BEFORE THE

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

REGULAR MEETING

LOCATION: AS INDICATED IN THE AGENDA

DATE JANUARY 30, 2019
11 A.M.

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

FILE NO. 2019-01

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JANUARY 30, 2019; 11 A.M.

CHAIRMAN THOMAS: WELCOME, EVERYBODY. WOULD LIKE TO CALL THE FIRST REGULARLY SCHEDULED MEETING OF 2019 FOR THE ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

UNIDENTIFIED SPEAKER: HE'S NOT TO SPEAK YET.

MS. BONNEVILLE: DAVID, WE'RE GIVING YOU THE ABILITY TO PIPE IN IN JUST A SECOND. SORRY ABOUT THAT.

STEVE JUELSGAARD.

DR. JUELSGAARD: HERE.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: PRESENT.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

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MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: HERE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: PRESENT.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: HERE.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: HERE.
MS. BONNEVILLE: OS STEWARD. JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: HERE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: HERE.
MS. BONNEVILLE THANK YOU. ARE THERE ANY OTHER BOARD MEMBERS ON THE LINE WHOSE NAME I DID NOT CALL?
DR. GASSON THIS IS JUDY GASSON. I'M ON THE LINE.
MS. BONNEVILLE: THANK YOU, JUDY.
CHAIRMAN THOMAS: THANK YOU, MARIA. ON TO ITEM NO. 3, CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLINICAL TRIAL STAGE PROJECTS, CLIN1, 2, OR 3. I'LL TURN THIS AT THIS POINT OVER TO MR.

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SHEEHY FOR THE PROGRAMMATIC REVIEW.

MR. SHEEHY: I BELIEVE DR. PATEL WILL TAKE US THROUGH THE RECOMMENDATIONS THIS MORNING.

DR. PATEL: THANK YOU, MR. SHEEHY. I HAVE A PRESENTATION PREPARED THAT'S GOING TO GUIDE US THROUGH THESE THREE APPLICATIONS THAT ARE UP FOR YOUR CONSIDERATION TODAY.

AS YOU ALL KNOW, THE CLINICAL PROGRAM IS ACTUALLY COMPOSED OF THREE DISTINCT FUNDING OPPORTUNITIES. TODAY I'LL BE PRESENTING ONE CLIN1 IND-ENABLING PROJECT AND TWO CLIN2 CLINICAL TRIAL PROJECTS FOR YOUR REVIEW.

AS IT INDICATES, ALL APPLICATIONS THAT COME TO YOU, THESE HAVE BEEN REVIEWED BY THE GRANTS WORKING GROUP, AND WE USE A THREE-TIER SCORING SYSTEM FOR THE CLINICAL PROGRAM. IF THE APPLICATION HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING, IT'S GIVEN A SCORE OF 1. IF IT NEEDS IMPROVEMENT AND DOES NOT WARRANT FUNDING AT THIS TIME, BUT CAN BE RESUBMITTED, IT'S GIVEN A SCORE OF 2. AND, LASTLY, IF IT'S SUFFICIENTLY FLAWED SUCH THAT IT DOES NOT WARRANT FUNDING, IT CANNOT BE RESUBMITTED FOR SIX MONTHS AND IS GIVEN A SCORE OF 3.

THE BOARD APPROVED $93 MILLION AS THE ANNUAL BUDGET FOR THE CLINICAL PROGRAM FOR THIS

YEAR. AND IF THE AWARDS UNDER CONSIDERATION TODAY ARE APPROVED, THEY TOTAL ABOUT $24 MILLION. THAT WILL LEAVE $69 MILLION AS THE UNUSED BALANCE FOR THE REMAINDER OF THIS YEAR FOR THE CLINICAL PROGRAM. THIS DOES NOT INCLUDE THE SICKLE CELL ALLOCATION IN THESE NUMBERS.

THE CIRM SETS INTERNAL TARGETS FOR THE NUMBER OF PROJECTS WE EXPECT TO FUND IN CLIN2 AND CLIN1. IN CLIN2 OUR ANNUAL TARGET IS EIGHT CLINICAL TRIALS FOR THIS YEAR. IF YOU APPROVE THE TWO CLINICAL TRIAL PROJECTS THAT ARE UNDER CONSIDERATION TODAY, THAT WOULD GET US A FOURTH OF THE WAY THERE. ON THE CLIN1 SIDE, WE EXPECT TO FUND TWO LATE STAGE PRECLINICAL PROJECTS. IF YOU FUND THE ONE THAT'S UP FOR CONSIDERATION TODAY, THAT GETS HALFWAY TO THE GOAL FOR THE YEAR.

SO I'M GOING TO GO THROUGH THE THREE PROJECTS STARTING WITH THE FIRST ONE. THIS IS CLIN1-10953. THIS IS THE IND-ENABLING STUDIES FOR HUNTINGTON'S DISEASE THERAPY. THE THERAPY ITSELF IS HUMAN EMBRYONIC STEM-CELL DERIVED NEURAL STEM CELLS. AND, AGAIN, THE INDICATION IS HUNTINGTON'S DISEASE. THE GOAL FOR THIS PROJECT IS AN IND FILING. ALONG THE WAY, THEY PLAN TO DO SOME MANUFACTURING OPTIMIZATION AS WELL AS THE NECESSARY IND-ENABLING

STUDIES FOR THIS PROJECT.

THE FUNDS REQUESTED ARE $6 MILLION WITH ZERO DOLLARS FOR CO-FUNDING, AND THE MAXIMUM FUNDS ALLOWABLE FOR THIS CATEGORY IS $6 MILLION.

I PREPARED A FEW SLIDES THAT CAN HELP YOU GUIDE THE DISCUSSION FOR THIS PROJECT. FIRSTLY, HD IS AN INHERITED DISEASE THAT AFFECTS 30,000 PATIENTS IN THE U.S. THE ADULT ONSET OF THIS DISEASE IS MORE COMMON THAN THE JUVENILE HD VERSION OF THIS DISEASE. AND HD PATIENTS TYPICALLY LIVE 15 TO 20 YEARS AFTER ONSET OF THESE SYMPTOMS.

AS MANY OF YOU KNOW, HD IS A PROGRESSIVE NEURODEGENERATIVE DISORDER CAUSED BY A DEFECT IN THE HUNTINGTON GENE THAT LEADS TO DEATH OF NEURONS IN VARIOUS REGIONS OF THE BRAIN.

THERE ARE CURRENTLY NO CURES OR EVEN DISEASE-MODIFYING THERAPIES FOR HD. THE PROPOSED CELL THERAPY THAT'S UNDER CONSIDERATION TODAY WOULD POTENTIALLY DELAY THE PROGRESSION OF THE DISEASE, BUT DOES NOT ADDRESS THE UNDERLYING GENETIC CAUSE OF THE DISEASE.

THE THERAPY ITSELF INVOLVES NEURAL STEM CELLS DERIVED FROM EMBRYONIC STEM CELLS, WHICH IS WHY IT QUALIFIES AS A STEM CELL PROJECT AND IS ELIGIBLE FOR FUNDING BY CIRM.

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WE CURRENTLY HAVE NO RELATED HD APPROACHES IN OUR PORTFOLIO FOR CLINICAL TRIAL PROJECTS. AND THIS PARTICULAR APPLICANT HAD RECEIVED PREVIOUS FUNDING FROM CIRM FOR THE TRANSLATIONAL WORK THAT WAS DONE TO GET TO THIS STAGE AS WELL AS THE INITIAL CANDIDATE DISCOVERY WORK TO IDENTIFY A SINGLE CANDIDATE.

THE GWG REVIEWED THIS PROPOSAL AND GAVE IT A SCORE OF 1. THERE WERE EIGHT VOTES IN TIER I, ONE VOTE IN TIER II, AND FIVE VOTES IN TIER III. THE CIRM TEAM CONCURS WITH THE GWG RECOMMENDATION FOR FUNDING OF THIS APPLICATION FOR THE AWARD AMOUNT REQUESTED, WHICH IS $6 MILLION. MR. SHEEHY.

MR. SHEEHY: THANK YOU. SO DO I HAVE A MOTION TO ACCEPT THE TEAM RECOMMENDATION?

MR. TORRES: SO MOVED.

MR. SHEEHY: MOVED BY SENATOR TORRES. DO I HAVE A SECOND?

CHAIRMAN THOMAS: SECOND.

MR. SHEEHY: SECOND BY CHAIRMAN THOMAS. SO ANY DISCUSSION FROM MEMBERS OF THE BOARD?

DR. DULIEGE: COULD SOMEONE EXPLAIN WHY THIS APPLICATION RECEIVED FIVE SCORES OF 3, WHICH IS QUITE SIGNIFICANT?

DR. PATEL: YEAH, SURE. I CAN DO THAT.

SO DURING THE REVIEW OF THIS APPLICATION, SOME REVIEWERS THOUGHT THAT CELL THERAPIES THAT DO NOT ADDRESS THE UNDERLYING GENETIC CAUSE OF THE DISEASE DON'T HAVE A ROLE IN THE CLINICAL TREATMENT OF HD. THEIR ARGUMENT WAS BASED ON THE FACT THAT THE BENEFITS FOR THIS PARTICULAR TYPE OF THERAPY WOULD NOT OUTWEIGH THE RISKS ASSOCIATED WITH THE INTERVENTION ITSELF, THE SURGERY AS WELL AS THE IMMUNOSUPPRESSION THAT WOULD BE NECESSARY.

OTHER REVIEWERS FELT THAT IT'S TOO EARLY TO RULE OUT THE ROLE OF CELL THERAPY IN HD. AND THEY THOUGHT IF THERE'S GOING TO BE ONE PARTICULAR CELL THERAPY THAT WOULD BE PERFECTLY SUITED TO STUDY THE ROLE, IT WOULD BE THIS ONE. THIS IS THE MOST ADVANCED AND HAS THE MOST DATA TO BACK IT UP.

MR. SHEEHY: DO WE HAVE ADDITIONAL QUESTIONS FROM MEMBERS OF THE BOARD?

MR. PANETTA: THIS IS JOE PANETTA.

MR. SHEEHY: PLEASE.

MR. PANETTA: I'VE GOT TWO QUESTIONS, PLEASE. THE FIRST IS I KNOW WE FUNDED TWO PREVIOUS PROJECTS FOR THIS PARTICULAR THERAPY. AND MY TWO QUESTIONS ARE DO WE HAVE THE SCORES FOR THOSE TWO, AND HOW MUCH IN AWARD MONEY HAVE WE GRANTED FOR THOSE TWO?

MR. SHEEHY: GIVE US A SECOND.

DR. PATEL: WE'RE GOING TO LOOK THAT UP FOR YOU. JUST TO CLARIFY, THAT IT'S THE SAME PROJECT THAT WAS FUNDED PREVIOUSLY FOR TRANSLATIONAL AND CANDIDATE DISCOVERY WORK.

MR. SHEEHY: I THINK YOU HAD A SECOND QUESTION.

MR. PANETTA: THOSE ARE THE TWO QUESTIONS, THE AMOUNT OF FUNDING AND THE SCORES. THANKS.

