BEFORE THE

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
AND THE APPLICATION REVIEW SUBCOMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION:	MARRIOTT LA JOLLA 4240 LA JOLLA VILLAGE DRIVE LA JOLLA, CALIFORNIA
DATE:	WEDNESDAY, SEPTEMBER 21, 2016 9 A.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
BRS FILE NO.:	98937

I N D E X

160 S. OLD SPRINGS ROAD, SUITE 270, ANAHEIM, CALIFORNIA 92808
1-800-622-6092 1-714-444-4100 EMAIL: DEPO@DEPO1.COM

I N D E X (CONT'D.)

LA JOLLA, CALIFORNIA; WEDNESDAY, SEPTEMBER 21, 2016

9 A.M.

CHAIRMAN THOMAS: SO THOSE WHO ARE STILL STANDING, IF YOU COULD TAKE YOUR SEATS, WE'RE GOING TO BEGIN. WE'LL MOMENTARILY HOLD TO CHECK THE FOLKS ON THE PHONE ARE PLUGGED IN HERE.

I'D LIKE TO CALL THIS MEETING OF THE ICOC TO ORDER. WELCOME FROM SAN DIEGO WHERE THERE'S SOMETHING OUTSIDE, IF I DIDN'T KNOW ANY BETTER, I THOUGHT MIGHT BE RAIN; BUT IT'S BEEN SO LONG THAT WE'VE SEEN ANY, IT'S NOT CLEAR. WHATEVER. WE'RE DELIGHTED TO HAVE EVERYBODY HERE AS ALWAYS.

IF YOU WOULD PROCEED HERE TO THE PLEDGE OF ALLEGIANCE. MARIA.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN THOMAS: MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: PRESENT.

MS. BONNEVILLE: DEBORAH DEAS.

DR. DEAS: HERE.

MS. BONNEVILLE: JACK DIXON. ANNE-MARIE DULIEGE.

DR. DULIEGE: HERE.

MS. BONNEVILLE: HOWARD FEDEROFF. ELIZABETH FINI.

DR. FINI: HERE.

MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY GASSON.

DR. GASSON: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

DR. LAPORTE: HERE.

MS. BONNEVILLE: BERT LUBIN.

DR. LUBIN: HERE.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: LAUREN MILLER. LLOYD MINER. ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA. FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: HERE.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. BONNEVILLE: OSWALD STEWARD. JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: HERE.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: HERE.

MS. BONNEVILLE: BRUCE WINTRAUB.

CHAIRMAN THOMAS: THANK YOU, MARIA. WE WILL PROCEED ON TO THE CHAIR'S REPORT. THE FIRST ITEM, I AM DELIGHTED TO INTRODUCE TO YOU OUR NEWEST MEMBER OF THE ICOC, DEAN DEBORAH DEAS FROM UC RIVERSIDE MED SCHOOL. DEBORAH, COULD YOU GIVE US A BIT OF YOUR BACKGROUND, PLEASE.

DR. DEAS: GOOD MORNING. GOOD MORNING. GREAT.

WELL, I'M DEBORAH DEAS, AND I'M FROM CHARLESTON, SOUTH CAROLINA. CURRENTLY I AM THE DEAN OF THE UNIVERSITY OF CALIFORNIA RIVERSIDE SCHOOL OF MEDICINE AND CEO FOR CLINICAL AFFAIRS. PRIOR TO COMING TO UC RIVERSIDE, I HELD A POSITION AS INTERIM

DEAN OF THE MEDICAL UNIVERSITY OF SOUTH CAROLINA. MY BACKGROUND: TRIPLE BOARDED, CHILD AND ADOLESCENT PSYCHIATRIST AND ADULT PSYCHIATRY, AS WELL AS ADDICTION PSYCHIATRY. OVER THE YEARS I'VE SERVED IN THE UNIVERSITY IN MULTIPLE POSITIONS, INCLUDING MY RESEARCH AND ADOLESCENT SUBSTANCE ABUSE, DEPRESSION AND ANXIETY, AS WELL AS ADHD, AND OTHER ADDICTIVE DISORDERS.

I'VE HELD POSITIONS WITHIN THE SCHOOL OF MEDICINE DEAN'S OFFICE AS THE SENIOR ASSOCIATE DEAN FOR MEDICAL EDUCATION WITH OVERSIGHT OF UNDERGRADUATE MEDICAL EDUCATION, RESIDENCY TRAINING, OUR GME, CME, ADMISSIONS, DIVERSITY, AS WELL AS STUDENT AFFAIRS.

I'M REALLY PLEASED TO BE HERE. I'M ENJOYING IT AT UC RIVERSIDE. I WENT TO RIVERSIDE BECAUSE ITS MISSION, TO TRAIN A DIVERSE PHYSICIAN WORKFORCE AND TO CREATE CLINICAL AND RESEARCH PROGRAMS ALIKE FOR THE UNDERSERVED POPULATION, REALLY ALIGNED WITH MY PASSION AND WITH MY VALUES.

I'M VERY HAPPY TO SERVE ON THIS BOARD. I CERTAINLY CAN RELATE TO THE MISSION OF THE BOARD BASED ON WORK THAT I'M INTERESTED IN AS WELL AS INDIVIDUALS THAT I'M CLOSE TO WHO HAVE HAD DISEASES, ILLNESSES THAT WILL BENEFIT FROM SOME OF THE WORK

THAT THE BOARD IS PROMOTING. IT'S GREAT TO BE HERE.

I TOOK A MOMENT TO GO AROUND THE ROOM TO INTRODUCE MYSELF TO THE BOARD MEMBERS, AND I LOOK FORWARD TO GETTING TO KNOW ALL OF YOU A LOT BETTER.

LASTLY, I HAD MY ORIENTATION LAST NIGHT, AND I THANK J.T. AND SCOTT, MARIA, ART, AMY, I DON'T WANT TO MISS ANYONE, FOR SUCH AN EXCELLENT ORIENTATION, AND HAD THE PLEASURE THIS MORNING OF MEETING WITH RANDY. SO I REALLY THINK THAT I GOT THE WRAPAROUND SERVICE. AND I WAS REALLY NICELY GREETED BY ANNE-MARIE FROM A DISTANCE, AND I'M JUST LOOKING FORWARD TO MEETING ALL OF YOU AND WORKING CLOSELY WITH YOU. I HOPE I DIDN'T MISS ANYTHING, J.T.

CHAIRMAN THOMAS: THAT WAS OUTSTANDING. THANK YOU VERY MUCH, DEAN DEAS. AND ON BEHALF OF THE BOARD WELCOME.

DR. DEAS: THANK YOU.

MS. BONNEVILLE: OS, HAVE YOU JOINED THE CALL? YOU MIGHT BE ON MUTE. WE GOT AN E-MAIL FROM YOU THAT YOU WERE ON THE CALL.

DR. STEWARD: YES, I AM ON THE CALL. THANK YOU.

MS. BONNEVILLE: THANK YOU. HOW ABOUT DR. DIXON? JACK, ARE YOU ON THE PHONE?

DR. DIXON: YES. I'M HERE AS WELL IN SUNNY SAN DIEGO AS ALLUDED TO EARLIER.

MS. BONNEVILLE: AND THAT'S IT. THANK YOU.

CHAIRMAN THOMAS: SO ON TO THE CHAIR'S REPORT. I THOUGHT I'D START WITH SOMETHING A LITTLE FUN. EVERYBODY, OF COURSE, RECALLS THAT PROPOSITION 71 WAS A FUNCTION OF A BAN ON EMBRYONIC STEM CELL RESEARCH FUNDING FOR NIH IMPOSED BY THEN PRESIDENT BUSH. SO THE AGENCY HAS IN ITS ROOTS DEEP INTEREST IN PRESIDENTIAL VIEWS ON STEM CELL RESEARCH. SO I THOUGHT THAT IN THIS SORT OF MOST UNUSUAL OF PRESIDENTIAL ELECTION CYCLES THAT THE BOARD MIGHT BE INTERESTED TO HEAR THE POSITIONS ON STEM CELL RESEARCH AS ARTICULATED BY THE FOUR CANDIDATES FOR PRESIDENT AND THE TWO VICE PRESIDENTIAL CANDIDATES. I THINK YOU'LL FIND THIS SORT OF INTERESTING AND INSTRUCTIVE. I WILL OFFER THIS UP MERELY FACTUALLY WITHOUT EDITORIAL COMMENT. EVERYBODY CAN SORT OF CONCLUDE WHAT THEY WANT FROM WHAT I HAVE TO SAY HERE.

WE'LL START WITH SECRETARY CLINTON, WHO IS A LONGTIME PROPONENT OF SCIENCE FUNDING IN GENERAL AS WELL AS STEM CELL RESEARCH IN PARTICULAR. AS A CANDIDATE WAY BACK IN 2007, SHE MADE A POINT OF

SAYING THAT SHE WOULD REVERSE PRESIDENT BUSH'S BAN ON FEDERAL FUNDING SHOULD SHE BE ELECTED PRESIDENT. SHE IS ON RECORD AS SAYING SHE WOULD INCREASE FUNDING TO NIH AND NSF FOR MEDICAL RESEARCH IN GENERAL AND WOULD PARTICULARLY EMPHASIZE LARGE AMOUNTS OF FUNDING TO GO TOWARDS ALZHEIMER'S AND AUTISM.

WITH RESPECT TO STEM CELLS, SHE'S A STAUNCH ADVOCATE OF RESEARCH FUNDING FOR ALL KINDS OF STEM CELL RESEARCH. INTERESTINGLY, THAT INCLUDES SOMATIC CELL NUCLEAR TRANSFER OR CLONING FOR THE PURPOSES OF DERIVING EMBRYONIC STEM CELLS. SHE'S EXPLICITLY AGAINST, I MIGHT ADD, USING CLONING TO HAVE HUMANS REPRODUCED. THIS IS STRICTLY A RESEARCH MEASURE. BUT SHE IS SOMEBODY THAT, SHOULD SHE ASCEND TO THE POSITION, WILL BE VERY MUCH OF A MIND TO HEAVILY FUND STEM CELL RESEARCH TO THE EXTENT THAT SHE CAN.

HER VICE PRESIDENTIAL NOMINEE, TIM KAINE, INTERESTINGLY, IS NOT ENTIRELY ALIGNED WITH HER ON THIS SUBJECT. HE IS A VERY LARGE PROPONENT OF ADULT STEM CELL RESEARCH, BUT IS NOT SOMEBODY THAT SUPPORTS USING TAXPAYER DOLLARS TO FUND EMBRYONIC STEM CELL RESEARCH. AND I THINK IT WILL BE INTERESTING TO SEE HOW, IF INDEED SECRETARY CLINTON

IS ELECTED, HOW THOSE TWO POSITIONS WILL MESH. I SUSPECT THAT HER POSITION WILL TAKE PRECEDENCE. AND SO, AGAIN, IF THE DEMOCRATS WERE TO WIN, I THINK WE WOULD BE IN A POSITION OF HAVING SUPPORTERS FOR WHAT WE DO IN THE WHITE HOUSE.

WITH RESPECT TO MR. TRUMP, HE'S NOT PARTICULARLY ARTICULATED A STRONG SCIENCE POLICY PLATFORM TO THIS POINT. AND SO YOU HAVE TO SORT OF GO BACK A BIT TO FIND ANY REFERENCE TO STEM CELLS IN WHAT HE'S SAID IN THE PAST. THERE WAS AN INTERVIEW HE HAD IN 2011 WITH THE *DES MOINES REGISTER* WHERE HE COMMENTED, IN RESPONSE TO A QUESTION ON THE SUBJECT, THAT HE IS UNDECIDED ON THE CONTROVERSIAL SCIENCE AND HE WANTS TO INVESTIGATE IT FURTHER BEFORE FORMULATING AN OFFICIAL POSITION.

BEST I'VE BEEN ABLE TO TELL, HE HAS NOT SAID MUCH MORE THAN THAT. ALTHOUGH IF HE DOES END UP GETTING ELECTED AND TENDS TO ALIGN HIMSELF WITH THE VIEWS ON THE SUBJECT OF THE OFFICIAL PLATFORM OF THE REPUBLICAN PARTY AS ADOPTED AT THE REPUBLICAN CONVENTION, ONE COULD FORESEE THAT HE WILL BE OPPOSED TO, AT A MINIMUM, FUNDING FEDERAL FUNDING FOR EMBRYONIC STEM CELL RESEARCH.

MIKE PENCE HAS HAD A NUMBER OF CONTROVERSIAL COMMENTS IN THE AREA OF SCIENCE OVER

TIME. INCLUDED IN THOSE ARE SMOKING DOESN'T KILL. GLOBAL WARMING IS A MYTH. AND MOST APPLICABLE TO US, EMBRYONIC STEM CELL RESEARCH IS OBSOLETE. HE BELIEVES THAT ADULT STEM CELL RESEARCH WILL TAKE CARE OF EVERYTHING AND THAT, INTERESTINGLY, HE DOESN'T BASE HIS ARGUMENT ON SAYING THAT YOU CAN ARRIVE AT A MUCH SIMILAR RESULT USING IPS TECHNOLOGY. HE'S NOT ON RECORD, AS FAR AS I CAN TELL, COMMENTING ONE WAY OR THE OTHER ON THAT, BUT IS A STAUNCH OPPONENT OF FEDERAL FUNDING FOR EMBRYONIC STEM CELL RESEARCH. AND HIS VIEWS, I THINK, ARE THOSE THAT ARE REFLECTED IN THE REPUBLICAN PLATFORM.

SO THOSE ARE THE VIEWS OF THE MAJOR CANDIDATES. THERE HAVE BEEN SOME INTERESTING QUOTES BY PEOPLE TRYING TO DISCERN EXACTLY WHERE THEY'RE GOING TO COME OUT. ONE REPUBLICAN ADVISOR SAYS, "TRUMP DOESN'T HAVE A PROMINENT POLICY, AND WE'RE NOT SURE WHERE HE'S GOING TO END UP. CLINTON, ON THE OTHER HAND, HAS A VAST BUREAUCRACY AND A 10-POINT PLAN FOR GOING OUT TO LUNCH." SO THEY SHOULDN'T BE SURPRISED IF SHE HAS A VERY ARTICULATED POSITION IN THIS AREA.

THE BROOKINGS INSTITUTE COMMENTED, "CLINTON HAS DESCRIBED SCIENCE AND INNOVATION AS A

FOUNDATION FOR THE FUTURE." FOR TRUMP, SCIENCE FUNDING SEEMS TO BE AN AFTERTHOUGHT. NOW, OBVIOUSLY THINGS COULD CHANGE IN THE NEXT STRETCH HERE. SO EVERYBODY SHOULD STAY TUNED.

WITH RESPECT TO THE THIRD AND FOURTH CANDIDATES FOR PRESIDENT, GARY JOHNSON IS STAUNCHLY OPPOSED TO FEDERAL FUNDING REALLY FOR ANY KIND OF STEM CELL RESEARCH. HIS VIEW IS THAT IT SHOULD BE ENTIRELY CONDUCTED BY THE PRIVATE SECTOR, ASSUMING THAT THE PRIVATE ENTITY IN QUESTION DOES NOT HAVE ANY FEDERAL FUNDING GOING INTO WHAT IT'S DOING.

JILL STEIN WOULD FEDERALLY FUND STEM CELL RESEARCH REGARDLESS OF WHERE THE CELLS ARE SOURCED.

SO THAT GIVES YOU A FEEL FOR THE STATE OF PLAY ON THE TOPIC. NOT GETTING A LOT OF ATTENTION, AS SCIENCE ITSELF ISN'T, OTHER THAN DEBATES ON GLOBAL WARMING AND A COUPLE OF OTHER THINGS.

SO THAT'S THAT.

SO OTHER ITEMS ON THE CHAIR'S REPORT HERE, I AND RANDY AND NEIL LITTMAN SPENT A LOT OF TIME OUT TALKING TO PEOPLE ABOUT ATP3, WHICH IS SOMETHING THAT COMES UP IN ONE CONTEXT LATER ON THE AGENDA, LOOKING TO GENERATE INTEREST OUT THERE FROM POTENTIAL PROPOSERS. AND THAT HAS BEEN SORT OF AN ONGOING EFFORT FOR A PERIOD OF MONTHS.

IN ADDITION TO THAT, WE HAVE BRIEFED OFFICIALS IN SACRAMENTO ON THE IDEA OF ATP3 AND ITS DETAILS. MARIA AND I MET WITH THE DEPARTMENT OF FINANCE AND THE GOVERNOR'S OFFICE TO BRIEF THEM. I PERSONALLY BRIEFED THE STATE TREASURER. WE HAVE THE STATE CONTROLLER COMING IN, COURTESY OF SENATOR TORRES, SHORTLY. WE'LL BRIEF HER. AND THEN WE WILL AS WELL BRIEF LIEUTENANT GOVERNOR NEWSOM ON THE SUBJECT JUST TO LET THEM KNOW WHAT'S GOING ON.

OVER THE COURSE OF THE LAST FEW MONTHS, WE'VE HAD OUR BRIDGES AND SPARKS PROGRAM. THESE ARE VARIOUSLY OUR FUNDING FOR COLLEGE AND POST-DOC STUDENTS WITH BRIDGES AND HIGH SCHOOL STUDENTS WITH SPARKS. I THOUGHT SINCE THE SPARKS CONFERENCE WAS THE MOST RECENT, I'D GIVE THE BOARD JUST A LITTLE FLAVOR, ADDITIONAL FLAVOR FOR THAT.

I'VE ALWAYS VIEWED THIS AS ONE OF THE COOLEST EVENTS WE HAVE BECAUSE YOU GET THESE KIDS WHO ARE HIGH SCHOOL STUDENTS WHO DON'T KNOW ANYTHING ABOUT THE FIELD WHO GO INTO OUR SUMMER INTERNSHIP PROGRAM AND COME OUT OF IT HAVING PRODUCED POSTERS ON THEIR RESEARCH. AND IF YOU LISTEN TO THEM DESCRIBE THEM, IT IS TRULY UNBELIEVABLY IMPRESSIVE THEIR GRASP OF THE SUBJECT MATTER IN A SHORT EIGHT WEEKS. AND YOU WOULD BE VERY SURPRISED TO LEARN

THESE WERE PREVIOUSLY UNEXPERIENCED HIGH SCHOOL KIDS. LET ME JUST GIVE YOU A BIT OF COMMENT ON THE SPARK PROGRAM.

SPARK PROGRAM SUPPORTS THE TRAINING AND EDUCATION OF CALIFORNIA HIGH SCHOOL STUDENTS IN CUTTING EDGE STEM CELL RESEARCH AND TECHNOLOGY. STUDENTS PARTAKE IN STEM CELL TRAINING AND COURSEWORK COMBINED WITH AN EIGHT-WEEK RESEARCH INTERNSHIP AT LEADING STEM CELL INSTITUTIONS IN CALIFORNIA. SPARK FOCUSES ON GIVING INTERNSHIP OPPORTUNITIES TO UNDERPRIVILEGED STUDENTS.

THIS WAS THE FIRST YEAR OF THE SPARK PROGRAM IN ITS NEW CIRM 2.0 FORMAT. THE PREVIOUS HIGH SCHOOL PROGRAM WAS CALLED CREATIVITY. YOU WILL REMEMBER REFERENCE TO THAT IN PAST YEARS. THIS YEAR WE FUNDED A TOTAL OF 55 SPARK STUDENTS FROM SEVEN PROGRAMS: CITY OF HOPE, CALTECH, CEDARS-SINAI, CHILDREN'S HOSPITAL OAKLAND RESEARCH INSTITUTE, STANFORD, UC DAVIS, AND UC SAN FRANCISCO.

UNDER THE NEW SPARK PROGRAM, STUDENTS WERE REQUIRED TO PARTICIPATE IN PATIENT ENGAGEMENT ACTIVITIES THAT INCLUDED PARTICIPATING IN BLOOD DONATION, BONE MARROW REGISTRY, AND MAKING CARE PACKAGES FOR ALS PATIENTS. THEY ALSO WERE REQUIRED TO DOCUMENT AND SHARE THEIR INTERNSHIP ACTIVITIES

THROUGH SOCIAL MEDIA, INCLUDING POSTING PICTURES ON INSTAGRAM AND BLOGGING.

THE SPARK CONFERENCE WAS HOSTED IN EARLY AUGUST AT THE CLAIRMONT HOTEL IN BERKELEY. SPARK STUDENTS PRESENTED THEIR RESEARCH THROUGH TALKS AND POSTER SESSIONS. THE CONFERENCE ALSO FEATURED TALKS BY SCIENTISTS, PATIENT ADVOCATES, AND SPARK ALUMNI ON THE IMPORTANCE OF STEM CELL RESEARCH. THE DAY WAS A CELEBRATION OF THEIR ACCOMPLISHMENTS AND A HUGE SUCCESS. MANY OF THE SCIENTISTS AND CIRM ATTENDEES COMMENTED ON HOW TALENTED AND SMART THESE YOUNG KIDS ARE.

I WANT TO GIVE A SPECIAL SHOUT OUT HERE TO KAREN RING, WHO WAS THE MEMBER OF THE CIRM TEAM WHO OVERSAW THE EVENT. SHE DID A WONDERFUL JOB. AND I ALWAYS, AS I DO EVERY YEAR, COME AWAY FROM THIS THINKING THAT THE FUTURE OF THE WORKFORCE IN STEM CELL RESEARCH IS IN GOOD HANDS AND THAT THESE KIDS AND OTHERS LIKE THEM WHO HAVE PRECEDED THEM AND THOSE OUT OF THE REMARKABLE BRIDGES PROGRAM WILL BE THE BACKBONE FOR FUTURE WORK DONE IN THE FIELD IN CALIFORNIA FOR MANY YEARS TO COME.

LASTLY, I WANTED TO REPORT TO YOU AS PART OF THE EFFORT TO LOOK FOR POTENTIAL CLINICAL TRIAL APPLICANTS THAT RANDY HAS PUT IN PLACE THROUGH MARIA

MILLAN WHO'S DOING A WONDERFUL JOB SOURCING POTENTIAL APPLICANTS. I HAPPENED TO HAVE A CALL WITH THE HEAD OF THE AGENCY FOR SCIENCE TECHNOLOGY AND RESEARCH IN THE GOVERNMENT OF SINGAPORE WHO IS VERY INTERESTED IN WHAT WE'RE DOING. THEY HAVE A MUCH SMALLER SCALE PROGRAM IN STEM CELL RESEARCH OVER THERE THAT IS TARGETING AT THE MOMENT CANCER, NEUROLOGICAL, DEGENERATIVE CONDITIONS, AND CARDIO.

AND I DESCRIBED TO THEM HOW WE ARE MOST INTERESTED IN LOOKING FOR THE BEST-IN-CLASS PROJECTS ALL OVER THE WORLD WHO CAN ESTABLISH A NEXUS WITH CALIFORNIA, WHICH WOULD QUALIFY THEM TO POTENTIALLY APPLY FOR CIRM FUNDING FOR THAT COMPONENT OF THEIR PROJECT. THEY THOUGHT THIS WAS A VERY INTERESTING CONCEPT. THEY, JUST LIKE EVERYBODY ELSE, VIEWS CIRM AS THE SORT OF WONDERFUL ENTITY THAT IS PROVIDING FUNDING FOR SO MANY DIFFERENT THINGS. AND THEY'RE GOING, AS A RESULT OF THAT CALL, AND KEVIN MCCORMACK WAS ON IT WITH ME, GOING TO GO BACK AND THINK AND SEE IF THEY CAN WORK ON COORDINATING WITH POTENTIAL AWARDEES OVER HERE IN CALIFORNIA. THEY ALREADY HAVE OUTSTANDING RELATIONSHIPS WITH, AS I RECALL, UCSF AND UCSD.

SO THAT CONCLUDES THE CHAIR'S REPORT. WE'RE ON TO THE PRESIDENT'S REPORT. DR. MILLS.

DR. LUBIN: I JUST WANTED TO COMMENT ON THE SPARKS PROGRAM BECAUSE IT WAS JUST SUCH A WONDERFUL OPPORTUNITY FOR THE STUDENTS WE HAD THIS SUMMER. BUT WE DID SOMETHING THAT WE'VE NEVER DONE BEFORE THAT'S GOING TO CONTINUE THAT ESTABLISHED A RELATIONSHIP BETWEEN THE STUDENT AND THE SPARK PROGRAM AND A CHILD WHO HAD A BONE MARROW TRANSPLANT. SO THEY BECAME PEN PALS.

SO THIS PATIENT THAT WAS TRANSPLANTED, SICKLE CELL, CANCER, WHATEVER, BECAME A PAL OF ONE OF THE STUDENTS. THEY MET THEM AND THEN THEY'RE COMMUNICATING AND CONTINUING TO COMMUNICATE. AND IT'S SUCH A WONDERFUL THING FOR A YOUNG PERSON WHO'S THINKING ABOUT A CAREER TO KNOW A PATIENT WHO BENEFITED FROM A STEM CELL TRANSPLANT OR PARTICIPATED IN IT. AND I THINK SPARK SHOULD TAKE CREDIT FOR SOMETHING LIKE THAT. AND THERE'S A GOOD PR OPPORTUNITY THERE AS WELL. AND THE FAMILIES ALL AGREED THAT THIS COULD BE DONE. WE DON'T GIVE THE NAMES OUT, BUT THE COMMUNICATIONS ARE BEAUTIFUL. AND IF PEOPLE WANT TO SEE EXAMPLES OF SOME OF THOSE, REALLY, IT'S HEARTWARMING. AND SO I JUST WANTED TO SHARE THAT WITH YOU.

CHAIRMAN THOMAS: THANK YOU, DR. LUBIN.

DR. MILLS: THANK YOU VERY MUCH. TODAY

I'LL BE GOING THROUGH THE PRESIDENT'S REPORT IN A VERY SIMILAR FORMAT TO THE WAYS WE'VE DONE IT BEFORE.

WHAT I'D LIKE TO DISCUSS TODAY FIRST, AS ALWAYS WE DO WITH EVERY PRESENTATION, IS TO REVIEW THE CIRM MISSION. I ALSO WANT TO TAKE JUST A SHORT AMOUNT OF TIME TO REVIEW THE STRATEGIC PLAN AND THE GOALS OF THE STRATEGIC PLAN SO WE KEEP THEM SQUARELY IN OUR MINDS AS WE MOVE FORWARD. THEN I WANT TO TALK ABOUT, NOW WE'VE HAD THE STRATEGIC PLAN, HOW IS IT STARTING TO PERFORM? AS WE'RE PUTTING IT ALL ONLINE, WE'RE PUTTING THE PIECES ALL IN PLACE, WE'RE STARTING TO BE ABLE TO GET ACTUAL PERFORMANCE METRICS OUT OF IT, AND HOW IS THAT PERFORMANCE GOING. AND THEN WE'RE GOING TO TALK ABOUT THE BUDGET REVIEW BECAUSE WE ALSO, VERY IMPORTANTLY, TO MAKE OUR STRATEGIC PLAN WORK, WE NEED TO PAIR UP THE THINGS WE NEED TO GET DONE WITH THE TIME AND MONEY THAT WE HAVE LEFT TO DO THEM. AND THE LAST THING I WANTED TO DO WAS TO HAVE A BRIEF DISCUSSION AROUND OUR CLINICAL PROGRAM AND THE CURRENT CONCEPT PLAN THAT WE HAVE IN OUR CLINICAL PROGRAM AND SOME OF THOSE COMPONENTS.

WE'VE HAD DISCUSSIONS IN RECENT APPLICATION REVIEW SUBCOMMITTEE MEETINGS WHERE THERE

WERE QUESTIONS THAT CAME UP ABOUT DIFFERENT TECHNOLOGIES THAT WERE BEFORE US AND WHETHER OR NOT THEY WERE IN SCOPE OR WHETHER OR NOT WE WANTED THEM TO BE IN SCOPE. AND I THOUGHT IT MIGHT BE A GOOD OPPORTUNITY FOR US TO FULLY, OR NOT FULLY, BUT IN AN OVERVIEW, AT LEAST, REVIEW THAT PROGRAM AND SEE IF THERE WAS ANYTHING WE HAD TO DISCUSS ABOUT OR WHETHER IN FACT WE WERE HAPPY WITH THE WAY IT IS.

SO OUR MISSION, TEN SIMPLE BUT POWERFUL WORDS, ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. WE ARE ALL ABOUT PATIENTS. AND BECAUSE THE WORD "ACCELERATE" IS IN THERE, WE ARE IN THE TIME BUSINESS, AND SO WE AT CIRM WILL NEVER FORGET THAT.

OUR STRATEGIC PLAN, WHICH WAS ADOPTED IN DECEMBER OF LAST YEAR, HAS THREE SIMPLE COMPONENTS TO IT. THE FIRST IS WHAT WE CALL PUSHING. THESE ARE ALL THE ACTIVITIES THAT WE WOULD NORMALLY UNDERTAKE AT CIRM TO HELP MOVE PROJECTS ALONG AS THIS SORT OF GIANT STEM CELL BOULDER TO GET IT OVER THE HILL. AND WHAT WE'RE DOING WITH THE PUSH COMPONENT OF THIS IS WE'RE TRYING TO INTEGRATE THESE PIECES BETTER. WE'RE TRYING HAVE THEM WORK MORE SEAMLESSLY. WE'RE TRYING TO GET MORE POWER OUT OF THAT PUSHING MACHINE THAT HAD ALREADY EXISTED.

ON THE OTHER SIDE OF THE HILL, WE HAVE THE PULL ASPECT OF THIS. THIS IS ONE OF THE THINGS THAT WAS GLARINGLY OBVIOUS. WE DIDN'T HAVE ENOUGH AND WE STILL DON'T HAVE ENOUGH ACTIVE INDUSTRY ENGAGEMENT IN STEM CELL THERAPY THAT'S HELPING PULL THESE THINGS TOWARDS INDUSTRY AS WE'RE DOING OUR BEST TO PUSH THEM TO PATIENTS. AND THEN, LASTLY, CENTERS ON SOME OF THE CHALLENGES THAT EXIST IN THE CURRENT REGULATORY PARADIGM IN ITS CURRENT FORM FOR CELL THERAPIES AND THE WORK THAT WE'RE DOING WITH FDA TO TRY TO LEVEL THAT FIELD AND MAKE MORE EFFICIENT AND COST-EFFECTIVE METHODS OF GETTING SAFE AND EFFECTIVE TREATMENTS TO PATIENTS.

