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

REGULAR MEETING

LOCATION: MIYAKO HOTEL
1625 POST STREET
SAN FRANCISCO, CALIFORNIA

DATE: MAY 9 & 10, 2007

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

BRS FILE NO.: 78260 & 78261

I N D E X

SAN FRANCISCO, CALIFORNIA; THURSDAY, MAY 10, 2007

CHAIRMAN LO: OKAY. LET ME SAY GOOD MORNING AND WELCOME, MARCY. I HOPE YOU HAD A FINE COMMUTE OVER FROM THE EAST BAY. I WOULD LIKE TO CALL US TO ORDER. WANT TO SAY GOOD MORNING TO EVERYBODY AND HOPE YOU ALL SLEPT WELL. NICE REFRESHING FOG TO KEEP YOU COOL.

WE HAVE A NUMBER OF THINGS TO DO THIS MORNING, PRIMARILY SOME INTERESTING THINGS THAT GEOFF HAS DONE WITH REGARD TO REACHING OUT TO THE INSTITUTIONS AND SCRO'S AROUND THE STATE AND SORT OF FINDING OUT WHAT THEY THINK OF THE REGULATIONS AND WHAT CONCERNS THEY HAVE AND PROBLEMS THEY HAVE APPLYING THEM. BUT I THOUGHT THAT I WOULD START BY TRYING TO BRING TOGETHER WHAT I THOUGHT WAS A VERY INTERESTING AND VERY RICH DISCUSSION FROM YESTERDAY.

MARY, IS YOUR SCHEDULE SUCH THAT YOU NEED TO GO? YOU WANT TO GO RIGHT AWAY? LET ME, SINCE MARY MAXON, WHO IS THE VICE CHAIR OF THE INTELLECTUAL PROPERTY TASK FORCE, IS HERE, LET ME START WITH HER AND ASK HER TO SHARE WITH US WHAT HER GROUP HAS BEEN DOING. AND THEN WE'LL SORT OF DO OTHERS THING. THANKS SO MUCH FOR COMING DOWN, MARY.

DR. MAXON: THANK YOU. GOOD MORNING. I'M HERE TO GIVE YOU ANOTHER STATUS REPORT ON THE WORK OF

THE INTELLECTUAL PROPERTY TASK FORCE. SO TO DATE WE'VE WORKED ON THE DEVELOPMENT OF TWO INTELLECTUAL PROPERTY POLICIES. FROM THOSE POLICIES, AS YOU WELL KNOW, SPRING REGULATIONS, AND I'LL GIVE YOU AN UPDATE ON BOTH THE POLICIES AND THE STATUS OF THE REGULATIONS.

SO TO DATE WE'VE HAD 13 PUBLIC MEETINGS DEVOTED TO INTELLECTUAL PROPERTY POLICY DEVELOPMENT. WE ALSO HAVE ANOTHER ONE SCHEDULED FOR LATER THIS MONTH. WE'VE HAD 18 PRESENTATIONS BY EXPERTS AND STAKEHOLDERS WHO HAVE BEEN FORMAL INVITEES TO COME AND GIVE PRESENTATIONS ABOUT TECHNOLOGY TRANSFER, HOW GRANTING AGENCIES GIVE GRANTS, AND THEIR INTELLECTUAL PROPERTY POLICIES. WE'VE HAD REPRESENTATIVES FROM THE NATIONAL ACADEMIES TALK TO US ABOUT INTELLECTUAL PROPERTY RECOMMENDATIONS, ETC. AND WE'VE DONE A SURVEY OF MORE THAN 20 FUNDING ENTITIES IN CALIFORNIA, IN THE UNITED STATES, AND IN OTHER COUNTRIES TO TRY TO GET AN IDEA OF BEST PRACTICES FROM WHICH WE COULD DERIVE SOME COMPONENTS TO PUT INTO OUR OWN POLICIES.

THERE HAVE BEEN MORE THAN ONE HUNDRED INTERVIEWS DONE BY TELEPHONE. AND WHAT'S MISSING FROM THE SLIDE ALSO IN TERMS OF RESEARCH IS A HUGE AMOUNT OF HOMEWORK INVOLVING LITERATURE SEARCHES, WEB SEARCHES. AND IF JEFF SHEEHY WERE HERE, HE COULD TELL YOU THAT THE AMOUNT OF READING MATERIAL STACKS ABOUT 3.5 FEET

HIGH THAT THE IP TASK FORCE MEMBERS WERE ASKED TO READ.

LET ME INTRODUCE YOU A LITTLE BIT TO THE CONCEPT OF CIRM FUNDING TO NONPROFIT AND FOR-PROFIT ENTITIES. THE RESEARCH SECTORS ACTUALLY HAVE DIFFERENTIAL FUNDING OPPORTUNITIES AVAILABLE. IF YOU LOOK TO THE RIGHT WHERE NONPROFIT IS LISTED, THE OUTCOME OF NONPROFIT RESEARCH IS KNOWLEDGE. THAT'S THE EXPECTED OUTCOME. OCCASIONALLY THERE'S AN INVENTION. AND THEN, IF LUCKY, THAT INVENTION GETS LICENSED TO A THIRD PARTY, USUALLY A COMPANY. AND YOU CAN SEE THAT THE ARROWS INDICATE THAT THE SCIENCE MAY BECOME AN INVENTION AND THAT INVENTION MAY BE LICENSED. THAT'S THE OPPORTUNITY FOR TRANSFER OF PATENTED INTELLECTUAL PROPERTY IN THE NONPROFIT SECTOR. YOU WILL SEE THAT THE BLUE ARROW EMANATING FROM THE MIDDLE WHERE IT SAYS CIRM FUNDING INDICATES THAT CIRM WILL FUND PRIMARILY BASIC SCIENCE AT NONPROFIT INSTITUTIONS. NOW, NOTICE I SAID PRIMARILY. WE CAN TALK MORE ABOUT THAT IF YOU WANT TO.

ON THE LEFT-HAND SIDE, THE FOR-PROFIT SCHEME SHOWS THAT CIRM FUNDING CAN GO TO BASIC SCIENCE ENDEAVORS AT COMPANIES. THERE WAS A SURVEY PUBLISHED LAST YEAR IN *NATURE BIOTECHNOLOGY* THAT SAID OF THE FDA-APPROVED NOVEL AGENTS FROM 1995 TO 2003, THE VAST MAJORITY OF THEM HAD THEIR INCEPTIONS IN FOR-PROFIT

COMPANIES, NOT IN NONPROFIT UNIVERSITIES. THAT WAS QUITE SURPRISING TO ME IN THE RESEARCH. SO YOU CAN SEE THAT CIRM FUNDING CAN GO FOR BASIC SCIENCE, IT CAN GO TO PRECLINICAL EXPERIMENTATION, AND IT CAN GO INTO CLINICAL TRIALS FURTHER DOWN THE SCHEME. SO THERE ARE A NUMBER OF DIFFERENT POINTS INTO THIS SCHEME WHERE CIRM FUNDING CAN BE INJECTED, AND THIS IS IMPORTANT IN TERMS OF HOW WE WRITE A POLICY TO HANDLE THE GRANTS THAT GO TO THESE ENTITIES.

NOTICE ALSO THAT AT THE STAGE THAT A FOR-PROFIT INVENTS A PATENTED -- GETS A PATENTED INVENTION, IT ALSO HAS THE OPPORTUNITY TO LICENSE IT AWAY. THIS HAPPENS REGULARLY. AND YOU CAN SEE THAT THAT'S THE ONE THING THAT THE FOR-PROFIT AND NONPROFIT SECTORS HAVE IN COMMON.

DR. ROWLEY: BEFORE YOU MOVE FROM THAT SLIDE, WHY IS IT THAT CIRM FUNDING IS SO ASYMMETRICAL, IF YOU WILL, IN THE THINGS IT CAN FUND IN FOR-PROFITS AS COMPARED WITH NONPROFITS?

DR. MAXON: I THINK IT'S BASICALLY BECAUSE THE OUTPUT OF THE TWO RESEARCH SECTORS IS DIFFERENT. THE OUTPUT OF THE RESEARCH IN A NONPROFIT SECTOR IS KNOWLEDGE. THAT'S THE EXPECTED OUTCOME. THE OUTPUT EXPECTED FROM FOR-PROFIT RESEARCH IS PRODUCTS. AND AS A CONSEQUENCE OF THAT, THERE ARE A NUMBER OF VERY

DIFFERENT STAGES OF RESEARCH INCLUDING BASIC RESEARCH LIKE THE NONPROFITS, BUT ALSO PRECLINICAL RESEARCH SUCH AS TOXICITY TESTING IN ANIMALS, ETC., AND, OF COURSE, CLINICAL TRIALS. NOW, I DID SAY PRIMARILY BECAUSE IT IS TRUE THAT NONPROFITS DO CLINICAL TRIALS. AND TO BE FAIR, THE SCIENTIFIC STRATEGIC PLAN CLARIFIES THAT CLINICAL TRIALS WILL BE FUNDED. SO I JUST WANT TO MAKE IT CLEAR THAT FOR THE PURPOSES OF THIS TALK THE REASON THAT THE DIFFERENT POLICY NEEDS EXIST IS LARGELY BECAUSE WE HAVE A DIFFERENT SCENARIO HERE AS IT RELATES TO INTELLECTUAL PROPERTY, NOT REALLY AS IT RELATES TO THE SCIENCE, AS I CAN TELL YOU THAT OBVIOUSLY NONPROFITS DO CLINICAL TRIALS TOO. IT'S DIFFERENT, THOUGH, AS IT RELATES TO THE INTELLECTUAL PROPERTY THAT'S CREATED. AND SO HOPEFULLY THAT ADDRESSES YOUR QUESTION.

SO WHAT I CAN SHOW YOU HERE IS THE DEVELOPMENT SCHEME FOR THE NON-PROFIT POLICY, AND THIS SHOULD LOOK FAMILIAR BECAUSE I THINK YOU'VE SEEN THIS BEFORE. WE STARTED IN OCTOBER OF 2005 WITH OUR VERY FIRST IP TASK FORCE MEETING AND HAD A SERIES OF TOPICS AND PRESENTATIONS THAT ARE LISTED AT THE BOTTOM OF THE SLIDE. THERE WAS ALSO A LEGISLATIVE HEARING IN WHICH WE PARTICIPATED ABOUT THE TOPIC OF INTELLECTUAL PROPERTY SPONSORED BY SENATOR ORTIZ. IN DECEMBER OF

2005, THE NON-PROFIT PRINCIPLES WERE APPROVED. THEREAFTER THE POLICY WAS DRAFTED, AND IT WAS PRESENTED TO YOUR WORKING GROUP IN JANUARY ON THE 30TH OF 2006.

IN ADDITION, REGULATIONS WERE PREPARED FOLLOWING THE FEBRUARY APPROVAL OF THE FORMAL ICOC'S NON-PROFIT POLICY. THIS IS WHAT IT LOOKS FOR THE FOR-PROFIT POLICY TIMELINE. OBVIOUSLY A LOT OF THE COMPONENTS THAT WE ESTABLISHED IN THE NON-PROFIT POLICY ARE RELEVANT TO THE FOR-PROFIT POLICY, BUT THERE ARE A LOT OF OTHER DIFFERENT ISSUES TO DISCUSS, AS I POINTED OUT.

WE BEGAN IN EARNEST OUR MEETINGS SPECIFICALLY FOR THE FOR-PROFIT POLICY IN MARCH, AND WE HAD A SERIES OF SPEAKERS FROM THE FOR-PROFIT SECTOR WHO WERE NOT STEM CELL RESEARCH COMPANIES TO TALK TO US ABOUT THE RECEIPT OF GRANTS FROM FUNDING ENTITIES JUST TO HEAR GENERALLY ABOUT WHAT THE ISSUES WERE AND WHAT THE RECOMMENDATIONS MIGHT BE.

AT THE APRIL TASK FORCE MEETING, WE ACTUALLY SOLICITED INPUT FROM STEM CELL COMPANIES AND OTHER PEOPLE, SO WE GOT THE NONSTEM CELL COMPANIES FIRST, THEN SOME STEM CELL COMPANIES. AND LET ME ALSO SAY THAT THIS IS AGAINST A BACKDROP OF OVER A HUNDRED INTERVIEWS THAT WERE DONE IN ADDITION TO PUBLIC MEETINGS.

IN JULY OF LAST YEAR, IN COLLABORATION WITH OUR SCIENTIFIC STRATEGIC PLANNING, WE HELD WHAT WE CALL A COMMERCIAL SECTOR CONFERENCE WHERE WE INVITED EIGHT REPRESENTATIVES FROM THE FOR-PROFIT SECTOR TO GET TOGETHER IN A PUBLIC FORUM AND ADDRESS THE ISSUES, WHETHER THEY WERE ADULT STEM CELL COMPANIES OR EMBRYONIC STEM CELL COMPANIES OR VENTURE CAPITALISTS, TO TELL US IF CIRM WERE TO FUND THE FOR-PROFIT SECTOR, WHAT DO YOU ALL AGREE WOULD ESSENTIALLY FLOAT ALL BOATS? AND SO THAT'S WHEN WE GOT SOME VERY CLEAR ADVICE FROM THE FOR-PROFIT SECTOR AS A UNIFIED FRONT THAT WAS VERY PRODUCTIVE FOR US.

TO MAKE A LONG STORY SHORT, WE THEN PRESENTED -- WE DRAFTED THE SECOND POLICY. IT WAS PRESENTED TO YOUR WORKING GROUP, I BELIEVE, ON NOVEMBER 18TH BY ED PENHOET. AND IN DECEMBER OF 2006, THE ICOC APPROVED THE FOR-PROFIT POLICY.

NOW, LET'S JUST COMPARE A LITTLE BIT THE TIMELINES HERE JUST FOR YOUR EDIFICATION. THE NONPROFIT POLICY WAS APPROVED IN FEBRUARY '06, AND THE REGULATIONS THAT SPRANG FROM THAT POLICY WERE APPROVED IN DECEMBER OF '06 WITH ONE EXCEPTION. AND I'LL TALK A LITTLE BIT MORE ABOUT THAT. THE FOR-PROFIT POLICY WAS APPROVED IN DECEMBER OF '06, AND THE REGULATIONS THAT HAVE SPRUNG FROM THAT HAVE JUST COMPLETED THEIR 45-DAY

PUBLIC COMMENT PERIOD IN APRIL. SO WE'RE NOW -- SCOTT IS SIFTING THROUGH THE PUBLIC COMMENT, AND WE'RE ABOUT TO HAVE AN IP TASK FORCE MEETING LATER THIS MONTH TO ADDRESS PUBLIC COMMENT.

SO WITH ONE EXCEPTION, THE PRICING BENCHMARK CONTINUES TO BE A MAJOR CHALLENGE. I'LL TALK MORE ABOUT THIS IN A MINUTE.

SO COMPONENTS OF THE FOR-PROFIT POLICY ARE HERE. PRINCIPAL COMPONENTS INCLUDE OWNERSHIP, AND THE OWNERSHIP IS EXACTLY AS IT IS FOR THE NON-PROFIT POLICY. THAT IS TO SAY THAT THE GRANTEES WILL OWN THEIR INTELLECTUAL PROPERTY, NOT CIRM. SIMILAR TO THE NON-PROFIT REQUIREMENT, FOR-PROFIT GRANTEES WILL SHARE PUBLICATION-RELATED BIOMEDICAL MATERIALS. THERE'S A SLIGHT MODIFICATION TO THAT, AND WE CAN TALK ABOUT THAT IF YOU'RE INTERESTED.

THERE IS ALSO A REVENUE SHARING REQUIREMENT UNDER LICENSE AGREEMENTS. FOR THE NONPROFITS, IT'S 25 PERCENT. SO THAT'S 25 PERCENT OF THE GRANTEE ORGANIZATION'S SHARE. AS YOU ARE PROBABLY WELL AWARE, THE FEDERAL BAYH-DOLE ACT REQUIRES THAT IF FEDERAL DOLLARS ARE USED TO SUPPORT A RESEARCH PROJECT AND THERE'S A PATENTED INVENTION THAT'S CREATED AND THAT PATENTED INVENTION IS LICENSED, THE GRANTEE ORGANIZATION MUST SHARE WITH THE INVENTORS A FRACTION

OF THAT INCOME. DOESN'T SAY HOW MUCH, BUT IT SAYS THAT THOSE INVENTORS MUST BE COMPENSATED. SO 25 PERCENT IS WHAT THE STATE'S GENERAL FUND WILL RECEIVE OF THE GRANTEE ORGANIZATION'S SHARE, NOT THE INVENTOR'S SHARE. SO BASICALLY IT'S 25 PERCENT OF APPROXIMATELY TWO-THIRDS BECAUSE USUALLY THE INVENTORS ARE COMPENSATED A THIRD.

SO IN THE CASE OF THE FOR-PROFITS, 17 PERCENT WOULD THEN BE THE EXACT SAME RETURN TO THE GENERAL FUND GIVEN THAT IN THE FOR-PROFIT SECTOR INVENTORS ARE NOT COMPENSATED.

REVENUE SHARING REQUIREMENTS ARE VERY DIFFERENT IN THE FOR-PROFIT POLICY, AND I'LL TAKE YOU THROUGH THAT IN MORE DETAIL. THE MARCH-IN REQUIREMENTS ARE PRETTY MUCH EXACTLY AS THEY ARE FOR THE NONPROFITS. THAT IS TO SAY, IF YOU DON'T EXECUTE ON THE INVENTION, THEN THE CIRM WILL HAVE MARCH-IN RIGHTS TO MAKE SURE THAT THE INVENTION IS PUT INTO PUBLIC USE.

THE ACCESS REQUIREMENTS, AND I'LL TALK MORE ABOUT THESE TOO, ARE EXACTLY AS NON-PROFIT LICENSING REQUIREMENTS ARE, AND THERE'S A LITTLE BIT OF EXTRA STUFF FOR THE FOR-PROFITS BECAUSE THEY NOT ONLY LICENSE, BUT THEY ALSO SELF-DEVELOP PRODUCTS. AND I'LL TAKE YOU THROUGH THAT TOO.

SO LET'S TALK ABOUT SHARING. IN SUMMARY, OUR

POLICIES ARE HEAVILY FOCUSED ON SHARING, SHARING OF DATA IN SCHOLARLY PUBLICATIONS, AND THIS IS WHY THIS IS IN THE INTELLECTUAL PROPERTY POLICY. SCHOLARLY PUBLICATIONS ARE COPYRIGHTED MATERIAL. COPYRIGHTED MATERIAL IS INTELLECTUAL PROPERTY. PUBLICATION-RELATED BIOMEDICAL MATERIALS MUST BE SHARED. THEY MUST BE SHARED WITH CALIFORNIA RESEARCHERS. USE OF LICENSED PATENTED INVENTIONS BY CIRM GRANTEES IS REQUIRED WHEN THOSE INVENTIONS ARE LICENSED THROUGH WHAT'S CALLED THE RIGHTS RETENTION CLAUSE. THAT IS TO SAY, IF USC INVENTS A TECHNOLOGY AND THEY LICENSE IT AWAY, THEY MUST RETAIN THE RIGHT TO USE THEIR OWN INVENTION FOR THEIR NON-PROFIT RESEARCH PURPOSES. THAT IS TO SAY, THEY CAN'T SELL AWAY, IF YOU WILL, THE RIGHTS TO THEIR OWN INVENTIONS. IN ADDITION TO THAT, THEY MUST MAKE AVAILABLE TO OTHER CIRM GRANTEES THAT TECHNOLOGY WHENEVER THEY'RE REQUESTED. SO WHENEVER WE'VE SUPPORTED A CIRM-FUNDED INVENTION, CIRM GRANTEES ARE ALLOWED TO USE THAT INVENTION FOR NON-PROFIT RESEARCH PURPOSES IN CALIFORNIA.

CHAIRMAN LO: MARY, COULD I ASK YOU? IS THAT ONLY ON A CIRM-FUNDED GRANT, OR IS THAT FOR OTHER WORK THEY'RE DOING NOT FUNDED BY CIRM?

DR. MAXON: SO THE WAY IT'S DEFINED IS IT'S FOR USE BY CIRM GRANTEES. NOW, YOU COULD ASK WHAT'S A

CIRM GRANTEE? IS THAT A PAST GRANTEE, A PRESENT GRANTEE, A FUTURE GRANTEE? THIS, I THINK, IS AN INTERESTING QUESTION. BUT IT'S LOOSELY DEFINED FOR USE BY CIRM GRANTEES. I WOULD ASSUME THAT CERTAINLY IF I'M A CIRM GRANTEE, I HAVE A GRANT FROM CIRM SOMEWHERE, I COULD ACTUALLY REQUEST THAT. WHETHER IT'S A BIOMEDICAL MATERIAL OR PERMISSION TO USE A TECHNOLOGY, I WOULD ASSUME THAT ONCE I AM NO LONGER A CIRM GRANTEE, I DON'T RELINQUISH THE RIGHT TO USE THAT. THAT WOULD BE MY ASSUMPTION. IT'S NOT CLARIFIED IN THE POLICY.

CHAIRMAN LO: YOU'RE TALKING ABOUT THE GRANTEES, THE INDIVIDUAL INVESTIGATOR OR THE INSTITUTION?

DR. MAXON: THE GRANTEE IS AN INSTITUTION ALWAYS.

CHAIRMAN LO: SO ANYBODY AT UCSF WHO HAS AN APPROVED PROTOCOL COULD USE THE --

DR. MAXON: LOOSELY DEFINED. I THINK THAT'S WITHIN THE RIGHTS OF INTERPRETATION.

DR. TAYLOR: SO THE ONUS OF RESPONSIBILITY FOR TRANSMITTING THOSE MATERIALS THEN FALLS ON THE CIRM GRANTEE THAT INVENTED THEM EVEN IF THEY SELL OFF A MAJOR BECAUSE THAT COULD BE A BIG PAIN, FRANKLY. IT IS FOR MOST INVESTIGATORS. SOMEBODY WANTS YOUR CELL LINE, YOU'VE GOT TO PUT IT IN THE ENVELOPE, YOU'VE GOT TO

SEND IT TO THEM, YOU'VE GOT TO COVER THE COSTS OF ALL OF THAT, OR SOMEHOW TRY TO RECOVER THEM. SO THIS IS SOMETHING THAT'S NOT GOING TO GO WITH THE LICENSE. IT'S SOMETHING THAT'S GOING TO STAY WITHIN THE INSTITUTION. SO THE INSTITUTIONS NEED TO PROTECT THEMSELVES, IT WOULD SEEM TO ME.

DR. MAXON: YES. THERE ARE TWO ISSUES HERE. ONE IS BIOMEDICAL -- PUBLICATION-RELATED BIOMEDICAL MATERIALS SHARING. THAT'S, I THINK, BY AND LARGE WHAT YOU'RE TALKING ABOUT AS A MAJOR BURDEN FOR RESEARCHERS.

NOW, WHAT WE'VE DONE, AND THIS IS WHERE I SAID WE COULD TALK ABOUT HOW IT'S A LITTLE BIT DIFFERENT FOR FOR-PROFITS THAN NONPROFITS, BUT WHAT WE'VE DONE GENERALLY IS TO SAY IF YOU MAKE THE WORLD AWARE OF A BIOMEDICAL MATERIAL THAT WAS FIRST CREATED AND ANNOUNCED AS A FUNCTION OF ITS PUBLICATION IN A SCIENTIFIC ARTICLE, YOU MUST SHARE THAT PUBLICATION-RELATED BIOMEDICAL MATERIAL WITHIN 60 DAYS OF RECEIPT OF REQUEST AND WITHOUT BIAS AS TO THE AFFILIATION OF THE REQUESTER.

SO WHAT THAT MEANS IS YOU HAVE TO SHARE IT. IF YOU GET A REQUEST, 60 DAYS, YOU GOT TO SHARE IT. IN THE EVENT OF A BURDENSOME SITUATION, WHETHER IT'S AN ANTIBODY OR A CELL LINE OR WHATEVER IT IS, THE GRANTEE HAS AN OPTION, AN OPPORTUNITY, TO APPEAL TO THE CIRM TO

SAY HELP ME. AND THE CIRM WILL HELP DEFRAY THAT BURDEN EITHER BY RECRUITING, LET'S SAY, A COMPANY TO PRODUCE IT AND TO DISTRIBUTE IT OR BY ANOTHER MECHANISM. BUT THE GOAL IS NOT TO BURDEN THE GRANTEES WITH THIS.

IN ADDITION, THE RIGHT TO USE CIRM-FUNDED PATENTED INVENTIONS, WHICH IS WHAT WE'RE TALKING ABOUT IN THE RIGHTS RETENTION CLAUSE, WILL APPLY SOMETIMES TO BIOMEDICAL MATERIALS, PROBABLY MOST TIMES TO TECHNOLOGIES THAT GET INVENTED AND LICENSED AWAY. BUT YOU'RE RIGHT. THE RIGHTS TO USE THAT ARE EMBODIED IN THE MANDATE FROM THE REGULATION FOR THE GRANTEE TO ALLOW ALL OTHER CIRM GRANTEES TO USE THAT. THE QUESTION REALLY BECAME WHY NOT SHARE EVERY CIRM-FUNDED PATENTED INVENTION WITH ANYBODY WHO WANTS TO USE IT? THAT'S A DIFFERENT ISSUE ALTOGETHER. THAT'S A RESEARCH USE EXEMPTION, WHICH WE ORIGINALLY STARTED OUT HAVING IN THE POLICY AND ACTUALLY TOOK OUT.

REVENUES. REVENUES FROM CIRM-FUNDED PROJECTS HAVE BEEN SPECIFICALLY TAILORED IN THE FOR-PROFIT POLICY TO ACCOUNT FOR THAT DIFFERENT FLOW CHART, THE DIFFERENT KIND OF FUNDING OPPORTUNITIES. I'LL TAKE YOU THROUGH THAT TOO. SO THIS IS THE DIAGRAM THAT I SHOWED YOU. ON THE RIGHT WHAT YOU CAN SEE IS THESE DIFFERENT POLICY NEEDS ARE A FUNCTION OF SOME VERY COMPLICATED ISSUES, INCLUDING PROPORTIONALITY ISSUES. FOR EXAMPLE,

IF CIRM GRANTS $100,000 TO A FOR-PROFIT ENTITY TO CREATE A BASIC RESEARCH SCIENCE OPPORTUNITY WITHIN THAT COMPANY, AND ULTIMATELY THAT RESEARCH PROJECT GOES ON TO GIVE RISE TO A COMMERCIALLY SUCCESSFUL PRODUCT AS DEFINED BY INCOME, NOT PROFITS, REVENUES THAT COME IN, THEN UNDER THAT CASE, YOU COULD IMAGINE THAT CIRM WOULD HAVE GIVEN $100,000 TO SOMETHING WHICH MAY HAVE COST 800 MILLION TO CREATE.

IT'S REALLY HARD FOR US TO LOOK AT A FOR-PROFIT ENTITY AND SAY, OKAY. NOW YOU'VE GOT TO GIVE US BACK 2 PERCENT ROYALTIES OR SOMETHING OF THAT NATURE. THE PROPORTIONALITY ISSUE OF THE INVESTMENT WITH REGARD TO WHAT IT TAKES TO MAKE THE PRODUCT IS A SIGNIFICANT ISSUE IN THE FOR-PROFIT SECTOR. TIME AND TIME AND TIME AGAIN WE HEARD THIS IN INTERVIEWS, IN PUBLIC MEETINGS, THROUGH PUBLIC COMMENT, WRITTEN PUBLIC COMMENT. THIS IS AN ISSUE.

THERE ARE MULTIPLE REVENUE TYPES, AS I EXPLAINED. LICENSING REVENUE, ALSO REVENUES FROM MARKETED PRODUCTS, SO WE HAD TO TAKE THAT INTO CONSIDERATION. EXTANT PATENTS. SO FAR I'VE TALKED TO YOU ABOUT WHAT IF CIRM FUNDS GO TO GIVE RISE TO A CIRM-FUNDED PATENTED INVENTION WHICH DIDN'T EXIST BEFORE? THAT'S EASY BECAUSE OUR NON-PROFIT POLICY LINKS EVERYTHING TO A PATENTED INVENTION. OUR

FOR-PROFIT POLICY WOULD BE REMISS IF IT DID ONLY THAT BECAUSE YOU CAN IMAGINE IF YOU LOOK AT THE PRODUCT DEVELOPMENT BOX THERE, WE'RE TALKING ABOUT CLINICAL TRIALS. IF WE WERE TO GIVE A COMPANY A MILLION DOLLARS TO DO A CLINICAL TRIAL, AND THEY WERE PROSECUTING THEIR EXTANT INTELLECTUAL PROPERTY, THEIR OWN PATENTS, THEN IF WE LINKED IT STRICTLY TO A PATENT, WE WOULDN'T NECESSARILY EXPECT A PATENT TO BE CREATED DURING A CLINICAL TRIAL. WE EXPECT A CLINICAL TRIAL TO BE CREATED DURING CLINICAL TRIALS.

SO IN THAT CASE WE HAD TO BE VERY -- WE HAD TO BE COGNIZANT OF THE FACT THAT LINKING EVERYTHING TO A PATENTED INVENTION MAY SHORTCHANGE THE STATE IN THE WAY OF REVENUES RETURNED.

SHARING OF REAGENTS WE JUST TALKED ABOUT. IT'S A LITTLE BIT COMPLICATED BECAUSE IN THE CASE OF A FOR-PROFIT ENTITY, I TOLD YOU THAT THE NON-PROFIT POLICY SAYS YOU MUST SHARE WITHOUT AFFILIATION -- YOU CAN'T HAVE BIAS AS TO THE AFFILIATION OF THE REQUESTER. IN THE COMPANY SETTING, THAT'S EXTREMELY CHALLENGING BECAUSE THERE ARE OCCASIONS WHERE IF THEY WERE FORCED TO SHARE, THEIR COMPETITIVE EDGE WOULD BE LOST. THEY WOULD HAVE NO PRODUCT IN THE END IF THEY WERE FORCED TO SHARE THAT REAGENT. SO WE HAVE A VERY SUBTLE CHANGE IN THE POLICY THAT SAYS YOU NEED TO CONTACT US IF YOU

BELIEVE THAT SHARING WILL COMPROMISE YOUR COMPETITIVE ADVANTAGE. DOESN'T SAY WE'LL LET THEM GET AWAY WITH IT. IT SAYS THEY NEED TO CONTACT US.

ALSO OF GREAT CONCERN IN DEVELOPING THIS POLICY WAS THE ISSUE OF CONTRACTS, GRANTS, AND LOANS ARE ALL THINGS THAT THE FOR-PROFIT SECTOR CAN AVAIL THEMSELVES OF UNDER PROPOSITION 71. SO I'LL SHOW YOU NOW WHAT WE LOOKED AT IN TERMS OF PROPOSED PRINCIPLES AND HOW THEY WERE MODIFIED OVER THE SUMMER. YOU CAN SEE THE PROPOSED PRINCIPLES APPROVED BY THE TASK FORCE IN AUGUST SAY THE GRANTEES WILL OWN THEIR IP. THE PUBLICATION REQUIREMENTS WILL BE THE SAME AS THE NON-PROFIT POLICY. BIOMEDICAL MATERIALS RELATED TO PUBLICATIONS ALWAYS WILL BE SHARED AS THEY ARE IN THE NONPROFIT POLICY.

YOU CAN SEE GRAYED OUT THERE, WHICH IT WAS REJECTED, WAS THAT A COMMERCIAL ENTITY COULD CHOOSE AT THE TIME OF APPROVAL OF THEIR APPLICATION WHETHER THEY WOULD LIKE A GRANT OR A LOAN. SO THIS WAS A TOPIC FOR A LOT OF DEBATE. IT WAS REMOVED, SO OUR POLICY HAS NOTHING TO DO WITH LOANS AT THIS TIME.

IF THE COMMERCIAL ENTITY CHOOSES TO LICENSE, 17 PERCENT VERSUS 25 FOR ALL THE REASONS I EXPLAINED. FOR GRANTS, IF THE COMMERCIAL ENTITY CHOOSES TO DEVELOP, PAYBACK WILL BE CONDITIONED UPON SUCCESS WITH

A MULTIPLE OF FUNDING. NOW, WE'LL TALK ABOUT THAT IN DETAIL IN THE NEXT SLIDE. NOT A FLAT ROYALTY STRUCTURE. A MULTIPLE OF FUNDING.

LOANS, AGAIN, GRAYED OUT IN TERMS OF PAYBACK. THAT'S WHAT THAT MEANS. FOR GRANTS AND LOANS, A ONETIME BLOCKBUSTER PAYMENT OF X WILL BE RETURNED TO THE GENERAL FUND AFTER REVENUES EXCEED X. SO YOU CAN SEE WE HAD A LOT OF WORK TO DO AROUND THIS AREA. BUT A BLOCKBUSTER, WE WANTED TO MAKE SURE IF A PRODUCT DID REALLY WELL, WE WANTED TO MAKE SURE THAT THE STATE COULD BENEFIT FROM THAT TOO.

SO HERE'S THE TRICKY PART. I TALKED TO YOU A LITTLE BIT ABOUT THE PROPORTIONALITY ISSUE. FOR GRANTS WHERE CIRM FUNDING REPRESENTS MORE THAN WHAT PERCENT OF THE INVENTION OR PROJECT WOULD WE REQUIRE A COMPANY TO PROVIDE GOODS TO THE UNINSURED, PROVIDE PRODUCTS TO PEOPLE WHOSE PRODUCTS WILL BE PAID FOR IN CALIFORNIA WITH PUBLIC FUNDS? AT WHAT PERCENTAGE WOULD WE BE APPROPRIATELY ENABLED TO GET THE COMPANIES TO DO THAT? IF WE GAVE THEM $100,000 AND THEY SPENT 500 MILLION, IS THAT THE RIGHT PLACE TO BE? IS IT FIRST DOLLAR? IS IT 50 PERCENT? THIS IS WHERE ALL THE INTERVIEWS WITH OTHER FUNDING ENTITIES THAT FUND FOR-PROFIT SECTOR AND GET REVENUES WERE VERY HELPFUL.

