENCE.

THERE ALSO, BY THE WAY, IS A SCHOOL OF THOUGHT THAT IF YOU DON'T PAY PEOPLE WHO UNDERGO RISKS FOR RESEARCH, YOU'RE TAKING ADVANTAGE OF THEM BECAUSE THEY'RE UNDERGOING THE RISKS. THEY OFTEN DO NOT -- IF THERE'S A COMPLICATION, UNLIKE WHAT WE PUT

IN PLACE FOR OOCYTE DONORS, THERE'S NO GUARANTEE IN ALMOST ALL INSTITUTIONS THAT CARE WILL BE COVERED WITH NO COST -- CARE FOR DIRECT AND PROXIMATE COMPLICATIONS OF THE RESEARCH PROCEDURE IS NOT NECESSARILY COVERED AT NO COST TO THE PATIENT.

SO THERE ARE CONCERNS ABOUT PAYING TOO LITTLE AS WELL AS PAYING TOO MUCH. MY SENSE IS THAT THIS IS NOT SOMETHING WE SHOULD TRY AND DECIDE TODAY. WE SHOULD PROBABLY CARVE OUT A NARROW EXCEPTION. WE SHOULD HIGHLIGHT THIS, PARTICULARLY THE LIVER BIOPSY ISSUE BEING A PROBLEM, AND LOOK AT THE SCIENCE, THE ETHICS, AND THE LAW BECAUSE I THINK IT MAY WELL BE THAT THE CONCERNS THAT, I AGREE WITH JEFF SHEEHY, THAT THE UNDERLYING CONCERNS THAT DROVE PROP 71 WAS THE IDEA OF PAYING PEOPLE FOR REPRODUCTIVE MATERIALS.

IT WASN'T JUST THE NOTION OF UNDUE INDUCEMENT TO HAVE WOMEN UNDERGO UNACCEPTABLE RISKS BECAUSE OF THE MONEY, BUT ALSO THERE WAS A NOTION THAT YOU SHOULDN'T HAVE COMMERCIAL TRANSACTIONS INVOLVING REPRODUCTIVE MATERIALS BECAUSE SOMEHOW THAT WAS COMMODIFYING SOMETHING THAT SHOULDN'T BE COMMODIFIED.

NOW, WE CAN ARGUE ABOUT WHETHER THAT'S AN APPROPRIATE PHILOSOPHICAL POSITION, BUT I THINK THAT

WAS PART OF WHAT DROVE THIS. I'M NOT SURE THERE ARE CONCERNS ABOUT COMMODIFYING SKIN CELLS AND LIVER CELLS. I THINK THE ISSUE'S REALLY SORT OF A PAYMENT TO RESEARCH SUBJECTS, IS THAT AN UNDUE INDUCEMENT? BUT THAT RUNS THROUGHOUT ALL RESEARCH. SO I WOULD SUGGEST WE NOT TRY AND SOLVE THIS, BUT JUST TODAY SEE IF WE AGREE ON THE GRANDFATHERING CLAUSE.

AND LET ME JUST POINT OUT THAT WE HAD A DIFFERENT CRITERIA FOR THE CUTOFF DATE WHEN THE ICOC ACTUALLY GRANDFATHERED IN EMBRYOS CREATED IN AN IVF CONTEXT, NOW FROZEN AND DONATED TO RESEARCH, AS AN ALTERNATIVE TO BEING THAWED AND DESTROYED. WE SET THE CUTOFF DATE, NOT THE PASSAGE OF PROP 71, BUT THE CUTOFF DATE FOR THE ACTION OF THE ICOC.

SO DOROTHY MAY WANT TO COMMENT ON THIS AS A LEGAL EXPERT, LEGAL SCHOLAR. OBVIOUSLY WE HAVE COUNSEL HERE WE HAVE TO CONSULT, BUT THERE'S THAT TIME PERIOD BETWEEN THE PASSAGE OF PROP 71 AND WHERE WE'RE ALLOWING FROZEN EMBRYOS WITH PAID OOCYTES IN IVF TO BE USED AS GRANDFATHERED IN. WHETHER LEGALLY AS A MATTER OF LAW POLICY THAT'S ACCEPTABLE OR NOT IS SOMETHING WE WOULD CERTAINLY WELCOME YOUR THOUGHTS ON. IT HASN'T COME UP BEFORE TODAY.

PROFESSOR ROBERTS: WELL, BUT THAT'S ALREADY HAPPENED, RIGHT? THAT'S --

CHAIRMAN LO: ICOC ACTED BACK IN AUGUST, WAS IT?

DR. LOMAX: CORRECT. BUT WE ARE REVISITING THAT TODAY.

PROFESSOR ROBERTS: THAT'S TRUE, BUT NOT THAT DATE, ARE WE?

CHAIRMAN LO: WELL, THAT'S COMING UP NEXT. ARE WE GLAD YOU'RE HERE.

PROFESSOR ROBERTS: I'LL DO MY BEST.

DR. KIESSLING: THE *NEW ENGLAND JOURNAL* HAD AN ARTICLE TWO OR THREE YEARS AGO THAT REVIEWED ALL OF THE MODELS FOR COMPENSATING HUMAN SUBJECTS FOR RESEARCH. AND SO IT MIGHT BE REALLY HELPFUL IF THAT WERE DISTRIBUTED TO THE COMMITTEE JUST SO THAT THEY CAN SEE THE THINKING THAT'S GONE INTO THIS IN THE PAST.

CHAIRMAN LO: THERE'S AN EXTENSIVE LITERATURE ON THAT. ACTUALLY IT'S CHRISTINE GRADY AND COLLEAGUES AT NIH. SINCE THEN, THEY'VE DONE FURTHER WORK ON THAT. I CAN SORT OF GET THEIR LATEST THINKING. THIS IS SOMETHING THAT HAS PERPLEXED SCIENTISTS, IRB'S, AND ETHICISTS WORKING IN THE RESEARCH AREA, SORT OF WHAT AMOUNT OF PAYMENT IS THE APPROPRIATE AMOUNT TO PAY A RESEARCH SUBJECT WHO UNDERGOES RISKS IN ORDER TO BENEFIT SCIENCE AND

SOCIETY. IT'S A TOUGH ISSUE. YOU'RE RIGHT. SO WE CAN CERTAINLY GET THOSE ARTICLES.

DR. PRIETO: I WOULD CERTAINLY APPRECIATE THOSE.

PROFESSOR ROBERTS: IS THERE ANYTHING THAT COULD HELP US ON THIS PROBLEM OF THE LANGUAGE OF PROPOSITION 71? I REALLY UNDERSTAND THE ARGUMENT, THAT THE VOTERS AND THE DRAFTERS WEREN'T THINKING OF SOMATIC CELLS AT THE TIME, BUT THE LANGUAGE COVERS SOMATIC CELL, IT COVERS ALL DONATIONS.

CHAIRMAN LO: IT'S BROAD LANGUAGE, ABSOLUTELY.

DR. TAYLOR: I WOULD ARGUE THAT ONCE WE GET THAT THROUGH, THEN I WOULD THINK IT'S COMPLETELY UNETHICAL NOT TO OFFER WOMEN $500 OR WHATEVER WE SET AS OUR MAXIMUM FOR THE RISK OF UNDERGOING OOCYTE DONATION.

PROFESSOR ROBERTS: SO THAT'S ANOTHER ISSUE, THAT EVEN IF WE THOUGHT THAT IT WAS OKAY TO ALLOW FOR THIS, FOR PAYMENT FOR SOMATIC CELL DONATION, BECAUSE THAT'S NOT WHAT PROPOSITION 71 REALLY REFERS TO, IT'S GOING TO HAVE AN IMPACT ON WHAT WE KNOW PROPOSITION 71 REALLY REFERS TO, OOCYTE DONATION. SO --

DR. TAYLOR: EXACTLY. IF I CAN MAKE A

PLEA, BERNIE, EVERY OTHER MEETING WE GO THROUGH THIS THING OVER AND OVER AGAIN. I AM PERSONALLY IN FAVOR OF PAYING EVERYBODY. I ALSO KIND OF GET NERVOUS NOT BEING A LEGAL PERSON. WHEN SOMETHING IS WRITTEN AS LAW, I TEND TO TAKE IT RELATIVELY SERIOUSLY.

PROFESSOR ROBERTS: THANK YOU. SO DO I. I THINK IT'S A REAL -- I DON'T THINK WE CAN JUST SAY THAT'S NOT WHAT PROPOSITION 71 MEANT.

DR. TAYLOR: CAN'T SOMEBODY ACTUALLY JUST KIND OF GO AFTER THE LAW, NOT OUR COMMITTEE, BUT SOMEBODY WHO REALLY DOES THAT SORT OF THING AND JUST TRY TO CHANGE IT AND MAKE IT REASONABLE BECAUSE IT IS UNREASONABLE, BUT I DON'T KNOW HOW WE'RE GOING TO GET AROUND IT.

DR. TROUNSON: BERNIE, THERE'S A BIG PROBLEM IN CHANGING, YOU KNOW, THOSE RULES BECAUSE IT IS IN PROPOSITION 71. IT TAKES TWO-THIRDS VOTE FROM BOTH HOUSES TO DO THAT. IT'S MOST UNLIKELY THAT YOU WOULD EVER GET THAT TO HAPPEN.

I THINK THE BROAD STRUCTURE OF THE WAY IT'S WRITTEN WOULDN'T ALLOW THE AGENCY TO IN ANY WAY COMPENSATE PATIENTS FOR ANY DONATED MATERIAL BECAUSE THE LEGAL SITUATION IS PRETTY CLEAR, THAT IT'S NOT CONFINED, DESPITE WHAT GEOFF SAID, IT'S NOT CONFINED TO SIMPLY OOCYTES OR EVEN EMBRYOS. WE HAVE A BIG

PROBLEM ABOUT CHANGING THAT LAW, AND I THINK IT'S MOST UNLIKELY THAT IT'S GOING TO HAPPEN.

DR. TAYLOR: WILL WE BE ABLE TO COME UP WITH GUIDELINES OURSELVES, THOUGH, THAT WILL GET AROUND IT?

PROFESSOR ROBERTS: I WOULD NOT ADVISE THAT.

MS. LANSING: THAT WOULD BE TERRIBLE GUIDANCE.

PROFESSOR ROBERTS: I THINK WE HAVE TO ABIDE BY WHAT THE PROPOSITION SAYS, WHICH IS NO PAYMENT FOR DONATION.

CHAIRMAN LO: IF THAT'S THE CASE AND THAT'S WHERE WE ARE NOW, DOROTHY, I'LL CONTACT YOU OFF LINE AND ASK YOU TO HELP US THINK THIS THROUGH AT THE NEXT MEETING. THEN WE HAVE A REAL PROBLEM IN THAT IF IT, IN FACT, IS THE CASE THAT OUR SCIENTIFIC ADVANTAGES TO TRYING TO REPROGRAM LIVER CELLS OR OTHER CELLS THAT ONE HAS TO OBTAIN WITH A MORE INVASIVE PROCEDURE THAN A SKIN BIOPSY, AND WE WANT CIRM SCIENTISTS TO BE ABLE TO USE THOSE CELLS BECAUSE OF THE SCIENTIFIC VALUE, THEN ARE WE GOING TO PERMIT CIRM-FUNDED RESEARCHERS TO USE THOSE CELLS THAT SOMEONE ELSE PAID THE LIVER DONOR FOR? THAT'S ONE QUESTION.

IF THE CELLS -- IF SOMEONE DID IT TOTALLY INDEPENDENTLY AND NOW A CIRM RESEARCHER WANTS TO USE IT, THERE'S NO CONNECTION BEFORE THE DERIVATION OF CELLS. OR ALTERNATIVELY I CAN IMAGINE A CIRM RESEARCHER SAYING, LOOK, I WANT TO DO THIS. I CAN'T DO IT WITH CIRM FUNDS, BUT I'M GOING TO SORT OF GET OUTSIDE FUNDS FROM WHATEVER SOURCE TO PAY LIVER DONORS TO GET THE TISSUE TO DERIVE THE CELL LINE, AND THEN APPLY FOR CIRM FUNDS TO, IN A SENSE, ALTHOUGH IT'S NOT USING CIRM FUNDING, IT'S REALLY PART AND PARCEL OF THE CIRM RESEARCH GRANT AND MAY BE ACTUALLY PART OF THE DISEASE TEAM HYPOTHETICALLY.

SO I THINK WE NEED TO THINK THROUGH EVEN IF WE DON'T PAY, WHAT CONDITIONS, IF ANY, ARE WE GOING TO SET ON THE USE OF CIRM RESEARCHERS USING LINES DERIVED BY OTHERS WHERE THEY PAID DONORS.

DR. PRIETO: MAYBE YOU ADDRESSED THIS EARLIER AND I JUST DIDN'T HEAR, BUT WHERE ARE OTHER BODIES LIKE THE NATIONAL ACADEMIES AND, FOR THAT MATTER, INTERNATIONAL BODIES COMING DOWN ON THIS ISSUE?

CHAIRMAN LO: WELL, NATIONAL ACADEMY, AGAIN, THEY TOOK A MUCH NARROWER APPROACH. THEIR GUIDELINES OPPOSE PAYMENT FOR OOCYTES. THEY DID NOT HAVE AS SWEEPING A BAN ON RESEARCH DONORS OR

PARTICIPANTS AS WE HAVE. SO THEY DON'T HAVE A PROBLEM. THEY CARVED OUT OOCYTES AS BEING A SPECIAL -- NOW, THERE ARE OTHER ISSUES WITH EQUITY BETWEEN LIVER DONORS AND OOCYTE DONORS, SO THAT'S NOT AN ISSUE ELSEWHERE. IT'S SOMETHING THAT WE HAVE BECAUSE OF PROP 71. SO, YEAH, IT'S A PROBLEM.

MR. SHEEHY: THIS MAY BE A QUESTION FOR THE LAWYERS. BUT HOW WOULD THIS BE IMPACTED IF THE DONATION WAS PAID WITH FEDERAL DOLLARS? WHAT KIND OF -- FRANKLY, WE HAVE A BETTER CHANCE OF GETTING FEDERAL PREEMPTION. IF WE COULD SUCCEED IN THE LEGISLATURE, WE'D HAVE A BUDGET. THE SAME PEOPLE WHO ARE STONEWALLING, NO NEW TAXES ALSO SAID THE SAME SORT OF --

DR. PRIETO: THEY'RE NOT GOING TO COME ON BOARD.

MR. SHEEHY: THEY'RE NOT GOING TO COME ON BOARD. BUT, YOU KNOW, DOES SOMETHING CHANGE WHEN IT BECOMES -- IF THIS IS FEDERALIZED GIVEN THAT MANY THINGS, WHAT HAPPENS AT A STATE LEVEL IS PREEMPTED BY FEDERAL ACTION. IF SOMEONE WAS FUNDED BY THE NIH, FOR INSTANCE, TO OBTAIN THESE CELLS COMPENSATED, HOW WOULD THAT -- DO WE HAVE ANY SENSE OF WHETHER THAT WOULD MATERIALLY CHANGE THIS?

CHAIRMAN LO: I WOULD SUGGEST THAT WE TRY

AND SEPARATE OUT THE ETHICS FROM THE POLITICS. I THINK IT WOULD BE VERY USEFUL, I THINK, FOR US TO DECIDE AND GIVE A RATIONALE FOR WHY WE THINK IT IS APPROPRIATE, FOR EXAMPLE, LIVER BIOPSY DONORS TO BE PAID A REASONABLE AMOUNT THAT'S NOT AN UNDUE INFLUENCE. AND THEN NOTE THAT THERE'S A CONFLICT BETWEEN THAT AND PROP 71, AND THEN SORT OF SAY, OKAY, HOW CAN THAT BE ADDRESSED?

I WOULD NOT START BY SAYING WE WANT TO DO A WORKAROUND WITHOUT HAVING ESTABLISHED WHY WE THINK IT'S ETHICALLY APPROPRIATE TO PAY LIVER DONORS OR OTHER DONORS IN THAT SITUATION. ONCE THAT FOLLOWS, THEN I THINK IT'S MORE OF A TECHNICAL ISSUE OF WHETHER THE LANGUAGE ALLOWS US TO USE LINES DERIVED BUT FROM PAYMENT THAT DOESN'T HAVE A CIRM CHECK BEHIND IT. I WOULD HOPE WE COULD ESTABLISH AND GET WIDE ACCEPTANCE ON THE RATIONALE FOR ALLOWING THESE PAYMENTS RATHER THAN JUST SAY WE'RE GOING TO LOOK FOR AN EXCEPTION.

MR. SHEEHY: CAN I ASK WHAT NOVEL ISSUES DO WE HAVE TO CONSIDER THAT MAKES THIS DIFFERENT FROM ACCEPTED PRACTICE OF PAYING FOR THESE DONATIONS ALREADY? HOW MUCH NEW STUFF -- HOW MUCH NEW -- WHAT IS DIFFERENT ABOUT USING SOMATIC CELLS TO CREATE PLURIPOTENT CELLS THAT DISTINGUISHES THAT FROM THESE

SAME TYPES OF DONATIONS THAT SEEM TO GO ON RATHER ROUTINELY NOW IN SCIENCE? ISN'T THAT THE REAL CRUX OF THE DIFFERENCE?