AS YOU KNOW, IT WAS VERY IMPORTANT THAT WE NOT JUST TALK ABOUT SORT OF GRAND VISIONS IN WHAT WE WANT TO DO WITH REGARDS TO CIRM AND ITS STRATEGIC PLAN, BUT ALSO LAY OUT VERY CLEAR AND MEASURABLE OBJECTIVES FOR US TO REACH. AND SO IN 2020 WE ARE GOING TO KNOW WHETHER OR NOT WE DID OR DIDN'T ACHIEVE ALL OF OUR SIX COMPONENTS. WE CALL THEM THE BIG SIX INSIDE CIRM.

JUST TO REVIEW THEM, STARTING AT THE LEFT, 50 NEW CANDIDATES INTO DEVELOPMENT. WE WANT TO INCREASE WHAT WE CALL PROGRESSION EVENTS. SO THAT'S WHEN WE HAVE A PROGRAM THAT'S IN ONE STAGE OF

DEVELOPMENT MOVE TO THE NEXT STAGE OF DEVELOPMENT WITHIN CIRM. WE WANT TO INCREASE PROGRESSION EVENTS BY GREATER THAN 50 PERCENT. WE WANT TO HELP ENACT A NEW, MORE EFFICIENT REGULATORY PARADIGM WITH FDA. WE WANT TO REDUCE THE TIME IT TAKES FROM A PRODUCT TO GO THROUGH THE TRANSLATION STAGE. THAT'S FROM WHEN A CANDIDATE IS DISCOVERED TO WHEN IT'S FIRST USED IN HUMAN CLINICAL TRIAL. CURRENTLY FOR STEM CELL THERAPIES, THAT TRANSLATION PHASE TAKES EIGHT YEARS. IN THE WORLD OUTSIDE OF CELL THERAPY, SO FOR SMALL MOLECULES, THAT NUMBER IS 3.2 YEARS TO ACCOMPLISH THE EXACT SAME ACTIVITY. SO WE'VE SET UP A PRETTY AMBITIOUS GOAL TO HELP SHORTEN THAT TIME FROM EIGHT YEARS DOWN TO AT LEAST LESS THAN FOUR YEARS.

THEN THERE'S A REALLY BIG ONE, AND THAT IS WE WANT TO INTRODUCE 50 NEW CLINICAL TRIALS INTO THE CLINIC THROUGH CIRM'S PROGRAMS. IT'S REALLY IMPORTANT AS WE ACCOMPLISH THAT GOAL THAT WE DON'T LOWER OUR QUALITY STANDARDS, THAT THIS HAS TO BE DONE WITH PERFECT QUALITY, THAT THOSE ARE THE THINGS THAT WILL GIVE US THE GREATEST CHANCE TO HAVE THOSE THERAPIES ACTUALLY TRANSLATE THROUGH AND HELP PATIENTS.

AND THEN, LASTLY, WHEN WE HAVE THESE

CLINICAL STAGE PROGRAMS AND THEY'RE SHOWING SUCCESS, WE WANT TO GET THEM PARTNERED UP WITH INDUSTRY SO THAT INDUSTRY CAN DO SOME OF THE HEAVY LIFTING AT THE END OF THE DEVELOPMENT CYCLE AND MAKE THOSE THERAPIES BROADLY AVAILABLE TO THE PATIENTS WHO NEED THEM. SO THOSE ARE OUR BIG SIX GOALS FOR 2020.

OVERARCHING THEMES BEHIND THIS STRATEGIC PLAN, ONE, WE WANTED IT OBVIOUSLY TO BE FASTER. I SAID WE'RE IN THE TIME BUSINESS, AND I'LL TALK MORE ABOUT THIS. BUT THERE ARE A LOT OF THINGS AT CIRM THAT WE HAVE BEEN ABLE TO DO THAT IN REAL TIME SIGNIFICANTLY SHORTEN THE DEVELOPMENT CYCLE.

WE WANTED OUR PROCESS TO BE PREDICTABLE. AND SO WE USED TO CALL THIS GRANT WHACK A MOLE WHERE THE APPLICATIONS WOULD POP UP AND GO AWAY. WE WANTED OUR USERS TO BE ABLE TO KNOW THAT CIRM WAS ALWAYS OPEN AND ALWAYS AVAILABLE FOR WHATEVER STAGE OF DEVELOPMENT THEY HAD, WHEN THEY COULD APPLY, AND HAVE THAT WORK FASTER.

SIMILARLY, AND THIS BOARD HAS SUPPORTED US ON THIS VERY STRONGLY, ACTUALLY ALMOST EVERY TIME WE ISSUE AN AWARD, IT'S PUT OUT THERE, WE WANTED OUR PROGRAMS TO BE PERFORMANCE BASED. SO WE WENT TO A MILESTONE-BASED PROCESS FOR THE GRANTS WE ISSUE. AND THAT IS, THE APPLICANTS COME, WE GIVE THEM A

MILESTONE TO GET STARTED, THEY HAVE TO REACH THEIR NEXT MILESTONE IN ORDER FOR THE APPLICATION TO CONTINUE. IF THEY ARE UNABLE TO DO THAT, THEN THE GRANT CANCELS OUT. AND THE NICE THING ABOUT THAT PERFORMANCE-BASED SYSTEM IS I'VE JUST SORT OF STEPPED BACK AND I'VE WATCHED THE BOARD EVALUATE IT AND ALSO THE GWG EVALUATE IT. WE'RE TAKING CHANCES ON APPLICATIONS WE PROBABLY OTHERWISE WOULDN'T TAKE CHANCES ON BECAUSE WE KNOW IF IT'S NOT WORKING OUT, THEN WE WILL BE ABLE TO STOP THAT BEFORE HAVING SPENT ALL OF THE MONEY. SO I THINK IT'S AN EXCELLENT PROGRAM, AND INTERNALLY WE KNOW WE'RE SEEING BENEFITS TO THIS.

LASTLY, IT WAS ESSENTIAL THAT THIS PROCESS BE CLEAR AND UNDERSTOOD BY ALL OF THE PEOPLE BOTH INTERNALLY AND EXTERNALLY, THAT IT BE OBVIOUS, INTUITIVE HOW IT WORKS AND THAT WE GET THE WORD OUT.

SO ACTUALLY RIGHT AFTER WE LEAVE HERE, THE CIRM TEAM AND I WILL BE KICKING OFF WHAT WE CALL THE CIRM ROAD SHOW. AND WE'LL BE GOING AROUND TO THE MAJOR RESEARCH FACILITIES THROUGHOUT CALIFORNIA, AND WE'LL BE TALKING AND SPENDING TIME WITH THE INVESTIGATORS THERE EXPLAINING TO THEM THE SYSTEMS THAT WE HAVE IN PLACE, THE PROGRAMS WE HAVE, HOW TO USE THEM, HOW TO CONTACT US, HOW TO INTERACT WITH US

SO WE CAN GET THE BEST PROGRAMS.

SO THIS IS THAT GIANT STEM CELL ENGINE THAT WE'RE TRYING TO CREATE. IT HAS ALL THESE DIFFERENT PIECES AND COMPONENTS TO IT. THE IDEA IS TO HAVE SOMETHING THAT ACCELERATES THINGS THROUGH THIS ENGINE FASTER AND MORE OF THEM THAN WOULD OTHERWISE HAPPEN WITHOUT CIRM. AND WE FEEL CONFIDENT THAT IF WE EXECUTE ON ALL OF OUR DIFFERENT PIECES, THAT THIS IS, IN FACT, WHAT WILL HAPPEN.

I'M PROUD TO SAY THAT AS OF TODAY ALL BUT TWO PIECES OF THIS ENGINE ARE NOW UP AND RUNNING. THE ONLY TWO THINGS WE HAVE LEFT TO DO ARE THE TRANSLATING CENTER AND THE ATP3, WHICH WE'LL BE TALKING ABOUT TODAY. SO IT'S STARTING TO COME ONLINE.

SO AS IT STARTS TO COME ONLINE, IT MAKES SENSE TO TALK ABOUT THE PERFORMANCE THAT WE'RE SEEING. IF THE WHOLE PROGRAM, OUR INFRASTRUCTURE, EDUCATION, AND EVERYTHING TOGETHER, MAKES UP THE ENGINE, THEN THE CORE OF THE ENGINE ARE REALLY OUR GRANTING PROGRAMS IN OUR DEVELOPMENT STAGES FROM DISCOVERY THROUGH TRANSLATION TO CLINICAL.

AND HERE IT WAS IMPORTANT FOR US TO CREATE A STRUCTURE WHERE WE COULD TAKE A BRAND-NEW IDEA FROM VERY SEED CONCEPT AND CREATE A CLEAR PATHWAY

THAT LINKED, WHERE THE PRODUCT OF ONE AWARD WAS THE PREREQUISITE FOR THE NEXT AWARD, SEAMLESSLY ALL THE WAY THROUGH PRODUCT APPROVAL, AND HAVE THAT BE DONE IN AN EFFICIENT TIME FRAME WHERE THE INVESTIGATORS WEREN'T LEANING ON US, BUT INSTEAD WE WERE READY WHEN THEY WERE READY. AND SO WE'VE DONE THIS HERE.

IN DISCOVERY, AGAIN, WE HAVE THE SEED AWARD WHICH GOES TO A BASIC DISCOVERY AWARD, WHICH IS OUR MAJOR WORKHORSE AWARD. WE OFFER THOSE ONE AND TWO TIMES A YEAR. THAT HANDS OFF, ONCE A SINGLE PRODUCT CANDIDATE HAS BEEN DEVELOPED, INTO TRANSLATION. WE OFFER THOSE THREE TIMES A YEAR NOW. AS SOON AS YOU HAVE YOUR PRE-IND MEETING, YOU'RE GETTING READY TO HAND IT OFF TO THE CLINICAL STAGE, WHERE WE OFFER THOSE PROGRAMS 12 TIMES A YEAR, AND THEN ON INTO CLINICAL TRIALS AND THEN HOPEFULLY AN APPROVED THERAPY.

SO THE GREAT THING ABOUT THE CORE IS THE CORE IS ALL UP AND RUNNING. EVERY SINGLE PROGRAM THAT WE HAVE WITHIN THESE, WE HAVE TEN TOTAL WITHIN THESE, ARE UP AND RUNNING AND WORKING, WHICH IS GOOD TO SEE.

THIS SYSTEM WHERE WE HAVE A PREDICTABLE NUMBER OF REVIEWS EACH YEAR FOR ALL OF OUR DIFFERENT PROGRAMS AND WE KNOW WHEN THEY'RE GOING TO HAPPEN

AND HOW THEY'RE GOING TO HAPPEN, NOT ONLY IS THAT USER FRIENDLY FOR OUR APPLICANTS THAT WANT TO COME AND APPLY TO THESE SYSTEMS, THEY'LL KNOW WHEN AND HOW AND THOSE TYPES OF THINGS, BUT FROM A BOARD STANDPOINT IT'S ALSO REALLY IMPORTANT, AND AS WE SEE AS WE GO INTO THE DECEMBER BOARD MEETING, THIS IS GOING TO ALLOW MUCH BETTER CONTROL OF BUDGETING GOING FORWARD. AND WE'LL ACTUALLY BE ABLE TO DO PROSPECTIVE BUDGETING BASED ON WHERE WE ARE AND DIFFERENT ADJUSTMENTS AND BALANCES WE NEED TO MAKE BETWEEN THESE DIFFERENT PROGRAMS.

SO WITH THE EXCEPTION OF REALLY WHETHER OR NOT WE WANT TO INCLUDE ALPHA CLINICS IN NEXT YEAR'S BUDGET, ALMOST ALL OF THE BUDGETING DECISIONS THAT WE HAVE TO MAKE AND THE BOARD HAS TO MAKE CENTER AROUND THESE THREE PROGRAMS AND IT BECOMES FAIRLY SIMPLE. WE PICK HOW MUCH MONEY WE WANT TO GO INTO EACH OF THESE PROGRAMS AND HOW MANY REVIEWS OR CYCLES WE WANT TO OFFER. SO DO WE WANT TO CONTINUE TRANSLATION AT THREE A YEAR? DO WE WANT TO CONTINUE THAT AT A RUN RATE OF $45 MILLION OVER THOSE THREE YEARS? AND THIS IS SOMETHING THAT SCOTT TOCHER IS GOING TO BE TALKING ABOUT A LITTLE BIT MORE COMING UP. BUT IT WILL BE MUCH CLEARER FOR THE BOARD WHAT WE'RE SPENDING MONEY ON AND WHY ON A PROSPECTIVE

BASIS.

SO NOW THAT WE HAVE THIS CORE, AT LEAST, IN PLACE AND THE CORE IS WORKING, LET'S TAKE A LOOK AT HOW IT'S DOING COMING ONLINE. SO IN DISCOVERY, SO WHAT YOU'RE SEEING HERE IS HOW WE ARE ESTIMATING WE'RE GOING TO FINISH THE YEAR, ETF, ESTIMATE TO FINISH THE YEAR, VERSUS WHAT WE ALLOCATED FOR THOSE PROGRAMS IN THAT YEAR. SO IN DISCOVERY WE'RE GOING FINISH, WE THINK, AT ABOUT $37 MILLION AWARDED. THAT IS VERSUS $53 MILLION ALLOCATED. SO THIS ONE COMES IN A LITTLE LOW. IT COMES IN LOW BECAUSE WE ACTUALLY JUST DIDN'T HAVE SUFFICIENT NUMBER OF MERITORIOUS AWARDS IN OUR QUEST AWARD. WE CAME IN LOW ON THAT. WE ALSO DIDN'T USE THE TWO CHALLENGE AWARDS, WHICH WAS $4 MILLION. AND BETWEEN THOSE TWO, THAT MAKES UP THE BULK OF THAT DIFFERENCE.

LOOKING AT TRANSLATION, TRANSLATION IS ACTUALLY RUNNING A LITTLE HIGH. SO WE'RE GOING TO ESTIMATE TO FINISH AT ABOUT $52 MILLION FOR THE YEAR VERSUS $40 MILLION ALLOCATED. BEFORE JAMES HAS A CONCERN ABOUT THAT, THE DIFFERENCE AND HOW WE WERE ABLE TO OVERALLOCATE IS YOU, THE BOARD, ACTUALLY WENT THROUGH THE PROCESS AND PUT ANOTHER $15 MILLION FUNDING ALLOCATION TO CONDUCT THE THIRD REVIEW IN TRANSLATION BECAUSE THERE WAS SUCH SIGNIFICANT

DEMAND.

AND THEN LASTLY IS CLINICAL. AND CLINICAL IS A REALLY IMPORTANT PIECE TO THE SUCCESS OF CIRM BECAUSE OUT OF THOSE GOALS, RIGHT NOW AS WE STAND HERE TODAY, THE MOST CHALLENGING ONE OF THOSE GOALS FOR US TO HIT ARE GETTING 50 HIGH QUALITY CLINICAL TRIALS INTO AND MOVING ALONG IN OUR SYSTEM. RIGHT NOW WE'RE ESTIMATING THIS YEAR TO FINISH AT ABOUT $80 MILLION OF AWARDS IN CLINICAL VERSUS A HUNDRED MILLION THAT WE ALLOCATED. BUT THE GOOD NEWS IS THIS IS RAPIDLY INCREASING. I'LL TALK MORE ABOUT THE SIGNIFICANCE OF THIS COMING UP. BUT THE NUMBER OF NEW APPLICATIONS COMING INTO CIRM NOW IS HIGHER THAN IT HAS EVER BEEN BEFORE. THE CLINICAL TEAM IS JUST DOING A PHENOMENAL JOB. I DON'T KNOW IF YOU'LL RECALL, BUT THE LAST TIME I PUT THIS SLIDE UP, OUR ESTIMATE TO FINISH WAS $35 MILLION. SO IN THE LAST THREE MONTHS, THEY'VE MADE INCREDIBLE PROGRESS.

SO LET'S TALK ABOUT SOME OF THAT PROGRESS PARTICULARLY IN THE CLINICAL STAGE. SO SINCE WE'VE INTRODUCED THIS CIRM 2.0 PROGRAM, WE HAVE RECEIVED 54 CLINICAL STAGE APPLICATIONS. THE FIRST THING WE DO WHEN THOSE APPLICATIONS COME IN IS WE PUT THEM THROUGH ELIGIBILITY REVIEW. SO JUST BEFORE WE GO OFF FOR SCIENTIFIC REVIEW, WE JUST MAKE CERTAIN THAT

THE APPLICATION IS WITHIN SCOPE, IT'S FROM A QUALIFIED APPLICANT, THEY MEET CERTAIN BLACK AND WHITE CRITERIA.

SO OUT OF THOSE 54 THAT HAVE COME IN, WE'VE HAD 39 PASS ELIGIBILITY, BUT WE HAVE SEVEN PENDING RIGHT NOW. AND THAT'S A TESTAMENT TO HOW QUICKLY WE'RE RAMPING UP IN THIS AREA. SO OUT OF THOSE 39 THAT PASSED ELIGIBILITY, WE HAVE 36 OF THEM WHICH HAVE FINAL DISPOSITIONS FROM THE GWG. WE HAVE THREE THAT ARE CURRENTLY UNDER REVIEW. SO OUT OF THOSE 36 WHERE WE HAVE FINAL DISPOSITIONS, 13 OF THOSE HAVE BEEN FAVORABLE WHERE THE PROGRAM HAS BEEN RECOMMENDED FOR FUNDING TO YOU GUYS. SO THE 13 OUT OF 36 IS 36 PERCENT. SO APPLICATIONS THAT WE CAN ACTUALLY GET IN AND WILL PASS ELIGIBILITY, 36 PERFECT ARE ADJUDICATED FAVORABLY. WHEN YOU LOOK AT VERSUS THE APPLICATIONS WE ACTUALLY RECEIVE, IT'S ABOUT 30 PERCENT.

SO HERE'S THE IMPORTANT POINT OUT OF ALL THESE NUMBERS. FOR US TO ACHIEVE OUR CLINICAL TRIAL GOALS, WE ARE GOING TO NEED TO TAKE IN AN ADDITIONAL 150, APPROXIMATELY, MORE CLINICAL APPLICATIONS OVER THE NEXT THREE AND A HALF YEARS TO REACH THESE GOALS. THAT THIS IS A TREMENDOUS AMOUNT OF WORK FOR THE CIRM TEAM, ONE, TO GO OUT AND FIND THOSE BECAUSE

WE'RE NOT PASSIVE ANYMORE. WE'RE IN THE HUNTING BUSINESS. WE GO OUT AND WE FIND GREAT PROGRAMS AND WE BRING THEM IN. SO MARIA MILAN'S TEAM IS DOING THAT. AND, AS I MENTIONED, THEY'RE DOING A PHENOMENAL JOB AT THAT. SEVEN APPLICATIONS LAST MONTH ALONE. SO KEEP THAT RATE UP AND WE'RE GOOD THERE, BUT WE ALSO HAVE A REVIEW TEAM THAT NEEDS TO REVIEW ALL THAT. AND THEN YOU GUYS COME INTO THIS. YOU GUYS PARTICIPATE IN THE GWG, AND THEN YOU GUYS ULTIMATELY HAVE TO DO THE FINAL APPROVALS.

THEN GRANTS MANAGEMENT AND GABE HAS TO ACTUALLY GO ON AND TURN THOSE THINGS INTO CONTRACTS. SO IF YOU LOOK AT THE PERFORMANCE HERE, IT'S REALLY QUITE STUNNING. SO IN 2016 THIS YEAR WE'RE GOING TO FINISH WITH 20 SEPARATE GWG REVIEWS. TO PUT THAT IN CONTEXT, OUR HISTORICAL AVERAGE IS 5.8 A YEAR. SO WE'RE OVER TRIPLE THE VOLUME WE'RE DOING RIGHT NOW WITH NO NEW PERSONNEL IN THIS AREA. SO WE'RE GETTING FAR BETTER PERFORMANCE OUT OF THE TEAM.

AGAIN, YOU GUYS ARE PLAYING AN IMPORTANT ROLE IN THIS. WE'RE NO LONGER TAKING THESE APPLICATIONS TO APPROVAL WHENEVER WE HAPPEN TO HAVE A BOARD MEETING. THE APPLICATION REVIEW SUBCOMMITTEE OF THIS BOARD IS MEETING MONTHLY. SO THAT'S HELPING US REALLY SQUEEZE DOWN THE TIME. SO

THE TIME RIGHT NOW FROM APPLICATION TO APPROVAL IS NOW UNDER 85 DAYS. IT'S VERY, VERY QUICK FOR CLINICAL APPLICATIONS. AND THE TIME FROM APPROVAL TO CONTRACTING IS NOW UNDER 45 DAYS, AND WE HAVEN'T MISSED THAT ONCE. WHY THAT NUMBER IS IMPORTANT IS THAT NUMBER WAS SEVEN MONTHS TWO YEARS AGO. SO IT'S A TREMENDOUS JOB THAT ALL OF THOSE TEAMS ARE DOING AND YOU GUYS ARE DOING WORKING TOGETHER.

SO WE ALSO HAVE A LOT OF BEHIND-THE-SCENES STUFF THAT GOES ON AT CIRM. YOU GUYS MOSTLY GET TO INTERFACE WITH THE REVIEW TEAM WHO PRESENTS OR THE CLINICAL TEAM THAT TALKS TO YOU ABOUT CERTAIN CLINICAL TRIALS AND THINGS AND THEN EARLY STAGE DISCOVERY AND TRANSLATIONAL, BUT THERE'S A LOT THAT GOES ON IN THE INNERWORKINGS OF THIS ENGINE TO MAKE IT ALL WORK AND TO MAKE IT COMPLIANT AND TRANSPARENT AND ALL OF THESE OTHER GOOD THINGS THAT WE NEED TO BE.

AND SO MARIA BONNEVILLE SPEARHEADED A PROGRAM CALLED THE CIRM 2.0 CORE. AND THAT WAS WE HAD DONE CIRM 2.0 FOR CLINICAL AND THAT WORKED GREAT, AND THEN WE DID CIRM 2.0 FOR DISCOVERY AND TRANSLATIONAL PROGRAMS, AND THAT WORKED GREAT. AND WE SAID, OKAY. SO WE HAVE ALL THESE SORT OF FRONT-STAGE THINGS WORKING. WE NEED TO DO THAT SAME

LEVEL OF OVERHAUL THROUGHOUT THE ENTIRE ORGANIZATION, THROUGH ALL THE BACK-STAGE THING. THIS GIVES US A LIST. THIS IS ALL DONE NOW. WE'RE REPORTING COMPLETE THIS GIANT LIST OF STUFF THAT THEY WERE ABLE TO GET DONE BEHIND THE SCENES THAT THEN CAN HAVE THE WHOLE ORGANIZATION PERFORM AT THE SAME LEVEL AS THESE THINGS THAT WE GENERALLY PUT OUT MORE IN FRONT STAGE AND TALK ABOUT. SO, AGAIN, A TREMENDOUS EFFORT BY LEGAL, HUMAN RESOURCES, GRANTS MANAGEMENT, FINANCE, I.T., THE APPLICATION REVIEW TEAM, AND THEN ALL OF THE PEOPLE THAT WE HAVE TO WORK WITH THE BOARD.

NOW, THIS IS ONE AREA, AND ACTUALLY THEY'RE ALL -- I SHOULDN'T SAY THIS IS ONE AREA. THEY'RE ALL LIKE THIS WHERE THERE WILL ALWAYS BE THE NEED FOR CONTINUAL UPDATE. SO YOU CAN ALWAYS IMAGINE IF THIS IS CIRM 2.0, THEN WE'RE ALWAYS WORKING ON CIRM 3.0 BECAUSE WE CAN ALWAYS GET BETTER AT DIFFERENT THINGS. AND THIS IS CERTAINLY AN AREA THAT WE'RE LOOKING TO DO THAT. BUT TREMENDOUS EFFORT BY THIS TEAM.

THE LAST THING I WANT TO TALK ABOUT WITH PERFORMANCE IS THE ACCELERATING CENTER. I GOT A CHANCE TO SEE WHAT IT LOOKED LIKE. IF YOU GUYS RECALL, THIS IS THE PROGRAM, ONE-HALF OF WHAT WE

CALL THE PITCHING MACHINE WHERE WE HAVE THE ACCELERATING CENTER AND THE TRANSLATING CENTER. THESE TWO CENTERS ARE DESIGNED TO WORK TOGETHER TO RADICALLY SPEED UP THAT TRANSLATIONAL PHASE, THAT PHASE WE HAVE TO TAKE FROM EIGHT TO FOUR YEARS IF WE WANT TO HIT OUR GOALS. THIS IS BASICALLY THE STEM CELL CRO SIDE OF IT. WE WERE ABLE TO GET THIS APPROVED, AND I WOULD LIKE TO SAY NOW THAT THIS IS NOT JUST APPROVED, IT'S BEEN CONTRACTED. IT WAS CONTRACTED IN JUST 65 DAYS WHICH FOR SOMETHING OF THIS SCALE IS REMARKABLE. IT IS OPEN FOR BUSINESS, AND WE'RE GOING TO BE HOLDING OUR GRAND OPENING CEREMONY ON OCTOBER 4TH. IT'S HERE IN LA JOLLA. SO IF YOU CAN, WE'D LOVE TO HAVE YOU OUT THERE.

THIS PROGRAM AND EVERYTHING THEY HAVE IN PLACE, AND, AGAIN, I SAW IT YESTERDAY. THIS IS SOMETHING YOU CAN WALK INTO AND YOU CAN SEE PEOPLE WORKING ON. IT'S SO WONDERFUL. THEY'VE GONE SO FAR ABOVE AND BEYOND WHAT WE ORIGINALLY HOPED THEY WOULD DO. WE WANTED THEM TO CREATE A CRO IN THE STATE OF CALIFORNIA THAT WOULD HELP RUN CLINICAL TRIALS AND MOVE THEM IN A FASTER AND HIGHER QUALITY FASHION. BUT THEY LOOKED AT OUR WHOLE THING, AND THEY SAID YOU KNOW WHAT. WE CAN HELP IN SOME OTHER AREAS.

FIRST, WE KNOW A LOT OF POTENTIAL HIGH

QUALITY APPLICANTS OUT THERE THAT WE CAN REFER INTO CIRM. SECOND, WE KNOW HOW TO PREPARE CIRM APPLICATIONS. WE CAN HELP THEM. THINK ABOUT THIS. WITH REGARDS TO THE MASSIVE WORKLOAD THAT THE GWG HAS TO DO IN REVIEWING APPLICATIONS, WELL, IF THE QUALITY OF APPLICATIONS STARTS COMING AT A MUCH HIGHER LEVEL, THEN WE WON'T NEED TO REVIEW 150 TO GET TO 45. WE MIGHT ONLY HAVE TO REVIEW A HUNDRED. SO THAT WOULD BE PHENOMENAL. THEY'RE JUMPING IN AND DOING THAT. THEY'RE ALSO PLAYING A VERY ACTIVE ROLE ON HELPING OUR APPLICANTS AND OUR AWARDEES -- NOT OUR APPLICANTS, OUR AWARDEES -- UNDERSTAND HOW TO PREPARE AN IND, PREPARE AN IND AND COORDINATE AND COMMUNICATE WITH FDA ON THAT.

WE'LL ACTUALLY BE GOING BACK. EARLIER THIS QUARTER I ACTUALLY HAD A MEETING WITH THE COMMISSIONER OF FDA, DR. CALIFF. THIS IS ONE OF THE THINGS THAT WE TALKED ABOUT, AND WE WILL BE GOING BACK WITH QUINTILES TO MEET WITH THE FDA AND SPECIFICALLY TALK ABOUT HOW WE CAN SET UP A RELATIONSHIP BETWEEN FDA, THE ACCELERATING CENTER, AND CIRM IN ORDER TO EXPEDITE OUR PROGRAMS. VERY EXCITING STUFF. I LIKE THIS ONE. YAY. GO. GOOD JOB, NEIL, TOO.

OKAY. NOW, THAT'S ALL THAT GOING ON, SO

WE HAVE A PLAN, WE KNOW WHAT OUR GOALS ARE, WE HAVE THE ENGINE, THE ENGINE IS COMING ALIVE, IT'S NOT UP TO FULL SPEED YET, BUT IT'S CERTAINLY COMING ONLINE. THAT'S ALL GOOD. BUDGET REVIEW, YOU CAN IMAGINE IN THIS ANALOGY, THIS IS OUR FUEL. WE HAVE TO HAVE ENOUGH FUEL IN ORDER TO GET ALL THOSE GOALS ACCOMPLISHED. SO LET'S TAKE A LOOK AT THAT.

FOR THOSE YOU WHO ARE NEW, UNDERSTANDING THIS STRUCTURE IS REALLY IMPORTANT. SO CIRM DOESN'T HAVE ONE BIG BUCKET OF MONEY THAT WHEN IT GOES TO ZERO, WE'RE DONE. WE ACTUALLY HAVE TWO BUCKETS OF MONEY. AND WHEN EITHER ONE OF THOSE BUCKETS GO TO ZERO, WE'RE DONE. SO ONE OF OUR CHALLENGES THAT WE HAVE AND SOMETHING I SPEND A LOT OF TIME ON IS MAKING SURE WE'RE BALANCING BASICALLY, YOU CAN IMAGINE, THE FLOW RATES OUT OF THESE BUCKETS SUCH THAT THEY END, THEY GO TO ZERO, AT THE SAME TIME. RIGHT NOW THAT TIME IS JUNE OF 2020. AND WE'RE REALLY MANAGING IT PRETTY WELL, AND WE HAVE SOME GOOD CONTROLS OVER IT.

