BEFORE THE

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

REGULAR MEETING

LOCATION:	HYATT REGENCY SAN FRANCISCO AIRPORT, CYPRESS ROOM
DATE:	JANUARY 25, 2024 9 A.M.
REPORTER:	BETH C. DRAIN, CA CSR CSR. NO. 7152
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I N D E X (CONT'D.)

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JANUARY 25, 2024; 9 A.M.

CHAIRMAN IMBASCIANI: THANK YOU. GOOD MORNING, EVERYONE. GOOD MORNING TO THE MEMBERS OF THE INDEPENDENT CITIZENS OVERSIGHT COMMITTEE, THE BOARD FOR CIRM. WELCOME TO MEMBERS OF THE PUBLIC IN ATTENDANCE. I'D LIKE TO CONVENE INTO ORDER TODAY'S BOARD MEETING. AND WE'RE GOING TO START IF SCOTT WOULD PLEASE CALL -- COULD YOU PLEASE CALL US TO ORDER WITH A ROLL CALL VOTE OF ATTENDANCE.

MR. TOCHER: SURE. HAIFAA ABDULHAQ. MOHAMED ABOUSALEM. KIM BARRETT.

DR. BARRETT: PRESENT.

MR. TOCHER: DAN BERNAL. GEORGE BLUMENTHAL. MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: MICHAEL BOTCHAN.

DR. BOTCHAN: PRESENT.

MR. TOCHER: JUDY CHOU. LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: PRESENT.

MR. TOCHER: HAL COLLARD.

DR. COLLARD: PRESENT.

MR. TOCHER: DEBORAH DEAS.

DR. DEAS: HERE.

MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: PRESENT.
MR. TOCHER: YSABEL DURON.
MS. DURON: HERE.
MR. TOCHER: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: HERE.
MR. TOCHER: FRED FISHER.
DR. FISHER: PRESENT.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MR. TOCHER: JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: LARRY GOLDSTEIN. DAVID HIGGINS.
DR. HIGGINS: PRESENT.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: PRESENT.
MR. TOCHER: STEPHEN JUELSGAARD.
MR. JUELSGAARD: HERE.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: PRESENT.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: PRESENT.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: HERE.

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MR. TOCHER: SHLOMO MELMED.
DR. MELMED: HERE.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: PRESENT.
MR. TOCHER: LAUREN MILLER-ROGEN. ADRIANA PADILLA.
DR. PADILLA: HERE.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: HERE.
MR. TOCHER: JOYCE SACKEY.
DR. SACKEY: PRESENT.
MR. TOCHER: MARVIN SOUTHARD. SUZANNE SANDMEYER. KEVIN XU. MICHAEL STAMOS.
DR. STAMOS: HERE.
MR. TOCHER: GEORGE BLUMENTHAL.
DR. BLUMENTHAL: PRESENT.
MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: HERE.
MR. TOCHER: WE'RE GOOD TO GO.

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CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

MAY I ASK THE MEMBERS IN ATTENDANCE HERE TO PLEASE STAND AND FACE THE COLORS.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH. WE HAVE A JAMPACKED AND VERY INTERESTING MEETING PLANNED FOR YOU TODAY WITH REPORTS ON THE PRESIDENTIAL SEARCH COMMITTEE, AN N OF 1 PROPOSAL, CLINICAL TRIALS, FINANCIAL AND PERFORMANCE AUDITS, CONCEPT PLAN REGARDING THE COMMUNITY CARE CENTERS OF EXCELLENCE, AND PARTICIPATION FROM INTERESTED MEMBERS OF THE PUBLIC.

FIRST OF ALL, I WANT TO TELL YOU HOW DELIGHTED EVERYONE AT CIRM IS TO WELCOME BACK TO OUR OFFICES AND TO HIS NEW ROLE JONATHAN THOMAS AS INTERIM CEO AND PRESIDENT OF CIRM. HE BEGAN THIS NEW PERFORMANCE OF HIS EARLY IN THE NEW YEAR. HE DOVE RIGHT IN, AND I'M GOING TO ALLOW HIM IN A SECOND IN THE PRESIDENT'S REPORT TO INFORM US ALL OF HIS MANY ACTIVITIES. AS FAR AS I CAN TELL, HE'S VERY, VERY INVOLVED. HE'S GOTTEN A GREAT RECEPTION FROM EVERYONE AND ALL THE TEAMS AT CIRM.

I THINK THE BIGGEST CHALLENGE FROM HIM IS THAT I OBSERVED IS WHEN HE GETS OFF THE ELEVATOR NOW ON THE FOURTH FLOOR, HE HAS TO TURN LEFT INSTEAD OF

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RIGHT TO GO TO HIS NEW OFFICE, BUT EVERYTHING IS GOING WELL. AND AS I PROMISED THE BOARD, I TRY TO BE IN THE OFFICE THE SAME TIMES THAT HE IS THERE. AND WE HAVE REGULAR COMMUNICATIONS BETWEEN BOTH SIDES OF THE HOUSE.

I'M GOING TO SHARE PART OF MY REPORT WITH VICE CHAIR BONNEVILLE, WHO WILL SPEAK IN A SECOND, ON ISSUES RELATED TO THE AAWG AND ON GOVERNMENT RELATIONS UPDATE.

BUT I DO WANT THE BOARD TO REALIZE WHAT A JAMPACKED MONTH IS COMING UP. ON JANUARY 30TH THE SECOND PART OF GRANTS WORKING GROUP WITH CONVENE. NOTICE IT'S THE SECOND DAY. IT'S TESTIMONY TO HOW MANY APPLICATIONS ARE COMING IN THAT HAVE TO BE REVIEWED BY OUR GRANTS REVIEW TEAM.

THERE'S ALSO GOING TO BE A MEETING OF THE MANUFACTURING STEERING COMMITTEE LATE IN JANUARY, PART OF THE INFRASTRUCTURE 5 PROGRAM. YOU WILL RECALL THIS BOARD APPROVED BACK IN DECEMBER NINE BUSINESS DEVELOPMENT AWARDS. AND THE AWARDEES, IF YOU WILL, FORM THE STEERING COMMITTEE. AND IT'S THAT COMMITTEE THAT WILL MEET ON JANUARY 30TH.

ON FEBRUARY 8TH THE REGULAR MEETING OF THE ACCESS AND AFFORDABILITY WORKING GROUP. ON FEBRUARY 9TH AT THE ASILOMAR CONVENTION CENTER, THERE IS A

MEETING THAT CIRM HAS FUNDED THAT HAS BEEN ORGANIZED BY THE KEYSTONE SYMPOSIUM SERIES, THE TITLE AND THEME OF WHICH IS "STEM CELL MODELS FOR EMBRYOLOGY." IT'S AN UPDATE ON HUMAN DEVELOPMENTAL BIOLOGY AND THE USE OF HUMAN EMBRYOIDS. AND ATTENDEES ARE COMING TO THIS CIRM-SPONSORED EVENT FROM ALL OVER THE WORLD, AND WE'LL HAVE A DELEGATION IN ATTENDANCE ALSO.

IN THE MIDDLE OF FEBRUARY ON THE 15TH AND 16TH IS A TWO-DAY GRANTS WORKING GROUP TO DISCUSS FUNDAMENTAL AWARDS IN THE DISC DISCOVERY ZERO PROGRAM THAT WERE PROMPTED BY PROPOSITION 14 FOR THE PURPOSE OF SUPPORTING REGENERATIVE MEDICINE, CELL AND GENE THERAPY.

THE ARS AND THE ICOC WILL MEET TO CONSIDER GRANTS ON FEBRUARY 22, AND ON FEBRUARY 23 THE SECOND MEETING THIS YEAR OF THE CONTROLLER'S AUDIT GROUP, IF YOU WILL, THE CFAOC.

WITH THAT, I'M GOING TO PASS THE GAVEL TO VICE CHAIR BONNEVILLE FOR HER REPORT.

VICE CHAIR BONNEVILLE: THANK YOU, VITO. I JUST WANTED TO UPDATE THE BOARD. IN MARCH, MARCH 20TH, VITO AND I WILL BE GOING UP TO SACRAMENTO TO TALK TO A HANDFUL OF LEGISLATORS ABOUT CIRM AND ALL THE GOOD WORK WE'RE DOING AND REMIND THEM THAT WE'RE

HERE AND HAVE MADE SO MUCH PROGRESS OVER THE LAST 20 YEARS. CAN YOU BELIEVE IT WILL BE 20 YEARS IN NOVEMBER?

AS VITO MENTIONED, WE HAVE AN ACCESSIBILITY AND AFFORDABILITY WORKING GROUP MEETING ON FEBRUARY 8TH WHERE WE WILL BE REVIEWING THE APPLICATIONS FOR THE PATIENT SUPPORT SERVICES PROGRAM. AND THOSE WILL BE COMING TO THE BOARD IN MARCH FOR A VOTE AND APPROVAL.

AND WE CONTINUE TALKING TO DIFFERENT POLICY FOLKS AND LOBBYISTS IN DC TO DETERMINE WHAT OUR PRESENCE THERE SHOULD BE. AND WE'LL UPDATE YOU WITH MORE ON THAT ONCE WE HAVE A REQUEST FOR A PROPOSAL AND THEY COME IN. SO THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, VICE CHAIR.

SO IT'S WITH GREAT PLEASURE WE GIVE YOU BACK AGAIN JONATHAN THOMAS FOR THE PRESIDENT'S REPORT.

DR. THOMAS: MR. CHAIRMAN, MADAM VICE CHAIR, DISTINGUISHED MEMBERS OF THE BOARD, AND ALL THE MEMBERS OF THE CIRM FAMILY, IT IS A DISTINCT PLEASURE, UNEXPECTED, TO BE BACK WITH YOU NOW IN THIS NEW CAPACITY. AS I NOTED AT THE END OF MY CHAIR TENURE IN MARCH, I'VE ALWAYS VIEWED THE

OPPORTUNITY TO SERVE THE TAXPAYERS OF CALIFORNIA AS PART OF THE CIRM FAMILY AS THE GREATEST PRIVILEGE OF MY PROFESSIONAL CAREER, AND I WAS DELIGHTED TO BE ASKED TO COME BACK IN THIS NEW CAPACITY TO LEAD THE TEAM AND TO CONTINUE CIRM'S GREAT WORK APACE.

I ALSO WANT TO THANK ALL OF YOU FOR THE OPPORTUNITY OF PUTTING ME IN A POSITION NOW TO HAVING OFFICIALLY TO REPORT TO MARIA, WHICH, AS I'VE NOTED TO A NUMBER OF YOU, IS REALLY NO DIFFERENT THAN IT ALWAYS WAS.

SO I'D BE REMISS IN MY REMARKS HERE IF I DIDN'T OPEN WITH GIVING THANKS TO MY PREDECESSOR, DR. MARIA MILLAN, WHO SERVED WITH GREAT DISTINCTION FOR MANY YEARS, FIRST AS VP OF THERAPEUTICS AND THEN AS OUR CEO AND PRESIDENT, AND LEADING CIRM TO THE POINT WHERE IT IS TODAY. MARIA WAS A TIRELESS WORKER, A TRUE ADVOCATE OF THE MISSION, WAS A GREAT PRESENCE THROUGHOUT THE NATION ON BEHALF OF CIRM AND THROUGHOUT CALIFORNIA WITH ALL OF OUR MANY GRANTEES OVER THE YEARS, AND REALLY, REALLY DID YEOMAN'S WORK TIRELESSLY IN A FASHION THAT REDOUNDED TO CIRM'S BENEFIT.

SO I WANT TO -- I DON'T KNOW IF MARIA IS WATCHING, BUT IF YOU ARE, THANK YOU FOR EVERYTHING YOU DID FOR CIRM, FOR PATIENTS EVERYWHERE, AND FOR

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THE PEOPLE OF CALIFORNIA FOR WHOM WE ARE PERFORMING OUR DAILY DUTIES TO ADVANCE OUR WONDERFUL MISSION.

SO ONE OF THE NICE THINGS ABOUT COMING INTO THIS JOB FROM MY PREVIOUS JOB IS I WAS ABLE TO HIT THE GROUND RUNNING, NOT A LOT OF EDUCATION NECESSARY TO IDENTIFY WHERE THINGS STAND. AND SO WE SET TO IT IMMEDIATELY WITH THE MEMBERS OF THE LEADERSHIP TEAM AND HAVE SET ABOUT IDENTIFYING ISSUES AND THINGS THAT WE NEED TO ADDRESS TO TAKE WHAT IS ALREADY A TREMENDOUS OPERATION WITH AN A-PLUS PRODUCT TO EVEN GREATER HEIGHTS.

AND SO WE HAVE HAD A NUMBER OF DISCUSSIONS, HAVE ZEROED IN ON SEVERAL AREAS WHERE WE COULD USE SOME IMPROVEMENT AND ARE GETTING AFTER IT. AND THOSE TOPICS WILL FORM THE BASIS FOR VARIOUS DISCUSSIONS WITH BOARD MEMBERS. THEY'VE ALREADY STARTED IN VARIOUS SUBCOMMITTEES AND TASK FORCES AND WILL END UP THE SUBJECT MATTER OF DISCUSSIONS THAT WE'RE GOING TO BE HAVING HERE AT THE BOARD IN THE NOT TOO DISTANT FUTURE.

BUT THE THING I WANT TO SAY IS AS CHAIR, AS WE ALL RECALL, WOULD TIRELESSLY PAY HOMAGE TO THE WONDERFUL TEAM THAT WE HAVE AT CIRM. AND VIEWING IT FROM A CHAIR'S PERSPECTIVE, THAT WAS ALWAYS MY TAKE. NOW BEING IN THE POSITION OF LEADING THE TEAM AND

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SEEING THEM AT EVEN CLOSER ACTION, I CAN REPORT TO THE BOARD THAT THEY'RE EVEN BETTER THAN WE THOUGHT VIEWING IT FROM THE PERSPECTIVE OF THE BOARD ITSELF. IT'S A WONDERFUL TEAM THAT IS SUPREMELY CAPABLE, AND I'VE SET FORTH TO THEM MY VISION OF HOW WE SHOULD OPERATE AS A COLLABORATIVE UNIT AND HOW I THINK, FROM A CEO'S PERSPECTIVE, THINGS SHOULD PROCEED FROM THIS POINT, AT LEAST HOWEVER LONG I'M IN THIS POSITION.

AND I CAN REPORT TO YOU THAT THE RECEPTION HAS BEEN VERY POSITIVE. I THINK THERE'S GREAT ENERGY AMONGST ALL MEMBERS OF THE TEAM. I HAD OCCASION TO SPEAK TO EVERYBODY ORGANIZATIONWIDE AND TO GIVE MY OPENING THOUGHTS. I WILL TELL YOU PARENTHETICALLY I WAS DELIGHTED THAT APRIL ON JENN'S TEAM ACTUALLY ASKED ME, PERHAPS INNOCENTLY, IF THIS MEANT I AM A GIANTS, WARRIORS, AND 49ERS FAN. I NEEDN'T TELL YOU WHAT MY ANSWER WAS. THE SHORT FORM WAS NO. AND THEN, OF COURSE, I TOOK THE OPPORTUNITY TO GO ON AT SOME LENGTH ELABORATING ON WHY THAT WAS THE CASE. BUT SPENT TIME TALKING, WANDERED AROUND, TALKED TO MEMBERS OF THE TEAM. THEY ALL KNOW MY DOOR IS ALWAYS OPEN. THEY ALL KNOW I AM HAPPY TO DISCUSS ANY SUGGESTIONS THAT THEY MAY HAVE. AND I THINK WHAT YOU ARE GOING TO SEE IS A WORK PRODUCT

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FROM ALL OF US THAT WILL BE SOMETHING FURTHER THAT WE CAN BE PROUD OF AS AN ENTIRE ORGANIZATION.

SO DELIGHTED TO BE HERE. I WANT TO SAY THAT, IN ADDITION TO DEALING WITH INTERNAL MATTERS, I'VE ALREADY GOTTEN AFTER IT ON INTERFACING WITH LONGTIME FRIENDS WHO ARE EXPERTS IN THE STEM CELL COMMUNITY AT LARGE. WE HAD, FOR EXAMPLE, A MEETING THE WEEKEND BEFORE JP MORGAN THAT IS AN ANNUAL EVENT DOWN AT SAND HILL ROAD WHICH CONVENES ACADEMICS, INVESTORS, COMPANIES, AND LUMINARIES FROM THE STEM CELL SPACE AT WHICH WAS ABLE TO SPEAK, HAVE SIDE BARS WITH DR. PETER MARKS, THE DIRECTOR OF CEBR, WHO IS A VERY IMPORTANT GUY FROM THE STANDPOINT OF ALL OF THOSE GRANTEES THAT WE FUND, HAD SORT OF AN INTERESTING DISCUSSION ON THE NOTION OF STEM CELL TOURISM AND HAVE AN IDEA I'M PUSHING WITH HIM AND HIS OFFICE. AND WE WILL SEE HOW THAT GOES. I THINK IT COULD VERY POSSIBLY HAVE SOME LEGS.

WE HAD DEANS OF MEDICAL SCHOOLS, MANY REPRESENTATIVES FROM THE EAST COAST, IN THE STEM CELL COMMUNITY WHO CONTINUE TO BE HIGHLY ENVIOUS OF CALIFORNIA BECAUSE OF ALL OF THE GREAT TALENT WE HAVE UP AND DOWN THE STATE AND THE GREAT LUXURY OF THE FUNDING TO ENABLE THEM TO DO WHAT THEY DO.

THIS PARTICULAR EVENT IS ONE THAT I ENJOY

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EVERY YEAR. AND THEY ALWAYS SAY THAT EVERY YEAR, AND I ALWAYS GET A BIG SMILE ON MY FACE EVERY YEAR. SO THIS WAS NO EXCEPTION. SO IT WAS GREAT TO SEE THEM.

WE'VE HAD JP MORGAN CONFERENCE WHICH FOLLOWED SUBSEQUENTLY, HAD A NUMBER OF MEETINGS THERE, INCLUDING WITH SOME BIG PHARMA, TO TALK ABOUT WHAT CIRM DOES WITH VENTURE FIRMS, TO TALK ABOUT OUR PORTFOLIO, AND HOW WE MIGHT INTERFACE AND GET FURTHER INTRODUCTIONS OF VENTURE PEOPLE TO OUR COMPANIES, WHO ARE, AS YOU KNOW, NOW IN A BIT OF A DIFFICULT TIME RAISING MONEY GIVEN THE ENVIRONMENT FOR BIOTECH IN GENERAL.

SO A LOT OF STUFF GOING ON. AND I THINK THAT THE FIRST THREE AND A HALF WEEKS HAS BEEN VERY BUSY. IT'S BEEN VERY REWARDING. I WASN'T SURE HOW I WAS GOING TO VIEW BEING IN THIS POSITION HAVING BEEN ON THE OTHER FOR 12 YEARS, BUT I'M DELIGHTED AND ALREADY CAN SEE THAT WE'RE GOING TO DO GREAT THINGS AND CONTINUE TO DO GREAT THINGS. SO I THANK EVERYBODY FOR THAT OPPORTUNITY.

I DO WANT TO GET BACK TO JUST THIS THING WITH MARIA. I'D JUST LIKE TO POINT OUT THAT THINGS HAVEN'T CHANGED MUCH AT ALL. SHE SEES ME IN THE HALL, INSTEAD OF SAYING SOMETHING KIND OF NICE LIKE

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NICE SUIT, SHE SAYS, "YOU'RE WEARING A SUIT. IT'S FREAKING ME OUT." SO SOME THINGS NEVER CHANGE.

SO IN CONNECTION WITH JP MORGAN WEEK, THE ALLIANCE FOR REGENERATIVE MEDICINE ALWAYS DOES A KICKOFF FIRST THING MONDAY MORNING THAT IS A STATE OF THE UNION SPEECH WITH RESPECT TO WHERE THE INDUSTRY IS AT THIS PARTICULAR POINT IN TIME. AND IT'S ALWAYS INTERESTING TO LISTEN TO BECAUSE YOU GET A PERSPECTIVE OF HOW -- THAT ALLIANCE IS THE TRADE ASSOCIATION PRINCIPALLY FOR FOR-PROFIT COMPANIES IN THE CELL AND GENE THERAPY SPACE. YOU GET THEIR PERSPECTIVE ON WHERE THINGS STAND. THEY DO A QUICK POWERPOINT THAT I THOUGHT MIGHT BE INTERESTING FOR THE BOARD BECAUSE IT HAS SOME STATS THAT ARE RELEVANT TO THIS ISSUE OF WHERE THINGS STAND. SO IF YOU WOULD BEAR WITH ME FOR A MINUTE, I'D LIKE TO SHOW YOU THESE.

THIS PARTICULAR SET OF SLIDES HAPPENS TO HAVE A FAIRLY SINGULAR FOCUS ON RARE DISEASE, WHICH IS, OF COURSE, JUST ONE COMPONENT OF EVERYTHING WE DO. BUT I THINK YOU WILL FIND SOME OF THESE STATS INTERESTING. SO HERE WE GO. PRESENTATION FROM THE ALLIANCE FOR REGENERATIVE MEDICINE.

SO THIS WAS THEIR LINEUP. THEIR CEO GAVE THIS TALK THAT I'M ABOUT TO GIVE YOU. IT THEN

SWITCHED TO PETER MARKS, WHO I REFERENCED WAS AT THE EVENT THE NIGHT BEFORE, WHO GAVE A TALK ON ACCELERATING THE DEVELOPMENT OF PRODUCT. AND THEN A MOST INTERESTING PANEL CONSISTING OF A MODERATOR AND THE TWO GENTLEMEN YOU SEE THERE WHO ARE THE CEO'S OF CRISPR THERAPEUTICS AND BLUEBIRD BIO, WHICH WITHIN THE TWO WEEKS PREVIOUS HAD JUST GOTTEN APPROVAL FROM THE FDA FOR THEIR SICKLE CELL THERAPIES AND AS SUCH WERE ABLE TO PROVIDE REALLY INTERESTING INSIGHTS INTO WHERE THEY SEE THE INDUSTRY. AND THEY TALKED, TO THE EXTENT THEY COULD WITHOUT GIVING ANYTHING AWAY, ABOUT SORT OF WHAT THEIR PRODUCT IS AND HOW IT'S DIFFERENTIATED FROM OTHERS.

I WOULD RECOMMEND TO YOU THAT, IF YOU HAVE THE TIME, I'M SURE THAT PANEL WAS ON YOUTUBE. YOU CAN GET IT OFF THE ARM SITE, AND IT'S WORTH WATCHING BECAUSE I THINK YOU GET SOME -- THESE ARE OBVIOUSLY PEOPLE AT THE TOP OF THEIR GAME IN THE FIELD WITH PERSPECTIVES THAT ARE WORTH HEARING.

SO THIS IS JUST A LITTLE PIECE OF PR FOR ARM, WHICH YOU CAN SORT OF THUMB THROUGH QUICKLY, WHICH IS 400 PLUS MEMBERS ALL OVER THE WORLD. AND YOU CAN SEE THE THEMES THAT THEY'RE EMBRACING AS THEY GO ABOUT THEIR WORK. THEY'RE A VERY PROMINENT PLAYER IN ADVOCACY IN WASHINGTON, D.C., ON BEHALF OF

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THE INDUSTRY. AND WE'VE WORKED WITH THEM IN VARIOUS CAPACITIES OVER THE YEARS FROM TIME TO TIME AND HAVE HAD A LOT OF INPUT. OUR VIEWS ON THINGS PERTAINING TO THE SPACE OBVIOUSLY CARRY CONSIDERABLE WEIGHT.

THIS IS A PAGE MEANT TO SORT OF SPOOK EVERYBODY. TALK ABOUT ALL THE HEADLINES THAT HIGHLIGHTED THE CHALLENGES OF CELL AND GENE THERAPY WHICH THEY'VE SEEN OVER THE PAST YEAR OR SO DEALING WITH DIFFICULTIES IN DEVELOPING AND THE EXPENSE AND PAYORS AND ALL THAT STUFF. THEN, OF COURSE, THAT TEES UP WHAT THEIR MAIN POINTS WERE, WHICH IS, IN FACT, THAT THINGS ARE PROGRESSING IN THE CELL AND GENE THERAPY SPACE. THEY CALL IT CGT. AND THEY HAVE THREE CATEGORIES OF WAYS THAT THEY WANT TO SHOW THAT THAT IS THE CASE.

THE FIRST ONE IS BREAKTHROUGHS ARE BECOMING THE NORM. AND WE GET TO THIS SLIDE WHERE IN FIVE YEARS, FROM 2017 TO 22, THE FDA APPROVED FIVE GENE THERAPIES FOR RARE, AGAIN THIS IS MORE OF AN EMPHASIS ON RARE DISEASE, RARE GENETIC DISEASES. YOU CAN SEE THAT, IN ADDITION TO THAT, THEY HAD PROPOSED THAT THERE WAS GOING TO BE AN EXPONENTIAL EFFECT IN TERMS OF APPROVALS IN SUBSEQUENT YEARS. AND, IN FACT, IN 2023 YOU HAD FIVE ADDITIONAL APPROVALS FOR THE CONDITIONS YOU SEE LISTED THERE

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JUST IN THAT YEAR ALONE. SO THERE WAS A MARKED ADVANCE IN THIS MARCH TO COMMERCIALIZATION, WHICH IS SOMETHING THAT IS SORT OF THE END GOAL FOR EVERYBODY AND CERTAINLY SOMETHING THAT WE NEED TO FOCUS ON AS AN ORGANIZATION. HOW ARE WE FUNDING THINGS THAT ARE GOING TO ULTIMATELY GET TO PATIENTS? SO THIS WAS SORT OF AN INTERESTING STAT.

IT LISTS HERE THAT YOU CAN SEE THE CONDITIONS THAT WERE APPROVED, WHICH IS QUITE AN INTERESTING LIST AND GROWING EVERY YEAR. THE BULK OF THESE WERE IN THE U.S., ONE WAS IN EUROPE, BUT YOU CAN SEE THAT THIS LIST A YEAR AGO WAS A LOT SHORTER. AND SO THE MAIN TAKEAWAY IS THAT GREAT WORK IS AT LAST FINALLY MAKING IT TO MARKET WHICH HAS TAKEN A WHILE. STEM CELLS WERE A BRAND NEW INDUSTRY. AND AS WITH ANY NEW INDUSTRY, IT TOOK A NUMBER OF YEARS TO GET TO WHERE YOU CAN COMMERCIALIZE PRODUCTS. SO THIS IS THE FRUIT OF THAT FOR THE YEAR 2023.

THEN THEY HAVE THESE STATS SO HOW MANY PRODUCTS ARE IN DEVELOPMENT, HOW MANY IN CLINICAL TRIALS, THE TOTAL INVESTMENT IN THE SECTOR, WHICH LAST YEAR WAS 11.7 BILLION, WHICH IS IMPRESSIVE. BY THE WAY, THE PRINCIPAL FOCUS ON THIS IS IN THE FOR-PROFIT SPACE, BUT OBVIOUSLY IT FACTORS IN OTHER

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WORK AS WELL.

FROM A REGULATORY PERSPECTIVE FOR THIS YEAR, THEY PREDICT UP TO 17 NEW PRODUCTS COULD BE IN THE U.S. AND EUROPE BROUGHT TO MARKET, WHICH WOULD, AGAIN, BE AN EXPONENTIAL JUMP FROM 2023 AND IS SORT OF WHAT YOU EXPECT GOING FORWARD. OBVIOUSLY THERE ARE LOTS OF BUMPS IN THE ROAD THAT CAN OCCUR FOR ANY OF THESE. THEY COULD END UP WELL NOT MAKING IT FOR ONE REASON OR ANOTHER, BUT THESE ARE THE ONES IN THE QUEUE THAT HAVE THE POTENTIAL TO MAKE IT TO MARKET.

THEY LIST THESE AS MILESTONES THAT COULD OCCUR IN 2024, WHICH YOU CAN SEE. ONE THAT IS SORT OF REALLY INTERESTING IS THE NOTION OF ALLOGENEIC T-CELL THERAPY, WHICH IS HERETOFORE CAR-T, AND ITS KIN HAVE ALL BEEN IN AUTOLOGOUS SPACE, WHICH HAS ITS CHALLENGES AND EXPENSES, ET CETERA. IF YOU, IN FACT, SUCCEED IN GETTING AN ALLOGENEIC PRODUCT TO MARKET, THAT WILL BE A BIG DEAL BECAUSE NOW YOU'RE TALKING OFF THE SHELF, AND THAT COULD BE A MAJOR ADVANCE.

IN CANCER THERAPY AND AT THE SAME TIME -- BY THE WAY, CAR-T, THEY'RE NOW MAKING A SERIOUS RUN IN ITS APPLICABILITY IN AUTOIMMUNE DISEASE OF VARIOUS KINDS AS WELL. I THINK WE WILL BE HEARING MORE AND MORE ABOUT THAT AS TIME GOES BY.

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THEN THESE DISEASES THAT THEY'VE HAD PRODUCTS FOR ALREADY THAT THERE ARE ADDITIONAL THERAPIES COMING TO MARKET: HEMOPHILIA, EPIDE -- SORRY. IT'S ALWAYS A MOUTHFUL. HELP ME OUT, ABLA -- EPIDERMOLYSIS BULLOSA. THANK YOU. YES. THERE WE GO. REPEAT THAT FIVE TIMES QUICKLY.

THEN THERE WAS THIS PREDICTION IN 2019 ABOUT HAVING 10 TO 20 THERAPIES PER YEAR APPROVED STARTING IN 2025. WE'RE SORT OF, IF WE HIT THE UP TO 17 NEXT YEAR, WE'RE GOING TO BE WELL WITHIN THAT PREDICTION AND WE WILL SEE. LOOK AT THIS CHART NEXT YEAR AND SEE WHAT THEY HAVE TO SAY ON THAT.

THEN THERE'S THE VALUE FOR PATIENTS AND SOCIETY, WHICH IS WHAT IT'S ALL ABOUT. THIS IS KIND OF INTERESTING. DO THESE QUOTES SOUND FAMILIAR? MOST EXPENSIVE DRUG SOLD IN THE U.S. THE PRICE THREATENS TO PUT THIS PROMISING TREATMENT OUT OF REACH OF MANY PATIENTS EVEN THOSE WHO ARE WELL INSURED. YOU HEAR THAT ALL THE TIME ABOUT WHAT WE'RE DEVELOPING. SO WHICH OF THE RECENT TREATMENTS THAT ARE EITHER JUST APPROVED OR WILL BE APPROVED IS THIS REFERRING TO? AND THE ANSWER IS NONE.

THIS IS ACTUALLY FROM 1991 WHEN THEY WERE TALKING ABOUT A TREATMENT BY GENZYME FOR GAUCHER'S DISEASE, WHICH AT THAT POINT WAS GIVEN A PRICE TAG

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OF $300,000, WHICH BY TODAY'S STANDARDS, GIVEN SOME OF THE PRICES WE'RE HEARING, WAS AN EXTREME BARGAIN EVEN ACCOUNTING FOR INFLATION.

BUT THE NOTION IS THIS REFRAIN HAS BEEN AROUND FOR MANY YEARS AND WILL CONTINUE BECAUSE, WHEN YOU CREATE WHAT ARE HOPEFULLY CURATIVE PRODUCTS THAT ARE GOING TO BE ONE TIME IDEALLY, THEY'RE GOING TO BE EXPENSIVE. AND THIS IS SOMETHING THAT WE'RE ALL GRAPPLING WITH AT THE MOMENT AND IS FUNDAMENTAL TO, AMONG OTHER THINGS, THE WORKINGS OF OUR ACCESSIBILITY AND AFFORDABILITY WORKING GROUP AS IT PROCEEDS ALONG IN ITS WORK.

ARM'S, THEY HAVE VARIOUS -- AGAIN, THESE ARE SORT OF TENETS OF THEIR POSITION, THAT THESE TREATMENTS, THOUGH PERHAPS EXPENSIVE, TARGET DEVASTATING, OFTEN DEADLY DISEASES. THEY ARE INCREDIBLY EXPENSIVE DISEASES. THEY ARE HIGHLY EFFECTIVE, WHEN YOU DO AN ANALYSIS, SAVE HEALTHCARE SYSTEMS A GREAT DEAL OF MONEY ONE TIME VERSUS REST OF YOUR LIFE, AND AT THE END OF THE DAY WILL BE AFFORDABLE. THAT OBVIOUSLY IS GOING TO TAKE SOME WORK AND A LOT MORE REVIEW AND THOUGHT BY THE PAYORS WHETHER IT'S THE GOVERNMENT OR PRIVATE SECTOR.

HERE, THIS IS AN EXAMPLE OF THE LIFESPANS OF PEOPLE WITH THESE HEINOUS DISEASES. YOU CAN SEE,

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SICKLE CELL, 45 TO 55; A FORM OF CEREBRAL DYSTROPHY, TEN YEARS; AND DUCHENNE'S MUSCULAR DYSTROPHY AT 22. SO THESE PEOPLE WITH THESE CONDITIONS HAVE HALF THE NORMAL LIFESPAN. AND SO THERE'S A LOT OF WORK BEING DONE ON THESE. AND THE LIFETIME COST OF ADMINISTERING THE THERAPIES THAT CURRENTLY EXIST YOU CAN SEE AT THE BOTTOM. AGAIN, THESE ARE SELECTIVE, ARE MANY MILLIONS OF DOLLARS, AND PLACE TREMENDOUS FINANCIAL STRAIN ON THE PATIENTS, THE FAMILIES, THE SYSTEM, ET CETERA. SO WHAT WE'RE ALL ABOUT IS COMING UP WITH STUFF THAT'S GOING TO BE ABLE TO ADDRESS THAT ISSUE.

A LOT OF THESE THINGS THAT ARE BEING PRODUCED, HIGHLY EFFECTIVE. AND THE STATS THERE, I'M NOT ENTIRELY SURE WHERE THESE ARE DERIVED FROM SINCE THEY AREN'T FOOTNOTED, BUT SUFFICE IT TO SAY THAT THEY TELL THE STORY THAT THE DRUGS HAVE, IN THIS CASE GENE THERAPIES, SHOULDN'T SAY DRUGS, GENE THERAPIES HAVE A REAL IMPACT IN TERMS OF YIELD AND COST SAVINGS, ET CETERA.

HERE WE GO. SYSTEM SAVES A LOT OF MONEY VERSUS LIFETIME EXPENDITURES. THEY ESTIMATE IN SICKLE CELL YOU'LL SAVE 2 MILLION PER PATIENT, HEMOPHILIA, 3 MILLION, VARIOUS OTHER THERAPIES YOU CAN SEE ARE SIMILAR IN SCOPE.

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AND THIS IS SORT OF AN INTERESTING PERSPECTIVE OF HOW THESE ARE AFFORDABLE. THEY TALK ABOUT NEWDIGS, BY THE WAY, A TUFTS MEDICAL SCHOOL INITIATIVE. IT'S SOME ACRONYM. I'M NOT QUITE SURE WHAT IT IS. IT'S ONE OF THOSE ACRONYMS THAT PULLS LETTERS FROM THE MIDDLE OF WORDS INSTEAD OF THE BEGINNING, BUT WHATEVER. SO THEY THINK THAT REVENUES JUST FROM GENE THERAPY ARE GOING TO REACH 7.5 BILLION IN 2030.

NOW, IT BEGS THE QUESTION, WHICH WE'RE IN THE MIDDLE OF ANALYZING RIGHT NOW, IS ULTIMATELY HOW MANY OF THESE THERAPIES ARE GOING TO MAKE IT TO COMMERCIALIZATION? HOW MANY ARE GOING TO HAVE SUCCESSFUL COMPANIES SET UP THAT CAN DEAL WITH THE ECONOMICS AND WHAT IT COSTS TO GET TO COMMERCIALIZATION, ET CETERA? SO THIS IS -- I THINK THERE ARE A NUMBER OF QUESTIONS THAT REMAIN TO BE SORTED OUT THAT AREN'T REPRESENTED IN THESE STATS.

BUT YOU CAN SEE HERE THAT THE POSITION IS THAT THIS IS GOING TO BE ULTIMATELY A MUCH MORE EFFICIENT, CHEAPER WAY TO GO AND MORE PRODUCTIVE FOR PATIENTS, WHICH IS, AFTER ALL, WHAT WE REALLY CARE ABOUT.

HERE'S ANOTHER STUDY DONE DEMONSTRATING COST OFFSETS, HOW IT'S MUCH MORE EFFICIENT AND

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CHEAPER TO ULTIMATELY HAVE THERAPIES THAT ARE ONE TIME AS OPPOSED TO OVER ONE'S LIFE.

AND I THINK I WENT BACK HERE. HOW DID THAT HAPPEN? I KNEW I'D HAVE SOME TECHNOLOGICAL CHALLENGE HERE AND THERE IT WAS. OKAY.

SO IT TALKS ABOUT U.S. HEALTHCARE SYSTEMS ARE GRAPPLING TO COME UP WITH HOW TO DEAL WITH ALL THIS STUFF. AND THIS IS AN EFFORT TO TALK ABOUT HOW CENTER FOR MEDICARE AND MEDICAID INNOVATIONS CGT ACCESS MODEL IS EVALUATING THE SITUATION RIGHT NOW. AND THIS IS, I THINK, A REAL OPPORTUNITY FOR CIRM BECAUSE, AS SORT OF THE WORLD'S LEADER IN FUNDING STEM CELL RESEARCH, WE HAVE A REAL CHANCE HERE TO GIVE INPUT INTO ALL OF THESE CONSIDERATIONS. AND MEMBERS OF OUR TEAM ARE BUSILY AT WORK AND HAVE BEEN CONTACTED VARIOUSLY BY DIFFERENT PEOPLE TO TALK ABOUT THAT.

WE JUST SUBMITTED A RESPONSE. GEOFF LOMAX WAS THE LEAD ON IT. IT WAS A REQUEST FOR INFORMATION ON THE SPACE, VARIOUS QUESTIONS PERTAINING TO THE SPACE BY THE SENATOR FROM LOUISIANA WHO'S TRYING TO GET A HANDLE ON THIS NEW INDUSTRY AS IT'S COMING INTO PLAY. I THINK IT WAS ALL MEMBERS OF THE TEAM HAD INPUT INTO THAT. I THINK IT WAS A VERY GOOD DOCUMENT, AND IT, AMONG

OTHER THINGS, WILL DEMONSTRATE, AS THEY READ THROUGH IT, THAT WE ARE PEOPLE THAT SHOULD BE IN THE DISCUSSION BECAUSE WE HAVE A REAL HANDLE ON THE GROUND ON WHAT'S GOING ON.

FDA IS PREPARING FOR THE WAVE THAT'S COMING. THIS IS JUST A BIT OF MINUTIAE ON THE HIGHLY QUALIFIED PEOPLE THAT ARE THERE AND THAT THEY KNOW THAT THIS IS, LIKE MONOCLONAL ANTIBODIES BEFORE IT, IT'S SOMETHING THAT NEEDS TO BE WORKED INTO THE OVERALL FDA FRAMEWORK. AND, AGAIN, WE ARE HAVING A REAL SAY IN THAT.

AND THIS IS JUST A THING ABOUT HOW ARM, ANOTHER LITTLE PR PIECE FOR ARM, ON BEHALF OF THE INDUSTRY. THE FDA ARE COLLABORATING TO PREPARE FOR THE FUTURE AND ALL OF THE ELEMENTS THAT INVOLVES. YOU CAN SEE THAT THERE. BY THE WAY, THIS WEBSITE, ARM HAS STUFF LIKE THIS ON THEIR WEBSITE ALL THE TIME. AGAIN, I WOULD RECOMMEND IT TO YOU.

SPECIFICALLY WITH RESPECT TO SICKLE CELL, BECAUSE THAT'S THE SUBJECT OF GREAT FANFARE AND GREAT NEWS WITH THE APPROVAL OF THE TWO RECENT THERAPIES WHICH WERE APPROVED IN DECEMBER, THIS IS JUST A LITTLE BIT OF COMMENTARY ON THAT. IT'S THE FIRST TIME, BY THE WAY, CRISPR HAS EVER BEEN USED IN A PRODUCT THAT IS NOW APPROVED FOR

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COMMERCIALIZATION, WHICH IS A BIG DEAL AS THAT WAS OBVIOUSLY ONE OF THE SEMINAL MEDICAL RESEARCH DEVELOPMENTS OF OUR TIME. IT'S NOW BEEN OVER TEN YEARS SINCE CRISPR WAS DISCOVERED, WHICH IS PRETTY IMPRESSIVE. HARD TO BELIEVE, BUT TRUE.

