BEFORE 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

VOLUME I

LOCATION: PAUL BREST HALL
MUNGER COMPLEX
STANFORD UNIVERSITY
STANFORD, CALIFORNIA

DATE: DECEMBER 9, 2009
4:30 P.M.

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

BRS FILE NO.: 86112

I N D E X

STANFORD, CALIFORNIA; WEDNESDAY, DECEMBER 9, 2009

4:30 P.M.

CHAIRMAN KLEIN: ALL RIGHT. WE'RE GOING TO COMMENCE. WE HAVE A NUMBER OF ITEMS THAT WE CAN PROCEED ON WHILE WE'RE WAITING FOR MEMBERS WHO ARE EN ROUTE. THIS IS A WONDERFUL FACILITY. IT, HOWEVER, PRESENTS CERTAIN INTELLECTUAL TESTS IN LOCATING THE BUILDING. AND THE INTELLECTUAL TEST CAN BE MORE OR LESS COMPLICATED BASED ON WHO YOU ASK ON THE WAY FOR DIRECTIONS. SO KNOWING THAT MANY OF OUR BOARD MEMBERS MAY HAVE TAKEN A WRONG TURN, WE WANT TO FULLY UTILIZE THE TIME OF THOSE THAT ARE HERE AND THE STAFF THAT IS HERE.

SO WE'D LIKE TO CALL THE MEETING TO ORDER. AND, MELISSA, WOULD YOU PLEASE PROCEED BY PROVIDING US WITH THE PLEDGE OF ALLEGIANCE AND THEN THE ROLL CALL. AND I WOULD LIKE TO SAY AT SOME POINT DR. FRIEDMAN MAY BE CONNECTED ON AN AUDIO LINE TO THIS. THE PROCEEDINGS BOTH DAYS ARE BEING AUDIO CAST AND MADE AVAILABLE BY THE INTERNET. SO WE HAVE A SIGNIFICANT AUDIENCE THAT'S NOT PRESENT IN THE ROOM. AND PLEASE REMEMBER, THEREFORE, TO USE YOUR MICROPHONES IN THE PROCESS.

MS. KING: PLEASE STAND IF YOU ARE ABLE.

(THE PLEDGE OF ALLEGIANCE.)

MS. KING: AND NOW, CHAIRMAN KLEIN, SHOULD I CALL THE ROLL?

CHAIRMAN KLEIN: PLEASE.

MS. KING: DONALD DAFOE FOR RICARDO AZZIZ.

DR. DAFOE: HERE.

MS. KING: ROBERT PRICE FOR ROBERT BIRGENEAU. FLOYD BLOOM. GORDON GILL FOR DAVID BRENNER. WILLIAM BRODY.

DR. BRODY: HERE.

MS. KING: SUSAN BRYANT.

DR. BRYANT: HERE.

MS. KING: MARCY FEIT.

MS. FEIT: HERE.

MS. KING: MICHAEL FRIEDMAN. LEEZA GIBBONS.

MS. GIBBONS: HERE.

MS. KING: MICHAEL GOLDBERG.

MR. GOLDBERG: HERE.

MS. KING: SAM HAWGOOD. BOB KLEIN.

CHAIRMAN KLEIN: HERE.

MS. KING: SHERRY LANSING. LEONARD ROME FOR GERALD LEVEY.

DR. ROME: HERE.

MS. KING: TED LOVE. ED PENHOET.

DR. PENHOET: HERE.

MS. KING: PHIL PIZZO. KEN BURTIS FOR CLAIRE POMEROY.

DR. BURTIS: HERE.

MS. KING: FRANCISCO PRIETO. CARMEN PULIAFITO. ROBERT QUINT. JOHN REED. DUANE ROTH.

MR. ROTH: HERE.

MS. KING: JOAN SAMUELSON. DAVID SERRANO-SEWELL.

MR. SERRANO-SEWELL: HERE.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. KING: JON SHESTACK. OSWALD STEWARD.

DR. STEWARD: HERE.

MS. KING: AND ART TORRES.

MR. TORRES: HERE.

CHAIRMAN KLEIN: THANK YOU. THANK YOU VERY MUCH. LIKE TO ALSO IN OPENING THANK JENNA PRYNE WHO'S STILL ACTIVELY WORKING ON FACILITATING PEOPLE'S ATTENDANCE, MELISSA KING, NICK WARSHAW FOR ALL OF THEIR EFFORTS IN PULLING TOGETHER THE MEETING HERE AT STANFORD.

I'M GOING TO DEFER SOME OF MY COMMENTS.

MR. GOLDBERG: ON BEHALF OF PHIL PIZZO, WHO WOULD BE OUR HOST, HE'S ASKED ME TO WELCOME

EVERYONE ON BEHALF OF THE BOARD OF TRUSTEES OF LELAND STANFORD, JR. UNIVERSITY.

CHAIRMAN KLEIN: AND THAT WAS A VOICE OF AUTHORITY THERE OF A FATHER WITH A DAUGHTER AT THE UNIVERSITY.

SO, DR. TROUNSON, COULD YOU BEGIN WITH YOUR REPORT? AS USUAL, THERE ARE A NUMBER OF EXTRAORDINARY SCIENTIFIC DEVELOPMENTS TO REPORT.

DR. TROUNSON: THANK YOU VERY MUCH, CHAIR. I MUST ADMIT THIS, THE LAST MEETING OF THE YEAR, I THINK IT'S WELCOME TO MANY OF US. IT'S BEEN ONE OF THOSE YEARS, I THINK, A LOT OF US HAVE EARNED OUR SALARIES AND PROBABLY A LITTLE MORE. IT'S BEEN A GREAT YEAR, AND IT'S BEEN CHALLENGING. AND I PRESUME IT'S GOING TO CONTINUE THAT WAY FOR ANOTHER FEW YEARS.

SO IF I CAN HAVE THE FIRST SLIDE, PLEASE. I ACTUALLY THOUGHT I'D START WITH THIS SLIDE BECAUSE I NORMALLY END WITH THIS SLIDE, AND IT'S REALLY THE STAFF OF THE INSTITUTE. AND I WANT TO THANK THEM, YOU KNOW, WITH YOU BECAUSE THEY'VE JUST BEEN A TREMENDOUS GROUP OF PEOPLE. AND EVERY ONE OF THEM HAS PUT IN MORE YARDS THAN YOU'D EXPECT FROM ANYBODY. AND IT'S VERY COMMON THAT BEYOND 11 O'CLOCK AT NIGHT AND THEY WERE UP. THIS MORNING, IT

WAS TWO IN THE MORNING, THEY WERE STILL RESPONDING TO E-MAILS FROM ME, SO YOU HAVE TO SAY THERE'S SOMETHING VERY SPECIAL ABOUT THIS GROUP OF PEOPLE. SO I'M VERY PROUD TO WORK WITH THEM, AND I'M SURE THOSE THAT DO WORK DIRECTLY WITH THEM, YOU'LL FIND THEM A GROUP OF PEOPLE THAT YOU ACTUALLY ENJOY THEIR COMPANY AND YOU RESPECT THEIR PROFESSIONALISM.

(APPLAUSE.)

DR. TROUNSON: SO THE NEXT SLIDE, IF I MAY. YOU WILL PROBABLY OR MIGHT HAVE SEEN THIS. IT'S A PIE CHART OF THE DISEASE TEAMS AND EARLY TRANSLATIONAL PROJECTS. AND, OF COURSE, THERE ARE PEOPLE LIKE JEFF SHEEHY AND OTHERS WHO ARE ON THE GRANTS WORKING GROUP WHO WILL PROBABLY RECOGNIZE THIS, BUT WHAT I THINK IS VERY IMPORTANT HERE, BEFORE I GIVE YOU SOME WHAT I THINK IS SOME OF THE REALLY INTERESTING PIECES OF WORK THAT HAVE HAPPENED THIS YEAR, IN THE GREEN YOU SEE, THESE ARE THE PROJECTS THAT WE'RE SUPPORTING IN TRANSLATION AND IN THE DISEASE TEAMS THAT ARE GENETICALLY MODIFIED CELL THERAPY.

NOW, THAT MEANS WHAT WE'RE DOING IS A CELL THERAPY. WE'VE ACTUALLY MODIFIED THE CELLS, GENETICALLY MODIFIED THE CELLS. SO IN A SENSE IT IS GENE THERAPY AS WELL AS CELL THERAPY. SO MORE THAN

40 PERCENT OF OUR PRIMARY PROJECTS ARE IN THAT AREA. YOU MIGHT NOT HAVE RECOGNIZED THIS, BUT I THINK IT'S WORTH THINKING ABOUT THIS. THIS IS THE CUTTING EDGE OF ACTUALLY WHERE WE ARE.

SO HAVING THAT PIECE OF INFORMATION ON THE PORTFOLIO, IF I CAN GO TO THE NEXT SLIDE, I WANTED -- THERE'S A VERY NICE PAPER THAT WAS PUBLISHED IN *SCIENCE* FROM CARTIER AND COLLEAGUES AT INSERM IN PARIS, PUBLISHED IN *SCIENCE*. AND IT REALLY TALKS ABOUT THE POSSIBILITY OF USING GENETICALLY MODIFIED CELL THERAPIES. AND THERE'S NOT A LOT OF THEM THAT ARE REALLY IN CLINICAL USE. BUT HERE IS AN EXAMPLE OF A VERY EFFECTIVE THERAPY. AND IF YOU THINK THAT WE'RE ON THE EDGE GOING FORWARD, WE'RE PROBABLY GOING TO GO SIMILARLY ON THIS KIND OF EDGE.

SO THE DISEASE THAT THEY WERE WORKING WITH IS X-LINKED ALD, ADRENOLEUKODYSTROPHY. IT'S A SEVERE BRAIN DEMYELINATING DISEASE, SO THE LOSS OF THE MYELIN SHEATH ON THE NEURONS IN BOYS. IT OCCURS IN BOYS, IT'S X LINKED, DUE TO A DEFICIENCY IN THE ALD PROTEIN. SO BY GENE THERAPY THEY EXTRACTED THE CD 34 PLUS CELLS. THESE ARE THE HEMATOPOIETIC OR BLOOD STEM CELLS. AND THEY CORRECTED THE PROBLEM, THIS ABERRANT MUTATION, USING A LENTIVIRAL VECTOR

BUT PUTTING THE CORRECT GENE IN. AND THEN THE PATIENTS WERE GIVEN MYELOABLATIVE THERAPY TO MAKE ROOM FOR THE NEW GENETICALLY MODIFIED CELLS AND THEN REINFUSED WITH THE GENETICALLY MODIFIED CELLS. SO THEY MADE SPACE FOR THESE CELLS.

COUPLE OF PATIENTS WERE FOLLOWED UP FOR 24 TO 30 MONTHS, SO IT'S TWO TO TWO AND A HALF YEARS. AND THEY SHOWED THAT THEY GOT A POLYCLONAL RECONSTITUTION SO THAT THE CELLS WHICH REALLY ARE IMPORTANT IN THIS, UP TO ABOUT 14 PERCENT OF THE GRANULOCYTES, THE MONOCYTES, AND THE T&B LYMPHOCYTES EXPRESSED THE PROTEIN THAT WAS MISSING. SO THEY WERE PROVIDING THE GENETICALLY MODIFIED PROTEIN THAT'S NECESSARY.

WHAT THEY SAW WAS THE PROGRESSIVE CEREBRAL DEMYELINATION STOPPED AT 14 TO 16 MONTHS AFTER INFUSION OF THESE CELLS, AND THE PATIENTS STARTED TO RECOVER. SO THIS IS A RATHER NICE DEMONSTRATION. I THINK IN THE NEXT, IT JUST SHOWS YOU THE -- I DON'T HAVE A POINTER HERE -- BUT IF YOU LOOK AT THESE GRAPHICS, WHAT'S SHOWING IS THE PERCENTAGE OF LYMPHOCYTES ON THE X AXIS, THE UP-GOING AXIS, AND THE MONTHS OF GENE THERAPY. SO YOU CAN SEE THAT THE CELLS ARE PUTTING OUT THE APPROPRIATE PRODUCT.

AND THEN IF YOU LOOK AT THE TYPE OF CELLS

IN THIS PARTICULAR PATIENT, ONE, YOU CAN SEE THERE'S SOME VARIATION; BUT, AGAIN, THE CELLS ARE PRODUCING THE PROTEIN OVER THAT PERIOD. THIS LOOKS LIKE IN THE TIMEFRAME THAT THEY LOOKED AT THE PATIENTS A VERY SUCCESSFUL GENE MODIFICATION CELL THERAPY, ONE OF THE ONES THAT WE'RE LOOKING FOR. THESE ARE THE KIND OF THINGS THAT WE'RE GOING TO BE ASKING OUT OF THE DISEASE TEAMS AND SOME OF THE TRANSLATION PROJECTS TO PERFORM. AND I THINK IT'S A GOOD EXAMPLE, A VERY NICE EXAMPLE, OF A STUDY WHICH HAS DEMONSTRATED THE REAL USAGE.

YOU WILL PERHAPS REMEMBER THAT GENE THERAPY WAS TRIED WITH VIRUSES ORIGINALLY SO THAT THEY GAVE THE PATIENTS A VIRUS WHICH WOULD THEN CONVERT, THAT WOULD TRANSFECT SOME OF THE CELLS AND CONVERT THEM TO CELLS THAT PRODUCE THE PROTEIN, BUT THEY GOT A LOT OF SIDE EFFECTS IN SOME OF THOSE STUDIES, ENOUGH TO CRASH THOSE GENE THERAPY PROGRAMS AND PUT GENE THERAPY REALLY BACK IN A VERY UNWELCOME STATE, WHICH IT REALLY HASN'T ESSENTIALLY RECOVERED FROM.

SO I THINK PEOPLE NOW THINK THAT THE USE OF THE CELL THERAPY WITH THE GENETICALLY MODIFIED MODIFICATION IS PROBABLY THE WAY TO GO. AND WE PREDICTED THIS, YOU KNOW, SOME YEARS AGO, THAT THIS

WOULD BE ONE OF THE BETTER WAYS OF DELIVERING A CELL THERAPY. SO THERE ARE A LOT OF OPPORTUNITIES OUT THERE FOR US TO DO THIS, AND I THINK WE'LL SEE A LOT MORE PROJECTS COMING THROUGH IN THAT AREA.

SO THE NEXT STUDY I WANTED TO REPORT TO YOU IS TO SHOW YOU THAT AN IPS-DERIVED CELL TYPE, SO THIS IS THE INDUCED PLURIPOTENTIAL CELL TYPE, THEY PRODUCE RETINAL PIGMENTED EPITHELIAL CELLS, AND THEN THEY USE THESE CELLS WHEN THEY DIFFERENTIATED THEM IN A MODEL OF RAT THAT LOSES SIGHT BECAUSE OF THE DESTRUCTION OF THE RETINAL CELL LAYER. SO IT'S A PARTICULAR RAT MODEL THAT'S USED PRETTY WIDELY FOR THESE STUDIES.

AND THESE IPS CELLS, YOU CAN ACTUALLY SEE THEM HERE IN THE GREEN. THESE WERE INTRODUCED AS A SHEET OR A MONOLAYER UNDER THE RODS AND CONES. AND THIS IS WHAT YOU WOULD DO IN THE HUMAN, AND YOU CAN SEE THESE CELLS PARTICIPATING HERE. THIS IS THE HUMAN CELLS IN THE GREEN AS THE MONOLAYER UNDERNEATH THE RODS AND CONES AS PART OF THE WHOLE RETINAL LAYER. HERE THIS IS IN CARTOON FORM SHOWING YOU THESE ARE THE PIGMENTED EPITHELIAL CELLS THAT SIT HERE. AND THESE RATS CAN ACTUALLY SEE COLOR, THEY CAN SEE LIGHT, AND THEY CAN SEE STRUCTURE.

SO, AGAIN, THIS IS WORK FROM A MAJOR GROUP

WHICH INCLUDES DENNIS CLEGG'S LABORATORY AT UNIVERSITY OF CALIFORNIA SANTA BARBARA AND PETE COFFEY'S LAB AT THE UNIVERSITY COLLEGE LONDON, AND THEY'RE BOTH INVOLVED IN THE HUMAN STUDIES THAT WE'VE TAKEN UP IN THE DISEASE TEAMS. I HAVEN'T SORT OF STUDIED THAT PROJECT BECAUSE I'VE BEEN IN CONFLICT WITH IT, BUT IT LOOKS LIKE A REALLY TERRIFIC TEAM. THEY'VE SHOWN THAT THIS WORKS RATHER WELL WITH IPS CELLS, SO WE MIGHT IMAGINE THAT NOT ONLY EMBRYONIC STEM CELLS, BUT IPS CELLS MIGHT TRAVERSE INTO THE CLINIC IN THIS WAY.

THE NEXT STUDY IS, AGAIN, FROM A GROUP AT INSERM IN FRANCE, AND I CHOSE TO SHOW YOU THIS BECAUSE YOU REMEMBER IN ONE OF OUR DISEASE TEAM PROJECTS, WE ARE GOING TO CONVERT IPS CELLS INTO KERATINOCYTES OR CELLS THAT MAKE UP NEW SKIN ON PATIENTS WHO'VE GOT A VERY SEVERE GENETIC DISEASE, EPIDERMOLYSIS BULLOSA. AND IN THAT DISEASE THERE'S A DEFECT IN COLLAGEN 7, WHICH MEANS THEIR SKIN LIFTS OFF. SO THIS IS ONE OF THE SORT OF DISEASES THAT THE NURSING STAFF AND EVERYBODY HATE TO SORT OF WORK WITH BECAUSE IT'S VERY DIFFICULT TO LOOK AFTER THESE KIDS. IT'S LIKE THEY GOT SEVERE BURNS ON THEM ALL THE TIME, AND THERE'S NO REAL TREATMENT FOR IT.

SO WE ACTUALLY APPROVED A PROJECT OF IPS

CELLS TO TREAT THAT PARTICULAR CONDITION. AND I WANTED TO SHOW YOU WHAT I THOUGHT WAS SOME REALLY BEAUTIFUL STUDY FROM THIS GROUP IN FRANCE, WHICH SHOWED HUMAN EMBRYONIC STEM CELLS CAN ACTUALLY FORM A FULL RECONSTRUCTION OF THE EPIDERMIS. SO THIS IS THE NORMAL EPIDERMIS HERE, AND THIS IS THE RECONSTRUCTED EPIDERMIS. AND IF YOU LOOK AT THE MARKERS THERE, YOU CAN SEE THAT ALL THE RIGHT MARKERS ARE PRESENT. AND IF YOU LOOK AT THIS, THIS IS HEMOTOXYLIN AND EOSIN STAIN, AND IT LOOKS LIKE REAL SKIN, THE WHOLE FULL DERMIS OF SKIN. THESE ARE THE BROWN CELLS OR THE HUMAN CELLS THAT ARE PRESENT. THIS IS TRANSPLANTATION OF HUMAN EMBRYONIC-DERIVED CELLS TO THE EPIDERMIS OF XENOGRAPHS ON SCID MICE, AND THIS KI 67 ARE CELLS WHICH ARE REPLICATING.

THIS LOOKS LIKE THE KIND OF THING THAT THAT PROJECT AT STANFORD WILL NEED TO DO FOR THOSE CHILDREN. BUT THIS METHODOLOGY LOOKS LIKE ROBUST METHODOLOGY. SO IT'S A GOOD PLANK, AGAIN, HOPEFULLY FOR THE IPS CELL PROJECT FOR THOSE KIDS TO GO FORWARD ON.

SO I ACTUALLY -- THERE WERE SOME NOTES -- IT'S HARD TO GET A PAPER IN THE JOURNAL *LANCET*. IT'S ONE OF THOSE PRIMARY JOURNALS. AND THE COMMENTS OF THIS WORK WERE REALLY VERY, VERY

POSITIVE. TERRIFIC WORK SHOWING REALLY THE FRONT LINE OF HOW TO DO IT. AND NOT GOING INTO ANY OF THE DETAIL, IT'S NOT A VERY COMPLICATED PROCEDURE THAT WORKS THERE. IT REALLY UTILIZES THE GROWTH FACTOR BMP 4 AND ASCORBIC ACID TO DO IT, SO IT'S NOT OVERLY COMPLICATED. SO A VERY NICE PIECE OF WORK.

THE LAST ONE I WANTED TO TALK TO YOU ABOUT WAS THERE'S BEEN SOME DISCUSSION ABOUT WHAT WOULD HAPPEN TO EMBRYONIC AND IPS-DERIVED CELLS WHEN THEY WERE PUT INTO PATIENTS WHERE YOU'VE STILL GOT AN ISCHEMIC ENVIRONMENT; THAT IS, WITH PATIENTS WHO HAVE STROKE, YOU'VE GOT ISCHEMIA. AND THAT IS AN ENVIRONMENT WHICH IS DIFFERENT TO THE NORMAL BRAIN. YOU'VE GOT REALLY A MAJOR INFLAMMATION GOING ON THERE DUE TO THE DAMAGE CAUSED BY STROKE.

