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:	CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE 1999 HARRISON STREET, SUITE 1650 OAKLAND, CALIFORNIA
DATE:	FEBRUARY 23, 2017 9 A.M.
REPORTER:	BETH C. DRAIN, CSR CA CSR. NO. 7152
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I N D E X

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I N D E X (CONT'D.)

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OAKLAND, CALIFORNIA; THURSDAY, FEBRUARY 23, 2017

9 A.M.

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY. WOULD LIKE TO CALL THE FIRST IN-PERSON MEETING OF THE ICOC TO ORDER HERE IN NONRAINY, BEAUTIFUL OAKLAND. VERY NICE CHANGE OF PACE UP HERE, AS I KNOW IT IS DOWN IN SOUTHERN CALIFORNIA AS WELL. THIS IS THE FIRST MEETING WE HAVE HAD OF THE BOARD IN OUR NOT-SO-NEW NOW HEADQUARTERS HERE IN OAKLAND, WHICH WE'VE BEEN IN FOR THE PAST 15 MONTHS.

FOR THOSE HERE IN THE ROOM, WELCOME TO OUR HEADQUARTERS. REALLY HAPPY TO HAVE EVERYBODY HERE AND ENCOURAGE YOU TO TAKE A LOOK AROUND WHEN YOU GET A CHANCE AFTER THE MEETING. FOR THOSE WHO ARE ON THE PHONE, WE LOOK FORWARD TO YOUR VISITING AT YOUR CONVENIENCE.

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

(THE PLEDGE OF ALLEGIANCE.)

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

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MS. BONNEVILLE: LINDA BOXER.

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DR. BOXER: HERE.
MS. BONNEVILLE: KEN BURTIS.
DR. BURTIS: HERE.
MS. BONNEVILLE: DEBORAH DEAS.
DR. DEAS: HERE.
MS. BONNEVILLE: JACK DIXON.
DR. DIXON: HERE.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: HERE.
MS. BONNEVILLE: HOWARD FEDEROFF.
DR. FEDEROFF: HERE.
MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: HERE.
MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: HERE.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: HERE.
MS. BONNEVILLE: STEPHEN JUELSGAARD. SHERRY LANSING.
MS. LANSING: HERE.
MS. BONNEVILLE: KATHY LAPORTE.
DR. LAPORTE: HERE.
MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.
DR. MELMED: HERE.

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MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: HERE.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: HERE.
MS. BONNEVILLE: JOE PANETTA. FRANCISCO PRIETO.
DR. PRIETO: HERE.
MS. BONNEVILLE: ROBERT QUINT. AL ROWLETT. JEFF SHEEHY.
MR. SHEEHY: HERE.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: HERE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: HERE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: HERE.
MS. BONNEVILLE: DIANE WINOKUR. BRUCE WINTRAUB.
CHAIRMAN THOMAS: THANK YOU, MARIA.
A COUPLE OF HOUSEKEEPING ITEMS. FOR THOSE HERE IN THE ROOM, IT'S BEST TO PULL YOUR MICS CLOSER TO YOU. I THINK THEY ALL HAVE SOME EXTENSION ON THEM. ALSO, WE CAN ONLY HAVE THREE MICS OPEN AT

ONCE, NOT THAT WE'RE ALL GOING TO BE TALKING OVER EACH OTHER, BUT OCCASIONALLY ONE FORGETS TO TURN IT OFF. IF THAT'S THE CASE, SOMEBODY GETTING ON WOULD BE THE FOURTH MIC AND WILL NOT ABLE TO SPEAK. SO IF YOU REMEMBER FIRST TO TURN YOUR MIC ON AND THEN TO TURN IT OFF WHEN YOU ARE FINISHED, THAT WOULD BE GREAT.

LASTLY, FOR THOSE OF YOU WHO ARE ON THE PHONE, AS YOU ALWAYS DO, IF YOU COULD PLEASE MUTE YOUR PHONES.

YES, MARIA.

MS. BONNEVILLE: I'D LIKE TO CONFIRM THAT BRUCE WINTRAUB IS ON THE PHONE. AL ROWLETT.

MR. ROWLETT: AL ROWLETT IS ON THE PHONE.

CHAIRMAN THOMAS: HELLO, AL. HOW YOU DOING, AL?

I'D LIKE TO START HERE BY WELCOMING OUR NEWEST MEMBER, CHANCELLOR GEORGE BLUMENTHAL FROM UNIVERSITY OF CALIFORNIA SANTA CRUZ TO MY LEFT. I WOULD LIKE TO HAVE THE CHANCELLOR SAY A FEW WORDS BY WAY OF INTRODUCTION TO THE GROUP.

DR. BLUMENTHAL: THANK YOU VERY MUCH, J.T. I REALLY APPRECIATE THE OPPORTUNITY TO SERVE WITH THIS GROUP. VERY BRIEFLY, I'VE BEEN A FACULTY MEMBER AT THE UNIVERSITY OF CALIFORNIA FOR 45 YEARS.

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I WAS HIRED AT THE AGE OF SEVEN. AND MY FIELD IS ASTRONOMY AND ASTROPHYSICS, AND MY SPECIALTY IS I'M A THEORETICAL ASTROPHYSICIST WHO STUDIES DARK MATTER IN THE UNIVERSE AND LARGE-SCALE STRUCTURE IN THE UNIVERSE.

I SERVED AS THE CHAIR OF THE ACADEMIC SENATE FOR THE WHOLE UC SYSTEM AND ALSO HAVE SERVED FOR TWO YEARS AS FACULTY REPRESENTATIVE TO THE BOARD OF REGENTS OF THE UNIVERSITY OF CALIFORNIA, AND THEN SUBSEQUENTLY WAS NAMED CHANCELLOR AT UC SANTA CRUZ WHERE I'M NOW IN MY ELEVENTH YEAR IN THAT ROLE. THANK YOU.

CHAIRMAN THOMAS: THANK YOU VERY MUCH, MR. CHANCELLOR. HE WILL ENTERTAIN ANY QUESTIONS THAT YOU MAY HAVE ON THE RECENT DISCOVERY OF THE SEVEN EARTH-LIKE PLANETS THAT WAS ANNOUNCED YESTERDAY AND ANY OTHER ASTRONOMY ISSUES YOU CARE TO DISCUSS.

MR. TORRES: GEORGE, YOUR ROLE IN DARK MATTER WILL BE ESPECIALLY HELPFUL IN SACRAMENTO IN THE DAYS AHEAD.

IT IS AN HONOR TO HAVE MY CHANCELLOR, I'M A USC GRADUATE AS WELL, SO NOW YOU HAVE TWO BANANA SLUGS ON THIS BOARD. BUT GEORGE HAS BEEN A TREMENDOUS FRIEND AND A TREMENDOUS ASSET FOR THE

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STATE OF CALIFORNIA. SO I'M GLAD THAT HE FOUND THE TIME AND THE COMMITMENT TO SERVE WITH US ON THIS BOARD AND TO KNOW THAT UC SANTA CRUZ IS WELL REPRESENTED FOR THE INTERESTS THAT THEY SHARE.

SECONDLY, I'M ALSO PROUD, IF I MAY TAKE THIS PERSONAL PLEASURE, TO INTRODUCE TO YOU THE NEWEST SUPERVISOR OF SAN FRANCISCO CITY AND COUNTY, JEFF SHEEHY, WHO WAS APPOINTED BY THE MAYOR LAST YEAR. ACCORDING TO MY SON IS HAVING A GREAT TIME ON THE BOARD, AND I JUST WANT TO MAKE SURE EVERYBODY KNEW HOW PROUD WE ARE THAT ONE OF OUR OWN IS NOW AN ELECTED OFFICIAL IN A VERY DIFFICULT TIME.

(APPLAUSE.)

MR. TORRES: FINALLY, I WANT TO SAY THAT THE TWO FLAGS IN THIS ROOM HAVE HAD QUITE A JOURNEY. THEY STARTED WITH ME IN THE ASSEMBLY AND IN MY OFFICE AND IN MY SENATE OFFICE. THOSE FLAGS HAVE BEEN WITH ME ALMOST 40 YEARS. I WANT TO SAY HOW PROUD I AM THAT THEY'RE BEING USED HERE FOR THIS PURPOSE.

CHAIRMAN THOMAS: THANK YOU. AND, JEFF, WOULD YOU LIKE TO SAY A FEW WORDS ABOUT THE NEW POSITION? WE'D REALLY LOVE TO HEAR HOW IT'S GOING.

MR. SHEEHY: SURE. AND THANK YOU, SENATOR TORRES; THANK YOU, J.T. IT HAS BEEN QUITE A RIDE.

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I WAS NOT ANTICIPATING THIS, AND I FOUND OUT ON A THURSDAY NIGHT, ANNOUNCED ON A FRIDAY, SWORN IN ON SUNDAY, FIRST BOARD MEETING ON MONDAY. SO THAT WAS REALLY A RUSH, NOT SO DIFFERENT FROM WHEN I CAME ONTO THIS BOARD. WHEN THE APPOINTMENT WAS MADE, I WAS LIKE WHAT? ALSO WHEN MY CHILD CAME INTO MY LIFE, THAT WAS ALSO VERY SIMILAR. NO WARNING.

I DO FIND IT INTERESTING THAT DR. BLUMENTHAL IS AN EXPERT ON DARK MATTER BECAUSE, TO REALLY BE SERIOUS, THESE ARE VERY, VERY DARK TIMES. AND WHAT I'M EXPERIENCING AND SEEING DIRECTLY IS THE FACES OF MUSLIMS WHO ARE TERRIFIED. SO WE JUST PASSED A BILL OUT OF COMMITTEE TO NOT COOPERATE WITH THE MUSLIM REGISTRY. AND THE FEAR THAT OUR MUSLIM BROTHERS AND SISTERS ARE FEELING IS REAL. WE'VE HAD ICE RAIDS IN SAN FRANCISCO AT A PRESCHOOL. THE FEAR THAT OUR IMMIGRANT COMMUNITY IS FEELING IS REAL, IS REAL.

AND BEFORE I GOT THIS APPOINTMENT, I WOULD HAVE BEEN READING STUFF IN THE NEWSPAPER. AND THEN OUR TRANS AND NONCONFORMING KIDS JUST TODAY, AND THERE'S SOMETHING REALLY, REALLY TERRIFYING TAKING PLACE IN THIS COUNTRY WHERE THE WEAK AND THE VULNERABLE ARE BEING PICKED OVER AND TARGETED ONE BY ONE BY ONE. SO I KNOW THIS IS A STATE BOARD AND

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WE'RE ROUGHLY APOLITICAL, BUT THERE'S SOMETHING UNIQUE THAT'S HAPPENING NOW. AND THIS AGENCY, FRANKLY, WAS CREATED IN RESPONSE TO WHAT WAS HAPPENING AT THE FEDERAL GOVERNMENT. BUT WHAT IS HAPPENING NOW IS SOMETHING WHERE ALL OF US, NO MATTER WHAT OUR POLITICAL AFFILIATIONS ARE, WE HAVE TO STAND TOGETHER BECAUSE THIS IS BEYOND ANYTHING I'VE EVER EXPERIENCED IN MY LIFE.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU, JEFF. SO ON TO THE CHAIRMAN'S REPORT. SO AS YOU MAY KNOW, EVERY YEAR IN JANUARY THERE IS A CONFERENCE HELD IN SAN FRANCISCO CONVENED BY JP MORGAN, WHICH IS REALLY THE PREMIERE CONFERENCE OF THE BIOTECH INDUSTRY WHICH BRINGS TOGETHER COMPANIES, INVESTORS, PATIENTS ALL TO GAUGE THE PROGRESS OF THE INDUSTRY FROM THE YEAR PAST. AND IT'S A TREMENDOUS NETWORKING EVENT WHICH MANY OF US HERE AT CIRM ANNUALLY GO TO FOR A VARIETY OF REASONS.

AS YOU KNOW, IN THE PAST I'VE RELAYED TO THE BOARD A FEW SLIDES. EVERY YEAR THE ALLIANCE FOR REGENERATIVE MEDICINE DOES A STATE-OF-THE-INDUSTRY SESSION WHICH GIVES SORT OF A REALITY CHECK ON THE PROGRESS OF THE FIELD. AND EVERY YEAR ONE COMES AWAY FROM THAT FEELING LIKE THE MOMENTUM CONTINUES

TO BUILD, PROGRESS CONTINUES TO BE MADE. AND TOWARDS THAT, SORRY THOSE OF YOU ON THE PHONE WON'T BE ABLE TO SEE THIS, BUT I'LL SPEAK TO IT, I HAVE A FEW SLIDES FROM THIS YEAR'S PRESENTATION THAT I WANTED TO SHARE WITH THE BOARD JUST SO YOU GET A FEEL FOR THE PRESENTATION THAT WAS MADE AND THE STATE OF THE INDUSTRY.

SO IF I COULD DIRECT EVERYBODY'S ATTENTION TO THE SCREEN HERE. SO, FIRST, GLOBAL LANDSCAPE. THIS IS ALL INFORMATION ON COMPANIES AROUND THE WORLD IN THE REGENERATIVE MEDICINE SPACE. THIS MAP IN FRONT OF US SHOWS 759 COMPANIES AND GROWING, OF WHICH THE BULK ARE IN THE UNITED STATES, OR I SHOULD SAY IN NORTH AMERICA AND IN EUROPE. THE NUMBER OF CLINICAL TRIALS IN THE REGENERATIVE MEDICINE SPACE AT THE END OF 2016 IS NOW 802, WHICH IS VERY IMPRESSIVE. A LOT OF THESE, I WILL HASTEN TO POINT OUT, DEAL WITH PROJECTS THAT ARE NOT THE KIND THAT CIRM FUNDS. IF YOU'RE WONDERING WHY THAT TOTAL IS SO HIGH, WE OPERATE A UNIQUE NICHE IN FUNDING, AS YOU KNOW, PROJECTS THAT ARE NOT FUNDED ELSEWHERE. SO MANY OF THESE ARE THE TYPES THAT WE WOULD NOT FUND. JUST FOR THE SAKE OF UNDERSTANDING THE TOTAL PICTURE FOR THE INDUSTRY, THIS IS A 21-PERCENT GROWTH OVER THE PREVIOUS YEAR, AND EACH YEAR THIS

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SLIDE CONTINUES TO SHOW A DRAMATIC IMPROVEMENT.

NEXT SLIDE IS CLINICAL TRIALS BY THERAPEUTIC CATEGORY. AGAIN, YOU CAN SEE HERE THAT ONCOLOGY IS THE VAST MAJORITY OF THESE. FOR THOSE ON THE PHONE, IN ORDER, CARDIOVASCULAR, CENTRAL NERVOUS SYSTEM, INFECTIOUS DISEASE, MUSCULOSKELETAL, DERMATOLOGY, IMMUNOLOGY, OPHTHALMOLOGY, AND SO ON DOWN TO A NUMBER OF VERY RARE DISEASES.

ON THE NEXT SLIDE WE'RE GOING -- A COUPLE OF THESE ARE GOING TO BE A LITTLE BUSY. WE'RE NOT GOING TO SPEND MUCH TIME. FOR THOSE IN THE ROOM, WANTED YOU TO SEE THIS. THIS SLIDE IS ENTITLED "CELL AND GENE THERAPIES, MAJOR THERAPEUTIC PLATFORMS, AND ENABLING TECHNOLOGIES." AND IT TALKS ABOUT MODIFIED T-CELLS, IPSC, CRISPR, OTHER GENE EDITING TECHNIQUES. THOSE OF YOU LOOKING AT THIS SLIDE WILL READILY RECOGNIZE THAT WE ARE FUNDING TECHNOLOGIES IN VIRTUALLY ALL OF THESE THINGS THAT ARE LISTED HERE.

A VERY BUSY SLIDE WHICH SHOWS, AS YOU KNOW IN THE GENE MODIFICATION AND GENE THERAPY FIELD THAT ALL INVOLVES EITHER THE INTRODUCTION OF VARIOUS THINGS THROUGH VECTORS OR GENE EDITING TECHNIQUES OR WHATEVER, THIS IS A LIST OF THE MANY COMPANIES WORLDWIDE THAT EMPLOY THOSE DIFFERENT TECHNIQUES.

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AND IT LISTS A WHOLE BUNCH OF COMPANIES, AND IT GROWS ANNUALLY.

WE'RE GOING TO SKIP OVER THE NEXT COUPLE. THIS IS JUST OR SOME THIS ONE AT ANY RATE, IT'S A SLIDE SHOWING WHAT IS VIEWED TO BE THE MAJOR EVENTS THAT WILL OCCUR IN CLINICAL TRIAL DATA OVER THE NEXT YEAR, AND IT SHOWS ABOUT TEN COMPANIES OR SO, AND LISTS THE ADVANCEMENTS THAT CAN BE EXPECTED LARGELY IN PHASE 3 REPORTING, WHICH SHOULD BE VERY EXCITING. AND I'M SURE NEXT YEAR AT THE JP MORGAN CONFERENCE, WE WILL HEAR ABOUT HOW THESE THINGS DID AT THAT POINT IN RETROSPECT.

THERE IS A LOT OF MOVEMENT THESE DAYS TOWARDS CORPORATIONS EITHER MERGING OR JOINT VENTURING OR WHATEVER WITH EACH OTHER. THIS SLIDE THAT I PUT UP HERE IS KEY CORPORATE PARTNERSHIPS OF 2016. SO WHETHER IT'S -- FOR EXAMPLE, JUST LOOK AT THE FIRST ONE, BIOGEN AND UNIVERSITY OF PENNSYLVANIA. THIS IS A RELATIONSHIP DEALING WITH GENE THERAPY PROGRAMS AND IS VERY MUCH THE KIND OF THING THAT WE ARE LOOKING TO ENCOURAGE WITH RESPECT TO PROJECTS THAT WE HAVE FUNDED IN ACADEMIA HERE AND SPENT A LOT OF TIME DEVELOPING TOWARDS GETTING INDUSTRY INVOLVEMENT IN OUR FUNDED PROJECTS.

IF YOU SORT OF GO DOWN THE LINE -- BY THE

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WAY, FOR THOSE ON THE PHONE, I'LL BE SENDING OUT THIS SLIDE DECK, SO YOU CAN, AT YOUR LEISURE, TAKE A LOOK AT THIS. THIS JUST SHOWS EXAMPLES OF VERY BIG TICKET THINGS THAT ARE GOING ON. I'LL MENTION ONE, FOR EXAMPLE, BAYER AND VERSANT, WHICH IS A LIFE SCIENCES VENTURE CAPITAL FIRM, LAUNCHED AN IPSC THERAPY COMPANY CALLED BLUE ROCK THERAPEUTICS AND HAD A VERY SIGNIFICANT SERIES A RAISE OF 225 MILLION LAST DECEMBER, WHICH, FOR THOSE OF YOU FAMILIAR WITH THE VENTURE BUSINESS, THAT'S A VERY SIZABLE INITIAL FINANCING AND A VERY INTERESTING ONE.

SO I THINK THE TAKEAWAY FROM THE SLIDE IS THERE'S A LOT OF MOVEMENT AFOOT IN INDUSTRY GETTING PROGRESSIVELY MORE INTERESTED IN THE REGENERATIVE MEDICINE SPACE AND IS SOMETHING THAT IS GOING TO BE A DEVELOPMENT THAT, AS MORE AND MORE PROJECTS PROVE OUT OVER TIME, WILL BE INCREASING DRAMATICALLY.

THERE WERE A NUMBER OF IPO'S IN THE REGENERATIVE MEDICINE AREA. THIS IS A LIST OF TEN OR SO HERE. A LOT OF THESE HAD TO DO WITH GENE EDITING TECHNOLOGIES, EDITAS CRISPR THERAPEUTICS, ETC., BUT YOU CAN SEE THAT THERE WERE SOME VERY SIGNIFICANT AMOUNTS RAISED, NOT JUST IN THE U.S., BUT IN EUROPE AS WELL.

AS FAR AS TOTAL FINANCINGS IN THE INDUSTRY

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IN 2016, IT WAS A BIT OF A DOWN YEAR IN TERMS OF DOLLAR AMOUNT. 2015 WAS A SPECTACULAR YEAR IN TERMS OF THE AMOUNT OF DEALS DONE. THIS PAST YEAR WE HAD, STILL A HUGE AMOUNT, $5.3 BILLION WORTH OF MONEY RAISED FOR REGENERATIVE MEDICINE COMPANIES. THAT WAS WELL DOWN FROM THE 11 BILLION IN 2015. OF THAT A LOT OF FUNDING IN THE AREAS OF GENE AND GENE-MODIFIED CELL THERAPY, TISSUE ENGINEERING, AND CELL THERAPY ITSELF THAT ADDED UP TO THAT FIGURE. THE TAKEAWAY HERE, AGAIN, IS THE CAPITAL MARKETS ARE VERY INTERESTED IN THE FIELD AND WILL CONTINUE TO BE MORE SO OVER TIME.

THIS NEXT SLIDE SHOWS TOTAL FINANCINGS BY TYPE, TYPE OF FINANCING, FOR THE YEAR 2016. THOSE ON THE PHONE, IT SHOWS THE DOLLAR AMOUNTS DEVOTED TO M & A PIPES, WHICH ARE INVESTMENTS IN COMPANY STOCK, VC FINANCING, PARTNERSHIPS OF ONE SORT OR ANOTHER, FOLLOW-ON FINANCINGS FOR COMPANIES THAT HAVE ALREADY DONE IPO'S AND IPO'S IN GENERAL, ALL OF WHICH ARE EITHER IN THE HIGH NINE-FIGURE OR LOW TEN-FIGURE RANGE. AGAIN, A LOT OF ACTIVITY.

I'M GOING TO SKIP OVER THIS. THIS SORT OF BREAKS DOWN THE SAME THING COMPARING 2014, 15, AND 16. YOU CAN LOOK AT THIS SLIDE WHEN I SEND IT OUT TO EVERYBODY. AND THAT IS IT.

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THERE WERE SOME OTHER SLIDES THAT THEY HAD IN THE PRESENTATION, BUT THOSE I WANTED SPECIFICALLY TO BRING TO THE BOARD'S ATTENTION BECAUSE IT JUST SHOWS THE MOMENTUM AND GENERAL STATE OF THINGS.

ANY QUESTIONS ABOUT ANY OF THESE OR COMMENTS ABOUT ANY OF THESE SLIDES? OKAY. HEARING NONE, NEXT, EVERY YEAR A NUMBER OF OUR GRANTEE INSTITUTIONS HOST ANNUAL SYMPOSIA WHERE THEY BRING TOGETHER A GREAT SERIES OF LECTURERS WHO ARE DOING WORK IN REGENERATIVE MEDICINE, ALWAYS INCLUDING A NUMBER OF CIRM GRANTEES. THERE WERE A COUPLE I WANTED TO HIGHLIGHT HERE, AND I WANTED TO ASK A COUPLE OF OUR TEAM MEMBERS WHO WERE THERE TO SAY A WORD OR TWO ABOUT THEM.

FIRST WAS UCLA, WHICH WAS NOTEWORTHY. I THINK THIS WAS LIKE THEIR ELEVENTH OR TWELFTH SUCH SYMPOSIA. THEY PULLED TOGETHER THE SCIENTISTS FROM USC, UCLA, AND UC SAN FRANCISCO, AND THE REASON FOR THAT GROUPING WAS THEY HAD IN ATTENDANCE ELI AND EDIE BROAD, WHO WERE GREAT BENEFACTORS OF CIRM IN GENERAL AND SPECIFICALLY WERE VERY MATERIAL CONTRIBUTORS TO THE CONSTRUCTION OF THE STEM CELL INSTITUTES AT THOSE THREE INSTITUTIONS, ALL OF WHICH ARE NAMED IN THEIR HONOR. SO THEY WERE IN ATTENDANCE. THEY HAD A VERY NICE LUNCH IN THE

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MIDDLE OF THINGS FOR THEM AT WHICH A NUMBER OF PEOPLE SPOKE THANKING THEM FOR WHAT THEY HAD DONE FOR CIRM, FOR THE FIELD, FOR THE INSTITUTIONS.

AND AMONGST THE SPEAKERS WERE THE PARENTS OF EVANGELINA, WHO WAS AT OUR DECEMBER BOARD MEETING, WHO IS ALSO THE COVER GIRL ON YOUR ANNUAL REPORT THAT'S AT YOUR DESK HERE. AND HER MOM AND DAD SPOKE AND WERE MOST ELOQUENT, AS THEY WERE AT OUR BOARD MEETING, AND HEARTFELT IN THEIR GRATITUDE TO THE BROADS FOR ALL THEY'VE DONE FOR THE FIELD IN GENERAL AND FOR THEIR DAUGHTER SPECIFICALLY. IT WAS A WONDERFUL MOMENT AND VERY MOVING SET OF TALKS BY THEM.

SO I WANTED TO ASK PAT IF SHE WOULD SAY A FEW WORDS ABOUT THE UCLA SYMPOSIUM ITSELF. WE HAD A NUMBER OF PEOPLE FROM CIRM REPRESENTED THERE AS WE DO EVERY YEAR. SO DR. OLSON.

DR. OLSON: THANKS, CHAIRMAN THOMAS, AND GOOD MORNING, EVERYONE. I JUST WANTED TO TAKE A COUPLE MINUTES AND SHARE SOME OF THE HIGHLIGHTS. THIS WAS A ONE-DAY MEETING. IT WAS ESTABLISHED AND YOUNG INVESTIGATORS FROM THE THREE INSTITUTIONS. AND I JUST WANTED TO SHARE WITH YOU SOME OF THE HIGHLIGHTS OF THE MEETING.

SO DR. KRIEGSTEIN FROM UCSF TALKED ABOUT

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HOW HIS LAB STUDIES ON HUMAN CORTICAL DEVELOPMENT HAVE LED TO A NUMBER OF INSIGHTS THAT ADDRESS THE PATHOGENESIS OF LISSENCEPHALY WHICH IS A GENETIC DISEASE WHERE YOU HAVE SMOOTH BRAIN. HE ALSO TALKED ABOUT HOW IT LOOKS LIKE IN GLIOBLASTOMA. SOME OF THE CANCER STEM CELLS LOOK LIKE THEY HAD A PROGENITOR CELL PHENOTYPE THAT RESEMBLES THAT OF THE ORIGINAL CELLS. AND FINALLY, ZIKA VIRUS INFECTION. HE'S ACTUALLY IDENTIFIED RECEPTORS IN SOME OF THESE NEURAL PROGENITORS AND IS REPURPOSING A DRUG THAT IS NOW IN CLINICAL TRIALS IN BRAZIL THAT MAY BLOCK SOME OF THOSE RECEPTORS.

WE HEARD ABOUT RESEARCH THAT COULD IMPACT KIDNEY FAILURE THROUGH STUDIES ON THE DEVELOPING HUMAN KIDNEY AND MIMICKING WHAT IS LEARNED IN VITRO AND IN ORGANOID CULTURE. THAT WAS ANDY MCMAHON AT USC.

WE HEARD ABOUT STUDIES THAT COULD IMPACT LIVER FAILURE BY DIRECTLY PROGRAMMING OF THE FIBROTIC CELLS IN A LIVER TO BECOME FUNCTIONAL HEPATOCYTES.

WE HEARD ABOUT RESEARCH THAT COULD IMPACT DEAFNESS BY ADDRESSING WHY THERE IS REGENERATION OF HAIR CELLS, WHICH THE LOSS OF WHICH OFTEN LEADS TO DEAFNESS, OCCURS IN NONMAMMALIAN VERTEBRATES, BUT

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DOESN'T OCCUR IN MAMMALIAN VERTEBRATES.

WE HEARD ABOUT STUDIES THAT COULD IMPACT INFERTILITY CAUSED BY CHEMOTHERAPY THROUGH THE GENERATION OF GERMLINE CELLS FROM IPSC, AND THIS IS FROM AMANDA CLARK.

WE HEARD ABOUT AN AGGRESSIVE SUBTYPE OF ADVANCED PROSTATE CANCER THAT REALLY HAS STEM CELL-LIKE CHARACTERISTICS. IT'S A NEUROENDOCRINE TUMOR. IT'S VERY RESISTANT TO ALL TREATMENTS. AND THE DISCOVERY OF IT BEING A STEM CELL PHENOTYPE HAS LED TO THE IDENTIFICATION OF NEW MARKERS AND HOPEFULLY NEW TREATMENTS.

AND FINALLY, WE HEARD FROM DON KOHN. WE HEARD FROM DON ABOUT THIS 25-YEAR ODYSSEY TO ESSENTIALLY TREAT SCID, IN PARTICULAR ADA-SCID, THAT HAS CULMINATED -- HE'S TREATED NOW, I THINK, ABOUT 30 OR 40 PATIENTS. WE'RE FUNDING ONE OF THE PHASE 2 TRIALS, AS YOU ALL HEARD AT OUR MOST RECENT BOARD MEETING, THAT HAS RESULTED IN A CURE OF A LITTLE GIRL, EVANGELINA VACCARO.

SO IT WAS A GREAT MEETING, AND THE INTERESTING FOCUS WAS IT WAS ALL TRANSFORMING MEDICINE. WHAT ARE WE DOING WITH STEM CELL RESEARCH THAT COULD TRANSFORM MEDICINE. THANKS.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU, PAT.

NOW FOR SOME COMMENTS ON THE STANFORD SYMPOSIUM, I WOULD LIKE TO ASK DR. MILLAN IF SHE WOULD SAY A FEW WORDS.

DR. MILLAN: THANK YOU, CHAIRMAN THOMAS AND MEMBERS OF THE BOARD. I AND MANY MEMBERS OF OUR TEAM HERE AT CIRM WERE FORTUNATE TO ATTEND THE FEBRUARY 3D FIRST ANNUAL SYMPOSIUM OF THE CENTER FOR DEFINITIVE AND CURATIVE MEDICINES AT STANFORD, WHICH WAS LED BY DR. MARIA GRACIA. AND THE MEETING WAS A FULL-DAY MEETING OF INDUSTRY AND ACADEMIC PARTICIPANTS. OVER 500 REGISTRANTS WERE IN ATTENDANCE.

THE MEETING WAS KICKED OFF BY OUR OWN DEAN MINOR, WHO GAVE AN INTRODUCTION AND EXPRESSED SUPPORT FOR THE CENTER, AND ALSO BY THE CEO'S OF STANFORD HEALTHCARE AND STANFORD CHILDREN'S HOSPITAL. SO THIS IS A JOINT INITIATIVE BETWEEN THE MEDICAL SCHOOL AND ALL THE HOSPITALS TO CREATE TRANSLATIONAL MACHINERY TO TAKE THE DISCOVERIES AT STANFORD ALL THE WAY THROUGH INTO CLINICAL TRIALS. SO THEY RECENTLY LAUNCHED THE GMP FACILITY AT STANFORD.

MEMBERS OF OUR BOARD WERE IN ATTENDANCE AS WELL AS MANY CIRM TEAM MEMBERS. IT WAS A VERY FULL

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DAY ABOUT FRESH-OFF-THE-BENCH RESEARCH AS WELL AS RESEARCH THAT'S LED TO CLINICAL TRIALS FOR INDICATIONS IN RARE DISEASES AND TOUGH-TO-TREAT INDICATIONS. SO IRV WEISSMAN KICKED OFF THE MEETING BY GIVING KIND OF A HISTORICAL PERSPECTIVE ON APPROACHES TO CANCER TREATMENT WITH STEM CELLS AS WELL AS NOVEL APPROACHES, ONE OF WHICH WE'RE FUNDING WHICH IS TARGETING AN ANTIGEN THAT HELPS CANCER CELLS EVADE THE IMMUNE SYSTEM. SO THAT WAS A NICE WAY TO START THE MEETING.

THERE WERE FOUR SESSIONS, AND MANY OF THE PRESENTERS WERE ACTUALLY CIRM GRANTEES. AND THROUGHOUT THE MEETING, THERE WAS A LOT OF THANKS GIVEN TO CIRM FOR SUPPORTING THE RESEARCH THAT HAS BROUGHT MANY OF THESE PROGRAMS FORWARD. AND SO THERE WERE PRESENTATIONS BY GARY STEINBERG IN STROKE AND SPINAL CORD INJURY, STEM CELL APPROACHES TO THOSE INDICATIONS, LESSONS LEARNED, AND WHAT THE FUTURE IS FOR THAT FIELD. JEFFREY GOLDBERG FOR CORNEAL DISEASE. THERE WERE PRESENTATIONS ON TISSUE REPLACEMENT APPROACHES FOR CARDIAC AS WELL AS DIABETES, AND AN EXCITING APPROACH THAT JUDY SHIZURU, ONE OF OUR GRANTEES, IS CURRENTLY RESEARCHING. IT'S CURRENTLY IN A CLINICAL TRIAL TO DO A NONCHEMOTHERAPY-BASED CONDITIONING REGIMEN BY

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TARGETING BONE MARROW STEM CELLS TO CREATE THE SPACE SO THAT TRANSPLANTED CELLS COULD ENGRAFT AND FUNCTION. AND THE IDEA BEHIND THIS IS THAT THIS WOULD IMPROVE THE CHANCES OF SUCCESS FOR TRANSPLANT AS WELL AS DECREASE THE MORBIDITY ASSOCIATED WITH CHEMOTHERAPY.

ONE OF THE COMPANIES THAT J.T. HAD MENTIONED IN HIS INTRODUCTION, CRISPR IS A SPIN-OFF OF SOME OF THE GENOME EDITING TECHNOLOGIES THAT'S COME OUT OF STANFORD. SO MATT PORTIAS, SOME OF THE PROGRESS WITH CRISPR-BASED GENOME EDITING AND SOME VERY EXCITING NEXT GENERATION CANCER IMMUNOTHERAPY APPROACHES, SUCH AS NEXGEN CAR T CHIMERIC ANTIGEN RECEPTOR T-CELL APPROACHES TO CANCER BY CRYSTAL MCCALL. AND ALSO REGULATING THE IMMUNE SYSTEM. MARIA GRACIA RONCAROLO AND HER TEAM HAVE NOW JUST ANNOUNCED, JUST RECENTLY DAYS BEFORE, THAT THEY RECEIVED APPROVAL FROM THE FDA, NOT APPROVAL, BUT AN ALLOWANCE TO GO AHEAD WITH THE CLINICAL TRIAL FOR T-REGULATORY CELLS IN TAMING THE IMMUNE SYSTEM. SO THAT'S FOR TREATMENT OF CANCER AS WELL AS FOR IMMUNE DISORDERS.

SO IT WAS A REALLY EXCITING MEETING, AND IT WAS CAPPED BY STANFORD'S NEW PRESIDENT MARC TESSIER-LAVIGNE GIVING A VERY INSPIRATIONAL TALK

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VERY, VERY SUPPORTIVE OF THIS AREA OF RESEARCH. THANK YOU VERY MUCH.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU, DR. MILLAN.

I'D LIKE TO ASK SENATOR TORRES TO SAY A FEW WORDS ABOUT A MEETING THAT HE CONVENED HERE IN THE CIRM OFFICES WITH SECRETARY OF STATE ALEX PADILLA.

MR. TORRES: I'VE BEEN TRYING TO BRING AS MANY CONSTITUTIONAL OFFICERS BY OUR HEADQUARTERS HERE TO LET THEM KNOW WHAT'S GOING ON. OUR FIRST VISITOR WAS BETTY YEE, CONTROLLER, WHO LIVES IN OAKLAND, SO IT WAS AN EASY COMMUTE FOR HER, AND ALSO SERVES AS HEAD OF OUR OVERSIGHT SUBCOMMITTEE, TO GO OVER OUR FISCAL ISSUES.

WE'RE MEETING MARCH 2D WITH KEVIN MULLIN, WHO'S THE SPEAKER PRO TEM OF THE ASSEMBLY, WHO ALSO CHAIRS THE COMMITTEE ON BIOTECHNOLOGY. AND HE'S GOING TO BE COMING BY AND GET AN INCREDIBLE BRIEFING BY DR. MILLS AS HE'S PRONE TO DO ON OCCASION. THAT'S A JOKE.

AND THEN JUST RECENTLY WE HAD ALEX PADILLA, WHO WAS MY CARREL FELLOW IN THE '90S AND IS THE SECRETARY OF STATE NOW, AND HAS ALWAYS BEEN VERY INTERESTED BECAUSE OF HIS PARENTS' CONDITION OF

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DIABETES AND ALSO HEADING UP THE L.A. COUNTY DIABETES ASSOCIATION FOR MANY YEARS. HE'S A FORMER MEMBER OF THE BOARD OF MIT AND THE ONLY LATINO TO DO SO. AND ALSO IS A VERY YOUNG, ASSERTIVE LEADER, AND I THINK WILL BE A GREAT ASSET AND ALLY FOR US.

AND THEN THE LAST ONE IS MAYOR LEE, MEETING WITH HIM TODAY, MY FORMER CHIEF OF STAFF, THE ATTORNEY GENERAL, XAVIER BECERRA, WHO I HOPE TO BRING BY HERE AS WELL AS WE COALESCE OUR SUPPORT IN ANTICIPATION OF WHATEVER MAY BE COMING DOWN THE ROAD.

SO I'M JUST TRYING TO MAKE SURE THAT THEY'RE AWARE AND ALSO THAT THE MEETING THAT OCCURRED LAST YEAR BETWEEN PRESIDENT MILLS AND CHAIRMAN THOMAS AND MARIA WITH KEVIN DELEON, PRESIDENT OF THE STATE SENATE, I THINK IS ANOTHER EXAMPLE OF HOW WE NEED TO MOVE FORWARD ON THIS ELEMENT. WHAT I DIDN'T REALIZE WAS THAT KEVIN IS PART CHINESE. THAT CAME OUT IN A *SACRAMENTO BEE* STORY EARLIER THIS WEEK. SO I GUESS WE'RE FINDING A LOT ABOUT OURSELVES AS WE MOVE FORWARD.

CHAIRMAN THOMAS: THANK YOU, MR. SENATOR.

I WANTED TO REITERATE WHAT A TERRIFIC JOB SENATOR TORRES DOES IN KEEPING EVERYBODY APPRISED UP IN SACRAMENTO ABOUT, NOT JUST THERE, BUT THROUGHOUT

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ALL OF THE STATE AND FEDERAL LEGISLATIVE DISTRICTS ABOUT WHAT WE DO HERE AT CIRM AND SENDS OUT ALWAYS PERSONAL NOTES HIGHLIGHTING PARTICULAR PROJECTS THAT ARE IN PEOPLE'S DISTRICTS. REALLY HE'S DONE A WONDERFUL JOB AND CONTINUES HELPING KEEP CIRM IN FRONT OF MIND WITH THE LEGISLATORS AND LET THEM KNOW WHAT GREAT WORK WE DO. SO THANK YOU VERY MUCH, MR. SENATOR.

THAT CONCLUDES MY COMMENTS. ANYBODY HAVE ANY QUESTIONS ON ANYTHING? OKAY. WITH THAT, THEN, I WILL TURN IT OVER TO DR. MILLS FOR THE PRESIDENT'S REPORT.

MS. WINOKUR: MAY I INTERRUPT. I'M HERE.

CHAIRMAN THOMAS: THANK YOU.

DR. MILLS: CHAIR THOMAS, MEMBERS OF THE BOARD, THANK YOU VERY MUCH. I JUST HAVE 178 QUICK SLIDES TO GO THROUGH. NO, I'M JOKING.

BUT LET'S GET IN WITH IT. SO THE THINGS I WANT TO BE TALKING ABOUT TODAY, FIRST, I'LL BE OBVIOUSLY REITERATING THE MISSION AS I ALWAYS DO. A QUICK REVIEW, AND I MEAN A QUICK, BRIEF REVIEW OF OUR STRATEGIC AND MORE SPECIFICALLY OUR ANNUAL PLAN JUST SO WE'RE ALL ON THE SAME PAGE OF WHAT IT IS WE'RE TRYING TO ACCOMPLISH THIS YEAR AND WHERE WE'RE GOING OVER THE FIVE-YEAR PERIOD.

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I'VE DONE THIS BEFORE, THIS 2.0 PERFORMANCE. I ACTUALLY HAVE A LOT MORE PERFORMANCE DATA HERE THAT YOU MIGHT FIND INTERESTING, BUT I'LL BE GOING OVER A BUDGET REVIEW JUST BECAUSE WE HAVE TO GO THROUGH THIS TO MAKE SURE WE DON'T GET OFF TRACK. AND THEN, LASTLY, A BRIEF UPDATE ON OUR ACCELERATING AND TRANSLATING CENTERS.

AS ALWAYS, OUR MISSION IS TO ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. WE ALWAYS ORIENT TOWARDS THIS AT CIRM. THIS IS OUR TRUE NORTH. IT IS THE IMMOVABLE THAT WE ALWAYS LOOK TO FOR GUIDANCE ON WHETHER OR NOT WHATEVER IT IS WE'RE DOING IS MOVING IN THE RIGHT DIRECTION OR NOT.

A LITTLE BIT ABOUT NOW OUR STRATEGIC PLAN AND WHY CIRM EXISTS. SO WE HAVE THESE VARIOUS COMPONENTS THAT EXIST AT CIRM: INFRASTRUCTURE, EDUCATION, DISCOVERY, TRANSLATIONAL, AND CLINICAL. AND WHAT WE'VE ATTEMPTED TO DO WITH OUR STRATEGIC PLAN IS ALIGN ALL OF THOSE TO CREATE A VERY POWERFUL ENGINE THAT WILL HELP US TAKE IDEAS AND TURN THEM INTO CURES, BUT DO SO VERY SPECIFICALLY AT A SPEED, AT A VOLUME, AND AT A SUCCESS RATE THAT IS HIGHER THAN WOULD OTHERWISE HAPPEN WITHOUT CIRM. IF WE ARE NOT WORKING ON VOLUME, SPEED, AND QUALITY IN THIS,

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THEN WE'RE NOT ACTUALLY DEMONSTRATING THE VALUE OF OURSELVES. SO A LOT OF WHAT WE MEASURE CENTERS AROUND THESE.