THEN THEY CLOSED WITH SOME GREAT QUOTES WITH RESPECT TO SICKLE CELL IN PARTICULAR WHICH YOU CAN SEE. ONE INTERVIEWEE IN THE *NEW YORK TIMES* COMMENTING IT MEANT A NEW BEGINNING. "IT IS MORE THAN I EVER DREAMED OF FOR EVERYTHING, THE SYMPTOMS TO BE GONE." SECOND, IN 2018 TALKING ABOUT THE PATIENT ON THE RIGHT RECEIVED AN AUTOLOGOUS GENE THERAPY TRANSPLANT. SHE WENT FROM EXPERIENCING DAILY PAIN AND SOMETIMES LIFE-THREATENING CONDITIONS TO HAVING MINIMAL OR NO PAIN. THIS IS THE PROMISE OF OUR TECHNOLOGY AND EVERYTHING WE COLLECTIVELY ARE STRIVING TO DO.

SO THAT WAS THE END OF THE ARM PRESENTATION. DON'T WANT TO GO BACK TO THE BEGINNING. IN ANY EVENT, I HOPE THAT WAS INTERESTING SORT OF AS A SET OF FRAMING STATEMENTS FOR ALL OF YOU ON WHERE WE ARE. SO THAT CONCLUDES MY PRESIDENT'S REPORT. SO HAPPY TO BE HERE, SEE EVERYBODY, AND REALLY LOOKING FORWARD TO PROCEEDING HERE AND DOING WHAT WE DO, WHICH IS GREAT WORK. SO

THANKS, EVERYBODY.

(APPLAUSE.)

CHAIRMAN IMBASCIANI: THANK YOU, INTERIM PRESIDENT AND CEO JONATHAN THOMAS. GREAT PRESENTATION.

WE'RE NOW GOING TO LOOK AT AGENDA ITEM 5 IF YOU WILL DIRECT YOUR ATTENTION THERE. KIM BARRETT, BOARD MEMBER BARRETT, IS GOING TO, AS CO-CHAIR OF THE PRESIDENTIAL SEARCH COMMITTEE, IS GOING TO LEAD THE DISCUSSION ON THE NEXT ITEM. THANK YOU.

DR. BARRETT: THANK YOU VERY MUCH, CHAIR IMBASCIANI. IT IS MY GREAT HONOR TO BE CO-CHAIRING THE SEARCH SUBCOMMITTEE FOR THE NEXT PRESIDENT AND CEO WITH GEORGE BLUMENTHAL. AND I WANT TO PROVIDE A BRIEF UPDATE AND PROGRESS THAT WE'VE MADE SINCE THE LAST BOARD MEETING.

SO YOU WILL REMEMBER AT THE LAST BOARD MEETING WE APPROVED A SET OF CHARACTERISTICS OF THE DESIRED NEXT PRESIDENT AND CEO. AND WITH THAT IN HAND, WE WERE THEN ABLE TO GO OUT AND ISSUE A REQUEST FOR PROPOSALS FROM EXECUTIVE SEARCH FIRMS TO ASSIST WITH THE SEARCH. AND EVEN THOUGH THIS TOOK PLACE OVER THE HOLIDAYS, WE WERE EXTREMELY PLEASED THAT THERE WAS A VERY ROBUST RESPONSE FOR THE RFP

WITH 12 FIRMS THAT TENDERED PROPOSALS. GEORGE AND I, WITH THE ASSISTANCE OF SCOTT AND MARIA, NARROWED THAT DOWN. ACTUALLY WE BOTH LOOKED AT THE FIRMS' PROPOSALS INDEPENDENTLY AND CAME UP WITH AN ALMOST IDENTICAL SHORT LIST.

OVER THE COURSE OF THE NEXT COUPLE OF WEEKS, WE INTERVIEWED FOUR OF THE FIRMS, ALSO FOLLOWED UP WITH THE FIRMS TO CLARIFY SOME ADDITIONAL QUESTIONS. I WILL SAY THAT THE TOP FIRMS WERE -- PROBABLY THREE OF THE FOUR THAT WE INTERVIEWED ALL COULD HAVE DONE THE JOB WELL, BUT IN THE END WE SELECTED THE FIRM SRI EXECUTIVE, ORIGINALLY FOUNDED IN IRELAND, I THINK, 27 YEARS AGO, TO HELP WITH SEARCHES IN THE LIFE SCIENCES SECTOR AND THE NOT-FOR-PROFIT SECTOR, BUT NOW SIGNIFICANTLY HAS BROADENED THEIR PRACTICE BOTH IN TERMS OF THE SECTORS THAT THEY COVER AND ALSO THEIR GLOBAL REACH. THEY ARE TRULY A WORLDWIDE FIRM.

I THINK THE POINTS THAT CHARACTERIZED THEM AS BEING VERY STRONG FOR THIS SEARCH INCLUDED THEIR DEEP KNOWLEDGE OF THE NOT-FOR-PROFIT AND LIFE SCIENCE SECTORS, INCLUDING BIOTECH AND PHARMA, BUT ALSO THE FACT THAT THEY HAVE WORKED EXTENSIVELY WITH GOVERNMENT BODIES, WITH FUNDING BODIES, AND HAVE PLACED INDIVIDUALS FROM THE PRIVATE SECTOR IN PUBLIC

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ORGANIZATIONS AND NGO'S. AND DURING OUR CONVERSATIONS WITH THEM, THEY OBVIOUSLY HAD A VERY NUANCED UNDERSTANDING BOTH OF CIRM, THE SPECIAL CONSIDERATIONS THAT APPLY FOR SOMEBODY TO WORK IN A STATE ORGANIZATION, AND INDEED PUBLIC AND QUASI-PUBLIC ORGANIZATIONS IN GENERAL. THEY GAVE US SOME VERY HELPFUL AND COMPELLING EXAMPLES OF THEIR UNDERSTANDING OF THAT AREA, AND THEY ALSO HAVE A VERY EXTENSIVE NETWORK AND REACH THAT I THINK WILL BE VALUABLE IN SURFACING A REASONABLY LARGE, BUT MANAGEABLE BODY OF HIGHLY QUALIFIED CANDIDATES.

WE PRESENTED OUR RECOMMENDATION FOR SRI EXECUTIVE TO THE SEARCH SUBCOMMITTEE AT THE MOST RECENT MEETING, AND THE SEARCH SUBCOMMITTEE CONCURRED WITH THAT SELECTION. AND SO THAT IS HOW WE ARE MOVING FORWARD, AND WE HAVE ALREADY HAD A KICKOFF MEETING WITH LEAD PRINCIPALS. THE PRIMARY SEARCH CONSULTANT WILL BE DAN PEREZ, WHO IS BASED IN WASHINGTON, D.C., BUT IS CLEARLY VERY FAMILIAR WITH THE CALIFORNIA ENVIRONMENT AS WELL. AND HE WILL BE ASSISTED BY, AS IS TYPICAL OF THESE FIRMS, A VARIETY OF PEOPLE WITH MORE SPECIALIZED EXPERTISE, PARTICULARLY IN THIS FIRST PHASE THAT THEY CALL THE SEARCH READINESS PROCESS, RESEARCHERS AND OTHER CONSULTANTS.

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SO THE NEXT STEPS THAT WILL BE COMING UP IN VERY SHORT ORDER WILL BE TO DO STAKEHOLDER INTERVIEWS. AND WE'VE IDENTIFIED A LIST OF, I THINK, ABOUT 20 PEOPLE THAT WE WOULD LIKE THE CONSULTANTS TO TALK WITH. THEY WILL, OF COURSE, TAKE THE LIST OF CHARACTERISTICS THAT WE'VE ALREADY IDENTIFIED AS DESIRABLE AND WILL DERIVE FROM THAT LIST AND THEIR DETAILED INTERVIEWS AND PERHAPS SOME WRITTEN COMMENTS, IF THEY CAN'T SCHEDULE ALL OF THE INTERVIEWS IN TIME, A SPECIFICATION PROFILE FOR THIS AND ALSO AN EVALUATION METRICS WHICH WILL BE HELPFUL DOWN THE ROAD.

SO MANY OF THE PEOPLE IN THIS ROOM AND ONLINE ARE LIKELY TO BE RECEIVING A REQUEST TO MEET WITH THE SEARCH CONSULTANTS TO BEGIN THAT PROCESS. BUT WE FEEL THAT WE CAN WORK WELL, THAT THE SUBCOMMITTEE WILL BE ABLY ASSISTED BY THIS COMPANY. AND OUR HOPE IS TO MOVE FORWARD TO PRESENT THE FINAL DOCUMENTS AT THE NEXT BOARD MEETING IN FEBRUARY. SO THAT'S MY UPDATE, AND I'D BE HAPPY TO TAKE ANY QUESTIONS.

CHAIRMAN IMBASCIANI: DO WE HAVE ANY QUESTIONS FROM BOARD MEMBERS REMOTE? DO WE HAVE PUBLIC COMMENT? NO. OKAY.

BOARD MEMBER BARRETT, THANK YOU SO MUCH

FOR YOUR PRESENTATION AND FOR YOUR GOOD WORK TO DATE.

DR. BARRETT: THANK YOU. AND I ALSO WANT TO ACKNOWLEDGE BOTH FANTASTIC SUPPORT FROM SCOTT TOCHER AND ALSO THE SEARCH SUBCOMMITTEE, WHICH IS A -- I THINK WE ARE REALLY WELL SERVED BY THE ENGAGEMENT, THE PASSION, AND THE INPUT FROM OUR COLLEAGUES.

CHAIRMAN IMBASCIANI: THANK YOU. CONTINUING ON, THE NEXT ITEM ON THE AGENDA IS THE CONSENT AGENDA. WE HAVE THREE SUBSECTIONS. I PRESUME YOU'VE ALL LOOKED AT THE MINUTES FROM FIVE MEETINGS OF VARIOUS COMMITTEES, INCLUDING OF THIS BOARD.

ITEM NO. 7 IN THE CONSENT AGENDA IS THE CONSIDERATION OF NEW APPOINTMENTS TO THE GRANTS WORKING GROUP OF DR. OR PROFESSOR BHOJ, ELIZABETH BHOJ, CHRISTOPHER MECOLI, AND REAPPOINTMENTS OF DR. RITA PERLINGEIRO, JUAN-CARLOS ZUNIGA-PFLUCKER, AND SHOULHRAT MITALIPOV.

AND THE LAST ITEM IN THE CONSENT AGENDA IS THE REQUEST TO ATTEND REMOTELY FROM TWO BOARD MEMBERS, FRED FISHER AND LARRY GOLDSTEIN.

DOES ANYONE ON THE BOARD WANT TO ABSTRACT ANYTHING FROM THE CONSENT AGENDA? IF NOT, WE

WILL -- DOES THIS REQUIRE A VOTE? IT DOES. OKAY, SCOTT, THEN I THINK YOU CAN --

MAY I HAVE A MOTION TO ACCEPT THE CONSENT AGENDA AS IS?

VICE CHAIR BONNEVILLE: SO MOVED.

DR. GASSON: SECOND.

CHAIRMAN IMBASCIANI: OKAY. WE HAVE A MOTION AND A SECOND. SCOTT, YOU CAN CALL THE ROLL. THANK YOU.

MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. ANY OPPOSED? ANY ABSTENTIONS? I HAVE TO DO ROLL CALL FOR THOSE ON THE PHONE.

HAIFAA ABDULHAQ.

DR. ABDULHAQ: YES.

MR. TOCHER: MOHAMED ABOUSALEM.

DR. ABOUSALEM: YES.

MR. TOCHER: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MR. TOCHER: MICHAEL BOTCHAN.

DR. BOTCHAN: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: HAL COLLARD.

DR. COLLARD: YES.

MR. TOCHER: DEBORAH DEAS.

DR. DEAS: YES.

MR. TOCHER: ANNE-MARIE DULIEGE. FRED FISHER.

DR. FISHER: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: LINDA MALKAS.

DR. MALKAS: YES.

MR. TOCHER: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

MR. TOCHER: MARVIN SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: AND MICHAEL STAMOS.

DR. STAMOS: YES.

MR. TOCHER: GREAT. THANK YOU. THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU, MR. TOCHER.

WE MAY NOW MOVE ON TO AGENDA ITEM NO. 12, WHICH IS A POLICY CONSIDERATION OF FUNDING PROPOSALS -- N OF 1 PROPOSALS. AND THAT DISCUSSION

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WILL BE LED BY BOARD MEMBER MARK FISCHER-COLBRIE.

MR.FISCHER-COLBRIE: THANK YOU, CHAIRMAN. AND WE WERE PRESENTED WITH A VERY INTERESTING SITUATION WITH RESPECT TO A SPECIFIC TERM OF N OF 1 IN TERMS OF FUNDING THAT AROSE FROM THE STANDARD PROCESS OF PROVIDING AN APPLICATION, SUBMITTING IT TO GRANTS WORKING GROUP, AND THE GRANTS WORKING GROUP RECOMMENDED APPROVAL FOR FUNDING FOR THAT PROGRAM.

AND TO GIVE A LITTLE BIT OF A CONTEXT, N OF 1 IS A SPECIFIC TERM OF ART THAT HAS BEEN DEFINED RELATED TO A THERAPY THAT HAS THE OPPORTUNITY TO ADDRESS A PARTICULAR PATIENT GIVEN THE CHARACTERISTICS THAT ARE UNDERLYING THE POTENTIAL TREATMENT FOR THAT INDIVIDUAL. AND WITH THAT IN MIND, IT OPENED UP THE UNDERLYING QUESTION OF HOW MIGHT CIRM ADDRESS THESE PARTICULAR CASES IN THE CONTEXT THAT, WHEREAS, THIS APPLICATION WAS RECOMMENDED FOR APPROVAL TO GO FORWARD, JUST ONE ORGANIZATION ALONE HAS ANOTHER 99 APPLICATIONS THAT COULD COME IN BEHIND THAT, AND THAT'S JUST FROM ONE GROUP.

AND SO WHAT IT DID IS IT THEN LED TO A DISCUSSION AT THE ARS IN TERMS OF HOW MIGHT CIRM CONSIDER THESE TYPES OF APPLICATIONS GOING FORWARD

IN THE FUTURE. AND THE CONSENSUS WAS TO ALLOW AND RECOMMEND FOR APPROVAL FOR THE BOARD TO GO AHEAD AND CLEAR AND APPROVE THE SUBMISSION THAT WAS MADE WITH RESPECT TO THIS PARTICULAR APPLICATION; HOWEVER, TO TAKE UNDER CONSIDERATION WHAT A POLICY MIGHT BE RELATED TO THESE CLINICAL TRIALS ESSENTIALLY OF A SPECIFIC INDIVIDUAL. AND, THEREFORE, WHAT SHOULD THAT RECOMMENDATION BE TO THE BOARD FOR DISCUSSION OF GOING FORWARD GIVEN THE CONTEXT OF THE UNDERLYING PHENOMENON OF WHAT ALL THESE PARTICULAR APPLICATIONS THAT MIGHT COME DOWN THE ROAD AND THE ASSOCIATED COSTS AND WHAT THAT MIGHT MEAN TO THE BUDGET AND ALLOCATION OF DOLLARS AND HOW THAT ALL TIES TO A BROADER DISCUSSION OF FOCUS AREAS NEEDS MORE CONSIDERATION AND MORE EVALUATION.

AND SO THE RECOMMENDATION WAS TO HAVE THE SCIENCE SUBCOMMITTEE KICK OFF THAT INTERNAL REVIEW AND DISCUSSION TO WORK WITH STAFF AND TO FURTHER COME UP WITH MATERIALS AND INFORMATION TO HAVE THAT BROADER DISCUSSION AS WE GO FORWARD. SO THAT'S THE UNDERLYING PHENOMENON THEREFOR, TWOFOLD. ONE IS A RECOMMENDATION FOR THIS PARTICULAR APPLICATION TO GO FORWARD AND, SECONDLY, THE OPPORTUNITY TO HAVE DISCUSSION, BROADER INPUT FOR DETERMINATION OF HOW MIGHT CIRM CONSIDER HANDLING THESE APPLICATIONS

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GOING FORWARD. AND SO THAT IS THE -- WHAT'S ON THE TABLE FOR DISCUSSION TODAY.

CHAIRMAN IMBASCIANI: WE'RE OPEN TO DISCUSSION FROM BOARD MEMBERS. SO WE HAVE SHLOMO.

DR. MELMED: IT WASN'T CLEAR FROM THE CORRESPONDENCE. IS THIS DISTINGUISHED FROM THE COMPASSIONATE USE PROGRAM, OR IS IT REDUNDANT OR OVERLAPPING? ARE THERE TWO DIFFERENT PROGRAMS? IT WASN'T REALLY CLEAR.

MR. FISCHER-COLBRIE: I'M NOT AS FAMILIAR WITH THE DISCUSSION, BUT MY UNDERSTANDING IS THAT IT IS DIFFERENT THAN SPECIFIC COMPASSIONATE USE. IT'S ON ITS OWN PARTICULAR TRACK, BUT THERE ARE OTHERS WHO ARE MORE KNOWLEDGEABLE ABOUT THAT THAN I AM.

DR. MELMED: SO THE COMPASSIONATE USE PROGRAM, USUALLY THE SPONSOR PAYS FOR THE TREATMENT.

DR. CREASEY: IT IS NOT COMPASSIONATE USE. THIS IS A REQUEST TO PROCEED FORWARD. THEY HAVE GENERATED ENOUGH DRUG. THEY NEEDED MATERIAL. THEY NEEDED ESSENTIALLY RESOURCES FOR OPERATIONS OF TAKING CARE OF THE PATIENT, PAYING THE PHYSICIAN WHO'S GOING TO TAKE CARE OF THE PATIENT. SO THIS IS NOT COMPASSIONATE USE. THIS WILL BE -- THEY CAN APPLY AGAIN AND AGAIN AND AGAIN FOR THE 99 OTHERS AND GET A MILLION DOLLARS FROM CIRM. AND WE'RE

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NOT -- IT'S NOT UNDER THE COMPASSIONATE USE AUSPICES.

WE HAVE NOT YET PUBLISHED THE FACT THAT WE ARE ACCEPTING COMPASSIONATE USE. BUT WAS THAT IN RELATIONSHIP ALSO TO A CLIN2, AND THAT WOULD HAVE HAD -- IN OUR PIPELINE THAT COULD HAVE THE PERMISSION TO DO COMPASSIONATE USE.

DR. MELMED: I'M STILL NOT CLEAR ON THE DISTINCTION. WHY DO WE NEED BOTH? COULDN'T THE COMPASSIONATE USE PROGRAM COVER ALL PATIENTS WHO NEED THIS?

DR. CREASEY: WE INCLUDED COMPASSIONATE USE IN THE CLIN2 ONLY IN CASES WHEN THE TRIAL HAS ENDED, THE FDA IS CONSIDERING APPROVING IT. AND AS A RESULT OF THAT, IF THERE'S A HIGH NEED, THAT WAS THE MAIN REASON, BUT NOT FOR THIS PURPOSE.

CHAIRMAN IMBASCIANI: DR. CREASEY, MAY I INTERRUPT FOR A SECOND? I JUST WANT TO REMIND THE BOARD MEMBERS THAT THE PURPOSE OF THIS DISCUSSION IS NOT TO TALK ABOUT THE APPLICATION, THIS SPECIFIC APPLICATION, BUT THE --

DR. MELMED: DEFINITION.

CHAIRMAN IMBASCIANI: THAT'S WHY I THINK THAT'S APPROPRIATE. DR. THOMAS.

DR. THOMAS: THANK YOU, MR. CHAIRMAN. SO

THE ISSUE OF N OF 1 WE'VE BEEN DISCUSSING AT THE LT LEVEL, AND IT'S REALLY A SUBSET ISSUE OF RARE DISEASE IN GENERAL AND THE ROLE THAT CIRM HAS IN THAT PARTICULAR AREA AND HOW WE WANT TO HANDLE THAT GOING FORWARD.

SO WHAT I'VE TALKED TO OUR TEAM ABOUT IS TO, AT THE SUGGESTION OF THE SCIENCE SUBCOMMITTEE, IS TO DEVELOP A RARE DISEASE STRATEGY THAT WILL BE BROUGHT FORWARD TO THE BOARD IN A NUMBER OF WEEKS. DR. CREASEY IS TAKING THE LEAD ON PUTTING THAT TOGETHER WITH OTHER MEMBERS OF THE TEAM. SO I THINK THAT, BASED ON THE FACT THAT WE'RE IN THE PROCESS OF DEVELOPING THAT STRATEGY, THAT THE IMPLICATIONS FOR THE MOMENT ARE THAT WE SHOULD HAVE A STRETCH HERE WHERE WE DON'T ENTERTAIN APPLICATIONS IN RARE DISEASE BECAUSE WE DON'T KNOW ULTIMATELY HOW THAT'S GOING TO FACTOR INTO THE BOARD'S GAME PLAN.

SO I JUST WANTED TO MAKE THAT POINT FOR THOSE WHO ARE LISTENING, THAT THAT IS WHERE WE ARE AT THE MOMENT. THANK YOU.

DR. CREASEY: IF I CAN JUST ADD ALSO THE N OF 1 IS REALLY PART OF A CLINICAL TRIAL, BUT COMPASSIONATE USE IS PROVIDED WHEN YOU ALREADY KNOW THE POTENTIAL SAFETY AND EFFICACY OF A DRUG.

CHAIRMAN IMBASCIANI: THANK YOU FOR THAT

CLARIFICATION. OTHER BOARD MEMBER COMMENT? I DON'T SEE ANY. IS THERE PUBLIC COMMENT?

VICE CHAIR BONNEVILLE: I'D LIKE TO MAKE A MOTION TO ACCEPT THE SCIENCE SUBCOMMITTEE RECOMMENDATION TO PAUSE ACCEPTANCE OF N OF 1 APPLICATIONS UNTIL THERE IS FURTHER DISCUSSION FOR THE TEAM AND A PLAN IS BROUGHT FORWARD AND TO ALLOW THE ARS TO CONSIDER THE APPLICATION THAT IS CURRENTLY ON THE TABLE. THANK YOU.

MR. JUELSGAARD: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOTION AND WE HAVE MULTIPLE SECONDS.

MR. TOCHER: I HAVE STEVE JUELSGAARD AS THE SECOND.

CHAIRMAN IMBASCIANI: DISCUSSION ON THE MOTION NOW THAT WE HAVE A FORMAL MOTION. I SEE NONE. INVITE MEMBERS OF THE PUBLIC TO MAKE A COMMENT ON THE MOTION. I SEE NONE. OKAY.

DR. GLEESON: IS IT OKAY IF I MAKE A PUBLIC COMMENT?

CHAIRMAN IMBASCIANI: I'M SORRY. WHO SPOKE?

DR. GLEESON: THIS IS JOSEPH GLEESON. I'M A PROFESSOR AT UNIVERSITY OF CALIFORNIA SAN DIEGO AND CO-PI ON THE APPLICATION THAT'S BEING DISCUSSED.

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CHAIRMAN IMBASCIANI: I SEE YOU, DR. GLEESON. OKAY. YES, THE FLOOR IS YOURS.

MR. TOCHER: JUST A SECOND. DR. GLEESON, JUST A PROCESS POINT. YOU HAVE THREE MINUTES. AND, SECONDLY, THE CONSIDERATION OF YOUR APPLICATION WILL COME UP AT THE ARS PORTION OF THIS MEETING LATER, BUT FEEL FREE TO MAKE A COMMENT NOW IF YOU WISH.

DR. GLEESON: I JUST WANT TO MAKE THE POINT, I'VE BEEN LISTENING TO THE DISCUSSION, THAT CIRM IS ALREADY INTO RARE DISEASE. A LOT OF THE CLINICAL TRIALS THAT ARE GOING ON ARE IN THE RARE DISEASE SPACE. THAT'S DEFINED AS LESS THAN 200,000 PATIENTS WITH THE CONDITION. SO THIS APPLICATION AND RARE DISEASE IS ALREADY QUITE WELL REPRESENTED AT CIRM.

THIS TRIAL IN PARTICULAR THAT IS BEING DISCUSSED ISN'T WHAT'S CALLED AN N OF 1, BUT IT'S PROBABLY REALLY BETTER REFERRED TO AS AN N OF FEW. THERE'S OVER 500 PATIENTS LISTED IN THE CLINVAR DATABASE WITH SCN2A MUTATIONS. THIS IS ONE OF THEM.

THE REASON THAT THIS APPLICATION IS BEING PUT FORWARD AS AN N OF 1 REALLY REFLECTS MORE THE FDA'S POSITION, THAT IT'S ALLOWING NOVEL THERAPEUTICS TO BE USED IN PATIENTS IF THE PATIENTS ARE SEVERELY DEBILITATED OR LIFE-THREATENING WHERE

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THERE'S NO OTHER OPPORTUNITY FOR THERAPY. THAT HAS TWO DIFFERENT BENEFITS. ONE IS IT ALLOWS PHYSICIAN RESEARCHERS TO ASSESS IF THAT DRUG BENEFITS THE PATIENT.

AND WE'VE SEEN JUST THIS WEEK AN N OF 1 THERAPY FOR HEARING WHERE A CHILD WHO WAS COMPLETELY DEAF IS NOW HEARING. YOU CAN SAY THAT'S NOT A FULL CLINICAL TRIAL, BUT I THINK WE LEARNED SOMETHING ALREADY FROM THAT. YES, THE PATIENT HAS BENEFITED AND THAT'S WONDERFUL, BUT WE'VE LEARNED SO MUCH FROM A SINGLE PATIENT. AND WHAT WE'RE SEEING NOW IS A WHOLE WAVE OF NOVEL THERAPEUTICS THAT ARE VERY MUCH TARGETED TO THE MUTATION DRIVEN BY ALL THE INFORMATION COMING IN WITH GENETICS. AND THAT'S REALLY THE ESSENCE OF THIS APPLICATION.

SO I HOPE YOU WOULD CONSIDER THIS TO BE AN EXPERIMENT. WE'RE GOING TO LEARN A HUGE AMOUNT. THIS IS NOT ABOUT TREATMENT. THIS IS NOT GETTING THIS PATIENT IN A DIFFERENT CLINICAL STATUS. WHAT WE'RE LOOKING FOR IS WHETHER THIS DRUG IS REALLY WORKING, AND I THINK THAT CIRM COULD SUPPORT THAT CLINICAL TRIAL. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR COMMENT, DR. GLEESON. IS THERE ANY OTHER MEMBERS WOULD LIKE TO MAKE A COMMENT? I DON'T HEAR ANY.

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MR. TOCHER: THE MOTION IS TO APPROVE THE RECOMMENDATION OF THE SCIENCE SUBCOMMITTEE TO PAUSE FURTHER ACCEPTANCE FOR APPLICATIONS FOR N OF 1 WHILE A POLICY IS DEVELOPED TO ADDRESS THOSE IN A RARE DISEASE STRATEGY AND TO ALLOW THE APPLICATION REVIEW SUBCOMMITTEE TO MOVE FORWARD WITH ITS CONSIDERATION OF THE N OF 1 APPLICATION THAT GAVE RISE TO THIS DISCUSSION.

MS. DURON: MR. CHAIR, I DON'T MEAN TO BE OUT OF ORDER. MAY I MAKE A COMMENT IN RESPONSE TO DR. GLEESON?

CHAIRMAN IMBASCIANI: YES.

MS. DURON: I'M VERY EXCITED ABOUT WHAT HE JUST CLARIFIED FOR SOMEONE LIKE MYSELF WHO IS NOT OBVIOUSLY DEEP INTO THE SCIENCE OF IT. BUT ONE OF THE THINGS THAT I WOULD LIKE TO SAY IS WE REALLY NEED, WHEN WE'RE TALKING ABOUT HUMANS, AND WE'RE TALKING TO THE PEOPLE OF CALIFORNIA, WE NEED TO BE SURE THAT OUR VOCABULARY IS NOT FRIGHTENING. AND SO WHEN YOU SAY WE'RE EXPERIMENTING HERE, THAT HAS SOME REALLY NEGATIVE CONNOTATIONS FOR SOME PEOPLE.

SO I APPRECIATE WHAT HE'S DOING, BUT I HOPE THAT WE ALL THINK ABOUT THESE THINGS BECAUSE WE'VE HEARD THESE THINGS AND FRIGHTENED A GOOD MANY PEOPLES WHO HAVE FELT LIKE THEY'VE BEEN EXPERIMENTED

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ON. AND SO I JUST WANTED TO ADD THAT BECAUSE I HEARD IT AND I SAID, OH, NO. AND THIS IS NOT JUST FOR DR. GLEESON. THIS IS FOR EVERYBODY AND ALL OF US. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, BOARD MEMBER DURON. MR. JUELSGAARD.

MR. JUELSGAARD: JUST A POINT OF CLARIFICATION ON THE MOTION. SO THE APPLICATION CLIN2-15085, WHICH WAS JUST SPOKEN TO A FEW MOMENTS AGO, IS NOT PART OF THE PAUSE; IS THAT RIGHT, OR IS THIS PART OF THE PAUSE?

VICE CHAIR BONNEVILLE: THAT'S CORRECT. IT'S UP FOR CONSIDERATION NEXT. SO THE MOTION WAS HOWEVER THE ARS WOULD LIKE TO VOTE ON THAT APPLICATION IS ACCEPTABLE AND WE SHOULD CONSIDER THAT ONE SINCE IT'S OPEN AND HAS GONE THROUGH REVIEW.

CHAIRMAN IMBASCIANI: NO OTHER COMMENT ON THE FLOOR? WE CAN PROCEED TO A VOTE, MR. TOCHER.

MR. TOCHER: ALL THOSE IN THE ROOM IN FAVOR SAY AYE. ANY OPPOSED? ABSTENTIONS? I'LL TAKE ROLL FOR THOSE ON THE PHONE.

HAIFAA ABDULHAQ.

DR. ABDULHAQ: YES.

MR. TOCHER: MOHAMED ABOUSALEM.

DR. ABOUSALEM: YES.
MR. TOCHER: GEORGE BLUMENTHAL.
DR. BLUMENTHAL: YES.
MR. TOCHER: MICHAEL BOTCHAN.
DR. BOTCHAN: YES.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: HAL COLLARD.
DR. COLLARD: YES.
MR. TOCHER: DEBORAH DEAS.
DR. DEAS: YES.
MR. TOCHER: ANNE-MARIE DULIEGE. FRED FISHER.
DR. FISHER: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: MARVIN SOUTHARD.

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DR. SOUTHARD: YES.
MR. TOCHER: AND MICHAEL STAMOS.
DR. STAMOS: YES.
MR. TOCHER: GREAT. THANK YOU. THE MOTION CARRIES.
MR. BERNAL: YOU MISSED DAN BERNAL HERE TOO ALSO. AYE.
MR. TOCHER: GOOD MORNING, DAN. THANK YOU.
MR. BERNAL: GOOD MORNING. THANK YOU.
CHAIRMAN IMBASCIANI: OKAY. THANK YOU, EVERYONE.
MOVING ON NOW TO AGENDA ITEM 9. THESE ARE THE CONSIDERATIONS OF THE APPLICATIONS FOR THE CLINICAL TRIAL STAGE PROJECTS. AND GIL SAMBRANO WILL LEAD THE DISCUSSION FROM THE PODIUM. THANK YOU.
DR. SAMBRANO: THANK YOU AND GOOD MORNING TO EVERYONE. I'M GOING TO PRESENT TO YOU THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP RELATED TO SOME OF THE LATEST ROUNDS OF THE CLIN PROGRAM. THIS GOES BACK ACTUALLY TO THE NOVEMBER CYCLE THAT WE HAD, THE NOVEMBER REVIEW, AS WELL AS ONE FROM OCTOBER.
AS ALWAYS, WE BEGIN OUR PRESENTATIONS WITH

OUR MISSION STATEMENT, AND WE DO THIS NOT JUST WITH THE BOARD, BUT ALSO WITH OUR GWG AND ALL OUR STAKEHOLDERS TO REMIND US OF WHAT IT IS THAT WE'RE DOING AND WHAT WE'RE STRIVING FOR. AND, OF COURSE, WHAT WE'RE STRIVING FOR IS TO ACCELERATE WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

I WANT TO PROVIDE A REMINDER OF WHERE WE ARE ON OUR BUDGET. WE HAD AN ALLOCATION OF 252 MILLION FOR THE FISCAL YEAR 23/24. THE AMOUNT THAT HAS BEEN APPROVED THUS FAR UNDER THIS BUDGET IS SHOWN IN ORANGE, THE 79.6 MILLION. THE AMOUNT REQUESTED TODAY, IF YOU CHOOSE TO FUND ALL OF THE APPLICATIONS THAT ARE BEFORE YOU, WOULD BE AN ADDITIONAL 41 MILLION. THAT WOULD LEAVE AN UNUSED BALANCE OF 131.4 MILLION.

THE SCIENTIFIC SCORING SYSTEM THAT'S USED BY THE GRANTS WORKING GROUP TO ASSIGN MERIT TO THE APPLICATIONS IS A SCORE OF 1, A 2, OR A 3. A SCORE OF 1 MEANS IT HAS EXCEPTIONAL MERIT AND WARRANTS FUNDING. A SCORE OF 2 MEANS IT NEEDS IMPROVEMENT. AND FOR THESE APPLICATIONS, WE PROVIDE A DETAILED SET OF CONCERNS AND ISSUES OR CLARIFICATIONS THAT THEY NEED TO ADDRESS, AND THOSE TYPICALLY GO BACK TO

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THE GWG. A SCORE OF 3 MEANS THAT THE APPLICATION IS SUFFICIENTLY FLAWED, THAT IT DOES NOT WARRANT FUNDING AND THE SAME PROJECT CAN'T BE RESUBMITTED FOR AT LEAST SIX MONTHS.

THE CRITERIA THAT ARE USED TO DERIVE THE SCORE IS BASED ON THESE FIVE KEY QUESTIONS. DOES THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT, BASICALLY ASKING WHAT IS THE VALUE PROPOSITION THAT IT IS OFFERING AND IS IT SOMETHING THAT IS WORTH DOING. DOES IT HAVE A SOUND RATIONALE? IS IT WELL PLANNED AND DESIGNED? AND IS IT FEASIBLE, MEANING THEY HAVE THE APPROPRIATE TEAM AND RESOURCES IN PLACE TO CARRY OUT THE PROJECT? AND LASTLY, DOES THE PROJECT UPHOLD THE PRINCIPLES OF DIVERSITY, EQUITY, AND INCLUSION IN ITS ACTIVITIES AND ITS CONSIDERATION OF DEVELOPING THE PROPOSED THERAPY?

WE ALSO INCLUDE, IN ADDITION TO THIS, A DEI SCORE THAT IS GIVEN BASED ON THE EVALUATION BY THE PATIENT ADVOCATE MEMBERS OF THE GWG. THE DEI SORE IS ON A SCALE OF ZERO TO TEN WITH TEN BEING THE BEST POSSIBLE SCORE. SO YOU WILL SEE TWO SCORES FOR EACH APPLICATION, THE SCIENTIFIC SCORE, WHICH DOES INCLUDE A DEI ELEMENT FROM THE SCIENTIFIC MEMBERS, AND THEN A SEPARATE DEI SCORE FROM THE PATIENT

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ADVOCATE MEMBERS OF THE BOARD.

AND JUST TO REVIEW THE COMPOSITION OF GRANTS WORKING GROUP, WE HAVE 15 SCIENTIFIC GRANTS WORKING GROUP MEMBERS WHO PROVIDE THE SCIENTIFIC EVALUATION. WE BRING IN A DIVERSITY OF EXPERTISE TO THE TABLE TO HELP US EVALUATE APPROPRIATELY THE MERIT OF THESE APPLICATIONS. SO THEY PROVIDE THE SCIENTIFIC SCORE ON ALL OF THE APPLICATIONS. WE HAVE GRANTS WORKING GROUP BOARD MEMBERS WHO ARE PATIENT ADVOCATE OR NURSE MEMBERS OF THE ICOC. THEY CONDUCT THE DEI EVALUATION, PROVIDE A PATIENT PERSPECTIVE ON THE SIGNIFICANCE AND POTENTIAL IMPACT, AND PROVIDE OVERSIGHT ON THE PROCESS. SO, AGAIN, THE DEI SCORE THAT YOU WILL SEE IS FROM OUR PATIENT ADVOCATE MEMBERS. THEY MAY PROVIDE A SUGGESTED SCIENTIFIC SCORE DURING THE MEETING.

WE ALSO AS PART OF THE GROUP BRING IN SCIENTIFIC SPECIALISTS AS NEEDED TO PROVIDE ADDITIONAL EXPERTISE WHETHER THERE MAY BE KNOWLEDGE GAPS IN THE PANEL OR WHERE WE FEEL THEY ADD OVERALL EXPERTISE AND BACKGROUND TO THE REVIEW.

SO WE ARE GOING TO GO INTO DISCUSSION OF EACH OF THE INDIVIDUAL APPLICATIONS. SO THERE ARE FIVE OF THEM. WE'RE GOING TO START WITH CLIN1-14840. SO AS A CLIN1, THIS IS AN

IND-ENABLING, NOT A CLINICAL TRIAL. THE TITLE OF THIS IS "PREVENTION OF GVHD IN PATIENTS RECEIVING HLA MISMATCHED RELATED OR UNRELATED ALLOGENEIC HSCT FOR THE TREATMENT OF HEMATOLOGIC MALIGNANCIES." SO THESE ARE BLOOD CANCERS.

THE THERAPY IS AN ALLOGENEIC REGULATORY T-CELL PRODUCT. THE INDICATION IS FOR PATIENTS THAT HAVE THESE BLOOD CANCERS AND ARE AT RISK FOR GRAFT VERSUS HOST DISEASE THAT CAN RESULT FROM A STEM CELL TRANSPLANT.

THEIR GOAL FOR THIS STUDY IS TO COMPLETE PRE-IND ENABLING ACTIVITIES AND FILE AN IND AT THE END OF THE AWARD PERIOD.

THE FUNDS REQUESTED ARE 4 MILLION. THEY PROVIDE A CO-FUNDING AMOUNT OF 1 MILLION, WHICH IS THE 20 PERCENT REQUIRED UNDER THIS CATEGORY.

SOME BACKGROUND INFORMATION ON THE INDICATION. HEMATOLOGIC MALIGNANCIES SUCH AS ACUTE LEUKEMIAS AND LYMPHOMAS ARE THE MOST COMMON TYPE IN CHILDREN AND YOUNG ADULTS. THE CURRENT STANDARD OF CARE FOR HIGH RISK OR REFRACTORY CANCERS IS TYPICALLY CHEMOTHERAPY OR ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTS. THERE IS, HOWEVER, A LACK OF MATCHED DONORS AND ALSO A HIGH RISK OF REJECTION OR GRAFT VERSUS HOST DISEASE WHERE THE TRANSPLANT

ACTUALLY ATTACKS THE IMMUNE SYSTEM OR OTHER ASPECTS OF THE PATIENT TISSUE.

THE PROPOSED THERAPY OFFERS THE OPPORTUNITY TO GREATLY IMPROVE OUTCOMES FOR PATIENTS UNDERGOING THESE TYPES OF TRANSPLANTS. AND WHY THIS QUALIFIES AS A STEM CELL PROJECT OR GENE THERAPY PROJECT, THE THERAPEUTIC CANDIDATE IS MANUFACTURED FROM CD4 POSITIVE T-CELL PROGENITOR CELLS AND IT IS COMBINED WITH A HEMATOPOIETIC STEM CELL TRANSPLANT.

SIMILAR PORTFOLIO PROJECTS THAT WE HAVE, THERE IS ONE OTHER THAT IS VERY MUCH RELATED. IT IS A CLIN2 PHASE 1 CLINICAL TRIAL THAT WE SUPPORTED THAT INCLUDES SOME OF THE SAME TEAM MEMBERS. IT IS ALSO FOR HEMATOLOGIC MALIGNANCIES, AND IT TAKES A SIMILAR APPROACH WITH A T-CELL IMMUNOTHERAPY WITH THE GOAL OF DEVELOPING A REGULATORY T-CELL PRODUCT THAT DECREASES GRAFT VERSUS HOST DISEASE RELATED TO STEM CELL TRANSPLANT. THE DIFFERENCE BETWEEN THE TWO PROJECTS, THIS PROJECT IS MORE OF AN AUTOLOGOUS OR IT INCLUDES AUTOLOGOUS COMPONENTS THAT ARE MORE CHALLENGING TO MANUFACTURE. THE NEW PROJECT IS FULLY ALLOGENEIC. AND SO THE EXPECTATION IS THAT THE MANUFACTURING AND THE PROCESSING AND THE AVAILABILITY TO PATIENTS WILL BE MUCH GREATER.

SO PREVIOUS CIRM FUNDING TO THE APPLICANT

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TEAM, SO THIS IS ESSENTIALLY THE SAME AWARD THAT I JUST SHOWED YOU. THAT PROJECT IS A PHASE 1 TRIAL WHICH IS EXPECTED TO COMPLETE IN OCTOBER OF 2025.

