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

REGULAR MEETING

LOCATION: MOSCONE CENTER SOUTH
747 HOWARD STREET, ROOM 250-260
SAN FRANCISCO, CALIFORNIA

DATE: THURSDAY, DECEMBER 1, 2005
10 A.M.`

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

BRS FILE NO.: 73897

I N D E X

ITEM	DESCRIPTION	PAGE NO.
CALL TO ORDER		003
ROLL CALL		006
APPROVAL OF MINUTES FROM OCTOBER 24, 2005		009
CIRM STAFF UPDATE IP TASK FORCE PROGRESS REPORT CIRM GRANTS ADMINSITRATION POLICY		
REVIEW OF CIRM DRAFT REGULATIONS LANGUAGE		
CONSIDERATION OF INFORMED CONSENT REQUIREMENTS CONSIDERATION OF ETHICALLY DERIVED		
CONSIDERATION OF WORK PLAN TO DEVELOP FINAL DRAFT REGULATIONS		
ADJOURNMENT		

SAN FRANCISCO, CALIFORNIA; THURSDAY, DECEMBER 1, 2005

VICE CHAIR LO: GOOD MORNING, EVERYONE. IF WE COULD GRAB YOUR COFFEE AND PLEASE COME TO THE TABLE. I WANT TO WELCOME YOU ALL TO TODAY'S MEETING OF THE STANDARDS WORKING GROUP OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE. I'LL START BY APOLOGIZING FOR THE WET WEATHER. WE WERE HOPING TO HAVE BLUE SKIES FOR YOU. I ASKED STAFF TO ARRANGE IT. AND ONLY THING THEY DIDN'T DO WAS TO GET THE BLUE SKIES TODAY.

WE HAVE A NUMBER OF PEOPLE WHO WILL BE PHONING IN DURING THE COURSE OF THE DAY AND PEOPLE SORT OF COMING IN AND OUT BECAUSE TODAY, FOR EXAMPLE, IS WORLD'S AIDS DAY, AND JEFF SHEEHY HAS A PRIOR IMPORTANT COMMITMENT TO THE WORLD'S AIDS DAY ACTIVITIES.

SO I WANT TO FORMALLY CALL THE MEETING TO ORDER. AND I GUESS WE WILL GO AROUND AND DO A FORMAL ROLL CALL.

MS. SHREVE: I CAN DO THE ROLL CALL.

VICE CHAIR LO: KATE CAN DO IT. EVEN BETTER. THANK YOU.

MS. SHREVE: SHERRY LANSING. BERNARD LO.

VICE CHAIR LO: HERE.

MS. SHREVE: ALTA CHARO. JOSE CIBELLI.

DR. CIBELLI: HERE.

MS. SHREVE: KEVIN EGGAN.

DR. EGGAN: HERE.

MS. SHREVE: MARCY FEIT. ANN KIESSLING.

DR. KIESSLING: HERE.

MS. SHREVE: PATRICIA KING. ROBERT KLEIN. JEFFREY KORDOWER. KENNETH OLDEN. TED PETERS.

DR. PETERS: HERE.

MS. SHREVE: FRANCISCO PRIETO. JANET ROWLEY.

DR. ROWLEY: HERE.

MS. SHREVE: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. SHREVE: JON SHESTACK. ROBERT TAYLOR.

DR. TAYLOR: HERE.

MS. SHREVE: JOHN WAGNER. JAMES WILLERSON.

DR. HALL: DO WE HAVE A QUORUM? DO WE HAVE PEOPLE JOINING US BY PHONE?

MS. SHREVE: WE DO, BUT WE EXPECT STARTING AT 11:30.

DR. HALL: OKAY. HOW MANY SHORT OF A QUORUM ARE WE?

MS. SHREVE: WE NEED 13 FOR A QUORUM, SO THIS WILL BE LARGELY --

DR. HALL: I COUNT. HOW MANY DO WE HAVE PRESENT?

MS. SHREVE: NINE.

DR. HALL: SO WE'RE SHORT FOUR.

VICE CHAIR LO: KATE, CAN YOU JUST FILL US IN? WHAT ARE THE IMPLICATIONS OF THAT IN TERMS OF WHAT WE'RE ALLOWED TO DO?

MS. SHREVE: I DON'T EXPECT ACTUALLY FORMAL VOTES TO BE TAKEN TODAY. WE NEED A QUORUM FOR FORMAL VOTES.

VICE CHAIR LO: FOR FORMAL VOTES. WE'RE STILL PERMITTED TO HAVE DISCUSSIONS?

MS. SHREVE: ABSOLUTELY.

VICE CHAIR LO: SO THE FIRST ORDER OF BUSINESS IS TO GO OVER THE MINUTES FROM OUR LAST MEETING IN LOS ANGELES ON OCTOBER 24TH, WHICH ARE IN YOUR BINDER UNDER AGENDA ITEM NO. 4, THE YELLOW TAB. SO ANY CORRECTIONS OR ADDITIONS TO THE MINUTES? IF NO CORRECTIONS, MAY I HEAR A MOTION TO APPROVE THEM?

MR. HARRISON: BECAUSE YOU DON'T HAVE A QUORUM --

VICE CHAIR LO: WE CAN'T.

MR. HARRISON: WE CAN JUST TAKE THEM UNDER ADVISEMENT.

VICE CHAIR LO: WE'LL TAKE THAT UNDER ADVISEMENT, AND WE'LL COME BACK TO THAT WHEN WE GET A QUORUM. THANKS, JAMES. FORGOT ABOUT THAT.

SO THE FIRST ITEM OF BUSINESS, THEN, FROM

TIME TO TIME THIS COMMITTEE DISCUSSED ISSUES OF INTELLECTUAL PROPERTY. AND THE CIRM IP TASK FORCE ON INTELLECTUAL PROPERTY IS CHAIRED BY ED PENHOET, WHO IS THE VICE CHAIR OF THE ICOC, AND HE IS HERE TODAY TO GIVE US A PROGRESS REPORT ON WHAT THAT TASK FORCE IS DOING AND THEIR THINKING IN THIS VERY IMPORTANT AND ALSO VERY COMPLICATED ISSUE.

OUR GOAL IS TO PROVIDE INPUT, BECAUSE WE DON'T HAVE A QUORUM, WE'RE NOT GOING TO BE ABLE TO DO ANYTHING FORMALLY, BUT I THINK IT'S A CHANCE FOR US TO HEAR ABOUT THE DELIBERATIONS OF THE IP TASK FORCE. AND THEN IF WE HAVE STRONG IDEAS, ALSO IT'S A WAY OF OUR PROVIDING INPUT.

ED, THANKS VERY MUCH FOR COMING TO SHARING WITH US WHAT YOUR COMMITTEE HAS BEEN DOING WITH GREAT INTEREST TO US.

DR. PENHOET: THANK YOU. GOOD MORNING. THANKS FOR THE OPPORTUNITY TO SHARE A WORK IN PROGRESS AT THE IP TASK FORCE WITH YOU. I'M GOING TO GIVE A LITTLE OVERVIEW OF THE INTELLECTUAL PROPERTY SPACE, SO TO SPEAK, AND THEN JEFF SHEEHY, WHO'S A MEMBER OF BOTH THE INTELLECTUAL PROPERTY TASK FORCE AND OF YOUR GROUP, IS GOING TO PRESENT WHERE WE ARE IN OUR DELIBERATIONS ABOUT HOW WE SHOULD HANDLE IP.

WE HAVE TWO GOALS, ONE SHORT-TERM GOAL AND

ONE LONG-TERM GOAL. OUR SHORT-TERM GOAL IS TO MAKE A RECOMMENDATION TO THE ICOC AT ITS DECEMBER 6TH MEETING ABOUT AN INTERIM POLICY, WHICH WOULD BE APPLICABLE FOR TRAINING GRANTS ONLY, AND THEN TO CONTINUE OUR WORK WITH A FINAL GOAL OF HAVING IN PLACE BY THE SPRING OF 2006 AN INTELLECTUAL PROPERTY POLICY FOR THE CIRM AS WE GO FORWARD.

SO WE ARE IN THE EARLY PHASES OF THIS PROJECT, AND WE'VE, I THINK, MADE GOOD PROGRESS AND WE'RE HAPPY TO HAVE THE OPPORTUNITY TO SHARE THAT PROGRESS WITH YOU.

IF YOU LOOK AT WHAT'S GOING TO BE REQUIRED FOR THE TRAINING GRANTS AND, IN FACT, FOR THE GRANTS IN GENERAL, ONCE WE GET TO THAT POINT, THERE ARE BASICALLY THREE SETS OF INPUTS WHICH WILL ALL BE INCORPORATED AT THE END OF THE DAY IN A GRANTS ADMINISTRATION POLICY.

SO THE IP POLICY GROUP IS DEVELOPING -- THE IP TASK FORCE IS DEVELOPING AN INTERIM IP POLICY WHICH WILL BE FED INTO THIS. YOUR GROUP IS CONFRONTING THE ISSUES OF INTERIM ETHICAL STANDARDS WHICH HAVE TO BE IN PLACE IN ORDER FOR US TO MAKE ANY GRANTS FOR THE TRAINING PROGRAM. THOSE WILL COME TOGETHER WITH A VARIETY OF OTHER ADMINISTRATIVE GUIDELINES IN A DOCUMENT WHICH WILL FORM THE INTERIM GRANTS ADMINISTRATION POLICY FOR CIRM, TO WHICH ALL GRANTEES

WILL HAVE TO AGREE AS PART OF THEIR RECEIVING A GRANT.

AND SO IF AND WHEN THEY AGREE THAT THEY WILL ESSENTIALLY CONDUCT THEMSELVES ACCORDING TO THE PRINCIPLES ARTICULATED IN THAT DOCUMENT, THEN THEY'LL PRESUMABLY SIGN THAT DOCUMENT AND AGREE TO DO SO GOING FORWARD.

SO AS I SAID, WE'VE BEEN WORKING ON THE LEFT-HAND SIDE THERE. JUST TO REMIND YOU ABOUT SOME OF THE BACKGROUND OF THE INTELLECTUAL PROPERTY, BECAUSE I KNOW NOT ALL OF YOU ARE INTELLECTUAL PROPERTY EXPERTS, TO BE SURE, FIRST OF ALL, WHAT KINDS OF THINGS CONSTITUTE INTELLECTUAL PROPERTY? AND THE FIRST AND THE ONE THAT RECEIVES THE MOST ATTENTION IS SUBJECT MATTER WHICH IS PATENTABLE. PATENTABLE SUBJECT MATTER CAN INCLUDE COMPOSITIONS OF MATTER. IF YOU INVENT A SUBSTANCE OR YOU INVENT A MACHINE, YOU CAN PATENT THAT THING, AND FREQUENTLY THOSE, FOR EXAMPLE, IN THE FIELD OF THERAPEUTICS, WHAT IS GENERALLY PATENTED IS THE SUBSTANCE ITSELF. THAT'S THE DRUG OR THERAPY OF ONE SORT OR ANOTHER, BUT ALSO DIAGNOSTICS. AND AS WE KNOW, STEM CELL LINES CAN BE PATENTED. THERE ARE A NUMBER THAT HAVE ALREADY BEEN PATENTED BY VARIOUS DIFFERENT GROUPS, ESPECIALLY BY THE UNIVERSITY OF WISCONSIN, AND OWNERSHIP OF THOSE CELL LINES NOW RESIDES IN THE RESEARCH FOUNDATION OF THE UNIVERSITY OF WISCONSIN.

PROCESSES ARE ALSO PATENTABLE. METHODS OF DOING SOMETHING, ASSAYS OF DOING SOMETHING; AND WHETHER OR NOT YOU GET A PATENT DEPENDS ON THE NUANCES OF THE PATENT LAW, BUT FUNDAMENTALLY PATENTS ARE ALLOWED IF PEOPLE INVENT SOMETHING THAT'S USEFUL; THAT IS, IT HAS TO HAVE UTILITY AND IT'S NOVEL. SO THOSE ARE THE TWO SORT OF BROAD CRITERIA THAT DEFINE PATENTABLE SUBJECT MATTER.

THERE ARE ALSO OTHER FORMS OF INTELLECTUAL PROPERTY. ONE OF THOSE IS KNOW-HOW; THAT IS, JUST THE ACCUMULATED KNOWLEDGE IN AN ORGANIZATION THAT IS CONDUCTING A RESEARCH PROGRAM OF ANY KIND. THAT KNOW-HOW GENERALLY, WHETHER IT'S PATENTED OR NOT PATENTED, IS A FORM OF INTELLECTUAL PROPERTY. IT'S NOT A FORMAL FORM OF INTELLECTUAL PROPERTY, BUT IT'S A VERY IMPORTANT FORM BECAUSE, IN FACT, A LOT OF THE NEW KNOWLEDGE WHICH IS GAINED AND THE NEW THINGS WHICH ARE DISCOVERED, PROBABLY THERE'S MORE IN THE CATEGORY OF KNOW-HOW THAN THERE IS ACTUALLY IN PATENTABLE SUBJECT MATTER OR PATENTED SUBJECT MATTER.

AND THEN FINALLY THE OTHER FORM OF INTELLECTUAL PROPERTY IS COPYRIGHTS. THIS HISTORICALLY HAD REFERRED TO WRITTEN DOCUMENTS, BUT NOW ALSO COVERS SOFTWARE AND DATABASES WHICH HAVE BEEN COPYRIGHTED. AND THEIR USE IS, THEREFORE, PROTECTED.

THERE'S JUST A GENERAL ISSUE. WHY DO PEOPLE FILE PATENTS? WHAT IS THE PURPOSE OF PATENTS? AS YOU CAN READ HERE, THE CONSTITUTIONAL CONVENTION ACTUALLY ANTICIPATED THE FILING OF PATENTS TO PROMOTE THE PROGRESS OF SCIENCE AND USEFUL ARTS BY SECURING FOR LIMITED TIMES TO AUTHORS AND INVENTORS THE EXCLUSIVE RIGHT TO THEIR RESPECTIVE WRITINGS AND DISCOVERIES.

THIS HAS TWO VERY IMPORTANT RAMIFICATIONS. THE FIRST IS TO FORCE THE INVENTOR TO DISCLOSE THE INVENTION TO ENABLE THE WORK OF OTHERS. AND OFTENTIMES THE REALITY OF PEOPLE WHO ARE GENERATING INTELLECTUAL PROPERTY GENERALLY IS THEY HAVE TWO WAYS OF GETTING SOME PRIVATE USE, IF YOU WILL, OF THEIR TECHNOLOGY THAT THEY INVENT. ONE IS TO FILE A PATENT, AND THEN THEY CREATE PROPERTY, REAL PROPERTY. IF THEY ARE GRANTED A PATENT, THE PATENT ITSELF IS REAL PROPERTY.

THE OTHER WAY IS TO KEEP IT A SECRET, SO-CALLED TRADE SECRET, WHERE THEY DON'T SHARE THEIR KNOW-HOW AND, THEREFORE, THAT IS NOT AVAILABLE TO THE COMMUNITY AT LARGE BECAUSE THEY HAVE, IN ESSENCE, DECIDED TO PROTECT THEIR INVENTIONS BY NOT TELLING ANYBODY ABOUT WHAT THEY'VE INVENTED. SO THE PATENT SYSTEM, ONE OF THE IMPORTANT PARTS OF THE PATENT SYSTEM, IN ADDITION TO ALLOWING INVENTORS TO GAIN SOME BENEFITS FROM HAVING MADE THE INVENTION, IS ACTUALLY TO

FACILITATE THE DISPERSION OF THE INFORMATION CONTAINED IN THE PATENT.

AND FORTUNATELY, I THINK, FOR SCIENCE IN THIS COUNTRY, A PATENT HAS TO BE, AS WRITTEN, HAS TO BE ENABLING. ENABLING MEANS IF SOMEBODY READS THAT PATENT, THAT THEY CAN REPRODUCE THE WORK. AND IN ADDITION TO BEING ENABLING, IT HAS TO DISCLOSE THE BEST MODE OF DOING IT. SO YOU CAN'T WRITE A QUARTER OF A PATENT ON YOUR INVENTION AND KEEP OUT KEY ISSUES ASSOCIATED WITH ALLOWING SOMEBODY ELSE TO REPEAT THE WORK. IF YOU DO, YOUR PATENT WILL BE INVALIDATED. SO YOU MUST DISCLOSE THE BEST MODE, AND YOU MUST DISCLOSE THE ENTIRETY OF THE METHODS THAT LED TO THE PATENT.

AND THEN, FINALLY, OF COURSE, THE PATENTS DO ALLOW THE INVENTOR TO ENJOY FINANCIAL BENEFITS OF THE INVENTION AFTER DISCLOSURE. OUR CURRENT PATENT LAW IS THAT A PATENT IS VALID FOR 17 YEARS AFTER THE DATE OF FILING.

SO TECHNOLOGY TRANSFER, WHICH IS WHAT WE ARE DEALING WITH PRIMARILY IN THE IP POLICIES, HAS REALLY TWO ROUTES. ONE IS LICENSING. THIS IS THE PROCESS BY WHICH AN OWNER OF AN INVENTION, ACTUALLY THE OWNER OF A PATENTED INVENTION GENERALLY, PERMITS A SECOND PARTY TO USE THE INVENTION. PATENTS PER SE DO NOT PROSCRIBE ANY PARTICULAR USE OF THE PATENT. IF YOU OWN A PATENT, YOU

CAN ALLOW PEOPLE TO FREELY USE YOUR PATENT. YOU CAN CHARGE THEM A LOT OF MONEY. YOU CAN SELECTIVELY LICENSE A FEW PEOPLE. IT'S LIKE ANY OTHER PROPERTY. IF YOU'RE THE OWNER OF THAT PROPERTY, YOU HAVE THE RIGHT TO CHOOSE HOW THAT PROPERTY IS ACTUALLY UTILIZED BY YOURSELF OR BY OTHERS. SO THERE IS NO -- THERE'S NOTHING IN THE OWNERSHIP OF A PATENT PER SE THAT DEFINES WHAT'S USED.

WE'LL GET BACK TO THAT A LITTLE BIT LATER ON BECAUSE SOME OF THE -- IN JEFF'S PRESENTATION, YOU WILL SEE THAT A NUMBER OF THINGS RELATED TO PATENTS AND NOT RELATED TO PATENTS WITH RESPECT TO INTELLECTUAL PROPERTY ARE DETERMINED BY SOME IMPORTANT PRINCIPLES WHICH HAVE BEEN IN PLACE FOR SOME TIME NOW IN THE U.S. SCIENTIFIC COMMUNITY, AND OFTENTIMES THERE'S CONFUSION ABOUT THE WAY IN WHICH THESE ARE APPLIED VERSUS THE PRINCIPLES THEMSELVES. AND ESPECIALLY AROUND THE LAWS THAT AROSE FROM THE BAYH-DOLE ACT IN 1980, FOR EXAMPLE. THERE'S GENERALLY BOTH CONTROVERSY AND CONFUSION ABOUT BAYH-DOLE, BUT IN GENERAL I THINK IT'S IMPORTANT FOR US TO SEGREGATE WHAT BAYH-DOLE SAYS AND HOW IT'S APPLIED, WHICH ARE FREQUENTLY QUITE DIFFERENT ISSUES.

THEN THE INFORMAL SHARING OF KNOW-HOW IS IN AGGREGATE PROBABLY MUCH LARGER THAN LICENSING; THAT IS, THE PUBLICATION OF RESEARCH RESULTS, THE MOVEMENT OF

PEOPLE, FRANKLY, IS A VERY SUBSTANTIAL -- EVERY TIME A PERSON MOVES FROM ONE ORGANIZATION TO ANOTHER, THEY CARRY THE KNOWLEDGE THAT THEY'VE ACCUMULATED IN THE FIRST ORGANIZATION TO THE SECOND ORGANIZATION. SO THIS INFORMAL SHARING OF KNOW-HOW, WHICH HAS NOTHING TO DO WITH LICENSING BECAUSE IT'S NOT BASED ON ANY FORMAL PATENTS, IS ACTUALLY QUANTITATIVELY PROBABLY, MY OWN GUESS, IT WOULD BE TEN TIMES AS LARGE AS TECHNOLOGY WHICH IS SUBJECT TO PATENTS. AND, THEREFORE, WE SPENT A FAIR AMOUNT OF TIME IN OUR TASK FORCE ON THIS ISSUE OF, IN ADDITION TO THE INTELLECTUAL PROPERTY ASSOCIATED WITH PATENTS, WE SPENT A FAIR AMOUNT OF TIME ON DISCUSSING AND THINKING HARD ABOUT THE ISSUES OF HOW UNPATENTED KNOW-HOW WILL BE SHARED WITHIN THE CIRM GRANTEES.

WITH THAT, LET ME STOP HERE AND TAKE SOME QUESTIONS FROM YOU, IF YOU HAVE ANY, ABOUT THIS SORT OF BRIEF INTRODUCTION TO THE PATENT SYSTEM AND THE ISSUES THAT WE'RE DEALING AS A RESULT. DO ANY OF YOU --

DR. CIBELLI: WE HAD A QUESTION. ACTUALLY LAST MEETING WE WERE DISCUSSING HOW WE CAN MAKE SURE THAT THE GRANTEE WILL SHARE REAGENTS, FOR EXAMPLE, WITH OTHER GRANTEES OR MEMBERS OF THE SCIENTIFIC COMMUNITY. IT'S UNDERSTOOD THAT WHEN YOU PUBLISH AN ARTICLE, THEN YOU HAVE TO SHARE THE REAGENTS WITH THE COMMUNITY. BUT

IF THE GRANTEE IS A COMPANY AND THEY MAY NOT WANT TO PUBLISH AN ARTICLE, YOU MAY WANT TO FILE A PATENT. SO WE WENT BACK AND FORTH AND TRIED TO RECONCILE THE TWO THINGS, TRYING TO MAINTAIN THE CONFIDENTIALITY OR WHATEVER THE COMPANY IS TRYING TO CREATE VALUE ON, BUT AT THE SAME TIME THE MONEY WAS GIVEN FROM THE INSTITUTE. THEY SHOULD BE ABLE TO SHARE WHATEVER THEY GENERATE. HAVE YOU THOUGHT ABOUT HOW TO FIX THAT?

DR. PENHOET: WE HAVE A PRINCIPLE THAT WE'VE ARTICULATED, AND I THINK IT WILL COME OUT IN JEFF'S PRESENTATION. WE THINK THERE ARE SOME WAYS TO HANDLE THAT ISSUE. AND AS YOU WILL SEE, ONE OF THE PRINCIPLES -- AND WHAT JEFF WILL SHOW YOU TODAY, WE HAVE NOT FORMULATED A POLICY. IT'S MUCH TOO SOON FOR US TO FORMULATE A POLICY. WE HAVE FORMULATED A SET OF PRINCIPLES UPON WHICH OUR POLICY WILL BE BASED. ONE OF THOSE PRINCIPLES IS MUCH EXPANDED SHARING OF REAGENTS AND KNOW-HOW ABOUT WHAT'S GENERALLY PRACTICED TODAY IN THE BIOMEDICAL COMMUNITY. SO THAT IS PART OF OUR PRESENTATION, AND JEFF WILL TALK ABOUT THAT. BUT IT'S AN EXTREMELY IMPORTANT POINT.

DR. PETERS: I HAVE TWO LARGE QUESTIONS. I'M WONDERING, MR. CHAIR, IF I SHOULD DO THAT NOW OR WAIT UNTIL THE ENTIRE PRESENTATION IS OVER. DISCUSSION QUESTIONS.

VICE CHAIR LO: AT THIS POINT WHY DON'T WE JUST HAVE QUESTIONS RELATED TO WHAT ED HAS PRESENTED, THE BACKGROUND, AND THERE WILL BE TIME AFTER ED FINISHES AND JEFF PRESENTS AND WE SEE WHAT THEIR IDEAS ARE TO HAVE BROADER COMMENTS.

DR. PENHOET: PROBABLY BE MORE CLEAR AFTER JEFF'S PRESENTATION, SO AT THIS POINT I'LL TURN IT OVER TO JEFF.

VICE CHAIR LO: THANKS VERY MUCH. THAT WAS VERY CLEAR AND HELPFUL.

MR. SHEEHY: AND THE FIRST THING I WANT TO DO WHILE WE HAVE THE ACTUAL STATUTE UP IS, WHILE YOU GUYS ARE READING THAT, IS TO TRY TO NARROW OUR DISCUSSION TO WHAT IT REALLY IS TODAY. AND I THINK JOSE HAS BROUGHT UP THE ISSUE OF COMPANIES, AND I THINK TED IS GOING TO BRING UP SOME LARGER ISSUES, BUT THE REALITY OF WHAT WE'RE LOOKING AT TODAY IS INTELLECTUAL PROPERTY GUIDELINES FOR TRAINING GRANTS, EXCLUSIVELY FOR THAT.

AND WHEN WE TALK ABOUT INTELLECTUAL PROPERTY GUIDELINES, LET'S TRY TO SEPARATE IN OUR MINDS BETWEEN THE GUIDELINES THAT ARE GOING TO APPLY MOSTLY TO UPSTREAM RESEARCH THAT'S DONE AT NONPROFIT ACADEMIC RESEARCH INSTITUTIONS AND THEN SOMETHING THAT'S MORE WHAT IAVI CALLS DEVELOPMENT WHERE YOU ACTUALLY MAKE A GRANT DIRECTLY TO A COMPANY, AND THAT COMPANY DEVELOPS

A PRODUCT. THOSE TWO ACTUALLY, I THINK, WILL NEED SEPARATE RULES. AND SO WHAT WE'RE TALKING ABOUT TODAY FOR TRAINING GRANTS ARE ONLY GOING TO GO TO NONPROFIT ACADEMIC INSTITUTIONS. I DO THINK THAT THIS MAY IN SOME WAYS SERVE AS A TEMPLATE FOR THE LONG-TERM POLICY FOR GRANTS THAT ARE MADE TO ACADEMIC RESEARCH INSTITUTIONS, BUT LET'S NOT CONFUSE THAT WITH WHAT WE MAY END UP DOING IN TERMS OF DEVELOPMENT IP POLICY THAT IS GOING TO GO TO A FOR-PROFIT ENTITY THAT IS GOING TO COMMERCIALIZE A PRODUCT. WE MAY END UP WITH A SOMEWHAT DIFFERENT SET OF INTELLECTUAL PROPERTY GUIDELINES FOR THAT, AND IT MAY BRING IN SOME OF THOSE LARGER ISSUES THAT I THINK FOLKS MAY WANT TO TALK ABOUT IN TERMS OF PUBLIC BENEFIT.

AND I REALLY THINK WE NEED TO LOOK AT THE LAW HERE FOR A SECOND BECAUSE THE LAW IS SOMEWHAT CONSTRICTING IN THAT IT GIVES US A VERY NARROW BALANCE BETWEEN PATENTS, ROYALTIES. AND WE HAVE REALLY HAVE A TEST TO BALANCE SOME SORT OF -- I TEND TO READ THIS AS A FINANCIAL RETURN. PATENTS, ROYALTIES, AND LICENSES TEND TO MEAN TO ME THAT WE'RE GOING TO DERIVE SOME SORT OF THE INCOME STREAM VERSUS PATENTING AND LICENSING THAT MIGHT INTERFERE WITH THE ABILITY OF THE SCIENCE TO MOVE FORWARD. SO AS I UNDERSTAND THIS, AND WE MAY WANT TO TALK ABOUT THIS LATER, THIS SEEMS TO BE OUR CORE

INTELLECTUAL PROPERTY KIND OF, IF YOU THINK ABOUT THE SCALE, IF WE PUT TOO MUCH ON LICENSING WITH THAT OR IF WE GET PEOPLE TO OVERPATENT, WILL THAT SLOW OR LIMIT THE ABILITY TO MOVE FORWARD WITH THE SCIENCE THAT A MORE OPEN IP POLICY MIGHT PRODUCE.

SO THIS JUST KIND OF SHOWS YOU WHERE WE ARE IN THE PROCESS AND THE DIFFERENT DATES. I THINK WE CAN JUST KIND OF FLY THROUGH THIS. THIS TAKES US TO WHERE WE ARE TODAY, DECEMBER 1ST. THE NEXT ICOC MEETING, WE'RE GOING TO TRY TO PUT IN PLACE A WHOLE SET OF INTERIM POLICIES THAT WILL ALLOW THE TRAINING GRANTS TO GO OUT.

DR. PENHOET: IT'S WORTH NOTING WE'VE HAD TWO MEETINGS OF THE IP TASK FORCE.

DR. HALL: COULD I ASK YOU, JEFF, TO GIVE US SOME SENSE OF THE WORK THAT THE TASK FORCE HAS DONE AT THOSE TWO MEETINGS?

MR. SHEEHY: I THINK THE NEXT COUPLE SLIDES. SO WE'VE LOOKED, AND AS YOU AN TELL, THIS IS FAIRLY LONG LIST OF REPORTS THAT HAVE BEEN DISCUSSED. WE HAVE HAD TWO EXTENSIVE MEETINGS. WE HAVE HAD -- WE ALSO HAD THE BENEFIT OF AN EXTRAORDINARILY INFORMATIVE MEETING CONDUCTED BY THE LEGISLATURE LED BY SENATOR DEBORAH ORTIZ THAT I FOUND TO BE VERY INFORMATIVE. IF YOU LOOK, A WHOLE SET OF DIFFERENT MODELS THAT HAVE BEEN

BROUGHT FORWARD AND DISCUSSED, AND I THINK WHAT I'D LIKE TO DO NEXT IS MAYBE TALK ABOUT -- WE ACTUALLY HAVE A LIST OF THE PRESENTATIONS THAT WE'VE SEEN.

SO THE FIRST IP TASK FORCE MEETING, WE GOT THE PRESENTATION ON THE CCST REPORT, WHICH IS THE CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY REPORT. WE HAD THE OCTOBER 31ST LEGISLATIVE HEARING, WHICH, AS YOU CAN SEE, WE HEARD FROM REBECCA EISENBERG, WHO'S A WELL-KNOWN EXPERT AND INNOVATOR IN IP POLICY; MERRILL GOOZNER HAD SOME GREAT IDEAS; WE HEARD FROM BOND COUNSEL ABOUT ISSUES RELATED TO TAX-EXEMPT BONDS. YOU FOLLOW TO OUR LAST TASK FORCE, WE HEARD FROM REBECCA EISENBERG AGAIN; RICHARD KLAUSNER FORMERLY WITH THE GATES FOUNDATION, WHO DISCUSSED WITH US HOW GATES DOES INTELLECTUAL PROPERTY FOR THEIR GRANTS, AND THEY'RE ACTUALLY INCREDIBLY INNOVATIVE, THEIR POLICY.

SO AS YOU CAN SEE, THERE'S A LITTLE BIT OF HOMEWORK THAT WE'VE DONE IN GETTING TO THIS POINT.

NOW, I'D LIKE TO JUST START WITH THE FIRST MODEL. I WANT TO SAY SOMETHING ABOUT THE CCST INTERIM REPORT BECAUSE THIS REPORT WAS COMMISSIONED BY THE LEGISLATURE BECAUSE THERE IS NO INTELLECTUAL PROPERTY POLICY FOR STATE-FUNDED RESEARCH. SO IN A WAY WHAT WE'RE DOING WITH CIRM IS WE'VE KIND OF GOT THE BULL'S-EYE DRAWN ON US, BUT THE LEGISLATURE IS ACTUALLY

SUPPOSED TO BE ADDRESSING THIS ISSUE FOR ALL INSTITUTIONS FOR ALL STATE-FUNDED RESEARCH AND PRESUMABLY WHEN THEY FINISH THEIR PROCESS, THAT WOULD BE SOMETHING THAT WE WOULD WANT TO TAKE PART IN.

WHAT WE GOT FROM THE CCST WAS AN INTERIM REPORT THAT THEY'RE PREPARING FOR THE LEGISLATURE IN THE HOPE THAT THE LEGISLATURE WILL ADOPT IT AS AN IP POLICY FOR ALL STATE-FUNDED RESEARCH. AND THEY BASICALLY DEFAULTED TO A BAYH-DOLE MODEL FOR, I THINK, ALL THE REASONS THAT BAYH-DOLE HAS -- IN THE WAYS IN WHICH BAYH-DOLE HAS WORKED UP TO THIS POINT. THERE WAS SOME CONCERN EXPRESSED AT THE UPSTREAM LEVEL ON THE SHARING OF MATERIALS AND KNOWLEDGE. I THINK THAT THAT IS THE THEME THAT COMES OUT IN ALMOST EVERY MODEL THAT WE LOOKED AT.

SO THIS WAS THE FIRST THING THAT WE GOT. I THINK ALSO WHAT THEY'RE LOOKING AT IS SOMETHING THAT IS MORE ORIENTED TOWARDS NONPROFIT ACADEMIC RESEARCH INSTITUTIONS AND NOT SOMETHING THAT NECESSARILY IS THAT INFORMATIVE IF YOU ARE GOING TO BE TALKING ABOUT MAKING GRANTS TO COMPANIES TO DEVELOP PRODUCTS OR TO CARRY OUT CLINICAL TRIALS.

THE NEXT MODEL WE'RE LOOKING AT IS IAVI, WHICH IS THE INTERNATIONAL AIDS VACCINE INITIATIVE. WHAT I LIKE ABOUT THEIR MODEL IS THAT THEY ACTUALLY

HAVE BROKEN IT DOWN INTO TWO PIECES THAT KIND OF CAPTURES THIS DICHOTOMY. SO FOR BASIC UPSTREAM RESEARCH, THEY ARE CREATED A CONSORTIUM WITH HALF A DOZEN RESEARCH INSTITUTIONS, ACADEMIC RESEARCH INSTITUTIONS, AND THAT CONSORTIUM RETAINS EXCLUSIVE IP RIGHTS WITHIN IT. SO IN A WAY THAT IS A PATENT POOL.

NOW, THEY DO HAVE VERY INNOVATIVE POLICY THAT THEY DO WHEN THEY GO TO DEVELOPMENT. THIS IS WHEN THEY GO TO A COMPANY OR A COMPANY COMES TO THEM. THEY HAVE A PRODUCT THEY WANT TO TRY. THEY ALLOW THE GRANTEES TO OWN THE IP, BUT THEY THEN GO INTO ALL OF THIS VERY IMPORTANT ACCESS ISSUE KIND OF AGREEMENTS. SO THEY REQUIRE, FOR INSTANCE, VACCINES BE PROVIDED AT REASONABLE COST TO DEVELOPING COUNTRIES. AND IF THEY DON'T, THEY RETAIN A MARCH-IN RIGHT THAT ALLOWS THEM TO LICENSE THAT VACCINE PRODUCT TO AN IN-COUNTRY MANUFACTURER SO THAT THAT VACCINE WILL BE AVAILABLE IN THAT COUNTRY.

THEY ENCOURAGE THE COMMERCIALIZATION OF DISCOVERIES. THIS IS NOT, BY THE WAY, THAT DIFFERENT FROM WHAT GATES DOES, EXCEPT THAT GATES NEGOTIATES A SEPARATE ACCESS POLICY FOR DEVELOPING COUNTRIES WITH EACH GRANTEE BEFORE THE GRANT IS MADE. SO AS A PART OF YOUR GRANT PROPOSAL, YOU HAVE TO SUBMIT YOUR PLAN FOR MAKING YOUR PRODUCT AVAILABLE TO PEOPLE IN THE

DEVELOPING WORLD OR IN LOW INCOME COUNTRIES.

AND THEN THE LAST WE HAVE IS REBECCA EISENBERG'S RECOMMENDATIONS. AND SHE RECOMMENDS THAT WE ALLOW OUR GRANTEES TO OWN IP RIGHTS. THIS IS AN IMPORTANT PART THAT'S COME UP. RESERVE THE RIGHT FOR CIRM RESEARCHERS TO USE CIRM-FUNDED IP. WE SHOULDN'T HAVE TO PAY FOR IP TWICE. IF SOMEONE AT AN INSTITUTION PATENTS SOMETHING, ONE OF OUR GRANTEES SHOULDN'T HAVE TO PAY A FEE TO THAT INSTITUTION IN ORDER TO GET ACCESS TO USE THE STEM CELL LINE, THAT REAGENT, OR WHATEVER IT MAY BE THAT WAS DEVELOPED IF IT WAS DEVELOPED WITH CIRM MONEY.

EVALUATE THE EXCEPTIONAL CIRCUMSTANCES ASPECT OF FEDERAL LAW FOR NONPROPRIETARY APPROACH TO FURTHERING CIRM TECHNOLOGY TRANSFER GOALS. I THINK WE'RE GOING TO BRING ED BACK AT SOME POINT TO TALK MORE SPECIFICALLY ABOUT THIS REALLY COMPLEX AREA OF LAW THAT I'M NOT SURE I UNDERSTAND YET, BUT IT REALLY IS ONE MORE ELEMENT AT THIS UPSTREAM LEVEL OF RESEARCH TOWARDS FURTHERING GREATER SHARING, WHICH IS THE ONE NEGATIVE ASPECT THAT'S BEEN BROUGHT UP AGAIN AND AGAIN ABOUT BAYH-DOLE IS THAT THERE'S THIS TENDENCY TO LICENSE, TO PATENT, AND TO IN SOME WAY IMPEDE THE SHARING OF THESE TOOLS AND THESE UPSTREAM PRODUCTS THAT EVERYONE NEEDS TO HAVE ACCESS TO IN ORDER FOR THE RESEARCH TO MOVE

FORWARD.

ENCOURAGE THE DISSEMINATION OF DATA AND BIOMEDICAL MATERIALS, SO THERE'S A REAL BIAS THERE TOWARDS OPEN-SOURCE PUBLICATION, SAY, PUBLIC LIBRARY OF SCIENCE.

AVOID A TAX ON ANY REVENUES GENERATED BY CIRM-FUNDED INVENTIONS. AND THIS WAS SOMETHING, AND IT WILL BE INTERESTING TO SEE HOW WE HANDLE THIS, BUT SHE'S BASICALLY SAYING DON'T TAKE A ROYALTY.

AND THEN THE LAST IS AVOID A PATENT POOLING APPROACH AS A FOUNDATIONAL PRINCIPLE, BUT RESERVE THE RIGHT TO ENABLE ONE IF A NEED ARISES.

MERRILL GOOZNER PUT FORWARD A VERY INTERESTING PATENT POOLING PROPOSAL, AND IT'S A VERY INTERESTING CONCEPT. MAYBE ONCE WE GET GOING, IT'S SOMETHING THAT WE MIGHT WANT TO LOOK AT. AND THAT WAS KIND OF REBECCA EISENBERG'S APPROACH IS THAT IT'S A VERY INTERESTING IDEA. THERE'S SOME MODELS. UC DAVIS IS PART OF A PATENT POOL FOR IP THAT'S BEEN DEVELOPED FOR AGRICULTURAL PRODUCTS. IF WE GET A GOOD MODEL THAT WORKS WITH OUR INSTITUTIONS THAT WE'RE WORKING WITH, THEN PERHAPS THAT'S SOMETHING WE MIGHT WANT TO LOOK AT DOWN THE ROAD.

DR. CIBELLI: WHAT DO YOU MEAN BY PATENT POOLING?

MR. SHEEHY: THAT IS A GOOD QUESTION. IF YOU LOOK, IF YOU TAKE THE IAVI MODEL, BASICALLY THE RIGHTS ARE ALL HELD COLLECTIVELY WITHIN THIS CONSORTIUM, SO THEY HAVE A NARROW GROUP OF RESEARCH INSTITUTIONS THAT THEY'RE FUNDING. ANYTHING THAT'S DEVELOPED BY ANY OF THOSE INSTITUTIONS IS HELD COLLECTIVELY IN THIS POOL, AND PRESUMABLY ANY BENEFIT FINANCIALLY THAT COMES FROM THAT WOULD BE SHARED OUT IN SOME WAY AMONGST THOSE DIFFERENT PARTICIPANTS. THIS IS NOT CLEAR YET HOW MANY PARTICIPANTS THERE ARE GOING TO BE. WHAT ARE WE? I THINK THE FIRST ROUND OF GRANTS WAS 16 DIFFERENT INSTITUTIONS GOT GRANTED. WE HAD 28 APPLICATIONS. WE REALLY DON'T KNOW WHAT OUR POOL IS -- AT LEAST FOR THE NONPROFIT ACADEMIC WORLD, WE DON'T REALLY KNOW WHAT THAT POOL WOULD BE, BUT THE IDEA IS THAT RATHER THAN EACH INSTITUTION LICENSING, PATENTING AND LICENSING FOR THEMSELVES, THAT PATENT WOULD BE HELD AS PART OF A LARGER SET THAT ANYONE WITHIN THAT POOL COULD USE FREELY. DOES THAT ENOUGH?

DR. CIBELLI: IT'S JUST THAT IF YOU ARE GOING TO ALLOW THEM TO OWN THEIR IP, YOU ARE SAYING FIRST THAT YOU ARE GOING TO ALLOW GRANTEES TO OWN THE IP RIGHTS.

MR. SHEEHY: THE POOL, OR LIKE THE IAVI EXAMPLE, A CONSORTIUM WOULD OWN THE IP RIGHTS.

DR. CIBELLI: I CAN SEE THAT AS A NIGHTMARE FOR THE TECHNOLOGY TRANSFER OFFICES OF ALL THE INSTITUTIONS TO COME UP WITH THE SAME POLICY.

DR. HALL: IT'S BEING RECOMMENDED THAT WE AVOID AND LEAVE OPEN THE POSSIBILITY OF LATER. I THINK THE ADVANTAGE IS, AND ED OR OTHERS ON THE GROUP MAY WANT, ADVANTAGE IS THAT YOU'RE ABLE -- ANY PARTICULAR THERAPEUTIC DEVELOPMENT MAY REQUIRE A NUMBER OF PATENTS THAT YOU HAVE TO NEGOTIATE SEPARATELY WITH A WHOLE LOT OF PEOPLE. SO THE IDEA IS IF YOU POOL THESE, IT'S BOTH EASIER AND IT'S A MORE POWERFUL POSITION; THAT IS, YOU CAN OFFER BUNDLED PATENTS, AS IT WERE, AROUND A PARTICULAR TECHNOLOGY THAT HAS EVERYTHING YOU NEED IN ORDER TO DO THIS. I THINK ONE OF REBECCA EISENBERG'S POINTS THAT SHE MADE IN HER PRESENTATION WAS THAT WE NEED VERY MUCH TO BE AWARE THAT WE ARE A SMALL PART OF A LARGER ENTERPRISE THAT EXTENDS NATIONWIDE AND WORLDWIDE AND ONE THAT'S WELL UNDERWAY. AND SHE RECOMMENDED ON THAT BASIS, FOR EXAMPLE, THAT WE BE SURE THAT WE ARE COMPATIBLE WITH BAYH-DOLE WHATEVER WE DO, BUT THE OTHER POINT THAT SHE MADE WAS THAT IT WASN'T CLEAR THAT OUR POSITION WAS GOING TO BE STRONG ENOUGH TO MAKE THIS WORTH THE TROUBLE AT THIS STAGE. AND SHE THOUGHT, FOR THE REASONS YOU SAY, AND LATER ON, IF WE HAVE IMPORTANT PIECES, I THINK THAT SHE URGED THAT WE

MIGHT CONSIDER THAT. IS THAT A FAIR SUMMARY? YEAH.

DR. CIBELLI: BEFORE WE MOVE ON, DO YOU MIND IF I ASK. SO RESERVING THE RIGHT OF THE CIRM RESEARCHERS TO USE CIRM FUNDED IP, YOU ARE GOING TO HAVE TO DEFINE CIRM RESEARCHER BETTER JUST BECAUSE I DON'T KNOW HOW YOU ARE GOING TO ENFORCE THAT. A PERSON MAY HAVE SOME MONEY OR PART OF A SALARY COMING FROM A GRANT FROM CIRM AND HAS THE RIGHT TO USE ANY IP FROM CIRM? I JUST DON'T KNOW HOW YOU ARE GOING TO -- YOU'RE GOING TO HAVE TO BE VERY --

DR. HALL: THEY HAVE SALARY COMING, IT'S PRESUMABLY ON A RESEARCH GRANT. AND IF SOMETHING IS DISCOVERED ON THAT RESEARCH GRANT, EVEN IF THEY DON'T HAVE SALARY, IT'S FUNDED BY CIRM, THEN WOULD BE IDENTIFIED AS CIRM IP, AND THEY WOULD BE A CIRM RESEARCHER.

DR. CIBELLI: THAT PERSON, LET'S SAY, STANFORD, WANTS TO USE A TECHNOLOGY THAT IS BEING DEVELOPED SOMEWHERE IN SAN DIEGO BY ANOTHER RESEARCHER THAT IS FUNDED BY CIRM, HE CAN DO IT WITHOUT VIOLATING THE IP?

DR. HALL: ONE OF THEM -- IF IT'S DEVELOPED BY CIRM AND IT'S DEFINED AS CIRM IP, THEN ANYBODY ELSE THAT'S FUNDED BY CIRM WOULD HAVE ACCESS TO THAT FOR RESEARCH PURPOSES WITHOUT PAYING A FEE.

DR. TAYLOR: I GUESS WHAT I FIND INTERESTING, AND THIS IS REALLY A WONDERFUL SUMMARY, BUT, JEFF, YOU INTRODUCED THIS AS POLICY FOR THE TRAINING GRANTS INITIALLY. AND THESE POLICIES ACTUALLY DON'T MAKE A LOT OF SENSE TO ME FROM A TRAINING GRANT POINT OF VIEW. THEY SOUND MORE LIKE THE POLICIES FOR THE RESEARCH GRANTS. NOW THAT WE'RE GETTING TO THE POINT THAT JOSE BROUGHT UP, I THINK THAT ANYONE WHO COMES UNDER THE TRAINING RUBRIC, WHICH COULD BE GRADUATE COURSES, IT SEEMS TO ME -- I DON'T KNOW HOW THE TRAINING GRANTS HAVE BEEN PROPOSED AND WHAT THE VARIOUS STRATEGIES ARE WITHIN THOSE TRAINING GRANTS, BUT IT'S GOING TO BE AN AWFULLY BROAD UMBRELLA TO DUMP ALL OF THE IP INTO, IT SEEMS TO ME.

DR. HALL: FOR THOSE PURPOSES, IT WOULD BE THE PEOPLE WHO ARE SUPPORTED BY STIPENDS, CIRM STIPENDS. IF IN A LAB THEY MAKE A DISCOVERY, WHICH IS THE WHOLE POINT OF THIS EXERCISE, THEN WE WOULD HAVE A CLAIM TO THAT DISCOVERY UNDER THIS RUBRIC. SO IT'S NOT ANYBODY WHO TAKES A CIRM-FUNDED COURSE. IT IS THOSE PEOPLE WHO ARE DIRECTLY SUPPORTED THROUGH STIPENDS THAT WOULD THEN -- IT MIGHT BE PART OF AN IMPORTANT DISCOVERY OR EVEN ALONE MAKE AN IMPORTANT DISCOVERY. AND SO IT IS TO COVER THOSE INSTANCES THAT WE HAVE THIS. SO THEY ARE TRAINEES, BUT IT IS THEIR

RESEARCH ACTIVITIES THAT WE ARE CONCERNED WITH. DOES THAT MAKE SENSE?

DR. TAYLOR: (NODS.)

MR. SHEEHY: AND TO ELABORATE, NO ONE ANTICIPATES A LOT OF THE IP COMING OUT OF TRAINING GRANTS, TO BEGIN WITH, BUT SO MAYBE I SHOULD CONTINUE.

SO THESE ARE THE QUESTIONS THAT WE'VE BEEN USING TO GUIDE OUR POLICY DISCUSSIONS WHICH HAVE LED US TO COME UP WITH THIS SET OF BROAD PRINCIPLES.

WHO SHOULD OWN ANY INVENTIONS THAT ARISE FROM CIRM FUNDING? HOW SHOULD CIRM REQUIRE THE SHARING OF DATA, TOOLS, TECHNOLOGY, AND INTELLECTUAL PROPERTY? SHOULD CIRM CREATE A RESEARCH EXEMPTION FOR THE USE OF INTELLECTUAL PROPERTY FOR BASIC RESEARCH PURPOSES? WHAT LICENSING REQUIREMENTS SHOULD BE ADOPTED BY CIRM GRANTEES? AND, LASTLY, SHOULD CIRM RETAIN MARCH-IN RIGHTS?

AND, AGAIN, THIS IS FOR TRAINING GRANT IP POLICY FOR NONPROFIT ACADEMIC INSTITUTIONS.

SO SHARING POLICY, THIS IS THE TYPES OF SUBJECT MATTER CATEGORIES THAT ARE UNDER DISCUSSION. SO WE HAVE DATA, WE HAVE TECHNOLOGY AND PROCESSES, BIOLOGICAL MATERIALS AS DEFINED BY THE NIH, TO INCLUDE CELL LINES, MONOCLONAL ANTIBODIES, REAGENTS, ANIMAL MODELS, COMBINATIONAL CHEMISTRY LIBRARIES, CLONES AND

CLONING TOOLS, DATABASES AND SOFTWARE. THIS IS THE STUFF WE'RE TALKING ABOUT WHEN WE SAY SHOULD WE REQUIRE THE SHARING, WHICH I THINK IS RELATED TO THE ISSUE THAT WE WERE TALKING ABOUT IN TERMS OF THE STEM CELL BANK.

AND SO THE INTERIM POLICY CONCEPTS FOR TRAINING GRANTS IS, TO ANSWER THE FIRST QUESTION, WHO SHOULD OWN THE INVENTIONS, THE GRANTEES SHOULD OWN THE TECHNOLOGY. THAT MEANS THAT THOSE NONPROFIT -- THOSE 16 NONPROFIT ACADEMIC RESEARCH INSTITUTIONS WHO ARE GETTING THE TRAINING GRANTS WOULD RETAIN THE RIGHT TO THEIR INVENTIONS.

DATA SHARING, WE WANT, AND THIS IS OUR PRINCIPLE, WE WANT TO PUSH THE ENVELOPE OF CURRENT PRACTICE TOWARDS MORE OPEN SHARING. SO WE SUPPORT THE WIDEST POSSIBLE SHARING. AND AN ISSUE THAT WE DIDN'T REALLY -- THAT BELONGS IN HERE, BUT DIDN'T REALLY GET INTRODUCED WELL, WAS A BIAS AGAINST NONEXCLUSIVE LICENSING. SO WHILE WE WANT THE GRANTEES TO OWN THEIR TECHNOLOGY, AS PART OF ENCOURAGING DATA SHARING, WE WANT TO ENCOURAGE OUR GRANTEES TO NOT OBTAIN EXCLUSIVE LICENSES. WE BELIEVE WE SHOULD CREATE A RESEARCH EXEMPTION. SO IF SOMEONE WANTS TO USE THE IP FOR RESEARCH, THEY SHOULD BE ABLE TO USE IT.

LICENSING, WE DISCUSSED A ROYALTY RETURN. AND IT WAS INTERESTING. WE HAD SOMEONE FROM THE

UNIVERSITY OF CALIFORNIA AND SOMEONE FROM STANFORD FROM THEIR OFFICE OF TECHNOLOGY TRANSFER. AND SO THE GENERAL FEELING WAS THAT THERE WASN'T A LOT OF ENTHUSIASM FOR A SO-CALLED TAX OR SOME FINANCIAL RETURN BACK TO CIRM, BUT IT WAS SOMETHING THAT SEEMED FEASIBLE. THEY SUGGESTED THAT WE SET A THRESHOLD BECAUSE A LOT OF PATENTS NEVER PRODUCE ANY MEASURABLE RETURN, AND IT'S COSTLY TO OBTAIN A PATENT. SO THE NUMBER THAT WAS THROWN OUT WAS $500,000. SO IF THEY RECEIVED A RETURN OF OVER 500,000, THEN SOME PORTION OF THAT IN THE WAY OF ROYALTY WOULD COME BACK TO CIRM.

AND AS THE PERSON FROM STANFORD SAID, I BELIEVE, OUT OF 400 PATENTS, THEY ONLY HAD TWO THAT REACHED THAT THRESHOLD. AND ONE CAN IMAGINE FOR TRAINING GRANTS, IT'S FAIRLY NARROW. BUT THAT SEEMS TO AT LEAST -- DIDN'T SEEM TO INDICATE THAT THAT WOULD IMPEDE THE PROGRESS OF THE SCIENCE, THAT IT WOULD FIT WITHIN THE EXISTING MODELS THAT ARE USED BY ACADEMIC RESEARCH INSTITUTIONS. IT SEEMED TO BE SOMETHING THAT COULD BE IMPLEMENTED BY THEIR OFFICES OF TECHNOLOGY TRANSFER AS LONG AS WE DON'T GET GREEDY.

DR. EGGAN: CAN I ASK OUT OF WHAT HAT THEY PULLED THAT NUMBER OF $500,000 AND HOW IT WAS JUSTIFIED BECAUSE ALTHOUGH IT'S EXPENSIVE TO PROCESS A PATENT, I THINK IT'S CERTAINLY MUCH LESS EXPENSIVE THAN THAT, AND

CERTAINLY IT'S A MUCH LOWER THRESHOLD THE UNIVERSITY IS MAKING SOME SUBSTANTIAL SUM OF MONEY WHICH COULD BE DISBURSED BACK TO OTHER RESEARCHERS AND CIRM.

MR. SHEEHY: ACTUALLY THE RETURN BACK DID NOT COME TO CIRM. THE RETURN BACK, I BELIEVE, AND THIS IS A LARGER POLICY ISSUE, BUT I BELIEVE THE RETURN BACK GOES TO THE GENERAL FUND OF THE STATE OF CALIFORNIA. IT'S NOT CLEAR THAT WE HAVE THE RIGHT TO COLLECT MONEY AND AGAIN REDISBURSE IT. WE HAVE OUR FUNDING STREAM.

DR. PENHOET: WE LISTENED TO THE NUMBER AND NOTED THAT THAT'S WHAT THEY SAID. IT'S NOT PART OF OUR PROPOSAL.

DR. HALL: AS A FORMER VICE CHANCELLOR FOR RESEARCH, MAY I ANSWER THAT QUESTION? I THINK THE ARGUMENT WAS MADE THAT THE POINT IS NOT TO PAY THE EXPENSES FOR THAT PARTICULAR PATENT, BUT THAT IN ACTUAL FACT TO PAY FOR THE LOSERS AS WELL. THAT WHEN YOU PATENT A LARGE NUMBER OF DISCOVERIES, YOU ARE MAKING AN INVESTMENT, AND YOU KNOW THAT ONLY ONE OF THOSE IS LIKELY TO PAY OFF. SO WHAT YOU NEED TO DO IS TO COVER THE EXPENSES FOR THE ENTIRE INVESTMENT BASED ON THAT. AND SO I THINK IT WASN'T A ONE-TO-ONE THING. WHETHER THE NUMBER IS CORRECT OR NOT, I DON'T KNOW, BUT I THINK THAT WAS THE GENERAL PRINCIPLE THAT WAS BEING ESPOUSED.

AND I THINK THE POINT THAT WAS MADE WAS

UNIVERSITIES MAKE AN INVESTMENT AND TAKE A RISK WHEN THEY DO THIS. AND IF WE'RE GOING TO SHARE THE BENEFITS, WE NEED TO EITHER SHARE THE RISK OR WE NEED TO ALLOW THEM TO RECOUP THEIR COSTS BEFORE WE CASH IN.

DR. CIBELLI: THIS IS A DEPARTURE FROM THE BAYH-DOLE ACT. I DON'T KNOW WHY YOU ARE GETTING SO GREEDY. YOU WANT TO SHOW THE STATE OF CALIFORNIA THAT YOU ARE GETTING SOMETHING BACK. IS THAT WHY YOU ARE DOING THIS, AS A POLITICAL MOVE?

MR. SHEEHY: I THINK IT ACTUALLY IS -- I MEAN I PERSONALLY AM AMBIVALENT ABOUT THIS TAX CONCEPT. I DO THINK, THOUGH, IT MEETS THE TEST THAT WE HAVE TO MEET IN PROP 71. SO IT'S LESS A POLITICAL QUESTION THAN REALLY A STATUTORY QUESTION. AND IT'S NOT CLEAR TO ME THAT WE CAN KIND OF BLITHELY IGNORE ASKING FOR A RETURN IF A RETURN CAN BE OBTAINED, ESPECIALLY ONE THAT DOESN'T SEEM TO UNDULY BURDEN THE INSTITUTION, IT DOESN'T INTERFERE WITH THEIR ABILITY TO DO RESEARCH. AND IT'S AT A POINT WHERE THEY'RE MAKING A LOT OF MONEY, A SIGNIFICANT AMOUNT OF MONEY, $500,000. HALF A MILLION DOLLARS, THEY'RE MAKING MONEY.

PERSONALLY, MY GOAL WAS, WHEN WE HAD THIS DISCUSSION, I ACTUALLY TRIED TO DO BAYH-DOLE ON A LITTLE BIT OF -- TRIED TO NARROW BAYH-DOLE, WHICH SAYS THEY'RE SUPPOSED TAKE THEIR RETURNS OFF THESE PATENTED

INVENTIONS AND REINVEST THEM IN RESEARCH AND EDUCATION AND DIRECT THAT BACK INTO STEM CELL RESEARCH. SO RATHER THAN LET THE INSTITUTIONS -- THERE SEEMED TO BE SOME WILLINGNESS FROM THE INSTITUTIONAL FOLKS ON THE IP TASK FORCE TO DIRECT IT, SAY, BACK FOR STEM CELL RESEARCH. I ALMOST FEEL LIKE THAT THAT WOULD BE MY BIAS, TO REINVEST IT WITHIN THE INSTITUTION BACK IN WHAT IS OUR PRIMARY MISSION AS -- CIRM'S PRIMARY MISSION, WHICH IS TO FURTHER RESEARCH AND STEM CELL THERAPIES. BUT IT REALLY IS ALMOST MORE AT THIS POINT A LEGAL QUESTION THAN ANYTHING ELSE.

DR. CIBELLI: CAN I ASK YOU THE BACKGROUND OF WHERE THIS CAME FROM? ARE THERE OTHER, LIKE THE GATES FOUNDATION HAS SOMETHING LIKE THIS. WHERE DID YOU GET THIS IDEA?

DR. PENHOET: PROP 71 SAYS THAT THE STATE WILL BENEFIT. IF YOU GO BACK TO THE FIRST SLIDE WE SHOWED YOU --

DR. CIBELLI: THE BENEFIT COULD BE ACTUALLY SEEN AS, I DON'T KNOW, MORE BUSINESS IN CALIFORNIA, MORE PEOPLE COMING TO CALIFORNIA.

DR. PENHOET: THOSE THINGS ARE TRUE, BUT THERE WAS AN EXPECTATION OF A DIRECT FINANCIAL RETURN IN PROP 71. WE'RE TRYING TO UNDERSTAND THE LAW WITH RESPECT TO THAT. THAT'S WHERE IT CAME FROM, PROP 71

ITSELF.

MR. SHEEHY: THE ACTUAL LANGUAGE -- I CAN THROW IT BACK UP. SEE, TO BENEFIT FROM THE PATENTS, ROYALTIES, AND LICENSES, THAT SEEMS TO ME -- I'M NO LAWYER, BUT IT SEEMS TO SAY GET THE CASH, TO JUST PUT REALLY NARROWLY.

DR. HALL: THE EXPECTATION THAT WE WILL DO THAT ON BEHALF OF MANY LEGISLATORS AND OTHERS, THAT THERE SOME FINANCIAL RETURN TO THE STATE FROM OUR IP.

DR. CIBELLI: IT'S A SHORTSIGHTED POLICY THAT YOU'RE DOING BECAUSE I THINK THAT THE MONEY WILL COME WHEN THE INSTITUTION GETS STRONGER OR WHEN THE COMPANY GETS A STRONG FOOTING. THEY'RE GOING TO HAVE TO PAY TAXES, OF COURSE, AND THAT'S THE WAY THE MONEY IS GOING TO COME BACK.

MR. SHEEHY: AGAIN, I'D LIKE TO SEPARATE THIS FROM COMPANIES. IT DOESN'T SEEM TO ME THAT THERE'S ANYTHING WRONG WITH ASKING FOR A RETURN. WE MAKE A DIRECT GRANT TO A COMPANY. THE COMPANIES, IT SEEMS TO ME, ARE IN THE HABIT OF PAYING FOR CAPITAL IN SOME FASHION, WHETHER STOCK OR ROYALTIES. IT JUST SEEMS KIND OF -- I'M NOT AN ARDENT CAPITALIST, BUT IT SEEMS LIKE PEOPLE IN BUSINESS --

DR. CIBELLI: I THINK COMPANIES SHOULD GET A LOAN, NOT A GRANT.

MR. SHEEHY: WHATEVER WE DO WITH COMPANIES, I THINK THAT THAT BECOMES A SEPARATE SUBJECT. THAT'S WHY I TRIED TO KEEP THIS FOCUSED ON NONPROFIT RESEARCH INSTITUTIONS. AND THE ONLY THING THAT MIGHT HAVE BIASED THIS IS THE OVERLY HONEST TECHNOLOGY TRANSFER PERSON FROM STANFORD, WHO DID ADMIT THAT THERE ARE CIRCUMSTANCES WHERE THEY DO CARVE OFF A PIECE. FOR INSTANCE, FOR THE HOWARD HUGHES INVESTIGATOR, THAT ACTUALLY THEY DO CARVE OFF A PIECE OF THE ROYALTY AND GIVE IT THE HOWARD HUGHES. IF THAT HAPPENS ALREADY, THAT THEY'RE NIBBLING FOR SOMEBODY ELSE, IT'S KIND OF HARD TO SAY, WELL, WHY CAN'T WE GET A NIBBLE WHEN WE HAVE THIS LIST STARING US STRAIGHT IN THE FACE.

DR. EGGAN: AGAIN, THIS IS A SUBTLY DIFFERENT SITUATION BECAUSE THOSE INVESTIGATORS FOR THE HOWARD HUGHES ARE EMPLOYEES OF THE MEDICAL INSTITUTE, AND, IN FACT, THERE ARE COUPLE QUESTIONS OVER OWNERSHIP OVER THAT IP IN THAT SITUATION. AND THESE PEOPLE AREN'T GOING TO BE EMPLOYEES PER SE OF CIRM. SO I THINK IT IS A DIFFERENT -- I THINK IT'S A DIFFERENT PRECEDENT IN THAT CASE. MAYBE OTHER EXAMPLES OF THAT'S TRUE, AND I THINK WE SHOULD PAY ATTENTION TO THAT, BUT THAT MAY NOT THE INFORMATIVE EXAMPLE.