CHAIRMAN LO: I THINK PARTLY IT'S DID THEY CONSENT TO THE SENSITIVE -- SO IT'S THE QUALITY OF THE CONSENT PROCESS AND THE QUALITY OF THE OVERSIGHT. WHAT YOU WOULD NOT WANT DONE, I DON'T THINK, IS PEOPLE GOING TO, PICK A COUNTRY THAT'S IN ECONOMIC FREEFALL, AND OFFERING, NOT $500, BUT $100 TO PEOPLE TO UNDERGO LIVER BIOPSY, AND HAVING A RELATIVELY VAGUE CONSENT PROCESS AND NOT SORT OF OUTLINING THE SENSITIVE KINDS OF RESEARCH WE TALKED ABOUT EARLIER. THERE MIGHT BE -- SO I THINK THAT IF IT WERE DONE WITH GOOD CONSENT AND GOOD OVERSIGHT AND REALLY WASN'T AN UNDUE INDUCEMENT AND PEOPLE REALLY KNEW THE RISKS AND WHAT WAS GOING TO HAPPEN TO THEIR CELLS, I THINK IT'S NO DIFFERENT THAN ANY OTHER RESEARCH.

SO IT'S REALLY -- FOR THAT IT'S REALLY A QUESTION OF GOING OFFSHORE TO PLACES WHERE THE FINANCIAL INDUCEMENTS BECOME MUCH MORE OF A PROBLEM.

SO I GUESS THE QUESTION IS SHALL WE JUST ALLOW IT WITH OTHER FUNDS OR ALLOW IT PROVIDED THAT THERE'S SOME ASSURANCE THAT THE CONSENT AND THE OVERSIGHT FOR THE ORIGINAL DERIVATION WERE

APPROPRIATE. LET ME JUST TELL YOU WHAT WE'VE TRIED TO DO AT UCSF. IT GETS TO BE A MESS TRYING TO SECOND-JUDGE A DONATION AND RESEARCH PROJECT CARRIED OUT IN ANOTHER INSTITUTION AND IN A DIFFERENT LANGUAGE. IT'S REALLY HARD TO KNOW WHAT HAPPENED. WE ACTUALLY HAVE SEEN THAT WITH SOME OF THE OLDER EMBRYONIC STEM CELL LINES THAT THE DEPARTMENT OF PUBLIC HEALTH STEM CELL RESEARCH GROUP IN CALIFORNIA IS STRUGGLING WITH KIND OF SOME OF THESE NIH LINES WHERE THE CONSENT PROCESS TURNS OUT TO BE LESS THAN WE THOUGHT.

BUT MY SUGGESTION WOULD BE WE TRY AND CARVE OUT A NARROW EXCEPTION TODAY AND REALLY COME BACK TO THAT AND REALLY GET DOROTHY'S INPUT AND GET SOME MATERIALS ON THIS ISSUE OF UNDUE INDUCEMENT FROM PAYMENT, AND ACTUALLY GET SOME IRB VIEWS ON THIS AS WELL. BECAUSE I THINK MOST OF THE INSTITUTIONS THAT, FOR EXAMPLE, ARE ACCREDITED BY AHRPP WOULD HAVE A PRETTY, IT SEEMS TO ME, ROBUST OVERSIGHT PROCESS OF PAYMENTS FOR THESE BASIC PROCEDURES. IRB'S, I KNOW, HAVE STRUGGLED WITH THIS A LOT AND ASK THEMSELVES IS THIS TOO MUCH? ARE WE GOING TO GET PEOPLE COMING IN AND SORT OF CLOSING THEIR EYES TO THE REAL RISKS OF THESE TYPES OF RESEARCH?

SO LET ME JUST POINT OUT -- DID I ALREADY SAY -- THAT WE TOOK A DIFFERENT GRANDFATHERING -- THE ICOC TOOK A DIFFERENT GRANDFATHERING DATE FOR THE -- I SAID THAT ALREADY.

TODAY IT SOUNDS LIKE I'M HEARING FROM OUR COMMITTEE THAT WE'RE COMFORTABLE WITH THE CUTOFF DATE BEFORE PROP 71. WE CAN'T -- IT'S UNFAIR TO EXPECT PEOPLE TO HAVE GUESSED WHAT PROPOSITION 71 WAS GOING TO DO; BUT AFTER THAT, WE'RE NOT COMFORTABLE WITH ANY PAYMENT, GRANDFATHERING IN ANY PAYMENTS GIVEN THE LANGUAGE OF PROP 71. I THINK THAT'S WHAT'S I HEARD EVERYBODY SAY.

DR. PETERS: WHY DO WE DISTINGUISH BETWEEN BEGINNING PROP 71 AND THE DATE THE ICOC SET? DOES IT MATTER WHICH DATE WE CHOOSE?

CHAIRMAN LO: NOT SURE. DOROTHY.

PROFESSOR ROBERTS: I HAVEN'T REALLY THOUGHT ABOUT IT MUCH BECAUSE I DIDN'T ANTICIPATE --

CHAIRMAN LO: WE DIDN'T EITHER. WE'RE GLAD YOU'RE HERE.

PROFESSOR ROBERTS: THERE'S A COUPLE THINGS THAT COME TO MIND. ONE IS IS THERE A VALUE TO CONSISTENCY, JUST HAVING THE SAME GRANDFATHERING DATE? PRESUMABLY IT'S IN THE SAME ISSUES, RIGHT, WHETHER RESEARCHERS WOULD HAVE THOUGHT TO FOLLOW

THESE GUIDELINES BEFORE THEY FOLLOWED -- WELL, TO FOLLOW PROP 71 RULES BEFORE PROP 71 EXISTED.

MR. SHEEHY: THERE IS A DISTINCTION BECAUSE THIS SPEAKS OF RESEARCH DONORS. WE WERE TALKING ABOUT EMBRYOS THAT WERE CREATED FOR REPRODUCTIVE PURPOSES. THOSE DONATIONS WERE NOT PAID FOR FOR RESEARCH. THOSE WERE NOT RESEARCH DONATIONS. THESE WERE ACTUALLY DONATIONS FOR REPRODUCTIVE PURPOSES. THAT DOES ALLOW A DIFFERENT STANDARD TO BE APPLIED.

PROFESSOR ROBERTS: HOW DID THE DATE RELATE TO THAT DISTINCTION?

MR. SHEEHY: THE DATE -- I BELIEVE THE THINKING, AND, AGAIN, I'M FUZZY TODAY, BUT I THOUGHT THAT WE WERE MAKING A DATE MORE TO MAINTAIN THE PURITY -- TO MAINTAINING THAT THESE -- OUR INTEREST IN SETTING A DATE WAS TO CLEARLY INDICATE THAT THESE DONATIONS WERE MADE FOR REPRODUCTIVE PURPOSES. THAT'S WHY WE SET A DATE SO THAT THERE WOULD BE NO -- WE WERE TRYING TO MAKE IT UNFEASIBLE FOR THOSE DONATIONS TO HAVE BEEN MADE. IN OTHER WORDS, IT WAS ILLEGAL FOR THOSE DONATIONS TO HAVE BEEN MADE WITH THE IDEA THAT THOSE COULD BE USED FOR RESEARCH PURPOSES BECAUSE THEY WERE CLEARLY NOT ABLE TO BE MADE FOR RESEARCH PURPOSES.

SO WE WERE TRYING TO MAKE SURE THAT AT NO POINT IN THAT DECISION-MAKING PROCESS, AND PLEASE CORRECT ME, BERNIE OR SOMEONE, IF I'M WRONG ON THIS, BUT THAT THE IDEA OF DONATING FOR RESEARCH WAS IN NO WAY PART OF THE INTERACTION THAT LED TO THE DONATION. THAT WAS PURELY FOR REPRODUCTIVE PURPOSES.

CHAIRMAN LO: I THINK THAT'S RIGHT, JEFF, THAT THESE WERE IN A SENSE TISSUES THAT WERE PROVIDED FOR A TOTALLY DIFFERENT PURPOSE, AND THE PAYMENT WAS MADE IN THAT REPRODUCTIVE CONTEXT. AND RATHER THAN DESTROYING THE MATERIALS AFTER THE WOMAN OR COUPLE DECIDED NOT TO GIVE THEM TO SOMEONE ELSE OR NOT TO GO FORWARD WITH FURTHER IVF, THAT THE IDEA WAS THAT THEY WOULD BE ALLOWED. BUT BECAUSE THEY WEREN'T ORIGINALLY -- THE PAYMENT WASN'T MADE WITH ANY VIEW TOWARDS USING THEM FOR STEM CELL RESEARCH, WE THOUGHT THERE WAS NO UNDUE INDUCEMENT IN THAT SITUATION. I GUESS WE SORT OF THOUGHT THAT, WELL, PROP 71 REALLY DIDN'T APPLY BECAUSE THEY WEREN'T RESEARCH DONORS OR RESEARCH PARTICIPANTS AT THE TIME THE COMPENSATION WAS MADE.

HERE FOR STEM CELLS -- I'M SORRY -- FOR LIVER BIOPSIES FOR IPS CELLS, I THINK THESE ARE RESEARCH SUBJECTS AND THEY'RE DONATING A LIVER

BIOPSY.

PROFESSOR ROBERTS: RIGHT. SO THEN MAYBE THE DATE OF THE PROP 71 PASSING DOES MAKE MORE SENSE FOR THESE, THE GRANDFATHERING DATE.

CHAIRMAN LO: WELL, IN POINT OF -- YEAH. MY OWN SENSE IS THE GRANDFATHERING IS NOT SO MUCH AN ISSUE BECAUSE I THINK THE ISSUE IS GOING TO BE WHAT ALAN RAISED, THAT IF SOMEONE WITHOUT CIRM FUNDING DERIVES A STEM CELL LINE THAT NOW CIRM RESEARCHERS WANT TO USE, WILL WE PERMIT THAT? I THINK THAT'S SOMETHING WE NEED TO THINK ABOUT AND GET -- TO THINK ABOUT AND SORT OF MAKE SOME PROPOSALS.

RIGHT NOW IT SEEMS TO BE VERY HARD -- I GUESS THE SECOND QUESTION IS ARE WE GOING TO ALLOW SORT OF COOPERATIVE ARRANGEMENTS WHERE SOME RESEARCH SAYS I'D LIKE A PIECE OF YOUR LIVER, A LIVER BIOPSY, I CAN'T PAY YOU, BUT WE HAVE TO MAKE ARRANGEMENTS TO GET THE BIOPSY FRESH AND INTO THE RIGHT HANDS, AND SO THERE'S GOING TO BE A LOT OF COORDINATION.

DR. TROUNSON: PRESUMABLY THE SOURCE OF LIVER CELLS JUST STRAIGHT FOR RESEARCH WOULD BE FROM CADAVERIC SAMPLES IF THE PERSON AGREED TO DONATE HIS MATERIAL.

CHAIRMAN LO: WOULD THAT WORK FOR DERIVATION OF IPS CELLS?

DR. TROUNSON: WELL, IT WOULD BE FOR THE RESEARCH PURPOSES. I IMAGINE THAT THAT'S PROBABLY THE SOURCE, WILL BE THE PRIMARY SOURCE FOR THESE CELLS, AND THAT WOULDN'T REQUIRE ANY PAYMENT.

CHAIRMAN LO: BUT THEN THOSE LINES, COULD THEY BE USED FOR CLINICAL TRANSPLANTATION?

DR. TROUNSON: NO, I DON'T THINK SO BECAUSE THE CELLS THAT ARE RELEVANT FOR THAT WOULD COME FROM THE PATIENTS, YOU KNOW, WHO WOULD BE PATIENT-SPECIFIC.

DR. TAYLOR: PATIENTS WOULDN'T NEED TO BE COMPENSATED.

DR. TROUNSON: THAT'S RIGHT. BUT, YOU KNOW, WHAT WAS CONCERNING ME A LITTLE BIT IS THAT THEY WOULD BE THE ONLY PART OF THE POPULATION WHO WOULD BE MOTIVATED TO DO THAT. AND SO YOU'RE ASKING SOMETIMES RELATIVELY SICK PEOPLE TO MAKE DONATIONS WHERE IT MAY -- I DON'T KNOW WHETHER THIS IS TRUE, BUT MIGHT NOT BE IN THEIR --

CHAIRMAN LO: WELL, THERE'S ANOTHER THING THAT HAPPENS IN THE CLINICAL TRANSPLANTATION CONTEXT, THAT IN A FAMILY WHERE THERE'S A VERY STRONG FAMILY HISTORY OF ONE OF THESE DISEASES THAT IT'S HOPED STEM CELL WILL TREAT, THE HEALTHY MEMBERS OF THE FAMILY MAY FEEL ENORMOUS PRESSURE. WELL, WE

CAN'T DONATE BECAUSE IT'S TOO RISKY FOR US. IF SOMEONE LIKE YOU DOESN'T DONATE, THE RESEARCH WON'T GET DONE, AND THE PERSON MAY NOT FEEL COMFORTABLE SAYING, GEE, I'M NOT REALLY COMFORTABLE WITH THAT. SO THIS GETS TRICKY.

I THINK WE NEED TO THINK THIS OUT. AND I GUESS -- LET ME JUST SAY AT THE VERY LEAST, EVEN IF WE END UP DECIDING IT'S FUTILE TO TRY AND CHANGE PROP 71, I THINK WE DO NEED TO BE CLEAR IN GIVING A PUBLIC RATIONALE FOR WHY WE'RE ALLOWING WHATEVER KIND OF ARRANGEMENTS WE END UP SUGGESTING SO IT DOESN'T LOOK LIKE WE'RE JUST TRYING TO SUBVERT THE INTENTION OF THE VOTERS.

I GUESS ALSO I WOULD LIKE TO GET A BRIEF FROM THE POLITICAL SORT OF CONSULTANTS WE HAVE.

SOMEONE ON THE PHONE WANTS TO SAY SOMETHING.

DR. PRIETO: BERNIE, I THINK THAT SHERRY AND JEFF CAN COMMENT ON THIS, BUT I JUST DON'T THINK THAT'S A FEASIBLE OPTION.

MS. LANSING: I WOULD LIKE TO SECOND THAT. I THINK AT THIS TIME IT WOULD BE ALMOST IMPOSSIBLE.

CHAIRMAN LO: OKAY. I NEVER SAID IT. I NEVER SUGGESTED IT.

MS. LANSING: I THINK, YOU KNOW, WE'VE

ALWAYS SAID WE'RE STILL AT THE EARLY STAGES. A LOT OF THINGS -- WE'LL SEE, BUT I'M HOPEFUL WE'LL CHANGE NATIONALLY, AND THEN IT MIGHT BE A DIFFERENT TIME.

CHAIRMAN LO: ALL RIGHT. SO DO I HAVE A SENSE OF THE COMMITTEE, THEN, THAT WE'RE GOING TO SUGGEST TO THE ICOC THAT WE MAKE A LIMITED EXCEPTION TO OUR VERY STRICT OVERSIGHT, CONSENT, PAYMENT STANDARDS, AND THE THINGS THAT WOULD BE ACCEPTED WOULD BE DONATIONS OF SOMATIC CELLS, DERIVATION OF IPS LINE, CHARACTERIZATION OF THAT LINE, PROOF OF PLURIPOTENCY, DERIVATION OF SPECIALIZED LINES, DERIVED LINES BUT NOT GAMETES, AND PROOF THAT THEY ARE, IN FACT, OF THAT LINEAGE?

FOR THOSE THE LEVEL OF REVIEW WOULD BE SCRO NOTIFICATION RATHER THAN FULL REVIEW. LEVEL OF CONSENT THAT WOULD BE PERMITTED WOULD BE GENERAL RESEARCH CONSENT, ALTHOUGH I THINK WE SHOULD SAY AS A MATTER OF SUGGESTION THAT WE WOULD CERTAINLY BE HAPPY TO SEE RESEARCHERS HAVE A MUCH MORE THOROUGH CONSENT PROCESS. AND FOR PAYMENT WE WOULD ALLOW GRANDFATHERING OF PAYMENTS WITH CELLS WHERE THE PAYMENTS WERE MADE BEFORE THE PASSAGE OF PROP 71, WHICH WAS FOUR YEARS AGO NOW.

IS THAT THE SENSE OF THE COMMITTEE? I DON'T KNOW IF HEARING NO OBJECTION MEANS NO ONE --

DR. PRIETO: I'M OKAY HERE.

CHAIRMAN LO: YOU WANT TO JUST DO A ROLL CALL?

MR. SHEEHY: I THINK A ROLL CALL IS A GOOD IDEA, BERNIE. WE MAY EVEN HAVE A QUORUM. I DON'T KNOW.

DR. LOMAX: WE ARE SHORT ON A QUORUM, I BELIEVE. SO I THINK BERNIE SUCCESSFULLY SUMMARIZED THE FRAMEWORK.

SHERRY LANSING.

MS. LANSING: YES.

DR. LOMAX: JEFF SHEEHY.

MR. SHEEHY: YES.

DR. LOMAX: BERNARD LO.

CHAIRMAN LO: YES.

DR. LOMAX: TED PETERS.

DR. PETERS: YES.

DR. LOMAX: DOROTHY ROBERTS.

PROFESSOR ROBERTS: YES.

DR. LOMAX: JOSE CIBELLI.

DR. CIBELLI: YES.

DR. LOMAX: ANN KIESSLING.

DR. KIESSLING: YES.

DR. LOMAX: JAMES WILLERSON. ROB TAYLOR.

DR. TAYLOR: YES.

