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: SACRAMENTO CONVENTION CENTER
1400 J STREET, ROOM 204
SACRAMENTO, CALIFORNIA

DATE: APRIL 21, 2012
9 A.M.

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

BRS FILE NO.: 91065

I N D E X

I N D E X (CONT'D.)

SACRAMENTO, CALIFORNIA; WEDNESDAY, MARCH 21, 2012

9 A.M.

CHAIRMAN THOMAS: EVERYBODY HEAR ME OKAY? GREAT. WE'D LIKE TO CALL THE MARCH MEETING OF THE INDEPENDENT CITIZENS OVERSIGHT COMMITTEE TO ORDER. MARIA, CAN YOU PLEASE LEAD US IN THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN THOMAS: MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: ROBERT PRICE.

DR. PRICE: HERE.

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: HERE.

MS. BONNEVILLE: JACOB LEVIN.

DR. LEVIN: HERE.

MS. BONNEVILLE: MARCY FEIT.

MS. FEIT: HERE.

MS. BONNEVILLE: MICHAEL FRIEDMAN.

DR. FRIEDMAN: HERE.

MS. BONNEVILLE: LEEZA GIBBONS. MICHAEL GOLDBERG. SAM HAWGOOD.

DR. HAWGOOD: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: HERE.

MS. BONNEVILLE: SHERRY LANSING. TED LOVE. BERT LUBIN.

DR. LUBIN: HERE.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: PHIL PIZZO. CLAIRE POMEROY.

DR. POMEROY: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. ELIZABETH FINI.

DR. FINI: HERE.

MS. BONNEVILLE: ROBERT QUINT. DUANE ROTH.

MR. ROTH: HERE.

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

MR. SERRANO-SEWELL: HERE.

MS. BONNEVILLE: JEFF SHEEHY. JON SHESTACK. OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: KRISTINA VUORI. EUGENE WASHINGTON.

DR. PIZZO: PHIL PIZZO IS HERE AS WELL.

CHAIRMAN THOMAS: THANKS, PHIL.

I'VE BEEN ADMONISHED TO TELL EVERYBODY WHEN THEY'RE SPEAKING TO MAKE A POINT OF GETTING THE MICROPHONE FAIRLY CLOSE. SO WHENEVER YOU DO HAVE COMMENTS, IF YOU WOULD DO THAT, THAT WOULD BE GREAT.

ON THIS, THE NATIONAL MS EDUCATION AND AWARENESS MONTH, I'D LIKE TO WELCOME EVERYBODY HERE. WE HAVE A VERY FULL AND MOST INTERESTING AGENDA TO GO OVER. AND WE, AS ALWAYS, LOOK FORWARD TO ROBUST CONVERSATION ON ALL OF THE VARIOUS ITEMS.

I'D LIKE TO GIVE YOU A CHAIRMAN'S REPORT. IT'S BEEN TWO MONTHS SINCE WE MET. THERE'S BEEN A LOT OF ACTIVITY. WE HAD SHORTLY AFTER OUR LAST BOARD MEETING OUR FIRST PUBLIC SESSION OF THE IOM WHICH TOOK PLACE UP IN SAN FRANCISCO. WE HAD A NUMBER OF CIRM FOLKS WHO GAVE TESTIMONY AT THAT IOM MEETING, INCLUDING DUANE, ALAN, ELONA, JEFF, AND MYSELF. THERE WAS A NICE DISCUSSION AMONGST A NUMBER OF THE PI'S IN A PANEL FORMAT, AND A LOT OF INFORMATION WAS PUT ON THE TABLE FOR THE MEMBERS OF THE IOM TO DIGEST.

SEVERAL OF THEM THE DAY BEFORE WENT ON

TOURS OF A NUMBER OF THE STEM CELL FACILITIES, INCLUDING THOSE AT UC DAVIS, UC SAN FRANCISCO, AND STANFORD, AND BY ALL ACCOUNTS FOUND THOSE TOURS TO BE VERY INTERESTING AND REWARDING.

SO WE ARE IN THE MIDST OF CONTINUED DIALOGUE WITH THEM. THERE'S BEEN LOTS OF INFORMATION REQUESTS, AND WE'RE PASSING THOSE ALONG TO THEM TO INFORM THEIR REVIEW. THE NEXT PUBLIC MEETING OF THE IOM IS GOING TO BE IN IRVINE ON APRIL 10TH, AND ALL MEMBERS OF THE PUBLIC ARE WELCOME TO ATTEND.

SECOND ITEM TO REPORT TO YOU ON IS THE STATUS OF THE FINANCING IN APRIL THROUGH THE TREASURER'S OFFICE FOR OUR ONGOING OPERATIONS AND AWARDS. THE TREASURER'S OFFICE THUS FAR HAS HAD A BOND ISSUE THAT WAS DEVOTED TO REFINANCING OUTSTANDING DEBT. AS YOU KNOW, NEEDN'T DWELL ON, INTEREST RATES ARE EXCEEDINGLY LOW, AND A NUMBER OF THE PAST BOND ISSUES HAD RATES THAT WERE HIGH ENOUGH THAT THEY WARRANTED DOING REFINANCING, SOMETHING CALLED ADVANCE REFUNDINGS. THE NEXT PART OF THE SPRING FINANCING IS GOING TO TAKE PLACE IN APRIL. AND IN DISCUSSIONS YESTERDAY WITH THE TREASURER'S OFFICE AND THE DIRECTOR OF FINANCE, I LEARNED THAT WE WILL BE TAKEN CARE OF FULLY TO OUR NEEDS.

AND AS YOU MAY RECALL, THERE'S SORT OF TWO WAYS TO GET FUNDED. ONE IS THROUGH BONDS ISSUED THROUGH THE STATE TREASURER'S OFFICE. THE OTHER IS THROUGH COMMERCIAL PAPER ISSUED BY THE STATE TREASURER'S OFFICE. AND IT LOOKS LIKE IN THIS PARTICULAR ROUND OF FINANCING WE WILL BE TAKEN CARE OF THROUGH THE COMMERCIAL PAPER ALTERNATIVE, BUT I WAS VERY HAPPY TO HEAR THAT THINGS ARE FULLY IN LINE THERE AND WE CAN LOOK FORWARD TO HAVING ALL THE MONEY WE NEED TO MEET OUR NEEDS FOR THE NEXT SIX-MONTH PERIOD.

ALSO SHORTLY AFTER THE LAST BOARD MEETING, WE HAD THE MEETING IN JANUARY OF THE CFAOC, WHICH IS THE OVERSIGHT COMMITTEE CHAIRED BY THE STATE CONTROLLER. THAT WAS DOWN IN LOS ANGELES. A NUMBER OF US PRESENTED THERE AS WELL, ALAN, MATT, AND MYSELF, JAMES. AND THAT MEETING, I'M HAPPY TO INFORM ALL OF YOU, WENT VERY WELL. THE CONTROLLER HIMSELF CAME UP TO TELL US AS MUCH AT THE END OF THE MEETING AND WAS VERY IMPRESSED WITH THE DEGREE OF INFORMATION THEY RECEIVED, THE ADVANCE NOTICE ON A LOT OF IT, AND THE HIGH LEVEL OF TRANSPARENCY IN THE DISCUSSION THAT WE HAD AT THAT MEETING. SO THINGS ARE LOOKING VERY GOOD WITH RESPECT TO THE CFAOC AS WELL.

AS FOR SOME ADDITIONAL ITEMS, YOU MAY RECALL AT THE LAST MEETING WE DISCUSSED OUR TRANSITION PLAN WHICH WE PUT TOGETHER TO RESPOND TO THE ALQUIST BILL WHICH WAS PASSED IN 2010 WHICH REQUIRED THAT BY MARCH 1ST OF 2012 WE DO PRESENT A PLAN FOR WHAT WILL HAPPEN AS FUNDING WINDS DOWN AT CIRM. WE PUT THIS PLAN TOGETHER. MATT TOOK THE LEAD ON WRITING IT UP.

YOU MAY RECALL THAT WE PRESENTED IT IN POWERPOINT FORM AT THE LAST MEETING. IN THIS INSTANCE MATT TURNED IT INTO A NARRATIVE. WE TOOK THAT TO SACRAMENTO TO DELIVER IT IN A TIMELY MANNER TO THE GOVERNOR'S OFFICE, THE TREASURER'S OFFICE, THE CONTROLLER'S OFFICE, SENATOR ALQUIST'S OFFICE, AND THE STATE TREASURER'S OFFICE. THOSE MEETINGS WENT VERY WELL.

IN ADDITION TO THE TRANSITION ELEMENTS, EVERYBODY WAS MOST INTERESTED TO HEAR SORT OF WHERE WE ARE TODAY IN OUR RESEARCH AND OUR FUNDED PROGRAMS. SO WE HAD A GOOD OPPORTUNITY TO DESCRIBE ALL THE VARIOUS EXTRAORDINARY THINGS THAT OUR SCIENTISTS ARE WORKING ON, AND EACH OF THOSE MEETINGS WAS, WE VIEWED, SENATOR TORRES, SAFE TO SAY, VERY SUCCESSFUL. THE SENATOR AND JAMES AND I MET WITH ALL OF THE FOLKS I JUST LISTED. WE HAD A

CONTINUATION OF THAT YESTERDAY WHERE WE MET WITH THE MINORITY LEADERSHIP. OH, I NEGLECTED TO SAY THAT. WE MET ALSO WITH THE SPEAKER'S OFFICE AND THE SENATE PRO TEM OFFICE IN THAT EARLIER MEETING. YESTERDAY WE MET WITH THE MINORITY LEADERSHIP TO GO OVER THE TRANSITION PLAN, AND IT WAS SIMILARLY WELL RECEIVED.

FEW OTHER QUICK ITEMS. I SPOKE -- THERE HAVE BEEN A NUMBER OF CONFERENCES SINCE THE LAST MEETING. I SPOKE AND ATTENDED A CONFERENCE AT UCLA ON STEM CELL RESEARCH WHICH FOCUSED ON CANCER AS WELL AS THE BUCK INSTITUTE CONFERENCE A COUPLE WEEKS AGO, BOTH OF WHICH WERE VERY WELL ATTENDED. ALAN, ELONA, AND I WENT TO SEE THE FDA COMMISSIONER SPEAK, WHICH WAS INTERESTING, SEVERAL WEEKS AGO UP IN SAN FRANCISCO. WE HAVE SINCE, AS YOU KNOW, HAD TWO ROUNDS OF THE GRANTS WORKING GROUP CREATIVITY AWARDS WHICH WILL BE PRESENTED FOR APPROVAL TODAY AND EARLY TRANSLATION III WHICH WILL BE PRESENTED FOR APPROVAL AT OUR NEXT BOARD MEETING.

ALSO HAD A NICE OPPORTUNITY TO TOUR THE IRVINE FACILITY AND MET A NUMBER OF THE SCIENTISTS DOWN THERE, WHICH WAS VERY ENLIGHTENING, AS HAVE ALL THESE TOURS BEEN.

AND LAST, BUT NOT LEAST, I WOULD LIKE TO INTRODUCE TO YOU, AFTER AN EXTENSIVE SEARCH WHICH

INVOLVED TALKING TO AND INTERVIEWING MANY POSSIBLE CANDIDATES, WE'RE DELIGHTED TO SAY THAT WE HAVE OFFICIALLY HIRED OUR DIRECTOR OF PUBLIC COMMUNICATION AND PATIENT ADVOCATE OUTREACH. AND THAT IS KEVIN MCCORMACK, WHO'S IN MY BACK RIGHT. KEVIN IS STANDING UP BACK THERE. KEVIN'S CV IS IN THE BACK OF YOUR BOARD PRESENTATION.

HE COMES TO US WITH MANY YEARS OF EXPERIENCE MOST RECENTLY FROM THE CALIFORNIA PACIFIC MEDICAL CENTER. AND HE HAS LOTS OF EXPERIENCE IN MEDIA CRISIS MANAGEMENT DEALING IN SORT OF PRESSURE COOKER POLITICAL SITUATIONS, FORMER TV PERSON, AND IS SOMEBODY WHO HAS DONE A LOT OF WORK WITH PATIENT ADVOCATES AND PATIENTS AND HAS A GOOD UNDERSTANDING OF SCIENCE. SO HE COMBINES MANY DIFFERENT ELEMENTS THAT WE THINK WERE CRUCIAL TO THE POSITION. HE OFFICIALLY BEGINS APRIL 2D, KEVIN; IS THAT CORRECT? BUT HE CAME HERE TO THE BOARD MEETING TODAY TO SORT OF SEE EVERYBODY IN ACTION SO HE GETS AN IDEA FOR HOW THINGS WORK WHEN HE BEGINS. SO WELCOME TO KEVIN AND WE'RE DELIGHTED TO HAVE YOU HERE AND NOT A MOMENT TOO SOON.

(APPLAUSE.)

CHAIRMAN THOMAS: SO THAT CONCLUDES MY CHAIRMAN'S REPORT. ALAN, TURN IT OVER FOR THE

PRESIDENT'S REPORT.

DR. TROUNSON: THANK YOU VERY MUCH, CHAIR, MEMBERS OF THE BOARD. I HAVE A LITTLE PROBLEM WITH MY THROAT. SO IF I SOUND SQUEAKY, PLEASE FORGIVE ME. IT'S THE PROBLEM OF FLYING AROUND IN AIRPLANES, AS EVERYONE KNOWS, I GUESS.

SO I WANTED TO DRAW YOUR ATTENTION TO SEVERAL, I THINK, VERY INTERESTING REPORTS IN THE LITERATURE THAT HAVE TURNED UP IN THIS LAST MONTH. AND THE FIRST ONE FROM MARIUS WERNIG'S LAB IN STANFORD WHERE THEY'VE BEEN DOING DIRECT REPROGRAMMING OF FIBROBLASTS TO NEURONS. SO INSTEAD OF TAKING THE CELLS ALL THE WAY BACK TO THE EQUIVALENT OF EMBRYONIC STEM CELLS, THAT IS, INDUCED PLURIPOTENTIAL STEM CELLS, THEY TOOK THE FIBROBLASTS AND SHOWED THAT THEY ACTUALLY PRODUCE NEURONS IN A MUCH SHORTER LOOP. PROBLEM WITH THAT IS THAT THOSE NEURONS COULDN'T BE EXPANDED. SO IF YOU REALLY WANT TO WORK CLINICALLY OR IN A RESEARCH WAY WITH THESE CELLS, YOU NEED TO BE ABLE TO EXPAND THEM.

SO THIS IS WHAT THEY'VE DONE. THEY'VE CREATED A METHOD FOR PROLIFERATION OF THE NEURAL PRECURSORS. SO THEY TOOK MOUSE EMBRYONIC FIBROBLASTS AND USED 11 TRANSCRIPTION FACTORS. THESE WERE THE ONES THAT THEY THOUGHT IMPORTANT FOR

THOSE PROGENITOR CELLS. AND THEN THEY CUT THEM DOWN, SO THEY DELETED THEM ONE AT A TIME. AND THEY FOUND THAT TWO OF THEM, SOX-2 AND FOXG1 ARE NEEDED TO PRODUCE CLONAL SELF-RENEWING NEURAL PROGENITOR CELLS. THAT MEANS THAT IT'S A STEM CELL POPULATION. IT CAN RENEW, PRODUCE LARGE NUMBERS OF NEURONS AND GLIA. IN THE CASE OF GLIA, THESE WERE ASTROCYTES, AND THE NEURONS WERE SHOWN TO BE FUNCTIONAL.

IF YOU ADDED A THIRD TRANSCRIPTION FACTOR, BRN2, THEN YOU COULD REDUCE OLIGODENDROCYTES. THESE ARE THE CELLS THAT PUT THE MYELIN SHEATHS BACK ON NEURONS. I THINK THIS IS A VERY MAJOR DEVELOPMENT AND A VERY GOOD EXAMPLE OF SCIENTISTS WHO ARE SORT OF CONCENTRATING ON THESE TRANSCRIPTION FACTORS AND HOW THEY CAN BE USED TO SHORT-CIRCUIT THE DEVELOPMENTAL PROCESS OR THE TRANSDIFFERENTIATION PROCESS AND PRODUCE YOU A CELL WHICH IS REMARKABLE AND MAY BE A VERY IMPORTANT DEVELOPMENT IN THE FUTURE FOR, I GUESS, RESEARCH, BUT I THINK EVEN LIKELY TO BE IN THE YEARS TO COME AN IMPORTANT WAY OF USING THESE MOLECULES FOR CONVERTING CELLS WITHIN THE BODY WITHOUT HAVING TO TRANSPLANT CELLS.

SO I HAVE A VIEW THAT THIS IS BECOMING A VERY NEW MAJOR PLATFORM IN STEM CELL BIOLOGY, AND WE MAY LOOK BACK IN 25 OR 30 YEARS TIME AND SAY WHY

WERE WE REALLY BOTHERING TO TRANSPLANT CELLS WHEN YOU COULD EFFECTIVELY DO THIS? THAT'S A LONG WAY OFF, BUT I THINK YOU'RE SEEING THE BEGINNINGS OF A NEW APPROACH IN STEM CELL BIOLOGY.

THE SECOND ONE WAS A PAPER BY JAN NOLTA. I DIDN'T SELECT IT BECAUSE WE'RE UP HERE IN SACRAMENTO. I ONLY SELECT THESE ON WHAT I THINK ARE IMPORTANT. AND I WAS VERY INTERESTED YEARS AGO WHEN I WAS A RECOGNIZED LABORATORY SCIENTIST, BEFORE I CAME TO CIRM, THAT IS, THAT MESENCHYMAL STEM CELLS, MSC'S, THESE BLOOD STROMAL CELLS, COULD ACTUALLY TRANSFER MITOCHONDRIA IN CULTURE FROM THEMSELVES TO ANOTHER CELL. THIS IS AN ORGANELLE. MITOCHONDRIA IS THE ENERGY FACTORY IN THE CELL, AND THEY COULD ACTUALLY TRANSFER THESE IN CULTURE.

SO THE GROUP HAS BEEN LOOKING AT THIS BECAUSE MSC'S HAVE GOT A HIGH SAFETY PROFILE IN THE CLINIC. THERE'S MANY THOUSANDS OF PATIENTS THAT HAVE BEEN TREATED WITH MSC'S. SO THIS IS A GOOD CELL IN THE SENSE OF TRANSPLANTATION. AND THE QUESTION WAS COULD THEY TRANSFER SHORT HAIRPIN RNA TO CELLS OF THE CENTRAL NERVOUS SYSTEM TO REDUCE THE PROTEIN, THE MUTATED FORM OF HUNTINGTON PROTEIN THAT IS RESPONSIBLE FOR THE NEURODEGENERATION IN HUNTINGTON'S DISEASE. SO THEY WERE ABLE TO SHOW

THAT THEY COULD TRANSFER THESE SHORT HAIRPIN RNA'S, AND THEY DID THAT IN USING GREEN FLUORESCENT PROTEIN. AND THEY ALSO THEN SHOWED THAT THEY COULD EXPRESS THE SHORT HAIRPIN RNA AND REDUCE THE HUNTINGTON PROTEIN, WHICH IS THE PROOF OF CONCEPT THAT YOU REALLY WANT. THIS IS ALL DONE IN CULTURE, OF COURSE. AND SOONER OR LATER YOU'RE GOING TO HAVE TO TRY TO DO THIS IN THE ANIMAL. AND I GUESS THE GROUP WOULD BE MUCH ON THE TRACK FOR THAT.

BUT THIS GIVES SOME SUPPORT TO THE STRATEGY OF INTRODUCING SHORT HAIRPIN RNAI'S EXPRESSING MSC'S INTO THE CENTRAL NERVOUS SYSTEM TO KNOCK DOWN HUNTINGTON, WHICH COULD SIGNIFICANTLY DELAY OR EVEN BLOCK THE HUNTINGTON'S PHENOTYPE. SO I THINK IT'S A VERY IMPORTANT STEP ALONG THE WAY, AND I THINK WE SHOULD FEEL THAT THIS IS ONE OF THOSE PAPERS WE SHOULD FEEL VERY GOOD ABOUT.

SO THIS IN THE FIGURE THERE SHOWS THAT THE CELLS IN THE MIDDLE CAN EITHER TRANSFER THE SHORT HAIRPIN RNA'S THROUGH THE PROCESSES THAT THESE CELLS PUSH OUT, OR POSSIBLY THEY COULD ALSO DO IT INDIRECTLY, BUT IT'S CLEAR THAT IN OTHER SYSTEMS THAT THE DIRECT CELL-CELL CONTACT IS THE WAY THEY TRANSFER THESE ORGANELLES AND, HENCE, THESE PACKAGES OF THE SHORT HAIRPIN RNA'S.

THE NEXT PAPER WAS LOOKING AT, I THINK, A DIFFERENT MODEL IN IPS CELLS. AND I REALLY HADN'T THOUGHT MUCH ABOUT IT, BUT MODELING HEPATITIS C VIRUS INFECTION USING INDUCED PLURIPOTENTIAL STEM CELLS WHICH WAS DONE BY THE HARVARD GROUP, SCHWARTZ, ET AL., PUBLISHED IN *PNAS*. THIS IS THE FIRST DEMONSTRATION OF IPS CELLS FOR THE STUDY OF SUSCEPTIBILITY TO INFECTION. SO THIS IS A PRETTY IMPORTANT SORT OF NEW DEVELOPMENT, I THINK, PARTICULARLY HEPATITIS C, IN THE RESPONSE OF HEPATOCYTE-LIKE CELLS.

SO THESE IPS CELLS WERE DERIVED. THEY DERIVED THE HEPATOCYTES AND THOSE HEPATOCYTES FROM PATIENTS WHO WERE EASILY INFECTED WITH THE VIRUS AND THOSE WHO WERE NOT. AND IN THE EASILY INFECTING PATIENTS, THEY WERE SHOWN TO SUPPORT THE ENTIRE LIFE CYCLE OF THE HEPATITIS C VIRUS INCLUDING ALL THE INFLAMMATORY RESPONSES TO INFECTION.

I THINK THIS MODEL WILL ENABLE EXAMINATION OF THE HOST GENETIC ROLE IN VIRAL PATHOGENESIS. AND IT'S REALLY, REALLY IMPORTANT, AND WE'VE NEVER REALLY HAD THIS KIND OF TOOL IN THE LABORATORY BEFORE. SO THE ROLE OF THE HOST GENETICS IS PRESENTLY UNKNOWN OF IPS CELLS THAT ARE RESISTANT OR SUSCEPTIBLE TO HEPATITIS C, AND THE PHENOTYPE

VARIANCE OR RESPONSE TO INFECTION WILL FORM A BASIS OF FURTHER STUDIES TO UNDERSTAND THIS HOST ROLE. SO I THINK THIS MAY LEAD TO MUCH BETTER STRATEGIES TO COMBAT THE SEVERE PATHOGENESIS OBSERVED WITH THIS PARTICULAR VIRUS.

AND IN THE LAST, I'D ACTUALLY CONCERNED MYSELF WITH THE LARGE NUMBER OF PUBLICATIONS AND NOW CLINICAL TRIALS USING MSC'S. AND, OF COURSE, WE'VE GOT A DISEASE TEAM WHICH IS USING CARDIAC CELLS TO TRY AND HELP PATIENTS WITH SEVERE HEART DISEASE, MYOCARDIAL INFARCT. SO I WAS PLEASED TO SEE EDUARDO MARBAN'S DIRECT COMPARISON OF DIFFERENT STEM CELL TYPES IN SUBPOPULATIONS IN HIS PAPER WHICH WAS PUBLISHED IN THE *AMERICAN JOURNAL OF CARDIOLOGY*.

AND IT WAS A COMPARISON OF HUMAN CARDIOSPHERE-DERIVED CARDIAC CELLS. AND THOSE WHO WERE HERE TO LISTEN TO DR. MARBAN REMEMBER HIS PRESENTATION. AND THEY COMPARED HUMAN BONE MARROW-DERIVED MSC'S, ADIPOSE DERIVED, THAT'S FAT CELL-DERIVED MSC'S, AND BONE MARROW MONONUCLEOCYTE CELLS FOR REPAIR OF DAMAGED HEARTS IN AN ANIMAL MODEL.

SO THE CDC'S, RCD105+, PARTIALLY C KIT+, AND CD 90S+. THEY'RE A MIXTURE -- THESE CELLS FROM THE HEART ARE A MIXTURE OF STROMAL, MESENCHYMAL, AND

PROGENITOR CELLS. SO THEY'RE PUTTING IN A MIXTURE OF CELLS, AND THEY'RE COMPARING THAT AGAINST MSC'S, WHICH ARE NOW BEING STUDIED IN A NUMBER OF CLINICAL TRIALS.

WHAT HAPPENS TO THE CDC'S, THE CARDIAC CELLS GET THE HIGHEST MYOGENIC DIFFERENTIATION AND ANGIOGENIC POTENTIAL, SO THEY WERE MUCH BETTER AT DOING THE JOB IN THE HEART. AND THEY GAVE THE BEST IMPROVEMENT IN SKID MOUSE CARDIAC FUNCTION AFTER INJECTION IN INFARCTED HEARTS AND THE HIGHEST CELL ENGRAFTMENT, MYOGENIC DIFFERENTIATION RATES, AND LEAST ABNORMALITIES OF HEART MORPHOLOGY.

SO THIS IS GOOD EVIDENCE THAT THE APPROACH TAKEN BY DR. MARBAN AND HIS COLLEAGUES IS A BETTER ONE AT THIS POINT IN TIME. BUT, OF COURSE, OTHERS MIGHT SAY, WELL, THEY DIDN'T COMPARE IT OUR PARTICULAR CELLS. BUT SHOWN ON THIS FIGURE UP IN WHATEVER YOU'RE LOOKING AT, THE TOP LEFT-HAND CORNER, IS THE HEART THAT WAS TREATED WITH THE CARDIAC CELLS. AND THEN THE REST ARE TREATED WITH BONE MARROW OR ADIPOSE MSC'S OR THE MONONUCLEOCYTES. AND IF YOU LOOK ACROSS TO THE GRAPH, YOU CAN SEE THAT IN WALL THICKNESS, YOU GET A MUCH BETTER RESPONSE WITH THE CARDIAC CELLS AND A REDUCED PERIMETER IN THE SCAR TISSUE. SO THAT'S WHAT YOU

WANT. YOU WANT YOUR HEART TO BE PERFORMING BETTER, AND YOU WANT AS LITTLE SCAR TISSUE AS NECESSARY.

SO I THINK THIS PAPER COULD EASILY GET BURIED, BUT I THINK IT'S A VERY IMPORTANT COMPARISON, AND I'D LIKE TO SEE SOME MORE COMPARISONS ON THIS, BUT I THOUGHT IT WAS A REALLY GOOD PIECE OF WORK.

MOVING ON NOW TO NEW APPOINTMENTS. SO WE HAVE OTHER PEOPLE JUST RECENTLY APPOINTED. DIANA ROBSON, GRANTS REVIEW SPECIALIST, IS JOINING THE GRANTS REVIEW TEAM. WE'RE ABSOLUTELY UNDER THE PUMP AT THE MOMENT FOR REVIEWING GRANTS. AND DIANA, WHO'S FROM THE CALIFORNIA ACADEMY OF SCIENCES, JOINED US, CAME VERY QUICKLY TO HELP US WITH THE GRANTS THAT WERE UNDER REVIEW. I THINK SHE'S A GREAT ADDITION TO THE GROUP AND ONE THAT'S NECESSARY BECAUSE WE'RE GETTING THROUGH A HECK OF A LOT OF GRANTS. THOSE PATIENT ADVOCATES WHO KNOW WHAT WE'RE DOING CURRENTLY AT THE MOMENT KNOW THAT THERE'S AN ENORMOUS AMOUNT OF WORK HAPPENING IN THAT SPACE.

KEVIN MCCORMACK HAS JOINED US, AS JON SAID, AS SENIOR DIRECTOR OF COMMUNICATIONS. AND INTERESTINGLY, AMY CHEUNG IS RETURNING TO CIRM AFTER A SHORT ABSENCE. AND I'M PLEASED TO SEE AMY BACK. SHE HAD A VERY INTERESTING ASSOCIATION WITH

AUSTRALIA, SO I'M GLAD TO SEE HER BACK, MARIA. SHE USED TO WORK FOR THE CONSULATE HERE IN SAN FRANCISCO. AND SO SHE UNDERSTANDS AUSTRALIANS, WHICH IS RATHER A GOOD START. SO IT WILL HELP ME IN MY NEGOTIATIONS WITH MARIA OVER REALLY TOUGH ACTIVITIES. MARIA AND I DON'T NEED TO NEGOTIATE. WE JUST AGREE ALL THE TIME AND FIND A WAY TO DO THINGS. THINGS ARE REALLY TERRIFIC, REALLY.

UPCOMING RFA'S, THE CREATIVITY AWARDS AT THIS MEETING. EARLY TRANSLATIONAL II, WE'VE BEEN THROUGH THAT. THE ICOC FUNDING DECISION IN MAY. I THINK IT'S AN IMPORTANT ONE. A VERY INTERESTING SET OF PROJECTS IN THERE. AND I THINK THOSE PEOPLE WHO WERE THERE AT THE REVIEW THOUGHT THIS WAS A PRETTY GOOD REVIEW. I THINK THAT WOULD BE A FAIR THING TO SAY, JEFF. IT WAS ONE OF THOSE REALLY GOOD QUALITY, AND ENJOYED IT VERY MUCH.

DISEASE TEAM THERAPY DEVELOPMENT IS COMING UP. THE REVIEW OF APPLICATIONS IN APRIL. SO THAT'S AN IMPORTANT MILESTONE FOR US, TO LOOK AT WHAT'S IN THE PIPELINE FOR THERAPY. THIS IS PRECLINICAL CLINICAL WORK. AND IN THE BASIC BIOLOGY REVIEWS, THE GRANTS WORKING GROUP WILL REVIEW THOSE APPLICATIONS IN JUNE.

NEW FACULTY SCIENTIST AWARDS WILL BE

POSTED APRIL. I'VE BEEN THROUGH THOSE, AND THEY'LL BE OUT -- APRIL IS NEARLY THIS MONTH. THAT'S EARLY NEXT MONTH. AND THE STRATEGIC PARTNERSHIP AWARDS, A VERY INTERESTING NEW AREA. THIS HAS EVOLVED OUT OF THE OPPORTUNITY FUND. I THINK YOU WILL FIND THIS REALLY QUITE DIFFERENT TO WHAT YOU'VE BEEN LOOKING AT IN THE PAST. WE HAVE A LOT OF INDUSTRY REALLY VERY KEEN ON THESE GRANTS. AND SO I EXPECT A LARGE NUMBER OF PROBABLY VERY GOOD QUALITY GRANTS. AND WE'LL BE CHALLENGED TO TRY AND DECIDE ON THE FEW TO SUPPORT. THIS IS ONE WAY IN WHICH WE'LL BE ABLE TO ACCELERATE FORWARD. AND WE'LL BE LOOKING FORWARD TO REVIEWING THOSE LATER IN THE YEAR. AND THEN THERE'S A GENOMICS INITIATIVE WHICH WE ANTICIPATE POSTING IN JUNE.

WE NOW HAVE 18 PARTICIPANTS IN OUR COLLABORATIVE PARTNERING PROGRAM. AND I'M UNFORTUNATELY JUST ABOUT TOMORROW I'M ON AN AIRPLANE, WHICH DOESN'T SOUND GOOD TO ME, TO GO TO BRAZIL AND ARGENTINA. WE JUST SIGNED UP WITH THE KEYSTONE SYMPOSIA. SO THOSE PEOPLE WHO ARE SCIENTISTS WOULD KNOW THAT THE KEYSTONE SYMPOSIA OF MOLECULAR AND CELLULAR BIOLOGY IS REALLY ONE OF THE TOP NOT-FOR-PROFIT ORGANIZATIONS WHO HOLD CONFERENCES AND PARTICULARLY CONFERENCES IN THE

AREAS THAT WE'RE INTERESTED IN.

SO WE'VE JOINED TOGETHER THERE TO TRY AND HELP ACCELERATE OUR INTEREST HERE IN CALIFORNIA, BUT ALSO MORE BROADLY FOR SOME OF OUR COLLABORATIVE FUNDING PARTNERS. SO THERE WILL BE A KEYSTONE CONFERENCE LATER THIS YEAR, AND WE'LL BE VERY MUCH PART OF THAT. AND WE EXPECT TO DO MORE CONFERENCES TOGETHER WITH THE KEYSTONE GROUP IN THE FUTURE.

WE'RE REACHING OUT TO DISEASE FOUNDATIONS, ALS, MDA, MICHAEL J. FOX, AND OTHERS, AND WE'RE HAVING SOME VERY INTERESTING RESPONSES. I WANT TO THANK MATT VERY MUCH FOR HIS WORK IN THIS AREA. HE KNOWS THESE ORGANIZATIONS WELL, SO OUR THIRD GO-ROUND WITH THEM IS A LITTLE BIT DIFFERENT THAN THE FIRST TWO GO-ROUNDS WITH THEM. AND I THINK THERE ARE SOME CHANGES IN THESE ORGANIZATIONS. NIH IS COMING ON VERY STRONG AS PARTNERS WITH IT.

WE HAVE A PARKINSON'S DISEASE WORKSHOP PLANNED FOR THE FALL THIS YEAR. AND THEY'RE PARTICIPATING IN THE DISEASE TEAM THERAPY GROUP. SO WE'VE ALREADY GOT NIH NOW PARTNERING WITH US, AT LEAST IN APPLICATIONS.

THE EARLY TRANSLATIONAL III RFA INCLUDED PARTNERS FROM AUSTRALIA, CHINA, GERMANY, AND JAPAN AS POTENTIAL CO-FUNDERS. SO THIS IS HAPPENING ALL

THE TIME. SO THERE ARE MORE AND MORE OF THESE INTERNATIONAL OR TRANSNATIONAL PROJECTS COMING FORWARD, AND I THINK THIS IS PARTICULARLY PLEASING.

IN GENOMICS UPDATE, A QUICK UPDATE ON THIS, IN FEBRUARY THE OXFORD NANOPORE ANNOUNCED A DNA SEQUENCING DEVICE THAT CAN PLUG INTO A LAPTOP AND SEQUENCE A WHOLE GENOME FOR A THOUSAND DOLLARS. SO IF YOU ARE INTERESTED, YOU CAN GET IT ON YOUR LAPTOP AND AWAY YOU GO. SO THIS HAS CHANGED REMARKABLY IF YOU SAW WHAT WAS NEEDED A FEW YEARS AGO. THERE HAVE BEEN CLINICAL SUCCESSES FROM WHOLE GENOME SEQUENCING OF PATIENTS FOR CANCER AND DIAGNOSTICS, AND HEALTHCARE PAYERS IN SOME CASES PAY FOR THIS. SO THIS IS IMPORTANT NEW DEVELOPMENTS THERE AND NOT WIDELY RECOGNIZED.

THE NONCODING RNA'S, THESE ARE THE ONES THEY THOUGHT WAS JUNK, MEDIATE LONG DISTANCE INTERACTIONS ON CHROMOSOMES. SO IT'S AN IMPORTANT ROLE AND WASN'T WELL RECOGNIZED, AGAIN, SOME YEARS AGO. AND NEW INSIGHTS INTO THEIR STRUCTURE AND ASSOCIATION ARE HAPPENING NOW WITH DISEASE. BIOINFORMATICS IS BECOMING A CROWDED SPACE WITH MANY NEW COMPANIES IN IT.

SO UNDERSTANDING THE THOUSANDS OF CODING VARIANCES IN AN INDIVIDUAL'S DNA IS VERY RELEVANT TO

DISEASE. AND SO THESE ARE SOME OF THE CHALLENGES HERE AS WELL AS ESTABLISHING A REFERENCE GENOME, COMPLETE GENOME, SEQUENCING WHOLE GENOMES OF WELLDERLY HEALTHY PEOPLE. WHO'S WELLDERLY? MAYBE THE WHOLE BOARD IS WELLDERLY. WE COULD GET THE WHOLE BOARD SEQUENCED, CHAIR. THE LONGEVITY OF THIS BOARD IS AMAZING. SO MIGHT NEED TO KNOW WHAT'S KEEPING YOU HARD AT IT.

OBTAINING THE SEQUENCE FROM DIPLOID GENOMES CONTAINING BOTH MATERNAL AND PATERNAL DNA, SO NEXT GENERATION TECHNOLOGIES DON'T REALLY PROVIDE THIS.

LOOKING AT GRANTEE FOLLOW-ON SURVEYS, YOU'D BE INTERESTED TO KNOW WE ASKED OUR GRANTEES, CIRM GRANTEES, WHAT KIND OF FUNDS DID THEY GENERATE AFTER THAT THEY GOT OUR GRANTS. WERE THEY USED IN DATA TO APPLY FOR NEW GRANTS? WERE THEY CITED CIRM RESOURCES TO SOLICIT DONATIONS, OR CITED CIRM FACILITIES IN GRANT APPLICATIONS? AND 45 PERCENT OF THE RESPONDENTS, WHICH WASN'T TOO BAD, BECAUSE ASKING SCIENTISTS FOR THIS KIND OF DATA IS OFTEN A MISERABLE TYPE OF THING TO DO, BUT WE GOT 45 PERCENT OF THEM TO RESPOND, WHICH IS GREAT.

AND IF YOU CARE TO EXTRAPOLATE THAT, GIVEN THAT THERE'S ERRORS IN DOING THAT FROM 45 PERCENT,

THIS IS CLOSE ON 400 MILLION THAT HAS BEEN GENERATED ALREADY FROM THOSE GRANTS. SO THAT'S A GREAT -- THIS IS MONEY COMING TO CALIFORNIA THAT WOULDN'T HAVE COME IF CIRM HADN'T BEEN THERE. SO I THINK WE OUGHT TO TAKE AN ACCOLADE OR TWO FOR DOING THAT. THIS IS A SUBSTANTIAL AMOUNT OF MONEY AND, OF COURSE, IT WILL GROW AS TIME GOES ON.

I WENT TO VISIT THE QATAR FOUNDATION, FOR THOSE WHO KNOW THE REGION, AND PARTICIPATED IN A CONFERENCE THERE. THIS GROUP HAS A VERY LARGE FOUNDATION. I UNDERSTAND IT'S AROUND 500 BILLION. SO THAT'S A FAIR BIT LARGER THAN WHAT WE'VE GOT. AND IT'S GOOD FOR A HUNDRED YEARS. SO EVERY TIME THE GAS PRICE GOES UP HERE, THE FOUNDATION GETS RICHER AND IT'S GOING TO HAPPEN FOR A WHILE NOW.

SO THIS FOUNDATION HAS LED THE MIDDLE EAST DIALOGUE ON EMBRYONIC STEM CELLS AND HAS RESULTED IN A FATWA PERMITTING USE IN QATAR, WHICH IS REALLY AN IMPORTANT DEVELOPMENT. AND THEY'RE ESTABLISHING A CENTER FOR EXCELLENCE IN STEM CELL RESEARCH AND INVITING INTERNATIONAL ORGANIZATIONS TO PARTICIPATE. THEY EXPECT TO FOCUS IN DIABETES, CANCER, NEUROLOGICAL AND CARDIOVASCULAR DISEASE. SO I'M LOOKING AT EVALUATING THE POSSIBILITIES THAT WE CAN BECOME ENGAGED IN SOME WAY IN THIS, AND IT'S NOT

CLEAR TO ME JUST YET HOW THAT WILL HAPPEN, BUT WE HAVE A VERY GOOD DIALOGUE WITH THEM, AND WE'LL KEEP YOU APPRAISED ABOUT HOW THAT DEVELOPS.

THERE'S A PARKINSON'S DISEASE SYMPOSIUM THAT WAS AT THE BUCK INSTITUTE, A VERY GOOD SYMPOSIUM. IT WAS ATTENDED BY A NUMBER OF OUR PEOPLE, ELLEN FEIGAL, PAT OLSON AMONG THOSE OF THE SENIOR STAFF, AND THE AIM WAS TO FOSTER A MULTIDISCIPLINARY DIALOGUE ON THE LEADING-EDGE TOPICS IN AGING AND STEM CELL RESEARCH TO DISCUSS EMERGING PARADIGMS IN THOSE AREAS AND TO FORGE NEW SCIENTIFIC COLLABORATIONS AND ALLIANCES WITH FUNDING ORGANIZATIONS. GEORGE DALEY GAVE THE OPENING TALK ON LIN28 IN DISEASE AND DEVELOPMENT. LIN28 IS ONE OF THOSE GENES THAT'S INVOLVED IN PLURIPOTENTIALITY. AND THERE WAS A KEYNOTE BY OLE ISACSON FROM HARVARD ON NEW MEDICINES AND TREATMENTS FOR PARKINSON'S DISEASE.

SO THERE'S NUMEROUS TALKS AND RESEARCH ON PROMISING RESEARCH. THERE'S INTERESTING REGENERATIVE MEDICINE TARGETED DIRECTLY AT THE PHENOMENON OF AGING AND UNDERLYING BIOLOGICAL MECHANISMS THAT CAN LEAD TO MANY DEGENERATIVE CONDITIONS. AND, FOR EXAMPLE, A HIGHLIGHT ON RECENT PROGRESS IN CELL REPLACEMENT THERAPY FOR

HUNTINGTON'S DISEASE, PAUL ROBSON ON POTENCY OF HUMAN BLASTOCYST-DERIVED STEM CELLS, AND SUSAN FISHER ON VARIATION OF POTENCY IN RELATIONSHIP TO A SUBSET OF GENES THEY'RE USING. SO CIRM AND THE NIH ROAD MAP TO PARKINSON'S DISEASE INCLUDED ELLEN AND MAHENDRA RAO, AND WE ARE MOVING TO OUR OWN WORKSHOP, WHICH WILL BE HELD IN SEPTEMBER THIS YEAR.

SO THOSE WHO ARE INTERESTED IN PARKINSON'S DISEASE, WE HAVE THE GOAL TO PROMOTE COLLABORATIONS IN CALIFORNIA WITH KEY INTERNATIONAL AND NIH INTRAMURAL AND EXTRAMURAL PARKINSON'S DISEASE RESEARCHERS TO TRY AND ACCELERATE PARKINSON'S DISEASE RESEARCH. I HAVE A FEELING THAT THE RESEARCH IS GOING VERY WELL, BUT IT'S NOT AT THE PACE I'D LIKE TO SEE IT HAPPENING, AND MAYBE WE CAN HELP BY FOCUSING ON SOME AREAS WHERE WE CAN MAKE A DIFFERENCE.

SO WE'RE GOING TO FOCUS ON THE DOPAMINE NEURON DEVELOPMENT AND THE TOOL DEVELOPMENT FOR DISCOVERY RESEARCH, IPS CELL LINES AND SCREENING USING PATIENT-SPECIFIC CELL LINES, ASSAY DEVELOPMENT AND NEURAL STEM CELL PRODUCTION, AND CELL-BASED THERAPY, MANUFACTURING OF CELLS, MODELS FOR DELIVERY OF CELL-BASED THERAPY DEVICES, AND SOURCES OF FUNDING. SO WE WELCOME ANY OF THE BOARD WHO WOULD

LIKE TO ATTEND THAT.

THERE'S A BRIDGES TO STEM CELL RESEARCH ANNUAL TRAINEE MEETING. WE HOLD THESE EVERY 12 MONTHS. IT'S BEING HELD IN SAN FRANCISCO IN MID-JULY JUST TO GIVE YOU A HEADS-UP ON THAT. PLANNED ATTENDANCE IS BY 200 PEOPLE, INCLUDING BRIDGES PROGRAM DIRECTORS, MENTORS, CIRM STAFF, ICOC MEMBERS, AND 160 BRIDGES TRAINEES. THESE ARE THE REALLY ENTHUSIASTIC BRIDGES YOUNG PEOPLE. IT WILL FEATURE TALKS BY LEADING SCIENTISTS AND POSTER PRESENTATIONS BY THE BRIDGES GROUP.

SO, AGAIN, WE'RE STARTING TO FILL UP. THIS PICTURE, EVERYONE IS GETTING SMALLER, GETTING SMALLER WITH TIME. BUT WE'RE PROBABLY GETTING CLOSE TO SATURATION. I THINK THERE'S CERTAINLY ARGUMENTS WITH ME WITH MOST PEOPLE ABOUT WHETHER WE CAN APPOINT NEW PEOPLE GIVEN THE POSITION WHERE WE ARE.

NOW, I THOUGHT I MIGHT JUST STOP THERE FOR A MOMENT BECAUSE THERE WAS A REPORT THIS MORNING ON THE SUPREME COURT. AND I THOUGHT I'D ASK OUR GENERAL COUNSEL TO MAKE A FEW COMMENTS ON THAT BEFORE WE GO TO MATT'S REPORT ON THE FINANCES BECAUSE MATT MIGHT ALSO HAVE COMMENTS WHEN HE COMES UP ON THE FINANCIAL SIDE.

ELONA, WOULD YOU LIKE TO MAKE A COMMENT

ABOUT THE SUPREME COURT FINDING? I THINK IT'S VERY RELEVANT FOR US AND VERY IMPORTANT. SO PERHAPS YOU COULD GIVE US A BIRDS-EYE VIEW OF IT.

MS. BAUM: SURE. I'M HAPPY TO DO SO. AND JUST KEEP IN MIND I REALLY JUST OPENED IT UP AND STARTED LOOKING INTO THIS, SO IT'S JUST A VERY BRIEF REMARK THAT I'LL HAVE.

IT RELATES TO A CASE KNOWN AS MAYO VS. PROMETHEUS. AND IN PARTICULAR IT'S ABOUT THE PATENTABILITY OF MEDICAL DIAGNOSTIC CLAIMS WHICH WERE MADE BY PROMETHEUS. AND BEFORE I START INTO A LITTLE THUMBNAIL SKETCH OF SOME OF THE FACTS, I THINK I SHOULD JUST GIVE YOU A LITTLE FOUNDATION AS TO HOW IT'S BEING PERCEIVED BECAUSE SOME OF THE EXPERTS ARE SEEING THAT IT COULD HAVE WIDERANGING EFFECTS, BUT MANY OF THEM JUST SAY, WELL, YOU KNOW, IT CREATES A LITTLE MORE UNCERTAINTY IN THE AREA, AND THEY'RE READING IT NARROWLY. SO I DON'T WANT TO OVERSTATE IT. SOME SAY, GEE, THIS COULD REALLY IMPACT PERSONALIZED MEDICINE SIGNIFICANTLY. OTHERS SAY, GEE, THIS IS A VERY NARROW CASE AND SHOULD BE APPLIED WITH A NARROW READING.

SO BASICALLY THIS A U.S. SUPREME COURT CASE HELD THAT PROMETHEUS' DIAGNOSTIC METHOD WHICH WAS USED TO DETERMINE SUITABLE DOSING RANGES OF

DRUGS USED TO TREAT AUTOIMMUNE DISEASES WAS NOT PATENTABLE BECAUSE IT REPRESENTED CONVENTIONAL APPLICATIONS OF THE LAWS OF NATURE WHICH ARE NOT SUBJECT TO PATENTS.

THE PARTICULAR DISCOVERY WHICH WAS IN THE PATENTS AS DESCRIBED JUST IDENTIFIED A CORRELATION BETWEEN THE CONCENTRATION AND BLOOD OF CERTAIN THIOPURINE METABOLITES AND THE LIKELIHOOD OF EFFICACY OR AN ADVERSE OR HARMFUL EFFECT OF CERTAIN TREATMENTS. BUT SINCE THIS RELATIONSHIP WAS KNOWN AS A FUNDAMENTAL ASPECT OF NATURE, IT IN AND OF ITSELF WASN'T A BASIS FOR PATENTABILITY. THEY WENT THROUGH AND ANALYZED A LOT OF THE ASPECTS OF THE CLAIM AND DIDN'T FIND THAT THE CLAIM ADDED ANY ADDITIONAL STEP TO THIS LAW OF NATURE AND, THEREFORE, DECLINED TO FIND THAT IT WAS ELIGIBLE FOR A PATENT.

THAT'S ABOUT ALL I CAN SAY ABOUT THIS. JUST LOOKED AT IT THIS MORNING VERY BRIEFLY.

DR. TROUNSON: OKAY. STEVE, DID YOU WANT TO MAKE A COMMENT? YOU LOOK LIKE YOU DID.

DR. JUELSGAARD: WELL, I THINK THE MOST INTERESTING PART OF THE CASE IS THE SUPREME COURT'S NOTION OF A LAW OF NATURE, WHICH CERTAINLY I SUPPORT THE EXISTENCE OF NONPATENTABILITY OF LAWS OF NATURE,

BUT THE SUPREME COURT SEEMED TO HAVE DECIDED AB INITIO THAT THIS WAS A LAW OF NATURE WITHOUT EXACTLY EXPLAINING WHY, LIKENING IT TO EINSTEIN'S THEORY OF RELATIVITY OR NEWTON'S LAW OF GRAVITY. AND THERE'S A BIT OF A LEAP OF LOGIC IN ALL OF THAT, AT LEAST FROM MY POINT OF VIEW.

SO THE SUPREME COURT SEEMS TO HAVE SAID THIS IS A LAW OF NATURE AND THAT ENDS THAT CONVERSATION. SO LET'S MOVE ON TO WHETHER YOU CAN PATENT LAW OF NATURE AND WHETHER THIS INVENTION ADDED ANYTHING BEYOND THE SIMPLE LAW OF NATURE. THAT'S THE PART OF THE CASE I FIND MOST INTERESTING IN ALL OF THIS.

DR. TROUNSON: I GUESS WHERE WE NEED TO KEEP A WATCH ON THIS IS WHERE AN INTERPRETATION FOR PEOPLE WHO ARE OPPONENTS TO STEM CELL RESEARCH MIGHT WANT TO TAKE THIS.

DR. JUELSGAARD: I THINK THE MORE IMPORTANT CASE, AND IT'S COMING DOWN THE ROAD, IS THE MARRIOTT GENETICS CASE, IN ESSENCE THE BRCA 1 GENE TEST, AND WHETHER OR NOT YOU CAN PATENT THAT UNDERLYING DNA, WHICH HAS BEEN THE MAINSTAY OF THE BIOTECHNOLOGY INDUSTRY FOR YEARS NOW. AND SO THAT FOR ME IS A MUCH MORE TELLING CASE THAN THIS PARTICULAR CASE. I THINK THIS IS MORE AT THE

MARGINS OF WHAT'S GOING ON IN THE THERAPEUTIC DEVELOPMENT AREA.

DR. TROUNSON: SO WITH THAT, I THINK I'LL JUST INVITE MATT TO GIVE YOU THE FINANCIALS AND I'LL SIT DOWN.

DR. PLUNKETT: GOOD MORNING. I'LL GIVE YOU A RECAP OF THE FINANCIAL RESULTS SINCE THE LAST TIME WE MET IN JANUARY. THE YEAR-TO-DATE EXPENSES THROUGH THE END OF JANUARY WERE 7.5 MILLION. THIS COMPARES TO THE PRIOR YEAR PERIOD OF 5.5 MILLION.

ON THE NEXT SLIDE I'LL GO INTO SOME MORE DETAIL ON THE VARIANCES THERE. GRANTS DISBURSEMENTS YEAR TO DATE HAVE BEEN 131.3 MILLION. THIS COMPARES TO 119.5 MILLION FOR THE PRIOR YEAR PERIOD. THE AVAILABLE BOND CASH AT THE END OF JANUARY WAS $157.8 MILLION. THIS IS A DECREASE OF $22.7 MILLION FROM THE END OF DECEMBER.

THIS SLIDE CONTAINS SOME DETAIL ON THE OPERATING EXPENSES. I'LL JUST HIGHLIGHT A COUPLE OF THE MAJOR VARIANCES FOR YOU. THE FIRST IS THE INCREASE IN EMPLOYEE EXPENSES WAS DUE TO THE ADDITION OF SIX FTE'S AT JANUARY 31, 2012, AS COMPARED TO A YEAR PRIOR. THE VARIANCE IN THE CONTRACTING IS ALMOST SOLELY DUE TO THE EXPENSE FOR THE IOM REVIEW. THE AMOUNT THAT WE PAID TO DATE IS

$350,000.

PART OF THE VARIANCE IN THE TRAVEL AND MEETINGS IS DUE TO THE $110,000 FOR THE WORLD STEM CELL CONFERENCE. AND IN ADDITION, THE GRANTEE MEETING, WHICH WAS HELD THIS PAST FALL, THE EXPENSES RECORDED IN THE PERIOD FROM JULY 2011 TO THE CURRENT DATE WERE $175,000. A REMINDER THAT WE HOLD OUR GRANTEE MEETING EVERY 18 MONTHS.

ANY QUESTIONS ON THIS SLIDE?

AND THEN THE LAST SLIDE. I JUST WANTED TO SHOW YOU, PARTICULARLY IN THE CONTEXT OF THE BUDGET DISCUSSIONS THAT WE'LL HAVE THIS AFTERNOON, A FORECAST TO YEAR-END. I THINK WE'RE PLANNING TO PROVIDE THIS TO YOU ON A QUARTERLY BASIS, NOT NECESSARILY AT EVERY BOARD MEETING. THIS ACTUALLY DOES TAKE AN INCREDIBLE AMOUNT OF EFFORT TO PREPARE SOME FORECASTING TO YEAR-END. WHAT I WOULD LIKE TO DO IS JUST HIGHLIGHT EACH OF THE DIFFERENT EXPENSE CATEGORIES, THE VARIANCES BETWEEN OUR CURRENT YEAR BOARD-APPROVED BUDGET, AND WHERE WE EXPECT TO END UP AT THE END OF THE YEAR.

THE BIGGEST VARIANCE HERE IS IN THE EMPLOYEE EXPENSES. WE'VE ACTUALLY BEEN GOING THROUGH THE YEAR WITH FIVE OR SIX OPEN APPOINTMENTS, AND WE EXPECT AT THE END OF THE YEAR THAT WILL

RESULT IN A CUMULATIVE VARIANCE OF ABOUT $1 MILLION OR 10 PERCENT UNDER BUDGET.

THE NEXT THING WHICH I WOULD LIKE TO FLAG FOR YOU IS THE VARIANCE IN GRANTS REVIEWS. WE EXPECT THAT TO BE ABOUT $400,000 UNDER THE BUDGET FOR THE YEAR. THAT'S REALLY DUE TO SAVINGS ON THE GRANTS WORKING GROUP MEETINGS AS WELL AS SOME OF THE CLINICAL DEVELOPMENT ADVISORY PANEL MEETINGS. SO SOME MEANINGFUL SAVINGS ACHIEVED THERE.

THE I.T., AS YOU CAN SEE, IS APPROXIMATELY $300,000 OVER BUDGET. ONE THING THAT I WOULD LIKE TO FLAG FOR YOU IS THE WAY THAT WE DID THIS ANALYSIS IS WE DID INCLUDE ENCUMBRANCES TAKEN IN THE FISCAL 10-11 FISCAL YEAR FOR SERVICES RENDERED IN THE CURRENT FISCAL YEAR. SO I REALLY WANT TO JUST UNDERSCORE THAT THE PURPOSE OF THIS IS REALLY TO UNDERSTAND WHAT THE TRUE RUN RATE OF EXPENSES IS AND NOT ACTUALLY WHERE THE BUDGET WILL BE AT THE END OF THE YEAR.

SO WE DID ACTUALLY HAVE ENCUMBRANCES RECORDED IN THE PRIOR FISCAL YEAR OF $500,000, AND THAT IS INCLUDED IN THE $1.6 MILLION FORECAST THAT YOU SEE HERE.

THE OTHER THING WHICH I'D LIKE TO FLAG ABOUT THE I.T. LINE ITEM IS THAT IN THE CURRENT YEAR

AND IN PRIOR YEARS, THIS HAS BEEN TYPE OF EXPENSE, A ROW ON THE FINANCIALS. WHAT WE'VE DONE GOING FORWARD IS MAKE THIS A COLUMN, A DEPARTMENT, A COST CENTER, SUCH THAT REALLY ALL OF THE EXPENSES ASSOCIATED WITH THE I.T. FUNCTION ARE IN ONE AREA, NOT NECESSARILY SPREAD OUT. AND YOU WILL SEE THAT THIS AFTERNOON WHEN WE GO THROUGH THE BUDGET.

AND THEN THE LAST ITEM HERE, AND ACTUALLY HAVE TO APOLOGIZE IN THAT I LUMPED TOGETHER TWO CONCEPTS EARLIER, THE SAVINGS ON THE CLINICAL DEVELOPMENT ADVISORY PANEL MEETINGS ARE HERE ON THE SECOND FROM LAST ROW ON THE SCIENTIFIC MEETINGS ITEM. WE'LL EXPECT TO SAVE ABOUT $300,000 OVER THE BUDGET, AND THAT IS ABOUT 1.9 MILLION OR A TOTAL SPENDING IN THE YEAR OF ABOUT 16.6 MILLION.

ANY QUESTIONS?

CHAIRMAN THOMAS: THANKS VERY MUCH, MATT.

DR. PLUNKETT: THANK YOU.

CHAIRMAN THOMAS: OKAY. MARIA, WERE YOU ABOUT TO SAY SOMETHING? IT'S LIKE RAISING YOUR HAND AT AN AUCTION. YOU GOT TO BE CAREFUL.

OKAY. WE'RE NOW PROCEEDING TO THE ACTION ITEMS. FIRST UP IS ITEM NO. 6, CONSIDERATION OF THE APPOINTMENT OF NEW SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP. DR. SAMBRANO.

DR. SAMBRANO: THANK YOU, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC. TODAY WE'RE BRINGING FOR YOUR CONSIDERATION SEVEN NOMINEES FOR GRANTS WORKING GROUP MEMBERS THAT ARE BRINGING KEY SCIENTIFIC, REGULATORY, AND PRODUCT DEVELOPMENT EXPERTISE. THE NOMINEES ARE LISTED, AND THERE'S A BRIEF BIO IN YOUR BOOKS UNDER TAB 6.

THE NOMINEES INCLUDE DR. NESSAN BERMINGHAM, DR. RAJESH CHOPRA, DR. BORO DROPULIC, DR. RUSSELL LONSER, DR. BRUCE MONTGOMERY, DR. DAVID J. PEPPERL, AND DR. DARIN WEBER. AND SO WE REQUEST YOUR APPROVAL AND APPOINTMENT OF THESE NOMINEES AS MEMBERS OF THE GRANTS WORKING GROUP.

CHAIRMAN THOMAS: DO WE HEAR A MOTION?

MR. TORRES: SO MOVED.

MR. ROTH: SECOND.

CHAIRMAN THOMAS: MOVED BY SENATOR TORRES, SECOND BY MR. ROTH. ANY DISCUSSION BY MEMBERS OF THE BOARD? YES, MR. JUELSGAARD.

DR. JUELSGAARD: JUST OUT OF CURIOSITY, WHO PROFFERS THESE NAMES TO YOU, THESE RECOMMENDATIONS FOR BEING APPOINTED TO THE GRANTS WORKING GROUP?

DR. SAMBRANO: SO THERE'S A VARIETY OF SOURCES. A LOT OF TIMES EXISTING GRANTS WORKING

GROUP MEMBERS PROVIDE THEM. WE GET SUGGESTIONS FROM FOLKS IN THE SCIENCE OFFICE. ELLEN FEIGAL HAS BEEN KEY IN ESPECIALLY IDENTIFYING FOLKS WITH PRODUCT DEVELOPMENT, REGULATORY EXPERTISE. SCIENTIFIC MEETINGS THAT SCIENCE OFFICERS ATTEND WHERE WE ACTUALLY CAN ENGAGE IN CONVERSATION, SEE THEIR PRESENTATIONS, UNDERSTAND WHAT EXPERTISE THAT THEY CAN CONTRIBUTE TO THE GRANTS WORKING GROUP. SO THAT'S WHERE WE KIND OF GET THE POOL OF NAMES.

I THINK THE OTHER IS ALSO OUR FUNDING PARTNERS. SOMETIMES WE GET RECOMMENDATIONS COMING FROM OUR FUNDING PARTNERS THAT IDENTIFY FOLKS THAT ARE OUTSIDE OF THE U.S. THAT MAY HAVE CRITICAL EXPERTISE. SO THAT'S THE POOL WE DRAW FROM.

DR. JUELSGAARD: DID YOU HAVE A LARGER POOL TO WORK FROM THAN THIS LIST OF RECOMMENDATIONS?

DR. SAMBRANO: SURE. SO CURRENTLY THE POOL IS ABOUT A HUNDRED FIFTY OR SO THAT WE DRAW FROM. AND SO THE EXPERTISE RANGES FROM BASIC BIOLOGY TO PRODUCT DEVELOPMENT, EXPERTISE IN DEVELOPING TRAINING PROGRAMS. AND SO WE DRAW FROM THAT POOL AND ASSEMBLE THE APPROPRIATE 15 GRANTS WORKING GROUP MEMBERS WHO ARE GOING TO BE THE SCORING AND VOTING MEMBERS FOR ANY PARTICULAR RFA.

AND THEN IN ADDITION TO THAT, EVEN WHEN WE

PUT A FULL PANEL TOGETHER, THERE ARE GOING TO BE GAPS IN EXPERTISE THAT WE USUALLY FILL WITH SPECIALISTS. AND SO THESE ARE REVIEWERS THAT PARTICIPATE BY PHONE, ADD THEIR EXPERTISE, AND THE PANEL LISTENS AND TAKES THEIR EXPERTISE INTO ACCOUNT DURING THE COURSE OF THE REVIEW.

DR. JUELSGAARD: LAST QUESTION. WHO MAKES THE DECISION AS TO WHICH NAMES TO PUT FORWARD?

DR. SAMBRANO: SO THAT'S THE SCIENCE OFFICE. SO THIS IS CLEARED WITH THE PRESIDENT AND THE EXECUTIVE DIRECTOR OF SCIENTIFIC ACTIVITIES. BUT I THINK A LOT OF IT IS IN SEARCH OF WHO THE BEST EXPERTS ARE IN THE FIELD IN ORDER TO ROUND OUT AND MAKE OUR REVIEWS AS BEST AS WE CAN MAKE THEM.