MR. SHEEHY: TO MY MIND, WHAT THAT WAS RELEVANT TO WAS THE FEASIBILITY FOR A TECHNOLOGY

TRANSFER OFFICE AT AN ACADEMIC INSTITUTION TO TAKE A -- IN OTHER WORDS, THEY HAVE AN EXISTING MODEL THAT THEY'RE USING FOR THEIR RESEARCH RIGHT NOW.

DR. ROWLEY: I THINK WE'RE JUST ARGUING OVER SOMETHING THAT'S VERY TRIVIAL BECAUSE IF THE STANFORD DATA ARE ACCURATE, YOU SAID TWO OUT OF 400, SO 398 GRANTS ARE NOT SUBJECT TO TAX. AND I THINK WE SHOULD LOOK AT THE LARGER PICTURE RATHER THAN THE OUTLIERS, AT LEAST AS WE'RE GOING THROUGH THIS.

VICE CHAIR LO: JEFF, LET ME -- I WANT TO SORT OF MAKE SURE WE'RE CLEAR ON SORT OF WHAT OUR GOALS HERE TODAY ARE, THAT WE DON'T WANT TO TRY AND REDO THE IP TASK FORCE. AS ONE OF THE SLIDES SHOWED, THEY LOOKED AT A TREMENDOUS AMOUNT OF INFORMATION, HEARD FROM A LOT OF DIFFERENT PEOPLE, AND I THINK OUR ROLE SHOULDN'T BE TO TRY AND REWRITE THEIR BROAD PRINCIPLES. I THINK WHAT WE SHOULD DO IS AFTER JEFF HAS A CHANCE TO FINISH, IF THERE ARE BIG PICTURE ITEMS IN TERMS OF LARGE PRINCIPLES THAT WE THINK THEY'VE MISSED OR IF THERE'S STRONG DISAGREEMENT WITH THE WAY THEY FRAMED IT, I THINK THAT WOULD BE IMPORTANT, BUT LET'S NOT TRY AND GET TO THE DETAILS OF HOW THESE PRINCIPLES WILL BE IMPLEMENTED. AS ED AND JEFF HAVE SAID, THIS IS JUST SORT OF THEIR FIRST STEP, AND THERE WILL BE MANY OPPORTUNITIES LATER TO WORK OUT THE DETAILS. AND I

THINK WE WOULD BE ABLE, EITHER AS INDIVIDUALS OR A GROUP, TO FEED INTO THAT PROCESS. THIS, I THINK, IS MEANT TO BE A BIG PICTURE.

JEFF, CAN I ASK YOU FINISH.

MR. SHEEHY: THE OTHER PARTS OF LICENSING IS THAT WE DID ASK THAT OUR RECIPIENT INSTITUTIONS, IN THE EVENT THAT THEY DO LICENSE THEIR PATENTED INVENTIONS, SHOW A PREFERENCE FOR COMPANIES WITH A PLAN FOR PATIENT THERAPY ACCESS. SO IT'S ALMOST KIND OF A REACH-THROUGH PROVISION.

AND THEN WE MAINTAIN MARCH-IN RIGHTS, BUT MARCH-IN RIGHTS IDENTICAL TO BAYH-DOLE. WE WANTED TO MIRROR BAYH-DOLE AT THIS POINT.

SO THAT'S IT. WE TRIED -- IF YOU NOTICE, WE REALLY ARE KIND OF HEWING TO BAYH-DOLE. AND THE THOUGHT IS, AT LEAST FOR NONPROFIT ACADEMIC INSTITUTIONS, WE SHOULD NOT GET TOO FAR AWAY.
AS I SAID, WHEN CCST DELIVERS THEIR FULL REPORT ON ALL STATE-FUNDED RESEARCH TO THE LEGISLATURE, PRESUMABLY THE LEGISLATURE WILL TAKE ACTION AND SET POLICY FOR ALL STATE-FUNDED RESEARCH, WE MIGHT THEN REVISIT THIS AND DO SOMETHING THAT -- IT WOULD MAKE SENSE TO DO SOMETHING THAT'S CONSISTENT WITH THAT. WE WOULD HATE TO PUT IN SOMETHING THAT IS BROADLY DIFFERENT FROM BAYH-DOLE AND THEN POTENTIALLY COMPLETELY DIFFER FROM

WHAT THE STATE DOES SOMETIME, I WOULD HOPE, IN THE NEXT YEAR WHEN THEY GET THEIR CCST REPORT AND ADDRESS INTELLECTUAL PROPERTY FOR ALL STATE-FUNDED RESEARCH.

VICE CHAIR LO: JEFF AND ED, AS I READ YOUR PRINCIPLES, IT STRIKES ME YOU ARE TRYING TO BE CONSISTENT WITH BAYH-DOLE AND PLAN TO BE CONSISTENT WITH THE STATE RECOMMENDATIONS. BUT IN A SENSE, I LIKE YOUR TERM OF PUSHING THE ENVELOPE OF CURRENT PRACTICE TO TRY AND DO MORE TO ENCOURAGE MORE OPEN SHARING THAN IS CURRENTLY THE PRACTICE OR IS CURRENTLY REQUIRED, BUT NOT WANTING TO MAKE A RADICAL CHANGE THAT IS UNTESTED AND REALLY DRAMATICALLY DIFFERENT THAN BAYH-DOLE.

DR. PENHOET: WE WERE ADVISED BY MANY OF OUR ADVISORS THAT WE COULD DO A NUMBER OF THINGS WITHIN THE BAYH-DOLE FRAMEWORK, BUT THAT IT WOULD BE UNWISE FOR US TO DO SOMETHING THAT'S INCOMPATIBLE WITH BAYH-DOLE BECAUSE IT WOULD REQUIRE, FIRST OF ALL, THE FEDERAL LAW SAYS IF THERE'S $1 OF FEDERAL MONEY INVESTED IN THE PROGRAM, YOU HAVE TO FOLLOW THE FEDERAL LAW. AND ONE OF THE THINGS WE'RE TRYING TO AVOID IS THAT CIRM-RELATED RESEARCHERS ARE ISOLATED FROM THEIR COLLEAGUES, AND YOU CAN'T COMMINGLE FUNDS AND PEOPLE BECAUSE OF AN IP POLICY WHICH IS FUNDAMENTALLY DIFFERENT THAN FEDERAL POLICY.

SO WE'RE TRYING TO COME UP WITH A SYSTEM

WHICH IS COMPATIBLE, BUT NOT IDENTICAL WITH BAYH-DOLE.

VICE CHAIR LO: TED, YOU HAD SOME COMMENTS EARLIER YOU WANTED TO RESERVE. I'LL LET YOU STEP IN.

DR. PETERS: JEFF KNOWS HOW I THINK, BUT I WOULD LIKE TO JUST INQUIRE TO SEE HOW THE IP TASK FORCE MIGHT RESPOND TO A SCENARIO THAT HAS ONE EXEMPTION TO THESE PRINCIPLES AND THAT'S STEM CELL LINES. LET ME RUN THIS SCENARIO BY YOU AS A POSSIBILITY.

SUPPOSE WE DECIDE THAT FOR SCIENTIFIC REASONS WE WANT A LARGE NUMBER OF STEM CELL LINES TO BE AVAILABLE. SUPPOSE IT'S 10,000 THAT WE WANT. AND WE COULD FORECAST THAT A PATENT ON EVERY SINGLE STEM CELL LINE WOULD BECOME OBSTRUCTIONIST IN ITS IMPACT. AND SUPPOSE WE SAY THAT ANYONE WHO TAKES CIRM MONEY TO ESTABLISH A STEM CELL LINE WOULD BE PROHIBITED FROM FILING FOR A PATENT ON IT. AND, IN FACT, CIRM WOULD ENCOURAGE A LARGE NUMBER OF STEM CELL LINES TO BE ESTABLISHED VERY EARLY IN THE PROGRAM. AND THEN WE COULD LEAVE ALL OF THESE PRINCIPLES OBTAIN FOR EVERYTHING THAT WOULD BE DOWNSTREAM PRODUCT DEVELOPMENT, ETC., BUT HAVE THAT SINGLE EXEMPTION FOR THE NO. 1 UNIT AT THE RESEARCH LEVEL, THE STEM CELL LINE.

HOW WOULD THE IP TASK FORCE RESPOND TO A SUGGESTION OF THAT NATURE?

MR. SHEEHY: I GUESS I COULD TELL YOU HOW I WOULD RESPOND. WE TALKED AT ONE POINT ABOUT FORCING OR REQUIRING RESEARCHERS AT THIS UPSTREAM LEVEL TO SHARE AS WIDELY AS POSSIBLE, WE HAD SOME DISCUSSION. EVERYBODY IN CALIFORNIA, EVERYBODY ACROSS THE COUNTRY, EVERYBODY AROUND THE WORLD. AND I THINK THAT THE IP COMMITTEE WAS BIASED TOWARDS AS WIDELY AS POSSIBLE. BUT, YOU KNOW, SHARING AND PATENTING ARE REALLY TWO DIFFERENT THINGS. IF YOU PATENT AND YOU SHARE, THAT GETS YOU WHERE YOU WANT TO GO.

AND ONE OF THE THINGS THAT I BROUGHT UP, WHICH I THINK I WAS A LITTLE SHOT DOWN ON, BUT I SAID THAT IF OUR RESEARCHERS ARE GOING TO SHARE, THEY HAD THE RIGHT TO NOT SHARE IF THE PEOPLE THEY WERE SHARING WITH WOULDN'T SHARE BACK. SO A RECIPROCITY CLAUSE BECAUSE WHY SHOULD WE GIVE EVERYTHING TO EVERYBODY AND THEN THEY, OH, NO, WE'RE NOT GOING TO SHARE WITH YOU?

BUT THAT KIND OF CAPTURES MY PROBLEM WITH JUST LETTING EVERYTHING GO. WHAT HAPPENS IF OTHER FOLKS HAVE MATERIALS OR STEM CELL LINES OR SOMETHING? WHERE IS OUR BARGAINING POWER? I HAVE A FEELING THAT WHATEVER COMES OUT IN TERMS OF THERAPY IS GOING TO BE WHOLE COLLECTIONS OF PATENTABLE MATERIAL FROM SEVERAL DIFFERENT ENTITIES AND PLACES AND INSTITUTIONS AND RESEARCHERS, AND I THINK PULLING THAT PRODUCT TOGETHER

IS GOING TO REQUIRE SOME LEVERAGING, BUT I COULD BE WRONG.

VICE CHAIR LO: ED, DO YOU WANT TO COMMENT ON THAT IN TERMS OF PATENTING VERSUS SHARING? DO YOU WANT TO COMMENT ON THIS ISSUE OF PATENTING AND NOT NECESSARILY PRECLUDING WIDE SHARING?

DR. PENHOET: THE RESEARCH EXEMPTION THAT WE WOULD HAVE IN MIND IF ALL 10,000 WERE PATENTED, FOR THE SAKE OF THE DISCUSSION, OUR RESEARCH EXEMPTION WOULD SAY THAT ANY OTHER CIRM-FUNDED RESEARCHER COULD USE THOSE ROYALTY FREE WITHOUT HAVING TO PAY ANYTHING FOR THE USE OF THOSE CELL LINES. SO THEY WOULD BE INCLUDED IN OUR LIST OF MATERIALS.

IF IT CAME TO SOMEBODY WANTING TO DEVELOP ONE OF THOSE CELL LINES INTO A THERAPY, THAT'S SOMETHING WE HAVE NOT YET DISCUSSED IN TERMS OF THAT PATENT. WOULD WE WANT TO MAKE -- IF THEY WERE ALL PATENTED, WOULD WE WANT TO MAKE NONEXCLUSIVE LICENSES ON ALL 10,000 AVAILABLE TO EVERYONE, OR WOULD WE PREPARED TO LICENSE EXCLUSIVELY TO AN ENTITY ONE OF THOSE CELL LINES WHICH HAPPENED TO BE THE KEY TO DIABETES OR SOME OTHER DISEASE. WE HAVEN'T REALLY GOTTEN INTO THAT LEVEL, AND I THINK THAT -- BUT HOW FAR THIS RESEARCH EXEMPTION REALLY GETS PUSHED AND HOW FAR YOU DEFINE RESEARCH.

ONE THING WE DO HAVE TO KEEP IN MIND, AND

THAT DOES WEIGH ON OUR DISCUSSION, IS THAT AS WE SPEAK THERE IS VERY LITTLE PRIVATE CAPITAL GOING INTO STEM CELL THERAPIES. AND WE DON'T WANT TO SET UP A SYSTEM WHICH DISCOURAGES COMPANIES FROM INVESTING IN THIS DEAL AND DEVELOPING THERAPIES BECAUSE NONE OF THE NONPROFIT GRANTEES WILL AT THE END OF THE DAY DEVELOP THERAPIES WHICH WILL BE BROADLY AVAILABLE. SO IT'S A BALANCE REALLY BETWEEN OUR DESIRE FOR SIGNIFICANTLY EXPANDED SHARING OF DATA, INFORMATION, TOOLS, CELL LINES AT THE SAME TIME NOT DESTROYING THE COMMERCIAL OPPORTUNITY WHICH WOULD BE A DISINCENTIVE FOR INVESTMENT BY THE PRIVATE SECTOR IN THIS WHOLE ENTERPRISE. IT'S THAT BALANCE THAT WE'RE TRYING TO ACHIEVE. WE'RE NOT THERE YET, SO LARGER DISCUSSION.

DR. KIESSLING: JEFF, IT WILL BE HELPFUL TO ME IF WE CAN DO LIKE A CONCRETE EXAMPLE OF HOW THIS IS GOING TO WORK BECAUSE ONE OF THE THINGS THAT I CAN SEE THE TRAINING GRANT DOING IS A POST-DOC IS GOING TO DEVELOP A VERY USEFUL CELL LINE, EITHER A MODIFICATION OF AN EXISTING LINE OR A BRAND NEW LINE. THAT'S WHAT THOSE KINDS OF PEOPLE ARE GOING TO BE DOING IN THE LAB.

NOW, THIS PERSON HAS LINE Q. HOW DO YOU SEE THAT LINE BEING SHARED LIKE INSTANTLY AND STILL PROTECT THE PATENT RIGHTS OF THE INSTITUTION OR THAT PERSON?

DR. PENHOET: I THINK IN THAT PARTICULAR

INSTANCE, FOLLOWING UP ON THIS, THE RESEARCH EXEMPTION THAT WE WOULD SEEK IS THE OWNER OF THE TECHNOLOGY, THE UNIVERSITY IN THIS CASE, WOULD BE ALLOWED TO FILE A PATENT ON THAT CELL LINE, BUT THEY WOULD BE OBLIGATED TO PROVIDE THE MATERIAL AND THE CELL LINE AND A ROYALTY FREE LICENSE TO USE IT TO ALL OTHER CIRM INVESTIGATORS FOR RESEARCH PURPOSES ONLY.

DR. KIESSLING: WHAT WOULD THE TIME FRAME OF THAT BE?

DR. PENHOET: THE STANDARD NOW IS SUBSEQUENT TO PUBLICATION. THERE'S A LOT OF CONCERN ABOUT PEOPLE GETTING CELL LINES WHICH ARE NOT VERY WELL CHARACTERIZED YET. THERE'S A RELUCTANCE FOR PEOPLE TO GIVE THEM AWAY THE NEXT DAY AFTER THEY'RE GENERATED WITHOUT KNOWING MUCH ABOUT THEM, WITHOUT STUDYING THEM FOR A WHILE TO MAKE SURE THAT THEY HAVE A GOOD UNDERSTANDING OF WHAT THAT CELL LINE IS. SO THE TRADITIONAL ROLE IS AT THE TIME OF PUBLICATION THEN YOU REQUIRE SHARING.

DR. KIESSLING: SO THIS DOESN'T SEEM TO BE DIFFERENT FROM THE WAY THINGS ACTUALLY WORK NOW.

DR. PENHOET: IT IS. THAT'S WHY WE'RE SAYING WE'RE TRYING TO PUSH THE ENVELOPE. THE PRIMARY CRITICISM OF BAYH-DOLE IS NOT OF THE ACT ITSELF. IT'S HOW IT'S PRACTICED BY THE UNIVERSITIES IN THIS COUNTRY.

SO WE DO WANT TO PUSH THEM FURTHER TOWARDS SHARING REAGENTS AND KNOW-HOW AND PATENTED TECHNOLOGY FOR RESEARCH PURPOSES.

VICE CHAIR LO: IF I JUST REMIND US THAT THIS TIES IN VERY CLOSELY WITH WHAT WE DISCUSSED LAST TIME WITH SHARING OF MATERIALS, AND WE TALKED ABOUT HAVING A REQUIREMENT FOR IN THAT SCENARIO, ANN, HAVING A DEPOSIT IN THE STEM CELL BANK THAT WAS APPROVED BY CIRM -- WE HAVE TO WORK THAT OUT -- TO MAKE IT WIDELY AVAILABLE SO THAT THE IP POLICY AND SORT OF A GRANTS REQUIREMENT TO SHARE REMEMBER, AND WE TALKED ABOUT SORT OF TIME LIMITS AND CHARACTERIZING THE LINES AND THINGS LIKE THAT, SO DIFFERENT PIECES THAT NEED TO BE PUT TOGETHER, BUT I THINK IT'S ALL CONSISTENT WITH WHAT ED AND JEFF PRESENTED AS USING THIS BASIC FRAMEWORK OF ALLOWING PATENTING, BUT TRYING TO PUSH IT TOWARDS MUCH BROADER SHARING THAN IS CURRENTLY THE PRACTICE AND USING A NUMBER OF TOOLS TO TRY TO ENCOURAGE THAT, AT LEAST IN THE UPSTREAM BASIC RESEARCH END OF THINGS, WHICH IS WHERE WE WOULD, I THINK, WANT TO SEE THE WIDEST USE OF THESE STEM CELL LINES.

MR. SHEEHY: ANY IDEAS THAT COULD BE PUT -- WE NEED REAL POLICY THAT GO INTO ADMINISTRATIVE LAW CODE THAT WE THEN PRESUMABLY WILL ENFORCE. I ACTUALLY THINK SOME OF THIS STUFF WE TALKED ABOUT HERE IN TERMS

OF BANKING SEEMS TO HAVE THAT DEGREE OF SPECIFICITY. AND BECAUSE THEY'RE REGISTERED WITH THE BANK, THERE SEEMS A BETTER OPPORTUNITY TO ENFORCE THAT TOO.

DR. PENHOET: WE'D BE HAPPY TO PROVIDE TO YOU ANY OF THOSE DOCUMENTS THAT WE LISTED ON THAT SHEET. I HOPE WE'RE GOING TO LEAVE YOU ALL WITH A COPY OF THIS PRESENTATION SO YOU HAVE IT. BUT I WOULD THINK A STUDY JUST RELEASED BY THE NATIONAL ACADEMIES, THE NATIONAL RESEARCH COUNCIL ON THIS WHOLE ISSUE OF PATENTING GENES AND PROTEINS, AND IT'S PERFECTLY APPLICABLE TO STEM CELLS AS WELL. IT'S A LOVELY DOCUMENT IN MANY DIFFERENT WAYS. IT HAS A GOOD REVIEW OF THE HISTORY OF ALL OF THIS, AND ABOUT A DOZEN SPECIFIC RECOMMENDATIONS ALONG THESE LINES. SO I THINK WE'D BE HAPPY TO MAKE COPIES FOR YOU BEFORE YOU LEAVE HERE TODAY AND MAKE SURE YOU GET A COPY OF THAT.

VICE CHAIR LO: THAT WOULD BE GREAT. WE VAN GET THAT ELECTRONICALLY.

DR. MAXON: NO, IT'S NOT AVAILABLE ELECTRONICALLY YET. IT'S A PREPUBLICATION COPY.

VICE CHAIR LO: AGAIN, THIS IS VERY MUCH A WORK IN PROGRESS. AND WHAT WE HEARD TODAY WAS SORT OF THE BIG PRINCIPLES WHICH WILL ANIMATE THE IP WORKING GROUP'S SUBSEQUENT DELIBERATIONS AS WE GET MORE SPECIFIC. I GUESS ONE THING WOULD BE VERY IMPORTANT IN

THE NEXT COUPLE OF MINUTES, ARE THERE OVERRIDING POINTS THAT WE WOULD WANT TO TRY AND CONVEY THROUGH ZACH BACK TO THE ICOC WITH THIS REPORT, NOT TO REWRITE OR UNDO THE REPORT, BUT IF THERE ARE ANY IDEAS.

DR. HALL: ED WILL MAKE A PRESENTATION TO THE ICOC NEXT TUESDAY THAT I PRESUME IS SIMILAR TO WHAT'S DONE HERE. IT WILL BE MY JOB, THEN, TO CONVEY WHATEVER POINTS THAT YOU WISH TO MAKE IN ADDITION ABOUT IT. I TAKE AS ONE TED PETERS' SUGGESTION THAT CONSIDERATION BE GIVEN TO THE IDEA OF EXEMPTING STEM CELL LINES FROM THE PATENT PROVISIONS. AND I DON'T KNOW IF YOU HAVE OTHER SPECIFIC POINTS THAT YOU WOULD LIKE ME TO CONVEY TO THE ICOC. NOW IS THE TIME TO RAISE THEM.

DR. PETERS: THANK YOU FOR THAT, ZACH. AND MY NEXT THOUGHT IS AT A VERY HIGH LEVEL OF ABSTRACTION, SO IT MAY OR MAY NOT CONTRIBUTE. THERE ARE ACTUALLY TWO DIFFERENT PRINCIPLES IN PROP 71 FOR US TO CONSIDER AT THIS PARTICULAR POINT. AND ONE OF THEM IS THE ONE ALREADY CITED; NAMELY, THAT THE STATE OF CALIFORNIA SHOULD GET SOME DIRECT FINANCIAL RETURN. ANOTHER ONE IS THAT AT THE END OF THE DAY, WE WANT LOW COST THERAPEUTIC PRODUCTS AVAILABLE TO THE LARGEST NUMBER OF CITIZENS OF CALIFORNIA IN THOSE IN THE WORLD ON THE OTHER END.

TO WHAT EXTENT, AND THIS IS A PHILOSOPHICAL

QUESTION, DID THIS CONCERN FOR LOW COST DELIVERY INFORM THE KIND OF DELIBERATIONS THAT THE TASK FORCE HAS WITH REGARD TO THE IP POLICIES?

MR. SHEEHY: I THINK IT WAS WHY WE WANTED TO LOOK AT IAVI, WHY WE HAD RICHARD KLAUSNER FROM THE GATES FOUNDATION ADDRESS US. BUT I THINK PHILOSOPHICALLY WE HAVE TO ASK OURSELVES WHAT IS OUR MISSION. WE ARE NOT A HEALTHCARE DELIVERY AGENCY. WE ARE A RESEARCH FUNDING AGENCY. AND AT LEAST AT THIS POINT IN TERMS OF THE SCIENCE WHAT WE'RE FUNDING IS VERY UPSTREAM. SO IT'S VERY DIFFICULT TO TALK ABOUT MOVING ACCESS WHEN THERE'S NOT A PRODUCT. WE DON'T KNOW WHAT THE PRODUCT LOOKS LIKE. WE DON'T KNOW HOW IT'S GOING TO BE DELIVERED. WE DON'T KNOW HOW MUCH IT'S GOING TO COST.

AND THAT'S WHERE I ALWAYS PREFERRED PERSONALLY TO SEPARATE HOW I LOOK AT THIS BETWEEN, AS IAVI DOES, BETWEEN RESEARCH AND BETWEEN DEVELOPMENT. I BELIEVE THAT IF WE ARE AT A POSITION -- IN A POSITION WHERE WE'RE ACTUALLY GOING TO MAKE A GRANT OR A LOAN OR WHAT HAVE YOU DIRECTLY TO A COMPANY, THAT IF A COMPANY IS DOING SOMETHING, THERE'S A PRODUCT. AND AT THAT POINT WE LOOK AT THE PRODUCT, AND WE SAY THEN WE HAVE MORE LEVERAGE. IF YOU LOOK AT GATES OR IAVI, THAT'S THE POINT THAT THEY TEND TO EXERT THEIR LEVERAGE IS

WHEN PEOPLE ARE TALKING SPECIFICALLY ABOUT A PRODUCT.

GATES ASKS THEM TO COME IN WITH A PLAN. IAVI HAS SPECIFIC STIPULATIONS WITH THE MARCH-IN RIGHT TO ALLOW THE MANUFACTURER IN COUNTRY OF THE VACCINE PRODUCT IF IT'S NOT PROVIDED AT APPROPRIATE COST. BUT THERE'S SOMETHING TANGIBLE THERE. AND HERE IT'S HARD FOR -- IT DOESN'T SEEM LIKE THAT IT WOULD DO ANYTHING BUT IMPEDE THE DEVELOPMENT OF THE SCIENCE TO ATTACH ALL OF THESE VERY NOBLE IDEAS AT THIS LEVEL OF RESEARCH AT THE RESEARCH INSTITUTION FUNDING LEVEL.

DR. PETERS: THANKS.

DR. PRIETO: IF I COULD JUST MAKE A COMMENT AS ANOTHER MEMBER OF THE TASK FORCE, THAT I THINK A NUMBER OF US ARE VERY CONCERNED ABOUT THIS ISSUE OF ACCESS, BUT REALLY DON'T KNOW SEE WE, AS THE CIRM, CAN SOLVE THAT ISSUE FOR THERAPIES THAT DON'T YET EXIST WHEN WE HAVE A HEALTHCARE SYSTEM THAT DOESN'T EVEN PROVIDE ACCESS TO CHEAP THERAPIES THAT EXIST WIDELY. SO IT'S SORT OF BEYOND ANYTHING WE'RE CAPABLE OF. WE HAVE TO KEEP THIS IN MIND, BUT IT'S NOT A PROBLEM WE CAN SOLVE.

DR. EGGAN: I KNOW IT'S NORMALLY THE ROLE OF THE RESEARCH INSTITUTION ITSELF TO SECURE LICENSE RIGHTS FOR DIFFERENT TYPES OF TECHNOLOGY FOR THEIR RESEARCHERS, BUT I WONDER IF THERE'S EVER BEEN A

PRECEDENT FOR THERE BEING A ROLE OF ORGANIZATIONS LIKE CIRM TO SECURE COLLECTIVE LICENSING RIGHTS FOR VARIOUS TECHNOLOGIES FOR THEIR GRANTEES. HAS THAT EVER BEEN DONE? I THINK IT'S IMPORTANT THAT WE NOT LOOK AT THESE ISSUES IN A VACUUM, BUT RECOGNIZE SORT OF THE IP LANDSCAPE THAT EXISTS TODAY WITH RESPECT TO STEM CELL SCIENCE AND RECOGNIZE THAT WARF AND UNIVERSITY OF WISCONSIN HAVE A VERY POWERFUL POSITION THAT ALL OF THESE INSTITUTIONS ARE GOING TO HAVE TO DEAL WITH INDIVIDUALLY. IT'S, IN FACT, IN A WAY ONE REASON WHY THE SPECIFIC OF PATENTING INDIVIDUAL CELL LINES PROBABLY ISN'T A VERY GOOD EXAMPLE BECAUSE THERE ISN'T A LOT OF ROOM TO MANEUVER ON NEW IP THERE PROBABLY.

IS IT POSSIBLE TO DO THINGS LIKE THAT?

DR. PENHOET: IT'S THEORETICALLY POSSIBLE, BUT CIRM WORKS UNDER A VERY, VERY STRONG FINANCIAL CONSTRAINT. THE AMOUNT OF MONEY AVAILABLE TO CIRM TO DO ALL OF HIS ACTIVITIES IS 6 PERCENT OF THE GRANT BUDGET. AND IT'S ONE OF THE REASONS WHY, FOR EXAMPLE, CIRM OWNING THE TECHNOLOGY FROM ITS GRANTEES' WORK WOULD NOT BE POSSIBLE. THE CIRM COULDN'T AFFORD TO PURSUE IT. IT SIMPLY DOESN'T HAVE ENOUGH MONEY.

FOR A COMPARISON SAKE, FOR EXAMPLE, I'M PRESIDENT OF GORDON AND BETTY MOORE FOUNDATION. OUR OVERHEAD ON GRANTS RUNS ABOUT 10 OR 11 PERCENT OF THE

GRANT-MAKING BUDGET, AND WE TRY TO RUN A PRETTY TIGHT SHIP. IT'S SIMILAR FOR THE GATES FOUNDATION, FOR THE HEWLETT FOUNDATION, FOR THE PACKARD FOUNDATION. SO WE HAVE ONLY ABOUT HALF THAT MONEY, CIRM, SO WE DON'T REALLY HAVE ANY MONEY TO INVEST IN OBTAINING LICENSES FOR OUR GRANTEES UNFORTUNATELY.

IF IT WAS POSSIBLE FOR US TO NEGOTIATE A ROYALTY FREE LICENSE WITHOUT ANY PAYMENTS, WE WOULD BE HAPPY TO TRY TO ENTERTAIN THAT, BUT THE COLD REALITY IS 6 PERCENT IS A VERY SMALL NUMBER TO ACTUALLY GET ALL OF THE WORK DONE THAT CIRM HAS TO DO JUST IN ADMINISTERING A GRANT PROGRAM. SO IT'S ONE OF OUR BIGGEST CONSTRAINTS.

DR. EGGAN: SO WHAT I'M SAYING IS THAT IN PRINCIPLE WARF SHOULD BE LICENSING THESE THINGS WITHOUT DIRECT ROYALTIES TO THESE ACADEMIC INSTITUTIONS, BUT I CAN TELL YOU, BEING FROM AN ACADEMIC INSTITUTION THAT'S DEALING WITH WARF, THEY ARE NOT EASY TO DEAL WITH INDIVIDUAL INSTITUTION TO INSTITUTION. THEY'RE TAKING A MUCH MORE DIFFICULT POSITION THAN MANY PEOPLE WHO SHARE ACADEMIC IP FROM UNIVERSITY TO UNIVERSITY. SO.

I'M WONDERING IF THE SORT OF COLLECTIVE POSITION MIGHT NOT BE A BAD ONE TO TAKE.

DR. PENHOET: IF IT'S POSSIBLE FOR US TO BROKER SUCH AN ARRANGEMENT, THAT WOULD -- I ACTUALLY

THINK ONE OF THE REASONS, NOT THE MOST IMPORTANT BY ANY MEANS, BUT FOR US TO CREATE A RESEARCH EXEMPTION AND TO SET A STANDARD FOR GOOD BEHAVIOR TO ENCOURAGE THEM TO DO THE SAME THING FRANKLY. WE HAVE HAD CONVERSATIONS WITH THEM ABOUT GLOBAL LICENSES FOR ALL OF OUR GRANTEES. THEY -- HOW TO SAY THIS IN A --

VICE CHAIR LO: DECLINED TO AGREE.

DR. HALL: I'M WATCHING WITH INTEREST HOW YOU'RE GOING TO DESCRIBE THIS.

DR. PENHOET: LET ME SAY NOT FORTHCOMING AT LEAST IN OUR INITIAL DISCUSSIONS.

DR. TAYLOR: I THINK THE OTHER SIDE OF THIS THOUGH DOES EXIST. I KNOW WHEN I WAS UCSF, I WAS GIVEN THE OPPORTUNITY TO PERSONALLY PURSUE A PATENT APPLICATION OUTSIDE OF THE UNIVERSITY MECHANISM ONCE THEY HAD KIND OF LOST INTEREST OR FELT THAT THE INVESTMENT WAS TOO GREAT. SO IF YOU COULD FIND SOMEONE TO BROKER THIS, AND SOUNDS LIKE CIRM ISN'T IT PRESENTLY, I DON'T BELIEVE THAT AT LEAST THE UC SYSTEM WOULD PREVENT THAT FROM OCCURRING TO DO IT OUTSIDE OF THE UNIVERSITY.

DR. PRIETO: QUESTION. IF WE DECIDE AS OUR BANKING MECHANISM TO CONTRACT OUT THE BANK RATHER THAN ADMINISTER IT OURSELVES, COULD THE BANK SERVE THAT PURPOSE?

MR. SHEEHY: THAT'S KIND OF MY QUESTION. BUT, AGAIN, YOU KNOW, THIS BECOMES A RESOURCE ISSUE BECAUSE NOT ONLY IS IT THE 6 PERCENT, BUT WE'RE LIMITED TO 50 EMPLOYEES. SO WE WOULD HAVE TO DO AN RFA FOR SOMEONE TO MANAGE IP FOR US. IS THAT A BETTER USE OF CIRM MONEY THAN GRANTING FOR RESEARCH? THAT'S --

DR. EGGAN: NO. BECAUSE IT WILL INHIBIT THE RESEARCH DIRECTLY.

MR. SHEEHY: THAT'S AN IMPORTANT -- THAT'S IMPORTANT INFORMATION THAT WE NEED TO KIND OF GRAPPLE WITH BECAUSE MY BIAS WOULD BE TOWARDS DOING WHAT WILL HELP THE RESEARCH. AS FRANCISCO SUGGESTED, WE'RE PROBABLY GOING TO HAVE TO SET UP AN ESCRO, WE'RE PROBABLY GOING TO HAVE TO SET UP A STEM CELL BANK. WE COULD LICENSE -- WE COULD EASILY WITH UC OR STANFORD OR ANY OFFICE OF TECHNOLOGY TRANSFER ASK FOR APPLICATIONS FOR INSTITUTIONS UP AND DOWN STATE AND ASK THEM TO MANAGE IP FOR US. IF THERE'S A CLEAR SENSE AND IF THAT'S FEEDBACK THAT WE NEED TO TAKE TO THE ICOC, THEN PLEASE I THINK WE NEED TO KNOW THAT BECAUSE WE DON'T WANT THE SCIENCE IMPEDED BECAUSE ALL THE PATENTS ARE HELD AT AN INDIVIDUAL INSTITUTE LEVEL.

VICE CHAIR LO: LET ME TRY AND SUM THIS UP BECAUSE I DON'T WAS TO TRY AND DO ALL THE FUTURE THINGS THE IP TASK FORCE IS DOING. BUT I'M HEARING STRONG

SUPPORT FOR THE IP TASK FORCE'S GOAL OF ENHANCING ACCESS TO BASIC RESEARCHERS TO THE MATERIALS THAT ARE DISCOVERED UNDER CIRM FUNDING AND PATENTED. AND THAT WE WOULD ALSO ENCOURAGE THE CIRM TO TRY AND FIND INNOVATIVE WAYS OF MAKING THAT HAPPEN IN PRACTICE, INCLUDING LOOKING AT SETTING UP A STEM CELL BANK, WHICH WE FAVOR FOR OTHER REASONS, THAT WOULD ALSO TRY AND CLEAR AWAY SOME ACCESS PROBLEMS THAT CURRENTLY NOW EXIST UNDER BAYH-DOLE WITH THE CURRENT PATENTS ON STEM CELL LINES. BUT I THINK -- LET'S TRY AND KEEP IT AT THAT LEVEL OF GENERALITY, AND I THINK THE SPECIFIC SUGGESTION OF TRYING TO NEGOTIATE WITH WARF IS SOMETHING I THINK WILL NEED TO BE WORKED OUT IN MUCH MORE DETAIL, BUT I'M NOT SURE THAT'S SOMETHING WE SHOULD BE TRYING TO DO TODAY.

SO IF THERE ARE ANY OTHER BIG, BURNING ISSUES THAT WE WANT TO SORT COMMUNICATE BACK TO THE ICOC, OTHERWISE I'D LIKE TO SORT OF MOVE ON.

DR. HALL: CAN WE ASK FOR, EVEN THOUGH WE DON'T HAVE A QUORUM AND CAN'T GET APPROVAL, COULD WE ASK FOR A MOTION THAT WOULD INDICATE SUPPORT FOR THE BROAD OUTLINES OF WHAT THE IP TASK FORCE DOES? YOU DON'T WANT TO DO THAT. YOU CAN'T DO THAT.

MR. HARRISON: WHAT YOU CAN DO IS ASK FOR A SENSE OF THE WORKING GROUP WITH RESPECT TO THE

PRINCIPLES THAT JEFF AND ED HAVE OUTLINED THIS MORNING.

DR. HALL: THAT'S EXACTLY WHAT. THANK YOU.

VICE CHAIR LO: PROCEDURALLY HOW WE ACTUALLY DO THAT? DO I ASK FOR SOMEONE TO SUGGEST THAT AS THE SENSE OF THE MEETING THAT WE SUPPORT --

MR. HARRISON: BERNIE, IF WE COULD CHECK FOR A MOMENT. I THINK A COUPLE OF PEOPLE MAY HAVE JOINED ON THE PHONE. SO IT'S POSSIBLE WE HAVE A QUORUM NOW.

VICE CHAIR LO: GREAT SUGGESTION. DO WE HAVE PEOPLE ON THE PHONE NOW?

MS. CHARO: HI, THIS IS ALTA. CAN BARELY MAKE YOU OUT, SO I'LL BE CALLING BACK AND FORTH LOT TRYING TO GET A BETTER CONNECTION.

VICE CHAIR LO: WELCOME, ALTA. ANYONE ELSE ON THE LINE?

DR. WAGNER: THIS IS JOHN WAGNER AT THE UNIVERSITY OF MINNESOTA. I ALSO AM HAVING A DIFFICULT TIME, BUT WE'LL KEEP ON TRYING.

VICE CHAIR LO: WE CERTAINLY WELCOME DR. WAGNER, AND WE WELCOME YOU TO THE GROUP. DO YOU WANT TO -- MAYBE WHAT CAN DO IS JUST GO AROUND THE ROOM AND INTRODUCE OURSELVES. WE ALSO HAVE ANOTHER NEW MEMBER. SO LET'S INTRODUCE OURSELVES AND ASK OUR TWO MEMBERS TO SAY A WORD.

I'M BERNIE LO FROM UCSF, CO-CHAIRING THE

MEETING TODAY.

DR. HALL: ZACH HALL, PRESIDENT OF CIRM.

MS. FEIT: MARCY FEIT, I'M A PATIENT ADVOCATE.

VICE CHAIR LO: AND A NEW MEMBER. WELCOME TO MARCY.

DR. CIBELLI: I'M JOSE CIBELLI FROM MICHIGAN STATE.

DR. KIESSLING: I'M ANN KIESSLING FROM HARVARD.

DR. PRIETO: I'M FRANCISCO PRIETO, DIABETES PATIENT ADVOCATE ON THE ICOC.

DR. PETERS: TED PETERS FROM THE CENTER FOR THEOLOGY IN THE NATURAL SCIENCES IN BERKELEY.

DR. ROWLEY: JANET ROWLEY FROM THE UNIVERSITY OF CHICAGO.

DR. EGGAN: KEVIN EGGAN FROM HARVARD UNIVERSITY AND THE *STOWERS MEDICAL INSTITUTE.

DR. TAYLOR: ROBERT TAYLOR FROM EMORY UNIVERSITY IN ATLANTA.

VICE CHAIR LO: MARCY, DO YOU WANT TO JUST SAY A FEW WORDS. JEFF, I'M SORRY.

MR. SHEEHY: JEFF SHEEHY, PATIENT ADVOCATE FOR HIV AND AIDS FROM THE ICOC.

VICE CHAIR LO: MARCY, WOULD YOU LIKE TO JUST

TELL US A LITTLE BIT ABOUT YOURSELF SO WE GET TO KNOW YOU BETTER.

MS. FEIT: I'M MARCY FEIT, AND I'M PRESIDENT AND CEO FOR VALLEY CARE HEALTH SYSTEM. IT'S A HEALTH SYSTEM IN THE EAST BAY. I'M A REGISTERED NURSE. I'VE BEEN IN HEALTHCARE FOR 35 YEARS, AND I'M A PATIENT ADVOCATE FOR DIABETES TYPE 2.

VICE CHAIR LO: JOHN, WOULD YOU LIKE TO JUST SAY A FEW WORDS ABOUT YOURSELF?

DR. WAGNER: OH, SURE. WELL, MY BACKGROUND, AS SOME OF YOU MAY OR MAY NOT KNOW, IS ORIGINALLY IN BONE MARROW TRANSPLANTATION, AND THERE I'M THE CLINICAL DIRECTOR OF OUR STEM CELL INSTITUTE HERE AT THE UNIVERSITY OF MINNESOTA. AND OUR DIRECTOR IS CURRENTLY KATHERINE *. OUR WORK HAS BEEN PRINCIPALLY IN ADULT STEM CELLS; HOWEVER, WE ALSO WORK ON EMBRYONIC STEM CELLS HERE. MY SPECIFIC ROLE IS REALLY IN DEVELOPING STRATEGIES FOR THE TRANSLATIONAL DEVELOPMENT AND MOVING TOWARDS CLINICAL TRIALS, AND HOPEFULLY WILL BE SOME BACKGROUND THAT MAY BE HELPFUL TO THIS COMMITTEE.

VICE CHAIR LO: GREAT. WELCOME TO THE BOTH JOHN AND MARCY. AND I HOPE JOHN AND ALTA WILL GET THE PHONES WORKING. WE'RE AT MOSCONE CENTER. IT'S KIND OF A CAVERNOUS ROOM.

WE DON'T HAVE A QUORUM, AND GIVEN SORT OF

THE --

DR. ROWLEY: WE DO WITH THE TWO ON THE PHONE, DON'T WE?

VICE CHAIR LO: NO, WE ACTUALLY DON'T, SO WE'RE TOLD. I WOULD SUGGEST THAT RATHER THAN TRYING TO TAKE A SENSE OF THE MEETING, THAT WE JUST ASK ZACH TO CONVEY BACK THE SENTIMENTS HERE. THIS IS AN ONGOING PROCESS, AND WE CERTAINLY WILL HAVE THE ABILITY TO SORT OF HAVE INPUT TO THE IP WORKING GROUP, AND WE'LL LOOK FORWARD TO FUTURE UPDATES FROM THEM.

AND JUST TO REMIND EVERYONE, THAT WE, OF COURSE, ARE ALWAYS WELCOME TO ATTEND THE IP MEETINGS AS MEMBERS OF THE PUBLIC. AND I THINK ALSO THEY'D BE WILLING TO SHARE WITH US DOCUMENTS THAT THEY RECEIVE TO HELP US IN OUR DELIBERATIONS. I WANT TO THANK ED AND JEFF FOR COMING AND MAKING SUCH A VERY LUCID AND CLEAR PRESENTATION.

SO WITH THAT, WHAT I'D LIKE TO DO IS TURN TO THE NEXT TOPIC ON OUR AGENDA, WHICH IS INFORMED CONSENT, AND I JUST WANT TO SORT OF TRY AND PUT A FRAME AROUND IT. THIS IS OBVIOUSLY A VERY IMPORTANT TOPIC THAT WE ARE GOING TO NEED TO ADDRESS IN THE STANDARDS THAT --

DR. CIBELLI: DID YOU ASK THE PUBLIC FOR COMMENTS ON THE IP POLICY?

VICE CHAIR LO: I'M NOT ACTUALLY NOT GOING TO DO THAT BECAUSE WE'VE HAD A SERIES OF PUBLIC MEETINGS, AND THEY'VE HAD OPPORTUNITY TO HAVE THAT INPUT. AND I THINK FOR THE SAKE OF -- I THINK THAT THAT WOULD BE THE BETTER WAY TO DO THAT. THIS IS REALLY MORE OF AN INFORMATIONAL UPDATE FOR US. I'LL MAKE SURE THE PUBLIC HAS INPUT ON THE SUBSTANTIVE ISSUES WE'RE GOING TO TALK ABOUT WHERE WE'RE REALLY MOVING TOWARDS OUR RECOMMENDATIONS.

SO I DON'T THINK THERE'S ANY NEED TO SORT OF REMIND OURSELVES THAT INFORMED CONSENT FOR DONATION OF MATERIALS TO BE USED IN STEM CELL RESEARCH, PARTICULARLY GENERATION OF NEW CELL LINES, IS A CRUCIAL ISSUE. CERTAINLY THE PUBLICITY OVER THE SOUTH KOREAN STEM CELL LINES SORT OF UNDERSCORES THE IMPORTANCE THE PUBLIC PLACES ON THE CONSENT ISSUES. AND WE HAVE A NUMBER OF CHALLENGES, I THINK, TO SORT THROUGH. AND HOPEFULLY I'D LIKE TO TRY AND MAKE THIS THE MAIN FOCUS OF THE MEETING TODAY.

I THINK OUR GOAL TODAY IS REALLY TO REACH AGREEMENT ON A CONCEPTUAL LEVEL, NOT NECESSARILY TO TRY AND GET THE LANGUAGE EXACTLY RIGHT, BUT TO SORT OF LEAVE CONSIDERABLE DISCRETION TO STAFF AND LEGAL COUNSEL TO HELP US CRAFT IN REGULATORY LANGUAGE THE IDEAS THAT WE CAN AGREE ON. SO IT'S SOMEWHAT SIMILAR

TO WHAT WE TRIED TO DO AT OUR LAST MEETING FOR THE BANKING AND THE ESCRO DEFINITIONS.

I JUST WANTED TO SAY A LITTLE BIT TO TRY AND PUT ALL THIS IN CONTEXT. ALREADY THERE'S A LOT OF EXISTING LAW, REGULATION, GUIDELINES THAT ALL RESEARCHERS AND I WOULD SAY EXCLUDING STEM CELL RESEARCHERS IN CALIFORNIA HAVE TO DEAL WITH. SO THE ONE ISSUE WE NEED TO THINK ABOUT AND I THINK TRY AND REACH AGREEMENT ON TODAY IS DO WE WISH TO INCORPORATE INTO THE RECOMMENDATIONS WE MAKE FOR REGULATIONS FOR CIRM-FUNDED RESEARCH, DO WE WANT TO INCORPORATE THE EXISTING REGULATIONS, LAWS, AND RECOMMENDATIONS ON INFORMED CONSENT? THESE WOULD INCLUDE, FOR EXAMPLE, THE COMMON RULE REGULATIONS THAT GOVERN ALL HUMAN SUBJECTS RESEARCH IN FEDERALLY FUNDED INSTITUTIONS, SUCH AS OUR UNIVERSITY.

THERE ARE STATE LAWS IN CALIFORNIA DEALING WITH INFORMED CONSENT FOR RESEARCH IN PARTICULAR. AND, OF COURSE, THE NATIONAL ACADEMY OF SCIENCE RECOMMENDATIONS FROM THEIR MAY 2005 REPORT, SOME OF WHICH DEAL WITH INFORMED CONSENT. ONE QUESTION IS DO WE WANT TO SAY OUR CIRM RESEARCHERS NEED TO COMPLY WITH THESE THREE DIFFERENT KINDS OF REGULATIONS? AND THEN IF WE DECIDE TO DO THAT, DO WE DO IT BY JUST CITING THE COMMON RULE OF CALIFORNIA LAW SUCH AND SUCH AND THE NAS

REPORT, OR DO WE ACTUALLY CUT AND PASTE THOSE SECTIONS AND PUT THEM INTO OUR REGULATIONS? IF WE DO, IT WILL MAKE OUR REGULATIONS A LOT LONGER, BUT A LOT MORE EXPLICIT. I THINK THAT'S ONE QUESTION OF SEVERAL I'D LIKE US TO TRY AND THINK ABOUT TODAY.

SECONDLY, WHEN WE LOOK AT ALL THAT, THERE ARE A NUMBER OF ISSUES THAT ARE PECULIAR TO DONATION OF BIOLOGICAL MATERIALS FOR STEM CELL RESEARCH THAT DON'T QUITE GET AS MUCH EMPHASIS AS PERHAPS WE MIGHT WANT THEM TO HAVE IN THOSE EXISTING REGULATIONS, LAWS, AND NAS RECOMMENDATIONS. I JUST LISTED SEVERAL THAT WE MIGHT WANT TO CONSIDER ADDING AS ADDITIONS AND REFINEMENTS.

ONE IS THE NOTION THAT CONSENT NEEDS TO BE FREE OR VOLUNTARY AS WELL AS INFORMED. IF YOU LOOK AT THE COMMON RULE IN CALIFORNIA LAW, MOST OF IT REALLY HAS TO DO WITH INFORMING WHAT DO RESEARCHERS NEED TO DISCLOSE TO RESEARCH PARTICIPANTS IN ORDER TO MAKE SURE THEIR CONSENT IS INFORMED?

CERTAINLY THE CONCERNS ABOUT UNDUE INFLUENCE WITH OOCYTE DONORS REMINDS US THAT CONSENT NEEDS TO VOLUNTARY AS WELL AS INFORMED.

SECOND ISSUE IS RECONTACT OF DONORS OF MATERIALS FOR NEW STEM CELL LINES. THE NAS GUIDELINES DEAL WITH THAT QUITE EXPLICITLY AS DO SOME OF THE

CALIFORNIA LAWS, BUT IN THE CONTEXT OF PROVIDING INFORMATION ON RESEARCH TESTS BACK TO THE PARTICIPANTS IN RESEARCH AS SORT OF THE REASON FOR RECONTACT. DO WE WANT ALSO TO MAKE CLEAR TO DONORS OF MATERIALS THAT THEY MAY WISH -- THAT THE RESEARCHERS MAY WISH TO RECONTACT THEM, NOT FOR THEIR BENEFIT, BUT TO BENEFIT POTENTIAL RECIPIENTS IN TRANSPLANTATION FROM CELL LINES DERIVED FROM THEIR MATERIAL; IN OTHER WORDS, THE RECONTACT WOULD BE TO GET MORE INFORMATION FROM THEM ABOUT THEIR HEALTH STATUS IN THE FUTURE.

DR. EGGAN: OR MORE MATERIAL.

VICE CHAIR LO: ALSO MORE MATERIAL. BUT THE RECONTACT WOULD BE NOT FOR THE BENEFIT OF PROVIDING POTENTIALLY BENEFICIAL INFORMATION BACK, BUT TO SORT OF ASK THEM TO SORT OF HELP RESEARCHERS OUT.

AND FINALLY, SPECIFIC CONCERNS ABOUT OOCYTE DONATION. AS YOU KNOW, THERE WAS A BILL INTRODUCED IN THE LEGISLATURE, PASSED BY BOTH HOUSES, VETOED BY THE GOVERNOR, SETTING FORTH ADDITIONAL REQUIREMENTS FOR CONSENT IN THE OOCYTE RETRIEVAL SITUATION.

MR. HARRISON: I THINK WE HAVE BOB KLEIN, WHO'S JUST JOINED.

VICE CHAIR LO: HI, BOB.

MR. KLEIN: HI. MY UNDERSTANDING IS YOU NEED ME FOR A QUORUM?

DR. HALL: NO. THE MOMENT IS PASSED. THANK YOU.

VICE CHAIR LO: WE NEED YOU IN SPIRIT, BUT WE DON'T NEED YOU FOR A QUORUM AT THIS POINT.

MR. KLEIN: OKAY. IF I COULD FINISH A FEW CRITICAL CALLS, THEN I'LL COME OVER.

VICE CHAIR LO: GREAT. WE'LL LOOK FORWARD TO SEEING YOU WHEN YOU GET HERE. THANKS, BOB.

SO THAT IN THIS CONTEXT OF PARTICULAR CONCERNS ABOUT OOCYTE DONATION, WE WANT TO PUT IN HEIGHTENED REQUIREMENTS FOR INFORMED CONSENT IN THAT CONTEXT. NEXT SLIDE. THERE HAVE BEEN SEVERAL SUGGESTIONS THAT ONE MIGHT MAKE ABOUT ENHANCING THE CONSENT PROCESS -- LET ME JUST BACK UP.

ONE PROBLEM, IF YOU LOOK AT, AND IN YOUR FOLDER UNDER BINDER TAB 7 YOU CAN SEE WHAT SPELLING OUT ALL THE DIFFERENT REQUIREMENTS FOR CONSENT LOOKS LIKE. AS ALL OF US WHO ARE EITHER RESEARCHERS, PATIENTS, OR RESEARCH PARTICIPANTS KNOW, WHAT HAPPENS IS THAT MEANS THE CONSENT FORM GETS LONGER AND LONGER AND LONGER. SO EVERY TIME SOMEONE ADDS MORE REQUIREMENTS, IT JUST LENGTHENS THE CONSENT FORM.

THE PROBLEM WITH THAT IS THAT ALL THE EMPIRICAL RESEARCH WE HAVE ABOUT HOW DOES CONSENT WORK IN EITHER CLINICAL OR A RESEARCH SETTING IS THAT

LENGTHENING THE CONSENT FORM DOESN'T HELP, AND THAT IN SPITE TERRIFIC CONSENT FORMS, MANY IF, IN FACT, LIKELY THE MAJORITY OF RESEARCH PARTICIPANTS, ARE SERIOUSLY MISINFORMED ABOUT THE PROJECT THEY'RE GETTING INVOLVED WITH AND THE NATURE OF RESEARCH. SO I THINK ONE OF THE BACKGROUND ISSUES IS WHILE IT'S IMPORTANT TO MAKE SURE PEOPLE HAVE ALL THE INFORMATION THEY NEED TO MAKE A CONSENT WHETHER OR NOT TO DONATE MATERIALS FOR RESEARCH, LENGTHENING THE CONSENT FORM IN AND OF ITSELF MAY NOT BE AN EFFECTIVE WAY TO ACHIEVE THAT GOAL.

WHAT ARE SOME OTHER OPTIONS FOR TRYING TO ENHANCE CONSENT RATHER THAN JUST HAVING MORE DETAILED CONSENT FORMS? ONE MIGHT BE TO ACTUALLY ASSESS COMPREHENSION RATHER THAN SIMPLY ADD TO THE FORM. SO IT'S ASKING QUESTIONS TO SEE WHETHER OR NOT THE RESEARCH PARTICIPANT ACTUALLY UNDERSTANDS KEY FEATURES, ESSENTIAL FEATURES, ABOUT THE RESEARCH. THE IDEA BEING IF THEY DON'T, THEY NEED MORE DISCUSSION BEFORE THEY'RE ALLOWED TO AGREE TO PARTICIPATE.

SECOND OPTION IS TO HAVE AN INDEPENDENT PERSON, SOMEONE WHO'S NOT PART OF THE RESEARCH TEAM, OBSERVE DISCUSSIONS BETWEEN THE RESEARCHERS AND THE POTENTIAL SUBJECT. THIS TENDS TO HAVE A LOT OF *SALUTORY EFFECT IN TERMS OF MAKING THAT DISCUSSION CLEARER, HELPING THE PERSON ASK QUESTIONS, CLARIFYING

THINGS, AND SO FORTH.

FINALLY, REPEATING DISCUSSIONS OVER TIME SEEMS TO HAVE SOME BENEFIT ON ENHANCING UNDERSTANDING. IF YOU REMEMBER ANN KIESSLING'S PRESENTATION AT OUR FIRST MEETING, WHERE SHE TALKED ABOUT THE PROCESS HER GROUP HAS DEVELOPED, I THINK ACTUALLY, ANN, I THINK, CORRECT ME IF I'M WRONG, I THINK YOU ACTUALLY USE ALL OF THESE APPROACHES. YOU ACTUALLY ASK QUESTIONS TO SEE WHAT PEOPLE UNDERSTAND. YOU HAVE SOMEONE WHO'S NOT PART OF THE RESEARCH TEAM BE PRESENT DURING THOSE DISCUSSIONS, AND YOU HAVE THOSE DISCUSSIONS REPEATED OVER TIME WITH OPPORTUNITIES TO ASK QUESTIONS, TO CLARIFY, AND SO FORTH.

SO THESE ARE THREE BROAD APPROACHES THAT WE MIGHT WANT TO THINK ABOUT, AND I WOULD SAY PERHAPS SPECIFICALLY IN THE CONTEXT OF OOCYTE DONATION BECAUSE THAT SEEMS TO HAVE RAISED THE MOST CONCERNS AMONG THE PUBLIC.

IF WE WANT TO THINK ABOUT HOW TO IMPLEMENT IN REGULATIONS SOME SORT OF ASSESSMENT OF WHAT PEOPLE ACTUALLY UNDERSTAND, THERE'S DRAFT LANGUAGE THAT ALTA AND I AND A FEW OTHERS HAVE WORKED ON, WHICH WE CAN SHOW IF WE GET TO THAT. IF WE GO BACK, I SORT OF PROPOSED AS A WAY OF JUST ORGANIZING OUR DISCUSSION, A SERIES OF NESTED QUESTIONS. GO BACK TO THE VERY FIRST

SLIDE, GEOFF. JUST BECAUSE IT'S SUCH A BIG TOPIC, I THINK WE REALLY WANT TO TRY AND WORK EFFICIENTLY. I WOULD SUGGEST, NOT THAT THIS IS NECESSARILY THE BEST MODEL OR THE ONLY MODEL, BUT ONE THAT WE THINK ABOUT USING JUST TO SORT OF GO THROUGH A SET OF ISSUES.

LET, WITH THAT, TOSS IT OPEN TO THE COMMITTEE FOR YOUR THOUGHTS.

LET ME JUST SAY, HAVING TRIED TO LEARN FROM THE LAST MEETING, WHAT I'LL TRY AND DO IS KEEP A LIST OF PEOPLE WHO WANT TO TALK, AND MAKE SURE WE GET TO EVERYBODY. JOSE AND KEVIN AND THEN MARCY.

DR. CIBELLI: I KNOW WE'RE NOT VOTING, BUT I SUPPORT THE IDEA OF HAVING PEOPLE THIS COOL-OFF PERIOD, I THINK YOU CALL IT, AFTER THEY HAVE BEEN ENGAGED IN WILLINGNESS TO DONATE. BUT ALSO I THINK WE SHOULD THINK ABOUT TRAINING, SOME SORT OF TRAINING FOR THE PERSON THAT IS GOING TO EXPLAIN THE INFORMED CONSENT TO THE DONOR. SO MAYBE THAT WOULD BE SOMETHING THAT THE ESCRO'S CAN DO, HAVE SOME SORT OF ONLINE TRAINING OR REFRESHMENT EVERY YEAR, THAT PEOPLE HAVE TO GO BACK AND RETRAIN THEMSELVES. SO HAVE A DESIGNATED PERSON TO DO THE INFORMED CONSENT. I THINK IT'S IMPORTANT TO HAVE SOMEONE QUALIFIED.

DR. EGGAN: JUST TO SPEAK TO THIS BROAD ISSUE OF HOW SPECIFIC YOU WANT TO BE, I WOULD AS A SCIENTIST

ARGUE FOR BEING AS SPECIFIC AS POSSIBLE. AND I THINK THERE ARE TWO REASONS TO DO THAT. ONE IS THAT IT WILL LEVEL THE PLAYING FIELD AMONG CALIFORNIA INSTITUTIONS. IT WILL BE CLEAR TO EVERYONE HOW THEY'RE SUPPOSED TO BEHAVE AND SO EVERYONE WILL BEHAVE MORE SIMILARLY INSTEAD OF ALLOWING THEM INTUIT WHAT THEY'RE SUPPOSED TO DO IN A VACUUM.

SECONDLY, IT WILL HELP THINGS GO FASTER. I CAN TELL FOR SOMEONE WHO'S BEEN WORKING THROUGH THESE ISSUES WITH A RELATIVELY NAIVE IRB OVER THE LAST COUPLE OF YEARS, THEY KEEP REALIZING THAT THERE ARE NEW THINGS THAT THEY HAVEN'T DEALT WITH AS THEY'VE GONE ALONG. SO IF A LARGER GROUP CONSIDERS THOSE ISSUES, CERTAINLY THE NATIONAL ACADEMY OF SCIENCE CONSIDERING ISSUES AND MAKING POLICY STATEMENTS HELPED IMMEASURABLY, AND TO HAVE THESE BE ENDORSED BY ANOTHER BODY WILL HELP GET CLEAR HOW DIFFERENT INSTITUTIONS ARE TO PROCEED AND WHAT THE BEST WAY AS AN INVESTIGATOR IT IS TO DO THESE TYPES OF EXPERIMENTS. IT WILL MAKE THINGS GO FASTER.

MS. FEIT: HAVING WORKED EXTENSIVELY WITH CONSENT FORM OVER 35 YEARS WITH THOUSANDS OF PATIENTS, I THINK -- I APOLOGIZE IF THIS WAS DISCUSSED EARLIER. I'M NEW TO THE COMMITTEE. I THINK A DEFINED TIME-OUT FOR THE INDIVIDUAL, A TIME WHERE THERE IS NO CONTACT FROM THE RESEARCH TEAM, BUT SOMEONE ELSE OFFERED A

NUMBER TO CALL, BUT IT GIVES THE INDIVIDUAL TIME TO LOOK UP WORD DEFINITIONS, TO UNDERSTAND THE MATERIAL THAT YOU ARE GIVING THEM SO THAT THEY FULLY UNDERSTAND WHAT THEY'RE DOING. AND THEN SOMEONE ELSE TO CALL OTHER THAN THE RESEARCH TEAM THAT THEY CAN ASK QUESTIONS ABOUT, THAT THEY FEEL COMFORTABLE, AND THEN COME BACK AFTER THAT AND THEN RESIGN SAYING THEY HAD THE TIME-OUT AND THEY HAD THE OPPORTUNITY TO REALLY THINK THIS THROUGH.

I MEAN THE SIMPLEST THINGS LIKE I'VE HAD PATIENTS SAY, I LOOKED UP DEFINITIONS OF WORDS THAT I DIDN'T UNDERSTAND AND WE TAKE FOR GRANTED A LOT IN SCIENCE WORDS AND MEANINGS OF WORDS AND NOT CLEARLY UNDERSTANDING THAT THE PATIENTS DON'T HAVE ANY IDEA WHAT WE'RE TALKING ABOUT. SO I WOULD JUST ADVOCATE FOR THAT TO BE SPELLED OUT. IF IT'S THREE DAYS, IF IT'S A FIVE-DAY TIME-OUT, WHATEVER IT IS, THAT IT'S SPELLED OUT, AND THAT THE RESEARCH TEAM SHOULD LET, THEN, THE DONOR ALONE AND LET THEM ABSORB THE MATERIAL AND HAVE SOMEBODY ELSE THEY CAN CONTACT TO GO THROUGH IT WITH THEM, THAT WOULD BE -- JUST BECAUSE THIS IS A VERY SENSITIVE AND HIGH PROFILE ISSUE. AND I THINK THAT WOULD HELP SUPPORT A CLEAR UNDERSTANDING THAT THE DONORS HAD TIME TO UNDERSTAND.

DR. ROWLEY: I THINK IT'S IMPORTANT TO

EMPHASIZE.

VICE CHAIR LO: ALTA.

