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

REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: FRIDAY, JUNE 10, 2011
10:30 A.M.

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

BRS FILE NO.: 90238

I N D E X

FRIDAY, JUNE 10, 2011

10:30 A.M.

DR. LOMAX: TIM KAMP. NOT YET. KEN PETERS.

DR. PETERS: HERE.

DR. LOMAX: SHERRY LANSING.

MS. LANSING: HERE.

DR. LOMAX: ROBERT TAYLOR. MAYBE WE DROPPED ROBERT. WE HAD ROBERT. WE'VE DROPPED HIM. WE'LL HEAR HIM COME BACK ON, I HOPE.

DR. TAYLOR: I'M HERE.

DR. LOMAX: MARCY FEIT, YOU'RE WITH US?

MS. FEIT: YES.

DR. LOMAX: JOHN WAGNER. STILL WAITING ON JOHN. DOROTHY ROBERTS.

DR. ROBERTS: HERE.

DR. LOMAX: BERNARD LO.

CHAIRMAN LO: HERE.

DR. LOMAX: ANN KIESSLING. JEFF SHEEHY.

MR. SHEEHY: HERE.

DR. LOMAX: SO WE MAY GET A COUPLE OTHER FOLKS JOINING US. IS THERE ANYONE I MISSED WHO'S ON THE LINE?

CHAIRMAN LO: HERE IN SAN FRANCISCO WE

HAVE JEFF, ELLEN FEIGAL, PAT OLSON, PAT BECKER.

DR. LOMAX: AND WHAT I WANTED TO DO IS START WITH AN UPDATE, AND THAT WILL GIVE TIME FOR SOME OF THE OTHER MEMBERS TO JOIN US. SO WELCOME, EVERYONE. THANK YOU FOR TAKING TIME OUT OF YOUR DAY.

I DID WANT TO UPDATE YOU ON THE PROGRESS FROM THE LAST MEETING. I'VE BEEN WORKING WITH DR. LO TO COMPLETE OUR REPORT FROM THE APRIL 29TH MEETING ON CELL REPOSITORIES. AND WE DO INTEND TO CIRCULATE A DOCUMENT TO YOU THAT WE REQUEST THAT YOU REVIEW FOR ACCURACY. THE REPORT WILL INCLUDE THE FOLLOW-UP RESEARCH THAT STAFF WAS DIRECTED TO PERFORM. AND AS YOU MAY RECALL, WE WERE ASKED TO LOOK AT FACTORS RELATING TO PATIENT'S DECISIONS TO DONATE BIOLOGICAL SPECIMENS FOR RESEARCH, PREFERENCES FOR RESEARCH PARTICIPANTS REGARDING COMMUNICATION OF RESULTS, AND GUIDELINES FOR COMMUNICATION OF SCIENTIFICALLY VALID AND CLINICALLY SIGNIFICANT FINDINGS.

WE WERE ABLE TO TRACK DOWN A FAIRLY EXTENSIVE SET OF LITERATURE ON THESE TOPICS. AND I'D ALSO LIKE TO --

WHO JUST JOINED US?

DR. PRIETO: HI. THIS IS FRANCISCO

PRIETO.

DR. LOMAX: WELCOME. WE'RE JUST GIVING FOLKS AN UPDATE ON THE STATUS OF THE REPORT.

I BELIEVE THE REPORT WILL INCLUDE A NUMBER OF VERY PRACTICAL RECOMMENDATIONS TO SUPPORT A HIGHLY CONSTRUCTIVE CIRM ROLE IN THE DEVELOPMENT OF IPS REPOSITORIES. AND I ALSO THINK IT WILL MAKE A MEANINGFUL CONTRIBUTION TO THE OVERALL LITERATURE ON THIS TOPIC.

BERNIE, I DON'T KNOW IF YOU'D LIKE TO ADD ANYTHING.

CHAIRMAN LO: I JUST WANT TO THANK GEOFF. HE'S REALLY DONE A LOT OF BACKGROUND RESEARCH AND WRITING PARTICULARLY ON THE ISSUES THAT WE ASKED HIM TO DO. AND SOMETIME MAYBE NEXT WEEK HE WILL HAVE A DRAFT THAT WE WILL CIRCULATE, AND WE'LL CALL ON THE SWG JUST TO MAKE SURE IT'S ACCURATE AND REFLECTS THE CHANGES. BUT GEOFF WENT BACK AND ACTUALLY LOOKED AT THE TRANSCRIPTS OF THE DISCUSSION AND HAS REALLY DONE A LOT TO SORT OF PUT THIS TOGETHER.

MS. LANSING: I ALSO WANT TO THANK YOU, GEOFF. YOU'RE JUST AMAZING IN ALL WAYS.

DR. LOMAX: I DO HAVE TO ACKNOWLEDGE DR. FEIGAL'S CONTRIBUTION HERE. SHE'S BEEN A TREMENDOUS HELP IN TERMS OF HELPING GET THIS EDITED AND TURNED

AROUND VERY QUICKLY. SO THANK YOU.

OKAY. I BELIEVE -- DID WE HAVE SOMEONE ELSE JUST JOIN THE CALL JUST FOR THE PURPOSES OF ROLL?

DR. KAMP: YES. THIS IS TIM KAMP FROM THE UNIVERSITY OF WISCONSIN.

DR. LOMAX: WELCOME, TIM. GREAT.

CHAIRMAN LO: DID SOMEONE ELSE JUST JOIN?

DR. WAGNER: THIS IS JOHN WAGNER FINALLY.

CHAIRMAN LO: OH, JOHN, WELCOME.

SO LET ME JUST GIVE YOU THE BACKGROUND AND SORT OF SET THE STAGE FOR WHAT WE'RE TRYING TO DO TODAY. SO AS WE KNOW, PROP 71 ENJOINS THE SWG TO MAKE RECOMMENDATIONS TO THE ICOC FOR STANDARDS WITH REGARD TO CLINICAL TRIALS. AND IN MAY THE ICOC APPROVED AN AWARD TO SUPPORT THE FIRST FDA-APPROVED CLINICAL TRIAL BASED ON CELLS DERIVED FROM EMBRYONIC STEM CELLS. AND PRIOR TO ACTIVATING THE AWARD, THE ICOC HAS ASKED THE SWG TO CONSIDER REGULATORY, STATUTORY, ETHICAL OVERSIGHT OF THESE FDA-APPROVED CLINICAL TRIALS. SO WE'RE ASKED TO PROVIDE GUIDANCE.

AND GEOFF AND ELLEN AND I AND OTHERS AT CIRM HAVE DRAFTED A RESOLUTION THAT WE SENT AROUND TO BRING TOGETHER THE STATUTORY, REGULATORY

REQUIREMENTS WITH REGARD TO SAFETY OF THERAPIES, PROTOCOL REVIEW, OVERSIGHT, MONITORING, AND SO FORTH.

IN ADDITION, WE WANTED TO DRAW IN CIRM'S REQUIREMENTS RELATING TO REPORTING OF ACCESS TO THERAPIES.

I JUST WANT TO TAKE A MINUTE TO SORT OF PUT THIS IN THE CONTEXT OF ALL THE OTHER THINGS WE'VE DONE IN THE SWG. FIRST, I HAVE TO SAY OBVIOUSLY EVERYONE IS EXCITED ABOUT THE PROSPECT OF A CLINICAL TRIAL DERIVED USING DERIVATIVES OF EMBRYONIC STEM CELLS BECAUSE ACTUAL THERAPIES, NEW THERAPIES, FOR CONDITIONS WHERE THERE ARE NO GOOD THERAPIES NOW HAS REALLY BEEN ONE OF THE LONG-TERM GOALS OF CIRM AND OF THE WHOLE FIELD OF STEM CELL RESEARCH.

AND SWG HAS BEEN INVOLVED FROM THE ONSET IN MAKING SURE PATH-BREAKING RESEARCH MEETS HIGH ETHICAL STANDARDS. WHAT WE'RE BEING ASKED TO DO TODAY, JUST TO BE CLEAR, IS WE'RE NOT BEING ASKED TO SORT OF RECOMMEND REGULATIONS. WE'RE REALLY BEING ASKED TO PROVIDE MUCH HIGHER LEVEL OR PERHAPS, I SHOULD SAY, BROADER GUIDANCE TO CIRM, PARTICULARLY CIRM STAFF, WHO WILL BE WRITING GRANTS MANAGEMENT, HANDLING THE GRANTS MANAGEMENT.

AND I WANTED TO JUST SORT OF REMIND US OF HOW WE'VE APPROACHED OUR TASK OVER THE YEARS. AND I THINK IT'S FAIR TO SAY THERE'S A NUMBER OF RULES OF THUMB THAT WE'VE SORT OF DRAWN ON OVER THE YEARS. THE FIRST IS THAT WE WANTED CIRM STANDARDS TO BE CONSISTENT WITH FDA STANDARDS, COMMON RULE STANDARDS, NATIONAL ACADEMY OF SCIENCE STANDARDS, PRECLINICAL PRACTICE STANDARDS. THERE ARE TIMES WHERE WE'VE GONE BEYOND THOSE STANDARDS, BUT WE'VE ALWAYS BEEN MINDFUL THAT OUR GRANTEES HAVE TO BE ABLE TO FULFILL BOTH OUR STANDARDS AND ALL THE OTHER STANDARDS THAT THEY'RE LIABLE FOR. SO WE DON'T WANT TO TRY AND SAY SOMETHING THAT'S CONTRADICTORY TO WHAT FDA REQUIRES OR THE COMMON RULE REQUIRES OR GCP STANDARDS REQUIRE.

OUR SECOND SORT OF RULE OF THUMB HAS BEEN WE'VE BEEN VERY MINDFUL THAT THE SCIENCE IS MOVING. IT'S ADVANCING VERY QUICKLY. AND WE DON'T WANT TO BE OVERLY PRESCRIPTIVE, OVERLY SPECIFIC IN WAYS THAT LOCK US INTO THINGS THAT BECOME OBSOLETE AS PROGRESS CHANGES.

AND WE FINALLY ALSO WANTED TO BE FLEXIBLE IN THAT AS WE ENTER INTO A NEW TYPE OF RESEARCH SUCH AS CLINICAL TRIALS, WE WANT TO APPRECIATE THAT THINGS WILL EMERGE IN THE COURSE OF THE TRIAL OR

AFTER THE FIRST OR SECOND TRIAL THAT WE NEED TO BE MINDFUL OF AND BE READY TO MODIFY OUR STANDARDS IF WE NEED TO. I THINK WE'VE ALWAYS BEEN OPEN TO RECONSIDERING OUR IDEAS IN LIGHT OF NEW DEVELOPMENTS.

I JUST WANTED TO SAY THAT AS SORT OF A FRAMEWORK FOR THIS DISCUSSION. SHERRY, I DON'T KNOW IF YOU WANTED TO ADD ANYTHING AT THIS POINT.

MS. LANSING: NOT REALLY, JUST TO SECOND THAT WE'VE ALWAYS TRIED TO BE CONSISTENT. SOMETIMES WE'VE ACTUALLY BEEN MORE CONSERVATIVE; BUT WHAT WE'VE ALWAYS SAID, YOU KNOW, WHICH I SAID A HUNDRED TIMES, THIS IS A WORK IN PROGRESS THAT WE CHANGE AS THE SCIENCE PROGRESSES. AND NOW WE'RE AT THE CLINICAL TRIALS PHASE, SO I THINK THIS IS A PERFECT EXAMPLE WHERE WE'RE TRYING TO ADAPT TO WHAT'S GOING ON.

CHAIRMAN LO: OKAY. SO I WANT TO THEN ASK GEOFF TO SORT OF GIVE US SOME MORE SPECIFIC CONTEXT FOR THIS RESOLUTION.

DR. LOMAX: THANK YOU, BERNIE. AND THANK YOU, SHERRY, FOR THAT INTRODUCTION.

WHAT I DID WANT TO DO IS TOUCH ON THE FACT THAT THE STANDARDS WORKING GROUP DOES, IN FACT, HAVE A HISTORY OF DIRECT AND INDIRECT INVOLVEMENT IN THE

DEVELOPMENT OF CIRM POLICIES GOVERNING THE CONDUCT OF INSTITUTE-SPONSORED TRIALS. AND I REALIZE THAT A NUMBER OF THE MEMBERS, WE'VE HAD SOME TURNOVER, AND SO SOME OF YOU ALL MAY NOT BE KIND OF AWARE OF SOME OF THOSE EFFORTS. SO I'D LIKE TO RECAP SOME OF THOSE EFFORTS.

SO, FOR EXAMPLE, IN 2005 THE STANDARDS WORKING GROUP INCORPORATED THE CALIFORNIA INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH ACT INTO THE REGULATIONS. THE CALIFORNIA ACT IS MODELED AFTER THE NIH POLICY, AND IT'S DESIGNED TO PREVENT DISCRIMINATORY PRACTICES IN CLINICAL RESEARCH. AND AGAIN, THIS WAS DIRECTLY INCORPORATED INTO THE MEDICAL AND ETHICAL STANDARDS REGULATIONS WHICH WAS SUBSEQUENTLY APPROVED BY THE GOVERNING BOARD.

DURING THE SAME PERIOD, THE STANDARDS WORKING GROUP COMMENTED ON CIRM'S INTELLECTUAL PROPERTY POLICY, WHICH WAS BEING DEVELOPED BY A TASK FORCE IN PARALLEL WITH THE DEVELOPMENT OF OUR REGULATIONS, THE MEDICAL AND ETHICAL STANDARDS REGULATIONS. AND THE STANDARDS WORKING GROUP VOICED ITS SUPPORT FOR THE PROVISION REQUIRING ACCESS PLANS DESIGNED TO PROVIDE THERAPIES TO UNINSURED CALIFORNIANS. AND THOSE PROVISIONS HAVE NOW BECOME LAW AND INCORPORATED AS PART OF OUR INTELLECTUAL

PROPERTY POLICY.

IN ADDITION TO THE SPECIFIC REGULATORY ACTIONS, CIRM HAS TAKEN STEPS TO ADDRESS THE ETHICAL CONSIDERATIONS IN ITS RESEARCH PROGRAM. SO, FOR EXAMPLE, CIRM STAFF WORKED WITH THE CHAIRS OF THE STANDARDS WORKING GROUP TO IDENTIFY CANDIDATES WITH CLINICAL ETHICS EXPERTISE TO PARTICIPATE IN THE GRANTS WORKING GROUP REVIEW OF OUR TARGETED CLINICAL DEVELOPMENT PROGRAM.