DR. JUELSGAARD: THANK YOU.

CHAIRMAN THOMAS: DR. PRIETO.

DR. PRIETO: SO SOME OF US WHO SERVE ON THE GRANTS WORKING GROUP HAVE HAD QUESTIONS, DISCUSSIONS ABOUT HOW THE GROUP IS CONSTITUTED AND WHAT THE PROCESS IS, AND IN PARTICULAR WONDERED ABOUT THESE DECISIONS, WHAT DR. JUELSGAARD ASKED ABOUT. HOW DO WE DECIDE WHAT MEMBERS ARE INVITED? BUT ALSO WHEN WE DO HAVE NEW MEMBERS, ONE OF THE CONCERNS THAT SOME OF US HAVE IS THAT THESE MEMBERS COMING ON AND DOING REVIEWS MAY NOT HAVE THE

BACKGROUND AND THE HISTORY AND THE UNDERSTANDING OF THE MISSION AND THE ROLE OF CIRM THAT SOME OF OUR ESTABLISHED REVIEWERS HAVE HAD. AND WE DON'T WANT TO LOSE THAT.

AND SO I WONDER IF YOU COULD TALK TO US A LITTLE BIT MORE ABOUT HOW THE DECISION IS MADE TO USE SOME OF THESE MEMBERS AS VOTING MEMBERS REVIEWERS RATHER THAN AS SPECIALISTS.

DR. SAMBRANO: SO OBVIOUSLY THE PRIMARY DRIVER IS THE SCIENTIFIC EXCELLENCE OF THE REVIEWERS. BUT BEFORE WE BRING THEM ON NECESSARILY AS A GRANTS WORKING GROUP MEMBER, WE USUALLY OBSERVE THEM IN A COUPLE OF POTENTIAL CAPACITIES. IN SOME CASES THEY PARTICIPATE AS SPECIALISTS. SO YOU MAY NOT NECESSARILY SEE THEM AT GRANTS WORKING GROUP, BUT YOU MAY CERTAINLY HEAR THEM. AND SO MANY OF THEM WILL HAVE HAD AT LEAST ONE OR TWO SESSIONS THAT THEY'VE PARTICIPATED IN THAT CAPACITY. SO THEY BECOME FAMILIAR WITH THE PROCESS. THEY BECOME FAMILIAR WITH THE BACKGROUND TO SOME EXTENT. SOME HAVE PARTICIPATED IN OUR CLINICAL DEVELOPMENT ADVISORY PANELS, OTHERS IN WORKSHOPS. SO WE DO GET A GOOD SENSE OF BOTH THEIR EXPERTISE, AND THEY DO BECOME SOMEWHAT FAMILIAR WITH CIRM AND WHAT OUR GOALS AND INTENT ARE.

BUT IT GOES WITHOUT SAYING THAT WE WOULD ALSO MAKE AN EFFORT, AS ANY NEW MEMBER COMES ON BOARD, TO MAKE IT CLEAR WHAT THE DIRECTIVES OF THE INSTITUTE ARE, WHAT THEY'RE COMING INTO, HOW IT DIFFERS FROM OTHER AGENCIES, ESPECIALLY NIH. SO IT'S CLEAR TO THEM THAT THIS IS A DIFFERENT TYPE OF REVIEW, A DIFFERENT GROUP. AND SO WE DO THE BEST WE CAN TO INTRODUCE THEM.

I THINK PART OF YOUR QUESTION IS ALSO ONE OF CONSISTENCY ACROSS REVIEWS. AND MEMBERS WHO HAVE HAD A LONGER HISTORY WITH US BRING SOME OF THAT CONSISTENCY TO THE GROUP. SO WE USUALLY SELECT ANY GIVEN PANEL WITH A SUBSET OF MEMBERS WHO HAVE PARTICIPATED BEFORE TO BRING SOME OF THAT. BUT WE ALWAYS HAVE A NEW SET OF MEMBERS THAT ARE BRINGING NECESSARY EXPERTISE TO THAT PANEL.

DR. PRIETO: I GUESS, YOU KNOW, SOME OF US HAVE HAD CONCERNS ABOUT THIS. WHEN WE HAD A GREAT DEAL OF EXPERTISE IN OUR INITIAL GROUP, ONE OF THE THINGS THAT I'M CONCERNED ABOUT THAT I DON'T WANT TO SAY WE'VE LOST, BUT MAY HAVE MOVED AWAY FROM IS WE HAD A NUMBER OF PEOPLE WHO WERE, I DON'T KNOW IF I WANT TO SAY MORE CLINICALLY FOCUSED, BUT PERHAPS MORE DISEASE FOCUSED IN THEIR OWN RESEARCH AND THEIR OWN WORK, AND THAT PERHAPS THERE'S BEEN A SHIFT

TOWARDS MORE OF A BASIC SCIENCE AND SPECIFICALLY STEM CELL BIOLOGY EXPERTISE AND CERTAIN SORT OF MORE NARROWLY FOCUSED EXPERTISE AMONG SOME OF THE MEMBERS.

AND I WONDER IF YOU CAN TALK A LITTLE BIT ABOUT THAT, PARTICULARLY AS WE'RE MOVING OR TRYING TO MOVE TOWARDS MORE TRANSLATIONAL AND CLINICALLY ORIENTED PROJECTS. WHERE DO WE WANT TO BE REGARDING THE COMPOSITION OF THE WORKING GROUP?

DR. SAMBRANO: I THINK THE OVERALL COMPOSITION, IF YOU LOOK AT THE MOST RECENT APPOINTMENTS, THEY'VE ACTUALLY BEEN MORE IN THE REGULATORY, PRODUCT DEVELOPMENT, CLINICAL DISEASE AREAS BECAUSE THAT'S WHERE THE NEED HAS BEEN. THERE ARE KEY AREAS IN BASIC BIOLOGY THAT WE BROUGHT ON BOARD AS WELL IN EPIGENETICS AND OTHER AREAS THAT ARE DEVELOPING AND WE KNOW WE NEED EXPERTS IN.

SO AT LEAST FROM MY PERSPECTIVE, I THINK WE'VE ACTUALLY BEEN INCLUDING AND BRINGING IN MORE DISEASE RELEVANT AND CLINICAL EXPERTS INTO THE GRANTS WORKING GROUP.

DR. PRIETO: ONE OTHER QUESTION THAT HAS COME UP IS THAT PROP 71 ENVISIONED THAT THE GRANTS WORKING GROUP WOULD HAVE A ROLE IN THE SORT OF PLANNING OF OUR FUTURE RESEARCH PROGRAM AND

FORMULATION OF RFP'S IN SOME WAY. I JUST WONDERED ARE WE USING THESE PEOPLE WHO WE'VE RECRUITED, ARE WE USING THEM IN THAT WAY?

DR. SAMBRANO: WE CERTAINLY GET FEEDBACK FROM THEM IN REVIEWS, THEIR PARTICIPATION IN WORKSHOPS. WE HAVEN'T USED THEM SPECIFICALLY AS A PANEL TO THAT END ALONE. I THINK A LOT OF IT COMES FROM THEIR COMMENTS, SUGGESTIONS, FEEDBACK DURING THE COURSE AND AFTER A REVIEW.

DR. PRIETO: YOU KNOW, I DON'T KNOW IF I CAN SAY WE'RE A MATURE ORGANIZATION NOW, BUT CERTAINLY MORE MATURE THAN WE WERE. I WANT US TO THINK ABOUT THESE THINGS AND THINK ABOUT THE PROCESS AND WHETHER WE SHOULD MAKE CHANGES IN THE PROCESS.

DR. SAMBRANO: I CERTAINLY WOULD APPRECIATE ANY SUGGESTIONS OR FEEDBACK THAT YOU HAVE. AND CERTAINLY MEMBERS OF THE BOARD WHO HAVE PARTICIPATED AS GRANTS WORKING GROUP MEMBERS CERTAINLY APPRECIATE THE CONSISTENCY THAT YOU BRING TO THAT GROUP. SO IF YOU HAVE OBSERVATIONS OR SUGGESTIONS, PLEASE FEEL FREE.

DR. PRIETO: THANK YOU.

CHAIRMAN THOMAS: MR. SERRANO-SEWELL.

MR. SERRANO-SEWELL: SO IN THE BALLPARK, HOW MANY GRANTS WORKING GROUP MEMBERS, SCIENTISTS,

DO WE HAVE?

DR. SAMBRANO: THAT ARE IN THE GRANTS WORKING GROUP?

MR. SERRANO-SEWELL: I KNOW THAT BY STATUTE THERE'S THE 15 THAT PARTICIPATE. BUT WE SEEM TO HAVE EXPANDED THE POTENTIAL LIST OF -- THE LIST OF GRANTS WORKING GROUP MEMBERS.

DR. SAMBRANO: THE BALLPARK POOL IS ABOUT A HUNDRED FIFTY.

MR. SERRANO-SEWELL: AND SO I WOULD JUST ASK DO WE NEED THAT MANY?

DR. SAMBRANO: YES.

MR. SERRANO-SEWELL: WHY?

DR. SAMBRANO: BECAUSE THE TYPES OF RFA'S WE ENCOMPASS UNDER CIRM HAVE A VERY BROAD RANGE FROM VERY BASIC BIOLOGY THROUGH CLINICAL TRIALS. AND SO THE EXPERTISE REQUIRED TO REVIEW, THEN, THE DIFFERENT AREAS WITHIN EACH OF THOSE IS EXTREMELY BROAD. I ACTUALLY DON'T THINK THAT A HUNDRED FIFTY NECESSARILY IS ENOUGH.

THE OTHER ISSUE THAT COMES INTO PLAY IS THE AVAILABILITY OF THE REVIEWERS THEMSELVES. SO YOU CAN IMAGINE FOR ANY GIVEN RFA, THAT YOU MAY WANT TO HAVE REPRESENTATION FOR ANY PARTICULAR AREA BY MORE THAN ONE OR TWO INDIVIDUALS SO THAT YOU'RE

ASSURED THAT YOU'RE GOING TO BE ABLE TO PUT A PANEL TOGETHER AT A GIVEN TIME OR DATE AND WILL BE ABLE TO FULLY PARTICIPATE.

MR. SERRANO-SEWELL: I SEE YOUR POINT. IT'S ONE OF SCHEDULING AND GETTING THE BEST SORT OF EXPERTS IN THE SUBJECT MATTER THAT'S RELATED TO THE RFA.

DR. SAMBRANO: RIGHT.

MR. SERRANO-SEWELL: BUT I WOULD ASK US TO THINK ABOUT SOMETHING FRANCISCO SAID, AND THAT IS THE CONSISTENCY OF THE GRANTS WORKING GROUP MEMBERS. AND AS THEY -- WHEN YOU GET CONSISTENCY, THEY GET FURTHER EDUCATED ON A VARIETY OF TOPICS AND CAN PARTICIPATE IN AS WELL EVEN IF IT MAY NOT BE THEIR AREA OF EXPERTISE. AND THERE IS A VALUE IN HAVING CONSISTENCY, NOT JUST WITH THE PATIENT ADVOCATE WORKING GROUP MEMBERS, BUT ON THE 15 SCIENTISTS AS WELL. I APPRECIATE YOU CAN'T HAVE THE SAME 15 ALL THE TIME. THAT'S JUST NOT POSSIBLE. WHEREAS, YOU SEE A HUNDRED FIFTY OR SO AS NOT ENOUGH, WHERE I SIT, I SEE IT AS GETTING AT KIND OF A HIGH NUMBER.

CHAIRMAN THOMAS: ANY FURTHER DISCUSSION? IT'S BEEN MOVED AND SECONDED. MARIA, DO WE NEED A VOICE VOTE OR A ROLL CALL VOTE?

ALL THOSE IN FAVOR IN THE ROOM OF THIS

MOTION PLEASE SIGNIFY BY SAYING AYE. OPPOSED? ABSTENTIONS? THEN, MARIA, COULD YOU JUST POLL THE MEMBERS ON THE PHONE?

MS. BONNEVILLE: PHIL PIZZO.

DR. PIZZO: YES.

MS. BONNEVILLE: MARCY FEIT.

MS. FEIT: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN.

DR. FRIEDMAN: YES.

CHAIRMAN THOMAS: MOTION CARRIES. THANK YOU.

ON TO ITEM 7, WHICH IS CONSIDERATION OF THE PROPOSED AMENDMENT TO REGULATION 100603 TO REQUIRE CIRM GRANTEES TO MAKE CIRM-FUNDED PUBLICATIONS AVAILABLE TO THE PUBLIC WITHIN 12 MONTHS OF PUBLICATION. MR. HARRISON.

MR. HARRISON: GOOD MORNING. ASSEMBLYMEMBER SKINNER'S OFFICE HAS APPROACHED CIRM ABOUT THE ASSEMBLYMEMBER'S INTEREST IN LEGISLATION THAT WOULD REQUIRE CIRM-FUNDED GRANTEES TO ABIDE BY NIH'S PUBLIC ACCESS POLICY WITH RESPECT TO CIRM-FUNDED PUBLICATIONS.

UNDER SENATOR TORRES' LEADERSHIP, WE ENGAGED IN DISCUSSIONS WITH THE ASSEMBLYMEMBER'S OFFICE ABOUT THE POSSIBILITY OF CIRM AMENDING ITS

PUBLIC DISCLOSURE REGULATION TO ADOPT NIH'S PUBLIC ACCESS POLICY. AND THE ASSEMBLYMEMBER IS AMENABLE TO THAT APPROACH, WHICH WOULD OBVIATE THE NEED FOR LEGISLATION.

LET ME JUST CURRENTLY REVIEW WHAT CIRM'S REGULATION COVERS. CIRM'S PUBLIC DISCLOSURE POLICY REQUIRES CIRM-FUNDED INVESTIGATORS TO SUBMIT A PUBLICATION DISCLOSURE FORM TO CIRM'S GRANTS MANAGEMENT OFFICE THAT INCLUDES A 500-WORD SUMMARY OF THE PUBLICATION ALONG WITH A COPY OF THE PUBLICATION WITHIN 60 DAYS.

THE REGULATION, HOWEVER, DOES NOT REQUIRE THAT GRANTEES SUBMIT AN ELECTRONIC COPY OF THE PUBLICATION, AND NEITHER THE 500-WORD SUMMARY NOR THE PUBLICATION ARE CURRENTLY AVAILABLE ON CIRM'S WEBSITE.

THE NIH PUBLIC ACCESS POLICY WHICH WAS ADOPTED IN 2008 REQUIRES NIH-FUNDED INVESTIGATORS TO SUBMIT AN ELECTRONIC COPY OF THE FINAL PEER REVIEWED MANUSCRIPTS THAT WERE PRODUCED IN WHOLE OR IN PART WITH NIH FUNDING TO THE NATIONAL LIBRARY OF MEDICINE'S PUBMED CENTRAL TO BE MADE AVAILABLE TO THE PUBLIC WITHIN 12 MONTHS OF THE OFFICIAL DATE OF PUBLICATION.

WE WOULD PROPOSE TO ALIGN CIRM'S PUBLIC

DISCLOSURE POLICY WITH THE NIH PUBLIC ACCESS POLICY FIRST BY REQUIRING CIRM-FUNDED GRANTEES TO SUBMIT AN ELECTRONIC COPY OF CIRM-FUNDED PUBLICATIONS TO PUBMED CENTRAL, IF POSSIBLE. AND IF THAT'S NOT POSSIBLE, TO CIRM TO BE MADE AVAILABLE TO THE PUBLIC WITHIN 12 MONTHS OF PUBLICATION. WE WOULD ALSO PROPOSE TO ELIMINATE THE 500-WORD SUMMARY THAT IS CURRENTLY REQUIRED UNDER THE REGULATION.

WE WOULD LIKE TO ASK THE BOARD FOR APPROVAL TO INITIATE A RULEMAKING WITH THE OFFICE OF ADMINISTRATIVE LAW IN ORDER TO AMEND THE REGULATION TO ALIGN CIRM'S POLICY WITH THE NIH PUBLIC ACCESS POLICY.

CHAIRMAN THOMAS: DO I HEAR A MOTION TO THAT EFFECT?

DR. HAWGOOD: SO MOVED.

CHAIRMAN THOMAS: MOVED BY DEAN HAWGOOD. IS THERE IS A SECOND?

DR. JUELSGAARD: SECOND.

CHAIRMAN THOMAS: ANY DISCUSSION BY MEMBERS OF THE BOARD? JOAN.

MS. SAMUELSON: A QUESTION. MAYBE I'M JUST MISSING SOMETHING. WHY 12 MONTHS? WHY WOULD IT NOT BE AVAILABLE TO THE PUBLIC INSTANTANEOUSLY, ESPECIALLY BECAUSE IT'S ELECTRONIC?

MR. HARRISON: I BELIEVE THE EXPLANATION IS THAT THE JOURNALS IN WHICH THE ARTICLES ARE PUBLISHED LIKE TO HAVE SOME TIME WHERE THE ONLY PLACE TO FIND THE PUBLICATION IS IN THE JOURNAL IN WHICH IT'S MADE AVAILABLE. SO THE NIH POLICY REQUIRES THAT IT BE DONE WITHIN 12 MONTHS, AND IT REQUIRES THE NIH-FUNDED INVESTIGATORS ACTUALLY TO INCLUDE A PROVISION IN THEIR CONTRACT WITH THE PUBLISHERS THAT ALLOWS THEM TO MAKE A COPY OF IT AVAILABLE TO PUBMED CENTRAL WITHIN THAT TIME FRAME.

MS. SAMUELSON: COULD IT BE REDUCED AT ALL AND GIVE THEM THAT SAME -- I'M TRYING TO THINK OF A WORD FOR PERK.

MR. HARRISON: I THINK THE DIFFICULTY IS THAT PUBLISHERS ARE ACCUSTOMED TO THE NIH RULE BECAUSE IT'S BEEN IN EFFECT NOW FOR THREE YEARS. AND BY ALIGNING OURSELVES WITH THE NIH RULE, WE'LL MAKE IT EASIER FOR INVESTIGATORS AND PUBLISHERS TO ABIDE BY CIRM'S POLICY BECAUSE IT WILL BE CONSISTENT WITH NIH. SO FROM AN IMPLEMENTATION STANDPOINT, I THINK THIS WOULD BE A FAR EASIER APPROACH.

MS. SAMUELSON: AND THAT'S AN IMPORTANT CRITERION. AT THE SAME TIME CALIFORNIANS WOULD LOOK AT IT THEY'RE FUNDING THE RESEARCH AND THE RESULTS, AND THEY WOULDN'T WANT TO WAIT SIGNIFICANTLY LONGER.

IF THERE'S ANY WAY TO ACCOMMODATE THAT AT ALL.

MR. HARRISON: WE CAN INVESTIGATE THAT THROUGH THE RULEMAKING PROCESS. WE'RE NOT ASKING THE BOARD FOR FINAL ADOPTION OF THE REGULATION AT THIS POINT IN TIME, AND IT WILL BE SUBJECT TO PUBLIC COMMENT, AND WE'LL TAKE INPUT AND COME BACK TO THE BOARD.

MS. SAMUELSON: THANK YOU. GREAT.

CHAIRMAN THOMAS: SO, MR. HARRISON, DO WE NEED A VOTE ON THIS?

MR. HARRISON: WE DO. WE'D LIKE TO ASK THE BOARD TO APPROVE INITIATING THE RULEMAKING PROCESS.

CHAIRMAN THOMAS: SO IS THIS ANOTHER VOICE VOTE? PUBLIC COMMENT. YES, MR. REED.

MR. REED: IF I UNDERSTOOD CORRECTLY, THERE WAS A TALK OF REMOVING THE REQUIREMENT FOR A 500-WORD SUMMARY. I WOULD STRONGLY OBJECT TO THAT. I ASKED FOR THAT A COUPLE YEARS AGO, AND THERE WAS A DISCUSSION ON THIS, AND IT WAS DECIDED TO DO THAT. THOSE 500-WORD SUMMARIES ARE VERY IMPORTANT FOR THE PUBLIC TO UNDERSTAND. THAT LETS US TAKE A LOOK AT WHAT THE SCIENTISTS UNDERSTAND. BUT FOR WE WHO TRY TO STRUGGLE TO UNDERSTAND, THOSE 500-WORD SUMMARIES ARE REALLY IMPORTANT. I WOULD URGE THAT WE DO NOT

REMOVE THAT.

CHAIRMAN THOMAS: MR. HARRISON.

MR. HARRISON: AGAIN, WE'RE NOT ASKING THE BOARD FOR FINAL APPROVAL OF THIS REGULATION TODAY. WE ASK ONLY FOR AUTHORITY TO INITIATE THE RULEMAKING DURING WHICH TIME WE'LL HAVE THE OPPORTUNITY TO TAKE COMMENT FROM PEOPLE LIKE DON AND FROM OTHER MEMBERS OF THE PUBLIC AND RESPOND AND MAKE CHANGES IF STAFF BELIEVE THEY'RE WARRANTED BEFORE WE BRING THE REGULATION BACK TO THE BOARD FOR FINAL ADOPTION.

CHAIRMAN THOMAS: THANK YOU. POINT DULY NOTED, MR. REED.

MR. REED: THAT WOULD REMOVE TRANSPARENCY, WHICH IS REALLY IMPORTANT TO US. THANK YOU.

CHAIRMAN THOMAS: ANY OTHER COMMENT BY MEMBERS OF THE PUBLIC? HEARING NONE, WE'LL PROCEED TO A VOICE VOTE. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MARIA, PLEASE POLL MEMBERS ON THE PHONE.

MS. BONNEVILLE: PHIL PIZZO.

DR. PIZZO: AYE.

MS. BONNEVILLE: MARCY FEIT.

MS. FEIT: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN.

DR. FRIEDMAN: YES.

CHAIRMAN THOMAS: MOTION APPROVED. THANK YOU VERY MUCH, MR. HARRISON.

ON TO ITEM NO. 8, THE CONSIDERATION OF THE CREATIVITY AWARDS. DR. SAMBRANO, WHO'S TAKING THE LEAD HERE?

DR. VESSAL: MR. CHAIRMAN, MEMBERS OF THE BOARD, I WOULD LIKE PRESENT TO YOU TODAY THE RECOMMENDATIONS MADE BY THE GRANTS WORKING GROUP FOR YOUR APPROVAL FOR THE CREATIVITY AWARDS RFA.

BRIEFLY, THE OBJECTIVES OF THIS RFA WAS TO INTRODUCE HIGH SCHOOL STUDENTS TO CUTTING-EDGE MEDICAL RESEARCH EDUCATION, EXPOSE THEM TO THE FIELD OF STEM CELL SCIENCE THROUGH FORMING PARTNERSHIPS WITH CALIFORNIA INSTITUTIONS THAT ALREADY HAVE AN EXISTING PROGRAM IN PLACE AND ENCOURAGING THE PROGRAMS TO FOSTER CREATIVITY BY ALSO ENCOURAGING THE STUDENTS TO PURSUE A SECOND DISCIPLINE OF THEIR CHOICE WHEN AVAILABLE. AND ALSO, OF COURSE, TO PROVIDE THE OPPORTUNITY TO THE SOCIOECONOMICALLY DISADVANTAGED STUDENTS.

THE AWARDED PROGRAMS WILL PROVIDE SUMMER STUDENTS WITH SUMMER INTERNSHIPS AND EDUCATIONAL PROGRAMS IN STEM CELL AND DEVELOPMENTAL BIOLOGY, AND THE PROGRAM WILL SUPPORT UP TO THREE YEARS OF FUNDING.

THE ICOC AT THE TIME OF THE CONCEPT PROPOSAL APPROVED UP TO $3 MILLION FOR ABOUT TEN GRANTS. THE AWARDS WILL PROVIDE DIRECT PROJECT COSTS UP TO 87,500 A YEAR AND A TOTAL COST OF THE PROGRAM OF UP TO $96,250 PER YEAR FOR EACH PROGRAM.

THE GRANTS WORKING GROUP MET ON FEBRUARY 16TH TELEPHONICALLY, AND THE REVIEW CRITERIA THAT THEY USED TO EVALUATE THE APPLICATIONS WERE AS FOLLOWS: ONE WOULD BE THAT THERE MUST BE AN EXISTING PROGRAM ALREADY IN PLACE WITH A TRACK HISTORY AT THE INSTITUTIONS AND APPROPRIATE AND AMPLE INTERNSHIP OPPORTUNITIES AVAILABLE AT THESE INSTITUTIONS. THERE MUST BE A STUDENT RECRUITMENT, PLACEMENT, AND PROGRAM ADMINISTRATION IN PLACE. AND THEY SHOULD HAVE BENEFICIAL AND APPROPRIATE SCIENTIFIC ACTIVITIES AVAILABLE FOR THE HIGH SCHOOL STUDENTS AND A DEFINED AND INTEGRATED SECOND DISCIPLINE ACTIVITY IN THE PROGRAM. OF COURSE, A QUALIFIED AND EXPERIENCED PROGRAM DIRECTOR TO MANAGE THIS.

THERE WERE 12 APPLICATIONS THAT WERE SUBMITTED AND REVIEWED BY THE GRANTS WORKING GROUP. AND THAT WAS HELD, AS I SAID, ON FEBRUARY 16TH TELEPHONICALLY. EIGHT APPLICATIONS WERE RECOMMENDED FOR FUNDING AT A TOTAL COST OF $1.5 MILLION.

AND I WILL TAKE ANY QUESTIONS IF YOU HAVE AND WOULD LIKE TO ASK FOR YOUR APPROVAL FOR THIS.

CHAIRMAN THOMAS: WE HAVE A MOTION TO APPROVE?

DR. PIZZO: MOVE APPROVAL.

CHAIRMAN THOMAS: MR. HARRISON HAS A CONFLICT ANNOUNCEMENT TO MAKE HERE.

MR. HARRISON: EACH OF THE MEMBERS SHOULD HAVE A SHEET IN FRONT OF THEM IDENTIFYING ANY CREATIVITY AWARD APPLICATION IN WHICH THEY HAVE A CONFLICT OF INTEREST. MEMBERS SHOULD CONSULT THAT SHEET BEFORE ASKING A QUESTION OR MAKING A MOTION WITH RESPECT TO A PARTICULAR APPLICATION. AND I WOULD REQUEST THAT ONLY THOSE MEMBERS WHO DO NOT HAVE AN INTEREST IN ANY OF THE APPLICATIONS MAKE ANY EN BANC MOTION.

CHAIRMAN THOMAS: DO WE HAVE A MOTION?

MR. ROTH: I HAVE ONE MORE QUESTION BEFORE WE GO TO THAT. YOU'RE RECOMMENDING EIGHT FOR APPROVAL AT 1.5 MILLION?

DR. VESSAL: YES.

MR. ROTH: HOW MANY STUDENTS WILL THAT TOUCH COLLECTIVELY?

DR. VESSAL: ROUGHLY A TOTAL FOR ALL EIGHT, IT WOULD BE 60 TO 70 STUDENTS FOR SUMMER, NOT

FOR ALL THREE YEARS. THIS IS FOR SUMMER, SO IT WOULD BE ROUGHLY ABOUT 200, 250.

DR. LEVIN: HOW MUCH WAS BUDGETED FOR THIS?

DR. VESSAL: WE HAVE $3 MILLION THAT WAS APPROVED BY THE ICOC.

CHAIRMAN THOMAS: DR. LEVIN.

DR. LEVIN: CAN WE DISCUSS ONE OF THE NOT RECOMMENDED FOR FUNDING AT THIS POINT?

CHAIRMAN THOMAS: LET'S GET A MOTION ON THE TABLE FIRST HERE. MR. SHEEHY.

MR. SHEEHY: IF WE DO AN OMNIBUS MOTION, DOES THAT PRECLUDE US MOVING OTHER GRANTS OR ATTEMPTING TO MOVE OTHER GRANTS INTO THE FUNDABLE CATEGORY?

MR. HARRISON: I WOULD LIKE TO SUGGEST THAT THE BOARD CONSIDER WHETHER IT IS INTERESTED IN MOVING ANY OF THE APPLICATIONS THAT ARE IN TIER 3 TO TIER 1, AND THEN CONSIDER WHETHER IT'S INTERESTED IN MOVING ANY APPLICATIONS FROM TIER 1 TO TIER 3, AND THEN WE CAN ENTERTAIN AN OMNIBUS MOTION.

CHAIRMAN THOMAS: THANK YOU.

DR. LEVIN: I GUESS I'D LIKE TO DISCUSS 6870, IF WE COULD, THE ONE THAT HIGH SCORED BUT WAS NOT RECOMMENDED FOR FUNDING. AND I'LL FREELY ADMIT

THAT ALL I KNOW ABOUT THESE GRANTS IS WHAT WAS IN THE REVIEW SUMMARIES. BUT IN LOOKING AT THEM, THIS GRANT SEEMED TO HAVE SOME POTENTIAL POSITIVE IMPACT. IT HAD GOOD REMARKS ON THE PI. IT DIDN'T HAVE ANY SEVERE DEFICIENCIES MENTIONED. IT WASN'T OUT OF SCOPE. IT SEEMED TO ME THAT THE GENERAL VIEW OF THE GRANTS WORKING GROUP WAS WHAT MY HIGH STUDENT CALLS (GUTTURAL SOUND), WHICH MAYBE FOR A RESEARCH GRANT OF A LARGE AMOUNT OF MONEY AND SIGNIFICANT POSSIBLE IMPACT WOULD BE SOMETHING THAT WE SHOULDN'T CONSIDER MOVING UP. BUT MY VIEW AT LEAST IS THAT ANYTHING THAT GETS HIGH SCHOOL STUDENTS INTO THE LAB AND PARTICIPATING IN SCIENCE AND IN SUCH AN ENVIRONMENT IS GOING TO HAVE GOOD BENEFITS. AND WHAT FOR US IS SMALL AMOUNT OF MONEY, IT IS WORTH CONSIDERING.

CHAIRMAN THOMAS: MR. SHEEHY.

MR. SHEEHY: AND IS THAT A MOTION, DR. LEVIN, TO MOVE IT INTO THE FUNDABLE CATEGORY?

DR. LEVIN: I'LL MAKE A MOTION.

MR. SHEEHY: I'D BE HAPPY TO SECOND THAT. ACTUALLY I THINK IF WE GO BACK TO THE CRITERIA, YOU DON'T NECESSARILY HAVE TO PUT THEM BACK UP, BUT IN A WAY THE CRITERIA WERE, IN MY MIND, INTERPRETED TOO STRICTLY IN THIS PARTICULAR CASE. THIS WAS NOT A PROGRAM THAT HAD A LONG TRACK RECORD. IN FACT, IT

STARTED ITS FIRST GROUP OF STUDENTS LAST SUMMER AS A CIRM-SPONSORED PILOT. SO WHEN COMPARED TO SOME OF THESE PROGRAMS WHICH HAVE BEEN DOING SUMMER PROGRAMS, SCIENCE PROGRAMS FOR KIDS FOR LIKE 20 YEARS, IT DOESN'T LOOK AS GOOD.

THERE ALSO -- SO THAT WAS ONE DEFICIENCY THAT ACTUALLY WASN'T APPROPRIATE. THIS PROGRAM, IN FACT, WAS SO WELL RECEIVED, THAT THERE WAS A NEWSPAPER ARTICLE ABOUT THE STUDENTS WHO PARTICIPATED IN THE PROGRAM AT A MAJOR CALIFORNIA DAILY LAUDING THE PARTICIPATION OF THE STUDENTS.

IT'S INTERESTING TOO THAT THIS WAS THE ONLY ONE WHERE THE STUDENTS GOT A CERTIFICATION. SO THE STUDENTS WHO PARTICIPATED IN THIS PROGRAM, AT LEAST THE ONES WHO DID LAST SUMMER, CAME OUT WITH A GMP FACILITY EXPERTISE MASTER'S DOCUMENTATION OF WORK THAT IS EQUIVALENT TO WHAT THE BRIDGES STUDENTS WERE ACCOMPLISHING IN A MUCH LONGER TIME PERIOD, WHICH WAS ALSO SIGNIFICANT.

THERE WAS ALSO FURTHER DAMAGE BECAUSE -- OF THIS PARTICULAR APPLICATION BECAUSE THERE WAS A MISPERCEPTION ABOUT THE STATUS OF THE PI. SO HIS TITLE WAS LISTED AS ASSOCIATE ADJUNCT PROFESSOR, AND THEY TOOK THAT TO ASSUME THAT THIS WAS SOMETHING OF A COWBOY WITHOUT THE FULL SUPPORT OF THE

INSTITUTION. AND THOSE OF US WHO KNEW THE INDIVIDUAL AND KNEW THE INSTITUTION KNEW THAT THIS WAS ABSOLUTELY ABSURD. THE REVIEWERS ARE LOOKING AT THIS AND SAID, YOU KNOW, THIS DOESN'T LOOK LIKE A FULL FACULTY POSITION.

SO I THINK -- AND THEN THERE WAS SOME CONCERNS ABOUT THE INTEGRATION OF THE SECOND DISCIPLINE EVEN THOUGH THE SECOND DISCIPLINE WAS A COLLEGE LEVEL COURSE THAT WAS TAUGHT AT THE ASSOCIATED UNIVERSITY BY THIS INDIVIDUAL. SO I JUST THINK THAT ON THIS ONE, ESPECIALLY THE ISSUES OF DURATION AND LONGEVITY OF THE PROGRAM AND THE ASSOCIATION OF THE PI WITH THE UNIVERSITY, THE WORKING GROUP JUST OVEREMPHASIZED THOSE PARTICULAR ASPECTS OF THE REVIEW. AND I THINK DR. VESSAL CAN TELL US ABOUT WHAT THEIR PERFORMANCE WAS. GIVEN THAT NOT MANY OF THESE DO WE HAVE DIRECT EXPERIENCE, WE PILOTED, WHAT, I THINK THREE OR FOUR LAST SUMMER.

DR. VESSAL: THERE WERE FOUR PROGRAMS.

MR. SHEEHY: THIS WAS ONE OF THEM. DID THEY PERFORM WELL? WHAT WAS THE --

DR. VESSAL: THEY REALLY EXCELLED. ALL FOUR EXCELLED, I HAVE TO SAY, AND THIS DEFINITELY DID NOT SHY AWAY FROM THE OTHER PROGRAMS.

MR. SHEEHY: SO WE'VE GOT A PROGRAM THAT

HAS A GREAT RECORD, STUDENTS WHO HAVE BEEN RECOGNIZED ALREADY IN PRINT, WHICH AS MANY OF US KNOW, WE DON'T GET THAT MANY FAVORABLE NEWS ARTICLES. I THINK THIS WOULD BE ONE THAT I THINK WE WOULD BE WELL SERVED BY MOVING INTO THE FUNDABLE CATEGORY.

CHAIRMAN THOMAS: SENATOR TORRES.

MR. TORRES: MR. HARRISON, IS THERE A REASON WHY WE DON'T HAVE THE NAME OF THE INSTITUTION HERE?

MR. HARRISON: YES. WE HAVE A POLICY OF CONDUCTING A BLIND REVIEW OF APPLICATIONS.

MR. TORRES: SO THEN WHAT WAS THE COURSE THAT YOU REFERENCED? WHAT WAS THE NAME OF THE COURSE?

MR. SHEEHY: IT WAS A FILM STUDIES COURSE.

MR. TORRES: OH, THIS IS THE ONE. I HAD STRONG OBJECTIONS TO THIS PROPOSAL BECAUSE I DID NOT FEEL IT WAS SERIOUS ENOUGH IN THE SECOND DISCIPLINE. I MADE THAT VERY CLEAR DURING OUR DISCUSSIONS, AND I FELT THAT THE APPLICANT SHOULD HAVE GIVEN A DIFFERENT APPROACH TO THE SERIOUSNESS AND ALIGNED ITSELF AS TO WHY THE SECONDARY DISCIPLINE WAS RELATED TO STEM CELL RESEARCH. THOSE WERE MY CONCERNS AS I ARTICULATED THEM DURING OUR REVIEW

PROCESS.

DR. JUELSGAARD: I UNDERSTAND FROM THE AGENDA THAT THERE'S TO BE A CLOSED SESSION TO DISCUSS THESE CREATIVITY AWARDS. IS THAT RIGHT? AND IF SO, WHEN DO WE ENTERTAIN THAT BECAUSE PART OF THIS DISCUSSION THAT JUST OCCURRED IS SORT OF A LIMITATION, AT LEAST WITH REGARD TO THE REST OF US UNDERSTANDING.

MR. HARRISON: YES, WE DO HAVE THE OPPORTUNITY TO GO INTO CLOSED SESSION TO DISCUSS CONFIDENTIAL AND PROPRIETARY INFORMATION RELATED TO THE APPLICATION.

MR. SHEEHY: I'D LIKE TO RESPOND TO THE SECOND DISCIPLINE.

CHAIRMAN THOMAS: HOLD ON, MR. SHEEHY. MR. JUELSGAARD STILL HAS THE FLOOR.

DR. JUELSGAARD: BUT WHEN DO WE DO THAT, MR. HARRISON?

MR. HARRISON: IN THE ORDINARY COURSE, WE WOULD DO THAT AFTER EXHAUSTING ALL QUESTIONS FROM THE BOARD THAT INVOLVE NONCONFIDENTIAL OR NONPROPRIETARY INFORMATION.

DR. JUELSGAARD: SO WE'LL HAVE MOTIONS ON THE FLOOR, BUT NOTHING WILL HAVE HAPPENED BEYOND THIS PUBLIC DISCUSSION. WE'LL HAVE A CLOSED

SESSION, AND THEN WE'LL GO BACK TO APPROVAL OR LACK OF APPROVAL.

MR. HARRISON: THAT'S CORRECT. IF THE BOARD FEELS THE NEED TO GO INTO CLOSED SESSION, THAT'S WHAT WOULD HAPPEN.

DR. PRICE: POINT OF INFORMATION. JAMES, IS THERE ANYTHING IN THESE PROPOSALS THAT FIT THE CATEGORY OF THINGS WE CAN DISCUSS IN EXECUTIVE SESSION?

MR. HARRISON: THERE MAY BE. I'D WANT TO CONSULT WITH THE SCIENTIFIC STAFF ON THAT QUESTION. BUT FOR THE MOST PART, I THINK THE CONVERSATION CAN LARGELY OCCUR IN PUBLIC SESSION.

CHAIRMAN THOMAS: MR. SHEEHY AND THEN DR. STEWARD.

MR. SHEEHY: I JUST THINK -- DR. VESSAL, COULD YOU GIVE US A SENSE BECAUSE I THINK THIS IS A POINT OF -- I MEAN THE GOAL OF THESE APPLICATIONS IS NOT THE SECOND DISCIPLINE, THE WEIGHTING OF THAT WITHIN THE CONTEXT OF THESE GRANTS.

DR. VESSAL: I JUST WANT TO MAKE A POINT THAT IN TERMS OF THE FUNDING AND THE MONEY THAT'S ACTUALLY BEING SPENT IN THE BUDGET PER APPLICATION, ALMOST ALL OF IT IS BEING SPENT ON THE STEM CELL SCIENCE ASPECT OF IT, NOT ON THE SECOND DISCIPLINE.

REALLY THE SECOND DISCIPLINE, THE ENTIRE IDEA BEHIND IT WAS TO, AS I SAID, REALLY JUST FOR CREATIVITY PURPOSES. AND GIVEN THAT AT LEAST HALF, IF NOT MORE, OF THE STUDENTS REPRESENTED IN THESE APPLICATIONS COME FROM A SOCIOECONOMICALLY DISADVANTAGED BACKGROUND, THEY ORDINARILY WOULDN'T HAVE AN OPPORTUNITY TO PARTICIPATE IN ANY OF THESE DISCIPLINES REALLY.

SO IT WOULD BE AN OPPORTUNITY FOR THEM TO BE EXPOSED TO ANY OF THE ACTIVITIES THAT WERE SET FORTH IN THESE APPLICATIONS. SO I DON'T KNOW IF THAT ANSWERS YOUR QUESTION, BUT CERTAINLY THE CONCENTRATION IS ON THE STEM CELL SCIENCE PORTION OF IT, AND THAT IS REALLY THE MEAT OF THE APPLICATIONS.

MR. SHEEHY: AND THEN LOOKING AT THE STEM CELL SCIENCE PORTION OF THIS, AT LEAST TO ME, BASED ON -- AND MAYBE FROM THE PILOT WORK THAT YOU'VE SEEN, THERE SEEMED TO BE AN UNUSUAL AMOUNT OF RIGOR IN TERMS OF DETERMINING THAT THE PEOPLE WHO PARTICIPATED IN THIS PROGRAM ACTUALLY MASTERED SOME SIGNIFICANT AMOUNT OF -- I MEAN IF I LEARN HOW TO FUNCTION IN A GMP ENVIRONMENT IN HIGH SCHOOL, MIGHT THAT NOT GIVE ME A LOT MORE OPPORTUNITIES ONCE I GOT OUT OF HIGH SCHOOL OR EVEN GOING FORWARD INTO COLLEGE? I MEAN THE RIGOR, IT SEEMED TO ME, IN THIS

PARTICULAR PROGRAM TO BE A LITTLE BIT HIGHER THAN ACTUALLY SOME OF THE PROGRAMS THAT WERE FUNDED IN THAT PEOPLE WERE ACTUALLY GETTING CERTIFIED, A REAL HANDS-ON EXPERIENCE IN LEARNING HOW TO OPERATE IN CLEAN SPACE IN A GMP COMPLIANT FACILITY IN A VERY RIGOROUS PROGRAM THAT I THOUGHT STOOD UP VERY WELL AGAINST THE OTHER PROGRAMS.

DR. VESSAL: AGAIN, I'M JUST GOING TO BASE MY FACTS ON THE PILOT PROGRAM THAT WE RAN LAST YEAR AND THE SURVEY THAT I CONDUCTED AND HAD A VERY SUCCESSFUL 75 PERCENT ROUGHLY RESPONSE RATE FROM THE STUDENTS AND THE MENTORS AND ALSO THE POSTERS THAT EACH STUDENT PRESENTED AT THE POSTER DAY AT THE END OF THE SUMMER BASED ON THEIR WORK. AND I HAVE TO SAY THEY WERE REALLY IMPRESSIVE, VERY IMPRESSIVE. ALMOST HUNDRED PERCENT OF THESE STUDENTS HAD ABSOLUTELY NO BACKGROUND IN STEM CELL BIOLOGY OR EVEN WORKING IN A LABORATORY SETTING. SO I HAVE TO SAY THAT THEY WERE ALL REALLY EXCESSIVELY IMPRESSIVE.

MR. SHEEHY: AND THEN AS A FURTHER AND I THINK A KEY PROGRAMMATIC CONSIDERATION, THIS WOULD BE THE ONLY PROGRAM WE APPROVED THAT IS NOT IN THE SAN DIEGO AREA, THE LOS ANGELES AREA, OR THE BAY AREA. SO I DO THINK WE HAVE AN OBLIGATION TO MAKE

THESE PROGRAMS AVAILABLE TO A MORE DIVERSE GROUP OF CALIFORNIANS AND NOT JUST THE PEOPLE WHO LIVE NEAR THE COAST.

SO WE'VE GOT A GREAT PROGRAM THAT I KNOW THE FILM CLASS YOU WERE NOT ENTHUSIASTIC ABOUT, SENATOR TORRES, BUT I DON'T THINK --

MR. TORRES: I LOVE GOING TO FILM CLASSES. I DON'T THINK IT'S PART OF SOMETHING THAT WE SHOULD BE FUNDING WITH STEM CELL MONEY. THAT'S ALL.

MR. SHEEHY: A MINOR PORTION. I THINK HAVING HIGH SCHOOL STUDENTS FROM MORE DIVERSE AREAS OF CALIFORNIA --

MR. TORRES: I'M SORRY, MR. CHAIRMAN. AND I'M SORRY, DR. STEWARD, YOU WERE NEXT. I'LL WAIT.

DR. STEWARD: ACTUALLY WHAT I WAS GOING TO ASK, I DON'T THINK THAT THIS IS PROPRIETARY. COULD WE GET A JUDGMENT ON THAT FIRST? AND IF NOT, THEN ACTUALLY WHAT I WAS GOING TO ASK YOU TO DO IS UNPACK A LITTLE BIT WHAT IT IS THAT THEY'RE PROPOSING AND WHY IT IS THAT YOU'RE OPPOSED TO IT.

CHAIRMAN THOMAS: MR. HARRISON, IS ANY OF THAT PROPRIETARY? I DON'T BELIEVE SO.

MR. HARRISON: BASED ON MY CONSULTATION WITH STAFF, I DON'T BELIEVE THAT ANY OF THE INFORMATION THE BOARD IS CURRENTLY DISCUSSING IS

PROPRIETARY. IT MIGHT HELP FOR THE BENEFIT OF MEMBERS WHO WERE NOT PRESENT AT THE GRANTS WORKING GROUP FOR MANI TO EXPLAIN WHAT THE CRITERIA WERE PARTICULARLY WITH RESPECT TO THE SECOND PROGRAM BECAUSE I THINK WE'VE KIND OF ENTERED UPON A DISCUSSION THAT HAS ALREADY OCCURRED AND SOME MEMBERS HAVE NOT BEEN PARTICIPANTS IN.

CHAIRMAN THOMAS: DR. VESSAL.

DR. VESSAL: SURE. AGAIN, THE CRITERIA THAT WE SET FORTH FOR THE SECOND DISCIPLINE WAS KIND OF IN A GRAY ZONE, AND INTENTIONALLY SO. WE THOUGHT THAT IT WOULD REALLY HINDER CREATIVITY, WHICH WAS REALLY THE VERY CONCEPT BEHIND THIS SECOND DISCIPLINE. IF WE WERE TO BORDER IT WITHIN CONFINEMENTS OF A SET OF RULES, EITHER ACADEMICALLY SPEAKING OR NOT, AND SO IT WAS REALLY LEFT UP TO THE APPLICANT INSTITUTIONS TO DEFINE WHAT THAT SECOND DISCIPLINE IS OR SET OF DISCIPLINES. WE DID NOT ACTUALLY HAVE ANY LIMITATIONS ON THE SUBJECT MATTER FOR THAT, FOR EXAMPLE. SO IT COULD HAVE BEEN REALLY IN ANY DISCIPLINE WHATSOEVER. NON-ACADEMICALLY BASED WOULD HAVE BEEN PERFECTLY FINE AS WELL, SO WE DIDN'T SAY THAT IT HAD TO HAVE BEEN IN AN ACADEMIC CATEGORY.

SO IT COULD HAVE BEEN SPORTS, IT COULD

HAVE BEEN MUSIC, IT COULD HAVE BEEN ART, FOR SURE. AS WE KNOW MULTIPLE EXAMPLES HISTORICALLY THAT HAVE LED TO AN AHA MOMENT WHEN IT HAS NOTHING TO DO WITH THE ACTUAL SUBJECT MATTER THAT THE PERSON HAS BEEN WORKING ON. SO REALLY WE DIDN'T HAVE ANY CONSTRAINTS ON THAT SECOND DISCIPLINE AS LONG AS THEY HAD THE POTENTIAL OR THE INSTITUTION ACTUALLY HAD THE CAPACITY TO OFFER IT TO WHATEVER EXTENT THAT WOULD BE. AND SO, AGAIN, IT WAS DEFINITELY LEFT IN THE GRAY ZONE, BUT PART OF THAT WAS REALLY INTENTIONAL JUST BECAUSE WE DIDN'T WANT TO RESTRICT IT TO ANY GIVEN SET OF RULES BECAUSE THAT WOULD HINDER CREATIVITY.

MR. TORRES: I'LL PUT MY VOTING RECORD ON THE ARTS AGAINST ANYBODY. BUT I DO BELIEVE THAT -- I'LL WAIT TILL MANI IS FINISHED. I DO BELIEVE THAT THE PI IN THIS CASE IS VERY WELL RESPECTED. I KNOW HIM. I RESPECT HIM GREATLY. I JUST DON'T THINK THE APPLICATION WAS WRITTEN WITH GREAT SENSITIVITY TO HOW THE PUBLIC WOULD REACT TO SUCH A PROPOSAL. AND THAT'S WHY I OPPOSED IT. THERE WAS ANOTHER PROPOSAL THAT TALKED ABOUT THE SECONDARY DISCIPLINE BEING YACHTING AND GARDENING. DID THAT MAKE THE FUNDING?

MR. SHEEHY: YES.

MR. TORRES: IT DID AS WELL. FOR MY

PURPOSES THERE WERE OTHER PROPOSALS THAT DIDN'T STRETCH THE CREATIVITY DEFINITION. THEY KEPT IT WITHIN THE STEM CELL SCIENCE FIELD. THAT'S WHERE I FELT THOSE PROPOSALS WERE APPROPRIATE. AND THAT'S WHY I OPPOSED THIS PROPOSAL AND THAT'S WHY I OPPOSED THE YACHTING AND GARDENING PROPOSAL. I JUST DON'T THINK THAT THE PUBLIC WILL UNDERSTAND THE AHA MOMENTS. AND QUITE FRANKLY, THEY GIVE US A TRUST AND A FIDUCIARY DUTY TO SPEND THE TAXPAYER'S MONEY FOR IMPORTANT STEM CELL RESEARCH. AND, YES, I SUPPORT HIGH SCHOOL STUDENTS. I SUPPORT THE BRIDGES PROGRAM, BUT I DO THINK THAT SUPPORT OUGHT TO BE TEMPERED WITH THE SENSITIVITY OF HOW THESE PROJECTS ARE PERCEIVED.

CHAIRMAN THOMAS: MR. SHEEHY AND THEN DR. PRIETO.

MR. SHEEHY: I THINK YOU'RE IN CONFLICT, BY THE WAY, DR. PRIETO. SO I WOULD ADVISE YOU. I JUST WANT TO SAY I CAN'T IMAGINE, AND MANY OF THE INDIVIDUALS SITTING HERE ARE WORKING SCIENTISTS, THAT A BETTER METAPHOR, ARTISTIC ENTERPRISE METAPHOR FOR THE SCIENTIFIC ENDEAVOR EXISTS IN MAKING A MOVIE. YOU HAVE A PRODUCT THAT AT THE END OF THE DAY LOOKS LIKE THE CREATION OF AN INDIVIDUAL, SCORSESE, COPPOLA, BUT REALLY IS THE RESULT OF A

HIGHLY ORGANIZED TEAM OF MANY INDIVIDUALS DOING DIFFERENT PIECES OF WORK COLLECTIVELY. AND, YOU KNOW, YOU LOOK AT SOMEBODY WINS A NOBEL PRIZE, AND PEOPLE THINK, WELL, THEY DID THIS ALL THEMSELF. NO. A GOOD RESEARCHER, AT LEAST IN MY EXPERIENCE, IS SOMEONE WHO CAN ASSEMBLE A STRONG TEAM OF CREATIVE INDIVIDUALS TO WORK COLLECTIVELY TOWARDS A COMMON GOAL, AND THEY DO THIS WITH A CERTAIN PANACHE AND CERTAIN FLARE AND CERTAIN ARTISTRY.

AND SO I THINK THE METAPHOR OF FILM MAKING AND SCIENCE FOR A HIGH SCHOOL STUDENT IS INCREDIBLY POWERFUL IF YOU WANT TO ENCOURAGE KIDS FROM SOCIALLY DISADVANTAGED BACKGROUNDS.

MR. TORRES: THESE KIDS AREN'T MAKING FILMS. THEY'RE VIEWING FILMS UNDER THIS PROPOSAL.

MR. SHEEHY: THEY'RE STUDYING THE HISTORY OF FILM IN A COLLEGE ACCREDITED CLASS SO THEY UNDERSTAND. YOU KNOW, AGAIN, WE COULD AGREE TO DISAGREE, BUT I DON'T THINK THAT THE POINT OF THESE GRANTS ARE THE SECONDARY DISCIPLINES. IT'S JUST A LITTLE WHIPPED CREAM ON TOP OF WHAT IS REALLY A STEAK DINNER. AND THE REAL MEAT OF THIS PROJECT IS WHAT'S GOING ON INSIDE THE LABS, AS DR. VESSAL SAID. WHAT PORTION OF THIS GRANT WILL REALLY BE DEDICATED TO THE SECONDARY DISCIPLINE?

DR. VESSAL: THAT WAS NOT BUDGETED IN THERE REALLY. IT COMES OUT OF THE ADMINISTRATION COST.

MR. SHEEHY: SO THE MONEY THEY'RE REALLY SPENDING IS GOING TOWARDS SCIENCE. I JUST THINK THIS WAS A GREAT GRANT.

MR. TORRES: SO YOU SEE US PAYING FOR THE REMAINDER OF THE ACTIVITY IS WHAT YOU'RE SAYING?

DR. SAMBRANO: IF I MAY JUST ADD SOMETHING. IN TERMS OF THE REVIEW CRITERIA AND THE INSTRUCTIONS THAT WENT TO REVIEWERS, THE SECOND DISCIPLINE, THERE WAS AN EXPECTATION THAT THERE WOULD BE SOME KIND OF DESCRIPTION OF HOW IT INCORPORATED INTO THE PROGRAM OVERALL. I THINK REGARDLESS OF WHAT THE DISCIPLINE, THAT SECOND DISCIPLINE IS, I THINK THERE WAS AN EXPECTATION THAT SOMEHOW IT WOULD INCORPORATE INTO THE PROGRAM.

SO WHERE YOU MAY HAVE HAD GARDENING OR SOME OTHER TYPE OF ACTIVITY, THERE IS THE EXPECTATION THIS IS SOMEHOW GOING TO RELATE TO THE PROGRAM IN SOME WAY. WHERE THIS PARTICULAR APPLICATION UNDER DISCUSSION MAY HAVE FAILED MAY HAVE BEEN IN THAT DESCRIPTION, BUT IT IS NOT NECESSARILY THE SUBJECT MATTER ITSELF THAT WOULD BE AN ISSUE FOR REVIEWERS. IT IS REALLY HOW THEY

PACKAGE THE FULL PROGRAM TOGETHER AND WAS PRESENTED AND THE REVIEWERS RANKED THEM AND RATED THEM ACCORDINGLY.

MR. SHEEHY: MY MEMORY OF THE REVIEW WAS THE TWO MOST DAMAGING PIECES OF WHAT THE REVIEWERS LOOKED AT WAS THE RELATIONSHIP OF THE PI TO THE INSTITUTION, WHICH SEEMED TO ME THE MOST FATAL FLAW THAT THEY PERCEIVED, WHICH IS A MISPERCEPTION, BY THE WAY. I DON'T THINK THAT THAT'S TRUE. NONE OF US KNOW THAT TO BE TRUE, AND WE KNOW THE PI AND THE INSTITUTION. AND THE OTHER FLAW WAS THE LENGTH OF THE PROGRAM. THE OTHER ONES HAVE BEEN GOING ON FOR QUITE SOME TIME, AND THIS ONE WAS ONLY IN ITS SECOND YEAR. AND THAT WAS THE NO. 1 CRITERION.

FRANKLY, I WOULDN'T BE RECOMMENDING IT IF WE DIDN'T HAVE A SOLID TRACK RECORD OF ACHIEVEMENT BY THIS INSTITUTION AS MEASURED BY CIRM IN ITS PILOT WORK LAST SUMMER THAT COULD SHOW THAT THEY DID A GREAT JOB.

CHAIRMAN THOMAS: OKAY. WE HAVE DR. STEWARD, DR. JUELSGAARD, AND MR. ROTH.

DR. STEWARD: ACTUALLY THIS FOLLOWS DIRECTLY FROM GIL'S STATEMENT OF THE REQUIREMENTS. SO, JEFF, YOU ELOQUENTLY EXPLAINED HOW THIS ACTIVITY COULD ACTUALLY BE SEEN AS A METAPHOR. I GUESS THE

QUESTION IS DID THE GRANT DO THAT OR IS THAT YOU?

MR. SHEEHY: THAT'S ME. BUT I WILL SAY THAT FOR MANY OF THE GRANTS THAT ARE IN THE FUNDABLE CATEGORY, THE INTEGRATION OF THE SECOND DISCIPLINE WAS NOT WELL EXPLAINED. SO THAT WAS NOT A FEATURE THAT WAS UNIVERSALLY -- IT DID NOT QUALIFY YOU FOR FUNDING. IT DID NOT DISQUALIFY YOU FOR FUNDING IF YOU DID A POOR JOB OF EXPLAINING IT. I DON'T THINK THAT THAT WAS THE FATAL FLAW, BY THE WAY, IN THIS APPLICATION. IF IT WAS, SOME OF THE OTHER APPLICATIONS WOULD NOT HAVE BEEN FUNDED.

DR. JUELSGAARD: WELL, I THINK OS JUST ASKED ONE OF THE QUESTIONS I WAS INTERESTED IN. PART OF THIS COLLOQUY GOING ON IS, IN ESSENCE, MR. SHEEHY'S PERCEPTION OF THE PROCESS, WHICH I ACCEPT THAT THAT'S YOUR PERCEPTION. THE QUESTION IS IS THERE SOMEBODY WHO'S IN HERE WHO PARTICIPATED IN THAT PROCESS WHO HAS A DIFFERENT PERCEPTION SO THAT WE HAVE KIND OF BOTH SIDES OF THE ISSUE TO BE LAID OUT? OTHERWISE WE'RE LEFT WITH WHAT'S WRITTEN VERSUS YOUR FIRSTHAND KNOWLEDGE, JEFF. I'M CURIOUS ABOUT THAT.

A SECOND POINT IS REALLY, AND THIS IS WHAT I'M NOT SURE I UNDERSTAND, IS REALLY WHAT IS THIS VALUE OF THE SECOND DISCIPLINE? FOR ME IT'S A

REALLY NOVEL NOTION, AND IT'S NOT CLEAR WHAT REALLY VALUE. I THINK MAYBE THAT'S WHY NOT SO MUCH ATTENTION IS BEING PAID TO IT. IF NOT MUCH ATTENTION IS BEING PAID IT BY THE GRANTS WORKING GROUP, IT'S BECAUSE IT'S SORT OF JUST AN ADD-ON, AND ONE HAS TO QUESTION ITS RELEVANCE TO WHAT REALLY IS BEING ACCOMPLISHED. I WASN'T HERE WHEN THIS WAS CREATED, BUT MY FUNDAMENTAL QUESTION IS WHAT'S THE VALUE OF THE SECOND DISCIPLINE?

CHAIRMAN THOMAS: LET'S TAKE DR. TROUNSON.

DR. TROUNSON: WELL, I'D LIKE TO ADDRESS THAT VERY SPECIFICALLY BECAUSE I ACTUALLY THINK THE DISCUSSION IS VERY TYPICAL ABOUT WHAT PEOPLE DO AND DON'T UNDERSTAND ABOUT CREATIVITY. YOU HAVE TO ACTUALLY GO AND BOTHER TO READ WHAT MAKES REALLY CREATIVE PEOPLE. IF YOU DO THAT, IF YOU DELVE INTO WHAT REALLY CHANGES THINGS, WHAT GETS PEOPLE TO DO THINGS DIFFERENTLY RATHER THAN TO FOLLOW A SINGLE LINE AND A SINGLE PROCESS IS THAT THEY BE EXPOSED TO SOME OTHER DISCIPLINE. NOW, THE ARGUMENT IS WHAT IS THE EXTENT TO THAT DISCIPLINE? IS LAW AND VETERINARY SCIENCE ENOUGH DIFFERENCE TO MAKE SOMEBODY VERY SPECIAL IN ONE AREA, OR HAS THE MOVEMENT OF BALLET AND STEM CELLS GOT SOME REAL MERIT IN MAKING PEOPLE THINK IN A DIFFERENT WAY?

WE WANTED TO TAKE YOUNG PEOPLE AND NOT JUST DUMP THEM INTO STEM CELLS, BUT GIVE THEM AN EXPERIENCE WHERE THEY WOULD BE EXPOSED TO THE DISCIPLINE WE'RE INTERESTED IN, WHICH IS STEM CELLS, BUT ALSO GIVE THEM THAT EXTRA OPPORTUNITY TO EXPRESS THEMSELVES.

NOW, WE DIDN'T WANT TO SORT OF FORMULATE WHAT THAT WAS BECAUSE IN CREATIVITY THEORY THAT'S THE WRONG THING TO DO BECAUSE WE CAN'T PREDICT WHAT MIGHT BE REALLY CRITICAL. AND SOME THINGS, YOU KNOW, IN THIS CASE THE THEATER MAY NOT BE THE BEST THING. BUT HOW MANY PEOPLE DO YOU KNOW THAT ARE TREMENDOUS IN MUSIC AND VERY GOOD IN SCIENCE OR FISHING AND SCIENCE, OR SAILING AND SCIENCE? THERE ARE A WHOLE LOT OF THINGS WHICH GO TO MAKE UP VERY CREATIVE PEOPLE; BUT IF YOU DISTILL IT DOWN, THEY'RE NOT NECESSARILY THE SINGLE-MINDED PERSON THAT'S JUST MAKING THE NEW DISCOVERIES. AND WE WERE TRYING TO FIND THOSE PEOPLE AND STIMULATE THOSE FROM THIS COHORT WHO WERE NOT ALREADY BURIED DEEP ALREADY IN THE DISCIPLINE, BUT GIVE THEM SOME OPPORTUNITY TO EXPRESS THEMSELVES IN A DIFFERENT WAY. I THINK THAT HAPPENED IN THE WORK THAT WE DID WITH THESE YOUNG PEOPLE THE FIRST TIME AROUND. I THINK WE'RE ALL EXCITED.

YOU'D HAVE TO SAY MANI AND I HAD A LOT OF TROUBLE SELLING THIS WHOLE CONCEPT INTERNALLY. WE HAD A LOT OF DISCUSSIONS LAST TIME WE WERE HERE. AND UNLESS YOU BOTHERED TO READ DEEP INTO CREATIVITY, YOU PROBABLY WON'T HAVE THE SAME VIEWS THAT MANI AND I HAVE; BUT IF YOU DO, YOU'LL BE REALLY INTERESTED TO SEE THE NUMBER OF PEOPLE WHO HAVE NOBEL PRIZES THAT DO THINGS IN RATHER DIFFERENT WAYS. THEY THINK DIFFERENTLY. AND THAT'S REALLY WHAT WE WERE TRYING TO DO.

