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

REGULAR MEETING

LOCATION:	WESTIN SAN FRANCISCO MARKET STREET 50 THIRD STREET SAN FRANCISCO, CALIFORNIA
DATE:	SEPTEMBER 17, 2009 5 P.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
BRS FILE NO.:	85050

I N D E X

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

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

SAN FRANCISCO, CALIFORNIA; THURSDAY, SEPTEMBER 17, 2009

5 P.M.

MS. LANSING: CAN I ASK EVERYBODY TO COME TO THEIR SEAT SO WE CAN START ON TIME? SO MY NAME IS SHERRY LANSING, AND I WANT TO WELCOME YOU ALL HERE AND THANK THE MEMBERS OF THE COMMITTEE FOR THEIR UNDYING COMMITMENT AND FOR THEIR TIME, WHICH WE SO VALUE. AND JUST TELL YOU A LITTLE BIT ABOUT TONIGHT, WHICH IS TONIGHT IS REALLY MOSTLY INFORMATIONAL TO BRING YOU UP TO DATE WITH WHAT IS GOING ON.

AND SO I WOULD LIKE US REALLY KIND OF TO LISTEN TO THE REPORTS, ASK QUESTIONS IF YOU NEED TO, BUT MOSTLY IT'S JUST TO ABSORB THE INFORMATION AND BRING US ALL UP TO DATE. AND WITH THAT, I'LL TURN IT OVER TO BERNIE.

CHAIRMAN LO: THANKS VERY MUCH. AND, AGAIN, I WANT TO WELCOME EVERYONE, AND WE EVEN ARRANGED FOR OPTIMAL SAN FRANCISCO WEATHER, WHICH YOU DON'T OFTEN GET AT THIS TIME OF YEAR.

I WANT TO PICK UP ON WHAT SHERRY SAID, THAT THIS AFTERNOON OR THIS EARLY EVENING WHAT WE REALLY HAVE IS AN INFORMATIONAL SESSION, THAT I THINK WE'VE MADE A COMMITMENT TO REALLY GROUND OUR DELIBERATIONS ON THE GOOD KNOWLEDGE OF THE SCIENCE OF STEM CELL BIOLOGY,

POLICY DEVELOPMENTS IN OTHER ARENAS, WHAT THE VARIOUS GOVERNMENT AGENCIES ARE DOING. AND SO THIS AFTERNOON WHAT WE'RE GOING TO DO IS TRY AND BRING OURSELVES UP TO DATE.

NOW, THERE WILL BE INFORMATION WE HEAR THAT WE WON'T BE ABLE TO ACT ON. IT'S EITHER OUT OF OUR CONTROL SORT OF WHAT THE FDA DOES TO SOME EXTENT, AND WE'LL HEAR THAT OTHER STATES, SUCH AS NEW YORK IN PARTICULAR, HAVE DEVELOPED STEM CELL POLICIES THAT BY STATUTE, BY THE WILL OF THE PEOPLE IN CALIFORNIA, WE CAN'T FOLLOW. BUT I THINK IT'S STILL IMPORTANT FOR US TO KNOW ABOUT WHAT'S GOING ON AND HOW THEY ARRIVED AT THE POLICIES THEY DID.

SO WE'RE GOING TO START WITH THE SCIENCE. ONE OF THE WONDERFUL THINGS ABOUT THIS AREA IS THAT THE SCIENCE IS PROGRESSING RAPIDLY, DRAMATICALLY. AND I'VE ASKED ALAN TROUNSON, WHO'S VERY GRACIOUSLY SORT OF PUT TOGETHER SORT OF A QUICK PRIMER FOR US ON SOME IMPORTANT DEVELOPMENTS IN GAMETE BIOLOGY. ALAN. THANKS VERY MUCH.

DR. TROUNSON: THANK YOU VERY MUCH, BERNIE. AND IT'S GOOD TO BE HERE. GOOD TO SEE YOU, SHERRY, OUT OF ALL OF YOUR MEETINGS TO GET YOU HERE AND OTHER MEMBERS OF THE BOARD AND PARTICULARLY TO ALTA CHARO BECAUSE NOW SHE'S GOT ANOTHER POSITION WITH THE FDA.

CONGRATULATIONS, ALTA. THAT'S WONDERFUL. SO I THINK THAT'S A VERY SPECIAL RECOGNITION OF YOUR CONTRIBUTIONS IN THE AREA.

MS. CHARO: JUST TO BE VERY CLEAR THOUGH, I'M NOT HERE AS A REPRESENTATIVE OF THE FDA TONIGHT.

DR. TROUNSON: CLEARLY UNDERSTOOD. SO WHAT I WANTED TO DO AND WHAT I WAS ASKED TO DO IS REALLY ADDRESS THE ISSUES OF PLURIPOTENTIAL STEM CELL-DERIVED GAMETES. AND I HESITATE TO DO THIS WITH JOSE CIBELLI SITTING ON THERE BECAUSE HE'LL BE ABLE TO CRITIQUE THIS QUITE WELL.

BUT I THOUGHT THAT ONE OF THE INTERESTING PAPERS WHICH I SPENT SOME TIME IN USING ON THIS WAS REALLY A PAPER THAT CAME OUT IN *CELL STEM CELL* JUST RECENTLY. AND IT'S QUITE AN EASY READ REALLY, BUT IT'S CALLED "PLURIPOTENTIAL STEM CELL-DERIVED GAMETES: TRUTH AND POTENTIAL CONSEQUENCES," PUBLISHED BY THE AUTHORS MATTHEWS AND DONOVAN. PETER DONOVAN IS WELL-KNOWN TO US AS HEAD OF THE STEM CELL RESEARCH GROUP AT UNIVERSITY OF CALIFORNIA AT IRVINE.

IT IS REALLY PRETTY CLEAR THAT YOU CAN ACHIEVE THE VERY EARLY STEPS OF GAMETE DEVELOPMENT FROM WHAT WE CALL PGC'S. THESE ARE THE PLURIPOTENTIAL GERM CELLS, AND YOU CAN ACHIEVE THE LATEST STEPS OF MATURATION OF GAMETES PRODUCED IN VIVO, PARTICULARLY

EGGS. YOU CAN DO THOSE THINGS IN THE SENSE THAT YOU MATURE EGGS FROM AN IMMATURE STATE, AND YOU CAN ALSO INITIATE THE DEVELOPMENT OF THE FIRST FEW STEPS OF DEVELOPMENT. REALLY, IT'S BEEN REPEATED AND IT'S BEEN SHOWN BY MANY PEOPLE. THE EFFECTIVENESS VARIES, BUT IT IS JUST PART OF THE ARMAMENT IN THE AREA.

IT'S THE INTERVENING STEPS THAT ARE DIFFICULT AND REPEATEDLY ACHIEVED, AND IT INVOLVES, IMPORTANTLY, THE ERASURE OF WHAT THEY CALL GENETIC IMPRINTING WHEN WE FORM GAMETES OR SPERM OR EGGS. THEY GET IMPRINTED TO BE MALE AND FEMALE. THEY'RE PRINTED IN A VERY SPECIAL WAY SO THAT WHEN THEY COME BACK TOGETHER AGAIN, THAT IMPRINTING ENABLES DEVELOPMENT TO OCCUR IN A VERY RATIONAL STEPWISE WAY. AND IT ALLOWS FOR PARTICULARLY THE DEVELOPMENT OF PLACENTA AND EMBRYONIC TISSUES.

SO THE ORGANIZATION IN REPRODUCTION IS SET UP WITH THE IMPORTANCE OF BEING ABLE TO ERASE WHAT WE CALL GENOME IMPRINTING AND SET IN SOME VERY SPECIFIC CELL CYCLE CONTROLS FOR ENTERING INTO MITOTIC ARREST. ANN KIESSLING KNOWS LOTS ABOUT THIS PARTICULAR SUBJECT. SO CLEARLY SHE'LL BE ABLE TO INFORM US ALSO A LOT ABOUT THIS.

AND THE REDUCTION DIVISION WHICH IS REQUIRED FROM TAKING A DIPLOID CELL, A 2N CELL, WHICH HAS BOTH COPIES OF CHROMATIN FROM THE MALE AND THE FEMALE

RESIDENT IN THE EMBRYO AND RESIDENT IN ALL THE CELLS OF OUR BODY, YOU'VE GOT TO GET A REDUCTION DIVISION BACK TO A HAPLOID STATE OR A 1N STATE, SO THAT WHEN YOU RECOMBINE SPERM AND EGGS, YOU END UP WITH A DIPLOID STATE, THE 2N STATE AGAIN. THESE STEPS ARE REALLY QUITE COMPLEX AND NOT EASILY ACHIEVED, NOT SIMPLY ACHIEVED. WHILE IT'S NOT IMPOSSIBLE THAT THIS CAN BE WORKED OUT IN THE LONG TERM, IT'S CLEAR THERE ARE PROBLEMS IN GETTING THIS DONE EFFECTIVELY AT THE MOMENT.

THERE IS ONE GROUP THAT'S REPORTED PLURIPOTENTIAL STEM CELL-DERIVED SPERM IN LIVE BORN MICE. SO THEY'VE TAKEN EMBRYONIC STEM CELLS AND THEY'VE TURNED THEM IN, THROUGH THE GERM CELL, THEY'VE TURNED THEM INTO THE GAMETE, THE SPERM GAMETE, AND THEY'VE USED THOSE SPERM TO RECONSTITUTE AN EMBRYO BY COMBINING IT WITH AN EGG AND THEN PRODUCING A BABY MOUSE. ALL THOSE MICE DIED SOON AFTER BIRTH. THIS WORK WAS PUBLISHED IN 2006. IT'S A GERMAN GROUP, AND AT THIS TIME I THINK NAYERNIA WAS WORKING IN GERMANY. HE NOW WORKS IN ENGLAND.

THE PLURIPOTENTIAL STEM CELL-DERIVED HUMAN GAMETES ARE LIKELY TO BE DEVELOPED, BUT NOT FOR A DECADE AT LEAST. THIS IS THE -- THIS WAS THE VIEW OF THE SCIENTISTS THAT IS PART OF THIS REPORT. AND

CLINICAL APPLICATIONS WILL HAPPEN SOME YEARS LATER. SO CLEARLY YOU HAVE TO SHOW THAT YOU CAN PRODUCE EGGS AND SPERM, AND THEN LATER ON YOU WILL, IF YOU CAN SHOW ON TESTS A DEGREE OF NORMALITY, THEN PERHAPS ALLOW YOU INTO THE CLINICAL TRIALS.

THE ISSUES OF QUALITY OF THE GAMETES WILL BE CRITICAL FOR THE FUTURE AS THESE FORM THE GENOMIC BASIS FOR DEVELOPMENT. SO IF IT'S NOT NORMAL, CLEARLY THAT WILL BE INHERITED AND THAT WILL FORM THE DEVELOPMENTAL EMBRYO. THE EMBRYO, IF IT'S NOT NORMAL, WILL HAVE ESSENTIALLY A CHROMOSOMAL OR GENETIC ABNORMALITY, AND THAT WOULD NOT BE ACCEPTABLE. SO YOU REALLY HAVE TO BEGIN WITH NORMAL GAMETES OR AS NORMAL AS YOU CAN DEMONSTRATE.

MS. CHARO: ALAN, CAN YOU STOP JUST FOR A CLARIFICATION, PLEASE? I UNDERSTAND THE 2006 PAPER, THEY START WITH AN EMBRYONIC STEM CELL AND THEN DIFFERENTIATE FORWARD. BUT FOR THE MATTHEWS-DONOVAN PAPER, I'M NOT FAMILIAR WITH PGC AND I'M NOT SURE I UNDERSTAND THE SEQUENCE OF CELLULAR STAGES THAT IT'S GOING THROUGH FOR THE FIRST PAPER.

DR. TROUNSON: WELL, I THINK WHAT YOU DO IS YOU START WITH AN EMBRYONIC STEM CELL. ALL THESE EARLY STUDIES WERE MOSTLY DONE IN MICE. SO YOU BEGIN WITH AN EMBRYONIC STEM CELL. NOW, THOSE CELLS ARE ARGUABLY

PRESENT IN THE EMBRYO, BUT PROBABLY NOT DEFINED. SO THESE ARE UNDIFFERENTIATED CELLS. AS THE EMBRYO DEVELOPS IN THE VERY EARLY STAGES, THESE PARTICULAR CELLS REMAIN UNDIFFERENTIATED AND THEY BECOME PRIMORDIAL GERM CELLS.

MS. CHARO: I SEE. SO THEY'RE SORT OF DEVELOPING IN PARALLEL WITH WHAT WE WOULD CALL EMBRYONIC STEM CELLS.

DR. TROUNSON: YES. SO YOU CAN TAKE THESE CELLS OUT OF THE VERY EARLY TESTES, AND YOU CAN SHOW THAT THOSE OR THE VERY EARLY OVARY, IF YOU LIKE, BUT YOU CAN SHOW THAT THOSE CELLS HAVE PLURIPOTENTIAL CAPACITY. SO THIS IS WHAT JOHN GERHARDT SHOWED. SO THESE ARE THESE CELLS ON THAT DIRECTION.

MS. CHARO: APPRECIATE IT.

DR. TROUNSON: AND IT'S AFTER THAT THEY BECOME MORE AND MORE SPECIALIZED, AND, OF COURSE, THEY HAVE TO MAKE A CHOICE AT SOME POINT IN TIME TO BECOME EGGS OR SPERM. AND IT'S DOMINATED REALLY BY THE ENDOCRINE ENVIRONMENT, WHICH DRAWS THE CELLS TOWARDS THE MALE, OR A NONENDOCRINE ENVIRONMENT THAT ALLOWS IN THE FEMALE FOR THE CELLS TO MOVE OFF TOWARDS THE EGG. THAT'S AN INCREDIBLY SIMPLE WAY OF DESCRIBING IT.

SO LET ME JUST TAKE YOU THROUGH HERE ABOUT WHAT IT IS ABOUT THE STRATEGIES THAT MIGHT INTEREST

PEOPLE IN THE AREA. AND YOU TAKE THE PATIENT'S OWN CELLS. SO HERE WE HAVE A PATIENT WHO HAS PRIMARY INFERTILITY OR STERILITY. WHAT WOULD THEY BE REALLY INTERESTED IN? WELL, A POSSIBILITY IS THAT YOU COULD TAKE THOSE PATIENT'S OWN CELLS AND USING TECHNIQUES THAT WERE PIONEERED BY NUCLEAR TRANSFER, IAN WILMOTT AND COLLEAGUES AND JOSE CIBELLI AND MANY OTHER PEOPLE USE NUCLEAR TRANSFER TO PRODUCE A NUCLEAR TRANSFER BLASTOCYST AND, HENCE, A PATIENT-SPECIFIC EMBRYONIC STEM CELL. RIGHT. YOU COULD DO THAT. THAT'S A NUCLEAR TRANSFER PROCEDURE. NOT ACHIEVED YET IN THE HUMAN, BUT IT'S DONE IN OTHER ANIMALS, IN PARTICULARLY MICE AND IN MONKEYS.

OR YOU CAN TAKE THE PATIENT'S OWN CELLS AND MAKE THOSE PATIENT-SPECIFIC PLURIPOTENTIAL STEM CELLS BY AN IPS PROCEDURE. YOU COULD CONVERT THOSE CELLS, PATIENT'S OWN CELLS, INTO PLURIPOTENTIAL STEM CELLS USING THE TRANSCRIPTION FACTORS, INSERTIONAL PROCEDURES, A TRANSDUCTION PROCEDURE TO CONVERT THEM BACK TO THE EQUIVALENT OF IPS CELLS. AND THEN WHAT YOU DO IS YOU USE A DIRECTED DIFFERENTIATION TO PRODUCE AN EGG, A PUTATIVE EGG SHOWN THERE ON THE BOTTOM. THIS WAS WORK THAT WAS DONE IN MY LAB SOME YEARS AGO. YOU CAN SHOW THAT YOU CAN GET A STRUCTURE THAT HAD SOME OF THE CHARACTERISTICS OF EGGS. YOU COULD DO THAT THROUGH

A DIRECTED DIFFERENTIATION THAT WOULD TAKE YOU THROUGH TOWARDS THE EGG. THESE EGGS DIDN'T REALLY HAVE ANY KIND OF DEVELOPMENTAL POTENTIAL, BUT THEY LOOK LIKE EGGS AND THEY SHOWED UP SOME OF THE MARKERS OF EGGS. OR YOU COULD GO OFF AND YOU COULD PRODUCE SPERM RATHER THAN EGGS IN ANOTHER DIRECTED DIFFERENTIATION PROCEDURE.

WHAT YOU WOULD WANT TO DO WITH THESE CELLS SOMEWHERE BEFORE THEY WERE EGGS OR SPERM WOULD BE TO TRANSPLANT THE PRIMORDIAL GERM CELLS, SO A PROGENITOR IN THAT PATHWAY, BACK INTO THE PATIENT, INTO THE OVARY. IF THE PATIENT HAD NO EGGS, YOU WOULD INJECT IT BACK AND YOU COULD REFRESH THE OVARY FOR THE POTENTIAL TO PRODUCE EGGS. THAT WOULD BE POSSIBLE. OR IN THE CASE OF A MALE, IF YOU TOOK ALONG THAT TRACK, YOU WOULD INJECT THE CELLS INTO THE REALLY TESTES OR SOMEPLACE IN THE TESTES AND THEY WOULD GO ON AND FORM SPERM. THEN THOSE PATIENTS MAY BE ABLE TO RECOVER THEIR FERTILITY. SO THAT WOULD BE THE LONG-TERM CLINICAL INTEREST, BUT THIS IS MILES AWAY. BUT I'M TRYING TO GIVE YOU A FORMAT FOR WHY THERE WOULD BE INTEREST IN ANY KIND OF CLINICAL APPLICATION.

DR. TAYLOR: ALAN, JUST A LITTLE COMMENT. SO ONE THING THAT, AT LEAST THEORETICALLY, IS KIND OF INTERESTING IS BECAUSE THE EGG SEEMS TO BE VERY

IMPORTANT IN DIRECTING THE DEVELOPMENT OF THE OVARY, THE OVARIAN FUNCTION MORE BROADLY DESCRIBED, I COULD IMAGINE A SITUATION WHERE YOU DON'T HAVE PERFECT EGGS, BUT THEY MIGHT BE ENOUGH TO INDUCE HORMONE PRODUCTION IN WOMEN WHO HAVE OVARIAN FAILURE FROM A PURELY ENDOCRINE POINT OF VIEW. SO THAT THIS TYPE OF A STRATEGY, EVEN IF YOU WEREN'T TRYING TO ACHIEVE FERTILITY, YOU MIGHT BE ABLE TO ACTUALLY ACHIEVE -- REVERSE MENOPAUSAL CHANGES OR PREMATURE OVARIAN FAILURE OR SOMETHING LIKE THAT. JUST KIND OF ANOTHER ANGLE.

DR. TROUNSON: THAT'S EXACTLY RIGHT. YES. SO IN MENOPAUSE WOMEN LOSE THOSE STEROID HORMONES, ESTROGEN AND PROGESTERONE, AND THAT MAY BE ONE WAY OF BRINGING IT BACK. SO IF A YOUNG WOMAN HAD GONE THROUGH PREMATURE MENOPAUSE, IT MIGHT BE ONE WAY OF BRINGING IT BACK, ALTHOUGH YOU CAN ADMINISTER STEROIDS.

SO THIS HAS ALSO BEEN DONE IN THE HUMAN, ALTHOUGH THIS PARTICULAR WORK HAS BEEN WITHDRAWN FROM PUBLICATION, NOT BECAUSE THEY DIDN'T ACHIEVE THE END POINTS THEY WERE LOOKING FOR, BUT THERE WERE SOME OTHER PROBLEMS WITH THE PAPER. SO THIS PAPER IS NOT PUBLISHED. I JUST WANTED TO TELL YOU THAT IN THE HUMAN YOU COULD DEVELOP IN VITRO STRATEGIES FOR ESTABLISHING MALE GERM CELLS FROM HUMAN EMBRYONIC STEM CELLS. AND THERE ARE PEOPLE CLEARLY INTERESTED IN DOING THESE.

THESE IN VITRO COULD EXPRESS MARKERS WHICH ARE SPECIFIC FOR THE STAGES OF INTEREST, INCLUDING ALL OF THE STAGES IN THE PATHWAY TO PRODUCE SPERM OR, INDEED, EGGS. IT WOULD APPEAR TO ME TO BE EASIER TO DO IT WITH SPERM BECAUSE EGG IS A MUCH MORE COMPLICATED CELL.

THESE IN VITRO DIVIDED GERM CELLS SHOULD BE ABLE TO ENTER MEIOSIS AND GENERATE HAPLOID MOTILE SPERMLIKE CELLS, AND THIS WOULD BE AN AIM OF THE WORK. AND THIS IN VITRO MODELING OF GAMETOGENESIS WOULD ENABLE A WHOLE LOT OF NEW WAYS OF STUDYING BIOLOGY OF HUMAN GERM CELLS AND THE POTENTIAL FOR THERAPEUTICS FOR REPRODUCTIVE MEDICINE THAT WOULD BE ALONG THE LINE THAT I'VE JUST TALKED TO YOU ABOUT.

