BEFORE THE
SCIENCE SUBCOMMITTEE
OF 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:	OAKLAND MARRIOTT CITY CENTER 1001 BROADWAY OAKLAND, CALIFORNIA
DATE:	MONDAY, NOVEMBER 30, 2015 1 P.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
BRS FILE NO.:	98029

I N D E X

OAKLAND, CALIFORNIA; NOVEMBER 30, 2015

1 P.M.

CHAIRMAN SHEEHY: OKAY. SO I BELIEVE THIS IS JEFF SHEEHY IN OAKLAND WHERE CIRM IS NEWLY RELOCATED. CONGRATULATIONS TO THE CIRM TEAM ON MANAGING TO MAKE THAT MOVE SO SUCCESSFULLY. SO I'M READY TO CALL THE MEETING TO ORDER OF THE SCIENCE SUBCOMMITTEE OF THE GOVERNING BOARD OF THE CALIFORNIA INSTITUTE OF REGENERATIVE MEDICINE. SO I THINK THE FIRST ORDER OF BUSINESS IS THE ROLL CALL. MS. BONNEVILLE.

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD. ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: KRISTINA VUORI.

CHAIRMAN SHEEHY: SO I THINK WE'RE ONE SHORT OF A QUORUM.

MS. BONNEVILLE: YES.

CHAIRMAN SHEEHY: I THINK DR. STEWARD IS ON HIS WAY. I BELIEVE WE'LL GO AHEAD AND START THE AGENDA BEGINNING WITH THE CONSIDERATION OF THE STRATEGIC PLAN. DR. MILLS, ARE YOU GOING TO LEAD US THROUGH THAT?

DR. MILLS: OKAY. THANK YOU, EVERYONE. APPRECIATE YOUR TAKING THE TIME TODAY TO GO THROUGH THIS AGENDA WITH US. I THINK WE'RE ON THE VERGE OF A NEW AND EXCITING TIME AT CIRM. THE STRATEGIC PLAN IS OBVIOUSLY SOMETHING WE WENT THROUGH ON OUR LAST BOARD MEETING. WE NOW HAVE A PUBLISHED VERSION OF IT OUT FOR COMMENT WHICH WE'LL BE CONSIDERING HERE TODAY AND THEN CONSIDERING AT THE FULL BOARD MEETING IN DECEMBER ON THE 17TH.

FOR US IN THE STRATEGIC PLANNING PROCESS, IT WAS A TIME TO REALLY TAKE A HARD LOOK NOT ONLY AT THE AGENCY BUT HOW THE ENVIRONMENT HAD CHANGED, THAT THE AGENCY EXISTED, AND HOW THE WORLD HAD CHANGED AND TRY TO DO THE BEST WE COULD TO MATCH UP WHERE THE AGENCY WAS TODAY AND WHAT THE AGENCY WAS DOING WITH ITS MISSION AND HOW THE WORLD HAD CHANGED AROUND IT. AND SO WE REALLY THOUGHT OF EVERYTHING.

WE ATTEMPTED TO THINK OF EVERYTHING I SHOULD SAY. WE ATTEMPTED TO TURN OVER EVERY STONE AND CONSIDER EVERY POSSIBLE IDEA THAT WOULD HELP US ACCOMPLISH OUR MISSION OF ACCELERATING STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS.

IN DOING SO, WE TALKED TO STAKEHOLDERS OF EVERY VARIETY. WE HELD IN-PERSON MEETINGS WITH EVERY MAJOR RESEARCH CENTER IN THE STATE, WE HELD STAKEHOLDER MEETINGS WITH PATIENT ADVOCATES, WE TALKED WITH INDUSTRY, WE TALKED WITH FDA, WE TALKED WITH THE GENERAL PUBLIC, WE HELD SURVEYS, WE OBVIOUSLY HAD DIALOGUE WITH THE BOARD AND REALLY TRIED TO PUT TOGETHER AS THOUGHTFUL A PLAN AS POSSIBLE.

WHAT I'LL SAY ABOUT THE PLAN, FIRST AND FOREMOST, IS THERE'S NOTHING ABOUT IT THAT'S EASY TO ACCOMPLISH. THERE ARE NO LAY-UPS HERE. WE'RE NOT SANDBAGGING. WE ATTEMPTED TO PUT TOGETHER A PLAN THAT REALLY WOULD STRETCH THE AGENCY TO ITS LIMITS IN ORDER TO ACCOMPLISH THE MOST WE POSSIBLY COULD ACCOMPLISH OVER THE NEXT FIVE YEARS. AND WHAT WE'RE LOOKING TO DO IS NOTHING SHORT OF CHANGE THE FACE OF REGENERATIVE MEDICINE AND STEM CELL THERAPIES BY 2020. AND WE HAVE TAKEN AN AGGRESSIVE APPROACH TOWARDS DOING THAT.

WITH THAT SAID, IT'S NOT AN IMPOSSIBLE APPROACH. WE DON'T HAVE TO BEND THE LAWS OF PHYSICS IN ORDER TO ACCOMPLISH IT, BUT WE WILL NEED TO BE VERY METHODICAL AND DISCIPLINED IN OUR EFFORTS IF WE ARE TO BE ULTIMATELY SUCCESSFUL. SO LET ME GET INTO IT.

THE STRATEGIC PLAN HAS TEN COMPONENTS TO IT. THE FIRST THREE ARE INTRODUCTORY, WHICH ARE BASICALLY SETTING THE STAGE OF WHERE WE ARE TODAY. IF YOU RECALL, AS I'VE TALKED ABOUT PREVIOUSLY, STRATEGIC PLANNING CAN BE BROKEN DOWN INTO THREE SIMPLE PROCESSES OR THREE SIMPLE COMPONENTS. ONE IS UNDERSTANDING REALLY WELL WHERE YOU ARE, AND THAT OFTEN IS THE MOST DIFFICULT AND OVERLOOKED PART OF STRATEGIC PLANNING, AND IT INVOLVES ASKING REALLY DIFFICULT QUESTIONS AND BEING VERY HONEST ABOUT THE SITUATION. SO THE FIRST THREE SECTIONS REALLY GO INTO WHERE WE ARE TODAY.

AND THEN THE NEXT PART OF STRATEGIC PLANNING IS WHERE DO YOU WANT TO BE, IN THIS CASE, OVER THE NEXT FIVE YEARS. AND THEN, LASTLY, HOW DO YOU GET THERE? WHAT'S THE PLAN OR ROAD MAP TO GET THERE? SO WHERE DO WE WANT TO BE AND HOW DO WE GET THERE COMBINE THE MEATIER SECTION OF THE STRATEGIC PLAN. AND THOSE ARE CHAPTERS 4, 5, 6, 7, 8, 9, AND

10.

SO I'M GOING TO GO THROUGH TODAY AT A HIGH LEVEL THESE DIFFERENT COMPONENTS, STARTING FIRST WITH THE STRATEGIC PLANNING PROCESS AND THEN SPECIFICALLY ITS PURPOSE. SO OUT OF THIS IT'S NOT JUST THAT WE WANT TO PLAN, BUT THE FIRST THING THAT STRATEGIC PLANNING ENABLES YOU TO DO IS TO REALLY BE SURE THAT YOU HAVE AWARENESS OF THE SITUATION AROUND. YOUR SITUATION AROUND AWARENESS IS THIS CONCEPT THAT YOU DON'T LIVE IN A VACUUM, BUT YOU HAVE ALL THESE OTHER INFLUENCES GOING ON AROUND YOU. AND THAT THE TACTICS THAT YOU'RE USING AND THE STRATEGY THAT YOU'RE USING TO ACCOMPLISH YOUR MISSION IS IN SYNC WITH THE ENVIRONMENT THAT SURROUNDS YOU.

SECOND IS ORGANIZATIONAL CLARITY. AND THIS IS A BIG ONE FOR ME. MAKING SURE THAT EVERYONE WITHIN THE ORGANIZATION KNOWS WHAT THEY'RE DOING, KNOWS WHY THEY'RE DOING IT, AND KNOWS HOW THEY'RE DOING IT, AND TO WHAT END BOTH UPSTREAM AND DOWNSTREAM. SO I UNDERSTAND WHAT THE MISSION IS, I UNDERSTAND WHERE MY PLACE IN THAT MISSION IS. AND IF WE'RE SUCCESSFUL, WE SHOULD BE ABLE TO SEE THE SPECIFIC GOALS WHICH LEADS TO THE LAST PART, WHICH IS MEASURABLE GOALS AND MILESTONES, BEING ABLE TO

LAY OUT A PLAN WITH ENOUGH SPECIFICITY AND WITH ENOUGH OBJECTIVE OUTCOMES THAT WE'LL BE ABLE TO TELL WHETHER OR NOT WE'VE ACCOMPLISHED THIS PLAN OR NOT. SO THAT'S THE SORT OF THREE PURPOSES BEHIND THE STRATEGIC PLANNING.

THE NEXT THING WE NEEDED TO DO WAS JUST TAKE A LOOK AT OUR CONSTRAINTS. AND FOR US THAT'S REALLY OUR FUNDING RUNWAY. AND SO I'VE PUT THIS SLIDE UP BEFORE AND WE'VE TALKED ABOUT IT. WE HAVE SUFFICIENT LEVELS OF FUNDING TO HAVE THE AGENCY WRITE NEW AWARDS AND OBLIGATIONS FOR APPROXIMATELY FOUR AND A HALF OR FIVE YEARS. WE HAD 2.75 BILLION IN AWARD FUNDING TO START WITH. WE HAVE TWO BILLION OF IT THAT'S BEEN EITHER AWARDED OR SPENT, WHICH LEAVES US 775 MILLION THAT'S UNCOMMITTED. WE ESTIMATE THAT IF WE MAKE BETWEEN 190 AND 200 MILLION IN NEW AWARDS EACH YEAR, THAT WILL GIVE US A NET AWARD SPEND OF ABOUT 170 BECAUSE, RECALL, JUST BECAUSE WE COMMIT FUNDING TO A PROGRAM DOESN'T MEAN ALL OF THAT FUNDING GETS SPENT, IF THEY'RE EITHER UNDERBUDGET, WHICH RARELY HAPPENS, OR MORE LIKELY THE PROGRAM ENDS UP NOT BEING SUCCESSFUL. PARTIALLY THROUGH ITS COMPLETION, THE PROJECT ENDS AND THE BALANCE OF THE MONEY GETS RETURNED TO CIRM FOR REINVESTMENT.

SO GOING THROUGH JUST SORT DISTILLING DOWN LOTS AND LOTS AND LOTS OF FEEDBACK AND CONVERSATIONS AND SURVEYS, THERE ARE REALLY SORT OF FIVE KEY POINTS THAT CAME OUT TO US AS WE LOOKED THROUGH THE STRATEGIC PLAN. FIRST IS THAT HISTORICALLY CIRM HAS EXISTED AS AN INITIATIVE-BASED AGENCY. AND THIS IS IN CONTRAST TO A SYSTEMS-BASED AGENCY. WHAT I MEAN BY THIS IS WHEN CIRM STARTED, THERE WASN'T REALLY CRITICAL MASS IN THE CONTINUUM FROM DISCOVERY THROUGH TRANSLATION INTO CLINICAL TO BE ABLE TO HAVE A PROCESS THAT RAN CONTINUOUSLY. SO INSTEAD CIRM, BEING AS RESPONSIVE AN AGENCY AS IT POSSIBLY COULD, CREATED FROM AN ANALOGY STANDPOINT WHAT WOULD BE SIMILAR TO CHARTER FLIGHTS.

AND SO WHENEVER THERE WAS SUFFICIENT INTEREST AND DEMAND IN A CERTAIN AREA, WHETHER THAT BE AN EARLY STAGE DISCOVERY PROGRAM OR IN A TRANSLATIONAL AREA, THERE WOULD BE AN INITIATIVE THAT WOULD BE CREATED, AN RFA WOULD BE ISSUED, AND THAT WOULD BE FILLED, AND SO ON AND SO FORTH WITHOUT THESE DIFFERENT INITIATIVES BEING LINKED TOGETHER IN ORDER TO CREATE A CLEAR AND SUSTAINABLE PATHWAY FROM DISCOVERY THROUGH TRANSLATION. AND THAT'S SOMETHING THAT UNDER CIRM 2.0 AND, AGAIN, SPECIFICALLY BECAUSE THE ENVIRONMENT HAS CHANGED SO MUCH AND THE WORLD

HAS CHANGED SO MUCH, WE'RE NOW ABLE TO TAKE ADVANTAGE OF THE FACT THAT WE HAVE ENOUGH DEMAND IN ALL OF THESE AREAS TO SET UP A CONTINUOUS SYSTEMS-BASED APPROACH.

WE DID A LOT OF QUESTIONING AND A LOT OF SURVEYING, AND THE THING THAT I'M MOST PLEASED WITH IS, WITH THE EXCEPTION OF A FEW, A VERY FEW, INSTANCES, MOST OF THE STAKEHOLDERS ARE ALIGNED WITH REGARDS TO THEIR PRIORITIES AND THEIR THINKING ABOUT CIRM. THERE'S A HIGH INTEREST IN CIRM DOING THOSE THINGS WHICH OTHERWISE WOULD NOT HAPPEN WITHOUT US. THERE'S A HIGH INTEREST IN CIRM TAKING BIGGER RISKS FOR BIGGER REWARDS. AND SO WE'RE GENERALLY ALIGNED AMONG STAKEHOLDERS.

THE THIRD THING THAT JUMPED OFF THE TABLE WAS THAT THE TRANSLATIONAL STAGE, SO THE AREA FROM ONCE A NEW DRUG CANDIDATE IS DISCOVERED THROUGH THE TIME THAT IT ENTERS CLINICAL TRIALS, IS CURRENTLY DISPROPORTIONATELY LONG FOR STEM CELL THERAPIES COMPARED TO THE SAME WORK WHICH IS REQUIRED FOR NONSTEM CELL THERAPIES, BASICALLY DRUGS AND BIOLOGICS. IT'S TAKING APPROXIMATELY EIGHT YEARS FOR A STEM CELL THERAPY TO MAKE THIS TRANSITION FROM SOMETHING BEING IDENTIFIED AS A CANDIDATE INTO A CLINICAL TRIAL. BASICALLY A TRADITIONAL DRUG WOULD

TAKE 3.2 YEARS. SO THAT SAYS THAT THERE'S SOME WORK THAT WE CAN DO. AND THE CAUSES FOR THAT ARE MULTIFACTORIAL, AND I WON'T GET INTO THEM NOW, BUT IT SAYS THERE'S A SIGNIFICANT OPPORTUNITY FOR US TO SPEED UP THIS TRANSLATIONAL ASPECT, AND WE NEED TO TAKE ADVANTAGE OF THAT OPPORTUNITY AND DO THAT.

IT'S BEEN POINTED OUT THAT SO FAR 91 PERCENT OF CIRM'S FUNDING HAS GONE TO ACADEMIC VERSUS ONLY 9 TO INDUSTRY. THAT AND LOTS OF OTHER DATA, INCLUDING THE VERY SMALL NUMBER OF STEM CELL THERAPIES WHICH ARE CURRENTLY MARKETED BY TECH TRANSFER OFFICES AND THE, RELATIVELY SPEAKING, LATE STAGE PARTNERING THAT TAKES PLACE, SAYS THAT CURRENTLY STEM CELL THERAPIES ARE VIEWED COMMERCIALLY AS A DISADVANTAGED CLASS. AND THAT SEEMS TO BE TRUE NOT ONLY FROM A COMMERCIAL STANDPOINT, BUT FROM A REGULATORY STANDPOINT AS WELL.

LASTLY, TYING INTO THAT, THE REGULATORY ENVIRONMENT IS SEEN AS THE SINGLE BIGGEST IMPEDIMENT TO STEM CELL THERAPY TODAY. OVER 70 PERCENT OF RESPONDENTS TO OUR SURVEY IDENTIFIED THE REGULATORY PATHWAY AS THE SINGLE BIGGEST IMPEDIMENT. AND SO THERE'S AN OPPORTUNITY FOR US TO WORK WITH THE FDA AND WORK WITH OTHER STAKEHOLDERS IN ORDER TO IMPROVE

UPON THAT.

SO WE TOOK ALL THAT INFORMATION, AND THE FIRST THING WE DID WAS WE WANTED TO MAKE SURE THAT WE HAD THE RIGHT MISSION AND THAT WE WERE ALL ALIGNED BEHIND THAT MISSION BECAUSE IN A STRATEGIC PLAN, WITHOUT HAVING SOMETHING TO ORIENT TOWARDS THAT IS ESSENTIALLY YOUR TRUE NORTH, IT BECOMES VERY DIFFICULT TO MAKE DECISIONS. SO OUR IMMOVABLE POINT HERE IS OUR MISSION, WHICH IS TO ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. ONE HUNDRED PERCENT OF OUR BOARD MEMBERS AND 95.4 PERCENT OF ALL OTHER STAKEHOLDERS AGREED THAT THIS WAS THE MISSION. SO WE, I THINK, SUCCESSFULLY HAVE CONFIRMED OUR MISSION.

THE SECOND THING WAS TO CREATE A VISION. I WON'T GO INTO ALL THE DETAIL BEHIND ALL THE WORDS HERE. IT'S IN THE STRATEGIC PLAN WHY WE PICKED THE WORDS THAT WE PICKED. BUT THE FIRST PART SAYS EXPONENTIALLY ADVANCE CIRM'S MISSION. I THINK THAT'S THE THING WE SHOULD FOCUS ON HERE. WE'RE NOT TALKING ABOUT MAKING INCREMENTAL ADVANCEMENTS. WE'RE TALKING ABOUT DOING THINGS WHICH SIGNIFICANTLY MOVE THE NEEDLE AND CHANGE FOR THE BETTER REGENERATIVE MEDICINE AND STEM CELL THERAPIES SUCH THAT WHEN THIS PLAN HAS REACHED ITS MATURITY IN

2020, WE CAN LOOK BACK AND SEE A VERY PROFOUND AND MEANINGFUL DIFFERENCE.

SO THEN WE GET INTO STRATEGIC THEMES. SO HOW ARE WE GOING TO MAKE THIS DIFFERENCE? HOW ARE WE GOING TO ACCOMPLISH THIS EXPONENTIAL IMPROVEMENT? IN PREVIOUS PRESENTATIONS I USED THE PUSHING THE GIANT BOULDER OVER THE HILL TO THE VALLEY OF CURES BELOW. AND STICKING WITH THAT, WE HAVE THREE STRATEGIC THEMES IN ORDER TO DO THAT. THE FIRST IS WE'RE GOING TO PUSH THAT BOULDER AS HARD AS WE CAN AND AS EFFICIENTLY AS WE CAN. THAT'S WHERE OPERATIONAL EXCELLENCE COMES INTO. THAT SAYS THE THINGS WE'RE DOING AT CIRM AND WE'VE HISTORICALLY BEEN DOING AT CIRM ARE GOOD AND RIGHT, AND WE NEED TO DO AS GOOD A JOB AT GETTING GREAT AT THAT AS POSSIBLE. AND THAT CENTERS AROUND THINGS LIKE GETTING BETTER AT CIRM 2.0 AND GETTING MORE EFFICIENT AT THE WAY WE DO THINGS, IMPLEMENTING OTHER CHANGES.

THE SECOND THING, THOUGH, IS THAT WE NEED HELP. AND THERE SHOULD BE -- WE SHOULDN'T JUST BE PUSHING ON THIS BOULDER, BUT WE SHOULD HAVE HELP DOWNSTREAM PULLING ON THIS BOULDER, NOT JUST FROM INDUSTRY, BUT FROM INVESTIGATORS THAT ARE FURTHER DOWN FIELD. AND THAT'S WHERE THE SECOND STRATEGIC

THEME, PULL, COMES INTO IT. IT'S ENGAGING DOWNSTREAM DEMAND TO HELP US MOVE THIS BOULDER.

AND THEN THE LAST IS LEVEL. STEM CELL THERAPIES FROM A REGULATORY STANDPOINT CURRENTLY DON'T EXIST ON A LEVEL PLAYING FIELD WITH REGARDS TO OTHER THERAPIES. AND WE NEED TO WORK WITH THE FDA IN ORDER TO CREATE A MORE LEVEL PLAYING FIELD HERE. SO THAT'S THE THIRD ASPECT OF IT. THE HILL THAT WE'RE PUSHING THIS BOULDER WITH IS JUST TOO HIGH.

SO SPECIFICALLY WHAT ARE WE GOING TO DO TO GET INTO THIS? AGAIN, THERE'S LOTS AND LOTS OF DETAIL CONTAINED WITHIN THE STRATEGIC PLAN ABOUT THIS. FROM A PUSH STANDPOINT, WE NEED TO FULLY OPERATIONALIZE CIRM 2.0. THE BOARD IN JULY PASSED THE LAST COMPONENTS OF IT, THE DISCOVERY AND TRANSLATIONAL. SO WE NOW HAVE DISCOVERY, TRANSLATIONAL, AND CLINICAL CIRM 2.0 IN PLACE. MARIA BONNEVILLE AND JAMES HARRISON ARE WORKING ON THE CIRM CORE INITIATIVE, WHICH IS BASICALLY TO GET THE REST OF CIRM'S COMPONENTS 2.0-IZED, IF YOU WILL, AND MAKE SURE WE HAVE A GOOD, STREAMLINED, EFFICIENT OPERATING SYSTEM IN PLACE.