CHAIRMAN THOMAS: BACK TO MR. JUELSGAARD.

DR. JUELSGAARD: I JUST WANT TO RESPOND TO THAT, ALAN. I DON'T DISAGREE WITH YOUR NOTION GENERALLY SPEAKING THAT CREATIVE SCIENTISTS HAVE OTHER INTERESTS THAT MAY HELP STIMULATE THAT CREATIVITY. BUT NONE OF THAT IS IMPOSED FROM THE OUTSIDE OR DICTATED FROM THE OUTSIDE. THOSE CREATIVITY AMBITIONS RANGE A WHOLE VARIETY OF THINGS, AND THESE INTERESTS ARE DEVELOPED BY THE INDIVIDUALS THEMSELVES.

SO BACK TO THE ISSUE OF THE HISTORY OF FILM, MAYBE ONE PERSON, I'M JUST SPECULATING, MAYBE ONE PERSON OUT OF 20 WOULD FIND THAT OF SOME CREATIVE INTEREST; WHEREAS, THE OTHER 19 HAVE NO INTEREST IN FILM MAKING, NO DESIRE TO BE INVOLVED.

THEIR DESIRE MIGHT BE MUSIC, IT MIGHT BE PHOTOGRAPHY, IT MIGHT BE SOMETHING ENTIRELY DIFFERENT. SO FOR ME ONE OF THE PROBLEMS IS WE PUT EVERYBODY TOGETHER IN SOME SORT OF CREATIVITY CONTEXT AND SAY, SO THIS IS YOUR CREATIVE MOMENT. I'M NOT SURE HOW MUCH VALUE THAT REALLY BRINGS WHEN YOU DO IT THAT WAY.

DR. TROUNSON: WE'RE TRYING TO PROVIDE SOME DEPTH TO WHATEVER THAT DISCIPLINE IS. SO THAT'S WHY WE WERE ASKING FOR THAT SECOND DISCIPLINE TO HAVE SOME SORT OF STRUCTURE TO IT. WE CAN'T ACTUALLY PROVIDE ALL OF THE POSSIBILITIES THAT EVERYONE WOULD LIKE TO CHOOSE FOR THEMSELVES. SO THIS WAS ONE WAY IN WHICH YOU CAN CREATE A RATHER DIFFERENT ENVIRONMENT FOR SOMEBODY. WHETHER IT WORKS FOR EVERYBODY? NO, PROBABLY DOESN'T. BUT IF IT WORKS FOR SOME OF THEM, I THINK THAT WOULD BE REALLY IMPORTANT.

MR. ROTH: JUST A QUICK CLARIFICATION ON THE PROCESS. HOW WERE THE ORIGINAL PILOTS CHOSEN?

DR. VESSAL: FIRST COME, FIRST SERVED BASICALLY. WE PUT A CALL OUT ACTUALLY, AND WE ONLY HAD VERY LIMITED RESOURCES AVAILABLE.

MR. ROTH: THE REASON I WANTED THAT QUESTION ANSWERED IS BECAUSE I WANT TO MAKE SURE WE

DON'T PREJUDICE ALL THE APPLICATIONS BY THE ONES WHO WERE FORTUNATE TO GET AN OUTBOUND CALL TO SAY WOULD YOU LIKE TO DO THIS. SO IN THE INTEREST OF MAKING SURE -- THE ONLY THING WE HAVE THAT'S REALLY LOOKED AT TOTAL IS THE SCORING SYSTEM THAT CAME THROUGH HERE. OTHERWISE CERTAIN PLACES, OBVIOUSLY THIS ONE, IS BEING LOOKED AT BECAUSE THERE'S AN EXPERIENCE HERE. WHAT ABOUT THE ONES THAT DIDN'T GET SCORED DOWN BELOW THE LINE THAT DIDN'T HAVE A CHANCE TO GET THAT EXPERIENCE SO THEY COULD SCORE HIGH ENOUGH?

DR. LEVIN: I BROUGHT THIS UP BASED ON THE REVIEW, AND I DIDN'T KNOW ANYTHING ABOUT THE --

MR. ROTH: BUT THE CONVERSATION HAS LED TO AN AWFUL LOT OF TRYING TO OUT WHO IT IS, WHY THEY DESERVE IT, AND IT'S BASED ON HISTORIC PRECEDENT WHICH WAS NOT EVENLY RANDOMLY SELECTED. SO THERE'S A BIAS BUILT IN HERE EXCEPT FOR THE REVIEW CRITERIA.

MS. SAMUELSON: I'D JUST LIKE TO MAKE SURE THAT WE DON'T HAVE THE APPLICANT IN THE ROOM OR SOMEONE ELSE WHO COULD EXPLAIN THIS BECAUSE WE'RE SPECULATING A BIT, AND THIS IS AN IMPORTANT QUESTION. TODAY IT TURNS OUT JAMES CAMERON, THE DIRECTOR OF *TITANIC*, IS GOING TO THE DEEPEST POINT ON THE PLANET SOLO, A SEVEN-MILE DESCENT TO THE BOTTOM OF THE SOUTH PACIFIC. AND THE FIRST THING

HE'S GOING TO DO IS DO A FILM ABOUT IT. AND THAT WHAT HE INTENTIONALLY WANTS TO DO, HE SAYS IN THE NEWS ARTICLES, IS CREATE EXCITEMENT ABOUT THE SCIENCE. SO IT MAY BE THAT THERE'S SOME LINK THAT WE MISSED.

AND I'D ALSO LIKE TO KNOW IF WE COULDN'T MAYBE USE THIS OPPORTUNITY TO, IN THIS CASE WHERE THERE'S LESS PROPRIETARY INFORMATION AT ISSUE, I WOULD THINK, THAT IN A LOT OF OUR GRANT RFA'S, WE COULD LIFT THE CLOAK OF SECRECY ABOUT THE NAMES. WE'VE GOT AN OPPORTUNITY TO COMMUNICATE HERE.

CHAIRMAN THOMAS: MR. HARRISON.

MR. HARRISON: YOU MAY WANT TO ASK FOR A PUBLIC COMMENT, CHAIR, AT THIS POINT.

CHAIRMAN THOMAS: WE DON'T HAVE A -- WE HAVE PUBLIC COMMENT BEFORE WE HAVE A MOTION?

MR. HARRISON: WE HAVE A MOTION ON THE TABLE, SO THE PUBLIC COMMENT BEFORE THE VOTE.

CHAIRMAN THOMAS: SO THE SPECIFIC MOTION IS WITH RESPECT TO THIS ONE ITEM. IS THERE PUBLIC COMMENT ON THIS? MR. REED.

MR. REED: FIRST, THERE IS NO GREATER CHAMPION FOR THE BRIDGES PROGRAM THAN THE SENATOR. BUT ON THIS SITUATION, AS A FORMER JUNIOR HIGH SCHOOL TEACHER, I KNOW THAT SCIENCE IS THE HARDEST

SELL IN SCHOOL TODAY. THEY DON'T SEE THE WHY. THEY DON'T UNDERSTAND. IF YOU ASK THEM WHAT'S THE MOST HATED SUBJECT, IT'S SCIENCE BECAUSE THEY DON'T UNDERSTAND WHY.

NOW, WHAT MADE THE DIFFERENCE FOR ME IN UNDERSTANDING GLOBAL WARMING WAS A MOVIE. IT WAS THE AL GORE MOVIE. THAT MADE IT REAL FOR ME. SUDDENLY I UNDERSTOOD. BUT WE'RE FACING A GENERATION OF SCIENTIFIC ILLITERACY. AND IF THIS IS A BORDERLINE CALL, THEN I WOULD URGE YOU TO ERR ON THE SIDE OF REACHING OUT TO THE PEOPLE WHO WILL BE MAKING THE SCIENTIFIC DECISIONS OF TOMORROW. IT'S NOT AN OVERWHELMINGLY EXPENSIVE ITEM, AND I REALLY APPRECIATE THE CONCEPT OF CREATIVITY AS CRUCIAL TO REACHING OUT TO YOUNG PEOPLE.

CHAIRMAN THOMAS: ANY OTHER COMMENTS FROM THE PUBLIC?

DR. VESSAL: I'D JUST ACTUALLY LIKE TO ECHO BOTH DR. TROUNSON AND MR. REED. I JUST WANTED TO MAKE A COMMENT THAT ANOTHER PURPOSE FOR THE SECOND DISCIPLINE, WHATEVER THAT MAY BE, REALLY I THINK DON REALLY HIT IT, IS POSITIVE REINFORCEMENT. AND JUST TO HAVE A POSITIVE EXPERIENCE OF DOING SCIENCE HANDS-ON AND HAVING FUN WITH IT TOO. BECAUSE AS A SCIENTIST, I CAN SAY THAT SCIENCE CAN'T

BE FUN ALL THE TIME. IT'S NOT FUN ALL THE TIME. BUT THIS IS THE VERY BEGINNING WHERE THE SEED IS BEING PLANTED IN THESE KIDS WHO OTHERWISE REALLY MOSTLY WOULDN'T HAVE THE OPPORTUNITY IN AT LEAST HALF OF THE GROUP TO BE EXPOSED AT THIS HIGH LEVEL TO A HANDS-ON SCIENCE.

SO I JUST -- ANY ACTIVITY, IF IT'S FUN, IT'S ALSO POSITIVE REINFORCEMENT FOR SCIENCE PERHAPS IN THE FUTURE AS A CAREER.

MR. TORRES: DR. VESSAL, COULD YOU GO VERY QUICKLY OVER ALL THE ONES THAT WE AGREED TO FUND AND GIVE US A QUICK HIT ON WHAT THE SECONDARY DISCIPLINE WAS FOR EACH OF THESE PROJECTS?

DR. VESSAL: THEY'RE PROVIDED IN THE SUMMARY ACTUALLY THAT HAS BEEN PROVIDED IN YOUR FOLDERS, I BELIEVE. THEY'RE ALL IN THERE.

MR. TORRES: WELL, I DON'T SEE IT. I DIDN'T SEE THEM.

DR. VESSAL: THE EXECUTIVE SUMMARIES ARE ALL IN THE FOLDER WITH ALL THE HIGHLIGHTS OF THE STRENGTHS AND WEAKNESSES IN A VERY SORT OF --

DR. JUELSGAARD: ARE THESE THE SAME ONES THAT WERE DISTRIBUTED BY MARIA PRIOR TO THIS MEETING? BECAUSE I READ EVERY ONE OF THOSE, AND I DIDN'T SEE ANY TALK ABOUT THE SECONDARY DISCIPLINES.

CHAIRMAN THOMAS: MR. SHEEHY.

MR. SHEEHY: COULD I JUST MAKE A FUNDAMENTAL POINT ABOUT WHAT THIS GRANT IS ABOUT? I THINK IN A WAY THIS IS A SUMMER PROGRAM. THESE COURSES ARE A FEW WEEKS IN THE SUMMER FOR HIGH SCHOOL STUDENTS FROM SOCIALLY DISADVANTAGED BACKGROUNDS PREDOMINANTLY. SO, YOU KNOW, WHEN PEOPLE LOOK AT THIS, WHEN THEY'RE PUTTING THEIR FRAME ON THIS, THINK ABOUT WHO THE TARGET IS. THESE ARE HIGH SCHOOL KIDS. MOST OF THEM MAY NOT HAVE ANY OPPORTUNITY. THIS MAY BE THEIR ONLY OPPORTUNITY TO GET INTO A LAB, TO HAVE CONTACT WITH THIS TYPE OF SCIENCE. AND I JUST -- I THINK -- THIS IS THE SAME THING THAT HAPPENED AT THE GRANTS WORKING GROUP. WE GOT CAUGHT UP ON THE SECONDARY DISCIPLINING.

THE POINT, I THINK, IS TO GIVE KIDS IN CALIFORNIA AN OPPORTUNITY AT THAT LEVEL OF THEIR LIFE TO EXPERIENCE SOMETHING OF THIS $3 BILLION ENTERPRISE THAT THE TAXPAYERS ARE PAYING FOR, TO GIVE THOSE KIDS WHO MAY HAVE NO OTHER OPPORTUNITY TO EXPERIENCE WHAT WE'RE DOING THE CHANCE TO GET INTO A LAB TO SEE THE SCIENCE, TO LEARN THE SCIENCE, TO GET ENGAGED, PERHAPS TO BECOME PART OF THIS ENTERPRISE.

CHAIRMAN THOMAS: SO DR. STEWARD.

DR. STEWARD: I'M JUST GOING TO SAY THIS

AND I'M GOING TO ACTUALLY CALL FOR THE QUESTION.

I THINK GOING BACK TO THE ISSUE OF WHETHER OR NOT IT'S A GOOD IDEA, IT'S TOO LATE. THAT'S WHAT WAS IN THE RFA. I'LL JUST SAY THAT AS A PERSON WHO ACTUALLY DOES THIS, I HAVE STUDENTS JUST LIKE THIS IN MY LAB EVERY SUMMER. WE DON'T DO ANYTHING ELSE BUT WORK IN THE LAB, AND THEY HAVE FUN. I THINK THEY ENJOY IT. ENOUGH SAID. THE RFA IS WHAT IT IS, AND I THINK WE'VE HAD PLENTY OF DISCUSSION, SO I'D JUST LIKE TO CALL FOR THE QUESTION.

CHAIRMAN THOMAS: OKAY. IS THERE -- YES. WE'RE GOING TO HAVE A VOTE BEFORE YOUR COMMENT, DR. PRIETO. THIS IS JUST ABOUT THE ONE APPLICATION.

DR. PRIETO: I WANTED TO COMMENT ON ANOTHER APPLICATION OR QUOTE SOMETHING FROM ANOTHER APPLICATION THAT MIGHT ILLUSTRATE A POINT.

CHAIRMAN THOMAS: DR. STEWARD, IS THAT OKAY?

MR. HARRISON: DR. PRIETO CAN'T PARTICIPATE IN THIS DISCUSSION. SO I'D REQUEST HIM TO RESERVE HIS COMMENT FOR AFTER THE VOTE.

CHAIRMAN THOMAS: WE'RE GOING TO HAVE A VOTE. I WOULD JUST LIKE TO SAY BEFORE THE VOTE THAT HAVING LISTENED TO THE CREATIVITY AWARD DISCUSSION IN THE GRANTS WORKING GROUP, I VERY STRONGLY AGREE

WITH THE SENTIMENT THAT WE NEED TO TRY TO DO WHATEVER WE CAN TO GET KIDS INTERESTED IN THE FIELD. AND THIS PROJECT, AS WELL AS THE OTHERS, ARE, IN MY OPINION, MORE THAN CAPABLE OF ACHIEVING THAT GOAL AND IS SOMETHING THAT WE SHOULD BE BEHIND. MOST, IF NOT ALL OF THE SECONDARY DISCIPLINES COME AT A DE MINIMIS COST. SO I DON'T THINK THAT'S A PARTICULARLY LARGE ISSUE. AND I THINK THE OVERARCHING GOAL OF GETTING KIDS INTERESTED GOING FORWARD TRUMPS, IN MY OPINION, CONCERNS, THOUGH THEY'RE VERY WELL FOUNDED BY THE SENATOR AND MR. JUELSGAARD. SO WITH THAT, CAN WE TAKE A -- IS THIS A VOICE OR ROLL CALL? ROLL CALL.

MS. BONNEVILLE: ROBERT PRICE.

DR. PRICE: YES.

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: YES.

MS. BONNEVILLE: JACOB LEVIN.

DR. LEVIN: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN. LEEZA GIBBONS. MICHAEL GOLDBERG. SAM HAWGOOD.

DR. HAWGOOD: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: TED LOVE. BERT LUBIN.

DR. LUBIN: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: PHIL PIZZO.
DR. PIZZO: YES.
MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: YES.
MS. BONNEVILLE: ROBERT QUINT. DUANE ROTH.
MR. ROTH: NO.
MS. BONNEVILLE: JOAN SAMUELSON.
MS. SAMUELSON: YES.
MS. BONNEVILLE: DAVID SERRANO-SEWELL.
MR. SERRANO-SEWELL: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: JONATHAN SHESTACK.
MR. SHESTACK: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: NO.
MS. BONNEVILLE: KRISTINA VUORI. EUGENE

WASHINGTON.

CHAIRMAN THOMAS: MOTION PASSES. ON ANOTHER APPLICATION YOU HAD A QUESTION, DR. PRIETO, OR IS IT ONLY AS PERTAINED TO THE LAST?

DR. PRIETO: WELL, IT'S PERHAPS MOOT AT THIS POINT. I JUST WANTED TO QUOTE FROM THE SUMMARY ON ONE OF THE OTHER HIGHLY RATED PROGRAMS AND THE RESPONSIVENESS TO THE RFA.

MS. SAMUELSON: COULD WE GET THE NUMBER?

DR. PRIETO: 5868. REVIEWERS EXPRESSED CONCERN THAT THE PROGRAM DOES NOT SUFFICIENTLY -- I'M SORRY. WAIT A MINUTE. MAKE SURE I'M ON THE RIGHT ONE.

BASICALLY THE CRITICISM WAS THAT ALTHOUGH THIS WAS VERY HIGHLY RATED, THAT THE SECONDARY DISCIPLINE WAS VERY MINIMALLY DESCRIBED. SO I THOUGHT IN SPITE -- THEY MAY HAVE BENEFITED FROM THE FACT THAT THEY JUST DIDN'T TALK ABOUT IT VERY MUCH.

CHAIRMAN THOMAS: THANK YOU, DR. PRIETO.

SO ANY OTHER DISCUSSION ON ANY OTHER APPLICATIONS? HEARING NONE, I WOULD ENTERTAIN A MOTION THAT, AS WE HAVE NOW MOVED THAT LAST DISCUSSED ITEM UP INTO TIER 1, WE ENTERTAIN A MOTION TO APPROVE THE ENTIRE GROUP OF ITEMS, AND THAT HAS TO BE MADE BY SOMEBODY WHO DOESN'T HAVE A CONFLICT

WITH ANY; IS THAT CORRECT, MR. HARRISON?

MR. HARRISON: THAT'S CORRECT.

DR. LEVIN: I'LL MAKE IT.

CHAIRMAN THOMAS: DR. LEVIN, YOU ARE MAKING THE MOTION?

DR. VESSAL: MR. CHAIRMAN, I JUST WANT TO POINT OUT THAT THE BUDGET IS NOW UPDATED TO $1,747,020.

CHAIRMAN THOMAS: THANK YOU. MOVED BY DR. LEVIN, SECONDED BY MR. SHESTACK. IS THERE DISCUSSION ON THE PACKAGE AS A WHOLE?

MS. FEIT: WHICH GRANT NUMBER?

CHAIRMAN THOMAS: THIS IS ON -- THE DISCUSSION NOW IS WE HAVE MOVED THE ITEM DISCUSSED A MOMENT AGO UP INTO TIER 1, AND WE NOW HAVE NINE RECOMMENDED AWARDS. THE MOTION REFERS TO ALL NINE.

MS. FEIT: OKAY.

CHAIRMAN THOMAS: DO YOU HAVE A QUESTION, OR DOES THAT ANSWER YOUR QUESTION?

MS. FEIT: THAT ANSWERS MY QUESTION.

CHAIRMAN THOMAS: THANK YOU. DISCUSSION BY THE BOARD? HEARING NONE, PUBLIC COMMENT.

MS. SAMUELSON: CAN I GET A POINT OF CLARIFICATION? IT APPEARS THAT 5868 WAS APPROVED, RECOMMENDED FOR APPROVAL. SO IT WASN'T IN A LOWER

TIER TO BE MOVED UP.

CHAIRMAN THOMAS: DR. PRIETO RECOGNIZED IT HAD BEEN MOVED FOR APPROVAL. HE WAS JUST NOTING A FEATURE OF THE APPLICANT REVIEW.

ANY OTHER QUESTIONS? NO COMMENTS BY MEMBERS OF THE PUBLIC. MR. HARRISON.

MR. HARRISON: JUST A REMINDER TO MEMBERS, TO THE EXTENT THAT YOU HAVE AN INTEREST IN A APPLICATION THAT'S SUBJECT TO THIS MOTION, PLEASE VOTE YES OR NO OR ABSTAIN EXCEPT WITH RESPECT TO THOSE APPLICATIONS IN WHICH YOU HAVE AN INTEREST.

CHAIRMAN THOMAS: MARIA, PLEASE CALL THE ROLL ON THIS MOTION.

MS. BONNEVILLE: ROBERT PRICE.

DR. PRICE: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: JACOB LEVIN.

DR. LEVIN: YES.

MS. BONNEVILLE: MARCY FEIT.

MS. FEIT: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: MICHAEL FRIEDMAN. LEEZA

GIBBONS. MICHAEL GOLDBERG. SAM HAWGOOD.

DR. HAWGOOD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. TED LOVE. BERT LUBIN.

DR. LUBIN: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: SHLOMO MELMED. PHIL PIZZO.

DR. PIZZO: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: CLAIRE POMEROY.

DR. POMEROY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: ELIZABETH FINI.

DR. FINI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. BONNEVILLE: ROBERT QUINT. DUANE ROTH.

MR. ROTH: YES.

MS. BONNEVILLE: JOAN SAMUELSON.
MS. SAMUELSON: YES.
MS. BONNEVILLE: DAVID SERRANO-SEWELL.
MR. SERRANO-SEWELL: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MS. BONNEVILLE: JONATHAN SHESTACK.
MR. SHESTACK: 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. EUGENE WASHINGTON.
CHAIRMAN THOMAS: THANK YOU. MOTION CARRIES.
WE'RE GOING TO TAKE OUT OF ORDER, JUST TO MAKE SURE WE GET A VOTE, THE MOST IMPORTANT PASSAGE OF THE MINUTES FROM THE JANUARY BOARD MEETING. IT APPEARS ON YOUR AGENDA AS ITEM NO. 14. DO I HAVE A MOTION TO APPROVE?
MR. TORRES: SO MOVED.

CHAIRMAN THOMAS: IS THERE A SECOND?

MR. JUELSGAARD: SECOND.

CHAIRMAN THOMAS: MOVED BY MR. ROTH, SECONDED BY MR. JUELSGAARD. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MOTION PASSED.

OKAY. NOW WE GET TO THE FIRST OF A NUMBER OF VERY IMPORTANT PRESENTATIONS ON DIFFERENT ITEMS. ITEM NO. 9 IS GOING TO BE A DISCUSSION OF THE STRATEGIC PLAN. AND PART AND PARCEL OF THAT, WHICH WILL BE LED BY DR. FEIGAL, WILL BE A DISCUSSION OF THE ALLOCATION AND PRIORITIZATION OF FUNDING, WHICH WILL BE LED BY DR. OLSON.

MS. BONNEVILLE: WE NEED TO POLL THE MEMBERS ON THE PHONE TO APPROVE THE MINUTES.

CHAIRMAN THOMAS: GOOD POINT. SORRY. SORRY ABOUT THAT PHIL, MARCY, AND MICHAEL.

MS. BONNEVILLE: PHIL PIZZO.

DR. PIZZO: YES. I WAS WONDERING.

MS. BONNEVILLE: MARCY FEIT.

MS. FEIT: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN.

CHAIRMAN THOMAS: THANK YOU, LADY AND GENTLEMAN.

MR. SHEEHY: SHOULD WE HAVE A BRIEF BREAK

BEFORE WE DIVE INTO THIS NEXT ONE, OR DO YOU WANT TO GO ALL THE WAY THROUGH BECAUSE I'M NOTICING PEOPLE.

CHAIRMAN THOMAS: FIVE MINUTES. FIVE-MINUTE BREAK. PLEASE BE BACK BECAUSE WE WANT TO GET AS MUCH AS POSSIBLE STAYING ON SCHEDULE. THANK YOU.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: IF EVERYBODY WILL TAKE THEIR SEATS SO WE CAN RESUME HERE. THE MIKES ARE BACK ON. SOMEBODY JUST CHECK TO SEE IF ANY BOARD MEMBERS ARE OUT IN THE HALL AND PLEASE ASK THEM TO COME BACK TO THEIR SEATS.

I'M REMINDED BY MR. HARRISON THAT WE WERE REMISS IN CLOSING OUT THE CREATIVITY AWARDS. WE DO NEED A BOARD VOTE TO NOT FUND THE TIER 3 PROJECTS. SO IF WE COULD PERHAPS HAVE A MOTION AND SECOND BY THE SAME PARTIES WHO MOTIONED ORIGINALLY.

DR. LEVIN: I'LL PUT FORTH THAT MOTION.

CHAIRMAN THOMAS: I GUESS THE MOTION WAS BY MR. SHESTACK -- SECOND WAS BY MR. SHESTACK. IS THERE SOMEBODY ELSE WHO'D LIKE TO SECOND THAT MOTION --

DR. STEWARD: SECOND.

CHAIRMAN THOMAS: -- WHO'S NOT CONFLICTED? SECONDED BY DR. STEWARD.

SO, AGAIN, PLEASE CONSULT YOUR LIST OF CONFLICTS. THERE ARE ONLY THREE AWARDS AFFECTED BY THIS. MOST OF YOU WILL NOT BE CONFLICTED AND THEREFORE DON'T NEED TO HAVE THE CAVEAT LANGUAGE ADDED TO YOUR VOTE. WITH THAT, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ROBERT PRICE.

DR. PRICE: YES.

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: YES.

MS. BONNEVILLE: JACOB LEVIN.

DR. LEVIN: YES.

MS. BONNEVILLE: MARCY FEIT. MICHAEL FRIEDMAN. LEEZA GIBBONS. MICHAEL GOLDBERG. SAM HAWGOOD.

DR. HAWGOOD: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD. SHERRY LANSING. TED LOVE. BERT LUBIN.

DR. LUBIN: YES.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: PHIL PIZZO.

DR. PIZZO: YES.

CHAIRMAN THOMAS: MR. HARRISON IS WAVING HIS HAND FRANTICALLY. NEVER A GOOD SIGN.

MR. HARRISON: FOR THE RECORD, I THINK DR. MELMED IS YES, EXCEPT FOR THOSE WITH WHICH YOU HAVE A CONFLICT.

DR. MELMED: CORRECT. YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

CHAIRMAN THOMAS: THAT'S EXACTLY WHAT HE MEANT, YES.

MS. BONNEVILLE: CLAIRE POMEROY.

DR. POMEROY: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: YES.

MS. BONNEVILLE: ELIZABETH FINI.

DR. FINI: YES.

MS. BONNEVILLE: ROBERT QUINT. DUANE ROTH.

MR. ROTH: YES.

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

MR. SERRANO-SEWELL: YES.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: JONATHAN SHESTACK. OSWALD STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: KRISTINA VUORI. EUGENE WASHINGTON.

CHAIRMAN THOMAS: THANK YOU. MR. HARRISON.

MR. HARRISON: ANOTHER CORRECTION FOR THE RECORD. FOR DR. FINI, THAT WAS YES, EXCEPT FOR THOSE WITH WHICH YOU HAVE A CONFLICT.

DR. FINI: YES, EXCEPT FOR THOSE WITH WHICH I HAVE CONFLICTS.

CHAIRMAN THOMAS: THANK YOU, MR. HARRISON, FOR CONTINUING TO KEEP US IN LINE HERE ON ALL MATTERS.

WE'RE GOING TO, BEFORE WE GET TO DR. FEIGAL, JUST VERY BRIEFLY, DR. KNOEPFLER IS HERE FROM UC DAVIS WOULD LIKE TO MAKE A PUBLIC COMMENT.

DR. KNOEPFLER: HELLO, EVERYONE. I'M DR. KNOEPFLER. I'M AN ASSOCIATE PROFESSOR HERE AT UC DAVIS AT THE MED CENTER HERE IN SACRAMENTO, AND I'M A RECIPIENT OF A NEW FACULTY AWARD. AND I JUST WANTED TO INTRODUCE MYSELF BECAUSE I HAVEN'T MET MOST OF YOU, AND I'M A LITTLE BIT INCOGNITO TO A FUND-RAISER WHERE YOU SHAVE YOUR HEAD TO RAISE MONEY

FOR ST. BALDRICK'S FOUNDATION. SO EVEN THOSE OF YOU WHO KNOW ME MAY NOT RECOGNIZE ME.

I JUST WANTED TO THANK YOU FOR THE SUPPORT THAT I'VE RECEIVED FROM CIRM AND GIVE YOU JUST A LITTLE BIT OF SOME OF THE OUTCOMES. BASED ON THE CIRM FUNDING, I'VE BEEN ABLE TO OBTAIN AN RO1 FROM NIH THAT IS ON A RELATED TOPIC TO MY CIRM NEW FACULTY GRANT. I'VE ALSO RECEIVED OTHER FUNDING THAT'S RELATED TO THE CIRM RESEARCH AS WELL.

MY LAB HAS ABOUT HALF A DOZEN PUBLICATIONS SO FAR IN JUST ABOUT THREE YEARS THAT ARE DIRECTLY RELATED TO THE CIRM FUNDING. THERE ARE ALSO A NUMBER OF TRAINEES IN MY LAB GETTING TRAINING BECAUSE OF CIRM FUNDING. SO I THINK THESE ARE WONDERFUL OUTCOMES.

I ALSO WANTED TO POINT OUT THAT I'M A LITTLE BIT OF AN UNUSUAL SCIENTIST IN THAT I'M ALSO A PATIENT ADVOCATE. I'M A CANCER SURVIVOR. I HAD PROSTATE CANCER AT AGE 42, TWO YEARS AGO. SO I REALLY FEEL I CAN SEE THINGS FROM BOTH THE LAB SIDE AND ALSO THE PATIENT SIDE, AND THIS REALLY MAKES ME VERY PASSIONATE ABOUT THE WORK THAT WE DO.

JUST A NOTE ON THAT, WE WORK ON BASIC MECHANISMS OF PLURIPOTENCY AND HOW THOSE RELATE TO THE TUMORGENICITY, THE TERATOMA FORMING ACTIVITY, OF

STEM CELLS. I ALSO RUN A BLOG THAT SOME OF YOU MIGHT BE AWARE OF CALLED IPSCELL.COM. AND TO MY KNOWLEDGE, THIS IS THE ONLY FACULTY LEVEL BLOG IN THE WORLD THAT IS ON STEM CELLS. AND I'M VERY MUCH A CIRM SUPPORTER, AND OFTENTIMES POSITIVE HEADLINES ABOUT CIRM ARE THINGS THAT I WRITE ABOUT OR EVEN START THE BALL ROLLING ON THOSE.

SO I JUST WANTED TO TAKE A FEW MINUTES TO INTRODUCE MYSELF AND TELL YOU A LITTLE BIT ABOUT WHAT I'M DOING. AND, AGAIN, THANK YOU VERY MUCH.

(APPLAUSE.)

DR. POMEROY: THANK YOU, PAUL. AND I JUST WANT TO SAY THAT DR. KNOEPFLER IS ONE OF OUR UC DAVIS STEM CELL SUPER STARS AND POINT OUT TO MY FELLOW BOARD MEMBERS THAT RETAINING DR. KNOEPFLER AT UC DAVIS HAS BEEN VERY MUCH ENHANCED BY THE OPPORTUNITY TO APPLY FOR THE CIRM FUNDING AND TO BUILD ON THAT CIRM FUNDING TO GET ADDITIONAL GRANTS. AND SO I THINK HE'S AN EXAMPLE OF THE BRAIN POWER THAT HAS BEEN KEPT IN CALIFORNIA BECAUSE OF THIS INITIATIVE. AND WE'RE VERY GRATEFUL TO HAVE HIM.

MR. TORRES: HERE. HERE.

MR. HARRISON: CHAIR, WE NEED TO CLOSE OUT THE VOTE ON THE MOTION NOT TO FUND THE APPLICATIONS IN TIER 3 OF THE CREATIVITY AWARDS BECAUSE THERE

WERE SEVERAL MEMBERS WHO WERE OUT OF THE ROOM WHEN THE VOTE WAS TAKEN. SO IF WE COULD JUST FOLLOW UP WITH THOSE MEMBERS.

MEMBER FEIT. MEMBER JUELSGAARD.

DR. JUELSGAARD: NOT TO FUND?

MR. HARRISON: YES.

DR. JUELSGAARD: YES.

MR. HARRISON: MEMBER SERRANO-SEWELL.

MR. SERRANO-SEWELL: I VOTED YES.

MR. HARRISON: MEMBER SHEEHY.

MR. SHEEHY: I VOTED YES.

MR. HARRISON: MEMBER SAMUELSON.

MS. SAMUELSON: YES.

CHAIRMAN THOMAS: THAT MOTION IS OFFICIALLY PUT TO BED.

DR. KNOEPFLER, THANK YOU VERY MUCH FOR YOUR COMMENTS. AND THANK YOU VERY MUCH FOR YOUR BLOG. IT'S NICE TO SEE POSITIVE NEWS REFLECTED IN YOUR REPORTING, AND WE VERY MUCH APPRECIATE IT.

OKAY. SO BACK NOW TO THE STRATEGIC PLAN DISCUSSION. DR. FEIGAL.

DR. FEIGAL: WELL, THANKS VERY MUCH FOR THE OPPORTUNITY TO GIVE YOU AN UPDATE ON THE 2012 REVISION OF CIRM'S STRATEGIC PLAN. YOU'VE SEEN THIS PLAN, DRAFTS OF IT, SEVERAL TIMES BEFORE AT THE

BOARD MEETINGS. WHAT I'D LIKE TO DO OVER THE NEXT APPROXIMATELY 15, 20 MINUTES IS REMIND YOU OF WHERE WE'VE BEEN WITH YOU IN TERMS OF SOME OF THE ELEMENTS OF THE STRATEGIC PLAN AND ALSO FOR TODAY FOCUS PRIMARILY ON THE ONE- AND FIVE-YEAR GOALS FOR THE STRATEGIC PLAN.

SO JUST TO REMIND YOU, WE HAVE TALKED ABOUT THE 2012 STRATEGIC PLAN ELEMENTS. WE HAVE REVIEWED WITH YOU THE STAKEHOLDER INPUT. AS IN PRIOR YEARS, WE WENT OUT TO SEEK INPUT ON OUR STRATEGIC PLAN FROM PATIENTS, PATIENT ADVOCACY ORGANIZATIONS, MEMBERS OF INDUSTRY, OTHER MEMBERS OF THE PUBLIC SO THAT WE CAN CONSIDER THEM AS WE REVISE AND EMBED THESE ISSUES IN THE REVISED PLAN.

THE OUTPUT INCLUDED THOSE OR THE INPUT INCLUDED THOSE FROM PUBLIC MEETINGS, ICOC MEETINGS, INDUSTRY MEETINGS, AND OTHER STAKEHOLDER DISCUSSIONS. AT THE LAST ICOC IN JANUARY, WE DISCUSSED OUR STRATEGIES TO ACHIEVE OUR STRATEGIC OBJECTIVES. AS I MENTIONED, TODAY WE'RE GOING TO FOCUS ON THE ONE- AND FIVE-YEAR GOALS, THE ALIGNMENT OF THESE GOALS WITH OUR 2012 STRATEGIC PLAN, AND ALSO TO CONSIDER THE PREREAD THAT YOU ALREADY RECEIVED A COUPLE OF WEEKS AGO, AS WELL AS THE PRESENTATION TODAY AS REFERENCE FOR THE SUBSEQUENT

DISCUSSION ON FUNDING PRIORITIES AND STRATEGIES, WHICH PAT OLSON IS GOING TO TALK ABOUT. SO CONSIDER THIS TALKING ABOUT THE GOALS, BUT ALSO TEEING IT UP FOR THE SUBSEQUENT DISCUSSION ON FUNDING PRIORITIES AND STRATEGIES.

JUST TO REMIND YOU OF WHERE WE'VE BEEN, THE STRATEGIC PLAN INITIALLY WRITTEN IN 2006, UPDATED IN 2009-2010 IN PREPARATION FOR THE EXTERNAL REVIEW PANEL. THE EXTERNAL REVIEW TOOK PLACE IN OCTOBER OF 2010, AND THEY PROVIDED A SERIES OF RECOMMENDATIONS. SO WE'RE UPDATING THE STRATEGIC PLAN IN 2012 TO REFLECT THE RECOMMENDATIONS FROM THE EXTERNAL REVIEW PANEL TO REFLECT SHIFTS IN THE FIELD AND TO REFLECT STAKEHOLDER INPUT THAT WE'VE GOTTEN SINCE WE STARTED THIS PROCESS BACK IN AUGUST OF 2011. AND IT'S GOING TO CONTINUE THROUGH BOARD CONSIDERATION IN MAY, IN A COUPLE MONTHS, 2012.

DISCUSSIONS TO DATE HAVE INCLUDED A CIRM SENIOR STAFF RETREAT IN AUGUST, A SCIENCE TEAM DISCUSSION BACK IN AUGUST OF LAST YEAR. YOU RECEIVED UPDATES IN AUGUST, OCTOBER, DECEMBER, AND JANUARY. THERE WERE DISCUSSIONS WITH THE STEM CELL RESEARCH LEADERSHIP IN SEPTEMBER; AND BETWEEN SEPTEMBER AND DECEMBER, WE'VE HAVE HELD MULTIPLE STAKEHOLDER DISCUSSIONS WITH INDUSTRY, PATIENT

ADVOCATES, COLLABORATIVE FUNDING PARTNERS, CLINICAL DEVELOPMENT ADVISORS, PROFESSIONAL SOCIETIES, AND THE ALLIANCE FOR REGENERATIVE MEDICINE.

IN ADDITION, WE'VE BEEN PROVIDING VERSIONS OF THE STRATEGIC PLAN TO OUR INSTITUTE OF MEDICINE REVIEW PANEL SO THAT THEY CAN SEE WHERE WE'RE THINKING AND WHERE WE'RE HEADED IN THE NEXT FIVE YEARS.

THE APPROACH HAS BEEN THREE-PRONGED: DEFINING THE STRATEGIC PLAN, SEEKING INPUT, AND THEN TODAY WHAT WE'RE GOING TO FOCUS ON IS THAT DRAFT OF THE ONE- AND FIVE-YEAR GOALS.

REMINDING YOU OF OUR MISSION IS TO SUPPORT ADVANCED STEM CELL RESEARCH AND REGENERATIVE MEDICINE WITH THE GOAL OF REALLY APPLYING THOSE TO THE DISCOVERY AND DEVELOPMENT OF CURES, THERAPIES, DIAGNOSTICS, AND RESEARCH TECHNOLOGIES TO RELIEVE HUMAN SUFFERING FROM CHRONIC DISEASE AND INJURY. AS YOU RECALL, THE LAST FIVE YEARS WERE EXPLORATORY, FUNDING PROJECTS, SEEDING THE FIELD, BRINGING IN RESEARCH LEADERS LIKE DR. KNOEPFLER, ESTABLISHING THE FOUNDATION FOR LEADERSHIP IN STEM CELL RESEARCH.

THESE NEXT FIVE YEARS ARE REALLY ABOUT PRIORITIZATION OF OUR PROJECTS AND OUR INVESTMENTS, ADVANCING THE SCIENCE INTO CLINICAL TRIALS FOR

PATIENTS TO GENERATE THAT PRELIMINARY EVIDENCE OF THERAPEUTIC BENEFIT, AND DEVELOPING PARTNERSHIPS BETWEEN ACADEMIA, WITH INDUSTRY, WITH PATIENT GROUPS, AND ALSO INTERNATIONALLY, GEOGRAPHICALLY AS WELL AS WITH DIFFERENT DISCIPLINES SO THAT BY 2016 WE'LL BE ABLE TO FACILITATE COMMERCIALIZATION OF THERAPIES, ADVANCE THESE THERAPIES TO PATIENTS, AND ALSO HAVE HELPED ENABLE A BUSINESS MODEL FOR STEM CELL-BASED THERAPIES.

OUR STAKEHOLDER INPUT WAS DONE PRIMARILY TO OBTAIN PERSPECTIVES ON HOW WELL WE'RE DOING, WHETHER THE PROPOSED REVISIONS ARE APPROPRIATE, AND ALSO TO IDENTIFY ADDITIONAL AREAS OR ACTIVITIES FOR CIRM TO CONSIDER IN MOVING FORWARD. WE DID CHANGE THE STRATEGIC OBJECTIVES FROM 2009 TO 2010 TO CONSOLIDATE THEM INTO FOUR: SCIENTIFIC, CLINICAL, ECONOMIC, AND COMMUNITY.

THESE ARE JUST THE PICTOGRAPHS, I GUESS, OF THE DIFFERENT PUBLIC DISCUSSIONS THAT TOOK PLACE WITH DIFFERENT MEMBERS OF THE PUBLIC.

AND THE KEY THEMES FROM ALL OF OUR DISCUSSIONS HAVE BEEN, NO. 1, THAT CIRM HAS ESTABLISHED MOMENTUM, THAT WE HAVE MADE GREAT INITIAL PROGRESS IN ESTABLISHING AN EXTENSIVE PROGRAM IN SUPPORT OF STEM CELL RESEARCH AND THE

ADVANCEMENT OF SCIENCE.

TWO, SUSTAINABILITY, THAT CIRM NEEDS TO BE MORE AGGRESSIVE IN FINDING ALTERNATIVE FUNDING RESOURCES AND TO IMPLEMENT GREATER CREATIVITY IN IDENTIFYING THE TYPES OF ORGANIZATIONS THAT MAY BE ABLE TO CONTRIBUTE TO THE SUSTAINABILITY OF OUR WORK.

THREE, COMMUNICATION AND PUBLIC AWARENESS. YOU JUST HEARD WE ADDED A POSITION ON APRIL 2D WITH A NEW SENIOR DIRECTOR OF PUBLIC COMMUNICATION AND PATIENT ADVOCATE OUTREACH, BUT THIS IS IN THE STRATEGY TO REALLY HAVE MORE ROBUST PUBLIC AFFAIRS TACTICS AND THAT WE NEED TO BETTER COMMUNICATE OUR ORGANIZATIONAL INITIATIVES, AS WELL AS EDUCATE THE PUBLIC MORE BROADLY.

FOURTH, GLOBAL NETWORKING. THAT WE NEED TO PROVIDE GREATER OPPORTUNITIES FOR NETWORKING AND BREED COLLABORATIVE PROJECTS THAT UNITE ACADEMIA AND INDUSTRY AS WELL AS RESEARCHERS ACROSS GEOGRAPHIC REGIONS.

AND FIFTH, PROCESS OPTIMIZATION. THAT WE NEED TO HAVE GREATER TRANSPARENCY IN OUR FUNDING PROCESS, AND THAT THERE'S A GREAT NEED FOR THE PROCESS TO BE LESS BUREAUCRATIC AND EASIER TO NAVIGATE.

I'M NOT GOING TO GO THROUGH ALL THIS, BUT I'M JUST REMINDING YOU THAT WE'VE DISCUSSED ALL THESE DIFFERENT ISSUES. YOU'VE SEEN IT IN OTHER PREREADS THAT YOU'VE BEEN PROVIDED. AND IT JUST SUMMARIZES THE PUBLIC, THE BOARD, AND THE INDUSTRY INPUTS.

IN ADDITION, WE RECEIVED STAKEHOLDER INPUT FROM INDUSTRY, FROM OUR COLLABORATIVE FUNDING PARTNERS, FROM PATIENT ADVOCATE ORGANIZATIONS, FROM CLINICAL DEVELOPMENT ADVISORS, FROM PROFESSIONAL SOCIETIES, AND ALSO FROM ASSOCIATIONS THAT ACTUALLY WORK ON POLICY AND LEGISLATIVE ISSUES. SO THAT'S JUST REMINDING YOU OF EVERYTHING THAT WE'VE TALKED ABOUT TO DATE.

SO WHAT WE'RE GOING TO TALK ABOUT RIGHT NOW, THEN, IS HOW DO OUR ONE- AND FIVE-YEAR GOALS FIT OR ALIGN WITH OUR REVISED STRATEGIC OBJECTIVES FOR THE NEXT FIVE YEARS AND OUR SINGLEMOST IMPORTANT KEY OUTCOMES. SO JUST TO REMIND YOU, IN SCIENTIFIC IT WAS TO ACCELERATE THE UNDERSTANDING OF STEM CELL SCIENCE AND ITS APPLICATIONS TOWARDS HUMAN DISEASES AND INJURY WITH THE SINGLEMOST IMPORTANT KEY OUTCOME BEING TO ACHIEVE TRANSFORMATIVE RESEARCH DISCOVERIES.

THE SECOND STRATEGIC OBJECTIVE, AND

THEY'RE NOT IN ANY PREFERENCE ORDER, IS CLINICAL, AND THAT'S TO ADVANCE SCIENCE INTO CLINICAL TRIALS TO ACHIEVE EVIDENCE OF THERAPEUTIC BENEFIT TO PATIENTS WITH THE SINGLEMOST IMPORTANT KEY OUTCOME BEING TO ACHIEVE CLINICAL PROOF OF CONCEPT FOR STEM CELL THERAPIES. AND THESE ARE IN THE NEXT FIVE YEARS, NOT THIS YEAR, BUT IN THE NEXT FIVE.

ECONOMIC IS TO DRIVE ECONOMIC DEVELOPMENT FOR CALIFORNIA FROM STEM CELL SCIENCE AND THERAPIES WITH THE KEY OUTCOME ECONOMICALLY BEING TO LEVERAGE CIRM'S INVESTMENT IN CALIFORNIA. YOU HEARD A LITTLE BIT ABOUT THE FOLLOW-ON FUNDING TODAY IN THE PRESIDENT'S REPORT WITH THE SURVEY THAT WAS DONE WITH GRANTEES IN TERMS OF THE 300 OR SO MILLION THAT WAS LEVERAGED UTILIZING CIRM FUNDS. YOU ALSO HAVE SEEN OTHER PAPERS OUT THERE ABOUT ECONOMIC IMPACT, AND THOSE WILL CONTINUE TO BE UPDATED.

AND THEN IN TERMS OF COMMUNITY, THE STRATEGIC OBJECTIVE IS TO MAINTAIN CALIFORNIA AS WORLD STEM CELL LEADER. AND OUR KEY OUTCOME IS THAT CALIFORNIA IS GLOBALLY RECOGNIZED AS THE STEM CELL STATE.

THE STRATEGIES YOU'VE SEEN BEFORE. THE CHANGE THAT WAS MADE BACK AT THE JANUARY ICOC IS IN THE ECONOMIC CATEGORY, THE THIRD BULLET, THAT CIRM

WOULD LAY THE GROUNDWORK FOR DEVELOPMENT OF NEW THERAPEUTIC APPROACHES TO TREAT OR CURE CHRONIC DISEASES AND INJURIES. THIS WAS RECOMMENDED AT THE LAST BOARD MEETING TO TAKE INTO ACCOUNT THE AGENCY'S ATTEMPT TO TAKE EVERY OPPORTUNITY TO ADVANCE THERAPY CANDIDATES THAT CAN DRAMATICALLY REDUCE THE COST OF CHRONIC ILLNESS AND INJURY.

THAT BRINGS US TO, THEN, OUR ONE-YEAR GOALS, REMEMBERING WHAT OUR ULTIMATE ASPIRATIONAL GOALS ARE. SO YOU ARE GOING TO HEAR NEXT ABOUT ONE-YEAR AND THEN FIVE-YEAR GOALS. SO THESE ARE GOALS THAT WE SEEK TO ACHIEVE IN THE COMING FISCAL YEAR.

THE FIRST IS THAT WE'LL ENSURE THAT CIRM'S PORTFOLIO INCLUDES AT LEAST TWO PROGRAMS WITH AN APPROVED INVESTIGATIONAL NEW DRUG FILING WITH THE U.S. FOOD AND DRUG ADMINISTRATION SO THAT THAT PRODUCT CAN ENTER CLINICAL TRIALS IN PATIENTS.

AND JUST SO EVERYBODY UNDERSTANDS, SOME OF WHOM MAY NOT BE FAMILIAR WITH REGULATORY PROCESSES, IT'S NOT JUST FILLING OUT A FORM TO FILE AN IND. IT'S YEARS OF STUDIES TO LOOK AT THE PROPOSED CANDIDATE, MAYBE IN PRECLINICAL MODELS, IN LABORATORY TESTS, IN PARTICULAR OTHER TYPES OF PRECLINICAL MODELS, AND REALLY TO LOOK AT SAFETY

ISSUES SO THAT IT'S SAFE TO BRING THAT PRODUCT INTO THE FIRST INVESTIGATIONAL TESTING. SO WHERE REAL ESTATE IS FOCUSED ON LOCATION, LOCATION, LOCATION, IND'S ARE FOCUSED ON DETAIL, DETAIL, DETAIL. THEY WANT TO HAVE A LOT OF INFORMATION ABOUT HOW THIS PRODUCT WORKS, WHAT ITS SAFETY PROFILE IS BEFORE IT CAN EVER GET INTO THE FIRST PATIENT. SO THIS IS REALLY AN IMPORTANT STEP IN MOVING THESE THERAPIES TOWARDS PATIENTS.

THE SECOND BULLET IS ABOUT ACHIEVING 50 MILLION IN NEW OUTSIDE FINANCIAL COMMITMENT FOR CIRM PROGRAMS. THIS OUTSIDE COMMITMENT CAN COME FROM COLLABORATIVE FUNDING PARTNERS, FROM INDUSTRY, FROM VENTURE CAPITALISTS, FROM MATCHING FUNDS FROM INSTITUTIONS, BUT IT'S OUTSIDE CIRM.

THE THIRD BULLET IS THAT WE ENSURE FUNDING OF POTENTIALLY HIGH IMPACT PROJECTS THAT COULD RESULT IN TRANSFORMATIVE RESEARCH BY MODIFYING THE PRIORITIES IN CIRM'S REQUEST FOR APPLICATIONS SO THAT WE ARE REALLY TRYING TO LOOK FOR THAT TRANSFORMATIVE RESEARCH THAT COULD POTENTIALLY HAVE A LARGER IMPACT.

THE FOURTH BULLET IS TO EDUCATE AND ENGAGE THE CALIFORNIA COMMUNITY IN CIRM'S MISSION AND ACHIEVEMENTS IN PART BY INCREASING THE NUMBER OF

MONTHLY ONLINE ENGAGEMENTS FROM THE CURRENT 70,000 TO A HUNDRED THOUSAND. THIS IS A METRIC THAT WAS PROPOSED, A GOAL THAT WAS PROPOSED BY OUR COMMUNICATIONS GROUP. IT'S ACTUALLY AN EVOLVING I THINK YOU'D CALL A METRIC IN TERMS OF HOW TO CATEGORIZE AND MEASURE THESE TYPES OF ENGAGEMENT, BUT IT INCLUDES HOW MANY TIMES PEOPLE ARE READING, WHAT YOU'RE WRITING ABOUT, HOW MANY TIMES THEY'RE ENGAGING IN THE CONVERSATION. AND I'M TOLD THERE IS SOFTWARE TO ACTUALLY MEASURE THIS IN A WAY. SO WE WERE TRYING TO GIVE YOU GOALS THAT HAD SOME ABILITY TO BE MEASURED.

AND THEN THE LAST BULLET IS TO OPTIMIZE CIRM'S WORKFORCE, STAFFING, AND OUR PROCESSES TO MEET CHANGING PRIORITIES WITHIN THE 6-PERCENT CEILING.

WE HAVE A LOT OF ACTIVITIES, A LOT OF IMPORTANT PROGRAMS THAT NEED TO GO ON, BUT WE ARE ALSO GOING TO ABSOLUTELY STAY TRUE TO MEETING ALL OF THESE PRIORITIES WITHIN THE CEILING.

LET ME FIRST ASK IF THERE'S ANY -- WOULD YOU LIKE ME TO GO THROUGH THE ONE-YEAR AND THE FIVE-YEAR AND THEN ASK QUESTIONS? WOULD THAT BE THE BEST WAY TO GO THROUGH THIS BECAUSE I CAN DO THAT? I'M GETTING THE NOD.

LET ME GO ON, THEN, TO THE FIVE-YEAR GOALS AND JUST SUMMARIZE WHAT IS WRITTEN IN YOUR PREREAD BECAUSE ACTUALLY FOR THE FIVE-YEAR GOALS, CIRM ALREADY HAD FROM 2006 COMMUNICATED FIVE-YEAR AND TEN-YEAR GOALS. AND THE TEN-YEAR GOALS THAT WERE WRITTEN BACK IN 2006 ARE BEING MODIFIED TO BE NOW OUR FIVE-YEAR GOALS. BUT I WANT TO ALSO SUMMARIZE WHAT PROGRESS CIRM HAS MADE ON THE FIVE-YEAR GOALS THAT WERE ARTICULATED BACK IN THE 2006 STRATEGIC PLAN.

WE'VE MET EIGHT OF THOSE TEN GOALS, AND WE'RE MEETING THE NINTH GOAL IN 2012, AND WE'RE WORKING ON PROGRESS TO DEMONSTRATE METHODS TO ADDRESS THE IMMUNOLOGIC CHALLENGES WITH TRANSPLANTED TISSUES.

YOU CAN RELOOK AT YOUR PREREAD THAT I PROVIDED TO YOU FOR THE FULL DETAILS. BUT TO SUMMARIZE, THE GOALS THAT CIRM FUNDING HAS MET TO DATE INCLUDE THAT SIX THERAPIES BASED ON STEM CELL RESEARCH ARE IN PRECLINICAL DEVELOPMENT, THAT WE HAVE DEVELOPED NEW METHODS FOR MAKING STEM CELL LINES, THAT OUR INVESTMENTS HAVE SUCCESSFULLY CREATED DISEASE-SPECIFIC STEM CELL LINES IN FOUR DISEASES, THE FUNDING HAS DEVELOPED METHODS FOR GROWING STEM CELLS IN DEFINED MEDIA. IT HAS ENABLED

ESTABLISHMENT OF STEM CELL BANK BY SUPPORTING DEVELOPMENT OF NEW LINES, ENCOURAGING THE REGISTRATION AND DOCUMENTATION, AND ULTIMATELY PROVIDING SUPPORT FOR SELF-SUSTAINING BANKING AND DISTRIBUTION EFFORTS.

IT HAS INCREASED THE WORKFORCE OF STEM CELL RESEARCHERS IN CALIFORNIA. IT HAS ESTABLISHED TOOLS FOR TOXICITY TESTING BASED ON STEM CELL RESEARCH. IT HAS ENABLED EFFECTIVE PARTNERSHIPS IN STEM CELL RESEARCH BETWEEN SCIENTIFIC TEAMS IN NOT-FOR-PROFIT AND COMMERCIAL SECTORS, AND IT HAS ESTABLISHED NATIONAL AND INTERNATIONAL COLLABORATIONS IN STEM CELL RESEARCH THAT LEVERAGES CALIFORNIA RESEARCHERS AND RESEARCHERS OUTSIDE OF CALIFORNIA TO ADVANCE TOWARDS THERAPIES.

THAT'S A QUICK, CONCISE SUMMARY OF WHAT WE HAVE ACCOMPLISHED. WHAT I'M GOING TO COMMUNICATE NOW ARE THE GOALS THAT WE WANT TO ACCOMPLISH IN THE NEXT FIVE YEARS. SO THIS WILL TAKE US OUT TO FISCAL YEAR 2017, 18. AND WHAT I'M GOING TO DESCRIBE IS THE GOAL AND WHETHER IT'S IDENTICAL OR SOMEWHAT MODIFIED FROM THE GOAL THAT WAS COMMUNICATED AS A TEN-YEAR GOAL BACK IN 2006. SO THAT WILL BE PERFECTLY TRANSPARENT IF THINGS ARE STAYING THE SAME OR IF WE'RE MODIFYING THEM.

SO THE GOAL 1 IS BASICALLY AN UNCHANGED GOAL 9. IT'S THROUGH RESEARCH SPONSORED BY CIRM AND OTHERS THAT THE FACTORS REGULATING SELF-RENEWAL IN TUMOR CAUSING POTENTIAL OF STEM CELLS AND THEIR DERIVATIVES WILL BE IDENTIFIED AND CHARACTERIZED.

MS. SAMUELSON: DR. FEIGAL, COULD YOU SAY WHERE YOU ARE IN YOUR OUTLINE? THE MATERIALS.

DR. FEIGAL: JUST GO AHEAD AND LOOK AT MY SLIDES. IF YOU CAN SEE THAT -- IF YOU WANT ME TO TELL YOU WHAT PAGE FROM THE PREREAD.

MS. SAMUELSON: THAT'S WHAT I PREPARED WITH.

DR. FEIGAL: LET ME TELL YOU CHAPTER AND VERSE. WE ARE ON PAGE 3.

MS. SAMUELSON: GREAT. THANKS.

DR. FEIGAL: STARTING ON PAGE 5 IS REALLY THE APPENDIX OF DETAILS. SO IT'S REALLY JUST THE FIRST FEW PAGES THAT ARE THE TOPIC FOR THIS PRESENTATION.

SO GOAL 2 IS AN UNCHANGED GOAL 8, THAT THROUGH RESEARCH SPONSORED BY CIRM AND OTHERS, A THOROUGH DESCRIPTION OF THE STEPS TO DIFFERENTIATION LEADING TO THE PRODUCTION OF CRITICAL CELLS OF THE BODY DESIRED FOR TRANSPLANTATION WILL BE ACHIEVED.

AND THEN GOAL 3 IS A MODIFIED GOAL 4. THE

GOAL 4 FROM 2006 STATED THAT CIRM WILL HAVE FUNDED NEW APPROACHES FOR ACHIEVING IMMUNE TOLERANCE FOR TRANSPLANTATION THAT ARE IN PRECLINICAL DEVELOPMENT. AND IT'S NOW BEEN MODIFIED TO READ CIRM WILL HAVE FUNDED NEW APPROACHES FOR ENSURING SUCCESSFUL ALLOGENEIC CELL TRANSPLANTATION THAT ARE IN CLINICAL DEVELOPMENT.

GOAL 4 IS A MODIFICATION FROM GOAL 5. WHERE GOAL 5 IN 2006 SAYS USING STEM CELL RESEARCH, CIRM-FUNDED INVESTIGATORS WILL HAVE ESTABLISHED PROOF OF PRINCIPLE IN PRECLINICAL ANIMAL MODELS FOR THE TREATMENT OF SIX TO EIGHT DISEASES. WE'RE BASICALLY UPPING THE ANTE TO MORE THAN TEN DISEASES.

GOAL 5 IS AN UNCHANGED GOAL 6, THAT CIRM-FUNDED INVESTIGATORS WILL HAVE CREATED DISEASE-SPECIFIC CELL LINES FOR 20 TO 30 DISEASES AND USED THEM TO GAIN NEW INFORMATION ABOUT THEIR UNDERLYING PATHOGENESIS AND TO IDENTIFY NEW DRUG TARGETS FOR DISCOVERY OF NEW THERAPEUTICS.

GOAL 6 IS A SLIGHT CHANGE FROM GOAL 7. GOAL 7 HAD SAID THAT WE HAVE ENABLED DEVELOPMENT OF NEW PROCEDURES FOR THE PRODUCTION OF A VARIETY OF STEM AND/OR PROGENITOR CELLS THAT MEET GMP REQUIREMENTS. WE MODIFIED THAT TO SAY ENABLE DEVELOPMENT OF NEW PROCEDURES FOR THE PRODUCTION OF

A VARIETY OF STEM AND PROGENITOR CELLS THAT MEET REQUIREMENTS FOR CLINICAL APPLICATION.

GOAL 7 ACTUALLY TRIED TO PROVIDE A MEASURABLE METRIC HERE. GOAL 3, IT'S FOCUSED ON WHAT WAS GOAL 3, WHICH SAID THAT CIRM-FUNDED PROJECTS WILL HAVE ACHIEVED SUFFICIENT SUCCESS TO ATTRACT PRIVATE CAPITAL FOR FUNDING FURTHER CLINICAL DEVELOPMENT OF STEM CELL THERAPY. IT NOW SAYS AT LEAST 20 CIRM-FUNDED PROGRAMS WILL HAVE OUTSIDE CAPITAL COMMITMENTS FOR FUNDING DEVELOPMENT WORK.

GOAL 8 IS AN AMALGAMATION OF GOALS 1 AND 2 FROM 2006. GOAL 1 HAD PREVIOUSLY STATED THAT CIRM GRANTEES WILL HAVE CLINICAL PROOF OF PRINCIPLE THAT TRANSPLANTS AND CELLS DERIVED FROM PLURIPOTENT CELLS CAN BE USED TO RESTORE FUNCTION FOR AT LEAST ONE DISEASE. AND GOAL 2, THAT CIRM-SPONSORED RESEARCH WILL HAVE GENERATED THERAPIES BASED ON STEM CELL RESEARCH THAT IS IN PHASE I OR II CLINICAL TRIALS FOR TWO TO FOUR ADDITIONAL DISEASES.

WE MODIFIED GOAL 8 TO READ THAT CIRM WILL HAVE FUNDED TEN THERAPIES AS OPPOSED TO TWO TO FOUR THAT ARE IN PHASE I OR II CLINICAL TRIALS, WE ADDED, IN AT LEAST FIVE DIFFERENT THERAPEUTIC AREAS BASED ON STEM CELL RESEARCH. AND WE MODIFIED THIS LATTER PART, AND HAVE ACHIEVED CLINICAL PROOF OF CONCEPT

THAT TRANSPLANTED CELLS THAT ARE DERIVED FROM PLURIPOTENT OR PROGENITOR CELLS CAN BE USED TO RESTORE FUNCTION FOR AT LEAST ONE DISEASE OR INJURY CONDITION.

AND WE CHANGED THE LATTER PART OF GOAL 8 BASED ON A VARIETY OF INPUTS THAT WE GOT FROM STAKEHOLDERS, INCLUDING THIS BOARD BACK IN JANUARY, THAT WE WERE BEING TOO NARROW IN OUR PREVIOUSLY DESCRIBED GOAL IN TERMS OF WHERE THAT CLINICAL PROOF OF CONCEPT COULD COME FROM. AND THAT'S WHY WE EXPANDED IT TO PLURIPOTENT OR PROGENITOR CELLS.