SO THEY SHOWED IN THESE STUDIES IN THE JOURNAL *STROKE*. AGAIN, IT WAS JUST BY CHANCE, THE STUDY FROM INSERM IN FRANCE. THEY TRANSPLANTED VERY IMMATURE NEURAL PROGENITORS AND FOUND THAT THEY INFLUENCED BY GRAFT SURVIVAL AND THE OCCURRENCE OF TERATOMA FORMATION. SO IF YOU TRANSPLANTED THE EMBRYONIC STEM CELLS VERY EARLY IN THE DIFFERENTIATION, YOU HAD BOTH AN EFFECT ON WHETHER THE GRAFTS SURVIVE, BUT YOU ALSO GOT THE APPEARANCE OF A TERATOMA. BUT BOTH EFFECTS WERE LOST IF YOU

DIFFERENTIATED THE CELLS FARTHER DOWN THE TRACK. AND WHAT YOU COULD GET IF YOU DIFFERENTIATED THEM INTO THE LATE CELLS, YOU COULD GET VERY HIGHLY PROLIFERATIVE GRAFTS OCCURRING LATER, BUT NO TERATOMA FORMATION, BUT YOU DID SOME INSTANCES GET AN OVERGROWTH OF NEURAL TISSUE WHEN YOU DID THE TRANSPLANTATION.

SO WHAT THEY'RE SAYING HERE IS IF YOU DIFFERENTIATE THEM FAR ENOUGH, YOU WILL NOT GET EVEN IN AN ISCHEMIC BRAIN, IN AN ANIMAL BRAIN, YOU WON'T GET TERATOMAS FORMED. BUT WHAT YOU NEED TO BE CAREFUL OF, IF IT'S A VERY RAPIDLY GROWING CELL LINE IN THE CULTURE DISH, DON'T USE THAT OR MODIFY, BRING THE CELL NUMBER DOWN BECAUSE THERE'S A RISK OF OVERGROWTH IF YOU PUT TOO MANY CELLS IN. SO THE BALANCING OF ALL OF THESE THINGS ARE GOING TO BE VERY IMPORTANT. AND CLEARLY, AS WE MOVE THROUGH THE TRANSLATIONAL PIPELINE, ALL OF THESE THINGS ARE GOING TO BECOME EXTREMELY IMPORTANT.

THE NEXT SLIDE. MY PRIORITIES, MOVING OUT OF THE RESEARCH AREAS, MY PRIORITIES AT THE PRESENT TIME HAVE REALLY BEEN WITH THE DISEASE TEAMS AND MEDIA AND COLLABORATIVE ISSUES THAT HAVE BEEN RISING OUT OF THIS. THERE'S BEEN A LOT OF WORK ON THE DISEASE TEAMS THAT WE BROUGHT FORWARD. PROVIDING A

LOT OF UPDATE FOR THE MEDIA ON THOSE PROJECTS.

WE'RE INVOLVED IN A VP R & D SEARCH, VICE PRESIDENT R & D, AND I'LL REPORT SOME PROGRESS ON THAT FOR YOU. WE'VE BEEN WORKING ON DIVERSITY ISSUES THAT IMPACT IN REGENERATIVE MEDICINE. WE'LL REPORT BRIEFLY ON THAT.

THE IMMUNOLOGY RFA, WHICH HAS JUST GONE OUT, IS TERRIBLY IMPORTANT. IT'S LOOKING AT TOLERANCE. WE NEED A MORE TOLERANT ENVIRONMENT FOR ALLOGENEIC CELLS. IF THEY'RE NOT YOUR OWN CELLS, THE BODY WILL GENERALLY HAVE AN IMMUNE REACTION, AND THE CELLS WILL BE CHALLENGED, GENERALLY CHALLENGED. SO IT'S IMPORTANT THAT WE GET MORE WORK DONE ON ACHIEVING THERAPIES THAT WOULD ALLOW FOR TOLERANT TRANSPLANTATION. AND SO WE'VE BEEN OUT THERE TRYING TO GET MORE SCIENTISTS TO COME IN FROM THE TRANSPLANTATION AND IMMUNOLOGY AREA, GET INTERESTED IN THIS PARTICULAR RFA.

THERE ARE LOANS AND COMPANY ISSUES. WE HAD A MEETING JUST BEFORE THIS MEETING ON THAT, AND IT'S CHALLENGING AGAIN, BUT I THINK WE'RE MAKING PROGRESS. BUT IT'S NOT THE SIMPLEST MATTER, AND IT'S CLEAR THAT WE'VE STILL GOT WORK TO DO, BUT WE'RE GETTING THERE.

THE FDA CONSORTIUM, WE'LL REPORT BRIEFLY

ON THAT TO YOU. IT'S, AGAIN, A VERY POSITIVE MEETING THAT WE HAD WITH THE FDA, AND WE WILL BE FOLLOWING THOSE UP REGULARLY.

WE'VE GOT INTERNATIONAL AGREEMENTS AND PROJECT MONITORING WHICH WE'RE STARTING. SO THERE'S STARTING TO BECOME ISSUES NOW, WORK FOR US IN THAT INTERNATIONAL AREA.

THE CIRM RESEARCH LEADERSHIP AWARDS, THERE'S A LOT OF INTEREST FROM UNIVERSITIES THROUGHOUT CALIFORNIA IN THAT LEADERSHIP PROGRAM, SO WE'RE TAKING A LOT OF CALLS ON THAT. DEVELOPING NETWORKS IN THE U.S. AS WE DO ALL THE TIME WITH BOTH SCIENCE AND INDUSTRY. CONTINUING DIALOGUE WITH THE MAJOR PHARMACEUTICAL COMPANIES WHO ARE VERY INTERESTED IN BECOMING PARTNERS WITH US, AND NOW WE'RE TRYING TO SORT OF FIGURE OUT HOW TO CONNECT THEM WITH WHAT WE'RE DOING. AND WE'LL BRING SOME PROPOSALS FORWARD TO YOU IN THE NEW YEAR.

LOOKING AT CIRM AND ECONOMIC STIMULUS ISSUES BECAUSE WE'RE STARTING TO GATHER SOME INFORMATION. AND, OF COURSE, WE'RE ALSO WORKING ON SOME OF OUR MEETINGS, OUR OWN MEETING AND ISSCR MEETING IN 2010, SO THERE'S A LOT OF WORK CURRENTLY GOING ON.

IF YOU LOOK AT THE FDA REGENERATIVE

MEDICINE CONSORTIUM, I THINK THIS IS A VERY IMPORTANT PROGRAM. AND DUANE AND TED LOVE WERE WITH US IN THE BEGINNING WITH BOB KLEIN GOING TO THE FDA, CULTIVATING THEM, GETTING THEM TO SORT OF START TO WORK WITH US. THE CONSORTIUM THAT WE HAVE IS A GROUP OF SCIENTISTS AND PARTICULARLY SCIENTISTS AND PROJECT MANAGERS FROM COMPANIES AND INSTITUTES THROUGHOUT CALIFORNIA, BUT ALSO THROUGHOUT THE U.S. THROUGH SOME OF THE NATIONAL COMPANIES AND INSTITUTES. WE HAD 18 ATTENDEES FROM THE FDA, WHICH IS A BIG ATTENDANCE TO A WHOLE THREE-, FOUR-HOUR MEETING. AND THE ACTING DIRECTOR, DR. MIDTHUN, WAS THERE, AS WAS DR. CELIA WITTEN, FOR THE WHOLE TIME, WHO'S THE DIRECTOR OF THE OFFICE OF CELL AND TISSUE AND GENE THERAPY, WHICH IS UNUSUAL TO GET THESE PEOPLE TO SORT OF COME AND LISTEN AND START TO WORK WITH US.

THE REGENERATIVE MEDICINE CONSORTIUM HAD 26 PEOPLE THAT INCLUDED MEMBERS OF CIRM, AND THEY'RE ALL ESSENTIALLY FROM THE SCIENCE SECTORS. WE'RE TALKING ABOUT HOW TO DO THE PROGRAM, WHAT WERE THE PRIORITIES, WHERE COULD WE FOCUS OUR ATTENTION, HOW CAN WE HELP ONE ANOTHER START TO UNDERSTAND THIS PATHWAY AND THE PRIORITIES OF TAKING THE CLINICAL WORK THROUGH THE TRANSLATIONAL PATHWAY. IT WAS VERY

PRODUCTIVE.

THE FDA PRESENTED ON PRECLINICAL STUDIES, CHEMISTRY, MANUFACTURING, AND CONTROLS, VERY INTERESTING AND IMPORTANT MATTERS. A BROAD LANDSCAPE OF ISSUES WERE HIGHLIGHTED. IN THE REGULATORY SCIENCE AREA, THE AREAS TO ADDRESS WERE ASSAYS FOR DETECTING, CHARACTERIZING UNDIFFERENTIATED CELLS, BIOCHEMICAL AND IMAGING BIOMARKERS THAT MAY BE PREDICTIVE, PREDICTIVE FOR BENEFIT, AND SURROGATES FOR EARLY CLINICAL TRIALS. SO CAN WE SEE IN A DISH SOMETHING THAT WE'RE GOING TO SEE IN THE ACTUAL CLINICAL TRIALS.

SO IN THE NEXT STEP, WE'RE SETTING A STEERING COMMITTEE WITH CIRM TO CHAIR AND ADMINISTER THAT. IDENTIFY THE TOP AREAS OF FOCUS FOR WEBINARS. THEY'VE OFFERED WEBINARS, REGULAR WEBINARS, SO THE FDA WILL DO THAT FOR US. FUTURE FDA ROUNDTABLES ON A QUARTERLY BASIS IF THAT'S WHAT THE WHOLE INDUSTRY WOULD LIKE. AND THE DEVELOPMENT OF WHITE PAPERS FROM OUR SIDE AND THEIR COMMENTS FROM THEIR SIDE. SO A GENUINE LINKAGE OF INTEREST HERE.

WE WANT TO ESTABLISH AN INFORMATION REPOSITORY ON THE CIRM'S WEB SITE FOR KEY GUIDANCE AND DOCUMENTS AND WHITE PAPERS FOR THE POSSIBILITY FOR SHARING AND POSTING PROTOCOLS, NEGATIVE DATA,

BEST PRACTICE, ETC., TRY AND SAVE SOME EFFORT IN THIS PIPELINE FOR EVERYONE WHO'S GOING THROUGH IT. SO WE HOPE THIS IS GOING TO BE A PRODUCTIVE PROCESS, AND ALL INDICATIONS ARE CURRENTLY THAT IT IS.

I WANTED TO SORT OF DRAW YOUR ATTENTION TO A FEW THINGS HERE. I HAD THE STAFF LOOK AT STEM CELL PUBLICATIONS IN 2004, WHICH IS SHOWN IN THE PURPLE OR BLUE THERE, 2006 IN THE ORANGE, AND 2009 IN THE GREEN. AND THESE ARE STEM CELL PUBLICATIONS. AND I WANTED TO LOOK AT COUNTRIES TO SEE WHERE THE MAJOR ACTIVITY IS. WE'VE GOT U.S.A. ON THE BOTTOM BECAUSE IT'S SO BIG COMPARED TO EVERYWHERE ELSE. IT DWARFS MOST OTHER THINGS.

I THINK YOU'LL BE INTERESTED IN THE RAPID PROGRESS OF COUNTRIES LIKE CHINA SHOOTING UP. THERE'S A TREMENDOUS DEVELOPMENT IN THERE. GERMANY, ITALY, AND THIS IS GENERALLY IN ADULT STEM CELLS IN ITALY, NOT IN EMBRYONIC STEM CELLS, JAPAN, THE UNITED KINGDOM, AND SOUTH KOREA, AND CANADA. YOU WILL SEE THAT WE'RE LINKED WITH MANY OF THESE COUNTRIES, AND WE'VE ACTUALLY, I THINK, CHOSEN WISELY TO LINK WITH THESE REALLY PRODUCTIVE COUNTRIES THAT ARE ON A BOOM TRACK.

IF YOU LOOK AT THE NEXT ONE, WHICH IS EMBRYONIC STEM CELLS, YOU WILL SEE A SIMILAR TYPE OF

DEVELOPMENT. IF YOU LOOK AT CHINA, SEE THEM SHOOTING UP THERE WITH EMBRYONIC STEM CELLS ALONG WITH GERMANY. I WOULDN'T HAVE PREDICTED THAT. I WOULD HAVE THOUGHT THAT THEY WERE INHIBITED IN EMBRYONIC STEM CELLS. NOT SO FROM THE LITERATURE. JAPAN, VERY STRONG IN EMBRYONIC STEM CELLS. YOU MIGHT THINK IT'S ALL IPS CELLS IN JAPAN. IT'S NOT SO. AND THE UNITED KINGDOM, AGAIN, VERY STRONG.

SO WE'VE TAKEN A LOOK AT THIS TO JUST SEE WHERE WE ARE WITH RESPECT TO SOME OF THE SORT OF RAPIDLY MOVING SCIENTISTS AND RAPIDLY MOVING AREAS. SOME OF THIS IS A PROCESS OF THE FUNDING THAT'S TURNING UP.

CHAIRMAN KLEIN: ALAN, IF YOU WILL GO BACK ONE SLIDE, I THINK IT'S IMPORTANT FOR THE BOARD, IN TERMS OF BENCHMARKING THESE NUMBERS, TO REALIZE THAT I JUST HEARD FROM DON THAT WE JUST PASSED 400 SCIENTIFIC PAPERS. SO IN THE LAST TWO YEARS, WE'VE FUNDED 400 PAPERS. AND IF YOU LOOK AT HOW THAT COMPARES TO THE COUNTRIES ACROSS THERE, IT GIVES YOU A SENSE OF HOW IMPORTANT THE AGENCY IS IN MOVING THIS WHOLE FIELD FORWARD.

DR. TROUNSON: THAT'S CERTAINLY TRUE. WE'RE A BIG COMPONENT PART OF THE USA, AND WE'VE LOOKED AT THAT IN THE PAST, BUT I WANTED TO GIVE YOU

A FLAVOR FOR WHAT WAS HAPPENING OUTSIDE BECAUSE SOMETIMES YOU HAVE -- IT'S EASY TO GET THE WRONG IDEA BECAUSE SOME PLACES ARE VERY GOOD AT CONNECTING WITH YOU; WHEREAS, YOU MIGHT LOOK AT ISRAEL, AND THEY'RE SORT OF KIND OF STATIC AT THE MOMENT, WHICH I THINK MIGHT BE A REFLECTION OF THE FUNDING PROBLEMS THAT THEY'VE GOT AT THE PRESENT TIME THERE, BUT IT'S PRETTY STATIC COMPARED TO WHAT'S HAPPENING IN SOME OTHER PLACES. SO IT'S JUST USEFUL TO REFLECT ON IT.

IF WE CAN GO TO THIS ONE, HERE YOU WILL SEE THE USA REALLY FLYING AGAIN ON IPS CELLS. YOU DO SEE THE USA LEADING OUT WITH JAPAN, CHINA, GERMANY, SPAIN, AND THE UK BEING STRONG. MY OLD COLLEAGUES IN AUSTRALIA SEEMED TO HAVE MISSED THE BUS COMPLETELY. BUT I THINK THIS IS ALSO PART OF THE LEADING EDGE BECAUSE, YOU KNOW, THE INNOVATIVE SCIENTISTS WILL MAKE THE MOVE TO THESE NEW AREAS. AND CLEARLY THE U.S. HAS GONE OUT VERY STRONGLY AS YOU WOULD EXPECT JAPAN TO DO. WE'RE CERTAINLY -- WE'RE REALLY SORT OF RACING AWAY THERE. IF YOU LOOK AT OUR PORTFOLIO, WE'RE VERY STRONG IN IPS CELLS. CLEARLY WE'VE COME ALONG WITH THE INNOVATION TRACK, PICKED THESE PROJECTS UP, AND ARE TAKING THEM FORWARD MOSTLY IN THE BASIC SCIENCE AREA. I THOUGHT

THAT WAS JUST INTERESTING FOR YOU. NEXT.

WE'RE GOING TO HAVE SOME STRUCTURAL NEEDS. WE HAVE AN OUTSIDE PANEL REVIEW LATE IN 2010. THAT'S SCHEDULED, SO WE'RE GOING TO HAVE AN EXTERNAL PANEL. I'M GOING TO BRING YOU SOME SUGGESTIONS, WE'LL BRING THAT FORWARD. WE'RE HAVING SOME SUGGESTIONS ABOUT THE NATURE OF THAT PANEL. SOME OF IT'S SET OUT IN THE STRATEGIC PLAN, BUT THERE'S A REVIEW FOR 2000 -- LATER IN 2010. AND WE'LL GET YOUR INPUTS INTO THAT. THAT'S REALLY IMPORTANT.

BUT SOME OF THE THINGS THAT THEY WILL ASK ABOUT WE KNOW ABOUT, YOU WILL BE AWARE ABOUT, IS WITH BOB KLEIN GOING TO STEP DOWN AT THE END, THINGS ARE GOING TO CHANGE FOR US. THEY'RE REALLY CLEARLY -- NO ONE HAS CLONED BOB KLEIN ESSENTIALLY. NO ONE SHOULD OR MAYBE HE WOULD LIKE TO, BUT, NO, HE SHOULDN'T DO THAT. BUT THERE'S NOT SOMEBODY LIKE BOB WHO'S LIKELY TO STEP INTO THAT POSITION. IT'S JUST UNLIKELY. WE NEED FINANCIAL EXPERTISE IN BOND FINANCING TO ACCOMMODATE FOR THE DEPARTURE OF THE CHAIR. WE NEED ADDITIONAL STAFF TO SUPPORT THE VICE PRESIDENT OF R & D FOR MONITORING THE TRANSLATION OF PRECLINICAL AND CLINICAL GRANTS THAT ARE COMING FORWARD. THIS IS CLEARLY A HUGE AMOUNT OF WORK IN THAT AREA, AND WE NEED TO GIVE THAT PERSON SOME

SUPPORT. WE RECOGNIZE THAT.

THERE'S THE FDA, THE NIH, AND INTERNATIONAL COLLABORATIONS AND CONNECTIONS TO INDUSTRY TO TAKE CARE OF. WE NEED ADDITIONAL SCIENCE OFFICER APPOINTMENTS TO ADDRESS THE INCREASING LOAD FROM THE RFA'S AND THE PROJECTS THAT WE'VE GOT AND THE MONITORING AND THE REPORTS THAT WE'RE DOING. WE JUST NEED MORE PEOPLE ON THE GROUND. SO I THINK WE'RE GOING TO NEED TO INCREASE THE INSTITUTE STAFF NUMBERS MAYBE BY FIVE OR TEN ABOVE 50, AND I THINK WE'VE GOT TO GET TO GRIPS WITH THIS. WANT TO STAY WITHIN THE 6-PERCENT LIMIT, AND I'M WORKING WITH THE CHAIR TO SORT OF LOOK AT HOW WE COMPOSE THIS. IT'S GOING TO BE VERY IMPORTANT FOR US BECAUSE I DON'T WANT TO GET TO A SITUATION WHERE WE CAN'T DO THE JOB PROPERLY IN SOME OF THESE AREAS. AND I DON'T THINK YOU WANT US TO SAY, WELL, WE JUST DON'T HAVE ENOUGH CAPACITY. SO WE'RE GOING TO HAVE TO CREATE SOME SOLUTIONS, AND I WANT TO WORK WITH MEMBERS OF THE BOARD AND PARTICULARLY WITH THE CHAIR IN GETTING SOLUTIONS TO THOSE ISSUES.

THE UPCOMING GRANT REVIEWS, WE HAVE A BASIC BIOLOGY II. WE'VE HAD INVITED APPLICATIONS. WE'VE INVITED APPLICATIONS FROM 57 GROUPS. THE APPLICATION DEADLINE IS DECEMBER THE 8TH, AND THE

GRANTS WORKING GROUP REVIEW IS IN FEBRUARY.

IN UPCOMING RFA'S, TO REMIND YOU, THERE'S A STEM CELL TRANSPLANTATION AND IMMUNOLOGY, AND THIS IS A LOT TO DO WITH THE INDUCTION OF TOLERANCE. THE APPLICATION DEADLINE IS IN JANUARY. THE REVIEWS WILL BE IN APRIL, AND WE EXPECT TO BRING IT TO THE ICOC IN JUNE 2010. WE HOPE -- WE'VE REALLY GOT TO MAKE SOME PROGRESS IN THAT AREA. IT'S VERY FUNDAMENTALLY IMPORTANT TO US TO DO THAT.

THE RESEARCH LEADERSHIP AWARDS HAVE BEEN POSTED JUST A DAY AGO, I THINK ONE DAY AGO. AND SO WE'LL EXPECT THE FIRST APPLICATION DEADLINE TO BE IN FEBRUARY 2010. SO I'M SURE THE INSTITUTES ARE INTERESTED AND ACTIVE ALREADY.

EARLY TRANSLATIONAL II, SO THAT'S OUR SECOND TRANSLATIONAL II PROJECT. THE CONCEPT CLEARANCE IS FOR THIS MEETING HERE, AND WE HOPE TO POST THAT RFA IN FEBRUARY. AND TOOLS, TECHNOLOGY, AND BOTTLENECKS, SO THIS IS THE PROJECT WHICH WILL ATTRACT, I THINK, QUITE A LOT OF THE BIOTECH COMPANIES. CONCEPT CLEARANCE IS SCHEDULED FOR FEBRUARY 2010, FEBRUARY NEXT YEAR. OKAY.