SO AS THE BOARD ADOPTED IN DECEMBER OF 2015 OUR STRATEGIC PLAN, WE LAID OUT WHAT WE CALL THE BIG 6, THE GOALS THAT WE WANT TO ACCOMPLISH BY 2020. FIFTY NEW CANDIDATES INTO DEVELOPMENT, PROGRESSION EVENTS. THIS IS WHEN A PROGRAM WE FUND IN AN EARLY STAGE MOVES TO THE NEXT STAGE OF DEVELOPMENT. WE WANT TO INCREASE THAT BY 50 PERCENT. NEW REGULATORY PARADIGMS THAT CAN HELP GET STEM CELL THERAPIES TO PATIENTS FASTER. WE WANT TO REDUCE TRANSLATIONAL TIME. RIGHT NOW TRANSLATIONAL TIME FOR A CELL THERAPY STANDS AT EIGHT YEARS. THE SAME EXACT JOURNEY MADE BY A NONCELL THERAPY TAKES 3.2 YEARS. OUR GOAL IS TO CUT THAT EIGHT YEARS IN HALF. FIFTY ADDITIONAL CLINICAL TRIALS, SO IT WOULD GIVE US ABOUT 65 BY 2020. AND THEN, LASTLY, WE WANT THOSE CLINICAL PROGRAMS TO BE VALIDATED, WE WANT THEM TO BE PARTNERED UP WITH INDUSTRY, SO INDUSTRY CAN GO FORWARD AND TAKE THEM OUT AND TREAT MASSES OF PEOPLE. SO THESE ARE OUR 2020 STRATEGIC GOALS.

ONE OF THE THINGS YOU NOTICE ABOUT THEM IS THEY'RE VERY OBJECTIVE. WE WILL HIT THESE OR WE WILL NOT HIT THESE, BUT IT WILL BE KNOWN ONE WAY OR

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THE OTHER. BY THE WAY, THE TEAM IS GOING TO HIT THESE.

SO IN THE DECEMBER MEETING, WE APPROVED, THE BOARD APPROVED, THE BUDGET FOR THIS YEAR. THIS IS THE BUDGET THAT WAS APPROVED IF YOU WILL RECALL. SO WE HAD ACTUALLY ALREADY FUNDED EDUCATION, SO JUST A MILLION DOLLARS IN CONFERENCE GRANTS; DISCOVERY, $52 MILLION IN FUNDING; $45 MILLION FOR TRANSLATIONAL RESEARCH; UP TO 215 MILLION FOR CLINICAL, BUT THAT INCLUDES 75 MILLION SET ASIDE FOR ALPHA CLINICS; AND INFRASTRUCTURE -- NOT ALPHA CLINICS. I'M SORRY. CLINICAL HAS 75 MILLION FOR ATP3 SET ASIDE. THEN INFRASTRUCTURE, WE HAVE SET ASIDE 16 MILLION FOR THE ADDITION OF TWO NEW ALPHA CLINICS TO OUR NETWORK TO BRING THEIR TOTAL TO FIVE.

IF YOU BACK OUT, 329 MILLION IS THE BUDGET SPEND FOR THIS YEAR IF ALL 75 IS ALLOCATED TO THE ATP3. IF NOT, THIS SPEND RATE IS ALMOST EXACTLY THE AWARD RATE WE HAD LAST YEAR.

SO IMPORTANTLY, WHAT DO WE GET FOR THAT? WHAT ARE WE GOING TO TRY TO ACCOMPLISH THIS YEAR? SO OUT OF THE 50 NEW CANDIDATES WE WANT BY 2020, WE WANT TO ADD 13 OF THEM INTO THE PIPELINE THIS YEAR. THIS IS THE FRONT END OF THE ENGINE. THIS IS THE IDEAS, THE NEW CANDIDATES THAT CAN THEN BE TAKEN

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FORWARD. PROGRESSION EVENTS, WE HAD 16 LAST YEAR. WE WANT TO HAVE 16 THIS YEAR. THIS IS A SIGNIFICANT INCREASE FROM WHAT WE USED TO HAVE. DEPENDING ON THE STAGE OF PROGRAM, OUR PROGRESSION EVENTS WERE AS LOW AS 8 PERCENT. THEY'RE NOW MUCH HIGHER FOR US.

LAST YEAR WE HAD THE ENACTMENT OF THE 21ST CENTURY CURES, WHICH WE WERE VERY HAPPY ABOUT AND VERY PLEASED TO TAKE A STRONG ROLE SPECIFICALLY ON THE STEM CELL SIDE OF IT. THIS YEAR WHAT WE'D LIKE TO SEE IS WE'D LIKE TO SEE THE VALIDATION OF THAT. WHAT WE'D LIKE TO SEE IS THE FIRST STEM CELL THERAPY PUT INTO THE ACCELERATED APPROVAL PATHWAY, AND WE THINK THAT IS POSSIBLE, AND WE THINK CIRM IS GOING TO PLAY A BIG ROLE IN THAT.

WITH REGARDS TO MOVING THINGS ALONG FASTER, ONE OF THE SURROGATE MILESTONES THAT WE USE FOR REDUCING TRANSLATIONAL TIME -- SO TRANSLATIONAL TIME, AGAIN, IS TAKING EIGHT YEARS, AND WE'RE TRYING TO GET IT TO FOUR. THAT'S A LONG STRETCH OF TIME TO MEASURE, PARTICULARLY WHEN YOU'RE TRYING TO SET GOALS WITHIN A YEAR. SO WE LOOK FOR SURROGATES THAT WE CAN DO THAT WITH.

ONE OF THEM THAT WE USE IS OUR ABILITY TO HIT MILESTONES ON TIME. ALL OF OUR PROGRAMS NOW, AND THE BOARD ASKS THIS A LOT OF US AND I WILL

REASSURE YOU EVERY TIME, ALL OF OUR PROGRAMS NOW HAVE OPERATIONAL MILESTONES ASSOCIATED WITH THEM. SO AN APPLICANT LAYS OUT THE WORK THAT THEY INTEND TO HIT AND DO; AND AS THEY HIT THOSE MILESTONES, WE THEN CONTINUE TO FUND THAT PROGRAM. IF THEY DON'T HIT THOSE MILESTONES, WE DON'T FUND THE PROGRAM UNTIL THEY DO. THIS HAS LED TO A DRAMATIC INCREASE IN THE ABILITY FOR US TO HIT OUR MILESTONES ON TIME, WHICH BEFORE THIS WAS BELOW 20 PERCENT AND IS NOW WELL OVER 50 PERCENT.

SO WE HAVE GOALS CENTERED AROUND HITTING IN THE TRANSLATION, WHICH IS THE MORE NEBULOUS AREA, AT LEAST 60 PERCENT OF OUR OPERATIONAL MILESTONES HIT ON TIME. AND CLINICAL HAS AN EVEN MORE AGGRESSIVE GOAL. THEY WANT THEIR MEDIAN MILESTONE TO BE HIT EARLY, WHICH IS PRETTY COOL.

IN ADDITION, 12 NEW CLINICAL TRIALS. WE ADDED TEN LAST YEAR ALONE. WE'RE UPPING OUR GAME. WE WANT TO HAVE 12 NEW CLINICAL TRIALS ADDED THIS YEAR. AND THEN, LASTLY, WE WANT TO HAVE THREE OF THOSE CLINICAL STAGE PROGRAMS FIND SOLVENT COMMERCIAL PARTNERS THAT CAN HELP CARRY THE LOAD FORWARD FINANCIALLY FOR US AS THEY GO INTO LATER STAGES OF DEVELOPMENT.

IMPORTANT AND I WILL ALSO SAY BUILT INTO

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ALL OF THIS CENTERS AROUND QUALITY. WE CANNOT DO ANYTHING TO ACHIEVE THESE GOALS THAT LOWERS THE QUALITY OF THESE PROGRAMS BECAUSE OUR ULTIMATE GOAL CENTERS AROUND ACTUALLY HELPING PATIENTS. SO WE BAKED INTO THESE THINGS SOME CHECKS ON QUALITY AS WELL. SO THAT'S IN A REALLY BRIEF, CONDENSED VERSION WHAT IT IS WE'RE DOING THIS YEAR.

NOW I'D LIKE TO TALK A LITTLE BIT ABOUT HOW THINGS HAVE BEEN GOING SINCE WE IMPLEMENTED 2.0. THIS IS THE CORE ENGINE OF 2.0. THESE ARE OUR RECURRING PROGRAMS: DISCOVERY, TRANSLATIONAL, AND CLINICAL. SO THE EARLIEST DISCOVERY GRANTS WE HAVE, WE CALL THEM DISC1 OR INCEPTION GRANTS. TAKE FROM A REAL HIGH RISK, HIGH REWARD IDEA, MOVE IT INTO LATER STAGE DISCOVERY. WE CALL THAT CLEVERLY DISC2. ONCE A CANDIDATE HAS BEEN FULLY DEVELOPED AND IDENTIFIED, IT THEN MOVES TO TRANSLATIONAL RESEARCH. THAT WAS THE TRANS GRANTS, TRAN1, 2, 3, AND 4, BECAUSE WE LIKE COMPLEXITY. AND THEN, LASTLY, ONCE IT'S COMPLETED TRANSLATIONAL RESEARCH, YOU'VE HAD YOUR PRE-IND MEETING WITH THE FDA, YOU THEN ENTER OUR CLINICAL STAGE. AND CLINICAL STAGE IS IND ENABLING AND THEN ULTIMATELY INTO CLINICAL TRIALS.

SO WE OFFER DISCOVERY PROGRAMS TWICE A YEAR, TRANSLATIONAL PROGRAMS NOW THREE TIMES A YEAR,

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AND CLINICAL PROGRAMS ACTUALLY EVERY SINGLE MONTH. A LOT FASTER FREQUENCY, A LOT FASTER TURNAROUND TIME.

SO I'M GOING TO GO THROUGH THESE STARTING WITH THE DISC1, THE INCEPTION GRANT, AND SHOW YOU HOW THIS HAS BEEN WORKING SINCE WE STARTED.

SO FOR DISC1 WE HAVE HAD ONE ROUND THAT'S ACTUALLY BEEN COMPLETED. WE HAVE ONE ROUND THAT'S STILL IN PROCESS. SO THAT WILL HELP YOU RECONCILE SOME OF THESE NUMBERS. BUT IN BOTH CASES WE'VE RECEIVED ALL THE APPLICATIONS WE'RE GOING TO GET FROM TWO ROUNDS. SO 173 APPLICATIONS RECEIVED, 172 OF THOSE HAVE PASSED ELIGIBILITY. YOU WILL SEE THIS IS NOT A COMMON THEME AS WE GO INTO A MORE COMPLICATED SERIES OF APPLICATIONS. SO ALMOST EVERYBODY IS PASSING ELIGIBILITY, BUT THAT'S BECAUSE THE ELIGIBILITY CRITERIA FOR THESE ARE WIDE OPEN. THESE ARE REALLY UNDEFINED, NOVEL, BIG IDEAS. SO IT'S HARDER TO FAIL ELIGIBILITY HERE.

WE THEN USE SOMETHING CALLED POSITIVE SELECTION WHERE THE GWG MEMBERS, THE PATIENT ADVOCATES ON THE GWG THEN PICK. THEY REVIEW ALL OF THE APPLICATIONS AND THEY PICK WHICH ONES THEY WANT TO BE CONSIDERED AT THE GWG MEETING. SIXTY OF 101. WE STILL HAVE 71 PENDING IN THE NEW ROUND, BUT THE

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FIRST WAVE OF APPLICATIONS AT 101. SIXTY OF THOSE WERE PICKED FOR POSITIVE SELECTION FOR COMPLETE REVIEW. SO ABOUT 60 PERCENT. OUT OF THOSE APPLICATIONS THAT WERE ULTIMATELY REVIEWED BY THE GWG FURTHER, 18 OF THOSE, AGAIN, 18 OUT OF 101, WERE ULTIMATELY RECOMMENDED FOR APPROVAL. SO THIS IS 30 PERCENT OF EVERYTHING THE GWG IS SEEING OR 18 PERCENT OF ALL OF THE APPLICATIONS THAT WE'RE RECEIVING. THIS IS IN DISC1.

WE GO ONE STEP DOWN THE LINE TO DISC2, THE LARGER DISCOVERY STAGE AWARD. IN THIS WE'VE HAD TWO COMPLETED ROUNDS, AND WE HAVE A THIRD ROUND THAT'S CURRENTLY IN PROCESS. SO WE HAVE 209 APPLICATIONS. NINETY-SEVEN PERCENT OF THOSE HAVE MET THE ELIGIBILITY CRITERIA, SO 141. AGAIN, WE'RE MIDSTREAM HERE, SO WE HAVE 63 PENDING. OUT OF THE 141, 78 PERCENT WERE PICKED FOR POSITIVE SELECTION, WHICH IS 55 PERCENT. AND OUT OF THOSE, 19 ULTIMATELY WENT ON AND WERE RECOMMENDED FOR FUNDING, WHICH IS 13 PERCENT OF ALL THE APPLICATIONS THAT WE'VE RECEIVED. THIS IS OUR MOST COMPETITIVE OF THE AWARDS WITH A 13-PERCENT APPROVAL RATING OF ALL APPLICATIONS RECEIVED.

DR. DEAS: ON THE EARLIEST STAGE OF DISCOVERY YOU MENTIONED ABOUT HAVING THOSE

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APPLICATIONS IN THE FIRST ROUND AND HAVING ENOUGH FOR THE SECOND ROUND ALREADY IN THE POOL. DOES THAT MEAN THAT YOU DON'T OPEN UP FOR NEW APPLICATIONS TO COME IN?

DR. MILLS: I'M NOT SURE I COMPLETELY UNDERSTAND THE QUESTION. SO THIS IS THE FIRST ONE. WE HAVE ONE COMPLETED ROUND AND WE HAVE ONE ROUND IN PROCESS. THESE WILL NOW BE -- THESE ARE RECURRING, SO THESE WILL NOW BE OCCURRING ABOUT EVERY SIX MONTHS. WE'RE DOING THESE TWICE A YEAR. THAT IS A CHANGE. WHEN WE IMPLEMENTED THE PROGRAM, WE WERE ONLY DOING IT ONCE A YEAR. WHAT WE FOUND WAS THERE'S PRETTY GOOD DEMAND HERE. WE HAD TWO ROUNDS, 173 APPLICATIONS IN JUST TWO ROUNDS. SO WE WANT TO GO TO A LITTLE BIT MORE FREQUENT CYCLE, EVERY SIX MONTHS, GET FRESH IDEAS IN, GET THEM TURNED OVER AND MOVED OUT.

DR. DEAS: THAT WAS THE QUESTION. I WAS WORRIED THAT WE WOULD MISS SOME OF THE FRESH IDEAS.

DR. MILLS: WE'RE SPEEDING UP BECAUSE OF THAT.

DR. DEAS: GREAT. THANKS.

DR. GASSON: RANDY, COULD YOU SAY A LITTLE BIT MORE ABOUT THE PROCESS OF POSITIVE SELECTION?

DR. MILLS: NO.

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DR. GASSON: OKAY. NEVER MIND.

DR. MILLS: POSITIVE SELECTION WAS SOMETHING THAT WE IMPLEMENTED AS A REPLACEMENT TO WHEN I WAS A GWG MEMBER -- SO I USED TO BE A GWG MEMBER AND ACTUALLY DO THESE REVIEWS -- FROM WHAT WE HAD BACK THEN WHICH WAS THE PREAPP. AND THE PREAPP PROCESS WAS YOU WOULD SUBMIT A FEW LETTERS. IT WOULD TAKE MONTHS AND MONTHS TO GO THROUGH THESE THREE TO FIVE PAGES. OUT OF THOSE, PEOPLE WERE THEN SELECTED TO COME BACK AND REAPPLY. AND BY THE TIME THAT HAPPENED, THE ORIGINAL DATA WAS USUALLY OUT OF DATE. AND IT ENDED UP BEING A TIME-CONSUMING PROCESS THAT PUT THE ACTUAL APPLICATION VERY FAR DISLOCATED IN TIME FROM THE ORIGINAL CALL.

HERE, BECAUSE WE'RE DOING THESE SO FREQUENTLY, WE CAME UP WITH THE CONCEPT OF POSITIVE SELECTION. WHAT THAT IS IS EVERYONE THAT WANTS TO APPLY APPLIES. EVERY APPLICATION IS REVIEWED. ALL OF THE MEMBERS OF THE GWG HAVE THE ABILITY TO SELECT APPLICATIONS THEY WANT REVIEWED. SO ALL THE APPLICATIONS ARE REVIEWED, AND ONLY THOSE THAT THE GWG AND PATIENT ADVOCATE MEMBERS THINK ARE SERIOUS AND WORTH CONSIDERING GO ON TO A FULL GWG PANEL FOR REVIEW. AND WE ONLY USE THIS IN THE LARGE VOLUME PROCESSES. SO DISC1 AND DISC2 ARE ACTUALLY THE ONLY

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TWO AWARDS THAT WE USE THIS PROCESS IN. AND IT'S POSITIVELY SELECTING BETWEEN 55 AND 60 PERCENT OF THE APPLICATIONS.

DR. GASSON: THANK YOU.

DR. MILLS: SO THAT'S DISC2, OUR MOST COMPETITIVE. THEN WE MOVE ON TO TRANSLATIONAL RESEARCH. HERE THE NUMBERS COME DOWN. BECAUSE THE NUMBERS COME DOWN, WE DON'T HAVE TO USE POSITIVE SELECTION. WE CAN JUST REVIEW ALL OF THE APPLICATIONS. WHEN I SAY REVIEW, I MEAN COMPLETELY AND FULLY VET THEM AT THE GWG. SO THIS IS FROM THREE COMPLETED ROUNDS, ALTHOUGH YOU HAVE ONE OF THEM THAT'S GOING TO BE COMING BEFORE YOU, BUT THIS PROCESS HAS BEEN COMPLETED ON THREE SEPARATE ROUNDS. WE OFFER THIS AWARD TYPE NOW THREE TIMES A YEAR. AGAIN, THAT'S AN ACCELERATION. WHEN WE STARTED, IT WAS ONLY TWICE A YEAR, BUT WE OFFER IT NOW THREE TIMES A YEAR.

AND I WILL SAY ONE OF THE THINGS ABOUT INCREASING THOSE PROGRAM OFFERINGS TO THREE TIMES A YEAR AND TWO TIMES A YEAR, IF YOU DON'T GET A GREAT SCORE IN THIS, YOU GET YOUR FEEDBACK JUST IN TIME TO AMEND YOUR APPLICATION AND THEN REAPPLY. SO IT'S ACTUALLY ELIMINATED THE NEED FOR THE APPEALS PROCESS BECAUSE YOU CAN ACTUALLY BE IN THE NEXT CYCLE WITH

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AN IMPROVED APPLICATION FASTER THAN YOU CAN HAVE YOUR OLD APPLICATION ACTUALLY APPEALED. JAMES IS VERY HAPPY ABOUT THAT.

DR. DIXON: THAT'S REALLY TERRIFIC.

DR. MILLS: SO 85 APPLICATIONS RECEIVED FOR TRANSLATIONAL. SIXTY-ONE OF THOSE PASSED ELIGIBILITY. SO HERE THE ELIGIBILITY CRITERIA IS MORE CONCRETE. IT'S MORE VERIFIABLE. THIS PROGRAM ISN'T AS NEBULOUS AND GRAND IDEA. WE'RE LOOKING FOR MORE SPECIFIC THINGS. SO YOU SEE A REDUCTION IN THE AMOUNT THAT ARE PASSING ELIGIBILITY. SO WE HAVE 61 THAT THE GWG HAS ISSUED A FINAL DISPOSITION ON. OUT OF THOSE, 14 HAVE BEEN RECOMMENDED FOR FUNDING, WHICH IS, IF YOU LOOK AT ALL THE APPLICATIONS WE RECEIVE, INCLUDING THOSE THROWN OUT FOR ELIGIBILITY, IT'S ABOUT 16 PERCENT. SO YOU CAN SEE AS WE MOVE THROUGH THIS, WE'RE BETWEEN 15 AND 20 PERCENT IN THESE EARLY STAGE GRANTS, WHICH ISN'T THAT DISSIMILAR FROM ABOUT 20 PERCENT THAT YOU WOULD SEE FROM NIH.

THEN WE MOVE TO OUR LAST STAGE, OUR CLINICAL STAGE OF AWARDS. WE OFFER THESE CONTINUOUSLY. SO THIS IS EVERY SINGLE MONTH WE'RE TAKING IN APPLICATIONS, WE'RE DOING REVIEWS. OUR TURNAROUND TIME ON THIS IS FROM THE TIME WE RECEIVE

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AN APPLICATION TO THE TIME THE GWG MAKES A DISPOSITION ON IT IS LESS THAN 60 DAYS NOW. SO THIS HAS BECOME A VERY EFFICIENT PROCESS. THESE ARE BIGGER APPLICATIONS, THEY'RE MEATIER APPLICATIONS, THE BUDGETS IN THESE ARE MUCH, MUCH LARGER. THIS IS A VERY LABOR INTENSE PROCESS TO DO THIS. WITH THAT SAID, 74 CLINICAL STAGE APPLICATIONS WE'VE RECEIVED. OUT OF THOSE, 50 PERCENT OR 72 HAVE BEEN ELIGIBLE. AGAIN, THE ELIGIBILITY CRITERIA HERE IS FAR MORE OBJECTIVE. IF YOU HAVEN'T HAD YOUR PRE-IND MEETING, YOU'RE NOT ELIGIBLE FOR A CLIN1. IF YOU DON'T HAVE AN ACTIVE CLINICAL TRIAL WITH AN IND APPROVED BY FDA, YOU'RE NOT ELIGIBLE. SO WE HAVE MORE OBJECTIVE CRITERIA HERE. AND SO WE HAVE AN APPLICATION PASSING ELIGIBILITY RATE OF 72 PERCENT. OUT OF THOSE, 50 THAT HAVE PASSED ELIGIBILITY. WE HAVE 48 WHERE WE HAVE FINAL DISPOSITIONS ON. WE HAVE FIVE THAT ARE UNDER REVIEW. AND THEN WHEN YOU LOOK DOWN AND SEE WHAT WE'VE ACTUALLY RECOMMENDED FOR FUNDING, WE HAVE 22 THAT HAVE GONE ON RECOMMENDED FOR FUNDING, WHICH IS 30 PERCENT OF OUR APPLICATIONS RECEIVED. SO THE CLINICAL STAGE COMES UP.

NOW, THIS IS BEING BALANCED, IT'S SORT OF INTERESTING AS YOU GO THROUGH THIS DATA, THIS DATA I'VE SHOWN YOU BEFORE. AND YOU MAY NOT REMEMBER HOW

IT'S MOVED. BUT I'LL TELL YOU HOW IT'S MOVED BECAUSE IT'S KIND OF INTERESTING.

THE APPLICATIONS PASSING ELIGIBILITY SINCE THE LAST TIME I SHOWED YOU THIS DATA, WHICH WAS IN SEPTEMBER, HAS ACTUALLY FALLEN FROM ABOUT 80 PERCENT TO 72 PERCENT. AND THAT HAS TO DO WITH WE'RE BEING MORE CLEAR UPFRONT WITH WHAT WE WANT. AND SO WE CAN MAKE ELIGIBILITY, WHICH IS A BLACK-AND-WHITE DETERMINATION THAT WE CAN MAKE PRETTY QUICKLY, WE'RE ABLE TO MAKE THAT. SO THAT 80 PERCENT HAS FALLEN TO 72 PERCENT. BUT IF YOU LOOK OVER THE TIME COURSE, IT'S BEEN A MUCH HIGHER INCREASE IN APPLICATIONS FAILING ELIGIBILITY, WHICH HAS BEEN COMPLETELY OFFSET BY THOSE THAT ARE BEING APPROVED. SO OUR APPROVAL RATING FOR APPLICATIONS ONCE THEY PASSED ELIGIBILITY IS GOING UP WHILE OUR SCREENING PASSING IS GOING DOWN. THAT'S ACTUALLY PRETTY EFFICIENT. WE WOULD MUCH RATHER HAVE THE GWG SPEND THE TIME AND FOCUS THESE APPLICATIONS, WHICH TAKE AN HOUR OR TWO EACH TO REVIEW, WE WOULD LIKE THEM TO BE FOCUSING THEIR TIME AND EFFORT ON THOSE APPLICATIONS THAT HAVE PASSED ELIGIBILITY AND THAT HAVE A CHANCE OF BEING FUNDED. SO WE'RE DOING A BETTER JOB OF SCREENING ON THE FRONT END, WHICH IS GIVING 44 PERCENT OF ALL THOSE THAT THE GWG ADJUDICATES THEY

APPROVED HERE, BUT THE 30 PERCENT HASN'T CHANGED. SO OUT OF ALL THE APPLICATIONS WE RECEIVE, OUR APPROVAL RATING IS THE SAME. IT'S JUST THAT THE GWG IS REVIEWING A HIGHER QUALITY OF APPLICATION.

DR. FEDEROFF: SO AMONG THE APPLICATIONS -- YOU MENTIONED EARLIER THAT THESE ARE BEING GATED BY THE PRE-IND DISCUSSIONS WITH THE FDA. IN THE APPLICATIONS THEMSELVES AS THEY ARE CERTAIN TO BE ADDRESSING SAFETY AND TOLERABILITY IN PHASE 1, HOW MANY ALSO ARE PROPOSING TO BRIDGE TO A PHASE 2 AT THE APPLICATION STAGE? AND IS THAT ANALYSIS WITH REGARD TO REVIEW A DETERMINANT WITH REGARD TO THEIR PRIORITIZATION?

DR. MILLS: OKAY. THIS IS A GOOD QUESTION BECAUSE IT TALKS ABOUT ACTUALLY A PRETTY SIGNIFICANT CHANGE WE MADE, BUT WE DIDN'T TALK ABOUT A LOT WHEN WE WENT FROM 1.0 TO 2.0. SO UNDER OUR 1.0 AWARDS, WE WOULD HAVE AWARDS THAT WOULD COVER LARGE SPANS OF RESEARCH. SO LITERALLY FROM LATE STAGE TRANSLATIONAL THROUGH IND-ENABLING WORK, SO POST PRE-IND MEETING, BUT BEFORE THE IND, ALL THE WAY INTO A CLINICAL TRIAL. A LITTLE BIT OF ONE CLINICAL TRIAL INTO A SECOND.

WE'VE NOW TAKEN THAT OUT BECAUSE WE OFFER THESE PROGRAMS WITH SUCH HIGH FREQUENCY,

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CONTINUOUSLY, WE'VE NOW JUST BUCKETED ALL OF THEM INTO DISCRETE AREAS. SO THE FIRST AWARD IN THE CLINICAL STAGE, CLIN1, IS GATED BY YOU'VE HAD A PRE-IND MEETING, WHICH MAKES YOU ELIGIBLE, BUT YOU DON'T YET HAVE YOUR IND. SO THAT AWARD ONLY COVERS GETTING YOUR IND.

THEN A CLIN2 AWARD IS FOR A PHASE 1 CLINICAL TRIAL AND ONLY THE PHASE I CLINICAL TRIAL, AND THEN PHASE 2 AND 3 AND SO FORTH. BECAUSE THEY WORK SO QUICKLY, THERE'S SUFFICIENT OVERLAP THAT THERE'S NOT A GAP TIME BETWEEN THERE, BUT WHAT WE DON'T DO IS WE DON'T MAKE AWARDS THAT COVER YOUR IND-ENABLING RESEARCH AND YOUR PHASE 1. WE REEVALUATE THEM EVERY TIME.

DR. DIXON: RANDY, THIS IS JACK DIXON. I HAVE A QUESTION, IF I MIGHT ASK. THE ONE THING -- I THINK YOUR CONTINUOUS REVIEW PROCESS IS REALLY SOMETHING TO BE COMMENDED. BUT THE QUESTION REALLY IS ARE YOU WEARING OUT YOUR REVIEWERS? IN OTHER WORDS, ARE YOU EXPERIENCING ANY REVIEWER FATIGUE, NOT BEING ABLE TO GET THE BEST PEOPLE TO BASICALLY REVIEW THE APPLICANTS, ETC., ETC.? MAYBE YOU COULD COMMENT ON THAT IN A GENERAL WAY.

DR. MILLS: IT'S A GREAT QUESTION. IF YOU LOOK DOWN ON THE KEY TAKEAWAYS, IT'S MY SECOND

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BULLET POINT, IT'S NOT JUST THE REVIEWERS. SO WE HAVE A GWG PANEL THAT'S MADE UP OF 15 EXTERNAL EXPERTS PLUS WE BRING IN THE AD HOC EXPERTS FOR THE DIFFERENT DISEASES. FOR ANY DIFFERENT REVIEW, WE MIGHT BE USING 20, 23 EXTERNAL EXPERTS AND ALL SEVEN OF OUR PATIENT ADVOCATE MEMBERS OF THE GWG WHO THEN HAVE TO GO ON, AS MANY OF YOU DO, AND HOLD APPLICATION REVIEW SUBCOMMITTEE MEETINGS. SO FOR THOSE BOARD MEMBERS THAT DON'T ATTEND THE APPLICATION REVIEW, THERE'S ONE HELD EVERY SINGLE MONTH TO REVIEW AND ULTIMATELY APPROVE.

AND SO WE ARE DEALING RIGHT NOW WITH A VERY HIGH WORKLOAD. I WILL TELL YOU THERE WAS A GWG MEMBER FOR THIS, ONE OF THE THINGS THAT'S CHANGED THAT I THINK DOES HELP WITH THAT FATIGUE IS, OUT OF THE GWG MEETINGS WE HAVE, WE'LL HOLD IN ANY GIVEN YEAR 12, AND LAST YEAR WE ACTUALLY DOUBLED UP ONE, SO WE ACTUALLY HELD 11. ONE OF THOSE IS IN PERSON HERE IN CALIFORNIA. WE DO THAT SO THE TEAM CAN GET AROUND THE TABLE AND WE CAN SPEND MORE TIME TALKING ABOUT OUR MISSION AND REALLY EXPLAIN AND CALIBRATE AND MAKE SURE WE'RE ON THE SAME PAGE. THE REST OF THEM NOW ARE TELEPHONIC. BECAUSE THE REST OF THEM ARE TELEPHONIC, IT'S A LOT LESS BURDEN ON THE REVIEWERS.

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I KNOW, FOR ME, WE WOULD COME OUT, BASICALLY LOSE A WEEK, BE FLYING FROM THE EAST COAST TO THE WEST COAST, SPEND A FEW DAYS OUT THERE, FLY BACK, DO THAT THREE TIMES A YEAR, AND IT WAS A LOT TO ASK. SO WHILE THEY'RE DOING MORE, THEY'RE DOING IT, WE THINK, IN A MORE EFFICIENT WAY. BUT THIS IS SOMETHING THAT GIL AND BECKY AND THE REST OF THE REVIEW TEAM KEEP A PRETTY GOOD EYE ON THE REVIEWERS. AND WE DO ADD NEW REVIEWERS INTO THE PROCESS AND ROTATE OTHERS OUT, SO WE MAKE SURE WE'RE NOT BURNING THEM OUT.

MS. LANSING: I JUST REALLY WANT TO COMMEND YOU. I WATCHED THIS PROCESS EVOLVE OVER A DECADE, AND I THINK WHAT YOU HAVE DONE IS JUST EXTRAORDINARY. AND I ALSO WANT TO SECOND WHAT YOU SAID ABOUT THE REVIEWERS. EVEN THOUGH THE INTENSITY OF THE WORK IS THE SAME, THEY'RE GAINING AT LEAST TWO FULL DAYS, ONE ON EACH END FOR TRAVEL. SO I WANT TO REEMPHASIZE THAT AND JUST COMMEND YOU. EVERYTHING THAT I THINK YOU'RE DOING IN HAVING THIS BE CONSTANT EVALUATION OPENS US UP TO GET THE BEST SCIENCE. SO THIS IS JUST REALLY CONGRATULATIONS.

DR. MILLS: THANK YOU VERY MUCH. I DO REALLY WANT TO POINT OUT THAT IT IS ALL ME. THAT'S A JOKE. THE JOKE IS --

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MS. LANSING: YOU WERE SPEAKING ON BEHALF OF THIS EXTRAORDINARY TEAM.

DR. MILLS: I AM. AND IT IS AN EXTRAORDINARY TEAM. WE HAVE TALKED. WE HAD A VERY GOOD YEAR LAST YEAR, AND YOU GUYS WILL SEE THE BOARDS HERE THAT HAVE THE SCOREBOARDS THAT WE USE. THIS TEAM IS ABSOLUTELY PHENOMENAL.

CHAIRMAN THOMAS: RANDY, I JUST WANTED TO ADD. FOR THE BENEFIT OF THE BOARD, RANDY'S ALLUDED TO THIS IN THE PAST, BUT JUST TO REITERATE, ONE OF THE GREAT THINGS THAT HE AND THE TEAM ARE DOING IS THEY CONTINUE TO EVALUATE WHETHER THE LATEST VERSION OF WHAT WE DO IS THE BEST. SO AS RANDY IS FOND OF POINTING OUT, CIRM 2.0 NOW IS REALLY 2.8 AND INCREASING. SO AS TIME GOES BY, THEY CONTINUE TO MAKE ADJUSTMENTS, CONTINUE TO MAKE THE PROCESS MORE EFFICIENT AND BETTER, AND I THINK YOU'RE SEEING THE RESULTS OF THAT IN WHAT HE IS SAYING HERE AND HAS SAID IN THE PAST. SO CONGRATULATIONS TO RANDY AND ALL THE TEAM FOR THAT.

DR. MILLS: OKAY. SO THE LAST BULLET POINT ON THE KEY TAKEAWAYS HERE, 74 APPLICATIONS HAVE YIELDED US 22 APPROVALS. LOOKING THAT WE NEED THAT NUMBER TO GO TO 50 OR ACTUALLY IT'S A LITTLE HIGHER BECAUSE CIRM 2.0 PREDATES THE STRATEGIC PLAN,

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WE STILL NEED TO BE RUNNING THIS AT VERY HIGH VOLUMES. BECAUSE IF WE'RE NOT RUNNING THEM AT HIGH VOLUMES, WE WOULD THEN LOWER OUR QUALITY STANDARDS, AND WE WILL NOT LOWER OUR QUALITY STANDARDS.

NOW, THIS IS LIKE EATING YOUR VEGETABLES, BUT WE GOT TO DO IT, GO THROUGH SOME BUDGET COMMENTS. I'LL START WITH A HIGH LEVEL. WE HAVE SOME NEW BOARD MEMBERS. I'D JUST LIKE TO TALK ABOUT THIS IN LESS SOPHISTICATED, BUT VERY CLEAR TERMS BECAUSE I THINK IT'S AN IMPORTANT THING THAT EVERYONE UNDERSTANDS.

AT CIRM WE TALK ABOUT THE $3 BILLION STEM CELL AGENCY. ITS FUNDING REALLY EXISTS IN TWO DISCRETE BUCKETS. ONE OF THEM WE CALL THE BIG BUCKET HAS $2.75 BILLION PUT IN IT INITIALLY. THAT IS THE AWARD BUCKET. SO WHEN WE APPROVE GRANTS, IT COMES OUT OF THE AWARD BUCKET. WE ALSO HAD 180 MILLION OF THAT 3 BILLION SPLIT OFF THAT WENT TO THE ADMINISTRATIVE BUCKET. THIS IS THE MONEY THAT WE USE TO FUND THE CIRM TEAM, THE BUILDING, THE REVIEW PROCESSES, AND ALL OF THE OTHER. SO THESE ARE TWO DISTINCT BUCKETS.

KEY POINT HERE IS WHEN EITHER ONE OF THESE BUCKETS GOES TO ZERO, CIRM IS OVER. AND SO WHAT WE'RE DOING IS WE'RE DOING EVERYTHING WE CAN TO

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ALIGN THESE TWO BUCKETS SO THAT THEY GO TO ZERO AT THE SAME TIME. BECAUSE IT WOULD BE A SHAME TO HAVE MONEY LEFT OVER IN ONE AND NOT THE OTHER. THAT'S WHERE JUNE OF 2020 COMES IS WHEN WE ANTICIPATE THE AWARD BUCKET WILL HAVE THE LAST AWARD DOLLARS ISSUED. THE ADMINISTRATIVE BUCKET OBVIOUSLY GOES ON A LITTLE FURTHER FOR THE ADMINISTRATION OF THOSE AWARDS AND THINGS LIKE THAT.

HOW ARE WE DOING? OUT OF THE ADMINISTRATIVE BUCKET, THE LITTLE BUCKET, WE'VE SPENT 123 MILLION. AGAIN, THIS IS SINCE OUR INCEPTION. KEEP IN MIND THIS IS AN ORGANIZATION THAT WAS ORIGINALLY DESIGNED WITH THIS BUCKET TO BE ABLE TO TAKE US TO 2014 OR TEN YEARS AFTER WE STARTED, MAYBE 2016. SO WE'RE ACTUALLY STRETCHING THIS OUT TO MAKE IT GO ALL THE WAY THROUGH 2020. WE HAVE 57 MILLION REMAINING AT A SPEND RATE RIGHT NOW OF ABOUT 15 MILLION PER YEAR OUT OF THIS. OBVIOUSLY AS WE GET CLOSER TO THE END, THERE WOULD BE ACTIVITIES THAT WE WOULDN'T NEED TO DO, THE BURN RATE COMES DOWN A LITTLE BIT AND LIFE GOES ON A LITTLE LONGER.

FISCAL RESPONSIBILITY HERE IS VERY IMPORTANT. BUT IT IS -- SHE'S NOT HERE, CHILA, WHO MANAGES FINANCING IS NOT HERE SO WE CAN TALK ABOUT

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HER. SHE DOES A GREAT JOB, HER AND HER TEAM DO A GREAT JOB MANAGING THIS, AND WE NEVER EVER, EVER GO OVER BUDGET.

THE BIG BUCKET IS A LOT MORE COMPLEX THAN THE LITTLE BUCKET BECAUSE THE LITTLE BUCKET IS REALLY A ONE-WAY STREET. THAT MONEY COMES OUT OF THAT AND IT STAYS OUT OF THAT. THE AWARD BUCKET IS A LITTLE DIFFERENT, AND IT WAS MADE A LOT DIFFERENT BY US IMPLEMENTING THE MILESTONE STRUCTURE THAT WE CURRENTLY HAVE. AND SO THIS IS THE 2016 ACTUALS. I ACTUALLY SHOWED YOU THIS AT THE DECEMBER MEETING. IT WAS AN APPROXIMATION OF WHAT WE THOUGHT IT WOULD END UP WITH. IT CHANGED BY A TINY AMOUNT, $3 MILLION. BUT THE WAY THIS WORKS IS WE MAKE AWARDS. SO IN 2016 WE MADE $259 MILLION IN NEW AWARDS. SO THAT MONEY WENT FROM THAT WE CALL UNCOMMITTED BIG BUCKET MONEY TO COMMITTED. THE AWARD WAS MADE. BUT BECAUSE WE HAVE THAT MILESTONE STRUCTURE, WE DON'T PAY THAT OUT ALL AT ONCE. WE DIDN'T WRITE $259 MILLION IN CHECKS LAST YEAR. WE, INSTEAD, SET UP THE MILESTONE SYSTEM. WHEN PEOPLE DON'T HIT THE MILESTONE OR AS PROGRAMS FAIL, AS IN BIOTECH AND CELL THERAPY YOU WOULD EXPECT PROGRAMS AT A CERTAIN RATE TO FAIL, THAT MONEY THEN IS TAKEN BACK, AND IT'S MOVED FROM THE COMMITTED BACK TO THE

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UNCOMMITTED BUCKET SO IT CAN BE REDEPLOYED.

SO $259 MILLION WE COMMITTED LAST YEAR. WE HAD REDUCTIONS AND REPAYMENTS OF 30 MILLION. SO OUR NET WAS 229. WHY THAT'S IMPORTANT IS WE HAVE $539 MILLION REMAINING IN THE AWARD BUCKET; BUT OUT OF THAT, WE PLAN TO ISSUE BETWEEN NOW AND MID-2020 ABOUT $659 MILLION IN NEW AWARDS. THAT'S BECAUSE THE CYCLE COMES OUT, AND WE HAVE MODELING. THE MODELS THAT WE USE ARE ACTUALLY FAR MORE COMPLEX THAN THIS TO EVALUATE THAT, BUT IT'S ABOUT 695 MILLION THAT WE'LL BE ABLE TO MAKE IN NEW AWARDS. SO THAT'S GOOD. THAT'S STILL ON TRACK AND WHAT WE WOULD EXPECT. QUESTIONS ABOUT THE BUDGET?

AND THEN THE LAST THING, THIS IS JUST A YAY, GO US, IS LAST YEAR WE IN ONE YEAR CAME UP WITH THE CONCEPT PLAN FOR ACCELERATING AND TRANSLATING CENTERS. SO THESE WERE TWO SPECIFIC CENTERS DESIGNED TO ADDRESS AND REALLY GO AFTER THAT GAP IN TRANSLATIONAL TIME RIGHT NOW. THAT'S EIGHT YEARS FOR US AND 3.2 YEARS FOR EVERYONE ELSE, AND WE LOOKED AT WHY SOME OF THOSE REASONS WERE. AND IT CENTERED AROUND THAT THERE WEREN'T A LOT OF EXPERTISE SPECIFICALLY IN CELL THERAPY, FDA-REQUIRED TRANSLATIONAL RESEARCH. THERE I DON'T MEAN THE INTERESTING ANIMAL STUDIES THAT SHOW EFFICACY OR

MECHANISM OF ACTION. INSTEAD, I'M TALKING ABOUT THE BORING STUFF LIKE STABILITY STUDIES AND TOX STUDIES, AND ALL OF THE THINGS THAT THE FDA REQUIRES THAT AN INVESTIGATOR MIGHT NOT BE THAT INTERESTED IN.