AND THEN GOAL 9, WHICH IS IN ADDITION, IS THAT WE BROADEN AND REINFORCE CIRM'S EFFORT TO EDUCATE AND ENGAGE THE CALIFORNIA COMMUNITY IN CIRM'S MISSION AND ACHIEVEMENTS IN PART BY INCREASING THE NUMBER OF MONTHLY ONLINE ENGAGEMENTS TO 250,000.

LET ME JUST FINISH, I ONLY HAVE TWO MORE SLIDES, ART, OR DID YOU HAVE A QUESTION RIGHT NOW?

MR. TORRES: NO.

DR. FEIGAL: I JUST WANT TO SHOW YOU WHAT THE STRATEGIC PLAN IS GOING TO LOOK LIKE. YOU SAW THIS BACK IN JANUARY. THIS IS WHAT THE TABLE OF CONTENTS WILL LOOK LIKE. SO YOU WILL HAVE AN EXECUTIVE SUMMARY, THE MISSION AND VISION, THE FOUR

STRATEGIC OBJECTIVES, THE SINGLE KEY OUTCOME AMONG THEM, THE GOALS AND METRICS, WHICH WE ARE TALKING ABOUT TODAY, THE FINANCIAL PROJECTIONS WHERE PAT IS GOING TO LEAD THAT DISCUSSION TODAY, AND THEN APPENDICES THAT INCLUDE THE EXTERNAL ADVISORY PANEL REPORT, OUR RESPONSE, THE PROCESS, AND THE SUMMARY OF STAKEHOLDER INPUTS, AND OUR PROGRESS ON THE 2006 FIVE- AND TEN-YEAR GOALS.

AND THEN THE NEXT STEPS WILL BE OVER THE NEXT TWO MONTHS WE'LL EMBED THE DISCUSSION TODAY, THE PREVIOUS INPUTS SO THAT BY MAY 24TH YOU WILL BE ABLE TO CONSIDER THIS FINALIZED DOCUMENT FOR YOUR CONSIDERATION.

CHAIRMAN THOMAS: THANK YOU, DR. FEIGAL. DR. STEWARD.

MR. HARRISON: I'M SORRY. QUICKLY, WE NEED TO ASK MEMBER SHESTACK AND MEMBER FEIT FOR THEIR VOTES ON MOTION 6, WHICH WAS NOT TO FUND THE APPLICATIONS IN TIER 3 TO CLOSE THIS OUT.

CHAIRMAN THOMAS: THIS IS BECOMING THE LONGEST MOTION IN CIRM HISTORY. PLEASE.

MR. HARRISON: MEMBER SHESTACK. THE MOTION IS NOT TO FUND THE APPLICATIONS IN TIER 3.

MR. SHESTACK: YES, I AGREE.

MR. HARRISON: AND MEMBER FEIT.

MS. FEIT: YES.

MR. HARRISON: THANK YOU.

CHAIRMAN THOMAS: ARE WE NOW FINISHED WITH THAT?

MR. HARRISON: YES. THE MOTION PASSES.

CHAIRMAN THOMAS: OUTSTANDING. THANK YOU, MR. HARRISON.

DR. STEWARD: I WAS INTERESTED IN THE ONE-YEAR GOAL. I THINK IT WAS BULLET 3 OR 4. AND IT WAS BULLET 3. AND I THINK THIS IS A REALLY IMPORTANT POINT. I GUESS I'D LIKE, IF YOU COULD, TO UNPACK THAT A LITTLE BIT. THE IDEA OF ENHANCING THE FUNDING OF THESE REALLY TRANSFORMATIVE THINGS I THINK IS REALLY IMPORTANT.

DR. FEIGAL: THIS IS PROBABLY THE MOST DIFFICULT TO QUANTITATE BECAUSE IT REALLY IS QUALITATIVE, AND AT SOME POINT IT REALLY REQUIRES STARGAZING BECAUSE WE DON'T KNOW WHERE THAT POTENTIALLY TRANSFORMATIVE DISCOVERY COULD COME FROM. BUT WHAT WE THINK WE COULD DO, BECAUSE WE'VE BEEN SITTING THROUGH A LOT OF REVIEWS AND LISTENING TO REVIEWER QUESTIONS AND GOING BACK AND READING THE RFA AND TRYING TO DECIDE IF SOMETHING WAS ELIGIBLE OR OUT OF SCOPE, SO WE THINK ACTUALLY WHEN WE DO PUT SOLICITATIONS OUT THERE, PERHAPS WE COULD BE CLEARER

TO THE APPLICANT ABOUT WHAT WE'RE REALLY LOOKING FOR AND CLEARER TO THE REVIEWER ABOUT THE TYPE OF INPUT THAT WE'RE REALLY GOING FOR.

BUT IF YOU HAVE SUGGESTIONS ON HOW WE COULD ACCOMPLISH THAT, I'D BE ALL EARS.

DR. STEWARD: WELL, I GUESS THIS IS A RECORD THAT I SORT OF KEEP PLAYING. AND I JUST WONDER IF IT WOULD BE POSSIBLE IN EFFECT TO GO IN THE OPPOSITE DIRECTION, TO ESSENTIALLY BE LESS CLEAR ABOUT WHAT YOU'RE LOOKING FOR BECAUSE, AS YOU SAY, YOU DON'T KNOW WHAT YOU'RE REALLY LOOKING FOR.

DR. FEIGAL: NOT BE TOO NARROW.

DR. STEWARD: YEAH. AND REALLY ENCOURAGE CREATIVITY FROM THE OUTSIDE. I KNOW IT'S HARD TO DEVELOP AN RFA THAT SAYS WE'RE REALLY LOOKING FOR OUT-OF-THE-BOX THINKING. BUT TO THE EXTENT THAT IT'S POSSIBLE TO ACTUALLY DO THAT AND TO HAVE GREATER FLEXIBILITY IN THE BOUNDARY CONDITIONS ON SOME OF THESE RFA'S, YOU MIGHT BE ABLE TO ATTRACT JUST THE KIND OF THING YOU'RE TALKING ABOUT HERE, SOMETHING THAT'S REALLY A LITTLE BIT OUT OF THE BOX AND THAT REALLY COULD BE TRULY TRANSFORMATIVE. EXACTLY HOW TO DO THAT, AGAIN, I'M NOT SURE, BUT IF YOU COULD THINK ABOUT THAT.

DR. LUBIN: SO I HAVE THREE COMMENTS.

THIS IS A LITTLE TANGENT TO THIS, BUT REALLY IMPORTANT, THAT IF A DISCOVERY OR WHEN A DISCOVERY IS MADE WITH ANY OF THE FUNDING THAT WE PROVIDED THAT CAN BE USED IN A CLINICAL SETTING, THIRD-PARTY PAYERS ARE GOING TO HAVE TO PAY FOR THIS. AND FOR THOSE OF YOU WHO ARE IN THE HEALTH BUSINESS, YOU REALIZE THAT THE ABILITY TO GET REIMBURSEMENT FOR MANY OF THESE THINGS IS GOING TO BE EXTREMELY CHALLENGING. AND THE WORST THING IS THAT WE'RE GOING TO HAVE A CURE FOR SOMETHING AND NOT BE ABLE TO GET IT FUNDED.

SO ONE STRATEGY TO CONSIDER IS AS WE GO FORWARD, TO HAVE A COMMITTEE OR SOME PEOPLE TAKE A LOOK AT HOW WE'RE GOING TO START LOBBYING WITH THE PAYERS BECAUSE IF YOU LOOK AT THE TOTAL COST OF CHRONIC ILLNESS AND THEN YOU LOOK AT THE THERAPY THAT'S GOING TO COME OUT OF THIS, IT MAKES SENSE TO DO THE THERAPY, BUT TO CONVINCE THE HEALTHCARE PROVIDERS THAT PAY THAT THIS MAKES SENSE TAKES A LONG TIME. AND THE LAST THING YOU WANT IS TO GET SOMETHING AND THEN HAVE IT SIT ON THE SHELF IN ANOTHER SECOND VALLEY OF DEATH THAT WE'VE TALKED ABOUT HERE.

SO I WOULD ENCOURAGE US TO BE THINKING IN OUR STRATEGIC PLAN HOW WE MIGHT WANT TO ADDRESS THAT

AND WHAT FORMAT. SO THAT'S ONE COMMENT.

THE SECOND IS, AS A RELATIVELY NEW MEMBER OF THE COMMITTEE AND AS A VERY LONGSTANDING REVIEWER AT THE NATIONAL INSTITUTES OF HEALTH FOR A VARIETY OF STUDIES, I'M IMPRESSED BY THE MAGNITUDE OF THE AWARDS THAT WE MAKE RELATIVE TO THE AWARDS THAT I SIT ON WHERE SIMILAR CONSIDERATIONS ARE MADE. AND I JUST WANT TO BE SURE THAT THE BOARD OR WHATEVER COMMITTEE OF THE BOARD LOOKS AT THIS CAREFULLY LOOKS AT ARE WE IN THE RIGHT BALLPARK ON THESE AWARDS, AND IS THIS WHAT WE WANT TO CONTINUE TO DO.

RESTRICTIONS ARE PLACED ON NIH GRANTS NOW FOR SALARIES FOR A WHOLE VARIETY OF THINGS. MAYBE THAT'S NOT GOOD. MAYBE WE DON'T HAVE TO DO IT, BUT IF WE COULD STRETCH OUT THE DOLLARS TO MORE, MAYBE WE CAN ENCOURAGE MORE PEOPLE. SO I THROW THAT OUT AS AN IDEA.

AND THEN THE THIRD IS WE DIDN'T HEAR ABOUT THE INSTITUTE OF MEDICINE'S REVIEW AND HOW THAT'S GOING TO FIT INTO OUR STRATEGIC PLAN OF WHAT RECOMMENDATIONS AND THINGS COME UP. SO AT LEAST THAT SHOULD BE A TRAILER AND SOMETHING FOR US TO BE THINKING ABOUT.

DR. FEIGAL: I COULD JUST MAKE A COMMENT. THEY CERTAINLY -- I CAN COMMENT AND THEN J.T. CAN

PROBABLY ANSWER BECAUSE HONESTLY AT THIS POINT, THEIR RECOMMENDATIONS, I BELIEVE, ARE GOING TO COME OUT MORE NEAR THE END OF THE YEAR. SO THEY'RE LOOKING AT WHERE WE SAY WE'RE GOING TO IMPACT ON MAYBE SOME OF THE RECOMMENDATIONS THEY MAKE. BUT, J.T., IF YOU HAVE OTHER THOUGHTS ON THAT.

CHAIRMAN THOMAS: JUST TO FURTHER THAT POINT, THE TIMING OF THE STRATEGIC PLAN WAS TO SOME EXTENT DICTATED BY A DESIRE TO HAVE IT DONE WELL IN ADVANCE SO THAT THE IOM COULD REVIEW IT AS PART OF THEIR ANALYSIS AND GIVE CRITICAL COMMENT IN DECEMBER WHEN THEY PRESENT THEIR REPORT.

MR. ROTH: SO I WOULD LIKE TO JUST COMPLIMENT ALL THE PEOPLE THAT WORKED ON THE STRATEGIC PLAN. THESE ARE TOUGH DOCUMENTS TO PULL TOGETHER, ESPECIALLY WHEN YOU INHERIT A GREAT DEAL OF THIS, AS MANY OF YOU DID. BUT I THINK AFTER ALL THE ITERATIONS WE'VE BEEN THROUGH, THE INPUT WE'VE HAD, THAT THIS IS A VERY SOLID DOCUMENT. IT ENCOMPASSES, I THINK, THE NEXT PERIOD OF TIME WE'RE MOVING INTO. IT DOESN'T JUST PICK UP THE PAST AND SAY EVERYTHING THAT WE DID THEN WILL CONTINUE.

SO I THINK EVERYBODY ON THE STAFF AND ALL THE PEOPLE THAT PARTICIPATED DESERVE GREAT CREDIT FOR DOING THIS.

CHAIRMAN THOMAS: THAT'S VERY WELL SAID, DUANE. THANK YOU.

MS. SAMUELSON: I'M THRILLED TO HEAR THAT BECAUSE OBVIOUSLY YOU'RE ONE OF THE PEOPLE ON OUR BOARD WHO HAS MUCH MORE EXPERTISE THAN I DO TO BE ABLE TO EVALUATE IT. I NEED TO UNDERSTAND IT BETTER, SO THAT'S WHERE MY QUESTIONS ARE GOING. IT'S NOT CRITICISM OF IT. IT'S JUST SEEKING TO UNDERSTAND IT.

THE FIRST QUESTION I HAVE IS WHAT ARE YOU ASKING FROM US TODAY? BECAUSE I THINK IT'S AN ACTION ITEM, BUT IT'S CALLED CONSIDERATION OF THE PRESENTATION TODAY.

DR. FEIGAL: LET ME TAKE A STAB AT IT. WE CERTAINLY DO WANT YOUR INPUT ON THE ONE- AND FIVE-YEAR GOALS AND IF YOU THINK THESE ARE THE APPROPRIATE GOALS TO MOVE ON. IT'S NOT MY IMPRESSION THAT IT'S A VOTE. IT'S MORE TO GET YOUR INPUT. MAYBE, J.T., YOU COULD COMMENT ON THAT.

CHAIRMAN THOMAS: THAT'S CORRECT. THIS IS THE LATEST OF A SERIES OF DISCUSSIONS THAT INFORM THE REFINEMENT OF PLAN WHICH WILL ACTUALLY BE PRESENTED FOR A VOTE AT THE MAY BOARD MEETING.

MS. SAMUELSON: THEN THERE'S LOTS OF TWEAKING. THAT'S NOT OF SERIOUS ENOUGH WORD FOR

WHAT'S GOING ON. FORGIVE ME. BUT MOVING THIS GOAL THIS MUCH AND SO ON, MAYBE DR. OLSON IS THE PERSON WHO WOULD ADDRESS SPECIFICS. I DON'T KNOW. BUT FOR EXAMPLE, THE ONE-YEAR GOAL SAYS ENSURE CIRM'S PORTFOLIO INCLUDES AT LEAST TWO PROGRAMS WITH AN APPROVED IND WITH THE FDA. WHERE DOES THAT COME FROM? ARE THERE CERTAIN THERAPEUTIC INTERVENTIONS THAT ARE MOVING TOWARD BEING READY FOR THAT, OR IS THIS MORE AT A CONCEPTUAL LEVEL? ARE THERE DISEASES WE'RE AHEAD IN, AND THAT WOULD BE REAL GOOD NEWS, OR ARE THERE IMPORTANT OBSTACLES THAT REALLY NEED A SORT OF FRONTAL ASSAULT WITH OUR RESEARCH IN THE NEXT FEW YEARS? PLEASE TRY TO ELABORATE ON THAT.

DR. FEIGAL: TO YOUR FIRST OF WHAT I TAKE WILL BE SEVERAL QUESTIONS, THE ONE-YEAR GOALS ARE SUPPOSED TO BE GOALS WITHIN OUR GRASP, NOT ASPIRATIONAL. SO THEY ARE BASED ON DATA THAT WE'VE OBSERVED TO DATE IN TERMS OF HOW THINGS ARE FUNCTIONING. IT'S BASED ON INFORMATION THAT WE HAVE KNOWLEDGE ABOUT OF WHAT'S GOING ON IN THE FIELD AND MAY BE COMING INTO US. I CAN'T SHARE THOSE DETAILS, OF COURSE, WITH YOU BECAUSE THEY'RE PROPRIETARY, BUT WE HAVE REASON TO BELIEVE THESE ARE REACHABLE GOALS.

MS. SAMUELSON: IS THERE NOTHING MORE YOU CAN SHARE?

DR. FEIGAL: I CAN SHARE MORE IN THE UPCOMING DISCUSSION.

MS. SAMUELSON: THIS BOARD NEEDS TO OWN THIS DOCUMENT. WE HAVE A FIDUCIARY RESPONSIBILITY. MAYBE IT HAS TO HAPPEN IN CLOSED SESSION. I DON'T KNOW, BUT I NEED TO KNOW MORE THAN THAT.

DR. FEIGAL: OKAY. WE HAVE REASON -- WE HAVE, AS YOU KNOW, DISEASE TEAMS THAT WE'RE FUNDING. WE ALSO HAVE KNOWLEDGE OF DISEASE TEAM II'S THAT ARE COMING IN THAT ARE YET TO BE REVIEWED AND PRIORITIZED. AND WE HAVE INITIATIVES COMING OUT IN APRIL FOR STRATEGIC PARTNERSHIP FUNDING WHERE WE KNOW THERE'S A TREMENDOUS AMOUNT OF INTEREST. AND THERE ARE POTENTIAL FOR THINGS TO COME IN THROUGH THAT DOOR. OF COURSE, THEY HAVE TO GO THROUGH REVIEW AND PRIORITIZATION. BUT WE HAVE REASON TO BELIEVE THAT THERE'S ENOUGH IN THE DENOMINATOR BETWEEN WHAT WE'RE CURRENTLY FUNDING AND WHAT WE ANTICIPATE MAY COME IN THE DOOR, THAT THE GOAL OF TWO IS SOMETHING REACHABLE. AND IT MAY BE WE HAVE TO GO INTO SOME OTHER SORT OF DISCUSSION FOR MORE DETAILS ABOUT THAT, BUT WE DO THINK THAT THIS IS A REACHABLE GOAL.

MR. ROTH: JOAN, MAYBE I COULD MAKE A COMMENT ON THAT. I THINK WHAT THIS GOAL WOULD SAY

IS IF THERE ARE IND'S THAT ARE GOING TO BE SUBMITTED AND MOVE FORWARD, THAT'S WONDERFUL. IF WE HELP FUND THOSE, WE'LL TAKE CREDIT. BUT IT ALSO SAYS IF THERE ARE POTENTIAL IND'S THAT COULD BE FUNDED, BUT THEY LACK THE MONEY TO ACTUALLY CONDUCT THE TRIAL AND WE CAN PUT THEM TOGETHER WITH A PHARMA COMPANY AND USE OUR SPECIAL FUNDS FOR THAT, WE SHOULD TAKE MAXIMUM OPPORTUNITY TO DO SO. SO WE CAN ENABLE, IF YOU WILL, HELPFUL AND EVERYBODY IS FOCUSED ON THAT. AND IF WE -- FOR EXAMPLE, MANY IND'S ARE POTENTIALLY THERE, BUT YOU DON'T SUBMIT AN IND IF YOU DON'T HAVE THE MONEY TO CONDUCT THE CLINICAL TRIAL ONCE THE FDA APPROVES IT. SO CAN WE HELP MAKE THAT HAPPEN?

DR. FEIGAL: WE WANTED TO PUT IT OUT THERE BECAUSE WE HAD AS A FIVE-YEAR GOAL TO ESTABLISH SOME PRECLINICAL PROOF OF CONCEPT. SO IF YOU WORK BACKWARDS, IT MEANS WE HAVE TO TAKE STEPS TODAY. AND WE HAVE BEEN TAKING STEPS FOR THE PAST SEVERAL YEARS NOW IN ADVANCING THE FIELD SO THAT WE HAVE THE ABILITY TO MAKE THIS A REALITY. SO IF WE'RE GOING TO BE ABLE TO ACHIEVE WHAT WE WANT TO ACHIEVE IN FIVE YEARS, THEN WE NEED WITHIN THIS NEXT YEAR TO HAVE STARTED MAKING PROGRESS THERE. BECAUSE WE KNOW IT TAKES TIME TO CONDUCT A CLINICAL TRIAL, IT TAKES TIME TO DO A CLINICAL TRIAL TO ESTABLISH PRECLINICAL

PROOF OF CONCEPT. AND IN ORDER TO GET THERE, WE NEED TO START MOVING THINGS IN THAT DIRECTION.

MS. SAMUELSON: INDEED. QUESTION FOR DUANE. DO YOU KNOW THIS DOCUMENT AND THE FIELD WELL ENOUGH THAT YOU CAN READ THIS AND KNOW HOW THIS RELATES TO SPECIFIC DISEASE AREAS?

MR. ROTH: I CAN'T SAY THAT I'M AN EXPERT ON ALL OF THESE DISEASE AREAS, BUT I THINK IT'S WRITTEN BROAD ENOUGH TO ENCOMPASS WHATEVER IS THERE, PLUS GIVES US A DIRECTION TO SAY THESE ARE THE PRIORITIES. SO IF YOU HAVE TO MAKE DECISIONS, THIS IS YOUR GUIDANCE DOCUMENT FOR THE NEXT YEAR. AND THEN THERE'S A FIVE-YEAR GUIDANCE DOCUMENT. SO TO ME IT'S VERY HELPFUL IN THAT REGARD. AND IT'S OPPORTUNISTIC. YOU CAN'T KNOW EVERYTHING THAT'S GOING TO MATERIALIZE; BUT IF YOU HAVE AN OPPORTUNITY, LET'S MAKE SURE WE GET AS MANY OF THESE PRODUCTS IN THE CLINIC AS WE CAN. THAT'S WHAT IT WOULD SAY TO ME.

AND THEN THERE ARE OTHERS THAT ARE THE SAME WAY. HOW DO WE GO OUT AND MAKE SURE THERE'S $50 MILLION WORTH OF CO-INVESTMENT?

MS. SAMUELSON: LET ME JUST FOLLOW ONCE MORE AND THEN I'LL STOP TALKING AND GIVE SOMEONE ELSE AN OPPORTUNITY. IT MADE SENSE TO ME IN THE

FIRST FEW YEARS OF OUR STRATEGIC PLANNING TO BE THAT THEORETICAL WITHOUT ANY CONNECTION TO THE SCOPE OF DISEASE AREAS THAT THE INITIATIVE SAYS WE ARE TO ADDRESS. BUT NOW WE'VE GOT -- IT'S NOT SEVEN YEARS OF FUNDING BECAUSE OF THE LAWSUITS, BUT MAYBE IT'S FOUR OR FIVE, BUT THAT'S A SIGNIFICANT TIME FRAME AND AMOUNT OF MONEY, THAT THERE IS SOMETHING TO SAY ABOUT WHAT IT'S DONE. AND PERHAPS IT'S THAT THERE'S NOTHING THAT CONCRETE BECAUSE SO MUCH BASIC FOUNDATIONAL WORK NEEDED TO BE DONE, BUT I DON'T KNOW THE ANSWER TO THAT. AND I DO KNOW THAT I HAVE NOT YET SEEN AN IMPACT ON THE SEVERAL NEURODEGENERATIVE DISEASES, INCLUDING PARKINSON'S, WHICH I HAVE, AND SO I HAVE TO ASK.

WHAT HAS BEEN THE IMPACT OF THE MONEY? AND I THINK WE NEED TO START TYING THE TWO TOGETHER.

DR. FEIGAL: WELL, YOU WILL HEAR --

MS. SAMUELSON: WE CAN'T JUST HEAR THE GENERIC WISH LIST THAT DOESN'T SHOW HOW IT RELATES TO WHAT'S GOING ON. AND I CAN'T LEARN IT JUST FROM PARTICIPATION IN THE GRANTS WORKING GROUP. SO THAT'S MY QUESTION.

DR. FEIGAL: ALL I WAS GOING TO SAY IS ANOTHER DISCUSSION THAT'S GOING TO TAKE PLACE TODAY ARE THE DISEASE TEAM I UPDATES. AND ALTHOUGH I

DON'T HAVE A CRYSTAL BALL IN TERMS OF SPECULATING WHICH HORSE IS GOING TO WIN THE RACE, SORRY FOR THE MIXED METAPHORS HERE, BUT I THINK THAT WE HAVE REASON TO THINK THAT A HORSE OR TWO IS GOING TO FINISH THE RACE. AND SO I DO THINK WE CAN AT LEAST PROVIDE YOU SOME INFORMATION TO THAT REGARD. BUT WE ALSO LEAVE IT OPEN THAT, AS OS SAID, WE'RE NOT OVERCIRCUMSCRIBING WHERE THAT SUCCESS HAS TO COME FROM.

MR. ROTH: JOAN, I DON'T THINK IN THE ONE-YEAR GOALS THAT YOU CAN PUT A LOT OF SPECIFICITY ON WHICH DISEASES WE SHOULD PAY ATTENTION TO. I THINK THEY'RE GOING TO BE OPPORTUNISTIC. I THINK WE NEED TO LOOK AT THE PIPELINE, HOWEVER, AND MAKE SURE THAT, AND THAT'S BULLET NO. 3, IF THERE ARE BREAKTHROUGHS, THAT WE BRING THOSE FORWARD AS QUICKLY AS WE CAN AND TO BE CONSCIOUS OF THE AREAS THAT ARE NOT MATURING AS FAST AS OTHERS AND ASK THE QUESTION WHY NOT.

MS. SAMUELSON: SO AT THAT POINT WE CAN TALK SPECIFICS.

MR. ROTH: I THINK WE WOULD BE IN GOOD SHAPE BY TALKING UNDER NO. 3 ABOUT REAL OPPORTUNITIES TO MOVE THINGS THAT ARE BREAKTHROUGHS FORWARD QUICKLY.

MS. SAMUELSON: AND HAVE THEY BECOME HIGH IMPACT. OKAY. GOOD.

DR. FEIGAL: DID YOU HAVE OTHER QUESTIONS TOO?

CHAIRMAN THOMAS: WE HAVE A QUESTION ON THE PHONE.

DR. FRIEDMAN: IF I COULD JUST ADD ONE QUICK THING, PLEASE. I ACTUALLY THINK THE STRATEGIC PLAN AS ARTICULATED HERE IS PRETTY REASONABLE. AND THIS IS MEANT TO BE A GENERAL GUIDELINE (UNINTELLIGIBLE). I'M VERY SYMPATHETIC WITH WHAT JOAN SAYS ABOUT AS MUCH SPECIFICITY AS POSSIBLE, BUT I THINK (UNINTELLIGIBLE) IS PREPARED TO TAKE ADVANTAGE OF THE OPPORTUNITIES AS THEY PRESENT THEMSELVES OR BYPASS CHALLENGES THAT I EXPECT WILL COME UP. SO I'M COMFORTABLE WITH THIS DEGREE OF SPECIFICITY. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, MICHAEL.

DR. JUELSGAARD: ELLEN, COULD YOU TURN TO YOUR FIVE-YEAR GOALS AND IN PARTICULAR GOAL 8?

CHAIRMAN THOMAS: CAN I ASK A QUESTION HERE, MR. JUELSGAARD? JUST INTERVENE ON A LOGISTICAL MATTER. I'M ASKING THIS OF MARIA. WE HAD ORIGINALLY CONTEMPLATED -- THIS ITEM 9 IS SORT OF A LENGTHY PRESENTATION INVOLVING BOTH DR. FEIGAL

AND DR. OLSON, AND IT CONTEMPLATED WE WOULD IN ALL LIKELIHOOD HAVE TO BREAK BECAUSE OF THE TIMING OF OUR SPOTLIGHT AT NOON AND TO RESUME DISCUSSION AFTER THAT.

SO, MR. JUELSGAARD, I WAS WONDERING IF I COULD ASK YOU IF WE CAN USE YOU AS THE KICKOFF QUESTION OF THE POST SPOTLIGHT DISCUSSION.

DR. JUELSGAARD: I YIELD.

CHAIRMAN THOMAS: THANK YOU.

DR. JUELSGAARD: IN ALL SENSES OF THAT WORD.

CHAIRMAN THOMAS: THANK YOU VERY MUCH. AND THANK YOU, DR. FEIGAL. WE WILL SEE YOU IN A LITTLE WHILE.

SO COULD EVERYBODY GO OVER TO ROOM 205, GRAB THEIR LUNCH. PLEASE COME BACK HERE IMMEDIATELY AND TAKE YOUR SEATS AGAIN. AND WE'RE GOING TO HAVE THE SPOTLIGHT WHICH WILL BE INTRODUCED BY DEAN POMEROY. SO WE WILL NOW ADJOURN TO GO OVER TO GET LUNCH. THANK YOU.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: CAN EVERYBODY PLEASE TAKE THEIR SEATS? WE ARE PREPARING TO RESUME. PLEASE TAKE YOUR SEATS.

WHEN LAST WE SPOKE WE WERE AT THE TAIL END

OF DR. FEIGAL'S PRESENTATION ON THE STRATEGIC PLAN. AND MR. JUELSGAARD WAS SO KIND TO DEFER TO AFTER WHAT WAS A FASCINATING SPOTLIGHT TO RESUME HIS LINE OF QUESTIONING OF DR. FEIGAL ON ONE ASPECT OF HER GOALS PRESENTATION. MR. JUELSGAARD, IF YOU COULD RESURRECT YOUR QUESTION AT THIS TIME, PLEASE.

DR. JUELSGAARD: YES. SO IN GOAL NO. 8, DR. FEIGAL, IF I READ IT CORRECTLY, SO WE TALK ABOUT ESSENTIALLY DOING TEN EITHER PHASE I OR PHASE II CLINICAL STUDIES IN FIVE DIFFERENT DISEASE STATES, AND THEN THERE'S THE ADDITION OF THE WORD "AND," AND THEN YOU SAY HAVE ACHIEVED PROOF OF CONCEPT. AND I READ THAT TO MEAN THAT YOU WOULD ACHIEVE PROOF OF CONCEPT IN TEN TRIALS. AND IT'S REALLY HARD TO DO THAT IN A PHASE I TRIAL.

DR. FEIGAL: BADLY WORDED SENTENCE. THAT WAS NOT THE INTENT.

DR. JUELSGAARD: WHAT WAS THE INTENT THEN?

DR. FEIGAL: THE INTENT, AND OPEN TO SUGGESTIONS TO MAKE IT GRAMMATICALLY ACCURATE, WE WERE TRYING -- PART OF OUR INTENT WAS TO DECREASE THE NUMBER OF GOALS FROM 2006 INTO A SMALLER, MEATIER NUMBER. IN DOING SO, WE MAY HAVE INADVERTENTLY CONVEYED THE WRONG MESSAGE. WHAT WE WERE TRYING TO DO IS TAKE GOAL 1 AND GOAL 2 AND

SOMEHOW MERGE THEM INTO ONE GOAL.

SO WHAT WAS INTENDED IS THAT WITHIN FIVE YEARS CIRM WILL HAVE FUNDED TEN THERAPIES IN PHASE I OR II CLINICAL TRIALS IN AT LEAST FIVE DIFFERENT THERAPEUTIC AREAS BASED ON STEM CELL RESEARCH. AND NOT NECESSARILY WITHIN THOSE TEN, WITHIN A MUCH BIGGER UNIVERSE OF WHAT COULD COME IN, WE WOULD HAVE WITHIN FIVE YEARS ONE ENTITY THAT COULD HAVE SHOWN CLINICAL PROOF OF CONCEPT, BUT NOT NECESSARILY FROM THE DENOMINATOR OF TEN IN FIVE THERAPEUTIC AREAS. AND THAT IS IN KEEPING WITH NOT MODIFYING OUR ORIGINAL GOAL FROM 2006 WHICH WAS TO HAVE A CLINICAL PROOF OF CONCEPT AT THAT TIME TEN YEARS FROM THE CREATION OF CIRM. WE ARE NOW FIVE YEARS CLOSER TO THAT, SO WE WERE ACTUALLY TRYING NOT TO MODIFY THAT ORIGINAL GOAL. DOES THAT HELP?

DR. JUELSGAARD: THAT DOES HELP. THANK YOU.

DR. FEIGAL: DO YOU HAVE A SUGGESTION? SHOULD WE SEPARATE IT INTO TWO GOALS AGAIN SO THAT OTHER PEOPLE DON'T MISCONSTRUE WHAT WE MEANT?

DR. JUELSGAARD: I REALLY DO SEE THOSE AS TWO DIFFERENT GOALS.

DR. FEIGAL: I THINK WE'LL SEPARATE IT INTO TWO THEN.

DR. JUELSGAARD: BESIDES THAT'S TEN. THAT'S A NICE ROUND NUMBER.

DR. FEIGAL: IT IS A GOOD NUMBER. ARE THERE OTHER QUESTIONS?

CHAIRMAN THOMAS: THANK YOU, MR. JUELSGAARD, FOR YOUR MATHEMATICAL, SYMMETRICAL SUGGESTION. OTHER COMMENTS ON THE STRATEGIC PLAN OF DR. FEIGAL?

MR. ROTH: I WOULD MAKE A MOTION THAT WE ACCEPT THESE GOALS WITH THAT MODIFICATION AS THE BASIS FOR THE FINAL APPROVAL WHICH WILL TAKE PLACE NEXT MONTH.

DR. HAWGOOD: SECOND.

CHAIRMAN THOMAS: FURTHER DISCUSSION BY MEMBERS OF THE BOARD? PUBLIC COMMENT? MR. REED.

MS. SAMUELSON: MR. CHAIRMAN.

CHAIRMAN THOMAS: HOLD ON. MR. REED, BEFORE WE GET TO PUBLIC COMMENT, WE HAVE ONE MORE BOARD COMMENT. JOAN.

MS. SAMUELSON: I DON'T FEEL PREPARED TO THINK THAT I KNOW ENOUGH TO APPROVE THIS. I THINK IT WOULD BE HELPFUL IF WE COULD GET A REDRAFT OF THE SUMMARY ON ACCOMPLISHMENTS BECAUSE THOSE WERE SOME REAL QUALITATIVE CHANGES, IT SOUNDED LIKE, IN THE STATEMENTS OF WHAT WE HAVE ACCOMPLISHED. IF WE HAVE

FUNDED SIX THERAPIES AS OPPOSED TO WE HAVE SIX THERAPIES, WHICH SOUNDS LIKE WE'VE DEVELOPED SIX THERAPIES, RIGHT?

DR. FEIGAL: I GUESS I'M NOT QUITE FOLLOWING.

MS. SAMUELSON: I'M LOOKING AT THE EXECUTIVE SUMMARY ON ACCOMPLISHMENTS.

DR. FEIGAL: THE EXECUTIVE SUMMARY IS A SUMMARY. THE DETAIL IS IN THE APPENDIX.

MS. SAMUELSON: AS I UNDERSTOOD YOUR DIALOGUE, IT CHANGED THE MEANING OF THE SENTENCE. AND I'D LIKE TO BASE MY UNDERSTANDING ON THE ACCURATE FACTS.

DR. FEIGAL: IF YOU ARE TALKING ABOUT -- WELL, FIRST OF ALL, WE'RE TALKING ABOUT TWO DIFFERENT THINGS. THE EXECUTIVE SUMMARY IS NOT A SUMMARY OF THE TEN-YEAR GOALS. IT WAS A SUMMARY OF THE FIVE-YEAR GOALS FROM 2006, WHICH IS BASICALLY THIS YEAR, AND IT HAS A DETAIL -- WE HAVE NOT MET THE TEN-YEAR GOALS YET. IT WAS JUST TALKING ABOUT THE STATUS OF WHERE WE ARE IN MEETING THEM. AND, FRANKLY, THE FIRST GOAL ABOUT SIX THERAPIES, THAT WAS THE FIVE-YEAR GOAL, NOT A TEN-YEAR GOAL.

MS. SAMUELSON: WHATEVER IT WAS, IF THE STATEMENT IS THAT CIRM GRANTEES WILL HAVE FUNDED

FUNDING FOR SIX THERAPIES AS OPPOSED TO --

DR. FEIGAL: PRECLINICAL. THAT IS TRUE.

MS. SAMUELSON: -- AS OPPOSED TO SAYING THAT THEY HAVE SIX THERAPIES, THAT TELLS ME SOMETHING VERY DIFFERENT. I'D JUST LIKE TO -- THAT'S JUST AN EXAMPLE TO SAY I DON'T THINK I KNOW ENOUGH ABOUT WHERE WE ARE AND HOW WE CAME UP WITH THESE PREDICTIONS IN TERMS OF WHERE WE ARE.

CHAIRMAN THOMAS: I THINK DR. STEWARD HAS SOME THOUGHTS ON THAT QUESTION.

DR. STEWARD: JUST TO SAY I THOUGHT THAT WE REALLY WEREN'T BEING ASKED TO DO ANYTHING FORMALLY AT ALL. I THINK I SAW JAMES SORT OF NODDING IN THAT RESPECT EARLIER ON.

DR. FEIGAL: WELL, I THOUGHT ALL WE WERE SUPPOSED TO DO TODAY PERSONALLY WAS TO GET INPUT ON THESE ONE- AND FIVE-YEAR GOALS BECAUSE YOU ARE GOING TO SEE THE FINAL STRATEGIC PLAN IN MAY. SO NOW IS THE LAST BOARD MEETING BEFORE MAY 24TH.

DR. STEWARD: I JUST RECOMMEND THAT WE NOT TAKE ANY ACTION AT ALL. IT'S A DOCUMENT THAT'S A WORKING DOCUMENT, AND I THINK WE ALL APPRECIATE THE OPPORTUNITY TO HAVE PROVIDED INPUT. IT'S COMING TOGETHER REALLY NICELY AND GO FORTH, SO TO SPEAK.

DR. FEIGAL: THAT SOUNDS GREAT. WHAT WE

DO WANT TO DO, THOUGH, IS MAKE SURE THAT YOUR INPUTS ARE RECEIVED. IT MAY BE THERE'S NOT A CONSENSUS, BUT WE'RE HEARING DIFFERENT INPUTS AND THAT WE ARE COMING FORWARD IN MAY WITH A FINALIZED STRATEGIC PLAN. SO IF YOU DO HAVE ISSUES OR CONCERNS, WE DO NEED TO HEAR ABOUT THEM.

CHAIRMAN THOMAS: MR. SHESTACK.

MR. SHESTACK: JUST, JOAN, HAVE YOU GOTTEN TO READ THIS IN DETAIL, OR YOU'RE REACTING MORE TO WHAT WAS PRESENTED ON THE SLIDES?

MS. SAMUELSON: SOME OF EACH.

MR. SHESTACK: OKAY. BECAUSE IN HERE THERE IS --

MS. SAMUELSON: I HAD A LOT OF QUESTIONS AFTER I READ IT THE FIRST TIME.

MR. SHESTACK: IN HERE THERE IS A LOT MORE DETAIL THAN THERE WAS THERE. I'M SURE WHAT MAY HAVE GOTTEN YOU A LITTLE BIT CONCERNED WAS THE WAY ON A SLIDE IT SIMPLY SAID LIKE WE'VE MET EIGHT OF OUR TEN GOALS. IT WAS LIKE VERY SELF-CONGRATULATORY WITHOUT PORTFOLIO, BUT THERE IS MORE DETAIL IN HERE. AND I THINK, IN GENERAL, WE SHOULD TALK -- ALL OF THE PATIENT ADVOCATES IN THE COMMUNITY SHOULD HAVE AS GOOD A SENSE AS POSSIBLE OF WHAT REALLY WE HAVE ACCOMPLISHED AND USING -- THE BENCHMARK THAT TEN

STATED GOALS EARLIER WAS A GREAT WAY TO DO IT. I WOULD SAY THAT WE SHOULD TRY AND -- I KNOW I HAVE TO READ THIS MORE CAREFULLY, BUT THEN I WILL NEED SOMEBODY WHO I CAN REALLY TALK TO DIRECTLY ABOUT IT AT THE OFFICE AND SORT OF MAKE SUGGESTIONS AND BE ABLE TO DO THAT IN A TIMELY FASHION. I IMAGINE YOU MIGHT WANT THE SAME OPPORTUNITY.

MS. SAMUELSON: I THINK THAT'S RIGHT. THANK YOU.

THE OTHER THING THAT WOULD BE HELPFUL IS SOME DOCUMENTATION. I THINK IT WOULD BE VERY USEFUL IF WE COULD GET DATA THAT SHOWS HOW THE MONEY HAS BEEN FUNDED IN TERMS OF ITS IMPACT ON SPECIFIC DISEASES AND THE STATUS OF THAT WORK. SO THAT WOULD MEAN LOOKING AT THE RECORD OF FUNDING FOR INDIVIDUAL GRANTS TO THE EXTENT THAT THEY PERTAIN TO THE SPECIFIC DISEASES THAT ARE PART OF THE MISSION IN THE LAW THAT WE HAVE TO FOLLOW AND HOW MUCH FUNDING THEY GOT AND IN WHICH RFA CATEGORY. THAT'S SOMETHING THAT WOULD HELP ME SEE HOW WE'RE EVOLVING AND WHAT IMPACT IT SEEMS TO BE HAVING.

DR. FEIGAL: SO WHAT I CAN SAY IS THE FIRST THING, AND EVEN IN THIS SLIDE, IT MAY SAY SEE BACKGROUND PREREAD FOR THE DETAILS, IS GO THROUGH THE PREREAD. AND THEN OBVIOUSLY IN A PREREAD,

THERE'S ONLY -- THERE'S MOUNTAINS OF INFORMATION. AND SO WE DO NEED TO DECIDE HOW TO PRESENT IT SO THAT IT'S WHAT YOU WANT. BUT THEN AGAIN, WE DO WANT TO MAKE SOME PROGRESS WITH GETTING A STRATEGIC PLAN OUT THERE. WE CAN THINK ABOUT WAYS TO HAVE INPUTS AND DIALOGUE, I GUESS, BEFORE THE NEXT BOARD MEETING, AND WE'RE HAPPY TO DO THAT. YOU JUST SUGGEST HOW WE CAN HAVE THOSE CONVERSATIONS WITH THE BOARD MEMBERS.

MS. SAMUELSON: THAT'S MY FIRST REQUEST AND ONE FOR TODAY. THAT WOULD BE VERY HELPFUL, AND THEN I'LL DO MY HOMEWORK REVIEWING THE RESULTS OF ALL OF THE APPLICATIONS IN RESPONSE TO RFA'S THAT WERE TRANSLATIONAL AND CLINICAL IN NATURE.

CHAIRMAN THOMAS: JOAN, JUST TO MAKE SURE I UNDERSTAND. WE'RE GETTING THE DISEASE TEAM -- EXACTLY, I THINK, WHAT YOU'RE LOOKING FOR WILL BE PRESENTED TODAY WITH RESPECT TO THOSE. YOU'RE SAYING YOU WOULD IN ADDITION LIKE A SIMILAR SORT OF REPORT ON, I GUESS IT'S, ET I AND II. IS THAT WHAT WE'RE TALKING ABOUT HERE?

DR. FEIGAL: JUST SO WE KNOW, THERE'S HUNDREDS OF AWARDS. WE DO NEED TO UNDERSTAND WHAT IT IS YOU WANT.

CHAIRMAN THOMAS: SHE DID SAY

TRANSLATIONAL.

MS. SAMUELSON: TRANSLATIONAL AND CLINICAL.

CHAIRMAN THOMAS: SO SHE'S NOT TALKING ABOUT THE BASIC RESEARCH.

DR. FEIGAL: SO WE HAVE 43 AT LEAST.

CHAIRMAN THOMAS: OF WHICH 14 YOU'RE DISCUSSING TODAY, CORRECT?

DR. FEIGAL: CORRECT.

MR. SHESTACK: THERE IS A LOT OF INFORMATION IN THE APPENDIX HERE. AND THEN I THINK IF WE LOOK AT IT CAREFULLY, WE CAN HAVE SPECIFIC QUESTIONS BACK FOR THEM, AND THEN ASK FOR ADDITIONAL KINDS OF BREAKDOWNS OR REPORTS. I THINK YOU'RE LOOKING FOR A LOT OF INFORMATION ON AWARD TYPE AND DISEASE TARGETED AND OUTCOME AND SORT OF TRYING TO TRACK A RELATIONSHIP IF THERE IS ONE. SO WE SHOULD TRY AND FIGURE OUT A WAY TO ASK THE QUESTION AS SUCCINCTLY AS POSSIBLE AND GIVE THEM AN OPPORTUNITY TO ANSWER IT. I DON'T THINK THEY CAN DO IT RIGHT NOW. IF YOU GIVE US SOMEBODY, AND MAYBE IT'S YOU, ELLEN, WE CAN TALK TO ABOUT IT AND ASK SPECIFIC QUESTIONS, THAT WOULD BE GREAT.

DR. TROUNSON: CHAIR, CAN I MAKE A SUGGESTION, THAT THE BOARD MEMBERS WHO WANT MORE

INFORMATION, IF THEY COULD CONTACT US AND WE WILL TRY AND SET ABOUT PROVIDING SOMEBODY TO BE ABLE TO ANSWER THOSE QUESTIONS IN A TIMELY FASHION. SO THOSE BOARD MEMBERS WHO WANT MORE INFORMATION, IF THEY COULD CONTACT US EITHER DIRECTLY OR THROUGH --

MR. SHESTACK: WHILE WE'RE ON THAT SUBJECT, FOR THREE YEARS I'VE BEEN ASKING. THERE'S NO WAY ON THE WEBSITE AND NO OTHER WAY EASILY FOR BOARD MEMBERS TO KNOW WHICH STAFF MEMBER IS RESPONSIBLE FOR WHICH AREA OF THE GRANTS OR TO ACTUALLY JUST -- OUR NAMES ARE HERE. YOU GUYS ARE HERE AT EVERY MEETING, BUT YOUR NAMES AREN'T HERE. SOMETIMES YOU CHANGE. I SEE YOU ONCE EVERY FOUR MONTHS. IT WOULD BE GREAT IF THERE WAS JUST A WAY WE KNEW WHAT PEOPLE WERE A LITTLE BIT MORE EXPERT OR RESPONSIBLE AND COULD HAVE A MORE PRODUCTIVE DIALOGUE.

DR. TROUNSON: IF IT COMES FROM MARIA'S OFFICE OR DIRECTLY TO MINE, WE CAN ENSURE WE DO THAT BECAUSE THERE'S A WIDE VARIETY OF PEOPLE. AND I WANT THEM TO BE AVAILABLE TO ANSWER THE KIND OF QUESTIONS YOU WANT TO ASK, SO IT MAY BE BETTER TO HAVE ONE SORT OF PERSON OR ANOTHER. SO I'M HAPPY TO DO THAT. IF WE DO IT THROUGH MARIA OR THROUGH MY OFFICE, THEN I THINK WE CAN GET IT. WE ARE HAPPY TO

TAKE TIME TO MEET WITH YOU TO CLEAR UP OR TO HELP ADDRESS SPECIFIC ISSUES THAT ARE EVOLVING.

CHAIRMAN THOMAS: I THINK THAT'S A GOOD SUGGESTION. I WOULD SAY THAT THE KINDS OF INFORMATION THAT JOAN AND JON ARE ASKING FOR WOULD BE OF INTEREST TO ALL MEMBERS OF THE BOARD. SO WHATEVER YOU CAN PRODUCE ON THAT AND UPDATE THE FULL BOARD, THAT WOULD BE APPRECIATED.

DR. STEWARD: I APPRECIATE THAT THERE'S A LOT OF STAFF TIME THAT WOULD BE INVOLVED IN THIS. ON THE OTHER HAND, THIS IS ALSO THE KIND OF THING THAT IT WOULD BE PERFECTLY FAIR TO ASK THE GRANTEES TO PROVIDE. I THINK WHAT JOAN IS LOOKING FOR IS A VERY CRISP DOCUMENT THAT IN MAYBE A PAGE SUMMARIZED ANSWERS TO A COUPLE OF KEY QUESTIONS ABOUT REALLY ACCOMPLISHMENTS RELATED TO TRANSLATABILITY. MAYBE WE COULD JUST SEND OUT A SIMPLE THING AND REQUIRE THE GRANTEES TO RESPOND TO IT TO PROVIDE SOMETHING ALONG THOSE LINES, AGAIN, IN A CONSISTENT FORMAT, IN A FORM THAT WOULD BE LAY LANGUAGE AND USEFUL TO ALL BOARD MEMBERS.

DR. FEIGAL: THE ONLY THING I WOULD SAY WE CAN FIGURE OUT HOW TO GET YOU WHAT YOU NEED; BUT IF IT'S GOING TO THE BOARD, WE DO HAVE TO CONSIDER IT'S A PUBLIC DOCUMENT. SO WE HAVE TO TAKE THOSE THINGS

INTO ACCOUNT AS WELL, BUT WE'LL FIGURE OUT HOW TO GET YOU THE ANSWERS. WHAT WE NEED TO KNOW IS -- MAKE SURE WHAT YOUR QUESTIONS ARE. AND IN PURSUIT OF TRYING TO KEEP THE STRATEGIC PLAN SOMEWHAT ON TRACK, INITIALLY WE WERE GOING TO PRESENT A FINAL VERSION TODAY, BUT THE DECISION WAS MADE LET'S HAVE A DISCUSSION ON FUNDING PRIORITIES AND STRATEGIES. IF WE ARE STILL GOING TO SET FOR A TRAJECTORY OF MAY, FIGURE OUT HOW TO DO IT UNLESS YOU WANT TO PUT IT OFF TO ANOTHER TIME. BUT IF WE DO WANT TO DO IT IN MAY, THEN LET'S FIGURE OUT A WAY TO GET THE QUESTIONS ANSWERED IN BETWEEN BOARD MEETINGS.

CHAIRMAN THOMAS: WE WANT TO HAVE A FINAL VOTE IN MAY FOR A VARIETY OF REASONS. I THINK MR. SHEEHY HAD HIS HAND UP.

MR. SHEEHY: I JUST WANT TO SAY AS SOMEBODY WHO'S READ EVERYTHING AND FOLLOWS THIS PRETTY CLOSELY, I ACTUALLY THINK A LOT OF THE DISEASE-SPECIFIC INFORMATION IS ON THE WEBSITE. IF YOU GO AND LOOK -- LIKE I MONITOR THE HIV STUFF FAIRLY CLOSELY. I READ THIS DOCUMENT. I THOUGHT DR. FEIGAL AND STAFF HAVE DONE A GREAT JOB. YOU GO THROUGH ALL THE APPENDICES, THERE ACTUALLY IS A TREMENDOUS AMOUNT OF INFORMATION. NOW, IT'S NOT NECESSARILY DISEASE SPECIFIC, BUT I WOULD REALLY

HOPE -- THERE'S A LOT OF WORK THAT'S GONE INTO THIS SO FAR, AND I THINK DUANE ROTH MENTIONED THAT. I THINK THIS IS GREAT. I LIKE THE METRICS IN IT, WHICH IS VERY IMPORTANT TO HAVE SOME KEY DELIVERABLES THAT ARE PUT OUT THERE WITH NUMBERS.

SO IF WE ARE GOING TO ASK STAFF FOR STUFF, LET'S JUST BE REALLY CLEAR ABOUT WHAT WE'RE ASKING FOR AND READ EVERYTHING THAT WE HAVE, LOOK ON THE WEBSITE BEFORE WE START SAYING -- OTHERWISE, I DON'T THINK WE'LL HAVE A STRATEGIC PLAN. IT MIGHT BE NEXT CHRISTMAS.

MR. SHESTACK: JEFF, I AGREE. I THINK THAT THE APPENDICES ARE FILLED WITH A LOT OF VERY DETAILED, GRANULAR INFORMATION. I UNDERSTAND WHAT JOAN'S SAYING. I JUST WANT TO MAKE SURE THAT WE HAVE THE OPPORTUNITY TO LIKE ASK SOME MORE SPECIFIC QUESTIONS IF WE NEED THEM. AND I DO AGREE, IF YOU READ IT CAREFULLY, THERE'S A LOT OF INFORMATION IN HERE WITH PERSPECTIVE.

DR. TROUNSON: JUST FOR JOAN, WE DO HAVE THIS WORKSHOP COMING UP IN PARKINSON'S WHERE WE'RE BRINGING REALLY ALL THE PEOPLE ACROSS THE U.S. AND WORLD TOGETHER. AND SO THERE WILL BE A REPORT EVOLVING OUT OF THAT. SO I WOULD HAVE THOUGHT THAT THAT WOULD BE A REALLY BIG SYNC OF IMPORTANT

INFORMATION FOR PARKINSON'S DISEASE.

MS. SAMUELSON: WONDERFUL.

DR. TROUNSON: OTHER CONDITIONS POSSIBLY NOT SO WELL VISITED MORE RECENTLY, BUT WE'LL PROVIDE AS MUCH INFORMATION AS WE CAN IN A TIMELY FASHION FOR YOU.

DR. PIZZO: THIS IS PHIL. CAN I RAISE A QUESTION? FIRST OF ALL, I WANT TO ECHO WHAT OTHERS HAVE SAID. THIS HAS BEEN AN OUTSTANDING SUMMARY AND A GREAT PRESENTATION. I HAVE A SLIGHTLY NUANCED ADDITION, WHICH IS THE REPORT IN A SENSE LEADS TO A CONCLUSION OF A JOB WELL DONE. AND I THINK THAT IN SOME WAYS, IN TERMS OF OUR OWN CONCLUSIONS AND THE PUBLIC REVIEW OF THIS, WE MAY BE CONVEYING THAT OUR EFFORTS ARE ALL COMPLETED, WHICH IS HARDLY THE CASE. I WOULD VERY MUCH WELCOME SEEING AS PART OF THE STRATEGIC PLAN A LIST OF, AS BEST AS WE CAN DEFINE THEM, KEY INITIATIVES AND QUESTIONS THAT ARE LIKELY TO TRANSCEND AND GO BEYOND THE FIVE-YEAR PERIOD TO MAKE CLEAR TO THOSE WHO READ IT THAT THERE'S A LOT MORE WORK THAT NEEDS TO BE DONE THAN JUST THE CONCLUSIONS WE SEEM TO BE REACHING AT THIS JUNCTURE IN TIME.

DR. FEIGAL: THAT'S AN INTERESTING NUANCE. WHEN WE FIRST STARTED WITH THE STRATEGIC PLAN BACK

IN AUGUST, WE DID HAVE A QUESTION, SHOULD WE FOCUS IT ON THE NEXT FIVE YEARS, OR SHOULD WE HAVE MORE OF A VISION THAT WOULD TRANSCEND THE LIFE SPAN, AT LEAST CURRENTLY, OF HOW THINGS ARE. AND THE DECISION WAS MADE AT THAT TIME TO FOCUS IT HERE. IF WE'RE GOING TO FOCUS IT BEYOND, I THINK THAT'S GOING TO TAKE ANOTHER DISCUSSION.

DR. PIZZO: WHAT I'M THINKING, ELLEN, IS THE FOLLOWING: THE SUMMARY AND THE REPORT FOCUSING ON THE NEXT FIVE YEARS IS TERRIFIC, AND I THINK THAT WAS A WISE DECISION. BUT TO THE READERS BOTH PUBLIC AND PRIVATE, FUNDERS AND OTHERS, THEY'LL LOOK AT THIS TO SAY, WELL, THE JOB OF CIRM HAS BEEN COMPLETED. WE FULFILLED THE GOALS THAT WE SET OUT TO DO. AND I DON'T, FOR ONE, BELIEVE THAT'S GOING TO BE THE CASE AT ALL.

SO I THINK WE NEED TO HAVE IN THIS AS AN EXTENSION OF IT A CLEAR DELINEATION THAT, A, STATES THAT AND, B, BEGINS TO OUTLINE SOME OF THE REALLY IMPORTANT CHALLENGES THAT ARE STILL LIKELY TO STAND BEFORE US SO THAT IT APPEARS TO BE WHAT IT SHOULD BE, AN ORGANIC DOCUMENT THAT WILL CONTINUALLY EVOLVE OVER TIME. AND IT WILL NEED AN ADDITIONAL REPORT TO MAKE THE INVESTMENT FULLY REALIZED OVER THE NEXT 10 OR 15 OR 20 YEARS.

DR. FEIGAL: I HEAR WHAT YOU ARE SAYING, AND I THINK WE ALL ACTUALLY CAN AGREE WITH THAT SENTIMENT. I'M JUST THINKING OUT LOUD IN TERMS OF HOW DO I GET THE NECESSARY INPUTS TO ACTUALLY GO BEYOND THAT NEXT FIVE YEARS, BUT WE CAN TALK ABOUT THAT OFFLINE PERHAPS.

DR. PIZZO: OKAY. I'M HAPPY TO.

CHAIRMAN THOMAS: THANK YOU, PHIL. JOAN.

MS. SAMUELSON: I'LL PUT IT ALL IN WRITING AND SHARE IT WITH THE REST OF THE BOARD.

CHAIRMAN THOMAS: I THINK DR. STEWARD IS RIGHT. THERE REALLY IS NO NEED FOR A MOTION HERE. THIS IS JUST AN INFORMATIVE SESSION TO GIVE DR. FEIGAL ADDITIONAL TAKEAWAYS TO REFINE.

MR. ROTH: THAT WAS THE BASIS OF THE MOTION WAS JUST TO BASICALLY BRING BACK IN MAY THE FINAL VERSION. BUT THE QUESTION WAS WERE THE FIVE-YEAR GOALS AS PRESENTED, THE ONE-YEAR AND FIVE-YEAR, ON THE RIGHT DIRECTION, RIGHT TRACK. AND THAT'S ALL I WAS TRYING TO REINFORCE. SO IF WE DON'T NEED A MOTION, I'M HAPPY TO WITHDRAW THE MOTION.

CHAIRMAN THOMAS: THANK YOU. WITHDRAWN SECOND. THANK YOU.

JAMES, IS THIS WHERE WE HAVE TO GO BACK

AND REVISIT THE CREATIVITY AWARD VOTE? JUST KIDDING. SO I THINK THAT WE NOW HAVE PUBLIC COMMENT. MR. REED.

MR. REED: I WAS GLAD TO HEAR DR. PIZZO SAY THAT BECAUSE I SEE THIS AS A SALES DOCUMENT FOR PROPOSITION 71, PART 2. WE'RE GOING TO HAVE TO HAVE SOME KIND OF A PART 2, WHETHER IT'S A GOVERNMENT THING OR WHETHER IT'S PRIVATE DONATIONS, WHATEVER. THIS IS TOO VALUABLE TO NOT BE SUSTAINED. EVERYONE AGREES ON THAT.

THIS IS GOING TO BE THE DOCUMENT PEOPLE WILL LOOK AT FIRST. I JUST RECENTLY LOOKED UP A LIST OF THE PEOPLE WHO DONATED TO PROP 71. ONLY ABOUT A HUNDRED PEOPLE DONATED ABOVE $5,000 AND MORE. THIS INCLUDED PEOPLE LIKE GATES. I THINK EVERY ONE OF THOSE DONORS AND THE MORE THAN 80 PATIENT ADVOCATE GROUPS SHOULD GET A COPY OF THIS SO THEY CAN SEE WHAT WE'RE DOING, WHAT WE'VE ACCOMPLISHED, AND KNOW WHY THEY MUST SUPPORT US EVEN HARDER NEXT TIME, NOT THINK OUR JOB IS DONE.

CHAIRMAN THOMAS: THANK YOU, MR. REED.

MR. TORRES: ON THAT POINT, DON, MAYBE YOU ARE AWARE, BUT 80 PERCENT OF THE SALES FOR THE BONDS, THE REVENUE BONDS, TO HELP US OUT WERE PURCHASED BY PRIVATE INDIVIDUALS, NOT INSTITUTIONS,

NOT OTHER TYPES OF ENTITIES, BUT PRIVATE INDIVIDUALS. THAT'S QUITE A STATEMENT FOR A CALIFORNIA BOND.

MR. REED: THAT'S HUGE AND THOSE PEOPLE SHOULD BE GIVEN A COPY OF THIS SO THEY CAN KNOW WHERE THEIR MONEY WENT AND IT WAS WORTHWHILE.

CHAIRMAN THOMAS: THANK YOU. OBVIOUSLY, AS WE'VE SAID BEFORE, WITH RESPECT TO FUTURE FUNDING, WE'RE IN THE PROCESS OF ANALYZING A VARIETY OF ALTERNATIVES AND HAVE MADE NO DECISIONS, BUT WE FIRMLY AGREE ON THE NOTION THAT THE MISSION SHOULD BE SUSTAINED, FOR SURE.

SO WITH THAT, THANK YOU, DR. FEIGAL, FOR A VERY GOOD PRESENTATION. LIKE TO TURN IT OVER NOW TO PART 2 OF ITEM 9 TO DR. OLSON.

DR. OLSON: THANK YOU, MR. CHAIR, MEMBERS OF THE BOARD. SO TODAY WHAT I'D LIKE TO DO IS PROVIDE A FRAMEWORK FOR DISCUSSION ON DISTRIBUTION OF THE REMAINDER OF THE CURRENT BOND ALLOCATION. YOU'VE HEARD -- WE'VE BEEN TALKING NOW OVER SEVERAL BOARD MEETINGS ABOUT THE STRATEGIC PLAN. YOU'VE BEEN PRESENTED WITH THE KEY STRATEGIC OBJECTIVES, THE KEY OUTCOMES WE HOPE TO GET. YOU'VE HEARD FROM ELLEN TODAY ABOUT OUR FIVE-YEAR GOALS, AND THEN OUR ONE-YEAR GOALS THAT HOPEFULLY WOULD PUT US ON TRACK

TO ACHIEVE THOSE GOALS.

WHAT I WOULD ASK YOU TO CONSIDER AND WHAT THE PURPOSE OF THIS DISCUSSION IS TODAY IS TO THINK ABOUT HOW WE WILL ALLOCATE THE MONEY -- FIRST I'D LIKE TO TALK ABOUT HOW WE HAVE ALLOCATED THE MONEY. THEN I'D LIKE TO TALK ABOUT THE ALLOCATION THAT HAS ALREADY BEEN CONCEPT APPROVED, AND THEN I'D LIKE TO TALK ABOUT CONSIDERATIONS FOR FUTURE FUNDING. AND I'D LIKE TO TALK ABOUT IT IN THE CONTEXT OF THESE FIVE-YEAR GOALS, THE KEY OUTCOMES, AND THE STRATEGIC OBJECTIVES.

SO FIRST, I'M NOT GOING TO TALK ABOUT SPECIFIC RFA'S. I'M GOING TO TALK ABOUT CATEGORIES OF FUNDING. I JUST WANT TO MAKE SURE WE HAVE A COMMON UNDERSTANDING OF THE CATEGORIES THAT I'M TALKING ABOUT, THE DEFINITIONS THAT I'LL USE BECAUSE THEY'RE A LITTLE BIT -- TRANSLATION GETS BANDIED ABOUT. AND THESE ARE THE DEFINITIONS THAT I AM GOING TO BE USING FOR THIS DISCUSSION.