WE'VE GOT SOME WORKSHOPS. THERE'S ONE ENHANCING DIVERSITY ON FEBRUARY THE 25TH. THE GOAL IS TO IDENTIFY HOW CIRM CAN ENHANCE DIVERSITY IN THE

FIELD OF REGENERATIVE MEDICINE. IT WILL BE LOCATED, THE WORKSHOP, AT CHARLES DREW UNIVERSITY, BUT WILL INCLUDE MERCED, RIVERSIDE, THOSE KIND OF UNIVERSITIES, THOSE PLACES WHERE DIVERSITY IS A VERY IMPORTANT ISSUE. WE'RE BRINGING THEM TOGETHER. THE TARGET AUDIENCE FOR US IS TO GAIN A BETTER UNDERSTANDING HOW DIVERSITY AFFECTS BENEFITS, INCORPORATES A FULFILLMENT OF CIRM'S MISSION. AND USE OF THIS KNOWLEDGE IS A FOUNDATION FOR THE DEVELOPMENT OF FUNDING INITIATIVES THAT SUPPORT DIVERSITY IN REGENERATIVE MEDICINE. WE WANT TO FIND OUT WHAT WE CAN DO TO ENHANCE DIVERSITY IN CALIFORNIA. ESSENTIALLY WE'RE ASKING THOSE QUESTIONS, WE'RE BRINGING THE PEOPLE TOGETHER TO GET SOME VIEWS SO THAT WE CAN THEN BRING THEM BACK HERE AND WORK ON THEM.

SO THE TOPICS ARE SCIENCE, DIVERSITY IN REGENERATIVE MEDICINE, AND HOW TO ATTRACT PATIENTS AND PHYSICIANS INTO CLINICAL TRIALS AS SEVERAL OF THEM. IT'S ON FEBRUARY THE 26TH, I'M TOLD, NOT 25TH. PLEASE, IT'S ON THE 26TH. MR. TORRES, WE GOT THE DATE WRONG. ART TORRES IS THE CHAIR OF THIS DIVERSITY. SO IF YOU WANT MORE INFORMATION AND YOU WANT SPECIAL INVITES AND SEATINGS, SEE ART. IT SHOULD BE A VERY IMPORTANT MEETING, I THINK, AND

IT'S VERY MUCH WELCOMED BY THAT SECTOR OF THE COMMUNITY. THEY'RE LOOKING FORWARD TO IT.

THE OTHER WORKSHOP YOU MIGHT BE INTERESTED IN, WE DECIDED TO HAVE ONE ON THE SOMATIC CELL NUCLEAR TRANSFER. THIS IS THE CLONING TECHNIQUE, THE USE OF EGGS FOR THE DEVELOPMENT OF SCNT; THAT IS, EMBRYONIC STEM CELLS UTILIZING NUCLEAR TRANSFER. WE'RE GOING TO HAVE THAT WORKSHOP IN SAN FRANCISCO. WE'RE CO-WORKING WITH THE MRC, THE MEDICAL RESEARCH COUNCIL OF THE UNITED KINGDOM. AND LORD PATEL, WHO'S REALLY ONE OF THE KEY PEOPLE IN THE UK GOVERNMENT AND HOUSE OF LORDS, HE'S VERY KEEN TO BE INVOLVED AND BE THE CHAIR OF THAT COMMITTEE.

THE TARGET AUDIENCE FOR CIRM IS TO ASSESS THE NEED FOR TARGETED SOMATIC CELL NUCLEAR TRANSFER SUPPORT. WE'VE ONLY GOT ONE PROJECT IN THIS AREA. IT WAS A BIG POLITICAL ISSUE. BOB AND MANY OTHERS ARGUED IN A VERY DEEP AND MEANINGFUL WAY FOR HAVING THIS TECHNOLOGY AVAILABLE. WE WERE REALLY UNABLE TO REALLY INFLUENCE IT THROUGH THE SCIENTIFIC PROCESSES. WE EXPECT THE AUDIENCE TO BE SCIENTIFIC LEADERS IN HUMAN SOMATIC CELL NUCLEAR TRANSFER AND THE STAKEHOLDERS IN THAT FIELD.

SO THE TOPICS WILL BE THE CURRENT STATUS OF HUMAN SCNT. AND THERE WILL BE PEOPLE COMING FROM

CHINA, THE UK, CALIFORNIA, AND OTHER PARTS OF THE U.S. HURDLES THAT NEED TO BE OVERCOME AND HOW TO OVERCOME THEM, IF IT'S POSSIBLE. AND REALLY I THINK WE'VE GOT TO ASK THE QUESTION AT SOME POINT, ASSESS THE CONTINUED NECESSITY OF PURSUING THE SOMATIC CELL NUCLEAR TRANSFER. SOMETIME WE MIGHT HAVE TO SET IT ASIDE. I DON'T MEAN TO BURY IT, BUT TO SET IT ASIDE AND GET ON WITH OUR LIFE DOING SOME OTHER THINGS IF WE CAN'T HAVE AN IMPACT ON IT. IF IT WON'T COME GOOD, THEN MAYBE WE OUGHT TO WAIT UNTIL THE ANIMAL STUDIES DELIVER SOME BETTER TECHNOLOGY FOR US. SO WE HOPE THIS WILL BE AN INTERESTING WORKSHOP.

OKAY. SO THE VP R & D SEARCH UPDATE, WE'RE FOCUSING OUR SEARCH ON M.D. OR M.D./PH.D. PEOPLE, AND SOME OF THOSE HAVE ALSO GOT BUSINESS DEGREES, WITH CLINICAL DEVELOPMENT AND EXPERIENCE, ESPECIALLY THE PRECLINICAL PHASE I AND PHASE II EXPERIENCE. THEY NEED TO HAVE A PROVEN TRACK RECORD REPRESENTING DEVELOPMENT PROGRAMS IN FRONT OF THE FDA WITH EXCELLENT COLLABORATOR AND FACILITATOR CAPABILITY. SO THESE PEOPLE ARE GENERALLY, PRIMARILY FROM THE PHARMACEUTICAL INDUSTRY, AND THEY ARE VERY WELL-KNOWN PEOPLE IN THE PHARMACEUTICAL INDUSTRY WHO ARE VERY INTERESTED IN JOINING US.

SO WE'VE GOT AN EXCELLENT GROUP OF PEOPLE

COMING FORWARD FOR WHICH WE NEED TO SHORTEN THE LIST AND BRING THAT FORWARD FOR DETAILED INTERVIEWS.

SO I THINK ONE MORE SLIDE. SO LEVIN & COMPANY HAVE BEEN DOING THE FINDING FOR US, AND THEY IDENTIFIED AROUND 75 CANDIDATES. WE'VE BEEN THROUGH QUITE A LOT OF MEETINGS LOOKING AT WHICH WOULD BE THE BEST PEOPLE ON PAPER AND GETTING SOME FEEDBACK FROM THE LEVIN & COMPANY EXECUTIVES.

WE'VE MET WITH FOUR CANDIDATES, AND WE'RE MEETING WITH ANOTHER FOUR OVER THE NEXT FEW WEEKS. MOSTLY WE'RE TRYING TO TELL THEM WHAT WE DO BECAUSE WE DON'T WANT THEM TO BE INTERESTED IF THEY THINK THIS IS A BIOTECH COMPANY BECAUSE IT'S NOT. WE WANT THEM TO UNDERSTAND WHAT WE DO. SO THE FIRST PART OF IT IS FOR US TO GIVE THEM A DOWNLOAD OF WHAT WE DO. AND WE'VE BEEN DOING THAT, AND ONLY ONE OF THEM WHERE WE'VE GONE INTO SOME DISCUSSION ABOUT THEIR BACKGROUND.

WE WILL HAVE SEVERAL PEOPLE FROM OVERSEAS, ONE OF WHOM I THINK WILL BE VISITING NEXT WEEK, AND WE WILL TRY AND DO MORE OF AN INTENSIVE INTERVIEW RATHER THAN TRY AND BRING THEM BACK TWICE. SO SOME OF THE BOARD MEMBERS, WE HOPE, WILL COME AND MEET THESE PEOPLE. WE ARE RESTRICTED IN THE NUMBER OF BOARD MEMBERS THAT WE CAN INTRODUCE IN THIS PROCESS.

SO I NEED TO BE VERY CAREFUL ABOUT ALL OF THIS. AND WE NEED TO LOOK AFTER THE NAMES OF THESE PEOPLE BECAUSE THEY'RE VERY HIGH IN THE COMPANIES THAT THEY WORK IN, AND WE DON'T WANT TO PUT THEIR INTERESTS AT RISK IN THEIR OWN POSITION. SO WE ANTICIPATE HAVING A VERY SHORT LIST BY FEBRUARY OR MARCH, HOPEFULLY BY FEBRUARY. HOPEFULLY WE'LL MAKE THE OFFER AROUND FEBRUARY AND THEN GET THE PERSON AS QUICKLY AS IS FEASIBLE. SO THAT'S THE KIND OF FRAMEWORK THAT WE'RE WORKING IN.

IF I MAY, CHAIR, CAN I ASK GEOFF LOMAX TO DO WHAT HE WAS NEEDED TO DO LAST TIME, GIVE US A QUICK VIEW OF THE COMPLIANCE PROGRAM THAT WE'VE RUN? THANKS, GEOFF.

DR. LOMAX: THANK YOU, DR. TROUNSON, MR. CHAIR, MEMBERS OF THE BOARD. WHAT I'M GOING TO PROVIDE IS AN UPDATE OUR COMPLIANCE PROGRAM, WHICH IS MODELED AFTER THE NIH PROACTIVE SITE VISIT PROGRAM. THE PROGRAM SERVES TO ACTIVELY SUPPORT COMPLIANCE WITH REGULATORY REQUIREMENTS.

WHAT THE COMPLIANCE PROGRAM INCORPORATES IS OUR INSTITUTIONAL -- WE DO A SITE VISIT TO EVALUATE THE INSTITUTIONAL RESEARCH OVERSIGHT, WHICH FUNDAMENTALLY IS THE SCRO COMMITTEE. WE THEN EVALUATE THE EFFECTIVENESS OF THIS COMMITTEE BY

LOOKING AT SPECIFIC GRANT APPLICATIONS AND HOW THAT COMMITTEE HAS SERVED TO REVIEW THOSE GRANTS. IN ADDITION, FOR THE SAME GRANTS, WE MEET WITH PRINCIPAL INVESTIGATORS AND WE LOOK AT THEIR PUBLICATIONS AND THEIR IP REPORTING BECAUSE, AGAIN, THERE'S PUBLIC POLICY REQUIREMENTS FOR REPORTING THERE. AND FINALLY, MY COLLEAGUE CYNTHIA SCHAFFER INCLUDES A COMPONENT WHERE SHE IS LOOKING AT EXPENDITURE TRACKING REALLY TO UNDERSTAND OUR GRANTEES' INTERNAL SYSTEMS FOR BUDGET MONITORING.

I DO WANT TO EMPHASIZE THAT THIS IS ONE PART OF A FAR MORE COMPREHENSIVE SYSTEM AT CIRM FOR LOOKING AT POLICY COMPLIANCE. AND FIRST AND FOREMOST, OUR GRANTS ADMINISTRATION TEAM IN THEIR PREFUNDING REVIEW LOOKS AT A WHOLE SERIES OF PUBLIC POLICY ASSURANCES, PERSONNEL, THEY COMPILE THE PUBLICATIONS AND IP REPORTING INFORMATION WHICH IS REQUIRED BY CIRM REGULATION, AND OBVIOUSLY THEY SPEND A SUBSTANTIAL AMOUNT OF TIME ON BUDGET AND EXPENDITURE REPORTING.

IN ADDITION, I WANT TO HIGHLIGHT THE WORK OF THE SCIENTIFIC PROGRAM. THEY ARE LOOKING VERY CAREFULLY AT SCIENTIFIC PROGRESS THROUGH THE SCIENTIFIC PROGRESS REPORTS. PUBLICATIONS, THERE'S AN ACTIVE SYSTEM FOR TRACKING PUBLICATIONS. AND,

AGAIN, THEY'RE ENSURING THAT BUDGETS ARE JUSTIFIED.

NOW, IF YOU JUST GO BACK ONE. JUST AS A REMINDER, BOTH GRANTS ADMINISTRATION AND SCIENTIFIC PROGRAM, THEY DO A VERY ACTIVE DRILL-DOWN ON EVERY CIRM-FUNDED GRANT; WHEREAS, IN THE COMPLIANCE PROGRAM, IT'S BASICALLY A SPOT-CHECK OF SELECTED GRANTS.

AND SO LET ME GIVE YOU -- SHOW YOU OUR PROTOCOL. WHAT WE DO IS WE FIRST DO AN INTERNAL REVIEW OF THE PORTFOLIO. AND BECAUSE THIS IS FOCUSING ON OUR MEDICAL AND ETHICAL STANDARDS, WE TEND TO LOOK FOR GRANTS IN WHICH THERE IS A FAIRLY SUBSTANTIAL LEVEL OF REVIEW REQUIRED. SO, FOR EXAMPLE, A GRANT INVOLVING THE DERIVATION OF HUMAN EMBRYONIC STEM CELL LINES WHERE THERE ARE EMBRYOS INVOLVED, AND THAT TRIGGERS A SERIES OF IMPORTANT REVIEW REQUIREMENTS. WE LOOK THROUGH THE FILES, WE PREPARE FOR THE FIELD, AND THEN WE ACTIVELY GO ON-SITE AT THE INSTITUTION. WE FIRST LOOK AT THEIR OVERALL PROGRAM FOR OVERSIGHT. SO, AGAIN, WE'RE LOOKING AT THE COMPOSITION OF THEIR OVERSIGHT COMMITTEE, MAKING SURE THE COMMITTEE IS COMPRISED OF THE APPROPRIATE EXPERTS, AND THEN WE LOOK AT HOW THAT COMMITTEE REVIEWED THE PARTICULAR GRANT IN QUESTION.

IN ADDITION, AS I MENTIONED, MY COLLEAGUE CYNTHIA SCHAFFER WILL ALSO BE LOOKING AT CERTAIN BUDGETARY PERFORMANCE WITHIN THAT GRANT. WE DOCUMENT THE COMPLIANCE STATUS THROUGH A SERIES OF CHECKLISTS. WE USE THOSE CHECKLISTS TO PROVIDE A DETAILED FEEDBACK REPORT TO THE GRANTEE. THE GRANTEE HAS AN OPPORTUNITY TO REVIEW THAT REPORT, AND THEN THE REPORT IS INCLUDED IN THE FILE FOR THIS PROGRAM.

SOME QUICK HIGHLIGHTS TO DATE. WE'VE COMPLETED SITE VISITS AT EIGHT INSTITUTIONS. AND AMONG OUR ACADEMIC RESEARCH CENTERS, WHICH ARE THE ONES WE'VE FOCUSED ON TO DATE, THE OVERSIGHT STRUCTURE IS CONSISTENT WITH OUR REGULATIONS, AND WE'VE BEEN QUITE PLEASED WITH THE ATTENTION TO DETAIL IN THE OVERALL STRUCTURE. THE REVIEW OF SPECIFIC APPLICATIONS BY THE COMMITTEE IS CONSISTENT WITH THE REGULATORY REQUIREMENTS, SO THEY'RE SORT OF TRIAGING THEIR REVIEWS IN ACCORDANCE WITH THE ETHICAL CHALLENGES FOR THAT PARTICULAR APPLICATION.

WE HAVE PROVIDED RECOMMENDATIONS TO TWO INSTITUTIONS REGARDING THE NEED FOR MORE EXPLICIT PROCEDURES AND POLICIES TO GOVERN THEIR OPERATIONS. IT'S REALLY A TRANSPARENCY ISSUE. WE REALLY WANT TO MAKE SURE THERE'S A HIGH LEVEL OF DOCUMENTATION

CONSISTENT WITH OUR REQUIREMENTS, AND THE GRANTEE INSTITUTIONS HAVE BEEN BOTH RESPONSIVE AND APPRECIATIVE OF OUR FEEDBACK. THIS IS A LEARNING EXPERIENCE FOR EVERYONE.

WE IDENTIFIED ONE PATENT THAT HAD NOT BEEN REPORTED, AND THE GRANTEE HAS NOW ADDRESSED THAT. CIRM HAS WORKED WITH TWO GRANTEE INSTITUTIONS TO ENSURE COMPLIANCE WITH ANIMAL CARE ACCREDITATION REQUIREMENTS. AND I THINK THE MOST IMPORTANT PART IS THAT THE SITE VISITS GENERALLY RESULT IN ONGOING COMMUNICATION BETWEEN CIRM AND THE INSTITUTIONS. WE DEVELOP RAPPORT, WE DEVELOP NAME RECOGNITION, AND THEY LEARN THAT THEY CAN VIEW US AS A RESOURCE TO SUPPORT COMPLIANCE OVERALL.

AND THAT'S MY REPORT. IF YOU HAVE ANY QUESTIONS, I'D BE HAPPY TO ANSWER.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND I'D LIKE TO POINT OUT THAT THIS LAST WEEK NIH RELEASED THE FIRST 13 HUMAN EMBRYONIC STEM CELL LINES WITH FULL APPROVAL. AND GEOFF LOMAX REALLY LED THIS AGENCY AND THE COUNTRY IN THE PROCESS OF GOING THROUGH THE COMMENTS THAT LED TO NIH'S FINAL APPROVAL PROCESS AND CRITERIA FOR EMBRYONIC STEM CELL LINES. I THINK WE SHOULD GIVE HIM A GREAT HAND OF APPLAUSE.

(APPLAUSE.)

DR. TROUNSON: SO CAN I ASK MARGARET TO COME FORWARD AND GIVE SOME OF THE -- JUST THE WINDUP OF LAST YEAR'S WHOLE BUDGET AND WHERE WE ARE AT THE MOMENT THIS YEAR.

MS. FERGUSON: OKAY. GOOD EVENING, MEMBERS OF THE ICOC, CIRM STAFF, AND MEMBERS OF THE PUBLIC. I'M HERE TODAY TO PRESENT THE FINAL OVERVIEW OF THE 2008-9 OPERATING BUDGET, REPORT ON THE OCTOBER 2009 BUDGET ALLOCATION AND EXPENDITURES, AND GIVE AN UPDATE ON DONATIONS RECEIVED THROUGH NOVEMBER OF 2009.

I WOULD LIKE TO BEGIN WITH THE FINAL EXPENDITURES OF THE 2008-9 OPERATING BUDGET. THIS PRESENTATION IS ONLY, AGAIN, ON WHAT CIRM SPENT ON OPERATIONS AND DOES NOT INCLUDE ANY GRANT FUNDING. THE SUMMARY BAR CHART OR THE BAR CHART SUMMARY YOU SEE ON THE SCREEN INDICATES THAT UNDER SALARIES AND BENEFITS, 5.4 MILLION OF THE $7 MILLION DOLLAR BUDGET ALLOCATION WAS EXPENDED. AND MOVING ONTO OE&E, WHICH IS OPERATING EXPENDITURES AND EQUIPMENT, WE EXPENDED 4.9 MILLION OF THE 6.3 THAT WAS ALLOCATED. AND FINALLY, CIRM EXPENDED A TOTAL OF $10.4 MILLION OF THE ENTIRE 2008-9 BUDGET OR $13.4 MILLION OR 78 PERCENT OF THE TOTAL BUDGET.

AS HAD BEEN PROJECTED, CIRM ENDED THE FISCAL YEAR WITH A 22-PERCENT SAVINGS, AND THOSE AREAS OF EXPENSE THAT RECORDED SAVINGS ARE INDICATED ON THE CHART THAT WAS PROVIDED IN YOUR BINDER. AND IF YOU HAVE ANY QUESTIONS CONCERNING THESE SAVINGS OR THE FINAL 2008-9 EXPENDITURES, I'D BE GLAD TO ADDRESS THEM AT THIS TIME.

MR. GOLDBERG: FIRST OF ALL, VERY NICE JOB. AND THANK YOU FOR YOUR HARD WORK ALL YEAR LONG AND YOUR TEAM'S HARD WORK AND TO JOHN ROBSON ALSO.

(APPLAUSE.)

MR. GOLDBERG: HOW MUCH OF THE SAVINGS IS ONGOING VERSUS TIMING ISSUES THAT WE'LL PICK UP IN THE NEXT FISCAL YEAR IN YOUR OPINION?

MS. FERGUSON: WELL, A PORTION OF THE SAVINGS ARE FOR THIS 2008 AND 9. IN SALARIES AND BENEFITS, WE HAD A SIGNIFICANT SAVINGS. AND THAT WAS DUE TO THE FACT THAT WE WERE UNABLE TO -- WE HAD BUDGETED FOR 44 POSITIONS AND WE CLOSED THE YEAR AT 38. SO WE WILL LOOK -- IT LOOKS LIKE WE WILL STILL GARNER SAVINGS IN SALARIES AND BENEFITS, AND THAT'S ALL DUE TO THE FACT THAT WE HAVE TO GO THROUGH A RIGID OR RIGOROUS HIRING PROCESS AND GET THE RIGHT CANDIDATES FOR THE POSITIONS. SO YOU ARE GOING TO HAVE A SAVINGS IN THAT AREA.

RIGHT NOW IN THE -- WELL, WHEN WE GET TO THE CURRENT YEAR, YOU WILL SEE THAT WE REDUCED OUR OVERALL BUDGET. WHEN WE CAME TO YOU LAST JUNE, WE MADE A SIGNIFICANT REDUCTION WHEN WE WENT THROUGH AND DEVELOPED THE BUDGET SO THAT WE COULD MORE CLOSELY RECORD EXPENDITURES TO WHAT WE ALLOCATED. NOW, I WOULD STILL SAY THAT IN SALARIES AND BENEFITS WE WILL GARNER A SAVINGS; AND BASED ON WHAT I'M LOOKING AT, WE -- IT'S TOO EARLY TO TELL IN THE OPERATING EXPENSES WHAT WILL HAPPEN THERE. BUT AS WE GO THROUGH THE OCTOBER ONE, I'LL GIVE YOU A SNAPSHOT OF WHERE WE ARE.

MR. GOLDBERG: THANK YOU.