DR. MARTIN: LET ME JUST ASK ANOTHER QUESTION ABOUT THESE FIVE NEGATIVE VOTES. AND OBVIOUSLY, THE COMPOSITION OF THIS WORKING GROUP INCLUDED SOPHISTICATED NEUROSCIENTISTS. WITHOUT KNOWING THE COMPOSITION, THE NAYSAYERS OR THE NEGATIVE OR PESSIMISTIC ONES ARE MORE NEUROSCIENCE ORIENTED OR MORE STEM CELL ORIENTED. I JUST WONDER ABOUT THE JUDGMENT THAT'S BEING USED HERE BECAUSE THIS IS JUST JUDGMENT WITHOUT REALLY KNOWING THE OUTCOME. IT WOULD BE INTERESTING TO KNOW HOW THOSE FIVE NEGATIVE VOTES OR THOSE THREE VOTES MIGHT BE WEIGHTED. IF THEY'RE ALL EQUAL, THEN THEY'RE ALL EQUAL AND WE CAN TAKE EIGHT OUT OF FIVE.

DR. PATEL: THERE WERE NEUROSCIENTISTS ON BOTH SIDES OF THE ARGUMENT. I'M NOT SURE IF THAT HELPS, BUT WE'RE LOOKING AT THE SCORES. THERE WERE

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NEUROSCIENTISTS ON BOTH SIDES OF THE ARGUMENT.

DR. MARTIN: ALL RIGHT. THAT MAKES IT A MORE DIFFICULT DECISION.

MR. SHEEHY: I THINK THESE DISCUSSIONS ARE ALMOST THEOLOGICAL IN NATURE.

MR. PANETTA: COULD I JUST ASK A DIFFERENT KIND OF A QUESTION ON THIS PLEASE?

MR. SHEEHY: SURE.

MR. PANETTA: SHYAM, WHAT I'D LIKE TO UNDERSTAND, IS IT BASICALLY THE IDEA TO GRANT THIS EVEN WITH THE DIVISION IN THE SCORES? IS IT -- THERE REALLY ISN'T ANYTHING IN THE WAY OF A PROMISING THERAPY TO TREAT HUNTINGTON'S. IS THAT PRETTY MUCH CORRECT?

DR. PATEL: SO THERE ARE CLINICAL TRIALS FOR OTHER APPROACHES. SOME ADDRESS THE GENETIC CAUSE OF THE DISEASE. IN TERMS OF CELL THERAPIES, THIS, IN THE OPINION OF THE GWG, IS THE MOST ADVANCED.

MR. PANETTA: OKAY. THANKS.

DR. MARTIN: JUST ANOTHER COMMENT. IT'S SORT OF STANDING AT 50,000 FEET. THERE ARE ONLY TWO SLOTS FOR CLIN1. AND HERE WE HAVE ONE THAT'S CLEARLY DIVIDED. IT MADE AN IMPRESSION AMONG THE REVIEWERS. THAT WOULD LEAVE US ONE FOR THE NEXT

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THREE QUARTERS. I'M JUST WORRIED ABOUT JUMPING IN ON THAT. I MEAN IF WE HAD FOUR, I'D BE MORE -- I GUESS MORE RECEPTIVE OF A SPLIT VOTE. I REALLY WONDER ABOUT OUR JUDGMENT GOING FORWARD IF WE SPEND HALF OF OUR AMMUNITION ON ONE THAT'S REALLY SPLIT. IS THAT WISE?

MR. SHEEHY: SO WE'VE GOT A LITTLE BIT OF A BACKUP. SO I HAVE DR. PRIETO AND THEN I HAVE CHAIRMAN THOMAS. I THINK SHYAM, DR. PATEL, AT THE TIME WANTED TO RESPOND TO THOSE QUESTIONS. AND WE DO HAVE THE ANSWERS TO MR. PANETTA'S PRIOR QUESTIONS. SO MAYBE WE COULD TAKE MR. PANETTA'S PRIOR QUESTIONS AND THEN SHYAM AND THEN FRANCISCO, DR. PRIETO, AND THEN CHAIRMAN THOMAS. DOES THAT SEEM REASONABLE TO KIND OF LINE IT UP?

DR. PATEL: I'M GOING TO ANSWER THE QUESTIONS WITH RESPECT TO THE PRIOR FUNDING FOR THIS PROJECT. SO THE TRANSLATIONAL PROJECT RECEIVED $4.9 MILLION, AND THE DISCOVERY STAGE PROJECT RECEIVED $1.65 MILLION.

AND THE QUESTION ABOUT THE ALLOCATION. SO THOSE ARE NOT CAPS. THE WAY THAT THOSE TARGETS ARE ARRIVED AT IS TAKING A $93 MILLION BUDGET AND REASONABLY APPROXIMATING HOW MANY CLIN2 AWARDS AND CLIN1 AWARDS WOULD HELP US PROGRESS TOWARD OUR BIG

SIX GOALS, BUT THOSE ARE NOT MEANT TO BE CAPS IN ANY WAY WHATSOEVER.

SO JUST TO PROVIDE SOME BACKGROUND ON THAT. LAST YEAR, IN 2018, THE BOARD HAD FUNDED QUITE A FEW MORE CLIN1 PROJECTS THAN WERE TARGETED FOR OUR ALLOCATION. AND SO IT'S NOT MEANT TO BE A CAP IN THAT RESPECT.

DR. MARTIN: THAT HELPS.

MR. SHEEHY: THANK YOU. THEN WE HAVE DR. PRIETO.

DR. PRIETO THAT MAY HAVE ANSWERED MOST OF THIS, BUT I JUST WANTED TO REITERATE THAT THE GWG FELT THAT THIS WAS THE MOST PROMISING APPROACH FOR A DISEASE THAT IS PRETTY DEVASTATING AND CURRENTLY UNTREATABLE AND ON WHICH WE HAVE NOT PUT A LOT OF ATTENTION.

MR. SHEEHY: CHAIRMAN THOMAS.

CHAIRMAN THOMAS: I JUST REITERATE WHAT DR. PRIETO SAID. THIS IS SORT OF THE INEXACT SCIENCE WHEN THEY'RE EVALUATING. AT THE GWG IT WAS THE MAJORITY VIEW THAT THIS WAS THE MOST PROMISING APPROACH THAT'S OUT THERE, AND AS SUCH IT WAS RECOMMENDED. BUT THIS IS SORT OF ONE OF THE CLASSIC PROGRAMMATIC REVIEW TYPE OF PROJECTS WHERE, AMONG OTHER THINGS, WE HAVE TO EVALUATE WHAT THE CURRENT

AMOUNT OF ATTENTION THE DISEASE HAS IN OUR PORTFOLIO. AND AS DR. PATEL NOTED, THIS IS NOT SOMETHING THAT WE HAVE A LOT OF COVERAGE ON, AND THIS IS A DISEASE THAT DESPERATELY NEEDS NEW APPROACHES TO TRY TO RESOLVE.

SO FOR THAT REASON -- AND THEY DID THINK THIS WAS THE MOST PROMISING CELLULAR THERAPY PROJECT. I UNDERSTAND, DAVE, WHAT YOU'RE SAYING. I WOULD POINT THAT, ON BALANCE, I THINK THIS IS SOMETHING WE SHOULD SUPPORT.

MR. SHEEHY: SENATOR TORRES HAD A COMMENT. I HEARD SOMEBODY ELSE SPEAK UP ON THE PHONE.

MR. TORRES: YES. I WANTED TO CONCUR WITH DR. PRIETO AND DR. THOMAS. HAVING BEEN PRESENT DURING THAT GWG, IT WAS VERY CLEAR THAT THIS IS THE MOST PROMISING WE HAVE ON THE TABLE. AND QUITE FRANKLY, WE'RE A LITTLE VACANT IN TERMS OF THIS DISEASE IN OUR PORTFOLIO. AND WE HAVE INVESTED SUBSTANTIALLY ALREADY IN OTHER PROJECTS THAT LED US TO THIS POINT; ISN'T THAT CORRECT, DR. PATEL?

DR. PATEL: YES, THAT'S CORRECT.

MR. TORRES: HE'S NODDING YES.

MR. SHEEHY: DO WE HAVE ADDITIONAL COMMENTS OR QUESTIONS FROM MEMBERS OF THE BOARD? I BELIEVE WE HAVE PUBLIC COMMENT ON THIS. PLEASE

ANNOUNCE YOUR NAME IF YOU DON'T MIND. YOU DON'T HAVE TO, BUT IT'S HELPFUL FOR THE RECORD.

MR. REED: THIS IS DON REED. WHENEVER CIRM TAKES ON A CHALLENGE, THERE'S ALWAYS TWO THINGS. ONE, PEOPLE ARE SUFFERING AND, SECOND, MAYBE THERE'S A WAY TO EASE THE AGONY. SELDOM IS THIS MORE CLEAR THAN THE BATTLE AGAINST HUNTINGTON'S. THE SUFFERING IS UNQUESTIONABLE AND THERE IS NO CURE, NOT YET. THE DISEASE ITSELF IS TERRIBLE. LIKE THAT SENTENCE FROM SHAKESPEARE, "THOSE WHOM THE GODS WOULD DESTROY, THEY FIRST MAKE MAD." HUNTINGTON'S DOES THAT. BAD ENOUGH THAT IT SLOWLY KILLS THE SUFFERER PHYSICALLY, FIFTEEN OR 20 YEARS OF SUFFERING BEFORE DEATH. IT AFFECTS THEIR MINDS AS WELL, MAKING THEM FOUL TEMPERED OR REMOVING THEIR GOOD JUDGMENT.

I THINK THIS MAY MAKE THE SUFFERERS LITERALLY INSANE. THE FAMILY CONSTANTLY HAS TO REMIND THEMSELVES THIS IS THE DISEASE, NOT HIM OR HER. AND THEY MAY GO THROUGH THIS FOR DECADES. IS THERE HOPE FOR THIS PARTICULAR APPROACH, CLIN1-10953? WILL BRAIN-DERIVED NEUROTROPHIC FACTORS SERVE AS NERVE FERTILIZERS HELP IN THE FIGHT AGAINST HUNTINGTON'S? AND THE SCIENTISTS DECREASED THE LEVELS OF SOMETHING CALLED HDT PROTEIN WHICH

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MAY, IN FACT, CAUSE THE CONDITION.

LASTLY, WILL THE NEWLY ADDED NEURAL STEM CELLS, HEALTHY ONES, OVERCOME THE SICKNESS OF HUNTINGTON'S DISEASE? ONE THING WE KNOW ALREADY WHEN YOU THINK OF PEOPLE QUALIFIED TO FIGHT HUNTINGTON'S, THERE THEY ARE, TOPNOTCH FOLKS, CHAMPIONS IN THE FIELD. SOME HAVE STUDIED HUNTINGTON'S FOR MORE THAN 30 YEARS. THEY EXAMINED THE POSSIBILITIES. THIS IS WHAT THEY BELIEVE WILL HELP.

I THANK THE BOARD FOR ITS ATTENTION. PLEASE GIVE THE EXPERT THE FUNDING THEY NEED TO CHALLENGE THIS VILE AND HATEFUL CONDITION. THANK YOU.

MR. SHEEHY: THANK YOU, MR. REED. WE HAVE ADDITIONAL PUBLIC COMMENT? THANK YOU.

DR. THOMPSON: MY NAME IS LESLIE THOMPSON AND I'M FROM UC IRVINE. IT'S OUR APPLICATION. AND AS YOU'VE HEARD IT AND HAVE HEARD OVER THE YEARS, HD IS UNRELENTING, PROGRESSIVE TO FINAL LIFE, AND THERE'S NOTHING THAT CHANGES THE COURSE OF DISEASE RIGHT NOW. I'VE WORKED ON THIS FOR 30 YEARS. I DO FEEL THIS IS VERY, VERY PROMISING. AND WE HAVE A LOT OF PROMISING PROSPECTS FOR TREATMENT, BUT WE DON'T HAVE ANYTHING NOW. AND THIS COULD BE

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SOMETHING THAT CAN BE LEVERAGED WITH THOSE EVEN IN COMBINATION POTENTIALLY.