SO WHEN WE TALK ABOUT FUNDING FACILITIES OR CORE RESOURCES, WE'RE TALKING ABOUT PROGRAMS IN THE PAST THAT WE HAVE FUNDED THAT RESULTED IN NEW AND REMODELED FACILITIES TO EXPAND OUR CAPACITY TO HOUSE RESEARCHERS IN CALIFORNIA. WE'RE ALSO TALKING ABOUT PROGRAMS THAT PROVIDE A CORE RESOURCE TO STEM

CELL RESEARCHERS. SHARED LABORATORIES ARE A GOOD EXAMPLE OF THAT.

WHEN I TALK ABOUT FUNDING IN A TRAINING OR CAREER DEVELOPMENT CATEGORY, I'M TALKING ABOUT THOSE PROGRAMS WHOSE FOCUS IS BROADENING AND/OR STRENGTHENING THE POOL OF STEM CELL RESEARCH, SEEDING THE FIELD, CREATING THE BASIS FOR GROWTH AND FOR CONTINUED RESEARCH GOING FORWARD. DR. PIZZO MENTIONED WHAT DOES THIS MEAN GOING FORWARD. WE'RE CREATING A WHOLE CADRE OF RESEARCHERS.

WHEN I TALK ABOUT BASIC RESEARCH, THAT IS FUNDING FOR RESEARCH THAT ADDRESSES THE FUNDAMENTALS OF STEM AND PROGENITOR CELL BIOLOGY. IT'S QUESTIONS ABOUT MECHANISM. IT'S THE DISCOVERIES THAT ARE THE BASIS FOR PATENT APPLICATIONS. IT'S THE BASIS FOR WHAT I'LL CALL THE NEXT CATEGORY, TRANSLATIONAL RESEARCH WHERE THE FOCUS IS ON TRANSLATING THE BASIC RESEARCH DISCOVERIES TO POTENTIAL THERAPEUTICS. IT'S THE STUDIES WHERE YOU HAVE A HYPOTHESIS, AND YOU DO A PROOF OF CONCEPT IN AN ANIMAL MODEL, THAT YOUR HYPOTHESIS ABOUT A MECHANISM OF ACTION MAY ACTUALLY HAVE SOME RELEVANCE TO A DISEASE. IT'S ABOUT ADDRESSING THE BOTTLENECKS TO TRANSLATION, SOME OF OUR TOOLS AND TECHNOLOGIES AWARDS.

AND THEN, FINALLY, THE CATEGORY THAT I'LL

CALL DEVELOPMENT RESEARCH. SO HERE THE FOCUS IS ACTUALLY ON NOW TAKING THOSE PRECLINICAL CONCEPTS, IF YOU LIKE, AND ACTUALLY THE PREPARATION FOR AND THE CONDUCT OF CLINICAL TESTING IN HUMANS OF A STEM OR CELL-BASED THERAPEUTIC CANDIDATE.

I DO WANT TO MAKE THE POINT, WE'VE TALKED TO YOU BEFORE ABOUT OUR TRANSLATIONAL PORTFOLIO. OUR TRANSLATIONAL PORTFOLIO INCLUDES VIRTUALLY EVERYTHING THAT FALLS IN THE DEVELOPMENT RESEARCH CATEGORY WITH THE EXCEPTION OF PLANNING AWARDS. AND IT INCLUDES A SUBSET OF THE PROJECTS THAT ARE IN THE TRANSLATIONAL RESEARCH CATEGORY. SO IT DOESN'T, FOR EXAMPLE, INCLUDE TOOLS AND TECHNOLOGIES. SO I JUST WANT TO MAKE SURE THAT WE HAVE A COMMON UNDERSTANDING ABOUT THAT.

LET ME REMIND YOU JUST OF WHAT WE'VE DONE. SO IF YOU LOOK AT THE -- THIS BOARD HAS AWARDED AND WE HAVE ALLOCATED OR WILL BE ALLOCATING MONEY TO PROGRAMS REPRESENTING $1.29 BILLION. YOU CAN SEE THAT IN LARGE PART THIS IS -- ROUGHLY HALF OF IT HAS GONE INTO WHAT I'LL CALL INFRASTRUCTURE, WHETHER IT BE PHYSICAL INFRASTRUCTURE, THE FACILITIES, OR WHETHER IT BE INTELLECTUAL STRUCTURE IN TRAINING CAREER DEVELOPMENT. ROUGHLY EQUAL AMOUNTS HAVE BEEN DISTRIBUTED TO THE BASIC, TRANSLATIONAL, AND

DEVELOPMENTAL RESEARCH CATEGORY.

THE GRAPH ON THE BOTTOM GIVES VERY MUCH A SENSE OF IT SHOWS YOU, IN ESSENCE, THE HISTORY OF OUR INSTITUTE. IT SHOWS YOU HOW A LOT OF OUR INITIAL FUNDING WAS IN THOSE INFRASTRUCTURE. THE RED BEING THE FACILITIES. SO THAT BIG BAR IN 2007 AND 8, THAT WAS WHEN WE STARTED FUNDING THE MAJOR FACILITIES. SO YOU SEE A HISTORY. YOU CAN SEE, AND WE'VE SEEN THIS IN OTHER FORMATS, THAT IT WAS IN 2009 AND 10 THAT WE ACTUALLY STARTED FUNDING THE TRANSLATIONAL AND THE DEVELOPMENT RESEARCH. SO THIS IS A HISTORY OF WHAT IT'S BEEN TO DATE.

I THINK WE CAN ALL BE PROUD. YOU'VE ALL HEARD ELLEN MENTION THE PROGRESS AND THE ACCOMPLISHMENTS ON OUR FIVE-YEAR GOALS THAT YOU APPROVED WITH THE 2006 PLAN. THE THINGS THAT YOU'VE HEARD ALAN AND MANY OF US TALK ABOUT IN TERMS OF THE ACCOMPLISHMENTS OF THE INSTITUTE, THE 12 NEW INSTITUTIONS, THE THOUSAND PAPERS PUBLISHED, MANY IN HIGH IMPACT JOURNALS, BUT IT'S ALSO THE INTANGIBLES. IT'S ESSENTIALLY HAVING CALIFORNIA RECOGNIZED AS A NEXUS AND A LEADER, THAT CALIFORNIA HAS ESSENTIALLY, I THINK, PROVIDED A BIT OF THE DRIVING OF FOCUS ON STEM CELL RESEARCH WORLDWIDE. SO IT'S MORE OF THOSE INTANGIBLES.

ELLEN HAS SPENT SOME TIME NOW TALKING TO YOU ABOUT ESSENTIALLY THE STRATEGIC OBJECTIVES, THE KEY OUTCOMES, AND THE FIVE-YEAR GOALS. AND I WANT TO SPEND A LITTLE BIT OF TIME BECAUSE REALLY THIS IS WHAT IS DRIVING -- I THINK NEEDS TO DRIVE OUR CONSIDERATION IN FUTURE RESEARCH FUNDING. SO YOU'VE HEARD ABOUT -- IN THE SCIENTIFIC GOALS, YOU'VE HEARD ABOUT UNDERSTANDING A LOT ABOUT SOME OF THE VERY FUNDAMENTAL QUESTIONS IN STEM CELL BIOLOGY, ABOUT A DESCRIPTION OF DIFFERENTIATION, ABOUT ESTABLISHING PROOF OF PRINCIPLE. A LOT OF THESE CAN BE ACHIEVED THROUGH SOME OF OUR CORE PROGRAMS IN BASIC BIOLOGY, IN EARLY TRANSLATION, ACHIEVING TRANSFORMATIVE RESEARCH DISCOVERIES. I MEAN IT'S WHEN YOU MAKE THIS BREAKTHROUGH DISCOVERY IS WHEN YOU SAY, AHA, MY HYPOTHESIS WORKS IN A MODEL. AND IT EVEN IS IN A CLINIC WHEN YOU GET PROOF OF PRINCIPLE. SO I THINK A LOT OF WHAT WE DO SPEAKS TO THAT.

I WANT TO FOCUS YOUR ATTENTION, THOUGH, ON THE CLINICAL GOALS THAT WE JUST TALKED ABOUT, THE FUNDED TEN THERAPIES IN PHASE I OR PHASE II CLINICAL TRIALS IN AT LEAST FIVE DIFFERENT THERAPEUTIC AREAS. AND I WANT TO ASK YOU TO REMEMBER THAT ONE. BUT THEN I WANT TO ALSO ASK YOU TO REALLY LOOK AT WHAT WE SAY IN THE ONE HIGHLIGHTED IN RED. WE SAY WE

WILL IN FIVE YEARS HAVE ACHIEVED CLINICAL PROOF OF CONCEPT THAT TRANSPLANTED CELLS, SO WHAT THIS MEANS IS A CELL THERAPY, DERIVED FROM PLURIPOTENT OR PROGENITOR CELLS CAN BE USED TO RESTORE FUNCTION IN AT LEAST ONE DISEASE OR INJURY CONDITION.

SO CLINICAL PROOF OF CONCEPT MEANS SUCCESSFUL COMPLETION OF A PHASE II STUDY, TYPICALLY. OKAY. WHAT DOES THIS MEAN? BECAUSE THIS IS ACTUALLY -- AND I WANT TO TALK ABOUT WHY I WOULD ASK YOU TO CONSIDER THIS TO BE A KEY DRIVER FOR THE FUNDING STRATEGY. THIS PARTICULAR GOAL, AND WHY DO I THINK IT REALLY IS A KEY DRIVER FOR THE FUNDING STRATEGY? LET'S TALK A LITTLE BIT ABOUT DRUG DEVELOPMENT. AND I'LL TALK ABOUT INDUSTRY STATISTICS, AND THERE IS AN APPENDIX IN THE DOCUMENT PROVIDED TO YOU AS A PREREAD THAT CITES SOME, BUT I WOULD SAY TO YOU THAT THIS INFORMATION, ESPECIALLY THE COST INFORMATION, COMES NOT JUST FROM THAT, BUT FROM OUR DISCUSSIONS WITH PEOPLE IN BIOTECHNOLOGY, FROM OUR DISCUSSIONS WITH PEOPLE IN PHARMA, AND FROM OUR TALKING TO -- FROM ACTUALLY MANY OF US HAVE EXPERIENCE IN THE BIOTECHNOLOGY INDUSTRY OURSELVES.

SO BASED ON INDUSTRY STATISTICS, AND I THINK ELLEN ALLUDED TO THIS TOO IN HER DISCUSSION, WHAT DO WE TALK ABOUT IN TERMS OF TIME WHEN WE TALK

ABOUT CLINICAL DEVELOPMENT? AND I SHOULD ALSO MAKE THE POINT, INDUSTRY STATISTICS ARE DRIVEN BY THE BIOTECH AND THE PHARMA INDUSTRY. THEY ARE PREDOMINANTLY SMALL MOLECULE FOCUSED, INCREASINGLY BIOLOGICS, MONOCLONAL ANTIBODIES, BUT THERE IS A LOT OF INFORMATION BACK HERE. SO THEY'RE FOR THERAPEUTIC CANDIDATES THAT HAVE WELL-KNOWN PATHS.

OKAY. IN PHASE I, TYPICAL TIMES ARE FROM ONE TO TWO YEARS. IN PHASE II, TYPICAL TIMES TO GO THROUGH A PHASE II TRIAL IS FROM TWO TO FOUR YEARS. SO IF WE LOOK AT PHASE I-II TOGETHER, WE WOULD HAVE TO SAY AT THE MINIMUM IT WILL TAKE -- FOR SOMETHING ENTERING PHASE I WILL TAKE A MINIMUM OF AROUND THREE YEARS AND A MAXIMUM FOR AROUND SIX YEARS. WHEN WE TALK ABOUT PROBABILITY OF SUCCESS, I KNOW WE WOULD ALL LOVE TO THINK THAT EVERYTHING THAT WE PUT IN THE CLINIC WILL BE SUCCESSFUL. UNFORTUNATELY THAT IS NOT THE -- THAT'S JUST NOT TRUE. IN AN IN VITRO SYSTEM, YOU CANNOT IN PRECLINICAL MODELS, YOU CANNOT DEFINE HOW THE HUMAN BODY IS GOING TO RESPOND, OR IF, IN FACT, HOW CENTRAL IS YOUR HYPOTHESIS OF IMPACT ON DISEASE REALLY GOING TO PLAY OUT IN THE CLINIC. IN FACT, THAT'S WHY THEY CALL IT CLINICAL RESEARCH. THAT'S THE STAGE WHERE WE FIND OUT DO THINGS WORK IN PEOPLE.

SO WHAT THAT MEANS IS THAT IT IS THE CASE, AND THIS IS UNFORTUNATELY TRUE, THAT IN GENERAL ONE IN FIVE CANDIDATES THAT INITIATE PHASE I WILL SUCCESSFULLY COMPLETE A PHASE II TRIAL, WILL GIVE YOU THE PROOF OF CONCEPT AT A CERTAIN LEVEL OF CERTAINTY, NOT ABSOLUTELY. THAT'S WHY YOU DO PHASE III TRIALS. BUT WILL GIVE YOU A GOOD INDICATION THAT IT IS WORTH PROCEEDING. ONE OUT OF FIVE UNFORTUNATELY, VERY UNFORTUNATELY, FAILURES TEND TO OCCUR IN PHASE II RATHER THAN IN PHASE I. SO THAT'S JUST SOMETHING THAT WE'RE WORKING WITH, AND THAT'S WHAT WE'VE TRIED TO USE IN THINKING ABOUT THIS.

THE COSTS, AGAIN, BASED ON INDUSTRY STATISTICS, BASED ON OUR DISCUSSIONS WITH MANY IN THE INDUSTRY. CLINICAL DEVELOPMENT IS AN EXPENSIVE PROPOSITION. PHASE I COSTS ROUGHLY 20 MILLION. PHASE II COSTS FROM 25 TO 40 MILLION. SO YOU TALK ABOUT A PROJECT IN BASIC BIOLOGY, ONE PROJECT WILL COST YOU MAYBE $1.5 MILLION. A CLINICAL PROJECT OR A PROJECT IN THIS DEVELOPMENT SPACE WILL COST YOU MORE ON THE ORDER OF, I WOULD SAY, THESE KINDS OF NUMBERS. THESE ARE WHY OUR DISEASE TEAM PROJECTS ARE PRICED THE WAY THEY ARE. NOT TO SAY THAT EVERYBODY SHOULD GO THAT, BUT WE WANTED TO MAKE SURE THAT WE COULD FUND ALL THE ACTIVITIES THAT IT

ACTUALLY TOOK TO DO THE WORK.

OKAY. WHAT ARE THE IMPLICATIONS OF THIS? IT JUST MEANS THAT A LARGER PERCENTAGE IN ORDER TO ACHIEVE THIS GOAL THAT REQUIRES PLANNING IN ADVANCE BECAUSE OF THE TIME FRAMES, BECAUSE OF THE COSTS, BECAUSE OF THE PROBABILITIES OF TECHNICAL SUCCESS, IN ORDER TO DO THAT, A LARGER PERCENTAGE OF OUR RESEARCH FUNDING WILL GO TO DEVELOPMENT STAGE PROJECTS, OR WE WOULD SUGGEST SHOULD GO TO DEVELOPMENT STAGE PROJECTS IF YOU WANT TO INCREASE YOUR LIKELIHOOD OF ACHIEVING THE GOAL.

GIVEN THE TIME FRAME AND GIVEN THE FIVE YEARS FROM NOW OF THAT FIVE-YEAR GOAL, OVER THE NEXT TWO YEARS, WE WOULD SUGGEST THAT WE SHOULD TARGET THE FUNDING OF MERITORIOUS PROJECTS THAT ARE ALREADY IN THE CLINIC. OUR MOST CHALLENGING PART OF THAT GOAL IS FOR CELL THERAPY. SO, YOU KNOW, WE NEED TO SEE IF THERE ARE GOOD PROJECTS THERE.

AND I WOULD JUST POINT OUT THAT THERE IS AN ASSUMPTION HERE, AND IT IS A RISK, THE NUMBER OF STRONG PROJECTS IN CALIFORNIA AT APPROPRIATE STAGES IS DEVELOPMENT. AND THAT'S SOMETHING WE'LL SEE. WE'LL SEE WHAT COMES TO US. WE'LL SEE IN THE DISEASE TEAM PLANNING AWARDS. WE'LL SEE IN ALL THESE PROJECTS. IT ALSO HAS AN IMPLICATION THAT

PROJECTS THAT ENTER IND-ENABLING DEVELOPMENT THIS YEAR ARE UNLIKELY TO BE ABLE TO COMPLETE A PHASE II STUDY WITHIN THE FIVE YEARS. WHAT I DIDN'T SPEAK TO WAS THE TIME IT TAKES TO BE AN IND-ENABLING DEVELOPMENT. I WOULD ARGUE THAT THAT IS, AGAIN, FOR A PROJECT THAT ACTUALLY ENTERS WITH A DEVELOPMENT CANDIDATE, THAT'S ONE TO THREE YEARS AS WELL, ONE TO TWO, ONE TO THREE.

SO, HOWEVER, ALL OF THESE PROJECTS ARE PART OF OUR DEVELOPMENT PIPELINE. THEY ARE PART OF MAYBE THEY WON'T HAVE COMPLETED A PHASE II IN 2017, BUT MAYBE THEY'LL COMPLETE IT IN 2018 OR 2019. AND, YOU KNOW, DR. PIZZO MENTIONED IT. DEVELOPMENT DOESN'T STOP. PEOPLE'S DESIRE TO HAVE BETTER THERAPIES, TO HAVE INNOVATIVE THERAPIES THAT CAN REALLY MAKE A DIFFERENCE DOESN'T STOP. WE ARE NOT GOING TO HAVE CURED ALL DISEASE IN FIVE YEARS. AND SO THIS IS OUR WAY TO KEEP GOING, AND THIS IS WHAT THAT OTHER PART OF THE GOAL, THAT WE ARE STILL -- WE ARE FUNDING THINGS, WE ARE PUTTING THINGS IN THE CLINIC, WE ARE MOVING THEM THROUGH.

SO WE HAVE $1.48 BILLION LEFT. CURRENTLY 649 MILLION OF THAT HAS BEEN APPROVED IN CONCEPT BY THIS BOARD. 836 MILLION IS AVAILABLE FOR FUTURE PROGRAMS. AMONG THOSE CONCEPT APPROVED PROGRAMS

WITH NEAR-TERM POTENTIAL TO CONTRIBUTE TO THE CLINICAL STRATEGIC OBJECTIVE ARE THE DISEASE TEAM THERAPY DEVELOPMENT, WHICH THIS BOARD HAS ALREADY APPROVED PLANNING AWARDS FOR, WHICH WE WILL BE REVIEWING IN APRIL, I BELIEVE, AND WHICH WILL COME TO THIS BOARD IN JUNE, I BELIEVE.

THE STRATEGIC PARTNERSHIP PROGRAM, WHICH, AS YOU WILL RECALL, THIS BOARD HAS APPROVED $30 MILLION OF THIS. THIS IS THE IDEA OF REALLY GETTING TOGETHER WITH PARTNERS WHO CAN HELP MOVE PROGRAMS FORWARD. APPROVED PROJECTS IN BOTH PROGRAMS WILL BE BROUGHT TO THIS BOARD ACTUALLY IN EITHER THIS FISCAL YEAR OR EARLY NEXT FISCAL YEAR, BUT FUNDING WILL CERTAINLY START IN FISCAL YEAR 12 AND 13.

JUST TO MAKE THE POINT THAT I DID, THAT JUST BECAUSE OF THE NATURE OF THE COST OF DEVELOPMENT PROJECTS, AND EVEN WHEN WE ASK FOR CO-FUNDING, STILL YOU WILL RECALL THE TARGETED CLINICAL DEVELOPMENT PROGRAM WITH GERON THAT UNFORTUNATELY IS NO LODGER THERE, BUT NONETHELESS, WE PUT FORTH 20 MILLION IN THAT PROGRAM AND THEY HAD 20 MILLION. THERE WAS A MATCH THERE. SO TO GET THROUGH A PHASE I TRIAL IN THAT CASE, WE WERE TALKING ABOUT $40 MILLION.

SO WE ARE GOING TO BE PUTTING UP THE

CONCEPT APPROVED PROGRAMS, AND THIS IS ALL THE DOLLARS ALLOCATED BY THE BOARD, AND JUST TO THE CATEGORIES AS DEFINED, IS THAT THIS IS WHAT THE DISTRIBUTION LOOKS LIKE.

LET'S TALK A LITTLE BIT ABOUT THE FUTURE FUNDING. SO I HAVE MADE SOME ASSUMPTIONS, AND I WOULD JUST PUT THEM FORTH. AND AGAIN, THE ASSUMPTIONS PUT FORTH HERE ARE BASICALLY IN THE CONTEXT OF WHAT IS ONE WAY OR WHAT IS A WAY OF ACHIEVING THOSE FIVE-YEAR GOALS, THE SCIENTIFIC, THE CLINICAL. AND THE ASSUMPTIONS ARE IN DEVELOPMENT RESEARCH, IT WILL BE A CONTINUED FOCUS OF FUNDING. THERE WILL BE NEW DISEASE TEAM, NEW STRATEGIC PARTNERSHIP PROGRAMS. THE FUNDING IS VERY MUCH FRONT-LOADED AT THE MOMENT, BUT IT ACTUALLY -- YOU KNOW, WE NEED TO CONSIDER, AND WE'RE OFFERING THROUGH OUR STRATEGIC PARTNERSHIP PROGRAM IS THAT WE'RE OFFERING PEOPLE TO COME IN TWICE A YEAR WHEN THEY'RE READY. HOPEFULLY WE COULD BE READY TO REVIEW THEM. WE ALSO HAVE THE ALPHA CLINICS. SO ALAN'S TALKED ABOUT THAT.

IN ORDER TO TALK ABOUT SOME OF THESE TRANSFORMATIONAL DISCOVERIES, REALLY MAKING A DIFFERENCE, WE THINK IT'S IMPORTANT TO FUND BASIC RESEARCH. YOU HAVE TO KEEP FUNDING THE NEW

DISCOVERIES THAT WILL DRIVE THE FUTURE THERAPEUTICS. THE TRANSLATIONAL RESEARCH WHERE YOU MAKE THE -- WHERE YOU SAY MY MECHANISM HYPOTHESIS REALLY COULD HAVE AN IMPACT ON DISEASE. SO WE INTEND -- WE BELIEVE THAT IT'S IMPORTANT TO KEEP FUNDING SOME OF THESE CORE PROGRAMS.

I'LL JUST TALK TO YOU A LITTLE BIT ABOUT THE SCENARIOS. SO THE COMMON ASSUMPTIONS THAT I LAID OUT FOR YOU THERE WERE VERY MUCH TRUE FOR ALL THESE SCENARIOS. AND WHEN I SAY FUNDING COMMITMENT, LET ME BE CLEAR WHAT THIS IS GRAPHING. THIS DOESN'T MEAN ALL THAT MONEY IS GOING OUT THAT YEAR. THAT MEANS THE BOARD HAS APPROVED IT AND NOTICE OF GRANT OR LOAN AWARDS HAVE BEEN SIGNED. THE CONTRACT BETWEEN THE AGENCY AND THE GRANTEE TO INITIATE THE FUNDING, MOST OF IT HAS HAPPENED IN THAT TIME PERIOD. SO IT IS A COMMITMENT OF THIS BOARD AND THE AGENCY TO FUND.

SO I JUST PUT FORTH FOR YOUR CONSIDERATION, AND THESE SCENARIOS REALLY DIFFER ONLY IN THE OUTER YEARS, WHICH IS A POINT I WANT TO MAKE AS WELL. AND THE DIFFERENCES BETWEEN THE TWO IS HOW MUCH MORE MONEY WE PUT IN TRAINING CAREER DEVELOPMENT OR IN SHARED LABS OR PUT IN YOUR FAVORITE THING. PUT MORE IN BIOLOGY INSTEAD OF

THAT. BUT THOSE KINDS OF DECISIONS, IF YOU ACCEPT THE PREMISE THAT IT IS IMPORTANT TO FUND DEVELOPMENT AND IT IS IMPORTANT TO FUND IT TO THE EXTENT TO WHICH I'VE OUTLINED IN ORDER TO GIVE US A REASONABLE ASSURANCE OF ACHIEVING THAT GOAL, IF YOU ACCEPT THAT PREMISE, THEN WE CAN TALK ABOUT WHAT WE MIGHT DO TWO YEARS DOWN THE ROAD AS FAR AS OTHER PROGRAMS FUNDED BECAUSE WHAT YOU ARE LOOKING AT IS A SNAPSHOT IN TIME. YOU ARE LOOKING AT WHAT THIS BOARD HAS COMMITTED IN CONCEPT, BUT NOT YET WHAT YOU HAVE AWARDED. YOU ARE LOOKING AT A FUTURE SCENARIO THAT I WANT YOU TO CONSIDER BECAUSE IF YOU BUY INTO THE STRATEGY, THERE ARE IMPLICATIONS OF THAT STRATEGY.

SO I JUST SHOW YOU HERE SCENARIO ONE. I SHOW YOU HOW THAT AS WE MOVE FORWARD, AS WE LOOK AT HOW WE SPENT OUR MONEY TO DATE, THE DISTRIBUTION OF THE CONCEPT APPROVED FUNDS, ALL THAT YOU HAVE APPROVED, AND THE DISTRIBUTION OF THE FUTURE FUNDING, WHAT IT MIGHT LOOK LIKE.

THE IMPLICATIONS OF THE COMBINED, IF WE AWARD ALL THE CONCEPT APPROVED, ALL THE $649 MILLION AS INDICATED, ALL THE $836 MILLION AS SUGGESTED, WE HAVE THE POTENTIAL FOR AN ADDITIONAL 25, AND I PUT IT NEW IN PARENTHESES BECAUSE IT COULD BE A CONTINUATION, THE NEXT STAGE OF A DISEASE TEAM

PROJECT, FOR EXAMPLE. THEN BY THE END OF FISCAL YEAR 13-14, SO THAT'S SORT OF THE MIDDLE -- TWO YEARS FROM JUNE THIS YEAR. OKAY -- WE WILL HAVE 16 PROGRAMS, ROUGHLY 16 ADDITIONAL PROJECTS IN OUR PORTFOLIO, DEVELOPMENT PROJECTS. LET ME MAKE THE POINT, DEVELOPMENT PROJECTS IN OUR PORTFOLIO DERIVED FROM CONCEPT APPROVED FUNDS. WE WILL HAVE ROUGHLY NINE ADDITIONAL DEVELOPMENT PROJECTS FROM EITHER STRATEGIC -- IT WOULD HAVE TO BE FROM STRATEGIC PARTNERSHIP-TYPE PROGRAMS IN FUTURE SCENARIOS. AND, AGAIN, I SAID SOME OF THESE COULD COME FROM DISEASE TEAM I FOLLOW-ON MOVING TO THE NEXT STAGE. THEY FILED THEIR IND. WE THINK THEY'RE GOOD INVESTMENTS. WE WANT TO REALIZE THE POTENTIAL OF OUR INVESTMENT, SO WE WOULD CONSIDER FUNDING THEM FOR A PHASE I TRIAL.

I WOULD ARGUE THAT OUR TARGET HAS TO BE MORE THAN FIVE STEM OR PROGENITOR CELL-DERIVED CELL THERAPIES IN PHASE I OR II, AGAIN, BECAUSE OF THAT FIVE-YEAR STRATEGIC GOAL, BECAUSE OF THE PROBABILITIES OF TECHNICAL SUCCESS. AND SO THAT'S WHAT I WOULD SUGGEST. UNFORTUNATELY, SINCE IT'S ALWAYS A BINARY THING, SOMETHING EITHER WORKS OR IT DOESN'T, BUT AT LEAST IF YOU GO BY THAT, I WOULD ARGUE WE NEED AT LEAST FIVE.

THE ASSUMPTIONS, AND I'VE MENTIONED THIS BEFORE, THE ASSUMPTIONS UNDERLYING THIS ARE THAT THERE ARE AN ADEQUATE POOL OF STRONG PROJECTS AT THIS STAGE OF DEVELOPMENT IN CALIFORNIA, THAT THEY WILL SUBMIT APPLICATIONS TO US, AND THEY WILL BE FUNDED BY US. I WOULD ALSO POINT OUT THAT CERTAINLY IN THE STRATEGIC PARTNERSHIP, WE ARE REQUIRING CO-FUNDING, WHETHER IT COMES FROM AN ACTUAL PARTNER, WHETHER IT COMES FROM -- CO-FUNDING WILL MAKE AN IMPACT, BUT I DON'T THINK THAT WE WILL STILL HAVE TO INVEST THE DOLLARS.

AND THEN I'LL JUST MAKE A POINT. AS FAR AS THE OPERATIONAL IMPACT, WE AS AN ORGANIZATION ARE REALLY WORKING TO MAKE SURE THAT WE CAN HANDLE THIS KIND OF REVIEW TWICE A YEAR OF DEVELOPMENT-TYPE PROGRAMS, THE STAFF TO ACTUALLY WORK WITH THESE VERY ACTIVELY MANAGED PROGRAMS. SO I JUST POINT OUT FOR YOU HERE, AGAIN, THIS IS JUST THE ONE SCENARIO, BUT AGAIN THE SCENARIO DIFFERENCES ARE VERY MUCH HERE IN THE OUTER YEARS. SO IT JUST LOOKS, YOU CAN SEE SORT OF HOW OUR FUNDING IS SHIFTING OVER TIME IN TERMS OF TYPE OF CATEGORIES WE'RE FUNDING. BUT, AGAIN, I THINK WE ACKNOWLEDGE THAT IT'S IMPORTANT TO CONTINUE FUNDING THE BASIC RESEARCH, THE TRANSLATIONAL RESEARCH THAT LEADS TO THE DEVELOPMENT PROGRAMS, AND

THEN THE DEVELOPMENT PROGRAMS THAT ACTUALLY CAN BRING THERAPIES TO PATIENTS.

THIS BASICALLY JUST GIVES YOU A TABLE AND SUMMARIZES WHAT IT LOOKS LIKE. AND I WOULD ARGUE THAT AT LEAST THIS IS ONE WAY, YOU KNOW, IT'S THE OUTLINE OF A STRATEGY THAT I DO THINK ALLOWS US TO DO WHAT WE ALL WANT TO DO, TO ACHIEVE THE CLINICAL PROOF OF CONCEPT FOR STEM CELL THERAPIES, TO ACHIEVE TRANSFORMATIVE RESEARCH DISCOVERIES BY WAY OF CO-FUNDING, BY LEVERAGE TO MULTIPLY CIRM'S INVESTMENT IN CALIFORNIA, AND TO CONTINUE TO GROW THE RECOGNITION OF CALIFORNIA AS THE STEM CELL STATE, AND THEN BASICALLY TO REALLY FURTHER OUR MISSION. SO I'M HAPPY TO ENTERTAIN ANY QUESTIONS. THANK YOU.

CHAIRMAN THOMAS: COMMENTS? MR. SHEEHY.

MR. SHEEHY: SO I JUST -- I'M TRYING TO WORK MY HEAD THROUGH THIS BECAUSE IT'S A LOT OF NUMBERS. THE RFA'S, IT'S HARD TO PUT ON A TIMELINE. BUT I GUESS, NO. 1, JUST LOOKING AT THESE SCENARIOS, I PERSONALLY THINK NOT EXTENDING BRIDGES OR TRAINING OR SHARED LABS, THOSE ARE KIND OF CORE INFRASTRUCTURE THAT DON'T COST US RELATIVELY THAT MUCH MONEY, THAT WE SHOULD EXTEND FOR THE, YOU KNOW, FOR THE FORESEEABLE FUTURE. I THINK THAT'S

IMPORTANT.

DR. OLSON: YOU DON'T EVEN NEED TO MAKE THAT DECISION FOR ANOTHER TWO YEARS.

MR. SHEEHY: THE SECOND THING IS, FOR INSTANCE, THIS PLAN SUGGESTS TWO MORE DISEASE TEAM ROUNDS. WHEN WE DO A DISEASE TEAM, IT'S ABOUT THREE YEARS BETWEEN DISEASE TEAM ROUNDS. SO THE NEXT ONE -- THIS ONE WE'RE GOING TO BASICALLY START FUNDING IN 2013, I'M GOING TO GUESS.

DR. OLSON: CURRENT ONE WE WOULD START FUNDING THIS YEAR.

MR. SHEEHY: IT TAKES FOUR TO SIX MONTHS. YOU GUYS MIGHT HAVE IT DOWN. WE'RE GOING TO APPROVE THE FUNDING IN JUNE. MAYBE BY THE END OF THE YEAR. I DON'T KNOW. YOU HAVE A LOT OF WORK. I KNOW HOW MUCH WORK.

DR. OLSON: FUNDED BY THE END OF THE YEAR.

MR. SHEEHY: I THINK THE WORK THAT YOU DO IN TERMS OF SETTING MILESTONES AND THE WORK YOU DO WITH THE TEAMS IS VERY IMPORTANT WORK. I'M RECOGNIZING THAT THAT IS NOT GOING TO -- WE DON'T GIVE THE MONEY AND THEN YOU --

DR. OLSON: THIS IS WHY THE TIMING I PUT IN IS ACTUALLY ONE OR TWO QUARTERS DELAYED FROM WHEN I EXPECT THE BOARD TO APPROVE, SO I DO ALLOW FOR

THAT.

MR. SHEEHY: SO ROUGHLY BEGINNING LATE 2012, BEGINNING 2013 THE SECOND DISEASE TEAM GOES IN. YOU GO THREE YEARS OUT --

DR. OLSON: NO. WE WOULD PUT IN THE NEW DISEASE TEAM AT THE END OF THIS YEAR.

MR. SHEEHY: END OF 2012.

DR. OLSON: AND IT WOULD ONLY BE ONE MORE DISEASE TEAM THAT COULD POSSIBLY IMPACT ON THAT FIVE-YEAR GOAL.

MR. SHEEHY: I'M JUST TRYING TO GET -- I'M LOOKING AT THIS, AND MAYBE THIS IS WHY I'M NOT GETTING THE NUMBERS WHEN YOU TALK ABOUT SCENARIO ONE VERSUS SCENARIO TWO. BOTH SCENARIOS HAVE TWO MORE DISEASE TEAM ROUNDS, AND I DON'T THINK, UNLESS WE GET REFUNDED, IT WILL MAKE SENSE. I'M ALSO WORKING OFF MR. PLUNKETT'S NICE BUDGET PROJECTIONS, WHICH ACTUALLY SHOW US STARTING TO GO DOWN. SO IF YOU DO THREE MORE YEARS, YOU'RE IN 2015 TO DO THE NEXT DISEASE TEAM, IF WE DID DISEASE TEAM III, AND THEN IN 2018 WE START -- 2017, 2018 WE ACTUALLY START REDUCING.

DR. OLSON: THIS IS CASH FLOW.

MR. SHEEHY: BUT I ALSO THINK THAT IF WE DON'T GET REFUNDED -- IN OTHER WORDS, PART OF IT IS

WHAT WE CAN ACCOMPLISH BETWEEN NOW AND, SAY, ABOUT 2016, 2017, RECOGNIZING THAT IF WE DON'T GET A SIGNIFICANT SOURCE OF NEW FUNDING, THAT WE'RE REALLY GOING TO START GOING THE OTHER DIRECTION. AND SO LIKE TWO MORE DISEASE TEAMS, I DON'T SEE HOW THAT FITS IN THE SCENARIO BECAUSE WE PROBABLY WON'T HAVE THE STAFF TO MANAGE A DISEASE TEAM AFTER 2017 IF WE DON'T HAVE -- YOU ARE GOING TO HAVE TO BUILD OUT JUST TO MANAGE THE 25 ADDITIONAL PROGRAMS.

THIS IS SAID WITH GREAT RESPECT FOR THE AMOUNT OF WORK THAT'S GONE INTO MANAGING THE DEVELOPMENT PROGRAMS WE HAVE ALREADY, WHICH WE'RE GOING TO HAVE TO BUILD OUT AS WE BUILD OUT, BUT THEN THIS IS GOING TO START TO GO THE OTHER DIRECTION IF WE DON'T GET REFUNDED.

I GUESS I'M JUST TRYING TO -- FIRST OF ALL, I'M NOT SURE WHAT YOU'RE ASKING US TO DO. BUT FOR ME I WOULDN'T NECESSARILY START PROJECTING THAT WE'RE NOT GOING TO DO BRIDGES AND SHARED LABS AND TRAINING.

DR. OLSON: NO. NO. NO. I WASN'T ASKING THAT.

MR. SHEEHY: BUT FOR DEVELOPMENTAL WORK THAT WE PROBABLY WON'T BE ABLE TO FUND AND MANAGE IF WE DON'T GET REFUNDED. THAT'S KIND OF WHERE, WHEN

I'M LOOKING AT THESE SCENARIOS, I'M TRYING TO GET A SENSE AND ALSO TRYING TO HAVE A SENSE OF WHERE THE RFA'S ARE GOING TO FALL OVER THE NEXT FIVE YEARS. I FEEL LIKE THERE'S A SCHEDULE EMBEDDED IN HERE, BUT I CAN'T REALLY SEE IT, AND SCHEDULE PLUS WHAT TYPE OF MONEY WE'RE GOING TO BE SPENDING, MAYBE HOW MANY PROJECTS WE'RE GOING TO BE MANAGING, WHAT KIND OF STAFFING THAT WILL TAKE, THERE SEEMS A LOT OF DIFFERENT MOVING PARTS HERE AND THAT I CAN'T REALLY SEE THEM ALTOGETHER MYSELF YET.

THAT'S WHAT I KIND -- WOULD BE REALLY HELPFUL FOR ME BECAUSE I THINK THE GOALS ARE LAUDABLE, I THINK THEY'RE ACHIEVABLE, AND I THINK THE RFA'S ARE HOW WE'RE GOING TO ACHIEVE THOSE GOALS. BUT IT WOULD BE GREAT TO HAVE THAT, BUT I DO THINK THAT SOME OF THESE UNDERLYING INFRASTRUCTURE ONES ARE CRITICAL AND THAT MAYBE SOME OF THOSE SHOULD EVEN SUNSET US IF THAT'S WHERE -- TRAINING AND SHARED LABS AND BRIDGES MIGHT BE SOME OF THE STUFF THAT DON'T REQUIRE A LOT OF STAFF TIME TO MANAGE THAT WE MIGHT CONTINUE ON THROUGH 2020 IF WE DON'T HAVE ADDITIONAL FUNDING THAT COMES IN.

I'M ASSUMING VOTERS WOULD BE WITH US, WE'LL HAVE SOMETHING TO SHOW. I JUST THINK WE NEED TO BE VERY PRACTICAL ABOUT THESE SCENARIOS. WE HAVE

A SCENARIO THAT BASICALLY CUTS THAT OFF WHILE WE'RE TALKING ABOUT DEVELOPMENTAL PROGRAMS THAT WE WOULDN'T BE ABLE TO STAFF AND MANAGE IF WE GOT TO BEING ABLE TO DO THEM. SIX YEARS FROM NOW, WHICH IS WHERE WE WOULD BE, WOULD BE -- FUND DISEASE TEAM II. DISEASE TEAM IV, I DON'T KNOW WHY WE WOULD BE SETTING ASIDE MONEY FOR THAT. AM I MAKING SENSE? I'M NOT VERY ARTICULATE.

DR. TROUNSON: JEFF, IT WAS SET ON THE KIND OF PROGRAM THEY'VE BEEN WORKING OFF BEFORE. SO WE DIDN'T WANT TO SORT OF ALTER IT TOO MUCH. IT'S LESS THAN THREE YEARS, BUT WE WOULD HAVE JUST GOT IT IN. AND SO WE DIDN'T SORT OF MESS WITH ANY OF THAT TOO MUCH. BUT WHAT YOU'RE RIGHT IS WE NEED TO COMPOSE IT WITH THE OUTCOMES IN MIND. I THINK THAT'S REALLY WHAT PAT'S TRYING TO GET TO US. THERE'S SOME SERIES OF OUTCOMES THAT'S IMPORTANT TO ACHIEVE. AND I THINK THE MOST IMPORTANT FIGURE THERE IS CURRENTLY THERE'S ONLY ABOUT 800 ODD MILLION TO ALLOCATE GIVEN THAT WE'VE ALREADY MADE ALLOCATIONS AND SO FORTH FOR THE REMAINDER.

SO IT BECOMES A VERY IMPORTANT TOUCHPOINT, I THINK, FROM NOW ON TO CONSIDER WHAT WE SHOULD DO. YES, ONE MORE DISEASE TEAM, OR SHOULD WE BUILD PERHAPS MORE THE COMPANY PROJECTS, SOME MORE OF

THOSE. WE HAVE THEM ON THE SORT OF SIX-MONTH BASIS. WHAT DO WE DO WITH THOSE? WE'RE GOING TO GET GOOD INPUTS FROM THOSE. THERE'S A FEW THINGS TO CONSIDER IN THE MIX, BUT I DON'T THINK WE'RE HOLDING ANYTHING HARD AND FAST HERE, BUT TRYING TO SORT OF LOOK AT WHAT WE'VE BEEN DOING AND THEN SAY, WELL, THERE'S EFFECTIVELY 800 MILLION LEFT TO ALLOCATE, GIVEN THAT WE MIGHT GET SOME BACK FROM DISEASE TEAMS THAT DON'T WORK, BUT WE HADN'T SORT OF FIGURED HOW MUCH THAT WOULD BE, BUT IT'S NOT GOING TO GET US OVER A BILLION DOLLARS, I DON'T THINK.

AND THE NEED -- HOPEFULLY I SEE THE NEED TO BUILD SOME PARTNERSHIPS HERE WHERE INDUSTRY CAN SAVE US SOME MONEY ON THOSE EXPENSIVE STUDIES, SO THEY MAKE A CONTRIBUTION AS WELL AS US AND SAVE US SOME --

MR. SHEEHY: NIH, FOR THAT MATTER.

DR. TROUNSON: NIH, BUT ALSO INDUSTRY, I THINK, WILL COME IN AT LEAST THROUGH THE STRATEGIC FUNDING GROUP AND START TO HELP US IN THIS. SO IT IS AN IMPORTANT TIME, I THINK, IF YOU THINK THAT WE'VE GOT $800 MILLION, AND THAT'S AN IMPORTANT FIGURE IN MY MIND, I THINK IN MOST PEOPLE'S MIND. ALMOST YOU THINK THAT WE HAVE 1.5 BILLION, BUT A LOT OF THAT HAS ALREADY BEEN ALLOCATED. WE MAY NOT

SPEND IT ALL, BUT IT'S BEEN ALLOCATED THUS FAR.

MR. SHEEHY: YOU KNOW, I'M ALMOST -- AGAIN, THIS GOES BACK TO THE ARGUMENT OF HOW BIG THIS DISEASE TEAM ROUND. I ALMOST FEEL LIKE THAT THIS IS REALLY THE LAST DISEASE TEAM ROUND, THE ONE THAT WE'RE DOING, THAT WILL BE ABLE TO HAVE A SIGNIFICANT IMPACT, YOU KNOW, ON WHAT WE'RE TRYING TO ACHIEVE. NOT THAT I THINK WE CAN'T AND WON'T DO ANOTHER, BUT LET'S FACE IT, THE NEXT ONE AFTER THIS IS GOING TO BE 2014, 2015 AT THE EARLIEST THAT THEY WOULD START. THOSE PROGRAMS CANNOT --

DR. TROUNSON: THEY CAN'T GET TO PROOF OF CONCEPT IN THAT TIME, MOST UNLIKELY.

MR. ROTH: SO, PAT, CAN YOU GO BACK TO SEVERAL SLIDES TO YOUR PIE CHART THAT SHOWS WHERE WE'VE BEEN? THIS ONE. SO WHEN I THINK ABOUT WHAT PAT IS DOING -- AND THANK YOU. THIS IS A CONTINUATION OF THE LAST MEETING WHEN WE HAD A VERY SIMPLE CHART. NOW WE HAVE A LOT MORE NUANCE AND DATA TO LOOK AT. BUT THIS CHART TO ME SAYS IT'S DIRECTIONALLY ALIGNED WITH WHAT WE JUST TALKED ABOUT IN THE STRATEGIC PLAN AND WE TALKED ABOUT IN THIS BOARD MANY TIMES, THAT NOW IS THE TIME THAT WE START TO MOVE TO THE TRANSLATIONAL, THE CLINICAL, CLOSER TO THE PATIENTS WHO ACTUALLY -- AND THAT'S ALL THIS

SAYS. HOW WE GO ABOUT ALLOCATING THE MONEY WILL REALLY DEPEND ON WHETHER THE ASSUMPTIONS MATERIALIZE OR NOT AND WHAT WE THINK THE PRIORITIES ARE TO GIVE THEM TIME.

THIS SETS A NICE DIRECTION, FOR ME ANYWAY, THAT SAYS I SEE THE SHIFT FROM A LOT OF RED TO MORE AND MORE OF THE GOLD COLOR, WHICH SAYS THAT WE'RE MOVING IN THE RIGHT DIRECTION. AND I THINK WE CAN GO THROUGH THIS, AS WE HAVE, THE CONCEPT APPROVALS, AND MAKE SURE WE ARE DOING EXACTLY AND RESPONDING EXACTLY AS WE SHOULD TO THAT.

DR. FEIGAL: I WAS JUST GOING TO COMMENT, YOU KNOW, EACH TIME WE DO THE DISEASE TEAMS, WE REFINE IT. SO, FOR EXAMPLE, DISEASE TEAM II IS MORE MATURE -- HERE I CAN USE THE WORD "MATURE" -- LEVEL OF DEVELOPMENT OF THE PROGRAM. AND FOR DISEASE TEAM III, WE MAY CONTINUE TO REFINE IT. SO IT'S NOT NECESSARILY IDENTICAL TO WHAT DISEASE TEAM I LOOKED LIKE SO THAT THERE ACTUALLY MIGHT BE THE POSSIBILITY WITH THE SUBSEQUENT SOLICITATION THAT WE'RE BRINGING IN MORE MATURE PROJECTS THAT COULD HAVE A CHANCE OF REACHING. SO WE ARE TRYING TO FOCUS ON SOME ADVANCEMENT ALONG THE WAY, NOT KEEPING THINGS STATIC.

MR. SHEEHY: THAT'S HELPFUL. THAT'S A

GOOD POINT. I HAD FORGOTTEN THAT ABOUT DISEASE TEAM II. IT'S CLEARLY FURTHER ADVANCED.

CHAIRMAN THOMAS: MR. JUELSGAARD.

DR. JUELSGAARD: I WOULD JUST AGREE WITH DUANE. SO FOR ME THIS PRESENTATION WAS MORE DIRECTIONAL THAN SPECIFIC, AND THIS CONVERSATION SHOULD BE MORE DIRECTIONAL THAN SPECIFIC. I WOULD ONLY POINT OUT THAT FOR ME THE 19 PERCENT OF THE FUNDS COMMITTED ARE GOING TO TRAINING AND DEVELOPMENT, THAT WHAT YOU ARE SUGGESTING IS THAT WE RATCHET THAT WAY BACK TO SOME MUCH SMALLER PERCENTAGE OF THE FUNDS THAT WE HAVE UNCOMMITTED, WHICH I WOULD COMPLETELY AGREE WITH IN FAVOR OF PUTTING THAT MONEY TOWARDS DEVELOPMENT WORK, WHICH IS, I THINK, REALLY WHERE WE OUGHT TO BE PUTTING OUR EFFORT AT THIS POINT.

DR. OLSON: I GUESS I WILL RESPOND TO THAT AS FOLLOWS. CONCEPT APPROVED PROGRAMS ARE PROGRAMS FOR WHICH RFA'S, IF NOT WRITTEN AND POSTED AND IN SOME CASES READY FOR REVIEW, RFA'S ARE GETTING READY TO BE POSTED. WHAT YOU'RE LOOKING AT IN THE GREEN IN THE CONCEPT APPROVED IS ACTUALLY A NEW FACULTY PHYSICIAN SCIENTIST FOR TRAINING. THAT IS THE BULK OF THAT. THAT IS $80 MILLION OF THAT. NOW, AGAIN, HOW MANY APPLICATIONS WE RECEIVE, HOW THE GRANTS

WORKING GROUP VIEWS THEM, AND HOW THE BOARD FUNDS THEM, BUT AT THIS POINT THE SCIENCE OFFICE IS PROCEEDING WITH EVERY CONCEPT APPROVED PROGRAM.

MR. SHEEHY: IN RESPONSE TO MR. JUELSGAARD, I DO THINK THAT I WOULD NOT AGREE WITH YOU, AND I THINK THAT WE SHOULD VOTE ON SOME OF THESE. I'M NOT SAYING THAT YOU'RE WRONG AND I'M RIGHT, BUT I THINK THESE ARE PRECISELY THE DECISIONS WE'RE HERE TO MAKE. I THINK, FOR INSTANCE, BRIDGES AND TRAINING ARE VERY IMPORTANT FOR MAINTAINING A CERTAIN INFRASTRUCTURE. WE BUILT BUILDINGS. SOME OF THIS IS JUST BASIC INFRASTRUCTURE THAT WE NEED TO CONTINUE REGARDLESS. YOU KNOW, IT WOULD BE GREAT TO LIKE CREATE SOME DECISION POINTS ON SOME OF THESE. SO IF I LOSE, THAT'S FINE. IT'S NOT A PERSONAL THING. BUT I DO THINK THAT THERE ARE DECISION POINTS, AND I'M NOT SURE WHERE WE'RE GOING TO COME TO THOSE. AND IF WE DO THE STRATEGIC PLAN AS PROPOSED, HAVE WE ALREADY MADE THE DECISION THAT WE'RE DOING SCENARIO ONE OR --

DR. OLSON: I APPRECIATE THAT. MR. CHAIRMAN, MAY I SPEAK IN RESPONSE TO THAT? I THINK WHAT I REALLY WAS TRYING TO COMMUNICATE HERE, AND FORGIVE ME IF I WAS LESS CLEAR, IS THE POINT THAT MR. ROTH AND MR. JUELSGAARD HAVE MADE, WHICH IS I'M

TRYING TO GET A DIRECTIONAL BUY-IN THAT WE WILL NEED TO SPEND SIGNIFICANT AMOUNTS OF OUR FUNDING GOING FORWARD ON DEVELOPMENT. I HAVE NO BIAS ONE WAY OR THE OTHER TO SCENARIO 1 OR SCENARIO 2 OR SOME VARIANT THEREON, BUT I DO THINK IT IS IMPORTANT FOR THE BOARD TO AT LEAST BUY INTO MINIMALLY THE FACT THAT A SUBSTANTIAL PROPORTION OF OUR FUNDING WILL BE GOING TO DEVELOPMENT. I THINK THAT IS A KEY STRATEGIC DECISION, THAT THAT FUNDING IS COMPATIBLE OR THAT DECISION FOR THAT DIRECTION IS COMPATIBLE WITH OUR STRATEGIC GOALS, WITH THE FIVE-YEAR GOALS, WITH THE KEY OUTCOME, AND THE STRATEGIC OBJECTIVE. AND TO NOT MAKE THAT COMMITMENT, I WOULD ARGUE, YOU WOULD HAVE TO REVISE THE GOALS, OR YOU WOULD HAVE TO CONSIDER THAT, AT LEAST THE CLINICAL GOAL.

CHAIRMAN THOMAS: MR. PLUNKETT, DID YOU HAVE A COMMENT EARLIER THAT WE MISSED?

DR. PLUNKETT: NOT TO JUMP AHEAD A COUPLE OF AGENDA ITEMS, BUT JUST IN TERMS OF THE TIE-IN OF OUR FUTURE FORECASTING OF EXPENSES THROUGH THE NEXT DECADE, WE'VE REALLY MADE AN EXPLICIT ASSUMPTION THAT THE HEAD COUNT OF THE AGENCY STAYS CONSTANT THROUGH AT LEAST A YEAR PAST THE LAST AWARD, AND AT THAT POINT WE START TO FADE DOWN OVER THE NEXT FOUR YEARS. SO THERE REALLY IS SUBSTANTIAL ROOM TO

MAINTAIN EVEN PROGRAMS WHICH WOULD REQUIRE A SIGNIFICANT DEGREE OF MANAGEMENT BY THE CIRM STAFF FOR THAT PERIOD OF TIME.

SO WE'VE LEFT SOME ROOM FOR THAT. AND YOU CAN CERTAINLY ALSO THINK ABOUT CONCEPTS WHERE MAYBE SOME OF THE MORE INVOLVED CLINICAL AWARDS, TO ELLEN'S POINT THAT THEY MIGHT BE LATER STAGED, MIGHT BE A THREE-YEAR DURATION TOWARDS THE END INSTEAD OF A FOUR-YEAR, FOR EXAMPLE.

CHAIRMAN THOMAS: THANK YOU. DR. LEVIN.

DR. LEVIN: SO I UNDERSTAND THE MARCH TOWARDS TRANSLATION IS PART OF OUR MISSION AND STRUCTURE OF CIRM, AND I'M FULLY AWARE OF THE SIGNIFICANT INCREASE IN COST FOR THE DISCOVERY PROJECTS AND THOSE THAT ARE ACTUALLY GETTING INTO TOWARDS CLINICAL TRIAL. BUT I STILL HAVE TO SAY THAT I'M NOT AT ALL COMFORTABLE WITH HAVING A SCENARIO ON THE BOOKS, MUCH LESS SCENARIO 1, THAT COMPLETELY ZEROS OUT ALL FUNDING FOR INFRASTRUCTURE FOR BASIC RESEARCH AND FOR TRAINING BECAUSE I THINK THAT THOSE ARE CORE ASPECTS OF WHAT CIRM HAS ALWAYS DONE AND WHAT CIRM SHOULD DO.

BASICALLY THERE'S TWO POTENTIAL SCENARIOS. ONE IS THAT CIRM WILL GO ON, AND THE OTHER IS THAT IT WILL SUNSET ITSELF AT SOME POINT IN THE FUTURE,

2017 OR WHAT HAVE YOU. AND IN EITHER SCENARIO, IF WE GO ON, THEN WE ARE GOING TO WANT TO HAVE THIS PIPELINE OF BASIC RESEARCH DISCOVERIES AND NEW BLOOD BROUGHT INTO THE FIELD AND EDUCATED. THAT'S GOING TO BE A CRITICAL COMPONENT OF OUR PORTFOLIO. AND IF NOT, THEN WHAT'S THE IMPACT IS GOING TO BE MAYBE FIVE, MAYBE NINE, MAYBE TEN DISEASE TEAMS, ONE OR TWO OF WHICH, WHEREVER THEY'VE GONE, THEY'VE HAD A THERAPEUTIC CANDIDATE THAT'S GONE ALL THE WAY TO BEING IN PRACTICE. BUT THE REAL IMPACT IS ON ALL THE PEOPLE BROUGHT INTO THE FIELD AND ALL THE GREAT DISCOVERIES THAT THEN WILL BE TAKEN UP BY OTHER MECHANISMS. AND IF WE SHUT THOSE PROGRAMS OR CONSIDER SHUTTING THOSE PROGRAMS DOWN ENTIRELY, THEN THAT STOPS. THAT'S HALF OF THE GOOD WORK THAT'S BEEN DONE.

CHAIRMAN THOMAS: BEFORE I GO TO DR. OLSON, JUST NOTE IF WE DO NOT HAVE ADDITIONAL FUNDING, WE WOULD SUNSET IN 2021 WOULD BE THE TIME OF THE LAST AWARD.

DR. OLSON: I'M HAPPY -- AS I SAY, I HAVE NO BIAS AS TO WHICH SCENARIO. I'M HAPPY TO PUT THAT ONE BECAUSE I, IN FACT, AGREE WITH YOU THAT A LOT OF WHAT WE'VE DONE, OVER 500 PEOPLE THAT JUST THROUGH TRAINING II THAT WE'VE TRAINED ARE AMBASSADORS,

THEY'RE STEM CELL AMBASSADORS. SO I'M HAPPY TO USE THAT AS THE SCENARIO WE INCLUDE AS SORT OF -- IT REALLY -- THAT'S FINE BECAUSE IT JUST CUTS DOWN TO SOME --

DR. LEVIN: I WOULD JUST BE MUCH HAPPIER IF THAT WERE SCENARIO 1 AND THIS WERE SCENARIO 2, JUST ASSUMING THAT THERE WOULD BE SOME BECAUSE FOR THE COST OF A SINGLE DISEASE TEAM, YOU CAN PRESERVE THE ENTIRE PROGRAM OF BASIC BIOLOGY FOR ANOTHER THREE YEARS OR AN ENTIRE PROGRAM OF THE TRAINING GRANTS OR SHARED RESEARCH LABS.

DR. OLSON: TRAINING GRANTS IS A $48 MILLION PROGRAM, SHARED LABS IS A $25 MILLION PROGRAM, AND BRIDGES IS A $22 MILLION PROGRAM. SO WE ARE WORKING.

DR. LEVIN: YOU'RE PROPOSING YOUR SCENARIO 2 TO BE --

DR. OLSON: YEAH. IN MY SCENARIO 2, WHAT DECREASES -- THERE'S DECREASES IN ALL OF THOSE, A LITTLE BIT IN ALL OF THOSE POTS. YES, I'M HAPPY TO USE THAT, SWITCH THEM AROUND IF YOU LIKE. BUT REALLY IS AN EXAMPLE. AGAIN, THE POINT, DO YOU BUY INTO THE NOTION THAT WE NEED TO SPEND A SUBSTANTIAL AMOUNT OF DOLLARS ON DEVELOPMENT? NOT TO SAY THAT WE'LL HAVE THE PROJECTS, BUT IN PRINCIPLE.

CHAIRMAN THOMAS: WE HAVE DR. STEWARD, DR. MELMED, MR. SHEEHY.

DR. STEWARD: JUST LOOKING FORWARD, I THINK LOOKING AT THESE KINDS OF THINGS IS VERY HELPFUL. AND I ACTUALLY THINK IT'S HELPFUL ON A ROLLING BASIS.

DR. OLSON: I AGREE.

DR. STEWARD: ONE OF THE THINGS THAT I'D LOVE TO SEE EACH TIME WE CONSIDER IMPROVING A ROUND OF FUNDING IS THIS CHART UPDATED. SO THIS IS WHAT WE'VE SPENT. THIS IS WHAT WE'VE COMMITTED. AND THEN ACTUALLY AFTER WE VOTE, IF YOU COULD EVEN JUST ADJUST IT A LITTLE BIT, BUT WE DON'T ALWAYS ACTUALLY SPEND EVERYTHING THAT'S ALLOCATED. JUST REMIND US ROLLING FORWARD WHAT IT ACTUALLY MEANS. I THINK THE MOST IMPORTANT POINT YOU MAKE HERE, AND IT'S REALLY AN IMPORTANT POINT, IS THAT THERE'S A LIMITED AMOUNT OF MONEY THAT IS LEFT TO SPEND AT THIS POINT. AND EACH OF THE DECISIONS WE MAKE GOING FORWARD, EACH TIME WE SAY, WELL, LET'S RAISE THIS GRANT UP, WE CAN AFFORD THIS, MAYBE WE CAN'T. IT'S JUST REALLY IMPORTANT TO KIND OF THINK ABOUT THAT EACH AND EVERY TIME WE VOTE FOR A NEW ROUND OF FUNDING.

CHAIRMAN THOMAS: DR. OLSON IN RESPONSE, THEN DR. MELMED.

DR. OLSON: THANK YOU FOR REITERATING THAT POINT. I DO WANT TO EMPHASIZE YOU ARE REALLY LOOKING AT A SNAPSHOT IN TIME. ALL THE CONCEPT APPROVED PROGRAMS MAY NOT BE FUNDED TO THE EXTENT APPROVED. ACTUALLY ALL THE CURRENTLY FUNDED PROGRAMS MAY NOT UTILIZE ALL THEIR MONEY, MAY NOT ALL CONTINUE. SO IT REALLY IS A SNAPSHOT IN TIME.

CHAIRMAN THOMAS: I THINK WE HAVE DR. TROUNSON IN RESPONSE ALSO BEFORE WE GET TO DR. MELMED.

DR. TROUNSON: SO, CHAIR, YOU AND I HAVE BEEN TALKING ABOUT THE OPPORTUNITY TO CO-FUND SOME OF THE TRAINING AREAS. AND I THINK THAT MIGHT BE A VERY IMPORTANT STRATEGY TO REALLY TAKE ON BOARD BECAUSE OTHERWISE YOU START TO FACE A CLIFF. YOU KNOW, IF YOU CONTINUE THE TRAINING ALL THE WAY TO THE END AND THEN IT DROPS, IT REALLY MAKES IT VERY, VERY DIFFICULT FOR EVERYBODY. SO I JUST WONDERED IF WE OUGHT TO INCLUDE IN OUR THINKING THE OPPORTUNITY TO NOT ONLY CO-FUND SOME OF THE RESEARCH, BUT CO-FUND WHERE APPROPRIATE SOME OF THE TRAINING GRANT PROGRAMS AND BRING IN THE NIH OR BRING IN SOME OTHER ORGANIZATIONS AS PART OF THAT. AND I THINK IT WOULD HELP WITH A MUCH SOFTER LANDING IN DUE COURSE IF WE'RE NOT CONTINUING IN A MAJOR WAY.

CHAIRMAN THOMAS: GOOD SUGGESTION, DR. TROUNSON.

