BEFORE THE

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

REGULAR MEETING

LOCATION:	CLAREMONT HOTEL 44 TUNNEL ROAD BERKELEY, CALIFORNIA
DATE:	JUNE 15, 2016 9 A.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
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I N D E X

BERKELEY, CALIFORNIA; WEDNESDAY, JUNE 15, 2016

9 A.M.

CHAIRMAN THOMAS: COULD EVERYBODY TAKE THEIR SEATS PLEASE. GOOD MORNING, EVERYBODY, HIGH ATOP THE BEAUTIFUL BERKELEY HILLS ON A WONDERFUL MORNING. WE'D LIKE TO WELCOME EVERYONE TO THIS MONTH'S MEETING OF THE ICOC.

MARIA, WOULD YOU PLEASE LEAD US IN THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

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

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: HERE.

MS. BONNEVILLE: LARS BERGLUND.

DR. BERGLUND: HERE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: HERE.

MS. BONNEVILLE: HOWARD FEDEROFF. ELIZABETH FINI. MICHAEL FRIEDMAN. JUDY GASSON.

DR. GASSON: HERE.

MS. BONNEVILLE: SAM HAWGOOD. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEPHEN JUELSGAARD. SHERRY LANSING.

MS. LANSING: HERE.

MS. BONNEVILLE: KATHY LAPORTE.

DR. LAPORTE: HERE.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED. LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: LLOYD MINOR.

DR. MINOR: HERE.

MS. BONNEVILLE: ADRIANA PADILLA. JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: ROBERT PRICE.

DR. PRICE: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. BONNEVILLE: ROBERT QUINT. AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. BONNEVILLE: OSWALD STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: CARL WARE.

DR. WARE: HERE.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: HERE.

CHAIRMAN THOMAS: THANK YOU, MARIA.

PROCEED NOW TO THE CHAIRMAN'S REPORT.

BEFORE WE BEGIN TODAY, I WANTED TO SAY A FEW WORDS ABOUT THE RECENT TRAGIC EVENTS IN ORLANDO. I THINK WE WERE ALL DEEPLY MOVED BY YET ANOTHER SENSELESS SHOOTING AND THE TERRIBLE LOSS OF LIFE, AND OUR THOUGHTS AND WISHES ARE WITH THE FAMILIES OF THOSE WHO LOST THEIR LIVES AND THOSE INJURED IN THE ATTACK ON THE LGBT NIGHT CLUB. WHILE THIS HAPPENED THOUSANDS OF MILES AWAY, THE IMPACT HAS QUITE CLEARLY BEEN FELT HERE IN THE SAN FRANCISCO BAY AREA AND INDEED ALL OVER CALIFORNIA.

JUNE IS PRIDE MONTH, AND I THINK THE STRONGEST STATEMENT THAT WE CAN GIVE IS TO SHOW THAT ATTACKS LIKE THIS WON'T DICTATE HOW WE LIVE OUR LIVES AND THAT WE WON'T GIVE IN TO FEAR AND HATRED AND MINDLESS BIGOTRY. AND IF YOU WOULD, WE'D LIKE TO HAVE A MOMENT OF SILENCE FOR THE VICTIMS OF THIS

SENSELESS ATTACK.

(MOMENT OF SILENCE.)

CHAIRMAN THOMAS: THANK YOU.

PROCEEDING ON NOW WITH THE CHAIR'S REPORT, THE LAST THREE MONTHS HAS SEEN A FLURRY OF ACTIVITY IN TALKING TO ANY NUMBER OF STAKEHOLDERS CONNECTED TO OUR EFFORTS TO LAUNCH OUR ACCELERATED THERAPIES PUBLIC PRIVATE PARTNERSHIP OR ATP3. I'VE HAD, AS WELL AS MANY OTHERS HERE AT CIRM, HAVE HAD MEETINGS ALL OVER CALIFORNIA, MEETINGS ON THE EAST COAST, MEETINGS AT BIO, WHICH, AS YOU KNOW, HAS BEEN GOING ON IN SAN FRANCISCO THIS LAST STRETCH, HAVE HAD MEETINGS -- WAS ON A SPEAKING ENGAGEMENT AT THE MILKEN GLOBAL CONFERENCE IN LOS ANGELES, HAD A NUMBER OF MEETINGS THERE. SIMILARLY, A MILKEN PUBLIC HEALTH CONFERENCE HE HAD BACK IN WASHINGTON, D.C., MEETINGS THERE. BEEN OUT TALKING TO FOLKS TO GENERATE INTEREST IN THIS INNOVATIVE PROGRAM FOR WHICH WE'LL BE LAUNCHING OUR RFA IN JULY, AND HAVE BEEN SPEAKING TO FOLKS FROM BIG PHARMA, FROM BIG BIOTECH, FROM THE LIFE SCIENCE VENTURE CAPITAL COMMUNITY, A NUMBER OF HIGH NET WORTH ENTREPRENEURS WHO ARE INTERESTED IN THE LIFE SCIENCE SPACE, AND HAVE BEEN GENERATING, I THINK, A LOT OF INTEREST IN THIS CONCEPT. AND WE'LL OBVIOUSLY BE BACK TO YOU

MORE ON THIS THEME AS THINGS PLAY OUT OVER TIME. BUT JUST TO LET YOU KNOW THAT THE EFFORT TO EDUCATE PEOPLE ON WHAT THIS PROGRAM IS ALL ABOUT IS IN FULL SWING, AND WE ARE VERY HAPPY WITH THE RESPONSE WE'RE GETTING BACK FROM POTENTIAL STAKEHOLDERS AND THE EFFORT.

AS I SAID, BIO WAS RECENTLY UNDER WAY IN SAN FRANCISCO. THIS BRINGS TOGETHER MEMBERS OF THE LIFE SCIENCES AND BIOTECH COMMUNITY THAT ARE HERE TO LARGELY NETWORK AND LET EVERYBODY KNOW WHAT THEY'RE ABOUT. THERE ARE LOTS OF INVESTORS WHO COME TO THESE THINGS, AND THAT HAS LED TO A SERIES OF MEETINGS THAT WE'VE HAD WITH PEOPLE HERE IN TOWN ON A VARIETY OF TOPICS, EDUCATING THEM ABOUT CIRM, TALKING ABOUT SPECIFIC PROGRAMS. AND, AS ALWAYS, THEY ARE VERY INTERESTED IN WHAT WE HAVE TO SAY ON THE ONGOING EFFORTS TO HAVE OUR PROJECTS INTO CLINICAL TRIALS AND HOPEFULLY DOWN THE ROAD TO GENERATE THERAPIES FOR PEOPLE IN NEED.

NEXT WEEK, I HOPE EVERYBODY, WE'VE HAD NOTICES ABOUT THIS, BIG DEAL IN TOWN AS WELL. WE'RE LUCKY WE GET BIO ONE WEEK AND THEN WE GET ISSCR COMING TO TOWN, WHICH IS A GREAT THING FOR US. WE'VE TRADITIONALLY HAD A MAJOR PRESENCE AT ISSCR WHEREVER IT MIGHT BE. LAST YEAR IT WAS STOCKHOLM.

AND IT BRINGS TOGETHER THE WORLD'S SCIENTISTS TO TALK ABOUT THEIR PROJECTS. AND IT IS AT ISSCR WHERE EVERY YEAR ONE CAN GO TO LEARN SORT OF WHERE THE CUTTING-EDGE RESEARCH IS BEING DONE ACROSS MANY DIFFERENT INDICATIONS. SO I WANTED TO REMIND YOU THAT THAT WILL BE HERE IN TOWN NEXT WEEK.

THE CONFERENCE ITSELF BEGINS ON WEDNESDAY, BUT CIRM IS KICKING THE EVENT OFF THE NIGHT BEFORE FOR THE PUBLIC SYMPOSIUM THAT IS FREE AND OPEN TO EVERYONE. THIS WILL FEATURE SOME OF OUR GRANTEES AND PATIENT ADVOCATES, INCLUDING DON KOHN FROM UCLA WHO IS NOW IN A CLINICAL TRIAL THAT WE ARE FUNDING TO TREAT SICKLE CELL DISEASE; KAT JAMIESON FROM U.C. SAN DIEGO, WHO HAS A NUMBER OF CLINICAL TRIALS UNDER WAY FOCUSING ON BLOOD CANCERS; AND HENRY CLAUSSEN OF UC IRVINE WHO IS IN A PHASE I CLINICAL TRIAL TO TREAT RETINITIS PIGMENTOSA, A DEVASTATING CAUSE OF EARLY VISION LOSS AND BLINDNESS. WE ALSO WILL HAVE EXPERTS ON HEART DISEASE AND PARKINSON'S DISEASE AND WILL HEAR FROM PATIENTS INVOLVED IN ALL OF THOSE PROJECTS.

THE NEXT MORNING DR. MILLS AND THE SCIENCE TEAM WILL HAVE A SPECIAL WORKSHOP LETTING RESEARCHERS KNOW ABOUT ALL THE FUNDING OPPORTUNITIES AT CIRM AND HOW WE ARE OPEN TO FUNDING ANYONE, ANY

TIME. SO, MEMBERS OF THE BOARD, IF YOU'RE INTERESTED IN ATTENDING, PLEASE LET MARIA KNOW AND WE'LL MAKE SURE YOU'RE REGISTERED. FOR THOSE WHO HAVE NEVER ATTENDED ONE OF THESE CONFERENCES AND HAVE THE TIME TO DO SO, IT'S WELL WORTH SEEING BECAUSE IT'S QUITE A MAJOR PRODUCTION, AND YOU WILL GET A FRONT ROW SEAT OF WHAT EVERYBODY IS WORKING ON WORLDWIDE. IT REALLY IS THE ONLY EVENT ANNUALLY AT WHICH YOU CAN DO THAT.

SO JUST WANT TO PUT IN A SHOUT-OUT HERE TO OUR COMMUNICATIONS TEAM, MARIA, KEVIN, DON, TODD, EVERYBODY WHO WORKS IN COMMUNICATIONS, WHO HAD A MAJOR PRESENCE AT BIO. WE'RE HAVING A MAJOR PRESENCE AT ISSCR, COMMUNICATION OF WHAT WE ARE DOING. AND, IN PARTICULAR, THE ADVANCES MADE UNDER DR. MILLS' DIRECTION AND CIRM 2.0 ARE STORIES THAT PEOPLE REALLY LIKE TO HEAR ABOUT AS THEY UNDERSTAND HOW CIRM'S PROGRAMS ARE CONTINUING TO EVOLVE AND BE PROGRESSIVELY MORE USER FRIENDLY.

SO ON THAT NOTE, WOULD LIKE TO NOW TURN IT OVER TO DR. MILLS FOR THE PRESIDENT'S REPORT.

DR. MILLS: THANK YOU VERY MUCH, CHAIRMAN THOMAS AND THE BOARD. THRILLED TO BE HERE TODAY AND GIVE YOU AN UPDATE ON HOW THINGS ARE GOING AT CIRM. FAIR NUMBER OF TOPICS TO COVER, SO LET'S JUMP INTO

IT.

JUST TO GIVE YOU A SUMMARY OF WHAT TO EXPECT, FIRST, AS ALWAYS, WE'LL START WITH A REVIEW OF THE CIRM MISSION. I'LL ALSO THEN JUST BRIEFLY GO OVER THE ELEMENTS OF THE STRATEGIC PLAN, BUT I PROMISE I'LL KEEP THAT BRIEF. THEN WANT TO GIVE YOU AN UPDATE ON THE BUDGET AND WHERE WE STAND WITH THAT. THAT'S VERY IMPORTANT FOR US TO ALWAYS KEEP A SHARP EYE ON. WE'RE GOING TO TAKE A LOOK AT CIRM 2.0 PERFORMANCE, AND THEN I WANT TO TURN TO A PROPOSAL THAT WE HAVE FOR BUDGETING AND REBALANCING OF OUR PORTFOLIO ON AN ANNUALIZED BASIS AND TAKE YOU THROUGH EARLY STAGE OF WHAT WE THINK ABOUT THIS TO GENERATE SOME THOUGHTS AND DISCUSSION AROUND IT. AND THEN, LASTLY, JUST TALK OPENLY AND FRANKLY ABOUT THE PROS AND THE CONS OF SHIFTING CIRM TO A MORE OBJECTIVE AND INFORMATION-BASED AGENCY.

SO, AS ALWAYS, IT IS ESSENTIAL FOR US TO REMEMBER THAT THE REASON WE ARE ALL HERE TODAY AND THE REASON CIRM EXISTS IS TO ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. WE MUST ALWAYS KEEP THE PATIENT FIRST AND FOREMOST IN EVERYTHING THAT WE DO.

BRIEFLY NOW TURNING TO THE STRATEGIC PLAN, AS YOU WILL RECALL, IN DECEMBER THIS BOARD

UNANIMOUSLY APPROVED OUR STRATEGIC PLAN. AND IT HAD THREE ELEMENTS ASSOCIATED WITH IT: PUSH, PULL, AND LEVEL. PUSH ARE ALL THE ACTIVITIES THAT WE CAN DO TO DRIVE OUR PROGRAMS FORWARD, WHETHER IT BE IMPLEMENTING CIRM 2.0, HAVING FASTER REVIEWS, GOING TO MILESTONE-BASED PAYMENTS, THE ACCELERATING CENTER THAT WE'RE GOING TO HEAR TODAY WHICH IS VERY EXCITING, TRANSLATION CENTER. ALL OF THOSE ACTIVITIES THAT SIGNIFICANTLY DRIVE PROGRAMS FORWARD FALL INTO THE PUSH CATEGORY.

THE PULL CATEGORY, AS YOU WILL RECALL, CAME FROM THE FACT THAT IT FEELS A LITTLE BIT TOO MUCH LIKE WE'RE IN THIS ALONE. SO IF WE LOOKED AT OUR CIRM PORTFOLIO OBJECTIVELY, WE SAW THAT 91 PERCENT OF THE PROGRAMS THAT WE HAD WERE UNPARTNERED WITH INDUSTRY. ONLY 9 PERCENT HAD AN INDUSTRY PARTNER. IN ORDER FOR THESE TECHNOLOGIES TO MAKE IT FULLY OVER THE HILL AND ALL THE WAY TO PATIENTS, WHICH IS OUR GOAL, TO ACTUALLY IMPACT PATIENTS, WE KNOW THAT WE NEED MORE COMMERCIAL INTEREST IN THIS.

SO WHAT WAS LACKING WAS, AS WE WERE PUSHING THESE THERAPIES OVER THE HILL, WHAT WAS LACKING WAS INDUSTRY DEMAND HELPING US PULL THAT. WE WANT TO COME UP WITH SOPHISTICATED AND NOVEL WAYS OF ENGAGING INDUSTRY IN STEM CELL RESEARCH.

AND THEN, LASTLY, CENTERS AROUND LEVEL. AND THAT HAS TO DO WITH THE INCONSISTENCIES THAT EXIST CURRENTLY IN THE REGULATORY PARADIGM FOR CELL THERAPY AND HOW DO WE CREATE A MORE CONSISTENT AND LEVEL PLAYING FIELD THAT WILL DERISK THE FIELD AND HELP DRIVE THE TECHNOLOGY FORWARD.

WE LAID OUT VERY OBJECTIVE GOALS IN OUR STRATEGIC PLAN. AND SO THE GOOD NEWS AND THE BAD NEWS IS WE WILL KNOW FULLY WHETHER WE HIT THESE IN 2020. JUST TO REVIEW WHAT THEY ARE, 50 NEW CANDIDATES INTO DEVELOPMENT. WE'RE GOING TO INCREASE PROGRESSION EVENTS. THAT'S SOMETHING FOR MOVING FROM ONE STAGE OF CIRM TO THE NEXT STAGE OF CIRM. WE'RE GOING TO INCREASE THOSE BY 50 PERCENT. WE WANT TO REFINE THE REGULATORY PARADIGM, AND WE'RE DOING THAT IN A NUMBER OF DIFFERENT WAYS WORKING WITH FDA AND OTHER STAKEHOLDERS. WE WANT TO REDUCE THE TIME IT TAKES FOR TRANSLATION. THAT'S THE TIME FROM WHEN AN INDIVIDUAL PRODUCT CANDIDATE IS DISCOVERED TO THE TIME IT ENTERS CLINICAL TRIALS. FOR THE WORLD OUTSIDE OF STEM CELL THERAPY, THAT TIME IS 3.2 YEARS. FOR STEM CELL THERAPIES, IT'S EIGHT YEARS. AND SO WE'VE GOT TO BE ABLE TO PULL THAT DOWN. WE'RE LOOKING TO CUT THAT TIME IN HALF AND BRING THAT DOWN FROM EIGHT YEARS TO FOUR YEARS.

VERY IMPORTANTLY, AND THE ONE THAT'S PROBABLY TALKED ABOUT MOST, IS WE'RE GOING TO ADD 50 NEW CLINICAL TRIALS OVER THE NEXT FIVE YEARS. THAT WOULD GIVE US 65 TOTAL BY 2020.

AND THAN, LASTLY, THIS GOES TO THE PULL ASPECT OF OUR MISSION, WE WANT TO HELP OUR CLINICAL STAGE PROGRAMS GET PARTNERS. SO WE WANT AT LEAST HALF OF OUR CLINICAL STAGE PROGRAMS PARTNERED BY THE TIME THAT THEY LEAVE CIRM.

SO WE'VE LAID OUT THESE VERY OBJECTIVE GOALS. THE REASON I BRING THEM UP AND I'LL CONTINUE TO BRING THEM UP IS THEY ARE DIFFICULT AND THEY ARE CHALLENGING. IF WE DO NOT KEEP THEM SQUARELY IN MIND AND AHEAD OF US, WE WON'T BY CHANCE RUN INTO THEM. WE HAVE TO DRIVE TOWARDS THESE GOALS. WE HAVE TO MEASURE OURSELVES AGAINST THESE GOALS. WE HAVE TO COURSE-CORRECT WHERE IT IS NECESSARY AND ALWAYS STAY FOCUSED ON THESE THINGS IF WE WANT TO HIT THEM. WE DO WANT TO HIT THEM. WE'RE GOING TO BE THE STATE AGENCY THAT SAYS WE'RE GOING TO DO SOMETHING AND THEN ACTUALLY GOES AHEAD AND DOES IT.

OKAY. NEXT, BUDGET REVIEW. SO IF YOU THINK ABOUT THAT STRATEGIC PLAN AND THOSE BIG SIX AS THE DESTINATION OF WHERE WE'RE GOING ON THIS BEAUTIFUL PLANE RIDE WE'RE ON, THE BUDGET WOULD BE

OUR FUEL. AND SO IT'S VERY, VERY IMPORTANT THAT WE KEEP AN EYE ON OUR BUDGET AS WE GO ON THIS JOURNEY TO MAKE SURE WE DON'T END UP JUST SHORT OF OUR DESTINATION.

SO, AGAIN, FOR CLARITY PURPOSES, YOU CAN THINK OF CIRM, I KNOW A LOT OF PEOPLE LIKE TO CALL IT THE $3 BILLION AGENCY, BUT FOR REAL, PRACTICAL PURPOSES, WE HAVE TWO BUDGETS AT CIRM THAT DON'T MIX, CAN'T CROSS, CAN'T COMMINGLE. FIRST IS THE AWARD BUCKET. THAT'S THE LARGER OF THE TWO. $2.75 BILLION APPROXIMATELY WENT INTO THAT AWARD BUCKET FOR US TO DISTRIBUTE AWARDS. SO EVERY TIME WE APPROVE GRANTS AND THE LIKE, IT COMES OUT OF THE AWARD BUCKET.

THE OTHER ASPECT WE HAVE IS THE ADMINISTRATIVE BUCKET. THAT'S THE AMOUNT OF MONEY THAT WE HAVE IN ORDER TO RUN CIRM OPERATIONALLY ON A DAY-TO-DAY BASIS. SO TO HOLD REVIEWS AND TO HOLD ALL OF THE FUNCTIONS THAT WE DO INSIDE CIRM ONLY EXCLUSIVELY COMES OUT OF THAT ADMINISTRATION BUDGET. AGAIN, THESE TWO BUCKETS CAN'T CROSS AND THEY ARE FIXED. SO WE ARE BY PROPOSITION 71 CAPPED AT THAT $180 MILLION UNLESS, OF COURSE, AS J.T. IS WORKING ON, HE CAN FIND PHILANTHROPIC SOURCES TO AUGMENT THAT, BUT WE CAN'T TAKE ANY MONEY OUT OF THE 2.75

BILLION AND USE IT TO RECHARGE THE 180 MILLION. AND I'LL TALK A LITTLE BIT ABOUT WHY THAT BECOMES IMPORTANT.

SO WHERE ARE WE? WE MEASURE AND WE KEEP TRACK OF BOTH OF THESE BUDGETS ON A VERY TIGHT BASIS. AND SO WE MODELED OUT WHAT WE NEED TO DO IN ORDER TO HIT OUR GOALS THROUGH 2020. CHILA AND I DO THIS, AND SO SHE'LL BE TALKING ABOUT THE BUDGET LATER ON TODAY. BUT WE HAVE THIS RIGHT NOW DOWN TO PLUS OR MINUS A FEW MONTHS ON EITHER SIDE ALL THE WAY THROUGH 2020.

WE'VE SPENT 115 OF THE 180. WE HAVE 65 MILLION LEFT. WE HAVE ABOUT A $16 MILLION BURN RATE OUT OF THIS BUCKET, BUT THIS IS SOMETHING WE HAVE TO KEEP TRACK OF, AND WE HAVE TO CONTINUALLY UPDATE AND ITERATE AS WE MOVE FORWARD TO MAKE SURE WE HAVE SUFFICIENT FUNDING TO AWARD ALL OF THE FUNDS THAT EXIST IN THE LARGE BUCKET.

TURNING TO LOOK AT THE LARGE BUCKET, WE HAVE I WOULD USE THE WORD "COMMITTED," WHICH IS EITHER AWARDED OR SPENT, 2.06 BILLION OF THE 2.75 BILLION. SO THAT GIVES US $686 MILLION THAT'S UNCOMMITTED THAT WE WILL BE EXECUTING THE REMAINDER OF OUR PLAN ON. THE PLANNED BURN IS APPROXIMATELY, IN ROUND NUMBERS, $170 MILLION A YEAR OF NET BURN

RATE. THIS WOULD ON AVERAGE EQUATE TO ABOUT $190 MILLION IN NEW AWARDS EACH YEAR AND A RETURN RATE OF 10, 10.5 PERCENT OR 20 MILLION OF THAT WOULD COME BACK.

SO SOMETIMES WHEN WE ISSUE AWARDS, AS YOU GUYS KNOW, WE'VE GONE TO MILESTONE-BASED AWARDS, AND CONTINUATION OF AN AWARD IS DEPENDENT UPON SUCCESS. SOMETIMES THE WAY IT WORKS IN BIOTECH IS YOU'LL GET INTO SOMETHING AND IT WON'T WORK. WE'VE HAD THIS HAPPEN A NUMBER OF TIMES. PERHAPS A TRIAL IS STOPPED FOR FUTILITY OR AN EXPERIMENT JUST DOESN'T SHOW THE RESULTS WARRANTED TO GO TO THE NEXT STAGE OF DEVELOPMENT. WHEN THAT HAPPENS, WE DON'T JUST CONTINUALLY FUND THOSE AWARDS. THE AWARD ENDS AND THE REMAINING MONEY GETS RETURNED BACK TO CIRM AND GOES INTO THE UNCOMMITTED BUCKET.

WE PLANNED OUR BUDGET BASED ON A RETURN RATE OF ABOUT 10, 10.5 PERCENT. THAT'S WHAT WE'RE FORECASTING HERE. WHY THAT'S IMPORTANT IS IF OUR RECOVERY RATE IS HIGHER THAN THAT, THEN WE WILL HAVE MORE MONEY TO RE-AWARD IN THE BIG BUCKET. THAT SOUNDS LIKE A GOOD IDEA, AND THAT IS A GOOD IDEA. IT'S RESPONSIBLE. IT'S THE WAY WE SHOULD BE BEHAVING USING THE TAXPAYERS' MONEY EFFICIENTLY. AND IF SOMETHING IS NOT WORKING, LET'S GET IT BACK

INTO CIRM AND GET IT REDEPLOYED ON THE NEXT TECHNOLOGY.

THE PROBLEM WE HAVE WITH THAT IS WE DON'T GET ANY MORE LITTLE BUCKET MONEY TO REDEPLOY THAT MONEY THAT WE BROUGHT BACK IN. WHY IS THAT IMPORTANT? GO TO THIS SLIDE. SO THIS IS NOW HOW THINGS ARE WORKING. I'VE SIMPLIFIED THIS GRAPHIC A LITTLE BIT FROM THE LAST TIME. THIS IS HOW MONEY IS FLOWING BETWEEN THE UNCOMMITTED AND THE COMMITTED PORTIONS OF THE BIG BUCKET. SO WE HAVE $686 MILLION UNCOMMITTED. SO THROUGH THE FIRST THREE QUARTERS OF 2016, WE'VE MADE $128 MILLION IN NEW AWARDS. THAT'S GONE. WE'VE COMMITTED. BUT DURING THAT SAME PERIOD OF TIME, WE'VE HAD $39 MILLION IN REDUCTIONS OR REPAYMENTS OF AWARDS THAT HAVE COME BACK FROM THE COMMITTED BACK TO THE UNCOMMITTED AMOUNT. SO WE'VE ONLY HAD A NET MOVEMENT INTO THE COMMITTED BUCKET OF $89 MILLION. THAT REPRESENTS A 30-PERCENT RECOVERY RATE ON OUR NEW AWARDS. AGAIN, WE MODELED FOR TEN AND A HALF. AND SO RIGHT NOW WE ARE RECOVERING MORE.

AGAIN, THAT IN AND OF ITSELF ISN'T A BAD THING. WE'RE RECAPTURING THAT MONEY AND WE'RE PUTTING IT BACK TO WORK ON MORE PROMISING TECHNOLOGIES; BUT IT DOES SUGGEST THAT IF THIS

CONTINUES, WE'RE GOING TO HAVE MORE MONEY TO AWARD OVER TIME THAN WE HAVE MONEY IN OUR LITTLE BUCKET TO SUSTAIN THOSE AWARDS. JUST TO SHOW YOU --

DR. MINOR: RANDY, DO YOU HAVE A SENSE AS TO -- I MEAN A 30-PERCENT RETURN RATE SOUNDS PRETTY HIGH. AND AS YOU LOOK BACK AT THE BUDGETS THAT WERE ORIGINALLY SUBMITTED WITH THOSE AWARDS, DO YOU HAVE A SENSE AS TO WHAT ARE THE MAJOR BUCKETS OR CATEGORIES THAT ARE LEADING TO THE HIGH RETURN RATE? AND MIGHT THAT THEN TRANSLATE INTO UPFRONT ADDITIONAL SCRUTINY OF THE BUDGETS AT THE TIME THEY'RE BEING REVIEWED?

DR. MILLS: IT'S NOT A RESULT OF A BUDGET OVERRUN TYPE OF SITUATION. REALLY WHERE IT'S COMING OUT OF -- SOMETIMES IT'S ACTUALLY GOOD EVENTS THAT LEAD US TO THIS, SOMETIMES IT'S BAD EVENTS. SO EARLIER THIS YEAR A MAJOR PART OF THIS $39 MILLION WAS WE HAD MADE A COMMITMENT TO FUND A PHASE III PIVOTAL CLINICAL TRIAL IN MELANOMA AND WE HAD MADE A $20 MILLION AWARD ON THAT. THEY ONLY GOT $3 MILLION INTO THAT AWARD WHEN THE TRIAL WAS TERMINATED FOR FUTILITY. SO THAT $17 MILLION CAME BACK, WHICH IS, AGAIN, GOOD AND RIGHT AND WHAT SHOULD HAPPEN. THAT'S GOING TO HAPPEN. TRIALS ARE NOT GOING TO WORK. SOMETIMES, AND WE HAD A VERY POSITIVE EXAMPLE

ACTUALLY HAPPEN OUT OF STANFORD, WE'VE GOT SOME OF OUR TECHNOLOGY OUT OF THE NEST TO INDUSTRY AND FORMED A COMPANY, SOMETHING WE'RE VERY PROUD TO BE INVOLVED WITH OUT OF STANFORD. IT'S A VERY EXCITING COMPANY. BUT THAT RESULTED IN THE UNDERLYING AWARD BEING TERMINATED. SO THAT MONEY CAME BACK.

SO THERE'S A LOT OF DIFFERENT REASONS THAT CAUSE THAT GREEN LINE, THAT AMOUNT OF MONEY COMING BACK, BUT IT'S SOMETHING TO BE AWARE OF. BECAUSE IF WE COULDN'T DO THIS PROJECTION, WE SHOULD BE SHOT. WHEN WE LOOK AT FULL YEAR, AND WE'RE TALKING HERE FULL YEAR THROUGH THE FISCAL YEAR, WE'RE GOING TO TRY TO CHANGE AWAY FROM DOING FISCAL AND GO MORE TO REPORTING ON A CALENDAR YEAR BECAUSE IT'S EASIER TO KEEP STRAIGHT.

BUT IF WE LOOK THROUGH THE REMAINDER OF THE MONTH WHAT WE EXPECT TO HAVE IN BOTH DIRECTIONS, WE EXPECT TO HAVE ABOUT $155 MILLION IN NEW AWARDS. SO THE AWARD ACTIVITY ISN'T QUITE WHERE WE WANTED IT TO BE, BUT IT'S UP THERE. IT'S PRETTY HIGH. AGAIN, WE'RE STILL LOOKING AT 46 MILLION IN REDUCTIONS AND REPAYMENTS THROUGH THE YEAR. SO STILL OR NEARLY 30, IT'S 29 PERCENT RECAPTURE RATE, WHICH GIVES US ABOUT A NET OF $109 MILLION NET MOVING FORWARD. IT'S JUST SOMETHING TO BE AWARE OF.

THE GOOD NEWS IS IT GIVES US MORE OPPORTUNITIES TO MAKE MORE AWARDS. BUT WE'D LIKE OUR AWARD MONEY TO GO OUT AND STAY OUT AND BE SUCCESSFUL AS OPPOSED TO COME BACK AND GET REDEPLOYED.