MS. CHARO: IN THAT OF THAT PREVIOUS COMMENT, I'D LIKE TO JUST ASK FOR CLARIFICATION. ARE WE TALKING ABOUT WHAT WE'RE GOING TO RECOMMEND AS BEST PRACTICES WITHIN THE WORLD OF CIRM-FUNDED RESEARCH, PERIOD? OR ARE WE ALSO TALKING ABOUT PRACTICES THAT WE WOULD REQUIRE TO HAVE BEEN FOLLOWED BY OTHERS BEFORE A CIRM-FUNDED RESEARCHER COULD USE SOMEBODY ELSE'S LINES? IN OTHER WORDS, I'M TRYING TO FIGURE OUT IF WE'RE TALKING ABOUT WHAT WE'RE GOING TO DO WHEN IT'S OUR MONEY BEING SPENT TO ACTUALLY RECRUIT AN EGG DONOR, OR IF WE'RE ALSO TALKING ABOUT WHAT CONSTITUTES THE MINIMUM STANDARD FOR AN ETHICALLY DERIVED LINE.

VICE CHAIR LO: GREAT DISTINCTION. LET'S RIGHT NOW TALK ABOUT WHAT WE'RE REQUIRING OF OUR RESEARCHERS. IF WE CAN AGREE ON THAT, THEN LET'S LATER ON COME BACK TO HOW MUCH OF THAT DO WE WANT TO APPLY TO OTHER RESEARCHERS DERIVING LINES WITH OTHER FUNDS.

MS. CHARO: THANKS. SORRY TO INTERRUPT.

VICE CHAIR LO: BY THE WAY, ALTA AND JOHN, IF YOU WANT TO SPEAK, JUST SORT OF SHOUT THAT YOU WANT TO SPEAK AND I'LL PUT YOU IN THE QUEUE.

DR. ROWLEY: I JUST WANT FOR A POINT OF CLARIFICATION AND ASKING YOU HOW YOU DEFINE RESEARCHERS

BECAUSE IT'S CLEAR HERE THAT THE GUIDELINES STATE THAT THE INDIVIDUAL DONOR IS CONTACTED BY A PHYSICIAN OR SOME INDIVIDUAL NOT DIRECTLY INVOLVED IN THE RESEARCH. SO IT ISN'T THE RESEARCHER WHO'S GOING TO DEVELOP THE CELL LINES WHO'S ASKING YOU FOR EITHER OOCYTES OR PERMISSION. IT'S ANOTHER INDIVIDUAL WHO'S DOING THAT.

VICE CHAIR LO: ROB AND THEN FRANCISCO.

DR. TAYLOR: MY POINT WAS REALLY QUITE SIMILAR. I ABSOLUTELY SUPPORT WHAT YOU ARE SUGGESTING HERE, AND I THINK IT IS IMPORTANT THAT THAT WAITING PERIOD, AS WELL AS THE COUNSELING AND ASCERTAINMENT OF UNDERSTANDING BY THE DONOR COMES FROM SOMEBODY OTHER THAN THE CLINICIAN WHO'S CARING FOR THAT PATIENT CLINICALLY BECAUSE MANY OF THESE MAY COME FROM THAT SOURCE AND ALSO THE RESEARCHERS. SO I THINK TRAINED INDIVIDUALS, SEPARATION OF CHURCH AND STATE, AND SORT OF WAITING PERIOD. COOLING OFF PERIOD REMINDS ME TOO MUCH OF HANDGUNS, BUT SOME KIND OF A WAITING PERIOD, I THINK, IS IMPORTANT.

DR. PRIETO: COMMENT BRIEFLY THAT I THINK IT IS IMPORTANT TO HAVE A TIME-OUT, BUT ALSO THAT I THINK THE DISTINCTION THAT JANET BROUGHT UP IS SOMETHING THAT DONORS MIGHT NOT REALLY SEE BETWEEN -- I THINK THEY WOULD PERCEIVE THE PERSON ASKING THEM TO DONATE AS A MEMBER OF THE RESEARCH TEAM. SO WE NEED TO LOOK AT A

COMPLETELY NEUTRAL OR MORE FURTHER REMOVED PERSON AS A SOURCE FOR THEM TO GO BACK TO ANSWER QUESTIONS.

DR. KIESSLING: TWO COMMENTS. ONE, THE PROGRAM THAT WE SET UP ESTABLISHED OR SOLVED THE COOLING OFF PERIOD BY INFORMING THE DONORS THAT NOBODY WOULD CONTACT THEM. THAT EARLY IN THE RECRUITMENT, WHEN THEY WERE GOING THROUGH THE INITIAL SCREENING PROCESS, THEY WERE RESPONSIBLE FOR CONTACTING THE OFFICE TO MAKE THEIR NEXT APPOINTMENT. NO ONE WOULD CALL THEM.

SECONDLY, THE CONFUSION OR THE INTEREST AROUND MAKING SURE THAT EGG DONORS ARE CONSENTED MAY -- THIS IS SOMETHING THAT'S OPEN FOR DISCUSSION BECAUSE WE'VE NOT DONE THIS, ALTHOUGH I'VE THOUGHT ABOUT IT. IT'S POSSIBLE THE TWO BIG ASPECTS FOR ASKING SOMEONE TO DONATE EGGS IS DO THEY UNDERSTAND WHAT MIGHT BECOME OF THE CELLS DERIVED FROM THEIR EGGS. THAT'S A BIG PIECE. DO THEY UNDERSTAND THE BIOLOGY. DO THEY UNDERSTAND EXACTLY WHAT'S GOING TO HAPPEN WITH WHAT THEY'VE DONATED? THAT'S ONE CONSIDERATION.

AND, TWO, DO THEY UNDERSTAND THE RISKS TO THEMSELVES? SO IT'S POSSIBLE THAT THE WAY TO REALLY ESTABLISH THIS KIND OF A CONSENT PROCESS IN THIS PARTICULAR CASE IS TO ACTUALLY HAVE TWO DIFFERENT CONSENT FORMS SO THAT THIS GETS SEPARATED IN THE

DONOR'S MIND. ON THE ONE HAND, SHE NEEDS TO JUST SIMPLY CONSIDER THE RISKS TO HERSELF, THE TIME COMMITMENT, WHAT THIS IS GOING TO MEAN TO HER AND HER FAMILY TO DO THIS. AND SECONDLY, AS A SECOND CONSIDERATION, DOES SHE FULLY UNDERSTAND THE LONG-TERM OUTCOME OF WHAT SHE'S DOING? AND THIS IS BASICALLY TWO PROCESSES THAT WHEN YOU TALK TO THESE WOMEN, YOU REALLY UNDERSTAND THEY'RE MIXING THEM TOGETHER, AND IT MIGHT BE CLEARER IF THEY WERE SEPARATE.

DR. EGGAN: COUPLE THINGS. I WOULD AGREE WITH ANN, THAT MAYBE A SOLUTION FOR THE COOLING OFF PERIOD IS THIS LEAVING THE RECONTACT IN THE HANDS OF THE POTENTIAL DONOR. THIS SEEMS LIKE A REASONABLE APPROACH.

I GUESS IT IS IMPORTANT THAT WE MOVE FORWARD IN SUCH A WAY THAT THINGS CAN BE AS, I GUESS, AS REMOVED FROM CRITICISM AS POSSIBLE, BUT ALSO THERE NEEDS TO BE A RECOGNITION THAT THESE MECHANISMS MUST WORK. AND SO I THINK IT'S DIFFICULT TO IMAGINE WHO THE PERSON WOULD BE THAT WOULD BE FULLY REMOVED FROM THE RESEARCH TEAM, WHO WOULD BE INVOLVED IN DONATION AND WHAT THAT MECHANISM WOULD BE IF THAT'S THE GOAL. SO CERTAINLY ONE APPROACH WOULD BE FOR THE RESEARCH TEAM TO HIRE A DEDICATED RESEARCH ADMINISTRATOR WHO WOULD TAKE CHARGE OF THESE THINGS AND WOULD BE A REGISTERED

NURSE AND WOULD BE AN INDEPENDENT PERSON. THAT WOULD BE ONE THING THAT COULD BE DONE AND HAS BEEN DONE BY PEOPLE.

THIS MAY NOT ALWAYS BE POSSIBLE DEPENDING ON WHAT THE PROJECT IS. AND SO I THINK TO EXPECT ALWAYS THIS SORT OF INFORMED CONSENT PROCESS TO BE FARMED OUT TO SOME SORT OF INDEPENDENT AGENT IS HARD TO IMAGINE AS BEING A FUNCTIONAL APPROACH FOR MOST RESEARCH STUDIES. SO I THINK BEFORE WE SAY ABSOLUTELY THAT'S THEY WAY IT SHOULD BE DONE, I THINK THERE SHOULD BE A BROADER DISCUSSION ABOUT THAT.

AND THEN I THINK IT'S ALSO IMPORTANT TO RECOGNIZE THAT MANY OF THESE PROCESSES SUCH AS EGG DONATION ARE MULTISTEP, COMPLICATED PROCESSES. AND ONE WAY TO HANDLE THOSE IS TO HAVE MULTISTEP INFORMED CONSENT. THAT IS, OF COURSE, THAT'S GOING TO HAPPEN ANYWAY FOR A PROCESS LIKE EGG DONATION IN THE UNITED STATES. IT'S GOING TO BE NEED INFORMED CONSENT RIGHT BEFORE THE PERSON, FOR INSTANCE, UNDERGOES GENERAL ANESTHESIA FOR THE EGG RETRIEVAL. THAT'S ANOTHER WAY TO SORT OVERCOME THE COMPLICATED NATURE OF THE PROCESS. I THINK THAT SHOULD BE ENCOURAGED.

VICE CHAIR LO: ROB.

DR. TAYLOR: JUST A QUICK POINT ABOUT IN WOMEN OR COUPLES WHO ARE UNDERGOING CONVENTIONAL IVF

AND MAY COMPLY AND WANT TO PARTICIPATE IN A PROGRAM LIKE THIS, THAT TIME-OUT PERIOD MAY BE A LITTLE BIT MORE DIFFICULT TO ACCOMPLISH IN THAT THE IVF PROCESS IS AN INTENSIVE AND RELATIVELY SHORT PERIOD OF TIME IN WHICH THERE'S LOTS OF CONTACT BETWEEN THE CLINICAL OFFICE AND THE PATIENT. AND IF PART OF THAT PROCESS REQUIRES SOME -- I'M JUST CONCERNED THAT IT MAY EXCLUDE COUPLES UNDERGOING IVF FOR THEIR OWN CLINICAL FERTILITY REASONS WHO MAY WANT TO PARTICIPATE. WE MIGHT HAVE LANGUAGE THAT WOULD ACTUALLY PREVENT THEM, BECAUSE OF A PERIOD OF TIME OF WAITING OR THIS REQUIREMENT THAT THEY CAN'T REALLY BE CONTACTED BY THE OFFICE, DEPENDING, AND I SEE THAT AS STILL PROBABLY BEING THE MOST PREVALENT MECHANISM FOR OBTAINING THESE MATERIALS. I WOULDN'T WANT TO WRITE THAT OFF RIGHT UP FRONT.

DR. KIESSLING: I ACTUALLY THINK IT'S MORE IMPORTANT FOR THE PATIENTS GOING THROUGH INFERTILITY TREATMENT TO HAVE A TIME-OUT.

VICE CHAIR LO: DO YOU WANT TO SAY A LITTLE MORE ABOUT THAT?

DR. KIESSLING: I ACTUALLY THINK IT'S MORE CRUCIAL THAT THE PEOPLE WHO ARE GOING THROUGH INFERTILITY TREATMENT BE ALLOWED THE OPPORTUNITY FOR A TIME-OUT. I THINK THERE'S A LOT OF THE PRESSURES ON THOSE COUPLE, AND I THINK FOR THEM TO PARTICIPATE IN

RESEARCH, IT'S EVEN MORE CRITICAL THAT THEY HAVE A LITTLE TIME TO REFLECT ON WHETHER THEY WANT TO DO IT IN ADDITION TO THEIR INFERTILITY NEEDS. SO I SORT OF THINK IT'S MORE CRITICAL FOR THAT GROUP THAN IT IS FOR THE WOMEN COMING FORTH BECAUSE THEY'VE GOT TYPE 1 DIABETES IN THEIR FAMILIES.

DR. ROWLEY: BUT, AGAIN, THIS WAS DEALT WITH IN THE NATIONAL ACADEMY REPORTS, THAT ANYONE WHO IS GIVING EMBRYOS NO LONGER NEEDED FOR THEIR OWN FAMILY HAVE TO BE RECONSENTED IN ORDER FOR THOSE EMBRYOS TO BE THEN USED FOR RESEARCH. SO THEY HAVE UP TO YEARS AS A TIME-OUT, IF YOU WILL.

VICE CHAIR LO: JUST TO CLARIFY, I THINK WE NEED TO BE VERY CAREFUL TO DISTINGUISH THE DONATION OF FROZEN EMBRYOS REMAINING AFTER INFERTILITY TREATMENT IS COMPLETED FROM DONATION OF FRESH OOCYTES FROM THE SAME HORMONAL MANIPULATION AND OOCYTE RETRIEVAL CYCLE AS WELL AS TO BE USED TO GENERATE OOCYTES FOR INFERTILITY TREATMENT. SO I THINK, AS I UNDERSTOOD YOU, ROB, YOUR COMMENTS HAD TO DO WITH IF YOU ARE GOING TO ASK THEM TO DONATE FRESH OOCYTES FROM A CYCLE WHERE THEY'RE ALSO DONATING FOR INFERTILITY TREATMENT, THERE ARE TIME CONSTRAINTS IN TERMS OF TIMING OF MANIPULATIONS.

DR. TAYLOR: I WAS THINKING OF THE FROZEN OOCYTE DONATION MODEL BECAUSE MOST COUPLES DON'T REALLY

KNOW WHAT THE OUTCOME IS OF THEIR PREGNANCY CYCLE UNTIL AFTER THE FACT. BUT I DO THINK THAT IF YOU SORT OF PROSCRIBED OR REQUIRED A WAITING PERIOD THAT COUPLES UNDERGOING IVF COULDN'T REALLY ACCOMMODATE IN THEIR INTENSE SCHEDULE, IT WOULD BE NICE FOR THEM TO STILL HAVE THE OPPORTUNITY, AND I AGREE WITH JANET, THAT THEY REQUIRED TO ACTUALLY RECONSENT. YOU COULD, I GUESS, MAYBE CALL THAT YOUR TIME-OUT.

VICE CHAIR LO: AGAIN, FOR MY UNDERSTANDING WAS THAT THE NAS REPORT SORT OF BUILT THAT TIMING AFTER THE OOCYTES ARE IN THE FREEZER. THERE'S LOTS OF MONTHS OR YEARS TO DECIDE WHAT TO DO WHAT TO DO. THAT IS A COOLING OFF -- LITERALLY A COOLING OFF PERIOD WHEN THEY'RE IN THE FREEZER, BUT A TIME-OUT WHICH WOULD SATISFY WHAT WE'RE TALKING ABOUT BEFORE, I THINK.

DR. EGGAN: WE SHOULD BE CAREFUL OUR TERMINOLOGY, EMBRYO, OOCYTE. I THINK THERE ARE CIRCUMSTANCES WHICH ARE NOT DIRECTLY SPOKEN TO BY THE NAS GUIDELINES. THERE MAY BE CIRCUMSTANCES WHERE A COUPLE IS UNDERGOING IVF WHERE THERE WILL BE DISCARDED MATERIAL THAT WE'LL BE USING. I THINK IT'S STILL AN ONGOING DISCUSSION ABOUT WHETHER OR NOT WE SHOULD SUPPORT THE SORT OF DIVERSION OF MATERIAL GENERATED FOR AN ACTIVE ATTEMPT AT PREGNANCY TOWARDS RESEARCH, BUT THERE MAY BE CIRCUMSTANCES WHERE IT IS USEFUL AND,

INDEED, WHERE IS NO QUESTION. SO, FOR INSTANCE, NAS DIRECTLY ENCOURAGES FREEZING OF EMBRYOS DONATED, BUT THERE MAY BE OTHER EMBRYOS, SUCH AS THOSE THAT ARE AFFECTED BY A VARIETY OF DISEASES WHICH HAVE BEEN DIAGNOSED BY PGD WHICH WOULD BE DE FACTO DISCARDED WHICH COULD BE USED FOR RESEARCH. THERE WOULD BE NO PROBLEM FOR THAT. THAT WOULD BE A SORT OF CIRCUMSTANCE THAT'S BEING DISCUSSED HERE WHERE THERE IS AN OPPORTUNITY TO USE THAT MATERIAL. IT WILL BE THROWN AWAY OTHERWISE, SO IT REALLY ISN'T THAT DIFFICULT OF A DISCUSSION. SO TO MANDATE A COOLING OFF PERIOD COULD BE DIFFICULT IN THAT SITUATION.

VICE CHAIR LO: KEVIN, WOULD YOU INCLUDE OOCYTES THAT FAIL TO FERTILIZE?

DR. EGGAN: I THINK THAT'S SOMETHING THAT WE SHOULD HAVE AS A BROAD CONVERSATION. I THINK ANN AND I AGREE THAT THAT'S A TROUBLED SOURCE OF MATERIAL FOR A VARIETY OF REASONS, PARTICULARLY WHAT I SAID BEFORE. OTHER PEOPLE DISAGREE WITH THAT. AND CERTAINLY *HEFA HAS SAID THAT THEY ENDORSE THAT, SO I THINK THAT'S AN OPEN --

VICE CHAIR LO: LET'S TRY AND FOCUS ON SORT OF THE NORMAL SITUATION, NOT THE UNUSUAL ONES. WE'LL PUT OFF FOR LATER.

MS. FEIT: I JUST WANT TO AGAIN GO BACK AND

SAY THIS. IF I'M DONATING ANY PART OF MY BODY AND YOU SAY I'M GOING TO FREEZE IT FOR FIVE YEARS OR TEN YEARS, I'VE CHECKED OUT. IT'S THERE. I DON'T HAVE TO WORRY ABOUT IT. THEN IF YOU COME BACK TO ME AND SAY, WELL, MARCY, WE'RE GOING TO DO THIS WITH IT. YOU'VE SET ME ON WHOLE ANOTHER PATH AND I DESERVE TIME TO THINK ABOUT WHAT YOU'RE GIVING ME, THE INFORMATION YOU'RE GIVING ME, AND WHAT YOU PLAN TO DO. I JUST WANT TO STATE THAT. THAT IS HOW PATIENTS AND DONORS THINK. SO DON'T UNDERESTIMATE THAT, BECAUSE THEY HAVE FIVE YEARS, THAT THEY CLEARLY UNDERSTAND WHAT YOU PLAN TO DO. THAT'S MY ONLY COMMENT.

DR. EGGAN: I THINK I AGREE WITH THAT FULLY.

VICE CHAIR LO: SO JUST TO CLARIFY, IT STRIKES ME THAT ONCE YOU THEN SAY NOW WOULD YOU LIKE TO -- THESE EMBRYOS ARE IN THE FREEZER. NOW WOULD YOU LIKE TO CONSIDER DONATING FOR RESEARCH, THE CLOCK STARTS AGAIN. AFTER THAT INITIAL CONVERSATION, YOU CAN THEN SAY WE'RE NOT GOING TO RECONTACT YOU FOR X, WHATEVER, AND THINK ABOUT IT, TALK TO SO AND SO.

MS. FEIT: IF YOU HAND ME A STACK OF INFORMATION AND GIVE ME A LOT OF TERMINOLOGY THAT I'VE NEVER SEEN BEFORE AND YOU GIVE ME A CONCEPT THAT I'VE NEVER HEARD OF BEFORE, I HAVE A LOT OF THINK OF, TWO, THREE DAYS, SOMETHING SO THAT I CAN SIT DOWN, I CAN ASK

SOME QUESTIONS WHETHER IT'S WITH A CASE MANAGER, A REGISTERED NURSE, A COUNSELOR, ANYBODY THAT I CAN JUST SORT OF DIGEST THE INFORMATION. YOU KNOW, IT'S A CRITICAL DECISION. I NO LONGER WANT THIS. I'M GOING TO GIVE IT TO YOU. I'M GOING TO LET YOU DO. I HAVE TO HAVE MORE INFORMATION AND SOME TIME TO THINK ABOUT IT. THAT'S ALL. I'M NOT SAYING IT HAS TO BE FOREVER. I'M JUST SAYING THEY CAN'T GO FROM ONE ROOM AND THEN SIGN A DOCUMENT AND ASSUME THAT THEY UNDERSTAND.

YOU POINTED OUT IN THE BEGINNING THEIR COMPREHENSION, THEIR APPREHENSION, AND THEN THE MORAL, ETHICAL DUTY WE HAVE TO MAKE SURE AS MUCH AS WE COULD THAT THEY UNDERSTOOD WHAT WE WERE GOING TO DO. THAT WAS ALL.

VICE CHAIR LO: THERE'S NO TIME CONSTRAINT AT THAT POINT BECAUSE THEY'RE FROZEN. YOU CAN TAKE DAYS, WEEKS, MONTHS EVEN.

LET ME JUST SAY THAT THIS WOULD BE A DEPARTURE FROM THE WAY CONSENT TO DONATE FROZEN EMBRYOS FOR RESEARCH PURPOSES IS CURRENTLY DONE. I THINK A LOT OF TIME THAT WAS ACTUALLY COUPLED WITH THE BILL GET FOR THE STORAGE FEES IN THE FREEZER. AND IT'S LITERALLY IF YOU DON'T WANT TO PAY AND YOU DON'T WANT TO KEEP THEM FROZEN, ONE OPTION IS DONATE TO RESEARCH, AND YOU DON'T HAVE ANY OF THIS KIND OF DISCUSSION NECESSARILY.

DR. EGGAN: WELL, BUT IN A SENSE MAYBE THAT'S A SIMILAR SITUATION. IF IT'S SENT OUT WITHOUT DIRECT PATIENT INTERACTION WITH THE BILL, AND THEY RECEIVE THE BILL AND THIS DOCUMENT IN THE MAIL, THEY CAN DECIDE TO WAIT AS LONG AS THEY WANT TO WAIT BEFORE THEY RECONTACT THE IVF CLINICIAN. SO THERE REALLY ALREADY IS BY THAT SORT OF APPROACH A DE FACTO TIME-OUT OR COOLING OFF PERIOD. THERE IS NO DIRECT COERCION OR ENCOURAGEMENT TO DONATE EMBRYOS. IT'S ON THOSE PEOPLE TO DECIDE WHAT TO DO. THEY COULD JUST AS EASILY NOT PAY THE BILL AND DECIDE TO DISCARD THE EMBRYOS, WHICH IS THE OTHER OPTION.

DR. TAYLOR: BUT I THINK -- SO WE ARE TALKING ABOUT A STAGED CONSENT PROCESS, AND I DON'T WANT US TO MISS THE FIRST STAGE BECAUSE REALLY ANYBODY FOR WHOM EMBRYOS ARE GOING TO BE FROZEN AND STORED POTENTIALLY FOR RESEARCH ARE GOING TO HAVE TO GO THROUGH THE INITIAL CONSENTING PROCESS. AND I JUST WANT TO MAKE SURE THAT THERE'S GOING TO BE ENOUGH TIME BUILT IN FOR THAT TO OCCUR WITH ALL OF THEIR CLINICAL CONSENTING AS WELL AND A GOOD MECHANISMS FOR THAT. I DON'T THINK -- WE DON'T WANT TO HAVE THE ONLY EMBRYOS THAT WE WOULD ULTIMATELY HAVE ACCESS TO WOULD BE CLINICALLY FROZEN EMBRYOS THAT THE COUPLE HAS NOW DECIDED NOT TO USE. THAT WOULD BE REALLY GOING BACK AFTER THE BARN DOOR IS

KIND OF CLOSED.

I THINK WE WANT TO HAVE CONSENT RIGHT UP FRONT AT SOME LEVEL, NOT THE FINAL CONSENT, BUT SOME LEVEL OF INFORMED, FREE, AND KIND OF UNDERSTOOD COMPREHENDED CONSENT. SO THAT NEEDS TO BE BUILT INTO THAT COUPLE OF WEEKS PERIOD THAT WE'VE BEFORE THE CASE IS EXECUTED.

DR. PRIETO: I WOULD AGREE THAT I THINK IN ANY INSTITUTION THAT'S CONSIDERING THAT SORT OF USE OF EMBRYOS DOWNSTREAM, THAT SOME INITIAL CONSENT SHOULD INVOLVE AT LEAST THE BASIC STATEMENTS, THAT ONE CONSIDERATION DOWN THE ROAD MAY BE THE USE OF EMBRYOS FOR RESEARCH, AND WE WANT YOU TO BE AWARE OF THAT AND THINK ABOUT IT WITHOUT THAT BEING THE FINAL STEP.

DR. EGGAN: OR, IN FACT, MORE EXPLICITLY THERE COULD BE A CHECK BOX OR SOMETHING LIKE THAT WHICH SAYS WOULD YOU -- DO YOU HAVE A RESEARCH DISPOSITION, AND WOULD YOU BE, IN PRINCIPLE, INTERESTED IN DONATING YOUR DISCARDED EMBRYOS OR OTHER MATERIALS FOR RESEARCH. AND IMMEDIATELY THAT PERSON COULD BE PROVIDED WITH THE PERTINENT INFORMATION.

DR. TAYLOR: THAT'S HOW I THINK A LOT OF PLACES ARE DOING IT.

VICE CHAIR LO: GIVE THEM THE OPTION TO RECEIVE MORE INFORMATION ABOUT THAT DURING THE INITIAL

EVALUATION. OTHER THOUGHTS?

DR. ROWLEY: I WANT TO MAKE TWO OR BRING UP TWO OTHER ISSUES. ONE, AND KEVIN COULD SPEAK TO THIS FAR MORE KNOWLEDGEABLY THAN I, BUT THERE NOW ARE REPORTS OF USING MATERIALS OTHER THAN OOCYTES FOR SOMATIC CELL NUCLEAR TRANSFER. THAT'S NOT DEALT WITHIN THE GUIDELINES RIGHT NOW AT ALL. AND IF, IN FACT, SOME OF THESE OTHER TECHNIQUES REALLY BECOME MORE WIDELY USED, THEN YOU CAN SAY OOCYTE DONATION IS ALMOST A MOOT POINT.

THE OTHER THING IN SOME OF THESE GUIDELINES THAT WE WERE SENT, YOU ARE GOING TO EXPLAIN TO THE PATIENT EXACTLY WHAT'S GOING TO BE DONE WITH THESE EMBRYOS AND THE RESULTANT CELL LINE. THAT'S ABSOLUTELY IMPOSSIBLE BECAUSE NO ONE KNOWS NOW WHAT SOME INVESTIGATOR IS GOING TO DO A YEAR OR TWO YEARS DOWN THE LINE WITH THOSE CELL LINES. SO I THINK THAT TO IMPLY THAT YOU CAN, A, TELL A PATIENT WHAT'S GOING TO HAPPEN IN TERMS OF RESEARCH OR ALLOW THE PATIENT TO SAY I DON'T WANT IT TO BE USED FOR THIS OR THAT KIND OF STUDY, WHICH IS, AGAIN, IN THESE GUIDELINES RIGHT NOW, THAT THE PATIENT CAN OPT OUT OF CERTAIN KINDS OF RESEARCH, I THINK THAT'S NOT GOING TO BE A PRACTICAL APPROACH. AND I WOULD URGE THAT WE NOT INCLUDE THAT IN THE GUIDELINES.

VICE CHAIR LO: JANET RAISED SEVERAL POINTS THAT WE NEED TO TRY AND KEEP TRACK OF.

DR. EGGAN: THERE IS JUST A BRIEF STATEMENT IN THE NAS GUIDELINES ENCOURAGING SCIENTISTS TO PURSUE ALTERNATIVES TO THE USE OF OOCYTES IN CREATING PATIENT-SPECIFIC OR GENETICALLY TAILORED STEM CELL LINES, AND I THINK IT'S IMPORTANT FOR US TO TRANSPOSE THAT TYPE OF MATERIAL INTO OUR GUIDELINES AND SUGGESTIONS, BUT I THINK IT'S ALSO IMPORTANT TO POINT THAT OUT THESE TECHNOLOGIES FOR THE TIME BEING ARE FAR FROM REPLACING THE TECHNIQUES THAT WE KNOW CAN WORK AND THAT HAVE BEEN DEVELOPED IN SOUTH KOREA AND THAT WERE USED TO CLONE DOLLY.

SO FOR THE TIME BEING, THE ONLY FUNCTIONAL MEANS THAT WE HAVE OF MAKING TAILORED CELL LINES IS THROUGH SOMATIC CELL NUCLEAR TRANSPLANTATION AND DONATED OOCYTES. AND, AGAIN, THE ONLY METHODOLOGY WHICH HAS WORKED IS SOMATIC CELL NUCLEAR TRANSPLANTATION INTO OOCYTES DIRECTLY AND SPECIFICALLY DONATED FOR RESEARCH. AND ATTEMPTS THUS FAR TO DO THAT WITH FAILED TO FERTILIZE OOCYTES HAVE NOT YET BEEN SUCCESSFUL.

SO I THINK FOR THE TIME BEING, IF THIS IS AN IMPORTANT PRIORITY, THEN WE HAVE TO PUT THE ETHICAL SAFEGUARDS IN PLACE TO MAKE SURE THE RESEARCH CAN GO

FORWARD AS WE KNOW IT CAN WORK.

AS FAR AS OPTING OUT, I THINK I TEND TO AGREE WITH JANET. AND IT'S GOING TO MAKE DOWNSTREAM USE OF ANY INDIVIDUAL CELL LINE EXTREMELY DIFFICULT, AND I THINK WE WOULD HOPE THAT ENOUGH PEOPLE WILL STEP FORWARD TO DONATE WITH A BROAD CONSENT THAT IT MIGHT BE SIMPLEST TO ONLY USE RESOURCES FROM THOSE DONORS TO MOVE FORWARD.

DR. KIESSLING: IT SEEMS LIKE FROM THIS DISCUSSION THAT IT'S GOING TO BE MORE FRUITFUL IF WE FOCUS ON THE TYPES OF THINGS BEING DONATED IN TERMS OF THE CONSENT. FOR INSTANCE, WHY DON'T WE JUST DISCUSS INFORMED CONSENT FOR WOMEN DONATING EGGS? AND THEN DISCUSS INFORMED CONSENT FOR COUPLES DECIDING TO DONATE LEFT-OVER EMBRYOS BECAUSE THE CIRCUMSTANCES, THEY'RE REALLY TWO VERY DIFFERENT PROCESSES.

DR. PRIETO: I JUST WANTED TO COMMENT ON WHAT KEVIN SAID. I THINK IT WOULD CERTAINLY BE PRACTICALLY DIFFICULT TO TRY TO PARSE OUT EVERY POTENTIAL AND IMPOSSIBLE REALLY POTENTIAL DOWNSTREAM USE OF MATERIALS. AND I THINK A BROAD GENERAL CONSENT IS WHAT WE WANT TO ASK PEOPLE FOR, POINTING OUT, AS THE NATIONAL ACADEMIES GUIDELINES OUTLINE SOME OF THIS, SOME OF THE POTENTIAL USES AND ALLOWING PEOPLE JUST TO OPT IN OR OUT AT THAT POINT.

VICE CHAIR LO: OKAY. I'M A LITTLE CONFUSED NOW.

DR. PRIETO: THE CONSENT SHOULD BE FAIRLY GENERAL AT THE BEGINNING AND INCLUDE THESE POTENTIAL USES, BUT NOT LIMITED TO, AND NOT GIVING PEOPLE MULTIPLE OPTIONS OF I'LL AGREE TO THIS, BUT NOT THAT, AND FAILING TO ADDRESS TECHNIQUES THAT DON'T EVEN EXIST YET, BUT THAT MIGHT TWO YEARS FROM NOW.

VICE CHAIR LO: AM I HEARING THAT WHAT YOU WOULD LIKE TO SEE IN TERMS OF FUTURE USES IS A CONSENT SAYING BASICALLY I'M GOING TO DONATE THESE. I UNDERSTAND THEY'RE GOING TO BE USED FOR STEM CELL LINES. AND IN THE FUTURE PEOPLE MAY WANT TO DO RESEARCH THAT WE CAN'T EVEN THINK ABOUT, CAN'T CONCEIVE OF TODAY, BUT AS LONG AS IT'S APPROVED BY THE IRB OR ESCRO OR WHATEVER, I GIVE MY CONSENT TO THAT RESEARCH AND NOT ALLOW THEM TO SAY, WELL, I DON'T WANT YOU TO USE IT -- DON'T USE CELLS DERIVED FROM ME TO BE INJECTED INTO NONHUMAN BLASTOCYSTS, FOR EXAMPLE, BUT I WILL ALLOW IT TO BE USED -- ARE YOU SAYING THAT WE WOULD LIKE TO HAVE DONATION OF OOCYTES FOR SORT OF ANY PURPOSE IN THE FUTURE THAT'S APPROVED BY AN ESCRO AND HAS SCIENTIFIC VALIDITY.

DR. EGGAN: THE OOCYTES ARE GOING TO BE DONATED FOR THE USE OF DERIVING STEM CELL LINES, AND

THOSE STEM CELL LINES, I THINK, SHOULD BE ABLE TO BE USED FOR MOLECULAR, CELLULAR, AND DEVELOPMENTAL BIOLOGY IN THE BROADEST SENSE.

DR. HALL: AS WELL AS FOR THERAPEUTIC.

DR. EGGAN: AND THE POTENTIAL FOR DEVELOPMENT OF THERAPEUTICS.

DR. TAYLOR: AGAIN, I GUESS IF WE HAD A TWO-STAGED CONSENT PROCESS, THE FIRST BEING FAIRLY GENERAL AND NOT ASKING FOR THESE SPECIFICS, BUT A SECOND STAGE IN WHICH YOU ARE ADDRESSING MORE SPECIFIC USES OF THE CELLS, I DO BELIEVE, AND THIS IS SOMETHING THAT WE DISCUSSED IN SAN FRANCISCO A COUPLE OF YEARS BACK, THAT THERE ARE GOING TO BE DONORS WHO ARE VERY INTERESTED IN DONATING MATERIALS TO UNDERSTAND EARLY HUMAN EMBRYOLOGY, BUT DON'T WANT TO SEE A PROPAGATED CELL LINE WITH THEIR GENETIC MATERIAL. SO I THINK THE OPPORTUNITY TO OPT OUT OF SPECIFIC THINGS SHOULD BE ONE OF THE RIGHTS THAT A DONOR HAS. AND THAT MAYBE IF WE HAD A MORE GENERAL CONSENTING PROCESS UP FRONT THAT WAS THEN LOOKED AT MORE SPECIFICALLY IN THE SECOND STAGE, WE COULD ACTUALLY SORT OUT WHERE THE CELLS GO FOR WHAT PURPOSES.

DR. EGGAN: BUT FOR THAT MIGHT NOT -- THAT SPECIFIC EXAMPLE, IT SEEMS LIKE THOSE ARE SEPARATE STUDIES WHICH MIGHT INVOLVE DIFFERENT TYPES OF CONSENT.

SO YOU'RE SAYING FOR THE DERIVATION, WOULD THERE BE CELL LINES DERIVED UNDER CERTAIN CIRCUMSTANCES WHICH WILL ONLY BE USED FOR CERTAIN PURPOSES. I SUPPOSE THAT'S POSSIBLE, BUT THEN THERE NEEDS TO BE SOME SORT OF ASTERISK PLACED BY THOSE CELL LINES. HOW WE DO THAT IN THE FUTURE. THAT CERTAINLY MAY BE SOMETHING WHICH FALLS ON THE INVESTIGATOR THEMSELVES AS FAR AS DISTRIBUTION OF THOSE CELL LINES INTO ANY PARTICULAR BANK.

DR. TAYLOR: I AGREE IT MAKES IT MORE COMPLICATED, BUT I THINK --

DR. EGGAN: MY GUESS I WOULD SAY THAT ONE MIGHT WANT AN ENTIRELY -- INSTEAD OF HAVING IT BE THAT IN A PARTICULAR CONSENT PROCESS, PEOPLE OPT FOR DIFFERENT COURSES, THAT SHOULD BE AN ENTIRELY DIFFERENT CONSENT STREAM IF THAT'S THE INTENTION. IF YOU WANT TO DO A PARTICULAR STUDY OR DERIVE CELL LINES FOR A PARTICULAR PURPOSE, THAT'S A TOTALLY DIFFERENT CONSENT PROCESS THAN IN GENERAL THE DERIVATION OF LINES FOR WHICH THE INTENTION IS BROAD DISTRIBUTION.

MS. FEIT: HOW ARE YOU GOING TO TRACK THAT? I MEAN HOW WOULD TRACK -- IF I'M THE DONOR, HOW ARE YOU GOING TO TRACK MY DONATION THROUGH ALL THAT? I THINK THAT WOULD BE VERY DIFFICULT. I THINK YOUR FIRST STATEMENT ABOUT KEEPING IT BROAD, BUT SAYING THAT IT

WILL BE USED FOR SCIENCE IN THESE MANNERS, AND THAT ANY TIME THAT MY DONATION WILL BE USED IN APPROVED RESEARCH VALIDATED BY THESE ORGANIZATIONS, AND ONLY THAT TYPE OF RESEARCH, I THINK I HAVE A COMFORT LEVEL THAT I'VE DONE THE RIGHT THING. BUT I THINK YOU HAVE TO ASK YOURSELF HOW ARE WE GOING TO TRACK AN INDIVIDUAL PERSON'S REQUEST THROUGH ALL OF THE DIFFERENT OPPORTUNITIES THAT MIGHT OCCUR AS A RESULT OF THE DONATION. THAT'S THE ONLY QUESTION I HAVE.

DR. EGGAN: I GUESS I CAN THINK OF ONE SPECIFIC EXAMPLE TO SORT OF ACTUALLY DRAW A BROADER LINE BETWEEN TWO DIFFERENT CONSENT PROCESSES. ONE PERSON MIGHT BE COMFORTABLE WITH DONATING THEIR EMBRYOS FOR THE DERIVATION OF STEM CELL LINES WHICH WILL BE PROPAGATED OVER A VERY LONG PERIOD OF TIME AND COULD HELP MANY DIFFERENT SCIENTISTS. ANOTHER STUDY OF INTEREST WOULD BE TO SAY TAKE HUMAN PREIMPLANTATION EMBRYOS AND DO SOME EXPERIMENTAL STUDY ON THOSE EMBRYOS THEMSELVES TO BETTER UNDERSTAND THE EMBRYO, WHICH COULD HELP ONE LATER IN DERIVING STEM CELL LINES, THAT EXPERIMENT ITSELF DOES NOT -- IT'S AN EMBRYOLOGICAL EXPERIMENT. IT DOESN'T RESULT IN THE GENERATION OF A STEM CELL LINE ITSELF; AND IN THE PROCESS OF THE EXPERIMENT, THE EMBRYO IS DESTROYED. THIS WOULD BE AN ENTIRELY TYPE OF CONSENT PROCESS. AND PEOPLE WHO WOULD

CONSENT TO A MAY NOT CONSENT TO B. AND I THINK THAT'S THE SORT OF THING THAT YOU ARE POINTING TOWARDS.

SO I THINK THOSE ARE SEPARATE --

DR. TAYLOR: YOU CAPTURE BOTH GROUPS.

DR. EGGAN: BUT I THINK -- I DON'T KNOW IF ONE CAN CAPTURE BOTH GROUPS UP FRONT.

VICE CHAIR LO: IT SOUNDS, IF I CAN TRY AND PURSUE THIS, I THINK IT'S AN IMPORTANT POINT. ON THE ONE HAND, YOU ARE SAYING IF YOU'RE GOING TO ASK FOR DONATION TO DERIVE A NEW EMBRYONIC STEM CELL LINE, WE ARE GOING TO SAY YOU HAVE -- THE DONOR MUST UNDERSTAND THAT THOSE STEM CELL LINES COULD BE USED FOR A LOT OF THE DIFFERENT PURPOSES, SOME OF WHICH WE MAY NOT BE ABLE TO PREDICT, BUT THEY WILL BE OVERSEEN BY THIS ESCRO MECHANISM. IF YOU ARE NOT COMFORTABLE WITH THAT, THERE'S STILL ANOTHER OPTION TO DONATE EMBRYOS FOR ALLY SCIENTIFIC PROJECTS THAT DO NOT INVOLVE CREATION OF STEM CELL LINES, BUT MAY INVOLVE GENETIC RESEARCH, DEVELOPMENTAL RESEARCH. BECAUSE WE DON'T EXPECT THOSE CELLS TO BE PROPAGATED IN THE LAB, WE SHOULD BE ABLE TO SAY WHAT THEY WILL BE USED FOR IN A MUCH MORE CLOSED-ENDED WAY, BUT THAT WOULD BE DIFFERENT TYPES OF RESEARCH.

DOES THAT CAPTURE, ROB, WHAT YOU WERE CONCERNED WITH?

DR. TAYLOR: THAT SOUNDS GOOD TO ME. JUST FOR MARCY, I THINK THAT THE TRACKING MECHANISM OF HOW THESE LEAST STEM CELL LINES ARE GOING TO BE USED, I SEE THAT FALLING TO THE ESCRO. I THINK IT'S GOING TO BE ACTUALLY ONE OF THE IMPORTANT RESPONSIBILITIES OF THE ESCRO, NOT ONLY TO MAINTAIN A RUNNING LIST OF THE KINDS OF CELLS THAT YOU HAVE IN YOUR SYSTEM, BUT ALSO TO BE SURE THAT THE THINGS THAT THEY'RE CONSENTED FOR ARE WHERE THEY'RE ACTUALLY GOING.

DR. EGGAN: I WOULD SAY THAT THE REAL RESPONSIBILITY LIES WITH THE INVESTIGATOR, AND THAT THERE SHOULD BE OVERSIGHT BY THE ESCRO.

VICE CHAIR LO: AGAIN, THE OTHER THING, WE NEED THIS TO TIE EVENTUALLY TO BANKING ISSUE. IF WE'RE DEPOSITING MATERIALS, INCLUDING STEM CELL LINES, IN BANKS, THEN PRESUMABLY I'M HEARING THAT WE DON'T WANT THE BANK TO HAVE TO TRY AND KEEP TRACK OF YOU CAN USE THIS LINE FOR PURPOSE ONE AND SEVEN, BUT NOT FOR TWO, SIX, AND 18. WE PREFER THAT ALL THOSE BE USED FOR ANYTHING AS LONG IT'S APPROVED BY THE ESCRO AND HAS SCIENTIFIC MERIT.

DR. ROWLEY: IT IS POSSIBLE FOR BANKS TO ACTUALLY SAY THAT THEY WILL ONLY ACCEPT CELL LINES THAT HAVE A BROAD CONSENT FORM FOR USE IN MANY DIFFERENT EXPERIMENTS, INCLUDING THOSE THAT WE DON'T ENVISION AT

THE PRESENT TIME. AND I THINK WE'RE GOING TO GET OURSELVES IN SO MANY KNOTS, THAT IT'S GOING TO BE JUST AN UNUSABLE, UNENFORCEABLE PROCESS. I THINK WE'VE GOT TO AVOID THAT BECAUSE WE DON'T FLOW WHAT THE FUTURE IS GOING TO BE. AND TO HAVE TO GO BACK AND REVISE THIS EVERY TIME SOME NEW NUANCE COMES FORWARD IS, I THINK, A MISTAKE.

VICE CHAIR LO: SO THEN IT STRIKES ME THIS SOUNDS TO ME LIKE SORT OF A KEY ELEMENT, YOU REALLY WANT TO MAKE SURE PEOPLE UNDERSTAND WHEN THEY DONATE THAT THERE'S LOT OF PURPOSES THAT WE CAN'T ANTICIPATE, AND YOU HAVE TO FEEL COMFORTABLE THAT THE SCIENTISTS AND THE OVERSIGHT BODIES WILL BE RESPONSIBLE IN ONLY ALLOWING RESEARCH THAT'S SCIENTIFICALLY MERITORIOUS AND ETHICALLY ACCEPTABLE.

DR. TAYLOR: AT THE RISK OF THROWING IN ANOTHER KNOT, I THINK THAT THE RECONTACT ISSUE IN THIS PARTICULAR FIELD IS ABSOLUTELY CRITICAL. WE REALLY DON'T KNOW WHAT THE FUTURE IS. WE REALLY DO NEED TO HAVE MECHANISMS TO GET BACK TO INDIVIDUALS AND FIND OUT BOTH HEALTH INFORMATION ABOUT THE DONORS AS WELL AS CONSENTING KINDS OF ISSUES, PARTICULARLY AS WE GO FORWARD. SO I CAN ENVISION THAT THERE WOULD BE PEOPLE WHO DON'T WANT TO BE RECONTACTED AND DO WANT TO DONATE, AND THERE CAN BE SOME SPECIFIED END POINTS THERE, BUT I

WOULD HOPE THAT THOSE DONORS THAT ARE WILLING TO BE RECONTACTED WILL FORM A SUBSET OF SAMPLES THAT CAN THEN BE USED IN MORE INNOVATIVE WAYS.

VICE CHAIR LO: CAN SOMEONE HELP ME UNDERSTAND THE PSYCHOLOGY OF DONORS, I SUPPOSE. HOW LIKELY IS IT THAT SOMEONE WHO DECIDES TO DONATE FOR THIS FUTURE RESEARCH WOULD SAY BUT I DON'T WANT TO BE RECONTACTED TO GIVE FURTHER INFORMATION THAT YOU TELL ME MIGHT BE USEFUL TO ASSURE THE SAFETY IN TRANSPLANTATION EXPERIMENTS. I'M TRYING TO GET -- BECAUSE IT STRIKES ME THAT IF WE FOLLOW THE PRINCIPLE, THAT WE'D REALLY LIKE TO HAVE CELL LINES THAT ARE UNRESTRICTED IN TERMS OF DONOR PREFERENCES BECAUSE IT WOULD GIVE YOU THE MOST FLEXIBILITY TO CARRY OUT DIFFERENT TYPES OF RESEARCH. ARE WE LOSING A LOT OF CELL LINES BECAUSE DONORS SAY, WELL, THAT GOES A LITTLE BIT TOO FAR. I WILL LET YOU DO ANY TYPE OF RESEARCH, BUT I DON'T WANT TO BE RECONTACTED. DO YOU HAVE ANY SENSE OF THAT?

MS. FEIT: HAVING WORKED WITH ORGAN DONORS A LOT, I CAN TELL YOU THAT IT'S VERY GRATIFYING, IT'S A VERY STRESSFUL DECISION, AND IT'S USUALLY TRAGIC TO MAKE A DONATION. BUT ONCE IT'S DONE MANY TIMES THEY GET A WONDERFUL LETTER OR CALL FROM THE NETWORK TELLING THEM WHAT HAPPENED. AND IT'S VERY REWARDING TO KNOW

THAT SOMETHING VERY POSITIVE CAME OUT OF A SITUATION.

I THINK IN TERMS OF THE GENERAL THINKING OF PEOPLE WHO MAKE THESE DECISIONS IS THAT WE CAN MAKE AN ASSUMPTION HERE THAT THE RESEARCH WE'RE LOOKING FORWARD TO IS GOING TO HAVE SOME VERY POSITIVE THINGS HAPPEN, THERAPIES, CURES, CHANGES IN HOW WE APPROACH DISEASE. SO HAVING A RECONTACT IS A VERY SUPPORTIVE THING TO ENCOURAGE DONATION.

IT'S BEEN MY IMPRESSION IF THEY AGREE TO BE CONTACTED, THAT THAT'S A VERY POSITIVE THING.

DR. EGGAN: I ALWAYS HATE TO BE CONTRARY, BUT I THINK CERTAINLY IN THE CASE OF ORGAN DONATION, THAT MAKES A LOT SENSE BECAUSE IN MANY CASES IT'S THIS INDEPENDENT DECISION TO DO SOMETHING PHILANTHROPIC. WITH AT LEAST DONATION OF DISCARDED EMBRYOS AFTER IVF, I THINK IT'S IMPORTANT TO NOTE THAT, ALTHOUGH DISSOCIATED FROM THE ORIGINAL PROCESS OF IVF, FOR MANY COUPLES IT'S, I THINK, REASONABLE TO SAY THAT IT MAY BE THE MOST DIFFICULT TIME IN THEIR LIVES, THE PROCESS OF UNDERGOING ASSISTED REPRODUCTION. AND AT LEAST SOME IVF CLINICIANS THAT I'VE TALKED TO FEEL VERY UNCOMFORTABLE ABOUT RECONTACTING PATIENTS AND CLIENTS WHO HAVE UNDERGONE THAT PROCESS, WHICH HAS NOW DISTANCE IN THEIR LIFE. SO CERTAINLY SOME TYPES OF DONORS, IT WOULD BE VERY APPROPRIATE TO RECONTACT. AND FOR OTHERS

I THINK WE SHOULD BE MORE CAREFUL AS TO WHAT THAT'S GOING TO MEAN TO THEM TO SORT OF DREDGE THAT PERIOD OF THEIR LIFE UP AGAIN. I'D LOVE TO HEAR ANN'S OPINION ON THAT.

DR. KIESSLING: AT THE RISK OF SOUNDING REDUNDANT, THIS IS GOING TO BE MUCH MORE CONSTRUCTIVE IF WE SEPARATE OUT WHAT WE'RE TALKING ABOUT. I THINK RECONTACTING A WOMAN WHO COMES FORWARD TO DONATE HER EGGS FOR STEM CELL RESEARCH IS A VERY DIFFERENT PROCESS FROM RECONTACTING COUPLES THAT HAVE GONE THROUGH IVF. I THINK TO GET THIS DISCUSSION REALLY WRAPPED UP, I THINK WE WANT TO SEPARATE OUT WHAT IT IS WE'RE CONSENTING TO OR WHO'S CONSENTING TO WHAT. WE KEEP LUMPING THESE TWO THINGS TOGETHER.

VICE CHAIR LO: LET'S KEEP FOCUSED NOW ON THE OOCYTE DONORS, WHICH I THINK ARE THE MOST COMPLEX AND SORT OF CONTROVERSIAL IN SOME WAY.

DR. CIBELLI: I THINK ANN READ MY MIND. I WANTED TO SAY THAT. THAT WE'RE JUST MIXING EVERYTHING. YOU'RE MIXING DONATION OF FROZEN EMBRYOS WITH EGGS OR WITH GAMETES, AND YOU THROW ANOTHER ONE, SOMATIC CELLS FROM PATIENT TO HAVE SOME SORT OF DISEASE. SO JUST PICK ONE. AND I THINK WE ARE GOING TO HAVE A SEPARATE CONSENT FORM FOR DIFFERENT THINGS.

DR. TAYLOR: BERNIE, I WOULD SAY IF WE'RE

GOING TO PICK OOCYTE DONATION AS THE ONE TO START WITH, I THINK IT SHOULD BE FURTHER SEPARATED FROM DONORS WHO ARE CONTRIBUTING OOCYTES TO AN IVF CYCLE VERSUS THOSE WHOA RE STRICTLY DONATING TO A SCIENTIFIC PROTOCOL. BECAUSE THOSE OOCYTES, I THINK, ARE SIMILAR TO THE EMBRYOS THAT ANN THINKS ARE BEING CONFUSED INTO THIS.

VICE CHAIR LO: RIGHT. WHY DON'T WE START WITH DONATION SOLELY EXPRESSLY FOR THE PURPOSE OF RESEARCH. SO I GUESS THAT'S SORT OF SIMILAR TO WHAT, ANN, YOUR GROUP IS SET UP TO DO. IT STRIKES ME THAT MAYBE IF WE SORT OF GO THROUGH SOME OF THE THINGS WE'VE BEEN TALKING ABOUT, WE WOULD WANT THERE TO BE A TIME-OUT PERIOD. WE WOULD WANT THERE TO BE SOME SORT OF ASSESSMENT THAT THEY UNDERSTAND CRUCIAL FEATURES. IT SEEMS LIKE ONE OF THE CRUCIAL FEATURES IS THAT A LOT RESEARCHERS ARE GOING TO HAVE ACCESS TO MATERIALS DERIVED FROM YOUR DONATION, THAT WE CAN'T REALLY EVEN PREDICT, AND WE DON'T WANT THERE TO BE ANY RESTRICTIONS ON THAT, AND THAT THERE ALSO THE POSSIBILITY OF RECONTACT.

AND SO IN THAT CONTEXT, MAYBE WE SHOULD JUST STOP THERE. DO WE WANT TO HAVE A COOLING OFF PERIOD FOR THAT TYPE OF OOCYTE DONATION -- NOT COOLING OFF PERIOD. MARCY, YOU TERM WAS TIME-OUT PERIOD, WHICH SEEMS TO BE FAIRLY EASY TO BUILD IN BECAUSE IT'S AN

ELECTIVE CYCLE. AND THAT COULD EITHER BE A TIME-OUT PERIOD OR YOU A HAVE TO -- WE'RE NOT GOING TO CONTACT YOU. YOU HAVE TO CONTACT US. WHY DON'T WE START WITH THAT, AND WE'LL JUST TRY AND CHIP AWAY AT THESE ISSUES ONE BY ONE.

DR. TAYLOR: I WAS JUST GOING TO SAY THAT WHAT'S NICE ABOUT THIS IS IT REMOVES THE COERCION FACTOR FROM THE CLINICAL CARE. IT'S NOT LIKE A WOMAN IS GOING TO BE UNDERGOING IVF FOR HER CLINICAL CARE, AND SHOULD SHE DO HER -- IT DOESN'T REMOVE THE INVESTIGATOR'S POTENTIAL COERCION AS WE'VE KIND OF RECENTLY HEARD IN THE LITERATURE RECENTLY. SO I THINK THAT'S JUST -- THERE IS STILL COERCIVE ELEMENT. IT SEEMS TO ME THAT A TIME-OUT PERIOD WOULD BE A APPROPRIATE.

VICE CHAIR LO: ANY OBJECTIONS TO A TIME-OUT PERIOD?

SECOND QUESTION, I GUESS, WOULD BE DO WE WANT THE PERSON OBTAINING CONSENT, WOULD YOU WANT THERE TO BE SOME ASSESSMENT OF WHAT THE DONOR ACTUALLY UNDERSTANDS AS OPPOSED TO WHAT WAS DISCLOSED? IS THAT WHAT SOMETHING WE WANT TO BUILD IN?

DR. EGGAN: IT'S HARD TO DO THAT. WHAT WOULD BE THE MECHANISM FOR DOING THAT TO REALLY TRY TO UNDERSTAND WHAT SOMEONE ELSE UNDERSTANDS, AND THE

PROCESS OF INFORMED CONSENT IS TRICKY.

DR. KIESSLING: I ACTUALLY THINK THAT'S REALLY IMPORTANT. AND I THINK THAT, AS I MENTIONED EARLIER, I THINK IT'S GOT TO BE BROKEN INTO TWO PIECES. SHE HAS TO UNDERSTAND WHAT THE RISKS ARE TO HER, AND I THINK THAT'S THE MOST CRITICALLY IMPORTANT, THAT SHE'S BEEN READ WHAT THESE RISKS ARE, BUT THAT SHE REALLY UNDERSTANDS THAT THIS IS NOT WITHOUT RISK, AND THAT SHE'S ASSUMING THOSE RISKS OF HER OWN FREE WILL.

AND THEN I THINK SHE NEEDS TO UNDERSTAND THE SCIENCE OF WHAT MIGHT HAPPEN. I THINK THOSE ARE TWO PIECES, AND I ACTUALLY THEY CAN BE PRETTY EASILY ASSESSED.

VICE CHAIR LO: ONE NOTION, KEVIN, MIGHT BE JUST TO ASK THE QUESTION AND TO SAY YOU'VE GOT TO GET THE RIGHT ANSWERS. IF WE COULD FLIP UP TO ONE OF THE LAST SLIDES WHERE I HAD SUGGESTED SOME LANGUAGE.

SO THIS IS SORT OF AN ATTEMPT TO SAY THIS IN REGULATORY TERMS. RESEARCHERS OBTAINING INFORMED CONSENT FOR THE DONATION OF OOCYTES -- WE NEED TO AMEND IT -- SOLELY FOR RESEARCH, NOT ALSO SIMULTANEOUSLY FOR CLINICAL IVF. SO ASCERTAIN THAT THE DONORS UNDERSTOOD THE ESSENTIAL FEATURES OF RESEARCH. RESEARCHERS MAY MEET THIS REQUIREMENT BY FOLLOWING A PROCESS THAT IS APPROVED BY THE RELEVANT IRB OR ESCRO. THE ESSENTIAL

FEATURES THAT MUST BE UNDERSTOOD SHALL INCLUDE AT LEAST, AND THEN THE LIST IS ON THE NEXT SLIDE, AND IT GIVES THE IRB, ESCRO OF THE INSTITUTION TO REQUIRE DONORS TO UNDERSTAND THE ADDITIONAL ISSUES.

AND THE NEXT SLIDE, KATE, THESE NUMBER OF THINGS ARE ALL SUGGESTIONS, AND THEY'RE ONLY SUGGESTIONS. ONE, EMBRYOS WILL BE CREATED FOR RESEARCH, WHICH WILL NOT BE USED FOR REPRODUCTIVE PURPOSES. THERE ARE MEDICAL RISKS IN OOCYTE DONATION. AND WE NEED TO THINK THROUGH HOW SPECIFIC, BUT ONE THING TO SAY, THAT THEY'RE GOING TO GET DETAILED INFORMATION ON THESE RISKS. I DON'T KNOW WHETHER YOU ACTUALLY WANT TO SAY YOU HAVE TO UNDERSTAND THERE'S RISK OF HYPEROVULATION SYNDROME. THE RESEARCH WILL NOT BENEFIT DONORS OR ANY OTHER INDIVIDUALS DIRECTLY AT THIS TIME. AND, FOUR, STEM CELL LINES DEVELOPED FROM THEIR OOCYTES WILL BE GROWN IN THE LAB AND SHARED WITH OTHER RESEARCHERS. AND I THINK THERE WE NEED TO SAY SOME MORE ABOUT THE WHOLE RANGE OF PURPOSES, SOME WHICH WE CAN'T PREDICT.

THE STEM CELL LINES MAY BE PATENTED, BUT DONORS WILL NOT SHARE IN ANY REVENUE. DONORS RECEIVE NO PAYMENT EXCEPT FOR REIMBURSEMENT FOR OUT-OF-POCKET EXPENSES.

IF STEM CELLS ARE TRANSPLANTED INTO PATIENTS,

RESEARCHERS MAY WANT TO CONTACT YOU TO GET MORE INFORMATION ABOUT YOUR HEALTH. AND POTENTIAL DONORS ARE FREE TO DECLINE TO DONATE OOCYTES FOR RESEARCH WITHOUT ANY NEGATIVE IMPACT ON THEIR CLINICAL CARE.

AGAIN, SOME OF YOU MAY SAY, WELL, NO, SIX IS NO GOOD OR THREE IS NO GOOD, BUT THESE ARE THE KINDS OF THINGS THAT ONE MIGHT THINK ABOUT.

DR. EGGAN: I'M NOT WORRIED ABOUT WHAT'S GOOD OR NOT GOOD, BUT HOW DO YOU ADMINISTER THIS TEST. THAT'S I'M WORRIED ABOUT IS HOW DO YOU -- IS IT YOU GIVE THEM A WRITTEN TEST, AND THEY HAVE TO GET A HUNDRED PERCENT RIGHT, AND IF THEY DON'T, YOU HAVE TO RETEST THEM. WHAT'S THE MECHANISM?

MS. FEIT: WE DO IT ALL THE TIME. WE ASSESS THE INDIVIDUAL'S KNOWLEDGE OF UNDERSTANDING A PROCEDURE. WE DO MAJOR SURGERIES, AND WE PUT THEM THROUGH A WHOLE BUNCH OF INFORMATION ABOUT THE RISKS, ANESTHESIA RISKS, RISKS AFTER. SO I THINK THERE ARE WAYS TO DO THAT.

DR. EGGAN: BUT I GUESS AS A RESEARCHER, WHAT IS THE MECHANISM? I REALLY WANT TO KNOW. WHEN I'M BUILDING MY RESEARCH STUDY AND THIS IS AN IMPORTANT COMPONENT OF THE STUDY, WHAT IS THE MECHANISM? IS IT A BACK-AND-FORTH CONVERSATION WITH THEM? IS IT SOME KIND OF TEST THAT I CAN SCORE, WHICH I CAN HAND TO MY IRB,

WHICH SAYS ABSOLUTELY OBJECTIVELY THIS PERSON UNDERSTANDS. I'M REALLY INTERESTED IN GETTING DOWN -- I CAN RECOGNIZE THAT IT'S IMPORTANT, AND I AGREE IT'S IMPORTANT. I WANT TO GET DOWN TO KNITTY GRITTY OF HOW WE DO IT.

MS. FEIT: IF IT WERE ME, I WOULD HAVE ONE OF MY RESEARCH NURSES DEVELOP AN INTERACTIVE MODULE, WHO PUTS THE DONOR PRIVATELY THROUGH AND ASSESS WHETHER THE DONOR REALLY UNDERSTANDS THE INFORMATION WE GAVE THEM. AND THAT'S REALLY HOW I WOULD APPROACH IT, SIMPLISTICALLY. I THINK THAT, AGAIN, DEFINITIONS, MAKING SURE THE DONOR UNDERSTANDS SOME OF THE DEFINITIONS, AND THEN JUST PUTTING THEM BACK THROUGH THE QUESTIONS, AND IT CAN BE DONE IN AN INTERACTIVE MODULE THAT THE DONOR SAYS YES, NO, I UNDERSTAND, YES. AND THEN YOU DO ASCERTAIN. THEY CAN SAY, NO, I DON'T UNDERSTAND THIS QUESTION. I DON'T UNDERSTAND THIS CONCEPT.

DR. EGGAN: IS IT ENOUGH TO SAY -- IF THEY SAY THEY UNDERSTAND IT -- WHAT I'M DRIVING AT IS BECAUSE THEY SAY THEY UNDERSTAND IT DOESN'T MEAN THEY DO. THIS IS THE COMPLICATION. THAT'S WHAT TRYING TO GET AT THE BOTTOM OF.

VICE CHAIR LO: THESE ARE VERY IMPORTANT PRACTICAL QUESTIONS.

DR. EGGAN: SIGNING AT THE BOTTOM OF THE CONSENT FORM SAYS THEY UNDERSTAND, RIGHT, SO IT'S NOT REALLY ANY DIFFERENT.

DR. KIESSLING: KEVIN, THE PERSON THAT WE FOUND TO DO THIS FOR US IS AN ATTORNEY WHO IS ALSO A NURSE, WHO ALSO WENT THROUGH INFERTILITY TREATMENT. AND SHE TALKS TO THE DONORS ONE ON ONE AND SIMPLY ASKS THEM. SHE'S A TRAINED QUESTION ASKER, SO SHE SIMPLY ASKS THEM QUESTIONS. DO YOU UNDERSTAND THE RISKS? WHAT ARE THE TOP THREE RISKS? DO YOU UNDERSTAND WHATEVER? AND THEN THAT PERSON PROVIDES A REPORT.