MS. FERGUSON: OKAY. HERE WE GO. AGAIN, IN EACH OF YOUR BINDERS, YOU HAVE THE SUPPORTING DETAIL FOR THE BAR CHART THAT'S NOW DISPLAYED ON THE SCREEN. AND I'LL BRIEFLY, AGAIN, SAY THAT THROUGH OCTOBER 31, 2009, WE HAVE RECORDED TOTAL EXPENDITURES OF 2.9 MILLION OF OUR TOTAL $12.9 MILLION BUDGET OR JUST 23 PERCENT. THE CHART INDICATES THAT 2.2 MILLION OF THE 7.4 THAT WAS BUDGETED FOR SALARIES AND BENEFITS HAS BEEN EXPENDED, AND $827,000 OF THE 5.5 THAT WAS ALLOCATED FOR OPERATING EXPENDITURES AND EQUIPMENT, THAT INCLUDES THINGS LIKE, BUT IT'S NOT LIMITED TO,

INTERAGENCY AGREEMENTS, CONTRACTS, MEETINGS, INFORMATION TECHNOLOGY, TRAVEL, OFFICE SUPPLIES, TRAINING, AND COMMUNICATIONS SERVICES. THE EXPENDITURES INDICATE THAT WE'VE RECORDED 15 PERCENT OF OUR OPERATING EXPENDITURE AND EQUIPMENT BUDGET AND 29 PERCENT OF OUR SALARIES AND BENEFITS ALLOCATION. OVERALL THE EXPENDITURE SUMMARY BEFORE YOU INDICATES THAT 23 PERCENT OF THE APPROVED BUDGET ALLOCATION HAS BEEN APPROVED -- I'M SORRY -- RECORDED.

HOWEVER, WHAT I WOULD LIKE TO BRING TO THE BOARD'S ATTENTION IS THAT THERE IS A MINIMUM ONE-MONTH LAG ON INVOICES AND AN EVEN GREATER LAG DURING THE FIRST FOUR MONTHS OF THE FISCAL YEAR BECAUSE AGENCIES ARE CLOSING BOOKS, PREPARING YEAR-END FINANCIAL STATEMENTS, AND SETTING UP FOR THE NEW FISCAL YEAR IN JULY AND AUGUST. TYPICALLY INVOICES FOR GOODS AND SERVICES RENDERED IN ONE MONTH ARE NOT PROCESSED FOR PAYMENT OR POSTED TO OUR BUDGET REPORTS UNTIL THE SUBSEQUENT MONTH. IN ADDITION TO THIS MONTHLY LAG IN PROCESSING INVOICES, WE HAVE CONTRACTS AND SOME INTERAGENCY AGREEMENTS THAT ARE NOT PAID ON A MONTHLY BASIS, BUT RATHER ON A QUARTERLY BASIS OR WHEN THE FINAL PRODUCT HAS BEEN RECEIVED AND APPROVED.

WE CURRENTLY HAVE OUTSTANDING ACCRUED OBLIGATIONS OF APPROXIMATELY $565,000 THROUGH OCTOBER '09 THAT HAVE NOT BEEN RECORDED ON THE OCTOBER BUDGET REPORT. WHEN WE RECOGNIZE THESE OUTSTANDING OBLIGATIONS, THE OPERATING EXPENSES AND EQUIPMENT BUDGET WILL REFLECT THAT 25 PERCENT OF THE BUDGET ALLOCATION WAS EXPENDED AND THAT OVERALL WE'VE EXPENDED 27 PERCENT OF OUR 2009-10 BUDGET. IF WE WERE SPENDING AT THIS POINT IN TIME EVERY -- I WOULDN'T SAY EVERY NICKEL THAT WE WOULD HAVE IN THE FIRST THIRD OF THE YEAR, IT WOULD BE ABOUT 33 PERCENT OF THE OVERALL BUDGET. SO WE'RE RUNNING ABOUT 6 PERCENT UNDER AT THIS POINT IN TIME WITH 4 PERCENT OF THAT BEING IN SALARIES AND BENEFITS.

NOW, IF YOU HAVE ANY QUESTIONS ON THE INFORMATION THAT WAS IN YOUR BINDER, I'D BE GLAD TO ADDRESS IT.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. WE ALWAYS APPRECIATE YOUR WORK. SHE SPENDS A LOT OF LATE NIGHTS. I THINK IT WOULD BE APPROPRIATE TO GIVE HER A HAND OF APPLAUSE.

(APPLAUSE.)

MR. GOLDBERG: AND TO CONGRATULATE REALLY ALAN AND THE WHOLE ORGANIZATION FOR YOUR SPENDTHRIFTNESS, AND IT'S APPRECIATED BY, NOT ONLY

THE BOARD, BUT ALSO BY ALL THE TAXPAYERS IN CALIFORNIA THAT MAKE THIS POSSIBLE.

DR. TROUNSON: THANKS, MICHAEL. WE APPRECIATE THAT. SO, CHAIR, JUST TO FINISH OFF, THERE'S A COUPLE OF SLIDES BY JOHN ROBSON.

MS. FERGUSON: I HAVE ONE MORE.

DR. TROUNSON: I'M SORRY.

MS. FERGUSON: THE DONATION REPORT. ALL RIGHT. DURING THE PERIOD JULY THROUGH NOVEMBER '09, WE RECEIVED $790 IN DONATIONS THAT WERE MADE IN MEMORY OF ROBERT QUIST. AND I WOULD LIKE TO READ THE DONOR NAMES AT THIS TIME BECAUSE IT IS IMPORTANT THAT WE ACKNOWLEDGE THESE DONATIONS THAT ARE MADE OR WERE MADE BECAUSE FAMILIES SUFFERED LOSSES TO DISEASES THAT HAVE NO CURES. AND THEY ARE ROD AND JUDY ALTHOUSE, NANCY AND PETER BELL, M. BENNETT, DR. ANDREW CHIN AND FAMILY, LORETTA CHIN, MR. AND MRS. BERNARD GOTTFRIED, PAMELA HAMILTON AND FAMILY, GARY HARRISON, THE KINGS INVESTMENT CLUB OF HANFORD, PHYLLIS MANN, BARBARA RAMOS, JOSEPH M. AND ELIZABETH D. SEAMUS, RICHARD C. AND MARCIA K. WINNEN, CLARENCE R. AND MILDRED C. WILLIAMS, HELEN WONG, J. K. WONG, JANET MAY WONG, AND WILLIAM AND PATRICK YICK.

I HAD THE OPPORTUNITY TO SPEAK WITH BOTH MRS. QUIST AND HER BROTHER WHO ACTUALLY MADE THE

ARRANGEMENTS FOR THE DONATIONS TO BE MADE IN MEMORY OF MR. QUIST. AND I HAD THE OPPORTUNITY TO TELL THEM THAT CIRM IS VERY FOCUSED IN ITS MISSION TO FUNDING THE BEST SCIENCE THAT WILL LEAD TO FINDING THOSE CURES. AND I THANK YOU.

CHAIRMAN KLEIN: THANK YOU VERY MUCH.

(APPLAUSE.)

DR. ROBSON: MR. CHAIRMAN, I'D LIKE TO GIVE YOU A REPORT ON OUR OVERALL FINANCES. THIS IS SORT OF AN EXTENSION OF WHAT MARGARET HAS JUST DONE. I'M GOING TO INCLUDE THE GRANT FUNDS AND SHOW YOU WHERE WE ARE, OUR OVERALL FINANCIAL SITUATION, AND GIVE YOU SORT OF A SNAPSHOT OF HOW THINGS LOOK INTO THE FUTURE FOR ABOUT THE NEXT YEAR AND A HALF.

SO FIRST SLIDE, SO THE PROJECTIONS THAT I'M GOING TO SHOW YOU, THIS IS WHAT'S INCLUDED IN THOSE PROJECTIONS IN ADDITION TO THE OPERATIONS COSTS THAT MARGARET GAVE YOU. IT WILL INCLUDE ALL PROGRAMS THAT ARE CURRENTLY ACTIVE, ALL PROGRAMS THAT HAVE BEEN APPROVED BY THE ICOC, AND THAT INCLUDES DISEASE TEAMS, WHICH WERE APPROVED AT $230 MILLION AT THE LAST MEETING. AND IT ALSO INCLUDES PROGRAMS THAT HAVE RECEIVED CONCEPT APPROVAL BY THE BOARD. SO THOSE INCLUDE BASIC BIOLOGY AT THE RECOMMENDED BUDGET OF 30 MILLION, IMMUNOLOGY AT

ANOTHER 30 MILLION, AND THEN THE RESEARCH LEADERSHIP AWARDS BUDGETED AT 44 MILLION. SO THIS IS WHAT'S INCLUDED IN THIS PROJECTION.

IT DOES NOT INCLUDE THE EARLY TRANSLATION PROGRAM II, WHICH YOU WILL BE ASKED TO APPROVE FOR CONCEPT APPROVAL AT THIS MEETING. SO THE NUMBERS WILL CHANGE A LITTLE BIT. THAT ONE PROBABLY WOULDN'T ACTUALLY BEGIN FUNDING UNTIL -- THE CASH FLOW WOULDN'T BEGIN UNTIL A YEAR FROM NOW OR A LITTLE BIT MORE THAN THAT, SO IT WON'T HAVE A HUGE IMPACT ON THIS, BUT LET ME JUST SHOW YOU WHERE WE ARE NOW.

SO I'VE SHOWN THIS DASHBOARD PICTURE BEFORE, BUT I DIDN'T SHOW IT AT THE LAST MEETING BECAUSE WE DIDN'T HAVE ENOUGH TIME, SO MAYBE I'LL JUST DESCRIBE IT TO YOU ONE MORE TIME BECAUSE IT IS COMPLICATED, ALTHOUGH I THINK IT'S A NICE WAY TO REPRESENT WHERE WE ARE. EACH OF THE VERTICAL BARS REPRESENT OUR EXPENDITURES IN THE DIFFERENT QUARTERS BEGINNING JANUARY OF '09 AND GOING UNTIL THE END OF JUNE 2011. THAT'S THE END OF THE FISCAL YEAR 2010-11. THE Y AXIS HERE ON THE LEFT, THOSE NUMBERS REFER TO THOSE VERTICAL BARS, AND EACH OF THOSE BARS, THE BLUE REPRESENTS THE PROJECTED EXPENDITURES ON GRANTS, AND THE TAN REPRESENTS THE EXPENDITURES

FOR OPERATIONS. SO YOU CAN SEE MOST OF OUR MONEY GOES OUT TO OUR GRANTEES.

THE GREEN LINE REPRESENTS THE AMOUNT OF MONEY THAT WE HAVE IN THE BOND FUND. SO THIS IS OUR BANK ACCOUNT. THE NUMBERS ON THE RIGHT, VERTICAL AXIS ON THE RIGHT, SHOW -- REFER TO THAT GREEN LINE. SO YOU CAN SEE A COUPLE OF TIMES IT'S GONE UP, AND THAT'S WHERE WE'VE RECEIVED NEW FUNDS. SO YOU REMEMBER LAST APRIL WE RECEIVED 270 MILLION. IN OCTOBER THIS YEAR WE RECEIVED ANOTHER 118 MILLION. UNFORTUNATELY I DIDN'T GET TO DO THIS PRESENTATION IN OCTOBER RIGHT AFTER THE MONEY CAME, BUT ANYWAY, IT'S STILL NICE TO BE ABLE TO SAY THAT TO YOU. WE GOT AN ADDITIONAL 118 MILLION. AT THE END OF THIS QUARTER, WE'LL HAVE ABOUT $406 MILLION AVAILABLE FOR OUR OPERATIONS AND OUR GRANT FUNDS.

AS YOU PROJECT FORWARD, YOU WOULD SEE THAT THAT WILL REACH ZERO HERE, THE RED LINE IS ZERO; AND AS I ALWAYS SAY, WE WANT TO KEEP THE GREEN LINE ABOVE THE RED LINE. SO WE WILL BE AT THE END OF THE FISCAL YEAR 2011, WE WILL BE DOWN TO ABOUT ZERO IN THE ACCOUNT. THAT'S NOT NECESSARILY THE WAY I SHOULD SAY IT. I SHOULD SAY WE HAVE ADEQUATE FUNDS TO FUND ALL OF OUR PROGRAMS BETWEEN NOW AND THE END OF THE FISCAL YEAR 2011. SO I WOULD SAY WE'LL BE

LOOKING AT TRYING TO RAISE SOME MORE MONEY THROUGH BOND SALES IN THE SECOND HALF OF NEXT YEAR.

SO ANY QUESTIONS ABOUT THAT?

CHAIRMAN KLEIN: IN TERMS OF THE TRANSLATIONAL GRANT THAT YOU REFERENCED, I THINK IT WOULD BE APPROPRIATE WHILE WE HAVE THIS SLIDE UP TO GIVE THE BOARD A SENSE OF THE EFFECT OF FUNDING THAT IN TERMS OF THESE NUMBERS.

DR. ROBSON: SO THE REQUEST FOR THAT IS $80 MILLION. IT'S A THREE-YEAR PROGRAM. REALISTICALLY THE FIRST GRANTS PROBABLY WON'T -- MONEY WON'T GO OUT TO THOSE UNTIL THE FIRST QUARTER OF 2011 BECAUSE IT'S NOT SCHEDULED TO COME TO YOU UNTIL NEXT OCTOBER FOR APPROVAL. IT USUALLY TAKES ABOUT A QUARTER BEFORE THEY ACTUALLY GET THROUGH ALL THE PFAR AND THE MONEY ACTUALLY FLOWS OUT.

NOW, YOU RECALL WE NOW HAVE BEEN DOING FOR THE LAST YEAR OR SO OUR PAYMENTS ON A QUARTERLY BASIS. SO A QUARTER -- THAT WOULD MEAN THAT TWO QUARTERS WOULD BE PAID BETWEEN JANUARY AND THE END OF JUNE PROBABLY. THAT WOULD AMOUNT TO ABOUT $13 MILLION. SO THE IMPACT ON THAT WOULD BE ABOUT 13 MILLION. THAT WOULD PUT US ABOUT 13 MILLION BELOW.

CHAIRMAN KLEIN: THAT'S RIGHT. AND REMEMBER OUR ORIGINAL GOAL WAS TO MAKE SURE THAT WE

GOT TO DECEMBER 2010 WITH RESERVES, SO WE'VE ACHIEVED THAT AND WE'RE BEYOND THAT.

DR. ROBSON: THAT'S TRUE, BUT I THINK FOR THE PURPOSES OF THE INFORMATION I'M TRYING TO GIVE TO YOU, I TRY TO KEEP ABOUT A 18- TO 24-MONTH LOOK FORWARD JUST SO YOU CAN SEE WHERE WE ARE. 2010 HAS MOVED BACK ON MY SCALE BECAUSE I'M GOING TO KEEP MOVING THIS THING FORWARD.

CHAIRMAN KLEIN: OUR PROJECTIONS THAT LYNN HARWELL AND I DO FOR THE TREASURER'S OFFICE HAS AN 18-MONTH TO TWO-YEAR, SOMETIMES A THREE-YEAR LOOK FORWARD TO MAKE SURE THAT WE'RE AT THE TOP OF THEIR LIST. AND CERTAINLY SENATOR TORRES MAKES CERTAIN THAT THAT HAPPENS AT THE TREASURER'S OFFICE.

IT IS IMPORTANT AS WELL, SINCE WE HAVE ANOTHER ITEM THAT WILL COME UP TOMORROW, WHICH IS THE BRIDGES AND CONSIDERATION OF THOSE RECOMMENDED FOR FUNDING IF FUNDS WERE AVAILABLE FOR BRIDGES AND TRAINING GRANTS II, TO GIVE THIS BOARD, I THINK, A SENSE OF HOW MUCH THAT WOULD AFFECT, A, OUR DECEMBER 2010 TOTAL AND THE JUNE 2011 TOTAL.

DR. ROBSON: WELL, OF COURSE, THAT DEPENDS ON THE AMOUNT OF MONEY.

CHAIRMAN KLEIN: ASSUMING THEY WERE TO APPROVE THEM ALL AND THEN THEY CAN STEP BACK FROM

THAT.

DR. ROBSON: I THINK THE TOTAL AMOUNT WAS SOMETHING IN THE NEIGHBORHOOD OF 11 AND A HALF, 11 AND A HALF MILLION. AGAIN, ASSUMING THAT THOSE THINGS WOULD START IN THE NEXT QUARTER, THE FIRST QUARTER OF NEXT YEAR, THAT WOULD BE ABOUT A YEAR AND A HALF GOING FORWARD. SO THAT WOULD BE ABOUT HALF OF THAT TO THE END OF JUNE 2011. SO THAT WOULD BE FIVE TO $6 MILLION IMPACT ON THAT. IT WOULD BE, WHAT, SIX MONTHS LESS THAN THAT GOING. SO IT'D PROBABLY BE ABOUT THREE TO FOUR MILLION GOING TO THE END OF 2010.

CHAIRMAN KLEIN: OKAY. THANK YOU VERY MUCH. ANY OTHER QUESTIONS? NO OTHER QUESTIONS. THANK YOU VERY MUCH, JOHN.

ALL RIGHT. SO IF I COULD GET ADVICE HERE IN TERMS OF WHERE WE ARE. IS DR. FRIEDMAN AVAILABLE AT THIS TIME?

MS. KING: HE'S WITH A PATIENT.

CHAIRMAN KLEIN: HE'S WITH A PATIENT.

MS. KING: HE WAS PLANNING TO JOIN BY PHONE, BUT HAD TO BE WITH A PATIENT.

CHAIRMAN KLEIN: SO AT THIS POINT ARE WE ONE SHORT OF QUORUM? YES. SO WHAT I'D LIKE TO DO TO EFFECTIVELY USE THE TIME IS PROCEED THROUGH THE

NEXT FEW ITEMS. AND WHAT WE WILL DO IS THEN WHEN WE BRING THEM UP TOMORROW WITH A QUORUM, WE WILL HAVE HAD THE OPPORTUNITY TO HAVE PRESENTATIONS, QUESTIONS, PUBLIC COMMENT. AND THEN FOR THOSE INCREMENTAL MEMBERS WHO ARE HERE, WE'LL TRY AND ADDRESS THEIR SPECIFIC QUESTIONS, BUT IT WILL GIVE US THE ABILITY HOPEFULLY TO MOVE THROUGH IT VERY QUICKLY.

SO ITEM 9 IS CONSIDERATION OF NEW SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP. DR. GIL SAMBRANO, WILL YOU PLEASE PRESENT THIS ITEM?

DR. SAMBRANO: YES, I'D BE HAPPY TO. MR. CHAIR AND MEMBERS OF THE BOARD, TODAY WE'RE BRINGING FOR YOUR CONSIDERATION SIX NOMINEES FOR THE ALTERNATE GRANTS WORKING GROUP OR AS ALTERNATE GRANTS WORKING GROUP MEMBERS WHO ARE GOING TO EXPAND OUR OVERALL EXPERTISE IN THE AREAS OF TUMOR SUPPRESSION, CELLULAR REPROGRAMMING, CELL SIGNALING, DIABETES, AND TRANSPLANTATION.

AS A REMINDER, ALL ALTERNATE GRANTS WORKING GROUP MEMBERS MAY BE CALLED UPON TO PARTICIPATE IN A GRANTS WORKING GROUP MEETING AS AN AD HOC REVIEWER OR ASKED TO BECOME A REGULAR MEMBER OF THE WORKING GROUP TO REPLACE CURRENT MEMBERS AS NECESSARY. THESE NEW MEMBERS WOULD ALSO BE SUBJECT

AND MUST AGREE TO ABIDE BY THE SAME CONFLICT OF INTEREST RULES AND THE SAME FINANCIAL DISCLOSURE POLICY AS REGULAR MEMBERS.

THE NOMINEES ARE SHOWN AND LISTED IN ITEM 9 IN YOUR BOOKS. WE PROVIDED A BRIEF BIO. THE SIX NOMINEES INCLUDE DR. WAFIK EL-DEIRY, DR. OLLE KORSGREN, DR. THEODORE RASMUSSEN, DR. NORMAN SHARPLESS, DR. IGOR SLUKVIN, AND DR. MICHAEL B. YAFFE. AND THIS WOULD BRING THE NUMBER OF ALTERNATE MEMBERS OF THE WORKING GROUP NOW TO A TOTAL OF 111. AND SO WE REQUEST YOUR APPROVAL AND APPOINTMENT OF THESE NOMINEES AS ALTERNATE MEMBERS OF THE WORKING GROUP.

MR. TORRES: ARE THERE ANY COMMENTS FROM MEMBERS OF THE BOARD?

MR. GOLDBERG: I WOULD JUST SAY THAT I KNOW DR. YAFFE. AND IF THE OTHER MEMBERS THAT YOU ARE PROPOSING ARE AT ALL IN HIS LEAGUE, I THINK IT'S AN EXTRAORDINARY SLATE.

MR. TORRES: ANY FURTHER COMMENTS? MR. PRESIDENT.

DR. TROUNSON: ACTING CHAIR, WE DO HAVE A MICHAEL YAFFE IN THE STAFF. I'M JUST WONDERING --

MR. GOLDBERG: I APOLOGIZE. I CONSIDER HIM IN THAT LEAGUE AS WELL. I WAS SPECIFICALLY

REFERRING TO THE PROFESSOR AT MIT, HOWEVER.

CHAIRMAN KLEIN: ALL RIGHT. SO IF THERE ARE NOT ANY OTHER QUESTIONS, I THINK I'D ASK FOR ADDITIONAL STAFF COMMENT. IS THERE ANY PUBLIC COMMENT ON THIS ITEM? SEEING NO PUBLIC, DR. SAMBRANO, I THINK WHAT WE'LL DO IS TRY AND PICK THIS UP TOMORROW AND BE ABLE TO MOVE THROUGH IT QUICKLY. THANK YOU VERY MUCH.