SO WE THOUGHT WE WOULD HAVE A TRANSLATING CENTER THAT WOULD DO THAT KIND OF RESEARCH. IN ADDITION, WE WANTED A STEM CELL-SPECIFIC CRO THAT COULD GET GOOD AT WORKING SPECIFICALLY WITH THE CENTER FOR BIOLOGICS AT FDA ON IND COMPILING AND FILING AND APPROVALS SO WE COULD HELP GET OUR TRANSLATIONAL PROGRAMS TO THE STAGE WHERE THE FDA HAS APPROVED THEM TO ENTER CLINICAL TRIALS. AND THAT WAS THE ACCELERATING CENTER. SO WE PUT UP BOTH OF THESE CONCEPTS LAST YEAR, HELD REVIEWS FOR BOTH OF THESE CONCEPTS, AND WE ACTUALLY GOT BOTH OF THEM AWARDED. AND GABE AND THE GRANTS MANAGEMENT TEAM ON DECEMBER 28TH GOT THE FINAL CENTER CONTRACTED AND UP AND RUNNING, AND IT'S WORKING VERY WELL. BECAUSE BOTH AWARDS WENT TO QUINTILES, THEY HAVE RENAMED THE CENTER TO, CLEVERLY, THE STEM CELL CENTER, MARKETING GENIUSES. SO NOW THAT CENTER IS OPERATING AS ONE.

THEY ALREADY HAVE FIVE PROGRAMS UP AND RUNNING, INCLUDING THREE THAT ARE 1.0 PROGRAMS. THAT'S A REALLY, REALLY EXCELLENT THING BECAUSE THEY'RE HELPING EARLIER STAGE PROGRAMS THAT HAVE

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BEEN MIRED DOWN A LITTLE BIT IN THIS PROCESS TO GET BACK ON TRACK AND MOVE ALONG. THEY ALSO HAVE LIKE TEN DIFFERENT, WE CALL THEM, HUNTING ACTIVITIES. THEY HAVE TEN DIFFERENT ORGANIZATIONS THAT THEY'RE WORKING WITH TO HELP BRING INTO CIRM, HELP WITH THEIR APPLICATIONS, ATTRACT THE BEST PROGRAMS. THEY'RE BASICALLY NOW GOING OUT AND ADVERTISING ON CIRM'S BEHALF THE DIFFERENT PROGRAMS THAT WE OFFER, AND THEY'RE HELPING THESE PEOPLE GET FAMILIAR WITH CIRM'S PROGRAMS AND APPLY. SO SO FAR THIS IS WORKING REALLY WELL.

THAT IS MERCIFULLY ALL I HAVE. ANY MORE QUESTIONS? OKAY. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, DR. MILLS.

ON TO THE MOST RIVETING ITEM AT EACH OF OUR BOARD MEETINGS, THE CONSENT CALENDAR. DOES ANYBODY HAVE ANYTHING THEY WANT TO PULL OUT OF THAT FOR SPECIFIC CONSIDERATION? MR. SHEEHY.

MR. SHEEHY: I JUST WANTED TO MAKE A COMMENT BECAUSE WE'RE RENEWING SOME OF THE GRANTS WORKING GROUP FOLKS WHO HAVE BEEN WITH US FOR QUITE A LONG TIME. AND PER THE DISCUSSION ABOUT BURNOUT AND THE WORKLOAD THAT THEY'RE DOING, SOME OF THE FOLKS THAT WE'RE RENEWING HAVE JUST BEEN EXTRAORDINARY CONTRIBUTORS TO OUR PROGRAM. IF YOU

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GET A CHANCE, LOOK THROUGH THAT. WE REALLY OWE THEM A HUGE DEBT.

CHAIRMAN THOMAS: HERE. HERE, MR. SHEEHY. THANK YOU FOR MAKING THAT POINT.

DO I HAVE A MOTION TO APPROVE THE CONSENT CALENDAR?

DR. PRIETO: SO MOVED.

DR. STEWARD: SECOND.

CHAIRMAN THOMAS: MOVED BY DR. PRIETO, SECONDED BY DR. STEWARD. ALL THOSE IN FAVOR IN THE ROOM PLEASE SAY AYE. OPPOSED? ABSTENTIONS? MARIA, CALL THE ROLL, PLEASE, FOR THOSE ON THE PHONE.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: YES.

MS. BONNEVILLE: KATHY LAPORTE. LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: YES.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

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MS. BONNEVILLE: BRUCE WINTRAUB.

DR. WINTRAUB: YES.

MS. BONNEVILLE: SHERRY LANSING.

MS. LANSING: YES.

CHAIRMAN THOMAS: THANK YOU, MARIA. ON TO THE ACTION ITEMS. THE FIRST IS CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO THE CLIN1, PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL PROJECTS, AND CLIN2, PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS. CLINICAL PRESENTATION, WE'RE GOING TO FIRST HEAR FROM DR. SAMBRANO.

DR. SAMBRANO: THANK YOU VERY MUCH, MR. CHAIRMAN. GOOD MORNING, EVERYONE. SO WE'RE BRINGING FOR YOUR CONSIDERATION TODAY APPLICATIONS THAT ARE RESPONDING TO OUR CLINICAL STAGE PROGRAMS. AND JUST A REMINDER, AGAIN, THAT WE HAVE THREE TYPES OF PROGRAMS. THESE ARE RESPONDING TO THE CLIN1, WHICH ARE IND-ENABLING WORK, AS WELL AS CLIN2, WHICH ARE THE PHASED CLINICAL TRIALS.

I WANT TO MAKE A NOTE, THAT ONE OF APPLICATIONS FOR WHICH WE PROVIDED MATERIALS, CLIN1-09759, IS GOING TO BE DEFERRED. THE APPLICANT FILED AN APPEAL REQUEST. SO WE ARE REVIEWING THAT, AND WE WILL BRING THAT BACK TO YOU WHEN THAT HAS

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BEEN RESOLVED.

A COUPLE OF NOTES AND REMINDERS ABOUT OUR PROCESS. EVERY TIME WE DO A CLINICAL REVIEW, AFTER THE CONDUCT OF AN APPLICATION REVIEW, WE HAVE THE FULL PANEL, INCLUDING THE PATIENT ADVOCATE MEMBERS, TAKE A VOTE ON THE OVERALL PROCESS. AND THESE ARE THE STATEMENTS WHICH THE VOTE IS TAKEN ON, AND ALL MEMBERS VOTE ON WHETHER THEY FELT THAT THE REVIEW WAS SCIENTIFICALLY RIGOROUS, WHETHER THERE WAS SUFFICIENT TIME FOR ALL VIEWPOINTS TO BE HEARD, AND THAT THE SCORES REFLECT THE RECOMMENDATION OF THE GRANTS WORKING GROUP. THE PATIENT ADVOCATE MEMBERS, WHO ARE ALSO MEMBERS OF THIS BOARD AND HAVE OVERSIGHT DUTY, TAKE A VOTE ON WHETHER THEY FEEL THAT THE REVIEW WAS CARRIED OUT IN A FAIR MANNER AND WAS FREE FROM UNDUE BIAS.

I WANT TO NOTE THAT THE VOTE, AS IT OFTEN HAS BEEN, WAS UNANIMOUS IN FAVOR ON BOTH STATEMENTS FOR ALL APPLICATIONS THAT I WILL BE PRESENTING TO YOU TODAY.

THE SCORING SYSTEM THAT WE UTILIZE FOR THE CLIN REVIEW IS A 1, 2, 3 SYSTEM. APPLICATIONS THAT RECEIVE A SCORE OF 1 FROM THE GRANTS WORKING GROUP MEANS THAT THESE ARE APPLICATIONS THAT HAVE EXCEPTIONAL MERIT AND FROM THEIR PERSPECTIVE WARRANT

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FUNDING. A SCORE OF 2 MEANS IT'S A PROMISING APPLICATION THAT NEEDS IMPROVEMENT, BUT WOULDN'T WARRANT FUNDING AT THIS TIME. AND IT'S SOMETHING THAT CAN BE RESUBMITTED TO ADDRESS THE AREAS THAT NEED IMPROVEMENT. AND THEN A SCORE OF 3 MEANS THE APPLICATION IS SUFFICIENTLY FLAWED SUCH THAT IT DOESN'T WARRANT FUNDING AND SHOULD NOT BE RESUBMITTED FOR AT LEAST SIX MONTHS. ESSENTIALLY MEANS PLEASE GO BACK AND TRY AGAIN. AND ALL APPLICATIONS ARE SCORED BY SCIENTIFIC MEMBERS WHO DO NOT HAVE A CONFLICT.

SO WE'LL GO THROUGH EACH OF THESE ONE AT A TIME, AND I'M GOING TO PRESENT THE HIGHLIGHTS OF THE FIRST ONE.

THE FIRST APPLICATION IS CLIN2-09284. THIS IS A CLINICAL TRIAL PROPOSAL FOR A CELL THERAPY FOR ALS OR LOU GEHRIG'S DISEASE. THE THERAPY THAT IS PROPOSED IS A NEUROPROGENITOR CELL THAT SECRETES GDNF FOR ALS PATIENTS. THEIR GOAL UNDER THIS PROPOSAL IS TO COMPLETE A PHASE 1/2A CLINICAL TRIAL TO TEST THE SAFETY IN PATIENTS. THE MAJOR ACTIVITIES INCLUDE THE ENROLLMENT OF THE PATIENTS INTO THE CLINICAL TRIAL, THE ASSESSMENT OF THE THERAPEUTIC PRODUCT, AND THEY ARE REQUESTING ABOUT $6 MILLION TO CONDUCT THIS WORK.

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WHEN WE TAKE THESE APPLICATIONS THROUGH THE REVIEW PROCESS, WE CONDUCT BOTH A BUDGET REVIEW INITIALLY BEFORE IT GOES TO THE GRANTS WORKING GROUP. SO THAT BUDGET REVIEW THAT WE CONDUCT INTERNALLY, THIS APPLICATION GOT A PASS. SO IT WENT ON TO THE GWG. THEY REVIEWED IT AND SCORED IT A 1 WITH SEVEN MEMBERS GIVING IT A SCORE OF 1, THREE MEMBERS GIVING IT A SCORE OF 2, AND NONE GIVING IT A SCORE OF 3. WE ALSO EVALUATE OUR PROCESS TO MAKE SURE THAT EVERYTHING THAT NEEDED TO BE DONE IN TERMS OF MAKING IT A FAIR REVIEW AND A COMPLETE REVIEW HAS BEEN DONE. AND SO THE CIRM TEAM, BASED ON ALL THAT, CONCURS WITH THE CONCLUSIONS OF THE GWG ON THAT RECOMMENDATION AND SUGGEST AN AWARD AMOUNT OF 6.2 MILLION.

AND JUST A NOTE, AND THIS WILL BE A NOTE ON EACH OF THE AMOUNTS THAT WE PRESENT TO YOU, THAT THE FINAL AWARD AMOUNT THAT'S APPROVED WILL NOT EXCEED THAT AMOUNT AND MAY BE REDUCED CONTINGENT ON CIRM'S ASSESSMENT OF ALLOWABLE COSTS AND ACTIVITIES AS WE GO FROM APPROVAL INTO THE CONTRACT PHASE WITH EACH OF THE APPLICANTS.

SO I WILL PAUSE HERE FOR YOU TO CONSIDER THIS APPLICATION.

CHAIRMAN THOMAS: SO WE'LL TURN THIS OVER

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TO SUPERVISOR SHEEHY, HAS A NICE RING TO IT, TO CONDUCT PROGRAMMATIC REVIEW ON THIS APPLICATION.

MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS. YOU KNOW IT'S FUNNY THAT YOU MENTION THAT I GET A TITLE NOW. I HAVEN'T HAD A TITLE SINCE I'M ON THE BOARD. IT SEEMED LIKE EVERYBODY ELSE HAD A TITLE. THEY USED TO PUT J.D. BECAUSE WE HAD A LOT OF LAWYERS AND THEN M.D. OR PH.D. IT'S ALWAYS JUST BEEN THIS. I DON'T KNOW IF THAT'S BETTER OR WORSE.

SO WHAT I WOULD DO NOW IS TAKE A MOTION TO EITHER APPROVE OR NOT APPROVE FUNDING FOR THIS PROJECT.

MR. TORRES: MOVE TO APPROVE, MR. CHAIRMAN.

MR. SHEEHY: MOTION BY SENATOR TORRES.

DR. DULIEGE: SECOND.

MR. SHEEHY: SECONDED BY DR. DULIEGE. I'M TALKING TOO MUCH. ANNE-MARIE. I KNOW.

IS THERE ANY DISCUSSION AMONGST THE BOARD MEMBERS? ANY PUBLIC COMMENT?

MR. REED: THIS IS OBVIOUSLY A TERRIFIC PROGRAM. EVERYBODY AGREES ON IT THAT I CAN SEE. BUT I JUST WANTED TO REMEMBER JOHN AMES WHO WAS A TERRIFIC PATIENT ADVOCATE, WORKED VERY HARD ON PROPOSITION 71. I REMEMBER WHERE I WAS WHEN HE GOT

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THE NEWS THAT HIS SON, DAVID AMES, HAD DIED OF ALS. SO THIS HAS A TERRIFIC MEANING, THAT WE'RE FIGHTING BACK AGAINST SOMETHING WHICH IS JUST A DEADLY FOE. AND THAT'S IT.

MR. SHEEHY: THANK YOU, DON. SEEING NO OTHER PUBLIC COMMENT, MARIA, COULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: KATHY LAPORTE. 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.

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MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: SHERRY LANSING.
MS. LANSING: YES.
MS. BONNEVILLE: THANK YOU. MOTION CARRIES.
DR. DULIEGE: IF I MAY JUST ASK A QUESTION. I DIDN'T WANT TO ASK IT BEFORE BECAUSE THIS HAS NOTHING TO DO WITH MY APPROVAL, BUT I CAN'T HELP BUT BE CURIOUS ABOUT THE SIZE OF THIS TRIAL, AND HOW LONG IS THE INVESTIGATOR EXPECTED TO HAVE RESULTS? IT'S JUST TO KNOW WHAT WILL BE THE NEXT STEP AFTER THAT.
DR. SAMBRANO: SO THIS PROJECT IS ACTUALLY A CONTINUATION OF A PROJECT THAT WE HAVE BEEN FUNDING. SO THEY'RE GOING ON NOW TO THE NEXT STAGE

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OF DOING THEIR PHASE 1 TRIAL. IT IS RELATIVELY SMALL, SO IT'S UNDER 20 PATIENTS THAT THEY INTEND TO TREAT. AND SO THE LENGTH OF TIME, I DON'T HAVE THE TIMELINE, BUT TYPICALLY IT'S ABOUT TWO TO THREE YEARS.

DR. DULIEGE: AND THEY HAVE ALREADY TREATED SOME PATIENTS INITIALLY?

DR. SAMBRANO: THEY HAVE NOT YET TREATED PATIENTS.

DR. DULIEGE: FIRST TIME. OKAY.

DR. SAMBRANO: SO THE NEXT APPLICATION IS CLIN1-09472. THIS IS A PROJECT TO CONDUCT PRECLINICAL DEVELOPMENT STUDIES FOR A CELL THERAPY FOR KNEE OSTEOARTHRITIS. THE THERAPEUTIC IS AN ADIPOSE-DERIVED MESENCHYMAL PROGENITOR CELL PRODUCT. THE INDICATION IS FOR KNEE OSTEOARTHRITIS. AND THEIR GOAL IS TO COMPLETE PRECLINICAL ACTIVITIES THAT WILL ALLOW THEM TO FILE AN IND TO TEST THE PRODUCT IN A CLINICAL TRIAL.

THE MAJOR ACTIVITIES THAT ARE PROPOSED INCLUDE MANUFACTURING OF THIS PRODUCT TO SUPPLY THE PROPOSED TRIAL, COMPLETE SOME NONCLINICAL SAFETY STUDIES THAT WERE REQUESTED BY THE FDA, AND PREPARE AND FILE THE IND. THIS PRODUCT IS SUPPORTED BY SOME PRECLINICAL AS WELL AS CLINICAL DATA OF AN

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AUTOLOGOUS PRODUCT, SO THEY'RE MAKING THIS INTO AN ALLOGENEIC PRODUCT. THAT IS WHY THEY HAVE SOME SPECIFIC REQUESTS FROM THE FDA AND THE NATURE OF THE WORK THAT IS BEING CONDUCTED.

IN THE NEXT SLIDE WE SHOW THAT THE BUDGET REVIEW THAT WE CONDUCTED RECEIVED A PASS. THE GWG GAVE IT A SCORE OF 1, MEANING THAT THEY FELT THAT THIS HAD EXCEPTIONAL MERIT. THERE WERE TEN MEMBERS THAT VOTED FOR A SCORE OF 1, ONE MEMBER THAT VOTED FOR A SCORE OF 2, AND ONE MEMBER THAT VOTED FOR A SCORE OF 3. WE CONCUR, CIRM, WITH THE RECOMMENDATION FROM THE GWG AND REQUEST AN AWARD AMOUNT OF 2.3 MILLION. MR. SHEEHY.

MR. SHEEHY: THANK YOU, DR. SAMBRANO. DO I HAVE A MOTION TO APPROVE OR NOT APPROVE THIS APPLICATION?

MR. TORRES: AS A PRECURSOR, I WILL NOT TAKE ADVANTAGE OF THIS AS I HAD A KNEE PUT IN TWO YEARS AGO. SO I CAN MOVE TO HAVE THIS APPROVED WITHOUT ANY CONFLICTS.

DR. DIXON: VERY DIFFICULT TO HEAR YOU.

MR. TORRES: MOVE TO APPROVE.

MR. SHEEHY: DO I HAVE A SECOND?

DR. JUELSGAARD: SECOND.

MR. SHEEHY: SECOND BY STEVE JUELSGAARD.

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DO WE HAVE ANY PUBLIC COMMENT? STEVE.

DR. JUELSGAARD: YES, GIL, SO IN THE LONGER PRESENTATION ASSOCIATED WITH THIS, THERE'S DISCUSSION OF WORK THAT'S PREVIOUSLY BEEN DONE IN CHINA. AND THIS WORK NOW IS BEING BROUGHT INTO CALIFORNIA TO CARRY THAT ON. CAN YOU TALK A LITTLE BIT ABOUT WHAT THE NEXUS WITH CHINA IS, WHAT'S BEEN DONE?

DR. SAMBRANO: WHAT I HAD JUST VERY BRIEFLY MENTIONED WAS THAT THEY HAVE AN AUTOLOGOUS PRODUCT THAT THEY TESTED IN CHINA. SO THIS IS FROM CELLS THAT WERE DERIVED FROM EACH OF THESE PATIENTS, THEY WERE WORKED UP, AND THE SAME PATIENTS TREATED. WHAT THEY'RE TRYING TO CREATE NOW IS AN ALLOGENEIC PRODUCT THAT CAN BE MORE BROADLY UTILIZED FOR MORE PATIENTS. SO THEY HAVE BOTH THAT PRECLINICAL DATA AND SOME OF THE CLINICAL DATA TO SUPPORT THE CONCEPT, BUT NOW THEY'RE GENERATING THE ALLOGENEIC PRODUCT THROUGH THE PRECLINICAL STUDIES THAT THEY ARE DOING. THEY HAVE ALREADY DONE PRECLINICAL STUDIES AND THEN PLAN TO CONDUCT A TRIAL HERE IN THE U.S. UNDER THE FDA TO BRING THE ALLOGENEIC PRODUCT TO THE U.S.

MR. SHEEHY: ANY OTHER BOARD COMMENTS OR QUESTIONS? PUBLIC COMMENT? MARIA, COULD YOU CALL

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THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: KATHY LAPORTE.

MS. LAPORTE: 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: NO.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: YES.

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MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
MR. SHEEHY: NEXT APPLICATION, DR. SAMBRANO.
DR. SAMBRANO: THE NEXT APPLICATION IS CLIN2-09504. THIS IS A PROJECT TO CONDUCT A CLINICAL TRIAL OF A CELL THERAPY FOR X-LINKED SEVERE COMBINED IMMUNODEFICIENCY OR SCID. THE THERAPY IS A GENE-CORRECTED AUTOLOGOUS BONE MARROW STEM CELL FOR PATIENTS WITH X-SCID. THE GOAL IS TO COMPLETE A PHASE 1/2A CLINICAL TRIAL TO TEST THE SAFETY AND INITIAL EFFICACY OF THIS THERAPEUTIC IN PATIENTS.
SOME OF THE PROPOSED ACTIVITIES INCLUDE OPENING A TRIAL WITH THE CALIFORNIA PARTNER INSTITUTION. THEIR APPROACH HERE IS THIS IS AN APPLICANT WHO IS FROM OUTSIDE OF CALIFORNIA THAT IS PARTNERING WITH THE CALIFORNIA INSTITUTION, SO SOME PATIENTS WILL BE TREATED IN CALIFORNIA AND SOME OUTSIDE OF CALIFORNIA. THE FUNDING THAT IS REQUESTED IS TO CONDUCT THE STUDY THAT WILL TAKE

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PLACE IN CALIFORNIA.

THEY WILL ENROLL PATIENTS AND THEN ANALYZE THE IMMUNE RECONSTITUTION AND SAFETY IN THE X-SCID PATIENTS. THE FUNDS REQUESTED IS 11.9 MILLION.

AND ON THE NEXT SLIDE, JUST A SUMMARY OF THE REVIEW. THEY HAD A PASS ON THE OVERALL BUDGET REVIEW. THE GWG GAVE IT AN OVERALL SCORE OF 1, WITH TEN MEMBERS GIVING IT A SCORE OF 1 AND TWO MEMBERS A SCORE OF 2. AND THE CIRM TEAM CONCURS WITH THIS RECOMMENDATION AND RECOMMENDS AN AWARD AMOUNT OF 11.9 MILLION.

MR. SHEEHY: THANK YOU, DR. SAMBRANO. COULD I GET A MOTION TO FUND THIS APPLICATION OR TO NOT FUND?

DR. HIGGINS: SO MOVED.

MR. SHEEHY: SO IT'S MOVED TO --

DR. HIGGINS: FUND.

MR. SHEEHY: -- FUND BY DAVID HIGGINS. DO I HAVE A SECOND?

DR. PRIETO: SECOND.

MR. SHEEHY: SECOND BY DR. PRIETO. ANY BOARD -- STEVE JUELSGAARD.

DR. JUELSGAARD: SO, DR. SAMBRANO, IN LOOKING AT THE BUDGET ASSOCIATED WITH THIS, WHICH IS APPROACHING $12 MILLION, BASICALLY TO ENROLL SIX

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PATIENTS IN A CLINICAL TRIAL. I GUESS WHEN THIS WAS REVIEWED BY OUR BUDGET REVIEWERS, THEY CONSIDERED THIS APPROPRIATE. IT JUST SEEMS, WHEN YOU LOOK AT THE OTHER -- IN THIS PARTICULAR ROUND, THE OTHER TRIALS THAT ARE BEING CONDUCTED WHERE PATIENTS ARE BEING ENROLLED, NOBODY APPROACHES A $2 MILLION PER PATIENT COST OF ENROLLMENT. SO I'M CURIOUS AS TO WHY IT COSTS SO MUCH, OR WHETHER THERE'S SOMETHING ELSE INVOLVED; AND, IF SO, WHAT AMOUNT OF MONEY IS ALLOCATED TO THAT SOMETHING ELSE?

DR. SAMBRANO: SO PART OF THE ACTIVITIES ALSO INCLUDE MANUFACTURING OF THE PRODUCT, BUT IT'S IMPORTANT TO NOTE THAT THIS IS AN AUTOLOGOUS PRODUCT. SO THAT ITSELF INCREASES THE COST SUBSTANTIALLY. IT IS SIMILAR TO OTHER PROJECTS OF THIS TYPE THAT BASICALLY INVOLVE AN AUTOLOGOUS BONE MARROW TRANSPLANT TO TREAT SCID OR OTHER SIMILAR DISEASES. SO IN TERMS OF THE OVERALL RELATIVE AMOUNT AND THE ACTIVITIES THAT ARE PROPOSED, IT IS NOT FAR FROM WHAT WE HAVE PREVIOUSLY APPROVED.

MR. SHEEHY: ANY OTHER BOARD COMMENTS OR QUESTIONS? PUBLIC COMMENT? MARIA, COULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: KATHY LAPORTE.
MS. LAPORTE: 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: ABSTAIN.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.

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MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
MR. SHEEHY: SO, DR. SAMBRANO, GO TO THE NEXT ONE PLEASE.
DR. SAMBRANO: THANK YOU. THE NEXT APPLICATION AND THE LAST ONE THAT WE WILL CONSIDER TODAY IS CLIN2-09730. THIS IS FOR A CLINICAL TRIAL OF A CELL THERAPY TO TREAT TYPE 1 DIABETES. THIS IS ALSO AN AUTOLOGOUS TYPE OF THERAPY THAT UTILIZES T-REGULATORY T CELLS THAT ARE EXPANDED EX VIVO. THE INDICATION IS FOR EARLY ONSET OF TYPE 1 DIABETES PATIENTS. SO THESE ARE FOR ADOLESCENTS.
THE GOAL IS TO COMPLETE A PHASE 2 CLINICAL TRIAL TO TEST THE SAFETY AND EFFICACY OF THE PRODUCT. AND ACTIVITIES INCLUDE ENROLLMENT AND TREATMENT OF 92 SUBJECTS IN THE PHASE 2 TRIAL, THE MANUFACTURING OF THE PRODUCT. AND THE FUNDS REQUESTED ARE 12.2 MILLION. THE APPLICANT IS PROVIDING CO-FUNDING AMOUNT OF ABOUT 8 MILLION, FOR AN APPROXIMATE TOTAL OF 20 MILLION FOR THE PROJECT.
AND ON THE NEXT SLIDE, A SUMMARY OF THE OVERALL REVIEW. THE BUDGET REVIEW RECEIVED A PASS. THE GWG SCORED THIS A 1 WITH 11 MEMBERS SCORING IT A

1 AND NONE SCORING IT IN THE 2 OR 3 CATEGORY. CIRM TEAM CONCURS WITH THIS RECOMMENDATION AND SUGGESTS AN AWARD AMOUNT OF 12.2 MILLION.

MR. SHEEHY: THANK YOU, DR. SAMBRANO. DO I HAVE A MOTION TO EITHER APPROVE OR NOT APPROVE FUNDING?

DR. PRIETO: MOVE TO APPROVE.

MR. SHEEHY: DR. PRIETO MOVES TO APPROVE. DO I HAVE A SECOND?

CHAIRMAN THOMAS: SECOND.

MR. SHEEHY: SECOND BY CHAIRMAN THOMAS. ANY BOARD COMMENTS OR QUESTIONS?

DR. JUELSGAARD: JUST TO CONTINUE ON. SO, DR. SAMBRANO, THIS PROGRAM IS DESIGNED TO ENROLL 92 PATIENTS IN A PHASE 2 CLINICAL TRIAL. AND THERE'S A SUGGESTION THAT IT'S A CONTINUATION OF A TRIAL THAT'S ALREADY IN PROGRESS; IS THAT RIGHT?

DR. SAMBRANO: IT'S A FOLLOW-ON TO A PHASE 1 TRIAL.

DR. JUELSGAARD: SO THERE IS NO PHASE 2 WORK DONE TO THIS POINT. I MISREAD IT. THANK YOU.

MR. SHEEHY: ANY OTHER BOARD COMMENTS OR QUESTIONS?

DR. DULIEGE: YES. I THINK --

MR. HARRISON: ANNE-MARIE, YOU CAN'T

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PARTICIPATE IN THIS DISCUSSION.

MR. SHEEHY: ANY OTHER BOARD COMMENTS OR QUESTIONS? IS THERE ANY PUBLIC COMMENT? MARIA, COULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: KATHY LAPORTE.

MS. LAPORTE: 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: OS STEWARD.

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DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
MR. SHEEHY: THANK YOU. DR. SAMBRANO, THE NEXT ONE PLEASE.
DR. SAMBRANO: THAT'S IT. WE'RE DONE.
MR. SHEEHY: GREAT. THANK YOU. SO IT'S BACK TO YOU, CHAIRMAN THOMAS.
CHAIRMAN THOMAS: THANK YOU, MR. SUPERVISOR.
WE ARE GOING TO TAKE A FIVE-MINUTE BREAK HERE TO ALLOW BETH TO REGROUP. I WOULD SAY I UNDERSTAND THERE ARE SOME INTERNET ISSUES SOME MEMBERS MAY BE HAVING. I'M INFORMED WE ARE LOOKING INTO IT AND HOPE TO HAVE THOSE CORRECTED ASAP. SO FIVE-MINUTE BREAK.
(A RECESS WAS TAKEN.)
CHAIRMAN THOMAS: OKAY. WE ARE RESUMING NOW. WE'RE GOING TO ACTION ITEM NO. 9, WHICH IS CONSIDERATION OF THE ALPHA CLINICS CONCEPT PLAN.

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DR. MILLAN PRESENTING.

DR. MILLAN: GOOD MORNING. THANK YOU, CHAIRMAN THOMAS AND MEMBERS OF THE BOARD. IT'S MY PLEASURE, ON BEHALF OF THE CIRM TEAM, TO PRESENT AN UPDATE ON THE ALPHA CLINICS NETWORK AS WELL AS TO PRESENT TO YOU A CONCEPT PROPOSAL FOR THE EXPANSION OF THIS NETWORK.

IN KEEPING WITH CIRM'S MISSION OF ACCELERATING STEM CELL TREATMENTS TO PATIENTS, CIRM FUNDED THE CREATION OF THE ALPHA CLINICS NETWORK AND IT'S BEEN NOW IN EXISTENCE FOR JUST A LITTLE BIT OVER TWO YEARS. THE MISSION OF THIS NETWORK IS TO ACCELERATE STEM CELL TREATMENTS BY PROVIDING SERVICES AND SUPPORT TO CONDUCT HIGH QUALITY CLINICAL TRIALS WHILE ACCELERATING ALL THE PIECES THAT GO INTO MAKING THE TRIAL A SUCCESS.

CURRENTLY THERE ARE THREE ALPHA CLINICS PROGRAMS. THERE'S A COMBINED PROGRAM BY UCLA, UC IRVINE AS A CONSORTIUM, UC SAN DIEGO, AND THE CITY OF HOPE.

OVERALL CIRM, EITHER THROUGH DIRECT FUNDING OR THROUGH SUPPORT OF CLINICAL TRIALS IN THIS, ALPHA CLINICS NETWORK HAS BEEN INVOLVED IN SUPPORTING OVER 50 STEM CELL CLINICAL TRIALS. EIGHT OF THE CIRM-FUNDED CLINICAL TRIALS ARE BEING

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CONDUCTED WITHIN THE ALPHA CLINICS NETWORK.

AS A GRAPHIC REPRESENTATION OF HOW THE ALPHA CLINICS NETWORK HAS CATALYZED THE EXPANSION OF SUPPORT OF CLINICAL TRIALS IN CALIFORNIA, I PRESENT HERE TODAY A GRAPHIC REPRESENTATION OF THE NUMBER OF TRIALS THAT WERE PRESENT BEFORE THE FORMATION OF THE ALPHA CLINICS IN BLUE AT EACH OF THE GIVEN SITES, CITY OF HOPE, THE COMBINED UC IRVINE/UCLA ALPHA CLINICS, AND THE UCSD ALPHA CLINIC. AND THE GROWTH AND NUMBER OF TRIALS AT THOSE CENTERS IN ORANGE.

IT SHOULD BE NOTED THAT WITH CITY OF HOPE, THE GRANT EXPANSION OF THOSE PROGRAMS IS DUE TO INDUSTRY ENGAGEMENT WITH MULTICENTER TRIALS IN THE AREA OF HEMATOPOIETIC STEM CELL TRANSPLANT IN ONCOLOGY, WHICH IS REALLY A TESTAMENT TO THE FACT THAT THOSE TECHNOLOGY PLATFORMS AND INDICATIONS ARE THE FURTHEST ALONG.

MUCH LIKE THE CIRM PORTFOLIO, THE TRIALS, THERE'S A BROAD RANGE OF TRIALS, DISEASE INDICATIONS, AND STEM CELL TECHNOLOGY PLATFORMS THAT ARE BEING TESTED IN CLINICAL TRIALS ACROSS THIS ALPHA CLINICS NETWORK AS LISTED HERE. AND EVEN WITHIN THE BROADEST INDICATION, WHICH IS CANCER, THERE'S A GOOD REPRESENTATION OF BOTH LIQUID AS WELL AS SOLID CANCERS OF THE VARIOUS TYPES AS LISTED ON

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THE RIGHT.

IN ADDITION TO PROVIDING SERVICES AND SUPPORT FOR THE CONDUCT OF THESE TRIALS, THESE NETWORKS HAVE REALLY BROUGHT VALUE-ADD RESOURCES TO ACCELERATING THE CONDUCT OF THESE CLINICAL TRIALS WHILE MAINTAINING THE HIGHEST QUALITY AND RIGOR IN CONDUCTING THESE TRIALS.

AND THE RESOURCES WHICH HAVE BEEN DEVELOPED IN THE NETWORK OVER THE PAST TWO YEARS, SOME OF THEM ARE JUST LISTED HERE, INCLUDE THE IRB RELIANCE, WHICH ALLOWS FOR CONCURRENT IRB APPROVAL AT MULTIPLE SITES WITH A SINGLE IRB REVIEW. SO, FOR INSTANCE, AN APPROVAL OF A CLINICAL PROTOCOL AT UCSD COULD RESULT IN AUTOMATIC APPROVAL AT UCLA, UC IRVINE, CITY OF HOPE, ALONG WITH UCSD VIA THE MOU'S AND RECIPROCAL UNDERSTANDING BETWEEN ALL OF THE IRB'S OF THOSE INSTITUTIONS. THIS REPRESENTS SIGNIFICANT TIME SAVINGS, EFFICIENCY, AND IT REALLY INVOLVES A NETWORK IN ORDER TO DO THIS.

IN ADDITION, THE NETWORK WAS ABLE TO LEVERAGE EXISTING REGISTRIES, THE UC REX REGISTRY AS WELL AS THE L.A. DATA REPOSITORY, WHICH ARE DEIDENTIFIED AND HIPAA COMPLIANT MEDICAL RECORDS OF OVER 20 MILLION PATIENTS IN CALIFORNIA. THIS TOOL ALLOWS FOR A DATABASE SEARCH FOR COHORT FINDING AND

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ALLOWS INVESTIGATORS TO REALLY FIND HEAT MAPS OF WHERE AFFECTED PATIENTS WHO WOULD BE ELIGIBLE FOR THESE TRIALS COULD BE LOCATED AND IS A REALLY VALUABLE TOOL IN TERMS OF PLANNING THE TRIAL FOR PATIENT ENROLLMENT AND RECRUITMENT.

WE CURRENTLY HAVE INVESTIGATORS UTILIZING THIS SERVICE, AND WE'VE BEEN REALLY PLEASED WITH HOW THAT'S GOING SO FAR AND IT'S CONTINUING TO BE DEVELOPED.

ADDITIONALLY, AT THE VERY START OF THE FORMATION OF THE NETWORK AND ONGOING, WE HAD EMBEDDED METRICS TRACKING IN KEEPING WITH THE APPROACH THAT CIRM HAS BEEN TAKING, AS DR. MILLS HAD PRESENTED EARLIER. AND WE REALLY HAVE ALREADY SEEN THAT METRICS TRACKING BY THE CENTERS HAVE BEEN ABLE TO TRACK AS WELL AS DRIVE PERFORMANCE IMPROVEMENTS. PRELIMINARY REPORTS FROM A SINGLE CENTER WHICH HASN'T VARIED THE TYPES OF TRIALS YET, BUT HAS INCREASED ITS VOLUME, HAVE SHOWN THAT THE TIME FROM IRB SUBMISSION TO APPROVAL WAS REDUCED BY 40 PERCENT, AND THE TIME FROM IRB APPROVAL TO FIRST PATIENT ENROLLMENT REDUCED BY 72 PERCENT. AGAIN, SPEAKING TO THE MISSION OF ACCELERATION AND, IN INDUSTRY TERMS, TIME IS MONEY. SO THIS IS A VERY VALUABLE ASSET THAT THE NETWORK BRINGS TO CLINICAL

RESEARCH.

ADDITIONALLY, THE POWER OF THE NETWORK IS REALLY DEMONSTRATED IN THIS PARTICULAR INSTANCE OF A *NEW ENGLAND JOURNAL OF MEDICINE* REPORT FROM A TRIAL THAT WAS CONDUCTED OUT OF THE CITY OF HOPE ALPHA CLINICS. IT'S A CHIMERIC ANTIGEN RECEPTOR T-CELL APPROACH TO TREATMENT OF GLIOBLASTOMA, WHICH IS A SOLID CANCER IN THE BRAIN. IT LEVERAGES THE NURSING BEST PRACTICES AND CELL HANDLING AND FUSION TREATMENTS THAT ARE REALLY UNIQUE TO STEM CELL CLINICAL TRIALS, PATIENT SUPPORT, EDUCATION, AND INFORMED CONSENT TOOLS THAT ARE BEING DEVELOPED IN THE NETWORK. ALL OF THESE TOGETHER AND MUCH MORE THAT ARE PROVIDED BY THE NETWORK REALLY ALLOWS THE PERFORMANCE OF THESE COMPLEX CLINICAL TRIALS.

SO THESE ENCOURAGING RESULTS, WHICH ARE REPORTED HERE IN THE *NEW ENGLAND JOURNAL* IS JUST A START OF WHAT WE BELIEVE IS DEVELOPMENT OF MORE OF THESE TYPES OF TRIALS AND THERAPIES.

GIVEN THE PERFORMANCE OF THE NETWORK AND THE ENCOURAGING RESULTS WE'RE SEEING SO FAR, WE ARE, THEREFORE, BRINGING FOR YOUR CONSIDERATION A CONCEPT PROPOSAL TO EXPAND THIS NETWORK. THE OBJECTIVE OF THIS NETWORK EXPANSION AWARD IS TO SUPPORT ADDITIONAL ALPHA CLINIC SITES THAT WILL INCREASE THE

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CAPACITY AND ACCESS TO SERVICES TO CONDUCT THESE TRIALS AND INCREASE ACCESS TO PATIENTS ALL OVER CALIFORNIA.

THE FUNDING WOULD ALSO SUPPORT THE CREATION OF TRAINING AND CAREER DEVELOPMENT OF PHYSICIANS SEEKING TO CONDUCT THESE SPECIALIZED CLINICAL TRIALS AND TO AID IN THE DEVELOPMENT OF THESE THERAPIES INTO THE CLINICS FOR EVENTUAL ADOPTION. AND WE EXPECT THAT THE FUNDED ADDITIONAL ALPHA CLINICS WILL BRING EVEN MORE ASSETS TO THE NETWORK TO ADD TO THE VALUE PROPOSITION OF THE NETWORK AS A WHOLE.

THE REQUIREMENTS FOR THESE APPLICANTS AND AWARDEES WOULD BE THAT THEY WOULD BE LOCATED IN AN ACADEMIC CALIFORNIA MEDICAL CENTER WITH CLEAR INSTITUTIONAL SUPPORT FOR THIS, DEMONSTRATE THE ABILITY TO PERFORM STEM CELL CLINICAL TRIALS, AND DEMONSTRATE THE ABILITY TO BE ABLE TO SUSTAIN THIS IN THE LONG TERM BEYOND CIRM FUNDING, AND THAT THEY WOULD PROVIDE SERVICES AND PROGRAMS FOR PATIENT RECRUITMENT, EDUCATION, CARE, AND SERVING CALIFORNIA'S DIVERSE POPULATION, AND CONTINUE TO PROVIDE CLINICAL TRIAL OPERATIONS AND MANAGEMENT SERVICES, LEVERAGING WHAT'S ALREADY IN EXISTENCE IN THE NETWORK AND ADDING TO THAT, CREATION OF THE

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ALPHA CLINICS FELLOWSHIP PROGRAM AND, OF COURSE, JUST ENHANCING THE OVERALL NETWORK.

WE'RE REQUESTING THAT $8 MILLION OF FUNDING FOR TWO AWARDS BE ALLOCATED FOR THIS EXPANSION CONCEPT. WE PROPOSE THAT IF YOU APPROVE THIS CONCEPT THAT WE WOULD ISSUE THE APPLICATION WITH AN APPLICATION DEADLINE OF MAY, REVIEWED IN JULY 2017, AND BROUGHT BACK TO YOU FOR YOUR APPROVAL IN AUGUST OF 2017 FOR THOSE AWARDS THAT THE GWG RECOMMENDS. AND WE BELIEVE THAT THESE CENTERS COULD BE LAUNCHED BY THE END OF Q-3, EARLY Q-4 OF THIS YEAR. THANK YOU.

CHAIRMAN THOMAS: QUESTION, MR. JUELSGAARD.

DR. JUELSGAARD: YES, MARIA. SO AS PART OF THE JUSTIFICATION FOR TRYING TO BRING ON BOARD TWO MORE OF THE ALPHA CLINICS, THE FIRST OF THE THREE THAT YOU MENTIONED DEALT WITH ACCESS AND CAPACITY. SO MY QUESTION IS IS THERE A LIMITATION RIGHT NOW ON ACCESS AND CAPACITY AT THE EXISTING ALPHA CLINICS? IS THAT A PROBLEM, AND THAT'S WHY WE'RE TRYING TO ADDRESS THIS? WHEN YOU LOOK AT THE CITY OF HOPE, THEY HAVE OBVIOUSLY A WHOLE LONG LIST OF PARTICIPANTS, BUT THE OTHER THREE INSTITUTIONS ARE NOT NEARLY AS ENGAGED AS THE CITY OF HOPE. AND,

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HENCE, MY QUESTION ABOUT THIS ACCESS CAPACITY CONSTRAINT THAT YOU ALLUDE TO.