AS A RESULT, DOUG DIEKEMA, DIRECTOR OF THE EDUCATION FOR PEDIATRIC BIOETHICS AT THE UNIVERSITY OF WASHINGTON AND CHAIR OF THE IRB AT SEATTLE CHILDREN'S HOSPITAL, PARTICIPATED IN THE REVIEW WHERE THIS AWARD WAS CONSIDERED.

FINALLY, CIRM REQUIRES A NUMBER OF POLICIES WITHIN THE APPLICATION OR OUR CONTRACTS. SO, FOR EXAMPLE, CIRM REQUIRES PUBLIC REGISTRATION ON CLINICALTRIALS.GOV. IN ADDITION, IT REQUIRES THE IRB REVIEWING A TRIAL TO BE REGISTERED WITH THE OFFICE OF HUMAN RESEARCH PROTECTION. SO BASED IN LARGE PART ON THE EFFORTS OF THE WORKING GROUP AND ITS CHAIRPERSONS, WE FEEL CIRM HAS STAYED TRUE TO THEIR COURSE IN ADVANCING RESPONSIBLE RESEARCH BY REALLY BUILDING ON ESTABLISHED POLICY, AS DR. LO REFERRED TO EARLIER.

I WANTED TO HIGHLIGHT THESE EFFORTS BECAUSE THEY'RE ACTIONS CIRM HAS INITIATED IN ADVANCE OF EXISTING FEDERAL REQUIREMENTS. AND AS INDICATED IN THE RESOLUTION, ANY FDA-REGISTERED TRIAL MUST ALSO MEET A SERIES OF FEDERAL REQUIREMENTS. AND AGAIN, THESE REQUIREMENTS ARE THE SAFETY OF THERAPIES, AND THOSE REQUIREMENTS WERE PROMULGATED BY THE FOOD AND DRUG ADMINISTRATION, THE INSTITUTIONAL REVIEW AND OVERSIGHT REQUIREMENTS AS DESCRIBED IN THE COMMON RULE, WHICH IS INCORPORATED BOTH INTO OUR MEDICAL AND ETHICAL STANDARDS AND OUR GRANTS ADMINISTRATION POLICY, AND INDIRECTLY PRIVACY PROTECTIONS AND HIPAA ARE RELEVANT IN THE CONDUCT OF A CLINICAL TRIAL BY NATURE OF THE FACT THAT WE'RE DEALING WITH A PATIENT'S MEDICAL INFORMATION.

SO THE RESOLUTION YOU HAVE BEFORE YOU IS DESIGNED TO REALLY ENCAPSULATE THESE SELECTED REGULATORY OR POLICY REQUIREMENTS GOVERNING TRIALS INITIATED UNDER AN FDA INVESTIGATIONAL NEW DRUG APPLICATION WITH CIRM SUPPORT. AND AGAIN, IT'S OUR HOPE TODAY THAT THE STANDARDS WORKING GROUP WILL ENDORSE THIS RESOLUTION AND WE CAN TAKE IT TO OUR GOVERNING BOARD AT THE END OF JUNE.

SO I'D LIKE TO TURN IT BACK OVER TO DR. LO TO CONSIDER QUESTIONS, COMMENTS, OR ANY DISCUSSION.

CHAIRMAN LO: OKAY. AND SO YOU ALL SHOULD HAVE RECEIVED ELECTRONICALLY THE ACTUAL DRAFT RESOLUTION. IT'S TWO PAGES. AND IT'S SORT OF ORGANIZED BY THESE BOLD HEADERS. JUST TO SORT OF CALL YOUR ATTENTION TO THEM ON THE FIRST PAGE, THE HEADER FOR SAFETY REQUIREMENTS WHICH REVIEWS ALL THE EXISTING REGULATORY REQUIREMENTS. INSTITUTIONAL REVIEW AND OVERSIGHT AND INFORMED CONSENT WHICH, AS GEOFF ALREADY DESCRIBED FOR US, IS REQUIRED BOTH BY FDA AND BY 45 CFR 46.

AND ON THE SECOND PAGE WE HAVE OTHER ISSUES WITH REGARD TO MONITORING PLANS, REPORTING OF THE TRIAL RESULTS, ACCESS REQUIREMENTS, WHICH IS CIRM'S SPECIFIC ISSUE THAT WE'VE BEEN VERY CONCERNED ABOUT, AND THEN THE FINAL RESOLUTION THAT FOLLOWS ALL THIS TEXT.

SO LET ME JUST STOP THERE AND OPEN IT UP TO THE WORKING GROUP FOR COMMENTS AND QUESTIONS, IF ANY.

DR. ROBERTS: THIS IS DOROTHY.

CHAIRMAN LO: HI, DOROTHY. GO AHEAD.

DR. ROBERTS: I HAVE A QUESTION. SINCE THIS RESOLUTION BASICALLY RELIES ON OTHER PROTECTION FOR HUMAN SUBJECTS, AND I UNDERSTAND THAT THERE ARE MANY OF THEM AND IT SEEMS AS IF EVERY PROJECT, EVERY

RESEARCH PROJECT FUNDED BY CIRM WOULD BE COVERED, BUT I JUST WANT TO GET ASSURANCE THAT EVERY SINGLE CURRENT OR POTENTIAL CIRM-FUNDED PROJECT WOULD BE COVERED BY THESE PROTECTIONS THAT ARE LISTED IN THE RESOLUTION. THERE ISN'T ANY THAT COULD SLIP THROUGH THE CRACKS BECAUSE IT, FOR EXAMPLE, WASN'T REGISTERED WITH THE FDA OR THERE ISN'T AN IRB BECAUSE IT'S PRIVATE AND IT'S A PRIVATE ENTERPRISE AND NOT CONNECTED TO A UNIVERSITY.

I DON'T THINK THAT COULD HAPPEN, BUT I JUST WOULD LIKE TO HAVE ASSURANCE THAT THAT COULDN'T POSSIBLY HAPPEN.

CHAIRMAN LO: GOOD QUESTION. SO THIS REALLY ONLY PERTAINS TO CIRM-FUNDED -- CIRM GRANTS FOR CLINICAL TRIALS THAT ARE CARRIED OUT UNDER THE AUSPICES OF AN FDA IND. SO SPECIFICALLY WITH REGARD TO YOUR QUESTION, DOROTHY, THE FDA, ALL THE FDA REGULATIONS ARE IN PLAY, AND THEY DO REQUIRE AN IRB APPROVAL OF BOTH THE PROTOCOL AND OVERSIGHT OF THE INFORMED CONSENT PROCESS. AND I THINK CIRM HAS DRAFTED THIS, SO I DON'T THINK THEY CONCEIVE OF FUNDING CLINICAL TRIALS IF THEY AREN'T CARRIED OUT UNDER FDA SUPERVISION.

DR. ROBERTS: OKAY. AND SO IS THAT PART OF THE REGULATIONS OF CIRM, OR IS THERE SOMETHING IN

THIS RESOLUTION THAT STATES THAT?

DR. FEIGAL: WHAT I CAN SAY -- THIS IS ELLEN FEIGAL SPEAKING RIGHT NOW. AND WHAT I CAN COMMENT UPON IS THAT WITH THE INITIATIVES THAT WE HAVE IN PLAY SO FAR WITH IND-ENABLING STUDIES FOR DISEASE TEAM INITIATIVES AND WITH THE TARGETED CLINICAL DEVELOPMENT, ALL OF OUR WORK IS FOCUSED ON THE IND. THOSE THERAPIES, SINCE MUCH -- EVERYTHING THAT WE'RE DEALING WITH ARE INNOVATIVE-TYPE THERAPIES, AND THEY'RE ALL DIRECTED TOWARDS A REGULATORY PATHWAY. SO AT THIS POINT IN TIME, WITH THE SOLICITATIONS WE'VE ALREADY PUT OUT, WITH THE SOLICITATIONS WE PLAN IN THE NEAR FUTURE, THIS COVERS THE WATERFRONT OF THE TYPE OF STUDIES THAT WE WOULD BE CONDUCTING THAT COULD BE COVERED BY THIS RESOLUTION.

I'M NOT PROMISING YOU FOREVER AND EVER. IF WE DID SEEK TO GO INTO ADDITIONAL SCOPE AREAS, THEN WE COULD REVISIT THIS.

DR. ROBERTS: OKAY. SO I WOULD JUST WANT TO PUT ON THE RECORD THAT MY APPROVAL OF THIS WOULD BE CONTINGENT ON THAT, THAT IF EVER THERE WERE FUNDING OF RESEARCH CLINICAL TRIALS THAT WERE NOT WITHIN THE FDA FRAMEWORK, THAT WE WOULD HAVE TO REVISIT.

MS. LANSING: WHY DON'T WE PUT THAT, THAT THESE ARE ALL -- I HEAR YOUR POINT. WHY DON'T WE PUT THAT AS PART OF OUR APPROVAL, THAT WE'RE ONLY APPROVING THINGS THAT ARE UNDER THE FDA FRAMEWORK; AND SHOULD WE EVER APPROVE SOMETHING OUT OF THAT, WE WOULD HAVE TO COME BACK TO REVISIT.

CHAIRMAN LO: LET ME JUST SAY THE FDA HAS ASSERTED ITS JURISDICTION OVER STEM CELL TREATMENTS. AND SO THE FDA HAS GONE ON RECORD AND WARNED PURVEYORS OF, QUOTE, STEM CELL THERAPIES THAT IF THEY'RE NOT USING -- IF THEY DON'T HAVE FDA APPROVAL OR AN FDA IND, THEY WILL BE SHUT DOWN. ACTUALLY I'LL DEFER TO ELONA HERE, BUT SEVERAL OF THESE SORT OF CLINICS THAT PURPORT TO OFFER STEM CELL THERAPIES THAT ARE TOTALLY UNPROVEN AND, IN FACT, UNSPECIFIED HAVE BEEN WARNED BY THE FDA THAT THEY CAN'T DO THAT WITHOUT FDA OVERSIGHT. BUT, ELONA, WHY DON'T YOU --

MS. BAUM: THERE ARE CERTAIN TYPES OF STUDIES THAT DO NOT NEED FDA IND APPROVAL. THOSE ARE NOT THE TYPES OF STUDIES IN THE PAST THAT WE HAVE FUNDED, FOR INSTANCE. IF THEY WERE MORE THAN MINIMALLY MANIPULATED, WE FALL OUTSIDE OF THE NONOTOLOGOUS USE EXCEPTION. SO THOSE ARE RARE EXCEPTIONS. THOSE AREN'T THE TYPES OF STUDIES WE

FUND BECAUSE THEY'RE NOT, IN OUR VIEW, THE TYPES OF RESEARCH THAT ADVANCE MEDICINE. BUT I CAN UNDERSTAND THE INTEREST IN INCLUDING RECOGNITION OF THAT WITHIN THE RESOLUTION.

MS. LANSING: I REALLY LIKE THAT BECAUSE WE'RE GOING TO HAVE A NEW CHAIRMAN. THERE'S A LOT OF PRESSURE ON US TO GET INTO CLINICAL TRIALS. THERE'S ARTICLES ALL OVER THE PLACE. SO I THINK IT'S A NICE WHAT YOU CALL SAFETY GUARD.

DR. FEIGAL: I WANT TO CLARIFY WE'RE FOCUSED ON CELL THERAPY. THEY ARE ALSO WORKING WITH BIOLOGIC SMALL MOLECULES THAT MIGHT ATTACK A STEM CELL AREA. RIGHT NOW NONE OF THOSE ARE IN THE CLINICAL TRIAL ARENA FOR US, BUT I JUST WANTED TO CLARIFY THAT THE FDA, IN ADDITION TO THE OFFICE OF CELLULAR AND TISSUE THERAPIES, THERE MAY BE OTHER CENTERS WITHIN THE FDA THAT WE'RE ALSO WORKING WITH, AND I THINK THIS SHOULD BE COVERED BY THE RESOLUTION BEFORE YOU TODAY.

CHAIRMAN LO: SO I WOULD SUGGEST, TO SORT OF IMPLEMENT DOROTHY'S POINT, THAT IN THE TEXT OF THE DRAFT WE PUT IN LANGUAGE TO SAY THAT SWG'S UNDERSTANDING IS THAT THIS RESOLUTION ONLY APPLIES TO FDA-APPROVED TRIALS AND THAT WE WOULD NEED TO REVISIT.

DR. LOMAX: WE WILL REEMPHASIZE THAT IN OUR COVER MEMO TO THE BOARD. BUT I'D LIKE TO ACKNOWLEDGE ELONA BAUM WHO IS VERY HELPFUL IN THIS PROCESS, AND SHE VERY CLEARLY EXPLAINED TO ME RIGHT UP FRONT THE INTENT WAS CLEARLY TO LIMIT IT TO THAT SPECIFIC CONTEXT. SO WE WILL DO DOUBLE DUTY. AND, AGAIN, WE BELIEVE, UNLESS THERE'S A CONCERN THAT THE LANGUAGE DOES REFLECT THAT NARROW CONTINGENCY, AND WE WILL REEMPHASIZE THAT AS SORT OF OUR REPORT BACK FROM THE DELIBERATION.

MS. BAUM: AND JUST TO RESTATE WHAT IS PROBABLY THE OBVIOUS, THIS IS WITH RESPECT TO U.S. CLINICAL TRIALS. I THINK THAT WE REALLY HAVE TO NOODLE ON WHAT THE ORGANIZATION SHOULD SET FORTH IN INSTANCES WHERE CLINICAL TRIALS ARE NOT FUNDED NECESSARILY BY US, BUT EVEN BY PARTNERS, AND WHAT OUR ROLE AND WE WANT TO SEE FROM THAT IF WE HAVE A JOINT COOPERATIVE FUNDING PROJECT.

DR. LOMAX: AND, DOROTHY, JUST TO EMPHASIZE WHAT THAT BRINGS, I BELIEVE THAT WAS PART OF YOUR INITIAL QUESTION, THAT BRINGS IN THAT SAFETY PIECE. THAT'S REALLY WHERE THE FDA -- IN TERMS --

DR. ROBERTS: RIGHT.