NEXT I WANT TO TALK ABOUT CIRM 2.0 PERFORMANCE. WE WON'T TRIP INTO BEING GREAT. WE NEED TO LOOK AT IT VERY OBJECTIVELY AND VERY CLEARLY AND SEE WHAT'S WORKING AND NOT WORKING AND COURSE-CORRECT AS NECESSARY. THAT'S SOMETHING I PROMISED TO YOU, THE BOARD, I WOULD DO AND CONTINUE TO DO AS WE IMPLEMENTED THIS.

SO, FIRST, THIS SOMEWHAT BUSY SLIDE IS STILL, I THINK, A VERY BEAUTIFUL THING THAT WE'VE CREATED. SO THIS IS NOW THE RECURRING VERSION OF CIRM THAT EXISTS. SO THESE PROGRAMS, AGAIN, ASSUMING THE BOARD CONTINUES TO ALLOCATE FUNDING TO THEM, WILL CONTINUE FOR THE NEXT FIVE YEARS. AND THEY COVER EVERY STAGE OF DEVELOPMENT FROM THE ABSOLUTE EARLIEST IDEA, SEED FUNDING, WE CALL THE INCEPTION AWARD OR DISC 1, THROUGH TRANSLATIONAL RESEARCH ALL THE WAY THROUGH CLINICAL RESEARCH. THESE PROGRAMS RUN NOW ON A SCHEDULE LIKE A TRAIN OR A PLANE. YOU KNOW WHEN THEY ARE.

SO WE OFFER THE EARLIEST SEED FUNDING ONCE

A YEAR. WE OFFER THE NEXT STAGE, THE DISCOVERY STAGE RESEARCH, TWICE A YEAR. WE OFFER TRANSLATIONAL NOW THREE TIMES A YEAR, AND WE OFFER THE CLINICAL APPLICATIONS 12 TIMES A YEAR.

SO THIS IS NOW ALL UP AND RUNNING. I'M VERY EXCITED TO SAY YESTERDAY WE HELD OUR REVIEWS FOR THE DISC2 AND DISC3 APPLICATIONS THAT WERE THE LAST TWO TO COME ONLINE, AND SO WE HAD THOSE REVIEWS. THEY'RE SUCCESSFUL. SO NOW EVERY PROGRAM YOU SEE UP HERE IS ACTUALLY RUNNING AND IN PROGRESS. I WOULD GO BACK TO MY AIRPLANE ANALOGY. THE ENGINE IS UP AND RUNNING, AND SO WE'RE VERY EXCITED ABOUT THAT.

AS WE LOOK AT HOW THIS IS GOING THROUGH THE DISCOVERY, TRANSLATIONAL, AND CLINICAL, AND THIS IS IN TERMS OF US BEING ABLE TO MAKE AWARDS, WE'RE ON TARGET IN THE DISCOVERY STAGE RESEARCH. WE'RE RUNNING AT ABOUT A $45 MILLION RUN RATE IN MAKING AWARDS. THIS WAS AGAINST ABOUT A $53 MILLION PROJECTION FOR THIS YEAR.

IN TRANSLATION WE'RE ACTUALLY HIGH. WE'RE GOING TO ISSUE PROBABLY 55-ISH MILLION IN AWARDS THIS YEAR VERSUS A TARGET OF 45. SO WE'RE ACTUALLY 10 MILLION OVER IN TRANSLATION. THAT'S BALANCED AGAINST WE'RE WAY LOW IN CLINICAL. SO WE'VE MADE

THREE CLIN1 AWARDS, WHICH ARE IND-ENABLING AWARDS, THIS YEAR. WE'VE ONLY MADE ONE CLIN2, WHICH IS A CLINICAL TRIAL AWARD. THAT GIVES US ABOUT $15.5 MILLION IN AWARDS THROUGH THE FIRST HALF OF THE YEAR. WE EXPECTED TO BE AT ABOUT 50. SO OUR RUN RATE THERE IS 35 VERSUS AN ANNUALIZED TARGET OF ABOUT A HUNDRED. BUT THE TEAM IS WORKING ON THAT, AND WE'RE GOING TO MOVE THAT ALONG.

JUST A LOOK AT THE CIRM 2.0 CLINICAL PERFORMANCE BECAUSE IT'S THE ONE WE HAVE THE MOST DATA ON WE CAN OBJECTIVELY LOOK AT AND SEE HOW IT'S RUNNING. IT'S BEEN UP AND RUNNING NOW FOR JUST ABOUT YEAR AND A HALF. WE'VE RECEIVED A TOTAL 42 APPLICATIONS. TWENTY-NINE OF THOSE 42 PASSED ELIGIBILITY. SO OFTENTIMES WE'LL GET AN APPLICATION AND THERE WILL BE JUST SOMETHING WRONG ABOUT IT OR IT WILL BE OUT OF SCOPE OR IT'S NOT ELIGIBLE FOR A NUMBER OF DIFFERENT REASONS. SO 29 PASSED ELIGIBILITY.

OUT OF THOSE 29 WE HAVE FINAL DISPOSITIONS ON 25. DEPENDING ON HOW THE BOARD VOTES TODAY, WE'LL HAVE FINAL DISPOSITION ON 26. WE HAVE FOUR APPLICATIONS UNDER REVIEW WHICH WOULD DROP TO THREE IF THE BOARD APPROVES THE APPLICATION TODAY, WHICH GIVES US APPLICATIONS THAT HAVE BEEN FUNDED OF NINE

OR 36 PERCENT. AGAIN, IF TODAY'S APPLICATION IS FUNDED, THAT WILL GO TO TEN. IT'S ABOUT 38 PERCENT WHEN YOU MOVE THE NUMERATOR AND DENOMINATOR AROUND.

SO ON THE CLINICAL SIDE, WE DO HAVE VOLUME THAT WE'VE HAD RUN THROUGH HERE. THE PROCESS IS WORKING FROM A TIME STANDPOINT THE WAY WE LIKE IT. AND WE ARE FUNDING A REASONABLE AMOUNT OF APPLICATIONS. WE ARE FUNDING 38 PERCENT OF THE APPLICATIONS THAT COME BEFORE US. A LOT OF THIS HAS TO DO, AND WE HAD A DISCUSSION ABOUT IT YESTERDAY, THE 1-2-3 SYSTEM OF REVIEW THAT WAS IMPLEMENTED WHERE, INSTEAD OF JUST SAYING SOMETHING CAN GET FUNDED OR NOT GET FUNDED, IT EITHER CAN GET FUNDED, GET A 1, IT CANNOT GET FUNDED AND DEFINITIVELY GET A 3, WHICH WE SET AS A SIX MONTHS DEFERRAL. GO MAKE YOUR APPLICATION BETTER, BUT TAKE SOME TIME DOING IT. OR THE CATEGORY WHICH HAS BEEN UTILIZED A LOT BY THE GWG, AND I THINK WE'RE MAKING BETTER APPLICATIONS OUT OF THIS, IS THE 2. AND THE 2, AGAIN, IS THE APPLICATION IS GOOD, WE LIKE IT, BUT IF WE WERE ABLE TO CHANGE THESE FEW THINGS, WE COULD TAKE THIS APPLICATION FROM A 75 TO A 95. AND THAT'S THE KIND OF THING THAT WE WANT TO DO. WE DON'T WANT TO JUST HAVE FUNDABLE APPLICATIONS. WE WANT TO HAVE A+ WORK. AND SO THAT'S THE 2 CATEGORY.

AND THAT 2 CATEGORY HAS RESULTED IN BASICALLY THE SALVAGE OF A LOT OF GOOD APPLICATIONS THAT OTHERWISE MIGHT HAVE NOT BEEN FUNDED BECAUSE THEY WEREN'T QUITE READY FOR PRIME TIME. SO ALL IN ALL IT SEEMS TO BE WORKING REASONABLY WELL. WE KEEP LOOKING FOR WAYS TO GET BETTER, AND THERE ARE PLENTY AND WE'RE WORKING ON THAT.

OKAY. NEXT TOPIC, I'D LIKE TO TALK ABOUT A PROPOSAL WE HAVE FOR GOING TO ANNUALIZED BUDGETING. AND THIS IS REALLY NOW THAT WE HAVE A STRATEGIC PLAN AND WE HAVE THIS CIRM 2.0 MACHINE IN PLACE WHICH IS RECURRING, HOW DO WE THEN FROM A BUDGET STANDPOINT MANAGE THAT? HOW DO WE FROM A STRATEGIC PLAN STANDPOINT MAKE SURE THAT WE'RE REVIEWING OUR PERFORMANCE, WE'RE COURSE-CORRECTING, AND WE'RE REBUDGETING IN A WAY THAT GIVES US THE GREATEST CHANCE OF SUCCESS? SO WHAT I'M GOING TO PROPOSE HERE IS BY NO MEANS NOVEL. IT'S JUST SOMETHING THAT IT'S TIME THAT WE IMPLEMENT HERE AT CIRM.

SO THIS IS BASICALLY THE PROPOSAL IN A NUTSHELL IS EVERY DECEMBER AT THE ICOC MEETING WE WOULD CONDUCT A REVIEW OF CIRM'S ACTUAL PERFORMANCE FOR THAT YEAR. THE REASON WE CAN DO IT IN DECEMBER IS THAT WILL BE THE LAST MEETING AT WHICH ANYTHING

CAN GET APPROVED, SO WE WILL KNOW ALL OF THE AWARDS THAT WILL BE APPROVED, WE WILL KNOW ALL OF THE FUNDING THAT WE WERE ABLE TO LAY OUT, WE WILL KNOW ALL OF THE RETURNS THAT HAVE COME IN. AND WE CAN TAKE THAT PERFORMANCE AND WE CAN BENCHMARK IT AGAINST THE STRATEGIC PLAN AND LOOK AT IT AND SAY, THIS WAS WORKING WELL, THIS WASN'T WORKING AS WELL, THIS IS WHERE WE NEED TO FIX, AND MAKE THESE COURSE CORRECTIONS OR CHANGES AS NECESSARY.

SO ONCE WE HAVE THAT OBJECTIVE DATA ON OUR PERFORMANCE FOR THE PREVIOUS YEAR, ACTUALLY FOR THE END OF THAT CURRENT YEAR, WE CAN THEN USE THAT INFORMATION TO REBALANCE THE BUDGET GOING FORWARD FOR THE NEXT YEAR. SO IN JUST PRACTICAL EXAMPLES, THE END OF THIS YEAR IN DECEMBER 2016, WE WOULD LOOK AT OUR ACTUAL PERFORMANCE, HOW MUCH MONEY WE SPENT IN EACH OF THESE DIFFERENT BUCKETS, DISCOVERY, TRANSLATIONAL, AND CLINICAL, FIGURE OUT WHICH AREAS WE WANTED TO EMPHASIZE MORE OF AND DE-EMPHASIZE LESS OF, WHICH AREAS WE SPENT OVER IN, WHICH AREAS WE SPENT UNDER IN, AND THEN REBALANCE THAT.

NOW, ONE OF THE REASONS WE PICKED DECEMBER IS BECAUSE IT'S NICE, EASY ROUND NUMBERS. PEOPLE CAN THINK IN CALENDAR YEARS. BUT THE OTHER ONE IS IN DECEMBER THIS YEAR, AND WE CAN MAKE SURE THIS

CONTINUES TO HAPPEN GOING FORWARD, WE HAVE A SITUATION WHERE THE BOARD IS ACTUALLY IN ITS BASICALLY LEAST CONFLICTED WINDOW. WHAT I MEAN BY THAT IS WE WON'T HAVE ANY PENDING APPLICATIONS IN FRONT OF THE BOARD EXCEPT FOR MAYBE A CLIN APPLICATION, BUT THAT'S KIND OF A HIT OR A MISS THING, BUT WE WON'T HAVE ANY OF THE MAJOR ONES THAT TEND TO KNOCK OUT OUR ACADEMIC MEMBERS OF THE BOARD IN CONFLICT. SO WE WON'T HAVE A DISCOVERY APPLICATION IN FRONT US, WE WON'T HAVE A TRANSLATIONAL. THAT WILL ALLOW NEARLY FULL BOARD PARTICIPATION IN THE REBALANCING AND THE REBUDGET THAT WOULDN'T BE ABLE TO HAPPEN AT OTHER TIMES OF THE YEAR BECAUSE WE HAVE A PROPOSAL IN FRONT OF YOU, AN INSTITUTION HAS AN APPLICATION IN FRONT OF US, THEN YOU HAVE TO RECUSE YOURSELF FROM PARTICIPATING IN THOSE DECISIONS. SO WE'RE LOOKING FOR A TIME WHERE WE CAN GET MAXIMUM BOARD PARTICIPATION IN THIS.

AND SO WE WOULD GO THROUGH THAT. AS A FULL BOARD, THEN WE WOULD SET THAT BUDGET. WE WOULD THEN, BECAUSE WE WOULD OBVIOUSLY BE ABLE TO SEE THIS COMING, WE WOULD THEN ISSUE JANUARY 1ST, LET'S JUST CALL IT EARLY JANUARY, AN ANNUAL REPORT OUT TO EVERYBODY, ALL OF THE STAKEHOLDERS, THE PUBLIC,

EVERYONE ELSE, DESCRIBING WHAT WE HAD ACCOMPLISHED THE YEAR BEFORE, WHAT WE'VE REBALANCED THE BUDGET FOR GOING FORWARD, AND HOW WE'RE DOING WITH REGARDS TO THE STRATEGIC PLAN SO THAT WE NEVER EVER LOSE FOCUS ON WHERE WE'RE TRYING TO GO. EVERYTHING IS BEING MEASURED AGAINST THE ULTIMATE DESTINATION.

JUST REAL QUICK EXAMPLE ON WHAT THIS MIGHT LOOK LIKE. LET'S JUST SAY WE HAVE 2016. THIS IS WHAT WE PUT IN THE STRATEGIC PLAN AS HOW THESE DIFFERENT CATEGORIES MIGHT BE BALANCED. WE MIGHT COME ALONG IN 2016 AND SAY IT DIDN'T QUITE WORK OUT THAT WAY. WE UNDERSPENT MAYBE -- OVERSPENT IN DISCOVERY. IT WAS 15, WE SPENT 40. AND IN CLINICAL, INSTEAD OF 90, WE SPENT 75. SO THOSE ARE THE ACTUALS AS THEY CAME IN. WE WOULD THEN SAY, OKAY, BASED ON WHAT WE WANT AND WHAT WE SEE AND WHAT WE IMAGINE WILL HAPPEN, WE'RE GOING TO CHANGE 2017 TO REBALANCE MORE LIKE THIS. I'M USING THIS EXAMPLE JUST REALLY SORT OF HIGH LEVEL, BUT THE CONCEPT IS WE WOULD BE REBALANCING BETWEEN THE DISCOVERY, TRANSLATIONAL, AND CLINICAL BUCKETS.

REALLY EDUCATION AND INFRASTRUCTURE ARE SOMEWHAT LOCKED IN ALREADY. EDUCATION ACTUALLY IS LOCKED IN THROUGH THE REMAINDER OF 2020. AND OTHER THAN THE ATP3 CONCEPT PLAN WHICH HAS GONE THROUGH,

THERE REALLY ISN'T ANYTHING LEFT TO REBALANCE ON INFRASTRUCTURE. BETWEEN DISCOVERY, TRANSLATION, AND CLINICAL, WE WOULD BE MAKING THESE REBALANCING DECISIONS ON DO WE WANT TO GO MORE EARLY STAGE, WE WANT TO GO MORE LATE STAGE, AND THE LIKE.

SO TO GET JUST A LITTLE BIT MORE INTO DETAIL AND TO GET YOU THINKING, BASICALLY WHAT WE WOULD BE DOING IS WE WOULD BE SPECIFYING THE NUMBER OF CYCLES THAT ANY PARTICULAR PROGRAM WOULD HAVE. FOR EXAMPLE, WE WOULD SAY WE'RE GOING TO HAVE 12 CLINICAL CYCLES THIS YEAR. IT'S WHAT WE RUN AT RIGHT NOW, ONE EVERY SINGLE MONTH. FOR THE CLINICAL BUDGET, BECAUSE WE RUN EVERY SINGLE MONTH, WE WOULD PUT IN AN ANNUALIZED BUDGET. SO WE WOULD SAY WE WANT TO HAVE 12 CLINICAL CYCLES IN THE CALENDAR YEAR 2017 NOT TO EXCEED $100 MILLION IN AWARDS.

FOR TRANS AND DISC, IT'S A LITTLE DIFFERENT BECAUSE THERE WE WOULD PUT IN PER-CYCLE BUDGETS. SO WE SAY WE WANT TO HAVE THREE TRANSLATIONAL REVIEWS IN 2017 WITH MAXIMUM AWARDS PER CYCLE OF $15 MILLION A CYCLE. SO THAT WAY THE BOARD IS PARTICIPATING IN -- THE FULL BOARD IS GETTING TO PARTICIPATE IN THE AMOUNTS OF MONEY THAT CAN BE SPENT SPECIFICALLY ON EACH OF THESE DIFFERENT PROGRAMS AND EACH OF THESE DIFFERENT REVIEW CYCLES

WHERE THEN THE APPLICATION REVIEW SUBCOMMITTEE THEN GOES ON AND ACTUALLY MAKES THE FINAL DECISION ON WHAT TO FUND WITHIN THERE.

THAT'S WHAT I HAVE ON THIS. THE IDEA, AGAIN, WASN'T TO GO INTO EXCRUCIATING DETAIL ON THIS, BUT TO GIVE YOU A THUMBNAIL SKETCH OF WHAT WE'RE THINKING AND PROPOSING. SO NOW OR ANY TIME AFTER OR DURING THE MEETING OR LATER ON FEEL FREE TO COME UP AND TALK TO US. PLEASE GIVE US FEEDBACK ON THIS, WHAT YOU LIKE, WHAT YOU DON'T LIKE, OTHER IDEAS AND THE LIKE.

MR. SHEEHY: I JUST HAVE A COUPLE OF QUESTIONS. I DON'T MEAN TO INTERRUPT YOU. SORRY. SO MY MEMORY, I CAN'T QUITE REMEMBER. I SAW IN THE INFRASTRUCTURE, SO THERE'S 15 WHICH IS THE ACCELERATING CENTER WE'RE GOING TO TALK ABOUT TODAY THIS YEAR AND THEN 15 NEXT YEAR, WHICH WILL BE THE TRANSLATION CENTER, AND THEN 2018 THERE WERE $20 MILLION, AND I CAN'T REMEMBER WHAT THAT WAS FOR.

DR. MILLS: WE'RE HOLDING ANOTHER BIT OF MONEY OUT IN INFRASTRUCTURE FOR THE POTENTIAL REINTRODUCTION OF ADDITIONAL ALPHA CLINIC CENTERS.

MR. SHEEHY: GREAT. GREAT. WE'LL HAVE A LOT OF DATA BY THAT POINT, I ASSUME. GREAT JOB.

DR. MILLS: TO THE EXTENT WE'RE READY TO

DO THAT, THAT WOULD GET PULLED FORWARD. WE WOULDN'T HAVE TO PUT THAT MONEY THAT FAR OUT.

MR. SHEEHY: GREAT. AND THEN WILL WE HAVE A COUPLE OF TRANSLATION AND DISCOVERY CYCLES BEFORE WE START -- I JUST WONDER IF THERE'S A LITTLE PENT-UP DEMAND. FOR INSTANCE, WHEN WE LOOK AT THE TRANSLATION THAT WAS OVERBUDGET, ONE CAN ASSUME THAT, ONE CAN THINK THAT MAYBE THAT WAS PENT-UP DEMAND BECAUSE WE HADN'T DONE IT IN A WHILE, OR MAYBE THAT'S A PLACE WHERE WE NEED TO METER IT OUT MORE DELIBERATELY.

SO I GUESS I WONDER ABOUT HAVING THE CYCLES TIED TO 15 MILLION BECAUSE THOSE WOULD BE PRETTY MUCH HANDCUFFS, RIGHT? IF WE DID 15 MILLION IN A CYCLE AND WE HAD $20 MILLION IN PROJECTS THAT WERE IN THE FUNDABLE RANGE, THE BOARD WOULD HAVE, WHICH I THINK IS GOOD DISCIPLINE, BUT WE'D BE IN A POSITION WHERE WE'D HAVE TO DECIDE WHICH OF THE PROJECTS TO MOVE FORWARD THAT ADDED UP TO 15 MILLION. WE COULDN'T DO WHAT WE'VE BEEN DOING IN THE PAST AND PRETEND LIKE WE HAD LIMITLESS MONEY AND WE'LL JUST DO 20 MILLION AND WE'LL FIND IT DOWN THE ROAD. THAT IS THE CONCEPT THERE, RIGHT?

DR. MILLS: CORRECT.

MR. SHEEHY: THANK YOU. I JUST WANTED TO

GET SOME CLARIFICATION.

DR. BRENNER: COULD YOU SAY A FEW WORDS ABOUT HOW WE CAN HELP, HOW CIRM CAN HELP PARTNERSHIPS BETWEEN COMPANIES AND ACADEMIC RESEARCHERS TO TRY TO HELP TO ADVANCE THE CLINICAL TRIALS?

DR. MILLS: SURE. SO WE ACTUALLY DEAL WITH THAT ON A NUMBER OF FRONTS. ONE IS WE HAVE A BUSINESS DEVELOPMENT OFFICER WHO SPENDS A LOT OF THEIR TIME DIRECTLY TRYING TO ENGAGE IN THOSE PARTNERSHIPS. ANOTHER THING WE DO IS WE HAVE A LEGAL TEAM THAT IS IMPORTANT BECAUSE WE'RE NOT AN AGENCY THAT COMES WITH NO STRINGS ATTACHED. WE HAVE REQUIREMENTS THAT ARE STATUTORILY MANDATED TO US, IP, ACCESS, PRICING, ALL OF THOSE OTHER THINGS THAT CAN SOMETIMES MAKE THIS ROAD TO PARTNERSHIP DIFFICULT TO NAVIGATE.

SO JAMES AND HIS LEGAL TEAM HAVE ACTUALLY TAKEN THAT ON STRAIGHT ON AND ARE HELPING NAVIGATE THOSE. WE HOLD DIFFERENT EVENTS WHERE WE BRING TOGETHER CIRM UNPARTNERED TECHNOLOGY TO PRESENT IN FRONT OF VC'S AND OTHER COMPANIES THAT MIGHT BE INTERESTED IN MAKING THOSE INVESTMENTS. SO WE DO A NUMBER OF DIFFERENT THINGS LIKE THAT THROUGHOUT THE YEAR.

THE BIG ONE WE HAVE COMING, IF WE'RE SUCCESSFUL, WILL BE ATP3, WHICH IS WE'RE GOING TO TRY TO AGGREGATE A LOT OF THAT TECHNOLOGY AND GET IT PAIRED UP.

SO LASTLY, WANT TO TALK ABOUT OBJECTIVITY AND WHAT I MEAN BY THAT. SO CIRM HAS BEEN DOING REALLY EVERYTHING IT CAN TO DRIVE HOME A COUPLE OF PRINCIPLES ON WHICH IT OPERATES. ONE IS WE WANT TO BE EXCELLENT IN WHAT WE DO. WE REALLY DO TRY TO LOOK AT THE INFORMATION THAT COMES TO US AND USE THAT INFORMATION TO PERFORM BETTER. THINK CREATIVELY, THINK OUTSIDE OF THE BOX, FIGURE OUT HOW WE CAN DO OUR JOBS IN THE MOST EFFECTIVE WAY POSSIBLE IN ORDER TO HIT OUR MISSION OF ACCELERATING STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS.

THROUGH THIS WE'VE IMPLEMENTED SOME PROCESS AND SOME DISCIPLINE. WE DO THIS BECAUSE WE WANT TO BE FAIR. WE DON'T WANT TO FAVOR ONE GROUP OR ONE INSTITUTION OVER ANOTHER. WE DON'T WANT TO BE -- FROM A TRANSPARENCY STANDPOINT, WE WANT PEOPLE TO UNDERSTAND WHY WE DO WHAT WE DO AND HAVE THAT, TO THE EXTENT IT'S POSSIBLE, OUT IN THE OPEN. THAT IS VERY IMPORTANT FOR US BECAUSE THAT INSTILLS CONFIDENCE IN THIS ORGANIZATION. WE WANT TO BE

CONSISTENT. SO WE TRY NOT TO MAKE ARBITRARY DECISIONS THAT CHANGE FROM DAY TO DAY.

LASTLY, WE WANT TO BE OBJECTIVE ABOUT THIS. I THINK WE'RE DOING A PRETTY GOOD JOB. I THINK WE'VE MADE TREMENDOUS PROGRESS. DOESN'T MEAN WE GET IT ALL RIGHT EVERY TIME. WE DON'T, BUT WE'RE DOING EVERYTHING WE CAN TO GET BETTER IN EACH OF THESE AREAS AS WE CAN. AND FOR THE MOST PART, THAT'S BEEN VERY WELL RECEIVED. THE WHOLE CONCEPT OF CIRM 2.0 AND MILESTONE-BASED AND PERFORMANCE-BASED CONTRACTS AND HAVING STRUCTURE AND SYSTEMS IN PLACE THAT PEOPLE CAN UNDERSTAND AND YOU DON'T NEED A DECODER RING OR YOU DON'T NEED TO KNOW SOMEBODY IN ORDER TO GET THIS THING TO WORK, YOU CAN JUST USE THE SYSTEM AS IT IS. AND IT'S WORKING.

BUT, AND HERE'S THE BUT, IT IS A BIG CHANGE FOR CIRM. CIRM WAS PRACTICED WITH A BIT MORE INFORMALITY IN THE PAST THAN THIS. AND THAT'S LEADING TO SOME FRUSTRATION AMONG, AGAIN, A SMALL NUMBER, BUT A SMALL NUMBER OF OUR APPLICANTS AND OUR AWARDEES. AND THERE ARE FOUR BASIC AREAS WHERE THIS COMES UP. THIS IS NOT NEW TO CIRM. THIS IS AS OLD AS TIME. IF YOUR APPLICATION GETS SUCCESSFULLY REVIEWED BY CIRM, YOU THINK WE HAVE THE BEST REVIEW TEAM THERE IS. IF IT DOESN'T, NOT SO MUCH.

THE REGULATIONS THAT WE HAVE, THIS IS ONE WHERE IT'S COME UP, WHY I BRING THIS UP, DR. BRENNER, WE'VE HAD PEOPLE GET VERY, VERY FRUSTRATED THAT WE DON'T EXEMPT THEIR GRANT OR THEIR APPLICATION OUT OF THE ACCESS OR PRICING OR IP PROVISIONS WE HAVE. WE HAVE NO ABILITY TO EXEMPT THEM OUT OF THOSE, BUT STILL IT'S A SOURCE OF FRUSTRATION.

SCOPE IS ANOTHER ONE. NOT ALWAYS, BUT SOMETIMES, WE HAVE PEOPLE COME TO US AND SAY, HEY, THE GWG REVIEWED A HUNDRED-PATIENT CLINICAL TRIAL FOR $20 MILLION AND THE BOARD REVIEWED THAT AND MADE THE DECISION TO FUND THAT $100 MILLION TRIAL. WE WANT TO CHANGE THAT AND ACTUALLY HAVE IT BE ONLY 20 PATIENTS, BUT WE STILL WANT THE $20 MILLION. SO THOSE KINDS OF SITUATIONS WE HAVE TO SAY NO, AND WE DO THAT TO BE CONSISTENT, AGAIN, WITH THE PROCESS, THAT WHAT WE IMPLEMENT IS WHAT THE GWG REVIEWED AND WHAT THE BOARD APPROVED. AND SO IF WE WERE TO MAKE THOSE KINDS OF CHANGES, THEN WE WOULD LOSE THAT FIDELITY WITH YOU. WE WOULD BASICALLY BE ABLE TO CIRCUMVENT THE BOARD. SO WE DON'T DO THAT. WE'LL SAY, NO, THAT'S NOT WHAT WE AGREED UPON. WE CAN SCALE IT, BUT WE CAN'T TRADE THESE TWO THINGS. THE EXAMPLE I USE IS WE CAN'T ORDER A WHOLE PIZZA, A GET

A FEW SLICES OF IT AND PAY FOR A WHOLE PIZZA.

AND THEN LASTLY, MILESTONES. WE'VE GONE TO OBJECTIVE MILESTONE-BASED ON REPORTING. WE DON'T MAKE THESE MILESTONES. THESE MILESTONES ARE PROPOSED BY THE APPLICANT. THEY ARE AGREED ON BY THE APPLICANT. SOMETIMES THEY DON'T HIT THOSE MILESTONES. AND WHEN AN AWARD IS CONTINGENT TO GO FROM MILESTONE A TO MILESTONE B AND MILESTONE B TO MILESTONE C AND YOU HAVE TO HIT B TO GO TO C, IF YOU DON'T HIT B, THEN THERE'S NO GOING ON WITH THAT BY VIRTUE OF THE CONTRACT THAT WE HAVE.

ANYWAY, SO THESE ARE FOUR AREAS WHERE THIS THEN CAUSES SOME FRUSTRATION. THE REASON I'M BRINGING IT UP, I'M NOT BRINGING IT UP TO COMPLAIN, I'M NOT BRINGING IT UP ANYTHING LIKE THAT. I'M BRINGING IT UP BECAUSE I DON'T WANT THERE TO BE ANY INFORMATION ASYMMETRY. SO IF YOU HEAR WE DON'T LIKE CIRM BECAUSE THEY MADE US DO X, Y, OR Z, THEY MADE US ADHERE TO THE ACCESS PROVISIONS, OR THEY HELD US TO OUR MILESTONES, TALK TO US. WE WILL TELL YOU WHETHER OR NOT WE LAID AN EGG, AND SOMETIMES WE DO. SOMETIMES IT'S US. BUT WE ALSO WANT TO MAKE SURE YOU UNDERSTAND SORT OF THE FULL PICTURE ABOUT ALL OF THAT. THAT'S THE ONLY PURPOSE OF THIS.

FOR THE MOST PART, AGAIN, ADDING THIS

STRUCTURE AND THIS PROCESS TO IT HAS BEEN VERY GOOD, BUT IT IS SUCH A DIFFERENCE, THAT IT IS CAUSING SOME FRUSTRATION AMONGST SOME OF OUR APPLICANTS. I WANT TO BRING IT UP BEFORE ANYONE ELSE.