DR. LOMAX: FRANCISCO PRIETO.
DR. PRIETO: YES.
DR. LOMAX: DID I MISS ANYONE? THANK YOU.
CHAIRMAN LO: A BREAK. AND WHEN ARE WE SCHEDULED TO GO TO, GEOFF?
DR. LOMAX: THE AGENDA SAYS 1 O'CLOCK.
CHAIRMAN LO: CAN WE TAKE A 15-MINUTE BREAK? IS THAT OKAY? SO 15 MINUTES FROM NOW.
(A RECESS WAS TAKEN.)
CHAIRMAN LO: COULD WE TAKE A ROLL CALL AND SEE WHO'S BACK FROM THE BREAK AND SEE IF WE HAVE ENOUGH TO START. WE HAVE A GUEST THAT WE WANT TO ACCOMMODATE AS WELL.
DR. LOMAX: SHERRY LANSING.
MS. LANSING: YES.
DR. LOMAX: JEFF'S IN. BERNIE. TED. DOROTHY ROBERTS IS ON THE LINE. JOSE. WE MAY HAVE LOST JOSE. I'LL SEND HIM ANOTHER E-MAIL. ANN.
DR. KIESSLING: YES.
DR. LOMAX: ROB TAYLOR AND FRANCISCO.
DR. TAYLOR: YES.
DR. ADAMSON: AND DAVID ADAMSON IS HERE TOO.
CHAIRMAN LO: DO YOU WANT TO INTRODUCE DAVID?

DR. LOMAX: WE HAVE DR. DAVID ADAMSON ON THE LINE. WE ASKED HIM TO PARTICIPATE. HE WAS -- THE NEXT DISCUSSION WILL CONSIDER OUR INTERIM REGULATION CONCERNING THE USE OF EMBRYOS CONTAINING GAMETES FOR WHICH A DONOR MAY HAVE BEEN PAID. AND ONE OF THE PERSPECTIVES OR ONE OF THE ISSUES THAT WE WOULD ASK HIM TO SPEAK TO IS THE ROLE OF THE IVF PHYSICIAN AND THE PROCESS FOR WHICH THERE'S AN INTERACTION BETWEEN THE GAMETE DONOR AND THE COUPLE IN IVF TREATMENT.

IN OUR LAST DISCUSSION, A NUMBER OF ISSUES WERE RAISED ABOUT POSSIBLE CONFLICTS, ROLES, RESPONSIBILITY, WHAT HAVE YOU. SO WE WERE ASKED TO SORT OF IDENTIFY SOMEONE WHO COULD SPEAK TO THE CLINICAL SIDE OF THINGS, AND HE'S PREPARED SOME COMMENTS, WHICH, AS WE MOVE THROUGH THE DISCUSSION, BERNIE CAN INVITE HIM IN.

CHAIRMAN LO: SO WE'RE NOW SORT OF TACKLING 4(B) ON THE AGENDA, WHICH IS USE OF IVF EMBRYOS FOR WHICH THE GAMETE DONORS WERE PAID, BUT PAID IN A REPRODUCTIVE CONTEXT. AND THIS, AGAIN, IS COMPLICATED AND DIFFICULT.

I'M GOING TO ASK GEOFF TO START, AND WE ARE GOING TO, AGAIN, GO BACK TO THAT PDF WITH THE SLIDES. AND NOW THE FOURTH SLIDE ON PAGE 2, BOTTOM

OF PAGE 2, KIND OF JUST TO REVIEW WHAT THE CURRENT REGULATIONS ARE FOR NBO DERIVATION, AND THEN PROPOSED CHANGES.

DR. LOMAX: THANK YOU, BERNIE. THE STANDARD -- THE FIRST SLIDE, THE ONE WITH THE ARROW, I BELIEVE IT'S SLIDE NO. 4, IT'S TRYING TO ILLUSTRATE OR ATTEMPTING TO ILLUSTRATE THE CURRENT STANDARDS FOR CIRM FOR USE OF EMBRYOS IN CIRM-FUNDED RESEARCH, AND SPECIFICALLY EMBRYOS THAT WERE CREATED IN IVF CONTEXT AND FOR WHICH THE GAMETE DONOR MAY HAVE BEEN PAID IN THE CREATION OF THAT EMBRYO.

NOW, WHAT I'VE DONE IS SORT OF ILLUSTRATE REALLY TWO THINGS ON THAT SLIDE. IT'S A BIT MORE COMPLICATED THAN THE ISSUE AT HAND. THE LAST SET OF RECOMMENDATIONS PUT FORWARD BY THE WORKING GROUP WAS THAT PRIOR TO 11/22/06, WHICH IS THE EFFECTIVE DATE OF THE REGULATIONS, THERE IS A WILLINGNESS BOTH TO USE EMBRYOS FOR WHICH -- IT'S ACCEPTABLE TO USE EMBRYOS FOR WHICH A GAMETE DONOR WAS PAID AND IT'S ACCEPTABLE AS LONG AS THERE WAS SOME TYPE OF EXPLICIT CONSENT FOR USE OF THE EMBRYO IN RESEARCH.

AGAIN, THAT FOLLOWS THE RATIONALE WE'VE ALLUDED TO A NUMBER OF TIMES TODAY, WHICH IS WE DON'T WANT TO RETROSPECTIVELY APPLY A CONSENT STANDARD ON MATERIALS WHERE THEY DIDN'T KNOW THE

STANDARD EXISTS PRIOR TO THAT DATE.

CHAIRMAN LO: GEOFF, IF I MAY INTERRUPT FOR A SECOND. JUST TO BE SPECIFIC, THAT'S CONSENT FROM THE OOCYTE DONOR IN IVF, THAT SHE NEEDED TO GIVE SOME GENERAL CONSENT FOR RESEARCH, BUT NOT SPECIFICALLY FOR DERIVATION OF STEM CELL LINES, WHICH WOULD BE REQUIRED AFTER THE EFFECTIVE DATE OF THE REGULATION; IS THAT RIGHT?

DR. LOMAX: THAT'S CORRECT. AND THEN FROM THE POINT BETWEEN 11/22/06 AND 8/13/08, THAT'S WHEN THE NEW -- WELL, NEW CONSENT STANDARD APPLIES ALL THE TIME, BUT FOR THOSE THERE'S A WINDOW OF OPPORTUNITY, IF YOU WILL, THERE TO USE IVF EMBRYOS FOR WHICH THE DONOR WAS PAID, BUT YOU'D ALSO HAVE TO CONFORM TO THE SORT OF PROSPECTIVE CONSENT STANDARD, IF YOU WILL, OR THE CIRM CONSENT STANDARD.

NOW, THE 8/13/08 IS A SORT OF CUTOFF DATE FOR WHICH GOING FORWARD EMBRYOS WITH GAMETES WHICH THE DONORS WERE PAID ARE NO LONGER ALLOWED FOR USE IN CIRM-FUNDED RESEARCH. THAT WAS PRESENTED -- THAT WAS THE RECOMMENDATION OF THIS WORKING GROUP. IT WAS THEN PRESENTED TO THE ICOC. AND DURING THAT PRESENTATION, THERE WERE COMMENTS RECEIVED THAT PERHAPS THERE SHOULD BE CONSIDERED A STANDARD THAT WOULD BE FLEXIBLE TO ALLOW USE OF MATERIALS GOING

FORWARD.

WHAT WAS THEN PROPOSED IN THE NEXT SLIDE OR WHAT IS SUGGESTED AS AN OPTION IS A STANDARD THAT WOULD CREATE A PERIOD OF TIME FOR WHICH EMBRYOS WITH PAID GAMETES COULD NOT BE USED. THE IDEA, I THINK, RELATES TO THE THOUGHTS OF THE WORKING GROUP THAT YOU DON'T WANT TO CREATE A SITUATION WHERE THERE'S AN INDUCEMENT TO CREATE EMBRYOS UNDER THE SORT OF GUISE OF IVF, IF YOU WILL, BUT THEY'RE REALLY INTENDED FOR RESEARCH. SO THE CONCEPT OF A WAITING PERIOD IS TO AVOID ANY SITUATION WHERE YOU'RE CREATING EMBRYOS WITH PAID DONORS WITH THE INTENT SOMEHOW OR THE INTENT OF DEVELOPING THEM FOR RESEARCH, BUT RATHER THAN A FIXED DATE IN TIME, YOU HAVE SOME ROLLING PERIOD OF TIME.

SO IN A SENSE YOU'RE CREATING A WAITING PERIOD, IF YOU WILL, TO ENSURE THAT DURING THAT PERIOD OF TIME, THE COUPLE HAVE ADDRESSED THEIR REPRODUCTIVE NEEDS OR THERE'S SORT OF OTHERWISE NO COERCION OR INDUCEMENT TO GET THOSE MATERIALS INTO RESEARCH. THAT'S SORT OF THE CONTOURS OF THE INTENT THERE. I HAVEN'T EXPLAINED THAT VERY WELL, BUT I'M SURE, BERNIE, YOU CAN KIND OF NOW CLARIFY IT.

CHAIRMAN LO: LET ME TRY AND SORT THIS THROUGH, AND PARTICULARLY TO HELP ORIENT DOROTHY.

SO WE'RE REALLY FOCUSING HERE ON THE PAYMENT ISSUE RATHER THAN THE CONSENT ISSUE. AND, AGAIN, THE STARTING POINT IS WHAT WE JUST LOOKED AT IN PROP 71 BEFORE THE BREAK, THE PROHIBITION ON PAYMENT BEYOND OUT-OF-POCKET EXPENSES TO RESEARCH DONORS OR PARTICIPANTS.

AND WHAT WE DID -- WHAT THE ICOC DID AT ITS MEETING IN AUGUST 2008 WAS TO CARVE -- TO ALLOW AN EXCEPTION FOR EMBRYOS FROM OOCYTE DONORS WHO WERE PAID, BUT PAID IN THE IVF CONTEXT. AND THAT EXCEPTION WAS A GRANDFATHERING TO SAY THAT BEFORE THAT DATE OF THAT MEETING THAT WOULD BE PERMITTED. AND I THINK IMPLICITLY WAS THE INTERPRETATION OF PROP 71 THAT THESE WERE NOT REALLY RESEARCH DONORS BECAUSE THEY WERE DONORS FOR CLINICAL IVF, AND THEN THERE WAS EXCESS MATERIAL THAT WASN'T NEEDED FOR THE ORIGINAL REPRODUCTIVE INTENT.

SO THAT WAS, I THINK, THE RATIONALE FOR THE GRANDFATHERING. THERE CAN BE NO UNDUE INDUCEMENT GOING BACKWARDS, AND THAT WHATEVER THE RISKS THE OOCYTE DONOR UNDERWENT HAD ALREADY BEEN FACED. THERE'S NO ADDITIONAL RISK TO HER OF ALLOWING THE EMBRYOS TO BE USED FOR RESEARCH RATHER THAN BEING DESTROYED AT THE REQUEST OF THE -- RATHER THAN BEING DESTROYED.

SO NOW THE QUESTION WAS RAISED AT THE MEETING AND WE WERE ASKED TO CONSIDER WAS IS THAT AUGUST '08 CUTOFF DATE GOING TO BE FIRM BECAUSE, AS WE GO FORWARD IN TIME, THERE WILL BE EMBRYOS CREATED AFTER THAT DATE WHICH MAY WELL TURN OUT TO BE EXCESS AFTER THE WOMAN AND COUPLE IN IVF HAVE COMPLETED THEIR FERTILITY TREATMENT. SO THE PROPOSAL THAT WAS RAISED WAS SHOULD WE ALLOW FOR A DIFFERENT CUTOFF DATE OR A MOVING CUTOFF DATE. IS THAT FAIR, GEOFF?

DR. LOMAX: YES. I THINK THAT'S A HELPFUL CLARIFICATION.

CHAIRMAN LO: YOU WANT TO SAY A LITTLE BIT MORE ABOUT THE RATIONALE FOR WANTING TO GO TO THIS ROLLING DEADLINE OR ROLLING CUTOFF DATE, IF I CAN CALL IT THAT, IN TERMS OF THE NEED FOR MORE EMBRYOS TO DERIVE STEM CELL LINES?

DR. LOMAX: I'LL SPEAK TO TWO ISSUES THAT HAVE COME UP, AND THEN PERHAPS, DR. TROUNSON, THERE MAY BE SOME SCIENTIFIC POINTS THAT COULD BE RAISED AS WELL. THE TWO ISSUES THAT HAVE COME SORT OF THROUGH MY INTERACTION BOTH WITH RESEARCHERS AND THE PUBLIC IS, ONE, THAT THERE ARE INDIVIDUALS WHO, AS PART OF THEIR SORT OF PLANNING PROCESS WHO ARE IN IVF TREATMENT, SO IVF PATIENTS, THE IDEA OF THE FINAL DISPOSITION BEING RESEARCH IS ATTRACTIVE AND A

SENSE THAT THEY WOULD LIKE TO HAVE THE OPTION OF RESEARCH DONATION OPEN TO THEM. AND SO THAT OBVIOUSLY WOULD APPLY TO PATIENTS SORT OF MOVING FORWARD OF THE EXISTING CUTOFF DATE.

THE OTHER COMMENT COMING, NOT FROM THE PATIENT SIDE, BUT FROM THE INSTITUTION SIDE, IS THAT THEY FEEL THAT FROM THE STANDPOINT OF CONSENT, THERE IS AN OPPORTUNITY, IF THEY KNOW MOVING FORWARD THERE MAY BE A POTENTIAL TO USE MATERIALS FROM THESE DONORS, THAT THEY CAN -- IT GIVES A VERY STRONG INCENTIVE TO DO VERY COMPREHENSIVE CONSENT AT THE FRONT END WHEN THE DONOR IS AVAILABLE AT THE CLINIC BECAUSE FROM THAT POINT FORWARD, THE ABILITY TO CONSENT THE DONOR IS VERY LIMITED. IT'S VERY DIFFICULT TO GET BACK TO A DONOR. SO IT GIVES A VERY POWERFUL OR VERY STRONG INCENTIVE OR A CLEAR INCENTIVE THAT THE CONSENT IS WORTH DOING AT THAT TIME BECAUSE AT SOME POINT IN THE FUTURE, THE MATERIALS MAY BE AVAILABLE FOR RESEARCH.

WITH THE CURRENT CUTOFF, THAT INCENTIVE DOES NOT EXIST. SO CERTAINLY ON THE DONOR SIDE AND THE CONSENT SIDE, THERE WERE POINTS THAT WERE RAISED THAT SEEMED REASONABLE AND WORTHY OF CONSIDERATION OF THIS GROUP.

THE OTHER QUESTION THAT HAS COME UP A

NUMBER OF TIMES IS THE QUESTION OF SCIENTIFIC UTILITY. IF I MAY, DR. TROUNSON, PERHAPS DEFER TO YOU TO COMMENT ON GIVEN THAT THESE EMBRYOS REPRESENT A SMALL SUBSET, APPROXIMATELY 10 TO 12 PERCENT OF ALL EMBRYOS THAT TEND TO BE IN FREEZERS, IS THERE SOMETHING UNIQUE SORT OF SCIENTIFICALLY ABOUT THEM THAT MAKES THEM -- YOU KNOW, WHAT'S THE VALUE?

DR. TROUNSON: WELL, GENERALLY THE EMBRYOS THAT ARE CREATED BY DONOR EGGS, USUALLY THE EGG DONOR IS A YOUNG WOMAN, A RELATIVELY YOUNG WOMAN. WHEREAS, A LOT OF THE IVF PATIENTS TEND TO BE IN THEIR LATER 30S AND EARLY 40S. SO IT'S MUCH EASIER TO DERIVE EMBRYONIC STEM CELL LINES FROM EMBRYOS DERIVED FROM YOUNGER EGGS. AND THAT'S KIND OF RECOGNIZED WORLDWIDE JUST AS MUCH EASIER TO DO.

SO FOR THAT REASON, THERE IS SOME INTEREST IN BEING ABLE TO ACCESS THESE PARTICULAR EMBRYOS.

CHAIRMAN LO: ALAN, COULD YOU SAY SOMETHING ABOUT THE SCIENTIFIC VALUE OF HAVING EMBRYOS CREATED AFTER 8/13/08, WHICH WAS THE CUTOFF DATE THAT THE ICOC SET AT ITS LAST MEETING, SO WANTING TO MOVE THAT FORWARD IN TIME.

DR. TROUNSON: I THINK IT'S STILL THE SAME ISSUE, BERNIE, THAT IT'S THE EMBRYOS THERE ARE USUALLY DERIVED FROM YOUNGER PATIENTS. SO THEY HAVE

A HIGHER VITALITY, IF YOU LIKE, AND THEY'RE EASIER TO DERIVE EMBRYONIC STEM CELLS. THOSE CELLS BEHAVE BETTER THAN THOSE FROM OLDER PATIENTS. SO --

CHAIRMAN LO: I DIDN'T PHRASE MY QUESTION RIGHT. IS THERE A NEED FOR MORE EMBRYOS TO DERIVE NEW EMBRYONIC STEM CELL LINES THAN WOULD BE AVAILABLE USING THE 8/08 CUTOFF POINT FOR USING PAID OOCYTE DONORS?

DR. TROUNSON: THERE MAY BE. I THINK, FOR EXAMPLE, THE NEED TO DERIVE GMP COMPATIBLE EMBRYONIC STEM CELL LINES FROM VERY HIGH QUALITY MATERIAL IS A RECOGNIZED NEED. AND SO I THINK THAT THAT'S REALLY THE PRIMARY ARGUMENT FOR THOSE ACCESSING THAT MATERIAL.