SO LET'S TAKE A LOOK HERE JUST FOR

COMPARISON. THE NON-PROFIT, THEY LICENSE AND THE STATE PROPOSES TO GET 25 PERCENT OF THE REVENUES AFTER THE INVENTORS ARE PAID. THERE'S ALSO A PLAN FOR ACCESS. I'LL TELL YOU WHAT THAT IS IN A MINUTE. YOU MUST SHARE PUBLICATION-RELATED BIOMEDICAL MATERIALS. AND WE DON'T ANTICIPATE THAT A NON-PROFIT ENTITY WILL EVER DEVELOP A PRODUCT TO COMMERCIAL SUCCESS. UNDER THE FOR-PROFIT POLICY, LICENSING, AGAIN, 17 PERCENT RATHER THAN 25, BUT IT'S THE EXACT SAME AMOUNT BACK INTO THE GENERAL FUND. WE WANT IT TO BE FAIR UNDER THE TERMS OF LICENSING. ALSO REQUIRED IS AN ACCESS PLAN. I'LL GO INTO THAT IN DETAIL IN A MINUTE. SHARING OF PUBLICATION-RELATED BIOMEDICAL MATERIALS IS REQUIRED UNLESS SUCH SHARING CAN BE SHOWN TO DAMAGE THE COMPANY. THAT'S THE SLIGHT DIFFERENCE.

NOW, SELF-DEVELOPMENT IS POSSIBLE. NOT ONLY IS IT POSSIBLE, IT'S DESIRABLE FOR THE STATE OF CALIFORNIA. WE WOULD MUCH RATHER HAVE THESE COMPANIES DO WHAT'S CALLED FORWARD INTEGRATION. TAKE THAT INVENTION AND TAKE IT ALL THE WAY THROUGH RESEARCH, MANUFACTURING, AND MARKETING IN CALIFORNIA RATHER THAN LICENSE IT AWAY TO ANOTHER STATE. SO BECAUSE OF THAT, WE TIERED THE REVENUE SHARING STRATEGIES AROUND THAT CENTRAL TENET OF SELF-DEVELOPMENT.

SO I CAN TELL YOU BRIEFLY AND THEN I'LL SHOW

YOU ON THE NEXT SLIDE THAT THE EXPECTED RETURN IS PROPOSED AT A CAPPED THREE TIMES THE AMOUNT OF THE GRANT. IF WE GIVE YOU A MILLION DOLLARS, IF YOUR PRODUCT IS SUCCESSFUL IN THE END, WE'LL EXPECT $3 MILLION BACK. HOWEVER, IF YOUR PRODUCT IS EXTREMELY SUCCESSFUL, AND THAT IS IT ACHIEVES A STATUS OF $250 MILLION PER YEAR, YOU WILL OWE THE STATE ANOTHER THREE TIMES THE INVESTMENT FOR A SIX TIMES RETURN ON THE INVESTMENT. IF IT MAKES THE $500,000 REVENUE MARK PER YEAR, THEN ANOTHER THREE TIMES, FOR A TOTAL OF NINE TIMES THE ORIGINAL INVESTMENT IS WHAT'S REQUIRED.

NOW, THERE'S A LITTLE BIT OF ANOTHER COMPLICATION HERE, AND I'LL SHOW YOU THIS AGAIN, AS I MENTIONED, ON THE NEXT SLIDE IN DIAGRAMMATIC FORM. IF CIRM INVESTED MORE THAN $5 MILLION AND THERE'S A CIRM-FUNDED PATENTED INVENTION INVOLVED, THEN OVER $500 MILLION THERE WILL BE 1-PERCENT ROYALTY FOR THE LIFE OF THE PATENT. THIS, AGAIN, IS TO MAXIMIZE THE RETURN TO THE STATE IN THE EVENT THAT SOMETHING DOES WELL AND IN THE EVENT THAT CIRM INVESTED SIGNIFICANTLY.

SO, LASTLY, THERE YOU CAN SEE THAT THE ACCESS TRIGGER IS AT FIRST DOLLAR. WHAT THAT MEANS IS IF YOU'RE A COMPANY AND YOU TAKE $1 OF CIRM FUNDS AND THAT GOES ON TO CREATE A MARKETED PRODUCT THAT BRINGS IN REVENUES, BECAUSE YOU SPENT $1, YOU MUST PROVIDE ACCESS

TO UNINSURED AND YOU MUST PROVIDE GOODS AT DISCOUNT PRICES TO CALIFORNIANS WHOSE THERAPIES WILL BE PURCHASED IN CALIFORNIA WITH PUBLIC FUNDS.

SO HERE IT IS A LITTLE BIT MORE LAID OUT IN BLACK AND WHITE. FOR THE FOR-PROFIT ENTITIES, IF THEY LICENSE IT AWAY, THE LICENSEES MUST PROVIDE THOSE COMMERCIAL PRODUCTS TO -- THERE MUST BE A PLAN TO PROVIDE THOSE COMMERCIAL PRODUCTS TO UNINSURED CALIFORNIANS. ALSO, THE FOR-PROFIT RESEARCHERS THEMSELVES MUST DO THE SAME THING, NOT JUST FOR LICENSEES, BUT THEY MUST ALSO DO IT IF THEY SELF-DEVELOP A PRODUCT.

LICENSEES OF PATENTED INVENTIONS MUST ALSO PROVIDE THOSE COMMERCIAL PRODUCTS AT A DISCOUNT PRICE FOR CALIFORNIANS. THAT'S FOR LICENSEES. ALSO, THE FOR-PROFIT COMPANIES THEMSELVES DO THAT IF THEY SELF-DEVELOP A PRODUCT.

SO IF YOU LOOK AT THE DIAGRAM I'M ABOUT TO SHOW YOU, YOU CAN SEE THAT THERE ARE A BUNCH OF DIFFERENT VARIABLES THAT WERE FACTORED INTO THE REVENUE SHARING SCHEME, WHETHER IT'S EXTANT PATENT PROSECUTION OR CIRM-FUNDED PATENT PROSECUTION, LICENSING VERSUS SELF-DEVELOPMENT. A TIER FOR SUCCESS. IF THERE'S A BLOCKBUSTER PRODUCT, THE STATE WILL GET MORE. THERE'S ALSO AN INVESTMENT THRESHOLD WITH REGARD TO WHETHER

IT'S A SIGNIFICANT INVESTMENT, $5 MILLION OR LESS. AND THAT'S ALSO, THIS IS AN IMPORTANT POINT, THAT THIS POLICY PROVIDES AN OPPORTUNITY FOR A CAPPED RETURN, WHICH IS WHAT COMPANIES NEED. THEY NEED CERTAINTY IN ORDER TO INVEST -- IN ORDER TO ATTRACT OTHER INVESTORS TO FURTHER THE PROGRESS OF THEIR PRODUCTS ALONG THAT DEVELOPMENT PATH. BUT THERE'S ALSO AN UNCAPPED ASPECT TO THIS TOO. IT'S UNCAPPED WITH REGARD TO LICENSING, JUST LIKE THE NONPROFITS, AND IT'S UNCAPPED IN THE EVENT THAT THERE IS A PATENT INVOLVED IN TERMS OF A 1-PERCENT ROYALTY.

LET'S TAKE A LOOK AT THIS DIAGRAM I TOLD YOU ABOUT JUST TO MAKE SURE THAT WE ALL UNDERSTAND HOW THIS WORKS. SO FOR-PROFIT GRANTEES WILL RETURN THREE TIMES THE TOTAL GRANT AWARD AFTER REVENUES EXCEED $500,000. THIS IS JUST LIKE FOR NONPROFITS. NONPROFITS ARE ALLOWED TO KEEP $500,000 TO RECOVER COST FOR THE PATENTING, AND THEN THEY GIVE US THEIR 25 PERCENT. SO THAT COMES FROM THE EARLIER PROVISIONS FROM THE NONPROFIT POLICY. IF BLOCKBUSTER STATUS IS ACHIEVED, LOOK TO THE LEFT, AND THERE'S LESS THAN $5 MILLION INVESTED, IT WILL BE $250 MILLION PER YEAR AS A BLOCKBUSTER. THAT'S EQUIVALENT TO ANOTHER THREE TIMES EXPECTATION. AND OVER 500 MILLION PER YEAR, SAME THING, FOR A TOTAL OF NINE TIMES THE RETURN IF LESS

THAN FIVE MILLION IS INVESTED.

ON THE RIGHT SIDE, IF MORE THAN FIVE MILLION IS INVESTED AND THERE ARE NO CIRM-FUNDED PATENTS INVOLVED, IT'S THE SAME AS IT IS FOR THE LEFT-HAND SIDE. IF FIVE MILLION IS INVESTED OR MORE, AND IF THERE'S A CIRM-FUNDED PATENT INVOLVED, THEN YOU CAN SEE THE REVENUE STRUCTURE IS EXACTLY THE SAME WITH ONE DIFFERENCE. THAT IS, OVER $500 MILLION PER YEAR, THERE'S A 1-PERCENT ROYALTY ON EVERYTHING OVER 500 MILLION FOR THE LIFE OF THE PATENT. SO THIS IS A COMPLICATED REVENUE SHARING SCHEME. WE THINK THAT IT TAKES INTO ACCOUNT THE LICENSING REVENUES THAT COMPANIES WILL GET, THE SELF-DEVELOPED PRODUCT REVENUES THAT COMPANIES WILL GET, AND IT TAKES INTO ACCOUNT THE MANY VARIABLES, CIRM'S INVESTMENT, WHETHER THERE WAS A PATENT INVOLVED OR NOT, ETC. SO THERE ARE A NUMBER OF VARIABLES THAT GAVE RISE TO THIS RATHER COMPLICATED BUT, WE THINK, FAIR SCHEME.

DR. TAYLOR: IS THAT 1 PERCENT INDEPENDENT OF THE PROPORTIONALITY OF FUNDING THAT CAME FROM CIRM?

DR. MAXON: THAT'S AN EXCELLENT QUESTION. IT CAN'T BE. SO IF WE FUND IT ALL, THEN WE GET ALL OF 1 PERCENT. BUT IF WE FUNDED 10 PERCENT OF IT AND THE COMPANY FUNDED THE 10 PERCENT, IT GETS REALLY TRICKY. SO WE DO HAVE THE RIGHT FOR ACCOUNTING OF ALL OF THESE

THINGS, WHETHER THERE'S PROPORTIONALITY OF CIRM'S INVESTMENT INTO PROJECTS IS EXPECTED THROUGH COMPANIES AND CIRM'S AUDITING FUNCTION WITH RESPECT TO REVENUES THAT COME IN. SO WE WILL KNOW UP FRONT BEFORE THIS THING EVER MAKES IT TO A PATENTED INVENTION HOW MUCH OF CIRM'S MONEY WENT INTO THAT PATENTED INVENTION BASED ON THEIR DISCLOSURES, AND WE CAN AUDIT IT AT THAT STAGE OF THE GAME TO MAKE SURE WAY BEFORE IT GETS TO A MARKETED PRODUCT THAT THE NUMBERS MAKE SENSE.

SO THE ACCESS PLAN. AT THE TIME OF COMMERCIALIZATION, FOR-PROFIT GRANTEES WILL PROVIDE A PLAN FOR ACCESS TO RESULTANT THERAPIES FOR UNINSURED CALIFORNIA RESIDENTS. I MENTIONED THIS ALREADY. THIS IS TRUE FOR LICENSEES. THIS IS TRUE FOR COMPANIES THAT GO THROUGH AND DEVELOP THESE THINGS THEMSELVES. THEY MUST ALSO PROVIDE DISCOUNT PRICING FOR THERAPIES TO CALIFORNIA RESIDENTS WHOSE THERAPIES WILL BE PURCHASED WITH PUBLIC FUNDS. HERE'S SOMETHING I HAVEN'T MENTIONED TO YOU. IN THE UNFORTUNATE EVENT OF LIMITED THERAPEUTIC AVAILABILITY, PREFERENCE WILL BE GIVEN TO CALIFORNIA RESIDENTS WHEREVER POSSIBLE. THAT'S ANOTHER WAY THAT CALIFORNIANS CAN BENEFIT THROUGH THIS ACCESS PLAN. AND THE ABOVE ACCESS REQUIREMENTS ARE TRIGGERED AS A CONSEQUENCE OF FIRST DOLLAR SPENT. SO THAT'S IN SUMMARY WHAT THE ACCESS PLANS LOOK LIKE.

AT THE TIME OF THE TASK FORCE DISCUSSIONS, THERE WERE A NUMBER OF THINGS THAT NEEDED TO BE CLARIFIED. SO WHY IS THERE A CAP ON THE FOR-PROFITS AND NO CAP ON THE NONPROFITS? HOPEFULLY I'VE EXPLAINED THAT. IT'S NOT STRICTLY TRUE. THAT'S NOT STRICTLY TRUE. THERE IS A CAP FOR THE THREE TIMES INVESTMENT. THERE IS NO CAP ON LICENSING REVENUES JUST LIKE FOR THE NONPROFITS. IT'S EXACTLY THE SAME.

WHY IS THERE 17-PERCENT RETURN, AND IS IT RELATED TO THE $500,000 THRESHOLD? SO IT'S 17 PERCENT INSTEAD OF 25 PERCENT BECAUSE IT'S EQUIVALENT TO THE SAME AMOUNT INTO THE GENERAL FUND. AGAIN, FAIRNESS ACROSS OUR GRANTEES. IT IS AFTER THE $500,000 THRESHOLD. AGAIN, JUST LIKE FAIRNESS TO THE NON-PROFIT GRANTEES.

WHAT IF THE REQUEST FOR PUBLICATION-RELATED BIOMEDICAL MATERIAL COMES FROM A COMPETITOR? DOESN'T MATTER. YOU HAVE TO SHARE IT UNLESS YOU CAN MAKE A CASE TO THE CIRM THAT THERE IS A REAL DANGER THAT YOUR COMPANY WILL BE DAMAGED AS A CONSEQUENCE OF THIS.

WHO REVIEWS AND APPROVES EXCLUSIVE LICENSES BY AWARDEES? CIRM DOES NOT. THOSE CONFIDENTIAL DETAILS ARE KEPT WITHIN THE LICENSEE AND THE GRANTEE. THOSE DETAILS ARE COMPETITIVE -- ARE UNDER A CONFIDENTIALITY AND ARE STRICTLY KEPT BETWEEN THE TWO.

WE'RE NOT THE THIRD PARTY THAT LOOKS AT OR APPROVES THEM.

IS THE BLOCKBUSTER PAYMENT THE RIGHT SIZE? WHO KNOWS? BUT SO FAR IT SEEMS TO BE. BLOCKBUSTERS, BY THE WAY, FOR DRUGS ARE ON THE ORDER OF A BILLION DOLLARS. WE THINK FOR CELLULAR THERAPIES, IT'S HARD TO KNOW, SO OUR STAKE IN THE GROUND IS 250 MILLION PER YEAR.

THRESHOLD FOR ACCESS AND PRICING TRIGGER ON SELF-DEVELOPED PRODUCTS. $1, THAT'S THE THRESHOLD.

SO FURTHER DISCUSSION AND RESOLUTION, WE HAVE A BIG CHALLENGE. FIND AND FINALIZE LANGUAGE FOR A PRICING BENCHMARK. I SORT OF FINESSED THE WHOLE THING BY TELLING YOU THAT THEY HAVE TO PROVIDE THESE THINGS AT DISCOUNT PRICES. WELL, WHAT DOES THAT MEAN? IT MEANS THAT WE NEED TO FIND CLEAR LANGUAGE FOR THE REGULATIONS THAT WILL INFORM THE REGULATED COMMUNITY WHAT THEY NEED TO DO IN TERMS OF PRICING FOR THOSE PRODUCTS.

ORIGINALLY WE STARTED WITH THE FEDERAL MEDICAID PRICE. SOUNDED RIGHT. NOT TO EXCEED FEDERAL MEDICAID PRICE. WE THOUGHT THIS IS GREAT. WE CAN TAG ONTO SOMETHING THAT EXISTS ALREADY IN THE FEDERAL INFRASTRUCTURE AND IT MAKES SENSE FOR THE FEDERAL GOVERNMENT. WE CAN USE SOMETHING SIMILAR. HUGE

AMOUNTS OF HOMEWORK ON SCOTT'S PART HAVE DETERMINED THAT THE FEDERAL MEDICAID PRICE IS NOT A WORKABLE SOLUTION UNFORTUNATELY AND HERE'S WHY.

FEDERAL MEDICAID PRICE, THIS IS A LITTLE BIT COMPLICATED, SO I'M GOING TO TRY TO SIMPLIFY IT. IF I GET INTO TROUBLE, SCOTT'S HERE. HE KNOWS WAY MORE ABOUT THIS THAN I DO.

FEDERAL MEDICAID PRICE IS CALCULATED LONG AFTER THE PRODUCT IS SOLD. BASICALLY THAT MEANS EVEN IF WE WANTED THE REGULATED COMMUNITY, THE COMPANY, TO PROVIDE THE FEDERAL MEDICAID PRICE FOR A PRODUCT, THEY CAN'T DO IT BECAUSE TODAY IN TIME THERE IS NO SUCH THING. IT'S CALCULATED AFTER THE FACT. AND IT'S A FORMULA THAT EXISTS IN FEDERAL STATUTES, AND IT'S DEPENDENT ON A LARGE NUMBER OF THINGS. IT'S DEPENDENT ON HAVING A SIGNIFICANT FEDERAL HEALTHCARE DELIVERY SYSTEM INFRASTRUCTURE TO DO THIS. SO THAT'S A BIG CONSIDERATION FOR CIRM.

WHAT THAT INFRASTRUCTURE DOES IS SURVEYS A LOT OF DIFFERENT PURCHASERS TO FIND OUT WHAT DID THEY BUY THAT PRODUCT FOR? THEN THEY CALCULATE AN AVERAGE MANUFACTURER'S PRICE. ONCE THAT AVERAGE MANUFACTURER'S PRICE IS CALCULATED, THEN THE FEDERAL GOVERNMENT TAKES A 15.1-PERCENT REDUCTION CALCULATION ON THAT, AND THEN LOOKS AT THAT NUMBER AND TAKES INTO ACCOUNT THE

CONSUMER PRICE INDEX TO UNDERSTAND WHETHER A FURTHER REBATE NEEDS TO BE ADDED. AND FINALLY, THERE'S A REBATE FROM THE MANUFACTURER TO THE FEDERAL GOVERNMENT. HAPPENS LONG AFTER THE DRUGS OR PRODUCTS HAVE BEEN SOLD.

SO THAT'S PART OF THE PROBLEM WITH FEASIBILITY. THE FEDERAL MEDICAID PRICE TODAY DOESN'T EXIST. IT WILL EXIST RETROSPECTIVELY ESSENTIALLY.

ANOTHER PROBLEM IS IF OUR REGULATION, AND IT DOES, SAYS THAT THIS IS ELIGIBLE FOR PEOPLE WHOSE THERAPIES WILL BE PURCHASED IN CALIFORNIA WITH PUBLIC FUNDS, THERE'S NO WAY UNDER THIS FEDERAL MEDICAID PRICE FOR THE ELIGIBILITY REQUIREMENT TO BE MET BY THE REGULATED PARTY. IT'S JUST NOT GOING TO WORK. AND SO CIRM IS LOOKING TO A STATE SYSTEM SUCH AS CALRX TO HELP US OUT WITH THIS. WE THINK THAT'S A GOOD SOLUTION, BUT IT ONLY WORKS FOR DRUGS. WE'RE TALKING ABOUT DRUGS AND NONDRUG THERAPIES. SO WE STILL HAVE A LOT OF WORK TO DO TO TRY TO FIGURE OUT HOW CAN WE PROVIDE CLEAR LANGUAGE TO THE REGULATED COMMUNITY SUCH THAT THEY WILL BE ABLE TO PROVIDE NONDRUG THERAPIES, CELLULAR THERAPIES, TO PEOPLE IN CALIFORNIA WHOSE THERAPIES WILL BE PURCHASED WITH PUBLIC FUNDS. WE ARE WORKING VERY HARD TO DO THAT.

SCOTT ORGANIZED AN INTERESTED PARTIES MEETING

IN SACRAMENTO ON APRIL 9TH, AND WE GOT TO HEAR FROM A LOT OF PEOPLE HOW CAN WE HELP WORK ON THIS LANGUAGE TO MAKE IT WORK.

I'M GOING TO SHIFT GEARS UNLESS YOU HAVE SOME QUESTIONS ABOUT THE POLICIES.

DR. KIESSLING: HAVE ANY FOR-PROFIT ENTITIES SIGNED ONTO THIS AS A CONCEPT? I'M BEGINNING TO WONDER WHY A FOR-PROFIT ENTITY IN CALIFORNIA WOULD WANT CIRM MONEY.

DR. MAXON: THAT'S EXACTLY THE QUESTION. HAVE THEY SIGNED ONTO THIS? IN GENERAL, FOR-PROFIT COMPANIES DON'T LIKE PRICING REGULATIONS. AND THEY'RE PRETTY MUCH SPLIT 50-50. 50-50 IS AN EXAGGERATION. THEY'RE SPLIT ON THE ISSUE OF ACCESS. SOME OF THEM ARE MORE THAN HAPPY TO DO IT. THEY HAVE HUGE PROGRAMS BUILT FOR PATIENT ASSISTANCE. SOME OF THEM DON'T HAVE A PRODUCT YET, AND THEY DON'T HAVE ANY IDEA ABOUT IT, AND THEY CAN'T PREDICT TODAY WHAT THAT'S GOING TO COST THEM IN THE LONG RUN, SO THEY'RE AVERSE, THEY'RE RISK AVERSE. THEY'RE AFRAID OF IT.

SO WHEN YOU THINK ABOUT THIS STACKED REQUIREMENTS THAT WE'RE PUTTING ON THEM, WE ARE VERY CAREFUL, AS I SAID, TO GET A LOT OF INPUT FROM THE FOR-PROFIT COMPANIES TO UNDERSTAND WHAT IS TOLERABLE TO THEM BECAUSE, AS YOU KNOW, WE NEED THEM TO CREATE THE

PRODUCTS. YOU CAN'T MAKE A PRODUCT WITHOUT A FOR-PROFIT RESEARCH COMPANY. SO HOW DO WE ENSURE THAT THIS WILL WORK? WELL, WE LISTENED TO THEM, WE TALKED TO THEM, WE TAKE THEIR PUBLIC COMMENT, WE CONSIDER IT VERY CAREFULLY, AND WE HOPE THAT WE'VE DONE THE RIGHT THING.

DR. KIESSLING: I THINK THIS IS A FABULOUS MODEL. I'M JUST WONDERING, I'M JUST CURIOUS. HAS ANY COMPANY COME FORTH AND SAID, "I CAN HARDLY WAIT TO GET YOUR MONEY"?

DR. MAXON: COMPANIES HAVE COME FORWARD PUBLICLY IN MEETINGS AND IN NEWSPAPER ARTICLES AND SAID WE CAN LIVE WITH WHAT THE CIRM HAS PROPOSED.

MORE QUESTIONS BEFORE I SHIFT GEARS?

DR. KIESSLING: THERE'S NO LINE FORMING?

DR. MAXON: I WOULD SAY A LINE FORMING WOULD BE AN EXAGGERATION.

DR. TAYLOR: NUMBER OF APPLICATIONS, FOR EXAMPLE, AS AN INDICATION.

DR. MAXON: TO DATE WE HAVE NOT OPENED ANY OF THE RFA'S FOR FOR-PROFITS BECAUSE WE DIDN'T YET HAVE -- TWO PIECES ARE LACKING, A FOR-PROFIT POLICY, WHAT TO DO WITH THE INTELLECTUAL PROPERTY AND HOW TO HANDLE THE REVENUE SHARING. AND A FOR-PROFIT GRANTS ADMINISTRATION POLICY IS VERY DIFFERENT THAN A

NONPROFIT GRANTS ADMINISTRATION POLICY. SO WE NEED THOSE TWO PIECES. WE'RE VERY -- WE NOW HAVE AS OF DECEMBER -- THE POLICY THAT WAS APPROVED IN DECEMBER FOR FOR-PROFIT IP ALLOWS COMPANIES TO APPLY, IF THEY WANT TO, BUT I THINK THEY'RE GOING TO BE VERY CAREFULLY WATCHING HOW THESE REGULATIONS TAKE SHAPE OVER THE NEXT FEW MONTHS. I'M HOPING THAT WE'LL GET A LOT OF HELP FROM THEM TO MAKE THE REGULATIONS FAIR TO THE STATE AND TOLERABLE TO THE FOR-PROFITS. IT'S A BIG CHALLENGE, ESPECIALLY AS I MENTIONED WITH THAT NONDRUG THERAPIES LANGUAGE FOR PRICING.

MR. SHEEHY: I WAS JUST GOING TO ADD. THERE WAS SUBSTANTIAL FOR-PROFIT INPUT. SO THE IP TASK FORCE INCLUDED PEOPLE FROM INDUSTRY. AND IF YOU LOOK AT IT, THE ACCESS PLANS ARE SELF-GENERATED. IF YOU LOOK AT MOST DRUGS, I SAW A LIST OF ABOUT 150 DRUGS THAT ARE PROVIDED THROUGH EXPANDED ACCESS PROGRAMS FOR PEOPLE WITH HIV. SO I THINK IT'S KIND OF THE RULE OF THUMB IN TERMS OF ACCESS, SO I DON'T THINK THAT'S A PROBLEM.

THIS IS THE BIGGEST STICKING POINT IS THIS PRICING THING AND WHY WE'RE KIND OF BOGGED DOWN. BUT I THINK THE REST OF IT IS ACTUALLY QUITE REASONABLE. AT LEAST FROM THE INDUSTRY PEOPLE WE'VE HEARD FROM, THERE DOES NOT SEEM TO BE A LOT OF -- ONCE YOU START MAKING TONS OF MONEY, KICKING A LITTLE BIT BACK TO THE STATE

ISN'T THAT BIG OF A DEAL.

DR. KIESSLING: I THINK THE BOTTOM LINE -- I THINK THIS IS VERY INTERESTING AND WONDERFUL. I THINK THE BOTTOM LINE IS DO THESE COMPANIES NEED CIRM MONEY, OR ARE THEY GOING TO BE ABLE TO GET VENTURE CAPITAL ON THEIR OWN?

MR. SHEEHY: THERE'S A COUPLE OF PLACES. ONE PLACE THAT WE'VE IDENTIFIED FAIRLY EARLY ON IS THIS SO-CALLED VALLEY OF DEATH BETWEEN PRECLINICAL AND CLINICAL DEVELOPMENT. AND THERE SEEMED A LOT OF INTEREST IN HEARINGS WE HAD THAT WERE JOINTLY TO INFORM THE INTELLECTUAL PROPERTY TASK FORCE AND THE STRATEGIC PLAN WHERE THEY SAID THEY'D BE QUITE HAPPY TO GET SOMEWHERE IN THE RANGE OF TWO TO $10 MILLION TO KIND OF MAKE THAT LEAP.

DR. KIESSLING: BECAUSE IT SORT OF SHARES THE RISK.

DR. MAXON: AS JEFF POINTED OUT, THAT WAS THE ONE THING ON WHICH THEY ALL AGREED. THEY SAID IF YOU COULD GIVE US TWO OR FIVE OR $10 MILLION TO GET PROOF OF CONCEPT, THE VENTURE CAPITAL DOLLARS WILL FLOW. AT THAT POINT, YOU CAN SEE WHERE IF WE GAVE TWO OR FIVE OR $10 MILLION TO A COMPANY WHO IS PROSECUTING THEIR OWN INTERNALLY GENERATED INTELLECTUAL PROPERTY, WE HAVE A PROBLEM IF WE LINK ALL OF THE OTHER REVENUE SHARING

WITH INTELLECTUAL PROPERTY PER SE THAT WE'VE CREATED. SO THAT WAS EXACTLY THE POINT WHERE THEY SAID THIS IS HOW YOU COULD FLOAT ALL BOATS, AND THAT'S THE POINT WHERE WE SAID, HMM, WE HAVE TO UNLINK IT FROM INTELLECTUAL PROPERTY. THAT'S WHY.

OKAY. SO GEOFF HAS ASKED ME TO QUICKLY TALK ABOUT A COUPLE OF OTHER THINGS THAT THE IP TEAM IS WORKING ON. THE INTERSTATE ALLIANCE FOR STEM CELL RESEARCH IS A COLLABORATIVE -- WE'RE COLLABORATING WITH THIS ENTITY, AND THE FORMATION OF THIS GROUP WAS INITIATED BY THE STATE OF CONNECTICUT IN MARCH OF THIS YEAR. ITS GOAL IS TO FOCUS ON AWARENESS AND COMPATIBILITY OF STATE POLICIES AND REGULATIONS SO THAT THE RESEARCHERS IN DIFFERENT STATES CAN COLLABORATE.

SO AS IT RELATES TO OUR TEAM, I'M SURE GEOFF IS GOING TO TELL YOU MORE ABOUT THIS AS IT RELATES TO THE WORK THAT YOU DO, IN THE ABSENCE OF ANY NATIONAL OR INTERNATIONAL GUIDANCE ON THIS WHOLE IP THING, THE IP ISSUES ARE A BIG BLACK BOX. REVENUE SHARING, OPEN ACCESS, RESEARCH EXEMPTION, WHAT ARE THESE THINGS AND WHY IS CALIFORNIA THINKING ABOUT THEM, AND SHOULD WE AS OTHER STATES BE THINKING ABOUT THEM?

THE NATIONAL ACADEMIES IS HOSTING LATER THIS MONTH A MEETING WITH THIS COALITION OF STATES TO DRILL DOWN ON SOME OF THESE IMPORTANT AREAS, INCLUDING

INTELLECTUAL PROPERTY AND MEDICAL AND ETHICAL STANDARDS. I'LL BE THERE REPRESENTING THE STATE OF CALIFORNIA TO TELL THEM THIS IS WHAT A RESEARCH EXEMPTION IS. THESE ARE THE COMPONENTS OF IT. THESE ARE THE PROS AND CONS OF HAVING ONE. THIS IS THE ISSUE SURROUNDING OPEN ACCESS FOR YOUR GRANTEES. THESE ARE REVENUE SHARING STRATEGIES. CALIFORNIA CAN'T TAKE EQUITY, BUT YOUR STATES CAN. SO LISTEN TO WHAT WE DID AND DO WHATEVER YOU CAN WITH BEST PRACTICES. THAT'S THE WORK THAT WE'RE DOING WITH THAT ALLIANCE IN THE AREA OF INTELLECTUAL PROPERTY.

AND LASTLY, THE OTHER THING THAT WE'RE DOING IS WORKING ON UNDERSTANDING A NEW BILL, SB 771, WHICH IS SPONSORED BY SENATORS KUEHL AND RUNNER. AND SPECIFICALLY THIS BILL DRAWS UPON SOME OF THE COMPONENTS OF OUR IP POLICY AND TAKES SPECIFIC COMPONENTS OUT FOR LEGISLATION.

FOR-PROFIT GRANTEES, THIS BILL PROPOSES TO HAVE AN UNCAPPED 2- TO 5-PERCENT ROYALTY REQUIREMENT FOR FOR-PROFIT GRANTEES. WE CAN TALK ABOUT THAT IF YOU WANT TO. FEDERAL MEDICAID PRICE BENCHMARK FOR CIRM PRODUCTS PURCHASED WITH PUBLIC FUNDS IN CALIFORNIA. WE KNOW FROM OUR RESEARCH THAT THAT'S PROBABLY NOT GOING TO WORK, AND THAT'S EMBODIED IN THIS LEGISLATION. IT ALSO REQUIRES A PLAN FOR ACCESS TO CIRM-FUNDED PRODUCTS

BY THE UNINSURED AT THE TIME OF THE LICENSE AS OPPOSED TO AT THE TIME OF COMMERCIALIZATION. THIS DOESN'T SOUND LIKE A BIG DEAL, BUT IT IS. IT'S VERY HARD AT THE TIME THAT A LICENSE IS MADE TO KNOW WHAT THAT ACCESS PLAN MIGHT LOOK LIKE SINCE YOU DON'T EVEN KNOW WHAT THE DRUG MIGHT BE OR WHAT THE THERAPY MIGHT BE.

SO THE LAST THING THAT IT CALLS UPON THAT I'LL CALL OUT IS THE 25 PERCENT VERSUS 17 PERCENT. THIS PIECE OF LEGISLATION STRIVES TO GET 25 PERCENT FROM THE FOR-PROFITS JUST LIKE 25 PERCENT FROM THE NONPROFITS. SO CURRENTLY -- KIRK, CORRECT ME IF I'M WRONG -- THIS BILL HAS PASSED THE SENATE HEALTH COMMITTEE, IT'S PASSED THE JUDICIARY COMMITTEE, AND IT'S UP ON MONDAY FOR THE SENATE APPROPRIATIONS COMMITTEE. SO IT'S MOVING. AND WE'RE WORKING VERY HARD MEETING WITH LEGISLATORS TO INFORM THEM ABOUT THE VERY COMPLICATED ASPECTS OF THE PROPOSED COMPONENTS OF OUR IP POLICY AND TRYING TO EDUCATE THEM AS TO WHY SOME OF THESE THINGS MAY OR MAY NOT BE FEASIBLE.

DR. TAYLOR: WOULD THIS BILL TRUMP YOUR POLICY THEN?

DR. MAXON: YES. THAT'S IT FOR MY REPORT UNLESS YOU HAVE ANY MORE QUESTIONS.

MR. SHEEHY: IT TRUMPS IF IT'S PASSED BY 70 PERCENT OF THE LEGISLATURE AND SIGNED BY THE GOVERNOR.

THE THRESHOLD IS A BIT HIGH IS THE ONLY POINT I'D MAKE ABOUT THAT LEGISLATION.

DR. PETERS: TWO SEPARATE QUESTIONS, BUT THEY OVERLAP. HOW FAR UPSTREAM DO YOU EXPECT A GRANT TO PERMIT INTELLECTUAL PROPERTY APPLICATIONS? FOR EXAMPLE, IF A UNIVERSITY ESTABLISHES A NEW CELL LINE, IN YOUR JUDGMENT WILL THAT BE PATENTABLE?

THEN SECONDLY, WHAT SCENARIO ARE YOU WORKING WITH IN TERMS OF CALIFORNIA GRANTEES USING WARF EXISTING PATENTS AND LICENSES AND THAT KIND OF THING? WHAT LEVEL OF COMPLICATION ARE YOU EXPECTING THERE?

DR. MAXON: SO THE TASK THAT THE IP TASK FORCE FACED AND CONTINUES TO FACE IS THE DEVELOPMENT OF POLICIES FOR CIRM GRANTEES. THE DEVELOPMENT OF POLICIES IS SEPARATE FROM FREEDOM TO OPERATE. SO WE'VE BEEN VERY CAREFUL TO KEEP OUR EFFORTS FOCUSED ON DEVELOPMENT OF POLICIES.