SO WE'VE SEEN THIS ALREADY WITH REGARDS TO THE CLINICAL PROGRAM OF CIRM 2.0. THE MORE WE DO IT REPETITIVELY, THE BETTER WE GET AT IT. AND THE

BETTER WE GET AT IT, THE MORE LIKELY WE ARE TO HAVE SUCCESSES OUT OF IT. SO THE FIRST SPECIFIC ACTION IS JUST GET REALLY GOOD AT WHAT WE'RE DOING UNDER 2.0.

THE SECOND CENTERS AROUND CONSTRUCTING TRANSLATING CENTERS AND ACCELERATING CENTERS, AND WE CAN TALK ABOUT THESE TERMS, BUT BASICALLY WHAT WE'RE SAYING IS AN AGENCY OR AN ENTITY IN THE TRANSLATING CENTER THAT WILL ACTUALLY HELP US CONDUCT AND HELP OUR APPLICANTS CONDUCT THE PRECLINICAL WORK NECESSARY IN ORDER TO GET AN IND IN A COORDINATED FASHION WITH FDA AS QUICKLY AS POSSIBLE. THIS ISN'T THE KIND OF WORK THAT TYPICALLY OUR TRANSLATIONAL INVESTIGATORS LIKE TO DO. IT'S MORE OF THE REGULATORILY REQUIRED IND-ENABLING WORK. AND THAT PAIRED WITH WHAT WE CALL AN ACCELERATING CENTER OR BASICALLY A STEM CELL-SPECIFIC CRO THAT WOULD HELP COMPILE THE IND, FILE THE IND, AND HELP THEM RUN CLINICAL TRIALS.

AND THEN THE LAST PIECE CENTERS AROUND REALLY COORDINATING AND FOCUSING THESE PROGRAMS. MAKING SURE WE HAVE TRIALS THAT ARE WORTH DOING, MAKING SURE THAT ONCE WE HAVE A PROGRAM THAT'S SUCCESSFUL AND IT'S MET ITS END POINTS, IT EFFICIENTLY MOVES ON TO THE NEXT STEP. BASICALLY

JUST CLEANING UP SOME SCOPE ISSUES WE HAVE. SO THAT'S PUSH.

PULL, THERE'S TWO SPECIFIC INITIATIVES WITHIN PULL. ONE OF THEM IS TO LAUNCH WHAT WE CALL THE CIRM EXCHANGE. THIS IS IN CONCEPT PHASE STILL, BUT THIS IS WHERE WE SET UP SOMETHING ALONG THE LINES OF THE CIRM'S VERSION OF MATCH.COM WHERE WE CONNECT EARLY STAGE RESEARCHERS WITH DOWNSTREAM RESEARCHERS INTERESTED IN THOSE PROGRAMS WHO ARE QUALIFIED AND VETTED SO PEOPLE AREN'T WASTING THEIR TIME. SO AS A PROGRAM MOVES FROM EARLY TO LATE STAGE AND TO COMMERCIAL STAGE, WE HAVE A GOOD, EFFICIENT SYSTEM IN PLACE FOR MATCHING UP INTERESTED PARTIES.

THE SECOND IS CREATING THESE PUBLIC/PRIVATE PARTNERSHIPS, OR IN JUST PLAIN TERMS, CIRM WORKING WITH AN INTERESTED PARTY OR PARTIES TO CREATE A NEW ENTITY OR COMPANY WITHIN CALIFORNIA, OR COULD BE COMPANIES WITHIN CALIFORNIA THAT WOULD TAKE AND AGGREGATE SOME OF CIRM'S MOST PROMISING BUT UNLICENSED TECHNOLOGIES AND FORMULATE THEM INTO A COMPANY AND ULTIMATELY COMMERCIALIZE THEM. WE'LL TALK MORE ABOUT THAT.

AND THEN THE LAST PIECE CENTERS AROUND LEVELING THE PLAYING FIELD AGAIN. HERE REALLY

THERE'S TWO ASPECTS. ONE IS TO ORGANIZE WHAT WE CALL AN ARMY OF STAKEHOLDERS. ONE OF THE THINGS WE HEARD REPEATEDLY FROM PATIENT ADVOCATES, WHICH I TOTALLY GET, IS THEY DON'T WANT TO JUST BE SPECTATORS TO CIRM. THEY WANT TO BE ACTIVE PARTICIPANTS AND ADVOCATING ON BEHALF OF CIRM IN A NUMBER OF DIFFERENT AREAS, BUT PARTICULARLY WITH THE REGULATORY AGENCIES IS SOMETHING THAT WE CAN USE AND WELCOME THEIR HELP WITH AND ACTUALLY HELP THEM BE AS EFFECTIVE, MAXIMALLY EFFECTIVE, WHICH IS WHAT WE WANT TO DO.

AND THEN THE SECOND THING IS WE NEED TO DRIVE REGULATORY REFORM. THERE'S TWO PARTICULAR AREAS THAT WE NEED TO ADDRESS. ONE IS THE IND-ENABLING AREA, WHICH IS CURRENTLY TOO LONG FOR STEM CELL THERAPIES. AND THE OTHER CENTERS AROUND WITH THE RISK-BASED APPROACH THAT FDA HAS TO CELL THERAPY, REALLY NOT BEING A RISK-BASED APPROACH, BUT REALLY A LIGHT SWITCH. IT'S EITHER ON OR IT'S OFF, AND THERE IS NO MIDDLE GROUND. AND WE THINK THERE'S GOOD OPPORTUNITY FOR THERE TO BE MIDDLE GROUND. SO WE WANT TO WORK WITH THE AGENCY ON ESTABLISHING THAT.

SO THE GREATER THING TO UNDERSTAND IS NOT ONLY HAVE WE LAID OUT THESE SPECIFIC ACTIONS IN

THESE THREE CONCEPTS AS PUSH, PULL, AND LEVEL, BUT WE'RE REALLY MAKING THIS BIG SHIFT FROM BEING AN INITIATIVE-BASED AGENCY TO A SYSTEMS-BASED AGENCY WHERE ALL OF THE DIFFERENT COMPONENTS WORK TOGETHER IN HARMONY, IN CONCERT, ROWING IN THE SAME DIRECTION TO PRODUCE, NOT JUST A ONE-OFF OUTCOME, BUT A CONTINUUM. THE ANALOGY WE USE HERE IS TAKING THESE PARTS AND PUTTING THEM TOGETHER AND CREATING AN ENGINE WHERE ALL THE PIECES IN THE ENGINE FROM EARLY STAGE DISCOVERY THROUGH LATE STAGE CLINICAL RESEARCH AND COMMERCIALIZATION EFFORTS ALL WORK TOGETHER IN HARMONY TO CREATE AN OUTCOME WHICH IS NOT JUST A ONE-OFF SUCCESS, BUT A CONTINUAL PIPELINE OF SUCCESS, WHICH, IF WE DO THIS, WON'T EXIST ANYWHERE ELSE IN THE WORLD OTHER THAN IN CALIFORNIA AND BECAUSE OF CIRM. THE VISION HERE IS TO HAVE PEOPLE NO MATTER WHERE WE THEY ARE, IF THEY'RE IN CELL THERAPY, THEY WANT TO COME AND THEY HAVE TO COME TO CALIFORNIA BECAUSE WE'RE GOING TO ACCELERATE THEIR PROGRAMS AND GET THEIR TECHNOLOGIES TO PATIENTS WITH UNMET MEDICAL NEEDS FASTER THAN YOU COULD ANYWHERE ELSE IN THE WORLD.

SO WE LAY OUT VERY SPECIFIC AND MEASURABLE RESULTS HERE WITH THIS PROGRAM. WE GOT A LOT OF FEEDBACK SINCE THE FIRST VERSION OF THIS, AND SO

WE'VE LINED THEM UP BASICALLY FROM THE FRONT OF THE ENGINE TO THE BACK OF THE ENGINE. THE FIRST THING WE WANT TO DO IS MAKE SURE EVERYONE UNDERSTANDS WE ARE NOT JUST IN THE LATE STAGE BUSINESS. WE HAVE SET A VERY, VERY AGGRESSIVE DISCOVERY GOAL THAT SAYS WE'RE GOING TO INTRODUCE 50 NEW THERAPEUTIC OR DEVICE CANDIDATES AT THE FRONT END OF THIS. WE WANT TO MAKE SURE THAT, ONCE WE DISCOVER THESE NEW AND PROMISING TECHNOLOGIES, WE'RE ACTUALLY ABLE TO MOVE THEM DOWN THE TRACK. AND SO WE WANT TO MAKE SURE THAT OUR PROJECTS ADVANCE TO THE NEXT STAGE OF DEVELOPMENT OR INCREASE THAT BY AT LEAST 50 PERCENT OVER WHAT WE'RE CURRENTLY DOING. WE WANT TO REFINE THE REGULATORY PATHWAY. AND IF WE THINK WE REFINED THE REGULATORY PATHWAY, THAT WILL ACTUALLY HELP US ACCELERATE. SO NOT JUST HAVE THESE THINGS MOVE DOWN THE FIELD WITH A HIGHER PROBABILITY OF SUCCESS, BUT ALSO DECREASE THE TIME AT WHICH IT TAKES THEM TO DO THAT.

SPECIFICALLY, IN THE TRANSLATIONAL AREA, WE WANT TO CUT THAT TIME IN HALF, WHICH WOULD BE FROM THE EIGHT YEARS TO THE FOUR YEARS WHICH WOULD BE A VERY SIGNIFICANT GOAL.

WE WANT TO WHAT WE CALL VALIDATE, WE WANT TO ADD 50 NEW PROGRAMS INTO THE CLINIC, SO 50 NEW

CLINICAL TRIALS, COVERING AT LEAST 20 UNIQUE DISEASES WITH AT LEAST TEN THAT ARE ORPHAN AND FIVE THAT ARE PEDIATRIC. AND THEN, LASTLY, WE WANT TO HAVE THESE THINGS FIND COMMERCIAL HOMES WHERE THEY CAN ULTIMATELY GO ON TO HELP, NOT JUST INDIVIDUALS IN TRIALS, BUT POPULATIONS OF PEOPLE SUFFERING FROM THESE DISEASES. THAT'S OUR GOAL AT THE END IS PARTNERING WHERE WE WANT 50 PERCENT OF OUR CLINICAL STAGE PROJECTS THAT ARE UNPARTNERED TO FIND COMMERCIAL PARTNERS.

FROM A FINANCIAL STANDPOINT, THIS ISN'T AN OPERATING PLAN, SO IT DOESN'T GO INTO DETAILED OPERATING BUDGETS, BUT WHAT WE'RE TRYING TO DO REALLY WITH THE FINANCIAL SUMMARY IS TO LAY OUT TWO THINGS. ONE IS SHOW THAT THERE IS SUFFICIENT MONEY IN ORDER TO ACCOMPLISH THESE GOALS, AND THERE IS. YOU WILL NOTICE THERE'S 890 MILLION IN FUNDING TO BE COMMITTED, AND WE LAID OUT 775 THAT WAS UNCOMMITTED. THAT IS, AGAIN, THE DIFFERENCE BETWEEN THE 775 AND THE 890 IS THE RATE AT WHICH WE'RE ANTICIPATING, ABOUT 10 PERCENT, THAT FUNDS WILL BE RETURNED BACK TO THE AGENCY FOR PROGRAMS THAT WE ATTEMPT, BUT END UP NOT BEING SUCCESSFUL.

THE SECOND THING WE WANT TO DO IS MAKE SURE THAT EVERYONE UNDERSTANDS THESE ASSUMPTIONS,

SUCH AS THE RECOVERY RATE BEING 10 PERCENT, WHAT THESE DIFFERENT PROGRAMS WILL COST, THE ACCELERATING AND THE TRANSLATING CENTERS. I THINK SORT OF A KEY HERE IS THAT WE'RE NOT TRYING TO SPREAD THIS OUT LIKE PEANUT BUTTER. WE'RE TRYING TO GET THIS ENGINE UP AND RUNNING AT MAXIMAL POWER AS FAST AS WE CAN. SO THERE'S NOTHING IN THIS, EITHER THE FINANCIAL PLAN OR THE STRATEGIC PLAN, THAT ISN'T ALL ABOUT GETTING EVERYTHING GOING RIGHT NOW AS QUICKLY AS WE CAN.

AND THAN LASTLY, AND I IDENTIFIED THESE IN OUR LAST MEETING AND THEY REMAIN, IS THERE ARE RISKS TO THIS PLAN. SO IT'S A VERY AMBITIOUS PLAN. IT'S FEASIBLE, BUT WE HAVE TO IDENTIFY THE RISKS, AND WE HAVE TO BE PREPARED TO DO WHATEVER WE CAN TO MITIGATE THESE RISKS. WE NEED TO BE VERY DILIGENT ABOUT MONITORING. IN THIS OVERVIEW I LAID OUT ONLY THE END GOALS THAT WE EXPECT TO HAVE; BUT IN THE ACTUAL PLAN ITSELF, WE LAY OUT THE MONITORING THAT'S GOING TO TAKE PLACE AT THE DEPARTMENT LEVEL FOR EVERY DEPARTMENT WITHIN CIRM. SO WE NEED TO BE VERY VIGILANT THAT WE REMAIN ON TRACK AND THAT WE REMAIN ON SCHEDULE AND ON BUDGET. AND IF WE DO ALL OF THAT, I THINK WE SHOULD BE SUCCESSFUL.

EVEN WITH THAT SAID, THERE ARE A NUMBER OF

RISKS THAT ARE IMPORTANT. FIRST AND FOREMOST IS THERE MAY NOT BE SUFFICIENT HIGH QUALITY PROGRAMS THAT EXIST IN ORDER TO ENABLE US TO REACH OUR GOALS. WE'RE DOING EVERYTHING WE CAN INTERNALLY TO HAVE THAT NOT BE TRUE, BUT THAT'S CERTAINLY A RISK. AND ONE OF THE THINGS, I THINK, AS A GROUP WE FEEL VERY STRONGLY ABOUT IS THE METRIC WE SHOULDN'T LOWER IN ORDER TO ACHIEVE THIS GOAL AND TO MITIGATE THIS RISK IS QUALITY. WE MAY NOT HAVE SUFFICIENT APPLICANTS FOR OUR DIFFERENT PROGRAMS IN ORDER TO WIN BIDS, AND THAT WOULD MEAN THAT THE SPECIFIC PROGRAMS THAT WE'RE TRYING TO SET UP WE COULD HAVE A FAILURE IN.

WE WORRY INTERNALLY ABOUT THE TEAM THAT WE'VE ASSEMBLED. THE TEAM WE HAVE AT CIRM IS ONE OF THE BEST TEAMS I'VE EVER WORKED WITH IN MY LIFE, BUT WE HAVE A VERY REAL SITUATION, WHICH IS CIRM HAS A FINITE FUNDING LIFE AHEAD OF IT. AND THAT FUNDING LIFE COULD AND WILL AFFECT OUR ABILITY TO ATTRACT AND RETAIN THE CALIBER OF TALENT WE CURRENTLY HAVE AT CIRM. SO THAT'S SOMETHING WE NEED TO BE VERY COGNIZANT ABOUT.

NO MATTER WHAT WE DO, WE MAY NOT BE ABLE TO CONVINCE INVESTORS THAT STEM CELL THERAPIES ARE A GOOD IDEA.

AND THAN, LASTLY, THERE'S NO GUARANTEES

THAT WE'LL BE ABLE TO CONVINCE FDA OR CONGRESS THAT CHANGE IN THE REGULATORY PARADIGM IS NECESSARY AND GOOD.

BUT WITH ALL OF THAT, THOSE ARE NO REASONS TO NOT GO FORWARD WITH AN AMBITIOUS PLAN. SO THAT IS WHAT WE'RE DOING. WE ARE GOING TO DO EVERYTHING WE CAN IN ORDER TO MOVE THESE STEM CELL THERAPIES FROM WHERE THEY ARE TODAY TO THE PATIENTS THAT SO DESPERATELY NEED THEM. WE'RE GOING TO PUSH, WE'RE GOING TO PULL, WE'RE GOING TO LEVEL, AND WE'RE GOING TO DO IT IN A COORDINATED FASHION IN ORDER FOR CIRM TO BE MAXIMALLY SUCCESSFUL. WITH THAT, I WILL STOP TALKING.

CHAIRMAN SHEEHY: THANK YOU, DR. MILLS, FOR THAT INCREDIBLE PRESENTATION.

SO JUST A COUPLE OF POINTS BEFORE WE HAVE DISCUSSION OF THE PLAN AMONG BOARD MEMBERS. ONE IS, BECAUSE DR. STEWARD ISN'T HERE YET, I THINK WE'LL ACTUALLY DELAY A VOTE ON THE STRATEGIC PLAN TILL AFTER WE LOOK AT THE THREE CONCEPTS THAT ARE GOING TO BE INTRODUCED TODAY, WHICH PROBABLY MAKES SENSE LOGICALLY AS WELL BECAUSE APPROVING THE PLAN AND NOT APPROVING THE CONCEPTS WOULD KIND OF SEND AN AMBIGUOUS MESSAGE.

THE SECOND QUESTION I HAD WERE FOR DR.

MELMED AND DR. HIGGINS, WHETHER OR NOT THERE WAS PUBLIC AT THEIR SITE SO THAT WE KNOW FOR PUBLIC COMMENT.

DR. HIGGINS: THERE'S NOT.

DR. MELMED: NOT HERE IN LOS ANGELES EITHER.

DR. HIGGINS: UNLESS ONE OF MY DOGS COUNTS.

CHAIRMAN SHEEHY: AT THIS POINT WE'RE READY TO HAVE DISCUSSION ABOUT THE PLAN. EITHER OF YOU HAVE COMMENTS YOU'D LIKE TO MAKE OR QUESTIONS FOR DR. MILLS OR ANY OF THE CIRM TEAM?

DR. MELMED: JUST COMPLIMENT RANDY ON HIS PASSION AND ON HIS INITIATIVE.

DR. HIGGINS: I WOULD SECOND THAT, AND I ALSO WOULD ADD THE THING THAT STRIKES ME OR HAS STRUCK ME OVER THE PAST MONTH IS THE CONSISTENCY OF THE MESSAGE. I THINK MORE THAN ANYTHING HAVING A CONSISTENT MESSAGE NOT ONLY TEACHES THE CIRM TEAM TO HAVE A FOCUS AND A MISSION, IT ALSO TRAINS THE PUBLIC TO HAVE A MESSAGE AND A FOCUS FOR CIRM. I THINK THAT THAT'S ONE OF THE MOST IMPORTANT SERVICES THAT RANDY HAS DONE FOR US.

CHAIRMAN SHEEHY: SO ANYONE HERE IN SAN FRANCISCO. SENATOR TORRES? CHAIRMAN THOMAS?

CHAIRMAN THOMAS: JUST WANTED TO REITERATE SOMETHING RANDY SAID BECAUSE I THINK THAT WHAT'S SO INTERESTING ABOUT THIS PLAN IS THE EXTREME AMOUNT OF DILIGENCE THAT HE AND THE CIRM TEAM DID WITH EVERY CONCEIVABLE STAKEHOLDER GROUP OVER A MANY-MONTH PERIOD AND COUNTLESS DISCUSSIONS INTERNALLY ALL TOWARDS DRIVING WHAT HE AND THE TEAM BELIEVES IS A GRAND VISION THAT IS AT ONCE STRATEGIC AND DIFFICULT, BUT DOABLE IF EVERYBODY PITCHES IN AND DOES AS HE ANTICIPATES. SO I WANT TO ECHO THE COMMENTS, JUST TO CONGRATULATE RANDY ON A MOST THOUGHTFUL DOCUMENT WHICH I THINK SETS THE TONE FOR WHAT SHOULD BE A VERY EXCITING FIVE YEARS.

CHAIRMAN SHEEHY: I'D LIKE TO CONGRATULATE DR. MILLS AND THE CIRM TEAM AS WELL FOR THIS PRODUCT. HAVING BEEN INVOLVED IN MANY STRATEGIC PLANNING PROCESSES OVER THE COURSE OF THE LIFE OF THIS AGENCY, THIS IS CERTAINLY THE MOST IMPRESSIVE DOCUMENT I'VE SEEN SINCE THE FIRST ONE THAT WE CREATED WHICH WAS CLOSE TO THIS LENGTH. SO THE DILIGENCE THAT HAS GONE INTO THIS PLANNING IS INCREDIBLE AND IMPRESSIVE.

I ALSO AM IMPRESSED BY THE METRICS THAT HAVE BEEN PUT INTO PLACE. I REALLY ADVISE PEOPLE, IF YOU GET A CHANCE, READ THE ENTIRE PLAN. NOT ONLY

DO WE HAVE CLEAR METRICS FOR OUTCOMES, BUT EACH TEAM WITHIN THE LARGER CIRM TEAM HAS PUT IN PROCESS METRICS TO INCREASE OUR PROBABILITY OF SUCCESS. SO THE WILLINGNESS OF BOTH SENIOR LEADERSHIP AND INDIVIDUAL TEAM MEMBERS TO HOLD THEMSELVES ACCOUNTABLE AND TO SET AMBITIOUS GOALS IS LAUDABLE. SO THANK YOU FOR ALL THIS WORK.

UNLESS THERE'S OTHER BOARD COMMENT, I WILL OPEN IT UP TO ANY PUBLIC COMMENT HERE IN SAN FRANCISCO. SEEING NONE, WE'LL TAKE CONSIDERATION OF THIS UP AFTER WE LOOK AT THE THREE CONCEPTS THAT ARE BEING PRESENTED. AND THE FIRST ONE IS THE ACCELERATING CENTER. AND, DR. MILAN, WILL YOU BE PRESENTING ON THIS?

