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

LOCATION: HILTON SAN FRANCISCO AIRPORT BAYFRONT
600 AIRPORT BOULEVARD
BURLINGAME, CALIFORNIA

DATE: MARCH 13, 2014
9 A.M.

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

BRS FILE NO.: 95375

I N D E X

I N D E X (CONT'D.)

BURLINGAME, CALIFORNIA; THURSDAY, MARCH 13, 2014

9 A.M.

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY. WELCOME TO THE MARCH 2014 MEETING OF THE ICOC. IT IS A SPECTACULAR DAY IN THE BAY AREA AND HOPEFULLY IS SIMILAR NO MATTER WHERE YOU ARE. KEN, THAT INCLUDES YOU IN JAPAN. KEN BURTIS GETS THE LONGEST DISTANCE AWARD FOR THIS MEETING WITHOUT ANY QUESTION JOINING US BY PHONE FROM JAPAN. SO, KEN, THANK YOU FOR YOUR DEDICATION. IT'S MUCH APPRECIATED.

DR. BURTIS: MY PLEASURE.

CHAIRMAN THOMAS: LET'S GO -- MARIA, COULD YOU LEAD US IN THE PLEDGE OF ALLEGIANCE.

FOR THOSE ON THE PHONE, WE'RE IN SEARCH OF A FLAG. AMY CHEUNG IS GETTING A FLAG UP ON HER SCREEN. OURS SEEMS TO BE AWOL IN HERE AT THE MOMENT.

(PLEDGE OF ALLEGIANCE.)

CHAIRMAN THOMAS: THAT IS UNQUESTIONABLY A FIRST. FOR THOSE ON THE PHONE, WHICH FLAG IS THAT, AMY, WHICH VERSION? VALLEY FORGE FLAG. VERY NICE. VERY NICE. OKAY. LET IT NOT BE SAID WE AREN'T CREATIVE IN THIS ORGANIZATION.

MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: HERE.
MS. BONNEVILLE: DAVID BRENNER.
DR. BRENNER: HERE.
MS. BONNEVILLE: KEN BURTIS.
DR. BURTIS: PRESENT.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: HERE.
MS. BONNEVILLE: ELIZABETH FINI. MICHAEL FRIEDMAN.
DR. FRIEDMAN: HERE.
MS. BONNEVILLE: JUDY GASSON.
MR. GASSON: HERE.
MS. BONNEVILLE: SAM HAWGOOD.
DR. HAWGOOD: HERE.
MS. BONNEVILLE: STEPHEN JUELSGAARD. SHERRY LANSING.
MS. LANSING: HERE.
MS. BONNEVILLE: JACOB LEVIN.
DR. LEVIN: HERE.
MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: HERE.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: HERE.

MS. BONNEVILLE: AL ROWLETT.

DR. ROWLETT: HERE.

MS. BONNEVILLE: JOAN SAMUELSON. JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. BONNEVILLE: OSWALD STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: HERE.

MS. BONNEVILLE: DONNA WESTON. DIANE WINOKUR.

CHAIRMAN THOMAS: THANK YOU, MARIA.

WE HAVE A NUMBER OF TOPICS THAT REQUIRE VOTES THIS MORNING, AND WE HAVE SOME ISSUES LATER ON WITH QUORUM. SO WE WANT TO TAKE A FEW THINGS A BIT OUT OF ORDER HERE AND MAKE SURE THAT WE GET THROUGH ALL THAT WE NEED TO GET THROUGH THAT REQUIRES A VOTE.

TO SORT OF SET CONTEXT, WE'RE GOING TO START

TODAY WITH AGENDA ITEM NO. 10. I SHOULD NOTE, ALAN, THE CHAIR AND PRESIDENT'S REPORT WE'RE PUSHING TO THE BACK END OF THE MEETING IF THAT'S OKAY.

ITEM NO. 10 IS DR. FEIGAL GIVING US A DEVELOPMENT PORTFOLIO UPDATE.

DR. FEIGAL: WELL, THANK YOU VERY MUCH. AND I'M VERY PLEASED TO BE HERE TODAY TO TALK WITH YOU ABOUT --

CHAIRMAN THOMAS: ART JUST WENT TO THE LENGTH OF DETERMINING WHAT TIME IT IS. JUST SO EVERYBODY KNOWS, IT'S ABOUT 1:10 A.M. IN JAPAN RIGHT NOW.

DR. BURTIS: OKAY.

DR. FEIGAL: OKAY. I'LL TRY AND KEEP THIS LIVELY FOR YOU. I WANT TO -- FIRST, I'M DELIGHTED TO BE HERE TODAY TO PRESENT THE UPDATE ON OUR PROGRESS FROM THE DEVELOPMENT PROJECTS. AND WE'RE REALLY MAKING PROGRESS ON THAT PATHWAY TO TREATMENTS AND CURES FOR PATIENTS WITH SERIOUS DISEASES AND WITH CHRONIC INJURIES. SO I'M VERY PLEASED TO BE ABLE TO PRESENT THIS UPDATE TO YOU TODAY.

THE UPDATE IS ALWAYS GOING TO BE TIED INTO OUR STRATEGY FOR THIS ENTIRE RESEARCH INSTITUTE. THE VISION AND STRATEGY, THE VISION, OF COURSE, IS THAT WE WANT TO HAVE EFFECTIVE TREATMENTS AND CURES FOR PATIENTS WITH THESE DEVASTATING DISEASES AND THESE

CHRONIC INJURIES.

OUR MISSION IS WHAT WE'RE STAYING LASER FOCUSED ON, AND THAT'S REALLY TO ADVANCE THE SCIENCE SO THAT WE CAN PUT TOGETHER APPLICATIONS, DEVELOP THERAPIES FOR PATIENTS WITH THOSE DEVASTATING DISEASE AND INJURIES. THE FIRST FIVE YEARS WERE REALLY CULTIVATING THE FIELD, BRINGING IN THE RESEARCH INTELLECTUAL CAPITAL, AND CATALYZING THE WHOLE FIELD. THE PART WE'RE IN RIGHT NOW IS WHAT WE CALL THE FOCUS PHASE WHERE WE'RE ADVANCING THE SCIENCE BEYOND THE LAB AND BEYOND THE ANIMAL MODELS. WE'VE CURED A LOT OF MICE. WE'VE DONE GREAT THINGS IN RODENTS. WHAT WE'RE TRYING TO DO IS WORK IN THE SPECIES THAT WE'RE MOST INTERESTED IN AND THAT'S THE HUMAN. AND THAT'S WHERE THE RUBBER MEETS THE ROAD.

AND WHAT WE'RE TRYING TO DO IS TO BRING THIS TECHNOLOGY INTO HUMAN CLINICAL TESTING TO PATIENTS WHO ACTUALLY HAVE THESE DISEASES AND CHRONIC INJURIES. AND THAT'S THE PHASE WE'RE IN RIGHT NOW, AND THAT'S REALLY THE FOCUS OF THE DEVELOPMENT PROJECTS.

PART OF THE STRATEGY THAT WE'RE ALSO WORKING ON IS TO DEVELOP THOSE PARTNERSHIPS WITH INDUSTRY, THOSE INTERACTIONS WITH THE FOOD AND DRUG ADMINISTRATION, WHICH IS THE BODY IN THE UNITED STATES THAT HAS TO APPROVE THESE TREATMENTS GETTING INTO

PEOPLE AND APPROVING WHETHER THEY GET INTO THE MARKETPLACE. SO THAT BY THE TIME WE GET TO THE NEXT FIVE YEARS, WE WILL HAVE ESTABLISHED THOSE TYPES OF INTERACTIONS AND THOSE PARTNERSHIPS SO THAT THE WORK WE DO HERE AT CIRM CAN BE THE FOUNDATION FOR MOVING IT FORWARD TO COMMERCIALIZATION AND TO THE MARKETPLACE.

I'M GOING TO FOCUS ON THE DEVELOPMENT PROJECTS. WE'VE GIVEN -- WE'VE AWARDED 1.8 BILLION TO A VARIETY OF DIFFERENT AWARDS ACROSS THE BASIC EARLY RESEARCH TO CLINICAL TRIAL CONTINUUM. OF THAT 1.8 BILLION, ABOUT 1.2 BILLION HAS BEEN DISBURSED. OF THOSE 600 AWARDS, ABOUT 90 ARE FOCUSED ON TRANSLATIONAL PROJECTS. AND OF THOSE 90, ABOUT ONE-THIRD ARE THE DEVELOPMENT PROJECTS. AND THAT'S THE SUBJECT OF MY PRESENTATION TODAY. AND THOSE DEVELOPMENT PROJECTS HAVE BEEN AWARDED ABOUT 450 MILLION. OF THAT 450 MILLION, APPROXIMATELY HALF HAS BEEN DISBURSED.

THE PROGRAMS I'M GOING TO BE TALKING ABOUT ARE THE DEVELOPMENT PROGRAMS. THERE'S TWO MAIN INITIATIVES THAT THIS BOARD HAS APPROVED FOR THOSE PROJECTS. THEY'RE THE DISEASE TEAMS AND THEY'RE THE STRATEGIC PARTNERSHIPS. BOTH OF THESE DIFFERENT PROGRAMS HAVE THE GOAL OF COMPLETING AN EARLY PHASE CLINICAL TRIAL SO THAT WE CAN DETERMINE WHETHER THERE'S EVIDENCE OF SAFETY. DOES THIS NOT HURT PATIENTS?

THAT'S THE FIRST THING IS DO NO HARM, BUT DOES IT HELP PATIENTS? DOES THE THERAPY WORK? ARE WE FINDING THAT THERE'S PRELIMINARY EVIDENCE OF BENEFIT TO PATIENTS? BECAUSE IF THERE IS, THAT'S GOING TO BE THE INFLECTION POINT TO REALLY ATTRACT INDUSTRY, TO REALLY ATTRACT LEVERAGED FUNDING SO THAT PEOPLE WILL LEVERAGE CIRM FUNDING WITH THEIR FUNDING AND BE ABLE TO TAKE IT FORWARD INTO COMMERCIALIZATION AND EVENTUALLY INTO THE MARKETPLACE.

THE WAY WE TRY AND POSITION THESE DIFFERENT DISEASE TEAMS AND STRATEGIC PARTNERSHIPS, AND THESE TEAMS ARE MADE UP OF INDIVIDUALS WITH BOTH MEDICAL EXPERTISE AND LABORATORY SCIENTIFIC EXPERTISE, AND TO AN INCREASING AMOUNT OF EXPERIENCE SOME DEVELOPMENT EXPERTISE. BECAUSE DEVELOPMENT EXPERTISE, HOW TO DEVELOP A PRODUCT, IS NOT NORMALLY IN THE MIDDLE OF THE RADAR SCREEN OF MANY OF THE RESEARCHERS THAT WE'RE WORKING WITH, WE TRY TO SUPPLEMENT AND COMPLEMENT THAT EXPERIENCE AND EXPERTISE BY PROVIDING ADDITIONAL ACCESS TO EXPERTISE TO THEM THROUGH THE INDIVIDUALS THAT WE HAVE ON OUR OWN STAFF HERE AT CIRM WHO HAVE INDUSTRY EXPERTISE, BUT BY BRINGING IN PANELS OF EXTERNAL EXPERTS WHO HAVE EXPERTISE IN PRECLINICAL ANIMAL MODELS, IN MANUFACTURING, AND CLINICAL TRIALS IN DEALING WITH REGULATORY ISSUES AS YOU'RE TRYING TO

BRING A PRODUCT FROM THE LAB TO PATIENTS AND TO THE MARKETPLACE AND BUSINESS EXPERTISE. WHERE DOES THIS PRODUCT POTENTIALLY FIT IN THE COMMERCIAL LANDSCAPE?

SO THE PROGRAMS ARE DRIVEN BY THE SCIENCE AND THE EVIDENCE, BUT THEY'RE ALSO DRIVEN BY THE REGULATORY CONSIDERATIONS THAT ARE NEEDED TO TAKE A PRODUCT INTO HUMANS AND EVENTUALLY INTO THE MARKETPLACE. SO PRIOR TO ANY MONEY GOING OUT THAT DOOR -- SO YOU DEDICATED ABOUT 450 MILLION TO DATE FOR THESE DISEASE TEAMS AND FOR THOSE STRATEGIC PARTNERSHIPS. BUT BEFORE ANY MONEY GOES OUT THE DOOR, OUR SCIENCE AND MEDICAL OFFICERS WORK WITH THE AWARDED DISEASE TEAMS TO WORK ON MILESTONES, TO SET THE THRESHOLD BEYOND WHICH WE WILL NOT GO UNLESS THEY MEET THEM. SO THEIR MILESTONES IN THEIR MANUFACTURING, MILESTONES IN WHAT THEY NEED TO MEET IN THEIR PRECLINICAL ANIMAL MODELS, AND MILESTONES IN WHAT THEY NEED TO MEET IN GOING FROM THE PRECLINICAL TO THE CLINICAL.

AND DURING THE RESEARCH, THERE'S ACTIVE INTERACTION ON THEIR PROTOCOLS, ON THEIR REGULATORY STRATEGY, PREPARATION FOR THEIR INTERACTIONS WITH THE FOOD AND DRUG ADMINISTRATION, ATTENDANCE AT THEIR TEAM MEETINGS, AND ASSESSING THE MILESTONES. IN ADDITION TO THOSE DIRECT INTERACTIONS, THERE'S ALSO A VARIETY OF TOOLS THAT CIRM MAKES AVAILABLE FOR EDUCATION AND

TRAINING OF THE TEAMS THROUGH WEBINARS, THROUGH ROUNDTABLES, THROUGH CONFERENCES, AND THROUGH SEMINARS.

THIS IS WHERE WE ARE. IN 2010 THERE REALLY WAS NOTHING ON THE HORIZON. I JOINED CIRM IN JANUARY OF 2011. THE DISEASE TEAMS HAD JUST BEEN FUNDED. THEY WERE IN THEIR FIRST FEW MONTHS OF FUNDING. THIS IS THEIR TRAJECTORY. WHAT I'VE LISTED HERE IN BLUE ARE THE MILESTONE MEETINGS WITH THE FDA. THESE ARE ESSENTIAL MEETINGS WHERE THE INVESTIGATORS WHO ARE TRYING TO DEVELOP A PRODUCT HAVE DIRECT INTERACTIONS WITH THE FDA TO TALK ABOUT WHERE THEY ARE IN TERMS OF THEIR EVIDENCE PACKAGE ON SAFETY AND THE PRECLINICAL ANIMAL STUDIES.

THE COPPER COLORED BAR IS WHEN THEY ACTUALLY ACCUMULATE THAT BODY OF EVIDENCE TO FILE IT WITH THE FDA. WITHIN 30 DAYS THE FDA HAS TO MAKE A DECISION ON WHETHER OR NOT THAT BODY OF EVIDENCE IS SUFFICIENT TO ALLOW THAT THERAPEUTIC PRODUCT TO GO INTO HUMAN CLINICAL TESTING.

AND THEN THE PURPLE BAR ARE THE CLINICAL TRIALS THAT ARE ENROLLING PATIENTS.

SO YOU CAN SEE THE TRAJECTORY FROM 2010 THROUGH TODAY'S DATE, THROUGH 2014 SO FAR. WE'VE GONE FROM TWO TO FIVE TO SEVEN TO TEN SUCCESSFUL PRE-IND MEETINGS THAT HAVE TAKEN PLACE WITH OUR COHORT OF

DEVELOPMENT TEAMS. YOU CAN SEE THAT THERE HAVE BEEN NOW THREE IND FILINGS WITH THE FDA AND TWO ACTIVE CLINICAL TRIALS ACTIVELY ENROLLING PATIENTS. BEFORE THE END OF THIS YEAR, WE EXPECT TO HAVE UP TO 15 PRE-IND MEETINGS HAVING BEEN COMPLETED AND TEN IND FILINGS THAT HAVE BEEN APPROVED TO BE COMPLETED. AND IF THOSE GO ACCORDING TO PLAN, THERE SHOULD BE TEN CLINICAL TRIALS READY TO ENROLL PATIENTS BY THE END OF THIS YEAR.

THIS IS A BACKUP SLIDE FOR THE TABLE OF WHERE WE ARE WITH THE FIRST COHORT OF DISEASE TEAMS. THE DEVELOPMENT TEAMS ARE SUCCESSFULLY PROGRESSING THROUGH THEIR FDA MILESTONES, AND THEY ARE ABLE TO GO INTO THE CLINIC TO ENROLL PATIENTS ONTO THESE CLINICAL TRIALS. NINE OF THE FIRST COHORT OF DISEASE TEAMS HAVE SUCCESSFULLY PROGRESSED AND ARE EITHER ENROLLING PATIENTS ARE WILL BE ENROLLING PATIENTS ON CLINICAL TRIALS THIS YEAR.

THIS IS JUST SHOWING YOU THE YEAR IN WHICH THE DISEASE TEAM WAS FUNDED OR THE STRATEGIC PARTNERSHIP WAS FUNDED, THE NUMBER OF AWARDS, THE PERCENTAGE THAT ARE SUCCESSFULLY GOING THROUGH THEIR PRE-IND MEETING, THE IND APPROVED, THE IND EXPECTED, AND THE CLINICAL TRIALS EITHER ENROLLING OR EXPECTED IN 2014.

THESE ARE THE CLINICAL TRIALS WE'RE TALKING ABOUT, SO I WANT TO HIGHLIGHT THOSE. THE MAIN THEME OF MY PRESENTATION TODAY IS REALLY GOING TO FOCUS ON THE PROGRESS OF OUR DEVELOPMENT TEAMS, TO GIVE YOU HIGHLIGHTS OF THAT, TO GIVE YOU A HIGH LEVEL SUMMARY OF OUR INTERACTIONS WITH INDUSTRY AND WITH THE FDA, AND, THIRDLY, TO END WITH A LOOK FORWARD AND A LOOK FORWARD IN THE NEAR TERM. WHERE DO WE WANT TO BE WITH OUR INITIATIVES BY THE END OF THIS YEAR?

SO FOR THE CLINICAL TRIALS THAT ARE ENROLLING NOW, WE HAVE PATIENTS ENROLLING INTO A CLINICAL TRIAL FOR PATIENTS WITH AIDS. WE HAVE A CLINICAL TRIAL IN CONGESTIVE HEART FAILURE. SO THESE ARE INDIVIDUALS WHO HAVE HAD A HEART ATTACK AND WITHIN THE FIRST YEAR OF THEIR HEART ATTACK HAVE SCARRING OF THE HEART AND HAVE DYSFUNCTION OF THAT HEART AND HAVE SYMPTOMS. EXPECTED TO BE ENROLLING BY THE END OF THE YEAR ARE PATIENTS WITH CANCER. AND THESE ARE PATIENTS WHO EITHER HAVE ACUTE LEUKEMIA OR CHRONIC LEUKEMIA OR HAVE A VARIETY OF SOLID TUMORS. PATIENTS WITH VISION LOSS DUE TO DEGENERATIVE EYE DISEASE, PATIENTS WITH DIABETES. THIS AFFECTS BOTH THE YOUNG AND THE OLD IN A VARIETY OF DIFFERENT ETHNICITIES. AND ALSO THE LESS COMMON DISEASES, PATIENTS WITH SERIOUS BLOOD DISORDERS.

THE CLINICAL TRIALS WE EXPECT TO ENROLL

BEFORE THE END OF THIS YEAR ARE PATIENTS WITH SICKLE CELL DISEASE AND FOR PATIENTS WITH BETA THALASSEMIA. AND THIS IS PARTICULARLY IMPORTANT BECAUSE IT IMPACTS ON PATIENTS AT A RELATIVELY YOUNGER AGE. AND WHEN THEY HAVE A LONG LIFE SPAN AHEAD OF THEM, IF WE COULD MORE EFFECTIVELY TREAT THEM. AND IT ALSO IS OCCURRING IN PEOPLE WITH DIVERSE ETHNIC BACKGROUNDS. SO IT'S A VERY GOOD REPRESENTATION OF THE POPULATION IN CALIFORNIA AND ACROSS THE UNITED STATES.

I'M NOT GOING TO READ THROUGH THESE SLIDES. THESE ARE ACTUALLY HANDOUTS THAT YOU HAVE IN YOUR BINDER. AND IN ADDITION, YOU HAVE A MUCH MORE DETAILED COMPREHENSIVE VIEW OF WHERE WE ARE WITH OUR PROJECTS IN THE THERAPEUTIC AREAS. BUT WHAT I'M GOING TO BRIEFLY GO OVER IS THE BURDEN OF DISEASE BOTH MEDICALLY AND FINANCIALLY AND THE APPROACHES WE'RE TAKING TO TREAT THEM.

FOR HIV/AIDS, CALIFORNIA IS THE SECOND HIGHEST OF 50 STATES IN REPORTED AIDS CASES. IT'S CLAIMED THE LIVES OF MORE THAN HALF A MILLION AMERICANS, AND THERE'S ABOUT 1.1 MILLION AMERICANS NOW LIVING WITH HIV. THIS IS TAKEN FROM THE CENTERS FOR DISEASE CONTROL AND PREVENTION, DATA FROM 2010. IT'S NOT UP TO DATE TO THE PRESENT, BUT IT'S THE LATEST NATIONAL DATA THAT'S AVAILABLE. IT DISPROPORTIONATELY

AFFECTS BLACKS AND AFRICAN-AMERICANS, HISPANICS, AND LATINOS. THE COST OF CARE IS 1.8 BILLION LIFETIME TREATMENT COST BASED ON NEW HIV DIAGNOSES IN CALIFORNIA IN 2009.

THE CIRM-FUNDED APPROACHES WE HAVE GOING FORWARD THAT ARE NEAR TERM ARE TWO. THERE'S THE COMPANY CAL-IMMUNE WHO HAS A TECHNOLOGY WHERE THEY'RE INTERFERING WITH THE RECEPTOR FOR HIV ON THE PATIENT'S OWN HEMATOPOIETIC BLOOD STEM CELLS. THEY'RE INTERFERING WITH THAT RECEPTOR BOTH AT THE CCR5 AND AT A FUSION PROTEIN, AND IT'S PREVENTING -- THE INTENT IS THAT IT WILL PREVENT THE HIV/AIDS VIRUS FROM ENTERING THOSE BLOOD CELLS AND DAMAGING THAT PERSON'S IMMUNE SYSTEM AND THEIR ABILITY TO HAVE A MORE NORMAL IMMUNE SYSTEM. SO PATIENTS WITH HIV/AIDS ARE ENROLLING ON THIS CLINICAL TRIAL, AND THIS TRIAL IS ASSESSING SAFETY, FEASIBILITY, AND EXPLORING A VARIETY OF MEASURES OF ACTIVITY ABOUT WHETHER OR NOT THIS TECHNOLOGY IS WORKING.

WE HAVE A DIFFERENT TEAM WORKING AT CITY OF HOPE. IT'S WITH DR. JOHN ZAIA. HE'S WORKING WITH A COMPANY CALLED SANGAMO BIOSCIENCES WHERE THEY'RE USING A DIFFERENT TECHNOLOGY, A ZINC FINGER NUCLEASE, WHICH IS BASICALLY ACTING LIKE A PAIR OF MOLECULAR SCISSORS THAT CUTS A PLACE ON THE GENE WHERE THE HIV CAN ENTER

AND DISRUPTING IT SO THAT THE HIV CAN NO LONGER ENTER AND DO ITS DAMAGE. THE PLAN IS FOR A CLINICAL TRIAL LATER THIS YEAR AFTER A SUCCESSFUL IND HAS BEEN FILED AND APPROVED. AND THEN THERE WERE THREE OTHER APPROACHES HEADING TOWARD THE CLINIC IN THIS DISEASE.

WE HAVE FUNDED EIGHT HEART FAILURE APPROACHES IN CIRM'S PORTFOLIO AND ONE IN PERIPHERAL VASCULAR DISEASE. THE ONES THAT ARE MOST NEAR TERM ARE THE ONES I'M GOING TO TALK TO YOU ABOUT RIGHT NOW. THE BURDEN OF DISEASE, THIS, ONCE AGAIN, IS FROM THE CENTERS FOR DISEASE PREVENTION AND CONTROL. THERE'S ALMOST FIVE MILLION AMERICANS WHO HAVE HEART FAILURE, AND THE MOST COMMON CAUSE OF HEART FAILURE IS DUE TO A HEART ATTACK. THE SYMPTOMS ARE NUMEROUS AND INCLUDE SHORTNESS OF BREATH, INABILITY TO GET OUT OF BED, INABILITY TO WALK. THERE'S A VARIETY OF SEVERITY OF THE TYPES OF SYMPTOMS THAT IMPACT ON PEOPLE WHO HAVE THIS DISEASE. BUT IT'S A LEADING CAUSE OF DEATH FOR MOST ETHNICITIES IN AMERICA. AND THE ESTIMATED ANNUAL COST OF HEART FAILURE CARE IN CALIFORNIA IS APPROXIMATELY 1.5 BILLION.

THE APPROACHES WE HAVE IS THE ONE THAT'S IN THE CLINIC RIGHT NOW IS CAPRICOR. THAT'S A CALIFORNIA COMPANY. THEY'RE USING CELLS THAT WERE DERIVED FROM A DONOR HEART AND DEVELOPING THIS INTO A PRODUCT CALLED

CARDIOSPHERES. THEY'RE INJECTING THIS TYPE OF PRODUCT INTO PATIENTS WHO HAVE HAD HEART FAILURE DUE TO A HEART ATTACK, AND THEY'RE INSERTING -- THEY'RE INJECTING THESE CELLS INTO THE BLOOD VESSELS THAT FEED THE HEART. THEY COMPLETED THE PHASE I CLINICAL TRIAL FOR SAFETY IN 2013, AND THEY'RE NOW ENROLLING PATIENTS ON THE RANDOMIZED PHASE II TRIAL TO DETERMINE WHETHER OR NOT THIS THERAPY CAN REDUCE THE SCARRING OF THE HEART AND IMPROVE FUNCTION OF PATIENTS WHO HAVE HEART FAILURE.

WE ALSO HAVE EIGHT OTHER PROGRAMS THAT ARE MOVING TOWARDS THE CLINIC IN HEART DISEASE.

FOR PATIENTS WITH CANCER, THIS IS A MAJOR BURDEN OF DISEASE. THERE'S OVER 18 MILLION AMERICANS EXPECTED TO BE IMPACTED BY 2020. THAT'S 30 PERCENT MORE THAN IN 2010. THE COST OF CANCER CARE IS ENORMOUS, $157 BILLION ACROSS THE UNITED STATES. AND THE ANNUAL COST OF CARE IN CALIFORNIA IS $15 BILLION. THE REASON FOR THIS INCREASE IN PREVALENCE IS DUE TO THE AGING OF THE POPULATION. IT AFFECTS ALL ETHNICITIES. IT'S AN EQUAL OPPORTUNITY EMPLOYER. IT ATTACKS MEN AND WOMEN.

WE HAVE THREE MAJOR CIRM-FUNDED APPROACHES THAT ARE HEADED TO THE CLINIC THIS YEAR. WE HAVE WORK WITH DRS. CARSON, KIPPS, AND JAMIESON WHERE THEY'RE TARGETING THE CANCER STEM CELL WITH A MONOCLONAL

ANTIBODY CALLED ROR-1, AND THEY'RE IN PARTICULAR LOOKING AT PATIENTS WHO HAVE CHRONIC LYMPHOCYTIC LEUKEMIA. THEY'RE FILING THEIR IND AND PLAN TO START A CLINICAL TRIAL THIS YEAR.

THE SECOND TEAM WE'RE WORKING WITH IS THE DR. WEISSMAN TEAM AT STANFORD UNIVERSITY. THEY'RE ALSO WORKING WITH A GROUP IN THE UK ON THIS PROGRAM. AND I SHOULD HAVE MENTIONED DR. CARSON WAS ALSO WORKING WITH A GROUP IN CANADA ON THEIR PROGRAM. THE WEISSMAN TEAM IS ALSO TARGETING THE CANCER STEM CELL WITH A MONOCLONAL ANTIBODY CALLED ANTI-CD 47. AND DR. WEISSMAN HAS CALLED THIS THE DON'T EAT ME SIGNAL, AND IT'S THE SIGNAL THAT WE'RE TRYING TO INTERRUPT WITH THAT MONOCLONAL ANTIBODY. HE'S FILING THE IND THIS YEAR BOTH IN THE UNITED STATES AND IN THE UK, AND THE CLINICAL TRIAL IS EXPECTED TO START LATER THIS YEAR.

THE DR. DANNY SLAMON TEAM IS TARGETING THE CANCER STEM CELL WITH A SMALL MOLECULE. HE'S GOING FOR SOLID TUMORS. THE IND HAS ALREADY BEEN APPROVED IN U.S. AND IN CANADA, AND THE CLINICAL TRIAL WILL START WITHIN THE NEXT MONTH OR TWO.

AND THERE ARE SEVEN OTHER APPROACHES HEADING TO THE CLINIC IN THE CANCER ARENA.

FOR VISION LOSS, THIS IS A MAJOR BURDEN OF DISEASE, AND A MAJOR CAUSE OF VISION LOSS IN PEOPLE WHO

ARE OLDER IS MACULAR DEGENERATION. IT'S WHERE IT AFFECTS YOUR CENTRAL VISION. YOU CAN'T LOOK IN PEOPLE'S FACES, YOU CAN'T READ THE WRITING IN A BOOK, YOU WOULDN'T BE ABLE TO SEE THESE SLIDES. IT'S A LEADING CAUSE OF BLINDNESS IN PEOPLE OVER AGE 55. THE MACULAR DEGENERATION DISEASE IS EXPECTED TO CLIMB TO ALMOST THREE MILLION AMERICANS BY THE YEAR 2020, AND THE ANNUAL COSTS TO CALIFORNIA EXCEED $4 BILLION FOR THERAPIES DEVOTED TO VISION LOSS AND ABOUT ONE BILLION TO PATIENTS WHO HAVE AMD.

WE HAVE TWO MAJOR CIRM-FUNDED APPROACHES THAT ARE NEAR TERM FOR THE CLINIC. THERE'S THE DR. HUMAYUN TEAM WHO'S USING HUMAN EMBRYONIC-DERIVED STEM CELLS AS A STARTING POINT. AND WHAT HE'S DOING IS TRYING TO REPAIR AND REPLACE THE DAMAGED CELLS IN PATIENTS WHO HAVE MACULAR DEGENERATION. HE'S PUTTING THESE CELLS ON A SYNTHETIC SCAFFOLD TO REPLACE THE CELLS THAT ARE LOST, AND HE'S INSERTING THEM IN THE BACK OF THE EYE INTO PATIENTS WHO HAVE THIS KIND OF DISEASE. HE'S GOING TO BE FILING HIS IND AND STARTING THE CLINICAL TRIAL LATER THIS YEAR.

THERE'S ALSO A GROUP, A DR. CLASSEN TEAM, WHO'S WORKING ON A DIFFERENT CAUSE OF VISION LOSS CALLED RETINITIS PIGMENTOSA. THIS IS A GENETIC DEFECT THAT CAN MANIFEST EARLY IN LIFE IN TERMS OF VISION

LOSS, SO IT AFFECTS A YOUNGER AGE GROUP. AND OPPOSED TO HAVING CENTRAL VISION LOSS, IT STARTS WITH PERIPHERAL VISION LOSS. SO THIS GROUP IS WORKING, HEADING TOWARDS THE CLINIC. AND IN ADDITION TO THIS, WE HAVE SEVERAL OTHER APPROACHES HEADING TOWARDS THE CLINIC IN EYE DISEASE.

IN DIABETES THE MAJOR MEDICAL AND FINANCIAL BURDEN ACROSS CALIFORNIA, ACROSS THE UNITED STATES, IT AFFECTS 25.8 MILLION PEOPLE, WHICH IS ABOUT 8 PERCENT OF AMERICANS. IT DISPROPORTIONATELY AFFECTS HISPANICS AND LATINAS, AND ALSO BLACKS AND AFRICAN-AMERICANS. IT'S MOST COMMON IN PEOPLE OVER THE AGE OF 65, BUT IT ALSO IMPACTS PEOPLE AT A MUCH YOUNGER AGE. IT'S THE LEADING CAUSE -- DIABETES ITSELF IS A DISEASE, BUT IT'S ALSO THE LEADING CAUSE OF KIDNEY FAILURE, OF AMPUTATIONS, IN NEW CASES OF BLINDNESS, AND IS A MAJOR CAUSE OF HEART DISEASE AND STROKE. AND THE ANNUAL COST IN CALIFORNIA ALONE IS $13.8 BILLION.

OUR MAJOR CIRM-FUNDED APPROACH THAT IS HEADED TOWARD THE CLINIC THIS YEAR IS WITH A CALIFORNIA COMPANY. AND THEY'RE WORKING WITH HUMAN EMBRYONIC STEM CELLS THAT ARE PRODUCING BETA CELLS THAT PRODUCE THE INSULIN THAT PATIENTS WITH DIABETES ARE LACKING. THEY'RE PUTTING THESE CELLS INTO A DEVICE THAT WILL PROTECT THE CELLS FROM THE HOST DEFENSE SYSTEM. SO

THEY'RE TRYING TO PROTECT THE CELLS FROM BEING DESTROYED BY THE HOST IMMUNE SYSTEM.

THIS DEVICE IS ABOUT THE SIZE OF A CREDIT CARD, IS IMPLANTED UNDER THE SKIN. THEY PLAN THEIR IND FILING AND THEIR CLINICAL TRIAL FOR LATER THIS YEAR.

OTHER FUNDED APPROACHES THAT ARE RELATED TO THE DISEASE AREA OF DIABETES ARE FOCUSED ON COMPLICATIONS OF DIABETES. AND THESE INCLUDE WOUND ULCERS, VISION LOSS, LOSS OF LIMBS DUE TO LACK OF BLOOD SUPPLY TO THE LIMB. IT'S CALLED CRITICAL LIMB ISCHEMIA, HEART DISEASE, AND STROKE.

THE OTHER CLINICAL TRIALS THAT ARE GOING TO BE, PLANNED TO BE OPEN LATER THIS YEAR ARE IN BLOOD DISEASES. AND THEY'RE SICKLE CELL DISEASE AND IN BETA THALASSEMIA. THE BURDEN OF DISEASE IS LESS AS A POPULATION, BUT IT'S MAJOR IN TERMS OF THE INDIVIDUAL. THERE'S ABOUT 80,000 AMERICANS WHO HAVE SICKLE CELL DISEASE. IT PREDOMINANTLY AFFECTS BLACKS AND AFRICAN-AMERICANS AND TO A LESSER EXTENT HISPANICS AND LATINOS.

IT'S THE SICKLE SHAPE OF THE CELL THAT CAUSES CLOGGING OF THE BLOOD VESSELS AND CAN LEAD TO EXCRUCIATING EPISODES OF PAIN AND ALSO LEADS TO PROGRESSIVE ORGAN DAMAGE. I DON'T HAVE CDC DATA FOR THIS, BUT FROM OTHER DATA THAT I'VE BEEN ABLE TO LOOK

AT, THE COST TO CALIFORNIA, LOOKING AT AN AVERAGE, IS 75,000 HOSPITALIZATIONS BETWEEN 1989 TO 93. THE COST IS APPROXIMATELY $475 MILLION.

THE CIRM-FUNDED APPROACHES TO TACKLE THIS DISEASE IS THE DR. KOHN TEAM. HE'S CORRECTING THE BETA GLOBIN GENE DEFECT IN THE PATIENT'S OWN BLOOD CELLS, SO HE'S REENGINEERING THE PATIENT'S OWN CELLS, CORRECTING THEM, AND THEN INFUSING THEM BACK INTO THE PATIENT. HE PLANS THE IND FILING AND THE CLINICAL TRIAL THIS YEAR.

WE ONLY HAVE ONE OTHER APPROACH IN SICKLE DISEASE, AND THAT'S BY THE SAME INVESTIGATOR, DR. KOHN, WHO'S WORKING ON A DIFFERENT APPROACH, BUT IT'S MUCH EARLIER IN DEVELOPMENT.

THE OTHER BLOOD DISORDER WE'RE LOOKING AT IS BETA THALASSEMIA. THE BURDEN OF DISEASE HERE, ONCE AGAIN, IS NOT MAJOR ACROSS THE POPULATION AS A WHOLE, BUT IT'S MAJOR IN TERMS OF THE INDIVIDUAL. THE INCIDENCE IS ABOUT ONE IN A HUNDRED THOUSAND IN THE U.S., BUT IT'S ACTUALLY MORE COMMON IN CALIFORNIA DUE TO IMMIGRATION PATTERNS. IT OCCURS IN ONE OUT OF 55,000 BIRTHS, AND THE PREVALENCE IN CALIFORNIA IS ABOUT A THOUSAND PEOPLE. IT'S OFTEN FATAL DUE TO THE DISEASE ITSELF, BUT ALSO DUE TO THE TREATMENT USED TO TREAT THE DISEASE. SO IT'S A TWO-STEP PROCESS.

THESE PATIENTS GET ANEMIC, THEY NEED FREQUENT

BLOOD TRANSFUSIONS. AND THE IRON THAT IS IN THESE BLOOD TRANSFUSIONS CAN ACCUMULATE IN CRITICAL ORGANS; AND IF THE IRON IS NOT PROPERLY FILTERED OUT, IT CAN LEAD TO LETHAL DAMAGE TO THESE ORGANS. ONCE AGAIN, I DON'T HAVE CDC DATA FOR THIS, BUT I LOOKED AT SOME UK DATA AS WELL AS SOME CALIFORNIA DATA, AND THE COSTS IN CALIFORNIA APPROACH $11 MILLION ON AN ANNUAL BASIS.

OUR CIRM-FUNDED APPROACH FOR THIS IS WITH SANGAMO BIOSCIENCES. THEY'RE USING A TECHNOLOGY THAT I PREVIOUSLY BRIEFLY MENTIONED, THE ZINC FINGER NUCLEASE, WHICH IS ACTING AS A MOLECULAR SCISSORS TO SNIP AT THE DEFECT. AND WHAT THEY'RE DOING, ONCE AGAIN, IS TAKING THE PATIENT'S OWN BLOOD CELLS, CORRECTING THE DEFECT, AND REINFUSING THE PATIENT'S CORRECTED CELLS BACK INTO THE PATIENT. THE IND FILING AND THE CLINICAL TRIAL IS PLANNED FOR THIS YEAR.

SO WHAT I'D LIKE TO DO NOW IS TAKE A STEP BACK. THOSE ARE THE CLINICAL TRIALS THAT ARE EITHER ENROLLING PATIENTS NOW OR WILL BE ENROLLING PATIENTS BY THE END OF THE YEAR. I WANT TO GIVE YOU -- TAKE ONE STEP BACK AND GIVE YOU A BIGGER PICTURE OF OUR TRANSLATIONAL PORTFOLIO AND SHOW YOU THE THERAPEUTIC AREAS THAT WE'RE WORKING ON THAT ARE WORKING THEIR WAY TOWARDS THE CLINIC.

YOU CAN SEE NEURODEGENERATIVE DISORDERS AND

NEUROLOGIC INDUSTRY IS OUR BIGGEST SLICE OF THE PIE IN TERMS OF WHAT WE'RE SPENDING ON THE TRANSLATIONAL PORTFOLIO. THE NEXT BIGGEST IS IN CARDIOVASCULAR DISEASE AND IN MUSCULOSKELETAL DISORDERS. AND THEN YOU SEE IT'S ANYWHERE FROM 7 TO 8 PERCENT IN METABOLIC DISEASES, HIV/AIDS, AND EYE DISEASES, AND IN BLOOD DISORDERS, ABOUT 12 PERCENT IN ONCOLOGY, AND ABOUT 2 PERCENT IN A RARE SKIN GENETIC DISORDER.

THIS IS SHOWING YOU THE DIFFERENT TYPES OF PROJECTS THAT ARE GOING FORWARD VISUALLY. SO THE RED ARE THOSE PROGRAMS -- ON THE LEFT ARE THE NUMBER OF AWARDS, ON THE RIGHT IS THE AMOUNT OF THE AWARD. SO IN RED ARE THOSE PROJECTS WHO ARE TRYING TO ESTABLISH IN PRECLINICAL RESEARCH EVIDENCE OF PROOF OF CONCEPT, EVIDENCE OF WHETHER IN THE ANIMAL MODEL OR SOME APPROPRIATE MODEL DOES IT LOOK LIKE THIS THERAPEUTIC APPROACH COULD HAVE A CHANCE OF WORKING.

THE YELLOW IS ACTUALLY PRECLINICAL DEVELOPMENT OF A THERAPEUTIC CANDIDATE.

THE GREEN ARE THOSE PROJECTS THAT ARE TRYING TO FILE THAT INVESTIGATIONAL NEW DRUG APPLICATION WITH THE FDA SO THAT THEY HAVE THE OPPORTUNITY TO ENTER CLINICAL TRIALS IN PATIENTS.

THE BLUE ARE THOSE PROJECTS THAT ARE GOING INTO THE FIRST-IN-HUMAN CLINICAL TRIAL.

THE PURPLE IS THE PHASE I-II CLINICAL TRIAL WHERE IT'S LOOKING, NOT JUST AT SAFETY, BUT TRYING TO GET VERY EARLY PRELIMINARY EVIDENCE OF ACTIVITY.

AND THEN I GUESS THE BROWN IS THE ONE CLINICAL TRIAL WE'RE FUNDING IN THE PHASE II. AND THAT'S APPROXIMATELY THE $20 MILLION AWARD THAT WE'VE AWARDED TO CAPRICOR ON THEIR ALLSTAR TRIAL IN CONGESTIVE HEART FAILURE.

WHAT I'D NOW LIKE TO BRIEFLY SUMMARIZE ARE THE PROJECTED AND THE EXPECTED COSTS TO CALIFORNIA AND THE UNITED STATES OF CHRONIC DISEASES. AND THANKS TO NEIL LITTMAN WHO ACTUALLY WORKED WITH THE CDC COST CALCULATOR TO PUT TOGETHER THESE NUMBERS FOR THIS PRESENTATION.

ON THE BOTTOM YOU CAN SEE THE DIFFERENT DISEASE AREAS THAT THE CDC IS COLLECTING TO GIVE THIS ECONOMIC BURDEN DATA. YOU CAN SEE THERE'S ARTHRITIS, ASTHMA, CANCER, DISEASES OF THE HEART, WHICH INCORPORATE CORONARY HEART DISEASE, CONGESTIVE HEART FAILURE, AND OTHER TYPES OF HEART CONDITIONS SUCH AS VALVE DISEASES, VIRAL CONDITIONS THAT IMPACT ON THE HEART. IN ADDITION, THE OTHER THERAPEUTIC AREAS ARE HIGH BLOOD PRESSURE, STROKE, DEPRESSION, AND DIABETES.

AND YOU CAN SEE THE ANNUAL COST OF CHRONIC DISEASES TO CALIFORNIA, THE MOST COSTLY ARE CANCER, THE

VARIOUS DISEASES OF THE HEART, DIABETES, AND ARTHRITIS. AND THEN YOU CAN SEE IN DESCENDING ORDER THE OTHER COST BURDEN.

TO THE UNITED STATES, OBVIOUSLY THE SCALE IS DIFFERENT ON THE Y AXIS, BUT YOU CAN SEE, ONCE AGAIN, THE ECONOMIC BURDEN OF THESE CHRONIC DISEASES AND THEIR COST IN THE UNITED STATES. AND ONCE AGAIN, THE FRONT RUNNERS ARE CANCER, DISEASES OF THE HEART, ARTHRITIS, AND DIABETES.

THESE ARE THE PROJECTED COSTS OF CHRONIC DISEASES IF WE PROJECT THEM OUT TO 2020. AND THIS IS DATA THAT WAS ACCUMULATED FROM THE CDC. AND USING THEIR COST CALCULATOR, WE CAN PROJECT THOSE COSTS OUT TO THE NEXT SEVERAL YEARS. WHAT YOU SEE IN THIS FIRST GRAPH ARE THE PROJECTED COSTS OF CHRONIC DISEASES TO CALIFORNIA THROUGH THE YEAR 2020. THE VERY TOP LINE ARE OVERLAPPING LINES OF CANCER AND HEART DISEASE. THE NEXT LINE IS THE COST FROM DIABETES. THE LINE AFTER THAT IS DUE TO ARTHRITIS. AND THEN THE LINE AFTER THAT IS DUE TO HIGH BLOOD PRESSURE. SO THOSE ARE THE TOP FIVE MEDICAL COST PROJECTIONS TO CALIFORNIA. AND SIMILARLY, THOSE ARE THE SAME DISEASE AREAS OF HIGH ECONOMIC BURDEN TO THE UNITED STATES.

SO THAT'S GIVING YOU A SENSE OF THE MEDICAL BURDEN, OF THE ECONOMIC BURDEN. I NOW JUST WANT TO

BRIEFLY TOUCH ON THE INTERACTIONS THAT WE HAVE WITH THE FDA AND WITH INDUSTRY, AND THESE COLLABORATIONS ARE ESSENTIAL IN ORDER FOR US TO MEET OUR GOAL OF TAKING THESE PATIENTS FORWARD TO HELP PATIENTS WHO HAVE THESE DEBILITATING DISEASES AND INJURY.

SO WE WORK ON A VERY STRATEGIC BASIS WITH THE FDA, WITH EXTERNAL ADVISORS, AND WITH OUR INVESTIGATORS TO MAKE THESE PROJECTS MOVE FORWARD.

WE WORK WITH THE FDA AND OTHER AGENCIES ON THAT REGULATORY PATHWAY. ONE OF THE BIG ISSUES WITH STEM CELL TECHNOLOGY IS THAT IT'S NOT JUST CHALLENGING SCIENCE. IT'S AN UNCERTAIN REGULATORY PATHWAY. WHATEVER WE CAN DO TO DECREASE THAT UNCERTAINTY IS GOING TO BE HELPFUL TO DERISK THIS TYPE OF TECHNOLOGY SO THAT PEOPLE WILL INVEST WITH IT.

WHAT WE'RE DOING IN CALIFORNIA IS DERISKING A VERY INNOVATIVE TECHNOLOGY AND A VERY HIGH RISK ENTERPRISE. AND SO EVERYTHING THAT WE'RE TRYING TO DO IS TO COLLECT THE DATA AND CREATE THOSE INTERACTIONS TO DERISK THE INTERACTION FOR COMPANIES AND PEOPLE WHO CAN ACTUALLY COMMERCIALIZE THESE THERAPIES TO ENTER INTO THIS AREA.

SO ONE OF THE THINGS, THESE ARE JUST SOME HIGHLIGHTS, WE WORKED WITH ALL THESE DIFFERENT ORGANIZATIONS, BUT WE LED THIS EFFORT. WE WORK WITH

THE ALLIANCE FOR REGENERATIVE MEDICINE, WITH CATAPULT CELL THERAPY IN THE UK, WITH THE CANADIAN CENTER OF COMMERCIALIZATION, WITH THE ECONOMIC AND SOCIAL RESEARCH COUNCIL IN THE UK, AND WITH THE MEDICAL RESEARCH COUNCIL TO PUT TOGETHER A WORLDWIDE WORKSHOP THAT TOOK PLACE IN WASHINGTON, D.C. IN SEPTEMBER WHERE WE BROUGHT ALL THESE REGULATORY AGENCIES TOGETHER, INCLUDING THE JAPANESE REGULATORY FRAMEWORKS, BECAUSE WE WERE PARTICULARLY INTERESTED IN THE VERY UNIQUE MODEL THAT JAPAN IS USING FOCUSED ON A VERY SPECIFIC TECHNOLOGY, IPS, AND THE MASSIVE COUNTRY EFFORT THAT THEY'VE PUT INTO PLACE TO TRY AND MOVE THAT TECHNOLOGY FORWARD. IT'S A VERY INTERESTING CASE STUDY.

SO WE WERE INFORMED BY THOSE DISCUSSIONS. WE'LL BE PUTTING TOGETHER A PAPER TO DISSEMINATE OUR FINDINGS FROM THAT WORKSHOP, BUT WE BROACHED THE TOPICS OF DONOR CELL ELIGIBILITY, MANUFACTURING ISSUES, CLINICAL TRIALS, AND PARTICULARLY TALKED ABOUT ACCELERATED PATHWAYS SO THAT PATIENTS COULD GET ACCESS TO INNOVATIVE TECHNOLOGY AT AN EARLIER STAGE AND WHAT COULD BE DONE TO ADDRESS THAT.

IN ADDITION, WE PUT ON WEBINARS, ROUNDTABLES, AND WORKSHOPS WITH THE FDA WITH TOPICS RANGING ON ISSUES THAT ARE IMPORTANT IN GOING FROM THE LAB INTO THE CLINIC. AND ALL OF THOSE ARE AVAILABLE ON OUR

WEBSITE.