WITH RESPECT TO YOUR FIRST QUESTION, YOU ASKED IF A UNIVERSITY CREATES A STEM CELL LINE, WOULD THAT BE PATENTABLE? ONLY A PATENT OFFICE OFFICIAL REALLY WOULD KNOW THAT. DOES IT PASS THE CRITERIA FOR NOVELTY AND UTILITY AND ALL THIS? SO I WOULDN'T BE BRAVE ENOUGH TO ANSWER THAT QUESTION.

DR. PETERS: THAT WAS NOT A TECHNICAL QUESTION. ARE YOU ENCOURAGING UPSTREAM AS OPPOSED TO

LIMITING JUST DOWNSTREAM?

DR. MAXON: I WOULD SAY THAT ENCOURAGING IS A STRONG WORD. I WOULD SAY THAT THE POLICY ALLOWS FOR THE UNIVERSITIES TO MAKE THEIR OWN DECISIONS. SO THEY --

DR. PETERS: LET ME JUST ASK. WHEN YOU MADE THAT DECISION, WAS IT DISCUSSED IN THE IP COMMITTEE WHETHER OR NOT THIS MIGHT EVENTUALLY RAISE THE PRICE OF THE DELIVERABLE PRODUCTS AT THE FAR END? HOW MUCH DID ACCESS PLAY A ROLE IN THAT KIND OF DECISION-MAKING?

DR. MAXON: I WOULD REFER TO JEFF FOR HIS RECOLLECTION, BUT WHAT I CAN TELL YOU IS THAT WE WORKED PRETTY HARD TO TRY TO EMPLOY A RESEARCH USE EXEMPTION FOR THAT VERY PURPOSE, FOR ACCESS TO PATENTED INVENTIONS IN CALIFORNIA, NOT JUST FOR CIRM GRANTEES, BUT FOR ALL RESEARCHERS IN CALIFORNIA. AND IT DIDN'T FLY. IT FAILED. SO WITH REGARD TO DISCUSSIONS ABOUT THE PRICE, I DON'T REMEMBER SPECIFIC CONVERSATIONS ABOUT PATENTING UPSTREAM INVENTIONS AND WHETHER OR NOT THAT WOULD OR WOULDN'T INCREASE THE PRICE. IT DOES POSSIBLY CONTRIBUTE TO ROYALTY STACKING, BUT I THINK THAT PATENTING OF EMBRYONIC STEM CELL LINES, WHO KNOWS TODAY WHETHER THAT'S ACTUALLY GOING TO BE AN AREA THAT THE PATENT OFFICERS ARE GOING TO LOOK AT. I THINK THE HURDLE IS PRETTY HIGH.

DR. PETERS: OKAY. WHAT'S YOUR SCENARIO? WHAT DO YOU PREDICT IS GOING TO HAPPEN OVER THE NEXT COUPLE OF YEARS WITH REGARD TO CALIFORNIA AND WARF?

DR. MAXON: SO THE WAY THAT WE VIEWED THE FREEDOM TO OPERATE ISSUE IS WE VIEW OUR GRANTEES TO BE KNOWLEDGEABLE THIRD PARTIES REGARDING THEIR RIGHT TO USE RADIOACTIVE MATERIALS, ANIMALS, AND PATENTED INVENTIONS. SO OUR VIEW OF THAT IS WE GIVE GRANTS TO THE GRANTEES UNDER THE CONDITIONS THAT THEY HAVE PERMISSION TO DO THE WORK THEY'VE REQUESTED FUNDING FOR.

SO IF THEY HAVE ACTUALLY GOTTEN A MEMORANDUM OF UNDERSTANDING FROM WARF FOR USE OF THE TECHNOLOGIES, THAT'S REALLY UP TO THEM. JUST AS MY OWN SURVEY, MOST OF THEM HAVE.

DR. PETERS: SO YOU'RE EXPECTING NO DIFFICULTIES?

DR. MAXON: I'M AFRAID TO THINK ABOUT WHAT COULD HAPPEN, BUT I AM NOT EXPECTING VERY MANY DIFFICULTIES. WHAT WOULD YOU SAY, JEFF?

MR. SHEEHY: I DON'T KNOW ABOUT WARF. I WOULD SAY, YOU KNOW, THE WHOLE PRICING ISSUE IS AN EASY MARK, BUT I THINK PRICING IS -- YOU KNOW, ALL I HAVE IS THE EXPERIENCE OF HIV/AIDS. AND I THINK AZT JUST IN THE LAST YEAR WAS THE FIRST AIDS DRUG TO BECOME

GENERIC. PEOPLE PATENTED, THEY MADE A TON OF MONEY, THEN WE BEAT THE DAYLIGHTS OUT OF THEM TO MAKE THEM ACCESSIBLE. WE SEEM TO HAVE HAD SOME SUCCESS WITH THAT. I THINK ANY KIND OF FRONT-END PRICING SCHEME DETERS DEVELOPMENT AND IS NOT REALLY AN APPROPRIATE WAY TO APPROACH THAT, ESPECIALLY WHEN WE HAVE ABSOLUTELY NO IDEA WHAT THESE THERAPIES ARE GOING TO LOOK LIKE OR HOW THEY'RE GOING TO BE DEVELOPED.

JUST FROM A PATIENT POINT OF VIEW, THE KEY THING IS TO GET DEVELOPMENT AT THIS POINT. AND THEN, YOU KNOW, THIS IS A VERY ACTIVE PATIENT COMMUNITY COVERING A WHOLE RANGE OF DISEASES. AND I THINK THAT THERE'S ENOUGH FORCE THERE TO CREATE THE KIND OF MORAL SUASION THAT WE HAVE SEEN IN OTHER DISEASES TO PROVIDE BETTER ACCESS AT THAT POINT. BUT RIGHT NOW GETTING INTO PRICING ISSUES SEEMS TOUGH.

THE WARF PATENTS HAVE BEEN CHALLENGED AND SEEM TO BE ON FAIRLY SHAKY GROUND IN PART THANKS TO ONE OF OUR ERSTWHILE ADVERSARIES AND COLLABORATORS, THE FOUNDATION FOR CONSUMERS AND TAXPAYER RIGHTS. THEY'VE DONE ACTUALLY AN EXTRAORDINARY JOB OF PARTICIPATING IN THE PROCESS AND HOLDING US ACCOUNTABLE, BUT AT THE SAME TIME DOING A BIT OF ADVOCACY FOR US UNBIDDEN TO TAKE ON THE WARF PATENTS. SO IT'S BEEN A VERY SUCCESSFUL KIND OF THING FOR US SO FAR THAT WE DIDN'T ASK FOR.

DR. KIESSLING: IS THIS POWERPOINT PRESENTATION IN OUR PACKET? IT WOULD BE HUGELY HELPFUL TO ME.

DR. LOMAX: WE WILL CIRCULATE SLIDES. I JUST DIDN'T HAVE THEM AVAILABLE AT THE TIME OF PRODUCTION.

CHAIRMAN LO: ANY OTHER QUESTIONS? MARY, LET ME THANK YOU VERY MUCH. THAT WAS A VERY CLEAR PRESENTATION ON SOME VERY DIFFICULT AND VERY SOPHISTICATED WORK.

MY ONLY QUESTION IS ARE YOU PLANNING TO WRITE UP KIND OF THE RATIONALE FOR YOUR POLICY SO IT CAN BE SHARED WITH OTHER GROUPS INTERESTED IN THESE ISSUES? YOU'VE DONE A LOT OF THINKING HERE AND HAVE A PRETTY SOPHISTICATED NUANCED SORT OF APPROACH TO BALANCING DIFFERENT GOALS OR ETHICAL PRINCIPLES. I THINK IT WOULD BE A REAL CONTRIBUTION TO PUBLISH THAT.

DR. MAXON: WITH RESPECT TO SHARING IT WITH OTHERS, CERTAINLY WITH OTHER STATES, THAT'S PART OF OUR EFFORTS TO COLLABORATE WITH THE ALLIANCE. WITH REGARD TO WRITING IT UP, ED PENHOET HAS BEEN PESTERING ME FOR QUITE SOME TIME TO PUT TOGETHER A MANUSCRIPT FOR A POLICY FORUM OR SOMETHING TO THAT.

CHAIRMAN LO: OR REALLY FOR *SCIENCE* OR *NEW ENGLAND JOURNAL* BECAUSE THIS REALLY IS A LEAP FROG BEYOND THE CURRENT DISCUSSIONS ON INTELLECTUAL POLICY.

DR. MAXON: *SCIENCE* HAS A SECTION CALLED "POLICY FORUM" THAT I THINK IS WHAT ED WAS THINKING, BUT I THINK THAT'S A LITTLE -- I'LL WAIT AND SEE HOW THAT WORKS OUT. BUT, YES, WE ARE PLANNING TO PUT SOMETHING TOGETHER. I THINK WE'RE KIND OF WAITING TO SEE HOW THE DUST IS GOING TO SETTLE ON THE PRICING PIECE BEFORE WE CAN REALLY MAKE THAT WORK. BUT THE PROCESS ITSELF IS, I THINK, QUITE INTERESTING TO SHARE WITH OTHERS.

CHAIRMAN LO: ALSO I THINK YOU'VE DEVELOPED A SET OF SORT OF ETHICAL GUIDELINES OR SORT OF RULES OF THUMB TO FOLLOW. YOU CERTAINLY MENTIONED PROPORTIONALITY AND NEED TO BALANCE ACCESS VERSUS SORT OF NOT DETERRING INVENTION IN THE FIRST PLACE. AND THAT KIND OF CONSIDERATION OF THE ISSUES IS, I THINK, MORE SOPHISTICATED AND MORE REALISTIC THAN A LOT OF THINGS THAT HAVE BEEN PUBLISHED IN THOSE KINDS OF JOURNALS.

DR. MAXON: TO THAT POINT I WOULD SAY YOU'RE ABSOLUTELY RIGHT, AND IT CAME STRICTLY AS A WILLING -- AS A CONSEQUENCE OF THE WILLINGNESS ON THE PARTS OF FUNDING ENTITIES FOR THE FOR-PROFIT SECTOR. NONE OF THEM WOULD COME FORWARD PUBLICLY TO SPEAK AT THE MEETINGS ABOUT WHAT THEIR STRATEGIES WERE; BUT WHEN I WENT TO THEM AND I SAID SHOW ME THE TEMPLATES, I

LEARNED SO MUCH HOW NOT TO DO THIS FROM THOSE ENTITIES WHO FUNDED THEM AND HAD MADE MISTAKES. SO THEY SHARED WITH US THE BENEFIT OF THEIR MISFORTUNE AND ALLOWED US TO CHART A COURSE THAT, I THINK, IS A WELL-INFORMED ONE.

CHAIRMAN LO: THANKS VERY MUCH.

DR. LOMAX: THE ONLY OTHER COMMENT TO ADD IS I'D LIKE TO THANK MARY. IF YOU DO REMEMBER AT ONE POINT IN TIME, WE WERE ACTUALLY NOODLING A LITTLE BIT OF THIS, AND I AM SO HAPPY THAT SOMEONE WAS ABLE TO CARRY THE BALL ON THIS BECAUSE OBVIOUSLY IT IS FAR DEEPER AND FAR BIGGER THAN ANYTHING WE COULD HAVE CONTEMPLATED.

MS. KING: WE'RE HAPPY TOO.

DR. LOMAX: THANK YOU, MARY.

I'D LIKE TO DO ROLL CALL. MARCY FEIT.

MS. FEIT: HERE.

DR. LOMAX: ROBERT KLEIN. SHERRY LANSING. FRANCISCO PRIETO.

DR. PRIETO: HERE.

DR. LOMAX: JEFF SHEEHY.

MR. SHEEHY: HERE.

DR. PRIETO: I HAVE TO SAY MY CONNECTION IS VERY BAD.

DR. LOMAX: HOW DO I SOUND TO YOU?

DR. PRIETO: YOU SOUND OKAY NOW. ANN KIESSLING AND TED PETERS ARE PRETTY AUDIBLE. A LOT OF THE REST NOT SO GOOD.

CHAIRMAN LO: A LOT OF THE REST OF US ARE NOT CLOSE TO THE PHONE.

DR. PRIETO: I WOULD HAVE MORE COMMENTS IF I COULD HEAR BETTER.

DR. LOMAX: JONATHAN SHESTACK. ALTA CHARO. BERNARD LO.

CHAIRMAN LO: HERE.

DR. LOMAX: PATRICIA KING.

MS. KING: HERE.

DR. LOMAX: TED PETERS.

DR. PETERS: HERE.

DR. LOMAX: JOSE CIBELLI. KEVIN EGGAN. ANN KIESSLING.

DR. KIESSLING: HERE.

DR. LOMAX: JEFFREY KORDOWER. KENNETH OLDEN.

DR. OLDEN: HERE.

DR. LOMAX: JANET ROWLEY.

DR. ROWLEY: HERE.

DR. LOMAX: ROBERT TAYLOR.

DR. TAYLOR: HERE.

DR. LOMAX: JOHN WAGNER. JAMES WILLERSON.

CHAIRMAN LO: WHAT I WOULD LIKE TO DO IS TO

SORT OF GO BACK AND SEE IF WE CAN REACH SOME INTERIM CLOSURE ON WHAT WE TALKED ABOUT YESTERDAY, WHICH I THOUGHT WAS VERY STIMULATING AND VERY IMPORTANT. AS YOU REMEMBER, THERE WERE THREE ISSUES. ONE, TO HAVE A GROUP OF CONSULTANTS MAKE SUGGESTIONS TO US ABOUT GUIDELINES FOR DECREASING OR FOR MINIMIZING OHSS IN WOMEN DONATING OOCYTES FOR RESEARCH. I THINK WE TALKED ABOUT THAT AND GOT A SENSE OF THE COMMITTEE.

THE SECOND ISSUE, LET ME OFFER ON SHARING OUR EXPERIENCE WITH REGARD TO GRANTS OR APPLICATIONS CIRM MAY GET. LET ME OFFER THE FOLLOWING SORT OF LANGUAGE TO MAYBE START A DISCUSSION OF WHAT THE SENSE OF THE COMMITTEE IS. SO IS IT THE SENSE OF THE SWG THAT WE WOULD LIKE TO OFFER OUR EXPERTISE TO OTHER SECTIONS OR PARTS OF CIRM WORKING GROUPS, FOR EXAMPLE, THE GRANTS-MAKING GROUP, WITH REGARD TO ETHICAL CONCERNS ABOUT OOCYTE DONATION, SPECIFICALLY RESEARCH, IN PROPOSALS THAT CIRM RECEIVES OR GRANTS THAT MAY CONSIDER FUNDING.

IF THIS WOULD BE USEFUL TO THE PARTS OF CIRM THAT HAVE PRIMARY RESPONSIBILITY FOR GRANTS REVIEW OR OVERSIGHT, WE MIGHT CONSIDER AMONG OTHERS OPTIONS SUCH AS, ONE, HAVING US PARTICIPATE IN LOOKING AT PROPOSALS OR GRANTS INVOLVING OOCYTE DONATION. AND I THOUGHT WE SUGGESTED WE WOULD NOT BE PART OF THE ACTUAL GRANTS

REVIEW PROCESS; BUT IF A PROPOSAL RECEIVED A FUNDABLE SCORE, BUT INVOLVED DONATION OF RESEARCH OOCYTES, THAT WE MIGHT GET INVOLVED AT THAT LATER STEP TO EITHER MAKE SURE THAT THE CIRM REGULATIONS WERE BEING FOLLOWED OR TO OFFER SUGGESTIONS, ADVICE ON HOW THE INVESTIGATORS MIGHT BEST ADDRESS THE ETHICAL CONCERNS IN THE GUIDELINES.

SECOND THING WE MIGHT DO IS ACTUALLY AFTER INVESTIGATORS WHO ARE RETRIEVING OOCYTES FROM WOMEN FOR RESEARCH ACTUALLY GET STARTED, THERE MAY BE ETHICAL CONCERNS THAT COME UP, AND PERHAPS WE MIGHT BE USEFUL AS A SORT OF A PLACE WHERE THE INVESTIGATORS COULD COME AND DISCUSS ISSUES THAT ARISE IN THE COURSE OF RESEARCH.

AND THE THIRD SUGGESTION THAT I HEARD YESTERDAY WAS THAT THERE WOULD ALSO BE AN EDUCATIONAL VALUE TO US AS A WORKING GROUP IN STUDYING OR READING REDACTED PROTOCOLS REALLY FOR OUR EDUCATION SO WE HAD A CLEAR SENSE OF WHAT SOME OF THE ISSUES ARE, WHAT SOME OF THE CHALLENGES WERE, AND CURRENT PRACTICES WITH OOCYTE DONATION.

SO THIS, IN SUMMARY, IS MEANT TO SORT OF OFFER TO THE REST OF CIRM WAYS TO BEGIN TO DISCUSS WAYS IN WHICH WE MIGHT GET INVOLVED IN THE REVIEW OF PROPOSALS OR THE GRANTING OF GRANTS THAT INVOLVE OOCYTE

DONATION. SO THAT'S A VERY LONG-WINDED ATTEMPT TO SUMMARIZE. BUT LET'S SEE.

DR. PETERS: I'D LIKE TO RESPOND. I THINK THIS IS A REPEAT OF YOUR THREE-PART SUMMARY YESTERDAY. THE FIRST ONE IS SHOULD WE CONSULT WITH BEST PRACTICES EXPERTS, AND I THINK WE ALL AGREED ON THAT. SO THAT'S A SETTLED MATTER. NOW WE'RE VISITING NUMBERS TWO AND THREE, THE SECOND ONE OF --

CHAIRMAN LO: THIS WAS ACTUALLY JUST MEANT TO BE TWO. WE CAN GET TO THREE A LITTLE LATER.

DR. PETERS: NO. 2 IS SHOULD WE GET INVOLVED IN THE EXISTING GRANT APPLICATION PROCESS? THAT'S WHAT I THOUGHT I HEARD.

CHAIRMAN LO: GRANT APPLICATION PROCESS.

DR. PETERS: ONE OF THE THINGS I WANTED TO SAY YESTERDAY, AND I HEARD IT COME UP AGAIN, JEFF HAD SAID HE'S CONCERNED ABOUT POLICING. AND MY THINKING IS I DON'T THINK WE WANT TO GET INTO THAT. THERE'S A RISK THAT IF YOU TRY TO POLICE IN ONE INSTANCE, YOU MIGHT SET A PRECEDENT THAT YOU ARE SORRY ABOUT.

I WOULD SEE OUR PRIMARY OBJECTIVE HERE IS HEURISTIC. THAT IS TO SAY, TO DRAW TO ATTENTION TO THE GRANTEES AND THOSE WHO ARE APPROVING THE GRANTS THAT THIS IS VERY IMPORTANT, AND WE COMMEND THEM TO INCLUDE THAT IN THEIR PROTOCOL. BUT THEN, SECONDLY, WHAT I

HEARD TODAY, BERNIE, WAS MAYBE AN OVERLAP BETWEEN NUMBERS TWO AND THREE. THAT IS TO SAY, IF A FUNDABLE PROPOSAL COMES IN THAT LOOKS LIKE IT'S IN THE AREA WHERE WE WANT TO SEE RESEARCH DONE, I DON'T THINK WE NEED TO POLICE IT. THE QUESTION WOULD BE COULD WE NEGOTIATE WITH THE POTENTIAL GRANTEE TO GET SOME OF OUR WORK DONE, OR MAYBE WE SHOULD GO TO NO. 3, AND THAT IS TO SAY HOW, IF WE SEND OUT A REQUEST FOR PROPOSALS, WE COULD ACTUALLY GET QUITE SPECIFICALLY THE WORK DONE THAT WE WOULD LIKE.

NOW, THAT'S WHAT I THINK I'M HEARING, AND I THINK YOU'RE GETTING MY RESPONSE.

DR. OLDEN: WELL, I LIKE THE LAST OPTION THAT YOU PRESENTED. I THINK WE SHOULD GET -- WE SHOULD REVIEW FUNDED GRANT APPLICATIONS TO HELP US DECIDE WHETHER THERE ARE ISSUES THAT WE STILL SHOULD TAKE A LOOK AT. I DON'T THINK WE SHOULD GET INTO THE GRANTS REVIEW PROCESS BECAUSE I THINK IT'S SO IMPORTANT TO GET THE GRANT APPLICATIONS TURNED AROUND AS SOON AS POSSIBLE; IN OTHER WORDS, THE TIME FROM SUBMISSION TO FUNDING SHOULD BE AS SHORT AS POSSIBLE BECAUSE THAT'S VERY APPEALING TO INVESTIGATORS. AND I THINK FOR US TO GET INVOLVED WOULD ADD ANOTHER LAYER TO THE REVIEW.

BUT I DO THINK WE NEED TO KNOW ARE THERE ISSUES THAT WE SHOULD THINK ABOUT OR IMPROVE OUR

PROCESS AND OUR GUIDELINES. AND I THINK WE COULD DO THAT BY RANDOMLY SAMPLING SOME OF THE APPLICATIONS THAT HAVE BEEN FUNDED. SO I THINK THAT'S WHAT WE WANT TO DO IS IMPROVE THE ASSIGNMENT, THE TASK THAT WAS GIVEN TO US, AND IT SEEMS TO ME THAT WE COULD DO THAT BY JUST RETROSPECTIVELY REVIEWING SOME GRANT APPLICATIONS.

DR. TAYLOR: I AGREE. I THINK THE IDEA OF HAVING REDACTED AND ANONYMIZED APPLICATIONS SORT OF GIVES US THE OPPORTUNITY TO SEPARATE CHURCH AND STATE A LITTLE BIT AND KEEPS US SO THAT WE ARE -- BECAUSE THIS IS GOING TO BE A WORK IN PROGRESS OBVIOUSLY. IT WILL CHANGE POTENTIALLY WITH NEW APPLICATIONS AS THEY COME IN. WE CAN MAYBE KEEP UP WITH SOME OF THOSE AND RETHINK PRINCIPLES THAT GUIDELINES WILL BE BASED ON.

DR. ROWLEY: IT SEEMS TO ME THAT THERE WAS ANOTHER ISSUE THAT WAS CONSIDERED IMPORTANT YESTERDAY, AND THAT WAS THE LACK OF DATA. AND I'M NOT SURE BECAUSE IT SEEMED TO ME THE WAY THINGS WERE PHRASED TODAY IT WAS MORE RELATED TO GRANTS.

CHAIRMAN LO: THAT WAS GOING TO BE SUGGESTION THREE.

DR. ROWLEY: OKAY.

MS. KING: LET'S JUST MAKE SURE I UNDERSTAND THIS. WHAT KEN JUST PROPOSED WOULD LEAVE OUT OR THE WAY KEN RESTATED IT WOULD LEAVE OUT THE POSSIBILITY OF

IN THE GRANT PROCESS ITSELF. I BELIEVE THE DISCUSSION YESTERDAY WAS THE PROBLEM OF UP OR DOWN WITHOUT AN OPPORTUNITY TO HAVE A GRANT APPLICATION REWORKED IN TERMS OF THINKING ABOUT THE ETHICAL IMPLICATIONS. I DON'T RESIDE IN THAT PART OF THE WORLD, SO I'M WILLING TO GO ALONG WITH IT, BUT I WANT -- WHAT I JUST HEARD, I JUST WANT TO KNOW IF THE CONSENSUS IS THAT THAT'S WHAT WE DON'T WANT TO DO.

DR. OLDEN: I ASKED DO REVIEWERS. IS THE PEER REVIEW COMMITTEE LOOKING AT ACTUALLY MAKING JUDGMENTS ABOUT THE ETHICAL AND ALL THE ISSUES THAT WE DEAL WITH, OR ARE THEY SIMPLY MAKING JUDGMENTS ABOUT THE QUALITY OF THE SCIENCE?

CHAIRMAN LO: LET'S TRY AND GET JEFF SHEEHY BECAUSE I THINK HE'S THE ONE THAT RAISED IT FROM THE POINT OF VIEW OF THE REVIEWERS. YOU'RE ASKING QUESTIONS THAT I DON'T KNOW THE ANSWERS TO. MARCY, ARE YOU ON THE REVIEW COMMITTEE AS WELL?

MS. FEIT: YES. I THINK I'M ON EVERY CIRM COMMITTEE. I'VE BEEN LIVING HERE AT THE MIYAKO LATELY. I SAT IN ON SEVERAL DAYS OF GRANT REVIEWS. AND THE QUESTION IS IS THERE AN ETHICAL ISSUE -- IS THERE ETHICAL INPUT? TO A VERY MINOR DEGREE. WHAT YOU HAVE IS A PROCESS WHERE THERE'S A FIRST AND SECOND REVIEWER. THEY'RE EXPERTS IN THEIR PARTICULAR FIELD. SO THEY

GIVE -- AND THE BODY OF THEIR REVIEW IS BASED ON THE SCIENCE, NOT ON THE ETHICAL. SO I THINK THAT IS PROBABLY A MISSING COMPONENT. AND SO I THINK THE ABILITY FOR THIS GROUP TO RANDOMLY SELECT GRANTS AND REVIEW THEM AND ADVISE CIRM AND THE GRANTS WORKING GROUP ON CONCERNS OR MAYBE THINGS THAT YOU PICK UP, THAT WOULD BE HELPFUL GOING FORWARD. BUT I THINK OVERALL THE REVIEW DOES NOT EMBODY PARTICULARLY THAT ISSUE.

DR. KIESSLING: BUT ALL THE REVIEWS ARE BOTH IRB AND ESCRO REVIEWED. ALL THE GRANT APPLICATIONS HAVE BOTH IRB AND ESCRO REVIEW.

DR. ROWLEY: JEFF SAID YESTERDAY THAT ONE WAS APPROVED WITHOUT A SCRO REVIEW.

CHAIRMAN LO: GRANTS ARE APPROVED -- THE GRANTS ARE APPROVED FOR FUNDING PRIOR TO IRB AND SCRO REVIEW.

DR. KIESSLING: REALLY?

CHAIRMAN LO: AS IT IS WITH NIH.

DR. OLDEN: SURE.

DR. KIESSLING: MY NIH GRANT IS NOT.

DR. TAYLOR: JUST IN TIME.

DR. OLDEN: ALL THE NIH GRANTS ARE JUST IN TIME.

MS. KING: I DON'T KNOW WHAT JUST IN TIME

MEANS.

CHAIRMAN LO: THAT WHEN YOU SUBMIT TO THE FUNDING AGENCY, YOU NEED NOT HAVE IRB REVIEW. BEFORE YOU CAN START THE GRANT, BEFORE YOU GET THE MONEY, YOU'VE GOT TO GET IRB APPROVAL.

MS. KING: IS THERE STILL NO ETHICAL QUESTIONS RAISED AT THE STUDY SECTION?

CHAIRMAN LO: NIH, I THINK, IS DIFFERENT THAN WHAT I UNDERSTAND FROM WHAT MARCY SAID AND WHAT JEFF SAID. NIH, THE STUDY SECTIONS, HELP ME, KEN, SORT OF IN THE LAST COUPLE OF YEARS HAVE BEEN REALLY GETTING TOUGH ON THE HUMAN SUBJECTS SECTION, SECTION D. THEY'RE REVIEWING IT. THEY'RE MARKING PEOPLE DOWN. THEY'RE ACTUALLY NOT FUNDING PEOPLE. WE'VE HAD GRANTS THAT GOT VERY NICE PRIORITY SCORES, BUT THEY WEREN'T FUNDED BECAUSE THEY SAID YOU HAVE TO RESUBMIT TO TAKE CARE OF THE FOLLOWING ETHICAL CONCERNS. CONSENT, CONFIDENTIALITY, UNDUE INFLUENCE, ALL SORTS OF THINGS GET RAISED, JUSTICE, VULNERABLE POPULATIONS. AND THAT'S BEEN A CHANGE OVER THE LAST 10, 15 YEARS. AND MY UNDERSTANDING IS THAT'S NOT REALLY HAPPENING AT THE CIRM REVIEW.

MS. FEIT: THERE IS A DUE DILIGENCE PHASE THAT WILL TAKE PLACE TO MAKE SURE THAT CERTAIN ELEMENTS ARE THERE AND ARE PROVEN; BUT EXCLUSIVE OF THAT, I

THINK THE REVIEW IS BASED ON THE BODY OF SCIENCE THAT'S BEING PRESENTED.

MS. KING: JUST TO REMIND US OF THE CONTEXT, I THINK THAT ORDINARILY WE WOULD NOT HAVE AN ISSUE. WE WERE TALKING ABOUT USE OF DONOR OVA, WHICH IS, I WOULD IMAGINE, UNUSUAL IN THIS PROCESS. SO THE DISCUSSION IS NOT ABOUT THE GENERAL -- THE GRANTS THAT WOULD COME IN WHERE IT WOULD BE APPROPRIATE TO DO A SCIENTIFIC REVIEW. WE'RE TALKING ABOUT A SPECIFIC SUBSET OF APPLICATIONS WHERE WE DO HAVE HUMANS INVOLVED AS DONORS. AND THE QUESTION IS, BECAUSE THAT'S STILL OUT, IS BECAUSE OF THAT FACT, SHOULD WE HAVE SOME REVIEW EVEN AT THIS STAGE ABOUT THE ETHICS OF HOW WE HAVE INVOLVED THE DONORS AND INFORMED CONSENT OF THE DONORS?

SO I THINK THAT'S THE QUESTION WE'RE FOCUSED ON, NOT ALL APPLICATIONS, BUT IS THERE SOMETHING -- SHOULD WE BE DOING ANYTHING EVEN IF WE JUST OFFER ASSISTANCE AT THAT STAGE WITH RESPECT TO THAT SUBSET OF GRANTS? THAT'S WHAT I UNDERSTOOD YESTERDAY'S ISSUE.

CHAIRMAN LO: THAT IS WHAT I WAS TRYING.

DR. ROWLEY: AND I THINK THAT IT WOULD BE VERY IMPORTANT TO KNOW, FOR WOMEN WHO ARE RESEARCH DONORS, WHAT KIND OF FOLLOW-UP IS BEING OFFERED TO THAT INDIVIDUAL TO MAKE SURE THAT SHE DOESN'T SUFFER SOME UNTOWARD CONSEQUENCE; OR IF SHE DOES, THEN WHAT KIND OF

HELP IS SHE GOING TO GET IN THE EVENT THAT SHE UNFORTUNATELY EITHER GETS A HIGH DOSE OR IS PARTICULARLY SENSITIVE TO HCG, FOR EXAMPLE?

CHAIRMAN LO: SO WHAT I'M HEARING IS THAT IT SOUNDS LIKE WE'RE ALL AGREED THAT WOULD BE USEFUL FOR US TO STUDY RETROSPECTIVELY SORT OF ANONYMIZED REDACTED PROTOCOLS REALLY, AS KEN PUT, TO HELP US CARRY OUT OUR CHARGE BETTER. I THINK WE ALL AGREE TO THAT.

SECOND ISSUE WOULD BE SHOULD WE OFFER TO BE INVOLVED IN LOOKING AT FUNDABLE PROPOSALS OR FUNDED PROPOSALS, WHICH EVERYONE IS SAYING ONLY THOSE THAT INVOLVE OOCYTE DONATIONS. AND THE IDEA I HEARD YESTERDAY WAS WE DIDN'T WANT TO SLOW DOWN THE GRANTS MAKING PROCESS, SO IT WOULD BE AFTER THEY HAD SORT OF BEEN AWARDED FUNDING, BUT BEFORE THEY ACTUALLY GOT THE MONEY AS PART OF THAT DUE DILIGENCE TO SAY, WELL, FOR THIS SMALL SUBSET OF GRANTS, WE WOULD OFFER TO REVIEW THEM IF THE GRANTS-MAKING AGENCY OR THE GRANTS-MAKING COMMITTEE OR OFFICERS THOUGHT THAT WAS USEFUL. I DON'T KNOW, JEFF AND MARCY, IF THAT SORT OF -- WE DON'T WANT TO SORT OF TRY AND DO TOO MUCH AND SORT OF MESS THINGS UP, BUT WE WANT TO BE AVAILABLE IN THESE SORT OF RELATIVELY FEW CASES WHERE THERE ARE ETHICAL CONCERNS IMPLICATED BECAUSE OF THE NATURE OF OOCYTE DONATION FOR RESEARCH.

JEFF, YOU MISSED THE BEGINNING. WE'RE SORT OF GOING BACK TO WHAT YOU RAISED YESTERDAY WITH REGARD TO IF THERE ARE --

MR. SHEEHY: I THINK IT'S FEASIBLE. YOU KNOW, THERE IS A RELATIVELY LONG GAP BETWEEN THE GRANTS APPROVAL, NOT APPROVAL, THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP AND THE ACTUAL PROCESSION TO THE ICOC. PART OF THAT IS THAT SCORES, COMMENTS, THERE'S QUITE A BIT OF INFORMATION THAT IS COLLECTED, ANALYZED, AND THEN PUT INTO A PACKAGE FOR THE ICOC FOR US TO BE ABLE TO DO THE GRANT REVIEW AT THE ICOC. SO AS YOU CAN IMAGINE, MANY OF US SAT THROUGH PEER REVIEW. THERE'S A LOT THAT GOES ON THERE, AND TO DISTILL THAT INTO SOMETHING FOR A LARGE NUMBER OF GRANTS THAT CAN BE MEANINGFUL FOR ANOTHER BODY THEN TO MAKE APPROVAL TAKES -- I MEAN IT'S NOT MONTHS, BUT IT'S -- I DON'T THINK IT'S BEEN DONE IN LESS THAN A MONTH, AND USUALLY IT'S A MONTH, ONE TO TWO MONTHS, FOUR TO SIX WEEKS.

SO YOU CAN IMAGINE THAT IF WE COULD DESIGN THE RIGHT KIND OF DOCUMENTATION IN THE GRANT APPLICATION PROCESS TO COLLECT THE INFORMATION IN A REALLY USABLE FORM BECAUSE RIGHT NOW THE PROTOCOLS AND PROCEDURES THAT THEY'RE USING -- THAT AN APPLICANT MAY BE USING FOR EGG DONATION OR OOCYTE COLLECTION ISN'T REALLY EVIDENT, THOUGH OBVIOUSLY THEY'RE HAVING TO

PREPARE THAT FOR THEIR SCRO'S OR THEIR IRB.