BUT THE TWO BUCKETS THAT WE HAVE, THE LARGE BUCKET IS THE $2.75 BILLION AWARD BUCKET. SO WHEN WE GIVE OUT GRANTS, IT COMES OUT OF THE LARGE BUCKET. EVERYTHING ELSE WE DO AT CIRM, RUNNING THE BOARD, RUNNING THE INFRASTRUCTURE, THE TEAM

INTERNALLY, THOSE ALL COME OUT OF THE ADMINISTRATIVE BUCKET. THAT BUCKET IS CAPPED AT $180 MILLION. SO EVERYTHING WE HAVE TO DO OVER OUR ENTIRE LIFE HAS TO COME OUT OF THAT BUCKET.

NOW, YOU WILL RECALL ORIGINALLY CIRM WAS PROJECTED TO BE A TEN-YEAR ORGANIZATION, SO THAT $180 MILLION WAS SUPPOSED TO GO TEN YEARS. WELL, WE'RE GOING TO RUN WELL, WELL, WELL PAST TEN YEARS BY MAYBE ABOUT SIX YEARS. SO WE HAVE TO BE VERY, VERY SMART IN HOW WE MANAGE THE ADMINISTRATIVE BUCKET TO MAKE SURE THAT WE'RE AROUND BECAUSE YOU CAN'T GET MONEY OUT OF THE BIG BUCKET AND YOU CAN'T ADMINISTER MONEY EFFICIENTLY OUT OF THE BIG BUCKET IF THERE'S NOBODY THERE TO DO IT, WHICH GETS PAID OUT OF THE SMALL BUCKET.

LET'S SEE HOW WE'RE DOING. WITH REGARDS TO THE SMALL BUCKET OR THE ADMINISTRATIVE BUCKET, SO WE HAVE FUNDING AVAILABLE THROUGH MID-2020. THIS IS SOMETHING THAT I WORK WITH CHILA ON ON A REGULAR BASIS. WE WATCH THIS LIKE A HAWK. WE'RE HAPPY WITH WHERE WE ARE ON THIS, BUT IT'S SOMETHING WE WATCH. SO WE SPENT 119 MILLION OUT OF THIS, WE HAVE 61 REMAINING. OUR CURRENT SPEND RATE IS ABOUT 16 MILLION. YOU DO THE MATH, THAT PUTS US THERE RIGHT AROUND JUNE OF 2020. AND WE HAVE SOME FLEXIBILITY

AROUND THAT.

WHEN YOU LOOK AT THE BIG BUCKET, WE ESTIMATE TO DEPLETE THE BIG BUCKET IN 2020. WE HAVE $2.11 BILLION THAT WE'VE AWARDED OUT OF THIS BUCKET, WHICH LEAVES US 639 MILLION THAT'S UNCOMMITTED. IT'S AN IMPORTANT NUMBER HERE, AND I'M KIND OF UPPING THE LEVEL OF SOPHISTICATION THAN WHAT WE TALKED TO PREVIOUSLY. ANOTHER NUMBER THAT'S IMPORTANT TO WATCH IS THE AMOUNT OF MONEY WE HAVE UNDER ACTIVE AWARD MANAGEMENT. SO THESE ARE THINGS THAT THE BOARD HAS APPROVED AND THE AWARD IS IN SOME PHASE OF OPERATION. THE AWARD HASN'T BEEN CLOSED OUT.

SO RIGHT NOW WE HAVE $900 MILLION ACTIVELY UNDER MANAGEMENT. SO THAT'S WHAT OUR GRANTS MANAGEMENT GROUP, OUR THERAPEUTICS, OUR DISCOVERY, AND OUR TRANSLATIONAL GROUPS DO IS THEY SIT OVER THESE AWARDS AND THEY MAKE SURE THESE AWARDS PERFORM. AND WHEN THESE AWARDS DON'T PERFORM, WE GET THE MONEY BACK, OR WE MOSTLY TRY TO HELP THEM GET BETTER; BUT IF IT DOESN'T WORK, WE GET THE MONEY BACK. THE REASON THAT NUMBER IS SO IMPORTANT IS THAT'S THE NUMBER THAT OUR RETURN COMES TO. SO WHEN I USE THE TERM "RETURN," I'M TALKING ABOUT THE AMOUNT OF MONEY THAT WAS LEFT ON AN AWARD THAT

WASN'T USED FOR SOME REASON.

SO LET'S SAY WE SAID WE WERE GOING TO DO A $20 MILLION CLINICAL TRIAL. $5 MILLION INTO THAT CLINICAL TRIAL IT WAS STOPPED FOR FUTILITY. THAT $15 MILLION COMES BACK TO US. THAT'S A RETURN. OUT OF OUR ACTIVE BALANCE, OUR HISTORICAL RETURN RATE HAS BEEN BETWEEN 3 AND 5 PERCENT. AND SO THAT IS OUR ASSUMPTION GOING FORWARD. THE REASON THAT'S IMPORTANT IS IT'S A LOT OF MONEY ANNUALLY TO GET BACK. SO $40 MILLION COMING BACK TO US ANNUALLY. WE HAVE TO ACCOUNT FOR THAT, AND WE HAVE TO PLAN FOR THAT. OTHERWISE WE'D BE LEFT WITH A WHOLE LOT OF MONEY IN JUNE OF 2020 THAT WE WOULDN'T BE ABLE TO DISBURSE. SO THIS IS SOMETHING WE WATCH. THIS IS WHY I HAVE THIS SLIDE, AND I'VE SHOWN YOU THIS SLIDE NOW FOR A FEW YEARS.

SO THIS IS JUST TO RECONCILE WHAT WE ENDED UP ACTUALLY DOING FOR THE FULL YEAR 2016. WE AWARDED $155 MILLION IN NEW AWARDS. THAT'S MONEY GOING FROM THE UNCOMMITTED BUCKET TO THE COMMITTED BUCKET. LAST YEAR WE RECOVERED 46 MILLION. THOSE ARE THE RETURNS THAT I'M TALKING ABOUT. SO FOR VARIOUS REASONS, ALL DIFFERENT PROGRAMS, ACROSS ALL SECTORS, $46 MILLION CAME BACK. THAT IS ALMOST EXACTLY 5 PERCENT ON OUR AWARD BALANCE. SO THAT'S

WORKING OUT AT THE HIGH LEVEL. THAT MEANS OUR NET MOVEMENT FROM THE UNCOMMITTED BUCKET TO THE COMMITTED BUCKET IS $109 MILLION. AGAIN, OUR ASSUMPTION WOULD BE ABOUT 40. SO THAT WOULD BE GOOD.

SO THIS YEAR SO FAR, WE'RE ONE QUARTER INTO THIS FISCAL YEAR, WHICH I APOLOGIZE BECAUSE I KNOW THAT'S CONFUSING, WE'RE DOING OUR BEST TO GO OVER TO A CALENDAR YEAR IN DESCRIPTIONS, BUT FOR RIGHT NOW IN THIS FIRST FISCAL QUARTER, WE'VE MADE $33 MILLION IN NEW AWARDS. WE'VE HAD $6 MILLION IN REDUCTION, SO IT'S A NET OF 27 MILLION. THE 6 MILLION YOU WOULD IMAGINE AGAINST THAT 40, IT WOULD BE A LITTLE LOW, BUT IT'S KIND OF LUMPY, IT'S NOT PREDICTABLE, SO IT'S ABOUT RIGHT ON TRACK.

SO ALL OF THIS TAKEN TOGETHER SAYS WE UNDERSTAND HOW MUCH MONEY WE HAVE IN THE TWO BUCKETS. WE UNDERSTAND AND CAN CONTROL THE RATE OUT OF THE ADMINISTRATIVE BUCKET OR THE SMALL BUCKET WITH MUCH MORE PRECISION THAN WE CAN CONTROL WITH THE LARGE BUCKET. BUT WITH THAT SAID, WE HAVE GOOD ASSUMPTIONS, WE HAVE MODELS THAT WE CONTINUE TO UPDATE THAT HELP US MAKE REFINEMENTS AS WE GET CLOSER AND CLOSER ALONG.

OKAY. DOES ANYONE HAVE ANY QUESTIONS ON

THE PERFORMANCE AND BUDGET BEFORE WE GET INTO THE NEXT SECTION BECAUSE THE NEXT SECTION I HOPE THERE ARE SOME QUESTIONS ON IT? THEY MIGHT BE VERY DIFFERENT IN NATURE.

DR. DIXON: I HAVE A QUESTION. AS I REMEMBER, THE MORE BASIC STUDIES, NUMBER OF GRANTS YOU'VE GOT IN UNDER THAT UMBRELLA WERE QUITE A BIT LESS THAN EXPECTED. IS THIS A TREND OR IS THIS SORT OF A ONE-TIME THING?

DR. MILLS: SO WE DON'T KNOW. WE'VE ONLY DONE ONE ROUND OF AWARDS UNDER OUR TWO EARLIEST STAGES, SO OUR SEED AWARD AND OUR QUEST AWARD, WHICH ARE THE SMALLEST AWARDS, AND EARLIEST STAGE AWARD IS SEED, AND THEN OUR QUEST AWARD, WHICH IS SORT OF OUR BIG POWERHOUSE DISCOVERY AWARD. BOTH OF THOSE CAME IN WITH LOWER NUMBERS OF MERITORIOUS APPLICATIONS THAN WE EXPECTED. WE DON'T KNOW WHETHER OR NOT THAT'S A TREND OR NOT BECAUSE RIGHT NOW IT'S A DATA POINT OF ONE FOR BOTH OF THEM.

THE OTHER THING TO NOTE IS SO THAT ACCOUNTED, I WANT TO SAY THAT ACCOUNTED FOR ABOUT $7 MILLION OF THAT GAP. FOUR MILLION OF IT WAS WE HAD A MERITORIOUS AWARD FOR A CHALLENGE GRANT, WHICH THE ICOC DECLINED, AND THAT WAS TWO MILLION, AND THEN WE JUST DIDN'T OFFER A CHALLENGE GRANT, WHICH WAS

ANOTHER TWO MILLION. SO 4 MILLION OF IT WAS SORT OF DECISIONS WE MADE, AND THEN $7 MILLION OF THAT GAP WAS THE LACK OF HIGH QUALITY PROJECTS. SO WE'LL HAVE TO KEEP AN EYE ON IT.

DR. DIXON: THANKS.

DR. MELMED: THAT WAS A TERRIFIC REPORT. CONGRATULATIONS.

I HAVE A COMMENT AND A QUESTION. MY COMMENT IS I'M A LITTLE BIT CONCERNED ABOUT TOP-DOWN DRIVING OF PEER REVIEWED DISCOVERY. AND WHEN YOU SAY THAT WE EXPECT OR WE'RE PLANNING FOR 150 SUBMISSIONS FOR A CLINICAL PROGRAM, MAYBE WE SHOULD BE FUNDING 50 PERCENT IN ONE YEAR IF THEY'RE EXCELLENT AND NONE IN ONE YEAR IF THEY'RE NOT EXCELLENT. SO IT'S THE PEER REVIEW PROCESS WHICH SHOULD DRIVE THE AWARD RATHER THAN A TOP-DOWN BUDGET OF A NUMBER OF CLINICAL GRANTS WHICH WE EXPECT TO FUND. THAT'S A CONCERN.

AND MY QUESTION IS, MAYBE YOU'RE GOING TO TALK ABOUT IT LATER, BUT CAN YOU GIVE US ANY UPDATE ON THE ALPHA CLINICS BECAUSE THEY'RE AN IMPORTANT COMPONENT OF THE CLINICAL PROGRAM?

DR. MILLS: SO TO THE FIRST COMMENT, ABSOLUTELY. SO THE 150 APPLICATIONS TO MEET 50 ARE ESTIMATES USING OUR HISTORICAL DATA AND SAYING WE'RE

NOT GOING TO LOWER QUALITY, BUT THAT IS OVER THE ENTIRE LIFE OF CIRM. THAT'S NOT THIS YEAR WE NEED TO DO IT. IT'S JUST --

DR. MELMED: WE BARELY GET 20 GOOD GRANTS WHICH ARE SUPERB.

DR. MILLS: WE MIGHT, SO THAT'S WHY, AND THIS IS ONE OF THE THINGS THAT WE TALK ABOUT WITH GWG ALL THE TIME IS DON'T EVER MOVE A GRANT ALONG TO TRY TO SAY WE HAVE ANOTHER NUMBER. SO THE GWG, OUR REVIEW TEAMS INTERNALLY HAVE NO GOALS SET UP AROUND THE NUMBER OF GRANTS THAT GET APPROVED. WE SET UP THIS WALL AROUND THAT.

DR. MELMED: WHAT YOU JUST SAID NOW SHOULD BE EMPHASIZED IN YOUR REPORT.

DR. MILLS: SO WE TALK ABOUT THAT A LOT, BUT IT'S ALSO OUR ABILITY TO NOT BE A PASSIVE AGENCY ANYMORE AND SIT BACK AND WAIT AND SAY, BOY, WE HOPE WE GET SOME GOOD APPLICATIONS BECAUSE WE KNOW THERE ARE GOOD CLINICAL PROGRAMS OR PROGRAMS NEARING THE CLINIC OUT THERE THAT JUST DON'T KNOW CIRM EXISTS TO HELP THEM. SO THAT'S WHERE WE'RE TRYING TO DO, WE CALL IT HUNTING, FOR US TO GO OUT MORE AGGRESSIVELY AND TRY TO BRING THOSE APPLICATIONS IN. WE HAVE SOMETHING JAMES WOULD LOVE TO TALK TO YOU MORE ABOUT IT, BUT WE'VE SET UP SOMETHING CALLED THE WALL

INSIDE CIRM. AND THAT IS -- YOU CAN IMAGINE IT'S SORT OF A STERILE ZONE.

THE PEOPLE THAT ARE RESPONSIBLE FOR TRYING TO BRING GOOD PROGRAMS INTO CIRM ARE ALLOWED TO HAVE NO CONTACT OR INFLUENCE OVER THE PEOPLE THAT REVIEW. AND THE PEOPLE WHO REVIEW AREN'T INVOLVED WITH BRINGING THEM IN. SO WE'VE REALLY SEPARATED THESE TWO COMPONENTS. IT'S SEPARATION OF POWERS BECAUSE WE DON'T WANT THERE TO BE INCENTIVE THAT WOULD INADVERTENTLY DRIVE DOWN QUALITY BECAUSE, AGAIN, OUR MISSION IS ULTIMATELY TO HELP PATIENTS. SO IF WE DON'T HAVE GOOD QUALITY, WE MIGHT FEEL GOOD FOR A LITTLE BIT IN THE SHORT TIME THAT THERE ARE BIG NUMBERS, BUT THESE PROGRAMS HAVE TO ACTUALLY GO ON AND WORK TOO. I APPRECIATE YOUR COMMENT.

WITH REGARDS TO ALPHA CLINICS, I DON'T HAVE AN UPDATE HERE FOR ALPHA CLINICS. I'LL TELL YOU THIS. WE HAVE 22 CLINICAL PROGRAMS RIGHT NOW BEING RUN THROUGH THREE ALPHA CLINICS. OUR PRELIMINARY ASSESSMENT IS WE LIKE THE WAY THAT PROGRAM IS GOING. AND WE ARE PLANNING RIGHT NOW TO COME IN DECEMBER AND ASK FOR AN ADDITIONAL ALLOCATION TO CREATE TWO MORE ALPHA CLINICS TO EXPAND THE NETWORK. BUT WE'LL HAVE MORE ON THAT WHEN WE MAKE THAT PROPOSAL IN DECEMBER.

DR. DEAS: SO I REALLY THINK THAT THE STRATEGY OF STIMULATING THE RESEARCH GRANTS IS A GOOD ONE. AS YOU SAID, THERE MAY BE SCIENTISTS OUT THERE WHO REALLY DON'T KNOW ABOUT WHAT CIRM DOES, AND THEY MAY HAVE ONGOING RESEARCH PROJECTS THAT THEY MAY FEEL IS JUST NOT THE RIGHT TIME. BUT IF WE STIMULATE THAT, PERHAPS THEY DO SUBMIT SOMETHING AND IT MAY NOT MEET THAT CRITERIA FOR MERITORIOUS AWARD AT THAT POINT; BUT BY THE TIME THEY COME AROUND AGAIN, IT WILL. AND I THINK THAT STRATEGY IS A GOOD ONE TO FILL THAT PIPELINE.

DR. MILLS: YEAH. ABSOLUTELY. AND A LOT OF THE WAY WE'VE SET UP REVIEW, PARTICULARLY IN CLINICAL REVIEW, WE'VE SET IT UP WHERE OUR SCORING SYSTEM IS 1, YEAH, YOU SHOULD GET APPROVED; 3, THIS IS REALLY, REALLY A LONG WAY OFF, AT LEAST SIX MONTHS OFF FROM GETTING RECONSIDERED; OR, 2, IT'S A GOOD CONCEPT, BUT WE HAVE SOME QUESTIONS ABOUT IT. WE HAVE SOME IDEAS WHERE WE THINK IT COULD BE MADE BETTER, AND WE WANT TO APPROVE 95S NOT 75S. AND SO WE'VE ACTUALLY SET UP A SYSTEM IN OUR SCORING TO ALLOW THAT.

WITH REGARDS TO YOUR COMMENT ABOUT OUTREACH, WE HAVE SORT OF TWO DIFFERENT PROBLEMS WHEN IT COMES TO COMMUNICATION EXTERNALLY. ONE IS

PEOPLE JUST DON'T KNOW OF CIRM, AND THERE'S A LOT OF PEOPLE THAT FALL INTO THAT BUCKET. THEY JUST DON'T KNOW THE PROGRAMS AVAILABLE. THE SECOND ARE PEOPLE THAT DID KNOW CIRM, BUT THEY KNEW THE 1.0 VERSION OF CIRM AND THEY DON'T KNOW THAT THE NEW SYSTEM IS BETTER AND EASIER TO USE AND THINGS LIKE THAT. THAT'S WHY, AS I SAY, WE TAKE THAT VERY SERIOUSLY. SO THIS WHOLE GROUP OF PEOPLE IS GOING TO BE GOING OUT AND DOING LOTS AND LOTS AND LOTS OF OUTREACH, BOTH ACADEMIC AND INDUSTRY, TO MAKE SURE WE GET THIS WORD OUT.

CHAIRMAN THOMAS: SO, RANDY, FIRST OF ALL, JUST WANT TO MAKE SURE THE BOARD FULLY APPRECIATES JUST WHAT A GREAT PROGRAM WE'VE GOT GOING HERE AND HOW ALL ASPECTS HAVE BEEN LOOKED AT AND IMPROVED. AND THE AGENCY AND YOU SHOULD ALL FEEL GREAT ABOUT THIS. IT'S REALLY SMOKING ALONG. AND IT'S ALL DUE TO RANDY AND TO THE TEAM, THE VISION, THE IMPLEMENTATION, ETC. SO I JUST WANT TO CONGRATULATE YOU, RANDY, AND ALL MEMBERS OF CIRM ON THE TERRIFIC JOB THAT ALL OF YOU GUYS ARE DOING. THAT'S POINT NO. 1.

POINT NO. 2, RANDY, PERHAPS FOR DR. MELMED'S BENEFIT, YOU NOTED THAT THERE ARE 22 PROGRAMS IN THE ALPHA CLINICS RIGHT NOW. JUST TO

SHOW YOU HOW THAT IS EXCEEDING EXPECTATIONS, YOU MIGHT JUST TELL THE BOARD WHAT NUMBER YOU ASSUMED MIGHT HIT THE FIRST YEAR THAT THE ALPHA CLINICS WERE UP AND RUNNING.

DR. MILLS: CAN I PHONE A FRIEND?

DR. MILLAN: SO WHEN WE SET UP THE ALPHA CLINICS PROGRAM, WHAT WE WERE TARGETING AT THAT TIME IS TO BRING IN AT LEAST SIX PROGRAMS, AND THAT THAT AT THAT TIME WE FELT WAS VERY AMBITIOUS. SO THAT JUST REFLECTS THE ACTIVITY, AND IT'S EXCEEDED OUR EXPECTATIONS IN TERMS OF THEIR CAPACITY TO SUPPORT THE TRIALS AS WELL AS NUMBERS COMING IN.

CHAIRMAN THOMAS: THANK YOU. I JUST WANTED TO MAKE SURE THE BOARD WAS AWARE OF THAT. SO THAT'S THREE AND A HALF X OF WHAT WAS ANTICIPATED, AND THAT ANTICIPATED NUMBER WAS BOLD. SO SOMETHING ELSE WE SHOULD FEEL VERY GOOD ABOUT. I'M SURE WE'LL HEAR IN MORE DETAIL IN DECEMBER WHEN RANDY COMES BACK WITH THE ITEM HE NOTED.

LASTLY, RANDY, FOR THE BOARD'S BENEFIT, ONE OF THE THINGS THAT DISTINGUISHES CIRM FROM VIRTUALLY EVERY OTHER GRANTMAKING ENTITY IS THE CONTINUED PARTICIPATION AND HELP IN REFINING THE PROJECTS. AND YOU REFERRED TO ACTIVE AWARD MANAGEMENT. I THINK THE BOARD WOULD BE INTERESTED

TO HEAR A LITTLE DRILLING DOWN ON THAT SO THEY ALL APPRECIATE JUST EXACTLY WHAT THAT MEANS AND WHY IT'S SO VERY HELPFUL.

DR. MILLS: SO WE DO IT IN A NUMBER OF DIFFERENT WAYS, AND IT DEPENDS ON THE STAGE OF PROGRAM THAT EXISTS. SO IN THE EARLIER STAGE PROGRAMS, GRANTS MANAGEMENT AND A SCIENCE OFFICER, GRANTS MANAGEMENT OFFICER, A SCIENCE OFFICER WILL PAIR UP AND ACTIVELY RIDE OVER AN AWARD. THEY'LL GET PROGRESS REPORTS; THEY'LL VALIDATE THOSE PROGRESS REPORTS. IT'S PROGRESS BEING MADE. IT'S NOT TO COME UP WITH COURSE CORRECTION STRATEGIES TO GET THEM BACK ON AND THAT LIKE. WE HAVE THAT ACTUALLY FOR EVERY PROGRAM.

FOR OUR CLINICAL STAGE PROGRAMS, WE ALSO HAVE INTRODUCED SOMETHING ELSE, WHICH IS MUCH BIGGER. THESE ARE BIG AWARDS, SO THESE ARE TENS OF MILLIONS OF DOLLARS TYPES OF AWARDS WHERE THEY'RE RUNNING CLINICAL TRIALS. AND THERE WE'VE INSTITUTED THE CAP PROGRAM, THE C-A-P PROGRAM, WHICH IS THE CLINICAL ADVISORY PANEL, WHICH IS MADE UP OF AT LEAST TWO PEOPLE INTERNALLY FROM CIRM, AT LEAST TWO SUBJECT MATTER EXPERTS ON WHATEVER THE MAJOR ISSUES ARE ASSOCIATED WITH THE TRIAL THAT'S BEING RUN, AND THEN AT LEAST ONE PATIENT WHO HAS THAT OR IS

DIRECTLY AFFECTED BY THAT DISEASE OR CONDITION. AND THOSE WORK TOGETHER. AND THEY ARE PURELY, AND THIS IS REALLY IMPORTANT, THEY ARE PURELY ADVOCATES FOR THE TRIAL. SO THEIR JOB IS TO TRY TO DO ABSOLUTELY EVERYTHING THEY CAN TO MAKE THAT PROGRAM SUCCESSFUL.

THE REASON I SAY PURELY IS BECAUSE IT'S REALLY IMPORTANT THAT THE CAP DEVELOP A VERY GOOD AND TRUSTING RELATIONSHIP WITH THE INVESTIGATORS. SO OUR BAD COPS, OUR LEGAL TEAM AND/OR GRANTS MANAGEMENT TEAM, AREN'T INVITED TO CAP MEETINGS. THEY COME IN LATER WHEN THERE ARE ISSUES ASSOCIATED WITH IF AN AWARD NEEDS TO SCALED BACK OR CANCELED OR TERMINATED. SO THE CAP IS PURELY AN ADVOCACY GROUP FOR IT.

AND SO IT'S VERY DIFFERENT. IT'S WHAT WE CALL FULL CONTACT CIRM. THE IDEA IS WE WILL DO EVERYTHING AND ANYTHING WE CAN TO HAVE THESE PROGRAMS ULTIMATELY BE SUCCESSFUL.

MS. WINOKUR: I JUST WANT TO INCLUDE SOMETHING ABOUT THE REVIEW PROCESS AND HOW FORTUNATE WE ARE TO HAVE THE SCIENTIFIC REVIEW COMMITTEE BE AS IMPRESSIVE AS IT IS AND BE WILLING TO SPEND THE TIME THAT THEY DO ON EVALUATING THESE PROPOSALS ON A SCIENTIFIC BASIS.

DR. MILLS: IT'S A VERY GOOD POINT. WHEN

WE TALK ABOUT HAVING 20 REVIEWS, THERE ARE 15 EXTERNAL MEMBERS TO CIRM THAT HAVE TO ALSO SIT ON THOSE REVIEWS AND 7 INTERNAL PATIENT ADVOCATES THAT SIT ON THAT REVIEW. SO IT IS A BIG GROUP TO HAVE TO GET TOGETHER THAT MANY TIMES AND TO BE ABLE TO MAINTAIN THAT GROUP AT THAT QUALITY. I AGREE. I THINK OUR GWG IS ONE OF THE MOST IMPRESSIVE ASSETS WE HAVE AT CIRM.

MR. SHEEHY: SO I JUST WANT TO COMMEND THE ENTIRE CIRM TEAM. I MEAN IT'S AMAZING WORK THAT THEY'VE DONE OVER THE LAST YEAR. IT'S IMPRESSIVE.

ALSO I WANTED TO ASK ABOUT THE BIG SIX. WE HAVE FEEDBACK ON WHERE WE ARE IN TERMS OF THE TARGETS YOU HAVE FOR THOSE?

DR. MILLS: SO THE BIG SIX IS SOMETHING INTERNALLY THAT WE MEASURE ALWAYS. AND SO I'LL JUST ROUGHLY BREAK DOWN HOW WE DO THAT. SO THE BIG SIX ARE THROUGH 2020. WE THEN HAVE SOMETHING CALLED THE BIG SIX 2016. THAT IS, WHAT PORTIONS OF THOSE PROGRAMS HAVE TO GET DONE THIS YEAR IN ORDER FOR US TO BE ON TRACK TO HIT THAT GOAL.

WE THEN HAVE THAT BROKEN DOWN BY QUARTER. SO EVERY QUARTER AS AN ORGANIZATION WE GET TOGETHER AND WE GO THROUGH THOSE BIG SIX GOALS, HOW WE DID PREVIOUSLY, WHAT WE PLAN TO DO THE NEXT QUARTER

GOING FORWARD. BEYOND THAT, THOSE BIG SIX GOALS FOR EACH QUARTER ARE THEN BROKEN DOWN INTO THE EIGHT UNITS THAT MAKE UP CIRM. GRANTS MANAGEMENT HAS ITS OWN SET OF GOALS FOR THAT QUARTER. CLINICAL, DIAGNOSTIC, LEGAL, THEY ALL HAVE THEIR OWN. THERE ARE BIG POSTERS AND THEY COLOR THEM IN AS THEY MAKE PROGRESS ON THEM. ALL OF THOSE GOALS ROLL UP INTO THE QUARTER, AND ALL OF THE QUARTERS ROLL UP INTO THE YEAR, AND THE YEAR ROLLS UP INTO 2016.

GOING BACK SPECIFICALLY TO YOUR QUESTION ABOUT THE BIG SIX, SO THAT'S HOW WE MONITOR IT. FOR SOME OF THE BIG SIX GOALS WE CAN MEASURE DIRECTLY. NUMBER OF CLINICAL TRIALS THAT WE BRING IN, RIGHT, THAT'S JUST SOMETHING WE CAN MEASURE DIRECTLY. WE NEED 50; WE HAVE THREE IN SO FAR.

NUMBER OF NEW CANDIDATES INTO DISCOVERY AND TRANSLATION, WE WANTED 50; WE HAVE 13 SO FAR. SO PAT'S A BIG BELIEVER IN THIS 3X PHENOMENA. WHATEVER YOUR GOAL IS ACHIEVE IT THREEFOLD. FOR OTHER ONES, THOUGH, WE'RE NOT ABLE TO MEASURE THEM YET. SO WE WANT TO REDUCE TRANSLATION TIME FROM EIGHT YEARS DOWN TO FOUR YEARS. WE'RE ONLY SEVEN MONTHS INTO IT, SO WE HAVE NO ABILITY TO MEASURE. SO WE START MEASURING COMPONENTS OF THAT WHICH WILL ADD UP AS SURROGATES GO INTO THAT.

SO I DON'T WANT TO STEAL TOO MUCH OF THE DECEMBER MEETING, BUT THE DECEMBER MEETING WILL BE A FULL RECONCILIATION OF THE STRATEGIC PLAN, HOW WE DID IN '16, AND WHAT WE'RE DOING IN '17, AND HOW THOSE LINES ALL CONNECT OUT. AND THAT'S WHERE THE BUDGETING COMES IN AS WELL, HOW WE MATCH UP THAT BUDGET, AND THE DECISIONS WE HAVE TO MAKE THERE. IT'S BEING MEASURED, AND IN THE DECEMBER MEETING IT WILL BE ALL SHOWN.

CHAIRMAN THOMAS: ANNE-MARIE.

DR. DULIEGE: SO YOU KNOW I'M A BIG ADVOCATE OF ALL THE STRATEGIC INITIATIVES YOU'VE BEEN TAKING OVER THE PAST FEW YEARS. SO THANK YOU TO ENTIRE TEAM.

WILL YOU TALK MORE TODAY ABOUT YOUR INTERACTIONS WITH THE FDA, AND I'M HOPEFUL YOU ARE, THAT THAT INFLUENCED DRASTICALLY THE FIELD. BECAUSE IT'S QUITE COURAGEOUS. YOU PEOPLE GO AT THE TABLE WITH THE IDEA AND SAY YOU SHOULD BE DOING THIS BETTER, OBVIOUSLY IN A VERY DIPLOMATIC FASHION, BUT VERY COURAGEOUS AND I WANT TO APPLAUD YOU FOR THAT AS WELL.