IN ADDITION, AS I SAID, SOMETIMES WHEN YOU'VE GOT A CHILD, YOU'VE GOT A BABY, YOU DON'T SEE THEIR BLEMISHES, YOU DON'T SEE THEIR PROBLEMS. SO TO ALWAYS KEEP OURSELVES IN CHECK, I PUT TOGETHER WHOLE PANELS OF DIFFERENT EXTERNAL ADVISORS WHO COME IN AT KEY MILESTONE MEETINGS TO ACTUALLY ASSESS HOW THE PROJECTS ARE GOING AND PROVIDE THEIR INPUTS AND ADVICE IN TERMS OF THESE INDIVIDUAL PROJECTS. AND THESE ARE EXPERTS IN PRODUCT DEVELOPMENT, IN PRECLINICAL CELL PROCESS AND MANUFACTURING, CLINICAL TRIALS, THE REGULATORY PATHWAY, AND COMMERCIAL RELEVANCE.

THESE ARE IN-PERSON MEETINGS WITH THE DISEASE TEAMS OR THE STRATEGIC PARTNERSHIP TEAMS WITH THE EXTERNAL ADVISORS AND WITH CIRM SCIENTIFIC STAFF, AND WE GO OVER THE PROJECT, WE GO OVER THE CHALLENGES, WE GO OVER THE PROBLEMS THEY'RE HAVING AND WAYS TO MITIGATE THOSE RISKS. AND THIS ADVICE REALLY HELPS INFORM AND STRENGTHEN THOSE PROGRAMS BECAUSE WHAT WE WANT TO DO IS POSITION THESE TEAMS TO BE SUCCESSFUL.

WE ALSO WORK ON THE WHOLE PORTFOLIO TO GET ADVICE ON THE CRITICAL ATTRIBUTES FOR THE DISEASES AND ON THE PRODUCT CHARACTERISTICS AND ISSUES THAT ARE IMPORTANT ON EARLY END POINTS AND PROOF OF CONCEPT ISSUES.

WE WORK WITH COMPANIES. THIS IS A GRAPH OF THE DIFFERENT AWARDS THAT WE'VE MADE TO DIFFERENT COMPANIES AND THE DIFFERENT STAGE OF MATURATION FOR THESE DIFFERENT PROJECTS. THESE ARE THE NUMBER OF CIRM AWARDS TO FOR-PROFITS. THERE'S BEEN 21 AWARDS TO COMPANIES, AND THERE'S BEEN 126 MILLION AWARDS TO THESE COMPANIES. SO THAT'S THE NUMBER AND THAT'S THE AMOUNT OF MONEY.

THE MONEY THAT CIRM HAS PUT INTO THESE PROJECTS IS 126 MILLION. THE POTENTIAL AMOUNT OF MONEY THAT'S LEVERAGED BY WORKING WITH THESE COMPANIES HAS BEEN 5.4 FOLD. IT'S TO THE TUNE OF 685 MILLION. THAT INCLUDES LEVERAGED FUNDING, UP-FRONT PAYMENT, AND MILESTONES, PAYMENTS THAT ARE MADE IF MILESTONES ARE REACHED.

THESE ARE JUST A LISTING OF THE DIFFERENT COMPANIES, THE TOTAL AMOUNT OF THE AWARD, THE NUMBER OF THE AWARD, THE TYPE OF AWARD. YOU ACTUALLY HAVE ALL THIS INFORMATION IN YOUR PREREAD, BUT THIS IS JUST GIVING YOU THE DETAIL BEHIND IT. THIS IS GIVING YOU REALLY THE DETAIL OF THE AMOUNT OF MONEY OF LEVERAGE THAT THESE COMPANIES ARE PUTTING INTO THE GAME OF MOVING THESE PROJECTS FORWARD. AND THIS, ONCE AGAIN, IS THE VALUE OF THE POTENTIAL MILESTONES FROM THOSE INDUSTRY TRANSACTIONS. THEY PUT IN, YOU CAN SEE THE

AMOUNT ON THE LEFT, 6.4 MILLION INTO THE SANGAMO, 10 MILLION PLUS, 10.6 INTO THE VIACYTE PROJECT BOTH FROM DIFFERENT COMPANY INVESTMENTS AS WELL AS FROM THE JUVENILE DIABETES RESEARCH FOUNDATION, THE AMOUNT OF MONEY THAT CAPRICOR AND JANSSEN HAVE PUT INTO IT, AND THE AMOUNT OF MONEY THAT BIOGEN IDEC AND SANGAMO HAVE PUT INTO THEIR PROJECT.

AND ON THE RIGHT YOU SEE THE AMOUNT OF -- THE VALUE OF POTENTIAL MILESTONE PAYMENTS FROM THE INDUSTRY TRANSACTIONS WITH SANGAMO AND THEIR INTERACTIONS WITH BIOGEN IDEC AND FROM CAPRICOR FROM THEIR INTERACTIONS WITH JANSSEN.

CAPRICOR WAS AWARDED A DISEASE TEAM GRANT TO WORK ON THE ALLSTAR TRIAL, THE CONGESTIVE HEART FAILURE TRIAL. WE AWARDED 20 MILLION FOR A COMPLETION OF THAT PHASE II CLINICAL TRIAL FOR PATIENTS WHO HAVE SUFFERED A LARGE HEART ATTACK. THAT TRIAL IS ONGOING. IT'S ENROLLING PATIENTS.

JANSSEN HAS THE RIGHT TO ENTER INTO AN EXCLUSIVE LICENSE AGREEMENT FOR THIS PRODUCT FOLLOWING THE DELIVERY OF THE RESULTS FROM THE CIRM-FUNDED PHASE II CLINICAL TRIAL. SO THIS COMPANY IS INTENSELY INTERESTED IN THAT PARTICULAR THERAPEUTIC AREA AND THAT TRIAL. THEY PROVIDED THE COMPANY WITH 12.5 MILLION UP FRONT AND UP TO 325 MILLION IN ADDITIONAL MILESTONE

PAYMENTS.

THE SECOND ONE WAS WITH SANGAMO WHERE THEY WERE AWARDED 6.4 MILLION FROM CIRM TO WORK ON A STRATEGIC PARTNERSHIP IN THE AREA OF HEMOGLOBINOPATHIES. AND FOR OUR AWARD, IT'S IN THE AREA OF THALASSEMIA, BUT THEY ALSO HAVE A PLATFORM TO WORK ON SICKLE CELL DISEASE.

FROM SANGAMO BIOSCIENCE'S COLLABORATION WITH BIOGEN, THEY WERE GIVEN 20 MILLION UP FRONT, AND THEY ALSO ARE GIVEN REIMBURSEMENT OF THEIR R&D RELATED COSTS AND MILESTONES OF UP TO 300 MILLION BASED ON DEVELOPMENT, REGULATORY, COMMERCIALIZATION, AND SALES MILESTONES. AND THIS IS JUST A QUOTE FROM THE EXECUTIVE VICE PRESIDENT OF BIOGEN REALLY TALKING ABOUT BUILDING ON THAT EMERGING SCIENCE RELATED TO REGULATION OF THE HEMOGLOBIN IN PATIENTS WHO HAVE THAT KIND OF DISEASE AND REALLY VALUING THE NOVEL TECHNOLOGY OF SANGAMO BIOSCIENCES TO EDIT THOSE GENES. AND THAT'S WHAT'S ENABLING THEM TO MOVE THIS PRODUCT FORWARD TO TREAT PATIENTS WITH THOSE BLOOD DISORDERS.

VIACYTE IS THE OTHER COMPANY THAT'S SUCCESSFULLY MATCHED $10 MILLION OF A CIRM STRATEGIC PARTNERSHIP AWARD. THEY DID THAT THROUGH A VARIETY OF EFFORTS WORKING WITH THE JOHNSON & JOHNSON DEVELOPMENT CORPORATION, SANDERLING VENTURES, AND AN ASSET

MANAGEMENT COMPANY. THOSE FUNDS WERE USED TO SUPPORT THE DEVELOPMENT OF THAT PRODUCT. IN ADDITION, THEY'RE WORKING WITH THE JUVENILE DIABETES RESEARCH FOUNDATION WITH LEVERAGING FUNDING FROM CIRM TO MOVE THAT PROJECT FORWARD.

THIS IS INCEPTION 3 THAT WAS CREATED BASED ON TECHNOLOGY FROM STANFORD TO WORK ON A THERAPEUTIC AREA OF HEARING LOSS WHICH IS OF PARTICULAR INTEREST TO INDUSTRY. SO THIS IS A COLLABORATION WITH ROCHE, WITH VERSANT VENTURES, AND WITH INCEPTION SCIENCES. SO THIS IS WORKING ON A VERY CRITICAL AREA OF SENSORY NEURAL HEARING LOSS TO MOVE THIS TYPE OF TECHNOLOGY FORWARD.

LOOKING FORWARD, THESE ARE THE INITIATIVES. THIS IS WHAT I WANTED TO END WITH. I GAVE YOU A SNAPSHOT OF WHERE WE ARE WITH THE DEVELOPMENT PROJECT UPDATES. I GAVE YOU A SNAPSHOT OF THE TYPE OF COLLABORATIONS WE HAVE WITH INDUSTRY AND WITH THE FDA. I'D NOW LIKE TO END ACTUALLY WITH A LOOK FORWARD OF WHERE WE WANT TO BE BY THE END OF THE YEAR.

FOR CLINICAL TRIALS, WE'RE GOING TO HAVE REVIEW OF THE ALPHA STEM CELL CLINIC IN JUNE. THIS IS ACTUALLY DEVELOPING A RESOURCE TO HAVE A ONE-STOP SHOP, SO TO SPEAK, OF HIGH QUALITY, WELL-VETTED INVESTIGATORS WITH WELL-VETTED CLINICAL TRIALS WHERE WE'RE GOING TO HAVE A COORDINATING CENTER THAT'S GOING TO BE ABLE TO

PROVIDE REGULATORY ADVICE, CLINICAL TRIAL ADVICE, BIOSTATISTICAL ADVICE, REALLY A MORE EFFICIENT AND EFFECTIVE WAY TO CONDUCT CLINICAL TRIALS IN THE STATE OF CALIFORNIA. SO IT'S CREATING THAT CRITICAL MASS OF CLINICAL SITES AND A COORDINATING CENTER THAT IS NOT JUST ONE-OFF RESEARCH PROJECTS THAT WE FUND WILL BE ABLE TO COME TO, BUT CLINICAL TRIALS FROM ALL ACROSS THE COUNTRY OR ALL ACROSS THE WORLD WILL BE ABLE TO COME AND HAVE ACCESS TO EXPERTISE AND EFFICIENT WAYS TO WORK IN CALIFORNIA.

THE OTHER INITIATIVES THAT YOU ARE GOING TO BE HEARING ABOUT TODAY AND THEN LATER IN THE YEAR IS THE ACCELERATED DEVELOPMENT PATHWAY. WE PUT OUT A PROGRAM ANNOUNCEMENT EARLIER THIS MONTH TO TEAMS THAT WERE ALREADY FUNDED TO COMPLETE CLINICAL TRIALS THAT WITH ACCESS TO ADDITIONAL EXPERTISE AND FINANCIAL RESOURCES COULD SHOW THAT THEY COULD ACCELERATE THE TIME TO ACHIEVE EVIDENCE OF CLINICAL BENEFIT FOR PATIENTS. WE ALSO EXPECT THAT FUTURE GRANTEES WILL HAVE FUTURE OPPORTUNITIES TO COMPETE GOING INTO THIS PATHWAY.

LATER TODAY YOU'RE GOING TO HEAR TWO CONCEPTS. ONE FOR THE NEXT ITERATION OF STRATEGIC PARTNERSHIPS. AS I SAID, THE DEVELOPMENT TEAMS THAT GO INTO THE CLINIC, THE ONLY WAY THEY CAN GET THERE IS

THROUGH OUR FUNDING. AND THAT'S BY DEVELOPMENT TEAMS CONSISTING OF DISEASE TEAMS OR STRATEGIC PARTNERSHIPS. SO AT TODAY'S ICOC, YOU ARE GOING TO HEAR FROM DR. INGRID CARAS, AND SHE'S GOING TO TALK ABOUT THE NEXT CONCEPT FOR YOU TO HEAR ABOUT AND DECIDE WHETHER OR NOT TO APPROVE WHERE WE'RE REALLY TRYING TO ENGAGE INDUSTRY TO CONTINUE ON THAT FORWARD PATH TO DEVELOP THERAPIES FOR PATIENTS.

LATER IN THE YEAR WE'RE GOING TO COME BACK TO YOU FOR THE NEXT ITERATION OF DISEASE TEAMS WHICH WILL DRAW RESEARCHERS FROM ACADEMIA AND FROM INDUSTRY. AND WE EXPECT TO PRESENT THAT CONCEPT TO YOU IN THE FALL.

ALSO TODAY WE'RE VERY, VERY MUCH IN NEED OF ADVANCING OUR PIPELINE. THERE'S VERY PROMISING PROJECTS THAT NEED TO GO FORWARD. SO DR. LISA KADYK IS GOING TO PRESENT A CONCEPT CALLED THE PRECLINICAL DEVELOPMENT PROJECT. THIS IS REALLY TO ADVANCE THE MOST PROMISING PRECLINICAL PROJECTS IN THE PIPELINE AND CAN ALSO INCLUDE NEW PRECLINICAL PROJECTS THAT HAVE SOME TYPE OF COMMERCIAL PARTNERING TOWARDS THOSE FDA INTERACTIONS ON THE DEVELOPMENT PATHWAY. SO DR. KADYK IS GOING TO PRESENT THAT CONCEPT LATER TODAY.

LAST, BUT NOT LEAST, I WANT TO THANK THE BOARD WHO'S BEEN INCREDIBLY SUPPORTIVE IN GUIDING THE DIFFERENT PROGRAMS THAT WE HAVE, TO OUR PATIENTS WHO

ARE ESSENTIAL PARTICIPANTS IN THE RESEARCH AND HELPING TO SHAPE WHAT GOES FORWARD, TO OUR INVESTIGATORS WHO ARE DOING THE HARD WORK, AND ALSO TO OUR STAFF WHO ARE IN THE DAY-TO-DAY REALLY WORKING WITH THESE INVESTIGATORS, WORKING WITH THESE DIFFERENT COLLABORATIONS TO MAKE THIS WORK GO ON.

SO I WANT THANK THE SCIENCE AND THE MEDICAL STAFF WHO ARE WORKING ON THE DEVELOPMENT PROJECTS, TO OUR CIRM GRANT MANAGEMENT PEOPLE WHO ARE WORKING VERY HARD TO MAKE SURE THAT ALL THE DIFFERENT -- COMPLIANCES WITH THE DIFFERENT ISSUES ARE TAKEN CARE OF AND THAT THE BUDGET IS WELL OVERSEEN, WITH OUR CIRM BUSINESS DEVELOPMENT AND LEGAL, THAT'S LED BY ELONA BAUM, AND PARTICULAR THANKS TO NEIL LITTMAN FOR HIS WORK ON THE BUSINESS DEVELOPMENT, AND BEN HUANG ON THE IP, OUR CIRM PORTFOLIO TABLE WHICH GETS UPDATED ON A REGULAR BASIS. IT'S AN ENORMOUS EFFORT. AND I WANT TO THANK DR. THAKAR WHO, BY THE WAY, IS A NEW FATHER THIS PAST WEEK. SO HE HAS LOTS OF THINGS TO CELEBRATE. AND OUR CIRM PROJECT COORDINATOR WHO REALLY HANDLES ALL THE LOGISTICS FOR ALL OUR CLINICAL DEVELOPMENT ADVISORY MEETINGS.

SO I COULD GO THROUGH, BUT I KNOW I'M OVER ON TIME, AND I DON'T WANT TO GIVE THIS SHORT SHRIFT, BUT I CAN'T EMPHASIZE ENOUGH HOW ESSENTIAL THESE INDIVIDUALS

HAVE BEEN IN MAKING THESE PROGRAMS GO FORWARD. SO IT'S BEEN A REAL PRIVILEGE TO WORK WITH THEM. SO THANK YOU VERY MUCH. IF YOU HAVE ANY QUESTIONS.

MR. TORRES: DR. FEIGAL, IT'S SO IMPORTANT FOR US TO MAKE SURE THAT WE PUT THE MOST CORRECT NUMBERS OUT THERE. I'M CONFUSED BECAUSE IN SPEECHES THAT I'VE GIVEN AND REFERENCES WITH THE CALIFORNIA DIABETES ORGANIZATION, THEY HAVE THE COST TO DIABETES FOR US HERE IN CALIFORNIA AT 24.5 BILLION. AND THE NUMBERS THAT I GUESS NEIL GAVE YOU FROM THE FDA, IS THAT WHERE YOU GOT THEM?

DR. FEIGAL: NO. THE CENTERS FOR DISEASE CONTROL. THESE NUMBERS MAY NOT BE IDENTICAL TO OTHER DATABASES. SO THE CAVEAT WITH THESE NUMBERS IS YOU HAVE TO SAY THE SOURCE FROM WHICH THEY CAME. AND THE SOURCE FOR THESE NUMBERS IS FROM THE CENTER FOR DISEASE CONTROL AND PREVENTION.

MR. TORRES: THEN WE BETTER EDUCATE DIABETES.ORG AND THE CALIFORNIA DIABETES PROJECT BECAUSE THEY'RE PROJECTING 24.5 BILLION.

DR. FEIGAL: ALL I'M SAYING IS THAT THERE MAY BE DIFFERENT ASSUMPTIONS IN THE MODEL. SO IT'S NOT THAT THIS IS RIGHT AND THEY'RE WRONG. THEY MAY BE USING DIFFERENT ASSUMPTIONS IN THEIR MODEL. BUT I'D BE HAPPY TO GO OVER THAT WITH YOU IN MORE DETAIL LATER.

MR. TORRES: I CAN TALK TO NEIL, BUT I JUST WANT TO MAKE SURE WE GOT THE NUMBERS OUT THERE BECAUSE OBVIOUSLY THE HIGHER THE COST, THE BETTER WE PROVIDE AN INITIATIVE TO GET THIS DISEASE DEALT WITH.

DR. FEIGAL: WELL, I SHOULD SAY FOR THESE COSTS, THE COST FOR THE CDC COST CALCULATOR IS DIRECT MEDICAL COSTS AND ABSENTEEISM. SO IT DOESN'T INCLUDE ALL THE COSTS DUE TO LOSS, ECONOMIC ACTIVITY, OR PREMATURE DEATH.

MR. TORRES: THAT'S IMPORTANT TO KNOW.

DR. FEIGAL: SO THEY'RE DIFFERENT ASSUMPTIONS.

MR. TORRES: THOSE ARE THE ASSUMPTIONS THAT ARE USED IN THE WEBSITES THAT I WAS CITING, ANCILLARY COSTS, ABSENTEEISM, ETC.

MS. LANSING: EVEN THOUGH THEY'RE INACCURATE NUMBERS, NO MATTER WHAT, IT'S A VERY HIGH NUMBER.

DR. FEIGAL: ACTUALLY THEY BOTH ARE ACCURATE. THEY JUST HAVE DIFFERENT ASSUMPTIONS.

MS. LANSING: EXACTLY. BOTH NUMBERS ARE HIGH.

MR. TORRES: SO I'M STICKING WITH 24.5.

DR. FEIGAL: SOUNDS GREAT.

MS. LANSING: I JUST WANT TO SAY I THOUGHT IT WAS AN EXCELLENT PRESENTATION, VERY INFORMATIVE.

CHAIRMAN THOMAS: THANK YOU. THANK YOU. DR. DULIEGE.

DR. DULIEGE: I WANT TO SECOND THAT, ELLEN. AND A COUPLE OF COMMENTS AND A QUESTION. ELLEN, THANK YOU AGAIN. IT WAS VERY COMPREHENSIVE. AND I JUST WANT TO SAY IF INDEED THIS OR WHAT YOU PRESENTED IS THE RESULT OF $450 MILLION INVESTED BY CIRM, THIS IS AN OUTSTANDING RESULT. AND I THINK CALIFORNIANS SHOULD BE VERY PROUD OF WHAT HAS BEEN DONE SO FAR.

I ALSO WANT TO SAY THAT I REALLY APPRECIATE YOU PROVIDING A PERSPECTIVE OF PURE GOALS AND THE GOAL OF CIRM FOR THIS YEAR AND WHERE WE SHOULD BE AT THE END OF THE YEAR. AND WOULD LIKE TO THANK ALAN ALSO BECAUSE ALL OF THIS WAS GENERATED, INITIATED AND GENERATED DURING HIS LEADERSHIP AS PRESIDENT.

DR. FEIGAL: ABSOLUTELY.

DR. DULIEGE: ONE QUESTION NOW IS CAN YOU COMMENT ON AREAS WHERE THERE ARE GAPS BETWEEN PRECLINICAL DEVELOPMENT AND CLINICAL DEVELOPMENT? I THINK YOU SHOWED US THE NUMBER OF PROJECTS IN NEURODEGENERATIVE DISORDERS, THE PRECLINICAL LEVEL. WHAT WILL HAPPEN TO THEM?

DR. FEIGAL: ACTUALLY YOU ARE GOING TO HEAR A LITTLE BIT ABOUT -- THE CONCEPT THEY'RE PRESENTING IS TRYING TO FILL THAT GAP AND ADDRESS SOME OF THE ISSUES

OF WHY THERE'S -- RIGHT NOW YOU HAVE TO MAKE QUITE A BIG LEAP BETWEEN THE RESEARCH AND GETTING FUNDING TO ACTUALLY GO DOWN THE DEVELOPMENT PATHWAY. SO THERE'S ISSUES WITH ASCERTAINING THE PRECLINICAL PROOF OF CONCEPT, WITH THE ANIMAL STUDIES, A LOT OF WORK ON MANUFACTURING. THERE'S MANY DIFFERENT ISSUES. THOSE ARE JUST A FEW. AND THAT'S WHY WE THINK IT'S VERY ESSENTIAL TO HAVE THIS CONCEPT THAT YOU'RE GOING TO HEAR TODAY BE DISCUSSED AND HOPEFULLY MAKE A POSITIVE DECISION ON BECAUSE WE THINK THAT WOULD FILL A GAP IN WHAT WE'RE DOING RIGHT NOW. WE'RE FUNDING A LOT OF EXCELLENT RESEARCH, BUT WE NEED TO GET IT DOWN A DEVELOPMENT PATHWAY SO WE CAN HELP PATIENTS.

CHAIRMAN THOMAS: MR. PANETTA.

MR. PANETTA: THANK YOU. FIRST OF ALL, AS THE FRESHMAN INDUSTRY REP ON THIS BOARD, I HAVE TO SAY THAT THE KIND OF PROGRESS THAT YOU'VE MADE IS REMARKABLE. AND I THINK GOING FORWARD AS WE DELIBERATE ABOUT WHETHER THIS EFFORT SHOULD CONTINUE INTO THE COMING YEARS, THIS IS EXACTLY THE KIND OF INFORMATION THAT WE NEED TO BE GETTING OUT INTO THE PUBLIC TO MAKE PEOPLE AWARE OF THE FACT THAT WE'RE TRULY MAKING PROGRESS TOWARD DEVELOPING THE KINDS OF THERAPIES THAT WE TALKED ABOUT TEN YEARS AGO.

SO I'VE GOT TWO QUESTIONS. FIRST OF ALL,

GOING BACK TEN YEARS, I REMEMBER TALKING WITH FOLKS IN THE VENTURE COMMUNITY BACK THEN WHO SAID THAT IT WOULD BE A VERY, VERY LONG TIME BEFORE VENTURE CAPITAL WOULD INVEST IN STEM CELL RESEARCH. I THINK BASED ON SOME OF WHAT YOU PRESENTED, IT WOULD PROBABLY BE SAFE TO SAY THAT WE'RE BEGINNING TO SEE THAT HAPPEN.

DR. FEIGAL: THEY'RE DEFINITELY PUTTING THEIR TOE IN THE WATER.

MR. PANETTA: IT'S A GOOD START.

DR. FEIGAL: IT'S A GOOD START. WE'D LIKE TO SEE MORE OF THE BODY IN.

MR. PANETTA: AND SECONDLY, I'VE HEARD SOME DISCUSSION IN SAN DIEGO ABOUT THE NEED FOR THE CONSTRUCTION, POTENTIAL CONSTRUCTION OF A STEM CELL MANUFACTURING FACILITY. I'M WONDERING IF YOU COULD COMMENT ON WHERE WE ARE IN OUR PROGRESS IN TERMS OF THE POTENTIAL NEED FOR THAT KIND OF EFFORT.

DR. FEIGAL: YOU KNOW, WE'RE EXPLORING THE ISSUES REGARDING MANUFACTURING. WE THINK THERE'S TWO DIFFERENT ISSUES WITH MANUFACTURING. ONE, THE NEXT GENERATION OF BIOPROCESSING AND THE TOOLS FOR THAT. AND WE HAVE STARTED THE CONVERSATION ON THAT, AND YOU'LL BE HEARING MORE ABOUT THAT PROBABLY IN SUBSEQUENT MEETINGS. WE'RE THINKING NOW ABOUT WHAT THOSE NEXT GENERATION BIOPROCESSING TOOLS NEED TO BE.

IN ADDITION, WE'RE THINKING ABOUT CAPACITY.

SO RIGHT NOW WE'RE TALKING ABOUT RELATIVELY SMALL CLINICAL TRIALS. BUT PLANNING FOR SUCCESS, WE NEED TO THINK ABOUT THE MANUFACTURING CAPACITY AND HOW TO DO THAT IN THE MOST EFFICIENT WAY SO THAT WE HAVE A REASONABLE COST OF GOODS. SO THE WAY WE'RE DOING THINGS NOW, ONE, REALLY WOULDN'T BE SCALABLE AND, TWO, WOULD BE ENORMOUSLY EXPENSIVE. SO WE'RE THINKING OF BOTH THOSE ISSUES. ONE, HOW TO DO IT BETTER AND, TWO, HOW TO SCALE IT UP.

CHAIRMAN THOMAS: OTHER COMMENTS, QUESTIONS BY MEMBERS OF THE BOARD?

I WOULD LIKE TO ECHO THAT THIS BODY OF WORK IS MOST IMPRESSIVE, AND I THINK IT SHOWS THAT THERE'S BEEN TREMENDOUS PROGRESS ACROSS A WIDE RANGE OF INDICATIONS THAT WOULD BE OF GREAT INTEREST TO THE CITIZENS OF CALIFORNIA. SO, MR. JENSEN, I KNOW YOU'RE LISTENING. THIS IS A GREAT SUBJECT FOR A GLOWING REPORT.

DR. FEIGAL: ANYWAY, WE'RE SO PLEASED WITH THE PROGRESS. AND ONCE AGAIN, I WANT TO THANK THE BOARD BECAUSE WITHOUT YOU, WE WOULDN'T HAVE THE FUNDING TO MOVE THOSE THINGS FORWARD. SO THANK YOU AGAIN.

CHAIRMAN THOMAS: THANK YOU VERY MUCH, DR. FEIGAL. I WOULD LIKE TO ALSO CONGRATULATE EVERY MEMBER

OF OUR TEAM. I THINK THIS IS A FULL TEAM EFFORT AND IS THE PRODUCT OF A GREAT MANY, MANY, MANY HOURS SPENT BY EVERYBODY. SO CONGRATULATIONS TO ALL.

WOULD ALSO LIKE TO SEND OUT A SPECIAL SHOUT OUT TO DR. STEFFEN WHO IS RECOVERING FROM RECENT KNEE SURGERY AND HOPEFULLY WILL BE BACK WITH US VERY SHORTLY. SO, BETTINA, IF YOU'RE LISTENING, COME BACK SOON. WE MISS YOU. OKAY. SO WE'RE GOING -- MARIA.

MS. BONNEVILLE: I JUST WANTED TO ASK THE MEMBERS ON THE PHONE IF THEY COULD MUTE THEIR PHONE. THERE SEEMS TO BE SOME BACKGROUND NOISE THAT'S AFFECTING THE AUDIO.

CHAIRMAN THOMAS: WE'RE GOING --

DR. BURTIS: I JUST WANTED TO MAKE SURE I COULD BE HEARD. I PLUGGED IN EARPHONES TO GET RID OF THE SOUND, BUT I WANTED TO MAKE SURE THE MIC WAS STILL WORKING.

CHAIRMAN THOMAS: YES, YOU'RE VERY CLEAR. THANK YOU, KEN.

WE'RE GOING TO TAKE ONE PIECE OF THE PRESIDENT'S REPORT HERE AND HAVE IT FOLLOW UP DR. FEIGAL'S PRESENTATION AS IT SORT OF HELPS TO PAINT CONTEXT ON WHERE WE ARE AND WILL HELP IN THE SUBSEQUENT DISCUSSIONS ON TODAY'S AGENDA. SO TURN THIS OVER NOW TO DR. OLSON.

FOR THOSE OF YOU WITH YOUR MATERIALS OUTSIDE THE BUILDING HERE, IT'S AGENDA ITEM NO. 5.

DR. OLSON: THANK YOU, MR. CHAIRMAN, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND STAFF. WHAT I'D LIKE TO DO IS PROVIDE AN UPDATE ON OUR RESEARCH PROGRAM FUNDING, AND I WANT TO DO THIS IN THE CONTEXT OF THE FUNDING SCENARIO THAT WAS AGREED TO BY THE BOARD AT THEIR DECEMBER MEETING. SO WHAT I'M GOING TO DO IS JUST REVIEW THAT FUTURE FUNDING ALLOCATION THAT WAS PROPOSED AND AGREED TO AS OF DECEMBER 11, 2013. I'M THEN GOING TO GO ON INTO THE CURRENT STATUS OF THE RESEARCH FUNDING AS OF MORE OR LESS THE END OF FEBRUARY OR TODAY, AND THEN WHAT I'M NOT GOING TO TALK ABOUT PARTICULARLY, BUT WHAT IS IN YOUR HANDOUT, AND IT'S JUST FOR YOUR INFORMATION, IS SPECIFIC DEFINITIONS TO HELP YOU BE AWARE OF WHAT I'M TALKING ABOUT.

SO AS OF DECEMBER 11TH, THIS IS WHAT THE BOARD HAD TALKED ABOUT IN TERMS OF THE FUTURE FUNDING, THE DOLLARS THAT WERE AVAILABLE IN THAT CATEGORY, I.E., HAD NOT YET BEEN AWARDED, HAD NOT BEEN APPROVED IN CONCEPT BY THE BOARD, LOOKED LIKE THIS. IN THE TRAINING AND CAREER DEVELOPMENT CATEGORY, SO THOSE AWARDS THAT COULD BE USED TO TRAIN CLINICIANS, POST DOCS, GRADUATE STUDENTS, UNDERGRADUATES, MASTER'S STUDENTS, CAREER DEVELOPMENT FOR NEW FACULTY, IN THAT

CATEGORY THE BOARD AGREED TO NEW COMPETITIONS FOR BOTH TRAINING AND FOR THE BRIDGES PROGRAM AS WELL AS AN EXTENSION OF THE CREATIVITY HIGH SCHOOL PROGRAM INTERNSHIP. THAT'S A VERY SMALL PROGRAM THAT WE'VE BEEN RUNNING FOR THE LAST COUPLE OF YEARS.

THE BOARD ALSO AGREED TO IN THE BASIC RESEARCH FUNDING TO TWO ADDITIONAL ROUNDS OF THE BASIC BIOLOGY PROGRAM. IN THE TRANSLATIONAL RESEARCH CATEGORY, SO THAT'S THE CATEGORY WHERE WE TAKE THE DISCOVERIES FROM BASIC BIOLOGY AND DO THE TESTING TO SEE IF THERE IS A THERAPEUTIC CANDIDATE THAT'S POSSIBLE. AND WE ALSO LOOK AT THE NEW TOOLS AND TECHNOLOGIES. IN THAT CATEGORY THE BOARD AGREED TO TWO ROUNDS OF MOVING THE PIPELINE FORWARD FROM THE EARLY PROOF OF CONCEPT STUDIES TO A CANDIDATE FOR THERAPEUTIC DEVELOPMENT, A SO-CALLED DEVELOPMENT CANDIDATE. BUT MOSTLY WHERE THE BOARD HAS CHOSEN TO PUT OUR FUTURE FUNDINGS, AND APPROPRIATELY SO SINCE THIS IS THE MOST EXPENSIVE STAGE OF THE PIPELINE, IS THAT THERE WOULD BE THE FUNDING FOR ACCELERATED PATHWAY. THE BOARD AGREED TO ALLOCATE $200 MILLION ESSENTIALLY FOR THOSE PROGRAMS THAT WERE DEEMED PRIORITY PROGRAMS TO ENSURE THAT THEY COULD MOVE FORWARD AS QUICKLY AS POSSIBLE TOWARDS PROOF OF CONCEPT.

AND THEN THERE WAS ADDITIONALLY ROUGHLY $262

MILLION THAT REMAINED FOR NEW STRATEGIC PARTNERSHIPS, NEW DISEASE TEAMS, AND FOR MOVING OUR PRECLINICAL RESEARCH PIPELINE FORWARD INTO DEVELOPMENT. SO THAT'S WHAT WE CALLED THE ET PRECLINICAL DEVELOPMENT. IN ADDITION, THE BOARD WANTED TO SET ASIDE A $30 MILLION STRATEGIC RESERVE.

SO THAT IS WHAT OUR FUTURE FUNDING LOOKED LIKE AS OF DECEMBER, AND I JUST WANTED TO REMIND THE BOARD THAT THAT'S WHAT THEY HAD TALKED ABOUT.

GIVEN THAT, I'D NOW LIKE TO MOVE FORWARD AND SAY WHERE ARE WE AS OF NOW. SO OUR CURRENT FUNDING ALLOCATION, AS YOU CAN SEE, SO I'VE INCLUDED BOTH THE GRAPHIC AND THE DETAIL BEHIND IT. THE CURRENT BREAKDOWN OF OUR RESEARCH FUNDING IS OBVIOUSLY THE LARGEST SECTION. THE BLUE IN THE GRAPH IS AWARDED; THAT IS, THESE ARE AWARDS THAT HAVE BEEN APPROVED FOR FUNDING BY THE BOARD. THE RED AREA IN THE GRAPH IS CONCEPT APPROVED; THAT IS, THE ICOC HAS AGREED TO ALLOCATE A GIVEN AMOUNT OF FUNDS TO BE AVAILABLE FOR A GIVEN PROGRAM. IT'S NOT YET AWARDED, BUT IT HAS BEEN IN PRINCIPLE APPROVED FOR CONCEPT.

CURRENTLY, FOR PURPOSES OF THIS MEETING, CURRENTLY INCLUDED IN THIS CATEGORY ARE THE CONCEPTS THAT WE'RE BRINGING FORWARD TO YOU TODAY. SO IF YOU FUND THEM, THEY CURRENTLY ARE IN THAT CATEGORY, AND

THAT'S WHAT IT WOULD LOOK LIKE.

FUTURE FUNDING ARE THOSE REMAINING RESEARCH FUNDS. AND, AGAIN, THEY WERE ALLOCATED IN ACCORDANCE WITH THE SCENARIO I JUST OUTLINED FOR YOU IN THE PREVIOUS SLIDE. AGAIN, KEY POINTS HERE, OF THE AMOUNT THAT'S ACTUALLY BEEN AWARDED, WE STILL HAVEN'T PAID OUT YET ROUGHLY $500 MILLION. AND THEN ALSO ACTUALLY $914 MILLION DOES REMAIN TO BE AWARDED. THE BOARD HAS NOT APPROVED SPECIFIC AWARDS IN CONCEPTS, SO ROUGHLY 512 MILLION AT THIS POINT. AND ROUGHLY 400 MILLION IN FUTURE FUNDING.

I JUST WANTED TO GO INTO A LITTLE BIT MORE DETAIL. AS NOTED BY DR. FEIGAL, WE ARE TRYING TO MOVE OUR PROGRAMS INTO DEVELOPMENT. SO AS YOU CAN SEE HERE, THE BULK OF THE CONCEPT APPROVED FUNDING DOES EXIST IN THE DEVELOPMENT AND CLINICAL TRIALS SECTOR. AND YOU CAN SEE AS FAR AS THE CONCEPT APPROVED, THE TRAINING AND CAREER DEVELOPMENT, THE RESEARCH LEADERS EXTENSION, THAT WILL BE COMING TO YOU FOR ACTUALLY A FUNDING DECISION AT OUR NEXT BOARD MEETING IN MAY.

IN THE TRANSLATIONAL RESEARCH CATEGORY, THE TOOLS AND TECHNOLOGIES RFA, WHICH IS ACTUALLY IN PROGRESS, WE'LL BE COMING FOR BOARD DECISION IN DECEMBER OF THIS YEAR. BUT AS I NOTED, THE BULK OF THE FUNDING IS IN THE DEVELOPMENT AND CLINICAL TRIALS

CATEGORY.

THE STRATEGIC PARTNERSHIP III PROGRAM WILL BE COMING TO YOU FOR A FUNDING DECISION ALSO AT OUR NEXT BOARD MEETING IN MAY. THE ALPHA STEM CELL CLINICS WILL BE COMING FOR A FUNDING DECISION IN SEPTEMBER. THE ACCELERATED PATHWAY WILL BE COMING FOR A FUNDING DECISION IN SEPTEMBER. THE PRECLINICAL DEVELOPMENT CONCEPT AND THE SP IV CONCEPTS WE ARE BRINGING FORTH FOR YOUR CONSIDERATION TODAY.

IN THE NEXT SLIDE I GO OVER WHAT THE FUTURE FUNDING LOOKS LIKE. AND, AGAIN, IN THE TRAINING AND CAREER DEVELOPMENT CATEGORY, THESE CONCEPTS FOR TRAINING AND BRIDGES WILL BE BROUGHT TO YOU IN JULY SO THAT WE CAN GET THEM GOING SO THAT THERE'S NOT MUCH OF A GAP BETWEEN WHAT'S CURRENTLY HAPPENED EVEN THOUGH THOSE PEOPLE MAY NOT BE THE SAME PEOPLE TO RECEIVE THE AWARDS. WE'LL SEE. THE BASIC BIOLOGY VI CONCEPT WILL BE BROUGHT FOR YOUR CONSIDERATION AT THE MAY MEETING.

IN TRANSLATIONAL RESEARCH, THE FIRST EARLY TRANSLATIONAL TRANSITIONAL ROUND, WHICH IS MOVING THOSE PROJECTS THAT HAVE EARLY PROOF OF CONCEPT FORWARD ACTUALLY TO READINESS TO ENTER DEVELOPMENT, SO THEY REACHED THE DEVELOPMENT CANDIDATE STAGE. THAT WE'LL BE BRINGING FOR YOUR CONSIDERATION AND CONCEPT IN DECEMBER OF THIS YEAR.

AND THEN FINALLY, THE DISEASE TEAM AND STRATEGIC PARTNERSHIPS, WE'LL BE BRINGING DISEASE TEAM IV AGAIN PROBABLY LATER THIS YEAR IN THE FALL IN OCTOBER.

SO I JUST WANTED TO HIGHLIGHT FOR YOU THAT WE ARE IMPLEMENTING THE DECISIONS THAT WERE MADE IN DECEMBER OF THIS PAST YEAR. WE ARE ACTUALLY IMPLEMENTING THE DECISIONS THAT THE SCIENTIFIC -- RECOMMENDATIONS OF THE SCIENTIFIC ADVISORY BOARD WHICH ARE CAPTURED IN OUR ACCELERATED PATHWAY. WE'RE BUILDING ON THE STRATEGY THAT WE DEVELOPED AND THAT THE BOARD APPROVED IN EARLY 2012, AND WE KEEP THE FOCUS ON OUR KEY STRATEGIC OBJECTIVES. SO THANK YOU VERY MUCH, AND I'LL BE HAPPY TO ANSWER ANY QUESTIONS.

CHAIRMAN THOMAS: THANK YOU, DR. OLSON. QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD? THANK YOU VERY MUCH.

WE'RE NOW GOING TO PROCEED TO AGENDA ITEM NO. 6, CONSIDERATION OF CONCEPT PLAN FOR STRATEGIC PARTNERSHIP IV. DR. CARAS IS GOING TO LEAD US IN THIS DISCUSSION.

DR. CARAS: SO, MR. CHAIRMAN, MEMBERS OF THE BOARD, AND THE PUBLIC, THIS CONCEPT PROPOSAL ADDRESSES THE CONTINUATION OF CIRM'S STRATEGIC PARTNERSHIP INITIATIVE WHICH WAS APPROVED BY THE ICOC IN OCTOBER OF

2011. SO THE GOALS OF THIS PRESENTATION ARE, FIRST, TO REVIEW WHAT THE STRATEGIC PARTNERSHIP INITIATIVE IS ABOUT, ITS PURPOSE AND OBJECTIVES, AND THEN PRESENT THE CONCEPT PLAN FOR STRATEGIC PARTNERSHIP IV, WHICH IS THE FOURTH CALL UNDER THE STRATEGIC PARTNERSHIP INITIATIVE.

SO STARTING WITH THE PURPOSE, THE STRATEGIC PARTNERSHIP INITIATIVE WAS CREATED TO ATTRACT INDUSTRY ENGAGEMENT AND INVESTMENT IN CIRM-FUNDED STEM CELL RESEARCH. THE REASONS FOR DOING THIS ARE THREEFOLD. FIRST, TO PROVIDE A SOURCE OF CO-FUNDING IN THE EARLY STAGES OF DEVELOPMENT AND LEVERAGE CIRM DOLLARS. SECOND, TO ENABLE CIRM-FUNDED PROJECTS TO ACCESS THE VERY EXTENSIVE DEVELOPMENT EXPERTISE THAT EXISTS WITHIN LARGE PHARMA AND BIOTECH PARTNERS. AND THIRD, AND PROBABLY MOST IMPORTANT, TO ENHANCE THE LIKELIHOOD THAT CIRM-FUNDED PROJECTS WILL OBTAIN FOLLOW-ON FINANCING FOR THE LATER STAGES OF DEVELOPMENT AND COMMERCIALIZATION WHICH CIRM WILL NOT BE ABLE TO SUPPORT.

I THINK IT'S IMPORTANT TO POINT OUT THAT THE STRATEGIC PARTNERSHIP INITIATIVE IS ALIGNED WITH BOTH THE CLINICAL AND ECONOMIC OBJECTIVES OF CIRM'S STRATEGIC PLAN. SO IT'S ALIGNED WITH CIRM'S FIVE-YEAR STRATEGIC GOAL TO ATTRACT INDUSTRY ENGAGEMENT AND INVESTMENT IN CIRM-FUNDED STEM CELL RESEARCH, AND IT'S

ALIGNED WITH THE CLINICAL STRATEGIC OBJECTIVE, WHICH IS TO ADVANCE STEM CELL SCIENCE INTO CLINICAL TRIALS TO ACHIEVE EVIDENCE OF THERAPEUTIC BENEFIT TO PATIENTS.

SO WITH THAT IN MIND, THE OBJECTIVE OF A STRATEGIC PARTNERSHIP IV AWARD WILL BE TO COMPLETE A PHASE I OR PHASE II CLINICAL TRIAL WITHIN THREE YEARS.

THIS DIAGRAM SHOWS WHERE THE STRATEGIC PARTNERSHIP RFA, WHICH IS SHOWN DOWN IN THE BOTTOM RIGHT-HAND CORNER, WHERE IT FALLS ALONG THE SPECTRUM OF RESEARCH THAT'S FUNDED BY CIRM AND ALSO HOW IT RELATES TO OTHER CIRM PROGRAMS. AND AS YOU CAN SEE, SP IV IS DESIGNED TO CAPTURE MATURE PROGRAMS THAT HAVE ALREADY ARRIVED AT THE EARLY CLINICAL DEVELOPMENT STAGE.

AS YOU JUST HEARD FROM DR. FEIGAL IN THIS BRIEF STATUS UPDATE OF SP AWARDS, WHICH IS SHOWN ON THIS SLIDE, VIACYTE HAS AN SP I AWARD TO COMPLETE A PHASE I TRIAL OF HUMAN EMBRYONIC STEM CELL-DERIVED PANCREATIC CELLS IN A DEVICE. THIS IS FOR TYPE 1 DIABETES. SANGAMO HAS AN SP II AWARD TO FILE AN IND AND COMPLETE A PHASE I TRIAL FOR GENETICALLY ENGINEERED BLOOD STEM CELLS TO TREAT A BLOOD DISORDER, BETA THALASSEMIA. THIS IS A DISEASE THAT AFFECTS RED BLOOD CELLS. AND SP III RECOMMENDATIONS WILL BE BROUGHT TO THE ICOC SHORTLY IN MAY OF THIS YEAR.

AS WAS ALREADY MENTIONED BY DR. FEIGAL, BUT

IT'S IMPORTANT AND SO I'LL REMENTION IT, IN JANUARY OF THIS YEAR BIOGEN IDEC AND SANGAMO ANNOUNCED THAT THEY'RE ENTERING INTO A GLOBAL COLLABORATION TO CO-DEVELOP TREATMENTS FOR BETA THALASSEMIA AND A RELATED DISEASE THAT ALSO AFFECTS RED BLOODS CELLS, SICKLE CELL ANEMIA. THIS IS A VERY EXCITING DEVELOPMENT BECAUSE IT BRINGS A LARGE, PRESTIGIOUS BIOTECH COMPANY INTO A CIRM-FUNDED PROJECT WITH A FIRM COMMITMENT TO TAKE THE THERAPY ALL THE WAY TO COMMERCIALIZATION IF MILESTONES ARE MET, WHICH IS EXACTLY WHAT WE WANT AND ARE HOPING FOR WITH THE STRATEGIC PARTNERSHIP INITIATIVE.

FOR NEW MEMBERS I WANT TO POINT OUT THAT THE STRATEGIC PARTNERSHIP INITIATIVE HAS SOME UNIQUE FEATURES. FIRST, IT REQUIRES APPLICANTS TO SHOW THAT THEY HAVE FINANCIAL CAPACITY TO MOVE THE PROJECT THROUGH DEVELOPMENT OR THAT THEY'RE ABLE TO ATTRACT THE CAPITAL TO DO SO. WE'VE TERMED THIS COMMERCIAL VALIDATION. AND IT CAN BE EVIDENCED EITHER BY HAVING INVESTMENTS FROM VC FIRMS, PUBLIC MARKETS, COMPANIES OR DISEASE FOUNDATIONS, AND/OR SIGNIFICANT LIQUID ASSETS, OR VIA A RESEARCH OR DEVELOPMENT AGREEMENT WITH A LARGE PHARMA OR BIOTECH COMPANY.

SECONDLY, THE INITIATIVE REQUIRES APPLICANTS TO PROVIDE CO-FUNDING FOR THE PROPOSED PROJECT IN THE

FORM OF A ONE-TO-ONE MATCH.

REGARDING ELIGIBILITY, STRATEGIC PARTNERSHIP IV, AS WAS THE CASE FOR THE PREVIOUS CALLS, WILL BE OPEN TO BOTH FOR-PROFIT AND NOT-FOR-PROFIT INSTITUTIONS. AND IN ADDITION, SP IV WILL BE FOCUSED ON MATURE CLINICAL STAGE PROJECTS WHERE AN IND HAS ALREADY BEEN FILED.

AS WAS THE CASE WITH THE PREVIOUS CALLS, ALL APPLICANTS MUST PROVIDE EVIDENCE OF COMMERCIAL VALIDATION. FOR-PROFIT APPLICANTS CAN DO THIS EITHER BY DEMONSTRATING FINANCIAL STRENGTH AND/OR VIA A RESEARCH OR DEVELOPMENT AGREEMENT WITH A LARGE BIOTECH OR PHARMA PARTNER. NOT-FOR-PROFIT APPLICANTS MUST HAVE A RESEARCH OR DEVELOPMENT AGREEMENT WITH A PARTNER.

THIS SHOWS ACTIVITIES THAT WOULD BE IN SCOPE UNDER AN SP IV AWARD. SO IT INCLUDES THE CONDUCT OF AN EARLY CLINICAL TRIAL, PHASE I OR PHASE II, AS WELL AS SUPPORTING ACTIVITIES SUCH AS THE MANUFACTURE OF PRODUCT FOR THAT TRIAL. WHAT WOULD BE OUT OF SCOPE FOR THIS ROUND ARE IND-ENABLING ACTIVITIES AND PHASE III TRIALS.

THIS IS A SUMMARY OF THE AWARD INFORMATION. THE PROPOSED TOTAL COSTS FOR SP IV WOULD BE UP TO 32 MILLION FOR UP TO THREE AWARDS. THE AWARD AMOUNT WOULD BE 10 MILLION PER PROJECT WITH THE POSSIBILITY TO

INCREASE THAT UP TO 12 MILLION UNDER EXCEPTIONAL CIRCUMSTANCES. THE AWARD TERM WOULD BE THREE YEARS. CO-FUNDING ONE TO ONE WOULD BE REQUIRED. AND THE AWARD MECHANISM WOULD BE A GRANT IF NOT-FOR-PROFIT, A LOAN OR GRANT IF FOR-PROFIT.