WITH ITEM NO. 10, THE GRANTS WORKING GROUP BYLAWS, DR. SAMBRANO IS GOING TO PRESENT THAT AS WELL.

DR. SAMBRANO: SO THAT'S OKAY. SO WITH REGARD TO THE BYLAWS, SO ON SEPTEMBER 9TH THE GRANTS WORKING GROUP CONSIDERED AND RECOMMENDED TO THE ICOC AN AMENDMENT TO THE GRANTS WORKING GROUP BYLAWS IN ORDER TO REFLECT CHANGES PROPOSED FOR SELECTING AND APPOINTING THE CHAIR OF THE GRANTS WORKING GROUP.

THESE PROPOSED CHANGES INCLUDE MODIFICATIONS IN ARTICLE 4, SECTION 9 AND AN ADDITION OF SECTION 9.5, BOTH RELATED TO THE PROCESS OF APPOINTMENT OF WHAT WE WERE CALLING ADMINISTRATIVE CHAIR AND ACTING CHAIR OF THE GRANTS WORKING GROUP WITH THEIR RESPECTIVE DUTIES. THESE WERE PRESENTED TO YOU, THE BOARD, ON OCTOBER 28TH. TO CONSIDER THESE RECOMMENDATIONS, THIS ITEM WAS

POSTPONED IN ORDER TO MAKE SOME NECESSARY CORRECTIONS.

SO SINCE THAT TIME, WE'VE MADE A CORRECTION TO THE BYLAWS. ALL THE CHANGES, INCLUDING THE NEW ONES, SHOULD BE IN YOUR NOTEBOOKS UNDER ITEM 10. THE NEW CHANGES INCLUDE A CORRECTION TO A REFERENCE UNDER THE VICE CHAIR DUTIES WHICH CAN BE FOUND ON PAGE 4. IT WAS INCORRECTLY REFERENCING ARTICLE 6, SECTION 2(B). THE CORRECT REFERENCE IS ARTICLE 7, SECTION 2(C).

WE HAVE ALSO UPDATED THE PARAGRAPH DISCUSSING COMPENSATION TO ICOC MEMBERS OF THE GRANTS WORKING GROUP AND MADE REFERENCE TO THE ICOC BYLAWS AS THE DEFINING SOURCE FOR UPDATED AMOUNTS. AND THAT WAS SECTION 11(A) ALSO ON PAGE 4.

AND THEN WE'VE ALSO MADE A CHANGE IN THE TERMINOLOGY SLIGHTLY TO THE CHAIRS. THE ADMINISTRATIVE CHAIR HAS NOW BEEN CHANGED SIMPLY TO CHAIR. THE ACTING CHAIR TO REVIEW CHAIR. AND WE THINK ACCURATELY THEY REFLECT THE INTENDED ROLE OF THESE INDIVIDUALS.

AND SO WE ARE, AGAIN, BRINGING THESE FOR YOUR CONSIDERATION AND DISCUSSION.

CHAIRMAN KLEIN: OKAY. ARE THERE COMMENTS TO BE MADE BY THE BOARD MEMBERS? JEFF, DID YOU HAVE

A COMMENT? NO. ALL RIGHT. IS THERE ANY COMMENTS BY THE PUBLIC ON THIS ITEM?

AND, DR. SAMBRANO, THE CHAIR, THE REVIEW CHAIR, THE PROCESS FOR THAT IS THAT THE PRESIDENT WILL LOOK AT EACH REVIEW AND TRY AND SELECT SOMEONE APPROPRIATE TO THAT REVIEW; IS THAT CORRECT?

DR. SAMBRANO: YES, THAT'S CORRECT.

CHAIRMAN KLEIN: JOAN SAMUELSON HAD A POINT THAT SHE WANTED ME TO RAISE. AND I'M GOING TO RAISE IT IN THE CONTEXT THAT I THINK WOULD WORK WELL WITH THESE POINTS, WHICH IS THAT SHE WAS CONCERNED THAT THERE WOULD BE A CONVERSATION, I THINK, BETWEEN THE VICE CHAIRS AND THE PRESIDENT WHEN A REVIEW CAME UP, DR. TROUNSON. AND I THINK YOU'VE USUALLY LOOKED -- BEEN WILLING TO JUST CONVERSE WITH MEMBERS OF THE PEER REVIEW COMMITTEE TO TAKE INPUT.

BUT MY CONVERSATION WITH JOAN IS, I THINK, THE PRESIDENT, AS THE HEAD OF OUR SCIENTIFIC TEAM, IS IN THE POSITION TO MAKE THIS APPOINTMENT, BUT CERTAINLY WOULD GENERALLY DISCUSS THIS IF THERE WERE A QUESTION WITH THE VICE CHAIRS. IS THAT AN APPROPRIATE RESPONSE I GAVE HER?

DR. TROUNSON: WELL, I THINK THE IMPORTANT PART IS TO GET THE BEST CHAIR POSSIBLE FOR WHATEVER GRANTS THAT WE'VE GOT. SO, YOU KNOW, WE WANT TO BE

AS ACTIVE AS WE CAN. AND I THINK WE'VE DONE THAT. FOR EXAMPLE, IN THE CASE OF THE IMMUNOLOGY PROGRAM, WE'VE GONE OVERSEAS TO GET SOMEONE VERY SPECIAL.

SO I'M VERY OPEN TO SUGGESTIONS, BUT I'M VERY KEEN TO GET THE VERY BEST SCIENTIST TO BE IN PLACE. AND WE HAD A DISCUSSION WITH THE SCIENCE COMMUNITY OF CALIFORNIA, THE LEADING SCIENTISTS, ALL THE HEADS OF THE PROGRAMS, AND THEIR VIEW WAS VERY MUCH THAT WE NEED TO MAINTAIN THE VERY BEST QUALITY OF THE REVIEWERS AND PARTICULARLY THE CHAIRS. AND SO WE UNDERTAKE TO GET AS BEST POSSIBLE THE BEST PERSON FOR THAT PARTICULAR REVIEW. IF IT'S A TRANSLATIONAL PROGRAM, WE'LL BE LOOKING FOR A TRANSLATIONAL SCIENTIST. IF IT'S A VERY BASIC ONE, IT MAY BE MORE APPROPRIATE TO GET A MORE BASIC PERSON, BUT THE BEST QUALITY PERSON THAT IS REALLY AVAILABLE.

SO, YES, WITHIN THE FRAMEWORK OF TRYING TO GET THE BEST PERSON, OF COURSE, I'M VERY OPEN TO ANY ASSISTANCE AND SUGGESTION, BUT I THINK WHAT WE WANT IS THE VERY BEST PERSON IN THAT POSITION THAT WE CAN FIND.

CHAIRMAN KLEIN: SURE. SO INFORMATIONALLY I KNOW WHEN YOU'RE SEARCHING FOR THESE PEOPLE, YOU'VE ALWAYS DISCUSSED IT IN EXECUTIVE MEETING OR

HAD INFORMAL DISCUSSIONS ABOUT IT. JEFF, I THINK THAT THE OPPORTUNITIES EXIST FOR INFORMAL DISCUSSION AND TRADING IDEAS, AND I THINK IT'S WORKING PRETTY WELL. IS THAT --

MR. SHEEHY: YOU KNOW, I THINK WE HAVE A NICE DIALOGUE, DON'T YOU THINK, ALAN? I JUST THINK -- I HAVEN'T TALKED TO JOAN ABOUT THIS, SO I'M NOT EXACTLY SURE. I THINK SHE'S HAD CONVERSATIONS WITH YOU, BUT I THINK MAYBE SOME MORE CONVERSATIONS WITH HER PRIOR TO THE GRANT REVIEWS IF SOMETHING COMES UP. BUT IN GENERAL THE INDIVIDUALS, BOTH IN TERMS OF MEMBERSHIP AND IN TERMS OF CHAIRING THE GRANT REVIEWS, HAVE BEEN EXTRAORDINARY, AND WE'VE BEEN BLESSED. AND I REALLY HAVE TO COMMEND GIL AND THE REST OF THE SCIENTIFIC STAFF. IT'S NO SMALL JOB RECRUITING ALL THESE INDIVIDUALS AND GETTING THEM IN THE CHAIRS. AND SO I THINK IT'S BEEN A PHENOMENAL PROCESS. IT'S WORKED REALLY WELL. I THINK WE HAVE A GOOD DIALOGUE.

CHAIRMAN KLEIN: GREAT. SO I JUST TOLD JOAN I WOULD COVER THE SUBJECT, BUT I THINK IT IS, AS JEFF SAYS, A HUGE EFFORT TO GET THE RIGHT CHAIR. I KNOW, ALAN, YOU SPEND A LOT OF TIME ON THAT AS DOES THE REST OF THE STAFF. IT'S VERY TOUGH SOMETIME TO CONVINCE SOMEONE TO TAKE ON THESE MAJOR

ROLES.

SO WITH THAT, I THINK WE'VE COVERED THIS SUBJECT TO THE EXTENT THAT WE CAN AT THIS MOMENT. AND I'D LIKE TO MOVE ON TO ITEM 11, IF WE CAN. DR. SAMBRANO, I THINK YOU ARE GOING TO PRESENT THIS ITEM AS WELL.

DR. SAMBRANO: RIGHT. SO THIS IS A NOMINATION FOR THE POSITION OF NOW THE CHAIR. ASSUMING THAT THE BYLAWS ARE APPROVED, THIS IS THE PERSON THAT WE WOULD BE NOMINATING TO FILL THAT ROLE AND TO BE APPROVED BY YOU, THE BOARD. AND JUST TO GIVE YOU A LITTLE BIT OF BACKGROUND, WE HAVE A BIO FROM DR. JOHN SLADEK THAT'S IN YOUR NOTEBOOKS UNDER ITEM 11.

HE HAS SERVED ON THE GRANTS WORKING GROUP ALREADY FOR APPROXIMATELY TWO YEARS. DURING THE TIME HE HAS BEEN A VERY ACTIVE PARTICIPANT WITH THE WORKING GROUP, AND HE'S ACTUALLY PRESIDED OVER TWO REVIEW MEETINGS AS THE ALTERNATE CHAIR AND DONE A TERRIFIC JOB. HE HAS A VERY BROAD ADMINISTRATIVE EXPERIENCE AND BACKGROUND. HE SERVED AS PRESIDENT AND CEO OF THE CALIFORNIA LUTHERAN UNIVERSITY AS VICE CHANCELLOR FOR RESEARCH AND PROFESSOR OF PSYCHIATRY AND NEUROSCIENCE AT THE UNIVERSITY OF COLORADO AT DENVER HEALTH SCIENCE CENTER WHERE HE IS

CURRENTLY AT AND CONDUCTING RESEARCH ON THE EFFECTS OF DOWN'S SYNDROME AND PARKINSON'S DISEASE.

HE HAS BEEN EDITOR IN CHIEF OF THE JOURNAL *EXPERIMENTAL NEUROLOGY* FOR 15 YEARS. HE HAS BEEN INVOLVED IN REGULATORY COMPLIANCE, HAD OVERSIGHT OVER BILLIONS OF DOLLARS IN ANNUAL RESEARCH EXPENDITURES AT THE UNIVERSITY OF COLORADO, AND ALSO HELPED GUIDE SUCCESSFUL CAMPUS INITIATIVES, INCLUDING THE DEVELOPMENT OF A 400-ACRE, $2 BILLION CAMPUS.

SO HE HAS, I THINK, VERY BROAD EXPERIENCE AND HAS BEEN CERTAINLY VERY ACTIVE AND ACCESSIBLE TO THE WORKING GROUP, AND WE FEEL HE WOULD BE AN APPROPRIATE CHOICE FOR THIS POSITION.

CHAIRMAN KLEIN: OKAY. IS THERE DISCUSSION? I KNOW A NUMBER OF THE INDIVIDUALS HERE HAVE BEEN IN PEER REVIEW SESSIONS WITH DR. SLADEK BEFORE. AS GIL SAID, HE'S COMMITTED A LOT OF TIME AND ENERGY TO OUR ENTERPRISE AND HAS THE BACKGROUND THAT HE HAS YEARS OF CELLULAR THERAPY TRIALS RELATED TO PARKINSON'S, AS STATED. SO HE'S ONE OF THOSE PEOPLE THAT HAS SOME ACTUAL EXPERIENCE IN THE DOWNSTREAM CLINICAL TRIALS RELATED TO CHRONIC DISEASE WITH CELLULAR THERAPIES.

IS THERE ANY ADDITIONAL COMMENTS, DR.

PRIETO OR MR. SHEEHY, OR ANYONE WANT TO MAKE ANY OTHER COMMENTS?

MR. SHEEHY: I WOULD JUST SAY THAT DR. SLADEK HAS BEEN A GREAT MEMBER OF THE WORKING GROUP. SO THE TWO SESSIONS HE'S CHAIRED, HE DID A GREAT JOB. THANK YOU. SO I THINK THIS IS A GREAT SELECTION BY STAFF. AND HE'S A GREAT GUY, DON'T YOU THINK, ALAN? I THINK THIS WILL BE GOOD.

I WOULD LIKE TO SAY, THOUGH, WE SHOULD TAKE A MOMENT FOR DR. ORKIN WHO HAD FILLED THIS ROLE. HE WAS SUCH A TREMENDOUS PRESENCE. AND YOU GO BACK TO THE EARLY DAYS WHEN WE JUST HAD A LITTLE BIT OF SCOTCH TAPE AND CARDBOARD HOLDING US TOGETHER, AND THIS REALLY WAS A SCIENTIST OF THE HIGHEST ORDER WHO CAME AND REALLY HELPED US SET UP OUR PROCESSES. AND WE OWE A HUGE DEBT OF GRATITUDE TO STU ORKIN FOR THE WORK AND THE LEADERSHIP HE'S PROVIDED US UP TO THIS POINT. BUT I LOOK FORWARD TO DR. SLADEK IN THIS ROLE. THANK YOU.

CHAIRMAN KLEIN: YOU KNOW WE'RE GETTING OLDER AS AN ORGANIZATION WHEN WE CAN HAVE REMINISCENCES. SO, DR. PRIETO, ANYTHING TO ADD?

DR. PRIETO: NO. I THINK I'D REALLY JUST ECHO WHAT JEFF SAID. I THINK DR. SLADEK IS AN EXCELLENT CHOICE. AND ALSO WOULD LIKE TO

ACKNOWLEDGE WHAT THE REVIEWERS HAVE DONE FOR US, COMING IN FOR VERY LITTLE COMPENSATION, GIVING TREMENDOUSLY OF THEIR TIME, AND THE EFFORT INVOLVED IS REALLY IMPRESSIVE.

DR. PENHOET: COULD WE AT SOME POINT MAKE SOME KIND OF OFFICIAL RESOLUTION RELATED TO DR. ORKIN TO RECOGNIZE HIS WORK? IS THAT WHAT YOU WERE --

MR. SHEEHY: THAT'S WHERE I WAS HEADED. I JUST DON'T KNOW -- WE DID SOMETHING FOR DR. CHARO, I THINK. I THINK IF WE COULD DO SOMETHING SIMILAR MAYBE AT OUR MEETING FOR DR. ORKIN.

CHAIRMAN KLEIN: WE WILL DEFINITELY CALENDAR THAT. IT'S AN OUTSTANDING IDEA.

SO AT THIS POINT, DR. SAMBRANO, I THINK THAT WHAT I'D LIKE TO DO IS GO FORWARD TO ITEM 16. PRIOR TO THE MEETING, THERE WAS A SHORT DISCUSSION WHERE I THINK THAT JEFF SHEEHY RAISED SOME ITEMS THAT WE COULD HAVE EXPLAINED IN DISCUSSION THAT WOULD BE HELPFUL TO GET THROUGH THAT PROCESS. THE EARLY TRANSLATIONAL AWARDS IS A CONTINUATION OF A PROGRAM, BUT THIS IS SLIGHTLY DIFFERENT THAN PREVIOUSLY.

MS. KING: WE DO NEED TO DO ITEM NO. 15 BEFORE NO. 16 CAN BE PRESENTED, I WAS JUST REMINDED.

CHAIRMAN KLEIN: WE'RE NOT ACTING, SO WE DON'T NEED TO DO THAT IN THAT ORDER.

DR. TROUNSON: SORRY. BECAUSE IT'S THE PREAPPLICATION PROCESS, WE WOULD LIKE THAT CONSIDERED BECAUSE, YOU KNOW, THE EARLY TRANSLATIONAL PROGRAM, IF IT CAN BE A PREAPPLICATION, THEN IT WOULD BE RATHER DIFFERENT TO WHAT WE WOULD -- HOW WE COULD CONSIDER IT.

CHAIRMAN KLEIN: IT'S JUST THAT I'M -- I'M TRYING TO JUST MOVE FORWARD WITH ITEMS THAT WE -- I'D LIKE TO GET SOME CLARIFICATION OF THIS ITEM. IF YOU'D LIKE, I CAN THEN GO BACK TO ITEM 15 JUST SO THAT EVERYONE UNDERSTANDS WHAT WE'RE DOING BECAUSE WE'RE NOT ACTING ON IT. THE ORDER IS NOT AS SEQUENTIALLY IMPORTANT AS IT OTHERWISE WOULD BE.

AND SO I'D JUST LIKE TO HAVE DR. OLSON LEAD US THROUGH THIS EARLY TRANSLATIONAL AWARD SO THAT WE CAN PROVIDE A CONCEPT UNDERSTANDING OF HOW THIS RELATES TO THE OTHER PROPOSALS THAT DR. TROUNSON PREVIOUSLY PRESENTED, CONCEPT APPROVALS THAT WILL BE OUT THERE.

DR. OLSON: DR. LYLA COLLINS WILL BE PRESENTING THIS CONCEPT FOR YOUR CONSIDERATION.

DR. COLLINS: GOOD EVENING, MR. CHAIRMAN, MEMBERS OF THE BOARD, AND AUDIENCE. TODAY I'D LIKE

TO PRESENT TO YOU THE CONCEPT PROPOSAL FOR YOUR APPROVAL OF THE SECOND CALL OF THE EARLY TRANSLATIONAL RFA.

AND, FIRST, I'D LIKE TO ORIENT YOU AS TO WHERE THIS RFA FALLS ON OUR DEVELOPMENTAL PIPELINE. REALLY THE PURPOSE OF THIS RFA IS TO TAKE THESE EXCITING RESEARCH DISCOVERIES THAT WE HEAR ABOUT IN THE PRESIDENT'S REPORT AND PROGRESS THEM TOWARDS THE POINT WHERE THEY CAN EVENTUALLY BECOME TREATMENTS FOR HUMAN DISEASE. NOW, THE EARLY TRANSLATIONAL PART OF THIS PROCESS INCLUDES ACTIVITIES SUCH AS LEAD SELECTION, OPTIMIZING PROCESS, PROCESS DEVELOPMENT, ASSAY DEVELOPMENT, AND THE PRECLINICAL RESEARCH THAT'S REALLY REQUIRED TO ESTABLISH DISEASE-MODIFYING ACTIVITY OF A CANDIDATE THERAPY.

SO REALLY AT THE END OF THESE AWARDS, WE EXPECT TO HAVE DEVELOPMENT CANDIDATES READY FOR FURTHER PRECLINICAL DEVELOPMENT AND IND-ENABLING STUDIES.

WE PROPOSE TWO TYPES OF AWARDS UNDER THIS RFA, AND REALLY THE MAIN DIFFERENCE BETWEEN THE TWO TYPES OF AWARDS IS WHAT WE WILL HAVE AT THE END OF THE RESEARCH PROJECT. THE FIRST TYPE ARE LARGER AWARDS UNDER THESE DEVELOPMENT CANDIDATE AWARDS. ALL OF THE ACTIVITIES THAT ARE REQUIRED TO RESULT IN

A DEVELOPMENT CANDIDATE, LIKE THE ACTIVITIES THAT I MENTIONED TO YOU IN THE PREVIOUS SLIDE, MUST BE COMPLETED BY THE END OF THE AWARD TO RESULT IN A CANDIDATE THAT'S READY FOR IND-ENABLING STUDIES. WHILE THE SMALLER SORT OF RESEARCH SIZE DEVELOPMENT CANDIDATE FEASIBILITY AWARDS WILL ENCOMPASS A SUBSET OF THESE ACTIVITIES THAT WILL MOVE A POTENTIAL THERAPY TOWARDS A DEVELOPMENT CANDIDATE.

AND WE PLAN TO PRIORITIZE PROJECTS THAT WILL RESULT IN CELL-DERIVED THERAPIES, IN PARTICULAR PLURIPOTENT STEM CELL-BASED THERAPIES, UNDER THIS PROGRAM. AND YOU MAY RECALL, AND WAS MENTIONED EARLIER IN THE PRESIDENT'S REPORT, THAT THE FIRST CALL OF THIS RFA INCLUDED A BOTTLENECK CATEGORY OF AWARDS. AND THESE ARE GOING TO BE THE FOCUS OF AN UPCOMING RFA. THIS RFA WILL REALLY FOCUS ON ACHIEVING DEVELOPMENT CANDIDATES.