SO WE PROPOSE TO USE THIS HUMAN STEM CELL-DERIVED PRODUCT. AS YOU'VE HEARD, IT'S HAD EXTENSIVE INVESTMENT, GUIDANCE FROM CIRM. WE'VE BEEN WORKING VERY CLOSELY WITH THE FDA, WITH AN INTERNATIONAL COLLABORATION OF INVESTIGATORS WHO ARE ALL THINKING ABOUT HOW TO BEST USE THIS TYPE OF APPROACH: IMMUNOLOGISTS, TRANSPLANT SURGEONS, OTHER INDIVIDUALS WHO EVEN HAVE PARTICIPATED IN FETAL CELL TRANSPLANTS PREVIOUSLY.

WE HAVE -- WE'D LIKE TO CARRY OUT THE PIVOTAL SAFETY TRIALS AND ALSO SAFETY STUDIES AND IND-ENABLING ACTIVITIES. WHAT WE DO KNOW ABOUT THIS IS THAT IT PROVIDES EXTENSIVE NEUROPROTECTION, REPLACES SOME OF THE FACTORS, NURSING FACTORS, THAT ARE LEFT IN THE DISEASE IN THREE DIFFERENT HUNTINGTON'S DISEASE MOUSE MODELS. AS YOU HEARD FROM DON, IT REDUCES THE FORMATION OF THIS TOXIC POISON THAT BUILDS UP IN THE BRAIN, AND THAT'S ONE OF THE MOST EXCITING THINGS TO US ABOUT THIS. IT DOES GET AT THE ROOT CAUSE OF HUNTINGTON'S DISEASE TO SOME DEGREE. DOESN'T CHANGE THE MUTATION, BUT IT DOES REDUCE THE FORMATION OF SOMETHING WE KNOW IS REALLY DEADLY. AND IT HAS THIS VERY ROBUST EFFECT

IN THREE MODELS.

WE WANT TO DELVE DEEPER INTO THE MECHANISM THAT'S INVOLVED AS PART OF THE CLIN1 ACTIVITIES. AND, AGAIN, I'VE REALLY COMMITTED MYSELF TO THIS, AND I FEEL THAT IS A VERY PROMISING APPROACH. AND REALLY THANK YOU FOR YOUR CONSIDERATION OF THE PROPOSAL. THANKS.

MR. SHEEHY: THANK YOU.

MS. SALDANA: THANK YOU FOR LETTING ME TAKE A FEW MINUTES OF YOUR TIME. MY NAME IS FRANCES SALDANA, HUNTINGTON'S DISEASE PATIENT ADVOCATE. I SPENT HALF OF MY LIFE FIGHTING AGAINST A DISEASE THAT HAS TERRORIZED MY FAMILY FOR GENERATIONS. THE DISEASE TOOK MY MOTHER-IN-LAW, THE FATHER OF MY CHILDREN, AND ALL THREE OF MY CHILDREN. THE DISEASE KILLS OUR MOMS, OUR DADS, OUR BROTHERS, SISTERS, AND OUR CHILDREN, AND IT DOES NOT DISCRIMINATE.

HUNTINGTON'S DISEASE HAUNTS ME EVERY DAY IN KNOWING THAT MY OWN GRANDCHILDREN ARE AT RISK TO INHERIT THE KILLER GENE. WE HAVE NO CURE OR EVEN A TREATMENT FOR HD, NOT EVEN SOMETHING TO SLOW IT DOWN. THOUGH THIS TRULY IS A STATE OF EMERGENCY FOR US, OUR FAMILY MEMBERS CONTINUE TO DIE. FURTHERMORE, HD FAMILY MEMBERS THAT HAVE STILL NOT BEEN TESTED LIVE IN UNCERTAINTY AND FEAR.

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BUT THE GOOD NEWS IS THAT HAVING A TREATMENT FOR HD IS NO LONGER JUST A FANTASY. IT IS WITHIN OUR REACH, AND HD FAMILIES CLING TO THAT HOPE THAT COMES FROM THE WORK OF OUR AMAZING SCIENTISTS. THROUGH THEIR ORGANIZED KNOWLEDGE AND TESTABLE EXPLANATION AND PREDICTION, THE HARD WORK OF SCIENTISTS HAS FINALLY PUT US IN THE CUSP OF TRULY HAVING A TREATMENT FOR HD. IT IS NOT, HOWEVER, ENOUGH TO PUT ALL OUR EFFORT INTO ONE TREATMENT OPTION. WE NEED TO TRY AS MANY OPTIONS AS POSSIBLE AS NOT DOING SO COULD MEAN THAT YET ANOTHER GENERATION OF HUNTINGTON'S DISEASE FAMILIES WILL LOSE THE FIGHT WHILE THE POSSIBLE TREATMENT WE LEAVE IN THE HD LAB WITHOUT EVER BEING DISCOVERED.

HD FAMILIES ECHO THE WORDS OF DR. STANLEY CROOKE, CEO OF IONIS PHARMACEUTICALS, WHO STATES THE FOLLOWING ABOUT HIS COMPANY, "OUR CULTURE IS BUILT ON OPEN SCIENCE AND AN ABSOLUTE AVERSION TO THE WORD "NO." A DESPERATE PATIENT WITH FEW OPTIONS FOR TREATMENT SHOULD NEVER HEAR THAT WORD.

MY DAUGHTER MARIE LOST THE FIGHT TO HD NINE YEARS AGO. MY SECOND DAUGHTER MARGIE ALSO LOST THE FIGHT TO HD FIVE YEARS AGO AND HER MEMORIAL IS COMING UP NEXT WEEK. AND MY SON MICHAEL, THE FIGHTER, LOST THE FIGHT, A LONG, DRAWN-OUT FIGHT

JUST A YEAR AGO. HE'S GONE; THEY'RE GONE, BUT TO ME THE PAIN IS AS FRESH AS IF IT JUST HAPPENED YESTERDAY.

MARGIE GAVE ME TWO BEAUTIFUL GRANDCHILDREN WHO ARE NOW AT RISK FOR HD. SHE WOULD HAVE GIVEN HER LIFE TO SAVE HER CHILDREN'S LIFE. SHE WOULD HAVE RISKED HER OWN LIFE, TRIED ANY NEW, ANY NEW, NOVEL THERAPY. IT WAS NOT AVAILABLE TO HER. WITHOUT A TREATMENT FOR HD, MY CHILDREN AND THOUSANDS OF OTHER HD FAMILIES WHO HAVE FOUGHT SO HARD WILL HAVE DIED IN VAIN AND MANY MORE WILL CONTINUE TO DIE. SO IN MEMORY OF MY CHILDREN AND ON BEHALF OF ALL HD FAMILY MEMBERS WHO ARE ANXIOUSLY AWAITING A TREATMENT, PLEASE FUND DR. THOMPSON'S THERAPEUTIC TRIAL FOR HUNTINGTON'S DISEASE. THANK YOU.

MR. SHEEHY: THANK YOU. MY HEART GOES OUT TO YOU. I CAN'T IMAGINE.

MS. SALDANA: I KNOW. I KNOW IT DOES.

MR. SHEEHY: SO I THINK WE'RE AT A POINT WHERE WE CAN TAKE A VOTE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

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MS. BONNEVILLE: STEVE JUELSGAARD.
DR. JUELSGAARD: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: NO.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: THANK YOU. THE MOTION

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CARRIES.

MR. SHEEHY: THANK YOU. AND I HOPE THIS HELPS.

MS. SALDANA: OH, IT DOES. THANK YOU SO MUCH.

MR. SHEEHY: AND I KNOW THIS, DR. THOMPSON'S WORK, HOW MANY YEARS NOW, SIX, EIGHT?

DR. THOMPSON: YEAH. IT'S BEEN AWHILE.

MR. SHEEHY: I HOPE WE HAVE IT IN TIME FOR YOUR GRANDCHILDREN.

DR. THOMPSON: THEY'RE VERY HOPEFUL. I KNOW -- REALLY, MY HOPE COMES FROM WHEN YOURS STARTS. THAT'S REALLY GOING TO HELP. SOMETHING IS ABOUT TO HAPPEN HERE. SO THANK YOU SO MUCH. THANK YOU.

MR. SHEEHY: OKAY. I THINK WE'RE BACK TO DR. PATEL FOR THE SECOND APPLICATION UNDER CONSIDERATION TODAY.

DR. PATEL: THANK YOU, MR. SHEEHY. SO THE SECOND APPLICATION IS CLIN2-11400. THIS IS A CLINICAL STUDY OF A THERAPY FOR RENAL FAILURE. THE THERAPY ITSELF IS DONOR HEMATOPOIETIC STEM CELL GRAFT PLUS DONOR T-CELLS AS WELL AS RECIPIENT EXPANDED T REGULATORY CELLS. I'LL EXPLAIN ALL THAT IN A LITTLE BIT.

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THE INDICATION ITSELF IS THESE ARE PATIENTS WHO HAVE KIDNEY DISEASE THAT REQUIRE KIDNEY TRANSPLANTATION. THE GOAL OF THIS PROJECT IS TO COMPLETE THE PHASE 1 STUDY. AND THEY'RE REQUESTING $11.9 MILLION OF FUNDING. THERE IS ZERO DOLLARS OF CO-FUNDING, AND THE MAXIMUM FUNDS ALLOWABLE FOR THIS CATEGORY IS ALSO $12 MILLION.

SO JUST A LITTLE BIT OF BACKGROUND ON THE IMPACT, VALUE PROPOSITION, AND WHY THIS IS ELIGIBLE FOR CIRM FUNDING. OVER A 100,000 NEW CASES OF KIDNEY FAILURE ARE REPORTED EACH YEAR, AND 17,000 KIDNEY TRANSPLANTS ARE PERFORMED ANNUALLY. HOWEVER, THERE IS A WAITING LIST OF A 100,000 PATIENTS ON THE TRANSPLANT LIST.

EVEN WITH IMPROVEMENTS IN IMMUNOSUPPRESSION REGIMENS, 50 PERCENT OF HLA MISMATCHED TRANSPLANTS ARE LOST TO CHRONIC REJECTION. AND THESE PATIENTS REQUIRE LIFELONG IMMUNOSUPPRESSION, WHICH CARRIES MANY RISKS, INCLUDING INFECTION, CARDIOVASCULAR DISEASE, AND DIABETES. THE PROPOSED THERAPY HERE AIMS TO ACHIEVE MIXED HEMATOPOIETIC CHIMERISM, SO THE DONOR KIDNEY PLUS THE DONOR HEMATOPOIETIC STEM CELLS ARE TRANSFUSED INTO THE PATIENT. AND THE INTENT HERE IS TO INDUCE LONG-TERM TRANSPLANT TOLERANCE AND TO

ELIMINATE THE NEED FOR IMMUNOSUPPRESSION. IT'S ELIGIBLE FOR CIRM FUNDING BECAUSE THE THERAPY ITSELF INCLUDES HEMATOPOIETIC STEM CELLS.

THERE ARE 2 OTHER RELATED CIRM PORTFOLIO PROJECTS IN THE CLINICAL STAGE THAT WE ARE FUNDING, AND THEY ALL HOPE TO ACHIEVE THE SAME OUTCOME, WHICH IS MIXED CHIMERISM IN THE PATIENT AS WELL AS TO ACHIEVE LONG-TERM KIDNEY TOLERANCE. AND THEY ALL KIND OF BUILD ON TOP OF EACH OTHER.