I JUST WANT TO REMIND YOU THAT WE HAVE ALSO A MANAGEMENT AND REVIEW PROCESS POSTFUNDING APPROVAL AS WAS ALREADY DESCRIBED BY DR. FEIGAL. PRIOR TO GRANT INITIATION AND BEFORE ANY DOLLARS GO OUT THE DOOR, THE CIRM SCIENCE OFFICER AND THE AWARDEE WILL SET MUTUALLY AGREED TO MILESTONES. THIS INCLUDES KEY GO/NO-GO DECISION POINTS AND CRITERIA FOR THOSE DECISIONS. IN ADDITION, THERE IS ACTIVE MANAGEMENT OF FUNDED DEVELOPMENT PROJECTS WHICH INCLUDES ASSESSMENT BY CIRM'S EXTERNAL CLINICAL ADVISORY PANEL, CDAP, EITHER ANNUALLY OR AT KEY DECISION POINTS.

THIS IS THE PROVISIONAL TIMETABLE. IF YOU APPROVE THE CONCEPT, WE WOULD POST THE RFA IN APRIL OF THIS YEAR. FULL APPLICATIONS WOULD BE DUE IN Q 3. THE GRANTS WORKING GROUP WOULD REVIEW THEM IN Q 4, AND THE RECOMMENDATIONS WOULD BE BROUGHT TO THE ICOC FOR APPROVAL IN Q 1 OF 2015.

I THINK THAT'S MY LAST SLIDE. YES. AND CAN I ANSWER ANY QUESTIONS?

CHAIRMAN THOMAS: THANK YOU, DR. CARAS. MR.

SHEEHY.

MR. SHEEHY: SO THANK YOU FOR YOUR PRESENTATION, DR. CARAS. AND NOT TO INDICATE ANY LACK OF SUPPORT FOR THIS PROGRAM, BUT I'M NOT GOING TO SUPPORT THE APPROVAL OF THIS CONCEPT OR THE FOLLOWING CONCEPT. AND THE REASON IS WE'RE HIRING A NEW PRESIDENT. SO WE'RE KIND OF PUTTING HANDCUFFS ON WHOEVER THAT INDIVIDUAL IS GOING TO BE BY CONTINUING TO DO THIS FUNDING AS WE MOVE OUT. I MEAN IT'S NO SECRET THAT WE'RE SEEKING THE PRESIDENT IN A RELATIVELY NEAR TERM. AND WITH THAT HAPPENING, I THINK THESE CONCEPTS COULD EASILY BE DELAYED UNTIL THAT NEW INDIVIDUAL GETS IN PLACE AND THEN CAN START TO EXERCISE THEIR IMPACT ON THE PROGRAM.

SPECIFICALLY, WHEN THIS PERSON COMES IN, I WOULD LIKE THIS PERSON TO HAVE SOME INFLUENCE OVER THE CONSTRUCTION OF RFA'S. SO BEFORE I WOULD APPROVE A CONCEPT THAT WOULD LET AN RFA GO OUT, I'D LIKE TO HAVE OUR NEXT LEADER HAVE SOME OWNERSHIP OF THAT PROJECT. AND JUST TO BE CLEAR, WE'RE SPENDING AND BURNING THROUGH OUR MONEY AT JUST AN ALARMING PACE. SO IF YOU LOOK AT WHAT WE'RE PLANNING TO SPEND THIS YEAR, WE SPENT 66 MILLION ON GENOMICS AND BASIC BIOLOGY IN JANUARY, WE'RE SCHEDULED TO SPEND 200 MILLION ON ACCELERATED PATHWAY, WE ARE SCHEDULED TO SPEND 70

MILLION ON ALPHA CLINICS. WE'LL GO UP TO 80 MILLION ON STRATEGIC PARTNERSHIP III. WE HAVE 23 MILLION SCHEDULED FOR RESEARCH LEADERSHIP. WE HAVE 35 MILLION FOR TOOLS AND TECHNOLOGIES. SO IF YOU TOTAL ALL THAT UP, THAT'S $466 MILLION. THAT'S A LOT OF MONEY FOR ONE YEAR.

AND I THINK, FRANKLY, BOTH IN TERMS OF STAFF AND NEW LEADERSHIP, DIGESTING ACCELERATED PATHWAY AND ALPHA CLINICS ARE NOT GOING TO BE -- DIGESTING THOSE PROGRAMS IS NOT GOING TO NECESSARILY BE -- THOSE ARE FAIRLY COMPLEX, FAIRLY BIG PROJECTS AND FAIRLY BIG INITIATIVES. AND I THINK IT BEHOOVES US TO KIND OF SLOW DOWN THE PACE AT WHICH WE'RE BURNING THROUGH THIS MONEY.

THESE TWO PROGRAMS WILL EQUAL -- WE'RE ASKING TO SPEND ABOUT 10 PERCENT OF THE REMAINING FUNDS THAT ARE AVAILABLE TO US. AND I ACKNOWLEDGE THAT IN DECEMBER WE KIND OF ADOPTED A STRATEGIC VISION, BUT THAT VISION IS GOING TO BE RELIANT ON OUR NEXT LEADER TO IMPLEMENT IT. AND WE ARE HAVING ACTIVE DISCUSSIONS AS BOARD MEMBERS ABOUT WHAT WE WANT IN OUR NEXT LEADER, BUT CLEARLY HAVING SOME SORT OF INFLUENCE OVER THE FUTURE COURSE OF OUR SCIENTIFIC PROGRAM IS GOING TO BE IMPORTANT. I THINK BEING ABLE TO WEIGH IN ON THESE LATE STAGE PROJECTS IS GOING TO BE VERY IMPORTANT. I

THINK TO CONTINUE TO PUT FORWARD CONCEPTS, TO ISSUE RFA'S, AND TO SPEND MONEY WHEN WE KNOW WE'RE GOING TO HAVE NEW LEADERSHIP IS NOT ACTUALLY, IN MY MIND, BEING FAIR TO THAT INDIVIDUAL BEFORE WE HIRE THAT INDIVIDUAL.

MS. LANSING: CAN I ASK A QUESTION?

CHAIRMAN THOMAS: YES, SHERRY.

MS. LANSING: I'M A LITTLE CONFUSED. I'M SITTING HERE WITH THE SLIDES THAT -- I'LL WAIT. I JUST NEED TO KNOW THE HIGH CORE NUMBER. AM I TALKING? I JUST NEED TO KNOW THE HIGH CORE NUMBER OF IF WE APPROVE THIS, WHAT WOULD BE LEFT FOR THE NEW PRESIDENT AND WHAT FUTURE FUNDING WOULD BE LEFT.

DR. CARAS: I THINK DR. OLSON CAN ANSWER THAT QUESTION.

MS. LANSING: I THINK JEFF BRINGS UP AN INTERESTING POINT.

DR. OLSON: AS I NOTED IN THE PRIOR PRESENTATION, THERE WOULD BE 400 MILLION LEFT IN FUTURE FUNDING. CONCEPT APPROVALS DO TRIGGER A PROGRAM ANNOUNCEMENT AND AN RFA. I WOULD ARGUE THAT ONCE YOU PUT OUT AN RFA, THE BOARD OBVIOUSLY MAKES THE FUNDING DECISION, BUT THAT DOES INITIATE THE PROCESS FOR US. WE'D GO THROUGH AN RFA, WE'D PUT TOGETHER A REVIEW COMMITTEE. SO THE NEW PRESIDENT WOULD HAVE 400 MILLION LEFT.

OBVIOUSLY THE ACCELERATED PATHWAY, WE PUT OUT A PROGRAM ANNOUNCEMENT. WE EXPECT TO -- THAT'S TO MOVE THINGS FORWARD TO ACHIEVE CLINICAL PROOF OF CONCEPT. SO THAT'S WHERE WE ARE.

MS. LANSING: I'M STILL CONFUSED. I KNOW YOUR NUMBERS. IF WE DO IT THE WAY THAT YOU'RE SUGGESTING, ONCE YOU PUT OUT THE RFA, YOU HAVE TO ASSUME WE'RE GOING TO FUND IT. SO WE'LL HAVE TO SUBTRACT THAT FROM THE 400 MILLION.

DR. OLSON: WELL, THERE'S 512 MILLION IN CONCEPT APPROVALS. THE 400 MILLION DOES NOT -- HAS NOT BEEN APPROVED IN CONCEPT. IT'S FUTURE FUNDING. IT IS CURRENTLY ALLOCATED AS THE BOARD DISCUSSED AT ITS DECEMBER MEETING.

MS. LANSING: WITH JEFF'S PROPOSAL, YOU'RE SUGGESTING HOLDING BACK HOW MUCH, JEFF?

MR. SHEEHY: YES, SHERRY. AGAIN, ASSUMING THAT THE NEW HIRE WISHES TO GO AHEAD WITH THESE PROGRAMS, I DON'T THINK WE'RE DELAYING IT BY THAT LARGE OF AMOUNT OF TIME. BUT IF THE NEW INDIVIDUAL IS NOT SUPPORTIVE OF THESE PROGRAMS, I FEEL VERY UNCOMFORTABLE WITH US, WITH THIS SERIOUS TIMELINE FOR MOVING FORWARD ON THIS, TO KEEP GOING AHEAD AND ISSUING NEW RFA'S THAT THIS INDIVIDUAL IS GOING TO HAVE TO IMPLEMENT.

I WOULDN'T APPRECIATE THAT IF I WAS COMING

INTO A JOB, I'D WONDER IF YOU'RE SERIOUS ABOUT HIRING ME IF YOU CONTINUE TO BURN THROUGH YOUR CASH AS FAST WE'RE BURNING THROUGH OUR CASH. AND I JUST -- I JUST, IN TERMS OF PROPER BOARD OVERSIGHT, DON'T FEEL IT'S APPROPRIATE TO CONTINUE TO ISSUE RFA'S WHEN WE KNOW THAT THE PERSON WHO'S GOING TO BE RESPONSIBLE FOR THAT RFA HASN'T BEEN BROUGHT ON BOARD AND WE'RE PLANNING TO BRING THAT INDIVIDUAL ON BOARD IN THE NEAR TERM.

MS. LANSING: JEFF, WOULD YOU REMIND THE BOARD OF WHAT OUR TIMELINE IS TO BRING THAT NEW INDIVIDUAL ON?

CHAIRMAN THOMAS: SHERRY, I'LL ADDRESS THAT. SO THE PRESIDENTIAL SEARCH SUBCOMMITTEE HAS BEEN PROCEEDING APACE UNDER A SCHEDULE WHICH ENVISIONS THE COMPLETION OF INTERVIEWS BY KORN FERRY OF PROSPECTIVE APPLICANTS THIS MONTH. WE'LL HAVE A TELEPHONIC MEETING OF THE SEARCH SUBCOMMITTEE AT THE END OF THE MONTH TO WHITTLE DOWN TO A LIST OF ANYWHERE UP TO EIGHT POTENTIAL CANDIDATES THAT WILL BE INTERVIEWED BY THE SEARCH SUBCOMMITTEE IN PERSON MID-APRIL TOWARDS PICKING THREE CANDIDATES TO BE INTERVIEWED BY THE FULL BOARD IN CLOSED SESSION AT THE END OF APRIL. AND AT THAT POINT WE PLAN TO MAKE OUR DECISION.

MS. LANSING: SO MAY. SO IT'S EIGHT MORE WEEKS OF A DELAY. THAT'S REALLY ALL WE'RE TALKING

ABOUT, TO TAKE SOME TIME TO LOOK AT THEM ALSO OR HER TIME.

CHAIRMAN THOMAS: I WOULD POINT OUT, JUST SINCE AS WE GO THROUGH THIS PROCESS, I WOULD LIKE TO INFORM THE BOARD WE HAVE A NUMBER OF VERY QUALIFIED PEOPLE INTERESTED IN THE POSITION, THAT DEPENDING ON WHERE THAT PERSON WHO ULTIMATELY IS SELECTED LIVES AND WHAT IT MAY OR MAY NOT TAKE TO TRANSITION OVER, WE DON'T HAVE AN EXACT DATE CERTAIN AT WHICH A NEW PRESIDENT WILL START. AND WE REALLY WON'T KNOW THAT UNTIL WE GET DOWN TO THE SELECTION ITSELF.

DR. FRIEDMAN: SO I THINK THAT JEFF RAISES A REALLY IMPORTANT QUESTION, NOT SO MUCH FOR THIS PROPOSAL, BUT A MORE GENERAL ISSUE, WHICH IS WHAT DO WE SEE AS THE RESPONSIBILITIES AND THE AUTHORITIES OF THE NEW PERSON WHO'S BEING RECRUITED. I THINK THAT'S A REALLY VALID DISCUSSION TO HAVE.

SHERRY, I THINK THAT IF WE DELAY THIS, AND I HAVEN'T DECIDED WHICH WAY I FEEL ABOUT THIS YET, IF WE DELAY IT, WE'RE REALLY DELAYING IT FOR A YEAR, NOT EIGHT WEEKS, BECAUSE YOU'RE GOING TO HAVE TO NOT ONLY BRING THE PERSON HERE, YOU NEED TO GIVE THAT PERSON TIME TO REALLY UNDERSTAND THE PROGRAM. AND YOU CAN'T DO THIS VERY QUICKLY. THAT MAY BE THE RIGHT THING TO DO, IT MAY BE THE WRONG THING TO DO, BUT IT REALLY PUTS

A MAJOR HIATUS IN WHAT WE'RE DOING.

MS. LANSING: I APPRECIATE THAT. THAT REALLY HELPS ME NOW KNOW WHICH WAY TO VOTE. WE'RE TALKING ABOUT A YEAR. IN MY OPINION, THAT'S TOO LONG A DELAY.

DR. FRIEDMAN: MAYBE I'M WRONG, AND WE CAN TALK ABOUT THAT, BUT I THINK THIS IS A DISCUSSION THAT HAS TO DO MORE WITH THE RECRUITMENT EXPECTATIONS THAN IT DOES WITH THIS PARTICULAR INITIATIVE, WHICH, TO ME, I HAVE TO TELL YOU, SOUNDS LIKE A REALLY GOOD INITIATIVE. THE TIMING, I GRANT YOU, JEFF, IS WHAT WE'RE DISCUSSING, BUT I THINK IT'S VALUABLE, SHARING THE CLINICAL APPLICATIONS, ALL THAT STUFF.

MR. CHAIRMAN, YOU NEED TO SORT OF SUGGEST TO US WHEN WE HAVE THAT DISCUSSION. IS THAT AN OPEN DISCUSSION? IS THAT A CLOSED DISCUSSION? IS THAT A DISCUSSION WE HAVE NOW? IS THAT A DISCUSSION WE HAVE LATER? BUT I THINK WE NEED TO DISCUSS THAT BEFORE WE GET TO THE TWO SPECIFIC TOPICS BECAUSE JEFF'S INDICATED, I THINK, A REALLY LEGITIMATE QUESTION TO ASK.

CHAIRMAN THOMAS: MR. HARRISON, WOULD YOU LIKE TO ANSWER THAT? I BELIEVE CERTAINLY WE COULD HAVE IT.

MR. HARRISON: IT'S A TOPIC FOR OPEN SESSION DISCUSSION. SO IN LIGHT OF THE POINTS THAT HAVE BEEN

MADE, IT'S PROBABLY APPROPRIATE FOR YOU TO CONSIDER IT NOW.

DR. DULIEGE: ALL THE COMMENTS, BUT, IN FACT, WE SHOULD ALSO COME BACK TO YOUR POINT, MICHAEL. CAN YOU JUST CLARIFY INDEED THAT WE STILL HAVE APPROXIMATELY $500 MILLION TO BE SPENT FOR HOW LONG?

DR. OLSON: COULD YOU REPEAT THE QUESTION?

DR. DULIEGE: CAN YOU JUST CLARIFY FOR ALL OF US THAT THE CIRM AND ICOC STILL HAVE THE MANDATE TO SPEND, IF I UNDERSTOOD CORRECTLY, APPROXIMATELY $500 MILLION OVER HOW LONG PERIOD OF TIME?

DR. OLSON: SO ASSUMING THE BOARD APPROVES THE TWO CONCEPTS TODAY, THERE IS 512 MILLION IN CONCEPT APPROVED THAT THE BOARD WILL ACTUALLY MAKE FUNDING DECISIONS ON OVER THE NEXT YEAR. OUTSIDE OF THAT MONEY, THERE IS $400 MILLION THAT HAS BEEN ALLOCATED IN PRINCIPLE TO CERTAIN TYPES OF FUNDING, BUT HAS NOT COME FORTH TO THE BOARD FOR CONCEPT. SO THAT MONEY WOULD NOT BE AWARDED BY THE BOARD UNDER THE CURRENT TIMELINE UNTIL PROBABLY FIRST PART OF -- FIRST HALF OF 2017.

SO THE BOARD WILL BE MAKING AWARDS ESSENTIALLY UP TO THE FIRST HALF OF 2017 OR SO. PART OF THE RATIONALE FOR THAT IS, GIVEN THE TIMELINE OF AWARDS AND GIVEN THE 6-PERCENT LIMIT ON OUR GNA AND THE STAFF TIME REQUIRED TO MANAGE AND DO THESE AWARDS, THAT

WE ARE TARGETING, I BELIEVE, 2021 TO HAVE THINGS WRAPPED UP UNDER THIS CURRENT ROUND OF FUNDING.

NOW, OBVIOUSLY IF ALL THE EFFORTS THAT ARE BEING LOOKED AT, MOVED FORWARD, THAT WILL NOT BE THE ISSUE. BUT THE CURRENT FUTURE FUNDING DOES NOT EXPECT TO BE FULLY AWARDED BY THIS BOARD UNTIL THE FIRST HALF OF 2017 UNDER THE CURRENT TIMELINE.

DR. TROUNSON: I FIND IT A LITTLE DIFFICULT TO COME IN ON THIS CONVERSATION. IT'S SORT OF STRANGE FOR ME BECAUSE I AM PRESIDENT, BUT I WANTED TO MAKE JUST ONE REALLY IMPORTANT POINT HERE.

THESE ARE ESSENTIALLY INDUSTRY AWARDS. AND THE WAY WE SET THIS UP WAS TO GIVE INDUSTRY A CHANCE TO COME, AND THEY'VE BEEN COMING IN, AS YOU KNOW, WITH THE MORE MATURE PROJECTS. THEY CAN'T WAIT THESE LONG INTERVALS. THESE ARE REALLY INDUSTRY AWARDS THAT WE'VE MADE SEVERAL OF THEM ALREADY, AND I THINK THERE WERE SIX IN THE LAST ROUND FOR WHICH WE MIGHT MAKE SOMETHING OF THOSE WHEN THEY COME TO THE BOARD. BUT INDUSTRY CAN'T WAIT THESE LONG TIME FRAMES. THEY ARE READY AT CERTAIN POINTS. AND ELONA IS NOT HERE BECAUSE SHE'S UNFORTUNATELY ILL, SERIOUSLY QUITE ILL AT THE MOMENT. SHE'S SEEING A DOCTOR. SO I'M SPEAKING FOR BOTH SHE AND I.

WE KNOW THAT THERE ARE A NUMBER OF INDUSTRY

PLAYERS WHO WANT TO COME IN, AND THEY'RE TALKING ABOUT HOW CAN THEY GET IN EVEN EARLIER THAN WE MIGHT HAVE FOR THIS ONE. THEIR TIMING IS THAT THEY'RE ONLY ENABLED TO GET IN ON THESE TIME FRAMES AND NOT THE MUCH LONGER ONES.

WHETHER WE WOULD MAKE ANY MORE THAN ZERO, ONE, OR TWO AWARDS FROM THESE, THIS IS WHAT'S REALLY BEEN COMMON FOR THERE. BUT THE INDUSTRY HAS BEEN ABLE TO PARTICIPATE REASONABLY WELL IN THESE PROGRAMS, AND IT HAS BEEN EFFECTIVELY INDUSTRY ONLY EVEN THOUGH YOU COULD COME IN AS AN ACADEMIC IF YOU HAD A PARTNER. BUT THEY HAVE BEEN INDUSTRY ONLY. THE INDUSTRY HAS REALLY APPRECIATED THIS FROM US. THEY'VE STOPPED CRITICIZING US FOR DUMPING THEM IN WITH ACADEMICS AND GIVING THEM A CHANCE TO COMPETE WITH EACH OTHER IN AN RFA. AND I THINK IT'S WORKED VERY WELL FOR THEM.

I THINK IT'S SOMETHING THAT WE OUGHT TO CONSIDER IN THIS PARTICULAR RFA, THE NEEDS OF INDUSTRY, AND MY UNDERTAKING TO INDUSTRY TO ENABLE THEM TO BE ABLE TO COME IN ON A REASONABLY REGULAR BASIS THAT FITS THEIR ECONOMIC NEEDS.

MR. SHEEHY: SO, AGAIN, I DON'T REALLY WANT TO GET INTO THE MERITS OF THE RFA BECAUSE THAT'S NOT REALLY MY CORE ISSUE. I REALLY WANT TO COME BACK. I THINK THE LARGER QUESTION DR. FRIEDMAN WAS ASKING,

WHICH I THINK WE'RE FREE TO ADDRESS, IS WHAT OUR EXPECTATIONS ARE IN THE NEXT PRESIDENT. AM I CORRECT THAT WAS YOUR PREDICATE FOR THE DISCUSSION?

DR. FRIEDMAN: IT DEPENDS IF YOU THINK THAT'S A WISE MOVE, IN WHICH CASE --

MR. SHEEHY: I'M JUST TRYING TO CAPTURE THE THREAD. BECAUSE I DO THINK -- I DO ACCEPT YOUR POINT THAT THAT COULD WEIGH IN ON THIS DECISION-MAKING PROCESS. AND CLEARLY, I KNOW STEVE JUELSGAARD HAS BEEN FAIRLY EMPHATIC THAT WE WOULD LIKE SOMEONE WITH OPERATIONS EXPERIENCE AND CERTAINLY FURTHER DOWN IN THE PIPELINE, EXPERIENCE FURTHER DOWN THE PIPELINE. AND IN THAT CASE, I WOULD EXPECT THAT INDIVIDUAL TO HAVE A SIGNIFICANT IMPACT ON THESE LATE STAGE CONCEPTS.

IF WE WERE DOING BASIC BIOLOGY, I WOULD FEEL DIFFERENTLY. BUT WE'RE TALKING ABOUT LATE STAGE PROJECTS. WE'RE TALKING ABOUT ACCELERATED PATHWAY. WE'RE TALKING ABOUT ALPHA CLINICS. THESE ARE ALL MIXED UP TOGETHER. AND THIS INDIVIDUAL, IT IS MY EXPECTATION, IS GOING TO HAVE THE EXPERIENCE TO MAKE SENSE OF THIS AND MAKE -- NOT THAT IT'S NOT SENSIBLE AND IT'S NOT COHERENT, BUT WE'VE GOT A LOT OF THINGS HAPPENING. AND TO MAKE THIS INTO A COHERENT PROGRAM THAT GETS US TO SUCCESS IN MY HOPE IS FAIRLY SOON BECAUSE I AM VERY TAKEN BY THE COMMENTS OF THE CFAOC

MEMBER WHO BASICALLY SAID TO US WHERE IS THE BEEF.

I DON'T KNOW IF YOU GUYS READ JENSEN'S COLUMN, BUT HE'S LIKE, YOU KNOW, WE'VE GIVEN YOU BILLIONS OF DOLLARS, YOU'VE SPENT IT, AND WE DON'T HAVE ANY THERAPIES YET. AND I'M NOT -- I DON'T WANT TO ARGUE THAT POINT, BUT I THINK IT IS A VALID POINT FOR CALIFORNIA TAXPAYERS TO ASK.

AND I THINK GIVEN THAT WE'RE STARTING TO RUN OUT OF MONEY, WE'RE TALKING ABOUT OUR LAST 400 MILLION, AND HOW ATTRACTIVE IS THIS POSITION GOING TO BE TO SOMEBODY IF WE'VE ALLOCATED ALL THE MONEY THAT'S LEFT? I MEAN HONESTLY. HOW WOULD YOU FEEL? HERE, I'M GOING TO HIRE YOU TO BASICALLY MANAGE THE LAST EMBERS OF A DYING FIRE. I MEAN REALLY? WE WANT THIS PERSON TO BE ABLE TO HAVE AN IMPACT, AND WE HAVE THE NUMBERS FROM STEVE JUELSGAARD THAT IT'S ABOUT $70 MILLION TO GET A PROJECT THROUGH PHASE II WHERE WE NEED TO BE IN ORDER TO GET THE KIND OF PICKUP TO HAVE SUCCESS. WE PUT ASIDE 200 MILLION, WHICH IS MAYBE THREE PROJECTS. AND JUST TO CONTINUE TO FUND, FUND, FUND WHEN WE'RE IN THIS TRANSITION PHASE, JUST TO ME, IS THE HEIGHT OF IRRESPONSIBILITY IN MY VIEW.

AND FRANKLY, I WOULD GO AHEAD AND MAKE A MOTION NOT TO APPROVE THIS CONCEPT AT THIS TIME SO WE HAVE SOMETHING ON THE FLOOR. I DON'T KNOW IF THERE'S A

SECOND OR ANYTHING. IT'S BACK TO YOU.

CHAIRMAN THOMAS: THERE'S BEEN A MOTION AS JUST STATED. IS THERE A SECOND ON THAT?

MR. TORRES: I'LL SECOND FOR DISCUSSION PURPOSES.

CHAIRMAN THOMAS: SENATOR TORRES SECONDS. MR. SHEEHY, JUST A POINT OF CLARIFICATION. IF YOU STIPULATE THAT DR. FRIEDMAN'S NUMBER OF A ONE-YEAR DELAY AS THE OPERATIVE NUMBER HERE, DOES THAT AT ALL, IN LIGHT OF DR. TROUNSON'S COMMENTS, DOES THAT AT ALL CHANGE YOUR VIEW AT LEAST WITH THIS PARTICULAR DEAL HERE?

MR. SHEEHY: FIRST OF ALL, I DON'T THINK -- NO, I DON'T ACCEPT A YEAR BECAUSE I THINK WE'RE GOING TO BE ASKING FOR ENOUGH EXPERTISE THAT SOMEONE SHOULD BE ABLE TO HIT THE GROUND RUNNING. IT WOULD BE MY EXPECTATION THAT IT'S NOT GOING TO TAKE FOREVER FOR SOMEONE TO GET UP TO SPEED. THEY KNOW THE FIELD AND KNOW THE ENVIRONMENT IN WHICH WE'RE WORKING. AND IT WOULD BE MY EXPECTATION THEY HAVE SOME FAMILIARITY WITH CIRM. I DON'T THINK WE'RE GOING TO BE INVITING A STRANGER.

THE SECOND POINT IS THAT WE ARE DOING A LOT. OVER $515 MILLION GOING OUT OVER A YEAR IS A HECK OF A LOT OF MONEY. AND I THINK EVEN IF IT DID TAKE A YEAR

FOR A NEW INDIVIDUAL TO GET THEIR HANDS AROUND ACCELERATED PATHWAY AND ALPHA CLINICS, THAT WOULD MEAN THAT WAS TIME WELL SPENT. DON'T FORGET. WE'RE GOING TO BE APPROVING MORE -- WE'RE APPROVING SP III. NEXT MONTH WE'RE GOING TO BE APPROVING -- THE CURRENT PRIOR ITERATION OF THIS, AND THEN WE'RE GOING INTO THE NEXT ONE. CAN'T WE APPROVE THAT AND DIGEST THOSE PROGRAMS?

AND REMEMBER THESE PROJECTS ARE GOING TO BE STARTING AT THE BEGINNING MID TO LATE 2015. SO THOSE PROJECTS AREN'T EVEN GOING TO BEAR FRUIT UNTIL 2016 OR 2017. SO, AGAIN, I JUST THINK IT BEHOOVES US TO KIND OF PUT ON THE BRAKES AT LEAST UNTIL WE HAVE NEW LEADERSHIP BECAUSE WE'RE GETTING NEW LEADERSHIP.

DR. LEVIN: THANKS. I THINK THAT JEFF BRINGS UP SOME VERY GOOD POINTS. AND NOT JUST IN TERMS OF HOW ARE YOU GOING TO ENCOURAGE SOMEBODY TO TAKE THIS JOB IF THEY'RE NOT GOING TO HAVE ANY APPROPRIATE POWERS OR ANYTHING THAT THEY CAN DO. BUT ALSO, AS YOU MENTION, I DON'T AGREE NECESSARILY WITH DR. FRIEDMAN'S POINT THAT IT'S GOING TO TAKE A YEAR FOR THEM TO GET UP TO SPEED. HOPEFULLY BY THE TIME WE HIRE SOMEBODY, THEY WILL KNOW ENOUGH ABOUT CIRM. HOPEFULLY WE WON'T HIRE SOMEBODY TO LEAD THE ORGANIZATION THAT DOESN'T UNDERSTAND THE ORGANIZATION AND ITS HISTORY AND ITS PROCESS, AND MAYBE THEY'LL BE ABLE TO COME IN AND FIND AN EVEN FASTER WAY

TO ENGAGE WITH INDUSTRY TO GET THE MONEY OUT, AN EVEN BETTER WAY TO GET INDUSTRY INVOLVED IN THE WAY THAT INDUSTRY WANTS TO DO IT. IT'S A POSSIBILITY.

AND I ALSO LOOK AROUND AND THINK, YOU KNOW, WHO ELSE IS NEW? A LOT OF THE BOARD. I THINK THIS IS THE FIRST MEETING THAT I AM NOW ONE OF THE OLDER MEMBERS OF THE BOARD, MAYBE NOT IN TERMS OF YEARS, BUT IN TERMS OF --

CHAIRMAN THOMAS: DR. LEVIN, BENJAMIN IS BEING CONSIDERED FOR ONE OF THE VACANT BOARD SEATS. IT'S HIS NEWBORN SON.

DR. LEVIN: I THINK IF WE REALLY ARE GOING TO HAVE A NEW PRESIDENT IN MAY, THAT'S NOT VERY LONG AT ALL. AND THAT IT IS A SHOW OF RESPECT EVEN TO ALLOW THAT PERIOD OF TIME FOR OUR NEW BOARD MEMBERS TO CONSIDER WHAT WE'RE DOING WITH THE REMAINING FUNDING AND FOR THE NEW PRESIDENT TO BE ABLE TO THINK ABOUT WHAT THEY WANT TO DO. MAYBE IT'S THE SAME, BUT MAYBE THERE'S NEW PROGRAMS THAT ARE EVEN BETTER.

CHAIRMAN THOMAS: MR. ROWLETT.

MR. ROWLETT: I DON'T WANT TO RESTATE COLLOQUIALISM AD NAUSEAM, BUT THAT THE EXPECTATIONS THAT A NEW PRESIDENT HITS THE GROUND RUNNING, I THINK THAT, AS ONE OF THE NEWER BOARD MEMBERS, YOUNGER NEWER BOARD MEMBERS, I MIGHT ADD, MY ENTHUSIASM ABOUT THE

PROJECTS IS REAL, BUT THE DELIBERATION AND THE ENGAGEMENT OF A NEW PRESIDENT, THAT'S ALSO, I THINK, A REAL PRIORITY FOR US. AND TO BE ABLE TO DO THAT AND TO RECRUIT THE KIND OF CANDIDATE THAT I ENVISION WILL LEAD THIS VERY DYNAMIC ORGANIZATION, I THINK IT DOES NECESSITATE THAT WE WAIT. SO I DO SUPPORT JEFF'S PERSPECTIVE AND POINTS.

DR. BOXER: THANKS. I THINK THAT THIS IS A REALLY IMPORTANT TOPIC. I GUESS I HAVE A SLIGHTLY DIFFERENT VIEW OF THE ROLE OF LEADERSHIP IN GENERAL. AND OBVIOUSLY I'M RELATIVELY NEW TO THE CIRM BOARD, SO I'M SPEAKING ABOUT LEADERSHIP IN GENERAL. HAVING BEEN THROUGH A LOT OF CHANGES IN LEADERSHIP OF INSTITUTIONS, I FIND IT SOMEWHAT UNUSUAL THAT THERE WOULD BE A 180-DEGREE TURN WHEN A NEW LEADER COMES IN.

AND I ALSO THINK THAT ONE HAS TO CONTINUE WITH THE WORK THAT IS GOING ON. I DO GET THE POINT THAT WE DO HAVE TO BE RESPECTFUL OF A NEW LEADER AND MAKE CERTAIN THAT THEY'RE GOING TO HAVE DECISIONS TO MAKE WITH MONEY LEFT TO SPEND. ON THE OTHER HAND, I THINK THAT THERE WAS A LOT OF DISCUSSION AND THOUGHT BY A LOT OF PEOPLE THAT WENT INTO THESE DECISIONS ABOUT THE CONCEPTS THAT WE WANTED TO FUND. AND I THINK THERE'S A LOT OF GOOD MOMENTUM THAT I FEEL WOULD BE LOST.

SO I WOULD ACTUALLY BE IN FAVOR OF GOING AHEAD WITH THIS, BUT I DO SEE THE ISSUES, AND THAT'S NOT TO SAY THAT I DON'T SEE THE POINTS THAT ARE BEING RAISED. I THINK THERE HAS TO BE A BALANCE BETWEEN KEEPING SOME OF OUR EFFORTS GOING, BUT BEING RESPECTFUL OF THE NEW PRESIDENT COMING IN TO MAKE CERTAIN THAT THEY'RE GOING TO BE ABLE TO MAKE IMPACTFUL DECISIONS AND HAVE MONEY LEFT TO DO THAT WITH.

DR. PRIETO: YES. I UNDERSTAND THAT THESE ARE SOME OF THE MOST IMPORTANT AND VALUABLE PROPOSALS OR PROJECTS THAT WE HAVE, AND THAT PROBABLY SOME OF THE ONES WITH THE GREATEST POSSIBILITY OF LEADING US TO CURES IN THE CLINIC IN THE RELATIVELY NEAR FUTURE, BUT THEY'RE ALSO SOME OF THE MOST EXPENSIVE ONES WE HAVE. AND I HAVE TO AGREE WITH JEFF, THAT GIVEN THAT WE'RE EXPECTING TO HAVE A NEW PRESIDENT BEFORE THE END OF THE YEAR, I THINK THAT THAT'S NOT AN UNREASONABLE EXPECTATION THAT THAT PERSON WILL BE ABLE TO HAVE SOME INPUT AND FUNDS TO WORK WITH TO DETERMINE OUR DIRECTION.

DR. DULIEGE: SO I DON'T WANT TO COMMENT ON THE PREROGATIVE AND RESPONSIBILITY OF THE NEW PRESIDENT, BUT I WANT TO ECHO AND SECOND, LINDA, WHAT YOU SAID. AND ON THAT, JEFF, I WILL POLITELY DISAGREE WITH YOU. I HATE TO DO THAT. IT'S A RISKY PROPOSAL TO

DO THAT, BUT I WILL TAKE IT TODAY.

FIRST OF ALL, I JUST WANT NO ONE TO FORGET WHAT WAS SAID ABOUT TIMELINES. IT'S NOT JUST TWO MONTHS OR EVEN FOUR MONTHS. IT'S ACTUALLY MOMENTUM HERE THAT HAS BEEN CREATED. AND AS YOU SAID SO RIGHTFULLY, LINDA, THIS PROPOSAL HERE IS COMPLETELY ALIGNED WITH THE OVERARCHING STRATEGY OF CIRM. I DON'T SEE ANYTHING THAT IS NOT ALIGNED THERE. SO I WOULD BE VERY SURPRISED THAT A NEW PERSON WOULD STRONGLY DISAGREE WITH IT.

AND FINALLY I WANT TO CORRECT SOMETHING. I DON'T REALLY WANT ANY MISPERCEPTION TO BE CREATED WHEN I HEAR, WELL, THE PUBLIC IS WONDERING WHAT CIRM AND THE ICOC DID WITH THIS MONEY. YOU HAVE NOTICED THAT WE HAVE, TO MY UNDERSTANDING SO FAR, NEVER FUNDED PHASE III TRIALS. IT'S GOING TO BE THE INDUSTRY WHO FUND PHASE III TRIALS. SO ULTIMATELY PUBLIC MAY HEAR IN, I DON'T KNOW, FIVE YEARS FROM NOW AT BEST MAYBE THAT A NEW DRUG HAS BEEN APPROVED AND IS AVAILABLE TO THEM. AND WHAT WILL THEY HEAR? THEY WILL HEAR CAPRICOR HAS PUT A NEW DRUG ON THE MARKET. THEY WILL HEAR JOHNSON & JOHNSON, THEY WILL HEAR VIACYTE. THEY WILL CERTAINLY NOT HEAR CIRM UNLESS WE REMIND THEM THAT THESE PROJECTS WOULD HAVE NEVER SEEN THE MARKET UNLESS CIRM HAD FUNDED AND ALLOWED THEM TO GET STARTED.

SO LET'S BE CAREFUL EACH TIME WE WANT TO TALK ABOUT PERCEPTION OF THE PUBLIC ABOUT THE ROLE OF CIRM. I THINK WHAT WAS DEMONSTRATED BY ELLEN TODAY AND MANY OTHERS IS THAT CIRM'S CONTINUED TO DO A TERRIFIC JOB IN FULFILLING THE WISHES OF THE CALIFORNIA PUBLIC.

MS. LANSING: I'D LIKE TO SPEAK.

DR. FRIEDMAN: LET SHERRY GO FIRST.

CHAIRMAN THOMAS: DR. FRIEDMAN WOULD YIELD THE FLOOR TO YOU, SHERRY.

MS. LANSING: I THINK THIS HAS BEEN A VERY, VERY HEALTHY DISCUSSION. AND I SO RESPECT THE ISSUE THAT JEFF BROUGHT UP, BUT UNFORTUNATELY I'M JUST AFRAID, THOUGH I KNOW WE'RE CLOSE, WE HAVE A TIMELINE FOR THE NEW PRESIDENT, SOMETIMES TIMELINES DON'T WORK OUT, SOMETIMES THE PERSON WHO WE SEE THAT WE HIRE MAY NOT BE IMMEDIATELY AVAILABLE. AND AFTER LISTENING TO EVERYBODY, I THINK THERE'S STILL AMPLE MONEY LEFT, BUT I ALSO THINK WE AS A BOARD HAVE A RESPONSIBILITY TO CONTINUE THE MOMENTUM TO SERVE THE PATIENTS QUICKLY AND EFFICIENTLY. AND I THINK STOPPING THIS MOMENTUM WILL BE REALLY SENDING A SIGNAL THAT WE'RE REALLY STOPPING THE WORK OF CIRM UNTIL WE HAVE A NEW PRESIDENT. AND I THINK THAT'S A BAD MESSAGE TO SEND. SO I'M GOING TO VOTE FOR THE FUNDING.

DR. FRIEDMAN: SO I TOO WOULD LIKE TO SAY

THAT, AS I ANALYZE THIS, I DO HAVE THIS STRONG SENSE OF SORT OF THE COMMENT ABOUT THE TIDES TAKEN, THAT THE CREST LEAD ON, AND EVEN THOUGH THE CHARACTER WHO SAID IT DIDN'T DO SO WELL, BUT I DO FEEL THAT WE DO HAVE A CERTAIN MOMENTUM HERE. I THINK THAT THE PRESIDENT HAS AN ENORMOUSLY IMPORTANT ROLE TO PLAY IN THIS ORGANIZATION. AND THAT ROLE IS AN IMPLEMENTATION, A LEADERSHIP OF THE EXECUTION OF THE STRATEGY THAT WE, THE BOARD, HAVE ARTICULATED THE STRATEGY WITH GOOD OUTSIDE COMMENTS. I THINK THAT'S AN IMPORTANT ROLE, AND I THINK JEFF'S POINT ABOUT THE PERSONAL PERSPECTIVES OF THAT INDIVIDUAL SHOULD WEIGH WITH US AS WE PROCEED.

I SEE ONE OF TWO SCENARIOS THAT ARE LIKELY TO HAPPEN. ONE IS THAT JEFF IS CORRECT AND THERE WILL BE A RELATIVELY SHORT TIME BETWEEN GETTING SOMEBODY WHO'S AT LEAST IDENTIFIED. WHETHER THAT INDIVIDUAL IS ACTUALLY LIVING HERE OR NOT, THERE ARE ALL SORTS OF SOCIAL THINGS THAT HAVE TO BE ACCOMMODATED. BUT THAT PERSON WILL BE QUICKLY IDENTIFIED, WILL BE FAMILIAR WITH THE ORGANIZATION, WILL UNDERSTAND THE RISKS AND BENEFITS, THE OPPORTUNITY COSTS, AND THE ADVANTAGES OF MOVING AHEAD WITH ONE PROGRAM OR ANOTHER. IF THAT'S THE CASE, THEN THE TIMING FOR THIS WILL BE JUST RIGHT BECAUSE THAT INDIVIDUAL WILL BE HERE AT A TIME WHEN HE

OR SHE CAN LOOK OVER THE PROGRAM AND SAY THESE ARE THE THINGS THAT CAME IN. I DON'T THINK ANY OF THEM ARE RESPONSIVE TO WHAT WE NEED. OR I THINK THREE OF THEM ARE OR WHATEVER THAT INDIVIDUAL MIGHT SAY.

THE OTHER POSSIBILITY IS THE ONE THAT WE DON'T WANT TO HAPPEN, WHICH IS IT TAKES A LONGER PERIOD OF TIME TO FIND SOMEBODY, AND THAT PERSON COMES IN AND WANTS TO SPEND MORE TIME THOUGHTFULLY ANALYZING THE PROS AND CONS OF THE PROGRAMS TO PROCEED WITH. AND, AGAIN, I WOULD RESPECT THAT IF THAT'S WHAT THE INDIVIDUAL WISHED TO DO, BUT THAT THEN DELAYS US EVEN FURTHER.

I'M NOT MAKING THE ARGUMENT THAT JUST BECAUSE WE'VE COMMITTED OURSELVES IN WRITING TO SAY THIS IS A GOOD IDEA THAT WE HAVE TO FOLLOW IT. I'M NOT SAYING THAT. I'M SAYING I THINK IT'S PROBABLY THE RIGHT THING TO DO BECAUSE THE TIMING SEEMS RIGHT. I AM AS WORRIED AS JEFF AND OTHERS ARE ABOUT HOW EXPENSIVE THESE PROJECTS ARE AND HOW QUICKLY THE MONEY DISSIPATES AND HOW, NOT FOR PUBLIC PERCEPTION, NOT FOR GETTING EDITORIALS THAT APPLAUD US, BUT BECAUSE WE ALL RECOGNIZE THE VAST HUMAN NEED THAT WE'RE TRYING TO ADDRESS THAT WE WANT TO MAKE THOSE CONTRIBUTIONS MORE QUICKLY AND MORE EFFECTIVELY. I THINK ON BALANCE I WOULD PROBABLY URGE THAT WE CONTINUE THE PROGRAMS AS

THEY'RE BEING LAID OUT HERE. THANK YOU.

MR. TORRES: I LOVE JEFF DEARLY, WHICH IS WHY I SECONDED HIS MOTION FOR THE PURPOSES TO HAVE A ROBUST DISCUSSION.

DR. CARAS, WHAT IS THE AMOUNT OF MONEY THAT WE'RE TALKING ABOUT IN RESPECT TO THE STRATEGIC PARTNERSHIP WITH INDUSTRY?

DR. CARAS: YOU'RE ASKING HOW MUCH WE'RE ASKING FOR FOR THIS PARTICULAR ROUND? UP TO 32 MILLION, WHICH WOULD BE UP TO THREE PROJECTS.

I ALSO WANT TO REMIND YOU THAT THIS WILL BE LEVERAGED ONE TO ONE WITH MONEY COMING IN FROM THE APPLICANT.

MR. TORRES: RIGHT. NOW OF THE 466 MILLION THAT JEFF HAS TALKED ABOUT, BOTH STEVE JUELSGAARD AND MYSELF AND OTHERS HAVE OPINED THAT WE NEED TO BE CAREFUL ABOUT THE MONEY SITUATION. I THINK, BECAUSE IT IS MY NATURE, I THINK IN ELECTORAL TERMS. AND, THEREFORE, ELECTORAL TERMS TO ME MEANS 2016 WHERE OUR FATE MAY BE DECIDED AGAIN BY THE VOTERS. AND THAT WEIGHS HEAVY ON MY MIND, NOT BECAUSE JIM LOTT SAID WHERE'S THE BEEF, BUT, MORE IMPORTANTLY, THAT WE ARE TRUE TO THE TAXPAYERS IN TERMS OF HOW WE ARE ADJUDICATING THE EXPENDITURE OF MONEY.

BUT I ALSO WANT TO ASSOCIATE MYSELF, I KNOW

HE'LL BE SURPRISED BY THIS, WITH DR. TROUNSON'S REMARKS IN THAT INDUSTRY HAS BEEN ON OUR RADAR, BUT WE HAVEN'T BEEN PROVIDING AN INPUT ENOUGH FOR INDUSTRY. AND I THINK THAT THESE COMMENTS BY DR. TROUNSON AND OTHERS THAT ARE HERE, THIS STRATEGIC ABILITY TO MOVE WITH INDUSTRY IN PARTNERSHIP IS EXTREMELY IMPORTANT, NOT ONLY FOR 2016, BUT FOR BEYOND. AND SO THAT STILL LEAVES US A LITTLE OVER 400 MILLION TO CONTINUE TO REVIEW AND TO DIGEST, AS JEFF AND I HAVE TALKED ABOUT IN THE PAST, AND STILL BE BEHOLDEN TO WHERE WE NEED TO MOVE IN THE FUTURE.

I WOULD ARGUE THAT -- I WOULD SUPPORT THE FUNDING OF THIS PARTICULAR INITIATIVE, BUT I RESERVE THE RIGHT TO CONTINUE THESE DISCUSSIONS REGARDING THE REMAINDER OF THE MONEY THAT WE MAY OR MAY NOT HAVE COMMITTED.

DR. BRENNER: SO THIS IS AN INTERESTING PHILOSOPHICAL DECISION. WHEN AN ORGANIZATION IS IN TRANSITION, YOU HAVE TO DECIDE DO YOU WAIT FOR A NEW KEY PERSON OR DO YOU PROCEED. IN GENERAL, I REALLY THINK IT'S THE OBLIGATION OF THIS GROUP TO PROCEED. I THINK THIS IS WHAT WE WERE APPOINTED TO DO AND THAT WE SHOULD DO WHAT WE THINK IS BEST FOR CIRM AND ITS PATIENTS. AND THAT WHETHER WHILE WE'RE LOOKING FOR SOMEONE, THERE'S ALWAYS SOMEONE WE'RE LOOKING FOR. YOU

CAN'T JUST COME TO A SCREECHING HALT. I THINK WE SHOULD BE FISCALLY RESPONSIBILE, AS SENATOR TORRES POINTS OUT, IRREGARDLESS OF WHETHER WE HAVE A NEW PRESIDENT OR NOT. THAT'S OUR OBLIGATION ANYWAY.

SO I THINK THAT WE HAVE TO USE -- TO THE BEST OF OUR KNOWLEDGE PROCEED EXPEDITIOUSLY AND EFFICIENTLY TO USE THE RESOURCES THAT WE'VE BEEN ENTRUSTED WITH AND THAT WE SHOULDN'T DEFER THAT WHILE WE WAIT FOR SOMEONE ELSE. I THINK THIS IS OUR JOB AND ENOUGH PEOPLE HERE TO DO IT.

MR. SHEEHY: JUST IF I CAN REBUT A COUPLE. FIRST, WITH THE RFA QUESTION, ONCE WE ISSUE AN RFA, THE PRESIDENT CANNOT, AND I WOULDN'T SUPPORT A PRESIDENT NOT AGREEING TO REVIEW ALL THOSE APPLICATIONS. TO ME THE RFA ISSUANCE IS VIRTUALLY A CONTRACT. AND PEOPLE IN GOOD FAITH SUBMIT PROJECTS, ESPECIALLY IN THIS INSTANCE WHERE THEY'VE GONE AND GOTTEN MATCHING FUNDING. WE'RE OBLIGATED TO REVIEW THOSE AND THOSE WILL COME TO THE BOARD; AND IF THEY'RE MERITORIOUS PROJECTS, WE'RE GOING TO FUND THEM.

I'M JUST STRUCK BY -- EVEN IN YOUR WORST-CASE SCENARIO, I AM EVEN MORE ALARMED WITH CONTINUING TO FUND PROJECTS. NOW, WE JUST HEARD WE ANTICIPATE HAVING EIGHT CLINICAL TRIALS BY THE END OF THE YEAR. REMEMBER, ACCELERATED PATHWAY, ALPHA CLINICS, EIGHT

CLINICAL TRIALS. SO LET'S SAY WE HAVEN'T GOTTEN A PRESIDENT AND WE'RE STILL CONTINUING AS WE ARE. THAT IS A FULL BOAT. AND EITHER WAY, MY ARGUMENT FROM MY PERSPECTIVE WORKS EITHER WAY. AND I GUESS I'M ALARMED THAT THE PERCEPTION IS BY DELAYING A COUPLE OF MONTHS CONSIDERING THIS, WE'RE STOPPING OUR PROGRESS WHEN WE'RE TALKING ABOUT SPENDING $515 MILLION THIS YEAR, WHICH IS MORE MONEY THAN WE'VE EVER SPENT, I THINK, IN A YEAR EXCEPT WHEN WE WERE BUILDING FACILITIES, AND WE'RE ACCELERATING OUR BURN RATE.