DR. MILLS: THANK YOU. I WAS ABLE TO GET A MEETING WITH THE HEAD OF THE FDA, BOB CALIFF, AND HE'S RELATIVELY NEW TO THE AGENCY. AND I'D HEARD,

LIKE, YOU KNOW, THE FDA IS GOING TO BE UPSET. YOU WROTE A PIECE THAT MIGHT NOT HAVE BEEN PARTICULARLY GLOWING OR THIS OR THAT. THEY ARE THERE AT THAT LEVEL BECAUSE THEY ARE PROFESSIONALS, JUST LIKE WE ARE PROFESSIONALS. SO WE SIT DOWN AND WE HAVE A CONVERSATION ABOUT COMMON OBJECTIVES AND HOW WE GET THERE. AND THEN WE HAVE DIFFERENCES ON MAYBE HOW THE BEST WAY IS, BUT I FOUND DR. CALIFF TO BE REMARKABLY ENGAGING. I BELIEVE HE IS VERY HANDS-ON. I FEEL HE IS REALLY LISTENING AND HE REALLY WANTS THE BEST OUTCOME. I DON'T THINK THIS IS AN FDA THAT HAS THE ANSWER MADE UP AND NOW THEY'RE JUST GOING TO GO ASK THE QUESTION. I THINK THEY ACTUALLY ARE THINKING AND FORMULATING.

SIMILARLY, I THINK IT WAS LAST WEEK THERE WAS A MUCH BIGGER MEETING AT FDA WHERE THERE WAS A HUNDRED OR SO PARTICIPANTS INVITED, AND WE SPOKE THERE. AND I THINK THE SAME THING TOO. HAVING GONE THROUGH THOSE EXPERIENCES, IT MAY SEEM LIKE THERE'S SO MUCH VOLUME, THAT THERE'S NO WAY THE FDA COULD BE LISTENING, BUT THEY REALLY DO LISTEN TO THOSE COMMENTS.

CHAIRMAN THOMAS: OKAY.

DR. MILLS: ONE MORE TOPIC. THIS IS JUST THE LAST ONE. AND, AGAIN, THIS UNFORTUNATELY IS

GOING TO BE A DISCUSSION TOPIC.

BUT AS I SAID, AS WE WERE REVIEWING CERTAIN CLINICAL APPLICATIONS, THERE WERE SOMETIMES QUESTIONS THAT CAME UP WHERE MEMBERS OF THE BOARD SEEMED SURPRISED THAT SOMETHING MIGHT BE IN SCOPE OR IS THAT THE TYPE OF THING WE WOULD FUND, OR DO WE NOT HAVE RESTRICTIONS ON IT. SO I WANTED TO REALLY GO OVER WHAT OUR CLINICAL PROGRAM IS IN ITS CURRENT FORM AND SEE IF THERE IS ANY CONSENSUS OF THE BOARD THAT YOU MIGHT WANT US, NOT TODAY, BUT TO BRING BACK POTENTIAL OR PROPOSED CHANGES.

SO WITH REGARDS TO CLINICAL, WE HAVE THREE DIFFERENT CLINICAL PROGRAMS. CLINICAL 1 OR CLIN1 STARTS FROM A PRE-IND MEETING. SO YOU HAVE TO HAVE A PRE-IND MEETING. THAT'S THE PREREQUISITE. AND IT ENDS WHEN YOU GET YOUR IND APPROVED FROM FDA. WE ANTICIPATE THAT TO BE ABOUT 18 MONTHS. WE DON'T LIKE IT WHEN PEOPLE TAKE LONGER BECAUSE WE NEED TO GET THOSE GOALS DOWN BECAUSE WE NEED TO MEET OUR ACCELERATION GOAL.

IF YOU'RE SUCCESSFUL CLIN1 OR YOU JUST HAPPEN TO HAVE AN IND, THEN YOU CAN APPLY FOR CLIN2 GRANTS. A CLIN2 GRANT IS ANY CLINICAL TRIAL OF ANY PHASE, SO PHASE I, II, OR III, OR ANY HYBRID IN BETWEEN.

AND THEN WE HAVE A CLIN3 PROGRAM. CLIN3 IS WHEN, AND THESE SHOULD BE RARE AND UNIQUE CIRCUMSTANCES, WHEN THERE IS AN ACCELERATING ACTIVITY OR AN OPPORTUNITY THAT COMES UP THAT IS JUST NOT FORESEEN WHEN THE ORIGINAL APPLICATION'S PROPOSED, THEN YOU CAN COME BACK AND APPLY FOR AN ACCELERATING ACTIVITY. CLIN3 APPLICATIONS, AND THIS IS WHAT WE'RE STRUGGLING WITH, ARE NOT CONTINGENCY PLANS. CLIN3 IS NOT SUPPOSED TO BE WE DIDN'T DO A GOOD JOB DESIGNING OUR CLIN2, SO NOW WE WANT A CLIN3. IT REALLY NEEDS TO BE AN UNUSUAL CIRCUMSTANCE WHERE WE SAY UNUSUAL EFFICACY, AND IF WE EXPAND THIS COHORT, WE CAN MAKE THIS PHASE II TRIAL A REGISTRATION TRIAL, THAT KIND OF THING.

SO THOSE ARE THE THREE PROGRAMS. WE OFFER THEM 12 TIMES A YEAR. THESE ARE PROGRAMS WHERE THEY ARE NOT RATED AGAINST ONE ANOTHER. ANYTHING THAT'S FOUND TO BE MERITORIOUS THROUGH THE REVIEW PROCESS IS FORWARDED ON TO THE ICOC FOR APPROVAL.

THE SCOPE OF THESE GRANTS, AGAIN, HAS TO BE YOU HAVE TO HAVE A PRE-IND MEETING THROUGH ANY STAGE OF THE CLINICAL TRIAL. THERAPIES THAT ARE IN PLAY ARE ANY STEM CELL OR PROGENITOR CELL THERAPEUTIC CANDIDATE. SO THE BIG WORD HERE IS PROGENITOR CELL. THIS IS ACTUALLY PART OF

PROPOSITION 71. THIS ISN'T SOMETHING THAT WE CAME UP WITH. PROGENITOR CELL IS A REALLY BIG WORD. PROGENITOR CELLS CAN BE TRULY CELLS THAT GO ON AND LOOK A LOT LIKE STEM CELLS. A PROGENITOR CELL CAN BE A MONOCYTE TURNING INTO A MACROPHAGE OR A B CELL TURNING INTO A PLASMA CELL. THOSE ALL FIT WITHIN THE DEFINITION OF PROGENITOR CELL. SO THIS IS A BIG, BIG WIDE SCOPE TO ENTER.

SECOND ONE IS HEMATOPOIETIC CELLS, SO THESE ARE THINGS LIKE BONE MARROW OR CORD BLOOD, BUT HERE THEY HAVE TO BE BEING DEVELOPED IN A WAY WHERE THEY'RE ADDRESSING A NOVEL OR RARE CONDITION OR AN UNMET MEDICAL NEED. SO WE WOULDN'T DO HEMATOPOIETIC CELLS -- WE WOULDN'T DO BONE MARROW FOR BONE MARROW TRANSPLANT IN SOMEONE WITH AML. THAT'S A KNOWN THING. IT WOULD HAVE TO BE AN UNUSUAL INDICATION, CORD BLOOD INTO BABIES WITH CEREBRAL PALSY, FOR EXAMPLE.

AND THEN, LASTLY, AND THIS IS ONE THAT KIND OF SURPRISES PEOPLE, SMALL MOLECULES, SO ANY SYNTHETIC DRUG, ANY BIOLOGIC, PROVIDED THAT IT TARGETS STEM CELLS, AND THEY'RE NOT LIKELY TO RECEIVE FUNDING FROM OTHER SOURCES. ALTHOUGH I'LL TELL YOU THAT SPECIFIC LINE IS REALLY, REALLY, REALLY SUBJECTIVE AND DIFFICULT FOR US TO ENFORCE OR

DETERMINE. AND THESE APPLICANTS CAN BE FROM OUT-OF-STATE OR THEY CAN BE FROM IN STATE FOR THE CLINICAL STAGE PROGRAMS. IF THEY'RE FROM OUT-OF-STATE, WE ONLY FUND THE PORTION OF THE TRIAL THAT'S CONDUCTED AT SITES WITHIN CALIFORNIA. SO WE JUST BASICALLY PRORATE THE TRIAL. IF THEY HAVE A HUNDRED PATIENTS AND THEY PUT 25 OF THEM IN CALIFORNIA LOCATIONS, THEN WE CAN COVER 25 PERCENT.

AND THEN, LASTLY, THESE PROGRAMS ARE OPEN TO NONPROFIT AND FOR-PROFIT. DEPENDING ON THE STAGE OF DEVELOPMENT, THERE ARE DIFFERENT CO-FUNDING REQUIREMENTS. SO PRECLINICAL AND PHASE I, WE HAVE NO COFUNDING REQUIREMENT FOR NONPROFIT INSTITUTIONS. WE WILL COVER 100 PERCENT OF THE COST. A FOR-PROFIT IN PRECLINICAL, WE'LL COVER 20 PERCENT -- THEY'LL COVER, I'M SORRY, 20 PERCENT, WE'LL COVER 80 PERCENT. WE'LL COVER 70 PERCENT OF A PHASE I. ONCE WE GET TO PHASE II, THEY MATCH UP. AND THAT'S BECAUSE WE REALLY DON'T WANT TO DISINCENTIVIZE THESE TECHNOLOGIES FROM GETTING PARTNERED OUT WITH INDUSTRY PARTNERS AS THEY GO TOWARDS CRITICAL REGISTRATION TRIALS. SO THE PHASE II PARTNERING OR MATCHING FUND REQUIREMENT IS 40 PERCENT FOR BOTH. IT'S 50 PERCENT FOR BOTH FOR PHASE IIIS. AND IF WE AWARD A CLIN1, AND I DON'T THINK WE'VE EVER ACTUALLY

AWARDED A CLIN1 YET, BUT IF WE WERE TO AWARD A CLIN1, IT WOULD CARRY THE SAME FUNDING REQUIREMENT AS THE PARENT AWARD -- I'M SORRY -- CLIN3, IF WE WERE TO OFFER A CLIN3, IT WOULD HAVE TO HAVE THE SAME MATCHING FUND REQUIREMENT AS THE PARENT AWARD. EVERY CLIN3 HAS TO HAVE A PARENT AWARD. IT'S A PREREQUISITE.

AND THEN, LASTLY, SOLVENCY HAS TO BE DEMONSTRATED. SO THERE IS NO TOO BIG TO APPLY TO CIRM. THIS IS ONE OF THE QUESTIONS THAT CAME UP. THERE IS TOO SMALL TO APPLY TO CIRM. SO IF YOU CAN'T DEMONSTRATE SOLVENCY, AND FOR US THESE AWARDS, THAT'S 180 DAYS OF CASH AT YOUR RUN RATE ON HAND AT THE TIME OF THE AWARD, THEN YOU'RE NOT ELIGIBLE FOR THE AWARD, BUT THERE IS NO UPPER LIMIT TO THAT.

SO THAT'S WHAT I WANTED TO THROW OUT TO STIMULATE THE DISCUSSION TO SEE IF THERE WAS ANYTHING THERE NOW THAT WE DON'T HAVE GRANTS IN FRONT OF US, WE DON'T HAVE SPECIFIC APPLICATIONS. IS THERE ANYTHING ABOUT THIS THAT DOESN'T SIT WELL WITH PEOPLE OR WE WANT TO ASK QUESTIONS ABOUT OR YOU WANT TO GIVE TO US TO CONSIDER TO COME BACK?

DR. JUELSGAARD: JUST TO THAT VERY LAST COMMENT ABOUT NOT TOO BIG TO FAIL, SORT OF IN OTHER WORDS, WITH RESPECT TO AN APPLICATION, IS THAT A

STUDIED DECISION THAT'S BEEN MADE, ONE THAT'S BEEN THOUGHT THROUGH, AND THE DECISION IS IT DOESN'T MATTER WHETHER IT'S A VERY SMALL COMPANY OR WHETHER IT'S JOHNSON & JOHNSON AND ASTRA ZENECA OR SOMEBODY LIKE THAT?

DR. MILLS: JAMES MAY WANT TO CHIME IN HERE AS WELL. BUT WE JUST HISTORICALLY HAVEN'T SEEN THE LARGER APPLICANTS COME IN FOR ANY OF THESE KINDS OF CLINICAL TRIALS. WE HAVE SEEN THEM IN TOOLS AND TECH AREAS, AND THOSE ARE LIKELY THINGS THAT THEIR COMPANIES WOULDN'T HAVE FUNDED THEM TO DO UNLESS FOR CIRM. I THINK FOR US, AND MY CONCERN CAPPING THIS COMPANY IS TOO BIG, IS IT'S CERTAINLY POSSIBLE THAT A LARGE COMPANY THAT COULD RUN A TRIAL COMPETENTLY WOULDN'T RUN IT UNLESS IT COULD GET FUNDING FOR IT SOMEWHERE ELSE. THEY WOULDN'T ALLOCATE THOSE DOLLARS. THAT MIGHT BE BECAUSE IT'S A PARTICULARLY ORPHAN DISEASE OR IT'S A TECHNOLOGY THAT THEY'RE NOT PARTICULARLY COMFORTABLE WITH. BUT IF WE WERE TO DRAW A LINE AND SAY YOU'RE TOO SOLVENT TO COME TO CIRM, I WOULDN'T KNOW WHERE TO BEGIN TO DRAW THAT LINE.

MR. HARRISON: I THINK RANDY SUMMARIZED IT ACCURATELY. I DON'T HAVE ANYTHING TO ADD TO THAT. IT WOULD BE A VERY DIFFERENT LINE DRAWING EXERCISE,

SO WE HAVEN'T UNDERTAKEN IT.

DR. MILLS: I WOULD ALSO SAY, AS SMOOTH AND STREAMLINED AS WE'VE MADE THIS PROCESS, IT'S FAIRLY CUMBERSOME. SO THERE'S A LITTLE BIT OF SELECTION, AND YOU HAVE TO DO A LOT OF DIFFERENT THINGS TO COMPLY WITH OUR -- WE HAVE A LOT OF PRICING ACCESS REQUIREMENTS, ALL OF THAT STUFF THAT COMES ALONG, AND THEY HAVE TO REPAY IT.

DR. LUBIN: RANDY, FIRST OF ALL, THE TOTAL REPORT WAS PHENOMENAL. I MEAN CONGRATULATIONS TO ALL OF YOU. I'M LOOKING AT THIS THINKING IF I EVER MADE A REPORT LIKE THIS TO MY BOARD IN AS CLEAR A WAY, CLEAR A FASHION, SO I LEARNED A GREAT DEAL FROM YOUR PRESENTATION TODAY.

DR. MILLS: I'LL GIVE YOU THE TEMPLATE.

DR. LUBIN: I WAS CURIOUS ABOUT HOW YOU'RE GOING TO BRING THIS OUT TO THE MARKET. LIKE YOU HAVE A TRAVELING TEAM NOW. WHO YOU'RE GOING TO GO TO. ARE YOU GOING TO TELL EVERYBODY THAT POTENTIALLY COULD DO ANYTHING IN THE STATE OF CALIFORNIA YOU HAVE THIS TRAVELING TEAM AND WOULD THEY LIKE TO HEAR FROM YOU? BECAUSE LIKE THAT COULD BE AN OVERWHELMING NUMBER OF PEOPLE THAT MIGHT LIKE TO HEAR ABOUT IT. I WAS JUST CURIOUS WHAT YOUR STRATEGY FOR THAT IS.

DR. MILLS: MARIA OR KEVIN, WHOEVER WANTS TO SUMMARIZE FROM THE TRAVELING TEAM.

MS. BONNEVILLE: WE DECIDED WE WOULD APPROACH IT, DIVIDE UP THE STATE, AND APPROACH IT WITH TWO DIFFERENT AUDIENCES IN MIND, BOTH THE ACADEMIC GROUP AND THE INDUSTRY GROUP. AND WE'RE GOING TO DIFFERENT RESEARCH ORGANIZATIONS THROUGHOUT THE STATE STARTING TODAY. WE'RE GOING TO HAVE ONE AFTER THIS MEETING FOR THE ACADEMIC FOLKS IN SAN DIEGO. HOW MANY DID WE HAVE RSVP FOR TODAY? I THINK WE HAVE 60 PEOPLE RSVP FOR TODAY.

DR. LUBIN: A TOWN HALL AND INVITE EVERYBODY, AND THEN THOSE THAT COME HERE --

MS. BONNEVILLE: YES. WE HAVE PRESENTATIONS BASED ON THE DIFFERENT PROGRAMS WE HAVE AVAILABLE FOR FUNDING. AND THEN ALSO THE GRANT REVIEW PROCESS, SO THE HOW THE GWG WORKS. AND THEN OUR GRANTS MANAGEMENT PROCESS, HOW CONTRACTING WORKS. SOME LEGAL ELEMENTS THAT NOT ALL OF OUR GRANTEES ARE AWARE OF. SO HOPEFULLY SHEDDING SOME LIGHT ON THAT WILL HELP THEM THROUGHOUT. AND ALSO, THEN, SOME OF THE OTHER PROGRAMS LIKE THE ATP3 THAT'S COMING UP AND THE ACCELERATING CENTER.

DR. LUBIN: I'M SURE YOU'RE GOING TO DO THIS, GET SOME FEEDBACK FROM EACH OF THESE ABOUT HOW

YOU DID IT AND WHETHER THEY LIKED IT AND WHAT WAY YOU COULD DO IT BETTER.

MS. BONNEVILLE: YES. WE'LL BE IN LOS ANGELES TOMORROW. WE WILL BE AT UCLA AND USC, AND THEN IN THE EVENING WE'LL BE HAVING AN INDUSTRY EVENT DOWNTOWN L.A. NEXT WEEK WE'LL BE IN THE BAY AREA, AND WE WILL DO IT AS OFTEN AND AS IS NECESSARY.

DR. LUBIN: SO HOW DID YOU SEND OUT THE NOTICES? WHO DID YOU SEND THEM TO?

MS. BONNEVILLE: WE SENT THEM TO EVERYONE ON OUR E-MAIL LIST. WE DID TWITTER, FACEBOOK. WE CONTACTED THE RESEARCH INSTITUTES THEMSELVES AND HAD THEM SEND OUT NOTICES TO ALL OF THEIR RESEARCHERS. SO WE DID A PRETTY BIG PUSH.

DR. LUBIN: DOES THE BOARD GET A COPY OF WHAT YOU SENT OUT?

MS. BONNEVILLE: YOU SHOULD HAVE RECEIVED A COPY.

DR. DULIEGE: IS IT THE SAME THING AS WE RECEIVED FROM KEVIN AS EXACTLY?

MS. BONNEVILLE: YES.

DR. DULIEGE: SO KEVIN SENT TO ALL OF US RECENTLY, AND I WANT TO APPLAUD THAT EFFORT, THE LIST OF EVENTS IN OUR AREA. AND REALLY THERE'S

SEVERAL, SO I PLAN TO ATTEND THE ONE IN SOUTH SAN FRANCISCO WITH THE CLSA, THE CALIFORNIA LIFE SCIENCES ASSOCIATION, BUT THERE'S A VARIETY OF OTHERS. THAT'S GREAT. IT'S VERY EASY REALLY TO ATTEND.

DR. DEAS: IF WE WOULD LIKE TO HAVE AN EVENT IN OUR AREA, I KNOW YOU'RE IN L.A., BUT IN THE INLAND EMPIRE, THAT WOULD REALLY BE GOOD TO HAVE THAT.

MS. BONNEVILLE: ABSOLUTELY. SURE.

DR. MILLS: I WAS IN KANSAS LAST FRIDAY AND SOMEBODY SAID, "HEY, I HEAR YOU'RE HOLDING A STEM CELL MEETING AT STANFORD NEXT WEEK." AND I SAID, "REALLY?" I DIDN'T THINK IT WAS NEXT WEEK. IT WASN'T NEXT WEEK FORTUNATELY, BUT WORD'S GETTING OUT.

MR. SHEEHY: SO I ACTUALLY THOUGHT THERE MIGHT BE THREE THINGS THAT WE MIGHT RECONSIDER ON THE PREVIOUS SLIDE. BUT, NO. 1, THE PHASE II MATCHING FOR NONPROFIT INSTITUTIONS, THAT REALLY, I THINK, COULD BE A BARRIER ESPECIALLY FOR SOME OF THE PROJECTS THAT WE WANT TO FUND IN THAT THEY HAVE TO SOMEHOW BE ABLE TO GET THEIR INSTITUTION TO COME UP WITH THAT MONEY. SO AN INVESTIGATOR DOING AN EMBRYONIC STEM CELL PROJECT OR A GENE THERAPY

PROJECT AND THEY GET BASIC SAFETY AND THEN THEY WANT TO ROLL INTO A PHASE II, AND THEY'RE AT AN ACADEMIC RESEARCH INSTITUTION, THERE'S THE ASSUMPTION THAT THE INSTITUTION WILL PROVIDE THAT MONEY, BUT THAT IS MORE OF A POLITICAL ISSUE, I WOULD SUSPECT, THAN ACTUALLY BEING ABLE TO EASILY ACCESS THOSE FUNDS.

AND IT'S ALSO -- THE ACADEMIC RESEARCH INSTITUTIONS I DON'T THINK THEY'LL HAVE INFINITE RESOURCES. SO WHERE THEY WOULD COME UP FOR THAT MONEY IS KIND OF A MYSTERY TO ME. SO I WONDER -- WE KNOW IN SOME OF THESE HIGH RISK APPROACHES THAT SAFETY ALONE, UNLIKE A SMALL MOLECULE OR A BIOLOGIC, IS NOT SUFFICIENT TO GET INDUSTRY INTERESTED, THAT YOU REALLY NEED TO PRODUCE SOME SORT OF EFFICACY SIGNAL WHICH YOU WOULD NEED TO DO IN A PHASE II. SO I WONDER IF WE HAVE INADVERTENTLY PUT A BARRIER THERE FOR SOME OF THE HIGHEST RISK, HIGHEST REWARD PROJECTS THAT WE MIGHT BE ABLE TO BRING IN. SO THAT'S ONE.

NO. 2 IS ON THE PRE-IND REQUIREMENT. THAT'S NOT ALWAYS THE CASE, THAT PEOPLE NEED TO GO FOR A PRE-IND. IF THEY'RE DOING -- IF THEY'VE ALREADY TAKEN A PROJECT THROUGH THE IND AND THEN THEY'RE REFINING IT AND ADDING TO IT, THEY'RE NOT GOING TO GO BACK. SO THAT CAN KEEP PROJECTS THAT

ACTUALLY HAVE A LOT OF MERIT THAT ARE BEING FURTHER DEVELOPED FROM ACTUALLY BEING ABLE TO COME INTO CIRM BECAUSE THERE'S THIS LIMBO.

DR. MILLS: AT THIS POINT IT'S SHORTHAND. SO THE FULL, WRITTEN OUT IS PRE-IND WHEN NECESSARY. SO THERE ARE -- IF THE PRE-IND MEETING IS NOT NECESSARY, THEN IT'S NOT A REQUIREMENT.

MR. SHEEHY: AND THEN FOR THE SMALL MOLECULES AND BIOLOGICS, I THINK THAT SHOULD PERHAPS BE FURTHER REFINED BECAUSE IF SOMEONE IS COMING IN JUST TO OPEN A CLINICAL TRIAL SITE IN CALIFORNIA FOR A BIOLOGIC OR A SMALL MOLECULE, I DON'T KNOW THAT I SEE THE VALUE ADDED TO DO THAT. THAT SEEMS TO ME -- THEY'RE GOING TO DEVELOP THE PROJECT ANYWAY. IF THERE'S A SMALL MOLECULE OR BIOLOGIC, IT'S PROBABLY AMPLY FUNDED. SO THAT IS ONE PLACE I THINK WE MIGHT NEED SOME REFINEMENT.

AND I JUST WANTED TO RESPOND TO STEVE'S COMMENT. I THINK IF A MAJOR PHARMA CAME INTO CIRM ASKING FOR MONEY, I THINK THAT MIGHT BE A BIT OF A RED FLAG FOR THE REVIEW GROUP, THAT THEY WOULD ASK THE SAME QUESTION YOU ASKED AND WONDER WHY THEY DIDN'T HAVE SUFFICIENT FUNDING, AND SOMEHOW THAT MIGHT REFLECT ON THE MERIT OF THE PROJECT THAT THEY'RE PRESENTING TO US. SO I JUST WANTED TO MAKE

THAT. THERE IS KIND OF LIKE SOMETIMES THE QUESTION WHY ARE THEY HERE HAS COME UP IN THE PAST.

CHAIRMAN THOMAS: HAVE A QUESTION FROM THE MEMBER OF THE PUBLIC? CAN I JUST ASK A QUESTION? IS THIS THE APPROPRIATE TIME, JAMES, FOR A COMMENT FROM A MEMBER OF THE PUBLIC?

MR. HARRISON: SURE. YOU CAN TAKE PUBLIC COMMENT AT ANY POINT IN TIME. THERE'S NO MOTION PENDING OR NO ACTION, BUT YOU ARE FREE TO ACCEPT PUBLIC COMMENT.

DR. LORING: THANK YOU. I'LL MAKE THIS SHORT. THIS IS JEANNE LORING. I'M FROM THE LOVELY, SUNNY CITY OF SAN DIEGO, CALIFORNIA, SCRIPPS RESEARCH INSTITUTE.

WHAT I WANTED TO ASK WAS SOMETHING, I THINK, THAT ONLY PEOPLE WHO ARE INVOLVED IN APPLICATIONS AND GRANT REVIEW WOULD ASK. AND THAT IS THAT SO FAR ALL OF THE GRANTS HAVE COME FROM PI'S, NOT QUITE SO FAR, BUT MOST OF THE GRANTS HAVE COME FROM PI'S WHO ARE AT CALIFORNIA INSTITUTIONS. AND THE REVIEWERS HAVE BEEN REQUIRED TO BE OUTSIDE CALIFORNIA. SO NOW IF YOU ARE GOING TO HAVE PI'S WHO ARE FROM OUTSIDE CALIFORNIA, DOES THAT MEAN THAT YOU ARE GOING TO START RECRUITING PEOPLE INSIDE CALIFORNIA TO REVIEW THEIR GRANTS, WHICH WOULD SEEM

LIKE THE PROPER THING TO DO, FAIR THING TO DO?

AND THE OTHER QUESTION IS WHEN THERE ARE PEOPLE OUTSIDE OF CALIFORNIA, THEN, SINCE THEY'RE ALSO IN THE GRANT REVIEW POOL IN GENERAL, I THINK WE NEED TO BE EXTRA CAREFUL TO MAKE THAT SURE THE CONFLICTS OF INTEREST ARE VERY CAREFULLY VETTED BECAUSE THERE'S A MUCH HIGHER PROBABILITY OF SOMEBODY HAVING A CONFLICT IF THEY ARE ALLOWED TO HAVE A GRANT. THANKS.

CHAIRMAN THOMAS: THANK YOU. ANY OTHER QUESTIONS OR COMMENTS? OKAY. THANK YOU VERY MUCH, DR. MILLS.

SO WE ARE GOING TO TAKE AN ITEM OUT OF ORDER, WHICH IS ITEM NO. 14, CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLIN1: PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL PROJECTS. AND PRESENTING ON THIS ITEM WILL BE DR. SAMBRANO.

DR. SAMBRANO: GOOD MORNING. THANK YOU, MR. CHAIRMAN. I AM BRINGING FOR YOUR CONSIDERATION AN APPLICATION AND RECOMMENDATIONS FROM THE GRANTS WORKING GROUP. AND THIS IS AN APPLICATION THAT WAS RESPONDING TO THE CLIN1 PROGRAM ANNOUNCEMENT UNDER OUR CLINICAL STAGE PROGRAM. SO THE CLIN1 SUPPORTS PROJECTS TO COMPLETE IND-ENABLING WORK AND GET THEM

TO THE POINT WHERE THEY SUBMIT THEIR IND AND CAN START A TRIAL.

JUST TO REMIND YOU ONCE AGAIN OF THE SCORING SYSTEM THAT WE UTILIZE IN THE CLINICAL PROGRAM, REVIEWERS ASSIGN A SCORE OF A 1, 2, OR 3. A 1 MEANS THAT THE APPLICATION IS GREAT, HAS EXCEPTIONAL MERIT, WARRANTS FUNDING. A SCORE OF 2 MEANS THAT IT'S PROMISING, BUT IT NEEDS IMPROVEMENT, AND IT CAN BE RESUBMITTED TO ADDRESS THOSE AREAS FOR IMPROVEMENT. AND THEN, FINALLY, A SCORE OF 3, WHICH MEANS IT'S SUFFICIENTLY FLAWED THAT WE WOULDN'T WANT TO FUND THIS, AND THAT THE PROJECT SHOULD NOT BE RESUBMITTED FOR AT LEAST SIX MONTHS. IT'S BASICALLY PLEASE GO BACK AND RETHINK THIS.

SO THE APPLICATION UNDER CONSIDERATION IS CLIN1-09230, WHICH IS PRECLINICAL DEVELOPMENT OF A GENE THERAPY APPROACH FOR CYSTINOSIS. THE THERAPY ITSELF IS HEMATOPOIETIC STEM CELLS WHICH HAVE BEEN GENETICALLY MODIFIED, THAT IS, IT'S A GENE CORRECTION APPROACH, FROM HEMATOPOIETIC STEM CELLS THAT ARE IN THE PERIPHERAL BLOOD OF PATIENTS WITH CYSTINOSIS. AND CYSTINOSIS IS A LYSOSOMAL STORAGE DISEASE THAT AFFECTS CHILDREN AND YOUNG ADULTS.