I THINK IT'S ALSO POSSIBLE TO DRAW UP A PAPER TEST THAT WOULD ALSO SATISFY THAT. THIS IS VERY COMPLICATED. WE HAVEN'T DRAWN UP A PAPER TEST BECAUSE WE'VE BEEN VERY SATISFIED THAT THIS INDEPENDENT PERSON WHO GETS TO TALK TO THE DONOR IN PRIVATE KIND OF IS TRAINED TO UNDERSTAND IF THIS PERSON IS REALLY COMFORTABLE WITH WHAT THEY'RE DOING.

A BIG SIDELINE CONCERN ABOUT THIS IS THAT THIS DONOR IS DOING THIS FREE OF COERCION FROM ANYONE IN HER FAMILY. SO THIS INDEPENDENT MONITOR IS ABLE TO FIGURE OUT DOES SHE UNDERSTAND WHAT SHE'S BEEN TOLD? AND THIS IS FREQUENTLY TWO OR THREE MONTHS AFTER SHE INITIALLY READ THE CONSENT FORM. THIS IS NOT TWO OR THREE DAYS. IT TAKES MONTHS TO GET THROUGH THE

SCREENING PROCESS. SO IF SHE STILL UNDERSTANDS IT, IF SHE REMEMBERS IT, IF SHE STILL UNDERSTANDS IT, IF SHE KNOWS THE RISKS, THE MONITOR CAN FIGURE THAT OUT PRETTY COMFORTABLY.

YOU COULD ALSO DEFINE A SET OF QUESTIONS THAT YOU WOULD LIKE ASKED AND THE ANSWERS THAT YOU EXPECT, BUT THIS IS REALLY NOT HARD TO DO.

VICE CHAIR LO: THE OTHER THING, I GUESS, WE SHOULD TRY AND DISTINGUISH BETWEEN REGULATIONS AND BEST PRACTICES. MY SENSE IS, KEVIN, YOU'RE GOING TO WANT TO DO THIS REALLY WELL AND PUT A FAIR AMOUNT OF EFFORT, GET SOME COLLABORATORS WHO ARE PSYCHOLOGISTS. THAT'S GREAT. I THINK YOU AND ANN AND GROUPS LIKE YOU SHOULD PUBLISH HOW YOU DO IT AS A MODEL, AS A TEMPLATE.

IN REGULATION, I'M NOT SURE WE WANT TO BE TOO PRESCRIPTIVE AT THIS POINT. THAT'S WHY ONE SUGGESTION WAS TO SAY THESE ARE THE TOPICS. ULTIMATELY IT IS UP TO YOUR IRB OR ESCRO TO SAY WE APPROVE OF YOUR PLAN. BUT TO GIVE A LOT OF FLEXIBILITY AT THIS POINT TO ALLOW DIFFERENT INVESTIGATIVE TEAMS TO FIGURE OUT HOW TO BEST DO THIS. I THINK THERE ARE CLEARLY MODELS FROM THE TRANSPLANT SETTING WHERE, FOR EXAMPLE, PEOPLE WHO DO LIVE DONORS OF LIVER SEGMENTS AND KIDNEYS GO THROUGH THIS VERY, VERY COMPLICATED PROCESS WHERE ALL THESE ISSUES GET TALKED ABOUT IN DETAIL.

THE OTHER EXTREME IN AIDS CLINICAL TRIALS IN DEVELOPING COUNTRIES WHERE THERE'S A LOT OF CONCERN THAT PEOPLE DON'T UNDERSTAND THAT IT'S RESEARCH AND NOT CLINICAL CARE, AND THEY CAN STILL GET AIDS EVEN THOUGH THEY'RE GETTING A VACCINE. IT'S A PAPER AND PENCIL QUESTIONNAIRE. IT'S A YES/NO. SO IT'S REALLY BASIC, AND THAT MAY BE TOO BASIC FOR HERE.

SO THERE'S A WHOLE GAMUT, THAT WE MAY NOT WANT TO BE TOO PRESCRIPTIVE.

DR. ROWLEY: IF I CAN JUST COMMENT ON THAT FOR A MINUTE. IN THE MATERIAL WE WERE SENT, THERE WAS A PLEA, THAT AT LEAST IN CALIFORNIA, THAT IT BE UNIFORMLY DONE AND THAT ONE INSTITUTION DOESN'T HAVE A SINGLE QUESTION -- THAT WAS THE EXAMPLE GIVEN IN THE MATERIALS DISTRIBUTED -- AND SOME OTHER INSTITUTION HAVE A 20-QUESTION QUESTIONNAIRE. SO YOUR IDEA IN ONE SENSE IS APPEALING, BERNIE, BUT AT LEAST, AS I SAY, THE MATERIAL WE WERE SENT, THERE WAS THE IDEA EXPRESSED THAT THERE SHOULD BE UNIFORMITY WITHIN THE STATE OF CALIFORNIA.

VICE CHAIR LO: ABSOLUTELY. THANK YOU.

DR. CIBELLI: GOING BACK TO THE CONSENT FORM. WE'RE TALKING ABOUT DONATING EGGS EXCLUSIVELY. ARE YOU GOING TO TELL THEM IN THE CONSENT FORM WHAT ARE YOU GOING TO DO WITH THE EGGS, OR WHAT YOU'RE NOT GOING TO

DO WITH THE EGGS? SO HOW MUCH DETAIL ARE YOU GOING TO PROVIDE ON THAT CONSENT FORM ABOUT THE USE OF THE EGGS? YOU CAN DO MANY THINGS. YOU CAN JUST DESTROY THEM RIGHT AWAY AND DO SOME PROTEOMIC ANALYSIS, OR YOU CAN JUST DO NUCLEAR TRANSFER, PRODUCE A CELL LINE, AND IT WILL BE USED FOR MANY, MANY YEARS. SO WHAT ARE THE THINGS YOU ARE GOING TO TELL THEM?

VICE CHAIR LO: AGAIN, I THOUGHT WE WERE TALKING PRIMARILY IN THE CONTEXT OF DERIVING A STEM CELL LINE FROM THEIR EGGS, BUT YOU'RE RIGHT. OTHER RESEARCHERS MAY WANT TO DO SOMETHING THAT DOES NOT INVOLVE A STEM CELL LINE CREATION.

DR. CIBELLI: WE CAN CREATE A LINE BY FERTILIZATION, NUCLEAR TRANSFER, YOU CAN DO IT BY PARTHENOGENESIS, SO HOW MUCH INFORMATION --

VICE CHAIR LO: THOSE ARE ISSUES THAT CERTAINLY THE IRB NEEDS TO DEAL WITH. I GUESS THE QUESTION IS DO WE WANT TO BE THAT SPECIFIC IN THE REGULATIONS? THAT'S A CHOICE POLICY I THINK WE NEED TO MAKE.

DR. CIBELLI: WHAT ARE THE RIGHTS OF THE DONOR? ISN'T SHE ENTITLED TO KNOW, OR IT'S JUST TRUST TO THE ESCRO THAT THEY ARE GOING TO DO THE RIGHT THING?

DR. EGGAN: I WOULD THINK THAT IT'S NOT ENOUGH TO ASK A WOMAN TO DONATE HER EGGS FOR STEM CELL

RESEARCH IN GENERAL. AND THE PROXIMAL EVENT SHOULD BE WELL PRESCRIBED IN THE CONSENT. SO WE'RE ASKING YOU TO DONATE YOUR EGGS FOR A SOMATIC CELL TRANSPLANTATION TO MAKE A CELL LINE WHICH WILL BE BROADLY USED, OR WE'RE ASKING YOU TO DONATE YOUR EGGS FOR PARTHENOGENESIS, OR MAYBE PERHAPS IN THE SAME CONSENT FORM, ONE OR THE OTHER IF YOUR INTENT WITH THAT.

BOTH OF THOSE HAVE A RELATIVE -- THE GOAL IS THE SAME, TO DERIVE THE CELL LINE WHICH WILL BE USED BROADLY, BUT THEN IT SEEMS LIKE IT'S FORT OF A DIFFERENT THING TO DONATE YOUR EGG, WHICH THEN MAY BE DESTROYED FOR AN EXPERIMENT AND A NEW STEM CELL LINE WILL BE MADE. I DON'T KNOW.

DR. HALL: DNA CONTRIBUTION IS DIFFERENT FOR ONE THING.

VICE CHAIR LO: CERTAINLY I GUESS IF YOU ARE DEALING WITH FRESH OOCYTES, YOU KNOW WHAT YOU ARE GOING TO BE DOING WITH IT, RIGHT. IT'S NOT AN OPEN-ENDED THING. THERE'S ONLY SEVERAL EXPERIMENTS YOU'RE LIKELY TO DO AT THAT POINT BECAUSE YOU HAVE TO BE SET UP TO USE THE OOCYTES RIGHT AWAY.

DR. TAYLOR: I WAS JUST GOING TO SAY THAT IRB'S REQUIRE A CERTAIN LEVEL OF EXPLANATION ABOUT THE PROTOCOL. I DON'T THINK THIS PROCESS IS GOING TO MOVE BEYOND AN EXISTING EXPECTATION THAT DONORS ARE GOING TO

HAVE A PRETTY CLEAR IDEA ABOUT WHAT THE EXPERIMENTAL PROTOCOL INVOLVING THEIR MATERIALS IS GOING TO INCLUDE.

DR. CIBELLI: SO WHAT ARE YOU SAYING, THAT WE DON'T HAVE TO WORRY ABOUT?

DR. TAYLOR: I THINK THAT YOUR IRB IS GOING TO MAKE YOU WORRY ABOUT THAT, SO YOU'RE NOT GOING TO HAVE THE OPPORTUNITY JUST TO TAKE SOMEBODY'S EGGS AND DO WHATEVER YOU WANT WITH THEM.

DR. CIBELLI: NO. WHAT I'M SAYING WE DON'T HAVE TO WORRY ABOUT TALKING RIGHT NOW ABOUT THAT.

DR. TAYLOR: I DON'T THINK SO.

VICE CHAIR LO: THAT'S A CHOICE WE NEED TO MAKE, OR WE MAY WANT TO SAY THAT YOU NEED TO, FOR EXAMPLE, SAY WHETHER OR NOT IT'S GOING TO BE USING SOMATIC CELL NUCLEAR TRANSFER RATHER THAN FERTILIZATION RATHER THAN PARTHENOGENESIS. PEOPLE MAY HAVE VERY -- IT'S CONCEIVABLE SOMEONE SAY, WELL, THAT'S PERFECTLY OKAY. I'M NOT SO SURE ABOUT THAT. AND I DON'T WANT IT FOR THAT.

DR. CIBELLI: CAN I ASK YOU QUESTION ABOUT THE LAW, THE CALIFORNIA LAW. ARE THERE ANY STATEMENTS ABOUT DONATION OF GAMETES, LIKE YOU CAN'T DO THIS WITH THE GAMETES YOU GET, THINGS THAT YOU CANNOT DO?

DR. LOMAX: THE EXISTING LAW TALKS ABOUT STATEMENTS THAT WHAT THEY WILL BE USED FOR, BUT IT

DOESN'T -- IT'S ACTIVE STATEMENTS ABOUT THE INTENDED USE, BUT THERE'S NO STATEMENTS ABOUT PROHIBITION IN THE LAW, THAT ACTUALLY WE'RE CURRENTLY EXEMPTED OUT OF IN PROPOSITION 71. BUT THE INTENT OF THAT LAW IS TO PROVIDE KNOWLEDGE ABOUT THE INTENDED USE OF THE MATERIAL THAT'S BEING DONATED.

DR. CIBELLI: WHAT IF WE WANT TO MAKE STEM CELLS FROM A DAY 21 EMBRYO THAT HAS TO BE PUT INTO THE UTERUS AND SOMEHOW FLUSH IT OUT TO GET A CELLS FROM THAT?

VICE CHAIR LO: THERE'S A PROHIBITION BEYOND 14 DAYS.

DR. ROWLEY: TWELVE.

VICE CHAIR LO: TWELVE DAYS. SORRY. YOU'RE ABSOLUTELY RIGHT.

DR. CIBELLI: THAT TAKES CARE OF THAT. THAT'S NOT A PROBLEM. AND ANN ACTUALLY ASKED THE QUESTION TO ME. CAN YOU FERTILIZE GAMETE AND PRODUCE EMBRYONIC STEM CELLS FROM IT, OR DO YOU HAVE TO USE JUST EMBRYOS THAT HAVE -- TO GET A CELL LINE THAT IS PRODUCT OF FERTILIZATION, CAN YOU GET IT FROM AN EGG THAT SOMEONE DONATED?

DR. LOMAX: YES.

VICE CHAIR LO: AND FERTILIZE THE EGG.

DR. EGGAN: ONLY IN THE STATE OF

MASSACHUSETTS IS THAT EXPRESSLY FORBIDDEN. AND OTHER STATES -- ONLY IN MASSACHUSETTS IS THAT SPECIFICALLY PROHIBITED. THERE ARE OTHER STATES WHERE EVERYTHING IS OFF THE BOOKS. AS FAR AS I KNOW, MASSACHUSETTS IS THE ONLY STATE WHICH WOULD ALLOW YOU TO DERIVE FROM DISCARDED IVF EMBRYOS OR OTHER IVF EMBRYOS, BUT NOT SPECIFICALLY ALLOW YOU TO MIX OOCYTE AND SPERM IN A DISH FOR THE PURPOSE OF STEM CELL RESEARCH.

VICE CHAIR LO: AGAIN, JUST SO WE'RE CLEAR, WE WERE TALKING ABOUT INCORPORATING EXISTING CALIFORNIA LAW, EVEN THOUGH WE'RE NOT REQUIRED TO UNDER PROP 71, INTO OUR GUIDELINES. AND ON THE FOURTH PAGE BEHIND TAB 7 ON THIS SIDE, WE'VE REPRODUCED THE RELEVANT LAW THAT HAS TO DO WITH DONATION OF GAMETES, EMBRYOS, AND SOMATIC CELLS FOR CELL LINES. SO, AGAIN, TO ANSWER YOUR QUESTION, THE EXISTING LAW FOR THAT DOES NOT EXCLUDE CERTAIN TYPES OF THINGS, BUT IT SPECIFIES CERTAIN THINGS THAT MUST BE TOLD TO PROSPECTIVE DONORS. BY INCORPORATING THAT INTO OUR REGULATIONS, THIS WILL NEED TO BE DISCLOSED DONORS DONATING OOCYTES SOLELY FOR RESEARCH.

DR. KIESSLING: THIS IS SAFETY CODE SECTION 24175?

VICE CHAIR LO: NO. THIS IS SAFETY CODE SECTION 125315, ACTUALLY PAGE 4 BEHIND TAB 7.

DR. LOMAX: YES, THAT'S CORRECT.

DR. ROWLEY: SECTION B.

DR. LOMAX: SECTION B STARTS ON THE PREVIOUS PAGE, AND THE LIST OF REQUIREMENTS FOLLOWS.

VICE CHAIR LO: NEXT PAGE.

DR. PRIETO: I THOUGHT I WAS HEARING FROM KEVIN EARLIER THAT HE FEELS MOST SCIENTISTS WOULD PREFER THAT THIS BE PRETTY CLEARLY LAID OUT SO THAT THE EXPECTATIONS WERE CLEAR FROM THE BEGINNING. I THINK THE ADVANTAGE OF REFERENCING THESE IS THAT IT IS ALREADY LAID OUT THERE, BUT I DON'T THINK THAT IT ADDRESSES SOME OF THE SPECIFIC ISSUES WITH REGARDS TO STEM CELL RESEARCH THAT ARE ADDRESSED. I THINK WE WOULD WANT TO ADD THAT BECAUSE THERE ARE CERTAINLY UNIQUE FEATURES OF THIS RESEARCH THAT ARE ADDRESSED IN THE NATIONAL ACADEMIES' GUIDELINES, BUT ARE NOT IN CALIFORNIA LAW NOW.

VICE CHAIR LO: SO, AGAIN, ONE PROPOSAL FOR US TO DO IS TO INCORPORATE, NOT JUST THESE CALIFORNIA LAWS, BUT ALSO THE NAS RECOMMENDATIONS FROM THEIR REPORT. WE HAVE TO THINK ABOUT HOW TO ACTUALLY DO THAT TECHNICALLY, BUT THAT WOULD THEN ALSO BE INCORPORATED AS REQUIREMENTS THAT RESEARCHERS MUST DISCLOSE IN THE PROCESS OF OBTAINING CONSENT. SO THAT'S --

DR. PRIETO: IT'S SOMETHING I WOULD FAVOR,

AND I THINK IT WOULD GIVE US THE ADVANTAGE OF BEING CONSISTENT WITH THE ELEMENTS OF EXISTING CALIFORNIA LAW.

VICE CHAIR LO: RIGHT. THESE ARE ALL THINGS THAT CURRENTLY STEM CELL RESEARCHERS IN CALIFORNIA WOULD BE SUBJECT TO -- REQUIRED TO DO ANYWAY UNDER THEIR EXISTING OBLIGATIONS.

FIRST, I WANT TO MAKE SURE. I DON'T KNOW IF WE'VE LOST JOHN AND ALTA.

MS. CHARO: NO, I'M HERE.

VICE CHAIR LO: DO YOU HAVE ANY COMMENTS OR THOUGHTS AT THIS POINT?

MS. CHARO: WELL, TO BE HONEST, I'M HERE, BUT I REALLY CAN'T HEAR.

VICE CHAIR LO: WE CAN HEAR YOU.

MS. CHARO: I'M GLAD YOU CAN, BUT YOU GUYS ARE BASICALLY JUST A LOT OF FUZZ.

DR. WAGNER: I THINK I'M ON THE SAME LINE AS ALTA, BUT I MADE -- I'VE WRITTEN A LOT OF COMMENTS ALONG THE WAY. UNFORTUNATELY, YOU'VE CHANGED DIRECTION A NUMBER OF TIMES FOR A NUMBER OF GOOD REASONS. BUT FROM A PRACTICAL POINT OF VIEW, I ACTUALLY DO SOME OF THIS WORK. I CAN TELL YOU THAT, FIRST OFF, WHEN I'M WORKING IN AN IVF CENTER, I'M NOT INVOLVED WITH THE OOCYTE DONATIONS. THERE WILL BE PREIMPLANTATION

GENETIC DIAGNOSIS IN AN IVF. THERE'S A CLEAR-CUT -- THERE'S SOME PRACTICAL ISSUES, AND THERE'S THINGS TO OVERCOME SOME OF THOSE ISSUES. BUT TYPICALLY FAMILIES OR COUPLES WILL COME IN, AND THEY WILL -- IF THEY'RE GOING THROUGH IN VITRO FERTILIZATION FOR THE PURPOSE OF INFERTILITY, THOSE COUPLES WILL COME IN. AND THOSE EXCESS EMBRYOS, IF THAT'S WHAT YOU WANT TO CALL THEM, ARE THEN STORED, AND THEN THEY'RE RECONNECTED WITH ANYBODY FOR YEARS. AND SOMEWHERE DOWN THE LINE, SOMEONE CONTACTS US FROM THE IVF CENTER AND SAYS HERE'S A COUPLE THAT MAY BE INTERESTED.

BUT IN ANY EVENT, THERE'S WAYS THAT WE CAN DO THAT BETTER PERHAPS. FROM A PRACTICAL POINT OF VIEW, IF IT WAS DISCUSSED, AND MAYBE YOU'RE GOING TO DO THAT NOW BECAUSE IT'S COME AROUND, BUT THE ISSUE OF RECONTACT IS REALLY A DIFFICULT ISSUE, AS WAS STATED BY A FEW PEOPLE.

THE IVF CENTERS, REMEMBER THE IVF CENTERS ARE NOT REALLY PART OF THE RESEARCH TEAM IN AT LEAST IN THE ONES I'VE DEALT WITH. THEY PLAY A ROLE, BUT ON THE OTHER HAND, THEY ALSO ARE NOT THAT INVOLVED. AND SO WE CAN ONLY ASK SO MUCH OF THEM. I THINK I CAN COME UP WITH SOME IDEAS ON HOW WE MIGHT BE ABLE TO GET A MORE BALANCED OR BETTER CONSENT PROCESS, BUT WE CAN ONLY EXPECT SO MUCH FROM THEM, OR ELSE WE'RE GOING TO HAVE

TO PROVIDE THE CONSENTER BECAUSE THEY DON'T UNDERSTAND NECESSARILY ALL THE DETAILS OF WHAT MIGHT BE DONE WITH IT.

ON THE OTHER HAND, THEY MAY KNOW A CURSORY AMOUNT ABOUT OF ES CELL LINES AND WHAT THEY MIGHT BE USED FOR, BUT OPTIMAL PEOPLE TO PROVIDE THAT CONSENT. AS A RESEARCHER, I MAY BE 2,000 MILES AWAY. IT'S A BIT DIFFERENT IN CALIFORNIA PERHAPS, BUT I'M WORKING WITH THE IVF CENTER IN ATLANTA, I CAN'T JUST POP DOWN THERE OR ANYONE ON MY TEAM OR EVEN TO HIRE SOMEONE TO GET THAT, BUT WE COULD COME UP MAYBE WITH STRATEGIES ON HOW YOU MIGHT BE ABLE TO HELP THAT ALONG. BUT LET ME TELL YOU THE IDEA OF RECONTACT, IVF CENTERS WHO ARE PRIMARY POINT PEOPLE, DON'T WANT TO DO THAT A LOT OF THE TIME, AT LEAST IN MY OWN EXPERIENCE.

THE OTHER THING IS THAT GIVEN THE IDEA OF RECONTACT FOR THE PURPOSE OF HEALTH SCREENING, REMEMBER THAT WE'RE DEALING WITH ADULT COUPLES ALREADY. AND SO HEALTH SCREENING SHOULD BE DONE REALLY PART OF THE ENTIRE PROCEDURE UP FRONT RATHER THAN HAVING TO GO BACK AND DECIDE THAT BECAUSE DO I WANT TO ES CELL LINE, WHICH BY THE WAY WE ARE CREATING ES CELL LINES, IF YOU GO BACK AND PLANT IT AFTER THE FACT, AFTER YOU'VE SPENT ALL THE MONEY AND TIME CREATING THE CELL LINE, WHICH IS STILL A VERY INEFFICIENT PROCESS. THEN YOU GO BACK AND

FIND OUT, OH, THERE'S SOME PROBLEM THAT WOULD HAVE PREVENTED ME FROM USING IT. I WANT TO KNOW THAT UP FRONT. I DON'T WANT TO HAVE TO GO BACK AND DO THAT ANYWAY.

YOU WANT TO HAVE A CLEAR WAY OF CONNECTING IF YOU REALLY HAD TO. THINK ALSO ABOUT THE CORD BLOOD BANKING PROCESS THAT'S BEEN PUBLICIZED IN THE RECENT PAST. WE DON'T GO BACK FOR THEM IN THE MAJORITY OF CASES, IF EVER. EVEN THOUGH WE DON'T HAVE A CHILD -- REMEMBER, A BABY IS BORN, WE DON'T HAVE ANY GENETIC HISTORY ON THAT BABY, AND WE DON'T GO BACK THERE EITHER BECAUSE OF THE FACT THAT WE LIVE IN A MOBILE POPULATION, AND IT'S JUST NOT EASY IF WE SAY THAT WE LOCK OURSELVES INTO DOING THAT. THAT'S A REALLY DIFFICULT THING TO HAVE TO GO BACK AND DO. IF YOU'RE REALLY PLANNING UP FRONT TO DO IT, WELL, GREAT, BUT JUST KNOW THAT WHAT ARE YOU GOING TO DO IF YOU CAN'T GO BACK? IF YOU CAN'T CONNECT WITH THEM, DO YOU NOT USE THAT CELL LINE? DO I REALLY WANT TO INVEST IN SOMETHING OR MAKING A CELL LINE, WHICH, AGAIN, DON'T FORGET THE EFFICIENCY IS POOR; THEREFORE, YOU GOT TO GO THROUGH A LOT OF POTENTIAL EMBRYOS TO CREATE A CELL LINE TO THEN FIND OUT AT THE END WE CAN'T USE IT FOR SOME REASON BECAUSE THEY CAN'T GO BACK AND REDISCUSS THIS WITH THE FAMILY OR EVEN WITH CONSENT BECAUSE OF

THE FACT THAT I HAVE A NEW IDEA, A NEW PROTOCOL THAT I WANT TO USE IN TERMS OF STUDYING SOME NEW AREA WITH THE ES CELLS.

SO YOU GOT TO KEEP THAT IN MIND THAT IT'S JUST NOT VERY PRACTICAL TO DO. I'M NOT SURE THAT WE REALLY NEED TO DO IT ALTHOUGH MAYBE IN THE ARGUMENT TODAY, WE MIGHT HAVE GIVEN RESPONSES WHY WE SHOULD AND I JUST COULDN'T HEAR THEM. IN ANY EVENT, FROM A PRACTICAL POINT OF VIEW, IT IS REALLY TOUGH.

I AGREE WITH YOU THAT IVF SHOULD BE SEPARATED FROM THE EGG DONATION, BUT IVF -- AND I THINK THIS WAS BROUGHT UP. IVF IS NOT ALWAYS THE SAME. INFERTILITY AND PGD ARE VERY DIFFERENT, AND THERE IS REASONS WHY WITH PGD YOU MIGHT WANT TO USE FRESH EMBRYOS AND, THEREFORE, YOU'RE GOING TO HAVE TO CONSIDER THE CONSENT EARLY ON. BUT REMEMBER, THIS IS A DECISION THAT CAN BE DISCUSSED WELL IN ADVANCE OF THE ACTUAL IVF PROCEDURE IF YOU REALLY WANTED TO BECAUSE THESE ARE PEOPLE THAT ARE GOING INTO THIS, NOT FOR INFERTILITY, BUT GOING INTO IT FOR OTHER REASONS. THEREFORE, THE CONSENT PROCESS -- I AGREE WITH THE WHOLE CONCEPT OF HAVING PLENTY OF TIME TO GET THE CONSENT AND HAVING TIME TO THINK ABOUT IT AND TIME TO ASK QUESTIONS. AND I GET CONSENTS EVERY DAY FOR A LIFE THREATENING PROCEDURE CALLED BONE MARROW TRANSPLANT, AND WE CERTAINLY KNOW

HOW TO GET CONSENTS FOR SUCH TRICKY THINGS AS TRANSPLANTS. I THINK WE CAN COME UP WITH WAYS, FOR EXAMPLE, HOW DO YOU THIS SO THAT THE INVESTIGATOR WHO REALLY IS THE EXPERT IN ES CELLS, NOT THE IVF TEAM, CERTAINLY CAN DO THAT BY CREATING A VIDEO. THERE'S THINGS THAT YOU CAN DO THAT YOU CAN MAKE IT A LESS COERCIVE AND MOST OBJECTIVE AS POSSIBLE, EVEN ENDING THAT WITH THE WAY WE DO IT IN TERMS OF TRYING TO FIND OUT HOW WELL THEY UNDERSTAND THE PROCESS IS THAT, AS SOME OF YOU HAVE ALREADY STATED, IS SIMPLY TO ASK A NUMBER OF KEY QUESTIONS.

I THINK IN THIS PARTICULAR CASE, YOU ARE ALSO GOING TO HAVE TO FIGURE A WAY THAT YOU CAN HAVE A WAY OF ADDRESSING QUESTIONS THAT THE IVF TEAM MIGHT NOT NECESSARILY KNOW HOW TO ADDRESS. BUT THINK ABOUT THAT SOME MORE.

SO THE ELEMENTS THAT YOU'VE ALL DISCUSSED ARE IMPORTANT, BUT SOMETIMES WHAT I'M HEARING IS SOMETHING THAT ISN'T GOING TO BE EASY TO PUT INTO PRACTICE. I'M NOT REALLY SURE WHAT YOU GAIN FROM SOME OF THIS IN THE END.

MS. CHARO: SINCE OF MY MANY OTHER COLLEAGUES, ONE OF THE FEW PEOPLE I CAN HEAR CLEARLY, I JUST WANTED TO ADD A WORD, WHICH IS THAT I WOULD LIKE TO ENDORSE THE NOTION OF PRACTICALITY. BERNIE MAY

REMEMBER, WE WENT AROUND ON THIS QUESTION ABOUT DONOR CONTROL OF TISSUE USES IN THE CONTEXT OF THE CLINTON BIOETHICS COMMISSION. WE FOUND THAT THERE WAS A GENUINE DISAGREEMENT ABOUT WHETHER IT WAS REALISTIC FOR PEOPLE TO CONSENT PROSPECTIVELY TO AN UNKNOWN RANGE OF RESEARCH FACILITIES, SOME OF WHICH WEREN'T EVEN CONCEIVABLE AT THE TIME OF DONATION. THE MAJORITY OF US FELT THAT THIS IS A CHOICE PEOPLE OUGHT TO BE ABLE TO MAKE ESPECIALLY WHEN WE HAVE ASKED FOR PROTECTION FOR THEIR OWN CONFIDENTIALITY DOWN THE LINE BECAUSE THE PROBLEM WITH TRACING EACH LINE BACK TO ITS ORIGINAL SET OF CONDITIONS IS TREMENDOUS AND MAKES IT SO MUCH HARDER FOR THE LINES TO BE SHARED AROUND.

I WOULD JUST LIKE TO URGE THAT WE KEEP OUR EYE ON FACILITATING THE RESEARCH AS MUCH AS ON MAKING SURE THAT AS A SUBSTANTIVE AND POLITICAL MATTER WE PROTECT THE ETHICS OF THE DONATIONS.

VICE CHAIR LO: OKAY. THANKS TO BOTH. WE ARE REQUIRED, AS A MATTER OF UNION REGULATIONS, TO BREAK FOR LUNCH AT 12:45. I'M NOT SURE WHETHER IT'S THE UNIONS PROTECTING US OR IT'S REALLY A WORK RULE FOR THE EMPLOYEES, BUT WE PROBABLY SHOULD ADHERE TO THAT.

DR. TAYLOR: IS THAT THE PLUMBING UNION?

VICE CHAIR LO: I'M JUST BEING TOLD WHAT -- REPORTING WHAT I WAS TOLD. WHY DON'T WE BREAK NOW FOR

LUNCH, AND OUR LUNCH PERIOD IS HOW LONG, 45 MINUTES, WHICH MEANS WE'LL COME BACK HERE AT 1:30. THANKS VERY MUCH.

(A RECESS WAS TAKEN.)

VICE CHAIR LO: WHY DON'T WE RECONVENE FROM OUR LUNCH, WHICH I DON'T THINK REPRESENTS THE FINEST IN SAN FRANCISCO CUISINE. WHY DON'T WE RECONVENE, AND I THOUGHT WE WOULD START BY WE'VE NOT HAD AN OPPORTUNITY FOR PUBLIC COMMENT YET, AND I WANTED TO START BY INVITING MEMBERS OF THE PUBLIC TO MAKE COMMENTS IF THERE'S ANYONE WHO WOULD LIKE TO COMMENT. AND FOR THE RECORD, COULD YOU JUST STATE YOUR NAME AND AFFILIATION, PLEASE.

MR. REED: YES, DON REED. GOING BACK TO THIS MORNING -- BY THE WAY, WE APPRECIATE THE OPPORTUNITY FOR PUBLIC COMMENT. YOU MIGHT HAVE NOTICED THAT ONE PARTICULAR ATTACK THAT THE OPPOSITION HAS NOT MADE AGAINST PROP 71 FOR A LONG TIME IS THAT THE PUBLIC HAS NOT BEEN INCLUDED. THEY HAVE NOT SAID THAT BECAUSE YOU GUYS HAVE MADE A SPECIFIC COMMITMENT TO GET PUBLIC INVOLVEMENT ALL THE WAY, 51 PUBLIC MEETINGS, FANTASTIC, AND WITH PUBLIC COMMENT AT EACH ONE.

GOING BACK TO THIS MORNING, WE DON'T WANT -- AS A PERSON WHO WANTS EVERY DOLLAR TO BE SPENT ON RESEARCH AND EVERY POSSIBLE AVENUE MADE EASY FOR THE

SCIENTISTS, WE DON'T WANT ONE MORE RESTRICTION ON THE SCIENTISTS OR INSTITUTION THAN WE ABSOLUTELY HAVE TO HAVE. LAST I HEARD, THERE WAS A COMMITTEE, CIRM COMMITTEE, WHICH WAS A LIAISON COMMITTEE BETWEEN THE CIRM AND SACRAMENTO. IF WE ONLY HAVE FIVE DAYS BETWEEN NOW AND THE DECEMBER 6TH WHEN YOUR RECOMMENDATIONS ARE MADE, I WONDER IF THERE ISN'T SOME WAY TO AT LEAST SPEAK TO THAT COMMITTEE AND MAKE SURE THAT WE'RE NOT OFFERING SOMETHING NOT NEEDED.

FOR INSTANCE, WE'VE TALKED ABOUT THE REVENUE STREAM AND THE TAX. THE LAST I HEARD, THE SCA 13 THREAT, WHICH SENATOR ORTIZ AUTHORED, DID NOT -- SHE WAS NO LONGER TRYING FOR REVENUE STREAM. SO I DON'T THINK WE SHOULD OFFER SOMETHING THAT'S NOT BEING DEMANDED. WE NEED EVERY PRECIOUS DOLLAR. WE DON'T WANT TO GIVE ANYTHING AWAY. ALL FOR RESEARCH.

SECONDLY, ON THE EGG SITUATION, ENGLAND TEACHES A COURSE IN EGG DONATION. THEY TEACH A COURSE, AND EVERY EGG DONOR HAS TO PASS A TEST. NOW, JUST LIKE CALIFORNIA DRIVING TEST, IF YOU DON'T PASS IT, YOU TAKE IT AGAIN. AND THEN ONCE YOU ARE FULLY UNDERSTANDING IT, THERE'S MY OPINION COMES IN, ONCE THE RESEARCH HAS BEEN MADE CLEAR, ONCE YOU HAVE EXPLAINED ALL THE POSSIBLE USES, THEN I THINK THERE SHOULD BE ONE QUESTION. WOULD YOU LIKE TO HELP POSSIBLY SAVE LIVES

AND ALLEVIATE SUFFERING WITH THE PRECIOUS GIFT OF OOCYTES? IF THEY SAY YES, THEN THAT'S IT. WE DON'T GO BACK AND ASK THEM A YEAR LATER CAN WE DO IT FOR SOMETHING DIFFERENT. WE MAKE CLEAR THAT THERE'S A VARIETY OF POSSIBILITIES, AND THEN ONE QUESTION AND THE ANSWER AND THAT'S IT.

ALSO, THEY MAY NOT EVEN WANT TO BE REASKED AGAIN. THEY'D SAY, NOW WE'VE GOT TO GO THROUGH THIS BIG DECISION AGAIN? MAYBE NOT. LET'S EDUCATE THEM THOROUGHLY, MAKE SURE THEY UNDERSTAND, MAKE SURE THEY SEE THE PROMISE AND THE POSSIBILITY OF THE RESEARCH, AND ASK THEM A QUESTION. THEY SIGN, HAVING PASSED THE TEST, SO THEY CAN NEVER SAY THEY DIDN'T UNDERSTAND, AND THEN WE LET IT HAPPEN. THANK YOU.

VICE CHAIR LO: THANK YOU. ANY OTHER PUBLIC PERSONS WANT TO COMMENT? OKAY. THANKS.

I WANTED TO TRY AND GO BACK TO SOME OF THE ISSUES -- FOR THOSE MEMBERS OF THE PUBLIC WHO JUST CAME IN, WE WERE ASKING FOR PUBLIC COMMENTS. SO IF YOU WANTED TO MAKE A COMMENT, THIS WOULD BE A TERRIFIC TIME.

GOING BACK TO THIS MORNING, I WANTED TO TRY AND SUMMARIZE OUR DISCUSSION AND SEE IF WE HAVE AGREEMENT ON AT LEAST SOME OF THE BROAD ISSUES. AND, AGAIN, LIMITING OUR DISCUSSION FOR THE MOMENT TO OOCYTE

DONATION SOLELY FOR THE PURPOSE OF RESEARCH, AND THESE ARE WOMEN DONATING JUST FOR RESEARCH, NOT SIMULTANEOUSLY FOR INFERTILITY TREATMENTS.

SOME OF THE THINGS WE DISCUSSED THIS MORNING I'D LIKE TO GET A SENSE, EVEN THOUGH WE CAN'T DO A QUORUM, WAS WHETHER WE HAVE BROAD AGREEMENT ON THIS. ONE IS THERE'D BE A, QUOTE, TIME-OUT. I DON'T THINK THAT'S THE MOST ELEGANT LANGUAGE, BUT IT'S WHAT WE WERE USING. SOME TIME FOR REFLECTION, QUESTION/ANSWER BEFORE ORIGINALLY BEING ASKED TO MAKE A DECISION.

SECOND WAS THAT WE HAVE SOME ASSESSMENT TO ENSURE THAT THE OOCYTES DONORS UNDERSTAND CRUCIAL FEATURES, INCLUDING, ONE, THE SCIENCE OF HOW MATERIALS WILL BE USED; AND, TWO, THE MEDICAL RISKS OF OOCYTE RETRIEVAL.

AND I GUESS THE NEXT IS SORT OF A SUB-BULLET. OVER LUNCH ANN MENTIONED THAT ONE OF THE THINGS HER DONORS ARE VERY INTERESTED IN IS WHAT'S ACTUALLY GOING TO HAPPEN TO THE OOCYTES IN THE LAB. AND SHE MENTIONED THAT MANY WOMEN ARE WILLING TO HAVE -- IN FACT, THEIR DONORS ARE WILLING TO HAVE THEIR OOCYTES USED FOR SCNT OR EVEN FOR PARTHENOGENESIS, BUT NOT TO FERTILIZATION IN ORDER TO PRODUCE AN EMBRYONIC STEM CELL LINE. SO THAT BE SORT OF A SUB-BULLET UNDER THE SCIENCE OF HOW MATERIALS WILL BE USED.

I THOUGHT I HEARD AGREEMENT, BUT I WANT TO CHECK, THAT WE DIDN'T WANT DONORS TO IMPOSE RESTRICTION ON SPECIFIC SUBSEQUENT DOWNSTREAM RESEARCH USES OF OOCYTES. AND THIS WOULD BE WITH THE UNDERSTANDING THAT IT WOULD PASS ESCRO APPROVAL. AND SOMEONE REMINDED ME OVER LUNCH OBVIOUSLY THERE ARE THINGS THAT ARE NOT PERMISSIBLE UNDER CIRM-FUNDED, KEEPING THE 12- TO 14-DAY RESTRICTION, NO BREEDING OF HUMAN ANIMAL CHIMERAS, AND SO FORTH. SO WE NEED TO PUT LAWFUL DOWNSTREAM USES.

IS THERE ANOTHER SLIDE? BACK UP. THAT'S OUR NEXT TOPIC. SO I JUST WANTED TO SEE IF WE CAN SUMMARIZE THIS MORNING'S DISCUSSION AND MAYBE JUST GO THROUGH EACH OF THESE POINTS AND SEE WHETHER THERE'S BROAD AGREEMENT AS TO TRYING TO PUT INTO REGULATORY LANGUAGE THIS NOTION OF, FIRST, A TIME-OUT PERIOD. ANY CONCERNS ABOUT THAT OR OBJECTIONS TO TRY TO MAKE THAT ONE OF THE REGULATIONS?

NOD YOUR HEADS. I CAN'T TAKE A VOTE. NOD YOUR HEADS IF YOU AGREE.

AND THEN SOME ASSESSMENT OF THE CRUCIAL FEATURES OF THE SCIENCE AND THE RISKS, INCLUDING THE IMMEDIATE USE TO WHICH THE OOCYTES ARE BEING USED.

DR. TAYLOR: I WAS GOING TO SAY THAT IT SEEMS TO ME THAT WE SHOULD PROBABLY HAVE A BULLET POINT FOR

THE DONOR'S OWN PERSONAL HEALTH RISKS.

DR. PRIETO: ISN'T THAT UNDER THE RISKS OF PARTICIPATION.

VICE CHAIR LO: SECOND BULLET NO. 2.

DR. PRIETO: TALKING ABOUT THE MEDICAL RISKS, SPECIFIC RISKS THAT THE DONOR.

VICE CHAIR LO: WE WANT TO TRY AND HAVE SOME -- NOW, THERE'S ONE THING THAT WAS LEFT -- I WASN'T QUITE CLEAR ON HOW WE LEFT IT. THE NOTION OF HOW UNIFORM OR PROSCRIPTIVE SHOULD WE BE ABOUT HOW THAT ASSESSMENT IS DONE. ON THE ONE HAND, THERE WAS SOME SENTIMENT THAT EVERYBODY IN CALIFORNIA OUGHT TO DO THE SAME THING SO THAT PEOPLE DON'T SAY, WELL, GEE, THAT PLACE IS REALLY HAVING A PRETTY EASY TEST.

ON THE OTHER HAND, THERE'S THE IDEA THAT WE MAY WANT TO ALLOW FLEXIBILITY FOR DIFFERENT INVESTIGATIVE INSTITUTIONS TO DEVELOP WAYS OF DOING THIS THAT WORK WELL AND SORT OF TEST DIFFERENT MODELS. A QUESTION FOR US IS DO WE WANT TO -- HOW PRESCRIPTIVE DO WE WANT TO BE IN TERMS OF NOT JUST THE ISSUES THAT NEED TO BE ADDRESSED, BUT HOW THEY'RE ACTUALLY GOING TO BE EVALUATED.

DR. CIBELLI: I DO HAVE A COMMENT, MORE LIKE A QUESTION TO MARCY HERE. DO YOU THINK THAT THE PERSON THAT ACTUALLY WILL ASK THE DONOR TO SIGN THE CONSENT

FORM IN THIS CASE A RESEARCH NURSE? DO THEY HAVE TO GO THROUGH SOME TRAINING JUST FOR THIS PARTICULAR EXERCISE, OR IS IT SOMETHING THAT WE CAN GIVE THEM THE FORM AND READ IT, AND THEY WILL BE QUALIFIED ENOUGH TO SAY I CAN INFORM THE PERSON AND GET A STRAIGHT ANSWER?

MS. FEIT: I KNOW THE RESEARCH NURSES I'VE WORKED WITH ARE EXTENSIVELY TRAINED IN WHAT THEY'RE DOING. THEY HAVE TO UNDERSTAND WHAT THEY'RE ASKING. THEY HAVE TO FULLY UNDERSTAND EVERYTHING.

DR. CIBELLI: DO THEY GO THROUGH A TRAINING PERIOD?

MS. FEIT: YES.

DR. CIBELLI: THERE IS A TRAINING PERIOD.

VICE CHAIR LO: TO FOLD IT BACK, DO YOU WANT THERE TO BE IN THE REGULATIONS THE PERSON OBTAINING CONSENT HAS TO HAVE ADEQUATE TRAINING, AND WE SAY LEAVE IT UP TO THE IRB TO ENSURE.

DR. CIBELLI: IT DOESN'T HAVE TO BE A BURDEN THAT IS GOING TO LIMIT THE RESEARCH AND MAKE THINGS MORE BUREAUCRATIC. IN MY INSTITUTION, FOR EXAMPLE, MICHIGAN STATE, IF I WANT TO USE -- IF I'M WORKING BIOSAFETY LEVEL TWO, I HAVE TO BE TRAINED EVERY YEAR. MAYBE THE FIRST TIME IT TAKES THREE OR FOUR HOURS, AND THEN EVERY YEAR ON THE WEB I HAVE TO DO A REFRESHMENT COURSE, AND IT TAKES 15 MINUTES, SOMETHING LIKE THAT.

VICE CHAIR LO: DO YOU WANT TO SORT OF MAKE A RECOMMENDATION?

DR. CIBELLI: MY RECOMMENDATION WOULD BE THAT THE PERSON THAT IS GOING TO INTERVIEW THE DONOR HAS TO BE TRAINED IN HOW TO DO IT BECAUSE AT THE END, LIKE KEVIN WAS SAYING, WHEN YOU SIGN THE INFORMED CONSENT, YOU'RE SAYING THAT YOU UNDERSTOOD EVERYTHING. WELL, DO YOU REALLY UNDERSTAND IT OR NOT?

DR. TAYLOR: I WAS JUST GOING TO SAY THAT IRB'S SORT OF ALLOW THIS TO HAPPEN IN A LOT OF DIFFERENT WAYS. I THINK THAT THIS MIGHT BE AN ESCRO REQUIREMENT OR AN ESCRO RESPONSIBILITY BECAUSE, PARTICULARLY IF WE'RE TALKING FOR A RELATIVELY UNIFORM PROCEDURE ACROSS THE VARIOUS CENTERS, I THINK THE ESCRO'S SHOULD PROBABLY APPROVE OR FOLLOW THE QUALIFICATIONS OF THIS CONSENT OBTAINING INDIVIDUAL.

THE WAY THE IRB'S DO IT NOW IN MOST INSTITUTIONS ARE THE PI OF THE PROJECT SORT OF VERIFIES THAT THERE'S AN APPROPRIATE PERSON TO DO IT, BUT WE COULD ADD ANOTHER LAYER OF SUPERVISION. AND I THINK IT PROBABLY ISN'T REALLY THE IRB'S RESPONSIBILITY TO DO THAT. THEY DON'T HAVE THAT RESPONSIBILITY FOR OTHER PROTOCOLS, SO IT SEEMS TO ME THAT IT WOULD BE MORE OF AN ESCRO THING.

MS. FEIT: WOULDN'T IT BE BETTER FOR US TO

HAVE A MORE GLOBAL POSITION AND SAY THAT WE WILL REQUIRE THAT A THOROUGH ASSESSMENT BE MADE OF THE PATIENT'S UNDERSTANDING OF THE CONDITIONS AND THE EXPECTATIONS OF THE DONATION. AND THEN HAVE AVAILABLE A BEST PRACTICE PROGRAM FOR PEOPLE TO LOOK AT. THIS IS WHAT WE EXPECT. YOU DON'T HAVE TO ADOPT IT IDENTICALLY. EACH INSTITUTION HAS ITS NUANCES, BUT CERTAINLY WE COULD PUT OUT WHAT WE BELIEVE IS THE BEST PRACTICE IN THIS BEHAVIOR.

DR. EGGAN: I'D AGREE WITH MARCY IN THAT REGARD. ANOTHER WAY THAT ONE CAN HELP SAFEGUARD AGAINST COERCION AND LACK OF CLARITY AND UNDERSTANDING IN THE DONOR IS TO HAVE A SAFEGUARD WHERE ANY PARTICULAR MEMBER OF THE RESEARCH TEAM, BE IT THE RESEARCH NURSE WHO'S CONSENTING OR A CLINICIAN WHO'S DIRECTLY INVOLVED IN THE RETRIEVAL PROCEDURE CAN ESSENTIALLY VETO THE PARTICIPATION OF THAT PERSON IF SOME REASON THEY BELIEVE THEY ARE AN INAPPROPRIATE DONOR, THE WORD OF A SINGLE ONE OF THE MEMBERS OF THE TEAM TO REMOVE THEM SHOULD BE ENOUGH TO DISQUALIFY THEM FROM PARTICIPATION. THIS WOULD BE A REASONABLE SAFEGUARD WHICH COULD HELP TOO.

DR. PRIETO: THAT'S SETTING A PRETTY HIGH BAR.

DR. KIESSLING: THAT'S ACTUALLY HOW WE DO IT.

ANYBODY ON THE TEAM HAS QUESTIONS, THE DOCUMENT DOESN'T COME THROUGH. I DON'T KNOW THAT YOU WANT TO PUT THAT IN THE REGULATION.

DR. HALL: THE OTHER WAY AROUND, THAT IT REQUIRES THE APPROVAL OF ALL THE PEOPLE WHO HAVE HAD CONTACT.

DR. EGGAN: THAT'S CERTAINLY A MORE POSITIVE WAY TO SPIN IT.

MS. FEIT: BUT THAT COULD BE PUT IN BEST PRACTICE. I THINK IF WE HAVE IN OUR REGULATIONS THAT WE SAY DEFINITELY AN ASSESSMENT, THERE HAS TO BE PROOF OF A THOROUGH ASSESSMENT OF THE PATIENT'S UNDERSTANDING AND WILLINGNESS TO MOVE FORWARD WITH DONATION, AND THEN WE HAVE AVAILABLE A BEST PRACTICE MODEL THAT INCORPORATES THE STANDARDS THAT YOU'VE TALKED ABOUT. AND SAY THIS IS WHAT THE INSTITUTE RECOMMENDS AS A BEST PRACTICE UNDER THIS GUIDELINE.

VICE CHAIR LO: LET ME JUST SORT OF INSERT THE REGULATORY ISSUE, THAT IN PUTTING BEST PRACTICES INTO THESE REGULATIONS IS GOING TO CAUSE PROBLEMS WITH THE ADMINISTRATIVE LAW OFFICE. SO WE'LL NEED TO CONSULT WITH LEGAL COUNSEL AND STAFF AS TO WHETHER IT'S POSSIBLE. WHAT YOU CAN DO IS SAY THIS MAY BE FULFILLED, FOR EXAMPLE, IN THE FOLLOWING WAY, NOT EXCLUSIVELY, BUT, FOR EXAMPLE, SOMETHING. SO WE'LL

HAVE TO FIGURE OUT HOW TO COUCH THAT, AND THAT MAY BE A PROBLEM THAT WE NEED TO SORT THROUGH.

DR. EGGAN: I DON'T KNOW IF MARCY IS WILLING, BUT THAT'S SOMETHING OFFLINE THAT MAYBE I'M HAPPY TO WORK WITH HER ON.

VICE CHAIR LO: MARCY, ANN, AND KEVIN COULD SORT OF COME UP WITH SOME OF THAT, THAT WOULD BE USEFUL. I THINK THIS DOES GIVE A CHANCE TO SORT OF FORGE NEW TERRITORY.

DR. CIBELLI: I DO WANT TO ADDRESS THE COMMENT THAT THE MEMBER OF THE PUBLIC MADE ON THE FACT THAT ENGLAND HAS THIS COURSE FOR DONORS. AND I THINK IT'S A GREAT IDEA, BUT THE PROBLEM WOULD BE TO BE ABLE TO MAINTAIN CONFIDENTIALITY OF WHO ACTUALLY IS ATTENDING TO THIS CLASS ON HOW TO LEARN ABOUT RISKS AND BENEFITS OF DONATING EGGS. SO THAT'S THE DRAWBACK OF HAVING SOMETHING OPEN LIKE THAT.

DR. KIESSLING: ONE OF THE THINGS THAT WE MIGHT HAVE TO CONSIDER IS THAT WE SPEND SOME TIME WITH THE DONORS ACTUALLY FOR THEM TO UNDERSTAND WHY IT'S DECIDED THAT THEY CAN'T PARTICIPATE BECAUSE THIS CAN GET TO BE A PRETTY PERSONAL THING. AND SO WE ACTUALLY SPEND SOME TIME EXPLAINING TO THEM THAT THERE'S A WHOLE VARIETY OF REASONS THAT THEY MAY NOT BE ALLOWED TO GO FORWARD.

I DON'T KNOW HOW YOU WANT TO SAY THAT. IT'S PART OF THEM UNDERSTANDING THERE ARE RISKS OF PARTICIPATION, THAT THEY MAY BE -- IT MAY BE DECIDED THAT THEY CAN'T PARTICIPATE, AND THEY NEED TO BE PREPARED FOR THAT.

VICE CHAIR LO: OKAY. FINE. ANY OTHER COMMENTS ON THIS? ANY PUBLIC COMMENTS ON THESE?

LET'S MOVE ON THEN. KATE, ON THE NEXT SLIDE THERE IS AN ISSUE -- REMEMBER WE VERY RIGHTLY, I THINK, SAID WE'RE GOING TO LIMIT THE FIRST PART OF THE DISCUSSION TO DONATION OF OOCYTES SPECIFICALLY FOR RESEARCH. THERE'S OBVIOUSLY A COMPLEMENTARY ISSUE OF WOMEN WHO ARE ALSO DONATING OOCYTES FOR A WOMAN IN AN INFERTILITY PRACTICE OTHER THAN THEMSELVES OR ANOTHER WOMAN. WHAT ABOUT THE ISSUE OF THEY'RE ALSO DONATING SOME OOCYTES FOR RESEARCH PURPOSES?

SO I GUESS THERE ARE TWO ISSUES. ONE, IT'S NOT JUST A CONSENT ISSUE. SOME OF IT IS HOW DO WE CHANGE THE CONSENT. THE OTHER ISSUE IS IS SOMETHING THAT WE WOULD APPROVE OF OR ENCOURAGE OR DISCOURAGE? AND IT'S A COMPLICATED ISSUE. I KNOW SEVERAL OF YOU HAVE THOUGHT ABOUT THIS IN SOME DETAIL, BUT IT MIGHT BE WORTH PAYING ATTENTION TO THAT BECAUSE THAT'S ANOTHER POTENTIAL SORT OF SOURCE OF OOCYTES FOR RESEARCH PURPOSES. WHY DON'T WE ADDRESS THIS TOPIC NEXT.

DR. TAYLOR: WELL, I GUESS A COUPLE OF THE ISSUES THAT I THINK ARE OF INTEREST HERE ARE THAT WOMEN WHO ARE RECRUITED FOR OOCYTE DONATION FOR IVF PROGRAMS TEND TO BE YOUNG WOMEN FROM WHOM WE CAN GET LOTS AND LOTS OF EGGS ACTUALLY, OFTENTIMES MANY MORE THAN WHAT ARE NEEDED FOR THE IVF PROCEDURE ITSELF BECAUSE THEY ARE EGGS FROM YOUNG, TYPICALLY FERTILE WOMEN. THEIR SUCCESS OF IMPLANTATION AND PROGRESSION TO PREGNANCY IS ALSO VERY HIGH, SO THE YIELD IS ACTUALLY TYPICALLY VERY GOOD. SO BECAUSE OF THE COMBINATION OF THEIR AGE, PLUS THE REQUIREMENT TO TRANSFER FEWER OF THE EMBRYOS THAT ARE DERIVED FROM THOSE WOMEN, THEY DO HAVE EXTRA EXCESS EMBRYOS THAT OBVIOUSLY PREDOMINANTLY ARE USED FOR THAT COUPLE'S FUTURE FAMILY BUILDING, BUT CERTAINLY WOULD HAVE MATERIALS THAT COULD BE USED FOR RESEARCH.

ONE OF THE COMPLICATING FEATURES IS THAT THERE IS COMPENSATION FOR THESE INDIVIDUALS THAT IS PROSCRIBED IN PROP 71. AND WHETHER -- I'M HAVING DIFFICULTY CONCEPTUALLY THINKING OF HOW ONE MIGHT BE ABLE TO SEPARATE COMPENSATION FOR A CERTAIN NUMBER OF OOCYTES FOR PURPOSES OF IVF AND NONCOMPENSATION FOR ONES THAT WOULD GO TOWARDS RESEARCH PURPOSES, BUT THAT WOULD BE AN ISSUE THAT I THINK SHOULD BE DISCUSSED. AND, AGAIN, AS ANN HAS POINTED OUT, THESE WOMEN ARE PROBABLY MOTIVATED SOMEWHAT DIFFERENTLY THAN THE WOMEN

WHO WOULD PRESENT FOR OOCYTE DONATION FOR PURE SCIENTIFIC PURPOSES.

SO I GUESS THOSE WOULD BE THE COMMENTS THAT I HAVE TO MAKE.

DR. EGGAN: IT SEEMS TO ME THAT THERE'S EVEN A BROADER ISSUE AT STAKE IN THIS SITUATION, AND THAT IS THAT BECAUSE OF THE INFERTILITY OF THE COUPLE THAT'S BEING DONATED FOR AND THE FACT, AS I UNDERSTAND IT, THAT AT LEAST THROUGH THE STRUCTURE OF THE PAYMENT FOR IVF, ESSENTIALLY THE INFERTILE COUPLE BEARS THE COST OF THE OOCYTE DONATION OF THE WOMAN. IN A SENSE THOSE OOCYTES IN A DE FACTO SENSE BECOME THAT WOMAN'S EGGS. AND THEY ARE RELYING ON THOSE EGGS TO TREAT THEIR INFERTILITY. AND SO IN A SENSE IN MY MIND, WITH COMPELLING EVIDENCE I COULD BE CONVINCED OTHERWISE PERHAPS, BUT IT SEEMS THAT THAT IS IN A SENSE DE FACTO THE SAME AS DIVERTING THE WOMAN'S OWN EGGS FROM HER OWN REPRODUCTIVE EFFORTS. AND I CAN SEE HOW THAT'S A CHALLENGING THING TO WANT TO CONSIDER.

I THINK THE PRIMARY THING TO BE CONCERNED ABOUT HERE IS THE POTENTIAL OF CONFLICT OF INTEREST BETWEEN THE CLINICIAN AND THE PATIENT AND THE CLINICIAN AND THE RESEARCH SCIENTIST WITH WHICH HE'S COLLABORATING. AND I GUESS THIS IS CERTAINLY SOMETHING THAT ANN HAS MENTIONED TO ME AS PROBLEM BEFORE, AND I

GUESS THERE NEEDS TO BE SOME SORT OF SYSTEMATIC DISCUSSION ABOUT HOW AND/OR IF THAT CONFLICT OF INTEREST CAN BY RESOLVED BECAUSE IT SEEMS TO ME THAT'S THE CENTRAL CONCERN.

DR. CIBELLI: I WANT TO ASK WHAT IS THE LIKELIHOOD OF THE SCENARIO OF THIS TO HAPPEN, ACTUALLY THAT A COUPLE IS COMING TO YOUR CLINIC AND SAY, OKAY. TAKE HALF OF WHAT I'M GIVING YOU CAN COLLECT. FERTILIZE THOSE FOR ME AND THEN DONATE THE OTHER ONES. IS THAT -- IS IT WORTH TALKING ABOUT THIS OR THIS WILL NEVER HAPPEN?

DR. TAYLOR: I'M NOT AWARE OF THAT SITUATION COMING UP BEFORE, BUT IT'S NOT COMPLETELY UNUSUAL TO HAVE A SINGLE DONOR HAVE TWO SETS OF COUPLES APPROACH A SINGLE DONOR AND SAY WE'D LIKE HALF OF YOUR EGGS FOR OUR CYCLE AND HALF OF YOUR EGGS. SO FOR COST SHARING PURPOSES, THERE HAVE BEEN SHARED DONORS. THERE'S BEEN SOME DISCUSSION ABOUT THIS WITHIN THE IVF PRACTICES AS TO WHETHER YOU CREATE CONFLICTS AND ISSUES WHEN ONE COUPLE GETS PREGNANT AND THE OTHER ONE DOESN'T. BUT THAT PRACTICE HAS BEEN USED IN THE PAST. SO I DON'T SEE IT BEING NECESSARILY INTRINSICALLY DIFFERENT THAN A SPLIT BETWEEN A SCIENTIFIC PROJECT AND A FERTILITY SEEKING COUPLE, BUT ADMITTEDLY THERE ARE CONCERNS. I THINK MAYBE SOME OF THE CONCERNS THAT COME FORWARD IF

SOMEBODY FAILS AT GETTING PREGNANT, THEN DO THEY SAY, WELL, IF WE HAD ACCESS TO ALL OF THE EGGS THAT THE DONOR GAVE US, WE MIGHT HAVE HAD A DIFFERENT PREGNANCY OUTCOME.

DR. EGGAN: IT SEEMS LIKE IF THAT'S PREPRESCRIBED BEFORE THE PROCEDURE ACTUALLY OCCURS, THAT THAT'S GOING TO BE THE SITUATION, THAT IT COULD BE THAT NEITHER COUPLE GOT PREGNANT FROM THE DONATION TOO. ONE THING I WOULD BE CONCERNED ABOUT WOULD BE IS THERE SOME SORT OF OBJECTIVE CRITERION THAT CAN BE USED FOR SPLITTING THOSE DONATED EGGS INTO TWO POOLS BECAUSE THAT WOULD BE THE PROBLEMATIC THING. SO IF YOU'RE SPLITTING THE MATERIAL, IS IT AN UNBIASED SPLIT OF THE MATERIAL AND IS THERE A CHANCE FOR THE COUPLE WHO'S TRYING TO GET PREGNANT TO WORRY ABOUT THAT SORT OF THING?

DR. TAYLOR: I THINK TYPICALLY YOU WOULD WANT TO IDENTIFY WHAT LOOKED TO BE THE HEALTHIEST LARGEST TYPICALLY FOLLICLES FOR FERTILITY PURPOSES; AND IF THERE WERE SMALLER FOLLICLES THAT COULD BE OOCYTES THAT COULD BE RECOVERED, YOU MIGHT SORT OF CALL THEM AS SORT OF SECOND RATE. BUT THE TRUTH IS THE CORRELATION NOW BETWEEN FOLLICLE SIZE AND OOCYTE QUALITY ISN'T REALLY LINEAR, AND THERE'S SOME QUESTION NOW ABOUT SOME OF THE CRITERIA THAT WE USE FOR IDENTIFYING WHAT'S A GOOD

LOOKING FOLLICLE LIKELY TO HAVE A GOOD EGG VERSUS A NOT SO GOOD LOOKING FOLLICLE. SO I THINK IT'S A BIT OF A GRAY AREA, BUT IT MIGHT BE DIFFICULT, PLUS YOU CAN SEE HOW MANY FOLLICLES ON ULTRASOUND THERE ARE, BUT TYPICALLY YOU GET 80 PERCENT OF THAT NUMBER IN TERMS OF OOCYTES RECOVERED, BUT THERE ARE EXCEPTIONS TO THAT RULE. IT MAY BE YOU'RE GOING IN AND YOU THINK YOU ARE GOING TO GET 30 EGGS AND YOU ONLY GET SEVEN, AND THAT WOULD KIND OF CHANGE YOUR MANAGEMENT IN MIDSTREAM.

DR. CIBELLI: COULD I ASK YOU ANOTHER QUESTION? DID YOU EVER GET A DONOR THAT DID IT FOR FREE?

DR. TAYLOR: WE'VE NOT HAD THAT EXPERIENCE IN SAN FRANCISCO.

DR. CIBELLI: IF YOU'RE TALKING OF A SCENARIO WHERE YOU HAVE TO PAY, WE CAN'T BECAUSE IT'S PROHIBITED BY LAW. THAT'S A MOOT POINT.

DR. TAYLOR: ANN'S CERTAINLY HAD EXPERIENCE GETTING DONORS THAT ARE JUST COMPENSATED FOR THEIR TIME AWAY FROM -- TRAVEL TIME OR WHATEVER, RIGHT. I THINK IT'S JUST A MATTER OF WE'VE NEVER REALLY TRIED TO ESTABLISH THAT TYPE OF A PROGRAM HERE.