CHAIRMAN LO: BUT THAT NEED COULD NOT BE MET BY EMBRYOS CREATED BEFORE THE CUTOFF DATE.

DR. TROUNSON: IT MAY NOT BE BECAUSE, AGAIN, THEY'RE LOOKING FOR THE HIGH QUALITY EMBRYOS FROM YOUNG PATIENTS, AGAIN, IN ORDER TO PRODUCE CELL LINES WITH HIGH VITALITY.

CHAIRMAN LO: OKAY. ANY QUESTIONS FROM THE COMMITTEE ON THIS ISSUE? AND THEN I'M GOING TO TURN TO DR. ADAMSON TO HELP US. COMMITTEE?

PROFESSOR ROBERTS: I WOULD LIKE SOME MORE CLARIFICATION ABOUT THE TWO YEARS, THE REASON FOR

THE TWO-YEAR PERIOD. I ASSUMED, WHEN I SAW THIS, THAT IT WAS -- IT HAD TO DO WITH THE COUPLES HAVING ACHIEVED WHATEVER REPRODUCTIVE OUTCOMES THEY WANTED WITH THE EGGS; AND, THEREFORE, THIS WOULD TAKE CARE OF CONCERN ABOUT THEIR INTERESTS. BUT IT SOUNDS LIKE IT HAS SOMETHING TO DO WITH ACTUALLY ADDRESSING THE INDUCEMENT TO USE THE EGGS FOR RESEARCH.

ARE THOSE TWO COMBINED? I DON'T UNDERSTAND WHAT -- HOW THE TWO-YEAR PERIOD PROTECTS THE INTEREST OF THE EGG DONOR AS OPPOSED TO THE RECIPIENT. SO COULD SOMEONE EXPLAIN THAT TO ME?

DR. LOMAX: I THINK IT'S SORT OF FLEXIBLE. THE COMMENT INVOLVES A LITTLE BIT OF DECIPHERING THE MINUTES OF THE LAST MEETING. I THINK THERE'S NOTHING MAGIC ABOUT TWO YEARS. IT COULD BE TWO YEARS. IT COULD BE SOME OTHER TIMEFRAME, BUT THE IDEA WAS THAT THERE'S SOME TYPE OF INTERVAL IN TIME WHERE THERE WASN'T AN ABILITY TO SORT OF RAPIDLY DIRECT MATERIALS INTO RESEARCH FOR SOME, WANT OF A BETTER TERM, CLANDESTINE PURPOSE.

SO I THINK THE TWO YEARS REALLY CAME ABOUT FROM INTERVIEWS WITH FOLKS WHO DEAL WITH -- WHO ARE LOOKING OUT FOR THE INTERESTS OF THE PATIENT, THAT YOU WOULD ALMOST NEVER SEE MATERIALS EVEN BECOME AVAILABLE FOR RESEARCH TILL AFTER A TWO-YEAR PERIOD.

THAT'S JUST DEALING WITH ISSUES OF THE TIME IT TAKES TO MAKE ANY KIND OF DETERMINATION THAT IVF HAS EITHER BEEN SUCCESSFUL OR UNSUCCESSFUL. SO --

PROFESSOR ROBERTS: RIGHT. THAT'S WHAT I WAS SAYING. SO I UNDERSTAND THE PERIOD ADDRESSING CONCERN FOR THE PATIENT. I DON'T UNDERSTAND HOW THAT ADDRESSES THE CONCERN FOR THE GAMETE DONOR AND THAT'S WHAT -- THE EGG DONOR. DOES IT? OR THAT'S THE CONNECTION I DON'T SEE.

CHAIRMAN LO: DOROTHY, I THINK YOU'RE RIGHT. THAT TWO-YEAR WAITING PERIOD IS REALLY TO PROTECT THE REPRODUCTIVE INTERESTS OF THE WOMAN AND COUPLE IN IVF.

PROFESSOR ROBERTS: SO THEN THERE ISN'T ANYTHING IN THIS PROPOSAL THAT ADDRESSES THE CONCERNS THAT EXISTED BEFORE FOR THE DONOR. IT'S JUST A DECISION THAT THE CUTOFF, YOU KNOW, WAS WRONG THEN. IN OTHER WORDS, IT'S RECONSIDERING THE DECISION TO HAVE THE CUTOFF AT AUGUST '08 IN TERMS OF CONCERNS FOR THE DONOR.

CHAIRMAN LO: THAT'S RIGHT. ALTHOUGH I THINK THERE IS -- THERE IS A CONCERN, BUT IT'S THE OPPOSITE CONCERN, THAT IF WE SAY THAT WE'RE HAVING A FIRM CUTOFF DATE AND THE EMBRYO HAD TO BE CREATED BEFORE 8/08, THEN THERE IS NO WAY THERE COULD BE ANY

INCENTIVE ON EITHER IVF PHYSICIANS OR PATIENTS IN IVF OR DONORS TO THOSE PATIENTS TO TRY AND INCREASE THE YIELD OF OOCYTES IN ORDER TO HAVE A COUPLE LEFT-OVER EMBRYOS THAT MIGHT THEN GO TO RESEARCHERS IF THEY'RE NOT NEEDED IN IVF TREATMENT.

SO I THINK THERE'S A CONCERN THAT BY ALLOWING FUTURE IVF CYCLES TO BE USED FOR RESEARCH, THAT THE CONCERN MIGHT BE THAT IT WOULD AFFECT THE PRACTICE OF IVF CARE, BUT NOTHING IN THIS PROPOSITION WOULD -- IN THIS PROPOSAL WOULD INCREASE PROTECTIONS FOR THE OOCYTE DONOR.

PROFESSOR ROBERTS: SO ANYONE WHO HAD CONCERNS ABOUT THE OOCYTE DONOR, AND THOSE CONCERNS WERE THE BASIS FOR WANTING THE 8/13/08 CUTOFF AND NOTHING PROSPECTIVELY, NO PAID GAMETES PROSPECTIVELY, NO EMBRYOS -- NO USE OF EMBRYOS CREATED WITH PAID GAMETES PROSPECTIVELY, THERE'S NOTHING IN THE TWO-YEAR WAITING PERIOD THAT ADDRESSES THAT.

CHAIRMAN LO: YES, I THINK THAT'S RIGHT.

PROFESSOR ROBERTS: I JUST WANTED TO MAKE SURE I UNDERSTOOD THE PROPOSAL, AND I THINK I DO. SO REALLY THE QUESTION IS DO THE ISSUES THAT HAVE COME UP SINCE THE 8/08 -- SINCE CREATING THAT CUTOFF, WHETHER THOSE ISSUES -- THESE NEW ISSUES

OUTWEIGH THE CONCERNS THAT EXISTED BEFORE; IS THAT RIGHT?

DR. LOMAX: THOSE ARE -- IF YOU LOOK AT THE -- BEFORE I JUMP TO THE FINAL SLIDE, DO YOU WANT TO HAVE DR. ADAMSON. WE ASKED HIM -- I THINK PART OF THE QUESTION WAS -- THERE'S A SET OF SCENARIOS THAT WERE ANTICIPATED PREVIOUSLY. WHAT'S THE VALIDITY OF THOSE SCENARIOS? THAT'S SPECIFICALLY WHY WE ASKED HIM TO COME IN AND PRESENT.

DR. ADAMSON: WOULD YOU LIKE ME TO MAKE SOME COMMENTS?

DR. LOMAX: ARE YOU THE -- I BELIEVE YOU'RE THE FORMER PRESIDENT OF THE AMERICAN SOCIETY OF REPRODUCTIVE MEDICINE; IS THAT CORRECT?

DR. ADAMSON: YES. I'M THE IMMEDIATE PAST PRESIDENT. WE HAD OUR ANNUAL MEETING IN SAN FRANCISCO JUST ONE MONTH AGO, AND I WAS PRESIDENT THEN, AND I'M IMMEDIATE PAST PRESIDENT NOW. AND I'M PAST PRESIDENT OF THE SOCIETY FOR ASSISTED REPRODUCTIVE TECHNOLOGY AND HAVE A LARGE IVF CLINIC IN PALO ALTO AND SAN JOSE.

DR. LOMAX: WE HAVE REPRODUCED THE SLIDES THAT YOU PROVIDED FOR US. WOULD THAT BE A HELPFUL STARTING POINT?

DR. ADAMSON: SURE. AND I'D BE HAPPY TO

ANSWER ANY QUESTIONS TOO. BUT I HAVE NOT, OF COURSE, BEEN INVOLVED IN THE PRIOR DISCUSSIONS, SO FORGIVE ME IF I, YOU KNOW, MISS SOMETHING THAT YOU'VE DEALT WITH THAT I'M NOT AWARE OF OR BRING UP SOMETHING THAT YOU'VE ALREADY DEALT WITH.

BUT JUST WHEN I LEARNED ABOUT THE SITUATION AND THE QUESTIONS THAT WERE BEING ASKED, I FRANKLY THOUGHT IT WAS A LITTLE CURIOUS BECAUSE IT WAS DIFFICULT FOR ME TO IDENTIFY THE POTENTIAL FOR INDUCEMENT OR RISKS TO THE EGG DONORS IN ANY LEGITIMATE TYPE OF MEDICAL SITUATION. AND I THINK WE CAN ALL AGREE THAT THERE ARE SOME BAD PEOPLE IN THE WORLD NOT CONFINED TO THE U.S. AND OTHER COUNTRIES AND WHAT HAVE YOU. AND CERTAINLY THERE'S ALWAYS A POTENTIAL FOR AN UNDUE INDUCEMENT OR RISK IN ANY TYPE OF HUMAN BEHAVIOR. SO I WOULDN'T WANT TO SOUND SO NAIVE THAT I THOUGHT THAT THAT WAS NEVER A POSSIBILITY, BUT I THINK THE REALITY OF MEDICAL PRACTICE, IVF PRACTICE, IN THE UNITED STATES TODAY IS SUCH THAT SOME OF THE STORIES YOU READ OR THINGS THAT PEOPLE BECOME CONCERNED ABOUT REALLY REPRESENT A VERY EXAGGERATED TIP OF THE ICEBERG.

SO WHAT I WANTED TO DO IS JUST SORT OF GIVE MY PERSPECTIVE ON WHAT IT'S LIKE ON A DAY-TO-DAY BASIS ACTUALLY PRACTICING MEDICINE AND

HOW, FROM MY PERSPECTIVE, THE DIFFERENT PARTIES INVOLVED WOULD LOOK AT AND DO, IN FACT, LOOK AT, BECAUSE THIS IS WHAT WE DO EVERY DAY, THE REPRODUCTIVE PROCESS. AND SO WE COULD TRY TO IDENTIFY AREAS WHERE THERE MAY BE LEGITIMATE CONCERNS OVER RISK OR INDUCEMENT FOR ANY OF THE PARTIES INVOLVED.

SO I MADE THESE SLIDES I ASSUME YOU HAVE THERE, BUT JUST LOOKING AT THE INTEREST OF THE EGG DONOR, THEY CLEARLY WANT TO GET THE EGGS REMOVED FROM THEIR OVARIES WITH THE LEAST AMOUNT OF INCONVENIENCE, DISCOMFORT, AND RISK, AND THEY ALSO WANT TO AVOID ANY CYCLE CANCELLATION BECAUSE IN THE VAST MAJORITY OF PROGRAMS, IF THE EGG DONOR DOES NOT, IN FACT, HAVE AN EGG RETRIEVAL, THEN THE REIMBURSEMENT THEY'RE PAYING FOR DISCOMFORT, TIME, ETC., IS LESS. SO THEY DEFINITELY WANT TO GO THROUGH WITH THE EGG RETRIEVAL ONCE THEY'VE STARTED TAKING THE MEDICATION.

IF THE EGG DONOR HAS EXCESSIVE STIMULATION, WHICH IS WHAT ONE WOULD HAVE TO DO IN ORDER TO GET EXTRA EGGS, BY DEFINITION, APPROPRIATE STIMULATION BEING WHAT WOULD OPTIMIZE THE OUTCOME FOR THE RECIPIENT WHILE CLEARLY TAKING INTO ACCOUNT THE HEALTH ISSUES FOR THE DONOR, THEN TRYING TO GET

EXTRA EGGS SO THAT YOU CAN MAKE EXTRA EMBRYOS FOR RESEARCH WOULD, BY DEFINITION, LEAD TO EXCESSIVE STIMULATION. THIS WOULD CAUSE INCREASED DISCOMFORT AND RISK IN THE DONOR, WHICH WOULD CAUSE HER TO PROBABLY HAVE LESS DESIRE TO COME BACK AND DO ANOTHER CYCLE.

AND SINCE THERE'S A LARGE INVESTMENT BY THE PRACTICE IN IDENTIFYING EGG DONORS, FINDING THEM, ADVERTISING FOR PEOPLE TO CALL YOU, AND THEN ONCE THEY CALL YOU, GOING THROUGH ALL THE HISTORY AND PHYSICAL AND GENETIC SCREENING AND INFECTIOUS DISEASE SCREENING, THE PSYCHOLOGICAL COUNSELING WE DO AND THE CONSENTING OF THEM TAKES A HUGE AMOUNT OF TIME AND MONEY. AND SO THERE'S A LARGE SORT OF SUNK INVESTMENT IN THE EGG DONOR. AND EXTRA STIMULATION TO GET EXTRA EGGS FOR RESEARCH WOULD NOT MAKE SENSE.

AND SO THE EGG DONOR IS NOT GOING TO WANT THE EXTRA STIMULATION, SHE'S NOT GOING TO WANT THE CYCLE TO BE CANCELED. SO SHE'S NOT GOING TO HAVE ANY MOTIVATION TO PROVIDE EXTRA EGGS. AND, OF COURSE, EGG DONORS ARE NOT PAID FOR THE NUMBER OF EGGS THEY GET, NOR FOR THE QUALITY OF THE EGGS THEY GET. THEY'RE PAID A SET AMOUNT REGARDLESS. IF WE GET NO EGGS, THEY STILL GET PAID THE FULL AMOUNT IF THEY GO THROUGH AN EGG RETRIEVAL.

SO THEY'RE NEVER PAID FOR THE NUMBER OF EGGS OR THE QUALITY OF EGGS. SO THERE'S ABSOLUTELY NO MOTIVATION FROM A REIMBURSEMENT PERSPECTIVE, FROM A PHYSICAL PERSPECTIVE FOR THEM TO WANT TO MAKE MORE EGGS.

THE OTHER THING IS THAT IN ESSENTIALLY ALL CASES, WHEN THE EGG DONOR HAS THE EGGS REMOVED FROM HER BODY, SHE DONATES THOSE TO THE RECIPIENTS WHO AT THAT POINT HAVE THE ABILITY TO CONSENT FOR SUBSEQUENT USE OF THOSE EGGS ONCE FERTILIZED AND BECOMING EMBRYOS. SO EVEN THOUGH WE WOULD CLEARLY CONSENT THE EGG DONOR FOR RESEARCH JUST AS WE CONSENT HER IN ADVANCE FOR WHAT TYPE OF SITUATION SHE WANTS THE EGGS USED IN, IF SHE HAD CONSENTED FOR RESEARCH IN GENERAL, ONCE THE EGGS ARE RETRIEVED, SHE'D HAVE NO FURTHER AUTHORITY OVER THOSE EGGS. SO THERE WOULD BE NO MOTIVATION FOR HER TO WANT TO TRY TO EXTEND THAT.

SO MY PERSPECTIVE IS THAT THE EGG DONOR WOULD HAVE NO MOTIVATION TO WANT TO PARTICIPATE IN A CYCLE IN WHICH MORE EGGS ARE RETRIEVED BY EXCESSIVE STIMULATION. IN TERMS OF THE RECIPIENT, IT'S VERY CLEAR THAT THESE PEOPLE WHO ARE RECIPIENTS JUST WANT A BABY. NOT ONLY HAVE THEY EXPERIENCED INFERTILITY FOR A LONG TIME IN ALMOST ALL SITUATIONS, BUT A

LARGE PROPORTION OF WOMEN WHO GO THROUGH EGG DONOR CYCLES HAVE ALREADY BEEN THROUGH UNSUCCESSFUL IVF CYCLES WITH THEIR OWN EGGS, AND THAT'S WHY THEY'RE USING DONOR EGGS. NOT EVERYBODY, BUT THE LARGE MAJORITY. AND SO THEIR PRIMARY INTEREST IS ABSOLUTELY REPRODUCTION, AND THEY NEVER WANT TO DO ANYTHING THAT'S GOING TO POTENTIALLY LIMIT THAT.

SO THEY'RE NOT GOING TO BE PREPARED TO TAKE SOME OF THEIR EMBRYOS AND GIVE THEM AWAY PRIOR TO HAVING THE OPPORTUNITY FOR THEM TO FULFILL THEIR COMPLETE OR MAXIMUM REPRODUCTIVE POTENTIAL. THEY'RE NOT GOING TO WANT THE EGG DONOR TO GET EXTRA STIMULATION BECAUSE IF THE CYCLE IS CANCELED, THEN ALL THE PREPARATION THAT THE WOMAN RECIPIENT HAS UNDERGONE IS GOING TO BE LOST, NOT TO MENTION ALL THE MONEY THAT WILL HAVE BEEN SPENT BECAUSE THEY STILL HAVE TO SPEND THE MONEY TO PAY PART OF THE EGG DONOR CYCLE, OF COURSE, AND THEY HAVE TO PAY FOR THEIR OWN TREATMENT, AND THIS WOULD ALL BE LOST COMPENSATION, LOST TIME, AND LOST EFFORT. SO THEY HAVE NO INTEREST IN GETTING THE DONOR STIMULATED SO MUCH THAT SHE MIGHT BE CANCELED.