AND THESE ARE SOME PICTURES FROM THE WITHDRAWN PAPER, SO YOU CAN SEE ACTUALLY AT THE TOP THERE THAT THERE IS SOME KIND OF STRUCTURE THAT LOOKS LIKE SPERM, BUT THEY'RE NOT PARTICULARLY ATTRACTIVE LOOKING SPERM FROM A MORPHOLOGIST POINT OF VIEW, BUT THAT DOESN'T NECESSARILY MEAN THAT THEY'RE NOT FUNCTIONAL. AND THERE'S, OF COURSE, NOT ANY REALLY GOOD WAYS OF TESTING WHETHER THESE ARE FUNCTIONAL IN THE HUMAN BECAUSE DOING THE EXPERIMENT TO FORM EMBRYOS IS, AGAIN, CHALLENGING.

BUT IN THE BOTTOM PART, THOSE SINGLE DOTS WOULD INDICATE THAT YOU MIGHT BE ABLE TO GET THE CELLS

TO COME DOWN TO BE HAPLOID; THAT IS, ONLY CONTAIN ONE SET OF CHROMOSOMES. AND IF YOU'RE ABLE TO ACHIEVE THAT, THAT WOULD BE ALSO A GOOD STEP. THIS KIND OF WORK WILL BE GOING ON IN SEVERAL LABS THROUGHOUT THE WORLD. I DON'T THINK THERE'S ANYTHING QUITE LIKE THIS GOING ON IN CALIFORNIA, BUT THERE COULD BE. I KNOW THAT THERE ARE PEOPLE INTERESTED IN SOME OF THESE PATHWAYS IN MATURING EGGS FROM PRIMORDIAL STAGE, BUT NOT NECESSARILY GOING ALL THE WAY FROM EMBRYONIC STEM CELLS.

SO WHAT ARE THE POLICY ISSUES THAT MIGHT CONFRONT THE SUBCOMMITTEE? WELL, THE USE OF PLURIPOTENTIAL STEM CELL-DERIVED CELLS, WE JUST CALL IT IN THIS CASE PSCD, SPERM OR EGGS IN RESEARCH. YOU HAVE A CHOICE ABOUT PROHIBIT, RESTRICT, PERMIT, FUND. ALL I'VE DONE IN THE ORANGE HERE IS SAY WHERE WE PROBABLY ARE IN CALIFORNIA IN THAT SPACE. WE WOULD PROBABLY BE INTERESTED IN SEEING WHETHER THESE CELLS COULD GO THROUGH THEIR PATHWAY. WHETHER WE EVER PERMIT IT OR FUND IT, THAT'S NOT WHAT I'M TRYING TO SUGGEST TO YOU. THAT'S WHERE I THINK WE'RE MORE LIKELY TO HAVE BEEN SITTING WITH OUR CURRENT STANDARDS.

THE CREATION OF EMBRYOS FROM THESE GAMETES, PROHIBITED IN SOME PLACES, MIGHT BE A POLICY OPTION, RESEARCH ONLY. I THINK THAT'S MORE LIKE THE SITUATION

IN CALIFORNIA. YOU WOULD BE ABLE TO DO THIS ONLY AS A RESEARCH OBJECTIVE WITH THE RESEARCH AND REPRODUCTION PROBABLY PROHIBITED.

NOW, THE THIRD SITUATION IS WHERE THESE CELLS WERE USED FOR REPRODUCTION. AND THAT WOULD BE, I'M SURE, RESTRICTED IN CALIFORNIA, AS IT WOULD BE IN MOST PLACES.

THE OPTIONS HERE FOR POLICY, THAT THEY MIGHT BE CONSIDERED EQUIVALENT TO IVF, THEY MIGHT BE ABLE TO BE CONSIDERED FOR SAME SEX COUPLES, WHICH IS AN INTERESTING APPLICATION, OF COURSE, IF YOU HAVE IPS CELLS. POSTMENOPAUSAL WOMEN, AND THAT MAY BE BECAUSE OF AGE, BUT IT MAY BE BECAUSE OF PREMATURE MENOPAUSE. SOME WOMEN GO THROUGH MENOPAUSE AT THE AGE OF 20, FOR EXAMPLE. WHILE IT'S NOT COMMON, IT DOES CERTAINLY HAPPEN.

AND THE POLICY MAY HAVE TO IDENTIFY WHETHER THERE'S ISSUES OF INFORMED CONSENT, FOR EXAMPLE, WHETHER IT WAS APPLIED TO MINORS. ALL OF THOSE POLICY ISSUES ARE SOMETHING THAT MIGHT NEED TO BE CONSIDERED IN DUE COURSE WITH ALL OF THOSE PARTICULAR OPTIONS.

THE CONTROVERSIES HERE, AND I JUST POINT IT OUT JUST SO THAT YOU ARE AWARE, IS THAT IN SAME SEX COUPLES WHERE YOU COULD PRODUCE BOTH SPERM AND EGGS, RIGHT, IPS CELLS ENABLES YOU TO DO THAT IN THEORY, ONLY

IN THEORY. BUT FROM THE WORK THAT'S CURRENTLY GOING ON, IT WOULD BE DIFFICULT TO DERIVE SPERM FROM XX; THAT IS, FEMALE CELLS, GERM CELLS, BECAUSE YOU NEED THE Y CHROMOSOME OR THE GENES ON THE Y CHROMOSOME FOR THE DEVELOPMENT OF A SPERM. AND IT'S PRETTY CLEAR THAT YOU'VE GOT TO HAVE THOSE GENES FUNCTIONAL. SO IT WOULD BE QUITE DIFFICULT, I THINK, TO DEVELOP FUNCTIONAL SPERM WITHOUT A Y CHROMOSOME PRESENT AT SOME POINT IN TIME.

THE EGG IS AN EXTREMELY COMPLEX AND UNSTABLE STRUCTURE. IT'S A VERY LARGE CELL IN THE BODY. IT'S A VERY COMPLICATED STRUCTURE. IT HAS A VERY COMPLICATED SET OF FUNCTIONS. AND THAT'S UNLIKELY TO BE REPLICATED OUT OF CELLS WHICH WOULD BE XY BECAUSE BOTH XX CHROMOSOMES ARE UNMETHYLATED IN THE GAMETOGENESIS PROCESS, AND THEY NEED TO BE FUNCTIONAL FOR THAT PROCESS TO TAKE PLACE. SO IT'S NOT IMPOSSIBLE, BUT I'M JUST SAYING IT'S GOING TO BE DIFFICULT. BUT THIS WOULD BE THOUGHT TO BE A CONTROVERSIAL ISSUE, RIGHT, AND I'M BRINGING IT IN YOUR ATTENTION.

ALSO, THE CONSENT TO USE THE CELLS OR TISSUES FOR IPS CELL FORMATION OF GAMETES FROM INDIVIDUALS, INCLUDING THOSE THAT MIGHT BE FAMOUS OR DESIRABLE OR DECEASED, THESE ARE ISSUES WHICH WOULD PRODUCE A CONTROVERSY AS FAR AS I WOULD ESTIMATE.

WHAT ARE THE POTENTIAL MERITS OF THE RESEARCH? WELL, YOU MIGHT BETTER UNDERSTAND THE PATHOPHYSIOLOGY OF HUMAN INFERTILITY, PREMATURE MENOPAUSE, AND STERILITY. A BETTER UNDERSTANDING OF THAT WILL BE MUCH MORE HELPFUL IN OUR MEDICAL DECISIONS WHEN WE'RE WORKING WITH THOSE PATIENTS. YOU COULD ALSO DETERMINE THE FUNCTION OF GENE PRODUCTS AND THEIR MECHANISMS OF ACTION, WHICH UNDERPINS AN UNDERSTANDING OF REPRODUCTION, BUT ALSO ERRORS AND DEFECTS. SO IT MAY BE VERY IMPORTANT TO HELP US UNDERSTAND THE BASIS OF MAJOR DEFECTS AND ERRORS.

ALSO, THE UNDERSTANDING OF THE ROLE OF ASSOCIATED CELLS AND TISSUES BECAUSE GAMETES DEVELOP WITHIN THE TESTES AND THE OVARY, AND ALSO THERE ARE VERY IMPORTANT RELATIONSHIPS WITH THE TISSUES WHERE THEY'RE FOUNDED, BUT ALSO WITH THE CELLS WHICH THEY INTERACT WITH, INCLUDING THOSE SO-CALLED NICHE ENVIRONMENTS IN THE HEALTH OF HUMAN GAMETES. SO THAT'S AN IMPORTANT AREA OF FURTHER UNDERSTANDING.

IT IS ALSO A POTENTIAL SOURCE OF RECIPIENT OOCYTES FOR NUCLEAR TRANSFER IF YOU'RE ABLE TO DEVELOP OOCYTES FROM THIS PROCESS AND STEM CELL RESEARCH. SO IT'S A POSSIBILITY, AND IT'S BEEN ARGUED THAT WAS THE CASE. AND IT HAS A POTENTIAL FOR UTILIZATION OF TREATMENTS FOR PREMATURE OR POSTMENOPAUSAL INFERTILITY

OR MALE STERILITY. SO THERE ARE SOME MERITS AND THERE ARE SOME CONTROVERSIES AND THERE ARE SOME REAL DIFFICULTIES.

AND I HOPE THIS MAYBE, BERNIE, IS WHAT YOU WANTED, BUT THIS IS THE WAY, I THINK, GENERALLY THE FIELD FEELS ABOUT IT AT THE MOMENT. I DON'T THINK THERE'S REALLY ANY CHANCE OF THIS HAPPENING IN A WAY THAT WOULD IMPACT THE COMMITTEE WITHIN THE NEXT FIVE YEARS. BUT NEVERTHELESS, WE'VE BEEN SURPRISED SOMETIME AT THE RATE OF PROGRESS OF SOME RESEARCH, AND I THINK IT'S A VERY LONG TERM, 10 YEARS OR 15 YEARS, BEFORE ANY OF THESE KIND OF TECHNIQUES WOULD BE LIKELY TO BE APPLIED. AND THEY ARE GUESSTIMATES RATHER THAN ANY SORT OF VERY FIRM KNOWLEDGE, BUT I SUSPECT THERE WOULD BE A VERY SERIOUS LOOK AT THE NORMALITY OF THE GAMETES IF YOU'RE GOING TO PRODUCE CHILDREN AND THEN GROWN UP PEOPLE BECAUSE ALL OF THOSE ELEMENTS OF WHAT YOU DO WITH THE GAMETES WILL GO ON AND THEN BE INHERITABLE FROM THEN ON.

CHAIRMAN LO: ALAN, THANK YOU VERY MUCH FOR A VERY SORT OF ELEGANT OVERVIEW OF THIS. I THINK WHAT IT'S IMPORTANT FOR US TO UNDERSTAND IS ALTHOUGH WE MAY HEAR THINGS IN THE PRESS OR AN INFORMAL CONVERSATION ABOUT, WELL, THIS IS RIGHT AROUND THE CORNER, ONE OF THE THINGS I THINK ALAN IS SAYING IS THERE'S SOME VERY

INTERESTING WORK, BUT THERE'S A LOT OF OTHER WORK THAT NEEDS TO BE DONE THAT WILL TAKE MANY YEARS BEFORE ANY OF THESE SORT OF SCENARIOS REALLY COME TO PASS. SO THIS NEED NOT BE ON OUR PLATTER NOW, BUT IT'S CERTAINLY OF GREAT INTEREST AND SORT OF FORMS THE BACKGROUND WHY PEOPLE ARE JUST INTERESTED IN STEM CELL SCIENCE.

COMMENTS? JOSE, YOU WANT TO START US OFF.

DR. CIBELLI: JUST QUESTION TO ALAN. YOU ARE TRYING TO ADDRESS THE ISSUE OF EMBRYONIC STEM CELLS MAKING GAMETES OR THE NEED FOR GAMETES TO WORK IN REGENERATIVE MEDICINE OR HELPING PEOPLE OVERCOME INFERTILITY? WHAT IS THE CONCERN HERE?

DR. TROUNSON: WELL, I THINK THE CONCERN HERE IS THAT THERE WERE PUBLICATIONS WHICH DEMONSTRATED IN THE POPULAR PRESS THAT HUMAN SPERM HAVE BEEN DEVELOPED FROM EMBRYONIC STEM CELLS AND WITH IPS CELLS. IF YOU USE THE SAME SYSTEM, IT'S POSSIBLE YOU COULD DEVELOP FROM THEM. WHAT I'M SUGGESTING TO YOU IS THAT THAT IS SOME TIME OFF BECAUSE OF THE REQUIREMENT TO UNDERSTAND THIS PROCESS VERY MUCH BETTER THAN IT'S CURRENTLY UNDERSTOOD. AND THAT EVEN IF THERE ARE CLAIMS THAT YOU CAN PRODUCE A SPERMLIKE CELL AND THE FACT THAT YOU CAN PRODUCE MICE, BUT THOSE MICE CERTAINLY HAD PROBLEMS, THEY DIDN'T SURVIVE VERY LONG, WOULD MEAN THAT THERE'S A LOT OF BASIC RESEARCH THAT NEEDS TO BE GOING ON

THERE.

SO IT'S MORE ABOUT JUST BEING AWARE THAT THIS IS NOT -- WE'RE NOT REALLY RIGHT ON THE EDGE, AS BERNIE SAID, OF A NEW DEVELOPMENT. I THINK IT'S GOING TO BE SOME TIME AWAY BEFORE WE CAN ADOPT IT.

DR. CIBELLI: BUT IF THE ISSUE IS THE OTHER WAY AROUND, SO THAT THE NEED FOR GAMETES, I THINK WITH THE PUBLICATION OF THE PAPER IN *NATURE* LAST WEEK FROM OREGON WHERE THEY DID THIS SPINDLE TRANSFER, I THINK THERE WILL BE AN INCREASED NEED FOR OOCYTES. AND I'D LIKE TO KNOW YOUR VIEW ON THAT.

DR. TROUNSON: SO THIS IS WORK THAT WAS DONE BY MITALIPOV AND COLLEAGUES WITH MONKEYS IN OREGON. AND THEIR WHOLE AIM THERE WAS THE ADDRESSING OF MITOCHONDRIAL DISEASE. MITOCHONDRIAL DISEASE IS A COMPLEX DISEASE THAT IN THE MITOCHONDRIA YOU CAN HAVE DNA AND YOU CAN HAVE MUTATIONS IN THE DNA USUALLY ASSOCIATED WITH ENERGY SYSTEMS IN THE CELL, AND SO HEALTH OF THE CELLS, IF YOU LIKE. THEY ALSO RELATE, I THINK, TO SOME MENTAL RETARDATION CONDITIONS. SO THERE ARE ISSUES IF YOU HAVE A BROAD SPECTRUM OF THESE DISEASES IN THE MITOCHONDRIA WHICH ARE EXPOSED THROUGH MUTATIONS IN THE MITOCHONDRIAL DNA, HOW WOULD THAT BE REPAIRED.

WELL, IF YOU TOOK THE NUCLEUS OF THE CELL OF

THE INDIVIDUAL AND YOU PUT IT IN ANOTHER EGG THAT HAD A CLEAN SET OF MITOCHONDRIAL DNA, THAT YOU WOULD NOT THEN TRANSMIT THE MITOCHONDRIAL DISEASE. WHILE THE MONKEYS IN THE STUDY DID NOT HAVE MITOCHONDRIAL DISEASE, THEY SHOWED THAT YOU COULD TRANSPLANT THE CHROMATIN MATERIAL, THE SPINDLE, FROM ONE EGG, ONE MONKEY EGG, INTO ANOTHER EGG THAT HAD CLEAN MITOCHONDRIA OR ITS OWN MITOCHONDRIA AND THAT THAT DEVELOPED MONKEY COULD DEVELOP TO TERM. THAT EMBRYO COULD DEVELOP TO TERM.

SO IT PROVIDES THE BASIS FOR TREATMENT OF MITOCHONDRIAL DISEASE, A PROOF OF CONCEPT, IF YOU LIKE, IN AN ANIMAL.

THERE'S ANOTHER GROUP AT THE UNIVERSITY OF NEWCASTLE THAT HAS BEEN TRYING TO DO THAT IN THE HUMAN, AND I THINK THEIR WORK IS YET NOT ANYWHERE NEAR THAT DEVELOPED STATE. NOW, WHETHER THIS IS GOING TO BE ARGUABLY IMPORTANT FOR REMOVING GENETIC ABNORMALITIES FROM THE POPULATION, I'M UNSURE. BUT IT'S CERTAINLY A COMPLICATED PROCEDURE, AND IT'S A TECHNICALLY DIFFICULT ONE, BUT I DON'T THINK IT WILL IMPINGE UPON OUR WORK IN STEM CELLS NECESSARILY, OR I DON'T UNDERSTAND WHERE IT WOULD, BUT IT IS IMPORTANT FROM POINT OF VIEW OF GENETIC DISEASE IN FAMILIES THAT HAVE GOT KNOWN MITOCHONDRIAL DISORDERS, PARTICULARLY THOSE DISORDERS WHICH LEAD TO VERY SERIOUS CONDITIONS.

CHAIRMAN LO: OTHER QUESTIONS? ALTA.

MS. CHARO: THIS IS MORE BY WAY OF A COMMENT THAN A QUESTION, ALAN. FIRST, I WANT TO APOLOGIZE FOR FOOLING AROUND WITH THE IPHONE WHILE YOU WERE SPEAKING, BUT IT WAS BECAUSE I RECALLED THAT THERE ACTUALLY HAD BEEN A GROUP ABOUT 18 MONTHS AGO THAT HAD DONE SOME CONCENTRATED WORK ON THIS, I WAS ABLE TO SIT IN ON THE MEETINGS, CALLED THE HINXSTON GROUP, WERE FAMILIAR WITH IT. I'M NOT SURE EVERYBODY ELSE IS. BUT FOR WHAT IT IS WORTH, THIS IS A KIND OF GLOBALLY BASED GROUP, SELF-APPOINTED, OF PEOPLE WHO ARE MOSTLY RESEARCHERS AND A SMATTERING OF ETHICS AND POLICY TYPES THAT SPENT TWO AND A HALF CONCENTRATED DAYS IN ENGLAND TALKING ABOUT THE SCIENCE AND KEEPING IN MIND THE KIND OF POLITICAL CONTEXT AT THE TIME AT APRIL 2008.

THE CONVERSATION PROGRESSED IN THE FOLLOWING WAY, THAT THERE WAS ABSOLUTE AGREEMENT THAT THIS WAS IN NO WAY REMOTELY SAFE FOR HUMAN REPRODUCTION. AND THE QUESTION ON EVERYBODY'S MIND WAS WHETHER OR NOT GOVERNMENTS MIGHT WANT TO CRIMINALIZE THE VERY RESEARCH ON A KIND OF SLIPPERY SLOPE ARGUMENT BECAUSE THERE HAD BEEN SUCH FUSS IN THE PAPERS ABOUT THE POSSIBLE DOWNSTREAM HUMAN REPRODUCTIVE APPLICATIONS. AND SO THEY CAME UP WITH A STATEMENT, BUT BECAUSE, OF COURSE, IT HAD TO SERVE THE JAPANESE AND THE GERMANS AND THE

ENGLISH AND THE AMERICANS AND THE FRENCH, IT'S PRETTY BENIGN.

BUT NONETHELESS, JUST BECAUSE I WANTED TO KIND OF UNDERSCORE WHAT YOU ALL WERE JUST SAYING, THAT JUST BECAUSE IT'S ON YOUR SLIDE DOESN'T MEAN THAT THIS GROUP IS ABOUT TO START FUNDING RESEARCH ON USING SYNTHESIZED GAMETES FOR HUMAN REPRODUCTION, THAT THERE'S ALSO A GLOBAL CONSENSUS ON THAT POINT ALREADY KIND OF IN PLACE AMONG SOME OPINION LEADERS.

DR. TROUNSON: IT'D BE FAIR TO SAY, ALTA, THAT THAT WAS EXACTLY THE ARGUMENT THAT WAS RAISED WHEN WE FIRST DEVELOPED IVF, OF COURSE. SO WHAT'S REQUIRED IS THAT THE SCIENTISTS NEED BE ABLE TO PROVE AS BEST THEY CAN THAT THEY ARE NORMAL. SO WE'RE UNDERPINNING THE SAME ISSUE, I THINK. IT'S JUST THAT, YOU KNOW, WE MIGHT HAVE CONFIDENCE THAT IN A 20-YEAR TIMEFRAME THAT THEY MAY WELL HAVE GOT TO THAT POINT IN 15 YEARS OR 10 YEARS WHERE THEY'RE ABLE TO DEMONSTRATE THAT ADEQUATELY. AND THERE MIGHT BE A DIFFERENT DISCUSSION HERE OR IN THE COMMUNITY ABOUT THE MERITS OF IT.