AND THEIR GOAL FOR THIS CLIN1 PROJECT IS TO COMPLETE IND-ENABLING ACTIVITIES THAT WILL

SUPPORT THE FILING OF AN IND IN ORDER TO CONDUCT A FUTURE CLINICAL TRIAL IN THESE PATIENTS. AND THE MAJOR PROPOSED ACTIVITIES INCLUDE PERFORMING PHARMACOLOGY AND TOXICOLOGY STUDIES, DEVELOP LARGE-SCALE MANUFACTURING GMP METHODS, AND PREPARE AND SUBMIT THEIR IND. AND THE FUNDS REQUESTED IS ABOUT $5.3 MILLION FROM THIS APPLICANT.

AND A SUMMARY OF THE REVIEW PROCESS, JUST SO YOU KNOW FOR THOSE OF YOU WHO ARE NEW, THAT WE CONDUCT A THREE-STAGE REVIEW. THE FIRST ONE IS ELIGIBILITY, WHICH RANDY TALKED ABOUT BRIEFLY, AND WE ALSO CONDUCT A BUDGET REVIEW. BECAUSE THESE ARE MULTIMILLION DOLLAR PROPOSALS, WE WANT TO ENSURE THAT THE BUDGET IS APPROPRIATE AND REASONABLE FOR THE COSTS THAT ARE BEING REQUESTED. SO WE CONDUCT SUCH A BUDGET REVIEW BEFORE WE TAKE IT TO THE GWG.

SO THE BUDGET REVIEW THEY PASSED. WE TOOK IT ON TO THE GWG, WHICH GAVE IT A SCORE OF 1, AND THE VOTES THAT CONTRIBUTED TO THAT SCORE OF 1 WERE 14 MEMBERS FROM THE GWG GAVE IT A SCORE OF 1, ONE MEMBER GAVE IT A SCORE OF 2, AND ZERO GAVE IT A SCORE OF 3.

THE CIRM TEAM ALSO REVIEWS THE PROCESS THAT WE TAKE ON FOR EACH OF THESE PROPOSAL REVIEWS TO ENSURE THAT EVERYTHING WAS CONDUCTED IN A FAIR

AND APPROPRIATE MANNER. WE CONCUR WITH THE GWG RECOMMENDATION AND FEEL IT'S AN APPROPRIATE SCORE, AND THAT AN AWARD AMOUNT OF 5.3 MILLION BE AWARDED. HAPPY TO TAKE QUESTIONS.

CHAIRMAN THOMAS: MEMBERS OF THE BOARD HAVE QUESTIONS? MR. SHEEHY.

MR. SHEEHY: JUST MAYBE A LITTLE BIT MORE, WHAT THE DISEASE TARGET, A LITTLE BIT MORE ABOUT WHAT CYSTINOSIS IS AND WHAT THAT MEANS FOR A PATIENT AND FOR A FAMILY.

DR. SAMBRANO: CYSTINOSIS IS A LYSOSOMAL STORAGE DISEASE. SO WHAT HAPPENS IS CYSTINE ACCUMULATES IN THE CELLS OF THE BODY, AND THIS IS IN ALL THE CELLS OF THE PATIENTS. AND SO WHAT HAPPENS, IT EVENTUALLY LEADS TO MULTI-ORGAN FAILURE IN THESE PATIENTS. AND THIS CAN BEGIN AT A VERY YOUNG AGE. AND SO THE CURRENT TREATMENT IS CYSTEAMINE WHICH ATTEMPTS TO BREAK DOWN THE CYSTINE IN THE CELLS. BUT IT DOESN'T WORK EFFECTIVELY, MEANING THERE IS MORE TO THIS DISEASE THAN THE DRUG CAN ACCOMPLISH ON ITS OWN.

AND SO THE APPROACH IS BASICALLY DOING WHAT IS A BONE MARROW TRANSPLANT, INTRODUCING HEMATOPOIETIC STEM CELLS THAT HAVE THE CORRECTED GENE. AND BY DOING SO, THE HEMATOPOIETIC STEM CELLS

DISTRIBUTE THROUGHOUT ALL THE TISSUES IN THE BODY, AND THEY APPEAR, AT LEAST IN ANIMAL MODELS, TO CORRECT THE DEFECT SO THAT THEY OVERCOME ORGAN FAILURE, ESPECIALLY KIDNEY FAILURE AND OTHER AREAS THAT THIS IMPACTS.

SO THAT'S A BIG PICTURE OF WHAT THE APPROACH IS AND WHAT THE DISEASE IS.

CHAIRMAN THOMAS: ANY OTHER QUESTIONS OF DR. SAMBRANO? DO I HEAR A MOTION TO APPROVE?

DR. DULIEGE: MAYBE I MISSED IT, BUT, FIRST OF ALL, SO IT'S CLEAR. RARELY DO WE HAVE A PROPOSAL WHERE EVERYONE AGREES THAT IT'S A GREAT PROPOSAL. SO THAT MAKES IT VERY EASY.

JUST IN TERMS OF THE INTERVENTION, OUT OF CURIOSITY, IS THIS GOING TO BE A PHASE I STUDY?

DR. SAMBRANO: THIS IS A CLIN1, SO THESE ARE IND-ENABLING ACTIVITIES THAT WILL LEAD TO AN IND FILING.

DR. DULIEGE: SO IT'S CRITICAL. IT'S, WHAT, IT'S TOXICOLOGY, IT'S --

DR. SAMBRANO: TOXICOLOGY, PHARMACOLOGY. THEY HAVE TO DO THE MANUFACTURING AND DEVELOP THE PROTOCOL FOR THE VECTOR THAT WILL BE UTILIZED FOR THE GENE CORRECTION.

DR. DULIEGE: AGAIN, PURELY OUT OF

CURIOSITY, SO BRIEFLY, DID THE GROUP PROPOSING THIS GRANT ALREADY HAVE MEETINGS WITH THE FDA, PRE-IND MEETINGS --

DR. SAMBRANO: THEY HAVE.

DR. DULIEGE: -- IS THAT GOING TO ALLOW A FULL-FLEDGED PRE-IND MEETING?

DR. SAMBRANO: SO THEY'VE ALREADY HAD A FULL PRE-IND MEETING, WHICH IS ONE OF THE REQUIREMENTS COMING IN. SO THEY'VE ALREADY HAD THOSE DISCUSSIONS. AND THOSE ARE IMPORTANT BECAUSE IT HELPS BOTH THE REVIEW PANEL UNDERSTAND WHERE THE FDA IS ON ISSUES RELATED TO REGULATING AND ALLOWING APPROVAL FOR THEM TO BEGIN THEIR CLINICAL TRIAL. SO THEY ARE ON THAT PATH. AND SO THIS AWARD WOULD ALLOW THEM TO CONDUCT THOSE FINAL STUDIES AND TO SUBMIT THEIR IND.

DR. DULIEGE: EXCELLENT. AND THIS IS IMPORTANT BECAUSE, I ASSUME, ONE OF THE REASONS WHY THE SCORE WAS SO HIGH AND SO UNANIMOUS IS BECAUSE THE PRE-IND MEETING WAS PRETTY SUPPORTIVE, AND THAT ALLOWS THE COMPANY OR THE GROUP, I'M NOT SURE, TO REALLY DELIVER ON THE STRATEGY THAT WILL BE SUPPORTED BY THE FDA, MOST LIKELY.

DR. SAMBRANO: THAT'S A PART OF IT. IT IS PUTTING TOGETHER, REALLY, A PROPOSAL THAT MAKES

SENSE THAT REVIEWERS RESPOND TO. CERTAINLY HAVING A PRE-IND MEETING CERTAINLY HELPS THEM ALIGN WITH THAT.

CHAIRMAN THOMAS: WE'RE NOW UNDER THE AUSPICES OF THE APPLICATION REVIEW SUBCOMMITTEE. SO, MR. SHEEHY, YOU HAVE THE FLOOR.

MR. SHEEHY: SO I THINK OUR NEXT STEP IS TO EITHER TAKE A MOTION TO ACCEPT THE CIRM TEAM RECOMMENDATION AND THE GWG RECOMMENDATION OR TO NOT ACCEPT THAT RECOMMENDATION AND NOT FUND.

MS. WINOKUR: SECOND.

DR. JUELSGAARD: I MOVE TO ACCEPT.

CHAIRMAN THOMAS: SO WE HAVE A MOTION BY MR. JUELSGAARD AND A SECOND BY MS. WINOKUR. IS THERE A DISCUSSION ABOUT THIS APPLICATION?

DR. LUBIN: JUST A QUESTION ABOUT THE FREQUENCY IN THE STATE OF CALIFORNIA OR IN THE UNITED STATES OF THIS CONDITION. HOW MANY CHILDREN ARE KNOWN TO HAVE THIS OR ANNUALLY HOW MANY CHILDREN HAVE IT?

DR. SAMBRANO: SO THE INCIDENCE, BASED ON THE APPLICATION, IS REPORTED TO BE ABOUT ONE IN A HUNDRED TO 200,000.

DR. LUBIN: SO IT'S RARE, BUT I THINK THE TECHNOLOGY COULD APPLY TO A LOT OF LYSOSOMAL STORAGE

DISEASES. I'M NOT AGAINST IT BECAUSE OF THAT, BUT I JUST WAS CURIOUS WHAT NUMBERS THEY GAVE IN THE APPLICATION.

DR. DIXON: I AGREE. THIS WORK IS LIKELY TO OPEN UP OTHER LYSOSOMAL STORAGE DISEASES TO SIMILAR STRATEGIES.

MR. HARRISON: I'M SORRY, DR. DIXON. YOU CAN'T PARTICIPATE IN THIS DISCUSSION.

DR. DIXON: OKAY. EXCUSE ME.

MR. SHEEHY: DO WE HAVE ADDITIONAL DISCUSSION ON THE MOTION? DO WE HAVE PUBLIC COMMENT? COULD WE CALL THE ROLL, THEN, PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: LAUREN MILLER. ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA. FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: DR. QUINT, ARE YOU ON THE LINE?
THE REPORTER: I HEARD YES.
MS. BONNEVILLE: YOU DID?
THE REPORTER: YES.
MR. TOCHER: FROM DR. QUINT?
THE REPORTER: YES.
MR. HARRISON: MOTION CARRIES.
MR. SHEEHY: IT'S BACK TO YOU, CHAIR THOMAS.
CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY. I JUST WANTED TO MAKE A POINT ALSO OF SINGLING OUT

THE BACKBONE OF WHAT WE DO IS REALLY THE REVIEW OF GRANTS AND THE WORK OF THE GWG, WHICH, AS YOU HEARD FROM DR. MILLS, HAS INCREASED SEVERAL FOLD, WHICH INCREASES THE WORKLOAD THAT OUR TEAM HAS. AND I WANTED TO, SINCE HE SORT OF ALWAYS PRESENTS AND IS TAKEN GREATLY FOR GRANTED, TO CONGRATULATE DR. SAMBRANO ON THE CONTINUING TERRIFIC WORK THAT HE AND THE MEMBERS OF HIS TEAM DO IN MARSHALLING ALL THE GRANTS THROUGH THE PROCESS THAT MAKES ALL OF THIS POSSIBLE. SO, DR. SAMBRANO AND TEAM, CONGRATULATIONS.

OKAY. WE ARE TO GIVE BETH A BREAK HERE. SO WE'RE GOING TO TAKE A TEN-MINUTE BREAK. SO WE WILL RECONVENE ROUGHLY AT 11 O'CLOCK.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: YES. COULD THOSE MEMBERS WHO ARE MILLING ABOUT PLEASE TAKE YOUR SEATS. OKAY. WE'RE GOING TO PROCEED BACK ON NUMERIC ORDER TO THE CONSENT CALENDAR, WHICH IS ITEMS 6 THROUGH 10. DO ANY MEMBERS HAVE ANY OF THE ITEMS ON THE CONSENT CALENDAR THAT THEY WOULD LIKE TO PULL OFF FOR INDIVIDUAL CONSIDERATION?

MR. SHEEHY: COULD WE PULL OFF NO. 10, PLEASE.

MR. TORRES: NO. 10?

CHAIRMAN THOMAS: NO. 10 HAS BEEN PULLED OFF.

MR. TORRES: MOVE TO APPROVE THE REMAINING.

MR. SHEEHY: SECOND.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. I BELIEVE WE CAN DO THIS WITH A VOICE VOTE IN THE ROOM AND A ROLL CALL FOR OTHERS. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: AYE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: THANK YOU.

MR. HARRISON: MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.

WITH RESPECT TO ITEM NO. 10, MR. HARRISON, HOW SHALL WE PROCEED?

MR. HARRISON: YES. IF MR. SHEEHY WOULD LIKE, GABE THOMPSON IS PREPARED TO MAKE A PRESENTATION; OR IF YOU'D RATHER POSE QUESTIONS, WE CAN HANDLE HOWEVER YOU LIKE.

MR. SHEEHY: I THINK I JUST HAD TWO QUESTIONS ABOUT TWO ITEMS SO THAT PEOPLE ARE AWARE JUST TO KIND OF GET IT OUT THERE.

SO GABE, MR. THOMPSON, SO MY FIRST QUESTION IS ABOUT THE NON-CALIFORNIA PIECE OF THIS, THE ELIGIBILITY OF NON-CALIFORNIA RESEARCHERS TO APPLY FOR DISCOVERY, TRANSLATION, AND EDUCATION GRANTS. I DON'T THINK WE'VE REALLY TALKED ABOUT THAT BEFORE. SOMEBODY FROM THE COMMUNITY RAISED THAT. I HAD ALWAYS CONTEMPLATED THAT THAT WAS A CLINICAL STAGE THING, BUT NOW, LIKE AT THE DISCOVERY STAGE, CALIFORNIA RESEARCHERS COULD BE COMPETING OR WILL BE COMPETING POTENTIALLY WITH NON-CALIFORNIA APPLICANTS. SO CAN WE -- JUST WHAT THAT MEANS.

MR. THOMPSON: I'M GABRIEL THOMPSON. I'M THE DIRECTOR OF PORTFOLIO OPERATIONS AND PERFORMANCE AT CIRM. AND SO YOU ARE CORRECT. THERE IS OUR

DISCOVERY, TRANSLATION PROGRAMS DO ALLOW FOR NON-CALIFORNIA APPLICANTS TO APPLY TO CIRM. WE DEFINE NON-CALIFORNIA APPLICANT ORGANIZATIONS AS THOSE WHO EMPLOY AND PAY 50 PERCENT OR LESS OF ITS EMPLOYEES OUTSIDE THE STATE OF CALIFORNIA.

SO IF YOU HAVE A NON-CALIFORNIA APPLICANT, CIRM WILL PAY FOR COSTS FOR ACTIVITIES WHOLLY CONDUCTED IN CALIFORNIA AS WELL AS ANY COSTS OUTSIDE THE STATE OF CALIFORNIA THAT ARE DIRECTLY ATTRIBUTABLE TO THOSE ACTIVITIES OCCURRING IN THE STATE OF CALIFORNIA.

SO I CAN GIVE AN EXAMPLE. IF AN INVESTIGATOR AT UNC, FOR INSTANCE, HAD SOME CELLS AND THEY WANTED TO USE AN ANIMAL MODEL THAT WAS AT UCLA, THE UCLA TEAM COULD GET THE ANIMAL STUDIES FOR THAT ANIMAL MODEL COVERED BY THE GRANT, AND THEN UNC COULD GET THE COST TO PREPARE THOSE CELLS THAT THEY THEN HAND OVER TO UCLA COVERED BY THE GRANT. IT IS ALSO LIMITED TO NO MORE THAN 50 PERCENT OF THE CALIFORNIA FUNDS REQUESTED. SO WE DO TRY TO IMPOSE A LIMIT ON THAT NON-CALIFORNIA.

MR. SHEEHY: SO OBVIOUSLY THIS -- TO HAVE A FURTHER DISCUSSION ABOUT THIS AND MAYBE TAKE ACTION I THINK WOULD HAPPEN AT A DIFFERENT PLACE BECAUSE THIS IS JUST CLARIFYING THE GAP. BUT I

PERSONALLY WOULD LIKE TO HAVE A DISCUSSION AND PERHAPS MAYBE EVEN AN ACTION ITEM IN THE FUTURE ON THIS ISSUE BECAUSE CIRM, IN A LOT OF WAYS, PREFERENTIALLY BENEFITS RESEARCHERS IN CALIFORNIA. CERTAINLY AT THE CLINICAL STAGE, ANY CLINICAL WORK THAT WE CAN DO TO CURE PATIENTS, WHEREVER IT COMES FROM, I'M SUPPORTIVE OF FUNDING. BUT I THINK GIVEN WHAT'S GOING ON WITH THE NIH, FOR EARLIER STAGE RESEARCH, I WOULD REALLY LIKE TO BE THOUGHTFUL ABOUT WHETHER OR NOT WE RESERVE THAT FOR CALIFORNIANS, CALIFORNIA-BASED RESEARCHERS.

SO I'D LIKE TO FLAG THAT ISSUE, AND PERHAPS WE CAN COME BACK TO THAT. I DON'T KNOW WHAT THE APPROPRIATE MECHANISM IS BECAUSE THIS IS JUST ADMINISTRATION POLICY.

DR. MILLS: SO THIS IS SOMETHING INTERNALLY WE ACTUALLY SHARE THAT FEELING. SO WHAT GABE IS DOING TODAY IS CLEANING UP EXISTING POLICY TO MATCH THE CONCEPT PLANS WHICH ARE IN EFFECT ALREADY. BUT IT IS OUR INTERNAL INTEREST TO COME BACK TO THE BOARD WITH A MODIFICATION TO THE CONCEPT PLANS TO REMOVE THE OUT-OF-STATE FUNDING COMPONENT FROM ALL OF THE CONCEPT PLANS UP TO ONLY THE CLIN2 SERIES, WHICH IS THE ACTUAL CLINICAL TRIAL WHERE WE WANT TO BE -- WE'RE GOING TO BE ACTIVELY PULLING

CLINICAL TRIALS INTO IT. SO WE ACTUALLY SHARE THIS CONCERN AND WANT TO COME BACK AND MODIFY IT, BUT WE DO THAT THROUGH THE MODIFICATION OF THE CONCEPT PLAN. IS THAT CORRECT, JAMES? DID I GET THAT RIGHT?

MR. HARRISON: THAT'S CORRECT. SO WE PLAN ON BRINGING THESE BACK IN DECEMBER AND HAVE A SCIENCE SUBCOMMITTEE FIRST IF YOU WOULD LIKE.

MR. SHEEHY: GREAT. THANK YOU.

AND THEN, MR. THOMPSON, THE OTHER THING IS JUST FOR CLARIFICATION, THE PROGRESSION AWARD MECHANISM. CAN YOU KIND OF EXPLAIN HOW THAT WORKS AND WHAT'S GOING ON THERE? I ACTUALLY THINK IT'S VERY INNOVATIVE, AND I THINK WE'VE TALKED ABOUT IT BEFORE, BUT JUST ANOTHER CHANCE.

MR. THOMPSON: ABSOLUTELY. SO, AGAIN, THIS GRANTS ADMINISTRATION POLICY IS ACTUALLY JUST REFERENCING THE DISCOVERY, IN PARTICULAR THE QUEST PROGRAM, THE WORKHORSE OF DISCOVERY, AND WHAT THIS IS, AS RANDY TALKED EARLIER, ONE OF OUR BIG SIX GOALS ARE TO INCREASE PROGRESSION EVENTS OVERALL BY 50 PERCENT. SO MOVING ANY PROJECT FROM ONE STAGE OF DEVELOPMENT TO THE NEXT.

THIS IS SPECIFIC TO, WE THINK, THE MOST IMPORTANT PROGRESSION EVENT THAT WE WANT TO

INCENTIVIZE IS GOING FROM A QUEST AWARD, WHICH ENDS IN IDENTIFYING A CANDIDATE FOR TRANSLATION, AND THEN GETTING THE TRANSLATIONAL AWARD OR TRANSLATIONAL FUNDING TO FURTHER DEVELOP THAT CANDIDATE. SO WHAT THE QUEST PROGRAM ANNOUNCEMENT ALLOWS IS IF A QUEST AWARDEE WITHIN 12 MONTHS AFTER THEY FINISH THEIR AWARD FINDS EITHER CIRM FUNDING OR CIRM EQUIVALENT FUNDING TO BRING THAT CANDIDATE INTO TRANSLATION, CIRM WILL PROVIDE THEM WITH ONE OF OUR SEED AWARDS. AND IT'S SUBJECT TO CIRM'S PRIOR APPROVAL. IT HAS TO BE A STEM CELL PROJECT THAT FALLS WITHIN CIRM'S SCOPE, BUT THEY WOULD BASICALLY BE ELIGIBLE TO RECEIVE A SEED AWARD.

MR. SHEEHY: GREAT. THANK YOU. SO THOSE WERE MY QUESTIONS. IF NO ONE ELSE HAS QUESTIONS, I'LL MOVE TO APPROVE THIS.

MR. TORRES: SECOND.

CHAIRMAN THOMAS: ANY FURTHER DISCUSSION? DISCUSSION FROM MEMBERS OF THE PUBLIC? VOICE VOTE HERE. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? MARIA, PLEASE POLL THOSE ON THE PHONE.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: KATHY LAPORTE.
MS. LAPORTE: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: AYE.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
CHAIRMAN THOMAS: THANK YOU. ON TO ACTION ITEM, NO. 11, CONSIDERATION OF AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS. MR. HARRISON.
MR. HARRISON: GOOD MORNING. AS DR. MILLS EXPLAINED EARLIER DURING HIS PRESIDENT'S REPORT, WE ARE SORT OF ON A CONSTANT BASIS REVIEWING OUR POLICIES TO MAKE SURE THAT THEY ARE AS EFFECTIVE AND AS EFFICIENT AS POSSIBLE. AND AS PART OF THAT REVIEW, WE HAVE BEEN TAKING A CLOSE LOOK AGAIN AT THE GWG BYLAWS AND IN PARTICULAR OUR SCORING PROCESS. AND WE BRING TO YOU TODAY PROPOSALS FOR AMENDMENTS ON SEVERAL DIFFERENT ASPECTS OF THE BYLAWS: SCORING FOR OUR DISC, TRAN, AND EDUCATION PROGRAMS, SCORING FOR OUR CLINICAL APPLICATIONS, SCORING FOR INFRASTRUCTURE APPLICATIONS, AND SOME

TECHNICAL CLEANUPS THAT WE WOULD LIKE THE BOARD TO APPROVE.

LET ME START WITH THE CURRENT SCORING MECHANISM FOR OUR DISC, TRAN, AND EDUCATION PROGRAM APPLICATIONS. UNDER OUR CURRENT SYSTEM, GWG SCIENTIFIC MEMBERS ASSIGN A SCORE OF 1 TO 100. AND UNDER THE GWG BYLAWS, AN AVERAGE SCORE OF 85 OR ABOVE INDICATES THAT THE APPLICATION IS FUNDABLE IF FUNDS ARE AVAILABLE; WHEREAS, AN AVERAGE SCORE BELOW 85 IS DEEMED TO BE NOT RECOMMENDED FOR FUNDING.

ON A COUPLE OF OCCASIONS WE HAVE ENCOUNTERED REVIEWS IN WHICH AN APPLICATION WAS SCORED AT 85 OR ABOVE BY A MAJORITY OF THE MEMBERS OF THE GWG, BUT BECAUSE OF AN OUTLIER SCORE OR TWO, THE AVERAGE SCORE WAS BELOW 85. AND AS A RESULT, THE APPLICATION WAS NOT RECOMMENDED FOR FUNDING. WE THINK THAT THE MEDIAN SCORE RATHER THAN THE AVERAGE SCORE BETTER REFLECTS THE SENSE OF THE GRANTS WORKING GROUP. IF A MAJORITY OF THE SCIENTIFIC MEMBERS BELIEVE AN APPLICATION WARRANTS FUNDING, THEN WE THINK THAT SHOULD BE WHAT DRIVES THE GWG'S RECOMMENDATION. AND IT ALSO HAS THE BENEFIT OF ADDRESSING OUTLYING SCORES.

SO WHAT WE WOULD PROPOSE TO DO IS TO USE THE MEDIAN SCORE RATHER THAN THE AVERAGE SCORE FOR

PURPOSES OF DETERMINING WHETHER AN APPLICATION IS RECOMMENDED FOR FUNDING OR NOT RECOMMENDED FOR FUNDING. HOWEVER, WE WOULD CONTINUE TO USE THE AVERAGE SCORE FOR PURPOSES OF DISPLAYING THE RANK OF APPLICATIONS WITHIN THE TWO DIFFERENT TIERS.

SO WE HAVE A DEPICTION OF THAT IN THE CHART IN FRONT OF YOU SO YOU CAN GET A SENSE OF WHAT IT MIGHT LOOK LIKE. SO THE AVERAGE SCORE WOULD JUST BE USED TO RANK APPLICATIONS WITHIN THE FUNDABLE CATEGORY AND SEPARATELY TO RANK APPLICATIONS WITHIN THE NOT FUNDABLE CATEGORY.

WE'D ALSO LIKE TO PROPOSE MODIFICATIONS TO THE SCORING SYSTEM FOR CLINICAL APPLICATIONS FOR MUCH THE SAME REASONS. CURRENTLY OUR CLINICAL SCORING SCIENTIFIC MEMBERS ARE ASKED TO ASSIGN A NUMERICAL SCORE OF 1, WHICH INDICATES THAT THE APPLICATION HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING IF FUNDS ARE AVAILABLE. TWO MEANS THE APPLICATION AS PRESENTED COULD BE IMPROVED AND IS NOT RECOMMENDED FOR FUNDING AT THIS TIME. AND A SCORE OF 3, WHICH INDICATES THAT THE GRANTS WORKING GROUP SCIENTIFIC MEMBERS BELIEVE THE APPLICATION DOESN'T WARRANT FUNDING.

UNDER THE CURRENT BYLAWS, WE HAVE A BIFURCATION. SO IF AN APPLICATION RECEIVES A

PLURALITY OF SCORES OF 1 OR 2, THEN THAT'S THE TIER TO WHICH THE APPLICATION IS ASSIGNED. HOWEVER, IF IT'S TIER III, IT REQUIRES A MAJORITY OF MEMBERS TO ASSIGN AN APPLICATION TO TIER III. AND WHERE THERE IS EITHER NO PLURALITY OR NO MAJORITY, THEN THE GRANTS WORKING GROUP TAKES A MOTION TO ASSIGN THE APPLICATION TO A PARTICULAR TIER.

HERE TOO WE HAVE ENCOUNTERED INSTANCES IN WHICH A MAJORITY OF THE SCIENTIFIC MEMBERS OF THE GWG BELIEVE THAT AN APPLICATION DID NOT WARRANT FUNDING, AT LEAST AS PRESENTED TO THE GWG, BUT IT WAS NONETHELESS RECOMMENDED FOR FUNDING. SO FOR THE SAME REASON WE EXPRESSED WITH RESPECT TO THE DT&E SCORING SYSTEM, HERE WE THINK REQUIRING A MAJORITY OF THE SCORES TO ASSIGN AN APPLICATION TO TIER I, TIER II, OR TIER III BETTER REFLECTS THE SENSE OF THE GRANTS WORKING GROUP. AND IF THE GRANTS WORKING GROUP IS UNABLE TO REACH A MAJORITY VOTE OR SCORE, RATHER, FOR ANY TIER, THEN IT WOULD AUTOMATICALLY BE DEEMED TO BE A TIER II APPLICATION, WHICH MEANS THE APPLICANT WOULD HAVE A CHANCE TO REVIEW THE GWG'S COMMENTS, IMPROVE THE APPLICANT'S APPLICATION, AND RESUBMIT IT FOR THE GWG AND ULTIMATELY THE APPLICATION REVIEW SUBCOMMITTEE'S CONSIDERATION.

BRIEFLY, FOR OUR INFRASTRUCTURE PROGRAMS,

WE HAVE ONE PROGRAM THAT IS CURRENTLY UNDER REVIEW BY THE GRANTS WORKING GROUP. THAT'S THE TRANSLATING CENTER. FOR THE SAME REASONS WE EXPRESSED WITH RESPECT TO DT&E, WE PROPOSE TO USE A SCORING MECHANISM, RATHER, TO MODIFY OUR EXISTING SCORING MECHANISM BY USING THE MEDIAN SCORE RATHER THAN THE AVERAGE SCORE.

WITH RESPECT TO THE ATP3 PROGRAM, WHICH YOU'RE GOING TO HEAR MORE DETAIL ABOUT LATER TODAY, WE PROPOSE TO MAKE A MORE SIGNIFICANT MODIFICATION TO THE SCORING SYSTEM. RATHER THAN USING OUR TRADITIONAL 1 TO 100 SCORE, WE PROPOSE TO USE THE SCORING SYSTEM THAT WE USE FOR CLINICAL APPLICATIONS. SO WE WOULD ASK GWG SCIENTIFIC MEMBERS TO ASSIGN A SCORE OF 1, INDICATING THE APPLICATION HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING IF FUNDS ARE AVAILABLE; 2, THAT IT'S NOT RECOMMENDED FOR FUNDING AT LEAST AS PRESENTED; AND 3, THAT IT'S NOT RECOMMEND FOR FUNDING AT ALL. AND WE WOULD REQUIRE A MAJORITY OF SCORES FOR ASSIGNMENT TO TIER I, II, OR III. AND IF THERE'S NO MAJORITY, THE APPLICATION WOULD BE ASSIGNED TO TIER II AUTOMATICALLY.

THERE ARE A NUMBER OF TECHNICAL AMENDMENTS WE'D LIKE TO MAKE. NONE OF THEM ARE PARTICULARLY

SIGNIFICANT. WE WOULD DELETE AN OUTDATED REFERENCE TO ADMINISTRATIVE CHAIR, A POSITION THAT NO LONGER EXISTS. WE CLARIFY THAT ACTIONS OF THE GWG MAY ONLY BE TAKEN BY A MAJORITY OF THE MEMBERS PRESENT AND VOTING, CONSISTENT WITH ROBERTS RULES OF ORDER, AND WE'D MAKE SOME TECHNICAL EDITS TO LANGUAGE FOR CLARITY.