DR. LOMAX: IT'S ABOVE AND BEYOND WHAT WAS ALREADY IN EFFECT. IT'S THE SAFETY ASSESSMENT, GOOD

MANUFACTURING PIECE THAT UP UNTIL THIS POINT WE DON'T INDEPENDENTLY HAVE -- WE DON'T WRITE REGULATIONS, FOR EXAMPLE. THAT'S THE ADD-ON THAT GOES WITH THAT.

DR. ROBERTS: EXACTLY. AND I'M HAPPY IT'S THERE. I JUST WANTED TO MAKE SURE THAT IT WOULD ALWAYS BE THERE FOR ANY RESEARCH THAT THIS RESOLUTION COVERS.

DR. FEIGAL: YEAH. THAT'S OUR INTENDED SCOPE THAT YOU SEE HERE.

DR. ROBERTS: YEAH. I THINK YOU'VE ADDRESSED MY CONCERN.

CHAIRMAN LO: OKAY. GREAT. OTHER COMMENTS, CONCERNS, QUESTIONS?

DR. TAYLOR: BERNIE, THIS IS ROD TAYLOR. I KIND OF AM A LITTLE RELUCTANT TO TAKE THIS TO THE NEXT STEP, BUT ARE WE CONVINCED THAT THE FDA BAR IS ACTUALLY SET HIGH ENOUGH FOR THIS PARTICULAR APPLICATION? I'M NOT CONVINCED REALLY BASED ON THE STUFF THAT I'M LOOKING AT NOW. GOOD TISSUE PRACTICES, THERE MAY ACTUALLY BE MORE COMPLICATING FEATURES WITH STEM CELL THERAPIES THAN ARE FRANKLY ADDRESSED AT THIS LEVEL.

SO I'VE KIND OF BEEN ACCUSED OF BEING A LITTLE BIT OBSTRUCTIONIST ON THIS POINT IN THE PAST.

I KIND OF HATE TO GO THERE AGAIN, BUT I JUST SORT OF WANTED TO GET A SENSE OF THE REST OF THE GROUP IF THIS IS FELT TO BE SORT OF AN ADEQUATE STANDARD.

CHAIRMAN LO: ROB, DO YOU WANT TO SAY A LITTLE BIT ABOUT WHAT SORTS OF THINGS, SPECIFIC THINGS, YOU MIGHT BE CONCERNED ABOUT THAT THE FDA OVERSIGHT WOULDN'T BE SATISFACTORY FOR?

DR. TAYLOR: THE TWO KIND OF -- I DON'T EVEN KNOW WHAT SORT OF THE REGULATORY CFRS, TELL ME WHAT THAT STANDS FOR.

DR. FEIGAL: CODE OF FEDERAL REGULATIONS.

DR. TAYLOR: THE REGULATIONS THAT SEEM MOST RELEVANT ARE THE 21 CFR, PART 50, WHICH IS AN INFORMED CONSENT ONE. I ABSOLUTELY AM NOT TRYING TO CONSTRUE PERSONHOOD ONTO AN EMBRYO, BUT THIS IS REALLY FOCUSED AT THE DONOR, I THINK. AND I'M NOT SURE THAT WE ALWAYS HAVE -- IN FACT, IN THE CELL THAT'S SORT OF UNDERGOING CLINICAL TRIALS CURRENTLY, I WOULD SAY THAT THAT IS SUBOPTIMAL IN TERMS OF --

DR. LOMAX: ROB, THIS IS GEOFF. SORRY TO INTERRUPT. THIS IS A FAIRLY CRITICAL POINT. THAT PART OF THE CODE OF FEDERAL REGULATIONS IS THE CONSENT AS IT RELATES TO THE RECIPIENT OF THE THERAPY, NOT THE DONOR OF THE MATERIAL WHICH WAS THE BASIS FOR WHICH THE THERAPY WAS DERIVED.

DR. TAYLOR: OKAY. ALL RIGHT. I GUESS I DIDN'T --

DR. FEIGAL: THERE'S A SEPARATE INFORMED CONSENT ISSUE THAT DEAL WITH THE DONOR. WHAT WE WERE TALKING ABOUT HERE FOR CLINICAL TRIALS IS THE CONSENT FOR THE RESEARCH SUBJECT ON THE CLINICAL TRIAL.

DR. TAYLOR: OKAY.

DR. FEIGAL: THE PERSON WHO'S ACTUALLY GOING TO RECEIVE THE INTERVENTION.

DR. TAYLOR: ALL RIGHT. SO DO WE WANT TO CONSIDER THE OTHERS?

MS. BAUM: ISN'T THAT ALREADY BUILT IN?

DR. FEIGAL: THAT'S ALREADY PART OF THE CONSENT FOR DONATION OF TISSUE AND OTHER MATERIALS. GEOFF, I DON'T KNOW IF YOU LISTED ALL THE REGS FOR THAT.

DR. LOMAX: IN THIS CASE, ROB, IN TERMS OF HOW THE REGULATIONS PLAY OUT, THE SOURCE LINE THAT IS USED FOR THIS PARTICULAR INTERVENTION MEET OUR STANDARDS FOR ACCEPTABLE DERIVATION. IT'S ALSO A LINE THAT IS REGISTERED ON THE NIH REGISTRY. SO IT'S GONE THROUGH THAT PROCESS AS WELL. THAT'S A SORT OF TECHNICAL REGULATORY FRAME. THAT'S THE STATUS OF THE SOURCE OF MATERIAL.

DR. FEIGAL: AND WE ACTUALLY, EVEN WITH THE APPLICATIONS THAT CAME IN, WE REQUIRED THAT KIND OF CONSENT APPROVAL. THAT WAS THE FIRST STAGE OF EVEN LOOKING AT THESE APPLICATIONS WAS TO MAKE SURE THAT THAT WAS INTACT AND DONE.

DR. TAYLOR: AGAIN, I GUESS I WAS SORT OF ASKING DO WE FEEL THAT THAT'S AN ADEQUATE LEVEL OF INFORMATION FOR STEM CELLS GOING FORWARD?

DR. OLSON: THIS IS PAT OLSON. I JUST WANTED TO MAKE A COMMENT. I NOTICED THAT THE RESOLUTION BEFORE YOU HAS RIGHTLY CITED OTHER APPLICABLE FDA REGULATIONS. I THINK YOUR CONCERN -- SO WHAT IS NOT GONE INTO IN GREAT DETAIL HERE IS WE'RE NOT LISTING ALL THE REGULATIONS THAT APPLY. I MEAN THERE'S THE GOOD TISSUE PRACTICES, DEPENDING ON THE LEVEL OF THE TYPE OF THING THAT'S CITED THERE, THAT IMMEDIATELY TRIGGERS THE 21 CFR WHICH HAS TO DO WITH IND FILING, GMP, AND ALL OF THAT.

SO DEPENDING ON THE COMPLEXITY OF THE TYPE OF THERAPY, YOU HAVE A WHOLE SET OF FDA REGULATIONS THAT APPLY, WHICH HAS TO DO WITH MANUFACTURE AND SAFETY STANDARDS. SO I THINK ALL OF THOSE ARE INCLUDED IN THE STATEMENT "OTHER APPLICABLE FDA REGULATIONS."

CHAIRMAN LO: LET ME GO BACK TO ROB'S POINT THOUGH.

DR. TAYLOR: I ACCEPT THAT. I'M JUST WONDERING WHETHER THAT'S THE RIGHT LEVEL OF SCRUTINY.

CHAIRMAN LO: SO LET ME GO BACK TO YOUR CONCERN, ROB, ABOUT THE CONSENT FOR THE DONATION OF EMBRYOS FOR THE DERIVATION OF THE STEM CELL LINES.

DR. TAYLOR: AND I WOULD SAY THAT THIS GOES BEYOND ETHICS. THIS IS NOT ONLY CONSENT, BUT ALSO THE ABILITY TO FOLLOW UP, THE MONITORING AND SORT OF FOLLOW-UP OF THE DONORS.

CHAIRMAN LO: OKAY. SO LET'S TAKE THOSE SEPARATELY. IN TERMS OF CONSENT, IN TERMS OF CONSENT FROM THE -- FOR THE DONATION OF THE EMBRYO TO DERIVE THE STEM CELL LINE, SO WE HAVE REQUIRED THOSE LINES TO FOLLOW ACTUALLY CIRM STANDARDS, WHICH THIS WORKING GROUP DEVELOPED AND ARE QUITE STRICT IN TERMS OF INFORMED CONSENT FROM THE WOMEN OR COUPLE IN THE IVF PRACTICE THAT DONATES THE EMBRYOS.

THE NIH REGULATIONS TRACK THAT AS WELL. THERE ARE VERY SPECIFIC REQUIREMENTS AS TO WHAT'S INCLUDED IN THE CONSENT THAT HAS TO -- IT CAN'T BE -- THE IDEAL IS THAT THEY HAVE TO CONSENT FOR DERIVATION OF STEM CELL LINES, THEY HAVE TO BE

INFORMED OF OTHER OPTIONS, SO THAT WE HAVE WORKED THROUGH THOSE CONSENT PROCEDURES AS HAS THE NIH.

AND SO I GUESS IF THERE'S SPECIFIC ISSUES BEYOND THAT, WE CAN -- THESE BUILD ON -- THESE INCORPORATE THOSE, AND PERHAPS WE CAN, GEOFF, THINK OF MODIFYING THE CONSENT TO REFERENCE THAT BECAUSE IT'S A DIFFERENT KIND OF CONSENT THAN THE CONSENT FROM THE STEM CELL RECIPIENTS IN THE TRIAL.

DR. FEIGAL: CAN I JUST MAKE A COMMENT? IF YOU WANT US TO INCLUDE IN THE DRAFT RESOLUTION ON U.S. CLINICAL TRIALS A BRIEF SET OF STATEMENTS OVER THE ISSUES THAT CIRM ADDRESSES ON DONATION OF TISSUE, WE CAN DO THAT BECAUSE YOU ARE CORRECT. THAT'S NOT CURRENTLY PART OF THIS DOCUMENT, BUT WE CERTAINLY DO ADHERE TO THAT, AND WE DO HAVE POLICIES FOR THAT, AND WE DO MAKE SURE OUR APPLICANTS ARE COMPLIANT WITH IT.

SO IF YOU WANT THAT KIND OF ASSURANCE IN THIS DOCUMENT, WHICH REALLY IS FOCUSED ON CLINICAL TRIALS AND THE INTERVENTION, WE COULD DO IT, BUT WE WERE TRYING TO REALLY FOCUS NOT ON EVERYTHING THAT CIRM IS DOING BECAUSE THAT COULD GO WAY BACK IN RESEARCH ISSUES TOO, BUT TO FOCUS ON THE CLINICAL TRIAL ASPECT. SO LET US KNOW WHAT YOU THINK.

DR. TAYLOR: I'M NOT TRYING TO MAKE IT

PLUSH, BUT IT'S JUST I'M AFRAID THAT WE HAVE A CONDITION IN WHICH, UNLESS I'M NOT UNDERSTANDING THE FACTUAL DETAILS, THAT THE ONE CELL LINE THAT IS ACTUALLY IN CIRM-APPROVED TRIALS MIGHT NOT MEET OUR CRITERIA.

CHAIRMAN LO: ELLEN, DO YOU WANT TO COMMENT ON THAT?

DR. PETERS: THE ATLANTA CLINICAL TRIAL YOU'RE TALKING ABOUT?

DR. TAYLOR: YEAH.

DR. PETERS: THANKS.

CHAIRMAN LO: ELLEN, WHY DON'T YOU -- BECAUSE THIS IS IN REVIEW. WE'LL ACTUALLY ADDRESS THAT.

DR. FEIGAL: IT ACTUALLY HAS BEEN REVIEWED. I ASSUME YOU'RE TALKING ABOUT THE SPINAL CORD INJURY TRIAL?

DR. TAYLOR: RIGHT.

DR. FEIGAL: THAT HAS BEEN REVIEWED AND COMPLIANT WITH THE DIFFERENT PRACTICES THAT CIRM HAS IN PLACE. SO I DON'T KNOW WHAT SPECIFICALLY YOU'RE -- GEOFF, YOU MAY WANT TO MAKE ADDITIONAL COMMENTS.

DR. LOMAX: YOU KNOW, AGAIN, JUST AT FACE VALUE, THE SORT OF TECHNICAL REGULATORY COMPLIANCE,

IT IS A COMPLIANT LINE ACCORDING TO MULTIPLE CRITERIA ACTUALLY. IT WAS DETERMINED TO BE ACCEPTABLE BY OUR GRANTEES. AND THEN ONCE WITH THE REVISED -- WELL, BOTH THE FORMER AND REVISED NIH REGISTRY. SO IN THAT REGARD, IT MEETS THE MARK ACCORDING TO MULTIPLE CRITERIA.

DR. OLSON: IT ALSO MEETS THE GOOD TISSUE REQUIREMENT FOR DONOR ELIGIBILITY IN THE SENSE THAT IT MET ALL REQUIREMENTS THAT WERE APPLICABLE BEFORE MAY, I THINK, OF 200- --

DR. FEIGAL: YEAH. SO IT COULD BE -- PERHAPS YOU DON'T HAVE THE FACTS. BUT WE CERTAINLY DID MAKE SURE THAT THEY ADHERED TO ALL THE GUIDANCES AND REGULATIONS.

CHAIRMAN LO: MY POSITION IS THAT SINCE IT IS SOMETHING THAT WAS LOOKED AT AND IS AN INTEGRAL PART OF THE CIRM REVIEW PROCESS, THAT WE SAY SOMETHING IN THE FIRST PAGE, GEOFF, ABOUT THERE ARE OTHER -- ALL OTHER CIRM REQUIREMENTS ARE ALSO APPLIED TO THESE GRANTS.

DR. LOMAX: CORRECT. I THINK IF I UNDERSTAND ROB'S POINT, AGAIN, THE SOURCE MATERIAL HAS TO BE EVALUATED IN SUCH A MANNER WHERE THAT IS DETERMINED UP FRONT. WE DO THAT. WE CAN EASILY INCORPORATE THAT. THIS IS A BIT MORE DOWNSTREAM

FROM THAT POINT. AND SO SINCE THAT'S AN OMISSION, WE'RE HAPPY TO MAKE MODIFICATIONS TO CLARIFY THAT.