MS. CHARO: RIGHT. AND THAT'S ABSOLUTELY TRUE. IT WAS SIMPLY THAT THE PRESS HAD BEEN LEAPING SO QUICKLY FROM FIRST STUDY WITH MOUSE TO NEXT YEAR BABY IN SAN FRANCISCO, THAT IT SEEMED IMPORTANT TO KIND OF ADDRESS WHAT WAS CURRENTLY APPROPRIATE AS OPPOSED TO

LEAPING FORWARD LIKE THE PRESS HAD DONE.

DR. TROUNSON: I AGREE.

CHAIRMAN LO: VERY IMPORTANT POINT BY ALTA. QUESTIONS?

DR. ROBERTS: I JUST WONDER, ALAN, IF YOU COULD COMMENT ON WHAT YOU THINK IS THE VIEW OF THE NEED FOR THESE GAMETES. YOU'VE MENTIONED LOTS OF POSSIBLE USES. DO YOU THINK THESE RESEARCHERS HAVE A PARTICULAR USE IN MIND? ARE MOST OF THEM THINKING TOWARD HUMAN REPRODUCTIVE USES? OR IS IT THERE'S THE CURING OF DISEASED STEM CELLS OR IS IT TOO EARLY?

DR. TROUNSON: I THINK THE RESEARCHERS ARE THINKING MUCH MORE ABOUT FUNCTION AND UNDERSTANDING THE PROCESS. BUT IN THAT UNDERSTANDING OF THE PROCESS, THEY WILL CONTINUE TO SORT OF MOVE FORWARD ALL THE TIME AND IN UNDERSTANDING THE PROCESS BETTER WILL WORK OUT WAYS IN WHICH YOU CAN ACTUALLY MATURE THESE CELLS IN A MORE NORMAL FASHION. THERE MAY COME A TIME WHERE THE ARGUMENT IS FOR MENOPAUSE, FOR THE TREATMENT OF MENOPAUSE, PARTICULARLY PREMATURE MENOPAUSE, WHERE STERILITY IS THE SITUATION FOR SOME YOUNG WOMEN. I THINK THE COMMUNITY MIGHT CONSIDER SOME OF THE OTHER ISSUES MORE CONTROVERSIAL. WHO KNOWS IN TEN YEARS TIME HOW WE WOULD FEEL ABOUT THE USE OF CELLS IN THE SAME SEX COUPLE.

IT'S JUST NOT EASY TO PREDICT THAT NOW. RIGHT NOW I DON'T THINK THERE'S A BASIS FOR THE DISCUSSION. NEVERTHELESS, IT'S AN ISSUE THAT IS REAL AND OUGHT TO BE THOUGHT ABOUT IN DUE COURSE BECAUSE IF THE RESEARCH WORK CONTINUES TO SHOW THAT YOU CAN EVOLVE A SYSTEM FOR GENERATING EITHER SPERM OR EGGS, AND EGGS ARE GOING TO BE MUCH HARDER, BUT LET'S SAY THEY DO, AND, OF COURSE, THERE WILL BE A CALL FOR THEIR APPLICATION IN PATIENTS WHO REALLY DON'T HAVE ANY OF THE SPERM OR EGGS.

MR. SHEEHY: I GUESS, FIRST OF ALL, I JUST FIND THIS A LITTLE -- BRINGS TO MIND WHAT'S THE DIFFERENCE BETWEEN CLONING AND DOING THESE THINGS. ONE OF MY BIGGEST PROBLEMS WITH CLONING IS THAT THE ONLY WAY YOU KNOW YOUR EXPERIMENT IS SUCCESSFUL IS YOU GROW A HEALTHY BABY. AND IF YOU HAVE A COUPLE OF MISFIRES IN THE MIDDLE, WELL, THAT'S SCIENCE. AND I FEEL KIND OF THE SAME WAY ABOUT TALKING ABOUT THESE GAMETE EXPERIMENTS FOR REPRODUCTIVE PURPOSES, THAT THE ONLY WAY YOU KNOW IT REALLY WORKS IS IF YOU ACTUALLY ARE ABLE TO CREATE A HUMAN BEING THAT DOESN'T HAVE A LOT OF MISTAKES IN THE CODING ALONG THE WAY.

SO I SEE THIS AS OFF IN THE FUTURE, BUT THIS DISCUSSION AND LEADING INTO REPRODUCTIVE PURPOSES IS A LITTLE BIT BRAVE NEW WORLD. ALSO, I DON'T UNDERSTAND,

AND THIS IS FROM A VERY PERSONAL POINT OF VIEW, WHY SAME SEX COUPLES' REPRODUCTIVE URGES ARE A RATIONALE FOR THIS BECAUSE I'M SOMEWHAT FAMILIAR WITH THE GAY AGENDA, AND WE'RE NOT ALL DEMANDING DESIGNER GAMETES TO BE -- I MEAN I DON'T WANT TO MAKE A -- WELL, I'M NOT TRYING TO MAKE AN EGG. AND I THINK PEOPLE HAVE DONE VERY WELL WITH ADOPTION OR OTHER ASSISTED REPRODUCTION TECHNIQUES. SO IT DOES SEEM A BIT OF A CANARD TO HAVE THE SAME SEX COUPLE REPRODUCTIVE URGE. I'M NOT SURE WHAT'S THE STIMULUS FOR THAT. IT SEEMS NEEDLESSLY CONTROVERSIAL TO MY MIND. BUT THE WHOLE THING, IT DOES SEEM AT SOME POINT WE'RE DOING SOME FORM OF HUMAN EXPERIMENTATION.

DR. TROUNSON: I THINK I WAS TRYING TO SUMMARIZE THE ISSUES IN THAT PAPER. THOSE ISSUES WERE DRAWN OUT AS CONTROVERSIAL. SO YOU COULD READ THOSE PAPERS, BUT I THINK, AGAIN, IN MANY RESPECTS THE SAME ARGUMENTS APPLY PRIOR TO IVF. AND FOR GOOD REASON THEY SHOULD APPLY. BUT THE NECESSITY FOR THE RESEARCH, I THINK, AND MORE BETTER UNDERSTANDING OF GAMETOGENESIS, I THINK THAT'S WHERE THE SCIENTISTS ARE. BUT IT'S NOT WHERE THE NEWSPAPERS ARE FREQUENTLY. THEY'RE IN SOME OTHER SPACE.

SO I THINK WE WANTED TO ADDRESS IT IN ORDER TO MAKE SURE THAT WE'VE BROUGHT OUT ALL THE ISSUES AND

DEMONSTRATED WHAT MIGHT BE IN THE FUTURE SOMETIME, BUT PERHAPS A LONG WAY.

CHAIRMAN LO: ALAN, THANK YOU VERY MUCH. AS YOU JUST SAID, I THINK WHAT'S IMPORTANT TO US IS TO DISTINGUISH BETWEEN WHAT MAY BE TALKED ABOUT IN THE PRESS OR ON BLOGS AND WHAT, IN FACT, IS THE SCIENTIFIC REALITY, AND THERE OFTEN IS A DISCREPANCY.

NEXT WE'RE GOING TO TURN TO REGULATORY ISSUES. AND ELONA BAUM, WHO'S THE GENERAL COUNSEL FOR CIRM, IS GOING TO TALK TO US ABOUT TWO TOPICS: ONE, FDA REGULATION, WHICH REALLY IS A FOLLOW-UP TO WHAT WE TALKED ABOUT AT A PREVIOUS MEETING, AND THEN SHE'S ALSO GOING TO TALK WITH US ABOUT A STATEMENT OF PRINCIPLES RELATED TO CLINICAL OVERSIGHT IN CIRM GRANTS.

SO, ELONA, THANKS VERY MUCH FOR COMING.

MS. BAUM: THANK YOU VERY MUCH. I THINK THAT MY SLIDES ARE NOT HERE; IS THAT RIGHT? I'M VERY SORRY ABOUT THAT. I ONLY HAD THREE SLIDES, AND I CAN JUST SPEAK TO THE ISSUE.

DR. LOMAX: WE CAN GET THEM. GIVE US A MINUTE.

CHAIRMAN LO: YOU CAN TALK.

MS. BAUM: I CAN SPEAK TO THE ISSUE ANYWAY. OKAY. THAT'S FINE.

MY UNDERSTANDING FROM THE LAST WORKSHOP THAT

WAS CONDUCTED ON CLINICAL TRIALS BY THIS GROUP BACK IN FEBRUARY WAS THAT TWO PRECISE ISSUES OR GENERAL ISSUES ON FDA-RELATED MATTERS CAME UP. ON MY SLIDE I WOULD HAVE ACTUALLY SHOWN THOSE. BUT I THINK THAT THERE WAS A RECOMMENDATION OR A THOUGHT THAT CIRM CAN FUNCTION AS A BROKER FOR EXCHANGING INFORMATION BETWEEN OUR GRANTEES AND, OF COURSE, THE FDA. SO THERE WAS A RECOMMENDATION TO CONSIDER WHETHER OR NOT CIRM COULD BE EFFECTIVE IN PLAYING THAT ROLE, AND THERE WAS A THOUGHT THAT THAT WOULD SERVE THE GREATER GOOD FOR THE GRANTEES.

AND THEN THERE WAS ALSO A NOTE TO THE EFFECT THAT IT WOULD BE VERY HELPFUL IF WE HAD SOME STANDARDS IN PLACE, OF COURSE, FOR PRECLINICAL TESTING, THAT IT'S ALWAYS HELPFUL WHEN YOU HAVE AN FDA GUIDANCE THAT CAN HELP GUIDE THE WAY FORWARD.

WE TOOK THOSE RECOMMENDATIONS AND SUGGESTIONS VERY SERIOUSLY AND CERTAINLY AGREE WITH NEEDING AN EXPANDED INTERFACE WITH THE FDA. AND WHAT WE DID IS I HAD A NIFTY LITTLE SLIDE THAT SHOWED ALL THE WORK THAT WENT INTO ACTUALLY DOING JUST THAT VERY THING. SO WE HAVE CREATED A CONSORTIUM, WHICH WE'RE CALLING THE REGENERATIVE MEDICINE CONSORTIUM.

DR. KIESSLING: EXCUSE ME. WHILE WE'RE WAITING FOR SLIDES, COULD YOU PLEASE TELL US WHO WE IS?

MS. BAUM: STAFF. I'M THE GENERAL COUNSEL OF CIRM.

DR. KIESSLING: SO THIS JUST CIRM STAFF IS THE WE.

MS. BAUM: CIRM STAFF IS THE WE. I'LL CONTINUE TO TALK. IN APRIL OF THIS YEAR, ACTUALLY ON MY VERY FIRST DAY AT CIRM, A GROUP, WE BEING STAFF, WENT TO THE FDA AND MET WITH THEM TO TALK ABOUT THIS CONCEPT, THIS ABILITY FOR US TO ESTABLISH SOME CONDUIT FOR COMMUNICATION AND WHAT THAT CONDUIT WOULD LOOK LIKE. WE HAD MANY IDEAS. AND IN THE END, AFTER MANY DISCUSSIONS -- AFTER MANY DISCUSSIONS, AS YOU CAN SEE, WE STARTED IN APRIL. WE HAD MANY DISCUSSIONS ON WHAT THE BEST CONDUIT WOULD BE FOR DISCUSSIONS WITH FDA. WE SETTLED ON A SITUATION WHERE WE WOULD HAVE ROUNDTABLE DISCUSSIONS WITH THE FDA.

INITIALLY WE THOUGHT THAT MAYBE WE WOULD DO A LIAISON COMMITTEE. AND THOSE OF YOU WHO ARE FAMILIAR WITH WORKING WITH THE FDA WOULD KNOW THAT THAT IS MORE FORMALISTIC IN THAT YOU ACTUALLY HAVE NOTES THAT ARE PUBLISHED, BUT WE WANTED TO ALLOW FOR A VERY FULL DISCUSSION OF IDEAS AND A LITTLE LESS FORMALITY, A LITTLE MORE INFORMALITY. SO WE CAME UP WITH THE NOTION THAT WE WOULD FORM A CONSORTIUM OF RESEARCHERS, THE DISTINGUISHED SCIENTISTS IN THE COMMUNITY THAT ARE

WORKING ON THESE ISSUES THAT WOULD SIT IN A ROUNDTABLE AND FDA WOULD BE PRESENT.

SO WE HAVE, I'M HAPPY TO SAY, FIXED OUR FIRST DAY FOR THAT VERY FIRST MEETING WITH FDA. AND THAT DATE WILL BE NOVEMBER 5TH, AND WE WILL HAVE A CONSORTIUM OF NATIONAL RESEARCHERS AND FUNDING ORGANIZATIONS AND RESEARCHERS BOTH IN ACADEMIA AND INDUSTRY AS PART OF THIS ROUNDTABLE. AND WE WANTED TO MAKE SURE THAT THE ROUNDTABLE WOULD BE SUFFICIENTLY SMALL TO ENCOURAGE A FULL DIALOGUE OF IDEAS, BUT LARGE ENOUGH SO THAT WE COULD GET A BROAD REPRESENTATION.

WE PROBABLY HAVE ABOUT 20 TO 25 MEMBERS AS PART OF THE CONSORTIUM. RIGHT NOW WE'RE IN THE PROCESS OF FINALIZING THE MEMBERSHIP. AND ON NOVEMBER 5TH, AS I SAID, WE'LL HAVE THE VERY FIRST MEETING. FDA IS VERY EXCITED ABOUT THIS. THEY ACTUALLY WANT TO INVITE 22 TO 30 PEOPLE TO ATTEND. AND SO I THINK THAT WE'RE GOING TO HAVE VERY ROBUST CONVERSATIONS. AND WHAT THOSE CONVERSATIONS WILL LOOK LIKE WILL BE GEARED TOWARDS THE DEVELOPMENT OF EVENTUALLY A GUIDELINE FOR PRECLINICAL TESTING AND EVENTUALLY SPECIFIC AREAS FOR ASSAY DEVELOPMENT. IT WILL TAKE A LONG TIME AS THE FDA HAS TO BE VERY CAREFUL, AND THERE'S A LOT OF KNOWLEDGE THAT NEEDS TO BE GLEANED BEFORE THEY CAN GO TO THE GUIDANCE STAGE.

I WANTED TO ELUCIDATE A LITTLE BIT MORE ABOUT WHAT THE PARTICULAR MISSION AND THE OBJECTIVES ARE OF THIS CONSORTIUM, AND THAT WILL GIVE YOU A LITTLE MORE INFORMATION OF WHAT ROLE WE INTEND TO SERVE. WE BEING THE CONSORTIUM IN THIS CONTEXT. THE CONSORTIUM'S MISSION, OF COURSE, IS TO SHAPE THE DEVELOPMENT OF THE HIGHEST QUALITY AND THE MOST EFFICIENT REGULATORY PATHWAY FOR BRINGING VITAL STEM CELL THERAPIES TO PATIENTS.

AND HOW WILL WE DO THAT? WELL, THE FIRST STEP, AS I SUGGESTED, IS FOR DISCUSSION, DISCUSSION OF AREAS OF MUTUAL INTEREST TO BOTH THE FDA AND TO THE RESEARCHERS IN THE COMMUNITY. BUT WE WILL HAVE VERY DISTINGUISHED EXPERTS IN THESE ROUNDTABLES, AND IT IS THE HOPE THAT THESE ROUNDTABLES WILL SERVE AS A TECHNICAL RESOURCE, AS I INDICATED, FOR DEVELOPING THESE GUIDELINES THAT ARE SO CRITICAL FOR ADVANCING THE FIELD. AND, OF COURSE, I EXPECT THAT DURING THESE ROUNDTABLES, WE'LL BE IDENTIFYING VARIOUS SCIENTIFIC GAPS AND APPROACHES TO CLOSING THOSE GAPS.

SO WITH THAT SAID, I'M HAPPY TO EXPLAIN MORE ABOUT THE AGENDA OF THIS FIRST MEETING. IT WILL TOUCH ON EVERYTHING FROM WHAT FDA CONSIDERS ITS TOP ISSUES FOR ISSUING AN IND AND IND READINESS. WE WILL BE ALSO IDENTIFYING AREAS WHERE WE THINK THERE ARE SOME

ROADBLOCKS FOR PROGRESSING IN THE FIELD, SOME REGULATORY HURDLES. WE'LL TALK ABOUT ASSAYS THAT WE THINK SHOULD BE DEVELOPED, AND MIGHT EVEN START DELVING INTO SOME AREAS SUCH AS WHAT THE NATURE OF ANIMAL STUDIES NEEDS TO BE. WE'LL GET HOPEFULLY PRETTY DETAILED.

DR. PRIETO: QUESTION I HAVE IS WHO'S ACTUALLY CONVENING THE CONSORTIUM, AND WHO DECIDES WHO'S INVITED, WHO SETS THE AGENDA?

MS. BAUM: I'LL ANSWER ALL OF THOSE ONE BY ONE. CONVENING, CIRM IS TAKING THE LEADERSHIP ON THIS. MEMBERS INCLUDE VARIOUS ACADEMIC INSTITUTIONS ACROSS THE NATION. THIS COULD NOT BE SOMETHING THAT WAS CALIFORNIA CENTRIC. THAT WAS VERY CLEAR BY FDA AND UNDERSTANDABLY WHY.

AND SO WHO WILL LEAD IT, IT WILL BE CIRM IN TERMS OF DOING A LOT OF THE LOGISTICS, BUT THE AGENDA WILL BE DECIDED BY THE CONSORTIUM. I ACTUALLY HAD TO TAKE THE LEADING ROLE IN FORMING THE FIRST AGENDA BECAUSE I WANTED TO GET THIS PROCESS IN PLACE. AND I GAVE THE FDA A STRAW MAN PROPOSAL, WHICH THEY HAPPENED TO ACTUALLY LIKE AND MADE VERY LITTLE CHANGE TO. AS I'M TALKING TO VARIOUS MEMBERS WHO ARE INTERESTED IN JOINING THE CONSORTIUM, I'M ASKING THEM FOR ADDITIONAL COMMENTS ABOUT AGENDA ITEMS.

AND IN THE FUTURE, THE WAY THESE THINGS ARE NORMALLY SET UP AND PROGRESS IS THAT AT THE MEETING THAT YOU HAVE, YOU ASK THEM FOR AGENDA ITEMS FOR THE NEXT MEETING. AS I SAID, WE WANT TO DO THIS QUARTERLY. AND THAT'S THE GENESIS OF IT.

MR. SHEEHY: HAS THERE BEEN ANY CONSIDERATION TO ACTUALLY INVOLVING PATIENTS IN THIS PROCESS OR PATIENT ADVOCATES? YOU KNOW, WE ALWAYS TALK ABOUT THE JESSE GELSINGER CASE. AND ONE OF THE THINGS THAT'S BEEN BROUGHT UP AS A WAY TO POSSIBLY AMELIORATE THAT IS DO WHAT WE'VE DONE IN HIV AND INVOLVE PATIENTS AND PATIENT ACTIVISTS AND THAT COMMUNITY INTO THIS PROCESS. THAT'S ALWAYS BEEN A FEATURE THAT'S BEEN UNIQUE TO CIRM, BUT PERHAPS ISN'T PART OF THIS. BUT I THINK THAT THAT WOULD BE INTERESTING.

I KNOW AT LEAST IN THE HIV FIELD THERE ARE PEOPLE WITH ENORMOUS EXPERIENCE WITH THE FDA. AND PERHAPS ASKING SOME OF THE CONSORTIUM PARTNERS TO IDENTIFY, I MEAN CERTAINLY YOU COULDN'T PICK SOMEONE OFF THE STREET, BUT I THINK WITHIN VARIOUS DISEASE ORGANIZATIONS AND ADVOCACY GROUPS, THERE ARE PEOPLE WHO ARE VERY KNOWLEDGEABLE ABOUT THE FDA PROCESSES AND MIGHT BE ABLE TO SPEAK -- I KNOW JOAN IS VERY KNOWLEDGEABLE ABOUT APPROPRIATE DISEASE MODELS FOR PARKINSON'S PATIENTS AND CAN TALK QUITE ELOQUENTLY

ABOUT THAT.

I KNOW THAT OUR CO-VICE CHAIR, DUANE ROTH, HAS BEEN VERY EMPHATIC ABOUT THE NEED TO GET PATIENT ADVOCATES INTO MEETINGS WITH THE FDA IN ORDER TO PERHAPS PROPEL SOME OF THIS SCIENCE FORWARD. I THINK IT'S MORE COMPELLING TO THE FDA. MAYBE ALTA HAS SOME THOUGHTS ON THIS. BUT AT LEAST FROM THE HIV -- NO, YOU DON'T WANT TO SAY. I'M SORRY. I SHOULD LEAVE YOU OUT OF THIS. BUT IT SEEMS TO ME IN THE PAST WHEN THE FDA HAS BEEN CONFRONTED WITH THE ACTUAL CONCERNS OF ACTUAL PATIENTS, THAT THERE'S BEEN PERHAPS A LITTLE MORE ALACRITY. SO IT'S A SUGGESTION. IT WOULD SEEM LIKE IT WOULD BE APPROPRIATE TO THINK ABOUT HAVING PATIENTS INVOLVED.