DR. MILAN: YES, I WILL. GOOD AFTERNOON, MEMBERS OF THE SCIENCE SUBCOMMITTEE OF THE ICOC AND COLLEAGUES FROM CIRM. I'LL BEING PRESENTING TWO CONCEPT PLANS TOGETHER, THE ACCELERATING CENTER AND THE TRANSLATING CENTER, TWO INFRASTRUCTURE PROGRAMS THAT WE'RE PROPOSING FOR CONSIDERATION THAT WE FEEL ARE CRITICAL TO ACHIEVING THE STRATEGIC PLAN THAT WAS LAID OUT BY DR. MILLS JUST A LITTLE WHILE AGO.

SO BY WAY OF BACKGROUND, JUST TO REITERATE THAT WE ARE OBSERVING CIRM'S PIPELINE MATURING, WE ARE ANTICIPATING OR ACTIVELY PURSUING ACTIVE GROWTH,

AGGRESSIVE GROWTH OF THE PRECLINICAL AND CLINICAL STAGE PROGRAMS. AND AS WE'RE DOING SO, WE WANT TO MAKE SURE TO ADDRESS THE CHALLENGES AND MEET THE NEEDS OF THOSE PROGRAMS, INCREASE THE PROBABILITY OF THEIR PROGRESSION THROUGH TO GETTING TO THE CLINICAL TRIAL STAGE AND THEN TO PATIENTS.

IN THE CONVERSATIONS WITH STAKEHOLDERS THAT DR. MILLS HAD MENTIONED, THE RESEARCHERS, SPONSORS, REGULATORS, AND OTHER STAKEHOLDERS WE HAVE IDENTIFIED, AS WELL AS OUR OWN OBSERVATIONS FROM MANAGING OUR CIRM PROJECTS, WE HAVE IDENTIFIED KEY CHALLENGE AREAS WHERE WE FEEL WE CAN IMPACT IF WE PROVIDED THE PROPER INFRASTRUCTURE SUPPORT. AND THAT'S IN THE AREA OF IND-ENABLING ACTIVITIES, INCLUDING PROCESS DEVELOPMENT AND MANUFACTURING PLANS, AND ALL OF THE PRECLINICAL WORK THAT NEEDS TO GO INTO ASSEMBLING A STRONG IND PACKAGE. THE IND BEING THE REGULATORY PERMISSION BY WHICH INVESTIGATORS CAN GO AHEAD INTO CLINICAL TRIALS WITH THEIR DEVELOPMENT CANDIDATE, AND BY PROVIDING EFFICIENCIES AND A CONTINUOUS LOOP OF LEARNING TO CARRYING OUT THESE UNIQUE CLINICAL TRIALS, STEM CELL CLINICAL TRIALS, WHICH ARE VERY DIFFERENT FROM THE TRADITIONAL SMALL MOLECULES AND PHARMACOLOGIC TRIALS.

IN ADDITION, IN ADDRESSING THESE WITH THE CORE INFRASTRUCTURE PROGRAMS THAT I'LL BE PRESENTING SHORTLY, THESE INFRASTRUCTURE PROGRAMS, BY ADDRESSING THESE NEEDS, WOULD ACCUMULATE AGGREGATED EXPERIENCE AND VALUABLE DATASETS AND KNOWLEDGE THAT WILL INFORM BETTER OPERATIONS, CONTINUAL IMPROVEMENTS, AS WELL AS AGGREGATE KNOWLEDGE AND KEY INFORMATION THAT WOULD ALLOW VERY INFORMED AND POWERED CONVERSATIONS WITH THIRD-PARTY STAKEHOLDERS SUCH AS REGULATORY BODIES AND EVENTUALLY REIMBURSEMENT BODIES.

SO ONE OF THE OTHER ADVANTAGES IS THERE'S AN IDENTIFIABLE ENTITY OR ENTITIES, SO CALLED ONE-STOP SHOPS, THAT WOULD BE FAMILIAR WITH, BUILD RELATIONSHIPS WITH, AND BUILD STABLE AND DURABLE COMMUNICATION LINES WITH PATIENTS, REGULATORS, AND DEVELOPERS AND SPONSORS.

I PUT THIS UP AGAIN. IT'S A SCHEMATIC DIAGRAM OF A JET ENGINE THAT REPRESENTS HOW WE ENVISION IN THE FIVE-YEAR STRATEGIC PLAN THE NEW INFRASTRUCTURE PROGRAMS AS WELL AS ALL OF CIRM'S PROGRAMS WORKING COORDINATELY AND EFFICIENTLY TO BE AN ACCELERATING MACHINERY.

SO THE INFRASTRUCTURE PROGRAMS THAT I'LL DESCRIBE TO YOU IN A LITTLE BIT ARE PROPOSED TO GO

INTO THIS ENGINE, BUT FIRST I'D LIKE TO GIVE A BRIEF UPDATE ON THE ALPHA CLINICS NETWORK, WHICH IS AN INFRASTRUCTURE PROGRAM FOR CLINICAL TRIAL, STEM CELL CLINICAL TRIAL SUPPORT.

AS A REMINDER, THE ALPHA STEM CELL CLINIC NETWORK WAS FUNDED TO ACCELERATE THE DEVELOPMENT AND DELIVERY OF STEM CELL THERAPIES BY INTRODUCING EFFICIENCIES AND SCALABLE RESOURCES TOWARDS SUPPORTING STEM CELL CLINICAL TRIALS. AND THAT INITIATIVE WAS LAUNCHED EARLY THIS YEAR WITH THREE PROGRAMS AT THE CITY OF HOPE, UC SAN DIEGO, AND THE UCLA-UC IRVINE CONSORTIUM, AND THOSE WERE LAUNCHED BETWEEN FEBRUARY AND APRIL OF 2015.

JUST FOR A BRIEF OVERVIEW OF THE PROGRESS OF THE ALPHA CLINICS NETWORK, THE ICOC HAD APPROVED $24 MILLION OF FUNDING FOR THE NETWORK IN OCTOBER OF 2014. AND SINCE THEN, THERE WERE PRELAUNCH MEETINGS WITH ALL THE SITES WHERE THERE WAS ACTIVE ENGAGEMENT AND PLANNING EVEN BEFORE THE AWARDS HAD INITIATED. AND THEN THERE WERE LAUNCH MEETING SITE VISITS, AND WE INITIATED RIGHT AWAY QUARTERLY STEERING COMMITTEE MEETINGS WHERE WORK GROUPS WERE FORMED TO CREATE WHAT'S CALLED ACCELERATING AND VALUE-ADD RESOURCES, THE TOOLS BY WHICH THIS CLINICAL NETWORK IS GOING TO INTRODUCE EFFICIENCIES AND EXECUTE ON ITS PLAN AND

ITS GOALS TO IMPROVE CLINICAL TRIALS AND TO EFFICIENTLY SUPPORT THESE PROJECTS.

JUST TO BRIEFLY GIVE AN OVERVIEW OF WHAT THESE ACCELERATING AND VALUE-ADD RESOURCES LOOK LIKE, AS WE KNOW, AS MANY WHO ARE INVOLVED IN CLINICAL TRIALS KNOW, SOME OF THE POTENTIAL GATING ITEMS ARE PATIENT RECRUITMENT, IRB APPROVALS. SO THERE ARE EFFICIENCIES THAT CAN BE INTRODUCED RIGHT OFF THE BAT LEVERAGING RESOURCES THAT ARE ALREADY IN PLACE FROM NETWORKS SUCH AS A UC-BRAID, FOR INSTANCE, THAT THE CLINICAL NETWORKS HAVE BROUGHT INTO THE -- THAT THE ALPHA CLINICS HAVE BROUGHT INTO THIS NETWORK NOW GEARED TOWARD THE STEM CELL CLINICAL TRIALS.

FOR INSTANCE, RECIPROCAL IRB APPROVALS ARE NOW GOING TO BE PUT IN PLACE SO THAT ONE CAN GET APPROVALS AT MULTIPLE SITES AT ONCE, THEREBY IMPROVING THE EFFICIENCIES FOR THAT PROCESS, AND ALSO ENGAGING THE PATIENT REGISTRIES FOR COHORT FINDING, AND TO ACCELERATE THE PROCESS OF PATIENT RECRUITMENT AND ENROLLMENT. SO MANY OF THESE RESOURCES ARE ALREADY BEING UTILIZED, THEY'RE BEING FORMED, BUT A KEY MESSAGE IS THAT FORMATION OF -- BRINGING FORWARD THESE AVARS, AS WE CALL THEM, ACCELERATING AND VALUE-ADD RESOURCES, ACROSS THE

NETWORK AND TO OTHER CLINICAL SITES IN CALIFORNIA WOULD REQUIRE A CENTRAL ENTITY SUCH AS THE ACCELERATING CENTER.

SO I'LL NEXT GO ON TO DESCRIBING THE INFRASTRUCTURE PROGRAM, THE ACCELERATING CENTER, WHICH IS A STEM CELL-FOCUSED CLINICAL RESEARCH ORGANIZATION WITH THE GOAL OF SPEEDING THE PROGRESSION OF THERAPEUTIC CANDIDATES FROM THE TRANSLATIONAL, PRECLINICAL STAGE TO CLINICAL TRIALS BY PROVIDING EFFICIENCIES AND ACCELERATING RESOURCES TOWARD THE CONDUCT OF CLINICAL TRIALS WHILE MAINTAINING A HIGH DEGREE OF RIGOR AND QUALITY.

THE PROPOSED ACTIVITIES FOR THIS ACCELERATING CENTER OR THE CLINICAL RESEARCH ORGANIZATION INCLUDE SUPPORTING THE STEM CELL TRIALS BY ASSISTING THEM AND ACTUALLY TAKING A LEAD IN IND ASSEMBLY AND SUBMISSION, IN THE MANAGEMENT OF THE KEY ASPECTS OF CLINICAL TRIAL EXECUTION, AND IN DATA MANAGEMENT.

THIS ACCELERATING CENTER WOULD WORK IN COLLABORATION AND COORDINATELY WITH THE TRANSLATING CENTER TO ACCELERATE THE REGULATORY PATHS. SO THE TRANSLATING CENTER, WHICH WILL BE DESCRIBED IN A LITTLE BIT, WOULD PERFORM THE IND-ENABLING WORK AND WORK WITH THE ACCELERATING CENTER TO ASSEMBLE THAT

INTO A STRONG IND PACKAGE ALONG WITH A SPONSOR. AND BECAUSE THESE TWO INFRASTRUCTURE PROGRAMS WOULD DO THIS FOR A MULTITUDE OF STEM CELL TRIALS, THERE WOULD BE EFFICIENCIES THAT WOULD BE GAINED AND KNOWLEDGE THAT WOULD BE ACCUMULATED, AND IN ITSELF WOULD INTRODUCE A BETTER PRODUCT IN THE END.

THE ACCELERATING CENTER WOULD ALSO COORDINATE WITH THE ALPHA CLINICS NETWORK TO SCALE UP AND SCALE OUT THE AVAR'S, ACCELERATING AND VALUE-ADD RESOURCES, THAT I HAD JUST DESCRIBED SO THAT IT CAN BE MORE WIDELY AVAILABLE TO OTHERS IN THE STEM CELL CLINICAL DEVELOPMENT SPACE.

AND IT IS REQUIRED THAT THIS ACCELERATING CENTER HAVE A BUSINESS PLAN SO THAT IT'S SUSTAINABLE AND WOULD PROVIDE A RESOURCE FOR THE FUTURE GROWING PIPELINE OF STEM CELL TRANSLATIONAL AND CLINICAL PROGRAMS.

WITHOUT GOING INTO TOO MUCH DETAIL, I DID LIST SOME SPECIFIC ACTIVITIES HERE, BUT THE KEY THING FOR THE ACCELERATING CENTER IS THAT IT COULD ACT AS A CENTRAL ROLE IN FDA INTERACTIONS. AGAIN, FORMING THOSE KEY RELATIONSHIPS, BEING ABLE TO CALL UPON ACCUMULATED AND AGGREGATED KNOWLEDGE BASE, AND THAT WOULD IN ITSELF CREATE EFFICIENCIES AND IMPROVEMENTS IN THE PROCESS. AND THAT WOULD THEN BE

TRANSMITTED AS A BENEFIT TO THE SPONSORS WHO ARE SUBMITTING THEIR IND'S.

THE ACCELERATING CENTER WOULD HELP TO MANAGE AND PROVIDE SUPPORT SCALED TO THE NEEDS OF THE SPONSORS AND THE ALPHA CLINICS IN ALL OF THE ACTIVITIES RELATED TO INITIATING A CLINICAL TRIAL, RUNNING A CLINICAL TRIAL, AND COMPILING THE RESULTS OF THE CLINICAL TRIAL.

AND THE ACCELERATING CENTER, IN ADDITION TO PROVIDING CUTTING-EDGE AND TOP QUALITY DATA MANAGEMENT AND STATISTICAL AND ANALYTIC SUPPORT, WOULD ALSO ENABLE THE RESEARCHERS AND STEM CELL COMMUNITIES TO HAVE A PLACE TO DEPOSIT AND ACCUMULATE THE AGGREGATED KNOWLEDGE THAT WOULD INFORM THE BEST PATH FORWARD FOR CELL THERAPY DEVELOPMENT, BUT ALSO TO INFORM CONVERSATIONS WITH THE REGULATORS AND WITH REIMBURSEMENT GROUPS.

WE'RE PROPOSING A BUDGET OF UP TO $15 MILLION TO SUPPORT THIS ACCELERATING CENTER WITH THE PROPOSED TIMELINE AS SHOWN IN THIS CHART WITH APPLICATIONS BEING DUE IN THE FIRST HALF OF 2016 AND REVIEWED DURING THAT TIME PERIOD, AND WE ENVISION ICOC REVIEW AND APPROVAL OF THE GWG RECOMMENDATION FOR THE ACCELERATING CENTER RFA IN THE SECOND HALF OF 2016. WE ENVISION THAT THIS ACCELERATING CENTER

WOULD BE OPERATIONAL BY THE SECOND HALF OF 2016.

SO I DON'T KNOW IF YOU WANT TO TAKE QUESTIONS FIRST OR CONSIDER THE SCIENCE SUBCOMMITTEE MOTION.

CHAIRMAN SHEEHY: SINCE WE'RE NOT AT A POINT WHERE WE COULD CONSIDER A MOTION, I THINK WE'LL TAKE QUESTIONS FROM BOARD MEMBERS AND THE PUBLIC FIRST. JUST TO BE CLEAR WHAT THE EVENTUAL MOTION WOULD BE, IT WOULD BE TO RECOMMEND BOARD APPROVAL OF THE CONCEPT PLAN FOR THE ACCELERATING CENTER, AND IT WOULD AUTHORIZE A BUDGET OF UP TO 15 MILLION TO FUND A SINGLE AWARD OVER FIVE YEARS.

SO, DR. MELMED, DAVID, DO YOU GUYS HAVE ANY QUESTIONS, COMMENTS, ETC. ON THIS PARTICULAR CONCEPT?

DR. HIGGINS: I DON'T HAVE ANY QUESTIONS. IT WAS VERY CLEAR.

DR. MELMED: ME TOO. VERY CLEAR.

CHAIRMAN SHEEHY: DR. THOMAS, SENATOR TORRES, ANY QUESTIONS?

CHAIRMAN SHEEHY: SO I HAD JUST A COUPLE OF QUESTIONS TO REALLY CLARIFY. SO THIS ACCELERATING CENTER WILL BASICALLY BE AN ENTITY THAT --

DR. MELMED: HELLO.

CHAIRMAN SHEEHY: IS HE NOT HEARING US? WE HEAR YOU, DR. MELMED.

DR. MELMED: YOU CUT OUT THERE. SORRY.

CHAIRMAN SHEEHY: CAN YOU HEAR US NOW?

DR. HIGGINS: HEAR YOU NOW.

CHAIRMAN SHEEHY: I'M HERE. SO A COUPLE OF QUESTIONS. NO. 1, THIS WILL BE A SERVICE OFFERED. THE GRANTEES ARE NOT REQUIRED TO USE THIS SERVICE.

DR. MILAN: THAT'S CORRECT.

CHAIRMAN SHEEHY: IN TERMS OF MILESTONES, CAN YOU GIVE EXAMPLES OF A COUPLE OF MILESTONES?

DR. MILAN: FOR THE ACCELERATING CENTER. SO THE MILESTONES WOULD BE OPERATIONAL MILESTONES CONSISTENT WITH THE CIRM 2.0 CURRENT FUNDING SCHEME. AND IT WOULD INVOLVE THINGS SUCH AS HAVING THE NECESSARY OPERATIONS AND PERSONNEL IN PLACE BY A CERTAIN TIME POINT, BEING ABLE TO SUPPORT A VOLUME OF CLINICAL TRIALS AND PROJECTS WITHIN CERTAIN TIME POINTS, AND PRODUCING THE WORK PRODUCTS, SUCH AS ASSISTING WITH THE IND SUBMISSION, THINGS THAT ARE MEASURABLE QUANTITATIVELY. AND THEN, OF COURSE, WE'LL BE ALSO TRACKING QUALITY-TYPE METRICS AND SECONDARY OUTCOMES FROM THAT JUST BASED ON SOME OF THE OTHER METRICS THAT ARE IN PLACE.

CHAIRMAN SHEEHY: SO CIRM GRANTEES WILL RECEIVE SERVICES AT A DISCOUNT PRICE REFLECTING CIRM'S INVESTMENT. AND REALLY THE IDEA IS TO CREATE A SUSTAINABLE BUSINESS MODEL THAT WILL PROVIDE SERVICES TO THE FIELD AT LARGE?

DR. MILAN: YES. INITIALLY THE IDEA IS THAT THEY WOULD SERVE THE CIRM PROGRAMS AND THE CIRM ALPHA CLINICS AT A DISCOUNT. AND THEN AS THE YEARS GO ON, THEY COULD TAKE ON CLIENTS WHICH ARE CIRM OR NON-CIRM AND CHARGE THEM MARKET COMPETITIVE RATES TO BE ABLE TO SUSTAIN THE BUSINESS ENTITY.

CHAIRMAN SHEEHY: AND THEN JUST ONE FINAL QUESTION. I THINK IMPLICIT IN YOUR PRESENTATION IS THAT WE'VE SEEN SOME SUCCESS WITH THE ALPHA CLINICS, WHICH WAS A QUESTION THAT I THINK MANY OF US HAD WHEN WE APPROVED THE FIRST ALPHA CLINICS. IF THAT SUCCESS CONTINUES, IT'S STILL EARLY, IS THERE AN OPPORTUNITY IN THE NEAR FUTURE TO PUT FORWARD A CONCEPT FOR ADDITIONAL ALPHA CLINICS IF THE DATA SUPPORTS IT, IF THE EVIDENCE CONTINUES TO SHOW STRONG -- THAT WE'RE GETTING VALUE FROM THE CLINICS WE'VE SET UP SO FAR?

DR. MILLS: YEAH. SO ABSOLUTELY. THE ALPHA CLINICS, TO TAKE A SECOND HERE, MARIA MILAN HAS DONE A PHENOMENAL JOB WORKING WITH THE ALPHA

CLINICS AND GETTING THE THREE WE HAVE UP AND RUNNING. THE EARLY BASICALLY RETURNS THAT WE'RE GETTING ON THOSE CLINICS ARE VERY POSITIVE. AND IF THAT CONTINUES, WE WOULD BE COMING BACK TO THE BOARD WITH A RECOMMENDATION TO FUND ADDITIONAL ONES.

CHAIRMAN SHEEHY: THANK YOU, DR. MILLS. SO THOSE ARE ALL THE QUESTIONS I HAD. IF THERE ARE NO MORE QUESTIONS FROM ANY OTHER MEMBERS OF THE BOARD, I'LL ASK FOR PUBLIC COMMENT. IS THERE ANY PUBLIC COMMENT HERE IN SAN FRANCISCO? SEEING NONE, AGAIN, DR. STEWARD IS NOT HERE YET, THOUGH I'M TOLD HE'S ON HIS WAY. SO WE WILL DELAY A VOTE, A SUBCOMMITTEE VOTE, AT THIS TIME UNTIL HE GETS HERE. WE'LL HAVE A QUORUM AT THAT POINT.

I THINK THE NEXT ITEM ON THE AGENDA IS CONSIDERATION OF THE CONCEPT PLAN FOR THE TRANSLATING CENTER. AND I THINK, DR. MILAN, ARE YOU GOING TO DO THAT PRESENTATION AS WELL?

DR. MILAN: YES, I WILL. THANK YOU. SO THE PARTNER INFRASTRUCTURE PROGRAM TO THE ACCELERATING CENTER IS A SO-CALLED TRANSLATING CENTER, WHICH IS NOW THE PARTNER PRECLINICAL -- STEM CELL-FOCUSED PRECLINICAL RESEARCH ORGANIZATION. AGAIN, WITH THE SAME GOAL OF SPEEDING THE PROGRESSION OF THERAPEUTIC CANDIDATES FROM THE

TRANSLATIONAL PRECLINICAL STAGE TO THE CLINICAL TRIALS AND EVENTUALLY TO PATIENTS.

AND THE TRANSLATING CENTER'S ROLE WOULD BE TO PERFORM THE IND-ENABLING WORK. AND I'LL DESCRIBE THOSE A LITTLE BIT MORE IN A BIT. AND EFFICIENT CONDUCT OF PRECLINICAL ACTIVITIES THAT WOULD ENABLE THE SUCCESSFUL ASSEMBLY OF THE REGULATORY DOCUMENTS TO SUPPORT A CLINICAL TRIAL.