CHAIRMAN LO: ROB, LET ME MAKE SURE I'VE UNDERSTOOD YOUR COMMENT. I THINK YOU HAD A SECOND COMMENT THAT HAD TO DO WITH WHETHER THERE WAS SUFFICIENT TRACKING OF DONOR HEALTH, THE HEALTH OF THE ORIGINAL DONORS OF THE GAMETES THAT WENT INTO THE OOCYTE. SO THAT, FOR EXAMPLE, IF AFTER DONATING THEIR MATERIALS THAT WENT INTO THE STEM CELL LINE, THEY CAME DOWN WITH SOME SERIOUS HEREDITARY DISEASE THAT COULD POSSIBLY BE TRANSMITTED, WERE YOU CONCERNED THAT THAT'S NOT BEING TRACKED?

DR. TAYLOR: YEAH. THAT WAS THE CONCERN. HOW IS THAT BEING TRACKED?

DR. FEIGAL: WHAT I CAN SAY IS THERE'S EXTENSIVE TESTING AT THE TIME OF DONATION IN TERMS OF WHAT WE'RE ABLE TO DO. THE HISTORY, ALSO TESTING ACTUALLY OF THE LINE FOR DIFFERENT -- A VARIETY OF DIFFERENT THINGS THAT COULD BE TRANSMITTED, THAT'S DONE AT THE TIME OF THE ACTUAL DONATION.

MS. BAUM: AND THE FDA HAS REGULATIONS TO ADDRESS THIS CONCERN ALL WITHIN THE PRACTICALITIES OF THE CIRCUMSTANCES THAT PRESENT THEMSELVES IN TERMS OF PATIENT -- DONOR CONFIDENTIALITY, ETC. SO IT'S A LARGE ISSUE, VERY COMPLICATED ISSUE. THE FDA

HAS STRUCK A BALANCE ON THIS ISSUE, AND I DON'T SEE HOW WE COULD DO MORE IN THAT DEPARTMENT PERSONALLY.

CHAIRMAN LO: ROB, HAVE I CHARACTERIZED THE ISSUE YOU RAISED?

DR. TAYLOR: YEAH, YOU HAVE. AND I GUESS I'D JUST LIKE TO POINT OUT THAT I THINK THE FDA REGULATIONS ARE PRETTY MUCH BASED ON ORGAN TRANSPLANTATION WHICH I THINK HAS SORT OF DIFFERENT IMPLICATIONS MAYBE THAN THIS. BUT I THINK THAT'S -- YOU'VE SUMMARIZED IT WELL, BERNIE.

DR. FEIGAL: DO YOU THINK THERE NEEDS TO BE ANY -- I MEAN PART OF WHAT WE WANT TO DO HERE IS HEAR WHAT YOUR ISSUES ARE. THE OTHER PART IS THE MORE PRAGMATIC. OF THESE ISSUES THAT ARE RAISED, ARE THERE PARTS OF THEM THAT NEED TO BE INCORPORATED INTO THIS DOCUMENT?

DR. TAYLOR: I GUESS I WOULD SORT OF GO BACK TO SAY IF WE'RE HAPPY KIND OF RUBBER STAMPING THE FDA'S LEVEL OF SORT OF RIGOR, THEN I THINK WE'RE KIND OF FINE THE WAY THIS IS WRITTEN. SO THAT WAS REALLY JUST A QUESTION.

DR. FEIGAL: OKAY. I THINK WE'VE DONE MORE THAN RUBBER STAMP. I THINK CIRM ACTUALLY DOES HAVE QUITE A RIGOROUS LOOK AT THESE ISSUES. AND SO THOSE WERE LOOKED AT IN ADDITION TO ALL THE

REGULATORY ISSUES ON DONOR AND CELL LINES THAT CAN BE USED. SO I THINK WE ARE COMFORTABLE WITH THAT.

CHAIRMAN LO: ROB, LET ME TRY AND PUT THIS IN ANOTHER FRAME, WHICH IS THE SORT OF EVOLVING SCIENCE FRAMES. SO THE FDA HAS BEEN VERY, VERY SCRUPULOUS WITH REGARD TO TESTING FOR INFECTIOUS DISEASES, AND THEY HAVE A LONG HISTORY OF ADDING ADDITIONAL TESTING OF THE MATERIAL TO BE TRANSPLANTED TO RULE OUT TRANSMISSION OF INFECTIOUS DISEASES AND HAVE THOSE TRACKED, FOR EXAMPLE, BLOOD BANK CRITERIA AS WELL AND TRANSPLANTATION CRITERIA.

THERE ARE CONCERNS ABOUT WHETHER, WITH THE INCREASING GENOMIC KNOWLEDGE, THERE WILL BE A TIME WHEN FDA WILL SUGGEST OR ACTUALLY REQUIRE GENOMIC TESTING OF MATERIALS TO BE TRANSLATED. THAT'S WAY DOWN THE ROAD. I THINK THE ISSUE IS THAT THIS HAS COME UP IN VARIOUS CONFERENCES. AND THE ANSWER IS ALWAYS THERE'S NOT A CLEARLY DEFINED SET OF THINGS TO TEST FOR SO THAT IF IT BECOMES THE CASE IN THE FUTURE THAT THERE'S STRONG EVIDENCE THAT TESTING FOR CERTAIN MUTATION IN THE MATERIALS TO BE TRANSLATED HAS A (INAUDIBLE), I THINK THE EXPECTATION WOULD BE THE FDA WILL RECONSIDER THAT. AND I ASSUME, AGAIN, CIRM WOULD BE PART OF THAT CONVERSATION.

I THINK AT THIS POINT I DON'T THINK THERE

ARE SPECIFIC ADDITIONAL TESTS THAT THE FDA WOULD REQUIRE THAT HAVE STRONG SCIENTIFIC VALIDITY AND PREDICTIVE VALUE.

DR. TAYLOR: OKAY. NO. NO. I BUY THAT, AND I KNOW THAT THIS IS A MOVING TARGET AND IT'S GOING TO EVOLVE OVER TIME. SO MAYBE I'M COMPLETELY OFF BASE, BUT I GUESS MY CONCERNS ARE DERIVED FROM UNDERSTANDING, AND IF I'M WRONG, PLEASE CORRECT ME IMMEDIATELY, I APOLOGIZE, THAT THE EMBRYO THAT GERON USED FOR THIS STEM CELL LINE THAT'S UNDERGOING TRIALS HERE IN ATLANTA, THAT THE SPERM WAS DERIVED FROM AN ANONYMOUS DONOR. IS THAT A TRUE FACT?

CHAIRMAN LO: I'LL DEFER TO SOMEONE WHO KNOWS THE PROTOCOL. I ACTUALLY DON'T.

DR. PETERS: YOU'RE TALKING ABOUT KIERSTEAD'S DONOR THAT GERON IS CURRENTLY EXPERIMENTING WITH?

DR. TAYLOR: YES.

DR. PETERS: I DON'T KNOW.

DR. FEIGAL: YEAH. THIS IS THE WICELL LINE.

DR. OLSON: I THINK ALL THAT WE CAN SAY, AND I'M SORRY I DON'T KNOW THE EXACT RESPONSE TO YOUR QUESTION, BUT I KNOW THAT UNDER THE NEW NIH RULES FOR ACCEPTANCE ONTO THEIR REGISTRY, THEY ASK A

LOT OF QUESTIONS ABOUT THE DONORS. AND SO I THINK ALL WE CAN SAY IS THAT THE NIH HAS AGREED TO ACCEPT THAT LINE ON ITS REGISTRY IN COMPLIANCE WITH ITS CONCERNS ABOUT DONOR ELIGIBILITY. I BELIEVE CIRM HAS ACCEPTED IT FOR PURPOSES INTO OUR REGISTRY.

DR. TAYLOR: SO I GUESS I'M JUST ASKING DO WE WANT TO RATCHET THIS UP A LITTLE BIT GOING FORWARD?

DR. FEIGAL: YOU KNOW, I THINK THAT WE HAVE TO THINK ABOUT THE ISSUE THAT THERE'S FEDERAL REGULATIONS. WE ALREADY HAVE CIRM REGULATIONS. THERE'S ETHICAL REGULATIONS IN HERE. AND I DON'T THINK ON A CASE-BY-CASE BASIS WE CAN -- AT THIS POINT IN TIME, I DON'T THINK WE HAVE ENOUGH INFORMATION TO ADD ADDITIONAL REGULATIONS ON TOP OF THOSE THAT ALREADY EXIST THAT ARE THERE TO PROTECT PATIENT SAFETY.

I WOULD LIKE TO ADD THAT AS A CLINICAL TRIAL, AND MAYBE THIS CAN GET INTO SOME OF THE PRAGMATIC ISSUES, THERE IS GOING TO BE LONG-TERM FOLLOW-UP OF PATIENTS WHO ARE ENROLLED ON THIS TRIAL. SO REGARDLESS OF THE ISSUE OF THE DONOR, WHETHER OR NOT THERE WAS SOMETHING THAT MIGHT BE AT RISK OR NOT, WE ARE GOING TO BE FOLLOWING THE PATIENT OVER A LONG-TERM PERIOD OF TIME THROUGH THE

REGISTRY. SO THERE WILL BE LONG-TERM FOLLOW-UP TO LOOK FOR ADVERSE EVENTS IN THAT PATIENT OVER AN EXTENDED PERIOD OF TIME UP TO 15 YEARS. SO THERE IS CERTAINLY ADHERENCE TO LOOKING AT WHAT'S HAPPENING TO THE RESEARCH PARTICIPANT ON THAT TRIAL.

CHAIRMAN LO: ROB, LET ME AGAIN SORT OF TRY AND PUT THIS IN CONTEXT. SO SINCE I SERVE ON THE NIH WORKING GROUP TO ADVISE THE ADVISORY COMMITTEE ON APPROVING LINES FOR NIH FUNDING, THE REQUIREMENTS FOR CONSENT REALLY ARE CONSENT FROM THE EMBRYO DONOR TO DONATE THE LINES FOR STEM CELL DERIVATION AND RESEARCH. THERE IS NO NIH REQUIREMENT THAT THERE BE CONSENT FROM THIRD-PARTY GAMETE DONORS, ALTHOUGH THAT'S PART OF OUR CIRM REGULATIONS.

WITH REGARD, HOWEVER -- SO I ACTUALLY DON'T KNOW FOR A FACT, AND I GUESS WE CAN TRY AND FIND OUT, WHETHER THERE WAS AN ANONYMOUS DONOR OR NOT, BUT THE EMBRYO DONOR CLEARLY CONSENTED.

NOW, PART OF THE SCREENING PROCESS IS TESTING OF THE MATERIALS TO BE TRANSPLANTED. SO ALL THE INFECTIOUS DISEASES WERE TESTED FOR. EVEN WHEN THERE'S AN ANONYMOUS DONOR OF GAMETES, THERE IS A FAMILY HISTORY AND A HEALTH HISTORY TAKEN OF THAT PERSON. AND THAT WOULD HAVE BEEN TRANSMITTED BY THE

IVF PRACTICE. SO EVEN IF IT WERE AN ANONYMOUS DONOR, WE WOULD STILL HAVE HEALTH INFORMATION ABOUT THAT INDIVIDUAL AND SOME FAMILY HISTORY INFORMATION AS WELL.

I DON'T ACTUALLY KNOW THE EXACT PROCESS THAT THE FDA WENT THROUGH, BUT THERE IS THAT SCRUTINY AND OVERSIGHT.

DR. LOMAX: IN THAT CONTEXT, BECAUSE IT'S A NONINTIMATE PARTNER DONATION, IT HAS TO GO THROUGH A SCREENING OF ANY BIOLOGICAL PRODUCT THAT WOULD OTHERWISE BE TRANSPLANTED. SO IT HAD TO MEET THE STANDARD OF THE DAY AS IF IT WERE A BIOLOGICAL PRODUCT FROM A NONINTIMATE PARTNER.

CHAIRMAN LO: EVEN IF THE PARTNER WAS NOT IDENTIFIED BY NAME.

DR. FEIGAL: THAT'S RIGHT.

DR. TAYLOR: BUT I THINK THAT THE INFECTIOUS DISEASE SCREENING AND MAYBE WHAT WE'RE INTERESTED IN IN TERMS OF LONG-TERM CELL TRANSPLANTATION MIGHT BE DIFFERENT IS ALL I'M SAYING. SO I'M JUST -- I MEAN THIS IS HAPPENING, AND I'M HAPPY WITH IT. I'M REALLY GLAD THAT THESE TRIALS ARE GOING FORWARD, BUT I'M JUST SORT OF WONDERING -- WE HAVE AN OPPORTUNITY HERE TO DO MORE THAN WHAT'S BEEN DONE IN THE PAST. AND I'M JUST

ASKING THE QUESTION DO WE WANT TO.

I GET THE SENSE THAT AT LEAST ADMINISTRATIVELY THE CIRM PEOPLE ARE HAPPY WITH THIS PLAN. I JUST SORT OF FEEL OBLIGED TO KIND OF RAISE THAT QUESTION.

CHAIRMAN LO: RIGHT. AND LET'S SEE WHAT THE OTHER MEMBERS OF THE WORKING GROUP THINK AS WELL BECAUSE I THINK WE'RE HAVING THIS CALL BECAUSE WE WANT THOUGHTFUL INPUT, WHICH WE'RE CLEARLY GETTING.

SO LET'S ASK OTHER PEOPLE ON THE CALL TO SORT OF GIVE US YOUR THOUGHTS.

DR. PETERS: THIS IS TED. I THINK THAT THE ORIGINAL WORDING, I WAS IMPRESSED, SATISFACTORY, IT SOLVES THE PROBLEM. AND I WAS UNAWARE OF THE KIND OF NUANCES THAT THIS PARTICULAR COURSE OUR DISCUSSION HAS TAKEN.

DR. ROBERTS: I WROTE AT THE BOTTOM OF THE RESOLUTION IN MY NOTES "ARE SPECIAL STEM CELL PROTECTIONS NEEDED," WHICH IS SORT OF WHAT ROB WAS ASKING AS WELL. I JUST DON'T FEEL QUALIFIED TO ANSWER THAT MYSELF, BUT IT IS A QUESTION I HAD AFTER READING THE RESOLUTION IN ADDITION TO THE PRIOR CONCERN I EXPRESSED.