DR. TAYLOR: I'M GOING TO LEAVE ALTA OUT OF THIS. BUT ONE QUESTION IS MY EXPERIENCE WITH THE FDA IS THAT THEIR COMMITTEES TEND TO BE DISEASE FOCUSED. AND WITH SOMETHING AS BROADLY APPLICABLE AS STEM CELL, I'M KIND OF CURIOUS FROM YOUR PERSPECTIVE HOW ARE THEY GOING TO POPULATE THEIR SIDE OF IT? YOU'VE GOT YOUR CONSORTIUM MEMBERS, BUT WHO WILL REALLY BE REPRESENTING THE FDA? WHAT KIND OF EXPERTISE WILL THEY BE BRINGING, PRESENT COMPANY NOTWITHSTANDING? AND HOW DO YOU THINK THAT THAT'S GOING TO GO FORWARD BECAUSE THIS IS GOING TO BE BROADER THAN KIND OF A DISEASE-FOCUSED CARDIAC

DRUG SORT OF COMMITTEE.

MS. BAUM: YES, I UNDERSTAND. IN PRIOR EXPERIENCE, I VERY MUCH UNDERSTAND THAT THEY'RE DISEASE FOCUSED IN CDER. ALL OF MY DISCUSSIONS WITH DR. WITTEN, WHO IS THE DIRECTOR OF THE OFFICE OF CELLULAR, TISSUE, AND GENE THERAPY, DIDN'T EVER SEEM TO FOCUS ON AN INDICATION-BY-INDICATION BASIS. I THINK THAT WE'LL BE DRAWING MOSTLY FROM THAT OFFICE, BUT WE ALSO, WHEN I WAS IN DISCUSSIONS WITH HER, WERE TALKING ABOUT PULLING IN REPRESENTATIVES FROM, FOR INSTANCE, THE OFFICE OF POLICY. AND THEY DID MENTION ABOUT HAVING A MEMBER OR TWO FROM THE OFFICE OF COMPLIANCE COME.

AND WITHOUT OUR SUGGESTION, AND I THINK THIS REALLY SORT OF ILLUSTRATES THE IMPORTANCE THAT THEY'RE PLACING ON THIS WHOLE EXERCISE, THEY ACTUALLY SUGGESTED THAT WE HAVE THE CENTER DIRECTOR OF CBER COME AND PRESENT SORT OF THE VISION FOR THE FUTURE AT THIS VERY FIRST MEETING. AND THEY DID SAY THAT SCHEDULES MIGHT BE THAT THAT DOESN'T HAPPEN, BUT SOMEBODY FROM THE CENTER OFFICE WOULD CERTAINLY SHOW UP FOR THIS VERY FIRST MEETING.

ANOTHER TOPIC THAT I JUST WANTED TO TOUCH ON, BUT NOT SUGGEST THAT WE SPEAK TO TODAY, AND I DON'T THINK IT'S SOMETHING THAT WE SHOULD TALK ABOUT AND

DELIBERATE ON, IS THE ROLE OF THIS STANDARDS GROUP FOR SETTING STANDARDS FOR CLINICAL TRIALS. I JUST WANTED TO POINT UP THE FACT THAT THIS IS SOMETHING THAT IS PROBABLY GOING TO BE BROUGHT TO THE ATTENTION OF THIS GROUP. AND I DON'T WANT TO SUGGEST THAT IT BE DISCUSSED HERE TODAY BECAUSE WE HAVEN'T AGENDIZED IT, AND WE WANT TO BE RESPECTFUL OF THE BAGLEY-KEENE PROCESS THAT WE'VE ELECTED TO RESPECT IN THIS CONTEXT. BUT I THINK THAT WE SHOULD ALL EXPECT TO HAVE A DISCUSSION ON THAT AT SOME POINT IN THE FUTURE.

THAT'S ALL I WANTED TO SHARE WITH THE GROUP TODAY.

CHAIRMAN LO: ANY OTHER QUESTIONS, COMMENTS FOR ELONA? WELL, THANKS VERY MUCH. SOUNDS LIKE YOU HAVE BEEN VERY BUSY AND HAVE GOTTEN SOME REAL INTEREST AND MOVEMENT AT THE FDA. HOPEFULLY THIS WILL WORK OUT.

OUR NEXT SPEAKER IS FROM NEW YORK STATE, AND WE'RE VERY GRATEFUL FOR ROBERT KLITZMAN FOR COMING. HE'S AN ASSOCIATE PROFESSOR OF PSYCHIATRY AT COLUMBIA UNIVERSITY AND WAS THE CO-FOUNDER AND CO-DIRECTOR OF THE COLUMBIA UNIVERSITY CENTER FOR BIOETHICS. HE ALSO IS DIRECTOR OF THE ETHICS AND POLICY CORE IN THE COLUMBIA HIV CENTER. MORE TO THE POINT, HE WAS APPOINTED BY THEN GOVERNOR SPITZER TO THE EMPIRE STATE BOARD THAT OVERSEAS STEM CELL RESEARCH. AND THEY HAVE

AN ETHICS COMMITTEE AND SORT OF A FINANCE COMMITTEE, AND HE IS ONE OF THE MEMBERS OF THE ETHICS COMMITTEE. HE'S BEEN VERY INVOLVED IN HELPING SHAPE THE PUBLIC DISCUSSIONS ABOUT THEIR NEW POLICY ON DONOR COMPENSATION.

AGAIN, I JUST WANT TO UNDERLINE BECAUSE THERE'S BEEN A LOT OF MISCONCEPTIONS IN THE PRESS AND IN BLOGS THAT SOMEHOW WE DON'T UNDERSTAND ON THIS BOARD THAT WE'RE, OF COURSE, BOUNDED BY PROP 71, AND WE ARE NOT ABLE BY STATUTE TO PAY DONORS OF -- WOMEN WHO ARE DONATING OOCYTES DIRECTLY FOR RESEARCH BY STATUTE. AND, OF COURSE, WE RESPECT THAT. BUT I THINK IT'S IMPORTANT FOR US TO UNDERSTAND WHAT NEW YORK HAS DONE BECAUSE, AGAIN, I THINK SOME OF THE PRESS HAS BEEN NOT NECESSARILY ACCURATE, BUT ALSO I WANT US TO UNDERSTAND THE PROCESS THEY WENT THROUGH TO ARRIVE AT THAT DECISION SO THAT WE CAN SORT OF GET A FLAVOR FOR BOTH THE ISSUES THAT WERE RAISED AND THE PROCESS THEY USED TO DELIBERATE ABOUT THOSE ISSUES.

AND I THINK THERE'S SOME THINGS WE MIGHT LEARN OR THAT MIGHT REINFORCE IN TERMS OF THE BEST WAY TO HANDLE THIS PROCESS OF MAKING RECOMMENDATIONS ON DEEPLY CONTENTIOUS AND IMPORTANT ISSUES. BOB, THANKS VERY MUCH FOR COMING. AND WE'RE GOING TO HAVE YOU TALK FOR ABOUT HALF AN HOUR PERHAPS, AND WE LEFT A LOT OF

TIME FOR QUESTIONS. I THINK IT WOULD BE GOOD FOR US TO GET AN APPRECIATION FOR WHAT THEY'VE DONE IN NEW YORK. AND I'M SURE THERE WILL BE A LOT OF QUESTIONS THAT WE'LL WANT TO ASK AND COMMENTS WE'LL MAKE. SO, BOB, GO AHEAD.

DR. KLITZMAN: THANK YOU VERY MUCH. THANK YOU FOR INVITING ME. AND I ALSO WANT TO THANK CIRM ON BEHALF OF NEW YORK FOR ALL OF ITS WONDERFUL WORK OVER THE PAST FEW YEARS BECAUSE WE IN NEW YORK STATE CAME TO STATE FUNDING FOR STEM CELL RESEARCH AFTER YOU DID, AND WE REALLY VERY MUCH APPRECIATE THE HARD WORK THAT YOU HAD ALL DONE AND THE REPORTS THAT YOU HAD ISSUED, ETC., THINKING THROUGH SOME OF THE VERY COMPLEX ETHICAL ISSUES AS WELL AS THE SCIENTIFIC RESEARCH THAT YOU'VE DONE AND BEEN SUPPORTING, ETC. SO THANK YOU.

I THOUGHT I WOULD TALK A LITTLE BIT, AS BERNIE JUST SAID, ABOUT THE NEW YORK STATE INITIATIVE AND POINTS OF SIMILARITY AND PERHAPS DIFFERENCE. AT THE END OF THE PRESENTATION, I WOULD BE HAPPY TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

I THOUGHT I'D START JUST BY SAYING THAT WE HAVE A WONDERFUL WEB SITE THAT, IF YOU'RE INTERESTED, I'D ENCOURAGE YOU TO LOOK AT: WWW.NYSTEM.COM. NYSTEM BEING OBVIOUS WHAT IT STANDS FOR. AND WE HAVE A VERY OPEN, TRANSPARENT APPROACH. WE ARE MANDATED TO DO THAT

IN PART BY OPEN MEETING LAWS IN NEW YORK STATE, ETC., BUT WE REALLY MADE AN EFFORT TO PUT EVERYTHING WE DO ON THIS SITE.

JUST TO WALK YOU THROUGH QUICKLY, IF YOU LOOK ON THE RIGHT, THERE ARE PROGRAM UPDATES. IT SAYS EVENTS. IF YOU LOOK ON THE TOP RIGHT, IT SAYS ETHICS COMMITTEE MEETING. IF YOU WERE TO CLICK ON EVENTS, IT LISTS ALL THE UPCOMING MEETINGS. AGAIN, I APOLOGIZE. SOME OF THIS IS SMALL, BUT IT SAYS ETHICS COMMITTEE MEETINGS ON THE LEFT. IF YOU CLICK ONTO THAT, IT LISTS THE AGENDA OF OUR NEXT MEETING. AND IF YOU SCROLL DOWN, IT LISTS, YOU WILL SEE, MINUTES THAT ARE AVAILABLE FOR ALL OF THE MEETINGS THAT WE'VE HAD.

WE ALSO WEBCAST ALL OF OUR MEETINGS, AND THE WEBCASTS ARE THEMSELVES POSTED. SO IF YOU HAVE NOTHING BETTER TO DO WITH YOUR TIME, YOU CAN WATCH US IN PROCESS OF MEETING AND GET A FULLER FEEL FOR THE PROCESS.

AND I SHOULD SAY THE EMPIRE STATE STEM CELL BOARD WAS CREATED BY LAW IN 2008. JUST AS BACKGROUND, WHEN OUR FORMER GOVERNOR, ELIOT SPITZER, AND LIEUTENANT GOVERNOR DAVID PATTERSON RAN AND WERE ELECTED AS GOVERNOR AND LIEUTENANT GOVERNOR OF NEW YORK STATE, THEY MADE AS PART OF THEIR PLATFORM THE FACT THAT THEY WOULD SUPPORT STEM CELL RESEARCH. SO WHEN THEY WERE

ELECTED, THEY DEVOTED $600 MILLION THEY ALLOCATED OVER THE COURSE OF TEN YEARS FOR THIS. SO IT'S LESS THAN YOU ALL HAVE DONE IN CALIFORNIA, BUT WE HOPE WILL HELP MOVE THE SCIENCE ALONG IN THIS IMPORTANT GLOBAL ENTERPRISE.

AND SO IT'S PART OF HEALTH LAW. IN OTHER WORDS, UNLIKE HERE IN CALIFORNIA WHERE, AS I UNDERSTAND, THERE WAS A PROPOSITION 71 THAT WENT TO THE VOTERS, THIS WAS DONE THROUGH THE EXECUTIVE BRANCH IN CONJUNCTION WITH THE STATE LEGISLATURE. THE BOARD IS HEREBY EMPOWERED, SUBJECT TO ANNUAL APPROPRIATIONS AND OTHER FUNDING AUTHORIZED OR OTHERWISE MADE AVAILABLE, TO MAKE GRANTS TO BASIC, APPLIED, TRANSLATIONAL, OTHER RESEARCH AND DEVELOPMENTAL ACTIVITIES THAT WILL ADVANCE SCIENTIFIC DISCOVERIES IN FIELDS RELATED TO STEM CELL BIOLOGY. THIS, I MEANT TO SHOW EARLIER, WAS ALL THE MEETINGS YOU CAN CLICK ON TO SEE THEIR MINUTES. IF YOU DID DO THAT, BY THE WAY, IN THE MINUTES, YOU CAN SEE WHO ATTENDS, ETC.

SO JUST AS A LITTLE BIT OF BACKGROUND, THERE IS A FUNDING COMMITTEE AND ETHICS COMMITTEE. THE ETHICS COMMITTEE IS SORT OF THE EQUIVALENT OF THIS GROUP AS I UNDERSTAND IT. EACH COMMITTEE HAS 13 MEMBERS. THE COMMISSIONER OF HEALTH IS THE CHAIR AND IS A MEMBER OF BOTH. THERE ARE SIX DIRECT APPOINTEES

OF THE GOVERNOR, TWO NOMINATED BY THE MAJORITY LEADER OF THE SENATE, TWO NOMINATED BY THE SPEAKER OF THE ASSEMBLY, ETC., ETC. THEY'RE STAGGERED TERMS. THIS IS THE MEMBERSHIP. THE SCIENTIFIC MEMBERS INCLUDE OR DID ORIGINALLY HAROLD VARMUS UNTIL HE ACTUALLY STEPPED DOWN A FEW MONTHS AGO AFTER TAKING A POSITION WITH PRESIDENT OBAMA.

WE HAVE A DIVERSE GROUP ON THE LEFT OF THE ETHICS COMMITTEE. THERE HAVE BEEN PEOPLE WHO HAVE BEEN ADDED TO THAT, SOME WHO HAVE LEFT OVER TIME. DANIEL SULMASY, WHO'S WRITTEN EXTENSIVE ON THEOLOGICAL ISSUES AS WELL AS BEING A PHYSICIAN, MOVED TO CHICAGO AND IS NO LONGER A MEMBER, ETC.

FUNDING COMMITTEE RESPONSIBILITIES, THIS IS FROM THE WEB SITE, THERE'S A LOT OF TEXT HERE, BUT BASICALLY JUST TO HIGHLIGHT, THAT THIRD THING RECOMMENDS STANDARDS FOR THE SCIENTIFIC AND MEDICAL OVERSIGHT OF AWARDS AND, AS YOU MIGHT IMAGINE, REVIEWS THE APPLICATIONS, ETC. THE ETHICS COMMITTEE IS RESPONSIBLE TO MAKE RECOMMENDATIONS TO THE FUNDING COMMITTEE ON THE SCIENTIFIC, MEDICAL, AND ETHICAL STANDARDS, STANDARDS FOR ALL MEDICAL, SOCIOECONOMIC, AND FINANCIAL ASPECTS OF CLINICAL TRIALS AND THERAPY DELIVERY TO PATIENTS, OVERSIGHT OF FUNDED RESEARCH TO ENSURE COMPLIANCE WITH THE STANDARDS, AND OVERSEEING

RELEVANT ETHICAL AND REGULATORY ISSUES.

OTHER PROVISIONS, WE PROHIBIT HUMAN REPRODUCTIVE CLONING. THERE IS AN ANNUAL REPORT INCLUDING GRANT INFORMATION, AND THAT'S AVAILABLE ONLINE. WE'VE RECENTLY POSTED THE ANNUAL REPORT FROM THE FIRST YEAR.

RESTRICTIONS ON AMOUNT OF FUNDING DIRECTED TO ANY SINGLE INSTITUTION, RESTRICTION ON VOTING IN TERMS OF CONFLICT OF INTEREST, SUBJECT TO OPEN MEETINGS LAW, AS I MENTIONED. WE SERVE WITHOUT COMPENSATION. AND WE ESTABLISH STANDARDS FOR WORKING ON THIS FOR PATENT ROYALTIES, LICENSE REVENUES, ETC. WE'VE HAD A NUMBER OF MEETINGS. AND AS I MENTIONED, THEY'RE WEBCAST AND MINUTES ARE POSTED.

WE DEVELOPED A STRATEGIC PLAN. AGAIN, THIS IS BACKGROUND. AND WE LOOKED AT THE CALIFORNIA STRATEGIC PLAN, WHICH WAS VERY HELPFUL IN OUR THINKING THROUGH WHAT WE WOULD DO. AND WE WERE VERY ACTIVELY INVOLVED IN DOING THAT AND GOT A LOT OF INPUT FROM OTHERS AROUND THE STATE, ETC.

OUR OVERALL EXPENDITURES, AND, AGAIN, WE POSTED THIS, FOR THE FIRST FIVE YEARS $300 MILLION, PRETTY SELF-EXPLANATORY. ELSIE, FOLLOWING THE HUMAN GENOME RESEARCH INSTITUTE, WHICH HAS AN ELSI PROGRAM LOOKING AT ETHICAL, LEGAL, SOCIAL IMPLICATIONS OF THE

HUMAN GENOME PROJECT. WE'VE DONE THAT AS WELL AND ADDED AN E FOR EDUCATION AS WELL, AND A FEW OF US PUSHED TO HAVE A CERTAIN AMOUNT OF MONEY ALLOCATED FOR THOSE PURPOSES.

THE ELSIE, OUR MISSION IS TO ENSURE THAT STEM CELL RESEARCH IN NEW YORK STATE ADHERES TO THE HIGHEST STANDARDS OF MEDICAL ETHICS AND THAT ETHICAL, LEGAL, SOCIAL, AND PSYCHOLOGICAL IMPLICATIONS OF ADVANCES IN STEM CELL RESEARCH ARE APPROPRIATELY ADDRESSED BY ENGAGING DIVERSE COMMUNITIES IN RESEARCH, SCHOLARSHIP, AND EDUCATION ON THESE ISSUES. WE'VE WORKED VERY HARD TO FOLLOW THIS MISSION. OUR GOALS ARE TO EVALUATE ETHICAL, SCIENTIFIC, MEDICAL, LEGAL, AND SOCIAL ISSUES RELATED TO STEM CELL RESEARCH AND ESTABLISH ETHICAL STANDARDS, SUPPORT RESEARCH AND SCHOLARSHIP ON ELSIE ISSUES AS THEY RELATE TO STEM CELL RESEARCH THAT WILL HELP ADVANCE THE RESEARCH ITSELF AND ALSO INFORM PUBLIC POLICY AND ENGAGE DIVERSE COMMUNITIES TO ENHANCE PUBLIC UNDERSTANDING OF CRITICAL ELSIE ISSUES, AND PROVIDE OPPORTUNITIES FOR EDUCATION ON STEM CELL RESEARCH AND ITS IMPACT ON SOCIETY.

THERE'S ALSO EFFORTS THAT HAVE BEEN DONE BY THE ADMINISTRATION THROUGH THE DEPARTMENT OF HEALTH TO MAKE SURE THAT WE FOLLOW THE HIGHEST STANDARDS OF ACCOUNTABILITY AND INTEGRITY ON BEHALF OF THE PEOPLE OF

NEW YORK STATE. THEIR GOALS, JUST VERY BRIEFLY, ARE TO MANAGE THE PROGRAM TO ENGENDER PUBLIC TRUST AND MAKE SURE THAT WE FOLLOW ESTABLISHED PROCESSES TO ENSURE RESPONSIBLE CONDUCT OF RESEARCH, PROMOTE PUBLIC ACCESS TO INFORMATION ABOUT THE RESEARCH AND ALSO THE ACTIVITIES OF THE BOARD. PUBLIC BENEFIT AND ACCOUNTABILITY GOALS ARE VERY IMPORTANT. AND WE ANNUALLY ASSESS THIS, EVALUATE IP, TECHNOLOGY TRANSFER, FISCAL POLICIES, ETC.

AND THIS IS HOW MUCH WE'VE SPENT OVER TIME. WE'RE MOVING ALONG ON THESE THINGS. I'M HAPPY TO MAKE THESE AVAILABLE IF PEOPLE ARE INTERESTED. PARTLY IN THE INTEREST OF TIME, I THOUGHT I'D MOVE AHEAD TO THE MAIN REASON I WAS INVITED HERE IS TO TALK ABOUT OUR DECISION CONCERNING COMPENSATION FOR OOCYTE DONATION.

AND THIS WAS SOMETHING WE ANNOUNCED THIS PAST JUNE. IT FOLLOWS EXTENSIVE DELIBERATION WITH CONSIDERATION OF NATIONAL AND INTERNATIONAL ETHICAL STANDARDS AND MECHANISMS TO SAFEGUARD THE RIGHTS AND WELFARE OF OOCYTE DONORS. AND I THINK THE IMPORTANT POINT IS WE DID THIS AND DECIDED TO ADDRESS THIS ISSUE BECAUSE THE LACK OF COMPENSATION TO WOMEN HAS CREATED AND LIMITS THE PROGRESS OF STEM CELL RESEARCH. IN OTHER WORDS, IF YOU LOOK ACROSS THE COUNTRY, SPEAKING TO RESEARCHERS AT HARVARD, FOR INSTANCE, WHERE THEY

SPENT A GREAT DEAL OF MONEY TRYING TO GET WOMEN TO DONATE EGGS FOR STEM CELL RESEARCH, AFTER MANY YEARS AND HUNDREDS OF THOUSANDS OF DOLLARS OF RECRUITING EFFORTS, THEY FINALLY WERE ABLE TO GET JUST ONE PERSON RECENTLY TO DONATE.