SO IF WE JUST COULD PUT MAYBE ANOTHER BUTTON, THIS IS ALL ON COMPUTER, SO THEY FILE ALL THIS STUFF. WE CAN JUST PUT IN A COLLECTION POINT FOR THOSE SPECIFIC GRANTS, HAVE THEM SUBMIT THAT DATA. I DON'T THINK IT WOULD BE A TERRIBLY ONEROUS THING. REALLY YOU COULD JUST MAKE THOSE APPLICATIONS ACCESSIBLE TO US BY COMPUTER OR IF WE NEED TO PRINT DOCUMENTS, BUT YOU CAN GET THAT INFORMATION TO US AND WE CAN HAVE A LOOK AT IT FAIRLY EASILY.

DR. KIESSLING: HOW WOULD THIS RELATE TO THE IRB AND THE ESCRO REVIEW THOUGH? I DON'T THINK WE WANT TO UNDERWRITE OR IN ANY WAY SECOND-GUESS THOSE REVIEW BODIES.

MR. SHEEHY: SOMETIMES THOSE REVIEWS HAVEN'T TAKEN PLACE YET.

DR. KIESSLING: I DIDN'T KNOW THAT. I ASSUMED THAT THERE'S A PRETTY BIG BUTTON ON THE GRANT SUBMISSION LIST, IT LOOKS TO ME LIKE. HAS THIS BEEN ESCRO REVIEWED? CERTAINLY HARVARD'S GRANTS ARE ALL ESCRO REVIEWED BEFORE ANYTHING HAPPENS, ALTHOUGH SOME OF THOSE ARE PRETTY PRIVATELY FUNDED. SO NOW YOU ASSUME THAT THIS GRANT GOT A VERY HIGH PRIORITY SCORE AND IT'S VERY LIKELY TO BE FUNDED, AND SO NOW THIS INSTITUTION IS GOING TO GO TO THE TROUBLE TO PUT IT

THROUGH BOTH IRB AND ESCRO REVIEW. THEN WHERE WOULD WE FIT IN?

MR. SHEEHY: IT JUST SEEMS TO ME THAT BETWEEN THE GRANT RECOMMENDATION, AND WE GENERALLY HAVE THREE CATEGORIES OF GRANT RECOMMENDATIONS, SO I WOULD PROBABLY ASK FOR THIS REVIEW -- WE'VE NEVER REACHED INTO THE THIRD TIER. I THINK IT WOULD TAKE EXCEPTIONAL CIRCUMSTANCES FOR US TO DO SO. AND OUR TIERS ARE RECOMMENDED FOR FUNDING, RECOMMENDED FOR FUNDING IF FUNDS ARE AVAILABLE, AND THEN THE THIRD TIER IS NOT RECOMMENDED FOR FUNDING. AND THERE'S AN EXTREME RELUCTANCE, AS YOU CAN WELL IMAGINE, TO GO INTO THE THIRD TIER. BUT THE FIRST TWO TIERS, TO LOOK AT GRANTS THAT INVOLVE OOCYTE DONATION, MAYBE IT DOES OVERLAP WITH THE SCRO'S AND THE IRB'S, BUT TO BE PERFECTLY HONEST, THE SCRO'S ARE NEW INVENTIONS. I DON'T THINK WE'D BE UNDERMINING THEM. I THINK IT WOULD BE PROBABLY AN INTERESTING WAY TO HAVE A DIALOGUE BETWEEN THE POLICYMAKING BODY, WHICH IS US, AND THE POLICY IMPLEMENTATION BODY, WHICH IS THE SCRO'S.

I JUST WONDER WHEN ARE WE EVER GOING TO KNOW WHAT'S GOING ON. THIS MAY NOT BE SOMETHING THAT LASTS MUCH PAST THE INITIAL PHASE. ONCE WE CAN GET GUIDELINES, I THINK AS DR. KING WAS SAYING YESTERDAY, ONCE WE GET A GOOD GROUNDING IN THIS, WE MAY NOT NEED

TO DO THIS, BUT I THINK STARTING OFF BECAUSE OF THE NOVELTY.

CHAIRMAN LO: LET'S TRY AND DISTINGUISH AGAIN THE GOALS WE MIGHT HAVE. CERTAINLY THE GOAL OF EDUCATING OURSELVES, UNDERSTANDING WHAT ISSUES WE NEED TO PAY MORE ATTENTION TO, NOW, THAT CAN BE DONE AFTER THE MONEY HAS BEEN RECEIVED. BUT I THOUGHT I HEARD, JEFF, YESTERDAY YOU SORT OF RAISED A CONCERN ABOUT A PARTICULAR GRANT THAT WAS DEEMED FUNDABLE WHERE THERE SUBSEQUENTLY WERE CONCERNS RAISED ABOUT THE QUALITY OF A SCRO REVIEW. AND THAT I THOUGHT THE SUGGESTION WAS THAT CIRM AS A FUNDING AGENCY MIGHT NOT WANT TO ALWAYS TOTALLY DEFER TO THE LOCAL IRB AND SCRO IN TERMS OF DECIDING WHETHER THE ETHICAL ISSUES WERE FULLY ADDRESSED.

AND I THINK ANN HAS RAISED THE ISSUE OF THERE'S A -- IT REALLY HAS IMPLICATIONS FOR WHO'S RESPONSIBLE FOR WHAT. AND I THINK IT'S SOMETHING WE SHOULD THINK ABOUT. WE CAN SORT OF SAY, WELL, WE'RE NOT GIVING APPROVAL, DISAPPROVAL. WE'RE MAKING SUGGESTIONS, BEING HEURISTIC, I THINK, WAS KEN'S TERM, BUT IN POINT OF FACT, THERE'S A DIFFERENCE BETWEEN IF WE'RE TRYING TO SAY WE'D LIKE TO ENCOURAGE SOME IMPROVEMENTS IN THIS PROPOSAL RATHER THAN THIS PROPOSAL IS FUNDED. NOW LET'S LOOK AT IT TO SEE WHAT WE CAN

LEARN.

MR. SHEEHY: I'D MAKE AN ADDITIONAL POINT, WHICH IS JUST A FUNDAMENTAL STRUCTURAL REALITY OF EVERYTHING. THE ICOC IS THE DECISION BODY. SO EVEN THE GRANTS REVIEW IS ONLY RECOMMENDATIONS, SO IT DOESN'T SEEM -- THE IRB ACTUALLY AND THE SCRO'S ARE DECISION-MAKING BODIES AT THOSE INSTITUTIONS. WE WOULD NOT BE SUPPLANTING THEIR ROLES AS DECISION-MAKING BODIES. BUT IN THE CONTEXT OF A GRANT APPROVAL BODY, WHICH IS THE ICOC, FOR US TO HAVE SENT UP RECOMMENDATIONS ABOUT THIS, I MEAN CERTAINLY I THINK AS AN ICOC MEMBER, THAT WOULD BE VERY HELPFUL. I WOULD NOT WANT TO APPROVE A GRANT THAT HAS SOME QUESTIONABLE ETHICAL CONCERNS. AND TO BE ABLE TO POINT THOSE OUT, MAYBE OFFER SUGGESTIONS TO AMELIORATE THEM COULD BE VERY HELPFUL FOR US, BUT WE WOULD NOT BE GOING THUMBS UP OR THUMBS DOWN UNDER ANY CIRCUMSTANCES. THAT'S NOT REALLY HOW THESE ROLES ARE SUPPOSED TO WORK. THE ICOC IS SUPPOSED TO BE THE DECISION-MAKING BODY.

MS. KING: I'M GOING TO TRY TO COME FROM WHAT I UNDERSTAND AS A PRACTICAL ISSUE. THE PRACTICAL ISSUE IS THERE WILL BE SOME TIME BEFORE EXPERTS WE WOULD LIKE TO HIRE TO HELP US COME UP WITH GUIDELINES, ETC., FOR BEST PRACTICES THAT CAN BE PUT IN PLACE. SO THERE'S A TIME LAG. WHAT PROBLEM DOES THE TIME LAG CREATE FOR

CIRM?

I THINK THAT THE PROBLEM THAT IS POTENTIALLY CREATED IS THAT IN A REALLY DELICATE ASPECT OF STEM CELL RESEARCH, I.E., USING FRESH OVA FROM DONORS, THE QUESTION IS DO YOU WANT TO MAKE SURE -- THIS IS NOT ETHICAL. THIS IS PRACTICAL -- YOU WANT TO MAKE SURE YOU DON'T HAVE ANYTHING BLOW UP IN YOUR FACE. THAT'S ABOUT AS PRACTICAL AS I CAN MAKE IT.

I SUSPECT THAT ONE OF THE REASONS THAT AT NIH YOU'RE GETTING MORE ETHICAL QUESTIONS FROM THE STUDY SECTION IS THAT THEY FIND SOMETHING THAT WE'VE ALWAYS KNOWN TO BE TRUE, AND THAT IS THAT IRB'S CAN LOOK AT THE SAME PROTOCOL AND REACH VERY DIFFERENT CONCLUSIONS ABOUT THE PROTOCOL, WHICH IN THE MAIN IS NOT ALWAYS A HUGE ISSUE. IT'S SORT OF BUILT INTO THE SYSTEM. BUT WHERE YOU ARE HAVING -- YOU REALLY WORRIED ABOUT DOING SOMETHING AS BEST YOU CAN FROM THE VERY BEGINNING, EVEN IF YOU DIVEST WHAT YOU'RE DOING LATER WHEN THERE ARE GUIDELINES, ETC., IT SEEMS TO ME THAT IS THE ISSUE THAT WE'RE GRAPPLING WITH IN PRACTICAL TERMS.

AND SO THE QUESTION IS, ONE, YOU MAY NOT AGREE THAT YOU ALL THINK THAT THAT'S THE ISSUE, BUT FOR ME THE NEXT QUESTION BECOMES WHAT CAN WE DO CONSISTENT WITH WHAT OUR ROLE IS? WHAT I ACTUALLY HEARD BERNIE SAY WHEN HE DID HIS FIRST OUTLINE, HE KEPT USING THE

TERM "OFFER OF ASSISTANCE." I DON'T THINK THAT -- I THINK THAT ONE OF THE THINGS THAT WE CAN DO IS POSE THIS TO PEOPLE WHO ACTUALLY HAVE RESPONSIBILITY FOR GRANT MAKING AND IN THAT PROCESS ABOUT WHETHER THEY SEE THIS AS AN ISSUE. AND IF THEY DO, IN FACT, SEE THIS AS AN ISSUE, CAN WE HELP BY LOOKING AT SOME SUBSET AFTER INITIAL REVIEW OF APPLICATIONS THAT HAVE BEEN APPROVED, AT LEAST GOTTEN RECOMMENDED FOR FUNDING, TO HELP US GET SOME KIND OF HOLD OF THIS PROBLEM. AND THAT'S REALLY THE ONLY THING I SEE THAT'S GOING ON HERE. AND IF THERE'S NO INTEREST, THEN THERE'S NO INTEREST.

I THINK WHAT WE'VE DONE HERE IS, LEAVING ASIDE THE EDUCATIONAL VALUE TO US, THAT'S ANOTHER ISSUE, WHAT WE'RE DOING HERE IS WE SEE SOME EXPERTISE HERE THAT MIGHT BE USEFUL WITH A REAL WORLD PROBLEM FOR WHAT WE HOPE IS NOT A VERY LONG PERIOD OF TIME. AND IF OTHERS AGREE, THAT'S FINE. AND WE COULD DO THAT. IF THEY DON'T, WE WON'T.

DR. ROWLEY: WELL, I WANTED TO MAKE THE POINT THAT WHAT WAS RAISED YESTERDAY BY KEN IN HIS SHOCK OVER THE FACT THAT A HUNDRED IN 100,000 OR ONE IN A THOUSAND WOMEN HAS SOME TYPE OF OHSS, APPARENTLY THE MINIMAL FORM WITH MINOR SYMPTOMS THAT YOU TAKE CARE OF AT HOME, IS PRESENT IN 80 PERCENT OF THE WOMEN AND THE MORE SEVERE FORMS ARE PRESENT, OF COURSE, MUCH MORE RARELY.

THE QUESTION THAT WAS RAISED IS THESE MAY BE APPROPRIATE RISKS FOR A WOMAN AND A FAMILY THAT IS TRYING TO GET PREGNANT, BUT ARE THEY REASONABLE RISKS FOR SOMEONE WHO IS DOING THIS ALTRUISTICALLY?

THAT WAS SOMETHING THAT I HAVE TO SAY I NEVER THOUGHT ABOUT. AND SO WHAT WE'RE REALLY STRUGGLING WITH IS FOR EGG DONATIONS FOR RESEARCH PURPOSES, THEN, A, SHOULD THERE BE A DIFFERENT SET OF STANDARDS AS COMPARED WITH IVF; AND, B, IF THERE ARE A DIFFERENT SET OF STANDARDS, WHAT SHOULD THEY LOOK LIKE? AND THAT'S WHERE THE EXPERTS MAYBE WILL GIVE US SOME ADVICE, NOT ONLY WHAT'S PRESENTLY HAPPENING, BUT WHAT WOULD THEY THINK WOULD BE ACCEPTABLE IN THIS SPECIAL GROUP. AND THEN TO CALL ATTENTION TO THE INVESTIGATORS WHO ARE GOING TO USE THE DONATED OOCYTES THAT, IN FACT, THEY MAY HAVE TO TAKE SPECIAL CARE.

IT SEEMS TO ME IT'S THE LATTER THAT WE'RE REALLY CONCERNED ABOUT. ARE THEY AWARE THAT THIS ETHICAL ISSUE HAS BEEN RAISED, WHICH IN ONE SENSE WE HAVEN'T RESOLVED EXCEPT IT SEEMS TO ME THAT WE GENERALLY AGREE THAT THERE SHOULD BE A DIFFERENT LEVEL OF RISK IN THESE TWO CATEGORIES. AND HAVE THE INVESTIGATORS REALLY THOUGHT ABOUT THIS, AND ARE THEY IN THEIR PROTOCOL DEALING WITH THIS QUESTION IN TERMS OF REDUCING RISK? IF SO, HOW? THAT'S THE ETHICAL

ISSUE, IT SEEMS TO ME, WHERE WE NEED TO REVIEW IT. AND IF THEY HAVEN'T PAID ANY ATTENTION AND SAY THEY'RE GOING TO USE THE STANDARD PROCEDURES, THE QUESTION IS ARE STANDARD PROCEDURES APPROPRIATE IN THIS INSTANCE?

CHAIRMAN LO: OTHER QUESTIONS, COMMENTS? FRANCISCO, DO YOU WANT TO GET IN ON THIS DISCUSSION?

DR. PRIETO: NO. THAT'S OKAY. THANK YOU. THAT'S FINE.

CHAIRMAN LO: COULD I ASK A QUESTION TO JEFF AND MARCY BECAUSE I ACTUALLY HAVE NOT LOOKED AT THE APPLICATION FORM. IS THERE AN ETHICAL ISSUES/HUMAN SUBJECTS PART OF THE CIRM APPLICATION PROCESS?

DR. PRIETO: BERNIE, YOU STILL ARE BREAKING UP A BIT.

CHAIRMAN LO: I WAS ASKING WHETHER IN THE CIRM APPLICATION PROCESS THERE'S A HUMAN SUBJECTS OR ETHICAL ISSUES SECTION AS THERE IS IN NIH GRANTS.

MR. SHEEHY: YEAH. I DID NOT IDENTIFY THAT IN THE ONE THAT RAISED TROUBLING ISSUES FOR ME. AND THAT, AGAIN, COMES TO MY POINT, THAT IF WE HAD A UNIFORM POLICY, YOU KNOW, I LOOK AT THIS, I LOOK AT THEIR PROPOSAL, AND I USE THE EXAMPLE OF THE ONE THAT RAISED QUESTIONS FOR ME. I LOOKED AT WHAT THEY WERE PROPOSING. WELL, WHAT COULD I REALLY SAY? WHAT COULD I REALLY DO TO PULL AN INDIVIDUAL GRANT OUT ABSENT ANY

KIND OF UNIFORM POLICY DOESN'T -- YOU KNOW, FEELS, BASED ON A GUT INSTINCT, THAT ALBEIT TURNED OUT TO BE RIGHT, IS NOT AN APPROPRIATE POLICY FOR AN AGENCY TO FOLLOW. THERE NEEDS TO BE UNIFORMITY AND EQUITY.

SO THAT JUST DIDN'T READ RIGHT TO ME. AND THERE IS A REAL LACK OF DETAIL WITHIN THE APPLICATIONS ABOUT HOW THESE PROCEDURES ARE GOING TO BE DONE.

CHAIRMAN LO: SO IT SOUNDS LIKE -- I MEAN PAT RAISED THE ISSUE OF A TIME LAG. THERE ARE VARIOUS GAPS HERE THAT ONE MIGHT BE CONCERNED ABOUT. ONE THAT PAT IDENTIFIED WAS THE TIME LAG BETWEEN NOW AND WHEN OUR EXPERT CONSULTANTS MAKE RECOMMENDATIONS ON WHAT THEY SHOULD BE DOING. A SECOND GAP IS, I THINK, IN THE ACTUAL APPLICATION, THAT WE'RE NOT ASKING THEM NOW TO PROVIDE THE INFORMATION THAT WOULD ADDRESS THE QUESTIONS THAT JANET SUMMARIZED, I THINK, VERY NICELY AND THE EXPERT CONSULTANTS WILL HELP PROVIDE GUIDELINES.

DR. PRIETO: I'M STILL MISSING ABOUT HALF OF WHAT YOU SAY.

CHAIRMAN LO: I'M SORRY, FRANCISCO. I WAS SAYING THAT IS THERE'S A GAP IN THE CURRENT APPLICATION FORM THAT DOES NOT INCLUDE AN ETHICAL ISSUES/HUMAN SUBJECTS PART, AND THAT CONTAINS INFORMATION THAT FOR THIS SMALL GROUP OF PROTOCOLS INVOLVING OOCYTE

DONATION, WE WOULD WANT TO MAKE SURE THE ISSUES JANET VERY NICELY SUMMARIZED ARE ADDRESSED BEFORE THE RESEARCH STARTS. AND SO IN THE TIME BETWEEN THE RECOMMENDATION -- THE DELIBERATIONS OF THE GRANTS WORKING GROUP AND THE DECISION BY THE ICOC, THERE WOULD BE TIME TO ALERT -- WE NEED TO ALERT INVESTIGATORS THEY NEED TO REALLY THINK THIS THROUGH. THEY'LL NEED TO DO IF FOR THEIR SCRO APPLICATION, BUT WE WOULD BE MORE COMFORTABLE AS A FUNDING AGENCY TO MAKE SURE THEY HAD WORKED ON IT BEFORE WE SORT OF SAT HERE.

IT NEED NOT NEGATE THE FUNDING RECOMMENDATION, BUT IT WOULD BE SORT OF A MORE EXPLICIT RECOGNITION. OF COURSE, WE'RE ONLY FUNDING YOU SUBJECT TO GETTING THE PROPER APPROVAL AND ADDRESSING THESE ETHICAL ISSUES, WHICH ARE MORE COMPLICATED THAN THE USUAL KINDS OF CONCERNS ONE HAS WITH RESEARCH. THAT'S WHY WE, I THINK, MAKE THE OFFER TO REVIEW IF IT'S DEEMED HELPFUL TO THE REST OF CIRM TO REVIEW THIS SMALL NUMBER OF PROTOCOLS.

DR. KIESSLING: BERNIE, IT SOUNDS LIKE WHAT YOU'RE GETTING AT IS THAT WE NEED TO COME UP WITH A LIST OF POSSIBLE RESEARCH AREAS THAT WE THINK ARE SENSITIVE. EGG DONATION IS NOT THE ONLY ONE. HARVARD'S GOT ITS FIRST GRANT TO MAKE A CHIMERA. SO WE PROBABLY, RATHER THAN, YOU KNOW, KEEP PUTTING OUT BRUSH

FIRES, IT WOULD PROBABLY BE HELPFUL IF WE JUST HAD A SHORT LIST OF RESEARCH AREAS THAT WE THINK FALL UNDER THIS GET THIS ETHICALLY REVIEWED BEFORE WE CONSIDER IT FOR BASIC SCIENCE OR SOMETHING LIKE THAT.

DR. PRIETO: IF I COULD COMMENT. THAT SOUNDS LIKE A VERY GOOD IDEA. AND I GUESS THE OTHER QUESTION IS AT WHAT POINT DO WE ADDRESS GRANTEES OR POTENTIAL GRANTEES TO ALERT THEM THAT THEY HAVE TO PAY SPECIAL ATTENTION TO THIS? WHAT POINT IN THE PROCESS FROM RFA TO GRANT APPLICATION, ETC., ETC. DO WE RAISE THE RED FLAG, SO TO SPEAK?

CHAIRMAN LO: I THINK THAT WOULD BE UP TO THE GRANTS WORKING GROUP TO DECIDE. I THINK PROBABLY GRANTEES SHOULD BE ALERTED IF YOU'RE GOING TO SUBMIT A PROPOSAL ON A SENSITIVE TOPIC LIKE FRESH OOCYTE DONATION OR DERIVATION OF CHIMERIC HSC LINE.

DR. PRIETO: I THINK ANN'S IDEA OF IDENTIFYING THE AREAS IS A GOOD ONE THOUGH. AND THEN MAYBE THIS COULD JUST BECOME A ROUTINE PART OF THE GRANTS ADMINISTRATION PROCESS.

CHAIRMAN LO: RIGHT.

MR. SHEEHY: PROBABLY THE RFA PROCESS IS WHAT I WOULD SAY BECAUSE IT NEEDS TO BE UP FRONT.

DR. TAYLOR: IT SEEMS TO ME THAT THERE'S A BIG HOLE IN THE APPLICATION RIGHT NOW. AND WHILE IT'S

A GOOD IDEA TO IDENTIFY SOME PARTICULARLY SENSITIVE AREAS, IT SEEMS LIKE IT'S A REAL GAFF TO NOT HAVE A HUMAN EXPERIMENTATION/ETHICS COMPONENT OF THE ONLINE APPLICATION. AND IT WOULD JUST BE A BOX THAT COULD BE FILLED IN. IT SEEMS TO ME THAT THAT'S SOMETHING THAT SHOULD BE CORRECTED BY THE GRANTING SUBCOMMITTEE IMMEDIATELY.

CHAIRMAN LO: AGAIN, I DON'T KNOW WHAT KIND OF PROPOSALS YOU'RE GETTING, BUT I THINK A LOT OF THEM ARE IN VITRO WORK WITH EXISTING CELL LINES THAT MEET THE CIRM STANDARDS FOR ACCEPTABLE STEM CELL LINES SO THAT REALLY AREN'T FOR MANY APPLICANTS CONCERNS LIKE THIS. BUT, JEFF AND MARCY, I HAVEN'T SEEN WHAT YOU'RE REVIEWING.

MR. SHEEHY: SHORT OF SCNT, THESE HAVE ALL BEEN PRETTY MUCH BASIC SCIENCE TYPE. NO ONE IS TALKING ABOUT PUTTING THESE INTO HUMANS. THE MODELS ARE ALMOST ALL SMALL ANIMAL MODELS.

AND JUST WHILE WE'RE CREATING A LIST, AND I THINK WE SHOULD ADD CLINICAL TRIALS AS ONE OF THE OTHER AREAS THAT WE MIGHT PUT ON AS BEING AREAS THAT WE WOULD WANT TO HAVE A LOOK. AND THERE IS A BOX TO CHECK IF THERE'S BEEN SCRO OR IRB APPROVAL, BY THE WAY. IT'S A LITTLE BOX WITH A CHECK.

MS. FEIT: I THINK THE POINT, THOUGH, IS THAT

I'M SITTING HERE LISTENING TO THIS DISCUSSION AND REFLECTING BACK ON THE REVIEW PROCESS OF THE GRANTS, AND THE WORK THAT WAS DONE WITH THIS WORKING GROUP TO ESTABLISH THE ISSUES AND RAISE THE CONCERNS REGARDING EGG DONATION AND SET THE STANDARDS, I CAN TELL YOU THAT WAS NOT TRANSLATED OVER TO THE INVESTIGATORS WHO APPLIED FOR RESEARCH. AND THAT IS A GAP. AND I THINK THERE NEEDS TO BE SOME WAY OF THAT COMING RIGHT UP FRONT, SAYING FOR CIRM FUNDING, THIS HAS TO BE COMPLETED SO THAT WE ARE ENSURED, REGARDLESS OF OTHER REVIEW BODIES, I MEAN THIS IS A SEPARATE FUNDING AGENCY, AND SO THERE IS A GAP THERE. I REALLY FEEL STRONGLY IF YOU INTERVIEWED ANY OF THEM TODAY THAT APPLIED, THEY WOULD SAY I DIDN'T KNOW THAT. I DIDN'T KNOW YOU DID ALL THAT WORK. SO THERE IS A MISSING PIECE THERE.

CHAIRMAN LO: SO MAYBE WE CAN TRY AND SEE IF WE HAVE A SENSE OF THE COMMITTEE. IS IT OUR SENSE THAT WE WOULD LIKE TO OFFER TO LOOK AT PROPOSALS? I'M ASSUMING WE'RE ALL ASSUMING IT'S A GOOD THING TO EDUCATE OURSELVES, TO LOOK AT PROPOSALS THAT HAVE BEEN RECOMMENDED FOR FUNDING THAT INVOLVE OOCYTE DONATION OR CHIMERIC HSC LINES OR CLINICAL TRIALS, ALTHOUGH THOSE ARE IN THE FUTURE. AND WE WOULD WANT DO THIS IN A WAY THAT DOESN'T SLOW DOWN THE GRANTS APPLICATION PROCESS,

BUT IS MEANT TO KIND OF HELP STIMULATE THE INVESTIGATOR TO THINK THROUGH ALL THE ETHICAL ISSUES THAT WE HAVE BEEN THINKING ABOUT WITH REGARD TO OOCYTE DONATION.

DOES THAT SUMMARIZE WHAT WE'RE TRYING TO DO?

MR. TOCHER: BERNIE, THE WAY YOU ARTICULATED IT THERE, IT WAS SORT OF QUALIFIED ON PROPOSALS THAT HAVE BEEN RECOMMENDED FOR FUNDING. AND I UNDERSTAND THAT FROM AN EFFICIENCY STANDPOINT. AS WE KNOW, HOWEVER, WITH THE ICOC, IT'S THE DECISION MAKER AND OFTEN AS NOT SOMETIMES MAKES ITS OWN DECISION TO FUND APPLICATIONS WHICH MAY NOT HAVE BEEN RECOMMENDED FOR FUNDING AND VICE VERSA. THAT'S BEEN A CRITICAL POINT TO MAKE PUBLICLY IN LITIGATION AND ELSEWHERE.

AND I'M NOT SURE THAT YOU WOULD WANT TO MAKE A DISTINCTION ON ADDRESSING ONLY APPLICATIONS THAT ARE RECOMMENDED FOR FUNDING, BUT THAT IT MIGHT BE SOMETHING THAT YOU WOULD, IF YOU ARE GOING TO DO IT, YOU WOULD WANT TO DO IT ACROSS THE BOARD. I KNOW THAT THAT MAY OR MAY NOT CHANGE.

CHAIRMAN LO: WHAT DO YOU ALL THINK?

DR. OLDEN: THE THIRD CATEGORY ARE THOSE GRANTS APPROVED FOR FUNDING, OR THEY'RE DISAPPROVED FOR FUNDING? THEY'RE NOT RECOMMENDED FOR FUNDING, BUT THAT'S NOT THE SAME AS DISAPPROVED.

MR. TOCHER: CORRECT BECAUSE THEY DON'T

APPROVE OR DISAPPROVE. THE WORKING GROUP RECOMMENDATIONS ARE JUST THAT, AND TYPICALLY THEY FALL INTO THREE TIERS: RECOMMENDED FOR FUNDING, RECOMMENDED FOR FUNDING IF FUNDS ARE AVAILABLE, AND THEN NOT RECOMMENDED FOR FUNDING AT THIS TIME. THOSE RECOMMENDATIONS, THOUGH, ARE REVIEWED IN THEIR ENTIRETY BY THE ICOC, AND SO THE ICOC COULD AND HAS REACHED DOWN INTO THAT THIRD TIER, NOT RECOMMENDED FOR FUNDING AT THIS TIME, AND FUNDED AN APPLICATION.

SO MY ONLY POINT IS THAT IF IT'S JUST -- IF YOU ARE GOING JUST OFF THAT FIRST OR SECOND TIER, IT'S POSSIBLE THE ICOC WILL HAVE INCOMPLETE INFORMATION AS TO SOME APPLICATIONS WHICH WOULD BIAS THEIR ABILITY TO REVIEW.

CHAIRMAN LO: IT'S A SMALL NUMBER, RIGHT?

MR. SHEEHY: ACTUALLY I'D LIKE TO MAKE A POINT. WE ACTUALLY HAVE NOT REACHED INTO THE THIRD TIER EVER.

MR. TOCHER: IN THE TRAINING GRANTS THERE WAS --

MR. SHEEHY: THERE WAS ONE THAT WAS RECOMMENDED FOR FUNDING THAT DID NOT FUND. THERE WAS NOT ONE THAT WAS NOT RECOMMENDED FOR FUNDING THAT WE FUNDED. BUT MY POINT WOULD BE, AND THIS IS REALLY ALL ABOUT WORKLOAD AND EFFICIENCY, AND NOT TO

OVERCOMPLICATE IT, BUT I THINK IT WOULD BE MUCH EASIER TO DO THE FIRST TWO CATEGORIES BECAUSE IF YOU THINK OF YOUR RATIOS, WE'VE KIND OF FOLLOWED ABOUT A 30-70 RATIO ON MAJOR RESEARCH GRANTS. THAT'S A BALLPARK, 25, 30 PERCENT, THAT FALL IN THE FIRST TWO CATEGORIES WHO GET FUNDED.

YOU KNOW, WE DON'T WANT TO BE, YOU KNOW, LOOKING AT A WHOLE HOST OF GRANTS, AND WHAT WE MIGHT LET THE ICOC KNOW IS THAT IF THEY DO REACH INTO THE THIRD TIER, TO COME BACK, THAT WE HAVEN'T DONE THAT ETHICAL REVIEW, RATHER THAN PUT THIS BURDEN. ALSO, IT RELIEVES US OF WHAT I FORESEE BEING ANOTHER PROBLEM, WHICH WOULD BE TO MAKE US A DE FACTO REGULATOR, WHICH I DO NOT WANT TO SEE US BECOMING BECAUSE WE ONLY CAN -- WE MADE THE DECISION VERY EARLY ON IN THIS BODY, AND THERE'S A BIT OF DEBATE, DO WE WANT TO BE THE REGULATOR FOR STEM CELL RESEARCH IN CALIFORNIA, OR DO WE WANT TO GOVERN WHAT CIRM FUNDS?

SO IF WE'RE REVIEWING APPLICATIONS THAT REALLY IN ALL LIKELIHOOD WILL NOT GET FUNDED AND PROVIDING INSIGHT ON THOSE, WE ARE BECOMING A DE FACTO REGULATOR; WHEREAS, IF WE REALLY HOLD OUR -- FOCUS OUR ATTENTION ON THOSE THAT ARE MOST LIKELY OR HAVE A STRONG POSSIBILITY OF BEING FUNDED, AND THEN MAKE SURE THAT THE ICOC KNOWS THAT IF THEY DO REACH INTO THAT

THIRD TIER, THAT IT WOULD BE ADVISABLE FOR THEM TO SEND IT BACK TO US JUST FOR A LOOK WITHIN THESE SPECIAL AREAS THAT WE'VE IDENTIFIED AS BEING AREAS FOR ADDITIONAL -- ACTUALLY AREAS JUST FOR SCRUTINY, THAT WE THINK THE POLICIES, YOU KNOW, FOR ALL THE REASONS WE'VE ELABORATED.

MS. KING: FOR A SHORT PERIOD OF TIME.

MR. SHEEHY: FOR A SHORT PERIOD OF TIME, RIGHT.

DR. PETERS: I THINK WE'RE WORKING WITH THREE DIFFERENT MODELS HERE. I'M A LITTLE BIT NERVOUS HERE ABOUT WHAT JEFF WAS SAYING. I THINK THE MINIMALIST MODEL IS THAT WE'VE GOT A COMMUNICATION GAP THAT NEEDS TO BE FILLED. GRANTEE APPLICANTS NEED TO KNOW HOW IMPORTANT OUR ETHICAL CONCERNS WITH REGARD TO OOCYTE DONATION ARE.

I THINK THE SECOND MODEL IS KEN'S. THAT IS TO SAY, WE MIGHT LOOK AT APPLICATIONS IN ORDER TO TEACH OURSELVES AS TO WHAT IT IS THAT'S GOING ON, AND WE CAN DO THAT RANDOMLY.

THE THIRD MODEL TO ME SOUNDS LIKE POLICING, FRANKLY, AND THAT THAT WOULD MAKE US ACTUALLY A FACTOR IN THE DECISION-MAKING. I'M WONDERING IF THAT'S MORE THAN WE WANT TO DO.

CHAIRMAN LO: WELL, I THINK THAT'S AN

IMPORTANT CONCERN. I THINK WE PROBABLY DO NOT WANT TO -- I MEAN WE'RE NOT CONSTITUTED TO DO GRANTS REVIEW, BUT I THINK WHAT WE COULD DO IS TO LOOK AT -- I THINK THE DECISION TO FUND OR NOT SHOULD NOT BE IN OUR DOMAIN, BUT I THINK THE POINTING OUT OF ETHICAL ISSUES THAT NEED MORE CONSIDERATION OR MORE SPECIFICATION, PRESUMING THEY'RE GOING TO BE FUNDED.

DR. PETERS: IN GENERAL OR GRANT BY GRANT?

CHAIRMAN LO: WELL, FOR THESE I THINK WE'RE SAYING GRANT BY GRANT BECAUSE, AS PAT POINTED OUT, WE DON'T HAVE A SET OF UNIFORM -- WE DON'T HAVE A SET OF RECOMMENDATIONS. WE JUST SAY HERE'S WHAT YOU SHOULD BE THINKING ABOUT.

