BEFORE THE

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

REGULAR MEETING

LOCATION: 685 GATEWAY BLVD.
PRESENTATION ROOM
SOUTH SAN FRANCISCO, CA

DATE: JUNE 29, 2023
9 A.M.

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

FILE NO.: 2023-23

I N D E X

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I N D E X (CONT'D.)

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JUNE 29, 2023; 9 A.M.

CHAIRMAN IMBASCIANI: GOOD MORNING, EVERYONE. THIS IS DR. VITO IMBASCIANI, THE CHAIR OF THE ICOC OF CIRM, AND I'M DELIGHTED TO WELCOME EVERYONE IN THE ROOM, MEMBERS OF THE BOARD, MEMBERS OF THE STAFF, AND MEMBERS OF THE PUBLIC THAT ARE ATTENDING THIS JUNE 29TH MEETING OF THE CIRM'S BOARD. AND I'D ALSO LIKE TO WELCOME ANYONE WHO IS ATTENDING THIS MEETING ON THE TELEPHONE OR BY OTHER ELECTRONIC MEANS.

AND BEFORE WE START, I'M GOING TO ASK MR. SCOTT TOCHER TO LEAD US IN THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. IF YOU WOULD CONTINUE IN YOUR OFFICIAL CAPACITY AND CALL THE ROLL.

MR. TOCHER: HAIFAA ABDULHAQ. MOHAMED ABOUSALEM.

DR. ABOUSALEM: PRESENT.

MR. TOCHER: DAN BERNAL.

MR. BERNAL: PRESENT.

MR. TOCHER: KIM BARRETT.

DR. BARRETT: PRESENT.

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MR. TOCHER: GEORGE BLUMENTHAL.
DR. BLUMENTHAL: PRESENT.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: PRESENT.
MR. TOCHER: MICHAEL BOTCHAN. LINDA BOXER.
DR. BOXER: PRESENT.
MR. TOCHER: JUDY CHOU.
DR. CHOU: PRESENT.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: PRESENT.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: PRESENT.
MR. TOCHER: YSABEL DURON.
MS. DURON: PRESENT.
MR. TOCHER: MARK FISCHER-COLBRIE. FRED FISHER.
DR. FISHER: PRESENT.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MR. TOCHER: JUDY GASSON.
DR. GASSON: PRESENT.
MR. TOCHER: LARRY GOLDSTEIN. DAVID HIGGINS.
DR. HIGGINS: PRESENT.

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MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: PRESENT.
MR. TOCHER: STEPHEN JUELSGAARD.
MR. JUELSGAARD: PRESENT.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: PRESENT.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: PRESENT.
MR. TOCHER: DAVID LO.
DR. LO: PRESENT.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: PRESENT.
MR. TOCHER: SHLOMO MELMED.
DR. MELMED: PRESENT.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: PRESENT.
MR. TOCHER: LAUREN MILLER-ROGEN. ADRIANA PADILLA.
DR. PADILLA: PRESENT.
MR. TOCHER: JOE PANETTA. MARV SOUTHARD.
DR. SOUTHARD: PRESENT.
MR. TOCHER: MICHAEL STAMOS.
DR. STAMOS: PRESENT.
MR. TOCHER: KAROL WATSON. KEVIN XU. KEITH YAMAMOTO.

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DR. YAMAMOTO: PRESENT.

MR. TOCHER: THANK YOU. WE HAVE A QUORUM.

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DR. ABDULHAQ: SCOTT, THIS IS HAIFAA. I'M PRESENT.

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT.

I'D LIKE TO CONTINUE WITH A VERY SHORT REPORT FROM THE CHAIR. THIS BEING THE FIRST OFFICIAL MEETING, I'D LIKE TO THANK THE CIRM STAFF PARTICULARLY FOR THE VERY, VERY WARM AND ACCOMMODATING WELCOME THEY'VE GIVEN TO YOUR NEW CHAIR.

AND SINCE I'VE TAKEN OVER IN VERY, VERY LATE MARCH, I HAVE BEEN VERY ASSIDUOUSLY GETTING TO KNOW THE BREADTH OF CIRM'S PRESENCE ON THE CELL AND GENE THERAPY STAGE; TO WIT, I HAVE BEEN NOW TO VISIT SIX OF OUR NINE ALPHA CLINICS. I'VE BEEN TO UC DAVIS, UCSF, THE CHILDREN'S HOSPITAL IN OAKLAND, UCSD AND WITH A SIDE TRIP TO THE SANFORD CONSORTIUM, THE CITY OF HOPE, AND UCLA.