SIMILARLY ELSEWHERE, AS WE UNDERSTAND IT, THERE HAVE BEEN EXTENSIVE EFFORTS TO HAVE WOMEN DONATE EGGS. AND WITHOUT COMPENSATION THEY HAVE NOT BEEN SUCCESSFUL. SO THE LACK OF COMPENSATION, ONE CAN ARGUE, HAS, IN FACT, IMPEDED THE PROGRESS OF THE SCIENCE. I THINK THAT THIS IS SOMETHING THAT IS IMPORTANT TO BEAR IN MIND AS WE CONSIDER THIS ISSUE.

SO WE INTENSIVELY EXAMINED AND DISCUSSED WHETHER IT IS ETHICALLY APPROPRIATE TO PROVIDE WOMEN WHO DONATE OOCYTES TO STEM CELL RESEARCH WITH ANY FORM OF REIMBURSEMENT. AND WHEN WOMEN DONATE THEIR OOCYTES FOR REPRODUCTIVE PURPOSES, THAT IS FOR IVF, NEW YORK STATE AND OTHER STATES AS WELL PERMIT REASONABLE REIMBURSEMENTS FOR OUT-OF-POCKET EXPENSES, TIME, AND THE AMOUNTS ARE CONSISTENT WITH THE GUIDELINES DEVELOPED BY THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, ASRM, WHICH IN THEIR GUIDELINES BY THEIR ETHICS GROUP SAY THAT SUMS OF 5,000 OR MORE REQUIRE JUSTIFICATION AND SUMS ABOVE 10,000 ARE NOT APPROPRIATE.

IMPORTANT IN OUR THINKING WAS THE FACT THAT THE RISKS ASSOCIATED WITH DONATING OOCYTES TO STEM CELL RESEARCH ARE NOT MORE THAN THOSE ASSOCIATED WITH REPRODUCTIVE DONATIONS. THEY'RE THE SAME. SO BASICALLY IN THIS COUNTRY THROUGHOUT THE NATION COMMON PRACTICE NOW IS THAT WOMEN WHO DONATE OOCYTES FOR REPRODUCTIVE PURPOSES ARE COMPENSATED. THOSE WHO MIGHT BE INTERESTED IN DONATING OOCYTES FOR RESEARCH ARE NOT COMPENSATED.

AND IT SEEMS TO US, AFTER EXTENSIVE DELIBERATION, TALKING TO MANY PEOPLE FROM ACROSS THE COUNTRY, THAT THERE WAS NO PRINCIPLED REASON ONE CAN ARGUE TO DISTINGUISH BETWEEN DONATION OF OOCYTES FOR REPRODUCTIVE PURPOSES AND RESEARCH PURPOSES WHEN DETERMINING THE EFFICALITY OF REIMBURSEMENT, THAT DONATING OOCYTES TO STEM CELL RESEARCH ARGUABLY, IN FACT, CONFERS A GREATER BENEFIT TO SOCIETY THAN DOES OOCYTE DONATION FOR PRIVATE REPRODUCTIVE USE, AND THAT POTENTIALLY THERE MAY BE THERAPIES THAT COULD BE DEVELOPED THAT CAN HELP, ARGUABLY, HOPEFULLY, MILLIONS OF PEOPLE WITH VARIOUS KINDS OF ILLNESSES, AS YOU KNOW.

THERE IS NO ETHICAL BASIS FOR DIFFERENT PAYMENT POLICIES FOR WOMEN WHO DONATE OOCYTES TO STEM CELL RESEARCH AND FOR PARTICIPANTS IN OTHER TYPES OF HUMAN SUBJECT RESEARCH. IN OTHER WORDS, PEOPLE ARE

INTERESTED IN BEING INVOLVED IN OTHER KINDS OF RESEARCH WHO ARE USUALLY REIMBURSED FOR THEIR EFFORTS. AND NATIONAL AND INTERNATIONAL CONSENSUS BODIES GENERALLY HAVE FOUND IT ACCEPTABLE TO PROVIDE REASONABLE COMPENSATION TO SUBJECTS IN HUMAN SUBJECTS RESEARCH TO REMUNERATE THEM FOR THEIR TIME AND DISCOMFORT ASSOCIATED WITH PARTICIPATION IN SUCH RESEARCH.

SO TO TREAT DIFFERENTLY WOMEN WHO DONATE OOCYTES TO STEM CELL RESEARCH WOULD, WE FELT, BE UNJUST AND WOULD DEMEAN THE SIGNIFICANT CONTRIBUTION THAT OOCYTE DONORS MAKE TO SOCIETY BY PARTICIPATING IN STEM CELL RESEARCH. I SHOULD SAY, BY THE WAY, THERE ARE TWO DOCUMENTS THAT WERE HANDED OUT IN ADVANCE FOR THE MEETING. ONE IS A STATEMENT BY OUR BOARD WHICH DISCUSSES MANY OF THESE POINTS AS WELL IF PEOPLE ARE INTERESTED IN SEEING THIS MORE THOROUGHLY.

NOW, GRANTED, EXCESSIVELY HIGH PAYMENTS COULD POTENTIALLY ACT AS AN UNDUE INFLUENCE OR INDUCEMENT TO DONATE. BUT WE FELT REASONABLE REIMBURSEMENT COUPLED WITH OTHER SAFEGUARDS IMPORTANTLY, WHICH I'LL TALK ABOUT IN A MOMENT, PROTECT AGAINST THIS. PROHIBITING REASONABLE PAYMENTS BECAUSE THEY MAY INTERFERE WITH THE WOMAN'S ABILITY TO WEIGH THE RISKS AND BENEFITS OF DONATION MAY, IN FACT, ALSO BE UNNECESSARILY PATERNALISTIC, FEELING THAT WOMEN CANNOT EVALUATE THESE

ISSUES FOR THEMSELVES. AGAIN, THESE ARE A SERIES OF ETHICAL ARGUMENTS ON BOTH SIDES AS A RESULT OF WHICH WE IN NEW YORK CAME OUT AS WE DID.

WE FELT THAT IT IS ETHICAL AND APPROPRIATE, THEREFORE, FOR WOMEN DONATING OOCYTES FOR RESEARCH AND FOR REPRODUCTIVE PURPOSES TO BE COMPENSATED IN THE SAME WAY. WE DO NOT PERMIT PAYMENT FOR DONATION OF EXTRA OOCYTES OR EMBRYOS FROM IVF'S CALLED LEFTOVER EMBRYOS, AND THIS MEASURE AFFECTS ONLY DONATIONS OF OOCYTES FOR STEM CELL RESEARCH. IMPORTANTLY, RIGOROUS REVIEWS BY AN INSTITUTIONAL OVERSIGHT COMMITTEE, BOTH AN IRB AND AN ESCRO, ARE REQUIRED TO ENSURE THAT NO UNDUE INDUCEMENT OCCURS AND THAT NO CONSIDERATION IS GIVEN FOR THE NUMBER OR QUALITY OF THE OOCYTES.

IMPORTANTLY ALSO IS THAT THERE IS ADHERENCE TO ASRM'S GUIDELINES. AND IMPORTANTLY ALSO THERE IS FULL DISCLOSURE, ALL THE SHORT-TERM AND LONG-TERM RISKS, PHYSICAL AND PSYCHOLOGICAL RISKS, THAT IS, AND BENEFITS, AND THAT THESE ARE FULLY DISCLOSED TO THE DONOR. AND WE INCLUDED LANGUAGE BOTH IN THIS AND OUR CONTRACT PROVISIONS FOR ANY RESEARCH THAT WE FUND THAT INFORMED CONSENT IS OBTAINED THROUGH A DYNAMIC PROCESS, NOT MERELY SIGNING A 20-PAGE FORM, BUT, IN FACT, THAT THE PARTICIPANT IS ACTIVELY ENGAGED IN THE PROCESS AND REALLY UNDERSTANDS WHAT'S INVOLVED, THE RISKS AND THE

BENEFITS, AND THAT THERE IS AN AVAILABILITY OF PSYCHOLOGICAL COUNSELING PRIOR TO DONATION IF IT'S FELT TO BE NEEDED.

SO WE ARE CONFIDENT THAT PROCEDURES IMPLEMENTED BY INSTITUTIONAL OVERSIGHT COMMITTEES, BOTH IRB'S AND ESCRO'S, AS MANDATED BY LAW AND BY NYSTEM CONTRACT REQUIREMENTS, WHICH WE'VE ALSO INSTITUTED, CAN PROTECT AGAINST POTENTIAL EXPLOITATION OF DONORS AND ENSURE EQUITABLE ACCESS TO OPPORTUNITIES TO PARTICIPATE IN THE RESEARCH.

SO WHAT WE PERMIT ARE OUT-OF-POCKET EXPENSES WHICH MAY INCLUDE COSTS ASSOCIATED WITH TRAVEL, HOUSING, CHILDCARE, AND MEDICAL CARE, AND ALSO FOR THE TIME BURDEN AND INCONVENIENCE ASSOCIATED WITH OOCYTE DONATION IN AN AMOUNT CONSISTENT WITH NEW YORK STATE STANDARDS FOR REPRODUCTIVE PURPOSES. AND THERE'S A BODY OF LAW ABOUT THAT AND NOT TO EXCEED THE RANGE PERMITTED BY ASRM.

SO I THOUGHT THAT I WOULD GIVE YOU A SENSE OF SOME OF THE THINKING THAT WE WENT THROUGH, SOMETHING ABOUT OUR BOARD AS A WHOLE. AND I'D BE HAPPY TO ANSWER ANY QUESTIONS THAT YOU MIGHT HAVE. THANK YOU AGAIN.

CHAIRMAN LO: BOB, AGAIN, THANKS VERY MUCH FOR COMING ALL THE WAY FROM NEW YORK. COULD I START THE QUESTIONS BY ASKING YOU TO TALK ABOUT HOW YOU

ENGAGED THE PUBLIC IN YOUR DELIBERATIONS AND IN THE FINAL POLICY RECOMMENDED.

DR. KLITZMAN: SO AS I MENTIONED, ALL OF OUR MEETINGS ARE PUBLIC. THEY'RE OPEN TO THE PUBLIC. ANYONE CAN COME. THEY ARE ANNOUNCED WELL IN ADVANCE. PEOPLE WHO HAVE COMMUNICATED ABOUT THIS ISSUE ARE CONTACTED WHENEVER NEW MEETINGS ARE SET UP. ON OUR WEB SITE WE HAVE ANNOUNCEMENTS WELL IN ADVANCE. AGAIN, ANYONE IS INVITED TO ATTEND AND PEOPLE DO ATTEND. WE ALSO HAVE ALL OF OUR MEETINGS WEBCAST. ALL OF OUR EFFORTS ARE OPEN TO PUBLIC COMMENT, AND WE GET PUBLIC COMMENTS ON MANY OF THE THINGS THAT WE DO THAT ARE THEN SHARED WITH MEMBERS OF THE COMMITTEE. AND MINUTES ARE AVAILABLE. WE GET COMMENTS ON THOSE AS WELL.

CHAIRMAN LO: IF I COULD JUST ASK A LITTLE MORE. SO ARE YOU PART OF A FORMAL REGULATORY PROCESS WHERE YOU PUT OUT A POLICY PROPOSAL OR IN OUR CASE WITH THE REGULATION, AND THERE'S A FORMAL COMMENT PERIOD AND A FORMAL PROCESS BY WHICH YOU HAVE TO RESPOND TO COMMENTS?

AND SECOND QUESTION IS AT YOUR MEETINGS, DO YOU INVITE MEMBERS OF THE PUBLIC TO -- IS THERE AN OPPORTUNITY FOR MEMBERS OF THE PUBLIC TO ACTUALLY TESTIFY AT MEETINGS AS ISSUES ARE BEING DISCUSSED?

DR. KLITZMAN: WE HAVE NOT HAD PUBLIC

TESTIMONY. IN OTHER WORDS, PEOPLE HAVE -- WE'VE RECEIVED LETTERS FROM VARIOUS GROUPS AND CONCERNED CITIZENS, AND WE THEN OR THE STAFF LOOKS AT THOSE, AND WE OFTEN DO AS WELL, DEPENDING ON WHAT THEY ARE. IN THIS CASE, AS I RECALL, WE DID HAVE A PERIOD FOR PUBLIC COMMENT ON ISSUES CONCERNING COMPENSATION. AND SO WE DID HAVE ABOUT A MONTH AND A HALF, TWO MONTHS IN WHICH PEOPLE WERE WELCOME TO COMMUNICATE TO US ABOUT THAT.

CHAIRMAN LO: OTHER COMMENTS, QUESTIONS?

MS. LANSING: I APOLOGIZE. SO I HOPE THIS WASN'T COVERED IN YOUR PRESENTATION. WE, OF COURSE, HAVE A LAW THAT SAYS WE CAN'T DO SOME OF THIS. WHAT I'M REALLY CURIOUS ABOUT ON BEHALF OF A LOT OF PEOPLE IS HAVE YOU HAD ANY PUSHBACK AGAINST -- I DON'T KNOW HOW TO SAY IT POLITELY -- AGAINST THE EXPLOITATION OF WOMEN WHO WOULD NEED TO DO THIS FOR MONEY FOR ECONOMIC REASONS?

DR. KLITZMAN: TWO ISSUES. I SHOULD CLARIFY OF THE ELEVEN MEMBERS OF THE ETHICS BOARD, THERE WERE TEN VOTED IN FAVOR OF IT AND ONE, FATHER BERG, VOTED AGAINST IT, JUST TO SET THAT. AND HE HAS EXPRESSED HIS OPINIONS AS WELL IN WRITING. IN THE MINUTES IT RECORDS HIS STATEMENT.

I SHOULD SAY THAT WE HAVE HAD A DIVERSE RANGE OF VIEWS ON THE COMMITTEE. SO WE HAVE, IN ADDITION TO

FATHER BERG, DR. SULMASY, AS I MENTIONED, HAS WRITTEN EXTENSIVELY ON THEOLOGICAL PERSPECTIVES IN MEDICINE. WE HAVE REVEREND HUGH MAYNARD-REID, WHO IS A MINISTER AS WELL, WHO'S A MEMBER, VERY ACTIVE MEMBER, OF THE COMMITTEE. AND WE HAD A MONSIGNOR WHO UNFORTUNATELY PASSED AWAY ABOUT SIX MONTHS AGO, BUT HAD BEEN PART OF THESE DISCUSSIONS UP TO THAT POINT.

IN TERMS OF THE ISSUE OF EXPLOITATION OF WOMEN, WE FELT THAT, AND THIS MAY BE CONTROVERSIAL, BUT I'M HAPPY TO ENGAGE THE TOPIC. SO CURRENTLY, AS I SAID, FOR REPRODUCTIVE PURPOSES, THERE IS THROUGHOUT THIS COUNTRY THOUSANDS OF WOMEN WHO DECIDE TO DONATE OOCYTES AND ARE COMPENSATED FOR THAT. AND SO FAR AS I KNOW, THERE'S NO EVIDENCE WHATSOEVER THAT THERE'S ANY EXPLOITATION OR COERCION GOING ON. SO THE NOTION THAT COERCION OR EXPLOITATION COULD POTENTIALLY HAPPEN, GRANTED, BUT SO FAR, GIVEN THAT THIS HAS ALREADY BEEN OCCURRING FOR SEVERAL YEARS, THOUSANDS OF WOMEN, EVERY STATE IN THE COUNTRY, SO FAR AS I KNOW, IS HAVING THIS GO ON. AND THERE'S NO EVIDENCE OF EXPLOITATION OR COERCION. SO I THINK THAT'S IMPORTANT TO UNDERSTAND.

ONE OTHER POINT. WE HAVE ALSO ENCOURAGED RESEARCHERS TO, IN FACT, FOLLOW TO SEE WOMEN WHO COME FORWARD TO SEE IF THERE IS EVEN THE REMOTEST SIGN OF THAT.

IN ADDITION, I WOULD SAY, AND THERE WAS AN ARTICLE THAT I WROTE THAT WAS ALSO DISTRIBUTED WHICH TALKS A LITTLE BIT ABOUT THIS, BUT IT'S ESTIMATED THE AMOUNT OF TIME THAT IS INVOLVED FOR A WOMAN TO DO THIS, TO BE GETTING HORMONES, TO UNDERGO A SMALL, BUT THERE IS A RISK OF OVARIAN HYPERSTIMULATION SYNDROME, IT'S ABOUT, SAY, 56 HOURS IT'S BEEN ESTIMATED IN THE LITERATURE. SO IF YOU PAY, SAY, AND IT'S ESTIMATED, THAT FOR SPERM DONATION, WHICH IS 75 OR A HUNDRED DOLLARS, LET'S CALL IT, FOR AN HOUR, THAT IN OTHER WORDS WHAT WE WOULD BE DOING IS PAYING OOCYTE DONORS THE SAME PER HOUR RATE AS WE NOW PAY SPERM DONORS. IN OTHER WORDS, ONE CAN ARGUE, WELL, IS THERE EXPLOITATION OF SPERM DONORS AT $75 AN HOUR? ONE DOESN'T HEAR ABOUT THAT.

MS. CHARO: THEY'RE HAVING MORE FUN.

DR. KLITZMAN: WELL, WE SHOULD ARGUE WE SHOULD THEREFORE PAY THEM LESS ACTUALLY, RIGHT? SO YOU WOULD ARGUE THAT WE SHOULD PAY EGG DONORS EVEN MORE, BUT WE'RE PAYING THEM SORT OF EQUIVALENTLY. SO THAT WAS SOMETHING ELSE THAT I THINK IS INTERESTING JUST TO TAKE NOTE OF. AND, AS ALTA CHARO KNOWS AND BERNIE LO AND MANY OF YOU ALSO KNOW, THERE'S AN EXTENSIVE LITERATURE ABOUT UNDUE INDUCEMENT. AND, OF COURSE, THERE'S NO DEFINITION OF UNDUE INDUCEMENT OR UNDUE

INFLUENCE IN THE REGULATIONS AT ALL. IT'S NOT CLEAR WHAT THEY ARE, WHAT THEY MEAN, AT WHAT POINT IS SOMETHING UNDUE INDUCEMENT IS AN ALSO UNKNOWN. THERE HAVE BEEN SOME WHO HAVE ARGUED VERY STRENUOUSLY. EZEKIEL EMANUAL, FOR INSTANCE, HAS WRITTEN THAT -- WROTE AN ARTICLE "UNDUE INDUCEMENT: NONSENSE ON STILTS," SAYING THAT THIS IS REALLY -- SO THERE'S A LOT OF OVERCONCERN.

BUT BE THAT AS IT MAY, OUR SENSE WAS THAT THIS DID NOT SEEM -- THERE WAS NOT EVIDENCE THAT THIS WAS OCCURRING PRESENTLY; AND, THEREFORE, WE WERE LESS CONCERNED ABOUT IT GOING FORWARD.

MS. LANSING: WHAT'S THE AVERAGE -- I MEAN I DON'T KNOW THIS -- BUT PAYMENT FOR WOMEN FOR REPRODUCTIVE RIGHTS?

DR. KIESSLING: FOR EGG DONORS, YOU MEAN?

MS. LANSING: YEAH.

DR. KLITZMAN: IT FOLLOWS ASRM'S GUIDELINES. SO MORE THAN $5,000 IS -- I CAN READ YOU THE EXACT LINE HERE.

DR. TAYLOR: I THINK THEY THINK -- THE ANSWER ON THE GUIDELINES WOULD SUGGEST THAT MORE THAN $5,000 REQUIRES SOME SCRUTINY, AND IT SHOULD NEVER BE MORE THAN $10,000. BUT I WOULD GUESS THAT THE AVERAGE IS PROBABLY IN THE $8,000 RANGE.

MS. LANSING: I HEARD THAT. THAT'S HOW YOU ARRIVED AT YOUR NUMBERS THEN.

DR. KLITZMAN: YES. WE FOLLOWED WHAT THEY SAID, WHICH IS SUMS OF 5,000 OR MORE REQUIRE JUSTIFICATION AND SUMS ABOVE 10,000 ARE NOT APPROPRIATE.

MS. LANSING: THAT'S THE PART I MISSED. THANK YOU VERY MUCH.

DR. KLITZMAN: YOU'RE WELCOME.