AND TO SENATOR TORRES' POINT, IF THIS IS ALL ABOUT 2016, THESE PROJECTS ARE NOT GOING TO BE UP AND RUNNING UNTIL THE SECOND HALF OF 2015, MAYBE THE BEGINNING OF 2016. SO THEY HAVE NO IMPACT.

I STILL KIND OF COME BACK TO WHERE STEVE WAS. WE'VE GOT A NICE PIPELINE OF PROJECTS. THIS IS WHY I WAS SO SUPPORTIVE OF THE ACCELERATED PATHWAY AND SETTING ASIDE MONEY TO TRY TO PUSH HARD WHAT WE HAVE AS FAR AND FAST AS WE CAN. WE HAVE TO HAVE SOME FOCUS. AND WE CAN'T CONTINUE TO ADD MORE LATE STAGE PROJECTS, CONTINUE TO SPEND MONEY. SOMEBODY IS GOING TO NOT HAVE SOMETHING THAT THEY WANT. IT MAY BE THE TRAINING PROGRAMS, IT MAY BE BASIC BIOLOGY, IT MAY BE RESEARCH LEADERSHIP. BUT I TELL YOU THE FIRST THING I'M THROWING OFF THE BOAT ARE THESE KIND OF BASE

INFRASTRUCTURE THINGS THAT I THINK ACTUALLY PERSONALLY ARE IMPORTANT TO SUSTAIN WHAT WE'VE BUILT, BUT THEY'RE GOING TO BE THE FIRST THING TOSSED OVERBOARD ARE THESE CLINICAL PROGRAMS THAT FULFILL OUR PROMISE TO THE PEOPLE OF CALIFORNIA. RIGHT.

SO I JUST -- EVERYONE ACTS LIKE THERE'S NO TRADE-OFFS, THAT THIS MONEY IS INFINITE. AND IT'S NOT. AND WE CAN'T CONTINUE TO BURN IT AT THIS RATE WITHOUT NOT HAVING IT AT SOME POINT. AND EVERY TIME WE COME AROUND TO THINKING ABOUT THIS STRATEGICALLY, WE JUST GO FORWARD AND DO ANOTHER RFA. WE VOTE MORE FUNDS FOR THIS, MORE FUNDS FOR THAT. AND WHEN ARE WE GOING TO SAY I'D LIKE TO HAVE SOMETHING IN THE POT IN 2016? I'D LIKE TO NOT HAVE IT ALL GONE. I'D LIKE TO HAVE ENOUGH MONEY TO GET THAT PROGRAM THAT GOT THROUGH PHASE I ALL THE WAY THROUGH PHASE II. I'D LIKE TO HAVE ENOUGH MONEY TO MAKE SURE THAT THE PROGRAMS WE BUILT AT THE INSTITUTION LEVEL STILL CONTINUE TO MAINTAIN THEIR MOMENTUM. IF YOU GUYS WANT TO CONTINUE TO BURN THROUGH THIS, BE MY GUEST. I THINK WE HAVE A FULL PLATE.

DR. FRIEDMAN: INVEST RESPONSIBLY.

MR. SHEEHY: WE HAVE EIGHT CLINICAL TRIALS. WE HAVE ALPHA CLINICS, WE HAVE ACCELERATED PATHWAY. IT'S NOT LIKE, HEY, HIT THE BRAKES. I'M JUST SAYING COME ON. WE HAD A DISCUSSION IN JANUARY. WHAT I

REMEMBER WAS TRADE-OFFS. WHAT I REMEMBER WERE PEOPLE TALKING RATIONALLY ABOUT THE FACT THAT WE HAVE FINITE AMOUNTS OF MONEY. THEN WHEN THE RUBBER HITS THE ROAD, WE'RE LIKE, OH, NO. WE HAVE $3 BILLION ALL OVER AGAIN. IT'S GOING TO GO ON FOREVER. I DO THINK THE LESS MONEY WE PUT -- WE GIVE THE INCOMING PRESIDENT TO BE ABLE TO HAVE TO OPERATE WITH, THE LESS ATTRACTIVE THE JOB IS. THAT'S JUST A GIVEN.

SO I'M STILL HOLDING ON TO MY VOTE, AND I THINK THE DISCUSSION HAS VEERED OFF IN A DIRECTION THAT I DON'T THINK IS BORNE BY THE FACTS. I'M NOT ASKING THAT WE STOP OUR PROGRAM. I'M NOT ASKING WE COME TO A SCREECHING HALT. I'M JUST ASKING THAT WE ACT RATIONALLY AND RESPONSIBLY.

DR. STEWARD: SO I HAVE REALLY APPRECIATED THE DISCUSSION, AND I THINK IT'S VERY IMPORTANT THAT WE HAVE THIS SORT OF DISCUSSION EVERY TIME WE TALK ABOUT SPENDING MONEY. AND I HAVE TO SAY THAT JEFF'S POINTS ABOUT BEING VERY CAREFUL AND TRYING TO INVEST WISELY, I THINK WE NEED TO THINK ABOUT THAT EVERY TIME. SO MAYBE I HAVE A COMPROMISE HERE, MAYBE NOT.

WE'RE CONCERNED ABOUT THE DELAY HERE. AND I APPRECIATE THAT PART TOO, AND I ALSO THINK THAT IN THE CASE OF A UNIVERSITY, YOU WOULDN'T STOP ADMITTING STUDENTS BECAUSE YOU HAVE A NEW PRESIDENT COMING ON

BOARD, SO I DO THINK IT'S IMPORTANT TO CONTINUE THE PROGRESS.

MY COMPROMISE PROPOSAL IS WE COULD DELAY THIS DECISION UNTIL THE MAY BOARD MEETING, BY WHICH TIME WE WOULD HAVE A MUCH BETTER IDEA OF WHAT WAS GOING ON WITH THE PRESIDENTIAL SEARCH AND HAVE AN OPPORTUNITY TO DEAL WITH MORE FACTS THAN WE HAVE RIGHT NOW.

MR. SHEEHY: I TOTALLY ACCEPT THAT AS A FRIENDLY AMENDMENT. I'M VERY SUPPORTIVE. I WASN'T TRYING TO KILL THE PROGRAM. I WAS JUST SAYING CAN'T WE WAIT A WHILE. WE HAVE A KEY DECISION POINT COMING UP. IN FACT, I ASKED, WHEN THIS CAME UP, I CALLED MARIA AND I SAID WHY ARE WE DOING THIS NOW? WHY DON'T WE PUT THIS OFF TO THE MAY MEETING? SO GIVEN THAT WE WERE TALKING ABOUT -- I JUST DID NOT SEE THE ULTRA URGENCY TO GET THIS STUFF LINED UP AND OUT THE DOOR. I'M NOT SAYING DON'T DO IT. I'M SAYING JUST TAKE A MINUTE. WE JUST APPROVED $200 MILLION FOR ACCELERATED PATHWAY. WE'RE ONLY SPENDING IN MAY TO BEGIN WITH.

IF THE SECOND -- I DON'T KNOW IF THE SECOND IS STILL SECONDING, BUT IF HE WOULD TAKE THAT AS A FRIENDLY AMENDMENT.

MR. TORRES: REPEAT THE AMENDMENT BEFORE I SECOND.

DR. STEWARD: THE AMENDMENT WOULD BE TO DELAY

THIS DECISION UNTIL THE MAY BOARD MEETING. I'LL JUST SAY THAT THERE ARE WAYS THAT THE TIMELINE COULD BE ACCELERATED, MAYBE WITH SOME DIFFICULTY, BUT, FOR EXAMPLE, MAYBE THERE AREN'T PREPROPOSALS THAT WARRANT A PREREVIEW. YOU MIGHT BE ABLE TO JUST REVIEW THEM ALL THAT CAME IN. JUST A THOUGHT. I THINK WE COULD ACCELERATE THE CONSIDERATION PHASE.

MR. TORRES: I DON'T MIND THAT FRIENDLY AMENDMENT, BUT I'D LIKE TO HEAR FROM JOE IN TERMS OF HIS INDUSTRY PERSPECTIVE HOW HE FEELS ABOUT IT.

MR. PANETTA: THANK YOU. I GUESS, FIRST OF ALL, I'M BEGINNING TO HEAR SEVERAL DIFFERENT THINGS BECAUSE I THINK WHAT JEFF SAID INITIALLY WAS LET'S NOT DOING ANYTHING UNTIL WE GET A NEW PRESIDENT IN PLACE AND LET THAT NEW PRESIDENT TAKE RESPONSIBILITY FOR THE PROGRAMS GOING FORWARD, BUT ALSO HEARING MAYBE WE SHOULDN'T DO THIS AT ALL, MAYBE WE'RE BURNING THROUGH MONEY TOO QUICKLY.

I GUESS WHAT STRUCK ME IN LISTENING TO DR. FEIGAL'S PRESENTATION WAS THAT WE'RE BEGINNING TO SCRAPE AT THE SURFACE OF GETTING VENTURE CAPITAL INVOLVEMENT AND INDUSTRY INVOLVEMENT, AND WE'RE BEGINNING TO MOVE THINGS INTO THE CLINIC AND WE'RE BEGINNING TO MAKE PROGRESS TOWARD COMPLETING ULTIMATELY WHAT WE SET OUT TO DO TEN YEARS AGO HERE. AND SO THIS

TO ME SEEMS LIKE A PERFECTLY RATIONAL APPROACH TO MOVING TOWARD THAT GOAL.

I DON'T THINK DELAYING IT TWO MONTHS IS A BIG DEAL IF THAT'S WHAT WE'RE TALKING ABOUT DOING HERE. I GUESS WHERE I BECOME CONCERNED IS WHEN I BEGIN TO HEAR THAT MAYBE THIS ISN'T SOMETHING WE SHOULD BE DOING, OR MAYBE WE'RE NOT RESPONSIBLY SPENDING MONEY BY GOING INTO A PROJECT LIKE THIS BECAUSE, FROM MY PERSPECTIVE ON THE INDUSTRY SIDE, THIS IS EXACTLY THE DIRECTION THAT WE NEED TO BE MOVING IN. AND IF WHAT WE'RE TALKING ABOUT IS DELAYING THIS A YEAR, I DON'T THINK INDUSTRY HAS THAT KIND OF TOLERANCE TO WAIT A YEAR, TO PUT THINGS ON -- PUT THE BRAKES ON THIS AND THEN PICK IT UP AGAIN A YEAR FROM NOW.

AND THE FINAL THING I'LL SAY IS I THINK THAT, AGAIN, WITH THE PERSPECTIVE THAT THIS IS MOVING US IN THE RIGHT DIRECTION, I THINK IT WOULD BE OF GREAT BENEFIT TO THE NEW PRESIDENT FOR US TO BE MOVING IN THAT DIRECTION WITH A PROGRAM LIKE THIS ONE WHEN THE NEW PRESIDENT COMES IN. THANK YOU.

CHAIRMAN THOMAS: WE'D LIKE TO SORT OF WRAP THIS UP IF WE CAN, SO A COMMENT OR TWO LEFT.

DR. DULIEGE: I REALLY WONDER WHAT TWO MONTHS WILL BUY US HERE. WE'LL OBVIOUSLY NOT HAVE A NEW PRESIDENT AT THAT MEETING FOR SURE. SO WHAT KIND OF

NEW INFORMATION COULD WE GAIN IN TWO MONTHS THAT WILL INFLUENCE THE VOTE THAT WE SHOULD OR SHOULD NOT MAKE?

DR. STEWARD: I THINK WE'LL KNOW MORE IN TERMS OF THE TIMING, PERHAPS NOT THE EXACT PERSON, BUT AT LEAST OVER WHAT TIME FRAME WE'LL BE ABLE TO BRING ON A NEW PRESIDENT AND HAVE THAT INDIVIDUAL UP TO SPEED. WE'LL ALSO PERHAPS HAVE A BETTER IDEA OF THE KINDS OF PEOPLE WHO ARE INTERESTED IN THIS JOB AND THEIR EXPERTISE AND HOW WELL THEY KNOW THE CIRM PROGRAM. IT MAY BE THAT, AS WE TALKED ABOUT, THE IDEA WOULD BE TO HAVE SOMEBODY HERE WHO REALLY UNDERSTOOD THINGS AND WOULDN'T TAKE ANY TIME AT ALL TO GET UP TO SPEED.

IF THAT DOESN'T LOOK LIKE IT'S GOING TO BE THE OUTCOME, THEN I THINK IT'S CRITICAL TO MAKE A DECISION ONE WAY OR ANOTHER ON THIS. BUT IF IT IS SOMETHING THAT LOOKS LIKE WE KNOW WHAT'S GOING TO BE GOING ON, THAT WILL JUST GIVE US MORE COMFORT.

CHAIRMAN THOMAS: CAN I JUST COMMENT VERY QUICKLY THAT OUR TARGET DATE TO SELECT A NEW PRESIDENT IS APRIL 30TH. SO IF THINGS GO AS WE FULLY EXPECT, WE WILL KNOW WHO THAT PERSON IS AT THAT TIME PRIOR TO THE MAY BOARD MEETING.

MS. LANSING: I HAVE A QUESTION. CAN I JUST ADD?

CHAIRMAN THOMAS: CERTAINLY.

MS. LANSING: MY CONCERN IS THAT, AS MUCH AS I UNDERSTAND AND RESPECT WHAT JEFF IS SAYING, THE FUNCTION OF THIS BOARD IS ALSO TO SET STRATEGY AND DIRECTION. AND WE'VE BEEN WORKING ON THIS FOR A VERY, VERY LONG TIME. AND I THINK IF WE WEREN'T GOING THROUGH A TRANSITORY PHASE IN TERMS OF OUR PRESIDENT, WE WOULD ALL HAVE VOTED ENTHUSIASTICALLY YES FOR THIS. SO I DON'T KNOW WHY WE WOULD CHOOSE SOMEBODY WHO WOULD GO AGAINST ALL THE STRATEGY THAT WE ALL BELIEVE IN.

IF OUR GOAL IS TO GET SOMEONE BY MAY 1ST, THEY'RE NOT GOING TO KNOW ENOUGH BY THE TIME OF OUR BOARD MEETING TO CONVINCE ME THAT OUR STRATEGY IS WRONG ANYWAYS, I GUESS, IS WHAT I WOULD SAY. SO I STILL -- EVEN THOUGH I DO RESPECT SO MUCH THE ISSUES THAT JEFF IS RAISING, I WOULD STILL PROCEED NOW.

CHAIRMAN THOMAS: ARE WE THROUGH WITH BOARD COMMENT? LAST WORD, DR. DULIEGE, AND THEN WE HAVE TO GO TO PUBLIC COMMENT.

DR. DULIEGE: I JUST WANT TO SAY THAT I'M COMPLETELY IN AGREEMENT WITH WHAT WAS SAID JUST HERE NOW, AND THAT I DON'T SEE THE POINT OF WAITING FOR THESE TWO MONTHS. AGAIN, I HAVEN'T HEARD ANYONE SAYING THAT THERE SHOULD BE ANY DEBATE ABOUT THE VALUE OF WHAT IS BEING PROPOSED HERE. IT'S MORE ABOUT THE TIMING AND THE PERCEPTION THAT THE NEW PRESIDENT WOULD HAVE AN

IMPACT ON IT AND NOT THE VALUE. REMEMBER IF OUR MANDATE IS TO HAVE AS MANY DRUGS ON THE MARKET AVAILABLE TO PATIENTS IN A NOT TOO DISTANT FUTURE, RIGHT NOW WE HAVE, EVEN THROUGH THIS YEAR, EIGHT CLINICAL TRIALS. THE ODDS OF A PRODUCT COMING OUT OF THAT IS ONE, ONE OUT OF TEN. SO WE NEED MORE, MANY MORE IN THE YEARS TO COME, AND WE NEED INDUSTRY TO CHIME IN AS RAPIDLY AS POSSIBLE.

I'M NOT SAYING THAT THERE'S AN URGENCY IN TWO MONTHS. THAT'S NOT WHAT I'M TRYING TO SAY. I'M TRYING TO SAY I HAVEN'T HEARD ANYONE CHALLENGING THE VALUE, THE MOMENTUM, AND THE ALIGNMENT OF THIS PROPOSAL WITH THE OVERARCHING STRATEGY GOAL OF CIRM.

CHAIRMAN THOMAS: THANK YOU. OKAY. LET'S GO. PUBLIC COMMENT.

DR. BRATT-LEAL: HI. MY NAME IS ANDRES BRATT-LEAL FROM THE SCRIPPS RESEARCH INSTITUTE. WE CAME UP AS A GROUP FROM SAN DIEGO TO TALK ABOUT THE RFA THAT'S YET TO BE DISCUSSED THAT'S STILL ON THE AGENDA FOR THE PRECLINICAL DEVELOPMENT, BUT I THINK PROBABLY OUR COMMENTS ARE BETTER SERVED AT THIS POINT BEFORE THE BOARD VOTES ON THIS.

OUR PROJECT IS TO DEVELOP A CELL-BASED THERAPY FOR PATIENT SPECIFIC BASED ON INDUCED PLURIPOTENT STEM CELLS. AND IT'S IN THE LAB OF JEANNE

LORING WHO'S IN THE BACK HERE AT THE SCRIPPS RESEARCH INSTITUTE AND CLINICIANS AT THE SCRIPPS CLINIC. BUT ALSO I THINK THAT WAITING ON THESE PROPOSALS IS NOT IN THE BEST INTEREST OF THE PATIENTS OF CALIFORNIA AND WHO ARE HERE TO TALK ABOUT THAT TODAY. AND I'D LIKE TO INTRODUCE SOME OF THE PATIENTS: ED FITZPATRICK, MICHAEL REDONSKY, AND ALAN TRUITT, WHO WE HAVE CELLS IN THE LAB THAT WE'VE REPROGRAMMED. SHERRIE GOULD AND MICHELE SCHRINER AND GLORIA LYNCH ARE HERE, DAN DEPALLA, ERIC ROBERTSON. WE ALSO HAVE CELLS IN THE LAB. JIM ARNOLD, SUZANNE PETERSON, WHO'S A TSRI, AND BRAD ARENS.

SO THERE'S REALLY A LOT OF EXCITEMENT IN THE PARKINSON'S COMMUNITY RIGHT NOW, AND WE THINK THAT PARKINSON'S FUNDING RIGHT NOW IS UNDERFUNDED IN THE CIRM PORTFOLIO. THERE'S NO CURE FOR PARKINSON'S, AND THERE'S NO WAY EVEN TO STOP THE DEGENERATION. BUT WE HAVE A WAY TO MAKE THESE NEURONS FROM STEM CELLS. SO THERE'S A LOT OF EXCITEMENT RIGHT NOW. ALL THE MONEY HAS BEEN PRIVATE FUNDING FOR OUR PROJECT, AND IT'S BEEN FROM OVER 900 DONORS IN THE LAST THREE YEARS.

SO I THINK IT'S REALLY IN THE BEST INTEREST OF THE PATIENTS OF CALIFORNIA IF WE CAN MOVE THE PRECLINICAL DEVELOPMENT RFA THAT'S STILL ON THE AGENDA AND THIS AGENDA HERE, IF WE CAN MOVE FORWARD AS FAST AS

POSSIBLE. AND WHEN WE'RE TALKING ABOUT DELAYS OF UNKNOWN PERIOD, IT'S NOT IN THE BEST INTEREST. SO NOW ED FITZPATRICK WILL TALK.

MR. FITZPATRICK: HELLO. I WAS DIAGNOSED WITH PARKINSON'S WHEN I TURNED SIXTY YEARS OLD. AT THE TIME MY NEUROLOGIST SAID -- EXPLAINED THE DISEASE TO ME. AND MY COMMENT TO HIM WAS, WELL, THIS COULD CHANGE EVERYTHING. MY 67TH BIRTHDAY WAS TWO WEEKS AGO, AND I CAN TELL YOU FOR SURE IT CHANGED EVERYTHING.

RIGHT NOW I WANT TO BE CHANGED BACK. I DON'T HAVE THE TIME FOR THIS. WHEN I WAS SIXTY YEARS OLD, I HAD A HANDICAP IN GOLF OF TWO. AT 65 IT WAS NINE. I'M LUCKY TODAY TO BE ABLE TO PLAY TO A 2. THAT'S HOW FAST THIS IS GOING FOR ME. SO TIME FRAMES ARE CRITICAL HERE.

CIRM IS A TORCH FOR ME AND TORCH FOR MY FUTURE, STOP THINKING ABOUT BEING CONFINED TO A WHEELCHAIR. CIRM IS AN ENTITY THAT HAS TAKEN MY DESPAIR AWAY BECAUSE THE TALENT POOL IN THIS ROOM IS MASSIVE. WHY YOU THINK YOU NEED A PRESIDENT TO BE THE ONLY ONE TO MAKE A DECISION I DON'T KNOW BECAUSE I THINK YOU ALL ARE VERY CAPABLE OF MAKING YOUR OWN DECISIONS. THE FACT OF THE MATTER IS THAT CIRM IS GOING AFTER SOME MORE MONEY AND IT SHOULD BECAUSE THE PROGRAM IS VERY VITAL TO THE SAFETY AND THE HEALTH OF

THIS COUNTRY.

WE THINK WE HAVE A PROGRAM THAT WILL KNOCK PARKINSON'S INTO THE DEAD CATEGORY. IT'S NOT A CURE. WE DON'T KNOW WHERE THE CURE IS COMING FROM. I'M BEING TOLD TO BE PATIENT, THAT CURE IS COMING BEFORE TOO LONG. MY DEFINITION OF BEFORE TOO LONG IS IT BETTER BE TOMORROW BECAUSE I DON'T HAVE TOO MANY MORE TOMORROWS FOR MYSELF TO FEEL COMFORTABLE. BUT CIRM IS MY GUIDING LIGHT, AND I ASK YOU TO TAKE INTO CONSIDERATION THE ULTIMATE RECIPIENT OF YOUR LARGESSE, WHICH IS ME AND THESE PEOPLE HERE. WE ARE THE PATIENTS.

THERE'S A MILLION, MILLION AND A HALF PEOPLE IN THIS COUNTRY THAT HAVE THE DISEASE, ANOTHER MILLION OR MILLION AND A HALF THAT DON'T KNOW IT YET. SO IT'S A VERY BIG IMPACT, AND THAT BODY HERE IS AT THE LEAD OF THIS WHOLE PROGRAM, AND THEY CAN DELIVER AN END TO THE UNDEFEATED STRAIN OF PARKINSON'S DISEASE. THANK YOU.

MR. ARENS: HELLO. MY NAME IS BRAD ARENS. I HAVE PARKINSON'S DISEASE. MY ROLE HERE TODAY IS TO REPRESENT A MOVEMENT HEADED UP BY DR. JEANNE LORING AT THE TSRI AND MELISSA HOUSER AND SHERRIE GOULD FROM SCRIPPS CLINIC AND A GRASS ROOTS ORGANIZATION CALLED SUMMIT FOR STEM CELL WHEREBY WE'VE TAKEN UNDER ROUTE A PROCEDURE OFF DR. YAMANAKA'S IPS CELLS. AND WE'VE ACTUALLY GOT EIGHT PATIENTS' SKIN CELLS THAT WE HAVE

TRANSFORMED INTO IPS CELLS THAT WILL TURN INTO DOPAMINE PRODUCING CELLS. WITH THE BLESSING OF THE FDA, WE HOPE TO TRANSPLANT THEM BACK INTO PATIENTS, INTO THE HOST BRAIN AND GIVE SOME CORRECTION TO THIS PROCESS, THIS DISEASE.

I WAS DIAGNOSED WITH PARKINSON'S 12 YEARS AGO. I WAS 48 YEARS OF AGE. SO FOR THE LAST FIFTH OF MY YEARS, I'VE BEEN SEEKING OUT A SOLUTION. BEFORE I WAS DIAGNOSED WITH PARKINSON'S DISEASE, I WAS A VERY BUSY CHIROPRACTOR. AND BECAUSE OF THAT I SOUGHT OUT NOT ONLY EASTERN, BUT WESTERN TRADITIONAL AND NONTRADITIONAL MEANS OF CURING THIS DISEASE. AND I THINK THE BEST SOLUTION IS THE ONE THAT'S BEFORE US WITH DR. JEANNE LORING.

THERE'S A PARALLEL STUDY GOING ON RIGHT NOW IN JAPAN. DR. TAKAHASHI IS UNDERGOING THE SAME PROCESS THAT WE ARE WHICH HAS GIVEN MORE CREDIBILITY TO YAMANAKA'S WORK WHERE HE GOT THE NOBEL PRIZE IN 2012. AND THE SOLUTION IS WITHIN REACH. I'VE ALREADY UNDERGONE TWO SURGERIES. I WAS PART OF A GENE CELL THERAPY THROUGH UCSF IN 2005. I DO RECEIVE SOME BENEFIT FROM THAT. BUT WITH THE RELENTLESS PROGRESSION OF THE DISEASE, I'VE LOST ANY BENEFIT THAT I MAY HAVE GAINED.

I HAD DEEP BRAIN STIMULATION TWO YEARS AGO.

I GOT MIXED RESULTS FROM THAT. MY MOTOR SKILLS ARE DEPRECIATING AND DECREASING. AND THERE'S A WHEELCHAIR OUT THERE WITH MY NAME ON IT SOMEWHERE UNLESS WE FIND A SOLUTION SOON. SO TIME IS OF THE ESSENCE. WE NEED TO MOVE AND MOVE ON THIS QUICKLY. WE NEED TO DO IT WITH GOD SPEED. I FEEL THAT WHAT WORK HAS BEEN DONE PARALLELS THE MISSION STATEMENT OF CIRM VERY ACCURATELY. AND TO QUOTE THAT IS TO SUPPORT AND ADVANCE STEM CELL RESEARCH AND REGENERATIVE MEDICINE UNDER THE HIGHEST ETHICAL AND MEDICAL STANDARDS FOR THE DISCOVERY AND DEVELOPMENT OF CURES, THERAPIES, DIAGNOSTICS, AND RESEARCH TECHNOLOGIES TO RELIEVE HUMAN SUFFERING FROM CHRONIC DISEASE AND INJURY.

THIS PROGRAM EXEMPLIFIES THAT MISSION STATEMENT AND SHOULD BE AWARDED THE OPPORTUNITY TO PROCEED. THANK YOU FOR YOUR TIME AND MAY GOD SPEED GET US A SOLUTION SOON. THANK YOU.

I'D ALSO LIKE TO INTRODUCE ALAN TRUITT.

MR. TRUITT: GOOD MORNING. I WAS DIAGNOSED WITH PARKINSON'S DISEASE FOUR AND A HALF YEARS AGO. UPON LEARNING I HAD THE DISEASE, I DID A GREAT DEAL OF RESEARCH. AND TWO THINGS STRUCK ME MOST ABOUT PARKINSON'S DISEASE. NO. 1, IT WAS INCURABLE. NO. 2, I WOULD GET WORSE. IT WAS VERY, VERY DISCOURAGING.

I LEARNED OF THE PROPOSED RESEARCH BY THE

SCRIPPS RESEARCH INSTITUTE THAT HAVE USED THE SKIN CELLS OF PARKINSON'S PATIENTS AND DEVELOPED THEM INTO INDUCED PLURIPOTENT STEM CELLS. THESE CELLS WOULD BECOME DOPAMINE NEURONS AND IMPLANTED INTO THE PATIENT'S BRAIN TO REPLACE THE NEURONS DESTROYED BY THE DISEASE. AT LAST THERE IS HOPE.

WHEN I WAS ASKED TO BECOME ONE OF THE PILOT PROJECT PATIENTS, I WAS DETERMINED TO DO EVERYTHING POSSIBLE TO MAKE THIS CONCEPT A REALITY. A WORKING GROUP SET UP FOR STEM CELL THAT'S FORMED TO SUPPORT THIS RESEARCH. AND FUND-RAISING FOR THE PROJECT HAS BEEN DONE BY PATIENTS, THEIR FAMILIES AND FRIENDS STANDING ALONGSIDE CLINICAL AND LAB PERSONNEL.

MYSELF AND OTHERS DETERMINED TO RAISE FUNDS AND AWARENESS FOR THIS PROJECT CLIMBED TO MT. EVEREST BASE CAMP AND MOUNT KILIMANJARO. THIS RESEARCH HOLDS GREAT PROMISE.

MY DISEASE IS PROGRESSING. I'M CURRENTLY ON MY SECOND TYPE OF MEDICATION. WHEN IT BECOMES INEFFECTIVE, I WILL MOVE ON TO THE THIRD LEVEL. THE LIKELY SIDE EFFECTS OF THAT WILL BE UNCONTROLLED MOVEMENT AND POSSIBLY SOME BEHAVIORAL ISSUES, AND MY DISEASE WILL STILL CONTINUE TO PROGRESS.

OTHER TREATMENT MODALITIES ARE DESPERATELY NEEDED. I URGE THE MEMBERS OF CIRM TO AWARD FUNDS FOR

THIS TRULY GRASS ROOTS PROJECT TO ALLOW IT TO PROCEED TO A PRE-IND MEETING. THANK YOU.

MR. REED: DON REED. IN THE PATIENT ADVOCACY COMMUNITY, WE HAVE A SAYING. IF YOU WANT TO GET SOMETHING DONE, HIRE A PARKINSON'S PERSON. THEY HAVE THE FIRE. THEY WILL ALWAYS FIGHT. I RESPECT THAT SO MUCH.

I KNOW JEFF SHEEHY FEELS EXACTLY THE SAME WAY. HE'LL GIVE EVERY FIBER OF HIS BEING TO EVERY INCH OF THE FIGHT, BUT THIS IS A TACTICAL DECISION.

MR. SHEEHY: COULD I ASK A QUICK QUESTION OF JEANNE BECAUSE I JUST WANT TRANSPARENCY HERE? ARE YOU ELIGIBLE FOR EARLY TRANSLATION BECAUSE YOU DON'T HAVE AN EXISTING GRANT IN THE TRANSLATIONAL PORTFOLIO? AND UNLESS YOU HAVE EXTERNAL FUNDING, YOU'RE NOT GOING TO BE ABLE TO APPLY FOR EARLY TRANSLATION.

DR. LORING: SO MY UNDERSTANDING WAS THAT THE NEW APPLICATION, THE PROPOSAL FOR PRECLINICAL, IT WOULD BE GOOD TO HAVE AN EARLY TRANSLATION GRANT, BUT IT WASN'T REQUIRED.

MR. SHEEHY: IT REQUIRES. YOU MUST HAVE A PRIOR CIRM-FUNDED TRANSLATIONAL RESEARCH OR EXTERNAL FUNDED RESEARCH PARTNERED WITH A LARGE BIOPHARMA COMPANY.

DR. LORING: WE CAN HANDLE THAT.

MR. SHEEHY: BY AUGUST?

DR. LORING: OF COURSE.

DR. OLSON: I ALSO WANTED TO REMIND THE BOARD THAT OUR RFA'S TYPICALLY INCLUDE A PROVISION WHERE A PRESIDENTIAL EXCEPTION PROVISION WHERE THE PRESIDENT, BASED ON GOOD STRATEGIC REASONS OR SUCH, ALWAYS HAS THE RIGHT TO WAIVE ELIGIBILITY CRITERIA.

MR. REED: NOW, THIS IS A TACTICAL DECISION. WITH ALL MY HEART I WANT THERE TO BE A PART 2 OF PROP 71. I WANT THIS BOARD TO BE HERE FOR BASICALLY ETERNITY UNTIL CURES COME. AND THAT MEANS EVERY DAY I WAKE UP, HOW CAN I MAKE 2016 BE SUCCESSFUL. THE DECISION HAS NOT BEEN MADE YET. I'M NOT IMPLYING THAT IT HAS BEEN, BUT I WANT IT SO BAD. AND THIS IS CRUCIAL. THIS RIGHT HERE IS BRINGING TOGETHER OF ALL THE WORK THAT'S BEEN DONE SO FAR.

WHEN THEY FIRST CAME UP WITH THE STRATEGIC PLAN, THEY TALKED ABOUT MAYBE THEY'D HAVE ONE PROJECT IN A PHASE I TRIAL. NOW WE'RE TALKING ABOUT PHASE II TRIALS. PHASE II, PEOPLE CAN UNDERSTAND THAT BECAUSE THERE'S PEOPLE INVOLVED. PEOPLE ACTUALLY GETTING WELL. THERE'S EFFICACY INVOLVED, NOT JUST SAFETY, BUT EFFICACY. THAT'S A HUGE DIFFERENCE. THAT'S SOMETHING THE PUBLIC UNDERSTANDS.

I URGE YOU TO DO THIS NOW. DON'T WAIT. WE

DO NOT HAVE THE TIME. WE MUST ALLOW FOR DELAYS AMONG EVERYTHING. DO IT NOW. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, EVERYBODY. IS THERE ANY OTHER PUBLIC COMMENT? HEARING NONE, SO LET'S SEE. MR. HARRISON, COULD YOU RESTATE WHERE WE ARE AT THE MOMENT AND THE ORDER OF THINGS WE NEED TO BE VOTING ON HERE?

MR. HARRISON: THE MOTION THAT'S CURRENTLY ON THE TABLE AS AMENDED IS TO DELAY CONSIDERATION OF THE STRATEGIC PARTNERSHIP IV CONCEPT PLAN UNTIL THE MAY 29, 2014, BOARD MEETING. SO YOU'LL TAKE UP THAT MOTION FIRST. AND DEPENDING UPON THE OUTCOME OF THAT MOTION, WE'LL CONSIDER WHETHER ADDITIONAL MOTIONS ARE NECESSARY.

CHAIRMAN THOMAS: OKAY. THANK YOU VERY MUCH. THIS REQUIRES A ROLL CALL VOTE? MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: NO.

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: NO.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: I VOTE NO.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: NO.

MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: NO.
MS. BONNEVILLE: MICHAEL FRIEDMAN.
DR. FRIEDMAN: NO.
MS. BONNEVILLE: JUDY GASSON.
MR. GASSON: NO.
MS. BONNEVILLE: SAM HAWGOOD. STEPHEN JUELSGAARD. SHERRY LANSING. JACOB LEVIN.
DR. LEVIN: NO.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: NO.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: NO.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: NO.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
DR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: NO.
MS. BONNEVILLE: SHERRY, ARE YOU ON THE PHONE? I DIDN'T GET A VOTE FOR YOU.
MR. HARRISON: THAT MOTION FAILS BY A VOTE OF 7 YES VOTES TO 12 NO VOTES.
CHAIRMAN THOMAS: THANK YOU. MR. HARRISON, NOW COULD YOU STATE WHERE WE ARE AND WHICH MOTION WE ARE VOTING ON AT THIS POINT?
MR. HARRISON: AT THIS POINT IN TIME, IT WOULD BE APPROPRIATE FOR THE BOARD TO CONSIDER A MOTION TO APPROVE THE CONCEPT PLAN FOR STRATEGIC PARTNERSHIP IV.
DR. DULIEGE: DO WE NEED TO MAKE THAT MOTION? I'M HAPPY TO MAKE THAT MOTION, THAT WE CONSIDER APPROVING THE CONCEPT OF THE RFA.
DR. BOXER: I'LL SECOND IT.
CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. DO WE NEED FURTHER DISCUSSION AT THIS POINT, MR. HARRISON?
MR. HARRISON: NO. THOUGH YOU MAY WANT TO

SEE IF THERE'S ANY ADDITIONAL PUBLIC COMMENT.

CHAIRMAN THOMAS: LET'S JUST ASK. ANY MORE COMMENT BY MEMBERS OF THE BOARD FIRST? NO. PUBLIC COMMENT ON THIS? ANY COMMENT BY MEMBERS OF THE BOARD ON THE PHONE? WE KIND OF DISCUSSED THIS, I THINK, AT LENGTH. MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: ELIZABETH FINI.

DR. FINI: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN.

DR. FRIEDMAN: YES.

MS. BONNEVILLE: JUDY GASSON.

MR. GASSON: YES.

MS. BONNEVILLE: SAM HAWGOOD. STEPHEN JUELSGAARD. SHERRY LANSING. JACOB LEVIN.

DR. LEVIN: YES.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: ABSTAIN.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: NO.
MS. BONNEVILLE: AL ROWLETT.
DR. ROWLETT: NO.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: NO.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: ABSTAIN.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MR. HARRISON: THAT MOTION PASSES WITH 14 YES VOTES, THREE NO VOTES, AND TWO ABSTENTIONS.
CHAIRMAN THOMAS: YES. COULD WE -- BETH NEEDS A BREAK, SO CAN WE TAKE A FIVE-MINUTE BREAK HERE, PLEASE.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: OKAY. EVERYBODY PLEASE TAKE YOUR SEATS. OKAY. WE'RE GOING TO PROCEED NOW TO ITEM NO. 7 ON THE AGENDA, CONSIDERATION OF CONCEPT PLAN FOR PRECLINICAL DEVELOPMENT AWARDS. DR. KADYK.

DR. KADYK: THANK YOU, MR. CHAIRMAN, MEMBERS OF THE BOARD, AND MEMBERS OF THE PUBLIC. IN THE INTEREST OF CAPITALIZING ON THE MOMENTUM WE HAVE DEVELOPED IN THE CIRM PORTFOLIO AND AT THIS MEETING TODAY, I WANT TO PRESENT TO YOU A CONCEPT PLAN FOR A NEW INITIATIVE, THE PRECLINICAL DEVELOPMENT AWARDS.

AND THE MAIN GOAL OF THIS PARTICULAR INITIATIVE IS TO ADVANCE PROJECTS THAT HAVE ALREADY BEEN FUNDED WITHIN CIRM'S TRANSLATIONAL PIPELINE FURTHER TOWARDS THE CLINIC. WE HAVE FUNDED A LARGE NUMBER OF PROJECTS AT THIS POINT IN THE EARLIER STAGES OF PRECLINICAL RESEARCH THAT YOU SEE ON OUR ARROW DIAGRAM HERE, MOST NOTABLY THROUGH THE EARLY TRANSLATION RESEARCH RFA'S. AND THE MOST SUCCESSFUL OF THOSE PROGRAMS CULMINATE IN THE IDENTIFICATION OF A DEVELOPMENT CANDIDATE OR A DC THAT YOU WILL SEE IN AN ARROW ON THAT DIAGRAM. THAT IS TRADITIONALLY THE DEMARCATION BETWEEN THE END OF PRECLINICAL RESEARCH AND THE INITIATION OF THE MORE COSTLY AND MORE HIGHLY REGULATED DEVELOPMENT STAGE OF DEVELOPMENT OF A

THERAPEUTIC.

AND YOU WILL SEE FROM THE DIAGRAM HERE THAT OUR CURRENT DISEASE TEAM AWARDS REQUIRE FOR ELIGIBILITY TO ENTER THOSE AWARDS IS TO HAVE A PRE-IND MEETING ALREADY. SO WE ACTUALLY HAVE A LITTLE GAP IN OUR FUNDING MECHANISMS HERE BETWEEN THE INITIATION OF EARLY PRECLINICAL DEVELOPMENT AND THE ACTIVITIES NEEDED TO COMPLETE A PRE-IND MEETING. AND SO THE FOCUS OF THIS PARTICULAR RFA WOULD BE QUITE NARROWLY FOCUSED ON THOSE ACTIVITIES NEEDED TO HAVE A WELL-PREPARED PRE-IND MEETING.

THIS AWARD SHOULD POSITION PROJECTS TO BE MUCH MORE COMPETITIVE FOR FUNDING EITHER FUTURE FROM CIRM, IF POSSIBLE, OR OTHER FUNDING AGENCIES OR TO ATTRACT PARTNERSHIPS.

ALTHOUGH THE MAIN FOCUS HERE IS ON EXISTING PROJECTS WITHIN THE PIPELINE, WE DID ALSO ALLOW FOR APPLICANTS TO COME IN WITH DEVELOPMENT CANDIDATES THAT HAD BEEN FUNDED EXTERNALLY TO DATE, BUT WHICH HAD BEEN FUNDED BY LARGE PHARMA. AND I'LL HAVE A SLIDE ON THAT COMING UP. THAT'S JUST TO SAY THAT THIS PROPOSAL, WE FEEL, IS QUITE WELL ALIGNED WITH THE FOCUS OF CIRM'S 2012 STRATEGIC PLAN, TO ADVANCE THE STEM CELL SCIENCE FURTHER TOWARD CLINICAL TRIALS AS WELL AS TO LEVERAGE CIRM'S INVESTMENT THROUGH PARTNERSHIP WITH INDUSTRY.

SO THE OBJECTIVE OF THIS AWARD WOULD BE TO END BY HAVING A WELL-PREPARED PRE-IND MEETING WITH THE FDA WITHIN TWO AND A HALF YEARS. WE THINK SOME OF THEM MAY ADVANCE EVEN MORE QUICKLY THAN THAT. AND THE RATIONALE IS THAT WE WOULD BE ABLE TO ADVANCE OUR EXISTING PROJECTS FURTHER IN THE PIPELINE WITH A RELATIVELY LIMITED INVESTMENT IN THAT EARLY STAGE OF DEVELOPMENT WORK WHICH WOULD CULMINATE IN AN FDA MEETING WHICH WOULD GIVE US, THE TEAM, AND FUTURE FUNDERS CRITICAL FDA INPUT ON THE PROJECT BEFORE SOME FURTHER EVEN MORE COSTLY INVESTMENT. AND THIS WOULD ALSO POSITION THE PROJECTS TO HAVE PERHAPS MORE INTEREST FROM EXTERNAL PARTNERS BECAUSE THEY'D BE MORE WELL VALIDATED AND MORE ADVANCED.

SO TO BE ELIGIBLE FOR THESE AWARDS, THE APPLICANT COULD BE POTENTIALLY A FOR-PROFIT OR NOT-FOR-PROFIT, BUT THE DEVELOPMENT CANDIDATE IN PARTICULAR SHOULD HAVE EITHER COME FROM A PRIOR CIRM-FUNDED TRANSLATIONAL RESEARCH, AND I SHOULD SAY THAT'S NOT NECESSARILY LIMITED ONLY TO THE EARLY TRANSLATION RESEARCH AWARDS, THAT COULD COME FROM OTHER AWARDS WITHIN THE CIRM PIPELINE THAT HAVE MET SIMILAR REQUIREMENTS, OR FROM EXTERNALLY FUNDED RESEARCH IF PARTNERED WITH A LARGE BIOPHARMA COMPANY. WE'RE PROBABLY GOING TO REQUIRE THAT THEY BE ON THE ORDER OF

A $1 BILLION MARKET CAP IN ORDER TO GIVE SOME ASSURANCE THAT IF WE FUND SUCH PROGRAMS, THERE WOULD BE REASONABLE LIKELIHOOD THAT THEY COULD BE CONTINUED SHOULD THEY BE SUCCESSFUL.

SO JUST TO GIVE YOU AN IDEA OF THE RANGE OF APPLICANTS WHO WE THINK WOULD APPLY FOR THIS TYPE OF AWARD, MAINLY WE THINK IT WOULD BE A SUBSET OF THE EARLY TRANSLATIONAL RESEARCH AWARD PROJECTS THAT HAVE ALREADY BEEN FUNDED. TO DATE THERE HAVE BEEN 63 OF THESE PROJECTS FUNDED IN FOUR DIFFERENT CALLS SINCE 2009 IN 15 THERAPEUTIC AREAS. I MADE THIS LITTLE BAR GRAPH SO YOU CAN SEE THAT THE EARLIER CALLS -- WELL, WE PRESUME THAT THE EARLIER CALLS WOULD BE MORE LIKELY TO BE READY, PROJECTS FROM THOSE CALLS, AND SO THAT'S PROBABLY ABOUT HALF OF THE TOTAL MIGHT BE ELIGIBLE FOR THIS AWARD OR PERHAPS FEWER THAN THAT EVEN.

WE DO HAVE SOME OTHER CIRM-FUNDED PROJECTS FROM OTHER AWARD MECHANISMS THAT HAVE POTENTIALLY MET ALL THESE REQUIREMENTS TO APPLY TO THIS PARTICULAR RFA. AND THEN WE WOULD ALSO CONSIDER EXTERNAL PROJECTS, AS I MENTIONED, THAT WERE PARTNERED WITH A LARGE BIOPHARMA. BASED ON HISTORICAL EXPERIENCE, WE WOULD NOT EXPECT THAT NUMBER TO BE EXTREMELY LARGE.

SO TO BE READY AGAIN FOR THIS -- TO APPLY FOR THIS AWARD, THE PROJECT TEAM LEADERS WOULD NEED TO HAVE

IDENTIFIED A SINGLE THERAPEUTIC DEVELOPMENT CANDIDATE THAT HAS DEMONSTRATED STRONG REPRODUCIBLE EVIDENCE FOR PRECLINICAL DISEASE MODIFYING ACTIVITY AND HAS UNDERTAKEN PRELIMINARY ASSESSMENTS OF DOSE, SAFETY, AND HAS RESEARCH SCALE PRODUCTION ASSAYS IN PLACE. THESE ARE ESSENTIALLY THE REQUIREMENTS TO ACHIEVE A DEVELOPMENT CANDIDATE ACCORDING TO OUR EARLY TRANSLATIONAL RESEARCH AWARDS.

THIS JUST SHOWS YOU A LIST OF SOME OF THE ACTIVITIES THAT ARE IN AND OUT OF SCOPE. PRIMARILY WE'RE FOCUSING ON THAT VERY NARROW RANGE OF ACTIVITIES THAT WOULD BE REQUIRED PRIOR TO A PRE-IND MEETING MAINLY FOCUSED ON DEVELOPING STAGE APPROPRIATE GMP MANUFACTURING PROCESS AND THE ASSOCIATED QUALIFIED ASSAYS. BUT IT COULD INCLUDE SOME OTHER ACTIVITIES, INCLUDING MECHANISM OF ACTION STUDIES, OPTIMIZATION OF DOSE. AND, OF COURSE, WE WOULD WANT TO HAVE DEVELOPMENT OF A CLINICAL PLAN AND CULMINATE IN THE CONDUCTING OF A PRE-IND MEETING. THIS WOULD NOT FUND THE PIVOTAL IND-ENABLING SAFETY STUDIES THAT HAPPEN AFTER A PRE-IND MEETING.

SO WE ARE SUGGESTING TOTAL PROGRAM COSTS OF UP TO $40 MILLION WITH EACH AWARD BEING ALLOWED UP TO 5 TO $8 MILLION PER PROJECT, WITH MAYBE EXCEPTIONAL CIRCUMSTANCES COULD GO UP TO 10 MILLION. AND THE AWARD

TERM COULD BE UP TO TWO AND A HALF YEARS. AND THE AWARD MECHANISM WOULD BE EITHER A GRANT FOR A NONPROFIT OR A GRANT OR LOAN FOR A FOR-PROFIT APPLICANT ORGANIZATION.

THIS IS THE ANTICIPATED TIMELINE OF THIS AWARD SHOULD IT BE APPROVED. WE ARE, IN THE INTERESTS OF REALLY KEEPING THE MOMENTUM GOING FOR OUR PROJECTS, HOPING TO POST THIS RFA ACTUALLY AT THE END OF NEXT MONTH, THE FULL APPLICATIONS DUE IN AUGUST, REVIEW AT THE END OF THE YEAR, AND BEGIN FUNDING SOMETIME IN THE SECOND QUARTER OF 2015.

SO, AGAIN, THE BOTTOM LINE IS THAT I'M REQUESTING APPROVAL FOR THIS CONCEPT PLAN IN THE AMOUNT OF $40 MILLION. AND WONDER IF YOU HAVE ANY QUESTIONS.

MS. LANSING: I'M A LITTLE CONFUSED BECAUSE I COULD HEAR YOU, BUT THEN I LOST YOU. I JUST WANT TO MAKE SURE WHERE WE ARE. IS THIS NOW THE OFFICIAL VOTE FOR MOVING FORWARD, OR DID I MISS THAT VOTE?

DR. KADYK: WE'RE NOW ENTERTAINING THE PRECLINICAL DEVELOPMENT AWARD CONCEPT.

CHAIRMAN THOMAS: SHERRY, THIS IS THE NEXT ITEM. WE HAD THE VOTE ON THE PREVIOUS ITEM WHICH ULTIMATELY ENDED UP APPROVING IT FOR GOING FORWARD.

MS. LANSING: LET ME JUST FOR THE RECORD PLEASE SAY THAT I VOTED NO ON DELAYING IT, AND I VOTED

YES ON MOVING FORWARD. AND NOW I'M READY TO LISTEN TO THE NEXT THING, BUT I WANT BOTH OF MY VOTES RECORDED.