THE TRANSLATING CENTER, WHICH, AGAIN, IS AN ORGANIZATION THAT'S FORMED AND FUNDED BY THIS INITIATIVE TO PUT PERSONNEL AND OPERATIONS BEHIND PROVIDING CORE SERVICES THAT WOULD BE PROVIDED TO CIRM PROGRAMS. THE ACTIVITIES OF THE TRANSLATING CENTER WOULD INCLUDE CELL PROCESS DEVELOPMENT AND MANUFACTURING THAT ARE GMP, GOOD MANUFACTURING PRACTICE, COMPLIANT, OVERSEEING AND ASSEMBLING THE IND-ENABLING PRECLINICAL STUDIES, AND COORDINATING WITH THE ACCELERATING CENTER TO ASSEMBLE A WELL THOUGHT OUT AND STRONG IND PACKAGE ON BEHALF OF THE SPONSORS.

IN TERM OF PROCESS DEVELOPMENT AND MANUFACTURING, IT IS A VERY KEY AREA THAT WE'VE IDENTIFIED WHERE MANY INVESTIGATORS, ONCE THEY'VE IDENTIFIED A DEVELOPMENT CANDIDATE, THIS IS A VERY, VERY KIND OF RISKY AREA. AND THERE ARE IN CONTRACT

MANUFACTURING ORGANIZATIONS AND OTHER ORGANIZATIONS SOME STANDARD KIND OF APPROACHES TOWARD GETTING AT THE PROCESS DEVELOPMENT THAT'S REQUIRED. AND SO BY PROVIDING AN INFRASTRUCTURE WITH PERSONNEL WITH THAT TYPE OF EXPERTISE, WE BELIEVE THAT WE CAN CUT DOWN SOME OF THE COMPLICATIONS AND DECREASE THE TIME THAT IT WOULD TAKE FOR OUR INVESTIGATOR TO TAKE THEIR DEVELOPMENT CANDIDATES THROUGH THE STAGES WHERE THEY CAN GET A REPRODUCIBLE AND A ROBUST PROCESS THAT COULD THEN ENABLE THEM TO GO INTO CLINICAL TRIALS AND THEN TO LATER DEVELOPMENT.

AND SOME OF THESE KIND OF DETAILS ARE LISTED HERE ON THE SLIDE. THEY'RE ASSOCIATED ACTIVITIES RELATED TO QUALITY SYSTEMS AND ASSAY DEVELOPMENT AND KIND OF QUALITY-BY-DESIGN ACTIVITIES SO THAT WHEN THESE PROCESSES ARE CREATED, THEY ACTUALLY HAVE ENVISIONED FUTURE SCALE-UP AND TECH TRANSFER SO THAT OTHER MANUFACTURERS CAN REPRODUCE THIS AND PRODUCE THIS FOR LARGER STAGE TRIALS AND LARGER SCALE TRIALS AND THEN EVENTUALLY FOR COMMERCIAL MANUFACTURING.

THE TRANSLATING CENTER WOULD MANAGE THE PRECLINICAL DATASETS, ASSEMBLE THEM. THEY MAY NOT NECESSARILY CONDUCT ALL THE ANIMAL STUDIES. THEY MAY BE OUTSOURCED TO OTHER CLASSIC CRO'S TO DO SOME

SAFETY TOXICOLOGY STUDIES, SO THAT WOULDN'T NEED TO BE DUPLICATED, BUT THEY WOULD SHEPHERD THE PROCESS THROUGH, MAKE SURE THAT THEY AGGREGATE AND ASSEMBLE THE INFORMATION THAT THE SPONSOR PROVIDES REGARDING THE UNIQUE PRECLINICAL STUDIES AND CHARACTERIZATION THE CONTRACT RESEARCH ORGANIZATIONS PROVIDE IN TERMS OF THE STANDARD SAFETY TOXICITY DISTRIBUTION STUDIES THAT ARE REQUIRED WITH CELL THERAPIES, AS WELL AS ASSEMBLING THE INTERNAL DATASETS WHEN THEY DO THE PROCESS DEVELOPMENT RUNS AND CELL CHARACTERIZATION AND ASSAYS.

AND, AGAIN, THEY WOULD BE TAKING THE LEAD FROM THE ACCELERATING CENTER, WHICH IS LEADING THE FDA INTERACTIONS AND IND ASSEMBLY, BUT WOULD PROVIDE THE KEY PIECES OF THE CMC, WHICH IS THE CHEMISTRY MANUFACTURING CONTROL SECTION OF THE IND, AS WELL AS THE PRECLINICAL SECTIONS.

THE PROPOSED BUDGET FOR THIS TRANSLATING CENTER IS FUNDING OF UP TO $15 MILLION FOR A PERIOD OF FIVE YEARS. WE ARE PLANNING FOR APPLICATIONS TO BE -- THE RFA TO BE OUT IN 2016 WITH APPLICATION DUE DATES IN THE SAME YEAR WITH ICOC REVIEW AND APPROVAL OF THE GWG RECOMMENDATIONS IN 2016, IN LATE 2016. BUT WE BELIEVE THAT WE COULD LAUNCH THIS CENTER BY LATE 2016.

AND, AGAIN, THE SCIENCE SUBCOMMITTEE MOTION, PROPOSED MOTION, IS ON THE FINAL SLIDE. I'LL TAKE ANY QUESTIONS.

CHAIRMAN SHEEHY: THANK YOU, DR. MILAN. JUST TO BE CLEAR, THE PROPOSED MOTION IS TO RECOMMEND APPROVAL OF THE CONCEPT PLAN FOR THE CIRM TRANSLATING CENTER WITH BUDGET AUTHORIZATION OF UP TO 15 MILLION TO FUND A SINGLE AWARD OVER FIVE YEARS.

SO, DR. MELMED, DAVID, QUESTIONS, COMMENTS?

DR. HIGGINS: THIS MAY NOT BE AN APPROPRIATE QUESTION, BUT DO YOU HAVE POTENTIAL AWARDEES IN MIND? DO YOU KNOW SOMEONE THAT YOU WOULD HOPE WOULD APPLY FOR THIS OR THAT YOU WOULD SOLICIT TO APPLY FOR THIS? DO YOU HAVE GROUPS THAT ARE WELL-SUITED FOR THIS KIND OF WORK?

DR. MILAN: YES, WE DO. WHEN WE WERE WORKING ON THE EARLY STAGES OF THIS CONCEPT, WE ACTUALLY WENT AROUND TO DIFFERENT LARGE-SCALE CRO'S AND CMO'S AND EVALUATED THE NEED AS WELL AS INTEREST. AND WE HAVE REASON TO BELIEVE THIS WOULD INCENTIVIZE SOME OF THESE ORGANIZATIONS WITH THIS TYPE OF EXPERTISE TO CREATE A SUBDIVISION OR AN ENTITY THAT COULD BE FOCUSED ON STEM CELL AND

REGENERATIVE MEDICINE. THERE'S A LOT OF INTEREST IN CREATING BUSINESS UNITS AROUND STEM CELL AND REGENERATIVE MEDICINE, AND WE GOT THAT READ AT THE MOST RECENT STEM CELL ON THE MESA MEETING.

DR. HIGGINS: YOU FEEL PRETTY CONFIDENT THERE'S SOMEBODY OUT THERE THAT WE WOULD BE COMFORTABLE SPENDING OUR $15 MILLION TO ENABLE THEM TO DO THIS?

DR. MILLS: YEAH. I THINK, AGAIN, IT'S NOT JUST A. WE ACTUALLY FEEL PRETTY COMFORTABLE THAT WE WOULD HAVE MULTIPLE APPLICANTS TO THIS SO WE COULD PICK THE BEST ONE. I JUST WOULD REMIND YOU IF WE DIDN'T, THEN I WOULD HOPE THE GWG WOULD RECOMMEND IT BE NOT FUNDED, AND WE WOULDN'T SPEND THE MONEY ON IT. BUT I AGREE WITH DR. MILAN, THAT IN OUR CONVERSATIONS, ONE, THERE SEEMS TO BE A VERY STRONG INTEREST FOR THIS PROGRAM AMONGST, NOT JUST OUR APPLICANTS, BUT ACTUALLY, INTERESTINGLY, FDA WAS VERY INTERESTED IN US DOING THIS; AND, TWO, POTENTIAL APPLICANTS. WE WOULD HOPE WE WOULD HAVE A NUMBER OF HIGH QUALITY APPLICANTS TO THIS SO WE COULD ACTUALLY HAVE A REAL COMPETITION.

DR. HIGGINS: THANK YOU.

DR. MELMED: I HAVE A QUESTION. RANDY, IS THERE A REASON WHY WE'RE LIMITING IT TO ONE BY FIAT?

WHAT HAPPENS IF WE GET MORE THAN ONE EXEMPLARY APPLICATION? ARE WE CONSTRAINING OURSELVES UNNECESSARILY?

DR. MILLS: I THINK, AT LEAST INITIALLY, WHAT WE'RE TRYING TO DO IS SET UP THIS CENTER THAT WOULD GET GREAT AT SOMETHING AND BE SUSTAINABLE. AND I DON'T KNOW RIGHT NOW THAT THERE'S ENOUGH VOLUME FOR US TO SPLIT THAT BETWEEN MULTIPLE ENTITIES. AND SO I THINK, AT LEAST TO START WITH, WE'D LIKE TO SEE ONE UP AND RUNNING THAT WOULD HAVE ENOUGH VOLUME THROUGH IT THAT IT COULD SUPPORT ITSELF. BECAUSE WHAT WE'RE ASKING FOR IS A VERY HIGHLY SPECIALIZED BASICALLY CMC AND PRECLINICAL TOX CENTER BE ESTABLISHED SPECIFICALLY AROUND CELL THERAPY AND STEM CELL THERAPY, AND WE WANT THAT TO ENDURE. WE WANT THAT TO EXIST LONG AFTER THE CIRM SUPPORT OF IT STOPS. AND I'M NOT VERY COMFORTABLE THAT THERE'S SUFFICIENT VOLUME TO DO MULTIPLES.

DR. MELMED: I'M NOT DISAGREEING WITH YOU. ALL I'M SAYING IS THAT JUST BY PROTOCOL, IF WE'RE LIMITING IT TO ONE, WE MAY BE SORT OF CUTTING OUR NOSE TO SPITE OUR FACE JUST IN CASE MORE THAN ONE EXEMPLARY APPLICATION.

DR. MILLS: I'M HOPING THERE'S MORE THAN ONE EXEMPLARY APPLICATION. WHAT I'M SAYING IS I

DON'T THINK THERE'S SUFFICIENT DEMAND FOR THE APPLICANTS. AND SO THERE WILL PROBABLY BE MULTIPLE QUALIFIED APPLICANTS TO THIS, BUT NOT ENOUGH DEMAND FOR THE SERVICES TO SUPPORT MULTIPLE APPLICANTS.

CHAIRMAN SHEEHY: ADDITIONAL QUESTIONS? SO I JUST WANTED TO -- I THINK I HAVE THE SAME QUESTIONS I HAD ON THE LAST ONE. THIS WILL BE A SERVICE OFFERED TO OUR GRANTEES AT A DISCOUNT WITH THE IDEA THAT A BUSINESS MODEL AND A BUSINESS EMERGES THAT CARRIES ON.

DR. MILAN: WOULD BE ABLE TO OFFER THE SERVICES MORE GENERALLY OVER TIME AND CREATE A SUSTAINABLE ENTITY.

CHAIRMAN SHEEHY: AND THEN JUST EXAMPLES OF MILESTONES.

DR. MILAN: SIMILARLY, IT WOULD BE OPERATIONAL MILESTONES SUCH AS MAKING SURE THAT THE KEY PERSONNEL AND RESOURCES ARE IN PLACE TO ACTUALLY PROVIDE THE SERVICES. AND SO IT WILL BE VERY CONCRETE, SUCH AS TYPES OF EQUIPMENT THAT'S REALLY NECESSARY TO DO SOME OF THE PROCESS DEVELOPMENT WORK, FOR INSTANCE, OR CELL MANUFACTURING AND BANKING WORK. AND THEN, AGAIN, BASED ON ITS ABILITY TO SERVE THE CUSTOMERS, WHICH ARE OUR CIRM GRANTEES, SO IT WOULD BE VOLUME BASED AND PRODUCT BASED, BEING

ABLE TO DELIVER ON PACKAGES THAT WOULD SUPPORT IND'S.

CHAIRMAN SHEEHY: THANK YOU. ANY OTHER QUESTIONS? DR. THOMAS.

CHAIRMAN THOMAS: JUST A COMMENT, THAT FURTHER TO THE STRATEGIC PLAN ANALYSIS WHERE DR. MILLS AND THE TEAM UNDERTOOK A SYSTEMIC REVIEW TO SEE WHERE THE GAPS ARE IN THE WHOLE PROCESS, BOTH THE ACCELERATING AND TRANSLATING CENTER ARE SPECIFICALLY DESIGNED FOR THE GAPS THAT WERE OBSERVED THAT CAN FURTHER THE WHOLE CAUSE OF WHAT OUR GRANTEES ARE TRYING TO DO. SO I THINK THIS IS A MAJOR STEP UP IN THE CONTINUUM OF THINGS THAT NEED TO BE ATTENDED TO TO ACCELERATE THERAPIES TO PATIENTS WITH UNMET MEDICAL NEEDS.

CHAIRMAN SHEEHY: ANY OTHER BOARD COMMENTS OR QUESTIONS? ANY PUBLIC COMMENT? OKAY. SEEING NONE, WE'LL ALSO HOLD OFF ON THE VOTE -- ON PROPOSING A MOTION AND A VOTE ON A MOTION UNTIL DR. STEWARD GETS HERE.

SO I THINK WE SHOULD MOVE FORWARD AT THIS POINT TO CONSIDERATION OF THE CONCEPT PLAN FOR ACCELERATED THERAPIES PUBLIC/PRIVATE PARTNERSHIPS. IS IT YOU AGAIN, DR. MILAN? DO YOU THINK A BREAK WOULD BE HELPFUL? I THINK WE'LL BREAK FOR, WHAT DO

YOU SAY, TEN MINUTES, FIVE MINUTES? WE'LL RECONVENE AT 2:15.

(A RECESS WAS TAKEN.)

CHAIRMAN SHEEHY: SO I THINK WE'RE BACK FROM BREAK NOW. DR. STEWARD HAS JOINED US. THANK YOU, DR. STEWARD. DR. MELMED, DAVID, ARE YOU GUYS STILL WITH US?

DR. HIGGINS: I'M HERE.

DR. MELMED: I'M HERE ALSO.

CHAIRMAN SHEEHY: GREAT. SO I THINK WE'LL COME BACK -- WE'LL RECONVENE THE MEETING, AND WE ARE ON ITEM 6, WHICH IS CONSIDERATION OF CONCEPT PLAN FOR ACCELERATED THERAPIES PUBLIC/PRIVATE PARTNERSHIP. AND DR. MILAN WILL LEAD US THROUGH THAT.

DR. MILAN: THANK YOU VERY MUCH. SO I'LL BE PRESENTING THE ACCELERATING THERAPIES THROUGH PUBLIC/PRIVATE PARTNERSHIP, SO CALLED APT3. SO I MAY USE APT3 THROUGHOUT THE PRESENTATION.

AS A REMINDER OF OUR MISSION TO ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET NEEDS MEDICAL NEEDS AND IN LIGHT OF THE STRATEGIC PLAN PRESENTED BY PRESIDENT MILLS JUST A LITTLE WHILE AGO, THERE IS A CLEAR LACK OF INDUSTRY PULL FOR STEM CELL TREATMENTS. CIRM HAS THUS FAR INVESTED ABOUT

$2 BILLION IN DEVELOPING A PORTFOLIO OF OVER 300 TECHNOLOGIES. AND THE PROGRAMS ARE NOW MATURING, AND THEY'RE MOVING THROUGH PRECLINICAL AND CLINICAL DEVELOPMENT. AND SO THESE PROGRAMS ARE NOW GETTING TO THE STAGE WHERE THEY'RE GOING, TO BE SUCCESSFUL AND TO MAKE IT TO PATIENTS, GOING TO NEED TO BE BROUGHT SUCCESSFULLY TO THE COMMERCIALIZATION STAGE.

AND INDUSTRY IS BEGINNING TO SHOW INTEREST, BUT ONLY A SMALL PROPORTION OF CIRM'S ACTIVE THERAPEUTIC PROGRAMS HAVE INDUSTRY PARTNERS, WHICH ARE NECESSARY AND CRITICAL TO ACTUALLY BRINGING THESE PRODUCTS TO COMMERCIALIZATION. AND BRINGING THESE PRODUCTS TO COMMERCIALIZATION IS WHAT WILL BRING THEM TO PATIENTS WHO NEED THE TREATMENTS.

IN ADDITION, IN OUR KIND OF DISCUSSIONS WITH DIFFERENT UNIVERSITIES AND IP HOLDERS FOR STEM CELL TECHNOLOGIES, IT'S CLEAR THAT MANY OF THE IP OR THE INTELLECTUAL PROPERTY OR TECHNOLOGIES THAT HAVE BEEN DEVELOPED ARE NOT REALLY MAKING IT TO THE POINT WHERE THEY'RE BEING ACTIVELY MARKETED. OUT OF THE 3400 TECHNOLOGIES CURRENTLY BEING MARKETED BY THE UC SYSTEM, AND WE GOT THIS FROM AN INFORMAL DISCUSSION WITH THE UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT, ONLY 74 PROGRAMS ARE STEM CELL PROGRAMS THAT ARE EVEN BEING MARKETED.

IN DISCUSSIONS WITH THESE TECH TRANSFER OFFICES, IT'S CLEAR THAT PARTIALLY THERE IS JUST -- THERE'S JUST A VARIETY OF FORCES IN PLACE. THEY'RE VERY INTERESTED IN BEING ABLE TO BRING THESE TECHNOLOGIES SO THAT THEY CAN BE PARTNERED, BUT THEY HAVE A HUGE NUMBER OF TECHNOLOGIES TO BRING FORWARD. STEM CELL TECHNOLOGIES SPECIFICALLY ARE MUCH MORE DIFFERENT THAN OTHER TECHNOLOGIES THAT THEY MAY BE MORE CONVERSANT IN.

AND SO WE DO BELIEVE THAT AS PART OF OUR MISSION WE NEED TO OFFER ASSISTANCE SO THAT THESE TECHNOLOGIES CAN MAKE IT OUT AND HAVE A CHANCE AT BEING PARTNERED AND MAKING IT TO COMMERCIALIZATION.

THEREFORE, THE ACCELERATING THERAPIES FOR PUBLIC/PRIVATE PARTNERSHIP OR THE APT3 CONCEPT IS BEING BROUGHT FORTH FOR YOUR CONSIDERATION. THE IDEA BEHIND THE APT3 INITIATIVE IS TO ENGAGE INDUSTRY SO THAT THEY WILL PULL SO THAT THERE IS A CREATION OF PULL FOR THESE TECHNOLOGIES BY CREATING AN OPPORTUNITY TO AGGREGATE CIRM'S MOST PROMISING TECHNOLOGIES, OFFERING MULTIPLE SHOTS ON GOAL, AND OFFERING A WAY TO DERISK EARLY INVESTMENT INTO WHAT'S CONSIDERED HIGH RISK, BUT HIGH REWARD PROJECTS.

BY DOING SO, BY AGGREGATION IN ADDITION TO

DERISKING, IT DOES INCREASE THE PROBABILITY OF SUCCESS WITH JUST INCREASING THE DENOMINATOR OF ONE OR MORE OF THESE PROGRAMS WITHIN A GIVEN TIME MAKING IT THROUGH TO THE COMMERCIALIZATION PATH. AND, THUS, WE BELIEVE THAT THIS WOULD MAKE IT AND WE DO HAVE REASON TO BELIEVE THAT THIS WOULD MAKE IT MORE APPEALING AND ATTRACTIVE TO INDUSTRY INVESTORS.

IN ADDITION TO CREATING AN OPPORTUNITY TO AGGREGATE CIRM'S MOST PROMISING TECHNOLOGIES, WE PROPOSE THAT CIRM WOULD LEVERAGE ITS ADMINISTRATIVE AND REVIEW INFRASTRUCTURE AND ITS EXTERNAL TEAM OF ADVISORS AND SUBJECT MATTER EXPERTS TO PROMOTE ACCESS BY BEING ABLE TO PROVIDE INSIGHT INTO THESE PROGRAMS SO THAT THE SUCCESSFUL AWARDEE FOR APT3 WOULD HAVE PREVETTED, PREREVIEWED PROGRAMS FOR THEM TO CHOOSE FROM FOR IN-LICENSING FOR ONWARD DEVELOPMENT AND COMMERCIALIZATION.

IN ADDITION, CIRM WOULD FUND THE DEVELOPMENT OF THESE IN-LICENSE TECHNOLOGIES, THEREFORE, SHARING NOT ONLY IN THE RISK, BUT SHARING IN THE COST OF DEVELOPING THESE THERAPIES.