THAT IS, MERCIFULLY, ALL I HAVE TODAY. IF ANYONE HAS ANY QUESTIONS, I'LL BE HAPPY TO RAMBLE ON.

DR. DULIEGE: FIRST OF ALL, RANDY, I MAY BE SPEAKING ON MORE THAN MYSELF, BUT JUST FOR MYSELF, I CAN'T TELL YOU HOW APPRECIATIVE I AM OF THE TRANSPARENCY THAT YOU ARE PROVIDING THIS PROCESS, INCLUDING ON THE BUDGET FRONT, BUT ALSO YOUR CONSTANTLY BEING WILLING TO REVISIT WHAT YOU AND THE CIRM HAVE DONE AND NOT SIMPLY JUST BE SATISFIED WITH THE PROGRESS MADE, GRANTED THAT THE PROGRESS HAVE ALREADY BEEN ENORMOUS. SO CONGRATULATIONS TO YOU. TRYING TO LOOK AT YOU AND SPEAK IN THE MICROPHONE AT THE SAME TIME. CONGRATULATIONS TO YOU AND TO THE TEAM FOR THAT.

A QUESTION THAT IS SOMEWHAT SEPARATE FROM WHAT YOU MENTIONED, SO IF IT'S NOT RELEVANT OR LATER YOU'LL TELL ME. LAST TIME WE SPOKE YOU MENTIONED THAT YOU ARE INTERESTED IN TRYING TO DEEPEN THE RELATIONSHIP OF THE CIRM WITH THE FDA OR DEEPEN. ANYTHING HAS HAPPENED THAT YOU WANT TO SHARE WITH

US?

DR. MILLS: SO ON THE FIRST COMMENT YOU MADE, THANK YOU VERY MUCH. FOR ME AND FOR THE CIRM TEAM, I CAN TELL YOU SUCCESS IS ACCOMPLISHING OUR MISSION, NOT MAKING IT LOOK LIKE WE ACCOMPLISHED OUR MISSION. SO THERE IS NO -- WE ARE GOING TO BE AS OBJECTIVE AND HONEST AND STRAIGHTFORWARD AS WE POSSIBLY CAN BECAUSE THAT'S THE ONLY WAY WE CAN OBJECTIVELY HIT OUR MISSION. AND THAT'S JUST HOW WE'RE GOING TO ROLL.

WITH REGARDS TO THE FDA, WHAT WE'RE DOING TODAY WITH THE ACCELERATING CENTER, AND I'LL TALK A LITTLE BIT MORE ABOUT THAT WITH GIL, IS THE FIRST STEP IN A PIECE, AGAIN, I'LL PUT MORE WORDS AROUND IT WHEN WE COME UP, FIRST STEP IN A PIECE THAT I THINK IS GOING TO BE TRANSFORMATIONAL WITH REGARDS TO OUR RELATIONSHIP WITH FDA, AND IN OUR PRELIMINARY DISCUSSIONS, IN A WAY FDA LOVES. SOMETIMES WE'LL GO AND TALK TO FDA AND WE'LL DISAGREE WITH THINGS, BUT THERE'S COMMON GROUND THERE TOO. THERE ARE FRUSTRATIONS THAT FDA HAS THAT WE MIGHT ALSO HAVE THAT WE FIX. AND THE ACCELERATING CENTER AND THE TRANSLATING CENTER REALLY COME OUT OF THE CONCEPT OF AN INTERESTING, NEW, AND NOVEL WAY IN ORDER TO FIX THAT.

AND SO WE HOPE TO GET MORE FORMAL PROGRESS ON THAT AS THE REST OF THE YEAR GOES AND WE MAKE THESE AWARDS AND WE GET THOSE TWO CENTERS IN PLACE, BUT THAT'S WHERE WE'RE GOING WITH THAT.

CHAIRMAN THOMAS: MR. SHEEHY.

MR. SHEEHY: I JUST WANT TO THANK YOU, DR. MILLS. THAT WAS AN OUTSTANDING PRESENTATION. I LIKE GETTING THORNS WITH THE ROSES. THAT'S REFRESHING, THAT YOU KIND OF PUT THE CAVEATS AT THE END.

I ALSO JUST REALLY WANT TO CONGRATULATE YOU AND THE WHOLE CIRM TEAM BECAUSE I KNOW HOW MUCH WORK YOU'VE PUT INTO IT AND WHAT TREMENDOUS EFFORT, AND IT'S JUST ASTONISHING WHAT YOU'RE ACCOMPLISHING. FROM A USER, BECAUSE BEING BOTH AS A BOARD MEMBER AND ON THE REVIEW TEAM, IT FEELS SEAMLESS, IT FEELS EASY, IT FEELS FUN. BUT I KNOW THAT THERE'S A LOT OF REALLY HARD WORK GOING ON BEHIND THAT, AND I REALLY WANT TO ACKNOWLEDGE THAT.

DR. MILLS: THANK YOU. I WILL JUST SAY, JEFF, AND FOR ALL THE BOARD AND PARTICULARLY THOSE THAT PRODUCE -- I THINK WE'RE GOING TO DO 22 REVIEWS THIS YEAR, SOME ENORMOUS NUMBER OF REVIEWS. IT'S GREAT TO BE JUST PART OF A TEAM. AND THAT'S WHAT I TELL YOU. I THINK IT FEELS LIKE WE HAVE AN ALIGNED

TEAM FROM THE BOARD TO THE LEADERSHIP TO THE INDIVIDUALS. SO THANK YOU. THANK YOU, GUYS.

MS. LANSING: I ACTUALLY WANT TO ECHO WHAT JEFF SAID. HAVING BEEN HERE FROM THE BEGINNING, THIS IS REALLY TO ME AND I THINK TO ALL OF US AROUND THE TABLE AND ALL THE PATIENTS, THIS IS ONE OF THE MOST EXCITING PRESENTATIONS THAT I'VE EVER HEARD. TO SEE WHERE WE STARTED AND TO SEE WHERE WE ARE TODAY IS TO SEE THE GOOD USE OF THE MONEY THAT THE VOTERS OF CALIFORNIA GAVE TO THE STEM CELL BOARD. AND TO SEE IT UNDER YOUR GUIDANCE AND HOW IT'S GETTING TO THE PATIENTS QUICKER, BUT IN NO WAY COMPROMISING THE QUALITY GIVES ME GREAT HOPE AS A PATIENT ADVOCATE.

DR. MILLS: THANK YOU.

MS. LANSING: THANK YOU TO YOU FOR YOUR EXTRAORDINARY LEADERSHIP FROM DAY ONE AND TO THE WHOLE TEAM, ALL OF WHOM I'M VERY GRATEFUL TO.

DR. MILLS: THE TEAM IS PHENOMENAL, AND WE COULDN'T DO WITHOUT THEM. AND I DO APPRECIATE THE POINT YOU MADE BECAUSE PARTICULARLY WHEN YOU HAVE NUMBERS THAT ARE DRIVING YOUR SUCCESS, THE ABSOLUTE THING WE CAN'T DO IS LOWER QUALITY IN ORDER TO HIT A NUMBER, AND WE'RE NOT. THE MEMBERS OF THE BOARD THAT ALSO SIT ON THE GWG WILL ATTEST TO THAT. BUT

IT'S VERY, VERY IMPORTANT THAT WE ALWAYS KEEP THAT QUALITY UP. AND THAT'S -- AGAIN, DON'T TELL THEM, BUT THE TEAM IS PHENOMENAL.

CHAIRMAN THOMAS: THANK YOU VERY MUCH, DR. MILLS. SO THIS IS A NICE SEGUE INTO THE -- BY THE WAY, WE'RE GOING TO SKIP ITEM 6. WE'RE GOING TO SEGUE INTO ITEM 7, WHICH IS THE DISCUSSION OF THE FIRST OF OUR THREE LEGS OF OUR MAJOR INFRASTRUCTURE PROGRAM THAT WE ARE PUTTING IN PLACE. THOSE THREE BEING THE ACCELERATING CENTER, THE TRANSLATING CENTER, AND ATP3. WE HAVE TODAY FOR THE BOARD'S CONSIDERATION A MOTION TO APPROVE AN APPLICATION FOR THE ACCELERATING CENTER, WHICH I THINK YOU WILL FIND MOST EXCITING. AND WITH THAT, I WILL TURN IT OVER TO DR. SAMBRANO. ARE WE GOING TO HAVE DR. MILLS FIRST AND THEN DR. SAMBRANO?

DR. MILLS: I'M SORRY. I DIDN'T KNOW I WOULD BE UP NEXT AGAIN. SO YOU HAVE A LITTLE BIT MORE OF ME AND THEN DR. SAMBRANO.

I WANT TO JUST GIVE AN INTRODUCTION HERE INTO THE ACCELERATING CENTER CONCEPT. REALLY WE'LL BE CALLED A PITCHING MACHINE, WHICH IS THE COMBINATION OF THE ACCELERATING CENTER AND THE TRANSLATIONAL CENTER WORKING TOGETHER TO SPEED THINGS THROUGH TRANSLATION, HELP US REDUCE THAT

TRANSLATIONAL TIME FROM EIGHT YEARS TO FOUR YEARS, AND HELP US GET CLINICAL TRIALS MORE SUCCESSFULLY DRIVEN DOWN THE ROAD.

THIS CAME OUT OF -- THE CONCEPT FOR THE ACCELERATING CENTER AND TRANSLATING CENTERS CAME OUT OF MEETINGS THAT WE HAD WITH ALL THE MAJOR INSTITUTIONS WITHIN CALIFORNIA. WE WENT OUT -- WHEN WE WERE COMING UP WITH THE STRATEGIC PLAN, WE WENT OUT AND WE MET WITH EVERY MAJOR INSTITUTION. WE WERE PITCHING OUT IDEAS, BUT I PROMISE WE WERE ALSO LISTENING VERY CAREFULLY TO ALL THAT. AND THE ONE THING THAT WE HEARD PRETTY CONSISTENTLY, AND I'VE PERSONALLY OBSERVED AS A GWG MEMBER, IS PARTICULARLY THE ACADEMIC INSTITUTIONS REALLY, REALLY, REALLY KNOW AND UNDERSTAND AND ARE GREAT AT THEIR SCIENCE, AT WHAT THEY DO. BUT WHEN YOU'RE GOING FROM TRANSLATION INTO CLINICAL, YOU PICK UP A REGULATORY COMPONENT THAT IS NEW TO THEM. AND WE WENT AND WE MET WITH EVERY SINGLE INSTITUTION. WE DIDN'T FIND, WITHOUT EXCEPTION, WE DIDN'T FIND ONE SINGLE PERSON AT ANY OF THESE INSTITUTIONS THAT WERE REALLY, REALLY ENTHUSIASTIC ABOUT CONDUCTING AN FDA-COMPLIANT STABILITY STUDY OR DOING SOME REALLY COOL GENE TOX. THEY LIKE DOING THE WORK THAT CENTERS AROUND THE RESEARCH THAT THEY'VE BEEN

WORKING ON.

AND THE ANALOGY -- SOMETIMES I'LL USE THE PHRASE "WHY WOULD YOU TEACH A FISH TO FLY? JUST HAVE A FISH SWIM." IF THEY CAN SHOW THAT MECHANISM AND THEY CAN SHOW THE EFFICACY OF THEIR CELLS IN DIFFERENT KINDS OF ANIMAL MODELS AND THE LIKE AND PROVE OUT THAT THE BASE TECHNOLOGY WORKS, WHY WOULD YOU HAVE THEM LEARN THE SYSTEM? SO THE LARGER ANALOGY HERE IS IF YOU WANTED TO GIVE A PRESENTATION IN NEW YORK AND SOMEBODY CAME UP TO YOU AND SAID, "WELL, THEN YOU BETTER START LEARNING HOW TO FLY A PLANE BECAUSE IT'S A REALLY LONG WAY TO NEW YORK." THERE ARE AIRLINES THAT GO BETWEEN HERE AND NEW YORK, AND THERE ARE PROFESSIONALS THAT FLY THOSE PLANES THAT ARE PILOTS. AND INSTEAD OF US REQUIRING THAT OUR ACADEMIC INVESTIGATORS, WHO ARE BRILLIANT IN THEIR ONE AREA OF EXPERTISE, ALSO THEN HAVE TO LEARN A BRAND-NEW DISCIPLINE, WHICH IS A PROFESSION IN AND OF ITSELF, DIDN'T SEEM TO MAKE SENSE.

SO WE THOUGHT ABOUT THIS IDEA OF WHAT IF WE CREATED A CENTER THAT COULD DO THE, I WOULD CALL IT, THE BORING REGULATORY REQUIREMENTS NECESSARY TO GET AN IND, BUT THAT AREN'T THAT INTERESTING IN A WAY THAT'S COMPLETELY COMPLIANT AND UP TO FDA'S EXPECTATIONS? AND WHAT IF WE PUT TOGETHER A CRO

THAT WOULD HELP COMPILE AND FILE AN IND SO THAT INVESTIGATOR WOULDN'T HAVE TO LEARN THAT? WHAT IF WE DID THAT? EVERY TIME WE HAD AN AWARD, WE WOULD OFFER THE SUCCESSFUL APPLICANT THE OPPORTUNITY THEN TO PARTNER WITH THE TRANSLATING AND ACCELERATING CENTERS, DIVIDE THE WORK UP AMONGST THEM, HAVE THE APPLICANT FOCUS ON THE WORK THAT THEY WANT TO DO THAT'S INTERESTING TO THEM, AND HAVE THE TRANSLATING AND ACCELERATING CENTERS DO THE REGULATORY REQUIREMENTS THAT ARE NECESSARY IN ORDER TO GET AN IND.

THAT'S WHERE THE ACCELERATING CENTER CAME OUT OF. IT REALLY TOOK OFF WHEN WE HAD DISCUSSIONS WITH FDA, AND THEIR EYES GOT VERY BIG AND THEY WERE VERY INTERESTED BECAUSE THE FDA THEN CAME BACK AND SAID, "THIS WOULD BE PHENOMENAL. WE WOULD LIKE TO FIND OUT A WAY TO PARTNER WITH YOU" BECAUSE FROM THE FDA'S STANDPOINT, IT'S ALSO A POINT OF FRUSTRATION. SO AGAIN GOING BACK TO MY ANALOGY, WHAT IF EVERY PLANE FLYING INTO NEW YORK WAS THE FIRST TIME THAT THAT PILOT HAD EVER FLOWN A PLANE? YOU CAN IMAGINE AIR TRAFFIC CONTROL WOULD GET PRETTY FRUSTRATED TRYING TO TEACH THEM HOW TO NAVIGATE AND LAND.

WELL, THE FDA EXPERIENCES THAT SAME THING, IS THEY'RE BASICALLY TRYING TO COACH THESE

FIRST-TIME IND APPLICANTS ON HOW TO PREPARE AN IND AND HOW TO CONDUCT THESE STUDIES ACCORDING TO FDA'S EXPECTATIONS. THEY LOVED THIS IDEA BECAUSE THEY COULD LOOK AT THIS AND SAY THE INVESTIGATOR IS GOING TO DO THE WORK THAT THE INVESTIGATOR IS GOING TO BE GREAT AT, AND THEN THESE OTHER PEOPLE CAN COMMUNICATE WITH US IN THE LANGUAGE IN WHICH WE SPEAK AND PREPARE APPLICATIONS ON A REGULAR BASIS, ON A RECURRING BASIS THAT ARE THE WAY WE EXPECT THEM.

SO WE THOUGHT IF WE HAD THESE TWO THINGS AND WE BROUGHT THESE TWO THINGS INTO THE STATE OF CALIFORNIA, WE CAN HAVE A REAL PROPRIETARY ADVANTAGE INSIDE CALIFORNIA FOR THE DEVELOPMENT OF CELL THERAPY BECAUSE THIS GROUP WOULD FOCUS ON THAT WORK. WE WOULD HAVE A CELL THERAPY, A STEM CELL THERAPY CRO AND TRANSLATING CENTER IN CALIFORNIA THAT COULD GIVE US A COMPETITIVE ADVANTAGE UNLIKE WE HAD EVER SEEN. SO THAT'S WHERE THIS IDEA COMES FROM.

I THINK IT'S POSSIBLE THAT THIS MIGHT BE THE BEST THING CIRM DOES AND CIRM, IF IT DOESN'T GET REFUNDED, LEAVES. I AM SO, SO POSITIVE AND ENTHUSIASTIC ON THIS, I THINK IT COULD BE ABSOLUTELY TRANSFORMATIONAL FOR CELL THERAPY AND NEEDED. SO WE'RE VERY EXCITED ABOUT THIS PROGRAM.

WITH THAT SAID, WE'RE BASICALLY LOOKING TO FORM A STEM CELL-SPECIFIC CRO COMPANY IN CALIFORNIA AND A TRANSLATING CENTER IN CALIFORNIA. IT'S A LITTLE BIT UNUSUAL FOR CIRM, BUT WHERE I COME FROM IT'S NOT. AND THAT CENTERS AROUND WHAT CIRM GETS OUT OF IT. CIRM'S EXPECTATIONS OUT OF THIS ARE ACCESS FOR OUR PROGRAMS INTO THIS DEDICATED CELL THERAPY-SPECIFIC CRO. WE EXPECT THAT THEY WILL HELP US REDUCE THE AMOUNT OF TIME IT TAKES TO GO THROUGH TRANSLATION. WE EXPECT THAT THEY WILL HELP US BRING IN NEW APPLICATIONS AND RECRUIT NEW PROGRAMS INTO THE STATE OF CALIFORNIA.

THEIR EXPECTATION OUT OF IT IS THAT THEY'RE GOING TO CREATE A BUSINESS THAT OVER TIME IS GOING TO BE SUSTAINABLE. SO THOSE EXPECTATIONS, I THINK, ARE GOOD AND BALANCE OFFSETS. BUT WE'RE PUTTING IN A PRETTY SIGNIFICANT AMOUNT OF MONEY INTO THIS. AND MY EXPECTATION FINANCIALLY, AND I'M CONFIDENT THIS WILL BE REALIZED, IS THAT WE DON'T JUST WANT OUR INVESTMENT RETURNED. WE WANT A RETURN ON OUR INVESTMENT. AND I KNOW THERE WILL BE COMMENTS MADE BY THE APPLICANT AFTER I SPEAK AND AFTER GIL SPEAKS, BUT I JUST WANT TO LET YOU KNOW FROM OUR STANDPOINT OUR EXPECTATIONS, AND IN PRELIMINARY CONVERSATIONS, WE'RE ALIGNED HERE, THAT

WHILE WE'RE GOING TO BE MAKING AN INVESTMENT OF $15 MILLION INTO THIS ORGANIZATION, WE EXPECT OUR PROGRAMS TO BE OFFERED DISCOUNTS. AND WE WILL CONTRACT THIS AWARD IN THIS WAY TO WHERE OUR PROGRAMS WILL BE OFFERED DISCOUNTS AND SUBSTANTIAL DISCOUNTS. WE'RE MAKING AN UPFRONT INVESTMENT INTO THIS ORGANIZATION. WE EXPECT THAT THAT $15 MILLION INVESTMENT WILL ACTUALLY YIELD $22.5 MILLION OF DISCOUNTS OVER THE FIVE YEARS OF THE PROGRAM.

SO WE'RE MODELLING OUT AND WE WILL BE CONTRACTING THAT FOR THAT KIND OF FINANCIAL STRUCTURE. SO OVER THE FIVE-YEAR PERIOD, NOT ONLY WILL WE GET THE WORLD'S FIRST DEDICATED CRO IN THE STATE OF CALIFORNIA FOR STEM CELLS, BUT WE'RE ALSO GOING TO GET A FINANCIAL RETURN ON OUR INVESTMENT. I'LL LEAVE IT THERE. IF THERE ARE ANY QUESTIONS ABOUT THAT, I'LL BE HAPPY TO TAKE THEM; BUT, OTHERWISE, I'LL TURN IT OVER TO GIL, AND WE CAN GO ON WITH THE FORMAL PROGRAM.

DR. SAMBRANO: THANK YOU, RANDY. AND MR. CHAIRMAN, MEMBERS OF THE BOARD, THANK YOU VERY MUCH. WHAT I WANT TO DO IS I'M GOING TO REITERATE SOME OF WHAT RANDY SAID, BUT I THINK THAT WAS A GOOD INTRODUCTION INTO THE OVERALL ACCELERATING CENTER PROGRAM.

ON THIS FIRST SLIDE THERE'S JUST A TABLE THAT SHOWS YOU THE INFRASTRUCTURE PROGRAMS THAT WE ARE IN THE PROCESS OF PUTTING IN PLACE AND SOME OF WHICH ARE ALREADY IN PLACE. THESE INFRASTRUCTURE PROGRAMS ARE BEING ASSEMBLED AND COORDINATED THROUGH DR. MARIA MILAN'S TEAM AT CIRM. THE TRANSLATING CENTER THAT WAS MENTIONED, WHICH WILL BE -- THE RFA IS OUT FOR THAT. WE WILL BE REVIEWING LATER THIS YEAR TO PUT IN PLACE THE ACCELERATING CENTER, WHICH WE ARE CONSIDERING TODAY, AND THEN THE EXISTING ALPHA CLINICS NETWORK THAT HAS ALREADY BEEN PUT IN PLACE THAT WILL SERVE AS THE SPECIALIZED CLINICAL TRIAL SITES THAT WILL PARTNER AND COORDINATE WITH BOTH THE TRANSLATING CENTER AND ACCELERATING CENTER.

SO FOCUSING IN ON THE ACCELERATING CENTER RFA AND BASICALLY WHAT WE PRESENTED TO THE GRANTS WORKING GROUP OF WHAT IT IS THAT WE ARE LOOKING TO FUND AND WHAT WE'RE ASKING THEM TO ASSESS APPLICATIONS FOR. SO THIS RFA CALLED FOR A STEM CELL-FOCUSED CLINICAL RESEARCH ORGANIZATION. THIS IS SOMETHING THAT DOES NOT EXIST THAT WE WANT TO PUT IN PLACE IN ORDER TO FACILITATE AND ACCELERATE STEM CELL TREATMENTS TO PATIENTS.

OBVIOUSLY THIS CENTER WOULD OPERATE WITHIN CALIFORNIA AND WE WOULD PROVIDE UP TO $15 MILLION

OVER A FIVE-YEAR PERIOD TO OPERATE AND FUNCTION.

AND THERE ARE THREE BASIC ELEMENTS THAT THIS ACCELERATING CENTER WOULD PROVIDE IN TERMS OF SERVICES. IT WOULD FOCUS ON REGULATORY SUPPORT, CLINICAL TRIAL OPERATIONS, DATA MANAGEMENT, BIOSTATISTICAL AND ANALYTICAL SERVICES, AND THIS WOULD BE THE REPERTOIRE OF SERVICES THAT WOULD BE AVAILABLE. OF COURSE, DEPENDING UPON THE NEEDS OF THE SPECIFIC CLIENT, THEY WOULD TAILOR THOSE SERVICES TO MEET THOSE NEEDS.

AS WAS ALSO MENTIONED, ONE OF THE KEY ELEMENTS OF THIS PROGRAM IS THAT IF WE BUILD IT, WE WANT IT TO BE SUSTAINED, WE WANT IT TO EXIST AND CONTINUE BEYOND CIRM'S ABILITY TO FUND IT. AND ESPECIALLY IF IT PROVES TO BE A VALUE TO THE COMMUNITY, WE WANT IT TO CONTINUE TO BE PROVIDING SUCH A VALUE.

SO THAT WAS AN IMPORTANT ELEMENT BOTH OF ASSESSING THE APPLICATIONS, THEIR POTENTIAL TO BE SUSTAINABLE, AND THAT OVER TIME THEY WILL BUILD KNOWLEDGE THAT WILL CREATE A NEW ENTITY THAT WILL HAVE EXPERIENCE IN STEM CELL THERAPY TO ADVANCE THEM TO AND THROUGH THE CLINICAL TRIAL PHASES.

SO THE REVIEW CRITERIA, MORE SPECIFICALLY, THAT WE ASKED REVIEWERS TO USE TO ASSESS THESE

APPLICATIONS INCLUDE JUST THREE BASIC ONES. DOES THE PROPOSED CENTER HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT? THAT IS, WHAT IS THE LIKELIHOOD OF THE CENTER TO BE ABLE TO ACCELERATE PROJECTS INTO AND THROUGH THE CLINIC? DOES IT HAVE THE CAPACITY TO BE SUSTAINABLE? AND DOES IT OFFER A VALUE PROPOSITION THAT IS GOING TO BE MEANINGFUL AND IMPACTFUL? HAS THE APPLICANT DEVELOPED A PLAN THAT'S DESIGNED TO SUCCESSFULLY ESTABLISH AND OPERATIONALIZE THE CENTER? THAT IS, DO THEY OFFER A COMPETITIVE FEE? IS THE DESIGN IN THE PLAN, AGAIN, GOING TO BE PROVIDING MEANINGFUL RESOURCES THAT WILL AID IN ACCELERATING PROJECTS THROUGH TO THE CLINIC? AND IS THE PROPOSAL FEASIBLE? FROM A PRACTICAL PERSPECTIVE, HAVE THEY SET A TIMELINE TO ESTABLISH THE CENTER THAT IS REASONABLE AND ACHIEVABLE? DO THEY HAVE THE RESOURCES TO CONDUCT AND PROVIDE THE SERVICES THAT ARE REQUIRED? AND DOES THE TEAM HAVE THE QUALIFICATIONS TO BOTH LEAD AND IMPLEMENT THESE CORE SERVICES? SO THOSE ARE THE REVIEW CRITERIA.

DURING THE REVIEW WE ALSO IN THE PROCESS INTRODUCED A NEW ASPECT TO THE REVIEW WHICH WE CALLED THE PITCH. WE FELT THIS WAS VERY IMPORTANT, WHICH WAS TO BRING THE APPLICANT TEAMS FACE TO FACE WITH THE GRANTS WORKING GROUP. AND SO ALL OF THE

APPLICANT TEAMS WERE BROUGHT IN TO GIVE A 20-MINUTE PRESENTATION TO ADDRESS THE VISION, VALUE PROPOSITION, AND SUSTAINABILITY OF THEIR PROGRAM, AND ALSO GAVE THEM AN OPPORTUNITY, THE GRANTS WORKING GROUP, TO ASK QUESTIONS DIRECTLY OF EACH OF THE TEAMS SO THAT WE COULD HAVE A ROBUST REVIEW AND THEY CAN MAKE THEIR ASSESSMENTS WITH ALL THE INFORMATION THAT WAS NECESSARY TO IDENTIFY THE MOST MERITORIOUS APPLICATIONS.

THE SCORING SYSTEM THAT WE UTILIZED WAS FROM ONE TO A HUNDRED, WHICH YOU ARE FAMILIAR WITH, 85 BEING THE CUTOFF. SO ANYTHING THAT SCORES BETWEEN AN 85 AND A HUNDRED MEANS THAT IT'S OF EXCEPTIONAL MERIT AND WOULD WARRANT FUNDING. ONE CAVEAT UNDER THIS PROGRAM IS THAT WE ARE LOOKING FOR ONLY ONE WINNER. SO THAT MEANS THAT ONLY THE APPLICATION WITH THE HIGHEST AVERAGE SCORE IS THE ONE THAT CARRIES THE RECOMMENDATION OF THE GRANTS WORKING GROUP SHOULD THERE BE MORE THAN ONE IN THAT TOP CATEGORY. IT TURNED OUT IN THIS CASE THERE WERE NOT; BUT IF THAT WERE THE CASE, THAT WAS THE SYSTEM THAT WOULD BE USED.

AND ALSO, THIS IS SOMETHING THAT WE ARE NOW DOING AND IS JUST A REMINDER, THAT AT THE CLOSE OF EACH REVIEW THAT WE DO, WE ASK THE GRANTS WORKING

GROUP MEMBERS TO TAKE A TWO-PART VOTE ON THE RIGOR AND THE FAIRNESS OF THE REVIEW PROCESS. ALL MEMBERS VOTED UNANIMOUSLY IN FAVOR OF THE NO. 1 STATEMENT SHOWN ON THE SCREEN, AND THE PATIENT ADVOCATE MEMBERS FROM THE ICOC ALSO UNANIMOUSLY VOTED ON THE FAIRNESS OF THE PROCESS.

SO THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP ARE SHOWN IN THIS TABLE. THERE WERE FOUR APPLICATIONS THAT WERE ASSESSED. THERE IS ONE THAT WAS SCORED IN THE 85 TO 100 CATEGORY WITH FUNDS REQUESTED OF $15 MILLION, AND THERE WERE THREE OTHER APPLICATIONS THAT SCORED IN THE NOT RECOMMENDED FOR FUNDING.

THE APPLICANT 9166 IS THE APPLICANT THAT IS IN THAT TOP TIER, HAD A SCORE OF 89. THE ADDITIONAL STATISTICS ARE SHOWN. IN ASSESSING THE OVERALL COMMENTS FROM REVIEWERS AND THE PROCESS THAT WE WENT THROUGH, CIRM CONCURS WITH THE GRANTS WORKING GROUP RECOMMENDATION, AND WE ALSO RECOMMEND THAT THIS APPLICANT BE FUNDED FOR AN AWARD AMOUNT OF $15 MILLION. ARE THERE QUESTIONS?

DR. DULIEGE: JUST TO MAKE SURE THAT I UNDERSTAND THAT PARTICULAR PROPOSAL, THE APPLICANTS WERE MAKING A PROPOSAL FOR HOW TO BE THIS ACCELERATING CENTER FOR CIRM?

DR. SAMBRANO: YES. SO ALL THE APPLICANTS WERE TASKED WITH CREATING WHAT WILL BE THE ACCELERATING CENTER. SO IN MANY CASES A COMPANY THAT WILL FORGE A PORTION OF THEIR BUSINESS AROUND GENERATING AND CREATING AND ESTABLISHING A TEAM THAT WILL BE DEDICATED TO THE STEM CELL THERAPY ACCELERATING CENTER.

DR. DULIEGE: SO WAS IT AN EQUIVALENT OF A REQUEST FOR PROPOSAL FOR A CRO?

DR. SAMBRANO: YES.

DR. DULIEGE: AND HOW MANY APPLICANTS DID YOU GET, FOUR?

DR. SAMBRANO: FOUR.

DR. DULIEGE: SO THREE WERE REJECTED, ONE WAS APPROVED?

DR. SAMBRANO: CORRECT.