CHAIRMAN THOMAS: THANK YOU, SHERRY. SO QUESTIONS? I WANT THE BOARD TO UNDERSTAND THAT WE HAVE A GAP IN OUR FUNDING WHICH SORT OF STARTS WHERE EARLY TRANSLATION ENDS AND GOES TO THE AWARDS AND THE DISEASE TEAMS THAT AIM TO BE INTO THE CLINIC. AND SPECIFIC PURPOSE OF THIS IS TO FILL THAT GAP WHICH WE'VE NOT DONE TO DATE. SO THIS IS THE FIRST OF ITS KIND, DR. KADYK, CORRECT?

DR. KADYK: THAT'S RIGHT.

CHAIRMAN THOMAS: BUT I THINK IS SOMETHING THAT CLEARLY, IF YOU ARE VIEWING THE CONTINUUM HERE OF WHAT NEEDS TO BE ADDRESSED, THIS GAP DEFINITELY NEEDS TO BE ATTENDED TO, WHICH IS THE PURPOSE OF THIS RFA.

MR. SHEEHY: JUST ONE POINT OF CLARIFICATION. SO IF YOU HAVE NOT BEEN PREVIOUSLY FUNDED AS A PROJECT BY CIRM, YOU'RE NOT ELIGIBLE, RIGHT?

DR. KADYK: UNLESS YOU ARE ABLE TO DEMONSTRATE A PARTNERSHIP WITH A LARGE BIOPHARMA.

MR. SHEEHY: SO YOU HAVE TO HAVE A LARGE BIOPHARMA PARTNER IN ORDER TO BE ELIGIBLE FOR THIS?

DR. KADYK: THAT'S RIGHT.

MR. SHEEHY: OR YOU HAVE TO BE FUNDED BEFORE.

DR. KADYK: YES.

MR. ROWLETT: JUST A POINT OF CLARIFICATION. THE PRESIDENTIAL EXCEPTION MENTIONED IN THE LAST DISCUSSION, IS THAT APPLICABLE HERE AS WELL?

DR. KADYK: YES, THAT WOULD BE APPLICABLE.

DR. STEWARD: COULD YOU EXPLAIN THE RATIONALE FOR THAT LIMITATION?

DR. KADYK: RATIONALE FOR WHAT?

DR. STEWARD: THE LIMITATION OF PRIOR FUNDING BY CIRM IS REQUIRED.

DR. KADYK: WE'RE MAINLY FOCUSED ON TRYING TO ADVANCE OUR EXISTING PORTFOLIO RATHER THAN EXPAND IT. IF WE WERE TO OPEN IT UP TO ALL COMERS OUTSIDE OF THE EXISTING CIRM-FUNDED PROJECTS, THAT WOULD LIKELY -- WELL, FIRST OF ALL, IT WOULD DELAY THE AWARD BECAUSE WHEN YOU HAVE LARGE NUMBERS OF APPLICANTS, YOU WOULD HAVE TO GO THROUGH A PREAPPLICATION PROCESS BEFORE WE HAVE THE FINAL GRANTS WORKING GROUP. WE CAN'T REVIEW THAT MANY APPLICATIONS EARLY ON.

AND THIS IS REALLY UNDERTAKEN IN THE SPIRIT OF ADVANCING THE EXISTING PORTFOLIO RATHER THAN EXPANDING IT. WE KNOW THAT CIRM'S PIPELINE IS ALREADY PRETTY BROAD AND HAS A LOT THAT LOOKS PROMISING, AND WE WANT TO MOVE IT FORWARD.

DR. STEWARD: SO COULD I MAKE A COMMENT?

CHAIRMAN THOMAS: CERTAINLY.

DR. STEWARD: THIS IS MY SORT OF USUAL BROKEN RECORD. I ALWAYS WORRY ABOUT LIMITING THINGS AND MISSING SOMETHING OUT THERE THAT COULD BE REALLY SPECTACULAR. THERE VERY WELL COULD BE THINGS OUT THERE THAT ARE IN EXACTLY THIS SPACE THAT MAY NOT HAVE BEEN FUNDED BY CIRM. SO WHY WOULDN'T WE WANT TO SUPPORT THAT?

DR. KADYK: WELL, SO THAT'S, I THINK, WHERE IF IT'S REALLY THAT OUTSTANDING, THE PRESIDENTIAL EXCEPTION CLAUSE COULD COME INTO PLAY. IF THERE'S SOMETHING -- I THINK CIRM HAS MADE A DEDICATED EFFORT TO FIND PROJECTS THAT ARE -- AND TO DEVELOP PROJECTS THAT ARE AROUND THIS STAGE, AND WE DON'T EXPECT THAT THERE ARE THAT MANY OTHERS OUT THERE.

DR. STEWARD: I AGREE. SO WHY THE LIMITATION? IF YOU DON'T EXPECT THERE TO BE THAT MANY, WHY WOULD WE WANT TO CLOSE THE DOOR?

DR. KADYK: WE REALLY DO WANT TO FOCUS ON THE EXISTING PIPELINE. CIRM'S FUNDING HAS GOT A LIMITED TIME SPAN, A LIMITED AMOUNT. I THINK THE INITIAL THOUGHT HAD BEEN NOT TO EXPAND UNLESS THERE'S SOMETHING TRULY EXCEPTIONAL.

DR. FEIGAL: I THINK WHAT WE WERE TRYING TO DO WITH THIS IS, ONE, ADVANCE THE PIPELINE, BUT, TWO, DO HAVE A TRACK. PART OF THE THOUGHT, IF IT'S REALLY

THAT EXCEPTIONAL, THERE MIGHT BE A POSSIBILITY THAT THEY MIGHT BE ABLE TO GET SOME LEVERAGED FUNDING. AND THAT WOULD BE, SAY, A MARKER OF THEIR EXCEPTIONAL ABILITY. SO THAT AT LEAST WAS THE RATIONALE IN THINKING OF HAVING THIS ADDITIONAL OPENING, A POROUS WINDOW, SO TO SPEAK, FOR THOSE EXTERNAL OPPORTUNITIES.

SO IT'S NOT JUST A PRESIDENTIAL EXCEPTION, BUT THERE ALSO IS A TRACK FOR THOSE EXTERNAL ONES THAT LOOK PARTICULARLY PROMISING. WE THOUGHT THEY PROBABLY MIGHT HAVE OR ATTRACT A LOT OF INTEREST AND BE ABLE TO COME IN NORMALLY THROUGH THAT PATHWAY WITHOUT REQUIRING AN EXCEPTION.

I DON'T KNOW IF DR. OLSON WANTS TO MAKE ANY ADDITIONAL COMMENTS, BUT THAT IS THE RATIONALE.

DR. STEWARD: OKAY. JUST LET ME SAY JUST TO GO ON RECORD AS SAYING THAT I THINK IT'S EXTREMELY IMPORTANT NOT TO SHUT OUT SOME OF THESE POTENTIAL PROGRAMS AND TO MAKE THAT GATE AS POROUS AS APPROPRIATE FOR REALLY PROMISING PROJECTS THAT ARE OUT THERE. I DON'T KNOW EXACTLY HOW TO FRAME IT, BUT I AM CONCERNED THAT IF YOU HAVE ALL THESE LIMITATIONS, THEN YOU MIGHT PREVENT SOME OF THESE PROJECTS FROM EVEN APPLYING OR TALKING TO THE PRESIDENT OR ANYTHING ELSE. CIRM DOESN'T NECESSARILY KNOW EVERYTHING THAT'S OUT THERE.

DR. TROUNSON: THANKS. I WOULD AGREE WITH

THAT. BUT THE THINKING HERE IN SAYING WE'VE GOT QUITE A LOT OF PROJECTS IN THIS EARLY PHASE, AND WE WERE LOOKING FOR THE EXCEPTIONAL ONES AMONG THEM. THEY'VE GOT A WAY TO GROW, AND WE ARE CONCERNED ABOUT ADDING A LOT INTO THAT. AND IF THEY DID COME IN, THE REASON TO HAVE SUPPORT OF AN EXTERNAL PARTNER WOULD BE THEY'RE MORE LIKELY TO SURVIVE, OS. THE PROBLEM OF PUTTING THEM IN AND IF WE DON'T GET THE MONEY, NOT HAVING THEM SURVIVE WAS SOMETHING THAT WE WERE DEBATING OURSELVES.

SO WE'RE TRYING TO HELP THOSE ONES IN THE EARLY PIPELINE AND ALSO THOSE ONES THAT WOULD HAVE MAYBE THE STRENGTH TO CONTINUE IN THE SITUATION WHERE WE'RE UNSURE ABOUT WHETHER WE'RE GOING TO GET THAT ADDITIONAL FUNDING RATHER THAN ADDING MORE TO THE PIPELINE THAT MIGHT DIE. YOU KNOW WHAT I MEAN? SO THAT WAS SORT OF THE ACUTE REASONING. LET'S GET THE BEST ONES AND TAKE THEM FORWARD, BUT NOT TRY AND EXPAND THAT UNTIL WE KNEW THERE WAS ADDITIONAL FUNDING AVAILABLE FOR IT.

MR. SHEEHY: SO HOW DO YOU DEFINE LARGE?

DR. KADYK: WE WERE TALKING WITH ELONA ABOUT $1 BILLION MARKET CAP.

MR. SHEEHY: JUST SO THESE FOLKS OUT HERE WHO ARE THINKING THAT THIS MIGHT -- I DON'T KNOW IF JEANNE HAS AN ARRANGEMENT READY BY AUGUST WITH A LARGE PHARMA

WITH A BILLION CAP. I HOPE SO. I JUST WANT TO BE -- I FEEL TERRIBLE. I DON'T THINK WE'VE DONE ENOUGH FOR FOLKS WITH PARKINSON'S, BUT I GUESS -- MAYBE YOU GUYS HAVE A PARTNER LINED UP, I HOPE.

DR. BRATT-LEAL: I JUST WANT TO SAY THAT I THINK THAT LIMITING BY PUTTING A MARKET CAP NUMBER IS UNNECESSARILY LIMITING ON THESE APPLICATIONS BECAUSE IF YOU CAN SAY IF YOU CAN HAVE AN INDUSTRY PARTNER THAT CAN HELP YOU OR A HOSPITAL THAT CAN HELP DISTRIBUTE A THERAPY OR IF YOU HAVE SOMEONE THAT MAKE THE CELLS FOR YOU. AND I THINK BY PUTTING A BIG PHARMA ON, YOU'RE BIASING IT TOWARDS ANTIBODY THERAPIES OR OTHER THERAPIES THAT HAVE GONE THROUGH AND NOT FOR ACTUALLY STEM CELL-DERIVED THERAPIES.

YOU'RE ALSO PUTTING AN INCENTIVIZE TO PROFIT. BUT IF YOU HAVE SOMEBODY THAT WANTS TO DO IT TO DISTRIBUTE IT AS A HOSPITAL OR THERAPY WHERE YOU DON'T HAVE AN INCENTIVE FOR PROFIT, THEN I THINK YOU'RE KIND OF LIMITING THOSE OTHER APPLICATIONS. BY PUTTING A MARKET CAP LIMITATION ON YOUR INDUSTRY PARTNER, INSTEAD OF SAYING MAKE SURE THE INDUSTRY PARTNERS ARE CAPABLE OF HELPING YOU DISTRIBUTE THIS TO A LARGE NUMBER OF PEOPLE IN CALIFORNIA, I THINK IT'S REALLY UNNECESSARY TO DO THAT.

DR. FEIGAL: WELL, MAYBE IT DOESN'T NEED TO

BE SAID AGAIN, BUT AS I SAID, WE CAN DO EXCEPTIONAL CIRCUMSTANCES, MAKE THOSE EXCEPTIONS. BUT THE ITERATION IS REALLY BECAUSE RIGHT NOW WE DON'T HAVE A NEW FLUSH OF FUNDS COMING IN. WE WERE TRYING TO MAKE SURE THAT IF WE BRING SOME NEW ONES IN, THERE'S ACTUALLY AN OPPORTUNITY FOR THEM TO BE SUSTAINABLE BECAUSE WHAT WE'RE TRYING TO DO AS MUCH AS POSSIBLE IS ADVANCE THEM TO A STAGE WHERE THEY'LL BE ATTRACTIVE. THAT IS THE RATIONALE. WE'LL TAKE THIS INTO ADVISEMENT HOWEVER YOU WANT TO CLARIFY IT.

DR. STEWARD: I THINK THAT SOME FUNDING PARTNERSHIP OTHER THAN CIRM IS WHAT -- IT COULD BE THE NIH, IT COULD BE ANYTHING, BUT LIMITING IT TO PREVIOUSLY FUNDED CIRM APPLICATIONS JUST DOESN'T SEEM LIKE A REASONABLE STRATEGY.

CHAIRMAN THOMAS: OTHER COMMENTS BY MEMBERS OF THE BOARD? COMMENTS BY ANYONE ON THE PHONE? FURTHER PUBLIC COMMENT?

MR. REDONSKY: HELLO. THANK YOU FOR INVITING US HERE AND ALLOWING US TO SPEAK. MY NAME IS MICHAEL REDONSKY, AND I'M -- I WANT TO THANK DR. STEWARD FOR STANDING UP FOR THE POSSIBILITY OF OUR PROGRAM BEING FUNDED. SAYING THAT THE GATE SHOULD BE AS POROUS AS POSSIBLE, I THINK, IS A GOOD IDEA AS LONG AS THERE'S A GOOD GATEKEEPER TO WATCH THE POROSITY.

I'M AN EXTREMELY FORTUNATE PERSON. I'VE BEEN BLESSED WITH GOOD FORTUNE. I HAVE TWO LOVING CHILDREN AND A BEAUTIFUL WIFE. I LIVE IN SAN DIEGO WHERE IT'S INCREDIBLY BEAUTIFUL, AND I HAVE A STIMULATING CAREER WHERE I GO IN THE CIRCLE OF NOBEL LAUREATES IN PHYSICS. IT'S REALLY QUITE WONDERFUL. HOW COULD I BE LUCKIER? I'D LIKE TO TELL YOU HOW I COULD BE LUCKIER.

THREE YEARS AGO WHEN I WAS 50, MY NEUROLOGIST, DR. MELISSA HOUSER, CLINICAL DIRECTOR OF THE PARKINSON'S DISEASE AND MOVEMENT DISORDER CENTER AT SCRIPPS CLINIC, CONFIRMED TO BE TRUE WHAT I HAD ALREADY COME TO UNDERSTAND, THAT I HAD PARKINSON'S DISEASE. YOU CAN BET I DIDN'T FEEL SO LUCKY THAT DAY. WASN'T SO GREAT. BUT AS I BECAME MORE ACCUSTOMED WITH MY WIFE VISITING CLINICS MORE OFTEN THAN ANYONE PAYING TO DO WOULD LIKE TO THINK ABOUT.

DR. HOUSER'S NURSE PRACTITIONER, SHERRIE GOULD, BROACHED THE STUDY OF PARTICIPATING IN A STUDY WHERE MY OWN SKIN CELLS WOULD BE TRANSFORMED INTO DOPAMINERGIC NEURONS AND HELP ALLEVIATE MY PARKINSON'S SYNDROME AFTER TRAVERSING THE LAND OF HOPE IN REGENERATIVE MEDICINE PLURIPOTENT STEM CELLS. YES, THIS PROGRAM WOULD BE EXPERIMENTAL AND, YES, IT WOULD INCLUDE A BRAIN SURGERY, AND, YES, IT COULD NOT TURN OUT SO WELL. BUT, YES, IT MIGHT RESTORE MY

DOPAMINERGIC LEVELS TO SOMETHING LIKE NORMAL. YES, I MIGHT AVOID ELECTRODES PLANTED IN MY BRAIN. YES, I MIGHT STOP SHUFFLING, SHAKING, AND CARRYING MY LEFT ARM UP AT MY WAIST. AND, YES, IT MIGHT SLOW, HALT, OR EVEN REVERSE THE SHUFFLE TOWARDS INCAPACITY, DEPENDENCE, AND WORSE.

SO I REACHED FOR THE BRASS RING AS THE CAROUSEL ROLLED BY AND VOLUNTEERED WITH SEVEN OTHER AMAZING PEOPLE FOR THIS PROGRAM THAT DR. HOUSER ALONG WITH DR. JEANNE LORING AND ANDRES BRATT-LEAL AND SHERRIE GOULD ARE DRIVING. THIS PROJECT HAS PROMISE WITH A HIGH PROBABILITY OF SUCCESS TO HELP PAVE THE WAY TO A CLINICAL APPLICATION OF INDUCED PLURIPOTENT STEM CELL-BASED THERAPIES, NOT JUST FOR ME OR OTHER PEOPLE WITH PARKINSON'S DISEASE, BUT FOR MANY PEOPLE WITH AN ARRAY OF NEUROLOGICAL DISORDERS AND INJURIES.

AS THE ANIMAL TRIALS FOR OUR PROJECT BEGIN TO SHOW POSITIVE RESULTS, THE EIGHT HUMAN SUBJECTS ARE ALL IN A STATE OF UNBELIEVABLE HOPE, HOPE FOR RELIEF, HOPE FOR ALL PEOPLE WITH PARKINSON'S, HOPE FOR THE FUTURE OF REGENERATIVE MEDICINE, AND HOPE THAT WE WILL CONTRIBUTE IN A SMALL WAY TO SOMETHING REALLY BIG. NOW YOU SEE WHY I FEEL LUCKY.

BUT TO CONTINUE MY LUCKY STREAK, WE NEED TO ASK CIRM FOR SOME HELP FUNDING THIS PROJECT. SO PLEASE

HELP ME GRAB THAT BRASS RING AS IT GOES BY ME ONCE MORE.

MR. SHEEHY: SO I WONDER IF I COULD AMEND -- IF THERE'S A POSSIBILITY FOR A FRIENDLY AMENDMENT. COULD I ASK --

MR. HARRISON: THERE'S NO MOTION ON THE TABLE.

MR. SHEEHY: BUT I HAD ONE QUESTION. SORRY. I DON'T KNOW YOUR NAME. IT'S GOT TO BE DOCTOR SOMETHING.

DR. BRATT-LEAL: DR. BRATT-LEAL.

MR. SHEEHY: SO YOU GUYS HAVE FUNDED THIS PRIVATELY, SO WHAT DO YOU HAVE, AN ADVOCACY GROUP PARTNER?

DR. BRATT-LEAL: YES. SUMMIT FOR STEM CELL HAS RAISED OVER $700,000 JUST IN SOUTHERN CALIFORNIA. IT'S GETTING BIGGER. SO THEY RAISED THAT MONEY TO FUND THE PRECLINICAL WORK THAT WE'VE DONE SO FAR, BUT OUR PARTNERS INCLUDE THE HOSPITAL, AND WE ALSO HAD TALKS WITH OTHER PARTNERS WHEN WE SAW THE RFA FOR MAKING GMP CELLS, FOR BEING ABLE TO DISTRIBUTE THESE CELLS. I THINK IF YOU'RE PUTTING A CAP ON PHARMA, YOU'RE --

MR. SHEEHY: I WOULD LIKE TO MAKE A MOTION TO APPROVE THIS, BUT MAYBE FOLKS CAN HELP ME THINK ABOUT HOW TO FRAME THIS. I THINK DEFINITELY WE SHOULD ACCEPT

PARTNERSHIP IN DEVELOPMENT FROM ADVOCACY GROUPS. WE ALREADY HAVE THE EXAMPLE OF JDRF, WHICH IS A MAJOR PARTNER WITH VIACYTE, AND OBVIOUSLY HAS SHOWN THEIR COMMITMENT TO SEEING THAT THERAPY THROUGH. THEY PUT MORE INTO IT AT THIS POINT, I THINK, THAN WE HAVE.

IS THERE SOME WAY -- DR. FRIEDMAN, IF SOMEBODY HAS A WAY OF LANGUAGE TO SAY JUST MAYBE -- I GET STAFF'S CONCERN. WE DON'T WANT TO OPEN THE DOOR WIDE OPEN. AND THE PRESIDENTIAL EXCEPTION JUST FEELS VERY ARBITRARY TO ME. I'D RATHER FACILITATE SOMETHING THAT'S MORE OBJECTIVE.

DR. FRIEDMAN: I'D LIKE TO SPEAK IN FAVOR OF THE DIRECTION YOU'RE GOING. I REALLY LIKE WHAT OS SAID EARLIER. THERE ARE REALLY TWO ELEMENTS HERE WHERE WE WANT EXTERNAL INPUT. ONE OF THE MOST IMPORTANT TO ME IS THAT IT BE A SCIENTIFICALLY SOUND IDEA, AND WE'RE NOT THE ARBITERS OF THE ONLY GOOD SCIENTIFIC IDEAS. I THINK HAVING IT APPROVED BY US IS EXCELLENT AND THAT WOULD CERTAINLY QUALIFY. BUT I ALSO AGREE THAT HAVING IT APPROVED BY NIH, WE COULD LIST A LIMITED NUMBER THAT STAFF COULD SAY THESE ARE OTHER PEER ORGANIZATIONS THAT WITH THEIR APPROVAL, YOU HAD GOTTEN AN NIH GRANT FOR THIS OR YOU HAD GOTTEN A JDRF GRANT FOR THIS, THAT BESPEAKS A CERTAIN SCIENTIFIC CREDIBILITY WHICH WOULD LIMIT THE APPLICATIONS TO THOSE THINGS THAT SOMEBODY

ELSE HAS LOOKED AT ALREADY AND THOUGHT WAS A GOOD IDEA.

IF YOU WISH TO MAKE THAT PART OF YOUR PROPOSAL, I WOULD STRONGLY SUPPORT THAT.

THE OTHER IS THE SUSTAINABILITY. AND I'M LESS COMFORTABLE ACTUALLY BEING ABLE TO DEFINE WHAT THAT IS. I THINK ADVOCACY GROUPS ARE ENORMOUSLY IMPORTANT, BUT I THINK YOU REALLY NEED MORE THAN JUST THE DOLLARS OF THE BIOPHARMA SPONSOR. YOU NEED THE DEVELOPMENT CAPABILITIES. AND ACADEMICS ARE USUALLY NOT VERY GOOD AT DEVELOPING PRODUCTS THAT GO TO THE CLINIC. AND SO THAT WOULD BE -- I'M MORE AMBIGUOUS ABOUT THAT ONE AND WOULD WELCOME OTHER PEOPLE'S INPUT THERE, BUT I'D LOVE TO STRESS THE SCIENTIFIC PORES THAT YOU HAVE TO GO THROUGH.

MR. SHEEHY: IS THERE SOME WAY JUST TO FRAME AN AMENDMENT ALLOWING ANOTHER DOOR, IF SOMEBODY IS CREATIVE? I DON'T HAVE THE LANGUAGE BECAUSE I DON'T HAVE THE EXPERIENCE NECESSARY.

DR. STEWARD: I THINK MAYBE SOMETHING LIKE PREVIOUS OR CO-FUNDING BY ANY PEER REVIEW ORGANIZATION. SOMETHING LIKE THAT WOULD PROBABLY CAPTURE IT.

DR. OLSON: I'D LIKE TO COMMENT ON THAT. THIS IS GOING TO BE A DEVELOPMENT PROGRAM. I WOULD LIKE TO FOCUS MORE ON THE NOTION THAT MICHAEL FRIEDMAN BROUGHT UP, WHICH IS THE NOTION OF THAT IF YOU ARE

GOING TO BRING APPLICATIONS, THAT THEY HAVE IN-KIND OR DEVELOPMENT RESOURCES THAT WILL CONTRIBUTE. BECAUSE IF I SAY PRIOR FUNDING, THERE REALLY IS A BIG DIFFERENCE WHEN YOU MOVE FROM RESEARCH INTO DEVELOPMENT. AND I WANT -- I THINK I WOULD LIKE TO -- THAT'S PART OF THE REASON FOR THE PHARMA PARTNER IS THE IDEA THERE IS THEY'RE BRINGING EXPERTISE AND KNOW-HOW AS WELL AS PERHAPS CASH RESOURCES TO A PROJECT. AND SO THAT'S WHAT I WOULD LIKE TO EMPHASIZE, TO INCREASE THE POROSITY AS OPPOSED TO BEING ABLE TO CITE PERHAPS AN NIH RESEARCH GRANT, WHICH OBVIOUSLY IS IMPORTANT FOR THE DISCOVERY, OKAY, BUT REALLY IS NOT GOING TO HELP MOVE THE PROJECT FORWARD EFFECTIVELY. SO THAT'S WHAT I WOULD LIKE TO SUGGEST.

DR. STEWARD: WELL, I THINK THE EASIEST WAY IS CO-FUNDING. JUST LEAVE IT AT THAT.

DR. OLSON: EXACTLY. AND CO-FUNDING CAN INCLUDE IN-KIND RESOURCES OBVIOUSLY AND EXPERTISE.

DR. STEWARD: A JUDGMENT ON ALL THESE ASPECTS CAN BE MADE BY THE GRANTS WORKING GROUP AND CIRM STAFF AND THE BOARD EVENTUALLY. SO THAT'S AN EASY STATEMENT.

DR. FEIGAL: I THINK WE ALL AGREE INTERNALLY. THAT'S SOMETHING THAT ALIGNS WITH WHAT WE INTENDED, AND IT'S SOMETHING WE COULD EASILY ACCOMMODATE.

MR. PANETTA: THANK YOU. I THINK THAT MAKES

SENSE. WHERE I WAS BECOMING A LITTLE CONFUSED HERE IS I THINK I HEARD WAS THAT WE WILL BE LOOKING FOR A LARGE BIOPHARMA PARTNER AND A COMPANY WITH A MARKET CAP OF AT LEAST A BILLION DOLLARS. AND THOSE CAN BE TWO VERY DIFFERENT THINGS BECAUSE A COMPANY WITH A MARKET CAP OF A BILLION DOLLARS COULD BE A SMALL CAP BIOTECH COMPANY AS WELL. I DON'T KNOW IF --

DR. KADYK: I THINK THAT EXACT NUMBER HASN'T BEEN REALLY WELL WORKED OUT. ELONA BAUM IS OUR ADVISOR ON THAT. THE INTENT, I THINK, AND WE CAN MAYBE REDEFINE THE NUMBERS, IS TO HAVE A LARGE COMPANY THAT HAS DEVELOPMENT CAPABILITIES THAT IS NOT LIKELY TO FOLD, THAT IF THIS WAS A SUCCESSFUL PROJECT, WOULD BE ABLE TO CARRY IT THROUGH INTO DEVELOPMENT BECAUSE WE REALLY WANT TO MOVE THESE INTO DEVELOPMENT.

DR. TROUNSON: I THINK CO-FUNDING WOULD BE FINE. IT GETS A CHANCE TO REVIEW IT IN DIFFERENT FORUMS, AND THE DEGREE OF CO-FUNDING MAY WELL BE IMPORTANT. THAT THIS WILL BE FURTHER ON DOWN THE TRACK, SO OTHER PEOPLE WILL HAVE VIEWS AS WELL. I THINK THAT'S A REASONABLE THING TO INDICATE.

CHAIRMAN THOMAS: THANK YOU.

MS. LANSING: WHAT DID YOU SAY? I DIDN'T HEAR IT, ALAN.

DR. TROUNSON: I JUST SAID, SHERRY, THAT I

THINK CO-FUNDING THE PROJECTS, IF THEY WERE NEW PROJECTS, IF THEY WERE CO-FUNDED, YOU COULD REVIEW THEM ON THE BASIS THAT THEY HAD CO-FUNDING, AND EVENTUALLY THE BOARD COULD SEE WHETHER THAT WAS SIGNIFICANT CO-FUNDING OR NOT FOR SURVIVAL AND SO ON. SO THERE'S PLENTY OF CHANCES DOWNSTREAM TO LOOK TO SEE WHETHER THAT CO-FUNDING WAS REALLY SUBSTANTIAL AND APPROPRIATE. SO I THINK IF YOU PUT IN CO-FUNDING, WE CAN MAKE IT WORK.

CHAIRMAN THOMAS: THANK YOU. ANY OTHER COMMENTS BY MEMBERS OF THE BOARD? PUBLIC COMMENT.

MS. GOULD: I JUST WANTED TO ADD. MY NAME IS SHERRIE GOULD, A NURSE PRACTITIONER AT SCRIPPS CLINIC. AND THIS PROJECT WHICH WE VERY FONDLY CALL SUMMIT FOR STEM CELL IS THE EPITOME OF A PUBLIC PROJECT. IT IS THE EPITOME OF WHAT CIRM SHOULD REALLY SUPPORT AND REPRESENT BECAUSE OUR PROJECT, WE'VE HAD 900 PEOPLE DONATE $10, A $100, A $100,000 TO MAKE THIS PROJECT HAPPEN. WE'VE HAD PEOPLE CLIMB TO BASE CAMP AT MT. EVEREST. WE'VE HAD PEOPLE CLIMB UP KILIMANJARO, PATIENTS, IN SUPPORT AND IN BELIEF BEHIND THIS PROJECT.

IT'S BEEN DONE IN THE PAST WITH FETAL CELLS. IT'S BEEN DONE AND SOMETIMES VERY SUCCESSFULLY, AND THE TECHNOLOGY HAS ADVANCED BY 30 YEARS. SO WHAT WAS SUCCESSFUL BEFORE IN A VERY CRUDE TECHNIQUE AND WE SAW

SOME SUCCESS IN PARKINSON'S PATIENTS BY CURT FREED AND SOME NIH STUDIES THAT WERE DONE BACK IN THE '90S, IMAGINE 30 YEARS LATER AND THE TECHNOLOGY WE HAVE NOW. WE HAVE EIGHT PATIENTS. WE'RE IN ANIMAL TRIALS RIGHT NOW. THEY'RE LOOKING VERY SUCCESSFUL.

AND I JUST WANT TO TAKE THE OPPORTUNITY TO THANK YOU FOR ALLOWING US FROM SUMMIT TO BE HERE AND TO HAVE A FEW WORDS AND TO OPEN UP THIS POSSIBILITY OF CONSIDERING POSSIBLY OTHER PROJECTS OUTSIDE OF CIRM BECAUSE THIS IS INDEED AN INCREDIBLY, INCREDIBLY HOPEFUL PROJECT. AND ALL 2,000 OF OUR PATIENTS AT SCRIPPS CLINIC AS WELL AS PEOPLE AROUND THE WORLD THAT ARE STARTING TO HEAR ABOUT THIS PROJECT ARE SO BEHIND IT. SO I REALLY APPRECIATE YOUR TIME. THANK YOU.

MR. FITZPATRICK: ED FITZPATRICK AGAIN. I'M FROM THE BUSINESS COMMUNITY, AND WE INVEST IN PROPERTIES. AND WE HAVE WHAT IS CALLED A CO-INVESTOR. AND I THINK THAT'S WHAT WE'VE DONE HERE. WE'VE INVESTED OUR EFFORTS TO GAIN $700,000 WORTH OF GIFTS THAT HAVE TAKEN US AND WILL TAKE US THROUGH FDA APPROVAL.

DENNY SANFORD JUST GAVE A $100 MILLION TO UCSD FOR RESEARCH AS CRITERIA FOR PHILANTHROPIC GIVING. IT'S A GOOD CAUSE. IT WILL MAKE A DIFFERENCE. THE ENTITY THAT'S ASKING FOR IT HAS THE TALENT TO DELIVER

IT AND THE COMPASSION AS WELL. I THINK THAT THAT'S WHAT CIRM HAS AS WELL, AND I APPLAUD THAT.

WE ARE INTERESTED IN GOING FORWARD. IF CIRM DOESN'T GIVE US THE MONEY, WE'LL GET IT SOMEWHERE. BUT CIRM IS GOING TO GO AFTER ANOTHER $5 BILLION IN 2016 TO CONTINUE ITS GREAT WORK. WHAT BETTER WAY TO TELL THE WORLD THAT YOU JUST KNOCKED THE DISEASE ON ITS BUTT? THANK YOU.

MS. PETERSON: HI, THERE. MY NAME IS SUZANNE PETERSON. AND I GUESS WHAT I THINK IS THE BEST THING THAT COULD HAPPEN TO CIRM IS WE COULD COME UP WITH A CURE. ONE DISEASE. IT DOESN'T MATTER WHAT IT IS. I THINK THAT WOULD ALLOW CIRM TO GO ON PAST 2017 AND WHENEVER WE RUN OUT OF MONEY. I'VE ALWAYS HEARD OF PARKINSON'S DESCRIBED A LOW HANGING FRUIT IN TERMS OF STEM CELL CURES. WE'VE ALREADY RAISED 700,000. TO LIMIT IT ONLY TO PEOPLE WHO HAVE A CIRM GRANT SEEMS LIKE YOU'RE MISSING OUT ON SUCH AN OPPORTUNITY HERE. SO ANYWAYS, THANK YOU.

DR. TSKUMOTO: SO MY NAME IS ANNE TSKUMOTO FROM STEM CELLS, AND I WASN'T SPEAKING NECESSARILY OF THIS GROUP. I AGREE THAT WE NEED TO MOVE THINGS FORWARD. BUT I WANTED TO, SINCE MR. SHEEHY SO NICELY OPENED UP THE POSSIBILITY OF MODIFYING THE WORDING IN THIS PARTICULAR AWARD, I WANTED TO HAVE THE BOARD AND

THE MEMBERS OF THE ICOC THINK ABOUT OPENING THIS UP TO CLINICAL DEVELOPMENT. WE ARE AT THE STAGE NOW OF BEING ABLE TO DO THREE PHASE II CLINICAL STUDIES. WE HAVE PUBLISHED THE DATA ON ONE STUDY WE FINISHED AT UCSF IN A MYELIN DISORDER. AND WE ARE PUBLIC THAT WE WILL BE INITIATING PHASE II TRIALS FOR SPINAL CORD INJURY AND AGE-RELATED MACULAR DEGENERATION THIS YEAR.

HAVING THE ABILITY TO MOVE THESE THREE PROGRAMS FORWARD WILL BE INCREDIBLE FOR CIRM IF WE WANT TO HAVE THE CHANCE TO MOVE THESE THERAPIES INTO CLINICAL TESTING. SO I WOULD JUST LIKE TO OPEN UP THAT POSSIBILITY AS YOU CONSIDER WHAT THE SCOPE OF THESE NEW AWARDS SHOULD BE. THANK YOU.

DR. KADYK: THIS PARTICULAR AWARD UNDER DISCUSSION HERE IS VERY NARROWLY FOCUSED. IF YOU LOOK ON THE SLIDE TO THE PRECLINICAL DEVELOPMENT STAGE, THE EARLY PRECLINICAL DEVELOPMENT STAGE, THE CLINICAL TRIALS WOULD BE FUNDED UNDER LATER DISEASE TEAM AND SP MECHANISMS.

DR. FEIGAL: JUST TO BE CLEAR, WE JUST BROUGHT FORWARD THE CONCEPT FOR STRATEGIC PARTNERSHIPS THAT SMALL COMPANIES CAN COME IN FOR. AND THEN AS WE SAID EARLIER IN MY PRESENTATION, WE'RE GOING TO COME BACK TO THE BOARD IN THE FALL WITH THE DISEASE TEAM CONCEPT FOR CLINICAL TRIALS.

CHAIRMAN THOMAS: FURTHER COMMENT FROM EITHER BOARD OR MEMBERS OF THE PUBLIC?

DR. TSKUMOTO: SO I JUST WANTED TO COMMENT ON THOSE. SO I'VE LOOKED AT ALL OF THE POSSIBLE FUNDING MECHANISMS THROUGH CIRM BECAUSE IT WOULD BE GREAT IF WE COULD -- THE STRATEGIC PARTNERSHIPS REQUIRE A PARTNERSHIP, AND PHARMA HAS NOT EMBRACED CELL-BASED THERAPIES. THEY WORK ON STEM CELLS, BUT MAINLY AS TOOLS. THEY REALLY HAVEN'T EMBRACED STEM CELL, AND THEY'RE WAITING FOR THE PROOF OF CONCEPT, WHICH IS THE PHASE II DATA. AND AT THAT POINT THEY MAY COME IN, BUT THEY'RE NOT -- AS A WHOLE, THEY'RE NOT READY TO COME IN AT THIS POINT IN TIME.

SO THERE ARE REALLY NO MECHANISMS FOR WHICH WE CAN APPLY TO HAVE HELP TO FUND THESE AREAS. AND THEY'RE, AS YOU KNOW, VERY, VERY KEY AREAS. AND IF YOU LOOK AT THE CIRM PORTFOLIO, THERE ISN'T A LOT IN SPINAL CORD INJURY. AND WE HAD AN AWARD APPROVED THROUGH THE DISEASE TEAM, BUT BECAUSE OF THE TERMS AND CONDITIONS, AND AT THAT POINT THEY WERE LOANS, WE COULDN'T ACCEPT BOTH OF THEM. SO I WANT JUST TO POINT OUT THERE REALLY ISN'T A GOOD MECHANISM FOR US TO APPLY AT THIS POINT IN TIME. AND WE WILL MOVING FORWARD WITH THESE PROGRAMS. AND SO THE TIMELINES ALSO FOR THESE AWARDS ARE SO LONG, WE MAY BE WELL INTO DOING THE CLINICAL STUDIES BY THE

TIME YOU CAN GET FUNDING FOR THESE CLINICAL TRIALS. THANK YOU.

CHAIRMAN THOMAS: MR. HARRISON, COULD YOU RESTATE THE MOTION, PLEASE?

MR. HARRISON: THE MOTION, AS I UNDERSTAND IT, AND WE DON'T YET HAVE A MAKER. MR. SHEEHY IS THE MAKER.

CHAIRMAN THOMAS: HOLD ON ONE SECOND.

MR. TORRES: I'LL SO MOVE.

CHAIRMAN THOMAS: YOU'RE SECOND.

MR. HARRISON: NOW WE'LL FIGURE IF WHAT YOU'RE SECONDING IS, IN FACT, WHAT YOU INTENDED. APPROVE THE PRECLINICAL DEVELOPMENT AWARDS CONCEPT PLAN, BUT PERMIT APPLICATIONS FROM EXTERNALLY FUNDED PROJECTS PROVIDED THEY HAVE A CO-FUNDING PARTNER.

MR. SHEEHY: DR. TROUNSON, IS THAT KIND OF WHERE WE WERE HEADED? JUST CONFIRMING WITH DR. TROUNSON THAT THAT AMENDMENT IS SOMETHING STAFF WOULD BE COMFORTABLE WITH.

DR. TROUNSON: THE ANSWER IS YES, JEFF. IT WOULD FIT FINE.

MR. SHEEHY: OKAY. THEN THAT'S THE MOTION.

CHAIRMAN THOMAS: MARIA, PLEASE TAKE THE ROLL.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.
MS. BONNEVILLE: DAVID BRENNER. KEN BURTIS.
DR. BURTIS: YES.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: YES.
MS. BONNEVILLE: MICHAEL FRIEDMAN.
DR. FRIEDMAN: YES.
MS. BONNEVILLE: JUDY GASSON.
MR. GASSON: YES.
MS. BONNEVILLE: SAM HAWGOOD. STEPHEN JUELSGAARD. SHERRY LANSING.
MS. LANSING: YES.
MS. BONNEVILLE: JACOB LEVIN.
DR. LEVIN: YES.
MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
DR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: DONNA WESTON. DIANE WINOKUR.
CHAIRMAN THOMAS: I THINK WE CAN SAFELY SAY THAT MOTION PASSED, MR. HARRISON. THANK YOU FOR THAT DISCUSSION AS WELL, MEMBERS OF THE BOARD AND THE PUBLIC.
I BELIEVE NOW WE'RE GOING TO -- WHERE IS THE LUNCH?
MS. BONNEVILLE: LUNCH IS RIGHT OUTSIDE THIS ROOM IN THE HALLWAY. BRING YOUR LUNCHES BACK HERE, AND WE'RE GOING TO HAVE OUR SPOTLIGHT ON DISEASE DURING LUNCH.

CHAIRMAN THOMAS: EVERYBODY COULD PROCEED FORTHWITH TO THE LUNCH TABLE AND BRING IT BACK AND WE'LL HEAR FROM OUR LUNCHTIME SPEAKER.

MR. HARRISON: FOR THE RECORD, THE VOTE ON THAT LAST MOTION WAS 19 TO ZERO.

CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.

(A RECESS WAS TAKEN AND THEN THE SPOTLIGHT ON DISEASE WAS HEARD, NOT REPORTED, NOR HEREIN TRANSCRIBED. THE FOLLOWING PROCEEDINGS WERE THEN HEARD IN OPEN SESSION:)

CHAIRMAN THOMAS: WE WILL NOW PROCEED TO DISCUSSION OF AGENDA ITEM NO. 8, CONSIDERATION OF RFA 13-01 FROM THE DUANE ROTH DISEASE TEAM THERAPY DEVELOPMENT AWARDS III, APPLICATION DR 3-07201, WHICH WAS THE DR. MARBAN APPLICATION.

JUST A LITTLE CONTEXT AND TURN IT OVER TO CHAIR, THE DISCUSSION, TO MR. SHEEHY, AS THIS FALLS UNDER PROGRAMMATIC REVIEW. AS MEMBERS OF THE BOARD WILL RECALL, LAST FALL WE HAD THE PEER REVIEW EVALUATIONS IN THE GRANTS WORKING GROUP OF THE DISEASE TEAM III ROUND. AND AS A RESULT OF THAT ROUND, THERE WERE RECOMMENDATIONS IN TIERS I, II, AND III BROUGHT TO THE BOARD FOR ACTION AT THE DECEMBER BOARD MEETING.

THE ACTION REQUIRED OF THE BOARD IS BOTH TO APPROVE THOSE PROJECTS THAT IT WANTS TO BE FUNDED, BUT,

SIMILARLY, TO NOT APPROVE THE OTHER REMAINING PROJECTS THAT THE BOARD DOESN'T FEEL SHOULD BE FUNDED, OBVIOUSLY TAKING INTO ACCOUNT THE GUIDANCE OF BOTH THE GRANTS WORKING GROUP AND STAFF IN MAKING THOSE DETERMINATIONS.

AT THE TIME WE HAD THE DIFFERENT PROJECTS UP FOR APPROVAL OR NONAPPROVAL AT THE DECEMBER BOARD MEETING, DR. MARBAN REQUESTED ON A NUMBER OF GROUNDS THAT WE DEFER A VOTE ON HIS PARTICULAR PROJECT WHICH WAS IN THE TIER III AS PASSED TO THE BOARD FROM THE GRANTS WORKING GROUP. AND THAT SET OFF A SERIES OF EVENTS WHICH WILL BE DISCUSSED HERE TODAY AND WILL INFORM THE BOARD'S DECISION ON HOW TO DEAL WITH THIS GRANT GOING FORWARD.

WITH THAT, I'LL TURN IT OVER TO MR. SHEEHY.

MR. SHEEHY: USUALLY THE WAY WE START THIS IS WITH A MOTION TO EITHER FUND OR NOT FUND. DOES ANYONE --

MR. TORRES: SO MOVED TO FUND.

MR. SHEEHY: SO WE HAVE A MOTION TO FUND ON THE FLOOR. DO I HAVE A SECOND?

DR. QUINT: SECOND.

MR. SHEEHY: DID YOU HAVE A DIFFERENT MOTION, OS?

DR. STEWARD: I DID.

MR. SHEEHY: IF THIS ONE GOES DOWN OR IF YOU

HAVE A SUBSTITUTE. YOU WERE GOING TO MOTION NOT TO FUND, I SUSPECT.

DR. STEWARD: I WAS.

CHAIRMAN THOMAS: I THINK ART GOT THERE FIRST, BUT IF THIS GOES DOWN. I THINK DISCUSSION IS APPROPRIATE IF BOARD MEMBERS WANT TO HAVE -- IS THERE ANY DISCUSSION FROM ANY OF THE BOARD MEMBERS ABOUT THIS APPLICATION? WE HAVE A MOTION ON THE FLOOR TO FUND.

DR. QUINT: YES. DR. MARBAN HAS SUBMITTED A LETTER DEFENDING HIS POSITION. DR. MARBAN HAS SUBMITTED A LETTER IN SUPPORT OF HIS GRANT REQUISITION. AND I'M FULLY IN SUPPORT OF EVERYTHING HE'S PROPOSED IN THIS LETTER. IT ESCAPES ME AS TO WHY THIS WAS REALLY REJECTED IN THE FIRST PLACE. I UNDERSTAND THERE WAS SOME SORT OF CONFLICT OF INTEREST IN THAT HE HAS TWO PROJECTS USING THE SAME MOLECULE OR CARDIOMYOSPHERES TO TREAT TWO DIFFERENT DISEASES. HE'S TREATING CONGESTIVE HEART FAILURE IN BOTH PROJECTS; HOWEVER, THERE ARE DIVERSE CAUSES OF CONGESTIVE HEART FAILURE.

IN THE ONE CASE IT'S DUE TO AN INFARCTION DUE TO CORONARY ARTERY DISEASE WHICH HAS DESTROYED SOME OF THE HEART MUSCLE. IN THAT GROUP THEY'VE ALREADY DEMONSTRATED THAT THESE AUTOLOGOUS CARDIOMYOSPHERES CAN REGENERATE CARDIOMYOCYTES WHICH ARE LIVING, FUNCTIONING HEART MUSCLE CELLS.

IN THE OTHER GROUP IT'S A DIVERSE GROUP CALLED IDIOPATHIC DILATED CARDIOMYOPATHY FOR WHICH THERE IS NO KNOWN DEFINITE ETIOLOGY. IT'S NOT LIKE CHAGAS DISEASE WHERE YOU HAVE AN ACTUAL INFECTION THAT RESULTS IN DILATED CARDIOMYOPATHY. SO THE ETIOLOGY OF THAT GROUP IS UNKNOWN.

THEY'RE USING THE SAME TECHNIQUE OR THE SAME CELLS. MAY TREAT ONE DISEASE AND NOT THE OTHER. SO I SEE NO REASON WHY THE DILATED CARDIOMYOPATHY GROUP IS NOT INCLUDED OR IS NOT FUNDED SIMPLY BECAUSE HE HAS ANOTHER PROJECT USING THE SAME AGENT IN A DIFFERENT GROUP OF PATIENTS WHO HAPPEN TO END UP WITH THE SAME CLINICAL CONDITION CALLED CONGESTIVE HEART FAILURE. SO I WOULD VERY STRONGLY SUPPORT HIS REQUEST.

MR. SHEEHY: CAN I ASK A QUESTION OR TWO, DR. QUINT?

DR. QUINT: YES.

MR. SHEEHY: SO THESE CELLS HAVE ALREADY MADE IT TO PHASE II, RIGHT?

DR. QUINT: CORRECT.

MR. SHEEHY: AND THEY EVEN GOT A COFUNDER, JANSSEN.

DR. QUINT: CORRECT.

MR. SHEEHY: IT'S KIND OF IRONIC THAT WE DECIDED THIS MORNING THAT WE'RE GOING TO GO LOOK FOR

NEW PROJECTS IN LATE STAGE CLINICAL TRIALS WITH PARTNERS, AND WE HAVE SOMEBODY HERE WHO WANTS TO DO A LATE STAGE CLINICAL TRIAL AND HAS A PARTNER.

BUT ANOTHER QUESTION I HAD. THE TRIAL WE'RE FUNDING, THIS SEEMS LIKE THERE'S SOME SORT OF ISSUE ABOUT END POINT SO HE CAN SHOW REDUCTION OF SCAR TISSUE.

DR. QUINT: CORRECT.

MR. SHEEHY: AND HE CAN SHOW --

DR. QUINT: IMPROVEMENT IN CLINICAL STATUS.

MR. SHEEHY: INJECTION FRACTION, BUT HE HAS TROUBLE, I THINK, IN THE CURRENT TRIAL IN GETTING THOSE HARD END POINTS THAT THE FDA TYPICALLY LOOKS AT, WHICH ARE THESE MORTALITY AND MORBIDITY OUTCOMES. YET, IT SEEMS TO ME LIKE THIS TRIAL THAT WE'RE TALKING ABOUT TODAY, BECAUSE THE PATIENTS ARE SO MUCH SICKER, WILL PROVIDE CRITICAL DATA ON THOSE MORTALITY --

DR. QUINT: ANSWERING THOSE QUESTIONS.

MR. SHEEHY: YEAH, WHICH ARE VITAL TO GETTING INTO THE PIVOTAL PHASE III TRIAL THAT WOULD MAKE THIS A REAL THERAPY FOR THOUSANDS OF PEOPLE WITH HEART DISEASE.

I THINK I HAD OS AND THEN DR. FRIEDMAN AND THEN ANNE-MARIE.

DR. STEWARD: SO I ANNOUNCED THAT I WAS GOING

TO MAKE A MOTION NOT TO FUND, AND I'D LIKE TO OUTLINE A LITTLE BIT WHY THAT IS AND MAYBE SOME BACKGROUND HERE.

SO, FIRST OF ALL, ONE OF THE ISSUES HERE WAS THAT THERE WAS AN ALLEGATION OF CONFLICT OF INTEREST. I WANT TO BE VERY CLEAR TO THE PUBLIC. CONFLICT OF INTEREST HAS A VERY SPECIFIC DEFINITION, AND THERE WAS ABSOLUTELY NO EVIDENCE OF CONFLICT OF INTEREST AS DEFINED BY CIRM RULES IN THIS REVIEW PROCESS. THAT WAS THE CASE AT THE TIME OF THE REVIEW, AND IT WAS THE CASE IN THE RE-REVIEW GOING FORWARD.