THIS IS A SUMMARY OF THE RECOMMENDATION FROM THE GRANTS WORKING GROUP. WE HAD A UNANIMOUS SCORE OF 1 FROM ALL OF THE GRANTS WORKING GROUP MEMBERS. THE DEI SCORE WAS 7.5 FROM THE PATIENT ADVOCATE MEMBERS. THE CIRM RECOMMENDATION IS TO FUND THIS CLIN1 AWARD FOR IND-ENABLING STUDIES FOR THE AMOUNT OF 4 MILLION. MR. CHAIRMAN.

CHAIRMAN IMBASCIANI: THANK YOU. THANK YOU, GIL.

I JUST WANT TO ADD AN EDITORIAL COMMENT TO REMIND THE BOARD MEMBERS THAT WE ARE ENTERING, FOR FURTHER DISCUSSION OF THESE FIVE APPLICATIONS, THE APPLICATION REVIEW SUBCOMMITTEE PART OF THE BOARD MEETING. AND THAT WILL BECOME MORE CLEAR WHEN SCOTT CALLS ROLL OF ONLY 20 BOARD MEMBERS.

SO DISCUSSION FROM BOARD MEMBERS FIRST ON THIS APPLICATION AS PRESENTED BY MR. SAMBRANO.

MS. DURON: A NONSCIENTIFIC QUESTION, GIL. CAN YOU TELL ME WHAT WAS THE ISSUE IN REGARDS TO DEI IN WHICH IT GOT ONLY A 7.5 EVEN THOUGH WE KNOW THAT THAT'S ABOVE THE 6? TO ME THEY OUGHT TO COME IN PERFECT. SO TELL ME WHAT WERE SOME OF THE CONCERNS

AND CAUTIONS, AND WOULD THEY BE SENT BACK TO THEM SO THAT THEY CAN DO SOMETHING ABOUT IT?

DR. SAMBRANO: SO I THINK WITH THIS -- THERE'S A COUPLE OF THINGS WITH THIS SCORE. SO THIS WAS REVIEWED MORE THAN ONCE. AND SOME OF THE REVIEWERS UNFORTUNATELY DIDN'T HAVE ACCESS TO THEIR PREVIOUS REVIEWS. SO THEY ASSUMED A SCORE THAT WAS LOWER THAN WHAT THEY HAD ORIGINALLY GIVEN IT. SO THAT'S JUST ONE ELEMENT THAT MAY HAVE CONTRIBUTED TO THE LOWER SCORE.

THE OTHER, THOUGH, IN TERMS OF JUST WHAT MADE IT LESS THAN A PERFECT DEI IS THE APPLICANTS ARE RELYING A LOT ON THE INSTITUTION. AND SO WE SEE THIS IN MANY CASES WHERE THE APPLICANT TEAM MAY SAY, WELL, OUR INSTITUTION DOES A GREAT JOB WITH DEI, SO WE'RE RELYING ON THEM TO DO IT. I THINK WITH THE GRANTS WORKING GROUP AND THE PATIENT ADVOCATE MEMBERS IN THIS CASE ARE LOOKING FOR IS MORE ACTIONABLE, SPECIFIC THINGS THAT THEY CAN DO SPECIFICALLY FOR THIS PROJECT AND NOT SIMPLY TO RELY ON THE INSTITUTION ITSELF TO BE THEIR BACKUP OR BE THE ANSWER NECESSARILY TO ALL THE DEI. SO THAT WAS ONE ELEMENT.

THEY DID HAVE SPECIFIC ELEMENTS THAT WERE DESCRIBED, BUT I THINK FOR THE WORKING GROUP SEEING

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A LITTLE MORE ROBUSTNESS IN THAT WOULD HAVE BEEN APPRECIATED. CERTAINLY SOME OF THE PATIENT ADVOCATE MEMBERS ARE HERE. THEY MAY WANT TO SPEAK TO WHAT THEIR THOUGHTS ARE ON THIS AS WELL.

MS. DURON: MAY I FOLLOW UP? SO IN THE FUTURE ARE WE REQUIRING THEY MEET CERTAIN MILESTONES AND SHOW A GREATER SUCCESS IN IN FACT CREATING THEIR OWN DEI PLAN AS OPPOSED TO DEPENDING ON THEM OVER THERE --

DR. SAMBRANO: YES.

MS. DURON: -- SO THAT THEY BECOME BETTER AT THIS? AND I'M JUST WONDERING IF WE'RE ASKING THEM TO STEP UP AND DO THE WORK SO WE CAN SEE THEM IMPROVE THEIR INCLUSION.

DR. SAMBRANO: SO ONE OF THE THINGS, THE WAY WE APPROACH PARTICULARLY THE DEI, AND WE WANT DO THIS WITH ALL OUR APPLICANTS AND EVENTUAL AWARDEES, IS THAT THIS IS AN EDUCATIONAL PROCESS OVERALL. THE FIRST STEP IS THE EVALUATION THAT THEY GET SO THAT THEY CAN UNDERSTAND WHERE THERE MAY BE DEFICIENCIES. THAT ALLOWS US TO THEN TAKE ACTION AND WORK WITH THE TEAM IN ORDER TO MAKE IMPROVEMENTS.

PART OF THAT MAY BE WHAT HAPPENS WITH THEIR ADVISORY PANELS. ALSO IT MAY BE WHAT HAPPENS DIRECTLY WITH CIRM BECAUSE, AS PART OF THE

APPLICATION, WE ASK THEM TO LAY OUT MILESTONES THAT ALIGN WITH THEIR DEI ACTIVITIES AND GO THROUGHOUT THE PROJECT. SO WE WORK WITH THEM IN ORDER TO ENSURE THAT THEY'RE ACHIEVING THESE MILESTONES AS THEY GO ALONG.

WE'VE IMPLEMENTED THIS OVER THE LAST COUPLE OF YEARS. SO IT IS ALSO A WORK IN PROGRESS FOR US, AND WE WILL BE COLLECTING INFORMATION ABOUT HOW THIS WORKS AND WHERE IT WORKS WELL AND WHERE IT MAY NOT. SO IT IS AN ONGOING PROCESS FOR US. BUT, YES, OUR EXPECTATION IS WE'RE GOING TO BE WORKING CLOSELY WITH THE APPLICANTS TO IMPROVE THEIR DEI PLANS.

MS. DURON: SO AT SOME POINT IN TIME WE CAN HEAR A REPORT BACK FROM YOU ABOUT THE CHANGE OVER TIME AND WHAT WOULD BE CONSIDERED THE BEST STEPS FOR MOST APPLICANTS -- OR BEST PRACTICES.

DR. SAMBRANO: YOU WILL HEAR FROM US, PARTICULARLY DR. CREASEY AND JENNIFER LEWIS, WHO ARE SPECIFICALLY WORKING ON THIS POSTAWARD ELEMENT.

CHAIRMAN IMBASCIANI: THANK YOU. WE HAVE COMMENT FIRST FROM BOARD MEMBER FRED FISHER FOLLOWED BY STEVE JUELSGAARD.

DR. FISHER: I JUST WANT THANK GIL FOR HIS EXCELLENT DESCRIPTION OF OUR ACTIVITY AND OF THE

BASIS FOR THESE SCORES AND FOR WHAT WE'RE DOING TO OVERALL HELP APPLICANTS UNDERSTAND THE IMPORTANCE OF INTEGRATING DEI INTO THEIR ORGANIZATIONS AND NOT DEPENDING ON THE SITE DEI PLAN TO COVER THAT BASE. SO THANK YOU, GIL, FOR DESCRIBING THAT SO WELL.

CHAIRMAN IMBASCIANI: STEVE.

MR. JUELSGAARD: YES. I DON'T PROPOSE THAT WE GET INTO THIS OR RESOLVE THIS NOW, BUT JUST A COUPLE OF COMMENTS. AND THIS IS ALL PROMPTED BY AN ARTICLE THAT DAVID JENSEN, WHO'S HERE ON THE PUBLIC SIDE, WROTE A COUPLE OF WEEKS AGO ABOUT THE CONFIDENTIALITY OF OUR DEI ARRANGEMENTS, WHICH I UNDERSTAND WHERE IT STEMS FROM BECAUSE APPLICATIONS ARE CONSIDERED CONFIDENTIAL UNDER PROP 14.

HAVING SAID THAT, A COUPLE OF THOUGHTS. ONE IS GIVING MORE GUIDANCE TO APPLICANTS ABOUT WHAT WE THINK GOOD DEI LOOKS LIKE. SO THAT INSTEAD OF SAYING, WELL, WAIT A MINUTE, YOU DIDN'T DO ENOUGH OR WHATEVER, GIVING THEM SOME PARAMETERS TO WORK WITH SO THAT THEY KNOW WHAT IS EXPECTED FROM OUR SIDE I THINK WOULD BE VERY HELPFUL IN WORKING ON THAT. I'M PARTICULARLY FOCUSED ON THE CLINICAL TRIAL AREA BECAUSE THAT'S A BROADER AREA TO DEAL WITH.

AND THE SECOND IS, AND THIS IS PROBABLY MORE IN THE AREA OF INCLUSION, IN SOME OF THESE, TO

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BE ABLE TO BE MORE INCLUSIVE IN THE CLINICAL TRIAL AREA MEANS A GREATER ECONOMIC COST TO THE CLINICAL TRIAL SITES OR THE SPONSOR OF THE CLINICAL TRIAL. AND IF WE'RE GOING TO ASK THEM TO DO MORE IN TERMS OF DEI, THEN IT SEEMS TO ME PERHAPS WE COULD OFFER SOME ECONOMIC ASSISTANCE SEPARATE AND APART FROM THE CLINICAL TRIAL COSTS TO HELP THEM WITH THAT INSTEAD OF LAYING THAT COST JUST OFF ON THEM AS PART OF THE WHOLE CLINICAL TRIAL. AND THAT WAY THEY CAN APPLY FOR NOT ONLY THE CLINICAL TRIAL COST, BUT THEN A SUPPLEMENT FOR DEI WHICH CAN REALLY HELP THEM DO WHAT WE WANT THEM TO DO.

SO ANYWAY, AGAIN, THIS WAS PROMPTED MORE BY DAVID'S ARTICLE ON THE CONCERN ABOUT CONFIDENTIALITY OF DEI AND REALLY PEOPLE OUTSIDE OF THIS ROOM REALLY DON'T UNDERSTAND VERY MUCH ABOUT WHAT IT IS THAT WE'RE UP TO.

DR. SACKEY: THANK YOU, CHAIR. I WONDER WHETHER CIRM COULD ALSO REQUIRE, IN ADDITION TO AN INDEPENDENT OR THE PLAN, DEI PLAN, FROM THE INVESTIGATORS, TO ACTUALLY PUSH FURTHER TO HAVE THE INSTITUTIONAL PLAN FOR DEI BECAUSE ULTIMATELY IF WE WANT TO TRANSFORM THE INSTITUTIONS, I THINK IT'S GOING TO BE AWFULLY HARD TO JUST WORK AT THE INDIVIDUAL LEVEL.

SO I GUESS MY QUESTION IS WHETHER WE COULD, AS PART OF THIS PROCESS, REQUEST NOT ONLY A PLAN FROM THE APPLICANTS, BUT ALSO THE EXTENT TO WHICH THE INSTITUTION WILL BE SUPPORTING THE IMPLEMENTATION OF A DEI PLAN.

DR. SAMBRANO: SO I JUST WANT TO PROVIDE A COUPLE OF CLARIFICATIONS TO BOTH SETS OF COMMENTS. SO ONE IS THAT OUR APPLICANTS ARE ABLE TO IN THEIR BUDGET INCLUDE AN AMOUNT FOR THEIR DEI ACTIVITIES. SO THAT IS SOMETHING THAT NOT EVERYONE MAY BE CLEAR ON. BUT I THINK AS DR. CREASEY PRESENTED REGARDING THE UPDATES THAT WE WANT TO MAKE TO THE PROGRAM ANNOUNCEMENTS, WE WANT TO MAKE IT CLEAR IF YOU ARE APPLYING TO CIRM FOR A CLINICAL TRIAL OR ANY CLINICAL ACTIVITIES OR ACTUALLY FOR ANY AWARD TYPE, THAT YOU'RE GOING TO PROPOSE DEI ACTIVITIES, YOU CAN DEFINE A SPECIFIC PART OF THAT BUDGET TO BE FOR DEI ACTIVITIES. SO THAT IS AVAILABLE.

I THINK THE OTHER THING AS IT RELATES TO THE PLANS THEMSELVES, THERE IS A LOT OF COMPLEXITY THAT COMES WITH THESE PLANS, INCLUDING HOW THEY INTEGRATE SPECIFICALLY WITH THE OVERALL PLAN. SO A DEI PLAN, AN IDEAL DEI PLAN, MAY BE DIFFICULT TO COME UP WITH BECAUSE AN IDEAL PLAN FOR A RARE DISEASE TRIAL WHERE THERE ARE VERY FEW PATIENTS

VERSUS ONE WHERE THERE'S A LOT OF PATIENTS MAY BE QUITE DIFFERENT. AND A LOT DEPENDS ON THE VERY SPECIFIC ACTIVITIES THEY'RE DOING.

NEVERTHELESS, ONE OF THE THINGS THAT WE ARE TRYING TO DO IS AT LEAST SET SOME EXAMPLES OF WHAT THINGS WOULD BE VALUED IN A GOOD DEI PLAN AND WHAT THINGS MAY NOT GO SO FAR. SO WE JUST SPOKE TO THE EXAMPLE OF RELYING ON THE INSTITUTION VERSUS HAVING MORE SPECIFIC ACTIONABLE ITEMS. I THINK THAT'S ONE GENERAL BIT OF ADVICE THAT WE COULD CERTAINLY PROVIDE AS WE DEVELOP THIS. BUT I DO AGREE, AND I THINK WE ARE STRIVING TO DEVELOP SOMETHING THAT WOULD PROVIDE GUIDANCE FOR OUR APPLICANTS.

IN TERMS OF BRINGING IN THE INSTITUTION, I THINK THAT'S VERY IMPORTANT. PART OF THE PLAN THAT WE EXPECT TO BE INCLUDED IS HOW THEIR PROJECT FITS IN WITHIN THE INSTITUTION ITSELF. THEY MAY HAVE A CLINICAL SITE THERE, BUT ALSO EVEN THE OTHER INSTITUTIONS THAT MAY BE PARTICIPATING. SO ESPECIALLY IF YOU HAVE A MULTISITE TRIAL THAT IS UTILIZING OTHER INSTITUTIONS, WHAT IS THEIR TRACK RECORD, THEIR EXPERIENCE IN PROMOTING DEI AND ENROLLING A DIVERSITY OF PATIENTS. SO THIS IS SOMETHING THAT WE WOULD EXPECT TO BE PART OF THEIR

PLAN ALREADY. AND TO THE EXTENT THAT WE CAN ENCOURAGE THEM TO DEVELOP AN INSTITUTIONAL PLAN THAT THEY CAN INCLUDE IS GOOD. WE JUST WANT TO SEE MORE DETAIL ON WHATEVER THAT INSTITUTIONAL PLAN RELATES TO THE SPECIFIC PROJECT.

CHAIRMAN IMBASCIANI: THANK YOU, GIL. I'M GOING TO RECOGNIZE BOARD MEMBER LEVITT AND THEN JUELSGAARD.

DR. LEVITT: GIL, YOU TOUCHED UPON SOMETHING. SO WHEN YOU WRITE RESOURCE AND ENVIRONMENT PAGES FOR ANY GRANT, IT INCLUDES THE INSTITUTIONAL COMPONENTS THAT ARE EXPECTED. IN FACT, INCLUDING, IF YOU ARE DOING A TRAINING GRANT, FOR EXAMPLE, LETTERS OF SUPPORT FROM THOSE AT THE INSTITUTION THAT DESCRIBE EXACTLY WHAT THEY'RE GOING TO DO IN THE CONTEXT OF A FUNDED PROJECT. SO WHETHER IT'S A DISCOVERY RESEARCH, TRANSLATIONAL RESEARCH, OR CLINICAL RESEARCH, THE RESOURCE ENVIRONMENT COMPONENT DESCRIBING WHAT THE INSTITUTION IS DOING AND THEN A LETTER OF SUPPORT FROM AN INSTITUTIONAL OFFICIAL TO VALIDATE THAT THESE ARE THE THINGS THAT THEY'RE GOING TO PROMOTE, I THINK, IS REQUIRED AND NOT A CHOICE.

SO IF THERE ARE ISSUES AROUND A PLAN IN WHICH IT'S NOT CLEAR HOW THE PARTICULARS OF A STUDY

ARE GOING TO LEVERAGE WHAT IS GOING ON AT THE INSTITUTION OR THE INSTITUTION IS WEAK IN THAT AREA, THEN IT NEEDS TO BE A CONSIDERATION IN TERMS OF REVIEW. IT'S CERTAINLY DONE AT THE FEDERAL TRAINING GRANT LEVEL. IF YOU DON'T HAVE STRONG INSTITUTIONAL SUPPORT AND STRONG INSTITUTIONAL LETTERS THAT CLEARLY SPELL OUT, FOR EXAMPLE, DEI PLANS FOR RECRUITING UNDERREPRESENTED STUDENTS, THEN YOU DON'T GET THE TRAINING GRANT EVEN IF YOU HAVE THE GREATEST PLAN IN THE WORLD IN TERMS OF YOUR CURRICULUM AND EVERYTHING ELSE. SO I THINK MAYBE THAT NEEDS TO BE -- I'M SPEAKING FROM IGNORANCE NOW IN TERMS OF WHAT IS ACTUALLY DESCRIBED IN THE INSTRUCTIONS IN TERMS OF WHAT IS EXPECTED, BUT THAT CAN -- THAT'S EASILY DONE. I'M NOT SAYING AT ALL INSTITUTIONS. IT'S NOT EASY TO GET INSTITUTIONS TO COMMIT. THAT'S ONE OF THE PROBLEMS, BUT THAT'S THE ISSUE THAT THEY HAVE TO DEAL WITH. AND THERE SHOULD BE A SUPPORT LETTER FROM AN INSTITUTIONAL OFFICIAL TO VERIFY WHAT THE INFRASTRUCTURE IS FOR THIS.

CHAIRMAN IMBASCIANI: THANK YOU.

MR. JUELSGAARD: SO I WANT TO GO BACK TO SPEAKING ABOUT THE FUNDING FOR DEI EFFORTS. SO WE HAVE IN PARTICULAR CASE A LIMIT OF $4 MILLION FOR THIS GRANT. THAT $4 MILLION WAS ESTABLISHED BEFORE

WE INCLUDED DEI AS A REQUIREMENT OF AN APPLICATION. SO WE ADDED SOMETHING TO THE APPLICATION THAT WILL COST ADDITIONAL AMOUNTS OF MONEY.

AND SO MY CONCERN IS IS BY TAKING PART OF THE GRANT THAT'S SPECIFIED HERE AND USING IT FOR DEI ACTUALLY CUTS BACK ON THE SCIENCE PART OF THE GRANT. AND THAT'S WHY I THINK HAVING A SEPARATE BUCKET FOR DEI EFFORTS THAT PEOPLE CAN APPLY TO, YES, I'M APPLYING FOR $4 MILLION FOR WHATEVER SCIENCE WORK I'M GOING TO DO, BUT THEN I'M ALSO GOING TO APPLY FOR 500,000 OR WHATEVER IT IS FOR THE DEI WORK THAT'S VERY WELL LAID OUT AND WHY IT'S GOING TO COST ME THAT, ET CETERA. I'M LAYING THAT OUT AS SOMETHING WE CAN MAYBE THINK ABOUT OR COGITATE OR COME BACK TO AT SOME POINT. I DON'T MEAN TO SOLVE IT HERE, BUT I THINK WE SHOULD SUPPORT INSTITUTIONS IF WE EXPECT DEI OUT OF THEM.

CHAIRMAN IMBASCIANI: GOOD. THANK YOU, BOARD MEMBERS, FOR YOUR COMMENTS. DR. THOMAS.

DR. THOMAS: I DEFER TO BOARD MEMBER DURON. ALWAYS HAVE.

MS. DURON: THE SECOND MARIA IN HIS LIFE, BUT I DON'T DO BASEBALL.

ANYWAY, I ALMOST FEEL LIKE I'M HAVING TO TAKE OFF MY ONE HAT AND PUT ON ANOTHER. BUT I NEED

TO SAY AND THANK EVERY SINGLE MEMBER OF THIS BOARD AND THE ORGANIZATION FOR HAVING TAKEN UP THIS TOPIC AND DONE ITS BEST TO MAKE IT ITS BEST AND TO CONTINUE TO DO SO. AND THANK VERY MUCH ALL OF THE BOARD MEMBERS WHO HAVE ALSO TAKEN THIS VERY SERIOUSLY AND OFFERED WAYS TO REFINE THIS ISSUE WHICH IS SO CRITICALLY IMPORTANT IN THIS DAY AND AGE BECAUSE IT IS BECOMING POLITICIZED. AND I HAVE ADVOCATE FRIENDS AND COLLEAGUES AND ACADEMICS AND OTHERS CONCERNED THAT, AS A RESULT OF THAT, WE'RE SEEING SOME REAL STEP BACK AND CORPORATIONS AND OTHERS STEPPING BACK ON THIS ISSUE OF DEI.

SO I'M VERY GLAD THAT WE ARE MARCHING FORWARD, CONTINUING, AND NOT ALLOWING ANY NEGATIVITY ABOUT WHAT IS BEING SAID ABOUT DEI AND PROCEEDING. I REALLY, REALLY, REALLY WANT TO THANK YOU ALL FOR SUPPORTING THIS AND FOR RECOGNIZING THE VALUE ADD THAT IT MEANS NOT JUST IN TERMS OF SCIENCE AND IN TERMS OF LEARNING, BUT ALSO IN TERMS OF COMMUNITIES WHO HAVE CONTINUED TO HAVE TO HOPE THAT SOMEONE WILL INDEED INCLUDE THEM WITHIN THESE REALLY IMPORTANT MEASURES. SO THANK YOU VERY MUCH.

CHAIRMAN IMBASCIANI: THANK YOU, YSABEL, FOR THAT VERY GRACIOUS COMMENT.

SO DO YOU WANT TO GO BACK, JONATHAN?

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DR. THOMAS: SURE. SO I JUST WANTED TO INFORM THE MEMBERS OF THE BOARD AS A SORT OF FYI ON THE DEI TOPIC THAT AT THE RECENT GWG MEETING, THERE WAS A SESSION IN ADVANCE OF THE ACTUAL PEER REVIEW IN WHICH OUR CONSULTANT ON DEI PRESENTED TO THE GWG A PRESENTATION WHICH DEFINED OUR DEI PROGRAM AND EMPHASIZED THE INTEGRAL NATURE OF DEI INTO EVERYTHING WE DO TO DRIVE HOME THE SIGNIFICANCE AND TO EDUCATE THEM FURTHER ABOUT WHAT THE PARAMETERS WERE THAT WE VIEW AS PARTICULARLY IMPORTANT IN THE DEI SPACE.

I NOTED IN A COMMENT TO THAT GROUP, THIS IS SORT OF FOR THE BENEFIT OF MORE RECENT BOARD MEMBERS, THAT SEVERAL YEARS AGO WE HAD AN APPLICATION THAT HAD A TIER I RECOMMENDATION FROM THE GWG, BUT A DEI SCORE OF 5, WHICH SORT OF TESTED THE WATERS OF HOW MUCH VALUE WE PLACE ON DEI. AND I RECOMMENDED AT THAT BOARD MEETING THAT, BECAUSE OF THAT LOW DEI SCORE, NOTWITHSTANDING THE TIER I SCORE, THAT THAT APPLICATION BE SENT BACK TO WORK TO IMPROVE THE DEI ELEMENT AND AS A MESSAGE TO THE COMMUNITY AT LARGE ABOUT JUST HOW SERIOUSLY WE CONSIDER DEI TO BE CENTRAL TO EVERYTHING WE DO.

I'LL NOTE PARENTHETICALLY THAT THE APPLICATION WAS RESUBMITTED, IT NOT ONLY UPPED ITS

GAME ON THE DEI FRONT, BUT INTERESTINGLY ENOUGH THE SCIENCE WAS IMPROVED. EVEN THOUGH THEY REACHED A TIER I RESULT BEFORE, THEY HAD AN EVEN BETTER PROJECT COMING BACK. SO I THINK THAT WAS A MESSAGE TO THE COMMUNITY THAT WAS WELL TAKEN BY THAT APPLICANT AND SOMETHING THAT ALL APPLICANTS NEED TO KEEP IN MIND AS THEY PROPOSE GOING FORWARD. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH. I DO NOT SEE ADDITIONAL COMMENTS COMING FROM THE BOARD. AM I MISTAKEN ON THAT, SCOTT OR CLAUDETTE? NO. ARE THERE ANY COMMENTS ON THIS APPLICATION FROM THE PUBLIC?

MR. TOCHER: WE NEED A MOTION.

DR. FISHER: WE DON'T HAVE A MOTION YET, AND I'M HAPPY TO MAKE IT.

CHAIRMAN IMBASCIANI: THANK YOU FOR REMINDING ME.

DR. SOUTHARD: I WILL SECOND.

CHAIRMAN IMBASCIANI: IS THERE ADDITIONAL COMMENT FROM THE BOARD ON THE MOTION? OKAY. COMMENTS FROM THE PUBLIC? HEARING NONE, I THINK WE'RE READY FOR THE VOTE.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: AYE.

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MR. TOCHER: FRED FISHER.
DR. FISHER: AYE.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: DAN BERNAL.
MR. BERNAL: AYE.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: YES.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES.

MR. TOCHER: GREAT. THANK YOU. AND THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: MOVE ON TO THE SECOND APPLICATION, CLIN2-15085.

DR. SAMBRANO: OKAY. THANK YOU.

SO THIS IS CLIN2-15085. SO THIS IS A CLINICAL TRIAL APPLICATION. THE TITLE IS "PERSONALIZED ANTISENSE OLIGONUCLEOTIDE THERAPY FOR RARE PEDIATRIC GENETIC DISEASE."

DR. CLARK-HARVEY: APOLOGIES. WE CANNOT HEAR YOU ONLINE. IT SIMPLY LOOKS LIKE THE MIC HAS BEEN MUTED. SO IF SOMEONE CAN UNMUTE.

CHAIRMAN IMBASCIANI: START AGAIN, GIL, AND JUST TRY IT.

DR. SAMBRANO: CAN YOU HEAR ME NOW?

DR. CLARK-HARVEY: OH, GOOD.

DR. SAMBRANO: SO THIS IS CLIN2-15085. THIS IS A CLINICAL TRIAL APPLICATION. THE TITLE IS "PERSONALIZED ANTISENSE OLIGONUCLEOTIDE THERAPY FOR RARE PEDIATRIC GENETIC DISEASE SCN2A." SO THIS A PERSONALIZED ANTISENSE OLIGONUCLEOTIDE DRUG. SO THIS IS AN N OF 1, AND THIS IS THE ONE THAT I THINK

WAS REFERENCED DURING THE POLICY DISCUSSION.

THE INDICATION IS FOR SCN2A ASSOCIATED GENETIC DISORDER. THE GOAL OF THIS IS TO COMPLETE THE FIRST-IN-HUMAN TRIAL FOR THIS DRUG.

THE FUNDS REQUESTED ARE 985,713. THERE IS NO CO-FUNDING REQUIRED FOR THIS APPLICATION.

SOME BACKGROUND ON THIS DISEASE INDICATION. THE SCN2A-RELATED DISORDERS ARE CAUSED BY MUTATIONS IN THE RESPECTIVE GENE. SUCH DISORDERS RESULT IN A RANGE OF NEURODEVELOPMENTAL CONDITIONS MAINLY CHARACTERIZED BY THE SEVERITY OF EPILEPSY. AND SEVERE FORMS OF THE DISORDER CAN CAUSE SEIZURES BEGINNING IN INFANCY, AND ANTISEIZURE MEDICATIONS ARE TYPICALLY NOT EFFECTIVE FOR THESE PATIENTS.

THE VALUE PROPOSITION OF THIS PROPOSED THERAPY IS THAT IT WOULD TREAT A SINGLE PATIENT WITH SEVERE EPILEPSY AND SEVERE DEVELOPMENTAL DELAY. IF IT IS SUCCESSFUL, OTHERS WITH SIMILAR DISORDERS COULD BENEFIT FROM EQUIVALENT PRECISION THERAPIES.

WHY THIS IS A STEM CELL OR GENE THERAPY PROJECT, THIS IS AN ASO THAT IS INTRODUCED. SO IT QUALIFIES AS A GENE THERAPY UNDER OUR DEFINITION OF GENE THERAPIES.

THERE ARE NO OTHER PROJECTS IN OUR PORTFOLIO IN TRAN OR CLIN THAT ARE CURRENTLY

ADDRESSING SCN2A-RELATED DISORDERS.

THE APPLICANT TEAM HAS HAD A PREVIOUS DISC2 STAGE PROJECT IN NEURODEVELOPMENTAL DISEASES. THIS IS A STAGE FOR CANDIDATE DISCOVERY. THE AWARD ENDS JULY OF THIS YEAR. SEVEN MILESTONES WERE PROPOSED, TWO ARE COMPLETED WITH SOME DELAY, THREE ON TRACK, AND TWO HAVE NOT BEEN STARTED ON THAT PROJECT.

THESE ARE THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP RELATED TO THIS PARTICULAR APPLICATION. WE HAD EIGHT MEMBERS WHO SCORED THIS A 1, WE HAD SIX MEMBERS WHO SCORED IT A 2, AND NONE THAT SCORED IT A 3. THE OVERALL SCORE RECOMMENDATION, THEREFORE, IS A 1. THE DEI SCORE IS AN 8.5 AND THE CIRM TEAM RECOMMENDATION HAS BEEN TO FUND THIS APPLICATION FOR THE AWARD AMOUNT SHOWN.

MR. CHAIRMAN.

CHAIRMAN IMBASCIANI: THANK YOU. AT ANY POINT WE CAN ENTERTAIN A MOTION FOR THIS.

DR. SACKEY: SO MOVED.

MR. TOCHER: IS THAT A MOTION TO APPROVE FUNDING?

DR. SACKEY: MAKE A MOTION TO APPROVE FUNDING.

MR. TOCHER: THANK YOU.

CHAIRMAN IMBASCIANI: DO WE HAVE A SECOND?
MR. JUELSGAARD: SECOND.
CHAIRMAN IMBASCIANI: ONE SECOND. WE'RE CONSIDERING A POSSIBLE CONFLICT. DO WE HAVE?
MR. TOCHER: SORRY, JOYCE. IT NEEDS TO BE A MEMBER OF THE ARS.
MR. JUELSGAARD: I'LL MAKE THE MOTION.
CHAIRMAN IMBASCIANI: MEMBER JUELSGAARD HAS MOVED TO ACCEPT.
DR. FLOWERS: SECOND.
DR. CLARK-HARVEY: I WILL SECOND.
CHAIRMAN IMBASCIANI: OKAY. THANK YOU. SO WE CAN OPEN THE FLOOR TO DISCUSSION BY BOARD MEMBERS ON THIS APPLICATION. I DO NOT SEE ANY. OKAY. SO WE CAN -- ARE THERE ANY MEMBERS OF THE PUBLIC WHO ARE GOING TO SPEAK ON THIS?
DR. GLEESON: MAY I SPEAK? THIS IS JOSEPH GLEESON, PROFESSOR AT UNIVERSITY OF CALIFORNIA SAN DIEGO AND RADY CHILDREN'S HOSPITAL. MY CAMERA WON'T TURN ON. BUT I JUST WANT TO SAY THAT WE APPRECIATE THE COMMENTS FROM THE BOARD'S LAST CONSIDERATION OF THIS APPLICATION. AND WE UPLOADED A DETAILED REBUTTAL AND WANT TO EMPHASIZE THAT WE FEEL THAT WE VERY MUCH APPRECIATE THE CONSIDERATION OF THE BOARD. AND WE VERY CAREFULLY CONSIDER DEI ISSUES AND SCORED

8.5 AS YOU CAN SEE HERE.

SOME OF THE QUESTIONS FROM THE BOARD AT THE LAST MEETING WERE ABOUT DEI, AND WE WERE CAREFUL TO ADDRESS THOSE, AND SOME ISSUES RELATED TO N OF 1 THERAPY. AND AS I MENTIONED IN MY LAST COMMENTS A COUPLE MINUTES AGO, THIS IS REALLY MORE N OF A FEW TRIAL.

I DON'T THINK MORE COMMENTS ARE NECESSARY; BUT IF THERE ARE OTHER QUESTIONS FROM THE BOARD, WE'RE HAPPY TO ANSWER THEM.

CHAIRMAN IMBASCIANI: THANK YOU, DR. GLEESON. ANY OTHER MEMBERS OF THE PUBLIC WANT TO MAKE A COMMENT BEFORE WE PROCEED TO A VOTE?

MR. TOCHER, WOULD YOU PLEASE, BEFORE WE PROCEED TO A VOTE, WOULD YOU CLARIFY FOR THE BOARD MEMBERS WHAT A YES VOTE MEANS AND WHAT A NO VOTE MEANS ON THIS ITEM?

MR. TOCHER: THE MOTION IS TO FUND APPLICATION CLIN 15085. SO THE CONSEQUENCE WOULD BE AN AYE VOTE IS TO APPROVE FUNDING. A NO VOTE WOULD BE TO NOT APPROVE FUNDING.

CHAIRMAN IMBASCIANI: THANK YOU. THAT SOUNDS SIMPLE, BUT IN THE CONTEXT OF DISCUSSIONS WE HAVE HAD, I THINK IT WAS IMPORTANT TO STATE THAT. THANK YOU. LET'S PROCEED TO A VOTE.

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MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: NO.
MR. TOCHER: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: DAN BERNAL.
MR. BERNAL: AYE.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: NO.
MR. TOCHER: JUDY CHOU. LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: AYE.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: ABSTAIN.

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MR. TOCHER: YSABEL DURON.
MS. DURON: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: FRED FISHER.
DR. FISHER: NO.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: STAND BY. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANK YOU, MR. TOCHER.
THE REPORTER: MR. CHAIRMAN, MAY WE HAVE A TIMEOUT, PLEASE?
CHAIRMAN IMBASCIANI: YES.
(A RECESS WAS TAKEN.)
CHAIRMAN IMBASCIANI: COULD THE BOARD MEMBERS PLEASE RESUME, COME BACK TO THEIR SEATS. THANK YOU.
OKAY. WE'RE GOING TO CONTINUE WITH OUR CONSIDERATION OF CLINICAL APPLICATIONS TO THE ARS. GIL, YOU'D LIKE TO PRESENT THE THIRD CASE.
DR. SAMBRANO: YES. THANK YOU.
THE THIRD APPLICATION IS CLIN2-15395. THIS IS A CLINICAL TRIAL APPLICATION. IT'S ENTITLED

"A PHASE 2B-STUDY OF THE EFFICACY OF A NOVEL PRO-NEUROGENESIS/PRO-PLASTICITY DRUG FOR BIPOLAR DEPRESSION USING A PRECISION PSYCHIATRY APPROACH."

THE THERAPY IS A SMALL MOLECULE THAT HAS NEUROGENIC PROPERTIES, MEANING IT HELPS NEURONS DIVIDE. IT IS FOR BIPOLAR DEPRESSION, AND THEIR GOAL IS TO COMPLETE A PHASE 2B CLINICAL TRIAL.

THE FUNDS REQUESTED ARE 15 MILLION. THE CO-FUNDING PROVIDED BY THE APPLICANT IS 13.2, WHICH IS THE 40 PERCENT THAT'S REQUIRED FOR THIS CATEGORY OF AWARD.

THE BACKGROUND, BIPOLAR DISORDER, PARTICULARLY THE DEPRESSIVE PHASE, BDD, IS A SEVERE, LIFELONG PSYCHIATRIC CONDITION THAT'S ASSOCIATED WITH A VERY HIGH BURDEN OF ILLNESS AND THE RISK OF SUICIDE. AND THE APPROVED TREATMENTS THAT ARE AVAILABLE ARE LIMITED TO ANTIPSYCHOTIC DRUGS WITH LIMITED EFFICACY AND OFTEN POOR TOLERABILITY.

THE VALUE PROPOSITION, THE PROPOSED THERAPY COULD PROVIDE A NOVEL THERAPEUTIC OPTION THAT, UNLIKE AVAILABLE ANTIPSYCHOTICS, ADDRESSES DISEASE-RELATED PATHOPHYSIOLOGY. IT OFFERS BETTER TOLERABILITY AND INCLUDES A DIAGNOSTIC APPROACH TO IDENTIFY THOSE PATIENTS WHO ARE MOST LIKELY TO BENEFIT.

WHY THIS IS A STEM CELL OR GENE THERAPY PRODUCT. THE THERAPY IS A SMALL MOLECULE DRUG THAT ACTS ON NEUROPROGENITOR CELLS AND CAUSES NEUROGENESIS.

SIMILAR PROJECTS IN OUR PORTFOLIO, CIRM CURRENTLY DOESN'T HAVE ANY ACTIVE TRAN OR CLIN AWARDS ADDRESSING BIPOLAR DEPRESSION. AND THIS APPLICANT HAS NOT PREVIOUSLY RECEIVED A CIRM AWARD. THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP ARE SUMMARIZED HERE. THERE WERE TEN MEMBERS THAT GAVE THIS A SCORE OF 1, TWO MEMBERS THAT GAVE IT A SCORE OF 4. THE DEI SCORE IS A 9. AND THE CIRM TEAM RECOMMENDATION IS TO FUND THIS APPLICATION FOR 15 MILLION.

CHAIRMAN IMBASCIANI: THANK YOU, MR. SAMBRANO. SO I'D LIKE TO OPEN THE FLOOR TO DISCUSSION AND/OR A MOTION TO APPROVE.

DR. SOUTHARD: I WOULD MOVE TO APPROVE.

CHAIRMAN IMBASCIANI: THANK YOU, BOARD MEMBER SOUTHARD. DO WE HAVE A SECOND?

DR. HIGGINS: SECOND.

CHAIRMAN IMBASCIANI: SECOND FROM DAVID HIGGINS. THANK YOU. COMMENTS FROM BOARD MEMBERS ON THIS?

DR. MELMED: THANK YOU. MAYBE I'M MISSED

IT IN THE DESCRIPTOR. CAN YOU JUST ELUCIDATE FOR US WHAT THE STEM CELL BIOLOGY IS?

DR. SAMBRANO: YES. SO THIS IS A SMALL MOLECULE THAT ACTS ON NEUROPROGENITORS. AND SO IT LEADS TO NEUROGENESIS, AND SO IT FALLS INTO THE PROGENITOR STEM CELL ALLOWANCE THAT WE HAVE.

DR. MELMED: GOT YOU. THANKS.

CHAIRMAN IMBASCIANI: OTHER COMMENTS FROM BOARD MEMBERS?

MS. DURON: MR. CHAIR, I'M SITTING HERE WONDERING IF I SHOULD ASK GIL TO EXPLAIN THAT IN ENGLISH FOR THOSE OF US WHO DON'T HAVE THIS BACKGROUND.

CHAIRMAN IMBASCIANI: EXCELLENT SUGGESTION. THANK YOU, YSABEL.

DR. DURON: SO SORRY.

DR. SAMBRANO: THAT'S ABSOLUTELY FINE. ALWAYS STOP ME IF YOU FEEL YOU DON'T UNDERSTAND SOMETHING. SO I'M HAPPY TO EXPLAIN.

MS. DURON: I'M STILL IN THE LEARNING CURVE.

DR. SAMBRANO: SO CAN YOU LEAD ME WITH A QUESTION?

MS. DURON: WELL, SHLOMO JUST ASKED YOU AND I'M TRYING TO REINTERPRET HOW THIS WORKS USING

STEM CELLS.

DR. SAMBRANO: I SEE. SO THIS IS A SMALL MOLECULE DRUG. SO THIS IS SOMETHING THAT SOMEBODY WOULD TAKE AS A PILL, ENTERS THE SYSTEM, AND IT ACTS ON A PARTICULAR AREA IN THE BRAIN IN THE HIPPOCAMPUS, SO THIS PARTICULAR AREA THAT'S THOUGHT TO BE IN CERTAIN PATIENTS THE RESULT OF WHAT LEADS TO THE DEPRESSION. SO THE IDEA IS TO INCREASE THE NUMBER OF CELLS THAT EXIST THERE. AND SO NEUROGENESIS JUST SIMPLY MEANS THAT YOU ARE TAKING EARLY PROGENITOR CELLS THAT THEN MATURE AND BECOME THE RIGHT TYPE OF CELL IN THAT AREA OF THE BRAIN.