DR. DULIEGE: WHAT YOU ARE SUGGESTING, IF WE APPROVE THAT, IS THAT THAT WILL BECOME THE CRO FOR CIRM AND FOR ITS CONSTITUENTS?

DR. SAMBRANO: YES. IT WILL BE THE APPLICANT THAT WILL DEVELOP THE CIRM ACCELERATING CENTER AND WILL FUNCTION AS THAT FOR CIRM.

DR. DULIEGE: REALLY VERY GOOD. I COMPLETELY UNDERSTAND THE PROCESS.

WE'RE GOING TO VOTE ON THAT? IS THERE A

VOTE ON THAT?

CHAIRMAN THOMAS: I THINK, DR. SAMBRANO, YOU WOULD LIKE TO HAVE THE NOMINATED PARTY GIVE A PRESENTATION?

MR. SHEEHY: DON'T WE GO INTO APPLICATION REVIEW SUBCOMMITTEE? AND I THINK THE THOUGHT WAS, SO THERE'D BE MORE CLARITY, IS THAT THE WINNING TEAM WOULD ACTUALLY PRESENT TODAY SO YOU CAN SEE WHAT WE SAW IN REVIEW.

DR. DULIEGE: I WOULD BE VERY INTERESTED IN SEEING THAT. THIS IS A FIELD I KNOW WELL. OBVIOUSLY REPRESENTING INDUSTRY, OUR LIFE IS TO SELECT THE RIGHT CRO'S. BUT I WAS CURIOUS TO KNOW ABOUT HOW DIFFERENT IT WAS FROM THE OTHERS, THOSE WHO WERE REJECTED AND WHY WERE THEY REJECTED, AND WHERE THERE'S SUCH A DIFFERENCE BETWEEN THE WINNER AND THOSE WHO DIDN'T WIN. CURIOUS ABOUT THAT.

MR. SHEEHY: WELL, I WOULD SAY THERE WAS A DIFFERENCE. FRANKLY, FROM MY PERSPECTIVE WHEN WE WENT INTO THIS, AND IT WAS THAT WAY WITH THE TRANSLATING CENTER AND THE ATP3, THE VISION IS A BIT MURKY TO ME. AND WHEN THIS TEAM PRESENTED, SUDDENLY THE FOG LIFTED. IT REALLY WAS. IT WAS DRAMATIC. THE DIFFERENCE BETWEEN THE WINNERS -- I DON'T KNOW THIS SPACE, RIGHT, AND THIS IS THIS VISION THAT

RANDY HAS. THIS IS REALLY THE TRACTOR PULLING US UP OVER THE HILL. AND IT WASN'T JUST THEIR ABILITY TO MEET THE VISION, BUT IT WAS THEIR PASSION AND DEDICATION TO HELPING US FULFILL OUR MISSION.

SO THE ALIGNMENT BETWEEN WHAT THEY WERE PROPOSING AND WHAT WE WANT TO DO WAS SO MATCHED. I WOULD HAVE BEEN ONE OF THE ONES WHO VOTED 99 IF I WAS A VOTING MEMBER, IF I WAS A SCORING MEMBER. THEY REALLY WANT TO DO THIS WITH US, AND THEY REALLY KNOW WHAT THEY'RE DOING. AND SO I THINK, AGAIN, WE'LL SEE THEIR PRESENTATION AND HEAR FROM THEM, BUT I THINK I WAS VERY PLEASED AND I WAS VERY DELIGHTED.

DR. DULIEGE: I THINK IT WOULD BE GREAT TO GO THROUGH THE APPLICATION AND THEN HAVE FURTHER COMMENTS ON THAT.

MS. LAPORTE: JUST A QUESTION. SO THE NOTION OF THE DISCOUNTS THAT RANDY TALKED ABOUT EARLIER, THAT WAS EXPLICITLY BAKED INTO THE RFP SO EVERYBODY KNOWS THAT?

DR. SAMBRANO: YES.

MR. SHEEHY: COULD WE INTRODUCE QUINTILES?

CHAIRMAN THOMAS: YES. PROCEED, MR. SHEEHY.

MR. SHEEHY: IF YOU GUYS WOULD.

DR. KULKARNI: MR. CHAIRMAN, MEMBERS OF

THE ICOC, MANAGEMENT OF CIRM, PATIENT ADVOCATES, THANK YOU FOR INVITING US TO PRESENT OUR PROPOSAL TO YOU TODAY. THE PRESENTATION YOU ARE ABOUT TO SEE IS THE PRESENTATION WE MADE TO THE GRANTS WORKING GROUP WITH A FEW ADDITIONAL PAGES FOR THE SAKE OF CLARITY BASED ON QUESTIONS AND COMMENTS WE GOT WHEN WE PRESENTED TO THE GWG. SO NO OMISSIONS REALLY, JUST SOME CLARIFICATIONS.

THE AGENDA IS ON THE BOARD TODAY. AS YOU ARE READING IT, JUST A QUICK ALIGNMENT OF WHAT WE ARE TALKING ABOUT TODAY. WE'LL TALK ABOUT THE ALIGNMENT OF CIRM AND QUINTILES. WE'LL TALK ABOUT THE TEAM. THERE'S TWO MEMBERS PRESENT HERE TODAY, AND CERTAINLY CURIOUS ABOUT THE REST OF OUR, DEPENDING UPON HOW YOU COUNT IT, 36 TO 40,000 GLOBAL EMPLOYEES OF QUINTILES. WE'LL TALK ABOUT THE SPECIFICS ABOUT THE VALUE PROPOSITION. MOST IMPORTANTLY, WE HOPE THAT WE LEAVE TODAY'S SESSION WITH A SENSE OF THE ENTHUSIASM AND EXCITEMENT THAT WE AT QUINTILES HAVE IN BEING ASKED TO BE A PART OF THIS INITIATIVE.

ON SCREEN YOU HAVE THE CIRM AND THE QUINTILES MISSION. I WON'T BELABOR THE POINT. YOU CAN READ IT JUST AS FAST AS I CAN READ IT. BUT YOU CAN SEE A REMARKABLE CONGRUENCE BETWEEN OUR MISSION

STATEMENTS. I'LL TALK ABOUT MYSELF IN A MOMENT, ADRIAN WILL TALK ABOUT HIMSELF. THREE BULLET POINTS TO COVER ME. I'VE BEEN IN THIS BUSINESS AS A PHARMACIST BY EARLY TRAINING, A PH.D. AND MBA FROM A LOCAL UNIVERSITY, 25 PLUS YEARS IN THE BIOPHARMA SPACE. I'VE BEEN A MEMBER OF THE LOCAL BIOTECH COMMUNITY GOING BACK TO CHIRON, BAY AREA BIOTECH START-UPS, SAND HILL ANGELS, AND THEN MOST RECENTLY QUINTILES.

I'M THE CHIEF ACCOUNTABLE OFFICER FOR THIS PARTICULAR GRANT APPLICATION. I'M HAPPY AS OF TODAY RANDY TOLD US GO BY CHIEF BORING OFFICER. WE DO RUN IN MANY WAYS A FAIRLY STRAIGHTFORWARD BUSINESS AT QUINTILES. IT'S VERY COMPLEX. AND TRYING TO MAKE IT BORING IS PART OF THE EXCITEMENT. ADRIAN.

DR. MC KEMEY: GOOD MORNING, EVERYBODY. MY NAME IS ADRIAN MCKEMEY. I'M FROM THE PART OF QUINTILES WE CALL QUINTILES ADVISORY. AND MY JOB THERE IS TO HELP OUR ORGANIZATION GET INTO NOVEL AND DIFFERENT AND INNOVATIVE BUSINESS MODELS AS THE WHOLE NATURE OF DRUG DEVELOPMENT IS CHANGING.

I TOO STARTED MY LIFE IN THE U.S. DOWN AT STANFORD AT THE ACCELERATING CENTER. A FEW YEARS INTO MY CAREER THERE, SOMEBODY CONFUSED PHYSICIST WITH PHYSICIAN, AND I GOT INTO LIFE SCIENCES. AND

SINCE THEN I'VE TAKEN TERMS AT BOSTON CONSULTING GROUP AND THEN CO-FUNDING THIS ADVISORY SERVICES GROUP THAT WE HAVE WITHIN QUINTILES. ALONG THE WAY, SOME OF THE PARTNERSHIPS THAT WE HAVE FORMED OVER THE LAST THREE OR FOUR YEARS HAVE BEEN WITH STEM CELL COMPANIES, SUCH AS MESOBLAST, FOR INSTANCE, IN NEW YORK, MY HOMETOWN NOW. IT WAS AT THAT STAGE WHEN WE BECAME FASCINATED WITH THE POTENTIAL FOR THESE THERAPIES AND ALSO VERY AWARE THAT THERE WERE SO MANY DISPARATE AND VARIOUS APPROACHES BEING APPLIED, THAT SOME LEARNINGS COULD BENEFIT PATIENTS AND THE INDUSTRY. SO THAT'S WHY WE'RE VERY EXCITED TO BE HERE.

DR. KULKARNI: THE GRANTS WORKING GROUP HEARD ME SAY THIS, WHICH IS IN ADDITION TO THE SHORT BIO YOU HEARD, SEVERAL YEARS BACK I VOTED FOR PROPOSITION 71. WHAT BROUGHT ME FROM THAT TO QUINTILES? WHAT IS SO SPECIAL ABOUT QUINTILES? QUINTILES IS THE WORLD'S LARGEST CRO. $5 BILLION OF REVENUE. DEPENDING ON HOW YOU COUNT OUR FULL-TIME VERSUS PART-TIME, AND THERE'S LEGALITIES AROUND THAT, IT'S EITHER 36,000 OR 40,000 PEOPLE ON PAYROLL AND THEN MANY MORE CONTRACTORS THAT WE DEPLOY IN A HUNDRED COUNTRIES IN THE WORLD.

THE LARGEST PART OF QUINTILES' BUSINESS IS

OUR CLINICAL RESEARCH BUSINESS. WE ALSO HAVE COMMERCIAL SALES. WE HAVE ADVISORY. THAT IS RUN BY CINDY VERST. EIGHTY PERCENT OF OUR REVENUE FLOWS THROUGH CINDY. A KEY ELEMENT OF THIS PARTICULAR ORGANIZATION IS GOING TO BE THE DATA MANAGEMENT. THAT'S MARGARET KEEGAN. REAL WORLD LATE PHASE, WHICH IS A KEY ENABLER, WHICH IS IMPORTANT TO US, IS RUN BY NANCY DREYER. AND VERY IMPORTANTLY, A THIRD OF OUR BUSINESS IS SMALL EMERGING BIOPHARMA. AND FOR THAT WE HAVE LAURA MARQUIS WHO IS THE HEAD OF THAT UNIT. WE SAY THIS BECAUSE WE'VE BEEN IN DISCUSSIONS ON AND OFF ABOUT THE COMPOSITION OF MANAGEMENT AND THE TEAM AT QUINTILES.

IMPORTANTLY, WHAT'S OUR VISION? WE BRING PEOPLE AND KNOWLEDGE TOGETHER FOR A HEALTHIER WORLD. THAT SOUNDS PETTY. OUR CUSTOMER PROMISE IS IMPROVING YOUR PROBABILITY, OUR CUSTOMER'S PROBABILITY, OF SUCCESS. THIS IS VERY RELEVANT TO THIS PARTICULAR DISCUSSION.

HOW DO WE DO IT? WE HAVE TO HAVE A STRONG BIOPHARMACEUTICAL DEVELOPMENT SET OF CAPABILITIES, HAS TO BE INTEGRATED WITH ALL THE COMMERCIAL CAPABILITIES, WHICH WE CALL INTEGRATED HEALTHCARE SERVICES, AND WE PUT IT ALTOGETHER WITH PEOPLE, GOOD SCIENCE, AND TECHNOLOGIES. IF THIS WORKS RIGHT, WE

HAVE THE ABILITY TO BRING THE POWER OF QUINTILES TO CALIFORNIA STEM CELL RESEARCH, LEADING THE WAY TO GLOBAL CAPABILITIES IN STEM CELL RESEARCH AND DEVELOPMENT.

WHILE YOU ARE READING THIS PAGE, WHICH IS HEADLINED AS QUINTILES IS WELL POSITIONED TO BUILD AND RUN THE AC, I WANT TO MAKE THREE POINTS. WE HAVE AT QUINTILES STEM CELL RESEARCH AND DEVELOPMENT CAPABILITY. WE HAVE DONE THIS FOR OTHER COMPANIES AND CLIENTS ALONG THE WAY, AND OTHER CRO'S WILL ALSO CLAIM THAT. WE BELIEVE THIS MARKET IS POISED FOR GROWTH. AND, LASTLY, WE HAVE THE EXPERTISE AND THE DESIRE TO STAND UP AND THEN OPERATE THE ACCELERATING CENTER. MORE ABOUT THAT IN SUBSEQUENT PAGES.

THERE IS A MARKET NEED FOR THE ACCELERATING CENTER. IF THE EARLIER POINTS WERE TRUE, THIS BEGS A QUESTION. WHY DO WE NEED THIS? AND THIS IS IT. WE NEED IT BECAUSE THERE ARE AT LEAST THREE MAJOR POINTS TO BE MADE ABOUT WHY IS IT IMPORTANT TO HAVE A CENTER OF EXCELLENCE THAT WILL COORDINATE ALL OF THE ELEMENTS THAT GO INTO STEM CELL AND REGENERATIVE MEDICINE-BASED CLINICAL TRIAL AND DEVELOPMENT. NEW TECHNOLOGIES AND VECTORS ARE BEING DEVELOPED AND BROUGHT TO THE FORE. AND COMMERCIAL STANDALONE PHARMA AND PROCESSES SIMPLY

WILL NOT WORK. THEY HAVE TO BE TWEAKED. THEY HAVE TO BE MODIFIED.

THERE'S A NOVEL SET OF REGULATORY PATHWAYS, AND THERE'S A LOT OF DISCUSSION, RANDY LED SOME OF THAT, AROUND HOW THE FDA AND VARIOUS AGENCIES THAT REGULATE THIS BUSINESS ARE INTERESTED IN WORKING ON MODULATING THEIR PROCESSES, NOT COMPROMISING SAFETY AND EFFICACY, BUT TO MAKE IT WORK. AND LASTLY, THESE ARE CLINICAL STUDIES IN WHICH PATIENT POOLS ARE MUCH SMALLER. SO THINKING INNOVATIVELY ABOUT THE APPROPRIATENESS OF CLINICAL STUDIES, ABOUT POWERING THE PATIENT STUDIES IN THE APPROPRIATE FASHION, AND THEN ALSO ABOUT GOING FROM A STANDARD MODEL, WHICH HAS BEEN ABOUT REPEAT DOSING, TO A CURATIVE THERAPY. HOW TO THINK ABOUT ALL OF THAT IN THE CONTEXT OF A SUSTAINABLE PLAN FOR ANY ONE COMPANY OR ENTITY IN THE SPACE. THAT'S PART OF WHY WE THINK ALL OF THESE POINTS ARE IMPORTANT TO BEING ABLE AT THIS POINT IN TIME HELP STAND UP AN ACCELERATING CENTER IN THIS SPACE.

OUR PROPOSAL IS TO PROVIDE AN END-TO-END STEM CELL CLINICAL DEVELOPMENT SERVICE. WITH THE ACCELERATING CENTER AT THE CENTER OF A RANGE OF CONSTITUENCIES, CIRM ON THE ONE HAND ENABLING THIS, THE FDA AS A CRITICAL REGULATORY AGENCY, AND THEN

THE ALPHA CLINIC NETWORK ALREADY IN PLACE AND ULTIMATELY, WHEN IT GETS GOING, THE TRANSLATING CENTER, PUTTING ALL THIS TOGETHER WILL FORM THE ORGANIZATIONAL MILIEU IN WHICH THE AC, THE ACCELERATING CENTER, WILL WORK.

BELOW THAT WE HAVE LISTED SIX OF THE KEY FUNCTIONAL CAPABILITIES THAT WOULD NEED TO BE IN PLACE TO MAKE THE ACCELERATING CENTER WORK. EVERYTHING FROM STRATEGIC MANAGEMENT, PROGRAM MANAGEMENT, TO THE EXTREME RIGHT WHICH IS DATA MANAGEMENT AND BIOSTATISTICS. THERE ARE TWO WAYS OF LOOKING AT THE SUBCAPABILITIES THAT WOULD MAKE THIS WORK. AND ONE IS ALONG THE DRUG DEVELOPMENT SERVICES AND FUNCTIONS AND THE OTHER IS ADMINISTRATIVE AND BUSINESS OR GENERAL MANAGEMENT FUNCTIONS, AND THOSE ARE THE BUCKETS OR BOXES BELOW.

ALL OF THESE, EVERY ONE OF THOSE BULLET POINTS, ARE ONES THAT QUINTILES CURRENTLY DOES IN ITS BUSINESS. WE DON'T ALWAYS DO IT FOR A STEM CELL RESEARCH-BASED PRODUCT OR SERVICE, BUT NOW WE HAVE THE ABILITY TO PULL THIS KIND OF DEEP THINKING INTO A STEM CELL-FOCUSED CENTER.

DR. MC KEMEY: AND, AVI, I MIGHT JUST PAUSE AT THIS POINT TO ILLUSTRATE THE DIFFERENCE BETWEEN OUR TWO ROLES GOING FORWARDS. SO WE PROPOSE

THAT AVI IS THE ACCOUNTABLE EXECUTIVE FOR THE ACCELERATING CENTER TO CIRM AND THE CONSTITUENCIES, AND THEN MY ROLE IS TO PULL THROUGH, AS NECESSARY, ALL OF THOSE BORING OTHER FUNCTIONS LIKE PROGRAM MANAGEMENT OR DATA MANAGEMENT OR BIOSTATISTICS. THAT YOU MIGHT WANT TO HAVE A STANDING FORCE THERE ALL THE TIME, THAT WOULD BE VERY EXPENSIVE AND COSTLY. I WOULD BE BUILDING A FIRE STATION THAT'S READY IN CASE THE BELL RINGS. SO MY ROLE IS TO NAVIGATE BACK INTO THE GREATER QUINTILES ORGANIZATION AND BRING JUST THE RIGHT RESOURCES IN AT THE MORE GENERIC DEVELOPMENT LEVEL WHILE THE MORE STEM CELL-SPECIFIC LEVELS ARE LEFT WITH AVI IN THE ACCELERATING CENTER.

DR. KULKARNI: THIS IS A GREAT SEGUE TO THE NEXT PAGE, ADRIAN. THANK YOU. IF YOU LOOK AT ALL OF THE DEDICATED STAFF AND THE FUNCTIONAL CAPABILITIES OF THE ACCELERATING CENTER WITH ME, IF WE WERE TO TRULY POPULATE ALL OF THESE ON DAY ONE USING CIRM'S MONEY, WE FEEL WE WOULD HAVE USED CIRM'S MONEY NOT VERY WISELY. THE SMART PLAY IS TO HARNESS THE POWER OF QUINTILES AND PULL PEOPLE IN AS THE CENTER GETS GOING.

SO THE WAY WE FRAMED OUR PROPOSAL IS INITIALLY WE WILL PULL IN MORE AND MORE OF QUINTILES

WITH A VIEW TO MAKING PERMANENT THE STAFF ONCE THEY GET CLOSER TO HUNDRED PERCENT UTILIZATION SO WE ARE NOT BURDENING THE ACCELERATING CENTER WITH THE FULL COST OF EACH OF THESE PEOPLE. BUT THE PLAN, AND WE'VE GOTTEN ORGANIZATIONAL APPROVAL, IS TO START MOVING THEM INTO THE SAN DIEGO FACILITY AS APPROPRIATE. THIS IS PART OF THE ABILITY TO THEN CREATE AN ADDITIONAL FUND, WHICH WE'LL TALK ABOUT IN A MOMENT AND THE QUESTION WAS ASKED, THAT GOES TOWARDS DISCOUNTS TO GRANTEES. SO WE ARE NOT USING THE MONEY JUST TO BUILD THE FIRE STATION, BUT THE ABILITY THEN TO FUND ACTUAL GRANTEES WHEN WE GET THERE.

IT FEELS TO ME THAT WHILE I WAS TALKING FOLKS WERE SCANNING THIS PAGE, SO I'M GOING TO MOVE PAST THIS ONE AND THEN TALK ABOUT THE VALUE PROPOSITION. I FEEL ELABORATE SCALE AND EXPERTISE RESTS WITHIN QUINTILES, AND THAT WHICH WE INTEND TO CONTINUE TO BUILD, THERE IS A PART OF THE VALUE PROPOSITION WHICH IS ACCELERATING CLINICAL DEVELOPMENT AND THEN THE OTHER IS REDUCING COSTS. THE TUFTS CENTER, WHICH DOES A LOT OF PUBLICATIONS AND RESEARCH ON PHARMACEUTICAL RESEARCH AND COSTS HAS PUBLISHED NUMBERS WHICH SHOW THAT EVEN IN THIS EARLY STAGE R&D PROCESS, A DAY COSTS ABOUT $35,000

AND A MONTH IS ABOUT A MILLION DOLLARS. IF WE ACCELERATE TO THE POINT THAT RANDY WAS MAKING FROM EIGHT YEARS DOWN TO THE INDUSTRY NORM OF 3.X YEARS, WE'RE TALKING ABOUT A RETURN TO THE COMMUNITY THAT IS SO MUCH GREATER THAN THE $15 MILLION THAT CIRM IS PUTTING IN AND THAT WE WILL BE ALSO AS PART OF THIS VENTURE BE MAKING THROUGH THE APPROPRIATE DISCOUNT STRUCTURE AVAILABLE TO THE COMMUNITY OF GRANTEES.

I WON'T TALK ABOUT ALL THE STUFF ON THE EXTREME RIGHT WHICH FEELS A LITTLE BIT LIKE CHEST POUNDING TO ME. WE HAVE A THOUSAND PLUS M.D.'S AND PH.D.'S, BLAH, BLAH. THE KEY IS TO GO TO THE BOTTOM RIGHT AND SAY WE ALSO HAVE, IN ADDITION TO THE WAYS IN WHICH WE THINK THERE WILL BE VALUE PROVIDED, A SPECIFIC POOL OF MONIES THAT WE ARE DEDICATING, THAT WE'RE KEEPING, TO MAKE SURE THAT THESE CAN BE PASSED ON TO CIRM GRANTEES IN A DISCOUNTED FASHION.

IN OUR EARLY MODELS WE CALCULATED ABOUT 15 PERCENT, BUT WE ALSO REALIZED THAT IF WE JUST TAKE LATER ON ON THE PAGE WHICH SHOWS THE MENU OF SERVICES, IF WE JUST DO A JUST STRAIGHT MENU OF 15 PERCENT DISCOUNT, THAT DOES THE CENTER AND THE COMMUNITY A DISSERVICE. SO WHAT WE PROPOSE IS THAT WE'LL WORK WITH CIRM MANAGEMENT TO FIGURE OUT OVER TIME WHERE THESE MONIES NEED TO BE APPLIED TO REALLY

ACCELERATE GROWTH IN THIS SPACE. SO WE'LL BE TRUE TO THE DISCOUNT STRUCTURE, BUT WE'LL VARY IT FROM TIME TO TIME.

TO USE AN EXAMPLE, IF IT TURNS OUT THAT GRANTEES ARE GETTING STUCK ON THE REGULATORY PATHWAY, AND THAT'S WHERE THEY NEED THE DISCOUNTED HELP, THEN THAT'S WHERE WE'LL PUT THE MONEY ON THE DISCOUNT. IF IT TURNS OUT THAT THEY NEED THE BEST HELP WITH CLINICAL DEVELOPMENT PLANNING, WE'LL APPLY MORE OF IT IN THAT DIRECTION. SO WE'RE STAYING TRUE TO THE APPROXIMATELY 15-PERCENT DISCOUNT, BUT WE'RE KEEPING OPEN WHERE IT WILL BE APPLIED WITHIN THE KINDS OF SERVICES THE GRANTEES NEED AS THEY TAKE THEIR EARLY STAGE PRODUCT INTO THE CLINIC.

DR. MC KEMEY: I'D JUST PROBABLY MENTION THAT THERE'S AN ADDITIONAL COMPONENT TO OUR BUSINESS MODEL HERE, WHICH IS RATHER FOCUSED INITIALLY, IS ENTIRELY ON THE CIRM GRANTEES. WE DO BELIEVE THIS FACILITY WILL BECOME OF INTEREST GLOBALLY AND THAT THERE WILL BE OTHER ENTIRELY COMMERCIALLY INCENTED BIOPHARMA COMPANIES THAT WILL WANT TO COME IN AND USE THESE SERVICES. AND AS THOSE REVENUES BUILD, THAT GIVES US MORE OPPORTUNITY FOR SCALE.

DR. KULKARNI: THIS PAGE HAS THREE PARTS TO IT. SO THE LEFT IS THIS IS WHAT WE BRING, OUR

CORE CAPABILITIES. WE HAVE REGENERATIVE MEDICINE EXPERIENCE AND EXPERTISE. WE HAVE THE CORE CAPABILITIES WE'VE TALKED ABOUT. WE ALSO OFFER A FULL END-TO-END SERVICES MODEL FOR OUR INDUSTRY.

THE MIDDLE, IF YOU WILL, IS THE MENU, EVERYTHING FROM INTEGRATED PROGRAM PLANNING DOWN TO ACTUALLY MAKING THE REGULATORY SUBMISSION, PREPARING THE REGISTRATION DOSSIER THAT THE REGISTRATION AGENCY, WHICH THE PREMIERE ONE IN THIS COUNTRY IS THE FDA, WILL GET TO SEE. AND THE VALUE TO CUSTOMERS IS EVERYTHING FROM ACCELERATING DEVELOPMENT EFFORT DOWN TO A PRICE COMPETITIVE SERVICES MODEL. IF WE DO THIS CORRECTLY, THE TOTAL AMOUNT OF MONEY THAT WOULD BE AVAILABLE TO GRANTEES IS MORE THAN $15 MILLION. SO THIS IS THE POINT ADRIAN WAS ALSO MAKING. IF ALL WE DID AS PART OF THIS WAS TAKE $15 MILLION, PUT IT IN THE BANK ACCOUNT AND MAKE IT AVAILABLE TO GRANTEES, I'M NOT SURE THAT ALL OF US WOULD BE SPENDING OUR TIME DISCUSSING THIS. THE IDEA IS TO CREATE ENOUGH VALUE THAT WHAT FOLKS GET FROM APPLYING TO THE CENTER IS SIGNIFICANTLY GREATER THAN THAT AMOUNT THAT IS BEING OFFERED AS PART OF THE GRANT MONEY AND THAT WE'RE HAPPILY ACCEPTING WERE WE TO GET THE AWARD.

A KEY PART OF BUILDING AN ACCELERATING

CENTER, A CENTER OF EXCELLENCE, IS MAKING SURE THAT APPLICANTS COME FROM ALL AROUND THE WORLD TO UTILIZE IT. IF THIS REMAINED ENTIRELY JUST AN EFFORT BETWEEN CIRM MANAGEMENT AND QUINTILES, SAY, LET'S HAVE CIRM GRANTEES FLOW THROUGH, THAT WOULDN'T WORK QUITE AS WELL AS MAKING SURE THAT THE BUSINESS DEVELOPMENT ARM OF QUINTILES IS ENGAGED FULLY TO START DISSEMINATING THE WORK AND PULLING THROUGH GRANT APPLICANTS TO ENSURE THAT WE ARE MUCH MORE THAN JUST 50 GRANT APPLICATIONS THAT ARE EXPECTED AS PART OF THE FIVE-YEAR CLINICAL TRIAL GRANTS THAT CIRM EXPECTS TO MAKE IN THIS SPACE.

THESE LAST FEW PAGES DO GO FAST, THE VERY LAST WHERE I SUMMARIZE, AND THAT'S ANOTHER 20 MINUTES.

THE ACCELERATING CENTER ESSENTIALLY IS FOCUSED AROUND THE PATIENT. IT'S MAKING SURE THAT THE PATIENT -- THAT PATIENT CENTRICITY IS OUR MODEL. THE ACCELERATING CENTER THINKS ABOUT WHAT IS REQUIRED FOR THE BEST CLINICAL STUDIES IN THE SPACE. HOW WILL THE TRANSLATING CENTER SUPPORT IT? HOW DO THE ALPHA CLINICS NETWORK SUPPORT IT? ACROSS THAT WHAT ARE THE FUNCTIONAL CAPABILITIES AROUND COMMUNICATIONS, PRACTICE, AND THE BUSINESS OF RUNNING THIS PARTICULAR CENTER?

A GRAPHIC THAT WAS LOST AND FOR SOME REASON IS AVAILABLE HERE, BUT NOT ON THE SCREEN, THERE'S AN ARROW GOING FROM THE BOTTOM LEFT TO THE TOP RIGHT WHICH SHOW OUR FIVE-PLUS-YEAR PLAN AND THE KEY STEPS THAT WE INTEND TO TAKE. SO THE FIRST IS WE FOCUS ON STANDING UP AND GROWING THE ACCELERATING CENTER, MAKING SURE THAT WE WORK WITH CIRM AND NON-CIRM GRANTEES. SECOND, WE MAKE SURE THAT WE CREATE VALUE. THIS IS THE WHOLE VARIABLE COST RESOURCING STRUCTURE TO ENSURE THAT WE OFFER THE MOST EFFICIENT MODEL TO ENTITIES THAT CAN USE THE CENTER. THE THIRD IS TO LEVERAGE THIS IN A COST COMPETITIVE MANNER. THE GOAL IS TO MAKE SURE THAT THE CAPABILITIES THAT WE'RE GOING TO BE BUILDING CAN LOOK BEYOND STEM CELLS IF THE MARKET MOVES IN REGENERATIVE MEDICINE BEYOND STEM CELLS. AND, LASTLY, TO OFFER A VARIETY OF ADDITIONAL SERVICES. THIS POINT, SUSTAINABILITY, IS I THINK CRITICAL AND WE SHOULD TALK ABOUT THAT FOR AT LEAST A SECOND.