DR. MILLAN: SO IN TERMS OF CAPACITY, I DIDN'T PUT UP THERE WHAT THE ACTUAL ENROLLMENTS WERE. SO THE GRAPH THAT I PUT UP MAY HAVE BEEN A LITTLE MISLEADING BECAUSE EVEN THE SITES ON THE BAR GRAPH LOOKED LOWER BECAUSE IT'S RELATIVE TO CITY OF HOPE THAT IT LOOKED LOWER, THE ACTUAL PATIENT ENROLLMENTS IN THOSE SITES WERE NOT MUCH DIFFERENT IN TERMS OF PERCENT OF TOTAL ENROLLED PATIENTS IN THE NETWORK. IT WAS SOMETHING LIKE 25 PERCENT, 30 PERCENT, AND THEN THE REST CITY OF HOPE, SOMETHING LIKE THAT, OR SOMETHING TO THAT EXTENT.

SO IN TERMS OF CAPACITY, WE ALSO EXPECT A PIPELINE OF OTHER TRIALS BECAUSE NOW THAT THE NETWORK IS FORMED, WE ARE REFERRING MORE AND MORE PROJECTS. THE PI'S ARE NOW STARTING TO UNDERSTAND THE VALUE OF THE NETWORK, SO THEY HAVE A LOT MORE DEMAND THAT'S BEING PUT ON THEM. SO WE BELIEVE THAT THEY STILL HAVE CAPACITY, BUT THERE'S ALSO THIS ISSUE THAT CURRENTLY THREE ALPHA CLINICS ARE IN SOUTHERN CALIFORNIA. AND SO THE ACCESS IN TERMS OF SOME OF THE OTHER GEOGRAPHIC AREAS IN CALIFORNIA ARE SOMEWHAT LIMITED, AND FOR SOME OF THESE TRIALS, TRAVEL FOR THE PATIENTS AND RECRUITMENT

CONSIDERATIONS COULD BE AN ISSUE.

DR. JUELSGAARD: SO THEN THAT RAISES, I GUESS, FOR ME TWO QUESTIONS. THE FIRST IS I DIDN'T SEE IT AS PART OF THE CRITERIA, BUT YOU'RE IMPLYING THAT ONE OF THE CRITERIA IS A SITE OR SITES IN NORTHERN CALIFORNIA?

DR. MILLAN: I THINK THE GEOGRAPHIC ACCESS IS ONE. IT'S NOT AN ELIGIBILITY CRITERIA, BUT IT'S ONE OF THE REVIEW CONSIDERATIONS THAT WOULD BE ANTICIPATED TO BE IN THE APPLICATION ITSELF AND BE REVIEWED BY THE GWG.

DR. JUELSGAARD: AND SO IF IN THAT REVIEW WE HAVE NORTHERN CALIFORNIA SITES THAT THE GWG DOESN'T CONSIDER SUFFICIENT, BUT THERE IS AN ADDITIONAL ONE OR TWO SOUTHERN CALIFORNIA SITES, WOULD THEY SIMPLY BE ELIMINATED BY THEIR GEOGRAPHICAL LOCATION?

DR. MILLAN: MAYBE I CAN TURN IT OVER TO GIL SAMBRANO OR DR. MILLS.

DR. MILLS: SO IN ORDER FOR THEM TO BE COMPETITIVE, THEY WOULD HAVE TO MAKE AN ARGUMENT THAT THERE'S SUFFICIENT PATIENT DEMAND THAT THEY CAN SERVE THERE. NOW, SOUTHERN CALIFORNIA IS AN ENORMOUS PLACE. WE HAVE THREE. WE DON'T HAVE 300. SO I THINK WE WOULD LIKE TO SEE GEOGRAPHICAL

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REPRESENTATION ACROSS THE STATE, BUT AN ALPHA CLINIC NEED ONLY MAKE THE ARGUMENT THAT THEY CAN ADD VALUE.

GOING BACK TO, I THINK, YOUR FIRST POINT, WHAT WAS COMPELLING TO ME ABOUT THIS, AND I WAS ORIGINALLY, IF YOU WILL RECALL, SKEPTICAL OF THE PROGRAM, WAS THAT IN ESSENTIALLY EVERY PLACE WE WENT INTO, WE DOUBLED, AT LEAST, PARTICIPATION IN STEM CELL CLINICAL TRIALS AND PATIENT ENROLLMENT IN THOSE CLINICAL TRIALS. AND SO WE LOOK AT THAT WITHOUT NECESSARILY HAVING TO DOUBLE OUR INVESTMENT IN THOSE CLINICAL TRIALS. SO I THINK THAT GRAPH SHOWS THE OVERLAP IS A PARTICULARLY TELLING ONE. IT'S A GREAT EXAMPLE OF CIRM LEVERAGE WHERE WE GO INTO A PLACE, WE SET UP AN ALPHA CLINIC, THEY FUND A WHOLE LOT OF STEM CELL RESEARCH THAT WE DON'T HAVE TO DIRECTLY FUND, BUT WE'RE GETTING OUR MISSION ACCOMPLISHED.

THE HARMONIZED IRB, AS A PERSON THAT'S OVERSEEN A LOT OF CLINICAL TRIALS, PARTICULARLY STEM CELL CLINICAL TRIALS, BEING ABLE TO HAVE A COMMON IRB THAT'S SOPHISTICATED AND UNDERSTANDS THESE ISSUES, I THINK, IS A SIGNIFICANT VALUE ADD WHICH REDUCES THE AMOUNT OF TIME THAT IT TAKES TO GET A CLINICAL TRIAL STARTED AND THEN WHICH IS EXACTLY CONCURRENT WITH OUR MISSION TO ACCELERATE THIS STUFF.

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SO THAT'S KIND OF IN A NUTSHELL. I THINK THIS IS JUST A GOOD INVESTMENT FOR CIRM GIVEN THE FACT THAT WE PUT IN A RELATIVELY SMALL AMOUNT OF MONEY AND LEVERAGED THAT ACROSS A LOT OF NEW TRIALS THAT APPARENTLY WOULD NOT BE TAKING PLACE OTHERWISE.

DR. JUELSGAARD: AND SO HOW DID YOU ARRIVE AT THE NUMBER TWO VERSUS THE NUMBER ONE OR THE NUMBER THREE OR SOME OTHER NUMBER THAT YOU THOUGHT SHOULD BE FUNDED?

DR. MILLS: HOW MUCH MONEY WE HAD LEFT. IT'S LITERALLY BUDGETARY CONSTRAINT.

MR. JUELSGAARD: IT'S A CONSTRAINT. IT'S NOT A DESIRE TO SPEND THE MONEY THEN?

DR. MILLS: NO. NO. I WOULD SAY WE WOULD PROBABLY CONSIDER IN FUTURE ITERATIONS MORE IF IT CONTINUES TO WORK. THE ORIGINAL PLAN WAS FOR FIVE. WE DIDN'T CONSTRAIN THAT PLAN. THERE WERE ONLY THREE THAT MET THE REVIEW CRITERIA, IF YOU WILL RECALL. SO OUR SORT OF SECOND WAVE OF THIS IS LET'S BUILD OUT THE ORIGINAL FIVE THAT WERE CONTEMPLATED.

DR. JUELSGAARD: FINAL QUESTION. THIS HAS TO DO WITH THE CITY OF HOPE, AND MAYBE WE CAN GET THE CITY OF HOPE REPRESENTATIVE TO SPEAK TO IT. BUT ONE OF THINGS THAT'S A POSITIVE ABOUT THE CITY OF HOPE IS THAT THEY HAVE PROCESS DEVELOPMENT AND

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MANUFACTURING EXPERTISE ON BOARD, WHICH I DON'T BELIEVE ANY OF THE OTHER ALPHA CLINICS DO. AND I WONDER HOW MUCH THE SCOPE OF THE NUMBER OF CLINICAL TRIALS AT THE CITY OF HOPE SEES IS DRIVEN BY THAT EXPERTISE, AND WHETHER, IF IT IS, WE SHOULDN'T BE LOOKING AT WHETHER WE CAN DEVELOP SOMETHING SIMILARLY AT SOME OTHER INSTITUTION BECAUSE THAT CAN BE RESOURCE CONSTRAINED.

DR. MILLAN: THERE ARE GMP MANUFACTURING FACILITIES AT OTHER INSTITUTIONS, SUCH AS UC DAVIS, AND STANFORD JUST OPENED THEIRS. GENERALLY THEY'RE FOR EARLY PHASE TRIALS, SUCH AS CITY OF HOPE.

I SHOULD ALSO MENTION THAT PRESIDENT MILLS HAD PRESENTED THE PITCHING MACHINE. THE TRANSLATING CENTER HAS A FORMAL COLLABORATION WITH THE CITY OF HOPE. SO QUINTILES, CITY OF HOPE, AND ADDITIONAL OTHER MANUFACTURING ASSETS ARE GOING TO BE BROUGHT INTO THAT TRANSLATING CENTER TO PROVIDE ACCESS TO ALL CIRM GRANTEES AND STEM CELL CLINICAL TRIALS TO THOSE MANUFACTURING AND PROCESS DEVELOPMENT GMP FACILITIES.

DR. JUELSGAARD: SO IN YOUR EVALUATION CRITERIA FOR A NEW CENTER, ARE YOU INCLUDING AS A POSITIVE THE ABILITY TO DO PROCESS DEVELOPMENT/MANUFACTURING WORK? IS THAT ONE THE

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THINGS THAT YOU WOULD CONSIDER ONE OF THE THINGS THAT WOULD RANK SOMEBODY ABOVE SOMEBODY WHO DIDN'T HAVE THAT?

DR. MILLAN: IT'S NOT SPECIFICALLY CALLED OUT, BUT THAT WOULD BE AN ASSET THAT THE APPLICANT WOULD BE EXPECTED TO BRING FORWARD AS WHAT THEY WOULD BRING TO THE NETWORK. IN ADDITION, SPECIALIZATION AND VARIOUS TECHNOLOGY PLATFORMS THAT THEY MAY HAVE DEVELOPED AT THEIR CENTER FOR VARIOUS MAYBE GENOME EDITING SPECIALIZATION AS WELL AS IMMUNE THERAPY SPECIALIZATION TO EITHER EXPAND WHAT THE NETWORK ALREADY HAS OR TO BRING MORE TO IT. OTHER ASSETS IN TERMS OF EVEN DATABASE AND PATIENT ENGAGEMENT RESOURCES WHICH ARE GOING TO BECOME MORE AND MORE IMPORTANT IN THIS REGULATORY ENVIRONMENT.

DR. JUELSGAARD: I APOLOGIZE. THAT WASN'T MY LAST QUESTION. SO THIS IS BACK TO ACCESS AND CAPACITY. SO YOU DON'T SEE PROCESS DEVELOPMENT AND MANUFACTURING AS EITHER AN ACCESS ISSUE OR A CAPACITY ISSUE. THE DEVELOPMENT OF MORE PROCESS DEVELOPMENT AND MANUFACTURING EXPERTISE ASSOCIATED WITH ALPHA CLINICS, THAT DOESN'T SEEM --

DR. MILLAN: IT IS, BUT IT IS SOMETHING THAT, I BELIEVE, WE'RE ADDRESSING WITH THE TRANSLATING CENTER WHICH HAS THE PROCESS

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DEVELOPMENT.

DR. JUELSGAARD: THEY DON'T HAVE THE PROCESS DEVELOPMENT STUFF THEMSELVES.

DR. MILLAN: CITY OF HOPE IS THEIR PARTNER IN THIS.

DR. JUELSGAARD: SO WE'RE BACK TO CITY OF HOPE AS A SINGLE SOURCE. ONE OF THE THINGS THAT I LEARNED A LONG, LONG TIME AGO WAS THAT IT'S PROBLEMATIC TO RELY ON A SINGLE SOURCE. PARTICULARLY IN THE MANUFACTURING PROCESS SCIENCES AREA, YOU NEED TO HAVE A BACKUP OR SOME OTHER RESOURCES.

DR. MILLAN: ABSOLUTELY. IN FACT, QUINTILES IS ACTUALLY THE LEAD ON THAT TRANSLATING CENTER. AND THEY STARTED WITH THE CITY OF HOPE, BUT THEY MADE IT VERY, VERY CLEAR THAT WHAT THEY PLAN TO DO IS EXPAND UPON BOTH CAPACITY AND EXPERTISE EITHER THROUGH PARTNERSHIPS OR COLLABORATIONS WITH OTHER COMMERCIAL ENTITIES AND OTHER MANUFACTURING ENTITIES AS WELL AS GMP FACILITIES, ACADEMIC AND NONACADEMIC.

CHAIRMAN THOMAS: MARIA, JUST SO THE BOARD UNDERSTANDS THE SUCCESS OF THE ALPHA CLINIC PROGRAM, COULD YOU SPEAK A BIT TO WHEN WE FIRST LAUNCHED THE PROGRAM A COUPLE YEARS AGO HOW MANY TRIALS YOU EXPECTED TO SEE IN THE FIRST YEAR TO 18 MONTHS AND

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WHERE WE ARE NOW?

DR. MILLAN: YES. WE WERE VERY PLEASANTLY SURPRISED BECAUSE, IN KEEPING WITH SOME OF THE COMMENTS THAT RANDY JUST MADE, WE KNEW THAT WE NEEDED SUPPORT FOR STEM CELL CLINICAL TRIALS. WE DIDN'T KNOW WHAT THE VOLUME REALLY WOULD BE, OR WE UNDERSTOOD THAT THERE ARE SPECIALIZED NEEDS OF THIS, FOR THESE TRIALS, AND INITIALLY WE THOUGHT, OKAY, THREE TRIALS WERE GOING TO BE THE ABSOLUTE REQUIREMENT, THREE TOTAL TRIALS, ONE FOR EACH SITE WITHIN THE FIRST YEAR. AND WE WERE REALLY PLEASED TO SEE THAT EVEN WITHIN THE FIRST YEAR WE HAD BETWEEN SIX AND EIGHT THAT WERE BEING SUPPORTED BY A NETWORK, AND THEN IT JUST KIND OF INCREASED MARKEDLY FROM THERE.

SO ONCE WE BUILT IT, THEY DID COME IN TERMS OF THE NUMBERS OF TRIAL THAT CAME IN. I THINK THE CITY OF HOPE IN TERMS OF HOW IT REALLY ATTRACTED THOSE INDUSTRY STAKEHOLDERS TO PARTNER WITH THEM AND RUN THEIR MULTICENTER TRIALS OUT OF CITY OF HOPE IS A TESTAMENT TO HOW THIS IS VALUED EVEN BY INDUSTRY STAKEHOLDERS. SO NOT ONLY DID IT SUPPORT INVESTIGATOR-INITIATED TRIALS, BUT IT WAS AN ASSET THAT WAS VIEWED VALUABLE BY INDUSTRY STAKEHOLDERS AS WELL.

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CHAIRMAN THOMAS: THANK YOU. MR. SUPERVISOR.

MR. SHEEHY: I HAD A COUPLE OF SETS OF QUESTIONS. ONE, I'M STILL A LITTLE BIT CONFUSED WITH THE DIALOGUE WITH STEVE BECAUSE I HAD KIND OF THE SAME CONCERNS. I CAN'T REALLY SEE WHAT THE WEIGHTING IS GEOGRAPHICALLY. IT SEEMS LIKE THAT'S A CONSIDERATION, BUT IT'S NOT CLEAR HOW THAT'S GOING TO BE OPERATIONALIZED. AND THEN THERE SEEM TO BE SOME -- I FOUND IT KIND OF AMBIGUOUS. AND, AGAIN, I WANT TO COMMEND YOU FOR WHAT YOU'VE ACCOMPLISHED BECAUSE I WAS ANOTHER HUGE SKEPTIC OF HOW THIS WAS ROLLED OUT. SO CONGRATULATIONS ON JUST LIKE REALLY OPERATIONALIZING THIS AND TURNING THIS INTO A GREAT PROGRAM.

ONE OF MY BIG CONCERNS WHEN THIS WAS ROLLED OUT WAS THAT THERE WAS NO MANUFACTURING ASSOCIATED WITH THIS. AND SO I CAN'T TELL, AGAIN, HOW THAT'S GOING TO BE WEIGHTED BECAUSE IT SOUNDS LIKE, WELL, APPLICANTS KIND OF RELY ON QUINTILES, WHICH IS AT SOME POINT GOING TO HAVE OTHER PARTNERS TO MANUFACTURE, BUT RIGHT NOW IT'S ONLY CITY OF HOPE. OR HOW DOES THAT WEIGHT WITH SOMEBODY WHO ACTUALLY HAS MANUFACTURING? SO IT'S ALMOST LIKE A MATRIX OF CONSIDERATIONS, SO IT'S NOT CLEAR HOW

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THAT'S GOING TO WEIGHT OUT. SO THOSE TWO ISSUES. AND THEN I HAVE ANOTHER QUESTION AFTER THAT.

DR. MILLAN: I'LL RESPOND FIRST AND THEN TURN IT OVER. I THINK FOR THE REASONS THAT YOU AND MR. JUELSGAARD HAD RAISED, I BELIEVE THAT THOSE WILL BE CONSIDERATIONS THAT OUR REVIEWERS WILL BE TAKING INTO ACCOUNT BECAUSE, IN TERMS OF THE KEY ISSUES THAT MAKE OR BREAK A CLINICAL DEVELOPMENT PROGRAM, AND, OF COURSE, THE CONDUCT OF TRIALS AND EVENTUAL COMMERCIALIZATION, IT'S OBVIOUS IT'S HAVING A GOOD PROCESS MANUFACTURING TO TAKE YOU TO THE EARLY TRIALS AND BEYOND. SO THAT WILL BE SOMETHING THAT WE BELIEVE WILL BE GIVEN WEIGHT. WE JUST HAVEN'T IN THE CONCEPT FORMALIZED THAT.

AND IN TERMS OF GEOGRAPHIC ACCESS, I THINK RANDY HAD RESPONDED EARLIER. I THINK THAT OUR CURRENT NETWORK REALLY DOES DO A GREAT JOB TRYING TO PROVIDE THAT ACCESS, BUT THERE ARE MANY STRONG ACADEMIC CENTERS WITH STEM CELL PROGRAMS THAT ARE GROWING. SO WE BELIEVE THAT IT WILL BE AVAILABLE.

NOW, AS WITH ANY REVIEW, IF THERE ARE NO MERITORIOUS PROGRAMS THAT OUR GWG FINDS WILL ADD TO THIS NETWORK, WE DON'T EXPECT THAT THEY WOULD RECOMMEND IT FOR YOUR CONSIDERATION. WE'RE VERY ENCOURAGED BY WHAT WE SEE, THAT WE BELIEVE WE WILL

HAVE GOOD APPLICANTS FOR THIS THAT COULD EXPAND BOTH THE GEOGRAPHIC REACH AS WELL AS THE OFFERINGS OF THIS NETWORK.

MR. SHEEHY: BUT IT JUST SEEMS TO ME THAT IT WOULD REALLY BENEFIT SOMEONE TO EITHER HAVE A RELATIONSHIP WITH THE NORTHERN CALIFORNIA MANUFACTURER THAT ALIGNS WITH QUINTILES OR FOR THEIR MANUFACTURING FACILITY TO ALIGN WITH QUINTILES PRIOR TO THE SUBMISSION OF THE APPLICATION. THAT'S JUST A REAL-WORLD HYPOTHETICAL THAT COULD PLAY A ROLE IN HOW THIS ALL COMES DOWN.

SO I'M JUST CURIOUS. WE SAW A SIMILAR THING WITH THE GENOMICS CENTER. TO OUR NEW COLLEAGUE, WHOEVER ALIGNED AT THE BEGINNING WITH SANTA CRUZ WITH THEIR AMAZING CAPACITY ACTUALLY HAD A HUGE ADVANTAGE IN THAT COMPETITION. SO ARE WE ANTICIPATING THAT SORT OF SITUATION? HOW ARE WE LIKE THINKING AND TALKING ABOUT THAT? ARE WE THINKING ABOUT THAT?

DR. MILLAN: AS WE WORK WITH ALL OF OUR GRANTEES AND WE WORK WITH ALL OUR INFRASTRUCTURE PROGRAMS, WE COMMUNICATE WHAT THE ASSETS ARE THAT CIRM HAS FUNDED AND HAS IN PLACE SO THAT ALL THE STAKEHOLDERS ACTUALLY ARE VERY AWARE OF WHAT IS IN PLACE. AND WE'VE DONE THAT THROUGH VARIOUS WAYS

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THROUGH THE ROADSHOW, THROUGH OUR PARTICIPATION IN THE MEETINGS SUCH AS THAT THAT PAT AND I HAD SUMMARIZED EARLIER. IN THAT WAY THERE IS A LOT OF KIND OF AWARENESS OF WHO THE PLAYERS ARE, WHO'S CURRENTLY IN THE CIRM ECOSYSTEM, AND HOW PEOPLE ARE ENGAGING. AND OUR SCIENCE OFFICERS AS WELL AS OUR OTHER INTERNAL GROUP MEMBERS HELP TO CONNECT PEOPLE WHO HAVE NEEDS TO PEOPLE WHO HAVE POTENTIAL SOLUTIONS. AND SO ORGANICALLY WE DO ANTICIPATE THAT WILL HAPPEN. IT'S JUST NOT SOMETHING THAT WE HAVE FORMALIZED.

WE DO ADVISE OUR APPLICANTS OF KIND OF WHAT ARE THE REVIEW CRITERIA, WHAT FEATURES OF THEIR PROGRAM SHOULD BE HIGHLIGHTED, WHAT WOULD BE CONSIDERED STRONG KIND OF FEATURES OF THEIR PLANS OR THEIR PROPOSAL. AND SO WE BELIEVE WE TRY TO DO OUR VERY BEST TO INFORM APPLICANTS SO THEY UNDERSTAND WHAT'S CURRENTLY OUT THERE, WHAT'S CURRENTLY IN CIRM'S WORLD THAT THEY COULD TAKE ADVANTAGE OF AND BUILD UPON TO THEIR ALREADY STRONG PROGRAM.

SO I DON'T KNOW IF THAT'S TOO VAGUE, BUT WE DO TALK A LOT ABOUT THESE THINGS.

MR. SHEEHY: TWO MORE QUESTIONS.

MR. HARRISON: JUST TO INTERJECT BRIEFLY, JEFF. ONE OF THE THINGS WE STRUGGLE WITH SOMETIMES

IS THE LEVEL OF DETAIL WE INCLUDE IN THE CONCEPT PLAN, WHICH IS WHAT WE PRESENT TO YOU, THE BOARD, FOR YOUR APPROVAL AND THE RFA ITSELF WHICH INCLUDES THE DIRECTIONS TO THE APPLICANTS, INCLUDING THE CRITERIA THAT THE GWG WILL USE TO EVALUATE THESE APPLICATIONS. IN THIS CASE THE RFA IS QUITE SPECIFIC, THAT GEOGRAPHICAL DIVERSITY, BROADENING THE GEOGRAPHIC REACH OF THE NETWORK IS A REVIEW CONSIDERATION, AS IS AN APPLICANTS'S ABILITY TO ADD TO THE TECHNICAL CAPACITY OF THE NETWORK WHICH WOULD INCLUDE THINGS LIKE MANUFACTURING, ETC.

MR. SHEEHY: SO I HAD ONE OTHER QUESTION, TWO OTHER QUESTIONS. SORRY. HOW IS COLLABORATION BEING CONSIDERED? I THINK IT'S INTERESTING THAT UCLA AND UC IRVINE ARE COLLABORATING, AND I THINK THAT THAT'S ACTUALLY VERY POWERFUL. I THINK THERE'S A RELATIONSHIP BETWEEN CITY OF HOPE AND USC, AT LEAST I SEE IT IN A COUPLE OF THINGS. THE WHOLE SAN DIEGO AREA IS VERY COLLABORATIVE. I DON'T KNOW THAT WE ALWAYS PLAY SO NICE WITH EACH OTHER UP HERE. BUT ALSO GIVEN HOW HEALTHCARE IS DELIVERED BECAUSE DIFFERENT SYSTEMS, OBVIOUSLY ACO'S HAVE DIFFERENT PIPELINES, IS THAT SOMETHING THAT WE'RE LOOKING AT AS WELL TO EITHER MAYBE LOOK AT SUGGESTING THAT COLLABORATION WOULD BE AN ADVANTAGE IN THIS

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PARTICULAR CIRCUMSTANCE? OR IS THAT JUST A SUBJECTIVE ISSUE THAT THE WORKING GROUP MAY OR MAY NOT GIVE VALUE TO?

DR. MILLAN: SO THE STRENGTH OF THE ASSETS THAT THE APPLICANT WOULD BRING FORWARD IS SOMETHING THAT'S DEFINITELY A REVIEW CRITERIA. AND IF THOSE ASSETS ARE AUGMENTED OR SUPPLEMENTED OR SYNERGIZED WITH THE COLLABORATIONS IN THE OTHER INSTITUTIONS THAT THEY MAY BRING INTO THE FOLD, THEN THAT IS SOMETHING THAT WOULD BE TAKEN UNDER CONSIDERATION IN TERMS OF THE STRENGTH OF THE PROPOSAL.

DR. MILLS: WE'VE EXPERIENCED THIS HERE BEFORE. SO THE TERM "COLLABORATION" BY ITSELF DOESN'T GET YOU ANYTHING. WHAT YOU HAVE TO SHOW IS THAT THE COLLABORATION IS A BENEFICIAL, SYNERGISTIC SOMETHING THAT PROVIDES YOU SOME VALUE ADD. AND THE ONLY REASON I BRING THAT UP IS BECAUSE IT USED TO BE YOU NEED TO COLLABORATE IN ORDER TO GET THE EXTRA TEN POINTS OR WHATEVER. AND WE FOUND THAT SOMETIMES IN SORT OF FORCING COLLABORATIONS WHERE ONE ISN'T NECESSARY, WE DRAMATICALLY SLOW THINGS DOWN. SO IF YOU CAN SHOW IT'S A VALUE ADD, THEN, YEAH, BUT WE'RE NOT MANDATING IT.

MR. SHEEHY: MY LAST QUESTION. JUST TO REFRESH, WHAT SCORING SYSTEM WILL BE USED FOR THIS?

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MR. HARRISON: IT WOULD BE THE SAME SCORING SYSTEM THAT WE USE FOR CLINICAL PROGRAMS, SO A 1, 2, OR A 3.

MR. SHEEHY: THAT'S WHAT I THOUGHT, BUT I JUST WANTED TO BE CLEAR ON THAT.

CHAIRMAN THOMAS: OTHER QUESTIONS FROM MEMBERS OF THE BOARD? PUBLIC COMMENT? MR. REED.

MR. REED: JUST A COMMENT, THAT PAUL KNOEPFLER, THE GREAT SCIENTIST BLOGGER OF UC DAVIS, SAID THAT ONE OF THE MAJOR PROBLEMS THAT CIRM FACES IS THE OUTGROWTH OF THE DISREPUTABLE COWBOY CLINICS THAT ARE DOING ALLEGED STEM CELL PROGRAMS AND THEY DON'T HAVE ANYBODY TO BALANCE THEM. I THINK THIS IS A TREMENDOUS IDEA OF CIRM'S, TO HAVE A STANDARD TO HOLD. IF YOU ARE A LEGITIMATE CLINICAL TRIAL, THESE ARE THE THINGS YOU HAVE TO DO. DO YOU HAVE THEM? I THINK THIS WOULD BE A TREMENDOUS HELP TO LET THE PUBLIC SEE WHAT IS VALID AND WHAT IS NOT.

CHAIRMAN THOMAS: THANK YOU, MR. REED. DR. CHIU.

DR. CHIU: MEMBERS OF THE BOARD, MEMBERS OF CIRM, AND MEMBERS OF THE PUBLIC, I'M ARLENE CHIU FROM THE CITY OF HOPE. AND I WANTED TO MAKE A PLUG AND A COMMENT. THE PLUG IS THAT FOR THOSE OF YOU INTERESTED TO HEAR MORE ABOUT THE ACTIVITIES OF THE

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ALPHA CLINIC NETWORK, THE SECOND ANNUAL SYMPOSIUM ON THE NETWORK WILL BE HELD AT CITY OF HOPE ON MARCH 23D. AND I HAVE SOME ANNOUNCEMENTS. IF YOU WOULD REGISTER, PLEASE ATTEND BECAUSE I THINK YOU WILL FIND A LOT OF ANSWERS TO SOME OF THE QUESTIONS THAT HAVE BEEN BROUGHT UP. SO THAT'S THE PLUG.

IN TERMS OF THE COMMENT, IN THE BEGINNING, WHEN CITY OF HOPE PUT IN AN APPLICATION, IT WAS ALSO VERY UNCLEAR WHAT CITY OF HOPE COULD PROVIDE. AND THAT SORT OF GELLED MORE AND MORE AS THE PROCESS TOOK PLACE. I'M NOT SAYING THIS HAPPENS EVERY TIME. BUT WHAT HAPPENED WAS A CONFLUENCE OF IN-HOUSE ACTIVITIES ON THE CAR T TRIALS, WHICH ARE NOW BLOSSOMING, AS WELL AS OTHER ACTIVITIES WITH THE MANUFACTURING PROCESS, AND COLLABORATIONS WITH INSTITUTIONS WITHIN CALIFORNIA AND OUTSIDE. AND IT SORT OF BUILT CITY OF HOPE TO ITS POSITION NOW THAT IT DIDN'T HAVE MAYBE FIVE, EIGHT YEARS AGO.

SO THIS SORT OF STIMULUS IS AN EXERCISE IN BUILDING. I'M NOT SAYING THAT EVERY ALPHA CLINIC WILL HAVE THE SAME PATHWAY. BUT THE NETWORKING AND THE COLLABORATION AND HELPING EACH OTHER MANEUVER THROUGH FDA, ETC., MANUFACTURING PROCESSES, I THINK IS VERY BENEFICIAL IN LEVERAGING.

I JUST WANT TO POINT OUT ONE LAST THING,

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AND THAT IS CITY OF HOPE WAS POISED TO DO A LOT OF CAR T IMMUNOTHERAPY TRIALS ANYWAY, BUT HAVING THE ALPHA CLINIC REALLY GELLED IT AND MADE PARTNERS FIND IT VERY ATTRACTIVE TO PARTNER WITH CITY OF HOPE.

AND AS CHAIRMAN THOMAS AND I BOTH ATTENDED THIS JAPANESE MEETING IN NOVEMBER LAST YEAR, WHAT ASTONISHED ME WAS A PRESENTATION THAT TALKED ABOUT CAR T TRIALS IN THE WORLD. AND THE PRESENTERS SAID, FROM JAPAN SAID THERE'S ONE CAR T TRIAL ONGOING IN JAPAN, 18 IN CHINA, I BELIEVE SIX OR SEVEN OR MAYBE FIVE IN AUSTRALIA, EIGHT IN ALL OF EUROPE, AND 48 IN THE UNITED STATES. I DIDN'T DO THE RESEARCH, BUT THAT'S WHAT THEY SAID. OF THE 48, NINE OF THEM ARE BEING DONE AT THE CITY OF HOPE.

SO I THINK THIS SORT OF GROUND SWELL IS GOING TO BE VERY HELPFUL, AND IT WILL MAKE THE STATE OF CALIFORNIA, AS IT IS TODAY, ONE OF THE OUTSTANDING CENTERS WHERE EVERYTHING IS TRANSLATED ALL THE WAY INTO CLINICAL TRIALS. THANK YOU.

CHAIRMAN THOMAS: THANK YOU.

DR. DIXON: VERY NICELY SAID.

MR. TORRES: WHERE IS THE TRIAL IN JAPAN?

DR. CHIU: UNIVERSITY OF TOKYO MEDICAL CENTER.

CHAIRMAN THOMAS: OTHER PUBLIC COMMENT?

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HEARING NONE, DO I HEAR A MOTION TO APPROVE THIS MATTER?

DR. DEAS: SO MOVED.

MR. SHEEHY: SECOND.

CHAIRMAN THOMAS: MOVED BY DR. DEAS, SECONDED BY SUPERVISOR SHEEHY. ANY OTHER BOARD MEMBER COMMENT BEFORE WE PROCEED TO VOTE? HEARING NONE, MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: DEBORAH DEAS.

DR. DEAS: YES.

MS. BONNEVILLE: JACK DIXON.

DR. DIXON: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: HOWARD FEDEROFF.

DR. FEDEROFF: YES.

MS. BONNEVILLE: ELIZABETH FINI.

DR. FINI: YES.

MS. BONNEVILLE: JUDY GASSON.

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DR. GASSON: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: KATHY LAPORTE.
DR. LAPORTE: YES.
MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.
DR. MELMED: 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: OSWALD STEWARD.

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DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: DIANE WINOKUR. BRUCE WINTRAUB.
DR. WINTRAUB: YES.
MS. BONNEVILLE: SHERRY LANSING.
MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU VERY MUCH. ON TO ITEM NO. 10. THANK YOU, DR. MILLAN, AND CONGRATULATIONS ON WHAT IS A VERY SUCCESSFUL PROGRAM THAT WILL ONLY BECOME MORE SO AND WILL BE YET ANOTHER LEGACY OF CIRM GOING FORWARD.
ITEM NO. 10, CONSIDERATION OF AMENDMENTS TO THE DISCOVERY, TRANSLATION, AND CLINICAL CONCEPT PLANS. DR. SAMBRANO.
DR. SAMBRANO: THANK YOU, MR. CHAIRMAN. SO WE'RE BRINGING TO YOU FOR YOUR CONSIDERATION SEVERAL AMENDMENTS THAT SPAN MANY OF OUR PROGRAM ANNOUNCEMENTS FROM CLIN TO TRAN TO DISCOVERY. AND WE DO PERIODICALLY COME TO YOU TO REQUEST SOME

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UPDATES IN ORDER TO REALLY MAKE SURE WE'RE REFINING, IMPROVING, AND PROVIDING CLARITY WHERE IT'S NECESSARY. AND OUR GOAL ALWAYS IS TO TRY TO MAKE SURE THAT WE ARE ALIGNED WITH OUR MISSION. AND SO THAT'S WHAT WE ARE TRYING TO DO TODAY.

WE HAVE HAD SOME OF THESE OR MOST OF THESE AMENDMENTS REVIEWED BE THE SCIENCE SUBCOMMITTEE. THERE WERE TWO ITEMS THAT HAD QUESTIONS FROM THE SUBCOMMITTEE FOR WHICH WE ARE BRINGING ADDITIONAL INFORMATION AND DATA. SO WE THANK THE SUBCOMMITTEE FOR PROVIDING US IMPORTANT AND USEFUL FEEDBACK. AND THEN WE'VE ALSO ADDED A COUPLE OF ITEMS WHICH ARE ALSO DETAILED IN THE MEMO THAT WE PROVIDED THAT OUTLINES ALL THE CHANGES THAT WE INTEND TO DO. AS I GO THROUGH, PLEASE FEEL FREE TO HAVE ME PAUSE IF YOU HAVE QUESTIONS ABOUT THESE. THERE ARE QUITE A FEW.

I WANT TO START WITH A COUPLE OF ITEMS THAT ARE INTENDED TO PROVIDE CLARIFICATION. THE FIRST ONE IS THAT OF DETERMINING ELIGIBILITY. AND HERE WE SIMPLY WANT TO EXPLICITLY STATE THAT CIRM'S AUTHORITY TO MAKE AN ELIGIBILITY DETERMINATION, EXCEPT WITH RESPECT TO SOME OF THE SUBJECTIVE CRITERIA THAT ARE FOUND IN THE CLINICAL PROGRAM, EXIST UP UNTIL THE TIME OF THE CONTRACT EXECUTION; THAT IS, FROM THE TIME WE RECEIVE AN APPLICATION

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UNTIL THE TIME THAT THE AWARD IS MADE FOLLOWING THE CONTRACTING PHASE.

NOW, WE NORMALLY CONDUCT AN INITIAL ELIGIBILITY REVIEW WHEN APPLICATIONS COME IN. SO MOST ITEMS ARE IDENTIFIED AT THAT TIME, AND WE DEAL WITH MOST ISSUES THEN. BUT ON OCCASION, ESPECIALLY ONCE WE GET TO THE TIME OF CONTRACTING, WHEN WE ARE INTERACTING WITH THE APPLICANT, WE LEARN OF NEW INFORMATION OR INFORMATION THAT MIGHT DEEM AN APPLICATION INELIGIBLE. SO IN SUCH CASES WE WOULD LIKE TO EXERCISE OUR ABILITY TO DECLARE AN APPLICATION INELIGIBLE.

NOW, THIS WOULD APPLY PROSPECTIVELY TO AWARDS APPROVED FROM TODAY GOING FORWARD. OF COURSE, IN THE CASE WHERE WE RUN INTO A SITUATION WHERE AN APPLICATION HAS BEEN APPROVED BY THE APPLICATION REVIEW SUBCOMMITTEE, WE WILL INFORM THE SUBCOMMITTEE IF WE EXERCISE THAT AUTHORITY ON ANY AWARD. SO THAT'S THE FIRST ONE.

MR. SHEEHY: WHAT? YOU'RE TALKING ABOUT BASICALLY THE TEAM WILL DISAPPROVE APPLICATIONS THAT WE VOTED FOR?

DR. SAMBRANO: IT MEANS WE WOULD --

MR. SHEEHY: SO YOU'LL REEVALUATE.

DR. SAMBRANO: -- DEEM THEM INELIGIBLE.

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MR. SHEEHY: SO YOU'RE SAYING -- SO WE VOTE AN AWARD AND THEN YOU'LL DECIDE THAT THAT AWARD IS NOT --

DR. MILLS: SO A LOT OF WHAT WE'VE HAD TO DO IN ORDER TO GET THE TIME DONE IS WHAT WE CALL JUST-IN-TIME DOCUMENTS. SO WE HAVE ELIGIBILITY CRITERIA THAT SAYS YOU HAVE TO HAVE A, B, C, AND D. AND THEY CERTIFY TO US THAT A, B, C, AND D ARE REAL, AND THEY WILL PROVIDE THAT WITH WHAT WE CALL JUST-IN-TIME, JIT, DOCUMENTS TO BE PROVIDED LATER.

IF WE WERE TO GO BACK TO THE OLD WAY, WE WOULD PUT THAT IN FRONT, AND WE WOULD REQUIRE THEY DEMONSTRATE, THEY PROVE TO US A, B, C, AND D ARE REAL. WE WILL EVALUATE ALL OF THAT, THROW THEM OUT, THEY NEVER GET REVIEWED, NEVER COMES. SO WHAT WE DO IS WE FLIP THIS AROUND AND SAY WE'RE ONLY GOING TO DO THAT, BECAUSE, AGAIN, IF YOU LOOK AT THE MINORITY OF THINGS THAT MAKE IT THROUGH ALL THE WAY TO THE FUNDING STAGE, WHEN WE ASK FOR THAT CONFIRMATORY ELIGIBILITY CRITERIA AT THE END, IF THEY HAVE MISREPRESENTED SOMETHING THAT'S NOT A REVIEW CRITERIA, IT'S NOT SUBJECTIVE, THIS ISN'T ANY OF THAT, THIS IS ABSOLUTE IT WOULDN'T GO TO THE GWG, IT THEREFORE WOULDN'T GO TO THE BOARD HAD THEY BEEN TRUTHFUL IN THAT, YES, WE WANT THE ABILITY TO NOT

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MAKE REVIEW. ACTUALLY WE JUST WANT IT EXPLICITLY STATED THAT WE CANNOT MAKE THAT AWARD THEN, WHICH WE ALREADY HAVE THE ABILITY TO DO ON THE FRONT END.

MR. SHEEHY: SO A COUPLE OF THINGS. ONE -- THIS IS ALWAYS MY FAVORITE THING. HAS THIS HAPPENED? IS THIS A HYPOTHETICAL?

DR. MILLS: NO, IT'S NOT A HYPOTHETICAL. YES, IT'S HAPPENED.

MR. SHEEHY: WELL, WHAT HAPPENED? WHEN DID IT HAPPEN? CAN WE HAVE A DISCUSSION OF THAT? WE VOTED TO FUND SOMETHING, AND NOW SOMETHING HAS BEEN UNFUNDED.

DR. MILLS: I'M NOT SAYING IT'S BEEN UNFUNDED. WE HAVE UNCOVERED THINGS WHERE THEY DON'T MEET ELIGIBILITY CRITERIA.

MR. HARRISON: SO TO BE CLEAR, WE HAVE NEVER TERMINATED AN AWARD AFTER THE BOARD HAS APPROVED IT. WHAT WE'VE TRIED TO DO IN CIRCUMSTANCES WHERE WE HAVE RECEIVED INFORMATION AFTER THE BOARD HAS APPROVED THE AWARD, INDICATING THAT THE PROJECT WOULDN'T HAVE BEEN ELIGIBLE IN THE FIRST PLACE, IS TO USE OUR AUTHORITY TO SET MILESTONES TO TRY TO GET THE PROJECT ON THE APPROPRIATE TRACK. BUT, FOR EXAMPLE, WE HAD AN INSTANCE IN WHICH AN INVESTIGATOR ON A DISCOVERY

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AWARD ULTIMATELY WE DISCOVERED INTENDED TO USE A MOUSE MODEL RATHER THAN A HUMAN MODEL. HAD WE HAD THAT INFORMATION AT THE OUTSET, THE APPLICATION WOULD HAVE NOT BEEN ELIGIBLE FOR FUNDING.

LIKEWISE, FOR EXAMPLE, IF AN APPLICANT PROPOSES TO USE A CELL LINE, SAYS HE OR SHE HAS THE APPROPRIATE CONSENTS, AND THEN IN THE JUST-IN-TIME PHASE WE DISCOVER THAT THE CONSENTS ARE NOT APPROPRIATE FOR COMMERCIAL DEVELOPMENT, THEN THAT CANDIDATE CELL LINE IS REALLY OF NO USE. SO, AGAIN, WE HAVE TO USE OUR MILESTONE AUTHORITY TO TRY TO GET THE PROJECT ON TRACK.