DR. MELMED: I ECHO WHAT DR. LEVIN WAS SAYING. I'D LIKE TO JUST EXTEND THAT. I'M VERY NERVOUS ABOUT LONG-TERM, TOP-DOWN PLANNING. WE DON'T KNOW WHERE THE CLINICAL SCIENCE WILL BE IN TWO, THREE, FOUR, FIVE YEARS TIME, AND WE CAN'T DRIVE THE SCIENCE. THE SCIENCE HAS TO COME BOTTOM UP. AND IF THE CLINICAL TRIALS AREN'T READY, THEY WON'T BE READY. AND AS MUCH AS ALL THE GOODWILL IN THE WORLD THAT WE BELIEVE WE ALL HAVE THAT GOODWILL AND WE ALL WANT IT TO SUCCEED, BUT THESE CLINICAL TRIALS MAY TAKE TEN YEARS, MAY TAKE 20 YEARS. WE HAVE NO IDEA. AND BY INFLEXIBLE TOP-DOWN, LONG-TERM PLANNING, I THINK WE DO OURSELVES A DISSERVICE.

AND IN THE SPIRIT OF WHAT DR. LEVIN WAS SUGGESTING, I WOULD SUGGEST THAT WE BE VERY FLEXIBLE IN OUR LONG-TERM THINKING, AND THAT THIS BE REVISITED EVERY MEETING. WE MAY CHANGE DIRECTION EVERY YEAR FOR THE NEXT FIVE YEARS. AND I WOULD BE VERY RELUCTANT TO COMMIT OURSELVES TO A RIGID PIE GRAPH FOR FIVE YEARS TIME. WE JUST SIMPLY DON'T KNOW WHERE THE REAL QUALITY CLINICAL SCIENCE WILL BE IN FIVE YEARS.

MR. ROTH: IF I COULD JUST RESPOND

QUICKLY. BUT THAT'S PRECISELY IN THE ASSUMPTIONS. THAT'S WHAT LED UP TO THIS. IF THOSE ASSUMPTIONS AREN'T REAL, THEN WE DON'T SPEND THE MONEY THERE. THIS IS DIRECTIONAL.

DR. MELMED: JEFF HAD ASKED FOR SOMETHING ELSE. HE ASKED FOR REDIRECTING.

MR. ROTH: ONE OF THE CHALLENGES WE'RE GOING TO HAVE IS DECIDING BETWEEN THE VARIOUS OPPORTUNITIES WE HAVE. DO WE CONTINUE TO FUND BASIC SCIENCE? DO WE CONTINUE TO FUND ALL THE DEVELOPMENT OF PEOPLE, FACILITIES? OR DO WE FUND THE CLINICAL DEVELOPMENT PROGRAMS THAT WE THINK WILL ADVANCE THE SCIENCE THE MOST? THOSE ARE THE DECISIONS WE AS A BOARD HAVE TO MAKE.

THE CONCERN I HAVE IS THAT WE DON'T WANT TO TELEGRAPH TO ALL THE INSTITUTIONS THIS IS GOING ON INDEFINITELY BECAUSE IT'S NOT NECESSARILY GOING ON INDEFINITELY, AND WE HAVE TO START THINKING ABOUT, AS ALAN JUST SAID, HOW DO YOU SUPPLEMENT THIS STUFF? HOW DO YOU GET PEOPLE TO START THINKING ABOUT CREATIVE WAYS OF BRINGING MORE MONEY TO THE THINGS THAT WE'VE ALREADY SPENT A WHOLE LOT OF MONEY IN AS WE MOVE FORWARD TO THE NEXT.

CHAIRMAN THOMAS: I THINK, DR. MELMED, POINT VERY WELL TAKEN, BUT I DON'T THINK THERE IS

RIGIDITY IN WHAT WE'RE HEARING. WHAT WE'RE HEARING REALLY IS THE BASIC CONCEPT THAT WE WANT TO EMPHASIZE THE DEVELOPMENTAL PHASE MORE, AND THAT WILL BE EVALUATED ON AN ONGOING BASIS PER YOUR COMMENT AND EVERYBODY ELSE'S AS TO WHAT THAT MEANS.

DR. OLSON: DR. MELMED, I APOLOGIZE IF I GAVE YOU THE IMPRESSION THIS IS A TOP-DOWN RIGID. IT ISN'T. IT IS BASED ON A SERIES OF ASSUMPTIONS. THOSE ASSUMPTIONS MAY WELL NOT MATERIALIZE.

AND I WAS -- I POINT OUT A KEY RISK OF THIS AND, IN FACT, OF ACHIEVING THAT FIVE-YEAR CLINICAL GOAL IS THE STAGE OF MATURITY OF THE CLINICAL DEVELOPMENT OF THIS FIELD.

DR. POMEROY: SO GOOD DISCUSSION. THANK YOU. AND YOU ASKED REALLY FOR CONCEPTUAL DIRECTION. SO I'D LIKE TO SAY THAT I REALLY DO LIKE THE IDEA OF MOVING MORE TOWARDS DEVELOPMENT RESEARCH, BUT I AM PERSONALLY UNCOMFORTABLE WITH THE SCENARIO THAT EVEN SUGGESTS THAT WE WOULD CONTEMPLATE STOPPING ALL OF THE TRAINING AT THIS POINT. SO I THINK A MORE HYBRID APPROACH THAT PERHAPS DID TAPER BECAUSE WE WERE ABLE TO IDENTIFY OTHER SOURCES OF FUNDING FOR TRAINING, BUT I DON'T WANT EVEN THE POTENTIAL MESSAGE TO GO OUT THAT SOMEHOW WE'RE NO LONGER SUPPORTIVE OF ENSURING THE NEXT GENERATION OF

RESEARCHERS.

DR. PIZZO: CAN I UNDERSCORE CLAIRE'S COMMENT? I THINK THAT THIS IS A DELICATE BALANCE, AND IT ALLUDES TO THE POINT THAT I MADE EARLIER. I THINK WE'RE ALL SENSITIVE TO BEING RESPONSIBLE CUSTODIANS AND STEWARDS OF THE RESOURCES WE HAVE AND NOT ENGAGING IN FALSE PROMISES. BUT IF WE AT THE SAME TIME BEGIN TO CONVEY THE MESSAGE THAT WE ARE CURTAILING OR ANTICIPATING THAT OUR FUTURE WILL BE ENDING, IT WILL BECOME A SELF-FULFILLED PROPHESY, I FEAR. I THINK WE NEED TO REALLY WORK WITH OUR (TELEPHONE INTERFERENCE).

CHAIRMAN THOMAS: PHIL, CAN YOU HOLD ON ONE SECOND? WE'RE GETTING REAL STATIC. PHIL, ARE YOU ON A SPEAKER? MAYBE YOU COULD PICK UP. THAT MIGHT HELP A BIT.

DR. PIZZO: GEE, IT WAS SUCH A PROFOUND STATEMENT. I'M SORRY THAT YOU ALL MISSED IT. I'M GETTING INTERNAL FEEDBACK. SO IT'S JUST HARD TO SPEAK. BUT WHAT I WAS SAYING OR ATTEMPTING TO SAY WAS THAT I BASICALLY AGREE WITH THE POINT THAT CLAIRE WAS MAKING AND DO VERY STRONGLY BELIEVE THAT WHILE WE WANT TO BE RESPONSIBLE STEWARDS FOR THE RESOURCES THAT WE HAVE AND NOT ENGAGE IN FALSE PROMISES, WE ALSO WANT TO MAKE CLEAR THAT THERE IS

GOING TO BE A NEED TO MAKE THE INVESTMENTS SUCCESSFUL FOR THE FUTURE.

IF WE DON'T DO THAT WELL, I THINK WE'RE GOING TO BE PART OF A SELF-FULFILLED PROPHESY. AND I THINK THIS IS WHERE WORKING WITH THE COMMUNICATION TEAM IN TANDEM WITH STRATEGIC PLANNING AND RESEARCH TEAMS ARE GOING TO BE SO IMPORTANT IN TERMS OF GETTING THIS MESSAGE RIGHT. AND THE MESSAGE TO ME IS NOT RIGHT IF IT SAYS WE ARE CONCLUDING, AND IT WOULDN'T BE RIGHT IF WE SAID WE'RE ABSOLUTELY CONTINUING, BUT IT NEEDS TO BE A SUBTLE BLEND THAT CONVEYS THE IMPORTANCE OF BOTH.

CHAIRMAN THOMAS: THANK YOU. ARE THERE ANY OTHER COMMENTS BY MEMBERS ON THE PHONE? MR. SHESTACK.

MR. SHESTACK: I THINK WHAT DR. PIZZO IS SAYING A LITTLE BIT MORE MAYBE DIPLOMATICALLY THAN I WOULD WAS BEING TOO SELF-CONGRATULATORY. WE WALK THE BALANCE. BEING TOO SELF-CONGRATULATORY IN OUR ASSESSMENT OF HOW MUCH CIRM HAS DONE DOES SORT OF CLOUD THE ISSUE THAT WE'RE NOT MAKING THAT MANY PEOPLE BETTER YET. AND WE STILL HAVE TO DO IT, AND THE NEED WILL BE GREAT. I APPRECIATE EVERYTHING PAT HAS PRESENTED HERE, AND I THINK WHAT SHE POINTS OUT IS THAT IT'S JUST POSSIBLE THAT WE WILL HAVE SOME

VERY TOUGH CHOICES AHEAD OF US. OR WE COULD GET REALLY LUCKY IN ONE OF SEVERAL WAYS OR WE WON'T, BUT IT LOOKS LIKE WE WILL HAVE TOUGH CHOICES.

AND SO AS WE'RE THINKING GOING FORWARD, I WOULD JUST ASK THE BOARD, PARTICULARLY SINCE IT IS FILLED WITH THE DEANS OF THE MAJOR SCHOOLS IN CALIFORNIA, IS HOW CAN WE PUT THE ARM BACK ON YOU? AS AN ADVOCATE, I LOOK AT THIS AND I GO LIKE TAXPAYER MONEY DID AN AMAZING THING FOR THE FACULTIES IN CALIFORNIA, PARTICULARLY THIS ASPECT OF BASIC SCIENCE AND TRAINING WHEN CIRM PUT A LOT OF THE MONEY IN EARLY PURELY ON FAITH WITH NO SENSE -- NO IDEA THAT RESULTS WOULD COME FROM IT, BUT JUST YOU APPLIED, ASKED FOR MONEY TO TRAIN YOUR PEOPLE. SOME OF THEM TURNED OUT GREAT.

SO NOW I WOULD SAY AS A BOARD YOU HAVE TO REALLY LOOK TO YOURSELF AND SAY HOW CAN YOU FIND WAYS TO TAKE THIS BURDEN OFF OF CIRM AND DO IT YOURSELF AND POINT IT OUT SO WE CAN MOVE -- SO WE KNOW THAT THIS MISSION IS BEING ACCOMPLISHED WHILE WE MOVE THE MONEY INTO MORE DEVELOPMENT AND TRANSLATION. WE'VE GOT TIME TO THINK ABOUT IT, BUT I THINK WE SHOULD THINK ABOUT IT HARD.

CHAIRMAN THOMAS: OKAY. THANK YOU. I THINK WE NEED TO MOVE THE AGENDA ALONG HERE. IT'S

BEEN A VERY GOOD, ROBUST DISCUSSION ON THIS. PAT, THANK YOU VERY MUCH FOR YOUR PRESENTATION. VERY COMPREHENSIVE AND WE APPRECIATE IT.

SO WE'RE GOING TO TAKE ONE THING SLIGHTLY OUT OF ORDER BECAUSE DUANE HAS A TIME CONSTRAINT HERE. WE WANT TO MAKE SURE WE GET THROUGH THIS BECAUSE HE'S DIRECTLY INVOLVED. SO CAN WE MOVE TO THE HASTINGS ITEM ON THE AGENDA. AND, DR. FEIGAL, YOU WILL DO THE INTRODUCTIONS.

DR. FEIGAL: GOOD AFTERNOON. IT'S MY PLEASURE TO INTRODUCE DR. MICHAEL GUSMANO. HE'S RESEARCH SCHOLAR AT THE HASTINGS CENTERS, AND HE'S ALSO ASSOCIATE PROFESSOR OF HEALTH POLICY AND MANAGEMENT AT NEW YORK MEDICAL COLLEGE. ONE OF HIS PRIMARY ROLES AT THE HASTINGS CENTER, WHICH IS ACTUALLY THE WORLD'S FIRST CENTER FOR BIOETHICS AND HEALTH POLICY, IS THAT HE'S DIRECTING THE HASTINGS CENTER PROJECT ON THE FDA AND PATIENT VOICES WHICH IS FUNDED IN PART BY CIRM.

AND SO HE CAME HERE, HE FLEW ACROSS FROM THE EAST COAST LAST NIGHT, TO ACTUALLY BE HERE TO PRESENT TO THE BOARD ABOUT SOME OF THE WORK THE HASTINGS CENTER IS DOING IN TERMS OF TRYING TO GET INPUT FROM THE PATIENT PERSPECTIVE FROM PATIENT VOICES AS WELL AS FROM WHAT THEY CALL THE CONSUMER

VOICES AS NEW MEDICAL TECHNOLOGY IS DEVELOPED. HE'S GOING TO TELL YOU A LITTLE BIT ABOUT THE ROUNDTABLE THAT TOOK PLACE EARLIER THIS YEAR AND ALSO SOME OF THE DIRECTIONS THAT THE HASTINGS CENTER IS TAKING.

AND BECAUSE WE INFORMED HIM -- DUANE AND I WERE ABLE TO GO TO THAT ROUNDTABLE, AND WE ASKED DR. GUSMANO TO COME OUT, AND HE KINDLY AGREED BECAUSE WE LET HIM KNOW ABOUT ALL THE WORK THAT THE PATIENT ADVOCATES ON THE BOARD ARE DOING, THAT WE THOUGHT THIS WOULD BE A TOPIC OF GREAT INTEREST FOR OUR BOARD.

SO HE'S AGREED TO COME OUT TO TELL US ABOUT THAT PROJECT, AND I THINK HE'S GOING TO BE VERY INTERESTED IN YOUR INPUT AND PERSPECTIVES ON HOW TO MOVE FORWARD HERE. SO WITHOUT FURTHER ADO, LET ME INTRODUCE DR. GUSMANO.

DR. GUSMANO: THANK YOU, ELLEN. AND THANKS TO ALL OF YOU. IT'S A REAL PLEASURE TO BE HERE. I WANT TO THANK YOU FOR YOUR SUPPORT OF OUR WORK. I HAVE BEEN DOING RESEARCH AND THINKING ABOUT THE ROLE OF PATIENTS AND ADVOCACY GROUPS AND HEALTH POLICY FOR QUITE A NUMBER OF YEARS. I HAD THE PLEASURE LAST YEAR TO MEET DUANE ROTH AFTER HE HAD PUBLISHED AN ARTICLE IN THE *HASTINGS CENTER REPORT* INSPIRED IN LARGE PART TO HIS EXPERIENCE WORKING

WITH CIRM ON THESE SORTS OF ISSUES.

WE SUBSEQUENTLY HAD BEEN HAVING CONVERSATIONS WITH SOME OF THE STAFF AT THE FDA AND LEARNED THAT THEY ARE ACTUALLY DEVELOPING SOME NEW PROCESSES TO TRY TO EXPAND THE ROLE OF PATIENTS AND OTHER ADVOCATES IN WHAT THEY'RE DOING, BUT THEY WERE ACTUALLY STRUGGLING A BIT WITH HOW TO MOVE FORWARD WITH THIS. AS I'LL DESCRIBE TO YOU IN JUST A FEW MOMENTS, THEY ALREADY HAVE SOME EXISTING MECHANISMS FOR INVOLVING PATIENTS IN THEIR ADVISORY BOARDS, AND MANY OF YOU ARE FAMILIAR WITH THIS AND THEIR RESEARCH ADVOCACY PROGRAMS, BUT THESE ARE RELATIVELY LIMITED. AND THEY'RE LIMITED IN A COUPLE OF WAYS.

FIRST, THEY'RE LIMITED BECAUSE THE NUMBER OF PEOPLE INVOLVED IS ACTUALLY RELATIVELY SMALL WHEN YOU CONSIDER THE BROAD NUMBER OF STAKEHOLDERS THAT THEY MIGHT REACH OUT TO, AND IT'S LIMITED LARGELY TO SORT OF GO/NO-GO DECISIONS WITHIN REVIEW COMMITTEES. AND OUR DISCUSSIONS IN JANUARY, WHICH INVOLVED PEOPLE FROM THE FDA, PEOPLE FROM INDUSTRY, A NUMBER OF DIFFERENT ADVOCACY GROUPS, AND SEVERAL LEADING RESEARCHERS THAT HAVE THOUGHT A LOT ABOUT THE ROLE OF PATIENTS IN THE HEALTH POLICY PROCESS, ENCOURAGED A MORE EXPANSIVE VIEW OF THIS. AND I KNOW IT'S BEEN A LONG DAY, SO I'VE GOT A BUNCH OF SLIDES. I'M

GOING TO SKIP THROUGH MOST OF THEM RELATIVELY QUICKLY, BUT I'LL BE HAPPY TO TAKE YOUR QUESTIONS AS WE MOVE ALONG.

REALLY WHAT I WANT TO DO IS KIND OF TALK ABOUT THE CURRENT ROLE AND THE VALUE OF PUBLIC INVOLVEMENT IN THESE SORTS OF DECISIONS, THE CURRENT PROGRAMS AT THE FDA, AND A LITTLE BIT ABOUT HOW OUR CONVERSATION HAS EVOLVED IN TERMS OF WHAT THE AGENCY SHOULD DO, AND I'LL ALSO DESCRIBE TO YOU MY NEXT STEPS AND OUR NEXT STEPS AT THE HASTINGS CENTER WITH THAT PROJECT.

ONE OF THE THINGS THAT REALLY CAME OUT AT THE MEETING, IT WAS THE FIRST THING WE DISCUSSED, WAS THE EXTENT TO WHICH A BROADER INVOLVEMENT OF STAKEHOLDERS COULD REDEFINE OR AT LEAST POTENTIALLY BROADEN THE DEFINITION OF BENEFITS AND RISKS. AS I'LL MENTION TO YOU IN A FEW MOMENTS, THE FDA HAS ACTUALLY DEVELOPED A NEW TOOL, WHICH IT'S JUST ROLLING OUT, THAT I THINK HAS A LOT OF INTERESTING POTENTIAL TO TRY TO GET ITS REVIEW COMMITTEES AT LEAST INITIALLY LOOKING BACKWARDS TO TAKE A LOOK AT SOME OF THE DECISIONS THEY MADE AND UNDERLYING ASSUMPTIONS OF THOSE DECISIONS, AND WE THINK MOVING FORWARD COULD BE USED PROSPECTIVELY TO THINK ABOUT HOW THE FDA OUGHT TO THINK ABOUT BENEFITS AND RISKS

AND STRIKING THAT BALANCE.

THERE WAS ALSO A LOT OF DISCUSSION ABOUT HETEROGENEITY AND THE EXTENT TO WHICH YOU MIGHT WANT TO HAVE MORE NUANCED DECISIONS ABOUT THE APPROVAL OF NEW DRUGS FOR CERTAIN SUBPOPULATIONS. AND I'LL GET TO THAT IN A MOMENT. BUT PERHAPS MOST IMPORTANT, THE FOCUS WAS REALLY ON THE NEED TO BUILD TRUST IN THE PROCESS AND ENHANCE THE LEGITIMACY OF FDA DECISION MAKING. ONE OF OUR ATTENDEES NOTED THAT IF YOU LOOK OVER THE LAST SEVERAL DECADES, EVERY TIME THERE IS A SCANDAL OR A PROBLEM WITH A DRUG THAT'S BEEN APPROVED BY THE FDA THAT RESULTS IN SOME SORT OF HARM, PUBLIC CONFIDENCE IN THE AGENCY DIPS PRETTY DRAMATICALLY. AND THAT'S TO BE EXPECTED IN MANY WAYS, BUT TO SOME EXTENT WE THOUGHT THAT BROADENING THE ROLE OF PATIENTS IN THEIR PROCESS COULD ACTUALLY HELP INSULATE THE AGENCY FROM SOME OF THOSE HITS BECAUSE PEOPLE WOULD HAVE GREATER TRUST IN THE PROCESS.

DUANE WROTE QUITE ELOQUENTLY IN HIS PIECE ABOUT THE EXTENT TO WHICH INDUSTRY, PATIENT ADVOCATES, THE FDA ITSELF ARE ALL UNHAPPY AND FRUSTRATED WITH THE CURRENT WAYS OF MAKING DECISIONS AND BALANCING BENEFITS AND RISKS.

RIGHT NOW THEY HAVE A FAIRLY

WELL-ESTABLISHED PATIENT REPRESENTATIVE PROGRAM. THEY DRAW ON PATIENT REPRESENTATIVES AND FAMILIES OF PATIENTS WHO SERVE IN A COUPLE OF DIFFERENT CAPACITIES, ONE ON ADVISORY COMMITTEES, BUT ALSO AS CONSULTANTS TO THEIR REVIEW COMMITTEES. THIS IS A FAIRLY RIGOROUS PROCESS IN THE SENSE THAT THE PEOPLE WHO ARE SELECTED ARE ACTUALLY HIRED AS SPECIAL GOVERNMENT EMPLOYEES, WHICH MEANS THEY ARE SUBJECT TO THE FULL RANGE OF CONFLICT OF INTEREST STANDARDS OF GOVERNMENT EMPLOYEES, WHICH IS LARGELY A POSITIVE THING. AND IN DOING MY BACKGROUND READING FOR THIS PROJECT, THOUGH NOT ENTIRELY, I'LL GET TO THAT IN A MOMENT, IT'S HIGHLY RESTRICTIVE AND PROBLEMATIC. SO DESPITE THE GOOD INTENTIONS, IT CAUSES SOME PROBLEMS.

IT'S ALSO, I WOULD CHARACTERIZE IT AS, SOMEWHAT REACTIVE IN THE SENSE THAT THE FDA DOES NOT DO A LOT OF OUTREACH TO STAKEHOLDERS TO BRING PEOPLE IN. THE PEOPLE WHO ARE INVOLVED TEND TO BE PEOPLE WHO HAPPEN TO BE WORKING WITH THE FDA OR WHO HAPPEN TO STUMBLE ACROSS THE FDA WEBSITE AND MADE THEIR WAY THROUGH ALL THE LAYERS TO FIND OUT THE OPPORTUNITIES AVAILABLE TO THEM, AND THAT WAS A MAJOR PART OF OUR DISCUSSION.

SIMILARLY, THERE WAS A RESEARCH ADVOCACY

PROGRAM. EVEN THE PEOPLE AT THE FDA SAID THERE ARE VERY FEW STAKEHOLDERS WHO ARE ACTUALLY EVEN AWARE OF THE ADVOCACY PROGRAM OR THE FACT THAT ADVOCATES CAN COME TO THE FDA WITH QUESTIONS AND CONCERNS OR SUGGESTIONS FOR NEW RESEARCH. AND THAT WAS IMPORTANT.

THIS IS REALLY WHAT LED THEM TO WHERE THEY ARE NOW, WHICH IS, AND THIS HAS NOT GONE LIVE YET -- MY UNDERSTANDING FROM OUR MEETING IN JANUARY IS THEY'RE SUPPOSED TO ROLL THIS OUT NEXT MONTH -- WHICH IS THE DEVELOPMENT OF A NEW FDA PATIENT NETWORK. THIS, IN ADDITION TO PROVIDING ADDITIONAL INFORMATION, EDUCATIONAL INFORMATION, TO A NUMBER OF ADDITIONAL STAKEHOLDERS WILL RESULT IN A NEW WEBINAR ON THEIR WEBSITE AND WHAT THEY HOPE WILL BE AN ANNUAL CONFERENCE TO BRING TOGETHER DIFFERENT STAKEHOLDERS TO ENGAGE THEM IN BROADER DISCUSSIONS ABOUT THESE SORTS OF ISSUES.

RELATED TO THAT, ALTHOUGH NOT IDENTICAL, WAS THE DEVELOPMENT OF A NEW BENEFIT RISK TOOL. AND THIS BENEFIT RISK ASSESSMENT TOOL WAS FAIRLY SIMPLE, AND IT BEGAN WITH AN ANALYSIS OF EACH CONDITION AND A DISCUSSION OF UNMET NEED. AND THE IDEA WAS TO PRESENT THIS FAIRLY SIMPLE TEMPLATE TO STAKEHOLDERS WHO HAD BEEN INVOLVED IN THE REVIEW PROCESS TO GET

THEM TO THINK ABOUT HOW THEY MADE DECISIONS ABOUT UNMET NEED WITHIN PARTICULAR CONDITIONS AND THEIR ASSESSMENT OF EVIDENCE. WHAT DO WE KNOW? WHAT DON'T WE KNOW? AND HOW DID THAT INFORM THE DECISION?

TO MAKE A LONG STORY SHORT, WE REALLY FELT THAT THEY OUGHT TO TAKE THIS TOOL AND RUN WITH IT AND USE IT IN A VARIETY OF OTHER SETTINGS. I'LL COME BACK TO THAT IN JUST A MOMENT.

A LOT OF OUR DISCUSSION DID FOCUS ON THE LIMITED NUMBER OF PEOPLE WHO ARE CURRENTLY INVOLVED IN THE FDA PROGRAMS AND HOW PROBLEMATIC THAT COULD BE. FIRST, IT'S NOT CLEAR WHETHER THESE PEOPLE ARE REPRESENTATIVE IN ANY WAY, NOR IS IT CLEAR WHETHER THE PEOPLE WHO REPRESENT THEMSELVES AS MEMBERS OF GROUPS ARE REPORTING BACK TO THE GROUPS THAT THEY CLAIM TO REPRESENT OR HOW THEY'RE SEEKING INPUT. MUCH OF OUR CONVERSATION REVOLVED AROUND THE FACT THAT THE FDA, IN ADDITION TO PROVIDING TRAINING ABOUT THE REVIEW PROCESS AND THE LEGAL MECHANISMS AT STAKE AND THE SCIENCE, SHOULD ACTUALLY PROVIDE TRAINING TO EVERYONE INVOLVED, INCLUDING THE SCIENTISTS THAT ATTEND THE MEETINGS, ABOUT THE DELIBERATIVE PROCESS AND THE IMPORTANCE OF TAKING THESE THINGS SERIOUSLY.

THERE'S A LONG HISTORY IN THE UNITED STATES GOING BACK TO PROGRAMS STARTED IN THE 1960S AND 1970S OF TRYING TO INVOLVE THE LAY PUBLIC IN INFORMING POLICY. AND THERE'S A LOT OF CONCERN ABOUT DEFERENCE TO SCIENCE. BUT WE ACTUALLY BROUGHT IN SOME EXPERTS WHO HAVE DONE A LOT OF WORK LOOKING AT NEWBORN GENETIC SCREENING THAT MADE THE OPPOSITE ARGUMENT, SAYING THAT IN MANY STATES, FOR EXAMPLE, PATIENT ADVOCATES THAT WERE BROUGHT IN SORT OF PUSHED WHAT THEY CHARACTERIZED AS THE URGENCY NARRATIVE AND THE IDEA THAT THEY SORT OF PUSHED ASIDE THE SCIENCE IN WAYS THAT WERE SOMEWHAT PROBLEMATIC.

AND SO YOU REALLY WANT TO THINK CAREFULLY ABOUT BOTH OF THESE SORTS OF PROBLEMS, AND BROADENING THE NUMBER OF VOICES IN THE ROOM, WE THOUGHT, WAS THE ANSWER TO THAT.

ELLEN MENTIONED BRIEFLY THIS IDEA OF CONSUMERS. THERE WAS SOME DISCUSSION EARLY ON THAT I THINK WE PUSHED ASIDE WITH THE ASSUMPTION THAT PATIENTS ARE ALWAYS GOING TO WANT TO SORT OF CHANGE THE BENEFIT RISK SCENARIO IN WAYS OF TAKING GREATER RISKS, AND CONSUMERS, HOWEVER YOU DEFINE THAT, ARE GOING TO BE MORE RISK AVERSE. AND MOST OF THE PEOPLE IN THE ROOM ACTUALLY DISMISSED THAT

PRESUMPTION. PARTICULARLY A LOT OF THE LEADING CANCER ADVOCATES IN THE ROOM HAD SAID, DUE TO A NUMBER OF THINGS, INCLUDING THE CONTROVERSY OVER BONE MARROW TRANSPLANT TREATMENTS FOR BREAST CANCER, THAT IN FACT THE ADVOCACY COMMUNITY, THEY FELT, HAD BECOME MUCH MORE SOPHISTICATED ABOUT SCIENTIFIC EVIDENCE AND WAS CERTAINLY CAPABLE OF LOOKING AT THIS. THAT WAS ALSO SORT OF THE BACKBONE OF DUANE'S ARTICLE WITHIN THE *HASTINGS CENTER REPORT*.

SO OUR RECOMMENDATIONS IN PART FOCUS ON MOVING BEYOND JUST THE REVIEW PROCESS, AND A NUMBER OF PEOPLE IN THE ROOM INVOKED, ALTHOUGH I'M COGNIZANT OF THE TROUBLE DON BERWICK GOT INTO FOR REFERENCING ENGLAND, BUT I'LL REFERENCE THE NHS ANYWAY, AND SUGGEST THAT THE CITIZENS COUNCIL THAT HAS BEEN ADOPTED BY THE NATIONAL INSTITUTE FOR HEALTH IN CLINICAL EXCELLENCE WAS ONE KIND OF MODEL THAT PEOPLE TALKED ABOUT AS POTENTIALLY ANOTHER MECHANISM THAT THE FDA MIGHT CONSIDER WHEN BRINGING IN A BROADER SET OF VOICES.

THE IDEA HERE WAS NOT TO ONLY INVOLVE PATIENTS IN THE REVIEW PROCESS AND IN ADVISORY COMMITTEES, BUT ACTUALLY TO THINK ABOUT INVOLVING PATIENTS IN WHAT YOU MIGHT CONSIDER BROADER POLICY QUESTIONS ABOUT HOW TO CONSIDER RISKS AND BENEFITS

ABOUT HOW TO SHAPE THE DIRECTION OF RESEARCH AND TO USE OTHER MECHANISMS THAT WOULD NOT RESTRICT IT, IN FACT, TO HIRING PEOPLE AS SPECIAL GOVERNMENT EMPLOYEES SUBJECT TO ALL THE CONFLICT OF INTEREST RESTRICTIONS. THAT IF YOU MOVED BEYOND THOSE FAIRLY NARROW PROCESSES, YOU MIGHT ACTUALLY BE able TO ENGAGE A BROADER NUMBER OF STAKEHOLDERS IN WHAT THE FDA IS DOING AND THINKING ABOUT.

MY SORT OF SOBER COMMENTS ON THIS CAME FROM A LOT OF MY RESEARCH ON EFFORTS TO BRING ABOUT DELIBERATION IN THE U.S. AND OTHER COUNTRIES. IF YOU READ A LOT OF GOVERNMENT REPORTS, INCLUDING THE MOST RECENT PRESIDENTIAL COMMISSION ON BIOETHICS, THE IDEA THAT WE SHOULD CREATE DELIBERATIVE PROCESSES IS SOMETHING THAT IS VERY HOT IN POLICY CIRCLES RIGHT NOW. IT'S HARD TO FIND ANYBODY WHO OPPOSES THIS IDEA AND VERY FEW PEOPLE WHO ACTUALLY THINK ABOUT IT SERIOUSLY. AND THE PEOPLE WHO DO THINK ABOUT IT SERIOUSLY RECOGNIZE THAT IT'S REALLY HARD TO DO. IT'S HARD TO DO BECAUSE TAKING DELIBERATION SERIOUSLY MEANS AN INTENSE COMMITMENT OF TIME. IT OFTEN REQUIRES REGULAR INTERACTION AMONG SMALL GROUPS OF PEOPLE WHO GET TO KNOW EACH OTHER OVER TIME. AND THERE'S A TENSION BETWEEN WANTING TO EXPAND THE NUMBER OF VOICES INVOLVED IN

THE PROCESS AND THAT NEED FOR REGULAR INTERACTION.

SO WE TALKED QUITE A BIT ABOUT THIS, AND I THINK ONE OF THE THINGS THAT WE NEED TO DO MOVING FORWARD IS TO FIGURE OUT HOW TO HELP THE FDA UNDERSTAND HOW TO BALANCE THAT. ONE OF THE THINGS THAT CAME THROUGH VERY CLEARLY IN ALL OF OUR DISCUSSIONS WAS THE NEED TO ASK MORE FROM STAKEHOLDER GROUPS, THAT THE FDA COULD NOT, IN FACT, DO ALL OF THIS AND SHOULD NOT DO ALL OF THIS, BUT THE FDA COULD ACTUALLY FACILITATE DISCUSSIONS OF THIS SORT AMONG OTHER STAKEHOLDER GROUPS. SOME OF THE REPRESENTATIVES FROM THE FRIENDS OF CANCER RESEARCH, FOR EXAMPLE, TALKED ABOUT THE TRAINING THAT THEY DO WITH THEIR OWN MEMBERSHIP IN TERMS OF HOLDING ANNUAL MEETINGS AND EVEN BRINGING FDA REPRESENTATIVES TO THEIR MEETINGS.

I'LL JUST SORT OF SKIP THROUGH THIS EXCEPT TO SAY HERE ARE SOME OF OUR PRELIMINARY OBSERVATIONS. ONE IS THAT THE FDA NEEDS TO MOVE AWAY FROM THEIR SOMEWHAT PASSIVE INSTEAD OF REACTIVE PROCESS AND TO DO MUCH GREATER OUTREACH. AND HERE A NUMBER OF THE PEOPLE WHO WERE IN THE ROOM OFFERED TO GET INVOLVED AND SAID THAT THEY WANTED MORE INFORMATION, FOR EXAMPLE, ABOUT THE DEVELOPMENT OF THE PATIENT ADVOCACY NETWORK. I THINK ALL OF YOU

COULD HELP IN THIS PROCESS AS WELL. I'LL BE PUTTING TOGETHER A MEETING SUMMARY AND ALSO AN INITIAL ISSUE BRIEF THAT WILL BE AVAILABLE FOR YOUR COMMENT BY THE END OF APRIL, AND I'D VERY MUCH APPRECIATE YOUR INPUT INTO HOW THEY CAN DO A BETTER JOB WITH THEIR OUTREACH.

ONCE AGAIN, GOING BEYOND THE ADVISORY AND THE REVIEW COMMITTEES, TO STOP THINKING ABOUT THE INVOLVEMENT OF PATIENTS AND PATIENT ADVOCACY GROUPS NARROWLY IN TERMS OF THIS ONE DIMENSION OF A LONG SERIES OF DECISIONS. IN LISTENING TO YOUR DISCUSSION OF YOUR STRATEGIC PLAN AND THE NEED TO THINK OVER FIVE- AND TEN-YEAR PERIODS AND EVEN LONGER FOR THE DEVELOPMENT OF THE SCIENCE AND THINKING ABOUT HOW TO INVOLVE PATIENTS AT THE FDA LEVEL BEFORE THEY GET TO A STAGE IN THE PROCESS THAT IS SORT OF MUCH FURTHER ALONG IS IMPORTANT.

THERE WAS ALSO, I THINK, A FAIRLY LARGE CONSENSUS THAT THE FDA SHOULD THINK SERIOUSLY ABOUT THE MEANING OF REPRESENTATION IN GROUPS TO TRY TO ENCOURAGE THEM TO REPORT BACK TO THEIR GROUPS ABOUT THE CONVERSATIONS THAT THEY HAD AT THE FDA, BUT ALSO TO ENCOURAGE THE PEOPLE WHO WERE APPROVED FOR ATTENDING MEETINGS TO SEEK INPUT FROM THOSE GROUPS IN SOME SYSTEMATIC WAY AND TO PROVIDE SOME TRAINING

ALONG THOSE LINES.

AND THEN, FINALLY, OUR RECOMMENDATION WAS THAT THEY BUILD ON THE BENEFIT RISK ASSESSMENT TOOL THAT THEY DEVELOPED FOR THEIR REVIEW PROCESS BECAUSE THINKING VERY SERIOUSLY ABOUT THE CURRENT STATE OF DIFFERENT CONDITIONS, THE CURRENT STATE OF EVIDENCE ABOUT THOSE CONDITIONS, AND WHAT SHOULD BE CONSIDERED BENEFIT AND WHAT SHOULD BE CONSIDERED A RISK, HOW THOSE SHOULD BE MEASURED ARE IMPORTANT TOOLS, NOT JUST FOR THE REVIEW PROCESS, BUT FOR THE BROADER CONVERSATION THAT WE HOPE TO STIMULATE.

SO I WILL END THERE AND HAPPY TO TAKE ANY OF YOUR COMMENTS OR QUESTIONS.

CHAIRMAN THOMAS: MR. ROTH.

MR. ROTH: THANK YOU, MICHAEL, FOR THE OVERVIEW. AND TO ALL OF YOU THAT HAVE SAT AND LISTENED TO ME TALK ABOUT THIS FOR A WHILE, IT IS THE CREDIBILITY OF THIS ORGANIZATION THAT REALLY RESONATED, I THINK, WITH THE FDA. THE FACT THAT WE HAVE PEOPLE THAT HAVE SAT HERE AS PART OF THE PROCESS, INFORMED PROCESS, INSTEAD OF SAYING YOU CAN SIT OUT IN THE AUDIENCE AND WE'LL TALK IT OVER AND THEN YOU COME TO THE MICROPHONE AND GIVE US SOME ADVICE. THAT'S NOT WHAT HAPPENS HERE. AND THAT'S WHAT WE WERE TRYING TO DO.

BUT TO START WITH, YOU REALIZE, AND SOMEBODY SAID THIS, IT'S SO IMPORTANT TO THINK ABOUT, WE HAVE THE INVERSE OF MOORE'S LAW IN TERMS OF NEW THERAPIES. MOORE'S LAW YOU HAVE PRICE, TWICE THE POWER EVERY 18 MONTHS. IT'S COSTING TWICE AS MUCH, TAKING TWICE AS LONG, AND WE'RE GETTING HALF AS MANY NEW THERAPIES IN THE UNITED STATES. THAT CAN'T GO ON. THAT'S NOT SUSTAINABLE. IT HAS A DRAMATIC IMPACT ON WHAT WE'RE DISCUSSING TODAY. HOW DO YOU BREAK THAT LOGJAM?

THE SECOND PART OF THAT IS THAT THE FDA WAS QUITE RECEPTIVE TO THESE CONVERSATIONS, WHICH I THINK MICHAEL AND ELLEN AND ALL OF US WERE TAKEN BY, THAT THEY REALLY, REALLY ARE LOOKING FOR WAYS TO MAKE THIS WORK. AND THERE WAS CONSENSUS THAT IT WORKS FOR NOBODY RIGHT NOW. PATIENTS AREN'T HAPPY. THEY AREN'T GETTING THE THERAPIES. THE COMPANIES AREN'T HAPPY. THE FDA GETS CRITICIZED ALL THE TIME.

THIS INFORMED PATIENT INVOLVEMENT IS WHAT WE BELIEVE COULD FUNDAMENTALLY CHANGE THINGS. IF YOU SAT THROUGH THESE DECISION-MAKING PROCESSES, YOU COULD CONTRIBUTE AS YOU DO TO EVERYTHING WE'VE DONE TOGETHER ON THIS BOARD.

AND THEN FINALLY, THIS WHOLE THING OF TRUST. THESE DISEASES DON'T BELONG TO THE COMPANIES

THAT ARE DEVELOPING THE THERAPIES. THEY DON'T BELONG TO THE FDA. THEY BELONG TO THE PEOPLE WHO HAVE THE DISEASE. AND UNTIL THEY INSERT THEMSELVES IN THIS PROCESS, I THINK YOU'RE NEVER GOING TO GET RID OF THIS INHERENT BIAS. THE COMPANIES SEEING THE GOOD THEY CAN DO, THE FDA SEEING WHAT POSSIBLY COULD GO WRONG, AND THAT DANCE JUST GOES ON AND ON, AND WE GET VERY LITTLE NEW PRODUCTS. IF THE PATIENT'S IN THE ROOM, EVERYTHING CHANGES BECAUSE WE HAVE TO VIEW IT THROUGH YOUR EYES, WHICH I DON'T THINK IS POSSIBLE.

CHAIRMAN THOMAS: ADDITIONAL COMMENTS? MR. SHEEHY.

MR. SHEEHY: I'M GLAD YOU BROUGHT UP MOORE'S LAW. I DON'T KNOW IF SOME OF THIS ISN'T FIXING A BROKEN SYSTEM THAT IS IRREPARABLE. I THOUGHT THAT ANDY GROVE MADE A GREAT POINT IN HIS TALK, THAT THE FDA FUNDAMENTALLY NEEDS TO CHANGE WHAT IT DOES. HIS RADICAL SUGGESTION WAS THAT YOU JUST DO SAFETY, AND YOU USE THE POWER THAT'S AVAILABLE WITHIN THE INFORMATION TECHNOLOGIES TO COLLECT DATA ON PATIENTS AS THEY CHOOSE, ESPECIALLY IF YOU LOOK AT CANCER, WHICH IS BECOMING MORE AND MORE PERSONALIZED, AND COLLECT DATA ON PEOPLE WHO ARE TRYING THERAPIES. BUT RATHER THAN HAVE

THERAPIES THAT MIGHT WORK FOR A HANDFUL OF PATIENTS BOTTLED UP BECAUSE THEY'RE IN THESE LARGE RANDOMIZED CONTROLLED TRIALS AND THEY'RE BLOCKED FOR EFFICACY.

AND THE OTHER PART OF THIS TOO IS THE PAYER, WHICH I THINK DR. LUBIN WAS TALKING ABOUT TOO. THE REASON THE FDA IS SO AGGRAVATING IS NOBODY WILL PAY FOR ANYTHING TILL THE FDA APPROVES IT. SO YOU CAN HAVE PATIENT ADVOCATES IN THE ROOM AND THE FDA DOING WHAT'S IT'S GOING TO DO WITH MORE PATIENT ADVOCATES, BUT AS LONG AS THE FDA IS USING THESE REALLY, I THINK, ARCHAIC MEASURES OF EFFICACY AND THAT THEY REALLY ARE AN EFFICACY GATEKEEPER, WHICH I'M NOT EVEN SURE IS REALLY THE APPROPRIATE JOB FOR THEM. ANDY GROVE ARGUES THAT THAT'S NOT THE APPROPRIATE JOB FOR THEM. THEIR JOB IS SAFETY. AND THAT THE REAL THING WE SHOULD BE DOING IS COLLECTING ALL THIS INFORMATION SO THAT PEOPLE CAN MAKE INFORMED CHOICES ON WHAT MAY OR MAY NOT WORK WITH THEM ESPECIALLY AS WE'RE HEADING TOWARDS GENOMIC INFORMATION THAT WILL COST A NICKEL, IT LOOKS LIKE.

SO IT'S ALMOST LIKE WHAT WE'RE NEEDING IS NOT MORE BAND-AIDS, BUT WE NEED A WHOLE NEW BOAT. WE NEED TO RETHINK THE ENTIRE SYSTEM BECAUSE WE HAVE TO GET PEOPLE TO PAY FOR THESE THERAPIES, THAT IF THE SYSTEM WAS REALLY GOING TO WORK WELL, WOULD HAVE

A BASIC SAFETY PROFILE FROM THE FDA AND THEN PATIENTS WOULD MAKE THEIR OWN INFORMED DECISIONS ON WHAT THEY WANTED TO DO, ESPECIALLY IF THEY HAVE DISEASES OR CONDITIONS THAT ARE LIFE-THREATENING, AND THEY WANT TO TRY SOMETHING. THEY DON'T WANT TO GO GENTLY INTO THAT GOOD NIGHT.

SO I DON'T KNOW THAT JUST HAVING BETTER EDUCATED, BETTER REPRESENTATIVE PATIENT ADVOCATES BETTER INVOLVED IN THE CURRENT PROCESS IS GOING TO MAKE A DIME'S BIT OF DIFFERENCE.

DR. GUSMANO: I WOULD JUST SAY A COUPLE OF THINGS. FIRST, I THINK I AGREE WITH YOU IF WHAT YOU'RE DOING IS HAVING A BROADER RANGE OF BETTER EDUCATED PATIENTS INVOLVED IN THE CURRENT PROCESS. I THINK ONE OF THE THINGS WE WERE CALLING FOR, IN FACT, WAS AN INVOLVEMENT OF PATIENTS AT THE POLICY LEVEL TO ACTUALLY DEVELOP WHOLE NEW MECHANISMS. NOW, WHETHER THE FDA'S SORT OF LEGAL MANDATE OUGHT TO BE CHANGED IS AN IMPORTANT ISSUE THAT NEEDS TO HAVE SERIOUS CONSIDERATION. WHETHER THAT WOULD BE ALONE ENOUGH TO GET CMS, LET ALONE PRIVATE PAYERS, TO ACTUALLY PAY FOR ADDITIONAL THINGS IS YET ANOTHER MATTER.

ON A COMPLETELY DIFFERENT SIDE NOTE, I'M CURRENTLY SUPERVISING A DOCTORAL STUDENT WHO'S

LOOKING AT THE ROLE OF COMPARATIVE EFFECTIVENESS RESEARCH AND USE OF COMPARATIVE EFFECTIVENESS RESEARCH NOT ONLY BY CMS, BUT BY PRIVATE INSURANCE COMPANIES. SO SHE'S DONE A LOT OF CONFIDENTIAL INTERVIEWS. AND WHAT WAS SURPRISING TO HER, SHE EXPECTED TO FIND VERY LITTLE USE AT THE FEDERAL LEVEL AND A GREAT DEAL OF USE NOT ONLY OF COMPARATIVE EFFECTIVENESS RESEARCH, BUT ECONOMIC EVALUATION OF NEW TECHNOLOGIES BY PRIVATE INSURANCE COMPANIES, AND SHE DIDN'T ACTUALLY FIND AS MUCH AS SHE THOUGHT LARGELY BECAUSE THEY WERE SKEPTICAL OF THE INFORMATION AND THEY WEREN'T SURE THEY COULD ACT ON IT.

SO I THINK THIS OPENS UP A FAIRLY BROAD SET OF ISSUES THAT ARE VERY IMPORTANT, AND I THINK THE CALL FOR THE INVOLVEMENT OF PATIENTS AT A POLICY LEVEL GETS EXACTLY AT WHAT YOU'RE TALKING ABOUT, PARTICULARLY THE ISSUE AROUND PERSONALIZED MEDICINE AND HOW TO DEAL WITH THAT AS THE SCIENCE MOVES FORWARD BECAUSE THE REASON PEOPLE INVOKE THE CITIZENS COUNCIL AT NICE, EVEN THOUGH MOST OF THE POLITICAL RHETORIC IN THE U.S., NICE IS NOW ASSOCIATED WITH SAYING NO TO NEW TECHNOLOGY. IN FACT, THE EFFECT NICE HAS HAD IN THE NHS IS ACTUALLY TO EXPAND THE NUMBER OF DRUGS THAT THE NHS NOW PAYS

FOR. THE CITIZENS COUNCIL HAS REALLY PUSHED THE NHS IN THE DIRECTION OF CONDITIONAL APPROVAL FOR PARTICULAR SUBPOPULATIONS. THANK YOU.

DR. LUBIN: I THINK THE TOPIC IS FASCINATING, BUT ONE THING THAT'S ALWAYS STRUCK ME IN THIS IS THE EFFECTS OF LOBBY GROUPS AND THE LACK OF SOCIOECONOMIC CONSIDERATIONS, THAT THE POORER GROUPS ARE NOT AT THE TABLE. THAT THE GROUPS THAT HAVE THE STRONG LOBBIES ARE AT THE TABLE. I KNOW THIS FROM SICKLE SELL. QUITE CLEAR THAT THE ADVANCES AND THE THERAPIES IN THAT GROUP VERSUS A SMALLER GROUP OF PATIENTS IN THE UNITED STATES, THALASSEMIA, VERY EFFECTIVE AT THE LOBBY AND THEY'RE RIGHT AT THE TABLE AND THEY'RE RIGHT AT THE FDA AND THEY'RE RIGHT AT THE NIH AND CHANGES HAVE OCCURRED.

SO HOW DO WE AS A GROUP, CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE, TRYING TO BE INCLUSIVE. WE KNOW WHO VOTED IN THIS STATE FOR THIS INITIATIVE. HOW DO WE GET THAT SENSE OF VALUE IN THE CONCEPTS THAT WE'RE CONSIDERING THAT WILL MAKE US STAND OUT FROM OTHER ORGANIZATIONS?

DR. GUSMANO: I COULDN'T AGREE WITH YOU MORE. I THINK THIS IS ACTUALLY WHERE WE DESPERATELY NEED YOUR INPUT. I THINK IT'S WHY DUANE WROTE AND SUGGESTED THAT CIRM IS A BIT OF A MODEL. MY OWN

BIAS IN THIS AND THE REASON I'VE BEEN WRITING ABOUT THE ROLE OF PATIENTS AND OTHER ADVOCACY GROUPS IN THE HEALTH POLICY PROCESS FOR ABOUT 15 YEARS NOW IS, IN FACT, EXACTLY THAT CONCERN, THAT THERE WAS A REAL BIAS IN THE PROCESS IN THE SENSE THAT WELL-ORGANIZED, WELL-FINANCED GROUPS CAN HAVE A VOICE AT THE TABLE AND OTHER GROUPS DO NOT.

ONE OF OUR CONCERNS COMING OUT OF THE MEETING WAS THAT, IN FACT, WE HAD LESS DISCUSSION ABOUT SORT OF FINANCIAL RESOURCES, ALTHOUGH THAT WAS KIND OF UNDERNEATH ALL OF THE DISCUSSION ANYWAY, WAS THAT THE REASON IT WAS PROBLEMATIC THAT THERE ARE ONLY 160 APPROVED PEOPLE WITHIN THE POOL FOR PARTICIPATION IN ADVISORY GROUPS AND REVIEW COMMITTEES WAS THAT IT WAS A FAIRLY SORT OF NEGATIVE REACTIVE PROCESS WHERE IT WAS PEOPLE WHO ALREADY HAD THE RESOURCES, ALREADY HAD THE ORGANIZATION, ALREADY HAD THE WHEREWITHAL TO COME TO THE FDA AND TO GET THE APPROVAL. THE REASON FOR CALLING FOR THESE SORT OF BROADER MECHANISMS AND COUPLED WITH THAT A REAL COMMITMENT ON THE PART OF THE FDA TO, A, DO OUTREACH AND, B, PROVIDE TRAINING FOR GROUPS IN HOW TO PARTICIPATE IN THIS PROCESS WAS TO OVERCOME IT.

GIVEN MY TRAINING IN POLITICAL SCIENCE, I'M JUST DEEPLY SKEPTICAL. IT'S A DISCIPLINARY

BIAS. SO DO I THINK THAT WOULD BE SUFFICIENT TO OVERCOME THE KIND OF PROBLEM YOU'RE TALKING ABOUT? PROBABLY NOT. I THINK IT'S PROBABLY A STEP IN THE RIGHT DIRECTION.

CHAIRMAN THOMAS: HE CAME ALL THE WAY ACROSS COUNTRY, SO JUST WANT TO MAKE SURE THAT HE'S GIVEN HIS FULL DUE AND DISCUSSION ON THE TOPIC. JOAN.

MS. SAMUELSON: ONE THING TO ENCOURAGE PARTICIPATION OF MORE PATIENT ADVOCATES, I THINK YOU WOULDN'T HAVE TO LOOK VERY FAR. YOU COULD SUPPORT THE EXPERIMENT THAT'S GOING ON IN THIS ROOM. THIS IS ONE OF THE FEW PLACES THAT THERE ARE TRUE PATIENT ADVOCATES RATHER THAN JUST PATIENT REPRESENTATIVES WHO PERFORM ALL SORTS OF WONDERFUL FUNCTIONS, BUT TYPICALLY AREN'T PATIENT ADVOCATES. AND WHAT CAN BE DONE IS TO MAKE IT POSSIBLE TO DO THIS HELLISHLY DIFFICULT JOB. AND IT NEEDS SUFFICIENT FINANCIAL SUPPORT, SUPPORT IN TIME, SUPPORT IN RESOURCES, AND SUPPORT IN SCIENTIFIC TRAINING, AND STAFF SUPPORT.

DR. GUSMANO: I THINK THAT'S AN IMPORTANT POINT, AND IT'S ONE THAT WE REITERATED OVER AND OVER AGAIN. I THINK THE FDA WAS HAPPY WE DID THAT GIVEN THAT THEIR BUDGETS ARE CONTINUALLY BEING CUT AS WELL.

MY BIG CONCERN AND MY SKEPTICISM ABOUT CALLS FOR PATIENT INVOLVEMENT IS THAT IT JUST TURNS INTO WINDOW DRESSING. ONE WAY IT CAN TURN INTO WINDOW DRESSING IS NOT TO PROVIDE DOLLARS BEHIND IT TO MAKE SURE THAT YOU FACILITATE THE KIND OF HARD WORK YOU'RE DESCRIBING.

CHAIRMAN THOMAS: ARE THERE FURTHER COMMENTS? THANK YOU VERY MUCH FOR COMING OUT AND GIVING US YOUR REPORT. WE APPRECIATE A LOT OF GOOD INSIGHT AND FOOD FOR THOUGHT FOR US. AND PLEASE CONTINUE THE DIALOGUE WITH MEMBERS HERE OF THE BOARD, AND ANY WAY THAT WE CAN HELP, WE'D OBVIOUSLY BE VERY HAPPY TO. SO THANK YOU VERY MUCH.

(APPLAUSE.)

CHAIRMAN THOMAS: OKAY. DO MEMBERS -- WE HAVE TWO MORE ITEMS, ONE OF WHICH IS GOING TO BE FAIRLY LENGTHY. DO MEMBERS WANT TO TAKE ONE LAST BREAK FOR FIVE MINUTES? I THINK THE ANSWER IS YES. I SEE A LOT OF NODDING. LET'S BE BACK PROMPTLY.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: EVERYBODY PLEASE TAKE YOUR SEATS. WE ARE AROUND THE CLUBHOUSE TURN, HEADING FOR HOME. EVERYBODY PLEASE TAKE YOUR SEATS.

WE HAVE TWO ITEMS LEFT ON THE AGENDA. BOTH ARE VERY IMPORTANT. ONE, IN THEORY, COULD LEAD

TO CLOSED SESSION. SO I THINK WHAT WE'RE GOING TO DO IS TAKE THEM IN REVERSE ORDER AND LEAVE THE CLINICAL DEVELOPMENT ADVISORY PANEL TILL THE FINAL ITEM AND TAKE UP NOW THE DISCUSSION OF THE PROPOSED BUDGET, WHICH MATT HAS SPENT A GREAT DEAL OF TIME PUTTING TOGETHER FOR THIS PRESENTATION OVER SEVERAL MONTHS.

SO LET'S PROCEED TO THE ITEM, WHATEVER ITEM NUMBER, NO. 13, YES. NO. 13 ON THE BUDGET.

DR. PLUNKETT: THANK YOU. SO IN THE INTEREST OF TIME, I WILL TRY AND JUST HIT THE HIGH NOTES HERE, BUT I WILL DEFINITELY RESPOND TO AS MANY QUESTIONS AS COME IN HERE.

THE FIRST THING THAT I WANTED TO DO IS JUST BRIEFLY RECAP THE ANNUAL GOALS FOR CIRM, WHICH ELLEN ALREADY TOUCHED ON EARLIER. AND FROM THE CFO'S VIEW, THESE REALLY ARE VERY HELPFUL IN BOTH FOCUSING AND PLANNING THE BUDGET FOR THE ORGANIZATION BECAUSE THE DOLLARS THAT WE SPEND REALLY NEED TO TIE OUT TO WHAT WE'RE TRYING TO ACHIEVE IN THE NEXT YEAR AND VICE VERSA. SO WE HAD A VERY ROBUST INTERNAL PROCESS TO PUT THESE GOALS IN PLACE. I DON'T KNOW IF FOLKS HERE IN THE ROOM HAVE SEEN THIS TYPE OF ANNUAL GOAL BEFORE, BUT I THINK IT'S BEEN VERY HELPFUL FOR ALL OF US INTERNALLY AS

WE'RE MOVING FORWARD.

THERE'S JUST A COUPLE OF THINGS THAT I WOULD LIKE TO FLAG FOR YOU AND SOME OF THE CONSEQUENCES HERE. WORKING BACKWARDS FROM SOME OF OUR FIVE-YEAR GOALS, THERE'S THINGS LIKE A CERTAIN NUMBER OF TRANSLATIONAL PROGRAMS. I BELIEVE WE HAVE 42 TODAY. THAT NUMBER COULD INCREASE BY 25 OR 35 THIS YEAR ALONE. AND SO THE NEED TO MONITOR AND ASSIST AND GUIDE AND ALL THOSE THINGS THAT WE NEED TO DO FOR THOSE PROGRAMS WILL RESULT IN, FOR EXAMPLE, THE NEED FOR AN ADDITIONAL MEDICAL OFFICER AT THE ORGANIZATION. SO YOU WILL SEE HOW THESE GOALS FOR THE ORGANIZATION TIE BACK TO THE DOLLARS WE'RE SPENDING AND HOW THE DOLLARS WE'RE SPENDING HELP US ACHIEVE THE GOALS.

ON THE OTHER END OF THE SPECTRUM, IT WOULD CERTAINLY BE MUCH EASIER TO PUT TOGETHER A BUDGET THAT LIVES WITHIN OUR 6-PERCENT EXPENSE CAPS IF OUR GOALS WEREN'T NEARLY SO AMBITIOUS. THIS IS THE SAME SLIDE THAT I SHOWED YOU TWO MONTHS AGO, AND I WILL SHOW YOU AN UPDATED VERSION OF THIS AT THE END BASED ON SOME OF THE NEW WORK THAT WE'VE BEEN DOING.

JUST TO RECAP THE PROCESS, TO DATE AT THE END OF JANUARY, WE DISTRIBUTED THE CURRENT YEAR BUDGET YEAR-TO-DATE SPENDING AND A PLANNING TEMPLATE

TO THE GROUP HEADS. OVER THE PRESIDENT'S WEEKEND, I WAS ABLE TO PUT TOGETHER A FIRST DRAFT OF THE BUDGET AND HAD SOME INFORMAL REVIEWS WITH EACH OF THE GROUP HEADS AS WELL AS THE PRESIDENT AND THE CHAIR, TIGHTENED THINGS UP A LITTLE BIT, AND HAD A FURTHER REVIEW TOWARDS THE END OF FEBRUARY WITH J.T. AND WITH ALAN, HAD A CHANCE TO REVIEW SOME ADDITIONALLY UPDATED MATERIALS WITH MICHAEL GOLDBERG AND MARCY FEIT AT THE END OF FEBRUARY, AND THEN TODAY BRINGS US TO THE INITIAL REVIEW WITH THE ICOC.

AND TO ANSWER THE QUESTION WHICH I'M SURE MANY OF YOU ARE LOOKING FOR IS WE'RE REALLY NOT ASKING FOR A VOTE TO APPROVE THE BUDGET AT THIS POINT. THAT WILL COME AT THE MAY BOARD MEETING, BUT WHAT I'M REALLY LOOKING FOR IS FEEDBACK, GUIDANCE, INPUT ON WHERE THIS IS GOING AS WELL AS ANY SPECIFIC SUGGESTIONS, COMMENTS WHICH YOU MAY HAVE.

ONE OF THE THINGS THAT I WOULD LIKE TO HIGHLIGHT IS WE HAVE MADE SOME SIGNIFICANT CHANGES TO THE PRESENTATION OF THE BUDGET. WE'VE GREATLY EXPANDED THE NUMBER OF COST CENTERS. THESE ARE THE COLUMNS THAT YOU SEE IN THE BUDGET. SO THERE'S REALLY EIGHT DIFFERENT GROUPS NOW. YOU CAN SEE THEM LISTED ON THE LEFT. I WILL FLAG JUST A COUPLE OF THESE. ONE OF THEM IS THAT WE DO HAVE ALL OF THE

LEGAL EXPENSES FOR THE ORGANIZATION IN ONE COLUMN NOW. AND REALLY THIS IS TIED OUT TO FUNCTIONAL AREAS AND NOT REPORTING. I DO WANT TO REMIND EVERYBODY OF THAT.

THE SECOND THING IS THAT WE TRIED TO PUT SOME MORE SPECIFICITY AND CLARITY ON THE EXPENSE CATEGORIES. THESE ARE ONES THAT CERTAINLY MADE A LOT OF SENSE AS THE ORGANIZATION -- THE OLD ONES WERE ONES THAT MADE A LOT OF SENSE AS WE WERE BEING PUT TOGETHER OVER HALF A DECADE AGO. I REALLY JUST TRIED TO TAKE A FRESH LOOK AND GIVE SOME MORE CLARITY AS TO WHERE THINGS ARE GOING HOPEFULLY SO IT WILL BE MORE HELPFUL FOR YOU BOTH IN REVIEWING THE BUDGET AS WELL AS THE ONGOING FINANCIALS GOING FORWARD.

JUST A REMINDER ON HOW WE MAKE ALLOCATIONS AGAINST THE EXPENSE CAP. THERE'S REALLY BEEN NO CHANGES OR RECLASSIFICATIONS FROM PRIOR YEARS, BUT I WOULD LIKE TO HIGHLIGHT THE FACT THAT BECAUSE WE HAD PREVIOUSLY A NUMBER OF FUNCTIONS SPREAD ACROSS DIFFERENT DEPARTMENTS, THINGS LIKE LEGAL EXPENSES, AND PROPERLY CLASSIFYING THOSE DID TAKE AN ENORMOUS AMOUNT OF WORK FOR THE FINANCE STAFF AT THE ORGANIZATION. NOW THAT WE HAVE ALL OF LEGAL AND THE LEGAL DEPARTMENTS ACTUALLY GREATLY SIMPLIFIED

PROCESS TO BE ABLE TO DO THAT. THAT'S IMPORTANT AS THE ORGANIZATION CONTINUES TO GO WITHOUT ADDING ANY STAFF IN THE FINANCE ORGANIZATION.