I'M GOING TO START WITH THE PHASE 3 TRIAL THAT WE ARE FUNDING. THE THERAPY ITSELF IS DONOR HEMATOPOIETIC STEM CELLS AND THE DONOR T-CELLS, AND THIS IS FOR HLA-MATCHED RECIPIENTS. WE'RE ALSO FUNDING A PHASE 1 TRIAL WHICH IS THE SAME DONOR HEMATOPOIETIC STEM CELL GRAFT AND DONOR T-CELLS, BUT IT IS FOR HLA-MISMATCHED RECIPIENTS. AND THE CURRENT APPLICATION UNDER REVIEW FOR YOU TODAY IS IN THAT SAME HLA-MISMATCHED POPULATION, BUT IT INCLUDES EXPANDED RECIPIENT T REGS, WHICH THE AIM HERE IS TO HELP THAT MIXED CHIMERISM -- IMPROVE THE SUCCESS RATE OF MIXED CHIMERISM WITH THE T REGS BEING INJECTED IN THE PATIENT AS WELL.

I HOPE THAT'S KIND OF CLEAR. I'M HAPPY TO ANSWER ANY QUESTIONS ABOUT THAT DURING THE DISCUSSION. AS NOTED, WE ARE FUNDING THE PHASE 1

TRIAL THAT IS DIRECTLY RELATED TO THIS PARTICULAR INDICATION AND ITS THERAPY, AND THAT IS AN ONGOING TRIAL WHICH IS EXPECTED TO CONCLUDE IN 2021.

THIS APPLICATION WAS REVIEWED BY THE GWG AND UNANIMOUSLY GOT A TIER I SCORE. THERE WERE 14 VOTES IN TIER I. THE CIRM TEAM CONCURS WITH THAT RECOMMENDATION TO FUND THIS APPLICATION FOR THE FULL AWARD AMOUNT OF 11,969,435.

MR. SHEEHY: THANK YOU, DR. PATEL. DO WE HAVE ANY QUESTIONS OR COMMENTS FROM BOARD MEMBERS? SENATOR TORRES.

MR. TORRES: YES. IT IS A LARGE AMOUNT, NO. 1. NO. 2, WHAT PARTICULAR GOALPOSTS ARE WE PUTTING ON THIS AWARD? IN OTHER WORDS, AT WHAT POINT DO WE DECIDE WE'VE GIVEN ENOUGH, FIRST QUARTER, TWO QUARTERS, NOW WE'RE GOING TO REDUCE THE AMOUNT, OR WE'RE GOING TO STOP THE GRANT. WHAT DO YOU ANTICIPATE -- I KNOW IT'S ALL SPECULATIVE -- BUT WHEN DO YOU ANTICIPATE THAT MIGHT OCCUR?

DR. PATEL: SO THE WAY THAT THESE AWARDS ARE MANAGED IS THAT OUR SCIENCE TEAM WORKS WITH THE APPLICANTS AND GRANTEES TO DEVELOP APPROPRIATE MILESTONES. OFTENTIMES THOSE MILESTONES ARE BASED ON ENROLLMENT, ENROLLING AT A PARTICULAR TIME AND A PARTICULAR RATE. SOMETIMES THERE COULD BE

MANUFACTURING OR OTHER MILESTONES IN THERE. FOR THIS TYPE OF AN AWARD, THE ASSUMPTION WOULD BE THAT IT WOULD BE BASED ON ENROLLMENT.

MR. TORRES: AND WHAT DO WE ANTICIPATE?

DR. PATEL: IN TERMS OF ENROLLMENT? JUST TO KIND OF CLARIFY A LITTLE BIT HERE, THIS PARTICULAR TRIAL IS BUILDING ON THE PREVIOUS PHASE 1 TRIAL THAT WE'RE FUNDING. IN THAT ONE THEY WERE ESCALATING THE DONOR T-CELL DOSE, AND THEY WERE NOT ACHIEVING THE TYPES OF CHIMERISM THAT THEY EXPECTED. SO HERE THEY'RE GOING TO ESCALATE THE RECIPIENT. T REG DOSE TO ACHIEVE CHIMERISM. SO THERE COULD BE SOME MILESTONES BASED AROUND THAT. AGAIN, THAT'S GOING TO BE A DISCUSSION BETWEEN THE GRANTEE AND SCIENCE OUR TEAM.

MR. TORRES: THANK YOU.

MR. SHEEHY: IS THERE SOME RECOVERY FROM THE PHASE 1? SO WHAT IS THE INTERSECTION THERE? SO YOU HAD THE PHASE 1. THAT'S NOT COMPLETE, RIGHT? IT COMPLETES IN 2021. SO THEY'RE NOT GETTING RESULTS. SO IT SOUNDS LIKE WHAT THEY'RE DOING NOW IS JUST ADDING THE T REGS TO THE COCKTAIL. SO I GUESS I'M TRYING TO FIGURE OUT HOW THOSE TWO ALIGN. WE'RE PAYING FOR TWO TRIALS THAT ARE RUNNING -- HAVE THE SAME INDICATION, AND IT SEEMS -- I'M TRYING TO

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UNDERSTAND HOW WE WOULD END UP PAYING FOR BOTH SIMULTANEOUSLY WHEN THEY'VE IDENTIFIED SOMETHING THAT WOULD MAKE THE PRODUCT BETTER. DOES THAT MAKE SENSE? I'M NOT ARTICULATING CLEARLY.

DR. PATEL: IT COULD POTENTIALLY IMPROVE THE RATE OF CHIMERISM. SO YOU CAN THINK OF THIS AS TWO INDEPENDENT ARMS OF A BROADER STUDY. ALL WOULD BE INFORMATIVE FOR HOW TO ADDRESS THIS PATIENT POPULATION WITH PARTICULAR THERAPIES AIMED AT ACHIEVING THIS CHIMERISM. SO BOTH OF THEM WOULD BE INFORMATIVE FOR THE OVERALL PROGRESSION OF THIS STEM THERAPY. BUT YOU ARE RIGHT, THAT WE DON'T HAVE FULL READOUT FROM THAT OTHER TRIAL YET. AND THIS IS GOING TO BE A STEPWISE IMPROVEMENT OVER THAT.

MR. SHEEHY: AND HOW MUCH IS LEFT REMAINING ON THE FIRST TRIAL? YOU PROBABLY DON'T KNOW THAT. IT'S NOT FAIR TO ASK THAT. WHAT'S THE AMOUNT THAT WAS FUNDED FOR THIS BECAUSE I THINK YOU DID HAVE THAT ON THE SLIDE, RIGHT? THE AMOUNT WE PUT INTO THAT.

DR. PATEL: I DON'T HAVE IT ON THIS SLIDE, BUT WE CAN GET THAT FOR YOU.

MR. SHEEHY: I THOUGHT -- OH, WE DON'T HAVE THE MONEY IN THERE.

DR. PATEL: YEAH, WE DON'T. I'LL PULL

THAT UP FOR YOU RIGHT NOW.

MR. SHEEHY: IS IT POSSIBLE THAT AT LEAST GRANTS MANAGEMENT, AND, AGAIN, JUST TRYING TO BE FISCALLY RESPONSIBLE, SOMETIME IF WE DO FUND THIS THAT WE'LL MAYBE SLOW THE FIRST TRAIN DOWN AND PUT EVERYTHING -- AND NOT NECESSARILY FUND THAT ALL THE WAY THROUGH? IF THIS IS CLEARLY SHOWING BETTER RESULTS IN ACHIEVING CHIMERISM, WOULD WE NOT -- ONE, WE COULD CONTINUE FUNDING THE FIRST TRIAL ALL THE WAY THROUGH.

DR. PATEL: THE QUESTION, I GUESS, YOU'RE ASKING IS IF THIS TRIAL IS SHOWING RESULTS, WHY WOULD WE CONTINUE TO FUND THE OTHER ONE? THE OTHER TRIAL, I HAVE THE NUMBERS. TO BE INFORMATIVE, IT'S $6.6 MILLION FOR THAT OTHER TRIAL, CLIN2.

WITH RESPECT TO HOW THOSE ARE BEING MANAGED IN TANDEM, WOULD YOU BE ABLE TO ANSWER THAT? SO DR. THOMPSON DOES GRANTS MANAGEMENT. DO YOU THINK YOU HAVE SITUATIONS WHERE YOU HAVE TWO RELATED AWARDS WHERE ONE IS IMPACTING DISBURSEMENT ON THE OTHER ONE?

MR. THOMPSON: I DON'T THINK WE'VE EVER ENCOUNTERED THAT SITUATION CURRENTLY OR HAVE EVER IN THE PAST ENCOUNTERED THAT. SO AS LONG AS THE AWARDEE IS IN FACT CONDUCTING THE PROJECT ACCORDING

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TO WHAT THEY PROPOSED AND WITHIN THE SCOPE AND IS EXECUTING ON THAT ACCORDING TO THEIR TIMELINES, AS LONG AS THEY'RE NOT SLIPPING BEHIND, THEN I IMAGINE WE WOULD CONTINUE WITH THAT. WE'VE HAD AWARDEES IN THE PAST DECIDE TO NO LONGER PURSUE A PROJECT FOR A THERAPY FOR BUSINESS REASONS AND FOR KIND OF BECAUSE THE FIELD IS GOING IN A DIFFERENT DIRECTION THAN THE PRODUCT, BUT WE HAVEN'T EVER TAKEN THAT ACTION BASED ON THE OUTCOME OF ANOTHER PROJECT.

MR. SHEEHY: SO ARE THEY MEETING THEIR MILESTONES RIGHT NOW?

MR. THOMPSON: THEY ARE.

MR. SHEEHY: I HEARD SOMEBODY ELSE. I DON'T WANT TO MONOPOLIZE.

DR. MARTIN: I WAS GOING TO ASK A TECHNICAL QUESTION. I PRESUME THAT THIS ONGOING PHASE 1 IS WHAT IN ONCOLOGY WOULD BE CALLED A PHASE 1B, AND THAT IS THESE ARE NOT NORMAL VOLUNTEERS. THESE ARE PATIENTS, RIGHT, AND THEY'RE JUST IN PHASE 1. THE GRANTS MANAGEMENT COMMITTEE CONSIDERED REQUESTING AN ADAPTIVE TRIAL ON THIS PHASE 1 SINCE THESE ARE PATIENTS IN THE CONTEXT OF IS IT POSSIBLE, WITHOUT GOING INTO DETAILS AND PROTOCOLS, TO MODIFY THE CURRENTLY FUNDED TRIAL SUCH THAT IT COULD GAIN OR TAKE ADVANTAGE OF THE PROPOSED DIFFERENCE IN

USING AUTOLOGOUS T REGS, WHICH I GATHER IS THE MAJOR DIFFERENCE, IN WHICH CASE IT WOULD BE AN ADAPTIVE TRIAL, SAME PROTOCOL EXCEPT FOR THE ADOPTION. AND IF IT'S AUTOLOGOUS T REGS, THAT SHOULD BE A REALLY, IN THEORY, MINIMAL REGULATORY HURDLE TO DO THAT.

DR. PATEL: THAT'S A GOOD COMMENT. HOWEVER, THE ROLE OF GWG ISN'T DISCONTINUING TRIALS, AND SO THAT'S WHAT WAS REVIEWED AND THAT'S WHAT'S PRESENTED TO YOU HERE. THAT'S SOMETHING THAT COULD POTENTIALLY BE CONSIDERED, BUT, AGAIN, THAT WAS NOT REVIEWED BY THE GWG.