VICE CHAIR LO: MAYBE I CAN ASK JAMES A POINT OF CLARIFICATION. MY UNDERSTANDING WAS THAT PROP 71 DOES NOT ALLOW US TO COMPENSATE FOR TIME, ONLY FOR

OUT-OF-POCKET EXPENSES FOR DONATION.

DR. KIESSLING: ACTUALLY IT DOESN'T SAY OUT OF POCKET.

VICE CHAIR LO: IT SAYS EXPENSES.

DR. KIESSLING: BUT THE TERM "OUT OF POCKET," THAT WAS HOTLY DEBATED IN MASSACHUSETTS ACTUALLY, AND WE GOT INVOLVED IN THAT DEBATE. THEY SPECIFICALLY DID NOT USE THE TERM "OUT OF POCKET."

VICE CHAIR LO: BUT FOR CALIFORNIA, WHAT'S OUR UNDERSTANDING?

MR. HARRISON: THE SPECIFIC LANGUAGE READS, "STANDARDS PROHIBITING COMPENSATION TO RESEARCH DONORS OR PARTICIPANTS WHILE PERMITTING REIMBURSEMENT OF EXPENSES."

DR. KIESSLING: SO IT BECOMES THE DEFINITION OF EXPENSES.

VICE CHAIR LO: JAMES, DOES THAT INCLUDE COMPENSATION FOR TIME?

MR. HARRISON: I THINK BOB KLEIN, WHO WAS RESPONSIBLE FOR THIS PROVISION, HAS STATED IN THE PAST THAT IT WAS MEANT TO EXCLUDE COMPENSATION FOR TIME.

DR. PRIETO: HOW ABOUT LOST INCOME?

MR. HARRISON: INCLUDING LOST INCOME.

DR. TAYLOR: I MISSPOKE. DELETE THAT FROM THE RECORD.

DR. EGGAN: IT SEEMS IN THIS SAME VEIN ANOTHER EVEN PERHAPS MORE IMPORTANT THING TO DISCUSS IS THE SOURCE, WHICH FALLS INTO THIS RUBRIC, IS THE SOURCE OF MATERIAL WHICH IS CURRENTLY BEING USED IN GREAT BRITAIN FOR NUCLEAR TRANSPLANTATION EXPERIMENTS, WHICH ARE SO-CALLED FAILED TO FERTILIZE OOCYTES. AND I THINK IT'S PROBABLY IMPORTANT FOR THIS PANEL TO MAKE SOME SORT OF STATEMENT TO AT LEAST HAVE A DISCOURSE ON THE TOPIC OF THE USE OF THESE OOCYTES AND WHAT WE THINK THE CONCERNS THERE OR THE BENEFITS ARE.

VICE CHAIR LO: STRIKES ME WE SHOULD SEPARATE THAT AND MAKE THAT OUR NEXT TOPIC.

DR. KIESSLING: I THINK ONE OF THE WAYS THAT THIS MIGHT WORK IS TO HAVE A CLINIC, AS THERE IS ONE IN ENGLAND, AT LEAST ONE, IN WHICH THE ENTIRE POLICY OF THAT CLINIC IS THAT SOME EGGS GO FOR RESEARCH. IF THAT WERE A CLINICWIDE POLICY SO THAT EVERYONE WHO APPROACHED THAT CLINIC WHO WENT THERE SO THAT IT WAS NOT AN INDIVIDUAL PATIENT-BY-PATIENT CONSENT PROCESS, BUT IT WAS A KNOWN PRACTICE IN THAT CLINIC, THEN I THINK YOU MIGHT BE ABLE TO USE SOME OF THE EGGS THAT YOU RECOVERED. AND I DON'T KNOW HOW YOU ARE GOING TO WORK AROUND THE EXPENSES ISSUE, BUT I THINK YOU MIGHT BE ABLE TO USE SOME OF THE EGGS FOR RESEARCH UNDER THOSE CIRCUMSTANCES.

OTHER THAN THAT, I CAN'T THINK OF A PATIENT-BY-PATIENT SCENARIO IN WHICH YOU ARE GOING HAVE PEOPLE BEING ABLE TO DONATE EGGS, EITHER SHARED EGGS FROM THEIR DONORS OR DONATE EGGS THEMSELVES FOR RESEARCH.

DR. EGGAN: THAT WHOLE CLINIC WOULD HAVE TO FUNCTION, AS I WOULD INTERPRET THE LEGISLATION, AS SAYING THAT WHOLE POOL OF DONORS COULDN'T BE COMPENSATED.

DR. KIESSLING: IT STILL MIGHT WORK.

DR. CIBELLI: ANOTHER QUESTION FOR ROBERT. DO YOU EVER HAVE COUPLES THAT COME AND ACTUALLY SHE'S FERTILE, SO SHE CAN PRODUCE HER OWN EGGS, AND THEY SAID WE ARE GOING TO USE HALF OF EGGS AND FERTILIZE THEM, AND THE REST YOU CAN GIVE IT TO SOMEONE ELSE THAT NEEDS EGGS OR JUST FREEZE THEM FOR LATER USE? DID YOU EVER HAVE THAT? SO THEY DON'T WANT TO FERTILIZE MORE THAN THEY ACTUALLY NEED.

DR. TAYLOR: OUR BUILT TO ACTUALLY FREEZE EGGS SUCCESSFULLY IS STILL NOT VERY GOOD. IT'S IMPROVING AND THERE ARE SOME PROGRAMS THAT HAVE HAD SOME SUCCESS DOING THAT, BUT THERE ARE NOT VERY MANY PROGRAMS AROUND THE COUNTRY. AND THOSE THAT DO HAVE EGG FREEZING PROTOCOLS, THOSE ARE EXPERIMENTAL PROTOCOLS AT THIS STATE. SO IN GENERAL WHAT COUPLES

WILL DO IS THEY WILL FERTILIZED THE NUMBER OF OOCYTES THAT THEY GENERATE EVEN WITH THE EXPECTATION THAT THEY MAY ONLY TRANSFER SOME OF THEM. AND THEN THE REMAINING EMBRYOS THAT ARE MADE CAN EITHER BE DESTROYED, THEY CAN BE FROZEN FOR FUTURE USE, OR DONATED TO OTHER COUPLES, THAT ESSENTIALLY ARE ADOPTED OUT BECAUSE THAT'S REALLY AN EMBRYO ADOPTION. THERE ARE EXTRA EMBRYOS. THEY'VE ALREADY SORT OF MISSED THE OPPORTUNITY TO BE FERTILIZED MAYBE WITH THE SPERM OF ANOTHER PARTNER FOR ANOTHER COUPLE, SO IT'S A LITTLE DIFFERENT FROM EGG DONATION.

DR. CIBELLI: SO WE DON'T HAVE TO WORRY ABOUT THAT THEN? WE'RE NOT GOING TO GET SPARE EGGS FROM A COUPLE.

DR. TAYLOR: CERTAINLY IT'S GOING TO BE FEASIBLE TO DO THAT, TO GET SPARE EGGS. THERE REALLY HASN'T BEEN A PRACTICE OPPORTUNITY THAT'S BEEN --

DR. CIBELLI: IF CALIFORNIA DECIDES TO GO FORWARD WITH THIS RESEARCH AND THINGS ARE GOING WELL AND WE SEE A LOT OF PROGRESS, MAYBE PEOPLE WILL START COMING FORWARD AND SAY, WELL, IF I GIVE YOU MORE THAN TEN, YOU CAN GIVE FIVE FOR RESEARCH.

DR. EGGAN: THAT'S ALSO PERHAPS TROUBLING BECAUSE WHAT DOES IT MEAN TO BE A SPARE OOCYTE? IF THE COUPLE IS INFERTILE, THEY NEED EVERY EGG THEY'VE GOT IN ORDER TO GET PREGNANT, WHICH IS WHY THEY WALKED IN THE

DOOR. AGAIN, I WOULD LIKE TO THINK, AS A SCIENTIST, I WOULD LIKE TO THINK THIS IS A VERY WORTHWHILE AND REASONABLE SOURCE OF MATERIAL. I THINK WHEN AN INFERTILE COUPLE COMES TO A DOCTOR AND THEY'RE UNDERGOING MEDICAL TREATMENT TO TREAT THEIR FERTILITY, IT SEEMS LIKE IT'S THE DOCTOR'S RESPONSIBILITY TO DO EVERYTHING IN THEIR POWER TO GIVE THAT COUPLE A BABY. THAT'S WHY THEY ARE THERE FIRST AND FOREMOST.

AND SO EVEN IF THE WOMAN IS INFERTILE, THE MAN'S INFERTILE AND IT MAY NOT BE CLEAR WHY, SO YOU MAY NEED TO FERTILIZE EVERY SINGLE ONE OF THOSE EGGS OR ATTEMPT TO DO SO IN ORDER TO GIVE THAT COUPLE THE BEST CHANCE OF HAVING A CHILD. AND SO IT MAY BE A DIFFICULT THING TO DO MAY BE, IT MAY BE A DIFFICULT EQUATION TO COMPUTE TO KNOW HOW MANY OF THOSE EGGS IT'S SAFE TO GIVE AWAY TO RESEARCH AND STILL BE ABLE TO PROTECT THE OPPORTUNITY OF THAT COUPLE TO HAVE A BABY.

DR. CIBELLI: I'M JUST THINKING ON THE CONSENT FORM SCENARIO, THAT'S WHAT WE'RE TALKING TODAY. I'M NOT TALKING ABOUT THE ETHICS OF COERCING COUPLES TO START DONATING EGGS BECAUSE THEY HAVE BIGGER PROBLEMS IN THEIR MIND. BUT IF THEY WANT TO DO IT FOR X REASON, MAYBE ONE OF THE PARENTS WILL SAY, OH, THEY THINK THIS IS GOING TO HELP RESEARCH, DO WE HAVE MEDICAL CONSENT FORMS THAT WE'RE TALKING ABOUT? ARE WE GOING TO HAVE

THE COOLING OFF PERIOD THAT WE NEED ON THAT DONOR TO THINK THINGS THROUGH OR THINGS LIKE THAT?

DR. TAYLOR: I DON'T KNOW IF THIS IS WHERE YOU WANT THE DISCUSSION TO GO, BUT JOSE RAISES AN INTERESTING SCENARIO WHERE IN A KNOWN CASE OF MALE FACTOR WHERE THERE'S A VERY WELL LOW SPERM COUNT AND YOU'RE PLANNING TO DO ICSI, DIRECTLY INJECT SPERM INTO EGGS, AND IF YOU WERE TO COLLECT LOTS OF EGGS FROM AN OTHERWISE PROBABLY FERTILE WOMAN WHO JUST HASN'T BEEN SUCCESSFUL BECAUSE OF HER HUSBAND'S PROBLEM, PARTNER'S PROBLEM, YOU COULD EASILY GET TEN EGGS AND IT'S TECHNICALLY KIND OF DIFFICULT TO DO ICSI IN THAT MANY CASES IN A GIVEN PERIOD OF TIME. SO YOU COULD FIVE EGGS LEFT OVER THAT POTENTIALLY COULD BE USED FOR RESEARCH PURPOSES IF THAT COUPLE WERE APPROPRIATELY CONSENTED UP FRONT. SO I CAN SAY SOME SCENARIOS WHERE THAT COULD OCCUR.

VICE CHAIR LO: I HAVE A COUPLE OF PEOPLE. LET ME JUST CLARIFY. JOSE RAISED A POINT THAT I THINK WE NEED TO KEEP IN MIND. ALTHOUGH WE TALK ABOUT THE CONTEXT OF CONSENT, THIS IS REALLY A MUCH BIGGER ISSUE. I DON'T THINK WE CAN SEPARATE CONSENT FROM THE WHOLE ISSUE OF THE ETHICS OF DONATING OOCYTES SIMULTANEOUSLY FOR RESEARCH AND CLINICAL CARE. SORT OF AT THE RISK OF CONFUSING, WE NEED TO SORT OF COMBINE THOSE TWO ISSUES

JUST FOR THIS ONE TOPIC.

DR. HALL: JUST TO SAY THAT IT SEEMS TO ME THAT THE PROBLEM IS YOU DON'T WANT TO TAKE THE EGGS FOR RESEARCH PURPOSES UNTIL YOU KNOW THAT YOU'VE EXHAUSTED ALL POSSIBLE REMEDIES FOR FERTILITY PURPOSES. AND BY THE TIME YOU KNOW THAT, THAT IS, BY THE TIME YOU KNOW THAT YOU HAVE A SUCCESSFUL PREGNANCY, THE EGGS ARE NO LONGER USEFUL. SO I SEE THAT AS A REAL COMPLICATION IN TERMS OF THAT SCENARIO. THERE MAY BE SPECIFIC SITUATIONS SUCH AS THE ONE YOU MENTIONED, WHICH IS PROBABLY RELATIVELY RARE WHERE THERE MIGHT BE CASES IN WHICH THEY WOULD, BUT I THINK AS A GENERAL RULE, IT POSES A REAL ETHICAL DILEMMA TO GIVE UP. AND WE WERE JUST SAYING AT LUNCH TODAY FOR A WOMAN WHO MAY HAVE DONATED SOME EGGS FOR RESEARCH AND THEN DOES NOT GET PREGNANT, SHE MAY ALWAYS SAY HAD I NOT DONATED THOSE EGGS, I MIGHT HAVE A CHILD. SO I THINK IT'S A VERY TRICKY GROUND WE'RE ON HERE.

VICE CHAIR LO: I'M GOING TO PUSH A BIT. IS IT SO TRICKY THAT WE SHOULD NOT ALLOW CIRM FUNDS TO BE USED WITH THESE KINDS OF OOCYTES?

MS. FEIT: WELL, ZACH JUST SAID WHAT I WAS GOING TO SAY. I THINK UNLESS WE ENSURE THAT THERE'S SUCCESS WITH THE COUPLE AND THE PREGNANCY, THEN I DON'T THINK THAT WE CAN BECAUSE YOU WILL ALWAYS WONDER IF THE

TWO EGGS I GAVE AWAY WAS THE PREGNANCY. SO I REALLY THINK WE CAN'T. I DON'T SEE HOW WE CAN GO DOWN THAT PATH.

DR. PRIETO: BEFORE WE COMPLETELY PRECLUDE IT, I THINK WE SHOULD CONSIDER THAT WHAT WE'RE LOOKING AT RIGHT NOW IS THE CURRENT STATE OF THE ART AND THAT COULD CHANGE AND ALMOST CERTAINLY WILL CHANGE IN TERMS OF THE DIFFICULTY OF OBTAINING THE OOCYTES, THE RATES OF SUCCESS, YOU KNOW, THE PROBABILITY OF SUCCESS THAT YOU CAN OFFER TO A COUPLE COMING INTO THIS PROCESS, AND THAT MAY BE VERY DIFFERENT THREE OR FOUR YEARS FROM NOW FROM WHAT IT IS NOW. IF WE ANTICIPATE THAT SITUATION AND AT LEAST PUT APPROPRIATE SAFEGUARDS IN PLACE, EVEN THOUGH WE MAY NOT HAVE ANYONE COMING FORWARD NOW, FIVE YEARS FROM NOW CONCEIVABLY WE COULD.

VICE CHAIR LO: ANOTHER OPTION WOULD BE TO SAY AT THIS TIME WE DON'T PERMIT IT, BUT LEAVE IT OPEN TO CHANGE.

DR. EGGAN: THAT'S PRECISELY WHAT I WOULD ENCOURAGE BECAUSE I THINK IF WE DO SEE THAT OOCYTE FREEZING BECOMES A VIABLE OPTION, THAT'S GOING TO CHANGE THE ENTIRE LANDSCAPE IMMEDIATELY. AND THERE ARE SITUATIONS, ALTHOUGH IT MAY BE RARE IN ONE PARTICULAR PRACTICE, TO HAVE A SITUATION WHERE THERE'S AN INFERTILE MAN WHO IS HAVING HIS TESTES BIOPSIED TO FIND

A VERY RARE SPERM WHICH IS BEING USED TO INJECT INTO EGGS WHERE THERE ARE LEFT-OVER EGGS. THERE ARE CERTAIN CLINICS THAT SPECIALIZE IN MALE INFERTILITY AND PROBABLY HAVE THIS PROBLEM MORE. I KNOW SHERMAN SILBER IN ST. LOUIS WOULD PROBABLY BE A GOOD EXAMPLE OF THIS. HE'S SOMEONE WHO'S A REAL EXPERT IN TREATING MALE FERTILITY. INFERTILE MEN GO THERE AND ALMOST CERTAINLY THERE'S PROBABLY ON A REGULAR BASIS SURPLUS EGGS AT A CLINIC LIKE THAT.

I THINK, AGAIN, TO REALLY PRECLUDE IT ABSOLUTELY IS -- I HESITATE TO DO THAT. I DON'T KNOW HOW TO BALANCE THESE TWO CONCERNS OUT BESIDES WALKING THROUGH THE VARIOUS POSSIBILITIES VERY EXPLICITLY.

DR. HALL: I THINK IT'S SIMPLE; THAT IS, YOU HAVE A PHRASE "UNTIL FERTILITY IS ASSURED." AND THEN IF YOU FREEZE THE EGGS, THEN PRESUMABLY YOU WAIT UNTIL AFTER THE TREATED, OR YOU CAN DO IT ANOTHER WAY, FERTILITY METHODS ARE EXHAUSTED, WHICH WOULD BE MORE ADEQUATE. I THINK YOU COULD FIND LANGUAGE THAT WOULD -- I THINK WHAT WE'RE SAYING IS THAT IN THOSE SITUATIONS, THE PRIORITY HAS TO BE FERTILITY FIRST AND RESEARCH SECOND. AND THAT ONLY AFTER ONE HAS EXHAUSTED ALL POSSIBILITIES FOR FERTILITY CAN THEN RESEARCH BE CONSIDERED.

I THINK WE COULD LEAVE IT TO OUR VERY ABLE

STAFF TO FIND LANGUAGE THAT MIGHT EXPRESS THAT. I THINK IT SEEMS TO ME THAT'S THE IMPORTANT, IF WE WERE TO PULL ANYTHING OUT OF THIS DISCUSSION, THAT THAT'S WHAT IT WOULD BE.

DR. EGGAN: THAT SEEMS GREAT TO ME. I MIGHT SAY THAT THIS IS SUCH AN IMPORTANT POINT, THAT YOU MIGHT GIVE PEOPLE AN OPPORTUNITY FOR PUBLIC COMMENT ON JUST THIS.

VICE CHAIR LO: WE'RE NOT GOING TO VOTE, BUT THIS IS CERTAINLY AN ISSUE WHERE PUBLIC COMMENT WILL BE EXTREMELY HELPFUL. AND YOU THOUGHT THROUGH THIS AS YOU WERE SETTING UP YOUR PROGRAM AND CHOSE, AS I UNDERSTAND IT, TO NOT TO TRY AND RECRUIT OOCYTE DONORS FOR RESEARCH THROUGH IVF PRACTICES.

DR. KIESSLING: RIGHT.

VICE CHAIR LO: DO YOU WANT TO JUST SORT OF FILL US IN ON THE BACKGROUND OF THAT?

DR. KIESSLING: THE PRACTICE OF IVF AND ATTEMPTING FERTILITY FOR COUPLES IS REALLY DIFFERENT FROM WHAT YOU WOULD DO FOR SOMEBODY COMING THROUGH FOR RESEARCH PURPOSES. AND PART OF THE DIFFERENCE IS THE RISK OF OVARIAN HYPERSTIMULATION SYNDROME. SO PEOPLE WHO ARE GOING THROUGH AN INFERTILITY CYCLE ARE WILLING TO RISK THAT TO JUST GET THREE OR FOUR MORE EGGS. THAT'S NOT SOMETHING YOU CAN DO FOR PEOPLE WHO ARE

SIMPLY INVOLVED IN THE RESEARCH PROTOCOL.

SO YOU END UP ON THE VERY FAR SIDE OF BEING VERY, VERY CONSERVATIVE IN TERMS OF HOW MUCH STIMULATION THE DONORS FOR RESEARCH PURPOSES ARE GIVEN. THE EGG COLLECTION NUMBERS ARE MUCH, MUCH LOWER, BUT SIMULTANEOUSLY HER RISK OF ANY KIND OF OVARIAN COMPLICATION ARE ALSO EITHER ZERO OR MUCH, MUCH LOWER.

THE WHOLE -- PLUS THE FACT THAT DONOR SCREENING FOR RESEARCH PURPOSES IS DIFFERENT FROM DONOR SCREENING FOR INFERTILITY IN THAT INFERTILITY, ALL THE PRACTICE OF RECRUITING DONORS FOR INFERTILITY MORE HAS SORT OF DEFAULTED TO SPECIALISTS IN THAT AREA. THEY ALSO SCREEN PEOPLE FOR LOTS OF GENETIC DISEASES FOR DIFFERENT KINDS OF EVEN HISTORIES OF ALCOHOLISM AND THAT SORT OF THING, WHICH IS NOT SOMETHING THAT YOU NECESSARILY NEED TO SCREEN PEOPLE FOR IF THEY'RE DONATING EGGS FOR STEM CELL DERIVATION. SO THOUGH THE HISTORY TAKING IS DIFFERENT, THE ACCEPTANCE CRITERIA ARE ALSO DIFFERENT.

SO WE STARTED USING ALL THE CRITERIA FROM AN INFERTILITY PRACTICE, AND SORT OF SYSTEMATICALLY DELETED OR CHANGED A LOT OF THOSE GUIDELINES WHEN WE REALIZED THAT WHAT WE WERE DOING WAS SO VERY DIFFERENT FROM FAMILY PLANNING.

DR. TAYLOR: I THINK THAT'S EXACTLY RIGHT,

ALTHOUGH I MIGHT ARGUE THAT SCREENING BY HISTORY FOR DONORS THAT MAY BE USED TO DERIVE THERAPEUTIC STEM CELL LINES MIGHT, IN FACT, NEED TO BE MORE RIGOROUS THAN IT IS FOR INFERTILE COUPLES IF WE'RE TALKING ABOUT THERAPY. SO I'M ACTUALLY A PROPONENT FOR THE ABILITY TO RECONTACT INDIVIDUALS FOR DISEASES THAT DEVELOP LATER ON IN THEIR LIVES. AND I THINK THAT NOT ONLY IS THAT IMPORTANT, IT'S ALSO GOING TO BE EXTREMELY IMPORTANT UP FRONT, IF WE'RE TALKING ABOUT USING THESE CELLS AS THERAPEUTIC AGENTS, TO MAKE SURE THAT WE'RE BEING AS RIGOROUS ABOUT THE QUALITY OF THEIR GENETIC BACKGROUND, ETC., ETC., AS WE POSSIBLY CAN BE.

DR. KIESSLING: I THINK THAT THE DONORS FOR RESEARCH ARE ACTUALLY MORE OPEN TO BEING RECONTACTED THAN THE DONORS WHO DONATE EGGS FOR FERTILITY. I THINK PEOPLE WHO HAVE DONATED EGGS FOR FERTILITY WANT TO REMAIN ANONYMOUS BY AND LARGE, AND I THINK THE WOMEN WHO ARE WILLING TO DO THIS FOR RESEARCH PURPOSES, THEY WANT THEIR CONFIDENTIALITY PROTECTED, BUT I THINK THEY'RE TO BE RECONTACTED SHOULD THE SCIENCE NEED IT.

VICE CHAIR LO: SO WHAT I'M HEARING IS ETHICAL CONCERNS ABOUT ALLOWING WOMEN TO SIMULTANEOUSLY DONATE OOCYTES FOR RESEARCH AND FOR IVF, THAT AT THE CURRENT TIME FREEZING NOT BEING AN OPTION, IF WE ALLOW IT TO HAPPEN AT ALL, IT WOULD HAVE TO BE IN PRETTY

EXCEPTIONAL CIRCUMSTANCES, LIKE MALE INFERTILITY OR A CLINIC THAT REQUIRES IT. SO LET US TRY AND CRAFT LANGUAGE THAT AT LEAST DISCOURAGES THIS AND PERHAPS PROHIBITS IT EXCEPT FOR CERTAIN EXCEPTIONS.

THIS IS SUCH AN IMPORTANT TOPIC, SO I JUST WANT TO STOP FOR A MINUTE HERE AND JUST ASK IF THERE ARE ANY MEMBERS OF THE PUBLIC WHO WANT TO COMMENT ON THIS PARTICULAR ISSUE OF SIMULTANEOUSLY DONATING OOCYTES FOR BOTH RESEARCH AND IVF.

MR. REED: I JUST HATE THE THOUGHT THAT A WOMAN WHO IS WILLING TO GO THROUGH THE INCONVENIENCE AND HASSLE AND DISCOMFORT AND TIME LOST FROM WORK COULD NOT IN SOME WAY HAVE HER LOSSES MADE UP. I HOPE THAT THE TIME IN A WAY SEPARATE FROM US THAT SOME CHARITY CAN EVEN BE SET UP TO HELP THEM RECOVER FROM THE LOSSES THAT THEY ARE GOING TO BE ASKED TO GO THROUGH TO HELP FOR THIS ALTRUISTIC PURPOSE. THEY'RE TRYING TO HELP SAVE LIVES AND STOP SUFFERING. IT DOESN'T SEEM RIGHT THAT THEY SHOULD NOT AT LEAST HAVE THE TIME LOST FROM WORK MADE UP. I DON'T KNOW IF IT'S POSSIBLE NOW, BUT I JUST FROM MY HEART I THINK THAT IT'S RIGHT. DOWN IN TIME WE WILL HAVE TO FIND A WAY FOR THAT.

MR. REYNOLDS: MY NAME IS JESSE REYNOLDS. I'M WITH THE CENTER FOR GENETICS IN SOCIETY. FIRST, I THINK WE'VE SEEN FROM THE NEWS REPORTS THE LAST COUPLE

WEEKS HOW SERIOUS THE ISSUES ARE AROUND PROPERLY SOURCING EGGS FOR RESEARCH. AND I'M GLAD TO SEE THE SENSE OF THE BOARD IS THAT IN THE CASE OF FERTILITY DONATIONS, THAT THE FERTILITY COMES FIRST AND THEN THE RESEARCH SECOND. I THINK YOU'D AGREE THAT THE HEALTH OF THE WOMAN COMES BEFORE EITHER OF THOSE.

AND A COUPLE OF VERY IMPORTANT POINTS HAVE BEEN BROUGHT UP. I THINK DR. EGGAN BROUGHT UP THE IDEA, THE CONCERN THAT THE DOCTOR RESPONSIBLE FOR THE EGG EXTRACTION MIGHT FIND HIM OR HERSELF IN A SITUATION OF A CONFLICT BETWEEN SERVING THE INTERESTS OF THE PATIENT AND THE INTERESTS OF THE RESEARCHERS. AND DR. KIESSLING BROUGHT UP HOW THIS GETS MORE COMPLICATED WHEN YOU CAN GET MY MORE EGGS BY ADMINISTERING MORE HORMONES, WHICH RAISES THE RISK OF MEDICAL COMPLICATIONS. IT'S FOR THIS REASON THAT OUR CENTER HAS ADVOCATED HAVING A PHYSICIAN WHO IS FULLY INDEPENDENT OF THE RESEARCH BE RESPONSIBLE FOR THE ENTIRE EGG EXTRACTION PROCESS, BOTH MEDICALLY AND PROBABLY ALSO FOR THE INFORMED CONSENT, A PHYSICIAN WHO IS NOT AFFILIATED WITH THE RESEARCH OR RECEIVING ANY TYPE OF COMPENSATION FOR THE EGGS. THAT WOULD HELP BUILD IN A FIREWALL BETWEEN THE INTERESTS OF THE RESEARCH AND THOSE OF THE PATIENT.

VICE CHAIR LO: AS I UNDERSTAND IT, THIS IS

SIMILAR TO, FOR EXAMPLE, THE REQUIREMENTS WE HAVE IN TRANSPLANTATION, THAT THE PERSON WHO RETRIEVES THE ORGAN NOT BE RESPONSIBLE FOR THE CLINICAL CARE OF THE PATIENT WHO'S THE DONOR IN THE CADAVERIC CASE, OF THE LIVE DONOR IN A LIVING DONOR CASE.

DR. TAYLOR: YOUR FINAL RECOMMENDATION WENT BEYOND THAT, AND THAT WOULD BE SUGGESTING THAT A THIRD-PARTY SURGEON DO THE NEPHRECTOMY FOR THE RENAL TRANSPLANTATION. AND I GUESS AS A CLINICIAN WHO'S SPENT A LOT OF TIME IN CLINICAL TRAINING, I WOULD WANT TO KNOW THAT THAT PROCEDURE WAS BEING DONE UNDER THE BEST POSSIBLE CIRCUMSTANCES, I GUESS. IT'S AN INTERESTING MODEL. IT WOULD MEAN THAT THERE WOULD BE A STEM CELL RETRIEVAL CENTER, CLINIC WHERE EVERYBODY WAS CLINICALLY TRAINED AND HAD ALL THE EXPERIENCE THAT AN EXPERIENCED IVF PHYSICIAN WOULD HAVE, YET WAS NOT BEING REMUNERATED FOR THAT. AND IT'S KIND OF A CURIOUS MODEL, BUT UNDER THE RIGHT CIRCUMSTANCES, I WOULD BE ABLE TO ACCEPT THAT.

DR. CIBELLI: ARE YOU READY TO OFFER THIS, THIS PARTICULAR ONE.

VICE CHAIR LO: I THINK SO.

DR. EGGAN: JUST TO EXPAND ON THIS ISSUE OF COMPENSATION FOR EGG DONATION, I THINK IT IS AN IMPORTANT ONE. AND I THINK IT'S IMPORTANT TO MAKE THE

STATEMENT THERE ARE MANY PEOPLE THAT BELIEVE THAT THIS COURSE THAT WE'RE TAKING, WHICH IS PRESCRIBED BY CALIFORNIA LAW, IS THE WRONG ONE. I THINK WE SHOULD ACKNOWLEDGE THAT. THERE ARE LAW IN THE UNITED STATES WHICH ALSO STATE WHICH PEOPLE SHOULD HAVE EQUAL ACCESS TO THE ABILITY TO PARTICIPATE IN HUMAN SUBJECTS RESEARCH. AND THERE ARE THOSE THAT BELIEVE THAT BY NOT COMPENSATING, YOU RESTRICT CERTAIN PEOPLE FROM BEING ABLE TO PARTICIPATE. INDEED, AS YOU SAY, THERE ARE MANY PEOPLE WHO HAVE RELATIVES SUFFERING FROM DEBILITATING DISEASE WHO BELIEVE, TRUE OR NOT, THAT THIS RESEARCH MIGHT HELP THEIR LOVED ONES AND ARE INTERESTED IN PARTICIPATING. AND I THINK IT'S FAIR TO SAY THAT MANY OF THOSE PEOPLE WILL NOT BE ABLE TO PARTICIPATE BECAUSE WE WILL NOT BE ABLE TO COMPENSATE. NONETHELESS, THE LAW IS SPECIFIC TO THIS ISSUE, AND I THINK THAT'S WHERE WE HAVE TO LOOK TO THAT.

DR. KIESSLING: THE STATUTE, JUST TO KIND OF ELABORATE, THE STATUTE IS INTERESTING IN THAT IT ALLOWS COMPENSATION FOR EVERYONE INVOLVED EXCEPT THE DONOR. THE DOCTORS ARE TO BE COMPENSATED, THE CLINICS WILL BE COMPENSATED, CERTAINLY THE DRUGS WILL BE PURCHASED. SO THE ONLY INDIVIDUAL WHO'S PART OF THIS VERY EXPENSIVE PROCESS AND IT COSTS ABOUT 20 OR $25,000 FOR AN OOCYTE COLLECTION WHO WILL NOT BE COMPENSATED FOR THEIR TIME

IS THE DONOR. AND I THINK IT'S SIMPLY A MATTER OF HOW YOU INTERPRET EXPENSES. I DON'T THINK THAT THIS IS AN INSURMOUNTABLE PROBLEM WITH THE CALIFORNIA STATUTE.

DR. ROWLEY: ISN'T THAT TRUE FOR ALL ORGAN DONATION? THE ONLY PERSON NOT COMPENSATED FOR THE KIDNEY IS THE DONOR?

DR. EGGAN: THIS IS TRUE, BUT THEN IT'S A QUESTION OF WHETHER OR NOT OOCYTES ARE LIKE KIDNEY OR WHETHER OR NOT THEY'RE LIKE SPERM. IT'S TRUE -- OR BLOOD. IT'S TRUE THAT THE RISKS OF DONATING OOCYTES ARE GREATER THAN RISKS OF DONATING BLOOD, BUT THEY MAY NOT BE AS SEVERE AS THE RISKS OF DONATING A KIDNEY. AND SO THIS HAS BEEN ONE OF THE PROBLEMS WITH OOCYTE DONATION AND COMPENSATION IS THAT IT'S HARD FOR US TO DECIDE WHICH ONE OF THOSE THINGS IT'S LIKE.

VICE CHAIR LO: WHY DON'T WE MOVE ON BECAUSE I THINK THE LAW IS WRITTEN AND CANNOT AT THIS POINT BE AMENDED. SINCE THE AUTHOR OF THE PROPOSITION IS ON RECORD AS SAYING HE INTERPRETS IT TO MEAN WE CAN'T PAY PEOPLE FOR THEIR TIME, I THINK AT THIS POINT IT'S A MATTER OF HAVING TO CHANGE THE LAW.

DR. CIBELLI: THERE ARE CASES THAT I DON'T THINK WE EVER TALK ABOUT WHERE, FOR EXAMPLE, SOME WOMEN, YOUNG WOMEN MAY HAVE BEEN DIAGNOSED WITH CANCER AND HAVE TO UNDERGO CHEMOTHERAPY OR RADIOTHERAPY AND SO

THERE IS GOING TO BE A WIPE-OUT OF ALL THE GERM CELLS. AND NOW THERE ARE PROTOCOLS WHERE THEY CAN FREEZE THEIR PIECES OF OVARY AND BE LATER USED FOR MAKING BABIES IF THEY NEED TO.

I WONDER WHAT WE'RE GOING TO SAY ABOUT DONATING MATERIALS THAT CAN BE LATER USED AS A SOURCE OF EGGS. EVEN IN THE CASES OF OVARIAN CANCER, YOU MAY STILL HAVE PIECES OF THE OVARY THAT CAN BE -- YOU CAN IN VITRO MATURE EGGS EVEN THOUGH THAT TECHNOLOGY IS NOT QUITE READY.

VICE CHAIR LO: I THINK THAT IN THE FUTURE WE NEED TO BE OPEN TO, IF THAT BECOMES WIDESPREAD AND AVAILABLE AND SORT OF AN ACCEPTED PRACTICE, TO ALLOW THAT TO BE ANOTHER PATHWAY.

DR. EGGAN: I WOULD GO FURTHER THAN THAT. I WOULD SUGGEST THAT THIS A PARTICULAR TYPE OF RESEARCH THAT CIRM SHOULD DECIDE TO FUND, THAT IT SHOULD ENCOURAGE RESEARCH IN OOCYTE FREEZING, THAT IT MIGHT CONSIDER RFA'S FOR ALTERNATIVE SOURCES OF OOCYTES. IT MIGHT ENCOURAGE RESEARCH ON IN VITRO MATURATION OF EGGS, OVEROPTIMIZED MATERIAL FROM CANCER PATIENTS BECAUSE THESE ARE THE SORTS OF ENABLING ADVANCES THAT WE NEED IN STEM CELL SCIENCE TO TAKE OOCYTE DONATION OFF THE TABLE. AND THEY'RE WITHIN REACH. THEY'RE JUST NOT BEING DONE BECAUSE THERE'S NOT AN INTEREST. SORT

OF THE IN VITRO FERTILIZATION APPARATUS IS FUNCTIONAL AS IS FOR THE MOST PART.

VICE CHAIR LO: OKAY.

MS. COONEY: IS IT POSSIBLE -- MARY ANN COONEY. I'M A STUDENT AT THE GTU. IS IT POSSIBLE THAT IF THE PROCEDURES FOR FREEZING OOCYTES IMPROVED IN THE FUTURE, THAT A YOUNG WOMAN WHO IS DONATING EGGS COULD BE COMPENSATED BY HAVING SOME OF HER EGGS FROZEN IN CASE SHE COULD NOT, IN FACT, BECOME PREGNANT IN THE FUTURE?

VICE CHAIR LO: THANK YOU. I'M WANTING TO SWITCH TO ANOTHER TOPIC. AS WE GO THROUGH OUR LIST, WHAT I HAVE ON MY LIST ARE FAILED TO FERTILIZE OOCYTES, DONATION OF EMBRYOS AS OPPOSED TO OOCYTES, AND THEN CRITERIA FOR USE OF HUMAN EMBRYONIC STEM CELL LINES WHICH ARE NOT DERIVED WITH CIRM FUNDING, BUT WHICH CIRM-FUNDED RESEARCHERS WISH TO USE. DO WE SORT OF WANT TO SORT OF CHARACTERIZE THE KEY FEATURES OF CONSENT THAT NEED TO BE PRESENT IN THOSE LINES?

DO YOU WANT TO TALK ABOUT FAILED TO FERTILIZE OOCYTES AS A POTENTIAL SOURCE OF MATERIALS FOR DERIVATION OF NEW STEM CELLS? LET ME JUST SAY SORT OF AS BACKGROUND, WHEN ROB WAS AT UCSF, WE THOUGHT ABOUT THIS A LOT, ACTUALLY HAD APPROVED A PROTOCOL FOR THAT. AND WE THOUGHT THE KEY ISSUE WAS HOW IS THAT

DETERMINATION OF FAILED TO FERTILIZE MADE? AND WE SAID THAT IF THE EMBRYOLOGIST MAKING THAT DETERMINATION WAS TOTALLY INDEPENDENT OF THE RESEARCH TEAM AND DID NOT KNOW WHEN HE OR SHE WAS MAKING THE DECISION TO DISCARD OR NOT WHETHER IT COULD BE USED FOR RESEARCH, THAT THAT WOULD ENSURE SORT OF AN ABSOLUTELY OBJECTIVE ASSESSMENT. AND ONLY AFTER YOU DECIDED IT WAS GOING TO BE THROWN OUT, COULD YOU THEN SORT OF OPEN THE ENVELOPE AND SAY, OH, BUT THIS WOMAN OR THE DONOR AGREED TO ALLOW IT TO BE USED FOR RESEARCH, BUT TO MAKE SURE THERE WAS NO KIND OF SHADING OF THE DETERMINATION OF FAILED TO FERTILIZE BECAUSE THE PERSON MAKING THAT DETERMINATION KNEW IT MIGHT BE USED FOR RESEARCH.

ROB, YOU WERE INVOLVED VERY MUCH IN THIS DISCUSSIONS.

DR. TAYLOR: THAT KIND OF BLINDING WAS ACTUALLY QUITE EASY FOR US IN OUR OWN IVF PROGRAM JUST BECAUSE THE EMBRYOLOGY LABORATORY IS KIND OF ISOLATED AND IT'S A FAIRLY HIGH THROUGHPUT PLACE AND ALL THE MATERIALS GET HANDLED THE SAME WAY, AND IT'S NOT CLEAR TO THE EMBRYOLOGIST WHETHER PATIENTS HAD CONSENTED TO RESEARCH PROTOCOL OR NOT.

THE PRACTICE, AND IT'S EVOLVED A LITTLE BIT OVER THE YEARS, AND IT'S BEEN A WHILE SINCE I'VE BEEN INVOLVED IN IT DIRECTLY, BUT TYPICALLY WE WOULD DO AN

INSEMINATION OF THE FRESH OOCYTES, AND IF THEY FAILED TO FERTILIZE, THERE WAS A PERIOD OF TIME WHERE WE WERE DOING WHAT WE CALL A SECOND DAY INSEMINATION OR WE'D ASK THE PARTNER TO COME BACK IN WITH A FRESH SPERM SAMPLE AND TRY TO INSEMINATE THE SECOND DAY. TYPICALLY IT WAS EXTREMELY RARE, QUITE HONESTLY, FOR THOSE SECOND DAY INSEMINATIONS TO EVER BE SUCCESSFUL.

SO I THINK IN THINKING ABOUT UNFERTILIZED OOCYTES AS A POSSIBLE SOURCE, I THINK THAT MOST IVF PRACTICES WOULD FEEL THAT IF THERE'S A FAILURE TO FERTILIZE IN THE FIRST DAY, THAT THOSE OOCYTES ARE VERY UNLIKELY TO FERTILIZE NATURALLY OR WITH ICSI DIRECT SPERM INJECTION AND THAT THOSE POTENTIALLY COULD BE SET SIDE FOR THIS TYPE OF RESEARCH.

I THINK IF THEIR CLINICAL PRACTICE IS TO GO TWO DAYS, THOSE OOCYTES BECOME -- THEY'VE BEEN IN CULTURE FOR AN EXTENDED PERIOD OF TIME, AND WHETHER THEY WOULD REALLY BE PARTICULARLY USEFUL EVEN FOR THE RESEARCH PROTOCOLS I THINK BECOMES A LITTLE BIT QUESTIONABLE. THAT WAS ONE OF THE CONCERNS THAT WE HAD IN SAN FRANCISCO USING THIS FAILED TO FERTILIZE OOCYTE MODEL WAS THAT WE KNEW WE'D BE KIND OF WORKING WITH MATERIALS THAT PROBABLY WERE LESS LIKELY TO SUCCEED, AND THAT BECOMES EVEN MORE PROBLEMATIC IF YOU EXTEND THE LENGTH OF TIME IN CULTURE. SO THAT WAS THE

THINKING, AND THAT WAS KIND OF THE PRACTICE AT THE TIME.

IF ONE WERE TO DECIDE AT THE END OF THE FIRST DAY THAT FAILED TO FERTILIZE OOCYTES MIGHT BE ELIGIBLE THEN FOR EXPERIMENTATION, AND THAT WOULD HAVE TO DE FACTO MEAN THAT NOBODY WANTED TO DO ANYTHING MORE WITH THEM IN THE CLINICAL LABORATORY, IT WOULD BE A SOURCE OF MATERIAL THAT, BUT I WOULD SUSPECT, GIVEN THE RELATIVELY LOW RATES OF SUCCESS WITH NUCLEAR TRANSFER, ETC., NOW, I THINK IT WOULD BE EVEN WORSE PROBABLY IN THIS SETTING, BUT IT'S SOMETHING TO BE CONSIDERED. IT GETS AROUND A LOT OF THE ETHICAL ISSUES.

DR. EGGAN: AS I SEE IT, THAT IS THE ONE PRIMARY ETHICAL ISSUE WITH FAILED TO FERTILIZE OOCYTES IS THE DIFFICULT POSITION IT PUTS THE IVF CLINICIAN IN IF THERE'S A CONFLICT OF INTEREST. SO IF THERE IS SOME REASONABLY PRESCRIBED MECHANISM WHICH CAN TAKE THAT OUT OF EQUATION, AS YOU JUST SAID, YOU ONLY KNOW AFTER THE DISPOSAL WHETHER OR NOT THEY'RE GOING TO GO FOR RESEARCH, THEN IN MY OPINION THAT'S DISCARDED MEDICAL WASTE, AND IT'S SOMETHING THAT OBVIOUSLY CAN BE USED FOR RESEARCH.

SO I GUESS IT WOULD BE INTERESTING TO KNOW MORE ABOUT WHAT THAT MECHANISM WOULD BE LIKE SPECIFICALLY. BUT THEN, OF COURSE, I ALSO ECHO THESE

CONCERNS, THAT THAT MAY BE A SCIENTIFICALLY -- SO IT COULD A SITUATION WHERE DO THE SCIENTIFIC BENEFITS OUTWEIGH THE ETHICAL CHALLENGES TO THE MATERIAL? BUT I THINK IF YOU CAN TAKE CARE OF THAT ONE CENTRAL ISSUE, AND IF YOU'RE REALLY CERTAIN ABOUT THE TIMING IN YOUR CLINIC WHEN YOU'RE GOING TO MAKE THAT DECISION ABOUT FAILED TO FERTILIZE IN THE ABSOLUTE SENSE, THEN TO ME THAT SEEMS REASONABLE.

DR. KIESSLING: I SORT OF AGREE WITH ROB. I DON'T THINK THIS POSES A PROBLEM FOR THE CLINICAL LAB. I THINK IVF LABS HAVE PRETTY CUT AND DRIED ROUTINES ABOUT WHEN THEY DECIDE SOMETHING IS GOING TO GO FORWARD.

I THINK THE SINGLE PROBLEM WITH FAILED TO FERTILIZE EGGS IS WHERE DID THE SPERM GO? AND IF THE EGG WAS FERTILIZED NATURALLY, IF IT WAS FERTILIZED, INSEMINATED IN A DISH, THAT EGG IS ABSOLUTELY COVERED WITH SPERM PROBABLY. THEY DIDN'T GET IN AND SOMETHING DIDN'T HAPPEN, BUT THEY'RE STILL THERE. IF THAT FAILED TO FERTILIZE EGG HAD UNDERGONE THIS INTROCYTOPLASMIC SPERM INJECTION AND IT DIDN'T FERTILIZE, WHERE IS THE SPERM? SO IF YOU ACTIVATE THAT EGG, WHAT'S HAPPENED? HAVE YOU, IN FACT -- YOU ACTIVATED IT AND IT REALLY IS FERTILIZED AND IT JUST DIDN'T LOOK FERTILIZED IN THE IVF SETTING, OR DOES THAT MATTER? IN CALIFORNIA IT

OBVIOUSLY DOESN'T MATTER BECAUSE YOU CAN FERTILIZE EGGS IN CALIFORNIA TO DERIVE STEM CELLS. IN MASSACHUSETTS YOU CANNOT.

SO WE SPECIFICALLY ARE BLOCKED FROM USING ANY KIND OF FERTILIZATION PROCEDURES. SO MASSACHUSETTS, SOMEHOW YOU WOULD HAVE TO ASCERTAIN WHERE THE SPERM ARE AND WHAT HAPPENED TO THE SPERM THAT FAILED TO FERTILIZE EGG SO YOU WOULD NOT RUN THE RISK OF ACTUALLY ACTIVATING A QUIESCENT SPERM AND, IN FACT, FERTILIZING IT BY MISTAKE. MAYBE ROB HAS GOT A FEW MORE THINGS TO SAY ABOUT THAT, BESIDES THE FACT THAT THE BIOLOGY MAY BE WEAK, BUT THAT MIGHT VERY INTERESTING TO WORK OUT. I THINK THE SINGLE BIGGEST ISSUE FROM THE BIOLOGY STANDPOINT IS WHAT HAPPENED TO THE SPERM.

DR. TAYLOR: THERE'S SOME VERY INTERESTING SCIENTIFIC QUESTIONS THAT COME UP. IT MIGHT BE THAT INTRODUCING ANOTHER NUCLEUS, YOU COULD REACTIVATE AND END UP WITH TRIPLOID CELLS, AND IT COULD GET REALLY KIND OF CURIOUS AND COMPLICATED AS YOU THINK ABOUT IT. BUT I DO THINK THAT ONE OF THE KIND OF UNDERLYING PRINCIPLES IS THAT A FAILED TO FERTILIZE EGG PRESUMABLY HAS SOME INTRINSIC OR THE SPERM, BUT THE EGG MAY WELL HAVE SOME INTRINSIC ABNORMALITIES WITHIN IT THAT MIGHT NOT MAKE IT THE WORLD'S GREATEST CANDIDATE THERAPEUTIC STEM CELL RESEARCH.

I DON'T THINK WE SHOULD DISCOUNT THE IMPORTANCE OF KARYOTYPICALLY, CHROMOSOMALLY ABNORMAL EGGS AND EMBRYOS THAT COULD BE REALLY WONDERFUL RESEARCH TOOLS TO UNDERSTAND BETTER DOWN SYNDROME AND TURNER'S SYNDROME AND OTHER DISEASES THAT WE WOULD WANT TO STUDY AND UNDERSTAND BETTER IN THE LABORATORY, AND I THINK THOSE ARE THINGS THAT SHOULD COME FROM CIRM, SO WE MAY REALLY WANT TO HAVE -- BE ABLE TO PROPAGATE CELLS FROM ABNORMAL EGGS AND ABNORMAL SPERM AND ABNORMAL EMBRYOS, BUT FOR THE THERAPEUTIC PURPOSE OF GENERATING STEM CELLS FOR TREATING PATIENTS, I THINK THAT WE MIGHT NOT WANT TO START WITH KIND OF A LOW COMMON DENOMINATOR THAT YOU MIGHT GET WITH AN UNFERTILIZED EGG.

VICE CHAIR LO: SO I GUESS WHAT I'M HEARING IS THAT IF THE VARIOUS CONCERNS THAT HAVE BEEN RAISED, PARTICULARLY THE CONFLICT OF INTEREST CONCERN, COULD BE WORKED OUT, THIS COULD BE ANOTHER ACCEPTABLE APPROACH, BUT WE WANT TO SPECIFY PRETTY CAREFULLY HOW WE MAKE THAT DETERMINATION OF FAILED TO FERTILIZE IN AN OBJECTIVE AND UNBIASED MANNER, AND WE NEED TO TRY TO DRAFT SOME LANGUAGE.

DR. TAYLOR: WHAT SOME OF THE POTENTIAL CONSEQUENCES MIGHT BE IN TERMS OF OUTCOME.

VICE CHAIR LO: RIGHT. RIGHT. OKAY. HOW

ABOUT A HARD TASK BEFORE A BREAK? EMBRYONIC STEM CELL LINES THAT CIRM DOESN'T FUND, WHAT SHOULD BE THE RESTRICTIONS WE PLACE ON HOW THOSE LINES ARE DERIVED AND THE CONSENT FOR THEM?

DR. EGGAN: DO WE, BEFORE WE EVEN DO THAT, WANT TO TALK ABOUT DONATED EMBRYOS?

VICE CHAIR LO: WE COULD. I FIGURED WE COULD DO THAT WHEN WE'RE A LITTLE MORE TIRED BECAUSE THAT MAY BE A LITTLE SIMPLER.

DR. EGGAN: WE COULD SAY THAT -- WE MAY IMAGINE HAVING MORE SPECIFIC REQUIREMENTS FOR WHAT CAN BE DERIVED UNDER CIRM FUNDING THAN WHAT WE ALLOW IN, AND SO I'M WONDERING IF WE CAST THE LARGER NET. THAT'S JUST A SUGGESTION.

VICE CHAIR LO: LET'S TALK ABOUT PRIMARILY DONATION OF FROZEN OOCYTES THAT HAVE BEEN --

DR. EGGAN: FROZEN EMBRYOS.

VICE CHAIR LO: -- FROZEN EMBRYOS THAT WERE ORIGINALLY INTENDED FOR IVF, AND NOW THE COUPLE IN IVF HAS MADE THE DECISION RATHER THAN DISCARD OR GIVE TO ANOTHER COUPLE FOR THEIR FERTILITY TREATMENT, TO DONATE THEM FOR RESEARCH.

DR. EGGAN: I CAN TAKE A CRACK AT IT. THE NAS GUIDELINES SPEAK VERY CLEARLY TO THIS ISSUE, AND THEY SAY THAT THESE EMBRYOS SHOULD BE FROZEN TO

DISSOCIATE THE DECISION TO DONATE FROM THE REPRODUCTIVE EFFORT. THIS SEEMS, IN THE CASE OF THESE EMBRYOS, A VERY REASONABLE THING TO DO. HOWEVER, I THINK THERE ARE CERTAIN EXCEPTIONS TO THIS RULE THAT SHOULD BE ALLOWED. IN FACT, THAT I THINK ARE EXPLICIT IN THE WAY THE GUIDELINES ARE STATED. AND THERE ARE CERTAIN TYPES OF EMBRYOS, SUCH AS PGD EMBRYOS, WHICH SHOULD BE ALLOWED TO BE DONATED IN AN UNFROZEN STATE.

I THINK REALLY WHAT'S HAPPENING IS, AGAIN, THERE ARE CERTAIN TYPES OF EMBRYOS WHICH WILL ALWAYS BE DISCARDED AND WILL NEVER BE USED FOR REPRODUCTION OF THAT WOMAN. IN THE CASE OF THE COUPLE UNDERGOING PREIMPLANTATION GENETIC DIAGNOSIS, THOSE ARE THE EMBRYOS WHICH ARE AFFECTED BY THE DISEASE AS DETERMINED BY GENOTYPE. THOSE ARE ALWAYS GOING TO BE THROWN AWAY AND NEVER TRANSFERRED INTO THE WOMAN'S UTERUS.

THEREFORE, IT SEEMS TO ME THERE SHOULD BE NO REQUIREMENT TO FREEZE SOME EMBRYOS BEFORE THEY'RE DONATED FOR RESEARCH. IN FACT, THESE, FOR SCIENTISTS, A VERY IMPORTANT SOURCE OF MATERIAL BECAUSE THEY WOULD ALLOW RESEARCHERS TO DERIVE EMBRYONIC STEM CELL LINES WHICH CARRY DISEASE GENES. SO I THINK THAT SHOULD CERTAINLY BE ONE EXCEPTION TO THIS RULE. IN NO CIRCUMSTANCES WOULD BE THAT BE A DIVERSION OF MATERIAL AWAY FROM THE WOMAN'S REPRODUCTIVE EFFORTS. LIKEWISE,

THERE MAY BE OTHER TYPES OF EMBRYOS THAT BY ABSOLUTELY OBJECTIVE CRITERION WOULD BE OKAY. FOR INSTANCE, I KNOW IN SOME -- I'VE HEARD IN SOME PRACTICES THAT MULTINUCLEATE CELLULAR EMBRYOS ARE NEVER TRANSFERRED. AGAIN, I THINK THIS IS WHERE YOU HAVE -- IT IS TRUE THAT AFFECTED EMBRYOS AFTER PGD ARE NEVER TRANSFERRED, BUT IT MAY BE THAT IN SOME CIRCUMSTANCES THESE OTHER TYPES OF EMBRYOS THAT ONE MIGHT CONSIDER AS NEVER TRANSFERRED AND OTHER CLINICS ARE TRANSFERRED.

I THINK CERTAINLY THERE ARE CERTAIN TYPES OF EMBRYOS WHICH WE COULD ABSOLUTELY NEVER NEED TO BE FROZEN, OTHERS THERE'S ROOM FOR EXPANSION, I THINK YOU CAN MOVE INTO A GRAY AREA. THAT'S CERTAINLY ONE THING THAT I, AS A SCIENTIST, WOULD LIKE TO MAKE SURE IS CLEARLY STATED.

DR. CIBELLI: IS YOUR QUESTION RELATED TO THE CONSENT FORM RIGHT NOW? HOW THE CONSENT FORM SHOULD BE CRAFTED FOR THE EMBRYOS?

VICE CHAIR LO: I THINK THAT'S WHERE WE PRIMARILY SHOULD BE TALK ABOUT. AS WITH THE FRESH OOCYTES, IT'S ALSO AN ISSUE SHOULD WE ALLOW IT AT ALL. WE DON'T ALLOW IF -- WE DON'T ALLOW CERTAIN THINGS, THEN WE DON'T HAVE TO WORRY ABOUT IT.

DR. EGGAN: THIS IS IMPORTANT WITH RESPECT TO CONSENT BECAUSE ALLOWING DONATION OF THESE TYPES OF

EMBRYOS REQUIRES A TOTALLY DIFFERENT CONSENT STRUCTURE.

DR. CIBELLI: I AGREE WITH EVERYTHING YOU SAY, BUT I JUST WANT TO KNOW HOW WE MOVE FROM HERE NOW UNLESS SOMEONE DOESN'T WANT TO DO THAT. I AGREE WITH KEVIN, THAT WE SHOULD DO THE FROZEN AND THE FRESH THAT HAVE SOME MUTATIONS. THEY'RE GOING TO BE THROWN AWAY ANYWAY.

DR. TAYLOR: THE TIMING OF THE CONSENTING PROCESS, THOUGH, MIGHT BE DIFFERENT, I THINK, ON THESE TWO. YOU CAN SEE CERTAINLY HAVE A LONG TIME-OUT PERIOD WHEN YOUR EXCESS EMBRYOS HAVE BEEN FROZEN. YOU'VE GOT QUITE A SHORT TIME-OUT PERIOD IF THERE ARE FRESH EMBRYOS IN THE LABORATORY THAT HAVE SELECTED NEITHER TO FREEZE THEM NOR TO TRANSFER THEM BACK INTO THE UTERUS. THOSE EMBRYOS HAVE A SHORT PERIOD OF TIME IN WHICH SOME DISPOSITION WOULD NEED TO BE MADE.

DR. KIESSLING: IT'S TRUE. SOMETHING LIKE 10 PERCENT OF EGGS ARE TRIPLOID WITHIN THE FIRST 24 HOURS, 8 TO 10 PERCENT, AND THAT SEEMS TO BE UNIVERSAL. THE PROBLEM IS EXACTLY WHAT ROB SAYS. YOU'D HAVE EVERY IVF CLINIC, IN ORDER TO MAKE THOSE AVAILABLE FRESH FOR PURPOSES, EVERY IVF CLINIC WOULD HAVE TO HAVE THAT CAVEAT IN THEIR CONSENT FORM. IT WOULD HAVE TO BE AHEAD OF TIME. YOU HAVE A 10 PERCENT -- 8 TO 10 PERCENT CHANCE OF HAVING THIS. THIS MIGHT HAPPEN, AND

WE'D LIKE TO GIVE THAT FOR RESEARCH, THAT JUST SEEMS -- KEVIN IS TALKING ABOUT THE TRIPLOID.

DR. EGGAN: PRIMARILY, ANN, I'M TALKING ABOUT PGD.

DR. KIESSLING: THE PGD EMBRYOS IS A VERY, VERY LONG TIME-OUT. AND I CAN SEE WORKING OUT A CONSENT FORM FOR THAT REALLY EASILY.

DR. EGGAN: FOR PGD THE TIME-OUT WOULD BE AT THE TIME THE COUPLE PRESENTS TO UNDERGO PGD AND SAYS THAT WE'RE GOING TO SIGN A CLINICAL CONSENT TO UNDERGO PGD, THERE MIGHT ALSO BE A CHECK BOX IN THAT CONSENT FOR WHICH WOULD SAY IF WE HAVE AFFECTED EMBRYOS, NOT CARRIERS, NOT NORMAL EMBRYOS THAT MIGHT BE USED FOR OUR OWN REPRODUCTION, BUT IF WE HAVE AFFECTED EMBRYOS THAT WOULD BE DISCARDED, THEN WE WILL GIVE THEM UP. SO THEN THEY ESSENTIALLY HAVE -- THEY WOULD HAVE TO PRESUMABLY RECONSENT AT THE EXACT TIME WHEN THOSE EMBRYOS ARE DONATED. SO THEY ESSENTIALLY THE ENTIRE COURSE OF THEIR CARE AS A TIME-OUT.

DR. KIESSLING: RIGHT.

DR. EGGAN: I SUPPOSE ONE COULD DO THE SAME SORT OF THING WITH TRIPLOID EMBRYOS, BUT THAT SEEMS A LITTLE BIT RISKIER BECAUSE I UNDERSTAND SOMETIMES NOT ALL THE CELLS MIGHT BE TRIPLOID, AND SOMETIMES THEY'RE TRANSFERRED JUST AS A LAST RESORT.

DR. TAYLOR: AND THEY TEND TO BE SORT OF LATE OBSERVATIONS. SWITZERLAND, WHICH ISN'T MAYBE A VERY RELEVANT EXAMPLE FOR US, BUT THERE I THINK YOU CAN ONLY TRANSFER TWO EMBRYOS. SO WHAT THEIR PRACTICE THERE IS TO MAYBE HAVE FOUR EMBRYOS GROWING IN THE DISH, YOU SELECT THE TWO VERY BEST EMBRYOS THAT TRANSFER BACK TO THE RECIPIENT, AND THEY'RE FORCED TO DESTROY THE OTHER TWO EMBRYOS. IF WE WERE IN A SETTING LIKE THAT, THAT WOULD BE ANOTHER SITUATION, BUT I DON'T KNOW IF WE'RE GOING TO BE GETTING CIRM-APPROVED EMBRYOS FROM SWITZERLAND, BUT I CAN'T THINK OF TOO MANY OTHER SCENARIOS.

DR. CIBELLI: THEY USE THE FRESH.

DR. TAYLOR: THEY USE THE FRESH.

MS. FEIT: AREN'T WE GETTING BACK TO YOUR IDEA OF RIGHT FROM THE BEGINNING IN THESE CASES IT'S WELL-KNOWN THAT THAT'S GOING TO HAPPEN SO THAT THE COUPLE GOES INTO IT REALLY UNDERSTANDING WHAT'S GOING TO HAPPEN.

DR. KIESSLING: I CAN SEE THE ENTIRE INFERTILITY COMMUNITY BEING WILLING TO PUT OUT SOME KIND OF BLANKET POLICY THAT AFFECTED EMBRYOS ARE AVAILABLE FOR RESEARCH. I DON'T THINK ANYBODY WOULD OBJECT TO THAT. I THINK THAT COULD BE SOMETHING THAT'S ROUTINE.

DR. TAYLOR: AFFECTED SOMETIMES, ALTHOUGH DEGRANULATING OR DEGENERATING CELLS WITHIN AN EMBRYO, WE'VE CERTAINLY SEEN GOOD PREGNANCY OUTCOMES.

DR. KIESSLING: NO. NO. I MEAN THE ONES THAT ARE GOING TO GO THROUGH PGD.

DR. TAYLOR: I GO THAT. BUT I THINK IF YOU GET A LITTLE BIT SOFTER THAN A REAL GENETIC DIAGNOSIS, DETERMINING JUST ON VISUAL CRITERIA ALONE, IT MAY BE HARD FOR EVERYONE WAY OF ASSESSING GOOD VERSUS BAD EMBRYO.

DR. EGGAN: AS ANOTHER, I THINK, IMPORTANT CRITERION, IF A COUPLE UNDERGOES PGD AND THEY HAVE THREE EMBRYOS FROM THE PROCEDURE, AND ALL THREE OF THOSE EMBRYOS ARE AFFECTED BY THE DISEASE, THEY TRANSFER ZERO EMBRYOS. I THINK THAT SHOULD BE THE CUTOFF. BECAUSE IF A COUPLE UNDERGOES IVF AND THEY HAVE THREE EMBRYOS AND ALL THREE EMBRYOS ARE POTENTIALLY TRIPLOID OR HAVE ABNORMAL MORPHOLOGY, IT PROBABLY IS TRUE THAT ALL THREE OF THOSE EMBRYOS ARE TRANSFERRED ROUTINELY. I THINK THAT'S A VERY IMPORTANT DISTINCTION THAT WE NEED TO TAKE INTO ACCOUNT BECAUSE, AGAIN, THAT SPEAKS TO DIVERSION OF THE MATERIAL FROM ONE PURPOSE TO ANOTHER.