TAKING A PRODUCT THROUGH THE REGULATORY PROCESS JUST MEANS THAT IT'S APPROVED. MAKING SURE A PATIENT CAN ACTUALLY USE IT ALSO MEANS THINKING ABOUT WHAT WILL THE PRODUCT LOOK LIKE IN COMMERCIAL PRACTICE? ARE THEIR INDICATIONS RIGHT? ARE THE HEALTHCARE ECONOMICS CONSIDERED? WHAT'S THE REAL

WORLD OUTCOME, NOT JUST THE CLINICAL DATA THAT WAS PART OF THE REGISTRATION DOSSIER? MAKING SURE THAT IF THE PRODUCT NEEDS TO BE LICENSED SO THAT IT CAN BE AVAILABLE GLOBALLY, WHAT ARE THE ELEMENTS OF THAT? EVERY ONE OF THE BULLET POINTS THAT YOU ARE SEEING ON THE SCREEN ARE CAPABILITIES THAT ADRIAN AND HIS TEAM HAVE WORKED WITH CLIENTS ALREADY TO OFFER. SO WE BRING THIS EXPERTISE ALSO.

DR. MC KEMEY: JUST ONE POINT I'D EMPHASIZE IS THAT THOSE PATIENT-REPORTED OUTCOMES, HEALTH ECONOMICS, PAYOR REIMBURSEMENT CONSIDERATIONS, THEY START BETWEEN PHASE I AND PHASE II IF YOU GET THE PLAN RIGHT. AND SO ALTHOUGH THEY SOUND LIKE THEY'RE CLOSER TO THE LATE STAGE TRIALS AND COMMERCIALIZATION, THEY ACTUALLY HAVE TO BEGIN IN THE TRIALS THAT WE'LL BE HELPING GIVING GUIDANCE ON SETTING UP IF WE'RE SELECTED TO DO THIS.

DR. KULKARNI: YEAH. THANK YOU. WE APPRECIATE THE CHANCE TO MAKE THE PROPOSAL, AND WE LOOK FORWARD TO SERVING THE CITIZENS OF CALIFORNIA.

MR. SHEEHY: SENATOR TORRES AND OTHER FOLKS IF THEY HAVE QUESTIONS.

MR. TORRES: I WANT TO START OFF BY SAYING THANK YOU, JEFF, FOR THIS VERY IMPORTANT GRANTS WORKING GROUP MEETING THAT WE HAD REGARDING THESE

PROPOSALS. I WAS ONE OF THE UNANIMOUS VOTERS FOR THIS PROPOSAL SIMPLY BECAUSE I BELIEVE THAT YOU EXCELLED FAR GREATER THAN THE OTHER APPLICANTS IN TERMS OF THE SCIENCE AND IN TERMS OF THE CAPABILITY, IN TERMS OF THE QUALIFICATIONS.

BUT WE ARE A PUBLIC AGENCY, AND THE STATE OF CALIFORNIA HAS AN OBLIGATION TO HELP CREATE DIVERSITY. AND ONE OF THE ISSUES I HAD WITH YOUR COMPANY WAS THAT ONLY FOUR OUT OF 22 OF YOUR TOP MANAGEMENT ARE WOMEN. AND PEOPLE OF COLOR ARE NOT PART OF THAT MANAGEMENT EITHER AS I CAN SEE FROM THE WEBSITE. YOU'RE NOT ALONE. GOOGLE ONLY HAS 2 PERCENT BLACK EMPLOYEES AND 3 PERCENT LATINO EMPLOYEES. AND GOOGLE ONLY HAS 30 PERCENT WOMEN VERSUS 70 PERCENT MALE, WHICH IS SIMILAR TO WHAT YOU HAVE. ALL I'M CONCERNED ABOUT IS, AND I HOPE YOU WILL TAKE THE INITIATIVE AS GOOGLE IS DOING, TO HELP DIVERSIFY YOUR MANAGEMENT AT THE COMPANY SO THAT IT REFLECTS THE DIVERSITY IN THE POPULATION OF CALIFORNIA BECAUSE THAT'S WHERE THE MONEY COMES FROM, THE TAXPAYERS.

DR. KULKARNI: THANK YOU, SENATOR TORRES. FOR THOSE WHO WERE NOT PRESENT AT THE GRANTS WORKING GROUP, WE SHOWED UP, WE QUINTILES, EMBARRASSINGLY WITH SIX MEN IN SUITS AND MADE THE PRESENTATION.

AND SENATOR TORRES POINTED THAT OUT TO US. WE DID TAKE THAT FEEDBACK AND PRESENTED IT TO OUR MANAGEMENT. AND SO THE WORD HAS GONE UP THE CHAIN, SO TO SPEAK, ABOUT THE WAY WE CONDUCTED OURSELVES AT THAT PARTICULAR MEETING. DR. DIPTI AMIN, OUR CHIEF COMPLIANCE OFFICER, IS AWARE OF THIS AND PRIOR TO THESE COMMENTS WAS ALREADY LEADING AN INITIATIVE WHICH IS ABOUT DIVERSITY WITH APPROPRIATE COMPLIANCE.

AT ANY ONE STAGE, IF THAT IS A REMAINING CONCERN, WE ARE HAPPY TO HAVE VISITS, OFF-LINE DISCUSSIONS TO ENSURE THAT YOU UNDERSTAND THAT WE, QUINTILES, TAKE THIS MATTER VERY SERIOUSLY.

MR. TORRES: THANK YOU.

MR. SHEEHY: ADDITIONAL QUESTIONS OR COMMENTS FROM --

DR. DULIEGE: THANK YOU SO MUCH. REALLY GREAT PRESENTATIONS, AND I'M TOTALLY CONVINCED OF, NOT JUST THE NEED FOR A CRO, BUT ALSO THE CRITICAL IMPORTANCE OF HAVING A TRUE PARTNERSHIP BETWEEN THE CIRM AND THE CRO, MEANING IT'S A HAND-IN-HAND COLLABORATION. AND IF ONE LOSES, BOTH LOSE AND VICE VERSA ON THE WIN SIDE.

I HAVE ACTUALLY TWO QUESTIONS FOR YOU AS THE CLINICAL DEVELOPMENT AND REGISTRATION OF STEM

CELL PRODUCT IS MORE DIFFICULT THAN REGULAR PRODUCTS BECAUSE IT'S LARGELY AN UNTRODDEN PATH. WHAT IS YOUR TRACK RECORD OF SUCCESS SO FAR IN STEM CELL RESEARCH?

DR. MC KEMEY: STEM CELL RESEARCH DEVELOPMENT IN THE TRIALS THAT WE'VE BEEN WORKING ON HAVE LARGELY BEEN EARLY STAGE, PHASE I, PHASE IIS. SOME OF THE BIG PHASE IIIS ARE STILL -- I WON'T MENTION CERTAIN COMPANIES, BUT THERE'S BEEN SOME TRANSITIONS IN THE OWNERSHIP OF SOME OF THE CLOSURE REGISTRATION ASSETS OVER THE LAST FEW DAYS. SO WE HAVE NOT GONE FROM VERY EARLY CLINICAL RESEARCH ALL THE WAY THROUGH COMMERCIALIZATION WITH A STEM CELL COMPANY YET.

DR. DULIEGE: NOBODY ELSE HAS.

DR. MC KEMEY: THAT'S THE OPPORTUNITY TOO BECAUSE WE FEEL THAT WITHOUT THE CIRM MONIES TO HELP US FOCUS A TEAM TO DO THIS CONSISTENTLY AND REPRODUCIBLY, WE MAY NEVER GET THE CHANCE TO FOLLOW SOMETHING ALL THE WAY THROUGH. AND THAT'S REALLY WHERE THE CUMULATIVE COMPOUND LEARNINGS HAPPEN. SO WE HAVEN'T DONE IT, BUT WE'RE HOPEFUL.

DR. DULIEGE: I UNDERSTAND THAT. MY QUESTION WAS MORE IN WHAT YOU HAVE DONE, HOW HAVE YOU BEEN SUCCESSFUL? FOR INSTANCE, HOW MANY PHASE I

TRIALS HAVE YOU DONE IN STEM CELL RESEARCH, PHASE II? ENROLLMENT IS LIKELY TO BE A VERY -- NOT LIKELY -- IS A VERY SIGNIFICANT CHALLENGE. HAVE YOU HAD RECORD OF SUCCESS HERE? SO I WASN'T THINKING ALL THE WAY TO COMMERCIAL.

DR. MC KEMEY: I CAN GET YOU THE EXACT NUMBERS, BUT IT'S --

DR. DULIEGE: JUST A HIGH LEVEL SUMMARY.

DR. MC KEMEY: -- BETWEEN 10 AND 20 TRIALS IN REGENERATIVE MEDICINE, ABOUT HALF OF THOSE IN STEM CELLS, AND MET MILESTONES ON 80 PERCENT OF THEM THROUGH PATIENT RECRUITMENT. SOME OF THESE TRIALS ARE DIFFICULT TO FIND PATIENTS FOR. INTERESTINGLY, A LOT OF THE TIMES WHEN PATIENTS DROP OUT OF TRIALS, IT HAPPENS BECAUSE OF THE BURDEN OF THERAPY. INTERESTINGLY, WE'RE FINDING IN OUR INITIAL ANALYSES ABOUT HOW THE PATIENT FLOW HAPPENS, THE INITIAL INTEREST IN THE TRIAL IS VERY HIGH, BUT THERE TEND TO BE A LOT OF DROPOUTS EVEN BEFORE THE SCREENING BECAUSE PEOPLE REALLY SUDDENLY BEGIN TO THINK ABOUT THE UNKNOWNS ABOUT CELL-BASED THERAPIES. AND AS PART OF KEEPING PATIENTS MORE ENGAGED, WE'RE ACTUALLY JUST BEGINNING WITH SEVERAL COMPANIES TO DO UNUSUAL THINGS WHICH IS A MUCH MORE INTIMATE INVOLVEMENT WITH PATIENTS BEFORE THEY GO ONTO THE

TRIAL AND EVEN IN THE TRIAL TO MONITOR, AS AVI WAS SAYING, HOW THE NATURE OF THE PATIENT CONDITION CHANGES WHEN IT'S A MORE CURATIVE THERAPY AS OPPOSED A MORE TRADITIONAL THERAPY.

SO WE WOULD REGARD OURSELVES AS HAVING A SUCCESSFUL TRACK RECORD, BUT WE STILL BELIEVE THERE ARE A LOT OF LEARNINGS ALONG THE WAY TO TRULY CAPTURE THE PATIENT POPULATIONS AT THE BEGINNING AND TO KEEP THEM IN THE TRIALS THROUGH.

DR. DULIEGE: THANK YOU. I UNDERSTAND THAT. IT'S A PERFECT SEGUE INTO MY SECOND QUESTION, WHICH IS TAKING INTO ACCOUNT WHAT YOU HAVE LEARNED ALREADY, WHAT WOULD YOU DO DIFFERENTLY TO HELP COMPANIES AND CIRM DEVELOP STEM CELLS COMPARED TO DEVELOPING A REGULAR PRODUCT, BEING A SMALL MOLECULE OR PROTEIN OR WHATEVER?

DR. MC KEMEY: I THINK THERE ARE TWO MAIN THINGS, THREE THINGS COME TO THE TOP OF OUR LIST. I THINK THE FIRST ONE IS EARLY, VERY EARLY MEETINGS WITH THE REGULATORS. WE FIND IN GENERAL, BUT PARTICULARLY IN THE REGENERATIVE MEDICINE THERAPIES WHERE THE COMPANIES TEND TO BE QUITE YOUNG, THERE'S A SLIGHT AVERSION OR PERHAPS AN ANXIETY ABOUT GOING TO THE AGENCY EARLY AND TALKING ABOUT THE CLINICAL DEVELOPMENT PLAN. SO WE THINK THAT'S ONE, VERY

EARLY ENGAGEMENT.

I THINK THE SECOND ONE IS REALLY AROUND A BROADER AWARENESS CAMPAIGN ABOUT THE BENEFITS AND THE RISKS OF CELL-BASED THERAPIES. THERE'S STILL NOT A VERY BROAD UNDERSTANDING. IF YOU GO INTO A GESTATIONAL DIABETES TRIAL OR A CARDIOVASCULAR TRIAL, THERE'S SORT OF A BODY OF KNOWLEDGE ABOUT HOW THESE THINGS WORK. THERE'S VERY WELL ESTABLISHED, VERY LARGE PATIENT COMMUNITIES THAT ARE A RESOURCE. SO I THINK MORE EDUCATION AND AWARENESS ABOUT THE BENEFIT OF CLINICAL RESEARCH AS A PART OF CARE, AS A CARE PATHWAY, WOULD BE THE SECOND.

I THINK THE THIRD IS MORE COMPOUNDED EXPERIENCE BROUGHT TO BEAR ON THE POTENTIAL SAFETY SIDE EFFECTS AT SITES. A LOT OF WHAT YOU END UP DOING THROUGH THE APPLICATION OF THE CELL-BASED THERAPIES IS, PARTICULARLY IN CNS, YOU'RE ADDING FLUIDS INTO A PART OF THE BODY WHICH DOESN'T HAVE THAT MUCH ROOM TO EXPAND, AND THERE ARE CERTAIN PARTICULAR SETS OF SIDE EFFECTS WHICH ARE UNIQUE TO THAT KIND OF ADMINISTRATION. SO I THINK THAT IN GENERAL THE SITE AWARENESS OF INFORMATION MONITORING AND THE INFORMATION OF THE CRF TO TRULY REFLECT THOSE KINDS OF POTENTIAL SIDE EFFECTS IS IMPORTANT TOO.

THERE'S THREE IMMEDIATE ONES.

DR. KULKARNI: I'D LIKE TO ADD TO A FEW OF YOUR POINTS, ADRIAN. ONE IS TRULY AN ADD-ON. AS WE HAVE DISCUSSED WITH THE REGULATORY AGENCIES ABOUT CLINICAL DEVELOPMENT PLAN, WE ALSO REALIZED THAT THERE'S A BIG ELEMENT OF PATIENT-REPORTED OUTCOMES THAT'S BEEN MISSING. WE ARE AT THE FOREFRONT NOW OF DEVELOPING PRO AND EPRO WHAT'S CALLED INSTRUMENTS THAT AGENCIES ARE NOW FAVORABLY ACCEPTING. WE WERE NOT AS A COMMUNITY OF PEOPLE IN THE SPACE AS GOOD JUST A FEW YEARS BACK. SO THE GOOD NEWS IS WE ARE GETTING BETTER. THAT'S TO YOUR POINT ABOUT LEARNINGS.

THE SECOND IS WE RECOGNIZED THAT ENROLLMENT WAS FLAGGING BECAUSE OF REALLY TOP-DOWN APPROACH. AND THEY WERE SORT OF SAYING HERE'S THE KIND OF DISEASE, AND THAT DISEASE IS ADDRESSED AT THIS PARTICULAR CENTER. SO IF YOU CAN IDENTIFY THE CENTER, THE PATIENTS WILL COME. TURNS OUT THAT'S NOT THE RIGHT WAY TO DO IT. SO NOW WE'VE GOT A NEW APPROACH CALLED PATIENT-DRIVEN SITE SELECTION. AND FOR THIS PARTICULAR SPACE, IT'S TURNING OUT TO BE BETTER TO GO FROM PATIENT INVESTIGATOR AND DOING SITE SELECTION ON THAT BASIS.

AND, LASTLY, TO ENSURE THAT MANAGEMENT

BUY-IN IS CONSISTENT BECAUSE WE ALSO AT SOME OF THE LARGE PHARMA COMPANIES WHO WERE INTERESTED IN THE SPACE HAVE SEEN FLUCTUATING LEVELS OF INTEREST. WE WANT TO MAKE SURE -- WE HAVE MORE EXPERIENCE NOW TO GET EARLIER AND EARLIER VIEWS ON WHAT THE ECONOMIC VALUE WILL BE SO THAT THE PRODUCT DOESN'T GET LOST IN THE PROGRESSION THROUGH THE PIPELINE, THE PIPELINE DEVELOPMENT PROCESS, BECAUSE THAT'S WHERE WE'VE SEEN MANAGEMENT ATTENTION FAIL AND THE ABILITY TO BE CONSISTENT ABOUT WHAT THOSE NUMBERS WILL LOOK LIKE AND, THEREFORE, TO KEEP FUNDING IT ALL THE WAY THROUGH.

DR. MC KEMEY: I THINK WE'D LIKE TO CATCH UP WITH YOU LATER AND FIND OUT WHAT WE'VE MISSED AND WHAT ELSE WE CAN FOCUS ON.

DR. DULIEGE: THIS IS EXCELLENT, TRULY EXCELLENT. THANK YOU.

DR. BERGLUND: THANK YOU FOR SHARING YOUR VISION AND FOR THE PRESENTATION. SO WE HAVE, AND I ASSUME ACTUALLY MANY OF THE INSTITUTIONS HERE, HAVE RELATIONSHIP AND HAVE WORKED WITH QUINTILES BEFORE. SO I GUESS THAT YOU ALSO ON THE OTHER SIDE OF THE COIN HAVE A PRETTY GOOD IDEA ABOUT THE INSTITUTIONAL ENVIRONMENT IN WHICH MANY OF THESE TRIALS HAPPEN. AND ALTHOUGH IT'S BEEN SAID THAT WE HAVE A STRONG

INTEREST IN SCIENCE, THERE'S ACTUALLY SOME INTEREST IN THE SORT OF BORING ASPECTS OF THE REGULATORY SCIENCE AT OUR INSTITUTIONS.

IT SEEMS TO ME THAT, AT LEAST IN SOME AREAS, SOME OF THESE RESOURCES ARE AVAILABLE TO OUR SCIENTISTS, INCLUDING STEM CELL SCIENTISTS, ALTHOUGH NOT TO THE EXTENT THAT YOU ARE PROPOSING. SO THERE IS SORT OF, CONTINUING THE ANALOGY OF A FIRE BRIGADE, WE HAVE A BUDDING FIRE BRIGADE, I THINK, IN ALL OUR INSTITUTIONS. SO WHAT I'M WONDERING IS, HAVING THAT OPPORTUNITY FOR SYNERGY, WHAT ARE YOUR THOUGHTS OF DOING THAT TO MAKE SURE THAT IN A SENSE THIS DOES NOT BECOME A VERY COMPETENT AND STRONG, BUT YET MAYBE SILOED APPROACH AT A GIVEN INSTITUTION?

DR. KULKARNI: NOT ALL THE PAGES THAT WE CONSTRUCTED FOR EXPLAINING OUR CONCEPT MADE IT TO THIS PRESENTATION. THERE IS A VERY DETAILED SET OF THINKING THAT'S GONE INTO PUTTING TOGETHER A STEERING COMMITTEE THAT ACTUALLY THINKS ABOUT WHAT CIRM'S POINT OF VIEW WILL BE AND WHAT THE CLINICS' POINT OF VIEW WILL BE SO THAT WE CAN FIGURE OUT WHAT CAPABILITIES NEED TO BE BUILT AND MAINTAINED BY THE ACCELERATING CENTER BECAUSE THEY ARE DEFERENTIAL AND OF VALUE RELATIVE TO THE NETWORK.

THERE'S VERY LITTLE TO BE GAINED BY SILO-IZING OR PUTTING INTO THE ACCELERATING CENTER A CAPABILITY SET THAT ALREADY EXISTS IN THE NETWORK. AND SO WHILE TODAY I DON'T HAVE THE SPECIFIC ANSWER FOR WHICH EXACT CAPABILITY SET NEEDS TO BE BUILT AT THE APPROPRIATE HUNDRED PERCENT LEVEL HERE, IT'S PART OF THE QUESTION THAT WE'LL BE ASKING AS WE PUT TOGETHER THE STEERING COMMITTEE THAT WILL THEN WORK ON THIS.

MR. SHEEHY: ADDITIONAL QUESTIONS OR COMMENTS?

DR. BRENNER: UNLIKE ANNE-MARIE, I DON'T KNOW THAT MUCH ABOUT CRO'S. I KNOW A LOT ABOUT CORES WITH VERY MIXED SUCCESS. SOMETIMES FROM A TOP DOWN WE MAKE A CORE, LIKE FIELD OF DREAMS EFFECT, AND THINK IF WE BUILD IT, THEY WILL COME, AND IT DOESN'T WORK. AND SOMETIMES IT COMES OUT THAT PEOPLE WHO ARE ACTUALLY USING IT DEVELOP IT FROM THE GROUND UP AND IT'S REMARKABLY SUCCESSFUL.

SO I WANT YOU TALK ABOUT THAT, BUT ALSO TALK ABOUT AT WHAT POINT DO YOU EXPECT CIRM INVESTIGATORS TO INTERACT WITH YOU? WOULD YOU EVEN IMAGINE THEM EVEN BEFORE THEY GET THE GRANT TO SORT OF PLAN THE GRANT AND THINGS LIKE THAT?

DR. KULKARNI: YES.

DR. BRENNER: ALSO COMMENT ON HOW, AS PEOPLE IDENTIFY GAPS IN THEIR ABILITY TO DO THINGS, HOW YOU COULD RESPOND TO THAT.

DR. MC KEMEY: ON THE SECOND PART OF THE QUESTION, ABSOLUTELY. WE CONCEPTUALIZE THE PEOPLE -- THE SKILL SET THAT WE'RE MAKING AVAILABLE IS EXACTLY FOR THAT FIRST PURPOSE, FOR THOSE EARLY DISCUSSIONS WITH POTENTIAL APPLICANTS TO LOOK AND SEE, TO DIAGNOSE A LITTLE BIT, ABOUT HOW MUCH OF THE CLINICAL DEVELOPMENT PLAN OR THE PUTATIVE PROTOCOL IS OPTIMIZED AND WHERE THERE MAY BE ROOM FOR IMPROVEMENT.

AND ALSO, FRANKLY, THAT EARLIER POINT AGAIN ABOUT THE REGULATORY AGENCY, HOW SOON SHOULD THEY BE REALLY SEEKING THAT KIND OF GUIDANCE? SO ABSOLUTELY. I DON'T THINK THIS STARTS AT THE POINT OF GRANT. I THINK IT STARTS PRE.

DR. MILLS: IF I COULD JUST INTERJECT AND ADD TO THAT. THIS IS ONE OF THE THINGS ANNE-MARIE POINTED OUT VERY WELL WHERE THE ACTUAL TRUE NATURE OF THE PARTNERSHIP IS JUST SO CRITICAL AND SO VALUABLE, THAT WE'RE ALIGNED HERE, THAT QUINTILES IS HELPING US BRING IN, NOT JUST MORE PROJECTS, BUT BETTER PROJECTS. GETTING THE PROJECTS BETTER ON THE FRONT END OF THIS IS A VERY, VERY EXCITING THING FOR

US. THEY HAVE A BROAD REACH. THEY HAVE A LARGE KNOWLEDGE BASE.

BUT ANY HELP WE CAN GET THAT MAKES AN APPLICATION THAT COMES TO US OUT OF THE GATE CLOSER TO A 95 IS VERY EXCITING, AND THAT'S SOMETHING, SINCE THE DECISION, WE'VE ENGAGED IN CONVERSATION WITH THEM ABOUT.

MR. SHEEHY: OTHER QUESTIONS AND COMMENTS?

CHAIRMAN THOMAS: YES. I JUST WANT TO ASK YOU. MENTION WAS MADE EARLIER, I THINK DR. MILLS SAID, THAT YOU FOLKS WOULD BE INVOLVED IN ACTUALLY HELPING BRING NEW CLINICAL TRIALS, FOR EXAMPLE, TO CIRM THROUGH YOUR VAST NETWORK, WHICH WOULD BE A TREMENDOUS VALUE ADD FOR WHAT WE'RE TRYING TO DO. COULD YOU COMMENT ON THAT BRIEFLY?

DR. KULKARNI: WE CURRENTLY OPERATE OUR BUSINESS, THIS IS THE QUINTILES REGULAR BUSINESS, WITH A FAIRLY LARGE GLOBAL BUSINESS DEVELOPMENT FUNCTION THAT IS ORGANIZED TO STAY IN CONTACT WITH INVESTIGATORS FROM ACADEMIA THROUGH TO THE LARGER COMMERCIAL INSTITUTIONS. IN FACT, RECENTLY BIO, WE HAD A LARGE BOOTH. WE HAVE A PRESENCE AT EVERY MAJOR SCIENTIFIC AND COMMERCIAL QUASI SCIENTIFIC MEETING, AND THERE IS A NETWORK OF PEOPLE WHO SURFACE LEADS. IN THE STEM CELL RESEARCH AND

DEVELOPMENT CASE, THESE LEADS WOULD COME TO THE ACCELERATING CENTER BUSINESS DEVELOPMENT PERSON. AND THEN THAT PERSON WOULD TRIAGE AND PROSECUTE. SO THERE WOULD BE A FOLLOW-UP.

AN EXAMPLE, JUST TO COMPLETE THE THOUGHT, WOULD BE IF SOMEONE SAID THE CITY OF HOPE HAS THIS PARTICULAR PRODUCT THAT'S CURRENTLY BEING DISCUSSED. WE MET WITH THEM AT BIO. ADRIAN OR AVI, COULD YOU TAKE THIS DISCUSSION FORWARD? THEN WE WOULD SIT DOWN WITH THE APPROPRIATE INVESTIGATOR AT THE CITY OF HOPE AND SAY, "THIS IS WHAT WE HEARD. CAN YOU TELL US MORE ABOUT YOUR PROGRAM SO WE CAN START FIGURING OUT WHERE ARE THE POINTS WHERE YOU NEED HELP?" BECAUSE CLEARLY THEY'RE NOT GOING TO NEED HELP IN EVERY PART OF THEIR OVERALL DEVELOPMENT PLAN. IT'S AN IDENTIFICATION SURFACING CONNECTEDNESS TO THE AC AND THEN TRIAGE AND MOVE FORWARD.

DR. MC KEMEY: JUST TO GIVE A SPECIFIC EXAMPLE, TWO, THREE WEEKS AGO WE HAD A CALL WITH A BOSTON-BASED COMPANY, AND THEY HAD ACTUALLY RECENTLY END LICENSED A MACULAR DEGENERATION AND CELL-BASED THERAPY FROM A CIRM GRANTEE. SO THE CONVERSATION WE WOULD HAVE GOING FORWARD IS WHAT ABOUT THAT NEXT PHASE OF DEVELOPMENT? HOW ARE YOU GOING TO DO THAT?

HOW COULD WE OPTIMIZE IT BY VIRTUE OF USING THE ACCELERATING CENTER?

THE EXTRAORDINARY THING ABOUT THE GREATER QUINTILES IS IT'S JUST CONNECTED TO EVERY, AT SOME LEVEL, NOT NECESSARILY WORKING WITH THEM, BUT HAS AN AWARENESS OF, I DON'T KNOW, MAYBE 70, 80 PERCENT OF THE TOTAL MARKET IN MOLECULES IN DEVELOPMENT AND CELLS IN DEVELOPMENT. SO WE JUST HAVE THE BUY-IN FROM THE BUSINESS LEADERS AND FROM THOSE SEGMENTS TO HELP US GENERATE ADDITIONAL LEADS.

DR. KULKARNI: I'M JUST REMINDED OF THIS MEETING. SO ADRIAN AND I WERE SITTING NEXT TO EACH OTHER. THE HEAD OF THE ORGANIZATION WAS ON THE RIGHT. LAURA MARQUEE, OUR EMERGING BIOPHARMA SEGMENT LEADER, WAS OPPOSITE US; AND ELLIS, THE GLOBAL WEST COAST LEADER, WAS THE ONE WHO HAD SURFACED THIS LEAD. AND THAT'S THE WAY IT WORKS, IT'S SUPPOSED TO WORK.

MR. SHEEHY: OTHER QUESTIONS OR COMMENTS? WE'LL DO PUBLIC COMMENT IN A SECOND. I DID HAVE A QUESTION FOR YOU. YOU KIND OF STIMULATED IT BY MENTIONING PROS. SO WHAT IS YOUR PLAN TO INCLUDE PATIENT ADVOCATES IN THE PATIENT ORGANIZATIONS? I WAS IN A SERIES -- I WAS IN A GROUP DISCUSSING TRYING TO GET AN INDICATION FOR A SUBPOPULATION. IN

TRYING TO FIGURE OUT HOW TO DO IT, IN TALKING WITH FDA FOLKS, THE IDEA OF PROS CAME UP, AND IT WAS ACTUALLY MENTIONED THAT FLU PRODUCTS ARE APPROVED COMPLETELY ON THE BASIS OF PROS. AND IT SEEMS LIKE THAT MIGHT BE, ESPECIALLY FOR SOME OF THE CONDITIONS THAT WE MIGHT BE TRYING TO TREAT, THAT THAT'S AN INTERESTING AVENUE. BUT YOU NEED, I WOULD BELIEVE, DEEP ENGAGEMENT WITH PATIENTS AND PATIENT ADVOCACY GROUPS IN ORDER TO DO THAT, PLUS BRINGING THE POWER OF PATIENT ADVOCACY GROUPS AND PATIENTS TO BEAR ON THE FDA IN THOSE DISCUSSIONS IN TRYING TO MOVE THESE PRODUCTS TO THE MARKET WOULD ALSO, I THINK, BE HELPFUL.

DR. MC KEMEY: ABSOLUTELY. THERE'S THREE WAYS YOU TEND TO WORK WITH THE PATIENT ADVOCACY GROUPS. NO. 1 IS AWARENESS THAT THERE'S CLINICAL RESEARCH THAT COULD HAVE BENEFIT.

THE SECOND ONE IS REALLY AROUND UNDERSTANDING WHAT ELEMENTS OF THE REAL LIFE CLINICAL CONDITION ARE MOST IMPORTANT BECAUSE THE ENDPOINTS IN THE TRIAL, THEY'RE CLINICAL BIOMARKERS, BUT THEY DON'T NECESSARILY MOVE THE NEEDLE ON HOW THE PATIENT FEELS DAY TO DAY.

AND THE THIRD ONE IS IT'S VERY EASY FOR SOME VERY SMART PEOPLE IN AN ADULT ROOM IN

CAMBRIDGE, MASSACHUSETTS, SOMEWHERE TO CREATE THE IDEAL TRIAL FROM A SCIENTIFIC PERSPECTIVE, BUT THEN FIND OUT THAT IT'S COMPLETELY INFEASIBLE FROM A PATIENT BURDEN PERSPECTIVE, NUMBER OF VISITS OR LEVEL OF FOLLOW-UP OR WHATEVER. SO THE THIRD WAY SHOULD REALLY VALIDATE THE PROTOCOLS WITH THE PATIENT ADVOCACY GROUPS OR FOCUS GROUPS WITHIN THE PATIENT ADVOCACY GROUPS.