THERE IS ONE ADDITIONAL CHANGE THAT WE WOULD LIKE THE BOARD TO APPROVE WHICH IS NOT IN THE WRITTEN MATERIALS. AND, AGAIN, THIS IS OF A TECHNICAL NATURE. CURRENTLY WITH RESPECT TO REIMBURSEMENT OF EXPENSES, WE PROVIDE FOR REIMBURSEMENT OF EXPENSES FOR GWG MEMBERS, BUT WE DON'T EXPLICITLY STATE THAT THAT INCLUDES SPECIALIST MEMBERS. AS A MATTER OF PRACTICE, WE'VE ALWAYS TREATED SPECIALIST MEMBERS AS GWG MEMBERS FOR PURPOSES OF REIMBURSEMENT AND A DAILY CONSULTING RATE, BUT WE'D LIKE TO MAKE THE LANGUAGE IN ARTICLE IV, SECTION 9B EXPLICIT IN ORDER TO ENSURE THERE'S NO CONFUSION ABOUT THAT.

I'D BE HAPPY TO ANSWER ANY QUESTIONS. IF NOT, WE'D REQUEST THAT THE BOARD APPROVE THE PROPOSED AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS.

DR. JUELSGAARD: YES, MR. HARRISON. SO I

WANT TO KIND OF GO BACK TO SLIDE 5 FOR A MOMENT, THE CLINICAL SCORING. SO I WANT TO DEAL WITH THE PROPOSED SCORING, THE BULLET POINTS AT THE BOTTOM. AND I'M JUST GOING TO RAISE A HYPOTHETICAL. SO I WANT TO ASSUME THAT THERE ARE 15 VOTES ON THE GWG, AND THAT THE VOTES ARE SIX 1S, FIVE 2S, AND FOUR 3S. WHAT HAPPENS?

MR. HARRISON: IT WOULD AUTOMATICALLY BE ASSIGNED A SCORE OF 2.

DR. JUELSGAARD: SO WHEN YOU SAY THE MAJORITY OF SCORES, THAT'S WHERE I'M NOT CLEAR OR DON'T QUITE UNDERSTAND. WHAT IS THE MAJORITY OF SCORES REFERRING TO?

MR. HARRISON: YOU NEED A MAJORITY OF MEMBERS TO ASSIGN A SCORE OF 1, 2, OR 3 IN ORDER FOR THAT TO REFLECT THE RECOMMENDATION OF THE GRANTS WORKING GROUP.

DR. JUELSGAARD: GOT IT. SO IN MY HYPOTHETICAL, IT WOULD HAVE TO BE 8 OF THE 15 IN ORDER TO GET THERE?

MR. HARRISON: CORRECT.

MR. JUELSGAARD: OKAY. THANKS.

DR. DULIEGE: IS THIS INDEED IN THIS INSTANCE WHERE YOU ARE SUGGESTING TO USE SIMPLY A MEDIAN RATHER THAN THE MEAN?

MR. HARRISON: SO OUR CLINICAL SCORING IS A LITTLE BIT DIFFERENT BECAUSE OFTENTIMES WE ONLY HAVE ONE APPLICATION. AND SO IT'S REALLY BEING EVALUATED ON AN INDIVIDUAL BASIS. AND FOR THAT REASON, WHAT WE REALLY WANT THE GWG TO DO IS TO ADVISE US WHETHER THEY THINK IT MERITS FUNDING AS IS, WHETHER IT HAS PROMISE, BUT NEEDS IMPROVEMENT IN PARTICULAR AREAS, OR WHETHER IT SIMPLY SHOULDN'T GO FORWARD. SO IT'S A FINER APPROACH TO IT THAN THE 1 THROUGH 100 ALLOWS.

DR. DULIEGE: THANK YOU.

DR. DEAS: MY QUESTION IS ON THE DISCOVERY AND EDUCATION APPLICATION WITH USING THE MEDIAN. I CERTAINLY THINK THAT MIGHT BE A GOOD WAY TO GO. HOWEVER, THE QUESTION IS, OF THE GWG GROUP MEMBERS, HOW MANY INDIVIDUALS ACTUALLY REVIEW AND VOTE ON EACH GRANT?

MR. HARRISON: THERE ARE 15 SCIENTIFIC MEMBERS, ASSUMING THERE ARE NO CONFLICTS AND THEY'RE PRESENT, WHO WOULD ASSIGN A SCORE OF 1 TO 100. SO THE MEDIAN WOULD BE OF THOSE 15 MEMBERS.

DR. DEAS: I SEE. SO YOU USUALLY HAVE ALL 15 ACTUALLY PARTICIPATE?

MR. HARRISON: WITH SOME EXCEPTIONS. OBVIOUSLY IF THERE ARE CONFLICTS ON THE PANEL, WHICH

OCCURS FROM TIME TO TIME, WE'LL HAVE FEWER MEMBERS.

DR. DEAS: OKAY. GREAT.

MR. SHEEHY: I WANTED TO ASK A QUESTION ON THE INFRASTRUCTURE SCORING, IF WE COULD LOOK AT THAT. SO MAYBE THIS COULD BE SOME CLARIFICATION. SO THE REASON WE WENT TO 1-2-3 ON ATP WAS THESE INFRASTRUCTURE PROJECTS TEND TO BE VERY EXPENSIVE. AND THAT'S 75 MILLION, BUT EVEN IN OTHER CIRCUMSTANCES, THEY HAVE BEEN 10, 15 MILLION. THEY'RE NOT SMALL. AND THIS SCORING RANGE DOESN'T ALLOW FOR THE TYPE OF REFINEMENT THAT THE 1-2-3 SYSTEM DOES.

SO HOW DOES ONE CONTEMPLATE GETTING REFINEMENT ON INFRASTRUCTURE SCORING WITHOUT A 1-2-3 SYSTEM BECAUSE EVEN AN 85, IF I'M GOING TO SPEND 15 MILLION AND REVIEWERS HAVE IDENTIFIED FIVE OR SIX KEY ELEMENTS THAT COULD BE IMPROVED, HOW WOULD WE GET THOSE TYPES OF IMPROVEMENTS? FOR ME I STILL TEND TO BELIEVE THAT A 1-2-3 SCORING SYSTEM FOR INFRASTRUCTURE IS OPTIMAL SIMPLY BECAUSE THAT GIVES US THE MECHANISM BY WHICH WE CAN ENFORCE REFINEMENT OF PROJECTS THAT WE'RE GOING TO SPEND A LOT OF MONEY ON.

MR. HARRISON: THERE ARE PROBABLY THREE DIFFERENT MECHANISMS. THE GWG CAN REQUEST

ADDITIONAL INFORMATION IF IT DOESN'T FEEL THAT IT HAS SUFFICIENT INFORMATION TO SCORE THE APPLICATIONS BASED ON WHAT'S AVAILABLE.

SECONDLY, IF NO APPLICATION HAS A MEDIAN SCORE OF 85 OR ABOVE, THEN THE APPLICANTS WOULD HAVE AN OPPORTUNITY TO RESUBMIT TO ADDRESS THE GWG'S CONCERNS AND THERE WOULD BE A SUPPLEMENTAL REVIEW.

OR, THIRD, EVEN IF THE APPLICATIONS WERE TO COME FORWARD TO THE APPLICATION REVIEW SUBCOMMITTEE, IF THE APPLICATION REVIEW SUBCOMMITTEE WAS NOT COMFORTABLE MAKING A FUNDING DECISION, IT COULD ASK THE GWG TO CONDUCT A SUPPLEMENTAL REVIEW.

MR. SHEEHY: THAT'S PRETTY CUMBERSOME. I'M STILL UNDECIDED ON THIS ONE. I REALLY DO LIKE THE 1-2-3 ON ANYTHING WE START SPENDING BIG BUNCHES OF MONEY ON. IF IT'S GOOD, THEN IT'S GOOD; BUT IT'S NOT GOOD, IT'S NOT GOOD. BUT A LOT OF THINGS FALL INTO II AND WE GET TO SEND THOSE BACK. I JUST FOUND THAT TO BE SO VALUABLE IN CLINICAL REVIEW.

IT JUST GIVES ME TWO BITES AT THE APPLE, I GUESS. I JUST HAVE ALWAYS FOUND THE REVIEWERS' SUGGESTIONS TO BE VERY VALUABLE.

DR. STEWARD: COULD I ADD TO THAT?

CHAIRMAN THOMAS: YES. LITTLE HARD TO HEAR YOU, OS. GET A LITTLE CLOSER TO THE PHONE OR

WHATEVER.

DR. STEWARD: SO I HAVE TO SAY I WAS PROBABLY DUBIOUS ABOUT THE 1-2-3 SCORING SYSTEM WHEN IT WAS FIRST LAUNCHED, AND I HAVE BECOME A FAN REALLY FOR EXACTLY THE REASONS JEFF SAID. AND IT GOES BACK TO THE COMMENTS THAT RANDY MADE TODAY AND HAS MADE IN THE PAST. WE REALLY WANT TO BE FUNDING GRANTS THAT GET SCORES OF 95, A'S OR A PLUSES. AND ONES THAT ARE IN THE 85 RANGE, THAT'S A GOOD SOLID B. IF YOU KNOW YOU CAN MAKE IT BETTER, I THINK IT NEEDS TO BE MADE BETTER.

I DO AGREE WITH JEFF. I THINK ON THESE BIG MONEY ROUNDS, THE 1-2-3 SCORING SYSTEM REALLY GIVES A CHANCE FOR THE PROJECT TO BE MADE AS GOOD AS IT CAN BE MADE. THANK YOU.

DR. DIXON: I WOULD SORT OF SECOND THAT. I THINK YOU GUYS HAVE MADE SOME VERY GOOD POINTS ABOUT THE 1-2-3.

DR. MELMED: I DON'T WANT TO SECOND-GUESS AND GO THROUGH YOUR WHOLE PROCESS AGAIN. YOU'VE OBVIOUSLY GIVEN THIS A LOT OF THOUGHT. DID YOU THINK OF A MUCH SIMPLER APPROACH, BECAUSE I AGREE WITH JEFF'S INITIAL CONCERN, SIMPLER APPROACH OF JUST DISCARDING ANY SCORE THAT'S MORE THAN TWO STANDARD DEVIATIONS FROM THE MEAN AND THEN KEEP THE

MEAN? IF THERE'S A SCORE THAT'S AN OUTLIER THAT'S PULLING THE MEAN AWAY, JUST DISCARD IT IF IT'S MORE THAN TWO SD'S AND KEEP THE MEAN.

MR. HARRISON: WE HAVE. AND TO BE CLEAR, WE THINK ULTIMATELY THE BEST WAY FOR THE APPLICATION REVIEW SUBCOMMITTEE TO MAKE ITS DECISION IS PROVIDE YOU WITH ALL OF THE INFORMATION. SO WHEN WE PRESENT APPLICATIONS OR RECOMMENDATIONS OF THE GWG TO THE APPLICATION REVIEW SUBCOMMITTEE FOR ITS CONSIDERATION, WE INCLUDE THE STANDARD DEVIATION, WE INCLUDE THE MEAN, AND WE WILL INCLUDE THE MEDIAN. SO YOU WILL HAVE ACCESS TO ALL OF THAT INFORMATION BEFORE YOU MAKE A DECISION.

DR. MELMED: BUT THE REPORT WILL BE MEDIAN. THAT'S WHAT I'M SUGGESTING, WE KEEP THE MEAN, THAT MEANS EXCLUDE ANY ONE SCORE WHICH IS MORE THAN TWO ABOVE OR BELOW THAT MEAN.

MR. HARRISON: RIGHT. I UNDERSTAND. WE THINK GIVING YOU ALL OF THE INFORMATION, INCLUDING WHAT THE STANDARD DEVIATION IS, SO YOU KNOW WHAT THE LOWEST SCORES ARE AND THE HIGHEST SCORES, GIVES YOU THE FULL RANGE OF INFORMATION RATHER THAN SIMPLY EXCLUDING THAT INFORMATION.

CHAIRMAN THOMAS: FURTHER COMMENTS HERE? WE SEEM TO HAVE TWO DIFFERENT APPROACHES THAT ARE

BEING DISCUSSED. OTHER THOUGHTS ON ONE VERSUS THE OTHER? OKAY. HEARING NONE --

MR. SHEEHY: SO I THINK THAT I'M PRETTY COMFORTABLE WITH THIS, BUT I THINK THAT I WOULD MOVE TO ADOPT THIS BUT WITH 1-2-3 FOR ALL INFRASTRUCTURE. I WOULD MAKE THAT CHANGE.

MS. LAPORTE: I WOULD SECOND THAT.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED WITH THAT AMENDMENT TO APPROVE THE AMENDMENTS TO THE GWG BYLAWS. FURTHER DISCUSSION ON THIS?

MR. HARRISON: COULD I ASK FOR ONE CLARIFICATION ON THE MOTION? WOULD THAT INCLUDE THE TRANSLATING CENTER, WHICH IS CURRENTLY BEING REVIEWED UNDER THE 1 TO 100 SYSTEM?

MR. SHEEHY: NO.

MR. HARRISON: THANK YOU.

CHAIRMAN THOMAS: OKAY. HEARING NO FURTHER DISCUSSION, ANY COMMENTS FROM MEMBERS OF THE PUBLIC? JAMES, THIS IS STILL A VOICE VOTE EXCEPT FOR THOSE ON THE PHONE?

MR. HARRISON: YES.

CHAIRMAN THOMAS: OKAY. ALL THOSE IN FAVOR OF THE MOTION AS AMENDED PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MARIA, PLEASE CALL THE ROLL

ON THE PHONE.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: AYE.

MS. BONNEVILLE: DAVID HIGGINS. KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: AYE.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MR. HARRISON: MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.

ON TO ITEM 12, CONSIDERATION OF POLICY FOR CIRM RESEARCH BUDGET ALLOCATION. MR. TOCHER.

MR. TOCHER: THANK YOU. AMY HAS PULLED UP THE SLIDES FOR MY NEXT PRESENTATION, NEXT ITEM, BUT, FIRST, THIS IS ITEM 12 IN YOUR VIRTUAL BINDERS.

WITH THIS ITEM, WE'RE PROPOSING FOR ADOPTION A POLICY THAT ADDRESSES SOME OF THE ISSUES THAT DR. MILLS TOUCHED UPON EARLIER THAT HAVE ARISEN REGARDING HOW THE BOARD BUDGETS FOR CIRM RESEARCH

PROGRAMS AND HOW THOSE BUDGETS ARE IMPLEMENTED WHEN THE APPLICATION REVIEW SUBCOMMITTEE MEETS TO CONSIDER APPLICATIONS FOR AWARDS UNDER THOSE PROGRAMS.

NOW, HISTORICALLY THE ENTIRE BOARD MADE FUNDING DECISIONS ON SPECIFIC GRANT APPLICATIONS IN RESPONSE TO RFA'S THAT THE BOARD HAD ALREADY SET A BUDGET FOR. CONSEQUENTLY, THE BOARD FROM TIME TO TIME FUNDED PROJECTS THAT EXCEEDED THE BUDGET IF IT DETERMINED THAT THOSE ADDITIONAL PROJECTS WARRANTED FUNDING.

IN CONTRAST TODAY, OF COURSE, THE BOARD SETS THE BUDGET FOR A GIVEN PROGRAM, AND SUBSEQUENTLY A SUBCOMMITTEE OF THE BOARD MAKES THE FUNDING DECISIONS ON INDIVIDUAL GRANTS. AS DR. MILLS SHOWED YOU EARLIER, MOST PROGRAMS HAVE MORE THAN ONE FUNDING CYCLE WITHIN A GIVEN YEAR, WHICH PRESENTS AN ISSUE AS TO HOW THE APPLICATION REVIEW SUBCOMMITTEE SHOULD OPERATE UNDER THOSE BUDGETS. AND SO THAT'S THE SUBJECT OF THE PROPOSAL IN FRONT OF YOU IN THE MEMO WHERE WE LAY OUT STEPS TO ADDRESS THE FUNDING PROCESS.

SO BASICALLY WHAT WILL HAPPEN GOING FORWARD IS WE WILL PRESENT TO YOU ON AN ANNUAL BASIS TO THE FULL BOARD CONSIDERATION TO ADOPT A

CALENDAR-YEAR BUDGET FOR EACH ONGOING RESEARCH PROGRAM. SO YOU WILL SEE A SPECIFIC BUDGET FOR DISCOVERY, ANOTHER FOR TRANSLATION, AND ANOTHER FOR OUR CLINICAL PROGRAMS. THE CALENDAR-YEAR BUDGET FOR A PARTICULAR PROGRAM WILL INCLUDE ALL AWARDS THAT WE FORESEE BEING APPROVED FOR FUNDING BY THE APPLICATION REVIEW SUBCOMMITTEE DURING THAT CALENDAR YEAR. AND THE PROPOSED BUDGET FOR EACH PROGRAM WILL SPECIFY THE NUMBER OF CYCLES TO SUBMIT AN APPLICATION FOR THAT PROGRAM DURING THE CALENDAR YEAR. SO, FOR INSTANCE, IN CLIN THAT IS MONTHLY AND FOR TRAN THREE TIMES A YEAR.

AT THE END OF THE YEAR, ANY UNSPENT FUNDS WILL REVERT BACK TO THE GENERAL RESEARCH FUNDING BUCKET THAT WILL BE REALLOCATED FOR FUTURE RESEARCH BUDGETS IN SUBSEQUENT CALENDAR YEARS. HOWEVER, THE APPLICATION REVIEW SUBCOMMITTEE MAY NOT EXCEED THE BUDGET FOR A PARTICULAR PROGRAM EVEN IF ALL THE FUNDS HAVE BEEN AWARDED BY THE APPLICATION REVIEW SUBCOMMITTEE BEFORE EACH CYCLE IS COMPLETE.

AS A RESULT, THE NUMBER OF CYCLES WILL BE AUTOMATICALLY REDUCED IF THE FUNDS FOR THAT PROGRAM HAVE BEEN EXHAUSTED UNLESS THE BOARD ALLOCATES ADDITIONAL FUNDS FOR THAT PROGRAM. SO THE EMPHASIS HERE WILL BE ON THE BUDGET THAT THE BOARD APPROVES

FOR A GIVEN PROGRAM AND NOT SO MUCH ON THE NUMBER OF CYCLES.

TO DR. MILLS' POINT EARLIER, WE'RE IN THE TIME BUSINESS. SO IF THE MERITORIOUS PROJECTS EXHAUST THE FUNDING PRIOR TO THE NUMBER OF CYCLES, THEN SO BE IT. WE'LL FUND THE GOOD PROJECTS EARLY IF WE CAN.

AND IF THERE ARE ANY QUESTIONS, I'M HAPPY TO TAKE THEM.

CHAIRMAN THOMAS: SO WHERE THE ISSUE WILL ARISE SPECIFICALLY IS THAT PARTICULAR MEETING OF THE APPLICATION REVIEW SUBCOMMITTEE AT WHICH YOU HAVE MORE THAT HAS BEEN RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP THAN IS REMAINING TO BE ALLOCATED. AND AT THAT PARTICULAR MEETING, WHAT THIS MEANS IS THE APPLICATION REVIEW SUBCOMMITTEE IS GOING TO HAVE TO MAKE SOME CHOICES WITH RESPECT TO WHATEVER IS IN THE POT OF RECOMMENDED FOR FUNDING PROJECTS SO AS TO KEEP WITHIN THE BUDGET. THAT WILL GET INTO ITEMS THAT WILL BE DISCUSSED IN PROGRAMMATIC REVIEW AND COULD ENTAIL SOME HARD CHOICES WHEREIN PROJECTS THAT ARE RECOMMENDED FOR FUNDING MAY NOT BE FUNDED AT THAT APPLICATION REVIEW SUBCOMMITTEE MEETING OR FOR THE REMAINDER OF THE YEAR.

I JUST WANT EVERYBODY TO BE CLEAR ON THAT.

MR. TOCHER: THAT'S RIGHT.

DR. GASSON: I'M SORRY. I MUST HAVE MISUNDERSTOOD. I THOUGHT THAT RANDY SAID IN HIS PRESENTATION THAT OUR GOAL WAS TO ALWAYS FUND THE MOST MERITORIOUS APPLICATIONS AND THAT THERE WOULD BE A MECHANISM TO INCREASE THE BUDGET IN ORDER TO MAKE SURE THAT THAT WOULD HAPPEN. DID I MISUNDERSTAND THAT?

DR. MILLS: SO OVER TIME, EVERY CALENDAR YEAR IN DECEMBER WE'LL BE REBALANCING THE BUDGETS BETWEEN THE THREE GROUPS: DISCOVERY, TRANSLATIONAL, AND CLINICAL, WHERE WE'LL SET THE AMOUNT OF MONEY THAT WE WANT TO SPEND IN A PARTICULAR AREA, THE NUMBER OF CYCLES WE ANTICIPATE HOLDING IN ORDER TO GET THAT. AND SO THAT'S DONE EACH YEAR AND THEN REBALANCED.

AND ONE OF THE REASONS WE SET IT UP THAT WAY WAS TO MAKE SURE THAT WE COULD HAVE THE GREATEST NUMBER OF BOARD MEMBERS PARTICIPATE IN THE VOTE. SO IN THE DECEMBER MEETING, WE SPECIFICALLY CARVE OUT A TIME BETWEEN REVIEW CYCLES WHERE WE DON'T HAVE APPLICATIONS UNDER REVIEW WHICH WOULD CONFLICT OUT THE VAST MAJORITY OF THOSE WHO ARE FROM ACADEMIC INSTITUTIONS FROM PARTICIPATING IN THE BUDGET

SETTING PROCESS. AND SO WE DO THAT -- NOW THAT WE HAVE THESE PROGRAMS SET UP, WE KNOW ROUGHLY HOW MUCH WE WANT TO DO AND HOW MANY WE NEED IN ORDER TO ACHIEVE OUR GOALS, AND WE PICKED THAT DECEMBER MEETING AND WE DO IT. BUT WHAT'S VERY CLEAR IS THE AMOUNT OF DEMAND WE HAVE FOR THESE PROGRAMS IS DIFFERENT. YOU COULD ALSO THINK ABOUT A SUPPLY WE HAVE FOR POTENTIAL APPLICANTS IS VERY DIFFERENT.

SO WE HAVE LOTS AND LOTS AND LOTS OF SUPPLY FOR THE EARLIER STAGE APPLICATIONS. WITHOUT DISCIPLINE, WE COULD HAVE A THOUSAND NEW CANDIDATES IN DISCOVERY AND RUN OUT OF MONEY SO THAT WHEN THE REALLY HIGH QUALITY CLINICAL TRIAL THAT WE REALLY WANT TO FUND COMES ALONG, WE DON'T HAVE THE MONEY FOR THAT ANYMORE.

SO THE POINT OF THIS IS TO TRY TO PRESCRIBE WHAT WE WANT IN THESE THREE BUCKETS BY YEAR, RECOGNIZING THEY'RE NOT GOING TO END UP PERFECT AND THAT FROM YEAR TO YEAR WE'LL NEED TO REBALANCE IN ORDER TO GET BACK ON PLAN. DOES THAT MAKE SENSE?

DR. GASSON: YES. THANK YOU. THANK YOU, MR. TOCHER, AS WELL.

CHAIRMAN THOMAS: OTHER COMMENTS FROM MEMBERS OF THE BOARD? DO I HEAR A MOTION TO

APPROVE?

DR. JUELSGAARD: SO MOVED.

DR. DIXON: SO MOVED.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. COMMENTS FROM MEMBERS OF THE PUBLIC? ADDITIONAL COMMENTS FROM MEMBERS OF THE BOARD? MR. SHEEHY.

MR. SHEEHY: I WAS JUST HOPING WE HAD THAT ITEM ABOUT DISCUSSING PROGRAMMATIC REVIEW THAT WE COULD KIND OF BRING THAT UP.

CHAIRMAN THOMAS: I ACTUALLY BROUGHT THAT UP WHILE YOU WERE OUT OF THE ROOM.

MR. SHEEHY: SORRY.

CHAIRMAN THOMAS: ANY OTHER COMMENTS FROM MEMBERS OF THE BOARD? OKAY. ROLL CALL VOTE AGAIN. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MARIA, PLEASE POLL THOSE ON THE PHONE.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: AYE.

MS. BONNEVILLE: KATHY LAPORTE.

MS. LAPORTE: AYE.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MR. HARRISON: MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU, MR. HARRISON.
WE'RE NOW ON TO ITEM NO. 13, CONSIDERATION OF THE ATP3 REVIEW PROCESS. BEFORE WE TURN THIS OVER TO MR. TOCHER, I JUST WANTED TO SET THE TABLE FOR THIS.
AS YOU RECALL, ATP3 OR ACCELERATING THERAPIES PUBLIC PRIVATE PARTNERSHIP, IS A PROGRAM THAT WE LAUNCHED THROUGH AN RFA THAT WAS ISSUED AT THE BEGINNING OF JULY IN WHICH WE ARE LOOKING FOR PROPOSERS TO SUBMIT A BUSINESS PLAN TO IN-LICENSE SOME OF OUR MOST PROMISING TECHNOLOGIES ALL WITH AN EYE TOWARDS TAKING THOSE TECHNOLOGIES AND ACCELERATING THEM HOPEFULLY THROUGH COMMERCIALIZATION. IT'S ANOTHER WAY TO TAKE WHAT RANDY DESCRIBED AS THE PULL OF PUSH-PULL-LEVEL AND GENERATE MORE INDUSTRY INVOLVEMENT IN THE CIRM PROGRAMS.
THE PROPOSERS ARE TO SUBMIT BY OCTOBER 31 AND IN THEIR PROPOSAL TO SET FORTH A BUSINESS PLAN, A DESCRIPTION OF THE MANAGEMENT TEAM, AND A

WILLINGNESS TO MATCH WHAT CIRM IS PREPARED TO PUT INTO THIS PROJECT. ON CIRM'S END, WE ARE LOOKING TO PUT IN UP TO 75 MILLION IN THE FORM OF A CONVERTIBLE NOTE. THEREFORE, PROPOSERS WOULD NEED TO BE ABLE TO MATCH UP TO 75 MILLION. THE 75 MILLION THAT CIRM IS PUTTING IN IS TO GO TO CIRM-FUNDED PROJECTS. THE ENTITY THAT WOULD BE AWARDED THE ATP3 DESIGNATION CAN USE ITS 75 MILLION TO ALSO GO TO CIRM-FUNDED PROJECTS, BUT IT IS ALSO AT LIBERTY TO IN-LICENSE PROJECTS THAT ARE NOT CIRM FUNDED, AND ANY MONEY GOING TO THAT WOULD HAVE TO COME FROM THE ADDITIONAL 75 MATCH OR FROM ANY SUBSEQUENT FINANCING THAT THE ENTITY WOULD CHOOSE TO PUT IN PLACE.

WE HAVE SPENT -- AS I SAID, I AND RANDY AND NEIL SPENT A LOT OF TIME OUT ENCOURAGING PROPOSALS FOR THIS INFRASTRUCTURE PROJECT. WE, IN CONNECTION WITH THAT, ARE, FROM A CIRM POINT OF VIEW, NOT ONLY PROVIDING THE 75 MILLION, BUT FOR THOSE PROJECTS THAT ARE IN-LICENSED, THEY ARE TYPICALLY MULTIYEAR AWARDS. SO ANYTHING THAT'S IN-LICENSED INTO ATP3 WILL, IN ADDITION TO THE 75 MILLION THAT WE WOULD PUT IN, WOULD CARRY WITH IT THE REMAINING FUNDING ON THE PARTICULAR PROJECT AT ISSUE. WE ARE NOT PUTTING ANY CONSTRAINTS ON PROPOSERS AS TO THE TYPES OF PROJECTS THAT THEY MAY

CHOOSE TO INCLUDE IN THEIR BUSINESS PLAN. THEY MAY CHOOSE TO FOCUS ON PARTICULAR INDICATIONS OR DISEASES. THEY MAY FOCUS ON TECHNOLOGY CONNECTED TO PROJECTS SUCH AS IPS OR CRISPR. THEY CAN PROPOSE AS NARROW OR WIDE A RANGE AS THEY WANT. IT ALL COMES DOWN TO BEING ABLE TO JUSTIFY THAT IN A VERY COGENT AND TIGHT BUSINESS PLAN.

SO WHEN THE APPLICATIONS COME IN, IT IS CONTEMPLATED THAT THEY WILL GO TO PEER REVIEW IN THE JANUARY TIME FRAME SPECIFICALLY AROUND THE CONVENING OF THE JP MORGAN CONFERENCE IN SAN FRANCISCO. THE REASON WHY IT HAS BEEN CHOSEN THAT THAT WOULD BE THE APPROPRIATE TIME IS THIS IS, FIRST AND FOREMOST, A BUSINESS REVIEW. IT IS UNLIKE ANY THAT CIRM HAS HAD TO DATE. THIS IS NOT THE TYPICAL REVIEW OF SCIENTIFIC PROPOSALS. THIS IS REALLY REVIEW OF BUSINESS, BUSINESS STRATEGY, PROPOSED MANAGEMENT, ETC. AND, THEREFORE, THE MEMBERS OF THE TEAM ARE UNLIKE ANY PEER REVIEW GROUP THAT WE WILL HAVE PULLED TOGETHER IN THE PAST. AND THAT IS THE FOCUS OF THE MEMO THAT MR. TOCHER HAS PREPARED AND WILL BE PRESENTING TO US HERE.

SO AS INTRODUCTORY COMMENTS GO, I NOW TURN IT OVER TO MR. TOCHER.

MR. TOCHER: THANK YOU, J.T. AND SO FOR

THOSE OF YOU ON THE PHONE, I'M ON THE SLIDE PRESENTATION FOR ITEM 13. ANIMATING THIS PROPOSAL AS WITH ALL OF OURS IS OUR MISSION, ACCELERATING STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. AS J.T. HAS JUST SET FORTH, IN DECEMBER OF LAST YEAR, THE ICOC APPROVED THE CONCEPT PLAN FOR ATP3 PUBLIC PRIVATE PARTNERSHIP, A KEY COMPONENT OF OUR INFRASTRUCTURE PROGRAMS DESIGNED TO PULL CIRM TECHNOLOGIES THROUGH TO THE CLINIC AND TO PATIENTS.