THE TERM "CONFLICT OF INTEREST" IS IN THIS CASE BEING MISUSED TO MEAN THAT THERE WAS A REVIEWER WHO HELD AN OPINION THAT UNDULY INFLUENCED THE REVIEW PROCESS, BUT THAT'S NOT CONFLICT OF INTEREST. AND I JUST WANT TO SAY THAT FIRST.

THE SECOND THING I WANT TO SAY IS THAT, AS WE ALWAYS HAVE, WE HAVE, I THINK, A DUTY TO RESPECT THE OPINIONS OF THE GRANTS WORKING GROUP. THEY ARE THE ONES WHO HAVE LOOKED AT THIS PROPOSAL IN FAR MORE DETAIL THAN WE CAN AND HAVE COME TO A JUDGMENT OF ITS RELATIVE MERIT. AND BY RELATIVE MERIT, THAT'S IN COMPARISON TO OTHER THINGS.

ALONG THOSE LINES, BY THE WAY, I THINK THAT IT WOULD BE APPROPRIATE IF GIL COULD ACTUALLY SHOW US THE SCORES THAT THIS GRANT RECEIVED IN THE REVIEW

PROCESS BECAUSE THAT HELPS US UNDERSTAND WHERE IT WAS RATED. YOU CAN ANSWER THAT IN A SECOND, BUT JUST TO FINISH, I LOOKED AT THIS VERY CAREFULLY. AND, AGAIN, IT WAS REALLY RE-REVIEWED BY THE GRANTS WORKING GROUP TO MAKE SURE THAT THERE WASN'T ANY UNDUE INFLUENCE BY THE INDIVIDUAL WHO WAS PERCEIVED TO HAVE A COUNTER OPINION, LET'S JUST SAY. AND, AGAIN, THE GRANTS REVIEW GROUP INDICATED THAT THEY FELT THAT SUCH DID NOT OCCUR.

SO BECAUSE OF ALL THOSE THINGS AND THE FACT THAT THAT THE ICOC IS THE FINAL DECISION MAKER, BUT DOES HAVE TO DEPEND ON THE RECOMMENDATIONS, THAT'S THE REASON THAT I WAS GOING TO RECOMMEND AGAINST FUNDING, AND I'LL VOTE AGAINST THIS MOTION FOR ALL THOSE REASONS.

DR. SAMBRANO: IF I MAY, I WANTED TO PROVIDE YOU AT LEAST SOME BACKGROUND AND A HISTORY OF WHERE WE LEFT OFF BECAUSE, AS WAS INDICATED, THE BOARD REVIEWED THE APPLICATIONS FOR DISEASE TEAM IN THEIR DECEMBER MEETING, AND THERE WAS THIS ONE APPLICATION THAT YOU DID NOT. SO SEVERAL THINGS HAVE HAPPENED SINCE THEN. AND AT LEAST TO PUT EVERYBODY ON THE SAME PAGE AND GIVE YOU A HISTORY, I WANTED TO GO OVER THAT.

SO AS WAS INDICATED, THIS WAS DEFERRED BECAUSE THE APPLICANT FILED AN APPEAL REQUEST RELATED TO AN ALLEGED CONFLICT OF INTEREST. AND SO THAT WAS

EXAMINED VERY CAREFULLY. THERE WAS AN ALLEGATION THAT ONE MEMBER OF THE GRANTS WORKING GROUP TAINTED THE REVIEW THROUGH A PERCEIVED LACK OF OBJECTIVITY. THERE WAS NO SPECIFIC BASIS TO SUPPORT THAT ALLEGATION BASED ON FINANCIAL, PROFESSIONAL, OR PERSONAL CONFLICT OF INTEREST AS WOULD BE DEFINED IN OUR POLICY.

NEVERTHELESS, WE EXAMINED WHAT INFLUENCE THIS INDIVIDUAL MAY HAVE HAD ON THE APPLICATION. SO WE LOOKED AT SCORES, WE LOOKED AT NOTES, WE LOOKED AT WRITTEN CRITIQUES. WE FOUND NO EVIDENCE THAT THE REVIEWER HAD ANY SIGNIFICANT INFLUENCE ON THE SCORE OR ON THE RECOMMENDATION. THIS REVIEWER WAS NOT EVEN ASSIGNED TO THE APPLICATION AND, THEREFORE, DIDN'T CONTRIBUTE A WRITTEN CRITIQUE. EVIDENCE FROM NOTES AND FROM THOSE THAT ATTENDED THE REVIEW RECALL THAT THERE WERE NO SPECIFIC COMMENTS MADE BY THIS REVIEWER EITHER IN FAVOR OR AGAINST THE APPLICATION.

SO, IN SUMMARY, THERE WAS NOTHING SPECIFIC OR SUBSTANTIVE TO SUPPORT THE EXISTENCE OF A CONFLICT OF INTEREST AND, THEREFORE, THAT APPEAL WAS DENIED. AND SO WHAT THAT MEANT WAS THAT THERE IS NO -- THIS DOES NOT WARRANT A NEW REVIEW BASED ON THAT.

NOW, IN ADDITION TO THE CONFLICT OF INTEREST, THERE WAS ALSO ADDITIONAL INFORMATION THAT WAS SUBMITTED BY THE APPLICANT. AND SO THEY SUBMITTED A

REQUEST FOR RECONSIDERATION BASED ON MATERIAL NEW INFORMATION. AND SO THE APPLICANT DID PROVIDE SOME INFORMATION THAT WAS NEW THAT INCLUDED SOME MANUSCRIPTS AND INCLUDED SOME DATA FROM THE OTHER CLINICAL TRIAL THAT'S ONGOING. HOWEVER, IN EXAMINING THAT INFORMATION, WE FELT THAT IT DID NOT DIRECTLY ADDRESS THE MAIN CONCERNS THAT WERE BROUGHT UP BY THE GRANTS WORKING GROUP AND, THEREFORE, THE REQUEST WAS DENIED.

DESPITE THAT -- AND, AGAIN, CIRM STAFF TOOK THE ADDITIONAL STEP HERE OF SEEKING ADDITIONAL EXPERT OPINION ON THIS. AND SO WHAT I WANT TO CLARIFY IN DOING THIS, THIS WAS NOT, ALTHOUGH IT'S BEING CHARACTERIZED AS SUCH, IS NOT A RE-REVIEW OF THE APPLICATION AS THE ORIGINAL GRANTS WORKING GROUP REVIEW WAS STILL VALID. THE APPEALS DID NOT WARRANT DOING A NEW REVIEW. INSTEAD, WHAT WE WERE SEEKING WAS ADDITIONAL EXPERT ADVICE IN THE INTEREST OF BEING COMPREHENSIVE AND ATTENTIVE TO THE CONCERNS OF THE APPLICANT.

THE GOAL HERE WAS TO ENSURE THAT NOTHING WAS MISSED AND TO INFORM A RECOMMENDATION FROM CIRM STAFF AND TO INFORM YOU ABOUT THE RELATIVE MERITS OF THIS APPLICATION.

NOW, WHETHER OR NOT WE COULD SEEK ADDITIONAL ADVICE GIVEN THESE CIRCUMSTANCES AND HOW TO GO ABOUT

DOING SO WAS SOMETHING THAT WE VETTED WITH LEGAL COUNSEL, INCLUDING MR. JAMES HARRISON. NOW, GIVEN THAT BACKGROUND, WHAT THE ADDITIONAL EXPERT REVIEWERS FOUND WAS LARGELY SUPPORTIVE OF WHAT THE ORIGINAL GRANTS WORKING GROUP HAD CONCLUDED.

AND I ALSO WANT TO CLARIFY HERE THAT THE REVIEWERS REALLY HAD NO ISSUE AND HAVE NO ISSUE WITH CURRENT TRIALS THAT ARE TESTING THE SAME THERAPEUTIC PRODUCT IN A DIFFERENT POPULATION OF PATIENTS. THEIR CONCERNS WERE FOCUSED AND RELATED SOLELY TO THIS PROPOSAL THAT CAME IN UNDER THE DISEASE TEAM III COMPETITION.

SO THE CONCERNS, JUST TO BRIEFLY SUMMARIZE, WERE SEVERAL, BUT THEY INCLUDED WEAKNESSES IN THE CLINICAL TRIAL DESIGN, INCLUDING THE TARGET POPULATION BEING TOO HETEROGENEOUS AND, AS SUCH, THAT IT WOULD POTENTIALLY IMPAIR THE ABILITY TO GET MEANINGFUL DATA.

THE EXPERTS ALSO FELT THAT THE PRECLINICAL DATA DID NOT PROVIDE SUPPORT FOR AN EFFECT ON THE PROPOSED PATIENT POPULATION BECAUSE THE PRECLINICAL MODEL THAT WAS PRESENTED TO SUPPORT THAT WAS NOT REPRESENTATIVE OF THE CONDITION FOUND IN THESE PATIENTS. SO ALTHOUGH THEY ARE CHARACTERIZED AS BEING SICKER, WHICH IS ABSOLUTELY TRUE, THERE ISN'T THE DATA YET TO SUPPORT, AS WITH THE OTHER TRIAL, THAT THIS

PRODUCT WOULD ACTUALLY HAVE AN EFFECT ON THOSE PATIENTS. AND SO THAT'S CRITICAL.

AND THEN CONSISTENT WITH THE WORKING GROUP ASSESSMENT, THE EXPERTS ALSO ADVISED THAT SOME EVIDENCE OF EFFICACY IN ADDITION TO SAFETY FROM THE OTHER TRIAL CURRENTLY EVALUATING THE PRODUCT SHOULD BE ACQUIRED TO BETTER INFORM THE OVERALL SCOPE AND THE DESIGN OF THE CLINICAL TRIAL. INFORMATION GATHERED FROM THAT TRIAL WILL INEVITABLY INFORM HOW YOU DESIGN FUTURE TRIALS AND HOW YOU INTEND TO ADDRESS SPECIFIC OTHER POPULATIONS FOR THE SAME THERAPEUTIC.

SO, IN GENERAL, WHAT WE WENT THROUGH BETWEEN THE TIME THAT YOU LAST SAW THIS AND THIS WAS DEFERRED UNTIL NOW IS WE WENT THROUGH A SERIES OF STEPS, I THINK, TO ASSURE OURSELVES THAT WE ARE LOOKING AT A PROPOSAL THAT, IF SOMETHING WAS MISSED, WE HAVE CAUGHT IN SOME WAY AND THAT WE WERE ATTENTIVE TO ALL THE CONCERNS THAT WERE BROUGHT UP.

SO WITH THAT SAID, I CAN SAY ALSO BRING UP DR. MARIA MILLAN WHO CAN PRESENT A SUMMARY OF THE ORIGINAL GRANTS WORKING GROUP REVIEW IF YOU WOULD LIKE TO HEAR THAT AS WELL.

MR. SHEEHY: SO --

DR. QUINT: I'D LIKE TO HEAR IT.

DR. TORRES: THANK YOU.

MR. SHEEHY: I STILL HAVE DR. FRIEDMAN AND ANNE-MARIE.

MR. TORRES: I'LL RESERVE THE RIGHT TO SPEAK ON THE MOTION WHICH I MOVED LATER. I JUST WANTED TO ASK DR. SAMBRANO A QUESTION. IN THE LETTER THAT WAS SENT BY DR. EDUARDO MARBAN ON MARCH 12TH, WHICH IS IN OUR BINDER, WHAT'S TROUBLING TO ME IS THAT NO. 4, HE SAYS THE PRESENT PROPOSAL DYNAMIC, WHICH IS DIFFERENT FROM THE ALLSTAR THAT WE FUNDED ALREADY, IS READY TO GO INTO PATIENTS IMMEDIATELY. IT IS FDA AND IRB APPROVED. I'M NOT A CARDIOLOGIST LIKE DR. QUINT, BUT DID WE CHECK WITH THE FDA AS TO WHY THEY APPROVED IT?

DR. SAMBRANO: NO. THE FDA IS INTERESTED IN SAFETY. THIS IS AN ONGOING TRIAL. AS YOU KNOW, WE'RE ALSO SUPPORTING ANOTHER.

MR. TORRES: I'M TALKING ABOUT THIS ONE.

DR. SAMBRANO: I UNDERSTAND, BUT IT'S THE SAME PRODUCT. SO IN TERMS OF SAFETY CONCERNS, THERE WOULD BE MINIMAL, IF ANY. I DON'T THINK REVIEWERS HAD ANY ISSUE OR CONCERN ABOUT THE SAFETY OF THIS PRODUCT. SO IN TERMS OF WHAT THE FDA IS APPROVING, THERE'S NO DISAGREEMENT WITH IT BEING ABLE TO GO TO PATIENTS.

MR. TORRES: I'M ASKING WHETHER YOU OR OUR STAFF TALKED TO THE FDA REGARDING THE CURRENT PROPOSAL BEFORE US; IN OTHER WORDS, ITS USE.

DR. SAMBRANO: I DON'T KNOW IF ANYBODY ELSE --

DR. FEIGAL: I JUST WANT TO MAKE IT CLEAR. WE CAN'T DO THAT.

MR. TORRES: I DIDN'T REALIZE THAT.

DR. FEIGAL: WE CAN'T TALK ABOUT -- WE CAN'T CALL UP THE FDA. FIRST, WE CAN NEVER DO THAT. WE HAVE TO GO THROUGH THE SPONSOR. SO WE HAVE TO GET THEIR PERMISSION TO TALK TO PEOPLE ABOUT THEIR PROPRIETARY INFORMATION. THE FDA WILL NOT TALK TO ANYBODY BUT THE SPONSOR.

MR. TORRES: DID WE DO THAT?

DR. FEIGAL: THERE WAS NO REASON TO DO THAT BECAUSE WE WEREN'T QUESTIONING THAT THEY HAD THE ABILITY TO GO FORWARD INTO PATIENTS BECAUSE THE ISSUE IS NOT SAFETY. THE ISSUE IS THE RATIONALE FOR GOING INTO THIS PATIENT POPULATION, AND THE ISSUE IS ABOUT THE DESIGN OF THE TRIAL AND THE CONCERN THAT IT WOULDN'T ANSWER THE QUESTIONS. THAT WAS THE CONCERN. WE WEREN'T QUESTIONING WOULD IT NOT HURT PEOPLE. THAT WASN'T OUR QUESTION.

MR. TORRES: THE QUESTION WAS WHETHER IT WOULD BE EFFICACIOUS.

DR. FEIGAL: THE ISSUES WERE THE ONES THAT DR. SAMBRANO HAS ARTICULATED. THE RATIONALE FOR GOING

INTO THIS PATIENT POPULATION AND THE DESIGN OF THE TRIAL.

MR. TORRES: I'M SORRY. YOU DON'T NEED TO SPEAK OVER ME. I JUST WANTED TO RESPOND TO YOU. WHAT YOU SAID WAS THAT IT WOULD NOT HAVE THE DESIRED EFFECT. THAT'S WHAT YOU SAID. AND THAT'S WHAT ELLEN IS REFERRING TO?

DR. SAMBRANO: YES.

MR. TORRES: IS THAT CORRECT?

DR. FEIGAL: I WANT TO CLARIFY WHAT WE JUST SAID. THERE WASN'T A RATIONALE TO GO INTO THIS TARGET POPULATION. AND THE DESIGN OF THE TRIAL WAS SUCH THAT TWO SETS OF REVIEWERS THOUGHT IT WASN'T THE RIGHT PATIENT POPULATION BECAUSE IT WAS GOING INTO HEART FAILURE, BUT IT HAD A BROAD SPECTRUM OF ETIOLOGIES THAT COULD LEAD TO THAT HEART FAILURE. AND THE CARDIOLOGY EXPERT SAID IT WOULDN'T ANSWER THE QUESTION BECAUSE IT WASN'T TAKING INTO ACCOUNT THE DIFFERENT REASONS WHY PEOPLE GET HEART FAILURE. AND THEY WERE QUESTIONING THE DESIGN. AND THE WAY IT WAS DESIGNED, THEY FELT VERY CONCERNED THAT IT WOULDN'T ANSWER THE QUESTION.

SO AS A FUNDING AGENCY, WE'RE NOT JUST CONCERNED OF WILL IT NOT HURT PEOPLE. WE WANT TO MAKE SURE THAT THE TRIALS ARE DESIGNED TO ANSWER QUESTIONS THAT CAN ADVANCE THE FIELD. AND THE FDA IS NOT LOOKING

AT THAT AT THIS STAGE. THEY'RE LOOKING TO SEE WHETHER OR NOT IT IS SAFE TO PROCEED.

MR. TORRES: I UNDERSTAND YOU WERE IN CONSTANT CONTACT WITH DR. MARBAN. WAS THAT ISSUE RAISED AS WELL AS HOW TO REDO THE TRIAL?

DR. FEIGAL: THAT ACTUALLY WAS RAISED WITH DR. MARBAN, AND I SPOKE TO HIM ABOUT ALTERNATIVE OPTIONS TO THINK ABOUT REVISING THAT TO ACCOUNT FOR THE CONCERNS AND THAT WE WOULD HAVE SUBSEQUENT ALTERNATIVE AVENUES TO COME IN. BUT THE WAY IT WAS DESIGNED, BY TWO SETS OF REVIEWERS, THERE WERE SUBSTANTIVE ISSUES THAT NOBODY FELT COMFORTABLE FUNDING IT AS WRITTEN. THERE WERE THINGS THEY COULD DO TO CHANGE IT TO MAKE IT MORE INFORMATIVE.

MR. TORRES: WHAT WAS DR. MARBAN'S RESPONSE TO YOUR SUGGESTION?

DR. FEIGAL: HE LISTENED.

MR. TORRES: WE ALL LISTEN.

MR. SHEEHY: I WANT TO --

MR. TORRES: IF THERE WAS A --

DR. FEIGAL: I DON'T THINK I CAN COMMENT ON IT. I'M JUST SHARING THAT. AND DR. MARBAN IS HERE AND I'M SURE CAN SPEAK FOR HIMSELF ON THAT.

MR. SHEEHY: MAYBE IT MIGHT BE APPROPRIATE TO HEAR FROM DR. MARBAN BECAUSE I FEEL VERY UNCOMFORTABLE

ABOUT TALKING ABOUT AN INDIVIDUAL WHEN HE'S SITTING IN THE ROOM. AND I GUESS TOO DR. MARBAN KNOWS MORE ABOUT -- I DON'T KNOW ABOUT EVERYBODY HERE -- BUT PROBABLY KNOWS MORE ABOUT CARDIOLOGY THAN MOST OF US HERE. I THINK IF HE WOULD LIKE TO RESPOND, IT MIGHT -- THERE'S BEEN A WHOLE STREAM OF ISSUES AND POINTS; BUT IF YOU'RE COMFORTABLE, DR. MARBAN, IT'S YOUR CALL.

DR. MARBAN: I APPRECIATE THE OPPORTUNITY. AND, MR. SHEEHY AND LADIES AND GENTLEMEN, THANK YOU FOR THE OPPORTUNITY TO TALK ABOUT THIS. I'LL PARAPHRASE THE LETTER AND THEN EMPHASIZE SOME OF THE POINTS THAT WERE RAISED IN THE MOST RECENT COMMENTS.

I JUST WANT TO NOTE THAT I'M NOT A NOVICE HERE. I'VE PROBABLY DELIVERED MORE TO CIRM THAN ANYBODY ELSE WHO'S EVER BEEN GRANTED BY CIRM. MY DISEASE TEAM WITH A TOTAL DIRECT COST OF $5 MILLION DELIVERED THE FIRST VALIDATED IND-APPROVED THERAPEUTIC CANDIDATE THAT THEN WENT INTO CLINICAL TRIALS. THOSE CLINICAL TRIALS ARE IN PHASE II. THOSE CLINICAL TRIALS HAVE BEEN CHARACTERIZED BY MANY PEOPLE IN THE COMMUNITY AS VISIONARY AND PATH DEFINING. AND I THINK THAT IT IS DISMISSIVE AND ALMOST DISRESPECTFUL TO LISTEN TO SOME OF THE COMMENTS THAT HAVE BEEN MADE.

OUR CLINICAL PROGRAM IN A MORNING THAT'S BEEN SPENT ON ADVANCING -- TALKING ABOUT HOW TO ADVANCE

CLINICAL PROGRAMS IN THE CLINIC IS THE FURTHEST ALONG. WE'VE ALREADY INFUSED SIX PATIENTS IN A RANDOMIZED PLACEBO CONTROLLED CLINICAL TRIAL. WHO ELSE CAN SAY THAT? RANDOMIZED PLACEBO CONTROLLED MULTICENTER CLINICAL TRIAL.

THE COMMERCIAL POTENTIAL WITH THE THERAPEUTIC CANDIDATE HAS BEEN VALIDATED BY JOHNSON & JOHNSON. TALK ABOUT MARKET CAP, $240 BILLION. DO YOU THINK THEY'RE GOING TO STAKE THEIR REPUTATION ON SOME MICKEY MOUSE PRODUCT? WE SPENT A LOT OF TIME TALKING ABOUT THAT THIS MORNING. THE PRESENT PROPOSAL IS ABSOLUTELY READY TO GO INTO PATIENTS. AND IN THE TIME BETWEEN THE LAST ICOC AND THIS ICOC, WHEN WE MIGHT HAVE BEEN ABLE TO START THE TRIAL, WE ESTIMATE THAT ABOUT 10,000 PEOPLE HAVE DIED OF HEART FAILURE IN THE UNITED STATES AND ABOUT A THOUSAND OF THOSE IN THE STATE OF CALIFORNIA ALONE.

SO HOW LONG ARE WE GOING TO SIT ON OUR HANDS? ONE THING THAT WAS RAISED WAS LET'S WAIT FOR THE RESULTS OF THE EXISTING STUDY. LET'S WAIT THREE YEARS. IN THOSE THREE YEARS, ONE AND A HALF MILLION AMERICANS WILL DIE OF THIS DISEASE. DO WE REALLY WANT TO BE ABLE TO GO TO THOSE FAMILIES AND SAY WE SAT ON OUR HANDS AND REFUSED TO FUND THIS WHEN THEY FUND TRANSGENIC ANIMAL WORK IN MICE TO SEE IF SOMETHING MIGHT WORK?

IT'S VERY DIFFERENT THAN THE ALLSTAR TRIAL. IT'S POWERED, AS MR. SHEEHY SAID, TO LOOK AT DEATH. CAN WE SAVE LIVES? THIS IS WHAT WE'RE TRYING TO DO. WE'RE TRYING TO SAVE LIVES. AND, OF COURSE, WE WON'T BE ABLE TO TELL IF WE CAN SAVE LIVES UNTIL WE TRY IT. WE HAVE EVERY SCIENTIFIC RATIONALE TO INDICATE THAT THIS WILL WORK. FDA APPROVES IT AND IRB BOUGHT IT, OUR BIOSAFETY COMMITTEE, AND MULTIPLE MANUSCRIPTS THAT ARE IN PRESS, SOME OF WHICH HAVE BEEN PROVIDED TO THE REVIEW PANEL, VALIDATE THE CONCEPT. IT'S AN EXCITING CONCEPT. I'M INVITED TO TALK ABOUT IT EVERYWHERE IN THE WORLD. AND IRONICALLY I COME TO THIS BOARD, WHO IS CHARGED WITH TAKING TREATMENTS INTO PATIENTS, AND I GET A ROADBLOCK. WHAT IS THIS? WHY ARE YOU PUTTING A ROADBLOCK IN FRONT OF YOUR MOST ADVANCED CLINICAL PROGRAM?

THE RE-REVIEWER, I'M SORRY, BUT IT WASN'T REALLY A REVIEW. IT WASN'T REALLY A RE-REVIEW. YOU SAID IT WASN'T. IT WAS SOME KIND OF WHITEWASH. THERE IS SIGNIFICANT OUTRAGE IN THE SCIENTIFIC COMMUNITY OVER THE INITIAL REVIEW. I GOT FOUR UNSOLICITED PHONE CALLS FROM THE PEOPLE IN THAT ROOM SAYING THAT VENTURE CAPITALISTS HAD TANKED THE APPLICATION. SOMEBODY VOTED TWO OUT OF A HUNDRED. TWO OUT OF A HUNDRED. THAT'S JUST THOUGHT BALLING, AND IT WAS A VENTURE CAPITALIST.

IT WASN'T A SCIENTIST. PLEASE LET US UPHOLD THE INTEGRITY OF THIS INSTITUTION. THANK YOU VERY MUCH.

MR. SHEEHY: CAN I ASK ONE MORE QUESTION OF YOU, DR. MARBAN? SO THE PRODUCT THAT YOU NOW HAVE IN PHASE II YOU BROUGHT TO THE GRANTS REVIEW GROUP IN DISEASE TEAM II?

DR. MARBAN: IT WAS A DISEASE TEAM II.

MR. SHEEHY: AND WHAT SCORE DID YOU GET THEN?

DR. MARBAN: IT WAS IN THE SECOND TIER. WE HAD OTHER PROGRAMS --

MR. SHEEHY: BUT YOU GOT A LOW SCORE, RIGHT?

DR. MARBAN: YES. JOHNSON & JOHNSON SUBSEQUENTLY --

MR. SHEEHY: AND SUBSEQUENTLY YOU'VE BEEN APPROVED FOR PHASE II AND YOU'VE GOTTEN A COLOSSAL INVESTMENT FROM JOHNSON & JOHNSON. SO MAYBE THE GRANTS WORKING GROUP DOESN'T ALWAYS GET IT RIGHT.

DR. QUINT: AGREED.

MR. SHEEHY: JUST TO MAKE THE POINT, THIS IS PROGRAMMATIC REVIEW AND WHERE WE'RE SUPPOSED TO LOOK, NOT SO MUCH AT THE SCIENCE, BUT AT THE PORTFOLIO. AND REALLY WHAT YOU WERE TRYING TO DO IS MAKE A DIFFERENCE IN PATIENT'S LIVES. IF YOU PUT THIS PRODUCT INTO SOMEONE AND THEY DON'T DIE, WE WILL KNOW THAT A YEAR, TWO YEARS?

DR. MARBAN: ARE YOU TALKING ABOUT WITH THE EXISTING TRIAL?

MR. SHEEHY: DYNAMIC.

DR, MARBAN: DYNAMIC. WILL WE HAVE EFFICACY DATA? THE INTERESTING THING ABOUT THE DYNAMIC POPULATION IS THAT WE HAVE A 40-PERCENT YEARLY EVENT RATE FOR THE MAJOR EVENTS OF DEATH OR REHOSPITALIZATION. IF WE WERE TO DECREASE THIS BY 25 PERCENT, WE WOULD KNOW THAT WITHIN TWO YEARS THAT, WITHIN THIS PATIENT POPULATION THAT WE SEEK TO STUDY, WE WILL GET A ROBUST EFFICACY SIGNAL.

MR. SHEEHY: I HAD MICHAEL FRIEDMAN, ANNE-MARIE, OS. I'VE LOST CONTROL OF MY LIST, BUT I HAVE MICHAEL FRIEDMAN, ANNE-MARIE, ART, AND THEN OS. DOES THAT SOUND FAIR TO EVERYBODY? OS AND ART.

DR. FRIEDMAN: THANK YOU. MAY I ALSO JUST ASK A COUPLE OF QUESTIONS EITHER FROM STAFF OR FROM THE PRINCIPAL INVESTIGATOR? IS THE DOSE THAT YOU'VE IDENTIFIED FOR THE PHASE II TRIAL THAT'S CURRENTLY ONGOING, THE RANDOMIZED STUDY, IS THAT THE SAME DOSE AND SCHEDULE AS YOU'RE PLANNING TO USE IN THIS NEW POPULATION, NEW SET OF POPULATIONS?

DR. MARBAN: NO, IT'S NOT. ACTUALLY IT'S A VERY IMPORTANT POINT BECAUSE TO TRIVIALIZE THE SAFETY ASPECT OF THE VALIDATION BY THE FDA IS TO DO ME AND THE

FDA A DISSERVICE. IT'S A THREE TIMES HIGHER DOSE USING A NOVEL DELIVERY METHOD. SO IT'S NOT JUST A RUBBER STAMP TRIAL IN ANOTHER PATIENT POPULATION COMPLETELY REVALIDATED. THEY FORCED US TO DO A NEW IND. AS EVERYBODY IN THE ROOM WHO'S SAVVY ABOUT THESE THINGS WILL RECOGNIZE, THEY DON'T FORCE YOU TO DO AN IND WHEN IT'S JUST THE SAME PRODUCT IN A DIFFERENT POPULATION. THEY SAW IT AS SUBSTANTIVELY DIFFERENT.

DR. FRIEDMAN: AND THE SECOND QUESTION, PLEASE, IS JUST AN EXTENSION OF WHAT DR. QUINT WAS ASKING. IS IT POSSIBLE TO IDENTIFY ONE OR TWO MORE HOMOGENEOUS POPULATIONS IN THIS SICKER GROUP OF PATIENTS THAT YOU'VE TALKED ABOUT DEALING WITH?

DR. MARBAN: IT IS. AND MY UNDERSTANDING IS THAT THE MAJOR CONCERN, WHICH IS A GENUINE ONE IN THE FIELD, NOT SPECIFIC TO THIS TRIAL, BUT TO ALL PATIENTS WITH HEART FAILURE, IS WHETHER HEART FAILURE, ONCE IT GETS TO THE FINAL COMMON PHENOTYPE OF BREATHLESSNESS AND DECREASED EXERCISE TOLERANCE AND HIGH MORTALITY, WHETHER ALL THOSE PATIENTS SHOULD BE LUMPED TOGETHER OR NOT.

TRADITIONALLY THEY HAVE BEEN. THERE ARE PROBABLY 45 *NEW ENGLAND JOURNAL* PAPERS USING THAT PARADIGM OF LUMPING TOGETHER ISCHEMIC AND NONISCHEMIC DILATED CARDIOMYOPATHY. WE SEE NO FUNDAMENTAL

MECHANISTIC DIFFERENCE BETWEEN THE TWO ONCE YOU GET TO THAT ADVANCED HEART FAILURE STAGE. AND SO WE THOUGHT IT WOULD BE A DISSERVICE TO THE PATIENT POPULATION TO PRESUME THAT WE KNEW BETTER AND THAT WE WOULD ONLY STUDY A SUBSET.

DR. FRIEDMAN: WELL, I UNDERSTAND THAT AND RESPECTFULLY I PROBABLY DISAGREE WITH THAT, NOT BECAUSE I KNOW SO MUCH ABOUT CARDIAC PHYSIOLOGY, WHICH I DON'T, AND I'M VERY RESPECTFUL OF WHAT YOU ALL ARE SAYING. I'M LOOKING AT THIS FROM THE POINT THAT WAS MADE EARLIER TODAY, WHICH IS TIME IS THE MOST PRECIOUS RESOURCE, BUT DOLLARS -- TIME FOR PATIENTS IS THE MOST PRECIOUS RESOURCE, BUT DOLLARS IS PROBABLY THE SECOND MOST PRECIOUS RESOURCE. AND WHAT YOU WANT TO DO AT THE END OF A STUDY, WHETHER IT'S POSITIVE OR NEGATIVE, IS TO BE ABLE TO USE IT IN A CONSTRUCTIVE FASHION TO MAKE YOUR NEXT STEP JUST AS YOU'VE USED YOUR FIRST STUDY TO LEVERAGE THE SECOND STUDY. AND I THINK AT LEAST I'M VERY CONGRATULATORY ABOUT THAT. I THINK THAT'S A TERRIFIC WAY TO DO IT.

THE ONLY THING THAT I WOULD ASK FOR, AND I DON'T HAVE STANDING TO MAKE THIS REQUEST, BUT I'M JUST SAYING THAT IF YOU HAD A MORE HOMOGENEOUS POPULATION, IT WOULD MAKE IT MORE ATTRACTIVE TO INDUSTRY. I CAN PROMISE YOU THAT. IT WILL MAKE THE FDA REGULATORY PATH

FAR CLEARER AND FAR FASTER, AND WE'LL END UP HELPING MORE PATIENTS MORE QUICKLY. SO, AGAIN, YOU MAY TELL ME THAT THAT'S NOT POSSIBLE, AND I RESPECT YOUR KNOWLEDGE IN THIS REGARD, BUT IT'S A DIFFERENT STUDY, IT'S A DIFFERENT DOSE, IT'S A DIFFERENT SCHEDULE. AND TO LEARN SOMETHING POSITIVE OR NEGATIVE ABOUT IT, I THINK, WOULD ADVANCE THE FIELD.

DR. MARBAN: I THINK WHAT YOU'RE RAISING IS A SCIENTIFICALLY VALID QUESTION. AND THAT IS WHETHER, IF I MIGHT REPHRASE IT, COULD WE APPROPRIATELY POWER THIS STUDY SO THAT WE GET A YES-NO ANSWER FOR PROCEEDING EITHER WITH AN ISCHEMIC OR NONISCHEMIC DILATED CARDIOMYOPATHY BECAUSE OF THE 7 MILLION PEOPLE IN THE UNITED STATES THAT HAVE THIS, IT'S ABOUT HALF AND HALF. THAT WOULD BE SOMETHING THAT WE COULD EASILY MODIFY WITHIN PROTOCOL, BUT IF IT'S OBVIOUSLY GOING TO BE VOTED AWAY.

DR. FRIEDMAN: BUT THE MAIN CAUSE AND EFFECT HERE.

DR. MARBAN: WHEN I HAD DISCUSSIONS WITH DR. FEIGAL, I INDICATED THE WILLINGNESS TO WORK WITH CIRM TO REDEVELOP THE PROTOCOL AND REFINE IT. I DIDN'T JUST LISTEN.

MR. SHEEHY: SHOULD EITHER THE MOTION OR THE SECOND -- THE MAKER OF THE MOTION OR SECOND MAYBE WANT

TO ATTACH THAT CONDITION? IF EVERYBODY -- THAT THIS IS PURSUED IN A HOMOGENEOUS POPULATION, WHICH SEEMS TO BE ONE OF THE MAIN SCIENTIFIC OBJECTIONS?

DR. STEWARD: I'M SORRY. YOU CAN'T REWRITE THE PROPOSAL.

DR. BOXER: I'D LIKE TO SUGGEST THAT WE ACTUALLY HEAR FROM THE GRANT REVIEWERS. WE'VE HEARD THIS SIDE. I'D LOVE TO HEAR THE OTHER SIDE NOW.

MR. SHEEHY: THEY'RE NOT HERE.

DR. BOXER: SOMEBODY HAD A SUMMARY OF IT.

DR. SAMBRANO: WE CAN PRESENT THE SUMMARY OF THE GRANTS WORKING GROUP REVIEW THAT CAN HIGHLIGHT SOME OF THESE POINTS.

DR. PRIETO: AND CAN WE SEE THE SCORES?

DR. STEWARD: JUST IN THAT REGARD, CAN I JUST INTRODUCE THAT? WE'VE HEARD -- LET ME JUST SAY I AM HIGHLY RESPECTFUL OF THIS PROPOSAL. I'M HIGHLY RESPECTFUL OF THE PREVIOUS WORK THAT'S BEEN DONE. AND BY THAT I MEAN I'M RESPECTING THE PROPOSAL AS WRITTEN AND REVIEWING IT IN THAT CONTEXT, NOT IN THE CONTEXT OF OTHER WORK THAT'S BEEN TRULY SPECTACULAR. SO LET ME JUST MAKE THAT POINT.

IN TERMS OF SHOWING THE SCORES, WE HAVE HEARD THE CLAIM THAT ONE REVIEWER SKEWED THE RESULTS. AND SEEING THE SCORES WILL TELL US THE EXTENT TO WHICH

THAT'S TRUE.

DR. SAMBRANO: CERTAINLY. SO THE SCORE THAT THIS APPLICATION RECEIVED WAS A 48. THAT'S THE MEAN. THE MEDIAN WAS A 50. THE RANGE WAS 20 TO 74. SO THERE WAS NO ONE WHO SCORED A TWO. THE RANGE IN THE BROADNESS OF 20 TO 74 WAS ACTUALLY SIMILAR TO A LOT OF THE APPLICATIONS THAT WERE IN TIER III OR ABOVE. AND I THINK SOME OF THAT BREADTH IN THE SCORES WAS JUST DIFFERENT REVIEWERS SCORING -- IT CALIBRATED SLIGHTLY DIFFERENTLY. SO THIS WAS NOT UNUSUAL AMONG ALL THE TIER III APPLICATIONS.

SO THAT'S ALSO SOMETHING THAT WE EXAMINED WHEN WE WERE LOOKING AT THE CONFLICT OF INTEREST ALLEGATION. WAS THERE A CLEAR INDICATION THAT ANY GIVEN REVIEWER, NOT JUST THE ONE THAT WE WERE LOOKING AT, MAY HAVE INFLUENCED THE REVIEW IN SUCH A WAY THAT IT WAS UNFAIR. AND WE FOUND NONE DESPITE HAVING THE SCORES BEING BROAD BECAUSE I THINK THERE WAS JUST DIFFERENT WAYS IN WHICH THE REVIEWERS EXPRESSED THEIR FEELING ABOUT THE APPLICATION, BUT YOU WILL ALSO NOTE THAT NONE OF THEM SCORED WITHIN TIER I.

DR. DULIEGE: I'M HAPPY TO HEAR YOUR COMMENTS FIRST AND THEN I HAVE A QUESTION FOR DR. MARBAN AFTER THAT.

DR. STEWARD: I'M REALLY SORRY, BUT I HAVE TO

JUST MAKE A PROCEDURAL POINT HERE. WE'RE DOING SOMETHING TODAY THAT IS UNPRECEDENTED. I THINK THAT IF WE HAD GIVEN ALL OF THE PI'S ON ALL THE APPLICATIONS THE OPPORTUNITY TO ESSENTIALLY HAVE A DEBATE WITH US, THAT IT REALLY MAKES A HUGE DIFFERENCE IN TERMS OF HOW WE THINK. PROCEDURALLY I WOULD RECOMMEND THAT WE GO FORWARD WITH THE USUAL PROCEDURE IN WHICH ANYONE FROM THE PUBLIC CAN SPEAK AND MAKE THEIR POINTS, BUT NOT A CONTINUAL BACK AND FORTH DEBATING EACH AND EVERY POINT HERE. THANK YOU.

MR. SHEEHY: JUST IN TERMS OF PROCESS AND PRECEDENT, WE ACTUALLY DID HAVE A DEBATE WITH CLIVE SVENDSEN OVER HIS GRANT THAT WE DIDN'T APPROVE.

DR. STEWARD: I DIDN'T THINK THAT WAS RIGHT EITHER.

MR. SHEEHY: OKAY. MAYBE THAT REPRESENTS -- FOR ME PERSONALLY, BECAUSE THIS IS PROGRAMMATIC REVIEW, WE DON'T DO THAT AT THE WORKING GROUP ANYMORE, I THINK REALLY GETTING TO THE BOTTOM OF WHETHER OR NOT THIS IS GOING TO MAKE A DIFFERENCE IN A PATIENT'S LIFE IS PRETTY IMPORTANT TO ME. AND I WOULD THROW PROCESS OUT THE WINDOW FOR A RESULT. AND SO THAT'S KIND OF WHERE I COME FROM. WE STORM THE BARRICADES.

DR. MILLAN: MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND COLLEAGUES, I'LL BE PRESENTING THE

ORIGINAL SUMMARY FROM THE GRANTS WORKING GROUP REVIEW FOR THIS APPLICATION. SO IN THIS PROPOSAL, THE APPLICANT REQUESTS TO FUND A PHASE I-II CLINICAL TRIAL WITH CARDIAC-DERIVED STEM CELLS FOR THE TREATMENT OF PATIENTS WITH DILATED CARDIOMYOPATHY, AN ADVANCED FORM OF HEART FAILURE.

THE INVESTIGATOR PLANS TO ASSESS SAFETY AND TO EXPLORE PRELIMINARY EFFICACY MEASURES FOR THE THERAPEUTIC INTERVENTION BY PERFORMING FUNCTIONAL TESTS AND CARDIAC IMAGING ALONG WITH OBSERVATION FOR CLINICAL EVENTS.

THE REVIEWERS AGREED THAT THE PROPOSED THERAPEUTIC CANDIDATE ADDRESSES AN UNMET MEDICAL NEED WITH HIGH MORTALITY AND HIGH HEALTHCARE COSTS. THEY ALSO JUDGED THE TEAM TO BE STRONG AND, IN FACT, THAT THE PRODUCT IS READY TO GO INTO CLINICAL TESTING. HOWEVER, CIRM IS CURRENTLY FUNDING THE PHASE II ALLSTAR TRIAL WITH THIS SAME THERAPEUTIC PRODUCT CANDIDATE IN ANOTHER SUBGROUP OF CARDIAC PATIENTS.

THE REVIEWERS FELT THAT IT WOULD BE IMPORTANT TO FIRST GET EFFICACY AS WELL AS SAFETY DATA FROM THIS TRIAL TO INFORM DECISIONS AND THE DESIGN OF FUTURE TRIALS, INCLUDING THAT IN THIS PARTICULAR SUBGROUP OF PATIENTS.

IN ADDITION, THE REVIEWERS EXPRESSED STRONG

CONCERNS REGARDING THE CLINICAL TRIAL DESIGN AMONG WHICH IS THE INCLUSION OF AN OVERLY BROAD PATIENT POPULATION WITH HETEROGENEOUS ETIOLOGIES LEADING TO ADVANCED DILATED CARDIOMYOPATHY. THEY BELIEVE THAT THESE CONSIDERATIONS WOULD NEGATIVELY IMPACT THE ABILITY TO GAIN USEFUL INFORMATION.

THE REVIEWERS ALSO QUESTIONED THE SCIENTIFIC RATIONALE FOR GOING INTO THIS PARTICULAR DISEASE INDICATION. AND IN PARTICULAR, THEY QUESTIONED THE PLAUSIBILITY FOR A MECHANISM OF ACTION THAT WOULD IMPACT THE ADVANCED CARDIOMYOPATHY WHERE THERE'S SIGNIFICANT FIBROSIS AND SCARRING OF THE HEART.

SO THE FINAL SCORE FOR THIS APPLICATION IS 48, PLACING IT IN TIER III.

DR. DULIEGE: I REALIZE THE PROCESS, SO I'D LIKE TO HEAR IF I CAN ASK QUESTIONS OF DR. MARBAN OR IF IT'S INAPPROPRIATE IN TERMS OF THE PROCESS. WITH THE PERMISSION OF THE CHAIR, MAYBE CLARIFY FOR US, BECAUSE I CAN'T REMEMBER EXACTLY THE FOCUS OF THE ALLSTAR TRIAL, HOW THE TWO TRIALS ARE DIFFERENT. IS IT THE CASE THAT, IN FACT, IT'S THE TWO SPECTRUMS OF THE SAME DISEASE, THAT THEY ALSO MAY BE IN A LESS SICK PATIENT POPULATION, WHILE THE DYNAMIC TRIAL MAY BE IN A VERY SICK PATIENT POPULATION? THE VERY LAST COMMENT THAT YOU JUST MADE IS THE ONE THAT FOR ME HAS THE MOST

RELEVANCE. WE COULD DISCUSS ALL THE OTHERS, BUT THIS ONE IS. ISN'T THAT THE FACT, THAT GIVEN THE AMOUNT OF FIBROSIS, THERE MAY BE A LOWER LIKELIHOOD OF BEING ABLE TO REGENERATE SOMETHING COMPARED TO THE ALLSTAR TRIAL? THAT'S MY FIRST QUESTION.

AND THEN MY SECOND, IF YOU DON'T MIND TO ANSWER THOSE TOGETHER, AS JOHNSON & JOHNSON IS PART OF THE EQUATION, WHAT WAS THEIR REACTION, AND COULD THEY ACTUALLY SPONSOR THIS TRIAL?

DR. MARBAN: LET ME SPEAK TO THE FIRST QUESTION, WHICH IS THE ONE OF EXTENSIVE FIBROSIS. EVERYTHING WE KNOW ABOUT THE THERAPEUTIC CANDIDATE TELLS US THAT IT HAS MULTIPLE ACTIONS WHICH WE'RE BEGINNING TO UNDERSTAND THE MECHANISMS OF HOW THOSE ACTIONS COME TOGETHER. BUT ONE OF THE MOST PROMINENT ACTIONS IS AN ANTIFIBROTIC ACTION. INDEED IN THE CADUCEUS TRIAL, WHICH WE REPORTED IN THE *LANCET*, 50 PERCENT OF THE SCAR THAT WAS PRESENT IN THE HEART IN THOSE HEART ATTACK PATIENTS WENT AWAY AND WAS REPLACED BY LIVING MYOCARDIUM. AND IT WAS SCAR THAT WAS WELL ESTABLISHED.

THE MAJOR PATHOPHYSIOLOGIC DIFFERENCE WITH THIS PATIENT POPULATION IS THAT THEY HAVE MORE SCAR THAT'S LONGER ESTABLISHED. WE HAVE NO REASON A PRIORI TO THINK THAT THAT'S NECESSARILY GOING TO BE A MORE

REFRACTORY TARGET, BUT I FEEL WE OWE THIS PATIENT POPULATION THE OPPORTUNITY TO RECEIVE NEW THERAPY. THERE HAS NOT BEEN A SINGLE MAJOR THERAPEUTIC ADVANCE IN HEART FAILURE IN THE LAST 15 YEARS.

THE NATURE OF THE JOHNSON & JOHNSON AND CAPRICOR RELATIONSHIP IS ONE GOVERNED BY CORPORATE SECRECY. I REALLY CAN'T COMMENT ON THAT, BUT I WOULD BE HIGHLY OPTIMISTIC THAT JOHNSON & JOHNSON OR ANY OTHER CORPORATE PARTNER WOULD BE EXTREMELY ENTHUSIASTIC ABOUT GOING INTO A POPULATION AND THEY CAN FINALLY GET AWAY FROM SURROGATE END POINTS.

ALLSTAR IS GOING TO TELL US ABOUT SCAR SIZE. SCAR SIZE IN ITSELF IS A BEAUTIFUL END POINT BECAUSE IT THEN INCREASES THE RISK FOR DEATH. BUT HERE WE'RE GOING TO BE LOOKING AT DEATH AND REHOSPITALIZATION DIRECTLY. IF WE WERE TO WAIT AND DO THE SEQUENTIAL APPROACH, WE WOULD HAVE TO WAIT THREE YEARS AND LOSE THE OPPORTUNITY TO IMPACT MEANINGFULLY ON THOSE PATIENTS. WHY NOT TAKE MORE SHOTS ON GOAL WHEN WE ALREADY HAVE A THERAPEUTIC THAT'S AS ADVANCED AND IN WHICH CIRM HAS INVESTED AS MUCH AS THIS ONE?

MR. SHEEHY: OKAY. OTHER COMMENTS OR QUESTIONS? CHAIRMAN THOMAS.

CHAIRMAN THOMAS: SO I WANT TO START BY SAYING, DR. MARBAN, WE'RE VERY, VERY HOPEFUL ABOUT THE

CAPRICOR PROJECT AND OBVIOUSLY ARE STRONGLY ROOTING FOR IT TO SUCCEED. HAVING SAID THAT, THERE ARE ISSUES AS TO WHETHER OR NOT A PARTICULAR THERAPEUTIC CANDIDATE CAN WORK IN ONE VERSION OF AN INDICATION VERSUS ANOTHER AND IS FOR THAT REASON THAT YOU HAVE APPLIED HERE AND THAT WE HAVE GONE THROUGH THE PROCESS THAT DR. SAMBRANO HAS DESCRIBED.

WE HAVE, AS YOU KNOW, A FAIRLY IN-DEPTH APPELLATE PROCESS NOW IN LIGHT OF THE IOM RECOMMENDATIONS, WHICH IS THAT SOMEBODY CAN OBJECT ON THE GROUNDS OF CONFLICT, WHICH YOU HAVE. WE'VE HAD A DISCUSSION HERE ABOUT WHETHER OR NOT THAT CONFLICT WAS DEEMED SOMETHING THAT WAS, IN FACT, PROBLEMATIC TO THE PROCESS. AND ACCORDING TO WHAT IS, I'M SURE, AN EXTENSIVE REVIEW, IT WAS DETERMINED THAT IT WASN'T.

WE THEN HAVE ALSO AVAILABLE THE AVENUE OF APPEALING BASED ON A COUPLE OF DIFFERENT PARTICULAR CRITERIA. YOU'VE CHOSEN THE MATERIAL NEW INFORMATION APPROACH. AND UNDER OUR POST-IOM CRITERIA, THE REVIEW GOES TO STAFF TO MAKE A DETERMINATION AS TO WHETHER OR NOT THAT APPEAL HAS MERIT AND SHOULD RESULT IN A REVERSAL OF THE GRANTS WORKING GROUP RECOMMENDATION.