WE DO SUPPORT MULTIDISCIPLINARY EFFORTS AND COLLABORATIVE FUNDING PARTNERSHIPS. SO THIS IS ESPECIALLY IMPORTANT BECAUSE OF THE DIVERSE NATURE OF THE ACTIVITIES THAT ARE REQUIRED IN TRANSLATIONAL EFFORTS. SO WE PROPOSE TO INCLUDE COLLABORATIVE FUNDING PARTNERS UNDER THIS PROGRAM. IN ADDITION, AND THIS IS A CHANGE FROM WHAT YOU HAVE IN YOUR BINDERS, WE'D LIKE TO INCLUDE CO-PI'S FOR THE LARGER

DEVELOPMENT CANDIDATE AWARDS. AND BECAUSE OF THE IMPORTANCE OF THIS PROGRAM IN MAINTAINING OUR PIPELINE, WE'RE REQUESTING A 20-PERCENT EFFORT FOR PI'S AND 15-PERCENT EFFORTS FOR CO-PI'S.

AND THE AWARDS WILL BE OPEN -- THEIR COMPETITION, RATHER, WILL BE OPEN TO BOTH ACADEMIC AND FOR-PROFIT INSTITUTIONS. AND WE'LL DISCUSS THE PREAP LATER.

THESE ARE OUR PROPOSED FUNDING LEVELS: $6 MILLION FOR THE DEVELOPMENT CANDIDATE AWARDS AND $2 MILLION FOR THE FEASIBILITY AWARDS. AND I'D LIKE TO NOTE THAT THESE ARE TOTAL JUSTIFIABLE PROJECT COSTS, NOT DIRECTS. AND WE'RE PLANNING ON ABOUT TEN AWARDS OF EACH CLASS FOR A TOTAL PROGRAM COST OF $80 MILLION.

WE DO PLAN TO OFFER LOANS AS AN AWARD MECHANISM UNDER THIS RFA. AND I'D LIKE TO ASK FOR YOUR CONSIDERATION OF THE FOLLOWING LOAN TERMS. FOR OUR FOR-PROFIT APPLICANTS, WE'D LIKE TO OFFER LOAN OR GRANT AWARD MECHANISMS AS AN OPTION. IF THE LOAN IS SELECTED, THERE ARE REALLY ONE OF FOUR TYPES OF LOANS THAT APPLICANTS WILL HAVE AVAILABLE: EITHER RECOURSE OR NONRECOURSE LOANS AT A SIX-YEAR TERM AT PRIME PLUS 300 OR A TEN-YEAR TERM AT THE PRIME RATE PLUS 500 BASIS POINTS, AND THE RATE WE'LL SET UPON

YOUR APPROVAL OF THESE AWARDS, WHICH WE ANTICIPATE TO OCCUR NEXT FALL IN OCTOBER, AT WHICH TIME ROSA CANET-AVILES WILL PRESENT TO YOU THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP. AND THE REVIEW FOR THAT IS PLANNED FOR EARLY SEPTEMBER, AND WE HOPE TO POST THE RFA IN FEBRUARY OF NEXT YEAR.

SO I'D LIKE TO REQUEST YOUR APPROVAL AS SOON AS WE CAN OF THIS CONCEPT PLAN FOR THE EARLY TRANSLATIONAL II PROGRAM.

CHAIRMAN KLEIN: OKAY. THANK YOU. NOW, JEFF, THERE WERE SOME CLARIFICATIONS AND SOME ADDITIONAL INFORMATION, I THINK, THAT YOU HAD THE OPPORTUNITY TO DISCUSS WITH DR. TROUNSON AND DR. OLSON IMMEDIATELY BEFORE THIS. AND WE MIGHT WALK THROUGH THOSE FOR THE BENEFIT OF ALL THE BOARD MEMBERS.

MR. SHEEHY: I THINK THERE'S SEVERAL OF THEM, BUT A LOT OF THIS WAS JUST CLARIFICATION. PERHAPS I'LL START WITH THE -- GO BACK TO THE FIRST PAGE. WE DON'T -- MAYBE IF YOU LOOK IN YOUR BOOKS WHERE IT SAYS THIS AWARD WILL NOT FUND. AND I THINK WE NEED -- I'M JUST ASKING FOR A LITTLE BIT OF CLARIFICATION BECAUSE, FOR INSTANCE, THE ONE THAT JUMPED OUT AT ME IS RESEARCH ON INDUCTION OF TRANSPLANTATION TOLERANCE, WHICH IT SEEMS TO ME

WOULD BE AN ESSENTIAL FEATURE OF MOST EMBRYONIC OR PLURIPOTENT CELL. CERTAINLY EMBRYONIC STEM CELL THERAPIES WOULD REQUIRE AT LEAST SOME OF THE FUNDING TO THINK ABOUT TRANSPLANTATION TOLERANCE.

SO IT'S A LITTLE BIT OF -- IT'S A LITTLE BIT OF LINGUISTIC TECHNICALITY, BUT I THINK WHAT WE WERE SAYING IS THAT THE PRIMARY GOAL OF AN APPLICATION HERE WOULD NOT BE TO ACHIEVE THESE GOALS, WHICH ARE BEING ACHIEVED IN OTHER RFA'S, BUT THAT SOME OF THE COMPONENTS THAT ARE LISTED HERE, SOME OF THE FEATURES THAT ARE LISTED HERE WOULD NECESSARILY BE COMPONENTS OF AN APPLICATION. AM I MAKING SENSE?

SO I DID ASK FOR AND DR. OLSON GRACIOUSLY PROVIDED CLARIFICATION, BUT IT WAS -- BECAUSE WHEN YOU SAY YOU WILL NOT FUND, IT MEANS IT'S NOT GOING TO BE PART OF THE APPLICATION. I THINK WILL NOT FUND. AM I RECAPITULATING THIS CORRECTLY?

DR. OLSON: YEAH. LET ME JUST ADD TO JEFF. I THINK THE GOAL HERE WAS, AS YOU KNOW, WE CURRENTLY HAVE A STEM CELL TRANSPLANTATION TOLERANCE RFA OUT. AND THE GOAL OF THAT IS ESSENTIALLY NEW TOLERANCE INDUCTION STRATEGIES. WHAT I WANT TO CLARIFY AND WHAT I THINK JEFF WAS RIGHTLY CONCERNED ABOUT IS FOR THOSE APPLICATIONS, FOR EXAMPLE, UNDER

THIS EARLY TRANSLATION II AWARD WHERE IF YOU HAD AN ALLOGENEIC CELL THERAPY, OBVIOUSLY IMMUNOSUPPRESSION OR SOME SORT OF TOLERANCE IS A COMPONENT OF THAT. SO TO CONDUCT PRECLINICAL STUDIES THAT ADDRESS, SAY, AN IMMUNOSUPPRESSION REGIMEN IN THE CONTEXT OF YOUR PROPOSED DEVELOPMENT CANDIDATE WOULD BE SOMETHING THAT COULD BE FUNDED UNDER THIS AWARD. IT JUST IS WE DID NOT WANT THIS AWARD TO BE TOTALLY FOCUSED ON NEW STRATEGIES FOR TOLERANCE INDUCTION BECAUSE THAT IS THE SUBJECT OF A CURRENT RFA.

MR. SHEEHY: I THINK THAT REFERS TO SOME OF THE OTHER STUFF, TUMOROGENICITY OR GM PROCESS SCALE-UP, THAT THE MAIN TARGET OF THE GRANT WOULD NOT BE TO ADDRESS THESE BOTTLENECKS OR THESE ISSUES; BUT IN THE CONTEXT OF DEVELOPING YOUR THERAPY, YOU MIGHT NECESSARILY HAVE TO ADDRESS SOME OF THESE ISSUES AND THEY WOULD BE ELIGIBLE FOR FUNDING AS A PORTION.

DR. OLSON: I MEAN FOR THE GLP, TUMOROGENICITY STUDIES, THOSE ARE VERY EXPENSIVE STUDIES. SO THE THINGS HE'S CITING THERE ARE VERY EXPENSIVE STUDIES THAT ARE TYPICALLY CONDUCTED ONLY WHEN A DECISION HAS BEEN MADE TO ACTUALLY MOVE A COMPOUND INTO IND-ENABLING PRECLINICAL DEVELOPMENT. SO THAT'S WHY THEY ARE IN A STAGE FURTHER.

IF YOU LOOK AT THIS PARTICULAR CARTOON HERE, THOSE ARE THE KINDS OF ACTIVITIES THAT ARE TYPICALLY CONDUCTED HERE AND WILL BE INCLUDED IN A SUBSEQUENT DISEASE TEAM RESEARCH AWARD AND ARE ACTUALLY CURRENTLY INCLUDED IN THE DISEASE TEAM RESEARCH AWARD NOW.

THE GOAL OF THIS PROGRAM IS TO FUND ACTIVITIES IN THIS SPACE. EITHER THOSE THAT WILL GET TO A DEVELOPMENT CANDIDATE OR THOSE THAT WILL CONDUCT RESEARCH AND ACTIVITIES THAT WILL MOVE YOU ALONG THE PATH TO A DEVELOPMENT CANDIDATE.

CHAIRMAN KLEIN: RIGHT. AND SO, DR. OLSON, AS RELATES TO BOTTLENECKS, I THINK YOU PREVIOUSLY HAVE SAID, AND JUST TO EMPHASIZE FOR THE BOARD, WE HAVE A TOOLS, TECHNOLOGY, AND BOTTLENECK RFA --

DR. OLSON: THAT WILL BE COMING UP.

CHAIRMAN KLEIN: -- WILL BE COMING UP. BUT IF THERE IS A BOTTLENECK THAT'S IDENTIFIED WITHIN THE PROCESS OF GETTING TO THE DEVELOPMENT CANDIDATE, IT'S A SUBSIDIARY PART OF THAT PROCESS. IT'S NOT INTENDED TO ELIMINATE OVERCOMING IDENTIFIED HURDLES THAT SOMEONE MIGHT REFER TO AS A BOTTLENECK AS A PART OF AN OTHERWISE GRANT THAT IS PRIMARILY FOCUSED ON A DEVELOPMENT CANDIDATE.

DR. OLSON: LET ME CLARIFY. I MEAN THE FOCUS OF THESE AWARDS IS ACHIEVING A SPECIFIC CANDIDATE, MOVING A SPECIFIC CANDIDATE ALONG. THE FOCUS OF A BOTTLENECK OR TOOLS AND TECHNOLOGIES TENDS TO BE MORE GENERALLY APPLICABLE ACROSS AN AREA. THIS IS NOT TO SAY THAT IF YOU DEVELOP A CERTAIN KIND OF ASSAY IN THE CONTEXT OF TRYING TO MOVE YOUR SPECIFIC CANDIDATE ALONG, IT MIGHT NOT HAVE MORE GENERAL APPLICABILITY, BUT IT REALLY IS A SCOPE QUESTION, SPECIFIC VERSUS GENERAL. MR. CHAIR, I BELIEVE YOU HAVE SEVERAL --

CHAIRMAN KLEIN: YES.

DR. PENHOET: CAN YOU CLARIFY FOR ME WHAT THE DIFFERENCE IS BETWEEN A CANDIDATE FEASIBILITY STUDY AND A CANDIDATE STUDY BECAUSE IT SEEMS TO ME IN THIS CONVERSATION YOU'RE SORT OF BLENDING TWO THINGS.

DR. OLSON: OKAY. SO BY THE END OF THE DEVELOPMENT CANDIDATE AWARD, I EXPECT THE APPLICANT OR THE SUCCESSFUL AWARDEE TO HAVE COMPLETED ALL THE NECESSARY ACTIVITIES TO ESSENTIALLY GO INTO IND-ENABLING DEVELOPMENT. THOSE ACTIVITIES INCLUDE CMC, SO CHEMISTRY, MANUFACTURING, AND CONTROLS-TYPE ACTIVITIES, WHICH HAVE TO DO WITH HAVING A MOLECULE OR A CELL OR WHATEVER CAPABLE OF MOVING INTO GMP.

THERE'S CERTAIN THINGS ASSOCIATED WITH THAT. THAT INCLUDES HAVING IDENTIFIED DISEASE-MODIFYING ACTIVITY. THAT INCLUDES HAVING CERTAIN ASSAYS DEVELOPED. SO IT'S A SET OF ACTIVITIES THAT REALLY NEED TO BE DONE BEFORE YOU CAN TALK ABOUT EVEN GOING -- BEFORE IT EVEN MAKES SENSE TO CONSIDER PRECLINICAL DEVELOPMENT.

WHAT WE'VE SEEN IN A LOT OF OUR PREAPS AND SUCH IS PEOPLE WANTING TO DO SOME PARTS OF THAT. THEY MAY NOT WANT TO DO ALL THE WORK TO IDENTIFY A GMP-COMPATIBLE CELL LINE. THEY MAY BE MORE INTERESTED IN ADDRESSING SOME MECHANISM OF ACTION STUDIES FOR THEIR CANDIDATE. DOES IT DO WHAT I THINK IT'S GOING TO DO? THEY MAY BE INTERESTED IN ADDRESSING THE DISEASE-MODIFYING ACTIVITY. WE THINK THOSE ARE IMPORTANT TOO IN ESSENTIALLY MOVING THINGS ALONG THE PATH. PERHAPS IF THEY GET THAT DONE, THEN THEY WILL FIND, SAY, A COMPANY OR SOMEONE WHO IS MORE INTERESTED IN THESE OTHER ASPECTS TO COLLABORATE WITH THEM AND MOVE THEM FORWARD. SO WE WANTED TO MAKE BOTH TYPES OF AWARDS AVAILABLE.

DR. BRYANT: I JUST WONDERED IF IT COULD BE SOLVED BY A CHANGE IN THE WORDING TO SAY ALTHOUGH THESE ITEMS WILL BE NOT THE MAJOR FOCUS OF THESE GRANTS -- SORRY. THE OTHER WAY AROUND -- ALTHOUGH

SOME OF THESE ITEMS MAY APPEAR IN THE STUDIES, THEY WILL NOT BE ALLOWED TO BE THE FOCUS OF THE GRANT, SOMETHING LIKE THAT, SO THEY'RE NOT THE PRIMARY FOCUS, BUT IT DOESN'T MEAN YOU CAN'T PROHIBIT THEM IF THEY COME UP.

DR. TROUNSON: THAT'S WHAT I WAS GOING TO SUGGEST. AND IF THE TENOR OF THAT WAS WHAT WE'RE SEEKING TO DO, WE WOULD GET THE WORDS TOGETHER FOR THAT INTENTION, IF THAT WOULD SUIT, AND BRING IT FORWARD TOMORROW MORNING FOR YOU TO LOOK AT.

CHAIRMAN KLEIN: I THINK THAT WOULD BE VERY HELPFUL. DUANE ROTH.

MR. ROTH: I HAVE A SIMILAR CONCERN. I UNDERSTAND WHAT YOU'RE TRYING TO DESCRIBE, BUT I'M A LITTLE TROUBLED BY TRYING TO MAKE THIS BOX TOO TIGHT. I WOULD HATE TO SEE US TAKE THINGS THAT ARE PARTIALLY THROUGH THAT DISCOVERY RESEARCH AND SAY IF IT'S SPILLED OVER INTO EARLY PRECLINICAL DEVELOPMENT, LIKE TUMOROGENICITY, STUDIES THAT WOULD BE MAYBE NOT GLP, BUT CERTAINLY WOULD BE AIMED AT A CANDIDATE, I WOULD LIKE TO MAKE SURE WE DON'T ELIMINATE, ESPECIALLY IN LIGHT OF THE CONVERSATION THAT WE HAD EARLIER TODAY, WHERE I THINK A LOT OF THE PEOPLE WHO JUST DIDN'T FIT INTO THE DISEASE TEAM BOX WERE LOOKING AT THIS GRANT AS BEING A

POSSIBILITY FOR THEM.

DR. OLSON: PERHAPS IT'S HARD TO DESCRIBE ALL OPTIONS. CERTAINLY PEOPLE DO TRIAL DOSE FINDING STUDIES. PEOPLE WILL DO TRIAL TUMOROGENICITY STUDIES. IT'S THE SPECIFIC GLP-TYPE STUDIES DONE WITH THE PROCESS THAT'S INTENDED TO GO FORWARD INTO THE CLINIC THAT ARE THE STUDIES THAT I DON'T THINK ARE APPROPRIATE FOR THIS TYPE OF AWARD. BUT TRIAL DOSE FINDING STUDIES, YOU KNOW, TRIALS STARTING TO ADDRESS TERATOMA FORMATION, I MEAN YOU'D BE SILLY NOT TO LOOK AT THAT EARLY ON. IT'S THE GLP STUDIES I'M PARTICULARLY -- THAT I THINK ARE REALLY VERY BIG DOLLAR STUDIES AND ACTUALLY IMPLY A DECISION TO MOVE TO -- THE DECISION HAS BEEN MADE TO MOVE TO IND. I HOPE THAT THAT ADDRESSES YOUR CONCERN.

MR. ROTH: THERE IS AN ASSUMPTION THAT THOSE ARE VERY EXPENSIVE, BUT I THINK YOU ARE GOING UP TO SIX MILLION WITH THIS. THEY MAY HAVE OTHER MONEY WITH IT; BUT IF IT'S SOMETHING THAT CAN MOVE THIS FIELD AHEAD AND YOU CAN LOOK AT THAT, AND I THINK IT'S THE WILL NOT FUND LANGUAGE.

DR. TROUNSON: I THINK WE'VE TAKEN NOTE, AND WE'LL TRY AND BRING SOMETHING THAT'S MORE PALATABLE.

MR. ROTH: BUT I'M EVEN ANXIOUS TO SEE IT

A LITTLE MORE BROADER IF WE CAN.

DR. TROUNSON: THE OTHER THING, CHAIR, IS THAT I'M WORKING WITH THE STAFF ON LOOKING INTO THE POSSIBILITY OF THE MANUFACTURING AREAS FOR SOME OF THE CELLS THAT ARE BEGINNING TO EITHER ENTER THE CLINIC OR BECOME PART OF A MAJOR DISEASE TEAM WHERE THAT COMPONENT PART IS DIFFICULT TO FIT INTO THE RFA'S AND STILL BE COMPLEMENTARY TO THE AIM OF THE KIND OF PRECLINICAL ANIMAL STUDIES. FOR EXAMPLE, IF YOU GOT TO SPEND A LOT OF YOUR TIME DEVELOPING MANUFACTURING AND YOUR CELL BASE FOR YOUR ANIMAL STUDIES, IF IT TAKES YOU TWO YEARS TO DO THAT, THERE'S VERY LITTLE TIME FOR THE TWO YEARS, PARTICULARLY IN LARGE ANIMALS, TO GET THROUGH THE REST OF IT.

SO I'M WORKING WITH PAT AND OTHER MEMBERS OF CIRM TO SEE IF WE CAN ACTUALLY BRING FORWARD AN OPPORTUNITY THAT MIGHT USEFULLY ADDRESS THAT PARTICULAR ISSUE, WHICH SEEMS TO EXIST WITHOUT AN EASY SOLUTION.

CHAIRMAN KLEIN: SO AS THIS WOULD BE A SEPARATE RFA, JUST TO BE CLEAR, THAT MAY PROCEED ON A FASTER TRACK IF THAT'S VIEWED AS AN OBSTACLE TO MOVING SOME OF THESE THERAPIES DOWNSTREAM AND HELPING A NUMBER OF DEVELOPMENT CANDIDATES.

DR. STEWARD: I GUESS I JUST WANT TO AMPLIFY A LITTLE BIT ON WHAT DUANE SAID AND I THINK SUE AS WELL. THE CONCEPT OF BOXING THIS IN TOO TIGHTLY BOTHERS ME JUST A LITTLE BIT. I UNDERSTAND THE NEED TO SPECIFY, BUT WHAT I GUESS I WOULD ENCOURAGE IN PRINCIPLE IS AN EXPLANATION OF WHAT THE EARLY TRANSLATIONS AWARDS ARE TARGETED FOR AND LESS LANGUAGE ABOUT WHAT THEY'RE NOT GOING TO FUND. I JUST THINK WE MIGHT MISS OUT ON SOME REALLY GOOD THINGS IF YOU SAY IN ADVANCE WE'RE NOT GOING TO CONSIDER XYZ. AND THE PI'S MIGHT BE VERY CREATIVE IN HOW THEY PUT THESE THINGS TOGETHER AND SURPRISE US WITH SOME VERY EXCITING THINGS.

DR. TROUNSON: NO, THEY'RE VERY CREATIVE. THAT'S FOR SURE. WE JUST DIDN'T WANT -- AS YOU KNOW, IF WE'RE MOVING THROUGH A REVIEW, IT'S BETTER TO HAVE THOSE LIKE PROJECTS IN LIKE RFA'S.

DR. STEWARD: I WOULD UNDERSTAND THAT.

DR. TROUNSON: BECAUSE IT GIVES US A BETTER MEASURE OF ONE AGAINST THE OTHER. SO THE BOXING IS REALLY FOR REVIEW PURPOSES AND OUR PURPOSES TO GET A BETTER HANDLE AND LET THE PEOPLE -- REALLY LET THE PEOPLE KNOW A BIT MORE ABOUT WHAT WE'RE REALLY SORT OF SEEKING. BUT WE TAKE THE POINT, THAT THERE SHOULD BE SUFFICIENT

FLEXIBILITY NOT TO BE ULTIMATELY CONSTRAINING OUR MISSION ESSENTIALLY.

DR. OLSON: I WOULD LIKE TO MAKE ONE ADDITIONAL COMMENT. I WOULD JUST REMIND YOU ALL THAT IN THE DISEASE TEAM AWARD THAT YOU JUST FUNDED, THAT POINT RIGHT THERE, SO PROJECTS, YOU MAY RECALL THAT OUR FIRST DISEASE TEAM AWARD OVERLAPPED A LITTLE BIT WITH EARLY TRANSLATIONAL. SO IT STARTED MORE OR LESS BACK HERE AND MOVED FORWARD. THAT POINT RIGHT THERE IS THE SUBJECT OF WHAT WE'RE CALLING AN EXTERNAL EVALUATION COMMITTEE. IT'S CONSIDERED A GO/NO-GO DECISION POINT.