SO THE DRUG BASICALLY STIMULATES THE REPRODUCTION OF THOSE CELLS, INCREASES THE VOLUME IN THAT HIPPOCAMPAL AREA OF THE BRAIN IN ORDER TO ALLEVIATE THE DEPRESSION THAT OCCURS AS A RESULT. AT LEAST THAT BASICALLY IS THE IDEA BEHIND THE USE OF THE DRUG.

MS. DURON: SO IT INCREASES GOOD CELLS TO FIGHT THE BAD CELLS? AM I WRONG?

DR. SAMBRANO: NO. THERE'S NO BAD CELLS. THIS IS JUST --

MS. DURON: IT SOUNDS LIKE THERE IS AN ENEMY WITHIN.

DR. SAMBRANO: THIS IS A CONDITION WHERE

WHAT THEY OBSERVE IS THE HIPPOCAMPUS DOES NOT HAVE THE RIGHT AMOUNT OF VOLUME. SO IT IS CORRECTING WHAT THEY SEE AS A PROBLEM THAT IS LINKED TO THE DEPRESSION. AND SO THEY'RE CORRECTING IT BY CREATING MORE CELLS.

CHAIRMAN IMBASCIANI: THANK YOU. I'M REMINDED THAT LEONARD BERNSTEIN EXPLAINED MUSIC TO THE LAY PUBLIC, AND I THINK GIL SAMBRANO IS THE LEONARD BERNSTEIN OF NEUROGENESIS. THANK YOU FOR YOUR ANSWER, GIL.

DR. SAMBRANO: I TRY. I DON'T KNOW THAT I ALWAYS SUCCEED. THANK YOU.

DR. THOMAS: HE'S BEEN CALLED A LOT OF THINGS OVER THE YEARS, BUT NEVER THAT.

CHAIRMAN IMBASCIANI: THANK YOU. COMMENTS FROM OTHER BOARD MEMBERS? I'M LOOKING. I DO NOT SEE ANY. SO I'M GOING TO ASK IF THERE ARE COMMENTS ON THIS APPLICATION FROM THE PUBLIC. AND SEEING NONE THERE, I'M GOING TO ASK SCOTT TO CALL THE ROLL THEN. THANK YOU.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MR. TOCHER: YSABEL DURON.

MS. DURON: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: FRED FISHER.
DR. FISHER: YES.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: DAN BERNAL.
MR. BERNAL: AYE.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: YES.

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MR. TOCHER: ARE THERE ANY MEMBERS OF THE APPLICATION REVIEW SUBCOMMITTEE WHOSE NAME I HAVEN'T CALLED? GREAT. THANKS VERY MUCH. THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: OKAY. MR. SAMBRANO, COULD YOU PLEASE TAKE US INTO DISCUSSION OF NO. 4?

DR. SAMBRANO: OKAY. THE NEXT APPLICATION IS CLIN1-15450. SO THIS IS AN IND-ENABLING STAGE APPLICATION, NOT A TRIAL YET. THE TITLE IS "HUMAN EMBRYONIC STEM CELL-DERIVED NEURAL STEM CELLS FOR SEVERE SPINAL CORD INJURY."

THE THERAPY IS HUMAN EMBRYONIC STEM CELL-DERIVED NEURAL STEM CELLS. THE INDICATION IS FOR SUBACUTE SPINAL CORD INJURY. AND THEIR GOAL IS TO COMPLETE IND-ENABLING STUDIES AND FILE AN IND AT THE END OF THE AWARD PERIOD.

THE FUNDS REQUESTED ARE 6 MILLION. NO CO-FUNDING IS REQUIRED FOR THIS APPLICANT.

SO THE BACKGROUND, WE HAVE MORE THAN HALF A MILLION AMERICANS CURRENTLY LIVING WITH SPINAL CORD INJURY, AND THERE ARE NO APPROVED THERAPIES FOR PROMOTING RECOVERY OF LOST FUNCTION AFTER THE INJURY THAT WOULD BE AVAILABLE. THE SPINAL CORD INJURY CAN RESULT IN LOSS OF MOVEMENT, SENSATION, BOWEL AND BLADDER FUNCTION, BUT IT CAN ALSO LEAD TO CHRONIC

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NEUROPATHIC PAIN AND DISABLING BOUTS OF AUTONOMIC DYSREFLEXIA WHICH LEAD TO DANGEROUS ELEVATIONS OF BLOOD PRESSURE AND RISK OF CEREBRAL HEMORRHAGE.

THE VALUE PROPOSITION FOR THIS PROPOSAL IS THAT THE PROPOSED THERAPY OFFERS AN OPPORTUNITY TO RESTORE FUNCTION IN PATIENTS WITH SPINAL CORD INJURY BY IMPLANTING NEURAL STEM CELLS AT THE INJURY SITE AND TO REGENERATE AND REPAIR THE DAMAGED AXONS. THE APPLICANTS NOTE THIS IS A FUNDAMENTAL DIFFERENCE FROM OTHER APPROACHES THAT MAY SIMPLY AIM TO REMYELINATE THE SPARED HOST AXONS ON EITHER END OF THE INJURY.

WHY THIS IS A STEM CELL OR GENE THERAPY PROJECT. THE THERAPY IS COMPOSED OF HUMAN EMBRYONIC NEURAL STEM CELLS.

THE SIMILAR PROJECTS THAT WE HAVE IN OUR PORTFOLIO, WE HAVE ONE OTHER PROJECT AT THE TRANSLATIONAL STAGE FOR SPINAL CORD INJURY. THEIR GOAL TO ACHIEVE A PRE-IND MEETING BY OCTOBER 2025. THEIR CANDIDATE IS ALSO NEURAL STEM CELLS. THIS INVOLVES THE INTEGRATION OF THE TRANSPLANTED CELLS TO FORM NEW OLIGODENDROCYTES WHICH INCREASE REPAIR AND IMPROVE LOCOMOTOR FUNCTION. SO ONE PROJECT THAT IS SIMILAR.

PREVIOUS CIRM FUNDING TO THE APPLICANT

TEAM. SO THE APPLICANT TEAM HAS HAD SEVERAL PROJECTS SUPPORTED BY CIRM OVER THE YEARS THAT INCLUDE A TRANSLATIONAL PROJECT, A TRAN1, A DISC2 DISCOVERY, AND THE ANOTHER DISCOVERY LEVEL PROJECT ALL FOR SPINAL CORD INJURY. ALL PROJECTS HAD MULTIPLE MILESTONES THAT WERE ALL ACHIEVED ON TIME.

THIS IS A SUMMARY OF THE RECOMMENDATION FROM THE GRANTS WORKING GROUP. THERE WERE 13 MEMBERS THAT UNANIMOUSLY GAVE THIS A SCORE OF 1. THE DEI SCORE IS AN 8. AND CIRM TEAM RECOMMENDATION IS TO FUND THIS PROJECT FOR THE REQUESTED AMOUNT OF 6 MILLION.

CHAIRMAN IMBASCIANI: THANK YOU, GIL. MAY I HAVE A MOTION TO ACCEPT THIS APPLICATION?

MR. JUELSGAARD: SO MOVED.

MR. FISCHER-COLBRIE: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOTION FROM MEMBER JUELSGAARD, SECONDED BY MARK FISCHER-COLBRIE. THANK YOU. BOARD MEMBERS, OPEN TO DISCUSSION.

DR. BARRETT: I HAVE A QUESTION. SO I THINK THIS IS AN INCREDIBLY EXCITING PROJECT AND REALLY FILLS AN UNMET NEED. BUT I HAVE A QUESTION ABOUT THE DEI SECTION APROPOS OF THE COMMENTS EARLIER. THIS RECEIVED A SCORE OF 8, BUT I DON'T

SEE A SINGLE NEGATIVE COMMENT AND IN FACT COMMENTS TO THE EFFECT THAT IT IS A COMPREHENSIVE JOB. THEY'RE PROVIDING TRAVEL REIMBURSEMENTS FOR CAREGIVERS, THEY'RE HAVING SENSITIVITY TRAINING. THEY'RE HAVING ONGOING MONITORING BY A STUDY PANEL FOR THE DEI ASPECTS. WHAT MORE COULD HAVE BEEN DONE TO RAISE THIS ABOVE A SCORE OF 8?

DR. SAMBRANO: THAT'S A GREAT QUESTION. HARD FOR ME TO ANSWER HONESTLY. I THINK, AS MENTIONED, SOME OF THE PATIENT ADVOCATE MEMBERS ARE HERE. MAYBE THEY CAN SPEAK TO SOME OF THE DEFICIENCIES. BUT IN TERMS OF THE COMMENTS THAT WERE PROVIDED, I AGREE THERE WAS NOT MUCH THAT WOULD BE CONSTRUED AS BEING A NEGATIVE COMMENT OR SOMETHING THAT THEY COULD IMPROVE UPON.

DR. BARRETT: AND THEY SPECIFICALLY ARE RECRUITING IN AREAS WITH HIGH MINORITY REPRESENTATION AND HAVE SORT OF PROPOSED OVERSAMPLING FOR AFRICAN-AMERICANS, I BELIEVE. SO I JUST THINK WE HAVE TO THINK ABOUT THE CALIBRATION OF THESE SCORES IF WE'RE REALLY GOING TO USE THEM EFFECTIVELY, PARTICULARLY IN LIGHT OF J.T.'S COMMENT THAT A POOR SCORE, EVEN IN THE FACE OF AN EXCELLENT SCIENTIFIC RATING, SHOULD BE GROUNDS TO SEND SOMETHING BACK. IF WE CAN'T GET THIS RIGHT, THEN

THE CREDIBILITY IS AN ISSUE.

DR. SAMBRANO: I THINK THE ONLY OTHER THING I WOULD ADD IS THAT IN TERMS OF THE STAGE OF THIS PROJECT, IT IS NOT YET AT THE CLINICAL TRIAL STAGE. SO A LOT OF THESE ARE ASPIRATIONAL ASPECTS THAT WERE PRESENTED AND NOT NECESSARILY YET SOMETHING THAT THEY'RE GOING TO TAKE ON EVEN DURING THE COURSE OF THIS PARTICULAR PROJECT. TO SOME EXTENT, THAT MAY IMPACT ON THE SCORE.

CHAIRMAN IMBASCIANI: MEMBER DURON.

MS. DURON: THANK YOU, MR. CHAIR. AND I THINK THAT WHEN YOU'RE LOOKING AT QUALITY OF THAT DEI PLAN, THE FIRST THING YOU WANT TO SEE IS THAT THEY UNDERSTAND THE DEMOGRAPHIC BREAKDOWN FOR ALL OF THOSE PATIENTS WHO ARE IMPAIRED AND THAT THEY HAVE PLANS TO REACH OUT TO ALL OF THOSE KINDS OF GROUPS AND TO MAKE SURE THAT THEY'RE CULTURALLY AND LINGUISTICALLY APPROPRIATE MATERIALS SO THEY CAN DO SO AND WHO THOSE COMMUNITY PARTNERS ARE WITH WHOM THEY WILL BE WORKING IN ORDER TO, IN FACT, ENSURE THE SUCCESS OF THIS PLAN.

SO THERE ARE THOSE KINDS OF THINGS THAT I WOULD LOOK AT IN A PLAN TO BE SURE BECAUSE JUST BECAUSE THEY CHECKED THE BOX DOESN'T MEAN THEY HAVE IT SOLVED. AND SO THANK YOU, KIM, FOR ASKING THAT

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QUESTION BECAUSE I THINK IT'S REALLY CRITICAL FROM THE GIT-GO. IF THEY DON'T KNOW THE AUDIENCE OUT THERE THEY'RE SUPPOSED TO BE SERVING, THEN IT'S PIE IN THE SKY NUMBERS.

DR. BARRETT: BASED ON THE COMMENTS, THEY DO DO ALL THOSE THINGS. THAT'S WHY I'M ASKING WHY IT WAS ONLY AN EIGHT.

MS. DURON: I WAS JUST GOING TO SAY WHO WAS THE PATIENT ADVOCATE WHO SCORED IT.

MR. JUELSGAARD: WELL, JUST TWO COMMENTS. FIRST OF ALL, AS I UNDERSTAND IT, IT'S THE WORK THAT'S LEADING UP TO AN IND OR IND-ENABLING STUDY. SO WE'RE NOWHERE NEAR GETTING INTO THE HUMAN POPULATION AT THIS POINT. WE'VE GOT TO GET AN IND APPROVED BY THE FDA. SO YOU'RE TALKING ABOUT THE STEP AFTER THIS ONE.

I JUST WANTED TO REFLECT BECAUSE I THINK THIS IS EMBLEMATIC OF STEM CELL DEVELOPMENT. IN THAT ONE SLIDE THAT GIL PRESENTED, THIS BEGAN WITH DISCOVERY IN 2012. THIS IS 12 YEARS LATER AND WE'RE JUST GETTING TO WANTING TO APPLY FOR AN IND, DOING THE IND-ENABLING STUDIES. TWELVE YEARS AND WE'VE STILL GOT THE WHOLE CLINICAL ADVENTURE TO GO. SO VERY REPRESENTATIVE OF THE DIFFICULTY OF THE PROCESS FOR HOW THINGS PROCEED, THE TIMELINES, ET CETERA, IN

AREAS LIKE THIS.

CHAIRMAN IMBASCIANI: THANK YOU, STEVE. GOOD COMMENT. MARK, YOU'RE NEXT.

MR. FISCHER-COLBRIE: I'M OKAY.

CHAIRMAN IMBASCIANI: YOU'RE GOOD. JUST LOOKING OVER, I DON'T SEE ANY OTHER BOARD MEMBERS WITH THEIR HANDS RAISED. WE HAVE A MOTION ON THE FLOOR? YES. IS THERE ANY MEMBER OF THE PUBLIC WHO WOULD LIKE TO COMMENT ON THIS APPLICATION? NOTHING. OKAY. I THINK WE CAN PROCEED THEN TO A VOTE.

MR. TOCHER: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES.

MR. TOCHER: ADRIANA PADILLA.

DR. PADILLA: YES.

MR. TOCHER: JOE PANETTA.

MR. PANETTA: YES.

MR. TOCHER: MARV SOUTHARD.

DR. SOUTHARD: YES.

MR. TOCHER: DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: AYE.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: AYE.

MR. TOCHER: ANNE-MARIE DULIEGE. YSABEL

DURON.

MS. DURON: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: AYE.

MR. TOCHER: FRED FISHER.

DR. FISHER: AYE.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: DAVID HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: YES.

MR. TOCHER: STEPHEN JUELSGAARD.

MR. JUELSGAARD: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: I'LL CALL AGAIN FOR ANNE-MARIE DULIEGE. OKAY. THANK YOU. THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU, MR. TOCHER. GIL, WE'RE ON THE LAST APPLICATION.

DR. SAMBRANO: AND JUST A REMINDER FOR ONE CONFLICT OF INTEREST WITH THIS APPLICATION, CLIN2-15607. SO THIS IS A CLINICAL TRIAL PROPOSAL. THE TITLE IS "PHASE 3 PIVOTAL CLINICAL TRIAL FOR

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SPG50." THE THERAPY IS A GENE THERAPY THAT UTILIZES ADENO-ASSOCIATED VIRUS ENCODING A CODON-OPTIMIZED HUMAN AP4M1 TRANSGENE. SO THIS IS BASICALLY A CORRECTION OF THE GENE.

THE INDICATION IS FOR SPASTIC PARAPLEGIA TYPE 50, ABBREVIATED AS SPG50. THE GOAL IS TO COMPLETE A PHASE 3 CLINICAL TRIAL. THE FUNDS REQUESTED ARE 15 MILLION. THE CO-FUNDING THAT'S PROVIDED BY THE APPLICANT IS 10.1 MILLION, WHICH IS THE 40 PERCENT REQUIRED UNDER THIS CATEGORY.

SO FOR BACKGROUND, THE SPG50 IS AN ULTRA RARE GENETIC NEURODEGENERATIVE DISEASE THAT'S CAUSED BY A MUTATION IN THE ADAPTOR PROTEIN COMPLEX 4 OF AP4. THE DISEASE IS CHARACTERIZED BY THE GRADUAL ONSET OF SPASTIC PARAPLEGIA DURING THE INITIAL DECADE OF LIFE THAT ESCALATES INTO QUADRIPLEGIA DURING ADOLESCENCE OR EARLY ADULTHOOD. AND THERE ARE ABOUT 16 INDIVIDUALS IN NORTH AMERICA THAT ARE AFFECTED BY THIS VERY SPECIFIC DISORDER.

THE VALUE PROPOSITION OF THIS THERAPY IS THAT IT OFFERS THE POTENTIAL TO CORRECT THE GENE MUTATION FOR SPG50 PATIENTS AND TO DEVELOP A FRAMEWORK FOR APPLYING THIS APPROACH TO OTHER ULTRA RARE MONOGENIC DISEASES.

WHY IS THIS A STEM CELL OR GENE THERAPY

PROJECT? IT IS A GENE THERAPY APPROACH AND THEREFORE QUALIFIES.

CIRM PORTFOLIO PROJECTS THAT MIGHT BE SIMILAR, THERE ARE NONE IN OUR TRAN OR CLIN PORTFOLIO THAT ARE ADDRESSING SPG50 SPECIFICALLY.

PREVIOUS FUNDING BY THE CIRM APPLICANT. SO THE APPLICANT HAS A CLIN1 FOR SMT4J WHICH IS ALSO AN ULTRA RARE DISEASE. THE OUTCOME OF THAT PROJECT IS TO FILE AN IND. THIS PROJECT HAS JUST LAUNCHED, SO THEY HAVE SIX MILESTONES, BUT THERE'S NO PROGRESS YET SINCE IT IS IN THE PROGRESS OF LAUNCHING.

THIS IS THE RECOMMENDATION FROM THE GRANTS WORKING GROUP. SO THIS APPLICATION WAS GIVEN A SCORE OF 3. THERE WERE NO MEMBERS THAT GAVE A SCORE OF 1. THERE WERE FOUR MEMBERS THAT GAVE A SCORE OF 2 AND TEN MEMBERS THAT GAVE THIS A SCORE OF 3. THE DEI SCORE IS A 7. AND THE CIRM TEAM RECOMMENDATION IS TO CONCUR WITH THE GWG RECOMMENDATION OF NOT FUNDING THE APPLICATION FOR THE REQUESTED AMOUNT.

MR. CHAIR.

CHAIRMAN IMBASCIANI: THANK YOU, GIL. I'D LIKE TO ENTERTAIN A MOTION FROM A BOARD MEMBER. THE MOTION WOULD BE TO ACCEPT THE RECOMMENDATION OF THE CIRM WORKING GROUP.

MS. DURON: SO MOVED.

CHAIRMAN IMBASCIANI: WE HAVE YSABEL DURON MAKING A MOVE.

MR. JUELSGAARD: I'LL SECOND.

CHAIRMAN IMBASCIANI: AND STEVE JUELSGAARD SECONDING. THANK YOU. BOARD MEMBERS, OPEN TO DISCUSSION. JUST GOING TO WAIT FIVE SECONDS. I DON'T SEE ANY HANDS RAISED. OKAY.

SO I'M GOING TO OPEN THE FLOOR TO COMMENTS ON THIS MOTION FROM THE PUBLIC. WE DO HAVE -- YES. PLEASE COME FORWARD AND STATE YOUR NAME.

MR. PIROVOLAKIS: THANK YOU VERY MUCH. MY NAME IS TERRY PIROVOLAKIS. THANK YOU FOR ALLOWING ME THE TIME TO SPEAK TO YOU TODAY. MANY OF YOU HAVE HEARD MY STORY BEFORE, BUT FOR THOSE OF YOU WHO HAVEN'T, MY NAME IS TERRY PIROVOLAKIS, AND MY SON MICHAEL WAS DIAGNOSED WITH SPG50, A TERRIBLE DEVELOPMENTAL NEUROMUSCULAR DISEASE CAUSING COMPLETE PARALYSIS AND SEVERE DEVELOPMENTAL DELAY.

I CANNOT ACCEPT THIS FATE FOR MY CHILD. AND AFTER THREE YEARS AND 4.5 MILLION IN DONATIONS, WE WERE ABLE TO MAKE, TEST, AND GIVE HIM THIS LIFESAVING GENE THERAPY. WE WERE FORTUNATE TO HAVE TWO MORE DOSES AFTER TREATING MICHAEL, BUT NO ONE WANTED TO TAKE OUR PROGRAM ON OR FUND THE TREATMENT FOR THESE CHILDREN. SO I CREATED ELPIDA

THERAPEUTICS, A CALIFORNIA-BASED SOCIAL PURPOSE CORPORATION TO ADDRESS THIS ISSUE.

WE FINALLY FOUND AN AVENUE THROUGH A PROGRAM AT THE NATIONAL INSTITUTE OF HEALTH CALLED THE BESPOKE GENE THERAPY CONSORTIUM OF WHICH OUR PROGRAM WAS SELECTED BY THE WORLD EXPERTS AS THE LEAD PROGRAM OF 63 APPLICANTS.

SUBSEQUENTLY WE CREATED A PARTNERSHIP BETWEEN ELPIDA, CIRM, AND THE NIH TO DEVELOP A TREATMENT FOR SPG50 AND ANOTHER ULTRA RARE CONDITION CALLED CMT4J. WE WOULD LIKE TO TAKE THIS OPPORTUNITY TO EXPRESS OUR DEEPEST GRATITUDE TO THE BOARD FOR FUNDING THAT PROGRAM.

BETWEEN THE TIME THAT WE APPLIED TO THE BGTC ALMOST ONE AND A HALF YEARS HAVE PASSED, BUT WE CONTINUE TO PROGRESS AND TREATED THREE MORE PATIENTS IN A PHASE 1/2 STUDY AT UTSW MEDICAL CENTER, ONE OF WHICH WAS AN INFANT AND, TO OUR KNOWLEDGE, THE YOUNGEST HUMAN BEING TO RECEIVE INTRATHECAL GENE THERAPY AT FIVE MONTHS OLD. THIS PROGRAM MADE SIGNIFICANT MILESTONES IN THE FIELD OF GENE THERAPY AND PAVED THE PATH FORWARD FOR OTHER RARE DISEASES.

THROUGH THE PROCESS, WE REALIZED THAT THE ONLY WAY FOR THIS TREATMENT TO REACH ALL THE CHILDREN, IT NEEDED TO BE APPROVED BY THE FDA. WE

DELAYED OUR CLIN2 APPLICATION TO CIRM BY SIX MONTHS IN AN EFFORT TO ENSURE WE HAD A FORMAL PIVOTAL APPROVAL FROM THE FDA, WHICH WE RECEIVED ON NOVEMBER 10TH. IT MUST BE NOTED THAT THIS IS NOT A TYPICAL PATH FOR THE FDA, AND THE FLEXIBILITY AFFORDED TO US IN AN EFFORT TO PROVIDE A TEMPLATE AND PATH FORWARD FOR OTHERS TO ALLOW THE RARE DISEASE FIELD TO CONTINUE. TO DATE NO INTRATHECAL GENE THERAPY HAS MADE IT TO A PIVOTAL TRIAL. OUR PROGRAM WILL BE THE FIRST.

THE GWG COMMITTEE HAD VARIED COMMENTS, BUT OVERALL DENIED OUR APPLICATION. I WILL NOT GO INTO THE FULL DETAILS AS WE PROVIDED A REPLY TO THE COMMENTS. AND ALL THE COMMENTS ARE ADDRESSABLE EXCEPT FOR ONE MAIN FACT. ONE OF THE CONCERNS EXPRESSED BY THE REVIEWERS AROUND THE PRECLINICAL STUDIES, BIODISTRIBUTION AND NUMBER OF CELLS TRANSDUCED IN THE BRAIN AND THE ANIMAL STUDIES. UNFORTUNATELY THIS REFLECTS THE LIMITATIONS OF GENE THERAPY TECHNOLOGY AVAILABLE TO US TODAY AND ALL CNS DISORDERS APPLYING FOR GENE THERAPY IN GENERAL.

DESPITE THIS, IN OUR HUMAN STUDIES THERE IS EVIDENCE TO SUGGEST A POSITIVE TREATMENT IMPROVING THE QUALITY OF LIFE FOR THESE PATIENTS. ONE REVIEWER'S COMMENTS HIGHLIGHTS WHY WE ARE

APPEALING THE GWG DECISION, AND I QUOTE. IF THIS STUDY INCLUSIVE OF A MANUFACTURING PLAN AND CLINICAL PROTOCOL IS ALLOWED TO PROCEED BY THE FDA, IT WOULD PROVIDE A SIGNIFICANT INFORMATION NOT ONLY FOR THIS INDICATION, BUT FOR OTHER RARE DISEASES CAUSED BY A SINGLE GENE DEFECT. CIRM SUPPORT WOULD BENEFIT NOT ONLY PATIENTS WITH THIS CONDITION, BUT ALL PATIENTS WITH SIMILAR CONDITIONS.

THIS PROJECT DEFINITELY ADVANCES CIRM'S MISSION. TO DATE WE HAVE ALL THE ELIGIBLE PATIENTS IDENTIFIED, THE MAJORITY U.S. BASED, AND WE'LL BEGIN MANUFACTURING NEXT WEEK. WE WILL BE TREATING PATIENTS IN JULY ALL BASED ON THIS CRITICAL FUNDING. IF WE REVOKE OUR APPLICATION AND REAPPLY IN SIX MONTHS, WE'RE AT SIGNIFICANT RISK OF DELAYING THIS PROGRAM BY 18 MONTHS AND CHILDREN WILL BE EXCLUDED.

MR. TOCHER: PLEASE WRAP UP.

MR. PIROVOLAKIS: ONE SECOND. I'M SORRY. I IMPLORE THIS COMMITTEE TO PLEASE FUND OUR PROGRAM AND PROVIDE US A PATH FORWARD TO ALLOW US TO SAVE THESE CHILDREN. WITH YOUR SUPPORT, WE CAN CHANGE THE LIVES OF THESE CHILDREN LIVING WITH THIS RARE DISEASE. THANK YOU. SORRY FOR GOING OVER. I APOLOGIZE.

MR. TOCHER: ADDITIONAL COMMENT ON THE

PHONE?

CHAIRMAN IMBASCIANI: THANK YOU. WE HAVE A MEMBER OF THE PUBLIC ON THE TELEPHONE. PLEASE IDENTIFY YOURSELF.

DR.. GRAY: IS THAT DIRECTED TO ME? THIS IS STEVEN GRAY.

CHAIRMAN IMBASCIANI: YES, MR. GRAY, WE CAN HEAR YOU. MAYBE SPEAK A LITTLE CLOSER TO YOUR MICROPHONE.

DR. GRAY: THIS IS STEVEN GRAY. I'M CALLING FROM UT SOUTHWESTERN MEDICAL CENTER. IT'S MY LAB THAT CONDUCTED THE IND-ENABLING PRECLINICAL STUDIES THAT SUPPORTED THE INITIAL CLINICAL TRIAL FOR SPG50.

I JUST WANT TO TAKE A MOMENT TO AGAIN THANK CIRM FOR THEIR CONSIDERATION, BUT ADDRESS REALLY THE VARY SPECIFIC CONCERN THAT WAS RAISED BY THE REVIEWERS OF A SKEPTICISM THAT THE, I GUESS, THE PRECLINICAL DATA DOES NOT SUPPORT THE NOTION THAT PATIENTS WOULD RECEIVE A BENEFIT. AND THAT CONCERN WAS REALLY AROUND SOME BIODISTRIBUTION DATA THAT WAS PROVIDED WHERE THE REVIEWERS CONCLUDED THAT THE BIODISTRIBUTION WAS BASICALLY INSUFFICIENT TO WARRANT ANY POSSIBILITY OF BENEFIT TO THE PATIENTS. AND THAT CONCLUSION WAS DRAWN BY LOOKING AT

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PRECLINICAL DATA SHOWING TRANSIENT RNA EXPRESSION ACROSS THE BRAIN, AND THESE WERE NC2 HYBRIDIZATION HISTOLOGY IMAGES. AND UNFORTUNATELY THE REVIEWERS INCORRECTLY INTERPRETED THAT DATA TO THINK THAT ONLY ONE IN 10,000 CELLS RECEIVED THE TRANSGENE. BUT THEY BASICALLY INCORRECTLY READ THE Y AXIS OF THOSE GRAPHS. AND THIS WAS PRETTY CLEARLY EXPLAINED IN OUR PUBLICATION IN THE *JOURNAL OF CLINICAL INVESTIGATION*. AND IN REALITY I THINK IT'S A MUCH HIGHER NUMBER OF CELLS THAT ARE TRANSDUCED.

AND I THINK THAT A LOT OF THE CRITICISM UNDERLYING THIS PROPOSAL WAS REALLY BASED ON, I APOLOGIZE FOR SAYING THIS, BUT KIND OF FLAWED EVALUATION OF THE PRECLINICAL DATA.

AND SO THE INVASIVE -- THE BACKGROUND OF THIS IS THAT THE GENE TRANSFER APPROACH THAT'S BEING USED IN THIS CLINICAL TRIAL FOR SPG50 MIRRORS AND MIMICS KIND OF A LARGE BODY OF PRECLINICAL EVIDENCE ACROSS A VARIETY OF DISEASES. I THINK THERE'S OVER TWO DOZEN DISEASES THAT ARE USING A SIMILAR APPROACH THAT ARE IN CLINICAL TRIALS NOW. AND THERE'S A WEALTH OF PRECLINICAL DATA THAT'S PUBLISHED THAT'S SHOWING FAIRLY SUBSTANTIAL AMOUNTS OF TRANSDUCTION ACROSS THE BRAIN WITH THIS VECTOR, THIS ROUTE OF DELIVERY, AND THIS DOSE.

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SO THOSE ARE REALLY THE POINTS THAT I WANTED TO RAISE TODAY TO, I GUESS, REQUEST THAT CIRM CONSIDER ALLOWING ELPIDA TO REAPPLY FOR THIS WITHOUT IT WAITING FOR SIX MONTHS. I THINK THAT THIS WAS A FAIRLY EASY, BUT A SIMPLE MISTAKE THAT WAS MADE BY THE REVIEWERS THAT REALLY CLOUDED, GREATLY CLOUDED THEIR ENTHUSIASM FOR THE OVERALL PROPOSAL. I'LL END THERE. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU FOR YOUR COMMENT, DR. GRAY. GIL, DO YOU HAVE A COMMENT ON THAT?

DR. MESSAHEL: I ALSO HAVE A COMMENT. CAN YOU HEAR ME OKAY?

CHAIRMAN IMBASCIANI: LET'S SEE.

MR. TOCHER: YES, WE CAN. PLEASE CONFINE YOUR COMMENTS TO THREE MINUTES. THANK YOU.

DR. MESSAHEL: I'M SOUAD MESSAHEL FROM ELPIDA THERAPEUTICS AND THE PI OF THE CLIN2 GRANT. I'D LIKE TO PLAY A VOICE RECORDING FROM A PARENT WITH CHILDREN WITH SPG50 DISEASE WHO HAVE ASKED ME TO SHARE THIS WITH YOU TODAY. I HOPE YOU CAN HEAR THIS.

HELLO, BOARD MEMBERS OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE. MY NAME IS REBECCA LOCKERT, AND I AM MOM OF NAOMI AND JACK. I

SPEAK TO YOU TODAY TO HUMBLY REQUEST YOU PROVIDE ELPIDA WITH A GRANT TO CONTINUE THEIR WORK TREATING CHILDREN WITH SPG50 DISEASE.

MY CHILDREN ARE WONDERFUL, HAPPY KIDS, AND IN MANY WAYS THEY ARE TYPICAL. NAOMI IS TWO AND A HALF AND LOVES CHICKEN NUGGETS AND NURSERY RHYMES. JACK IS SEVEN MONTHS OLD AND ENJOYS EATING SWEET POTATO AND HE LOVES ROLLING AROUND. BUT THEIR DIFFERENCES ARE NOTABLE BECAUSE OF THEIR SPG50 DIAGNOSIS. NAOMI CANNOT WALK OR TALK AND IS JUST NOW LEARNING TO CRAWL. JACK WAS EVALUATED AT THREE MONTHS OLD FOR EARLY INTERVENTION THERAPIES, AND HE WAS ALREADY MONTHS BEHIND HIS PEERS.

FOR A LONG TIME WE WONDERED WHY NAOMI WASN'T MEETING MILESTONES AS SHE CONTINUED TO LAG FURTHER BEHIND HER PEERS DESPITE NUMEROUS INTERVENTIONS. ON FRIDAY, MAY 12, 2023, AFTER MANY MONTHS OF TESTING AND EVALUATIONS, WE RECEIVED NAOMI'S GENETIC TEST RESULTS. AND I WILL NEVER FORGET THE PANIC THAT SET IN WHILE I WAITED THE HOUR AND A HALF FOR A NEUROLOGIST TO CALL AND EXPLAIN THE RESULTS.

WHEN WE LEARNED THE SEVERITY OF THE CONDITION, THE WORLD FELL OUT FROM UNDER OUR FEET. WORSE, WE LEARNED THIS WAS AN INHERITED CONDITION.

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AND OUR SON, SCHEDULED TO BE BORN IN EXACTLY FOUR WEEKS, ALSO HAD A 25-PERCENT CHANCE OF BEING AFFECTED. WE FOUND TERRY AND ELPIDA THAT VERY NIGHT. WITHIN A DAY HE MADE TIME TO SPEAK TO US AND HELP US CONNECT TO THE EXPERTS AND OTHER FAMILIES. MORE IMPORTANTLY, HE AND ELPIDA PROVIDED HOPE FOR US. WE SPENT MANY NIGHTS CRYING OURSELVES TO SLEEP WITH THE THOUGHT OF WHAT WOULD HAPPEN TO OUR BEAUTIFUL DAUGHTER. BUT THE HOPE ELPIDA GAVE US HELPED US GET UP THE NEXT MORNING AND DO WHAT NEEDED TO BE DONE. THERE WAS A TREATMENT THAT EXISTED. IT WAS POSSIBLE FOR US TO CHANGE NAOMI'S LIFE.

AFTER JACK WAS BORN, WE SENT HIS DNA TEST OFF IMMEDIATELY. FOR WEEKS WE AGONIZED OVER HIS EVERY MOVEMENT, AND AT 27 DAYS OLD HE LANDED IN THE CHILDREN'S HOSPITAL DUE TO FORMULA ASPIRATION. AS WE WATCHED HIM STRAIN TO BREATHE EVEN WITH SUPPLEMENTAL OXYGEN, HIS GENETIC TEST RESULTS WERE RELEASED TO US. THE TEST WAS POSITIVE FOR SPG50.

I SAT SOBBING IN HIS HOSPITAL ROOM LETTING FAMILY AND PROFESSIONALS KNOW THE DIAGNOSIS. TERRY CALLED ME IMMEDIATELY AND AGAIN PROVIDED HOPE ON OUR DARKEST DAY. ELPIDA WOULD DO EVERYTHING IN ITS POWER TO TRY AND SAVE MY SON. AND THEY DID JUST THAT.

THE TEAM AT ELPIDA MADE INCREDIBLE EFFORTS TO TREAT MY BABY. JACK RECEIVED THE GENE THERAPY TREATMENT ON DECEMBER 6TH, 2023, JUST A FEW DAYS SHY OF HIS SIX-MONTH BIRTHDAY. HE'S DOING FANTASTIC. WE SEE A DIFFERENCE ALREADY. FOR EXAMPLE, MOST BABIES SMILE AT PEOPLE BY FIVE WEEKS, BUT JACK WAS NEVER ABLE TO CONNECT WITH US ANY ON SOCIAL LEVEL BEFORE TREATMENT. NOW, INSTEAD OF LOOKING THROUGH US, HE SMILES AT US, HE TALKS TO US, AND HE INTERACTS WITH US. AS A MOM, I CAN'T TELL YOU HOW GOOD THAT FEELS.

MR. TOCHER: EXCUSE ME. YOUR TIME IS UP. IS THIS ABOUT TO CONCLUDE? THE TIME LIMIT OF THREE MINUTES IS UP.

DR. MESSAHEL: IT JUST WRAPPED UP. THANK YOU VERY MUCH FOR CONSIDERATION OF OUR APPEAL. THANK YOU.

CHAIRMAN IMBASCIANI: THANK THE MEMBERS OF THE PUBLIC FOR THEIR COMMENTS. ARE THERE ANY OTHERS? YES, WE HAVE ANOTHER.

DR. IANNACCONE: HELLO.

CHAIRMAN IMBASCIANI: YES, HELLO. WE CAN HEAR YOU. PLEASE SPEAK CLOSE TO YOUR MICROPHONE. THANK YOU.

DR. IANNACCONE: THANK YOU SO MUCH. THIS

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IS SUSAN IANNACCONE, AND I'M A PEDIATRIC NEUROLOGIST AT UT SOUTHWESTERN AND THE SITE PI FOR THIS PHASE 1 STUDY OF THAT SPG50. AND I JUST WANT TO GIVE YOU AN UPDATE ON THIS PHASE 1 STUDY.

WE HAVE ENROLLED THREE PATIENTS. THE FIRST PATIENT WAS FIVE YEARS OLD AT DOSING AND IS COMING UP AT 12 MONTHS AFTER THIS INFUSION. PATIENT TWO WAS THREE YEARS OLD AT THE TIME OF DOSING AND IS NOW NINE MONTHS OUT FROM THAT TREATMENT. AND PATIENT THREE, AS YOU JUST HEARD, WAS FIVE MONTHS OLD AT DOSING AND IS NOW APPROACHING TWO MONTHS AFTER THE TREATMENT. ALL OF THE PATIENTS ARE DOING EXTREMELY WELL AT THIS TIME IN TERMS OF GENERAL MEDICAL STATUS.

THE FIRST PATIENT HAD SOME DIFFICULTY WITH EMESIS AFTER THE DOSING WHICH IS VERY COMMON AFTER AAV9 AND SUBSEQUENTLY THE OTHER TWO PATIENTS DID MUCH BETTER. THERE'S NO EVIDENCE OF OBJECTIVE IMPROVEMENT IN NEUROLOGIC STATUS RIGHT NOW, BUT THE CHILDREN ARE ALL STABLE FROM THE NEUROLOGIC STANDPOINT. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, DOCTOR. WE HAVE A BOARD MEMBER FISCHER-COLBRIE COMMENT.

MR. FISCHER-COLBRIE: I REALIZE THERE'S A MOTION ON THE TABLE. WOULD LIKE TO UNDERSTAND WHAT

THE CONSIDERATION MIGHT BE TO PROVIDE A SCENARIO OF ALLOWING FOR RESUBMISSION AND GOING IN EFFECT WITH A SCORE OF 2 FOR THIS. I'M NOT SURE WHAT THE PROTOCOL IS FOR PROVIDING THAT.

CHAIRMAN IMBASCIANI: GIL, CAN I ASK YOU TO ELABORATE?

DR. SAMBRANO: SURE. SO THIS APPLICATION HAD A SCORE OF 3. ALL APPLICANTS ARE ABLE TO RESUBMIT AND ADDRESS CONCERNS THAT COME UP FROM THE GRANTS WORKING GROUP. AND AS YOU KNOW, THE GRANTS WORKING GROUP IS VERY KEEN ON UNDERSTANDING WHAT THE DIFFERENCE BETWEEN A 1, 2, AND 3 IS. AND THEY'RE VERY DELIBERATE IN TERMS OF HOW THEY APPROACH THAT.

OFTEN THEY SEE SOMETHING THAT A SCORE OF 2 IS SIMPLY NEEDING SIMPLE CLARIFICATION AND IMPROVEMENT THAT CAN READILY COME BACK. I THINK IN THIS PARTICULAR APPLICATION, THERE WERE A GROUP OF FOUR THAT THOUGHT THAT MIGHT BE THE CASE, BUT WE HAD TEN THAT THOUGHT OTHERWISE, THAT THERE WERE MORE SIGNIFICANT CONCERNS THAT NEEDED TO BE ADDRESSED THAT WOULD PROBABLY NEED THE SIX-MONTH PERIOD BEFORE THEY COULD COME BACK.

SOME OF THOSE ARE RELATED TO THE PRECLINICAL DATA THAT WAS REFERENCED, BUT SOME OF IT WAS ALSO RELATED TO THE CURRENT STAGE OF THE PROGRAM

AND HEARING BACK FROM THE FDA ON SOME OF THE SPECIFIC ELEMENTS, SUCH AS THE CMC AND THE REDESIGN OF THEIR PLAN. SO CERTAINLY WE WOULD WELCOME THE APPLICANT TO REVISE THE APPLICATION AND RESUBMIT AT THE SIX-MONTH PERIOD AS WAS RECOMMENDED BY THE GRANTS WORKING GROUP.

CHAIRMAN IMBASCIANI: THANK YOU, GIL.

DR. MELMED: CAN YOU REPEAT --

MR. TOCHER: YOU HAVE A RECUSAL.