MR. SHEEHY: DO WE HAVE OTHER QUESTIONS OR COMMENTS? I WONDER IF PART OF THIS MIGHT BE A DIRECTION TO THE CIRM TEAM TO MAYBE SPEED UP THE INTERFACE. OBVIOUSLY IF THIS SECOND PRODUCT IS PRODUCING BETTER RESULTS, THAT WOULD OBVIATE THE NEED FOR THE FIRST TRIAL, RIGHT? AND SO THAT PROBABLY SHOULDN'T BE LEFT UP TO THE GRANTEE. YOU KNOW, WHERE WE ARE FINANCIALLY THESE DAYS, I THINK -- I DON'T KNOW. IS THAT ACCEPTABLE, DR. MILLAN?

DR. MILLAN: GABE THOMPSON ARTICULATED THERE IS A CONTRACT IN PLACE FOR THE FIRST AWARD THAT'S BEING REFERRED TO. AND SO THAT IS INDEPENDENT OF THIS AWARD. HOWEVER, WHEN ONE

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EVALUATES IT FROM THE INVESTIGATIVE PERSPECTIVE, I THINK THERE'S AN OPPORTUNITY WITH OUR SCIENCE TEAM AND OUR CLINICAL ADVISORY PANEL REGARDING THE RESULTS OF BOTH TRIALS IN TERMS OF CRAFTING THE BEST PATH FORWARD INFORMED BY BOTH TRIALS TO WHAT THE NEXT DEVELOPMENT STAGE WOULD BE FOR THE PRODUCT, WHETHER IT WOULD BE -- THEY MAY FIND FROM THE DATA THERE WOULD BE A SUBSET OF PATIENTS THAT ARE MORE SUITABLE FOR ONE APPROACH AND ANOTHER SUBSET THAT WOULD BE SUITABLE FOR ANOTHER APPROACH, OR THEY MAY FIND FROM THE DATA THAT THE FIRST TRIAL MAY GIVE EQUIVALENT RESULTS. SO WE DON'T KNOW THE ANSWER -- WE DON'T KNOW THE ANSWER UNTIL THE INVESTIGATORS HAVE A CHANCE TO DO THE CLINICAL TRIAL.

MR. SHEEHY: THANK YOU, DR. MILLAN. DO WE HAVE ANY OTHER QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD?

DR. MARTIN: DO YOU KNOW WHETHER THERE IS AN INTERIM LOOK SCHEDULED ON THIS EXISTING PHASE 1 TRIAL EVEN IF THE SLIDE DIDN'T?

DR. MILLAN: I'M GOING TO HAVE DR. TALIB, IF THAT'S OKAY, WHO'S A SCIENCE OFFICER MANAGING THE AWARD, RESPOND TO THAT, WHATEVER CAN BE DISCLOSED IN PUBLIC ABOUT THE TRIAL.

DR. TALIB: COUPLE OF COMMENTS. THE FIRST

CLINICAL TRIAL, WHICH IS ONGOING, IS, AGAIN, WE HAVE MILESTONES BASED ON CLINICAL TRIAL. WE'LL BE MONITORING THOSE CLINICAL TRIALS, HOW THEY'RE RESPONDING. SO THEY'RE MEETING THEIR MILESTONES. AND THERE IS A DIFFERENCE FROM THE FIRST CLINICAL TRIAL WHICH IS GOING ON. THERE'S A DOSE ESCALATION OF CD3D CELLS. SO THERE'S A DIFFERENCE. THESE ARE TWO INDEPENDENT CLINICAL TRIALS.

IN FIRST CLINICAL TRIAL, THEY'RE INCREASING THE CD3 T-CELL DOSE AND SEE WHETHER THEY CAN INCREASE THE CHIMERISM. SO RIGHT NOW AT THE MOMENT THEY'RE NOT SEEING VERY STABLE CHIMERISM, BUT THAT CLINICAL TRIAL NEEDS TO PROCEED IN TERMS OF INCREASING THE CD3 DOSE. SO IT'S POSSIBLE THAT THE FIRST CLINICAL TRIAL MIGHT SHOW THE RESULT. THEREBY, INCREASING THE CD3 DOSE, THEY MIGHT GET TO CHIMERISM.

THE SECOND CLINICAL TRIAL IS DIFFERENT. IN THERE THEY'RE ADDING THE T REG TO INCREASE THE CHIMERISM. SO IT'S POSSIBLE THAT WHAT WE LEARN FROM THE PHASE 1 CLINICAL TRIAL INDEPENDENTLY COULD INFORM ON THE DESIGN OF THE NEXT CLINICAL TRIAL. SO THESE TWO CLINICAL TRIALS ARE INDEPENDENT, AND THEY'RE BOTH FORMING A BOND HOW WE CAN MAKE THIS KIDNEY TRANSPLANT.

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IN TERMS OF THE INTERIM, IN TERMS OF THE INTERIM ANALYSIS, SO THEY'RE ANALYZING THE DATA AS THE CLINICAL TRIAL IS PROGRESSING. SO CLEARLY THE DATA WHICH IS COMING OUT, BECAUSE THE DATA IS AFTER 12 MONTHS, HOW MUCH CHIMERISM HAVE YOU RECEIVED AND CAN YOU REDUCE THE IMMUNOSUPPRESSION. THAT IS THE PURPOSE OF THIS CLINICAL TRIAL. CAN YOU TAKE OFF THE IMMUNOSUPPRESSION FROM THIS CLINICAL TRIAL. SO THAT DATA WILL BE AVAILABLE AT THE END OF THE 12 MONTHS. THIS CLINICAL TRIAL IS ONGOING. SO WE WILL LEARN AT THE END OF THIS YEAR WHETHER THE FIRST PATIENTS WHICH HAVE BEEN TREATED, THOSE WHICH HAVE ACHIEVED CHIMERISM, WHETHER THEY ARE ABLE TO MAINTAIN IT.

SO, YES, BY THE END OF THIS YEAR, WE WILL LEARN FROM THE FIRST CLINICAL TRIAL WHAT THE INTERIM DATA LOOKS LIKE.

MR. SHEEHY: ADDITIONAL QUESTIONS, COMMENTS? DO WE HAVE ANY PUBLIC COMMENT? CAN WE GO TO A VOTE? WE HAVE A MOTION, YEAH. NO. SORRY ABOUT THAT. I USUALLY DO THAT FIRST THING.

IS THERE A MOTION TO ACCEPT THE TEAM'S RECOMMENDATION?

CHAIRMAN THOMAS: SO MOVED.

MR. SHEEHY: MADE BY CHAIRMAN THOMAS. IS

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THERE A SECOND?

DR. HIGGINS: I SECOND IT.

MR. SHEEHY: OKAY. SECONDED BY DAVID HIGGINS. WOULD YOU LIKE TO CALL THE ROLL?

MS. BONNEVILLE: SURE.

ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: DAVE MARTIN.

DR. MARTIN: NO.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: ABSTAIN.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

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MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: NO.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: I ABSTAIN.
MS. BONNEVILLE: JUST A SECOND. THE MOTION CARRIES.
MR. SHEEHY: MOTION CARRIES.
SO THE NEXT APPLICATION, DR. PATEL.
DR. PATEL: THANK YOU, MR. SHEEHY. THE LAST APPLICATION UP FOR CONSIDERATION TODAY IS CLIN2-11431. THIS IS A CLINICAL STUDY OF A THERAPY FOR SEVERE COMBINED IMMUNODEFICIENCY. THE THERAPY ITSELF IS TWO PARTS. THERE'S A CONDITIONING REGIMEN AGENT, ANTI-TD117 ANTIBODY, FOLLOWED BY A PURIFIED ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION. THE GOAL IS TO COMPLETE THE PHASE 1 TRIAL IN SEVERE COMBINED IMMUNODEFICIENCY PATIENTS. THEY'RE REQUESTING FIVE POINT -- ESSENTIALLY $6 MILLION OF FUNDING WITH ZERO DOLLARS CO-FUNDING. THE MAXIMUM FUNDS ALLOWABLE FOR THIS PARTICULAR CATEGORY IS $12 MILLION.

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SO SCID IS A RARE DISEASE AFFECTING AN ESTIMATED ONE IN 58,000 INFANTS IN THE U.S. EACH YEAR. AND IT'S ACTUALLY DISPROPORTIONATELY AFFECTING THE NAVAJO POPULATION. UNTREATED, SCID PATIENTS WILL LIKELY DIE BEFORE REACHING THE AGE OF TWO. AN ALLOGENEIC HSC TRANSPLANTATION, WHICH IS THE CURRENT STANDARD OF CARE, IS CURATIVE IN 94 PERCENT OF INFANTS WHO HAVE BEEN SCREENED AND TREATED WITHIN THREE MONTHS OF BIRTH.

COULD EVERYONE PLEASE MUTE THEIR LINE? THANK YOU.

SO GIVEN THE ALLOGENEIC HSC TRANSPLANTATION IN THE STANDARD OF CARE, THERE ARE TWO MAJOR RISKS ASSOCIATED WITH THAT PARTICULAR TREATMENT. THE FIRST IS THAT THE SCID INFANTS THEMSELVES ARE VULNERABLE TO TOXICITY FROM THE CONDITIONING REGIMEN, WHICH TENDS TO BE HIGHLY DESTRUCTIVE AND, SECONDLY, THE ALLOGENEIC HSC TRANSPLANTATION ITSELF COULD INDUCE GRAFT VERSUS HOST DISEASE IN THIS PATIENT POPULATION.

THE PROPOSED TREATMENT SEEKS TO CORRECT BOTH THESE LIMITATIONS, FIRST WITH A NOVEL, TARGETED CONDITIONING AGENT, AND, SECONDLY, THE PURIFIED HSC GRAFT. AND IT SHOULD BE NOTED THAT THE CONDITIONING AGENT ITSELF HAS MANY -- COULD BE APPLICABLE IN

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TREATMENTS INVOLVING HEMATOPOIETIC TRANSPLANTS, EITHER AUTOLOGOUS OR ALLOGENEIC, FOR VARIOUS BLOOD DISEASES. THIS IS ELIGIBLE FOR CIRM FUNDING BECAUSE IT INVOLVES BOTH TARGETING OF ENDOGENOUS HSC AS WELL AS TRANSPLANTATION OF ALLOGENEIC HSC.

SO I HAVE A SLIDE PREPARED ABOUT RELATED CIRM PORTFOLIO PROJECTS WITH LOTS OF CLARIFICATIONS HERE. SO WE ARE FUNDING THREE OTHER SCID THERAPIES THAT ARE MEANT TO BE CURATIVE. ALL THREE OF THESE ARE GENE-MODIFIED AUTOLOGOUS HSC THERAPIES FOR DIFFERENT VARIANTS OF SCID, INCLUDING X-SCID, ADA-SCID, AND ART SCID. AND THEY'RE ON HERE BECAUSE THE INITIAL INDICATION FOR THIS -- INITIAL TARGET FOR THIS PARTICULAR THERAPY IS IN THAT SCID POPULATION AND FOR IT TO BE CURATIVE. HOWEVER, THE CONDITIONING AGENT ITSELF, THE ANTI-CD117 ANTIBODY, AS I MENTIONED PREVIOUSLY, IS BROADLY APPLICABLE IN OTHER BLOOD DISEASES, AND WE'RE NOT FUNDING ANY SIMILAR PROJECTS THAT ARE DEVELOPING NOVEL CONDITIONING AGENTS FOR THAT BLOOD DISEASE.
WE HAVE PREVIOUSLY FUNDED THIS PROJECT. IT'S A PHASE 1 STUDY THAT IS ONGOING AND EXPECTED TO COMPLETE IN 2020. THE GWG REVIEWED THIS APPLICATION AND GAVE IT A SCORE OF 1. THERE WERE NINE VOTES IN TIER I, SIX VOTES IN TIER II, AND ZERO VOTES IN TIER

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III. AND THE CIRM TEAM CONCURS WITH THE GWG RECOMMENDATION TO FUND THIS APPLICATION FOR THE AWARD AMOUNT REQUESTED, WHICH IS 5,999,984.