AND AS HAS BEEN POINTED OUT NOW ON THE ISSUE OF TWO YEARS OR WHATEVER THE TIMEFRAME IS, THE REALITY OF IT IS THAT ESSENTIALLY ALL THE PATIENTS

WHO GET FROZEN EMBRYOS EITHER USE THEM FOR A SUBSEQUENT CYCLE IMMEDIATELY IF THEY DID NOT CONCEIVE IN THE FRESH EMBRYO TRANSFER IN THE DONOR CYCLE OR THEY SAVE THEM FOR SUBSEQUENT SIBLING, AND IT USUALLY IS ONLY, YOU KNOW, A COUPLE YEARS OR THREE YEARS OR WHATEVER AFTER THEY'VE DONE THE INITIAL CYCLE THAT THE RECIPIENT COUPLES MAKE A DECISION ON DISPOSITION OF THE EMBRYOS.

SO AT THE TIME THAT THEY'RE GOING THROUGH THE CYCLE, THERE'S NO EMOTIONAL MOTIVATION OR OTHERWISE TO CONSIDER THE RESEARCH ISSUE. THAT'S A REALLY AFTER-THE-FACT CONSIDERATION. AT THE SAME TIME, I THINK A LOT OF COUPLES WHO GO THROUGH THIS FEEL THAT THEY MAY NOT WANT TO DONATE THESE EMBRYOS TO ANOTHER COUPLE BECAUSE THAT COULD POTENTIALLY, OF COURSE, RESULT IN SIBLING CHILDREN IN OTHER FAMILIES.

I THINK MY PERSPECTIVE IS THAT MANY OF THE PEOPLE WHO DO THIS WOULD BE VERY HAPPY TO DONATE THESE EMBRYOS TO RESEARCH AFTER THEY HAD COMPLETED THEIR FAMILY AND HAD ONE OR TWO OR THREE KIDS OR WHATEVER THEY WANTED, AND THESE CHILDREN ARE WELL ON THEIR WAY IN LIFE. THEN PEOPLE WOULD THINK OF DONATING THESE EMBRYOS AS OPPOSED TO THE ALTERNATIVE, WHICH IS EITHER PAYING TO KEEP THEM

FROZEN, WHICH CAN BECOME EXPENSIVE, OR JUST DISCARDING THEM, WHICH I THINK MANY PEOPLE WOULD LIKE. THEY HAVE THE ALTRUISTIC ALTERNATIVE OF DONATING TO RESEARCH. BUT I DON'T THINK THERE'S GOING TO BE ANY MOTIVATION FOR AT LEAST SIGNIFICANT TIME PERIOD AFTER THE CYCLE.

FINALLY, FROM THE PHYSICIAN, IT'S UNFORTUNATE IT'S ALWAYS THE BAD PHYSICIANS WHO SEEM TO MAKE THE NEWS, BUT I THINK THE REALITY OF IT IS THE VAST MAJORITY OF PHYSICIANS WANT TO DO THE RIGHT THINGS FOR THEIR PATIENTS AND TRY, AND THEY CLEARLY HAVE A PROFESSIONAL AND LEGAL DUTY AND OBLIGATION TO DO WHAT'S RIGHT FOR THE EGG DONOR. WE SEE THE EGG DONOR AS OUR PATIENT, AND WE SEE THE RECIPIENTS AS OUR PATIENTS, AND WE SEE OURSELVES AS PROFESSIONALS WHO MUST ENSURE THAT THE BEST INTERESTS OF EACH AND THE HEALTH OF EACH ARE ENSURED.

AND OUR CONSENT FORMS AND CONTRACTS AND EVERYTHING ELSE REFLECT THAT WE WILL NOT PUT THE HEALTH RISK OR THE MORAL OR OTHER INTERESTS OF EITHER PARTY AT RISK. THAT'S WHY WE DO THE EXTENSIVE CONSULTING AND COUNSELING, PSYCHOLOGICAL COUNSELING AND SCREENING BEFOREHAND SO THAT EVERYBODY KNOWS WHAT THE ARRANGEMENTS WILL BE.

OBVIOUSLY OUR GOAL IS TO OPTIMIZE THE

PREGNANCY RATE FOR THE RECIPIENTS BECAUSE THAT'S WHAT OUR PROFESSIONAL OBLIGATION IS, BUT ALSO WE ALL WANT TO HAVE THE BEST POSSIBLE PREGNANCY RATE SO THAT PEOPLE TELL THEIR FRIENDS AND COME BACK, SO THAT WHEN THE CDC PUBLISHES THEM, THEY LOOK GOOD. SO THE DOCTOR IS NOT GOING TO HAVE ANY INTEREST IN LOWERING THE PREGNANCY RATE BY TAKING SOME EMBRYOS AWAY.

THE CYCLE IS COUNTED AS A CYCLE ONCE THE OVARIAN STIMULATION HAS STARTED. SO THAT IF WE OVERSTIMULATE A DONOR AND THEN CANCEL THAT CYCLE AND DON'T GO TO EGG RETRIEVAL, THAT STILL COUNTS AS AN IVF CYCLE IN THE CDC RESULTS THAT GET REPORTED NATIONALLY. SO THAT MEANS THAT YOU HAVE A NUMBER IN THE DENOMINATOR, BUT YOU'RE GOING TO HAVE A ZERO IN THE NUMERATOR BECAUSE YOU COULDN'T EVEN DO THE EGG RETRIEVAL AND GET THE EMBRYOS. SO THE DOCTORS HAVE NO MEDICAL INTEREST ON BEHALF OF EITHER THE PATIENT OR THE RECIPIENT OR THEMSELVES TO HAVE TO DEAL WITH A CANCELED CYCLE.

FURTHERMORE, IF THE PATIENT GETS HYPERSTIMULATED, THEN WE HAVE TO TAKE CARE OF THEM, AND THAT MEANS, YOU KNOW, IF IT'S A SERIOUS CONDITION, WE HAVE TO CERTAINLY SEE THEM IN THE OFFICE A LOT MORE AND MAYBE PUT THEM IN THE HOSPITAL

AND VISIT THEM IN THE HOSPITAL AND TAKE CARE OF THEM THERE. BESIDES THE OBVIOUS FACT THAT NOBODY WANTS COMPLICATIONS, YOU CERTAINLY DON'T WANT TO HAVE TO DEAL WITH THOSE COMPLICATIONS AND POTENTIALLY DEAL WITH MEDICAL-LEGAL RISKS FROM INAPPROPRIATE TREATMENT OF THE PATIENT.

SO THERE ARE A NUMBER OF VERY MAJOR MOTIVATORS FOR THE PHYSICIAN NOT TO OVERSTIMULATE THE PATIENT. AND IT GOES WITHOUT SAYING THAT THE PHYSICIANS HAVE NO ECONOMIC INTEREST IN GETTING EXTRA EGGS OR EMBRYOS FOR RESEARCH BECAUSE THEY'RE NOT COMPENSATED FOR IT.

IN ACTUAL FACT, DONATING, TALKING TO PATIENTS, GOING THROUGH THE PROCESS OF DONATING THE EMBRYOS IS A VERY ALTRUISTIC ACTIVITY FOR PHYSICIANS BECAUSE WE GET NO MONEY FOR IT, AND IT TAKES A MASSIVE AMOUNT OF TIME TO DEAL WITH ALL THE CONSENTING AND DISCUSSION WITH PATIENTS AS WELL AS THE PAPERWORK AND THE ACTUAL TRANSFER OF IT. SO THERE'S ABSOLUTELY NO ECONOMIC BENEFIT OF TRYING TO DO IT. AND IT'S ONLY DONE FROM AN ALTRUISTIC PERSPECTIVE.

SO I GUESS JUST BEING SOMEONE WHO'S IN THE TRENCHES EVERY DAY DOING THIS, WHILE RECOGNIZING THAT THERE HAVE BEEN STORIES OUT THERE, AND

UNDOUBTEDLY THERE ARE SOME PEOPLE WHO HAVE TAKEN ADVANTAGE OF EGG DONORS, FROM ANY NORMATIVE PERSPECTIVE OF ANY OF THE PARTIES INVOLVED, I DON'T SEE ANY MOTIVATION TO DO THE WRONG THING. AND THERE'S A LOT OF MOTIVATION TO DO THE RIGHT THING. SO I WOULD BE, FROM MY PERSPECTIVE, VERY SUPPORTIVE OF NOT HAVING MORE LIMITATIONS THAN ARE NECESSARY.

CHAIRMAN LO: DR. ADAMSON, THANK YOU. THAT WAS VERY LUCID AND VERY HELPFUL. QUESTIONS FROM ANYONE ON THE COMMITTEE FOR DR. ADAMSON?

DR. TROUNSON: DAVID, DO YOU WANT TO COMMENT ON THE CONSENT PROCESS FOR RESEARCH, AND HOW WIDESPREAD THE GENERAL CONSENT IS FOR RESEARCH THAT MIGHT BE RELEVANT TO EMBRYONIC STEM CELLS?

DR. ADAMSON: CERTAINLY. I'M TALKING TO A GROUP OF EXPERTS ON THIS, SO I WOULDN'T WANT TO GET INTO ANY OF THE TECHNICAL REALMS OF IT. BUT WHAT I CAN SAY IS THAT WHEN WE TALK TO PATIENTS AND GIVE THEM THE MAJOR CHOICES THEY HAVE OF DISPOSITION OF EMBRYOS, CLEARLY THE FIRST ONE IS TO REPLACE THEM IN THEIR OWN UTERUS IN AN ATTEMPT TO HAVE A BABY. AND SECOND IS TO FREEZE THEM, WHICH WE CAN OFTEN DO WITH EGG DONORS, SO THAT WE CAN HAVE THEM FOR SUBSEQUENT CYCLES.

THE VAST MAJORITY OF PATIENTS CONSENT TO

EMBRYO FREEZING. THERE ARE VERY, VERY FEW WHO DON'T. I WOULD JUST ESTIMATE 1 OR 2 PERCENT AT THE MAXIMUM WHO WOULD NOT AGREE TO EMBRYO FREEZING. USUALLY ON RELIGIOUS OR MORAL GROUNDS, THEY DON'T FEEL IT'S THE RIGHT THING TO DO, BUT CERTAINLY HERE IN CALIFORNIA THAT WOULD BE, IN MY EXPERIENCE, AN EXTREMELY SMALL PROPORTION OF PATIENTS. AND THEN YOU GET INTO THE MORE DIFFICULT ONES, WHICH IS, YOU KNOW, DISCARDING THE EMBRYOS, DONATING THEM TO RESEARCH, OR DONATING THEM TO ANOTHER COUPLE.

IN MY PERSPECTIVE THE DONATION TO ANOTHER COUPLE SOUNDS TO MOST OF THE PATIENTS FAIRLY DISTANT BECAUSE THEY DON'T EVEN HAVE THEIR OWN CHILD, SO I THINK THAT'S AN OPTION THAT THEY HAVE A DIFFICULT TIME EMOTIONALLY UNDERSTANDING WHEN WE FIRST DISCUSS IT. OF COURSE, AT A LATER TIME, WHEN THAT CONCEPT COMES UP, THERE'S THE ISSUE THAT THE EMBRYOS THAT COULD BE DONATED TO ANOTHER COUPLE, IN FACT, WOULD BE SIBLING EMBRYOS TO THEIR OWN CHILDREN IF THEY HAVE CHILDREN BECAUSE ALMOST NOBODY DONATES UNTIL THEY'VE USED THEM ALL UP TO HAVE THEIR OWN CHILDREN, SO THEIR FAMILIES ARE COMPLETED. SO THAT'S NOT A VERY POPULAR OPTION FOR PEOPLE.

AND SO THEN WE'RE LEFT REALLY WITH THE TWO OPTIONS OF EITHER DONATING TO RESEARCH OR ELSE

DISCARDING. AND IN MY EXPERIENCE, WHEN YOU TALK ABOUT DONATING TO RESEARCH, THERE IS A GREAT DEAL OF INTEREST IN DONATING TO ANY TYPE OF STEM CELL RESEARCH BECAUSE, OF COURSE, PEOPLE ARE VERY EXCITED ABOUT WHAT THEY SEE AS THE POSSIBILITY FOR THERAPEUTIC INTERVENTION. AND I THINK ESSENTIALLY EVERYONE HAS A VERY STRONG ALTRUISTIC SENSE WHEN IT COMES TO THIS. THE INFERTILE PATIENTS WHO'VE GONE THROUGH ALL THEIR INFERTILITY, ALL THEIR TREATMENT, THEN END UP USING DONOR EGGS AND END UP HAVING A BABY, I THINK, DO HAVE A REAL INCREDIBLE SENSE OF GRATITUDE ABOUT WHERE THEY ARE. AND I THINK THAT THEY'RE VERY MOTIVATED TO TRY TO DONATE. YOU KNOW, IF THEY COULD DONATE TO RESEARCH, THEY WOULD.

AND I THINK THEY WOULD -- GENERALLY THE DONATION TO RESEARCH WOULD SORT OF FALL INTO TWO CATEGORIES. ARE YOU JUST GOING TO DO SOMETHING WITH THE EMBRYO IN THE LAB THAT, FOR EXAMPLE, IN THE LAB TO DO TESTING OF COMPOUNDS OR CHEMICALS OR SOMETHING IN A STANDARD KIND OF WAY. AND SOME PEOPLE ARE VERY COMFORTABLE WITH THAT, BUT THEY'RE MUCH MORE COMFORTABLE WITH THE CONCEPT THAT THEY WILL BE USED IN EXPERIMENTS THAT COULD POTENTIALLY LEAD TO REAL BENEFIT TO HUMAN KIND.

AND SO I THINK A VERY GENERIC CONSENTING

PROCESS OF THESE WILL BE USED IN STEM CELL RESEARCH WITH A VERY RESPONSIBLE BODY. I MEAN THAT'S SOMETHING THAT, FRANKLY, BECAUSE WE'RE HERE AND HISTORICALLY WE'VE BEEN ABLE TO TALK ABOUT, YOU KNOW, WE SENT OUR EMBRYOS TO UCSF, A FEW TIMES TO STANFORD, AND CERTAINLY WITH THE CIRM, IF PEOPLE KNOW THAT THERE'S A VERY, VERY LEGITIMATE BODY DOING THE RESEARCH AND OVERSEEING THE RESEARCH, MY SENSE IS THE PATIENTS, THE VAST MAJORITY OF PATIENTS, 95 PERCENT PLUS WOULD BE VERY COMFORTABLE WITH A VERY GENERAL RESEARCH DIRECTIVE TO THAT TYPE OF ORGANIZATION, TRUSTING IN THE SCIENTISTS AND THE PHYSICIANS WHO TALK TO THEM THAT THE RIGHT THINGS WILL BE DONE. AND I DON'T THINK A LOT OF SPECIFICITY WOULD BE NECESSARY AT ALL.

AND EVEN WITH THE EGG DONORS, THAT'S PROBABLY EVEN MORE SO BECAUSE YOU DON'T HAVE EMBRYOS. YOU STILL HAVE EGGS. AND THE REALITY OF IT IS, I'M SURE EVERYBODY ON THE COMMITTEE KNOWS, BUT THE REALITY OF IT IS THE WAY OVARIAN STIMULATION WORKS, WE ONLY STIMULATE EGGS THAT ARE POTENTIALLY READY TO BE MATURED AT THAT POINT IN TIME. WE DO NOT GO FORWARD AND TAKE EGGS OUT OF THE OVARY THAT THE WOMAN WOULD HAVE FOR THE FUTURE. THERE'S NO EVIDENCE AT ALL THAT WE DO THAT.

IN FACT, IN REALITY WHEN WE STIMULATE THE EXTRA EGGS AND REMOVE THEM FROM THE BODY, WE'RE SIMPLY TAKING EGGS THAT WOULD HAVE DIED DURING THAT CYCLE ANYWAY. AND SO WE'RE NOT CREATING A DELETERIOUS REPRODUCTIVE SITUATION FOR THE PATIENT IN THE FUTURE. SO THERE'S IN A SENSE AN OPPORTUNITY TO HAVE SOME RESEARCH VALUE COME FROM THOSE EGGS THAT THE DONOR IS GIVING RATHER THAN HAVE THEM DIE ON THEIR OWN DURING THAT CYCLE. WHEN WE EXPLAIN THAT TO THE EGG DONOR IN TERMS OF CONSENTING, THEY'RE VERY HAPPY TO THINK, WELL, THESE EGGS ARE GOING TO DIE, OR THEY COULD POTENTIALLY HELP SOMEBODY HAVE A FAMILY, AND THEY COULD POTENTIALLY BE USED IN RESEARCH TO HELP HUMANKIND.

AND EVEN THOUGH THESE DONORS DO GET PAID, MAKE NO MISTAKE, THERE'S A LOT OF ALTRUISM, AND THE VAST MAJORITY, I MEAN, YOU CAN IDENTIFY SOMEONE WHO SHOWS UP ONCE IN A WHILE, IT'S ABOUT THE MONEY. MOST OF THEM DON'T MAKE IT THROUGH IT BECAUSE THERE'S TOO MUCH TO DO. THERE'S TOO MUCH OF A COMMITMENT ON THE EGG DONOR PART, THAT IF THEY DON'T HAVE SOME SUBSTANTIAL DEGREE OF ALTRUISM, I THINK HARDLY ANY OF THEM GO THROUGH IT UNLESS THEY ARE FAIRLY -- HAVE A SUBSTANTIAL COMMITMENT ON THE ALTRUISTIC SIDE OF IT.