DR. MELMED: I CAN'T ASK A QUESTION?

CHAIRMAN IMBASCIANI: THANKS ANYWAY. DAVID.

DR. HIGGINS: I JUST WANT TO BE CLEAR. THERE'S TWO SCENARIOS HERE. ONE IS THAT A MISTAKE WAS MADE, AND IT CAUSED A DIFFERENT INTERPRETATION OF DATA. THE OTHER IS THAT A MISTAKE WASN'T MADE, AND THE STATE OF THE CLINICAL TRIAL WAS APPROPRIATE. CAN YOU SORT OF ASSURE US THAT THERE WASN'T JUST SIMPLY A MISTAKE IN ONE PIECE OF DATA, THAT IF IT HAD BEEN INTERPRETED DIFFERENTLY OR FLIPPED OR WHATEVER, THAT IT WOULD RESULT IN MORE ONES, I GUESS?

DR. SAMBRANO: SO I THINK AN IMPORTANT THING TO CONSIDER IS THAT THESE SCORES ARE NOT BASED ON ONE SINGULAR ITEM. SO IN THIS CASE IT WAS NOT

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SIMPLY THE PRECLINICAL DATA. BUT, NEVERTHELESS, THE WAY WE ENCOURAGE APPLICANTS TO DO THIS IS BY REVISING THEIR APPLICATION, ADDRESSING THE CONCERNS SO THAT THE GRANTS WORKING GROUP CAN SEE IT, AND CORRECT ANY MISINTERPRETATIONS OR PROVIDE ADDITIONAL INFORMATION THAT MAY CLARIFY WHAT IT IS THAT THEY MAY HAVE NOT SEEN THE WAY APPLICANTS WERE TRYING TO CONVEY.

SO TO THE PROCESS OF HAVING A 3 SIMPLY MEANS THEY CAN REVISE, ADDRESS THOSE CONCERNS, AND COME BACK IN SIX MONTHS.

DR. HIGGINS: AND THE SIX MONTHS IS NOT A DEADLINE. IT'S JUST --

DR. SAMBRANO: IT'S NOT A DEADLINE. IT'S JUST THE MINIMUM AMOUNT OF TIME BASED ON WHAT THE GRANTS WORKING GROUP THOUGHT THE APPLICATION NEEDS IN ORDER TO COME BACK.

DR. HIGGINS: GREAT. THANKS, GIL.

CHAIRMAN IMBASCIANI: THANK YOU, BOARD MEMBER HIGGINS. ANY OTHER COMMENT FROM BOARD MEMBERS?

MR. FISCHER-COLBRIE: GIL, JUST AS A REMINDER FOR EVERYBODY, IF YOU CAN REMIND PEOPLE WHAT A 2 DOES IN TERMS OF RESUBMISSION AND REAPPLICATION AND THE TIME PERIOD.

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DR. SAMBRANO: SURE. FOR A SCORE OF 2, IT IS UP TO THE APPLICANT TO DETERMINE WHEN THEY ARE READY TO COME BACK. BUT TYPICALLY, IN TERMS OF HOW IT'S GIVEN BY THE GWG, THE ASSUMPTION IS THEY CAN COME BACK WITHIN ABOUT A TWO-MONTH PERIOD. AND SO WHAT WE DO, WE PROVIDE A SUMMARY AS YOU'VE SEEN, LIKE THIS, THAT PROVIDES ALL OF THE COMMENTS AND HIGHLIGHTS SPECIFICALLY THE CONCERNS THAT WERE RAISED BY THE GRANTS WORKING GROUP FOR THEM TO ADDRESS. WHAT COMES BACK FOR A 2 IS ESSENTIALLY THE SAME APPLICATION WITH REVISIONS ON IT AND CORRECTIONS AND A STATEMENT FOR WHAT IT IS THAT THEY DID.

FOR A SCORE OF 3, THEY RESTART AN APPLICATION, BUT THEY SIMILARLY ADDRESS THE CONCERNS THAT ARE RAISED BY THE GRANTS WORKING GROUP. AND THE GRANTS WORKING GROUP HAS AN AWARENESS OF THE FACT THAT THIS CAME IN BEFORE.

CHAIRMAN IMBASCIANI: THANK YOU. ANY OTHER BOARD MEMBERS WISH TO MAKE A COMMENT?

DR. FLOWERS: I HAVE ALSO A CLARIFYING QUESTION. IF WE DO NOT VOTE IN FAVOR OF THE RECOMMENDATION TO NOT FUND THE GRANT, WHAT IS THE OUTCOME?

DR. SAMBRANO: SO THEN THEY CAN COME BACK

IN SIX MONTHS WITH A NEW APPLICATION.

DR. FLOWERS: SO THAT MAKES ME FEEL LIKE EITHER WAY IT'S SIX MONTHS.

DR. SAMBRANO: I'M SORRY. NO. WELL, IF YOU VOTE IN FAVOR OF THE MOTION, WHICH IS TO NOT FUND, THAT MEANS THAT THEY HAVE THE OPTION TO COME BACK IN SIX MONTHS BECAUSE THEY GOT A SCORE OF 3.

DR. FLOWERS: WHAT IF WE VOTE AGAINST THE MOTION?

MR. TOCHER: WE WOULD NEED ANOTHER MOTION.

CHAIRMAN IMBASCIANI: THANK YOU. OKAY.

DR. THOMAS: SO I HAVE A COUPLE OF COMMENTS. ONE IS I'LL PREFACE THIS BY SAYING I WASN'T ON BOARD WHEN THIS GWG WAS HELD. BUT I CAN REPRESENT, HAVING SAT IN ON VIRTUALLY EVERY ONE FOR THE 12 YEARS I WAS CHAIR, THAT THE LEVEL OF COMPETENCE OF THE REVIEWERS IS, IN GENERAL, EXTREMELY HIGH. AND IF YOU WERE TO LISTEN TO THE DEGREE OF DETAIL THAT THEY GIVE TO THE STUDY OF EACH OF THE APPLICATIONS AND THE COMMENTARY THEY GIVE AND THE EXPERTISE THEY BRING TO THE TABLE, GENERALLY SPEAKING, IT IS HARD TO BELIEVE THAT THEY MADE A FATAL MISTAKE IN THEIR EVALUATION OF SOMETHING. I'M NOT SAYING IT CAN'T HAPPEN, BUT I JUST WANTED TO LAY THAT OUT AS A GENERAL STATEMENT ABOUT THE GWG.

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ANOTHER THING, POINT I'D LIKE TO MAKE, AND I COMPLETELY APPRECIATE THE CIRCUMSTANCES HERE THAT THE FAMILY IS ENDURING, WHICH WE ALL FEEL TERRIBLE ABOUT FOR SURE. BUT IN TERMS OF CIRM'S PROCESS, WE HAVE -- THE SCORE OF 3 IS GIVEN FOR A REASON, AND THIS WASN'T A CLOSE CALL ON THAT NUMBER, AND THAT IT HAS NOT BEEN OUR PRACTICE THAT I'M AWARE OF TO EVER HAVE TAKEN A TIER III RECOMMENDATION AND TURNED THAT INTO ANYTHING BUT A TIER III RESULT, WHICH IS TO, GIL, YOU CAN CORRECT ME IF I'M WRONG ON THAT.

DR. SAMBRANO: YOU'RE CORRECT.

DR. THOMAS: AND THAT THE ASK HERE IS NOT FOR APPROVAL, ALTHOUGH I'M SURE THAT WOULD BE APPRECIATED, BUT FOR A HYBRID APPROACH, WHICH IS TO COME BACK IN A LESSER TIME PERIOD, BUT TOO HAS NEVER BEEN DONE PROCEDURALLY FOR ANY APPLICATION THAT RECEIVED A TIER III.

SO JUST TO LET THE BOARD KNOW THAT AND THEY HAVE A PROCESS CONCERN, THAT IF WE START DOING THAT, THAT WILL OPEN UP THE FLOODGATES FOR A SERIES OF TIER III APPEALS AND LIKE SUGGESTIONS, ET CETERA, WHICH IS NOT SOMETHING THAT CONFORMS TO WHAT WE'VE DONE HISTORICALLY. SO WITH ALL DUE RESPECT TO THE TIMING HERE, AND, AGAIN, WITH GREAT APPRECIATION FOR WHAT THE FAMILY IS DEALING WITH, I JUST WANTED THE

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BOARD TO KNOW THOSE TWO POINTS.

CHAIRMAN IMBASCIANI: THANK YOU, DR. THOMAS. I DON'T SEE ANY OTHER COMMENTS. I'M GOING TO ASK SCOTT TO TAKE THE ROLL THEN.

DR. HIGGINS: MR. CHAIRMAN, ONE QUICK COMMENT. I JUST WANT TO MAKE SURE THAT TO SAY PUBLICLY THAT I WAS NOT FOR A MOMENT CHALLENGING YOUR COMPETENCE OR THE END PRODUCT THAT YOU GIVE. WE RESPECT YOU BEYOND ANY STANDARD THAT ANYBODY ELSE COULD STAND UP THERE AND MAKE.

DR. SAMBRANO: WE APPRECIATE THE QUESTIONS, AND THAT'S PART OF THE PROCESS. AND SO THEY'RE ALWAYS WELCOME. THANK YOU, DAVID.

CHAIRMAN IMBASCIANI: SCOTT, BEFORE YOU CALL THE ROLL, FOR REASONS SIMILAR TO THE LAST TIME, I'M GOING TO ASK YOU TO REPEAT THE MOTION AND WHAT IT MEANS.

MR. TOCHER: THE MOTION IS TO ACCEPT THE RECOMMENDATION OF THE GRANTS WORKING GROUP AND TO NOT FUND THE APPLICATION AND NOT ALLOW RESUBMISSION FOR SIX MONTHS. SO A YES VOTE IS TO FOLLOW THE RECOMMENDATION AND ALLOW RESUBMISSION ONLY AFTER SIX MONTHS.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH. NOW CALL THE ROLL. THANK YOU.

MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: YES.
MR. TOCHER: ANNE-MARIE DULIEGE. YSABEL DURON.
MS. DURON: WITH HEAVY HEART, I SAY YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
MR. FISCHER-COLBRIE: YES.
MR. TOCHER: FRED FISHER.
DR. FISHER: YES.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.

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MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: DAN BERNAL.
MR. BERNAL: AYE.
MR. TOCHER: I'LL TRY ONE MORE TIME FOR ANNE-MARIE DULIEGE. THANK YOU. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANK YOU, MR. TOCHER. AND THANK YOU, BOARD MEMBERS, FOR WHAT WAS A DIFFICULT CONVERSATION, I KNOW. I'D LIKE TO MOVE TO --
DR. THOMAS: MR. CHAIR, MAY I ADD A COMMENT HERE? I'VE SORT OF CHOSEN THIS POINT IN THE AGENDA TO MAKE AN FYI FOR THE BOARD, WHICH I THINK YOU'LL APPRECIATE. SO WE'VE JUST HAD APPROVAL OF SEVERAL APPLICATIONS, MOST OF WHICH HAPPENED TO BE IN THE NEURO SPACE. WE HAD VERY RECENTLY -- AS THE BOARD RECALLS, YOU ALL APPROVED A FUNDING PLAN FOR NEUROPSYCH AT A RECENT BOARD MEETING. AND THAT WAS SORT OF THE KICKOFF TO HOW WE'RE GOING TO GO ABOUT DEPLOYING THE BILLION FIVE AUTHORIZED FOR NEURO CONDITIONS IN PROP 14.
THAT, OF COURSE, ONCE THAT WAS APPROVED, BEGGED THE QUESTION OF BECAUSE IT WAS A HUNDRED PLUS MILLION DOLLARS ALLOCATED, HOW WERE WE GOING TO ALLOCATE THE BALANCE OF THE 1.4 BILLION. AND SO

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THAT WAS THE QUESTION SQUARELY BEFORE THE NEURO TASK FORCE IN A RECENT MEETING THAT IT HAD IN WHICH CHAIRMAN OF THE TASK FORCE, WHICH WAS LARRY, DID AN EXPERT JOB IN GUIDING THE GROUP THROUGH A DISCUSSION WHICH CONTEMPLATED A FUNDING PLAN FOR NOT JUST ADDITIONAL NEUROPSYCH PROJECTS, BUT AS WELL FOR NEURODEGENERATIVE PROJECTS AND NEURO-INJURY PROJECTS.

AND THE UPSHOT OF THE DISCUSSION WAS A GAME PLAN FOR HOW TO PROCEED COMPREHENSIVELY GOING FORWARD TO DEPLOY THAT REMAINING FUNDING WE HAVE FOR THAT VERY IMPORTANT SET OF CONDITIONS SET FORTH IN THE PROPOSITION.

SO THIS WAS A -- DIDN'T WANT TO LET THIS GO WITHOUT MENTIONING THIS. THIS IS A MAJOR DEVELOPMENT FOR CIRM TO NOW HAVE THIS COMPREHENSIVE GAME PLAN. AND I WOULD LIKE TO SINGLE OUT ROSA SPECIFICALLY WHO WAS THE, ROSA AND HER TEAM, WHO DEVELOPED A VERY COMPREHENSIVE BACKGROUND PIECE THAT WAS THE UNDERPINNING OF THE ENTIRE NEURO TASK FORCE DISCUSSION THAT WE HAD. AND JUST TO COMMEND ROSA FOR HER EXCELLENT WORK AND HER TEAM IN DOING THAT. SO DIDN'T WANT TO LET THIS OPPORTUNITY PASS. I THOUGHT, AFTER HAVING ENTERTAINED THESE NEURO APPLICATIONS, IT WAS A GOOD TIME TO INFORM THE

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BOARD. SO THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, J.T., FOR YOUR COMMENTS. AND, GIL, THANK YOU AND YOUR WHOLE TEAM FOR ALL THE WORK ON THE PRESENTATION. APPRECIATE IT.

I'D LIKE INVITE TO THE PODIUM OUR FINANCIAL OFFICER, POUNEH SIMPSON FOR A DISCUSSION OF THE FINANCIAL AUDIT. THIS IS AGENDA ITEM 15.

MS. SIMPSON: MR. CHAIR, MADAM VICE CHAIR, AND MEMBERS OF THE BOARD. I'M POUNEH SIMPSON, SENIOR DIRECTOR OF FINANCE. THANK YOU FOR GIVING ME AN OPPORTUNITY TO PRESENT THE FISCAL YEAR 21/22 FINANCIAL AUDIT TODAY.

AS BACKGROUND, STATE AGENCIES ARE REQUIRED TO PROVIDE THEIR FINANCIAL STATEMENTS TO THE STATE CONTROLLER'S OFFICE EVERY YEAR AND THEY'RE DONE. CIRM HAS ADDITIONAL LAYERS OF AUDITING AND REVIEW. SPECIFICALLY, PROP 71 AND PROP 14 REQUIRE THAT CIRM HAVE AN ADDITIONAL FINANCIAL AUDIT PERFORMED BY AN INDEPENDENT ACCOUNTING FIRM BEFORE IT IS AUDITED BY THE STATE CONTROLLER'S OFFICE. THIS MAKES CIRM ONE OF THE MOST AUDITED STATE AGENCIES IN THE STATE OF CALIFORNIA.

THIS YEAR WE SELECTED MACIAS, GINI & O'CONNELL TO PERFORM THE FINANCIAL AUDIT THAT'S

BEFORE YOU. THE AUDIT LOOKS AT OUR PERFORMANCE WITH RESPECT TO OUR MANDATE AND MISSION. SO I WILL START BY READING OUR MISSION. ACCELERATING WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

TO PROVIDE SOME CONTEXT WITH REGARDS TO THIS AUDIT, I WANTED TO LET YOU KNOW THAT PROP 14 WAS ON THE BALLOT IN NOVEMBER OF 2020. SO IN JANUARY OF 2021, CIRM HAD A SIX-MONTH RELAUNCH. DURING THAT RELAUNCH, WE SOLD OUR VERY FIRST PROP 14 BOND, WHICH WAS AN INFLUX OF REVENUE THAT WAS REPRESENTED IN OUR FINANCIAL AUDIT THAT WAS BEFORE YOU LAST YEAR. BECAUSE IT WAS A SHORT SIX-MONTH RELAUNCH, WE DIDN'T SPEND ALL THE REVENUE AVAILABLE TO US.

SO WITH REGARDS TO THE AUDIT THAT'S BEFORE YOU TODAY, WHICH IS FISCAL YEAR 21/22 ENDING IN JUNE 30TH OF '22, WE HAD REVENUES CARRIED FORWARD FROM THE PRIOR YEAR. THEREFORE, NO ADDITIONAL BONDS WERE SOLD. BUT WE HAD EXPENDITURES OF $138 MILLION APPROXIMATELY THAT ARE REFLECTED IN THE AUDIT BEFORE YOU. THIS LEAVES A NET BALANCE OF NEGATIVE 90 MILLION BECAUSE WE DIDN'T HAVE REVENUE COMING IN. WE HAD THE CARRY-OVER.

THIS IS SOMETHING THAT IRONS OUT OVER THE YEARS AS THE INFLOW OF REVENUE AND THE OUTPUT OF EXPENDITURES EVENS OUT WITH OUR PROGRAM. AND YOU WILL SEE THAT IN FUTURE FISCAL AUDITS.

I WANTED TO TALK A LITTLE BIT ABOUT THE AUDIT AND WHAT IT WAS LOOKING AT. IT WAS TESTING THE FAIR REPRESENTATION OF OUR FINANCIAL DATA AND LOOKING AT OUR INTERNAL CONTROLS TO ENSURE THAT WE WERE NOT MISREPRESENTING ANY FINANCIAL DATA DUE TO ERROR OR FRAUD.

I'M HAPPY TO REPORT THAT, ONCE AGAIN, THERE WERE NO AUDIT FINDINGS IN OUR FINANCIAL AUDIT. THE AUDIT WAS CERTIFIED BY THE STATE CONTROLLER'S OFFICE SUBSEQUENT TO THE COMPLETION BY OUR INDEPENDENT AUDITING FIRM. OF SIGNIFICANT NOTE IS THAT IN THIS AUDIT YOU SEE THE FIRST LARGE INCREASE IN REVENUE TO FUND 1031, WHICH IS OUR PATIENT SUPPORT FUND. THIS IS THE VEHICLE BY WHICH WE'RE FUNDING THE PATIENT SUPPORT PROGRAM THAT YOU'VE HEARD SO MUCH ABOUT.

WE HAVE CRAIG HARNER, THE ASSURANCE PARTNER WITH MGO, WITH US TODAY WHO WILL GO OVER IN DETAIL THE FINANCIAL AUDIT AND ANSWER YOUR QUESTIONS. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, POUNEH.

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I PRESUME THE PRESENTATION IS COMING IN REMOTELY, YES?

MR. HARNER: YEAH. THIS IS CRAIG. I'M HERE REMOTE. SO I'LL SHARE MY SCREEN AND BRING UP THE FINANCIAL STATEMENTS. THANK YOU FOR THAT INTRODUCTION, POUNEH. AND THANK YOU TO THE MEMBERS OF THE ICOC FOR ALLOWING US TO PRESENT THE RESULTS OF OUR AUDIT TODAY.

POUNEH SUMMED UP THE SCOPE AND PURPOSE OF THE AUDIT VERY WELL. AS SHE NOTED, CIRM IS ONE OF THE MOST, IF NOT THE MOST AUDITED ENTITY IN THE WHOLE STATE OF CALIFORNIA. AND ON TOP OF THE AUDIT THAT THE STATE CONTROLLER DOES AND THAT WE DO, AFTER WE ISSUE OUR AUDIT REPORTS, JUST SO THE ICOC IS AWARE, THE STATE CONTROLLER THEN COMES IN AND REVIEWS OUR AUDIT AND OUR AUDIT WORKPAPERS AND MAKE SURE THAT WE PERFORMED THE AUDIT IN ACCORDANCE WITH THE APPROPRIATE AUDITING STANDARDS AND CALIFORNIA LAW, REGULATIONS, AND CONTRACTS. SO THERE'S ANOTHER LAYER ON TOP OF THIS AS WELL.

SO POUNEH MENTIONED WE PERFORMED THE AUDIT FOR THE FISCAL YEAR ENDED JUNE 30, 2022. AND I HAVE -- AND AS PART OF OUR AUDIT, WE ISSUE THREE REPORTS, AND THOSE THREE REPORTS ARE CONTAINED IN TWO DOCUMENTS WHICH I'LL GO OVER WITH YOU TODAY.

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THE FIRST DOCUMENT I HAVE AND SHARING ON THE SCREEN CONTAINS OUR INDEPENDENT AUDITOR'S REPORT, IT CONTAINS THE FINANCIAL STATEMENTS, AND THEN ALSO A SECTION CALLED MANAGEMENT DISCUSSION AND ANALYSIS. AND WHAT THIS IS IS MEANT TO BE READ IN CONJUNCTION WITH THE FINANCIAL STATEMENTS THAT MANAGEMENT PREPARES. THEY GO THROUGH AND THEY EXPLAIN ANY SIGNIFICANT CHANGES YEAR OVER YEAR.

SO THE VERY FIRST SECTION OF THE FINANCIAL STATEMENTS CONTAINS OUR INDEPENDENT AUDITOR'S REPORT. AND THE FIRST SECTION HERE CONTAINS OUR AUDIT OPINION. AND SO WE'RE HAPPY TO REPORT THAT WE ISSUED AN UNMODIFIED OPINION ON CIRM'S FINANCIAL STATEMENTS. AND, AGAIN, UNMODIFIED OPINION IS THE HIGHEST LEVEL OF ASSURANCE THAT AN INDEPENDENT AUDITOR CAN GIVE AN ORGANIZATION REGARDING THE FAIR PRESENTATION OF THEIR FINANCIAL STATEMENTS.

AS WE GO DOWN, WE PROVIDE OUR BASIS FOR OUR OPINIONS, WHICH IS HOW WE'RE ABLE TO CONCLUDE THAT WE CAN SUPPORT AN UNMODIFIED OPINION. AND WE TALK ABOUT HOW WE PERFORMED THE AUDIT IN ACCORDANCE WITH THE GENERALLY ACCEPTED AUDITING STANDARDS AND ALSO GOVERNMENT AUDITING STANDARDS. THAT ADDS AN ADDITIONAL LAYER ONTO THE SCOPE OF WORK WE HAVE TO DO, AND THERE'S A SPECIAL REPORT FOR THAT WHICH I'LL

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GET TO IN A FEW MINUTES.

THERE'S ANOTHER REPORT THAT GOES THROUGH THE RESPONSIBILITIES OF MANAGEMENT, WHICH POUNEH SUMMED UP VERY NICELY, AND THE RESPONSIBILITIES OF THE AUDITING FIRM. AND SO THIS GOES THROUGH ALL OUR REQUIREMENTS THAT WE HAVE TO DO IN PERFORMING AN AUDIT. WE HAVE TO EXERCISE PROFESSIONAL JUDGMENT, MAINTAIN PROFESSIONAL SKEPTICISM THROUGHOUT THE AUDIT, WHICH MEANS WE'RE CONSTANTLY ASKING QUESTIONS AND THE LIKE. WE ALSO HAVE TO MAINTAIN AND REMAIN INDEPENDENT OF MANAGEMENT AND THE ENTITY. AND THEN ALSO WE EVALUATE THE APPROPRIATENESS OF ALL THE ACCOUNTING POLICIES THAT ARE USED BY CIRM, ANY SIGNIFICANT JUDGMENTS OR ESTIMATES MADE BY MANAGEMENT, AND THEN WHETHER THERE'S ANY CONDITIONS OR EVENTS THAT CAUSE US TO BE BELIEVE THAT THERE'S A SUBSTANTIAL DOUBT ABOUT A GOING CONCERN, WHICH THERE WERE NOT.

AND THEN THE LAST PAGE OF OUR INDEPENDENT AUDITOR'S REPORT IS WHERE WE SIGN AND WE DATED THE REPORT. YOU WILL SEE THAT WE ISSUED OUR REPORT ON NOVEMBER 4, 2022, AND, AGAIN, WE ISSUED A MODIFIED OPINION.

THE NEXT SECTION IS THIS ND&A. THIS SECTION IS NOT, YOU WILL NOTICE, IT'S NOT AUDITED,

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IT'S UNAUDITED; HOWEVER, WE DO READ THROUGH IT AND MAKE SURE THERE'S NO MATERIAL INCONSISTENCIES WITH ANY OF THE NUMBERS AND AMOUNTS AND DISCUSSIONS WITH THE FINANCIAL STATEMENTS THEMSELVES, AND WE MAKE SURE THAT MANAGEMENT'S EXPLANATIONS MAKE SENSE.

THE FINANCIAL STATEMENTS THEMSELVES ARE WHAT WE AUDIT. WE HAVE THE BALANCE SHEET WHICH CONTAINS WHAT'S CALLED THE STEM CELL FUND AND WHAT WE CALL STATEMENT OF GOVERNMENTAL ACTIVITIES, WHICH IN THIS CASE IS JUST MADE UP OF ONE FUND, THE STEM CELL FUND.

AND THEN THE SECOND PAGE IS THE INCOME STATEMENT, WHICH IS A STATEMENT OF ACTIVITIES AND THE STATEMENT OF REVENUES, EXPENDITURES, AND CHANGES IN FUND BALANCES. THIS SHOWS THE CHANGES FOR THE YEAR, THE REVENUES THAT CAME IN, AND THE EXPENDITURES THAT WERE MADE.

AND THEN THE FINAL SECTION THAT THE AUDIT CONTAINS IS NOTES TO THE FINANCIAL STATEMENTS. SO THESE CONTAIN MORE INFORMATION ABOUT THE BALANCES THAT ARE IN THE FINANCIAL STATEMENTS THEMSELVES AND THE ACCOUNTING POLICIES THAT ARE USED.

THIS YEAR, BECAUSE OF THE AFOREMENTIONED PROP 14 PASSING AND THE NEW FUND CREATED FOR THE 2020 OR PROP 14 EXPENDITURES AND BOND MONIES, WE

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RECOMMENDED THAT MANAGEMENT INCLUDE WHAT'S CALLED A COMBINING STATEMENT AS SUPPLEMENTARY INFORMATION. THE PURPOSE OF THIS IS JUST TO PROVIDE MORE DETAILED INFORMATION ABOUT THE TOTAL STEM CELL FUND AND WHAT'S MADE OF IT.

SO YOU CAN SEE IT'S BEEN BROKEN OUT INTO THREE SUBFUNDS, IF YOU WILL. THE FIRST ONE WAS THE STEM CELL FUND OF 2004, WHICH IS THE PROP 71 FUND, AND THE NEW STEM CELL FUND OF 2020, WHICH IS THE NEW PROP 14 FUND, AND ALSO THE LICENSING AND ROYALTIES FUND WHICH IS FOR THE PATIENT SERVICES.

AND SO WHEN WE ADD UP THESE THREE FUNDS HERE, WE GET TO THE TOTAL STEM CELL FUND THAT WAS PRESENTED ON THE BALANCE SHEET EARLIER. AS WELL AS THE SAME WITH THE INCOME STATEMENT, IT SHOWS THE DIFFERENT REVENUES AND EXPENDITURES BROKEN OUT BY EACH OF THE DIFFERENT FUNDS. WHAT WE'LL START EXPECTING IS THAT AS THE PROP 71 FUNDS WIND DOWN, THESE EXPENDITURES AND THE MONIES COMING IN WILL START TO DIMINISH OVER THE NEXT FEW YEARS WHILE THE ACTIVITIES IN THE STEM CELL FUND OF 2020 OR PROP 14 FUNDS WILL START TO INCREASE SUBSTANTIALLY.

THE LAST REPORT IN THE FINANCIAL STATEMENT DOCUMENT IS WHAT WE CALL OUR INDEPENDENT AUDITOR'S REPORT OVER INTERNAL CONTROLS AND ON COMPLIANCE WITH

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OTHER MATTERS WHERE WE PERFORM AN AUDIT IN ACCORDANCE WITH GOVERNMENT AUDITING STANDARDS. SO AS I MENTIONED, THE GOVERNMENT AUDITING STANDARDS ADDS AN ADDITIONAL LAYER OF THINGS THAT WE HAVE TO DO AS PART OF OUR AUDIT. ONE IS OBTAIN AN UNDERSTANDING OF CIRM'S INTERNAL CONTROLS. AND WHILE WE DON'T PROVIDE ANY OPINION ON THE INTERNAL CONTROLS IN PLACE, IF WE DO COME ACROSS ANY INTERNAL CONTROLS DEFICIENCIES THAT RISE TO A SIGNIFICANT DEFICIENCY LEVEL OR MATERIAL WEAKNESS LEVEL, WE'RE REQUIRED TO REPORT THAT TO THE ICOC IN THIS LETTER. AND WE'RE HAPPY TO REPORT, AS POUNEH MENTIONED, THAT THERE WERE NO INTERNAL CONTROL DEFICIENCIES TO BE REPORTED.

AND THEN THE LAST SECTION DEALS WITH COMPLIANCE WITH LAWS, REGULATIONS, CONTRACTS AND GRANT AGREEMENTS. SO AS PART OF OUR AUDIT WE CONSIDER THE LAWS, REGULATIONS, ANY CONTRACTS, GRANT AGREEMENTS THAT COULD HAVE A MATERIAL IMPACT ON THE FINANCIAL STATEMENTS IF THERE WERE NONCOMPLIANCE. SO, FOR EXAMPLE, WHAT THE TWO BIGGER AREAS WE TEND TO LOOK AT ARE THE TWO LAWS THAT CREATED CIRM AND WHAT THOSE GRANT EXPENDITURES CAN BE USED FOR. SO WE TAKE THAT INTO ACCOUNT AS PART OF OUR TESTING DURING THE AUDIT. AND WE ARE HAPPY TO REPORT THAT

THERE WERE NO SUCH INSTANCES OF NONCOMPLIANCE THAT WOULD BE REQUIRED TO REPORT HERE.

AND OUR LAST DOCUMENT THAT WE ISSUE IS A REPORT DIRECTED TO THE INDEPENDENT CITIZENS OVERSIGHT COMMITTEE OR THE ICOC. WE CALL THIS -- IT'S KNOWN AS SAS 14 LETTER, WHICH IS THE AUDITING STANDARDS THAT'S REQUIRED AT THE END OF ANY AUDIT. THE AUDITOR PROVIDES A SUMMARY TO THOSE CHARGED WITH GOVERNANCE. SO WHAT THIS REPORT DOES, IT SUMMARIZES BASICALLY WHAT HAPPENED DURING THE AUDIT. IT TALKS ABOUT, AGAIN, OUR RESPONSIBILITY FOR THE FINANCIAL STATEMENT AUDIT, OUR PLAN, SCOPE, AND TIMING, AND THEN WE MENTION AGAIN THAT WE'VE COMPLIED AS A FIRM WITH ALL OF THE RELEVANT ETHICAL REQUIREMENTS AND INDEPENDENCE REGULATIONS THAT WE ARE REQUIRED TO FOLLOW.

WE MAKE A REFERENCE TO CERTAIN QUALITATIVE ASPECTS OF SIGNIFICANT ACCOUNTING POLICIES. MANAGEMENT'S RESPONSIBLE TO SELECT AND USE THE APPROPRIATE ACCOUNTING POLICIES AND THEN PROVIDE -- NOTE DISCLOSURES ABOUT THOSE. SO A SUMMARY OF THE SIGNIFICANT ACCOUNTING POLICIES IS THE FIRST NOTE OR NOTE TWO IN THE FINANCIAL STATEMENTS. AND FOR THE FISCAL YEAR 2022, THERE WERE NO NEW ACCOUNTING POLICIES IMPLEMENTED AND THERE WERE NO CHANGES TO

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EXISTING POLICIES DURING THE YEAR. AND THEN MORE IMPORTANTLY, THERE WERE NO MATTERS THAT CAME TO OUR ATTENTION, THAT MANAGEMENT IS USING CONTROVERSIAL POLICIES. EVERYTHING WAS IN ACCORDANCE WITH WHAT WE CALL GAP.

ALSO, WE HAD NO DIFFICULTIES WITH MANAGEMENT IN RELATION TO THE PERFORMANCE OF THE AUDIT, AND THEY WERE RESPONSIVE TO US, PROVIDING US WITH THE INFORMATION THAT WE ASKED FOR AND RESPONDING TO ALL OF OUR INQUIRIES. WE DIDN'T HAVE ANY DISAGREEMENTS WITH THEM. AND ALSO, WE DIDN'T HAVE ANY UNCORRECTED MISSTATEMENTS OR ANY CORRECTED MATERIAL MISSTATEMENTS. SO WITH THAT, I'M HAPPY TO ANSWER ANY QUESTIONS.

CHAIRMAN IMBASCIANI: MR. HARNER, THANK YOU VERY, VERY MUCH FOR YOUR PRESENTATION AND YOUR GOOD WORK ON THIS REPORT. DO BOARD MEMBERS HAVE ANY QUESTIONS OF OUR AUDITOR OR COMMENTS? MR. FISCHER-COLBRIE.

MR. FISCHER-COLBRIE: FIRST OF ALL, COMMENT. OUTSTANDING REPORT, JUST FANTASTIC ACROSS THE BOARD. SO KUDOS TO EVERYBODY WITH RESPECT TO THAT. UNBELIEVABLE, GREAT.

AND JUST WANT TO CONFIRM TYPICAL TIMING FOR THE CYCLE BECAUSE THERE'S A LOT OF LAYERS TO AN

AUDIT AS WAS DESCRIBED. OF COURSE, THERE'S THE CONSIDERATION FOR NOT JUST THE AUDIT, BUT THE STATE CONTROLLER REVIEW OF THE AUDIT. THERE'S ALSO A FINANCIAL OVERSIGHT COMMITTEE THAT NEEDS TO REVIEW ACTIVITIES. I JUST WANT TO GET CONFIRMATION THAT THIS IS A TYPICAL TIMING PATTERN RELATED TO THE RELEASE OF THE REPORT TO THE BOARD AND RECONFIRM THAT.

CHAIRMAN IMBASCIANI: THANK YOU. I THINK THAT WOULD BE A QUESTION FOR POUNEH SIMPSON.

MS. SIMPSON: THANK YOU FOR THAT QUESTION. SO TYPICALLY IT'S A YEAR CYCLE. BUT BECAUSE OF THE EFFECTS OF THE PANDEMIC AND SOME OF THE BACKLOG THAT WAS CREATED AT THE CONTROLLER'S OFFICE, THE CYCLE TOOK A LITTLE BIT LONGER. SO YOU'RE NOW SEEING THE 21/22 AUDIT, WHICH IS NOW TWO YEARS BEHIND US.

WE'RE HOPING THAT THAT BACKLOG IS REDUCED IN FUTURE YEARS AND THAT WE CAN BRING THE AUDITS TO YOU QUICKER.

MR. FISCHER-COLBRIE: THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, POUNEH. ANY OTHER COMMENTS FROM BOARD MEMBERS OR QUESTIONS TO OUR AUDITOR? I DO NOT SEE ANY. OKAY.

SO AT THIS HAPPY MOMENT, WE'RE GOING TO TAKE A RECESS FOR LUNCH. AND I WOULD -- LUNCH IS IN

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THE ROOM RIGHT BEHIND ME. AND CAN I ASK ALL THE BOARD MEMBERS TO PLEASE RETURN SO WE CAN RECONVENE 20 MINUTES TO ONE. THAT'S 12:40 P.M.

(A RECESS WAS TAKEN.)

CHAIRMAN IMBASCIANI: OKAY. LADIES AND GENTLEMEN OF THE BOARD, WE'VE COME BACK FROM OUR RECESS. AND WE HAVE REACHED THE POINT OF AGENDA ITEM NO. 14, THE DISCUSSION OF OUR PERFORMANCE AUDIT. AND WE HAVE -- WHERE ARE TAMMY -- WHO'S PRESENTING? TERRY. AND SHE'S DOING THIS FROM THE PODIUM.

MS. LOHR: GOOD AFTERNOON, EVERYONE. THANK YOU FOR HAVING ME. I'M DELIGHTED TO BE HERE IN THE FLESH. WE'RE GOING TO GO AHEAD AND GET STARTED WITH THE 2023 PERFORMANCE AUDIT RESULTS. MY NAME IS TAMMY LOHR. I'M A SENIOR MANAGER WITH MOSS-ADAMS. I HAVE BEEN WORKING ON CIRM'S PERFORMANCE AUDITS FOR THE LAST THREE AUDITS THAT YOU HAD. AND I'M DELIGHTED TO BE HERE TODAY TO TALK A LITTLE BIT ABOUT OUR RESULTS AND COMMENDATIONS.

SO TODAY I'LL COVER OUR SCOPE AND METHODOLOGY, COMMENDATIONS, AND OUR PERFORMANCE AUDIT RESULTS. AS A BRIEF REMINDER, CIRM IS REQUIRED BY PROPOSITION 14 TO CONDUCT A TRIENNIAL PERFORMANCE AUDIT TO ENSURE THAT YOUR OPERATIONS

COMPLY WITH THE PROPOSITION LANGUAGE. SO IN ORDER TO DO THAT, WE TAKE A LOOK AT HOW CIRM'S POLICIES AND PROCEDURES COMPLY WITH THE PROPOSITION LANGUAGE, HOW CIRM IS ACTUALLY OPERATIONALIZING AND FOLLOWING THESE POLICIES AND PROCEDURES. AND THEN WE ALSO IDENTIFY OPPORTUNITIES TO INCREASE THE EFFICIENCY AND EFFECTIVENESS OF OPERATIONS, LOOKING AT THE UTILIZATION OF YOUR AVAILABLE RESOURCES.

TO DO THAT, WE PERFORM INTERVIEWS WITH STAFF AND LEADERSHIP ACROSS CIRM. MANY BOARD MEMBERS WERE INTERVIEWED AS PART OF THIS PROCESS. WE ALSO TAKE A LOOK AT A LARGE VOLUME OF DOCUMENTS, INCLUDING YOUR POLICIES AND PROCEDURES, REPORTS, GUIDES, AND OTHER INFORMATION. WE PERFORM A PROCESS WALK-THROUGH WITH YOUR GRANT MANAGEMENT SYSTEM TO UNDERSTAND THE INS AND OUTS OF THAT SYSTEM AND PROCESSES. AND THEN IN THIS YEAR'S PERFORMANCE AUDIT, WE CONDUCTED DETAILED TESTING. SO WE LOOKED AT 25 GRANTS, 20 GRANT APPLICATIONS AND REVIEWS, AND 35 CONTRACTS TO EVALUATE FOR COMPLIANCE.

I WANT TO START OFF BY SHARING SOME OF THE GREAT NEWS THAT WE OBSERVED FROM CIRM OVER THE COURSE OF OUR AUDIT. SO ONE OF THE HALLMARKS OF WORKING WITH AUDIT IS THAT YOU HAVE VERY RESILIENT AND MISSION-DRIVEN EMPLOYEES. WE'VE ALSO FOUND THAT

THROUGHOUT THE AUDIT PERIOD THERE WAS AN INCREASED FOCUS ON INCREASING THE OPERATIONAL EFFECTIVENESS OF THE ORGANIZATION. SO WE SAW ENHANCED PROJECT MANAGEMENT SUPPORT, SOME INTERNAL SERVICE DEPARTMENT RESTRUCTURING, AS WELL AS AUTOMATION AND REPORTING PROCESSES.

CIRM HAS ALSO INCREASED ITS EMPHASIS ON DIVERSITY, EQUITY, AND INCLUSION PRACTICES. THAT WAS GOING ON PRIOR TO THE PROPOSITION EVEN THOUGH PROPOSITION 14 HAS SOME REQUIREMENTS IN THERE ABOUT THE DIVERSITY, EQUITY, AND INCLUSION PRACTICES. AND WE ALSO NOTED VERY STRONG GRANT MANAGEMENT PRACTICES.

SO THIS PERFORMANCE AUDIT HAS ISSUED FINDINGS, BUT THERE ARE NO COMPLIANCE FINDINGS. AND POUNEH WAS HERE PRESENTING ON A FINANCIAL AUDIT REPORT WHERE FINDINGS ARE A BAD THING TO HAVE IN THE EVENT OF A PERFORMANCE AUDIT. IT JUST INDICATES THAT THERE'S AN OPPORTUNITY FOR IMPROVEMENT.