MR. SHEEHY: THANK YOU, DR. PATEL. SO HOW MUCH HAS THIS PROJECT RECEIVED FROM CIRM?

DR. PATEL: THE INITIAL AWARD AMOUNT ON THAT PREVIOUS PROJECT WAS $20 MILLION. AND TO DATE I BELIEVE WE HAVE DISBURSED $18 MILLION.

MR. SHEEHY: SO QUESTIONS OR COMMENTS FROM BOARD MEMBERS?

DR. JUELSGAARD SO WHEN THE INITIAL APPLICATION WAS MADE FOR FUNDING THIS PHASE 1 STUDY, AND THAT'S THE $20 MILLION YOU JUST SPOKE TO, DO YOU KNOW, WAS THE EXPECTATION THAT THEY WERE GOING TO BE ABLE TO COMPLETE THE PHASE 1 WITH THAT GRANT, OR WAS THE EXPECTATION AT THAT TIME THAT THEY WERE GOING -- AND I KNOW WE HAD A $20 MILLION CAP -- WAS THE EXPECTATION THAT THEY WOULD NEED TO COME BACK AND ASK FOR MORE MONEY?

DR. PATEL: JUST TO CLARIFY, THAT INITIAL AWARD WAS A DISEASE TEAM AWARD, WHICH FUNDED LONGITUDINAL WORK ALL THE WAY FROM DISCOVERY UP TO THE PHASE 1 TRIAL THAT INCLUDED IND-ENABLING WORK AS WELL AND COMPLETION OF THE PHASE 1 TRIAL.

DR. JUELSGAARD ALL RIGHT. FINE. BUT MY

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QUESTION STILL STANDS. DID THEY THINK THEY WERE GOING TO BE ABLE TO COMPLETE THE PHASE 1 WITHIN THAT FUNDING, OR DID THEY CONTEMPLATE THEY WOULD HAVE TO COME BACK AND ASK FOR MORE, WHICH THEY HAVE DONE?

DR. PATEL: AS PROPOSED AND APPROVED FOR THAT PRIOR AWARD, YES, THAT THE PHASE 1 TRIAL WOULD BE COMPLETED WITHIN THAT AMOUNT.

DR. JUELSGAARD AND SO THEY WEREN'T ABLE TO COMPLETE IT WITHIN THAT AMOUNT, AND DO WE KNOW WHY?

DR. PATEL: YES. SO THERE WERE ENROLLMENT CHALLENGES WHICH DELAYED THE PROJECT.

DR. JUELSGAARD WELL, DELAY DOESN'T NECESSARILY ADD UP TO MORE MONEY. THEY OBVIOUSLY SPENT THE MONEY ON SOMETHING THAT THEY DIDN'T ANTICIPATE OR UNDERBUDGETED OR SOMETHING. THERE'S SOMETHING MORE TO IT. SO DO YOU KNOW EXACTLY WHAT THAT IS?

MR. THOMPSON: THIS IS GABRIEL THOMPSON. SO THE DISEASE TEAM II ROUNDS FUNDED BOTH IND-ENABLING AND THE CONDUCT OF THE INITIAL PHASE TRIAL. THIS PROJECT DID INCUR MORE COST TO GET TO THE IND FILING. AND SO THERE WAS A SET ASIDE UNDER THAT AWARD TO $5.5 OF THAT $20 MILLION AWARD TO CONDUCT THE PHASE 1 TRIAL. AND SO -- BUT THIS WAS

KIND OF UNIQUE TO THE DISEASE TEAM TO PROGRAM WHERE WE ARE FUNDING A WHOLE SET OF ACTIVITIES AND TRYING TO STAY ON TARGET.

DR. JUELSGAARD: ALL RIGHT. WELL, MY ONLY CONCERN IS THAT PEOPLE MANAGE THEIR BUDGETS APPROPRIATELY. I THINK WHEN YOU ESTABLISH A BUDGET TO DO SOMETHING, YOUR FIRST OBJECTIVE IS TO TRY AND STAY WITHIN THAT BUDGET. AND IF YOU CAN'T, THEN THERE NEEDS TO BE A GOOD REASON TO UNDERSTAND WHY YOU CAN'T. AND I'M HOPEFUL THAT WHEN THESE GET BROUGHT FORWARD AND THE BUDGET TARGET WASN'T MET, THAT WE TRULY UNDERSTAND WHY THAT WAS THE CASE AND THAT WE FEEL THAT THEY'VE SPENT THE MONEY WISELY. IT WAS JUST UNFORTUNATE THAT THEY WEREN'T ABLE TO MEET THEIR BUDGET TARGETS. HENCE MY QUESTIONS.

MR. SHEEHY: I HAVE A RELATED QUESTION. I THINK IT'S ONE OF THE REASONS THEY HAVE SIX IS THAT THE BUDGET THAT THEY'RE PRESENTING ACTUALLY WILL NOT ALLOW THEM TO COMPLETE THE PROJECT. SO THEIR LOT EXPIRES, THE PRODUCT LOT EXPIRES IN 2020. THEY RUN OUT IN 2020, AND THEY NEED TO RAISE ANOTHER ADDITIONAL 2.9 MILLION IN ORDER TO GET A NEW LOT OF THE PRODUCT PRODUCED. THEY HAVE A LETTER THAT THEY'RE WORKING WITH TO GET CIRM FUNDING, BUT THEY ACTUALLY DON'T HAVE THE MONEY TO COMPLETE THE TRIAL.

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AND GIVEN THAT ENROLLMENT HAS BEEN AN ISSUE, THAT'S A CONCERN. THERE SEEMS TO BE ONGOING BUDGET ISSUES ANYWAY.

THE OTHER CONCERN IS THAT WE UNLIKELY, GIVEN OUR PRESENT TRAJECTORY, HOPEFULLY WE HAVE AN EXTENSION OF PROPOSITION 71, BUT IF THAT WERE NOT TO HAPPEN, I'M NOT SURE HOW THIS PROJECT GETS COMPLETED. SO THERE'S AMBIGUITY. IT'S GOOD SCIENCE, I THINK, BUT IT JUST -- THE FUNDING ISSUES ARE PROBLEMATIC. AND I PERSONALLY WOULD NOT BE COMFORTABLE FUNDING THIS UNTIL THERE'S SOME RESOLUTION OF THAT. AND I THINK THIS SHOULD HAVE COME OUT OF THE TWO UNTIL WE CAN GET RESOLUTION. THEY STILL HAVE $2 MILLION LEFT. SO WE'RE NOT STOPPING THEM IN THEIR TRACKS.

CHAIRMAN THOMAS: I'D LIKE TO ASK A QUESTION OF GABE THOMPSON. DO THEY HAVE ENOUGH OF THE ANTIBODY AVAILABLE TO COMPLETE THE TRIAL? THAT'S SORT OF GETTING TO THE BOTTOM OF MR. SHEEHY'S QUESTION.

MR. SHEEHY: THEY SAY THAT THEY DON'T.

DR. PATEL: I THINK THIS IS ALSO NOTED IN THE LETTER. IT'S ON A STABILITY PROGRAM SO THEY CAN EXTEND THE EXPIRATION DATE FOR THE ANTIBODY. THEY HAVE ENOUGH SUPPLY TO FUND THE TRIAL, BUT THEY HAVE

TO DO A STABILITY PROGRAM TO SHOW THE ANTIBODY IS STABLE AS THEY'RE ENROLLING PATIENTS. AND THEY BELIEVE THAT THEY CAN EXTEND THE SHELF LIFE OF THIS PARTICULAR ANTIBODY TO ENROLL THE PATIENTS THEY NEED TO FOR THIS PARTICULAR TRIAL. AND THAT'S A COMMON PRACTICE IN BIOLOGICS DISCOVERY WHERE YOU DO HAVE THIS KIND OF LOT THAT IS BASICALLY FURTHER AHEAD THAN THE CURRENT LOT THAT THEY'RE USING, AND THEY USE THAT TO JUST BASICALLY KNOW IF THAT PRODUCT CAN BE STABLE WHEN THEY USE IT.

MR. SHEEHY: THEY STATE WE ANTICIPATE IN THE FUTURE BEYOND 2020 A NEW LOT OF AMG-191 WILL HAVE TO BE PRODUCED. DO WE ANTICIPATE THEM COMPLETING THE TRIAL IN THAT TIME?

DR. PATEL: THE WAY THEY PROPOSE IT IS THAT THEIR CURRENT LOT WITH THE STABILITY TESTING PROGRAM THEY HAVE GOING WOULD ALLOW THEM TO ENROLL THOSE PATIENTS. NOW, WHETHER THAT IS --

MR. SHEEHY: THAT ISN'T WHAT THEY SAID IN THE APPLICATION. THAT STATEMENT HAS BEEN REVIEWED BY THE GRANTS WORKING GROUP.

DR. PATEL: SO THERE WERE CONCERNS RAISED BY THE GRANTS WORKING GROUP ABOUT ENROLLMENT AS WELL AS THE STABILITY OF THE ANTIBODY, BUT I'M BASICALLY SYNTHESIZING BOTH THAT AS WELL AS WHAT WAS PROVIDED

BY THE APPLICANT.

CHAIRMAN THOMAS: DR. PATEL, NOT TO GET OVERLY TECHNICAL, BUT HAS THERE BEEN EVIDENCE OF INSTABILITY OF THE ANTIBODY TO DATE, AND IS THAT SOMETHING THAT IN THE ORDINARY COURSE ONE WOULD EXPECT?

DR. PATEL: THERE HAS NOT BEEN EVIDENCE OF THAT TO DATE FOR THIS PARTICULAR ANTIBODY.

DR. MARTIN: ANOTHER TECHNICAL QUESTION. IS IT FROZEN? IS THAT HOW THEY'RE STORING IT, MINUS 20 OR MINUS 80?

DR. PATEL: YES, IT'S FROZEN.

DR. MARTIN: THEN IT'S GOING TO BE STABLE. THAT EXTENSION IS FAIRLY EASY TO MANAGE IF IT'S FROZEN PROPERLY.

MR. SHEEHY: OTHER COMMENTS OR QUESTIONS?

MR. TORRES: YES. SO WHAT IS THE ALTERNATIVE IF WE WERE NOT TO FUND IT TODAY?

MR. SHEEHY: I WOULD SEND IT BACK TO THE GRANTS WORKING GROUP. FOR ME PERSONALLY, I'D LIKE TO SEE THE FINANCING FOR THE REST OF THE TRIAL SECURED.

MR. TORRES: THE TIME FRAME -- AS I SEE IT, THE TIME FRAME THAT YOU ARE OFFERING IS NOT GOING TO JEOPARDIZE THE PROJECT. THEY STILL HAVE,

WHAT, TWO MILLION LEFT?