SO THOSE ARE TWO INSTANCES IN WHICH WE'VE USED OUR MILESTONE AUTHORITY RATHER THAN EITHER COMING BACK TO YOU OR EXERCISING AUTHORITY THAT WE DIDN'T FEEL THAT WE HAD TO REFRAIN FROM EXECUTING A CONTRACT UNDER THOSE CIRCUMSTANCES.

MR. SHEEHY: HAVE YOU JUST THOUGHT ABOUT COMING BACK TO US?

DR. MILLS: YEAH. I THINK THE ISSUE, THOUGH, IS IT'S NOT -- IT WOULDN'T BE A BOARD ISSUE. IT'S NOT A BOARD LEVEL DECISION. IT'S AN ELIGIBILITY DECISION WHICH IS AT THE OPERATIONAL LEVEL. AND THOSE ARE THINGS THAT WE'VE FLIPPED AND WE'VE MOVED AROUND A LITTLE BIT FOR THE SAKE OF

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EFFICIENCY. BUT THESE ARE NOT -- WE DON'T COME TO THE BOARD EVERY TIME WE MAKE AN ELIGIBILITY DETERMINATION THAT AN APPLICATION IS INELIGIBLE. JUST BECAUSE WE FIND THAT OUT LATER IN THE PROCESS SHOULDN'T CHANGE THAT.

DR. DEAS: I UNDERSTAND --

DR. DIXON: COULD I ASK A QUESTION ABOUT THE MIX-UP WITH THE MOUSE MODEL VERSUS THE HUMAN MODEL? THAT'S A LITTLE HARD TO CONCEPTUALIZE. HOW COULD ONE MISS SUCH A THING?

DR. SAMBRANO: I CAN ADDRESS THAT. IT'S IN THE PROPOSAL ITSELF. IT ACTUALLY HAS TO DO WITH THE VAGUENESS OF THE LANGUAGE. IN SOME CASES IN THE PAST, WE'VE GOTTEN PROPOSALS THAT DON'T SPECIFICALLY STATE THEY ARE USING EITHER A HUMAN CELL LINE OR HUMAN CELLS. THEY JUST SAY WE ARE USING THIS TYPE OF STEM CELL. AND IT WAS UNDER THE ASSUMPTION BY EVERYBODY, INCLUDING REVIEWERS, THAT THEY WERE GOING TO UTILIZE THE HUMAN ONE SINCE THAT WAS AN ELIGIBILITY CRITERIA TO BEGIN WITH.

ONCE WE GOT STARTED WITH THE PROJECT, WE LEARNED THAT THEIR INTENTION WAS ACTUALLY TO USE MOUSE CELLS RATHER THAN HUMAN.

CHAIRMAN THOMAS: DR. DEAS, I'M SORRY. YOU HAD A QUESTION.

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DR. DEAS: NOT SO MUCH A QUESTION, BUT A COMMENT. I UNDERSTAND THE SITUATION, WHEN PROPOSALS ARE INELIGIBLE, THAT YOU MAKE THAT DETERMINATION AND IT DOESN'T INVOLVE THE BOARD. HOWEVER, I'M IN AGREEMENT WITH JEFF. IF THE PROPOSAL COMES TO THE BOARD, THE BOARD APPROVES THE PROPOSAL, THEN IT GOES BACK AND YOU FIND OUT SOMETHING THAT MAKES IT INELIGIBLE, I GET THAT. I DON'T GET NOT INFORMING THE BOARD, NOT THAT IT'S A BOARD DECISION AGAIN, BUT I THINK THE PUBLIC OPTICS ARE NOT REALLY GOOD BECAUSE IT IS A PUBLIC MEETING. THE PUBLIC HEARS THAT IT'S APPROVED BY THE BOARD. SOME PEOPLE HERE FROM THE PUBLIC MAY EVEN KNOW WHO THAT APPLICATION IS FROM OR WHAT INSTITUTION. THERE MAY BE SOME STATEMENT TO THE INSTITUTION THAT I WAS AT THE BOARD MEETING, I UNDERSTAND THAT YOUR APPLICATION IS APPROVED; THEREFORE, I DON'T THINK THE OPTICS ARE GOOD.

DR. MILLS: AGAIN, ON THAT SPECIFIC ISSUE, I THINK IT MIGHT HAVE BEEN LOST, BUT SPECIFICALLY WE ARE STATING THAT CIRM WILL INFORM THE APPLICATION REVIEW SUBCOMMITTEE, WHICH IS ESSENTIALLY THE BOARD, IF WE EVER EXERCISE. IF WE EVER DO IT, WE WILL COME BACK AND MAKE IT CLEAR THAT WE'VE DONE IT.

MR. SHEEHY: I GUESS MY CONCERN IS THAT

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THE BOARD HAS TAKEN ACTION. AND SO HAVING AN ACTION OF THE BOARD REVOKED, EVEN OVER AN ISSUE THAT MAY NORMALLY FALL WITHIN THE SCOPE OF ADMINISTRATION, STILL THE BOARD CAN'T HAVE AN ACTION THAT IT'S TAKEN REVERSED BY ADMINISTRATION. JUST AS A PRINCIPLE OF GOVERNANCE FOR ME, I'M TROUBLED BY THAT.

THE SECOND THING IS, AND THIS HAS COME UP BECAUSE WE'VE HAD VARIOUS ISSUES OVER THE YEARS, AND I STILL REMEMBER, AND I CANNOT REMEMBER WHO IT WAS, IT MIGHT HAVE BEEN MICHAEL FRIEDMAN, BUT ONE OF OUR ESTEEMED ACADEMICS, EXPLAINING IT'S OUR JOB TO TAKE THE HEAT. I DON'T THINK PEOPLE ARE GOING TO BE THRILLED TO HEAR THAT SOMETHING THAT THE BOARD VOTED FOR IS NOT GOING TO HAPPEN. USUALLY OUR AWARDS OFTEN INVOLVE SUBSTANTIAL AMOUNTS OF MONEY, THINGS ARE GOING ON. AND SO WHY ON EARTH WOULD ADMINISTRATION WANT TO BEAR THE BURDEN OF TAKING SOMEBODY'S GRANT AWAY WHEN REALLY WE'RE THE ONES -- IT'S KIND OF OUR JOB TO GET YELLED AT WHEN PEOPLE ARE UNHAPPY ABOUT THIS.

YOU'RE JUST PUTTING ON YOURSELF -- YOU'RE KIND OF LOSING SOME OF THE NEUTRALITY YOU HAVE THROUGH THE GRANTS WORKING GROUP AND THEN THE APPLICATION REVIEW AND THE BOARD MAKING DECISIONS ON FUNDING. YOU'VE NOW PUT YOURSELF INTO THAT CHAIN.

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SO THOSE ARE MY TWO CONCERNS.

DR. MILLS: SO IF YOU LOOKED AT THE NUMBERS THAT I PUT UP, 80 PERCENT OF WHAT WE DO IS SAY NO. WE ARE OKAY SAYING NO.

THE OTHER THING IS WE MAKE ELIGIBILITY DETERMINATIONS ALL THE TIME ON OBJECTIVE CRITERIA, AND WE ARE OKAY DOING THAT. IF WE GET FLAK FOR DOING THAT, WE'RE OKAY WITH THAT. WE NEVER DO IT SUBJECTIVELY. AND THERE ARE APPEAL MECHANISMS IF SOMEBODY THINKS THAT WE DO. BUT WHAT WE'VE DONE IN THIS CASE IS, IN AN EFFORT TO TRY TO MAKE A MUCH MORE EFFICIENT PROCESS BY NOT RUNNING OUT THIS VERY ELABORATE ELIGIBILITY SCREENING, WHICH, IF WE RAN ON EVERY SINGLE APPLICATION WE POSSIBLY GOT, WOULD TAKE AN ENORMOUS AMOUNT OF TIME AND SLOW IT DOWN.

WE'VE SAID WE'LL DO THAT FINAL VETTING ON ONLY THOSE THAT THE GWG SETS FORTH AS RECOMMENDED. AND IF THAT FAILS, WELL, THAT FAILS JUST LIKE IT WOULD IF WE WOULD HAVE WASTED THE TIME AND DONE IT ON THE FRONT END FOR ALL OF THE OTHER APPLICATIONS THAT HAVE NO CHANCE OF DOING IT. SO THIS IS REALLY A MATTER OF EFFICIENCY. WE CAN DO IT. WE CAN JUST GO BACK TO THE WAY IT WAS AND SCREEN ALL THESE OUT ON THE FRONT END. IT WILL JUST TAKE LONGER.

MR. SHEEHY: WITH ALL DUE RESPECT, THIS IS

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WHAT DRIVES ME NUTS. YOU'RE GIVING ME THE WRONG CHOICES. IT'S NOT LIKE I'M ASKING THAT YOU GO BACK AND DO IT THE OLD WAY. I'M JUST ASKING THAT YOU LET US DO OUR JOB AT THE END. SO YOU DON'T HAVE TO DO ANYTHING ELSE. THE ONLY ADDITIONAL STEP YOU HAVE TO DO IS SAY WE FOUND THAT THIS PROJECT WAS INELIGIBLE, PUT IT ON THE BOARD AGENDA, HAVE US VOTE TO TAKE AWAY THEIR MONEY. I THINK YOU COULD DO EVERYTHING THE WAY YOU'VE BEEN DOING IT, BUT THAT LAST STEP OF UNDOING AN ACTION BY THIS BOARD SHOULD COME TO THIS BOARD TO BE UNDONE.

AND, FRANKLY, I THINK THAT WOULD BE INFORMATIVE TO POTENTIAL GRANTEES BECAUSE THEY WOULD THEN KNOW -- FIRST OF ALL, THEY WOULD KNOW THAT THEY COULD LOSE THEIR GRANTS IF THEY MISREPRESENTED OR WERE SLOPPY IN THE PREPARATION OF THEIR GRANTS IN TERMS OF ALIGNING WITH OUR ELIGIBILITY REQUIREMENTS. OBVIOUSLY IT'S EITHER INTENTIONAL OR UNINTENTIONAL THAT THESE PROJECTS WOULD GET THIS FAR DOWN THE ROAD. AND SO PEOPLE WOULD KNOW, HEY, WE REALLY TAKE THESE SERIOUSLY. IF IT HAPPENS OFF CAMERA, THEN YOU'RE REALLY NOT GETTING -- IT ACTUALLY FROM MY PERSPECTIVE MIGHT BE MORE EFFICIENT TO BRING IT TO THE BOARD BECAUSE IT REQUIRES LITTLE EXTRA WORK ON BEHALF OF THE TEAM, BUT YOU WOULD BE SENDING A CLEAR

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SIGNAL TO FOLKS WHO ARE COMING IN TO APPLY, THAT IF YOU DON'T DO THIS RIGHT, THEN YOU CAN HAVE YOUR AWARD TAKEN AWAY AT THE ELEVENTH HOUR. AND IT ACTUALLY MIGHT SAVE YOU TIME AND MAKE YOUR PROCESSES MORE EFFICIENT.

DR. DEAS: THAT WAS MY EXACT POINT, THAT IT ADDRESSES THE GRANTEE, IT ADDRESSES THE BOARD, AND IT ADDRESSES THE PUBLIC OPTICS.

DR. MILLS: SO LET ME PROVIDE THE EXACT REVERSE OF THAT. HAVING SORT OF LIVED HOW A LOT OF APPLICATIONS SORT OF APPROACH THIS IS WHAT YOU'VE DONE IS, INSTEAD OF SAYING IF YOU DON'T HAVE THIS CRITERIA, YOU WILL NOT BE ELIGIBLE, YOU'VE NOW TURNED IT AROUND AND SAID IF YOU DON'T MEET THIS VERY OBJECTIVE CRITERIA, YOU MAY NOT BE ELIGIBLE. THAT'S THE CHANGE. AND SO I THINK IT'S A MUCH STRONGER MESSAGE TO SAY DON'T APPLY IF YOU DON'T MEET THESE ELIGIBILITY CRITERIA OR IF YOU'RE NOT TRUTHFUL VERSUS TRY IT, CHALLENGE IT. MAYBE YOU'LL GET THROUGH THE FIRST SCREENING, MAYBE YOU GET TO THE BOARD, THE GWG, YOU GET APPROVED, YOU GET CAUGHT LATER, AND YOU CAN PLEAD YOUR CASE TO THE BOARD. IT GOES FROM A CERTAINTY TO A MAYBE.

MR. SHEEHY: BUT SUCH LITTLE FAITH IN US. WHAT YOU'RE BASICALLY SAYING IS THAT WE WOULD LOOK

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AT OBJECTIVE CRITERIA THAT WE'VE ESTABLISHED AND WE WOULD REVERSE THOSE CRITERIA BASED ON -- I JUST -- THAT'S HARD.

DR. MILLS: I LOOK AT IT AND SAY IF IT'S OBJECTIVE CRITERIA, IT WAS DEBATED AND ACCEPTED IN THE CONCEPT PLAN PERIOD, AND WE JUST GO AND EXECUTE OUR WORK. WE'RE NOT TALKING ABOUT SUBJECTIVE DECISIONS. I THINK WHAT WE'RE TRYING TO SAY IS WE DON'T WANT TO TAKE AN OBJECTIVE DECISION AND MAKE IT A SUBJECTIVE DECISION.

CHAIRMAN THOMAS: SENATOR TORRES, MR. JUELSGAARD, AND THEN DR. STEWARD, DAVID AS WELL.

MR. TORRES: JAMES, IN PREVIOUS ISSUES NOT RELATED TO ELIGIBILITY, WHEN A PROJECT DOES NOT REACH A MILESTONE, WHAT'S BEEN THE PROCESS THAT WE'VE USED AT THAT POINT? WE STOP THE FUNDS FROM TRANSFERRING?

MR. HARRISON: SO IT DEPENDS ON THE CIRCUMSTANCES. BUT AS A RULE, CIRM HAS THE AUTHORITY. IN THE CLIN PROGRAMS, FOR EXAMPLE, IF A MILESTONE HASN'T BEEN MET MORE THAN FOUR MONTHS AFTER IT WAS SUPPOSED TO HAVE ACHIEVED, TO TERMINATE THE AWARD. OBVIOUSLY IF THE MILESTONE HASN'T BEEN MET, WE WON'T BE DISBURSING ANY ADDITIONAL FUNDS. BUT IF IT APPEARS TO CIRM THAT THE AWARDEE CANNOT

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COMPLETE THE PROJECT IN A TIMELY MANNER BECAUSE OF A DELAY OR OTHER PROBLEMS, THEN CIRM HAS THE POWER UNDER THE GRANTS ADMINISTRATION POLICY TO TERMINATE AFTER FOUR MONTHS.

MR. TORRES: SO THE PRECEDENCE ON THAT ISSUE HAS BEEN NOT TO BRING THAT BACK TO THE BOARD?

MR. HARRISON: CORRECT. THAT'S THE POWER THAT THE BOARD HAS DELEGATED TO THE CIRM TEAM. WE REPORT IT TO THE BOARD WHEN THAT OCCURS, BUT WE EXERCISE THAT AUTHORITY.

MR. TORRES: HOW IS THIS ISSUE DISTINCT IN PROCESS FROM WHAT I'VE STATED?

MR. HARRISON: THIS IS AT THE FRONT END. SO AS DR. SAMBRANO AND DR. MILLS HAVE EXPLAINED, WHEN AN APPLICATION COMES IN IN THE FIRST INSTANCE, BEFORE WE EVEN ASSIGN REVIEWERS, THE REVIEW TEAM REVIEWS THE APPLICATION AGAINST THE ELIGIBILITY CRITERIA ESTABLISHED BY THE BOARD THROUGH CONCEPT PLANS. AND IF WE DETERMINE THAT AN APPLICANT HAS NOT SATISFIED THOSE ELIGIBILITY CRITERIA, THEN WE DISCONTINUE ALL FURTHER WORK ON THAT APPLICATION AND NOTIFY THE APPLICANT.

WHAT WE'RE DESCRIBING HERE IS A SET OF CIRCUMSTANCES WHERE WE DON'T DISCOVER THE ELIGIBILITY ISSUE UNTIL AFTER THE GWG REVIEW AND THE

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BOARD APPROVAL. AND THIS WILL OFTEN HAPPEN IN THE CONTEXT ACTUALLY OF ESTABLISHING THOSE MILESTONES BECAUSE THAT'S THE POINT IN TIME WHERE CIRM'S SCIENTIFIC TEAM AND THE APPLICANT TEAM ENGAGE IN EXTENDED AND DETAILED DIALOGUE WHERE YOU MIGHT UNCOVER THE FACT THAT WHEN THE APPLICANT WAS TALKING ABOUT A MODEL OR CELL LINE, THEY WERE THINKING OF A MOUSE MODEL WHILE OUR ELIGIBILITY CRITERIA REQUIRED THAT IT BE A HUMAN LINE. SO IT'S OFTEN AT THAT STAGE THAT THESE SORTS OF ISSUES COME TO THE SURFACE.

MR. TORRES: SO, JEFF, ARE YOU SUGGESTING THAT WE SHOULD HAVE A UNIFORM POLICY THAT APPLIES TO BOTH NOT REACHING MILESTONE AND ELIGIBILITY? BECAUSE WE'VE DONE THE PREVIOUS ALREADY. THAT'S BEEN THE PRECEDENT. IF YOU ARE SUGGESTING THAT WE SHOULD CHANGE THAT TO APPLY ACROSS THE BOARD, THEN THAT'S AN ISSUE WE NEED TO DISCUSS.

MR. SHEEHY: I THINK MILESTONES FOR ME ARE DIFFERENT. FIRST OF ALL, BROAD BRUSH, THOSE ARE REVIEWED AT THE GRANTS WORKING GROUP. AND I GUESS I'M JUST TRYING TO WRAP MY HEAD AROUND HOW SOMEBODY GETS ALL THE WAY THROUGH AND NOT BEING ELIGIBLE. THAT'S DIFFERENT FROM MILESTONES BECAUSE THOSE ARE IN THE APPLICATION, THEY'RE FURTHER REFINED IN

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CONVERSATIONS BEFORE THEY GO FORWARD WITH THE CIRM TEAM. THOSE ARE MUTUALLY AGREED UPON, OBJECTIVE, THEY'RE THERE.

AND TO BE CLEAR, AS I UNDERSTAND IT, WHEN YOU DON'T HIT A MILESTONE, IT'S NOT THAT YOU ARE TERMINATED. YOU JUST DON'T GET ANY MORE MONEY. IF YOU WERE AT SOME POINT TO HIT YOUR MILESTONE, THEN THEY CAN CONTINUE WITH THE GRANT. THAT'S HOW I UNDERSTAND THAT THAT WORKS. THAT, OKAY, WE'LL PAY YOU X MONEY TILL THERE'S MILESTONE ONE. IF YOU DON'T HIT THAT MILESTONE, THEN THERE WILL BE NO MORE CHECKS. YOU MAY HAVE OTHER FUNDS THAT YOU'RE ABLE TO USE TO COMPLETE THAT WORK, AND THEN THE WORK CAN CONTINUE WITH OUR FUNDING. IF AT THAT POINT YOU RECOGNIZE THAT YOUR WORK IS NOT GOING TO GO ANYWHERE, THEN LIKE, YEP, IT'S OVER. BUT ISN'T THAT HOW IT'S GENERALLY THEORETICALLY SUPPOSED TO WORK?

DR. MILLS: THE MILESTONES DO FOR CONTRACTUAL ISSUES BECAUSE WE CAN'T HAVE A NEVER ENDING CONTRACT. JAMES CAN SPEAK MORE ABOUT THIS. AFTER A CERTAIN PERIOD OF TIME, WE HAVE THE ABILITY TO SAY YOU HAVEN'T MET YOUR MILESTONE, YOU'RE OVER ON YOUR MILESTONE SO SIGNIFICANTLY, THAT WE'RE GOING TO TERMINATE THE CONTRACT.

I THINK HERE WHAT WE'RE TALKING ABOUT --

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I'M GOING TO TRY A DIFFERENT ANALOGY -- IS IMAGINE IT'S A DIVING COMPETITION. AND WE SAY -- THE OLYMPIC COMMITTEE SAYS, LOOK, YOU CAN'T USE ANABOLIC STEROIDS AND PARTICIPATE IN THIS DIVING COMPETITION. AND THE DIVER GOES AND JUMPS AND GETS A NINE FIVE, NINE FIVE, NINE FIVE, WINS A SILVER MEDAL, AND THEN THE BLOOD TESTS COME BACK THAT WERE TAKEN ON THE DIVER AND THE BLOOD TEST TURNS OUT HE IS VIOLATING THE SUBSTANCE ABUSE POLICY. THEY DON'T GO BACK TO THE JUDGES AND SAY YOU GAVE IT A NINE FIVE, WHAT DO YOU THINK NOW? THEY SAY YOU FAILED AN OBJECTIVE CRITERIA ON THE FRONT END, AND WE ALL AGREED UPON PROSPECTIVELY THAT IF THIS WERE THE CASE, THEN YOU WOULD BE DISQUALIFIED FROM PARTICIPATION IF WE KNEW ABOUT IT BEFORE YOU DOVE OR AFTER YOU DOVE. BUT IF YOU WERE ON ONE OF THESE SUBSTANCES WHILE YOU DOVE, THEN YOU ARE NOT ELIGIBLE. THAT'S THE BEST ANALOGY I CAN THINK OF HERE. WE'RE NOT TALKING ABOUT SOMETHING THAT NEEDS TO BE OR THAT SHOULD BE IN MY MIND READJUDICATED OR REEVALUATED JUST BECAUSE OF THE TIMING OF WHEN THE BLOOD TEST CAME BACK.

MR. SHEEHY: I DON'T SEE US AS JUDGES THOUGH. I SEE US AS THE BODY APPROVING THE SPENDING OF MONEY AND ALSO TAKING BACK MONEY. SO THE ANALOGY FALLS FOR ME ON THAT. I'M NOT A JUDGE HERE. I'M

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FISCALLY RESPONSIBLE TO THE STATE OF CALIFORNIA FOR THE SPENDING OF THE $3 BILLION THAT WE'VE BEEN ALLOCATED.

CHAIRMAN THOMAS: MR. JUELSGAARD, DR. HIGGINS, DR. STEWARD.

DR. JUELSGAARD: SO I WANT TO ACTUALLY FOLLOW UP WITH THAT LAST POINT FIRST. SO YOUR ANALOGY, RANDY, CLEARLY TAKING DRUGS IN THE FACE OF AN ATHLETIC COMPETITION IS VERBOTEN, RIGHT? EVERYBODY WOULD AGREE WITH THAT. SO MY QUESTION IS WHEN PEOPLE HAVE VIOLATED THESE ELIGIBILITY CRITERIA IN THE PAST, WHETHER THERE'S BEEN ONE OR MORE, CAN YOU LOOK THROUGH TO SEE WHETHER THAT WAS DONE INTENTIONALLY, THERE WAS A REAL INTENT TO MISLEAD, OR IT WAS SIMPLY AMBIGUOUS?

DR. MILLS: IT'S DIFFICULT TO SAY. WE HAVEN'T HAD ANYONE COME AND SAY, YEAH, I LEFT THAT OUT OR I CHECKED THAT BOX BECAUSE I WANTED TO MISLEAD YOU. BUT WE HAD BOXES CHECKED AND THINGS LEFT OUT THAT WERE CLEARLY FACTUALLY INACCURATE.

DR. JUELSGAARD: SO I'M JUST GOING TO FINISH THEN. SO THE VALUE IN WHAT JEFF WOULD LIKE TO DO, WHICH IS FROM MY POINT OF VIEW, TO RUN IT BACK THROUGH THE APPLICATION REVIEW SUBCOMMITTEE, IS THAT IF SOMEBODY DID THIS INTENTIONALLY, THEIR HANDS

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WOULD GET SLAPPED BY BASICALLY WITHDRAWING THE FUNDING, AND THAT WOULD BE A MATTER OF PUBLIC RECORD. THAT WOULD HAPPEN IN AN OPEN MEETING AND EVERYBODY WOULD BE AWARE OF IT.

IF, ON THE OTHER HAND, THIS IS A SLOPPINESS ISSUE, NOT AN INTENTIONAL ISSUE, THEN HAVING IT RUN THROUGH THE APPLICATION REVIEW SUBCOMMITTEE DOESN'T REALLY HELP EXCEPT MAYBE PEOPLE WILL BE A LITTLE BIT MORE CAREFUL THE NEXT TIME AROUND.

SO, ANYWAY, I'M NOT SURE WHICH WAY I FALL ON THIS, JEFF. I HEAR WHAT YOU'RE SAYING. I SEE CERTAIN VALUE IN IT, BUT I SEE THE VALUE MOST PREDOMINANT WHEN IT'S CLEAR THAT SOMEBODY DID SOMETHING INTENTIONALLY TO MISLEAD THE GWG OR US.

MR. SHEEHY: IF WE STAY WITH THIS ANALOGY, THAT IS A VERY PUBLIC -- PEOPLE DON'T COME AND WHISPER GIVE YOUR MEDALS BACK. THAT BECOMES A VERY PUBLIC EVENT.

DR. HIGGINS: I ACTUALLY DON'T HAVE A PROBLEM WITH THE PROPOSAL AS IT STANDS, AND I WOULD BE HAPPY WITH IT AS IS, BUT I'M SYMPATHETIC TO WHAT JEFF IS SAYING AS WELL. IS THERE SOME SIMPLE SOLUTION TO LANGUAGE SAYING THAT THE BOARD APPROVES CONTINGENT UPON AS OPPOSED TO THE BOARD APPROVES?

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CHAIRMAN THOMAS: I THINK DR. STEWARD HAS A COMMENT FURTHER TO THAT QUESTION.

DR. STEWARD: YEAH. SO I'M LISTENING ACTUALLY TO EXACTLY WHAT YOU'RE SAYING. SO IT SEEMS LIKE THERE'S TWO ISSUES. ONE IS THAT THE BOARD HAS THE ULTIMATE RESPONSIBILITY FOR ALLOCATING FUNDS, AND TWO IS THE NEED FOR THIS ACTIVITY BEING DONE IN A PUBLIC FORUM, WHICH IS THE BOARD MEETING. AND IT SEEMS LIKE ACTUALLY THIS WOULD OCCUR UNDER THIS PLAN AS LONG AS THAT LAST STEP WAS THAT THE BOARD WOULD BE INFORMED, THE APPLICATION REVIEW SUBCOMMITTEE WOULD BE INFORMED, NOT IN WRITING, BUT IN OPEN MEETING. THAT'S THE POINT OF PUBLIC INFORMATION.

NO. 2, BEING INFORMED DOESN'T MEAN THAT THE BOARD CAN'T ACTUALLY TAKE ACTION THAT CONTRADICTS THAT. THIS BOARD ALWAYS HAS THE ULTIMATE AUTHORITY TO SAY, NO, WAIT A MINUTE. ACTUALLY WE WANT TO HEAR MORE, AND WE MIGHT EVEN MAKE A MOTION TO GO AHEAD AND FUND THIS. SO I ACTUALLY THINK THIS WHOLE THING FITS TOGETHER. MAYBE THERE'S A WORD OR TWO THAT COULD BE CHANGED TO MAKE IT A LITTLE BIT MORE CLEAR, BUT I THINK THAT IN THE END ALL OF THOSE THINGS ARE ACTUALLY IN PLACE, I THINK.

MR. SHEEHY: THE SOLUTION IS JUST

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AGENDIZING THE INFORMING AS AN ACTION ITEM, AND THEN YOU'RE OUT. THAT'S THE WAY SO THAT IF WE -- BECAUSE WHERE WE GET HUNG UP IS WE'RE INFORMED, SO IT'S AN INFORMATION ITEM. WE'D HAVE TO PUT IT ON THE AGENDA AND COME BACK TO THE NEXT MEETING. SO THE INFORMING OF THE BOARD WE CAN PUT ON AS AN ACTION ITEM, AND I THINK WE JUST SOLVED THE PROBLEM.

MR. TORRES: IN THAT INTERIM ARE YOU ADVOCATING THAT THE FUNDING STOP UNTIL A DECISION IS MADE?

MR. SHEEHY: NO. I'M NOT RECOMMENDING -- I THINK THIS IS FINE. THE FUNDING HAS BEEN STOPPED, THE TEAM COMES TO THE BOARD AND SAYS THIS HAPPENED. IT'S AGENDIZED AS AN ACTION ITEM IN CASE ANYBODY HAS A PROBLEM WITH THAT. SO WE STILL HAVE THE ABILITY TO DO SOMETHING. I HOPE WE DON'T EVER DO SOMETHING IN THESE CIRCUMSTANCES.

MR. TORRES: IS THAT WHAT THEY'RE DOING RIGHT NOW, INFORMING US?

DR. DEAS: THEY'RE INFORMING --

DR. MILLS: RIGHT NOW THERE'S NOT A REALLY -- THE PROBLEM WE'RE RUNNING INTO IS RIGHT NOW THERE'S NOT A REALLY CLEAR PLAN. WHAT WE DO IN ACTUAL PRACTICE IS ANYTHING WE POSSIBLY CAN TO TRY TO MAKE THE APPLICATION COME BACK INTO CONFORMANCE

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IN ANY WAY. IF NOT, WE'LL ASK TO WITHDRAW.

IF WHAT MR. SHEEHY IS SUGGESTING IS WE JUST ANY TIME THIS HAPPENS, WE PUT IT AS AN AGENDA ITEM NOTIFICATION OF THE BOARD OF FAILURE TO CONTRACT AN AWARD, WE ARE FINE WITH THAT. I THINK THAT'S KIND OF WHAT WE THOUGHT WE WERE DOING.

DR. DIXON: HOW MANY TIMES HAS THIS ACTUALLY HAPPENED?

MR. HARRISON: TWO OCCASIONS.

COULD I JUST ASK ONE CLARIFICATION TO MAKE SURE I UNDERSTAND WHAT THE INTENT WOULD BE. SO WE WOULD PUT ON THE AGENDA THAT WE HAD MADE A DETERMINATION BASED ON ELIGIBILITY CRITERIA NOT TO CONTRACT APPLICATION XYZ. AND IF THE BOARD DID NOT TAKE ACTION ON THAT ITEM, THE CIRM TEAM DETERMINATION NOT TO CONTRACT WOULD STAND?

MR. SHEEHY: YES. IT'S NOT AN ACTION WHERE WE HAVE TO TAKE ACTION, BUT IT'S JUST AGENDIZED IN A WAY THAT HOPEFULLY IN A SITUATION THAT IT NEVER HAPPENS. IT'S JUST HOW IT'S PUT ON THE AGENDA AS OPPOSED TO A DISCUSSION ITEM WHERE WE'D HEAR ABOUT IT AND THEN WE WOULD BE PRECLUDED FROM TAKING ACTION.

CHAIRMAN THOMAS: OKAY. I THINK WE'VE HIT ON THE APPROPRIATE SOLUTION HERE. THANK YOU,

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EVERYBODY. THAT WAS A GREAT DISCUSSION. SO COULD WE, GIL, MOVE ON TO --

MR. REED: PUBLIC COMMENT?

CHAIRMAN THOMAS: I THINK THAT WILL BE AT THE END, DON, AFTER GIL HAS GONE THROUGH THE WHOLE THING.

DR. SAMBRANO: THAT WAS ONE. SO WE'LL GO DOWN TO NO. 2. SO THE NEXT ONE IS RELATED TO HAVING A GOOD STANDING REQUIREMENT. THIS IS INFORMATION THAT WE HAVE ALREADY BEEN COLLECTING FOR SEVERAL YEARS FROM APPLICANTS, ASKING THEM DO THEY HAVE SYSTEMS IN PLACE TO TRACK CIRM FUNDS THAT WOULD BE APPROPRIATE, WHETHER THE PI HAS BEEN CONVICTED OF OR IS NOT UNDER INVESTIGATION FOR CRIMES INVOLVING FRAUD OR MISAPPROPRIATION, WHETHER THE PI IS UNDER INVESTIGATION OF RESEARCH MISCONDUCT, OR IS BARRED FROM RECEIVING RESEARCH FUNDS. BUT IT'S NEVER REALLY BEEN PART OF THE FORMAL ELIGIBILITY CRITERIA. SO WHAT WE WANT TO DO HERE IS SIMPLY INCLUDE IT WITHIN THAT SO THAT WE HAVE A MECHANISM TO DISQUALIFY AN APPLICANT THAT DOES NOT MEET THESE STANDARDS. SO THAT IS THAT ONE.

THE NEXT ONE --

DR. MELMED: WHY DO YOU LIMIT NO. 2 TO JUST FRAUD AND MISAPPROPRIATION? SHOULDN'T IT BE

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ANY CRIME?

DR. SAMBRANO: I SUPPOSE IT COULD BE.

DR. MELMED: IF IT'S A MURDER, IT'S OKAY THEN.

DR. SAMBRANO: WE HAVE NOT ASKED THAT QUESTION. THIS IS BASED ON THE QUESTIONS WE ASKED IN ORDER TO KNOW WHETHER THEY CAN MANAGE CIRM FUNDS.

NEXT ONE HAS TO DO WITH NOW A SERIES OF PERSONNEL ELIGIBILITY QUESTIONS. HERE, THIS IS ONE THAT WAS DISCUSSED AT SCIENCE SUBCOMMITTEE, AND THERE WERE QUESTIONS THAT WE'RE BRINGING HOPEFULLY A LITTLE MORE INFORMATION TO BEAR.

THE PROPOSED CHANGE HERE IS CURRENTLY THERE IS A MINIMUM PERCENT EFFORT IN THE CLINICAL PROGRAM, AND THIS JUST APPLIES TO THE CLINICAL PROGRAM, OF 30-PERCENT EFFORT BY THE PI. OUR EXPERIENCE WITH CLINICAL PROJECTS HAS BEEN THAT THESE VARY IN TERMS OF THE DEMAND FOR THE PI THROUGHOUT THE COURSE OF THE AWARD. THEY GO THROUGH DIFFERENT PHASES, SOME IN WHICH THEY ARE REALLY REQUIRED TO SPEND A LOT OF TIME TO GET THE PROJECT GOING, TO MOVE ENROLLMENT, TO TREAT PATIENTS, AND THERE ARE OTHER PHASES WHERE IT'S ALMOST THE EQUIVALENT OF WATCHING PAINT DRY. THEY ARE IN A STATUS WHERE THEY REALLY ARE NOT EXPENDING MUCH OF

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THEIR TIME ON THIS PARTICULAR PROJECT.

SO WHAT WE WANT TO DO IS ESSENTIALLY REQUIRE A PI TO PROPOSE AND JUSTIFY THE PERCENT EFFORT FOR EACH PHASE OF THE PROJECT TIMELINE TO MATCH THE PROPOSED ACTIVITIES, BUT THAT THIS WOULD BE NOT LESS THAN 15 PERCENT AVERAGED OUT OVER THE PROJECT PERIOD. BEFORE WE DID NOT HAVE A MINIMUM PERCENT EFFORT REQUIREMENT. I THINK FOLLOWING DISCUSSION WITH THE SCIENCE SUBCOMMITTEE, WE PROPOSED TO HAVE A MINIMUM EFFORT JUST TO ENSURE THAT THERE IS A COMMITMENT FROM THE PI TO THE PROJECT. BUT ULTIMATELY THIS IS TO ENSURE THAT EFFORT MATCHES THE ACTIVITY AND ALSO, IMPORTANTLY, TO ENSURE THAT CIRM IS NOT PAYING FOR UNNECESSARY WORK, ESPECIALLY DURING THOSE PERIODS WHERE THERE IS NO NEED OR DEMAND.

THE WAY WE CAME UP WITH THE 15 PERCENT, THIS IS IN PART BASED ON EXPERIENCE FROM OUR GWG CLINICIAN SCIENTISTS. SO WHAT WE DID WAS WE SURVEYED THEM -- THESE ARE FOLKS THAT ACTIVELY OVERSEE CLINICAL TRIAL PROJECTS -- AND ASKED THEM WHAT A REASONABLE EFFORT WOULD BE. THERE WAS AGREEMENT THAT 30 PERCENT WAS A BIT MUCH, AND THE RANGE THAT THEY SUGGESTED TO US WAS BETWEEN 10 AND 20 PERCENT. SO WE CHOSE FIFTEEN, AND THAT'S WHAT WE

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ARE PROPOSING HERE. ARE THERE QUESTIONS ON THIS ONE?

CHAIRMAN THOMAS: GIL, WHAT DO YOU DO ABOUT -- I KNOW WE HAVE SOME AWARDS WE'VE MADE IN THE PAST WHERE THERE'S BEEN LESS THAN THAT AMOUNT. AM I REMEMBERING CORRECTLY?

DR. SAMBRANO: THAN 15 PERCENT?

CHAIRMAN THOMAS: LESS THAN 15 PERCENT.

DR. SAMBRANO: NO. OUR MINIMUMS HAVE USUALLY BEEN AROUND 20.

CHAIRMAN THOMAS: OKAY. THANK YOU.

DR. SAMBRANO: SO THE NEXT ITEM RELATES TO PROJECT MANAGERS. SO THE FIRST ITEM IS ALLOWING APPLICANTS TO SATISFY THIS REQUIREMENT BY ENTERING INTO A CONTRACT WITH CIRM'S STEM CELL CENTER THAT DR. MILLAN DESCRIBED. THEY HAVE EXPERIENCE AND PROVIDE PROJECT MANAGEMENT SERVICES. SO IF THEY AGREE TO DO THAT FOR THE PROJECT, WE WOULD CONSIDER THAT MEETING THE ELIGIBILITY FOR THE PROJECT MANAGER AND EFFORT.

THE NEW ITEM THAT WE ARE BRINGING THAT WAS NOT CONSIDERED BY THE SCIENCE SUBCOMMITTEE IS A MINIMUM PERCENT EFFORT ON THE TRAN PROJECTS, ON THE TRANSLATIONAL PROJECTS. CURRENTLY WE HAVE A REQUIREMENT THAT PROJECT MANAGERS EXPEND A

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50-PERCENT EFFORT ON TRAN PROJECTS, AND WE'D LIKE TO REDUCE IT TO 35 PERCENT. AND THIS IS BASED ON ADVICE WE HAVE GOTTEN FROM INDEPENDENT CONSULTANTS AS WELL AS THE STEM CELL CENTER ITSELF THAT PROVIDES THESE KINDS OF SERVICES WHO FELT THAT 35 PERCENT IS A MORE REASONABLE NUMBER FOR SOMEBODY WHO IS AT THIS STAGE OF DEVELOPMENT.

SO FOR READINESS OF CLIN1 PROGRAM, THIS IS ANOTHER ONE THAT WAS DISCUSSED AT THE SCIENCE SUBCOMMITTEE, AND THERE WERE QUESTIONS ABOUT THIS ONE. WHAT WE PROPOSE HERE IS TO REDUCE THE TIME TO FILE AN IND FOR CLIN1 APPLICANTS. SO THESE ARE THE IND-ENABLING AWARDS UNDER THE CLIN PROGRAM FROM THE CURRENT 24 MONTHS TO 18 MONTHS.

AND THE RATIONALE BEHIND THIS IS TWOFOLD. IT IS TO ALIGN IT WITH OUR CIRM STRATEGIC GOAL TO REDUCE TIME FROM THE DISCOVERY PHASE TO THE INITIATION OF A CLINICAL TRIAL TO FOUR YEARS. CURRENTLY THE TRAN PROGRAM ALLOWS UP TO 30 MONTHS FOR SOMEBODY TO GET TO A PRE-IND MEETING FOR A THERAPEUTIC. AND 18 MONTHS IN THE CLIN1 WOULD ALLOW THIS TO ALIGN WITH THE FOUR-YEAR GOAL. AND THIS GOAL IS IF THEY HAVE ACHIEVED A SUCCESSFUL PRE-IND MEETING, REASONABLE, WE BELIEVE. AND WE GATHER DATA FROM APPLICANTS THAT HAVE APPLIED TO CLIN1, AND THE

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AVERAGE TIME THAT IS PROPOSED BY APPLICANTS THAT WE'VE GOTTEN TO GET FROM THE START OF THE AWARD TO THE IND FILING IS 16.8 MONTHS, WHICH IS WELL WITHIN THE PROPOSED 18 MONTHS.

SO THE NEXT ITEM HAS TO DO WITH CLARIFYING THE SCOPE OF ELIGIBILITY FOR SMALL MOLECULES AND BIOLOGICS. I THINK THIS IS SOMETHING THAT WAS ORIGINALLY INTENDED, BUT THE LANGUAGE CURRENTLY DOES NOT PERMIT RESEARCH INVOLVING SMALL MOLECULES OR FOR WHICH A STEM CELL IS NECESSARY TO MANUFACTURE THE THERAPY. SO AN EXAMPLE HERE MIGHT BE EXOSOMES THAT ARE DERIVED FROM A STEM CELL. SO THIS WOULD ALLOW SUCH PROJECTS TO COME IN.

AND ALSO SMALL MOLECULES OR BIOLOGICS THAT MODIFY A STEM CELL THERAPY, IN THIS CASE AN EXAMPLE WOULD BE A TRACKING AGENT OR IMAGING AGENT. THESE CHANGES WOULD BE APPLIED TO THE TRAN1, CLIN1, AND CLIN2 PHASE 1 TRIALS.

DR. STEWARD: DOES THAT AFFECT ANY OF THE CURRENTLY FUNDED PROGRAMS OR TRIALS?

DR. SAMBRANO: IT DOES NOT. NO, BECAUSE THIS IS EXPANDING THE SMALL MOLECULE, BIOLOGICS. SO IT'S ALLOWING PROJECTS THAT WE HAVE NOT PREVIOUSLY ALLOWED TO COME IN.