CHAIRMAN LO: MAYBE I COULD ASK TIM AND JOHN WHO HAVE DONE TRANSPLANTATION TO SORT OF GIVE

THEIR THOUGHTS AS WELL, AS WELL AS THE OTHERS.

DR. WAGNER: YOU KNOW, I THINK THAT THERE ARE SPECIAL ISSUES ASSOCIATED WITH STEM CELL TRANSPLANTS, INFECTIOUS DISEASE BEING ONE OF THEM. AND I THINK THAT THAT'S SOMETHING THAT DOES BECOME PROBLEMATIC WHEN YOU DON'T HAVE BOTH GAMETE DONORS. BUT CERTAINLY FOR THOSE INSTANCES WHERE WE HAVE THE EMBRYO, AND WE HAVE BOTH DONORS AVAILABLE TO US, THEY COULD BE TESTED.

BUT MANY OF THOSE THINGS ARE GOING TO BE TESTED. THE SPINAL PROJECT WAS MENTIONED. I THINK WHAT I'M MORE CONCERNED ABOUT IS MORE OF THE GENETIC HISTORY AND WHETHER OR NOT THERE IS ANY RISK OF GENETIC DISEASES, BUT THAT'S ALWAYS A RISK. I MEAN THAT'S A RISK OF HEMATOPOETIC STEM CELL TRANSPLANT TODAY ALTHOUGH AT LEAST WE HAVE BOTH PARENTS AVAILABLE TO US WHEN WE DO TRANSPLANTS IN MOST CASES, OR AT LEAST WE HAVE SOME GENETIC HISTORY WITHIN THE FAMILY WHICH WE DON'T NECESSARILY HAVE WITH A COUPLE WHO MAY NOT KNOW THEY HAVE A GENETIC DISEASE. SO IT'S NOT GOING TO BE A ZERO RISK NO MATTER WHAT. SO CERTAINLY IF WE DON'T HAVE BOTH PARENTS OF THIS EMBRYO, IT CERTAINLY MAKES THAT MORE OF A RISK, BUT IT WILL NEVER BE ZERO, I DON'T THINK.

THE ONLY COMMENTS I HAVE TO SAY IS THAT

WHEN I LOOK AT THE SAFETY REQUIREMENTS SECTION FOR CELL-BASED THERAPY, I'M NOT REALLY SURE HOW THIS IS ANYTHING MORE THAN A RUBBER STAMP OF WHAT THE FDA CERTAINLY REGULATES CURRENTLY. I GUESS MAYBE WHAT COULD HELP ME WITH THAT IS IF YOU COULD TELL ME AS CIRM, WHAT KIND OF CHECKLIST YOU WILL HAVE THAT WILL VERIFY THESE REQUIREMENTS? AND HOW WILL YOU INTERPRET WHAT'S GIVEN TO YOU RATHER THAN SIMPLY SAYING, WELL, YES, AN IND HAS BEEN APPROVED?

AS YOU MAY OR MAY NOT KNOW, AN IND IS APPROVED IF YOU DON'T HEAR THAT IT'S NOT APPROVED. IT'S A RATHER AWKWARD APPROVAL PROCESS BECAUSE IF THEY DON'T RESPOND TO YOU IN 30 DAYS, THEN YOU CAN GET ACTIVATED.

DR. FEIGAL: YEAH. WE'RE VERY FAMILIAR WITH THE REGULATORY PROCESS HERE. AND SEVERAL OF US DO HAVE EXPERIENCE WITH PRODUCT DEVELOPMENT AND WORKING WITH THE FDA AND ISSUES INVOLVED WITH MOVING A THERAPY SAFELY INTO FIRST-IN-HUMANS AND THEN ISSUES DURING THE CONDUCT OF A CLINICAL TRIAL.

WE HAVE ACTUALLY WITH -- WE HAVE HAD AND WILL CONTINUE TO HAVE INTENSIVE INTERACTION WITH THE SPONSOR, WITH THE INVESTIGATOR, AND WE ACTUALLY HAVE DOCUMENTATION THAT WE HAVE BEEN ABLE TO LOOK AT IN TERMS OF IND ISSUES, IN TERMS OF ANY ISSUES OR

CONCERNS THAT AROSE. EVEN IF IT WAS AUTHORIZED TO GO FORWARD, WE HAVE MANY WAYS TO WORK. WE HAVE THEIR ANNUAL REPORT. WE HAVE ACCESS TO OTHER TYPES OF CORRESPONDENCE. WE ALSO HAVE THE ABILITY TO PARTICIPATE IN SOME WAY PERHAPS DOWNSTREAM FROM ANY FDA MEETINGS OR TELECONS THAT TAKE PLACE. SO WE WILL BE KEPT IN THE LOOP.

WE ACTUALLY HAVE A COMMUNICATION PLAN WITH THE -- YOU KNOW, PARTICULARLY WITH THIS APPLICANT, AND WE PRESUME TO HAVE THAT WITH FUTURE APPLICANTS IN WHOM WE WORK IN TERMS OF HOW TO COMMUNICATE INFORMATION ON SAFETY, ON MANUFACTURING, ON ANY OF A VARIETY OF ISSUES THAT COULD TAKE PLACE.

IN ADDITION, AS I THINK YOU KNOW, ALL OF THESE TRIALS HAVE INDEPENDENT DATA SAFETY MONITORING BOARDS. WE WILL HAVE REAL-TIME REPORTING OF INFORMATION TO US. YOU KNOW, THE CAVEAT, OF COURSE, IS WE'RE NOT GETTING PERSONAL IDENTIFIERS, AND WE'RE GETTING FREQUENT REPORTING OF ISSUES AS THEY ARISE. IN ADDITION, WE HAVE PROACTIVE PLANS FOR COMMUNICATION.

SO WE'RE NOT JUST TAKING IT FACE VALUE THAT THE FDA SAID YES. WE ACTUALLY DO SEE DOCUMENTATION. WE DO IN SOME INSTANCES ASK FOR CORRESPONDENCE AND ACTUALLY SEE THAT. AND SO WE

DEFINITELY HAVE A VERY ROBUST OVERSIGHT OF THOSE TYPES OF ISSUES.

DR. WAGNER: I THINK THAT WILL BE HELPFUL. IT'S JUST THAT WE DON'T HAVE THAT ALL HERE IN THIS DOCUMENT TO KNOW. SO CERTAINLY MAYBE ALL THOSE THINGS ARE COVERED, JUST THAT YOU COULDN'T TELL BY LOOKING AT THIS DOCUMENT THAT ALL THOSE THINGS EXIST.

THE OTHER THING IS, FOR EXAMPLE, YOU SAY THAT ALL STUDIES REQUIRE DSMB. MAYBE I MISSED THAT. I SEE THAT GERON SAYS THERE WILL BE ROBUST OVERSIGHT WHICH INCLUDES STATE AND FEDERAL STATUTES, REGULATORY AND OVERSIGHT BY IRB'S, AND POTENTIALLY DSMB'S. SO, AGAIN, THERE'S A LITTLE BIT OF WIGGLE ROOM THERE. I THINK IT'S A GOOD IDEA HAVING DSMB'S FOR SUCH STEM CELL THERAPIES, BUT IT DOESN'T LOOK LIKE IT'S MANDATED IN A WAY TO GET THE INDEPENDENT OVERSIGHT OF THE REVIEW OF THE SAFETY PROFILE OF WHATEVER NEW CELL THERAPIES ARE MOVING FORWARD AND HOW THAT'S DECIDED BY CIRM FOR EACH INDIVIDUAL PROJECT THAT COMES FORWARD.

AND MY OTHER COMMENT RELATED TO THIS IS SAFETY REQUIREMENTS FOR CELL-BASED THERAPIES. ADHERENCE TO PRINCIPLES OF GCP AND GMP IS ALL GREAT, BUT HOW DO YOU HANDLE THE INCEST, ALTHOUGH YOU COULD

JUST SIMPLY SAY, WELL, THE FDA FOUND IT WAS GOOD ENOUGH.

DR. FEIGAL: NO. I SEE WHAT YOU'RE SAYING. SO WE ACTUALLY HAVE A DETAILED PLAN FROM THE COMPANY OR THE APPLICANT IN TERMS OF HOW THEY'RE MONITORING, HOW THEY'RE AUDITING THIS BY ANOTHER PARTY, A CRO. SO THERE'S ACTUALLY AUDITING PLANS IN PLACE --

DR. WAGNER: OKAY.

DR. FEIGAL: -- FOR CHECKING COMPLIANCE. AND WE WILL RECEIVE REPORTS OF IT. WE DIDN'T THINK THIS WAS THE DOCUMENT TO PUT IN ALL THE OPERATIONAL DETAILS OF HOW WE'RE GOING TO MONITOR THINGS. SO PERHAPS YOU CAN GIVE US GUIDANCE. THERE'S A RATHER LONG LIST OF THINGS THAT WE CHECK AND DO. AND SOMETIMES IT WILL BE INDIVIDUALIZED ACCORDING TO THE STAGE OF THERAPY, WHETHER IT'S THE FIRST-IN-HUMAN EVER OR WHETHER IT'S AN EARLY PHASE CLINICAL TRIAL.

SO, YOU KNOW, THIS IS MORE OF AN UMBRELLA DOCUMENT FOR CLINICAL TRIALS THAT CIRM IS FUNDING AND THE PARAMETERS OVER WHICH WE WILL BE MONITORING THEM AND EXPECTING THEM TO SUBMIT RESULTS.

DR. WAGNER: THIS IS JUST THE ELEMENTS. I THINK THAT THAT'S -- I'M NOT SURPRISED, BUT I GUESS, IT'S ONE THING -- I THINK THAT HAVING THIS DOCUMENT

BE MORE OF AN UMBRELLA DOCUMENT IS PERFECTLY REASONABLE; BUT I THINK IF THIS GROUP IS SIGNING OFF AND ENDORSING THIS, I GUESS WHAT I WOULD HAVE THOUGHT WOULD BE FROM -- WE JUST NEED TO BE REASSURED THAT WHAT'S BEEN STATED HERE HAS ACTUALLY BEEN DONE IN A WAY THAT OBJECTIVELY CAN ASSESS WHETHER OR NOT THESE THINGS ARE BEING DONE.

AGAIN, I DON'T THINK YOU NEED TO PUT THAT HERE. IT'S JUST THAT I THINK THAT THE GROUP NEEDS TO KNOW THAT, YES, IT'S BEING DONE AS YOU'RE DESCRIBING. SO THAT'S VERY HELPFUL.

AND ONE LAST THING I'M GOING TO MAKE A COMMENT ON. DO YOU HAVE ANY OVERSIGHT OR DO YOU HAVE ANY SPECIFIC REQUIREMENTS FOR THE MANUFACTURING FACILITY ITSELF?

DR. FEIGAL: WE DON'T HAVE ADDITIONAL SPECIFIC MANUFACTURING REQUIREMENTS FROM CIRM.

DR. WAGNER: NOT MANUFACTURING REQUIREMENTS, BUT ANY REQUIREMENTS FOR THE TYPE OF FACILITY THAT WOULD BE MANUFACTURING THE CELL PRODUCT? SO, FOR EXAMPLE, DO YOU HAVE A LIST OF WHAT THE ACCREDITATIONS MUST BE?

DR. OLSON: I KNOW THAT THE STATE OF CALIFORNIA HAS ESSENTIALLY THE SAME TYPE OF ACCREDITATION AS THE FDA DOES. SO, YOU KNOW, THAT

WOULD BE AN EXPECTATION.

DR. LOMAX: THAT WAS PATRICIA OLSON FOR THE RECORD COMMENTING.

DR. FEIGAL: I THINK YOUR SPECIFIC QUESTION IS HOW DO WE DOCUMENT --

DR. OLSON: HOW DO WE DOCUMENT THAT?

DR. FEIGAL: -- TO MANUFACTURER. AND THAT WOULD BE A PART OF OUR OVERSIGHT BEFORE WE LET MONEY GO OUT THE DOOR IN TERMS OF MAKING SURE ALL THOSE THINGS WERE IN PLACE.

DR. WAGNER: OKAY.

CHAIRMAN LO: IF I COULD JUST SAY SOMETHING IN DIRECT RESPONSE TO I THINK WHAT BOTH ROB AND JOHN WERE SAYING. IT SOUNDS LIKE THAT CIRM IS ACTUALLY DOING A LOT MORE SORT OF ACTIVE OVERSIGHT THAN MIGHT BE APPARENT FROM JUST READING THIS RESOLUTION. AGAIN, I'M WONDERING IF A COUPLE OF SENTENCES COULD BE ADDED TO SORT OF MAKE CLEAR THAT IT'S NOT A MATTER OF JUST SORT OF TAKING -- I FORGET HOW SOMEONE SAID IT -- TAKING FDA'S WORD THAT ALL THESE REQUIREMENTS WERE MET, BUT THAT CIRM WILL PLAY AN ACTIVE ROLE WITH THE SPONSOR AND WITH FDA AND WITH THE INVESTIGATOR TO MAKE SURE THAT ALL THESE REQUIREMENTS ARE CARRIED OUT.

THAT SEEMS TO BE WHAT YOU, IN FACT, DO,

AND IT WAS A CONCERN THAT A COUPLE PEOPLE RAISED. JUST TO SAY I DON'T THINK WE SHOULD LIST HERE ALL THE THINGS YOU DO, BUT TO SAY YOU'RE GOING TO BE DOING IT, I THINK, WOULD BE A GOOD THING.

DR. PRIETO: BERNIE, THIS IS FRANCISCO PRIETO. I THINK THAT WOULD BE A GOOD IDEA, WOULD HELP REASSURE PEOPLE. I DON'T KNOW IF WE'D ALSO WANT TO SPECIFICALLY REFERENCE AS PER THE REGULATIONS WE'VE PREVIOUSLY -- OR THE STANDARDS WE PREVIOUSLY APPROVED IN THIS GROUP IN THAT SENTENCE OR IN THAT STATEMENT.