THOSE ARE ALL THREE WAYS THAT WE WORK WITH PATIENT ADVOCACY.

DR. KULKARNI: WHILE ALL THESE POINTS ARE RIGHT, THERE'S ALSO BEEN A MIND SHIFT THAT'S TAKEN PLACE THE LAST SEVERAL YEARS. IT USED TO BE THAT WE USED TO LOOK TO PATIENT ADVOCACY GROUPS, LET'S SAY, A DECADE BACK AS HOW DO WE MAKE SURE THAT THEY DON'T CAUSE PROBLEMS FOR US DURING THE REGISTRATION PROCESS, ESPECIALLY THE OLD HIV DAYS, FOR EXAMPLE.

THAT HAS CHANGED SO DRAMATICALLY NOW THAT WE UNDERSTAND THAT PATIENT ADVOCACY GROUPS REPRESENT THE PATIENTS WE WANT FOR THE SUCCESSFUL ANALYTICAL STUDIES AND HAVE A BETTER UNDERSTANDING IN MANY CASES ABOUT THE OUTCOME THAT WILL BE REGISTERABLE OUTCOME. SO I THINK THE POWER DYNAMIC HAS SHIFTED FROM SHOULD WE INCLUDE THEM TO WE MUST INCLUDE THEM. THAT MIND SHIFT, I THINK, IS THE ONE THAT WE NOW

APPROACH THIS PART OF THE BUSINESS WITH.

MR. SHEEHY: THANK YOU. I THINK IT ALSO HELPS TO DERISK PROJECTS FOR THE FDA IF THEY KNOW PATIENT ADVOCACY GROUPS AND PATIENTS ARE GOING TO BEAR NEGATIVE OUTCOMES WITHOUT HOLDING THE FDA ACCOUNTABLE. I THINK IT MAKES A BIG DIFFERENCE AND WE SEE THAT IN HIV, IN FACT, SOME OF THE STUFF GOING ON NOW.

ARE THERE OTHER BOARD COMMENTS? ARE THERE COMMENTS FROM FOLKS ON THE PHONE? THERE IS A PUBLIC COMMENT QUESTION. SO I DO WANT TO TAKE THOSE IF YOU GUYS ARE COMFORTABLE DOING SO, BUT I WANT TO MAKE SURE EVERYBODY ON THE BOARD GETS A CHANCE TO COMMENT OR ASK QUESTIONS.

DON REED, I SAW YOU WANTED TO SAY SOMETHING. IF THERE'S ANYBODY ELSE IN THE PUBLIC THAT WOULD LIKE TO -- AND DON IS A LONGTIME SUPPORTER OF CIRM. IN A LOT OF WAYS, WE MIGHT NOT HAVE PROP 71, AND CERTAINLY THE WORK THAT DON HAS DONE OVER THE YEARS -- YOU MIGHT SAY A BIT ABOUT YOURSELF SO THAT THEY KNOW WHERE YOU'RE COMING FROM, DON, BECAUSE HE'S BEEN AN ARCH SUPPORTER OF OURS.

MR. REED: THANK YOU SO MUCH. WHAT A BEAUTIFUL THING TO SAY. MY SON, ROMAN REED, WAS PARALYZED IN A COLLEGE FOOTBALL ACCIDENT 21 YEARS

AGO, AND EVER SINCE THEN WE'VE BEEN FIGHTING FOR A CURE FOR PARALYSIS. WE WERE ABLE TO PASS A LAW CALLED THE ROMAN REED SPINAL CORD INJURY RESEARCH ACT, WHICH FUNDED $17 MILLION IN CALIFORNIA FUNDING AND ATTRACTED 85 MILLION FROM THE FEDS, BUT NOTHING COMPARED TO THE MAGNIFICENCE OF CIRM. IT IS JUST BEYOND BELIEF.

FIRST OF ALL, I HAVE THIS FEELING THAT I DIDN'T KNOW WE NEEDED SOMETHING LIKE THIS. AND ALL OF A SUDDEN YOU REALIZE, OH, MY GOSH. WE REALLY DO NEED SOMETHING LIKE THIS. I'M ALSO IMPRESSED BY YOUR PREPARATION AND BY THE FEELING THAT I HAD THAT YOU WEREN'T TRYING TO BS YOUR WAY THROUGH SOMETHING IF YOU DIDN'T KNOW. IF THERE'S SOMETHING WRONG, YOU TALKED ABOUT IT. I LIKE THAT.

I DO HAVE A QUESTION FOR YOU. CIRM WORKS REALLY HARD ON THEIR WEBSITE SO THAT THERE'S UNDERSTANDABLE PORTIONS FOR THE PATIENT ADVOCATE WHERE IT'S CLEAR, WHERE WE CAN UNDERSTAND WHAT'S HAPPENING. THAT'S CRUCIAL. IF YOU WANT OUR INVOLVEMENT, YOU MUST BE CLEAR ALSO.

MY QUESTION IS WILL YOU MAKE YOUR WEBSITE -- YOU'LL MAKE A WEBSITE ABOUT THIS. WHEN YOU DO IT, WILL YOU TRY AND MAKE IT SO IT IS ACCESSIBLE TO THE PUBLIC LEADERSHIP?

DR. KULKARNI: I THINK THAT QUESTION JUST DESERVES A YES.

MR. REED: THANK YOU VERY MUCH. WE'LL HOLD YOU TO IT.

MR. SHEEHY: IF WE HAVE NO MORE QUESTIONS OR COMMENTS, I DON'T KNOW, DO ANY OF THE OTHER SITES HAVE PUBLIC COMMENT FROM THERE? SO COULD I GET A MOTION THEN?

MR. TORRES: MOVE TO APPROVE.

DR. DULIEGE: SECOND.

MR. SHEEHY: BEFORE YOU GUYS SIT DOWN, I JUST WANT TO THANK YOU FOR YOUR PRESENTATION. IT'S BEEN INCREDIBLY HELPFUL. IT IS SO IMPORTANT THAT THE PUBLIC KNOWS, BECAUSE WE ARE A PUBLICLY FUNDED AGENCY, NOT ONLY KNOWS WHAT WE'RE PLANNING AND WHAT WE'RE DOING, BUT THAT THEY CAN SHARE OUR EXCITEMENT. I THINK DON REED'S COMMENTS REALLY CAPTURE THE ENTHUSIASM AND EXCITEMENT OF THE PATIENTS AND THE COMMUNITY IN CALIFORNIA TO MOVE FORWARD WITH THIS PARTNERSHIP WITH YOU. SO THANK YOU.

SO WE HAVE A MOTION; WE HAVE A SECOND. I'LL AGAIN ASK FOR PUBLIC COMMENT OR ANY BOARD COMMENTS. THERE ARE NONE, SO, MS. BONNEVILLE, COULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD. SHERRY LANSING.
MS. LANSING: YES.
MS. BONNEVILLE: KATHY LAPORTE.
MS. LAPORTE: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA. JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT. 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.

MOTION CARRIES.

MR. SHEEHY: MOTION CARRIES. CONGRATULATIONS TO QUINTILES. WE'RE REALLY LOOKING FORWARD TO THIS. THIS IS EXCITING FOR US.

I THINK WE HAVE TWO MORE APPLICATIONS TO LOOK AT FOR THE APPLICATION REVIEW SUBCOMMITTEE. I THINK IT MIGHT BE WISE, CHAIRMAN THOMAS, TO TAKE A BREAK MAYBE FOR THE TRANSCRIPTIONIST AND MAYBE SOME OF THE REST OF US COULD HAVE A MOMENT.

CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY. SO LET'S TAKE A SHORT BREAK. WE'LL CONVENE AT 11:15. RECONVENE 11:15.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: WE WOULD LIKE TO CONTINUE HERE, SO COULD EVERYBODY PLEASE TAKE YOUR SEATS. WE'RE GOING TO RESUME NOW WITH ITEM NO. 8, WHICH IS CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLIN1: PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL TRIALS. I'M GOING TO TURN THIS OVER AGAIN TO MR. SHEEHY.

MR. SHEEHY: THANK YOU, DR. THOMAS. SO HOPEFULLY EVERYONE CAN GET BACK TO THEIR SEATS. GREAT. SO I THINK IT'S OKAY TO GO AHEAD AND GO

INTO -- HOW ARE YOU GOING TO DO THIS, DR. SAMBRANO? ARE YOU GOING TO TAKE THEM ONE AT A TIME OR PRESENT THEM BOTH?

DR. SAMBRANO: YES. I'M JUST GOING TO INTRODUCE THE CONCEPT AND THEN GO INTO EACH ONE.

MR. SHEEHY: GREAT. GREAT. AND THEN WE'LL HAVE A DISCUSSION INDIVIDUALLY ON EACH PROJECT AND THEN A VOTE.

DR. SAMBRANO: YES.

MR. SHEEHY: GREAT. THANK YOU.

DR. SAMBRANO: THANK YOU, MR. SHEEHY.

SO I'M BRINGING TO YOU RECOMMENDATIONS FROM THE GRANTS WORKING GROUP REVIEW OF TWO APPLICATIONS THAT WERE CONSIDERED UNDER OUR CLINICAL PROGRAM. AND JUST A BRIEF REMINDER OF THE CLINICAL STAGE PROGRAM THAT WE HAVE INCLUDES APPLICATIONS UNDER A CLIN1, CLIN2, OR CLIN3 OPPORTUNITY. IN THIS CASE THESE ARE BOTH CLIN1 APPLICATIONS; THAT IS, LATE STAGE PRECLINICAL DEVELOPMENT FOR THOSE PROJECTS THAT INTEND TO DO IND-ENABLING WORK, TO SUBMIT AN IND, AND DO A FUTURE TRIAL.

ALSO A REMINDER OF THE SCORING SYSTEM THAT IS UTILIZED FOR THESE APPLICATIONS. IT WAS MENTIONED EARLIER WE HAVE A SYSTEM OF 1, 2, OR 3 WITH 1 BEING THOSE APPLICATIONS WITH EXCEPTIONAL

MERIT; SCORE OF 2 MEANS IT'S AN APPLICATION THAT NEEDS IMPROVEMENT AND WOULDN'T WARRANT FUNDING AT THIS TIME, BUT MAY BE RESUBMITTED TO ADDRESS THOSE AREAS OF CONCERN; AND THEN A SCORE OF 3, WHICH MEANS IT HAS FLAWS THAT REALLY WOULD NOT WARRANT FUNDING AND THE SAME PROJECT SHOULD NOT BE RESUBMITTED FOR AT LEAST SIX MONTHS.

THE FIRST APPLICATION IS 8686. IT IS AN APPLICATION FOR PRECLINICAL DEVELOPMENT OF A CELL THERAPY FOR CORNEAL BLINDNESS. SO THIS THERAPY UTILIZES LIMBAL STEM CELLS THAT ARE CULTIVATED FROM CORNEAL EPITHELIUM OF PATIENTS. THIS IS FOR CORNEAL BLINDNESS THAT MAY RESULT FROM INJURY OR AN INABILITY TO HEAL DUE TO CORNEAL EPITHELIAL STEM CELL DEFICIENCY. TYPICALLY WHAT HAPPENS HERE IS FROM HEALTHY TISSUE THIS IS AVAILABLE FROM THE PATIENT, LIMBAL STEM CELLS ARE CULTURED, EXPANDED, AND RETRANSPLANTED IN ORDER TO HEAL THE WOUNDS.

THE GOAL HERE IS TO COMPLETE PRECLINICAL RESEARCH ACTIVITIES NEEDED TO SUBMIT AN IND AND TO SUPPORT A FUTURE CLINICAL TRIAL. THE MAJOR ACTIVITIES THAT ARE PROPOSED ARE LARGELY TAKING THIS PRODUCT INTO THE MORE FORMALIZED MANUFACTURING DEVELOPMENT WITHIN A GMP FACILITY, DOING SOME BIOMARKER DEVELOPMENT, AND, OF COURSE, PREPARING A

PACKAGE FOR IND SUBMISSION. THE FUNDS THAT WERE REQUESTED ARE $4.2 MILLION.

AND THE GRANTS WORKING GROUP -- BEFORE APPLICATIONS GO TO THE GRANTS WORKING GROUP, WE DO A BUDGET REVIEW TO ENSURE THAT THE BUDGET IS APPROPRIATE. THIS PASSED THAT BUDGET REVIEW. THEN GOING ON TO THE GRANTS WORKING GROUP, THE GRANTS WORKING GROUP LOOKED AT THIS APPLICATION, AND IT WENT THROUGH A COUPLE OF REVISIONS, BUT ULTIMATELY THE GRANTS WORKING GROUP SCORED IT A 1 WITH NINE MEMBERS SCORING IT A 1, ONE MEMBER A 2, AND NONE SCORING IT A 3 IN THE LAST REVIEW. SO IT GOT A POSITIVE RECOMMENDATION.

CIRM, IN REVIEWING AND ASSESSING THE PROCESS AND COMMENTS FROM REVIEWERS, AGREES WITH THE FUNDING RECOMMENDATION AND SUGGESTS THE AWARD AMOUNT OF $4.2 MILLION AS INDICATED ON THE SLIDE.

MR. SHEEHY: THANK YOU, DR. SAMBRANO. DO I HAVE A MOTION TO ACCEPT THE RECOMMENDATION AND FUND THIS GRANT?

MR. HIGGINS: SO MOVED.

MS. LAPORTE: SECOND.

MR. SHEEHY: IS THERE ANY BOARD DISCUSSION? IS THERE ANY PUBLIC COMMENT? THEN, MS. BONNEVILLE, COULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD. KATHY LAPORTE.
MS. LAPORTE: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA. JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT. AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: ABSTAIN.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: MOTION CARRIES.

MR. SHEEHY: THANK YOU. SO THE NEXT PROJECT, PLEASE, DR. SAMBRANO.

DR. SAMBRANO: THE NEXT PROJECT IS APPLICATION 9187 FOR PRECLINICAL DEVELOPMENT OF A CELL THERAPY FOR CHRONIC WOUNDS IN DIABETICS. THIS IS AN AUTOLOGOUS STROMAL VASCULAR FRACTION CELLS, BASICALLY ADIPOSE-DERIVED STEM CELLS, THAT ARE ISOLATED AT THE POINT OF CARE FOR THE TREATMENT OF ULCERS AND CHRONIC WOUNDS THAT ARE ASSOCIATED WITH DIABETES. THE GOAL OF THIS PROPOSAL IS TO COMPLETE PRECLINICAL RESEARCH ACTIVITIES THAT THEY WOULD NEED TO SUBMIT AN IND AND SUPPORT A CLINICAL TRIAL.

THE MAJOR ACTIVITIES INCLUDE THE PREPARATION OF THE IND AND INVESTIGATOR'S BROCHURE, TO CONDUCT SOME PRODUCT CHARACTERIZATION STUDIES THAT HAVE BEEN REQUIRED BY THE FDA, AND TO INSTITUTE AN ENDOTOXIN TESTING INTO THEIR CLINICAL WORKFLOW.

THE FUNDS REQUESTED FOR THIS WERE $75,000 APPROXIMATELY. THIS PROPOSAL PASSED BUDGET REVIEW, BUT THE GRANTS WORKING GROUP IN ITS REVIEW SCORED THIS A 3, MEANING THEY DID NOT FEEL THAT THIS WAS A PROPOSAL THAT WAS OF SUFFICIENT MERIT AND WARRANTED

FUNDING AND, THEREFORE, SHOULD NOT BE RESUBMITTED FOR AT LEAST SIX MONTHS. THERE WERE ZERO GRANTS WORKING GROUP MEMBERS THAT GAVE IT A SCORE OF 1, THERE WERE TWO THAT GAVE IT A SCORE OF 2, AND NINE THAT GAVE IT A SCORE OF 3.

CIRM TEAM RECOMMENDATION CONCURS WITH THAT OF THE GRANTS WORKING GROUP, AND WE RECOMMEND NOT FUNDING THIS PROPOSAL.

MR. SHEEHY: THANK YOU, DR. SAMBRANO. DO WE HAVE A MOTION TO ACCEPT THE WORKING GROUP'S RECOMMENDATION?

DR. DULIEGE: I CAN MAKE A MOTION AND ALSO HAVE A QUESTION.

MR. SHEEHY: GREAT. GREAT. SO, DR. DULIEGE. DO WE HAVE A SECOND TO THAT MOTION?

MS. WINOKUR: I SECOND.

MR. SHEEHY: THANK YOU, MS. WINOKUR.

DR. DULIEGE: NOW I HAVE TO TURN IT ON. I THINK IT'S GOING TO BE HARD FOR THE ICOC TO GO AGAINST THE RECOMMENDATION OF CIRM, BUT MY QUESTION IS HOW COME -- IT'S NOT THAT WE GET TO REVIEW THAT, BUT IT'S OBVIOUS THE TEAM THAT PRESENTED OR REQUESTED THIS MONEY, PRESENTED THE APPLICATION AND REQUESTED THE MONEY, DIDN'T SEEM TO BE PREPARED AT ALL FOR THE TASK BECAUSE THEIR RATING WAS VERY BAD.

THAT'S CORRECT? SO WHY DO WE EVEN REVIEW IT? SHOULD THEY HAVE BEEN SENT BACK TO GO BACK TO THE BASICS AND DO A BETTER JOB UNLESS I MISSED A POINT? I'M TRYING TO SEE IF I MISSED A POINT HERE.

DR. SAMBRANO: NO. WE GET APPLICATIONS THAT THE GRANTS WORKING GROUP REVIEWS, SOME WHICH WE HAVE AN OPPORTUNITY BEFORE THE APPLICATION COMES TO PROVIDE ADVICE AND GUIDE, BUT NOT ALWAYS. SO SOMETIMES WE WILL GET AN APPLICATION THAT COMES IN THAT NEVER HAS TALKED TO SOMEBODY AT CIRM, WHETHER REVIEW OFFICE OR OUR THERAPEUTICS TEAM. SO THEY WILL COME IN WITH A PROJECT THAT JUST IS NOT READY OR NOT GOOD ENOUGH.

DR. DULIEGE: OBVIOUSLY.

MR. SHEEHY: SENATOR TORRES.

MR. TORRES: IT'S UNFORTUNATE THAT THIS DIDN'T GET THROUGH. WE SPEND IN THE STATE OF CALIFORNIA 24 BILLION A YEAR JUST FOR DIABETIC CARE. AND MUCH OF IT IS DISPROPORTIONATELY IN LATINO AND AFRICAN-AMERICAN COMMUNITIES. SO I HOPE THEY TAKE THE OPTION TO COME BACK IN SIX MONTHS BECAUSE WE NEED TO DO EVERYTHING WE CAN IN TERMS OF THIS AND ALSO HELPING TO FULFILL THE MISSION OF CIRM.

MR. SHEEHY: SO ARE THERE OTHER QUESTIONS OR COMMENTS FROM BOARD MEMBERS? IS THERE ANY PUBLIC

COMMENT EITHER HERE IN SAN FRANCISCO OR AT ANY OF THE SITES? COULD I THEN GET A ROLL CALL, PLEASE, MS. BONNEVILLE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD. KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA. JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT. 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: THE MOTION CARRIES.
MR. SHEEHY: I THINK THAT CONCLUDES THE BUSINESS OF THE APPLICATION REVIEW SUBCOMMITTEE.
CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY. THANK YOU, DR. SAMBRANO.
ON NEXT TO ITEM 9, CONSIDERATION OF THE CIRM BUDGET FOR FISCAL YEAR 2016-17. PRESENTATION BY CHILA SILVA-MARTIN.
MS. SILVA-MARTIN: GOOD MORNING, MR. CHAIRMAN, MEMBERS OF THE ICOC BOARD. THANK YOU FOR THE OPPORTUNITY TO PRESENT THE '16-'17 BUDGET. THE BUDGET PRESENTATION TODAY WILL COVER THE '15-'16 FISCAL YEAR. WE'LL LOOK AT THE BUDGET THAT THIS BOARD APPROVED. WE'LL ALSO LOOK AT WHERE WE EXPECT THE FINAL NUMBERS TO BE AT THE END OF THE FISCAL YEAR, AS WELL AS SOME MAJOR DRIVERS THAT ARE IMPACTING THE FINAL RESULTS. THEN WE'LL LOOK AT THE '16-'17 BUDGET REQUESTS. WE'LL LOOK AT SOME MAJOR FACTORS THAT ARE IMPACTING THAT REQUEST, ALSO SOME POTENTIAL RISKS THAT MAY IMPACT OUR ABILITY TO

REALIZE THE FINAL BUDGET RESULTS.

SO, FIRST, LOOKING AT THE '15-'16 FISCAL YEAR. THIS CHARTS PROVIDES A CATEGORICAL LEVEL OUR BUDGET. SO AS YOU CAN SEE FROM THE FIRST COLUMN, WE WERE ALLOCATED A TOTAL OF $18.7 MILLION. WE EXPECT THE BUDGET TO COME IN AT ABOUT $17.2 MILLION, AS REFLECTED IN COLUMN 2. AND THEN, FINALLY, THE VARIANCE OR THE UNDERRUNS OR OVERRUNS ARE REFLECTED IN THE LAST COLUMN. AND WE EXPECT THE BUDGET TO BE AT AN UNDERRUN OF $1.5 MILLION OR ABOUT 8 PERCENT.

SO WHAT I'D LIKE TO DO IS JUST BRIEFLY TALK ABOUT SOME OF THE MAJOR DRIVERS THAT ARE IMPACTING THAT VARIANCE. SO THERE ARE REALLY THREE AREAS WHERE WE ARE SEEING SOME PRETTY SIGNIFICANT EITHER UNDERRUNS OR OVERRUNS. SO WE DO SEE TWO MAJOR UNDERRUNS, AND THAT'S IN EMPLOYEE EXPENSES AND IN OUR REVIEWS, MEETINGS, AND WORKSHOPS CATEGORY. THERE IS ONE CATEGORY, HOWEVER, WHERE WE DO EXPECT TO HAVE AN OVERRUN, AND THAT'S IN OUR FACILITIES AND RELOCATION.

SO I'D JUST LIKE TO TALK ABOUT THOSE IN A LITTLE BIT MORE DETAIL. SO WHY ARE WE ANTICIPATING THAT OUR EMPLOYEE EXPENSES ARE GOING TO BE UNDERRUN BY ABOUT $1.2 MILLION? WELL, AS YOU MAY RECALL, DURING THE '14-'15 FISCAL YEAR, WE IMPLEMENTED A

MAJOR REORGANIZATION HERE AT CIRM. AND THEN DURING THE CURRENT YEAR, THE '15-'16 FISCAL YEAR, WE IMPLEMENTED OR BEGAN A STRATEGIC PLANNING PROCESS TO SUPPORT THAT REORGANIZATION.

SO AT THE BEGINNING OF THE FISCAL YEAR, WE HAD NUMEROUS POSITIONS THAT WERE VACANT. WE MADE THE DECISION NOT TO FILL THOSE POSITIONS AND TO KEEP THEM VACANT UNTIL WE FINISHED THE STRATEGIC PLANNING PROCESS SO THAT WE WOULD HAVE A FULL UNDERSTANDING OF WHAT TYPE OF RESOURCES WE WOULD NEED MOVING FORWARD.

NOW THAT WE'VE COMPLETED THE STRATEGIC PLANNING PROCESS, WE HAVE APPROVED THAT PLAN, WE ARE ACTIVELY RECRUITING TO FILL OUR POSITIONS. SO WE HOPE TO ELIMINATE THAT VARIANCE IN THE '16-'17 FISCAL YEAR. SO THAT IS WHY WE'RE SEEING A PRETTY SIGNIFICANT UNDERRUN IN EMPLOYEE EXPENSES.

ANOTHER AREA WHERE WE'VE SEEN AN UNDERRUN IS IN OUR REVIEWS, MEETINGS, AND WORKSHOPS CATEGORY. THERE ARE ACTUALLY TWO REASONS WHY WE HAVE THAT UNDERRUN. FIRST OF ALL, WE HELD FEWER MEETINGS THAN WHAT WE HAD BUDGETED, AND THEN WE RESTRUCTURED SOME OF OUR MEETINGS. SO DUE TO THE TIMING TO IMPLEMENT CIRM 2.0 FOR OUR DISCOVERY AND TRANSLATIONAL PROGRAMS, WE HAD BUDGETED TO HOLD FOUR REVIEWS

DURING THIS FISCAL YEAR. WE ACTUALLY ONLY HELD THREE. SO THAT'S WHERE SOME OF THE SAVINGS IS COMING FROM. WE'VE ALSO RESTRUCTURED HOW WE HOLD SOME OF OUR MEETINGS. SO, FOR EXAMPLE, FOR OUR ICOC BOARD MEETINGS, WE NOW ARE HOLDING LESS IN-PERSON MEETINGS AND HAVING MORE TELEPHONIC MEETINGS. AND THAT'S RESULTING IN SAVINGS FOR THIS COST CENTER.

IN ADDITION, WE RESTRUCTURED THE FORMAT FOR SOME OF OUR OTHER MEETINGS, SUCH AS THE ALPHA CLINIC AND THE CLINICAL ADVISORY PANELS. PREVIOUSLY WE HELD THOSE MEETINGS AT A PRIVATE VENUE AND WE HAD TO PAY FOR THOSE COSTS. DURING THIS FISCAL YEAR WE MOVED THE MEETINGS TO THE GRANTEE SITES AND WE ELIMINATED THOSE COSTS. SO AS YOU CAN SEE, MAKING THIS CHANGE HAS REALLY IMPACTED OUR BUDGET AND IS HAVING A POSITIVE IMPACT.

THERE IS ONE AREA, HOWEVER, WHERE WE DID HAVE AN OVERRUN, AND THAT IS IN OUR FACILITIES. SO WHY DID THAT HAPPEN? AS YOU KNOW, FOR THE FIRST ELEVEN YEARS OF CIRM'S EXISTENCE, WE HAD A VERY UNIQUE BENEFIT. WE HAD FREE RENT. BUT IN OCTOBER OF 2015 OUR LEASE FOR OUR FREE RENT EXPIRED. SO WE WERE REQUIRED TO GO OUT AND LOOK FOR SPACE. SO WE CONDUCTED AN EXTENSIVE SITE SEARCH, AND WE SELECTED OAKLAND AS OUR OFFICE HEADQUARTERS.

THE LOCATION THAT WE SELECTED WAS IN WHAT THEY CALL SHELL CONDITION, AND WE WERE REQUIRED TO BUILD IT OUT. SO WE HAD TWO OPTIONS FOR PAYING FOR THAT BUILDOUT. WE COULD HAVE FINANCED IT OVER THE FIRM TERM OF THE LEASE, WHICH IS FIVE YEARS, BUT THE OWNERSHIP OF THE BUILDING WOULD HAVE PASSED ON THOSE FINANCING COSTS TO US AND WOULD HAVE RESULTED IN INCREASED COSTS. OUR OTHER OPTION WAS TO JUST PAY THE COSTS UP FRONT AND ELIMINATE THE FINANCING COSTS, WHICH WAS A SAVINGS TO THE STATE. AND THAT'S WHAT WE ELECTED.

I DO WANT TO POINT OUT, THOUGH, EVEN THOUGH WE HAD TO PAY FOR THE BUILDOUT AND THE RELOCATION, MOVING TO OAKLAND WAS THE RIGHT DECISION. WE COULD HAVE STAYED IN SAN FRANCISCO AT OUR CURRENT LOCATION, BUT OVER THE TERM OF THE FIVE YEARS, IT WOULD HAVE COST US ABOUT $3 MILLION MORE TO STAY IN SAN FRANCISCO DESPITE THE FACT THAT WE PAID FOR THOSE ONE-TIME COSTS. THIS MOVE WAS THE RIGHT MOVE BECAUSE IT DID RESULT IN SAVINGS OVERALL.

SO NOW I'D LIKE TO MOVE INTO THE '16-'17 PROPOSED BUDGET. SO THIS CHART PROVIDES YOU A SNAPSHOT OF OUR BUDGET REQUEST SO YOU CAN LOOK AT IT AGAINST WHAT WE WERE ALLOCATED FOR THE '15-'16 FISCAL YEAR, WHICH IS IN THE FIRST COLUMN, AND THEN

WHAT WE THINK WE'LL BRING THE YEAR AT FOR THE '15-'16 FISCAL YEAR, OUR FINAL COSTS FOR THIS YEAR.

SO AS YOU CAN SEE, OUR BUDGET REQUEST FOR THIS YEAR IS $18.9 MILLION AS REFLECTED IN THE LAST COLUMN AS COMPARED TO WHAT WE HAD ALLOCATED FOR THIS YEAR, WHICH WAS $18.7 MILLION, OR WHERE WE EXPECT TO END THE YEAR, WHICH IS $17.2 MILLION. AS YOU CAN SEE, OVERALL THE BUDGET HAS ONLY INCREASED BY $200,000. THERE IS AN INCREASE OF $1.7 MILLION AGAINST WHERE WE EXPECT TO BRING THIS FISCAL YEAR.

SO I'D LIKE TO JUST BASICALLY ALSO TALK ABOUT WHAT IS DRIVING THAT VARIANCE BETWEEN THE BUDGET REQUEST AND WHERE WE EXPECT TO END THE YEAR. SO, AGAIN, THE VARIANCE IS REALLY DUE TO THE $1.7 MILLION IN OUR EMPLOYEE EXPENSES, OUR REVIEWS AND MEETINGS AND WORKSHOPS, AS WELL AS OUR FACILITIES. SO I'D JUST LIKE TO BRIEFLY TALK ABOUT EACH OF THOSE.

SO WHY ARE WE ANTICIPATING INCREASED EMPLOYEE EXPENSES? WELL, THERE ARE REALLY TWO REASONS BEHIND THAT. ONE OF THEM I'VE ALREADY TALKED ABOUT. I TALKED ABOUT HOW, DURING THIS FISCAL YEAR, WE HAD A PRETTY SIGNIFICANT VACANCY IN POSITIONS. WE PURPOSELY HELD THEM VACANT UNTIL WE FINISHED THE STRATEGIC PLANNING PROCESS, BUT THAT'S

BEEN DONE AND WE ARE ACTIVELY RECRUITING TO FILL OUR POSITIONS. AND WE REALLY DO HOPE TO ELIMINATE THAT SAVINGS IN THE '16-'17 FISCAL YEAR.