MS. KING: BUT I DON'T THINK WE SHOULD BE IN THE BUSINESS. THAT'S WHY I KEEP TALKING ABOUT GAPS. I THINK YOU WANT TO BE OUT OF THE BUSINESS OF LOOKING AT INDIVIDUAL GRANTS AS SOON AS HUMANLY POSSIBLE. I WOULD THINK THAT IS WHEN YOU PUT OUT THESE GUIDELINES, AND THAT WOULD ALSO INCREASE PRESSURE ON GETTING THE GUIDELINES OUT EARLIER RATHER THAN LATER BECAUSE I QUITE AGREE WITH YOU. YOU DON'T WANT TO -- YOU DON'T WANT TO BE A SUPER IRB OR ANYTHING LIKE THAT. I DON'T THINK ANYBODY WANTS TO DO THAT. AND ONLY FOR A -- ONLY FOR A SMALL SUBSET OF GRANTS FOR A SHORT PERIOD OF TIME.

AND THAT'S WHY I THINK MOST OF THE QUESTION IS WHETHER THE WHOLE CIRM SEES IT THIS WAY TOO, OR IS IT JUST US? IT'S SORT OF A PROBLEM OF INSTITUTING A NEW SYSTEM WHERE THINGS ARE MOVING FASTER. I SEE IT MOVING FASTER THAN YOU HAD ANTICIPATED BECAUSE I THINK GOING FROM THE BASIC SCIENCE TO THINGS THAT START TO INVOLVE A HUMAN BEING IS A QUICK MOVE, AND WE'RE SORT OF BEHIND THE EIGHT BALL ON THE IMPLICATIONS OF MOVING INTO THIS NEW AREA. THAT'S, ANYWAY, THE WAY I SEE IT.

CHAIRMAN LO: I THINK THESE CONCERNS ABOUT NOT BECOMING A BODY THAT LOOKS AT GRANTS INTO THE INDEFINITE FUTURE, I'VE HEARD SEVERAL PEOPLE SAY THAT'S SOMETHING WE SHOULD AVOID. BY THE WAY, AN IMPLICATION OR THE CONVERSE OF THAT IS THAT IF WE'RE CONCERNED ABOUT CHIMERA APPLICATIONS COMING INTO CIRM FOR FUNDING, IT SOUNDS LIKE, IF THAT'S GOING TO HAPPEN, WE OUGHT TO SORT OF FIRST LEARN ABOUT, EDUCATE OURSELVES; AND, SECONDLY, WE MAY NEED TO GET SOME GUIDELINES IN PLACE FOR THAT SO THAT, AGAIN, WE DON'T HAVE TO REVIEW THOSE ONE BY ONE.

DR. KIESSLING: THE HARVARD ESCRO, IN RESPONSE TO THAT, HAS ACTUALLY ORGANIZED ON PRETTY SHORT NOTICE A WORKSHOP JUNE 12TH IN THE AFTERNOON. I'LL BE THERE, AND I CAN BE THIS COMMITTEE'S REPRESENTATIVE, BUT I THINK THAT IT WOULD BE OPEN TO

ANYBODY WHO WOULD LIKE TO COME. AND THEY'RE GETTING SOME PEOPLE IN WHO HAVE A LOT OF SOCIOLOGY BACKGROUNDS ON ANIMAL/HUMAN BEHAVIOR, THAT SORT OF THING. THESE APPLICATIONS ALL INVOLVE MOUSE. IT'S JUST PUTTING HUMAN ES CELLS INTO MOUSE BLASTOCYSTS, BUT IT'S ONE OF THE TOUCHY AREAS, AND THEN WHAT DO YOU DO WITH THOSE BLASTOCYSTS AND HOW LONG CAN YOU WATCH THEM? SO THAT'S THE WHOLE PURPOSE.

CHAIRMAN LO: I THINK WE DON'T NEED TO REINVENT THE WHEEL SO THAT IF SOMEONE -- THE CURRENT LITERATURE ON THIS, THERE'S AN ARTICLE IN *SCIENCE* FROM THE HOPKINS GROUP WHICH IS NOT SPECIFIC ENOUGH TO BE OF GUIDANCE IN LOOKING AT A PARTICULAR PROTOCOL. SO I THINK THAT HANK GREELEY HAS WRITTEN ABOUT THIS; BUT, AGAIN, IT'S MORE ON A CONCEPTUAL LEVEL AND IT'S NOT REALLY GOING TO HELP AN INVESTIGATOR SORT OF THINK THROUGH THE ISSUES AS SHE'S WRITING HER GRANT AND SUBMITTING TO THE SCRO.

DR. KIESSLING: THE DECISION WAS MADE TO SORT OF NOT COVER THE WHOLE AREA OF CHIMERAS, BUT TO SPECIFICALLY FOCUS ON THESE ONE OR TWO APPLICATIONS AND JUST LOOK AT THESE SPECIFIC PROBLEMS WITH THOSE APPLICATIONS BECAUSE THE FIELD IS TOO BIG TO JUST SWALLOW IN AN AFTERNOON.

CHAIRMAN LO: HAVE WE REACHED CLOSURE ON

THIS, THAT WE'RE GOING TO OFFER FOR A LIMITED PERIOD OF TIME TO LOOK AT THESE GRANTS, BUT NOT TO BE INVOLVED IN A RECOMMENDATION FOR A FUNDING, BUT JUST SORT OF IN A QUALITY IMPROVEMENT SPIRIT, BUT ALSO TO REQUEST THAT, FOR OUR OWN EDUCATION, THAT WE BE GIVEN A CHANCE TO REVIEW REDACTED GRANTS? OKAY.

DO YOU WANT TO MOVE ON TO --

DR. ROWLEY: CAN I JUST ASK, GEOFF, IS THIS GOING TO CAUSE PROBLEMS THAT YOU CAN FORESEE IN TERMS OF GRANTS OR GRANT REVIEW OR THE PROCESS?

DR. LOMAX: I'LL OFFER SCOTT A CHANCE TO CHIME IN IF HE LIKES. I'M SOMEWHAT REMOVED FROM THE ACTUAL OR I AM REMOVED FROM THE PROCESS OF THE MECHANICS OF THE GRANT. I'M REALLY GOING TO GO BACK TO MY COLLEAGUES AND RELATE THIS CONVERSATION AND HOPEFULLY WE ABLE TO PROVIDE A BETTER ANSWER.

I CERTAINLY THINK, YOU KNOW, IN THE CONVERSATION I HAVE HAD WITH THE GRANTS TEAM, THEY HAVE ASKED ME IN TERMS OF THE REGULATIONS, THEY'VE STRICTLY SAID -- INITIATED A MUCH MORE FOCUSED PROCESS ON SORT OF, OKAY, NOW SPECIFICALLY WHERE DO WE NEED TO BE REALLY DRILLING DOWN? THAT, AS SCOTT WILL TOUCH ON IN HIS REPORT, IS BECAUSE WE ARE NOW PUTTING IN PLACE THE PHYSICAL INFRASTRUCTURE. IT'S REALLY COMING TOGETHER. AND SO I HAVE HIGHLIGHTED THE ISSUE OF THE OOCYTE

GRANTS. I'VE POINTED TO THAT PIECE IN THE REGULATIONS, AND WE HAVE BEGUN TO THINK THROUGH PROCEDURALLY ADDITIONAL CHECKS AND PROCEDURES WE'LL PUT IN PLACE. SO I THINK WITHIN THAT CONTEXT, WHAT I'M TAKING AWAY FROM THAT IS THAT THERE'S A CLEAR RECEPTIVENESS AND SPIRIT TO SORT OF SAY, YES, OKAY. GIVE US YOUR BEST THINKING HERE ON WHAT WE CAN DO.

THE CONTENT OF THIS DISCUSSION I'LL BE ABLE TO TAKE BACK. THAT WILL BE EXTREMELY HELPFUL BECAUSE IT SERVES TO REALLY ENDORSE SOME OF THE POINTS I'VE RAISED. I GUESS MY SENSE AT THIS POINT WOULD BE TO CONTINUE TO MOVE THAT CONVERSATION FORWARD. IT'S RELATIVELY NEW FOR EVERYONE NOW THAT THEY'RE THINKING ABOUT IT IN THE CONTEXT OF THE SORT OF MECHANICS OF REVIEW AND ADMINISTRATION OF THESE GRANTS, BUT IT'S ALL VERY CONSISTENT WITH THE TRAJECTORY THAT THE ORGANIZATION HAS AT THIS TIME. DOES THAT GET IT?

MR. TOCHER: I WOULD ONLY ADD THAT RIGHT NOW, AS YOU WILL SEE IN A FEW MOMENTS WHEN I JUST GO OVER A QUICK SLIDE TO SHOW YOU SORT OF THE ADMINISTRATION OF A GRANT ONCE IT'S FUNDED, SORT OF THE PROCESSES THERE, IS THAT RIGHT NOW THE CONVERSATIONS THAT GEOFF IS TALKING ABOUT OCCUR AFTER A GRANT HAS BEEN DETERMINED TO BE FUNDED BY THE ICOC, AND THEN IT INITIATES AN ADMINISTRATIVE REVIEW TO ENSURE COMPLIANCE WITH IACUC

AND OUR REGULATIONS AS THEY ARE IMPLICATED. SO THAT'S BEEN A CONVERSATION THAT IS OCCURRING SORT OF AT THE ADMINISTRATION STAFF LEVEL OF WHAT SORT OF DOCUMENTATION, THAT SORT OF THING.

SO THE ONE THING I WOULD NOTE IS THAT THE ADDED, I THINK, WRINKLE FOR WHAT WE'VE BEEN TALKING ABOUT TODAY, THOUGH, IS THE NOTION OF PARTICIPATING OBVIOUSLY EARLIER IN THAT PROCESS, SO PRIOR TO THE GRANT APPROVAL BY THE ICOC. AND SO THAT'S A DIFFERENT CONVERSATION AND I THINK ONE THAT OBVIOUSLY WE'D WANT TO TALK TO THE ICOC ABOUT SO THAT WE KNOW IS THIS SOMETHING WE NEED TO HIGHLIGHT IN RFA'S? IS THIS SOMETHING THAT WE NEED TO BUILD INTO THE REVIEW PROCESS SO THAT EVERYONE'S ON ALERT THAT THINGS WILL GET KICKED OUT AND HAVE SORT OF A SECONDARY LOOK BY THIS GROUP BEFORE IT GOES TO THE ICOC? DO THEY WANT YOU TO LOOK AT TIER 3 OR NOT? AT LEAST MAKE THEM AWARE THAT THIS IS SOMETHING THAT YOU'RE INTERESTED IN KICKING AROUND.

CHAIRMAN LO: I THINK THIS IS ALL AN OFFER. IT'S CONTINGENT ON THE ICOC, THE GRANTS-MAKING WORKING GROUP TO SAY, YES, WE'D LIKE YOU TO GET INVOLVED. IF THEY SAY, YOU KNOW, THIS IS REALLY GOING TO MESS THINGS UP AND IT'S GOING TO MAKE THE -- THEN I THINK --

MR. TOCHER: PLEASE, I'M ONLY SPEAKING TO THE PROPOSALS THAT WE'VE BEEN TALKING ABOUT ABOUT

PARTICIPATION PRIOR TO A SPECIFIC GRANT AND WEIGHING IN ON IT. THE NOTION OF COLLECTING THE DATA, NOT ONLY OF OTHER UNIVERSES, BUT OF OUR GRANTS AFTER THEY HAVE BEEN FUNDED TO EXAMINE, TO GO BACK AND SEE IS THERE COMPLIANCE? HOW ARE WE DOCUMENTING THAT? IS THERE A WAY TO IMPROVE THIS? THAT'S PART AND PARCEL OF YOUR EXISTING MISSION THAT I THINK YOU HAVE ALREADY APPROVAL AND AUTHORITY TO DO.

CHAIRMAN LO: IN TERMS OF THIS REVIEW OF LOOKING AT OOCYTE DONATION PROTOCOLS, IF THE ICOC SAYS WE'D RATHER MAKE OUR DECISION AND JUST HAVE YOU LOOK AT THE ONES WE'RE GOING TO FUND, IF THEY THINK THAT WOULD BE HELPFUL, THAT'S FINE TOO. I THINK WE'RE REALLY MAKING AN OFFER TO SEE WHAT MIGHT BE HELPFUL. I'D SORT LEAVE OF THE ICOC AND THE GRANTS WORKING GROUP TO SORT OF SEE WHAT THEY THINK ABOUT IT.

MR. TOCHER: I MIGHT SUGGEST THAT THE NEXT STEP IS TO AT THE NEXT AVAILABLE MOMENT FOR AN ICOC MEETING IS TO MAYBE MAKE A REPORT ABOUT WHAT WAS DISCUSSED HERE THAT WOULD AT LEAST ALERT THE BOARD ON A FORMAL LEVEL THAT THIS IS SOMETHING THAT WE'VE BEEN KICKING AROUND TODAY.

CHAIRMAN LO: WE COULD DO THAT, AGAIN, AS A SENSE OF THIS COMMITTEE.

WE ARE NOW AT 10:30. WE'VE BEEN DOING GOOD

WORK. DO YOU WANT TO TAKE A BRIEF BREAK, AND THEN WE NEED TO ADDRESS THE DATA ON OHSS, AND THEN WE HAVE SOME UPDATES FROM GEOFF AND SCOTT AND SOME NEW ISSUES TO RAISE. WE DESERVE A TEN-MINUTE BREAK.

(A RECESS WAS TAKEN.)

CHAIRMAN LO: SO AS WE'RE CONVENING, LET ME TRY TO QUICKLY BECAUSE I DO HAVE A SENSE OF WANTING TO COMPLETE SOME OF THE THINGS THAT WE NEED TO LOOK AT. WE TALKED YESTERDAY ABOUT GETTING MORE DATA ON THE INCIDENCE OF OHSS IN OOCYTE DONORS FOR RESEARCH. I THINK WE ALL AGREE THAT DATA ARE NOW LACKING. IT SOUNDED LIKE WHAT WE'RE SAYING IS THAT CIRM OUGHT TO CONSIDER DEVELOPING AN RFP TO TRY AND ASK SOMEONE TO SORT OF PROPOSE A STUDY FOR FUNDABILITY.

MY OWN SENSE IS THAT, GIVEN THAT CIRM IS IN A TRANSITION, AS THEY HAVE INTERIM LEADERSHIP NOW AND THEY'RE GOING TO HAVE, GEOFF SAID, A NEW PRESIDENT HOPEFULLY BY JUNE, THAT PERHAPS THAT RECOMMENDATION OR ACTION ON THAT BE PUT OFF UNTIL THERE'S A NEW EXECUTIVE IN PLACE BECAUSE I THINK THAT THAT PERSON WOULD BE KEY IN THAT. SORT OF TRYING TO GO AHEAD WITHOUT -- IT'S SOMETHING I THINK I HEARD AGREEMENT ON THAT, AND I THINK IT'S JUST A MATTER OF WHEN WE PROPOSE THAT CIRM DO IT, NOT WHETHER THEY DO IT. DOES THAT SEEM ACCEPTABLE TO PEOPLE?

DR. ROWLEY: WELL, AND THE QUESTION IS REALLY, AS YOU STATED IT, IT WAS WOMEN WHO ARE EGG DONORS WHO BELONG TO MINORITIES. AND I THINK THAT THE BROADER ISSUE IS IS THERE A DIFFERENCE IN RESPONSE IN WOMEN OF DIFFERENT ETHNIC GROUPS OR SOCIOECONOMIC BACKGROUNDS ACROSS THE BOARD, NOT JUST EGG DONORS, BUT A BROADER ISSUE? AND THEN NOT TO SAY THAT ONE SHOULDN'T GET DATA ON EGG DONORS, BUT THE ISSUE IS IF THERE'S GENERAL EVIDENCE THAT ONE GROUP IS MORE SENSITIVE TO WHATEVER SORT OF TREATMENT, THIS SHOULD BE PUBLIC KNOWLEDGE. AND WHAT WE'VE AGREED IS THAT, AT LEAST AS FAR AS WE'RE CONCERNED, AND I THINK I CAN SPEAK FOR ANN AS WELL, AS FAR AS AN EDUCATED PUBLIC IS CONCERNED, THERE ISN'T INFORMATION ON DIFFERENT SUSCEPTIBILITY OR DIFFERENT RESPONSE OF WOMEN OF DIFFERENT ETHNIC OR SOCIAL GROUPS TO THE TREATMENT. AND THIS IS WHAT WE WANT CIRM TO GET INFORMATION OF.

CHAIRMAN LO: GREAT.

DR. KIESSLING: YOU CAN SAY THAT FOR ME.

DR. LOMAX: THIS WAS A COMMENT I WAS GOING TO PUT IN MY PRESENTATION, BUT I THINK THE TIMING IS PERHAPS MORE APPROPRIATE HERE. ONE ITEM IN YOUR FOLDER IS A LETTER WE RECEIVED FROM THE PRO-CHOICE ALLIANCE FOR RESPONSIBLE RESEARCH, AND THAT ALSO TOUCHES ON SOME OF THE DATA COLLECTION ISSUES THAT THIS LETTER

ENCOURAGES YOU TO ADDRESS. ONE POINT I'D LIKE YOU ALL TO BE AWARE OF IS A LOT OF THE LANGUAGE IN THIS LETTER ECHOES LANGUAGE THAT'S ALREADY IN AN EXISTING STATE LAW THAT COVERS NON-CIRM-FUNDED RESEARCH.

SO I CHECKED IN WITH THE STATE HEALTH DEPARTMENT, THE MATERNAL CHILD HEALTH BRANCH, WHICH IS IN CHARGE OF IMPLEMENTING THESE REGULATIONS, AND THEY ARE CURRENTLY IN A PROCESS OF VETTING SORT OF DATA COLLECTION FORMS AND EVALUATING SORT OF HOW TO MOVE FORWARD WITH IMPLEMENTATION. SO THE POINT I MAKE AT THIS POINT IN TIME IS THAT I THINK IT'S USEFUL TO SORT OF SEE WHAT THEY COME UP WITH IN TERMS OF A DATA COLLECTION MECHANISM LARGELY BECAUSE, AS YOU WILL HEAR IN THE PRESENTATION THAT I'LL GIVE IN A FEW MOMENTS, THAT ONE OF THE MAJOR MESSAGES THAT CAME OUT MY INTERACTION WITH INSTITUTIONS IS THE SORT OF HAVING DUELING -- DIFFERENT STATE STANDARDS FOR THE SAME WORK IS VERY BURDENSOME AND VERY PROBLEMATIC. SO TO THE EXTENT THAT WE HAVE CONSISTENCY IN TERMS OF ANY KIND OF REPORTING REQUIREMENT, THAT SORT OF THING IS VIEWED AS VERY HELPFUL FROM AN IMPLEMENTATION STANDPOINT. I'D JUST LIKE TO ADD THAT AT THIS TIME AND ACKNOWLEDGE THIS OTHER EFFORT THAT IS OCCURRING IN CALIFORNIA.

CHAIRMAN LO: GREAT. AND ACTUALLY, GEOFF, IF THIS IS A GOOD TIME TO TRANSITION OVER TO STAFF REPORTS

AND UPDATES. SCOTT, DO YOU WANT TO GO FIRST ON THE GRANTS ADMINISTRATION UPDATE?

MR. TOCHER: GREAT. I'LL JUST BE VERY BRIEF SO WE CAN GET ON TO THE OTHER MATTERS. THIS PERHAPS SHOULD HAVE OCCURRED PRIOR TO OUR LAST DISCUSSION, AND I WOULD HAVE INTERRUPTED A LITTLE BIT LESS. THIS WAS JUST A SLIDE TO SHOW YOU HOW THE GRANTS PROCESS KIND OF TAKES PLACE FROM START TO FINISH AT LEAST IN TERMS OF THE DECISION-MAKING PROCESS TO FUND A GRANT.

INITIALLY, AS YOU CAN SEE, THE GRANTS ARE RECEIVED, AND THEN THEY ARE SUBJECT TO THE SCIENTIFIC GRANT REVIEW. THIS IS OBVIOUSLY FOR SCIENCE RESEARCH GRANTS AS OPPOSED TO FACILITIES GRANTS. AFTER THE SCIENTIFIC REVIEW, GRANTS ARE GROUPED INTO THE THREE TIERS THAT I MENTIONED EARLIER, AND THOSE RECOMMENDATIONS ARE THEN FORWARDED ON TO THE ICOC. ONCE THE ICOC REVIEWS ALL OF THE GRANTS AND MAKES ITS DETERMINATIONS AS TO WHICH GRANTS IT'S GOING TO FUND, THAT KICKS OFF AN ADMINISTRATIVE REVIEW.

AND THIS ADMINISTRATIVE REVIEW LOOKS AT ALL ASPECTS OF THE GRANT, NOT ONLY THE SUBSTANCE OF THE GRANT, BUT ALSO THE GRANTEE STATUS TO MAKE SURE THAT THEY QUALIFY AS A NON-PROFIT INSTITUTION, IF THAT IS A REQUIREMENT, TO MAKE SURE THAT THE PI IS QUALIFIED, THAT THE PARAMETERS OF THE SPECIFIC RFA ARE ADHERED TO,

BUT ALSO THIS ALLOWS, AS WAS DISCUSSED EARLIER, FOR A JUST-IN-TIME CERTIFICATION PROCESS WHEREBY THE GRANTEE VERIFIES ANY APPLICABLE IACUC REVIEW FOR THE APPROVAL OF THE PROJECT'S PROPOSED USE INVOLVING INVERTEBRATE ANIMALS. THIS IS WHERE THE GRANTEE CERTIFIES SCRO COMMITTEE REVIEW AND APPROVAL OF THE PROJECT'S PROPOSED USE OF THE COVERED STEM CELL LINES, WHICH IS REFERRED TO IN THE MEDICAL AND ETHICAL STANDARDS REGULATIONS, AND CERTIFIES ANY APPLICABLE IRB REVIEW AND APPROVAL OF PROPOSED USE OF HUMAN SUBJECTS.

WHEN THOSE ASSURANCES ARE OBTAINED AND THOSE CERTIFICATIONS ARE OBTAINED, THEN THE NOTICE OF GRANT AWARD IS SENT OUT TO THE GRANTEE. AND ONCE THE GRANTEE SIGNS OFF ON THAT AND RETURNS IT TO CIRM, CIRM THEN NOTIFIES THE STATE CONTROLLER'S OFFICE WHO ACTUALLY CUTS THE CHECKS FOR THE GRANT.

THE GRANTS ADMINISTRATION POLICY FOR THE NONPROFIT GRANTEES HAS BEEN ALREADY APPROVED BY THE OFFICE OF ADMINISTRATIVE LAW, AND THAT POLICY IS IN EFFECT, AND IT'S WHAT WE'RE WORKING OFF OF FOR THE SEED AND COMPREHENSIVE GRANTS. SO THOSE GRANTS RIGHT NOW ARE GOING THROUGH THIS INTERIM ADMINISTRATIVE REVIEW RIGHT NOW. NO GRANTS HAVE BEEN FUNDED BY CIRM YET.

THE FOR-PROFIT GRANTS ADMINISTRATION POLICY IS STILL IN DEVELOPMENT AT THE STAFF LEVEL. AND I

BELIEVE WE ANTICIPATE A FIRST DRAFT PERHAPS IN JUNE, BUT I WOULD HAVE TO CONFIRM THAT WITH ARLENE CHIU. JUNE OR AUGUST WE'LL HAVE A DRAFT READY FOR ICOC APPROVAL THAT WE CAN USE IN UPCOMING FOR-PROFIT GRANTS.

AND IN THE LONG TERM, WE WILL MOVE ALL OF THIS INTO AN ELECTRONIC FORMAT THAT WILL MAKE IT EASIER FOR GRANTS ADMINISTRATION AND MONITORING AND AUDITING. THE CERTIFICATIONS AND REVIEWS THAT THE GRANTEE WILL MAKE IS SOMETHING THAT IS SUBJECT TO AUDIT BY CIRM STAFF AT ANY POINT DURING THE GRANT. SO IF AT SOME POINT, IN ADDITION TO THE ASSURANCES, THIS COMMITTEE WANTED TO EXAMINE, SAY, THE SPECIFIC PROPOSALS AND DISCUSSIONS AND CERTIFICATION OF APPROVAL BY AN IRB OR SCRO, THAT WOULD BE DOCUMENTATION THAT THE GRANTEE WOULD BE OBLIGED TO PROVIDE ON DEMAND.

DR. PETERS: DO YOU ANTICIPATE JUST DOING SPOT AUDITS FROM TIME TO TIME?

MR. TOCHER: I THINK THAT THAT'S THE APPROACH THAT WE'RE LOOKING AT RIGHT NOW. THERE JUST ISN'T THE INFRASTRUCTURE AT THE MOMENT TO DO A FULL-BLOWN AUDIT OF EACH AND EVERY GRANT AT EVERY SORT OF ANNUAL RENEWAL. SO I THINK THE NOTION IS, UNLESS IT'S A UNIQUE GRANT OR RFA THAT'S BEEN FUNDED WHERE WE HAVE JUST A SMALL NUMBER, SAY, A FACILITIES GRANT OR SOMETHING LIKE THAT, IT WOULD PROBABLY BE SOMETHING

WHERE WE WOULD DO A RANDOM SELECTION ON AN ANNUAL BASIS THAT WOULD BE AN INTENSIVE FINANCIAL AND PROGRAMMATIC AUDIT.

DR. OLDEN: DO YOU RECEIVE GRANTS AT ANY POINT, OR ARE THERE DESIGNATED SUBMISSION DEADLINES AND SO FORTH?

MR. TOCHER: YES, THERE ARE. THERE IS THE CERTIFICATIONS, OF COURSE, WHICH ARE JUST IN TIME WHICH MUST BE DONE PRIOR TO FUNDING. BUT THEN THERE ARE ALSO ANNUAL PROGRAMMATIC REPORTS AND FINANCIAL REPORTS, AND THOSE MUST BE SUBMITTED VARIOUSLY BETWEEN 60 AND 30 DAYS PRIOR TO THE ANNUAL RENEWAL OF THE GRANT, AND THAT MUST BE IN PLACE BEFORE THE --

DR. OLDEN: I'M ASKING A DIFFERENT QUESTION. CAN AN INVESTIGATOR SUBMIT A GRANT APPLICATION AT ANY POINT THROUGHOUT THE YEAR, OR ARE THERE DESIGNATED RECEIPT DEADLINES?

MR. TOCHER: THEY'RE KEYED OFF OF SPECIFIC RFA'S WHICH HAVE GIVEN TIMELINES FOR RECEIPT.

DR. OLDEN: ALL RIGHT. SO THEY'RE ALL IN RESPONSE TO RFA'S?

MR. TOCHER: THAT'S CORRECT.

CHAIRMAN LO: THANKS, SCOTT. GEOFF, YOU WANT TO GIVE US AN UPDATE ON THE REPORT ON THE CIRM EVALUATION INITIATIVE?

DR. LOMAX: YES. FRANCISCO, I BELIEVE YOU HAVE THESE MATERIALS, BUT I AM JUST GOING TO RESEND THEM RIGHT NOW FOR YOUR BENEFIT.

DR. PRIETO: OKAY.

DR. LOMAX: OKAY. BEFORE I BEGIN AGAIN TO DRAW ATTENTION TO THE MATERIALS IN YOUR PACKET, I'M NOW GOING TO DESCRIBE OUR EVALUATION INITIATIVE, WHICH I TOUCHED ON BRIEFLY YESTERDAY. AND A REMINDER, THERE'S TWO SETS OF MATERIALS IN YOUR PACKET. ONE IS THE FOUR-FOLD DOCUMENT THAT KIND OF CONCEPTUALLY DESCRIBES THE INITIATIVE AND DOCUMENTS SOME OF THE SPECIFIC ACTIVITIES WE ENGAGED IN. AND THEN INSERTED WITHIN THAT DOCUMENT IS A SUMMARY REPORT. I BELIEVE IT'S SIX PAGES LONG. MOST OF THE POINTS I'M GOING TO MAKE IN THIS PRESENTATION HOPEFULLY ARE AMPLIFIED AS WELL IN THE SUMMARY REPORT, BUT I'D LIKE TO TOUCH ON SOME OF THE HIGHLIGHTS.

DR. PRIETO: GEOFF, JUST TO MAKE SURE, YOU'RE TALKING ABOUT THE EVALUATION INITIATIVE SUMMARY REPORT?

DR. LOMAX: THE SLIDES I'M WORKING OFF OF NOW SHOULD HAVE JUST COME OVER TO YOU AS WELL. I THINK YOU GOT THEM EARLIER, BUT WE SENT ANOTHER SET JUST TO BE SURE.

DR. PRIETO: NO, I'M NOT SURE IF I GOT THOSE EARLIER, BUT I'LL LOOK FOR THEM NOW.

DR. LOMAX: SHOULD BE RIGHT UP FRONT.

SO THE MAJOR OBJECTIVE IS TO UNDERSTAND HOW THE REGULATIONS ARE WORKING AND REALLY TO THE EXTENT THEY'RE ACHIEVING THEIR INTENDED PURPOSE. THE PROCESS WAS DESIGNED TO IMPROVE REGULATORY PRACTICE. AND WE USE A NUMBER OF MECHANISMS. JUST TO SORT OF CHARACTERIZE THOSE MECHANISMS, WE HAD SOME VERY ACTIVE-TYPE MECHANISMS WHICH WERE GOING OUT AND HOLDING WORKSHOPS AND TALKING TO PEOPLE, AND THERE WAS A SET OF PASSIVE MECHANISMS, WHICH A LOT OF INFORMATION COMES BACK TO ME THROUGH PHONE CALLS FROM SCRO CHAIRMEN TRYING TO SORT OF SORT OUT WHAT TO DO OR DIFFERENT MEMBERS OF THE COMMUNITY. SO WHAT I'M GOING TO TRY TO DO THROUGH THIS REPORT IS FOCUS MAINLY ON OUR ACTIVE PROGRESS, AND THAT'S WHAT THE REPORT SUMMARIZES, BUT I'LL TOUCH ON A FEW OF THE INFORMATION WE PICKED UP THROUGH SOME OF THESE MORE PASSIVE MECHANISMS.

AGAIN, THE GOAL IS WE WOULD LIKE TO BE ABLE TO HAVE AN EVIDENCE BASE TO REFINE REGULATORY PRACTICE, PROMOTE CONSISTENCY IN COLLABORATION, AND REALLY BUILD A SET OF SUSTAINABLE FEEDBACK MECHANISMS WITH INSTITUTIONS TO, AGAIN, IMPROVE THE OVERALL RESEARCH AND RESEARCH OVERSIGHT.

AGAIN, THE MAJOR FOCUS OF THIS PRESENTATION WILL BE OUR REGIONAL WORKSHOPS, BUT TO KEEP IN MIND WE

HAVE BEEN PARTICIPATING IN CONFERENCES AND OTHER EVENTS. FOR EXAMPLE, MARY TALKED ABOUT THE STATE ALLIANCE, WHICH WE THINK WILL BE VERY PRODUCTIVE BOTH ON THE IP SIDE AND WITH STANDARDS. STANDARDS HAVE BEEN A MAJOR PART OF THOSE DISCUSSIONS. AND, AGAIN, WE WANT TO CONTINUE TO RECEIVE PUBLIC INPUT TO INFORM THIS PROCESS.

A BIT OF A CONCEPTUAL DIAGRAM. WE SHARED THIS WITH THE GRANTEES. JUST TO SORT OF SHARE WITH YOU WE SORT OF ENVISION SORT OF A PROCESS THAT STARTS WITH WE'RE GOING OUT AND SEEKING INFORMATION. WE'VE DONE THAT. WE'VE COLLECTED IT AND TRIED TO SYNTHESIZE IT, AND THAT'S WHAT I'M HOPING TO ACCOMPLISH TODAY. AND THEN WE CAN SORT OF APPRAISE AND INTERPRET THE EVIDENCE. PART OF THAT IS YOUR JOB, AND HOPING TO WORK WITH YOU ON THAT. AND, AGAIN, TO CONTINUE TO DEVELOP PUBLIC FORUMS TO CONSIDER ANY POLICY RECOMMENDATIONS. AND, AGAIN, THAT WOULD BE ANY FUTURE RECOMMENDATIONS COMING OUT OF THIS GROUP. THAT WOULD BE A PUBLIC PROCESS.

AND ONE OF THE THINGS I TRIED TO EMPHASIZE WITH THE INSTITUTIONS IN THE FIELD WAS REALLY THAT WE DON'T WANT PEOPLE TO TAKE AWAY THE SENSE THAT THIS IS A ROAD MAP TO JUST INCREASING REGULATION BECAUSE I DON'T THINK THAT'S THE GOAL. THE IDEA IS THAT WE HAVE A

VARIETY OF MECHANISMS. WE'VE TALKED ABOUT BRINGING IN CONSULTANTS, WHATEVER THE MECHANISMS MAY BE OF THE RESEARCH PROGRAM, THAT WE WANT TO USE THE BEST -- BRING ALL THE RESOURCES TO BEAR TO BRING ABOUT THE BEST OUTCOME, BUT CERTAINLY MORE REGULATION IS NOT IN EVERY CASE THE BEST OUTCOME.

SO I'M GOING TO FOCUS NOW ON OUR REGIONAL WORKSHOPS FOR A FEW MINUTES. WE HELD TWO OF THEM, ONE AT STANFORD UNIVERSITY IN FEBRUARY AND THE BURNHAM INSTITUTE IN APRIL. I THINK THE PICTURES ARE ALWAYS HELPFUL. YOU SEE ZACH HALL IN THE LOWER LEFT-HAND CORNER THERE, I THINK, TALKING TO SOME OF THE INSTITUTIONAL REPRESENTATIVES ABOUT AT THAT POINT IN THE CONVERSATION SOME IDEAS ABOUT STEM CELL BANKING. BUT JUST TO GIVE YOU A FLAVOR FOR WHAT THE SETUP IS, IT WAS DESIGNED TO BE VERY SORT OF CONVERSATIONAL, TRIED TO MAKE IT IN THE ROUND. WE WERE TRYING TO GET AS MUCH INTERACTION AS POSSIBLE.

I'D LIKE TO ACKNOWLEDGE SHAKTI NARAYAN IN THAT MIDDLE SLIDE ON THE LEFT THERE TALKING TO DAVID MAGNUS. SHAKTI WAS FROM BOLT HALL AND HE WAS A REAL HEAVY LIFTER. HE WAS BASICALLY AN INTERN WHO WORKED WITH ME FOR ABOUT FOUR MONTHS AND MADE A HUGE CONTRIBUTION TO THIS EFFORT BOTH IN TERMS OF HELPING ORGANIZE THE EVENTS AND SUMMARIZE AS WELL. AND PAT WAS

ALSO A HUGE HELP. SO THANK YOU, PAT, AS ALWAYS MAKING LOGISTICAL THINGS HAPPEN.