DR. TAYLOR: BOB, I ACTUALLY HAVE A QUESTION ABOUT THAT. AND I REALLY -- I LIKE THE WAY YOU DEVELOPED THE ARGUMENT THAT DONATION IS GOING ON ESSENTIALLY IN THE PRIVATE KIND OF THE INFERTILITY SECTOR AND ALSO THE PARALLEL ARGUMENT THAT WE DO COMPENSATE OTHER EXPERIMENTAL SUBJECTS, HUMAN SUBJECTS, FOR PARTICIPATION IN TRIALS OR STUDIES SUCH AS THIS. AND MARK SAUER, WHO I KNOW IS YOUR COLLEAGUE, HE ACTUALLY CAME AND PARTICIPATED WITH US ABOUT A YEAR AND A HALF AGO IN A PANEL TO DISCUSS SOME OF THESE ISSUES.

I THINK HE WAS IMPLYING THAT OVER THE LAST SEVERAL MONTHS YOUR AVERAGE IS PROBABLY PRETTY CLOSE TO ABOUT $8,000 FOR COMPENSATION FOR A DONOR. IS THAT ABOUT RIGHT?

DR. KLITZMAN: COMPENSATION, I SHOULD SAY, VARIES IN REGION OF THE COUNTRY. I THINK AROUND NEW

YORK IT IS ABOUT 8,000, YES.

DR. TAYLOR: SO I WAS JUST KIND OF CURIOUS. ARE THERE OTHER EXAMPLES WHERE RESEARCH SUBJECTS ARE COMPENSATED AT THAT KIND OF A LEVEL FOR OTHER TYPES OF CLINICAL TRIALS OR PRECLINICAL KINDS OF TRIALS THAT WHEN YOU KIND OF SCANNED THE LITERATURE TO SORT OF BUILD THIS, WAS THERE -- CLEARLY WE KNOW -- AND, IN FACT, EIGHT TO $10,000, THERE CERTAINLY ARE PLACES WHERE YOU GET $20,000 FOR EGG DONATION.

DR. KLITZMAN: RIGHT. SO THERE'S A SMALL UNFORTUNATELY LITERATURE ON HOW MUCH DO RESEARCH PARTICIPANTS IN STUDIES OUTSIDE OF STEM CELL RESEARCHERS, IN GENERAL HOW MUCH DO THEY GET PAID. AND THE ANSWER IS IN THE LITERATURE WE DON'T KNOW EXACTLY, WHICH IS DISAPPOINTING. BUT THERE ARE MANY OTHER STUDIES THAT DO PAY. LET'S SAY FOR ARGUMENT SAKE THAT THIS WOULD BE $80 AN HOUR. THERE ARE MANY STUDIES THAT PEOPLE GET PAID $80 AN HOUR. FOR INTERVIEW STUDIES, JUST AN INTERVIEW STUDY THAT WE DO, IN NEW YORK CITY WE USUALLY OFTEN PAY $60 AN HOUR. SO DEPENDING ON THE NATURE, THE CONTENT OF THE INFORMATION, AND MANY OTHER THINGS.

SO TO ME IT SEEMS THAT THAT IS WITHIN THE BALLPARK OF OTHER STUDIES WHERE THERE ARE RISKS. YOU'RE ASKING A WOMAN TO UNDERGO QUITE A BIT OF TIME

AND BURDEN TO UNDERGO CERTAIN RISKS. NOW, MANY WOMEN WANT TO DO THIS. THEY SAY, YOU KNOW, "GEE, WE HAVE PARKINSON'S IN MY FAMILY, OR THERE'S DIABETES IN MY FAMILY. AND IF I COULD BE INVOLVED IN THIS, I'D LIKE TO DO IT. BUT YOU KNOW IT'S A LOT OF TIME, SO WHY IS IT THAT I'M NOT BEING PAID FOR THIS? IF I GO THROUGH THE SAME PROCEDURE OVER HERE IN YOUR HOSPITAL, I'M PAID $8,000; BUT IF I WANT TO DO IT FOR RESEARCH AND HELP MY FAMILY, I'M NOT PAID AT ALL. THAT'S NOT FAIR." SO I WOULD ARGUE THAT THE $80 IS WELL WITHIN THE BALLPARK OF OTHER STUDIES IN WHICH THERE IS SOMETHING INVASIVE GOING ON.

MS. CHARO: I SUSPECT MANY PEOPLE HERE HAVE SERVED ON IRB'S OVER THE YEARS. I'VE CERTAINLY PUT IN, I DON'T KNOW, 10, 15 YEARS ON THEM. FOR WHAT IT'S WORTH, AND THIS IS ANECDOTAL AND IT'S ONLY FROM ONE IRB IN THE MIDWEST, THE ONLY TIME I SAW SUM TOTALS THAT CAME UP INTO THE THOUSANDS LIKE THIS WAS FOR INPATIENT STUDIES OR REPEAT VISIT STUDIES THAT INVOLVED REPEAT BLOOD DRAWS OR EVEN BONE MARROW SAMPLES. BUT I DID SEE THOSE NUMBERS FOR STUDIES LIKE THAT, NOT FREQUENTLY BECAUSE MOST OF THE TIME YOU DIDN'T HAVE THAT MANY STAYS. BUT THAT WAS THE ONE TIME YOU'D BEGIN TO SEE THESE KINDS OF NUMBERS WAS FOR INVASIVE, BUT REPEATED. SO IT WASN'T JUST THE HOURLY RATE. IT IS ALSO ABOUT

THE SUM TOTAL OF TIME AND DISCOMFORT AND RISK.

SO IT HAPPENS. IT'S JUST THAT THERE AREN'T THAT MANY RESEARCH PROTOCOLS THAT REQUIRE IT, SO YOU DON'T SEE IT VERY OFTEN, AT LEAST IN MY EXPERIENCE.

DR. TAYLOR: BONE MARROW SAMPLING, THAT'S ACTUALLY A GOOD ANALOGY. THAT IS A GOOD ONE.

DR. KLITZMAN: IF I CAN JUST SAY TWO THINGS ON THAT. THERE'S INTERESTING LITERATURE, AS I MENTIONED, ON PAYMENT. SO DENISE GRADY -- CHRISTINE GRADY, WHO'S AT NIH, HAS WRITTEN WHAT KIND OF MODEL SHOULD WE USE. AND SHE ARGUES THAT A WAGE MODEL, THINKING HOW MUCH PER HOUR, IS SOMETHING THAT WE SHOULD SERIOUSLY CONSIDER DOING.

IN ADDITION, I SHOULD SAY JUST BY WAY OF BACKGROUND, I DID A STUDY RECENTLY, I'VE BEEN DOING A STUDY OF HOW IRB'S MAKE DECISIONS. AND I STARTED THIS BY GOING TO, A LITTLE BIT OF AN ANECDOTE, BUT I WENT TO SOUTH AFRICA TO DO STUDIES OF IRB MEMBERS THERE. AND I ASKED THERE MUST BE BIG CULTURAL DIFFERENCES THAT HAPPEN. WHAT ARE THE BIGGEST ISSUES YOU DEAL WITH? AND THEY SAID, WELL, THE BIGGEST ISSUE WE DEAL WITH IS HOW MUCH TO PAY SUBJECTS BECAUSE IF WE PAY THEM THE SAME AS YOU DO, WE'RE COERCING THEM. IF WE PAY LESS, WE'RE EXPLOITING THEM. WHAT DO WE DO?

SO I WENT BACK AND I LOOKED AT THE LITERATURE

AND FOUND THAT THERE'S BASICALLY NOTHING WRITTEN ON THIS. THERE'S VERY FEW ARTICLES THAT ACTUALLY LOOK AT THIS, SO I KNOW THIS LITERATURE. SO I THEN HAD THESE TWO SUMMER STUDENTS TWO YEARS AGO. AND I SAID, "WHY DON'T WE JUST LOOK UP, LET'S PICK TWO OR THREE FIELDS AND LOOK AT ALL THE ARTICLES PUBLISHED IN THE PAST YEAR, AND WHAT DO THEY SAY ABOUT HOW MUCH THEY PAY?" OVER 85 PERCENT OF PUBLISHED ARTICLES IN A VARIETY OF FIELDS MAKE NO MENTION OF HOW MUCH THEY, IN FACT, PAID PEOPLE, TO GIVE YOU AN EXAMPLE. SO WE DON'T KNOW.

DR. TAYLOR: I'VE NEVER SAID IN A STUDY THAT I PUBLISHED.

DR. KLITZMAN: SO IT'S SORT OF LIKE A DIRTY LITTLE SECRET. NO ONE REALLY TALKS ABOUT IT. IN FACT, AS ALTA MENTIONED, 56 HOURS IS MORE THAN -- THERE ARE VERY FEW STUDIES THAT COME CLOSE TO THAT, BUT THESE AMOUNTS ARE INVOLVED IN SUCH STUDIES.

CHAIRMAN LO: OTHER COMMENTS? JEFF AND THEN DOROTHY.

MR. SHEEHY: I GUESS, MAYBE IF I COULD HAVE A LITTLE DIALOGUE BECAUSE IT TROUBLES ME THAT YOU TALK ABOUT PEOPLE DONATING TO HELP PEOPLE WITH PARKINSON'S IN THEIR FAMILY OR DIABETES. AND I HAVE TROUBLE UNDERSTANDING THE NECESSITY WITH INDUCED PLURIPOTENT SOMATIC CELLS. I DON'T DISAGREE NECESSARILY WITH

PAYING. THAT SEEMS TO ME A DIFFERENT ISSUE. BUT YOU KIND OF IMPLIED THAT IN SOME WAY CLONING IS GOING TO BE THE MAGIC BULLET IN STEM CELL RESEARCH. I THINK IT'S KIND OF BECOME SOMEWHAT OF A BACKWATER. AND TO SUGGEST THAT THE NECESSITY OF OBTAINING A LARGE NUMBER OF EGGS TO DO CLONING EXPERIMENTS IS NECESSARY TO MOVE THE STEM CELL FIELD FORWARD DRAMATICALLY FOR PATIENTS WHOSE FAMILIES ARE AFFECTED BY THESE DISEASES SEEMS -- I'M NOT SURE I UNDERSTAND AND MAYBE ALAN CAN TALK ABOUT HOW MANY EGGS ARE NEEDED.

AND ALSO THERE'S THIS COMMODIFICATION ISSUE FOR ME BECAUSE HOW MANY EGGS ARE ACTUALLY NEEDED TO DO ONE OF THESE EXPERIMENTS? AND WE STILL HAVE NOT SUCCESSFULLY BEEN ABLE TO DO A HUMAN CLONING EXPERIMENT. AND SO MY UNDERSTANDING IS THAT THE PURPOSE FOR SOMATIC CELL NUCLEAR TRANSFER WAS TO CREATE A DISEASE MODEL, AND WE'RE CREATING DISEASE MODELS LEFT AND RIGHT WITH IPS CELLS.

AND THE SECOND PART WAS PERSONALIZED MEDICINE. AND SEVERAL FOLKS, I THINK, ARE GETTING CLOSER AND CLOSER TO THE FDA IN TERMS OF BEING ABLE TO DO CLINICAL TRIALS. I THINK WE'RE STILL SEVERAL YEARS AWAY, BUT USING IPS CELLS TO DO CLINICAL TRIALS.

SO I MEAN HOW MUCH DID YOU REALLY THINK ABOUT HOW NECESSARY IT WAS TO GET THE TYPES? AND TO DO ONE

EXPERIMENT, ALAN, HOW MANY EGGS DOES IT TAKE TYPICALLY WITH THE STATE OF THE SCIENCE NOW?

DR. TROUNSON: WELL, IT'S A LITTLE HARD TO KNOW BECAUSE IN THE MONKEY, I THINK IT IS TAKING AROUND A HUNDRED OR SOMEWHERE BETWEEN A HUNDRED AND 150 EGGS, I THINK, LAST COUNT, TO DERIVE AN EMBRYONIC STEM CELL LINE. SINCE THAT'S NOT HAPPENED IN THE HUMAN, CLEARLY WE DON'T KNOW WHETHER IT WOULD TAKE MORE OR LESS. BUT ONE WOULD ASSUME THAT FROM THE WORK IN OTHER SPECIES, AND JOSE IS REALLY THE EXPERT HERE, ONE WOULD THINK THAT IT'S A LARGE NUMBER OF EGGS. AND ANYTHING OVER 20, 40 EGGS IS A VERY LARGE NUMBER OF EGGS FOR ANY PURPOSE.

SO IN THE SENSE THAT WHAT YOU ARE ALLUDING TO IS AN ISSUE FOR US, THAT THE REVIEWERS, FOR EXAMPLE, HAVEN'T FELT THAT THIS IS A COMPELLING ARGUMENT ON THE SCIENCE SIDE. WHETHER THAT'S BECAUSE THERE ARE IPS CELLS THERE OR THE COMPELLING ARGUMENT IS INGRAINED IN SOME OTHER ASPECTS OF THE PROPOSED WORK, THE REVIEWERS FOR CIRM REALLY HAVEN'T BROUGHT ANY OF THOSE PROJECTS EXCEPT IN THE EARLY DAYS FORWARD FOR RECOMMENDED FOR FUNDING.

THE BRITISH GROUPS ALSO HAVE THE SAME. THEY HAVE AN ISSUE WHERE THEY HAVE BEEN VERY STRONGLY COMMITTED TO NUCLEAR TRANSFER AND CONTINUE AT THE

UNIVERSITY OF NEWCASTLE TO DO IT IN THE HUMAN, BUT THEY ALSO NOW HAVE A NUMBER OF GROUPS WHO ARE WORKING WITH ANIMAL EGGS AND HUMAN CELLS IN ORDER TO TRY AND OBTAIN MATERIAL MADE WITH SPECIES OTHER THAN THE HUMAN WHERE EGGS ARE MORE AVAILABLE, FOR EXAMPLE, THE COW OR THE PIG, AND I THINK BEEN TOTALLY UNSUCCESSFUL AT THIS STAGE. AND SO TO THE WORK ON NUCLEAR TRANSFER, THE HUMAN WORK IN NEWCASTLE HAS NOT BEEN SUCCESSFUL. AND THEY ALSO TRIED USING THE MONKEY PROCEDURES THERE WITH THE SCIENTISTS THAT WENT FROM OREGON TO NEWCASTLE.

SO IN MANY RESPECTS IT'S AN ISSUE FOR US THAT IS NOT NECESSARILY COMPELLING AT THE MOMENT BECAUSE WE'RE NOT BEING FORCED TO ADDRESS IT THROUGH HAVING GRANTS BEING AWARDED IN THE AREAS AND NOT REALLY RISING TO THE UPPER, HIGHER PERCENTAGE OF GRANTS AS CONSIDERED SCIENTIFICALLY.

MR. SHEEHY: SO WE'VE ONLY FUNDED ONE SCNT GRANT, I THINK. SO I GUESS, JUST TO KIND OF FINISH UP, HOW DO YOU AVOID -- AND I'VE HEARD IN EARLIER DISCUSSIONS THAT REALLY, I MEAN, IF YOU'RE NOT JUST GIVING A LOT OF HORMONE, PROBABLY ABOUT A DOZEN, 15 EGGS IS WHAT YOU CAN EXPECT. HOW DO YOU AVOID THE COMMODIFICATION OF HUMAN OOCYTES? WHEN YOU NEED TO GET PROBABLY TEN DONORS FOR ONE EXPERIMENT, HOW DO YOU MAKE SURE THAT YOU ACTUALLY ENSURE SAFETY FOR THE WOMEN

INVOLVED, THAT YOU'RE NOT GIVING THEM A LOT OF HORMONES SO THAT YOU NEED FEWER WOMEN AT $8,000 A POP? A LITTLE MORE HORMONE IS CHEAPER THAN ANOTHER DONOR BROUGHT IN. AT THE END OF THE DAY, IF THE ONLY SUCCESS FOR YOUR EXPERIMENT IS THAT YOU MANAGED TO PERFECT HUMAN CLONING, IS THAT REALLY WORTH IT?

DR. KLITZMAN: THANK YOU FOR YOUR COMMENTS. I HAVE SEVERAL RESPONSES TO THAT. IN TERMS OF IPS, AS I MENTIONED, HAROLD VARMUS ON OUR BOARD AND GERRY FISCHBACH, WHO IS FORMERLY HEAD OF THE NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES, BOTH ARGUED VERY STRONGLY, AS DID OTHER SCIENTISTS WE HAD SPEAK, THAT IT'S NOT ENOUGH TO SAY AT THIS POINT WE WILL ONLY DO IPS RESEARCH. IPS RESEARCH, AS YOU KNOW, HAS SO FAR LED TO NO THERAPY, NO TREATMENT FOR ANYONE. AND IT'S PREMATURE TO SAY THAT THIS IS THE ROAD TO HAVING SUCCESSFUL TREATMENTS OR THERAPIES BE DEVELOPED.

RATHER, THEY ARGUE, AND I WAS PERSUADED BY THEIR ARGUMENTS, THAT WE NEED TO LOOK AT BOTH POSSIBILITIES, BOTH SCNT AS WELL AS IPS, GIVEN THAT NEITHER HAS YET DEVELOPED TREATMENTS. BOTH MAY BE ABLE TO EXPAND OUR UNDERSTANDING OF THE ISSUES SO THAT WE CAN DEVELOP THE MOST EFFECTIVE TREATMENTS FOR AS MANY ILLNESSES AS POSSIBLE. SO I WOULD ARGUE THAT IT'S NOT ENOUGH. I PERSONALLY WOULD ARGUE, FOLLOWING WHAT

HAROLD VARMUS, FORMERLY HEAD OF NIH, AS YOU KNOW, AND GERRY FISCHBACH HAVE SAID. ANYWAY, SO I WOULD SAY THAT IT'S -- SCIENTIFICALLY THAT IT'S PREMATURE TO SAY IPS WILL BE THE ANSWER.

NOW, YOU CAN SAY, ANYONE CAN SAY, WELL, WE'RE ONLY GOING TO FUND IPS. THAT'S FINE. THERE ARE PEOPLE WHO SAY WE'RE ONLY GOING TO FUND THIS KIND OF RESEARCH OR THAT KIND OF RESEARCH. I SHOULD SAY IN NEW YORK, WE'RE NOT MANDATING THAT RESEARCHERS ALL GO DO SCNT RATHER THAN IPS. FAR FROM IT. WHAT WE'RE DOING IS SAYING THAT IF THERE ARE RESEARCHERS WHO HAVE SCIENTIFIC PROJECTS THAT THEY ARE SEEKING FUNDING FOR TO DO SCNT IN WHICH THEY WOULD LIKE TO EXPLORE SCNT AND SEE WHAT'S POSSIBLE AND THEY FIND THAT THEY'VE NOT BEEN ABLE TO GET DONORS FOR FREE, THAT WE ARE ALLOWING THEM TO COMPENSATE DONORS. AND THAT'S ALL WE'RE DOING. SO WE'RE NOT SAYING THIS IS INSTEAD OF IPS. WE'RE NOT FORCING THIS DOWN THE THROAT OF RESEARCHERS, SAYING YOU'RE ALL GOING TO BE OUT THERE PAYING PEOPLE, ETC., ETC. IT'S JUST ALLOWING THEM TO DO THAT.

I WOULD SAY IN TERMS OF COMMODIFICATION, AS I MENTIONED, RIGHT NOW IN EVERY STATE THERE ARE THOUSANDS AND THOUSANDS OF WOMEN WHO ARE DONATING OOCYTES FOR REPRODUCTIVE PURPOSES. AND THAT HAS BEEN THAT, GIVEN WE LIVE IN A POLITY WITH DIVERSE VIEWS, THE CONSENSUS

OF OUR SOCIETY HAS BEEN THAT THAT IS OKAY. AND ONE MAY PERSONALLY NOT WANT TO DO THAT OR NOT AGREE WITH THAT, BUT THAT IS WHAT IS STANDARD PRACTICE AT THIS POINT. THAT IS STANDARD MEDICAL PROCEDURE AT THIS POINT. AND WHAT WE FELT IS THAT IT'S UNJUST TO SAY TO A WOMAN THAT THE FACT THAT SHE CAN GET COMPENSATED IF SHE GOES FOR REPRODUCTIVE PURPOSES, THAT SHE CAN'T GET COMPENSATED FOR DOING THE SAME EXACT THING FOR DOING IT FOR RESEARCH PURPOSES, THAT THAT WAS UNFAIR. THAT WAS DISCRIMINATORY. AND THAT'S SOMETHING THAT WE FELT NEEDED TO BE ADDRESSED. IT WAS WE FELT THERE WAS NO ETHICAL JUSTIFICATION FOR TREATING HER UNFAIRLY, ESPECIALLY WHEN WHAT SHE WANTED TO DO WAS TO HELP SOCIETY, TO HELP RESEARCH, TO HELP OTHER PATIENTS. ONE COULD ARGUE WE HAD MORE SOCIAL BENEFIT, IN FACT, THAN THE WOMAN WHO JUST WANTED TO SELL HER EGGS TO HELP SOMEONE HAVE A CHILD. NOT THAT THAT'S BY ANY MEANS NOT AN IMPORTANT GOAL, BUT WE FELT THAT THERE IS, ONE COULD ARGUE, IMPORTANT SOCIAL BENEFIT THAT THE WOMAN WHO WANTS TO DONATE FOR REPRODUCTIVE PURPOSES WOULD NOT GET. AND, THEREFORE, WE FELT THAT WE SHOULD DO THE JUST THING AND TREAT THEM FAIRLY, EQUALLY.