SO I'LL BE COVERING OUR PERFORMANCE AUDIT RESULTS. WE HAVE 13 FINDINGS IN THIS YEAR'S PERFORMANCE AUDIT. SO THOSE FALL UNDER THE CATEGORIES OF LEADERSHIP, OPERATIONS, PLANNING, AND PROGRAM DEVELOPMENT, AND HUMAN RESOURCES. A LOT OF THESE WERE JUST DUE TO THE TIMING OF THIS AUDIT. SO

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WE LOOKED AT FISCAL YEAR 2022 TO 2023. SO LAST TIME THAT WE WERE HERE CIRM WAS SORT OF THINKING ABOUT RAMPING DOWN, WAS UNSURE IF PROPOSITION 14 WAS GOING TO PASS. SINCE THEN, YOU'VE HAD PROPOSITION 14 PASS. YOU'VE HAD TO REVITALIZE YOUR OPERATIONS AND ALSO EXPAND YOUR MISSION. SO A LOT OF SORT OF ROOT CAUSE OF SOME OF THESE FINDINGS IS DUE TO THAT.

OUR FIRST TWO FINDINGS AND RECOMMENDATIONS RELATED TO LEADERSHIP. SO THE FIRST FINDING IS THAT AT THE TIME THAT WE WERE PERFORMING THIS ANALYSIS, ALL 11 LEADERSHIP POSITIONS AT CIRM REPORTED DIRECTLY TO THE CEO. THAT'S A VERY HIGH NUMBER. TYPICALLY WE LIKE TO SEE THAT NUMBER AT ABOUT FOUR TO SIX DIRECT REPORTS. AND USUALLY THERE'S A HIGH LEVEL LEADERSHIP ROLE THAT REALLY ENDS UP FOCUSING ON INTERNAL OPERATIONS, LIKE I.T., HR, AND FINANCE, SO THAT YOUR CEO CAN FOCUS ON PROGRAMS, SERVICE DELIVERY, AND EXTERNAL RELATIONS.

WITH THE TRANSITION OF THE CEO AND THE INTERIM CEO, WE ALSO JUST WANTED TO REVISIT A PAST AUDIT FINDING AND REVISIT THIS RECOMMENDATION TO MAKE SURE THAT ROLES AND RESPONSIBILITIES BETWEEN THE INCOMING CEO AND THEN THE BOARD CHAIR AND VICE CHAIR ARE VERY CLEAR TO HELP ENSURE THAT THOSE RELATIONSHIPS CAN BE STRONG AND HIGHLY

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COLLABORATIVE.

THE NEXT FINDING THAT RELATED TO LEADERSHIP HAD TO DO WITH THE SIZE OF THE ICOC. SO YOU'RE NOW UP TO 35 MEMBERS. AND AS WE ARE DOING TODAY, YOU HAVE THE OPPORTUNITY TO HAVE HYBRID PARTICIPATION IN YOUR BOARD MEETINGS. BASED ON OUR INTERVIEWS AND OUR OBSERVATIONS, WE FOUND THAT PARTICIPATION AMONG THE ICOC MEMBERS IN THIS HYBRID ENVIRONMENT DOES SEEM TO BE GOING PRETTY WELL. BUT THESE TWO FACTORS OF HAVING A LARGE BOARD AND HAVING HYBRID ENVIRONMENT JUST PRESENTS SOME INHERENT RISKS IN MAKING SURE THAT ALL BOARD MEMBERS ARE VERY ACTIVELY ENGAGED.

SO WE'VE PROVIDED SOME BEST PRACTICES AROUND WORKING IN THIS HYBRID ENVIRONMENT THAT REALLY BALANCES THE NEED FOR EVERYONE'S INSIGHT AND PARTICIPATION ALONGSIDE TIME MANAGEMENT TO MAKE GOOD USE OF YOUR MEETING TIME TOGETHER.

ONE OF THE WAYS THAT CIRM IS USING ITS MEMBERS REALLY EFFECTIVELY IS THROUGH THE USE OF BOARD COMMITTEES. SO WE HAVE A RECOMMENDATION TO CONTINUE USING YOUR BOARD COMMITTEES, DOING THAT DEEP DIVE ANALYSIS WITHIN THOSE COMMITTEES, AND THEN BEING ABLE TO MAKE SURE YOU'RE USING THE BEST TIME POSSIBLE TOGETHER AS A FULL BOARD.

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OUR NEXT TWO FINDINGS RELATE TO OPERATIONS. SO IN THIS AUDIT WE LOOKED AT YOUR CONTRACTING PROCESSES. SO WE TOOK A LOOK AT SOME OF YOUR SOLE SOURCE CONTRACTS, AND WE FOUND THAT ABOUT 25 PERCENT OF THE AGREEMENTS DURING THE FISCAL YEAR THAT WERE OVER $100,000 WERE SOLE SOURCE AGREEMENTS. ALL OF THOSE AGREEMENTS FULLY COMPLIED WITH CIRM'S POLICIES AND PROCEDURES. WE DID NOTE THAT THERE WERE SOME DIFFERENCES IN HOW THEY WERE RECORDED IN THE SYSTEM DUE TO SYSTEM LIMITATIONS. SO WE PROVIDED A RECOMMENDATION TO JUST MAKE SURE THAT THE RECORDING OF THOSE SOLE SOURCES IS CONSISTENT.

AND THEN WE HAVE A RECOMMENDATION TO ALSO HAVE THE RESPONSIBLE ADMINISTRATIVE OFFICIAL, WHICH IS THE DIRECTOR OF FINANCE, HAVE A BIANNUAL REPORTING PROCESS OF THE SOLE SOURCE CONTRACTS TO THE GOVERNANCE COMMITTEE AND THEN JUST ONCE A YEAR REPORTING TO THE ICOC TO ENHANCE THE TRANSPARENCY AROUND THOSE SOLE SOURCE CONTRACTS.

WE ALSO TOOK A LOOK AT CIRM'S LOAN POLICIES, AND WE FOUND SOME OUTDATED REFERENCES TO HOW CIRM WOULD DETERMINE AN INTEREST RATE ON A POTENTIAL LOAN. SO CURRENTLY POLICIES REFERENCE LIBOR WHICH CEASED TO EXIST AS OF LAST JULY. AND SO WE JUST NEED TO MAKE SURE THAT THOSE POLICIES ARE

UPDATED TO REFLECT THE APPROPRIATE BENCHMARK FOR DETERMINING INTEREST RATE FOR A POTENTIAL LOAN.

OUR NEXT FINDING RELATES TO GRANTEE COMPLIANCE WITH TECHNOLOGY DISCLOSURES. WE'VE TALKED ABOUT THIS IN PAST AUDITS. BECAUSE UNDER PROPOSITION 14 ANY REVENUES ASSOCIATED WITH ROYALTIES ARE NOW GOING INTO THE PATIENT SUPPORT FUND, THIS MONITORING PROCESS HAS BECOME EVEN MORE IMPORTANT FOR CIRM TO COMPLETE. TO DATE MOST OF THE COMPLIANCE MONITORING HAS BEEN CONDUCTED ON AN AD HOC BASIS IN RESPONSE TO THE 20/21 PERFORMANCE AUDIT. CIRM ISSUED A DISCLOSURE SURVEY FOR ALL OF ITS TRANSLATION AND CLINICAL GRANTS IN THE SPRING OF 2023, AND STAFF REPORTED THAT THAT WAS A VERY PRODUCTIVE PROCESS AND THAT THEY WERE ABLE TO IDENTIFY ADDITIONAL DISCLOSURES THROUGH THAT PROCESS.

SO WE WOULD RECOMMEND THAT CIRM IMPLEMENT THAT EVERY THREE YEARS, GO AHEAD AND ISSUE THAT SURVEY, AND ALSO CONSIDER DEVELOPING A RISK-BASED AUDIT PROGRAM TO BE ABLE TO MAKE SURE THAT GRANTEES ARE COMPLYING WITH THOSE REQUIREMENTS.

SPEAKING OF THE PATIENT SUPPORT FUND AND THE PATIENT SUPPORT PROGRAM, DURING OUR INTERVIEWS WE HEARD SOME CONCERNS ABOUT UNCERTAINTY THAT IS

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RELATED TO THE PROGRAM AND ITS FINANCIAL SUSTAINABILITY BASED ON WHAT REVENUES ARE COMING INTO THAT AND HOW MANY PATIENTS WE WOULD BE ABLE TO SERVE THROUGH THE PROGRAM. THIS IS A NEW PROGRAM FOR CIRM. SO THERE'S NOT A LOT OF DATA THAT'S CURRENTLY AVAILABLE TO ANSWER THOSE QUESTIONS. SO, INSTEAD, WE'VE PROVIDED A RECOMMENDATION FOR STAFF TO MAKE SURE THAT THEY'RE REPORTING THAT INFORMATION UP TO THE ICOC AND THEN USING THAT DATA TO CREATE PROJECTIONS SO THAT YOU CAN UNDERSTAND THE FINANCIAL SUSTAINABILITY OF THE PROGRAM AND WHETHER ADDITIONAL FUNDING MAY BE NECESSARY IN THE FUTURE.

WE ALSO HAVE A FINDING AND RECOMMENDATION TO HELP CIRM TAKE ADVANTAGE OF THE VAST AMOUNTS OF DATA THAT YOU COLLECT THROUGH YOUR GRANTEES TO HELP ADVANCE AND SUPPORT YOUR MISSION. YOU'VE A LOT OF DATA AND INFORMATION THAT WOULD BE VERY USEFUL TO OTHER STEM CELL AND REGENERATIVE MEDICINE RESEARCHERS. IN ORDER TO ORGANIZE AND SHARE THAT DATA, YOU HAVE TO START PUTTING TOGETHER A DATA GOVERNANCE FRAMEWORK AND STRUCTURE TO HELP FACILITATE THAT DATA SHARING CAPABILITY. SO WE HAVE SOME RECOMMENDATIONS WITHIN THE REPORT TO HELP CIRM REALLY START TO PUT TOGETHER THAT FRAMEWORK, AND WE KNOW IT'S BEEN A TOPIC OF DISCUSSION FOR THE

ORGANIZATION FOR A COUPLE OF YEARS.

THE NEXT TWO FINDINGS RELATE TO CIRM'S EXPANDED OPERATIONS UNDER PROPOSITION 14 AND, AGAIN, THAT RAMP-UP PERIOD THAT YOU'VE BEEN IN FOR THE LAST COUPLE OF YEARS. BECAUSE YOUR OPERATIONS WERE RAMPING UP, IT WAS SOMETIMES HARD TO GET STAFFING SUPPORT AT THE RIGHT LEVEL AT THE RIGHT TIME. SO WE HAVE SOME RECOMMENDATIONS TO PERFORM A WORKLOAD ANALYSIS TO MAKE SURE THAT TEAMS HAVE THE RIGHT STAFFING IN ORDER TO COMPLETE THEIR WORK, WHICH THEN ENHANCES EFFICIENCY AND EFFECTIVENESS IN OPERATIONS.

WE ALSO HAVE SOME RECOMMENDATIONS AROUND CHANGE MANAGEMENT. SO THERE WAS JUST A LOT GOING ON DURING THE LAST FEW YEARS AND A LOT OF CHANGES. AND SO DEVELOPING A CHANGE MANAGEMENT FRAMEWORK WILL HELP MAKE SURE THAT EVERYONE IS REALLY AWARE OF THE CHANGES THAT ARE UP AND COMING AND THAT THEY UNDERSTAND HOW THAT FITS INTO CIRM'S OVERALL MISSION AS WELL AS THEIR TO DAY-TO-DAY WORK.

OUR LAST SET OF FINDINGS RELATES TO HR OPERATIONS. SO CIRM HAS RELIED QUITE A BIT ON MANUAL PRACTICES HISTORICALLY TO COMPLETE ITS HR TRANSACTIONS, ANYTHING FROM HIRING TO UPDATING EMPLOYEE ADDRESSES, PERFORMING LEAVE REQUESTS. AND HR RECENTLY IMPLEMENTED A SYSTEM CALLED BAMBOO HR TO

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HELP SUPPORT AUTOMATION AND ALLOW EMPLOYEES TO HAVE MORE SELF-SERVICE OPTIONS. AND THAT'S FANTASTIC. SO LET'S JUST KEEP IMPLEMENTING THAT AND POTENTIALLY EXPANDING THE IMPLEMENTATION OF THAT SYSTEM TO ENHANCE THAT AUTOMATION.

ALONGSIDE THAT, WE'D LIKE TO SEE ADDITIONAL DOCUMENTATION OF HR POLICIES AND PROCEDURES. THOSE WEREN'T ALWAYS DOCUMENTED, WHICH SOMETIMES CREATED DELAYS OR INCONSISTENCIES IN HOW PROCESSES, PARTICULARLY HIRING AND ONBOARDING AND PERFORMANCE MANAGEMENT, WERE REALLY TAKING PLACE. BECAUSE YOU WERE IN THE PROCESS OF HIRING A LOT OF NEW EMPLOYEES TO HELP SUPPORT YOUR OPERATION, THIS WAS REALLY FELT BY THE TEAM DURING THE AUDIT PERIOD THAT WE EVALUATED.

THE LAST TWO FINDINGS WERE RECOMMENDATIONS THAT WE HAVE. SO ALSO RELATED TO HR, WE HEARD CONCERNS ABOUT PAY EQUITY BETWEEN TENURED EMPLOYEES AND NEW EMPLOYEES THAT CAME ONTO THE ORGANIZATION RECENTLY. THIS IS A PHENOMENON THAT A LOT OF AGENCIES HAVE BEEN EXPERIENCING OVER THE LAST FEW YEARS BECAUSE THE EMPLOYMENT MARKET WAS VERY HIGHLY COMPETITIVE. SO A NEW EMPLOYEE HAD TO BE DRAWN TO THE ORGANIZATION AND PAID A HIGHER AMOUNT THAN SOME OF YOUR EXISTING EMPLOYEES IN ORDER TO GET SOMEONE

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TO FILL THAT ROLE. HR IS AWARE OF THIS CONCERN, AND THEY HAVE BEEN WORKING TO UPDATE CIRM'S COMPENSATION POLICY TO HELP MITIGATE THIS RISK IN THE FUTURE. ONCE THAT POLICY IS APPROVED BY THE ICOC, HR CAN THEN TAKE THE NEXT STEP OF PERFORMING AN EQUITY ANALYSIS AND THEN RECTIFYING THOSE COMPENSATION INEQUITIES.

THE LAST FINDING AND RECOMMENDATION RELATES TO CIRM'S HYBRID WORK POLICY WITH SOME DISCUSSION, I UNDERSTAND, THAT THIS IS ALREADY SORT OF IN THE WORKS OF BEING LOOKED AT. THIS IS, AGAIN, SOMETHING THAT A LOT OF AGENCIES ARE GRAPPLING WITH RIGHT NOW. THIS IS NOT UNIQUE TO CIRM, BUT IT REALLY DOES IMPACT CIRM'S EMPLOYEES AND THEIR EMPLOYEE EXPERIENCE.

SO BASED ON THE ENGAGEMENT SURVEY FROM LAST YEAR, IT SEEMED LIKE A LOT OF EMPLOYEES WERE REALLY QUESTIONING IF THE WORK FROM HOME POLICY WAS INCREASING PRODUCTIVITY AND SUPPORTING THEIR WORK-LIFE BALANCE BECAUSE OF THE LONG COMMUTE TIMES TO GET INTO THE OFFICE. THERE WAS ALSO SOME PERCEPTION ISSUES WHERE SOME TEAMS WERE FOLLOWING THE WORK FROM HOME POLICY AND SOME TEAMS MAY NOT HAVE BEEN FOLLOWING IT TO THE SAME LETTER. SO WE HAVE SOME RECOMMENDATIONS HERE AND BEST PRACTICES

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AROUND HOW TO THINK THROUGH THE HYBRID WORK POLICY AND BE ABLE TO MAKE EXCEPTIONS WHEN THAT MAKES SENSE FOR YOUR EMPLOYEES.

OUR LAST SLIDE JUST SHOWS PROGRESS TOWARD PRIOR AUDIT IMPLEMENTATION. SO ALL OF THE AUDIT FINDINGS PRIOR TO THE 2019 TO 2020 AUDIT HAVE BEEN IMPLEMENTED. WITHIN THE 2018 TO 2020 AUDIT, FIVE RECOMMENDATIONS ARE IN PROGRESS. MOST OF THOSE RELATE TO I.T. SYSTEMS, AND WE ALREADY KNOW THAT THERE ARE PLANS TO BE ABLE TO ADDRESS THOSE THAT ARE IN PLACE RIGHT NOW. AND THEN THREE RECOMMENDATIONS WERE COMPLETED, AND ONE RECOMMENDATION WAS CLOSED BECAUSE IT WAS NO LONGER RELEVANT TO YOUR OPERATIONS.

THAT CONCLUDES MY PRESENTATION.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH, TAMMY, FOR THAT EXCELLENT OVERVIEW AND LIST OF RECOMMENDATIONS. THE FLOOR IS NOW OPEN TO COMMENT FROM BOARD MEMBERS OR QUESTIONS.

MR. AGUIRRE-SACASA: THANK YOU, CHAIR AND BOARD MEMBERS HERE. ON BEHALF OF THE LEADERSHIP TEAM OF CIRM, I'M HERE TO REPORT THAT WE ARE PREPARING THE MANAGEMENT RESPONSE. IT WILL BE GOING THROUGH THE FEBRUARY GOVERNANCE SUBCOMMITTEE AND THEN THE FEBRUARY ICOC, AND WE WILL HAVE RESPONSES

TO EACH OF THESE FINDINGS. AND WE THANK MOSS-ADAMS FOR THEIR PARTNERSHIP ON THIS. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, RAFAEL. PAT LEVITT.

DR. LEVITT: CAN YOU PROVIDE A LITTLE BIT MORE DETAIL ABOUT WHAT YOUR RECOMMENDATION IS IN TERMS OF DEALING WITH WORKFORCE ISSUES ON THE VERY LARGE NUMBER OF PROJECTS THAT ARE ONGOING WITHIN CIRM AND WHAT YOUR RECOMMENDATION IS FOR HOW THE LEADERSHIP CAN KEEP UP WITH THAT SO THAT WE DON'T EXPERIENCE THESE GAPS IN STAFFING THAT MAKE IT REALLY DIFFICULT TO MEET THE GOALS OF A PARTICULAR AREA? WHAT'S THE RECOMMENDATION FOR KEEPING UP WITH THAT?

MS. LOHR: ABSOLUTELY. GREAT QUESTION. SO WE HAVE PROVIDED SOME INFORMATION WITHIN THE REPORT THAT INCLUDES A RECOMMENDATION, DETAIL, AS WELL AS AN ACTUAL SAMPLE WITH AN APPENDIX ON HOW TO PERFORM A WORKLOAD ANALYSIS. SO USING DATA TO ACTUALLY TRACK INDIVIDUAL'S TIME AND ANTICIPATE THOSE NEEDS DURING ANNUAL OPERATING PLANNING IS THE RECOMMENDATION THAT WE WOULD HAVE. AND THEN AS NEW INITIATIVES COME UP OR THE FOCUS OF THE ORGANIZATION SHIFTS AND CHANGES, ALSO MAKING SURE THAT THERE'S A CONSIDERATION OF DO WE HAVE THE STAFF RIGHT NOW TO

BE ABLE TO ACCOMPLISH THIS OR DO WE NEED TO ADD STAFF, IN PARTICULAR GIVEN THE STAFFING CAP THAT YOU HAVE.

DR. LEVITT: I DON'T KNOW THIS. I SHOULD KNOW THIS AS A BOARD MEMBER. WHAT'S THE RATIO OF EXEMPT COMPARED TO NONEXEMPT EMPLOYEES? THEY'RE ALL EXEMPT? EVERYBODY IS EXEMPT AT ANY LEVEL. INTERESTING.

WHAT IS YOUR -- I JUST SAID IT WAS INTERESTING. I'M INTERESTED IN THE EXPERT'S OPINION ABOUT HAVING -- WHAT ARE THE CHALLENGES AND THE OPPORTUNITIES IF YOU HAVE A FULLY EXEMPT WORKFORCE?

MS. LOHR: SURE. SO TYPICALLY YOUR NONEXEMPT STAFF WOULD BE ASSISTANT LEVEL INDIVIDUALS AND FOLKS LIKE THAT. THE BENEFIT OF HAVING EVERYONE BE EXEMPT IS THAT THEY CAN WORK AS MANY HOURS AS REQUIRED TO GET THE JOB DONE. AND IN OUR EXPERIENCE WITH CIRM, NO ONE IS WORKING LESS THAN 40 HOURS PER WEEK.

AND SO THAT'S THE ADVANTAGE. I'M NOT AN EXPERT IN THE CLASSIFICATION OR HR LAW ON WHAT FALLS UNDER EXEMPT OR NONEXEMPT.

MS. DURON: SO AT LEAST 40 HOURS A WEEK. IS THERE A MECHANISM TO ALLOW THEM TO SAY I'M BURNED OUT AND I NEED SOME HELP? CUT TO THE CHASE.

DR. LEVITT: IT'S ESSENTIALLY HOW DO YOU -- HOW IS THE LEADERSHIP TEAM GOING TO IDENTIFY -- IT RELATES TO THIS ISSUE ABOUT HAVING ENOUGH TEAM MEMBERS TO COMPLETE A PROJECT. IF YOU'VE GOT A SMALLER NUMBER TRYING TO GET TO THAT GOAL, HOW ARE THEY GOING TO MANAGE THE BURNOUT OR GETTING TEAM MEMBERS TO EVEN SAY THAT THEY'RE FEELING COMPLETELY OVERWHELMED?

DR. THOMAS: SO I'LL TAKE THAT ONE, PAT. SO WE'RE DEALING WITH THAT ISSUE IN THE LT RIGHT NOW IN REAL TIME DUE TO A VERY DRAMATIC INCREASE, SPECIFICALLY WITH RESPECT TO THE REVIEW TEAM, DRAMATIC INCREASE IN APPLICATIONS OVER THE LAST FEW MONTHS. AND SO THIS AN ABSOLUTELY RIPE ISSUE. AND SO WE'RE GRAPPLING WITH THAT, HOW TO GIVE GIL THE SUPPORT HE NEEDS. WE'RE NOT CLEAR IF THIS IS A NEW NORMAL OR NOT. BUT IN THE EVENT THAT IT IS, SO, FOR EXAMPLE, ABLA HAS TWO MEMBERS OF THE THERAPEUTICS TEAM WHO ARE NOW WORKING ON LOAN, IF YOU WILL, WITH THE REVIEW TEAM TO HELP. AND GIL IS ALSO IN THE PROCESS OF INTERVIEWING AND BRINGING ON ADDITIONAL STAFF THAT WILL BE DEALING WITH THESE ISSUES. BUT MORE BROADLY, THE FORM AND THE LT IS THERE TO DISCUSS EXACTLY WHAT YOU ARE ASKING ABOUT.

AND SO AT THE MOMENT WE'RE DEALING WITH IT

CASE BY CASE BECAUSE THIS HAPPENS TO BE THE CASE BEFORE US, BUT IT IS SOMETHING WE'RE ACUTELY AWARE OF AND WILL BE TRACKING.

VICE CHAIR BONNEVILLE: QUICK COMMENT. I THINK SOMETHING TAMMY MENTIONED WAS THAT THERE'S AN OPPORTUNITY FOR US TO TAKE A LOOK AT ALL THE TEAMS AND UNDERSTAND WHAT THE WORKLOAD IS PER TEAM AND AUDIT THAT WORKLOAD AND WHETHER OR NOT THE TEAMS ARE WELL STAFFED. THERE ARE TEAMS AT CIRM THAT ARE WELL STAFFED. THERE ARE TEAMS THAT ARE UNDERSTAFFED. SO BEING ABLE TO SIT DOWN AND MAKE THAT DETERMINATION AND COME BACK WITH A PLAN AND MAKE ADJUSTMENTS AS NECESSARY IS REALLY IMPORTANT. SO I HIGHLY ENCOURAGE YOU, J.T. AND RAFAEL, TO START THAT PROCESS.

DR. THOMAS: DULY NOTED.

CHAIRMAN IMBASCIANI: OKAY. WE HAVE ANY OTHER COMMENTS? I DON'T SEE THE BOARD.

VICE CHAIR BONNEVILLE: ONE OTHER THING. I KNOW WHEN YOU MENTIONED THE SOLE SOURCE CONTRACTS, WE DO SEND A REPORT, NOT WE, A REPORT IS SENT TO US NOW SIX MONTHS, EVERY SIX MONTHS TO THE GOVERNANCE, ONCE A YEAR TO THE BOARD THAT HAS A LIST OF CONTRACTS. IT COULD BE VERY EASY TO JUST ADD A COLUMN THERE WITH AN S THAT SAYS SOLE SOURCE. GO

THAT WAY INSTEAD OF CREATING AN ENTIRE NEW REPORT. SO THAT CAN BE VERY EASILY ACCOMPLISHED PRETTY IMMEDIATELY.

MR. AGUIRRE-SACASA: WE TALKED ABOUT THAT. THANK YOU.

DR. CLARK-HARVEY: THANK YOU. I JUST WANT TO SAY FIRST I APPRECIATE THE REVIEW AND THE ASSESSMENT OF PRACTICES, ET CETERA. AND I JUST WANT TO SAY OUT LOUD THAT AS A CEO I ALSO APPRECIATE THAT THE BOARD'S JOB ISN'T NECESSARILY TO MICROMANAGE THE DECISIONS OF SENIOR STAFF AS THEY WORK WITH THE TEAM THAT IS HIRED. I DO BELIEVE THAT WE HAVE A NUMBER OF HIGHLY EDUCATED AND PROFESSIONAL STAFF PERSONS. SO THE JUSTIFICATION AROUND EXEMPT VERSUS NONEXEMPT I'M NOT NECESSARILY INTERESTED IN. I DO TRUST THE BOARD LEADERSHIP WILL MAKE THE BEST DETERMINATION THERE. AND I DO THINK THAT WHAT'S BEEN DETERMINED TO DATE MAKES SENSE CONSIDERING THE CALIBER OF THE LEVEL OF THE INDIVIDUALS THAT ARE WORKING ON THE CIRM TEAM THERE. SO I JUST WANTED TO SHARE THAT.

CHAIRMAN IMBASCIANI: THANK YOU. J.T.

DR. THOMAS: MR. JUELSGAARD GO FIRST AND I'LL FOLLOW.

MR. JUELSGAARD: ACTUALLY JUST A QUESTION. SO WHAT ARE THE TOTAL NUMBER OF EMPLOYEES WE HAVE

PLUS OPEN POSITIONS? SO IF WE WERE FULLY EMPLOYED AT THIS POINT, HOW MANY EMPLOYEES WOULD WE HAVE? 66? SO WE'RE FOUR SHORT OF THE MAXIMUM OF 70. 85, 15 OF THOSE ARE VERY SPECIFICALLY DEDICATED TO ACCESS AND AFFORDABILITY.

MS. SIMPSON: OF THE 66 THAT ARE AUTHORIZED BY THE ICOC, SIX ARE RELATED TO THE ACCESS AND AFFORDABILITY, 60 ARE RELATED TO THE OTHER AREAS OF CIRM. AND OF THOSE 66, 62 ARE FILLED. SO FOUR ARE VACANT.

DR. THOMAS: SO, FIRST OF ALL, TAMMY, THANK YOU AGAIN FOR YOUR GREAT WORK ON THESE AUDITS. REALLY APPRECIATE IT.

I WANT TO HIGHLIGHT FOR THE BOARD, WHILE WE HAVE 13 FINDINGS, THIS IS, IN EFFECT, AN AUDIT TO REALLY CELEBRATE. JENN HAS FRAMED VERY NICELY AN LT, AND I'D LIKE TO ASK HER TO COME UP TO CONVEY THAT SENTIMENT IN MORE DETAIL.

MS. LEWIS: THANK YOU, J.T. J.T. WANTED ME TO SHARE WHAT I SHARED WITH HIM WHEN HE CAME ON BOARD AS WELL AS THE LEADERSHIP TEAM. THAT IS, FOR CIRM STAFF, WE REALLY CELEBRATE THIS AUDIT FOR A YEAR OF TREMENDOUS GROWTH. GRANTS MANAGEMENT DOUBLED IN SIZE. SO THE AMOUNT OF TRAINING AND ONBOARDING THAT WENT OUT THROUGHOUT THE WHOLE

ORGANIZATION THIS TIME WAS TREMENDOUS. AND TO HAVE NO COMPLIANCE FINDINGS IS REALLY GREAT AND SHOWS A TESTAMENT TO THE PROCESSES WE HAVE AS AN AGENCY. SO JUST WANTED TO SHARE THAT. AND THANK YOU, J.T., FOR THE OPPORTUNITY TO SHARE THAT.

MS. LOHR: WE'D LIKE TO ECHO THAT SENTIMENT, THAT THIS REALLY IS A REPORT TO CELEBRATE. THERE ARE NO COMPLIANCE FINDINGS. EVERYTHING NOTED WITHIN THE REPORT ARE JUST OPPORTUNITIES TO CONTINUE IMPROVING CIRM, AND IT'S A VERY-HIGH FUNCTIONING ORGANIZATION AS IT IS.

CHAIRMAN IMBASCIANI: THANK YOU AGAIN, TAMMY. ANY OTHER COMMENTS OR QUESTIONS?

(APPLAUSE.)

CHAIRMAN IMBASCIANI: THANK YOU. I'D LIKE TO MOVE ON TO AGENDA ITEM NO. 11. THIS IS GOING TO BE A PRESENTATION OF CONCEPT PLAN ON THE COMMUNITY CARE CENTERS OF EXCELLENCE. AND OUR ASSOCIATE DIRECTOR OF MEDICAL AFFAIRS, GEOFF LOMAX, IS GOING TO MAKE THE PRESENTATION FROM THE PODIUM.

DR. LOMAX: THANK YOU VERY MUCH, CHAIRS AND MEMBERS OF THE BOARD.

WHAT I'D LIKE TO DO IS DESCRIBE TO YOU A PROPOSED INFRASTRUCTURE PROGRAM THAT REALLY WILL BE FUNDAMENTAL TO SUPPORTING THE DELIVERY OF TREATMENTS

IN CALIFORNIA.

SO THE COMMUNITY CARE CENTERS OF EXCELLENCE, THE CONCEPT PLAN BEFORE YOU HAS BEEN IN PROCESS FOR ABOUT A YEAR AND A HALF. AND I'D LIKE TO DESCRIBE TO YOU THE PROCESS WE'VE GONE THROUGH TO GET TO THE DOCUMENT YOU HAVE BEFORE YOU TODAY.

WE STARTED WITH A SERIES OF LISTENING SESSIONS MOSTLY IN THE CENTRAL PART OF THE STATE. AND THOSE LISTENING SESSIONS INCLUDED PARTICIPATION FROM BOTH CIRM LEADERSHIP AND THIS BOARD, AND THAT PARTICIPATION WAS REALLY FUNDAMENTAL TO SHAPING THIS PROPOSAL.

WITHIN THESE SESSIONS WE BROUGHT IN NEW STAKEHOLDERS, WE BROUGHT IN NEW POTENTIAL PARTNERS. WE THEN BROUGHT THOSE PARTNERS TO A STATEWIDE WORKSHOP IN SACRAMENTO IN JUNE OF 2023. WITHIN THAT WORKSHOP THAT REALLY PRESENTED AN OPPORTUNITY FOR TEAMS TO COME TOGETHER AND NETWORK, BOTH POTENTIAL APPLICANTS AND OUR ALPHA CLINICS TEAMS. SO WHAT WE HAVE AT THAT STAGE IS A CONCEPT AND THEN TEAMS COMING TOGETHER TO REALLY WORK AROUND HOW THEY COULD DEVELOP THAT PROGRAM.

AFTER THE SACRAMENTO WORKSHOP, WE SET FORWARD ON DEVELOPING A CONCEPT PLAN AND WORKING THAT CONCEPT PLAN THROUGH THE VARIOUS BOARD

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COMMITTEES. AND WE'VE RECEIVED A TREMENDOUS AMOUNT OF BOARD GUIDANCE BOTH FROM THE ACCESS AND AFFORDABILITY WORKING GROUP, THE SCIENCE SUBCOMMITTEE, AND VARIOUS BOARD MEMBERS ALONG THE WAY. AND THAT DOCUMENT NOW IS, AGAIN, WHAT YOU HAVE BEFORE YOU TODAY. WITH YOUR APPROVAL, WE WOULD THEN MOVE TO THE APPLICATION, AND THAT WOULD BEGIN -- THE APPLICATION STAGE WOULD BEGIN EARLY THIS SPRING.

JUST AS A REMINDER, THE COMMUNITY CARE CENTERS, AGAIN, ARE INFRASTRUCTURE INTENDED TO SUPPORT ACCESS. AND THEY'RE DESCRIBED IN PROPOSITION 14. SO THIS IS AN ATTEMPT TO IMPLEMENT A PROGRAM THAT'S FUNDAMENTAL TO THE PROPOSITION. AND GOING BACK TO OUR MISSION STATEMENT AGAIN, IF WE'RE DEVELOPING REGENERATIVE MEDICINE TREATMENTS FOR A DIVERSE CALIFORNIA, THIS INFRASTRUCTURE IS REALLY FUNDAMENTAL TO REACHING THE DIVERSE POPULATION OF OUR STATE. AND ONE OTHER REMINDER, WITHIN THE PROPOSITION THERE IS EXPRESSED A FIVE-YEAR TIMELINE FOR THIS PROGRAM. SO CURRENTLY WHERE WE STAND TODAY WE'RE ON TRACK TO HIT THAT FIVE-YEAR TIMELINE WITH THE PROPOSED PLAN MOVING FORWARD WITH APPLICATIONS FOR THE FIRST HALF OF THIS YEAR, REVIEW TOWARDS THE END OF THE YEAR, AND BY THE END OF THE YEAR BEING ABLE TO ANNOUNCE THIS PROGRAM.

SO THERE IS A TIMING ELEMENT TO THIS THAT I WANTED TO REMIND YOU ALL OF.

SO A LITTLE BIT ABOUT WHAT A CLINICAL INFRASTRUCTURE LOOKS LIKE BECAUSE THIS CAME UP QUITE A BIT BOTH AMONG BOARD MEMBERS AND AMONG STAKEHOLDERS. THE BASIC QUESTION IS WHAT IS A COMMUNITY CARE CENTER. SO REALLY THAT MODEL EMANATES FROM OUR ALPHA CLINICS. AND IN THIS CASE WE'RE REALLY LOOKING AT PEOPLE AS OPPOSED TO BUILDINGS, ALTHOUGH THERE IS A FACILITIES ASPECT OF THIS PROGRAM. SO IT'S TEAMS. AND SO WHAT DO THOSE TEAMS LOOK LIKE?

SO IN THE CELL AND GENE THERAPY SPACE, IF WE'RE PERFORMING CLINICAL RESEARCH OR ULTIMATELY THE DELIVERY OF THOSE THERAPEUTICS, IT TAKES A TEAM THAT HAS EXPERTISE WITH THE UNIQUE ISSUES THAT EXIST IN THAT SPACE. IF YOU LOOK AT THE STAFFING PROFILES OF THE ALPHA CLINICS, WE HAVE INDIVIDUALS THAT HAVE TO SORT OF ENGAGE WITH SPONSORS AND HAVE THOSE DISCUSSIONS ABOUT IS THIS MEDICAL CENTER GOING TO DELIVER ON WHAT YOU NEED. SO THERE'S THAT INITIAL ENGAGEMENT WITH THE SPONSOR.

THERE ARE TEAMS THAT ARE INVOLVED IN PATIENT EDUCATION, PATIENT NAVIGATION. SO WHEN THE PATIENT ARRIVES AT THAT FACILITY, THEY'RE REALLY

UNDERSTANDING AND GETTING THE TREATMENT THEY NEED TO GO THROUGH THIS PATIENT JOURNEY.

THERE'S A WHOLE LAYER OF REGULATORY AND COVERAGE ANALYSIS. AND THIS GETS TO THE FINANCING OF THE TREATMENT AND THE FINANCING OF THE TRIAL.

THERE'S PRODUCT MANAGEMENT ISSUES. THESE ARE POTENTIALLY THERAPIES THAT EITHER HAVE TO BE MANUFACTURED OR HAVE TO GO THROUGH SOME CRITICAL PROCESSING PHASE OF THE FACILITY. SO A LOT OF OUR AWARDS INCLUDE SUPPORT FOR LABORATORY TECHNICIANS AND PHARMACISTS.

AND THERE'S A DATA MANAGEMENT PIECE. THAT MIGHT BE THE RESEARCH COORDINATORS OR PEOPLE WHO HAVE TO DEAL WITH THE INFORMATION SYSTEMS.

SO OUR AWARDS REALLY SUPPORT ACROSS THAT SPECTRUM, THAT STAFFING SPECTRUM. AND, AGAIN, IT'S THE GENE AND CELL THERAPY EXPERTISE WHICH IS SO IMPORTANT. SO THIS IS ESSENTIALLY A HORIZONTAL INTEGRATION ACROSS THE CENTER. YOU MIGHT HAVE DEPARTMENTS THAT HAVE LITTLE OR NO EXPERIENCE WITH CELL AND GENE THERAPY. SOME OF THE AWARDS TODAY, FOR INSTANCE, IN NEURO SPACE, MAYBE THE NEUROLOGISTS JUST HAVEN'T HAD THE EXPERIENCE OF WORKING WITH A PRODUCT LIKE THAT. THESE TEAMS CAN REALLY FACILITATE THAT TRIAL FROM OPENING UP.

I'D LIKE TO DESCRIBE THIS PROGRAM IN THE CONTEXT OF OUR BROADER SET OF PROGRAMS THAT ARE DESIGNED TO SUPPORT CLINICAL RESEARCH BECAUSE THERE'S REALLY A SYSTEM HERE AND THIS IS A CRITICAL PIECE TO THAT DELIVERY SYSTEM.

THE ALPHA CLINICS IN THE TOP LEFT CORNER OF THIS SLIDE, THERE ARE NINE AWARDS, TEN MEDICAL CENTERS. THEY'RE REALLY SUPPORTING ESSENTIALLY THE CIRM PORTFOLIO. IF YOU LOOK AT THE CIRM CLINICAL TRIAL PORTFOLIO, THEY'RE BEING SUPPORTED. THESE SITES, THEY PROVIDE THE EXPERTISE. THESE SITES ALSO ARE PART OF OUR MANUFACTURING NETWORK. SO WE HAVE AT THAT LEVEL A SYSTEM TO DELIVER THESE TREATMENTS TO PATIENTS.

IF YOU LOOK AT THE LOWER RIGHT-HAND CORNER, AGAIN, WE'VE GOT OUR PORTFOLIO. IT'S SOMEWHERE ON THE ORDER OF 50 PLUS TRIALS ACTIVE AT THE MOMENT. AGAIN, THE MAJORITY, ALMOST ALL OF THEM SUPPORTED BY THE ALPHA CLINICS NETWORK.

THE LOWER LEFT CORNER, THE PATIENT SUPPORT PROGRAM. AGAIN, AS NOTED, THE ACCESS AND AFFORDABILITY WORKING GROUP WILL BE REVIEWING THOSE PROPOSALS BEGINNING OF FEBRUARY. SO THAT PROGRAM IS IN PLACE SPECIFICALLY, AS A REMINDER, TO SUPPORT THE FINANCIAL AND LOGISTICAL BARRIERS ENCOUNTERED BY

PATIENTS, PARTICULARLY PATIENTS OF MORE LIMITED MEANS. SO IT'S A WAY OF ADDRESSING, I THINK, SOME OF THE ISSUES THAT WERE DISCUSSED DURING THE APPLICATION REVIEW PORTION OF THIS MEETING. AGAIN, THAT INFRASTRUCTURE WILL BE COMING ONLINE. WE'LL BE DEVELOPING IT WITH THE ALPHA CLINICS, AND WE WILL EXPECT THAT THAT INFRASTRUCTURE WILL BE FED INTO THE COMMUNITY CARE CENTERS PROPOSAL, WHICH, AGAIN, BRINGS ME TO THE TOP RIGHT CORNER OF THIS SLIDE.

AND, AGAIN, THE COMMUNITY CARE CENTERS ARE SORT OF AN INTEGRATING COMPONENT HERE WHERE THEY CAN BRING THOSE CLINICAL TRIALS CLOSER TO THE COMMUNITIES AND IN PARTICULAR HAVE A UNIQUE FOCUS ON THE SOCIAL DETERMINANTS THAT WILL IMPACT PATIENT PARTICIPATION IN OUR TRIALS. SO THIS KIND OF ROUNDS OUT A REALLY HOLISTIC AND COMPLETE PICTURE OF GETTING PATIENTS INTO TRIALS.

I WANT TO WALK THROUGH JUST KIND OF CONCEPTUALLY, AND THIS GOES BACK TO SORT OF THE WORKSHOPS AND HOW WE -- THIS WAS SORT OF DESCRIBED AS HOW THIS SYSTEM CAN AND SHOULD WORK. WHEN WE GET TO THE SPECIFICS OF THE CONCEPT PLAN, WE ACTUALLY PROPOSED TWO TYPES OF CENTERS, ONE THAT COULD SERVE AS A SITE THAT WOULD FACILITATE ACCESS TO CLINICAL TRIALS, AND THE SECOND OPTION IS A SITE THAT COULD

BOTH DELIVER CLINICAL TRIALS AND SUPPORT ACCESS.