TO JUST GO AND DESCRIBE THIS A LITTLE BIT MORE, THE CONCEPT IS AS FOLLOWS: THE PRIVATE PARTNER, WHICH WOULD BE THE SUCCESSFUL AWARDEE FOR THE APT3 RFA, WOULD IN-LICENSE, DEVELOP, AND DRIVE

TOWARD COMMERCIALIZATION AN AGGREGATED PORTFOLIO OF NONPARTNERED CIRM PROJECTS. AND WHAT WE ENVISION IN THE RFA IS THAT THIS PRIVATE PARTNER WOULD PROPOSE THEIR SCHEME FOR AGGREGATION, WOULD THERE BE DISEASE FOCUS OR CLASS SPECIFICS; FOR INSTANCE, NEURO OR CARDIOVASCULAR OR ORPHAN DISEASES, MAKE A CASE FOR WHAT THEY WOULD DO IN TERMS OF THEIR BUSINESS PLAN FOR BRINGING THESE PROJECTS FORWARD, AND MAKE A CASE FOR WHY THAT MANAGEMENT TEAM WOULD BE ABLE TO SUCCESSFULLY DO SO.

CIRM, AS I MENTIONED JUST A LITTLE WHILE AGO, WOULD ENABLE THE IDENTIFICATION AND ASSEMBLY OF THE MOST PROMISING TECHNOLOGIES, AGAIN, LEVERAGING ITS REVIEW AND INFRASTRUCTURE TO DO SO, AND WOULD FUND THE CONTINUED DEVELOPMENT OF THESE PROJECTS. BY BEING ABLE TO PROVIDE THIS TYPE OF PROGRAM, OUR BROAD GOAL IS TO GET THE CIRM-FUNDED THERAPIES THROUGH TO PATIENTS WITH UNMET MEDICAL NEEDS BY INCENTIVIZING INDUSTRY PARTNERS TO COME IN AND, USING THEIR EXPERTISE AND THEIR KNOW-HOW, TO BRING IT TO COMMERCIALIZATION FOR THESE PATIENTS.

THE INTENDED OUTCOMES AND THE BENEFITS AND INCENTIVES TO THE VARIOUS STAKEHOLDERS ARE LISTED. SO FOR RESEARCHERS, FOR THOSE WHO HOLD THE IP, WHO HAVE THE DEVELOPMENT CANDIDATES, THIS INITIATIVE

OFFERS CONTINUED FUNDING TO THEM FOR ADVANCEMENT OF THEIR CIRM PROJECT BEYOND WHAT'S ALREADY FUNDED. SO, FOR INSTANCE, IF A CIRM AWARDEE IS CURRENTLY FUNDED TO TAKE THEIR DEVELOPMENT CANDIDATE THROUGH PHASE I TRIALS, FOR INSTANCE, AND THIS IS CONSIDERED A PROMISING PROGRAM AND CIRM AGREES THAT IT SHOULD BE BROUGHT ON AND DEVELOPED FURTHER BY THIS MANAGEMENT TEAM, THE PROGRAM WOULD THEN GO ON TO BE IN-LICENSED BY THIS AWARDEE, THE PRIVATE PARTNER, AND CIRM WOULD CONTINUE TO FUND THAT PROGRAM THROUGH THE NEXT STAGES OF DEVELOPMENT THAT WOULD BE OPERATIONALIZED AND EXECUTED BY THIS MANAGEMENT TEAM.

FOR THE UNIVERSITIES, THE ADVANTAGE OF THIS PROGRAM IS THAT IT WOULD ACTUALLY HELP THEM ALONG AND BOLSTER WHAT THEY CAN ACTUALLY DO THEMSELVES IN TERMS OF OUT-LICENSING THESE TECHNOLOGIES. AND BY DOING SO, THEY WOULD HAVE A GREATER OPPORTUNITY TO ACHIEVE A FINANCIAL RETURN DUE TO AGGREGATION OF RISK BECAUSE NOT ONLY WOULD THEIR TECHNOLOGIES BE GOING INTO THIS ENTITY, BUT OTHER INTELLECTUAL PROPERTY OR DEVELOPMENT CANDIDATE PROJECTS WOULD BE GOING IN FROM OTHER UNIVERSITIES. AND IN THIS AGGREGATED FORM, IF THERE IS A VALUE CREATION, THERE'S AN OPPORTUNITY FOR RETURN BACK TO

THEM EVEN IF IT'S NOT NECESSARILY THEIR PROGRAM THAT HAD SUCCEEDED.

AND FOR THE CITIZENS OF CALIFORNIA, THIS WOULD CREATE AN OPPORTUNITY TO GROW A THERAPEUTIC POWERHOUSE THAT INCREASES THE LIKELIHOOD OF COMMERCIALIZATION OF STEM CELL TREATMENTS. AND THIS, AGAIN, IS IN KEEPING WITH THE ORIGINAL MISSION OF CIRM AND ITS FORMATION.

THE PRIVATE PARTNER OR THE APT3 AWARDEE, AND, AGAIN, WE'VE HAD DISCUSSIONS WITH POTENTIAL APPLICANTS FROM VARIOUS SECTORS, FROM PHARMA, BIOTECH, SERIAL ENTREPRENEURS, VENTURE CAPITAL FIRMS, AND THERE IS INTEREST IN THIS TYPE OF MODEL FOR THOSE WHO REALLY HAVE AN INTEREST IN GOING INTO THE REGENERATIVE MEDICINE SPACE, BUT THIS WOULD BE INCENTIVIZING THEM BECAUSE IT WOULD DERISK THE PROPOSITION AS WELL AS OFFER ACCESS TO THIS RICH PORTFOLIO OF STEM CELL PROJECTS.

BUT THE PARTNER COULD ACTUALLY BE AN ESTABLISHED COMPANY THAT DECIDES TO REPURPOSE OR REDIRECT ITS EFFORT TOWARD THIS INITIATIVE, A SPIN-OFF OF THE LARGE COMPANY OR A SMALLER COMPANY OR A NEW COMPANY ALTOGETHER WHICH WOULD BE FORMED BECAUSE OF THIS INITIATIVE. AND THE REQUIREMENTS FOR THE AWARDEE WOULD BE THAT THEY WOULD NEED TO PUT

FORTH A VERY STRONG AND EXCEPTIONAL BUSINESS PLAN THAT DESCRIBES THE MOST PROMISING TECHNOLOGY PORTFOLIO THEY WOULD IN-LICENSE AND THE BUSINESS PLAN FOR HOW THEY WOULD DEVELOP THESE PROJECTS, EVEN FINANCING-TYPE SCHEMES, ETC., THOSE WOULD BE WHAT THEY WOULD BE JUDGED ON. AND THEY WOULD ALSO BE JUDGED ON THEIR TRACK RECORD AND THE STRENGTH OF THEIR MANAGEMENT TEAM AS WELL AS THEIR PROPOSED BOARD OF DIRECTORS. THEY WOULD BE REQUIRED UP FRONT TO COMMIT A SIGNIFICANT INVESTMENT CAPITAL THAT MATCHES CIRM'S COMMITMENT SO THAT THEY CAN EXECUTE ON THIS BUSINESS PLAN AND CARRY OUT THE ACTIVITIES OF THIS INITIATIVE.

AND THEY WOULD HAVE ACCESS TO CIRM FUNDING COMMITMENT, AND THIS WOULD BE IN THE FORM A GRANT OR A LOAN. AND FOR THE PURPOSES OF TODAY, THE CIRM TEAM DOES NOT CURRENTLY HAVE A RECOMMENDATION FOR WHAT THE STRUCTURE OR THE NATURE OF THE TERMS OF THAT AWARD WOULD BE. WE ARE CONTINUING TO DO DUE DILIGENCE AND SEEKING EXTERNAL ADVICE AND MODELING. AND WE, AS I'LL MENTION LATER, WE PROPOSE TO BRING THIS BACK TO THE SCIENCE SUBCOMMITTEE AND THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE IN THE NEAR FUTURE.

THE TERMS OF THE AWARD WOULD BE THE

FOLLOWING: WE WOULD REQUIRE THAT THE AWARDEE WOULD INVEST $75 MILLION UP FRONT, ASSUMING THE CIRM AWARD IS UP TO $75 MILLION IN FUNDING OVER A FIVE-YEAR PERIOD, TO EXECUTE ON THE BUSINESS PLAN AND TO DRIVE IN-LICENSE CIRM PROJECTS TO THE NEXT STAGES OF DEVELOPMENT AND TOWARD COMMERCIALIZATION. AND THEY WOULD BE SUBJECT TO THE PRICING AND ACCESS PROVISIONS COMMON ON OTHER CIRM AWARDS AS WELL AS MARCH-IN RIGHTS IN CASES WHERE THEY IN-LICENSED THE PROGRAM AND CHOSE TO EITHER SHELVE IT OR DECIDED NOT TO FURTHER DEVELOP IT SO THAT CIRM WOULD ACTUALLY DELEGATE THAT MARCH-IN RIGHT -- I DON'T KNOW WHAT THE TERMINOLOGY IS -- BY OFFERING RIGHT OF FIRST REFUSAL TO THE ORIGINAL INSTITUTION THAT HELD THAT IP.

SO THE MOTION IS STATED IN THIS SLIDE.

CHAIRMAN SHEEHY: SO, AGAIN, THIS MAY BE WHERE WE ACTUALLY START MAKING MOTIONS, BUT FOR NOW WE'LL HOLD OFF, I THINK, FOR DISCUSSION.

THE MOTION THAT'S PROPOSED IS TO RECOMMEND BOARD APPROVAL OF THE CONCEPT PLAN FOR APT3 WITH A BUDGET AUTHORIZATION OF UP TO 75 MILLION TO FUND ONE OR MORE AWARDS OVER FIVE YEARS AND DELEGATION OF AUTHORITY TO THE SCIENCE AND THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEES TO APPROVE THE

AWARD TERMS AT A JOINT MEETING.

SO I WANT TO ASK A COUPLE OF QUESTIONS MYSELF JUST FOR CLARITY BEFORE WE START TAKING OTHER BOARD MEMBER'S QUESTIONS. SO WHAT IS EXPLICITLY CONTEMPLATED IS THE ESTABLISHMENT OF A NEW ENTITY IN WHICH CIRM WOULD BE A STAKEHOLDER; IS THAT CORRECT?

DR. MILAN: YES, THAT'S CORRECT.

CHAIRMAN SHEEHY: SO EVEN IF IT WAS AN ESTABLISHED COMPANY, THEY WOULD PUT THEIR MONEY INTO SOMETHING THAT WOULD BE NEW AND SEPARATE SO WE COULD TRACK WHATEVER HAPPENED WITH IT?

DR. MILLS: THAT WOULD BE A REQUIREMENT.

CHAIRMAN SHEEHY: ALL RIGHT. SO THE SECOND QUESTION IS WE'RE LEAVING THE FINANCING DOWN THE ROAD. WE'RE BASICALLY OFFERING A LINE OF CREDIT TO THIS NEW ENTITY THEN. OUR 75 MILLION, THEY WOULD BE ABLE TO DRAW DOWN AS NEEDED FOR FURTHER DEVELOPMENT OF THE PROJECT. SO WE'VE IDENTIFIED THAT THEY CAN PUT INTO THIS ENTITY, RIGHT?

DR. MILAN: RIGHT. AND JUSTIFIABLE COSTS. THE FUNDS WOULD BE USED TO DEVELOP THE IN-LICENSED CIRM TECHNOLOGIES.

CHAIRMAN SHEEHY: AND THEN JUST TO WALK THROUGH THE PROCESS. SO WE'LL DO AN RFA, PEOPLE WOULD COME IN. THOSE PROPOSALS WOULD BE EVALUATED

BY THE GRANTS WORKING GROUP AND A PARTNER, WHETHER IT'S AN INDIVIDUAL OR A COMPANY OR A GROUP OF INVESTORS OR WHAT HAVE YOU, TO SET UP THIS NEW ENTITY WOULD BE IDENTIFIED. AND THEN I JUST WANT TO BE CLEAR. SO THEY WOULD THEN BE LOOKING ACROSS OUR PORTFOLIO AND AT THAT SAME MEETING OR IS THERE CONTEMPLATED -- THIS IS A TWO-STAGE PROCESS.

DR. MILLS: TWO-STAGE OR PRACTICALLY MAYBE MORE. SO THE FIRST THING THE GWG WOULD DO WOULD PICK WHICH APPLICATION AND WHICH PLAN TEAM INVESTMENT CAPITAL, THE WHOLE THING WAS MOST MERITORIOUS, AND THEY WOULD LAY OUT A STRATEGY FOR WHAT THEY WANTED TO DO.

THE NEXT THING THAT WE ENVISION WITH THIS IS THAT THAT GROUP WOULD THEN IDENTIFY THE SPECIFIC PROGRAMS THAT THEY WANT TO GO AFTER FOR IN-LICENSING. NOW, THEY MAY DO THAT IN ONE BIG BASKET, AND THEY MAY SAY HERE ARE THESE 12 THINGS THAT WE WANT TO IN-LICENSE, IN WHICH CASE THE GWG WOULD REVIEW THEM AS CURRENT AS OF THAT DAY AND SAY, YES, RIGHT NOW, KNOWING WHAT WE KNOW, NOT HISTORICALLY WHAT WE USED TO KNOW, BUT WHAT WE KNOW NOW TODAY ABOUT THOSE PROGRAMS, WE WOULD COMMIT TO FUNDING THOSE PROGRAMS AGAIN. WE WOULD REUP.

MORE LIKELY, THOUGH, THEY'RE GOING TO SAY

FOR SURE WE WANT THESE THREE AND WE'RE WORKING ON THESE OTHERS. AND SO I COULD IMAGINE WE WOULD BE USING THE GWG ON A ROLLING BASIS UNTIL THEIR BASKET WAS COMPLETE.

CHAIRMAN SHEEHY: OKAY. AND THEN WOULD THIS BE -- IF WE HAVE EXISTING COMPANIES THAT ARE GRANTEES, WOULD THEY BE PART OF THIS MIX TOO POTENTIALLY? LET'S SAY SOME OF OUR GRANTEES, SMALL BIOTECHS OR INVESTIGATOR, HAS CREATED A SMALL BIOTECH.

DR. MILAN: IF THEY COULD PUT TOGETHER A STRONG PLAN --

CHAIRMAN SHEEHY: I MEAN WOULD THEY BE POTENTIALLY ONE OF THE PROJECTS?

DR. MILAN: POTENTIALLY. SO --

CHAIRMAN SHEEHY: AS YOU SAY, THEY COULD BE A LEAD TOO ON THIS POTENTIALLY.

DR. MILAN: THEY COULD BE A LEAD. WE INITIALLY HAD THOUGHT THAT JUST UNPARTNERED PROGRAMS WOULD BE COMING IN. IT'S ALSO POSSIBLE THAT THERE ARE SOME PROGRAMS THAT ARE PARTNERED TO AN EXTENT THAT STILL WOULD BE ATTRACTED TO ENTERING INTO BEING IN-LICENSED BY THIS ENTITY.

CHAIRMAN SHEEHY: SO I THINK THE LAST QUESTION FOR ME, AT LEAST FOR NOW, SO WE ANTICIPATE

WITHIN THE FIVE YEARS OF THE AWARD A LIQUIDITY EVENT. THAT IS OUR HOPE AND OUR EXPECTATION. EVERYTHING COULD GO BUST. SO THAT LIQUIDITY EVENT WOULD OFFER POTENTIALLY THE OPPORTUNITY FOR RECOVERY OR EVEN MULTIPLE RECOVERY OF OUR INITIAL INVESTMENT. IS THAT HOW THE PLAN IS ENVISIONED?

DR. MILAN: YES, THAT'S ENVISIONED. WHAT WE ARE DOING RIGHT NOW IS WORKING WITH SOME EXTERNAL ADVISORS TO MODEL THIS OUT IN TERMS OF DIFFERENT TYPES OF FUNDING AND LOAN STRUCTURES.

CHAIRMAN SHEEHY: GREAT. SO OTHER QUESTIONS? DR. STEWARD.

DR. STEWARD: SO AS AN ACADEMIC SCIENTIST, I HAVE ABSOLUTELY NO EXPERTISE IN ANY OF THIS, BUT IT SEEMS TO ME JUST TO BE AN INCREDIBLY CREATIVE WAY TO SOLVE SOME OF THE PROBLEMS THAT CIRM HAS SEEN COME INTO EFFECT AS THINGS GO FORWARD. CONGRATULATIONS ON REALLY A LOT OF HARD WORK ON THIS. I REALLY THINK IT'S VERY INTERESTING.

ONE QUESTION THAT I HAD WAS REALLY JUST IN TERMS OF THE NUMBERS HERE. SO IF WE'RE TALKING ABOUT FUNDING ONE THING AT ROUGHLY 75 MILLION AND WE HAVE AN APPROVED BUDGET AUTHORIZATION OF UP TO 75 MILLION, WE'RE OBVIOUSLY TALKING ABOUT ONE THING. AND I JUST KIND OF WAS INTERESTED IN THE THINKING

ABOUT THAT. ARE YOU THINKING THAT THERE REALLY IS LIKELY ONLY TO BE ONE COMPETITIVE PROGRAM, OR WOULD THERE -- I REALIZE THAT THE ICOC CAN ALWAYS BUDGET MORE, BUT I'M JUST CURIOUS ABOUT YOUR THINKING.

DR. MILLS: SO THE THOUGHT ON THIS IS WHAT WE DIDN'T WANT TO DO IS BE OVERLY PRESCRIPTIVE ON PEOPLE'S VIEWS OF WHAT SYNERGY LOOKS LIKE IN BUNDLING THESE PROGRAMS TOGETHER. AND SO TO SORT OF TAKE YOU THROUGH THE EVOLUTION OF THIS, WE ORIGINALLY SAID WHAT IF WE COULD DO THIS PROGRAM AND GET SOMEBODY TO JUST IN-LICENSE FLAT OUT ALL OF THEM? LET'S SAY THERE WERE 30 THAT WERE WORTHY OF IN-LICENSING AND JUST CREATE THIS MASSIVE PIPELINE. AND THAT WAS WHAT WE WERE GOING TO SORT OF DRIVE TO INCENTIVIZE TO DO. ALMOST YOU HAVE TO DO IT IN ORDER TO BE RESPONSIVE.

AS WE VETTED THE PROGRAM THROUGH VARIOUS PEOPLE, WE JUST GET THIS OVERWHELMING REACTION OF THAT'S CRAZY, THERE WILL BE A LACK OF FOCUS, IT WILL BE A MESS, NOBODY IS GOING TO WANT TO DO IT. AND THAT'S WHERE WE BACKED OFF TO LET THEM BASICALLY DRAW THE CIRCLE AROUND THE PROGRAMS THAT THEY WANT TO INCLUDE AND DESCRIBE THEIR STRATEGY ON WHY THEY THINK THEY CAN DO THE BEST WITH THAT.

NOW, SINCE WE DON'T KNOW WHETHER THE

WINNING APPLICANT FOR THAT DRAWS THEIR CIRCLE AROUND TWO THINGS OR 30 THINGS, WE DON'T KNOW WHETHER OR NOT ULTIMATELY THIS IS ONE AWARD OR COULD END UP BEING MULTIPLE AWARDS. I THINK THE CONCEPT IS IT COULD BE MULTIPLE AWARDS. I THINK IT WOULD HAVE TO BE IN SERIAL RFA'S BECAUSE WE WOULD HAVE TO MAKE SURE -- WE WOULD HAVE TO KNOW WHICH ONES WERE CARVED OUT BY THE FIRST WINNER. BUT THE IDEA IS TO NOT BE PRESCRIPTIVE. SINCE WE'RE NOT PRESCRIPTIVE ON WHETHER IT'S TWO OR 20 THINGS YOU PULL TOGETHER, THEN, THEREFORE, WE CAN'T BE OVERLY DETAILED ON WHETHER OR NOT IT'S ONE OR FIVE OF THESE AWARDS WE ULTIMATELY HAVE.

I WOULD SAY IF YOU CIRCLED TWO THINGS AND SAID WE WANT TO TAKE THOSE TWO THINGS TOGETHER, I WOULD THINK WE COULD ARGUE THAT THAT'S NOT MERITORIOUS OF THE FULL 75 IN A LINE OF CREDIT. WE'D WANT TO SAVE SOME FOR SUBSEQUENT AWARDS.

DR. STEWARD: AND JUST TO SORT OF UNPACK THAT, ARE YOU THINKING OF DIFFERENT LEVELS OF FUNDING FOR DIFFERENT PACKAGES?

DR. MILLS: AGAIN, THE IDEA IS THAT IT BE -- A KEY COMPONENT TO THIS IS AGGREGATION. SO I ACTUALLY SHOULDN'T HAVE BROUGHT IT UP AS AN EXAMPLE OF A WINNING APPLICANT WITH TWO THINGS BECAUSE

THAT'S -- I WOULD SAY THAT PROBABLY WOULD BE A NONRESPONSIVE APPLICANT. THE IDEA IS TO AGGREGATE THESE THINGS TOGETHER TO INCREASE YOUR LIKELIHOOD OF SUCCESS OF ONE OF THEM AND AGGREGATE THE RISK OUT OF THE REST OF THEM SO THE RETURN FOR THE LICENSING INSTITUTIONS COULD BE HIGH ENOUGH.

IT SHOULD BE SUFFICIENT. THAT 75 ISN'T NEARLY A ONE-TO-ONE MATCH OVER THE LIFE OF IT BECAUSE FOR POTENTIALLY MULTIPLE AWARDS, DEVELOPMENT OF THESE THERAPIES IN LATE STAGE REQUIRES A LOT MORE THAN $150 MILLION OVER A PERIOD OF TIME. HOPEFULLY THERE ONLY WOULD BE ONE.

DR. STEWARD: THANK YOU.

CHAIRMAN SHEEHY: DR. MELMED, DAVID, DO YOU HAVE QUESTIONS, COMMENTS ABOUT THIS PROPOSAL?