CHAIRMAN LO: A LOT OF PEOPLE WHO WANT TO ASK A QUESTION, MAKE A COMMENT, SO I'M JUST GOING TO GO AROUND.

DR. ROBERTS: I COULD PICK UP RIGHT THERE BECAUSE I DID THINK THE ARGUMENTS YOU MADE WERE VERY LOGICAL EXCEPT THAT THERE WERE COUNTERARGUMENTS THAT YOU DIDN'T INCLUDE IN YOUR PRESENTATION LIKE THE ONE YOU JUST MADE ABOUT BECAUSE IT HAPPENS IN THE REPRODUCTIVE CONTEXT, THEREFORE IT'S UNFAIR NOT TO EXTEND IT TO THE RESEARCH CONTEXT. AND I THINK THERE'S ALSO AN ARGUMENT THAT, YES, IT MAY HAPPEN IN THE REPRODUCTIVE CONTEXT, BUT THAT WE MAY WANT TO LIMIT IT TO THAT. IN OTHER WORDS, IF THERE ARE RISKS THAT WE AS A SOCIETY, IF THERE IS A CONSENSUS WE'RE WILLING TO TAKE IN THE REPRODUCTIVE CONTEXT, IT'S NOT NECESSARILY THE CASE THAT WE AS A SOCIETY ARE WILLING TO EXTEND THOSE RISKS EVEN FURTHER TO ANOTHER DOMAIN.

SO IN OTHER WORDS, LET'S SAY WE RECOGNIZE THAT THERE ARE RISKS TO WOMEN IN DONATING THEIR EGGS, AND MAYBE WE'RE WILLING TO SAY IT'S OKAY TO DO THAT, THE BALANCE IS STRUCK ALL RIGHT IN THE REPRODUCTIVE CONTEXT, BUT WE DON'T WANT TO EXTEND THOSE RISKS EVEN FURTHER INTO RESEARCH. THAT CREATES A WHOLE EXTRA CATEGORY OF WOMEN WHO ARE UNDERGOING THESE RISKS. YOU MAY HAVE DECIDED THAT ON BALANCE THE RISKS ARE SO MINOR, OR WOMEN SHOULD BE ABLE TO DECIDE FOR THEMSELVES TO TAKE ON THOSE RISKS, BUT I DON'T THINK IT'S TRUE THAT BECAUSE IT'S DONE IN THE REPRODUCTIVE CONTEXT,

THAT NECESSARILY MEANS THAT IT CAN BE EXTENDED TO ANOTHER CONTEXT.

AND THEN THAT -- SO THEN THAT RAISES THE QUESTION OF, WELL, WHAT'S WRONG WITH EXTENDING IT TO ANOTHER CONTEXT? AND THAT GETS INTO THE ISSUE OF EXPLOITATION. AND YOU SAID THERE'S NO EVIDENCE THAT EXPLOITATION HAS OCCURRED IN THE REPRODUCTIVE CONTEXT. SO I GUESS THAT DEPENDS ON WHAT EXPLOITATION MEANS. OF COURSE, THAT RAISES ALL SORTS OF COMPLICATED QUESTIONS THAT YOU SAID ABOUT UNDUE INDUCEMENT. BUT IF THERE'S A CONCERN THAT PAYING WOMEN FOR EGGS AND FOR UNDERGOING RISKS THAT WE'RE NOT EVEN SURE ABOUT, THE RISKS OF HYPEROVULATION AND OTHER RISKS ENTAILED IN DONATING EGGS, THEN HOW DO YOU SAY -- WHAT DOES IT MEAN TO SAY NO EXPLOITATION HAS OCCURRED? BECAUSE IF YOU BELIEVE THAT PAYING FOR THIS PROCESS WHERE THERE ARE RISKS THAT ARE NOT KNOWN AND THAT IT MAY BE DIFFICULT TO EVEN PREDICT FOR WOMEN WHO ARE DONATING EGGS, THEN JUST INDUCING WITH MONEY TO PARTICIPATE IN THIS COULD BE CONSIDERED EXPLOITATION BY ITSELF.

AGAIN, I'M NOT SAYING THAT IT NECESSARILY IS, BUT THAT IS AN ARGUMENT. THAT IS ONE OF THE ARGUMENTS ABOUT EXPLOITATION. SO I DON'T KNOW THAT YOU CAN SAY WE KNOW THAT NO EXPLOITATION HAS OCCURRED IN THE REPRODUCTIVE CONTEXT. IT DEPENDS ON HOW YOU DEFINE

WHAT THE EXPLOITATION IS.

AND ALSO I THINK IT'S IMPORTANT TO ASK -- I THINK YOU ACTUALLY RAISED THIS IN YOUR ARTICLE -- ARE WE TALKING ABOUT THE SAME WOMEN? BECAUSE THERE WILL BE A WHOLE DIFFERENT CLASS OF WOMEN, PERHAPS, WHO WOULD BE PAID FOR EXTRA RESEARCH THAT WOULDN'T BE PAID FOR EGGS IN THE REPRODUCTIVE CONTEXT. SO WE MAY BE TALKING ABOUT A DIFFERENT GROUP OF WOMEN. AND SO THE FACT THAT EVEN IF WE FOUND THERE WAS NO EXPLOITATION IN THE REPRODUCTIVE CONTEXT, IT DOESN'T MEAN THAT THERE WOULDN'T BE IN THE RESEARCH CONTEXT BECAUSE IT MAY BE A DIFFERENT GROUP OF WOMEN WHO ARE BEING PAID FOR EGGS.

AND, YOU KNOW, THE HOURLY RATE, I THINK ALTA SUGGESTED THIS, IT'S NOT JUST TIME. IT'S ALSO THE RISKS THAT YOU ARE TAKING IN ORDER TO DONATE EGGS. SO THE SPERM DONOR CONTEXT, ALTA ALSO SUGGESTED THIS, BUT, YOU KNOW, IT'S NOT THAT THEY'RE JUST HAVING MORE FUN. MEN ARE NOT UNDERGOING THE RISKS THAT WOMEN ARE IN DONATING GAMETES. SO IT'S A DIFFERENT -- IT'S COMPLETELY DIFFERENT THAN PAYING INTERVIEW SUBJECTS, FOR EXAMPLE.

SO THEN YOU RAISED ANOTHER GOOD POINT, WHICH WAS THE OTHER RESEARCH PARTICIPANTS WHO ENGAGE IN PERHAPS RISKY RESEARCH. AND THERE WAS THIS QUESTION ABOUT, WELL, ARE THEY PAID THIS HIGH AMOUNT OF MONEY?

ALTA MENTIONED PERHAPS WITH BONE MARROW DONATIONS. I JUST WONDER IF THERE IS A COMPARABLE GROUP OF RESEARCH PARTICIPANTS WHO AREN'T ENGAGING IN THE RESEARCH BECAUSE THEY BELIEVE THEY PERSONALLY MAY BE BENEFITED FROM IT. MY IMPRESSION IS THAT MANY CLINICAL RESEARCH PARTICIPANTS ENGAGE IN THE RESEARCH BECAUSE THEY BELIEVE THEY MAY THEMSELVES PERSONALLY GET A BENEFIT FROM IT. AND THAT'S NOT THE CASE WITH EGG DONATION. AND SO --

MS. CHARO: DOROTHY, JUST TO CLARIFY, I WAS TALKING ABOUT PHASE I KINDS OF TRIALS WHERE THEY WERE PURE RESEARCH SUBJECTS. THESE WEREN'T PEOPLE WHO HAD A DISEASE. IT WAS REALLY WHAT I HAD SEEN WERE THE KIND OF CLASSIC, TRULY CLASSIC RESEARCH SUBJECT MODE.

DR. ROBERTS: THEN THAT WOULD BE MORE COMPARABLE, BUT THAT'S PROBABLY EXCEPTIONAL, I WOULD THINK.

MS. CHARO: IT WAS VERY UNUSUAL.

DR. ROBERTS: I WOULD THINK THAT WOULD BE EXCEPTIONAL. AND THEN, OF COURSE, THE ISSUE OF WHETHER EGGS ARE A DIFFERENT TYPE OF PART OF YOUR BODY THAN BONE MARROW OR PERHAPS ANY OTHER PART OF YOUR BODY BECAUSE OF THE REPRODUCTIVE IMPLICATIONS, THE COMMODIFICATION OF WOMEN, THE IMPLICATIONS THAT JEFF MENTIONED. SO I GUESS I JUST FELT IT WAS IMPORTANT TO

POINT OUT THAT THERE ARE ARGUMENTS AGAINST -- COUNTERARGUMENTS TO WHAT YOU PRESENTED, WHICH DOES SOUND VERY LOGICAL; AND YOU MAY HAVE CONSIDERED ALL OF THESE AND COME OUT WITH YOUR CONCLUSIONS, BUT THERE MIGHT BE SOME WHO WEREN'T AWARE OF THESE OTHER ARGUMENTS. I JUST FELT IT WAS IMPORTANT TO MENTION THEM.

DR. KLITZMAN: NO. WE HAVE SPENT A LOT OF TIME. WE SPENT A YEAR AND A HALF, MANY MEETINGS DISCUSSING THIS. SO ESSENTIALLY THE ARGUMENTS THAT YOU RAISED WERE THINGS THAT WE CONSIDERED. AND WE FELT THAT ON BALANCE THAT THE BENEFITS OF DOING THIS OUTWEIGHED THE HARM. THERE WERE ETHICAL ISSUES BOTH SIDES. IF WE DO THIS, HERE'S THE BENEFITS. HERE'S THE DOWNSIDES. AND WE FELT THAT ON BALANCE IT MADE SENSE TO DO IT.

NOW, LET ME JUST CLARIFY. I'M NOT HERE TO PERSUADE YOU.

DR. ROBERTS: I KNOW. I KNOW.

DR. KLITZMAN: I THOUGHT I WOULD SHARE WHAT OUR THINKING WAS, AND YOU, BELIEVE ME, YOU SHOULD MAKE YOUR OWN DECISION WHAT YOU THINK IS RIGHT.

I WILL -- IF I CAN JUST RESPOND TO A FEW OF THE POINTS. VERY IMPORTANT FOR US WAS THAT THERE IS A VERY FULL INFORMED CONSENT PROCESS SO THAT WOMEN

UNDERSTAND THIS IS WHAT WE KNOW. I SHOULD CLARIFY. THE RISKS ARE SMALL. THIS HAS BEEN STUDIED, WHAT ARE THE RISKS. THERE IS A POSSIBLE SMALL RISK OF HYPEROVARIAN STIMULATION SYNDROME, NOT HUGE, BUT IT'S THERE. WE MAKE THAT CLEAR. YES, THERE MAY BE OTHER RISKS DOWN THE ROAD, JUST LIKE WHENEVER YOU OPEN A BOTTLE OF TYLENOL OR ANYTHING ELSE. THERE'S ALL KINDS OF ANY OTHER MEDICATION OR ANY MEDICAL PROCEDURE, THERE'S VARIOUS RISKS, SMALL PERCENTAGES, PEOPLE DECIDE FOR THEMSELVES. SO WE FELT THAT IT WAS IMPORTANT TO ALLOW WOMEN WHO PERHAPS MAY NOT RIGHT NOW BE ABLE OR HAVE BEEN PAID FOR DONATING OOCYTES, THAT TO EXTEND THIS TO PERHAPS OTHER GROUPS OF PEOPLE, THOUGH THAT MAY NOT BE THE SAME GROUP OF WOMEN, WE DON'T KNOW, AND WE FELT THAT IT WAS IMPORTANT TO GIVE THEM THE RIGHT TO MAKE THE CHOICE THEMSELVES. THAT WE FELT IT WAS IMPORTANT. WE TOOK A VERY FULL INFORMED CONSENT TO HAVE THEM UNDERSTAND THESE ARE THE POSSIBLE RISKS, THESE ARE THE POSSIBLE BENEFITS, ETC., ETC., LET THEM MAKE THE DECISION.

AND ONE COULD ARGUE THAT TO MAKE THE DECISION FOR WOMEN, THAT THIS IS TOO RISKY, YOU SHOULDN'T DO THIS MAY, IN FACT, BE PATERNALISTIC. IN OTHER WORDS, IT MAY BE DENYING AUTONOMY OF WOMEN TO SAY, NO, THIS IS TOO DANGEROUS FOR YOU TO EVEN THINK ABOUT. EVEN IF YOU

WERE TO UNDEREXPLAIN THE RISKS AND BENEFITS, WE DON'T THINK YOU'LL BE ABLE TO RATIONALLY UNDERSTAND THIS. SO I THINK THAT VIEW, THE COUNTERARGUMENT IS THAT THAT VIEW MAY NOT BE RESPECTING THEIR AUTONOMY SUFFICIENTLY. SO --

CHAIRMAN LO: BOB, I'M GOING TO TAKE THE PREROGATIVE OF SORT OF CUTTING YOU OFF. WE'RE NOT HERE TO SORT OF -- I WANT TO MAKE IT VERY CLEAR THAT, YOU KNOW, NO MATTER HOW STIMULATING THIS IS INTELLECTUALLY FOR US, AND I THINK MANY OF US ARE ENGAGED, IT'S JUST NOT ON THE TABLE FOR US TO BE THINKING ABOUT THIS IN A POLICY CONTEXT. WE CANNOT DO IT, BUT WE CAN TALK. SO I DON'T WANT THIS TO TURN INTO SORT OF A POINT-BY-POINT REBUTTAL, BUT I DO WANT TO GIVE, OTHER PEOPLE INDICATED THEY WANTED TO TALK, A CHANCE TO RAISE THEIR QUESTIONS. THESE MAY REALLY JUST BE COMMENTS RATHER THAN QUESTIONS REQUIRING YOUR RESPONSE. I DON'T WANT YOU TO BE PUT ON THE SPOT YOU HAVE TO SORT OF DEFEND NEW YORK.

I HAVE JOSE AND THEN, ALTA, DID YOU HAVE YOUR HAND UP, AND THEN FRANCISCO AND ANN AND, MARCY, IF YOUR HAND IS UP, I'LL TAKE YOU AS WELL.

MS. FEIT: I DON'T HAVE ANY QUESTIONS, BUT I'M LISTENING.

DR. CIBELLI: I JUST WANT TO THANK YOU FOR YOUR TALK, BUT I WANT TO GET BACK TO THE POINT THAT

JEFF WAS MAKING ABOUT CLONING. AND I THINK WE'RE HERE AND PEOPLE ARE EXPECTING FROM US THAT WE TAKE OR WE AT LEAST MAKE DECISIONS BASED ON THE SCIENCE. AND FOR WHAT WE KNOW AS OF NOW, WE SPEND A LOT OF MONEY IN OUR LAB TRYING TO COMPARE HUMAN IPS CELLS AND HUMAN EMBRYONIC STEM CELLS PRODUCED BY FERTILIZATION. SO WE PRODUCE AN INCREDIBLE AMOUNT OF DATA, EXTREMELY BORING TO THE POINT THAT'S IT'S GOING TO BE HARD TO PUBLISH. BUT WE COMPARE THE TRANSCRIPTOME OF THE CELLS, THE 27,000 DIFFERENT VARIOUS USES FOR METHYLATION TO SEE IF THEY'RE METHYLATED THE SAME OR NOT.

WE ALSO COMPARE THE -- WE SEQUENCED SIX MILLION MICRO-RNA'S IN EACH TYPE OF CELL LINE. AND WE FOUND NO DIFFERENCE, STATISTICAL DIFFERENCE, BETWEEN THE TWO, THE IN VITRO FERTILIZED LINE AND THE IPS CELL LINE. SO WE EMBARKED IN THIS VERY AMBITIOUS PRECLINICAL STUDY USING IPS CELLS WITH THE HOPE THAT WE'LL NOT NEED OOCYTES ANY LONGER.

THEN AFTER THAT SOME OFFICIAL PAPERS AND EXTRA, I GUESS, RUMORS CAME FROM JAPAN, SHOWING THAT IPS CELLS IN THE MOUSE SEEM TO BE MORE AGGRESSIVE IN TERMS OF MAKING TERATOMAS WHEN COMPARED WITH FERTILIZED EMBRYONIC STEM CELLS. THEN THE QUESTION IS, WELL, YOU STILL HAVE THE GENES IN THERE, AND THAT'S WHY THEY ARE BEHAVING THAT WAY. OKAY. HE DID IT WITHOUT THE GENES,

AND STILL THE CELLS BEHAVE MORE AGGRESSIVE, MAKING TERATOMAS EASIER THAN NORMAL FERTILIZED.

SO I WOULD SAY THE JURY IS STILL OUT AS TO THE MECHANISM OF DEDIFFERENTIATION THAT WE USE NOW IS GOING TO BE THE SAME AS THE ONE WE SUPPOSED TO MAYBE IN THE FUTURE SOMETIME TRY WITH SCNT. IT WILL BE NICE TO SEE SOMETHING DONE IN MONKEYS, AND SOMEONE IS DOING IT. IF SOMEONE DOES IT IN THE MOUSE, WE'RE ALWAYS GOING TO SAY, WELL, YOU STILL HAVE TO DO IT IN PRIMATES. SO IT'S A MATTER OF TIME.

AND I'LL BE FIRST ONE TO SAY, YEAH, THEY'RE THE SAME, JUST FORGET ABOUT THE OOCYTE, AND WE DON'T HAVE TO DEAL WITH THIS ANYMORE. I'M AFRAID THAT THEY'RE GOING TO COME OUT LIKE EXPERIMENTS LIKE THIS WHEN WE'RE TALKING ABOUT THAT SPINDLE TRANSFER FOR PEOPLE WITH MITOCHONDRIAL DISEASE WHERE YOU ARE GOING TO STILL NEED OOCYTES. BUT WE DON'T HAVE THE ANSWER, SCIENTIFIC ANSWERS, TO MAKE A DECISION WE DON'T NEED SCNT ANYMORE. HOPEFULLY WE'LL BE THERE SOON, BUT NOT YET.

MR. SHEEHY: YOU KNOW, IN A LOT OF WAYS I'M GOVERNED BY THE DISCUSSIONS THAT HAVE TAKEN PLACE WITHIN OUR WORKING GROUP MEETINGS WHICH YOU ATTEND ALSO, OUR GRANTS WORKING GROUP. AND THERE HAS NOT BEEN -- I THINK THAT THERE'S MORE CAUTION ABOUT GOING

DOWN THE SCNT ROAD THAN THERE WAS WHEN WE FIRST STARTED OUR MEETINGS. I THINK PEOPLE ARE REALLY LOOKING AT THIS. I'M JUST TRYING TO GET A SENSE OF SCALE, AND I DO FEEL THAT TO HOLD OUT SCNT AS LIKE SOME SORT OF MAGIC BULLET IN THE SAME WAY WE DID AT THE BEGINNING WHEN I FIRST CAME ONTO BOARD, LIKE, WE NEEDED IT FOR DISEASE MODELS, FOR INSTANCE.

DR. CIBELLI: WE NEED IT TO VALIDATE IPS CELLS RIGHT NOW. IF I WERE IN CALIFORNIA AND ABLE TO WRITE A GRANT, THAT'S THE GRANT I WOULD WRITE. LET ME DO THE SCNT COUPLE OF TIMES TO SEE IF THEY'RE BEHAVING EXACTLY THE SAME AS IPS DONE WITH THE SAME CELL FROM THE SAME INDIVIDUAL.

MR. SHEEHY: WE HAVEN'T BEEN ABLE TO DO IT. WE CAN'T DO IT. AND THERE IS -- EVERY TIME YOU START TALKING ABOUT SCNT, THE OOCYTE DONATION ISSUE, WHICH I'M BOUND BY LAW, SO I'M FULLY IN ACCORD WITH WHERE WE ARE PER PROP 71. I DON'T KNOW WHAT I WOULD DO IF I WERE IN NEW YORK AND I COULD ACTUALLY MAKE A CHOICE. AND I GIVE THEM ENORMOUS AMOUNT OF CREDIT FOR THE DILIGENCE IN WHICH THEY'VE APPROACHED IT. AND I RESPECT -- YOU KNOW, I SEE BOTH SIDES. ONCE YOU TELL A WOMAN SHE CAN'T DO SOMETHING WITH HER BODY, YOU BECOME INCREDIBLY PATERNALISTIC. SO I SEE THAT. BUT, AGAIN, THE SCIENCE -- IT JUST -- I DON'T KNOW IF THIS IS

REALLY SOMETHING WE DO. THERE IS ALWAYS, WHEN SOMEBODY DOES DO IT, AND THERE WILL BE A TECHNIQUE THAT EXISTS IN THE WORLD TO DO HUMAN CLONING. TO SAY THAT THAT'S GOING TO GO CONTAINED WITHIN THE REALM OF SOLELY RESEARCH EXPERIMENTS IS HOPEFUL, BUT I DON'T KNOW IF, BASED ON HUMAN HISTORY, IF THAT'S REALISTIC.