SO I'M GIVING YOU THE ACCESS FACILITATOR EXAMPLE HERE. SO AS YOU SEE, WE ANTICIPATE A STRONG FOCUS, AND I'LL SPEAK TO THAT IN A BIT MORE DETAIL LATER IN THE PRESENTATION, OF COMMUNITY-CENTERED ENGAGEMENTS. SO REALLY ENGAGING PATIENTS, AGAIN, THAT TYPICALLY ARE NOT REPRESENTED IN TRIALS OR HAVE HISTORICALLY BEEN UNDERREPRESENTED IN SOME OF THIS WORK. THERE'S AN ACTIVE PROGRAM, THERE'S A RESOURCE ENGAGEMENT PROGRAM. AND THROUGH THAT ENGAGEMENT, WE CAN THEN CONNECT THE PATIENT TO THE COMMUNITY CARE CENTER OF EXCELLENCE. SO THEY GET CONNECTED UP.

AT THAT STAGE THEY CAN BE REFERRED TO A TRIAL IN AN ALPHA CLINIC. THERE MAY EVEN BE SOME WORK UPFRONT TO DETERMINE IF THAT PATIENT IS RIGHT FOR THAT TRIAL. AND THAT'S WHERE THE NAVIGATION PIECE COMES IN. AND THEN THE PATIENT WILL BE TREATED, AND OPTIMALLY THE FOLLOW-UP OF THAT PATIENT, BECAUSE MANY OF THESE PROTOCOLS INVOLVE MULTIPLE, MULTIPLE VISITS, IDEALLY THE FOLLOW-UP COULD THEN OCCUR IN THE COMMUNITY, WHICH, AGAIN, BASED ON ALL THE EVIDENCE, THE DATA, THE NEEDS ASSESSMENT, IT'S THAT ASPECT OF PROXIMITY WHICH REALLY WILL MAKE A DIFFERENCE IN TERMS OF PATIENTS BEING ABLE TO COMPLETE THESE EXTREMELY DEMANDING

PROTOCOLS.

ON TOP OF THAT, WE SORT OF OVERLAY THE PATIENT SUPPORT PROGRAM WHICH CAN SUPPORT PATIENTS AT ANY STAGE THROUGH THAT JOURNEY.

I DO WANT TO HIGHLIGHT, AGAIN, WHAT THIS SLIDE REPRESENTS. IT'S FOUR PLUS PROGRAMS HAVING TO COME TOGETHER AND COORDINATE AND OPERATE. SO WE'VE ALSO, WITH DR. THOMAS TAKING THE LEAD HERE, WE'RE REALLY STARTING SOME INTERNAL DISCUSSIONS TO REALLY THINK ABOUT HOW WE REALLY INTEGRATE AN INTERNAL MANAGEMENT PLAN. THAT WAS ALSO A RECOMMENDATION COMING FROM THE SCIENCE SUBCOMMITTEE AND OTHER COMMITTEES. I THINK THE COMMENT THAT STICKS OUT IS YOU HAVE A LOT OF MOVING PIECES HERE. WE DO, AND WE ARE WORKING ON A PLAN TO COORDINATE THOSE PIECES IN A MANNER THAT WILL RESULT IN THE SUCCESS OF THIS PROGRAM.

SO I'M GOING TO TRANSITION NOW AND JUST BREAK DOWN THE THREE CORE ELEMENTS OF THE CONCEPT PLAN ITSELF. THESE ARE THE THREES PIECES THAT REALLY DESCRIBE WHAT AN APPLICANT WILL BE PROPOSING TO DO. THEY MUST PROPOSE A -- THEY MUST BE A CLINICAL SITE AND PROPOSE A PLAN TO EITHER SUPPORT OR SUPPORT AND CONDUCT CLINICAL TRIALS. AGAIN, I'LL DESCRIBE THAT IN A BIT MORE DETAIL ON ANOTHER SLIDE.

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THE CLINICAL SITES MUST DELIVER APPROVED REGENERATIVE MEDICINE PRODUCTS. AGAIN, I'LL EXPAND ON THAT MOMENTARILY. AND THEY CAN SERVE AS A REFERRAL HUB FOR BOTH OUR ALPHA CLINICS AND THE PATIENT SUPPORT PROGRAM.

CONSISTENT WITH OTHER INFRASTRUCTURE PROGRAMS, THERE'S A CAREER DEVELOPMENT COMPONENT TO THIS CONCEPT. THE MAIN THRUST HERE IS TO REALLY ADAPT AND DEPLOY CURRICULA THAT HAVE BEEN DEVELOPED AND EXIST. SO IT'S REALLY TRYING TO LEVERAGE OUR INVESTMENT IN EDUCATION. IT'S ALSO INTENDED TO SERVE AS A PLACEMENT SITE FOR CIRM TRAINEES. I THINK, AGAIN, THROUGH BOTH THE NEEDS ASSESSMENT PROCESS AND PARTICULARLY THE STATEWIDE WORKSHOP, THERE WAS A LOT OF ENTHUSIASM AMONGST THE EXISTING ALPHA CLINICS TO BRING PEOPLE OUT TO SITES OUTSIDE OF THE ACADEMIC CENTERS. THERE WAS A LOT OF ENTHUSIASM FOR THAT. THAT WAS VIEWED AS A VERY USEFUL WAY OF EXPANDING THE PERSPECTIVE OF CLINICIANS AND OTHER RESEARCHERS AT THESE SITES.

AND ONE AREA IN PARTICULAR WE FOCUSED ON IS SUPPORT FOR COMMUNITY HEALTH WORKER AND PATIENT NAVIGATOR PROGRAMS. AGAIN, I'LL COME TO THAT IN A MOMENT IN A BIT MORE DETAIL IN A FUTURE SLIDE.

AND THEN, FINALLY, THE PIECE THAT'S UNIQUE

OR REALLY DEFINES THIS PROGRAM AS OPPOSED TO OUR OTHER CLINICAL INFRASTRUCTURE IS THE COMMUNITY ENGAGEMENT PIECE, TO ENGAGE PATIENTS IN COMMUNITIES, TO HAVE ACTIVE PARTNERSHIPS WITH COMMUNITY-BASED ORGANIZATIONS, AND THE COMMITMENT TO RESOURCING THAT, AND TO FOCUS THOSE ENGAGEMENT EFFORTS ON UNDERREPRESENTED POPULATIONS CONSISTENT WITH OUR DEI OBJECTIVES.

SO I WANTED TO CALL OUT JUST THREE PARTS OF THE CONCEPT PLAN BECAUSE, AGAIN, THESE ARE POINTS THAT WERE QUESTIONS THAT CAME TO US FROM THE VARIOUS BOARD COMMITTEES. IF THE OTHER COMMITTEES HAD QUESTIONS, I THINK PERHAPS THE FULL BOARD MIGHT HAVE SOME OF THE SAME QUESTIONS.

SO THE FIRST POINT HERE, THE QUESTION THAT WAS COMING FROM BOARD MEMBERS IS THERE'S AN IMPORTANT ROLE FOR SOCIAL WORKERS IN THIS EFFORT IN SUPPORTING THE PATIENT JOURNEY. AND SO HOW ARE WE INCORPORATING THAT INTO THIS PROGRAM? AND I THINK FUNDAMENTALLY THE FRAMING AROUND THE NEED TO ADDRESS SOCIAL DETERMINANTS AS A GUIDING STATEMENT FOR THE CONCEPT PLAN, SORT OF THAT'S THE STARTING POINT, THAT SOCIAL DETERMINANTS ARE CRITICAL TO THE SUCCESS OF ADDRESSING THIS PARTICIPATION GAP IN CLINICAL RESEARCH. SO IT'S FUNDAMENTAL TO THE FRAMING.

AND THEN, AGAIN, IN TERMS OF THEN HOW DO WE REALIZE THAT OPPORTUNITY, WE REALLY VIEW COMMUNITY HEALTH WORKERS AND PATIENT NAVIGATORS AS KEY PLAYERS IN MAKING THIS OPPORTUNITY REAL IN PART, FIRST OF ALL, THEY ARE FRONTLINE COMMUNITY HEALTH WORKERS. THEY HAVE THE TOUCH THAT AS OF NOW OUR CLINICAL RESEARCH PROGRAMS DON'T. IN ADDITION, I THINK THERE'S A REAL OPPORTUNITY TO DEVELOP AT THAT LEVEL, IN PART BECAUSE THERE ARE REIMBURSEMENT PROGRAMS FOR BOTH COMMUNITY HEALTH WORKERS AND PATIENT NAVIGATORS, AND IF WE GET THIS PROGRAM RIGHT, THAT PROVIDES AN OPPORTUNITY REALLY TO MAKE THIS SUSTAINABLE BECAUSE THEY'RE NO LONGER DEPENDENT SOLELY ON A CIRM AWARD TO CONDUCT THESE ACTIVITIES. BUT WE CAN UTILIZE ESTABLISHED REIMBURSEMENT MECHANISMS TO CONTINUE THOSE ACTIVITIES.

AND THEN, FINALLY, I THINK THIS WAS REALLY CREDIT TO THE SCIENCE SUBCOMMITTEE FOR HELPING US REALLY THINK THIS THROUGH. A LOT OF QUESTIONS CAME UP AROUND WHAT WILL OUR MEASURES OF SUCCESS BE? HOW WILL WE KNOW IF WE ACHIEVED, ACCOMPLISHED SOMETHING HERE? AND SO WE'VE ADDED AS A MAJOR OBJECTIVE, WHICH WILL THEN INFORM, THE APPLICANTS HAVE TO RESPOND TO THIS, IS PROPOSED TARGETED INTERVENTIONS AIMED AT REDUCING DISPARITIES IN REFERRALS TO

CLINICAL TRIALS WITH THE OVERALL AIM OF INCREASING PARTICIPATION RATES. AND TO ME THAT WAS A REALLY INSIGHTFUL COMMENT BECAUSE ONE CAN SEPARATE -- YOU CAN REFER SOMEONE TO AN ALPHA CLINIC, TO A PATIENT NAVIGATOR. IT DOESN'T NECESSARILY MEAN THEY'RE GOING TO ENROLL IN THE TRIAL BECAUSE THESE ARE COMPLEX TRIALS. AND WHEN THE PATIENT PROCESSES THAT INFORMATION AND MAKES THEIR BEST DECISION, THE BEST DECISION FOR THEM MIGHT BE I DON'T WANT TO ENROLL.

BUT THE NOTION THAT REFERRAL RATES IN THEMSELVES ARE IMPORTANT MEASURES OF SUCCESS, I THINK TO ME WAS REALLY A LIGHT BULB WENT OFF. SO I WANT TO SORT OF ACKNOWLEDGE THAT WE WILL BE BUILDING THOSE TYPES OF -- APPLICANTS WILL HAVE TO RESPOND WITH STRATEGIES FOR HOW THEY WOULD ATTEMPT TO SORT OF GO AT THOSE METRICS.

SO, AGAIN, I'M GOING TO KIND OF SHIFT A LITTLE BIT NOW TO A LITTLE BIT MORE ON THE DETAILS. I'VE KIND OF GIVEN YOU THE CONCEPTUAL OVERVIEW. THESE ARE AREAS OF THE APPLICATION. AGAIN, WE WILL HAVE TO HAVE -- THE FIRST ONE ON THE CLINICAL OPERATIONS, IT'S BOTH THE ACTIVITIES, BUT THE CORE ELIGIBILITY REQUIREMENTS. AND I WANT TO EMPHASIZE THE ELIGIBILITY ASPECTS HERE BECAUSE THAT'S IMPORTANT FROM A STANDPOINT OF MAKING SURE WE GET

THE BEST APPLICANTS.

SO FIRST OF ALL, THEY HAVE TO HAVE A LICENSED AND CERTIFIED HEALTHCARE FACILITY WITH A DEMONSTRATED CAPACITY TO SUPPORT HUMAN SUBJECTS PROTOCOLS IN A HEALTH RESEARCH CONTEXT. THE HUMAN SUBJECTS PIECE IS CRITICAL THERE. THAT MEANS THAT WHATEVER THEY'RE DOING IS GOING TO BE REVIEWED BY AN IRB. WE GET THE ETHICS RIGHT. AND, AGAIN, THIS CAPACITY TO SUPPORT CLINICAL RESEARCH PROTOCOLS IN CELL AND GENE THERAPY. SO THEY HAVE TO REALLY WANT TO DEVELOP THAT SPACE.

AGAIN, WE REACHED OUT TO A NUMBER OF INSTITUTIONS IN THE NEEDS ASSESSMENT THAT ARE EXTREMELY INTERESTED IN DEVELOPING THIS SPACE. I THINK THE SPIRIT OF THE CONVERSATION WAS WE'VE BEEN WAITING A LONG TIME TO REALLY GET INTO THE CIRM ECOSYSTEM. AND THIS IS AN OPPORTUNITY WE'VE REALLY BEEN LOOKING FORWARD TO. SO THERE ARE LOT OF CENTERS OUT THERE THAT ARE NOT MAJOR ACADEMIC CENTERS, BUT THEY DO HAVE THE CAPACITY TO SUPPORT US IN OUR WORK, AND THEY'RE REALLY EAGER TO DO THAT WORK.

FROM A CAREER DEVELOPMENT STANDPOINT, AGAIN, THE CAPACITY TO SUPPORT EDUCATION, TRAINING, AND CAREER DEVELOPMENT. AGAIN, MANY OF THE CENTERS

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ARE DOING THIS ALREADY. THEY ARE VERY INTERESTED IN BUILDING THAT OUT TO INCLUDE THE CELL AND GENE THERAPY FOCUS.

AND THEN IN TERMS OF OUTREACH AND ENGAGEMENT, A TRACK RECORD OF CONDUCTING AND COORDINATING HEALTH EDUCATION IN A COMMUNITY SETTING. AND, AGAIN, THAT IS SOMETHING THAT A LOT OF THESE SITES DO THEY'RE GOING TO NEED HELP WITH. AND WHERE THIS NETWORK WILL REALLY HELP IS IN TERMS OF, AGAIN, THE CELL AND GENE THERAPY EXPERTISE.

SO I MENTIONED THIS EARLIER. I JUST WANT TO COME BACK. ON THE CLINICAL SIDE, I THINK THIS IS AN AREA WHERE WE SAW THE LARGEST SPREAD IN TERMS OF CAPACITY. I THINK THERE ARE SITES THAT TODAY THEY'RE ALMOST INDISTINGUISHABLE FROM AN ALPHA CLINIC OR THEY'RE VERY CLOSE TO BEING ALPHA CLINIC-LIKE. THEY COULD REALLY DELIVER INVESTIGATIONAL PRODUCTS TO PATIENTS.

THERE ARE OTHER SITES THAT AREN'T THERE OR CERTAINLY REALLY WON'T BE ABLE TO GET THERE WITHIN THE FIVE-YEAR AWARD PERIOD AND MAY NOT EVER NEED TO GET THERE, BUT THEY CAN SUPPORT PATIENTS, THEY CAN NAVIGATE PATIENTS, THEY CAN SCREEN PATIENTS, AND THEY CAN ENGAGE POPULATIONS, AGAIN, THAT WE ARE TRYING TO REACH.

SO WE'VE BROKEN THE CLINICAL LANE, IF YOU WILL, INTO SORT OF PROPOSING TWO AREAS. AGAIN, A SITE THAT CAN, OVER THE AWARD PERIOD, WOULD SIMPLY BE SUPPORTING TRIALS AND WORKING WITH THE ALPHA CLINICS MAINLY AS REFERRAL SITES OR THEY CAN BE SUPPORT AND DELIVERY SITES WHERE THEY'RE GOING TO BE DELIVERING THE CAPACITY TO HANDLE INVESTIGATIONAL PRODUCTS. AND JUST, AGAIN, TO SORT OF GIVE YOU A SENSE OF READINESS OR EAGERNESS, THERE ARE ALREADY DISCUSSIONS GOING ON WITH POTENTIAL APPLICANTS AND ALPHA CLINICS TO REALLY DESCRIBE THAT PROCESS. SO THEY'RE IN PROCESS, AND THIS AWARD WOULD REALLY ACCELERATE THE COMPLETION OF THAT PROCESS.

AGAIN, CAREER DEVELOPMENT. I THINK THE MAIN ASPECT HERE, YOU HEARD DR. KELLY SHEPARD AT THE LAST MEETING, I BELIEVE. WE'RE REALLY PUTTING A LOT OF FOCUS ACROSS THE ORGANIZATION IN DEVELOPING OUR EDUCATION PLATFORMS AND SYSTEMS. THE AIM THERE IS TO BRING TOGETHER THOSE PROGRAMS IN A STRUCTURED WAY SO THAT THE PROGRAM DIRECTORS, THE PROGRAM MANAGERS CAN TAKE THOSE RESOURCES AND REALLY SHARE THEM, WHETHER IT'S SHARED CURRICULUM, WHETHER IT'S HERE WE'RE TRYING TO PLACE PEOPLE, THE WHOLE RANGE OF ACTIVITIES THAT THOSE OPPORTUNITIES IN THE EDUCATION SPACE, REALLY BRING THAT TOGETHER IN A

STRUCTURED WAY SO THAT WE CAN MAKE THESE PROGRAMS VISIBLE AND SUCCESSFUL. AND THE AIM HERE WOULD BE TO TIE INTO THAT INTERNAL INFRASTRUCTURE TO PROMOTE THESE EDUCATION OPPORTUNITIES.

AND, AGAIN, THE OUTREACH AND ENGAGEMENT PIECE, I THINK THAT'S WHAT'S REALLY DIFFERENT HERE. AND SO WE WOULD REALLY EXTEND THE OUTREACH AND ENGAGEMENT TO INCLUDE COMMUNITY-BASED ORGANIZATIONS TO SUPPORT CLINICAL DEVELOPMENT -- TO SUPPORT CAREER DEVELOPMENT IN THIS AREA. AND I THINK WHAT WE WOULD ANTICIPATE, A LOT OF OUR INFRASTRUCTURE PROGRAMS INCLUDE STEERING COMMITTEES AND COORDINATING COMMITTEES THAT CUT ACROSS DIFFERENT PROGRAMS. AND I WOULD IMAGINE WE WOULD REALLY WANT TO APPLY THAT STEERING COMMITTEE STRATEGY SPECIFICALLY AROUND OUTREACH AND ENGAGEMENT TO THIS PROGRAM BECAUSE THIS IS THE PROGRAM WHERE THE RESOURCES WILL BE THERE, THE EXPERIENCE WILL BE THERE, AND TO REALLY USE THAT STEERING COMMITTEE PROCESS TO DISSEMINATE LESSONS LEARNED, STRATEGIES, MATERIALS, ET CETERA. SO IT'S, I THINK, A REAL OPPORTUNITY WITHIN THIS PROGRAM TO DEVELOP THAT.

ANOTHER QUESTION THAT I WAS GOING TO CREDIT THE AAWG WITH THIS ONE. HOW DOES A COMMUNITY CARE CENTER, HOW IS IT DIFFERENT THAN AN ALPHA

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CLINIC? AND HERE'S KIND OF AT LEAST THE SORT OF TECHNICAL ANSWER, IF YOU WILL. THE ALPHA CLINICS, IN ORDER TO COME IN, HAD TO BE ABLE TO DELIVER CELL AND GENE THERAPY PRODUCTS. THEY HAD TO BE ABLE TO SERVICE OUR CLIN2 AWARDS FROM DAY ONE. COMMUNITY CARE CENTER IS A LITTLE BIT DIFFERENT. AGAIN, WE WANT THEM TO BE ABLE TO SUPPORT THOSE TRIALS. AND IF THEY'RE INTERESTED IN DEVELOPING THE CAPACITY TO CONDUCT THEM, THEN THIS AWARD WOULD SUPPORT THAT DEVELOPMENT PROCESS, BUT THAT'S NOT A REQUIREMENT.

THE ALPHA CLINICS, IN TERMS OF TRAINING REALLY DEVELOPED A LOT OF DE NOVO TRAINING PROGRAMS. AGAIN, COMMUNITY CARE CENTERS, THE AIM IS TO APPLY THOSE PROGRAMS, APPLY THOSE CURRICULUM, AND SERVE AS SITES FOR PLACEMENT AND CROSSTALK.

FROM THE ALPHA CLINIC SIDE, I DON'T WANT TO IMPLY THEY'RE NOT DOING COMMUNITY ENGAGEMENT BECAUSE THEY ARE, BUT THEY TEND TO REALLY FOCUS ON ENGAGEMENT IN THE CONTEXT OF CLINICAL PROTOCOLS AND THEY DO THAT VERY WELL. THE COMMUNITY CARE CENTERS, AGAIN, MORE OF THE SAME IN THE SENSE OF WE STILL NEED CLINICAL TRIAL ENGAGEMENT AND NAVIGATION THAT'S PROTOCOL SPECIFIC, BUT ALSO BROADER ENGAGEMENT AROUND REGENERATIVE MEDICINE.

ONE OF THE STAKEHOLDERS EVEN TOOK US A

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STEP FURTHER BACK AND SAID THERE'S A HUGE NEED JUST TO EDUCATE PEOPLE ON WHAT'S A CLINICAL TRIAL. WHAT DOES IT MEAN TO ME? WHAT DOES IT MEAN TO MY COMMUNITY? THOSE SORTS OF ISSUES. THIS IS REALLY, I THINK, AN OPPORTUNITY TO DEVELOP THAT LITERACY.

AGAIN, I THINK THESE WERE QUESTIONS LARGELY COMING OUT OF THE SCIENCE SUBCOMMITTEE. WE WANTED TO SORT OF POINT TO SOME OF THE ETHICS POLICY GUARDRAILS THAT ARE BAKED INTO THE CONCEPT PLAN. I NOTED THIS EARLIER. IT'S HUMAN SUBJECTS. YOU HAVE TO BE COMPETENT IN HUMAN SUBJECTS RESEARCH SO THAT WHATEVER YOU'RE DOING IS OVERSEEN BY AN IRB. THERE'S A PROVISION IN STATE LAW THAT REQUIRES PRACTITIONERS THAT ARE PROVIDING STEM CELL THERAPIES, AND STEM CELL THERAPIES ARE DEFINED UNDER THE LAW, IF THEY'RE NOT APPROVED BY THE FDA OR THEY DO NOT HAVE AN IND, THEY HAVE TO PROVIDE A WARNING TO THE PATIENTS THAT THESE ARE NOT APPROVED TREATMENTS. IF YOU'RE DOING THAT, THEN YOU'RE NOT ELIGIBLE FOR THIS PROGRAM. IF YOU'RE PROVIDING THAT WARNING IN YOUR CLINICAL PRACTICE, PLEASE DON'T APPLY.

RESEARCH ETHICS TRAINING, THIS WAS A BIG THEME WHEN WE ENGAGED PROGRAMS THAT HAVE DONE ENGAGEMENT AROUND CLINICAL RESEARCH, THAT THE

INDIVIDUALS THAT ARE DOING THE OUTREACH AND ENGAGEMENT NEED TO UNDERSTAND SORT OF THE ETHICAL ASPECTS OF THAT WORK. AND THERE ARE A LOT OF TRAINING PROGRAMS AND OPPORTUNITIES OUT THERE. SO WE'D LIKE TO BRING THAT IN. APPLICANTS WOULD BASICALLY BE ABLE TO BUDGET FOR THOSE TYPES OF ACTIVITIES AND ASKED TO DO THAT.

AND, AGAIN, THE RESEARCH ETHICS PIECE SORT OF GOES BACK TO WE HAD THIS DISCUSSION WITHIN THE STANDARDS WORKING GROUP AND, AGAIN, THIS IDEA OF ACCREDITATION AND TRAINING WAS REINFORCED BY THE STANDARDS WORKING GROUP.

LEVERAGE, AGAIN, IF WE GO BACK TO THAT FOUR-PIECE, THAT FOUR-PART CIRCLE EARLY ON WHERE I WAS TRYING TO DESCRIBE THE CONNECTIONS TO OTHER CIRM INFRASTRUCTURE AND OTHER CIRM PROGRAMS. AGAIN, JUST TO REITERATE HOW WE'RE LEVERAGING OUR ASSETS. THIS IS A WAY OF TAKING WHAT WE DO WELL AT THE CLINICAL LEVEL, BUT REALLY EXPANDING IT OUT BEYOND OUR EXISTING REACH. AGAIN, POINTING TO THE COMMUNITY BASED -- THE ROLE FOR COMMUNITY-BASED ORGANIZATIONS IN THIS AWARD. THEY WOULD HELP US AND PARTNER WITH US TO REACH POPULATIONS THAT ARE LESS SERVED OR UNDERSERVED BY OUR CURRENT PROGRAMS.

THERE'S A SUSTAINABILITY ASPECT. I

REFERRED TO THAT AND I JUST REITERATED IT HERE, THAT WE'RE REALLY LOOKING TO TAP INTO EXISTING REIMBURSEMENT MECHANISMS. OR IF THOSE REIMBURSEMENT MECHANISMS CURRENTLY AREN'T PROVIDING REIMBURSEMENT FOR THIS WORK, HOW CAN WE USE THIS PROGRAM TO GET REIMBURSEMENT FOR THAT TYPE OF WORK. SO WE'RE WORKING ON LOOKING AT THOSE FUNDING STREAMS FOR, AGAIN, COMMUNITY HEALTH WORKERS AND PATIENT NAVIGATORS.

THE FOCUS, AGAIN, COMING BACK TO THAT POINT THAT WE'RE REALLY LOOKING AT BOTH DISPARITIES AND REFERRAL RATES AND PARTICIPATION RATES. I THINK THAT WILL BE A MAJOR AIM OF THE PROGRAM, AND WE WILL ASK APPLICANTS TO PROPOSE HOW THEY'RE GOING TO DO THAT. AND THE GRANTS WORKING GROUP WILL BE ASKED TO SCORE THEM ON THE EFFICACY OR THE PERCEIVED EFFICACY OF WHAT THEY'RE PROPOSING. AND, AGAIN, REALLY TO BUILD COMPETENCY, WE REALLY TO WANT DEVELOP CIRM-MEDIATED ENGAGEMENT NETWORKS. SOME OF THIS WORK IS ALREADY GOING ON, AGAIN, WITHIN THE ORGANIZATION. AND AS I ALLUDED TO, WE WOULD DEVELOP A STEERING COMMITTEE SPECIFICALLY AROUND ENGAGEMENT PRACTICE, BEST PRACTICE, AND HOW TO DO THAT EFFECTIVELY.

AND ALSO, AGAIN BACK TO THE CONVERSATION A

FEW MINUTES AGO, I THINK DURING THIS PROCESS IT WAS INDICATED THAT WE'RE REALLY TRYING TO DO A LOT HERE IN TERMS OF THIS PROGRAM IN RELATION TO OUR STAFFING RESOURCES. SO I'VE BEEN SPEAKING WITH DR. THOMAS AND OTHERS. WE REALLY WILL PROPOSE SOME ADDITIONAL STAFFING. WE THINK IT WOULD BE PARTICULARLY USEFUL IN THIS PROGRAM TO HAVE INDIVIDUALS WHO HAVE EXPERIENCE WITH BOTH PROGRAM PLANNING AND EVALUATION IN A SORT OF HEALTH EDUCATION CONTEXT TO SUPPORT THE ENGAGEMENT WORKING GROUP. SO THAT'S ONE PARTICULAR AREA WHERE I WOULD -- I'M ADVOCATING INTERNALLY TO SORT OF BUILD SOME RESOURCES TO MAKE SURE THIS GOES SMOOTHLY.

AGAIN, THIS IS A LITTLE BIT REDUNDANT. I'LL TICK THROUGH IT VERY QUICKLY. SO BUILDING PARTNERSHIPS WITH ALPHA CLINICS. AGAIN, THAT'S HAPPENED THROUGHOUT THIS PROCESS. THERE ARE VERY SPECIFIC PROPOSALS THAT ARE BEING DEVELOPED THAT POTENTIAL APPLICANTS WILL BE PROPOSING. THE MANUFACTURING NETWORK, TO THE EXTENT WE HAVE SITES THAT WANT TO GET INVOLVED IN MANUFACTURING, AND THERE ARE CERTAINLY ONES OUT THERE THAT OUR MANUFACTURING NETWORK CAN SUPPORT THAT, THE COORDINATION WITH OUR EDUCATION PROGRAMS. I'VE ALLUDED TO THAT, AGAIN, REFERENCING THE WORK OF DR.

SHEPARD. AND WE'VE ALSO BEEN REACHING OUT TO SOME RARE DISEASE ORGANIZATIONS AND PROVIDING VISIBILITY TO THIS PROGRAM. SO THEY HAVE A POTENTIAL TO PARTNER IN WITH OUR APPLICANTS.

SO FINAL STAGE, THIS IS BASICALLY THE ASK. THE ALLOCATION WE'RE REQUESTING IS 60.2 MILLION. AND JUST AS A GUIDEPOST, PROPOSITION 14 ACTUALLY AUTHORIZED UP TO 78 MILLION FOR THIS PROGRAM. THAT'S A FIGURE THAT WAS PRESENTED IN JANUARY OF 2021 WHEN YOU RECEIVED A BROAD OVERVIEW OF PROPOSITION 14. SO WE'RE REFERENCING THAT FIGURE. IT MEANS WE HAVE SOME HEADROOM IN TERMS OF IF WE WANT TO HAVE A SECOND ROUND OR ADD SITES. JUST AS A REMINDER, THAT'S THE PROPOSITION 14 ALLOCATION. IF FOR WHATEVER REASON THE BOARD DETERMINES THAT THIS PROGRAM WOULD BENEFIT FROM FURTHER RESOURCES, YOU HAVE THE DISCRETION TO ADD RESOURCES AT YOUR DISCRETION.

AGAIN, THE BUDGET IS DESIGNED TO SUPPORT CORE OPERATIONS. THAT'S THE CLINICAL ASPECTS, COMMUNITY PARTNERSHIPS. AND IN ADDITION, THERE'S, AS I ALLUDED TO EARLIER, THERE'S FACILITIES FUNDING IN THERE. AND FACILITIES IS BUILDING, RENOVATION, AND FACILITIES OVER THE FIVE YEARS OF THE AWARD. SO WE WILL WORK WITH -- WE MAY OR MAY NOT NEED TO BRING

IN THE FACILITIES WORKING GROUP. THAT'S TO BE DETERMINED DEPENDING ON THE FINAL APPLICATION.

AND AS WE MODEL THIS OUT, WE THINK THAT THIS COULD SUPPORT THREE SITES THAT WOULD PROPOSE TO BOTH SUPPORT AND DELIVER CLINICAL TRIALS. SO, AGAIN, SITES THAT WOULD BE AKIN TO AN ALPHA CLINIC. THAT'S 10 MILLION PER AWARD. THAT'S RIGHT AROUND THE SAME BUDGET ALLOCATION AS THE CURRENT ALPHA CLINICS AWARD. AND THEN THE SUPPORT SITE AWARDS WOULD BE COMING IN AT 7.5 MILLION AS A PROPOSED BUDGET. SO THAT'S THE BREAKDOWN ON THE DIFFERENCES BETWEEN THE TWO SITES.

AND I THINK THAT'S IT. THANK YOU FOR YOUR TIME AND ATTENTION.

CHAIRMAN IMBASCIANI: YOU WERE THINKING ABOUT THANKING US. OKAY. I LIKE THAT. THANK YOU, GEOFFREY. THAT WAS VERY COMPREHENSIVE AND WELL ORGANIZED.

SO IN A SENSE YOU'RE LOOKING AT WHAT I'M HOPING TO SEE WILL BE A MOTION FROM THE BOARD TO ACCEPT THIS CONCEPT PLAN AND ITS BUDGET ALLOCATION.

VICE CHAIR BONNEVILLE: SO MOVED.

MR. FISCHER-COLBRIE: SECOND IT.

CHAIRMAN IMBASCIANI: WE HAVE A SECOND FROM MARK FISCHER-COLBRIE, AND MARIA MADE THE

PRIMARY MOVEMENT. SO THE BOARD IS OPEN FOR DISCUSSION. YSABEL, YOU CAN GO FIRST.

MS. DURON: I KNOW WE'RE INCHING UP INTO SIESTA TIME. BUT ONE OF THE THINGS THAT I DIDN'T WANT TO INTERRUPT YOU ON, GEOFF, BUT WHEN YOU TALK ABOUT PATIENT EDUCATION AT THE VERY BEGINNING AND IT WAS MIXED IN WITH THE OTHER PARTS THAT I THOUGHT WERE DEALING WITH THOSE WHO WOULD BE THE APPLICANTS, I WASN'T SURE WHO THAT WAS AIMED AT. AND I THINK THAT THOSE OF US IN THE ADVOCACY WORLD LIKE TO THINK OF PATIENT EDUCATION THAT IS NECESSARY FOR THE APPLICANTS AS WELL. SO IT WORKS BOTH WAYS. SO THEY UNDERSTAND THAT PATIENTS ARE NOT WIDGETS, PATIENTS ARE NOT DATA BITS, BUT THAT, IN FACT THEY UNDERSTAND THE COMMUNITIES WITH WHOM THEY ARE TRYING TO PARTNER AND TO GET THEM TO PARTICIPATE.

SO THAT I THINK THE PART OF PATIENT EDUCATION FOR THE APPLICANTS IS THAT THEY SHOULD KNOW, AND THIS MIGHT BE PART OF A CORE CURRICULUM THAT YOU'RE DEVELOPING OR ONE THAT YOU SAY ALREADY EXISTS, AND THAT IS THAT THEY SHOULD UNDERSTAND THE FOOTPRINT OF THE DEMOGRAPHICS AND WHERE THEY OPERATE. WHO ARE THESE PEOPLE THAT WE HOPE TO BRING INTO OUR SPACE? AND UNDERSTAND THEM ON A CULTURAL LEVEL, ON A RACIAL LEVEL, ON AN ETHNIC LEVEL, ON AN

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EXPERIENTIAL LEVEL FOR THEIR LIVED EXPERIENCE. A LOT OF TRAUMA IN SOME OF OUR COMMUNITIES CONTINUALLY.

SO WHEN YOU'RE TRYING TO BRING THEM INTO SOMETHING LIKE SCIENCE, WHICH THERE'S STILL MISINFORMATION OUT THERE, YOU HAVE TO BE SUPER SENSITIVE TO ALL OF THIS. AND I THINK THAT SOMETIMES WHEN YOU'RE LOOKING AT IT FROM A VERY HIGH LEVEL, YOU'RE THINKING YOU'RE DOING GOOD, BUT IN REALITY, UNTIL YOU ADDRESS PEOPLE WHERE THEY LIVE AND HOW THEY FEEL AND WHAT THEY THINK AND WHAT THEY KNOW, I DON'T THINK YOU GET THE SAME KIND OF BUY-IN. AND WHEN WE'RE TALKING ABOUT BRINGING SCIENCE TO COMMUNITY AND COMMUNITY TO SCIENCE, WE NEED TO MAKE SURE BOTH SIDES ARE EDUCATED.

DR. LOMAX: THAT MESSAGE CAME -- IF YOU GO BACK, WE DID PRODUCE SOME SUMMARIES OF LISTENING SESSIONS AND TRIED TO RANK ORDER -- I WON'T SAY RANK ORDER. IT'S A BIT STRONG -- BUT GIVE WEIGHT TO THE MESSAGES WE HEARD. SO WHEN WE LOOKED AT THE MESSAGES FROM INDIVIDUALS WHO WORK WITH THE COMMUNITIES THAT YOU DESCRIBE OR THAT ARE AS CLOSE TO THE COMMUNITIES YOU DESCRIBE, IT WAS THOSE THEMES OF TRUST, RESPECT, RECIPROCITY, BUILDING UP. AND SO IN TERMS OF RELATING THAT BACK TO THE CONCEPT PLAN,

WE DID TRY TO EMBRACE THEM IN THE PLAN. I THINK THAT'S THE AIM, AT LEAST, OF MANDATING THAT THERE ARE THESE COMMUNITIES-BASED PARTNERSHIPS AND THEY'RE IN THE APPLICATION ON THE FRONT END AND THAT THOSE CONVERSATIONS -- THE CONVERSATIONS BETWEEN THE COMMUNITY PARTNERS AND THE APPLICANTS WOULD NEED TO BE TOWARDS A DIRECTED AIM AS YOU DESCRIBE.

LINKING IT BACK TO THE METRICS, I THINK IT'S HOW DO WE -- OUR ISSUES LIKE REFERRAL RATES. AND SO I KNOW IT MOVES VERY QUICKLY BACK INTO SORT OF METRICS OF MEDICAL METRICS; BUT I THINK IN ORDER TO DO THAT, YOU DO HAVE TO SORT OF ADDRESS THE ISSUES OF TRUST AND THOSE SORTS OF THINGS. SO I HOPE WE'VE GOT THAT RIGHT. WE WERE ENCOURAGED, AGAIN, BY THE BOARD TO BUILD IT AROUND THINGS WE CAN MEASURE. SO I THINK IT'S THAT, BUT IT'S FUNDAMENTAL. IT'S THE RELATIONSHIP BETWEEN THE AIMS AND THEN THAT PARTNERSHIP AND THE APPLICANTS COMING IN WITH A DEFINED PLAN, NOT SIMPLY SAY WE'RE GOING TO PARTNER WITH GROUP X. TOWARDS WHAT END? WHAT POPULATIONS ARE YOU INTERESTED IN? WHAT'S THE DEMOGRAPHIC?

THAT'S HOW I SEE WE CAN GET AT THAT THROUGH THE APPLICATION PROCESS. I HOPE THAT'S SUFFICIENT TO ADDRESS, BUT I DON'T KNOW. BUT I

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HOPE -- THAT'S THE THINKING.

CHAIRMAN IMBASCIANI: THANK YOU, GEOFF. WE HAVE COMMENTS FROM BOARD MEMBER ABOUSALEM FOLLOWED BY DULIEGE.

DR. ABOUSALEM: THANK YOU, MR. CHAIRMAN. THANK YOU FOR THIS PRESENTATION. I'M REALLY PLEASED TO SEE THAT THIS PROGRAM IS TAKING SHAPE AND YOU'RE COMING TODAY WITH THIS PROPOSAL.

I HAVE A QUESTION OR COMMENT AND MAYBE A RECOMMENDATION AROUND ONE OF THE OBJECTIVES OF THE PROGRAM. AND I'M LOOKING AT THE DOCUMENT AND I'M LOOKING AT THE OBJECTIVE NO. 5. IT'S BULLET NO. 5, WHICH IS PROPOSED TARGETED INTERVENTIONS AIMED AT REDUCING DISPARITIES AND REFERRALS TO CLINICAL TRIALS AND THE REST. I'M WONDERING WHY THIS OBJECTIVE. TO ME IT SEEMS IT'S A LITTLE AMBIGUOUS AND TOO SOFT IN THE SENSE THAT IT'S NOT CLEAR WHO'S PROPOSING TO WHOM. AND ALSO TO WHAT END? THE PROPOSAL IS JUST A VERY SOFT ACTION. AND IF IT IS TO A THIRD PARTY OR IF THIS IS GOING TO BE PART OF THE APPLICATION, WHY IS IT NOT SIMILAR TO THE OTHER OBJECTIVES LIKE CONDUCT TARGETED OR PLAN AND CONDUCT TARGETED INTERVENTIONS?

AND I WANT TO SAY EVEN FURTHERMORE, WHEN YOU LOOK AT THE CORE PROGRAM ACTIVITIES, I COULD NOT

PUT MY FINGER ON ANY ACTIVITY THAT DIRECTLY ALIGNS WITH THIS OBJECTIVE. SO I FEEL THAT THIS OBJECTIVE MAY GET LOST, AND WE WON'T BE ABLE TO MEASURE HOW WE'RE DOING ON THIS ONE OBJECTIVE. SO IF YOU CAN TALK ABOUT THAT, AND HOPEFULLY YOU WILL CONSIDER IMPROVING THE LANGUAGE AND THE ALIGNMENT WITH THE CORE ACTIVITIES.

DR. LOMAX: THANK YOU FOR THAT COMMENT. YES. SO WE ALWAYS HAVE A LITTLE BIT OF A STRUGGLE AT THE CONCEPT LEVEL BECAUSE IT IS CONCEPTUAL WHERE THE REAL -- I THINK WHERE WE CAN DRIVE INTO THE SPECIFICITY IS WHEN WE GET INTO THE QUEST FOR APPLICATIONS. THE NEXT STEP WILL BE TO ADD SPECIFICITY AND THAT LEVEL OF DETAIL.