DR. PATEL: THERE IS, I THINK, ABOUT TWO, TWO AND A HALF MILLION UNDER THE CURRENT AWARD. IT ALSO HAS -- THE CURRENT AWARD ALSO HAS CO-FUNDING REQUIREMENTS ON IT.

MR. TORRES: ARE THEY FULFILLED OUT?

DR. PATEL: THEY FULFILLED INITIAL CO-FUNDING REQUIREMENTS, BUT THOSE ARE SPREAD OUT THROUGH THE REMAINDER OF THE DURATION, AND THAT IS -- ADDITIONAL CO-FUNDING HASN'T COME FORWARD YET.

MR. SHEEHY: THE OTHER THING IS THIS IS A VERY COMMERCIALIZABLE PRODUCT. SO WE'RE IN PHASE 1. WE'VE GOT PATIENT DATA. I JUST WOULD LIKE TO SEE SOME ACCELERATION FOR ITS COMMERCIALIZATION. JUST BECAUSE IT'S AN ANTIBODY, IT'S GOING TO BE A COMMERCIAL PRODUCT IF IT'S SUCCESSFUL. SO I DON'T KNOW. THE INDUSTRY PEOPLE HAVE A BETTER SENSE OF THIS THAN I DO.

DR. JUELSGAARD: I HAVE A DIFFERENT QUESTION, JUST TO BACK UP TO THE COMMENT THAT WAS MADE ABOUT CO-FUNDING. SO THE $20 MILLION HAD A CO-FUNDING COMPONENT TO IT; IS THAT RIGHT?

DR. PATEL: THAT'S CORRECT.

DR. JUELSGAARD: AND WHAT WAS THE AMOUNT OF THE CO-FUNDING?

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DR. PATEL: AROUND FOUR TO FIVE MILLION, SOMEWHERE IN THAT RANGE. I DON'T KNOW THE EXACT NUMBER.

DR. JUELSGAARD: THAT'S FINE. SO DID SOMEONE THEN SAY THAT THEY HAVEN'T BEEN ABLE TO RAISE THE CO-FUNDING?

DR. PATEL: THEY HAVE RAISED INITIAL CO-FUNDING, BUT THERE IS ADDITIONAL CO-FUNDING REQUIREMENTS AS THEY ACHIEVE -- AS THEY GO FURTHER AND ACHIEVE MILESTONES. THAT HASN'T BEEN RAISED YET.

DR. JUELSGAARD: I SEE. SO THEY'RE STILL ON THE CO-FUNDING TRACK. IT ISN'T THAT THEY HAVEN'T BEEN ABLE TO ACHIEVE THE CO-FUNDING THAT THEY WERE PUT TO DO, BUT RATHER THE CO-FUNDING IS DETERMINED UPON BENCHMARKS THAT HAVEN'T YET BEEN MADE?

DR. PATEL: THAT'S CORRECT, STEVE.

DR. JUELSGAARD: I'M JUST CURIOUS. HOW FAR THIS 20 MILLION -- WHERE ARE THEY LIKELY TO ACHIEVE THE NEXT CO-FUNDING LEVEL AND HOW MUCH WOULD THAT BE?

DR. PATEL: I'M NOT EXACTLY SURE WHEN IT WOULD BE.

DR. JUELSGAARD: HERE'S THE CONCERN I HAVE, AND THAT IS THEY'RE ASKING FOR CLOSE TO SIX

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MILLION. AND THAT IF WE GIVE THEM THE SIX MILLION, IT'S GOING TO TAKE THE PRESSURE OFF THEM TO RAISE THE CO-FUNDING, RIGHT, BECAUSE THE MONEY NO LONGER WENT TO THE SAME POT. UNLESS THEY ULTIMATELY RAISE THE CO-FUNDING, IT CERTAINLY GIVES THEM A LOT OF BREATHING ROOM.

MY CONCERNS RELATE MOSTLY TO HOW THEY'RE BUDGETARILY HANDLING ALL OF THIS STUFF, AND IT'S NOT CLEAR TO ME THAT THEY'RE BEING FRUGAL WITH THE MONEY THAT THEY HAVE BEEN GIVEN. SO I'M JUST TRYING TO GET A BETTER HANDLE ON THAT.

DR. PATEL: THERE IS -- THE NEXT CO-FUNDING MILESTONE IS ABOUT 1.6 MILLION, I BELIEVE. AND WE EXPECT THE NEXT MILESTONE TO BE ACHIEVED SOMETIME IN THE SPRING, THIS SPRING.

MR. SHEEHY: WHO'S PROVIDING THE CO-FUNDING? IS IT COMMERCIAL?

DR. PATEL: THE INITIAL CO-FUNDING WAS PROVIDED BY THE AWARDEE INSTITUTION.

MR. SHEEHY: THAT'S GOING TO BE ADDITIONAL CO-FUNDING WILL BE FROM THE AWARDEE INSTITUTION?

DR. PATEL: NOT NECESSARILY.

MR. SHEEHY: AND THEN WE HAVE THIS OTHER ENTITY THAT THEY'RE TARGETING -- THEY'RE CHANGING MANUFACTURING. THEY'RE NO LONGER -- THEY'RE MOVING

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TO A NEW MANUFACTURER NO MATTER WHAT, RIGHT? THAT'S WHAT IT SAYS IN THE APPLICATION, THAT THEY'RE MOVING TO A NEW MANUFACTURER. AND THE ENTITY THAT'S GOING TO PROVIDE -- THAT THEY HOPE TO SET UP TO PROVIDE THE FUNDING TO MOVE TO A NEW MANUFACTURER, WHAT'S THE RELATIONSHIP BETWEEN THEM AND OTHER SOURCES OF CO-FUNDING? I JUST THINK THERE'S A FINANCIAL -- FINANCIALLY IT SEEMS VERY MUDDY TO ME. AND WE'VE GIVEN $20 MILLION FOR A PRODUCT THAT WAS ALREADY DEVELOPED, RIGHT? WE DIDN'T HAVE TO DISCOVER THE PRODUCT; WE JUST HAD TO APPLY IT. AMGEN ACTUALLY IS MANUFACTURING THE PRODUCT NOW, RIGHT?

DR. PATEL: AMGEN MANUFACTURED THAT LOT AND THAT'S WHAT THEY HAVE BEEN USING.

DR. HIGGINS: I HAVE A QUESTION WHEN I CAN FIT IN. IS NOW A GOOD TIME?

MR. SHEEHY: YEAH, DAVID, GO AHEAD.

DR. HIGGINS: I WAS JUST -- JUST TO FOLLOW UP ON WHAT JEFF IS SAYING OR I THINK HE'S LEANING TOWARD, CAN YOU VOTE NEITHER A ONE OR A THREE? CAN YOU ESSENTIALLY KIND OF VOTE A TWO? IN OTHER WORDS, IF YOU ANSWER SOME OF THESE QUESTIONS, YOU CAN COME BACK TO US. NOT GO BACK TO GWG, BUT CAN IT JUST COME BACK TO THE COMMITTEE HERE? I DON'T KNOW IF THERE'S A PRECEDENT FOR THAT OR IF THAT'S EVEN

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POSSIBLE.

MR. SHEEHY: JAMES.

MS. BONNEVILLE: HE'S GOING TO KILL ME FOR LETTING YOU KNOW THAT HE'S ON THE LINE.

MR. SHEEHY: I KNOW. YOU JUST PULLED A THREAD.

MR. HARRISON: SO, DAVID, IN ANSWER TO YOUR QUESTION, THE APPLICATION REVIEW SUBCOMMITTEE CAN TAKE ANY ACTION IT WANTS. IN OTHER WORDS, IT COULD ESSENTIALLY VOTE TO DELAY CONSIDERATION OF THIS APPLICATION UNTIL IT RECEIVES ADDITIONAL INFORMATION. IT COULD ASK THE GWG TO CONSIDER NEW INFORMATION. IT COULD TAKE ANY NUMBER OF STEPS SHORT OF EITHER APPROVING IT FOR FUNDING OR DECLINING TO FUND IT.

DR. HIGGINS: IS THERE A MOTION ON THE TABLE? WOULD WE HAVE TO MAKE THAT AS A SEPARATE MOTION TO MODIFY IT THAT WAY?

MR. SHEEHY: THERE'S NO MOTION AT THIS POINT.

DR. HIGGINS: OKAY. GOTCHA.

MR. TORRES: WELL, THEN, LET'S MOVE IT TO THE RECOMMENDATION THAT OUR COUNSEL SUGGESTED, AND THAT IS TO DELAY.

MR. SHEEHY: YEAH. I THINK THE OTHER

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THING IS TOO BECAUSE WE HAVE, WHAT, ONE AND A HALF LEFT ON THE ORIGINAL AWARD. WE HAVE ANOTHER 1.6 COMING IN FOR CO-FUNDING, PERHAPS OTHER CO-FUNDING. COULD WE JUST GET ALL THE BUDGETING ALIGNED AND TRY TO BE AS -- I GUESS THAT'S HOW I WOULD HOPE THE MOTION WOULD BE FRAMED SO THAT WE ARE THE MOST CONSERVATIVE IN HOLDING ON TO CIRM FUNDS FOR OTHER PROJECTS AS WE GO FORWARD, AND MAYBE WE CAN ACCELERATE COMMERCIAL PARTNERSHIPS. OR IT SOUNDS LIKE A COMPANY IS BEING THOUGHT OF AS BEING FORMED. WHATEVER THAT COMMERCIAL ENTITY, TO KIND OF TAKE THIS OFF OUR HANDS, IF POSSIBLE, AT THE LOWEST POSSIBLE COST.

MR. TORRES: THESE OBVIOUSLY NEED TO BE EXPLORED, NO. 1. NO. 2, I DON'T THINK IT'S A GOOD MOVE TO SEND IT BACK TO THE GWG.

MR. SHEEHY: YEAH. I DON'T THINK IT'S A GWG ISSUE.

MR. TORRES: SO MY MOTION, AGAIN, IS TO -- FOR US TO DELAY UNTIL THESE QUESTIONS ARE ANSWERED APPROPRIATELY TO OUR SATISFACTION.

DR. HIGGINS: I AGREE, ART.

MR. SHEEHY: DO I HAVE A SECOND?

MR. HARRISON: AS I UNDERSTAND IT, THE MOTION IS TO DELAY CONSIDERATION OF CLIN2-11431

UNTIL ADDITIONAL BUDGET INFORMATION IS PROVIDED BY THE CIRM TEAM AND THE APPLICANT TO THE APPLICATION REVIEW SUBCOMMITTEE.

MR. SHEEHY: IF I CAN MAKE A FRIENDLY AMENDMENT, ALSO A CLEAR PATH TO COMMERCIALIZATION AND PARTNERING WITH THE COMMERCIAL ENTITY.

MR. TORRES: I ACCEPT THAT FRIENDSHIP.

MR. SHEEHY: IS THAT OKAY WITH YOU TOO, DAVID?

DR. HIGGINS: YES, ABSOLUTELY. ENTHUSIASTICALLY, YES.

MR. SHEEHY: OKAY. ANY OTHER BOARD COMMENT OR QUESTIONS? DO WE HAVE PUBLIC COMMENT?