DR. PRIETO: EVEN WITH PGD, THIS NEEDS TO BE A PART OF THE CONSENT PROCESS UP FRONT, THAT THOSE

WOMEN ARE AWARE OF THIS POSSIBILITY. I CAN'T IMAGINE THERE BEING MANY DISAGREEMENTS.

VICE CHAIR LO: I THINK THAT'S UNDERSTOOD, BUT NEEDS TO BE EXPLICIT. DO WE NEED TO SAY ANYTHING ABOUT EMBRYO DONATION WHEN THE EMBRYOS ARE FROZEN AND THE COUPLE COMPLETES THEIR REPRODUCTIVE GOALS IN TERMS OF THE KINDS OF PROTECTIONS.

DR. EGGAN: I THINK THERE ARE SOME INTERESTING ISSUES TO CONSIDER WITH RESPECT TO RECONTACTING PEOPLE AFTER PGD TOO. I CAN TELL YOU, AS A SCIENTIST, WHEN YOU HAVE A COUPLE THAT UNDERGOES PGD AND YOU WISH TO OBTAIN THE AFFECTED EMBRYOS WHICH WOULD MANIFEST THE PHENOTYPE OF THE DISEASE, PRESUMABLY IN TISSUE CULTURE AFTER DERIVATION OF STEM CELL LINES, AS A CONTROL, IT WOULD BE VERY USEFUL AND INTERESTING TO HAVE ES CELLS DERIVED FROM THE CARRIER EMBRYOS AS WELL AS THE UNAFFECTED EMBRYOS FROM THAT SAME COUPLE. IT MAY BE THAT IF THEY'RE VERY SUCCESSFUL IN THEIR ATTEMPTS, THAT THEY'LL HAVE OTHER LEFT-OVER EMBRYOS WITH THE SAME SORTS OF GENOTYPES IN THE FREEZER ONCE THEY'VE COMPLETED THEIR FAMILY. IT WOULD BE VERY USEFUL TO BE ABLE TO RECONTACT THOSE FAMILIES AND HAVE THEM DONATE THOSE EMBRYOS JUST AS OTHER COUPLES WHO HAVE FINISHED THEIR FAMILY DONATE EMBRYOS. SO I THINK THAT'S SOMETHING THAT WE SHOULD ENCOURAGE OR FIGURE OUT

HOW TO WORK INTO THIS PGD CONSENT, WHICH IS A DIFFERENT TYPE OF THING. SO THIS MIGHT BE ONE RARE EXAMPLE WHERE IT MAY BE WORTHWHILE TO RECONTACT THE FAMILY.

ALSO, THE FAMILY MAY NOT -- THERE MAY NOT BE THE SAME STIGMA TO RECONTACTING THESE PEOPLE BECAUSE THEY'RE PRESUMABLY UNDERGOING IVF, NOT BECAUSE THEY'RE INFERTILE, BUT BECAUSE THEY HAVE THESE OTHER CONCERNS OF OVERT DISEASE IN THEIR FAMILY. SO THE NEED TO CONTACT THEM TO STUDY THEIR DISEASE THAT RUNS IN THEIR FAMILY MAY FAR OUTWEIGH THE NEGATIVE CONNOTATION OF RECONTACT.

DR. CIBELLI: THAT'S DIFFERENT FROM WHAT KEVIN WAS SAYING. IS THERE ANY NEED TO TELL A TIME, NOT A COOLING OFF PERIOD, BUT CERTAIN PERIOD OF TIME THAT HAS TO PASS TO MAKE SURE THE COUPLE IS REALLY DONE WITH FAMILY PLANNING TO SAY, OKAY, NOW YOU CAN'T DONATE. LET'S SAY THEY'RE IN THEIR TWENTIES. THEY'RE DONE, THEY THINK THEY'RE DONE, AND THEY WANT TO DONATE EVERYTHING, AND THEN LATER ON SOMETHING HAPPENS, YOU CAN'T HAVE ANY MORE CHILDREN?

DR. TAYLOR: THAT'S A CHALLENGE. WE'RE GETTING EMBARRASSINGLY GOOD AT GETTING 50-YEAR-OLD WOMEN PREGNANT WITH DONATED EMBRYOS. SO IT CAN BE A LITTLE BIT HARD TO KNOW WHEN TO DRAW THE LINE. I THINK THERE ARE SOME SORT OF OTHER EVOLVING ISSUES IN

SOCIETY, AND ONE IS LATER PREGNANCIES AS A RESULT OF POSTPONING PREGNANCY AND DEVELOPING CAREERS AND THEN COMING BACK LATER. SO KNOWING EXACTLY WHEN, BUT I THINK THE COUPLES THAT HAVE DONATED AND FROZEN EMBRYOS WILL ALWAYS HAVE THE RIGHT TO MAINTAIN THOSE EMBRYOS IN A FROZEN STATE AND BE ABLE TO USE THEM AND RELEASE THEM AT A TIME THAT THEY MAKE THAT DECISION.

SO I DON'T THINK THAT'S SOMETHING THAT WE'RE GOING TO USURP FROM THEM, BUT TRYING TO DECIDE WHEN IS AN APPROPRIATE TIME TO CONTACT THEM OR HOW LONG IS TOO LONG, I DON'T KNOW THAT WE'RE GOING TO BE ABLE TO RESOLVE THAT QUESTION VERY EASILY.

THE OTHER IS THAT THERE'S KIND OF A RECENT DEVELOPMENT OF EMBRYO ADOPTION PROGRAMS THAT HAVE COME UP AS A REALLY RESPONSE TO THE LARGE NUMBER OF FROZEN AND UNUSED EMBRYOS THAT CURRENTLY EXIST AROUND THE COUNTRY NOW IN IVF PROGRAM FREEZERS. MANY INFERTILE COUPLES NOW ARE BEGINNING TO GO TO SOME OF THESE PROGRAMS TO ACTUALLY ADOPT THESE HEALTHY -- THEY'RE TYPICALLY HEALTHY EMBRYOS BECAUSE THE REASONS THAT NOBODY TOOK THEM OUT OF THE FREEZER IS BECAUSE THEY GOT PREGNANT WITH THEIR FIRST TWO EMBRYO TRANSFERS AND HAVE THE FAMILY THAT THEY WANT, AND THESE ARE REALLY INDEED EXCESS EMBRYOS. SO THOSE SHOULD HEALTHY, VIABLE EMBRYOS. NOW THEY'RE BEING DONATED TO OTHER COUPLES

FOR FERTILITY PURPOSES.

DR. CIBELLI: THIS IS WAY I SEE IT RIGHT NOW. SO WE HAVE ALL THESE TRAINING GRANTS GOING OUT, SO THERE WILL BE A LOT OF PEOPLE REQUESTING FROZEN EMBRYOS TO START PRODUCING MORE CELL LINES AND SO FORTH. AND SO HERE WE ARE VERY HUNGRY FOR EMBRYOS. AND IT'S TRUE THERE ARE MANY THAT ARE FROZEN, BUT ARE WE JUST BEING TOO AGGRESSIVE ON THAT ON END? HOW ABOUT THE COUPLE THAT HAVE DIFFERENT PLANS? THEY DIDN'T THINK IT THROUGH VERY WELL. DO WE HAVE TO GIVE THEM SIX MONTHS TO THINK ABOUT IT? WHAT WOULD BE THE APPROACH? HOW WOULD YOU DO THIS?

DR. KIESSLING: FREQUENTLY THE PRESSURE IS PUT ON THESE COUPLES BY THE CLINIC. THE CLINICS HAVE A TIMELINE THAT THEY WANT TO STORE THESE EMBRYOS. AND THE COUPLE HAS TO MAKE A DECISION, OR THEY HAVE TO START PAYING IN SOME CIRCUMSTANCES SUBSTANTIAL AMOUNTS OF MONEY TO MAINTAIN THEIR EMBRYOS THERE. SO THE PRESSURE IS NOT BEING PUT BY THE RESEARCH COMMUNITY. THE PRESSURE IS PUT ON THESE COUPLES BY THE CLINICS.

DR. CIBELLI: WE DON'T KNOW.

DR. KIESSLING: I KNOW. THE CLINICS THEMSELVES ALL HAVE GUIDELINES IN TERMS OF HOW LONG THEY WANT TO STORE CRYO PRESERVED EMBRYOS. AND THOSE GUIDELINES ARE PROBABLY MOSTLY DRIVEN BY A NEED TO KEEP

CONTACT WITH THESE PEOPLE BECAUSE IF THEY WANDER OFF AND YOU'VE LOST CONTACT WITH THEM AND YOU DON'T HAVE A DEFAULT MECHANISM FOR DOING SOMETHING WITH THEIR EMBRYOS, YOU'RE STUCK WITH A HUGE POPULATION. AND THERE'S A LOT OF CLINICS WITH THAT PROBLEM NOW. THE COUPLES HAVE JUST WANDERED OFF, AND WE CAN'T FIND THEM ANYMORE, SO THEY'RE LEFT WITH THESE EMBRYOS. THAT'S NOT A TRIVIAL PROBLEM. SO CLINICS HAVE GOTTEN A LOT MORE AGGRESSIVE ABOUT FORCING PEOPLE TO MAKE DECISIONS ABOUT WHAT THEY HAVE IN THE CRYO BANK.

VICE CHAIR LO: MY UNDERSTANDING IS THAT TYPICALLY WHAT HAPPENS IS IF YOU HAVE EMBRYOS FROZEN IN AN IVF CLINIC, EVERY YEAR THEY SEND YOU -- THEY CONTACT YOU AND YOU'VE AGREED TO THIS UP FRONT, AND YOU'RE ASKED WOULD YOU LIKE TO PAY YOUR NEXT MONTH'S FREEZER STORAGE TO KEEP THEM IN THE FREEZER? OPTION B IS WOULD YOU LIKE TO DONATE TO ANOTHER COUPLE FOR REPRODUCTIVE PURPOSES. THIRD OPTION IS WOULD YOU LIKE TO JUST DESTROY THEM? AND FOURTH OPTION WOULD YOU LIKE TO, INSTEAD OF DESTROYING THEM, DONATE THEM TO A RESEARCHER FOR RESEARCH PURPOSES?

SO IT REALLY COMES AS SORT OF AN ANNUAL TIME TO RENEW YOUR SORT OF LITTLE PARKING PERMIT AT THE STORAGE FREEZER.

DR. TAYLOR: UNFORTUNATELY A LOT OF PEOPLE

CHOOSE THE FIFTH OPTION. WHEN YOU'RE RUNNING AN IVF PROGRAM, THERE ARE A LOT OF PEOPLE WHO ACTUALLY DON'T GET BACK TO YOU. AND WE'RE VERY RELUCTANT TO DO ANYTHING OTHER THAN JUST KEEP THE EMBRYOS IN STORAGE, BUT IT DOES BECOME AN ECONOMICS ISSUE AT SOME LEVEL TOO.

VICE CHAIR LO: CONTACT IS NEVER, AS I UNDERSTAND IT, INITIATED BY A RESEARCHER. THE COUPLE NEEDS TO MAKE, THE WOMAN OR COUPLE NEEDS TO MAKE SOME INDICATION THAT THEY'RE WILLING TO CONSIDER RESEARCH, AND THEN THEY'RE PUT IN CONTACT WITH THE RESEARCHER.

DR. CIBELLI: WHAT YOU'RE SAYING IS THAT WE'RE GOING TO HAVE TO WORRY THAT THERE ARE SO MANY EMBRYOS STORED, AND WE'RE NOT GOING TO DRAIN THE BANKS, AND WE'RE NOT GOING TO BE COMPETING WITH COUPLES THAT MAY CHANGE THEIR MIND IN THE FUTURE.

VICE CHAIR LO: THERE'S SO MANY IN THE BANK. YOU RAISE THE IMPORTANT POINT, JOSE, THAT THERE'S ALWAYS SOMEONE WHO CAN DONATE AND A COUPLE YEARS LATER SOME TRAGEDY OCCURS AND THEIR KIDS ARE IN A CAR ACCIDENT, AND SAY, WELL, MY GOSH, NOW I WISH WE HAD THOSE FROZEN EMBRYOS AND HADN'T GIVEN THEM FOR RESEARCH. THERE'S ALWAYS THAT KIND OF UNFORESEEN CALAMITY. OTHERWISE, I THINK MOST COUPLES, IF THEY CAN AFFORD IT, JUST KEEP STORING THESE FROZEN EMBRYOS FOR

LONG PERIODS OF TIME IF THEY'RE NOT REALLY SURE THEY WANT TO GIVE THEM UP FOR RESEARCH PURPOSES.

DR. HALL: PERHAPS KNOWS MORE ABOUT THIS AND CAN GIVE A MORE AUTHORITATIVE ANSWER THAN I CAN. BUT I UNDERSTAND THERE'S A MAN IN FLORIDA WHO HAS MADE AN ESTIMATE OF THE NUMBER OF EMBRYOS IN STORAGE AND HOW MANY OF THOSE HAVE ALREADY BEEN CONSENTED FOR RESEARCH PURPOSES. AND THE CLAIM IS THAT SOMETHING ON THE ORDER OF 10,000 EMBRYOS COULD BE USED FOR RESEARCH IF THERE WERE FUNDS AVAILABLE TO STUDY THEM.

SO IF THAT IS CORRECT, AND AS I SAY, SOMEBODY ELSE HAS BETTER KNOWLEDGE OF THAT OR BETTER FIGURES, I ADVANCE THAT VERY TENTATIVELY, BUT THAT'S MY UNDERSTANDING THAT THERE'S QUITE A LARGE NUMBER OF THESE EMBRYOS THAT ALREADY HAVE BEEN CONSENTED FOR RESEARCH, BUT THERE IS NO OUTLET FOR THEIR USE RIGHT NOW, NO RESEARCH OUTLET. IS THAT CONSISTENT WITH WHAT YOU KNOW, ROB?

DR. TAYLOR: IT SOUNDS VERY REASONABLE. I DON'T KNOW THE STATISTICS ANY BETTER THAN THAT, BUT THERE ARE A LOT OF EMBRYOS THAT HAVE BEEN COMPLETED FAMILIES, EMBRYOS HAVE BEEN ASSIGNED OVER FOR RESEARCH PROTOCOLS, AND KIND OF ARE WAITING TO BE USED.

DR. HALL: THE ESTIMATE IS ABOUT 5 PERCENT OF THOSE -- 4 TO 5 PERCENT OF THOSE THAT HAD BEEN STORED

HAD BEEN CONSENTED FOR RESEARCH PURPOSES.

DR. ROWLEY: IT'S MY IMPRESSION, AND KEVIN CAN CERTAINLY CORRECT ME, BUT, IN FACT, FOR INDIVIDUALS, FOR SCIENTISTS WHO ARE REALLY SERIOUSLY INTO THE DEVELOPING STEM CELL LINES, AND I THINK I HEARD THIS FROM THE PRACTICE OF DOUG MELTON'S LABORATORY. HE WORKS WITH ONE IVF CLINIC THAT HE KNOWS HAS VERY GOOD PRACTICES OF BOTH FERTILIZATION AND CULTURING, MAINTAINING THE EMBRYOS SUCH THAT EMBRYOS OBTAINED FROM THAT PARTICULAR PRACTICE HAVE A HIGHER LIKELIHOOD OF SUCCESS THAN JUST GOING OFF TO CLINIC A THAT YOU'VE NEVER HAD EXPERIENCE WITH AND GETTING THESE EMBRYOS.

I REALIZE THAT'S A PRACTICAL PROBLEM, NOT AN ETHICAL ISSUE, BUT I THINK ONE HAS TO SORT OUT WHAT ARE REALLY ACCEPTABLE FROZEN EMBRYOS AS COMPARED WITH 600,000 IN PEOPLE'S FREEZERS THAT INDIVIDUALS WOULDN'T REALLY GO TO BECAUSE YOU ARE GOING TO GET ONE OR TWO FROM THIS CLINIC AND TWO OR THREE FROM THAT CLINIC.

DR. EGGAN: I CAN SPEAK TO THAT, BEING CLOSELY RELATED IN THE SAME COLLABORATION. THE REAL DIFFICULTY IS THAT THESE EXPERIMENTS HAVE SO MANY MOVING PARTS AND THEY'RE REGULATED AT SUCH A HIGH LEVEL, THAT YOU WANT TO HAVE A HIGH LEVEL OF CONFIDENCE AND TRUST WITH THE IVF COLLABORATOR, AND YOU WANT TO

UNDERSTAND VERY CAREFULLY WHAT THEY'RE DOING AT EVERY LEVEL. I THINK THAT THE INCONSISTENCIES AND THE REPORTS COMING OUT OF KOREA AND WHAT IS APPARENTLY A LACK OF COMMUNICATION BETWEEN THE TWO HANDS AND THE SAME EXPERIMENT THERE LEAD US TO NOTE HOW IMPORTANT IT IS TO HAVE A CLOSE RELATIONSHIP, A SPECIFIC RELATIONSHIP, A COLLABORATIVE OPEN RELATIONSHIP WITH THE GROUP WHICH IS DOING THIS CLINICAL PRACTICE.

I THINK IT'S CRITICAL. I THINK NOT JUST FOR SCIENTIFIC REASONS, BUT TO ASSURE THE ETHICAL STANDARDS OF THE EXPERIMENTS WHICH ARE BEING DONE.

DR. TAYLOR: I THINK THOSE ARE ALL EXTREMELY IMPORTANT POINTS, AND IN PARTICULAR THE ETHICAL ASPECTS OF IT. IT'S PUBLISHED ACTUALLY. IVF PROGRAMS AROUND THE U.S. ARE MANDATED TO REPORT THEIR STATISTICS TO THE CDC, AND THOSE STATISTICS ARE ACTUALLY AUDITED. SO ONE CAN GO THROUGH AND FIND OUT WHAT THE SUCCESS RATE IS OF ONE PROGRAM VERSUS ANOTHER. THEY'RE QUITE VARIABLE ACROSS THE COUNTRY. BUT I SAY THAT THE PRACTICE OF EMBRYO FREEZING IS A FAIRLY SELECTIVE PRACTICE. BECAUSE OF THE COSTS INVOLVED WITH EMBRYO FREEZING, YOU DON'T JUST FREEZE EVERY EMBRYO THAT YOU'VE CREATED. SO BY THE TIME THE DECISION IS MADE IN THE EMBRYOLOGY LABORATORY, THAT AN EMBRYO THAT HASN'T BEEN TRANSFERRED BACK INTO THE PATIENT IS GOING TO BE FROZEN, THOSE

EMBRYOS, AT LEAST MORPHOLOGICALLY, HAVE THE APPEARANCE THAT THEY'RE GOING TO BE VIABLE, HEALTHY EMBRYOS.

SO I WOULD ARGUE THAT THE EMBRYOS THAT ARE FROZEN ARE KIND OF THE BEST, WE'VE SORT OF CULLED OUT, AT LEAST THAT WE CAN GROSSLY APPRECIATE, THE EMBRYOS WITH THE GREATEST LIKELIHOOD OF SUCCESS OF DEVELOPING INTO BABIES OR INTO STEM CELL LINES AS FAR AS WE UNDERSTAND IT. SO I THINK THAT WE DO HAVE SOME REASONABLY GOOD MATERIAL TO WORK WITH IF WE CAN GET TO IT.

DR. KIESSLING: THIS IS SORT OF A COROLLARY QUESTION, AND I DON'T KNOW IF WE WANT TO DISCUSS IT OR NOT. BUT THERE ARE A COUPLE OF RECENT REPORTS THAT YOU CAN DERIVE STEM CELL LINES FROM BIOPSIED EMBRYOS, FRESH EMBRYOS WITH ONE CELL. IS THAT ANYTHING THAT WE NEED TO DISCUSS?

DR. EGGAN: I THINK WE PROBABLY SHOULD SPEAK. THIS IS SOMETHING THAT WE PROBABLY SHOULD SPEAK TO. THIS IS THE PAPER FROM ACT ABOUT BOB LANSA'S REPORT ABOUT DERIVATION, AT LEAST WORK CARRIED OUT IN MOUSE WHICH REPORTED ESSENTIALLY THAT COULD YOU TAKE A SINGLE BLASTOMERE FROM A PREIMPLANTATION MOUSE EMBRYO AT THE EIGHT-CELL STAGE, CO-CULTURE THAT WITH AN EXISTING EMBRYONIC STEM CELL LINE, AND DERIVE A NEW EMBRYONIC STEM CELL LINE FROM THAT BLASTOMERE. ESSENTIALLY THIS

WAS BASED ON THE PREMISE THAT YOU COULDN'T DESTROY THE EMBRYO IN THE COURSE OF DERIVING THE STEM CELL LINE IN THAT WAY.

THERE'S TWO PRIMARY THINGS TO SAY ABOUT THAT, IN MY OPINION. ONE IS THAT'S NOT AN ISSUE FOR US TO REALLY CONSIDER AS A GROUP BECAUSE THE CALIFORNIA LEGISLATION HAS ALREADY SAID THAT DESTROYING AN EMBRYO IS OKAY. ESSENTIALLY THERE'S NO NEED, IN MY OPINION, TO DO THAT TYPE OF EXPERIMENT BECAUSE ESSENTIALLY CALIFORNIA LEGISLATION SAYS IT'S OKAY TO DESTROY THE BLASTOCYST TO DERIVE EMBRYONIC STEM CELL LINES. THAT WAS THE PURPOSE OF THE EXPERIMENT.

AND THEN I WOULD FURTHER GO TO SAY THAT IF YOU ARE SOMEONE WHO FEELS THAT THESE EMBRYOS MUST BE PROTECTED AND YOU TAKE THAT POSITION, THEN I THINK THE EXPERIMENT IS TROUBLING IN THAT SENSE BECAUSE I THINK YOU WOULD NEVER EXPOSE A PERSON TO SUCH A POTENTIALLY DANGEROUS PROCEDURE FOR NO PARTICULAR GAIN OF THEIR OWN. AND SO BASED -- ALTHOUGH I THINK THIS IS SCIENTIFICALLY A VERY INTERESTING EXPERIMENT AND IT'S INTERESTING THAT IT DEMONSTRATES THAT ONE CAN DERIVE THESE TYPES OF CELL LINES, AND I THINK THAT THESE TYPES OF EXPERIMENTS ARE INTERESTING FROM A HUMAN EMBRYOLOGICAL AND PEOPLE IN CALIFORNIA MIGHT WANT TO DO THEM AND WE SHOULD ENCOURAGE THEM TO DO THEM FROM THAT

PERSPECTIVE. WE CERTAINLY SHOULDN'T ENCOURAGE THEM TO DO THAT TYPE OF EXPERIMENT BECAUSE IT PROTECTS THE STAGE OF HUMAN EMBRYO.

DR. CIBELLI: I KIND OF DISAGREE WITH THAT. I THINK THERE ARE SO MANY OTHER BETTER EXPERIMENTS TO DO AND BETTER WAYS TO SPEND THE MONEY. BUT IF YOU GET AN IDEA AND YOU SEND A PROPOSAL TO SEE -- YOU ARE GOING TO SOME PROPOSALS FROM PEOPLE MAYBE PERHAPS FROM ACT SENDING IN A PROPOSAL AND TELL YOU I WANT TO DO IT IN HUMAN. WOULD CIRM PAY FOR IT OR NOT? THEY'VE DONE IT IN THE MOUSE. SOONER OR LATER IN HUMAN. THE EFFICIENCY WAS VERY LOW. IT WAS ABOUT 10 PERCENT. SO FOR EVERY TEN BLASTOMERES, ONE PRODUCED A CELL LINE. BUT IF YOU ARE GOING TO HAVE A CHILD AND IF YOU ARE WILLING TO DO PGD, YOU ARE REALLY RISKING THE EMBRYO TO TAKE ONE BLASTOMERE OUT, I WOULD ARGUE THAT, GEE, JUST HAVING YOUR CUSTOM MADE EMBRYONIC STEM CELLS MAYBE CHEAPER THAN SOMATIC CELL NUCLEAR TRANSFER. YOU DON'T HAVE TO WAIT FOR THE DONATION YOU EGGS. WHY NOT?

DR. EGGAN: THIS IS A VERY SPECIFIC AND DIFFERENT CASE THOUGH, RIGHT. SO IT CERTAINLY -- SO PGD IS OKAY PRESUMABLY BECAUSE YOU'RE ENSURING THE HEALTH OF A FUTURE CHILD AND THE TREATMENT. SO, AGAIN, I DO NOT HOLD THIS PERSPECTIVE, SO I AM MERELY ARGUING FROM THE PERSPECTIVE OF ONE THAT WOULD SAY THAT WE

SHOULD NOT AS A SOCIETY DESTROY THESE EMBRYOS. THAT'S A POINT OF VIEW I DO NOT HOLD.

I THINK ONE FIRST HAS TO BE AT THAT PARTICULAR POINT OF VIEW TO SAY THAT. SO THEN I AGREE. THIS IS A DIFFERENT SITUATION. NOW IF AS A COURSE OF TREATMENT YOU THOUGHT IT WOULD BE WORTH -- IF ONE WAS UNDERGOING IVF AND ONE WANTED TO MAKE A GENETICALLY TAILORED STEM CELL LINE FOR THEIR OWN CHILD, AND ONE THOUGHT THAT THIS -- I THINK ONE WOULD HAVE TO ASK WE UNDERSTAND THAT THERE'S A SUBSTANTIAL RISK TO THE FUTURE CHILD, WHICH IS ESSENTIALLY OUTWEIGHED BY THE FEAR THAT THEY WILL HAVE THIS GENETIC DISORDER, RIGHT, SO IS THE BENEFIT THAT ONE WOULD HAVE BY DERIVING THAT PATIENT-SPECIFIC STEM CELL LINE OUTWEIGH THE RISK TO THAT FUTURE CHILD TOO. WHEN YOU'RE TALKING, IF THAT'S THE CLINICAL EQUATION, THEN I THINK THAT'S THE ONE WE HAVE TO MEET. I THINK THAT'S A GOOD IDEA. IF ONE WEIGH THAT EQUATION AND FIND THE ANSWER IS YES, THEN I THINK ABSOLUTELY.

AGAIN, TO SAY VERY CLEARLY, FROM THE SCIENTIFIC POINT OF VIEW, I THINK THESE TYPES OF EXPERIMENTS ARE VERY INTERESTING. SINCE WE HOLD THAT THESE THINGS ARE HUMAN EMBRYOS, BUT ARE NOT PEOPLE, IT IS PERFECTLY UNDERSTANDABLE THAT WE WOULD SUBJECT THEM TO THESE TYPES OF EXPERIMENTS. IT'S PERFECTLY

REASONABLE.

DR. CIBELLI: CIRM AS AN ENTITY WILL GET PROPOSALS. WHAT HAPPENS IF YOU GET A VERY GOOD PROPOSAL THAT WANTS TO DO THIS, THAT WANTS TO DERIVE HUMAN ES CELLS FOR EIGHT-CELL EMBRYOS?

DR. EGGAN: WHAT I'M SAYING IS THAT I THINK THAT'S SOMETHING WE SHOULD FUND BECAUSE IT'S A TYPE OF EMBRYOLOGY THAT WE SHOULD UNDERSTAND, BUT I THINK THAT --

DR. HALL: I THINK THE QUESTION THAT WE'RE CONCERNED WITH HERE IS WHAT ARE THE ISSUES FOR THE DONOR AND THE CONSENT FOR THAT; ISN'T THAT CORRECT? OUR ISSUE IS NOT SHOULD WE FUND THAT RESEARCH HERE. I THINK, UNLESS YOU WANT TO CONSIDER THAT IT SHOULD BE PROHIBITED, BUT I THINK THE ISSUE HERE IS THAT A DONOR CLASS WE WANT TO ADDRESS AS WE WORK OUR WAY THROUGH THESE ISSUES. ISN'T THAT RIGHT?

DR. EGGAN: I GUESS THAT'S RIGHT.

DR. KIESSLING: I JUST ASKED IF WE NEEDED TO TALK ABOUT THIS AS A NEW REPORT.

DR. TAYLOR: I ACTUALLY THINK IT FALLS INTO WHAT WE'RE ALREADY DISCUSSING. I DON'T SEE IT AS AN OUTLIER PARTICULARLY. AS FAR AS I KNOW, BLASTOMERE BIOPSY FROM HUMAN EMBRYOS, I DON'T KNOW HOW SUCCESSFULLY IT'S BEEN FROM THAWED EMBRYOS. SO IT

MA -- TYPICALLY IT'S DONE IN A FRESH EMBRYO SETTING, SO IT MAY BE ONE OF THESE SITUATIONS. AND WE DON'T HAVE TOO MANY FRESH HUMAN EMBRYOS THAT ARE GOING TO BE DONATED TO SCIENCE, BUT THIS MIGHT BE ONE OF THE INTERESTING WAYS TO GO. I COMPLETELY AGREE WITH JOSE THAT THESE ARE EXTREMELY IMPORTANT EXPERIMENTS TO DO BECAUSE ULTIMATELY YOU WANT TO HAVE -- EVERY EMBRYO, EVERY FETUS, EVERY BABY WOULD HAVE ITS OWN EMBRYONIC STEM CELL LINE POTENTIALLY. IT WOULD A LOT BETTER THAN CORD BLOOD STUFF THAT WE'RE DOING IN SOME SETTINGS.

IF THAT'S REALLY THE END POINT THAT YOU WANT TO GET TO, THE TIME TO DO IT WOULD BE IF YOU COULD DEMONSTRATE THAT IT'S SAFE TO BIOPSY A SINGLE CELL BLASTOMERE FROM AN EMBRYO AT THE EIGHT-CELL STAGE AND GO ON, WHICH I EXPECT WE'RE GOING TO BE TECHNOLOGICALLY ABLE TO DO THAT PRETTY WELL. SO I THINK THAT IT WOULD BE AN APPROPRIATE THING TO FUND.

DR. CIBELLI: THIS WOULD BE A CASE WHERE WE HAD TO OBTAIN A CONSENT FORM OF HEALTHY, OTHERWISE HEALTHY FRESH HUMAN EMBRYO.

DR. TAYLOR: I THINK YOU WOULDN'T KNOW THE HEALTH NECESSARILY.

DR. EGGAN: CORRECT ME IF I'M WRONG, BUT EMBRYOS ARE OFTEN FROZEN AT THE FOUR OR THE EIGHT-CELL STAGE; ISN'T THAT CORRECT? SO SINCE THIS IS AN

EXPERIMENTAL TECHNIQUE, THIS WOULD HAVE NOT TO BE ANY DIFFERENT FROM THE NORMAL -- IN PRINCIPLE THE NORMAL CONSENT THAT WE DO FOR STEM CELL DERIVATION. IT'S JUST THAT THE CONSENT WOULD BE SPECIFIC TO THIS EXPERIMENT. IT WOULD BE A SITUATION WHERE, OF COURSE, PEOPLE WHO HAVE SOME BLASTOCYSTS CAN'T CONTRIBUTE OR CAN'T PARTICIPATE, BUT THOSE WHO HAVE FROZEN FOUR-CELL OR EIGHT-CELL EMBRYOS, THEY COULD DONATE THEIR EMBRYOS, WHICH WOULD THEN BE THAWED AND EACH OF THE BLASTOMERES OR ONE INDIVIDUAL BLASTOMERE WOULD BE BIOPSIED OUT AND USED FOR THIS EXPERIMENTAL APPROACH TO SEE IF THE SAME THING THAT WAS TRUE IN MOUSE WAS POSSIBLE IN HUMAN. THIS SEEMS LIKE A VERY REASONABLE THING.

DR. TAYLOR: I'VE SEEN FROZEN THAWED GROWN EMBRYOS BIOPSIED.

DR. EGGAN: THAT MIGHT BE A WORTHWHILE RESEARCH GOAL.

VICE CHAIR LO: LET ME SUGGEST THAT WE SORT OF SEPARATE OUT WHERE THE STANDS ON THE LIST OF RESEARCH PRIORITIES FROM OTHER DISTINCT CONSENT ISSUES. AFTER WE WRITE UP WHAT WE'VE DISCUSSED TODAY, THERE'S A LOT OF GROUND WE COVERED ON SORT OF ALL THE OTHER CATEGORIES, TO THEN ASK ANN, JOSE, AND KEVIN TO COME BACK TO THIS AS A SPECIAL CASE AND SEE IF THERE ARE SPECIAL CONSENT ISSUES IN THIS SITUATION THAT WOULD

NEED SOME ADDITIONAL GUIDELINES, BUT NOT TO TRY DO IT TILL WE'VE ACTUALLY SEEN HOW WE'RE GOING TO HANDLE OUR SORT OF MORE COMMON PARADIGMATIC CASES.

I ACTUALLY THINK WE'VE DONE A LOT SO FAR, AND I WANT TO KEEP US FRESH, SO I WAS GOING TO SUGGEST THAT WE ACTUALLY TAKE A BREAK NOW IF THAT'S OKAY WITH PEOPLE UNLESS YOU WANT TO KEEP WORKING. WE WILL REWARD OURSELVES WITH A 15-MINUTE BREAK, AND THEN COME BACK AND BOTH HEAR ABOUT THE GRANTS ADMINISTRATION GROUP AND THEN SOME OTHER ISSUES WE NEED TO ADDRESS. SO LET'S TAKE A 15-MINUTE BREAK AND COME BACK.

(A RECESS WAS TAKEN.)

VICE CHAIR LO: WE'RE GOING TO START WITH A REPORT FROM THE GRANTS ADMINISTRATION WORKING GROUP, AND ARLENE CHIU FROM CIRM, WHO IS DIRECTING THE GRANTS ADMINISTRATION EFFORT, HAS VERY KINDLY AGREED TO COME AND GIVE US AN UPDATE ON THE GRANTS ADMINISTRATION POLICY WHICH, AGAIN, I WOULD REMIND US ALL IS A WORK IN PROGRESS, BUT WE CERTAINLY ARE INTERESTED IN HEARING WHAT THAT GROUP IS THINKING. AND THERE'S PARTICULAR QUESTIONS, ARLENE, THAT I THINK WE'LL PROBABLY WANT TO DISCUSS WITH YOU WHERE THERE'S A LOT OF OVERLAP. THANKS VERY MUCH AND WELCOME.

DR. CHIU: GOOD AFTERNOON. LET ME MAKE A CORRECTION. I'M THE STAFF MEMBER, CIRM STAFF MEMBER

ASSIGNED TO THE GRANTS WORKING GROUP. I'M CERTAINLY NOT ANYWHERE IN THE LEADERSHIP OF THAT GROUP, AND I WANT TO REPORT TO YOU WHAT HAS BEEN TAKING PLACE.

SO CIRM STAFF HAS BEEN WORKING ON A GUIDANCE STATEMENT FOR GRANTEES, AND THAT MEANS INDIVIDUALS AND INSTITUTIONS THAT WILL BE RECEIVING CIRM AWARDS. AND THE GOAL IS TO HAVE A COMPREHENSIVE CIRM GRANTS ADMINISTRATION POLICY FOR THIS PURPOSE. SO TODAY WHAT I'D LIKE TO PROVIDE THIS WORKING GROUP WITH IS AN UPDATE ON OUR PROGRESS IN CRAFTING SUCH A DOCUMENT.

AND WHAT I PLAN TO DO IS TO REVIEW BRIEFLY THE BACKGROUND AND THE PURPOSE FOR SUCH A POLICY STATEMENT, PRESENT FOR YOU A BRIEF SYNOPSIS ON ITS CONTENTS, AND THEN END WITH A CURRENT STATUS OF DIFFERENT DRAFTS OF THIS DOCUMENT.

FIRST A BRIEF BACKGROUND. IN MAY OF THIS YEAR, THE CIRM ISSUED A REQUEST FOR APPLICATIONS TO SUPPORT TRAINING GRANTS THAT WILL TRAIN AT RESEARCH AND ACADEMIC INSTITUTIONS IN CALIFORNIA THE NEXT GENERATION OF STEM CELL SCIENTISTS AND CLINICIANS.

TWENTY-SIX APPLICATIONS WERE RECEIVED AND SUBSEQUENTLY REVIEWED BY OUR SCIENTIFIC AND MEDICAL RESEARCH FUNDING WORKING GROUP. THEIR EVALUATIONS AND RECOMMENDATIONS WERE THEN PRESENTED TO THE ICOC AT THEIR SEPTEMBER MEETING, AND THE BOARD APPROVED 16 OF

THESE TRAINING GRANTS FOR -- THESE TRAINING APPLICATIONS FOR FUNDING.

SO NOW IN ORDER TO FOR CIRM TO IMPLEMENT THESE AWARDS ONCE BRIDGE FUNDING BECOMES AVAILABLE, WE HAVE TO SET UP THE NECESSARY INFRASTRUCTURE TO DO SO. AND THAT MEANS THAT BEFORE FUNDING CAN TAKE PLACE, WE HAVE TO COMPLETE THREE TASKS. THE FIRST, IF YOU CAN SEE IT AGAINST THE PALE BACKGROUND, IS THAT WE HAVE TO REVIEW THE BUDGETS OF EACH APPROVED APPLICATION FOR ANY CHANGES THAT WERE APPROVED, FOR ARITHMETIC ERRORS, AND TO SCREEN UNALLOWABLE CHARGES AS DEFINED IN THE ORIGINAL RFA. WE NOW HAVE COMPLETED THIS TASK AND HAVE PRECISE FINAL BUDGETS FOR EACH APPROVED APPLICATION.

THE SECOND TASK, WE NEED TO FIND A WAY TO MAKE THE APPROVED PAYMENTS. AND AT PRESENT WE'RE DEVELOPING A PROCEDURE WITH THE STATE CONTROLLER'S OFFICE SO THAT THE STATE CAN TRANSFER THE APPROPRIATE FUNDS TO EACH GRANTEE IN A RESPONSIBLE AND IN A TRACEABLE AND TRACKABLE MANNER.

AND THIRD, WE HAVE TO MAKE SURE THAT EACH GRANTEE OR RECIPIENT UNDERSTANDS OUR, THE CIRM, THE PRINCIPLES OF OPERATION AS WELL AS THEIR ROLES AND RESPONSIBILITIES WHEN THEY CHOOSE TO ACCEPT AN AWARD FROM THE CIRM.

AND THAT LEADS US TO THE PURPOSE OF A GRANTS

ADMINISTRATION POLICY OR A GAP, G-A-P IN SHORT. THE POLICY STATEMENT WILL SET OUT TERMS AND CONDITIONS OF GRANT AWARDS FROM THE CIRM. IT WILL TELL RECIPIENTS WHAT ARE THEIR RESPONSIBILITIES AS GRANTEES. AND THIS INFORMATION WILL BE DIRECTED AT RECIPIENT INSTITUTIONS; THAT IS, OFFICIALS AUTHORIZED TO REPRESENT THE INSTITUTIONS AS WELL AS THE PRINCIPAL INVESTIGATORS OR PI'S.

AND FINALLY, RECIPIENT INSTITUTIONS AND PI'S MUST THEN AGREE TO COMPLY WITH THESE CONDITIONS AND PROCEDURES BEFORE THEY CAN RECEIVE FUNDS FROM CIRM.

SO WHAT'S COVERED IN SUCH A POLICY STATEMENT? THE CONTENTS WILL INCLUDE INFORMATION THAT WILL BE USEFUL TO GRANTEES AND APPLICATIONS, SUCH AS WHO ARE THE CIRM STAFF MEMBERS THAT THE GRANTEES ARE LIKELY TO INTERACT WITH AND WHAT ARE THEIR FUNCTIONS? WHAT ARE THE ELIGIBILITY REQUIREMENTS FOR INSTITUTIONS AND PI'S? I WILL PROVIDE GENERAL INFORMATION ON SUBMITTING AN APPLICATION, HOW APPLICATIONS ARE REVIEWED, AND HOW ARE THEY APPROVED FOR FUNDING.

THE GRANTS ADMINISTRATION POLICY WILL SPELL OUT TERMS AND CONDITIONS OF THE AWARD, INCLUDING HOW PAYMENT IS MADE, WHAT COSTS ARE ALLOWED, AND WHAT ARE NOT. WHAT TO DO IF CHANGES NEED TO BE MADE ONCE A GRANT HAS BEEN AWARDED, ISSUES OF REBUDGETING. WHAT IF

THE PI MOVES TO ANOTHER INSTITUTION OR EVEN OUT OF STATE? THE CIRM POLICY ON INTELLECTUAL PROPERTY THAT YOU HEARD THAT'S CURRENTLY BEING DEVELOPED BY THE IP TASK FORCE WILL BE INCLUDED. POLICIES ON SHARING RESEARCH DATA, TECHNOLOGIES, AND MATERIALS POLICIES THAT WOULD BE APPROVED EVENTUALLY BY THE ICOC WILL ALSO BE INCLUDED. PROCEDURES FOR ANNUAL REPORTS ON SCIENTIFIC PROGRESS AND BUDGETS SO THAT WE CAN FOLLOW WHAT'S GOING ON, HOW THE GRANTEES SPENT THE MONEY.

THE POLICY STATEMENT WILL INCLUDE CIRM REQUIREMENTS -- I HAVE TO GO BACK -- WILL INCLUDE CIRM REQUIREMENTS AND STANDARDS ON MATTERS SUCH AS USE OF HUMAN STEM CELLS, USE OF VERTEBRATE ANIMALS, USE OF BIOHAZARDOUS MATERIALS AND HUMAN SUBJECTS.

DR. HALL: ARLENE, COULD YOU JUST BACK UP SLIDE BEFORE. THIS WENT BY VERY QUICKLY JUST SO WE ALL SEE.

DR. CHIU: THIS IS THE INTELLECTUAL PROPERTY SHARING REQUIREMENTS AND REPORTING REQUIREMENTS. AND THEN WE WILL BE STATING IN THE POLICY STATEMENT CIRM REQUIREMENTS AND STANDARDS THAT YOU PROVIDE FOR US AND THAT WILL EVENTUALLY BE APPROVED BY THE ICOC. THESE INCLUDE USE OF HUMAN STEM CELLS, VERTEBRATE ANIMALS, BIOHAZARDOUS MATERIALS, AND HUMAN SUBJECTS.

OKAY. SO HOW DID WE DEVELOP SUCH A POLICY?

WHAT'S GOING ON? EARLIER IN THE YEAR CIRM CONTRACTED THE FIRM LMI TO IDENTIFY AND COMPARE POLICIES USED BY A NUMBER OF PUBLIC AND PRIVATE GRANT-MAKING AGENCIES, INCLUDING THE AMERICAN CANCER SOCIETY, JUVENILE DIABETES RESEARCH FOUNDATION, THE CALIFORNIA SPECIAL RESEARCH PROGRAMS FOR BREAST CANCER, TOBACCO, AND AIDS, AMERICAN HEART ASSOCIATION, AND THE NIH.

LMI'S COMPREHENSIVE REPORT COVERED A VERY LONG LIST OF TOPICS INCLUDING TYPES OF SUPPORT, ROLES AND RESPONSIBILITIES OF ORGANIZATIONAL STAFF, PUBLIC POLICY REQUIREMENTS, AND INTELLECTUAL PROPERTY. THEY ALSO PROVIDED US WITH INFORMATION ON PROCEDURES SUCH AS HOW DIFFERENT AGENCIES NOTIFIED THE SUCCESSFUL APPLICANTS AND THEIR PARTICULAR REPORTING REQUIREMENTS.

WE THEN HAD A CIRM TEAM THAT HAS BEEN MEETING REGULARLY TO DEVELOP A FIRST DRAFT OF AN INTERIM GRANTS ADMINISTRATION POLICY STATEMENT. NOW, OUR TEAM CONSISTS OF ZACH HALL, MARY MAXON, WALTER BARNES, GIL SAMBRANO, AND MYSELF, AND MORE RECENTLY WE WERE JOINED BY DAN BEDFORD, WHO'S HERE TODAY, A LAWYER FROM ORRICK, HERRINGTON & SUTCLIFFE, WHO IS PROVIDING HIS LEGAL EYE AND HIS SERVICES PRO BONO.

SO AS A RESULT OF THIS GROUP ACTIVITY, WE DEVELOPED A DRAFT OF THE INTERIM CIRM GRANTS ADMINISTRATION POLICY FOR TRAINING GRANTS. NOW, THE

TRAINING GRANTS WAS A PRIORITY BECAUSE WITH THE BOARD'S APPROVAL, WE NEEDED TO BE TO READY TO AWARD THESE APPLICATIONS AS SOON AS POSSIBLE.

THIS FIRST DRAFT OF THE TRAINING GRANTS ADMINISTRATION POLICY WAS POSTED ON THE CIRM WEBSITE, PRESENTED TO THE ICOC ON NOVEMBER 2D SO THAT THE BOARD IS AWARE OF THE PROGRESS OF THIS DOCUMENT. THE SCIENTIFIC AND MEDICAL RESEARCH FUNDING WORKING GROUP, WHO REVIEWED GRANTS, ALSO MET BY TELECONFERENCE ON NOVEMBER 28TH TO REVIEW THIS DRAFT. THEY RECOMMENDED APPROVAL OF THIS DOCUMENT WITH TWO AMENDMENTS, AND THE VOTE WAS UNANIMOUS IN FAVOR OF IT. SO WE HAD A QUORUM AND A VOTE. AND THE TWO AMENDMENTS ARE THE LENGTH OF TIME THAT MEDICAL STUDENTS COULD SPEND IN ORDER TO FULFILL CLINICAL DUTIES THAT ARE OUTSIDE OF THE SCOPE OF RESEARCH. THEY ARE ARGUED FOR A 25-PERCENT CAP, AND THAT'S BEEN ADDED TO THE AMENDED DOCUMENT. AND ALSO STANDARDS FOR REPORTING IRB, ESCRO, ETC., THAT'S NEEDED, AND THAT'S THE LAST SECTION IN THE REPORT.

SO THIS AMENDED DRAFT OF THE INTERIM CIRM GRANT ADMINISTRATION POLICY FOR TRAINING GRANTS IS NOW PROVIDED FOR YOUR INFORMATION IN TAB 5 IN YOUR BINDERS. AND WE INTEND TO PRESENT THIS AMENDED DOCUMENT TO THE ICOC ON DECEMBER 6TH FOR THEIR DISCUSSION AND APPROVAL SO THAT THE TRAINING GRANTS CAN BE AWARDED IN A TIMELY

FASHION WHEN FUNDS BECOME AVAILABLE.

COMING BACK TO A SLIDE THAT YOU HAVE SEEN EARLIER TODAY WITH THE IP PRESENTATION, YOU CAN SEE THAT THERE ARE MULTIPLE INPUTS THAT COME TOGETHER IN ORDER TO FORM A POLICY TO ENABLE US TO FUND THE TRAINING GRANTS. THE MULTIPLE INPUTS ARE THE INTERIM IP POLICY FOR TRAINING GRANTS, THIS PARTICULAR TRAINING GRANT ADMINISTRATION POLICY, AS WELL AS THE INTERIM ETHICAL STANDARDS THAT THIS WORKING GROUP HAS COME UP WITH. SO YOU CAN SEE THAT IT'S IMPORTANT TO HAVE GOOD COMMUNICATIONS BETWEEN THE WORKING GROUPS AND THE TASK FORCE OVER ISSUES OF SHARED INTEREST.

THIS PROCESS IS JUST THE FIRST IN A SERIES OF STEPS IN ORDER TO GET A FINAL PRODUCT WHICH IS A COMPREHENSIVE GRANTS ADMINISTRATION POLICY AND REGULATIONS FOR ALL RESEARCH AWARDS IN GENERAL. AND SO IN THAT PIECE THAT YOU SEE BELOW, THE GENERAL IP POLICY, WHICH IS GOING TO BE HAMMERED OUT, LOOKS LIKE IN THE SPRING, PLUS THE ETHICAL STANDARDS COMING FROM THIS WORKING GROUP WILL ALL COME TOGETHER FOR THE FINAL COMPREHENSIVE POLICY.

SO IN SUMMARY, I'D LIKE TO JUST POINT OUT THE DEVELOPMENT THUS FAR. YOU HAVE SEEN THE DRAFT. YOU HAVE IN YOUR BINDERS A DRAFT OF THE INTERIM GRANTS ADMINISTRATION POLICY FOR TRAINING GRANTS. YOU'VE

HEARD THAT WE'RE IN THE PROCESS OF DEVELOPING A DRAFT OF AN INTERIM GRANTS ADMINISTRATION POLICY FOR ALL AWARDS IN GENERAL. AND FROM THIS WE WILL CRAFT AN INTERIM GRANTS ADMINISTRATION REGULATION PURSUANT TO THE CALIFORNIA ADMINISTRATIVE PROCEDURES ACT.

THANK YOU AND I'D BE HAPPY TO TAKE QUESTIONS.

VICE CHAIR LO: ARLENE, THANKS VERY MUCH. COULD I START BY ASKING YOU TO COMMENT ON TWO ISSUES THAT WE HAVE THOUGHT ABOUT AND WHICH WE THINK THERE'S A CLEAR OVERLAP WITH THE GRANTS ADMINISTRATION WORKING GROUP. THE FIRST IS THE TIMING OF ESCRO REVIEW BY THE INSTITUTION THAT'S APPLYING FOR FUNDING AND THE TIMING OF GRANT REVIEW BY CIRM? WE'VE SORT OF THOUGHT ABOUT BOTH OPTIONS, FIRST REQUIRING THAT THE ESCRO APPROVE A PROPOSAL BEFORE IT'S SUBMITTED TO CIRM VERSUS THE OBVERSE, WHICH IS THE NIH SYSTEM OF ONCE YOU GET FUNDING, THEN YOU NEED TO HAVE IRB -- ONLY THEN ARE YOU REQUIRED TO GO GET IRB APPROVAL. SO THAT'S THE FIRST ISSUE OF TIMING OF IN-HOUSE ESCRO REVIEWS VERSUS CIRM GRANT REVIEW.

SECOND IS THE ISSUE IS OF ENFORCEMENT THAT WE'VE SORT --

DR. CHIU: SO LET ME ADDRESS THE FIRST ONE FIRST BEFORE I FORGET THE QUESTION. I'M SURE YOU'VE GONE THROUGH BOTH ARGUMENTS IN FAVOR OF PRE AND POST.

THE ARGUMENT FOR PRE IS THAT YOU WEED OUT GRANTS THAT ESCRO HAS DEEMED UNETHICAL OR NOT APPROPRIATE STANDARDS. AND THEN THERE WILL BE LESS GRANTS FOR THE GRANT REVIEW GROUP TO HAVE TO GO THROUGH. THE GRANT REVIEW GROUP'S TASK IS TO ASSESS BOTH SCIENTIFIC AND PROGRAMMATIC EXCELLENCE, AND THEY DEPEND ON LOCAL IRB, ESCRO, ETC., TO DETERMINE WHETHER ETHICAL STANDARDS AND LOCAL STANDARDS HAVE BEEN ADHERED TO.

THE ARGUMENT FOR HAVING IT DONE AFTERWARD IS THAT IT DOESN'T STOP RESEARCHERS FROM SUBMITTING A VERY EXCITING APPLICATION. AND IF THE RFA DOESN'T GIVE THEM AMPLE TIME TO NOT ONLY CRAFT THE APPLICATION, BUT ALSO TO GET ALL THEIR DUCKS IN ORDER IN TERMS OF ALL APPROVALS, THEY CANNOT SUBMIT AN APPLICATION IN TIME BY THE DUE DATE, RIGHT. SO THERE ARE ON THE TWO TENSIONS. IF YOU WANT TO THE RFA'S TO MOVE IN AN EXPEDITIOUS MANNER AND GET EVERYTHING REVIEWED AND FUNDED, THEN TO KNOW THAT YOU'RE GOING TO GET FUNDED, YOU WOULD WANT TO HAVE A FAST TRACK AFTER THE FACT. ONLY APPROVED APPLICATIONS WILL TO BE ASKED TO HAVE WHAT'S KNOWN AS CLOSING PACKAGE, WHICH IS TO HAVE ALL YOUR DUCKS LINED UP BEFORE YOU ACTUALLY TRIGGER THE FUNDING, THE AWARD PROCESS.

THE PREPROCESS, RESEARCHERS WOULD ARGUE THAT IT TAKES THEM A LONG TIME, IT MIGHT EVEN PREVENT THEM

FROM REVIEWING. SO WE HAVE NOT GOING TO THE WORKING GROUP TO IRON OUT THIS PARTICULAR ISSUE. WE WILL BE PRESENTING IT TO THEM AS TWO OPTIONS. THE THOUGHT IS THAT IF WE OFFER THE CLOSING PACKAGE OPTION, IT WOULD BE A BURDEN ON THE REVIEWING GROUP TO REVIEW ALL GRANTS WHETHER THEY HAVE ESCRO APPROVAL OR NOT. ON THE OTHER HAND, IT WILL ALLOW RESEARCHERS TO BE ABLE TO SUBMIT GRANTS QUICKLY AND WOULD NOT HOLD UP THE WHOLE BATCH. AND NOT EVERY APPLICATION MAY HAVE SUCH ONEROUS -- SUCH EXTENSIVE ESCRO REVIEW. ALSO, IT HOLDS THE APPLICATIONS HOSTAGE BY THE ESCRO AND THE IRB REVIEWS. MONEY WILL NOT GO OUT UNLESS THOSE ARE APPROVED, AND THAT WOULD DELAY FUNDING. AT LEAST ONLY THOSE APPLICATIONS THAT ARE DEEMED SCIENTIFICALLY AND PROGRAMMATICALLY MERITORIOUS WILL HAVE TO GO THROUGH THEIR INTERNAL REVIEW.

A FINAL THOUGHT WAS THAT SOMETIMES DURING REVIEW, THE REVIEWERS PUT IN COMMENTS AND RECOMMENDATIONS SUCH AS WE WOULD LIKE TO SEE THIS ELIMINATED AND THAT ELEMENT ADDED. THAT MIGHT CHANGE THE ESCRO REVIEW PROCESS OR CONSIDERATIONS FOR ESCRO. AND THAT COULD BE INCLUDED IF IT'S A POST ACTIVITY. SO TO CUT A LONG STORY SHORT, IT MAY BE THAT WE WOULD ASK IN GENERAL FOR THIS INFORMATION, THE APPROVALS TO BE PROVIDED, AFTER AN APPLICATION HAS BEEN APPROVED FOR --

DEEMED APPROPRIATE FOR FUNDING, BUT THAT UNDER CERTAIN SPECIAL CIRCUMSTANCES PARTICULAR RFA'S WE MAY REQUEST IT BEFOREHAND AS SPECIAL CONDITIONS. DOES THAT --

VICE CHAIR LO: I THINK THAT'S VERY HELPFUL. IT'S IMPORTANT FOR US TO KNOW HOW THE GRANTS WORKING GROUP IS THINKING ON THIS ISSUE. WE CERTAINLY DON'T WANT TO DO ANYTHING THAT RUNS COUNTER TO WHAT YOU'RE THINKING.

SECOND QUESTION FOR YOU HAD TO DO WITH VIOLATIONS OF CIRM POLICIES AND ENFORCEMENT MECHANISMS. AS WE WERE THINKING ABOUT WHAT MIGHT HAPPEN OR WHAT OUGHT TO HAPPEN IF A CIRM-FUNDED INSTITUTION OR RESEARCHER DOESN'T COMPLY WITH CERTAIN THINGS. HAS THE GRANTS ADMINISTRATION WORKING GROUP THOUGHT ABOUT THIS? AND DO YOU HAVE THOUGHTS AS TO WHETHER PENALTIES MIGHT GO BEYOND JUST SUSPENDING OR WITHHOLDING THE REMAINDER OF THE GRANT TO DISQUALIFICATION FROM APPLYING FOR FUTURE FUNDING, FOR EXAMPLE?

DR. CHIU: SO THIS ELEMENT OF IMPLEMENTATION AND CHECKING FOR VIOLATIONS AND CONSEQUENCES WE HAVE NOT BROUGHT IN FRONT OF THE WORKING GROUP. BUT ALL I CAN DO IS ADDRESS SOME WAYS OF DEALING WITH IT THAT I'VE SEEN FROM OTHER AGENCIES. AND AS YOU SAID, WITHHOLDING OF FUNDS IS THE EASIEST AND THE MOST DIRECTLY FELT WAY AND MOST TARGETED TO THE INDIVIDUAL

THAT VIOLATED THE PROGRAM, BUT THAT'S AFTER THE FACT. USUALLY AT ABOUT THE TIME OF THE PROGRESS REPORT WHEN YOU REVIEW AND FOR PROGRAM DIRECTORS TO GO IN AND CALL ABOUT SPECIFIC ACTIVITIES OR IF YOU HEAR ABOUT SPECIFIC VIOLATIONS FROM PEOPLE REPORTING ON IT, A BROADER CONSEQUENCE MAY BE, AND I'M JUST SAYING MAY BE, HAS NOT BEEN DISCUSSED -- IT'S JUST BRINGING IT TO YOUR ATTENTION -- MIGHT BE SOME PERIOD OF PROHIBITION FOR THAT INDIVIDUAL TO APPLY FOR CIRM APPLICATIONS. AND A MUCH MORE SEVERE ONE THAT THE NIH THREATENS AND WITH GREAT EFFECT IS TO WITHHOLD ALL FUNDING FROM A PARTICULAR INSTITUTION UNTIL A CERTAIN VIOLATION HAS BEEN CORRECTED. THIS WILL HAPPEN, SAY, IF THE ANIMAL QUARTERS ARE FOUND TO BE IN COMPLETE VIOLATION SO THAT ALL GRANTS ARE AFFECTED, FOR EXAMPLE.

BUT WE HAVE NOT DISCUSSED THIS PARTICULAR ISSUE OF IMPLEMENTATION AND SEVERE CONSEQUENCES YET.

VICE CHAIR LO: ANY OTHER QUESTIONS, COMMENTS?

DR. CIBELLI: I HAVE A QUESTION. ARLENE IS GOING TO GIVE US AN UPDATE OR MAYBE ZACH. I AM VERY CURIOUS ABOUT THE FUNDING SITUATION AT THE INSTITUTE. WE HAVEN'T -- I HAVEN'T RECEIVED ANY UPDATE. I WOULD LIKE TO AN UPDATE FROM ZACH OR ARLENE AS TO WHEN THE FUNDS WILL BE AVAILABLE FOR RELEASE. WHAT'S THE LEGAL

SITUATION AT THE MOMENT?

DR. HALL: I LOOKED AT JAMES TO OFFER ANY COMMENT OR CORRECTION ON THE LEGAL SITUATION. LET ME GIVE YOU THE LAYMAN'S TAKE-HOME MESSAGE, WHICH IS WHAT I'M INTERESTED IN. I PRESUME YOU ARE AS WELL. THERE WAS A HEARING ON THE 17TH OF NOVEMBER OF THE TWO SUITS THAT HAVE NOW BEEN COMBINED, WHICH CHALLENGE OUR ABILITY TO -- OUR CONSTITUTIONALITY. BASICALLY THEY SAY WE ARE GIVING OUT THE STATE'S MONEY, BUT WE'RE NOT A STATE AGENCY. AND SO THAT PREVENTS US FROM RAISING MONEY IN THE BOND MARKET.

AND WE JUST HEARD YESTERDAY THAT ALL EXCEPT A SMALL PORTION OF THOSE SUITS HAVE BEEN DISMISSED. THERE WILL BE A MEETING NEXT WEEK TO DISCUSS THE SCHEDULE AND THEN A TRIAL, WE SUSPECT, SOMETIME IN THE SPRING TO DISCUSS THOSE ISSUES. JAMES, MAYBE YOU WANT TO COMMENT ON THAT LITTLE MORE EXPERTLY THAN I JUST DID.

MR. HARRISON: THAT'S A PRETTY GOOD LAY SUMMARY. IN ESSENCE, THOUGH THE COURT FOUND IN THE CIRM'S FAVOR ON SEVERAL OF THE DIFFERENT LEGAL THEORIES THE PLAINTIFFS HAVE ADVANCED IN SUPPORT OF THEIR ARGUMENT, THAT PROPOSITION 71 IS UNCONSTITUTIONAL, SHE CONCLUDED THAT SHE COULDN'T GRANT JUDGMENT IN OUR FAVOR AT THIS TIME BECAUSE, IN HER VIEW, SEVERAL OF THE

CLAIMS, THREE OF THEM, REQUIRE FURTHER DEVELOPMENT BEFORE WE SHE CAN REACH A CONCLUSION AS TO THOSE CLAIMS. AND WHAT THAT MEANS AS A PRACTICAL MATTER IS AT THE CASE MANAGEMENT CONFERENCE THAT SHE SCHEDULED FOR NEXT TUESDAY, WE'LL HAVE AN OPPORTUNITY TO TALK ABOUT THE SCOPE OF THE ISSUES THAT REMAINS, WHAT DISCOVERY, IF ANY, IS NECESSARY IN ORDER TO RESOLVE THOSE ISSUES, AND WHEN WE CAN SET A HEARING DATE TO BRING IT TO CLOSURE.

THE ONE ADDITIONAL POSITIVE ASPECT ABOUT THE COURT'S RULING IS THAT SHE RECOGNIZED THAT THIS ACTION IS ENTITLED TO PREFERENCE ON THE COURT'S CALENDAR, AND SHE EXPRESSED A DESIRE TO BRING IT TO THAT HEARING AND TO A CONCLUSION PROMPTLY. SO WE'RE HOPEFUL THAT WE CAN CONTINUE TO PUSH THIS FORWARD AS QUICKLY AS POSSIBLE TO GET TO A RESOLUTION IN THE TRIAL COURT.

DR. CIBELLI: IF IT WERE THE CASE -- I'M ASSUMING THIS IS GOING TO GO BACK AND FORTH SEVERAL TIMES. SO THAT MEANS THAT THE FUNDS WILL BE STRANDED UNTIL WHEN? WHEN ARE YOU GOING TO BE --

MR. HARRISON: WELL, YOU'RE CORRECT, THAT THERE ARE DIFFERENT STAGES IN THE LITIGATION. WE'RE HOPEFUL TO GET THROUGH THIS FIRST STAGE IN THE TRIAL COURT SOMETIME IN THE SPRING, AND THE EARLIER, THE BETTER; BUT OBVIOUSLY IF WE'RE SUCCESSFUL, THE

PLAINTIFFS WILL HAVE AN OPPORTUNITY TO APPEAL. AND THAT WILL CONTINUE TO HAVE AN EFFECT ON THE STATE'S ABILITY TO MARKET THE BONDS. A POSITIVE RULING AND, IN FACT, EVEN THE RULING THAT THE COURT ISSUED THIS WEEK, WHICH DOES INDICATE THAT THE COURT FEELS THAT SEVERAL OF THE PLAINTIFF'S CLAIMS LACK MERIT, DOES HELP US IN TERMS OF CONVINCING POTENTIAL PURCHASERS OF BOND ANTICIPATION NOTES THAT THEIR OF RISK NOT BEING REPAID IS MINIMAL.