I THINK ONE OF THE THINGS, AND, AGAIN, I'VE TALKED TO DR. THOMAS ABOUT THIS ALREADY, WOULD LIKE TO BE ABLE TO, AS WE GO THROUGH THAT PROCESS OF EXPANDING AND ELABORATING THE CONCEPTUAL BULLETS TO ASKS WITHIN THE APPLICATION, THAT WE CAN ACTUALLY COME BACK TO SOME OF YOU ALL TO SEE DOES THIS ADDRESS YOUR CONCERN OR DID WE GET IT RIGHT. BECAUSE I THINK IT'S THAT NEXT STAGE WHERE WE GET THAT LEVEL OF SPECIFICITY THAT IS REALLY IMPORTANT TO, I THINK, WHAT YOU'RE ASKING. SO THAT'S ONE THING, AGAIN, WE'VE SORT OF ALREADY PROPOSED. I

DON'T KNOW IF THERE'S CHANGE AT THE CONCEPT LEVEL THAT WE COULD DO IN THE NEARER TERM THAT WOULD ADDRESS THAT.

DR. ABOUSALEM: SO I'D JUST LIKE TO COMMENT ON THAT. I WANT TO PUSH BACK A LITTLE BIT ON THAT. WE ARE ASKED TO APPROVE A PROGRAM BASED ON A CONCEPT. AND LOT OF THE OBJECTIVES YOU HAVE ARE DEFINITIVE ENOUGH ABOUT WHAT THE GOAL IS, EVEN HOW YOU CAN MEASURE IT, YOU CAN EXTRAPOLATE, AND THE ACTIVITIES THAT ARE GOING TO BE ALIGNED WITH IT. TO ME IT'S A NICE GOAL TO PROPOSE TARGETED INTERVENTIONS, BUT DOESN'T DO MUCH. SO I APPRECIATE WHAT YOU'RE SAYING, THIS IS THE CONCEPT PHASE, BUT EVERYTHING ELSE IS REALLY WHAT YOU EXPECT THE ACTIVITY TO ACHIEVE AND THE APPLICANT TO DEMONSTRATE. AND IT'S ONLY SOFT ON THIS ONE, AND WE SHOULD REALLY FINE-TUNE THIS ONE UPFRONT. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU. MEMBER DULIEGE.

DR. DULIEGE: HI. I'M GOING A LITTLE BIT IN LINE OF WHAT YOU SAID, MOHAMED. IN FACT, I HAVE A COMMENT, A SUGGESTION FOR CLARIFICATION, A QUESTION AND, FINALLY, A RECOMMENDATION. SO BEAR WITH ME, AND I'LL TRY TO BE FAIRLY QUICK ON THAT.

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MY COMMENT IS IT'S AN EXCELLENT PRESENTATION, VERY WELL THOUGHT OUT, EXTREMELY CLEAR. AND I PARTICULARLY APPRECIATE THE CLARIFICATION OF THE ROLE, THE IMPORTANT ROLE OF COMMUNITY-BASED ORGANIZATIONS. I WILL SAY CBO FROM NOW ON. TWO POINTS I WANTED TO MENTION ABOUT THAT. THE ENROLLMENT IS THE RESPONSIBILITY OF THE INVESTIGATOR OF THE ALPHA CLINIC. HOWEVER, USUALLY MOST TEAMS DON'T HAVE A LOT OF TIME TO HELP PATIENTS REALLY TRULY UNDERSTAND WHAT MIGHT BE GOING ON THERE, AND THAT'S WHERE A CBO WOULD BE PARTICULARLY USEFUL. LIKEWISE, A PATIENT MAY WANT TO BE IN A TRIAL AND AT THE LAST MINUTE HE OR SHE IS ELIGIBLE. THERE IS A HUGE DISAPPOINTMENT THERE, HUGE. AND, AGAIN, THE TEAM AT THE CLINIC MAY NOT HAVE THE TIME TO ACCOMPANY THIS PERSON DURING THIS DIFFICULT PHASE. AND A CBO WOULD HAVE MORE TIME AND PROBABLY BE BETTER AT THAT. SO THAT'S GREAT.

WHAT ISN'T CLEAR TO ME IS THE ROLE THAT YOU'RE THINKING ABOUT THE CLINICAL OPERATIONS. SO WHEN YOU'RE SAYING SUPPORT AND DELIVERY SITES DEVELOP, THAT WASN'T CLEAR. THE SITES ARE CURRENTLY BEING GIVEN MONEY TO BEING TRAINED TO BECOME ENROLLMENT SITES OR ENROLLING SITES. IF YOU CAN CLARIFY THAT BECAUSE YOU'RE A SITE OR YOU'RE NOT.

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THERE IS A NEED FOR MORE SITES OR THERE IS NOT. AND A SITE TRAINING FOR ENROLLMENT, KNOWING HOW MUCH INFRASTRUCTURE IS NEEDED TO BECOME AN ENROLLING PER SE IS A QUESTION FOR ME.

BUT MY TRUE QUESTION THAT WAS REALLY MORE OF A CLARIFICATION IS THAT THE VAST MAJORITY OF GRANTS WE SUPPORT ARE FOR VERY RARE DISEASE, ULTRA RARE DISEASES FOR WHICH THE REFERRAL COMES ESSENTIALLY FROM THE HOSPITAL SETTING AND HOSPITAL NETWORK OF SPECIALISTS AND PARTICULARLY THE GENETIC CENTERS. I CAN'T THINK ABOUT A PATIENT THAT YOU WOULD FIND NEAR A COMMUNITY THAT YOU FIND THERE BECAUSE HE'S NOT BEEN SEEN BY A DOCTOR, AND SOME WILL GET HIM OR HER TO A STEM CELL CLINICAL TRIAL. SO THAT IS CLEAR. AND FOR THAT MATTER, I'M CONCLUDING HERE, I WONDER, $60 MILLION IS STILL A LARGE AMOUNT OF MONEY EVEN IF WE STARTED WITH DEEP POCKETS, IF IT WILL BE WISE TO GO IN A STEPWISE APPROACH, TEST A FEW THINGS OF WHICH YOU'RE PROPOSING, EVALUATE IT, SHARE THIS EVALUATION WITH THE BOARD, AND THEN MOVE ON TO A FULL USE OF THE $60 MILLION. THAT'S ONLY A RECOMMENDATION ON MY PART. OVER.

DR. LOMAX: YES. THANK YOU. AND THANKS FOR THAT. THE ONE I CAN -- I'M JUST GOING TO START

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HERE BECAUSE I THINK IT HOPEFULLY GETS AT A SUBSTANTIAL PART OF THAT COMMENT. SO WE DID GO -- WE ACTUALLY VISITED A NUMBER OF SITES. AND SO IN TERMS OF THE PATIENT PIECE OR THE REFERRAL PIECE, THERE ARE SITES THAT WERE ENGAGED IN THIS PROCESS THAT ARE ALREADY SERVING AS REFERRAL SITES FOR THE ALPHA CLINICS. THEY'RE ALREADY SUPPORTING PATIENTS, THEIR PATIENTS GETTING TREATMENTS, SAY, AT AN ALPHA CLINIC SITE. THIS IS PRIMARILY ONCOLOGY.

SO I THINK YOUR POINT ABOUT RARE GENETIC DISEASE IS WELL TAKEN. BUT IN TERMS OF PARTICULARLY THE ASPECTS OF OUR PORTFOLIO THAT ARE IN ONCOLOGY, THESE RELATIONSHIPS ALREADY EXIST. AND WHAT WE RECEIVED THROUGH THE NEEDS ASSESSMENT PROCESS WAS HERE'S HOW WE COULD EXPAND THIS IN A WAY THAT WOULD HELP YOU ACHIEVE YOUR AIM. SO I THINK, AGAIN, ANOTHER AREA SIMILAR TO ONCOLOGY IS IN SICKLE CELL. THERE ARE CENTERS THAT ARE ENGAGED IN THIS PROCESS THAT DO MANAGE THOSE PATIENTS AND COULD SUPPORT WORK IN SICKLE CELL AND THOSE RELATED DISORDERS.

SO AT LEAST IN THAT CLINICAL SPACE, THERE SEEMED TO BE A SUBSTANTIAL PATIENT POPULATION THAT WOULD BE WITHIN THE REACH OF THESE CENTERS. AGAIN, THAT DOESN'T NECESSARILY ADDRESS THE RARE AND ULTRA RARE. I THINK, AGAIN, THAT WAS A POINT THAT CAME UP

WITHIN THE SUBCOMMITTEE CONTEXT. AND I THINK THERE ARE -- ONE OF THE AREAS WE'VE LOOKED AT IN TERMS OF, AGAIN, COLLABORATION WITH THE ALPHA CLINICS AND WHAT CAN THEY BRING IN HERE, THERE ARE PATIENT REGISTRIES, THERE IS THE ABILITY TO INTERROGATE MEDICAL RECORDS. AND, AGAIN, IF WE CAN IDENTIFY THOSE PATIENTS, WOULD A FIRST LINE OF INTERACTION BE WITHIN A COMMUNITY SETTING? SO, AGAIN, BUILDING THOSE. SO, AGAIN, THEY SERVE AS A REFERRAL SITE AND POTENTIALLY A PLACE WHERE, IF THE PATIENT WERE TO COME IN AND LEARN ABOUT A CLINICAL TRIAL OR GET THAT NAVIGATION, THAT THAT WOULD BE INITIATED CLOSER TO HOME.

SO SOME OF THE SCENARIOS AT LEAST WERE DESCRIBED THROUGH THIS PROCESS. I DON'T KNOW IF THAT GETS AT ALL OF YOUR QUESTION, BUT CERTAINLY IT INFORMED CONCEPTUALLY, THEN, THIS NOTICE BETWEEN REFERRAL SITE AND TREATMENT SITE OR SORT OF REFERRAL SITE OR -- LET ME USE THE CORRECT TERMINOLOGY -- SUPPORT SITE OR SUPPORT AND TREATMENT SITE.

DR. DULIEGE: THANK YOU. I'M WONDERING IF YOU HAVE COMMENTS OR CLARIFICATION ABOUT THE SITES THAT ARE BEING TRAINED TO BECOME ENROLLMENT SITES. IT'S UNDER CLINICAL OPERATIONS POINT NO. 2.

AND THEN FINALLY, WHAT DID YOU THINK OF MY

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RECOMMENDATION, GIVEN IT'S PRETTY LARGE, TO GO IN A STEPWISE APPROACH AND START A FEW OF THE STEPS AND THEN REEVALUATE FOR EFFICIENCY?

DR. LOMAX: ON SOME LEVEL I ALMOST DEFER TO THE BOARD ON THAT. WE BROUGHT FORWARD A PROPOSAL. THAT'S CERTAINLY -- I THINK WHEN THE ALPHA CLINICS PROGRAM STARRED, WE STARTED WITH -- WELL, YES, WE ORIGINALLY STARTED WITH THREE AWARDS AND NOW WE'RE UP TO TEN. SO THAT IS A MODEL THAT WE HAVE DEPLOYED IN THE PAST. I THINK THE DOWNSIDE POTENTIALLY TO THAT APPROACH IS WE DON'T KNOW THE FUTURE OF THE ALPHA CLINIC AWARDS. THEY'RE GOING TO BE MOVING INTO YEAR THREE OF THEIR FIVE-YEAR AWARDS. THE ALPHA CLINICS ARE COMMITTED OR HAVE MADE SUBSTANTIAL COMMITMENTS TO SUPPORTING POTENTIAL APPLICANTS TO THIS PROGRAM. IF THE TIME HORIZON FOR THIS PROGRAM STRETCHES BEYOND THE ALPHA CLINIC AWARDS, WE POTENTIALLY HAVE A RISK THAT WE DON'T HAVE THE ALPHA CLINICS AT THE SAME -- WITH THE SAME RESOURCE TO SUPPORT THIS THAT WE OTHERWISE WOULD IF WE FUNDED MORE SITES AT THIS TIME.

SO I THINK THERE'S A BALANCING THERE. AGAIN, AT A CERTAIN LEVEL I WOULD DEFER TO THE BOARD AS THE DECIDER, BUT THESE ARE SOME OF THE CHALLENGES IN TERMS OF TIMING AND NUMBER OF AWARDS THAT SORT OF

ONE HAS TO THINK THROUGH IN TERMS OF A FINAL DECISION.

DR. DULIEGE: THANK YOU.

CHAIRMAN IMBASCIANI: BOARD MEMBER SACKEY.

DR. SACKEY: THANK YOU, MR. CHAIR. I HAVE A COUPLE OF COMMENTS AND QUESTIONS. SO FIRST ONE IS, FIRST OF ALL, I THINK THIS IS A WONDERFUL PRESENTATION OF SOMETHING THAT IS VERY MUCH NEEDED TO REALLY FULFILL THE OVERALL AIMS OF PUSHING ACCESS TO CLINICAL TRIALS INTO THE COMMUNITY.

GIVEN THE FACT THAT ENROLLMENT OF MEMBERS OF COMMUNITIES THAT ARE TYPICALLY NOT REPRESENTED IN CLINICAL TRIALS, IT'S SO CONNECTED WITH BUILDING TRUST WITH THE COMMUNITY. I WOULD HOPE THAT WE WOULD TAKE ADVANTAGE, CIRM WILL TAKE ADVANTAGE OF THIS TO HAVE SOME VISIBILITY INTO THE TEAM THAT IS ACTUALLY GOING TO BE PUT TOGETHER TO DO THAT OUTREACH BECAUSE WE KNOW THAT REPRESENTATION MATTERS. AND TO THE EXTENT THAT THE COMMUNITY WE ARE TRYING TO DO OUTREACH TO SEES ON THE TEAM MEMBERS THAT LOOK LIKE THEM, IT WOULD ENHANCE THE CHANCES THAT WE CAN INCREASE ENROLLMENT, NOT JUST THE REFERRAL RATE, BUT ACTUALLY SUCCESSFULLY ENROLLING PEOPLE IN CLINICAL TRIALS. THAT'S ONE COMMENT I THINK IT WOULD BE IMPORTANT TO SORT OF

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THINK OF EVEN HAVING A METRIC FOR THE LEVEL OF DIVERSITY OF THE WORKFORCE ITSELF.

MY SECOND COMMENT, AND I'M NOW GOING TO WEAR THE OTHER HAT AS SOMEBODY WHO'S BEEN AN ACADEMIC PHYSICIAN ALL MY PROFESSIONAL LIFE, I HAVE APPRECIATED VERY MUCH THE POWER OF HAVING COMMUNITY HEALTH WORKERS AND PATIENT NAVIGATORS, PARTICULARLY IN THE GLOBAL SETTING. THERE'S ACTUALLY MANY EXAMPLES OF EFFECTIVELY INCORPORATING COMMUNITY HEALTH WORKERS IN INTERNATIONAL SETTINGS TO REALLY HAVING A VERY SUCCESSFUL OUTCOME.

IT IS A CONCEPT THAT I THINK ACADEMIC MEDICAL CENTERS HAVE BEEN SLOW IN PICKING UP. SO I WANT TO MAKE SURE THAT THIS REQUIREMENT FOR HAVING NOT ONLY COMMUNITY WORKERS AND PATIENT NAVIGATOR TRAINING, BUT GOING TO THE NEXT LEVEL OF HAVING CERTIFICATION DOES NOT HAVE THE UNINTENDED CONSEQUENCES OF ACTUALLY DISADVANTAGING ACADEMIC MEDICAL CENTERS. I TOTALLY GET IF WE WANT TO TIP THE SCALE TOWARDS MAYBE COMMUNITY HOSPITALS AND CENTERS; BUT I WOULD HOPE THAT, SINCE WE ALSO WANT AN ORGANIZATION THAT HAS THE CAPACITY TO CONDUCT CLINICAL TRIALS AS WELL AS DO TRAINING, THAT WE WOULD NOT DISADVANTAGE ACADEMIC MEDICAL CENTERS.

PART OF THE LAST THING I'LL SAY THERE IS

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THAT THIS IS A CONVERSATION WE'RE ACTUALLY HAVING AT MY INSTITUTION. AND ONE POTENTIAL ROADBLOCK COULD BE SOME INSTITUTIONS HAVE HAD TO DEAL WITH STRIKES FROM NURSING COLLEAGUES. AND, IN GENERAL, I'M NOT PICKING -- I'M NOT ATTEMPTING TO PICK ON NURSES, BUT I THINK THAT COMMUNITY HEALTH WORKERS AND SOME OF THE FUNCTIONS THEY'VE CONDUCTED SOMEWHERE ELSE SOMETIMES CAN OVERLAP WITH SOME OF THE NURSING TASKS. AND THAT MAY THEN BECOME A PROBLEM FROM SOME AMS'S WHO ARE TRYING TO DO CERTIFICATION FOR THIS GROUP. JUST A COUPLE OF COMMENTS. OTHERWISE, EXCELLENT CONCEPT.

DR. LOMAX: TO YOUR FIRST POINT IN RELATION TO WHAT MAKES AN EFFECTIVE MESSENGER, THERE'S A PREPONDERANCE OF EVIDENCE THAT SUGGESTS -- TO REINFORCE WHAT YOU DESCRIBE. SO I THINK, AGAIN, THIS IS AN OPPORTUNITY TO USE THE QUEST FOR APPLICATION TO REALLY CITE THAT BODY OF EVIDENCE. AND THE APPLICANT THEN NEEDS TO SPEAK -- IF THEY DON'T ADDRESS -- IF THEY DON'T COME UP WITH AN APPROACH THAT IS CONSISTENT WITH THAT, THAT'S GOING TO POTENTIALLY RAISE QUESTIONS ABOUT HOW EFFECTIVE THIS PROGRAM CAN BE. SO WE HAVE TO BE EXPLICIT AT THE APPLICATION LEVEL OF REALLY LAYING OUT WHAT THE EVIDENCE IS AS WE KNOW IT. BUT I THINK THAT IS A

FAIRLY WELL -- THIS IS SOMETHING FROM THE NEEDS ASSESSMENT TO THE LITERATURE. SO I THINK IT'S A QUESTION OF GIVING VISIBILITY TO THAT IN THE APPLICATION, AND WE CAN DO THAT.

IN TERMS OF THAT WORK DYNAMIC, I THINK ONE OF THE BIGGEST CHALLENGES HERE IS ACTUALLY WE HAVE TO BE VERY CAREFUL ABOUT THE HANDOFF, IF YOU WILL, PASSING THE BATON FROM AN ENGAGEMENT OR EDUCATION OF AN INDIVIDUAL TO A CLINICAL PROTOCOL BECAUSE THAT'S A VERY IMPORTANT STEP. AND I THINK THAT'S WHERE THERE'S POTENTIALLY, I GUESS, FOR WANT OF A BETTER TERM, A KIND OF BUFFERING IF I UNDERSTOOD THE POINT CORRECTLY BECAUSE WE REALLY NEED -- ONCE YOU'RE IN THE CLINICAL PROTOCOL, THAT'S IN A VERY DEFINED SPACE AND THERE'S A SET OF PEOPLE. THAT'S PROBABLY NOT GOING TO BE THE COMMUNITY WORKER. IT MAY BE THE NAVIGATOR, BUT IT WON'T BE THE COMMUNITY HEALTH WORKER.

AGAIN, WHEN WE'RE ALLUDING TO TRAINING AND CERTIFICATION, IT'S AN APPRECIATION AND UNDERSTANDING OF THE INDIVIDUALS CONDUCTING THAT ACTIVITY AND WHERE THOSE LINES ARE, WHERE THOSE BOUNDARIES ARE, AND HOW WE HAVE BOUNDARY INTEGRITY. I HOPE THAT GETS AT IT. AT LEAST THAT'S THE HYPOTHESIS, BUT, AGAIN, SUBJECT TO TESTING.

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DR. SACKEY: I THINK YOU ARE GETTING TO IT EXACTLY. MY CAUTION IS THAT TO EXPECT THE APPLICANTS TO ALSO SATISFY COMMUNITY HEALTH WORKERS MAY REQUIRE SOME INTERNAL CONVERSATION ABOUT TURF WARS THAT --

DR. LOMAX: THERE'S EXISTING PROGRAMS. MY SENSE WOULD BE THAT THE KNOWLEDGE AND EXPERTISE OF OUR COLLECTIVE NETWORK, CLINICAL NETWORKS, COULD INFORM THE EXISTING CERTIFICATION PROGRAMS, THINGS LIKE A REGENERATIVE MEDICINE MODULE. AND THIS WOULD BE BEYOND CLINICAL TRIALS. THIS WOULD BE HERE'S WHAT SNAKE OIL IS. IF SOMEONE IS TELLING YOU ABOUT THIS, YOU COULD BE HARMED PHYSICALLY OR FINANCIALLY. SO IT'S A VERY BROAD SORT OF SET OF CONTENT AROUND REGENERATIVE MEDICINE THAT INFORMS THOSE ACTIVITIES. BUT I DON'T THINK -- AGAIN, WE IDENTIFIED PROGRAMS THAT ALREADY EXIST. WE'D LIKE TO BUILD INTO THOSE AND NOT CREATE DE NOVO PROGRAMS JUST BECAUSE OF OPPORTUNITY COSTS AND REDUNDANCY.

CHAIRMAN IMBASCIANI: PAT LEVITT IS NEXT THEN.

DR. LEVITT: FIRST, I JUST WANT TO CONGRATULATE YOU AND YOUR SCRAPPY TEAM BECAUSE YOU PUT IN A TON OF WORK. AND THE CONCEPT PLAN HAS GONE FROM, I THINK, FROM A DEVELOPMENTAL PERSPECTIVE

CRAWLING TO WALKING TO NOW RUNNING. SO IT'S REALLY FANTASTIC. YOU'VE INCORPORATED SO MANY RECOMMENDATIONS FROM THE VARIOUS GROUPS THAT YOU'VE ENGAGED WITH.

I DO WANT TO GET ONE THING TO BE MORE EXPLICIT ABOUT, AND WE'VE TALKED ABOUT THIS, THAT REFERRAL BIASES IN GENERAL FROM A GENERALIST TO A SPECIALIST ARE THE DATA ARE PRETTY GRIM IN TERMS OF UNDERREPRESENTED LATINO INDIGENOUS POPULATIONS, AFRICAN-AMERICANS, AND THE POOR. THOSE WHO ARE ON MEDICAID, THEIR REFERRAL RATES FOR JUST SPECIALIST CARE IS LOWER.

THIS PROGRAM IN THE END IS GOING TO DEPEND COMPLETELY ON THE START OF THE RACE WHICH IS REFERRAL. AND SO IN YOUR COMMUNITY ENGAGEMENT COMPONENT, I REALLY WOULD LIKE TO SEE A CALL-OUT THAT THE CCCE'S ARE IN A POSITION TO NOT ONLY ENGAGE WITH PATIENTS AND COMMUNITIES, BECAUSE THEY'RE NOT KNOCKING ON DOORS AND SAYING WOULD YOU LIKE TO JOIN A CLINICAL TRIAL. THEY'RE GOING TO BE DEPENDENT UPON COMMUNITY PHYSICIANS, HEALTHCARE PROVIDERS. AND THE ENGAGEMENT NEEDS TO BE WITH THEM JUST AS MUCH AS IT NEEDS TO BE WITH THOSE WHO MAY PARTICIPATE. SO I THINK IF YOU CALL THAT OUT, IT MEANS THAT THEY HAVE TO HAVE A PLAN WHICH MAY

ADDRESS THIS ISSUE ABOUT PROPOSED TARGETED INTERVENTIONS AIMED AT REDUCING DISPARITIES AND REFERRALS TO CLINICAL TRIALS. HAVE THE CONNECTION DIRECT. AND THEN THERE ARE METRICS THAT ONE CAN THEN USE TO DETERMINE WHETHER WHATEVER THEIR PLANS ARE ARE SUCCESSFUL OR NOT. BUT I THINK IF YOU CALL THAT COMPONENT OF THE OUTREACH OUT, I THINK YOU REALLY HAVE IT, AT LEAST IN TERMS OF WHAT YOU ARE ASKING THEM TO PROPOSE.

THE ISSUE AROUND SUSTAINABILITY IS A GIANT ONE WHICH WILL BE FOR ANOTHER CONVERSATION AT ANOTHER TIME, BUT THAT'S A BIG ISSUE.

DR. LOMAX: CAN I JUST MAKE ONE JUST TO BUILD ON THAT. THIS IS, AGAIN, WE REALLY LOOK FORWARD TO COMING BACK AND GETTING -- CONSULTING WITH BOARD MEMBERS. ONE GROUP I FAILED TO MENTION, BUT, AGAIN, THIS WAS IN THE CONVERSATION. WE DID MEET WITH PRIMARY CARE GROUPS, GROUPS THAT REPRESENT PRIMARY CARE PROVIDERS. WE DO HAVE TEAMS WITHIN THE ALPHA CLINICS THAT HAVE DEVELOPED LITERALLY POSTERS THAT GO INTO PRIMARY CARE. HAVE YOU CONSIDERED A CLINICAL TRIAL, THESE VERY SPECIFIC TYPES OF VISUAL THINGS TO PROMPT THAT CONNECTION. SO THAT IS AN AREA, I THINK, THAT PROBABLY WE WOULDN'T SAY EVERYONE HAS TO HAVE A PRIMARY CARE PROGRAM

NECESSARILY, BUT ADD THAT AS A GROUP, A COMMUNITY, IF YOU WILL, THAT IS IMPORTANT TO ENGAGE WITHIN THE CONTEXT OF THIS APPLICATION AND PUT THAT OUT THERE. AGAIN, IT'S THAT GRANTSMANSHIP OR APPLICATIONSHIP WHERE YOU SORT OF GIVE PEOPLE THINGS THAT WE THINK ARE GOING TO BE REALLY IMPORTANT TO MAKING THIS HAPPEN WITHOUT TELLING THEM THEY HAVE TO DO EVERYTHING BECAUSE IF THEY TRY TO BOIL THE OCEAN, THAT WON'T WORK EITHER. SO HOW DO WE GET IT RIGHT?

CHAIRMAN IMBASCIANI: THANK YOU, GEOFF. YSABEL.

MS. DURON: THANK YOU. I WANTED TO SORT OF PICK UP ON THE STATEMENT OF JOYCE. I THINK IT'S ALSO VERY IMPORTANT, GEOFF, TO ACTUALLY CLARIFY AMONGST YOURSELVES THE LANGUAGE BECAUSE WHEN YOU TALK ABOUT COMMUNITY HEALTH WORKERS, AKA PROMOTORES IN SPANISH, AND YOU TALK ABOUT PATIENT NAVIGATORS, TO THEM SOMETIMES THEY ARE ONE AND THE SAME. THEY ARE NOT DIFFERENT WITHIN COMMUNITIES BECAUSE THEY'RE HELPING PATIENTS, THEY'RE MOVING. AND THE SECOND THING YOU CAN TALK ABOUT THEM AS BEING BRIDGES, BRIDGES INTO SYSTEMS.

IT IS A DIFFICULTY SOMETIMES WITH THE PROFESSIONAL CLASS THAT THEY'RE NOT BEING DISPLACED. EVEN WHEN WE'RE TALKING ABOUT CERTIFICATION, IT'S

DIFFERENT TYPE OF LEVEL OF CERTIFICATION. SOME OF IT IS LEARNING THE LANGUAGE SO THAT YOU CAN TALK ACROSS THESE SYSTEMS, BUT SOME OF IT IS OTHER WAYS IN WHICH THEY MUST BE AND LEARN IN ORDER TO OCCUPY THAT COMMUNITY HEALTH WORKER SPACE. AND I SEE IN THE WORK WE'VE DONE THEY'RE VERY EAGER TO LEARN AND TO BE PART OF. THEY DON'T ASSUME THAT THEY'RE THE SOLUTION. THEY'RE PART OF THE TEAM. AND I THINK IT'S REALLY CRITICAL IN THAT LANGUAGE SPACE TO REMIND THE PROFESSIONAL CLASSES THAT THESE PEOPLE WILL BECOME A PART OF YOUR TEAM. THEY'RE NOT HERE TO TAKE OVER YOUR JOB OR EVEN ASSUME THAT THEY CAN.

SO WHAT WE HAVE SEEN WORK, AT LEAST IN THE PUBLIC HEALTHCARE SETTING, WITH THE CANCER CENTER WAS THAT WE PILOTED ONE COMMUNITY HEALTHCARE WORKER IN A CANCER CENTER IN A PUBLIC CARE SYSTEM. AND THE NURSES ALWAYS TURNED TO HER TO HELP THEM. SHE WAS WORKING STRICTLY WITH SPANISH SPEAKING. AND SHE'S NAVIGATED OVER TIME A THOUSAND SPANISH-SPEAKING PATIENTS. AND SHE BECAME INDISPENSABLE TO THE DOCTORS, THE CLINICIANS, AND THE NURSES.

BUT WHEN I ASKED THE PATIENT WHAT THE MOST IMPORTANT THING THIS WOMAN HAS DONE FOR YOU, THIS WAS A TERMINAL COLON CANCER PATIENT, SHE THOUGHT ABOUT IT AND SHE SAID, "SHE SPOKE MY LANGUAGE." SO

WE KNOW THAT LANGUAGE IS CRITICAL TO THIS BRIDGING.

AND I DON'T EVEN TALK ABOUT THE LANGUAGE OF SPANISH. I'M TALKING ABOUT SPEAKING SOMETHING I UNDERSTAND. WHAT THE HECK ARE YOU SAYING? WHAT ARE YOU TELLING ME? AND THAT IS WHY THAT COMMUNITY HEALTHCARE WORKER WHO COMES FROM THERE, UNDERSTANDS THE CULTURAL REFERENCES, CAN BE CREATING -- CAN BE THAT TRANSLATOR FOR THE DOCTOR WHO MAKES NO SENSE TO THEM OR WHO CAN'T TELL THEM WHAT THEY NEED TO KNOW.

SO I JUST THINK THERE ARE DIFFERENT INTERPRETATIONS, AND I THINK WE NEED TO BE VERY CLEAR ABOUT THOSE WHEN WE START ASKING FOR CERTIFICATIONS AND WE START NAMING TITLES AND SO ON AND SO FORTH. SO EVEN WHEN YOU'RE SPEAKING WITH THE APPLICANT, AND WE'LL GET THERE, THAT WE'RE CLEAR ON WHAT WE'RE TRYING TO SAY TO THEM. I SEE COMMUNITY HEALTH WORKERS AS BRIDGES BETWEEN SYSTEMS AND COMMUNITY.

CHAIRMAN IMBASCIANI: THANK YOU, YSABEL.

I WANT TO GO BACK TO ANNE-MARIE DULIEGE. YOU'RE STILL WITH US, RIGHT? YOU ASKED A THIRD QUESTION. I'M NOT SURE THAT GOT COMPLETELY ANSWERED, AND I DON'T WANT TO USURP THE PREROGATIVE OF SPEAKING FOR THE BOARD. SHE ASKED A QUESTION ABOUT INCREMENTALISM, WHETHER THIS CONCEPT SHOULD BE

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ABSORBED AS A PIG THROUGH A PYTHON OR WHETHER IT SHOULD BE BROUGHT BACK AT VARIOUS STAGES. AND GEOFF LOMAX IN HIS ANSWER TO ANNE-MARIE VERY CORRECTLY FOCUSED ON THAT PIE THAT'S CUT INTO FOUR PIECES WHERE THE ALPHA CLINICS ARE ONE PART OF THAT. AND BEING IN YEAR THREE OF A FIVE-YEAR, ACTUALLY YEAR EIGHT OF TEN YEARS OF SUPPORT, FIVE YEARS OF THE GRANT, THEY'RE A CRITICAL PART OF THE PUZZLE AND HOW WILL EVERYTHING ALIGN.

SO, ANNE-MARIE, MAYBE YOU WOULD LIKE TO ASK THAT QUESTION AGAIN, AND I'D INVITE BOARD COMMENT.

DR. DULIEGE: THANK YOU, VITO, BECAUSE I THOUGHT ABOUT HOW TO SIMPLIFY MY QUESTION. I TRUST THE CIRM TEAM. THEY HAVE ALWAYS DONE THE RIGHT THING IN TERMS OF STARTING A PROJECT AND THEN REPORTING REGULARLY TO THE BOARD BECAUSE THAT'S THEIR ROLE AND THEIR RESPONSIBILITY. SO I DON'T NEED TO FOCUS SO MUCH ON AMENDING THIS MOTION. BUT AS LONG AS, GEOFF, YOU AND THE CIRM TEAM HAVE A PLAN TO IMPLEMENT THAT IN A STEPWISE MANNER AND THAT, PARTICULARLY IN THE BEGINNING, YOU REPORT THAT TO THE BOARD SO THAT WE'RE REALLY CONVINCED, TOGETHER WITH YOU AND THE TEAM, THAT THIS IS MONEY WELL SPENT. IT'S A NEW EFFORT. THE FIRST CAREFUL STEP

MIGHT BE USEFUL. THAT'S ALL I'M SAYING.

CHAIRMAN IMBASCIANI: THANK YOU. ELENA.

DR. FLOWERS: THIS WOULD BE TAKING US IN A DIFFERENT DIRECTION IN CASE THERE'S FOLLOW-UP.

VICE CHAIR BONNEVILLE: JUST AS A REMINDER, WHEN WE DID THE FIRST ALPHA CLINICS AWARDS, IT WAS TO FUND UP TO FIVE AWARDS AT 55 MILLION. WE FUNDED THREE BECAUSE NOT ALL GOT RECOMMENDED FOR FUNDING. SO IT'S UNLIKELY THAT ALL THE AWARDS THAT COME IN FOR THIS PROGRAM WOULD BE RECOMMENDED FOR FUNDING, ALTHOUGH YOU NEVER KNOW. AND THE TEAM DID SORT OF SCAN THE LANDSCAPE OF WHO WOULD BE ELIGIBLE TO APPLY UNDER EACH CATEGORY AND SORT OF DEVELOPED IT FROM THERE UNDERSTANDING THAT THE UNIVERSE IS FAIRLY SMALL AT THIS MOMENT.

SO I THINK JUST BY THE NATURE OF THAT, IT WILL BE A LIMITED PROGRAM. WE'VE ALSO TALKED INTERNALLY A LOT ABOUT MAKING SURE THAT THE RFA IS FLEXIBLE ENOUGH THAT WE CAN PIVOT AT ANY POINT IF SOMETHING IS NOT WORKING AND LOOKS LIKE SOMETHING ELSE COULD WORK AND THAT VERY CLOSE MANAGEMENT OF THESE GRANTEES WILL BE NECESSARY IN ORDER TO BE ABLE TO MAKE IT A VERY SUCCESSFUL PROGRAM.

DR. DULIEGE: THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU. ANY

OTHER COMMENT ON THAT QUESTION?

DR. FLOWERS: WELL, THAT ACTUALLY -- THANK YOU. MARIA SAID IT WELL TO MY COMMENTS, WHICH ARE THAT I THINK -- WELL, THE POINTS ARE VERY WELL TAKEN ABOUT SORT OF THE SPECIFIES AROUND PROMOTORES VERSUS IMPRIMERES AND THE STRUCTURES OF THESE PROGRAMS AND THAT WE WANT TO MAKE SURE THAT THERE'S FIDELITY TO OUR ULTIMATE GOALS. I THINK THAT WE CAN ALSO TRUST THE GRANTS WORKING GROUP PROCESS A LITTLE BIT IN THAT A LOT OF THIS WILL GET FLESHED OUT IN THE REVIEW. I WANT TO CAUTION US TO NOT TAKE QUITE SUCH A TOP-DOWN, ONE SIZE FITS ALL APPROACH TO HOW THIS WILL LOOK IN DIFFERENT COMMUNITY SETTINGS. I THINK THAT'S ACTUALLY KIND OF IN OPPOSITION WITH WHAT OUR GOALS ARE TO REALLY BE EMBEDDED IN THE ACTUAL COMMUNITIES AND ADDRESSING THEIR NEEDS.

SO I THINK I'M MORE IN FAVOR OF NOT KIND OF BEING QUITE SO DRILLED DOWN AT THIS CONCEPT POINT AND, AGAIN, LIKE REALLY TRUSTING IN OUR GRANT AND PEER REVIEW PROCESS FOR THE APPLICATIONS.

DR. LOMAX: AGAIN, JUST TO EMPHASIZE SOMETHING I HOPE CAME OUT DURING THE CONVERSATION. THE EVOLUTION OF THIS SORT OF TWO DIFFERENT APPLICANT OPPORTUNITIES FROM THE CLINICAL SIDE REALLY REFLECTS THE HETEROGENEITY I THINK YOU'RE

ALLUDING TO. THAT'S WHY YOU DO NEEDS ASSESSMENTS. THE QUOTE THAT REALLY STOOD OUT TO ME, A SITE, A GROUP THAT WOULD WILL LOVE TO COME IN, PROBABLY HAS AN AMAZING POTENTIAL TO SERVE THIS COMMUNITY, SAID, WE'RE NEVER GOING TO GET TO THAT STAGE, AND THEY WERE POINTING TO A FULL-BLOWN ALPHA CLINIC. THANK YOU.

CHAIRMAN IMBASCIANI: OKAY. I DON'T SEE ANY OTHER HANDS FROM COMMENTS FROM BOARD MEMBERS. SO ARE THERE MEMBERS OF THE PUBLIC THAT WOULD LIKE TO COMMENT ON THE MOTION? I'M LOOKING AT THE BACK TABLE. THERE ARE NONE. ALL RIGHT. MR. TOCHER, I THINK WE'RE GOOD TO GO FOR A VOTE.

MR. TOCHER: FOR ALL THOSE IN THE ROOM IN FAVOR SAY AYE. ANY OPPOSED? ANY ABSTENTIONS? AND I'LL POLL THE MEMBERS ON THE PHONE.

MOHAMED ABOUSALEM.

DR. ABOUSALEM: YES.

MR. TOCHER: DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: GEORGE BLUMENTHAL. MICHAEL BOTCHAN. LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: AYE.

MR. TOCHER: HAL COLLARD.

DR. COLLARD: YES.

MR. TOCHER: MONICA CARSON.
DR. CARSON: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: YES.
MR. TOCHER: CHRIS MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA. JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: MARV SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: SUZANNE SANDMEYER.
DR. SANDMEYER: I THINK DEAN STAMOS MAY BE VOTING. I WILL VOTE YES IF HE'S NOT PRESENT.
MR. TOCHER: MICHAEL STAMOS, ARE YOU ON?
SUZANNE, WE'RE CONFIRMED IT'S YOU.
DR. SANDMEYER: YES.
MR. TOCHER: THANK YOU. GREAT. THANKS VERY MUCH. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANK YOU SO MUCH. OKAY. GREAT.

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DR. LOMAX: CHAIRMAN IMBASCIANI, CAN I JUST ASK EMILY REYES TO STAND UP FOR A MOMENT PLEASE?

CHAIRMAN IMBASCIANI: OF COURSE.

DR. LOMAX: EMILY REALLY DROVE THE NEEDS ASSESSMENT AND IS GOING TO BE A PART OF THE CORE TEAM. WE DON'T GET A LOT OF CAREER OPPORTUNITIES IN OUR LIFETIME, AND THIS IS ONE OF THEM. SO THANK YOU FOR THAT. AND THANKS TO EMILY FOR HER WORK.

(APPLAUSE.)

CHAIRMAN IMBASCIANI: WELL DESERVED. THANK YOU, GEOFF, FOR A GREAT PRESENTATION.

WE NOW ENTER THE FINAL PHASE OF THE MEETING, WHICH IS WHERE WE OPEN UP TO PUBLIC COMMENT. I'D LIKE TO DIVIDE PUBLIC COMMENT FIRST INTO COMMENTS ON ITEMS THAT WERE PART OF TODAY'S AGENDA, INCLUDING ANY OF THE APPLICATIONS. AND IF THERE ARE NONE, I'LL OPEN THE FLOOR TO COMMENTS FROM THE PUBLIC ON ANY SUBJECT MATTER THAT WAS NOT ON TODAY'S AGENDA. IF NOT, OKAY. SCOTT, COULD YOU TELL US WHEN THE NEXT BOARD MEETING IS?

MR. TOCHER: WELL, WE'RE LOOKING TO SCHEDULE ONE CONCURRENT WITH THE EXISTING FEBRUARY 22D ARS MEETING. SO I BELIEVE WE'RE IN THE MIDST OF POLLING FOR THAT. SO IF YOU HAVEN'T HAD A CHANCE

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YET TO REPLY TO CLAUDETTE, I'M SURE SHE WOULD LOOK FORWARD TO THAT REPLY. WE'RE REALLY HOPEFUL TO GET SOME IMPORTANT BUSINESS DONE THAT DAY.

CHAIRMAN IMBASCIANI: THANK YOU FOR THAT. IN THAT CASE, THANK YOU, BOARD MEMBERS FOR YOUR ATTENTION, YOUR PRESENCE TODAY. THE MEETING IS ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 2 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 ON JANUARY 25, 2024, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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