IN THE LOWER RIGHT CORNER, PART OF THE WORKSHOP, AT THE END OF THE DAY, WE HAD LUNCH FOR PARTICIPANTS. AND PART OF WHAT WE WANTED TO ACCOMPLISH IS WE'D HAVE A BACK AND FORTH WHERE CIRM IS PRESENT, BUT WE ALSO WANTED TO GIVE THEM AN OPPORTUNITY TO REALLY TALK AMONGST THEMSELVES AND SHARE IDEAS. AS WE'LL LEARN LATER, I THINK THAT REALLY PAID OFF, SORT OF BUILDING A SORT OF ENVIRONMENT WHERE FOLKS COULD TALK AMONGST THEMSELVES AND SHARE IDEAS AND ULTIMATELY BUILD COLLABORATIONS.

SO I'VE SORT OF TOUCHED ON THIS. THE GOALS, AGAIN, TO MEET US AND LEARN WHO WE ARE, TO NETWORK WITH PEERS, AND THEN CONTRIBUTE TO THE SORT OF BROADER INITIATIVE, WHICH I'VE DESCRIBED TO YOU AND IS DESCRIBED FURTHER IN THE PACKET. AND SPECIFICALLY THE GOAL WAS TO IDENTIFY ANY POLICY ISSUES FOR FUTURE CONSIDERATION.

SO THE WORKSHOP STRUCTURE IS THAT WE KIND OF BROKE THE CONVERSATION INTO A SERIES OF VIGNETTES, IF YOU WILL. THERE WERE FIVE OF THEM. THE TOPICS COVERED IN EACH VIGNETTE, WE THINK, KIND OF CUT UP THE REGULATIONS IN A SORT OF LOGICAL WAY. WE FIRST TALKED ABOUT THE SCRO COMMITTEE REQUIREMENT AND HOW THAT'S

GOING IN TERMS OF PEOPLE ACTUALLY IMPLEMENTING THAT REQUIREMENT. ISSUES THAT HAVE COME UP DURING THE SCIENTIFIC AND ETHICAL REVIEW OF PROPOSALS. THE ISSUE OF VERIFICATION OF ACCEPTABLE RESEARCH MATERIALS WAS IDENTIFIED ACTUALLY IN ADVANCE OF THE WORKSHOP THROUGH SOME KEY INFORMANT INTERVIEWS AS A PARTICULAR TOPIC THAT PEOPLE FELT AT THIS TIME WAS WORTH HAVING A CONVERSATION ABOUT. SOME ISSUES ABOUT INFORMED CONSENT AND PROTECTION OF RESEARCH DONORS, AND SPECIFICALLY THE OOCYTE DONORS WAS THE FINAL TOPIC.

WITH REGARD TO THE COMMITTEE REQUIREMENT, AGAIN, MOST PARTICIPATING INSTITUTIONS HAD ALREADY ESTABLISHED A COMMITTEE. AND A LOT OF THE WORK, PARTICULARLY KEEP IN MIND WE HAD A FEBRUARY WORKSHOP, WHICH WAS JUST IN ADVANCE OF GRANTS BEING RELEASED, AND THEN AN APRIL WORKSHOP WHERE WE ALREADY HAD PUT OUT NOTICE THAT PEOPLE WERE ELIGIBLE FOR FUNDING. SO IN FEBRUARY PEOPLE WERE VERY MUCH DESCRIBED. WE'VE PRETTY MUCH GOT IT NAILED DOWN, AND WE'RE JUST KIND OF TINKERING AROUND THE EDGES. ACTUALLY IN APRIL EVERYONE THERE WAS REALLY DESCRIBING THE FACT THAT THEY'VE GOT THEIR SCRO'S TOGETHER, AND THEN TALKING A LITTLE BIT MORE ABOUT VERY SPECIFIC ISSUES. SO YOU CAN JUST SEE THE DIFFERENCE BETWEEN FEBRUARY AND APRIL WAS SORT OF CONSIDERABLE IN THE NATURE OF THE CONVERSATION.

ONE OF THE INTERESTING SORT OF PIECES OF HOW THIS ENTERPRISE HAS EVOLVED WAS, IF YOU REMEMBER, WE HELD A WORKSHOP IN DECEMBER OF 2005. AND THIS WAS VERY EARLY ON TO INFORM OUR REGULATIONS. AT THAT TIME THE INSTITUTIONS, THE SCRO COMMITTEES IN PARTICULAR, WERE IN SOME CASES SOMEWHAT INFORMAL ENTITIES WITHIN THE INSTITUTIONS THAT COULD BE -- SORT OF EXPERTISE THAT COULD BE ON CALL AND SORT OF WORK WITH THE IRB'S, BUT IN A SOMEWHAT DECENTRALIZED, AND I DON'T WANT TO SAY INFORMAL, BUT THE PRIMARY POINT IS IT WAS A DECENTRALIZED BODY THAT WAS AVAILABLE TO SORT OF COME IN WHEN STEM CELL PROPOSALS, WHEN THE IRB COULD REALLY BENEFIT FROM EXPERTISE IN STEM CELL RESEARCH.

THAT MODEL, I THINK, WITH THE ADVENT OF OUR REGULATIONS, HAS GONE SOMEWHAT OUT THE WINDOW. I THINK FOR THE MOST PART THE INSTITUTIONS HAVE REALLY MOVED TOWARDS FORMALIZED SCRO COMMITTEES, AND THEN VERY MORE FORMALIZED SORT OF COORDINATION WITH THE IRB. AND I THINK, AGAIN, THAT'S THE RESULT OF THE FACT ONCE YOU PUT FORMAL REGULATIONS IN PLACE, IT JUST INITIATES THE LAWYERS GET INVOLVED AND PEOPLE LOOK FOR MUCH MORE EXACT KIND OF PROCEDURES AND POLICIES IN THE INSTITUTIONS. AND I THINK OVERALL THAT'S PROBABLY A GOOD THING, BUT IT CERTAINLY WAS EVIDENT FROM OUR EARLIER DISCUSSIONS TO OUR LATER DISCUSSIONS WHERE

INSTITUTIONS HAVE TAKEN OUR REGULATIONS AND INSTITUTIONALIZED THEM MORE FORMALLY, IF YOU WILL.

THERE WERE A NUMBER OF QUESTIONS ABOUT SOME OF THE MEMBERSHIP AND VOTING REQUIREMENTS. AND I THINK WE WERE ABLE TO CLARIFY THOSE. THEY WERE RELATIVELY STRAIGHTFORWARD; BUT, FOR EXAMPLE, SOME PEOPLE HAD SOME QUESTIONS LIKE ARE THE OUTSIDE MEMBERS, DO THEY HAVE FORMAL VOTING AUTHORITY? WE SAID ABSOLUTELY. WE RELATED SOME OF THE CONVERSATIONS. THIS IS A CONVERSATION I REMEMBER QUITE CLEARLY IN LOS ANGELES ABOUT THE ROLE OF THE OUTSIDE MEMBERS. AND I WAS ABLE TO ASSURE THEM THAT BOTH THE PATIENT ADVOCATES AND THE OUTSIDE MEMBER SHOULD HAVE FULL POWER AND AUTHORITY, VOTING POWER AND AUTHORITY, IN THE COMMITTEE.

IN ADDITION, I THINK THIS WAS ONE OF THE MOST SORT OF EXCITING THINGS WE LEARNED. IN THE REGULATIONS ONE OF THE THINGS WE EXPLICITLY SORT OF CALL OUT IS THAT THERE MAY BE SHARED OR JOINT COMMITTEES, PARTNERSHIPS AMONG INSTITUTIONS. THERE ARE SOME INSTITUTIONS THAT HAVE RECEIVED ONE GRANT, FOR EXAMPLE. SO WE NOW KNOW OF A PARTNERSHIP BETWEEN THE UNIVERSITY OF CALIFORNIA AT DAVIS, WHICH IS A LARGER INSTITUTION, WORKING WITH THE BUCK INSTITUTE, WHICH IS A SMALL INSTITUTION, AND UC MERCED. AND WE WERE ABLE TO FOLLOW UP. THE SMALLER INSTITUTIONS, THEY'VE GOT A JOINT

AGREEMENT NOW. THE SMALLER INSTITUTIONS APPRECIATE SORT OF THE OVERHEAD THAT UC DAVIS BRINGS, AND UC DAVIS VERY MUCH APPRECIATES THE EXPERTISE THAT THE SMALLER INSTITUTIONS BRING. SO NOT ONLY DOES IT CREATE SORT OF AN ECONOMY OF SCALE, BUT ALSO IT RESULTS IN A LOT OF SHARED EXPERTISE. AGAIN, IF YOU GO BACK TO THE RECORD, I THINK SOME OF THIS WAS SORT OF ENVISIONED, AND I'M PLEASED TO REPORT THAT I THINK IT'S WORKING OUT AND IT'S REALLY SERVING TO PROMOTE EFFICIENCY IN THE REVIEW AND RESULT, I THINK, IN BETTER REVIEWS BECAUSE YOU'VE GOT THIS SHARED EXPERTISE.

DR. ROWLEY: I NOTICED IN YOUR SUMMARY THAT ONE OF THE CONCERNS WAS PAYMENT FOR OUTSIDE MEMBERS. AND APPARENTLY THAT'S PROHIBITED BY STATE LAW. HOW WAS THAT RESOLVED?

DR. LOMAX: WELL, AT THE MOMENT WE HAVE WHAT WE HAVE. IT'S CERTAINLY SOMETHING IF AT SOME POINT IN TIME WE WANTED TO DISCUSS, WE COULD DISCUSS. I DON'T KNOW IF YOU'RE INVOLVED, BUT I'LL REFRESH THE CONVERSATION. AT ONE POINT IN TIME, THERE WAS CONCERNS THAT IF THE INSTITUTION MADE PAYMENT TO THE OUTSIDE MEMBER, THAT THAT MIGHT SOMEHOW BE COERCIVE OR COLOR THEIR JUDGMENT IN TERMS OF THEIR REVIEW. SO OUR POLICIES STATE THAT THEY CANNOT RECEIVE MONEY FOR PART OF THEIR PARTICIPATION ON THE SCRO COMMITTEE.

WHAT CAME UP SUBSEQUENTLY WAS THAT ONE INSTITUTION THAT WAS PARTICULARLY VOCAL ON THIS POINT SAID, AS AN INSTITUTIONAL POLICY, THEY WANT TO TREAT ALL COMMITTEE MEMBERS FAIRLY WITH AN IDENTICAL POLICY, AND THAT THEY DIDN'T FEEL THAT THE PRESENCE OR ABSENCE OF A MODEST REMUNERATION, BASICALLY A DAILY STIPEND, WAS COLORING THE JUDGMENT, AND THAT IT ACTUALLY CREATED SOMETHING THAT MADE THE INSTITUTION UNCOMFORTABLE WHERE THEY HAD TO HAVE DIFFERENTIAL POLICIES AND ESSENTIALLY DISCRIMINATE AGAINST DIFFERENT MEMBERS. THAT WAS THE NATURE OF THE COMMENT. THAT COMMENT OBVIOUSLY NEEDS TO BE BALANCED AGAINST THE SORT OF POLICY GOALS OF THE REGULATION, BUT IT WAS CALLED OUT AS SOMETHING THAT THIS PARTICULAR INSTITUTION FELT WAS UNUSUAL. AND I THINK THAT COMMENT CAME TO ME.

I HAD AN OPPORTUNITY TO KIND OF ASK AROUND A BIT, AND PEOPLE SAY, "YOU KNOW, WE'RE LIVING WITH IT, BUT IN GENERAL WE'D LIKE TO HAVE LEVEL POLICIES FOR ALL OUR MEMBERS." SO IT'S CREATED THIS.

DR. ROWLEY: IT SOUNDS AS THOUGH YOU HAVEN'T RESOLVED.

DR. LOMAX: THERE'S NOTHING TO RESOLVE. IN A SENSE OUR REGULATIONS SAY THEY CAN'T PAY THEM. AND SO IN A SENSE THEY FEEL SORT OF STUCK WITH A REGULATION THAT THEY WISH WAS WRITTEN DIFFERENTLY, BUT THAT'S THE

REGULATION.

DR. PRIETO: GEOFF, IS THAT SOMETHING THAT COMES OUT OF THE TERMS OF THE INITIATIVE, OR IS THAT SOMETHING THAT WE CAME UP WITH AS A POLICY AND COULD MODIFY?

DR. LOMAX: THAT IS A DISCRETIONARY POLICY THAT COULD BE MODIFIED IF THE WORKING GROUP CHOSE TO MODIFY IT. IF THE ICOC CHOSE TO MODIFY IT, YOU COULD RECOMMEND MODIFICATION ON THAT.

DR. PRIETO: JUST AS A PATIENT ADVOCATE WHO'S GIVEN UP A LOT OF DAYS OF WORK FOR THIS ENDEAVOR, I THINK THAT I WOULD BE IN FAVOR OF ALLOWING SOME SORT OF A PER DIEM. I THINK THAT FOR A LOT OF PATIENT ADVOCATES, AND I THINK VIRTUALLY ALL OF US HAVE DAY JOBS, YOU KNOW, THE TIME LOST TO PROVIDE A SERVICE LIKE THIS CAN BECOME A SIGNIFICANT ISSUE, AND IT BECOMES A BARRIER TO PARTICIPATION. IT LIMITS WHO WOULD BE AVAILABLE AND WHO COULD SERVE, AND THERE ARE PEOPLE WHOSE INPUT I THINK WE'D WANT WHO REALLY CAN'T DO IT IF IT MEANS GIVING UP A DAY OF WORK OR GIVING MANY DAYS OF WORK REALLY. SO I'D BE IN FAVOR OF MODIFYING THAT TO ALLOW SOME PER DIEM.

DR. LOMAX: I THINK WHAT I SUGGEST IS OUT OF ALL THIS, THE IDEA WOULD BE THAT YOU ALL CONSIDER SOME SORT OF SHORT LIST OR LONG LIST OF ISSUES THAT YOU MAY

CHOOSE TO ADDRESS AT FUTURE MEETINGS. AND CERTAINLY AS THE STAFF, I WOULD BE PREPARED TO DO SORT OF BACKGROUND WORK IN THESE AREAS TO PREPARE FOR THOSE DELIBERATIONS. AGAIN, IT WOULD BE SORT OF TYPICAL OF ANY POLICY DELIBERATION PERFORMED BY THIS WORKING GROUP. WE WOULD COME UP WITH A SET OF OPTIONS. IT COULD BE SUBJECT TO PUBLIC COMMENT, AND WE WOULD GO FROM THERE.

SO I'M OFFERING THIS INFORMATION FOR YOUR BENEFIT AT THIS TIME. I SUGGEST PERHAPS YOU MAY CONSIDER SOME TRIAGE AS WE GO THROUGH THE LIST OF ITEMS AND ALSO BASED ON YOUR REVIEW OF THE WRITTEN REPORT BECAUSE THIS IS NOT A COMPREHENSIVE REVIEW IN THIS PRESENTATION, BUT I LEAVE TO THE DISCRETION OF THE CO-CHAIRS.

I'M MOVING TO THE NEXT SLIDE. IT'S TITLED "SCIENTIFIC AND ETHICAL REVIEW." I THINK ONE AREA WHERE THE INSTITUTIONS, I THINK, WERE VERY APPRECIATIVE OF YOUR WORK WAS THE DEFINITION OF COVERED STEM CELL LINES. WE SPENT QUITE A BIT OF TIME ON THAT DEFINITION. I ACTUALLY ALSO, SORT OF IN RESPONSE TO THE INSTITUTIONS, ACKNOWLEDGED THAT THEY CONTRIBUTED THROUGH THE PUBLIC COMMENT PROCESS TO HELP US IMPROVE THAT DEFINITION. BUT THE SENSE IS THAT BY NARROWING THE DEFINITION IN A VERY PRECISE WAY TO EXACTLY THIS SET OF MATERIALS THAT WE'RE CONCERNED WITH FOR REVIEW,

THAT IT'S MADE FOR A VERY CLEAR REGULATION.

AND I THINK IN CONTRAST, AND IN ALL FAIRNESS, IN CONTRAST, THEY RAISED SOME ISSUES ABOUT EXISTING CALIFORNIA REGULATIONS. AND IN ALL FAIRNESS, THOSE REGULATIONS WERE WRITTEN MUCH EARLIER. SO YOU PERHAPS DIDN'T HAVE THE BENEFIT OF THE DELIBERATIONS AND THE KNOWLEDGE WE HAD AT THE TIME WE PUT OURS FORWARD. THEY WERE GRAPPLING BECAUSE EXISTING LANGUAGE, AND I'VE GOT IT HIGHLIGHTED HERE, THESE WERE SORT OF SOME OF THE ISSUES THAT CAME UP.

SOME OF THE EARLY STATE REGULATIONS, WHICH, AGAIN, THEY STILL HAVE TO IMPLEMENT IN THEIR OTHER PROGRAMS, BECAUSE NOT ALL THEIR STEM CELL PROGRAMS ARE FUNDED THROUGH CIRM GRANTS, IS LANGUAGE THAT SPEAKS MORE BROADLY ABOUT HUMAN ADULT STEM CELLS FROM ANY SOURCE. IF YOU HAVE AN OVERLY BROAD UNIVERSE OF MATERIAL THAT YOU SORT OF SUBJECT TO THIS REVIEW, THE REAL CONCERN WAS THAT THERE WAS A REAL POTENTIAL FOR DUPLICATIVE REVIEWS. YOU START GETTING INTO ISSUES OF DOES THIS INCLUDE BONE MARROW TRANSPLANT OR EVEN BLOOD TRANSFUSION, FOR THAT MATTER. SO I THINK, AGAIN, THESE WERE ISSUES THAT WE GRAPPLED WITH AND SPENT QUITE A BIT OF TIME. TO REPORT BACK TO YOU, I THINK IT WAS TIME WELL SPENT.

NOW, THE BENEFIT IS THAT THE MOST RECENT

STATE LEGISLATION HAS LANGUAGE THAT SORT OF TRIES TO HARMONIZE. IT SORT OF CHARGES THE STATE WITH HARMONIZING SORT OF STATE REGULATIONS WITH CIRM REGULATIONS. SO I THINK FOLKS FELT, GIVEN THAT LANGUAGE, THEY COULD SORT OF INDEPENDENTLY MOVE TOWARDS HARMONIZATION. I ONLY CALL THIS OUT AGAIN TO SORT OF EMPHASIZE SORT OF THE VALUE OF THE PRECISION OF OUR REGULATORY DEFINITION. AGAIN, THAT WAS RAISED BY THE INSTITUTIONAL REPRESENTATIVES.

I THINK, AGAIN, ONE OF THE OTHER AREAS THAT INSTITUTIONS WERE -- IT'S CONTINUING TO EVOLVE, BUT EVOLVING IN A POSITIVE DIRECTION, I THINK, IS CONTINUING TO SORT OF COORDINATE WITH THE IRB IN TERMS OF WHO'S RESPONSIBLE FOR WHAT REVIEWS OR HOW THEY'RE GOING TO COORDINATE THAT. I THINK THE MESSAGE THAT CAME OUT, WHICH IS, I THINK, FINE FROM TO OUR PERSPECTIVE IN TERMS OF WHAT WE ENVISION IN THE REGULATIONS, IS THAT INSTITUTIONS ARE DEALING WITH SOME OF THESE THINGS VERY DIFFERENTLY. AND THERE'S EVEN ONE INSTITUTION THAT WAS CONSIDERING HAVING THEIR SCRO MEMBERS OR THEIR SCRO MEMBERS GO THROUGH THE IRB TRAINING SO THEY WOULD STILL BE A SCRO, BUT THEY WOULD HAVE THE TRAINING TO SORT OF LOOK AT HUMAN SUBJECTS ISSUES SO THAT IN THAT PARTICULAR CASE, WHEN THE PROPOSAL CAME TO THE IRB FOR REVIEW, IT WOULD HAVE THE

BENEFIT OF BEING PROCESSED BOTH IN TERMS OF WHAT OUR REGULATIONS ENVISION FOR THE ESCRO COMMITTEE, BUT ALSO THERE COULD BE SORT OF COMMENTARY ON THE HUMAN SUBJECTS ISSUES. SORT OF THE PUMP WOULD BE PRIMED SO THE IRB COULD THEN REVIEW IT IN A MORE EXPEDIENT MATTER.

SO THERE WAS A LOT OF CREATIVITY THERE AND A LOT OF REFINEMENT GOING ON, AND I'M HOPING ACTUALLY TO ENCOURAGE SOME OF THE INSTITUTIONS TO CONSIDER WRITING SOME OF THIS UP BECAUSE I THINK IT'S REALLY OF BENEFIT BOTH IN CALIFORNIA, BUT NATIONALLY IN TERMS OF OTHER STATES AND OTHER INITIATIVES. SO WE'LL SEE WHAT HAPPENS. THERE WAS CERTAINLY SOME INTEREST THERE.

AGAIN, I THINK AS THE STORIES GOT TOLD AND PEOPLE -- THERE WAS A LOT OF THE GIVE-AND-TAKE AND SOMETIMES BEING VERY SPECIFIC ABOUT HOW DO YOU COORDINATE THIS AND THAT. PEOPLE FOUND THAT QUITE USEFUL, AND SO PART OF THE TAKE-HOME MESSAGE WAS IF WE CAN CONTINUE SORT OF ON A PERIODIC BASIS HAVING THESE CONVERSATIONS, THEY STILL SEEM TO BE PRODUCTIVE. I THINK THAT'S A REFLECTION OF THE FACT THAT IT'S AN EMERGING SORT OF AREA THAT HASN'T QUITE REACHED MATURITY. IN THIS SORT OF EMERGENT PHASE IN PARTICULAR, THERE'S A VALUE TO THIS LEVEL OF INTERACTION. AND I THINK THAT'S ALSO REFLECTED IN SOME OF THE EVALUATION COMMENTS WHICH ARE ON THE FINAL PAGE

OF THE SUMMARY.

I THINK THE BIGGEST SOURCE OF CONCERN AND FRUSTRATION FOR THE INSTITUTIONS ARE STILL THE ESSENTIALLY FOREIGN CELL LINES, CELL LINES THAT COME FROM OUTSIDE THE UNITED STATES. A NUMBER OF INSTITUTIONS SORT OF DESCRIBED THEIR EFFORTS TO DO DUE DILIGENCE AROUND LOOKING AT ISSUES ABOUT CONSENT, NOT JUST THE FORMS, BUT TRYING TO DEVELOP A BETTER UNDERSTANDING OF THE CONSENT PROCESS. I WAS QUITE IMPRESSED WITH SOME OF THE INSTITUTIONS THAT REALLY FELT AN OBLIGATION TO CONTACT PEOPLE OVERSEAS AND GET SOME KIND OF UNDERSTANDING OF THE PROCESS.

AND THE UPSHOT OF IT ALL WAS THEY FELT THEY COULD MAKE DETERMINATIONS THAT CELL LINES HAVE BEEN ACCEPTABLY DERIVED, BUT THE AMOUNT OF WORK INVOLVED, THEY WOULD HATE TO HAVE TO SEE SOMEONE SORT OF REPEAT THE PROCESS. SO THE BIG QUESTION TO US WAS IS THERE SOME WAY CIRM COULD CREATE A REGISTRY OF THESE LINES OR DEVELOP SOME KIND OF LIST THAT WOULD ALLOW THEM TO BE ABLE TO THEN SAY THESE ARE LIKE SAFE HARBOR CELL LINES.

AND I TOOK THAT QUESTION BACK TO CIRM. UNFORTUNATELY AT THE MOMENT WE DON'T REALLY HAVE A MECHANISM THAT WE CAN SORT OF IMMEDIATELY IMPLEMENT. I THINK PERHAPS THE BEST LONG-TERM SOLUTION IS IN THE CONTEXT OF A STEM CELL BANK, AND WE'RE NOT QUITE THERE

YET. I THINK UNFORTUNATELY WE'RE IN THIS SORT OF GAP, WE CALL IT, OR THIS INTERMEDIATE PHASE WHERE THERE'S PROBABLY MORE INEFFICIENCY IN THE SYSTEM THAN IS DESIRABLE, BUT THERE'S NO REAL QUICK FIX HERE. I THINK THE REAL VALUE WILL BE AS MORE CIRM-FUNDED CELL LINES ARE DERIVED, HOPEFULLY, IF THEY'RE DERIVED BY OUR GRANTEES, THEN WE HAVE THE ASSURANCE THAT THESE ARE GOOD CELL LINES. SO HOPEFULLY AS THOSE LINES COME INTO PLAY, IT WILL ALLEVIATE THIS PROBLEM, BUT THIS WAS CLEARLY THE BIGGEST PROBLEM FOR WHICH WE DIDN'T HAVE A GOOD ANSWER. AT THIS POINT IN TIME, I DON'T THINK THERE'S A SIMPLE SOLUTION.

MOVING ON TO CONSENT AND DONOR PROTECTION. THEY FELT THE CONSENT REQUIREMENTS WERE VERY CLEAR IN THE REGULATIONS. AND, IN FACT, IT WAS INTERESTING. I THINK AT ONE POINT WE HAD CONCERNS ABOUT THEM BEING OVERLY PROSCRIPTIVE. I THINK ACTUALLY A NUMBER OF FOLKS FELT THE CLARITY WAS ACTUALLY QUITE HELPFUL IN THIS PARTICULAR AREA, THE FACT THAT WE LIST OUT A SET OF CONSENT REQUIREMENTS.

THERE WAS A LOT OF DISCUSSION REALLY AMONGST THE PARTICIPANTS ABOUT MATERIALS AND METHODS. AND MY SENSE IS THERE WAS A LOT OF SHARING GOING ON THERE, AGAIN, SORT OF HOW PEOPLE ARE DEVELOPING THE CONSENT PROCESS. HAVE THEY DEVELOPED SORT OF MATERIALS

TAILORED TO THESE TYPES OF DONORS, THAT ARE TAILORED TO SORT OF HELP AMPLIFY THE INFORMATION REQUIREMENTS OF OUR REGULATIONS?

THE OTHER POINT I THINK THAT CAME OUT IS THAT DONORS THAT COME THROUGH THE IVF EXPERIENCE, SO THIS WOULD BE PEOPLE WHO HAVE EMBRYOS CREATED FOR IVF OR HAVE ACCOMPLISHED THEIR REPRODUCTIVE GOALS AND ARE NOW SORT OF AT THE STAGE WHERE THEY'RE PREPARED TO DONATE TO RESEARCH, THE SENSE WAS THAT YOU'RE DEALING THERE WITH AN EXTREMELY EDUCATED POPULATION, SO THEY FELT REALLY THE SPIRIT OF THE CONSENT PROCESS, YOU'RE ABLE TO REALLY ACCOMPLISH THE GOALS OF THE CONSENT BECAUSE THIS IS A HIGHLY, HIGHLY INFORMED POPULATION. SO THAT WAS KIND OF AN INTERESTING COMMENT.

AND TO DATE THE ONLY EGG DONATION ISSUES THAT THE INSTITUTIONS THAT PARTICIPATED IN THESE WORKSHOPS HAD INITIATED WERE EGG DONATION WITH FAILED-TO-FERTILIZE OOCYTES. SO THE ISSUES OF SORT OF FRESH EGGS AT THIS POINT IN TIME, THERE WAS NO EXPERIENCE WITH THE FRESH EGGS.

DR. ROWLEY: CAN I ASK ANOTHER QUESTION? THE ACADEMY GUIDELINES WERE THAT EVEN IF DONORS HAD GIVEN PERMISSION AT THE TIME OF THE INITIAL DONATION OF GAMETES TO FORM EMBRYOS FOR EXCESS EMBRYOS TO BE USED FOR RESEARCH, THAT, IN FACT, DONORS HAD TO BE -- THEY

HAD TO REAUTHORIZE, IF YOU WILL, THE USE OF EXCESS EMBRYOS AT THE TIME THAT THE EMBRYOS WERE GOING TO BE RELEASED FOR RESEARCH PURPOSES. AND WHAT'S THE CALIFORNIA REGULATION ON THAT?

DR. LOMAX: WE ACTUALLY HAD SOME EXTENSIVE PUBLIC COMMENT IN THAT AREA. AND THE WAY OUR REGULATIONS WERE ULTIMATELY CRAFTED AS A RESULT OF THAT FEEDBACK, AND THIS IS WHERE THE OAL PROCESS WAS EXTREMELY PRODUCTIVE, IS WE HAVE A MORE EXTENSIVE SET OF CONSENT REQUIREMENTS. AND THOSE REQUIREMENTS TAKE EFFECT AFTER THE EFFECTIVE DATE OF THE REGULATIONS. SO IN TERMS OF THE VERY FINE DETAILS OF THE CONSENT, NOW THAT THOSE REGULATIONS HAVE BEEN IMPLEMENTED, THAT'S THE STANDARD OF CONSENT.

NOW, YOU DO HAVE A SET OF EMBRYOS THAT HAD BEEN COLLECTED WITH CONSENT FROM THE GAMETE DONORS, BUT NOT TO THE LEVEL OF GRANULARITY SPECIFIED IN OUR REGULATIONS. THOSE ARE STILL AVAILABLE BECAUSE THEY HAVE BEEN CONSENTED FOR. THEY CONSTITUTE SORT OF ACCEPTABLE -- THEY MEET THE SORT OF CONDITIONS OF CONSENT, OVERSIGHT, REVIEW, BUT WE SPECIFICALLY WROTE THAT BECAUSE THEY'D BEEN COLLECTED PRIOR TO THE DATE OF THE REGULATIONS. YOU CAN'T RETROACTIVELY GO BACK. THAT'S ACTUALLY A VIOLATION OF STATE LAW. YOU CAN'T RETROACTIVELY APPLY A SET OF STANDARDS IN THAT DETAIL.

NOW, THE FACT THAT THE CONSENT REQUIREMENT STILL HOLDS BECAUSE THERE WAS ALREADY EXISTING STATE LAW THAT DEALS WITH CONSENT, THAT'S HOW THE BASIC REQUIREMENTS APPLY, BUT THE MORE DETAILED REQUIREMENTS COME ONLINE WHEN THE REGULATIONS THEMSELVES TAKE EFFECT. THAT WAS HOW WE DEALT WITH THAT, BUT IT DID COME UP BECAUSE THERE WERE A NUMBER OF INSTITUTIONS ALREADY SORT OF BANKING THE EMBRYOS WITH THE INTENT OF DOING CELL LINE DERIVATION LONG BEFORE OUR REGULATIONS.

DR. ROWLEY: SO THE PRACTICAL THING IS DO THEY HAVE TO GO BACK TO THE DONORS AND RECONSENT THEM, OR ARE THEY SORT OF GRANDFATHERED IN?

DR. LOMAX: WELL, THE CONSENT HAS BEEN OBTAINED FOR THE DONORS UNDER A RESEARCH PROVISION, AND THAT WAS STATE LAW THAT PRECEDED THE CIRM REGULATIONS, SO THOSE CONSENTS WERE OBTAINED.

DR. ROWLEY: THEY'RE STILL CONSIDERED VALID EVEN THOUGH THEY WERE BEFORE THIS MORE DETAILED REGULATION?

DR. LOMAX: THAT'S RIGHT. SO THAT EMBRYOS COLLECTED AFTER THE DATE OF THE REGULATIONS TRIGGER THE MORE ADVANCED, THE MORE DETAILED REQUIREMENTS OF OUR CONSENT.

AGAIN, THE COVERED STEM CELL LINE DEFINITION, AGAIN, WE THINK THAT'S BEEN VERY EFFECTIVE. THAT'S

SOMETHING IN THE SORT OF STATE DISCUSSIONS WE SORT -- I TRIED TO BRING TO THAT DISCUSSION THE FEEDBACK WE GOT.

MAJOR THEMES. AGAIN, I'VE TOUCHED ON THE NEED FOR AN EFFICIENT MECHANISM FOR IDENTIFYING ACCEPTABLY DERIVED CELL LINES AND A COUPLE OF SORT OF MINOR RECOMMENDATIONS WHICH WE'LL TOUCH ON IN THE SORT OF NEXT SEGMENT, BUT NOT A WHOLE LOT WE CAN DO THERE.

AND, AGAIN, SOME THOUGHT ABOUT EDUCATIONAL MATERIALS MAY ENHANCE THE QUALITY AND CONSISTENCY OF THE CONSENT PROCESS. I THINK THIS IS, AGAIN, ONE OF THOSE AREAS WHERE OVER TIME, IF WE -- PERHAPS EVEN CIRM CAN PLAY A ROLE OF WORKING WITH A GRANTEE OR SOMEONE TO CONTINUE TO IMPROVE EDUCATION MATERIALS.

IT CERTAINLY SEEMED THERE WAS A LOT OF DISCUSSION ABOUT THE VALUE OF GOOD MATERIALS FOR DONOR CONSENT AND THAT SORT OF THING. EVEN THINGS, FOR EXAMPLE, LIKE INTERACTIVE WEB PLACES WHERE PEOPLE COULD GO. AND THE DISCUSSION THERE SORT OF CENTERED AROUND SORT OF THE TYPICAL CRITIQUE OF THE CONSENT PROCESS THAT THERE MAY BE SORT OF TIME OR PRESSURES AND THAT IF SOMEONE CAN STEP AWAY FROM THE PROCESS AND GO TO A SOURCE WHERE THEY CAN SORT OF PROBE IN THEIR OWN PERSONAL SPACE, THAT COULD ENHANCE CONSENT. EXAMPLES LIKE THAT CAME UP AS POSSIBLE WAYS OF ENHANCING AND IMPROVING DONOR EDUCATION.

I WANT TO JUST TOUCH -- NOW, THIS IS STEPPING AWAY FROM THE WORKSHOPS AND SOME OTHER ACTIVITIES THAT I THINK HAVE BEEN USEFUL. AGAIN, MARY TOUCHED ON THIS. I'VE TOUCHED ON IT AGAIN. THE INTERSTATE ALLIANCE FOR STEM CELL RESEARCH, AGAIN, WITH A MEETING COMING UP, WE THINK THAT'S GOING TO BE A VERY PRODUCTIVE FORUM FOR PROMOTING CONSISTENCY AMONG REGULATIONS.