THE NEXT ONE IS ON THE FLIP SIDE LOOKING

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AT THE SCOPE OF PHASE 2 AND PHASE 3 TRIALS IN CLIN2. AND HERE THE PROPOSAL IS TO RESTRICT THESE TWO CELL THERAPIES OR STEM OR PROGENITOR CELL EITHER COMPOSES THE THERAPY OR ARE USED TO MANUFACTURE THE CELL THERAPY. AND THEN IN THE PHASE 3 TRIALS, SIMILAR, BUT ALSO WHERE THE THERAPY IS FOR RARE INDICATIONS. AND THE RATIONALE BEHIND THIS IS THAT FOR SMALL MOLECULE AND BIOLOGIC PRODUCTS THAT GO THROUGH A SUCCESSFUL PHASE 1 TRIAL, WE BELIEVE THEY SHOULD BE ABLE TO ATTRACT FUNDING FROM OTHER SOURCES WHERE IT IS MUCH MORE DIFFICULT FOR A CELL THERAPY TO BOTH NAVIGATE THROUGH THE REGULATORY ENVIRONMENT AND GET ADDITIONAL FUNDING FOR LATER STAGE PHASE TRIALS.

IN ADDITION, FOR THE PHASE 3 TRIAL CATEGORY, WE ARE ADDING -- THIS WAS NOT PRESENTED AT THE SCIENCE SUBCOMMITTEE -- TO ALLOW APPLICANTS THAT HAVE BEEN INFORMED BY THE FDA THAT THEIR PHASE 2 TRIAL QUALIFIES FOR MARKETING APPROVAL OR WOULD QUALIFY TO BE A PIVOTAL TRIAL TO APPLY UNDER THE PHASE 3 FUNDING. I'M GOING TO GO OVER SOME PROPOSED CAPS FOR A PHASE 3, BUT ESSENTIALLY THIS WOULD ALLOW SOMEBODY WHO HAS A PIVOTAL PHASE 2 TO REQUEST PHASE 3 FUNDING.

DR. MELMED: COULD YOU CLARIFY? THE WAY IT'S WRITTEN, DOES THAT MEAN TO IMPLY THAT

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PARKINSON'S TRIALS COULD NOT BE SUPPORTED BY CIRM?

DR. SAMBRANO: NO. SO THEY WOULD, IF THEY ARE A CELL THERAPY, THEY WOULD QUALIFY.

DR. MELMED: IT SAYS AND RARE INDICATIONS.

DR. SAMBRANO: SO THE RARE INDICATION IS AS DEFINED BY THE FDA. SO THAT IS NORMALLY FOR --

DR. MELMED: SO IT'S ORPHAN DISEASES ONLY?

DR. SAMBRANO: IT'S ORPHAN DISEASES OR DISEASES THAT ARE 200,000 OR LESS.

DR. MELMED: SO WE APPROVED AN OSTEOARTHRITIS FOR THE KNEE THIS MORNING.

DR. MILLS: ONLY FOR PHASE 3 TRIALS.

DR. MELMED: WHY WAS THAT? WAS THAT DISCUSSED AT THE BOARD? WE'VE GOT IN THE PIPELINE PHASE 2S OF COMMON DISEASES.

DR. MILLS: WHAT WE HAVE FOUND, AND WE TALKED ABOUT THIS AT THE APPLICATION REVIEW SUBCOMMITTEE, IS THAT A CLINICAL TRIAL FOR A MAJOR INDICATION, A NON-ORPHAN, THAT'S GOING INTO A PHASE 3 THAT ACTUALLY IS READY AND APPROPRIATELY IN A PHASE 3 WHERE THEY HAVE GOOD PHASE 2 SUPPORTING DATA. A PHASE 3 ELIGIBLE PRODUCT IS ONE THAT NO LONGER -- IT HAS SATISFIED PROOF OF CONCEPT, IT HAS EFFICACY AND SAFETY DATA BEHIND IT, AND NO LONGER MEETS CIRM'S REQUIREMENT OF FUNDING THOSE THINGS

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WHICH ARE NOT ABLE TO SEEK -- WHICH WOULD NOT BE ABLE TO BE FUNDED OTHERWISE.

DR. MELMED: WOULDN'T WE WANT TO SHOW THE VOTERS THAT WE HAVE A CURE FOR DISEASE REGARDLESS OF WHETHER IT'S RARE OR NOT A RARE DISEASE? I DON'T RECALL US HAVING A DISCUSSION ON THIS. HAVE WE RESTRICTED PHASE 3 TO ONLY ORPHAN DISEASES?

DR. MILLS: I THINK, AGAIN, WHAT WE'RE DOING IS WE'RE ALIGNING OUR POLICY WITH OUR ACTUAL CONSTITUTIONAL MANDATE, WHICH ISN'T LET'S JUST GO SHOW THE VOTERS THAT WE PUT SOME MONEY INTO A PHASE 3 TRIAL THAT WOULD HAVE BEEN FUNDED ANYWAY, BUT INSTEAD FUND THOSE THINGS THAT WITHOUT US WOULDN'T GET FUNDED.

DR. MELMED: THE PIPELINE YOU SHOWED US THIS MORNING IS A CONTINUUM. I'M PUZZLED WHY SOMETHING WOULD BE FUNDED BY US FOR PHASE 2, GREAT SUCCESS, AND THEN WE STOP.

DR. MILLS: BECAUSE IF IT DID, IT WOULDN'T NEED OUR FUNDING. THERE AREN'T GREAT PHASE 2 TRIALS THAT GO INTO PHASE 3 THAT DON'T GET FUNDED IF THEY ACTUALLY HAVE GOOD PHASE 2 DATA. THEY'RE INCREDIBLY LUCRATIVE ENTITIES. THIS IS WHAT WE DISCOVERED WHEN WE DID OUR, IF YOU REMEMBER, BACK TO OUR OWN ELECTION POLICY, WAS WHEN WE WERE SETTING THE

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DISCOUNTED RATES, PHASE 3 TRIALS THAT ARE GOOD PHASE 3 TRIALS --

DR. MELMED: I'M VERY AWARE OF THE ADVANTAGES AND PITFALLS OF PHASE 3 TRIALS. WHY WOULD WE WANT TO RESTRICT OURSELVES? THIS IS A VERY RESTRICTIVE LANGUAGE. IF SOMEBODY COMES UP WITH A GREAT PROGRAM WHICH IS GOING TO EXTEND PHASE 2 INTO PHASE 3 FOR PARKINSON'S DISEASE, WE'RE CUTTING OURSELVES OUT HERE.

DR. MILLS: WHAT WE'RE DOING IS WE'RE FOCUSING ON THOSE THINGS THAT, WHEN WE FUND, WE'RE ADDING VALUE TO AS OPPOSED TO FUND JUST TO SAY THAT WE WENT ALONG FOR THE RIDE.

DR. MELMED: WE FUND THE PHASE 1 AND PHASE 2. THAT'S NOT THE RIDE. THAT'S US.

DR. MILLS: RIGHT. AND SO, THEREFORE, WE TOOK IT --

DR. MELMED: IT JUST SOUNDS IRRATIONAL TO ME AND OVERLY RESTRICTIVE.

MR. SHEEHY: I WONDER IF A WAY TO ADDRESS THIS MIGHT BE THAT MAYBE PUTTING IN A LITTLE ADDITIONAL LANGUAGE THAT WE'LL FUND OUR CHILDREN. I DON'T KNOW IF THAT MIGHT -- IF THIS IS -- HYPOTHETICAL YOU'RE SAYING IS WE STARTED WITH THE PROJECT IN PHASE 1, IF THAT ACTUALLY GETS ALL THE

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WAY AND ACTUALLY STILL NEEDS OUR MONEY. BUT I SEE YOUR POINT, BUT I ALSO SEE RANDY'S. WHAT WOULD A PHASE 3 TRIAL COST IN A CELL THERAPY?

DR. MILLS: IN THOSE MAJOR INDICATIONS, WE WOULDN'T DENT A PHASE 3 TRIAL. SO WE WOULD BE PUTTING MONEY IN LITERALLY FOR SHOW. AND BECAUSE WHERE WE ARE NOW IS A ZERO-SUM GAME, ANYTHING WE FUNDED THERE WE WOULDN'T FUND WHERE IT ABSOLUTELY NEEDED US. SO WE WOULD NOT FUND PROGRAMS THAT NEED OUR HELP FOR THE PURPOSES OF SAYING, HEY, LOOK. THE WAY WE DESIGNED IT WASN'T TO RESTRICT MONEY FROM THOSE THINGS THAT NEEDED US. IT WAS TO MAKE SURE WE HAD MONEY AVAILABLE FOR THOSE THINGS THAT NEEDED US.

DR. STEWARD: THANKS. I GUESS, IN GENERAL, I'M ALWAYS ONE WHO IS SORT OF ARGUING AGAINST OVERLY RESTRICTIVE LANGUAGE. I WONDER IF THIS COULD BE FIXED, IF YOU WANT, BY CHANGING IT FROM ELIGIBILITY CRITERION TO A REVIEW CRITERION. IT HAS THE SAME EFFECT, BUT ONE CAN IMAGINE A SITUATION WHERE SOMETHING WOULD COME ALONG, AND I CAN'T QUITE PUT ALL THE PIECES TOGETHER, THAT WE WOULD REALLY WANT TO FUND EVEN THOUGH IT DIDN'T QUITE FIT HERE. THAT COULD BE SOMETHING THAT COULD BE REVIEWED AND CONSIDERED BY THIS BOARD, AND ON THE BASIS OF THIS AS A REVIEW CRITERION VOTE IT DOWN,

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VOTE IT UP, DOWN WHATEVER YOU WANT. IT JUST KIND OF MAKES IT A LITTLE BIT MORE OPEN TO OPPORTUNITIES THAT MIGHT ARISE. THANK YOU.

MR. SHEEHY: BUT I THINK THAT THERE'S A RANGE OF NUMBERS HERE WE'RE TALKING ABOUT. YOU WILL KNOW -- WE'RE NOT TALKING ABOUT ANOTHER 10 OR $15 MILLION, ARE WE? WE'RE TALKING ABOUT FOR A PHASE 3 TRIAL IN THIS SPACE OF BEING, WHAT, JUST AT A MINIMUM?

DR. MILLS: SO BIG PHASE 3, PARTICULARLY BIG PHASE 3 CELLULAR THERAPY TRIALS, OUR MAXIMUM THAT WE'RE GOING TO WITH A CAP FOR ANY TRIAL IS 15. BIG PHRASE 3 TRIALS ARE 50 TO $200 MILLION APIECE. AND NON-ORPHAN INDICATIONS ARE ALWAYS REQUIRED TO BE DONE IN DUPLICATE. SO I GUESS THE POINT OF IT IS THEY CAN GET FUNDED, UNLESS IT'S AN ORPHAN INDICATION, WHICH WOULD STRUGGLE PERHAPS, MAYBE NOT, THERE'S CERTAINLY NO SHORTAGE OF LARGE, PROFITABLE PHARMACEUTICAL COMPANIES THAT HAVE DONE A GOOD JOB MAKING A BUSINESS IN ORPHAN INDICATIONS, GENZYME, SHIRE, AND THE LIKE, BUT A NON-ORPHAN INDICATION THAT'S ACTUALLY READY TO BE IN A PHASE 3 TRIAL, ONE, HAS SUCH AN ENORMOUS BURDEN ASSOCIATED WITH THAT PHASE 3 TRIAL, THAT OUR CONTRIBUTION TO IT WOULD BE NOT VERY MUCH; AND, TWO, HAVE THE ABILITY TO RAISE

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THAT FUNDING WITHOUT US.

DR. MELMED: THAT'S A REVIEW ISSUE. IT'S NOT A POLICY ISSUE. THAT SHOULD BE A REVIEW ISSUE.

DR. JUELSGAARD: SO JUST TO TRY AND BRIDGE THE GAP A LITTLE BIT. SO I UNDERSTAND IT, THAT IT COULD WELL BE A REVIEW ISSUE. BUT IF WE WERE TO GO IN THAT DIRECTION, I WOULD LIKE TO SEE THIS STATED AS A PREFERENCE THEN. A PREFERENCE OVER FUNDING A BIGGER TRIAL SO THAT WE AT LEAST HAVE SOME INTERNAL GUIDANCE WHEN IT COMES TO THAT.

MR. SHEEHY: I GUESS I'M TRYING TO VISUALIZE HOW THIS BECOMES A REVIEW ISSUE. BECAUSE WE'VE SET UP THE REVIEW TO REVIEW SCIENCE. NOW THERE IS A WHOLE FINANCIAL ELEMENT THAT YOU'RE BRINGING IN AS TO WHETHER OR NOT -- I GUESS THAT'S WHERE, AS A REVIEW ISSUE, I'LL LISTEN TO MY COLLEAGUES ON THIS.

DR. STEWARD: MAYBE THIS ISN'T A GOOD EXAMPLE, BUT I'M THINKING OUT LOUD HERE, ONE COULD IMAGINE A SITUATION WHERE THERE'S SOME VALUE-ADDED COMPONENT, FOR EXAMPLE, TO A LARGE CLINICAL TRIAL THAT CIRM COULD FUND THAT WOULDN'T OTHERWISE BE ACTUALLY CARRIED OUT. THAT WOULD BE ONE EXAMPLE OF THE KIND OF FLEXIBILITY THAT MIGHT MAKE US WANT TO BUY INTO ONE OF THESE VERY LARGE CLINICAL TRIALS, OR

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ONE POPULATION WASN'T BEING SERVED ADEQUATELY.

I'M JUST ARGUING FOR FLEXIBILITY RATHER THAN AN ABSOLUTE THAT WE NEVER SEE THESE THINGS COMING IN AND HAVE THE OPPORTUNITY TO SAY NO.

DR. DIXON: I'M ALSO A SUPPORTER OF THE FLEXIBILITY PIECE. I THINK MAKING IT TOO RESTRICTIVE IS TOO LIMITING.

CHAIRMAN THOMAS: OKAY.

MR. SHEEHY: HAVING BEEN HERE FOR SO LONG, I MEAN WE REALLY -- WHEN WE FIRST STARTED TALKING ABOUT THIS, OUR FIRST STRATEGIC PLAN, WE DIDN'T CONTEMPLATE FUNDING ANY PHASE 3 TRIALS JUST BECAUSE OF THE COST. EVEN WITH THE AMOUNT OF MONEY WE HAD WHEN WE HAD $3 BILLION, IT WAS KIND OF UNDERSTOOD THAT IF WE GOT PEOPLE THROUGH -- ISN'T THAT YOUR RECOLLECTION?

DR. PRIETO: I ALWAYS THOUGHT -- I THINK OUR THINKING AT THE TIME WAS THAT THEY WOULD BE PROHIBITIVELY EXPENSIVE. AND I THINK, AS RANDY WAS SAYING, THAT IF SOMETHING GETS TO THAT POINT AND APPEARS TO BE SUCCESSFUL THROUGH PHASE 2, WE'RE NOT GOING TO BE NEEDED ANYMORE. THE INITIATIVE IS WORDED TO SAY THAT OUR FUNDING SHOULD BE DIRECTED TO THOSE AREAS THAT OTHERWISE WOULD NOT GET FUNDING FROM OTHER SOURCES. THAT'S WHAT WE'RE SUPPOSED TO

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PRIORITIZE. AND THIS DOESN'T SEEM -- PHASE 3 TRIALS FOR A NON-ORPHAN DRUG DON'T REALLY SEEM TO FALL INTO THAT CATEGORY.

MR. SHEEHY: AND NOT TO BELABOR THE POINT, BUT THE PERSON -- THE ENTITY THAT TAKES IT THROUGH PHASE 3 HAS TO MARKET, SELL IT, MANUFACTURE IT, DISTRIBUTE IT. AND I DON'T THINK CIRM EVER VISUALIZED ITSELF AS DOING THAT. WHEN YOU GET THROUGH PHASE 2, IT'S SAFE AND YOU KNOW THAT IT WORKS IN SOME FASHION. AND SO THE REAL THING IS HOW DO YOU GET IT TO PEOPLE? RIGHT? HOW DO YOU FINALLY PROVE IT? WHAT IS THE SUCCESS RATE IN PHASE 3?

DR. MILLS: DEPENDS ON WHETHER IT'S A BIOLOGIC OR A SMALL MOLECULE. HE'S SAYING WHAT IS THE PROBABILITY OF SUCCESS. THIS IS A REVERSAL FOR ME. YOU'RE RIGHT. THERE WEREN'T PHASE 3 PROGRAMS. WHEN WE LAUNCHED CIRM 2.0, WE LAUNCHED IT ALL THE WAY THROUGH PHASE 3 PROGRAMS. THIS IS PART OF WHAT DR. THOMAS REFERRED TO AS THE CIRM 2.8, SORT OF LEARNING AS WE GO THROUGH HERE.

IT'S HARD TO LOOK BACK ON OUR PHASE 3 EXPERIENCES AND SAY THAT IF BUT NOT FOR US, THOSE ONES WOULDN'T BE THERE, OR IF THEY ARE, THEY SHOULDN'T HAVE BEEN THERE. THIS IS A CHANGE IN POSITION FOR SOMETHING -- THIS IS A CLOSING OF A

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DOOR THAT WE WERE THE ONES THAT OPENED IT.

CHAIRMAN THOMAS: OKAY. I'M NOT HEARING A LOT OF CONSENSUS HERE. I THINK BOTH SIDES HAVE ARGUED ADMIRABLY. TO THE EXTENT, PERHAPS, THAT YOU COULD PUT IN SOME LANGUAGE THAT KEPT SOME DOOR OPEN WITH A CLEAR PREFERENCE FOR RARE INDICATIONS ON THE PHASE 3, YOU MIGHT CONTEMPLATE THAT, GIL. SO THAT WOULD ADDRESS THE NUMEROUS COMMENTS TO THAT EFFECT. AS A MATTER OF PRINCIPLE, I DOUBT THAT WE WILL EVER ACTUALLY BE DOING PHASE 3S FOR LARGER INDICATIONS FOR THE VARIOUS REASONS, BUT THIS DOES ALLOW SOME FLEXIBILITY ON A CASE-BY-CASE BASIS.

DR. STEWARD: JUST WHATEVER PROCESS. IS THIS AN ACTION ITEM?

DR. SAMBRANO: YES.

CHAIRMAN THOMAS: YES.

DR. STEWARD: SO I THINK THAT WE HAVE A SIGNIFICANT AMOUNT OF LACK OF CONSENSUS, LET'S CALL IT HERE. I GUESS I GO BACK TO WHETHER WE'RE GOING TO VOTE ON THESE INDIVIDUALLY OR THE WHOLE THING ALTOGETHER.

DR. MILLS: I WOULD JUST LIKE TO POINT OUT THAT AS A REVIEW ISSUE, THIS IS A REVIEW ISSUE. IF WE JUST SAID WE'RE GOING TO MAKE THIS A REVIEW ISSUE, WE HAVE THAT LANGUAGE NOW. IT'S A REVIEW

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ISSUE, AND WE GIVE PRIORITY TO THOSE INDICATIONS ON A REVIEW THAT HAVE THE GREATEST IMPACT, THE NEED, ORPHAN, ALL OF THAT OTHER STUFF. WHAT WE HAVE TODAY IS AS A REVIEW ISSUE.

CHAIRMAN THOMAS: WELL, BUT IT ISN'T BECAUSE IT WILL NEVER MAKE REVIEW UNDER THIS AMENDMENT HERE.

DR. MILLS: WHAT WE'RE SAYING IS WE WANTED TO MOVE FROM A REVIEW ISSUE TO AN ELIGIBILITY ISSUE BECAUSE WE ALREADY HAVE IT AS A REVIEW ISSUE, AND IT DOESN'T VET OUT.

DR. STEWARD: JUST TO SAY I THINK THAT MOST OF THE THINGS THAT YOU HAVE ON THE LIST ARE GOING TO BE PRETTY EASY VOTES, BUT THIS ONE MAY NOT BE. JUST TO RAISE IT AS A PROCESS QUESTION.

DR. MELMED: I THINK WHAT STEVE PROPOSED IS GOOD LANGUAGE. IF YOU PROPOSE AN AMENDMENT AS TO THE PREFERENCE LANGUAGE --

DR. JUELSGAARD: YOU CAN FREE RIDE.

DR. MELMED: NO. NO. IT'S YOUR LANGUAGE. IT'S YOUR IDEA.

CHAIRMAN THOMAS: SO-CALLED JUELSGAARD AMENDMENT.

DR. JUELSGAARD: WELL, AT THE SUGGESTION OF DR. MELMED, I WANT TO PREFACE IT THAT WAY, I

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WOULD MOVE TO AMEND THE ELIGIBILITY CRITERIA TO STATE THAT THE SECOND BULLET POINT IS A PREFERENCE, BUT NOT AN EXCLUSIONARY ITEM.

DR. SAMBRANO: ESSENTIALLY THAT WOULD BASICALLY MAKE IT THE SAME AS TWO, AND THEN WE WOULD RETAIN THE REVIEW PREFERENCE FOR RARE INDICATIONS.

DR. JUELSGAARD: I ASSUME THAT'S RIGHT. I GUESS I WOULD LEAVE PHASE 3 AS IT SAYS. INSTEAD OF SAYING RESTRICT, PREFERENCE TO DA-DA-DA-DA.

DR. SAMBRANO: THE REASON I'M SAYING THAT IS BECAUSE FOR ELIGIBILITY CRITERIA, WE WANT TO MAKE IT AS OBJECTIVE AS POSSIBLE. SO THEY EITHER QUALIFY OR THEY DON'T. AND LEAVE THE MORE SUBJECTIVE WHETHER IT'S APPROPRIATE OR NOT TO THE GWG TO ASSESS.

DR. STEWARD: I THINK THAT THE QUESTIONABLE PART ISN'T THE RESTRICT. I THINK THE QUESTIONABLE PART IS THE "AND." IF WE JUST KIND OF DELETED THAT, AND YOU COULD SAY "AND WITH A PREFERENCE FOR THERAPIES FOR RARE INDICATIONS" RATHER THAN CHANGING THE RESTRICT PART, WHICH I THINK IS AN ALTERNATE MOTION.

DR. MILLS: I THINK, OS, WHAT HE'S SAYING IS THE WORD "PREFERENCE" CAN'T BE HERE BECAUSE THIS IS ELIGIBILITY. SO THIS IS THE IT'S BLACK OR WHITE.

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DR. STEWARD: I WOULD SAY JUST DROP THE "AND."

DR. SAMBRANO: RIGHT, BUT WE WOULD RETAIN THE PREFERENCE, THEN, IN INSTRUCTION TO REVIEWERS.

MR. TORRES: SO WHAT'S THE MOTION?

DR. JUELSGAARD: I HAVE TO GET YOUR APPROVAL TO AMEND, SENATOR TORRES, SINCE WE SEEMED TO HAVE THIS PROBLEM ONCE BEFORE.

MR. TORRES: OH, NO. NO. NO. WASN'T A PROBLEM FOR ME. YOU CHOSE NOT TO EXERCISE YOUR RIGHT TO AMEND.

DR. JUELSGAARD: NO, BECAUSE I WAS CUT OFF AT THE PASS, AS I RECALL.

MR. TORRES: WHO CUT YOU OFF?

DR. JUELSGAARD: SOMEBODY IN THIS ROOM WHO WILL GO UNNAMED. IN ANY EVENT, SO I WOULD LIKE TO AMEND MY AMENDMENT TO EXCLUDE THE "AND" WHERE THE THERAPY IS RARE INDICATIONS AS AN ELIGIBILITY CRITERIA, BUT TO HAVE THE GWG INSTRUCTED THAT THERE'S A PREFERENCE FOR THAT WHEN THEY DO THE REVIEW.

MR. TORRES: I'LL SECOND THAT.

DR. JUELSGAARD: WAS THAT A FRIENDLY SECOND? I'M NOT SURE I'LL ACCEPT IT ANYWAY.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND

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SECONDED. DO WE HAVE A COMMENT?

DR. DULIEGE: I JUST WANT TO CLARIFY THAT WHAT THAT MEANS IS SOME OF US WANT TO RETAIN THE OPPORTUNITY TO FUND LARGE PHASE 3 TRIALS THAT ARE NOT FOR RARE INDICATIONS? IS THAT WHAT WE'RE SAYING?

DR. STEWARD: AGAIN, MY POINT WAS NOT JUST TO BE OVERLY RESTRICTIVE. I THINK THAT IT WOULD BE HIGHLY UNLIKELY THAT MANY SUCH TRIALS WOULD BE FUNDED; BUT, AGAIN, I CAN IMAGINE A SITUATION WHERE WE MIGHT WANT TO CONSIDER IT AND NOT ELIMINATE IT ENTIRELY FROM CONSIDERATION. THAT WOULD BE MY VIEW ON IT.

DR. DULIEGE: I JUST WANT TO SAY I UNDERSTAND THAT, JUST HAVING A PREFERENCE RECONCILE EVERYONE'S PERSPECTIVE AND ALLOWS US TO MOVE AHEAD. AND FROM THAT STANDPOINT, IT'S FINE, AND THAT LEAVES SORT OF ALL DOORS OPEN. BUT I JUST WANT TO ECHO WHAT WAS SAID, WHICH IS SEVERAL LARGE PHASE 3 TRIALS NONRARE OR NON-ORPHAN DRUG INDICATIONS ARE NOT JUST OUTSTANDINGLY EXPENSIVE, BUT INCLUDE THINGS THAT WERE MENTIONED SO FAR IN TERMS OF MEDICAL, COMMERCIAL, MANUFACTURING, AND SO FORTH THAT I THINK GO BEYOND THE SCOPE OF WHAT CIRM WOULD HAVE TO DO, CLEARLY. SO FINE, IF WE WANT COSMETICALLY TO LEAVE

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ALL DOORS OPEN, BUT REALISTICALLY THIS WOULD NOT SEEM PROPER TO DO.

CHAIRMAN THOMAS: SUPERVISOR SHEEHY.

MR. SHEEHY: NOT TO CARRY THIS ON TOO FAR, I'M NOT GOING TO BE VOTING FOR THIS. AND I DO WANT TO REMIND PEOPLE THERE ARE OPPORTUNITY COSTS, AND OPPORTUNITY COSTS IN TERMS OF REVIEW, OPPORTUNITY COSTS IN TERMS OF THE EXPENSE OF INVESTING IN TRIALS WHERE I JUST DON'T THINK WE SHOULD BE. WE'RE DOWN TO OUR LAST MONEY. SO THAT'S JUST MY VIEW. THANK YOU.

CHAIRMAN THOMAS: ANY OTHER COMMENTS ON THE SO-CALLED JUELSGAARD AMENDMENT AND THE FRIENDLY ACCEPTED SECOND BY SENATOR TORRES? OKAY. SO DO WE NEED A ROLL CALL VOTE ON THIS?

DR. SAMBRANO: I HAVE TO KEEP GOING. I THINK THIS WOULD END UP BEING AN AMENDMENT TO A MOTION BECAUSE THERE'S NO MOTION ON THE FLOOR.

CHAIRMAN THOMAS: FOR AN OMNIBUS AMENDMENT.

MR. HARRISON: THERE IS A MOTION ON THE TABLE SECONDED. WE SHOULD, IF THERE IS NO PUBLIC COMMENT ON THIS MOTION, TAKE THIS MOTION BEFORE PROCEEDING WITH DR. SAMBRANO'S PRESENTATION.

CHAIRMAN THOMAS: ANY PUBLIC COMMENT?

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MR. REED: WILL THERE BE AN OPPORTUNITY FOR PUBLIC COMMENT ON THE PREVIOUS ONE WHICH THERE WAS NO VOTE?

CHAIRMAN THOMAS: YES.

DR. BURTIS: JAMES, COULD YOU RESTATE WHAT WE'RE VOTING ON?

MR. HARRISON: AS I UNDERSTAND IT, THE MOTION IS TO AMEND THE CONCEPT PROPOSALS IN FRONT OF YOU TODAY SUCH THAT FOR PHASE 3 TRIALS, THE FACT THAT THE INDICATION IS A RARE INDICATION WOULD BE A PREFERENCE IN REVIEW RATHER THAN AN ELIGIBILITY CRITERION.

DR. JUELSGAARD: TO SAY IT DIFFERENTLY, AND I AGREE WITH THAT, BUT IT'S JUST SIMPLY TO DELETE THE LANGUAGE FROM THE WORD "AND" IN THE FIRST CLAUSE TO THE END WHERE THE SEMICOLON IS, AND THEN TO GIVE GUIDANCE DURING GWG REVIEW THAT THERE'S A PREFERENCE FOR RARE INDICATIONS, IF THAT HELPS.

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

MS. BONNEVILLE: I WOULD LOVE TO. GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: NO.

MS. BONNEVILLE: KEN BURTIS.
DR. BURTIS: YES.
MS. BONNEVILLE: DEBORAH DEAS.
DR. DEAS: YES.
MS. BONNEVILLE: JACK DIXON.
DR. DIXON: NO.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: NO.
MS. BONNEVILLE: HOWARD FEDEROFF. ELIZABETH FINI.
DR. FINI: YES.
MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: NO.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: KATHY LAPORTE.
DR. LAPORTE: NO.
MS. BONNEVILLE: BERT LUBIN. SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: LAUREN MILLER.
MS. MILLER: NO.
MS. BONNEVILLE: ADRIANA PADILLA.

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DR. PADILLA: NO.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: NO.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: NO.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: NO.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: NO.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: DIANE WINOKUR. BRUCE WINTRAUB. SHERRY LANSING.
MOTION CARRIES.
MR. TORRES: WHAT WAS THE VOTE?
MR. HARRISON: TWELVE YES, ELEVEN NO.
DR. JUELSGAARD: BEFORE YOU ASK THOSE ON

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THE PHONE, I'M WORRIED --

(PAUSE IN PROCEEDINGS.)

DR. SAMBRANO: I'LL KEEP GOING THEN. SO THE NEXT ITEM IS RELATED TO ELIGIBILITY FOR DEVICES. HERE WE WANT TO ALIGN THE TRAN3, WHICH IS FOCUSED ON TRANSLATIONAL STUDIES FOR MEDICAL DEVICES, AND ALIGN IT WITH THE CLIN PROGRAM AND MAKE THE ELIGIBILITY CRITERIA THE SAME. SO THAT WOULD MEAN TO INCLUDE STUDIES ON A DEVICE WHERE THE THERAPEUTIC MECHANISM OF ACTION REQUIRES THE RECRUITMENT OR INCORPORATION OF AN ENDOGENOUS HUMAN STEM OR PROGENITOR CELL.

AND THEN THE SECOND ITEM FOR CLIN2, TO LIMIT DEVICE TRIALS TO FEASIBILITY STUDIES AS OPPOSED TO THE PIVOTAL OR PHASE 3 EQUIVALENT TO ALIGN IT WITH THE PREVIOUS SLIDE'S GOAL OF FOCUSING OUR PIVOTAL TRIALS TO CELL THERAPY.

SO FOR THE CLIN3 PROGRAM, SO THIS IS THE THIRD ARM OF OUR CLINICAL PROGRAM, YOU HAVE NOT HEARD FROM US BRINGING APPLICATIONS RELATED TO THAT AND BASICALLY BECAUSE THERE HAVEN'T BEEN MANY. IN THE LAST 22 CYCLES THAT WE'VE HAD, WE'VE HAD THREE THAT HAVE COME AND NONE HAVE BEEN RECOMMENDED, AND SO THEY'VE IN MOST CASES WITHDRAWN.

AND SO WE FEEL THAT OVERALL THE CLIN3 PROGRAM AS CURRENTLY STRUCTURED IS NOT REALLY

SERVING OUR GOALS. AND IN RETHINKING THIS, WE DECIDED THAT THE WAY IN WHICH IT COULD SERVE OUR MISSION BEST WOULD TO BE TO LIMIT IT TO AWARDEES TO CONDUCT NEW ACTIVITIES THAT WOULD ENABLE FDA MARKETING APPROVAL OF THE PROPOSED STEM CELL PRODUCT; THAT IS, SOMEBODY, FOR EXAMPLE, THAT MAY HAVE A PHASE 2 TRIAL AND BY, SAY, BRINGING IN ADDITIONAL PATIENTS AND TREATING THEM, IF THE FDA AGREES THIS WOULD BE SUFFICIENT TO MAKE IT A PIVOTAL OR REGISTRATION TRIAL, THE CLIN3 WOULD ALLOW FUNDING FOR THOSE NEW ACTIVITIES TO TAKE PLACE. SO WE WANT TO FOCUS IT ON ENABLING SUCH CLINICAL TRIALS TO ADVANCE TO THE MARKETING APPROVAL STAGE.

WE ALSO ARE PROPOSING ON CHANGING WHAT IS CURRENTLY A $20-MILLION BLANKET CAP ACROSS ALL OF OUR CLINICAL PROGRAMS, SO THIS IS CURRENTLY INCLUDING IND ENABLING THROUGH PHASE 3, AND REALLY MATCH THEM UP TO THE STAGE OF DEVELOPMENT. AND THEN ALSO UTILIZE OUR EXPERIENCE WITH APPLICATIONS THAT WE HAVE RECEIVED AND THE AMOUNT OF FUNDS THAT ARE REQUIRED TO EXECUTE ON THOSE PROJECTS AND SET UP CAPS THAT REFLECT THAT.

SO THE PROPOSED CAPS ARE SHOWN ON THIS SLIDE HERE, BUT I ALSO WANT TO AUGMENT THAT WITH THE MODEL WE'VE USED IN ORDER TO DERIVE THESE. THIS WAS

A QUESTION THAT CAME UP DURING THE SCIENCE SUBCOMMITTEE.

SO HERE IS A TABLE THAT PRESENTS, BASED ON THE STAGE OF DEVELOPMENT, WHETHER THEY ARE A FOR-PROFIT OR NONPROFIT AND THE NUMBER OF ESTIMATED AWARDS AND THE CORRESPONDING CAPS. AND THE WAY THIS WAS DERIVED WAS BASED ON A COUPLE OF KEY PARAMETERS. FIRST, WE HAVE ABOUT 480 MILLION AVAILABLE IN THE CLINICAL PROGRAM TO WORK WITH BETWEEN NOW AND 2020. OUR GOAL ULTIMATELY, ONE OF OUR BIG SIX, IS TO FUND 50 CLINICAL TRIALS. WE DID 10 LAST YEAR, WE HAVE 40 TO GO. SO 480 MILLION, 40 TRIALS, AND THEN ALSO UTILIZING THE AVERAGE AWARD AMOUNTS FOR EACH STAGE THAT WE RECEIVED, AND UTILIZING THAT INFORMATION DERIVING FROM THAT AN APPROPRIATE AWARD CAP AND AWARD AMOUNT.

SO, AS YOU CAN SEE, THE PERCENT SHARE, WHICH IS THE LAST COLUMN, SHOWS OUT OF THE 480 MILLION, ABOUT 15 PERCENT OF THAT IN THIS ESTIMATE WOULD BE FOCUSED ON IND-ENABLING WORK, 33 PERCENT WOULD BE GOING TO PHASE 1 STUDIES, 40 PERCENT TO PHASE 2, AND THEN OVERALL ABOUT 12 PERCENT FOR PHASE 3 OR PIVOTAL TRIALS.

AND THEN IF YOU PLOT THAT OUT, THIS SHOWS A GRAPH SHOWING THE AREA UNDER THE CURVE FOR THE

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FUNDS. IT STARTS WITH WHERE WE CURRENTLY ARE, WHERE WE'VE EXPENDED OR COMMITTED 87 MILLION TO THE CLINICAL PROGRAM IN 2016. SO THAT'S OUR STARTING POINT FOR 2017 THROUGH 2020 EXPENDITURES OF 480 MILLION ACROSS THE DIFFERENT PHASES OF CLINICAL DEVELOPMENT FOR FOR-PROFITS AND NONPROFITS. AND STARTING FROM THE BOTTOM WITH THE IND-ENABLING NONPROFIT UP THROUGH THE TOP WHERE WE WOULD HAVE THE CLIN3 AND PHASE 3 TRIALS AT THE TOP.

AND THE LAST ITEM --

DR. MELMED: TWO QUESTIONS. FIRST OF ALL, THOSE OF US WHO LIVE IN THE NIH WORLD, THESE NUMBERS ARE VERY GENEROUS FOR EACH PROJECT. CAN YOU GIVE US AN IDEA OF THE RELATIVITY TO NIH AND HOW YOU DERIVED THESE MAXIMUM CAPS?

DR. SAMBRANO: RIGHT. SO IT'S NOT AT ALL BASED ON NIH. THIS IS DERIVED FROM OUR EXPERIENCE WITH GRANTS THAT WE HAVE FUNDED OVER THE LAST COUPLE OF YEARS. SO WE TOOK THOSE ACROSS THE DIFFERENT PHASES, AND WE SEGREGATED THEM BETWEEN FOR-PROFIT AND NONPROFIT ENTITIES, AND ESTIMATED, WE GOT THE MINIMUMS AND THE MAXIMUMS THAT WE'VE EXPENDED FOR EACH ONE, AND THEN THE MEDIANS AND AVERAGES. SO, IN GENERAL, ESPECIALLY FOR THE IND-ENABLING, IN PHASE 1 WE ARE ON THE HIGHER END. WE'RE ABOVE THE AVERAGE.

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SO WE'RE GIVING FLEXIBILITY. AS WE APPROACH THE PHASE 3, WE COME PRETTY CLOSE AND JUST ABOUT UNDER THE AVERAGE FOR THE PHASE 3S.

DR. JUELSGAARD: SO, DR. SAMBRANO, JUST FOR A POINT OF CLARIFICATION. SO A LITTLE EARLIER THIS MORNING WE APPROVED, AMONGST OTHER PROJECTS, ONE FOR SEVERE COMBINED IMMUNODEFICIENCY FOR THE TUNE OF ALMOST $12 MILLION. THERE WAS NO COFUNDING, SO I SUPPOSE IT CAME FROM A NONPROFIT INSTITUTION.

DR. SAMBRANO: CORRECT.

DR. JUELSGAARD: UNDER THIS CRITERIA, IF WE STOP AT 9 MILLION, IF THEY NEEDED MORE THAN THAT, THEY WOULDN'T GET APPROVED. AND YOU WERE INDICATING THE REASON FOR THE HIGH COST OF THAT CLINICAL TRIAL WAS THAT IT WAS AN AUTOLOGOUS-BASED TRIAL, NOT AN ALLOGENEIC. SO I'M WONDERING HOW THIS PROPOSAL SQUARES WITH SOME ISSUE LIKE THAT.

DR. SAMBRANO: AGAIN, WE'RE BASING IT NOT ON THE MAXIMUM AMOUNT THAT WE HAVE FUNDED, BUT APPROXIMATING THE MEDIANS AND THE AVERAGES AND BEING GENEROUS JUST ABOVE THAT, SO IT'S NOT GOING TO COVER ALL. THERE ARE PROJECTS THAT MANY OF THEM, EVEN IF THEY'RE ACADEMIC, WILL PROVIDE COFUNDING, AND IT WOULD NOT NECESSARILY BE UNEXPECTED FOR A PROJECT LIKE THAT TO ADJUST ITS COSTS. SO, FOR EXAMPLE, IF

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WE WANT TO USE THAT ONE AS AN EXAMPLE, THE MANUFACTURING COSTS WOULD BE SOMETHING THAT MAYBE THEY WOULD CHOOSE TO CONTINUE TO DO AT THEIR CURRENT SITE RATHER THAN HAVE IT DONE LOCALLY. THEY COULD STILL HAVE THE TRIAL HAPPEN AND SAVE ON THE OVERALL AMOUNT.

SO IT WOULD CERTAINLY REQUIRE THEM TO ADJUST THEIR COSTS. BUT WHEN THEY'RE COMING IN, SOMEBODY WOULD KNOW UP FRONT THAT THEY WOULD NOT BE ABLE TO REQUEST MORE THAN 9 MILLION IF THEY'RE COMING IN FOR A PHASE 2.

DR. JUELSGAARD: SO THE COUNTER TO THAT IS THAT THEY COULD COME IN WITH A SUBOPTIMAL PROPOSAL SIMPLY BECAUSE THEY'RE BEING LIMITED BY THE AMOUNT OF MONEY WE'RE WILLING TO PROVIDE. SO WHAT MY HYPOTHESIS IS IS THAT THE PROPOSAL THAT WAS MADE ABOUT SEVERE COMBINED IMMUNODEFICIENCY WAS AN OPTIMAL PROPOSAL. THAT'S THE STANDARD I'M USING. I DON'T KNOW WHETHER THAT'S THE CASE OR NOT, BUT I'M ASSUMING FOR A MOMENT THAT THAT WOULD BE THE CASE. YOU WOULD THEN HAVE TO APPLY FOR SOMETHING THAT'S LESS THAN OPTIMAL IN ORDER TO BE ABLE TO GET FUNDING AT LEAST AT THE $9 MILLION LEVEL AND YOU'RE NOT ABLE TO GET IT ABOVE THAT. SO ANYWAY.

DR. MILLS: I WOULD JUST SAY DO THE

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OPTIMAL TRIAL AND SECURE ADDITIONAL SOURCES OF FUNDING.

DR. JUELSGAARD: WELL, I'M ALL FOR THAT, BUT I THINK WE'VE HEARD BEFORE IN THESE MEETINGS THAT FOR NONPROFIT ORGANIZATIONS -- IN FACT, WE HEARD THIS WHEN WE HAD THE BIG DISCUSSION ABOUT TRYING TO SCALE BACK OTHER AWARDS THAT WERE MADE IN ORDER TO FIT A SIXTH ONE IN. IT'S BEEN SEVERAL MEETINGS AGO. WHAT WE HEARD FROM A SPEAKER WHO HAD HIS PROJECT APPROVED WAS THAT'S JUST NOT VERY PRACTICAL IN A NONPROFIT INSTITUTION TO GO OUT AND FIND OTHER SOURCES OF FUNDING.

I DON'T KNOW WHETHER THAT'S TRUE OR NOT, BUT THAT WAS SOMETHING PUT FORTH AS AN ASSUMPTION. SO I'M NOT SAYING THAT WE SHOULDN'T DO 9 MILLION. I THINK WE JUST NEED TO UNDERSTAND WHAT MAY OR MAY NOT HAPPEN, WHETHER WE'VE GOT THE RIGHT NUMBER OR NOT. I'M JUST TRYING TO RAISE SOME AWARENESS ABOUT IT.