SO I THINK WE HAVE MADE SOME PROGRESS. UNFORTUNATELY WE STILL HAVE A WAYS TO GO UNTIL WE CAN ULTIMATELY REACH THE END OF THE ROAD, WHICH IS A FINAL JUDGMENT WITH ALL APPEALS EXHAUSTED.

DR. HALL: WE ARE TRYING RAISE BRIDGE FUNDING; AND WHILE I THINK WE HAVE POSITIVE RESULTS IN THAT AREA, WE HAVE NOT REACHED CONCLUSION, AND WE ARE HOPEFUL THAT SHORTLY AFTER THE FIRST OF THE YEAR, WE WILL HAVE SOME MONEY THAT WILL ALLOW US TO AT LEAST TO FUND THE TRAINING GRANTS.

DR. ROWLEY: HOW MUCH IS THE TOTAL FOR THE 16 TRAINING GRANTS APPROVED?

DR. CHIU: $12.1 MILLION FOR THE FIRST YEAR OF TRAINING, AND A TOTAL OF ALMOST $38 MILLION TO FULLY FUND THE THREE YEARS.

DR. TAYLOR: I THINK I'M IN AGREEMENT, BUT

I'M JUST SORT OF CURIOUS AS TO A PRIORI, THE TRAINING GRANT, WAS THAT COMPONENT SET OUT AS THE MOST IMPORTANT FIRST STEP WITH OBVIOUSLY THE FIRST 12 MILLION THAT YOU CAN RAISE, NOT THAT I -- I WAS JUST SORT OF CURIOUS AS TO WHAT THE THINKING WAS.

DR. HALL: THERE ARE TWO REASONS FOR THAT. WE DECIDED TO ISSUE THAT RFA EARLY ON. ONE WAS THAT WE SAW THE TRAINING OF STEM CELL RESEARCHERS AS A CLEAR AND URGENT NEED FOR THE ENTIRE PROJECT AND ONE THAT WAS A SORT OF LONG-TERM INVESTMENT. THERE WILL BE AN ENORMOUS EXPANSION OF STEM CELL RESEARCH IN THE STATE AS A RESULT OF THIS. THAT WILL TAKE A LARGE INCREASE IN MANPOWER. AND SO ALSO OUR SENSE HAD BEEN THAT BECAUSE OF FEDERAL POLICY, A LOT OF YOUNG PEOPLE WERE AVOIDING THIS AREA BECAUSE OF THE UNCERTAINTY IN FUNDING DOWN THE LINE, SO WE WANTED TO SEND A LOUD AND CLEAR SIGNAL.

AND THE OTHER IS A MORE PRACTICAL MATTER, AND THAT IS THAT WE WANTED TO GET OUR GRANT-MAKING ACTIVITY STARTED AS QUICKLY AS POSSIBLE. IT WAS AT A TIME WHEN OUR STAFF WAS VERY LIMITED. WE WERE JUST PUTTING TOGETHER OUR GRANTS WORKING GROUP, OUR PROCEDURES WERE UNCLEAR, WE'RE STILL WORKING THESE THINGS OUT, AND WE THOUGHT THAT IF WE PUT OUT A CALL FOR RESEARCH GRANTS, WE WOULD GET PROBABLY HUNDREDS OF APPLICATIONS AND

WOULD BE OVERWHELMED. BUT WE RECEIVED, I THINK, IN THE END 26 APPLICATIONS, IF I'M NOT MISTAKEN. THIS IS A MANAGEABLE NUMBER. ACTUALLY IT WORKED OUT VERY WELL, SO WE WERE ABLE TO WALK THROUGH THE PROCEDURES, AND WE WERE VERY PLEASED WITH THE WAY THAT CAME OUT. WE HAVE, WE THINK, AN EXCELLENT TRAINING PROGRAM ONCE WE HAVE THE FUNDS.

AND I WILL SAY THAT THE PROCEDURES ALSO PRESENT SOME CHALLENGES FOR US. THE FINAL DECISION IS MADE IN A PUBLIC MEETING, FOR EXAMPLE, BY OUR BOARD, WHICH IS UNUSUAL FOR THE KINDS OF PROCESS THAT WE'RE USED TO RATHER THAN WITH THE NIH. AND SO TO MANAGE THE DIFFERENT STEPS OF THE PROCESS AND TO DO IT IN ACCORDANCE WITH BOTH STATE LAW AND TO HAVE A MAXIMUM POSSIBLE TRANSPARENCY WHILE MAINTAINING CONFIDENTIALITY WAS A BIT OF A CHALLENGE FOR US. WE WERE ABLE TO WORK THROUGH HOW WE DID THAT ON A RELATIVELY SMALL SCALE, AS I SAY, WITHOUT HAVING TO HANDLE EXTREMELY LARGE NUMBERS OF GRANTS. SO IT WAS A VERY GOOD WAY FOR US TO GET GOING. WE HAVE THE TRAINING PROGRAM IN PLACE.

ALSO, I THINK IT'S, IN RETROSPECT, A MODEST AMOUNT OF MONEY GIVEN OUR DIFFICULTIES. IF WE HAD TO RAISE 200 MILLION, LET'S SAY, TO FUND A BROAD RESEARCH PROGRAM, I THINK THAT'S MUCH MORE DIFFICULT THAN THIS. SO IT WAS BOTH A SUBSTANTIVE AND SCIENTIFIC RATIONALE

AND A PRACTICAL RATIONALE FOR DOING IT IN THAT WAY.

DR. TAYLOR: IT'S HARD TO KNOW WHETHER YOU SHOULD BUILD AUTOMOBILES FIRST OR PETROLEUM PROCESSING PLANT, BUT I THINK IT WAS A GOOD DECISION.

DR. HALL: MODERN VERSION OF THE CHICKEN OR THE EGG.

VICE CHAIR LO: ANY OTHER QUESTIONS FOR ARLENE? THANKS VERY MUCH. WE'LL LOOK FORWARD TO HEARING FROM YOU AGAIN IN THE FUTURE.

I WANT TO SORT OF SHIFT GEARS A LITTLE BIT AND MOVE ON TO SOME ISSUES THAT ARE DIFFERENT THAN THE CONSENT ISSUES WE'VE BEEN DISCUSSING, OR SOMEWHAT DIFFERENT AT LEAST. I THINK WE'VE HAD A VERY RICH AND VERY PRODUCTIVE AND VERY USEFUL DISCUSSION. GIVEN WE HAVE A LOT OF THINGS FOR STAFF TO KIND OF TRANSLATE INTO REGULATORY LANGUAGE, WHICH I THINK WE'LL TRY AND DO BEFORE OUR NEXT MEETING, THERE'S ANOTHER SET OF ISSUES THAT REALLY HAVE TO DO WITH THREE DIFFERENT CATEGORIES OF RESEARCH YOU MIGHT FUND.

HERE, LET ME JUST DIRECT YOUR ATTENTION TO TAB 6, PAGE 4 OF THE DRAFT CIRM REGULATIONS. IT'S A PAGE THAT LOOKS LIKE THIS. IT'S GOT A RED LINE TOWARDS THE BOTTOM. AND WHAT WE'VE DONE -- LET ME JUST GIVE YOU A SECOND. IT'S SECTION 100006.

WE SET OUT HERE THREE DIFFERENT BROAD

CATEGORIES OF RESEARCH. ONE IS STEM CELLS DERIVED WITH CIRM FUNDING AFTER THIS POLICY GOES INTO EFFECT. B IS STEM CELLS DERIVED WITHOUT CIRM FUNDING, BUT AFTER THE EFFECTIVE DAY OF THIS POLICY. AND THE CONTEXT IS A CIRM-FUNDED RESEARCHER WANTS TO WORK WITH A STEM CELL LINE DERIVED WITHOUT CIRM FUNDING. SO YOU MIGHT THINK OF SOMEONE WANTING TO USE LINES THAT DOUG MELTON MIGHT DERIVE AFTER THESE GUIDELINES GO INTO EFFECT OR DR. HWANG'S GROUP MIGHT HAVE DERIVED. AND A THIRD CATEGORY IS STEM CELL LINES DERIVED BEFORE THE EFFECTIVE DATE OF THE FUNDING. SO THINK OF SOMETHING SITTING IN KEVIN'S LAB OR DOUG MELTON'S LAB OR DR. HWANG'S LAB.

OBVIOUSLY FOR THE FIRST CATEGORY, IT'S DONE WITH CIRM FUNDING AFTER THE IMPACT OF THE POLICY. ALL THE OTHER THINGS THAT WE'RE TALKING ABOUT HAVE TO -- ALL THESE CRITERIA HAVE TO BE MET. AND THERE'S A COUPLE OF EXTRAS THAT ARE LISTED UNDER 1, 2, 3, 4.

B RAISES THE QUESTION OF IF WE'RE NOT FUNDING THE RESEARCH, BUT OUR SCIENTISTS ARE GETTING FUNDS TO WORK WITH A CELL LINE, WHAT ARE THE MINIMAL REQUIREMENTS THAT WE WANT TO HAVE FOR THOSE CELL LINES, TAKING INTO ACCOUNT ALL THE PRACTICAL DIFFICULTIES OF FINDING OUT A LOT OF THE DETAILS IF THEY'RE DERIVED UNDER SOMEBODY ELSE'S AUSPICES.

SO THE CHALLENGE HERE IS TO FIND WHAT ARE THE THINGS THAT WE WOULD WANT AS SORT OF MINIMAL REQUIREMENTS SO THAT IF THEY WEREN'T -- IF THERE WAS NONCOMPLIANCE, WE WOULD NOT ALLOW CIRM FUNDS TO BE USED FOR RESEARCH WITH THOSE LINES.

AND THE THIRD CATEGORY IS GOING BACKWARDS EVEN MORE IN TIME, SORT OF THE GRANDPARENTING ISSUE. THIS WOULD INVOLVE NIH STEM CELL LINES, FOR EXAMPLE, WHERE THEY MAY NOT MEET THE CRITERIA THAT ARE SET OUT IN A OR B. THEY WERE DERIVED SOME TIME AGO, BUT THEY'RE SCIENTIFICALLY IMPORTANT. AND SINCE THEY'RE ALREADY IN EXISTENCE, SHOULD WE ALLOW CIRM FUNDS TO BE USED FOR RESEARCH WITH THEM?

JEFF AND STAFF HAVE FORMATTED THIS AS SORT OF ONE WAY OF LOOKING AT IT IS THE EQUIVALENT PROTECTION STANDARDS. INCLUDED IN OUR BRIEFING WERE SOME MATERIALS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, WHICH ARE THE FEDERAL KIND OF GUIDELINES FOR IF SOMETHING IS DERIVED WITHOUT FEDERAL FUNDING AND DOESN'T NEED TO FALL UNDER FEDERAL REGULATIONS, WHAT ARE THE SORT OF EQUIVALENT PROTECTIONS YOU WOULD WANT TO HAVE IN PLACE TO DEEM THEM ACCEPTABLE FOR FUNDING?

SO WITH THAT FRAMEWORK IN MIND, I WAS GOING TO ASK US TO TURN OUR ATTENTION TO -- MAYBE WE COULD START WITH B FOR STEM CELL LINES DERIVED WITHOUT OUR

FUNDING, WHAT ARE THE MINIMAL STANDARDS WE WOULD WANT TO SEE APPLIED TO THOSE STEM CELL LINES?

AND SOME OF THE THINGS THAT HAVE BEEN SUGGESTED WERE THAT IT HAVE SOME SORT OF IRB AND/OR ESCRO APPROVAL. IT STRIKES ME SOMETHING ABOUT CONSENT, WHICH ACTUALLY ISN'T UNDER B(1) HERE, BUT FREE AND VOLUNTARY CONSENT, I THINK WE'D WANT THIS PERHAPS. WITHOUT PAYMENT BEYOND REIMBURSEMENT, AGAIN TO BE CONSISTENT WITH PROP 71, AND I GUESS GIVEN OUR DISCUSSION TODAY, WOULD WE WANT TO SAY WITHOUT ANY RESTRICTIONS PLACED ON FUTURE DOWNSTREAM SCIENTIFIC USES?

BUT I THINK THIS IS A CHANCE FOR US TO THINK ABOUT WHAT WE WOULD WANT TO SEE IN THIS CONTEXT.

DR. EGGAN: WHAT YOU JUST SAID, CAN WE SEE THAT LANGUAGE FROM THE CIRM LEGISLATION AGAIN, OR CAN THAT BE READ AGAIN BECAUSE DOES THE CIRM LEGISLATION SPEAK ABOUT -- IT CERTAINLY SAYS THAT CIRM RESEARCH DOLLARS CAN'T BE USED FOR RESEARCH INVOLVING DERIVATION, WHICH INCLUDES COMPENSATION, BUT DOES IT SPEAK TO OUTSIDE CELL LINES SPECIFICALLY?

MR. HARRISON: IT DOES NOT SPECIFICALLY SPEAK TO THAT. THE LANGUAGE, AS I READ IT, IT SIMPLY SAYS STANDARDS PROHIBITING COMPENSATION TO RESEARCH DONORS OR PARTICIPANTS WHILE PERMITTING REIMBURSEMENT OF

EXPENSES. IT'S NOT SPECIFICALLY ADDRESSED. I THINK THERE IS A QUESTION REGARDING THE INTENT THAT WE WOULD HAVE TO EVALUATE.

DR. EGGAN: I THINK THIS IS A BIG DEAL. I THINK THERE MAY BE OTHER GROUPS WHICH DECIDE IT'S REASONABLE TO, SAY, COMPENSATE FOR LOST TIME AND MAY MAKE VERY VALUABLE REAGENTS THAT CIRM RESEARCHERS MAY WANT TO USE. AND THIS IS A SITUATION -- I DON'T SEE THIS AS A LOOPHOLE. I SEE THIS AS A DIFFERENCE IN OPINION. AND CERTAINLY I DON'T THINK THAT WE SHOULD -- I DON'T THINK -- I'M NOT SURE THAT WE THIS AS WRITTEN HERE AT THIS TIME.

DR. HALL: I'D JUST LIKE TO ECHO WHAT KEVIN SAID. I THINK IT WAS STATED BEFORE THAT THIS IS AN ISSUE IN WHICH A VERY THOUGHTFUL AND CONSIDERED CASE CAN BE MADE ON BOTH SIDES OF THIS ISSUE. IT'S NOT SO SIMPLE. AND ALTHOUGH WE MAY AGREE THAT OUR OWN STANDARD IS FOR DERIVING CELL LINES, WE CHOOSE ONE, I WOULD LIKE TO ASK THE WORKING GROUP TO AT LEAST CONSIDER THE POSSIBILITY OF WHETHER IT MIGHT NOT ACKNOWLEDGE THAT THERE MAY BE AN HONEST DIFFERENCE OF OPINION BY OTHER GROUPS ON THIS ISSUE, AND THAT TO CATEGORICALLY RULE OUT THE USE OF THOSE CELL LINES BY CALIFORNIA RESEARCHERS MIGHT NOT BE A MISTAKE. SO JUST TO CONSIDERATION AND DISCUSSION OF THAT ISSUE, I JUST

ECHO KEVIN, I THINK WOULD BE VERY USEFUL AND HELPFUL TO US.

DR. KIESSLING: AGAIN, I WOULD LIKE TO HAVE WHETHER OR NOT THE DONORS ARE COMPENSATED BE NOT THE MOST IMPORTANT CONSIDERATION. THE MOST IMPORTANT CONSIDERATION IS WHETHER THEY HAD FULLY INFORMED CONSENT AND THAT THEY KNEW EXACTLY WHAT THEY WERE DOING. I THINK THE ISSUE OF COMPENSATION SHOULD BE --

DR. HALL: INFORMED AND VOLUNTARY.

DR. KIESSLING: RIGHT. I THINK HOW THE DONORS WERE RECRUITED AND HOW THEY WERE TREATED DURING AND AFTER, I THINK THAT IS A FAR BIGGER ISSUE AND FAR MORE IMPORTANT THAN WHETHER OR NOT THEY WERE COMPENSATED.

SECONDLY, I THINK IT'S REALLY IMPORTANT TO NOT SUBSTITUTE THE TERM "OUT OF POCKET." I THINK THAT SHOULD NOT APPEAR BECAUSE THAT'S NOT WHAT THE STATUTE SAYS.

VICE CHAIR LO: COMMENTS, THOUGHTS?

DR. PRIETO: I AGREE THAT THAT SEEMS TO RESTRICT US UNNECESSARILY AND RATHER JUST GO BACK TO THE ORIGINAL LANGUAGE OF REIMBURSEMENT OF EXPENSES.

DR. EGGAN: AGAIN, THIS IS MAYBE EVEN MORE LIMITING THAN WE NEED TO BE BECAUSE THE LEGISLATION MAY SAY THAT WE CANNOT DERIVE CELL LINES EXCEPT UNDER THESE

CONDITIONS, BUT IT DOESN'T SPEAK TO CELL LINES DERIVED OUTSIDE. AGAIN, IS THAT THE LANGUAGE THAT WE WANT TO HAVE IN PART B?

DR. PRIETO: JAMES, DOES THE INITIATIVE ACTUALLY SPECIFICALLY REFER TO DERIVATION?

MR. HARRISON: NO. WHAT THE ACT PROHIBITS IS CIRM COMPENSATION OF DONORS FOR ANYTHING OTHER THAN REIMBURSEMENT OF EXPENSES. SO WE'RE REALLY TALKING ABOUT CIRM FUNDING TO THE DONORS AS THE LIMITATION.

DR. EGGAN: ACTUALLY THIS IS EVEN A MUCH BROADER ISSUE BECAUSE ONE CAN CONSIDER A SITUATION WHERE CIRM FUNDS DERIVATION, BUT FROM OTHER FUNDS FROM THAT RESEARCH GROUP COME THE FUNDS FOR COMPENSATION.

DR. HALL: LET'S LEAVE THAT TECHNICALITY ASIDE FOR THE MOMENT AND JUST CONSIDER THE ISSUE OF THE USE OF LINES DERIVED ELSEWHERE WHERE COMPENSATION IS PERMITTED. I THINK THAT'S THE FIRST ISSUE TO REALLY HAVE A CLEAR, WHATEVER IT IS, CLEAR POLICY ON WHETHER TO SAY WE WANT TO APPLY THIS STANDARD TO ALL OR TO SAY THAT WE RECOGNIZE THERE MAY BE A DIFFERENCE.

DR. EGGAN: I THINK THE FIRST IS A LOOPHOLE WE WANT TO CLOSE, AND THE SECOND ONE IS A LOOPHOLE THAT WE PROBABLY WANT TO LEAVE OPEN, AT LEAST IN MY OPINION.

DR. HALL: IT'S FINE. JUST TAKE THEM IN ONE ORDER OR THE OTHER.

DR. TAYLOR: FOR THIS ONE IT SEEMS THAT THE VOLUNTARY INFORMED CONSENT SHOULD BE ENOUGH. AND WITHOUT A DISCUSSION, I AGREE WITH ANN, WITHOUT A DISCUSSION, NOT ONLY MAKE IT A LOWER PRIORITY. IT DOESN'T SEEM TO ME IT NEEDS TO BE A PRIORITY LISTED IN OUR CRITERIA FOR ACCEPTANCE. I THINK THAT PREVIOUS CELL LINES, IF THEY WERE DERIVED UNDER APPROPRIATE INFORMED CONSENT, COULD BE ELIGIBLE AND WITH NO DISCUSSION OF COMPENSATION.

DR. ROWLEY: I WOULD SUPPORT ROB'S POINT OF VIEW.

DR. HALL: TECHNICALLY CONSIDERING ONES THAT ARE DERIVED AFTER THIS AND AS IT'S WRITTEN HERE.

VICE CHAIR LO: WE'VE SEPARATED OUT BEFORE AND AFTER.

DR. HALL: IN THE FUTURE WILL WE TAKE CELL LINES, AND THEN WE'LL DEAL WITH THE OTHERS LATER.

VICE CHAIR LO: THAT'S A SEPARATE ISSUE.

MS. FEIT: FOR THOSE OF YOU HAVE -- ARE WITH WORKING STEM CELL LINES, OBVIOUSLY YOU WORKED WITH THEM BEFORE THIS POINT IN TIME THAT PROP 71 CAME ALONG. SO I'M ASSUMING, OR MAYBE THAT'S A WRONG ASSUMPTION, THAT YOU APPLIED MAYBE THE ACADEMY GUIDELINES TO YOUR CELL LINES, OR IS THAT A WRONG ASSUMPTION, OR YOU HAD STANDARDS THAT YOU USED?

DR. EGGAN: I THINK THE DIFFICULT ISSUE HERE IS THAT THIS SITUATION IS DYNAMIC. AND I CAN CERTAINLY TELL YOU THAT IN MY CLOSE COLLEAGUE'S LABORATORY, DOUG MELTON'S LABORATORY, THERE HAVE BEEN ISSUES, JUST HOW BROAD IS BROAD ENOUGH WITH RESPECT TO INFORMED CONSENT? THIS IS VERY MUCH A MOVING TARGET, AND SCIENTISTS ARE DOING THE BEST THAT THEY CAN, BUT THEY'RE STILL LEARNING A LOT ABOUT WHAT'S BEST. AND SO CERTAINLY, YOU KNOW, FOR INSTANCE, FOR SOME OF THE ORIGINAL LINES DERIVED IN THE MELTON LABORATORY, THE CONSENT WAS NOT AS BROAD AS ONE MIGHT HAVE LIKED TO HAVE SEEN, BUT THERE ARE CERTAINLY DECISIONS BY GROUPS LIKE THE CANADIAN GOVERNMENT THAT THE INTENT DONORS WAS BROAD EVEN THOUGH THE LANGUAGE MAY NOT HAVE BEEN THE LANGUAGE YOU MIGHT HAVE LIKED TO HAVE SEEN IN THE MOST SPECIFIC CASE.

THIS IS A LONG WAY OF SAYING THAT THERE -- I THINK THERE NEEDS TO BE SOME SORT OF UNDERSTANDING, THAT THERE ARE DIFFERENCES OF OPINIONS. AS LONG AS THERE WAS FREE AND INFORMED CONSENT, THEN I THINK THAT WE MAY WANT TO LET SOME THINGS GO BY IN ORDER TO ENABLE THE SCIENCE. I'M NOT SURE.

VICE CHAIR LO: LET'S DISTINGUISH LINES THAT ARE GOING TO BE DERIVED AFTER OUR REGULATIONS GO IN EFFECT, WHICH IS WHAT I'D LIKE TO TALK ABOUT FIRST.

THEN THE HARDER SITUATION IS THESE GRANTS --

DR. EGGAN: THAT'S WHAT I'M SAYING. I'M SAYING THE THINGS MAY CONTINUE -- IT'S GOING TO CONTINUE TO BE A MOVING TARGET EVEN AFTER. WE'RE GOING TO SAY WHAT IT'S GOING TO BE, BUT THEN THINGS ARE GOING TO CONTINUE TO CHANGE.

DR. KIESSLING: I THINK THE ANSWER TO MARCY'S QUESTION IS THAT THE TECHNOLOGY FOR DERIVING STEM CELLS FROM EGG DONORS IS NEW. WHAT KEVIN IS TALKING ABOUT ARE CELLS THAT ARE DERIVED FROM FROZEN EMBRYOS. SO THE EGG DONOR ISSUES ARE BRAND NEW.

DR. HALL: LET ME JUST ADD TO THAT. IN ACTUALLY HISTORICAL FACT, PROPOSITION 71 INCLUDED THE NO COMPENSATION. THE NATIONAL ACADEMY GUIDELINES APPEARED ONLY LAST APRIL, AND THEY ADOPTED A STANDARD THAT WAS IN PROPOSITION 71. THEY MADE CONSCIOUS REFERENCE TO THE FACT THAT IT HAD BEEN FIRST IN PROPOSITION 71. AND SO JUST TO UNDERSTAND THE HISTORY OF THAT.

SECONDLY, THE NATIONAL ACADEMY GUIDELINES HAVE ONLY BEEN IN EFFECT SINCE APRIL. SO AS KEVIN SAYS, IT'S VERY MUCH A CHANGING STANDARD AND A MOVING TARGET. BUT I THINK RIGHT NOW, JUST TO EMPHASIZE THE POINT, WE'RE TALKING ABOUT ONES THAT MIGHT BE DERIVED IN THE FUTURE. THAT'S THE REAL ISSUE.

DR. CIBELLI: I WONDER IF -- SO THERE ARE TWO THINGS HERE. ONE IS ASK THE QUESTION WHETHER THIS RESEARCH -- THIS CELL LINES WERE DERIVED AFTER IRB APPROVAL, INDEPENDENT IRB APPROVAL. I THINK WE ALL AGREE WITH THAT.

THE THING THAT IS A LITTLE BIT MORE DIFFICULT IS TO JUDGE HOW WAS THE CONSENT FORM MADE. AND I WONDER FOR US IT WOULD BE TOO HARD TO JUDGE THAT BECAUSE THERE ARE NOT TOO MANY CELL LINES DERIVED BY IN THIS CASE SOMATIC CELL NUCLEAR TRANSFER THAT WILL COME TO CALIFORNIA. SO IT WOULDN'T BE TOO HARD FOR THIS COMMITTEE TO SAY, OKAY, IF WE JUDGE THE CONSENT FORMS ARE ETHICALLY -- THE WORD HERE IS ETHICALLY DERIVED MATERIALS. SO IF WE CAN LOOK AT THE CONSENT FORM AND DECIDE THAT IT'S NOT A CONSENT FORM, IT'S JUST A JOKE, WE SHOULDN'T ALLOW THOSE CELL LINES TO BE SPONSORED BY CIRM. AND IF WE THINK THAT THOSE CONSENT FOR ARE APPROPRIATE, WE SHOULD GO FORWARD.

I DON'T THINK IT'S AN ENORMOUS TASK BECAUSE I DON'T THINK THERE ARE TOO MANY CELL LINES. HONESTLY, I DON'T THINK THERE ARE TOO MANY.

DR. HALL: IT'S NOT JUST EGG DONORS AS WE'RE TALKING HERE. THAT'S CERTAINLY THE ONE ISSUE, BUT ALSO EMBRYO DONORS.

DR. CIBELLI: SO YOU HAVE A HANDFUL OF

CLINICS AROUND THE WORLD. WE HAVE A COUPLE IN ISRAEL, WE HAVE SPAIN, AUSTRALIA, YOU MAY HAVE SINGAPORE, THE UK, SO THERE ARE NOT TOO MANY. AND WE COULD GO -- I THINK THIS IS GOING TO BE OUR ROLE JUST TO MAKE SURE THAT IF YOU ARE GOING TO APPROVE THAT, IF YOU ARE GOING -- THIS WILL BE A NICE PLACE WHERE WE CAN BE VERY, VERY VULNERABLE. IF WE JUST LET THEM -- IF WE ALLOW FUNDS TO BE USED AND THE CELL LINES WERE DERIVED IN A WAY THAT WE NEVER APPROVED, BUT, OOPS, WE FORGOT TO LOOK AT THE CONSENT FORM, WE NEVER ASKED FOR IT. THIS SHOULD BE OUR ROLE. WE SHOULD BE THE ONES LOOKING FOR THE CONSENT FORM.

DR. HALL: THERE IS A PROBLEM, HOWEVER, LET ME JUST POINT OUT. THAT IS, THAT WHATEVER WE PUT HERE WILL BECOME A CALIFORNIA REGULATION, AND IT WILL BE VERY, VERY DIFFICULT TO CHANGE. SO WHAT WE WANT TO DO IS SET OUT PROCEDURES THAT WILL, I THINK, GUIDE WHATEVER DECISIONS ARE MADE. THAT IS, I'M NOT SURE WHAT YOU ARE SAYING HERE, BUT I THINK WHAT WE DON'T WANT TO DO IS TO HAVE SPECIFIC APPROVALS HERE.

DR. CIBELLI: WHAT I'M SAYING IS LET'S SAY THERE ARE 30 DIFFERENT LABORATORIES AROUND THE WORLD AND THEY HAVE CELL LINES ALREADY CIRCULATING AROUND, AND PEOPLE FROM CALIFORNIA WANTS TO USE THOSE CELL LINES. ALL WE HAVE TO DO IS SEND US THE CONSENT FORMS.

IF THEY ARE OKAY --

DR. HALL: I DON'T THINK WE WANT TO DO THAT. WHAT WE WANT TO DO IS TO SAY TO THE ESCRO'S THAT THEY MUST BE ASSURED THAT THE FOLLOWING PRINCIPLES HAVE BEEN FOLLOWED. THAT'S WHAT I THINK THIS -- TO PUT INTO THIS REGULATION, THAT'S WHAT WE NEED TO DO.

DR. CIBELLI: YOU REALIZE THAT EVERY SINGLE COUNTRY WILL HAVE A DIFFERENT WAY OF DOING THINGS.

DR. HALL: I KNOW, BUT WE CAN'T EXAMINE THOSE AND PUT IT IN THE REGULATION TO SAY -- SO THAT'S MY ONLY POINT, THAT WE NEED TO ESTABLISH THE PRINCIPLES AND TO SAY WHAT IT IS WE'LL ACCEPT, AND THEN THE ESCRO'S WILL HAVE TO ENFORCE THAT.

DR. EGGAN: UNLESS WE TOOK AN ENTIRELY DIFFERENT TACT, AND THAT ENTIRELY DIFFERENT TACT COULD BE TO SAY THAT CIRM-FUNDED RESEARCH CAN ONLY BE CONDUCTED ON EMBRYONIC STEM CELL LINES WHICH ARE DEPOSITED IN THE CIRM STEM CELL BANK. AND ONLY CIRM BANK LINES WILL HAVE BEEN APPROVED BY THIS OR SOME OTHER GROUP THAT WE APPROVE OF, RIGHT, SO THAT WOULD BE ANOTHER -- THAT WOULD CERTAINLY LIVE UP TO THE MODEL THAT JOSE WAS JUST SAYING. SO IT WOULD BE A TOTALLY DIFFERENT TACK -- I'M NOT SAYING THAT'S ONE WE SHOULD TAKE, BUT THAT COULD BE DONE.

DR. HALL: YES. THAT NEEDS TO BE BROUGHT

INTO, AND THE PROBLEM IS THAT'S ALSO A MOVING TARGET. WE WILL HAVE TO HAVE PLANS FOR THE BANK, SET IT UP, AND BE SURE THAT IT'S IN EXISTENCE. OTHERWISE, YOU MAY RESTRICT -- NOBODY CAN USE THESE THINGS UNTIL WE SET THE BANK UP. THAT'S NOT WHAT WE WANT. THAT MAY TAKE AWHILE, PARTICULARLY GIVEN OUR FUNDING SITUATION. SO I THINK WE NEED TO HAVE SOMETHING, IN MY VIEW --

DR. EGGAN: IN THE MEANTIME.

DR. KIESSLING: ARE WE DISCUSSING SECTION 6 AS THIS IS A DRAFT THAT YOU WANT TO US TO DISCUSS, SECTION 6, IS THAT WHAT WE'RE DOING? COULD I SUGGEST, BERNIE, THAT YOU JUST TAKE US THROUGH THAT POINT BY POINT AND WE CAN TALK ABOUT EACH POINT AND WE CAN GET THROUGH THIS FOR YOU PRETTY QUICKLY?

DR. TAYLOR: THE FACT THAT WE HAVEN'T BEEN ABLE TO GET THROUGH ONE POINT.

DR. KIESSLING: SOME OF THESE THINGS WE'RE GOING TO REALLY AGREE WITH, AND OTHERS ARE GOING TO CHANGE BECAUSE OF OUR DISCUSSION TODAY. I THINK IF YOU TOOK US THROUGH SECTION 6(A)(1), (2), (3), (4).

DR. EGGAN: MAYBE SOME OF THESE THINGS AREN'T A PROBLEM.

VICE CHAIR LO: SECTION A, I THINK THAT'S NOT GOING TO BE AS CONTROVERSIAL BECAUSE WE GET TO CALL THE SHOTS WITH THINGS WE FUND.

DR. KIESSLING: NO. 4 HAS CHANGED NOW, (A)(4).

VICE CHAIR LO: LET'S GO THROUGH GO. OKAY. SO (A) IS STEM CELLS DERIVED WITH CIRM FUNDING AFTER THE EFFECTIVE DAY OF THIS POLICY.

DR. HALL: LET ME JUST ASK ISN'T (A) WHAT WE'VE BEEN TALKING ABOUT MOST OF THE DAY? AND THAT WILL BE REDONE IN ACCORDANCE WITH -- THAT WILL BE REDONE IN ACCORDANCE WITH ALL THE DISCUSSION WE'VE HAD UP TO NOW, SO WE DON'T NEED TO DO THAT.

VICE CHAIR LO: (B) AND (C) WE HAVEN'T TALKED ABOUT TODAY, AND I THINK I'D LIKE TO HAVE THAT DISCUSSION.

DR. LOMAX: JUST SO FOLKS ARE CLEAR ON THE ORIGINS OF WHAT WE ARE WORKING OFF OF, (A) IS ESSENTIALLY TAKING WHAT WAS IN THE NATIONAL ACADEMIES GUIDELINES, AND THOSE SETS OF CONDITIONS THAT WERE APPROPRIATE FOR THE REVISED FRAMEWORK WERE DROPPED IN. SO (2), (3), AND (4) ARE ESSENTIALLY THE RAW MATERIAL FROM THE NATIONAL ACADEMIES' GUIDELINES. AND CORRECT, WE NOW NEED TO UPDATE THIS SECTION BASED ON TODAY'S DELIBERATIONS.

DR. KIESSLING: SO NOW WE'RE JUST TALKING ABOUT (B).

VICE CHAIR LO: LET'S TALK ABOUT (B) FOR A

MINUTE. FIRST WOULD BE IRB OVERSIGHT OR FROM AN EQUIVALENT BODY TO AN IRB. ANY DISAGREEMENT ON THAT?

DR. KIESSLING: I WOULD REALLY LIKE TO JUST DISREGARD THE WHOLE PAYMENT ISSUE. I THINK THAT JUST REALLY CLOUDS THIS DISCUSSION.

VICE CHAIR LO: LET'S GO THROUGH EVERYTHING BUT PAYMENT, BUT LET'S SEE IF WE CAN AT LEAST AGREE ON THE OTHER ONES. SO IRB OVERSIGHT, ANY CONCERNS ABOUT -- ANYONE NOT WANT TO HAVE THAT AS ONE OF OUR CORE CRITERIA? I THINK WE HAVE TO.

SECOND, WHICH ISN'T IN HERE, AND I THINK PROBABLY SHOULD BE IS FREE AND VOLUNTARY CONSENT FROM THE DONORS.

DR. PRIETO: AND THE WORDING THAT ANN MENTIONED, FULLY INFORMED, FREE, VOLUNTARY, AND FULLY INFORMED CONSENT.

DR. EGGAN: THAT'S RIGHT.

DR. CIBELLI: YOU CONSIDER THAT THE CONSENT FORM SHOULD BE -- YOU CONSIDER THE CONSENT FIRM SHOULD BE MADE AVAILABLE UPON CIRM REQUEST OR SOMETHING OF THAT NATURE.

DR. HALL: I THINK ANN'S POINT WAS THAT IT'S NOT JUST THE FORM. IT'S THE WHOLE PROCESS THAT NEEDS TO BE ACCEPTABLE. AND SO WE NEED TO WRITE IT TO REFLECT THAT, THAT THE FORM AND THE PROCESS SHOULD BE

SOMEHOW --

VICE CHAIR LO: IF WE GET THE CONCEPT THAT INFORMED AND FREE OR VOLUNTARY CONSENT ARE ESSENTIAL, AND THEN CRAFT THE LANGUAGE, LET US HAVE STAFF WORK ON THAT AND COME BACK TO US. JOSE'S POINT IS WE HAVE TO HAVE ACCESS TO INFORMATION.

DR. CIBELLI: YOU DON'T WANT TO FIND OUT A YEAR LATER YOU WERE PAYING FOR SOMETHING THAT WAS -- I DON'T KNOW -- TAKEN UNETHICALLY.

VICE CHAIR LO: DIDN'T REALLY HAVE CONSENT. I THINK YOU'RE RIGHT. OKAY.

AND THEN LET'S SKIP OVER THE PAYMENT ISSUE FOR A MINUTE. AND SHOULD WE REQUIRE THAT IF CIRM RESEARCHERS ARE GOING TO BE FUNDED TO WORK WITH, THERE SHOULD BE NO RESTRICTIONS ON THE DOWNSTREAM USE OF THE CELLS? NO.

DR. EGGAN: NO, I DON'T THINK SO. I DON'T THINK SO. AND ALSO I THINK THE POINT WAS MADE THAT, SORT OF I THINK THE LANGUAGE EXPLICITLY WAS USED TO TRY TO PRECLUDE FUTURE ANONYMOUS GAMETE DONORS, WHICH IS ONE OF THE PROBLEMS IN THE PAST. ALMOST CERTAINLY WE'RE ENDING UP GRANDFATHERING IN CELL LINES THAT WERE PROBABLY DERIVED USING SOME ANONYMOUS GAMETE DONORS. IN MY OPINION I THINK WE WANT TO MOVE TO PREVENTING THE USE OF THOSE TYPES OF CELL LINES IN THE FUTURE. SO

THAT SHOULD BE -- I THINK, MY OPINION IS THAT SHOULD BE EXPLICITLY STATED.

DR. KIESSLING: SO COMES UNDER THE FULLY INFORMED CONSENT.

VICE CHAIR LO: ALL GAMETE DONORS.

DR. EGGAN: I JUST WOULD BE MORE COMFORTABLE IF IT ABSOLUTELY SAID THAT.

VICE CHAIR LO: I THINK THAT'S A GOOD SUGGESTION.

DR. CIBELLI: I FORGOT. WHAT WAS YOUR POINT?

VICE CHAIR LO: I GUESS THE CONCERN IS - REMEMBER, WE TALKED EARLIER THIS MORNING, I THINK IT WAS, ABOUT HOW IF WE'RE DERIVING UNDER CIRM FUNDING, WE'D LIKE THE LINES TO BE AVAILABLE FOR ALL KINDS OF USES THAT WE MAY NOT ANTICIPATE. SO WE WOULD NOT WANT CIRM FUNDING TO BE USED TO DERIVE LINES OR THE DONOR PUT RESTRICTIONS ON FUTURE USES THAT YOU CAN'T USE THEM FOR ANIMAL TRANSFER EXPERIMENTS OR --

DR. EGGAN: I THINK THERE MIGHT HAVE BEEN A MISUNDERSTANDING. I THINK WHAT WE WANT TO AVOID IS IN A SINGLE STUDY TO HAVE CERTAIN DONORS LINE ITEM VETOING CERTAIN THINGS THAT COULD BE DONE. I THINK THAT'S VERY IMPORTANT SO THAT WITHIN A PARTICULAR STUDY WHICH WAS PRESCRIBED FOR A PARTICULAR PURPOSE, THAT YOU HAVE DIFFERENT CLASSES OF EMBRYOS WITHIN THAT ONE PARTICULAR

STUDY. I THINK THAT MAKES FOR AN IMPOSSIBLE SITUATION.

BUT THERE MAY BE CASES WHERE ONE DERIVES A LINE OR ONE HAS EMBRYOS DONATED FOR SPECIFIC THINGS WHICH ARE PRESCRIBED. THERE MAY BE A DIFFERENCE OF OPINION ON THAT, BUT THAT'S WHAT I WAS -- I THINK THERE WAS LANGUAGE WHICH SAID THAT THE DONOR SHOULD HAVE THE ABILITY TO BE ABLE TO RULE OUT ANY PARTICULAR USE OF A PARTICULAR CELL LINE THAT'S DERIVED WITHIN A STUDY. I GUESS I'M A LITTLE MORE -- THAT GETS TO BE MORE -- BECAUSE THEN WITHIN ONE RUBRIC OF A STUDY WHERE YOU HAVE ALL OF THESE -- BECAUSE THEN YOU DON'T HAVE TO TRACK THE PARTICULAR DOCUMENTS THAT WERE USED IN THAT STUDY. YOU HAVE TO TRACK EVERY SINGLE DOCUMENT THAT WAS USED FOR THAT STUDY, AND THAT'S WHERE THINGS BECOME IMPOSSIBLE.

DR. HALL: THAT'S AN NOT ISSUE, IS IT, FOR LINES DERIVED ELSEWHERE? THAT IS, IF SOMEBODY SAYS THEY WANT TO DO SOME EXPERIMENTS ON A LINE THAT SOMEBODY HAS DERIVED AND THAT LINE HAS RESTRICTIONS ON IT, THEN DO WE -- WE'RE NOT GOING TO SAY YOU CAN'T USE THAT.

DR. EGGAN: NO. NO. NO. BUT THE LANGUAGE, AS STATED, SAID THAT BEFORE. THAT'S WHERE I WAS RAISING THE OBJECTION.

DR. HALL: IN THIS PART WE DON'T NEED TO DEAL

WITH THAT.

DR. EGGAN: I WAS SPECIFICALLY SPEAKING TO THIS.

VICE CHAIR LO: SO I HEAR THAT WE WANT NOT HAVE -- WE WANT TO REMOVE THAT SUGGESTION.

DR. KIESSLING: I'M NOT SURE EVERYBODY UNDERSTANDS. I THINK THAT CIRM FUNDING SHOULD NOT BE USED FOR LINES THAT HAVE RESTRICTIONS. I THINK THAT'S TOO COMPLICATED. I DON'T KNOW HOW YOU'RE GOING TO TRACK IT, AND I THINK IT'S A HUGE PROBLEM --

DR. HALL: WAIT. WAIT. LINES THAT WE DERIVE OR SOMEBODY ELSE DERIVES?

DR. KIESSLING: SOMEBODY ELSE DERIVES. I DON'T KNOW THAT YOU WANT TO SPEND MONEY ON A LINE THAT CAN ONLY BE USED FOR TYPE 1 DIABETES RESEARCH.

DR. HALL: SUPPOSING AN INVESTIGATOR COMES UP AND THEY HAVE SOME VERY SPECIFIC QUESTION THEY WANT TO ANSWER? THAT'S A SCIENTIFIC QUESTION AND IT'S WITHIN THE -- IT'S NOT DEALING WITH A PARTICULAR RESTRICTED USE. SHOULD WE SAY YOU CAN'T DO THAT BECAUSE THEY ARE USES THAT ARE RESTRICTED?

DR. KIESSLING: I SEE WHAT YOU ARE SAYING.

DR. TAYLOR: I GUESS I WOULD SAY THAT, AND THIS MAY BE TOO ONEROUS, BUT IT ALMOST SEEMS TO ME, I KNOW YOU DON'T WANT TO GET INTO THE CIRM BANK RIGHT

NOW, BUT I THINK THAT ALL THE LINES SHOULD BE IN CIRM BANK. I THINK THAT LINES THAT CIRM INVESTIGATORS HAVE ACCESS TO WITHIN CIRM FUNDING SHOULD BE DONE UNDER SORT OF THE CIRM UMBRELLA. AND I ACTUALLY THINK THAT IT'S A NICE IDEA TO HAVE THOSE BE CARTE BLANCHE LINES WHERE THERE'S NOT A LOT OF CRAP THAT YOU'VE GOT TO TRACK. NOW, THAT'S GOING TO LIMIT THE NUMBER, BUT I STILL THINK THAT PRAGMATICALLY IT'S GOING TO BE EASIER GOING FORWARD WITH THAT.

I THINK THAT IF YOU FUND ONE CIRM INVESTIGATOR TO DO ONE SET OF EXPERIMENTS IN A LINE THAT CAN'T BE USED IN OTHER WAYS, IT DOESN'T MAKE MUCH SENSE TO HAVE THAT LINE IN THE CIRM BANK BECAUSE IT'S GOT --

DR. HALL: I'M JUST RELUCTANT TO PUT THAT RESTRICTION ON NOT KNOWING. I THINK IF AT THE TIME IT COMES UP AND IS REVIEWED, IF SOMEBODY HAS A GRANT, I THINK YOU NEED TO LOOK AT IT ON ITS OWN MERITS. I WOULD BE VERY RELUCTANT TO PUT A BLANKET RESTRICTION ON THAT.

I THINK THE OTHER POINT IS STEM CELL BANK, IF WE HAVE TO HAVE ALL LINES THAT ARE USED BY CIRM INVESTIGATORS FOR WHATEVER PURPOSES BE IN OUR BANK, THIS IS GOING TO BE A BIG REQUIREMENT. IT'S GOING TO TAKE TIME TO GET THAT BANK GOING. I THINK IT'S GOING

TO BE A BIG ISSUE HOW WE DO IT, AND I THINK THAT, AGAIN, IS UNNECESSARILY RESTRICTIVE. I WOULD LIKE TO LEAVE THAT OPEN. OTHER CRITERIA FOR WHAT WE USE.

DR. PRIETO: WHEN YOU HAVE VERY WELL CHARACTERIZED ETHICALLY DERIVED LINES FROM THE UK STEM CELL BANK, FOR EXAMPLE, AND I THINK WE WOULD WANT TO FUND RESEARCH ON THOSE LINES, AND THEY MAY NOT WANT TO PUT TO CELL LINES --

DR. HALL: WE PROBABLY WOULD END UP WITH A RECIPROCAL RELATIONSHIP WITH THEM IN SOME WAYS THAT WE WOULD SHARE BETWEEN OUR BANKS, BUT WE WOULDN'T NECESSARILY BANK AND CHARACTERIZE EVERY LINE. SOMETHING LIKE THAT.

MS. FEIT: DIDN'T YOU SAY EARLIER THAT THE ESCRO WOULD BE RESPONSIBLE FOR COMPLYING WITH ANY RESTRICTIONS ON THE STEM CELL LINE? IS THAT WHAT I HEARD EARLIER?

DR. HALL: YES. I THINK IF SOMEBODY WERE TO APPLY FOR A GRANT, THEN IT WOULD BE TO USE A STEM CELL LINE IN A CERTAIN WAY, THEN IT WOULD BE UP TO THEIR ESCRO COMMITTEE TO BE SURE THAT THEY WEREN'T VIOLATING A RESTRICTION ON THAT LINE. WE COULD NOT BE RESPONSIBLE FOR THAT.

MS. FEIT: ISN'T THAT WHAT WE, IN FACT, SHOULD PUT IN THERE, SO THAT LEAVES IT BROAD, THAT WE

LEAVE UP TO THAT BODY OF PEOPLE TO FOLLOW ANY RESTRICTION THAT MAY BE ATTACHED TO A STEM CELL LINE?

DR. HALL: YES. THAT GOES WITHOUT SAYING. WHAT I'M OBJECTING TO IS TO SAY THAT IF A LINE HAS ANY RESTRICTIONS ON IT ALL, IT CAN'T USED FOR ANYTHING, WHICH IS WHAT -- WE'RE LOOKING AT THE LINES, IT'S MINIMUM REQUIREMENTS TO HAVE LINES USED OR APPROVED.

VICE CHAIR LO: AS I UNDERSTAND IT, THE POINT IS THAT YOU DON'T WANT TO PUT THAT AS A BLANK PROHIBITION BECAUSE SOMEONE MAY SUBMIT A VERY MERITORIOUS GRANT THAT USES A VERY RESTRICTED LINE TO ANSWER AN IMPORTANT QUESTION. YOU DON'T WANT THAT PRECLUDED AUTOMATICALLY BY THIS RESTRICTION, BUT THERE'S NOTHING TO PREVENT A GRANTS REVIEW TEAM FROM SAYING, GIVEN EVERYTHING ELSE, WHY AREN'T THEY USING A STEM CELL LINE THAT DOESN'T HAVE RESTRICTIONS.

DR. PRIETO: I THINK THAT THINGS WILL COME TO THE GRANTS WORKING GROUP, GRANT PROPOSALS WITH LINES THAT HAVE LOTS OF RESTRICTIONS, AND THEY MAY GET TURNED DOWN FOR THAT REASON.

DR. EGGAN: I THINK IT'S A VERY DIFFERENT THING ALTOGETHER TO ACTIVELY ENCOURAGE OR TO FORCE PEOPLE WITH CIRM FUNDING WHEN THEY DERIVE NEW LINES, EXCEPT FOR SOME EXTENUATING CIRCUMSTANCES, TO REQUIRE THAT THEY DO SO UNDER INFORMED CONSENT THAT WOULD ALLOW

GENERAL USE OF THOSE LINES.

VICE CHAIR LO: WHICH IS WHAT WE TALKED ABOUT THIS MORNING.

SO LET ME NOW RAISE THE -- WE'LL COME BACK AGAIN TO THIS DOLLARS ISSUE. I HEARD BEFORE A LOT OF PEOPLE SAYING THAT THEY DON'T WANT TO APPLY TO LINES DERIVED WITH OTHER FUNDING TO CIRM RESTRICTIONS ON PAYMENT FOR TIME BEYOND OUT-OF-POCKET EXPENSES. IT'S VERY HARD TO KNOW SORT OF WHAT YOU'RE PAYING FOR WHEN YOU SORT OF WRITE A CHECK TO SOMEONE WHO DONATES OOCYTES. I MEAN PAYING FOR TIME SOMEHOW SEEMS DIFFERENT FROM SAYING WE'RE BUYING THE OOCYTES.

LET ME JUST PUT THIS IN CONTEXT. THE FIRST ORTIZ BILL, WHICH IS SEVERAL YEARS OLD, HAD A PROHIBITION ON PURCHASING OR SELLING EMBRYONIC CADAVERIC OR FETAL TISSUE FOR RESEARCH PURPOSES. NOW, WE'RE TECHNICALLY EXEMPT FROM THAT BECAUSE OF PROP 71. I THINK THERE'S A LOT OF SENTIMENT TO SORT OF BUYING AND SELLING OOCYTES, WHICH IT'S HARD SOMETIMES TO DRAW THE LINE BETWEEN PAYING FOR PEOPLE FOR THEIR TIME IT TAKES TO GO THROUGH AN EXTENSIVE COUNSELING, EDUCATION, AND MANIPULATION PROCESS. BUT DO WE WANT TO SAY IF WE'RE NOT -- AND I DIDN'T HEAR A LOT OF SUPPORT FOR PROHIBITING PAYMENT FOR TIME. DO WE WANT TO SAY THAT PAYING FOR TIME MAY BE PERMISSIBLE, BUT PAYING FOR

OOCYTES OUTRIGHT IS NOT, TO THE EXTENT THAT THAT LINE CAN BE DRAWN? SO WE DRAW THE LINE ELSEWHERE IN RESEARCH OR AT LEAST TRY TO.

DR. CIBELLI: I ALWAYS THINK -- I ALWAYS SAID THIS IS SOMETHING THAT WE ARE GOING TO HAVE TO LIVE WITH. UNFORTUNATELY PROPOSITION 71 HAD THAT CLAUSE IN, BUT I THOUGHT ACTUALLY THAT WHEN THE KOREANS ANNOUNCED THAT THEY HAVE DONE ALL THIS NUCLEAR TRANSFER EXPERIMENT WITH DONATED EGGS, I THOUGHT THAT MAYBE WE COULD LEARN SOMETHING FROM KOREAN WOMEN. BUT THE TRUTH IS THAT THOSE WERE COMPENSATED.

DR. HALL: ONLY IN THE FIRST PAPER, AS I UNDERSTAND IT. THERE'S ACTUALLY --

DR. CIBELLI: NOBODY REALLY KNOWS WHAT'S GOING ON RIGHT NOW.

DR. HALL: THERE WAS A RECENT PAPER IN THE AMERICAN BIOETHICS JOURNAL.

VICE CHAIR LO: AMERICAN JOURNAL OF BIOETHICS, BUT THAT WAS BEFORE -- THAT WAS ACCEPTED BEFORE THE REVELATIONS DURING THE PAST WEEK AND A HALF.

DR. HALL: I THOUGHT THAT HAD A SERIES OF PROCEDURES THAT HAD BEEN PUT IN PLACE AFTER THE FIRST PAPER AND BEFORE THE SECOND, AND THEY HAD QUITE AN EXTENSIVE PROCEDURE, WHICH, AS I RECALL, HAD SEVERAL LAYERS OF COUNSELING. IT WAS, I THOUGHT, IN MANY WAYS

AN ADMIRABLE PROCEDURE. I CAN'T SAY THAT THAT'S WHAT THEY FOLLOWED, BUT MY UNDERSTANDING IS ALL THE CONTROVERSY HAS BEEN ABOUT PROCEDURES THAT WERE DONE FOR THE 2004 PAPER THAT INVOLVES ONE CELL LINE. AS FAR AS I KNOW, THERE'S BEEN NO CONTROVERSY OVER THE 2005 PAPER. THAT'S NOT TO SAY THERE MAY NOT BE, BUT I JUST WANT TO MAKE THAT RECORD, MAKE THAT POINT CLEARLY.

AND, KEVIN, YOU MAY HAVE MORE UP-TO-DATE INFORMATION THAN I DO, BUT THAT'S -- AT THE PRESENT THAT'S MY UNDERSTANDING OF THE MATTER.

DR. EGGAN: AGAIN, I WOULD SAY, YES, THAT'S MY UNDERSTANDING AS WELL, BUT WOULD ECHO WHAT JOSE SAID. AND WE'LL WONDER AND SEE. AND I THINK THAT THIS IS PROBABLY SOMETHING THAT WE SHOULD MAKE A STATEMENT ON.

DR. CIBELLI: I WOULD ARGUE THAT WE HAVE TO COMPENSATE, WE HAVE TO FIND A WAY TO COMPENSATE, AND YOU CAN VERY EASILY PUT A CAP ON IT AND JUST SAY THIS IS THE AMOUNT OF EXPENSES THAT GOING TO BE REIMBURSED, PERIOD. OTHERWISE, YOU ARE GOING TO HAVE A VERY HARD TIME FINDING WOMEN WILLING TO HELP OUT.

DR. PRIETO: WE CAN'T CALL IT COMPENSATION. WE MAY HAVE A LITTLE BIT OF LATITUDE IN TERMS OF HOW DEFINE EXPENSES, BUT THAT'S ALL THE LATITUDE WE HAVE. BUT THIS IS TALKING ABOUT OUTSIDE LINES, AND THE

QUESTION IS DO WE ACCEPT OTHER PEOPLE'S COMPENSATION, MONEY THAT WE DID NOT PROVIDE?

DR. HALL: IT'S AN INTERESTING QUESTION. ANN RAISED THE POINT OF THE VERY WELL-ESTABLISHED CLINIC IN BRITAIN THAT REQUIRES THAT ANYBODY WHO GOES THROUGH FERTILITY TREATMENT THERE DONATE A CERTAIN NUMBER OF EGGS. IS THAT PAYMENT OR WOULD WE REFUSE LINES?

DR. PRIETO: ARE ANY CELL LINES DERIVED FROM THAT IN THE UK BANK?

DR. HALL: I DON'T KNOW.

DR. KIESSLING: I WOULD GUESS YES.

DR. HALL: WE DON'T KNOW.

DR. PRIETO: DO WE CONSIDER THOSE TO BE ETHICALLY DERIVED AND CELLS THAT WE WOULD FUND RESEARCH ON?

DR. HALL: SO THE ISSUE -- I GUESS WHAT I WOULD ARGUE FOR IS TO SOMEHOW HAVE A MORE NUANCED CONSIDERATION OF THE CONDITIONS UNDER WHICH A CONSENT WAS GIVEN THAN SIMPLY -- THIS IS WHAT ANN WAS SAYING BEFORE -- THAN SIMPLY TO HAVE SORT OF FIXED -- TRY TO GET TO THE CORE ISSUES HERE. WHAT DO WE REALLY CARE ABOUT, AND MAYBE COMPENSATION ISN'T THE MOST IMPORTANT ISSUE, BUT IT'S A NUMBER OF OTHER ISSUES THAT WE SPECIFY.

DR. KIESSLING: I THINK IT WOULD BE VALUABLE

TO THIS CONVERSATION TO GO THROUGH A LIKE A BRIEFING I DID TO THE MASSACHUSETTS LEGISLATURE WHEN THEY WERE LOOKING AT THEIR DERIVING THEIR STEM CELL LAW. AND THE WOMEN LEGISLATORS HAD A CAUCUS, AND THIS CAUCUS HAD RECEIVED INFORMATION FROM SOME WOMEN'S GROUPS THAT WERE VERY CONCERNED ABOUT THE EXPLOITATION OF WOMEN WITH RESPECT TO THIS DONOR EGG ISSUE. AND I UNDERSTAND THOSE CONCERNS. I ALSO HAVE A VERY STRONG FEELING THAT WOMEN REALLY HAVE THE ABILITY TO MAKE DECISIONS.

BUT THE WOMEN'S CAUCUS IN THIS GROUP, THEIR CONCERNS ABOUT COMPENSATION WERE TWOFOLD. AND I THINK THAT'S WHY THERE'S INFORMATION IN PROPOSITION 71 ABOUT THIS. YOU DON'T WANT TO EXPLOIT ANYONE. THE IDEA IS THAT SOMEHOW YOU MUST PROTECT WOMEN FROM PUTTING THEMSELVES AT RISK TO MAKE MONEY.

NOW, THERE'S LOTS OF WAYS TO DO THAT BESIDES TALKING ABOUT SIMPLY NOT PAYING THEM AT ALL. AND AS I EXPLAINED TO THIS GROUP OF WOMEN LEGISLATORS, THEIR CONCERNS WERE SEVERALFOLD. THEY WERE MOSTLY BLACK. AND THEIR CONCERNS WERE SEVERALFOLD, THAT WOMEN FROM THEIR COMMUNITIES WOULD BE RECRUITED TO DONATE EGGS FOR LARGE SUMS OF MONEY, AND THAT THE STEM CELLS DERIVED FROM THOSE EGGS WOULD NOT GO BACK INTO THEIR COMMUNITIES. SO THEY COULD SEE THEMSELVES BEING EXPLOITED TO THE EXPENSE OF WEALTHY PEOPLE.

WHEN I SORT WENT THROUGH WHAT THE CONSENTING PROCESS IS ABOUT, WHAT YOU DO TO EDUCATE SOMEBODY ABOUT WHAT THE EGGS ARE GOING TO BE USED FOR, HOW THIS IS GOING TO WORK, WITHIN ABOUT AN HOUR THAT SAME GROUP OF WOMEN FROM THE BLACK COMMUNITY DECIDED WHY SHOULD WE LIMIT THE ABILITY OF WOMEN WHO WANT TO BE EGG DONORS TO MAKE SOME MONEY. SO THEY WENT FROM NOT BEING WORRIED ABOUT COMPENSATING WOMEN TO BE WORRIED ABOUT RESTRICTING THE RIGHTS OF WOMEN TO ACTUALLY RECEIVE COMPENSATION FOR THIS EFFORT.

SO I REALLY THINK THE IDEA BEHIND COMPENSATING EGG DONORS FOR THIS RESEARCH NEEDS TO BE LEFT ALONE FOR A WHILE BECAUSE I THINK THE MORE PEOPLE THINK ABOUT IT, THE MORE THEY REALIZE THAT'S NOT THE IMPORTANT POINT. THE IMPORTANT POINT IS WHETHER SHE'S COMPENSATED OR NOT. THE IMPORTANT POINT IS THAT SHE REALLY UNDERSTANDS WHAT SHE'S DOING, THAT SHE FULLY UNDERSTANDS THE RISKS TO HER, HOW LONG IT'S GOING TO TAKE HER, THE SHORT-TERM RISKS, THE LONG-TERM RISKS, AND WHAT'S GOING TO HAPPEN TO THE CELL LINES. AND WHETHER SHE IS COMPENSATED FOR THE TIME IT TAKES HER TO DO THAT OR NOT IS IRRELEVANT.

SO I THINK THAT IN THE CONSENTING PROCESS ITSELF, YOU CANNOT ESTABLISH GUIDELINES FOR PEOPLE IN SINGAPORE OR OTHER PARTS OF THE WORLD WHO MAY ACTUALLY

VIEW THIS AS A WAY FOR WOMEN TO GET TOGETHER AND ACTUALLY CREATE A SMALL BUSINESS TO DONATE EGGS. I DON'T THINK THAT SHOULD BE ABSOLUTELY PREVENTED. WHAT YOU WANT TO PREVENT IS HAVING SOMEBODY GO THROUGH THIS PROCEDURE WHO WAS NOT FULLY INFORMED AND NOT DOING IT OF THEIR OWN FREE WILL.

DR. PETERS: WHAT IS -- I'M TRYING TO RESPOND TO THE QUESTION ABOUT WHAT'S THE CORE MATTER. SO WHAT IS THE PHILOSOPHICAL PRINCIPLE THAT WE'RE TRYING TO HONOR HERE AS WE FORMULATE OUR ETHICAL MANDATE? IS THAT IT THAT WE SHOULDN'T TREAT SOMETHING THAT IS DISTINCTIVELY HUMAN AS MERCHANDISE THAT CAN BE BOUGHT OR SOLD? IS THAT WHAT IT IS? IF SO, THEN WE COULD MINIMALLY SAY THAT YOU CAN'T PURCHASE OOCYTES AND THEY CANNOT BE SOLD.

IS IT TO AVOID THE EXPLOITATION OF WOMEN? THEN GIVEN THE COMPLEXITIES THAT ANN JUST ANNOUNCED, THEN WE WOULD GET IN THE BUSINESS OF DECIDING WHAT A FAIR PRICE IS. I'M NOT SURE WE WANT TO DO THAT.

OR IS IT A THIRD CORE ISSUE? SO WHAT IT IS THAT WE'RE TRYING TO RESPOND TO THAT THIS POLICY SHOULD BE FORMULATED TO HONOR AND RESPECT?

DR. HALL: I THINK ANN BROUGHT UP AN INTERESTING POINT, BUT I JUST WANT TO UNDERLINE. AND THAT IS, THAT BY TAKING THE COMPENSATION STAND THAT'S

IN HERE, ONE COULD ARGUE THAT IT MAKES IT MUCH MORE DIFFICULT FOR POOR WOMEN TO BE INVOLVED IN THESE ACTIVITIES THAN WOULD OTHERWISE BE THE CASE. I THINK THAT'S SOMETHING THAT DESERVES REAL CONSIDERATION. AND I THINK AS WE DO THIS, WE NEED TO BEAR THAT IN MIND. THAT'S ALL.

DR. CIBELLI: I THINK WE HAVE TO REMEMBER -- I THINK OUR MANDATE IS TO MOVE THIS RESEARCH AS FAST AS POSSIBLE WITHOUT PUTTING ANYBODY AT RISK.