THE UNITED KINGDOM CONSUL OF SCIENCE AND INNOVATION HAS SPONSORED A NUMBER OF EVENTS WHERE THERE HAVE BEEN A NUMBER OF THEMES AROUND PROMOTING CONSISTENCY AND COLLABORATION AND SHARING INTERNATIONALLY. ONE EXAMPLE IN PARTICULAR IS WE'VE BEEN CHATTING WITH HFEA. AS YOU WELL KNOW, IN OUR REGULATIONS WE SORT OF AUTHORIZE CERTAIN CELL LINES THAT HAVE BEEN, FOR EXAMPLE, DEPOSITED IN THE UK STEM CELL BANK. THAT'S SORT OF A SAFE HARBOR THAT ALLOWS PEOPLE TO USE THOSE LINES MORE EFFICIENTLY.

I'VE BEEN SORT OF POINTING THAT OUT TO FOLKS IN THE UK AND OTHER PLACES TO SUGGEST THAT THEY SHOULD NOW BE LOOKING AT OUR REGULATIONS, EVALUATING OUR GUIDELINES, AND CONSIDERING RECIPROCAL-TYPE POLICIES BECAUSE IF YOU ACTUALLY LOOK CAREFULLY AT THE UK STEM CELL BANK REQUIREMENTS, THERE IS ACTUALLY LANGUAGE IN THERE WHERE THEY FEEL COMPELLED TO EVALUATE WHAT SOMEONE MAKING A WITHDRAWAL FROM THE BANK WILL BE DOING

WITH THOSE CELL LINES, WHICH AGAIN ADDS ANOTHER LAYER.

AND WE HAD SOME DISCUSSIONS WHERE SOME RESEARCHERS WERE PRESENT IN A MEETING, AND THEY'RE SAYING, "SO I'VE GOT TO NOT ONLY DO MY IRB AND MY SCRO POTENTIALLY, BUT I'VE ALSO GOT TO DO AN APPLICATION TO THE UK STEM CELL BANK." THAT'S ANOTHER DISINCENTIVE FOR THAT RESOURCE.

SO WE'VE SORT OF PITCHED THIS IDEA OF HERE'S HOW WE'VE HANDLED IT. WHAT DO YOU THINK? I THINK THAT MESSAGE IS STARTING TO COME INTO THE CONVERSATION, AND WE'LL SEE. TO SORT OF AMPLIFY THE POWER OF THIS IDEA, THERE'S THE -- WE HAD A DELEGATION FROM THE RIKEN INSTITUTE IN JAPAN, WHICH IS AN INSTITUTE THAT IS SORT OF ANALOGOUS TO THEIR -- IT INCLUDES THEIR STEM CELL BANK. IT'S ACTUALLY A MUCH BIGGER INSTITUTE. THEY SORT OF MANAGE A LOT OF BIOMEDICAL MATERIALS FOR RESEARCH IN JAPAN, AND THEIR DELEGATION BROUGHT THEIR REGULATIONS AND PRESENTED THEIR REGULATIONS TO US. THEY'RE INCLUDED IN THE PACKET TODAY. AND THEY SPECIFICALLY WERE INTERESTED IN SEEING THAT STEM CELL LINES DERIVED UNDER THEIR REGULATIONS BE SPECIFICALLY APPROVED FOR USE BY CIRM.

I HAVE HAD AN OPPORTUNITY TO REVIEW THE REGULATIONS. I THINK THEY'RE MOST COMPATIBLE WITH THE CANADIAN GUIDELINES, WHICH ARE A BIT MORE RESTRICTIVE

EVEN THAN OUR REGULATIONS. AND CERTAINLY FROM A POLICY LEVEL, BASED ON MY ANALYSIS, I SEE NO INCONSISTENCY WITH WHAT WE'VE ALREADY DONE IN TERMS OF SAYING IF IT'S -- LIKE WE SAY WITH THE CANADIAN LINES, IF IT'S DERIVED UNDER THIS AUTHORITY, IT CAN BE USED IN CIRM-FUNDED RESEARCH. SO, AGAIN, PUT THAT OUT AS ANOTHER SORT OF POLICY OPTION THAT DOESN'T SOLVE THIS PROBLEM OF INTERNATIONAL STEM CELL LINES, BUT PERHAPS TAKES ANOTHER SMALL STEP TOWARDS ALLEVIATING SOME OF THE PROBLEMS.

DR. KIESSLING: GEOFF, IS THAT THIS DOCUMENT LABELED "THE GUIDELINES"?

DR. LOMAX: CORRECT.

DR. KIESSLING: THAT'S FROM THE RIKEN?

DR. LOMAX: IT'S JAPANESE LEGISLATION THAT GOVERNS RIKEN, BUT IT'S NOT FROM THE RIKEN TECHNICALLY. IT'S ACTUALLY THE LAW OF JAPAN. I CAN CLARIFY THAT. I NEED TO -- I THINK IT'S THE EQUIVALENT OF SORT OF HOW HFEA POLICIES WORK. IT COMES FROM A FEDERAL MANDATE. THE DIAGRAM ON THE BACK, I THINK, IS AN EXCELLENT DIAGRAM. IT SORT OF SHOWS THEIR OVERALL PROCEDURES AND PROCESS FOR REVIEW, EXCHANGE, AND I THINK IT'S, AGAIN, PERHAPS MORE ELABORATE THAN EVEN THE --

DR. KIESSLING: THIS IS ACTUALLY JAPAN'S. I THINK EVERYBODY MAY BE AWARE OF THIS, BUT THIS IS

ACTUALLY JAPAN'S HUMAN GENOME, BASIC HUMAN GENOME PROJECT. AND THEY MAINTAIN A VERY POWERFUL WEBSITE THAT IS A MAJOR RESOURCE FOR HUMAN GENOME RESEARCH AND THE RIKEN GROUP DOES. THEY'RE MAJOR CONTRIBUTORS TO OUR GEN BANK INFORMATION.

DR. ROWLEY: I WAS GOING TO SAY ACTUALLY IT'S BROADER THAN HUMAN, OF COURSE, BECAUSE THEY HAVE THE MOUSE AND THE REST OF IT. SO THAT IS GENOME INSTITUTE OR THE GENOME GEN BANK OF JAPAN.

DR. KIESSLING: THIS IS WHAT THEY BROUGHT TO THIS MEETING, THESE GUIDELINES?

DR. LOMAX: CORRECT. THOSE ARE THE GUIDELINES WHICH GOVERN THE USE OF HUMAN EMBRYONIC STEM CELLS IN JAPAN.

DR. ROWLEY: WELL, IT JUST POINTS OUT THE FACT THAT THE UNITED STATES HAS NO GUIDELINES IS REALLY A SCIENTIFIC DISGRACE. WELL, IT'S A MORAL AND ETHICAL DISGRACE AS WELL.

DR. LOMAX: OKAY. MOVING FORWARD TO OUTCOMES AND OBJECTIVES. OVERALL, AGAIN, WE'VE TOUCHED ON A FEW NEW REGULATORY ISSUES. I'M GOING TO SKIP THAT POINT. NEW COLLABORATIONS HAVE EMERGED, WHICH, AGAIN, WE'VE TOUCHED ON BOTH AT THE STATE AND NATIONAL LEVEL. AGAIN, I THINK THIS IS VERY POSITIVE. IT GIVES US KIND OF A KNOWLEDGE BASE TO SORT OF NETWORK TO TRY TO

EVALUATE OUR POLICIES AGAINST. AND, AGAIN, TOWARDS THE GOAL OF MAXIMUM SORT OF ADVANCING SORT OF RESEARCH AND EXCHANGE, IT GIVES US SOME IDEAS AT THE POLICY LEVEL.

IN ADDITION, SORT OF A VERY PRACTICAL OUTCOME OF THIS EFFORT IS WE NOW HAVE A SHARED CONTACT LIST FOR THE INSTITUTIONS IN CIRM. AND WE'VE SORT OF PUT THAT LIST OUT TO THE INSTITUTIONS SO THEY CAN CONTINUE TO TALK AMONGST THEMSELVES, AND THEN USING THAT LIST TO CONTINUALLY UPDATE THEM ON ANY NEW ISSUES OR POLICY MATTERS. AND, AGAIN, I THINK THESE NEW INTERNATIONAL COLLABORATIONS ARE EXTREMELY POSITIVE.

AGAIN, THIS IS NOW TWO NEW REGULATORY ISSUES. I'VE TOUCHED ON THESE, BUT THE ACCEPTABLY DERIVED LINES, AGAIN, I DON'T THINK THE REGISTRY IS GOING TO BE A PRACTICAL SOLUTION IN THE NEAR TERM, BUT WE COULD CONSIDER THE JAPANESE REGULATIONS AND CONTINUE TO LOOK AT OTHER NATIONAL PROGRAMS. SOME FOLKS HAVE SUGGESTED THERE MAY BE OTHER COUNTRIES TOO THAT WE COULD DO OUTREACH TO. CERTAINLY THAT'S OF BENEFIT.

FINALLY, I WANT TO MOVE TO ONE ISSUE WHICH I HAVEN'T TOUCHED ON. IT CAME UP THROUGH ONE OF THESE MORE SORT OF OPPORTUNISTIC MECHANISMS. AND IT WAS AN INTERESTING CONVERSATION. I WAS APPROACHED BY AN ATTORNEY WHO WORKS WITH IVF COUPLES WHO HAVE PAID EGG DONORS TO CREATE EMBRYOS. AND IF YOU RECALL, IN OUR

DISCUSSIONS WE LOOKED AT THIS, THE CURRENT REGULATIONS, IF YOU HAVE PAID A GAMETE DONOR TO CREATE AN EMBRYO, THAT EMBRYO IS NOT ELIGIBLE FOR CIRM-FUNDED RESEARCH BY VIRTUE OF THE PAYMENT.

AT THE TIME ONE OF THE RATIONALES, BASED ON THE RECORD, IS THAT WE LOOKED AT THE OVERALL PERCENTAGE OF EMBRYOS, AND THOSE NUMBERS WERE REFLECTED IN DR. GIUDICE'S SLIDES, THAT IT WAS A VERY SMALL PROPORTION, ROUGHLY 8 TO 10 PERCENT, I BELIEVE, OF THE EMBRYOS THAT ARE IN FREEZERS ARE EMBRYOS THAT WERE CREATED AS A RESULT OF THE COUPLE OR THE WOMAN WHO'S INTENDING TO GET PREGNANT PAYING AN OOCYTE DONOR. I THINK AT THE TIME IT WAS A FAIRLY UTILITARIAN SORT OF CALCULATION TO SAY THIS DOESN'T APPEAR LIKE IT'S GOING TO UNDERMINE THE RESEARCH. IT AVOIDS SORT OF CONCERNS ABOUT PAYMENT AND COERCION; THEREFORE, OUR REGULATIONS ARE WHAT THEY ARE. I THINK I'M PARAPHRASING, BUT I THINK THAT WAS THE ESSENTIAL LOGIC OF THE DISCUSSION.

SINCE THEN WHAT WE'VE HAD IS -- THE POINT THAT THIS ATTORNEY MADE IS THERE IS ACTUALLY A CONSTITUENCY OUT THERE OF COUPLES THAT HAVE THESE EMBRYOS, THEY HAVE A DESIRE TO DONATE THEM TO RESEARCH, AND THEY SORT OF SEE CIRM-FUNDED RESEARCH AS THE ATTRACTIVE SORT OF VENUE OF DONATION, AND THEY'RE NOT ABLE TO DO THAT. AND, AGAIN, I SORT OF DON'T WANT TO

PASS JUDGMENT ON THAT REGULATION, BUT I THINK AT THIS POINT IT IS INTERESTING THAT WE NOW HAVE A SORT OF NEW CONSTITUENCY THAT EMERGED, AND IT'S, I SUPPOSE, AT A SORT OF ETHICAL LEVEL, WE'VE IN A SENSE EXCLUDED A CONSTITUENCY.

AND I THINK THE QUESTION BECOMES IS THERE ANY CONCERN ABOUT THAT AMONGST THE WORKING GROUP? AGAIN, I DON'T THINK THERE'S AN IMPERATIVE HERE, BUT THERE'S A NEW CONSTITUENCY OUT THERE THAT HAS CONCERNS ABOUT THE SPECIFICS OF THIS REGULATION.

AS A SIDE NOTE, ACTUALLY THE ATTORNEY WHO APPROACHED ME ON THIS WOULD HAVE LIKED TO HAVE BEEN AT THIS MEETING TO PRESENT TO YOU AND WAS ACTUALLY ALSO INTERESTED IN BRINGING SOME FOLKS IN WHO ARE AFFECTED BY THIS, BUT UNFORTUNATELY SHE'S AT A CONFERENCE ON THE EAST COAST FOR THIS MEETING AND EXPRESSED AN INTEREST IN FOLLOWING UP WITH THE COMMITTEE IF THIS WAS AN ITEM OF INTEREST. SO I BRING THAT TO YOUR ATTENTION.

AND I THINK WE'VE -- JAPANESE REGULATIONS I'VE TOUCHED ON. THIS IS A SLIDE. I'M CHECKING THROUGH MY SLIDES. THE EMBRYOS CREATED FOR REPRODUCTIVE PURPOSES.

DR. PRIETO: ARE YOU ASKING US TO ADDRESS THAT PARTICULAR QUESTION NOW?

DR. LOMAX: I'M NOT. REALLY IT'S JUST A

STRAIGHT REPORT BACK. THIS IS SORT OF A FINAL POINT THAT I SORT OF PUT OUT THERE FOR THE COMMITTEE, AND I LEAVE IT TO THE CO-CHAIR TO DECIDE WHERE HE'D LIKE TO TAKE IT. I THINK THAT FINALIZES MY REPORT.

CHAIRMAN LO: GREAT. THANK YOU, GEOFF. FIRST, ANY QUESTIONS FOR GEOFF ABOUT THE REPORT, CLARIFICATIONS?

THERE WERE A NUMBER OF ISSUES THAT --

MR. SHEEHY: JUST THAT LAST SLIDE THAT YOU FLASHED, SO THE DONOR PROVIDED CONSENT FOR EMBRYO DESTRUCTION OR RESEARCH DONATION AT THE TIME OF DONATION?

DR. LOMAX: YES.

DR. PRIETO: WHICH SLIDE ARE YOU REFERRING TO, GEOFF?

DR. LOMAX: EMBRYOS CREATED FOR REPRODUCTIVE PURPOSES.

DR. PRIETO: WHAT WAS THE COMMENT?

MR. SHEEHY: SO THE DONOR WAS PAID AND THEN PROVIDED CONSENT FOR RESEARCH DONATION.

DR. LOMAX: OR DESTRUCTION.

MR. SHEEHY: YOU KNOW, I'M JUST TRYING TO GET MY HEAD AROUND THIS ISSUE, THIS NEW ISSUE THAT YOU RAISE. IT WOULD HAVE BEEN DIFFERENT IF IT WAS THE DONOR HAD MADE THE DONATION AND WAS INTENDING

DESTRUCTION OR USE. THE RECIPIENT OF THE DONATION DECIDED THEY NO LONGER NEEDED THEM, AND THEN THE COMPENSATION ISSUE PROBABLY COULD HAVE BEEN FINESSED, BUT THE FACT THAT THE DONOR WAS AWARE THAT THE DONATION WAS GOING TO BE MADE FOR RESEARCH AT THE TIME MAKES IT PART OF THE COMPENSATION CALCULATION. DO YOU SEE KIND OF WHERE I'M GOING? IF THIS WAS ALL POST HOC --

DR. LOMAX: I POSED THAT QUESTION, BUT I THINK WHAT'S GOING ON THERE, MY UNDERSTANDING, BECAUSE I PROBED ON THIS A LITTLE BIT, IS THAT THIS IS A FAIRLY STANDARDIZED PROCEDURE. AND, ROB, PERHAPS YOU HAVE, I IMAGINE, MORE INSIGHT HERE. THAT THE CONSENT PROCEDURES ARE FAIRLY STANDARDIZED, AND THE KIND OF, AS I UNDERSTOOD IT, THE KIND OF MOST LIBERAL SORT OF STANDARD APPROACH IS TO SORT OF SAY THE RECIPIENT HAS FULL CUSTODY OF THE DISPOSITION. THEY CAN MAKE THAT DECISION. AND THE DONOR, AS PART OF THAT FINAL DISPOSITION, CAN INCLUDE EITHER DESTRUCTION OR DONATION TO RESEARCH, WHICH I THINK EXHAUSTS ALL POSSIBILITIES.

SO IT'S THE IDEA THAT THERE'S AN OPEN-ENDED CONSENT ON THE ORIGINAL DONOR'S END TO SORT OF GIVE TOTAL CUSTODY TO THE COUPLE RECEIVING THEM. THE POINT BEING THAT, AGAIN, THAT THE INITIAL INTENT ON THE COUPLE RECEIVING THEM IS THEY'RE TRYING TO HAVE A BABY.

MR. SHEEHY: FOR THE DONOR THAT BECOMES PART

OF THE COMPENSATION. SO THE COMPENSATION INCLUDES A RESEARCH USE. SO SHE HAS BEEN COMPENSATED FOR THE RESEARCH USE BECAUSE SHE CONSENTED TO IT WHEN SHE MADE THE DONATION AS OPPOSED TO SHE -- IN OTHER WORDS, THE OVERLY BROAD CONSENT KIND OF TAKES -- IF THIS IS THE CONSENT THAT WE'RE WORKING OFF OF, IT KIND OF TAKES THIS ISSUE OFF OUR TABLE BECAUSE IF SHE HAD JUST CONSENTED TO DESTRUCTION OR USE FOR CREATING A FAMILY -- IT'S JUST THAT POINT KIND OF MAKES THIS WHOLE ISSUE MOOT BECAUSE, GIVEN THAT THE CONSENT WAS GIVEN AT THE TIME OF COMPENSATION, THEN THIS WOULD BE A COMPENSATED EGG AS OPPOSED TO IF THE CONSENT FOR RESEARCH HAD NOT BEEN GIVEN AT THAT TIME.

THEN IF AFTER THE FACT THE RECIPIENT OF THE DONATION WAS FINISHED WITH THEIR REPRODUCTIVE OR WHATEVER USE THAT THEY MAY HAVE HAD FOR THAT EMBRYO, AND THEN WE WENT BACK AND CONTACTED THAT DONOR, THAT DONOR WOULD HAVE ALREADY BEEN COMPENSATED FOR THAT ONE USE, AND AT THIS POINT IT WOULD HAVE BEEN A PURELY ALTRUISTIC DONATION AS OPPOSED TO ONE THAT WOULD HAVE BEEN COMPENSATED. BUT THIS IS COMPENSATED AT THE BEGINNING WITH THE KNOWLEDGE THAT THIS COULD BE A RESEARCH DONATION, SO THE RESEARCH POSSIBILITY IS PART OF THE COMPENSATION.

DR. PRIETO: SO YOU'RE SAYING THAT THAT WOULD

CLOSE OFF OUR ACCESS; WHEREAS, IF IT WERE NOT CONSENTED UNTIL LATER, THEN IT WOULD NOT?

DR. TAYLOR: ISN'T OUR ACCESS CLOSED OFF? HAVEN'T WE BEEN THROUGH THIS ENOUGH TIMES? I HAVE TO ADMIT I DON'T WANT TO BE A --

DR. LOMAX: THAT MAY BE FAIR ENOUGH. COULD I JUST MAKE ONE OTHER POINT BECAUSE I KNOW, JESSE, YOU'RE HERE, AND I JUST WANT TO NOT APPEAR THAT WE WERE OVERLOOKING. I JUST WANTED TO POINTED OUT, BECAUSE I DON'T THINK YOU WERE IN THE ROOM AT THE TIME, I DID POINT OUT THE LETTER THAT WE RECEIVED. I DON'T KNOW IF YOU RECEIVED A COPY OF THE LETTER FROM SUSAN, AND THAT CAME UP IN THE DISCUSSION EARLIER. SO I JUST DIDN'T WANT TO APPEAR REMISS THAT WE WERE SORT OF SELECTIVELY CHOOSING WHAT COMMENTS WE BROUGHT TO THE COMMITTEE. SO I JUST WANTED TO STATE THAT FOR THE RECORD.

DR. ROWLEY: AT THE RISK OF APPEARING OBTUSE, IT SEEMS TO ME THAT THE TIME THAT THE PAID GAMETE DONOR PROVIDES THE GAMETES, THAT INDIVIDUAL HAS NO IDEA AS TO WHETHER ALL EMBRYOS ARE GOING TO BE USED FOR INTENDED PARENTS' USE AND HAS NO IDEA THAT THERE WILL BE ANY LEFT OVER FOR ANYTHING. SO I WOULD THINK THAT, IN FACT, TO THEN SAY THAT THE DONOR HAS BEEN COMPENSATED FOR RESEARCH DONATION IS A STRETCH. AND I PERSONALLY WOULDN'T HAVE ANY PROBLEM WITH USING THAT EMBRYO IF

IT'S NOW GOING TO BE DESTROYED.

AND IF THIS IS BOILERPLATE IN THE CONSENT FORM THAT EVERYBODY SIGNS OR SIGNED AT THAT POINT, I DON'T THINK THAT IT SHOULD BE CONSIDERED AS A COMPENSATED GAMETE.

DR. KIESSLING: DO YOU WANT TO DEBATE THIS NOW?

CHAIRMAN LO: NO. I ACTUALLY DON'T. LET ME TRY AND SUGGEST A PROCEDURE AND SEE IF THIS IS AGREEABLE TO YOU. WHAT I WOULD LIKE TO DO IS IDENTIFY ISSUES THAT WE WOULD LIKE TO REALLY CONSIDER IN-DEPTH. I DON'T THINK RIGHT NOW IS THE TIME TO GO OVER THIS SPECIFIC ISSUE. I THINK I WOULD PREFER OR SUGGEST THAT, INSTEAD, WE SAY HERE ARE THREE, FOUR, HOWEVER MANY ISSUES THAT WE WOULD LIKE TO GET INTO IN MORE DEPTH. IF WE MAKE THAT DECISION, THEN I THINK WE CHARGE GEOFF WITH PREPARING A SORT OF POLICY BRIEFING MEMO FOR US SORT OF SUMMARIZING WHAT WE'VE ALREADY -- GO BACK AND LOOK AT THE RECORD AND SEE WHAT WE DID WHEN -- IF WE CONSIDERED THIS BEFORE, LOOK AT OTHER AVAILABLE THINKING ON THE TOPIC OF BOTH PUBLICATIONS, ADVOCACY POSITIONS, PERSONAL COMMENTS, WHATEVER, TRY AND PREPARE A MEMO FOR US THAT WE CAN LOOK AT THAT LAYS OUT THE ISSUES, THE OPTIONS FOR DEALING WITH THEM, THE PROS AND CONS OF EACH OPTION. AND AT THAT POINT I

THINK WE'D BE IN A BETTER POSITION TO REALLY GET INTO THIS.

FIRST, I WANT TO SORT OF GET YOUR AGREEMENT TO AT THIS POINT IDENTIFY ISSUES RATHER THAN SORT OF TRY AND RESOLVE THE ISSUES. AND IF THAT'S -- MAYBE I'LL JUST DO A CHECK. DOES THAT SEEM REASONABLE? TRY AND IDENTIFY THE ISSUES, AND ON EACH ONE SEE IS THERE ENOUGH INTEREST THAT WE SHOULD ASK GEOFF TO PREPARE A BRIEFING MEMO.

IN TERMS OF JUST IDENTIFYING ISSUES RATHER THAN TRYING TO RESOLVE THEM, DOES THAT SOUND REASONABLE GIVEN WHERE WE ARE?

I HEARD SEVERAL ISSUES THAT WE MIGHT WANT TO CONSIDER. I'M JUST OFFERING THESE. THERE MAY BE OTHERS. ONE IS CERTAINLY THIS ISSUE HERE. THE OTHER IS COMPENSATION FOR SCRO MEMBERS WHO ARE NOT AFFILIATED WITH THE INSTITUTION. ANOTHER IS SHOULD WE MAKE AN EXPLICIT AMENDMENT TO THE REGULATIONS TO DEEM IN -- TO EXAMINE THE PROCEDURE FOR HSC STEM CELL LINE DERIVATION IN JAPAN AND SEE IF IT SHOULD BE DEEM -- IF CELL LINES FROM JAPAN SHOULD BE DEEMED ACCEPTABLE FOR CIRM RESEARCH AS THE UK AND CANADA ARE.

AND THEN, FINALLY, I GUESS IT'S THE ISSUE THAT IS REALLY A REMNANT FROM BEFORE THE BREAK, THAT ANN RAISED THE ISSUE OF CHIMERAS OR CYCLOIDS, I THINK,

IS WHAT THEY'RE CALLING THEM IN THE UK, SHOULD WE BE PREPARING, AT LEAST EDUCATING OURSELVES ON WHAT ARE THE ISSUES IN TERMS OF THE ETHICAL PERMISSIBILITY OF FUNDING SUCH RESEARCH BY THIS BODY? I THINK ANN SUGGESTED THAT MAYBE WE SHOULDN'T DO ALL OF CHIMERAS, BUT TRY AND GET SOME SCIENTIFIC IDEAS ON WHAT ARE THE MOST LIKELY KINDS OF RESEARCH WE'D BE PRESENTED WITH. I THINK YOU IDENTIFIED INSERTION OF HUMAN STEM CELLS OR DERIVATIVES INTO MOUSE BLASTOCYSTS.

SO THAT'S A NUMBER OF ISSUES. I DON'T KNOW IF OTHERS EXTRACTED OTHER THINGS, BUT MAYBE WE COULD SORT OF JUST SEE WHAT ISSUES DO WE WANT GEOFF TO SORT OF REALLY RESEARCH IN DEPTH FOR US AND PREPARE A BRIEFING MEMO FOR US AS HE'S DONE IN THE PAST. OTHER ISSUES?

MS. KING: LOOKING AT JAPAN, THAT'S AN OBVIOUS ONE.

CHAIRMAN LO: SHOULD WE ACCEPT THEM AS ALL LINES FROM JAPAN ARE AUTOMATICALLY ELIGIBLE FOR CIRM FUNDING PROVIDED THEY MET THE JAPANESE STANDARDS?

MS. KING: WE SHOULD LOOK AT THAT.

DR. KIESSLING: THE ISSUE WE WERE TALKING ABOUT WITH THESE SUPERNUMERARY EMBRYOS WHERE THE DONOR, NOT THE COMPENSATION ISSUE, BUT WHERE THE DONOR -- ONE OF THE GAMETE DONORS WAS NOT AWARE THAT THEY MIGHT BE

USED TO DERIVE A STEM CELL LINE. I DON'T THINK THAT'S A TRIVIAL ISSUE. I THINK THE ISSUE OF COMPENSATION IS SEPARATE, BUT I THINK THAT A LOT OF PEOPLE SIGNED CONSENT TEN YEARS AGO THAT THEIR EMBRYOS COULD BE USED FOR RESEARCH, BUT THAT DIDN'T INCLUDE THE CONCEPT THAT THEY COULD EXPAND INTO A CELL LINE AND HAVE THEIR GENETICS DISTRIBUTED WIDELY FOR RESEARCH. THAT WAS A DIFFERENT CONCEPT FOR THOSE RESEARCH CONSENT FORMS.

CHAIRMAN LO: ACTUALLY THERE MAY BE A SERIES OF ISSUES. ONE IS SUPPOSE THEY DIDN'T EVEN CONSENT FOR RESEARCH, BUT JUST SAID TO THE COUPLE IN IVF, "DO WHATEVER YOU WANT WITH THEM. I DON'T CARE ANYMORE."

DR. KIESSLING: BUT THE ASSUMPTION WAS THEY WOULD END UP IN SOME BABY FORM, NOT NECESSARILY A STEM CELL LINE.

CHAIRMAN LO: RIGHT. RIGHT. SO IS CONSENT TO SORT OF RESEARCH IN GENERAL ALLOW RESEARCH FOR STEM CELLS, OR DO WE REALLY NEED, AS WE'VE -- CURRENT REGULATIONS SAY THEY HAD TO HAVE CONSENTED FOR STEM CELL RESEARCH, BOTH GAMETE DONORS. THAT'S WHAT WE DID. SO LET'S DO THE JAPAN ISSUE FIRST. IS IT THE SENSE OF THIS COMMITTEE THAT WE WOULD WANT GEOFF TO REALLY GO INTO THIS IN DEPTH AND PREPARE THE ARGUMENTS PRO AND CON DEEMING THEM IN? I GUESS I WOULD ALSO SAY ANY OTHER COUNTRIES? I MEAN AUSTRALIA IS SUPPOSED IN THE

NEXT MONTH OR TWO TO BE REVISING ITS STEM CELL LINES -- NATIONAL STEM CELL POLICY. SHOULD WE SORT OF HAVE GEOFF BE ON THE LOOKOUT FOR COUNTRIES WHOSE POLICIES ARE SO CONSISTENT WITH OURS, THAT WE SHOULD JUST ACCEPT ALL THEIR STEM CELL LINES? THEY ALSO HAVE AN OVERSIGHT BODY.

DR. KIESSLING: GEOFF, ARE YOU GOING TO THE INTERNATIONAL MEETING IN AUSTRALIA?

DR. LOMAX: I'M NOT GOING TO BE ATTENDING THAT MEETING, NO.

DR. KIESSLING: IS ANYBODY -- WHO FROM --

CHAIRMAN LO: I'M NOT GOING AS CIRM. I'M GOING.

DR. KIESSLING: YOU'RE GOING BECAUSE THAT WOULD BE A GOOD PLACE THAT WE COULD FIND THESE.

DR. LOMAX: IN TERMS OF THAT MEETING, ONE OF THE FOLKS I'VE BEEN SORT OF CARRYING THIS CONVERSATION WITH VERY CLOSELY IS THE HFEA PRESIDENT, AND SO SHE WILL -- WE'VE ALSO BEEN TALKING ABOUT THIS SORT OF SAME LEVEL OF EVALUATION BECAUSE WE'RE BOTH INTERESTED IN IT FOR THE SAME REASONS. I HAVE A COLLABORATOR, IF YOU CAN CALL IT THAT, WHO WILL HOPEFULLY BE FACT-FINDING ON THE GROUND IN AUSTRALIA.

CHAIRMAN LO: SO IT SOUNDS LIKE THERE'S A SENSE OF THE COMMITTEE THAT WE WANT GEOFF TO SORT OF

LOOK OUT FOR OTHER COUNTRIES WHOSE LINES MIGHT BE DEEMED ACCEPTABLE WITHOUT FURTHER REVIEW?

THE ISSUE OF COMPENSATION --

DR. ROWLEY: BEFORE YOU LEAVE THAT TOPIC, ARE YOU IMPLYING THAT GEOFF IS TO DO MORE WORK THAN PROVIDE US WITH THE GUIDELINES OR --

CHAIRMAN LO: WELL --

DR. ROWLEY: I'M A BIT CONFUSED BECAUSE THESE REGULATIONS SEEM TO BE FAIRLY CAREFUL. THE ONLY THING I NOTICED WAS THAT THEY ALLOW FOR USE OF EMBRYO CELLS UP TO 14 DAYS, AND I THOUGHT CALIFORNIA LAW WAS 12. BUT OTHER THAN THAT DIFFERENCE, IT SEEMS TO ME THEY'RE PRETTY COMPATIBLE.

DR. LOMAX: I THINK YOU'VE KIND OF NAILED IT ON THE HEAD. I THINK AS A DUE DILIGENCE RESPONSIBILITY, HIGHLIGHTING WHERE THOSE EXACT DIFFERENCES LIE, AS BERNIE INDICATED, IN SOME TYPE OF PUBLIC BRIEFING MEMO WHICH HAS THE BENEFIT OF PUBLIC INPUT AND PUBLIC REVIEW. WE JUST HAVE TO HIGHLIGHT ANY AND ALL DIFFERENCES DEEMED SIGNIFICANT, AND THAT'S PART OF THE PROCESS.

CHAIRMAN LO: I THINK IT ALSO WOULD BE WORTH, GEOFF, TO SORT OF QUOTE EXACTLY HOW IT COMPLIES WITH EACH OF OUR BROAD REQUIREMENTS. SO THIS IS THE PART WHERE THEY TALK ABOUT INFORMED CONSENT. THAT SOUNDS

LIKE THAT'S SOMETHING WE DO WANT GEOFF TO DO.

SHALL WE MOVE ON TO ANOTHER TOPIC, AND NO PARTICULAR ORDER HERE. THE NONAFFILIATED SCRO MEMBERS AND COMPENSATION FOR THEM, IS THAT SOMETHING WE WANT TO READDRESS, AGAIN, WHETHER WE WANT TO CONSIDER READDRESSING AFTER GETTING MORE INFORMATION ON IT? SO IT WOULD BE SORT OF REVIEWING THE PREVIOUS DISCUSSIONS THAT WE'VE HAD ON THIS TOPIC AND ANY SORT OF NEW ARGUMENTS PRO AND CON. YOUR THOUGHTS?

DR. OLDEN: YES.

CHAIRMAN LO: LOTS OF YESES. OKAY. I THINK, GEOFF --

MS. KING: ACTUALLY I HAVE A PROBLEM. AND THAT IS, IT'S GOT NOTHING TO DO WITH THE MERITS OF THE ISSUE. IT IS THE QUESTION OF HOW OFTEN AND FOR WHAT REASONS YOU ARE GOING TO READDRESS SECTIONS OF REGULATION THAT HAVE NOT BEEN OUT THERE VERY LONG. SO THIS WOULD APPLY TO SEVERAL ISSUES, AND I WANT TO MAKE IT CLEAR I'M NOT GOING TO THE MERITS OF THE DISCUSSION. I'M GOING TO HOW WE SEE THE INTEGRITY OF THE REGULATIONS WE'VE ALREADY RECOMMENDED BECAUSE I THINK YOU OPEN A CAN OF WORMS IF YOU DON'T PRETHINK THE CIRCUMSTANCES THAT MIGHT WARRANT REOPENING BECAUSE AFTER THAT EVERYTHING IS UP FOR GRABS THAT ANYBODY DOESN'T LIKE. ALL THEY GOT TO DO IS CONVINCE US ONE

MORE TIME THAT WE SHOULD VOTE OR WAIT FOR THE RIGHT NUMBER OF PEOPLE WHO ARE HERE WHEN WE HAVE A QUORUM TO VOTE. SO IT'S THE INTEGRITY OF THE REGULATION ISSUE I RAISE.