DR. HIGGINS: NOTHING FROM ME.

DR. MELMED: NO FURTHER COMMENTS.

CHAIRMAN SHEEHY: OTHER BOARD MEMBERS HERE IN SAN FRANCISCO?

CHAIRMAN THOMAS: MR. SHEEHY, JUST TO REITERATE A POINT, SORT OF A CONSTANT THEME HERE, THIS IDEA FIRST CAME UP PROBABLY 15 MONTHS AGO IN A DISCUSSION THAT RANDY AND I HAD AND HAS SINCE THEN UNDERGONE MASSIVE AMOUNTS OF THOUGHT AND INTERVIEWS WITH STAKEHOLDERS AND TRYING TO FIGURE OUT. THIS

BEING A VERY NOVEL IDEA, WANTED TO MAKE SURE WE GOT THE MOST INFORMED OPINIONS THAT EVERYBODY WOULD HAVE ON THE SUBJECT AS WE TRY TO FORMULATE WHAT THE PROPER FORM FOR THIS IS. SO THIS IS, AGAIN, THE PRODUCT OF A LOT OF THINKING AND CONTINUE TO HAVE MORE THINKING AS WE GO FORWARD AND LOOK FORWARD TO INPUT FROM THE BOARD WHEN WE GET TO THAT, SHOULD THIS BE APPROVED TODAY, TO PASS ALONG TO FURTHER REFINE, BUT WE THINK WHAT WE HAVE HERE IS AN IDEA THAT WILL CREATE SOMETHING THAT'S TRULY INNOVATIVE AND TRULY, AS DR. STEWARD SUGGESTS, WILL HELP DRAW OUR PROJECTS ALONG TOWARDS COMMERCIALIZATION. SO THANK YOU.

CHAIRMAN SHEEHY: SO I HAVE ONE MORE QUESTION. SO WHEN DO WE ANTICIPATE THE SCIENCE AND THE INDUSTRY SUBCOMMITTEE ACTUALLY MEETING TO DISCUSS AND APPROVE THE AWARD TERMS?

MS. BONNEVILLE: WE HAD DISCUSSED JANUARY IF EVERYTHING WAS AVAILABLE BY THEN.

CHAIRMAN SHEEHY: SO I KNOW THAT THERE'S A MEETING OF THE APPLICANT REVIEW SUBCOMMITTEE IN JANUARY. WOULD THAT BE POSSIBLE TO STRETCH TO A FULL BOARD MEETING IF THE TIMELINES -- THE TIMELINES MAY BE TOO AGGRESSIVE, BUT JUST FOR ME PERSONALLY, I THINK THE FINANCIAL PIECE OF THIS MIGHT BE

SOMETHING, IF POSSIBLE, THAT WOULD BE BETTER RECEIVING THE APPROVAL OF THE FULL BOARD. THE DISCUSSION AND KIND OF WORKING THE KINKS OUT, I THINK, SHOULD HAPPEN AT THE SCIENCE AND INDUSTRY SUBCOMMITTEE, BUT TO FULLY VET AND DISCUSS THIS PIECE OF IT, FOR ME PERSONALLY I THINK THERE WOULD BE VALUE HAVING SIGN-OFF OF THE BOARD AS A WHOLE, IF THAT WAS POSSIBLE.

AGAIN, I THINK LIKE MAYBE THE 18TH OR THE 17TH IS WHEN THE APPLICATION REVIEW SUBCOMMITTEE WOULD MEET, AND I KNOW THAT THAT'S INCREDIBLY AGGRESSIVE.

MS. BONNEVILLE: I THINK IF THE DOCUMENTS ARE READY AND IF WE'VE RECEIVED THE FEEDBACK WE NEED, WE CAN WORK TO MAKE THAT HAPPEN. I JUST DON'T KNOW WHAT THAT TIMING IS, SO I WOULD LEAVE IT UP TO MARIA.

CHAIRMAN SHEEHY: MAYBE YOU GUYS CAN LOOK AT THAT. THAT'S A PREFERENCE. IT'S NOT SOMETHING THAT I WOULD THROW MY BODY IN FRONT OF THE BUS ABOUT, BUT I JUST THINK FOR GOOD GOVERNANCE, GIVEN THAT THE TIMES MAY SYNCHRONIZE WITH AN EXISTING MEETING WE'RE EXPECTING MUCH OF THE BOARD TO BE AT, TO GET THAT FINAL APPROVAL FROM THE BOARD AS A WHOLE I WOULD FEEL THAT THAT WOULD BE A BETTER PROCESS.

THE OTHER QUESTION I HAVE IS I THINK MAYBE OUR LEGAL TEAM CAN LOOK AT THE CONFLICTS OF INTEREST ISSUES. I THINK THOSE ARE GOING TO BE KIND OF COMPLICATED BOTH AT THE GRANTS WORKING GROUP AND AT THE BOARD BECAUSE WE MAY HAVE HOW THAT IS IMPACTED BY THE POTENTIAL INCLUSION OF PROJECTS FROM AN INSTITUTION WHO HAS AN AFFILIATION WITH BOARD MEMBERS, HOW THAT IMPACTS THAT ONCE WE GET INTO THE APPROVAL PROCESS. WE SHOULD HAVE THAT THOUGHT THROUGH FAIRLY CAREFULLY IN ADVANCE.

OTHERWISE, THOSE ARE THE EXTENT OF MY QUESTIONS. AND IF NO ONE ELSE HAS ANY OTHER QUESTIONS OR COMMENTS, I'LL -- WHY DON'T WE PERHAPS GET A MOTION AT THIS POINT, AND I CAN READ THE MOTION AND SOMEONE CAN MAKE IT AND SECOND IT.

THE SCIENCE SUBCOMMITTEE RECOMMENDS THE BOARD APPROVAL OF THE CONCEPT PLAN FOR APT3 WITH A BUDGET AUTHORIZATION UP TO 75 MILLION TO FUND ONE OR MORE AWARDS OVER FIVE YEARS AND DELEGATION OF AUTHORITY TO THE SCIENCE AND INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEES TO APPROVE THE AWARD TERMS AT A JOINT MEETING. SO WE HAVE A MAKER?

DR. HIGGINS: SO MOVED.

CHAIRMAN SHEEHY: DAVID IS THE MAKER. SECOND?

CHAIRMAN THOMAS: SECOND.

CHAIRMAN SHEEHY: SECOND FROM CHAIRMAN THOMAS. PUBLIC COMMENT? NO PUBLIC COMMENT. DO WE NEED TO DO A ROLL CALL? YES.

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

CHAIRMAN SHEEHY: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: KRISTINA VUORI.

CHAIRMAN SHEEHY: MOTION PASSES.

SO NOW I THINK WE'LL GO TO THE TRANSLATION CENTER. SINCE WE HAVE A QUORUM, WE'LL DO THE MOTION FOR THE TRANSLATION CENTER. AND THE MOTION IS -- WE'LL DO THE ACCELERATING CENTER SINCE THAT ONE'S UP. THE SCIENCE SUBCOMMITTEE RECOMMENDS BOARD

APPROVAL OF THE CONCEPT PLAN FOR THE CIRM ACCELERATING CENTER WITH A BUDGET AUTHORIZATION OF UP TO 15 MILLION TO FUND A SINGLE AWARD OVER FIVE YEARS. DO I HAVE A MAKER OF THE MOTION?

DR. HIGGINS: SO MOVED.

DR. MELMED: SECOND.

CHAIRMAN SHEEHY: I THINK WE'LL COUNT THAT AS DAVID HIGGINS FOR THE MOTION AND DR. MELMED FOR A SECOND. PUBLIC COMMENT? THEN I THINK WE'LL CALL THE ROLL.

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

CHAIRMAN SHEEHY: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: KRISTINA VUORI.

CHAIRMAN SHEEHY: MOTION CARRIES. THANK YOU.

THE THIRD MOTION IS THE SCIENCE COMMITTEE RECOMMENDS APPROVAL OF THE CONCEPT PLAN FOR THE CIRM TRANSLATING CENTER WITH BUDGET AUTHORIZATION OF UP TO 15 MILLION TO FUND A SINGLE AWARD OVER FIVE YEARS. DO I HAVE A MAKER OF THE MOTION?

DR. HIGGINS: SO MOVED.

CHAIRMAN SHEEHY: SECOND?

DR. STEWARD: SECOND.

CHAIRMAN SHEEHY: DR. STEWARD IS THE SECOND. DO WE HAVE ANY PUBLIC COMMENT? NO PUBLIC COMMENT. CALL THE ROLL PLEASE.

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

CHAIRMAN SHEEHY: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: KRISTINA VUORI.

CHAIRMAN SHEEHY: THE MOTION PASSES. THANK YOU.

ONE LAST MOTION ON AT LEAST THE FIRST PART OF THIS MEETING. WE STILL HAVE TWO OTHER ITEMS, I'LL REMIND PEOPLE. THIS IS A MOTION FOR APPROVAL OF THE STRATEGIC PLAN AS PRESENTED TODAY AND CONTAINED IN THE DOCUMENT THAT IS ONLINE AND AVAILABLE TO US.

MR. TORRES: SO MOVED.

CHAIRMAN SHEEHY: MOVED BY SENATOR TORRES. SECOND?

DR. HIGGINS: ENTHUSIASTIC SECOND.

CHAIRMAN SHEEHY: DAVID HIGGINS IS THE SECOND. PUBLIC COMMENT?

MR. TORRES: YES. I WOULD LIKE TO PROFOUNDLY THANK DR. MILLS, DR. MILAN, AND THE INCREDIBLE STAFF THAT WE'RE PRIVILEGED TO WORK WITH HERE AT CIRM. I AM SO PROUD OF HAVING WORKED HERE AND EVEN MORE SO AFTER REVIEWING THESE DOCUMENTS IN BETWEEN TURKEY LEFTOVERS TO SEE THE HARD WORK THAT WENT INTO ALL OF THESE PRESENTATIONS THAT WE RECEIVED TODAY. AND I JUST THINK THAT THE

CALIFORNIA PUBLIC WOULD BE VERY PROUD OF HOW THEIR TAXPAYER MONEY IS BEING UTILIZED.

CHAIRMAN SHEEHY: HERE. HERE.

(APPLAUSE.)

DR. MILLS: I JUST WANT TO SAY THANK YOU, SENATOR TORRES. I THINK THE SECOND PART OF YOUR COMMENT IS SO TRUE. THE WORK THAT THE CIRM TEAM, THIS TEAM AND THE TEAM BACK AT OAKLAND NOW, PUTS INTO THE JOB THAT THEY DO AND THE SERIOUSNESS AT WHICH THEY HANDLE IT AND THE DEDICATION WHICH THEY HAVE TOWARDS IT, IT'S RIVALED BY NO ONE. FOR ME, WHAT A WONDERFUL OPPORTUNITY IT IS TO GET TO WORK WITH THAT GROUP OF PROFESSIONALS. I JUST THANK YOU FOR RECOGNIZING THAT THEY ARE SPECIAL.

CHAIRMAN SHEEHY: ANY OTHER COMMENT, PUBLIC OR FROM MEMBERS OF THE BOARD? SEEING NONE, MS. BONNEVILLE, IF WE CALL THE ROLL.

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
CHAIRMAN SHEEHY: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: KRISTINA VUORI.
CHAIRMAN SHEEHY: THE MOTION PASSES. THANK YOU.
SO THE NEXT ITEM WE HAVE IS CONSIDERATION OF CHANGES TO THE GRANTS WORKING GROUP BYLAWS, AND MR. HARRISON WILL TAKE US THROUGH THAT.
MR. HARRISON: WE'RE STILL HERE. WE'RE HAVING SOME TECHNICAL DIFFICULTIES, DR. MELMED. IT'S JAMES HARRISON. AND I'D LIKE TO PRESENT TO YOU TODAY SOME PROPOSED AMENDMENTS TO THE GRANTS WORKING GROUP BYLAWS.
AS YOU KNOW, WE HAVE PROMISED TO ALWAYS LOOK FOR OPPORTUNITIES TO REFINE AND IMPROVE OUR POLICIES AND PROCEDURES. AND IN REVIEWING THE GRANTS WORKING GROUP BYLAWS, WE'VE IDENTIFIED THREE SIGNIFICANT CHANGES THAT WE WOULD LIKE TO MAKE BOTH TO IMPROVE AND STRENGTHEN OUR PEER REVIEW AS WELL AS TO RECONCILE THE BYLAWS WITH THE RECENTLY APPROVED CONCEPT PROPOSALS FOR OUR TRANSLATION AND DISCOVERY

PROGRAMS AS WELL AS THE OTHER CIRM 2.0 PROGRAMS THAT YOU CONSIDERED TODAY.

THE FIRST ITEM IN THE BYLAWS WE'D LIKE TO BRING YOUR ATTENTION TO IS A PROVISION PROBABLY NEAR AND DEAR TO SENATOR TORRES' HEART, TERM LIMITS. PROP 71 IMPOSED TERM LIMITS ON MEMBERS OF THE GRANTS WORKING GROUP OF TWO CONSECUTIVE TERMS, BUT IT DID NOT DEFINE WHAT AN APPROPRIATE GAP WAS IN BETWEEN TERMS IN ORDER FOR A MEMBER TO BE ELIGIBLE TO BE REAPPOINTED.

IT FURTHER CONFUSED MATTERS BECAUSE THE SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP, AFTER THE INITIAL TERMS, ARE APPOINTED TO STAGGERED TERMS OF TWO, FOUR, OR SIX YEARS. SO WE DON'T HAVE UNIFORM TERMS.

WHAT WE PROPOSE TO DO IS TO DEFINE AN APPROPRIATE GAP IN BETWEEN A MEMBER WHO HAS SERVED TWO CONSECUTIVE TERMS AND AN OPPORTUNITY TO BE REAPPOINTED AS TWO YEARS. IN OTHER WORDS, IF TWO YEARS HAS PASSED SINCE A MEMBER'S TERM HAS EXPIRED, THE MEMBER WOULD BE ELIGIBLE TO BE REAPPOINTED TO A NEW TERM OR THIRD TERM.

THAT'S THE FIRST PROPOSAL.

THE SECOND PROPOSAL RELATES TO OUR REVIEW OF NONCLINICAL PROGRAM APPLICATIONS. AS YOU ARE ALL

NOW FAMILIAR WITH, UNDER OUR CLINICAL PROGRAMS, THE MEMBERS OF THE GRANTS WORKING GROUP ASSIGN A SCORE OF ONE, TWO, OR THREE. ONE INDICATING THAT THE APPLICATION IS OF EXCEPTIONAL MERIT AND SHOULD BE FUNDED. TWO MEANING THAT THERE IS SOME MERIT TO THE APPLICATION, BUT THAT IT COULD BE IMPROVED AND RESUBMITTED. AND THREE, RECOGNIZING THAT AN APPLICATION IS SUFFICIENTLY FLAWED THAT IT SHOULD NOT BE FUNDED AND SHOULD NOT BE RESUBMITTED IN THE SAME FORM.

FOR PURPOSES OF OUR OTHER 2.0 PROGRAMS, WE'VE CONCLUDED THAT THAT IS NOT THE APPROPRIATE SCORING MECHANISM AND INSTEAD PROPOSE TO REVERT TO OUR OLDER SYSTEM OF SCORING 1 THROUGH 100 IN LIGHT OF BOTH THE VOLUME OF APPLICATIONS WE ANTICIPATE RECEIVING AS WELL AS THE LESS FREQUENT REVIEW CYCLE. WITH CLINICAL PROGRAMS, IT'S A MONTHLY BASIS. WITH DISCOVERY AND TRANSLATION PROGRAMS, BY CONTRAST, IT WILL BE EVERY SIX MONTHS.

SO WHAT WE PROPOSE TO DO IS TO HAVE SCORES OF 1 OR 2. A SCORE OF 1 WOULD BE AN AVERAGE SCORE OF 85 OR ABOVE, SO THAT APPLICATION WOULD BE ASSIGNED TO TIER I, WHICH WOULD MEAN IT'S RECOMMENDED FOR FUNDING. IF AN APPLICATION RECEIVES AN AVERAGE SCORE OF 84 OR BELOW, IT WOULD BE

ASSIGNED TO TIER II, AND TIER II WOULD INDICATE THAT IT'S NOT RECOMMENDED FOR FUNDING AT THIS TIME.

WITH RESPECT TO APPLICATIONS WHERE WE INTEND TO AWARD ONLY ONE AWARD, WE PROPOSE TO RECOGNIZE THAT THE APPLICATION THAT RECEIVES THE HIGHEST AVERAGE SCIENTIFIC SCORE WOULD BE DEEMED TO BE THE APPLICATION THAT GWG RECOMMENDS FOR FUNDING.

THE LAST PROPOSED CHANGE WE WOULD LIKE TO MAKE RELATES TO THE FINAL MOTION THE GWG CONSIDERS AT THE END OF EACH REVIEW. CURRENTLY, AFTER THE GWG HAS COMPLETED ITS REVIEW OF EACH APPLICATION, THE ENTIRE MEMBERSHIP OF THE GWG, INCLUDING THE PATIENT ADVOCATE MEMBERS, CONSIDER A MOTION TO FORWARD THE SLATE OF RECOMMENDATIONS ON TO THE APPLICATION REVIEW SUBCOMMITTEE. EFFECTIVELY THIS MOTION CONFIRMS THAT THOSE SCORES REFLECT THE RECOMMENDATIONS OR RATHER ARE AN ACCURATE REFLECTION OF THE RECOMMENDATIONS MADE BY THE GWG DURING THE REVIEW.

WE PROPOSE TO MODIFY THAT SLIGHTLY IN TWO WAYS. ONE, WE WOULD ASK THE ENTIRE GWG TO CONSIDER WHETHER THERE WAS SUFFICIENT TIME FOR ALL VIEWPOINTS TO BE HEARD DURING THE REVIEW AND ALSO THAT THE REVIEW WAS SCIENTIFICALLY RIGOROUS. WE WOULD THEN REQUEST THAT A SECOND COMPONENT BE ADDED TO THE

MOTION TO BE VOTED ON BY THE PATIENT ADVOCATES, AND THAT WOULD BE TO CONSIDER WHETHER THE REVIEW WAS CONDUCTED IN A FAIR MANNER AND WAS FREE OF UNDUE BIAS.

AND THE REASON FOR THIS LAST PART IS THAT THE PATIENT ADVOCATE MEMBERS OF THE GWG REALLY SERVE AS A BRIDGE BETWEEN THE GWG AND THE BOARD. AS A MATTER OF PRACTICE, WE FREQUENTLY HEAR PATIENT ADVOCATE MEMBERS OF THE GWG CONVEY TO THEIR COLLEAGUES ON THE APPLICATION REVIEW SUBCOMMITTEE HOW RIGOROUS AND FAIR THE REVIEW WAS. SO WE WANTED TO FORMALIZE THAT PRACTICE AND ACTUALLY CONVEY IN A MOTION THAT THE PATIENT ADVOCATE MEMBERS WHO ARE PARTICIPATING IN THE REVIEW BELIEVED THAT IT WAS FAIR AND FREE FROM UNDUE BIAS. SO WE WOULD PROPOSE TO ADD THAT TO THE FINAL MOTION FOR CONSIDERATION BY THE GWG.

THOSE WERE THE THREE SIGNIFICANT CHANGES WE WANTED TO PRESENT TO YOU TODAY. I'D BE HAPPY TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

CHAIRMAN SHEEHY: ANY QUESTIONS?

DR. STEWARD: YEAH. THE TERM LIMIT. SO I'M ASKING THIS BECAUSE, AS WE ALL KNOW, GETTING QUALIFIED REVIEWERS IS CHALLENGING. AND REALLY THERE IS A TRAINING CURVE HERE. IT TAKES A LONG

TIME TO UNDERSTAND CIRM AND WHAT WE'RE TRYING TO DO HERE. THIS IS GOING TO SOUND A LITTLE STRANGE BY COMPARISON TO WHAT I WOULD SAY MAYBE ABOUT THE STATE LEGISLATURE. SORRY, ART. I DON'T MIND HAVING PEOPLE TURN OVER ON THE STATE LEGISLATURE, BUT SOMEHOW LOSING THAT TALENT FOR A TWO-YEAR PERIOD, IT SEEMS A PITY. ONE QUESTION IS WHY TWO YEARS? WHAT'S THE LOGIC BEHIND THAT?

AND THE SECOND QUESTION IS COULD THESE PEOPLE CONTINUE TO SERVE AS SPECIALISTS WHEN NEEDED?

MR. HARRISON: LET ME TAKE YOUR FIRST QUESTION. PROP 71 BY STATUTE IMPOSES A LIMIT OF TWO CONSECUTIVE TERMS FOR THE SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP. WE HAVE CONSTRUED THAT, AS THE ADMINISTRATIVE AGENCY CHARGED WITH ENFORCING THE LAW, TO IMPOSE THE SMALLEST CONCEIVABLE GAP BECAUSE THE SHORTEST TERM TO WHICH A MEMBER WOULD BE ELIGIBLE IS TWO YEARS. SO WE'VE CONSTRUED IT TO REQUIRE ONLY A TWO-YEAR GAP IN BETWEEN THE END OF THE MEMBER'S SECOND CONSECUTIVE TERM AND THE BEGINNING OF A NEW TERM OR ELIGIBILITY FOR APPOINTMENT TO A NEW TERM.

THE OTHER ALTERNATIVES WERE FOUR OR SIX YEARS, AND WE THOUGHT THAT TWO WAS THE APPROPRIATE ONE SINCE, FRANKLY, IT WAS THE SHORTEST AND WE

RECOGNIZE THE NEED TO RETAIN THAT EXPERTISE.