I WOULD NEXT LIKE TO TAKE YOU THROUGH WHAT SOME OF THE MAJOR DRIVERS AND CHANGES ARE FROM THE CURRENT YEAR TO THE NEXT YEAR. I'LL START OFF WITH REALLY SOME GLOBAL DRIVERS ACROSS THE ENTIRE ORGANIZATION. THE FIRST IS THAT WE'RE RECOMMENDING AN ORGANIZATIONWIDE POOL FOR COMPENSATION INCREASES OF 4 PERCENT. THIS IS BASED ON A 3-PERCENT MERIT INCREASE PLUS AN INSTITUTIONWIDE POOL OF 1 PERCENT OF OUR TOTAL PAYROLL FOR ADJUSTMENTS. THAT 1 PERCENT COULD BE 10 PERCENT OF THE PEOPLE RECEIVE A 10-PERCENT RAISE FOR PROMOTIONS AND THAT SORT OF THING. THIS IS BASED ON THE COMPARABLE INSTITUTIONS THAT ARE SPECIFIED WITHIN THE TEXT OF PROPOSITION 71. AND FOR A POINT OF REFERENCE, THE LARGEST BARGAINING UNIT WITHIN THE STATE, IF I UNDERSTAND IT CORRECTLY, DOES HAVE BUILT IN AN AUTOMATIC 5-PERCENT MERIT INCREASE ON A PER ANNUM BASIS.

THERE ARE FOUR FTE'S ADDED. I WILL GET TO THOSE LATER ON. WITHIN PAT OLSON'S GROUP, THE RESEARCH GROUP, WE'RE ADDING ONE GRANTS TECHNICAL ASSISTANT. AND PAT HAS REALLY IDENTIFIED A NUMBER OF SAVINGS TO THE MEETING BUDGETS SUCH THAT WE CAN

REALLY GET OUR GOALS DONE OF HAVING THE REVIEWS COMPLETED IN A TIMELY FASHION WITHOUT CUTTING ANY CORNERS. I WILL COMMENT, YOU DID SEE THAT WE WERE SIGNIFICANTLY UNDERSPENDING THIS YEAR. AND I WOULD SAY THAT THE ACTUAL SPENDING PROBABLY WON'T BE THAT MUCH DIFFERENT ON A YEAR-ON-YEAR BASIS.

IN TERMS OF THE DEVELOPMENT GROUP, DR. FEIGAL'S GROUP, WE'RE LOOKING TO ADD ONE ADDITIONAL MEDICAL OFFICER WITHIN HER GROUP. AS I MENTIONED, WE EXPECT TO NEARLY DOUBLE THE NUMBER OF TRANSLATIONAL PROGRAMS WITHIN THE ORGANIZATION BY YEAR-END, AND WE CERTAINLY EXPECT TO SEE MORE POTENTIALLY ADDED BY JUNE OF 2013. SAME COMMENT ON THE MEETING BUDGETS.

ON THE I.T., I KNOW THIS HAS BEEN A TOPIC THAT'S BEEN OF LONGSTANDING INTEREST TO A NUMBER OF FOLKS IN THE ROOM HERE. WE HAVE HAD OPEN THROUGHOUT THE YEAR AN OPEN I.T. DIRECTOR POSITION. WE ARE NOW CURRENTLY PLANNING ON FILLING THAT POSITION. AND AS MANY OF YOU KNOW, WE REALLY TARGETED TO GET THE GRANTS MANAGEMENT PROJECT, SOFTWARE DEVELOPMENT PROJECT, TO BE IN A MAINTENANCE MODE AT SOME POINT WITHIN THE COMING YEAR, PROBABLY AROUND YEAR-END OR EARLY CALENDAR 2013. BY FISCAL YEAR-END, WE'D EXPECT NOT TO HAVE ANY CONTRACTORS AT THE AGENCY,

BUT WE WOULD LOOK TO HAVE ONE ADDITIONAL PROGRAMMER AS WE CONTINUE TO ROLL OUT NEW RFA'S OR LOOK FOR MORE INFORMATION FROM OUR AWARDEES SUCH AS THE PROJECT DOESN'T END, BUT WE'RE MORE IN A MAINTENANCE MODE. WE WILL BE HEARING FROM ADAMS, THE PERFORMANCE AUDITORS, IN MAY. I DO EXPECT THAT THEY WILL RECOMMEND A NUMBER OF ONGOING OPERATIONAL IMPROVEMENTS FOR US, WHICH WILL COST US A LITTLE BIT OF MONEY. THE BUDGET FOR THE NEXT YEAR DOES INCLUDE $150,000 FOR WHAT I'VE CALLED PERFORMANCE AUDIT ENHANCEMENTS. AND BY SPRING 2013, THE RUN-RATE EXPENSE WILL BE AT ONE MILLION A YEAR VERSUS $1.5 MILLION A YEAR THAT'S IN THE FISCAL 11-12 BUDGET.

IN ALAN TROUNSON'S BUDGET THERE WERE SOME SIGNIFICANT CUTS TO EXTERNAL CONTRACTS AND MEETING BUDGETS. AND I WILL POINT OUT THAT THE TRAVEL IN ALAN'S BUDGET AS WELL AS IN MY OWN REALLY REFLECTS OUR GOAL TO FIND $50 MILLION IN ADDITIONAL FINANCIAL SUPPORT, OUTSIDE FINANCIAL SUPPORT, FOR CIRM PROGRAMS. SO IN MY MIND THAT'S A TREMENDOUS RETURN ON INVESTMENT IF A FEW TENS OF THOUSANDS OF DOLLARS IN TRAVEL CAN RESULT IN EVEN A FRACTION OF THAT $50 MILLION IN OUTSIDE SUPPORT FOR A PROGRAM.

ON THE CHAIR'S BUDGET WE DID HAVE CUTS TO TRAVEL. AND I APOLOGIZE THE TEXT IS CUT OFF AT THE

BOTTOM THERE. SIGNIFICANT CUTS TO THE MEETING BUDGETS.

FOR COMMUNICATION, OBVIOUSLY WE'RE DELIGHTED THAT KEVIN IS ABLE TO JOIN US, AND WE PLAN TO SHIFT WHAT HISTORICALLY HAS BEEN EXTERNAL FUNCTIONS TO INTERNAL ACTIVITIES WITH THE ADDITION OF A FOURTH FTE WITHIN THAT GROUP.

WITHIN THE FINANCE GROUP WE'VE CUT SOME EQUIPMENT AND OTHER MISCELLANEOUS EXPENSES, BUT REALLY THE BIGGEST DELTA HERE IS THAT WE ONLY HAVE TO PAY FOR A PERFORMANCE AUDIT EVERY THIRD YEAR.

IN THE LEGAL, THE ONE SIGNIFICANT CHANGE IS THAT WE REPLACED 190,000 IN EXTERNAL LEGAL SERVICES WITH AN IN-HOUSE IP AND TRANSACTIONAL FTE. AND THAT'S ESSENTIALLY A VERY MARGINAL IN THE NOISE INCREASE IN OVERALL EXPENSE.

ANY QUESTIONS ON WHAT I'VE JUST GONE THROUGH BEFORE I SHOW YOU THE BOTTOM LINE HERE?

MS. SAMUELSON: THE MEETING BUDGET, CAN YOU SAY A LITTLE MORE ABOUT IN TERMS OF IS IT CHANGING THE SCOPE OF THE MEETINGS OR THE QUALITY OR WHAT?

DR. PLUNKETT: JOAN, THAT'S A VERY GOOD QUESTION. I DON'T THINK IT'S CHANGING THE SCOPE OR THE QUALITY AT ALL. AS ONE EXAMPLE, FOR THE CURRENT

YEAR WE HAD BUDGETED $125,000 TIMES FOUR FOR EACH OF THE FOUR CLINICAL DEVELOPMENT ADVISORY PANEL REVIEWS. THOSE HAVE COME IN AT AN AVERAGE OF EITHER 50 OR $60,000. I CAN'T REMEMBER WHICH IT IS. AND THAT'S THE NUMBER THAT WE'VE USED, THE $60,000 FIGURE FOR THE COMING YEAR. SO THAT'S ONE CASE WHERE WE HAVEN'T DONE SOMETHING BEFORE, WE DIDN'T KNOW HOW MUCH IT WOULD COST, AND THE BUDGET GOING FORWARD REFLECTS WHAT WE NOW KNOW.

MS. SAMUELSON: IT JUST SEEMS TO ME IT'S THE TIME WHEN WE WANT TO DO MORE COLLABORATING INTERNATIONALLY AND SO ON. I ALSO THINK WE MIGHT SAVE MONEY AND IMPROVE THE QUALITY BY OUTSOURCING MEETING DEVELOPMENT AND MANAGEMENT. WE'VE GOT A LOT OF EXPERT PEOPLE ON OUR STAFF. AND FOR THEM TO HAVE TO SPEND TIME WORRYING ABOUT HOW WE GET BETTER PHONE ACCESS TO PEOPLE WHOSE OPINIONS I RELY ON AND CAN'T HEAR DURING A MEETING, THAT'S JUST ONE LITTLE EXAMPLE. IT'S MADE UP OF SO MANY DIFFERENT KINDS OF EXPERTISE, AND WE SHOULDN'T HAVE TO BE SPECIALISTS IN ALL OF THAT.

DR. PLUNKETT: EACH OF YOU HAS THESE NUMBERS IN FRONT OF YOU AS WELL.

DR. JUELSGAARD: SO JUST TO SPEAK TO THESE NUMBERS JUST A MINUTE, AND THIS IS PROBABLY MORE

DIRECTED AT ELONA, BUT IT'S THE OUTSIDE LEGAL SERVICES BUDGET, WHICH IS ALMOST EQUAL TO THE IN-HOUSE COMPENSATION BUDGET. WHAT ARE THOSE OUTSIDE LEGAL SERVICES THAT WE'RE BUYING?

MS. BAUM: THERE'S AN EXTENSIVE ITEM FOR -- FIRST OF ALL, OUR LOAN PROGRAM, WHICH THE REMCHO CONTRACT, JAMES HAS PROVIDED SOME OF THOSE OVER TIME. I THINK IF WE IN-HOUSE THOSE SERVICES, WE WOULD BE A LOT MORE COST-EFFECTIVE. AND WE'RE AT THE POINT NOW WHERE I THINK YOU COULD EVEN GET A MORE JUNIOR ATTORNEY TO DO LOAN AGREEMENTS SINCE WE HAVE SORT OF THE BASE AGREEMENT CREATED, RESERVING A LITTLE FOR SOPHISTICATED OUTSOURCING ON WARRANT ISSUES. SO THAT WAS THE BIG BOLUS OF THE NUMBER.

AND THEN, OF COURSE, WHENEVER YOU OUTSOURCE LEGAL SERVICES, WHEN YOU HAVE THE HOURLY RATES THAT THESE SERVICES COMMAND, IT'S VERY, VERY EXPENSIVE. SO WE'RE TRYING TO BE A LOT MORE COST-EFFECTIVE BY BRINGING SOMEBODY IN-HOUSE.

DR. JUELSGAARD: I CAN'T READ THAT NUMBER THAT'S UP THERE RIGHT NOW FOR THE NEXT FISCAL YEAR. IN THE PRESENTATION THAT WE WERE GIVEN BY MARIA, IT'S 1,262,000. WHAT'S THE NEW NUMBER?

DR. PLUNKETT: THE NEW NUMBER IS 1,057,000. AND I CAN JUST --

DR. JUELSGAARD: SO WE'RE HIRING A $190,000 PERSON. SO IT'S BASICALLY A BREAK-EVEN PROPOSITION?

MS. BAUM: IT WAS ALMOST BUDGET NEUTRAL, THOUGH I'VE GOT TO SAY I THOUGHT IT WAS 200, BUT THAT'S IT. GIVE OR TAKE, IT SHOULD BE BUDGET NEUTRAL OR APPROXIMATELY BUDGET NEUTRAL.

MR. JUELSGAARD: BUT I THOUGHT I JUST HEARD YOU SAY YOU EXPECTED IT WILL BE MORE EFFICIENT IN TERMS OF OUTSIDE LEGAL SERVICES BY HIRING THE OTHER PERSON, NOT BUDGET NEUTRAL.

MS. BAUM: WELL, ACTUALLY IN REALITY I THINK THEY'LL BE ABLE TO DO A LOT MORE TOO, AND AT SOME POINT MAYBE RELIEVE SOME OF THE OTHER OUTSIDE EXPENSES THAT WE HAVE. I THINK WE HAVE TO ON-BOARD THEM AND DEVELOP THEM AND SEE WHAT ELSE THEY COULD DO.

MR. TORRES: I'M CONFUSED. DOES THAT INCLUDE HEALTH BENEFITS AND PENSION AS WELL IN THE 190,000?

MS. BAUM: NO.

DR. PLUNKETT: NO. THAT'S IN SALARY AND BENEFITS. THAT'S 1.27. IT'S 1.279 MILLION, OVERALL 11.2 MILLION FOR THE ORGANIZATION.

MR. TORRES: I WAS TALKING ABOUT THE

LAWYER THAT ELONA NEEDS.

DR. PLUNKETT: WE HAVE IT A LITTLE BIT HIGHER THAN THAT, INCLUDING BENEFITS A LITTLE BIT HIGHER THAN 190. I THINK WE HAD IT A 225 ALL IN.

DR. LUBIN: WHAT'S THE BENEFIT RATE?

DR. JUELSGAARD: WELL, I WOULD JUST ASK YOU TO RETHINK THIS. I THINK IF YOU'RE GOING TO HIRE A NEW INSIDE LAWYER, AND THE IDEA IS YOU'RE GOING TO TRY AND REDUCE OUTSIDE LEGAL EXPENSES, I WOULD EXPECT MORE THAN ONE-FOR-ONE TRADE-OFF EVEN FROM THE VERY BEGINNING. AND IF YOU'RE GOING TO HIRE SOMEBODY FOR 200,000, OBVIOUSLY THEY'RE NOT FRESH OUT OF LAW SCHOOL, THEY'VE GOT SOME EXPERIENCE AND HAVE BEEN DOING THIS FOR A WHILE. SO YOU MIGHT THINK ABOUT THAT.

MS. BAUM: I THINK THAT THERE'S ALSO A LOT OF ACTIVITY THAT HAS NOT BEEN UNDERTAKEN IN TERMS OF IP REVIEW AND TRANSACTIONAL ASSISTANCE FOR SOME OF OUR TEAMS. AS WE'RE GETTING MORE MATURE AND WE HAVE TO START TAKING A LOOK AT SORT OF THE FREEDOM TO OPERATE ISSUES, THAT WE REALLY NEED TO START ENGAGING IN THIS ACTIVITY. IT'S EITHER OUTSOURCED OR WE GET SOMEBODY IN-HOUSE THAT COULD DO IT. YES, I AGREE. WE'LL LOOK AT IT.

CHAIRMAN THOMAS: ELONA, ALL OF THE

DISCUSSION THAT WE HAD INTERNALLY ABOUT BRINGING SOMEBODY IN HAD TO DO WITH IP AND TRANSACTIONAL AND THAT SORT OF THING. I'M NOT SURE HOW THAT RELATED. YOU MADE SOME COMMENT ABOUT REMCHO. WHAT WAS THE POINT OF THAT COMMENT? I DIDN'T SEE THAT AS ONE THING AFFECTING THE OTHER.

MS. BAUM: WELL, BECAUSE REMCHO IS DOING SOME OF THE TRANSACTIONS WORK ON THE LOANS, SO THAT'S SOME OF THE EXTERNAL EXPENSE WE COULD SAVE BY INTERNALIZING IT.

MR. TORRES: HOW MUCH WOULD WE SAVE BY TAKING THAT RESPONSIBILITY AWAY FROM REMCHO?

MS. BAUM: I THINK I HAD CALCULATED FIVE LOANS FOR THE NEXT FISCAL YEAR. AND I THINK, JAMES, YOU COULD CORRECT ME IF I'M WRONG, BUT I THINK WE HAD DISCUSSED THAT YOU'RE RUNNING 30,000 A LOAN.

MR. HARRISON: AS WE HAD DISCUSSED, WE HAVEN'T -- WE HAVE NOT SEPARATELY BILLED FOR THE LOAN WORK THAT WE'VE DONE. I THINK THAT WAS AN ESTIMATE INCLUDING OUTSIDE COUNSEL AT FARELLA. SO WHAT I SUGGESTED WAS THE NEXT TIME WE DID ONE, WE'LL ACTUALLY TASK BILL FOR THAT PARTICULAR ITEM SO WE HAVE A MORE ACCURATE BASIS. THAT WAS AN ESTIMATE FOR BOTH ASPECTS OF IT.

MR. SERRANO-SEWELL: THANKS, J.T. ON A

MORE BROADER QUESTION ON OUTSIDE COUNSEL, WE HAVE VALUED OUTSIDE COUNSEL THAT HAS BEEN WITH US FROM DAY ONE. AND AS A BOARD, WE RELY ON THEM EXTENSIVELY FOR LEGAL ADVICE AND GUIDANCE. THEY ARE PART OF OUR FABRIC, AND WE'RE LUCKY TO HAVE JAMES AND HIS TEAM.

SO THE QUESTION I HAVE FOR THE CHAIR, IS THERE -- OR THE BUDGET GUY, IS THERE GOING TO BE ANY DECREASE IN THAT, IN THOSE SERVICES AT ALL, FROM REMCHO BECAUSE THAT WOULD BE A CONCERN TO ME?

DR. PLUNKETT: THE BUDGET NUMBER THAT WE HAVE IS ESSENTIALLY FLAT. IT'S 545,000 VERSUS 550,000 FOR THE COMING YEAR.

MS. SAMUELSON: DOES THAT CONTEMPLATE A DECREASE IN SERVICES? FLAT ORDINARILY MEANS THAT, I WOULD THINK, GIVEN ANNUAL INCREASES FOR INFLATION OR WHATEVER.

DR. PLUNKETT: I CAN'T ANSWER THAT. JAMES?

MS. SAMUELSON: FROM THE BUDGET STANDPOINT, IF YOU'RE ALLOCATING A FLAT AMOUNT, IS THAT TYPICALLY CONTEMPLATING EQUAL SERVICES OR ACTUALLY A DECREASE?

DR. PLUNKETT: GENERALLY SPEAKING, THERE'S A NUMBER OF ITEMS IN HERE WHERE WE HAVE KEPT IT

FLAT, FOR EXAMPLE, OR WE SAID THE COST OF A TRIP NEXT YEAR WILL BE THE SAME AS THE COST OF A TRIP THIS YEAR, THE COST OF A MEETING NEXT YEAR WILL BE THE SAME AS THE COST OF A TRIP THIS YEAR. FOR THINGS LIKE EMPLOYEE PAYROLL, COST OF PAYROLL WILL BE HIGHER. OBVIOUSLY WHEN YOU HAVE A MEETING OR FLY IN AN AIRPLANE, YOU'RE PAYING EMPLOYEES AND THOSE COSTS DO GO UP. SOMETIMES THOSE ARE RIGHT AND SOMETIMES THEY'RE NOT.

MS. SAMUELSON: SOMETIMES IT REFLECTED ACTUAL CUTS IN THE DEGREE OF ACTIVITY, RIGHT?

DR. PLUNKETT: IT CAN.

MS. SAMUELSON: I THINK WE SHOULD KNOW WHAT WE'RE DOING ABOUT THAT BEFORE WE APPROVE IT.

CHAIRMAN THOMAS: I THINK WE'VE ADDRESSED THE LEGAL ISSUES. ARE THERE OTHER ISSUES HERE ON THE BUDGET THAT PEOPLE WOULD LIKE TO COMMENT ON?

DR. PRICE: CAN YOU GIVE US SOME IDEA ABOUT THE MILLION PLUS DOLLARS A YEAR FOR I.T. GOING FORWARD?

DR. PLUNKETT: ABSOLUTELY. AS I MENTIONED BEFORE, WE EXPECT TO HAVE AT SOME POINT DURING THE YEAR TWO FULL-TIME EMPLOYEES, AN I.T. DIRECTOR AND A LEAD SOFTWARE ARCHITECT. WE CURRENTLY HAVE FIVE CONTRACTORS WITHIN THE I.T. GROUPS. WE EXPECT TO GO

DOWN TO THREE CONTRACTORS WITH TWO EMPLOYEES. THOSE THREE CONTRACTORS WILL THEN GO AWAY. THE COMPENSATION FOR THE TWO EMPLOYEES IS APPROXIMATELY $380,000. THE COMPENSATION FOR THE STUB PERIOD OF THE YEAR FOR THE CONTRACTORS IS APPROXIMATELY $600,000. THERE'S A SERVICE WHICH WE USE WHICH GIVES US 24 BY 7 SOFTWARE DESKTOP SUPPORT. WE EXPECT THAT THAT WILL BE $150,000 NEXT YEAR. I ALREADY MENTIONED $150,000 IN PERFORMANCE AUDIT ENHANCEMENTS. WE ARE PLANNING FOR $75,000 IN ENHANCEMENTS TO BASICALLY GET OUR WEBSITE TO HAVE REAL-TIME DATA. NOW IT'S CURRENTLY MANUALLY FED EVERY TIME WE UPDATE OUR GRANTS MANAGEMENT DATABASE. AND THE REST OF THE ITEMS ON THE LIST THAT I HAVE HERE ARE $40,000, AND IT WILL GO DOWN TO $3,000. DOES THAT ANSWER YOUR QUESTION?

CHAIRMAN THOMAS: OTHER QUESTIONS AND COMMENTS?

MR. SERRANO-SEWELL: JUST THE LAST POINT -- THANK YOU FOR THE DETAILED PRESENTATION. THE 5 PERCENT PER ANNUM INCREASE THAT YOU REFERENCED EARLY ON, RARELY DO THOSE COLLECTIVE BARGAINING GROUPS GET A -- I'M PART OF THOSE DISCUSSIONS WITH THE CITY. IT'S JUST IN THE CONTRACT. IT MAY VERY WELL SAY IT, BUT I CAN'T -- I CAN'T THINK OF A YEAR,

UNLESS YOU'RE A POLICE OFFICER OR A FIREFIGHTER, WHERE YOU'VE GOTTEN THE RAISE THAT YOU'RE SUPPOSED TO IN THE CONTRACT. IT JUST -- I HAVEN'T SEEN IT HAPPEN IN THE LAST SEVEN, EIGHT YEARS.

MR. TORRES: SO ARE YOU SUGGESTING THAT -- WE HAVEN'T BEEN GIVING THESE MERIT INCREASES, HAVE WE?

MR. SHEEHY: YES, WE HAVE.

DR. TROUNSON: THAT'S NOT CORRECT. WE HAVE BEEN GIVING MERIT INCREASES OF AROUND 3 PERCENT.

MR. SHEEHY: THAT COMPARATOR, UC HAS NOT BEEN IN HERE.

MR. SERRANO-SEWELL: I WAS COMMENTING --

MR. TORRES: NEITHER HAS THE CHAIR OR VICE CHAIR JUST FOR THE RECORD.

MR. SERRANO-SEWELL: I UNDERSTOOD IT WHEN YOU MADE THAT --

CHAIRMAN THOMAS: CHAIR IS NOT LOOKING FOR ANY JUST FOR THE RECORD.

MR. SERRANO-SEWELL: I UNDERSTOOD IT TO BE LIKE A SUPPORTING -- IT'S THE LARGEST COLLECTIVE BARGAINING UNIONS GET THIS 5 PERCENT, AND HERE'S OUR FIVE. I DIDN'T UNDERSTAND WHAT THE NEXUS BETWEEN THE TWO WAS. BUT IF THERE WAS ONE, KNOW THAT PEOPLE

AREN'T GETTING THEM.

DR. PLUNKETT: THE MOST RELEVANT STATISTIC IS THE COMPARATOR INSTITUTIONS. WE HAVE OBTAINED SOME CONFIDENTIAL DATA FROM NINE DIFFERENT INSTITUTIONS. WE HAVE OBTAINED CONFIDENTIAL INFORMATION FROM NINE DIFFERENT COMPARATOR INSTITUTIONS WITHIN THE STATE.

DR. JUELSGAARD: MATT, CAN YOU DESCRIBE GENERALLY WHO THOSE COMPARATOR INSTITUTIONS ARE BY NAME?

DR. PLUNKETT: THOSE ARE PRIVATE ACADEMIC RESEARCH INSTITUTIONS AS WELL AS SOME OF THE UC'S.

DR. JUELSGAARD: SOME OF THE --

DR. PLUNKETT: UC'S.

CHAIRMAN THOMAS: FURTHER DISCUSSION?

DR. TROUNSON: I THINK THE ONE ELEMENT THAT THE BOARD NEEDS TO BE AWARE OF IS OUR CONCERN TO REMAIN BELOW THE 6 PERCENT FOR THE WHOLE LENGTH OF TIME THAT THE AGENCY IS OPERATING. SO WE ARE OPERATING IN A CONSTRAINED BUDGET ENVIRONMENT. SO WE ARE KEEPING THAT DOWN, AND ONE OF THE ONE-YEAR GOALS WAS TO MAKE SURE THAT WE HAVE A COMPOSITION THAT IS ABLE TO DELIVER ON THE BUSINESS OF THE AGENCY WITHIN THAT FRAMEWORK OF THE 6 PERCENT. SO IF WE NEED TO MAKE SOME ADJUSTMENTS, THAT WE NEED TO

DO IT BECAUSE, AS YOU EXPAND IN SOME AREAS, THERE'S A LOT MORE PRESSURE ON THE PARTS OF THE ORGANIZATION TO DO THAT.

SO WE'RE GIVING A LOT OF THOUGHT TO WHAT CAN BE CONSTRAINED AND WHAT CAN BE KEPT TO A MINIMUM.

DR. LUBIN: I UNDERSTAND HOW JUSTIFICATION FOR THE BUDGETS ARE MADE, AND I APPRECIATE THAT, SO I'M NOT SAYING THAT'S NOT APPROPRIATE. BUT THERE'S A PUBLIC AWARENESS OF WHERE BUDGETS ARE AND WHAT INCREASES ARE. AND IN THIS ECONOMY WE'RE ALL STRUGGLING TO KEEP THINGS REALLY TIGHT. I JUST WANT TO BE SURE THAT WHEN A DECISION IS MADE, AND I WOULD TRUST YOUR OPINIONS AS HOW THAT'S MADE, THIS BECOMES PUBLIC INFORMATION. AND WE WANT TO KEEP THINGS ROLLING HERE WITH THE HOPE THAT WE'RE GOING TO HAVE A FUTURE. I'M NOT SAYING THIS ISN'T IN KEEPING. WHAT ALAN JUST SAID MAKES ME FEEL THAT'S THE CASE, BUT WE'RE STRUGGLING, EVERY INSTITUTION IN THE UNIVERSITY OF CALIFORNIA SYSTEMWIDE IS STRUGGLING WITH THESE KINDS OF THINGS. I JUST THINK WE HAVE TO BE CAREFUL ABOUT THESE MOVES. AND I KNOW, ESPECIALLY WHEN THE INFORMATION BECOMES PUBLIC, I THINK THAT'S AN IMPORTANT THING TO KEEP IN MIND.

CHAIRMAN THOMAS: THANK YOU. WE'VE GONE

TO GREAT LENGTHS TO TRY, FURTHER TO ALAN'S COMMENTS, TO CONSTRUCT A BUDGET THAT IS PRUDENT AND KEEPS WITHIN OUR RESTRAINTS WHICH ARE CONSIDERABLE. SO POINT VERY WELL TAKEN.

DR. PLUNKETT: JUST TO SUMMARIZE THIS PAGE VERY BRIEFLY, I THINK THE POSITIVE THINGS HERE IS THAT THE OVERALL BUDGET, YEAR-ON-YEAR BUDGET-TO-BUDGET NUMBER IS DOWN 3.5 PERCENT OR $650,000. SOME OF THE DEPARTMENTS ARE UP, SOME ARE A LITTLE BIT DOWN. I THINK THAT, AS I MENTIONED BEFORE, I.T. HAS BEEN A HOT BUTTON THAT IS DOWN MODESTLY ON THE YEAR. AS I SAID BEFORE, BY THE COMING SPRING, WE EXPECT TO BE AT A RUN RATE THAT'S 1.0 MILLION AND NOT 1.5 MILLION A YEAR WHICH I FEEL IS A LITTLE MORE APPROPRIATE. YOU SEE THE CUTS THERE ACROSS THE BOTTOM ROWS.

CHAIRMAN THOMAS: DEAN POMEROY.

DR. POMEROY: JUST ONE MORE QUESTION ABOUT THE COMPENSATION INCREASES. SO THE 3-PERCENT MERIT, DOES THAT IMPLY THAT SOME PEOPLE ARE GETTING 6 PERCENT AND SOME PEOPLE ARE GETTING ZERO? IT'S NOT GIVEN OUT UNIFORMLY.

DR. PLUNKETT: NO, WE'RE NOT CONTEMPLATING A FLAT, ACROSS THE BOARD PERCENTAGE. IT WOULD BE, IF MY UNDERSTANDING OF OUR PERSONNEL POLICIES ARE

CORRECT, IT WOULD BE A MAXIMUM OF 5 PERCENT, BUT AVERAGING TO 3 PERCENT ACROSS THE ORGANIZATION.

DR. POMEROY: THANK YOU.

CHAIRMAN THOMAS: OTHER COMMENTS? I WOULD ENCOURAGE YOU, IF YOU GET A CHANCE TO DIGEST THIS DOCUMENT BETWEEN NOW AND THE NEXT BOARD MEETING AT WHICH WE WILL VOTE ON IT, TO FEEL FREE TO ASK ANY QUESTIONS OR RAISE ANY SUGGESTIONS, ETC.

MS. FEIT: I WANT TO MAKE A COMMENT. MICHAEL GOLDBERG COULDN'T BE HERE TODAY, BUT HE WANTED ME TO REITERATE AS WELL AS MYSELF WE MET EXTENSIVELY WITH MATT ON THE BUDGET. HE'S ATTEMPTED TO BE VERY TRANSPARENT WITH ALL THE ELEMENTS THAT WE'VE BEEN TALKING ABOUT IN PAST YEARS THAT THE BOARD WANTED TO SEE IN A BUDGET FORMAT. I THINK HE'S DONE A GREAT JOB.

I THINK IN THE CONTEXT OF WHAT'S BEEN PRESENTED, THE MOST IMPORTANT ELEMENT IS THE TIMELINESS OF THIS BUDGET AND THE ABILITY NOW FOR THE BOARD TO SPEND SOME TIME LOOKING AT IT AND GIVING FEEDBACK BEFORE IT HAS TO HAVE FINAL APPROVAL. SO MICHAEL AND I BOTH APPROVE GOING FORWARD WITH WHAT MATT HAS PRESENTED. WE WANT TO THANK HIM FOR HIS HARD WORK AND FOR HIS GREAT LISTENING TO SOME OF THE THINGS THAT WE WANTED TO

SEE IN THE BUDGET FORMAT.

CHAIRMAN THOMAS: THANK YOU, MARCY. THAT IS A SUMMARY STATEMENT. MATT, THANK YOU VERY MUCH.

DR. PLUNKETT: ONE MORE MINUTE AND THAT'S JUST TO SHOW THE FORECAST.

CHAIRMAN THOMAS: YES, PLEASE.

DR. PLUNKETT: I'LL JUST CLOSE REALLY QUICKLY HERE. I WON'T GO THROUGH ALL THE ASSUMPTIONS THAT WENT INTO THE EXPENSE FORECAST. YOU CAN SEE WHAT THEY ARE ON THE PREVIOUS SLIDE. AS I SAID TWO MONTHS AGO, YOU CAN PUT TOGETHER AN INFINITE NUMBER OF PERMUTATIONS OF SCENARIOS THAT GET YOU TO $90 MILLION. WHAT THIS SHOWS IS THAT WE CONTINUE WITH MODEST INCREASES IN OUR SPENDING THROUGH THE SUMMER OF 2017, WHICH WOULD BE FIVE YEARS FROM NOW, A YEAR AFTER OUR LAST SIGNIFICANT AWARDS ARE MADE. THIS SLOWLY TAPERS OFF THROUGH THE SUMMER OF 2022. AND ALL THIS, OF COURSE, ASSUMES THAT PROP 71 IS THE SOLE FUNDING WHICH CIRM RECEIVES.

THIS DOES REQUIRE THAT WE IDENTIFY AN ADDITIONAL $200,000 PER YEAR IN ONGOING EXPENSE SAVINGS TO KEEP THAT NUMBER AT 90 MILLION AND NOT 91 MILLION ON EACH SIDE OF THE GRANTS MANAGEMENT AND GNA. AND WE EXPECT TO COME BACK TO YOU WITH A PLAN

FOR THAT IN THE NEXT TWO MONTHS. WE'RE NOT TOO FAR AWAY.

ANY QUESTIONS? THANK YOU VERY MUCH FOR THE INPUT.

CHAIRMAN THOMAS: THANK YOU, MATT. OKAY. GOOD THINGS COME TO THOSE WHO WAIT. WE'VE HAD MANY VERY INTERESTING ITEMS ON THE AGENDA TODAY. PERHAPS WE HAVE LEFT THE MOST INTERESTING FOR LAST, WHICH IS THE REVIEW OF THE PROGRESS OF OUR DISEASE TEAMS VIA THE CLINICAL DEVELOPMENT ADVISORY PANELS. I'D LIKE TO NOW TURN IT BACK OVER TO DR. FEIGAL.

MR. HARRISON: JUST A REMINDER TO MEMBERS OF THE BOARD. WE'VE PROVIDED THOSE OF YOU WHO HAVE AN INTEREST IN AN AWARD WITH A SHEET OF PAPER THAT IDENTIFIES THE AWARD BY APPLICATION NUMBER, AND WE WOULD REQUEST THAT YOU REFRAIN FROM PARTICIPATING IN THE DISCUSSION OF THOSE AWARDS IN WHICH YOU HAVE AN INTEREST.

I WOULD ALSO LIKE TO POINT OUT QUICKLY THAT ELLEN AND STAFF HAVE PROVIDED A LOT OF INFORMATION PUBLICLY REGARDING THE DISEASE TEAMS AND THEIR PROGRESS. THERE MAY, HOWEVER, BE INFORMATION THAT YOU'D LIKE TO DISCUSS THAT IS CONFIDENTIAL OR PROPRIETARY IN NATURE, SUCH AS PREPUBLICATION DATA OR CONFIDENTIAL PRE-IND DISCUSSIONS WITH THE FDA, OR

THE SELECTION OF THERAPEUTIC TARGET, OR OTHER INFORMATION THAT'S OF THE NATURE WOULD GIVE ITS HOLDER A COMPETITIVE ADVANTAGE.

IF YOU HAVE QUESTIONS THAT PERTAIN TO THAT TYPE OF INFORMATION, PLEASE RESERVE THEM FOR CLOSED SESSION DISCUSSION, AND LET US KNOW AT THE END OF THE PUBLIC DISCUSSION IF YOU WOULD LIKE TO HAVE INFORMATION THAT FALLS INTO THOSE CATEGORIES.

CHAIRMAN THOMAS: JAMES, WE WOULD ASK THAT YOU CLOSELY MONITOR THE CONVERSATION IN CASE SOMEBODY GOES OVER THE LINE ONE WAY OR ANOTHER AND DIRECT THAT FOR CLOSED SESSION DISCUSSION. THANK YOU.

DR. FEIGAL: THANKS VERY MUCH. SO WHAT I'M GOING TO PRESENT TO YOU TODAY IS ACTUALLY SORT OF A SUMMARY OF THE CURRENT STATUS OF OUR 14 DISEASE TEAMS AS OF THIS MONTH, THE CONTEXT OF THE DISEASE TEAM PROGRAMS AT CIRM, A BRIEF OUTLINE OF EACH DISEASE TEAM PROJECT, THEIR KEY PROGRESS AND ACCOMPLISHMENTS TO DATE, THE STATUS OF THEIR PROGRESS TOWARDS FILING A SUCCESSFUL IND WITHIN FOUR YEARS, THE BUDGET ALLOCATED, AND THEN JUST A LITTLE BIT OF TIME ON HOW WE MAKE OUR ASSESSMENTS IN THE PROCESS BECAUSE WE THINK THAT'S IMPORTANT TO BE TRANSPARENT ABOUT HOW THESE DECISIONS ARE BEING

MADE.

FIRST OF ALL, WITH THE CONTEXT, YOU HEARD A TALK ABOUT THE STRATEGIC PLAN. YOU'VE HEARD A TALK ABOUT THE FUNDING PRIORITIES. TO REITERATE, OUR MISSION IS TO ADVANCE STEM CELL RESEARCH FOR THE DISCOVERY AND DEVELOPMENT OF CURES, THERAPIES, DIAGNOSTICS, AND RESEARCH TECHNOLOGIES TO RELIEVE HUMAN SUFFERING FROM CHRONIC DISEASE AND INJURY. WITH THAT MISSION IN MIND, OUR KEY STRATEGY TO PROGRESS THE STEM CELL SCIENCE INTO CLINICAL TRIALS, CIRM FUNDED 14 MULTIDISCIPLINARY DISEASE TEAMS IN 2010 WITH THE GOAL OF INITIATING THE DEVELOPMENT STUDIES THAT COULD POTENTIALLY LEAD TO THE SUCCESSFUL FILING OF AN INVESTIGATIONAL NEW DRUG APPLICATION WITH THE U.S. FOOD AND DRUG ADMINISTRATION FOR THESE STEM CELL-BASED THERAPIES TO ENTER HUMAN CLINICAL TRIALS OVER THE NEXT FOUR YEARS.

SO THIS IS PLACING THE DISEASE TEAM I, TRIED TO OUTLINE IT IN RED, WITHIN THE CONTEXT OF ALL THE OTHER PROGRAMS THAT WE FUND. YOU CAN SEE DISEASE TEAM I IS COVERING SOME OF WHAT WE CALL AS PRECLINICAL RESEARCH, STILL TRYING TO ESTABLISH SOME OF THE PRECLINICAL PROOF OF CONCEPT, THE SELECTION OF A DEVELOPMENT CANDIDATE, ALL THE WAY THROUGH TO

THE FILING OF AN IND. AS YOU CAN SEE A LITTLE BIT FARTHER DOWN ON THE BAR, DISEASE TEAM RESEARCH II, WHICH WE'RE GOING TO BE REVIEWING IN APRIL, NEXT MONTH, IS STARTING A LITTLE BIT MORE MATURE PRODUCT. SO THEY'RE ACTUALLY STARTING AT WHERE THEY'VE ALREADY SELECTED THE DEVELOPMENT CANDIDATE WITH THE HOPES BEING WE REALLY WANT TO TRY AS MUCH AS POSSIBLE TO FOCUS THAT COHORT OF DISEASE TEAMS SO THAT THEY'RE MORE LIKELY TO BE ABLE TO BE SUCCESSFUL WITHIN THAT PERIOD OF TIME.

WHAT YOU DON'T SEE ON HERE, OF COURSE, ARE THE DISEASE TEAM III'S WHICH WE'RE PLANNING TO HAVE COME OUT PROBABLY SOMETIME IN 2013 AND ALSO THE STRATEGIC PARTNERSHIP FUND, WHICH WE'RE GOING TO BE PUTTING OUT FOR POSTING IN APRIL, NEXT MONTH, AND ACTUALLY APPLICATIONS WILL COME IN IN JUNE FOR REVIEW IN AUGUST AND PRESENTATION TO THIS BOARD IN OCTOBER BECAUSE WHAT WE'RE ALSO TRYING TO THINK OF IS PLANNING FOR SUCCESS IF THESE PEOPLE DO -- RESEARCHERS ARE ABLE TO MEET THEIR GOAL, DO WE HAVE SOME KIND OF FOLLOW-ON INITIATIVE THAT COULD SEAMLESSLY TAKE THESE ON TO THE NEXT STEP?

SO THAT'S JUST PAINTING THE BIG PICTURE OF WHAT WE'RE TRYING TO DO HERE.

TO RECAP, THESE 14 DISEASE TEAMS ARE PART

OF A TRANSLATIONAL PORTFOLIO THAT PAT TALKED TO YOU ABOUT EARLIER -- ACTUALLY PAT AND I SPOKE TO YOU BACK IN OCTOBER OF LAST YEAR -- THAT INCLUDES EARLY TRANSLATION I AND II. WE HAVE PART OF THAT TRANSLATIONAL PORTFOLIO, JUST SO YOU HAVE THE CONTEXT, 20 THAT ARE IN EARLY TRANSLATION WHERE THEY'RE LOOKING AT TARGET IDENTIFICATION AND SELECTION OF A DEVELOPMENT CANDIDATE AND NINE THAT ARE IN EARLY TRANSLATION II WHERE A SUBSET OF THE STUDIES TO REALLY IDENTIFY A DEVELOPMENT CANDIDATE THAT COULD BE A POTENTIAL FOR MOVING ON.

IN TERMS OF THE TRANSLATIONAL PORTFOLIO, A LOT OF OUR -- THE PROPORTION OF OUR RESEARCH ARE DIRECTED TO THESE PARTICULAR DISEASE AREAS. FOR CANCER WE HAVE EIGHT AWARDS, FIVE IN DISEASE TEAMS, THREE IN EARLY TRANSLATIONAL. IN NEURODEGENERATION WE HAVE 14 AWARDS, TWO DISEASE TEAMS AND 12 IN EARLY TRANSLATIONAL.

SO, JOAN, YOU HAD ASKED EARLIER A LITTLE BIT ABOUT SOME OF THE SPECTRUM OF THE DIFFERENT GROUPS THAT WE'RE FUNDING.

MS. SAMUELSON: WERE THOSE NUMBERS IN HERE, OR COULD YOU PROVIDE THEM?

DR. FEIGAL: THEY ARE IN -- NO, THEY'RE IN MY PRESENTATION, WHICH WILL BE PROVIDED TO YOU.

THE DISEASE TEAMS, AS WE ALL KNOW, ARE ADDRESSING MAJOR UNMET CLINICAL NEEDS AND ARE MOVING TOWARDS THE CLINIC. I'M GIVING YOU THEIR POINT IN THE DIFFERENT DISEASE AREAS. WE HAVE ONE DISEASE TEAM IN DIABETES, TWO IN NEUROLOGIC DISORDERS, ONE IN EYE DISEASE, ONE IN CARDIAC, TWO IN HIV/AIDS, FIVE IN CANCER, ONE IN A BLOOD DISORDER, SICKLE SELL ANEMIA, AND ONE IN A VERY RARE SKIN DISORDER, DYSTROPHIC EPIDERMOLYSIS BULLOSA.

THIS IS AN OVERVIEW OF ALL 14 DISEASE TEAMS. AND WHAT YOU HAVE HERE IS THE GRANT AND THE PI, THE PROJECT START DATE. YOU CAN SEE THEY STARTED ANYWHERE FROM FEBRUARY THROUGH JUNE OF 2010. THE AMOUNT OF AWARD THAT THEY RECEIVED AND THEIR CURRENT STATUS.

WHAT YOU CAN SEE IS THAT 13 OF THE 14 DISEASE TEAMS ARE CONTINUING. ONE OF THEM IS TERMINATING AS OF THE END OF THIS MONTH. THAT'S THE DR. BERGER TEAM. AND ONE IS CONTINUING WITH REVISIONS, AND THAT'S THE DR. CARSON TEAM. AND I'LL BE EXPLAINING THAT AS I GO THROUGH EACH TEAM.

I WANTED TO TELL YOU A LITTLE BIT ABOUT THE PROCESS BEFORE I TELL YOU ABOUT THE ACCOMPLISHMENTS AND PROGRESS. ALL OF THESE TEAMS HAVE WORKED WITH CIRM SCIENTIFIC STAFF AND ALSO WITH

OUR BUDGET PEOPLE TO WORK ON MILESTONES AND THE EXPERT ADVICE THEY MAY NEED TO BETTER POSITION THE TEAMS FOR SUCCESS. SO AFTER THE BOARD APPROVES THESE AWARDS AND BEFORE FUNDING GOES OUT THE DOOR, CIRM AND THE DISEASE TEAMS AGREED ON GO/NO-GO AND ON PROGRESS MILESTONES AND ON CRITERIA TO INFORM DECISIONS AND THEN A BUDGET TO SUPPORT THOSE PROPOSED ACTIVITIES.

IN ADDITION, COMPLEMENTING THEIR QUARTERLY AND ANNUAL REPORTING TO US WITH CIRM, THE DISEASE TEAMS MEET WITH CIRM AND PANELS OF CLINICAL DEVELOPMENT ADVISORS AT THEIR 12- TO 18-MONTH MARK OF THEIR PROGRESS. AND THIS TYPE OF MEETING IS GOING TO CONTINUE ON AN ANNUAL BASIS.

THIRDLY, THE CONVENING OF THE CLINICAL DEVELOPMENT ADVISORS TO PROVIDE EXTERNAL INPUT INTO THE MILESTONES PROCESS WAS APPROVED IN CONCEPT PLAN FOR THE DISEASE TEAM SOLICITATION. IT WAS IDENTIFIED IN THE DISEASE TEAM RFA, AND IT WAS SUBSEQUENTLY COMMUNICATED TO ALL OF THE DISEASE TEAMS.

AND I DO WANT TO CLARIFY THAT TO PREVENT EVEN THE APPEARANCE OF A CONFLICT OF INTEREST, CIRM HAS APPLIED THE GRANT WORKING GROUP CONFLICT OF INTEREST RULES TO THE CLINICAL DEVELOPMENT ADVISOR

PANELS, THAT CLINICAL DEVELOPMENT ADVISORS WHO HAD A FINANCIAL, PROFESSIONAL, OR PERSONAL CONFLICT OF INTEREST WITH RESPECT TO ONE OF THE AWARDS WERE DISQUALIFIED FROM PARTICIPATING IN THE PANEL'S DELIBERATIONS.

THE PANELS THEMSELVES ARE COMPOSED OF EXPERTS IN PRODUCT DEVELOPMENT. THEY INCLUDE PRECLINICAL AND CLINICAL RESEARCH, PROCESS DEVELOPMENT AND MANUFACTURING, REGULATORY STANDARDS, STEM CELL-DISEASE SPECIFIC BIOLOGY, DISEASE-SPECIFIC CLINICAL EXPERTISE, AND COMMERCIAL RELEVANCE.

THEY'RE CONVENED TO REALLY PROVIDE ADVICE AND RECOMMENDATIONS ON PROJECT STRATEGY, ON PROGRESS IN MEETING GOALS, AND ON GO/NO-GO DECISION POINTS, AND APPROACHES TO MEETING CHALLENGES IN THE PRODUCT DEVELOPMENT RESEARCH. SO THEY'RE REALLY THERE IN REAL TIME TO HELP PROVIDE ADVICE TO THE TEAMS TO US. THEY PROVIDE RECOMMENDATIONS. THEY DO NOT MAKE DECISIONS. THE RECOMMENDATIONS ARE PROVIDED TO ME, TO THIS POSITION, AND WE CONSIDER IT INTERNALLY, AND WE, UNDER THE GUIDANCE OF THE PRESIDENT OF CIRM, WE MAKE THE FINAL DECISIONS AND FOLLOW UP WITH THE DISEASE TEAMS ON THESE ISSUES.

THESE ARE THE ADVISORS THAT WE'VE ASKED TO COMMENT ON THE VARIOUS TEAMS. AND I HAVE TWO SLIDES

OF THIS WHICH YOU WILL GET. BUT WE'VE HAD 28 DIFFERENT ADVISORS BE PART OF THESE VARIOUS PANELS.

IN ADDITION, FOR FOUR OF THESE 14 DISEASE TEAMS, WE'VE HAD COLLABORATIVE FUNDING PARTNERS, TWO FROM THE UK AND TWO FROM CANADA. FROM CANADA THESE HAVE BEEN DRS. CARSON AND SLAMON TEAM, AND FOR THE UK, IT'S BEEN THE DR. HUMAYUN AND DR. WEISSMAN TEAM.

AND THE COLLABORATIVE FUNDING PARTNERS PARTICIPATE IN THE CLINICAL DEVELOPMENT ADVISOR PANEL DISCUSSIONS, AND THEY ALSO PROVIDE RECOMMENDATIONS FOR ADVISORS FOR THOSE JOINTLY FUNDED PROJECTS.

I ALSO WANT TO MENTION THAT OUR SCIENCE OFFICERS ARE ACTIVELY INVOLVED IN THE DAY-TO-DAY MANAGEMENT OF THESE DISEASE TEAMS. THIS IS NOT THE ONLY THING THEY DO. THEY ALSO HAVE A VERY LARGE PORTFOLIO OF OTHER ACTIVITIES, BUT I DID WANT TO DRAW ATTENTION TO THE PEOPLE WHO ARE DOING THE LION'S SHARE OF THE WORK IN TERMS OF MANAGEMENT. THAT'S DR. CAREN BERRY, DR. KARIS, DR. OLSON, DR. STEFFEN, DR. TALIB. AND ALSO PROVIDING SCIENTIFIC SUPPORT IS DR. SHINER AND DR. WHITTLESEA.

SO TO GET TO THE MEAT, I'M GOING TO BASICALLY SUMMARIZE CONCISELY THE 14 DIFFERENT DISEASE TEAMS, THE THERAPEUTIC CANDIDATE, THE KEY

ACCOMPLISHMENTS, AND THEIR STATUS. YOU WILL HAVE ACCESS TO ALL OF THESE SLIDES, BUT YOU ALSO HAVE THE PREREAD WHICH I THINK GOES THROUGH MUCH OF THIS MATERIAL.

IN THIS FIRST DISEASE TEAM, THE INVESTIGATOR WAS REALLY FOCUSED ON A VERY DIFFICULT TUMOR TO TREAT, AND THAT'S RECURRENT GLIOBLASTOMA, A TYPE OF BRAIN TUMOR THAT HAS A PARTICULARLY POOR PROGNOSIS AND WHICH THERE ARE VERY FEW THERAPEUTIC OPTIONS. AND THE THERAPEUTIC OPTIONS THAT ARE THERE HAVE VERY MODEST IMPACT ON THE TUMOR. HERE THEY'RE WORKING ON AN ALLOGENEIC HUMAN NEURAL STEM CELL LINE TO TARGET THE TUMORS. AND HERE IT'S REALLY ENGINEERED TO DELIVER AN ENZYME CALLED CARBOXYESTERASE TO CONVERT A CHEMOTHERAPY DRUG CALLED CPT 11 TO MORE POTENT ACTIVE METABOLITE SN38 AT THE SITE OF THE INVASIVE TUMOR.

IN THE BRAIN YOU USUALLY DON'T HAVE THE CONVERTING ENZYME PRESENT. SO HERE THE STEM CELLS ARE BEING UTILIZED AS A TOOL TO DELIVER THE CHEMOTHERAPY PAYLOAD. AND IN ORDER FOR THE CHEMOTHERAPY PAYLOAD TO BE EFFECTIVE IN THE BRAIN, IT NEEDS TO HAVE THE CONVERTING ENZYME BE PRESENT AT THE SITE WHERE THE TUMOR IS LOCATED. SO THAT'S WHY THEY'VE ENGINEERED IT THIS WAY, THAT THE NEURAL STEM

CELLS ARE HOMING TO THE BRAIN TUMOR. THE ENZYME IS THERE TO CONVERT THE CHEMOTHERAPY TO THE ACTIVE METABOLITE.

THEIR KEY ACCOMPLISHMENTS ARE THAT THEY HAVE SELECTED THEIR FINAL THERAPEUTIC CANDIDATE THAT'S BEING DEVELOPED UNDER GOOD MANUFACTURING PRACTICES FOR THE CLINIC. THEY HAVE INVESTIGATED THE OPTIMAL ROUTE OF ADMINISTRATION AND THE DOSE OF NEURAL STEM CELLS TO ACHIEVE THE MAXIMUM PERCENTAGE OF TUMOR COVERAGE. THEY HAVE ELECTED TO INJECT BY THE INTRACRANIAL ROUTE DIRECTLY INTO THE BRAIN TUMOR. BUT IN ADDITION, THEY DO HAVE EVIDENCE OF EFFICACY WITH AN INTRAVENOUS APPROACH. SO THEY ARE ALSO GOING TO BE PURSUING AN I.V. ROUTE AS WELL BECAUSE THEY FEEL THAT THAT WOULD BE A MORE FEASIBLE WAY TO DELIVER THE CHEMOTHERAPY AND SOMETHING THAT COULD BE DONE MORE EASILY IN THE CLINIC.

THE DRUG WHEN DELIVERED IN THIS WAY HAS A THOUSAND MORE TOXICITY TO BRAIN TUMOR CELLS THAN CHEMOTHERAPY ALONE. THIS TEAM HAS ALSO DEVELOPED A WAY TO TRACK THE CELLS ONCE THEY'RE INJECTED. THEY DEVELOPED A NOVEL IRON NANOPARTICLE TO TRACK THE STEM CELLS THROUGH NONINVASIVE IMAGING THROUGH MAGNETIC RESONANCE IMAGING. THEY'VE HAD ONE PUBLICATION, 200 REVIEWS, AND 11 PRESENTATIONS.

IN ADDITION, THEY FOUNDED A COMPANY CALLED THERABIOLOGICS. AND THEIR STATUS RIGHT NOW IS THAT THEY'RE COMPLETING THEIR PRECLINICAL PROOF OF CONCEPT EFFICACY, THEY SHOULD COMPLETE THAT IN THE FALL OF THIS YEAR, AND HAVE A PRE-IND DISCUSSION WITH THE FDA. AT THIS POINT IN TIME, THERE'S NO FINANCIAL OR TIMELINE IMPACT TO THE PROJECT.

THE NEXT TEAM, ALSO WORKING ON RECURRENT GLIOBLASTOMA, THE SAME INDICATION MENTIONED EARLIER, IS DR. BERGER. HE WAS TAKING A DIFFERENT APPROACH. HE WAS LOOKING AT ALLOGENEIC HUMAN NEURAL STEM CELLS OR MESENCHYMAL STEM CELLS. THEY WERE ACTUALLY LOOKING AT THREE DIFFERENT SOURCES TO TRY AND SELECT A THERAPEUTIC CANDIDATE TO TARGET THE TUMORS. HERE IT WAS ENGINEERED TO DELIVER A GENE PRODUCT THAT WAS TOXIC TO TUMORS. IT WAS 5FC IN THIS INSTANT. THEY WERE USING TWO DISTINCT -- THEY WERE TRYING TO DISTINGUISH WHICH GENE MODIFICATION TO MAKE. AND SO THEY HAD TWO DIFFERENT GENE MODIFICATIONS THEY WERE LOOKING AT. AND THEY WERE ALSO LOOKING AT ROUTE OF ADMINISTRATION, WHETHER IT COULD BE GIVEN INTRAVENOUSLY, WHICH COMMERCIALLY MIGHT BE OF BETTER BENEFIT, OR DID IT NEED TO BE DELIVERED INTRACRANIALLY DIRECTLY TO THE TUMOR SITE.

SO THEY HAVE THREE DIFFERENT SOURCES OF

THERAPEUTIC CANDIDATE TO LOOK AT. THEY HAD TWO DIFFERENT GENE PRODUCTS TO LOOK AT. AND THEY HAD TWO DIFFERENT ROUTES OF ADMINISTRATION TO LOOK AT. SO THEY HAD A LOT OF VARIABLES THAT THEY NEEDED TO MAKE A DECISION ABOUT.

WHAT THEY FOUND FROM THEIR RESEARCH IS THAT THE STEM CELLS DID NOT REACH THE BRAIN TUMORS BY THE INTRAVENOUS ROUTE. THIS IS ACTUALLY DIFFERENT THAN WHAT THE OTHER TEAM WAS ABLE TO SHOW. THEY SHOWED THAT THEY COULD NOT DISTINGUISH BETWEEN THE NEURAL OR THE MESENCHYMAL STEM CELLS IN TERMS OF THEIR ABILITY TO DISPERSE TO TUMORS. THEY WERE ABLE TO SHOW THAT THEY WERE AROUND THE TUMOR. THEY WERE NOT ABLE TO SHOW ACTUALLY THAT IT COULD SELECTIVELY HOME TO THE TUMOR.

THEY DID SHOW THAT THE UNMODIFIED NEURAL STEM CELLS DID NOT HAVE SUFFICIENT PROLIFERATIVE CAPACITY FOR PRODUCTION AS THERAPEUTIC STEM CELLS.

THEY HAD SOME IN VITRO STUDIES THAT SHOWED SOME BETTER ANTITUMOR ACTIVITY WHEN THE STEM CELLS WERE MODIFIED WITH ONE GENE PRODUCT AS OPPOSED TO THE OTHER GENE PRODUCT.

THEY WERE ABLE TO PUT OUT TWO PUBLICATIONS, AND THEY ALSO DEVELOPED TWO METHODS FOR DETECTING HUMAN CELLS, AND THEY ALSO DEVELOPED A

XENOGRAPH PRECLINICAL MODEL THAT COULD POTENTIALLY BE USEFUL IN THERAPEUTIC TESTING FOR PEOPLE WHO ARE TRYING TO DEVELOP INTERVENTIONS IN THIS CLINICAL INDICATION THAT HAS A VERY HIGH UNMET NEED.

SO WE HAVE A TEAM THAT ACTUALLY WAS VERY MUCH PURSUING THE RIGHT STUDIES. THE DATA DID NOT GO IN THE DIRECTION THEY WOULD HAVE LIKED FOR THEM TO BE ABLE TO SELECT A THERAPEUTIC CANDIDATE, A GENE PRODUCT, AND HAVE SUFFICIENT EVIDENCE THAT THIS WOULD HAVE A CHANCE FOR SUCCESS. THIS DID GO THROUGH AN EVALUATION WITH THE CLINICAL DEVELOPMENT ADVISORS. WE DID HAVE MULTIPLE DISCUSSIONS WITH THE TEAM. AND THE STATUS IS THAT THEY WERE NOT ABLE TO SELECT A CELL CANDIDATE ACCORDING TO THE SELECTION CRITERIA, AND THIS IS A NO-GO MILESTONE. THEY WERE NOT ABLE TO MEET IT. AND SO WE ARE TERMINATING THE AWARD AS OF THIS MONTH, AND THE ESTIMATED SAVINGS ARE APPROXIMATELY 13 MILLION.

THE NEXT TEAM IS DR. CARSON'S TEAM. THIS IS A TEAM THAT'S WORKING IN COLLABORATION WITH THE CANADIAN COLLABORATIVE FUNDING PARTNER, JOHN DICK IN TORONTO. HERE THE TEAM IS LOOKING IN THE DISEASE INDICATION OF LEUKEMIAS. THEY WERE GOING TO LOOK IN FOUR DIFFERENT INDICATIONS IN ACUTE LYMPHOCYTIC LEUKEMIA, CHRONIC LYMPHOCYTIC LEUKEMIA, ACUTE

MYELOGENOUS LEUKEMIA, AND CHRONIC MYELOGENOUS LEUKEMIA, AND THEY WERE ALSO GOING TO LOOK AT T-CELLS AND B-CELLS IN THESE DIFFERENT TYPES OF LEUKEMIAS.

JUST OF NOTE, LEUKEMIAS HAVE DIFFERENT TYPES OF CHEMOTHERAPY THAT ARE GIVEN TO THEM DEPENDING ON THE TYPE OF CELL TYPE THAT IT IS AND ALSO WHETHER IT'S ACUTE OR CHRONIC. SO THERE'S DIFFERENT TYPES OF THERAPEUTIC INTERVENTIONS THAT TAKE PLACE. AND ALSO THESE DIFFERENT TYPE OF LEUKEMIAS HAVE DIFFERENT BIOLOGICAL CHARACTERISTICS AND MOLECULAR CHANGES THAT DRIVE THE TUMOR.

THIS TEAM WAS LOOKING AT THREE SMALL MOLECULES AND THREE MONOCLONAL ANTIBODIES, ALL OF WHICH WERE LOOKING AT VARIOUS MARKERS IN THE CANCER STEM CELL TO DEVELOP THERAPIES TARGETING SURVIVAL AND SELF-RENEWAL PATHWAYS IN THE LEUKEMIC STEM CELLS.

THEIR KEY ACCOMPLISHMENTS WERE THAT THEY WERE ABLE TO SHOW SOME EFFICACY WITH ONE OF THE MONOCLONAL ANTIBODIES THAT BLOCKED A PARTICULAR PATHWAY THAT'S IMPORTANT FOR SIGNALING IN ONE OF TYPES OF LEUKEMIAS, CHRONIC LYMPHOCYTIC LEUKEMIA, AND THEY HAVE EVIDENCE OF SOME ACTIVITY WITH A SMALL MOLECULE INHIBITING THE JAK2 KINASE IN ACUTE

MYELOGENOUS LEUKEMIA, AND THEY ALSO LOOKED AT THIS IN SERIAL TRANSPLANT MODELS IN PRECLINICAL SETTING USING PATIENT LEUKEMIA CELLS.

THEY'VE ALSO BEEN ABLE TO CONDUCT EXTENSIVE GENOMIC STUDIES TO DEVELOP A LEUKEMIA STEM CELL BIOMARKER SIGNATURE, LOOKING FOR RESPONSE AND RESISTANCE. AND THEY FEEL THAT THIS MARKER-TYPE STUDIES COULD HAVE POTENTIAL UTILITY IN HELPING TO INDIVIDUALIZE THERAPIES AND HOPEFULLY IMPROVING RESPONSE.

SO THEIR STATUS, THERE WAS A CLINICAL DEVELOPMENT ADVISORY MEETING. THEY CONSIDERED A VARIETY OF ISSUES. WE HAD INTERNAL DELIBERATIONS. AND WHAT WE RECOMMENDED TO THE TEAM IS THAT THEY FOCUS THEIR WORK ON TWO THERAPEUTIC INTERVENTIONS AND TWO DISEASE INDICATIONS, THOSE THAT ACTUALLY HAD THE HIGHER LIKELIHOOD OF HAVING THE POTENTIAL FOR SUCCESS. AND SO THEY'RE FOCUSING THEIR ATTENTION -- THIS IS STILL WITHIN THE SCOPE OF THEIR ORIGINAL RESEARCH. IT'S JUST FOCUSING THEM. AND SO WE FOCUSED ON CHRONIC LYMPHOCYTIC LEUKEMIA AND ACUTE MYELOGENOUS LEUKEMIA, AND WE WERE FOCUSED ON THE MOLECULES BY WHICH THEY THINK THEY WILL HAVE A BETTER PROBABILITY OF SUCCESS. THEIR BUDGET AND TIMELINES ARE BEING ASSESSED AND REALIGNED

ACCORDINGLY.