THIS AGENDA WILL DISCUSS CIRM'S PROPOSED PROCESS TO SELECT THE ATP3 AWARDEE AND THEN TO REVIEW THE PROPOSED CIRM RESEARCH PROJECTS THAT WILL LATER BE IN-LICENSED AND DEVELOPED BY THE ATP3 AWARDEE.

FIRST I'LL JUST SPEND A FEW MINUTES REFRESHING YOUR RECOLLECTION, IF J.T. HASN'T ALREADY, OF THE KEY ATTRIBUTES OF THIS PROGRAM. AS I MENTIONED, THIS PROGRAM FUNCTIONS AS A PULLING FORCE, BRINGING CIRM TECHNOLOGIES FORWARD THROUGH THE DEVELOPMENT PIPELINE. THE PULL COMES FROM CREATING AN OPPORTUNITY TO FORM A NEW ENTITY THAT WILL AGGREGATE CIRM'S MOST PROMISING INVENTIONS AND TECHNOLOGIES IN A WAY THAT INCREASES THE PROBABILITY OF COMMERCIAL SUCCESS AND ENTICES INDUSTRY INVESTMENT.

IN ADDITION TO THE OPPORTUNITY TO AGGREGATE CIRM TECHNOLOGIES, ATP3 WILL HARNESS CIRM'S EXISTING ADMINISTRATIVE AND REVIEW INFRASTRUCTURE, INCLUDING EXPERTS ON THE GRANTS WORKING GROUP REVIEW PANEL TO PROVIDE THE ADDED VISIBILITY INTO CIRM'S PORTFOLIO.

FINALLY, SINCE THIS IS, IN FACT, A PARTNERSHIP, CIRM PROJECTS THAT ARE IN-LICENSED BY THE NEW ENTITY WILL BE ELIGIBLE FOR CONTINUED CIRM FUNDING OF THOSE TECHNOLOGIES.

OBVIOUSLY THE ULTIMATE SUCCESS OF THE PROGRAM RIDES ON CIRM FINDING THE BEST POSSIBLE PRIVATE PARTNER. IN TERMS OF THE TYPE OF ENTITY WE'RE LOOKING FOR, WE'RE OPEN TO WHOMEVER MAKES THE BEST CASE. THAT COULD BE AN ESTABLISHED COMMERCIAL COMPANY, IT COULD BE SPINOFF, OR EVEN A NEW TEAM FORMED BY VARIOUS PHARMA AND BIOTECH STAKEHOLDERS.

WHAT CIRM WILL INSIST ON, HOWEVER, IS THAT THE PROPOSED ENTITY MUST HAVE AN EXCEPTIONAL BUSINESS PLAN THAT DESCRIBES THE SYNERGIES, THE VALUE CREATION, AND THE FINANCIAL RETURN TO ALL THE STAKEHOLDERS THE ENTITY EXPECTS TO CREATE THROUGH ITS TECHNOLOGY AGGREGATION STRATEGY, BUT THIS WON'T BE TAKEN ON FAITH. THE APPLICANT MUST PROPOSE A TOP TIER LEADERSHIP TEAM WITH A DEMONSTRATED SKILL SET

NECESSARY TO SUCCESSFULLY EXECUTE THE BUSINESS PLAN.

AND THIS IS A PARTNERSHIP IN EVERY SENSE. CIRM WON'T BE THE ONLY SKIN IN THE GAME. THE AWARDEE, AS J.T. JUST LAID OUT, WILL BE REQUIRED TO COMMIT SIGNIFICANT UPFRONT INVESTMENT CAPITAL NECESSARY TO EXECUTE ON THE BUSINESS PLAN. IN RETURN FOR ALL THIS, THE SUCCESSFUL APPLICANT WILL HAVE ACCESS TO CIRM FUNDS TO CONTINUE SUPPORTING DEVELOPMENT COSTS FOR THE IN-LICENSED PROGRAMS.

AS YOU CAN SEE, THEN, THE ATP3 PROGRAM IS A HYBRID OF OUR TRADITIONAL INFRASTRUCTURE AND RESEARCH PROGRAMS. ON THE ONE HAND, CIRM IS PARTNERING TO CREATE A NEW ENTITY THAT WILL IN-LICENSE, DEVELOP, AND DRIVE TOWARD COMMERCIALIZATION AN AGGREGATED PORTFOLIO OF CIRM PROJECTS. AND ON THE OTHER HAND, CIRM WILL PROVIDE INFRASTRUCTURE TO REVIEW AND ADMINISTER THE IN-LICENSING OF THOSE PROJECTS. THEREFORE, BECAUSE THE IDENTIFICATION AND VETTING OF ATP3 CANDIDATES WILL ENTAIL DIFFERENT CRITERIA FROM THE SCIENTIFIC CONSIDERATION OF PROJECTS TO BE IN-LICENSED, CIRM PROPOSES A TWO-STEP REVIEW PROCESS FOR THE ATP3 PROGRAM, A FIRST GRANTS WORKING GROUP REVIEW TO SELECT THE ATP3 AWARDEE AND THEN SUBSEQUENT GRANTS WORKING GROUP REVIEWS TO CONSIDER THE CIRM PROJECTS

PROPOSED TO BE IN-LICENSED.

AS A FIRST STEP, THEN, THE GRANTS WORKING GROUP WILL CONVENE TO REVIEW APPLICATIONS FOR THE ATP3 AWARD AND MAKE FUNDING RECOMMENDATIONS TO THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD WHICH WILL CHOOSE A SINGLE AWARDEE. THE GRANTS WORKING GROUP WILL EVALUATE WHETHER A GIVEN APPLICATION SETS FORTH THE FOLLOWING. FIRST IS AN AGGREGATION STRATEGY. THE PROPOSAL SHOULD OUTLINE THE STRATEGY AND SCIENTIFIC RATIONALE FOR THE TYPES OF TECHNOLOGIES OR TECHNOLOGY PLATFORMS THE APPLICANT INTENDS TO IN-LICENSE. SOME EXAMPLES OF THE TECHNOLOGIES WOULD BE THE DISEASE INDICATIONS TARGETED BY THE APPLICANT. OR THE PLATFORMS WOULD BE IPS CELLS, HUMAN EMBRYONIC STEM CELLS, GENE MODIFIED PLURIPOTENT OR PROGENITOR CELLS, SMALL MOLECULES, OR SOME COMBINATION OF THESE.

THE REVIEW WILL ALSO EVALUATE THE OPERATIONAL PLAN, WHICH WOULD BE A DESCRIPTION OF HOW THE APPLICANT INTENDS TO DEVELOP AND COMMERCIALIZE THESE TECHNOLOGIES. WE'LL ALSO LOOK CAREFULLY AT THE VALUE PROPOSITION TO EVALUATE THE SYNERGIES AND BENEFITS THAT THE APPLICANT INTENDS TO REALIZE THROUGH THE TECHNOLOGY AGGREGATION APPROACH THAT IT PROPOSES THAT WOULD RESULT IN A WORLD-CLASS

CELL THERAPY COMPANY.

AFTER THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD HAS MADE THE AWARD TO NEWCO, A SECOND REVIEW WILL THEN OCCUR, AND NEWCO WILL BE REQUIRED TO IDENTIFY CIRM PROJECTS TO IN-LICENSE. DEVELOPMENT MILESTONES WILL BE AGREED TO IN THE RESEARCH AND FINANCING AGREEMENT THAT NEWCO SIGNS TO ENSURE THAT NEWCO ADHERES TO THE APPROPRIATE TIMELINES FOR IN-LICENSING PROJECTS. ALL THE PROPOSED PROJECTS FOR IN-LICENSING MUST UNDERGO A REVIEW BY THE GRANTS WORKING GROUP AND THE APPLICATION REVIEW SUBCOMMITTEE.

AND THE FOLLOWING SLIDE WILL DESCRIBE HOW THAT REVIEW OF THOSE PROJECTS WILL OCCUR. ESSENTIALLY THE LEVEL OF REVIEW OF THE PROJECTS TO BE IN-LICENSED WILL DEPEND ON THE RECENCY OF THEIR LAST GRANTS WORKING GROUP REVIEW. ESSENTIALLY, IF THE PROPOSED PROJECT HAS HAD A FULL GRANTS WORKING GROUP REVIEW IN THE PRECEDING 12 MONTHS, A NEW GRANTS WORKING GROUP REVIEW WILL NOT BE REQUIRED UNLESS CIRM DETERMINES THAT A REVIEW IS WARRANTED BASED ON THE STATUS OF THE PROJECT, IN WHICH CASE THE PROJECT WILL BE SUBJECT TO A GOOD STANDING REVIEW, WHICH I'LL DESCRIBE IN STEP 2. IF IT'S BEEN MORE THAN 12 MONTHS SINCE THAT GRANTS WORKING GROUP

REVIEW, BUT THE PROJECT IS STILL ACTIVE, THEN A GOOD STANDING REVIEW WILL BE CONDUCTED TO ENSURE THAT THE PROJECT HAS MET OR IS ON TARGET TO MEET MILESTONES; OR IF THEY HAVEN'T MET THEIR MILESTONES, THAT THEY'VE ESTABLISHED A VIABLE PATH TO ACCOMPLISH THEM. FOR ALL OTHER PROJECTS, A FULL GRANTS WORKING GROUP REVIEW WILL BE ADMINISTERED.

AND WITH THAT, I'M HAPPY TO TAKE ANY QUESTIONS.

DR. JUELSGAARD: SO I THINK IT'S ON SLIDE 8, YOU REFER TO A RESEARCH AND FINANCING AGREEMENT, WHICH WOULD BE AN AGREEMENT BETWEEN CIRM AND THE ENTITY THAT'S CHOSEN; IS THAT RIGHT?

MR. TOCHER: THAT'S RIGHT.

DR. JUELSGAARD: IS THERE A DRAFT OF THAT AGREEMENT THAT'S BEEN PREPARED AT THIS POINT?

MR. TOCHER: YES, THERE IS. I BELIEVE IT'S AVAILABLE ONLINE.

MR. HARRISON: STEVE, WE'RE JUST IN THE PROCESS OF MAKING FINAL REVISIONS TO THE DRAFT, WHICH WE WOULD BE HAPPY TO SHARE WITH YOU AND OTHERS ONCE WE'VE COMPLETED THAT PROBABLY IN THE NEXT WEEK.

DR. JUELSGAARD: BECAUSE IT LEADS TO THE SECOND QUESTION, WHICH I KNOW YOU CONTEMPLATE THAT THE OUTCOME OF THIS PROCESS WOULD BE THE SELECTION

OF A SINGLE COMPANY, IN ESSENCE, TO CARRY FORWARD WITH THE ATP3 PROPOSAL. AND THAT'S OBVIOUSLY THE ULTIMATE GOAL. THE QUESTION IS HOW DOES ONE GET THERE.

AND SOMETIMES, IN DEALING WITH THESE ISSUES, IN ORDER TO ACHIEVE WHAT YOU WANT TO, SOMETIMES YOU WIND UP DEALING IN A COMPETITIVE SITUATION WHERE YOU MIGHT HAVE TWO DIFFERENT COMPANIES THAT SEEM TO BE VIABLE ALTERNATIVES AND YOU DON'T SELECT ONE AT THE OUTSET, BUT RATHER AS A RESULT OF NEGOTIATION WITH THEM ON AN AGREEMENT BETWEEN CIRM AND THE OTHER COMPANY BECAUSE THEY MAY HAVE SLIGHTLY DIFFERENT VIEWS OF WHAT SHOULD BE IN SUCH AN AGREEMENT AND WHAT MIGHT NOT. SO HAS ANY THOUGHT BEEN GIVEN TO THIS PROCESS? IS IT JUST THAT WE'RE GOING TO, NOT WE, BUT THE GRANTS WORKING GROUP WILL SELECT A SINGLE COMPANY, OR IS IT POSSIBLE THAT THEY MIGHT SELECT TWO THAT SEEM TO BE OF EQUAL MERIT AND ALLOW FOR A LITTLE MORE COMPETITIVE BACK AND FORTH? HOW HAVE WE THOUGHT ABOUT THAT?

MR. TOCHER: WE HAVE CONSIDERED THAT, AND THE FOCUS OF THE PROJECT AT THIS POINT IS TO JUST IDENTIFY AND FUND A SINGLE AWARDEE.

DR. JUELSGAARD: SO THAT DECISION WOULD PREDATE THE FINAL NEGOTIATION AND EXECUTION OF THIS

RESEARCH AND FINANCING AGREEMENT? IS THAT HOW YOU PERCEIVE THE TIMELINE?

MR. TOCHER: YES, THAT'S RIGHT.

DR. JUELSGAARD: WELL, JUST I WOULD ASK THAT WE THINK ABOUT WHETHER -- HOW WELL THAT MIGHT OR MIGHT NOT WORK. ONCE A PARTY IS IN A MONOPOLISTIC POSITION, THAT IS, THEY'VE BEEN SELECTED, THEY CAN EXERT THAT MONOPOLY POWER IN TERMS OF NEGOTIATION; WHEREAS, IF THEY'RE NOT A MONOPOLIST, IF THERE'S SOMEBODY OUT THERE COMPETING WITH THEM, THEIR BEHAVIOR MAY BE DIFFERENT. I JUST RAISE THAT AS A CONSIDERATION.

MR. HARRISON: COULD I ADDRESS THAT? SO THE GWG, UNDER THE SCORING SYSTEM, COULD RECOMMEND TWO OR MORE APPLICATIONS FOR FUNDING IF FUNDS ARE AVAILABLE IF IT FELT THAT THE TEAMS MERITED FUNDING. AND THEN IT WOULD BE UP TO THE APPLICATION REVIEW SUBCOMMITTEE WHICH COULD SELECT ITS TOP CHOICE WITH A SECOND CHOICE ON DECK IN THE EVENT THAT WE WERE UNABLE TO COMPLETE NEGOTIATIONS WITH THE FIRST CHOICE.

YOU WILL ALSO REMEMBER WHEN THE IP AND INDUSTRY AND SCIENCE SUBCOMMITTEE APPROVED THE TERMS FOR THE AWARD, THE TERM SHEET INCLUDED A PROVISION SPECIFYING THAT THE TERMS HAD BEEN APPROVED AND

WOULD NOT BE MATERIALLY MODIFIED. SO WE WANTED TO PUT POTENTIAL APPLICANTS ON NOTICE THAT THESE TERMS WERE THE TERMS THAT WE WERE OFFERING AND THEY WERE NOT SUBJECT TO WIDE-SCALE CHANGE.

DR. JUELSGAARD: GREAT.

CHAIRMAN THOMAS: OTHER QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD? ANY COMMENTS ON THE PHONE? OKAY. DO I HEAR A MOTION TO APPROVE?

DR. JUELSGAARD: I SO MOVE.

CHAIRMAN THOMAS: MOVED BY MR. JUELSGAARD.

DR. DEAS: SECOND.

CHAIRMAN THOMAS: SECONDED BY DEAN DEAS. ANY FURTHER DISCUSSION? COMMENTS FROM MEMBERS OF THE PUBLIC? THIS IS, AGAIN, A ROLL CALL VOTE ON THE PHONE, VOICE VOTE IN THE ROOM. ALL IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MARIA, PLEASE POLL THOSE ON THE PHONE.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: AYE.

MS. BONNEVILLE: KATHY LAPORTE. FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MR. HARRISON: MOTION PASSES.

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

WE ARE NOW GOING TO MOVE DOWN TO ITEM 16, CONSIDERATION OF AMENDMENTS TO CIRM'S TRAVEL POLICY. HEAR FROM MS. SILVA-MARTIN.

MS. SILVA-MARTIN: GOOD AFTERNOON, MR. CHAIRMAN, MEMBERS OF THE BOARD. I WILL BE PRESENTING REVISIONS -- RECOMMENDED REVISIONS TO CIRM'S TRAVEL POLICY.

THE PRESENTATION WILL COVER SOME BACKGROUND INFORMATION AS WELL AS SOME OF THE AMENDMENTS THAT ARE BEING PROPOSED TO THE TRAVEL POLICY.

THE LAST TIME THAT THE TRAVEL POLICY WAS REVISED AND APPROVED BY THIS BOARD WAS IN DECEMBER OF 2014. IN LARGE PART THE POLICY IS MODELED AFTER THE UC TRAVEL POLICY. EARLIER THIS YEAR THE UC MADE SOME FAIRLY SIGNIFICANT REVISIONS TO THEIR TRAVEL POLICY, AND CIRM PROPOSES SIMILAR REVISIONS. THESE AMENDMENTS TO THE TRAVEL POLICY HELP TO REDUCE COSTS, THEY CONFORM TO IRS REQUIREMENTS, AND, MOST

IMPORTANTLY, THEY PROMOTE FISCAL ACCOUNTABILITY.

SOME OF THE CHANGES IN THE POLICY ARE REALLY TO CLARIFY THE APPROVALS THAT ARE REQUIRED IN ORDER FOR A PERSON TO TRAVEL AS WELL AS THE FORMS THEY NEED TO COMPLETE TO SEEK REIMBURSEMENT. OTHER CHANGES ARE FAIRLY SIGNIFICANT, AND THEY ENSURE CONFORMANCE WITH IRS POLICY AND UC POLICY AND, AS I INDICATED EARLIER, HELP TO MAINTAIN FISCAL ACCOUNTABILITY.

WHAT I'D LIKE TO DO NOW IS BRIEFLY REVIEW SOME OF THE MAJOR CHANGES TO THE POLICY THAT ARE BEING RECOMMENDED.

SO THE FIRST MAJOR CHANGE IS JUST A DEFINITION TO INCIDENTALS. SO THE IRS RECENTLY CHANGED WHAT CONSTITUTES INCIDENTALS, AND CIRM POLICY IS BEING REVISED TO CONFORM TO THE NEW IRS STANDARDS. INCIDENTALS INCLUDE FEES AND TIPS THAT ARE GIVEN TO PORTERS, BAGGAGE CARRIERS, AND HOTEL AND SHIP STAFF. PREVIOUSLY -- AND THOSE ARE THE ONLY THINGS THAT CAN BE CLAIMED UNDER INCIDENTAL. PREVIOUSLY ONE COULD CLAIM THINGS LIKE NEWSPAPERS, TELEPHONE CALLS, AND THOSE ARE NO LONGER CONSIDERED INCIDENTALS AND CANNOT BE CLAIMED UNDER THIS CATEGORY.

THE POLICY ALSO ESTABLISHES A NEW TRAVEL

MANAGEMENT PROGRAM. SO UNDER THE DIRECTION OF OUR GOVERNOR, THE STATE WAS TASKED WITH IDENTIFYING COST EFFICIENT TRAVEL SERVICES. THIS REALLY RESULTED IN A ONE-STOP TRAVEL PROGRAM. THAT TRAVEL PROGRAM IS CALLED CONCUR. THIS CONCUR PROVIDES REALLY THE MAXIMUM VALUE TO STATE AGENCIES BECAUSE IT UTILIZES PRENEGOTIATED AIRFARES AND RENTAL CAR RATES AS WELL AS LODGING ESTABLISHMENTS THAT HAVE AGREED TO THE STATE-APPROVED RATES. OUR POLICY IS BEING REVISED TO ESTABLISH CONCUR AS CIRM'S OFFICIAL TRAVEL AGENCY.

ANOTHER AREA WHERE THERE IS SIGNIFICANT CHANGE IS IN THE MEAL, INCIDENTAL, AND LODGING AREA. SO NOW WE ARE INCLUDING RESTRICTIONS THAT PREVIOUSLY WERE NOT THERE BEFORE. SO UNDER OUR CURRENT POLICY, WE DO NOT HAVE ANY RESTRICTIONS WITH REGARD TO MEAL AND INCIDENTALS AND LODGING WITHIN THE VICINITY OF AN EMPLOYEE'S HEADQUARTERS OR THEIR HOME. BUT THE POLICY HAS BEEN REVISED TO INCLUDE A SECTION THAT WILL ELIMINATE REIMBURSEMENT FOR MEALS AND INCIDENTALS WITHIN THE VICINITY OF AN EMPLOYEE'S HEADQUARTERS, AND THEN LODGING EXPENSES CANNOT BE INCURRED IF THEY ARE WITHIN 40 MILES OF THE INDIVIDUAL'S HOME OR THEIR HEADQUARTERS.

WHAT THIS MEANS IS, FOR EXAMPLE, IF A CIRM

TEAM MEMBER OR A BOARD MEMBER LIVES IN SAN FRANCISCO AND THEY WANT TO GO TO A GWG MEETING IN OAKLAND, WE WOULD NOT BE ABLE TO PROVIDE THEM WITH LODGING. ON THE OTHER HAND, IF A BOARD MEMBER FROM SACRAMENTO WAS TRAVELING TO OAKLAND FOR A GWG MEETING BECAUSE IT IS 40 MILES OR MORE FROM THEIR HOME, WE WOULD BE ABLE TO PROVIDE THEM LODGING. SO THIS IS A MAJOR SIGNIFICANT CHANGE. THIS IS A CHANGE THAT THE UC'S ALSO MADE, AND THIS CONFORMS TO THEIR POLICY AS WELL.

ANOTHER AREA THAT PREVIOUSLY WASN'T IN OUR TRAVEL POLICY THAT WE'VE NOW INCLUDED IS LONG-TERM PARKING ACCOMMODATIONS. RIGHT NOW WE DON'T HAVE ANY REQUIREMENT WITH RESPECT TO PARKING AT AIRPORTS OR COMMON CARRIERS. WE ARE PROPOSING AN AMENDMENT TO INTRODUCE A NEW REQUIREMENT THAT SAYS THAT TRAVELERS MUST UTILIZE LONG-TERM PARKING WHEN THE TRAVEL IS EXPECTED TO EXCEED MORE THAN 24 HOURS. I DO WANT TO POINT OUT THAT IF AN INDIVIDUAL CHOOSES TO PARK IN SHORT-TERM PARKING, THEY CAN DO SO, BUT THEY CAN ONLY CLAIM THE LONG-TERM RATE FOR REIMBURSEMENT.

TRAVEL OF LESS THAN 24 HOURS. SO OUR CURRENT POLICY ALLOWS FOR MEALS AND INCIDENTALS WHEN A TRIP IS MORE THAN FIVE HOURS, BUT LESS THAN 24 HOURS. SO THE POLICY IS BEING REVISED, AGAIN

CONSISTENT WITH UC POLICY, TO ELIMINATE THE MEAL AND INCIDENTAL REQUIREMENT FOR REIMBURSEMENT FOR TRAVEL OF LESS THAN 24 HOURS UNLESS THE TRAVEL INCLUDES AN OVERNIGHT TRIP. SO, FOR EXAMPLE, IF AN INDIVIDUAL TRAVELS FROM OAKLAND TO LOS ANGELES AND IT'S A ONE-DAY TRIP, THEY LEAVE IN THE MORNING AND COME BACK IN THE AFTERNOON, THEY CANNOT CLAIM MEALS OR INCIDENTALS. ON THE OTHER HAND, IF THE TRIP IS FROM OAKLAND TO LOS ANGELES, BUT THEY HAVE AN OVERNIGHT HOTEL EXPENSE, THEN THEY ARE ENTITLED TO MEALS AND INCIDENTALS. AGAIN, THESE ARE ALL IN CONFORMANCE WITH IRS REQUIREMENTS.

AND THE LAST MAJOR CHANGE TO THE POLICY IS THE INSURANCE REQUIREMENTS WHEN USING A PRIVATE VEHICLE. SO WE HAVE ESTABLISHED MINIMUM LIABILITY INSURANCE RATES AT 50,000 FOR PERSONAL INJURY OF ONE PERSON, A HUNDRED THOUSAND ON THE INJURY OF TWO OR MORE INDIVIDUALS, AND THEN 50,000 FOR PROPERTY DAMAGE.

THIS CONCLUDES THE PRESENTATION. I'M HAPPY TO ANSWER ANY QUESTIONS. WE REQUEST YOUR APPROVAL OF THE PROPOSED AMENDMENTS TO THE CIRM TRAVEL POLICY.

CHAIRMAN THOMAS: ANY COMMENTS FROM MEMBERS OF THE BOARD? NOT SURE THERE'S A LOT ONE

CAN DO WITH THIS.

MR. TORRES: MOVE TO APPROVE.

CHAIRMAN THOMAS: MOVED BY SENATOR TORRES. IS THERE A SECOND?

DR. PRIETO: SECOND.

CHAIRMAN THOMAS: ANY DISCUSSION BY MEMBERS OF THE BOARD? ANY DISCUSSION BY MEMBERS OF THE PUBLIC? ANOTHER VOICE VOTE, ROLL CALL ON THE PHONE. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: AYE.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: ABSTAIN.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

MR. HARRISON: MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU. THANK YOU, CHILA, FOR THAT REPORT.

WE NOW ARE ON TO -- THAT CONCLUDES THE ACTION ITEMS. WE'RE NOW ON TO DISCUSSION ITEMS, NO.

18, DISCUSSION OF PROGRAMMATIC REVIEW OF APPLICATIONS. MR. SHEEHY.

MR. SHEEHY: I WAS JUST HOPING -- I THINK PEOPLE -- I DON'T KNOW HOW MUCH OF THIS CAME UP WHEN WE WERE DISCUSSING THE LIMITS NOW THAT WE HAVE ON THE APPLICATION REVIEW SUBCOMMITTEE TO BE ABLE TO EXPAND OUT THE FUNDING THAT WE GET. SO HISTORICALLY THE BOARD HAS ALWAYS BEEN ABLE TO USE -- HAS OFTEN DONE A FORM OF PROGRAMMATIC REVIEW AT THE BOARD TO FUND PROJECTS BEYOND THE ANNOUNCED BUDGETS. NOW THAT OUR ANNOUNCED BUDGETS ARE FIRM AND CANNOT BE CHANGED, IT IS HIGHLY LIKELY THAT FOR THE FIRST TIME IN POSSIBLY SIGNIFICANT NUMBERS WE WILL BE TAKING PROJECTS OUT OF THE FUNDABLE RANGE. AND THE MECHANISM BY WHICH WE WILL DO THAT WILL BE PROGRAMMATIC REVIEW AT THE APPLICATION REVIEW SUBCOMMITTEE.

SO I THOUGHT IT MIGHT BE HELPFUL FOR PEOPLE TO FIRST BE AWARE THAT THAT'S LIKELY GOING TO BE HAPPENING, THAT WE MAY HAVE -- A GREAT EXAMPLE IS WE HAVE 45 MILLION IN TRANSLATION, AND WE BLEW THROUGH 40 IN THE FIRST ROUND. IT MAY BE THAT WE HAVE TEN PROJECTS WORTH 15 OR $20 MILLION AND WE'RE DOWN TO OUR LAST 4 OR 5 MILLION. SO THE APPLICATION REVIEW SUBCOMMITTEE WILL HAVE TO MAKE TOUGH CHOICES,

AND THE CRITERIA FOR WHICH THEY MAKE THOSE CHOICES, I THINK, EACH INDIVIDUAL WILL HAVE TO ASK THEMSELVES WHAT THEY'RE DOING. BUT I THINK IN ANTICIPATION OF THAT HAPPENING, IT MIGHT BE -- IT SEEMED TO ME IT MIGHT BE USEFUL TO HAVE AN OPPORTUNITY TO DISCUSS WHAT THOSE KINDS OF CONSIDERATIONS WOULD BE.

LIKE FOR ME, JUST TO USE AN EXAMPLE, I MIGHT BE REALLY INTERESTED IN AN EMBRYONIC STEM CELL APPLICATION OR IPSC APPLICATION THAT GOT AN 88, AND I WOULD BE RELATIVELY UNINTERESTED, JUST AS A HYPOTHETICAL, IN A SMALL MOLECULE APPLICATION THAT GOT A 96 OR 97. BUT FOR THOSE OF US WHO ARE GOING TO BE MAKING THOSE TYPES OF THINGS, I THOUGHT AT THIS MEETING, SINCE WE ARE KIND OF BECOMING AWARE OF THE LIMITS ON THE APPLICATION REVIEW SUBCOMMITTEE, THAT IF PEOPLE WANTED TO DISCUSS OR HAVE A CONVERSATION. I DON'T THINK IT'S APPROPRIATE TO SET IN PLACE HARD AND FAST CRITERIA THAT HANDCUFF PEOPLE, BUT THIS IS JUST AN OPPORTUNITY. IF NO ONE REALLY FEELS LIKE THAT'S SOMETHING THEY NEED TO DISCUSS OR THEY WANT TO WAIT TILL IT ACTUALLY HAPPENS, BUT I THINK IT'S GOOD FOR THE PUBLIC TO KNOW, FOR APPLICANTS TO KNOW THAT THAT 90 THAT THEY GET IN THE THIRD ROUND OF TRANSLATION MAY NOT BE SOMETHING THEY CAN COUNT ON BEING FUNDED.

SO I DON'T KNOW IF THAT NUANCE REALLY CAME UP IN THE DISCUSSION OF THE BUDGETING CHANGE, BUT I THINK IT'S SOMETHING THAT WE NEED TO BE AWARE OF AND THAT THE PUBLIC NEEDS TO BE AWARE OF AND POTENTIAL APPLICANTS NEED TO BE AWARE OF.

CHAIRMAN THOMAS: ANY THOUGHTS, COMMENTS ON MR. SHEEHY'S REMARKS? ANY COMMENTS FROM MEMBERS ON THE PHONE?

DR. STEWARD: JEFF, ARE YOU SUGGESTING MAYBE A BROADER DISCUSSION OF THE DEGREE TO WHICH INSTITUTIONAL MEMBERS CAN PARTICIPATE IN DISCUSSIONS OF FUNDING IN GENERAL? IS THAT A FAIR SUMMARY?