SECONDLY, IN RESPONSE TO YOUR QUESTION, WE COULD HAVE MEMBERS WHO HAVE SERVED TWO CONSECUTIVE TERMS AND ARE NOT ELIGIBLE BECAUSE OF THAT TWO-YEAR TIME PERIOD FOR REAPPOINTMENT, SERVE AS EXPERTS. THEY WOULD OBVIOUSLY NOT BE ELIGIBLE TO SUBMIT A FORMAL SCORE OR VOTE, BUT THEY COULD PROVIDE EXPERT CONSULTATION.

DR. STEWARD: THANK YOU.

CHAIRMAN SHEEHY: OTHER QUESTIONS? ON THE PHONE?

DR. HIGGINS: NOT FROM ME. THIS IS GOOD.

CHAIRMAN SHEEHY: SO COULD WE GET A MOTION TO ADOPT?

MR. TORRES: SO MOVED.

CHAIRMAN SHEEHY: MOVED BY SENATOR TORRES. SECOND?

DR. HIGGINS: I SECOND.

CHAIRMAN SHEEHY: SECOND BY DAVID HIGGINS. PUBLIC COMMENT? NO PUBLIC COMMENT. THEN COULD WE CALL THE ROLL PLEASE.

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO

MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

CHAIRMAN SHEEHY: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: KRISTINA VUORI.

CHAIRMAN SHEEHY: THE MOTION CARRIES.

COULD WE GO TO THE NEXT ITEM ON THE AGENDA, AND I THINK THIS IS THE FINAL ITEM, CONSIDERATION OF INCLUSION IN CURRENT AND FUTURE CIRM GRANT PROPOSALS PAST PERFORMANCE OF CIRM GRANTEE AND REVIEW CRITERIA AND ACCURACY AND COMPLETENESS OF APPLICATION AND ELIGIBILITY CRITERIA. DR. SAMBRANO WILL TAKE US THROUGH THIS.

DR. SAMBRANO: THIS IS GIL SAMBRANO. GOOD AFTERNOON, EVERYONE. SO WE'RE BRINGING FOR YOUR CONSIDERATION A COUPLE OF PROPOSED UPDATES TO THE CIRM 2.0 CONCEPT PLANS. AND THESE UPDATES ARE GLOBAL IN NATURE, MEANING THEY WOULD APPLY TO THE CLINICAL, TRANSLATIONAL, AND DISCOVERY PROGRAMS THAT

HAVE BEEN LAUNCHED, AS WELL AS THOSE THAT ARE STILL TO BE LAUNCHED. AND SO I'LL GO OVER EACH ONE OF THOSE.

THE FIRST ONE IS TO INCLUDE PAST PERFORMANCE AS A CIRM AWARDEE IN THE REVIEW CRITERIA. SO IN THE PAST WE HAVE HAD GRANTS WORKING GROUP MEMBERS, AS AN EXAMPLE, ASK US FOR RELEVANT PROGRESS AND ASSESSMENT OF THAT PROGRESS FOR AN APPLICANT THAT HAS COME TO US FOR A CONTINUATION OF THEIR PROJECT OR ON A RELATED PROJECT. AND WE WANT TO BE ABLE TO PROVIDE A UNIFORM WAY IN WHICH WE CAN PROVIDE THAT FEEDBACK TO THE WORKING GROUP FOR THEIR ASSESSMENT. AND SO THERE IS LANGUAGE IN THE MEMO THAT WE PROVIDE IN WHICH WE INDICATE THAT THE GRANTS WORKING GROUP MAY CONSIDER AN APPLICANT'S PAST PERFORMANCE IN CONNECTION WITH THE RELATED CIRM AWARD AS PART OF ITS REVIEW.

SO THIS WOULD INCLUDE THREE TYPES OF RELATED CIRM AWARD, MEANING WE CAN DEFINE IT AS BEING AN AWARD FOR WHICH THE APPLICANT PI SERVED AS THE PI, CO-PI, OR CO-INVESTIGATOR OF THE PREVIOUS AWARD OR SUBSTANTIALLY PARTICIPATED IN THE CONDUCT OF THAT AWARD.

SECOND, THAT AN AWARD INVOLVING THE SAME RESEARCH PROJECT OR PRODUCT IS BEING PROPOSED; OR,

THREE, FOR AN AWARD THAT INCLUDES OVERLAPPING TEAM MEMBERS. OF COURSE, THE GRANTS WORKING GROUP, DEPENDING ON THE EXTENT OF THE RELATIONSHIP, WOULD TAKE THAT INTO ACCOUNT IN THEIR ASSESSMENT.

THE SECOND ITEM IS INCLUDING ACCURACY AND COMPLETENESS OF THE APPLICATION IN THE ELIGIBILITY CRITERIA FOR AN APPLICATION COMING IN. IN GENERAL, APPLICANTS ARE REQUIRED TO CHECK A BOX AND AFFIRM TO THE ACCURACY AND COMPLETENESS OF THE INFORMATION THAT'S SUBMITTED IN THE APPLICATION. BUT IN ORDER TO ENSURE A MECHANISM OR THAT WE HAVE A MECHANISM IN PLACE TO ADDRESS CONCERNS REGARDING ACCURACY OR COMPLETENESS WHEN THEY COME UP, WE WANT TO PROPOSE THAT THESE BE INCLUDED AS PART OF THE ELIGIBILITY CRITERIA.

SO IF THERE IS ANY DOUBT ABOUT THE ACCURACY OR COMPLETENESS OF THE APPLICATION, AN APPLICANT WILL BE GIVEN THE OPPORTUNITY TO REMEDY THIS. AND IF THEY DO, THEN THEY CAN GO FORWARD ONTO REVIEW. IF THEY DON'T TO CIRM'S SATISFACTION, THEN WE WILL HALT THE REVIEW PROCESS AT THAT POINT FOR THAT APPLICATION, ALTHOUGH THE APPLICANT HAS THE OPPORTUNITY TO APPEAL THAT DECISION, AND THEN THE ELIGIBILITY DETERMINATION CAN THEN BE MADE BY THE GRANTS WORKING GROUP. AND THIS PROCESS MIRRORS WHAT

WE'VE DONE FOR OTHER ELIGIBILITY CRITERIA IN OUR CLINICAL PROGRAMS. SO WE WANTED TO FOLLOW THAT SAME PATH.

AND SO OUR REQUEST TO YOU IS A RECOMMENDATION FOR APPROVAL OF THESE MODIFICATIONS FOR CONCEPT PLANS FOR CIRM 2.0 PROGRAMS.

CHAIRMAN SHEEHY: DR. STEWARD.

DR. STEWARD: SO, GIL, I UNDERSTAND THE RATIONALE FOR THE ACCURACY AND COMPLETENESS, BUT I'M JUST REACTING AND SORT OF THINKING OUT LOUD TO IT HERE. IT REALLY OFFERS APPLICANTS ALMOST AN OPPORTUNITY TO BE INACCURATE AND INCOMPLETE COMING IN KNOWING THAT THERE'RE GOING TO GET A SECOND SHOT AT IT. AT NIH, FOR EXAMPLE, YOU DON'T GET THAT OPPORTUNITY. IF YOUR GRANT PROPOSAL IS NOT IN LINE, NOT ACCURATE, NOT COMPLETE, YOU SUBMIT FOR THE NEXT ROUND, WHATEVER THAT IS. I SAY THOSE THINGS AND WOULD ASK YOU TO REACT TO IT.

DR. SAMBRANO: SO WE ASK AT THE TIME OF APPLICATION FOR APPLICANTS TO SIGN AWAY AND TELL US THAT EVERYTHING IS ACCURATE AND COMPLETE TO THE BEST OF THEIR KNOWLEDGE. SO THEY ARE ATTESTING TO THAT ALREADY. AND THIS ALLOWS US, IF WE NOTICE SOMETHING THAT SEEMS INCONSISTENT, TO BE ABLE TO ACT IN A UNIFORM, CONSISTENT WAY.

SO IT GOES ONE STEP BEYOND THAT AFFIRMATION WHICH ALREADY EXISTS.

DR. MILLS: I THINK TOO, THOUGH, OS, IT'S A WAY OF BUILDING THE APPEAL. WHAT WE WANT TO DO IS WE WANT TO BE ABLE TO PROVIDE INFORMATION TO THE GWG THAT'S COMPLETELY RELEVANT TO THE DECISION THEY'RE MAKING WITHOUT CIRM SORT OF UNILATERALLY MAKING THE CONTENT OF THE INFORMATION AVAILABLE THAT COULD PREJUDICE OR BIAS. SO WE'RE TRYING TO WORK THIS REALLY FINE LINE OF SAYING YOU SHOULD KNOW THIS, BUT DOING IT FAIRLY AND CONSISTENTLY IN A WAY THAT'S APPEALABLE.

I THINK WHAT WE'RE PROPOSING IS, UNLESS YOU JUST FLAT OUT WIN AND WE WERE WRONG, THE GWG IS GOING TO GET THE HISTORY OF YOU TRIED TO SUBMIT SOMETHING THAT WASN'T FAIR AND THIS WAS YOUR RESPONSE TO THAT. AND I THINK THAT KNOWN UP FRONT THAT WE ARE DISCLOSING TO THE GWG BASICALLY EVERYTHING WE KNOW ABOUT YOUR PERFORMANCE AND IF YOU DON'T COME FORWARD AND FAIRLY DESCRIBE THAT, WE'RE GOING TO SHOW THE GWG THAT TOO IS A PRETTY STRONG I WOULDN'T WANT TO HAVE AN APPLICATION WITH I LEFT ALL OF THIS STUFF OUT, BUT HERE'S MY EXPLANATION ATTACHED TO IT. THAT'S KIND OF OUR THOUGHT ON IT. I KNOW WHAT YOU'RE SAYING.

DR. STEWARD: SO LET ME JUST UNPACK ONE EXAMPLE OF WHERE IT MIGHT COME UP. THERE'S A DEADLINE, RIGHT, AND THERE'S INFORMATION THAT IS SUBMITTED WITH THE GRANT AS BACKUP INFORMATION. AND I GUESS WHAT I'M CONCERNED ABOUT IS THAT EFFECTIVELY WHAT YOU'RE DOING IS EXTENDING THE DEADLINE, RIGHT? AND YOU WOULD LIKE EVERYTHING TO BE THERE IN PLACE AT THE TIME THE APPLICATION WAS SUBMITTED. AND IF EVERYBODY HAS THAT SAME OPPORTUNITY TO KIND OF SUBMIT ADDITIONAL INFORMATION, I GUESS MAYBE THAT WOULD BE OKAY. BUT IF SOMEHOW IT WORKS OUT THAT THE PEOPLE WHO WERE THE LEAST COMPLETE ARE THE ONES WHO ACTUALLY GET THE ADDITIONAL TIME, THEN THAT JUST ADDS UNEVENNESS TO THE PLAYING FIELD THAT I'M A LITTLE CONCERNED ABOUT.

LET ME JUST UNPACK ONE PROPOSITION IN THAT REGARD, AND THAT WOULD BE THE OPPORTUNITY TO SUBMIT SOME TYPE OF ADDITIONAL OR SUPPLEMENTARY INFORMATION FOR THE GRANT IF IT MET SPECIFIC GUIDELINES. I THINK YOU GUYS CAN UNPACK WHAT THOSE GUIDELINES ARE BETTER THAN I CAN ON THE FLY HERE. THAT, AGAIN, USED TO BE THE WAY IT WAS WITH NIH. YOU COULD SEND IN SUPPLEMENTAL MATERIAL. IT ISN'T THAT WAY ANYMORE. BUT GIVEN THAT WE DO HAVE LIMITED SUBMISSIONS, IT MIGHT BE MORE FAIR TO MAKE THIS

AVAILABLE TO ALL GRANTEES.

DR. MILLS: NOT TALKING ABOUT, HEY, WE JUST CAME UP WITH SOME NEW DATA. WE WANT TO GET IT IN. WE'RE TALKING ABOUT INFORMATION ASYMMETRY, REALLY, RIGHT? CIRM AND THE APPLICANT KNOW THAT THERE'S DATA THAT THE REST OF THE WORLD DOESN'T KNOW. AND THE APPLICANT IS SELECTIVELY NOT DISCLOSING THAT DATA BECAUSE IT'S NOT FAVORABLE TO THEIR APPLICATION. THAT'S WHAT DRAWS THIS FLAG HERE, THIS FOUL, WHICH IS A CONCERNING THING RIGHT NOW. RIGHT NOW WE DON'T HAVE A MECHANISM. SO WE'RE HOPING THAT BY MAKING IT REALLY CLEAR THAT IF WE SEE AN INFORMATION ASYMMETRY THAT YOU'VE CREATED, WE'RE GOING TO CORRECT IT. WE HOPE THAT JUST KNOWING WE'RE GOING TO DO THAT IS PLENTY OF DETERRENT. DOES THAT HELP?

DR. STEWARD: UNDERSTOOD. AND I GUESS THEN I WOULD ASK WHAT WOULD HAPPEN IF CIRM DIDN'T IDENTIFY SOMETHING AS BEING INCOMPLETE AND THE APPLICANT CAME IN WITH AGAIN, SORT OF LET'S CALL IT, SUPPLEMENTAL MATERIAL AFTER A DEADLINE. WOULD YOU ALLOW THAT OR NOT? HOW WOULD THAT WORK?

DR. SAMBRANO: SO DEPENDING ON THE PROGRAM, WE ALLOW SUPPLEMENTARY MATERIALS TO COME IN. SO THAT'S ALREADY PART IN A SEPARATE ELEMENT

FROM THIS. SO THIS IS REALLY TO CORRECT A PROBLEM THAT WE SEE. SO WE GO THROUGH THE INITIAL WEEK OF ASSESSING ARE THESE APPLICANTS ELIGIBLE OR NOT. AND IF, DUE TO INCOMPLETENESS, WE DETERMINE SOMEBODY IS INELIGIBLE, WE DO WANT TO GIVE THEM THE OPPORTUNITY TO REMEDY THAT RATHER THAN WAIT PERHAPS SIX MONTHS TO THE NEXT OPPORTUNITY.

DR. STEWARD: OKAY. THANK YOU.

CHAIRMAN SHEEHY: DO WE HAVE COMMENTS OR QUESTIONS FROM THE BOARD MEMBERS ON THE PHONE?

DR. HIGGINS: NOT ME.

DR. MELMED: NO.

CHAIRMAN SHEEHY: I ACTUALLY HAD ONE QUESTION ABOUT CONSIDERATION OF PAST PERFORMANCE, AND MAYBE IT'S JUST A CLARIFICATION. SO IF WE HAVE A PRODUCT THAT WE'VE REVIEWED AND WE'VE FUNDED BEFORE, WHAT TYPES OF INFORMATION MIGHT BE MADE AVAILABLE IF THERE'S QUESTIONS, FOR INSTANCE, OR PERHAPS MISCONCEPTIONS OR A LACK OF DEPTH OF UNDERSTANDING ABOUT A PRODUCT THAT WE'RE CURRENTLY DEVELOPING AND THAT COMES OUT IN A REVIEW, DOES THIS ADDRESS THAT? DOES THAT PROVIDE A MECHANISM FOR ADDRESSING THAT?

DR. SAMBRANO: EASIER QUESTION THAT THE GRANTS WORKING GROUP HAS A MISCONCEPTION FOR WHAT

THE PRODUCT IS THAT'S BEING PROPOSED?

CHAIRMAN SHEEHY: ACTUALLY SOME OF ITS PERFORMANCE FEATURES IN, FOR INSTANCE, HUMANS.

DR. SAMBRANO: SURE. SO WHAT WE WANT TO PROVIDE IS, FOR EXAMPLE, THE LATEST PROGRESS REPORT THAT MAY BE AVAILABLE, BUT ALSO A SUMMARY OF THE PROJECT AS IT CURRENTLY STANDS. SO IT IS WHAT THE MILESTONES THAT WERE PROPOSED AND AGREED TO AND WHAT THE STATUS OF ACHIEVING THOSE MILESTONES ARE AT THE CURRENT TIME. SO THAT'S AN EXAMPLE OF WHAT WE WOULD PROVIDE TO THE WORKING GROUP IN THE SAME WAY, THE SAME FASHION FOR ANY APPLICANT THAT COMES IN THAT MEETS THESE CRITERIA.

CHAIRMAN SHEEHY: IS THERE ANY WAY TO INTRODUCE INFORMATION ABOUT THE PRODUCT'S PERFORMANCE -- IF THE GRANTS WORKING GROUP, IF A MEMBER OF THE GRANTS WORKING GROUP IN EVALUATING A PRODUCT COULD MAKE ASSUMPTIONS OR LACK INFORMATION ABOUT THE PRODUCT, THAT THE APPLICANT MAY ASSUME THAT CIRM IS ALREADY WELL INFORMED ON CERTAIN CHARACTERISTICS OF THE PRODUCT, HAVING BEEN DEVELOPING THE PRODUCT IN ITS PIPELINE, THEN YOU HAVE THIS ASYMMETRY OF INFORMATION. AND THAT ASYMMETRY OF INFORMATION THEN SKEWS THE REVIEW AND MAKES IT A LESS VALID AND VALUABLE REVIEW.

DR. SAMBRANO: SO WE WANT TO PROVIDE INFORMATION THAT INCLUDES CIRM'S TEAM ASSESSMENT OF THE PROGRESS. SO IF IT INCLUDES THEIR PROGRESS ALONG ACHIEVING A SUCCESSFUL PRODUCT, THEN THAT WOULD BE INCLUDED WITHIN THE MATERIALS. SO IT'S TRYING TO PROVIDE SOMETHING -- I THINK YOUR QUESTION IS IF THE APPLICATION PURPORTS INFORMATION THAT DIFFERS FROM CIRM'S ASSESSMENT, WOULD THAT COME TO LIGHT BY PROVIDING INFORMATION IN CIRM'S ASSESSMENT.

CHAIRMAN SHEEHY: I THINK YOU'RE CASTING THE NET A LITTLE NARROWLY. WHAT I'M THINKING ABOUT IS PRODUCTS BEING DEVELOPED, THERE'S INFORMATION ABOUT CHARACTERISTICS OF THE PRODUCT; I.E., HOW IT BEHAVES IN HUMAN TRIALS. ANOTHER REVIEWER LOOKING AT THAT PRODUCT IN A DIFFERENT SETTING, BUT THE SAME PRODUCT, MAY MAKE ASSUMPTIONS ABOUT PERFORMANCE IN HUMANS, BUT THEY HAVEN'T SEEN WHAT WE KNOW ABOUT PERFORMANCE IN HUMANS OF THIS PRODUCT. SO THEY MAY MAKE STATEMENTS ABOUT PERFORMANCE OF THIS PRODUCT IN HUMANS THAT ACTUALLY ARE NOT SYMMETRICAL TO OUR OWN EXPERIENCE WITH THE DEVELOPMENT OF THIS PRODUCT.

SO THAT'S MY ARGUMENT. MY ARGUMENT WOULD BE FOR THE FULLEST USE OF INFORMATION THAT WE HAVE WITHIN THE CIRM KNOWLEDGE BASE IN ORDER TO GET THE BEST OUTCOMES WHEN WE GO THROUGH THE PROCESS OF

REVIEW.

DR. MILLS: SO YOU'RE SAYING A REVIEWER HAS AN ASSUMPTION ABOUT THE PRODUCT BASED ON THE LAST PUBLIC STATEMENT MADE BY THE APPLICANT, BUT CIRM KNOWS SINCE THAT TIME THERE'S -- I'M GOING TO USE A SPECIFIC EXAMPLE -- THERE'S 20 MORE PATIENTS THAT HAVE BEEN TREATED SINCE THE FIRST FIVE, AND THAT DATA FROM THOSE 20 IS DIFFERENT THAN THE DATA PUT OUT FROM THE FIRST FIVE?

CHAIRMAN SHEEHY: MORE IN LIGHT IS THAT THERE MIGHT BE KEY PERFORMANCE BARRIERS THAT WERE ADDRESSED IN PRIOR EXPERIENCE WITH THE PRODUCT POTENTIALLY OVERCOME, BUT STILL A FEATURE THAT ANYONE WOULD NATURALLY ASK ABOUT A PRODUCT. IF THEY DON'T HAVE INFORMATION ABOUT HOW THAT PRODUCT ACTUALLY INTERACTED IN A HUMAN BEING, AND THE GRANTEE WOULD ASSUME WE ALREADY KNEW THAT, THEY MAY BE LIGHT ON PROVIDING THAT INFORMATION OR INCOMPLETE IN PROVIDING THAT INFORMATION KNOWING THAT CIRM ALREADY KNOWS THAT CERTAIN PERFORMANCE FEATURES OF THIS PRODUCT HAVE BEEN ACHIEVED.

SO YOU COULD END UP IN A SCENARIO WHERE A REVIEWER ASSUMES THAT THIS QUESTION IS STILL UNANSWERED AND/OR QUESTIONS, YET WE KNOW WE HAVE AN ANSWER FOR THAT QUESTION. EITHER POSITIVE OR

NEGATIVE WE MAY ALREADY KNOW THAT, AND THE GRANTEE IS ASSUMING THAT WE KNOW THAT AND IS NOT REALLY SPENDING A LOT OF TIME IN THE DISCUSSION OF THE APPLICATION. AND I FEEL LIKE THAT THERE SHOULD BE FULL ACCESS TO INFORMATION ABOUT A PRODUCT THAT WE'VE BEEN DEVELOPING, BOTH GOOD AND BAD, MADE AVAILABLE TO THE WORKING GROUP, IF NOT IN ADVANCE, AT LEAST SOMETHING WE CAN QUERY IN THE CONTEXT OF A REVIEW.