STAFF SPENT A VERY CONSIDERABLE AMOUNT OF EFFORT AND DILIGENT TIME LOOKING INTO THAT AND DETERMINED THAT THE MERIT OF THAT REVIEW WAS NOT THERE.

NONETHELESS, AS THEY SAID, IN ABUNDANCE OF CAUTION, WHICH IS NOT SOMETHING THAT WAS NECESSARY, THEY PUT TOGETHER A PANEL OF THREE CONSISTING OF THE GRANTS WORKING GROUP CHAIR AND, MOST NOTABLY, TWO EXPERTS IN HEART CONDITIONS AND CARDIOLOGY. AND IN REVIEWING THAT, THE MATERIAL NEW INFORMATION THAT YOU DID SUBMIT, THEY DETERMINED THAT IT DID NOT GIVE RISE TO A CONCLUSION THAT, HAD THAT INFORMATION BEEN AVAILABLE TO THE GRANTS WORKING GROUP, IT WOULD HAVE ALTERED THE SCORING IN ANY WAY THAT WOULD HAVE MATERIALLY IMPROVED EITHER THE SCORE OR LED TO A RECOMMENDATION FOR FUNDING.

STAFF TOOK ANOTHER LOOK AT THAT, AND THEY CONCUR WITH THAT AND HAVE COME BACK TO US, STICKING TO THE RECOMMENDATION THAT WE NOT APPROVE THIS AWARD. NOW, AS YOU KNOW, IN CAPRICOR'S INSTANCE, THE GRANTS WORKING GROUP DID NOT APPROVE ORIGINALLY. AND ONE OF THE ISSUES THAT THEY DIDN'T APPROVE WITH RESPECT TO THAT FUNDAMENTALLY CHANGED BETWEEN TIME OF THE GRANTS WORKING GROUP AND THE TIME WHERE THE BOARD CONSIDERED DISEASE TEAM II AWARDS, AND IN THAT INSTANCE STAFF CAME TO US WITH A STRONG RECOMMENDATION THAT WE MOVE TO PUT THAT UP INTO THE RECOMMENDED FOR APPROVAL CATEGORY, WHICH WE DID. AS WE SAY, WE ARE STRONG ROOTERS, IN FACT, THE STRONGEST THAT YOU HAVE OUT THERE OF THAT.

IN THIS INSTANCE, WE'VE GONE THROUGH AN EXHAUSTIVE NUMBER OF STEPS. WE HAVE LITERALLY RUN THROUGH OUR ENTIRE APPELLATE PROCESS, AND AT EACH STAGE OF THE GAME, THE RECOMMENDATION HAS BEEN NOT TO FUND.

NOW, YOU'VE MADE SOME FAIRLY SERIOUS COMMENTS ABOUT THE PROCESS, HOW VENTURE CAPITALISTS TANKED THE SCORING IN THE GRANTS WORKING GROUP REVIEW. DR. SAMBRANO, I'M JUST CURIOUS. WERE THERE ANY VENTURE CAPITALISTS IN THAT GRANTS WORKING GROUP?

DR. SAMBRANO: NOT IN THIS PARTICULAR REVIEW.

CHAIRMAN THOMAS: OKAY. YOU'VE ALSO MADE SOME COMMENTS ABOUT HOW THE ADVICE GIVEN BY THE IMPANELED GROUP OF THREE, INCLUDING TWO HEART SPECIALISTS, AMOUNTED TO AND I THINK YOUR WORD WAS A WHITEWASH, WHICH SORT OF DIRECTLY CHALLENGES THE INTEGRITY OF THAT REVIEW PROCESS OR ADVISORY PROCESS, I SHOULD SAY. THOSE ARE SERIOUS CHARGES.

I BELIEVE THAT AS A BOARD, WHEN FACED WITH A FULL SLATE OF DIFFERENT PARTIES REVIEWING A PARTICULAR APPLICATION AND THE WORD COMES BACK THAT WE SHOULD NOT APPROVE FOR FUNDING, THAT THE BOARD HAS TO TAKE THAT VERY SERIOUSLY NOTWITHSTANDING THE HOPE THAT MIGHT BE ENGENDERED BY YOUR PROJECT. AND I DO BELIEVE THAT STAFF, IN TALKING TO YOU ABOUT WAYS TO PERHAPS ALTER THE TRIAL DESIGN, GIVES AN OPPORTUNITY TO COME BACK AT

A LATER DATE; IS THAT CORRECT?

DR. FEIGAL: YES.

CHAIRMAN THOMAS: AND SO WITH ALL OF THAT IN MIND, IT IS MY OPINION THAT WE SHOULD FOLLOW THE ADVICE AND FOLLOW THE PROCESS AND NOT APPROVE THIS FOR FUNDING.

MR. SHEEHY: CAN I ASK A QUESTION OF DR. SAMBRANO? SO WERE THERE ANY CALIFORNIA RESIDENTS AS REVIEWERS?

DR. SAMBRANO: AS REVIEWERS IN THE GRANTS WORKING GROUP? IN THE PANEL, YES.

MR. SHEEHY: HAS THAT EVER HAPPENED BEFORE?

DR. SAMBRANO: WELL, THEY HAVEN'T -- SO WHENEVER WE HAVE A CALIFORNIA RESIDENT, THEY ONLY FUNCTION AS SPECIALISTS. SO, YES, THAT HAS OCCURRED AT DIFFERENT GRANTS WORKING GROUP REVIEWS AS NEEDED. SO OFTEN WHEN WE HAVE THE REQUIREMENT FOR A SPECIFIC SPECIALTY, WE'LL BRING SOMEBODY IN. BUT NONE OF THOSE REVIEWERS THAT FUNCTIONED AS SPECIALISTS WHO WERE CALIFORNIA RESIDENTS AT THE DISEASE TEAM REVIEW PARTICIPATED SPECIFICALLY IN THE REVIEW OF THIS APPLICATION.

MR. SHEEHY: I'M JUST ASKING BECAUSE IT'S BEEN MY UNDERSTANDING THAT CALIFORNIA RESIDENTS, WE WENT FOR ALL OF OUR REVIEWERS OUTSIDE OF CALIFORNIA.

THAT'S ALWAYS BEEN MY UNDERSTANDING.

DR. SAMBRANO: WELL, THAT'S CORRECT. AS MEMBERS OF THE GRANTS WORKING GROUP.

MR. SHEEHY: DON'T WE ALWAYS HAVE TO APPROVE SPECIALISTS AND REVIEWERS GENERALLY?

DR. SAMBRANO: IT DOES NOT APPLY TO SPECIALISTS. IT APPLIES TO ALL GRANTS WORKING GROUP MEMBERS. BUT BASED ON CONVERSATIONS WITH LEGAL COUNSEL, AND THAT WAS A QUESTION WE HAD IN TERMS OF WHEN WE NEED PARTICULAR EXPERTISE AND IT HAPPENS THAT SOMEBODY IS A CALIFORNIA RESIDENT, DOES THAT BECOME AN ISSUE FOR BRINGING THEM IN AS A SPECIALIST. AND IT DOES NOT, AT LEAST NOT LEGALLY.

SO BECAUSE A SPECIALIST DOES NOT ACTUALLY SCORE ON AN APPLICATION, AND THEY ALSO DO NOT VOTE, IT DIDN'T BECOME AN ISSUE FOR US.

MR. SHEEHY: WAS THE BOARD MADE AWARE THAT THIS POLICY CHANGE HAD TAKEN PLACE?

DR. SAMBRANO: I DON'T KNOW THAT --

MR. SHEEHY: THIS HAS BEEN THE POLICY --

DR. SAMBRANO: -- IT WAS A POLICY CHANGE.

MR. SHEEHY: IT HAS BEEN THE PRACTICE, FROM MY UNDERSTANDING, THE CALIFORNIANS WOULD NOT BE PART OF THE REVIEW PROCESS.

DR. SAMBRANO: FOR GRANTS WORKING GROUP,

THAT'S CORRECT. I DON'T THINK WE EVER ADDRESSED WHAT THE QUALIFICATIONS OF THE SPECIALISTS WOULD BE OTHER THAN THEY WOULD RESPECT THE SAME CONFLICT OF INTEREST RULES.

MR. SHEEHY: THEN ALSO WAS THERE ANYBODY PARTICIPATING IN THE REVIEW WHO WAS CONFLICTED ON THE GRANT BECAUSE THEY WERE CONSULTING OR A MEMBER OF A GRANT THAT WAS ALSO UNDER CONSIDERATION?

DR. SAMBRANO: I DON'T KNOW THAT. I KNOW THERE WAS ONE INDIVIDUAL THAT IS LISTED AS HAVING A CONFLICT. SO THERE WAS A GRANTS WORKING GROUP MEMBER THAT WAS RECUSED. AND THE REASON THAT THEY HAD THAT CONFLICT, I DON'T KNOW, BUT IT CERTAINLY COULD HAVE BEEN BECAUSE THEY HAD CONSULTED.

MR. SHEEHY: THERE WERE PEOPLE IN THE ROOM -- THERE WAS AT LEAST ONE MEMBER OF THE GRANTS REVIEW GROUP WHO WAS CONFLICTED ON A GRANT BECAUSE THAT REVIEWER WAS ON A GRANT THAT WAS ALSO UNDER REVIEW IN THAT ROUND, WHICH IS ALSO NOVEL FOR OUR PROCESS.

DR. SAMBRANO: I DON'T BELIEVE THAT'S THE CASE, BUT WE CAN TALK ABOUT IT OFF LINE.

MR. SHEEHY: WE PROBABLY SHOULD. SO I JUST HAVE ISSUES. IT JUST SEEMS LIKE THERE HAVE BEEN CHANGES IN THE GRANTS REVIEW GROUP. SO I THINK ACTUALLY, UNLESS THERE'S MORE DISCUSSION, ARE WE READY

TO VOTE?

MS. LANSING: I'D LIKE TO CALL FOR THE VOTE.

MR. SHEEHY: PUBLIC COMMENT. DON REED.

MR. REED: I DISLIKE ALL OF THE NEGATIVITY SURROUNDED WITH SOMETHING THAT SHOULD BE SO BEAUTIFUL. I LOVE THIS CIRM STAFF. I THINK THEY'RE HONORABLE PEOPLE, AND I THINK THEY'RE TRYING TO DO THE BEST THEY CAN WITH A DIFFICULT JOB.

THAT BEING SAID, THIS IS THE NO. 1 KILLER OF PEOPLE. THIS IS THE NO. 1 KILLER OF PEOPLE. THINK WHAT IT WOULD MEAN TO EVERY CONDITION IF CIRM COULD GET A VICTORY AGAINST THE NO. 1 KILLER OF PEOPLE. THIS IS THE GUY WITH THE BEST RECORD IN THE FIELD. I THINK HE REALLY KNOWS WHAT HE'S TALKING ABOUT. I ALSO THINK THAT HE TAKES IT ON AS A PERSONAL CHALLENGE THAT HE WILL NOT REST UNTIL HE SUCCEEDS. I THINK THIS IS THE KIND OF PERSON WE SHOULD FUND. I THINK THIS IS THE KIND OF PROJECT THAT WE SHOULD FUND. THANK YOU.

MR. SHEEHY: SO ARE WE READY FOR A ROLL CALL?

MR. ROWLETT: CAN YOU RESTATE WHAT WE'RE VOTING ON?

MR. SHEEHY: THE MOTION ON THE FLOOR IS TO APPROVE THIS APPLICATION FOR FUNDING.

MS. LANSING: DID THE MOTION -- THE MOTION ON THE FLOOR IS TO APPROVE THIS APPLICATION WHICH HAS

ALREADY BEEN REJECTED; IS THAT RIGHT?

MR. SHEEHY: YES. IT'S TO APPROVE IT FOR FUNDING, SHERRY. SO THIS IS THE MARBAN.

MS. LANSING: I KNOW WHAT IT IS. I JUST WANT TO SAY THAT I AGREE WITH J.T. THAT WE FOLLOWED THE PROCESS AND I THINK THAT WE SHOULD NOT MAKE EXCEPTION.

MR. HARRISON: JUST ONE CLARIFICATION. THE APPLICATION REVIEW SUBCOMMITTEE WILL BE CONSIDERING THIS MOTION. SO MEMBERS WHO ARE APPOINTED FROM INSTITUTIONS THAT ARE ELIGIBLE FOR FUNDING, ALTHOUGH YOU WERE PERMITTED TO PARTICIPATE IN THE DISCUSSION, WILL NOT BE CALLED UPON TO VOTE.

MR. ROWLETT: CAN YOU REMIND US OF WHO THAT IS?

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: NO.

MS. BONNEVILLE: SHERRY LANSING.

MS. LANSING: NO.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: NO.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: NO.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: NO.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: NO.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: NO.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: NO.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MR. HARRISON: THAT MOTION FAILS WITH THREE YES VOTES AND EIGHT NO VOTES.
CHAIRMAN THOMAS: THANK YOU, EVERYBODY.
NOW MOVE ON TO THE NEXT ITEM, WHICH IS ITEM 16, CONSIDERATION OF APPOINTMENT OF NEW SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP AND REAPPOINTMENT OF EXISTING MEMBERS. DR. SAMBRANO.
DR. SAMBRANO: MR. CHAIRMAN AND MEMBERS OF THE BOARD, WE ARE BRINGING FOR YOUR CONSIDERATION TWO THINGS. FIRST ARE FIVE NOMINEES FOR GRANTS WORKING GROUP MEMBERSHIP AND REAPPOINTMENT OF EIGHT EXISTING MEMBERS. THE NAMES AND BIOGRAPHIES OF THE NOMINEES FOR NEW MEMBERSHIP ARE IN YOUR BOOKS. THESE INCLUDE MARGO DEMASER, JANE LARKINDALE, RITA PERLINGEIRO, MICHAEL

PFENNING, AND ROBERT SIMARI.

NOW, IN ADDITION, GRANTS WORKING GROUP MEMBERS THAT WERE ORIGINALLY APPOINTED IN LATE 2007 AND EARLY 2008 HAVE TERMS THAT ARE NOW EXPIRING OR JUST EXPIRED. THE INITIAL APPOINTMENTS ARE USUALLY FOR SIX YEARS EACH. SO WE ARE SEEKING THE REAPPOINTMENT OF THE INDIVIDUALS ON THE TABLE THAT ARE ALSO FOUND IN YOUR BOOKS. I WILL READ THOSE AS WELL. JUST SO YOU KNOW, IN ACCORDANCE WITH THE RULES SET FORTH IN PROPOSITION 71, REAPPOINTMENTS SHOULD BE STAGGERED INTO THIRDS. THAT IS, EACH WITH A TWO-, A FOUR-, OR A SIX-YEAR TERM.

SO WE'RE PROPOSING 2-, 4-, 6-YEAR, THE APPOINTMENT TERMS FOR THE COHORT AS INDICATED IN THE TABLE, AND THESE INDIVIDUALS ARE CHAD COWAN, FREIDA DIANE MILLER, STEPHEN MINGER, PAUL J. SIMMONS, STEPHEN C. STROM, MEGAN SYKES, VIVIANE TABAR, AND JOEL VOLDMAN. SO WE REQUEST YOUR APPROVAL AND APPOINTMENT OF THESE NOMINEES.

CHAIRMAN THOMAS: IS THERE A MOTION TO THAT EFFECT?

MR. TORRES: SO MOVED.

CHAIRMAN THOMAS: MOVED BY SENATOR TORRES.

DR. STEWARD: SECOND.

CHAIRMAN THOMAS: SECONDED BY DR. STEWARD.

WE'RE NOT GOING TO NEED A WHOLE LOT OF

CONVERSATION ON THIS. THESE ARE OBVIOUSLY HIGHLY QUALIFIED PEOPLE WHO WILL BE GOOD ADDITIONS TO THE TEAM. SO WITH THAT, WE NEED A VOICE VOTE. SO ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? OKAY. UNANIMOUSLY PASSED. THANK YOU, EVERYBODY. THANK YOU, DR. SAMBRANO.

NEXT ITEM IS --

MR. HARRISON: YOU HAVE TO DO ROLL CALL OF MEMBERS ON THE PHONE.

CHAIRMAN THOMAS: ON THE LAST ITEM, PLEASE, MARIA IS GOING TO CALL ROLL. SO IF YOU'D JUST SPEAK INDIVIDUALLY TO WE MAKE SURE WE CONFIRM UNANIMITY.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: YES.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: SHERRY LANSING.

CHAIRMAN THOMAS: STILL UNANIMOUS. THANK YOU, EVERYBODY.

NOW GO TO ITEM 13, CONSIDERATION OF THE FINAL ADOPTION OF POLICY AMENDMENTS APPROVED IN RESPONSE TO THE INSTITUTE OF MEDICINE RECOMMENDATIONS.

SO JUST TO SET THE TABLE HERE BEFORE I TURN

IT OVER TO MR. HARRISON, YOU WILL RECALL THAT IN DECEMBER OF 2012, THE IOM ISSUED ITS REPORT WHICH HAD IN IT BOTH A GREAT VALIDATION OF THE WORK THAT CIRM IS DOING IN GALVANIZING THE FIELD OF STEM CELL RESEARCH AND THE PORTFOLIO OF PROJECTS IT HAS PUT TOGETHER AND THE MISSION, BUT AT THE SAME TIME IT HAD A HOST OF RECOMMENDATIONS ON VARIOUS ISSUES RELATED TO CIRM'S PROCESS THAT THEY FELT NEEDED TO BE ADDRESSED.

AT THE JANUARY BOARD MEETING, WHICH HAPPENED THAT WE HAD SCHEDULED A WORKSHOP, YOU WILL RECALL WE SPENT A FULL DAY GOING OVER A SLATE OF RECOMMENDED STEPS THAT I PUT TOGETHER TO ADDRESS THE VARIOUS AND SUNDRY ISSUES RAISED BY THE IOM. WE HAD A LENGTHY AND VERY ROBUST DEBATE OF MANY HOURS THAT DAY. IT ENDED UP WITH A VOTE TO APPROVE THE SLATE OF THE RECOMMENDATIONS. AND MR. HARRISON WILL BE RECOUNTING SORT OF THE KEY ONES IN A MINUTE.

BUT THE NEXT STEP WAS TO PUT ALL OF THOSE STEPS INTO SOMETHING THAT WE ACTUALLY COULD VOTE TO APPROVE. AND THAT WAS DONE AT THE MARCH 2013 BOARD MEETING, AT WHICH POINT WE BOTH APPROVED ALL OF THE RECOMMENDED STEPS AND CHANGES, AMENDMENTS, ETC. AND ALSO AGREED TO SEE HOW EVERYTHING WORKED FOR A YEAR AND TO COME BACK TO THE BOARD WITH A REPORT ON HOW THAT WAS GOING AND HAVE THE BOARD HEAR THAT AND JUST BE PROPERLY

INFORMED AND HAVE ANY DISCUSSION THAT MIGHT BE NECESSARY FLOWING FROM THAT PRESENTATION.

SO, MR. HARRISON, IF YOU COULD PROCEED HERE AND TELL THE BOARD AGAIN WHAT WE ALL VOTED ON ON THE MARCH 2013 AGENDA. AND PLEASE INVITE DISCUSSION FROM ANY MEMBERS OF THE BOARD ON WHAT YOU'RE ABOUT TO HEAR.

MR. HARRISON: THANK YOU. SO AS YOU WILL RECALL, THERE WERE A NUMBER OF IOM RECOMMENDATIONS. SOME OF THEM REQUIRED BOARD ACTION, SOME OF THEM WERE DIRECTED TO STAFF AND WITHIN STAFF'S JURISDICTION. SO WHAT WE'RE BRINGING TO YOU TODAY ARE THOSE ACTIONS THAT YOU APPROVED IN THE FORM OF POLICY CHANGES. AND THERE WERE THREE MAJOR ONES.

YOU MADE AMENDMENTS TO THE BOARD'S BYLAWS, YOU MADE AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS, AND YOU REPEALED THE EXTRAORDINARY PETITION POLICY AND ADOPTED IN ITS PLACE THE APPEALS AND REQUESTS FOR RECONSIDERATION POLICY. SO THOSE ARE THE THREE TOPICS THAT I PLAN ON TAKING YOU THROUGH TODAY.

THE MEMO THAT IS IN YOUR BINDERS PROVIDES A SUMMARY OF THE OTHER ACTIONS IN RESPONSE TO THE IOM REPORT. AND IF YOU HAVE ANY QUESTIONS ABOUT THOSE, I'D BE HAPPY TO ANSWER THEM.

BUT AS THE CHAIR SAID, OUR TASK TODAY IS TO REVISIT THOSE POLICIES THAT WERE ADOPTED WITH THE

PROVISO THAT YOU WOULD HAVE THE OPPORTUNITY TO REVISIT THEM WITHIN ONE YEAR OF ADOPTION TO HAVE A CONVERSATION ABOUT WHETHER OR NOT YOU BELIEVE THE CHANGES HAVE BEEN EFFECTIVE.

SO LET ME BRIEFLY TAKE YOU THROUGH ALL OF THEM. FIRST, AS I MENTIONED, THE BOARD AMENDED ITS OWN BYLAWS AND MADE TWO SIGNIFICANT CHANGES. AS YOU WILL RECALL, ONE OF THE IOM'S MAJOR CONCERNS RELATED TO PARTICIPATION BY MEMBERS ON THE BOARD FROM INSTITUTIONS THAT ARE ELIGIBLE TO RECEIVE CIRM FUNDS IN THE CONSIDERATION OF APPLICATIONS FOR FUNDING, EVEN IF THOSE APPLICATIONS DIDN'T COME FROM THEIR OWN INSTITUTIONS. WHILE THE IOM NOTED THAT IT HAD NOT IDENTIFIED ANY CONFLICTS OF INTEREST, IT STATED THAT THE STRUCTURE OF THE BOARD CREATED THE RISK OF A PERCEPTION OF CONFLICT OF INTEREST.

AS YOU KNOW, WE HAVE ADOPTED VERY RIGOROUS CONFLICT OF INTEREST POLICIES AND HAVE PUT IN PLACE RIGOROUS CONFLICT OF INTEREST PROCEDURES IN ORDER TO GUARD AGAINST ANY CONFLICTS. AND EVEN BEFORE THE IOM REVIEW AND YOUR RESPONSE, YOU DID NOT PARTICIPATE IN ANY APPLICATION IN WHICH YOU HAD A FINANCIAL INTEREST. IN FACT, THE REVIEW WAS CONDUCTED ON A BLIND BASIS, AND WE PROVIDED EACH OF YOU WITH A LIST OF APPLICATIONS IN WHICH YOU HAD AN INTEREST AND VERY DILIGENTLY MONITORED

THE DEBATE TO MAKE SURE THAT NONE OF YOU PARTICIPATED IN THE DISCUSSION OF AN APPLICATION IN WHICH YOU HAD AN INTEREST.

NONETHELESS, THE IOM SEIZED ON THE PERCEPTION OF CONFLICT OF INTEREST AS A CONCERN. AND OUR CHAIR RIGHTLY UNDERSTOOD THAT WE NEEDED TO TAKE THAT SERIOUSLY. SO IN RESPONSE TO THAT, WE DEVELOPED A POLICY WHICH WAS A COMPROMISE, PURSUANT TO WHICH WE CREATED WHAT IS NOW CALLED THE APPLICATION REVIEW SUBCOMMITTEE. IT'S A COMMITTEE OF THE BOARD THAT MEETS CONCURRENTLY WITH THE BOARD, AND IT IS COMPOSED OF THE PATIENT ADVOCATES, THE MEMBERS APPOINTED FROM LIFE SCIENCE COMMERCIAL ENTITIES, AND THE CHAIR AND THE VICE CHAIR. IT ALSO INCLUDES THOSE MEMBERS WHO ARE APPOINTED FROM ACADEMIC AND RESEARCH INSTITUTIONS, BUT THEY ARE CONSIDERED EX OFFICIO MEMBERS, WHICH MEANS THAT THEY HAVE THE OPPORTUNITY TO PARTICIPATE IN THE DISCUSSION OF APPLICATIONS PROVIDED THAT THEY DON'T HAVE AN INTEREST IN THE APPLICATION; BUT, AS THE LAST VOTE MADE CLEAR, THEY DON'T PARTICIPATE IN THE ROLL CALL VOTE.

AS MR. SHEEHY NOTED, THE SUBCOMMITTEE'S CHARGE IS TO CONDUCT PROGRAMMATIC REVIEW, WHICH WAS SHIFTED FROM THE GRANTS WORKING GROUP TO THE BOARD. AND WE HAVE NOW CARRIED OUT SIX MEETINGS AT WHICH THE

BOARD HAS CONDUCTED PROGRAMMATIC REVIEW. AND THUS FAR I THINK IT'S GONE FAIRLY SMOOTHLY.

THE SECOND MAJOR CHANGE THAT THE BOARD MADE TO THE BYLAWS WAS THE TRANSFER OF PROGRAMMATIC REVIEW TO THE APPLICATION REVIEW SUBCOMMITTEE FROM THE BOARD. THE IOM HAD ALSO EXPRESSED CONCERN ABOUT PARTICIPATION BY THE PATIENT ADVOCATES ON THE GRANTS WORKING GROUP AND NOTED THAT, AS A RESULT OF PROGRAMMATIC REVIEW BEING CONDUCTED AT THE GWG, THE PATIENT ADVOCATES EFFECTIVELY VOTED TWICE ON THE SAME APPLICATIONS.

IN RESPONSE TO THAT CONCERN, THE BOARD AMENDED THE BYLAWS TO SHIFT PROGRAMMATIC REVIEW FROM THE GWG TO THE BOARD. OF COURSE, THE PATIENT ADVOCATES CONTINUE TO PARTICIPATE AS MEMBERS OF THE GRANTS WORKING GROUP AND ACT AS A BRIDGE BETWEEN THE GRANTS WORKING GROUP AND THE BOARD, BUT THEY DON'T PARTICIPATE IN VOTES TO MAKE RECOMMENDATIONS TO FUND SPECIFIC APPLICATIONS.

LET ME TURN NEXT TO THE CHANGES TO THE GRANTS WORKING GROUP BYLAWS. AGAIN, THERE WERE THREE IMPORTANT CHANGES HERE. THE FIRST WAS THAT WE ESTABLISHED FIXED FUNDING TIERS. IN THE PAST, BEFORE THE IOM REVIEW, THE GRANTS WORKING GROUP ITSELF USED TO SET THE FUNDING TIERS AFTER IT DID A SCORE OF ALL THE APPLICATIONS BASED ON THE DISTRIBUTION. NOW WE ADVISE

THE GRANTS WORKING GROUP MEMBERS IN ADVANCE OF THE FUNDING TIERS AND MAKE CLEAR TO THEM THAT IF THEY SCORE SOMETHING FROM 75 OR ABOVE, IT MEANS THEY THINK IT SHOULD BE FUNDED. IF IT'S BETWEEN 65 AND 74, IT FALLS WITHIN TIER II. AND IF THEY ASSIGN A SCORE OF 64 OR LESS, IT MEANS THEY DON'T THINK IT SHOULD BE FUNDED.

AS I MENTIONED EARLIER, WE ALSO TRANSFERRED RESPONSIBILITY FOR PROGRAMMATIC REVIEW FROM THE GWG TO THE APPLICATION REVIEW SUBCOMMITTEE. THIS CHANGE DID REQUIRE SOME ADJUSTMENT BY MEMBERS OF THE GRANTS WORKING GROUP WHO HAD BECOME ACCUSTOMED, AFTER COMPLETING THEIR SCIENTIFIC REVIEW OF APPLICATIONS, TO CONSIDERING MOTIONS TO MOVE AN APPLICATION FROM ONE TIER TO ANOTHER BASED ON SCIENTIFIC OR PROGRAMMATIC CONCERNS.

NOW, ONCE THE SCIENTIFIC REVIEW IS COMPLETE AND THEY ASSIGN SCORES, THE ENTIRE GRANTS WORKING GROUP TAKES A MOTION TO FORWARD THE SLATE OF RECOMMENDATIONS ON TO THE BOARD.

THE OTHER SIGNIFICANT CHANGE THAT WAS MADE TO THE GRANTS WORKING GROUP BYLAWS WAS TO INCORPORATE A PROVISION ASSIGNING RESPONSIBILITY TO CIRM STAFF TO REVIEW THE GRANTS WORKING GROUP'S RECOMMENDATIONS AFTER THE REVIEW WAS COMPLETE AND PARTICULARLY WITH RESPECT TO THOSE APPLICATIONS THAT FELL WITHIN TIER II WHERE

THEY COULD BE ELIGIBLE FOR CIRM FUNDING PARTICULARLY IF THERE WERE PROGRAMMATIC RATIONALE TO DO SO. AND THE BOARD ASKED STAFF TO REVIEW THOSE RECOMMENDATIONS AND MAKE ANY RECOMMENDATIONS OF ITS OWN. STAFF HAS NOW DONE THIS 13 TIMES, AND THE BOARD HAS FOLLOWED THOSE RECOMMENDATIONS ALL BUT ONCE.

THE LAST SET OF POLICY CHANGES I WANT TO DISCUSS INVOLVE THE APPEAL AND REQUEST FOR RECONSIDERATION POLICY. THIS WAS OBVIOUSLY PUT INTO PLAY WITH THE APPLICATION SUBMITTED BY DR. MARBAN WHO DID FILE AN APPEAL. IN RESPONSE TO COMMENTS BY THE IOM REGARDING PRESENTATIONS BY PATIENT ADVOCATES AND APPLICANTS BEFORE THE BOARD, PARTICULARLY ON SCIENTIFIC ISSUES, WHERE THE BOARD WAS PUT IN THE POSITION OF TRYING TO MEDIATE THESE SCIENTIFIC DEBATES ON THE FLY, THE BOARD DECIDED TO REPEAL THE EXTRAORDINARY PETITION POLICY.

THIS WAS A POLICY THAT TRIED TO PUT SOME RULES AROUND INTERACTIONS, COMMENTS, AND PUBLIC COMMENT BY APPLICANTS. IN ITS PLACE THE BOARD ADOPTED THE APPEAL AND REQUEST FOR RECONSIDERATION POLICY. AND AS THE CHAIR POINTED OUT, THIS IS AN AVENUE THAT ALLOWS APPLICANTS TO FILE AN APPEAL WITH CIRM STAFF IF THEY BELIEVE THAT THE GRANTS WORKING GROUP MADE A MATERIAL MISTAKE OF FACT OR IF, SUBSEQUENT TO THE GWG REVIEW,

THEY FEEL THEY HAVE MATERIAL NEW INFORMATION THAT ADDRESSED A CRITICISM OF THE GRANTS WORKING GROUP, SUCH AS NEW DATA, A PATENT FILING, OR SOMETHING OF THAT NATURE.

STAFF REVIEWS THESE APPEALS TO MAKE A DETERMINATION OF WHETHER THEY'VE SATISFIED THE THRESHOLD SET BY THIS BOARD FOR MATERIAL NEW INFORMATION AND MATERIAL MISTAKES OF FACT. IF THEY DETERMINED THAT THAT THRESHOLD HAS BEEN SATISFIED, THE PRESIDENT MAKES A DETERMINATION WHETHER ADDITIONAL SCIENTIFIC REVIEW IS WARRANTED. AND IF SO, A SUBGROUP OF THE GRANTS WORKING GROUP IS PULLED TOGETHER, INCLUDING A PATIENT ADVOCATE MEMBER, TO TAKE ANOTHER LOOK AT THE APPLICATION AND DETERMINE WHETHER OR NOT, IN THE VIEW OF THE GROUP, IT WARRANTS RECONSIDERATION OF THE GWG'S RECOMMENDATION.

OF COURSE, MEMBERS OF THE PUBLIC, INCLUDING APPLICANTS AND PATIENT ADVOCATES, CONTINUE TO BE FREE TO APPEAR BEFORE THE BOARD AND TO MAKE PUBLIC COMMENTS AND TO SUBMIT THINGS TO YOU IN WRITING. BUT SINCE THE APPEAL -- SINCE THIS POLICY HAS BEEN ADOPTED, THE BOARD HAS NOT TAKEN ACTION ON A VERBAL APPEAL.

THAT'S A SUMMARY OF THE THREE MAJOR POLICY CHANGES WHICH WERE EMBODIED IN POLICIES ADOPTED BY THE BOARD LAST MARCH. I'D BE HAPPY TO ANSWER ANY QUESTIONS

YOU HAVE ABOUT THEM.

CHAIRMAN THOMAS: SENATOR TORRES ASKED DO WE NEED A MOTION FOR ANYTHING HERE?

MR. HARRISON: WE DO. WE WOULD REQUEST A MOTION TO APPROVE THE AMENDMENTS TO THE BOARD BYLAWS, THE GWG BYLAWS, AND THE ADOPTION OF THE APPEAL AND REQUEST FOR RECONSIDERATION POLICY.

MS. LANSING: I WOULD LIKE TO MOVE THAT MOTION IF THAT'S OKAY.

MR. TORRES: SECOND.

CHAIRMAN THOMAS: MOVED BY SHERRY, SECONDED BY ART. ANY COMMENTS, QUESTIONS FROM MEMBERS OF THE BOARD?

DR. FRIEDMAN: I'M VERY MUCH IN FAVOR OF THIS MOTION. I JUST -- AND IT DOESN'T REQUIRE A MODIFICATION OF THE MOTION. I JUST WOULD LIKE TO RECOMMEND TO STAFF I THINK THERE'S REAL VALUE IN LOOKING CRITICALLY AT HOW SOMETHING HAS FUNCTIONED AND WHETHER WE'VE ACHIEVED THE ENDS THAT WE HOPED TO. AND SO I WAS GLAD THAT WE BUILT IN THIS AUTOMATIC RE-REVIEW AT THIS POINT.

I'M NOT GOING TO ENCUMBER THE MOTION, BUT I'D LIKE TO REALLY STRONGLY SUGGEST THAT YOU PLEASE BRING BACK TO US THE OPPORTUNITY TO DISCUSS TO MAKE FURTHER REFINEMENTS AS WE MIGHT SEE NECESSARY IN THE FUTURE. I

KNOW WE MIGHT DO THIS ON OUR OWN, BUT HAVING SOMETHING FORMAL AND DISCIPLINED BUILT IN, I THINK, SHOWS REALLY RESPONSIBLE GOVERNANCE. AND SO I JUST WOULD REQUEST THAT. THANK YOU.

CHAIRMAN THOMAS: THAT'S AN EXCELLENT IDEA AND LET'S LET IT BE DONE. OTHER COMMENTS? MR. ROWLETT.

MR. ROWLETT: AS PART OF MY ORIENTATION TO THE BOARD, J.T., IT WAS VERY BENEFICIAL TO HAVE YOU AND MARIA AND JAMES COME DOWN AND CHAT WITH ME ABOUT THIS. I THINK THAT THIS POLICY REQUIRES A BIT MORE COMPREHENSION, A MORE COMPREHENSIVE CONVERSATION AND ORIENTATION FOR A NEW BOARD MEMBER. IT WOULD HAVE BEEN VERY HELPFUL TO HAVE GOTTEN A LITTLE BIT MORE OF THIS IN THE BEGINNING AS IT BENEFITS ME IN MAKING DECISIONS AS A BOARD MEMBER. SO THANK YOU VERY MUCH FOR THE INFORMATION. BUT FOR THE NEWER BOARD MEMBERS, I WOULD REALLY CONSIDER HOW YOU ORIENT THEM TO THIS ASPECT OF THE POLICY.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS? JUST A LAST ONE FROM MY PERSPECTIVE AT ANY RATE. I THINK THAT THE BOARD TOOK A BOLD STEP HERE ON A NUMBER OF FRONTS IN RESPONDING TO THE RECOMMENDATIONS OF THE IOM. WE MADE SOME VERY FUNDAMENTAL CHANGES. AND HAVING SEEN IT PLAY OUT OVER THE COURSE OF THE YEAR, I

THINK WE SHOULD BE VERY HAPPY WITH HOW THINGS HAVE DEVELOPED AND HOW WE'VE CAPTURED THE SPIRIT OF WHAT THE IOM WANTED US TO DO AND, IN FACT, HAVE IMPROVED OUR PROCESS. SO I THINK WE SHOULD BE HAPPY WITH WHAT WE DID.

SO, JAMES, JUST VOICE VOTE OR WHAT DO WE NEED HERE?

MR. HARRISON: PUBLIC COMMENT.

CHAIRMAN THOMAS: PUBLIC COMMENT. YES.

MR. REED: I JUST WOULD LIKE TO GO ON RECORD AS SAYING THAT THIS WAS DONE ON THE BASIS OF AFFECTING A PERCEPTION, NOT A REALITY. THERE WAS NOT A CONFLICT OF INTEREST. NOBODY CONCRETELY CAME FORWARD AND SAID THERE WAS. THE ONE WAS TAKEN FOR A FULL YEAR AND A HALF BY THE FAIR POLITICAL PRACTICES COMMITTEE, AND THEY CAME BACK AND SAID THERE HAD BEEN NO CONFLICT OF INTEREST, NONE.

LISTEN TO WHAT THE *LOS ANGELES TIMES* SAID. WE THINK CHAIRMAN THOMAS AND THE OVERSIGHT BOARD SHOULD GO FURTHER AND ADOPT THE INSTITUTE OF MEDICINE RECOMMENDATION. THAT IS POLITICALLY UNLIKELY AS IT IS NOW OBVIOUS IT WILL BE UP TO THE LEGISLATURE TO FULLY REMOVE REPRESENTATIVES OF FUNDING ELIGIBLE INSTITUTES FROM BEING INVOLVED IN DECISIONS ABOUT GRANTS THAT COULD COME BACK TO THEM.

THOSE WHO ARE NOT SATISFIED WILL NEVER BE SATISFIED. WE HAD A GREAT THING. I UNDERSTAND THE POLITICAL REASONS FOR DOING THIS, BUT I JUST, IN MY HEART, I FEEL A RESENTMENT THAT WE HAD TO BOW TO THE UNFAIR CRITICISMS THAT WERE PUT AGAINST US.

CHAIRMAN THOMAS: THANK YOU, MR. REED.

DR. TROUNSON: I KIND OF SUPPORT DON REED IN THAT REGARD. IN SOME RESPECTS, AS I'M TRAVELING OUT THE DOOR, THE NEED TO HAVE REALLY GOOD QUALITY SCIENCE ON THE BOARD, I THINK, IS REALLY IMPORTANT. AND I THINK IT'S SOMETIMES A BIT DISAPPOINTING THAT THE MEMBERSHIP OF THOSE IMPORTANT UNIVERSITIES CAN'T BE PART OF IT AND HAVE CONFLICTS BECAUSE I THINK THEIR ROLE IS REALLY VERY CRITICAL. AND SO I HOPE IF THERE IS ANOTHER PROPOSITION SOMETIME, THAT THERE'S SOME THOUGHT GIVEN TO THAT BECAUSE I THINK SCIENCE IN THIS AREA REALLY, LIKE BUSINESS, NEEDS TO BE PART OF THE BOARD AS WELL AS THE PATIENT ADVOCATES. AND IT'S IMPORTANT FOR THAT TO EVOLVE.

AND I THINK -- I DON'T THINK THERE WAS ANY EXAMPLE OF CONFLICTS FROM THOSE MEMBERS. I THINK THEY KNEW PRETTY WELL WHAT THEY WERE DOING, BUT I UNDERSTAND THAT THAT WAS THE BEST WAY WE COULD GO FORWARD WITH THE IOM REPORT. BUT IT'S IMPORTANT IN THE FUTURE, HOPEFULLY, IF THERE'S ANOTHER PROPOSITION, TO SORT OF

THINK THEIR WAY THROUGH THAT KIND OF ISSUE.

CHAIRMAN THOMAS: THANK YOU, DR. TROUNSON. I WILL SAY THAT WE MADE A VERY STRONG POINT IN FASHIONING THE COMPROMISE WITH RESPECT TO THE POINTS DR. TROUNSON MAKES TO ALLOW FOR FULL PARTICIPATION AND DISCUSSION OF ALL THE SCIENTIFIC MEMBERS OF THE BOARD AS WE JUST SAW IN THIS LAST DISCUSSION, AND THAT PROVIDED EXTREMELY VALUABLE INPUT TO THE WHOLE PROCESS. AND WHILE IT IS ABSOLUTELY TRUE THERE'S NEVER BEEN ANY DEMONSTRATED CONFLICT OF INTEREST, PERCEPTION CAN BE REALITY. SO WE DID NEED TO DO SOMETHING, AND I THINK THIS COMPROMISE IS THE BEST THAT WE COULD FASHION ON THAT AND STILL MAINTAIN FULL INPUT FROM VERY VALUABLE MEMBERS OF THE SCIENTIFIC COMMUNITY.

SO, MR. HARRISON, AGAIN, VOICE VOTE, ROLL CALL VOTE?

MR. HARRISON: IT CAN BE A VOICE VOTE, BUT ROLL CALL FOR THOSE ON THE PHONE.

CHAIRMAN THOMAS: THANK YOU. OKAY. ALL THOSE IN FAVOR OF THIS MOTION TO APPROVE THE IOM RECOMMENDATIONS PLEASE SAY AYE. MR. SHEEHY, WAS THAT AN AYE FROM BACK THERE? MARIA, CAN YOU POLL THOSE ON THE PHONE?

MS. BONNEVILLE: SHERRY LANSING.

MS. LANSING: YES.

MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: KEN BURTIS.
DR. BURTIS: YES FROM KEN BURTIS HERE IN JAPAN WHERE THE SUN IS ABOUT TO COME UP.
CHAIRMAN THOMAS: I JUST GOT TO SAY, KEN, THIS IS SO FAR ABOVE AND BEYOND THE CALL, AND I HOPE EVERYBODY APPRECIATES THIS IS AN ENORMOUS SACRIFICE ON YOUR PART. AND THANK YOU VERY, VERY MUCH.
DR. BURTIS: THANK YOU, J.T. ACTUALLY I'M OVER HERE AS A GUEST OF THE NARA INSTITUTE OF SCIENCE AND TECHNOLOGY, WHICH SOME OF YOU MAY KNOW AS THE FIRST HOME OF SHINYA YAMANAKA WHERE HE DID HIS FIRST EXPERIMENTS ON IPS CELLS. AND SO I SAW THE SMALL SHRINE THEY PUT UP FOR HIM IN THEIR INSTITUTE WHERE THEY'VE ENSHRINED HIS MICROSCOPE. AND IT REMINDED ME ABOUT THE INTERNATIONAL STEM CELL BIOLOGY AND HOW IMPORTANT BOTH BASIC RESEARCH AND THE KIND OF LEVERAGING THAT CIRM HAS DONE AS TO PROGRESS IN THIS FIELD. IT'S A PLEASURE TO SPEND THE NIGHT WITH YOU.
CHAIRMAN THOMAS: THANK YOU, AND IT'S ONLY FITTING THAT THAT'S WHERE YOU ARE AT THIS MOMENT.
MR. TORRES: I JUST WANT TO SAY, KEN, YOU'VE

MADE ALL CAL. ID'S PROUD.

DR. BURTIS: THANK YOU, SIR.

CHAIRMAN THOMAS: NEXT, WE ARE GOING TO POSTPONE ITEM 15, WHICH IS THE RESOLUTION FOR MARCY BECAUSE SHE'S SINCE MOVED TO NORTH CAROLINA, VERY REGRETTABLY, AND WAS NOT ABLE TO BE ON THE PHONE EITHER. SO WE'D LIKE TO TRY TO BRING IT BACK IN MAY WHEN SHE CAN BE PROPERLY THANKED AND HAVE HER PARTICIPATE. SO IF YOU WOULD TABLE THAT, MARIA, FOR THE NEXT MEETING, PLEASE.

LET'S SEE. YES. THE ALWAYS IMPORTANT CONSIDERATION OF THE MINUTES.

MS. LANSING: SO MOVED.

CHAIRMAN THOMAS: THANK YOU. SHERRY, YOU'D BE PLEASED TO KNOW THAT IT'S NOT ONE, BUT TWO MEETINGS WORTH OF MINUTES THAT YOU'RE MOVING ON.

MS. LANSING: OH, MY GOD. I'M SO HAPPY.

MR. TORRES: I'LL KEEP MY RECORD OF SECONDING SHERRY'S MOTIONS.

CHAIRMAN THOMAS: VERY GOOD. SMART MAN, SENATOR TORRES. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED?

ON TO COMMUNICATIONS UPDATE. KEVIN.

MR. MCCORMACK: WHY DON'T WE TAKE A TWO-MINUTE BREAK WHILE WE ADJUST FOR COMMUNICATIONS.

THERE'S ICE CREAM.

CHAIRMAN THOMAS: TAKE A COMMUNICATIONS ICE CREAM BREAK. BE BACK IN A FEW.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: OKAY, EVERYBODY. LET'S PLEASE RESUME HERE. ON NOW TO COMMUNICATIONS. THE ESTEEMED MR. MCCORMACK.

MR. MCCORMACK: THANK YOU, CHAIRMAN THOMAS, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND MY ESTEEMED COLLEAGUES. I WAS ALWAYS TOLD THAT IF YOU WANT TO GET PEOPLE'S ATTENTION, ALWAYS SPEAK AFTER A BATHROOM BREAK AND WHEN THEY'VE HAD ICE CREAM. SO EVERYTHING IS DONE FOR A PURPOSE.

I'D LIKE TO TALK FIRST ABOUT THE ANNUAL REPORT WHICH IS -- YOU ALL GOT A COPY OF IT. THAT JUST CAME OUT THIS WEEK, AND IT'S SOMETHING WE'RE OBLIGED TO DO, BUT I THINK IT'S SOMETHING THAT WE DO PARTICULARLY WELL BECAUSE WHEN I WAS IN NEWS JOURNALISM, WE WERE ALWAYS GETTING ANNUAL REPORTS FROM PEOPLE THAT WERE AMAZINGLY THICK, VERY GLOSSY, AND VERY EXPENSIVE LOOKING, AND NO ONE EVER READ THEM. I ALWAYS WONDERED WHAT WAS THE POINT.

THE LAST COUPLE OF YEARS WE'VE SWITCHED TO A MUCH SLIMMER MODEL WHERE WE HAVE SOME FAIRLY BASIC INFORMATION, BUT IT'S PERTINENT INFORMATION. IT'S

ABOUT THE WORK WE'VE DONE IN THE LAST YEAR. I THINK IT'S REALLY IMPORTANT AND REALLY INTERESTING, AND MORE IMPORTANT IS IT GUIDES YOU BACK TO THE WEBSITE SO YOU CAN GET AS MUCH MORE INFORMATION AS YOU WOULD LIKE.

I'D LIKE TO THANK TODD DUBNICOFF FOR HELPING SPEARHEAD THIS PROJECT. TODD'S OVER THERE. HE DID AN AMAZING JOB OF PULLING TOGETHER ALL THE INFORMATION THAT GOES INTO THIS. IT'S QUITE A COMPLICATED PROJECT. I'D ALSO LIKE TO THANK DR. KELLY SHEPARD, OUR SCIENCE OFFICER, AND DOUG KEARNEY IN OUR GRANTS MANAGEMENT SYSTEM FOR HELPING PROVIDE ALL THE BACKUP STATISTICS.

I ALSO JUST WENT ROUND AND GAVE YOU A COPY OF THIS, WHICH IS A BROCHURE, THE "INDUCED PLURIPOTENT STEM CELL INITIATIVE." AND THIS WAS PUT TOGETHER BY GEOFF LOMAX. THIS WILL BE A KIND OF SUPPLEMENT TO OUR IPS BANKING INITIATIVE. AND THE IDEA IS THAT IF PEOPLE ARE THINKING OF GIVING TISSUES, IF PEOPLE ARE THINKING OF GIVING SAMPLES, THEY NEED TO KNOW WHAT IT IS THEY'RE DOING, WHAT IT'S GOING TO BE USED FOR, AND HOW IT'S GOING TO BE USED. THIS IS A WONDERFUL BROCHURE THAT REALLY WALKS PEOPLE THROUGH ALL THE DIFFERENT STEPS OF WHAT A STEM CELL IS, WHAT IT DOES, HOW IT WORKS, AND HOW IT CAN BE REALLY A USEFUL TOOL IN HELPING US DISCOVER TREATMENTS FOR A LOT OF THE DIFFERENT DISEASES.

GEOFF DID AN AMAZING JOB IN PULLING IT TOGETHER, AND A LOT OF OTHER PEOPLE WHO HELPED HIM. I THINK IT WILL BE A VALUABLE TOOL, NOT JUST FOR THIS INITIATIVE, BUT I THINK FOR ANYONE WHO'S TRYING TO COME UP WITH WAYS TO INCREASE PARTICIPATION IN RESEARCH, WHICH IS SUCH AN IMPORTANT PART OF WHAT WE DO.

IN TERMS OF MEDIA COVERAGE, WE'VE HAD QUITE A LOT LATELY. AND I THINK MOST OF YOU SAW THE CLIP ON PBS ON THE *NEWS HOUR* ABOUT THE SEARCH FOR A CURE FOR HIV/AIDS. IT WAS A GREAT PIECE. IT WAS MORE THAN SEVEN MINUTES LONG, WHICH IN TV TIME IS AN ETERNITY. AND IT ALSO AIRED ON NPR STATIONS AROUND THE COUNTRY. SO IT REALLY GOT A GREAT AUDIENCE.