DR. ROWLEY: WELL, IT SEEMS TO ME IMPLICIT IN WHAT WE'VE SAID IS THAT THESE ARE IN A SENSE REGULATIONS THAT ARE GOING TO BE MODIFIED AS THE IMPACT ON THE USERS, IF YOU WILL, BECOMES APPARENT. AND THE NATIONAL ACADEMY HAS ISSUED SOME MODIFICATIONS AND CLARIFICATION OF THEIR GUIDELINES IN LIGHT OF QUERIES THAT HAVE COME FORWARD AND NEW INFORMATION. SO YOU'RE RAISING A PERFECTLY VALID POINT, BUT IT ALSO SEEMS TO ME THAT IF WE DISCUSS THIS AND DECIDE THAT, IN FACT, THIS PARTICULAR ISSUE WILL GO WITH THE ORIGINAL GUIDELINES AFTER DISCUSSION, FAIR ENOUGH. BUT I THINK THAT TO SORT OF SAY WE'RE NOT GOING TO CONSIDER SPECIFIC THINGS FOR RECONSIDERATION IS ALSO TOO RIGID.

MS. KING: I DIDN'T SUGGEST WE NOT RECONSIDER. WHAT I SAID IS BEFORE WE START DOWN THE RECONSIDERATION, THAT WE PRETHINK THE CIRCUMSTANCES UNDER WHICH YOU WOULD RECONSIDER, AND WITHOUT RESPECT TO ANY PROPOSAL ON THE TABLE. ONE, I WOULD SAY A REGULATION IS NOT LIKE A GUIDELINE. LAWYERS THINK THAT WAY. A REGULATION IS A MUCH MORE DIFFERENT PROCESS AND IS NOT INTENDED TO BE -- MAYBE THAT'S A FLAW IN THE

SYSTEM -- TO BE RECONSIDERED. BUT I CAN THINK OF REASONS THAT YOU WOULD WANT TO REDO YOUR REGULATIONS.

I'M ASKING FIRST THAT WE HAVE SOME UNDERSTANDING ABOUT WHAT THOSE REASONS ARE AND WE HAVE SOME UNDERSTANDING ABOUT THE EVIDENTIARY BASIS ON WHICH WE WOULD RECONSIDER. THAT'S ALL I'M SAYING.

IT SHOULDN'T BE THAT -- WE NEED TO KNOW HOW EXTENSIVELY THIS IS CAUSING A PROBLEM, FOR EXAMPLE. THAT'S ONE WAY OF THINKING ABOUT THIS, THAT YOU CAN'T PAY OR COMPENSATE A NONAFFILIATED PERSON. IF WE STARTED GETTING EVIDENCE THAT SAID THIS IS A REAL HANDICAP TO ACHIEVING A GOAL THAT WE SET OUT, THEN I WOULD SAY, YES, WE SHOULD RECONSIDER IT. I JUST THINK THAT WE'RE ASKING FOR RECONSIDERATION WITHOUT HAVING THOUGHT THROUGH FIRST THOSE THINGS THAT WOULD JUSTIFY RECONSIDERATION. THAT'S ALL I'M SAYING. I'M NOT OPPOSED TO ANY PARTICULAR ITEM OR FOR IT, FOR THAT MATTER.

DR. LOMAX: JUST ONE. THIS DID COME UP, AND I THINK INSTITUTIONS DID INDICATE A SENSITIVITY THAT KNOWING THAT THERE'S STABILITY. IT CAME UP IN SORT OF A STABILITY. ONLY THOUGHT TO OFFER FROM THE PERSPECTIVE OF HAVING KIND OF THOUGHT THROUGH THIS A BIT IS JUST TO HIGHLIGHT PERHAPS A QUALITATIVE DIFFERENCE BETWEEN THE TWO ITEMS THAT HAVE BEEN

DISCUSSED BY THE COMMITTEE.

THE JAPANESE EXAMPLE IS ONE WHERE I THINK WE'RE SIMPLY APPLYING AN EXISTING STANDARD WHICH WE'VE ESTABLISHED AS POLICY AND SORT OF BUILDING IT OUT AS THE EVIDENCE EMERGED. WHEREAS, THE SECOND ONE IS SORT OF MORE OF A POLICY CONSIDERATION. DOES THAT MAKE SENSE? SO I JUST OFFER THAT, WHICH IS THE POINT YOU ARE MAKING, HOW DO WE DISTINGUISH BETWEEN -- I CERTAINLY THINK THAT IF WE HAVE A TEMPLATE IN THE CASE OF THE JAPANESE LINES THAT WE'VE ALREADY APPLIED AND IT'S JUST A QUESTION OF THAT TEMPLATE IS SORT OF THE POLICY TEMPLATE WE'VE USED TO MAKE AN EVALUATION, AND THAT IF WE CONTINUE TO APPLY THAT TEMPLATE, WE'RE NOT DOING ANYTHING THAT WE HAVEN'T ALREADY DONE.

BUT THE SECOND QUESTION ABOUT THE COMPENSATION OF MEMBERS CLEARLY FALLS MORE INTO A POLICY CATEGORY. I OFFER THAT DISTINCTION PERHAPS AS INFORMATIVE.

MS. KING: I AGREE. I THINK THAT'S A VERY USEFUL DISTINCTION.

CHAIRMAN LO: I THINK PAT HAS RAISED A QUESTION WHICH BEHOOVES US TO THINK A LITTLE BIT ABOUT. I MEAN THERE CLEARLY ARE ISSUES WHICH WE SAID EITHER MAYBE WE GOT IT WRONG OR THE SITUATION HAS CHANGED ENOUGH IN SOME WAY THAT WHAT WE DECIDED IS NO LONGER

APPLICABLE. THERE ARE OTHER REASONS WHICH AN INDIVIDUAL COULD SAY I DISAGREE WITH YOU. I WANT YOU TO RECONSIDER AND MAYBE THIS TIME YOU WILL CHANGE YOUR MIND. SO I THINK THERE IS A BALANCE BETWEEN SETTING EXPECTATIONS THAT THE INSTITUTIONS, THAT PEOPLE BEING REGULATED CAN ANTICIPATE, AND BEING FLEXIBLE FOR NEW SITUATIONS OR RECONSIDERATION WHEN WE DIDN'T GET IT RIGHT.

I THINK I'M NOT SURE -- I THINK IT WOULD BE USEFUL TO TRY AND SPECIFY INDEPENDENTLY OF THE INDIVIDUAL PROPOSALS WHAT ARE THE CRITERIA FOR RECONSIDERING. GEOFF SUGGESTED HE CAN ACTUALLY -- SOME OF THIS COULD BE EMPIRICALLY BASED. HE COULD ACTUALLY ASK THE INSTITUTIONS IN CALIFORNIA HOW BIG A PROBLEM IS THIS IN TERMS OF -- I MEAN I THINK WE SET AS A GOAL WE REALLY WANT NONAFFILIATED PUBLIC MEMBERS TO PARTICIPATE IN THIS REVIEW. AND IF, IN FACT, THAT'S NOT POSSIBLE BECAUSE OF THIS COMPENSATION PROBLEM, IT STRIKES ME THAT WOULD BE A NEW FACT THAT MEANS WE'RE NOT ACHIEVING THE BROADER GOALS. AND WE CAN GET SOME EMPIRICAL DATA ON THAT.

MS. KING: WE SHOULD BE VERY CAREFUL ABOUT THIS BECAUSE IF YOU SURVEYED ME AND I REALLY THOUGHT THAT MY LIFE WOULD BE EASIER IF I COULD PAY MY UNAFFILIATED PERSON, THEN I'M CERTAINLY GOING TO

CONTRIBUTE TO YOUR EVIDENTIARY BASE. I THINK WE'RE HEADED IN THE RIGHT DIRECTION WITH WHAT YOU ARE SAYING, BERNIE, BUT THAT'S THE REASON WE SHOULD THINK CAREFULLY ABOUT WHAT WE'RE DOING. OTHERWISE I THINK WE'RE SUGGESTING THAT WE DIDN'T KNOW WHAT WE WERE DOING IN THE FIRST PLACE, AND THAT IS SOMETHING THAT WE WANT TO BE VERY CAREFUL ABOUT.

CHAIRMAN LO: OR THAT ANYTHING CAN BE CHANGED IF PEOPLE JUST SORT OF RAISE IT.

MS. KING: I DO THINK A GOOD EMPIRICAL BASE, NEW INFORMATION. JANET MENTIONED NEW INFORMATION. WE'RE MOVING IN A FAST-MOVING AREA. SO NEW INFORMATION THAT WAS NOT AVAILABLE TO US AT THE TIME WE MADE THE DECISION IS AN OBVIOUS WAY TO THINK ABOUT WHAT WOULD WARRANT A REVIEW OF WHAT WAS EFFECTED. THAT'S THE KIND OF THING I WANT US TO THINK ABOUT.

DR. ROWLEY: WELL, I HAVE TO SAY, AT THE RISK OF APPEARING TO BE LIKE JAMES THOMPSON, WHO WAS HEAD OF THE FINANCIAL COMMITTEE AT THE *SUN TIMES* WHO ADMITTED HE DIDN'T LOOK AT THE DOCUMENTS. I HAVE TO SAY THAT NONCOMPENSATION FOR NONASSOCIATED PEOPLE COMES TO ME AS A SURPRISE. AND I CERTAINLY DON'T REMEMBER EVER VOTING FOR SUCH A THING, BUT IT ALSO COULD BE DISCUSSED AT A MEETING I WASN'T AT. SO PEOPLE AROUND HERE ARE SAYING IT WASN'T DISCUSSED, WHICH I'M SURE IS NOT SO. IT CAME

FROM SOMEWHERE. AND IT'S JUST SURPRISING TO ME THAT FOR IRB MEMBERS, UNAFFILIATED PEOPLE ARE APPARENTLY REIMBURSED, AND FOR ESCRO PEOPLE, YOU'RE NOT REIMBURSED. I WOULD -- AS A HOSPITAL OR A UNIVERSITY OR WHATEVER INSTITUTE, I WOULD FIND THAT A PRETTY UNTENABLE SITUATION.

CHAIRMAN LO: ONE SCREEN WE COULD DO IS TO SAY AS THESE ISSUES COME UP, GEOFF COULD EXTRACT FOR US FROM THE RECORD, THERE'S AN EXTENSIVE RECORD, SORT OF THE DELIBERATIONS WE'VE HAD ON THIS TOPIC. GEOFF HAS DONE THAT IN THE PAST. IT'S ACTUALLY BEEN A REAL EYE-OPENER TO ME AS TO HOW MUCH DEPTH WE'VE PUT INTO A LOT OF THESE DISCUSSIONS. AND SO I THINK THEN THE QUESTION IS IS THERE SOME VERY PERTINENT FACT THAT WAS NOT AVAILABLE TO US AT THE TIME.

THE OTHER ARGUMENT IS IS THERE A REALLY COMPELLING ARGUMENT THAT WE DIDN'T CONSIDER THAT'S NOW BEING MADE AS OPPOSED TO YOU THOUGHT ABOUT THIS BEFORE, BUT YOU KIND OF FACED THE WRONG WAY. THAT'S SORT OF A HOLDING POLICY THAT BEFORE WE DECIDE, WE SHOULD GET MORE INFORMATION FROM GEOFF.

DR. ROWLEY: ABSOLUTELY.

CHAIRMAN LO: ANY OTHER CRITERIA? ANY OTHER CRITERIA PEOPLE WANT TO TOSS OUT FOR OUR CONSIDERATION, OFFER FOR OUR CONSIDERATION? TOSS OUT IS A PEJORATIVE

TERM. PAT, YOU'VE THOUGHT ABOUT THIS A LOT AS A POLICY.

MS. KING: I THOUGHT ABOUT THIS HERE.

DR. OLDEN: I THINK AN ORGANIZATION, THOUGH, REALLY GETS ITS CREDIBILITY, EVEN IF IT HAS MADE A MISTAKE, TO ACKNOWLEDGE IT PUBLICLY AND GO ON. EVEN IF WE HAVE DEBATED THIS ISSUE, I WOULD AGREE WITH JANET, AND MAYBE I WAS HERE. I THINK IT DOESN'T MAKE SENSE AS I THINK ABOUT IT TODAY. EVEN IF I WAS HERE AND VOTED FOR IT, I WOULD CHANGE MY MIND. SO I THINK THAT'S HOW CREDIBILITY IS ACTUALLY GAINED BY PUBLIC ORGANIZATIONS SUCH AS THIS. LET'S ADMIT THAT WE MADE A MISTAKE AND LET'S READDRESS IT IF WE THINK SO IRRESPECTIVE OF WHETHER THE DATA HAS CHANGED OR NOT.

CHAIRMAN LO: BEFORE WE DO THAT, I THINK IT WOULD BE HELPFUL TO SAY LET'S LOOK AT THE REASON BY WHICH WE --

DR. OLDEN: WELL, WE ARE GOING TO LOOK AT IT, BUT I THINK CREDIBILITY, THOUGH, IS THE ISSUE HERE.

CHAIRMAN LO: WELL, YOU LOSE CREDIBILITY BY NOT ADMITTING MISTAKES, AND YOU LOSE CREDIBILITY BY REOPENING ISSUES THAT APPARENTLY WERE SETTLED. WE NEED TO DO THIS RIGHT.

MR. TOCHER: BERNIE, IT SOUNDS LIKE FROM, JUST THROWING THIS OUT, YOU'RE TALKING ABOUT SORT OF

THE CRITERIA WOULD BE CHANGED CIRCUMSTANCES. EITHER A CIRCUMSTANCE THAT CHANGED FACTUALLY THAT MEANS THAT THE DATA IS SHIFTING OR THERE'S NEW EXPERIENCE THAT SUGGESTS THERE'S AN AREA YOU DIDN'T COVER THAT YOU SHOULD COVER OR ADDRESS, OR A CHANGED CIRCUMSTANCE BEING THAT THERE'S AN ERROR IN THE ASSUMPTION THAT UNDERLIES SOME ASPECT OF THE REGULATION, THAT A CERTAIN POLICY WAS NEEDED THAT'S NOT, OR, YOU KNOW, THAT IT JUST REFLECTS SOME ERROR IN ASSUMPTION. WHEN YOU'RE TALKING ABOUT APPEALS AND ENDLESS APPEALS IN A LEGAL CONTEXT, YOU'RE NOT -- A GROUND IS NOT WE WANT TO RELITIGATE IT. IT'S YOU HAVE TO SHOW THAT THERE WAS SOME ERROR OR SOMETHING LIKE THAT, SOME FUNDAMENTAL MISTAKE THAT NEEDS TO BE ADDRESSED AS OPPOSED TO OPENING UP A POLICY DISCUSSION ALL OVER AGAIN JUST BECAUSE YOU DISAGREE WITH THE CONCLUSION.

DR. TAYLOR: BASED ON THAT, IT WOULD SEEM TO ME THAT WE'D HAVE TO HAVE EVIDENCE THAT PEOPLE CAN'T SET UP THEIR SCRO'S BECAUSE THEY CAN'T BRING THESE PEOPLE -- THEY CAN'T BRING OUTSIDE PEOPLE IN. I'M ACTUALLY NOT AWARE THAT IRB'S COMPENSATE THEIR COMMUNITY OR OUTSIDE OF THE INSTITUTION. THAT WOULD BE NEW INFORMATION FOR ME IF THAT'S ACTUALLY THE CASE. MAYBE THAT PRECEDENT EXISTS, BUT IT SEEMS TO ME I AGREE THAT YOU HAVE TO HAVE SOME EVIDENCE THAT THIS IS A REAL

PROBLEM.

CHAIRMAN LO: LET ME TAKE THIS AS AN EXAMPLE OF WHAT WE MIGHT REQUEST GEOFF DO. FIRST IS GO OVER THE TRANSCRIPTS AND SORT OF RECONSTRUCT THE ARGUMENT.

SECOND, THERE'S SOME NEW FACTS THAT WERE BROUGHT FORTH, AND ONE IS THAT IRB MEMBERS ARE PAID, NONINSTITUTIONAL IRB MEMBERS. IS THAT WIDESPREAD? IS THAT, IN FACT, THE CASE? IS THE ARGUMENT, THEN, THAT WE DIDN'T CONSIDER THAT, AND IT'S UNFAIR TO TREAT ONE SET OF COMMITTEE MEMBERS -- MEMBERS OF ONE COMMITTEE DIFFERENTLY FROM ANOTHER COMMITTEE?

I THINK THERE'S A SET OF THINGS THAT WE COULD TRY AND CONSTRUCT. THE REASONS WHY WE SHOULD RECONSIDER WOULD, I THINK, GO BACK TO WE WEREN'T AWARE OF THE FACT THAT IRB MEMBERS ARE FOR THE MOST PART PAID, AND WE HADN'T CONSIDERED THE FACT -- THE ARGUMENT THAT IT WOULD BE UNFAIR TO PAY THERE AND NOT PAY HERE. AND ALSO THERE'S NO EVIDENCE THAT PAYING IRB MEMBERS CORRUPTS THE INDEPENDENCE.

THERE'S A SET OF -- I THINK IF THERE ARE ARGUMENTS LIKE THAT THAT CAN BE MADE OR THAT FROM THE RECORD SHOW WE JUST DIDN'T THINK OF IT AND IT SOMEHOW GOT IN THERE, THEN I THINK THERE WOULD BE MORE PERSUASIVE GROUNDS FOR RELOOKING.

IF IT TURNS OUT WE'VE CONSIDERED THAT

ARGUMENT, IT TURNS OUT THAT WE DID DISCUSS THE FACT, WELL, BUT YOU PAY IRB MEMBERS, AND IT WOULD BE UNFAIR. AND SOMEONE SAID, WELL, YOU DON'T PAY. A LOT OF PEOPLE CAN RECRUIT IRB MEMBERS, LIKE OUR INSTITUTION, WITHOUT PAYING THEM MORE THAN OUT-OF-POCKET REIMBURSABLE EXPENSES. THE ARGUMENT AT MY INSTITUTION NOW IS WHERE CAN WE GET SOMEONE TO PAY FOR THE PARKING AS OPPOSED TO PAYING THEM THE LOSS OF THEIR WAGES. THERE'S STUFF THAT WE COULD GENERATE THAT WOULD FORM A REASON TO RECONSIDER.

MR. SHEEHY: I THINK PAT MADE A REALLY GOOD POINT, AND ACTUALLY I KIND OF REMEMBER THE DISCUSSION. I REMEMBER ONE OF THE CRITERIA THAT WE WERE LOOKING AT. WE JUST FOUND OURSELVES ON A SLIPPERY SLOPE. WE WERE ASKING QUESTIONS ABOUT WHETHER OR NOT SOMEONE CAN BE A PATIENT AT THE FACILITY OR RECEIVE MEDICAL CARE AT THE FACILITY, IF THAT MAYBE RINGS SOME BELLS. THIS IS ONE, ON REFLECTION, I THINK MAYBE WE OUGHT TO JUST MAYBE LET IT REST UNLESS THERE'S SOME CONVINCING EVIDENCE THAT PEOPLE ARE HAVING TROUBLE GETTING PEOPLE TO SERVE. I SHARE FRANCISCO'S FRUSTRATION.

DR. PRIETO: I'M NOT HEARING YOU VERY WELL.

MR. SHEEHY: I'M JUST SAYING THAT I SHARE YOUR FRUSTRATION AT THE BURDENS THAT ARE IMPOSED ON PEOPLE FOR SERVICE WHEN THEY'RE NOT COMPENSATED. BUT I

DO REMEMBER THIS DISCUSSION, AND I REALLY THINK THAT WE WERE FAIRLY EXHAUSTIVE ON IT AND REALLY PREFER THAT WE DEAL WITH NEW ISSUES. I THINK PAT IS RIGHT. WE NEED TO LET THESE STAND AND HAVE A STRONGER EVIDENCE BASE BEFORE WE PROCEED FORWARD BECAUSE THIS WAS -- COMPENSATION WAS JUST ONE OF MANY CRITERIA THAT WE WERE USING TO ENSURE THAT THE OUTSIDE PARTICIPANTS ON THESE SCRO'S WERE PROPERLY INSULATED FROM INFLUENCE FROM THE INSTITUTIONS.

CHAIRMAN LO: IT SOUNDS LIKE WE NEED TO UNDERSTAND THE RECORD AND THE DELIBERATIONS THAT GOT US HERE. THAT WOULD BE USEFUL TO DO. I THINK IT'S CERTAINLY VERY GOOD FOR US TO SAY WE NEED TO MAKE SURE -- WE NEED TO SEE HOW WE THOUGHT ABOUT IT TO CHECK IT AND MAKE SURE WE DID IT RIGHT.

DR. ROWLEY: THIS, OF COURSE, BRINGS UP A POINT THAT, IN FACT, I GUESS I AS A MEMBER WASN'T NECESSARILY THINKING ABOUT AT THE TIME, BUT THIS IMPLIES THAT WE'RE AN ONGOING GROUP.

MS. KING: DON'T WE HAVE TERMS? DON'T WE HAVE TERMS? WE HAVE TERMS BECAUSE I CHECKED THAT OUT. I HAVE LEARNED THAT. I KNOW WE HAVE TERMS.

CHAIRMAN LO: YOU HAVE THE 50-YEAR TERM.

MS. KING: NO, I DON'T. I CAN'T REMEMBER WHEN MINE IS UP, BUT I DID ASK THE QUESTION.

DR. LOMAX: I WOULD NEED TO REFER TO DOCUMENTATION AND PROPOSITION 71, BUT PROPOSITION 71 DOES ACTUALLY SPECIFY TERMS OF WORKING GROUP MEMBERS, AND THERE IS A CYCLE OF TURNOVER CONTEMPLATED FOR THIS WORKING GROUP.

CHAIRMAN LO: LET ME SEE IF I CAN -- THERE ARE ISSUES WHERE WE'RE GOING TO ASK GEOFF TO GO BACK AND MAKE A RECORD OF THE DELIBERATIONS AND JUST REFRESH OUR MEMORY. I THINK THAT SHOULD BE A RELATIVELY LOW HURDLE, JUST SORT OF PROVIDING INFORMATION. SO I WOULD SUGGEST THAT ON ALL THE ISSUES I RAISED WE CERTAINLY ASK GEOFF TO DO THAT.

ON THE ISSUE OF DEEMING IN LINES FROM JAPAN, IT SOUNDS LIKE WE WANT HIM ACTUALLY TO DO MORE THAN THAT AND TO PREPARE A POLICY BRIEFING MEMO ON WHETHER WE SHOULD PROPOSE AN AMENDMENT TO THE REGULATIONS TO ALLOW THOSE LINES TO BE DEEMED LIKE THE UK LINES ARE.

I THINK FOR THE EMBRYOS CREATED FOR REPRODUCTIVE PURPOSES, THE GAMETE DONOR THAT DIDN'T EXPLICITLY CONSENT AND THE COMPENSATION FOR NONAFFILIATED MEMBERS, WE SHOULD PROBABLY AT THE FIRST THING JUST ASK HIM TO SUMMARIZE THE DELIBERATIONS WE HAD. WE CAN CIRCULATE THAT, AND BASED ON THAT, WE CAN SAY, "WELL, NO. THERE'S STUFF THAT WE DIDN'T CONSIDER. THERE ARE NEW FACTS," AND BASE OUR DECISION TO

RECONSIDER ON THAT.

TRYING TO ARTICULATE WHEN WE DO SO, WHAT ARE THE REASONS FOR DOING THAT INDEPENDENT OF HOW I MIGHT PERSONALLY FEEL ABOUT THE ISSUE. IT'S NOT ENOUGH THAT I DISAGREE, BUT THERE'S SOMETHING ABOUT THE PROCESS BY WHICH WE MADE THAT DECISION THAT WE THINK NOW THE CIRCUMSTANCES HAVE CHANGED. I THINK THAT WOULD BE USEFUL TO DO.

AND THEN I GUESS FOR THE CHIMERAS. LET ME JUST STOP THERE AND SAY IS THAT ACCEPTABLE TO FOLKS IN TERMS OF THESE CONSIDERATIONS WHERE WE'VE THOUGHT ABOUT THEM BEFORE, BUT THERE'S SOME SENSE THAT MAYBE WE NEED TO RECONSIDER? LET'S SEE WHAT WE THOUGHT BEFORE AND THEN DECIDE, AND WE CAN CIRCULATE THAT ELECTRONICALLY AND HAVE A CONFERENCE CALL IF NEED BE. IS THAT THE SENSE OF THE COMMITTEE?

AND THEN, ANN, I BELIEVE IT WAS YOU WHO RAISED THE ISSUE OF IF WE'RE GOING TO BE GETTING GRANTS THAT INVOLVE CHIMERA RESEARCH IN A LIMITED SENSE, AND WE WANT TO MAKE SURE THAT CIRM IS ON TOP OF ETHICAL CONCERNS ABOUT THAT RESEARCH, SHOULD WE BE KIND OF EDUCATING OURSELVES AT THE VERY LEAST ABOUT THE CURRENT THINKING ON THAT? AND THERE IS A LOT IN PROGRESS ON THAT. ASK GEOFF TO SORT OF BRING THAT TOGETHER AS AN EDUCATIONAL -- FIRST, AS AN EDUCATIONAL ACTIVITY FOR

US, BUT WITH A VIEW TO DOWN THE ROAD IS THE QUESTION OF SHOULD WE HAVE A POLICY ON THAT, WHICH WOULD MEAN AN AMENDMENT TO REGULATIONS?

DR. KIESSLING: WE ACTUALLY TOUCHED ON THAT LAST YEAR. I KNOW WE HAD A LITTLE COMMITTEE OF TED PETERS AND JEFF KORDOWER AND I BECAUSE WE TALKED ABOUT THIS. YOU'RE GOING TO BE GETTING SOME APPLICATIONS THAT RELATE TO THAT, AND SOME OF THEM ARE NOT GOING TO BE AN ISSUE AND SOME OF THEM ARE GOING TO BE REALLY TOUCHY. RATHER THAN HAVE TO BE REACTIONARY AT THE TIME, IT'S PROBABLY A GOOD IDEA TO JUST SAY, WELL, THESE ARE GOING TO BE, AND THIS IS WHAT YOU DO. IT MIGHT BE JUST AS SIMPLE AS NOT BREEDING THE ANIMAL, WHICH ARE THE NAS GUIDELINES, BUT IT WOULD BE USEFUL, I THINK, IF IT WERE AN UP-FRONT PREDISCUSSION RATHER THAN A --

CHAIRMAN LO: AGAIN --

DR. KIESSLING: -- BRUSH FIRE.

CHAIRMAN LO: AGAIN, JANET, CORRECT ME IF I'M WRONG, BUT THE NAS GUIDELINES DISTINGUISH SORT OF WHAT ARE YOU GOING TO DO -- IF THEY'RE GOING INTO A BLASTOCYST, THAT'S OF MORE CONCERN THAN PUTTING THEM INTO AN ADULT ANIMAL AS OPPOSED TO DEVELOPING AN ANIMAL AND CERTAIN ORGAN SYSTEMS.

DR. ROWLEY: THE BRAIN.

CHAIRMAN LO: RIGHT. SO I THINK THERE IS SOME SENSE THAT THESE ARE MORE SENSITIVE, BUT I LIKE ANN'S SUGGESTION THAT WE OUGHT TO BE PROACTIVE AND ANTICIPATORY.

DR. ROWLEY: I THINK THAT ONE COULD BROADEN THIS A LITTLE BIT ON TRYING TO BE -- AVOID BEING CATCHING UP ALL THE TIME. THE NAS IN THEIR GUIDELINES OF WHAT ESCRO'S SHOULD BE PAYING SPECIFIC ATTENTION TO AND HOW THEY MIGHT -- WHAT THE PARAMETERS OR THE CONSTRAINTS WOULD BE, AND I DON'T REMEMBER RIGHT NOW WHAT THE NAS GUIDELINES WERE FOR ESCRO'S, BUT THEY CERTAINLY DID SPELL OUT THOSE THINGS THAT THE ESCRO'S SHOULD BE PAYING PARTICULAR ATTENTION TO. ONE MIGHT SAY WHAT GRANTS ARE COMING WITHIN THOSE GUIDELINES THAT THE NAS AT THE TIME, REALIZING THAT THIS WAS SEVERAL YEARS AGO, WHAT THINGS CAME FORWARD THAT THE ESCRO SHOULD PAY PARTICULAR ATTENTION TO AND WHAT CATEGORIES OF CALIFORNIA GRANTS ARE COMING THROUGH IN THOSE CATEGORIES AND GRANTS ELSEWHERE THAT WE SHOULD AT LEAST BE AWARE OF AND BEGIN TO SEE IF WE AGREE WITH THE NAS RESTRICTIONS, OR DO WE NEED TO DO SOMETHING DIFFERENT BASED ON WHAT'S HAPPENED IN THE LAST COUPLE OF YEARS?

DR. KIESSLING: I THINK THAT'S SORT OF THE BASIS FOR THIS INTERSTATE MEETING THAT YOU ARE PLANNING, ISN'T IT, GEOFF, THIS KIND OF TRYING TO STAY

AHEAD OF THE TIDE?

DR. LOMAX: YES. IF I'M RECALLING THE AGENDA PROPERLY, I THINK THE CHIMERA ISSUE HAS BEEN SORT OF CALLED OUT AS ONE THAT PEOPLE ARE GETTING THEIR HEAD AROUND. BUT I WOULD, JUST TO REPRESENT THE MEETING ACCURATELY, I THINK IT'S STILL AT A STAGE WHERE OUR EXPERIENCE IS FAR MORE FURTHER OUT, I THINK, THAN MOST OF THE OTHER PARTICIPANTS. SO I THINK THE LEVEL OF DISCUSSION IS REALLY STILL GETTING FOLKS ONTO THE SAME -- UP TO THE SAME LEVEL AND NOT SORT OF PUSHING FORWARD, ALTHOUGH WITH THE NAS AS PARTICIPANTS, CERTAINLY THERE'S THINKING THERE. ALTA IS INVOLVED.

SO CERTAINLY THE THINKING IS THERE, BUT I THINK IN THE NEAR TERM, IT'S REALLY GETTING PEOPLE UP TO THE SAME LEVEL IN TERMS OF THEIR UNDERSTANDING OF THESE ISSUES.

CHAIRMAN LO: ANOTHER THING WE COULD DO, WHICH I THINK BOTH JANET AND ANN ALLUDED TO, IS THAT THE SCIENCE IS MOVING SO QUICKLY, THAT WE SHOULD SEE ARE THERE THINGS THAT WEREN'T REALLY THOUGHT OF A YEAR OR TWO AGO THAT NOW ARE BEING TALKED ABOUT THAT NEED TO BE EVALUATED IN TERMS OF CHIMERAS OR CYCLOIDS OR WHATEVER.

DR. ROWLEY: RIGHT. BECAUSE IT'S INTERESTING, AGAIN, COMING BACK TO THE JAPANESE

GUIDELINES, IT SEEMS TO ME, AND I READ A NUMBER OF THINGS AND I COULD BE MIXING THEM UP, BUT NO USE OF ES CELLS TO MAKE GERM CELLS. NOW, IT'S MY IMPRESSION THAT GEORGE DALY AND PROBABLY OTHERS ARE, IN FACT, ACTIVELY TRYING TO DO THAT. AND WE ALL AGREE IF YOU COULD GET GERM CELLS FROM ES CELLS, A LOT OF THE PROBLEM THAT WE DISCUSSED ABOUT DONORS WOULD DISAPPEAR. SO, A, IN YOUR COMPARISON OF THE GUIDELINES FROM JAPAN AND U.S. GUIDELINES, YOU'RE GOING TO COMPARE AND SEE WHAT THE DIFFERENCES ARE. BUT THE ISSUES OF USING ES CELLS TO MAKE GERM CELLS MIGHT BE A SPECIFIC ISSUE ON WHICH WE WOULD LIKE SOME CURRENT INFORMATION AS WELL AS WHAT ARE THE ETHICAL ISSUES SURROUNDING THAT.

DR. LOMAX: JUST TO CLARIFY ONE ITEM. THESE ANALYSES, FOR THE SAKE OF SORT OF BREVITY AND CLARITY, I'VE GENERALLY TRIED TO CALL OUT ANY ISSUES WHERE THERE MAY BE A -- WHERE WE HAVE SET A BAR AND THAT THE UNIT OF ANALYSIS, IN THIS CASE THE JAPANESE REGULATIONS, THE EXAMPLE YOU HELD FURTHER THAT DIFFERS BY TWO DAYS, I HAVE GENERALLY REFRAINED FROM A KIND OF COMPREHENSIVE. I THINK, IN PART, THAT'S WHY WE TRIED TO PROVIDE YOU WITH THE REGULATIONS FOR THAT BENEFIT, SO I TRY TO LIMIT MY ROLE TO ISSUES OF WHERE REGULATORY CONSISTENCY IS GERMANE TO SORT OF THE POLICY AND NOT ANY SORT OF COMPREHENSIVE REVIEW, IF THAT MAKES SENSE.

I WOULD HOPE TO SORT OF CONTINUE ALONG THOSE LINES IN THIS CAPACITY. OTHERWISE THE DETAIL AND MY COMPETENCE IN THE ANALYSES DIMINISHES.

CHAIRMAN LO: WE'VE GIVEN GEOFF, WHO'S BEEN OUR STALWART HERE, A LOT OF ADDITIONAL THINGS TO DO, BUT INTERESTING AND IMPORTANT THINGS. ARE THERE OTHER ISSUES PEOPLE WANT TO BRING UP? ARE THERE OTHER ISSUES WE NEED TO DISCUSS? IS THERE ANY PUBLIC COMMENT ON WHAT WE'VE JUST BEEN TALKING ABOUT WITH REGARD TO RECONSIDERING CRITERIA FOR RECONSIDERING PROVISIONS? IF NOT, I WOULD BE GLAD TO ENTERTAIN A MOTION TO ADJOURN.

MS. KING: SO MOVED.

CHAIRMAN LO: ALL IN FAVOR. THANK YOU VERY MUCH FOR COMING. YOU ARE INVITED TO A LUNCHEON IN THE ADJACENT ROOM. THANKS TO GEOFF AND THE STAFF FOR MAKING THE ARRANGEMENTS AND THE BACKGROUND WORK THAT'S SO IMPORTANT. THANK YOU.

(THE MEETING WAS THEN ADJOURNED AT 12:19 P.M.)

REPORTER'S CERTIFICATE

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

MIYAKO HOTEL
1625 POST STREET
SAN FRANCISCO, CALIFORNIA
ON
MAY 10, 2007

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

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

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