DR. SAMBRANO: OUR GOAL IS TO PROVIDE AS MUCH CLARITY AS WE CAN IN THE REVIEW PROCESS. SO IF THERE IS AN OUTSTANDING QUESTION THAT COMES UP AND WE ALREADY HAVE THIS IN PLACE, REVIEWERS ARE FREE TO ASK US QUESTIONS AND FOR THE APPLICANT TO PROVIDE A RESPONSE. FOR EXAMPLE, IF THEY FEEL SOMETHING IS NOT ADDRESSED COMPLETELY OR CONSISTENTLY ENOUGH, THEY CAN DO THAT. IF THERE IS AN ELEMENT THAT WE THINK IS RELEVANT TO THE PREVIOUS EXPERIENCE WITH THE PROPOSED PRODUCT THAT WE KNOW ABOUT, THERE'S AN OPPORTUNITY TO INCLUDE IT IN THE MATERIALS THAT WE PROVIDE TO THEM.

SO WE WANT TO PROVIDE WHATEVER INFORMATION MAKES IT CLEAR, BUT WE ALSO WANT TO GIVE THE APPLICANT AN OPPORTUNITY IF IT'S A QUESTION THAT'S TO THEM AS PART OF A DIFFERENT PROCESS THAT WE HAVE

ALREADY IN PLACE. THIS ONE IS FOCUSED SIMPLY ON MAKING SURE THAT WE PROVIDE CONSISTENT INFORMATION FROM PREVIOUS PROJECTS THAT WE HAVE AND WE PROVIDE THAT INFORMATION IN A UNIFORM WAY.

DR. MILLS: I WANT JAMES TO THINK ABOUT WHETHER HE WANTS TO CHIME IN HERE TOO BECAUSE ONE OF THE THINGS WE'RE DOING AT CIRM IS CHANGING TO BE A MORE PROACTIVE AGENCY. AND SO IN DOING THAT, THE MORE PROACTIVE WE BECOME, WE WANT TO MAKE SURE WE GET THE BEST THINGS IN AND WE'RE GOING TO MAKE SURE EVERYONE KNOWS ABOUT CIRM. IN MY MIND THE MORE STRINGENT WE NEED TO BE THAT THE REVIEW IS DONE IN THE MOST OBJECTIVE, UNBIASED FASHION POSSIBLE. AND SO THE MORE PROACTIVE WE BECOME ON THE THERAPEUTIC SIDE, THE MORE WALLED OFF REVIEW HAS TO BE.

SO THE THING WE'RE TRYING TO BALANCE WITH HERE'S ALL OF THIS INFORMATION IS WE'RE FINE GIVING ALL OF THE INFORMATION TO THE GWG THAT'S USEFUL AND OBJECTIVE, BUT WE GET REALLY CONCERNED WHEN IT GETS INTO SUBJECTIVITY WHERE CIRM IS SAYING WE THINK THIS IS GOOD OR WE THINK THIS IS BAD AND WE'VE TAKEN FACTUAL DATA AND WE'VE PUT AN ASSESSMENT ON IT AND NOW WE'RE GIVING THAT TO REVIEWERS. THAT'S JUST A CONCERN THAT WE'RE TRYING TO BALANCE AGAINST HERE, THAT WE DON'T MIX OUR SUBJECTIVE PUSHING AND GETTING

THE BEST PROGRAMS INTO REVIEW WHICH WE WANT TO KEEP OBJECTIVE.

CHAIRMAN SHEEHY: I GUESS I'M JUST NOT QUITE COMFORTABLE WITH THIS CONSIDERATION OF PAST PERFORMANCE RIGHT BECAUSE RIGHT NOW IT FEELS LIKE SOMETHING THAT CARRIES A HIGH NEGATIVE BIAS AND WE EXPECT PEOPLE TO FAIL. WE'RE PUTTING IN PLACE PROCEDURES THAT WE WANT PEOPLE TO TAKE RISK, BUT WE KNOW THEY'RE GOING TO FAIL. I THINK INCLUDING PAST PERFORMANCE AND SHOWING A RECORD OF FAILURE, THOSE FAILURES MAY HAVE CREATED THE STAIRWAY TOWARDS SUCCESS. YOU LEARN WHEN YOU FAIL.

SO THE SUBJECTIVE PART COMES TO THE DEGREE TO WHICH THE PROGRESS REPORTS REFLECT THE RELATIONSHIP BETWEEN THE APPLICANT AND CIRM AND MANAGING THAT FAILURE. AND IF THEY COME BACK WITH ANOTHER PROJECT, LEARNING FROM THEIR FAILURE, HOW DOES THE GRANTS REVIEW GROUP ACTUALLY INTERPRET THE RECEIPT OF INFORMATION THAT FAILURE WAS ACHIEVED. I'M NOT COMPLETELY SURE THAT HEARING ABOUT FAILURE, IF IT'S NOT CONTEXTUALIZED WELL, CAN ACTUALLY CREATE A NEGATIVE BIAS TOWARDS THE PROJECT IN MY VIEW.

SO I WOULD NOT SUPPORT AT THIS TIME THE CONSIDERATION OF PAST PERFORMANCE OF A CIRM AWARDEE UNTIL WE GET A LITTLE MORE CLARITY AND MAYBE THINK

ABOUT MORE EXAMPLES OF HOW THIS MIGHT WORK OUT PERSONALLY.

THE OTHER ONE I'M FINE WITH, BUT I'M NOT SUPPORTIVE OF THAT ONE AT THIS TIME.

DR. HIGGINS: CAN I PIGGY-BACK ONTO YOUR COMMENTS, JEFF?

CHAIRMAN SHEEHY: SURE.

DR. HIGGINS: I APPRECIATE EVERYTHING YOU'RE SAYING, BUT I DON'T THINK YOU ARE SAYING THAT THERE IS NO EXAMPLE, THERE ARE NO EXAMPLES OF PAST PERFORMANCE THAT SHOULDN'T BE TAKEN INTO CONSIDERATION FOR FUTURE FUNDING OR CURRENT FUNDING. I HEAR WHAT YOU'RE SAYING ABOUT BEING CAUTIOUS ABOUT OVERINTERPRETING AND THAT THERE'S VALUE IN HAVING FAILURES, BUT THERE ARE PROBABLY SOME FAILURES THAT SHOULD BE REFLECTED ON THE PERFORMANCE OF A GROUP THAT DO MATTER. I WOULD BE MAKING STUFF UP TO GIVE EXAMPLES.

SO I AGREE WITH YOU ON ONE HAND. ON THE OTHER HAND, YOU MIGHT NOT BE ABLE TO NEUTRALIZE EVERY FAILURE INTO A POSITIVE EXPERIENCE.

CHAIRMAN SHEEHY: I'M NOT SUGGESTING THAT. IN FACT, I WOULD PREFER MORE INFORMATION WAS AVAILABLE. I JUST AM NOT SURE WE REALLY CAPTURED WHAT WE WANT TO GET FROM PAST PROGRESS REPORTS IN

ORDER TO IMPACT THE DISCUSSION AT THE GRANTS WORKING GROUP.

MR. HARRISON.

MR. HARRISON: JUST ONE CLARIFICATION. THE CONSIDERATION OF PAST PERFORMANCE WOULDN'T BE LIMITED TO FAILURES. IT COULD BE SUCCESSES IN ACHIEVING MILESTONES IN A TIMELY WAY. IT COULD BE POSITIVE RESULTS. IN OTHER WORDS, IT'S OBJECTIVE INFORMATION NOT LIMITED TO FAILURE. IT COULD BE POSITIVE OUTCOMES AS WELL.

OUR GOAL WAS TO TRY TO KEEP IT OBJECTIVE, AS RANDY SUGGESTED, TO AVOID CIRM BEING DRAWN INTO A SITUATION WHERE IT WAS OFFERING ITS OPINIONS TO THE GWG. WE WANTED TO GIVE THE GWG ALL OF THE RELEVANT INFORMATION AND LET THE GWG MAKE ITS OWN ASSESSMENT.

CHAIRMAN SHEEHY: THANK YOU. SO DO WE HAVE ANY OTHER COMMENTS?

DR. HIGGINS: ONE LAST COMMENT TO POINT OUT THE OBVIOUS. WE DO HAVE PRECEDENTS WHERE WE DO TAKE IN PAST PERFORMANCE AS A CRITERIA FOR GOING FORWARD IN THE SPARK AND BRIDGES APPLICATIONS, I BELIEVE.

CHAIRMAN SHEEHY: THANK YOU, DAVID.

SO DO WE HAVE -- DR. STEWARD.

DR. STEWARD: I'M JUST LOOKING BACK AT THE

LANGUAGE HERE, AND MAYBE I'M MISINTERPRETING WHAT IT SAYS, JEFF. BUT IT SEEMS LIKE IT'S REALLY MOST RELATED TO PERFORMANCE AGAINST MILESTONES, DATA, AND OUTCOMES RATHER THAN NECESSARILY PRODUCT ADVANCEMENT. AM I MISREADING THAT? IS THAT WHAT YOU HAD IN MIND, THAT THEY DID THE WORK THEY PROPOSED TO DO AND DID IT AND THEY MET THEIR MILESTONES AND THEY DIDN'T AND THAT'S IT?

DR. SAMBRANO: IT'S MEANT TO PROVIDE A REFLECTION OF HOW THEY'VE DONE IN PAST AWARDS. SO IT'S NOT NECESSARILY FOCUSED ON THE PRODUCT. IT'S FOCUSED ON THE COURSE OF A PREVIOUS AWARD.

DR. STEWARD: RIGHT. IN THAT REGARD, I ACTUALLY DON'T HAVE PROBLEMS WITH THAT. IT'S JUST SAYING DID THE PEOPLE DO THE WORK THAT THEY PROPOSED TO DO AND DO IT IN THE TIME FRAME THAT THEY PROPOSED TO DO AND, IF NOT, WHY AND SORT OF IRRESPECTIVE OF THE IDEA OF WHAT'S HAPPENING WITH THE PRODUCT ITSELF. IT'S REALLY JUST A MATTER OF DID THEY DO THE GRANT IN THE WAY THEY WERE SUPPOSED TO. I'M ACTUALLY FINE WITH THAT.

CHAIRMAN SHEEHY: LIKE I SAID, I CANNOT AT THIS TIME SUPPORT THIS. I REALLY THINK THAT IT INTRODUCES A NEGATIVE BIAS TOWARDS PEOPLE WHO EXPERIENCE FAILURE. SO I THINK THAT THAT, THEN,

COLORS WHATEVER THEY SUBMIT TO CIRM. AND I WOULD HOPE THE FOLKS LEARN FROM THEIR FAILURE. A FAILED EXPERIMENT, IN MANY WAYS, HAS SEVERAL FEATURES OF A SUCCESSFUL ONE.

DR. STEWARD: I TOTALLY AGREE. ABSOLUTELY.

SO I GUESS MY QUESTION WOULD BE I THINK IT PROBABLY ISN'T MAYBE THE RIGHT THING TO TAKE IT TO THE BOARD AT THIS POINT IF YOU'RE REALLY UNCOMFORTABLE WITH IT. SO I GUESS MY QUESTION WOULD BE HOW WOULD IT BE FIXED? WHAT WOULD WE DO TO MAKE IT RIGHT? BECAUSE I DO THINK THE CONCEPT OF EVALUATING PAST PERFORMANCE IS REALLY A GOOD ONE. THAT, I THINK, IS A VERY VALUABLE THING FOR REVIEWERS TO HAVE IN HAND, AND IT ISN'T ALWAYS THERE IN THE PROGRESS REPORTS ITSELF. YOU REALLY WANT TO SEE SORT OF THE BROAD HISTORY OF PERFORMANCE OF THE GROUP OR GROUPS INVOLVED.

DR. SAMBRANO: APPLICANTS ARE ASKED TO PROVIDE A HISTORY, AND OFTEN THEY DO, OF A PROJECT. SO WHAT YOU SEE IN AN APPLICATION IS OFTEN THEIR REITERATION OF WHAT THEY BELIEVE THE PROGRESS HAS BEEN. SO WHAT WE'RE TRYING TO DO IS PROVIDE AN OBJECTIVE WAY OF PRESENTING IT. SO IT MAY MIRROR EXACTLY WHAT THEY SAY, BUT IT ALSO PROVIDES IN AN

OBJECTIVE WAY, IN A CONSISTENT MANNER ACROSS ALL APPLICATIONS.

DR. HIGGINS: NOT TO BEAT A DEAD HORSE, BUT, JEFF, TO FOLLOW UP AGAIN ON YOUR POINT, YOU MADE THE COMMENT SOMETHING TO THE EFFECT OF YOU CAN LEARN FROM YOUR MISTAKES, OR IF YOU HAVE A FAILED EXPERIMENT, YOU CAN LEARN FROM IT AND THAT'S VALUABLE INFORMATION. I THINK THAT'S DIFFERENT THAN NOT MEETING TIMELINE OR NOT DOING THE EXPERIMENT. I THINK NOT DOING THE EXPERIMENT IS DIFFERENT THAN DOING THE EXPERIMENT AND HAVING A NEGATIVE OUTCOME, WHICH I THINK IS EXTREMELY VALUABLE.

SO I DON'T WANT TO GET INTO SEMANTICS, BUT SORT OF FOOD FOR THOUGHT. I DON'T THINK WE SHOULD PENALIZE SOMEONE FOR DOING WHAT THEY SAID THEY WERE GOING TO DO AND GETTING A DIFFERENT RESULT VERSUS NOT DOING WHAT THEY SAID THEY WERE GOING TO DO.

CHAIRMAN SHEEHY: I WOULD JUST SAY FOR OUR STRUCTURE AN EXPERIMENT THAT FAILED BECOMES A MISSED MILESTONE. SO A MISSED MILESTONE -- SO I GUESS I DON'T SEE THAT AS A DELAY OR A FAILURE TO PERFORM. I SEE IT AS A FAILURE OF THE EXPERIMENT WHICH IS NATURAL AND INEVITABLE IN SCIENCE. I DON'T KNOW THAT -- MY PERSONAL OPINION WOULD BE TO TAKE THIS ITEM OUT OF THIS, APPROVE THE OTHER ITEM, AND THEN

DO SOME MORE THINKING. THIS IS A SUBJECT ACTUALLY THAT I'VE BEEN THINKING ABOUT MORE BROADLY. AGAIN, I THINK THIS IS TOO NARROWLY TAILORED, AND I THINK IF WE GET ACCESS TO THE FULL RANGE OF INFORMATION THAT MIGHT HELP THE GRANTS WORKING GROUP MAKE THE BEST DECISION POSSIBLE, THEN I THINK WE WOULD HAVE -- THAT'S WHAT I WOULD LIKE TO SEE BE THE OUTCOME OF THIS.

I THINK THE WAY THIS IS WRITTEN, IT'S TOO NARROW. AND I DO THINK IN MY MIND IT CREATES A BIAS TOWARDS APPLICANTS WHO HAVE HAD SUCCESS AND CREATES A BIAS AGAINST APPLICANTS WHO HAVE NOT HAD SUCCESS, YET THEIR PRODUCTS MAY BE EQUALLY VALUABLE IN THE END, AND THEY'RE BOTH LEARNING NEW INFORMATION AS THEY MAKE THEIR WAY THROUGH THE PROCESS.

DR. HIGGINS: I AGREE WITH YOU, JEFF, TO THE EXTENT WE MAY BE TALKING SEMANTICS. I DON'T THINK WE'RE ACTUALLY SAYING DIFFERENT THINGS. I THINK WE'RE JUST SAYING THE SAME THING DIFFERENTLY, AND THAT COULD BE WORKED OUT.

CHAIRMAN SHEEHY: WITH RESPECT, I THINK WE ARE SAYING DIFFERENT THINGS, BUT IT'S A LARGER DISCUSSION.

SO ANYWAY, SO WHAT DO WE HAVE? DO WE HAVE EITHER A MOTION TO APPROVE THIS OR A MOTION TO

APPROVE PART 2 AND DEAL WITH PART 1 AFTER LATER DISCUSSION? I WOULD TAKE EITHER MOTION FROM ANY MEMBER.

DR. HIGGINS: I WOULD SUPPORT A MOTION THAT PULLS THIS OUT OF THE CURRENT APPROVAL REQUEST AND FOR FURTHER DISCUSSION, HOWEVER YOU WANT TO WORD THAT PROPERLY, JAMES.

CHAIRMAN SHEEHY: AND THEN THIS MOTION WOULD APPROVE PART 2 OF THIS, WHICH I THINK THERE'S NO -- YES, DAVID?

DR. HIGGINS: CORRECT. RIGHT. THE PART NOT IN QUESTION HERE.

CHAIRMAN SHEEHY: COULD I GET A SECOND ON THAT?

MR. TORRES: AMENDMENT TO THE MOTION THAT'S BEFORE US. CAN WE SET A TIME CERTAIN TO RESOLVE THIS ISSUE BECAUSE I THINK THAT'S GOING TO BE EXTREMELY IMPORTANT AS WE MOVE FORWARD. SO CAN WE SAY THAT WE WILL RESOLVE THIS LANGUAGE BY OUR DECEMBER BOARD MEETING?

DR. STEWARD: I WAS GOING TO ASK THE QUESTION. WHAT WOULD IT IMPACT TO DELAY THIS? AND THAT'S SORT OF THE SAME QUESTION BECAUSE I AGREE -- I ACTUALLY DO THINK THAT A RETROSPECTIVE ANALYSIS OF PERFORMANCE, NOT SUCCESS, BUT PERFORMANCE IS REALLY

QUITE VALUABLE IN EVALUATING A GROUP'S ABILITY TO MOVE FORWARD. I'D LIKE TO SEE IT WORKED OUT QUICKLY AS WELL SO THAT IT DIDN'T -- SO THAT ITS ABSENCE DIDN'T IMPACT THE NEXT ROUND OF REVIEW IF WE COULD POSSIBLY DO THAT.

MR. TORRES: IT'S NOT PRECLUDED FROM MAKING AN AMENDMENT AT THE BOARD MEETING, CORRECT, A NEW MOTION?

MR. HARRISON: YES. IF FOLKS AT THAT THE SUBCOMMITTEE WERE COMFORTABLE GOING DIRECTLY TO THE BOARD, WE COULD CERTAINLY DO THAT.

MR. TORRES: SURE. IF THIS MOTION WERE TO COME OUT AS AMENDED AS PROPOSED BY -- IF THIS MOTION WERE TO COME OUT AS PROPOSED BY YOU, JEFF, THEN IT WOULD COME TO THE MAIN BOARD, AND THE BOARD COULD SEEK TO AMEND THAT MOTION TO ADD WHATEVER LANGUAGE HAD BEEN WORKED OUT.

MR. HARRISON: YES. YOU COULD TODAY APPROVE THE SECOND PART OF THE PROPOSAL, INCLUSION OF ACCURACY AND COMPLETENESS OF AN APPLICATION, AS AN ELIGIBILITY CRITERIA AND REQUEST FURTHER CONSIDERATION OF THE PROPOSAL TO INCLUDE PAST PERFORMANCE AS A REVIEW CRITERIA TO BE PRESENTED TO THE BOARD FOR ITS CONSIDERATION IN DECEMBER, IF THAT WAS YOUR DESIRE.

CHAIRMAN SHEEHY: I MEAN IT'S WHATEVER THE REST OF THE COMMITTEE WISHES TO DO. I CANNOT SUPPORT IT IN ITS PRESENT FORM.

MR. TORRES: I'M NOT SUGGESTING THAT YOU DO. I'M SUGGESTING THAT WE MOVE AHEAD WITH THE PROPOSED AMENDED MOTION, WHICH I HAVE PROVIDED, BUT ALSO TO AMEND TO HAVE A TIME CERTAIN, AND WE COULD BRING IT UP AGAIN AT OUR BOARD MEETING IN DECEMBER. IF YOU DON'T HAVE THE LANGUAGE WORKED OUT BY THEN, AT LEAST UNTIL JANUARY.

CHAIRMAN SHEEHY: OKAY. THAT SEEMS REASONABLE. MOTION MAKERS ALL FINE WITH THAT?

DR. HIGGINS: THAT'S A FINE AMENDMENT FOR ME.

CHAIRMAN SHEEHY: GREAT SUGGESTION, SENATOR TORRES. OKAY. SO WE HAVE A MOTION; WE HAVE A SECOND. PUBLIC COMMENT? CAN WE CALL THE ROLL PLEASE?

MS. BONNEVILLE: MICHAEL FRIEDMAN. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.

DR. MELMED: YES.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: YES.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

CHAIRMAN SHEEHY: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: KRISTINA VUORI.

CHAIRMAN SHEEHY: MOTION CARRIES. AND I THINK THAT FULFILLS OUR AGENDA TODAY. THANK, EVERYONE, FOR YOUR TIME. THIS HAS BEEN GREAT. AND THANK YOU TO THE CIRM TEAM FOR A TREMENDOUS, TREMENDOUS PRODUCT. THANK YOU.

DR. STEWARD: HERE. HERE.

CHAIRMAN SHEEHY: WE'RE NOW ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 3:39 PM.)

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 SCIENCE SUBCOMMITTEE OF 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

OAKLAND MARRIOTT CITY CENTER
1001 BROADWAY
OAKLAND, CALIFORNIA
ON
NOVEMBER 30, 2015

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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