CHAIRMAN LO: OKAY. THANKS. ANY OTHER QUESTIONS FROM THE COMMITTEE FOR DR. ADAMSON?

PROFESSOR ROBERTS: I HAVE A QUESTION. DR. ADAMSON, THIS IS DOROTHY ROBERTS. I UNDERSTOOD EVERYTHING YOU WERE SAYING ABOUT THE LOW TO NO MOTIVATION ON THE PART OF EVERYBODY TO PRODUCE EGGS FOR RESEARCH. BUT THAT SEEMED TO APPLY TO THE SITUATION WHERE THE DOCTOR, LIKE YOURSELF, WAS NOT CONNECTED TO RESEARCH AT ALL. ARE THERE SITUATIONS WHERE THE FERTILITY DOCTOR MIGHT BE EITHER A COLLEAGUE OF SOMEONE WHO IS DOING STEM CELL RESEARCH WHERE THE MOTIVATION MIGHT CHANGE, MIGHT BE DIFFERENT?

DR. ADAMSON: I THINK, YOU KNOW, EVERYBODY IS HUMAN. AND SO THERE'S CERTAINLY MOTIVATION. I THINK IT WOULD BE FAIR TO STATE, AND WE'VE CERTAINLY SEEN A LOT OF EXAMPLES IN THE PAPERS RECENTLY, THAT IF SOMEBODY HAD A SUBSTANTIAL FINANCIAL INTEREST IN RESEARCH THAT WERE BEING DONE, THAT THAT WOULD CLEARLY CREATE AN INDUCEMENT THAT SOME PEOPLE WOULD FIND TOO GREAT TO IGNORE. AND SO I'M NOT SO NAIVE AS TO THINK THAT IF SOME PHYSICIAN, YOU KNOW, WERE IN SOME WAY SELLING EMBRYOS TO COUNTRY X, I DON'T WANT TO NAME ONE SOMEWHERE ELSE, THAT THAT WOULD BE PROBLEMATIC.

SO I CERTAINLY DON'T THINK THERE SHOULD BE FINANCIAL INDUCEMENTS THAT ARE AVAILABLE TO PHYSICIANS WHO ARE DOING THAT BECAUSE I THINK THAT COULD CREATE A PROBLEM. THAT DOESN'T MEAN I DON'T THINK PHYSICIANS SHOULD GET COMPENSATED FOR A LEGITIMATE AMOUNT OF WORK THAT'S DONE. THERE'S A LOT OF WORK THAT'S REQUIRED TO CONSENT SOMEBODY AND MOVE THEM. BUT THERE CERTAINLY SHOULDN'T BE ANY TYPE OF MONEY THAT COULD BE CONSIDERED AN INDUCEMENT.

NOW, WHETHER YOU JUST GIVE -- YOU HYPEROVERSTIMULATE A PATIENT OR WHATEVER BECAUSE YOU HAD A COLLEAGUE, I FRANKLY CAN'T IMAGINE THAT. WHY WOULD A DOCTOR GO OUT AND PUT HIS NAME AND HIS PRACTICE AND HIS REPUTATION AT RISK, NOT TO MENTION PRACTICE BAD MEDICINE, BECAUSE SOMEBODY THEY KNEW WAS DOING STEM CELL RESEARCH? FRANKLY, THAT DOESN'T MAKE ANY SENSE TO ME AT ALL. NO, I DON'T SEE THAT.

I DO SEE A POTENTIAL HAZARD IF THERE'S A SIGNIFICANT FINANCIAL INDUCEMENT. BUT TO THINK THAT A DOCTOR, BECAUSE THEY'RE GOING TO GET PAID 250 BUCKS FOR THE WORK INVOLVED WITH TRANSFERRING EMBRYOS FROM THEIR FACILITY TO A RESEARCH FACILITY, IS GOING TO INDUCE SOMEBODY TO HYPERSTIMULATE A PATIENT AND THEN THE NUMBER OF PHONE CALLS AND

OFFICE VISITS AND TRIPS TO THE HOSPITAL AND WHATEVER TO DEAL WITH THE SICK PATIENT, NO, I THINK THE PROBABILITY OF THAT IS SO CLOSE TO ZERO AS NOT TO BE IMPORTANT. WE'RE ALWAYS GOING TO HAVE PSYCHOPATHS, SOCIOPATHS, AND FELONS. I DON'T THINK WE CAN GET RID OF THEM IN ANY PROFESSION. BUT I THINK THAT THE PROCESS OF LOOKING AT THIS SHOULD LOOK AT WHAT 99 PERCENT OF THE PEOPLE ARE GOING TO DO. I WOULDN'T SEE ANY AVERAGE PHYSICIAN BEING INDUCED TO UNLESS THERE WERE SIGNIFICANT AMOUNTS OF FINANCIAL BENEFIT, WHICH I THINK CLEARLY SHOULD NOT BE POSSIBLE, SHOULD BE ILLEGAL TO DO THAT.

CHAIRMAN LO: ANY OTHER QUESTIONS FROM THE COMMITTEE? DR. ADAMSON, WHILE WE HAVE YOU HERE, I'M GOING TO ASK IF THERE ARE ANY QUESTIONS FROM THE PUBLIC MEMBERS HERE IN DOWNTOWN SAN FRANCISCO.

MS. FOGEL: I'M SUSAN FOGEL. I'M WITH THE PRO-CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH. AND I GUESS THE QUESTION I WANT TO RAISE IS TO GO BACK TO THIS QUESTION OF THE FACT THAT 88 PERCENT OF THE EMBRYOS ARE CREATED WITH A WOMAN'S OWN EGGS. AND IT WAS INTERESTING TO HEAR WHAT YOU HAD TO SAY, DR. ADAMSON, ABOUT THE RESEARCH BECAUSE -- ABOUT THE DESIRE TO CONTRIBUTE TO RESEARCH BECAUSE THERE IS A NEW STUDY OUT OF DUKE UNIVERSITY SHOWING THAT 60

PERCENT OF COUPLES WHO'VE CREATED EMBRYOS IN FERTILITY CONTEXT WOULD LIKE TO BE ABLE TO DONATE THEM TO RESEARCH. THEY DON'T HAVE A GOOD MECHANISM, AND STEM CELL RESEARCH IN PARTICULAR, THERE'S NOT A GOOD MECHANISM TO HELP THEM DO THAT.

SO I FEEL THAT WE'VE DRAWN A LINE ABOUT PAYMENT. AND SINCE WE'RE TALKING ONLY ABOUT 12 PERCENT, I REALLY WOULD LIKE TO HEAR A LOT MORE ABOUT THE RESEARCH THAT SUGGESTS THAT THESE 12 PERCENT ARE SO IMPORTANT VERSUS THE REST OF THE 88 PERCENT WHEN YOU HAVE A REALLY WILLING GROUP OF PEOPLE WHO WANT TO MAKE THEM AVAILABLE FOR RESEARCH.

DR. ADAMSON: THANK YOU, SUSAN. I WOULD AGREE WITH YOUR COMMENTS. I THINK THAT DR. TROUNSON MENTIONED SOME OF THE REASONS THAT I THINK WE REALLY DO WANT TO BE ABLE TO OBTAIN THE EMBRYOS FROM DONORS -- THAT HAVE BEEN CREATED THROUGH DONOR EGG CYCLES THAT WERE THERAPEUTIC CYCLES IN WHICH THE EGG DONOR WAS PAID BECAUSE THE EGGS DO COME FROM YOUNGER PATIENTS, AND EVEN THOUGH IT'S A SMALLER -- IT'S A SMALL PROPORTION OF THE PATIENTS. IT'S ONLY 12 PERCENT OF THE PATIENTS, BUT BECAUSE THEY'RE YOUNGER, THEY WILL MAKE MORE EMBRYOS AND THE PREGNANCY RATES ARE HIGHER.

AND SO PROPORTIONALLY I DON'T KNOW THE

NUMBER, BUT I AM ABSOLUTELY CERTAIN THAT THEY WILL PRODUCE OR HAVE STORED FROZEN SIGNIFICANTLY MORE THAN 12 PERCENT OF THE EMBRYOS.

SO I THINK THE EGG DONOR SOURCE OF EMBRYOS IS VERY IMPORTANT, BUT I AGREE COMPLETELY WITH YOU ABOUT FACILITATING THE OPPORTUNITIES FOR INFERTILE COUPLES WHO HAVE UTILIZED THEIR OWN GAMETES TO HAVE A FAMILY AND WHO THEN HAVE FROZEN EMBRYOS THAT THEY DO NOT WANT TO REPLACE IN THEIR OWN UTERUS BECAUSE THEIR FAMILY IS COMPLETED TO BE ABLE TO DONATE THEM MUCH MORE EASILY TO RESEARCH.

WE HAVE TRIED -- WHEN WE FIRST STARTED DOING THIS, IT PROBABLY SOUNDS UNBELIEVABLE, BUT WE SPENT TWO AND THREE YEARS TRYING TO GET THROUGH THE CONSENT FORMING PROCESS WITH UCSF TO TRY TO GET SOME EMBRYOS FROM THEM, WILLING PARTIES. EVERYBODY WAS A WILLING PARTY. THE DOCTORS WERE A WILLING PARTY, THE PATIENT WANTED TO DONATE, AND UCSF WANTED THEM, AND TO GO THROUGH THE PROCESSES TOOK YEARS. AND, FRANKLY, UNLESS THE PHYSICIAN AND THE PATIENTS HAVE A LARGE COMMITMENT TO THIS, IT JUST DOESN'T HAPPEN BECAUSE THE TIME AND EFFORT, AND THAT DOES TRANSLATE INTO COST FOR EVERYBODY, BECOMES TOO GREAT.

SO I THINK IT'S IMPERATIVE THAT WE FIND, IN MY VIEW, THAT WE FIND MUCH SIMPLER WAYS THAT

STILL TAKE INTO ACCOUNT THE NECESSARY CONSENTING, COUNSELING FOR THE PATIENTS SO THAT THEY ARE COMFORTABLE THAT THEY HAVE MADE THE RIGHT CHOICE FOR THEMSELVES, AND THE APPROPRIATE PROTECTIONS CLEARLY NEED TO BE IN PLACE, BUT I THINK IT IS IMPERATIVE THAT WE SOLVE THIS ISSUE.

CHAIRMAN LO: THANK YOU. ANY OTHER QUESTIONS, COMMENTS? ONE OTHER PUBLIC QUESTION FOR YOU, DR. ADAMSON.

DR. DARNOVSKY: DR. ADAMSON, THIS IS MARCY DARNOVSKY FROM THE CENTER FOR GENETICS AND SOCIETY. YOU SAID THAT YOU THOUGHT YOU COULD POTENTIALLY SEE A HAZARD IF THE DOCTOR WAS RECEIVING SOME KIND OF A FINANCIAL RETURN, A SIGNIFICANT FINANCIAL RETURN BEYOND, YOU KNOW, APPROPRIATE REIMBURSEMENT FOR HIS OR HER TIME AND EFFORTS. SO I GUESS MY QUESTION IS WOULD YOU ALSO SEE A HAZARD IF THE FERTILITY DOCTOR WAS NOT RECEIVING MONEY, BUT WAS HIMSELF OR HERSELF ENGAGED IN STEM CELL RESEARCH AS EVIDENCED BY PAPERS PUBLISHED IN PEER REVIEW JOURNALS AND THINGS LIKE THAT?

DR. ADAMSON: I THINK THAT THAT -- WHILE I WOULDN'T SAY THAT ANY TIME THERE WAS A RELATIONSHIP LIKE THAT THERE WAS DEFINITELY A HAZARD. I WOULD ABSOLUTELY AGREE THAT IF A PHYSICIAN WERE INVOLVED

IN DOING -- DIRECTLY INVOLVED IN DOING STEM CELL RESEARCH OR IN OTHER ACTIVITIES THAT CREATED ECONOMIC BENEFIT FOR THEM, THAT IT WOULD CERTAINLY BE POTENTIALLY PROBLEMATIC FOR THEM TO BE CREATING EMBRYOS.

NOW, I WANT TO MAKE IT VERY CLEAR THAT I USE POTENTIALLY BECAUSE I THINK IT'S INAPPROPRIATE TO CONSIDER THAT EVERY PHYSICIAN WHO IS INVOLVED IN AN ACTIVITY IS GOING TO TRY TO IDENTIFY A WAY TO, YOU KNOW, ENSURE THAT THEIR SELF-INTEREST IS OPTIMIZED POTENTIALLY AT THE EXPENSE OF OTHERS. I THINK THAT'S A PEJORATIVE PERSPECTIVE ON PHYSICIANS WITH WHICH I WOULD NOT AGREE.

HAVING SAID THAT, IT'S ABSOLUTELY CLEAR THAT WHERE ECONOMIC FINANCIAL INDUCEMENTS OR RELATIONSHIPS ARE SUCH THAT ONE COULD GAIN SUBSTANTIALLY FROM AN ACTIVITY IN ONE SPHERE, GAIN IN ANOTHER SPHERE, I THINK THAT ANY TYPE OF SITUATION LIKE THAT WOULD HAVE TO BE EVALUATED EXTREMELY CAREFULLY TO MAKE SURE THAT IT WAS A LEGITIMATE RELATIONSHIP. AND IT MAY WELL BE THAT A DECISION WAS MADE THAT MOST OF THE TIME OR ALL THE TIME THEIR RELATIONSHIP, EVEN IF IT APPEARED TO GIVE THE POTENTIAL OR HAZARD TO THE PATIENT, THAT IT SHOULD NOT BE ALLOWED.

AND I WOULDN'T -- I DON'T FEEL I'M IN A POSITION TO PROVIDE DETAILS AND EVERYTHING RIGHT AT THIS POINT, BUT, YES, I WOULD SHARE A CONCERN ABOUT A PROBLEM. AND I THINK IF SUCH RELATIONSHIPS WERE ALLOWED, THEY'D HAVE TO BE VERY, VERY CAREFULLY STRUCTURED AND THAT WHATEVER WAS STRUCTURED NOT ONLY BE LEGITIMATE AND APPROPRIATE FOR THAT INDIVIDUAL, BUT SHOULD BE FOR THE PROCESS OVERALL AND SHOULD APPEAR TO BE SO FOR THE PUBLIC CONFIDENCE IN THE ENTIRE ARRANGEMENT FOR THE EMBRYO DONATION TO RESEARCH.

I THINK CREATING A LEGITIMATE PROCESS WITH INTEGRITY THAT THE PUBLIC HAS CONFIDENCE IN WOULD BE THE BEST WAY TO OPTIMIZE THE UTILIZATION OF THESE FROZEN EMBRYOS. AND I THINK THAT LIMITING CERTAIN RELATIONSHIPS OR ECONOMIC RELATIONSHIPS IN ORDER TO ACHIEVE THIS WOULD BE LEGITIMATE.

CHAIRMAN LO: OTHER QUESTIONS? DR. ADAMSON, THIS IS BERNIE LO. COULD I ASK YOU A COUPLE QUESTIONS? IT SOUNDS LIKE FROM WHAT YOU SAID THAT IN THE U.S. AND PARTICULARLY FOR PHYSICIANS WHO ARE MEMBERS OF SART, THERE ARE MANY INCENTIVES FOR DOCTORS NOT TO PUT EITHER DONORS OR RECIPIENTS AT RISK IN ORDER TO FURTHER STEM CELL RESEARCH. I THOUGHT YOU LAID THAT OUT VERY NICELY.

I'M JUST WONDERING IF WE SHOULD HAVE CONCERNS IN SITUATIONS OTHER THAN SORT OF THE ONE YOU SKETCHED. I GUESS THE COUPLE OF QUESTIONS I WOULD LIKE TO GET YOUR THOUGHTS ON, YOU MENTIONED THAT HAVING TO REPORT OUTCOMES IN IVF CENTERS BASED ON SUCCESS RATES WHICH INCLUDE CYCLES THAT HAVE STARTED IS A BIG DISINCENTIVE TO TRYING TO OVERSTIMULATE A PATIENT AND POTENTIALLY CANCEL A CYCLE.

SO MY FIRST QUESTION IS SHOULD THERE BE A PROVISION IN OUR DISCUSSION THAT THE EMBRYOS SHOULD EITHER BE FROM SART MEMBER PROGRAMS OR THE PROGRAMS THAT REPORT THEIR SUCCESS RATE TO THE SART CDC DATABASE?

AND MY SECOND QUESTION REALLY HAS TO DO WITH INTERNATIONAL CONTEXT BECAUSE THIS IS PERHAPS AN INTERNATIONAL SITUATION. I'M JUST WONDERING IF IN OTHER COUNTRIES THE PROTECTIONS YOU OUTLINE OR THE INCENTIVES OUTLINED IN THE U.S. WOULDN'T HOLD, AND THERE WOULD BE CONCERNS ABOUT OVERSTIMULATION.