MR. SHEEHY: I SHARE STEVE'S CONCERN. AND SO, FIRST OF ALL, WHAT WE APPROVED TODAY FOR 12 MILLION, WAS THAT A PHASE 1 TRIAL?

DR. SAMBRANO: NO. THAT WAS A PHASE 2, THE SCID.

DR. JUELSGAARD: THAT'S ANOTHER QUESTION. IT ACTUALLY CALLS IT ON WHAT WAS PRESENTED TO US --

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(PROCEEDINGS WERE INTERRUPTED.)

DR. JUELSGAARD: IT'S CALLED A PHASE 1/2 TRIAL. SO WHEN YOU BRING THOSE IN, WHICH OF THOSE TWO LITTLE AREAS DO WE CONSIDER? THAT'S KIND OF A SEPARATE.

MR. SHEEHY: I HAD THE SAME QUESTION BECAUSE WE SEE PHASE 1/2. WHICH BUCKET WOULD THAT FALL UNDER?

DR. SAMBRANO: THE WAY WE'VE BEEN DOING IT CURRENTLY, A PHASE 1/2A FALLS INTO THE PHASE 1 BUCKET.

MR. SHEEHY: WE KNOW THAT WE -- I HAVE STEVE'S CONCERNS. I DON'T KNOW ABOUT THESE CAPS. I WASN'T THAT COMFORTABLE WITH THEM WHEN WE HAD IT AT THE SCIENCE SUBCOMMITTEE.

DR. SAMBRANO: THE DATA WE PROVIDED IN THE MEMO SHOWS THE ACTUAL AWARDS THAT THESE ARE BASED ON. SOME OF THEM ARE PHASE 1/2S. THAT INCLUDES THE MINIMUM AND MAXIMUM THERE, SOME CERTAINLY WITHIN THE CAP AMOUNT. AND SO WHEN WE DERIVED THESE, WE ATTEMPTED TO DO THIS ON THE HIGHER END RATHER THAN JUST THE AVERAGE.

MR. SHEEHY: THERE'S A CONTRADICTION HERE BECAUSE WE JUST SAID THAT WE WANTED TO DO PHASE 3 TRIALS IN THESE ORPHAN DISEASES INVOLVING STEM AND

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PROGENITOR CELLS, WHICH ARE EXPENSIVE, BUT WE'RE KIND OF CUTTING OFF OUR PIPELINE TO GET THEM INTO PHASE 3 BY NOT PUTTING ENOUGH MONEY OUT THERE FOR THOSE TO GO FORWARD AND TELLING THEM THAT THEY NEED TO FIND ADDITIONAL MONEY, BUT WE SAID THAT WE'RE GOING TO FUND THEM IN PHASE 3 BECAUSE THEY CAN'T FIND ADDITIONAL MONEY. SO IT'S ALL --

DR. SAMBRANO: I THINK WHAT'S KEY HERE, THOUGH, IS THAT IF YOU LOOK AT THE NUMBER OF AWARDS ACROSS EACH PHASE, THIS ESTIMATE BASICALLY SAYS THAT ACROSS THE NEXT FOUR YEARS, WE'D BE FUNDING TWO PHASE 3S. AND THEN THE MAJORITY WOULD BE FOCUSED ON PHASE 1 AND 2S.

MR. SHEEHY: NO. WHAT YOU JUST SAID IS THAT IS SOMETHING LIKE WE HAD THIS MORNING, WHICH IS AN ORPHAN DISEASE THAT INVOLVES STEM OR PROGENITOR CELLS, WHICH WE ARE WILLING TO FUND IN PHASE 3, WE NOW EXPECT THEM TO FIND ADDITIONAL MONEY IN PHASE 1/2 EVEN THOUGH WE'RE FUNDING THEM IN PHASE 3 BECAUSE THEY CAN'T FIND MONEY. THERE'S A FUNDAMENTAL CONTRADICTION THERE. SO WE HAVE AN EXAMPLE OF AN APPLICATION THAT WE WOULD NOT BE ABLE TO FUND BASED ON THESE CAPS IN PHASE 1/2, BUT WE COULD FUND IN PHASE 3. AND THE LOGIC FOR FUNDING IT IN PHASE 3 CONTRADICTS THE LOGIC FOR PUTTING THE CAP

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IN IN PHASE 1 AND 2.

DR. MILLS: THE ONLY THING I'LL SAY IS WE GET THE APPLICATIONS WE GET BASED ON THE CRITERIA THAT WE HAVE. AND RIGHT NOW THAT CRITERIA SAYS THERE ESSENTIALLY ISN'T A CAP, AND SO WE GET, AS DR. JUELSGAARD POINTED OUT, A VERY UNUSUALLY EXPENSIVE PHASE 1 TRIAL. AND SO I THINK THERE MIGHT NEED TO BE SOME CONSIDERATION THAT, JUST LIKE IN 1.0, WHEN WE HAD A $20-MILLION CAP ON THE AWARDS, ALL OF THE AWARDS MAGICALLY CAME IN AT $19.9 MILLION. THERE IS SOME NEED FOR SAYING, LOOK, CIRM CAN GO THIS FAR, PARTICULARLY WHEN YOU THINK THIS ISN'T AN ORGANIZATION THAT CAME IN FOR A CLIN1, BUT COULD HAVE, AND WOULD HAVE HAD A LOT OF THIS WORK SUPPORTED THERE. AND THEN WE FUND ONE, WE FUND TWO. IF IT'S A PHASE 1/2, THEY COULD HAVE OPTED FOR THE TWO AND HAVE THAT NUMBER GO UP. THEY COULD DO IT IN PHASE 1, THEY CAN COME BACK AND GET ANOTHER ROUND IN PHASE 2, AND PARTICULARLY AGAIN IN PHASE 3.

AS DR. MELMED SAID, WE'RE EXTRAORDINARILY GENEROUS IN THIS, BUT IT'S A LITTLE BIT LIKE THE LAW OF PHYSICS THAT SAYS A GAS WILL TAKE THE SHAPE OF ITS CONTAINER. IF WE MAKE THAT CONTAINER BIG, OUR TRIALS WILL BE VERY EXPENSIVE.

MR. SHEEHY: BUT THAT WAS AN INNOVATION IS

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NOT TO HAVE CAPS, RIGHT? SO THIS IS ANOTHER REVERSAL OF WHAT WE USED TO DO. SO WE GOT AWAY FROM CAPS. AND I'M JUST NOT FOLLOWING THE TRAIN OF LOGIC THAT SAYS WE NEED TO GO BACK TO CAPS BECAUSE THE REASON WE GOT AWAY FROM CAPS IS THAT WE DID OUR BUDGET ANALYSIS UP FRONT SO THAT WE ACTUALLY SPENT TIME COSTING OUT WHAT THESE THINGS SHOULD COST. I MEAN, AGAIN, THE LOGIC ISN'T HOLDING UP FOR ME. WE NOW PUT IN PLACE WHERE BEFORE YOU CAN GET REVIEWED, EVERYONE HAS TO AGREE THAT THE BUDGET IS RATIONAL. IF PEOPLE GIVE US CRAZY NUMBERS, WE JUST SAY WE'RE NOT GOING TO REVIEW. WE'VE GONE WITH THAT. SO THIS FEELS LIKE BELT AND SUSPENDERS, AND I'D BE HAPPY WITH THE BELT.

DR. MILLS: SO I THINK WHAT THE PHILOSOPHICAL DIFFERENCE IS IS SOMEBODY COMES TO US NOW AND SAYS THIS IS A CHEVY, AND WE DETERMINE WHETHER OR NOT IT'S A CHEVY. IT COSTS AS MUCH AS A CHEVY COST OR IT DOESN'T COST AS MUCH AS A CHEVY COSTS. WE DON'T DO ANY THIS IS A ROLLS ROYCE OR THIS IS A CADILLAC OR THIS IS A LAMBORGHINI ASSESSMENT HERE. BUT WE'RE ONLY ASSESSING WHAT THEY PUT IN FRONT OF US.

MR. SHEEHY: IT JUST FEELS LIKE WE'RE GOING THROUGH THIS PROCESS. WE WENT THROUGH A

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PROCESS WHERE IT FELT LIKE WE KIND OF SIMPLIFIED THINGS, AND NOW I FEEL LIKE YOU'RE PUTTING FINS AND ALL SORTS OF THINGS. WE HAD A FAIRLY STRIPPED-DOWN MODEL, AND NOW THE MODEL IS GETTING REALLY COMPLEX. AND THE RATIONALE FOR THIS RULE, AGAIN, WHY DO WE NEED THIS RULE? A LOT OF THESE THINGS I HAD TROUBLE IN THE SCIENCE SUBCOMMITTEE. WHAT IS DRIVING THIS? ARE YOU FINDING THAT THE APPLICATIONS THAT WE RECEIVE ARE MORE EXPENSIVE THAN THEY NEED BE BECAUSE WE DON'T HAVE CAPS? WHAT IS THE EVIDENCE?

I HAVE TO SAY I ALMOST FEEL LIKE CONTINUING THE WHOLE THING OR BRINGING IT UP AGAIN BECAUSE I'M NOT UNDERSTANDING AGAIN AND AGAIN, AND I DIDN'T GET IT IN THE SCIENCE SUBCOMMITTEE, CLEARLY WHAT'S DRIVING THESE CHANGES WITH ACTUAL REAL-WORLD EXAMPLES.

DR. MILLS: SO WE REDUCED -- FIRST OF ALL, EVERYTHING WE HAD WAS SORT OF ARBITRARILY SET AND WE WANTED TO SEE HOW THINGS WOULD GO. JUST AS AN EXAMPLE, WE REDUCED THE TRAN AWARD AMOUNT BY 25 PERCENT, AND WE DID NOT HAVE A SINGLE COMPLAINT OR REDUCTION IN APPLICATIONS FOR THAT.

MR. SHEEHY: WE DO HAVE A REDUCTION IN APPLICATIONS, SO THAT DOESN'T HOLD. COMPARED TO OTHER ROUNDS, THE UPCOMING ROUND HAS A REDUCTION IN

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APPLICATIONS.

DR. MILLS: THAT CHANGE WAS MADE BEFORE. WE'VE BEEN THROUGH ROUNDS. AND LITERALLY NO ONE IS SAYING WE JUST CAN'T GET IT DONE UNDER THAT. FROM OUR STANDPOINT, THERE'S JUST A FISCAL RESPONSIBILITY ASPECT OF IT HERE. IT SAYS WE HAVE A REALLY GOOD IDEA OF WHAT THESE CLINICAL TRIALS SHOULD COST. AND A PHASE 1 CLINICAL TRIAL, A PHASE 1 CLINICAL TRIAL, COSTING MORE THAN $9 MILLION, THAT IS AN ENORMOUSLY EXPENSIVE PHASE 1 CLINICAL TRIAL. AND I THINK FROM OUR STANDPOINT, AS PEOPLE THAT ARE RESPONSIBLE FOR THE TAXPAYER OF CALIFORNIA'S MONEY, IF YOU WANT TO CONDUCT A REALLY ELABORATE, OVERLY EXPENSIVE PHASE 1 CLINICAL TRIAL, WE'LL BRING $9 MILLION TO THE TABLE, WHICH IS, AGAIN, VERY, VERY GENEROUS, BUT MAYBE BEYOND THAT, IT'S INCUMBENT UPON OTHER PEOPLE TO ALSO PARTICIPATE.

MR. SHEEHY: THE LOGIC ACROSS ALL THESE THINGS IS JUST NOT HOLDING UP FOR ME.

DR. STEWARD: I'M, I GUESS, AGAIN, A LITTLE CONCERNED ABOUT THE -- IT'S NOT ARBITRARY. IT JUST IS INFLEXIBLE TO HAVE THESE KINDS OF CAPS. AND SO A COUPLE OF OBSERVATIONS. THIS IS A QUESTION, BUT I'LL FINISH WHAT I'M SAYING AND THEN YOU CAN ANSWER THE QUESTION.

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TO WHAT EXTENT IS THE FIT HERE BECAUSE YOU WANT TO FUND 40 CLINICAL TRIALS? IN OTHER WORDS, IS THIS A MATTER OF SAYING THESE ARE THE NUMBERS THAT ACTUALLY MAKE SENSE, OR ARE YOU SAYING WE HAVE 478 LEFT, I WANT TO FUND 40 CLINICAL TRIALS, AND SO I'M GOING TO DO THE MATH AND FIGURE THIS OUT? I THINK THAT'S AN IMPORTANT DISTINCTION BECAUSE I'D RATHER FUND 30 REALLY GOOD ONES THAN 40 THAT ARE COMPROMISED BY THESE LIMITS. SO THAT'S NO. 1.

AND THEN -- GO AHEAD ON THAT, AND I HAVE A FOLLOW-UP.

DR. MILLS: THAT'S A VERY FAIR QUESTION. BUT AS GIL SAID, THE WAY WE ACTUALLY CAME UP WITH THE NUMBERS WAS BY LOOKING JUST ALL OF THE DATA THERE FOR WHAT CAME TO US AND THEN SAY, OKAY, WHAT DRIVES WHETHER OR NOT WE FUND 30, 40, OR 50 CLINICAL TRIALS ISN'T REALLY THESE CAPS BECAUSE, AS GIL SAID, ALMOST EVERYTHING WE HAVE FITS WITHIN THESE CAPS. IT'S RATIOS WHICH WE'RE PROPOSING NO CONTROL OVER. BUT IF WE WERE TO FUND EVERYTHING NOW, THAT WE CAN THREES FOR EVERYTHING TOO AT THE HIGH END, THEN WE WON'T COME CLOSE. SO THIS WAS SIMPLY A MATTER OF PUTTING IN GUIDANCE AROUND THE DATA THAT WE WERE COLLECTING THAT SAID WERE REASONABLE AMOUNTS?

DR. STEWARD: MY SECOND COMMENT, I GUESS,

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REALLY IS ALL ABOUT THE QUESTION OF WHETHER OR NOT YOU CAN ACTUALLY COME UP WITH ADDITIONAL MONEY. AND IT SEEMS TO ME THAT THE ABILITY TO DO THAT REALLY DEPENDS ON THE PROJECTED PROFITABILITY OF WHATEVER IT IS THAT YOU'RE TRYING TO MOVE FORWARD. AS A STATE AGENCY, I THINK WE NEED TO THINK ABOUT THINGS OTHER THAN PROJECTED PROFITABILITY. WE NEED TO THINK ABOUT THINGS THAT RELATE MORE TO IMPACT ON THE HEALTH OF CALIFORNIANS. SO I'M JUST, AGAIN, A LITTLE BIT CONCERNED THAT WITH THESE CAPS WE MIGHT NOT GET SOME OF THE TRIALS FOR WHICH RAISING MONEY WOULD BE VERY DIFFICULT, BUT THEY COULD ACTUALLY HAVE A HUGE IMPACT. I DON'T KNOW HOW TO BALANCE THAT, BUT THAT'S JUST AN OBSERVATION.

MR. SHEEHY: IT DOES SEEM LIKE IT WOULD TAKE US FURTHER AWAY FROM OUR ORIGINAL MANDATE, RIGHT? CAN YOU IMAGINE AN EMBRYONIC STEM CELL-DERIVED PRODUCT, ESPECIALLY THAT HAS SOME GENE MODIFICATION IN IT. IT DOES PUSH US TOWARDS MAYBE THINGS THAT OTHER PEOPLE MIGHT BE WILLING TO FUND.

CHAIRMAN THOMAS: MR. SUPERVISOR, ARE YOU SUGGESTING THAT WE SHOULD HAVE NO CAPS OR INCREASE THE CAPS OR YOU'RE NOT SURE BECAUSE YOU DON'T HAVE ENOUGH DATA TO MAKE THAT DECISION?

MR. SHEEHY: I'M NOT SURE BECAUSE I DON'T

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KNOW WHAT THE INPUTS ARE. IT JUST SEEMS THAT WE LOOKED AT EVERYTHING WE'VE DONE, AND THEN WE BASICALLY DREW AN AVERAGE, MADE A CAP EVEN THOUGH WE JUST APPROVED SOMETHING THIS MORNING THAT WOULD NOT HAVE BEEN FUNDABLE -- WOULD NOT HAVE GOTTEN THE MONEY THAT THEY ASKED FOR. IT'S ABOUT A TRAIN OF LOGIC THAT MAKES SENSE TO ME.

CHAIRMAN THOMAS: SO WHAT ARE YOU SUGGESTING HERE?

MR. SHEEHY: I THINK THAT A COUPLE OF THESE MIGHT NEED A LITTLE MORE THOUGHT. MAYBE SEND THIS PARTICULAR PIECE BACK TO THE SCIENCE SUBCOMMITTEE AND TRY TO UNDERSTAND -- I MEAN WE HAD THIS WHEN WE HAD THE SCIENCE SUBCOMMITTEE. A LOT OF THESE THINGS WERE JUST NOT CLEAR TO US, AND WE HAD TROUBLING DETERMINING WHAT THE INPUTS WERE THAT WERE DRIVING THE CHANGE IN POLICY.

CHAIRMAN THOMAS: DR. MILLS.

DR. MILLS: NO COMMENT.

CHAIRMAN THOMAS: SHAKING YOUR HEAD MEANS NO COMMENT AS OPPOSED TO A QUALITATIVE COMMENT ON THE COMMENT. OKAY.

DR. DULIEGE: TWO COMMENTS. ONE, THE NOMENCLATURE OF PHASE 1 AND PHASE 2 IS VERY BLURRY, MORE BLURRY THAN PEOPLE WOULD WANT TO THINK, AND

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PARTICULARLY WHEN IT COMES TO STEM CELL RESEARCH WHERE, ADMITTEDLY, YOU CAN HARDLY EVER DO A STUDY IN NO MORE HEALTHY VOLUNTEERS. WE JUST DON'T DO THAT. YOU IMMEDIATELY END UP IN THOSE 1B, 2A, 2, WHATEVER PEOPLE DECIDE. I THINK WE SHOULD FORGET TRYING TO ARGUE THE POINT OF PHASE 1 VERSUS PHASE 2.

SECOND, WHEN IT COMES TO THESE CAPS, I THINK THEY ARE VERY GENEROUS. IF THESE APPLICATIONS ARE SO MERITORIOUS, I WOULD BE SURPRISED THAT THEY CANNOT FIND ANY EXTRA FUNDING SHOULD THEY NEED THAT. BUT THAT IN ITSELF, AS WE DISCUSSED THIS MORNING, VERY GENEROUS. SO I'M IN FAVOR OF THAT. I THINK IT'S CLEAR AND SIMPLE AND LOGICAL TO ME.

DR. STEWARD: MAYBE JEFF MADE A MOTION, THAT THIS ONE NEEDS TO GO BACK TO THE SCIENCE SUBCOMMITTEE AND THE IP SUBCOMMITTEE. IF YOU DID, I SECOND THAT MOTION.

MR. SHEEHY: I THINK THAT'S WHAT I DID.

DR. STEWARD: OKAY.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED IN A RATHER CLEVER FASHION TO SEND THIS PARTICULAR ITEM BACK TO THE SCIENCE SUBCOMMITTEE. JAMES, DO WE NEED A ROLL CALL VOTE ON THAT? YES. OKAY. IS THERE DISCUSSION ON THE MOTION?

MR. TORRES: YES. WHAT'S THE TIME

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SENSITIVITY ISSUE HERE, OR IS THERE ONE?

DR. SAMBRANO: I DON'T KNOW THAT IT IS. WE PRESENTED A MODEL BASED ON --

MR. TORRES: SO REFERRAL BACK TO THE SUBCOMMITTEE WOULDN'T HAVE THAT MUCH OF AN IMPACT?

DR. SAMBRANO: SO THE IMPLEMENTATION OF THESE WOULD BE FOR APPLICATIONS THAT WOULD BE COMING TO US IN APRIL, ASSUMING THERE WERE APPROVAL TODAY. SO IT WOULD DELAY THAT DEPENDING ON WHEN THE SCIENCE SUBCOMMITTEE AND WHEN IT COMES BACK TO THE BOARD FOR CONSIDERATION.

MR. TORRES: WHATEVER WE DO ON THIS ISSUE, THAT WOULDN'T PREVENT APPLICATIONS FROM COMING IN.

DR. SAMBRANO: IT WOULD NOT PREVENT APPLICATIONS FROM COMING IN AT ALL.

CHAIRMAN THOMAS: OKAY. SO FURTHER DISCUSSION ON THE MOTION?

MS. WINOKUR: WE NEED TO GIVE ADDITIONAL INFORMATION ON PERSONNEL TO THE SUBCOMMITTEE.

CHAIRMAN THOMAS: SORRY, DIANE. I THINK I MISSED A WORD THERE. COULD YOU REPEAT THAT PLEASE?

MS. WINOKUR: I'M JUST CONCERNED THAT THE SUBCOMMITTEE WON'T HAVE ADDITIONAL INFORMATION OR MEMBERSHIP IT HAD BEFORE, AND WE'LL BE AT A LOSS TO COME UP WITH SOME OTHER PROPOSAL OR TO BE

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COMFORTABLE WITH THIS ONE.

CHAIRMAN THOMAS: THERE WAS A BIT OF A TECHNICAL ISSUE THERE, DIANE. I THINK YOU SAID YOU'RE CONCERNED THAT BACK AT THE SCIENCE SUBCOMMITTEE WE MIGHT NOT HAVE ADEQUATE INFORMATION TO BASE A DECISION ON. IS THAT WHAT YOU SAID?

MS. WINOKUR: DIFFERENT INFORMATION THAN WAS HAD WHEN IT FIRST CAME TO THE SUBCOMMITTEE.

CHAIRMAN THOMAS: DR. SAMBRANO, COULD YOU PERHAPS COMMENT IN TERMS OF ADDITIONAL DATA THAT MIGHT BE BROUGHT TO BEAR HERE?

DR. SAMBRANO: WELL, OUR ATTEMPT WAS TO PROVIDE AS MUCH AS WE COULD IN TERMS OF HOW WE DERIVED THESE NUMBERS. SO WE PROVIDED THE SPECIFIC GRANTS THAT HAVE BEEN FUNDED THAT WE USED ACROSS ALL OF THESE STAGES OF DEVELOPMENT ALONG WITH THE AMOUNTS THAT WERE APPROVED BY THE BOARD. THESE WERE NOT AMOUNTS THAT ULTIMATELY WENT OUT THE DOOR OR HAVEN'T UP GONE OUT THE DOOR, BUT THIS IS WHAT WAS REQUESTED AND APPROVED. AND THEN THAT DATA IS THERE, AND THE TABLE REPRESENTS HOW IT IS THAT WE USE THE PARAMETERS OF 40 TRIALS AND $480 MILLION THAT REMAINS IN ORDER TO DERIVE THE APPROXIMATE NUMBER THAT WOULD BE FOR EACH STAGE. THAT'S WHAT WE HAVE. IF THERE IS DATA OR INFORMATION THAT YOU FEEL

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IS IMPORTANT OR USEFUL TO ADD TO THAT, WE CAN PROVIDE THAT.

CHAIRMAN THOMAS: SUPERVISOR SHEEHY -- GO AHEAD, DIANE.

MS. WINOKUR: THE ONLY INFORMATION THAT I COULD SUGGEST IS THE BASIS OF THE DISCUSSION WE'VE HAD THIS MORNING. THE SUBCOMMITTEE NEEDS TO HAVE THAT BECAUSE IT CERTAINLY ADDED CONCERNS THAT WEREN'T BEFORE THEM IN THE LAST DISCUSSION.

CHAIRMAN THOMAS: THANK YOU.

MR. SUPERVISOR, WHAT OTHER DATA WOULD YOU LIKE TO SEE THAT COULD BETTER INFORM THE DISCUSSION ABOVE AND BEYOND WHAT WE'VE HAD ALREADY?

MR. SHEEHY: I WOULD LIKE TO -- WE'RE KIND OF STUCK IN A CIRCLE HERE. I'M NOT SURE I AGREE WITH CAPS BECAUSE WHAT I'M SEEING IS THAT WE'VE AVERAGED OUT WHAT WE'VE DONE IN THE PAST, AND WE BASED IT, IT SEEMS, ON OUR ABILITY TO FUND 40 CLINICAL TRIALS, NEITHER OF WHICH ARE ADEQUATE INPUTS FOR ME TO THAT MAKE DECISION WHEN WE INTENTIONALLY CAME IN AND DECIDED NOT TO DO CAPS. AND WE DO DO THE BUDGET REVIEW. SO WHAT MIGHT BE INTERESTING TO UNDERSTAND IS WHAT DEFICIENCIES WE HAVE IN BUDGET REVIEW PRIOR TO REVIEW OF THE GRANTS. THAT SEEMS TO ME TO BE THE PLACE WHERE I COULD USE

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MORE INFORMATION.

DR. MILLS: I'D JUST LIKE TO, AGAIN, POINT OUT THAT THE BUDGET REVIEW ONLY LOOKS AT WHETHER OR NOT THE PROPOSED TRIAL IS APPROPRIATELY BUDGETED. IT DOESN'T LOOK AT WHETHER OR NOT THE PROPOSED TRIAL IN ITSELF IS APPROPRIATE. SO YOU CAN RUN A $40 MILLION PHASE 1 TRIAL. IT'S POSSIBLE. THERE'S CRO'S THAT WILL TAKE YOUR MONEY FOR IT AND CONTRACT MANUFACTURING ORGANIZATIONS. AND IF YOU PUT ALL OF THAT TOGETHER AND YOU RAN A HUNDRED-PATIENT PHASE 1 CELL THERAPY TRIAL AND YOU PUT IT BEFORE OUR BUDGET REVIEW, OUR BUDGET REVIEW WILL ONLY BE ABLE TO SAY IT'S FAIRLY COSTED OUT FOR THAT. BUT THE BUDGET REVIEW DOESN'T SAY BUT IT'S ABSURD TO SPEND A $100 MILLION ON A PHASE 1 TRIAL.

DR. STEWARD: RANDY, MAYBE THAT'S THE POINT. MAYBE THE BUDGET REVIEW NEEDS TO BE ACTUALLY WHAT YOU'RE TALKING ABOUT. IS THAT SOMETHING THAT CIRM STAFF COULD DO? I THINK THAT WOULD BE WELCOME, TO REALLY EXACTLY ASK THE KINDS OF QUESTIONS WE WERE TALKING ABOUT ON SOME OF THE ONES THIS MORNING. DOES IT REALLY COST, IS IT REALLY WORTH 12 MILLION BUCKS TO CARRY OUT THIS TRIAL? I DON'T KNOW. IS THAT SOMETHING THAT WOULD BE POSSIBLE TO DO?

DR. MILLS: THAT FEELS LIKE REVIEW

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CRITERIA.

DR. STEWARD: OKAY. COULD IT BE DONE AT THE LEVEL OF THE GWG?

MR. TORRES: WE JUST DID IT TODAY, AS STEVE POINTED OUT. WE APPROVED 12 MILLION WITHOUT A CAP.

MR. SHEEHY: CAN I JUST SUGGEST, SINCE WE HAVE A MOTION ON THE FLOOR, CLEARLY WE NEED TO TALK ABOUT THIS MORE. I DON'T THINK WE'RE GOING TO GET TO A POINT WHERE WE'RE GOING TO APPROVE THIS TODAY. SO THE MAIN THING IS JUST TO GET US INTO ANOTHER VENUE SO WE CAN HAVE A DEEPER DISCUSSION.

DR. JUELSGAARD: CAN I SAY THIS ONE QUICK THING? IF THIS MOTION GETS APPROVED, THIS IS AT LEAST WHAT I WOULD LIKE TO SEE, AND THIS IS WHAT FOR ME STARTED THIS WHOLE CONVERSATION. THAT IS, HOW MANY PHASE 1, PHASE 1/2A PROJECTS, APPLICATIONS HAVE WE PREVIOUSLY FUNDED? WHAT WERE THEY ABOUT THAT WOULD NOT HAVE MET THIS CRITERIA OF $9 MILLION? BESIDES THE SCID ONE TODAY, WHAT HAVE THE PROJECTS IN THE PAST BEEN BECAUSE IF THESE ARE HIGH-VALUE PROJECTS THAT ARE JUST REALLY EXPENSIVE TO DO, THEN THAT SORT OF, FOR ME, UNDERCUTS THE NOTION OF LIMITING US TO 9 MILLION. SO HOPEFULLY THAT INFORMATION IS FAIRLY STRAIGHTFORWARD TO FIND.

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CHAIRMAN THOMAS: THANK YOU, AGAIN, FOR VERY ROBUST DISCUSSION. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: NO.

MS. BONNEVILLE: HOWARD FEDEROFF. ELIZABETH FINI.

DR. FINI: I'M SORRY. I DON'T KNOW WHAT WE'RE VOTING ON.

CHAIRMAN THOMAS: TO SEND THIS BACK.

DR. FINI: YES, DEFER.

MS. BONNEVILLE: JUDY GASSON. DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: KATHY LAPORTE.

DR. LAPORTE: JUST TO CLARIFY, SO WE'RE JUST VOTING TO DEFER.

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CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: YES, THIS PARTICULAR ITEM.
MS. LAPORTE: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: 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: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.

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DR. VUORI: YES.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU. DR. SAMBRANO, HAVE YOU CONCLUDED YOUR REVIEW HERE?

DR. SAMBRANO: I HAVE NOT UNFORTUNATELY, BUT THERE'S JUST ONE MORE. AND SO THIS LAST ITEM IS RELATED TO FUNDABLE ACTIVITIES. AND SO HERE WE WANT TO PROVIDE FLEXIBILITY ON A COUPLE OF ITEMS. SO FOR CLIN1 AND 2 IS TO PERMIT FUNDING FOR NECESSARY MANUFACTURING ACTIVITIES FOR A FOLLOW-ON TRIAL. SO SOMETIMES THERE IS A LOT PRODUCED, SAY, DURING IND-ENABLING THAT CAN BE UTILIZED FOR THE IND-ENABLING ACTIVITIES AS WELL AS PHASE 1. WE WANT TO ALLOW IT, ASSUMING IT'S APPROPRIATE TO DO SO, AND HAVE THAT FLEXIBILITY.

AND THEN, SECONDLY, FOR CLIN2S, TO PERMIT FUNDING FOR COMPARABILITY STUDIES AND COMMERCIAL DEVELOPMENT ACTIVITIES, WHICH ARE ACTIVITIES SOMETIMES REQUIRED BY THE FDA IN ORDER TO ADVANCE THE PROJECT. AND WE WANT TO PERMIT APPLICANTS TO REQUEST FUNDING FOR THESE ITEMS.

AND THAT WAS THE LAST ONE. AND SO WE ARE ASKING FOR APPROVAL ON THESE AMENDMENTS.

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CHAIRMAN THOMAS: OKAY. WITH THE EXCEPTION OF THE ONE WHICH HAS BEEN SENT BACK TO THE SCIENCE SUBCOMMITTEE, DO I HEAR A MOTION TO APPROVE?

MS. BONNEVILLE: AND THE CHANGE.

CHAIRMAN THOMAS: AND THE CHANGE, CORRECT. DO I HEAR A MOTION TO APPROVE?

DR. STEWARD: SO MOVED.

CHAIRMAN THOMAS: MOVED BY DR. STEWARD, SECONDED BY?

DR. DULIEGE: SECOND.

CHAIRMAN THOMAS: FURTHER DISCUSSION BY MEMBERS OF THE BOARD ON THIS MOTION? HEARING NONE, MEMBERS OF THE PUBLIC?

MR. REED: GOING BACK TO THE FIRST ONE, IT SOUNDS LIKE A COMPROMISE HAS BEEN REACHED, BUT I WANT TO BE SURE I UNDERSTOOD, PARTICULARLY SINCE THERE WAS NO VOTE ON IT. IN THE EVENT DESCRIBED, IF SOMEONE IS ABOUT TO HAVE HIS OR HER FUNDING STOPPED BECAUSE OF A MISREPRESENTATION ON THEIR PART OR OTHER CONTRACTUAL FAILURE, THIS INFORMATION WILL BE BROUGHT TO THE BOARD. IF THE BOARD AGREES WITH THE CHARGES AGAINST THE SCIENTIST, THEY DO NOTHING AND IT STANDS. IF, HOWEVER, THEY OBJECT, THE MATTER WILL BE DISCUSSED AND THE FINAL DECISION WILL STILL BE IN THE BOARD'S HANDS; IS THAT CORRECT? THIS IS

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FOR JAMES.

MR. HARRISON: ROUGHLY. JUST TO BE CLEAR, THOUGH, WE'RE NOT IN MOST CASES TALKING ABOUT MISREPRESENTATIONS. WE'RE TALKING ABOUT MISUNDERSTANDINGS WHERE THE APPLICANT PROVIDED INFORMATION, WE UNDERSTOOD IT DIFFERENTLY THAN THE APPLICANT INTENDED, AND WE DETERMINED, BASED ON WHAT WE LEARNED THROUGH THE JUST-IN-TIME PROCESS, THAT, IN FACT, THE APPLICANT WAS NOT ELIGIBLE. SO UNDER THOSE CIRCUMSTANCES, WE WOULD PUT AN ITEM ON THE AGENDA, AND THE BOARD WOULD HAVE THE OPPORTUNITY TO TAKE ACTION IF IT CHOSE. IF NOT, THE CIRM TEAM DETERMINATION THAT THE APPLICANT WAS NOT ELIGIBLE WOULD HOLD.

MR. REED: THANK YOU.

CHAIRMAN THOMAS: THANK YOU, MR. HARRISON. VERY ELOQUENTLY PUT, AS ALWAYS. ANY OTHER PUBLIC COMMENT ON THE MOTION? HEARING NONE, MARIA, PLEASE TAKE THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: NO.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

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MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: KATHY LAPORTE.
DR. LAPORTE: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
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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: OSWALD STEWARD.

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DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
CHAIRMAN THOMAS: OKAY. ON TO ITEM NO. 11. THIS SHOULDN'T BE TERRIBLY LONG. I KNOW MR. JUELSGAARD WILL BE SUCCINCT ON THIS ITEM. CONSIDERATION OF INITIATION OF PROCESS TO ADOPT NEW INTELLECTUAL PROPERTY RULES FOR NEW AWARDS. GOING TO HAVE MR. JUELSGAARD SAY SOME INTRODUCTORY REMARKS AND THEN MOVE TO MR. TOCHER FOR DISCUSSION.
DR. JUELSGAARD: THIS WILL BE VERY BRIEF BECAUSE SCOTT'S ACTUALLY THE MORE IMPORTANT PERSON TO TALK HERE. BUT AWHILE BACK SCOTT APPROACHED ME AND JEFF SHEEHY REGARDING SOME OF OUR EXISTING REGULATIONS DEALING WITH INTELLECTUAL PROPERTY AND REVENUE, HOPEFULLY, TO BE GENERATED BY THE STATE FROM INVENTIONS THAT WERE MADE ALONG THE WAY OR DATA THAT WAS USED.

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AND I REMEMBER JOINING THIS ORGANIZATION AND LOOKING AT WHAT WE HAD AT THE TIME, AND IT WAS ONE OF THE MOST CONVOLUTED SCHEMES THAT I HAD EVER SEEN IN TERMS OF TRYING TO GAUGE RESPONSIBILITY FOR PROJECTS AND WHERE TO ASSIGN PAYMENT FOR VALUE RECEIVED. I WANT TO APPLAUD SCOTT FOR WHAT HE'S ABOUT TO PRESENT BECAUSE IT'S DESIGNED TO REALLY TRY AND SIMPLIFY AND CLARIFY HOW WE APPROACH THIS ISSUE. SO THANK YOU, SCOTT.

MR. TOCHER: THANK YOU, DR. JUELSGAARD. SO AS DR. JUELSGAARD JUST SAID, WE'VE TAKEN A LOOK, PER RANDY'S CHARGE, ACROSS THE ORGANIZATION TO FIND WAYS TO STREAMLINE WHAT WE DO AND IMPROVE IT IN ORDER TO BETTER ACHIEVE OUR MISSION. AND OBVIOUSLY YOUR AGENDAS FOR THE PAST COUPLE OF YEARS HAVE BEEN FILLED WITH THOSE PROPOSALS AND THOSE EFFORTS. SO ON THE LEGAL TEAM, I AND JAMES HARRISON AND BEN HUANG LOOKED AT SORT OF WHAT WE SPENT A LOT OF TIME ON. ONE OF THOSE THINGS IS OUR IP REGULATIONS, AND WE THOUGHT THOSE WOULD BE RIPE FOR ANALYSIS TO HOW WE COULD IMPROVE THEM TO BETTER ACHIEVE CIRM'S MISSION. SO WE HAVE A FEW IDEAS THAT WE'D LIKE TO SHARE WITH YOU TODAY.

SO, FIRST, WHEN WE CONSIDER RULES GOVERNING INTELLECTUAL PROPERTY, WE START WITH THE

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CHARGE CONTAINED HERE, WHICH IS IN PROPOSITION 71. IT DOESN'T CONTAIN ANY SPECIFICS ABOUT WHAT OUR IP POLICY SHOULD CONTAIN, BUT DOES SET UP SORT OF THE BALANCING TEST, WHICH IS TO BALANCE THE OPPORTUNITY FOR THE STATE TO BENEFIT FROM ROYALTIES AND REVENUES FROM OUR IP VERSUS THE NEED TO AVOID UNREASONABLY HINDERING THE ESSENTIAL RESEARCH. AND SO IT'S THIS BALANCING TEST THAT HAS GUIDED OUR AGENCY'S DEVELOPMENT OF OUR IP POLICIES SINCE 2005 AND THEIR PERIODIC CALIBRATIONS SINCE.

SO BEFORE WE GET, HOWEVER, TO THE PROPOSED REVISIONS, I JUST WANT TO REMIND YOU OF A FEW OF THE VERY BASIC COMPONENTS AND PRINCIPLES OF OUR REGULATIONS. FIRST, CIRM DOESN'T TAKE ANY OWNERSHIP OVER THE IP. LIKE THE FEDERAL GOVERNMENT, CIRM BELIEVES THAT OUR AWARDEES ARE MORE INCENTIVIZED TO EXPLOIT IP WHEN THEY OWN THEIR DISCOVERIES.

SECOND, ALTHOUGH WE WON'T OWN THE IP, WE DO WANT TO MAKE SURE THAT OUR AWARDEES TAKE REASONABLE STEPS TO PUSH THAT IP FORWARD. SO WE MAKE THAT A REQUIREMENT IN OUR REGULATIONS.

THIRD, WHILE WE DON'T OBLIGE OUR AWARDEES TO PUBLISH, WE DO HAVE A VERY COMMONLY ACCEPTED REQUIREMENT THAT, IF THEY DO, THEY SHOULD MAKE THOSE MATERIALS AVAILABLE FOR RESEARCHERS IN CALIFORNIA.

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AND, FINALLY, WHILE THE VAST BULK OF THE RETURN TO THE STATE AS A RESULT OF OUR INVESTMENTS WILL BE IN THE FORM OF, OF COURSE, REDUCED HEALTHCARE COSTS, INCREASED PRODUCTIVITY, AND SUCH RESULTING FROM THERAPIES AND CURES, WE HAVE IMPOSED A DIRECT RETURN TO THE GENERAL FUND THROUGH OUR PRICING AND ACCESS PROVISIONS AS WELL AS REVENUE SHARING. AND DIRECT REVENUE SHARING WITH THE STATE GENERAL FUND IS WHAT WE WANT TO FOCUS ON IN THESE REVISIONS.

SO TO APPRECIATE HOW OUR FINANCIAL RETURN WORKS AND WHAT WE'D LIKE YOU TO CONSIDER TODAY, IT'S IMPORTANT TO HAVE JUST A VERY GENERAL UNDERSTANDING OF THE WAYS THAT OUR REVENUE SHARING REQUIREMENTS WORK, WHICH WILL BE COVERED IN THIS SLIDE AND THE NEXT.

SO WHEN WE TALK ABOUT REVENUE SHARING WITH OUR AWARDEES, WE PRIMARILY TALK ABOUT EITHER OF TWO TYPES: LICENSING REVENUE OR COMMERCIAL REVENUE. LICENSING REVENUE IS A CUT THAT THE STATE GETS WHEN OUR AWARDEE LICENSES TECHNOLOGIES TO THIRD PARTIES DOWNSTREAM AND LATER RECEIVES REVENUE AS A RESULT OF THOSE LICENSES. AND IT'S IMPORTANT TO NOTE THAT THE LICENSING REVENUE HERE THAT THE STATE WILL COLLECT IS NEVER COLLECTED FROM THAT THIRD PARTY. IT'S

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COLLECTED FROM OUR AWARDEE. HOW MUCH OUR AWARDEE MUST SHARE DEPENDS ON A FORMULA THAT CONSIDERS HOW GREAT CIRM'S INVOLVEMENT WAS IN THE PROJECT DURING THE PROJECT PERIOD OF THE GRANT, AND THE SHARE WILL BE EITHER 15 OR 25 PERCENT. HOWEVER, IN PRACTICAL EFFECT, THE ONLY TYPE OF AWARDEE THAT IS ESSENTIALLY SUBJECT TO THIS LICENSING REVENUE IS A NONPROFIT AWARDEE. FOR-PROFIT AWARDEES ARE LARGELY TREATED DIFFERENTLY AS YOU WILL SEE NEXT.

SO THIS IS THE SECOND TYPE OF REVENUE SHARING, COMMERCIAL REVENUE. HERE, IF OUR AWARDEE LICENSES OR IT COULD BE THE CASE THAT THEY ACTUALLY SELF-COMMERCIALIZE A THERAPY OR DRUG OR SUCCESSFUL PRODUCT, THEN WE IMPOSE A ROYALTY ON THE NET COMMERCIAL REVENUES ACCORDING TO THE FORMULA HERE. WHAT'S IMPORTANT TO UNDERSTAND ABOUT THIS NET COMMERCIAL REVENUE IS THAT IT ONLY APPLIES TO FOR-PROFIT AWARDEES. SO, IN ESSENCE, AND, AGAIN, THIS IS JUST A GENERAL WAY OF THINKING ABOUT IT, IS THAT IF YOU'RE A NONPROFIT AWARDEE, YOU WILL SHARE LICENSING REVENUE WITH THE STATE. IF YOU'RE A FOR-PROFIT AWARDEE, YOU WILL SHARE IF YOU COMMERCIALIZE OR YOUR DOWNSTREAM COMMERCIALIZING ENTITY WILL SHARE WITH THE STATE A FRACTION OF ITS NET COMMERCIAL REVENUES.