CHAIRMAN LO: ALTA AND THEN FRANCISCO.

MS. CHARO: VERY QUICK. SINCE THE POLICY CHANGED, HAS ANYBODY PROPOSED A PROTOCOL THAT INVOLVES RECRUITING WOMEN TO OBTAIN THEIR EGGS? IF SO, HAS ANYBODY TRIED TO RECRUIT WOMEN? AND IF SO, HAS ANY WOMAN EVER BEEN RECRUITED UNDER THE NEW POSITION?

DR. KLITZMAN: IT'S TOO SOON. SO OUR NEXT RFA COMES OUT IN, YOU KNOW, A FEW MONTHS. SO PEOPLE WOULD THEN, IF THEY'RE INTERESTED, BE ABLE TO INCLUDE THAT IN AN RFA -- THE RFA WILL BE RELEASED IN A FEW MONTHS. THE DEADLINE FOR GRANT SUBMISSIONS WOULD BE A FEW MONTHS AFTER THAT. IT WOULD TAKE SEVERAL MONTHS TO REVIEW THEM, FOR THEM TO GET UP AND STARTED, ETC. SO YOU'RE TALKING, YOU KNOW, TIME, A YEAR AND A HALF, A YEAR, SOMEWHERE NINE MONTHS AND A YEAR AND A HALF.

MS. CHARO: THANK YOU.

DR. TAYLOR: I THINK AT LEAST MARK SAUER TOLD ME THAT HE, I THINK, RECRUITED ABOUT EIGHT PATIENTS SO FAR.

DR. KLITZMAN: SO A NUMBER OF PEOPLE HAVE COME FORWARD AND SAID THEY WOULD BE WILLING TO DO THIS. WHEN WE DID THIS, IT GOT SOME MEDIA ATTENTION, ETC. AND I SHOULD SAY THAT WHAT THIS ALLOWS -- I KNOW THIS, THEREFORE, PERMITS IT IN NEW YORK STATE AND PERMITS USE OF OUR FUNDS FOR THIS PURPOSE, BUT I KNOW THERE ARE PEOPLE WHO HAVE PHILANTHROPIC SOURCES OF FUNDING, AND SO THEY MAY HAVE ALREADY STARTED AS A RESULT.

DR. PRIETO: MORE OF A PROCESS-RELATED QUESTION BECAUSE, OF COURSE, WE'VE GONE THROUGH A VERY SIMILAR OR PARALLEL PROCESS WITHIN THE CONSTRAINTS IMPOSED ON US BY THE INITIATIVE. BUT I'M NOT SURE IF I UNDERSTOOD CORRECTLY. IS THERE NOT AN OPPORTUNITY FOR DIRECT PUBLIC COMMENT AT YOUR -- IN PERSON AT YOUR MEETINGS? AND THEN SORT OF A FOLLOW-UP OR A SEPARATE QUESTION IS WHAT IS THE REPRESENTATION OR IS THERE REPRESENTATION OF MEMBERS OF THE PUBLIC AND PATIENT ADVOCATES ON YOUR BOARD AND ON THE COMMITTEES?

DR. KLITZMAN: SO WE RESPOND TO COMMENTS IN WRITING, SO PEOPLE SUBMIT COMMENTS TO US. MANY OF US HAVE BEEN CONTACTED INDEPENDENTLY BY PEOPLE WITH THEIR VIEWS, WHICH WE FORWARD ON TO THE STAFF WHO THEN DISTRIBUTES COMMENTS.

AND IN TERMS OF REPRESENTATION, WE HAVE -- I CAN GIVE YOU SORT OF A LITTLE BIO OF EACH OF THESE

PEOPLE, BUT BROOKE ELLISON, FOR INSTANCE, IS A WOMAN WHO IS A PATIENT WHO HAS BEEN VERY VOCAL ABOUT THE NEED FOR STEM CELL RESEARCH AND IS DISABLED AND ETC. AND WE HAVE THE PRESIDENT OF THE PARKINSON'S DISEASE FOUNDATION IS A MEMBER OF THE BOARD. WE HAVE, AS I SAID, PEOPLE FROM BOTH ACADEMICIANS AS WELL AS FROM OTHER FOUNDATIONS WHO HAVE BEEN INVOLVED. SUSAN SOLOMAN FROM THE NEW YORK STEM CELL FOUNDATION HAS BEEN INVOLVED WITH THE STRATEGIC PLAN.

SO THERE HAS BEEN QUITE A BIT OF INPUT -- THERE'S BEEN QUITE A BIT OF INPUT THAT WE'VE GOTTEN FROM THE PUBLIC ON EACH OF THESE AREAS. WE DEBATED AT ONE POINT WHETHER TO GO AROUND THROUGHOUT THE STATE AND HAVE SORT OF TOWN HALL MEETINGS. AND WE FELT THAT HAVING PEOPLE SUBMIT WRITTEN COMMENTS WOULD BE EFFECTIVE TO ALLOW PEOPLE TO HAVE THEIR OPINIONS EXPRESSED AND TAKEN INTO ACCOUNT AS WE WENT THROUGH THE WORK THAT WE DO.

DR. PRIETO: DO YOU RESPOND TO ALL WRITTEN COMMENTS?

DR. KLITZMAN: IN OUR MEETINGS, WHICH ARE WEBCAST, WE DISCUSS COMMENTS THAT COME IN, YES.

DR. PRIETO: I WILL TELL YOU THAT THE TOWN HALL MEETING MODEL, AS YOU PUT IT, IS SORT OF WHAT WE'RE DOING HERE IN CALIFORNIA. WE DO GO ALL AROUND

THE STATE, AND OUR BOARD MEETINGS ARE, PARTICULARLY IN THE FIRST FEW YEARS, I THINK, MAYBE CONSIDERABLY LIVELIER AS A RESULT.

DR. KLITZMAN: TOWN HALL MEETINGS ON HEALTHCARE HAVE BEEN QUITE LIVELY LATELY, I UNDERSTAND.

IF I COULD JUST SAY, BY THE WAY, IF YOU NOTICED, WE ARE -- WE'RE CHOSEN BY OUR ELECTED OFFICIALS, BY THE WAY ALSO. SO IF YOU NOTICED BEFORE, BOTH THE MINORITY AND THE MAJORITY LEADERS IN THE STATE LEGISLATURE APPOINTED WHO THEY WANTED TO BE ON THE BOARD, AND THE GOVERNOR AS WELL. SO TO A CERTAIN DEGREE, WE ARE BEHOLDEN TO OUR STATE'S ELECTED OFFICIALS WHO PUT US THERE, AND WE'RE THERE FOR TWO-YEAR TERMS.

DR. PRIETO: NOT UNLIKE THE SYSTEM HERE. BUT THE INITIATIVE ALSO SPECIFIES THAT THERE WILL BE CERTAIN NUMBER OF PATIENT ADVOCATES AND REPRESENTATIVES OF SPECIFIC GROUPS.

DR. KLITZMAN: IF I COULD JUST CLARIFY. I THINK ONE OF THE REASONS WE DECIDED NOT TO HAVE TOWN HALL MEETINGS IS BECAUSE I THINK PARTLY BECAUSE OF THE EXPERIENCE YOU ALL WENT THROUGH. AND THERE'S BEEN A LOT WRITTEN ON WHAT THE RANGE OF OPINIONS AND WHAT THE RANGE OF CONCERNS ARE, AND WE TAKE ALL OF THOSE INTO CONSIDERATION. AND WE HAVE SOME PEOPLE WHO ARE -- WHO

BELIEVE THAT THE MORAL STATUS OF AN EMBRYO IS SUCH THAT WE SHOULD NOT DO RESEARCH ON IT. SO FATHER BERG IS A VERY VOCAL PRO LIFE ADVOCATE, IF I COULD SPEAK ON HIS BEHALF, AND HE MAKES HIS VIEWS HEARD IN EVERY MEETING, AND WE RESPECT THOSE AND INCORPORATE THOSE INTO OUR PROCESS.

THERE ARE PEOPLE WHO ARE VERY CONCERNED ABOUT ISSUES OF EXPLOITATION, VULNERABILITY, EXPLOITATION OF VULNERABLE GROUPS IN OUR SOCIETY, AND WE TAKE THOSE -- THAT, IF YOU LOOK AT OUR WEBCAST, IF YOU LOOK AT OUR MINUTES, THOSE ARE ISSUES THAT ARE REALLY THE HEART OF WHAT WE DISCUSS OF HOW TO DEAL WITH THESE VERY DIFFICULT, COMPLEX, COMPETING ISSUES. SO I THINK THAT WE'VE NOT HAD COMMENTS SAYING YOU'VE NOT CONSIDERED MY ISSUE. I THINK WE MAKE A POINT TO EXPRESS THE RANGE OF OPINIONS THAT WE BELIEVE ARE IN SOCIETY. I THINK IT'S PRETTY CLEAR, WITH ALL DUE RESPECT, IF ANYONE FEELS THAT'S NOT THE CASE, I WELCOME HEARING THAT, BUT I THINK THE RANGE OF DIVERSE VIEWS ON THIS ISSUE HAVE BEEN VERY WELL EXPRESSED BY ADVOCATES. AND THAT'S GIVEN US AN OPPORTUNITY TO THINK ABOUT THOSE IN A VERY SERIOUS AND SUSTAINED WAY.

MS. FEIT: JUST TO THANK YOU FOR BEING HERE TONIGHT. IT'S BEEN REALLY ENLIGHTENING TO LISTEN TO THE PROCESS THAT YOU ALL HAVE BEEN THROUGH. AND I

THINK FOR THOSE OF US IN CIRM, I THINK WE WILL BE HAVING A LOT MORE ETHICAL DISCUSSIONS. EVEN THOUGH OUR PROPOSITION TIES US TO A CERTAIN PROCESS, I THINK WE'RE GOING TO BE FACED WITH A LOT MORE CONSIDERATION GOING FORWARD IN THE FUTURE FOR THE BODY OF SCIENCE IN CALIFORNIA AND HOW IT'S AFFECTING WHAT WE'RE WANTING TO FUND AND WHAT WE'RE GOING TO BE DOING. SO I WANT TO THANK YOU FOR BEING HERE ON TONIGHT.

CHAIRMAN LO: BOB, IF I MAY, I WANT TO ASK YOU TO COMMENT ON A SLIGHTLY DIFFERENT ISSUE. WE'VE TALKED A LOT ABOUT PAYMENT PER SE AND WHAT'S UNDUE INFLUENCE AND IS IT POSSIBLY COERCIVE OR IS IT A VIOLATION OF A WOMAN'S AUTONOMY NOT TO ALLOW HER TO CHOOSE. I WANT TO GO BACK TO THE ISSUE OF MEDICAL RISK. AND SO ONE CAN MINIMIZE THE MEDICAL RISKS OF OOCYTE DONATION, AT LEAST THE SHORT-TERM RISKS, BY THE WAY THE HORMONAL MANIPULATION AND RETRIEVAL ARE CARRIED OUT.

DR. KLITZMAN: BY THE WHAT? I'M SORRY.

CHAIRMAN LO: BY THE WAY YOU CARRY OUT HORMONAL MANIPULATION AND RETRIEVAL. AND CIRM ACTUALLY HAD ACTUALLY ASKED THE NATIONAL ACADEMY OF SCIENCES TO EXAMINE THIS, TO HOLD A WORKSHOP. LINDA GUIDICE FROM UC CHAIRED. AND THAT REPORT SUGGESTED THAT BY SELECTION OF DONORS, BY MONITORING OF THE DEVELOPMENT

OF FOLLICLES, BY WITHHOLDING THE SURGE DOSE OF LH OR HEG, YOU COULD REALLY MINIMIZE OR ELIMINATE THE RISK OF SEVERE HYPEROVULATION SYNDROME.

SO I NOTICED IN YOUR REPORT YOU SAY THAT IN ORDER TO QUALIFY FOR THIS FUNDING UNDER THE GRANT, IN ADDITION TO ALL THESE STIPULATIONS ABOUT PAYMENT, YOU SAID THAT THE STANDARDS OF ASRM HAD TO BE FOLLOWED. I WANTED TO SORT OF ASK YOU TO GIVE US A LITTLE MORE DETAIL ABOUT HOW IS THAT ACTUALLY DONE. DOES THE INVESTIGATOR -- DOES THE REPRODUCTIVE SCIENTIST WHO'S ACTUALLY HARVESTING THE EGGS, IF IT WERE TO COME TO A GRANT, JUST SAY -- MAKE A DECLARATION I'M GOING TO FOLLOW THE ASRM GUIDELINES? IS THERE ANY OTHER ADDITIONAL OVERSIGHT?

AND SECONDLY, I WANTED TO SORT OF ASK YOU ABOUT THERE WAS A SUGGESTION MADE IN THE NAS -- IT'S NOT A REPORT. IT'S A WORKSHOP -- THAT YOU MAY ACTUALLY WANT TO BE EVEN STRICTER IF YOU'RE RETRIEVING OOCYTES FOR RESEARCH AS OPPOSED TO REPRODUCTION AND TO TOLERATE LESS OF A RISK IN THAT CONTEXT. SO I JUST WANTED TO ASK YOU TO WALK US THROUGH HOW YOU THOUGHT ABOUT THE MEDICAL RISK ISSUE BECAUSE IF IT REALLY IS THE CASE THAT BY SAYING WE WILL FOREGO THE LAST GONADOTROPIN SURGE AND ELIMINATE THE POSSIBILITY OF SEVERE OHSS AT, OF COURSE, THE SAME TIME SAYING WE'RE NOT GOING TO

RETRIEVE OOCYTES, BUT WE CAN PROTECT WOMEN, THAT IT SEEMS TO ME TO BE A VERY PRACTICAL, PRAGMATIC WAY OF ADDRESSING THE ISSUE OF RISKS.

DR. KLITZMAN: EXCELLENT POINTS. VERY IMPORTANT TO THIS AND WHAT WE MAKE VERY CLEAR IN WHAT WE'VE WRITTEN ON THIS IS THAT THIS IS ALL SUBJECT TO LOCAL IRB APPROVAL AND SCRO APPROVAL. SO IRB'S ARE CHARGED WITH VERY CAREFULLY EVALUATING THE RISKS AND THE DESCRIPTION OF RISKS, WHAT THEY ARE, MAKING SURE THAT THE BENEFITS OUTWEIGH THE RISKS, THAT THE RISKS ARE AT LEAST COMMENSURATE WITH THE BENEFITS, ETC. SO WE ARE NOT MAKING THE FINAL -- AND THE SCIENCE IS GOING TO CHANGE. THE UNDERSTANDING OF RISKS IS GOING TO CHANGE, MAY GO UP, MAY GO DOWN, MAY BE CLARIFIED, MAY BE DIFFERENT. SO ALL THIS IS SUBJECT TO VERY, VERY CAREFUL IRB REVIEW. WE MADE THAT VERY CLEAR IN MANY, MANY WAYS, THAT GIVEN THE POSSIBILITY THAT RISKS CAN CHANGE, ETC., SO IRB'S, SINCE THEY NEED TO DO THIS WITH EVERY RESEARCH PROTOCOL, BE IT BONE MARROW TRANSPLANTS OR CHEMOTHERAPIES OR HIV, ANYTHING ELSE, TO REALLY VERY CAREFULLY LOOK AT THE RISKS AND BENEFITS INVOLVED IN EVERY PROTOCOL, NOT ONLY HOW THEY'RE EXPLAINED, BUT EVEN FOR THE EXPERIMENT TO GO FORWARD, WHAT ARE THE RISKS, AND ARE THEY TO MINIMIZE RISKS, ETC.

SO WE REALLY SEE THAT AS THE PURVIEW OF THE

IRB. ALL WE'VE DONE IS ALLOWED IRB'S TO CONSIDER THE POSSIBILITY AND ALLOW INVESTIGATORS TO CONSIDER THE POSSIBILITY OF COMPENSATING WOMEN FOR THE DONATION IF THAT MAKES SENSE SCIENTIFICALLY. SO AT THE SAME TIME WE ENCOURAGE THE RESEARCHER OBVIOUSLY TO SORT OF STAY UP TO DATE WITH WHATEVER THE CURRENT THINKING IS IN TERMS OF REDUCING RISKS AND WHAT THE RISKS ARE.

CHAIRMAN LO: SO IF I CAN ASK YOU AGAIN. SO YOU SAY THAT THERE NEEDS TO BE ADHERENCE TO ASRM'S GUIDELINES IN THE CONTEXT OF STANDARDS OF PRACTICE RATHER THAN JUST PAYMENT. AND I GUESS I WANT TO SORT OF ASK YOU TO BE MORE SPECIFIC. HOW IS THAT ACTUALLY DONE? IS IT JUST A DECLARATION? IS IT LEFT UP TO THE IRB TO GO OVER THE PROTOCOL LINE BY LINE AND MAKE SURE IT'S CONSISTENT WITH ASRM GUIDELINES?

DR. KLITZMAN: IN TERMS OF THOUGHT, THERE'S A CONTRACT PROCESS. SO WHEN THE EMPIRE STATE STEM CELL BOARD DECIDES WE'RE GOING TO FUND A PARTICULAR RESEARCHER, THERE IS A LENGTHY CONTRACT PROCESS THAT'S INVOLVED IN WHICH THIS IS IN THE -- ALL OF OUR PROVISIONS IN TERMS OF INFORMED CONSENT, IN TERMS OF IRB, IN TERMS OF ESCRO, ETC., THEY'RE CONTRACTUALLY AGREED UPON BY THE RESEARCHER AND THE INSTITUTION.

THE DETAILS OF THE CONTRACT PROCESS, ACTUALLY I WOULD REFER YOU TO THE STAFF SINCE THEY, FRANKLY,

DEAL WITH THAT MORE SPECIFICALLY THAN I DO.

CHAIRMAN LO: OKAY. WELL, AGAIN, I WANT TO ECHO WHAT THE OTHER MEMBERS OF THE SWG HAVE SAID, TO THANK YOU VERY MUCH FOR COMING, FOR ENGAGING US IN THIS DISCUSSION. AND, AGAIN, I WANT TO REITERATE FOR THE RECORD AND FOR THOSE IN THE ROOM THAT THIS IS SORT OF AN INTELLECTUAL EXERCISE TO JUST KEEP US ABREAST OF WHAT'S HAPPENING AROUND THE WORLD AND IN THE U.S. ON IMPORTANT DEVELOPMENTS. THIS IS NO WAY MEANT TO SIGNAL THAT SOMEHOW WE ARE TRYING TO UNDERMINE OR SUBVERT THE VERY CLEAR LANGUAGE IN PROP 71. WE CANNOT DO UNDER PROP 71 WHAT YOU ARE DOING, BUT IT'S CERTAINLY GOOD FOR US TO THINK ABOUT IT AND TO BE UP TO DATE ON THE ISSUES.

MS. LANSING: I ECHO THAT. I THOUGHT IT WAS FASCINATING. AND I THANK YOU FOR COMING. I KNOW IT'S THE EVE OF ROSH HASHANAH, AND I REALLY APPRECIATE THAT YOU MADE SUCH AN EFFORT TO BE HERE. I KNOW THAT WAS HARD ON YOU. AND I THINK I SPEAK FOR ALL OF US AND EVERYONE IN THE AUDIENCE AS WELL, THAT IT WAS FASCINATING TO HEAR THIS OTHER POINT OF VIEW.

DR. KLITZMAN: THANK YOU VERY MUCH AND GRATEFUL FOR THE CHANCE TO TALK TO YOU ABOUT IT.

CHAIRMAN LO: WITH THAT, I WOULD LIKE TO ADJOURN THE MEETING PART. WE WILL START TOMORROW AT,

WHAT TIME, 9 A.M. SHARP. AND TOMORROW WE WILL HAVE SOME ISSUES THAT WE NEED TO MAKE SOME DECISIONS OR RECOMMENDATIONS. THERE IS DINNER COMING UP. AND, PAT, WHERE IS DINNER GOING TO BE?

MS. BECKER: OLYMPIC ROOM.

CHAIRMAN LO: SO WE HAVE TEN MINUTES TO SORT OF -- TOMORROW, I GUESS I SHOULD SAY, SHERRY REMINDED ME, THAT WE REALLY HAVE TO PLAN ON BEING DONE BY 3 O'CLOCK. PEOPLE HAVE PLANES TO CATCH AND OTHER THINGS THAT THEY HAVE TO DO, SO WE NEED TO REALLY -- NOT A WHOLE DAY MEETING. IT'S NINE TO THREE.

(THE MEETING WAS THEN CONCLUDED AT 07:18 P.M. TO RECONVENE AT 9 A.M. ON SEPTEMBER 18TH, 2009.)

REPORTER'S CERTIFICATE

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

WESTIN SAN FRANCISCO MARKET STREET
50 THIRD STREET
SAN FRANCISCO, CALIFORNIA
ON
SEPTEMBER 17, 2009

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

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