DR. ADAMSON: I THINK THAT, YES, I WOULD RESTRICT DONATION TO PROGRAMS THAT AGREED TO ADHERE TO CERTAIN STANDARDS. I SINCERELY HAVE SOME BIAS IN THINKING THAT SART WOULD BE A VERY APPROPRIATE PLACE, ORGANIZATION WITH WHOM TO WORK TO ESTABLISH

ANY ADDITIONAL STANDARDS AND TO LOOK AT THE STANDARDS THEY HAVE AND TO COMMUNICATE WITH SART AND WITH ASRM ABOUT ANY ISSUES SO THAT THEY COULD BE ADDRESSED AND MUTUALLY AGREEABLE GUIDELINES, PRINCIPLES, ARRANGEMENTS COULD BE ESTABLISHED FOR THAT. SO I THINK THAT WOULD BE VERY APPROPRIATE.

FROM AN INTERNATIONAL PERSPECTIVE, AND I HAVE BEEN -- I'M ON THE BOARD OF THE INTERNATIONAL COMMITTEE MONITORING ART, SO WE ACTUALLY PUBLISH THE IVF RESULTS FROM ALL AROUND THE WORLD, THE WORLD REPORT ON IVF RESULTS. SO I'VE HAD A LOT OF EXPERIENCE WITH THE INTERNATIONAL COMMUNITY IN THE PUBLISHING OF ART RESULTS THROUGH REGISTRIES AND HAVE DONE SOME WORK WITH THE WHO ON THIS AS WELL.

I THINK THE INTERNATIONAL SITUATION IS VERY VARIABLE. THERE ARE UNQUESTIONABLY SOME COUNTRIES FROM WHICH I THINK WE COULD HAVE A LOT OF CONFIDENCE THAT STANDARDS THAT WERE SIMILAR TO OURS WOULD BE IN PLACE AND THAT WE POTENTIALLY HAVE INTERNATIONAL ARRANGEMENTS. THERE ARE UNQUESTIONABLY SOME COUNTRIES, WHICH I PREFER NOT TO NAME AT THIS POINT, BUT WITH WHICH THERE MAY, IN FACT, BE SOME REAL CONCERN ABOUT THE REGULATORY FRAMEWORK AND THE ABILITY TO PROTECT ALL THE INVOLVED PARTIES.

AND SO I THINK THAT RELATIONSHIPS COULD BE ESTABLISHED, BUT IT WOULD BE IMPORTANT TO HAVE A GUIDELINE/REGULATORY FRAMEWORK UNDER WHICH THAT COULD BE DONE. AND EACH ONE WOULD HAVE TO BE ASSESSED INDIVIDUALLY.

CHAIRMAN LO: ANY FURTHER QUESTIONS FROM THE COMMITTEE FOR DR. ADAMSON? I WANT TO ACTUALLY -- WE ARE SCHEDULED TO END AT 1 O'CLOCK. AND SO I WOULD LIKE TO SORT OF GET US BACK TO THE SUGGESTION, THE PROPOSAL TO CHANGE THE CUTOFF DATE. AND I WANTED TO SEE IF, AFTER DR. ADAMSON'S PRESENTATION, DISCUSSION, ANYONE WANTS TO SUGGEST ANY CHANGES OR MAKE ANY COMMENTS ON THE PROPOSAL TO HAVE WHAT GEOFF HAS CALLED A ROLLING STANDARD FOR USE OF EMBRYOS? OKAY. PUBLIC COMMENT ON THE PROPOSAL?

MS. FOGEL: THIS IS SUSAN FOGEL AGAIN. I GUESS WE -- THE PRO-CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH WOULD NOT LIKE TO SEE THE CUTOFF DATE CHANGED. WE DON'T THINK THERE'S YET BEEN SUFFICIENT EVIDENCE. I RESPECT OBVIOUSLY YOUR EXPERTISE, DR. TROUNSON, BUT I THINK THAT THE WORKING GROUP REALLY OUGHT TO LOOK MUCH MORE CAREFULLY AT THE EVIDENCE THAT THERE'S A NEED TO CHANGE IT.

WE'VE ALREADY HEARD ABOUT HOW THERE ARE

PEOPLE WHO WANT TO DONATE THEIR EMBRYOS, WHO HAVEN'T BEEN ABLE TO. APPARENTLY IT'S ALL YOUR FAULT, BERNIE, BUT I THINK THAT OTHER AVENUES OUGHT TO BE INVESTIGATED BEFORE WE CROSS THE LINE. WE ARE CROSSING A LINE ABOUT PAYMENT, AND I THINK WE HAVE TO BE REALLY CONSCIOUS AND CLEAR ABOUT THE FACT THAT WE ARE CROSSING A PAYMENT LINE, AND THAT THERE NEEDS TO BE MORE AND BETTER INFORMATION BEFORE THE WORKING GROUP BEFORE THEY RECOMMEND THAT THAT LINE BE CROSSED.

PROFESSOR ROBERTS: I JUST WANT TO ADD TO WHAT SUSAN IS SAYING. WHAT I FIND LACKING OR I'D LIKE TO SEE MORE ABOUT IS NOT JUST WHETHER THERE ARE WAYS SO THAT PEOPLE WHO CREATED EMBRYOS WITH THEIR OWN GAMETES AND THERE ARE NO PAID GAMETES INVOLVED COULD DONATE, BUT ALSO, THEN, THE QUESTION OF WHETHER THEIR EMBRYOS ARE OF LESS QUALITY FOR STEM CELL RESEARCH PURPOSES THAN THOSE OF PAID DONORS. AND A COUPLE PEOPLE HAVE STATED THAT. AND MAYBE I JUST DON'T HAVE ALL THE INFORMATION THAT OTHERS HAVE, BUT I JUST -- I WONDER IS THAT SOMETHING THAT HAS BEEN SHOWN IN EVIDENCE-BASED RESEARCH, OR IS IT A GENERAL SENSE THAT LOGICALLY THE YOUNGER DONORS, THAT THEIR EMBRYOS WOULD BE OF HIGHER QUALITY AND VITALITY? WHAT IS THE SCIENTIFIC BASIS FOR THAT?

AND ALSO, DO WE KNOW WHAT IMPACT THAT ACTUALLY HAS ON STEM CELL RESEARCH?

SO IS THERE EVIDENCE THAT LACKS A SUPPLY OF EMBRYOS CREATED WITH YOUNGER WOMEN'S EGGS IS HAVING A DETRIMENTAL IMPACT ON STEM CELL RESEARCH?

DR. ADAMSON: COULD I JUST ANSWER THAT? THIS IS DR. ADAMSON, AND I AM NOT GOING TO ANSWER THIS WITH RESPECT TO STEM CELLS BECAUSE DR. TROUNSON CAN CERTAINLY DO THAT. BUT I JUST, YOU KNOW, NEED TO MENTION THAT FROM A CLINICAL PERSPECTIVE, WE WORK WITH PATIENTS OF ALL AGES, OF COURSE, FROM EARLY TWENTIES UP THROUGH MID-FORTIES. AND FROM A BIOLOGIC PERSPECTIVE, THERE ARE LITERALLY THOUSANDS, IF NOT TENS OF THOUSANDS, OF PAPERS IN THE LITERATURE WHICH DEMONSTRATE THAT AS A WOMAN GETS OLDER, THE EGG QUALITY AS EVIDENCED BY ITS CHROMOSOMAL CONTENT AND EVIDENCED BY ITS ABILITY TO MAKE AN EMBRYO THAT WILL IMPLANT AND GROW INTO A BABY, NOT TO MENTION THE FACT THAT THE CHROMOSOMAL ABNORMALITIES GO UP AS THE EMBRYOS GET OLDER, THAT THERE IS JUST ABSOLUTELY OVERWHELMING EVIDENCE THAT THE BIOLOGIC VIABILITY AND REPRODUCTIVE POTENTIAL OF THE OLDER EMBRYO IN THE CLINICAL SITUATION IS DRAMATICALLY LESS THAN THAT OF THE YOUNGER EGG DONOR WHO COMES FROM A, QUOTE, NORMAL, QUOTE, POPULATION,

NOT AN INFERTILE POPULATION.

SO I'M NOT TRYING TO SPEAK TO THE STEM CELL, BUT THE BIOLOGIC REALITY AND PLAUSIBILITY THAT A STEM CELL WOULD BE AFFECTED IS CLEARLY OVERWHELMING, I THINK.

PROFESSOR ROBERTS: IS THERE THAT CONNECTION BECAUSE YOU'RE SPEAKING OF THE POTENTIAL FOR CREATING AN EMBRYO, BUT WE'RE TALKING ABOUT EMBRYOS THAT ALREADY HAVE BEEN CREATED AND EXIST FOR STEM CELL RESEARCH. AND MAYBE I'M WRONG. ARE WE CONCERNED NOW WITH THE REPRODUCTIVE CAPACITY? ISN'T THAT DIFFERENT FROM USE FOR STEM CELL RESEARCH?

DR. ADAMSON: I'D LET DR. TROUNSON RESPOND. WE ARE TALKING ABOUT CELL POTENTIAL. AND CERTAINLY YOU HAVE AN EMBRYO FROM A 42-YEAR-OLD AND AN EMBRYO FROM A 23-YEAR-OLD, AND THEY'RE BOTH EMBRYOS, AND THEY CAN ACTUALLY LOOK THE SAME, BUT THEIR REPRODUCTIVE POTENTIAL IS COMPLETELY DIFFERENT. BUT I DON'T WANT TO GET PAST MY AREA, WHICH IS CLINICAL EMBRYOS AND IMPLANTATION RATES AND WHAT HAVE YOU. BUT CERTAINLY THERE'S ABSOLUTELY NO QUESTION ABOUT THAT DIFFERENTIAL, WHICH IS VERY LARGE.

PROFESSOR ROBERTS: I DON'T MEAN TO BELABOR THE POINT, BUT IS THAT REPRODUCTIVE

POTENTIAL THE SAME POTENTIAL THAT'S IMPORTANT FOR STEM CELL RESEARCH?

CHAIRMAN LO: I WOULD ASK ALAN TO COMMENT ON THAT.

DR. TROUNSON: WELL, IT IS BECAUSE THE DEGREE IN WHICH THE EMBRYO IS CABLE OF MULTIPLYING IN VIVO IS ALSO HIGHLY CORRELATED TO WHETHER THEY GROW IN THE LABORATORY AND FORM STEM CELLS. WE WOULD HAVE TO GET OUT THE LITERATURE FOR THAT, AND I DON'T KNOW HOW MUCH OF IT IS ANECDOTAL AND HOW MUCH OF IT IS REALLY PRESENT IN CAREFULLY DEFINED EXPERIMENTS. BUT TO MY KNOWLEDGE, AT LEAST WHEN I WAS MAKING EMBRYONIC STEM CELLS, THE VAST MAJORITY CAME FROM YOUNG WOMEN, AND VERY FEW CAME FROM WOMEN OVER THE AGE OF 35.

SO YET THE VAST MAJORITY OF EMBRYOS IN THE FREEZER, DAVID, WOULD COME FROM PATIENTS WHO ARE OVER THE AGE OF 35. SO WE COULD LOOK UP THAT INFORMATION AND PROVIDE THAT TO YOU AS BEST WE CAN. I CAN ASK GEOFF TO SCAN THE LITERATURE AND PROVIDE THAT.

MR. SHEEHY: COULD I ASK A QUESTION, BERNIE?

CHAIRMAN LO: YES, PLEASE, JEFF.

MR. SHEEHY: YOU KNOW WHAT WOULD REALLY

HELP ME IS IF -- MAYBE IF THERE WAS SOME SORT OF SUMMATION, MAYBE YOU OR GEOFF. I'M REALLY TRYING TO UNDERSTAND THE RISK-BENEFIT KIND OF BALANCING THAT WE'RE DOING HERE. WHAT ARE THE REAL RISKS OF SOME NEGATIVE CONSEQUENCE TO A DONOR IF WE MAKE THIS CHANGE? AND HOW IMPORTANT IS THE TWO YEARS? DOES IT NEED TO BE TWO YEARS? IS IT JUST SIMPLY -- WELL, I'M HAVING A LOT OF TROUBLE TODAY. MY COLD IS MUDDLING MY THOUGHTS.

WHAT ARE WE -- WHY ARE WE PROPOSING THIS CHANGE? IS THERE A BENEFIT TO THE PARENTS BEING ABLE TO KNOW THAT THEIR DONATION IS PART OF THIS PROCESS WHEN THEY'RE DOING IT? WHAT'S GOING ON WITH THE RECIPIENT, YOU KNOW, THE PEOPLE WHO ARE ACTUALLY HAVING THE KIDS AND HAVE THE CUSTODY OF THE EMBRYOS? YOU KNOW WHAT I MEAN? WHAT AM I BALANCING HERE? AND THEN HOW DOES THAT TIMEFRAME IMPACT THAT? IS THE TIMEFRAME FAIRLY ARBITRARY? JUST TRYING TO GET A LAY OF ALL THAT. DOES THAT MAKE SENSE, OR IS THAT TOO MUDDY?

DR. TROUNSON: I DON'T KNOW WHETHER DAVID ADAMSON WOULD CARE TO COMMENT ON THAT. IT WAS A LITTLE DIFFICULT TO FOLLOW THE THREADS.

MR. SHEEHY: IT SEEMS LIKE THAT WHAT OUR REAL BALANCE HERE IS THE REAL OR PERCEIVED RISK TO

THE DONOR OF THE EGGS. AND IT SEEMS TO ME THAT THE ONLY REASON TO CHANGE IT IS TO SOMEHOW -- WHY WOULD WE CHANGE IT, MAYBE CONVENIENCE? IS THERE SOME BENEFIT THAT ACCRUES TO THE PARENTS BY US CHANGING THIS? DOES IT HELP THEM IN THEIR DECISION-MAKING PROCESS, OR IS THAT IRRELEVANT?

CHAIRMAN LO: JEFF, LET ME TAKE A STAB AT THIS, AND OTHERS CAN CERTAINLY CORRECT ME OR SUPPLEMENT. I THINK THE RATIONALE FOR DOING THIS, AS I UNDERSTAND IT, IS, FIRST, THE ARGUMENT THAT THE PAID DONORS ARE YOUNGER AND EMBRYOS FORMED FROM THEIR OOCYTES MAY BE BETTER FOR STEM CELL RESEARCH AS THEY ARE FOR CLINICAL PURPOSES. THAT'S BEEN DISCUSSED, AND ALAN TRIED TO ANSWER THAT.

I THINK THE OTHER RATIONALE STRIKES ME WOULD BE THAT ONCE A WOMAN HAS MADE OR A COUPLE IN IVF IS THE RECIPIENTS NOW HAVE MADE THE DECISION NOT TO CONTINUE TO USE THESE FROZEN EMBRYOS FOR THEIR OWN REPRODUCTION AND NOT TO DONATE THEM TO ANOTHER COUPLE FOR REPRODUCTION, THIS DECISION BETWEEN EITHER LEAVING THEM IN STORAGE INDEFINITELY OR THAWING THEM AND DISCARDING THEM OR GIVING TO RESEARCH IS DIFFICULT. AND ALLOWING THAT DECISION FOR RESEARCH TO BE MADE FOR EMBRYOS THAT WERE MADE FROM PAID OOCYTE DONORS AFTER 8/08 MAY BE A BENEFIT

TO SOME WOMEN AND COUPLES. I THINK THAT WOULD BE THE ARGUMENT.

IN TERMS OF THE WHY WOULD THEY NOT WANT TO DO IT, I THINK THE ARGUMENTS I'VE HEARD IN THE DISCUSSION ARE THAT THERE ARE EVIDENTLY -- IT SOUNDED LIKE THERE WERE STILL CONCERNS ABOUT ANY PAYMENT FOR REPRODUCTIVE MATERIALS IN A RESEARCH CONTEXT EVEN THOUGH THEY ORIGINALLY WERE MEANT FOR CLINICAL PURPOSES.

I THINK THE SECOND THING WOULD BE DR. ADAMSON, I THINK, GAVE US A LOT OF INFORMATION TO ADDRESS THE CONCERN THAT SOMEHOW ALLOWING DONOR-PAID OOCYTE-DERIVED EMBRYOS TO BE USED FOR RESEARCH WOULD SOMEHOW PUT THE OOCYTE DONORS AT RISK. I THINK DR. ADAMSON PRESENTED ARGUMENTS THAT THE INCENTIVES WOULD NOT WORK THAT WAY AT ALL. ANOTHER CONCERN HAD BEEN RAISED FOR PROTECTION OF THE OOCYTE DONORS.

JEFF SHEEHY ALSO ASKED A QUESTION OF WHY TWO YEARS RATHER THAN THREE YEARS. I'M NOT SURE THERE'S AN EVIDENCE-BASED RATIONALE FOR THAT. SO I THINK THAT WAS SORT OF A FIGURE THAT WAS JUST SUGGESTED.

MR. SHEEHY: WE COULD ACHIEVE THE SAME THING -- I MEAN PRESUMABLY WE'VE OPENED UP A WHOLE NUMBER OF PAID-DONOR EMBRYOS WITH OUR PREVIOUS

SHIFT, HAVEN'T WE? IF WE JUST WAIT A YEAR, WE OPEN UP ANOTHER. I'M NOT SURE -- I'M HAVING TROUBLE UNDERSTANDING -- I'M REALLY HAVING TROUBLE UNDERSTANDING THE RATIONALE FOR THE CHANGE GIVEN THAT EVERYBODY WHO DONATED BEFORE AUGUST, THAT WE HAVE THIS WHOLE -- WE HAVE A WHOLE BUNCH OF MATERIALS THAT WERE NOT AVAILABLE FOR RESEARCH THAT WERE SUDDENLY MADE AVAILABLE FOR RESEARCH, PRESUMABLY, OR SOME NUMBER OF MATERIALS.