DR. ROBERTS: I HAVE ONE OBSERVATION IS THAT UNDER REPORTING RESULTS, THE RESOLUTION SAYS WHEREAS, CIRM WILL PERFORM ONGOING MONITORING OF TRIALS FOR SCIENTIFIC PROGRESS. AND I NOTED IN THE MARGIN THERE SHOULD BE A SENTENCE LIKE THAT ABOUT PROTECTION OF HUMAN SUBJECTS AND SAFETY. SO JUST, AGAIN, A SENTENCE OR TWO THAT REFERS TO ONGOING MONITORING. OR UNDER THE MONITORING PLAN, FOR EXAMPLE, IT SAYS THAT CIRM REQUIRES THE SUBMISSION OF DATA SAFETY MONITORING PLANS, BUT IT DOESN'T SAY ANYTHING ABOUT FOLLOW-UP. SO I THINK EITHER AT THE BEGINNING OR IN EITHER OF THOSE AREAS ADDING A COUPLE SENTENCES WOULD BE GREAT.

DR. FEIGAL: OKAY. JUST SO YOU KNOW,

WE'RE NOT -- WE ARE NOT -- YOU KNOW, WE HAVE X NUMBER OF PEOPLE IN THIS INSTITUTE. SO WE'RE NOT GOING TO BE ACTIVELY DOING THE MONITORING OURSELVES, BUT THE SPONSOR HAS TO HAVE ACTIVE MONITORING. WE RECEIVE REPORTS. SO I WANT TO MAKE CLEAR WE'RE NOT, YOU KNOW, GOING OUT EN MASSE TO DO ALL THIS. WE DON'T HAVE THE BODY COUNT HERE TO DO THAT. BUT THEY DO HAVE PEOPLE IN THE FIELD THAT ARE DOING THAT, AND WE ARE RECEIVING SUMMARIES. AND IF INDEED ISSUES ARISE, WE WILL BECOME INFORMED OF IT AND THEN HOW IT IS ADDRESSED AND RESOLVED. SO WE WILL GET THAT.

CHAIRMAN LO: I THINK THAT WOULD BE IMPORTANT TO SAY, THAT YOU WILL GET THE RESULTS OF THESE MONITORING PLANS AND REVIEW THEM CAREFULLY AND MAKE IT -- RESPOND APPROPRIATELY SO THAT, AGAIN, IT'S A VERY ACTIVE ROLE YOU'RE PLAYING WITHOUT DOING THE ACTUAL MONITORING, BUT LOOK INTO RESULTS OF THE MONITORING.

SO I THINK, DOROTHY, YOUR COMMENT ON BOTH OF THOSE SECTIONS, DOROTHY AND FRANCISCO, YOUR COMMENTS ON BOTH THOSE SECTIONS IS AN OPPORTUNITY TO SORT OF CLARIFY THE WORDING TO MAKE IT CLEAR THAT YOU'RE LOOKING -- CIRM WILL LOOK CAREFULLY AT THE RESULTS OF THE MONITORING PLANS.

DR. FEIGAL: MAYBE WHAT WE CAN HAVE IS A

PARAGRAPH CALLED DURING THE CONDUCT OF THE TRIAL BECAUSE WHAT WE HAVE NOW IS WE SORT OF HAVE A GAP. WE HAVE PLANS AND THEN WE HAVE RESULTS. WE CAN SAY DURING THE CONDUCT.

DR. ROBERTS: EXACTLY. EXACTLY. I THINK THAT WOULD --

DR. OLSON: CLARIFY THE ROLE OF THE FUNDER WITH THE SPONSOR.

DR. FEIGAL: THE SPONSOR HAS THE ENORMOUS RESPONSIBILITY, AND THEY'LL PRIMARILY BE MAKING SURE ALL THESE PLANS, ALL THESE SUMMARIES OF THEIR REPORT COME TO US, BUT THEY ARE THE ULTIMATE GROUP RESPONSIBLE. AND AS RESPONSIBLE STEWARDS, BEING THE FUNDERS, AND ALSO WANTING TO MAKE SURE THE PATIENTS ARE SAFELY PROTECTED, WE'LL BE IN THE LOOP. IT'S THE SPONSOR WHO'S ACTUALLY PUTTING TOGETHER ALL THE REPORTS.

CHAIRMAN LO: OTHER COMMENTS FROM THE COMMITTEE?

DR. KAMP: THIS IS TIM. AND I HAD AN ISSUE WITH THE REPORTING OF THE RESULTS SECTION AS WELL. AND MY CONCERN WAS THAT THE FINAL RESULT OF THIS STUDY SHOULD BE MADE PUBLICLY AVAILABLE WHETHER IT'S POSITIVE OR NEGATIVE. AND THE STATEMENT THAT CIRM HAS THE EXPECTATION THAT RESULTS WILL BE

SUBMITTED FOR A PUBLICATION IN A TIMELY MANNER IS PRETTY SOFT. AND IF THE INVESTIGATORS DON'T WANT TO PUBLISH, IT'S PRETTY EASY TO PUT IN A LOUSY MANUSCRIPT TO GET SUBMITTED AND NOT ACCEPTED.

SO I WOULD THINK YOU MIGHT WANT TO BE A LITTLE STRONGER TO SAY THAT THERE WILL BE SOME PUBLIC DOCUMENTATION OF THE RESULTS OF THIS STUDY.

DR. TAYLOR: I WOULD AGREE.

DR. WAGNER: THIS IS JOHN. CIRM CAN ACTUALLY PUBLISH IT.

DR. FEIGAL: WELL, YOU KNOW, THAT'S A GOOD QUESTION. I MEAN WHEN I WAS BACK AT NIH, AS YOU RECALL, VARMIS WAS TRYING TO GET A NATIONAL LIBRARY OF MEDICINE PUBLICATION OF ALL RESULTS THAT WERE FREE TO THE PUBLIC. AND SO WHAT HE'S GOTTEN SO FAR IS THE REGISTRATION OF TRIALS AND SOME ASPECTS OF THAT.

I THINK WHAT WE COULD DO, PARTICULARLY WITH THE WORK THAT WE'RE DOING RIGHT NOW, THIS GROUP ACTUALLY PRESENTS AN INTERIM UPDATE AT A SCIENTIFIC CONFERENCE AND ACTUALLY SENT OUT A RELEASE ON THAT, TO WHICH WE LINK. SO WE ALSO EXPECT THERE WILL BE ONGOING INTERVAL PROGRESS BEING RECORDED AS APPROPRIATE IF IT DOESN'T JEOPARDIZE THE INTEGRITY OF ACTUALLY CONDUCTING THE TRIAL.

WE CAN'T FORCE. I'VE ALSO BEEN ON THE OTHER END WHERE YOU SUBMIT AND YOU CAN'T FORCE A PUBLICATION. THE JOURNAL EDITORS, EVEN IF IT'S VERY WELL WRITTEN, MAY OR MAY NOT DECIDE TO ACCEPT THAT PAPER. SO WE'RE REQUIRING THEM TO SUBMIT RESULTS FOR PUBLICATION. WE CAN LOOK INTO WHETHER CIRM, OR PERHAPS WE COULD WORK WITH NIH, IF THERE'S SOME WAY AS PART OF CLINICALTRIALS.GOV IS THEY'RE EXPECTED EVEN IN THAT MANNER TO REPORT RESULTS.

DR. WAGNER: I CAN TELL YOU I'VE DEALT WITH CLINICALTRIALS.GOV, AND THE WAY WE REPORT RESULTS AT THE CONCLUSION OF THE TRIAL, THERE ARE LOOPHOLES TO GET AROUND THAT.

DR. FEIGAL: I KNOW.

DR. WAGNER: AND WORKING WITH IT IS ALSO, AT LEAST IN MY ONE EXPERIENCE OF HAVING COMPLETED ONE TRIAL AND REPORTING THAT RESULT, IT IS NOT VERY EASY TO GET THE DATA I THINK YOU'RE LOOKING FOR BECAUSE IT'S NOT PRESENTED IN A WAY THAT WE'RE USED TO READING.

SO IN ANY EVENT, I THINK THAT ONE EASY WAY -- I KNOW THAT YOU GET ALL THE INVESTIGATORS ANYWAY COMING TOGETHER AT CIRM AT VARYING TIME POINTS IF THEY HAVE BEEN CIRM-FUNDED. THIS MAY BE A WAY OF AT LEAST PUBLISHING RESULTS IN A REALLY NOT

THAT DIFFICULT WAY. EVEN IF PUBLISHED ONLINE, IT COULD BE DONE IN A WAY WHERE YOU COULD HAVE MEANINGFUL DATA COME OUT AND ENSURE THE PUBLICATION IS OUT THE WAY YOU WOULD LIKE IT.

MR. SHEEHY: CAN I COMMENT?

CHAIRMAN LO: OKAY. JEFF, AND THEN I JUST WANT TO SAY THIS IS AN IMPORTANT TOPIC, AND WE HAVE TWO PEOPLE HERE, ELONA AND PAT, ALSO HAVE IMPORTANT COMMENTS TO MAKE. BUT, JEFF, WHY DON'T YOU GO AHEAD AND WE'LL GO TO ELONA.

MR. SHEEHY: YEAH. SO CIRM IS FUNDING A JOURNAL, RIGHT, A TRANSLATIONAL MEDICINE JOURNAL I THINK THROUGH THE GROUP THAT FUNDS *CELL* -- THAT PUBLISHES *CELL*. AND I THINK ANTHONY ATALA IS SUPPOSED TO BE THE EDITOR OF THAT.

DR. FEIGAL: YOU'RE CORRECT. WE'RE HELPING TO SUPPORT --

MR. SHEEHY: IT'S HARD WHEN YOU INTERRUPT ME. SO I THINK TO GET -- BECAUSE WE'VE TALKED ABOUT THIS FROM THE VERY BEGINNING IN VARIOUS CONTEXTS, THAT WE NEED TO HAVE NEGATIVE RESULTS PUBLISHED. AND THAT WAS EXPLICITLY THE RATIONALE THAT WAS OFFERED FOR CIRM'S INVESTMENT IN A NEW JOURNAL. SO PERHAPS, YOU KNOW, AS PART OF THIS RESOLUTION, WE SHOULD REALLY TIGHTEN THAT LOOP. I MEAN GIVEN THAT

WE'RE SUPPORTING THE ESTABLISHMENT OF A NEW JOURNAL SPECIFICALLY TO PUBLISH NEGATIVE RESULTS AND THAT WE HAVE THIS EXPECTATION THAT RESULTS WILL BE PUBLISHED THAT WE'RE KIND OF SOFTLY EXPRESSING IN THIS DOCUMENT, PERHAPS WE COULD TIGHTEN THIS RESOLUTION TO BE STRONGER TO LINK IT AT LEAST TO THAT ONE PUBLICATION THAT WE HAVE FUNDED TO PUBLISH THESE TYPES OF RESULTS.

IF WE'RE FUNDING BOTH THE PUBLICATION AND THE STUDIES, WE OUGHT TO BE ABLE TO GET THE NEGATIVE RESULTS THAT WE FUNDED PUBLISHED IN THE PUBLICATION THAT WE FUNDED TO PUBLISH NEGATIVE STUDIES.

CHAIRMAN LO: ELONA AND THEN PAT.

MS. BAUM: THANK YOU. I THINK THAT IT'S A LAUDABLE GOAL TO GET NEGATIVE RESULTS, AND I THINK IT COULD BE VERY HELPFUL IN ACCELERATING THE FIELD. I ALSO WANT TO RECOGNIZE THAT THE PARTICIPATION OF FOR-PROFITS AND INDUSTRY IN CIRM-FUNDED GRANTS IS ESSENTIAL, I THINK, FOR THE SUCCESS OF THE MISSION. A LOT OF THE REGULATORY KNOW-HOW, MANUFACTURING KNOW-HOW, ETC., LIES WITHIN INDUSTRY. AND I KNOW THAT INDUSTRY WILL BE WILLING IN MANY RESPECTS TO PUBLISH A LOT OF INFORMATION, AND AS WE'VE SEEN, THEY'VE ALREADY PROVIDED RESULTS AT AN INDUSTRY MEETING.

BUT I THINK WE REALLY HAVE TO LOOK VERY CAREFULLY IN TERMS OF WHAT EXACTLY WE REQUIRE OF THEM IN TERMS OF PARTICIPATING IN CIRM FUNDING BECAUSE IF WE REQUIRE THEM TO DISCLOSE ANY INFORMATION OTHER THAN WHAT THEY DEEM IS APPROPRIATE AND SATISFACTORY TO THEIR GOAL, THEY MIGHT NOT WANT TO PARTICIPATE IN OUR PROGRAM, WHICH WILL SLOW DOWN THEIR RESEARCH. GETTING FUNDING FROM CIRM ACCELERATES THE FIELD FORWARD; BUT IF THEY FEEL THERE ARE TOO MANY STRINGS ATTACHED, AND THAT THIS REQUIREMENT WOULD RUN COUNTER TO THEIR BUSINESS OBJECTIVES, THE RESPONSIBILITIES THEY HAVE NOT ONLY TO PATIENTS, BUT ALSO TO THEIR SHAREHOLDERS, I HAVE SOME GRAVE CONCERNS ABOUT THE SCOPE OF ANY REQUIREMENT AS IT WOULD APPLY TO A FOR-PROFIT ENTITY.

DR. OLSON: SO I JUST WANTED TO MAKE THE POINT THAT IN THE RFA FOR THE TARGETED CLINICAL DEVELOPMENT AND PERHAPS IN SOME FORM IN ANY CLINICAL PROGRAM GOING FORWARD, WE DID MAKE THE STATEMENT, AND THIS SPEAKS TO ELONA'S POINT TO SOME EXTENT, IN THAT NOT BEING TOO PRESCRIPTIVE, BUT BY SAYING WE STATED CIRM WILL ALSO REQUIRE AWARDEES TO SHARE THE RESULTS OF THEIR STUDY FOR THE BENEFIT OF THE FIELD. SO IT DOES NOT SPECIFY THE FORUM IN WHICH THAT WILL

HAPPEN, BUT IT IMPLIES THAT IT HAS TO BE SUCH THAT IT COULD BE BENEFIT THE FIELD, WHETHER IT'S NEGATIVE OR POSITIVE.

AND I DO THINK THAT'S AN IMPORTANT CONSIDERATION. AND WE TRIED TO USE LANGUAGE THAT GETS INFORMATION OUT THERE, BUT NOT NECESSARILY IN THE CONTEXT OF A *NEW ENGLAND JOURNAL* ARTICLE.