CHAIRMAN THOMAS: I HAVE A QUESTION ON THAT, ELLEN. I KNOW THAT THE TEAM WAS QUITE HIGH ON THE LEUKEMIA STEM CELL SIGNATURE ASPECT OF THE PROJECT AND SORT OF WAS A PORTENT OF INDIVIDUALIZED THERAPY, ETC. UNDER THE RECOMMENDATION ON HOW TO PROCEED AS MODIFIED, WHERE DOES THAT ELEMENT FACTOR IN?

DR. FEIGAL: WELL, THE GENOMICS WORK WOULD CONTINUE TO BE DONE AS RELEVANT FOR THE DEVELOPMENT IN THOSE TWO DISEASE INDICATIONS.

DR. LEVIN: JUST REAL QUICK. I'M WONDERING IF YOU'RE ANTICIPATING ANY COST SAVINGS FROM THAT, OR YOU'RE JUST REFOCUSING THE MONEY THAT HAS BEEN ALLOCATED INTO THOSE TWO CANDIDATES.

DR. FEIGAL: WE'RE IN THE PROCESS OF LOOKING AT IT RIGHT NOW BECAUSE PART OF IT IS TAKING A HARD LOOK AT THE BUDGET TO SEE DID THEY REALLY BUDGET APPROPRIATELY FOR ALL THE ACTIVITIES THEY REALLY NEED TO DO TO BRING IT ALL THE WAY FORWARD. SO RIGHT NOW WITH THE REFOCUSING, WE DON'T KNOW IF WE'RE GOING TO HAVE COST SAVINGS, BUT WE DEFINITELY KNOW THAT THEY'RE GOING TO BE MORE FULLY RESOURCED TO ACTUALLY BE FOCUSING ON THOSE TWO INDICATIONS AND THOSE TWO THERAPEUTIC INTERVENTIONS.

DR. LEVIN: IT'S MORE A REALLOCATION OF RESOURCES.

DR. FEIGAL: AT THIS POINT IN TIME, IT'S A REALIGNMENT, AND WE'RE STILL GOING THROUGH THE DIFFERENT DISCUSSIONS ABOUT THIS. OKAY?

THE NEXT TEAM IS DR. HUMAYUN. DR. HUMAYUN IS WORKING ON A PROBLEM IN VISION. IT'S CALLED AGE-RELATED MACULAR DEGENERATION. IT'S A DISEASE AS ONE GETS OLDER, THERE'S A PROBLEM AT THE BACK OF THE EYE WHERE THE RETINAL EPITHELIUM IS NO LONGER ABLE TO NOURISH THE PHOTORECEPTORS WHICH ARE CRITICAL FOR OUR VISION. SO THEY'RE WORKING -- THEIR THERAPEUTIC CANDIDATE IS ACTUALLY A COMBO PRODUCT. THEY'RE WORKING ON HUMAN EMBRYONIC STEM CELL-DERIVED RETINAL PIGMENT EPITHELIUM ON A SYNTHETIC MATRIX WHICH IS NONBIODEGRADABLE. THIS MATRIX MIMICS THE MEMBRANE, THE BRUCH'S MEMBRANE, IT'S CALLED, AT THE BACK OF THE EYE. AND IT'S IMPORTANT FOR THESE CELLS TO BE ON THIS TYPE OF A SCAFFOLD BECAUSE IT'S NOT JUST THE CELLS. IT'S THE LOCATION OF THE CELLS IN THE EYE AND THEIR ABILITY TO CONNECT WITH THE PHOTORECEPTORS. SO THERE'S A CERTAIN ORIENTATION THAT THESE CELLS NEED TO HAVE. SO THAT'S WHY IT'S ON A SCAFFOLD. SO IT'S IMPORTANT FOR ATTACHMENT SURVIVAL AND DIFFERENTIATION OF THESE CELLS.

THIS IS A GROUP THAT IS WORKING PARTIALLY FUNDED BY THE UK, MRC, AS A COLLABORATING FUNDING PARTNER. PETER COFFEY, AS YOU KNOW, ALSO MOVED HIS LOCATIONS TO UC SANTA BARBARA, AND SO THAT COLLABORATION IS CONTINUING.

THEIR KEY ACCOMPLISHMENTS ARE THAT THEY DESIGNED A VERY THIN MATRIX THAT HAS SUFFICIENT MECHANICAL STRENGTH FOR CULTURING AND SURGICAL HANDLING, AND IT HAS PERMEABILITY CHARACTERISTICS SO THAT THAT MIMICS THE MEMBRANE AT THE BACK OF THE EYE SO THAT IT ALLOWS THE PASSAGE OF PROTEINS THAT NEED TO GET IN TO HELP NOURISH THINGS, BUT IT PREVENTS THE MIGRATION OF STEM CELLS TO LOCATIONS WE DON'T WANT THE STEM CELLS TO GO.

THEY HAVE SEVEN PATENT FILINGS THAT COVERS THIS MATRIX, INCLUDES THE PLACEMENT OF THE CELLS ON THE MATRIX, THE METHODS TO PRODUCE THE RETINAL PIGMENT EPITHELIAL CELLS, A PATENT TO TRACK THE CELLS AFTER IMPLANTATION, AND THE SPECIALIZED INSTRUMENTATION THAT'S NEEDED FOR SURGERY DELIVERY OF IMPLANT.

THEY HAVE DONE A PROOF OF CONCEPT PRECLINICALLY AFTER IMPLANTATION IN A PRECLINICAL MODEL. THEY'VE SHOWED SUCCESSFUL CONNECTIONS, THAT INTERDIGITATION OF THE TRANSPLANTED CELLS AND MATRIX

WITH THE HOST PHOTORECEPTORS THAT HAVE SHAPE AND FUNCTIONAL RESCUE OF THE PHOTORECEPTORS AND RESCUE OF VISION. THEY'VE ALSO CREATED A SPIN-OFF COMPANY, REGENERATIVE PATCH TECHNOLOGIES.

THEIR STATUS IS THAT THEIR TIMELINES AND FINANCIALS ARE UNCHANGED, AND THEY ARE CONTINUING TO MAKE PROGRESS.

THE NEXT TEAM IS DR. SLAMON.

DR. PRIETO: I HAD A QUESTION. IF YOU COULD GO BACK TO THE PREVIOUS SLIDE. IN THE ACCOMPLISHMENTS, THE PROOF OF CONCEPT, HOW ARE THEY ASSESSING RESCUE OF VISION?

DR. FEIGAL: THIS IS IN A PRECLINICAL ANIMAL MODEL IN MICE WITH -- THERE'S ACTUALLY A GUIDANCE DOCUMENT OUT THERE BY THE FDA THAT JUST CAME OUT PROBABLY WITHIN THE PAST FEW MONTHS ABOUT HOW TO DO END POINTS IN CLINICAL ASSESSMENT OF VISION AND PRECLINICAL. SO THEY'RE ACTUALLY FOLLOWING VALIDATED MODELS FOR LOOKING AT HOW TO ASSESS THIS IN MICE. THERE'S ACTUALLY -- I COULD GO INTO MORE DETAIL.

DR. PRIETO: I'M JUST CURIOUS HOW YOU DO THAT.

DR. FEIGAL: IT'S TRACKING. OBVIOUSLY MICE ARE NOT READING AN EYE CHART. SO IT WOULD BE

INTERESTING TO TRY. BUT THERE'S A WAY TO TRACK THE EYE MOVEMENTS AND TRACKING -- I'M NOT AN EXPERT IN THIS, BUT I DID LOOK INTO IT BECAUSE I TOO WAS CURIOUS HOW YOU DO THAT. SO THEY DISTINGUISH BETWEEN BLACK AND WHITE, TO SEE THE DIFFERENCE BETWEEN LIGHT AND NIGHT. AND THEY ALSO CAN SHOW THAT THEY'RE TRACKING. THEY'RE PUT INTO THIS DEVICE WHERE SOMETHING ROTATES AROUND THEM, AND THEY MONITOR THE TRACKING OF THE EYE. IT'S VERY INTERESTING.

DR. PRIETO: ALSO JUST CURIOUS. THANK YOU.

DR. FEIGAL: I CAN SEND YOU SOME REFERENCES ON IT IF YOU'RE INTERESTED IN READING MORE ABOUT IT.

DR. SLAMON IS WORKING ON CANCER STEM CELLS IN SOLID CANCER. SO THE PREVIOUS TEAM YOU HEARD ABOUT, DR. CARSON, IS WORKING ON HEMATOLOGIC MALIGNANCIES. DR. SLAMON IS WORKING ON CANCER STEM CELLS IN SOLID CANCERS.

HE'S LOOKING AT NOVEL SMALL MOLECULE INHIBITORS OF TWO KINASES THAT TARGET CANCER STEM CELLS IN BRAIN TUMORS, A GLIOMA, IN COLON CANCER AND OVARIAN CANCER. AND HE'S WORKING IN COLLABORATION WITH A CANADIAN COLLABORATIVE FUNDING PARTNER,

DR. TAK MAK IN TORONTO.

THEIR ACCOMPLISHMENTS IS THAT THEY DO HAVE A FIRST LEAD CANDIDATE MOLECULE THAT HAS SHOWN EFFICACY IN PRECLINICAL MODELS USING HUMAN TUMORS SPECIFICALLY TARGETING CANCER STEM CELLS ALTHOUGH IT DOES APPEAR THAT THEY HAVE DO HAVE IMPACT ON THE NONCANCER STEM CELLS AS WELL. HE IS WORKING AT SOME OF THE VERY INTERESTING NONINVASIVE IMAGING TECHNIQUES TO TRY AND DISTINGUISH THE IMPACT ON THE CANCER STEM CELL VERSUS THE NONCANCER STEM CELL TUMOR. HE IS MOVING INTO IND-ENABLING STUDIES. THE TEAM IS ALSO WORKING ON A SECOND MOLECULE TARGETING A DIFFERENT NOVEL PATHWAY IN THE CANCER STEM CELL. HE IS MAKING VERY GOOD PROGRESS, AND HIS TIMELINES AND FINANCIALS REMAIN UNCHANGED.

DR. WEISSMAN IS LOOKING AT CANCER STEM CELLS IN ACUTE LEUKEMIA. HIS THERAPEUTIC CANDIDATE IS A MONOCLONAL ANTIBODY. IT'S A HUMAN ANTI-CD47 MONOCLONAL ANTIBODY. IT'S DIRECTED AGAINST THE CELL SURFACE TARGET THAT'S PREFERENTIALLY EXPRESSED ON ACUTE MYELOID LEUKEMIA, AND ALSO IT DOES APPEAR TO BE EXPRESSED ON OTHER CANCER STEM CELLS IN OTHER SOLID TUMOR. CD47 FUNCTIONS AS IN DR. WEISSMAN'S TERM A DON'T EAT ME SIGNAL. SO BASICALLY LEUKEMIA CELLS HAVE THIS ON THEIR SURFACE, AND THE CELLS THAT

WOULD NORMALLY CHEW THEM AND EAT THEM UP, SOMEHOW IT SENDS OUT A SIGNAL TO DON'T EAT ME. SO THE LEUKEMIA STEM CELLS ARE ABLE TO SURVIVE.

AND HE'S NOW DEVELOPED A MONOCLONAL ANTIBODY TO APPARENTLY INTERRUPT THIS SIGNALING SO THAT THE LEUKEMIA STEM CELLS CAN NOW BE EATEN. HIS KEY ACCOMPLISHMENTS ARE THAT HE'S HUMANIZED AND EVALUATED A NUMBER OF CANDIDATE ANTI-CD47 ANTIBODIES THAT ARE AIMED AT THE CANCER STEM CELL IN ACUTE MYELOGENOUS LEUKEMIA. HE'S FILED A PATENT COVERING THE SEQUENCE AND USES FOR THE LEAD THERAPEUTIC CANDIDATE. HE'S SHOWN OF PROOF OF CONCEPT EFFICACY. HE HAS ERADICATED LEUKEMIA IN A TUMOR-BEARING XENOGRAPH MODEL OF PRIMARY LEUKEMIC CELLS FROM PATIENTS WITH ACUTE MYELOGENOUS LEUKEMIA. HE'S CONDUCTING PRECLINICAL DOSE EXPLORATION AND PILOT SAFETY STUDIES IN THESE PRECLINICAL MODELS.

THE MRC-FUNDED UK COMPONENT IS COLLECTING AND ANALYZING SAMPLES FROM PATIENTS ENROLLED IN ACUTE MYELOGENOUS LEUKEMIA TRIALS IN THE UK TO EVALUATE THE DIAGNOSTIC AND PROGNOSTIC VALUE OF CD47 AS BEING A DRIVER FOR LEUKEMIA RELAPSE. SO HE HAS A NICE TRANSLATIONAL COMPONENT WITH PEOPLE WORKING ON HUMAN SPECIMENS IN THE UK THAT'S COMPLEMENTARY TO WHAT HE'S DOING HERE.

THE STATUS OF THIS TEAM IS THAT THEY'RE PURSUING PRECLINICAL SAFETY AND EFFICACY, AND THE TIMELINES AND FINANCIALS REMAIN UNCHANGED.

DR. GOLDSTEIN IS WORKING ON AMYOTROPHIC LATERAL SCLEROSIS. IT'S A NEURODEGENERATION DISEASE. AT THIS POINT IN TIME, THERE REALLY ARE NO GOOD THERAPEUTIC OPTIONS TO TREAT THIS DISEASE. HE'S WORKING ON HUMAN EMBRYONIC STEM CELL-DERIVED ASTROCYTE PRECURSOR CELLS FOR SUBSEQUENT DEVELOPMENT OF A PRODUCT THAT WILL BE INJECTED INTO THE PATIENT'S SPINAL CORD.

HIS KEY ACCOMPLISHMENTS ARE THAT HE HAS GENERATED CELLS FROM DIFFERENT SOURCES OF THESE CELLS. HE'S IN THE PROCESS OF IDENTIFYING CELL LINES WITH THE BEST CHARACTERISTICS OF MINIMAL TOXICITY AND EFFICIENT PRODUCTION OF THE FINAL CELL TYPE. AND HE HAS LOOKED AT PRECLINICAL PROOF OF CONCEPT DEMONSTRATING THAT THESE STEM CELLS CAN PROTECT MOTOR NEURON VIABILITY IN A PRECLINICAL MODEL.

HIS STATUS IS THAT HE IS ON TRACK FOR SELECTING A SINGLE CELL LINE IN MID-2012, AND THE TIMELINES AND FINANCIALS REMAIN UNCHANGED.

MR. TORRES: ON THE GOLDSTEIN PROPOSAL, WHAT TYPE OF ANIMALS ARE BEING USED?

DR. FEIGAL: THESE ARE IN MICE.

CHAIRMAN THOMAS: NOT THE PORCINE THAT WE HEARD ABOUT EARLIER. THANK YOU.

DR. FEIGAL: MARBAN IS WORKING ON -- YOU ACTUALLY HEARD MARBAN AT THE LAST JANUARY BOARD MEETING. HE WAS NOT TALKING ABOUT THE THERAPEUTIC CANDIDATE THAT WE'RE FUNDING. HE WAS ACTUALLY TALKING ABOUT AN AUTOLOGOUS CANDIDATE. HE INITIALLY CAME INTO THIS DISEASE TEAM WANTING TO LOOK AT AUTOLOGOUS WHAT'S CALLED CARDIAC-DERIVED CARDIOSPHERES. THEY'RE SORT OF CLUMPS OR BALLS OR CLUSTERS OF STEM CELLS OR CARDIOSPHERE-DERIVED CELLS. THEY'RE SEPARATED CELLS. THEY'RE NOT TOGETHER IN A SPHERE AND A CLUMP FOR EVALUATING THEIR UTILITY IN ADVANCED ISCHEMIC CARDIOMYOPATHY, BASICALLY POST-MI HEART FAILURE.

HIS KEY ACCOMPLISHMENTS ARE THAT HE'S DISCOVERED THAT ALLOGENEIC CELLS APPEAR TO BE AS EFFECTIVE AS THE AUTOLOGOUS CELLS IN IMPROVING CARDIAC FUNCTION IN A PRECLINICAL MODEL AND THAT THE IMMUNE CONSEQUENCES OF THE CELL BEING ALLOGENEIC APPEAR TO BE NEGLIGIBLE. AND WITH CIRM SUPPORT, HE'S EXTENDED THAT FINDING TO ANOTHER PRECLINICAL MODEL. SO HE'S SHOWN IN TWO DIFFERENT ANIMAL MODELS THAT HE CAN GET THIS EFFECT.

THE ALLOGENEIC CELLS CAN BE OBTAINED IN LARGE NUMBERS FROM A DONOR HEART WHICH WOULD GREATLY FACILITATE SCALE-UP AND MANUFACTURING, ENABLING MORE STANDARDIZED OFF-THE-SHELF PRODUCT. WHEN YOU'RE DEALING WITH AUTOLOGOUS, THERE'S A LOT OF VARIABILITY IN TERMS OF WHAT DOSE YOU CAN GET OUT OF THE PATIENT, WHETHER OR NOT THEY'RE SUFFICIENTLY MANUFACTURED. HAVING ANOTHER SOURCE THAT THEY CAN GO TO CAN GREATLY STANDARDIZE THE PROCESS AND MAKE IT MORE OFF THE SHELF.

CIRM APPROVED THIS SWITCH TOWARDS AN ALLOGENEIC PRODUCT. THIS ALSO HAD BEEN A TOPIC OF DISCUSSION AT THE CLINICAL DEVELOPMENT ADVISORS. SO HE SELECTED THE CARDIOSPHERES AS THE THERAPEUTIC CANDIDATE. THEY WILL BE DELIVERED BY DIRECT INJECTION INTO THE HEART USING A SPECIAL MAGNETICALLY GUIDED CATHETER. THESE ARE ACTUALLY TOO BIG TO BE DELIVERED BY INTRACORONARY CATHETER INJECTION, SO THERE'S ACTUALLY A SPECIAL DEVICE THAT INJECTS IT DIRECTLY INTO THE HEART RATHER THAN THROUGH THE VASCULATURE.

THE STATUS THAT HE WAS WILLING TO HAVE US SHARE IS THAT HE IS ANTICIPATING IND FILING FOR THIS PRODUCT IN MID-2012. AT THIS POINT IN TIME, THERE'S NO CHANGE IN TIMELINE OR FINANCIALS.

DR. CHEN IS WORKING ON HIV/AIDS. HERE HE'S WORKING ON A THERAPEUTIC CANDIDATE THAT TAKES THE PATIENT'S OWN HEMATOPOETIC STEM CELLS THAT ARE GENETICALLY MODIFIED WITH A LENTIVIRAL VECTOR THAT ENCODES A SHORT RNA THAT'S DIRECTED AGAINST THE RECEPTOR FOR HIV CALLED CCR5. AND HE'S ALSO LOOKING AT A FUSION INHIBITOR AS WELL FOR PATIENTS WITH HIV INFECTION.

HE'S CONSIDERING HIS TARGET INDICATION EITHER PATIENTS WHO HAVE -- AT THIS POINT IN TIME, HE'S THINKING FOR REFRACTORY, FOR NAIVE, OR FOR PATIENTS WITH AIDS-RELATED MALIGNANCIES.

HIS KEY ACCOMPLISHMENTS ARE THAT HE HAS IDENTIFIED UNIQUE ANTI-HIV RNA'S THAT CAN PREVENT HIV INFECTION THROUGH PREVENTING HIV ENTRY INTO CELLS BY TARGETING CCR5 AS WELL AS HIV REPLICATION THROUGH THESE SHORT RNA'S THAT INHIBIT DIFFERENT STEPS OF THE HIV REPLICATION CYCLE. IN HIV, IN GENERAL, HE'S GOING FOR MULTIPLE HITS AGAINST PREVENTING HIV FROM TAKING OVER THE CELLS. SO HE'S NOT JUST LOOKING AT CCR5. HE'S TRYING TO LOOK AT A SECOND TARGET SITE WHERE THAT WILL CRIPPLE THE HIV.

HIS ONGOING STUDIES ARE DEMONSTRATING HIV INHIBITION IN THE TEST TUBE AS WELL AS IN AN IN VIVO PRECLINICAL MODEL. AT THIS POINT IN TIME, THERE'S

NO IMPACT ON TIMELINES OR FINANCIALS.

MS. SAMUELSON: I HAVE A QUESTION BACK ON THE ALS. SHALL WE TAKE THAT NOW OR LATER? IT TALKS ABOUT PRECLINICAL PROOF OF CONCEPT WITH A MOUSE MODEL. AND I WOULD THINK THERE'S A LOT OF OVERLAP BETWEEN ALS AND PARKINSON'S. PRETTY CONSISTENTLY IN PARKINSON'S THE MOUSE MODELS HAVEN'T BEEN PREDICTIVE. IS THAT BEING TAKEN INTO CONSIDERATION? HAS THAT BEEN UNDER DISCUSSION BY THE ADVISORS? AND HOW DOES THAT FIT WITH SAYING THAT THERE IS PRECLINICAL PROOF OF CONCEPT?

DR. FEIGAL: THAT CERTAINLY IS A TOPIC OF DISCUSSION IN TERMS OF WHAT DOES HE NEED TO DO TO SHOW EFFICACY. SO I'M SAYING HE HAS DEMONSTRATED SOME EVIDENCE OF PRECLINICAL ACTIVITY. I THINK I'M ENCROACHING ON THINGS THAT MIGHT BEST BE DONE UNDER A MORE CLOSED SESSION AT THIS POINT.

MS. SAMUELSON: I THINK IT WOULD BE GOOD TO DO THAT WHENEVER IT'S CONVENIENT BECAUSE THAT DOES INFORM A LARGER QUESTION, QUESTIONS ABOUT PRECLINICAL PROOF OF CONCEPT AND THE FEASIBILITY OF GETTING TO AN IND WITHIN THE TIME FRAMES AND SO ON.

DR. FEIGAL: SINCE DR. BERRY HAS BEEN IN COMMUNICATION WITH THE TEAM ABOUT WHAT WE CAN AND CAN'T PUBLICLY SHARE, I'M GOING TO HAVE HER JUST

GIVE YOU AN UPDATE AT LEAST ON THE MODEL THAT THEY'RE USING THAT WE CAN PUBLICLY SHARE.

DR. BERRY: SO DR. GOLDSTEIN IS USING AN SOD RAT MODEL ACTUALLY. AND HE'S PUBLISHED ON THAT. AND DON CLEVELAND, HE DEVELOPED THAT MODEL, AND HE'S WORKING IN CONJUNCTION WITH DON, OF COURSE. AND THE SOD MODEL IS ALSO THE MODEL THAT, I THINK IT'S NEURALSTEM WHO IS IN CLINIC NOW IN ALS. NICK BOLUS IS THE SURGEON. JONATHAN GLASS IS THE PI IN EMORY WHERE THEY'RE INJECTING STEM CELLS INTO ALS PATIENTS.

SO THIS IS THE SAME MODEL AND THE SAME PATH THAT THAT CLINICAL TRIAL IN THAT PARTICULAR PRODUCT IS MOVING THROUGH.

MS. SAMUELSON: MY QUESTIONS ARE THE SAME, BUT PERHAPS IT NEEDS TO BE IN A CLOSED SESSION.

DR. FEIGAL: I'M NOT SURE I CAN ANSWER YOUR QUESTION ABOUT THE RELATIONSHIP OF THIS.

DR. BERRY: YOU WERE TRYING TO DRAW SOMETHING OF AN ALS AND PARKINSON'S, AND I HAVE NO ANSWER TO THAT.

MS. SAMUELSON: WELL, I GUESS IT'S A LARGER QUESTION HAVING TO DO WITH HOW DO YOU DETERMINE SUCCESS, PREDICT SUCCESS, OR SO-CALLED FAILURE FOR THE DISEASE TEAM GRANT MODEL PURPOSES

WHEN THE DATA IS IN MICE OR RATS OR EVEN PRIMATES OFTEN IN THE PARKINSON'S INSTANCE. IT SEEMS TO ME IT WOULDN'T NECESSARILY BE FAILURE AT THE CLINICAL TRIAL THERE TO BE LACK OF SUCCESS BECAUSE WHAT IT'S REALLY ABOUT IS TRYING TO GET TO AN EFFECTIVE THERAPY. AND IT SEEMED LIKE EARLIER TODAY YOU WERE SAYING THAT MAYBE IT WAS ONE IN SIX WHERE IT SUCCEEDED.

DR. FEIGAL: I THINK YOU ARE REFERRING TO PAT OLSON'S SLIDE WHERE SHE WAS QUOTING FROM PHARMA AND BIOTECH WHERE GOING FROM PHASE I TO PHASE II, NOT SUCCESS, WAS ABOUT ONE IN FIVE, AND GOING FROM PHASE II TO PHASE III MIGHT BE ONE IN THREE. IT WASN'T SPECIFIC TO A DISEASE, AND IT WAS JUST GOING FROM ONE CLINICAL PHASE TO THE NEXT.

MS. SAMUELSON: OKAY. THIS WOULD BE CONSISTENT WITH THAT. MY EARS PERKED UP AT THAT POINT. AND IT SEEMS TO ME IMPORTANT TO THE DISCUSSION ABOUT WHEN -- WELL, THERE ARE A COUPLE DIFFERENT ISSUES. ONE BEING WHETHER A GRANT HAS TO BE TURNED DOWN WHEN THEY ARE PERHAPS REALISTICALLY SAYING THEY CAN'T GET TO AN IND FILING WITHIN THE NORMAL TIME FRAME BECAUSE REALISTICALLY THAT DOESN'T HAPPEN BECAUSE THEY MAY BE MAKING GREAT STRIDES IN DEVELOPING A CELL LINE, FOR EXAMPLE, BUT RELYING ON

MOUSE DATA, WHICH ARE NOT GOING TO BE PREDICTIVE OF WHAT HAPPENS AT THE CLINICAL TRIAL. ALL THAT MAY BE USEFUL TO THE EVENTUAL --

DR. FEIGAL: RIGHT. SO YOU'RE BRINGING UP AN IMPORTANT POINT. IT'S NOT UNIQUE TO THIS SPECIFIC AWARD. YOU'RE BRINGING UP A GENERAL PRINCIPLE, I THINK. SO WHAT IF THEY'RE FINDING OUT IMPORTANT THINGS THAT COULD BE USEFUL? DO WE HAVE THE FLEXIBILITY TO EITHER REFINE THE MILESTONES, CHANGE THE MILESTONES, GIVE THEM EXTRA TIME. IS THAT WHAT YOU'RE ASKING?

MS. SAMUELSON: WELL, IT RAISES SEVERAL QUESTIONS, I THINK, TO DO WITH BUDGETING AND WITH THE USE OF THIS GRANT MODEL VERSUS OTHERS, AND THE NEED FOR BASIC SCIENCE, FURTHER BASIC RESEARCH AT THIS LATER STAGE WHEN THEY THINK THEY'RE ON TRACK TO DEVELOPMENT OF A THERAPY AND, BOOM, THE THING FALLS APART IN THE CLINICAL TRIAL. THIS IS JUST STANDARD PROCEDURE IN THE PARKINSON'S THERAPY DEVELOPMENT WORLD. THIS IS HAPPENING OVER AND OVER. AND SO THEY CAN'T GET A GRANT BECAUSE THEY CAN'T MEET THE TIME FRAMES, ETC.

DR. FEIGAL: WELL, ANYWAY, TO ANSWER YOUR QUESTION THAT I'M NOT SURE THAT YOU'VE ASKED IS CIRM DOES HAVE THE ABILITY TO POTENTIALLY CHANGE THE

DIRECTION BASED UPON RECOMMENDATIONS OF THE CLINICAL ADVISOR PANEL IN ADDITION TO INTERNAL DELIBERATION. SO IF I CAN ANSWER THAT QUESTION, WHICH IS NOT THE QUESTION YOU ASKED, BUT THERE IS AN IDEA THAT WE ARE TRYING -- IS THERE SOMETHING OF VALUE OR GOOD THAT WE CAN OBTAIN FROM THIS EXCELLENT TEAM EVEN IF THEY CAN'T PURSUE MOVING FORWARD? SO IF THAT'S A QUESTION, I'M HOPING I ANSWERED IT A LITTLE BIT.

MS. SAMUELSON: THAT IS AND I AGREE WITH THE STATEMENT BEHIND THE QUESTION. IT ALSO SHOULD BE APPLIED TO THE OTHER DISEASES FOR WHICH IT'S RELEVANT, FOR EXAMPLE, PARKINSON'S.

DR. FEIGAL: THANK YOU.

DR. PRIETO: ACTUALLY I THINK DR. FEIGAL JUST ANSWERED. I GUESS I WAS WONDERING SORT OF ALONG THOSE LINES WHETHER WE HAD A PROCEDURE FOR EXTENDING OR CHANGING THE TIMELINE IF IT LOOKS LIKE A TEAM IS MAKING PROGRESS, BUT HITS BUMPS IN THE ROAD, BUT IS NOT GOING TO HIT THEIR TIMELINE TARGET.

DR. FEIGAL: WE DO HAVE THAT FLEXIBILITY. WHAT WE DON'T HAVE THE FLEXIBILITY TO DO NOW IS TO INCREASE THE BUDGET. SO WE HAVE A CEILING THAT THIS GROUP HAS BEEN ALLOCATED. WHEN WE START -- SO AT THIS POINT IN TIME, I'D SAY THE BUDGET IS LIMITING RIGHT NOW. SO WE HAVE TO TAKE THAT IN MIND IN TERMS

OF WHAT WE ARE ABLE TO DO. OKAY.

THE NEXT DISEASE TEAM IS DR. KOHN, WHO IS WORKING ON SICKLE DISEASES. HE IS WORKING ON TAKING THE PATIENT'S OWN BONE MARROW HEMATOPOETIC STEM CELLS. HE'S GENETICALLY MODIFYING IT WITH A LENTIVIRAL VECTOR THAT ENCODES AN ANTISICKLING BETA GLOBIN GENE. SO BASICALLY IT'S A VERY SPECIFIC DEFECT IN SICKLE CELL DISEASE PATIENTS THAT'S BEING CORRECTED WITH A COMBINATION OF USING STEM CELLS, HEMATOPOETIC STEM CELLS, AND GENE THERAPY.

SO HIS ACCOMPLISHMENTS ARE THAT HE HAS SELECTED THE SINGLE THERAPEUTIC CANDIDATE, THAT DISEASE MODIFYING ACTIVITY. HE'S DEMONSTRATED THIS IN VITRO AND IN AN IN VIVO PRECLINICAL MODEL. HE HAS HAD HIS PRE-IND MEETING WITH THE FDA, AND THEY ARE PLANNING THEIR PRECLINICAL TOXICOLOGY STUDIES NOW. HE HAS PRESENTED RESULTS OF ONGOING STUDY AT THE DECEMBER MEETING OF THE AMERICAN SOCIETY OF HEMATOLOGY ANNUAL MEETING IN SAN DIEGO JUST A FEW MONTHS BACK.

THEIR STATUS IS THAT TEAM IS ABLE TO DEMONSTRATE FEASIBILITY OF OBTAINING SUFFICIENT NUMBERS OF THESE HEMATOPOETIC STEM CELLS. BY DUAL BONE MARROW HARVESTING, THEN THERE WILL BE NO IMPACT ON THE TIMELINES AND FINANCIALS. THE TEAM HAS

ALREADY DONE, AS WE MENTIONED, THE PRECLINICAL PROOF OF CONCEPT STUDIES WITH THE BONE MARROW DERIVED CD34+ CELLS. AT THIS POINT IN TIME, HIS ACTIVITIES ARE CONTINUING, AND THE TIMELINES AND FINANCIALS HAVE NOT CHANGED.

DR. LANE IS WORKING ON A VERY RARE GENETIC TUMOR. FOR THOSE OF YOU -- I GUESS MOST OF YOU DIDN'T COME TO THE GRANTEE MEETING, BUT HE WAS ACTUALLY ONE OF THE SPEAKERS ALONG WITH DR. WAGNER ON THE DISEASE CONDITION CALLED DYSTROPHIC EPIDERMOLYSIS BULLOSA. THIS IS A DEVASTATING DISEASE THAT EVEN AT BIRTH INFANTS ARE BORN BASICALLY WITH THEIR -- JUST THE TRAUMA OF BEING BORN SLOUGHS THEIR SKIN. THEY HAVE A DEFECT IN TYPE SEVEN COLLAGEN FORMATION.

AND SO THIS TEAM IS WORKING AT AUTOLOGOUS IPS-DERIVED GENE CORRECTED KERATINOCYTES, AND THE TEAM IS TARGETING TWO FORMS OF THIS PARTICULAR TYPE OF DEVASTATING ILLNESS, THE RECESSIVE FORM AND THE FORM. THE TEAM HAS ACTUALLY SUCCESSFULLY GENERATED CELL LINES FROM PATIENTS WITH THE RECESSIVE FORM OF THIS TYPE OF RARE DISEASE. THEY HAVE A LOT OF WORK AHEAD OF THEM, BUT THEY ACTUALLY ARE MAKING SIGNIFICANT PROGRESS. AND AT THIS POINT IN TIME, THERE'S NO IMMEDIATE IMPACT ON THEIR TIMELINES OR ON

THE FINANCIALS.

DR. ROBINS IS WORKING AS PART OF A COMPANY, VIACYTE, ON TYPE 1 DIABETES. HERE THE THERAPEUTIC CANDIDATE IS AN ALLOGENEIC SOURCE. IT'S HUMAN EMBRYONIC CELL-DERIVED PANCREATIC PROGENITORS THAT WOULD THEN MATURE ONCE IT'S IN THE BODY TO BETA CELLS THAT SECRETE INSULIN IN RESPONSE TO GLUCOSE. AND THIS WOULD BE DELIVERED IN A RETRIEVABLE IMMUNO ISOLATION DEVICE THAT'S IMPLANTED UNDER THE SKIN.

THEIR KEY ACCOMPLISHMENT -- YOU KNOW, TYPE 1 DIABETES IS A DEVASTATING DISEASE. THERE CERTAINLY ARE THERAPIES OUT THERE, INSULIN BEING THE MAINSTAY OF TREATMENT. BUT THESE PATIENTS, ALTHOUGH THEY LIVE AND THEY SURVIVE, THEY HAVE A MULTITUDE OF COMPLICATIONS RELATED TO THEIR DISEASE, INCLUDING MAJOR ORGAN FAILURE, INCLUDING KIDNEY TRANSPLANTATION, VASCULAR PROBLEMS, THEY'RE PRONE TO HAVING CARDIOVASCULAR ISSUES AND MYOCARDIAL INFARCTIONS, AND PROBLEMS WITH BLOOD FLOW TO THEIR LIMBS WHICH CAN RESULT IN AMPUTATIONS OF DIGITS AND TOES AND LEGS. THERE'S DEFINITELY ROOM FOR IMPROVEMENT IN THERAPEUTIC OPTIONS FOR THESE PATIENTS.

THE KEY ACCOMPLISHMENTS IS THAT THEY'VE LOOKED AT PROTOTYPES. THEY'VE TESTED THE PROTOTYPES

IN PRECLINICAL MODELS. IN PRECLINICAL PROOF OF CONCEPT STUDIES THIS CELL DEVICE COMBINATION CURED A DRUG-INDUCED DIABETES. THEY'VE ESTABLISHED CELL MANUFACTURING, DEVICE MANUFACTURING AT A SCALE AND LEVEL OF QUALITY TO ENABLE PRECLINICAL AND CLINICAL TEST OF THE COMBO PRODUCT. I'M PROBABLY NOT GOING TO GO THROUGH ALL THE SPECIFICS HERE, BUT BASICALLY THEY'RE DOING A LOT OF THE BANKING AND THE MANUFACTURING THAT WILL PUT THEM IN A GOOD POSITION WHEN THEY'RE READY TO GO INTO THE CLINIC. AND SO THIS TAKES TIME TO DO ALL THE MANUFACTURING AND GET THIS READY FOR THE CLINIC. AND SO THEY'RE WELL ON THEIR WAY TO GETTING SOME OF THIS WORK DONE.

THEY'RE PREPARING FOR THEIR PIVOTAL IND-ENABLING STUDIES, AND THEY'RE IN THE PROCESS OF DEVELOPING THEIR CLINICAL PLAN FOR FIRST-IN-HUMAN TESTING. THEY HAVE TWO INVENTION DISCLOSURES.

THEIR STATUS IS THAT THEY HAVE RECEIVED SUPPLEMENTAL FUNDING FROM THE JUVENILE DIABETES RESEARCH FOUNDATION. THEY ARE IN DISCUSSION WITH A POTENTIAL PARTNER. AND THEIR TIMELINES ARE PROCEEDING WELL, BUT CIRM MAY NEED TO CONSIDER PROVIDING ADDITIONAL BRIDGING OR SOME TYPE OF FUNDING TO SUPPORT ACTIVITIES NEEDED TO SUPPORT THEIR IND FILING WITHIN THE FOUR-YEAR TIME FRAME.

DR. LUBIN: HOW DOES THAT GET DECIDED? JUST OUT OF CURIOSITY, THAT LAST POINT YOU MADE ON THIS PROJECT. I HEARD THIS PRESENTATION AT THAT MEETING WE WERE AT IN SAN DIEGO. LOOKED EXCITING. SO YOU JUST RAISED THE QUESTION ABOUT CIRM WOULD HAVE TO MAKE SOME DECISIONS. DO THEY WRITE TO YOU ANOTHER APPLICATION? OR HOW DOES THIS GO ABOUT?

DR. FEIGAL: WELL, IT COULD BE POTENTIALLY WE HAVE SOME INITIATIVES COMING UP WHERE THERE MIGHT BE AN OPPORTUNITY FOR THEM TO APPLY FOR ADDITIONAL FUNDING. SO IT WOULD BE SOME SORT OF A COMPETITIVE REVIEW.

IF IT'S WITHIN THE SCOPE, IF IT WAS POTENTIALLY SOMETHING THAT WAS EXTENDED, WE ALSO DO HAVE SOMETHING CALLED BRIDGING FUNDS. WE'D HAVE TO THINK ABOUT WHETHER IT COULD BE ELIGIBLE FOR THAT KIND OF FUNDING.

DR. STEINBERG'S TEAM IS WORKING ON STROKE. HE'S WORKING ON AN ALLOGENEIC HUMAN EMBRYONIC STEM CELL-DERIVED NEURAL STEM CELL LINE THAT'S TRANSPLANTED RIGHT NOW ALONE, BUT HE'S ALSO LOOKING AT IT IN COMBINATION WITH A MATRIX MATERIAL THAT COULD BE INJECTED INTO THE INFARCTED AREA OF THE BRAIN. AND HE'S ALSO CONSIDERING DOING THIS WITH CONCOMITANT IMMUNOSUPPRESSION.

HIS KEY ACCOMPLISHMENTS ARE THAT HE'S UTILIZING A RESEARCH BANK OF CANDIDATE CELLS, SHOWN FUNCTIONAL RECOVERY IN THREE PRECLINICAL MODELS OF STROKE IN THREE INDEPENDENT LABS. HE'S CONTINUING TO ESTABLISH, HE AND HIS TEAM, TO ESTABLISH CELL MANUFACTURING AND TESTING PROCESSES TO ENABLE THE PRECLINICAL AND CLINICAL TESTING. HE'S PRODUCED TWO QUALIFICATION LOTS THAT CAN BE ELECTED FOR THE MASTER CELL BANK AND THE WORKING CELL BANK. AND THIS HAS BEEN BASED ON EXTENSIVE CHARACTERIZATION, FUNCTION, AND SAFETY TESTING. HE HAS CONDUCTED WHAT'S CALLED A PRE-PRE-IND MEETING WITH THE FDA. THE CENTER FOR BIOLOGICS EVALUATION RESEARCH CALLED CIBR AT THE FDA IS UNIQUE IN ALLOWING MORE THAN ONE PRE-IND MEETING. SO HE'S TAKEN ADVANTAGE OF THAT OPPORTUNITY TO HAVE A DISCUSSION WITH THE AGENCY.

ALTHOUGH INITIALLY HE WAS TRYING TO PURSUE A CELL CANDIDATE THAT MIGHT BE COMBINED WITH HYDROGEL, RIGHT NOW HE'S PURSUING THE LESS COMPLEX MANUFACTURING PROCESS IN ORDER TO BRING THIS CANDIDATE TO IND FILING AND FIRST-IN-HUMAN TESTING EXPEDITIOUSLY. SEPARATELY HE'S EXPLORING THE USE OF THE HYDROGEL AS PART OF A SEPARATE GRANT, A CIRM TOOLS AND TECHNOLOGY AWARD, TO TRY AND OPTIMIZE THE TECHNOLOGY.

AT THIS POINT IN TIME, THERE'S NO IMPACT TO THE ORIGINAL TIMELINES AND FINANCIALS.

DR. ZAIA IS WORKING ON HIV/AIDS. HE'S WORKING ON AN ADENOVIRUS MODIFIED HEMATOPOETIC STEM CELL THAT EXPRESSES A NUCLEASE THAT TARGETS CCR5. YOU'VE HEARD THE STORY BEFORE, BUT BASICALLY IT'S THE RECEPTOR FOR HIV. HE'S TRYING TO TARGET IT.

I SHOULD HAVE MENTIONED ALSO IN THE -- I THINK I CAN MENTION THIS. I'LL TAKE THE RISK OF DOING IT. WITH THE OTHER GRANT THEY'RE LOOKING AT CCR5, BUT THEY WERE ALSO NOT JUST WORKING ON -- HE WAS TRYING TO LOOK AT TWO DIFFERENT STRAINS THAT MIGHT BE ABLE TO CORRECT AND INDUCE THEIR ENTRY. ZAIA'S TEAM IS PRIMARILY LOOKING AT THE STRAIN OF HIV THAT USES THE CCR5 RECEPTOR. HE'S TARGETING THIS TO AIDS LEUKEMIA PATIENTS AS OPPOSED TO THE OTHER. HE'S PRIMARILY LOOKING AT PATIENTS WHO ALREADY HAVE A HEMATOLOGIC MALIGNANCY BECAUSE HE'S PLANNING TO DO ABLATION OF THE PATIENT'S BONE MARROW. AND CONVENTIONALLY THESE ARE THE TYPES OF PATIENTS THAT ONE WOULD TAKE TO THAT TYPE OF MORE AGGRESSIVE THERAPY.

SO ULTIMATELY THE METHOD COULD BE IMPROVED USING NONABLATIVE HEMATOPOETIC STEM CELL TRANSPLANTATION, AND THEN WOULD THEN EXPAND THE

POPULATION OF AIDS PATIENTS THAT COULD POTENTIALLY TAKE THIS TYPE OF THERAPY.

THEIR KEY ACCOMPLISHMENTS ARE THAT THEY ARE OPTIMIZING METHODS FOR THE ADENOVIRAL VECTOR MEDIATED TRANSDUCTIONS OF THE HEMATOPOETIC STEM CELLS AND DISRUPTION OF THE CCR5 RECEPTOR. AND THEY'RE OPTIMIZING METHODS FOR EXPRESSION OF THE ZINC FINGER NUCLEASE TO TARGET CCR5. HE HAS DEVELOPED A PRECLINICAL MODEL TO TEST THE STEM CELL THERAPY FOR HIV. AND ACTUALLY I THINK THIS HAS BEEN THE TOPIC OF SOME OF AMY ADAMS' BLOGS ABOUT PAULA CANNON AND SOME OF THE OTHER INVESTIGATORS ABOUT SOME OF THE WORK THAT'S HE'S BEEN DOING.

HE'S SHOWN THAT WHEN THE ALTERED HEMATOPOETIC STEM CELLS ARE GIVEN TO THIS PRECLINICAL MODEL THAT LACKED AN EFFECTIVE IMMUNE SYSTEM, THESE CELLS ARE ABLE TO BE COLONIZED IN THE BONE MARROW. THEY CREATE A NEW BLOOD SYSTEM WITHIN THAT HOST BODY WITH MUTATED CCR5, AND THEN THEY EXPOSE THIS PRECLINICAL MODEL TO HIV, AND THEY ARE ABLE TO BEAT BACK THE INFECTION.

THE STATUS OF THIS TEAM IS THAT THEY'RE PROGRESSING TOWARDS THEIR IND-ENABLING STUDIES FOR SCALE-UP CELL PROCESSING. AT THIS POINT IN TIME, THERE'S NO IMPACT ON THE TIMELINES OR BUDGET. AND

THEY HAVE A CLINICAL DEVELOPMENT ADVISORY MEETING THAT'S PLANNED FOR THE END OF THIS YEAR.

I SHOULD MENTION THAT ALL OF THE TEAMS ARE GOING TO HAVE ANOTHER CLINICAL DEVELOPMENT ADVISORY MEETING THIS YEAR. SO THEY HAD THEIR FIRST MEETING AT THEIR 12- TO 18-MONTH MILESTONE PERIOD, AND THEN THEY'RE GOING TO HAVE -- WE'RE GOING TO GO THROUGH ANOTHER SERIES OF ADVISORY MEETINGS WITH THEM TO KEEP TRACK OF THEIR PROGRESS.

THIS IS JUST A SLIDE, A PIE CHART, SHOWING THE DIFFERENT DISEASE AREAS. YOU CAN SEE THE LEGEND AT THE BOTTOM. THE AMOUNT OF MONEY THAT CIRM HAS INVESTED, 225 MILLION, THE AMOUNT OF MONEY IN COMBINATION WITH THE COLLABORATIVE FUNDING PARTNERS THAT'S BEEN INVESTED.

SO I THINK AT THIS POINT IN TIME, I HAVE A LOT OF SLIDES THAT I THINK FOR PURPOSES OF TIME I WON'T GO INTO THAT JUST SHOW THE CONTEXT OF THESE DISEASE TEAMS IN THE BROADER CONTEXT OF OUR TRANSLATIONAL PORTFOLIO. YOU WILL HAVE THESE SLIDES, BUT I'M NOT SURE IF WE REALLY HAVE TIME TO GO INTO IT RIGHT NOW.

MR. TORRES: WILL YOU SEND THEM TO US?

DR. FEIGAL: YOU WILL GET EVERYTHING. I THINK AT THIS POINT, OPEN FOR ANY QUESTIONS. THE

POINT WAS REALLY TO GIVE YOU HOPEFULLY A CONCISE UPDATE. THE TEAMS ARE DEFINITELY MAKING PROGRESS. THEY'RE BEING MONITORED QUITE CLOSELY. AND WHAT WE'RE DOING IS TRYING TO PROVIDE EXPERTISE AND ADVICE TO TRY AND HOPEFULLY POSITION THEM TO BE SUCCESSFUL; OR IF THEY'RE NOT ON THE RIGHT TRAJECTORY, TO AT LEAST NOT INVEST FURTHER DOLLARS IN SOMETHING THAT REALLY DOESN'T HAVE THE POTENTIAL OF BEING SUCCESSFUL.

CHAIRMAN THOMAS: ADDITIONAL COMMENTS? I'M NOT SURE I HEARD ANYTHING THAT WARRANTS CLOSED SESSION, JAMES.

MR. HARRISON: NOT AT THIS POINT. MEMBERS HAVE QUESTIONS FOR PUBLIC SESSION, WE CAN ASK THEM TO ASK THOSE QUESTIONS NOW. IF THAT REVEALS A CAUSE FOR A CLOSED SESSION, WE CAN CONVENE IN CLOSED SESSION AT THAT POINT IN TIME.

DR. HAWGOOD: I HAVE A GENERAL QUESTION, BUT, JAMES, YOU'LL HAVE TO TELL ME WHETHER I'M CONFLICTED. IF A GRANT IS WOUND DOWN AS THERE WAS ONE IN THIS SESSION, IS THERE A WIND-DOWN PERIOD?

DR. FEIGAL: YES. THERE IS A WIND-DOWN PERIOD. SO THEY HAVE ADVANCE DISCUSSIONS BECAUSE WE CERTAINLY DON'T WANT THINGS TO FALL OFF A CLIFF. SO WE DO TALK WITH THEM. WE TALK ABOUT WHAT'S

REASONABLE. WE HAVE SOME BACK AND FORTH. WE DO MAKE IT CLEAR WE'RE TERMINATING IT, BUT WE WANT TO DO IT IN A REASONABLE WAY.

MS. SAMUELSON: THIS IS, I GUESS, A COMMENT THAT IS PART OF A MUCH LONGER DISCUSSION I DON'T THINK ANYBODY HAS THE ENERGY FOR RIGHT NOW. I'M PRETTY SURE I DON'T. IT'S VERY IMPORTANT TO PARKINSON'S AND NEURODEGENERATIVE DISEASE RESEARCH. IT'S ON THE TABLE ALL THE TIME. THESE ARE VERY COMPLEX DISORDERS AND WITH TERRIBLY DIFFICULT THERAPEUTIC ENDS. AND IT MAY BE A BACK-AND-FORTH CYCLING AROUND FROM PRECLINICAL TO CLINICAL TO BACK TO BASIC RESEARCH EXPLORATIONS, AND THAT DOESN'T FIT THE MODELS THAT WE HAVE. AND I'M THINKING THAT WE SHOULD BE DOING SOMETHING ABOUT THAT NOW IN OUR STRATEGIC PLANNING.

DR. FEIGAL: YEAH. WE'RE THINKING TOO. LET'S JUST SAY HYPOTHETICALLY, NOBODY SPECIFICALLY. ONE EXAMPLE YOU GAVE IS SOMEBODY'S NOT SUCCESSFULLY GOING THROUGH. CAN WE SOMEHOW HAVE THEM DO A REVISED PROPOSAL AND TELL US WHAT COULD THEY DO IN TERMS OF THE AMOUNT OF TIME AND TIME FRAME, AND AS LONG AS IT'S WITHIN SCOPE, HOW TO TAKE ACCOUNT OF IT. IF SOMEBODY HAS ALREADY GOTTEN TO THE CLINIC AND THEY'RE RUNNING INTO A CHALLENGE, FOR EXAMPLE,

THEY'RE LACKING A CELL TRACKING, THEY INJECT THE CELLS, BUT WHO KNOWS WHERE THEY'RE GOING? AND SO THEY REALLY WOULD HAVE BENEFITED FROM SOME SORT OF A NONINVASIVE IMAGING OR TRACKING TO ASSESS WHETHER OR NOT THE CELLS ARE EVEN SURVIVING. MAYBE THE FACT YOU'RE NOT SEEING TOXICITY IS THE CELLS HAVE DIED. SO THERE'S NOTHING THERE TO CAUSE TOXICITY.

SO ONE MIGHT ENVISION IS THERE SOMETHING THAT THEY'VE LEARNED FROM THAT THAT THEY CAN THEN TAKE IT BACK. WE DO HAVE TOOLS AND TECHNOLOGY. I THINK WE DO HAVE SOME THINGS THAT ARE AVAILABLE. THEY'RE NOT SPECIFICALLY CALLED IF YOU FIND SOMETHING IN THE CLINIC AND NEED TO COME BACK, BUT WE MAY HAVE SOME -- THE ONE THAT COMES TO MIND THE EASIEST IS TOOLS AND TECHNOLOGY THAT MIGHT APPLY TO THAT.

BUT I AGREE WITH YOU. THERE'S THINGS THAT YOU WON'T FIND OUT ARE PROBLEMS UNTIL YOU GET TO THE CLINIC.

MS. SAMUELSON: AND THERE'S A LOT OF EVIDENCE NOW THAT THERE ARE GOING TO BE PROBLEMS THERE IN THESE COMPLEX DISORDERS THAT ARE AMONG OUR KEY OBJECTIVES. AND GIVEN THAT, I THINK WE SHOULD START WITH CHANGING THE RHETORIC. IT MAY NOT BE SUCCESS TO HAVE A PRECLINICAL PROOF OF CONCEPT AND

THEN BE TRACKING TOWARD A VERY LIMITED TIME FRAME TO THE FDA WHEN THAT IS UNLIKELY TO BE ENOUGH. AND TO DISCOURAGE OR PENALIZE A TEAM THAT REACHES THAT POINT IS BLAMING THE WRONG PIECE, I THINK. IT'S THE INTRACTABLE DISORDER THAT'S SO COMPLICATED AND IS INDUCING FAILURE, AND THE FACT THAT THEY ARE SLOGGING AWAY AT IT WITH THE STATE OF THE ART TRYING TO GET SOMEWHERE IS TO BE REWARDED WITH MORE MONEY SO THAT THEY CAN TAKE ANOTHER WHACK AT IT, GOING BACK TO SOME BASIC RESEARCH TO TRY TO FIGURE OUT WHAT THE OPTIONS MIGHT BE AND COMING UP WITH SOME NEW HYPOTHESES. THAT'S GOOD.

DR. FEIGAL: I WAS A LITTLE BIT TOO RESTRICTIVE. WE DO HAVE CONTINUING CYCLES OF BASIC BIOLOGY.

MS. SAMUELSON: IT'S IN THE TRANSLATIONAL CONTEXT. IT'S NOT JUST THIS OR THAT. IT'S NOT JUST TOOLS AND TECHNOLOGY. THEY MIGHT NEED THIS KIND OF IMAGING, BUT NOT TO THE EXCLUSION OF REMAINING ENGAGED IN THE ENTIRE COMPLEX QUESTION. AND I THINK WE NEED GRANT MODELS FOR THAT.

DR. FEIGAL: ALL I WAS SUGGESTING IS ACTUALLY WE DO HAVE CONTINUING CYCLES OF NOT JUST TOOLS AND TECHNOLOGY, BUT BASIC BIOLOGY FUNDAMENTAL, TRYING TO UNDERSTAND WHAT WENT WRONG. WE DO HAVE

RECURRING CYCLES OF TRYING TO LOOK AT THAT THERAPEUTIC, TAKE ANOTHER WHACK AT TRYING TO FIND WHAT COULD BE DONE DIFFERENTLY TO MAKE IT MORE LIKELY TO BE BETTER NEXT TIME AROUND.

SO I THINK WE DO HAVE SOME THINGS THAT MIGHT BE APPLICABLE FOR THAT. WHAT WE PROBABLY DON'T HAVE IS -- BUT, ANYWAY, THOSE ARE SOME THOUGHTS ABOUT HOW WE MIGHT BE ABLE TO TACKLE THAT.

IF YOU HAVE SUGGESTIONS ON OTHER WAYS OF WHAT WE COULD DO, WE'RE VERY RECEPTIVE TO HEARING ABOUT IT.

MS. SAMUELSON: I THINK ESSENTIALLY IT'S REMAINING IN THE TRANSLATIONAL MODE WITH ENOUGH FUNDING RESOURCES AND DIFFERENT FUNDING TOOLS TO MEET THE COMPLEXITY. SO IT MIGHT BE SIMULTANEOUSLY SOME IMAGING QUESTIONS THAT NEED AN IMAGING STUDY AND HAVING A TRACK THAT'S PARALLEL TO THE TRANSLATIONAL ONE OF THE ONGOING BASIC QUESTIONS THAT GET RAISED WHEN THE PRECLINICAL MODELS IN MICE, FOR EXAMPLE, ARE NOT PROVING OUT. AND, FOR EXAMPLE, THERE'S THIS OTHER ENORMOUS QUESTION IN PARKINSON'S, WE'RE NOT EVEN GETTING TO IT BECAUSE WE'RE NOT GETTING THROUGH ALL THESE OTHER QUESTIONS, BUT THE STATE-OF-THE-ART METHOD IN THE CLINICAL TRIAL IS A DOUBLE BLIND SHAM SURGERY. AND THOSE ARE ALL

FAILING. AND THERE'S BEGINNING TO BE A THOUGHT THAT APPEARS, FROM WHAT I'M READING, THAT IT'S ABOUT THAT MODEL, THAT DOUBLE BLIND, THE STATE OF THE -- YOU KNOW, IT'S REGARDED AS THE HEIGHT OF THE DESIGN OF THE TRIAL, BUT THERE'S SOMETHING GOING ON WITH IT AND THE COMPLEXITY OF PARKINSON'S. IT SEEMS THAT IT ISN'T HELPING GET OUT THE OTHER END TO SOMETHING THAT PROVES TO BE EFFECTIVE.

DR. FEIGAL: MAYBE ONE THING WE COULD DO, YOU'RE BEING INVITED TO THE SEPTEMBER 2012 PARKINSON'S DISEASE WORKSHOP WHERE WE --

MS. SAMUELSON: I DON'T JUST WANT TO COME. I WANT TO BE INVOLVED IN THE DEVELOPMENT.

DR. FEIGAL: WE WOULD LOVE TO HAVE YOU BE INVOLVED IN THE DEVELOPMENT, BUT MY POINT OF BRINGING IT UP IS MAYBE -- I KNOW THAT'S SEVERAL MONTHS AWAY; BUT SINCE WE ARE PLANNING THAT MEETING RIGHT NOW, MAYBE THAT WOULD BE A GOOD TIME TO HAVE INPUT INTO THAT.

MS. SAMUELSON: RIGHT. I THINK THERE'S PROBABLY WIDER APPLICATION OF THESE QUESTIONS FOR LOTS OF DISORDERS THAT WE'RE LOOKING AT. THANK YOU.

DR. JUELSGAARD: ELLEN, SO IN THE PREREAD IT WAS INDICATED THAT THESE EVALUATION WERE DONE LAST YEAR; IS THAT RIGHT, OVER A PERIOD OF TIME?

DR. FEIGAL: 2011, AND THEY'RE GOING TO BE DONE IN 2012 ALSO.

DR. JUELSGAARD: THAT WAS MY QUESTION IS WHEN IS THE NEXT EVALUATION?

DR. FEIGAL: THEY'LL START IN JULY OF THIS YEAR AND GO THROUGH NOVEMBER.

DR. JUELSGAARD: GREAT. THANKS.

MR. TORRES: I WANTED TO GET A QUESTION TO -- ARE WE DONE ON THIS?

DR. FEIGAL: THAT'S UP TO YOU.

MR. TORRES: ALL I WANT TO SAY IS GREAT, GREAT WORK, BUT I WANTED TO ASK A QUESTION OF MATT ON THE BUDGET. IS THAT ALL RIGHT?

CHAIRMAN THOMAS: BEFORE YOU DO THAT, MR. SENATOR, I JUST WANT TO, ELLEN, THANK YOU. IT'S DIFFICULT TO COMMENT ON HOW MUCH WORK WENT INTO THIS. THIS IS BETWEEN AN AWFUL LOT OF PEOPLE OVER A LONG PERIOD OF TIME.

DR. FEIGAL: I JUST WANT TO ONCE AGAIN THANK THE SCIENCE OFFICERS FOR REALLY GATHERING THE DATA. AND ACTUALLY THE TEAMS HAVE BEEN -- ALSO THE INTERNAL TEAM HAS BEEN GREAT, BUT THE EXTERNAL INVESTIGATORS HAVE BEEN EQUALLY VERY GOOD ABOUT PROVIDING THAT BECAUSE ALTHOUGH YOU MIGHT THINK, OH, NO, ANOTHER MEETING, BUT THEY ARE REALLY THIRSTY FOR

ANYTHING THAT WILL HELP POSITION THEM BETTER FOR SUCCESS. SO THEY HAVE ACTUALLY BEEN VERY, VERY COLLEGIAL AND HELPFUL IN SUPPLYING INFORMATION THAT WOULD BE HELPFUL.

CHAIRMAN THOMAS: THERE WERE MANY, MANY PEOPLE WHO PUT AN AWFUL LOT OF TIME INTO THIS. AS THIS IS EXACTLY WHAT WE'RE ALL ABOUT, AND TO HEAR ALL THIS IS VERY INSTRUCTIVE. JUST THANK ALL THE SCIENCE STAFF AND TO THANK THE PANEL MEMBERS AS WELL ON BEHALF OF THE BOARD FOR VERY, VERY HELPFUL, INSTRUCTIVE WORK.

MR. TORRES: I JUST WANT TO SAY THAT I WAS PARTICULARLY TROUBLED BY SOME OF THE COMMENTS THAT WERE MADE DURING OUR DISCUSSIONS OF THE BUDGET, AND I WANTED A TIMELINE FOR MY OWN PURPOSES. WHEN IS THE BUDGET TO BE APPROVED FORMALLY BY THIS BOARD? IS IT IN JUNE?

DR. PLUNKETT: MAY 21ST, 22D MEETING. I DON'T BELIEVE WE HAVE A MEETING IN JUNE.

MR. TORRES: SO WE HAVE TO MOVE DURING THAT PERIOD OF TIME TO DISCUSS SOME OF THE ISSUES THAT WERE RAISED TO GET A SENSE OF WHAT OUGHT TO BE IN THE FINAL DOCUMENT, CORRECT?

DR. PLUNKETT: CORRECT.

MR. TORRES: THANK YOU, MR. CHAIRMAN.

CHAIRMAN THOMAS: OKAY. WE'VE NOW REACHED PUBLIC COMMENT ON THE AGENDA. DO WE HAVE ANY COMMENT BY THE PUBLIC? HEARING NONE, I BELIEVE WE HAVE REACHED THE END OF A LENGTHY, EXHAUSTIVE, HIGHLY INFORMATIVE DAY. THANK EVERYBODY FOR THEIR ATTENDANCE, PARTICIPATION, AND CONTINUED HIGH LEVEL OF INTEREST. WE ARE NOW LOOKING FOR A MOTION TO ADJOURN.

DR. PRICE: SO MOVED.

CHAIRMAN THOMAS: WE HAVE MOTIONS AND SECONDS ALL OVER THE PLACE. WE'RE NOT EVEN GOING TO BOTHER WITH A VOTE. WE STAND ADJOURNED, AND WE'LL RECONVENE AT THE END OF MAY. THANK YOU VERY MUCH.

(THE MEETING WAS THEN CONCLUDED AT 04:44 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

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SACRAMENTO, CALIFORNIA
ON
APRIL 21, 2012

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

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