CHAIRMAN LO: JEFF, YOU'RE CERTAINLY RIGHT, IF I UNDERSTAND THE NUMBERS RIGHT, THAT WE'RE TALKING ABOUT A TWO-YEAR SORT OF WAITING PERIOD. SO YOU COULD NOT USE ANY EMBRYO CREATED ON 8/14/08 UNTIL 8/14/10, SO WE DON'T HAVE TO MAKE A DECISION TODAY OR HAVE THE ICOC DO IT RIGHT NOW. SO THIS IS NOT AN URGENT MATTER. THERE'S BEEN SEVERAL PEOPLE THAT HAVE ASKED FOR MORE INFORMATION, AND WE CAN CERTAINLY COME BACK TO THAT. I THINK YOU'RE CERTAINLY RIGHT, THAT WE CAN WAIT AND SEE WHAT HAPPENS WITH THE CHANGE THAT WAS MADE LAST AUGUST.

MR. SHEEHY: BECAUSE WE CAN JUST AT SOME ARBITRARY POINT IN THE FUTURE MOVE THAT LINE.

CHAIRMAN LO: YES.

MR. SHEEHY: WE WILL HAVE KNOWN -- WE WILL STILL HAVE THAT ASSURANCE THAT THOSE EMBRYOS WERE

NOT CREATED WITH RESEARCH IN MIND BECAUSE THAT WOULD NOT HAVE BEEN POSSIBLE. AS LONG AS NO ONE ANTICIPATES US MOVING THAT LINE OR WE DECLARE THAT WE ARE GOING TO MOVE THAT LINE, THERE'S NOT ENOUGH ASSURANCE FOR ANYONE TO DO THAT, ESPECIALLY IF THEY DON'T KNOW WHEN THAT LINE IS GOING TO BE MOVED, RIGHT?

CHAIRMAN LO: LET ME JUST SAY, THOUGH, DR. ADAMSON, IF HE'S STILL ON THE LINE CAN ADDRESS THIS. GEOFF LOMAX RAISED THE CONCERN EARLIER THAT FROM THE POINT OF VIEW OF THE IVF CLINIC, TO GO THROUGH THE CIRM CONSENT PROCESS FOR OOCYTE DONORS WHOSE EMBRYOS IS A BIG DEAL. SO TO THE EXTENT THAT WE WANT THE WOMEN WHO ARE PAID OOCYTE DONORS FOR IVF, WHEN THEY GIVE -- BECAUSE NOW THEY'RE GOING TO HAVE TO CONSENT FOR STEM CELL RESEARCH, NOT JUST GENERAL CONSENT FOR RESEARCH IN GENERAL BECAUSE WE CHANGE THAT DEADLINE. WE WOULD WANT THAT TO BE A PRETTY DETAILED DISCUSSION. AND DR. ADAMSON ALREADY SAID, AS I UNDERSTAND IT, THAT'S NOT COMPENSATED. IT TAKES TIME TO DO WELL, AND THERE'S NOT -- THERE WOULD BE EVEN LESS INCENTIVE TO HAVE THAT DISCUSSION IF PEOPLE THOUGHT THAT THE OOCYTES -- THE EMBRYOS RESULTING FROM THOSE PAID DONORS WOULDN'T BE USED FOR RESEARCH. SO TO SIGNAL SOMEHOW THAT THERE'S

THAT POSSIBILITY AND SO, THEREFORE, THAT THE IVF PRACTICES SHOULD PUT REAL EFFORT INTO SORT OF MAKING THAT CONSENT FOR RESEARCH BY THE OOCYTE DONOR TO BE THOROUGH MIGHT BE A FACTOR TO CONSIDER.

DR. ADAMSON, WOULD YOU LIKE TO COMMENT ON THAT POSSIBILITY?

DR. ADAMSON: I REALLY BELIEVE THAT THE BENEFITS OF HAVING THE EMBRYOS POTENTIALLY AVAILABLE FOR DONATION FOR RESEARCH SO GREATLY OUTWEIGH ANY THEORETICAL RISKS, IN THE ABSENCE OF FELONIOUS OR PSYCHOPATHIC BEHAVIOR, WHICH CLEARLY OCCURS, BUT NOT OFTEN, THAT A GUIDELINE THAT WOULD OPTIMIZE OUR ABILITY TO CONSENT PATIENTS AHEAD OF TIME AND TO FACILITATE THE EMBRYO DONATION WOULD BE HELPFUL. AND SO I THINK THE CONCEPT OF A ROLLING TIMELINE LOOKS VERY ATTRACTIVE TO ME. I THINK IT PROVIDES EVEN ADDED PROTECTION INTO THE SYSTEM. AND CERTAINLY IF THAT WERE DONE IN CONJUNCTION WITH A LIST OF REQUIREMENTS THAT HAD TO BE FOLLOWED OR GUIDELINES, ETC., I THINK WOULD REALLY REPRESENT A PROTECTION TO THE INTEREST OF THOSE INVOLVED.

I'M NOT SURE IF EVERYONE IS AWARE OF THE FACT THAT EGG DONORS HAVE EXTENSIVE SCREENING ALREADY. HISTORY AND PHYSICAL EXAMINATION, THEY HAVE GENETIC -- IN OUR PRACTICE THEY HAVE GENETIC

QUESTIONNAIRES, THEY HAVE GENETIC COUNSELING WITH A GENETICIST AND GENETIC SCREENING, THEY HAVE INFECTIOUS DISEASE SCREENING. IN OUR PRACTICE, NOT NECESSARILY ALL OF THEM, THEY GO THROUGH DRUG AND ALCOHOL SCREENING. THEY HAVE PSYCHOLOGICAL QUESTIONNAIRES AND FORMAL ASSESSMENT AND FORMAL COUNSELING IN A SESSION WITH A MENTAL HEALTH PROFESSIONAL.

AND SO THERE'S A LOT THAT'S DONE, AND THE ADDITION OF, YOU KNOW, ANOTHER CONSENTING GUIDELINE OR TWO THAT WOULD ENABLE THEM TO DONATE THEIR EMBRYOS IN A VERY ETHICAL AND ALTRUISTIC WAY, I THINK, WOULD BE EXTREMELY HELPFUL. BUT AT SOME POINT, THIS IS CLEARLY AN EVOLUTIONARY ISSUE, BUT I THINK TO THE DEGREE THAT MORE CERTITUDE CAN BE BROUGHT TO THE PROCESS, THE MORE MOTIVATION THERE'S GOING TO BE FOR PHYSICIANS, EGG DONORS, AND THE RECIPIENTS TO PARTICIPATE IN IT. NOBODY WANTS TO SPEND HUGE AMOUNTS OF TIME, ENERGY, AND EFFORT DISCUSSING OPPORTUNITIES THAT MAY NEVER COME TO FRUITION.

CHAIRMAN LO: ONE OTHER PUBLIC COMMENT.

MS. SMITH-CROWLEY: SHANNON SMITH-CROWLEY ALSO REPRESENTING AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE. ONE COMMENT, ONE QUESTION.

THE COMMENT IS IN ORDER TO GET THE REGULATION WHERE IT IS RIGHT NOW, YOU'VE ALREADY SAID THAT WOMEN WHO ARE PAID TO DONATE FOR IVF ARE OUTSIDE OF PROP 71. YOU'VE ALREADY SAID IT'S OUTSIDE, AND WHY SHOULD WE NOT GO AHEAD AND CONTINUE THIS. AND AS DR. ADAMSON SAID, THE TWO-YEAR ROLLING TIME WOULD ALSO GIVE TIME IF THERE WERE FOUND IN THAT TIME PERIOD TO BE NEFARIOUS ACTIVITY, THAT THAT WOULD HAVE PROBABLY SHOWN UP WITHIN THOSE TWO YEARS.

THE OTHER QUESTION IS, MAYBE DR. TROUNSON CAN SAY, IS ARE THERE SITUATIONS WHERE EMBRYOS THAT WOULD GO THROUGH PREIMPLANTATION GENETIC DIAGNOSIS THAT WOULD BE IMMEDIATELY DISCARDED, WOULD NOT BE CONSIDERED FOR USE FOR IVF, WOULD THOSE BE SOMETHING THAT WOULD BE USEFUL IN STEM CELL LINES? AND WOULD THAT BE ANY REASON TO WAIVE A TWO-YEAR REQUIREMENT?

DR. TROUNSON: WELL, I THINK IN THOSE CASES, THOSE EMBRYOS ARE NOT -- THERE'S NO DONOR INVOLVED. IT'S REALLY DIRECTLY FROM THE PATIENT WHO IS AT RISK FOR THAT GENETIC DISEASE. SO I'LL HAVE TO JUST ASK GEOFF. YOU'RE SAYING COULD WE USE THEM WITHOUT FREEZING, WHICH HAS CERTAINLY BEEN DESIRABLE BY THE STEM CELL NETWORKS BECAUSE YOU GET A MUCH BETTER OUTCOME IF YOU DON'T HAVE TO FREEZE AS WELL. BUT WHAT'S OUR RULING ON THAT? IT WOULD BE

DIFFERENT TO WHAT WE'RE TALKING ABOUT.

DR. LOMAX: THERE'S NOTHING EXCEPTIONAL ABOUT PGD EMBRYO, BUT YOU EFFECTIVELY HIT THE NAIL ON THE HEAD. IN PRACTICE, THEY ARE COMING FROM NONPAID DONOR SITUATIONS, SO THEY REALLY FALL OUTSIDE SORT OF THE SET OF ISSUES THAT WE HAVE ON THE TABLE.

MS. SMITH-CROWLEY: SO PGD WOULD NEVER BE DONE WHEN YOU'VE GOT A DONOR EGG? IT'S LESS LIKELY BECAUSE SHE'S YOUNGER. DR. ADAMSON, MAYBE YOU WOULD BE IN THE BEST POSITION TO SAY. IS THAT TYPICAL OR VERY UNUSUAL THAT WHEN USING A DONOR EGG FOR IVF, THAT YOU WOULD ALSO GO THROUGH PREIMPLANTATION GENETIC DIAGNOSIS?

DR. ADAMSON: IT WOULD BE VERY COMMON. I SUPPOSE YOU COULD HAVE THE MALE EGG DONOR WITH A MALE WITH POTENTIALLY HUNTINGTON'S, SAY, THAT YOU'D DO PGD. SO I THINK YOU COULD IDENTIFY SITUATIONS. IT WOULD BE VERY UNUSUAL.

MS. SMITH-CROWLEY: BUT VALUABLE.

DR. ADAMSON: BUT I WOULDN'T SAY NEVER.

MS. SMITH-CROWLEY: SO SHOULD THERE BE AN EXCEPTION MADE FOR SOMETHING LIKE THAT WHERE THERE IS ABSOLUTELY NO WAY THAT THE EMBRYO IS GOING TO BE USED FOR IVF?

DR. ADAMSON: I GUESS MY GENERAL SENSE IS THAT AS LONG -- IF ALL THE PARTIES ARE FULLY INFORMED AND FULLY CONSENTED AND ARE ENABLED TO DONATE A RESULTANT EMBRYO, THEN I THINK IT WOULD BE APPROPRIATE TO HAVE THE REGULATORY FRAMEWORK SUCH THAT THAT'S POSSIBLE. SO THAT'S A LONG WAY TO SAY YES. BUT, YOU KNOW, IT'S A BALANCING OF THE LANGUAGE. BUT, YES, YOU WOULD WANT TO BE ABLE TO MAKE THAT POSSIBLE IF IT WOULD BE DESIRED BY THE PARTIES.

MS. SMITH-CROWLEY: BECAUSE YOU COULD DOCUMENT WHY THIS IS NOT JUST A GENERIC EMBRYO, THAT THIS IS WHY WE'RE NOT USING IT.

MR. SHEEHY: I'M WONDERING IF THE PROCESS THAT WE'RE ON NOW IS LESS ONE OF COMING TO A DECISION POINT TODAY AS MAYBE AS RATHER ONE WHERE WE'RE IDENTIFYING ISSUES THAT NEED -- THIS IS, AGAIN, ANOTHER ISSUE THAT WE HAVEN'T -- I HAVEN'T EVEN REALLY THOUGHT ABOUT. IT'S NOT REALLY INCLUDED IN THE MATERIALS THAT HAVE COME BEFORE US. I'M WONDERING IF WE WANT TO KICK THIS ONE DOWN THE ROAD A LITTLE BIT AND MAYBE GET SOME ADDITIONAL INFORMATION AND MAYBE SPEND THE REST OF OUR TIME TRYING TO IDENTIFY WHAT WE REALLY NEED TO KNOW BEFORE WE CAN COME TO A DECISION.

CHAIRMAN LO: I CERTAINLY, SINCE WE'VE ALREADY LOST JOSE CIBELLI, AND I THINK WE'RE ACTUALLY PAST THE CUTOFF TIME FOR THE MEETING, I WOULD BE VERY GLAD TO ENTERTAIN A MOTION TO TABLE THIS WITH THE UNDERSTANDING THAT WE WOULD POLL -- I'M NOT SURE, GEOFF, WE COULD EVEN DO IT TODAY, BUT TO SORT OF POLL THE COMMITTEE OFFLINE AS TO WHAT FURTHER INFORMATION WE NEED TO PRESENT FOR ANOTHER DISCUSSION AT A LATER MEETING. I'M HEARING --

MS. LANSING: THIS IS SHERRY. I WOULD LIKE TO SECOND THAT, THAT WE ALL E-MAIL YOU OR WHATEVER WE HAVE TO DO TO TELL YOU WHAT OTHER ISSUES WE WANT TO DISCUSS TO MAKE AN INFORMED DECISION.

MR. SHEEHY: ONE THING I WOULD LIKE TO ACKNOWLEDGE IS DR. ADAMSON. I AM SO GRATEFUL. HE HAS BEEN SO HELPFUL. AND THIS IS -- IT'S VERY HARD FOR MANY OF US TO UNDERSTAND WHAT'S ACTUALLY GOING ON, AS YOU SAY, IN THE TRENCHES. AND YOUR TIME AND YOUR SERVICE HERE HAS BEEN INVALUABLE.

MS. LANSING: YES. I SECOND THAT.

CHAIRMAN LO: I THINK WE, DR. ADAMSON, I THINK WE ALL ARE VERY GRATEFUL. YOU WERE JUST SO CLEAR AND UNDERSTANDABLE ON SORT OF THE ISSUES LAID OUT, WHICH HAS REALLY HELPED US A GREAT DEAL. AND WE MAY ACTUALLY CALL ON YOU AGAIN.

DR. ADAMSON: THANK YOU. I'D BE HAPPY TO GIVE YOU MY THOUGHTS IF I CAN BE HELPFUL.

CHAIRMAN LO: MY SENSE FROM THE COMMITTEE IS THAT WE SHOULD THINK MORE ABOUT THIS, GET INFORMATION FIRST, THINK MORE ABOUT THIS, AND THERE'S NO URGENCY TO DECIDE THIS TODAY. I THINK WE DO WANT TO GET THIS RIGHT.

GEOFF, IS THERE ANYTHING ELSE WE NEED TO ADDRESS HERE? I THINK WE'VE LOST THE QUORUM, SO I DON'T THINK --

DR. LOMAX: WE WERE QUORUM LIMITED ALL DAY. THIS IS HELPFUL. WE'RE AT A REASONABLE STOPPING POINT. WE UNDERSTAND WHY WE'RE STOPPING. THE SENSE OF THE COMMITTEE REGARDING THE SOMATIC CELL ISSUES WAS EXTREMELY HELPFUL. IT GIVES US AN OPPORTUNITY TO MOVE FORWARD IN SOME AREAS THAT I THINK WILL BE VERY HELPFUL TO THE RESEARCH COMMUNITY. AND I THINK WHAT IT MEANS AT THIS POINT IS WE SIMPLY MOVE FORWARD WITH THE EXISTING RULE THAT WAS APPROVED BY THE ICOC IN AUGUST, AND WE'LL JUST START THE PROCESS OF FINALIZING THAT ONE. IT GIVES US SOMETHING THAT ADDRESSES THIS ISSUE IN THE NEAR TERM ANYWAY.

CHAIRMAN LO: SO WITH THAT, I WANT TO THANK YOU ALL FOR YOUR PARTICIPATION. I THINK WE

ACTUALLY DID SOME VERY GOOD WORK TODAY.

AND ALSO I WANT TO AGAIN REMIND YOU THAT WE'RE GOING TO MEET FEBRUARY 17TH, 18TH IN LOS ANGELES. AND HOPEFULLY THE AIRLINES WILL STILL BE FLYING THEN SO WE CAN GET THERE, AND WE LOOK FORWARD.

MS. FOGEL: THE PROBLEM IS GOING TO BE DRIVING. THEY'LL BE MAKING NO CARS.

CHAIRMAN LO: THEY'LL BE MAKING GASOLINE. SHERRY, I TAKE IT YOU'VE PROMISED US GORGEOUS SOUTHERN CALIFORNIA WEATHER.

MS. LANSING: ABSOLUTELY.

CHAIRMAN LO: THANK YOU VERY MUCH. EVERYBODY HAVE A GREAT, GREAT HOLIDAY SEASON.

(THE MEETING WAS THEN CONCLUDED AT 01:14 P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

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ON
DECEMBER 12, 2008

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
BARRISTER'S REPORTING SERVICE
1072 BRISTOL STREET
SUITE 100
COSTA MESA, CALIFORNIA
(714) 444-4100