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SO THAT BRINGS ME TO THE GOALS OF THE IP REVISION ASSESSMENT THAT WE'VE MADE. AND AS WE'VE DONE WITH OTHER POLICIES AND RULES THAT WE'VE BROUGHT TO YOU SINCE RANDY HAS COME ON BOARD, WE WANT TO ENSURE THAT OUR REVENUE SHARING RULES ARE CLEAR AND SELF-EXECUTING WHERE POSSIBLE. IT SHOULDN'T DEPEND ON WHOM YOU TALK TO DETERMINE HOW THESE RULES OPERATE. AND PART OF MAKING THAT POSSIBLE IS ENSURING THAT THE RULES ARE OBJECTIVE INSTEAD OF SUBJECTIVE WHERE POSSIBLE. SO WE SHOULD EXPLICITLY STATE AN EXPECTED OUTCOME AS OPPOSED TO TRYING TO DESCRIBE A TYPE OF BEHAVIOR THAT WE'RE LOOKING TOWARD; SUCH AS, EXERCISING REASONABLE EFFORTS TO DO SOMETHING.

AND TIME AND TIME AGAIN, WE HEARD THROUGHOUT THE DEVELOPMENT, EVEN OF OUR POLICIES EARLY ON, WE HEARD CLEARLY FROM INDUSTRY THAT THEY WERE CONCERNED MORE SO THAN -- SORRY -- THEY WERE CONCERNED MORE ABOUT THE CLARITY AND THE PREDICTABILITY OF OUR STANDARDS AND THEIR OBLIGATIONS THAN THEY WERE ABOUT ANY GIVEN PRICE POINT THAT WE SET ON A ROYALTY RATE, FOR INSTANCE. SO THEY REALLY PRIZE CLARITY AND THE ABILITY TO PREDICT EARLY ON IN THE PROCESS WHAT THE COST OF CIRM FUNDING WOULD BE, AND THAT THEY COULD TAKE AND

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HAVE CONFIDENCE IN THOSE CALCULATIONS.

AND, FINALLY, WE KNOW WE'VE GOT IT ABOUT RIGHT WHEN CIRM TEAM RESOURCES ARE FOCUSED ON OUR LARGER MISSION AS OPPOSED TO EXPENDING OUR EFFORTS TRYING TO INTERPRET OUR OWN RULES AND DETERMINE HOW THEY APPLY IN A CASE-BY-CASE BASIS.

SO MEASURED AGAINST THOSE STANDARDS, WHAT HAS OUR EXPERIENCE BEEN? FIRST, A FUNDAMENTAL PREMISE OF OUR IP REGULATIONS SINCE THE BEGINNING HAS BEEN THE NOTION THAT THE STATE'S INTERESTS ARE ALIGNED WITH THOSE OF OUR AWARDEES, THAT THEY'LL MAKE THE BEST DEAL AND, IN TURN, THE STATE WILL SHARE IN THAT REWARD. IN PRACTICE, HOWEVER, THIS HAS NOT ALWAYS BEEN THE CASE. AND IT'S ESPECIALLY TRUE IN LIGHT OF THE FACT THAT SOME GRANTEES DON'T TYPICALLY LICENSE DATA WHICH IS UNFORTUNATELY USUALLY THE IP THAT'S GENERATED IN THE LARGE, LATE CLINICAL STAGE AWARDS THAT CIRM MAKES. AS I DEMONSTRATED, WHERE THERE'S NO LICENSE, IF YOU ARE A NONPROFIT AWARDEE, THEN THERE'S NO REVENUE TO THE STATE. MOREOVER, A LICENSE CAN BE FURTHER AVOIDED IF THE DATA OR OTHER INFORMATION IS MADE PUBLICLY AVAILABLE.

AND, FINALLY, THE CURRENT REQUIREMENT TO MAKE REASONABLE EFFORTS TO NEGOTIATE LICENSES CAN

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LEAD TO DISAGREEMENT AMONG OUR AWARDEES AND CIRM AS TO WHAT THOSE EFFORTS SHOULD BE AND WHAT THE RESULTS SHOULD BE. AND WHEN LICENSING REVENUE IS DUE, CALCULATING THE AMOUNT CAN BE PROBLEMATIC WHEN DETERMINING THE EXTENT OF THIRD-PARTY PARTICIPATION, FOR INSTANCE, WHICH CAN ALTER THE AMOUNT THAT THE STATE IS DUE. AND ALSO AS WE'VE DISCUSSED, THE SCOPE OF PAYMENTS AN AWARDEE RECEIVES THAT MAY BE SUBJECT TO SHARE WITH THE STATE DIFFER BASED ON THE STATUS OF THE AWARDEE, WHICH CAN ALSO RESULT IN VASTLY DIFFERENT RETURNS TO THE STATE.

AND THEN, FINALLY, APPLYING THE CURRENT RULES TO THE MANY COMPLEX DRUG DEVELOPMENT SCENARIOS CAN LEAD TO REASONABLE DISAGREEMENT, WHICH CREATES UNCERTAINTY REGARDING OUR AWARDEES' OBLIGATIONS. NOT SURPRISINGLY, BECAUSE OF THIS COMPLEXITY OF THE CURRENT SYSTEM, SIGNIFICANT ADMINISTRATIVE TIME IS SPENT INTERPRETING, EXPLAINING, AND ENFORCING OUR IP TERMS. AND BECAUSE THIS INTERPRETATION CAN BE SUBJECTIVE, SUCH AS WHAT I MENTIONED JUST A MOMENT AGO, THE EFFORTS TO MAKE REASONABLE EFFORTS TO LICENSE, THESE RULES CAN BE DIFFICULT FOR OUR AWARDEES TO PENCIL OUT IN ADVANCE AND DETERMINE WHAT THE COST IS PRIOR TO ACCEPTING AN AWARD. INDEED, EVEN OUR EFFORTS TO OBTAIN COMPLIANCE CAN CAUSE

DELAYS IN GETTING PROJECTS MOVING FORWARD AT THE OUTSET.

AND THEN, FINALLY, AS I DISCUSSED, OUR CURRENT SCHEME TREATS FOR-PROFITS AND NOT-FOR-PROFITS DIFFERENTLY. WHEN THE CONCEPT OF COMMERCIALIZING REVENUE WAS FIRST ADOPTED A COUPLE OF YEARS AGO, I THINK THERE WAS NATURALLY SOME UNCERTAINTY AS TO HOW THAT SYSTEM WOULD OPERATE AND HOW IT WOULD BE RECEIVED BY THE PRIVATE SECTOR. BUT BASED ON THE LAST COUPLE OF YEARS OF EXPERIENCE, I THINK THE FOR-PROFIT SECTOR HAS LARGELY EMBRACED THE CONCEPT OF COMMERCIAL REVENUE, AND IT DOES NOT APPEAR TO BE A SIGNIFICANT IMPEDIMENT TO COMMERCIAL PARTICIPATION IN OUR PROGRAMS OR IN TAKING UP OUR CIRM-FUNDED IP. THUS, WE FEEL ACTUALLY THE TIME IS RIPE NOW FOR TREATING OUR AWARDEES IN THE SAME FASHION.

TO ILLUSTRATE THE EFFECT OF THIS CURRENT SCHEME, THIS EXAMPLE ON THE SLIDE SHOWS THE DIFFERENCE TO THE STATE OF PHARMA LICENSES CIRM TECHNOLOGIES FROM A NOT-FOR-PROFIT AWARDEE VERSUS LICENSING FROM A FOR-PROFIT AWARDEE. THE UPSIDE TO THE STATE IN HARMONIZING THIS TREATMENT CAN BE SIGNIFICANT.

SO WITH THESE CHALLENGES, CIRM IS

PROPOSING THAT WE 2.0 OR 2.8 OUR REGULATIONS. SO IN ADDITION TO MAKING SOME REVISIONS TO OUR REPORTING REQUIREMENTS AND OTHER ASPECTS OF OUR IP REGULATIONS, WE WANT TO FOCUS PRIMARILY ON THE FOLLOWING REVISIONS. SO, FIRST, WE WANT TO ELIMINATE THE DISPARATE TREATMENT OF AWARDEES AND TREAT ALL AWARDEES ALIKE. AND, SECONDLY, WE PROPOSE TO ELIMINATE THE CONCEPT ENTIRELY OF LICENSING REVENUE FOR ALL AWARDEES AND, INSTEAD, FOCUS ON COMMERCIAL REVENUE AND COMMERCIAL SUCCESS AND THAT CONCEPT AS CURRENTLY APPLICABLE ONLY TO FOR-PROFIT AWARDEES. IN DOING SO, I WANT TO EMPHASIZE THAT WE DO NOT PROPOSE TO MAKE ANY CHANGES TO OUR CURRENT ACCESS AND PRICING REQUIREMENTS.

IN TERMS OF THE EFFECT AND WHAT WE FORESEE AS A RESULT OF THESE REVISIONS, WE BELIEVE THAT ELIMINATING LICENSING REVENUE AND FOCUSING ON COMMERCIAL SUCCESSES WILL OPTIMIZE OUR REMAINING RESOURCES, WHICH WILL ALLOW THE CIRM TEAM TO FOCUS BETTER ON ITS STRATEGIC MISSION. ALSO BY SIMPLIFYING OUR REVENUE SHARING RULES, WE WILL MAKE THEM EASIER TO UNDERSTAND, EXPLAIN, AND ADMINISTER. AND AS A RESULT, WE BELIEVE POTENTIAL APPLICANTS WILL BE MORE ACCURATELY ABLE TO PREDICT THE COST OF CIRM FUNDING AND, THUS, LIKELY MAKE CIRM'S PROGRAMS

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MORE ATTRACTIVE TO FOLLOW-ON INVESTMENT AND COMMERCIALIZATION.

AS DR. JUELSGAARD MENTIONED, LAST MONTH THE IP AND INDUSTRY SUBCOMMITTEE HAD A CHANCE TO EVALUATE THESE PROPOSED REVISIONS AND OFFERED VERY IMPORTANT AND VALUABLE FEEDBACK WHICH WE WILL CARRY FORTH IN THE PROJECT MOVING FORWARD. WITH THE ICOC'S APPROVAL TODAY, WE WOULD MOVE FORWARD WITH THE REGULATORY PROCESS TO PROPOSE, RECEIVE PUBLIC FEEDBACK, REFINE, AND ULTIMATELY ENACT THE REGULATIONS INTO LAW ESSENTIALLY. WE PREDICT THAT PROCESS COULD TAKE ANYWHERE FROM SIX TO POSSIBLY AS LONG AS NINE MONTHS, AND I SUSPECT THAT WE WOULD HAVE PROBABLY ANOTHER IP AND INDUSTRY SUBCOMMITTEE MEETING TOWARD THE END OF THAT PROCESS TO EVALUATE THE FEEDBACK AND EVALUATE FURTHER CHANGES AS WE REFINE THESE PROPOSALS, AND THEN WE WOULD BRING THEM ULTIMATELY BACK TO THE ICOC FOR FINAL APPROVAL. SO I WOULD TURN IT BACK OVER TO STEVE. THANK YOU.

DR. JUELSGAARD: I WILL TURN IT OVER TO CHAIRMAN THOMAS.

CHAIRMAN THOMAS: THANK YOU, MR. TOCHER. THANK YOU, MR. JUELSGAARD. DO I HEAR A MOTION TO ADOPT THESE PROPOSED AMENDMENTS?

DR. JUELSGAARD: SO MOVED.

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MR. TOCHER: IF I COULD JUST CLARIFY, ACTUALLY THE MOTION WOULD BE TO INITIATE THE PROCESS TO ADOPT THEM.

CHAIRMAN THOMAS: GOT IT.

DR. JUELSGAARD: SO MOVED.

CHAIRMAN THOMAS: THANK YOU FOR CLARIFYING. IS THERE A SECOND?

DR. PRIETO: SECOND.

CHAIRMAN THOMAS: SECONDED BY DR. PRIETO. DISCUSSION BY MEMBERS OF THE BOARD? COMMENTS FROM MEMBERS OF THE PUBLIC? HEARING NONE, MR. TOCHER, I'D LIKE TO ECHO MR. JUELSGAARD'S COMMENTS, THAT THIS IS VERY GOOD WORK, AND THANK YOU VERY MUCH FOR ALL THE TIME AND EFFORT YOU'VE PUT INTO THIS.

MR. TOCHER: AND THAT GOES TO DAN AND JAMES AS WELL.

CHAIRMAN THOMAS: THANK YOU. ALL MEMBERS OF THE AUGUST LEGAL TEAM. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

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MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MS. BONNEVILLE: ELIZABETH FINI.
DR. FINI: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA. FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: AYE.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.

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MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: DIANE WINOKUR. DIANE, I THINK YOU'RE ON MUTE AGAIN. IF YOU COULD PLEASE UNMUTE. JOE, YOU MAY BE ON MUTE AS WELL. IF WE COULD BREAK FOR LUNCH, WE WILL TRY AND GET JOE AND DIANE BACK ON THE LINE.
MR. TORRES: WHY DON'T WE JUST MOVE ON AND ADJOURN?
MS. BONNEVILLE: WE HAVE ONE MORE PRESENTATION AFTER THIS ONE.
MR. TORRES: HOW LONG WILL THAT TAKE?
MS. BONNEVILLE: I THINK PEOPLE ARE HUNGRY.
CHAIRMAN THOMAS: BRING YOUR LUNCH BACK. WE HAVE ONE MORE PRESENTATION AND A VERY IMPORTANT GUEST HERE WHO WISHES TO SPEAK TO THE BOARD. SO IF EVERYBODY COULD GRAB THEIR LUNCH AND BRING IT BACK AT YOUR EARLIEST CONVENIENCE BACK TO YOUR CHAIRS, AND WE WILL RECONVENE IN FIVE MINUTES OR SO.
(A RECESS WAS TAKEN.)
CHAIRMAN THOMAS: OKAY. WE ARE GOING TO START UP HERE. THE LAST ITEM ON TODAY'S AGENDA,

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WHICH INCLUDES A VERY IMPORTANT SPECIAL GUEST, IS AN UPDATE OF THE CLINICAL TRIAL PROGRAM -- FOR THE CLINICAL PROGRAM, I SHOULD SAY. DR. MILLAN.

DR. MILLAN: THANK YOU, CHAIRMAN THOMAS, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC. TODAY I'LL BE GIVING AN UPDATE ON OUR CLINICAL TRIALS THAT CIRM HAS FUNDED. AND IN KEEPING WITH CIRM'S MISSION TO ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEED, WE LAUNCHED A FIVE-YEAR STRATEGIC GOAL OF BRINGING 50 NEW CLINICAL TRIALS INTO OUR PORTFOLIO. AND AS REPORTED AT YEAR-END BY DR. MILLS, WE DID SUCCEED IN BRINGING IN TEN NEW TRIALS IN 2016. AND YOU APPROVED THREE ADDITIONAL CLINICAL TRIALS TODAY AS WELL AS ANOTHER PROJECT IN THE IND-ENABLING STAGE.

SO JUST AS A BRIEF OVERVIEW OF OUR PROGRAMS, IN THIS WHEEL GRAPH YOU WILL SEE THAT WE HAVE A DIVERSE PORTFOLIO OF CLINICAL PROGRAMS THAT WE HAVE FUNDED TO DATE. THE LARGEST STILL IS IN ONCOLOGY, COMPOSING 22 PERCENT OF OUR PORTFOLIO; HOWEVER, THERE'S A GROWING NUMBER OF PROJECTS IN THE OTHER DISEASE THERAPEUTIC AREAS AS WELL WITH 14 PERCENT IN HEMATOLOGY, 8 PERCENT IN INFECTIOUS DISEASE, 13 PERCENT IN EYE DISEASE, AS WELL AS 10 PERCENT EACH IN METABOLIC AND CARDIOVASCULAR

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DISEASE.

WE SUPPORTED 19 PHASE 1 CLINICAL TRIALS, FOUR PHASE 2S, AND THREE PHASE 3 CLINICAL TRIALS, AND ALSO AN OBSERVATIONAL HUNTINGTON'S DISEASE TRIAL WHICH IS NOT LISTED HERE. THERE ARE THREE ADDITIONAL TRIALS THAT WILL BE LAUNCHED SHORTLY AFTER TODAY'S APPROVAL.

ON A QUARTERLY BASIS, WE'LL BE UPDATING YOU ON OUR PROGRAMS, AND WE'LL BE DOING THAT BY THERAPEUTIC AREAS. THE IDEA IS TO CYCLE THROUGH ALL THESE SO THAT WE WILL COVER ALL OF THE PROJECTS IN OUR PORTFOLIO OVER THE COURSE OF 18 MONTHS OR SO.

SO THE THREE OPHTHALMOLOGY CLINICAL TRIALS THAT ARE CURRENTLY IN OUR PORTFOLIO AND WHICH ARE CURRENTLY ACTIVE ARE LISTED HERE. THERE'S A PHASE 1/2A TRIAL IN AGE-RELATED MACULAR DEGENERATION, WHICH IS CURRENTLY ENROLLING. A TRIAL FOR RETINITIS PIGMENTOSA, A PHASE 1/2A TRIAL, WHICH HAS COMPLETED ENROLLMENT AND IS NOW IN THE DATA COLLECTION AND FOLLOW-UP PERIOD, AND FOLLOW-ON TO THAT TRIAL A PHASE 2B TRIAL FOR THAT SAME INDICATION WITH THAT PRODUCT. IT IS LAUNCHING AND IS INITIATING ENROLLMENT. AND I WILL GO INTO THESE PROGRAMS IN A LITTLE BIT MORE DETAIL.

FOR THE FIRST TRIAL, THE FIRST TRIAL WHICH

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HAS A LONG TITLE, BUT IT'S A PHASE 1/2A SAFETY ASSESSMENT OF A STEM CELL-DERIVED RETINAL PIGMENTED EPITHELIAL CELL COATED WITH PARYLENE MEMBRANE IMPLANTS IN PATIENTS WITH ADVANCED DRY AGE-RELATED MACULAR DEGENERATION. IT IS LED BY DR. MARK HUMAYAN FROM UNIVERSITY OF SOUTHERN CALIFORNIA, AND IT'S A PHASE 1/2A TRIAL WHICH CIRM HAS FUNDED TO SUPPORT THAT TRIAL.

DRY AGE-RELATED MACULAR DEGENERATION IS DISTINCT FROM THE WET FORM OF AMD WHICH HAS A CURRENTLY APPROVED TREATMENT. YOU'VE HEARD IT'S REVOLUTIONIZED THE TREATMENT OF EYE DISEASE. IT'S CALLED ANTI-VEG-F THERAPY. BUT FOR DRY AMD THERE IS NO CURRENTLY APPROVED PRODUCT. SO THIS PROJECT SEEKS TO TARGET THE DRY FORM OF AMD, WHICH IS A PROGRESSIVE BLINDING EYE DISEASE THAT RESULTS IN GEOGRAPHIC ATROPHY AND CENTRAL VISION LOSS. ITS INCIDENCE IS LESS THAN 1 IN 1400 IN THE U.S. SO IT'S RARE. AND THE IDEA BEHIND THIS TREATMENT, WHICH ARE STEM CELL-DERIVED CELLS ON A BIOSTABLE MEMBRANE, IS THAT THE IMPLANTATION OF THIS CELL PRODUCT WOULD RESTORE THE NATIVE HEALTHY STATE OF THESE RETINAL PIGMENTED EPITHELIAL CELLS WHICH ARE NECESSARY FOR NORMAL VISION ON BRUCH'S MEMBRANE.

SO THE DESIGN IS THAT IT'S A PHASE 1/2A

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OPEN LABEL TRIAL WITH TWO COHORTS. THE FIRST COHORT WITH MORE SIGNIFICANT VISION LOSS OF BEST CORRECTED VISUAL ACUITY OF LESS THAN 20 AND 400. AND THEN PROCEEDING TO THE NEXT COHORT WITH LESS ADVANCED VISUAL LOSS WITH A BEST CORRECTED VISION OF BETWEEN 20 AND 100, BUT BETTER THAN 20 AND 400. THE THERAPEUTIC CANDIDATE IS DELIVERED INTO THE SUBRETINAL SPACE, AND IT'S A SINGLE DOSE. THE IDEA IS THAT THIS CELL DOSE ON THAT SIZE OF A MEMBRANE IS PURPORTED TO BE THE BEST SIZE TO REPLACE THE MACULA.

THE GOAL OF THIS STUDY IS PRIMARILY AS A PHASE 1 STUDY TO TEST SAFETY AND TOLERABILITY OF THE SURGICAL PROCEDURE AND OF THE CELLS ON THE MEMBRANE. BUT IN ADDITION, SECONDARY ENDPOINTS, MEANING DATASETS THAT ARE BEING COLLECTED, ARE RELATING TO ACTUAL VISUAL FUNCTION, INCLUDING VISUAL ACUITY MEASURES, VISUAL FIELD, AND PHOTORECEPTOR ELECTRICAL RESPONSES THAT ARE FUNCTIONAL MEASURES IN COMPARISON TO THE BASELINE FUNCTION IN THAT TREATED EYE AS WELL AS IN COMPARISON TO THE FUNCTION OF THE NONTREATED EYE.

THIS TRIAL IS CURRENTLY ENROLLING, AND SUBJECTS HAVE BEEN ENROLLED. THE PROJECT AWARD END DATE IS IN JULY OF 2018 WHEN WE'LL HAVE A DATASET THAT THE INVESTIGATORS WOULD BE ABLE TO REPORT UPON.

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THE NEXT TRIAL --

DR. STEWARD: AS FAR AS THE ENROLLMENT, IS IT MEETING THE ENROLLMENT TARGETS?

DR. MILLAN: IT'S CURRENTLY IN ENROLLMENT, YES. IT'S CURRENTLY ENROLLING.

THE NEXT TRIAL, OUR SPECIAL GUEST THAT CHAIRMAN THOMAS HAD ALLUDED TO HAD PARTICIPATED IN THIS TRIAL. THE TRIAL IS CALLED "RETINAL PROGENITOR CELLS FOR THE TREATMENT OF RETINITIS PIGMENTOSA." THE PRINCIPAL INVESTIGATOR ON THIS TRIAL IS DR. HENRY KLASSEN, AND THAT TRIAL SPONSOR WAS OUT OF UC IRVINE. THE AWARD WAS $17 MILLION TO FUND A PHASE 1/2A TRIAL FOR RETINITIS PIGMENTOSA.

SO RETINITIS PIGMENTOSA IS A SEVERE FORM OF BLINDNESS THAT RUNS IN FAMILIES AND HAS AN INCIDENCE OF 1 IN 4,000. IT'S CONSIDERED A GOOD TARGET FOR STEM CELL TREATMENT BECAUSE IT'S KNOWN WHAT THE PATHOPHYSIOLOGY IS. IT'S THE LOSS OF LIGHT SENSING PHOTORECEPTORS. SO THE IDEA IS IF YOU COULD SAVE THOSE PHOTORECEPTORS, THEN YOU COULD SAVE THE VISION IN THOSE DISEASED EYES.

THE PROPOSED MECHANISM IS THAT THE INVESTIGATIONAL PRODUCT WHICH IS A RETINAL PROGENITOR CELL WOULD RESCUE THESE LIGHT PHOTORECEPTORS. IT'S A PHASE 1/2A TRIAL, OPEN

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LABEL, SINGLE ARM STUDY. SO THE PATIENTS KNOW THEY'RE RECEIVING THE THERAPEUTIC CANDIDATE. IT'S AN INTRAVITREAL INJECTION OF THE HUMAN RETINAL PROGENITOR CELLS INTO THE WORST SEEING EYE. IN THIS TRIAL TWO COHORTS, ONE WITH 20 AND 200 VISION OR WORSE, AND THE OTHERS WITH LESS AFFECTED VISION, WERE DOSED WITH MANY ASCENDING DOSE RANGES OF THE INVESTIGATIONAL PRODUCT.

THE GOAL OF THAT STUDY WAS PRIMARILY TO TEST SAFETY AND TOLERABILITY OF THE PROCEDURE AND THE RPE CELLS, BUT ALSO TO TEST FUNCTIONAL STUDIES SUCH AS VISUAL ACUITY, VISUAL FIELD, AND ANATOMY BY WAY OF ANGIOGRAPHY AND TOMOGRAPHY.

THIS TRIAL OF 28 SUBJECTS HAS COMPLETED ENROLLMENT. THESE PATIENTS ARE IN THE FOLLOW-UP OBSERVATIONAL PERIOD. DATA IS BEING COLLECTED AND ANALYSIS WILL BE COMPLETE BY THE END OF THE YEAR. THE PRELIMINARY SAFETY AND EFFICACY DATA FROM THIS TRIAL WAS USED TO SUPPORT THE DESIGN AND THE APPROVAL OF THE PHASE 2 CLINICAL TRIAL FOR OUR FUNDING AS HAD BEEN ALLOWED BY THE FDA TO PROCEED WITH A PHASE 2B TRIAL.

PHASE 2B CLINICAL STUDY IS TERMED "STUDY OF EFFICACY AND SAFETY OF INTRAVITREAL INJECTION OF RETINAL PROGENITOR CELLS, JCELL, FOR TREATMENT OF

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RETINITIS PIGMENTOSA." THE SPONSOR NOW IS JCYTE, WHICH IS A SPINOUT OF THE IP FROM UC IRVINE. DR. HENRY KLASSEN REMAINS THE PRINCIPAL INVESTIGATOR ON THE GRANT AND ON THE TRIAL. IT'S AN $8 MILLION AWARD FOR A PHASE 2B TRIAL FOR THIS INDICATION.

THE GOAL OF THE STUDY IS TO CONTINUE TO ASSESS SAFETY AND TOLERABILITY, BUT ALSO TO GATHER DATA AS TO WHETHER THE PRODUCT IS EFFICACIOUS, MEANING THAT THERE'S BIOLOGIC ACTIVITY THAT RESULTS IN IMPROVEMENT OF THE RETINITIS PIGMENTOSA. IT'S A PHASE 2B SINGLE DOSE RANDOMIZED TRIAL WITH PLACEBO CONTROL, MEANING HALF OF THE PATIENTS RECEIVE JUST SOLUTION WITHOUT CELLS AND THE OTHER HALF RECEIVE THE INVESTIGATIONAL PRODUCT, WHICH ARE THE RETINAL PROGENITOR CELLS. THE PATIENTS WHO RECEIVE THE PLACEBO CONTROL, AFTER 12 MONTHS OF FOLLOW-UP AND DATA THAT'S GATHERED, WILL HAVE THE OPTION TO WHAT'S SO-CALLED CROSSOVER, MEANING TO ALSO RECEIVE THE INVESTIGATIONAL PRODUCT.

SO THE GOAL OF THIS TRIAL, WHICH AGAIN PROGRESSED FROM THE PHASE 1 TRIAL, IS TO GATHER EFFICACY DATA, FUNCTIONAL DATA. SO THE TESTS AND THE DATASETS THAT ARE BEING COLLECTED ARE LOOKING FOR IMPROVEMENTS IN VISUAL FUNCTION AT 12 MONTHS. AND THESE EVALUATIONS ARE UTILIZING MORE SENSITIVE

LOW VISION TESTS WHICH ARE MORE APPROPRIATE FOR PATIENTS WITH THIS LEVEL OF IMPAIRED VISION, MORE APPROPRIATE THAN THE TYPICAL VISUAL ACUITY TEST THAT MOST PEOPLE WOULD HAVE PERFORMED AT THEIR OPHTHALMOLOGIST. BUT IN ADDITION, THESE PATIENTS WILL HAVE BILATERAL MOBILITY TESTS. AND A PICTURE HERE IS A MAZE THAT THESE PATIENTS WOULD GO THROUGH. AND THESE MAZES HAVE VARIOUS CONTRAST AND OBJECTS, AND THEY VARY THE ILLUMINATION IN THE ROOM. AS PATIENTS GO THROUGH THIS MAZE, THEY CAPTURE DATA THROUGH THESE SENSITIVE CAMERAS. THE DATASETS ARE CAPTURED AS YES/NO, AND THIS MOBILITY TEST IS ACTUALLY THE BASIS, THE PRIMARY ENDPOINT FOR ONE OF THE GENE THERAPY TRIALS THAT'S CURRENTLY IN PHASE 3 THAT J.T. HAD MENTIONED EARLIER IN THE MEETING THAT'S BEING REVIEWED FOR APPROVAL EARLY THIS YEAR, THE SPARK TRIAL.

SO THIS MOBILITY TEST IS ACTUALLY AN APPROVABLE ENDPOINT. IT'S A FUNCTIONAL ENDPOINT, AND IT MEASURES RELEVANT PARAMETERS IN VISUAL ACUITY, VISUAL FIELD, CONTRAST SENSITIVITY, AND DIM LIGHT VISION. THOSE ARE THINGS THAT ARE VERY IMPORTANT AND RELEVANT TO ACTIVITIES OF DAILY LIVING AND QUALITY OF LIFE.

AND SPEAKING OF THOSE PARAMETERS AND

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RELEVANCE, IT IS MY PLEASURE TO TURN THIS OVER TO KEVIN MCCORMACK, WHO WILL INTRODUCE OUR PATIENT REPRESENTATIVE IF THERE ARE NO QUESTIONS.

DR. JUELSGAARD: SO CAN YOU DISTINGUISH FOR ME THIS TRIAL FROM THE ONE YOU JUST PRESENTED BEFORE IT? SO WE HAVE THE SAME PI, HENRY KLASSEN, WE HAVE THE SAME DISEASE, RETINITIS PIGMENTOSA. WE HAVE, I BELIEVE, THE SAME TYPE OF TREATMENT APPROACH USING PROGENITOR CELLS. SO WHAT MAKES THESE TRIALS DIFFERENT THAT WE'RE FUNDING TWO OF THEM?

DR. MILLAN: SO THE FIRST TRIAL, THERE WERE 28 SUBJECTS IN THAT TRIAL. THE FIRST TRIAL TESTED DIFFERENT DOSES FOR HALF MILLION TO THREE MILLION CELLS, AND LOOKED AT TWO COHORTS, PATIENTS WITH 20 AND 200 VISION AND THOSE WITH OTHERS. AND IT NARROWED DOWN WHAT WAS THE APPROPRIATE PATIENT COHORT. SO THEY ACTUALLY IN THIS NEXT TRIAL ARE JUST ENROLLING WORST VISION, THE MOST AFFECTED. AND IN ADDITION, THEY'VE CHOSEN A DOSE. SO THE DOSE WILL BE -- I DON'T KNOW IF I CAN DISCLOSE, BUT IT'S ONE OF THE DOSES IN THE MIDRANGE.

IN ADDITION, I THINK MAYBE I DIDN'T EMPHASIZE IT ENOUGH, THE FUNCTIONAL EVALUATIONS HAVE REALLY BEEN REVVED UP. IN FACT, THIS MOBILITY TEST THAT I MENTIONED IS BEING FASHIONED TO BE

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APPROPRIATE FOR THIS TRIAL. SO IT'S VERY RELEVANT BECAUSE IT'S AN APPROVABLE ENDPOINT. IT'S A PRIMARY ENDPOINT FOR THE SPARK TRIAL, AND NOW IT'S BEING CUSTOMIZED FOR THIS PARTICULAR TRIAL. SO THAT IS SOMETHING THAT HAS ADVANCED FROM THE OTHER. IT WAS INFORMED BY THE PREVIOUS TRIAL. THIS TRIAL IS A LITTLE BIT BIGGER, SIXTY PATIENTS. IT NARROWED DOWN THE SEVERITY OF THE DISEASE TO --

DR. JUELSGAARD: IT'S JUST A PROGRESSION TRIAL?

DR. MILLAN: YES, IT IS. THANK YOU. OKAY. SO HERE'S KEVIN.

MR. MC CORMACK: THANK YOU, DR. MILLAN. CHAIRMAN THOMAS, MEMBERS OF THE BOARD, I ACTUALLY HAD A REALLY LONG AND DETAILED INTRODUCTION PLANNED, BUT I THINK WE'LL SKIP THAT. KNOW YOUR AUDIENCE.

ONE OF THE GREAT PLEASURES OF MY JOB, OTHER THAN DOING EVERYTHING THAT MARIA BONNEVILLE ASKS ME TO, IS THE OPPORTUNITY TO MEET SOME EXTRAORDINARY PEOPLE IN THE PATIENTS AND PATIENT ADVOCATES. AND THE WOMAN WE'RE ABOUT TO MEET NOW CERTAINLY FITS INTO THAT CATEGORY.

ROSIE BARRERO, SEEN HERE ON PAGE 5 OF YOUR ANNUAL REPORT, OR CINCO IN THE SPANISH LANGUAGE VERSION, HAS BEEN A GREAT CHAMPION OF STEM CELL

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RESEARCH FOR A LONG TIME, AND IN PARTICULAR THE WORK OF DR. KLASSEN AT UC IRVINE. RECENTLY SHE MOVED OVER FROM BEING AN ADVOCATE TO BEING A CLIENT, AND SHE UNDERWENT ONE OF THE PROCEDURES IN THE FIRST GROUP OF PATIENTS THAT DR. KLASSEN TREATED. AND SHE'S HERE NOW TO TALK TO US ABOUT THE IMPACT THAT THAT'S HAD ON HER LIFE. SO, LADIES AND GENTLEMEN, ROSIE BARRERO.

(APPLAUSE.)

MS. BARRERO: GOOD AFTERNOON, EVERYONE. I DON'T KNOW IF ANYONE REMEMBERS ME, BUT I AM ROSIE BARRERO, AND I HAVE RETINITIS PIGMENTOSA. AND I WAS DIAGNOSED A LITTLE OVER 20 YEARS AGO. AND I HAD NEVER HEARD THAT WORD UNTIL THAT DAY 20 YEARS AGO, AND I HAPPENED TO BE PREGNANT WITH MY TWINS AND FEELING VERY EXCITED ABOUT BEING A MOM, BUT THEN LEARNING THAT I WOULD LOSE MY SIGHT WAS HEARTBREAKING. AND I DIDN'T DO ANYTHING ABOUT IT. I DIDN'T THINK THAT THERE WAS EVER GOING TO BE CURE. I DECIDED TO JUST CONTINUE MY LIFE AND BE A MOM AND RAISE OUR THREE KIDS. AND ONE OF OUR TWINS ENDED UP WITH AUTISM AND SEIZURE DISORDER AS WELL AS MILD CEREBRAL PALSY, SO HE IS MEDICALLY FRAGILE. AND THE HOPE OF REGAINING MY SIGHT WAS SO IMPORTANT BECAUSE HE HAS THOSE NEEDS.

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AND JUST BEING HERE, I'M SO GRATEFUL. EVERYONE THAT I'VE MET HERE IS AMAZING. AND THEY WERE SAYING, "OH, I'M SO SORRY YOU HAVE TO WAIT." AND I'M THINKING, "ARE YOU KIDDING ME? I'M THE ONE THAT IS SO GRATEFUL TO BE HERE." THANK YOU SO VERY MUCH FOR THIS OPPORTUNITY. JUST THANK YOU.

AND BEING IN THE CLINICAL TRIAL, IT HAS MADE A DIFFERENCE. I'M STILL AFRAID OF PUBLIC SPEAKING, AND EARLY ON IT WAS MUCH EASIER BECAUSE I COULDN'T SEE ANY OF YOU. BUT HELLO, EVERYBODY. I CAN SEE YOU GUYS. I CAN SEE THIS ROOM. I CAN SEE A LOT OF THINGS. I CAN SEE COLORS. I CAN SEE MOVIES. I SAW A DOCUMENTARY. IT WAS CALLED IRIS, AND IT WAS ABOUT THIS AMAZING INTERIOR DESIGNER SLASH FASHION ICON. I WAS SO INSPIRED BY HER, THAT I WANT TO BUY EVERYTHING SPARKLEY AND COLORFUL. I ALSO SAW *LA LA LAND*. LOVE IT. I'M GOING TO BUY IT.

AND THERE WAS SOMETHING ELSE THAT WAS JUST REALLY SIGNIFICANT. JUST BEING ABLE TO SHARE ALL THOSE THINGS WITH MY FAMILY AND MY HUSBAND, WHO'S OVER THERE. I'M SURPRISED HE'S NOT RIGHT HERE, BUT HE SAID, "NO. THIS IS YOUR THING. YOU NEED TO DO IT." AND I'M JUST FEARFUL, BUT I'M JUST HAPPY TO BE MOVING FORWARD AND TO HAVE MY VISION CONTINUE TO GET BETTER. IT'S BEEN A YEAR AND A HALF, AND I'M STILL

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SEEING PROGRESS IF YOU CAN BELIEVE IT. IT'S AMAZING. IT'S JUST AMAZING. AND NOW I'M GOING INTO THE SECOND PHASE OF THAT CLINICAL TRIAL, AND I WILL RECEIVE A SECOND STEM CELL INJECTION IN MY OTHER EYE HOPEFULLY, GOD WILLING, KNOCK ON WOOD, AND THAT JUST MEANS I WILL SEE MORE OF YOU.

AND I WON'T TAKE ANY MORE OF YOUR TIME, BUT THANK YOU SO MUCH FOR ALLOWING ME TO SPEAK TO YOU.

(APPLAUSE.)

MR. TORRES: ROSIE, YOU'RE SUCH AN INSPIRATION. AND YOUR HUSBAND, WHO I'VE KNOWN FOR MANY YEARS, AND YOUR FAMILY WERE CONSTITUENTS OF MINE IN LOS ANGELES. BUT PEOPLE IN THE ROOM NEED TO KNOW THAT THIS IS A LOVE STORY, AND THESE TWO PEOPLE OBVIOUSLY FELL IN LOVE. AND SO TO SEE THE DEDICATION AND THE COMPASSION AND THE LOVE BETWEEN THEM IS JUST EXTRAORDINARY. SO I JUST WANT TO THANK YOU FOR BEING THE INSPIRATION FOR US TO CONTINUE THIS WORK, ROSIE.

(APPLAUSE.)

CHAIRMAN THOMAS: WELL SAID. THANK YOU VERY MUCH, SENATOR TORRES. AND THANK YOU, ROSIE, VERY MUCH FOR YOUR COMMENTS.

SO THAT CONCLUDES THE AGENDA. I HAD A

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COUPLE OF ADDITIONAL COMMENTS. ONE IS I WANT TO MAKE SURE WE THANK -- THIS IS THE INAUGURAL EFFORT HERE TO HAVE THE MEETING IN OUR OFFICES, WHICH I FEEL HAS BEEN A GREAT SUCCESS. I THINK THE SETTING IS GREAT. I THINK THE MIKING, WHICH WE CONTINUE TO HAVE PROBLEMS WITH VIRTUALLY EVERY PLACE, IS SPECTACULAR HERE. AND I JUST WANT TO SINGLE OUT AMY, DOUG, JUSTIN, BILL, AND ANYBODY ELSE THAT I'M FORGETTING HERE. MANDA, THANK YOU. IT'S JUST WONDERFUL. WE APPRECIATE IT. MANDA, IS MANDA HERE? OKAY. I WAS GOING TO SAY SOMETHING ABOUT THE SEAL WITH THE GIANTS UNIFORM SITTING IN MY OFFICE THAT MANDA PUT THERE. SINCE SHE'S NOT HERE, I'M NOT GOING TO BRING THAT UP. SO THANK YOU, EVERYBODY, FOR YOUR VERY HARD WORK.

SECONDLY, RECOMMEND THAT YOU TAKE A GOOD LOOK AT OUR ANNUAL REPORT WHICH YOU HAVE BEFORE YOU IN ENGLISH AND SPANISH. IT IS A TERRIFIC DOCUMENT. THE COMMUNICATIONS TEAM LED BY MARIA AND KEVIN AND KAREN AND TODD AND EVERYBODY INVOLVED WITH THIS SPENT AN ENORMOUS AMOUNT OF TIME TO PRODUCE THIS DOCUMENT UNDER RANDY'S GUIDANCE. AND I THINK THAT ANYBODY WHO SEES THIS GETS A GREAT REAL-TIME FEEL FOR THE TERRIFIC WORK THAT THE AGENCY IS DOING AND THE PROMISE THAT WHAT WE'RE DOING HOLDS GOING

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FORWARD. SO WOULD INVITE YOU TO TAKE NUMEROUS COPIES, GIVE IT TO YOUR FRIENDS AND FAMILY. PEOPLE ALWAYS ENJOY LOOKING AT THAT. SO CONGRATULATIONS AND THANK YOU FOR ALL THE HARD WORK.

SO I THINK WITH THAT, OUR NEXT IN-PERSON MEETING IS IN JUNE; IS THAT CORRECT?

MS. BONNEVILLE: YES.

CHAIRMAN THOMAS: AND WE WILL BE HAVING THE MONTHLY MEETINGS TELEPHONICALLY GOING FORWARD BETWEEN NOW AND THEN. THANK YOU VERY MUCH, EVERYBODY, FOR COMING. WELCOME AGAIN, CHANCELLOR BLUMENTHAL. AND THE MEETING, SUBJECT TO MARIA MAKING A COMMENT --

MS. BONNEVILLE: DIANE, ARE YOU ON THE LINE? HOW ABOUT JOE? I DON'T NEED ANYTHING AFTER ALL.

CHAIRMAN THOMAS: THANK YOU AGAIN, FOLKS. THE MEETING STANDS ADJOURNED. THANK YOU.

(THE MEETING WAS THEN ADJOURNED AT 02:10 P.M.)

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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 PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
1999 HARRISON STREET
SUITE 1650
OAKLAND, CALIFORNIA
ON
FEBRUARY 23, 2017

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

BETH C. DRAIN, CA CSR 7152
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