SO I WAS TRYING TO AVOID THE COMPLEXITY OF INTRODUCING -- I MEAN I FEEL THAT IF WE HAVE THINGS MOVE INTO THIS STAGE, THAT YOU HAVE TO HAVE THE SAME CRITERIA. THE AWARDS WOULD HAVE TO HAVE COMPARABLE CRITERIA. SO I JUST WANTED TO SHARE A LITTLE BIT THE REASONING. AND I THINK ALAN HAS, I THINK, PICKED UP ON THAT. WE TRY AND PUT THINGS TOGETHER THAT SEEM APPROPRIATE BREAKS. AND I DO APPRECIATE THE FACT THAT IT'S HARD TO STOP THINGS OR THAT THEY GO TO A CERTAIN POINT. THIS JUST SAYS THE PROJECTS DON'T HAVE TO STOP. WE'RE FUNDING THROUGH A CERTAIN POINT IN THIS AWARD. THEY CAN APPLY FOR A DISEASE TEAM AWARD AND PICK UP AND MOVE FORWARD.

CHAIRMAN KLEIN: I THINK THAT, DR. OLSON, THAT THE TENOR HERE IS THAT WE RECOGNIZE WE HAVE A TREMENDOUS SCIENTIFIC STAFF, AND WE'RE OPPORTUNISTICALLY BIASED SO THAT WE WANT YOU TO HAVE THE AUTHORITY, IF YOU SEE SOMETHING OF TREMENDOUS OPPORTUNITY, THAT WHILE THESE ARE NOT THE FOCUS OF THE AWARD, IF THEY INCLUDE THESE ELEMENTS, TO HAVE YOU EMPOWERED TO BE ABLE TO MAKE THAT KIND OF RECOMMENDATION. I THINK THAT'S STATED.

NOW, MR. SHEEHY, DID YOU HAVE ANY OTHER COMMENTS?

MR. SHEEHY: I DID. SORRY. I APOLOGIZE IN ADVANCE. RIGHT ABOVE THAT WHERE IT SAYS CIRM WILL PRIORITIZE PROJECTS, I REALLY THINK WE SHOULD STRIKE INELIGIBLE FOR OR UNLIKELY TO RECEIVE FUNDING FROM THE UNITED STATES FEDERAL GOVERNMENT BECAUSE THE FEDERAL BAN HAS BEEN LIFTED, AND I THINK THAT'S VERY CONFUSING AND IMPLIES THAT WE'RE GOING TO BE DOING -- FRANKLY, THAT WE'RE GOING TO BE CREATING NEW STEM CELL LINES, WHICH WOULD NOT BE APPROPRIATE FOR THIS RFA, I DON'T THINK.

AND THE OTHER, RIGHT ABOVE THAT, AND I THINK THIS IS A LARGER POLICY QUESTION. I'LL JUST PRESENT MY BIAS UP FRONT. WE'RE GIVING A PRIORITY TO PLURIPOTENT STEM CELLS. I PERSONALLY WOULD

ALMOST -- I WOULD MULTIPLY THE PRIORITY. I'D ALMOST -- BECAUSE I DO TAKE TO HEART SOME OF THE COMMENTS THAT WERE MADE IN THE *NEW YORK TIMES* REGARDING THE DISEASE TEAM APPLICATIONS AND SOME OF THE CONCERN THAT WE MAY HAVE BEEN STRAYING FROM OUR CORE -- OUR ORIGINAL MISSION WAS TO FUND WHAT THE FEDS WOULDN'T FUND. AND I DO RECOGNIZE IN THE DISEASE TEAM AREA THAT WE NEED TO FUND THINGS THAT ARE VERY LIKELY TO LEAD TO THERAPIES, AND THAT INCLUDES THE WHOLE PANOPLY OF STEM CELL THERAPIES. HOWEVER, I THINK MAYBE THIS IS A PLACE WHERE, IF WE WANTED TO PUT OUR MARKER DOWN AND SAY THAT WE REALLY ARE GOING TO FOCUS, ONE OF OUR CORE MISSIONS IS TO MOVE THE PLURIPOTENT THERAPY FIELD FORWARD, THAT WE REALLY, YOU KNOW, MAKE THIS A MAJOR PART OF WHAT WE'RE DOING HERE BECAUSE WE'RE NOT GOING TO HAVE CANDIDATES. THIS SEEMS, FIRST OF ALL, TO BE WHERE A LOT OF THE SCIENCE IS AT THIS TIME. AND IF WE'RE NOT GOING TO HAVE THE CANDIDATES IN PLURIPOTENT CELLS, FORCED PLURIPOTENT CELL TRIALS, IF WE DON'T START REALLY MOVING THEM HERE NOW, I KNOW WE HAVE THAT PRIORITY, BUT I'D ALMOST TAKE IT TO A HIGHER LEVEL AND REALLY TRY TO MAKE THAT ALMOST THE EXCLUSIVE FOCUS OF THIS, TO HAVE CELL THERAPIES MOVING FORWARD. THAT'S JUST MY PERSONAL, I'M NOT A

SCIENTIST, BUT MY PERSONAL BIAS.

CHAIRMAN KLEIN: JEFF, I ALSO KNOW YOU'RE VERY FOCUSED ON ADDRESSING PATIENT NEEDS. AND IN A TIMING SENSE, THIS IS GOING TO COME UP FOR FUNDING AT THE END OF THIS NEXT YEAR. AT THAT TIME THE $10 BILLION BOLUS OF THE NIH WILL ESSENTIALLY HAVE BEEN SPENT. AND WHETHER OR NOT THERE'S ANY RENEWED FUNDING IS HIGHLY IN QUESTION. SO THERE MAY BE SOME VERY IMPORTANT THERAPEUTIC CANDIDATES THAT ARE, WHETHER THEY'RE CORD BLOOD BASED OR WHETHER THEY'RE MESENCHYMAL CELLS, STATE THE PRIORITY, BUT GIVING OURSELVES THE OPPORTUNITY TO RESPOND TO THESE OTHER THERAPIES WHEN THERE MAY BE A SCARCITY OF OTHER FUNDING AVAILABLE, I THINK, IS AN IMPORTANT FOCUS IN OUR COMMITMENT TO PATIENTS THAT YOU'VE ALWAYS BEEN VERY CENTERED ON.

MR. SHEEHY: AND, YOU KNOW, OBVIOUSLY AS AN HIV ADVOCATE, WE'RE REALLY LOOKING AT ADULT STEM CELLS. BY MAKING THIS POLICY RECOMMENDATION, I'M PRETTY MUCH CUTTING MYSELF OUT OF THE GAME AT LEAST AT THIS POINT. BUT IT DOES POINT TO A QUESTION OF IDENTITY AND PHILOSOPHICALLY WHAT WE WANT OUR FOCUS TO BE, AT LEAST AT THIS STAGE IN THE DEVELOPMENTAL PIPELINE. IT SEEMS TO ME THAT THIS IS A PLACE THAT THE NIH IS GOING TO -- IT'S GOING TO TAKE THEM A

LONG TIME TO REALLY FIGURE OUT HOW TO GET INTO THIS SPACE IN A MAJOR WAY GIVEN THAT THEY HAVEN'T DONE VERY MUCH PLURIPOTENT CELL FUNDING AT THIS POINT, ESPECIALLY EMBRYONIC STEM CELLS. THEY'RE STILL LEARNING HOW TO DO THAT AT THIS POINT. WE HAVE A LOT OF EXPERIENCE FUNDING EMBRYONIC STEM CELLS. THIS IS A PLACE WHERE WE CAN START TO REALLY DRIVE THE FIELD FORWARD, AND THIS SEEMS LIKE A TIME AND THE PLACE TO MAKE THAT -- TO MAYBE GIVE A BIG PUSH.

NOW, THAT'S JUST MY -- WE MAY BE LEAVING OTHER ADULT STEM CELL THERAPIES OUT THERE, BUT WE CAN'T FUND EVERYTHING IN THE WORLD. WHAT REALLY -- WHY ARE WE HERE? IT'S AN EXISTENTIAL QUESTION.

CHAIRMAN KLEIN: DR. TROUNSON AND THEN DR. PRIETO.

DR. TROUNSON: WELL, JUST IN RESPONSE TO THAT, I THINK THE MISSION, THE MISSION SORT OF DRIVES US PRETTY MUCH AT THE MOMENT, THAT THE DISCOVERIES NEED TO GET THROUGH TO THE CLINIC. SO THE PRIORITY IS CLEAR, THAT I THINK WE SHOULD KEEP THE PRIORITY ON THE PLURIPOTENTIAL STEM CELLS. BUT THERE IS -- YOU KNOW, WE HAVE CANCER STEM CELLS. THERE ARE SOME THINGS HERE THAT ARE AN OPPORTUNITY, A REAL OPPORTUNITY TO DO SOMETHING VERY SPECIAL IN A DISEASE SITUATION THAT I DON'T THINK WE SHOULD, YOU

KNOW, SAY IT'S RULED OUT BASICALLY BECAUSE WE'RE ONLY DOING PLURIPOTENTIAL STEM CELLS. I THINK MISSION SAYS THAT WE REALLY NEED TO GET THE DISCOVERIES THROUGH THE CLINIC.

AND I AGREE TO THE PRIORITY, BUT I'M NOT SO -- I'M MORE OPEN ABOUT LETTING SOMETHING THAT MIGHT SUDDENLY APPEAR VERY SPECIAL FOR SOME CONSIDERATION. AND IF IT'S NOT A PRIORITY, IT'S OBVIOUSLY GOING TO HAVE TO BE SPECIAL. AND I THINK THAT'S WHAT -- THAT'S THE WAY WE SHOULD BE THINKING ABOUT THIS PARTICULAR PROGRAM.

DR. PRIETO: RATHER THAN STRIKING THAT SECOND OR THE THIRD POINT UNDER THE PROJECTS WILL PRIORITIZE, TO RECOGNIZE SORT OF OUR SPECIAL POSITION SITUATION TO SAY THAT WE'LL PRIORITIZE THOSE THAT ARE INELIGIBLE FOR OR UNLIKELY TO RECEIVE FUNDING FROM OTHER SOURCES BECAUSE I DON'T THINK WE CAN SINGLE OUT THE FEDERAL GOVERNMENT ANYMORE, BUT WE'RE STILL DOING SOMETHING THAT NOT MANY OTHER PEOPLE WILL FUND, HOPEFULLY.

CHAIRMAN KLEIN: SO WHAT IS THE NATURE OF YOUR RECOMMENDATION, DR. PRIETO?

DR. PRIETO: RATHER THAN SAY THE UNITED STATES FEDERAL GOVERNMENT, THAT WE JUST SAY INELIGIBLE FOR OR UNLIKELY TO RECEIVE FUNDING FROM

OTHER SOURCES.

CHAIRMAN KLEIN: SO CERTAINLY IN OUR CHARTER, WE SPECIFICALLY DEAL WITH NOT ONLY WHETHER THE FUNDING WILL OCCUR, BUT WHETHER IT WILL BE TIMELY AND WHETHER THERE WILL BE SUFFICIENT FUNDING. SO IF THE NIH IS GOING TO FALL BACK TO A SITUATION WHERE THEY CAN ONLY FUND 5 PERCENT OF THE NEW APPLICATIONS, WE DON'T WANT TO BE IN THAT BOX. SO I WOULD THINK THAT WE REALLY NEED TO PROVIDE THE STAFF MORE ROOM HERE AGAIN ON AN OPPORTUNISTIC BASIS TO SAY WE'RE PRIORITIZING PROJECTS WHERE IT IS INELIGIBLE OR UNLIKELY TO RECEIVE SUFFICIENT FUNDING IN A TIMELY MANNER, WHICH TRACKS WITH THE INITIATIVE, BECAUSE TIMING IS CRITICAL TO PATIENTS AND CRITICAL TO WHETHER WE BREAK THE BACK OF A MOMENTUM OF A PARTICULAR TEAM THAT REALLY MAY HAVE SOME QUITE EXCITING WORK IN PROGRESS.

DR. PENHOET: I HATE TO BELABOR THIS POINT, BUT I'M GOING TO ANYWAY. YOU KNOW, ALL THESE NICE WORDS DON'T MEAN ANYTHING UNLESS YOU HAVE AN ALGORITHM IN PLACE THAT'S GOING TO SAY WHAT PRIORITIZATION MEANS OR WHAT SOMEBODY ELSE WON'T FUND MEANS BECAUSE OTHERWISE THEY'RE JUST WORDS THAT WE BANTER AROUND HERE. BUT IF YOU DON'T KNOW DOES PRIORITY MEAN YOU ARE GOING TO DEDUCT THE SCORE BY

20 POINTS IF SOMEBODY IS NOT A PLURIPOTENT STEM CELL, IT BECOMES -- I'M NOT QUITE SURE HOW YOU PARSE THIS THING IN THAT SENSE BECAUSE YOU'VE ALREADY PARSED IT A COUPLE OF WAYS. YOU PARSED IT AND SAID YOU'VE MADE THE BOX NARROW AS YOU CAN, PARSED IT ANOTHER WAY, DIVIDING THINGS BETWEEN THOSE WHICH ARE FEASIBILITY STUDIES AND THOSE WHICH ARE NOT, AND THEN YOU'RE GOING TO TRY TO PARSE IT AGAIN BETWEEN THINGS WHICH CAN'T BE FUNDED BY SOMEBODY ELSE OR POSSIBLY WOULDN'T BE AND THEN PARSE IT AGAIN BY, YOU KNOW, WHETHER OR NOT IT'S PLURIPOTENT STEM CELLS. IT'S AN OPERATIONAL ISSUE.

SO UNLESS YOU HAVE SOME REAL GUIDELINES ABOUT THAT, THESE WORDS DON'T MEAN VERY MUCH.

CHAIRMAN KLEIN: DR --

DR. PENHOET: I DON'T KNOW HOW -- WHAT PRIORITIZE PLURIPOTENT STEM CELLS MEANS.

DR. OLSON: IT MEANS --

DR. PENHOET: YOU NEED AN OPERATIONAL DEFINITION OF HOW YOU'RE ACTUALLY GOING TO WORK THE PROBLEM WHEN YOU'RE FACED WITH A BUNCH OF GRANTS.

DR. OLSON: IF WE HAD A PRIORITY, WE WOULD TELL THE REVIEWERS THAT. WE WOULD EMPHASIZE IT AS A PRIORITY. IF YOU REALLY WANT TO ENSURE, YOU MAKE IT A REQUIREMENT. I'M NOT SURE YOU WANT TO DO THAT. A

REQUIREMENT THEN MEANS WE DON'T ACCEPT APPLICATIONS THAT DO COME IN, BUT OTHERWISE IT ENDS UP BEING THE DISCRETION OF THE REVIEWERS WHERE WE CAN EMPHASIZE PRIORITIES AND WE CAN PUT IT INTO REVIEW CRITERIA AS FAR AS POSSIBLE, BUT THAT'S WHAT IT COMES DOWN TO.

CHAIRMAN KLEIN: DR. PENHOET, ON --

DR. PENHOET: I'M NOT ARGUING FOR MAKING IT MORE RIGID, BUT I AM SAYING IT LEAVES -- IF I'M A REVIEWER AND I'M READING THE QUALITY OF A GRANT, I'M SUPPOSED TO HAVE SOME BIAS TOWARDS MARKING IT DOWN AND YOU LEAVE IT TO MY DISCRETION TO DO THAT. THAT'S WHAT YOU ARE SAYING THE OPERATIONAL DEFINITION IS.

CHAIRMAN KLEIN: DR. PENHOET, ON AN OPERATIONAL BASIS IN PEER REVIEW, THE WAY THIS GENERALLY COMES UP IS AT PROGRAMMATIC REVIEW. IF WE HAVE AN EMBRYONIC PROPOSAL THAT IS LOWER DOWN, THEY MIGHT ANALYZE THE SPECIFIC MERITS OF THAT, REALIZE THAT THIS IS SOMETHING THAT MIGHT OTHERWISE BE FUND IF FUNDS ARE AVAILABLE AND ELEVATED BECAUSE THEY'RE CONCERNED THAT, IN FACT, THIS MIGHT BE THE ONLY SOURCE OF FUNDING FOR THAT GRANT.

JEFF SHEEHY, WOULD YOU LIKE TO COMMENT AS WELL?

MR. SHEEHY: WELL, I ACTUALLY AGREE WITH

DR. PENHOET, WHICH IS WHY I WANTED TO STRIKE THE LAST ONE. AND ACTUALLY I WAS HEADED TOWARDS A REQUIREMENT FOR PLURIPOTENT CELLS, TRYING TO GET A SENSE IF ANYBODY ELSE FELT THAT WAY ABOUT IT. JUST I TAKE ALAN'S POINT ABOUT CANCER STEM CELLS. BUT IF YOU LOOK, ABOUT 60 PERCENT OF OUR DISEASE TEAMS WENT TO CANCER, AND WE'RE KIND OF LEAVING THE PLURIPOTENT CELL FIELD AS KIND OF BRINGING UP THE REAR, AND I THINK IT SHOULD BE THE OTHER WAY AROUND BASED ON OUR MISSION.

AND I PERSONALLY WOULD FOR THIS YEAR FOR THIS TRANSLATION ROUND, I WOULD MAKE IT THE REQUIREMENT THAT IT BE PLURIPOTENT CELLS. AND THE REASON IS IS BECAUSE WE'RE NOT GOING TO GET THESE INTO THE PIPELINE. AND WE JUST FUNDED A LOT OF CANCER STEM CELL CANDIDATES. WHO IS ELSE IS GOING TO PUSH THIS FIELD FORWARD? AT SOME POINT WE'VE GOT TO SAY WE'RE GOING TO PUSH PLURIPOTENT CELLS AND WE'RE GOING TO PUSH THEM HARD IF THAT'S WHAT WE WANT TO DO. IF NOT, IF WE'RE GOING TO TAKE THAT BROAD -- YOU KNOW, THIS HAS BEEN A QUESTION THAT'S BEEN OUT THERE. IT WAS OUT THERE IN THE KIND OF DISCUSSIONS AROUND THE STRATEGIC PLAN, AND IT'S KIND OF BEEN PERIPHERAL. BUT FOR ME FOR THIS PARTICULAR ROUND, I WOULD PUSH HARD FOR SAYING LET'S DO PLURIPOTENT

CELLS. LET'S SEE IF WE CAN GET SOME THERAPIES INTO THE PIPELINE AND MOVE SOME STUFF FORWARD.

CHAIRMAN KLEIN: OKAY.

DR. GILL: I DON'T DISAGREE WITH THE PLURIPOTENT STEM CELL, BUT I THINK ALAN MADE AN IMPORTANT POINT, THAT IF YOU LOOK AT THE TWO OBJECTIVES OF THIS, IT MIGHT BE MET BETTER BY SOME THERAPIES THAT ACTIVATED ENDOGENOUS STEM CELLS FOR REPAIR AND REPLACEMENT OR CANCER STEM CELLS. YOU CAN THINK OF A VARIETY OF THINGS THAT MIGHT NOT BE IP'S. SO I WOULD TRUST THE REVIEWERS TO PICK OUT THE VERY BEST WITHOUT LIMITING THEM.

CHAIRMAN KLEIN: OKAY.

MR. SHEEHY: CAN I MAKE A POINT? THE ONLY THING IS I THINK WHEN YOU START MEASURING ADULT STEM CELLS OR SMALL MOLECULES ATTACKING CANCER STEM CELLS, THAT INEVITABLY EMBRYONIC STEM CELLS AND IPS CELLS, THE PLURIPOTENT CELLS ARE AT A DISADVANTAGE. THERE'S NOT A CLEAR REGULATORY PATHWAY. WE REALLY DON'T KNOW HOW THESE THINGS WORK. THERE'S ALL THESE PROBLEMS, TUMOROGENICITY, IMMUNE TOLERANCE. AND THE OTHER ONES, YOU KNOW, IT'S JUST YOU PUT THEM TOGETHER, AND IT'S NOT REALLY APPLES AND APPLES. IT'S APPLES AND ORANGES. AND YOU'VE KIND OF ALREADY BIASED THE WHOLE THING TOWARDS THE APPLES, AND WE'LL

END UP, YOU KNOW, WITH PROBABLY MORE ADULT STEM CELL THERAPIES MOVING FORWARD OR NONPLURIPOTENT STEM CELL THERAPIES.

AGAIN, THIS COMES TO A QUESTION OF -- I DON'T MIND LOSING ON THIS. I DON'T EVEN HAVE TO PUT IT TO A VOTE, BUT I PERSONALLY WOULD GO THE OTHER DIRECTION.

DR. PENHOET: ONE WAY TO DO IT --

CHAIRMAN KLEIN: DR. PENHOET, I THINK DR. PRICE HAS BEEN VERY PATIENT, AND THEN I'LL COME TO YOU.