MR. SHEEHY: I'M TRYING TO RAISE THE ISSUE SO THAT PEOPLE CAN KIND OF LOOK AT IT IN ALL OF ITS NUANCES. BECAUSE THE OTHER THING IS TOO THAT I FORGOT TO MENTION IS EVEN EARLIER IN THE REVIEW, WE MAY NOT NECESSARILY BE THAT EXCITED ABOUT FUNDING 85S IN THE FIRST ROUND. KNOWING THAT WE'RE LIMITED IN TERMS OF BUDGET, WE MAY DECIDE THAT EVEN FUNDABLE SCORES, EVEN WHEN WE HAVE AMPLE MONEY, WE MAY WANT TO RESERVE THAT FOR BETTER PROJECTS. I JUST THINK WE'RE LIVING IN -- WE HAVE TO ACKNOWLEDGE THAT WE'RE LIVING IN AN ERA OF SCARCITY, THAT WE'RE GETTING TOWARDS THE END OF OUR FUNDS. AND SIMPLY HAVING OUTSTANDING SCIENCE, ESPECIALLY IN THESE LIMITED

BUDGET ROUNDS, I THINK WE'RE GOING TO HAVE TO LOOK AT EACH APPLICATION AND REALLY CONSIDER HOW THAT IMPACTS OUR PROGRAM AND WHETHER IT FITS OR NOT, IN MY OPINION.

YES, I THINK EVERYBODY SHOULD BE FEEL FREE TO DISCUSS IF THEY HAVE ANY THOUGHTS.

DR. STEWARD: I WONDER IF THIS IS SOMETHING WE MIGHT TAKE UP AT THE SCIENCE SUBCOMMITTEE AS A FIRST PASS, AND THEN TRY TO GET SOMETHING AGENDIZED FOR MAYBE THE DECEMBER MEETING OR SOME OTHER IN-PERSON MEETING THAT'S COMING UP PRETTY QUICKLY. IT'S A LOT TO TALK ABOUT.

DR. JUELSGAARD: SO LET ME FIRST, JEFF, SAY THAT I COMPLETELY AGREE WITH YOU. IT'S GOING TO BE SOMETHING NEW THAT WE'RE GOING TO HAVE TO TACKLE; AND I AGREE WITH YOU, THAT I DON'T THINK WE CAN PREESTABLISH CRITERIA BECAUSE THERE ARE GOING TO BE DIFFERENT VIEWS ABOUT WHAT CRITERIA ARE IMPORTANT.

FOR EXAMPLE, ONE CRITERIA I MIGHT HAVE IS YOU DON'T THROW GOOD MONEY AFTER BAD. IN OTHER WORDS, IF A PROJECT HAS ALREADY SPENT A TREMENDOUS AMOUNT OF MONEY AND WE'RE NOT GETTING ANYWHERE, NO MATTER WHAT ITS SCIENTIFIC MERIT OF A PARTICULAR PROPOSAL, AT SOME TIME ENOUGH IS ENOUGH AND YOU MOVE ON. SO I THINK DIFFERENT VIEWS WILL BE BROUGHT TO

THE TABLE.

I WOULD DARE SAY THAT MOST OF THE PEOPLE THAT ARE IN THIS ROOM THAT ARE ASSOCIATED WITH AN ORGANIZATION ARE INVOLVED IN A BUDGETING PROCESS. BECAUSE ALMOST EVERY ORGANIZATION, CERTAINLY IN THE BUSINESS WORLD AND I WOULD IMAGINE IN THE ACADEMIC WORLD AS WELL AS RESEARCH INSTITUTIONS, BUDGETS ARE ESTABLISHED FOR PARTICULAR AREAS AS TO HOW MUCH MONEY IS GOING TO BE SPENT. WHEN THAT HAPPENS, THEN PRIORITIES ARE ESTABLISHED. AND IT'S JUST A NECESSARY OUTCOME OF BUDGETING.

AND I THINK I'M PLEASED THAT WE'RE MOVING TO A BUDGETING PROCESS AT THIS POINT. I THINK IT IS NECESSARY SO WE CAN SPEND OUR LAST DOLLARS WISELY. AND IT DOES MEAN THAT WE'RE GOING TO HAVE DIFFICULT DECISIONS TO MAKE THAT WE HAVEN'T HAD TO MAKE BEFORE; BUT, HEY, THAT'S WHAT COMES WITH THIS AUGUST BODY IS TO MAKE THOSE DIFFICULT DECISIONS WHEN WE ARE FACED WITH THEM ON THE BEST INFORMATION AVAILABLE AND WHAT OUR VIEWS ARE AS TO WHAT PROGRAMS ARE WORTHY OF PROCEEDING AND WHICH AREN'T. SO I SAY LET'S JUST DEAL WITH IT AS IT COMES.

DR. STEWARD: MY POINT WAS THAT I TOTALLY AGREE ON THE WADING AHEAD. IT IS JUST A SHAME THAT WE DON'T HAVE THE ABILITY TO HAVE FULL PARTICIPATION

BY SOME OF OUR MOST KNOWLEDGE AND TALENTED MEMBERS ON SOME OF THESE DECISIONS. AND I WONDER IF THAT'S SOMETHING THAT WE COULD AGENDIZE TO DISCUSS. THANK YOU.

DR. DEAS: SO MY ONLY COMMENT IS THAT I CERTAINLY UNDERSTAND THAT WE WILL HAVE TO MAKE DIFFICULT DECISIONS. AT THE SAME TIME, IF WE HAVE GRANTS THAT ARE 95 AND ONE THAT'S 88 AND WE CHOOSE THE 88 OVER THE 95, I THINK IT'S REALLY IMPORTANT THAT WE HAVE SOME GUIDING PRINCIPLES BY WHICH WE MAKE THOSE DECISIONS, EVEN PERHAPS SOME CRITERIA. OTHERWISE WE OPEN OURSELVES UP FOR SCRUTINY IN TERMS OF HOW WE MAKE THOSE DECISIONS.

CHAIRMAN THOMAS: ANY OTHER COMMENTS FROM MEMBERS OF THE BOARD? OKAY. THANK YOU. HEARING NONE, WE'LL NOW -- THIS DOES NOT REQUIRE A VOTE. IT SOUNDS LIKE THE SENSE OF THE DISCUSSION IS TO HAVE THIS CALENDARED AS A SCIENCE SUBCOMMITTEE TOPIC, SO WE WILL PLAN TO DO THAT HENCEFORTH.

WE MOVE ON NOW TO THE LAST ITEM ON THE AGENDA, WHICH IS A CLINICAL PROGRAMS UPDATE. DR. MILLAN.

DR. MILLAN: CHAIRMAN THOMAS AND MEMBERS OF THE BOARD, THANK YOU. IN THE NEXT TEN MINUTES OR SO, I'LL JUST BE GIVING A BRIEF OVERVIEW AND UPDATE

ON OUR CLINICAL PROGRAM.

SO TO DATE CIRM HAS AWARDED GRANTS TO FUND 21 CLINICAL TRIALS, AND 11 CURRENT PROJECTS ARE PREPARING IND'S TO GO INTO THE CLINICS.

LISTED ON THIS CHART ARE CURRENT AND PAST AWARDS TO FUND CLINICAL TRIALS. AND AS YOU CAN SEE, THE MAJORITY ARE PHASE I OR PHASE I/IIA TRIALS. WE DO HAVE TWO PHASE IIIS AND TWO PHASE II TRIALS THAT ARE CURRENTLY ACTIVE.

TODAY I'D JUST LIKE TO FOCUS THE UPDATE ON FOUR PROGRAMS IN THE CARDIOVASCULAR, OPHTHALMIC, AND NEUROLOGIC SPACE. FOR THE FIRST AWARD, THIS AWARD WAS GRANTED TO A COMPANY, CAPRICOR, WHICH IS A CALIFORNIA-BASED COMPANY, TO TEST THEIR CELL PRODUCT CALLED ALLOGENEIC CARDIOSPHERE-DERIVED CELLS. SO IT'S AN ALLOGENEIC PRODUCT FROM DONATED TISSUES THAT GIVE RISE TO A CELLULAR PRODUCT THAT GOES THROUGH THE QUALITY SYSTEMS AND HAS BEEN CLEARED BY THE FDA TO GO INTO CLINICAL TESTING.

THE TARGET FOR THIS PARTICULAR TRIAL CALLED THE HOPE TRIAL IS FOR DUCHENNE MUSCULAR DYSTROPHY CARDIOMYOPATHY, WHICH IS A LEADING CAUSE OF DEATH IN ADOLESCENTS AND YOUNG ADULTS WITH DUCHENNE MUSCULAR DYSTROPHY. THESE PATIENTS ARE TREATED WITH STANDARD OF CARE CARDIAC MEDICATIONS TO

DECREASE THE HEART LOAD AND TO TRY TO ALLEVIATE SOME OF THESE SYMPTOMS; HOWEVER, THERE IS NO CURE FOR THIS DISORDER.

THIS TRIAL, TESTING WHAT THEY CALL CAP-1002, WHICH IS A CELL PRODUCT, IS INTENDED TO TEST WHETHER THE CELL THERAPY RESULTS IN A BENEFIT TO THESE PATIENTS. SO THE OUTCOME MEASURES FOR THE STUDY ARE PRIMARILY SAFETY AND TOLERABILITY, BUT ALSO TESTING FOR EFFICACY IN TERMS OF HEART FUNCTION AND STRUCTURE AND QUALITY OF LIFE.

THE STATUS OF THIS TRIAL IS THAT THE ENROLLMENT ACTUALLY HAS BEEN COMPLETED. IN THE NEXT SLIDE, YOU'LL SEE THE DESIGN OF THIS TRIAL IS A ONE-TO-ONE RANDOMIZED, OPEN LABEL TRIAL, COMPARING PATIENTS WHO RECEIVE STANDARD OF CARE VERSUS THOSE THAT RECEIVE STANDARD OF CARE AND THE CELL THERAPY.

THE COMPANY REPORTS A FAVORABLE SAFETY PROFILE SO FAR. THE PATIENTS ARE UNDERGOING A ONE-YEAR FOLLOW-UP, RECEIVING IMAGING AND CARDIAC FUNCTION TESTING AS WELL AS CLINICAL EXAMS. AND WE'LL BE GETTING MORE RESULTS ON THAT IN THE UPCOMING YEAR.

THE NEXT TRIAL IS ALSO BEING PERFORMED BY CAPRICOR WITH THE SAME PRODUCT, ALLOGENEIC CARDIAC-DERIVED STEM CELLS, CAP-1002, FOR HEART

FAILURE FOLLOWING MYOCARDIAL INFARCTION. AS WE KNOW, HEART FAILURE FOLLOWING AN MI IS A PREVALENT CONDITION IN THE U.S., AND THE INCIDENCE IS INCREASING. THERE ARE MEDICATIONS THAT TREAT THE HEART FAILURE, BUT ARE IMPERFECT. AND THE COMPANY, BASED ON PRECLINICAL STUDIES THAT SHOW IN ANIMALS THAT THERE IS DECREASED INFARCT SIZE AND IMPROVED CARDIAC FUNCTION, HAS PURSUED THIS TRIAL. AND ALSO, THEY HAD A FAVORABLE PHASE I CLINICAL SAFETY TRIAL THAT WAS FUNDED BY THE NIH PRIOR TO THIS PHASE II TRIAL THAT'S BEEN SUPPORTED BY CIRM.

THE PRIMARY OUTCOME MEASURES ARE SAFETY FIRST, BUT IN ADDITION THEY'RE MEASURING THE INFARCT SIZE BY MRI AS WELL AS CARDIAC FUNCTION.

THE DESIGN OF THIS TRIAL, THE SCHEMATIC AS PROVIDED BY THE COMPANY, IS AS FOLLOWS. THE PATIENTS ARE TREATED BY INTRACARDIAC INFUSION IN THIS PHASE II 2:1 RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED TRIAL. PATIENTS WHO BOTH SUFFERED FROM A RECENT MI AS WELL AS THOSE WHO SUFFERED FROM AN MI REMOTE TO THE INFUSION ARE BEING TESTED WITH SOME PATIENTS RECEIVING THE CELLULAR PRODUCT AND THE SECOND ARM, THE CONTROL ARM OF EACH GROUP, RECEIVING PLACEBO.

THE TRIAL ENROLLMENT IS ALMOST COMPLETE.

A TOTAL OF 120 PATIENTS WERE TARGETED, AND THE COMPANY REPORTS SATISFACTORY ENROLLMENT. AND SO THERE SHOULD BE MORE INFORMATION ON THIS TRIAL SHORTLY. THERE IS A FAVORABLE SAFETY PROFILE AT THIS POINT, AND THE COMPANY IS ENCOURAGED SO FAR WITH THE STUDY.

SO SHIFTING GEARS --

MR. SHEEHY: CAN I ASK A COUPLE OF QUESTIONS? FIRST -- WELL, LET ME ASK THEM BOTH. SO ONE IS THEY HAVE DYNAMIC, AND I DON'T KNOW. I DIDN'T SEE ANYTHING ON DYNAMIC. IS THERE ANY INFORMATION ABOUT DYNAMIC THAT'S BEEN MADE AVAILABLE, WHICH IS THEIR OTHER CLINICAL TRIAL? AND THEN ALSO THEY ACTUALLY REDUCED THE NUMBER OF PATIENTS THEY'RE RECRUITING, RIGHT?

DR. MILLAN: RIGHT. THE DYNAMIC TRIAL, ONE OF THEIR FIRST TRIALS WAS WITH AUTOLOGOUS.

MR. SHEEHY: NO. DYNAMIC IS STILL CAP-1002. IT'S MORE ACUTE DISEASE.

DR. MILLAN: WELL, I'LL HAVE TO GET BACK TO YOU ON THAT BECAUSE THAT'S NOT THE TRIAL THAT WE'RE FUNDING. THEY HAVE REPORTED IN THE PAST SOME --

MR. SHEEHY: I THINK DYNAMIC IS OVER. I JUST DIDN'T KNOW IF THEY REPORTED OR NOT. BECAUSE I

WAS GETTING THIS FROM READING THEIR FINANCIALS, SO THAT'S WHY.

DR. MILLAN: SO I CAN GET BACK TO YOU ON THAT. THERE WERE SOME REPORTS ON THE DYNAMIC TRIAL WITH SOME DECREASE IN INFARCT SIZE AND SCARRING THAT SUPPORTED THE ALLSTAR TRIAL, THE CURRENT TRIAL. THIS IS THE TRIAL THAT CIRM IS FUNDING.

IN TERMS OF THE NUMBERS, THE COMPANY DID REDUCE THE SIZE OF THEIR PHASE II TRIAL BY A LITTLE BIT, APPROXIMATELY ONE-HALF, AND THAT WAS BASED ON A REVIEW OF THE PHASE I DATA AND INVOLVED A PANEL OF KEY OPINION LEADERS AS WELL AS BIOSTATISTICIANS LOOKING AT WHAT THEY WOULD NEED BASED ON THE OBSERVATIONS THEY MADE FROM THE PHASE I EARLY EFFICACY DATA TO SEE AN EFFECT IN THE PHASE II IN TERMS OF SCAR SIZE AND IN TERMS OF CARDIAC FUNCTION.

ANY MORE QUESTIONS ON THE CARDIOVASCULAR PORTFOLIO?

SO BACK TO THE OPHTHALMIC, THE INDICATION THAT'S BEING EXPLORED BY DR. HENRY KLASSEN FROM UC IRVINE IS RETINITIS PIGMENTOSA, WHICH AFFLICTS ONE IN 4,000 AMERICANS, RESULTING IN LEGAL BLINDNESS IN OTHERWISE HEALTHY INDIVIDUALS BY THE AGE OF 40. IT RESULTS FROM THE NEURODEGENERATION OF PHOTORECEPTORS. SO THE PRODUCT, WHICH IS AN

ALLOGENEIC, AGAIN FROM DONATED TISSUE, RETINAL PROGENITOR CELLS IS INTENDED, BY DIRECT INTRAOCULAR ADMINISTRATION, TO PROVIDE WHAT'S CALLED NEUROTROPHIC SUPPORT TO RESCUE THESE PHOTORECEPTORS. AND THEY HAD A STRONG PRECLINICAL DATA PACKAGE AS EVALUATED BY OUR REVIEW GROUP TO SUPPORT GOING INTO THIS CLINICAL TRIAL.

THE PRIMARY OUTCOME MEASURES FOR THIS TRIAL ARE SAFETY AND OCULAR FUNCTION, WHICH I'LL DESCRIBE IN A LITTLE BIT. AND THE STATUS OF THIS TRIAL IS THEY'VE COMPLETED ENROLLMENT OF 28 SUBJECTS WITH 12-MONTH FOLLOW-UP IN FIVE SUBJECTS. AND THIS IS SOMETHING THAT THE COMPANY DID GIVE CLEARANCE TO SHARE WITH YOU TO TODAY.

SO FAR IN THIS STUDY, THEY'VE HAD A FAVORABLE SAFETY PROFILE, AND THEY ARE ENCOURAGED BY THE TYPES OF SIGNALS THEY'RE SEEING AND WILL BE REPORTING ON THAT SHORTLY.

I'M JUST SHOWING THE SCHEMATIC HERE OF HOW THEY PERFORMED THIS PHASE I-IIA OPEN LABEL, SINGLE-ARM STUDY. THEY HAD TESTED FOR DOSES IN TWO TYPES OF PATIENTS. GROUP ONE ARE LEGALLY BLIND PATIENTS THAT HAD MEASURED VISION OF 20/200 TO BEING ABLE TO SEE HANDWAVING ONLY. AND GROUP TWO ARE THOSE WITH POOR VISION TESTED AS 20/63 TO 20/200

VISION.

THEY FIRST WENT INTO THE LEGALLY BLIND POPULATION WITH ONE-HALF MILLION CELLS ADMINISTERED INTO THE WORST SEEING EYE OF THE TWO EYES. AND AFTER DSMB REVIEW PROCEEDED TO GO ON TO THE NEXT GROUP OF PATIENTS WITH A HIGHER DOSE. AND THEN AFTER THAT, EXPERIENCE WAS CLEARED BY THEIR DSMB TO GO BOTH INTO THE HIGHER DOSE OF 2 MILLION AS WELL AS TO DO A DOSE, ESCALATING DOSE STUDY IN THOSE WITH POOR VISION, SO THE LESS AFFECTED PATIENTS.

THE OPTIC TREATMENT OF THE WORST SEEING EYE, THESE WERE FOLLOWED FOR 12 MONTHS BY CLINICAL EXAM, INCLUDING WHAT'S CALLED LOW VISION TESTS. THOSE ARE SPECIALIZED TESTS TO LOOK AT VISION IN PATIENTS WHO OTHERWISE CAN'T BE EVALUATED BY STANDARD VISION TESTS.

SO THERE IS, AS I MENTIONED, FAVORABLE RESULTS SO FAR, AND THE COMPANY DOES INTEND TO NOW GO FORWARD TO A PHASE IIB TRIAL.

THE FINAL PROGRAM I'D LIKE TO BRING TO YOUR ATTENTION IS OUR PROGRAM WITH FUNDING ASTERIAS. YOU MAY RECALL THAT THE FIRST TRIAL FUNDED BY CIRM WAS FROM A COMPANY CALLED GERON WITH EMBRYONIC STEM CELL-DERIVED OLIGODENDROCYTE PROGENITOR CELLS, WHICH ARE COMPANY LABELS AST-OPC1. SO THESE ASSETS HAVE

SINCE BEEN ACQUIRED BY ASTERIAS. THE PREVIOUS TRIAL WAS IN THORACIC SPINAL CORD INJURY. THE CURRENT TRIAL IS IN CERVICAL SPINAL CORD INJURY. AND AS MANY OF YOU ARE AWARE OF, A CERVICAL SPINAL CORD INJURY COULD RESULT IN QUADRIPLEGIA AND VERY SEVERE MANIFESTATIONS.

OVERALL APPROXIMATELY 12,000 AMERICANS AND OFTEN YOUNG AMERICANS SUFFER SPINAL CORD INJURY EACH YEAR WITH A SIGNIFICANT NUMBER OF THOSE BEING CERVICAL SPINAL CORD INJURY. THIS LEADS TO A HIGH LEVEL OF PERMANENT DISABILITY AND DECREASED LIFE EXPECTANCY. THERE IS NO CURRENT TREATMENT.

THE STUDY IS THE DIRECT INJECTION OF THE CELLULAR PRODUCT, AST-OPC1 INTO THE RADIOLOGICALLY CONFIRMED AREA OR LESION RESULTING FROM THE TRAUMA THAT LED TO THE SPINAL CORD INJURY. THE PRIMARY OUTCOME MEASURE IS SAFETY, BUT ALSO EFFICACY MEASURES, INCLUDING NEUROLOGIC FUNCTION BY UPPER EXTREMITY MOTOR SCORES, AS WELL AS EVALUATION OF THE DEFICIT BASED ON INTERNATIONAL STANDARDS FOR NEUROLOGIC CLASSIFICATION OF SPINAL CORD INJURY.

THE STATUS ON THIS AWARD IS THAT THEY HAVE COMPLETED ENROLLMENT OF TWO COHORTS. THE COMPANY HAS RECENTLY SUPPORTED THEIR OBSERVATIONS AT A MEETING IN SEPTEMBER OF THIS YEAR AT THE

INTERNATIONAL SPINAL CORD INJURY MEETING. AND I'LL GET INTO THAT A LITTLE BIT MORE.

ON THIS SLIDE YOU WILL FIND A SCHEMATIC OF THE CLINICAL TRIAL. THE FIRST TWO COHORTS IN THIS TRIAL ARE, THEY'RE ABBREVIATED INJURY SCORE, OR AIS A, WHICH IN SPINAL CORD INJURY MEANS IF THERE IS A COMPLETE DISRUPTION OF SENSORY AND MOTOR FUNCTION BELOW THE LEVEL OF THE LESION. THE FIRST TWO COHORTS HAVE COMPLETED DOSING. THE FIRST COHORT RECEIVED 2 MILLION CELLS AND THE NEXT COHORT RECEIVED 10 MILLION CELLS.

THE DATA MONITORING COMMITTEE HAS MET TWICE, AT LEAST TWICE, TO APPROVE STUDY PROGRESSION FROM COHORT 1 TO COHORT 2, AND HAS RECENTLY APPROVED THE COMPANY TO MOVE FORWARD FROM COHORT 2 TO COHORT 3 AND COHORT 4. COHORT 3 BEING PATIENTS WHO ALSO HAVE THE COMPLETE INJURY BELOW THE LEVEL OF THE LESION OF THE COMPLETE MOTOR AND SENSORY DEFICIT BELOW THE LEVEL OF THE LESION TO RECEIVE EVEN A HIGHER CELL DOSE OF 20 MILLION CELLS. AND COHORT 4 IS A NEW SUBSET OF PATIENTS THAT HAVE THE ABBREVIATED INJURY SCORE OF B, WHICH MEANS THAT THERE'S INCOMPLETE, MEANING THERE'S AN INCOMPLETE INJURY WHERE THEY HAVE PRESERVED SOME SENSORY FUNCTION BELOW THE LEVEL OF THE LESION ALTHOUGH

STILL HAVE MOTOR DEFICITS BELOW THE LEVEL OF THE LESION.

THE SIGNIFICANCE OF THIS IS PATIENTS WITH AIS B, IN ADDITION TO SOME RESIDUAL NEUROLOGIC FUNCTION, ALSO HAVE AN INCREASED CHANCE OF SOME SPONTANEOUS RECOVERY.

SO THE COMPANY PRESENTED AT THE INTERNATIONAL SPINAL CORD SOCIETY MEETING JUST SEVERAL WEEKS AGO, ACTUALLY SEPTEMBER 14TH, SO JUST A WEEK AGO, AND AT THAT MEETING THEY PRESENTED THE FOLLOWING RESULTS. YOU WILL SEE A PICTURE OF THE OR PROCEDURE WHERE THERE'S DIRECT INJECTION OF THE CELLS. BELOW IT IS THE ACTUALLY EXPOSED SPINAL CORD WHERE THEY INFUSE THE CELLS INTO THE AREA OF INJURY. THEY REPORTED NO SERIOUS ADVERSE EVENTS RELATED TO THE INVESTIGATIONAL CELL PRODUCT OR THE SURGERY, AND REPORTED THE SUBJECTS WITH SUBACUTE CERVICAL SPINAL CORD INJURY TOLERATED THE INTERVENTIONAL PROCEDURE WELL. AND THEY ALSO DID REPORT POSSIBLE EFFICACY SIGNALS AT 90 DAYS.

AS SHOWN IN THE PREVIOUS SLIDE, THEIR FOLLOW-UP IS UP TO ONE YEAR, SO THIS IS STILL EARLY, SO THERE'S SOME CAUTIOUS FAVORABLE SENSE FOR THIS DATASET, BUT THEY DO NOTE THAT THEY STILL NEED LONGER FOLLOW-UP WITH MORE PATIENTS.

SO THAT'S IT WITH --

CHAIRMAN THOMAS: ISN'T IT FAIR TO SAY THAT THE POTENTIAL EFFICACY THAT THEY'RE OBSERVING WAS A LITTLE SURPRISING TO THEM BECAUSE THEY DIDN'T EXPECT TO SEE THAT UNTIL LARGER DOSES?

DR. MILLAN: WHAT THEY REPORTED AT THE MEETING IS THAT THEY FOUND THIS TO BE A VERY FAVORABLE RESULT, AND THAT THERE IS, AS I MENTIONED, SOME RECOVERY BECAUSE THEY ARE GOING INTO THE SUBACUTE, MEANING JUST VERY PROXIMATE TO THE INJURY PHASE. SO THERE IS SOME NATURAL HISTORY OF SOME RECOVERY, BUT TYPICALLY THAT OCCURS AT NOT SUCH A FAST PACE. SO HAVING AN EARLY READ, I THINK, WAS A FAVORABLE SIGNAL. AND ALSO WHAT THEY REPORTED AT THE MEETING IS THAT THEY SAW THIS EFFECT IN THE HIGHER DOSE, IN THE 10 MILLION DOSE, WHICH THEY DIDN'T SEE IN THE 2 MILLION DOSE RANGE IN THAT SAME SUBSET OF PATIENTS. SO THAT TO THEM WAS ENCOURAGING FOR MAYBE EARLY INDICATION OF DOSE RESPONSE.

SO THEY ARE GOING INTO THE 20 MILLION DOSE RANGE AGAIN WITH THAT SAME AIS A SUBPOPULATION OF COMPLETE INJURY PATIENTS, AND WE'LL SEE WHAT THAT DATA HAS.

ONE THING THEY DID ACKNOWLEDGE IS THIS IS ENCOURAGING, BUT IT'S EARLY, AND THE NUMBER OF

PATIENTS THAT THEY'VE ENROLLED SO FAR, THEY STILL HAVE FOLLOW-UP ON THE PATIENTS THEY'VE ENROLLED AS WELL AS MORE PATIENTS TO ADD TO THEIR DENOMINATOR.

CHAIRMAN THOMAS: OKAY. DR. DULIEGE.

DR. DULIEGE: THIS IS EXACTLY WHAT WE'RE ALL HERE FOR, TO SEE THAT ULTIMATELY. MORE OF THAT. THAT'S WHAT THE PATIENTS AND THEIR FAMILIES ARE ALL HERE TO SEE.

BACK TO THE ALSO ENCOURAGING RESULTS IN THE RP PROGRAM AT UC IRVINE, THIS IS ONE OF -- THE THREE EXAMPLES, THE ONE THAT IS DONE BY A UNIVERSITY, DO YOU KNOW WHAT THEIR PLANS ARE? IF THEY CONTINUE TO SHOW SOME ENCOURAGING RESULTS TO BE FOR PHASE II, WILL THEY TRY TO PARTNER THIS OUT WITH A BIOPHARMACEUTICAL COMPANY? WILL THEY TRY TO CONTINUE TO PHASE III ON THEIR OWN? WHAT'S THE IDEA THERE?

DR. MILLAN: SO CURRENTLY DR. KLASSEN HAS PARTNERED WITH A SPINOUT COMPANY CALLED JCYTE. AND THEY'RE GOING THROUGH THEIR CORPORATE STRATEGY OF HOW TO PARTNER THIS. THE COMPANY HAS AND DR. KLASSEN HAVE BOTH SAID THAT I COULD SHARE THAT THEY ARE CURRENTLY IN THE PROCESS OF PLANNING AND PREPARING FOR THEIR PHASE IIB.

DR. DULIEGE: GREAT.

CHAIRMAN THOMAS: OTHER COMMENTS FROM MEMBERS OF THE BOARD?

MR. TORRES: MOVE TO ADJOURN.

CHAIRMAN THOMAS: OTHER COMMENTS FROM MEMBERS OF THE BOARD? THE ADMINISTRATIVE ISSUE HERE, WE HAVE LUNCH THAT WE HAVE PAID FOR IMMEDIATELY NEXT DOOR, ON THE OTHER SIDE OF THE WALL FOR THOSE IN THE ROOM. FOR THOSE ON THE PHONE, SORRY, YOU'RE ON YOUR OWN.

DR. DIXON: THOSE NEW TRAVEL RULES.

CHAIRMAN THOMAS: EXACTLY. SO OUR NEXT IN-PERSON MEETING IS DECEMBER 13TH IN THE BAY AREA AT A PLACE TBD. YES. WITH THAT, I KNOW WE WILL NOW ADJOURN, AND I KNOW EVERYBODY JOINS ME IN WISHING GREAT GOOD FORTUNE FOR THE DODGERS TO MAKE A DEEP RUN INTO THE PLAYOFFS. THANK YOU VERY MUCH.

MS. CHEUNG: JUST ONE MORE THING, OUR NEXT ICOC APPLICATION REVIEW SUBCOMMITTEE IS OCTOBER 19TH, AND I'LL BE SENDING INFORMATION ABOUT THAT SHORTLY.

CHAIRMAN THOMAS: THANK YOU. WE STAND ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 12:48 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 AND THE APPLICATION REVIEW SUBCOMMITTE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

MARRIOTT LA JOLLA
4240 LA JOLLA VILLAGE DRIVE
LA JOLLA, CALIFORNIA
ON
SEPTEMBER 21, 2016

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

BETH C. DRAIN, CSR 7152
BARRISTERS' REPORTING SERVICE
160 S. OLD SPRINGS ROAD
SUITE 270
ANAHEIM, CALIFORNIA
(714) 444-4100