BUT THERE IS ANOTHER FACTOR THAT'S IMPACTING THE INCREASE, AND IT'S A FACTOR THAT WE DON'T CONTROL, AND THAT IS OUR STATE-IMPOSED CONTRIBUTIONS THAT WE HAVE TO MAKE ON BEHALF OF OUR EMPLOYEES FOR SUCH THINGS AS RETIREMENT AND HEALTH. WE'VE BEEN ADVISED BY THE AGENCIES THAT ADMINISTER THOSE PROGRAMS THAT WE CAN ANTICIPATE ABOUT A 7-PERCENT INCREASE, AND THAT'S BEEN BUILT INTO OUR BUDGET. SO OVERALL WE EXPECT A $1.8 MILLION INCREASE OVER WHERE WE WILL END THE YEAR THIS FISCAL YEAR.

SO ANOTHER AREA WHERE WE ARE ANTICIPATING INCREASES IS IN OUR REVIEW ACTIVITIES. SO FOR THE '16-'17 FISCAL YEAR, WE ARE ANTICIPATING WE WILL HOLD OVER 20 REVIEWS. THAT'S IN COMPARISON TO FOUR TO SEVEN REVIEWS THAT WE HELD UNDER CIRM 1.0. BECAUSE WE HAVE IMPLEMENTED CIRM 2.0 THROUGH ALL OF OUR PROGRAMS, WE DO ANTICIPATE INCREASED REVIEW ACTIVITY THAT WILL RESULT IN INCREASED COSTS. RIGHT NOW WE'RE ESTIMATING THOSE TO BE ABOUT $400,000.

SO ONE AREA WHERE WE ARE SEEING AN OVERALL DECREASE IS IN OUR FACILITIES. SO '16-'17 IS THE

FIRST FISCAL YEAR WHERE WE'LL HAVE AN ANNUALIZED RENT EXPENDITURE FOR THE FIRST TIME IN OUR HISTORY. WE ARE ANTICIPATING THAT TO BE ABOUT $710,000. NOW, OVERALL YOU'RE SEEING A REDUCTION BECAUSE DURING THE '15-'16 FISCAL YEAR WE HAD THOSE RELOCATION AND ONE-TIME COSTS, AND THOSE WERE JUST UNDER $800,000. THAT IS THE NET VARIANCE IN THAT PARTICULAR CATEGORY.

SO THESE ARE THE MAJOR DRIVERS THAT ARE IMPACTING THE BUDGET REQUESTS, BUT THERE ARE SOME FACTORS WE CAN'T COMPLETELY PREDICT OR CONTROL. AND THESE FACTORS ARE RISKS THAT MAY RESULT IN A VARIANCE TO OUR BUDGET AND IMPACT OUR ABILITY TO MEET OUR FINAL EXPENDITURES FOR THE '16-'17 FISCAL YEAR. AND I WANT TO TALK BRIEFLY ABOUT SOME OF THOSE MAJOR ONES.

SO APPLICATION VOLUME, I TALKED ABOUT THE FACT THAT WE ARE INCREASING OUR REVIEW ACTIVITIES SIGNIFICANTLY, BUT WE DON'T REALLY CONTROL THE NUMBER OF APPLICATIONS THAT COME IN. SO IF WE EXPERIENCE A HIGHER VOLUME THAN WHAT WE BUDGETED FOR, IT'S VERY POSSIBLE THAT OUR EXPENSES WILL BE HIGHER THAN WHAT HAS BEEN ALLOCATED.

I'VE TALKED A LOT ABOUT OUR UNFILLED POSITIONS. SO WE ARE MAKING EVERY EFFORT TO FILL

OUR POSITIONS, BUT WE COULD RUN INTO A SITUATION WHERE WE'RE NOT ABLE TO ATTRACT QUALIFIED CANDIDATES, OR WE MAY EXPERIENCE A HIGHER THAN NORMAL TURNOVER. IF EITHER ONE OF THESE OCCURS, WE COULD SEE AN UNDERRUN IN THAT CATEGORY AS WELL DURING THE '16-'17 FISCAL YEAR.

AND LASTLY, I WANT TO TALK ABOUT THOSE STATE-IMPOSED CONTRIBUTIONS. SO AS A STATE AGENCY, WE ARE REQUIRED TO PAY CERTAIN AMOUNTS FOR RETIREMENT AND HEALTH BENEFITS, BUT WE DON'T CONTROL WHAT THOSE AMOUNTS ARE. THOSE ARE CONTROLLED AND ADMINISTERED BY VARIOUS STATE AGENCIES SUCH AS CALHR AND CALPERS. AND THEY HAVE GIVEN US INFORMATION ON WHAT THEY BELIEVE THOSE COSTS WILL BE NEXT YEAR, BUT OFTEN WHAT THEY DO, BECAUSE THEY ARE IN NEGOTIATIONS RIGHT NOW WITH VARIOUS UNIONS, THEY WILL MAKE ADJUSTMENTS DURING THE FALL. AND WHEN THEY MAKE ADJUSTMENTS IN THE FALL, THEY IMPLEMENT THEM FOR THE FOLLOWING JANUARY. SO IF THAT OCCURS AND THE COSTS ARE MORE THAN WE BUDGETED FOR, WE MAY EXPERIENCE AN OVERRUN IN THOSE COSTS.

SO THIS REPRESENTS THE BUDGET REQUEST. WE'VE LOOKED BRIEFLY AT THE CURRENT YEAR BUDGET, WHERE WE EXPECT TO BE AT THE END OF JUNE, AND SOME OF THE VARIANCES THAT ARE IMPACTING THAT. WE'VE

ALSO LOOKED AT THE '16-'17 BUDGET REQUEST. WE'VE TALKED ABOUT SOME OF THE MAJOR FACTORS THAT ARE INFLUENCING THAT BUDGET AS WELL AS SOME POTENTIAL RISKS THAT MAY LIMIT OUR ABILITY TO FULLY MEET OUR FINANCIAL GOALS FOR THE '16-'17 FISCAL YEAR.

SO THIS REPRESENTS THE PRESENTATION. WE DID SUBMIT THE BUDGET TO THE FINANCE SUBCOMMITTEE, THEY REVIEWED IT, AND VOTED UNANIMOUSLY TO RECOMMEND APPROVAL OF THE BUDGET AT OUR MEETING LAST WEEK. SO WE ARE NOW REQUESTING YOUR APPROVAL OF THE '16-'17 BUDGET. ARE THERE ANY QUESTIONS?

CHAIRMAN THOMAS: ANY QUESTIONS FROM MEMBERS OF THE BOARD? ANY QUESTIONS BY MEMBERS ON THE PHONE? HEARING NONE, DO WE HAVE A MOTION TO APPROVE?

DR. STEWARD: SO MOVED.

MR. SHEEHY: SECOND.

CHAIRMAN THOMAS: BEFORE WE VOTE, I JUST WANT TO MAKE THE POINT, AS WE DID AT THE FINANCE SUBCOMMITTEE, THAT THESE PRESENTATIONS TEND TO LOOK LIKE EVERYTHING IS SORT OF VERY EASY AND SEAMLESS, AND THAT IS A TRIBUTE TO CHILA AND HER TEAM. JUST WANT EVERYBODY TO UNDERSTAND THAT THERE'S A TREMENDOUS AMOUNT OF WORK THAT GOES INTO PREPARATION OF THESE BUDGETS ACROSS THE AGENCY. AND JUST WANTED

TO THANK CHILA, AS WE DO ANNUALLY, FOR ALL HER AND HER TEAM'S VERY HARD WORK IN MAKING THIS ALL LOOK SO EASY.

DR. STEWARD: I SAID THIS AT THE FINANCE COMMITTEE, BUT I JUST WANT TO SAY IT AGAIN. I'D JUST LIKE TO CONGRATULATE CIRM AND THE TEAM. I THINK THAT YOU GUYS ARE DOING A SPECTACULAR JOB AND REALLY MAKING THIS ORGANIZATION LEAN AND MEAN, BUT ALSO HIGHLY EFFICIENT. SO THANK YOU FOR ALL THE WORK THAT YOU DO.

MS. SILVA-MARTIN: THANK YOU VERY MUCH. WE ACTUALLY HAVE A GREAT ROLE MODEL, DR. MILLS. AND WE'VE BEEN WORKING VERY CLOSELY WITH HIM ON OUR BUDGET, AND WE REVIEW VERY FREQUENTLY TO MAKE SURE THAT WE ARE STAYING WITHIN BUDGET AND THAT WE WILL HAVE SUFFICIENT FUNDS. SO THANK YOU.

CHAIRMAN THOMAS: SO IT'S BEEN MOVED AND SECONDED. DO WE HAVE ANY PUBLIC COMMENT EITHER HERE OR AT ANY OF OUR OTHER SITES? HEARING NONE, MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: DAVID BRENNER.

DR. BRENNER: YES.

MS. BONNEVILLE: LARS BERGLUND.

DR. BERGLUND: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: HOWARD FEDEROFF. ELIZABETH FINI.

DR. FINI: YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: SAM HAWGOOD. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD. SHERRY LANSING.

MS. LANSING: YES.

MS. BONNEVILLE: KATHY LAPORTE.

DR. LAPORTE: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED. LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: LLOYD MINOR.

DR. MINOR: YES.

MS. BONNEVILLE: ADRIANA PADILLA. JOE PANETTA. ROBERT PRICE.

DR. PRICE: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT. AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: CARL WARE.
DR. WARE: YES.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU, CHILA.
WE WILL GO ON NOW TO ITEM NO. 10, CONSIDERATION OF AMENDMENTS TO THE CIRM CONTRACTING POLICY. WE WILL HEAR FROM CYNTHIA SCHAFFER.
MS. SCHAFFER: HELLO. MY NAME IS CYNTHIA SCHAFFER, AND I'M THE COUNSEL AND CONTRACTS MANAGER FOR CIRM. TODAY I'D LIKE TO PRESENT TO YOU THE PROPOSED CHANGE TO THE CIRM CONTRACTING POLICY. THIS PROPOSED CHANGE IS TO CONFORM OUR POLICY TO THE

UNIVERSITY OF CALIFORNIA CONTRACTING POLICY AS CONSISTENT WITH CIRM REGULATIONS. SPECIFICALLY THE CHANGE IS IN THE AMOUNT FOR SOLICITED PROPOSALS GOING FROM 50,000 TO 100,000. THIS CHANGE WAS MADE TO THE UNIVERSITY OF CALIFORNIA'S POLICIES BACK IN DECEMBER OF 2012. AND AS PART OF OUR PUSH, PULL, LEVEL IN CIRM 2.0, WE ARE NOW IMPLEMENTING IT OURSELVES.

THE CIRM TEAM WILL CONTINUE TO SEEK BEST VALUE FOR ALL OF ITS CONTRACTUAL AGREEMENTS INCLUDING THOSE WITH A VALUE OF $100,000 OR LESS. WE ALWAYS BALANCE THE COSTS, THE QUALIFICATIONS, AND EXPERIENCE OF THE CONSULTANT WITH THE NEEDS OF CIRM. AND WE HAVE A RESPONSIBLE ADMINISTRATIVE OFFICIAL AND A LOT OF POLICIES AND PROCEDURES AROUND CONTRACTING.

SO MY RECOMMENDATION IS TO REQUEST THE BOARD TO APPROVE THE AMENDMENT TO THE CIRM CONTRACTING POLICY, BUT I'D BE HAPPY TO ANSWER ANY QUESTIONS.

CHAIRMAN THOMAS: THANK YOU, MS. SCHAFFER. ARE THERE QUESTIONS ON THIS ITEM FROM MEMBERS OF THE BOARD? ANY QUESTIONS FROM MEMBERS ON THE PHONE? ANY QUESTIONS, COMMENTS FROM MEMBERS OF THE PUBLIC? WE HAVE A MOTION TO ADOPT?

DR. STEWARD: MOVE APPROVAL.

CHAIRMAN THOMAS: MOVED BY DR. STEWARD. SECONDED BY --

MS. LAPORTE: SECOND.

CHAIRMAN THOMAS: -- MS. LAPORTE. THANK YOU.

I AM INFORMED WE CAN DO THIS ON A VOICE VOTE WITH ROLL CALL OF MEMBERS ON THE PHONE. SO ALL THOSE IN FAVOR INSIDE THE ROOM PLEASE SAY AYE. OPPOSED? ABSTAIN?

MARIA, WILL YOU POLL THOSE ON THE PHONE PLEASE.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: CARL WARE.

DR. WARE: YES.

MS. BONNEVILLE: DIANA WINOKUR.

MS. WINOKUR: YES.

CHAIRMAN THOMAS: THANK YOU, MARIA. MOTION PASSES. AND, MS. SCHAFFER, THANK YOU VERY MUCH FOR ALL YOUR HARD WORK IN THIS AREA. IT'S ANOTHER THING THAT DOESN'T NECESSARILY GET A LOT OF VISIBILITY, BUT IS NONETHELESS VERY IMPORTANT. SO

THANK YOU VERY MUCH.

ONTO ITEM NO. 11, CONSIDERATION OF RENEWAL OF CONTRACT WITH REMCHO, JOHANSEN & PURCELL. DR. MILLS.

DR. MILLS: TALK ABOUT SOMETHING THAT I THOUGHT COULD BE PUT ON THE CONSENT CALENDAR.

SO CIRM REGULATIONS REQUIRE THAT WE SEEK BOARD APPROVAL FOR CONTRACTS OVER $500,000, WHICH IS THE CASE WITH OUR LEGAL COUNSEL, JAMES HARRISON, AT REMCHO.

FOR BACKGROUND, JAMES WAS INTEGRAL IN GETTING PROPOSITION 71 DRAFTED, PASSED, DEFENDED. HE'S BEEN CIRM COUNSEL SINCE ITS INCEPTION. AND HE DOES AN OUTSTANDING JOB NOW ALSO AS OUR GENERAL COUNSEL IN CIRM. I WILL ALSO JUST GO AND SAY ONE OTHER THING ABOUT JAMES. HE'S NOT ONLY EXCELLENT LEGAL COUNSEL AND PROVIDES EXCELLENT LEGAL ADVICE FOR THE ORGANIZATION, BUT HE HAS BECOME AN ABSOLUTELY INTEGRAL MEMBER OF THE LEADERSHIP TEAM AND HAS TAKEN ON RESPONSIBILITIES BEYOND JUST THAT OF PROVIDING US LEGAL ADVICE.

AND SO I ASK BOARD APPROVAL FOR MR. HARRISON'S CONTRACT FOR THE UPCOMING YEAR OF $575,000, WHICH I WILL ALSO POINT OUT IS VARIABLE. IT WOULD BE THE CEILING OF WHICH WE WOULD PAY HIM.

WE ACTUALLY GET BILLED ON A VARIABLE RATE.

MR. TORRES: SO MOVED.

DR. PRICE: SECOND.

CHAIRMAN THOMAS: MOVED BY SENATOR TORRES, SECONDED BY DR. PRICE. ANY COMMENTS BY MEMBERS OF THE BOARD? HERE'S YOUR CHANCE TO SAY THINGS ABOUT JAMES WHICH ALWAYS PUTS HIM IN A MOST UNCOMFORTABLE POSITION.

DR. DULIEGE: ACTUALLY I WOULD LIKE TO CHALLENGE THIS A LITTLE BIT. NO, NOT AT ALL, JAMES. OF COURSE NOT. GOT YOU. NO. OF COURSE. I DON'T KNOW IF IT'S ON BEHALF OF OTHERS, CERTAINLY ON MY OWN BEHALF, WHAT A PLEASURE TO HAVE YOU ON BOARD.

(APPLAUSE.)

MR. HARRISON: IF I COULD JUST SAY ONE THING BRIEFLY. I'VE HAD A CHANCE TO WORK AT CIRM NOW FOR THE LAST 12 YEARS NOW WITH MANY OF YOU, THE BOARD, AND WITH THE GREAT TEAM THAT'S BEEN ASSEMBLED HERE AT CIRM. BUT IN MY ROLE AS GENERAL COUNSEL OVER THE LAST TWO YEARS, I'VE GOTTEN A CHANCE TO WORK REALLY CLOSELY WITH MEMBERS OF THE LEGAL TEAM AND CIRM, AND THEY ARE REALLY OUTSTANDING. SCOTT TOCHER, BEN HUANG, CYNTHIA SCHAFFER, WHO JUST PRESENTED, AND GABE THOMPSON, WHO IS ALSO A MEMBER OF THE LEGAL TEAM, REALLY PROVIDE TERRIFIC SUPPORT

AND ARE AMAZING MEMBERS OF THE CIRM TEAM. I JUST WANT TO THANK THEM.

CHAIRMAN THOMAS: THANK YOU AND WELL SAID, JAMES. ANY FURTHER COMMENT BY MEMBERS OF THE BOARD? COMMENTS FROM MEMBERS OF THE PUBLIC? MR. REED WAS VIGOROUSLY CLAPPING EARLIER SO WE'LL NOTE THAT FOR THE RECORD AS HIS COMMENT ON THE SUBJECT. I BELIEVE, MARIA, THIS IS A VOICE VOTE WITH ROLL CALL AGAIN.

ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? ABSTAIN? MARIA, PLEASE CALL THE ROLL OF THOSE ON THE PHONE.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: A HEARTY, ENTHUSIASTIC YES.

MS. BONNEVILLE: CARL WARE.

DR. WARE: AYE.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

CHAIRMAN THOMAS: THANK YOU, EVERYBODY. MR. HARRISON, YOU LIVE TO FIGHT ANOTHER DAY. THANK YOU.

(APPLAUSE.)

CHAIRMAN THOMAS: AS THE LAST WORD ON THE

SUBJECT, I JUST WANT TO ECHO EVERYTHING DR. MILLS SAID. I'VE BEEN INVOLVED IN VARIOUS GOVERNMENT AGENCIES OVER THE YEARS AND HAVE NEVER HAD A COUNSEL TO A GOVERNMENT AGENCY WHO HAS PERFORMED ANY BETTER THAN MR. HARRISON. WE'RE TRULY LUCKY TO HAVE HIM ON BOARD. SO THANK YOU, JAMES.

THAT CONCLUDES THE ACTION ITEMS ON THE AGENDA. WE HAVE ONE DISCUSSION ITEM, WHICH IS ITEM NO. 12, A CLINICAL UPDATE. DR. TALIB.

DR. TALIB: MR. CHAIRMAN, MEMBERS OF THE BOARD AND MEMBERS OF THE PUBLIC, I'D LIKE TO GIVE YOU AN UPDATE ABOUT THE HEMATOPOIETIC STEM CELL GENE THERAPY PORTFOLIO. I THINK IT WILL BE IMPORTANT TO POINT OUT THAT THE RECENT ADVANCES WHICH HAS HAPPENED IN THE GENE EDITING TECHNOLOGY HAS PUT HSC GENE THERAPY AT THE FOREFRONT OF CLINICAL DEVELOPMENT. AND BECAUSE OF THESE ADVANCES, THE STEM CELL GENE THERAPY IS POISED TO TREAT A NUMBER OF UNMET MEDICAL NEEDS AND DISEASES WHICH OTHERWISE WOULD NOT BE POSSIBLE. AND I THINK IT WILL BE FAIR TO POINT OUT THAT CIRM IS PLAYING A LEADING ROLE IN ADVANCING THIS AREA OF MEDICAL RESEARCH.

BECAUSE OF THE LAST SEVEN YEARS, WE HAVE BEEN FUNDING BOTH STEM CELL RESEARCH, BASIC BIOLOGY, DISCOVERY RESEARCH, AS WELL AS TRANSLATIONAL

RESEARCH.

AS YOU WILL SEE FROM MY PRESENTATION, SOME OF THESE PROJECTS WHICH STARTED OUT AS EARLY TRANSLATION, BECAUSE OF THESE EFFORTS, HAVE BEEN PROGRESSED AND NOW STARTED TREATING PATIENTS IN PHASE I AND PHASE II CLINICAL TRIALS. SO WHAT I WILL DO IS GIVE YOU SOME UPDATE ABOUT THESE PROGRAMS, GIVE YOU SOME OF THE CHALLENGES IN HSC TRANSPLANTATION, STRATEGIES WHICH WE ARE USING TO OVERCOME THESE CHALLENGES, AND THEN FINALLY GIVE YOU UPDATE ON THE PORTFOLIO. SPECIFICALLY POINT OUT ABOUT THREE PROJECTS WHICH ARE NOW INTO THE CLINIC AND GIVE YOU A CLINICAL UPDATE.

HSC, THAT'S HEMATOPOIETIC STEM CELL, WHICH ARE ALSO KNOWN AS BLOOD-FORMING STEM CELLS, THEY'RE IMPORTANT BECAUSE THEY GIVE RISE TO OTHER CELLS IN OUR BODY, ALL THE BLOOD CELLS IN OUR BODY. FOR EXAMPLE, THEY PRODUCE RED BLOOD CELLS WHICH CARRY OXYGEN TO THE CELLS AND TISSUES, THEY PRODUCE WHITE BLOOD CELLS WHICH FIGHT INFECTIONS AND KEEP US HEALTHY, AND THEY PRODUCE PLATELETS, FOR EXAMPLE, THAT HELP CLOT THE BLOOD. SO ALL THESE BLOOD CELLS ARE VERY IMPORTANT AND THEY KEEP US HEALTHY. AND ANY FUNCTIONAL IMPAIRMENT IN ANY OF THESE CELL TYPES LEADS TO A NUMBER OF DISEASES OF THE IMMUNE SYSTEM

AS WELL AS THE BLOOD SYSTEM.

NOW THEY COME FROM BONE MARROW, FROM CORD BLOOD, AND FROM THE PERIPHERAL BLOOD. NOW IMPORTANT THING TO REMEMBER ABOUT THE HEMATOPOIETIC STEM CELL IS THAT THEY SELF-RENEW ITSELF. SO THEY GIVE RISE CONSTANTLY TO ALL THE BLOOD CELL TYPES IN OUR BODY FROM BIRTH TILL DEATH.

NOW, ONE OF THE THINGS WHICH HAS -- ONE OF THE REASONS THAT THESE CELL TYPES HAVE BEEN INTO THE CLINIC AND MAKING ADVANCES IS BECAUSE FROM LAST 50 YEARS THESE STEM CELLS HAVE BEEN USED FOR BONE MARROW TRANSPLANTATION; FOR EXAMPLE, TO PATIENTS WHICH ARE UNDERGOING HIGH DOSE CHEMOTHERAPY AND RADIATION TO TREAT THEIR CANCER, ALSO GET THE BONE MARROW STEM CELLS FROM THESE PATIENTS. SO THESE STEM CELL TRANSPLANT FROM A DONOR IS REQUIRED TO RESCUE THESE PATIENTS, OTHERWISE THEY WILL HAVE INFECTIONS AND THEY WILL DIE.

SO THESE CELLS HAVE BEEN USED IN THE CLINIC. THEY HAVE ALSO BEEN USED FOR THE TREATMENT OF GENETIC DISEASES. THEY HAVE ALSO BEEN USED, IN CASE OF HIV, THE CASE OF THE BERLIN PATIENT WHO RECEIVED A BONE MARROW TRANSPLANT FROM A HEALTHY DONOR, AND HAS BEEN FREE OF HIV SINCE 2008.

BUT THERE ARE A NUMBER OF CHALLENGES IN

TERMS OF USING THESE DONOR HSC FOR TRANSPLANTATION BECAUSE YOU MAY ASK OF THE WORK SO, WELL, WHY CAN'T THEY BE USED IN ALL THE PATIENTS? AND THAT ISSUE FOR THIS DONOR TRANSPLANTATION, IT RELATES TO THEIR DONOR MATCHING. AND THE EXPERIENCE LAST 50 YEARS OF THE BONE MARROW TRANSPLANT HAS SHOWN THAT THE HIGHEST POTENTIAL OF SUCCESS IN THIS DONOR TRANSPLANTATION IS IF THE HSC COMES FROM A CLOSELY MATCHED DONOR. BUT IF YOU SEE PRACTICALLY, THERE ARE FEWER THAN 15 PERCENT OF POPULATION WILL FIND A COMPLETELY MATCHED IMMUNOLOGICAL DONOR. SO 85 PERCENT OF THE POPULATION DOES NOT HAVE A MATCHED DONOR TO HAVE A TRANSPLANT.

NOW, IF YOU DO A TRANSPLANT IN A LESS MATCHED DONOR, THEN THERE ARE IMMUNOLOGICAL COMPLICATIONS BECAUSE THE HSC'S FROM A DONOR WHICH COMES TO THE PATIENT WOULD BE RECOGNIZED BY THE PATIENT'S BODY AS FOREIGN OR NONCELL AND WILL ATTACK THEM AND KILL THOSE CELLS. THERE'S A GRAFT REJECTION. AND THERE ARE OTHER COMPLICATIONS LIKE GRAFT VERSUS HOST DISEASE. AND BECAUSE OF THESE IMMUNOLOGICAL COMPLICATIONS, HUNDREDS AND THOUSANDS OF PATIENTS WORLDWIDE ARE NOT TRANSPLANTED BECAUSE THEY DON'T HAVE A DONOR MATCH.

HOW DO YOU SOLVE THIS PROBLEM? SO THE

PROBLEM CAN BE SOLVED, FOR EXAMPLE, OBVIOUSLY IF YOU CAN USE PATIENT'S OWN BLOOD CELLS. HOW DO YOU DEAL WITH THE PROBLEM OF THE GENETIC MUTATIONS WHICH ARE PRESENT IN PATIENT'S HSC AND THAT, IN FACT, ARE CONTRIBUTING OR CAUSING THE DISEASE IN THE PATIENT? SO HERE COMES THE RECENT ADVANCES IN GENE CORRECTION TECHNOLOGY. SO IT'S POSSIBLE THAT USING THESE GENE CORRECTION TECHNOLOGIES, ONE CAN TAKE PATIENT'S OWN STEM CELLS AND DO THE GENE CORRECTION AND PUT THEM BACK TO THE PATIENT. AND SINCE THESE ARE PATIENT'S OWN STEM CELLS, IMMUNOLOGICAL COMPLICATIONS WHICH ARE PRESENT IN A DONOR TRANSPLANT WILL NOT BE THERE.

THIS IS HOW IT IS DONE IN THE CLINIC. SO BASICALLY IT'S A SIMPLE PROCEDURE. THE PATIENT'S HSC'S OR STEM CELLS ARE TAKEN OUT EITHER FROM THE BONE MARROW OR FROM THE BLOOD AND THEY UNDERGO A GENE CORRECTION TECHNOLOGY, AND THAT IS BASICALLY EITHER ADDING A GENE WHICH IS MISSING IN THE PATIENT'S STEM CELL OR YOU CAN FIX THE MUTATION WHICH IS PRESENT IN THE STEM CELL. THAT'S BY USING THESE GENETIC SCISSORS LIKE ZINC FINGER NUCLEASE AND CRISPR IN WHICH YOU CAN CUT OUT A PORTION OF THE CELL WHICH IS DEFECTIVE AND REPLACE IT WITH A CORRECTED VERSION OF THE GENE.

AND THEN BEFORE THESE GENE CORRECTED CELLS

ARE GIVEN BACK TO THE PATIENT, A PATIENT RECEIVES A MILD FORM OF CHEMOTHERAPY, AND THAT IS TO CREATE A SPACE IN THE BONE MARROW BECAUSE THE PATIENT'S OWN BONE MARROW IS FILLED WITH THE DEFECTIVE OR THE DISEASED STEM CELLS. AND THEY NEED TO BE TAKEN OUT AND MAKE ROOM FOR INCOMING STEM CELLS.

SO AFTER THIS SHORT FORM, MILD FORM OF CHEMOTHERAPY, THE PATIENT'S CORRECTED CELLS ARE GIVEN BACK TO THE PATIENT. SO THIS PROCEDURE IS BECAUSE THE STEM CELLS HAVE THE CAPABILITY AND CAPACITY TO SELF-RENEW. THIS TREATMENT IS ONE TIME AND IT'S AN OUTPATIENT TREATMENT. THIS BASICALLY IS DONE OUTSIDE IN THE BODY AND IS A ONE-TIME TREATMENT.

THE ONLY PART WHICH STILL NEED TO BE IMPROVED IN THIS PROCEDURE IS THE CREATING A SPACE BY USING MILD FORM OF CHEMOTHERAPY. THIS MILD FORM OF CHEMOTHERAPY SOMETIMES HAVE SOME SIDE EFFECTS. SO A KINDER AND GENTLER APPROACH TO CREATE A SPACE IN THE BONE MARROW HAS ALSO BEEN CARRIED OUT, THOSE RESEARCH, AT STANFORD, AND THAT'S BEING FUNDED BY CIRM.

SO WHAT ARE THE APPLICATIONS OF THESE HSC GENE THERAPY? THESE GENE THERAPIES CAN BE APPLIED TO ALL THE DISEASES FOR WHICH DONOR TRANSPLANT HAS

BEEN USED PREVIOUSLY. AND NOW SINCE THESE ARE PATIENT'S OWN CELLS, ALL THE PATIENTS CAN BE TREATED BY THESE APPROACHES. LISTED HERE ARE THE DISEASES WHICH ARE NOW BEING TREATED BY STEM CELL GENE THERAPY. THESE ARE PRIMARILY IMMUNE DEFICIENCIES. THESE DISEASES, BECAUSE THESE CHILDREN OR THESE ADULTS ARE UNABLE TO PRODUCE IMMUNE SYSTEM CELLS, THEY'RE PRONE TO INFECTIONS. SO A DISEASE EXAMPLE IS BUBBLE BOY DISEASE, INHERITED BLOOD DISORDERS, WHICH WE ARE FAMILIAR WITH, SICKLE CELL DISEASE AND BETA THALASSEMIA, AND INHERITED METABOLIC DISEASES. THESE ARE THE DISEASES BECAUSE OF A DEFECT OF THE -- GENETIC DEFECT IN METABOLISM THAT LEADS TO SOME OF THE NEURODEGENERATIVE DISEASES LIKE ALD. AND, OF COURSE, IN CASE OF HIV/AIDS, IT'S POSSIBLE THAT BY USING THESE GENE CORRECTING TECHNOLOGY, IT'S POSSIBLE TO CREATE A NEW IMMUNE SYSTEM IN THE PATIENTS SUCH THAT HIV CANNOT INFECT IT.