DR. PRICE: I'D LIKE TO SORT OF, I GUESS, SUPPORT WHAT JEFF IS SAYING BY MAKING AN ANALOGOUS ARGUMENT REALLY FROM ECONOMICS AND ECONOMIC DEVELOPMENT THEORY. AND I START WITH A HYPOTHESIS, WHICH MAY BE WRONG, BUT THE HYPOTHESIS IS TO TRY TO EXPLAIN WHAT TO SOME OF US WAS THE SURPRISING WEIGHT, IF NOT DOMINANCE, OF NONPLURIPOTENT RESEARCH IN THE DISEASE TEAMS. MY HYPOTHESIS IS THAT'S BECAUSE THOSE FIELDS, THE ADULT STEM CELL FIELDS, THE CANCER STEM CELLS FIELDS, ARE SIMPLY MORE MATURE, THE SCIENCE IS MORE MATURE. SO THAT YOU GOT TO REVIEW, THERE'S MORE PROOF OF PRINCIPLE, THERE'S MORE BEHIND IT, THERE'S NOT A LEVEL PLAYING FIELD WITH RESPECT TO THE PLURIPOTENT FIELD. SO HERE'S MY

ANALOGY.

THROUGHOUT HISTORY WHEN, AT LEAST MODERN HISTORY, WHEN COUNTRIES HAVE DECIDED TO DEVELOP AN INDUSTRIAL CAPACITY IN AN AREA WHERE THEY DON'T HAVE IT BEFORE, IT HAS BEEN FAIRLY COMMON TO PURSUE WHAT IS CALLED INFANT INDUSTRY STRATEGY. THROUGH VARIOUS WAYS PROTECT THOSE LINES WHICH ARE NEW, THOSE AREAS OF ENDEAVOR WHICH ARE NEW THROUGH EITHER TARIFFS OR THROUGH GOVERNMENT SUBSIDIES SO AS TO ALLOW THE INFANT INDUSTRY TO COMPETE WITH THE MORE MATURE INDUSTRIES, AT WHICH POINT YOU CAN WITHDRAW THE SUBSIDIES.

I THINK WHAT JEFF IS ARGUING IS ESSENTIALLY AN ANALOGY TO WHAT WE'RE DOING IS THAT WE SHOULD USE SOME OF OUR RESOURCES TO ESSENTIALLY STIMULATE, TO BOLSTER THE PLURIPOTENT FIELD SO THAT IT CAN COMPETE AT A LEVEL PLAYING FIELD WITH ADULT STEM CELLS.

CHAIRMAN KLEIN: SO DR. PENHOET.

DR. PENHOET: WELL, ONE INTERMEDIATE SUGGESTION WOULD BE AN ALGORITHM FOR REVIEW WHICH SAYS YOU WILL REVIEW ALL THE PLURIPOTENT STEM CELL GRANTS FIRST AND DETERMINE WHICH ONES YOU RECOMMEND FOR FUNDING. THAT SAYS, OKAY, YOU'VE GOT X GOOD GRANTS. IF THERE'S STILL MONEY LEFT OVER, THEN YOU

REVIEW THE REST AND RANK ORDER THEM AND THEY FALL BELOW. THAT DOESN'T MEAN -- THERE ARE SOME INTERMEDIATE WAYS TO HANDLE THIS WHICH PUT TEETH IN PRIORITY. OTHERWISE I THINK IT WILL JUST END UP THE WAY IT ENDS UP.

CHAIRMAN KLEIN: SO WHAT I'D LIKE TO REMIND US HERE IS THAT OUR FUNDAMENTAL OBLIGATION IS TO MOVE THERAPIES TO PATIENTS. AND WHILE THE INITIATIVE CREATES A PRIORITY FOR PLURIPOTENT AND PROGENITOR STEM CELL RESEARCH, AND CERTAINLY IT IS THE PLURIPOTENT CELLS THAT HAVE THE LONGER LEAD-TIME AND THE MORE COMPLEX DEVELOPMENT PATH, WE HAVE THE ABILITY IN PROGRAMMATIC REVIEW TO RECOGNIZE THIS PRIORITY. AND I QUESTION WHETHER WE'RE HONORING OUR OBLIGATIONS TO PATIENTS IF WE PASS OVER AN OPPORTUNITY TO FUND A THERAPY THAT DOES NOT USE PLURIPOTENT STEM CELLS BECAUSE WE HAVE A PLURIPOTENT STEM CELL OPPORTUNITY THAT IS FURTHER OUT.

WE HAVE THE FLEXIBILITY FINANCIALLY WITH SOLID SCIENTIFIC OPPORTUNITY TO REALLY FUND HIGH QUALITY PLURIPOTENT AND NONPLURIPOTENT THERAPIES IN THIS DEVELOPMENT PATHWAY. I'M GOING TO CALL ON DR. OLSON THEN DR. BRYANT.

DR. OLSON: I WOULD SAY THAT HAVING BEEN LISTENING TO THIS DISCUSSION, I MEAN WHAT I WOULD

LIKE TO SUGGEST IS THAT WE WILL PUT THE EMPHASIS ON PLURIPOTENT. WE WILL TRY AND ADDRESS THE REVIEW CRITERIA TO AGAIN HIGHLIGHT THAT. I WOULD POINT OUT THAT IN THE FIRST EARLY TRANSLATION, BY PUTTING A PRIORITY ON DEVELOPMENT CANDIDATES, I THINK THAT PLAYED OUT QUITE NICELY.

SO BUT I DO WANT TO POINT OUT THAT REALLY, AS BOB HAS SAID, AS CHAIRMAN KLEIN HAS SAID, PROGRAMMATIC IS THE PLACE WHERE YOU CAN REALLY DO THAT IN CONJUNCTION WITH PRIORITY, EMPHASIZE THIS IS WHAT WE'RE LOOKING FOR. AND I WOULD SUGGEST THAT THAT COULD PROBABLY ADDRESS THE CONCERNS HERE IN THE FOCUS.

CHAIRMAN KLEIN: SO WE'VE HAD A VERY ACTIVE DISCUSSION. DR. BRYANT, I'M GOING TO GIVE YOU THE LAST WORD. AND THEN JUST SO WE SEE WHERE WE'RE GOING, SINCE WE CAN'T VOTE TONIGHT, WE'RE GOING TO ASK THAT RICH LARSON, WHO'S ASKED TO SPEAK, IF HE COULD SPEAK BECAUSE HE HAS TO LEAVE. AND DON REED WANTS TO SAY SOMETHING AFTER THAT. AND THEN WE'RE GOING TO ADJOURN FOR THE EVENING WITH DR. TROUNSON ACTUALLY -- RICH, WE'RE GOING TO DO DR. BRYANT, THEN DR. TROUNSON, THEN WE'RE GOING TO GO TO YOU.

DR. BRYANT: I DON'T HAVE VERY MUCH TO SAY

EXCEPT THAT I THINK YOU MENTIONED WE HAVE COMMITMENTS TO PATIENTS. WE ALSO HAVE A COMMITMENT TO THE VOTERS TO EXPLORE HUMAN EMBRYONIC STEM CELLS TO THE BEST OF OUR ABILITY. THIS IS OUR ONE SHOT, SO I WOULD SAY THOSE ARE COMPETING DEMANDS. I LIKE WHAT BOB SAID. I LIKED HIS ANALOGY VERY MUCH.

DR. TROUNSON: WELL, I THINK I MENTIONED CANCER STEM CELLS BECAUSE THERE'S SO MANY -- THERE'S CLEARLY SO MANY OPPORTUNITIES, BUT THERE ARE SOME VERY EARLY CLINICAL TRIALS ON AMNIOTIC-DERIVED CELLS THAT ARE BEING USED FOR PREMATURE BABIES. I DON'T THINK THAT WOULD BE ACTUALLY CLASSIFIED AS -- WELL, ARGUABLY CLASSIFIED AS PLURIPOTENTIAL. THERE ARE SOME DEVELOPMENTS OUT THERE THAT I THINK WE WOULD BE SILLY TO EXCLUDE AT LEAST FOR CONSIDERATION.

SO THE REQUIRED I STILL DON'T LIKE BECAUSE THE SENSE FOR THE MISSION IS TO GET THE DEVELOPMENTS TO THE CLINIC. AND IF IT IS A CERTAIN CELL TYPE THAT'S MORE AVAILABLE AND IT'S LESS LIKELY TO PRODUCE A REACTION AND LIKELY TO HAVE A BENEFIT FOR A PATIENT, EXCLUDING THAT AT THIS POINT IN TIME JUST DOESN'T SEEM TO MATCH WITH OUR MISSION.

NOW, YOU KNOW, AS YOU KNOW, I GREW UP WITH PLURIPOTENTIAL EMBRYONIC STEM CELLS, SO THEY'RE MY FAVORITE THINGS. BUT I SENSE THAT THE MISSION, THE

MISSION IS TO ACTUALLY GET THE BEST TREATMENT TO THE CLINIC. AND IF THERE ARE SOME VERY SPECIAL OPPORTUNITIES COME BY, WE'RE CRAZY IF WE CUT IT OFF SO THAT THE REVIEWERS CAN'T SAY THIS IS A VERY SPECIAL, A VERY SPECIAL OPPORTUNITY, AND WE THINK CIRM SHOULD BE THE PLACE IN WHICH WE DRAW THAT FORWARD IN AN EARLY TRANSLATION GRANT. SO I DON'T KNOW WHAT THEY NECESSARILY WILL BE, BUT I'M ASTONISHED ABOUT SOME OF THE WORK WHICH HAPPENING WOULD NECESSARILY EASILY FIT INTO THAT DEFINITION THAT INCLUDED REQUIRED.

CHAIRMAN KLEIN: THANK YOU. RICH, IF YOU WOULD PLEASE MAKE YOUR PRESENTATION. THIS IS PUBLIC COMMENT PRESENTATION BEFORE WE ADJOURN.

MR. LARSON: REALLY APPRECIATE THE OPPORTUNITY THIS EVENING AND FOR SQUEEZING ME IN HERE, AND YOU CAN ALL GO HOME AFTER I'M DONE TALKING. SO MEMBERS OF THE BOARD AND MR. CHAIRMAN, NICE TO SEE YOU AGAIN, BY THE WAY, AND THANKS AGAIN FOR COMING TO STANFORD ONE MORE TIME.

MY NAME IS RICH LARSON, AND I'M ON THE BOARD OF DIRECTORS OF THE HUNTINGTON'S DISEASE SOCIETY OF AMERICA, A NORTHERN CALIFORNIA CHAPTER. I'M HERE REPRESENTING JUDY ROBERSON, MANY OF WHOM YOU KNOW. SHE'S A VERY PASSIONATE PERSON WHO LOST

HER HUSBAND TO HD AND HAS THREE KIDS THAT ARE AT RISK. AND SHE ASKED ME TO COME HERE AND TELL OUR STORY ABOUT HD FROM KIND OF A USER PERSPECTIVE TO THIS GROUP OF DISTINGUISHED POLICYMAKERS.

AND SO I JUST WOULD LIKE TO START BY SAYING MOST OF YOU PROBABLY KNOW WHAT HD IS PROBABLY BETTER THAN I DO CONSIDERING ALL THESE WORDS THAT YOU ARE BOUNCING AROUND HERE. JUDY SAYS YOU MAKE THEM ALL UP, BY THE WAY, SO I DON'T KNOW IF THAT'S TRUE. JOKE. OBVIOUSLY A LITTLE LATE.

ANYWAY, HD IS AN ORGANIC BRAIN DISEASE. IT IS A DISEASE WITH NO CURE. IT'S ONE THAT IS VERY DISRUPTIVE OBVIOUSLY TO THE VICTIM, BUT ALSO TO THE CAREGIVERS, AND IT'S JUST REALLY ONE OF THOSE AWFUL SORT OF DISEASES. AND IT'S IN MY FAMILY AS WELL AS IT IS JUDY'S AND MANY MEMBERS ACROSS THE COUNTRY. I'M AT RISK. MY TWO SONS ARE AT RISK. AND UNFORTUNATELY I'VE GOT A LONG LINE OF FAMILY MEMBERS THAT HAVE GONE THROUGH HD. MY GRANDFATHER PASSED AWAY IN A MENTAL INSTITUTION, WHICH IS WHAT THEY DID TO PEOPLE WITH HD BACK IN THE DAY. MY GRANDMOTHER PASSED AWAY IN 1975. SHE SUFFOCATED IN BED DUE TO THE SYMPTOMS OF HD. MY MOTHER PASSED IN '97. SHE CHOKED TO DEATH DUE TO, AGAIN, THE LOSS OF MUSCLE CONTROL THAT HD BRINGS ABOUT.

AND SO THE NEED FOR A CURE IN OUR PERSONAL, VERY PERSONAL, POINT OF VIEW COULDN'T BE HIGHER, AS YOU WOULD IMAGINE. MY SISTER IS NOW SYMPTOMATIC. SHE'S GOT TWO KIDS AT 48 YEARS OLD, AND I'D HATE TO HAVE HER GO THROUGH WHAT MY MOTHER AND MY GRANDMOTHER DID. SO WITH THIS IN MY FAMILY AND SEEING OTHER PEOPLE AT RISK, I'VE SPENT WHAT TIME I HAVE AND WHAT MONEY I HAVE DEVOTING MY EFFORTS TO THE HDSA.

AND WE DO BASIC THINGS NOW. WE DO A LOT OF RESEARCH. WE'VE GOT CENTERS OF EXCELLENCE AROUND THE COUNTRY. MANY OF YOU HAVE HEARD OF JAN NOLTA, DR. JAN NOLTA, AND DR. VICKI WHEELOCK, VERY DISTINGUISHED SCIENTISTS IN OUR ORGANIZATION. FOR THE FIRST TIME IN MANY YEARS, THERE'S SOME HOPE ABOUT THE MSC STUDIES THAT THEY'RE DOING. AND WE THINK THAT THE ABILITY TO HELP THE NEURONS RECONNECT, FROM, AGAIN, OUR USER POINT OF VIEW, SEEMS LIKE A VERY HOPEFUL OPPORTUNITY.

THE OTHER ASPECT, IN ADDITION TO RESEARCH, WE DO A LOT OF CARE ADVOCACY, FUND-RAISING IN THE FORM OF HOOLA-HOOP DANCES AND WALKS AND SO FORTH, ALL OF WHICH REPRESENTS REALLY SMALL MONEY COMPARED TO WHAT WE'RE TALKING ABOUT HERE. SO WE'RE REALLY GLAD THAT THERE'S FEDERAL GOVERNMENT PROGRAMS IN

PLACE AS WELL. AND WE TRY TO SPREAD HOPE. WE TRY TO SPREAD HOPE WITH PEOPLE AND FAMILIES THAT ARE AFFLICTED WITH THIS DISEASE AND IT'S TOUGH. THEY ARE ALL TRULY SUFFERING. BUT WHEN YOU LOOK AT WHAT HAPPENED IN TERMS OF DISCOVERING THE GENE MORE THAN TEN YEARS AGO, YOU LOOK AT SOME OF THE PROGRESS THAT WE'RE SEEING WITH THE MSC CELLS NOW, MSC STUDIES, AND YOU LOOK AT WHAT'S HAPPENING HERE WITH THE CIRM. WE'RE SO HAPPY YOU'RE HERE. WE'RE JUST VERY PLEASED WITH EVERYTHING YOU'VE DONE, MR. CHAIRMAN AND THE REST OF THE ORGANIZATION, AND, OF COURSE, THE VOTERS OF CALIFORNIA. SO THANK YOU ALL FOR THAT.

OUR BASIC MESSAGE TO YOU ALL TONIGHT IS WE NEED YOUR HELP TO FUND THE BEST SCIENCE TO HELP US FIND A CURE FOR HD. SO IF I ASK YOU TO DO THAT, THAT'S MY SIMPLE REQUEST. BEST WISHES TO ALL OF YOU.

CHAIRMAN KLEIN: THANK YOU VERY MUCH AND THANK YOU FOR YOUR ADVOCACY. DON REED.

MR. REED: NATURALLY I HAVE ENORMOUS RESPECT FOR SCIENTIFIC STAFF. THEIR RECORD OF ACCOMPLISHMENTS IS GOING TO BE LEGENDARY. AND OUR CHIEF SCIENTIST IS A TREMENDOUS PIONEER OF IVF. NO QUESTION ABOUT THAT. BUT I DON'T LIKE WHAT I'M FEELING. WHAT I'M FEELING IS THAT WE'RE LOSING

TRACK OF WHAT WE FOUGHT FOR. THE ADULT STEM CELLS HAD HUGE ADVANTAGES, 40 YEARS HEAD START, MASSIVE OVERFUNDING. I JUST READ THE TRANSCRIPT OF THE MILITARY TALKING ABOUT $250 MILLION GRANT FOR ADULT STEM CELLS. AND ONE OF THE REPORTERS SAYS, "THIS ISN'T VERY MUCH," AND HE SAID, "OH, WE REGARD IT AS A STARTING POINT."

THEY'VE HAD HUGE ADVANTAGES. THE OPPOSITION HAS ATTEMPTED TO PUT SCIENTISTS IN JAIL FOR DOING SOMATIC CELL NUCLEAR TRANSFER. THIS IS OUR SHOT. I SUGGEST THAT WE LOOK AT THE WAY THIS IS SET UP, WHICH IS THREE TIMES AS MUCH FOR CLOSE TO THE IND AND ONE PART FOR THAT WHICH IS NOT CLOSEST TO IND. IF YOU LOOK AT WHAT'S CLOSEST TO IND, YOU HAVE TO SAY IT'S GOING TO BE ADULT BECAUSE THEY'VE HAD THIS HUGE ADVANTAGE. WE WANT TO CHANGE -- WE WANT TO ADVANCE THE FIELD. I SUGGEST DON'T MAKE IT A THREE-TO-ONE ADVANTAGE. JUST MAKE IT BE FOR WHAT'S BEST. MAKE IT BE THE BEST SCIENTISTS. DON'T SAY THREE TIMES FOR THAT AND ONE TIME FOR THIS.

THIS IS WHAT WE FOUGHT FOR. WE'RE THE ONLY PLACE IN THE WORLD THAT'S DOING THIS. I SEE WASHINGTON BEING VERY CAREFUL AND TIMID AND CAUTIOUS AND AFRAID. I HEARD THE HEAD OF -- DR. FRANCIS COLLINS, A FINE MAN, SAID HE WOULD NEVER PERSONALLY

ETHICALLY FEEL RIGHT ABOUT MAKING A STEM CELL LINE. WE ARE UNIQUE AND WE MUST ACT AS SUCH. I THINK WE ARE IRREPLACEABLE, AND I URGE YOU TO STRONGLY SUPPORT THE PLURIPOTENTIAL SIDE AND NOT TO GO -- IT'S NOT IMPORTANT THAT WE BE QUICK. IT'S IMPORTANT THAT WE BE RIGHT, AND I THINK WE'RE ON THE RIGHT TRACK AND WE NEED TO DO THIS. I VOTE PLURIPOTENTIAL ALL THE WAY. THANK YOU.

CHAIRMAN KLEIN: DON, WE DIDN'T EXCLUSIVELY FIGHT FOR EMBRYONIC STEM CELLS OR PLURIPOTENT STEM CELLS. WE HAVE A PRIORITY THAT WE FOUGHT FOR, WHICH IS IN THE INITIATIVE, BUT WE FOUGHT FOR THE BEST SCIENCE TO REACH THE PATIENTS AS SOON AS IT COULD. AND I REMIND YOU THAT, LIKE THE SPEAKER BEFORE YOU, HUNTINGTON'S DISEASE DOES NOT HAVE AS ITS BEST TARGET EMBRYONIC STEM CELL THERAPY.

WE HAVE A VERY IMPORTANT MISSION TO MEET AND CERTAINLY IN PROGRAMMATIC WE CAN ADDRESS EMBRYONIC STEM CELLS AND PLURIPOTENT STEM CELLS. BUT IT'S YOUR PASSION AND INDIVIDUALS LIKE YOU WHO HAVE DRIVEN THIS FIELD FORWARD AND FUNDING FOR ALL STEM CELL RESEARCH, AND WE CERTAINLY ARE INDEBTED TO YOU FOR YOUR PASSION AND COMMITMENT. SO THANK YOU VERY MUCH.

MR. REED: EVERY TIME I HELP MY SON GET

OUT OF BED IN THE MORNING, I'M REMINDED ON THE CRUCIAL NATURE OF WHAT YOU ARE DOING. AND THAT'S WHY I ALWAYS HAVE TO SPEAK MY MIND PASSIONATELY EVEN IF I DISAGREE. I LOVE YOU VERY MUCH, ALL OF YOU. THANK YOU.

(APPLAUSE.)

CHAIRMAN KLEIN: THANK YOU VERY MUCH. SO WE'D LIKE TO ADJOURN FOR THE EVENING. I WOULD LIKE TO EMPHASIZE THAT TOMORROW MORNING AT 8 A.M., REMEMBER 8 A.M. MEANS PARKED AND HERE AT 8 A.M., DR. MICHAEL CLARKE FROM STANFORD IS GOING TO DO A PRESENTATION ON CANCER STEM CELLS AND ANSWER A LOT OF THE QUESTIONS ABOUT COMPETING THEORIES ABOUT CANCER STEM CELLS. AND I THINK IT IS A VERY IMPORTANT SUBJECT THAT HE'S PUT A LOT OF PREPARATION INTO, SO I WOULD HOPE THAT WE'RE ALL HERE AT 8 A.M. TO HEAR THIS PRESENTATION. IT'S A CRITICAL THEORY IN THE CANCER AREA, AND THIS IS ONE OF THE LEADING INDIVIDUALS, SCIENTISTS IN THE WORLD. SO THANK YOU VERY MUCH. WE ARE ADJOURNED.

(THE MEETING WAS THEN ADJOURNED AT 06:32 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 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

PAUL BREST HALL, MUNGER COMPLEX
STANFORD UNIVERSITY
STANFORD, CALIFORNIA
ON
DECEMBER 9, 2009

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

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