DR. FEIGAL: I THINK THAT WHAT YOU'RE SAYING IS, YOU KNOW, AND ALSO HAVING COME FROM A FEDERAL GOVERNMENT INSTITUTION IN WHICH WE FUNDED COMPANIES, IS THERE IS AN EXPECTATION THAT THEY WILL PUBLISH IF THEY'RE USING TAXPAYER SUPPORTED DOLLARS. SO I THINK WHAT WE CAN DO IS WE CAN DEFINITELY STRONGLY ENCOURAGE AND EXPECT.

JEFF, I'M NOT SURE THAT WE WANT TO TIE IN TIT FOR TAT WITH A PUBLICATION BECAUSE RIGHT NOW I'M NOT SURE THAT'S A GOOD POSITION THAT WE SHOULD TAKE WITH THE JOURNAL, BUT I THINK WE DEFINITELY SHOULD DO EVERYTHING WE CAN TO MAKE SURE THAT RESULTS ARE, AFTER A TRIAL IS COMPLETED AND THE RESULTS ARE INTERPRETED, THAT THEY BE ASSEMBLED IN A WAY THAT THE FIELD CAN BENEFIT FROM THE RESULTS OF TAXPAYER SUPPORTED DOLLARS. AND WE AGREE WITH YOU 100 PERCENT THAT THAT SHOULD BE STRONGLY ENCOURAGED.

I THINK WE JUST NEED TO FIGURE OUT A

VIABLE WAY TO MAKE THAT HAPPEN. I CAN VERY CLEARLY TELL YOU THAT THE GROUP THAT WE'RE WORKING WITH HAS EVERY INTENT TO DO THAT AND IS ACTUALLY SHARING THE INFORMATION ALONG THE WAY AT SCIENTIFIC CONFERENCES, NOT JUST INDUSTRY VENUES.

SO WE WILL WORK ON THIS ASPECT BECAUSE I AGREE WITH YOU, THAT PUBLIC ACCESS TO TAXPAYER SUPPORTED STUDIES IS AN IMPORTANT THING WE SHOULD TRY AND PROMOTE.

MR. SHEEHY: BECAUSE I GUESS I'M NOT UNDERSTANDING THE DISCONNECT. WE SPECIFICALLY -- THE OVERWHELMING RATIONALE FOR FUNDING A NEW JOURNAL WAS TO GET NEGATIVE RESULTS PUBLISHED. I MEAN THERE'S NO SHORTAGE OF JOURNALS THAT WILL PUBLISH POSITIVE RESULTS. WE DECIDED TO FUND THE ESTABLISHMENT OF A NEW JOURNAL TO PUBLISH NEGATIVE RESULTS. AND I DON'T KNOW HOW WE CAN SPEND CALIFORNIA TAXPAYER MONEY ON CLINICAL TRIALS AND NOT REPORT THE RESULTS OF THE CLINICAL TRIALS THAT WE HAVE FUNDED SOMEWHERE. THAT JUST DOESN'T SEEM APPROPRIATE TO ME.

SO IF THIS IS NOT THE GROUP TO FINALIZE THAT DISCUSSION, THIS DISCUSSION DOES NEED TO COME TO A FAIRLY CLEAR CONCLUSION ABOUT WHAT OUR EXPECTATIONS ARE FOR THE PUBLICATION OR THE

DISSEMINATION OF NEGATIVE TRIAL RESULTS. THIS IS NOT A NEW ISSUE FOR CIRM, AND I HONESTLY THOUGHT THAT WE HAD COME TO A CONCLUSION ON THIS BY DECIDING TO FUND THE JOURNAL. BUT IF THAT --

DR. FEIGAL: THAT'S --

MR. SHEEHY: I CAN'T FINISH MY THOUGHTS. BUT IT WOULD BE HELPFUL IF WE COULD COME TO SOME SORT OF CONCLUSION ON THIS.

DR. PRIETO: IF I COULD RESPOND TO THAT JUST FROM THE POINT OF VIEW OF THIS GROUP, BUT ALSO THE BOARD. I THINK THAT IS A BIG PART OF OUR UNDERSTANDING. AND I THINK TO RESPOND TO ELONA'S POINT, THE REASON THAT THIS IS AN ISSUE IS BECAUSE RESULTS IN THE PAST HAVE NOT BEEN RELEASED WHEN THEY WERE NEGATIVE, AND THAT LED TO SOME INAPPROPRIATE BEHAVIOR, SHALL WE SAY. SO THIS IS A SAFEGUARD, AND I THINK IT'S AN IMPORTANT ONE, THAT THIS JOURNAL OR SOME OTHER VENUE, AND MAYBE THIS ISN'T THE PLACE TO DISCUSS THIS IN DETAIL, BUT IT SHOULD BE UNDERSTOOD THAT EVEN IF AN ARTICLE IS NOT PUBLISHED IN THE JOURNAL, THAT IT'S CLEAR THAT THROUGH THIS OR SOME OTHER VENUE, WE ARE RECEIVING THESE RESULTS AND WE'RE GOING TO MAKE THEM AVAILABLE POSITIVE OR NEGATIVE, THAT WE'RE GOING TO BE TRANSPARENT.

CHAIRMAN LO: LET ME TRY AND SORT OF

DISTINGUISH THREE DIFFERENT STRANDS HERE THAT I THINK I'M HEARING. I THINK THIS IS A VERY IMPORTANT ISSUE, AND I THINK IT'S IMPORTANT TO HIGHLIGHT IT.

FIRST IS THE IDEA THAT NEGATIVE RESULTS NEED TO BE DISSEMINATED AS WELL AS POSITIVE RESULTS. SECOND IS THAT WE WOULD LIKE THERE TO BE -- THESE RESULTS BE PRESENTED IN A WAY THAT ENABLES, FIRST OF ALL, OTHER SCIENTISTS IN THE FIELD TO UNDERSTAND THEM. AND MY OWN SENSE IS THAT PEER REVIEW IS -- PEER REVIEW ABSTRACTS AT MEETINGS AND PEER REVIEW PUBLICATIONS ARE GOOD BECAUSE IT PROVIDES SOME LEVEL OF ASSURANCE THAT THE DATA MEETS CERTAIN STANDARDS. AND THE THIRD IDEA WAS THAT THESE RESULTS ALSO NEED TO BE AVAILABLE TO THE PUBLIC AS WELL AS TO SCIENTISTS.

I THINK NO ONE IS DISAGREEING THAT THIS OUGHT TO HAPPEN, THAT CIRM-FUNDED, PUBLICLY FUNDED CLINICAL TRIALS, THE NEGATIVE RESULTS SHOULD BE DISSEMINATED AS WELL AS POSITIVE RESULTS. THEY SHOULD BE SUBJECTED TO PEER REVIEW, AND ALSO THAT THE PUBLIC AS WELL AS SCIENTISTS SHOULD HAVE ACCESS TO THE RESULTS.

SO I THINK WE COULD CERTAINLY STRENGTHEN THE LANGUAGE THAT HAS THE STRONG EXPECTATION THAT RESULTS, NEGATIVE AS WELL AS POSITIVE, WILL BE

DISSEMINATED, SUBMITTED FOR PUBLICATION IN PEER REVIEW JOURNALS. AND THAT ONCE THESE RESULTS ARE MADE AVAILABLE IN THAT WAY, THEY BE FURTHER -- THEY BE MADE AVAILABLE TO THE PUBLIC, THAT THESE PEER REVIEW ARTICLES BE AVAILABLE TO THE PUBLIC. AND CIRM COULD CERTAINLY PLAY A ROLE IN PUBLIC DISSEMINATION SOMETHING LIKE THE NIH.

AS A FORMER JOURNAL EDITOR, I MUST SAY I SORT OF CAN UNDERSTAND HOW A JOURNAL EDITOR WOULD WANT TO RETAIN CONTROL, EDITORIAL CONTROL, OVER SUBMISSION. I THINK JOHN CAPTURED IT WELL, SAYING YOU CAN ALWAYS ASSURE YOUR PAPER IS NOT PUBLISHED BY SUBMITTING A REALLY LOUSY DRAFT. I ALSO DON'T THINK TELLING THE EDITOR YOU'VE GOT TO PUBLISH IT EVEN IF IT'S TERRIBLE IS GOOD EITHER.

BUT I THINK MAYBE WHAT WE SHOULD BE DOING HERE IS REALLY STATING IN A MUCH STRONGER WAY THE IMPORTANCE OF THIS REPORTING, AS I SAID, THE NEGATIVE RESULTS, THE IMPORTANCE OF PEER REVIEW, AND THE IMPORTANCE OF PUBLIC ACCESS SINCE IT WAS PUBLICLY FUNDED. AND I THINK I AGREE WITH THOSE OF YOU IN THE COMMUNITY SAID THIS. THOSE MEMBERS OF THE SWG THAT ARE ALSO MEMBERS OF THE ICOC, AS THIS CONTINUES, FROM THE STAFF LEVEL, WORKING OUT THE DETAILS IS ALWAYS HARD, AND I THINK WE JUST NEED TO

CLARIFY THIS IN A WAY THAT MAKES IT TRANSPARENT TO EVERYBODY WHAT WE WANT TO HAPPEN.

OTHER COMMENTS ON THIS? I THINK THIS IS AN IMPORTANT ISSUE, AND WE ONLY HAVE ABOUT 15 MINUTES LEFT, SO I JUST WANT TO MAKE SURE IF THERE ARE OTHER ISSUES THAT PEOPLE HAVE, WE GET THOSE AS WELL. SO I'LL THROW IT BACK TO THE SWG.

DR. ROBERTS: I HAVE A RELATED QUESTION WHICH IS THE FOLLOWING WHEREAS. WHEREAS, CIRM REGULATIONS REQUIRE A PLAN TO PROVIDE ACCESS TO UNINSURED CALIFORNIANS WHEN TRIALS RESULT IN EFFECTIVE THERAPIES. THIS IS THE ONLY ONE THAT JUST SORT OF HANGS THERE, AND THERE'S NO FOLLOW-UP OR ANYTHING. I SUPPOSE YOU COULD SAY IT'S INCLUDED IN THE RESOLUTION WHICH REFERS TO EXISTING CIRM REGULATIONS. BUT THE OTHERS, THERE'S MORE EXPLANATION OF HOW CIRM IS GOING TO ABIDE BY THEM, AND THIS ONE JUST HAS THE WHEREAS CLAUSE AND NOTHING ELSE.

CHAIRMAN LO: IT DOESN'T HAVE THE ACTION CLAUSE.

DR. ROBERTS: THERE'S NO ACTION.

MS. BAUM: THIS IS REALLY JUST A VERY QUICK SUMMARY OF THIS ITEM OF OUR ROBUST IP REGULATIONS WHICH WOULD APPLY TO BOTH FOR-PROFITS

AND NONPROFITS. SO THIS DOCUMENT WASN'T MEANT TO SET FORTH EVERY SINGLE REGULATION. IT WAS REALLY ANSWERING THE QUESTION WHAT ADDITIONAL REGULATIONS ABOVE AND BEYOND THOSE WHICH CURRENTLY EXIST AT CIRM AND AT LAW ARE REQUIRED. THE CONCLUSION BEING THAT IN LIGHT OF THE FACT THAT CIRM HAS A ROBUST SET OF REGULATIONS IN ALL AREAS, WHETHER THEY BE IP AND OTHERS WE DISCUSSED, AND IN LIGHT OF THE FACT THAT THERE'S A ROBUST SET OF REGULATIONS AND STATUTES AT THE FEDERAL AND STATE LEVEL, THE RESOLUTION CONCLUDES THAT NO FURTHER ADDITIONAL REGULATIONS WILL BE REQUIRED. SO WE DIDN'T GET INTO EVERY SPECIFIC REGULATION OR MONITORING THE COMPLIANCE WITH THEM. THOSE ARE ALL TAKEN CARE OF IN OTHER CONTEXTS.

CHAIRMAN LO: I THINK DOROTHY'S SPECIFIC COMMENT WAS WITH THE SYNTACTICAL CONSTRUCTION OF THIS, SAYING THAT THERE'S A WHEREAS CLAUSE AND THE OTHER SECTIONS HAVE WHAT I WOULD CALL AN ACTION CLAUSE.

DR. ROBERTS: RIGHT.

DR. LOMAX: WE WILL ADD IT.

CHAIRMAN LO: THAT'S WHAT I THINK DOROTHY IS SAYING.

DR. ROBERTS: YES. YES. BECAUSE

OTHERWISE IT SEEMS LIKE THE OTHERS WERE PAID MORE ATTENTION TO THAN THIS ONE, AND WE WOULDN'T WANT TO LEAVE THAT IMPRESSION, I THINK.

DR. FEIGAL: OKAY.

DR. PRIETO: WE AGREE.

DR. ROBERTS: OKAY. THANKS.

CHAIRMAN LO: OTHER COMMENTS, THOUGHTS FROM THE SWG?

DR. KAMP: THIS IS TIM KAMP AGAIN. TO TOUCH ON THE ISSUE THAT ROB RAISED ABOUT THE SAFETY OF THE DONOR LINE AND ISSUES RELATED TO THAT, I THINK IT'S A GOOD CONSIDERATION ABOUT THE RISK OF PROPAGATING GENETIC DEFECTS WITH CELL PRODUCTS, BUT I THINK WE'RE AT THE SAME TIME LIMITED BY THE CURRENT STATE-OF-THE-ART. AND UNDOUBTEDLY, JUST AS IT HAS CHANGED FOR INFECTIOUS DISEASE TESTING, WE'LL GET SMARTER AND SMARTER FOR GENETIC TESTING AND BE ABLE TO MAKE SAFER AND SAFER PRODUCTS. BUT I JUST THINK WHERE WE ARE CURRENTLY, IT'S HARD TO DO MUCH MORE THAN IS ALREADY IN PLACE.

SO, FOR EXAMPLE, EVEN IF THE SPERM DONOR WASN'T ANONYMOUS, THIS SPERM DONOR WAS KILLED IN AN AUTO ACCIDENT TWO YEARS LATER, DIDN'T KNOW HIS FOLLOW-UP HEALTH HISTORY, DO WE PULL OUT THAT CELL LINE? IT STARTS TO GET HARD TO KNOW WHAT TO DO. SO

I THINK WE JUST HAVE TO ACKNOWLEDGE THAT WE CAN'T AVOID ALL POTENTIAL RISKS.

CHAIRMAN LO: GOOD. THANKS.