HERE ARE THE PORTFOLIO THAT CIRM IS FUNDING. IN THESE CASES WE HAVE A NUMBER THAT HAVE NOW PROGRESSED TO THE CLINIC. AND I WILL GIVE YOU EXAMPLES OF THREE GRANTS WHICH ARE NOW INTO THE CLINIC AND A CLINICAL UPDATE. FOR EXAMPLE, HERE IS DON KOHN. HE HAS A STEM CELL GENE THERAPY GRANT FROM US FOR AN IMMUNE DEFICIENCY AS A PHASE I-II

CLINICAL TRIAL. DR. KOHN AT UCLA ALSO HAS A GRANT, A DR3 GRANT, WHICH IS TREATING SICKLE CELL DISEASE.

NOW, DR. SHIZURU AT STANFORD HAS A GRANT IN WHICH SHE'S USING A NOVEL MEANS OF A KINDER AND GENTLER APPROACH OF CREATING A SPACE WHICH IS A CHEMOTHERAPY-FREE APPROACH, AND THAT BASICALLY WILL ALLOW DOING A TRANSPLANT IN A BETTER SETTING WITHOUT WORRYING ABOUT THE COMPLICATIONS OF THE CHEMOTHERAPY. AT THIS MOMENT THIS GRANT IS NOW BEING APPROVED BY THE FDA, AND SHE WILL BE STARTING CLINICAL TRIAL SOON.

THE OTHER TWO GRANTS WHICH ARE AT THE PRECLINICAL STAGE, AND THAT IS MATTHEW PORTEUS. HE'S USING THE MOST ADVANCED CRISPR TECHNOLOGIES TO DO THE GENE CORRECTION FOR THE SCID PATIENTS. AND JENNIFER PUCK AND MARK COWAN AT UCSF HAS A PRECLINICAL AWARD IN WHICH THEY ARE TREATING THESE PATIENTS, ARTEMIS-SCID PATIENTS. THIS IS A RARE DISEASE, BUT IT'S PREVALENT IN NATIVE AMERICAN POPULATION IN CALIFORNIA AND ARIZONA.

CIRM ALSO HAS A SUBSTANTIAL PORTFOLIO IN HIV. AS YOU KNOW, A NUMBER OF ADVANCES HAS BEEN MADE IN HIV, BUT STILL THERE IS NO CURATIVE TREATMENT FOR THESE PATIENTS. IT'S AN UNMET MEDICAL NEED. AND THE GOAL OF THESE GRANTS, THERE ARE FOUR

OF THEM, THE GOAL OF THESE GRANTS IS TO CREATE A FUNCTIONAL CURE FOR HIV.

I WILL GIVE YOU AN UPDATE ON ONE OF THESE GRANTS, BUT THESE THREE CLINICAL GRANTS NOW ARE INTO THE CLINIC. ONE WHICH IS SUPPORTED BY US IS A PHASE I-PHASE II CLINICAL TRIAL, CAL-IMMUNE, A BIOTECH WHICH IS FUNDED BY US. THE SECOND ONE IS DR. ABEDI AT UC DAVIS. HE RECENTLY RECEIVED A GRANT FROM CIRM AND THAT'S FOR THE TREATMENT OF AIDS LYMPHOMA. DR. ZAIA, IN COLLABORATION WITH SANGAMO BIOSCIENCE WHICH IS A BIOTECH IN THE AREA, IS DEVELOPING A STEM CELL GENE THERAPY FOR HIV/AIDS. THIS CLINICAL TRIAL IS OPEN AND ENROLLING PATIENTS.

THE LAST GRANT IS A PRECLINICAL AWARD, WHICH IS JEROME ZACK, UCLA. HE'S USING A MOST RECENT T CELL TECHNOLOGY TO TARGET HIV-INFECTED INDIVIDUALS WITH THIS NOVEL TECHNOLOGY. THIS IS A PRECLINICAL AWARD.

AND I SHOULD POINT OUT THAT THESE AWARDS STARTED OUT AS EARLY TRANSLATION, FOR EXAMPLE, AND THEN HAS PROGRESSED NOW INTO PHASE I-PHASE II CLINICAL TRIALS.

SO NOW WHAT I WILL DO IS GIVE YOU THREE EXAMPLES OF THE AWARDS WHICH ARE NOW INTO THE CLINIC AND GIVE YOU A CLINICAL UPDATE. SO THIS IS A SICKLE

CELL DISEASE, AS YOU KNOW, A DISEASE INHERITED FROM THE PARENTS. AND IT'S A DEFECT IN A BETA GLOBIN GENE. IT AFFECTS ABOUT 100,000 INDIVIDUALS IN US, DISPROPORTIONATELY AFFECTS AFRICAN-AMERICAN POPULATION, ONE IN 500. THEY HAVE SEVERE MEDICAL COMPLICATIONS OF PAIN CRISIS AND ANEMIAS. AND ALTHOUGH RECENT ADVANCES HAS BEEN MADE IN SICKLE CELL DISEASE, THE AVERAGE LIFE SPAN REMAINS TO BE 40 YEARS. SO THIS IS CLEARLY AN UNMET MEDICAL NEED.

NOW, THIS GRANT WHICH DR. DON KOHN AT UCLA IS THE PI IS A STEM CELL GENE THERAPY APPROACH IN WHICH THE PATIENT'S OWN MARROW STEM CELLS ARE ISOLATED AND THEY ARE GENE MODIFIED. THEY'RE PUTTING AN ANTISICKLING AGENT INTO THE STEM CELLS. THIS IS A PHASE I CLINICAL TRIAL. TARGET NUMBER OF PATIENTS FOR THIS CLINICAL TRIAL IS TEN PATIENTS. FIRST PATIENT WAS TREATED LAST YEAR. THE PATIENT WAS DISCHARGED AFTER 24 DAYS AND NO DRUG-RELATED ADVERSE EVENTS WERE NOTICED IN THESE PATIENTS SO FAR.

NEXT PATIENT IS SCHEDULED TO BE TREATED IN AUGUST. YOU MIGHT NOTICE THAT THERE'S QUITE A BIG GAP BETWEEN THE FIRST PATIENT AND SECOND PATIENT. THE REASON FOR THIS IS THE FDA-MANDATED WAIT PERIOD BECAUSE IT'S A FIRST-IN-HUMAN STUDY. SO FDA HAS

REQUIRED A SIX-MONTH WAIT PERIOD BETWEEN FIRST PATIENT AND SECOND PATIENT TO SEE HOW THESE PATIENTS WILL DO.

SO THE NEXT EXAMPLE I WILL GIVE YOU IS OF A PRIMARY IMMUNE DEFICIENT DISEASE. THESE CHILDREN HAVE -- THEIR PRIMARY IMMUNE SYSTEM IS DEFECTIVE IN FIGHTING INFECTIONS BECAUSE THEIR NEUTROPHILS HAVE A GENE DEFECT. NOW, THESE PATIENTS HAVE REPEATED BOUTS OF INFECTIONS AND SOMETIMES LETHAL. THIS IS A RARE DISEASE, ONE IN 200,000 IN U.S. SINCE IT'S AN X CHROMOSOME, DEFECTIVE X CHROMOSOME, IT PRIMARILY AFFECTS THE MALE.

SO DR. DON KOHN AT UCLA IS THE PI FOR THIS. IT'S A MULTICENTER CLINICAL TRIAL. THERE ARE THREE CENTERS: ONE AT BOSTON CHILDREN'S, NIH CLINICAL CENTER, AND UCLA. HERE, AGAIN, THE PATIENT'S OWN HEMATOPOIETIC STEM CELLS ARE GENE MODIFIED. AND THIS IS A PILOT STUDY OF SIX PATIENTS. SO THE FIRST PATIENT WAS TREATED IN DECEMBER. NO ADVERSE EVENTS WERE NOTICED IN THIS PATIENT. IT WAS DISCHARGED AT DAY 24 FROM THE HOSPITAL, AND THIS PATIENT REMAINS CLINICALLY WELL, IS ABLE TO PRODUCE THE DEFECTIVE ENZYME AND HAVE NO INFECTIONS. SO IT LOOKS VERY PROMISING ALTHOUGH IT'S TOO EARLY, BUT THIS BASICALLY SHOWS THAT THIS

CLINICAL TRIAL IS WORKING. NEXT PATIENT WILL BE TREATED IN JULY.

NEXT EXAMPLE I WILL GIVE OF AN HIV, AND THIS IS A TRIAL WHICH CAL-IMMUNE BIOSCIENCE IS CARRYING OUT. THIS IS A PHASE I-PHASE II CLINICAL TRIAL. AGAIN, HERE, THE PATIENT'S OWN WHITE BLOOD CELLS AND HEMATOPOIETIC STEM CELLS ARE MODIFIED TO CREATE HIV RESISTANCE IN BLOOD AND IMMUNE SYSTEM CELLS. SO THEY ARE PUTTING ANTI-HIV GENES INTO THE HSC'S AND IN THE WHITE BLOOD CELLS. AND THEN THE NEW IMMUNE SYSTEM AFTER THE TRANSPLANTATION WILL BE RESISTANT TO HIV. THIS, AGAIN, IS A PHASE I-PHASE II CLINICAL TRIAL. IT'S A THREE-DOSE COHORT BECAUSE PATIENTS RECEIVE THIS MILD FORM OF CHEMOTHERAPY TO CREATE A SPACE IN THE BONE MARROW. SO THE FIRST COHORT OF PATIENTS DOES NOT RECEIVE ANY OF THE CONDITION REGIMIN. SECOND AND THIRD HAVE INCREASING DOSES OF THIS CHEMOTHERAPY TO CREATE A SPACE IN THE BONE MARROW. THIS IS A 12-PATIENT CLINICAL TRIAL. NINE PATIENTS HAVE ALREADY BEEN TREATED FROM COHORT 1, AND COHORT 2 AND NOW THE COHORT 3 IS BEING TREATED. SO THEY WILL BE COMPLETING THESE PHASE I-PHASE-II CLINICAL TRIALS IN NEXT FEW MONTHS. NO EVIDENCE OF SEVERE ADVERSE EVENTS HAS BEEN NOTICED IN THESE PATIENTS. CLINICAL DATA IN TERMS OF

EFFICACY IS BEING TABULATED AS OF NOW.

I'LL LEAVE YOU WITH THIS PROMISE AND WITH THIS IMPORTANT ADVANCEMENT IN THE SCIENCE, THAT THE GENE EDITING TECHNOLOGY COMBINED WITH HSC PROVIDES A NEW APPROACH FOR DEVELOPING STEM CELL TREATMENTS FOR PATIENTS WITH UNMET MEDICAL NEED.

THIS CONCLUDES MY PRESENTATION, AND I'LL BE HAPPY TO ANSWER ANY QUESTIONS WHICH YOU MIGHT HAVE.

CHAIRMAN THOMAS: THANK YOU, DR. TALIB. I WOULD JUST LIKE TO COMMENT THAT IT'S PRESENTATIONS LIKE THESE THAT DRIVE HOME THE TREMENDOUS WORK THAT THE SCIENTISTS ARE DOING THROUGHOUT THE STATE OF CALIFORNIA THAT CIRM HAS HELPED FUND. AND I ALWAYS ENJOY, AS I KNOW ALL MEMBERS OF THE BOARD DO, HEARING THESE UPDATES BECAUSE THIS IS REALLY THE BREAD AND BUTTER OF EVERYTHING WE'RE DOING, AND IT'S VERY, VERY EXCITING. SO THANK YOU.

OTHER COMMENTS BY MEMBERS OF THE BOARD?

MR. SHEEHY: COULD WE GET A LITTLE MORE GRANULARITY ON THE CLINICAL TRIALS? WE JUST GOT THREE, I THINK, BUT THERE ARE OTHERS IN TERMS OF HOW THEY'RE MEETING THEIR MILESTONES, WHAT PROBLEMS THEY'RE ENCOUNTERING, HOW MANY PATIENTS THEY'VE ENROLLED. JUST A LITTLE BIT MORE DETAIL TO KIND OF

KNOW WHERE THOSE ARE.

DR. TALIB: IN TERMS OF THE CAL-IMMUNE BIOSCIENCES, THEY HAVE MET THEIR MILESTONES IN TERMS OF MOVING THIS CLINICAL TRIAL FROM STARTING AND COMPLETING ALL THE MILESTONES, ENROLLING THE PATIENTS, AND TREATING THOSE PATIENTS. SO OVERALL THIS PROGRAM HAS MOVED VERY WELL. THIS IS FIRST-IN-HUMAN CLINICAL TRIALS USING THESE GENE MODIFICATION TECHNOLOGIES.

NOW, AND SINCE IT HAS MOVED FROM COHORT 1 TO 2 TO 3 BASICALLY SHOWS THE SAFETY PART OF THE TRIAL. AGAIN, IT'S A PHASE I AND A PHASE II, SO THE CLINICAL EFFICACY IS SECONDARY, BUT THAT DATA IS BEING ANALYZED. SO WE WILL KNOW WHETHER THESE PATIENTS, IN FACT, HAS MADE ANY DIFFERENCE IN TERMS OF EFFICACY. BUT IN TERMS OF THE SAFETY, THIS CLINICAL TRIAL HAS PROGRESSED WELL.

MR. SHEEHY: I WAS ALSO THINKING ABOUT THE ABEDI TRIAL AND THE ZAIA-SANGAMO TRIAL.

DR. TALIB: THE ABEDI TRIAL IS READY TO START. THIS IS ACTUALLY INTERESTING. THIS IS A TRIAL IN WHICH THEY ARE USING THREE DIFFERENT ANTI-HIV GENES TO CREATE A RESISTANCE NOT ONLY ONCE, BUT HAVING THESE THREE DIFFERENT ANTI-HIV GENES INSERTED, THAT THERE WILL BE MULTIPLE APPROACH THAT

IF IT IS RESISTANT ONE, THEN THE SECOND, AND THE THIRD ONE. SO IT'S A VERY INTERESTING APPROACH. THEY ALSO ARE USING IN ALL OF THESE OF ENRICHING THESE CELLS SO THAT YOU WILL HAVE CHANCES OF PUTTING LARGE NUMBER OF GENE-MODIFIED CELLS. THIS PROGRAM HAS JUST STARTED. SO THEY HAVE CLEARED THE FDA CLEARANCE, THEY HAVE ALSO CLEARED ACTUALLY CDAP. AIDS CONSORTIUM IS A PARTNER WITH THIS TEAM. SO THIS IS A MULTICENTER CLINICAL TRIAL. THEY WILL BE ABLE TO GET PATIENTS FROM THROUGHOUT THE COUNTRY. SO THIS TRIAL NOW IS CLEAR AND THEY ARE ENROLLING PATIENTS. THE FIRST PATIENT HAS NOT BEEN ENROLLED YET, BUT IT'S OPEN AND THEY ARE READY TO START THIS CLINICAL TRIAL.

IN TERMS OF JOHN ZAIA'S TRIAL --

MR. SHEEHY: HOW MANY SITES DO THEY HAVE?

DR. TALIB: THEY HAVE THREE CLINICAL SITES AT THE MOMENT. THE PATIENTS WILL COME FROM ALL OVER THE U.S., BUT THERE ARE THREE CLINICAL SITES. ONE IS UC DAVIS, SACRAMENTO; THERE IS ONE IN UCSF; AND ONE IS IN SAN DIEGO. SO THERE ARE THREE CLINICAL SITES.

JOHN ZAIA'S CLINICAL TRIAL, THIS IS AGAIN FIRST-IN-HUMAN CLINICAL TRIAL USING ZINC FINGER NUCLEASE TECHNOLOGY TO KNOCK OFF CCF5. THAT'S A

CORECEPTOR FOR HIV. SINCE, AGAIN, THIS IS A MILESTONE BECAUSE THE FIRST TIME THIS GENE CORRECTION TECHNOLOGY OR ZINC FINGER NUCLEASE IS USED ON HUMAN HSC. THIS CLINICAL TRIAL IS OPEN AND ENROLLING PATIENTS.

MR. SHEEHY: HOW MANY PATIENTS HAVE THEY ENROLLED?

DR. TALIB: SO FAR THERE ARE THREE PATIENTS HAS BEEN ENROLLED IN THIS CLINICAL TRIAL.

MR. SHEEHY: SO HOW MANY TOTAL PATIENTS ARE THEY PLANNING TO ENROLL?

DR. TALIB: THERE WILL BE 12 PATIENTS. IT'S ACTUALLY THREE PATIENTS, THREE PATIENTS, THREE PATIENTS. BUT IF THREE PATIENTS DO WELL, THEY CAN INCREASE THE COHORT IN THE FIRST AND THE SECOND. THEY ARE ALSO USING THIS CHEMOTHERAPY APPROACH THAT WILL BE USED TO CREATE A SPACE IN THE BONE MARROW.

MR. SHEEHY: THANK YOU.

MS. LANSING: SO RIGHT NOW THOSE ARE THE CLINICAL TRIALS THAT ARE HAPPENING. ARE THERE OTHER CLINICAL TRIALS IN OTHER DISEASE AREAS CLOSE? I THINK I'VE READ THAT THEY ARE. SO I JUST WANT A CLARIFICATION.

DR. TALIB: SO IN THIS HSC TRANSPLANTATION FIELD, THAT IS HSC GENE THERAPY, THE ONE THE CLOSEST

WOULD BE THE ONE WHICH IS NOW -- IT'S AN EARLY TRANSLATION GRANT WHICH WILL BE FINISHING EARLY ON. IT'S JENNIFER PUCK AND MARK COWAN. SO THEY WILL BE ABLE TO FILE -- COMPLETE THEIR IND NEXT YEAR AND THEN FILE AN IND SO THEY WILL BE ABLE TO START THE CLINICAL TRIAL.

SECOND ONE ACTUALLY IS VERY CLOSE TO STARTING CLINICAL TRIAL IS THAT OF STANFORD. THAT IS JUDY SHIZURU. AND THAT CLINICAL TRIAL IS READY TO START BECAUSE THEY HAVE IND ALREADY APPROVED.

MS. LANSING: ARE THEY DISEASE SPECIFIC?

DR. TALIB: YES. THOSE ARE DISEASE SPECIFIC. IN THIS CASE OF JUDY SHIZURU, THIS IS ON SEVERE IMMUNE DEFICIENCY THAT SCID PATIENTS WILL BE TRIED. AGAIN, IT'S A PROOF OF CONCEPT. IF IT WORKS IN THE SCID, THE SAME APPROACH CAN BE APPLIED FOR OTHER DISEASES AS WELL.

DR. BRENNER: YOU MIGHT HAVE SAID THIS ALREADY AND I MISSED IT. WHAT'S THE ADVANTAGE OF THE GENE MODIFIED HSC THAT IT ALLOWS IT TO PROPAGATE IN THE PATIENT'S OWN BONE MARROW?

DR. TALIB: THAT'S RIGHT. SO BASICALLY WHAT IT HAS DONE IN THIS CASE, THE HSC HAVE ITSELF RENEWING CAPACITY. SO THEY CAN SELF-RENEW AND MAKE MORE OF THE BLOOD STEM CELLS.

DR. BRENNER: ANYTHING LIKE ENDOGENOUS?

DR. TALIB: SO IN THIS CASE AS A TRANSPLANT, BASICALLY YOU CREATE A SPACE TO WIPE OUT PATIENT'S OWN HSC'S. AND NOW THESE NEW CELLS WILL TAKE OVER, REPOPULATE THE IMMUNE SYSTEM.

MR. TORRES: I JUST THINK THAT -- I JUST WANT TO FOLLOW UP ON JEFF'S COMMENTS. I THINK IT WOULD HELPFUL IF YOU PROVIDED ALL OF THE BOARD MEMBERS WITH A MORE DETAILED REPORT SO THAT WE CAN HAVE THAT IN OUR POSSESSION. IT'S VERY IMPORTANT WHEN WE'RE TALKING TO GROUPS OUT THERE TO HAVE THAT INFORMATION IN TERMS OF WHERE WE'RE HEADED AND EVEN THOSE TWO TRIALS THAT ARE ABOUT TO HAPPEN. THANK YOU.

DR. TALIB: SURE, SENATOR. WE'LL DO THAT.

CHAIRMAN THOMAS: DR. TALIB, I WOULD GO SO FAR AS TO SAY IT WOULD BE NICE TO HAVE, PERHAPS, AT SOME REGULAR INTERVAL AN UPDATED DASHBOARD REPORT WHICH GIVES THE STATUS IN SORT OF THUMBNAIL FASHION THAT PEOPLE CAN HAVE AT THEIR HANDS SO IF THERE ARE QUESTIONS ASKED ABOUT WHERE OUR CLINICAL TRIALS ARE, THAT THEY'LL BE ABLE TO SPEAK ON A REAL-TIME BASIS.

DR. PRIETO: IT OCCURS TO ME THAT MAYBE WE HAVE A VEHICLE FOR DOING THAT AND SOMETHING THAT WE COULD USE ALREADY WITH OUR BLOG. HAVE A KIND OF

CAPSULE PROGRESS REPORT, SOMETHING IN LAY TERMS, AND WE'RE ALREADY SHARING A LOT OF THAT IN THAT SPACE ALREADY.

DR. TALIB: DR. PRIETO, LET ME REMIND YOU THAT SOME OF THESE CLINICAL TRIALS ARE DONE WITH THE COMMERCIAL ENTITIES LIKE CAL-IMMUNE. AND SO I THINK SOME OF THE INFORMATION WHICH IS CONFIDENTIAL WILL NOT BE AVAILABLE. WE DO VET SOME OF THE CONFIDENTIAL INFORMATION, BUT WE ARE NOT ABLE TO SHARE IT IN PUBLIC. BUT CLEARLY THE UPDATE ABOUT THE CLINICAL TRIALS CAN BE PROVIDED, AS YOU SAID, WHATEVER IS NONCONFIDENTIAL.

MR. SHEEHY: I DO LIKE THE IDEA OF A DASHBOARD. THAT'S A GREAT IDEA, CHAIRMAN THOMAS. EASY REFERENCE TO SEE WHAT WE'RE DOING. AND, AGAIN, WE WOULDN'T HAVE TO PUT CONFIDENTIAL INFORMATION ON THERE, BUT JUST BE ABLE TO TRACK THE PROGRESS OF OUR CLINICAL TRIALS.

DR. DULIEGE: THANK YOU AGAIN. THIS IS SO EXCITING. THIS IS REALLY THE FUTURE AT OUR DOORSTEP TO SOME EXTENT.

MY QUESTION IS MORE ON THE CLINICAL SIDE. I'M A LITTLE SURPRISED WHEN YOU MENTIONED THAT THERE WAS REALLY NO SIDE EFFECT, EVERYTHING WAS WELL TOLERATED. YET TO MY UNDERSTANDING, THESE ARE

PRETTY INVASIVE PROCEDURES, VERY MUCH WORTH IT, OBVIOUSLY, GIVEN THE ALTERNATIVE. BUT THIS IS, AS YOU MENTIONED, A MYELOABLATION. IS IT THAT NOW MYELOABLATION IS LESS INVASIVE, BETTER DONE THAN BEFORE, BECAUSE YET YOU HAD COMPLETE IMMUNOSUPPRESSION, RISK OF INFECTION, RISK OF BLEEDING. SO TELL US A LITTLE BIT MORE ABOUT HOW CHALLENGING IS TODAY A MYELOABLATION.

DR. TALIB: THANK YOU. I THINK THIS IS A VERY GOOD QUESTION. AS I POINTED OUT, THAT IS THE BIGGEST LIMITATION IN STEM CELL TRANSPLANTATION IS THE CONDITION REGIMENT OR THE MYELOABLATION.

SO IN PATIENTS WHICH HAVE BEEN TREATED, THEY ARE NOT RECEIVING A FULL MYELOABLATION. ONLY IN THE CASE OF SICKLE CELL DISEASE THE PATIENTS ARE RECEIVING A MYELOABLATION IN ORDER TO CREATE A SPACE. OTHER DISEASES NOW IN STEM CELL TRANSPLANTATION, THESE ARE REDUCED CONDITION REGIMENT OR LOWER DOSES OF THE CONDITION REGIMENT. AND ALSO THERE HAS BEEN SOME ADVANCES IN TERMS OF THE OLD MYELOABLATION PROCEDURES. HERE, ONLY THING ONE HAS TO DO IS CREATE A SPACE. SO THEY'RE USING BUSULFAN, WHICH IS A LITTLE BIT LESS TOXIC THAN THE PREVIOUS CONDITION REGIMENT WHICH PEOPLE HAD USED. SO THAT IS A DIFFERENCE. IN CASE OF CANCER

TREATMENT, YOU NEED MYELOABLATION AS WELL AS IMMUNOSUPPRESSION. AND THOSE WERE THE MOST TOXIC. HERE, ONLY YOU ARE CREATING A SPACE IN THE BONE MARROW. SO A SMALLER AMOUNT AND LOWER DOSES OF THESE CHEMOTHERAPY CAN BE USED.

AND AS I POINTED OUT, THE APPROACH THAT DR. SHIZURU IS TAKING, THAT WILL BE CHEMOTHERAPY FREE USING A MONOCLONAL ANTIBODY TO CREATE A SPACE IN THE BONE MARROW. AND THAT WILL BE A REAL ADVANCEMENT IN TERMS OF MOVING THESE PROCEDURES TO LESS TOXIC AND RISKY.

DR. DULIEGE: THANK YOU VERY MUCH FOR THIS CLARIFICATION. THIS IS VERY IMPORTANT. I WAS LEFT WITH THE IMPRESSION IT WAS A CANCER TYPE OF MYELOABLATION AND THE ANSWER IS NOT AT ALL. THANK YOU.

MR. SHEEHY: I THINK THAT'S ONE OF THE BIG QUESTIONS HERE THAT WE'RE GOING TO FIND OUT IS WHETHER THAT WORKS. THESE MILD TO MODERATE DOSES OF SUPPRESSIVE REGIMINS WILL ALLOW SUFFICIENT ENGRAFTMENT TO GET CLINICAL EFFECT OF THE NEW CELLS.

CHAIRMAN THOMAS: OKAY. ANY OTHER COMMENTS? OKAY. AS THIS IS AN INFORMATIONAL ITEM, WE THANK YOU, DR. TALIB, AND BY EXTENSION THANK YOU TO ALL THE MEMBERS OF THE TEAM FOR THIS KIND OF

EXCITING WORK ACROSS ALL INDICATIONS IN OUR PORTFOLIO.

THAT BRINGS US TO THE CONCLUSION OF -- YES, WE HAVE A VERY IMPORTANT PUBLIC COMMENT.

MS. ROBERSON: HELLO. ON BEHALF OF THE HUNTINGTON'S DISEASE COMMUNITY --

CHAIRMAN THOMAS: JUDY, IF YOU JUST GIVE YOUR NAME FOR THE RECORD.

MS. ROBERSON: I'M JUDY ROBERSON FROM SACRAMENTO. ON BEHALF OF THE HUNTINGTON'S DISEASE ADVOCACY COMMUNITY, WE SAY BRAVO TO PRESIDENT RANDY MILLS FOR HIS EDITORIAL DIRECTED AT THE FDA, "GIVE US OUR CURES." MANY OF US JOIN THE CIRM STEM CELL CHAMPION CAMPAIGN PROMOTED BY KEVIN MCCORMACK IN THE HOPES THAT THE FDA CREATES SOMETHING LIKE FDA 2.0 THAT WOULD BE MORE OPEN TO STEM CELL THERAPIES AND ALLOW THE INCREASED RISKS THAT NATURALLY GO ALONG WITH ANY NEW THERAPIES.

FOR PEOPLE WITH HUNTINGTON'S DISEASE, WHICH HAS ZERO TREATMENTS AND IS A HUNDRED PERCENT FATAL, LIKE MY HUSBAND AND HIS BROTHER, THEIR MOTHER, THEIR GRANDFATHER, AND MY CHILDREN ARE AT RISK, WE'RE WILLING TO TAKE ON RISK BECAUSE WE'RE DYING ANYWAY. THE FDA HAS DELAYED THE FULLY ENROLLED UC DAVIS, CIRM-FUNDED, FIRST-IN-HUMAN

CLINICAL TRIAL USING ADULT STEM CELLS WITH DRS. WHEELOCK AND NOLTA.

THE FDA ASKED FOR -- AND THEY CLEARED THE RAC COMMITTEE, THEY CLEARED EVERYTHING, FDA LIKES WHAT THEIR WORK IS. THEN THE FDA TACKS ON A NEW STUDY. THEY WANT THREE PIGS DONE. IT WILL COST $330,000. SOUNDS PRETTY REASONABLE. AND ONE YEAR RESEARCH, WE DON'T HAVE ANY FUNDING FOR THAT. ONE HD FAMILY IN NEW YORK SENT DR. NOLTA A CHECK, BUT IT COVERED ONE PIG.

ONE YEAR RESEARCH, NO FUNDING. I THINK OF THIS AS A DELAY BY THE FDA BECAUSE THEY'RE SO SCARED TO MOVE FORWARD. MAYBE IT'S NOT, BUT THAT'S HOW WE SEE IT. WE HAVE A FULLY ENROLLED TRIAL, AND PREVIOUSLY TODAY ONE OF THE DOCTORS SAID THEY HAVE TROUBLE ENROLLING THE TRIALS. NOPE. NOT FOR HD. IT WAS FULLY ENROLLED. AND IT MAY UNRAVEL AS THE PATIENTS PROGRESS AND DIE.

WE NEED AN FDA 2.0. BECAUSE DOING NOTHING IS DOING HARM. THANK YOU SO MUCH.

CHAIRMAN THOMAS: THANK YOU, JUDY. ANY OTHER COMMENTS BY MEMBERS OF THE PUBLIC? HEARING NONE, I AM INFORMED THAT LUNCH IS IN THE MENDOCINO ROOM WHERE YOU HAD BREAKFAST. THAT CONCLUDES A BUSY AGENDA FOR TODAY. WE LOOK FORWARD TO SEEING

EVERYBODY IN PERSON IN SEPTEMBER AND TO PARTICIPATING IN OUR MONTHLY ICOC CALLS IN THE INTERIM. THANK YOU, EVERYBODY, AND ENJOY A WONDERFUL SUMMER.

(THE MEETING WAS THEN CONCLUDED AT 12:29 P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

CLAREMONT HOTEL
44 TUNNEL ROAD
BERKELEY, CALIFORNIA
ON
JUNE 15, 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.

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