I WOULD LIKE TO THANK JEFF SHEEHY FOR HELPING MAKE THIS HAPPEN. JEFF HEARD THAT SPENCER MICHAELS AT PBS WAS DOING A PIECE ON THE SEARCH FOR THE CURE. AND SO HE HELPED US INSINUATE OURSELVES INTO THE PIECE AND GET THEM TO INTERVIEW CAL-IMMUNE BECAUSE, QUITE FRANKLY, IF YOU'RE DOING A STORY ABOUT THE SEARCH FOR A CURE, THE ONLY COMPANY DOING A CLINICAL TRIAL ON A CURE OR ON A THERAPY FOR HIV/AIDS RIGHT NOW IS CAL-IMMUNE. SO IT MADE PERFECT SENSE FOR THEM TO DO THAT, AND WE WERE MENTIONED AS PART OF THAT.

IT'S ALSO INTERESTING TO THINK THAT IT SPRANG OUT OF A TOWN HALL, AN HIV TOWN HALL MEETING THAT WE

HAD LAST YEAR THAT, AGAIN, JEFF WAS INSTRUMENTAL IN HELPING PLAN AND ORGANIZE. AND WE HAD SOMETHING LIKE A HUNDRED DIFFERENT MEMBERS OF THE PUBLIC THERE TO HEAR VARIOUS PRESENTATIONS FROM CIRM STAFF, FROM CAL-IMMUNE, AND MEMBERS AT UCSF, AND GLADSTONE INSTITUTE ON THE DIFFERENT APPROACHES THAT ARE BEING TAKEN TO TRY AND FIND A THERAPY. SO IT WAS A RELATIVELY SMALL MEETING. IT WAS A VERY GOOD MEETING, BUT IT WAS INTERESTING THAT OUT OF THAT MEETING OF MAYBE A HUNDRED, HUNDRED TEN PEOPLE, WE THEN HAD SOMETHING LIKE THIS THAT WAS HEARD AND SEEN BY MILLIONS. SO WE'RE GOING TO BE DOING MORE OF THOSE. WE'RE GOING TO BE DOING ANOTHER EVENT IN L.A. LATER THIS YEAR ON THAT SAME THEME.

THE GENOMICS INITIATIVE THAT YOU VOTED ON AT THE LAST BOARD MEETING GOT A LOT OF ATTENTION. IT WAS IN THE *CHRONICLE*, THE *SAN DIEGO UNION TRIBUNE*, *BUSINESS TIMES*, LOTS OF THE BUSINESS CHANNELS, IN FACT. WE'VE ALSO HAD STORIES ON ABC 7 TV AND NBC 4 AT THE NBC STATION IN LOS ANGELES. DID A REALLY GOOD PIECE ON DR. SLAMON'S CANCER THERAPY WHICH HOPEFULLY WILL BE GOING TO CLINICAL TRIALS THIS YEAR.

GETTING A STORY ON LOCAL NEWS IN AMERICA IS INCREASINGLY DIFFICULT BECAUSE THERE ARE VERY FEW SPECIALIST HEALTH REPORTERS LEFT. BUT DR. BRUCE HINSHAW AT NBC IN L.A. IS A VERY GOOD REPORTER AND DID

A REALLY INTERESTING, REALLY WELL THOUGHT OUT PIECE, AND IT HIGHLIGHTED ONE OF THE STORIES THAT COULD BE REALLY EXCITING FOR THE NEXT YEAR.

WE'VE ALSO BEEN DOING A LOT OF PATIENT OUTREACH, TALKING TO DIFFERENT COMMUNITY GROUPS. SUNDAY ASSEMBLY IS A RELATIVELY NEW ONE FOR US. THIS IS A GROUP, THEY CALL THEMSELVES CHURCH FOR PEOPLE WHO DON'T WANT TO GO TO CHURCH. IT BEGAN IN ENGLAND ABOUT A YEAR AGO. IT WAS ALL GOOD THINGS TOO. AND QUICKLY SPREAD TO AMERICA. AND WHAT IT IS IS IT'S FOR PEOPLE WHO WANT A SENSE OF COMMUNITY, A SENSE OF BELONGING AND ORGANIZATION, BUT WITHOUT ANY OF THE RELIGIOUS OVERTONES SO OFTEN INVOLVED IN GOING TO CHURCH.

AND SO I GAVE A TALK AT THE SAN JOSE SUNDAY ASSEMBLY, AND IT WAS ONLY THE SECOND ONE THEY'D EVER HAD. AND THERE WERE ABOUT 120 PEOPLE THERE, AND THIS WAS ON THE MORNING THAT THE 49ERS WERE PLAYING THE CAROLINA PANTHERS. SO CLEARLY THIS IS A VERY DEVOTED GROUP OF PEOPLE. AND THE RESPONSE WAS GREAT, AND IN FACT IT LED TO SEVERAL OTHER OPPORTUNITIES TO GO AND SPEAK TO OTHER GROUPS AROUND THE BAY AREA.

RECENTLY MY COLLEAGUE, DON GIBBONS, GAVE A TALK TO THE SAN FRANCISCO AND OAKLAND SUNDAY ASSEMBLY. AND, AGAIN, THE RESPONSE THERE WAS REALLY GOOD. SO THIS IS A GREAT WAY OF REACHING OUT TO PEOPLE WHO CARE

ABOUT SCIENCE, WHO CARE ABOUT THE WORLD AROUND THEM, AND ARE COMMITTED TO THAT AND WANT TO HEAR ABOUT WHAT WE'RE DOING.

AGAIN, THESE ALWAYS LEAD ON TO OTHER OPPORTUNITIES. WE'VE GIVEN A NUMBER OF TALKS AT THE ROTARY CLUBS AROUND THE BAY AREA AND DOING MORE OF THOSE. AND AT CAL. NORTH STATE UNIVERSITY IN RANCHO CORDOVA, WHICH I'D NEVER HEARD OF, BUT WHICH IS QUITE A BIT NORTH OF SACRAMENTO, SO IT MADE FOR A LOVELY DRIVE ON THE WETTEST NIGHT OF THE YEAR FOR ME. THE AUDIENCE WAS GREAT. IT WAS LIKE ABOUT 120 PHARMACY STUDENTS WHO WERE REALLY INTERESTED IN WHAT WE'RE DOING. THEY DIDN'T KNOW VERY MUCH ABOUT IT, BUT THEY HAD SOME GREAT QUESTIONS. AND HOPEFULLY THEY CAME AWAY WITH A BETTER PICTURE OF WHAT IT IS THAT WE'RE TRYING TO DO.

WE'VE HIT A COUPLE OF MILESTONES LATELY ON OUR SOCIAL MEDIA SITES. WE PASSED THE 1,000 BLOG NUMBER. AND HERE ARE SOME OF THE TOP THREE. THESE ARE THE TOP THREE BLOGS THAT WE'VE DONE OVER THE YEAR. AS YOU CAN SEE, IT'S A FAIRLY DIVERSE GROUP OF BLOGS REFLECTING THE DIFFERENT AUDIENCES WE REACH. MY FAVORITE IS THE FAMILY GUY TV CARTOON WHERE HE TALKED ABOUT STEM CELLS, AND THEY'VE GOT A GREAT AUDIENCE. AND I JUST THINK IT SHOWS THAT THERE ARE LOTS OF DIFFERENT APPROACHES TO SOCIAL MEDIA, LOTS OF DIFFERENT

WAYS OF TELLING THE SAME STORY OR REACHING OUT TO DIFFERENT AUDIENCES, AND WE HAVE TO BE FLEXIBLE AND OPEN ABOUT HOW WE DO THAT. AND THE MORE OPPORTUNITIES WE SEE, THE MORE THINGS WE TRY, THEN THE MORE EFFECTIVE WE'LL BE AS COMMUNICATORS BECAUSE THE PUBLIC IS EAGER FOR INFORMATION. WE JUST HAVE TO FIND WAYS TO REACH THEM AND GET THEM TO THAT.

SOME OF OUR OTHER MOST POPULAR BLOGS DEALT WITH VERY DISEASE-SPECIFIC AREAS, SUCH AS HIV, PARKINSON'S, AND ALZHEIMER'S. THE OTHER SOCIAL MEDIA MILESTONE WE HIT WAS OUR YOUTUBE CHANNEL HAS HAD A MILLION HITS. NOT QUITE MILEY CYRUS LEVEL, BUT WE'RE WORKING ON IT. TODD WAS GOING TO DO ONE ON A WRECKING BALL, BUT WE JUST COULDN'T GET THE PLANNING PERMISSION.

SO IT'S BEEN GREAT. WE HAVE SOMETHING LIKE 400 DIFFERENT VIDEOS ON OUR YOUTUBE CHANNEL RIGHT NOW, AND THEY REPRESENT A WIDE RANGE OF THINGS FROM OUR ELEVATOR PICTURES, WHICH ARE FAIRLY SHORT, TO FOUR- OR FIVE-MINUTE PIECES ON TYPE 1 DIABETES. WE GET A BROAD RANGE OF AUDIENCES FOR THESE, AND THEY'RE REALLY EFFECTIVE WAYS OF REACHING OUT TO DIFFERENT COMMUNITIES. AND THE VIDEO YOU SAW TODAY, THE MOTHER TALKING ABOUT HER SON, AGAIN, THAT'S AN AMAZINGLY POWERFUL TOOL TO BE ABLE TO USE WHEN YOU WANT TO TELL PEOPLE ABOUT WHY WHAT WE DO IS IMPORTANT, WHY WHAT WE

DO HAS VALUE. YOU CAN JUST SHOW A VIDEO LIKE THAT, AND IT CUTS THROUGH ALL THE CLUTTER, IT CUTS THROUGH ALL THE JARGON, AND DRIVES HOME A VERY IMPORTANT POINT ABOUT WHY STEM CELL RESEARCH IS SO IMPORTANT TO SO MANY PEOPLE.

COUPLE OF EVENTS COMING UP. WE HAVE A GOOGLE HANGOUT ON LEUKEMIA. THIS IS ONE OF OUR SERIES OF ONLINE WEBINARS THAT WE'VE BEEN DOING. THIS IS OUR FOURTH ONE NOW, AND THIS ONE IS GOING TO BE ON LEUKEMIA MARCH 25TH. IT'S GOT AN ALL STAR CAST OF DR. CATRIONA JAMIESON AT UC SAN DIEGO, DR. RAVI MAJETI AT STANFORD, AND OUR OWN DR. KAREN BERRY. SO THAT PROMISES TO BE REALLY INTERESTING.

AND THEN WE HAVE A PATIENT ADVOCATE MEETING IN SACRAMENTO ON MARCH 26TH. AGAIN, THIS IS ONE OF THE SERIES THAT WE'VE BEEN TRYING TO DO AROUND THE STATE WHERE WE VISIT THE MAJOR CITIES, THE MAJOR REGIONS AROUND THE STATE TO BRING OUR MESSAGES DIRECTLY TO THE PATIENT ADVOCATES. THEY'RE OUR BIGGEST SUPPORTERS, OUR BIGGEST CHAMPIONS, AND THIS IS A CHANCE TO GO TO SACRAMENTO AND WORK WITH OUR COLLEAGUES AT THE UC DAVIS INSTITUTE FOR REGENERATIVE CURES AND TALK TO ALL THE PATIENT ADVOCATES AND OUR FRIENDS THERE ABOUT THE WORK THAT WE'RE DOING.

CHAIRMAN THOMAS: KEVIN, CAN I JUST ADD A

LITTLE BIT TO THAT? THIS IS THE LATEST IN A SERIES OF MEETINGS WE'VE HAD AROUND WITH PATIENT ADVOCATES TO GET THEM FULLY UP TO SPEED ON WHAT WE'RE DOING, WHICH IS VERY IMPORTANT. THIS HAS GOT A LITTLE EXTRA GOING ON THIS ONE BECAUSE, IN ADDITION TO THE PATIENT ADVOCATES, WE HAVE INVITED A NUMBER OF SENIOR STAFF MEMBERS FROM THE CONSTITUTIONAL OFFICES TO JOIN US. AND WE'RE GOING TO HAVE SENIOR STAFF PEOPLE FROM THE GOVERNOR'S OFFICE, THE TREASURER'S OFFICE, AND THE CONTROLLER'S OFFICE COMING BOTH TO THE PATIENT ADVOCATE MEETING AND THEN STAYING FOR A TOUR OF THE UC DAVIS FACILITY.

SO THIS IS SOMETHING WE THINK WILL MAKE IT A LOT MORE REAL. THEY'VE HEARD ABOUT US FOR QUITE SOME TIME, OF COURSE, BUT THIS WILL BRING IT FRONT AND CENTER TO THEM AND I THINK WILL FURTHER INCREASE THEIR UNDERSTANDING AND SUPPORT FOR WHAT WE'RE DOING.

MR. MCCORMACK: AND AS ALWAYS, I'D LIKE TO SAY IF YOU HAVE ANY REQUESTS FOR SPEAKERS IN AND AROUND YOUR REGIONS, LET ME KNOW. WE'RE ALWAYS HAPPY TO TRY AND ARRANGE SOMEONE TO COME AND TALK ABOUT THE WORK THAT WE DO.

ON MARCH 29TH CHAIRMAN THOMAS IS GOING TO BE SPEAKING AT A PARKINSON'S EVENT IN PASADENA. THESE ARE GREAT WAYS TO REACH OUR AUDIENCE, TO REACH A GROUP OF PEOPLE WHO REALLY ARE HUNGRY FOR WHAT WE'RE TALKING

ABOUT. SO IF YOU HAVE ANY IDEAS, ANY THOUGHTS, FEEL FREE TO CONTACT ME. HAPPY TO TAKE ANY QUESTIONS. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, KEVIN.

SO WE'RE NOW BACK TO THE FUTURE HERE, CIRCLE BACK TO THE NORMAL FIRST COUPLE OF ITEMS. THE CHAIR'S REPORT, I'LL ATTEMPT TO BE FAIRLY BRIEF.

ON THE SUSTAINABILITY FRONT, WHICH IS PRIORITY NO. 1, I CAN JUST REPORT TO YOU THAT WE'VE HAD A LOT OF ACTIVITY IN THAT REGARD IN TRYING TO LOOK FOR AND IDENTIFY ALTERNATIVE FUNDING. AS I'VE SAID IN THE PAST, AT SUCH TIME AS WE'RE READY TO BRING A REPORT TO YOU ON THAT ACTIVITY, WE WILL DOWN THE ROAD, BUT JUST WANT EVERYBODY TO KNOW THERE'S QUITE A BIT GOING ON IN THAT REGARD, AND WE WILL BE BACK TO YOU AT A LATER DATE.

THE SECOND ITEM WE'VE ALREADY DISCUSSED IN QUITE A BIT OF DETAIL, WHICH IS THE PRESIDENTIAL SEARCH. I DON'T THINK WE NEED TO REVISIT THAT AT THIS POINT, BUT THAT HAS TAKEN UP A LOT OF TIME FOR THE CHAIR'S OFFICE AND A NUMBER OF MEMBERS OF THE BOARD WHO ARE PARTICIPATING.

LASTLY, JUST NOTE THERE HAVE BEEN A NUMBER IN THE SERIES OF OUR GRANTEE INSTITUTIONS HAVING CONFERENCES PULLING TOGETHER STEM CELL SCIENTISTS BOTH

FROM THEIR PARTICULAR FACILITY AS WELL AS OTHERS FROM OUTSIDE. I'VE HAD THE PRIVILEGE TO SPEAK AT A COUPLE OF THESE, AS I HAVE EVERY YEAR. IN THE LAST INTERIM BETWEEN THE LAST BOARD MEETING, UCLA HAD ITS 10TH ANNUAL WHICH DOUBLED AS A 65TH BIRTHDAY CELEBRATION FOR DR. WITTE, WHICH WAS A GOOD TIME HAD BY ALL.

AND SECONDLY, THE LATEST IN, I BELIEVE IT WAS, THE 7TH ANNUAL STEM CELL CONFERENCE AT CHILDREN'S HOSPITAL IN LOS ANGELES AT THE SABAN RESEARCH INSTITUTE. I HAD A GOOD OPPORTUNITY IN BOTH INSTANCES TO VISIT WITH A NUMBER OF OUR GRANTEES AND TO TALK TO A NUMBER OF ASPIRING GRANTEES WHO ARE HOPEFUL THAT THEY'LL HAVE AN OPPORTUNITY TO APPLY FOR AND GET FUNDING FROM US FOR THEIR PROJECTS GOING DOWN THE ROAD.

SO WITH THAT, LET ME TURN IT OVER TO DR. TROUNSON FOR THE PRESIDENT'S REPORT.

DR. TROUNSON: THANK YOU, CHAIR. IT'S A LITTLE DIFFERENT COMING IN THE END. I WANT TO THANK ALL THE BOARD MEMBERS FOR ALL THE SUPPORT OF THE WORK THAT MANAGEMENT'S DONE AND PRESENTED TO YOU TODAY, WHICH HAS BEEN OVER THE LAST FEW MONTHS. A NUMBER OF YOU WOULD BE AWARE THAT I'VE BEEN IN AUSTRALIA BEING A GRANDFATHER, AND SO THAT OCCUPIED ME FOR A WEEK OR SO AND, WITHOUT APOLOGY, TO LINK UP WITH FAMILY.

SO THE TEAM HAS DONE A GREAT JOB, HEADED BY

ELLEN IN MY ABSENCE. AS USUAL, SHE DID WONDERFULLY WELL, AND I HAVE SUCH ADMIRATION FOR ALL THE MANAGEMENT TEAM. EVERY ONE OF THEM, INCLUDING MANDA, WHO'S MY ASSISTANT HERE WHO GETS ME IN AND OUT PLACES ALL THE TIME, WHICH I CAN'T DO BY MYSELF. I KNOW. I TRIED AND I CAN'T ACTUALLY DO IT.

AND I HOPE THAT I WILL BE ABLE TO SEE MARCY FEIT BEFORE I LEAVE BECAUSE MARCY IS A GREAT FRIEND AND SUPPORTER FOR A LONG TIME, THE TIME I'VE BEEN ON THE BOARD. SO HOPEFULLY I'LL SEE HER BEFORE I GO; BUT IF I DON'T, YOU WILL PROMISE ME TO THANK HER FOR ALL THE SUPPORT THAT SHE'S GIVEN. AND I'LL TRY AND MAKE A POINT OF CONTACTING HER AS WELL.

SO JUST QUICKLY, THIS WON'T TAKE VERY LONG, I PROMISE YOU. BUT AS USUAL, THERE ARE SEVERAL PUBLICATIONS, AND YOU HAVE A HANDOUT. I THINK MARIA WOULD HAVE PROVIDED THAT TO YOU TODAY OR IN THE LAST COUPLE OF DAYS. BUT I THINK THERE'S, AS USUAL, SOME REALLY INTERESTING WORK. AND I THOUGHT ONE OF THE MOST IMPORTANT ONES HAD REALLY COME FROM A GROUP AT GLADSTONE AND UCSF ON MOUSE LIVER REPOPULATION WITH HEPATOCYTES THAT ARE GENERATED FROM HUMAN FIBROBLASTS.

IT'S BEEN DIFFICULT TO GET PLURIPOTENTIAL STEM CELLS TO DEVELOP INTO FUNCTIONAL HEPATOCYTES, LIVER CELLS, EFFECTIVELY IN CULTURE OR IN THE ANIMALS.

SO IF YOU START WITH PLURIPOTENTIAL STEM CELLS, IT'S REALLY BEEN A TOUGH TASK TO GET SOMETHING THERE THAT WILL ENGRAFT, BUT ALSO FUNCTION PROPERLY.

SO THERE'S ALWAYS BEEN A NEED TO ENABLE SOME LARGE-SCALE PRODUCTION SYSTEMS TO GET THAT DONE BECAUSE THE LIVER IS A VERY IMPORTANT ORGAN. IF YOU LOSE THE ORGAN, AS MIKE WILL TELL YOU, YOU GOT BIG TROUBLE. YOU NEED A LIVER, RIGHT? YOU NEED TO LOOK AFTER YOUR LIVER AS WELL.

DR. FRIEDMAN: VERY IMPORTANT.

DR. TROUNSON: IT'S A VERY IMPORTANT THING. SO THEY SHOWED THAT THEY'RE ABLE TO FORM WHAT THEY CALL INDUCED MULTIPOTENT PROGENITOR CELLS, NOT TAKING THE ADULT CELLS ALL THE WAY BACK TO IPS CELLS, BUT AN INTERMEDIARY. AND THEY CALL THEM IMPSC'S RATHER THAN IPSC'S. AND THEY SHOWED THAT THESE PROLIFERATE EXTENSIVELY IN CULTURE, SO THEY GROW HEAPS OF THEM. AND THEN THEY CAN BE DIRECTED BY SMALL MOLECULES, WHICH WAS THE CONTRIBUTION MADE BY SHEN DING AND COLLEAGUES AT THE GLADSTONE. IT CAN DIRECT THOSE INTO HEPATOCYTES THAT REALLY HAVE THE CLASSICAL GROWTH CHARACTERISTICS AND FUNCTION THAT YOU SEE IN ADULT CELLS. SO THIS IS REALLY AN IMPORTANT STEP FORWARD.

BECAUSE THEY GO BACK TO SORT OF MORE PROGENITOR STATE, THESE CELLS DON'T FORM TERATOMAS. SO

THAT'S ANOTHER IMPORTANT PROPERTY. YOU DON'T HAVE TO TAKE THEM ALL THE WAY BACK, SO YOU DON'T HAVE THE CONCERN THAT YOU MIGHT HAVE WITH IPS CELLS IF YOU'RE IN FRONT OF THE REGULATORY AUTHORITIES.

SO WHEN THEY'RE TRANSPLANTED INTO IMMUNE COMPROMISED MICE, THIS IS HUMAN CELLS, THERE IS EXTENSIVE REPOPULATION THERE IN THE DISEASED LIVERS, AND THERE'S GOOD EVIDENCE THAT THEY WERE TAKING OVER FULL FUNCTION. SO I THINK THAT'S EXTREMELY ENCOURAGING, AND I WOULD HOPE THAT WE MIGHT SEE SOME WORK COME THROUGH. I DON'T KNOW IF WE WILL, BUT SEE SOME WORK COME THROUGH ON THIS BECAUSE IT'S THE MOST ENCOURAGING, I THINK, THAT I'VE SEEN IN THE LIVER.

CHAIRMAN THOMAS: DID WE FUND ANY OF THIS?

DR. TROUNSON: IT'S A NEW FACULTY AWARD RATHER THAN A SPECIFIC GRANT. IT WAS AT THE UCSF. IT'S HOLGER WILLENBRING WHO'S ONE OF OUR GRANTEES, COMPREHENSIVE GRANTEE. SHEN DING HAS HAD MONEY FROM US, AND, OF COURSE, WE'RE STRONGLY SUPPORTIVE. SO IT'S ONE OF OUR DEVELOPMENTS, IF YOU LIKE, SO I THINK THIS IS A GOOD, BIG STRONG TIC.

I DON'T WANT TO SPEND TIME ON THE METHODS, BUT IT WASN'T THAT DIFFICULT. IN OTHER WORDS, IT'S NOT THAT COMPLICATED. IT DOES TAKE MONTHS, AS YOU CAN SEE THERE. SO ALL OF THESE PROCEDURES HAVE -- YOU HAVE TO

WIND YOURSELF THROUGH A PATHWAY, BUT THEY WELL CHARACTERIZED THIS. SO IT WILL BE INTERESTING TO SEE THIS COME FORWARD, I HOPE, NOT BEFORE I LEAVE, BUT I HOPE BEFORE YOU GUYS LEAVE THIS HOPEFULLY GET INTO THE CLINICAL PIPELINE BECAUSE IT LOOKS VERY ENCOURAGING.

THERE'S ALSO, I THOUGHT, QUITE AN INTERESTING PAPER FROM HELEN BLAU AT STANFORD ON REJUVENATION OF MUSCLES FROM ALL PEOPLE. I'M ONE OF THOSE OLD PEOPLE WHO, NO MATTER HOW I WORK, I CAN'T GENERATE MUSCLE LIKE I USED TO, AND I WAS A FOOTBALL PLAYER. BUT TODD'S SORT OF BEATEN ME IN MANY RESPECTS. IN THE ELDERLY, WHICH I'M JUST ABOUT, THEY HAVE SKELETAL MUSCLE WEAKNESS AND DIFFICULTY WITH THE REGENERATION.

SO TWO-THIRDS OF MUSCLES IN ALL THE PEOPLE ARE DEFECTIVE. THEIR STEM CELLS ARE DEFECTIVE WHEN YOU COMPARE THEM TO YOUNG ANIMALS. THEY HAVE REDUCED CAPACITY TO REPAIR THEIR MYOFIBERS AND TO REPOPULATE MUSCLE STEM CELL RESERVOIR. SO THERE'S A PROBLEM HERE, AND SO THE MUSCLE JUST DOESN'T WORK AS WELL AND IT DOESN'T REPOPULATE AS WELL. IT DOESN'T HELP TO TRANSPLANT OLD CELLS INTO YOUNG RECIPIENT ANIMALS. THAT DOESN'T GET IT. HOWEVER, IF YOU TREAT THE AGED MUSCLES WITH AN INHIBITOR FOR P38A AND BETA, WHICH ARE MITOGEN ACTIVATED KINASE PATHWAY, THE CELLS CULTURED ON SOFT HYDROGEL SUBSTRATE, SO YOU HAVE TO HAVE THIS SOFT

SUBSTRATE TO GROW THEM, THERE'S A REMARKABLE RENAISSANCE IN THOSE CELLS. FUNCTIONAL MUSCLE COULD BE USED FOR TRANSPLANTATION AND REGENERATION IN AGED, DEFECTIVE MUSCLE. SO THAT'S QUITE INTERESTING.

I THINK THE CELL THERAPIES FOR AGE REALLY WOULD BE VERY USEFUL IF WE COULD SORT OF TARGET THAT IN BOTH A BIOCHEMICAL AND BIOPHYSICAL WAY, NOT USING THAT TECHNIQUE BY ITSELF, BUT SOMEHOW TO USE A DRUG-RELATED SYSTEM TO TRY AND HELP OLDER PEOPLE REMAIN MOBILE AND HAVE AN EFFECTIVE LIFE AS THEY AGE BECAUSE WE'RE ALL GETTING OLDER AND WE WANT TO LIVE BETTER. AND SO I THINK THAT MAY WELL BE IMPORTANT IN THE LONGER TERM.

CHAIRMAN THOMAS: ALAN, WE ARE FUNDING THAT ONE AS WELL, CORRECT?

DR. TROUNSON: ARE WE FUNDING WORK ASSOCIATED WITH THAT? HELEN'S WORK. AND ON THE TRAINING GRANTS AS WELL.

SO THE LAST ONE, I THINK I SAID I WAS MENTIONING THREE PAPERS, AND I SPOKE BRIEFLY TO THAT WITH THE OUR LECTURE ON AUTISM. IT'S INTERESTING THAT THE RESEARCH IS IN RIKEN INSTITUTE IN JAPAN HAVE SHOWN AN INCREASED RETROTRANSPOSON ACTIVITY IN SCHIZOPHRENIA. RETROTRANSPOSON IS A JUMPING GENE. SO IF YOU KNOW ANYTHING ABOUT -- YOU DON'T HAVE TO KNOW A LOT ABOUT THAT, BUT THESE GENES POPULATE US IN OUR GENOME, BUT

THEY HAVE THE ABILITY TO JUMP AROUND. AND THEY DO JUMP AROUND, AND THAT'S WHAT PRODUCES SOME VARIABILITY IN OUR NEURONS AND OTHER CELLS BECAUSE THEY DO MOVE ABOUT. AND WHEN THEY MOVE, THEY CAN MOVE TO A SITE IN THE GENOME THAT CAN AFFECT ANOTHER GENE.

SO THE SUGGESTIONS THAT THESE WHAT THEY CALL THESE L1'S, THE LONG, INTERSPERSED NUCLEAR ELEMENT RETROTRANSPOSONS, ARE MOBILIZED IN THE NEURON PROGENITOR CELLS. THEY LOOK TO SEE WHAT WAS HAPPENING IN SCHIZOPHRENIA. AND LO AND BEHOLD, THEY FOUND THAT THERE WERE EXTRA COPIES OF THESE TRANSPOSONS THAT WERE INSERTED IN SYNAPSE AND SCHIZOPHRENIA-RELATED GENES. SO HERE WE HAVE A REASON, PERHAPS A REASON FOR SCHIZOPHRENIA. IF THERE'S A HIGH ACTIVITY OF THESE JUMPING GENES, FOR WHATEVER REASON THAT IS, IT MAY UNDERPIN THE PROBLEM OF SCHIZOPHRENIA OR SOME OF THE PROBLEM WITH SCHIZOPHRENIA BECAUSE IT'S VERY CLEARLY VERY DIFFERENT. IF YOU LOOK AT THE JOURNAL, YOU CAN SEE IN THE FIGURES A REALLY DRAMATIC DIFFERENCE THERE.

SO THESE HYPERACTIVE ELEMENTS CAN PROBABLY BE INDUCED BY ENVIRONMENTAL OR GENETIC FACTORS, PROBABLY BOTH. THE GENETIC FACTORS WE COULD WORK OUT AND MAYBE WE CAN DESIGN DRUGS FOR IT. AND ENVIRONMENTAL FACTORS WOULD BE WORTH KNOWING. PART OF THE PROBLEM IS, I GUESS, IS A LOT OF IT'S GOING TO BE HAPPENING DURING

FETAL LIFE. AND SO HOW DO YOU KNOW SOMEONE IS GOING TO HAVE A PROBLEM? WHAT'S A BIOMARKER FOR IT? AND IF AT BIRTH, IS THERE A BIOMARKER THAT YOU'RE GOING TO DEVELOP SCHIZOPHRENIA? SO THESE ARE IMPORTANT THINGS FOR MEDICINE TO WORK ON.

BUT THIS IS, I THINK, A RELATIVELY NEW OBSERVATION IN SCHIZOPHRENIA, AND I THINK IT WILL RELATE ALSO TO AUTISM. I'LL BE VERY SURPRISED IF IT DOESN'T RELATE TO OTHER MENTAL RETARDATION STATES AND AUTISM-RELATED FACTORS. SO WE NEED TO GET A BIT DEEPER, THE SCIENTISTS, IN THIS AREA IF WE WANT TO BE ABLE TO DO SOMETHING ABOUT THOSE CONDITIONS BECAUSE THEY REALLY DO HAVE A MAJOR IMPACT ON FAMILIES.

VERY QUICKLY, COUPLE OF NEW APPOINTMENTS. ONE IS MATT SOPER WHO'S JOINED US AS A SYSTEMS ENGINEER, AN I.T. PERSON. WE'RE DOING AWAY WITH OUR CONTRACT THERE. AND MATT HAS WORKED WITH US IN THE PAST, AND THIS IS A CHEAPER, MORE EFFICIENT SYSTEM, I THINK, HAVING MATT IN-HOUSE RATHER THAN A CONTRACT. SO WE'RE VERY HAPPY TO HAVE HIM.

RON WELLS HAS ALSO JOINED GRANTS MANAGEMENT AS WELL THIS WEEK, AND I'LL TRY AND REMEMBER TO GET HIS PHOTOGRAPH NEXT TIME AROUND, BUT THEY'RE VERY GOOD APPOINTMENTS.

YOU'VE HEARD ABOUT THE RFA'S FROM PAT. SO IF

YOU ARE INTERESTED IN THOSE RFA'S, JUST CHECK IN THE LIST THAT I HAVE THERE.

THERE ARE A LOT OF MEETINGS THAT ARE GOING ON, SO I AGAIN LISTED THOSE FOR PEOPLE, MEETINGS IN THE PAST AND AN ETHICS MEETING WE JUST HAD IN BERKELEY. AND I WANTED TO NOTE THAT ONE BECAUSE THIS WAS ONE OF THE RECOMMENDATIONS FROM THE IOM, THAT WE REALLY HAVE MORE IN THIS AREA. AND I THINK THERE ARE A NUMBER OF PEOPLE FROM THE BOARD WHO ATTENDED. SO I THINK THEY FOUND IT QUITE USEFUL, AND I THINK IT WAS WORTHWHILE. AND I THINK THERE WILL BE A REPORT COMING OUT THAT WE'LL SHARE WITH YOU SHORTLY FROM GEOFF LOMAX.

FUTURE MEETINGS ON STEM CELL ENGINEERING. AND SOME OF THE BOARD MEMBERS LIKE TO ATTEND THESE MEETINGS, SO JUST MAKING SURE THAT YOU KNOW THAT THEY'RE THERE. WE'RE HAVING SOME SPONSORSHIP IN THESE AREAS. A KEYSTONE MEETING IN APRIL, A REGENERATIVE MEDICINE FOUNDATION CONFERENCE, WHICH IS REALLY LOOKING AT TRANSLATION, AND THAT'S IN SAN FRANCISCO. SO YOU'RE WELCOME TO BE PART OF THOSE MEETINGS. THERE'S A NATO WORKSHOP IN BERLIN. THE ISSCR IS ON IN JUNE IN VANCOUVER, AND A NUMBER OF US GO THERE. OCCASIONALLY SOME PATIENT ADVOCATES AND BOARD MEMBERS GO TO THAT MEETING. AND THEN THERE'S A BIG BIO CONVENTION IN SAN DIEGO AT THE END OF JUNE, WHICH WE'RE HAVING A WHOLE

DAY, A PROGRAM THERE, A CIRM-ORGANIZED PROGRAM. SO I THINK THAT WILL BE VERY INTERESTING. AND BIO IS A MASSIVELY BIG PROGRAM.

NOW, THERE'S AN IMMUNE TOLERANCE WORKSHOP GOING ON, AGAIN, IN CALIFORNIA IN JULY. SO THESE ARE ALL SORT OF THINGS THAT I THINK IF YOU'RE INTERESTED IN, PLEASE LET US KNOW, AND WE'LL HELP YOU BE PART OF IT.

I NEED TO REPORT TO YOU AT DIFFERENT TIMES, AT LEAST ONCE A YEAR, ON THE CONFERENCE GRANT PROGRAM. THIS YEAR WE HAD UP TO 350,000 TO WORK ON THAT, AND THESE ARE THE -- THESE WERE THE -- I'M NOT SURE WHAT THE ATTENDEES IS THERE. LET ME GO OVER THE ACTUAL CONFERENCES. THESE ARE THE CONFERENCES THAT WE SUPPORTED WITH THAT CONFERENCE GRANT PROGRAM THROUGH THE YEAR. AND I'M JUST LISTING THEM THERE. YOU CAN LOOK AGAIN AT THE HARD COPY THAT WE PROVIDED FOR YOU. AND THERE'S A RANGE. YOU CAN SEE THAT WE SPENT BETWEEN 2000 UP TO ABOUT 50,000, I THINK, IN SOME INSTANCES.

ON THIS LIST HERE, THERE'S 35,000 FOR THE SANFORD CONSORTIUM FOR REGENERATIVE MEDICINE PARTNERING PROGRAM. IT'S THE STEM CELLS ON THE MESA MEETING. AND, AGAIN, THIS IS THE REST OF THAT MONEY THAT WAS ALLOCATED, WHICH INCLUDED 50,000 FOR THE ISSCR AND 50,000 FOR THIS YEAR'S BIO INTERNATIONAL CONVENTION.

SO THEY ARE ALL LISTED THERE IF YOU'RE INTERESTED. AND, AGAIN, IF YOU WOULD LIKE TO ATTEND ANY OF THOSE, YOU SHOULD LET US KNOW. WE'LL HELP YOU ATTEND THOSE MEETINGS AS WELL, OKAY, THE ONES THAT HAVEN'T BEEN HELD ALREADY.

THERE IS A REGENMED INVESTOR DAY. THIS IS THE BUSINESS PART. YOU'VE HEARD FROM ELLEN ABOUT CAPRICOR AND CELLULAR DYNAMICS AND OTHERS THAT WE'VE BEEN SUPPORTING THROUGH THE PROGRAM. THERE WAS A VERY GOOD MEETING HIGHLIGHTS OF 350 PLUS PEOPLE AT THIS PARTICULAR MEETING. THIS WAS HELD IN MARCH IN NEW YORK. AND THERE'S A NEW PARTNERING CAPITAL RAISING PROGRAM THAT SHOWS AGAIN VIACYTE WITH JDRF ANNOUNCING AN ADDITIONAL $7 MILLION FOR MILESTONE-BASED FUNDING FOR VIACYTE, WHICH IS A VERY GOOD ADD-ON TO OUR PROGRAM WITH VIACYTE.

AND CIRM GRANTEE STEVE FINKBEINER HAS TEAMED UP WITH ENGINEERS FROM GOOGLE FOR WORK RELATED TO A CIRM AWARD. THIS WORK WAS FOCUSED ON ANALYZING PROTEIN CLUMPS IN THE BRAIN, A CHARACTERISTIC OF NEURODEGENERATIVE DISEASES. SO I THINK THESE ARE REALLY INTERESTING. SO YOU'VE HEARD FROM PAT ABOUT THAT PROGRAM.

LET ME JUST GET YOU TO THE FINANCES, AND I'LL ASK CHILA JUST TO FILL YOU IN ON THE LAST PART WITH OUR

CURRENT FINANCE PROGRAM.

MS. SILVA-MARTIN: THANK YOU, DR TROUNSON. GOOD AFTERNOON, MR. CHAIR AND MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC AND STAFF. I WILL PROVIDE YOU WITH A VERY BRIEF FINANCIAL UPDATE.

FIRST OF ALL, I WANT TO LET YOU KNOW THAT OUR FINANCIAL OPERATIONS ARE ON TRACK. WE HAVE HAD NO SIGNIFICANT CHANGES SINCE I LAST REPORTED IN JANUARY, NOR DO I ANTICIPATE ANY MAJOR CHANGES FOR THE REMAINDER OF THE FISCAL YEAR.

OUR GRANT AND LOAN DISBURSEMENTS ARE ON TRACK. THE DEPARTMENT OF FINANCE AND THE STATE TREASURER'S OFFICE CONTINUE TO PROVIDE FUNDING THROUGH COMMERCIAL PAPER EACH MONTH. SO AS A RESULT, WE HAVE A VERY HEALTHY CASH RESERVE TO MEET OUR OPERATIONAL OBLIGATIONS.

I'M NOT GOING TO GO OVER THE NUMBERS HERE. THIS IS OUR EXPENDITURES THAT HAVE BEEN RECORDED THROUGH JANUARY. I DO WANT TO POINT OUT THAT OUR EXPENDITURES ARE RECORDED THROUGH JANUARY JUST UNDER 50 PERCENT OF WHAT WAS BUDGETED. WHAT'S NOT INCLUDED IN HERE IS ABOUT $400,000 IN LAGS OF INVOICES THAT JUST HAVE NOT HIT THE FINANCIAL STATEMENTS YET.

WE DO HAVE SEVERAL ONE-TIME COSTS AND OTHER MEETINGS AND OPERATIONAL EXPENDITURES THAT WILL HIT FOR

THE REMAINDER OF THE FISCAL YEAR, SO WE HAVE DEVELOPED A FORECAST. SOME OF THOSE OPERATIONAL COSTS ARE LIKE THE ONE-TIME COST FOR OUR PRESIDENTIAL SEARCH. AND SO THIS IS WHAT I AM ANTICIPATING FOR THE YEAR-END FORECAST, THAT WE WILL BE SOMEWHERE BETWEEN 5- TO 10-PERCENT SAVINGS.

AS YOU CAN SEE, FOR EACH OF OUR CATEGORICAL EXPENDITURES, I EXPECT ALL OF OUR EXPENDITURES TO BE WITHIN BUDGET. I SEE SAVINGS ANYWHERE FROM 2 TO 30 PERCENT IN SOME OF OUR CATEGORIES, AND THOSE SAVINGS ARE REALLY A RESULT OF EITHER EXPENDITURES THAT WE BUDGETED FOR THAT DID NOT MATERIALIZE AT ALL OR THAT CAME IN LOWER THAN WHAT WE BUDGETED.

AND THIS NEXT CHART JUST PROVIDES YOU OUR COST CENTER DATA. AGAIN, AS YOU CAN SEE, ALL OF OUR COST CENTERS ARE WITHIN BUDGET. AND, AGAIN, I DO NOT ANTICIPATE THAT ANY OF THE COST CENTERS WILL GO OVER BUDGET BY END OF THE FISCAL YEAR.

AND THEN LAST, I WANT TO POINT OUT OUR 6-PERCENT CAP. SO I EXPECT THAT WE WILL BE AT ABOUT 50 PERCENT OF OUR 6-PERCENT CAP BY THE END OF THE FISCAL YEAR, JUNE 30, 2014, LEAVING US JUST OVER $90 MILLION FOR OUR OPERATIONS FOR '14-'15 AND BEYOND. AND THIS ASSUMES, OF COURSE, THAT WE GET NO ADDITIONAL FUNDING.

ONE FINAL THING THAT I WANT TO SAY IS THAT WE

ARE IN THE DEVELOPMENT OF THE '14-'15 BUDGET. WE ARE UNDERGOING AN INTERNAL REVIEW NOW. WE WILL BE PREPARING DOCUMENTATION TO SUBMIT TO THE FINANCE SUBCOMMITTEE CHAIRS FOR THEIR INPUT. ONCE WE SECURE THEIR INPUT, WE WILL FINALIZE THE DOCUMENTS AND BRING THEM TO A FINANCIAL SUBCOMMITTEE MEETING IN APRIL FOR THEIR REVIEW AND APPROVAL AND THEN FOR PRESENTATION TO THIS BOARD IN MAY.

AND THAT REALLY CONCLUDES THE FINANCIAL UPDATE. IF THERE ARE ANY QUESTIONS, I'M HAPPY TO ANSWER THEM.

DR. STEWARD: JUST A BRIEF QUESTION. COULD YOU UNPACK THE CATEGORY EXTERNAL EXPENSES?

MS. SILVA-MARTIN: EXTERNAL SERVICES? YES. SO THAT IS WHERE WE SECURE SERVICES FOR A VARIETY OF DIFFERENT THINGS. SO, FOR EXAMPLE, OUR BOARD COUNSEL IS PART OF THAT. WE DO HAVE SOME SUPPORT FOR -- SOMETIMES WE NEED CONSULTANTS FOR EXPERTISE THAT WE DO NOT HAVE IN-HOUSE. WE HAVE SOME CDAP CONSULTANTS THAT COME IN AND HELP DR. FEIGAL. WE ALSO DO SOME COSTS FOR PROGRAMMING. SO WE DO HAVE TWO PROGRAMMERS ON STAFF, BUT SOMETIMES WE NEED TO DO OTHER WORK, AND WE'LL BRING IN SOME FUNDS FOR THAT AS WELL.

WE PREVIOUSLY WERE PAYING FOR OUR I.T. SUPPORT IN THAT CATEGORY, BUT WE JUST RECENTLY

CONVERTED, AS DR. TROUNSON INDICATED, THAT CONTRACT TO A POSITION. WE ALSO PAY FOR OUR ACCOUNTING SERVICES AND PAYROLL SERVICES THROUGH OUR EXTERNAL SERVICES, AND WE ALSO HAVE THE ANNUAL FINANCIAL AUDIT THAT'S COVERED THERE. SO THOSE ARE THE MAJORITY OF THE COSTS IN THAT CATEGORY.

CHAIRMAN THOMAS: I SHOULD NOTE FOR THE BOARD THAT, AS YOU MAY RECALL, PREVIOUSLY AND FOR MANY YEARS MICHAEL GOLDBERG AND MARCY FEIT HAD BEEN CO-CHAIRS OF OUR FINANCE SUBCOMMITTEE. WITH BOTH OF THEM HAVING LEFT THE BOARD IN THE LAST FEW MONTHS, WE'VE ASKED STEVE JUELSGAARD AND DONNA WESTON TO TAKE OVER THOSE TWO ROLES, AND THEY HAVE GRACIOUSLY AGREED TO DO THAT AND ARE IN THE PROCESS RIGHT NOW WORKING WITH CHILA AND OTHER STAFF TO DEVELOP THE BUDGET FOR THE NEXT YEAR. THANK YOU, CHILA.

DR. TROUNSON: I JUST THERE'S ONE THING THAT HAS TURNED UP TODAY THAT I THINK IS VERY RELEVANT, CHAIR, FOR THE BOARD. AND IT WILL, I THINK, NEED TO HAVE SOME DISCUSSIONS. SENATORS BARBARA BOXER, WHO'S CLEARLY A DEMOCRAT, AND MARK KIRK, A REPUBLICAN FROM ILLINOIS, HAVE INTRODUCED A REGENERATIVE MEDICINE BILL TO THE FEDERAL PARLIAMENT. AND THIS IS ONE IN ORDER TO SUPPORT REGENERATIVE MEDICINE RESEARCH. SO I THINK THAT THAT'S GOING TO BE OF SOME INTEREST, I THINK, TO

THIS BOARD AND WHAT YOU DO IN THE FUTURE. SO I WOULD TAKE A LOOK AT THAT BECAUSE I THINK IT IS SOMETHING THAT THE BOARD NEEDS TO PROBABLY HAVE A VIEW ON. AND SINCE THIS ONLY HAPPENED TODAY, CHAIR, WE'LL CERTAINLY TAKE IT IN-HOUSE AND LOOK TO SEE WHAT IMPACT IT MIGHT HAVE.

SO IT'S BEEN SUPPORTED BY BOTH SIDES OF THE SENATE. SO I GUESS, I DON'T KNOW, I GUESS IT MIGHT HAVE A CHANCE. I WOULDN'T LIKE TO PREDICT MYSELF IN THE SENATE OR THE CONGRESS THESE DAYS WHETHER THINGS WILL GET THROUGH OR NOT, BUT IT'S INTERESTING. I THINK IT'S VERY INTERESTING.

CHAIRMAN THOMAS: THANK YOU FOR BRINGING THAT TO OUR ATTENTION, DR. TROUNSON. ELONA CIRCULATED SOMETHING TO THAT EFFECT EARLIER TODAY. AND, MARIA, PERHAPS YOU COULD FORWARD THAT. COULD YOU PLEASE FORWARD IT TO ALL MEMBERS OF THE BOARD?

I WILL SAY THAT WE'VE HAD A BIT OF A HARDER TIME IN THE HOUSE THAN THE SENATE. SO IT WOULD BE GREAT. OBVIOUSLY ANYTHING THAT FURTHERS THE FIELD WOULD BE TREMENDOUS, AND WE SHOULD ALL DO WHATEVER WE CAN TO HELP SUPPORT THAT. SO THANK YOU FOR BRINGING THAT TO OUR ATTENTION.

LAST THING I'LL NOTE, I NEGLECTED IN THE CHAIRMAN'S REPORT TO COMMENT THAT, IN ADDITION TO THE

OTHER EVENTS, DEAN PULIAFITO AT USC HOSTED TWO LECTURES BY RECIPIENTS OF THE PRESTIGIOUS -- TOO MANY WORDS TODAY -- LASKER AWARDS. AND THEY SPOKE LAST WEEK AND GAVE VERY INTERESTING TALKS. SENATOR TORRES WAS THERE. DEAN HAD A DINNER AT HIS HOUSE THAT EVENING. AND WHAT I PARTICULARLY WANTED TO REPORT TO THE BOARD WAS THAT CLAIRE POMEROY, WHO, AS YOU KNOW, NOW RUNS THE LASKER FOUNDATION, WAS OUT FOR THAT EVENT. AND SHE JUST COULD NOT BE HAPPIER IN HER NEW POSITION AND IS CLEARLY THRIVING BACK THERE AND LOVING EVERY MINUTE OF WORKING IN HER NEW JOB AND BEING IN NEW YORK, ASIDE FROM THE FACT SHE COULD HAVE DONE WITHOUT THE LAST FOUR OR FIVE MONTHS, BUT SHE WANTED TO PASS ALONG A HELLO TO ALL HER OLD FRIENDS AT CIRM.

SO IS THERE ANYTHING ELSE THAT ANYBODY WANTS TO COMMENT ON? HEARING NOTHING, THAT BRINGS TODAY'S MEETING TO A CLOSE. THANK YOU, EVERYBODY, FOR ALL YOUR WORK AS ALWAYS, AND WE WILL SEE YOU IN MAY.

(THE MEETING WAS THEN CONCLUDED AT 03:14 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

HILTON SAN FRANCISCO AIRPORT BAYFRONT
600 AIRPORT BOULEVARD
BURLINGAME, CALIFORNIA
ON
MARCH 13, 2014

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

Beth C. Drain

BETH C. DRAIN, CSR 7152
BARRISTERS' REPORTING SERVICE
160 S. OLD SPRINGS ROAD
SUITE 270
ANAHEIM, CALIFORNIA
(714) 444-4100