I JUST WONDER IF IT'S WORTH ADDING SOME ADDITIONAL LANGUAGE HERE THAT PICKS UP ON WHAT TIM SAYS. AGAIN, CIRM IS GOING TO BE ACTIVELY INVOLVED AS THE FIELD MOVES FORWARD. AND AS THE SCIENCE PROGRESSES, CIRM'S GOING TO BE INVOLVED WITH RETHINKING SOME OF THESE MORE SPECIFIC THINGS THAT ARE MUCH MORE SPECIFIC THAN THIS RESOLUTION AND NEED TO BE READDRESSED. I THINK THAT IN ADDITION, MY SENSE IS THAT THERE'S A LOT OF ACTIVE SORT OF SCRUTINY AND MANAGEMENT THAT CIRM STAFF CARRIES OUT, IF THERE'S SOME WAY OF REFERENCING THAT GENERALLY IN THE DOCUMENT, I THINK THAT WOULD BE IMPORTANT BECAUSE THIS WILL BE A PUBLIC DOCUMENT. I THINK IT'S IMPORTANT THAT EVERYONE UNDERSTAND THAT THERE'S A LOT MORE GOING ON THAN JUST THE SORT OF RECITATION OF REGULATORY REQUIREMENTS.

I'M TRYING TO THINK OF HOW TO PROCEED NOW BECAUSE WE'VE MADE A WHOLE LOT OF SUGGESTIONS. UNFORTUNATELY I CAN'T SEE THE SWG, SO I CAN'T READ YOUR EXPRESSIONS AND BODY LANGUAGE. BUT I THINK THE REACTION HERE IN SAN FRANCISCO HAS BEEN NOT A SUBSTANTIVE DISAGREEMENT. IF ANYTHING, IT'S JUST A

MATTER OF NOT WANTING TO -- WANTING TO BE SURE THAT ANY CHANGES IN LANGUAGE ARE CAREFULLY DONE AND DON'T SORT OF ENTER INTO LEVELS OF DETAIL THAT REALLY AREN'T APPROPRIATE FOR THIS KIND OF DOCUMENT.

SO I THINK THERE'S GOING TO BE SOME REWRITING. I'M TRYING TO THINK, GEOFF, HOW BEST TO MOVE THAT AHEAD AND HOW TO SORT OF INVOLVE THE SWG IN LOOKING AT LANGUAGE THAT I THINK WILL BE CHANGED. GEOFF HAS A COPY THAT'S GOT SCROLLS ALL OVER IT.

DR. LOMAX: THANK YOU, BERNIE. THIS IS A DOCUMENT THAT, AGAIN, AS A RESOLUTION IS A STATEMENT. WE DO HAVE, I THINK, A SERIES OF VERY CONSTRUCTIVE, A SET OF CONSTRUCTIVE RECOMMENDATIONS WHICH I BELIEVE WE CAN INCORPORATE INTO A REVISED DRAFT OF THIS DOCUMENT. WE WOULD LIKE TO TAKE THIS TO THE BOARD. AGAIN, THIS IS A RECOMMENDATION TO THE ICOC IN JUNE. THIS IS -- AND WE HAVE, IN TERMS OF THE ICOC REPRESENTATION, WE HAVE REPRESENTATION ON THIS COMMITTEE THAT IS ALSO REPRESENTED ON THE BOARD.

I WOULD PROPOSE THAT WE INCORPORATE THE COMMENTS FROM TODAY, WE ALSO INCLUDE A DESCRIPTIVE NARRATIVE THAT SUMMARIZES THE MEETING. THAT'S WHAT WE'VE ALWAYS DONE WHEN WE'VE TAKEN ANY TYPE OF STATEMENT OR PRODUCT OF THIS WORKING GROUP TO THE

ICOC. WE CERTAINLY CAN GET -- THAT WOULD GET OUT TO BOARD MEMBERS. THERE WOULD BE AMPLE TIME TO REVIEW THAT, BUT I WOULD ENCOURAGE US TO MOVE THIS TO THE ICOC IN JUNE GIVEN THE TIMELINE WE'RE WORKING ON.

I THINK THESE ARE -- THANK YOU VERY MUCH FOR THE THOUGHTS AND THE INSIGHT. I THINK WE CAN DO A LOT WITH WHAT WE RECEIVED FROM THIS MEETING AND COME UP WITH A BETTER DOCUMENT, AND IT WILL REFLECT THE SPIRIT.

MS. LANSING: CAN I SECOND THAT? I AGREE WITH GEOFF'S RECOMMENDATION. I THINK WE REALLY NEED TO MOVE THIS FORWARD BECAUSE OF WHAT'S GOING ON.

CHAIRMAN LO: LET ME MAKE A SUGGESTION AND SORT OF FLOAT A TRIAL BALLOON FOR THE SWG. SO I THINK WHAT I'M HEARING IS THAT WE MAY WANT TO HAVE THE TEXT BE REVISED BY GEOFF IN ACCORDANCE WITH THE DISCUSSION TODAY, BUT WE WANT TO MOVE FORWARD ON THE RESOLUTION TO THE BOTTOM PARAGRAPH. I WANT TO SUGGEST, I DON'T KNOW IF THIS MEETS ROBERTS RULES OF ORDER OR NOT, BUT MAYBE ENCOURAGE ONE OF MY COLLEAGUES ON THE SWG TO SUGGEST THAT WE SLIGHTLY AMEND THE RESOLUTION AND JUST INSERT -- SO THE RESOLUTION IS RESOLVED THAT THE EXISTING OVERSIGHT INCLUDING BLAH, BLAH, BLAH PROVIDE ROBUST OVERSIGHT.

I'M JUST WONDERING IF BEFORE THE PROVIDE

WE INSERT SOMETHING LIKE COMMA AS WELL AS ONGOING CIRM, WHATEVER YOU WANT TO SAY, STAFF MONITORING. WHAT WE HEARD IS IT'S NOT JUST THE EXISTING REGULATIONS, BUT IT'S WHAT CIRM IS BRINGING IN ADDITION IN TERMS OF THE WORK THE STAFF IS PUTTING IN TO SORT OF MONITOR AND CHECK THINGS, THAT IT'S IMPORTANT IN PROVIDING THE ASSURANCE. AND IF THERE'S A WAY OF INCLUDING THAT IN THE RESOLUTION, WHICH I THINK IS KEEPING WITH THE SPIRIT OF WHAT WE WERE SAYING, SO THAT IT ACTUALLY REFLECTS WHAT STAFF IS NOW DOING. IF THERE'S SOMEONE WHO'S BETTER AT LANGUAGE THAN I COULD SUGGEST EXACTLY HOW TO WORD THAT.

DR. LOMAX: WHAT I TOOK FROM THE CONVERSATION, BERNIE, WAS THAT IN THAT SECTION SOMEWHERE BOTH IN THE MONITORING PLAN SECTION AND THEN THE DURING THE CONDUCT, WHICH IS THE PROPOSED NEW SECTION, WE ARE GOING TO ARTICULATE A SET OF PROGRAMMATIC PROCESSES THAT COME INTO PLAY WITH GRANTS AND TRIALS OF THIS NATURE. AND THAT ONCE WE'VE ARTICULATED THAT ABOVE, I THINK IT WOULD THEN BE THE NEXT STEP OBVIOUSLY THEN TO INCORPORATE THE THINKING OF THAT INTO THE RESOLUTION. SO I THINK IT'S A PROCESS THAT FALLS DIRECTLY FROM THE COMMENTS WE'VE RECEIVED, BUT IT'S CONDITIONED ON SORT OF

AMENDING EXISTING SECTIONS AND DEVELOPING IT. SO THAT WOULD COME OUT OF THE EDITING.

DR. TAYLOR: THIS IS JUST A SUGGESTION. THIS IS ROB. I THINK THAT IF PHILOSOPHICALLY THIS DOCUMENT WAS WRITTEN MORE IN A MORE FORWARD-THINKING RATHER THAN THE EXTANT FDA REGULATIONS, IT WOULD BE REASSURING PROBABLY TO EVERYONE. SO IT'S AS MUCH STYLE AS IT IS SUBSTANCE, I THINK. AND I REALLY APPRECIATE TIM'S COMMENTS. THIS IS A MOVING TARGET. WE CAN'T KNOW EVERYTHING NOW, AND WE'RE GOING TO GET BETTER AS WE GO FORWARD. AND I'M SURE OF THAT. BUT THERE SHOULD BE SOMETHING WRITTEN IN HERE THAT KIND OF CARRIES THAT SPIRIT THROUGH THE DOCUMENT.

CHAIRMAN LO: SO, AGAIN, I THINK WE CAN CHANGE THE TEXT THAT COMES BEFORE THE LAST PARAGRAPH TO REFLECT THAT, AND I'M WILLING TO WORK WITH GEOFF AND OTHERS TO TRY AND DO THAT. I WAS JUST TRYING TO FOCUS DIRECTLY AT THE RESOLUTION BECAUSE THAT'S WHAT'S GOING TO -- WE NEED TO SORT OF MOVE ON THAT. LET ME TRY ANOTHER LANGUAGE VARIANT.

SO BASED ON BLAH, BLAH, BLAH, WE'RE GOING TO LIST EVERYTHING, AND THE LAST THING WOULD BE AND EXISTING CIRM REGULATIONS, AS WELL AS CIRM STAFF OVERSIGHT, PROVIDE STRONG ASSURANCE THAT CLINICAL TRIALS WILL MEET THE HIGH STANDARDS, BLAH, BLAH,

BLAH.

SO I JUST WANT TO SOMEHOW WORK INTO THE RESOLUTION THE FACT THAT STAFF IS REALLY GOING TO BE PUTTING THEIR EAGLE EYES AND THEIR THOUGHTS INTO THIS. SO IT'S NOT JUST THE EXISTING STATUTORY, REGULATORY OVERSIGHT, BUT IT'S THE WORK THAT CIRM STAFF IS GOING TO DO.

DR. FEIGAL: IF YOU WANT, WE COULD PUT -- I MEAN IT GOES AT A HIGH LEVEL OF ACTIVE ENGAGEMENT WITH THE APPLICANT, WITH MULTIPLE CONVERSATIONS. SO WE COULD PUT THAT IN IF THAT WOULD --

CHAIRMAN LO: THIS IS A SUGGESTION. I DON'T KNOW WHAT THE SWG THINKS OF THAT.

DR. PRIETO: I WOULD BE FINE WITH THAT. DO WE NEED A MOTION?

MS. BAUM: IF WHAT YOU'RE TRYING TO DO IS CREATE A MOTION, I DON'T THINK WE HAVE A QUORUM HERE.

CHAIRMAN LO: WE HAVE A SENSE OF THE COMMITTEE. I JUST WANT TO GET A SENSE OF THE COMMITTEE. IS LANGUAGE LIKE THAT SOMETHING THAT WOULD BE -- WE ARE COMMITTED TO REWORKING THE FIRST PAGE.

MS. BAUM: I THINK YOU COULD TAKE IT

FURTHER. I THINK YOU COULD START WITH WE APPROVE THE RESOLUTION SUBJECT TO THE FOLLOWING.

CHAIRMAN LO: OKAY.

MS. LANSING: I LIKE THAT BETTER.

CHAIRMAN LO: OKAY.

MS. BAUM: THE CONDITION ONE BEING THAT IT INCLUDE A REFERENCE TO CONTINUING CIRM OVERSIGHT; TWO, THAT IT ONLY APPLIES WITH RESPECT, THIS IS AN EARLIER COMMENT, TO FDA-GOVERNED CLINICAL TRIALS. THAT WAS AN IMPORTANT ADD. THREE, THAT THERE IS EMPHASIS ON THE SHARING OF RESULTS. FOUR, THAT WE EXPAND THE ACCESS REQUIREMENTS SECTION TO INCLUDE AN IMPLEMENTATION -- A STATEMENT ON IMPLEMENTATION. AND I THINK --

CHAIRMAN LO: MAYBE ONE MORE JUST TO SORT OF REFERENCE -- TO ACKNOWLEDGE THAT AS THE SCIENCE ADVANCES, THAT WE ARE OPEN TO REVISITING SPECIFIC, NOT THE RESOLUTION, BUT THE SPECIFICS. THAT WAS GREAT, ELONA.

MS. FEIT: WAS THERE NEED TO PUT A COMMENT IN THERE ABOUT THE CERTIFICATION OF FACILITIES, THAT THEY MEET CERTAIN REQUIREMENTS?

CHAIRMAN LO: I WONDER IF THAT'S A LEVEL OF DETAIL THAT WE DON'T NEED -- THAT WE WANT TO LEAVE --

DR. PRIETO: MAYBE NOT IN THIS RESOLUTION.

MS. FEIT: OKAY. I JUST BROUGHT THAT UP AS A NOTE THAT I HAD ON SOME OF THE ISSUES THAT WERE RAISED.

CHAIRMAN LO: SO, AGAIN, SINCE WE ARE GETTING A SENSE OF THE COMMITTEE, DOES WHAT ELONA SUGGESTED, DOES THAT CAPTURE THE SENSE OF THE DISCUSSION? IT WILL GIVE GUIDANCE, I THINK, TO GEOFF AND ME AS WE REWORK THIS. ANYTHING FROM THE SWG THAT YOU'D WANT TO SORT OF ADD OR CORRECT ON THAT?

MS. FEIT: I'M GOING TO HAVE TO LEAVE THE CALL, BUT I FEEL COMFORTABLE WITH THE STATEMENTS THAT WERE JUST MADE FOR THE PROPOSED RESOLUTION.

CHAIRMAN LO: OKAY. GREAT.

DR. LOMAX: BEFORE WE MAKE IT DEFINITIVE, I KNOW IT'S TIME SENSITIVE, BUT WE SHOULD CHECK IF THERE'S ANY PUBLIC AT ANY OF THE SITES ON THE LINE.

MS. FEIT: THERE'S NONE HERE AT MINE.

DR. LOMAX: WE HAVE A PUBLIC MEMBER HERE. ANY PUBLIC COMMENT HERE?

CHAIRMAN LO: SO I WANT TO THANK ALL OF YOU VERY MUCH. AND THE THREE MEMBERS OF OUR GROUP, ACTUALLY FOUR OF YOU WHO ARE ACTUALLY ON THE ICOC, WE'LL DEPEND ON YOU TO MAKE SURE THE ICOC

UNDERSTANDS OUR THINKING.

(THE MEETING WAS THEN CONCLUDED AT 12 P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON FRIDAY, JUNE 10, 2011, 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
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