DR. TAYLOR: I GUESS I FEEL -- MAYBE I FEEL THAT THE LAW AS IT'S WRITTEN IN PROP 71 AT THIS POINT IS RELATIVELY IMMUTABLE, WHICH MAKES ME BELIEVE, AND THIS ISN'T TO CAST ANY ASPERSION, BUT I THINK WHEN KEVIN SAID THIS ISN'T A LOOPHOLE, I THINK IT'S AN ABSOLUTE LOOPHOLE. I THINK THAT WHAT WE'RE DISCUSSING NOW COULD EASILY BE INTERPRETED AS A COMPLETE LOOPHOLE TO MOVE STEM CELL DERIVATION OUT OF CIRM INTO AN ORGANIZATION NEXT DOOR THAT WOULD THEN JUST FEED STEM CELLS INTO CIRM. IF THAT'S WHAT WE WANT TO DO, THEN THIS SEEMS TO BE THE WAY TO GO TO DO THAT. THAT'S SORT OF A DARK INTERPRETATION, BUT WHAT'S TO SAY, THEN, IF WE SAY THAT WE WILL ACCEPT STEM CELLS DERIVED AFTER THE PROP 71, INDEPENDENT OF COMPENSATION, COMING INTO CIRM, THEN WHAT IT MEANS IS THAT INVESTIGATORS WITHIN CIRM WON'T BE ABLE TO COMPENSATE DONORS FOR STEM CELL

DERIVATION.

YOU CAN END UP IN THE SAME PLACE. IT'S JUST THAT YOU WILL HAVE CREATED ANOTHER SERVICE OUTSIDE OF CIRM THAT WILL COMPENSATE THEIR DONORS, WHICH I THINK MOST OF US BELIEVE SHOULD OCCUR, AND THEN THE STEM CELLS WOULD END UP BACK IN CIRM THROUGH THE BACK DOOR. IS THAT --

DR. HALL: WELL, I DON'T THINK WE WOULD -- WE CERTAINLY WOULD NOT DO. THAT COULD BE ARGUABLY AN INDIRECT CONSEQUENCE OF THIS, BUT I DON'T THINK PEOPLE ARE GOING TO SET UP TO SUPPLY CIRM WITH CELL LINES THROUGH SOME CIRCUITOUS THING. WE ALMOST CERTAINLY WILL PUT MONEY IN CALIFORNIA INTO THE DERIVATION OF CELL LINES, WITHOUT QUESTION, AND WE'LL PUT -- MY GUESS IS WE'LL PUT SUBSTANTIAL SUM INTO THAT. AND --

DR. TAYLOR: IF THERE'S NOT MONEY FOR THE DONORS, AND I THINK MOST OF US BELIEVE THAT THEY'RE NOT GOING TO BE --

DR. HALL: YOU THINK THERE WON'T BE DONORS WITHOUT MONEY? I THINK PEOPLE ARE GOING TO DO THIS ACCORDING TO A VARIETY OF WAYS. ALREADY WE'VE HEARD A NUMBER OF DIFFERENT WAYS PEOPLE ARE GOING TO BE DOING IT ANYHOW, AND THEY'RE NOT GOING TO BE DOING IT WITH AN EYE TO THE CALIFORNIA MARKET. I THINK THEY'RE JUST GOING TO BE DOING IT. IF IT TURNS OUT TO BE REALLY

DIFFICULT TO GET PEOPLE TO DO THIS, OR MAYBE PEOPLE WILL HAVE OVERRIDING CONCERNS ABOUT WHO CAN AFFORD TO DO THIS, THIS DEMOGRAPHICS OF THE DONORS UNDER THESE CONDITIONS, AND THEY MAY COME TO THE CONCLUSION THAT THEY WANT TO DO IT A DIFFERENT WAY. I THINK THAT'S WHAT'S GOING TO HAPPEN. I JUST -- SO THE QUESTION IS DO WE WANT TO EXCLUDE CELL LINES THAT ARE MADE BY WELL-MEANING, THOUGHTFUL, RESPONSIBLE PEOPLE WHO HAPPEN TO COME TO A DIFFERENT CONCLUSION FOR WHATEVER REASONS THAN WE DO ON THIS PARTICULAR ISSUE? THAT'S WHY I WAS PUSHING FOR THE CORE ISSUE. AND I THINK TED OUTLINED A NUMBER OF WAYS THAT ONE CAN DEFINE THAT, BUT THAT WAS --

DR. KIESSLING: I DON'T THINK THERE'S GOING TO BE -- WHETHER OR NOT YOU PAY WOMEN TO DO THIS IS GOING TO BE IRRELEVANT TO HOW MANY VOLUNTEER. YOU'RE NOT GOING TO HAVE TO COMPENSATE WOMEN IN CALIFORNIA OR THEY WON'T COME FORWARD. THAT'S NOT TRUE. LOTS AND LOTS OF WOMEN ARE GOING TO BE WILLING TO DO THIS BECAUSE THEY'RE GOING TO BE WILLING TO DO IT. IT'S GOING TO BE A SELECT GROUP. YOU ARE NOT GOING TO RECRUIT PEOPLE WHO CAN'T AFFORD TO TAKE OFF TWO WEEKS TO DO IT. SO ALL YOU ARE DOING IS SHIFTING THE POPULATION OF WOMEN WHO ARE GOING TO BE ABLE TO PARTICIPATE. YOU'RE NOT GOING TO RESTRICT IT. THERE'S

GOING TO BE PLENTY OF WOMEN WHO ARE GOING TO VOLUNTEER TO DONATE EGGS BECAUSE WOMEN DO THINGS LIKE THAT. THAT'S NOT THE ISSUE.

THE PROBLEM IS WHETHER YOU OUGHT TO ACCEPT LINES FROM OTHER PARTS OF THE WORLD OR OTHER PARTS OF THE COUNTRY THAT HAVE DIFFERENT GUIDELINES. SO THIS IS NOT GOING TO BE A RESTRICTION IN CALIFORNIA. AND I DON'T SEE YOU SETTING UP AN OUTSIDE MACHINE IN ARIZONA TO DO THIS EITHER. I DON'T THINK THAT'S GOING TO BE THE ISSUE.

MS. FEIT: I THINK MY CONCERN WOULD BE YOU SAID THERE'S A CELL BANK IN SINGAPORE. WHAT ASSURANCES DO WE HAVE THAT EVEN IF WE GET PAPERWORK THAT SAYS INFORMED CONSENT WAS GIVEN, HOW DO WE VALIDATE THE PROCESS OF INFORMED CONSENT? MANY TIMES CULTURES WORK UNDER DIFFERENT UNDERSTANDINGS OF PROCESSES THAN WE DO. AND SO I THINK WE HAVE TO GIVE REALLY CAREFUL CONSIDERATION TO LINES THAT WERE DERIVED BEFORE OUR STANDARDS WERE SET IN. AND I'M NOT SAYING I HAVE THE ANSWER OF HOW WE'RE GOING TO GO ABOUT THAT BECAUSE I HEAR THE PLEA FROM THE SCIENTISTS THAT YOU REALLY WANT TO INCLUDE AS MANY LINES AS POSSIBLE THAT ARE USABLE FOR RESEARCH. BUT GIVEN THAT, THE ATTACK ON CIRM WOULD BE VICIOUS INTERNATIONALLY IF WE ACCEPTED ONE CELL LINE THAT WASN'T PROPERLY HANDLED IN ANOTHER COUNTRY.

SO TO VALIDATE THAT PROCESS, TO REALLY UNDERSTAND, AS MUCH DISCUSSION AS WE HAD THIS MORNING REGARDING PROTECTING WOMEN, AND WE KNOW WHAT WE WANT, HOW DO WE VALIDATE THAT WITH CELL LINES THAT WERE CREATED PRIOR TO THIS UNDERSTANDING THIS MORNING?

VICE CHAIR LO: LET ME JUST DISTINGUISH. WE'RE RIGHT NOW TALKING ABOUT CELL LINES CREATED AFTERWARDS, THE GRANDFATHERING, THE SECTION WE HAVEN'T GONE TO YET.

DR. HALL: I THINK WE SHOULD ALL UNDERSTAND THERE'S A TREMENDOUS INTERNATIONAL EFFORT TO MAKE SURE THAT ALL THIS IS DONE ETHICALLY, AND THERE ARE GROUPS COOPERATING IN BRITAIN, IN SWEDEN AND ISRAEL. THERE'S AN INTERNATIONAL STEM CELL FORUM. I THINK THE EXAMPLE OF THE KOREANS IS GOING TO BE A VERY SALUTORY ONE FOR ANYBODY IN THIS AREA. SO I THINK THERE WILL BE INTENSE PRESSURE WITHIN THE COMMUNITY TO HAVE STEM CELL LINES DERIVED ACCORDING TO A HIGH ETHICAL STANDARD AND TO COOPERATE SO THAT WE WILL END UP KNOWING QUITE A BIT ACTUALLY ABOUT WHAT GOES ON IN OTHER COUNTRIES, AND THERE MAY BE ODD PLACES THAT SPRING UP HERE AND THERE. I THINK WE WILL NEED TO TAKE THE KIND OF CARE THAT YOU DESCRIBED, MARCY.

I THINK THE REAL ISSUE, AND I THINK THIS IS IN A WAY THAT ISSUE WITH THE KOREANS, I THINK YOU

CAN'T -- IT'S NOT OUR BUSINESS IN A WAY TO GO IN AND EXAMINE SPECIFIC CASES. IF A CELL LINE COMES UP, WHO GAVE THE OOCYTES AND WHO THEY WERE, ALL OF THAT WE DO NOT WANT TO GET INTO. WHAT WE WANT TO BE SURE IS THAT THERE IS A GOOD REGULATORY PROCESS COMPARABLE TO OUR OWN, AT LEAST IN BROAD OUTLINE, THAT OVERSAW THAT PROCESS AND THAT CHECKED IT OUT. IF WE CAN'T VALIDATE THAT, THEN I THINK WE CAN'T ACCEPT LINES FROM THAT SYSTEM. I THINK THAT'S THE WAY WE HAVE TO OPERATE AND TO FIGURE OUT A WAY TO INCORPORATE INTO WHAT WE DO.

DR. PRIETO: I THINK ZACH IS RIGHT, THAT THERE IS A LOT OF OVERSIGHT AND SCRUTINY OF THIS, AND IT IS AROUND THE WORLD, NOT JUST IN CALIFORNIA. AND THE EXAMPLE OF KOREA IS A GOOD ONE. NO ONE WILL BE ABLE TO KEEP SECRETS. IF PEOPLE ARE DOING THINGS IN A WAY THAT WOULD NOT PASS MUSTER, THAT'S GOING TO COME OUT.

VICE CHAIR LO: LET ME COME BACK TO A POINT FROM THE DISCUSSION THAT ANN RAISED AND TED PICKED UP A LITTLE BIT. I WANT TO SORT OF HAVE US THINK THROUGH A LITTLE BIT SORT OF WHAT THE CONCERNS ARE ABOUT PAYMENT. ANN VERY ELOQUENTLY, I THOUGHT, SORT OF EXPLAINED ONE CONCERN, WHICH IS THAT IF YOU HAVE PAYMENT THAT'S AN UNDUE INDUCEMENT AND WOMEN REALLY HAVEN'T GONE THROUGH A FULL INFORMED AND VOLUNTARY CONSENT PROCESS, THERE'S

THE RISK OF EXPLOITATION, AND PEOPLE ARE DOING THINGS AND NOT REALIZING WHAT THE RISKS AND CONSEQUENCES ARE.

THERE ARE OTHER CONCERNS ABOUT PAYMENT IN RESEARCH, AND TED ALLUDED TO ONE WHICH I THINK IS REALLY QUITE SALIENT IN THE MINDS OF SOME PEOPLE ON THIS TOPIC. THAT'S THE ISSUE OF SORT OF PUTTING A DOLLAR SIGN ON THINGS THAT SOME PEOPLE BELIEVE SHOULDN'T HAVE A DOLLAR SIGN, SHOULD BE BOUGHT AND SOLD. JUST AS WE DO NOT ALLOW SOLID ORGANS TO BE BOUGHT AND SOLD OVERTLY, THERE ARE SOME PEOPLE WHO THINK THAT CERTAIN THINGS SHOULD BE BEYOND PURCHASE.

NOW, HOW DO WE DRAW THE LINE BETWEEN PAYING FOR THE OOCYTES AS OPPOSED TO PAYING THE WOMAN FOR THE TIME SHE PUT IN? AND PAYING HER FOR OUT-OF-POCKET EXPENSES IS AN IFFY LINE. BUT AS AN EXAMPLE, WHEN ANN CALCULATES OUT THE TOTAL AMOUNT OF DOLLARS THAT AN OOCYTE DONOR GETS IN HER PROGRAM FOR GOING THROUGH THIS VERY DETAILED PROCESS, IT'S 10, $20,000 PROBABLY, BUT THE GOING RATE FOR OOCYTES ON THE OPEN MARKET IS A LOT DIFFERENT.

SUPPOSE A RESEARCHER IS SAYING I'M GOING TO PAY $50,000 BECAUSE I KNOW I WILL GET OOCYTES AND A LOT OF PEOPLE STEP FORWARD. IS THERE SOME CONCERN THAT THAT'S BEYOND PAYING FOR TIME, AND IT'S REALLY SOMEHOW PAYING FOR THE OOCYTES? AND IS THAT A CONCERN THAT

SOMEHOW PUTTING THAT AMOUNT OF DOLLAR ON THE OOCYTE SOMEHOW VIOLATES PEOPLE'S CONCERNS ABOUT SOME THINGS OUGHT TO BE NONCOMMODIFIABLE?

DR. HALL: POINT OF INFORMATION. WAS THE 20, $25,000 FIGURE THAT YOU USED, WHAT WAS THAT?

DR. CIBELLI: TOTAL CYCLE.

DR. KIESSLING: AN EGG DONOR CYCLES IS LIKE AN IVF CYCLE, ALTHOUGH IT'S A LITTLE MORE EXPENSIVE. ABOUT $20,000 A CYCLE.

DR. HALL: THAT'S NOT WHAT THE DONOR GETS.

DR. KIESSLING: NO, THE COMPENSATION TO THE DONOR IS VERY SMALL.

VICE CHAIR LO: THE COMPENSATION TO THE DONOR --

DR. KIESSLING: IS TINY. IT DEPENDS ON HOW MUCH THEY DO.

IF THEY GO THROUGH A FULL CYCLE, THEY SPEND ABOUT A HUNDRED HOURS AND WE COVER CHILD CARE TOO, SO IT COMES OUT TO ABOUT $4,000.

VICE CHAIR LO: THAT'S CALCULATED ON THE BASIS OF EXPENSES. BUT THERE ARE OTHER PEOPLE WHO MIGHT SAY WHY STOP AT FOUR. YOU CAN GET MORE DONORS FOR 10 OR 20. AT THAT POINT ARE YOU REALLY PAYING FOR THE OOCYTE?

DR. CIBELLI: I KNOW WE WOULD LIKE TO DEBATE

THIS FOR HOURS.

VICE CHAIR LO: I DON'T WANT TO DEBATE FOR HOURS. I JUST WANT TO MAKE SURE WE DON'T --

DR. CIBELLI: I THINK OUR MANDATE IS TO MOVE THE RESEARCH FORWARD FAST WITHOUT PUTTING ANYBODY AT RISK. SO IF THE CONSENT FORM EXPLAINED THE RISKS AND THE WOMEN ARE FREE WILL OF WHAT THEY'RE GETTING INTO, DOESN'T MATTER HOW MUCH YOU PAY THEM.

DR. PETERS: BERNIE, I THINK THAT WHAT YOU'RE FORMULATING RIGHT NOW IS THE CENTER OF THE ISSUE. AND IT APPLIES BOTH TO WHAT WE'RE GOING TO FUND AND WHAT WE'RE GOING TO ACCEPT. AND I JUST ONE MORE NUANCE TO IT. IS THAT THE PUBLIC IS OUTRAGED AT THESE ADS IN COLLEGE NEWSPAPERS FOR WOMEN TO DONATE THESE EGGS AND TO GET LOTS OF MONEY. AND PART OF BEING ETHICAL, WHETHER WE LIKE IT OR NOT, IS REALLY TO BE RESPONSIVE TO THE CULTURE AROUND US. AND I THINK PEOPLE WOULD EXPECT FROM PROP 71 TO REDUCE THE OUTRAGE SO THAT SOMEHOW OR OTHER THE STANDARDS THAT WE SET SHOULD NOT ENCOURAGE THIS KIND OF USE OF MONEY FOR THE BUYING OF PARTS OF HUMAN BODIES AND STUFF LIKE THAT.

I CALL IT YUCK. OR LEON KASS CALLS IT THE WISDOM OF REPUGNANCE. THERE IS SOMETHING HERE TO THIS. NOW, ONE OF THE THINGS WE CAN'T DO FROM OUR VANTAGE POINT IN PROPOSITION 71 IS REGULATE ALL THIS. WE CAN'T

DO THAT.

COULD WE MAYBE DO A MINIMALIST KIND OF THING, SIMPLY ARTICULATE A PRINCIPLE THAT SAYS YOU DO NOT BUY OOCYTES OR EMBRYOS OR SOMETHING LIKE THAT, AND THEN JUST LEAVE IT AT THAT? THE WAY THAT'S GOING TO GET INTERPRETED WILL BE IN MULTIPLE WAYS, BUT I THINK THAT AT LEAST WE WILL HAVE SPOKEN TO THE QUESTION OF YUCK OR THE WISDOM OF REPUGNANCE OR THE PROTECTION OF HUMAN DIGNITY, WHICH IS REALLY WHAT'S AT STAKE.

DR. EGGAN: WE NEED TO PROTECT HUMAN DIGNITY. I COULDN'T AGREE MORE. BUT I FIND THE WISDOM OF REPUGNANCE NOT TERRIBLY WISE BECAUSE THERE ARE MANY THINGS WHICH WE AS A SOCIETY ONCE FOUND REPUGNANT, BUT NOW WIDELY ACCEPT. THIS IS ONE AREA WHERE, AT LEAST PERSONALLY, I HAVE A GREAT DEPARTURE FROM THAT POINT OF VIEW. SOCIETY IS DYNAMIC AND IS EVER CHANGING, SO I DON'T THINK THAT -- I THINK THAT WE SHOULD TRY TO INTUIT OUR WAY THROUGH THE YUCK FACTOR AND FIGURE OUT WHAT IT IS ABOUT THESE THINGS THAT MAKE US UNCOMFORTABLE AND IS OR IS NOT RIGHT.

SO BUT THEN AGAIN, I ALSO THINK THAT BERNIE'S STATEMENT IS TAKEN IN GOOD SPIRIT. THERE ARE CERTAIN EXPECTATIONS IN SOCIETY THAT WE COULDN'T COMMODIFY CERTAIN PARTS OF OUR BODY. THE PROBLEM HERE IS THAT, AGAIN, AS A I SAID EARLIER, THAT EGGS SOMEHOW LIE

SOMEWHERE BETWEEN BLOOD AND SPERM AND A KIDNEY. AND SO I THINK THIS IS A DIFFICULT THING. THERE'S NOT -- I THINK IT'S FAIRLY CLEAR THAT WE SHOULD NOT IN ANY WAY ENCOURAGE PEOPLE TO BE PAID FOR SOMETHING WHICH THEY CAN NEVER GET BACK, LIKE A KIDNEY. SO TO DISSOCIATE THAT SORT OF DONATION FROM MONETARY REIMBURSEMENT IS IMPORTANT. I THINK THE RISKS ARE LESS CLEAR HERE THAN THEY ARE IN THAT SORT OF SITUATION.

DR. CIBELLI: ARE WE GOING TO VOTE ON THIS?

VICE CHAIR LO: I'M NOT SURE. AGAIN, WE CAN'T VOTE BECAUSE WE DON'T HAVE A QUORUM, BUT I'M HEARING A LOT OF DIFFERENT VIEWS. I'VE BEEN IGNORING JEFF BECAUSE I'VE BEEN LOOKING THAT WAY, BUT I WANT TO MAKE SURE I GET HIM.

MR. SHEEHY: JUST A COUPLE OF POINTS. FIRST OF ALL, PEOPLE ARE SELLING EGGS INTO IVF CLINICS. AND I HAVEN'T HEARD THE OUTRAGE. I THINK IF YOU TALK TO A PARENT WHO HAS A CHILD FROM THAT, I THINK THAT YOU HAVE A COMPLETELY OPPOSITE REACTION FROM OUTRAGE. I THINK THAT'S ONE WHERE -- I DON'T SEE THAT THAT PRACTICE WILL STOP AS LONG AS PEOPLE ARE ABLE TO HAVE KIDS THROUGH THAT METHOD. AND I THINK THAT'S WHERE A CERTAIN BALANCE HAS BEEN ACHIEVED WHERE PEOPLE SAY LOOK AT THIS KID. I DON'T OBJECT TO THE FACT THAT SOMEONE PAID A WOMAN TO MAKE A DONATION SO THAT THIS KID COULD EXIST.

THE OTHER POINT IS I'D BE VERY CAREFUL ABOUT TED'S POINT ABOUT NOT BUYING EMBRYOS. IT'S ONE THING TO BE TALKING ABOUT WHETHER OR NOT YOU'RE COMPENSATING A DONOR, BUT ACTUALLY THERE IS GOING TO BE A MARKET IN THIS, BUT IT'S GOING TO BE THIRD PARTY. A FERTILITY CLINIC IS NOT GIVE THIS AWAY.

THERE ARE COSTS ASSOCIATED WITH STORING, MOVING, DISTRIBUTING. WE WANT TO PRETEND LIKE THAT THERE'S NOT ALREADY A MARKET IN THESE THINGS. ONLY THING IS WHAT WE'RE ARGUING ABOUT IS WHETHER OR NOT THE PERSON WHO ACTUALLY GIVES THE VERY FIRST PRODUCT GETS ANYTHING. BUT EVERYBODY ELSE UP AND DOWN THE LINE IS GETTING SOMETHING. SO YOU CAN SAY THAT EMBRYOS WON'T BE FOR SALE; BUT WHEN SOMEONE GETS AN LEFT-OVER EMBRYO, THEY'RE NOT GIVEN AWAY BY THE FERTILITY CLINIC. THEY DON'T SAY, OH, HERE TAKE IT. THERE'S SOME COST, AND THAT COST INCLUDES SOMETHING THAT -- I DON'T THINK IT'S STRICT -- EVEN WITHIN A STRICT COST WHEN THEY MAKE A STRICT COST. THERE'S SOME ELEMENT OF THAT THAT'S PROFIT FOR SOMEBODY, SO I THINK WE HAVE TO BE VERY CAREFUL ABOUT THIS.

DR. PETERS: TWO POINTS. I THINK YOU'RE RIGHT, THAT THIS PROLIFERATION OF ACTIVITY AND PEOPLE GETTING A CUT OF THE PROFIT, THAT'S GOING TO GO ON. I DON'T THINK WE COULD CONTROL THAT. WE PROBABLY CAN'T

EVEN GUIDE IT. SO THAT'S WHY I'M FLOATING THIS IDEA OF JUST A MINIMALIST STATEMENT THAT THESE PARTS OF THE HUMAN BODY CANNOT BE BOUGHT OR SOLD.

AND I THINK KEVIN IS RIGHT IN RAISING THE QUESTION: WHAT IS THIS -- WHERE IS THE CLOSEST ANALOG? IS IT LIKE A LIVER, OR IS IT LIKE HAIR AND FINGERNAILS OR SOMETHING LIKE THAT? I THINK IT'S LIKE -- IT'S LIKE A HUMAN ORGAN. WHY? WELL, BECAUSE OF THE RISKS TO THE HEALTH OF THE WOMAN IN THE PROCESS. SO THAT WAS WHAT TIPS ME ON THE SIDE OF WANTING TO TREAT IT MORE LIKE AN ORGAN RATHER THAN TREATING IT AS SOMETHING THAT IS EASILY EXPENDABLE. I THINK KEVIN IS RIGHT IN THE SENSE OF LAYING DOWN THE CHALLENGE. WE OUGHT TO DECIDE WHAT ARE THESE OOCYTES LIKE? ARE THEY LIKE ORGANS OR THEY'RE REALLY LIKE GETTING A HAIRCUT?

MR. SHEEHY: WHY DO YOU MAKE A DISTINCTION BETWEEN AN EGG AND SPERM?

DR. PETERS: BECAUSE I THINK THERE'S A LARGE RISK TO EGG DONATION THAT ISN'T THERE FOR A SPERM.

MR. SHEEHY: NOT IF IT'S A BY-PRODUCT OF IVF, THAT THE RISK WAS TAKEN -- IF YOU ARE TALKING ABOUT, WHICH WE TALKED ABOUT EARLIER, THAT SOMEONE IS GOING IN FOR IVF AND THEY'RE GOING TO GIVE AWAY A COUPLE OF EGGS TO BE USED FOR RESEARCH WHILE THEY'RE HAVING A CHILD, THEY'RE NOT TAKING THAT RISK FOR THE PURPOSE OF

RESEARCH. THEY'RE TAKING THAT RISK FOR THE PURPOSE OF HAVING A CHILD, SO THAT RISK IS NOT THERE FOR THE RESEARCH PURPOSE.

DR. EGGAN: THAT'S NOT CORRECT BECAUSE IF THEY'RE TAKING THAT RISK FOR THEIR OWN FERTILITY SAKE, THEN THEY SHOULDN'T BE TAKING IT FOR RESEARCH. THOSE TWO THINGS WE'VE ALREADY ARGUED AND DISCUSSED TO BE DISSOCIATED FROM ONE ANOTHER. THAT'S ONE OF THE --

DR. TAYLOR: IN TERMS OF THESE ANALOGIES, RISK IS INVERSELY PROPORTIONAL TO COST. SO I'M HAVING TROUBLE FOLLOWING THIS ARGUMENT. SO THE LIVER DONOR GETS NOTHING. THE KIDNEY DONOR GETS NOTHING. THE SPERM DONOR GET $75 OR SOMETHING LIKE THAT. THE BLOOD DONOR WHO HAS PROBABLY A SLIGHTLY HIGHER RISK OF INJURY THAN THE SPERM DONOR, WHICH I WOULD SAY IS PROBABLY RELATIVELY MINIMAL RISK LAST TIME I THOUGHT ABOUT IT, GETS COMPENSATED TO THE TUNE OF $30. I'M JUST -- I'M STARTING TO -- SO COST AND RISK CLEARLY ARE EITHER DISSOCIATED OR INVERSELY RELATED. I CAN'T FIGURE THIS.

VICE CHAIR LO: LET ME LET MARCY GET IN, THEN LET ME OFFER A PROCEDURE HERE.

MS. FEIT: I AGREE WITH ANN. I JUST DON'T THINK WE SHOULD MAKE THIS THE ISSUE. I THINK PROP 71 IS WRITTEN AND EXPLAINS WHAT CIRM IS GOING TO PAY. IT'S GOING TO PAY EXPENSES, AND WE CAN DEFINE WHAT

THOSE ARE. THEY WON'T BE UNUSUAL OR INCREDIBLE, LIKE I WILL TO GO THROUGH PARIS TO GET HERE OR WHATEVER THAT WAS. I THINK IF WE JUST STAY WITH THAT. I DON'T THINK WE'RE GOING TO SOLVE IT. I THINK IF YOU GO AROUND THE ROOM, EACH OF US HAVE A MORAL, ETHICAL ATTITUDE TOWARD WHAT WE'RE TALKING ABOUT. I DON'T THINK YOU'RE REALLY GOING TO FIND A GENERAL CONSENSUS ON THIS.

BUT I THINK OUR CHARGE IS WRITTEN OUT ALREADY IN PROP 71 IN TERMS OF THE REIMBURSEMENT. AND I DON'T THINK WE CAN CHANGE THAT. I THINK THAT BY JUST STICKING TO THAT, WE ARE MAKING A STATEMENT THAT WE'RE NOT GOING TO BE BUYING THESE THINGS ON THE MARKET. WE'RE NOT GOING TO PUT OUT AN RFA TO BUY AS MANY IN THE WORLD MARKET AS WE CAN.

SO I THINK MOVING FORWARD, THERE ARE PLENTY OF STEPS THAT ARE BEING PUT IN PLACE, BOTH IN THE GRANTS PROCEDURES THAT WE'RE SETTING FORWARD, BOTH IN THE REGULATIONS THAT WE'RE SETTING FORWARD AND OTHER WORKING GROUPS TO PROTECT THE PROCESS OF WHAT WE'RE TRYING TO DO. AND I THINK WE'VE SPOKEN FOR HOURS ABOUT PROTECTING THE DONORS, AND WE KNOW WHAT WE WANT TO DO IS WE WANT TO PROTECT THE INDIVIDUALS AND MOVE THE RESEARCH AHEAD.

VICE CHAIR LO: ABSOLUTELY LAST COMMENT, AND THEN I WANT TO TRY AND TIE THIS TOGETHER AND OPEN TO

PUBLIC COMMENTS.

DR. PETERS: LET ME JUST FOLLOW THAT UP BY SAYING I THINK WE CAN OFFER A DISTINCTION. I'M SYMPATHETIC TO KEVIN'S CASE EARLIER. WHAT HAPPENS IF SOMEONE OFF-SITE HAS A STEM CELL LINE AVAILABLE AND THOSE PEOPLE COMPENSATED THE WOMEN AND THAT WE CAN CONSIDER THAT TO BE A CREDIBLE, ETHICAL ARGUMENT THAT THEY EMPLOYED, AND WE COULD PERMIT THAT TO BE USED BY CIRM RESEARCHERS.

HOW CAN WE MAKE THAT, THEN, CONSISTENT WITH WHAT WE'RE REQUIRING OF OUR OWN RESEARCHERS? MY SUGGESTION IS TO SAY THAT WE CANNOT USE STEM CELL LINES IN WHICH EGGS OR EMBRYOS WERE PURCHASED, PERIOD. THAT WOULD PERMIT, THEN, COMPENSATION FOR THE WOMEN DONOR. THOSE STEM CELL LINES WOULD BE PERMITTED. IT'S REALLY A LINGUISTIC KIND OF THING, BUT I THINK IT PRESERVES WHAT I THINK IS THE UNDERLYING PHILOSOPHICAL CONCERN THAT LED PROP 71 TO WHAT IT IS. I HAVEN'T TALKED WITH BOB KLEIN ABOUT THIS, BUT THAT'S THE WAY I READ IT.

MR. SHEEHY: IF A FERTILITY CLINIC SUPPLIES AN EMBRYO A RESEARCHER, WHAT IS THAT TRANSACTION?

DR. TAYLOR: IT THE COSTS THE IVF CLINIC WHATEVER THE SHIPPING CHARGE IS.

MR. SHEEHY: SO THERE'S NEVER AN EXCHANGE ON ANY OF THESE.

VICE CHAIR LO: ONLY FOR EXPENSES. THEY CAN ASK THEM TO COMPENSATE FOR THE FED EX CHARGE OR WHATEVER, BUT THEY CAN'T SAY BEYOND THAT WE WON'T, $500.

MR. SHEEHY: I'M JUST CURIOUS.

DR. TAYLOR: I THINK THAT'S TRUE, JEFF. IT'S NOT REALLY BUILT INTO THE PAYMENT SCHEDULE EITHER. WHEN THESE EMBRYOS WERE COLLECTED, NOBODY REALLY WAS USING THEM FOR THIS PURPOSE. GOING INTO THE FUTURE, MAYBE THAT WILL BE CALCULATED INTO THE COST OF THE CYCLE.

DR. CIBELLI: YOU'RE MAKING THEM A FAVOR OF JUST GETTING RID OF THOSE EMBRYOS.

VICE CHAIR LO: YOU SHOULD PAY US IN ADDITION.

LET ME SUGGEST THAT WE, FIRST OF ALL, THERE ARE A MEMBERS OF THE COMMITTEE THAT NEED TO BE PART OF THIS DISCUSSION. MAYBE WHAT WE CAN DO IS TRY AND HAVE A BRIEFING THAT SORT OF WITH LAYS OUT THE DISCUSSION WE HAVE AND SUGGEST SOME OPTIONS FOR WHAT WE MIGHT WANT TO SAY IN REGULATIONS.

WHAT I'M HEARING CLEARLY IS THAT WE THINK CONSENT IS THE KEY ISSUE, AND THAT THAT PROBABLY SHOULD COME FOREMOST, THAT THERE'S A LOT OF SENTIMENT HERE FOR ALLOWING PAYMENT FOR EXPENSES OF THE WOMAN OR GAMETE

DONOR, AND THAT WE THINK THAT SHOULD BE PERMISSIBLE FOR NON-CIRM FUNDED DERIVATIONS, BUT THAT THERE'S SOME DISEASE ABOUT HAVING IT TOTALLY OPEN-ENDED PAYMENT. AND TED HAS SUGGESTED LANGUAGE SAYING NO BUYING OR SELLING OR PAYMENT, BUT EXPENSES ARE ALLOWED. SOMETIMES IT'S PUT IN AS REASONABLE EXPENSES. I THINK IF THAT IS SOMETHING THAT SEEMS TO WORK, WE MIGHT TRY THAT.

I WANT TO ASK FOR PUBLIC COMMENTS BECAUSE THIS STRIKES ME AS A VERY IMPORTANT AND VERY CONTROVERSIAL ISSUE. AND, AGAIN, I KNOW THERE ARE OTHER PUBLIC PERSPECTIVES THAT ARE OBVIOUSLY HERE IN THE ROOM THAT WE NEED TO HEAR FROM AS WELL.

MR. REED: TWO THINGS COME TO MIND. NO. 1, THERE ARE ISSUES OF SOVEREIGN NATIONS. I DON'T THINK WE CAN IMPOSE OUR STANDARDS ON ANOTHER COUNTRY WHICH HAS DIFFERENT ETHICAL AND RELIGIOUS BACKGROUNDS. I'M TRYING TO LEARN CHINESE RIGHT NOW, WHICH VERY HARD, TAKES ABOUT AN HOUR A DAY, AND IT WILL PROBABLY TAKE THREE OR FOUR YEARS, BUT I WANT TO BE ABLE TO TALK TO THE CHINESE SCIENTISTS. I FEEL THEY'RE GOING TO MAKE HUGE BREAKTHROUGHS, AND PART OF THE REASON IS THAT THEY'RE NOT BOUND UP BY A LOT OF THINGS WE'RE HAVING TREMENDOUS BATTLES WITH.

I THINK ONE OF THE REASONS THAT WE PUT THE NO

COMPENSATION IN PROP 71 WAS IN A HOPEFUL ATTEMPT TO EASE OFF SOME OF THE ENEMIES OF THE RESEARCH. DIDN'T WORK. IT WILL NOT WORK. THEY'RE AGAINST IT, THEY'RE GOING TO STAY AGAINST IT UNTIL SOMEONE IN THEIR FAMILY GETS SICK AND THEY GET BETTER BECAUSE OF THE RESEARCH AFTER WHICH THEY WILL BECOME OUR BIGGEST SUPPORTERS.

THE SECOND THING IS THERE IS A SECOND KIND OF EXPLOITATION OF WOMEN. MY SISTER HAS BREAST CANCER. SHE'S GONE THROUGH THE MASS MASTECTOMIES, SHE'S GONE THROUGH THE CHEMO. NOW SHE'S OUT OF REMISSION. SHE'S GOING INTO ARSENIC, THEN SHE'S GOING TO GO INTO CHEMO AGAIN. I GAVE BLOOD DAY BEFORE YESTERDAY TO TRY AND SEE IF I CAN A BONE MARROW TRANSFER. I DON'T KNOW WHAT'S GOING TO HAPPEN, BUT I DO KNOW THAT THERE ARE CHARITABLE ORGANIZATIONS WHICH HAVE BACKED OFF FROM SUPPORTING STEM CELL RESEARCH BECAUSE OF RELIGIOUS PRESSURES. SO THAT'S ANOTHER KIND OF EXPLOITATION.

I DON'T WANT TO SEE US CUT OFF FROM THE REST OF THE WORLD BECAUSE OF THE FEAR OF SOMEONE ELSE'S BAD OPINION OF US. THOSE WHO DO NOT SUPPORT US DO NOT SUPPORT US, AND THE ONLY THING THAT'S GOING TO CHANGE THEIR MINDS IS CURE IN THEIR FAMILY. I REALLY WANT US TO BE A PART OF THE WORLD COMMUNITY AND NOT LET ANYTHING BLOCK THAT. THANK YOU.

MR. REYNOLDS: THANKS FOR THE OPPORTUNITY TO

SPEAK. TWO REGULATORY REGIMES, I CALL THEM, ARE ON MY MIND. AND THE FIRST ONE IS, OF COURSE, PROPOSITION 71, AND IT'S ALWAYS A LITTLE TRICKY TO TRY TO INTERPRET THE WILL OF THE VOTERS. BUT NOT ONLY IS THE LANGUAGE PROHIBITING COMPENSATION BEYOND REIMBURSEMENT WRITTEN INTO PROPOSITION 71 IN A FAIRLY CLEAR WAY, ALTHOUGH NOT ENTIRELY CLEAR. THAT WAS AMONG THE ETHICAL LIMITATIONS WRITTEN INTO PROPOSITION 71 THAT WERE PART OF THE ADVERTISING CAMPAIGN. AND THAT'S CERTAINLY CONTRIBUTED TO THE VOTERS, WHO I WOULD CONSIDER THAT PART OF YOUR MANDATE HERE. THAT'S NOT SOMETHING TO BE REVISITED.

I WOULD TEND TO AGREE WITH DR. TAYLOR, THAT THIS WOULD BE SEEN BY THE PUBLIC, INCLUDING YOUR SUPPORTERS, AS A LOOPHOLE THAT YOU'RE CAPITALIZING ON. A SIMILAR THING CAME UP A LITTLE BIT IN TERMS OF RETURNS TO THE STATE. IT'S IN THE LAW. IT WAS PART OF THE ADVERTISING THAT HELPED IT PASS, AND I DON'T THINK THAT THAT'S NECESSARILY ON THE TABLE.

THE OTHER REGIME THAT'S ON MY MIND IS THE NATIONAL ACADEMIES' RECOMMENDATIONS. AND I SUPPOSE I'M A LITTLE BIT CONCERNED THAT IN A COUPLE OF WAYS YOU'RE OPENING THE DOOR FOR LOWERING THE FLOOR A LITTLE BIT BELOW THE NATIONAL ACADEMIES' RECOMMENDATIONS. ONE WAY IS THE COMPENSATION ISSUE. BUT GOING BACK EARLIER TODAY, MY INTERPRETATION OF WHAT'S IN THE NATIONAL

ACADEMIES IS THIS THING ABOUT NO LIMITATIONS ON DOWNSTREAM USES OF THE CELLS DERIVED FROM THE DONORS, THAT THE NATIONAL ACADEMIES RECOMMENDED GUIDELINES EXPLICITLY RECOMMEND THAT THAT OPTION BE GIVEN TO GAMETE DONORS, SO I'D BE A LITTLE CONCERNED ABOUT CREATING MULTIPLE REGULATORY REGIMES THAT OVERLAP IN SOME WAYS, BUT NOT IN ALL WAYS.

VICE CHAIR LO: THANKS VERY MUCH FOR YOUR TWO IMPORTANT POINTS.

DR. EGGAN: I'D LIKE TO RESPOND TO BOTH THOSE POINTS. THOSE ARE, FIRST OF ALL, THAT THE NATIONAL ACADEMY OF SCIENCE GUIDELINES ARE JUST THAT, AND THAT THEY'RE WORKING GUIDELINES. I THINK THERE NEEDS TO BE A RECOGNITION THAT THEY'RE WORKS IN PROGRESS, AND THAT THIS IS A RAPIDLY EMERGING FIELD. AND THAT I THINK IT'S -- ESPECIALLY WITH THIS POINT HAVING TO DO WITH INFORMED CONSENT AND DOWNSTREAM USE, JUST AS IS REASONABLE FOR -- I THINK IT'S VERY IMPORTANT THAT A GAMETE DONOR BE ABLE TO SAY I'M NOT COMFORTABLE WITH THIS DOWNSTREAM USE OF THE CELL LINE, AND I THINK IT'S ALSO IMPORTANT TO SAY THAT IT'S JUST AS REASONABLE FOR THE SCIENTISTS TO TURN AROUND AND SAY THEN I'M NOT COMFORTABLE WITH YOU PARTICIPATING IN THIS RESEARCH STUDY.

BUT I THINK THERE NEEDS THAT SORT OF FRANK

AND OPEN CONVERSATION BETWEEN BOTH THE SCIENTISTS AND THE DONOR, AND THAT'S WHAT'S GOING TO PREVENT MISUNDERSTANDING, AND THAT'S CRITICAL.

I HAVE TO SAY, AS I READ THE NATIONAL ACADEMY OF SCIENCE GUIDELINES WITH RESPECT TO COMPENSATION, I BELIEVE THAT IT'S WORDED JUST THAT. AND I THINK IT'S ACTUALLY, IF ANYTHING, PROBABLY LEFT RATHER AMBIGUOUS WITH RESPECT TO WHAT COMPENSATION MEANS. I CAN'T REMEMBER WHAT THE EXACT WORDS ARE, BUT MY UNDERSTANDING IS THAT IT'S ACTUALLY LESS RESTRICTIVE IN ITS CHOICE OF WORDS THAN PROP 71 IS.

VICE CHAIR LO: ONE OF THE THINGS WE'LL ASK STAFF TO DO IN THE INTERIM BEFORE NEXT MEETING IS TO LOOK VERY CLOSELY AT THE LANGUAGE OF PROP 71, THE NAS GUIDELINES, AND OTHER COMPARABLE STATEMENTS ABOUT PAYMENT FOR RESEARCH AND PROVIDE SOME BACKGROUND.

I WANT TO SORT SWITCH GEARS AND START THINKING TOWARDS THE FUTURE. I THINK THIS WAS A VERY USEFUL MEETING. A LOT OF THE GOOD IDEAS. I THINK WE REACHED SOME IMPORTANT IDEAS ABOUT CONSENT.

IF I COULD ASK YOU TO TURN TO TAB 8, WHICH IS FUTURE PLANS. FIRST, THERE'S THIS COLOR-CODED CALENDAR ON THE SECOND PAGE. JEFF, MAYBE YOU COULD HELP US IF I DON'T GET THIS RIGHT JUST TO SORT OF KEEP OUR MINDS ON SORT OF THE BIG PICTURE. WE JUST HAD OUR 12/1 MEETING.

THERE'S A MEETING WE HAVE SCHEDULED, IT'S ACTUALLY GOING TO BE A TWO-DAY MEETING AT THE END OF JANUARY WHERE OUR GOAL IS TO ACTUALLY COME UP WITH RECOMMENDATIONS THAT GO BACK TO THE ICOC FOR FINAL REGULATIONS. SO THAT'S THE PRODUCT THAT WE WOULD LIKE TO PROPOSE TO THE ICOC.

THAT THEN GOES TO THE ICOC MEETING ON FEBRUARY 10TH, ABOUT TEN DAYS, ELEVEN DAYS LATER. AND IF THEY APPROVE, THEN THAT TRIGGERS THE APA PROCESS, THE 45-DAY PUBLIC COMMENT PERIOD, OUR REQUIREMENT TO RESPOND TO COMMENTS. AND THEN AFTER THAT, IF THERE ARE CHANGES, THOSE NEED TO BE MADE WITH AN ADDITIONAL COMMENT PERIOD, AND THEN IT GOES TO THE OFFICE OF ADMINISTRATIVE LAW REVIEW. AND THAT'S THE TIMETABLE THAT WILL ALLOW US TO HAVE REGULATIONS, FINAL REGULATIONS, IN EFFECT BY THE JULY 30TH, 2006, GUIDELINE, WHICH IS WHEN THE EXPIRATION OF THE INTERIM GUIDELINES THAT WERE APPROVED 11/2/05.

SO I JUST WANT TO SAY THAT THE NEXT MEETING OUR GOAL IS REALLY TO APPROVE LANGUAGE ON THESE PROPOSED GUIDELINES, FINAL GUIDELINES. AND SO BEFORE THEN, STAFF IS GOING TO HAVE A LOT OF WORK TO DO ACTUALLY WRITING THIS OUT, TRANSLATING IT INTO REGULATORY LANGUAGE. I WOULD SUSPECT I WOULD LIKE TO SORT OF BE ABLE TO CALL ON YOU EITHER ELECTRONICALLY OR

BY TELEPHONE TO TRY AND PUSH AHEAD ON SOME OF THE ISSUES THAT WE HAVEN'T QUITE RESOLVED, EITHER TO CHECK AND MAKE SURE THE LANGUAGE SEEMS RIGHT, BUT ALSO THERE'S SOME OUTSTANDING ISSUES THAT, IF WE THOUGHT A LITTLE BIT ABOUT AHEAD OF TIME, IT MAY FACILITATE OUR DELIBERATIONS NEXT MEETING.

I KNOW THAT THE HOLIDAY SEASON IS COMING UP, AND WE'RE ACTUALLY GOING TO NEED TO RESPECT THAT, BUT BETWEEN NOW AND JANUARY, WE'D LIKE TO CONTACT YOU EITHER ELECTRONICALLY AND MAYBE BY PHONE AND TO TRY AND GET SOME FEEDBACK FROM YOU AS WE SORT OF GO ABOUT PUTTING THE IDEAS FROM THE DAY INTO REGULATORY LANGUAGE.

ON THE FIRST PAGE UNDER THAT BINDER, WHICH IS THIS BIG BLACK CHART, SORT OF THE ISSUES THAT WE HAVE TO DEAL WITH, I THINK IF WE CAN GET THE INFORMED CONSENT SECTION WRITTEN UP IN REGULATORY LANGUAGE, THE THINGS THAT WE NEED TO REVISIT IN JANUARY, THE ESCRO REVIEW, CHARACTERIZATION OF ACTIVITIES NOT ELIGIBLE FOR FUNDING, ASSURANCES OF COMPLIANCE, I THINK ARE LESS FRAUGHT WITH KIND OF ETHICAL CONTROVERSY. IT'S MORE A MATTER OF GETTING THE LANGUAGE RIGHT AND MAKING SURE WE HAVEN'T LEFT OUT ANY KEY CONSIDERATIONS.

SO I THINK WE'RE IN PRETTY GOOD SHAPE, BUT STILL A LOT OF WORK LEFT TO DO. I'M GOING TO CALL ON

STAFF TO DO A LOT OF WORK AS THEY HAVE BEEN DOING, THANKS TO JEFF. AND THEN TO ACTUALLY GIVE YOU NOTICE THAT WE'LL BE SORT OF CALLING ON YOU IN THE INTERIM TO TRY AND CONTINUE TO GET YOUR IDEAS.

DR. EGGAN: MAYBE IT'S TOO LATE TO CHANGE IT, BUT IS TEN DAYS A REALISTIC AMOUNT OF TIME FOR THE STAFF TO TURN AROUND EVERYTHING WE DO IN OUR MEETING AT THE END OF THE MONTH AND GET IT TO THE HANDS OF THE ICOC FOR A REASONABLE REVIEW? WE HAVE A BIG JOB FOR THOSE TWO DAYS, AND IN TURN, IT WILL BE A VERY BIG JOB TO PUT THE FINAL REGULATIONS IN THE HANDS OF THE ICOC AND FOR THEM TO ACTUALLY READ IT BEFORE THEY DECIDE WHETHER OR NOT TO APPROVE IT. I'M SORT OF SITTING HERE WONDERING IF THAT PASSES THE RED FACE TEST ADMINISTRATIVELY.

DR. HALL: THE HOPE IS THAT YOU WOULD, IN FACT, ARE CONVERGING ON THESE ISSUES TOWARDS SOLUTION. THAT IS, THAT I THINK WHAT HAPPENED TODAY IS ILLUSTRATIVE; THAT IS, WE TALKED ABOUT A LOT OF PRINCIPLES, YOU DID, AND THEN THE STAFF WILL TRY TO REDUCE THOSE TO LANGUAGE. AND THE QUESTION IS WHETHER WE ARE GOING TO MAKE WHOLESALE CHANGES AFTER THAT OR NOT. MY GUESS IS THERE WILL BE INTENSE DISCUSSIONS OVER A FEW WORDS AND A FEW PHRASE. BUT IF YOU ACTUALLY LOOK AT THE GUIDELINES, WHICH ARE UNDER -- DRAFT

GUIDELINES UNDER TAB 6, THEN STARTING IN, THEN I THINK THERE ARE MANY AREAS IN HERE, THE HIGHLIGHTED AREAS INDICATE SOME OF THE RECENT CHANGES. YOU CAN LOOK THROUGH. THESE ARE ISSUES THAT WE'VE TALKED ABOUT A LOT BEFORE. MY GUESS IS THAT THE CHANGES WILL BE RELATIVELY SMALL. I COULD BE WRONG. IF WE'RE REQUIRED TO GO BACK AND COMPLETELY REWRITE SOMETHING, AND THEN BRING IT TO YOU YET AGAIN, I THINK THAT'S A DIFFICULTY. BUT MY HOPE IS THAT, YOU KNOW, WE GO FROM WHOLE SECTIONS TO PARAGRAPHS TO SENTENCES TO WORDS TO COMMAS, AND THAT EACH ITERATION WILL GET US CLOSER AND CLOSER TO WHERE WE ARE.

DR. KIESSLING: IS THERE A REASON IT'S NOT BEING HELD A WEEK BEFORE?

DR. LOMAX: UNFORTUNATELY THAT WAS SIMPLY SCHEDULING DIFFICULTY. I KNOW JENNIFER REALLY TRIED TO SHOOT FOR MUCH EARLIER IN JANUARY, BUT IT WAS JUST VERY DIFFICULT TO GET EVERYONE TOGETHER OTHER THAN THAT WEEK.

VICE CHAIR LO: WE CAN TRY AGAIN, BUT THIS IS A VERY GOOD GROUP, BUT IT'S A VERY BUSY GROUP, AND IT'S REALLY HARD TO GET A QUORUM TOGETHER, ESPECIALLY FOR A TWO-DAY MEETING. WE THOUGHT IT WAS IMPORTANT TO HAVE THE OPTION OF THAT SECOND DAY IF WE REALLY NEEDED IT.

DR. EGGAN: MAYBE I WOULD JUST SAY TO

ENCOURAGE STAFF TO POINT OUT THIS TIME LIMITATION THAT WE HAVE AND TO ENCOURAGE PEOPLE TO COME FORWARD WITH LARGER PROBLEMS THAT THEY HAVE IN THE INTERIM TIME TO MAKE SURE THAT WE CAN DO OUR BEST TO DEAL WITH THEM BEFOREHAND, SO THERE AREN'T ANY ENORMOUS SURPRISES. MEETING WILL BE WHAT THE MEETING IS AND I DON'T WANT TO STIFLE THAT IN ANY WAY, BUT IF PEOPLE HAVE SUBSTANTIVE DISAGREEMENTS WITH HOW THINGS ARE SHAPING UP, THEN WE'D HOPE THEY'D COME FORWARD BEFORE THAT DATE.

DR. HALL: ALSO ENCOURAGE A SENSE OF CONTINUITY, THAT WE REALLY DO BUILD EACH TIME ON WHAT WE'VE DONE BEFORE AND DON'T HAVE TO GO BACK AND HAVE THE SAME DISCUSSIONS OVER AGAIN. PART OF IT -- THAT'S DIFFICULT BECAUSE WE DON'T ALWAYS HAVE THE SAME PEOPLE. SO ONE NEW PERSON COMES IN AND SAYS WAIT A MINUTE. I DON'T AGREE WITH ANY OF THIS, AND THEN IT'S DIFFICULT. I THINK WE JUST HAVE TO DO THE BEST WE CAN.

WE DID TRY TO SCHEDULE IT DIFFERENTLY, BUT IT IS A VERY HARD GROUP TO GET TOGETHER.

VICE CHAIR LO: LET ME JUST UNDERLINE KEVIN'S POINT. I THINK AS WE SEND THINGS OUT, WE WILL TRY AND BE VERY SELECTIVE WITH WHAT WE SEND OUT. BUT IF WE SEND SOMETHING OUT AND YOU LOOK AT IT AND SAY, GOSH, I CAN'T LIVE WITH THIS, THEY'VE TOTALLY MISSED THE BOAT, PLEASE LET US KNOW AS QUICKLY AS POSSIBLE SO WE CAN

TAKE INTO ACCOUNT YOUR CONCERNS, OBJECTIONS, AND TRY AND FIGURE OUT HOW TO --

DR. HALL: FIRST OF ALL, WE URGE PEOPLE TO READ THEM BEFORE THEY GET ON THE PLANE TO COME OUT HERE.

DR. LOMAX: IF I COULD ADD ONE OTHER COMMENT THERE AS WELL. I THINK WE ARE, AT LEAST IN TERMS OF THE PROCESS, WE'VE REALLY HIT A CRITICAL STAGE WHERE WE'VE BEEN TRYING TO DO TWO THINGS AT ONCE, WHICH IS PROVIDE SYNTHESIZED BACKGROUND MATERIAL AND PUT A LOT EFFORT INTO GETTING MATERIAL AND THE SUPPORTING RESEARCH IN REALLY LEADING UP TO THIS MEETING. I WOULD SUGGEST THAT THE SECTIONS WE DEALT WITH TODAY ARE REALLY THE CORE OF THE ETHICAL HEART OF THIS DOCUMENT, AND A LOT OF THE ISSUES, PARTICULARLY IN JANUARY, ARE MORE TECHNICAL IN NATURE, AND WE WON'T NEED TO SPEND LOTS OF TIME ON THEM. SO THE FUTURE MATERIALS YOU'LL BE GETTING FROM US WOULD BE STRICTLY FOCUSED ON THIS CORE PART OF THE REGULATIONS AND DIRECT YOU INTO SORT OF REVIEWING LANGUAGE INSTEAD OF HAVING HAVE TO REVIEW BACKGROUND MATERIAL AND REVIEW DOCUMENTS.

SO WE'LL HOPEFULLY USE THAT TIME TO REALLY WORK THROUGH THE LANGUAGE OF THE REGULATIONS WITH YOU AND NOT ALL THE RELATED MATERIAL THAT GOES INTO THAT.

DR. EGGAN: PRESUMABLY THAT MEANS THAT ALL

THE SUGGESTIONS THAT WE MADE AS A NONQUORUM GROUP TODAY CAN BE ENTERED INTO THE SUGGESTED INTERIM GUIDELINES. THERE WILL BE NO NEED -- IS IT TRUE THAT THERE WILL BE NO NEED TO VOTE ON THOSE CHANGES INDIVIDUALLY, BUT THAT THERE CAN BE SORT OF A VOTE BY PRESUMABLY WHAT WOULD BE THE QUORUM GROUP ON THE ENTIRE GUIDELINES AT THE END OF THE DAY; IS THAT TRUE, OR WILL WE NEED TO REVISIT THESE ISSUES WITH THEM?

VICE CHAIR LO: AGAIN, WE DIDN'T APPROVE ANYTHING TODAY BECAUSE WE DIDN'T HAVE A QUORUM, BUT WE NEED TO HAVE YOUR APPROVAL OF FINAL LANGUAGE AT THE JANUARY MEETING. SO WE NEED SORT OF HAVE YOU APPROVE BEFORE WE LEAVE IF WE'RE GOING TO PRESENT IT TO THE ICOC IN FEBRUARY.

DR. PRIETO: I JUST WANT TO REMIND PEOPLE THAT THESE WILL STILL BE INTERIM REGULATIONS, AND THERE'S A LONG PUBLIC COMMENT PERIOD BEFORE THESE ARE CAST IN STONE.

DR. HALL: JUST TO KEEP OUR TERMINOLOGY STRAIGHT, WE NOW HAVE INTERIM REGULATIONS IN PLACE. THESE ARE DRAFT REGULATIONS WHICH WE WILL, IF APPROVED BY THE ICOC, WILL THEN BE SUBMITTED TO OR NOTICED WITH OAL AND THEN GO OUT FOR PUBLIC COMMENT.

DR. PRIETO: BUT WILL NOT BE FINAL UNTIL --

DR. HALL: AND THEN WE WILL GIVE WRITTEN

RESPONSES TO THE PUBLIC COMMENT. BUT IT'S NOT THAT WE WILL ABLE TO CHANGE IT MIDSTREAM AS IT GOES ALONG.

DR. PRIETO: FOLLOWING PUBLIC COMMENT, HOWEVER, IT CAN BE CHANGED AT THIS LEVEL OR THE ICOC LEVEL.

DR. HALL: CORRECT ME IF I'M WRONG HERE, BUT FOLLOWING PUBLIC COMMENT AND OUR WRITTEN RESPONSE, THEN OAL DECIDES WHETHER WE'VE MADE A MAJOR MODIFICATION OR A MINOR MODIFICATION. IF WE MADE MINOR MODIFICATIONS, THEN THEY ASK FOR 15 DAYS OF PUBLIC RESPONSE TO REITERATE. IF THEY BELIEVE THAT WE MADE A MAJOR CHANGE, THEN WE HAVE TO GO THROUGH ONCE AGAIN THE 45-DAY PROCESS OF HAVING PUBLIC COMMENT, WRITTEN RESPONSES, AND THEN WE KEEP ON THAT CYCLE TILL WE GET HOME. BUT IF WE WERE TO MAKE A MAJOR MODIFICATION DURING THAT PERIOD, THEN WE WOULD BE THRUST BACK INTO STARTING OVER AGAIN. IT IS NOT THE CASE THAT THIS WILL BE A LIVING DOCUMENT THAT WE CAN CONTINUE TO WORK ON THROUGH THIS PROCESS. ONCE WE SUBMIT IT IN FEBRUARY AND IT GOES TO OAL, THEN THAT'S WHAT -- THAT'S OUR WORD ON IT.

DR. KIESSLING: BECAUSE THERE WERE SOME PROBLEMS WITH ELECTRONIC INFORMATION THIS TIME AROUND, IS IT POSSIBLE THAT WHEN YOU SEND SOMETHING TO US, THAT YOU ASK US TO REPLY AND MAKE SURE WE GOT IT BECAUSE IT

DIDN'T HAPPEN FOR A NUMBER OF THINGS THIS TIME. IF YOU DON'T HEAR BACK FROM US, I THINK YOU SHOULD TRIGGER IT AGAIN.

VICE CHAIR LO: THAT'S A GOOD SUGGESTION.

DR. LOMAX: ABSOLUTELY. AS A RESULT, THE PAST FEW WEEKS, WE'VE HAD SOME CONCERNS WITH E-MAIL, AND WE'LL BUILD A CONTINGENCY IN TO MAKE SURE THAT ISN'T DISRUPTIVE TO THE PROCESS.

DR. HALL: WE'LL SEND IT EVERY DAY UNTIL YOU SAY STOP.

DR. KIESSLING: DO THAT. SOMETHING LIKE THAT WORKS.

VICE CHAIR LO: AND THEN ANY COMMENTS, QUESTIONS ABOUT THE PROCEDURES? I JUST WANT A POINT OF INFORMATION. A WEEK FROM TOMORROW THE UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT AND CIRM ARE COHOSTING A MEETING FOR REPRESENTATIVES OF THE INSTITUTIONS THAT APPLIED FOR CIRM TRAINING GRANTS TO SEND SEVERAL REPRESENTATIVES SO WE CAN GIVE THEM SORT OF OUR THINKING ON OUR GUIDELINES AND SO OBTAIN THEIR FEEDBACK, COMMENTS, AND THOUGHTS. AND AMONG THE TYPES OF PEOPLE WHO WILL BE THERE WILL BE MEMBERS AND CHAIRS OF ESCRO'S OR IRB'S, PEOPLE RESPONSIBLE FOR INSTITUTIONAL COMPLIANCE, RESEARCHERS. SO WE HOPE TO GET SORT OF A REPRESENTATIVE SAMPLE OF PEOPLE WHO WILL

BE LIVING WITH AND REGULATED BY THESE REGULATIONS. AND, AGAIN, THE POINT OF THIS IS TO MAKE SURE WE'RE NOT PROPOSING SOMETHING THAT'S GOING TO TRIGGER A VERY STRONG RESPONSE THAT'S GOING TO REQUIRE US TO TOTALLY REWORK THINGS. WE WANT TO FIND THAT OUT BEFORE WE ISSUE OUR RECOMMENDATIONS TO ICOC.

I WANT TO THANK ARLENE AND UCOP FOR TAKING THE LEAD ON THIS. I THINK IT'S GOING TO BE A VERY USEFUL MEETING. ALREADY SOME OF THE FEEDBACK WE'VE GOTTEN IS THAT A LOT OF THESE INSTITUTIONS REALLY ARE EAGER TO SORT OF HEAR WHAT WE'RE THINKING. A LOT OF WHAT WE'RE GOING TO SAY IS REASSURING AND THAT WE'RE NOT GOING TO BE MINUTELY PRESCRIBING WHAT WE'RE GOING TO DO.

DR. HALL: IT'S OUR USER GROUP BASICALLY. WE'RE CHECKING WITH OUR USER GROUP.

DR. PETERS: BERNIE, DID YOU WANT TO ENCOURAGE MEMBERS OF OUR WORKING GROUP TO SHOW UP, OR IS THAT ALREADY A SET?

VICE CHAIR LO: WELL, I THINK WE'RE ALWAYS EAGER. IT'S ACTUALLY IN THIS SIDE OF THE BAY. GLADSTONE. IT'S DOWN IN MISSION BAY. YES, I THINK ANYONE ON THE COMMITTEE IS CERTAINLY WELCOME TO COME. AND I THINK IT SHOULD BE INTERESTING AND EDUCATIONAL BECAUSE IT IS GOING TO GIVE US A WAY OF UNDERSTANDING

HOW THE PEOPLE WHO ARE SUBJECT TO OUR REGULATIONS ARE REACTING TO IT. ABSOLUTELY, I THINK WE'RE CERTAINLY WELCOME. WE'LL GET THE SAME LUNCH AS EVERYONE ELSE GETS.

WITH THAT, IF THERE IF THERE IS NO ADDITIONAL BUSINESS -- WE'RE NOT ALLOWED TO HAVE MOVEMENTS TO ADJOURN, SO I CAN JUST UNILATERALLY SAY I HOPE IT'S NOT RAINING. AND FOR THOSE WHO ARE TRAVELING, GOD SPEED AND SAFE TRAVELS AND HOPE THAT THE PLANES ARE FLYING ON TIME. FOR THOSE OF YOU ON DELTA, MY COMMISERATIONS. THANKS VERY MUCH. I THOUGHT THIS WAS A VERY USEFUL MEETING.

(THE MEETING WAS THEN ADJOURNED AT 05:34 P.M.)

REPORTER'S CERTIFICATE

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

{LOCATION}
{ADDRESS LINE 2}
***, CALIFORNIA
ON
THURSDAY, DECEMBER 1, 2005

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

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