DR. SHIZIRU: JUDY SHIZIRU. I'M THE PI ON THE DISEASE TEAM AWARD, AND I'M THE PI ON THIS ONE. I WANT TO START OUT BY THANKING CIRM FOR SUPPORTING THIS PROGRAM OVER THE YEARS. IT HAS BEEN AN EXCITING AND VERY GRATIFYING EXPERIENCE TO BE ABLE TO TAKE A CONCEPT FROM MICE ALL THE WAY THROUGH THE IND-ENABLING STUDY TO PATIENTS. AND WE'RE ALREADY -- IN THE EARLY STAGES OF THE TRIAL, WE'VE TREATED PATIENTS IN THE FIRST TWO COHORTS, AND WE'RE ALREADY SEEING THAT THESE PATIENTS ARE BENEFITING. AND SO I THINK, FROM MY PERSPECTIVE AS A CLINICIAN SCIENTIST, IT DOESN'T GET ANY BETTER THAN THAT.

AND I ALSO WANT TO BE SURE TO ACKNOWLEDGE AND THANK THE PATIENTS AND THE FAMILIES FOR BEING WILLING TO GO ON TO A CLINICAL TRIAL WITHOUT -- JUST BY ITSELF NATURE IS NOT GUARANTEED.

SO I ACTUALLY CAME HERE, I WASN'T PLANNING TO MAKE A PUBLIC COMMENT, BUT I DO WANT TO BE ABLE TO ADDRESS SOME OF THE ISSUES IN PARTICULAR WITH REGARD TO THE ANTIBODY. SO THE ANTIBODY WAS GENERATED BY AMGEN. IT'S THE SAME LOT THAT WE'VE BEEN USING ALL ALONG. AS PART OF THE DISEASE TEAM AWARD, WE DID DO A TECH TRANSFER, BUT WE'VE MAINTAINED A ROBUST STABILITY AND ONGOING STABILITY PROGRAM. AND I THINK CONSERVATIVELY WE'RE JUST EXTENDING THE EXPIRY BY A YEAR OR TWO. AND WE ALSO HAVE AN EXPERT AMGEN CONSULTANT WITH REGARD TO THE ANTIBODY EXPIRY AND HE HIMSELF THINKS THAT THE ANTIBODY IN ITS CURRENT STATE, WHICH HAS BEEN FROZEN ALL ALONG, IS GOING TO LAST WELL BEYOND 2020.

TO BE CONSERVATIVE, WE SAID, OKAY, WE'VE EXTENDED IT TO 2020, AND WE HAVE THE ONGOING STABILITY PROGRAM, AND WE'RE GOING TO EXTEND IT BEYOND 2021, AND WE'LL PROBABLY BE ABLE TO EXTEND IT BEYOND THAT TIME.

AND WITH REGARD TO THE FUNDING, I THINK THAT FOR THE CLINICAL TRIAL WE WERE -- ULTIMATELY

THE AGREEMENT WAS FOR $5.5 MILLION, AND WE DID HAVE DIFFICULTIES ENROLLING PATIENTS. THIS IS A RARE DISEASE. WE'RE STARTING AT A FAIRLY LOW DOSE OF ANTIBODY, SO IT WAS DIFFICULT TO RECRUIT PATIENTS. BUT NOW, EVEN AT THE LOWEST DOSE, WE'RE SEEING EFFICACY. THE TRIAL IS ACCELERATING.

I THINK WE'RE ALSO IN THE PROCESS OF INTERACTING AND TRYING TO COMMERCIALIZE THIS ENTITY. MY CONCERN IS THAT IF WE DON'T GET FUNDING, THEN WE WILL HAVE TO SLOW THE TRIAL DOWN BECAUSE IT'S TAKEN TIME. IT'S A COMPLEX PROPOSITION TO SEARCH OUT A COMPANY FROM AN ACADEMIC CENTER AND JUST GETTING THE PATIENT DATA NOW. SO MY CONCERN WOULD BE THAT IF WE DID NOT RECEIVE THIS FUNDING, THAT IT WILL DEFINITELY SLOW DOWN THE TRIAL. AND SO WE ALREADY HAVE PATIENTS IN THE QUEUE WHO ARE READY TO UNDERGO TREATMENT.

I UNDERSTAND CIRM'S CONCERNS, AND I CAN SEE YOU'RE VERY THOUGHTFUL ABOUT HOW THIS MONEY IS BEING SPENT. I DO THINK THAT THIS ANTIBODY HAS THE POSSIBILITY TO NOT ONLY IMPROVE THE SCID TRIAL BECAUSE THOSE KIDS ARE GETTING CHEMOTHERAPY. BUT IF WE CAN MOVE THIS ALONG, THE GENE THERAPY TRIALS COULD THEN ALSO USE THIS ANTIBODY IN THAT REGARD, AND IT'S APPLICABLE TO THE KIDNEY PROTOCOL THAT WAS

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UP THERE, AND IT'S APPLICABLE TO SICKLE CELL DISEASE. SO I DO THINK THIS IS REALLY IN LINE WITH THE MISSION OF CIRM.

I SEE THAT THERE ARE CONCERNS ABOUT THE WAY THE MONEY WAS SPENT. I HAVE TO SAY THERE WAS A DELAY FOR A LONG PERIOD OF TIME WHICH I WON'T GO INTO. SO I'M HOPING YOU'LL LOOK FAVORABLY AND ACTUALLY AGREE TO FUND THE STUDY TODAY SO THAT WE CAN MOVE THIS ALONG AND GET THIS INTO PATIENTS.

DR. JUELSGAARD: CAN I ASK A QUICK QUESTION? SO 22 DAYS FROM NOW WE HAVE ANOTHER CIRM MEETING AT WHICH WE CAN RECONSIDER THIS PROPOSAL. YOU THINK THOSE BUDGETARY QUESTIONS THAT WE'VE RAISED COULD BE ANSWERED WITHIN 22 DAYS?

DR. SHIZIRU: I THINK SO. I JUST WOULD BE, YOU KNOW, AGAIN, EXPLICITLY WHAT IT WOULD BE, OF COURSE, THE DEVIL IS IN THE DETAILS, BUT, OF COURSE, WE WOULD DO EVERYTHING WE COULD TO ANSWER EVERYTHING AS QUICKLY AS POSSIBLE.

DR. JUELSGAARD: OKAY. THANKS.

MR. SHEEHY: ANY OTHER QUESTIONS?

MR. TORRES: I HAVE THE ULTIMATE CONFIDENCE IN JUDY TO HELP US GET THROUGH THIS PROCESS, AND I DON'T THINK THE 22-DAY DELAY IS GOING TO REALLY GET YOU OFF THE RAILS. IF WE CAN SATISFY

THE BOARD BOTH PUBLICLY AND AS A BOARD IN TERMS OF MOVING APPROPRIATELY.

DR. SHIZIRU: YEAH. I THINK WE HAVE PATIENTS IN THE QUEUE RIGHT NOW. WE'RE LOOKING TO DO THE NEXT DOSE. WE WILL DELAY THAT PATIENT IF THAT'S THE CASE.

MR. TORRES: I THOUGHT YOU HAD TWO MILLION, RIGHT?

CHAIRMAN THOMAS: RIGHT, EXACTLY. I THOUGHT YOU ONLY SPENT 18 OF THE 20. DON'T YOU HAVE TWO MILLION TO APPLY TO THAT?

DR. SHIZIRU: WE ARE -- OUR CO-FUNDING REQUIREMENT IS IN APRIL, RIGHT. AND ALSO I THINK ONE OF THE OTHER ISSUES THAT WE'VE DISCUSSED IS ACCELERATING THE TRIAL BECAUSE OF THE DIFFICULTY ENROLLING THE NEWBORN PATIENTS. AND SO WHAT WE WANTED TO DO WAS OPEN UP THE STUDY IN OTHER CENTERS. BUT I THINK, GIVEN THERE'S NOT GOING TO BE MONIES TO SUPPORT THE TRIAL GOING FORWARD, THEN I THINK BUDGETARILY WE'RE BETTER OFF USING IT TO CONTINUE TO FOLLOW THE PATIENTS THAT WE'VE ALREADY TRANSPLANTED. FROM THAT BUDGETARY STANDPOINT, WE SHOULD DELAY THE TRIAL. WE SHOULD DELAY TREATING ANY MORE PATIENTS ON THE TRIAL.

MR. SHEEHY: SO STANFORD WON'T FRONT YOU

1.6 MILLION TO PATIENTS IF WE DON'T GIVE YOU THE MONEY TODAY?

DR. SHIZIRU: I HESITATE TO SAY WHAT THEY WOULD DO.

MR. SHEEHY: TO STANFORD, 50 MILLION FROM CIRM, THEY WOULD ACTUALLY PUT PATIENTS AT RISK?

DR. SHIZIRU: I'M NOT AT LIBERTY TO SAY WHAT STANFORD WOULD DO.

MR. SHEEHY: ANY OTHER QUESTIONS OR COMMENTS? ARE WE READY -- ANY OTHER PUBLIC COMMENT? ARE WE READY TO VOTE?

MS. BONNEVILLE: SURE.

MR. TORRES: WILL YOU RESTATE THE MOTION?

MR. SHEEHY: YEAH. COULD WE RESTATE THE MOTION, JAMES.

MR. HARRISON: THE MOTION AGAIN, AS I UNDERSTAND IT, IS TO DELAY CONSIDERATION OF CLIN2-11431 UNTIL THE CIRM TEAM AND THE APPLICANT PROVIDE ADDITIONAL BUDGET INFORMATION AND THE APPLICANT PROVIDES A CLEAR PLAN FOR COMMERCIALIZATION TO THE APPLICATION REVIEW SUBCOMMITTEE.

MR. TORRES: THE ONLY AMENDMENT THAT I WOULD ADD TO THAT MOTION, JAMES, IS TO PUT THE DATE OF OUR NEXT MEETING, WHICH IS WHEN?

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MS. BONNEVILLE: FEBRUARY 21ST.
MR. TORRES: TO RESOLVE IT BY THEN, A DATE CERTAIN.
MR. SHEEHY: YEAH. TWENTY-TWO DAYS.
MR. HARRISON: SO ADDED.
MR. TORRES: THANK YOU.
MS. BONNEVILLE: ANNE-MARIE DULIEGE. DAVE HIGGINS.
DR. HIGGINS: YES, WITH THE FOOTNOTE THAT I WANTED TO ACKNOWLEDGE FELLOW BOARD MEMBERS AT THEIR CONTINUED CONCERN ABOUT SPENDING TAXPAYER'S MONEY WISELY BECAUSE I THINK THIS IS A GREAT EXAMPLE OF THAT.
MS. BONNEVILLE: THANK YOU, DAVID.
STEVE JUELSGAARD.
DR. JUELSGAARD: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: THANK YOU. THE MOTION CARRIES.
MR. SHEEHY: THANK YOU. THAT CONCLUDES THE BUSINESS OF THE APPLICATION SUBCOMMITTEE.
CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY. THANK YOU FOR ALL WHO ATTENDED, COMMENTED. WE APPRECIATE IT AS ALWAYS. IS THERE ANY PUBLIC COMMENT ON ANY GENERAL TOPIC? HEARING NONE, THAT CONCLUDES TODAY'S AGENDA. THANK YOU, EVERYBODY. WE WILL ADJOURN THE MEETING AND LOOK FORWARD TO THE MEETING ON FEBRUARY 21ST.
MS. BONNEVILLE: THANK YOU, EVERYONE.

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(THE MEETING WAS THEN CONCLUDED.)

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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 TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE AND THE APPLICATION REVIEW SUBCOMMITTEE IN THE MATTER OF ITS REGULAR MEETING HELD ON JANUARY 30, 2019, 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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