THE STAFF OF EACH OF THESE ALPHA CLINICS HAS BEEN EXTRAORDINARY IN THEIR WELCOME OF THE CONTINGENT THAT I BROUGHT WITH ME. AND I WANT TO THANK GEOFF LOMAX AND OTHERS ON HIS TEAM FOR FACILITATING THAT. IT'S NO EASY MATTER. WE WERE QUITE A PERTURBATION IN THE DAILY ACTIVITIES OF ALL THESE CENTERS, BUT THEY CAME OUT IN GREAT NUMBERS, THEY WELCOMED US, THEY TOURED US AROUND. THEY

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ADVISED US AT A VERY HIGH LEVEL OF THE SCIENTIFIC ENDEAVORS THAT THEY WERE ENGAGED IN. AND IT WAS REALLY A VERY, VERY WONDERFUL THING, I THINK, FOR CIRM TO DO TO SHOW OUR PRESENCE ON ALL OF THESE CAMPUSES AND TO LEARN WHAT THEY'RE ABOUT. AND I THINK THE BENEFIT WAS MUTUAL.

AND I HAVE TO TELL YOU THAT NOT JUST IN CALIFORNIA, BUT IN ALL THE OTHER PLACES I'VE BEEN, OF WHICH I'LL NAME A FEW IN A SECOND, THE PERCEPTION OF CIRM'S PRESENCE AND ITS ACCOMPLISHMENT OVER THE LAST NINETEEN IS REALLY EXTRAORDINARY. PEOPLE ALL OVER THIS COUNTRY, I'VE TOURED YALE'S LABS AND OTHER PEOPLE AND I'VE BEEN TO A NUMBER OF THE NATIONAL MEETINGS, WHERE THE RECOGNITION OF WHAT CIRM HAS CREATED AND CONTINUES TO SUPPORT LEAVES PEOPLE BREATHLESS. I DON'T USE THE ADJECTIVE VERY LIGHTLY. WE ARE THE ENVY OF THE WORLD, WHAT HAS BEEN CREATED BY THE PEOPLE ON THIS BOARD AND IN THIS ROOM AND OTHER PEOPLE WHO HAVE SERVED WHO ARE NO LONGER ON THE BOARD. SO CONGRATULATIONS TO YOU ALL.

JUNE WAS EXTRAORDINARILY RICH IN THE NUMBER OF LARGE MEETINGS OF THE RESEARCH AND THERAPEUTIC COMMUNITIES. IT STARTED ABOUT A MONTH AGO WITH THE ASGCT MEETING AT THE CONVENTION CENTER IN LOS ANGELES. THOUSANDS OF PEOPLE FROM ALL OVER

THE WORLD COMING TO GIVE REPORTS ON THEIR SCIENTIFIC INQUIRY AND TO MAKE CONNECTIONS. FOLLOWED BY LABEST, AN EXTRAORDINARILY WELL RUN, BEAUTIFUL MEETING ON THE CAMPUS OF UCLA. AND THEN THE SPRAWLING MEETING IN BOSTON OF THE INTERNATIONAL STEM CELL RESEARCH ORGANIZATION HOSTED BY THE PRESIDENT, HAIFAN LIN, AT WHICH, BY THE WAY, YOUNG ROBERT KLEIN JR. WAS PUBLICLY AWARDED A COMMENDATION FOR HIS WORK IN HEADING UP THE CAMPAIGN THAT RESULTED IN THE SUCCESSFUL PASSAGE OF PROP 14. IT WAS A WELL-DESERVED HONOR, AND IT WAS THE ONLY ONE SUCH HONOR AT THAT MEETING AT THE PRESIDENT'S RECEPTION. AND ROBERT WAS THERE WITH HIS FAMILY TO RECEIVE THAT AWARD.

AND FINALLY, A VERY INTERESTING, VERY EXCITING MEETING FOR A NUMBER OF DAYS UP AT LAKE ARROWHEAD IN SOUTHERN CALIFORNIA, WHICH CALLED ITSELF THE FIRST ANNUAL SOUTHERN CALIFORNIA REGENERATIVE MEDICINE SYMPOSIUM, WHICH BROUGHT TOGETHER ALL OF THE ENTITIES IN SOUTHERN CALIFORNIA, EXPANDED TO INCLUDE PLACES THAT DON'T HAVE MEDICAL SCHOOLS, SUCH AS UC SANTA BARBARA AND CALTECH. AND THEY REPORTED ON ALL THE VIBRANT RESEARCH THAT WAS GOING ON IN THEIR CENTERS.

AND THEN FINALLY, I MET WITH THE

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PRESIDENT, OUR CEO, MARIA MILLAN, AND HER ENTIRE LEADERSHIP TEAM INDIVIDUALLY AND THEN SAT IN ON THEIR MEETINGS OF THEIR WHOLE TEAMS, TO MEET THEM ALL, FIND OUT A LITTLE BIT MORE ABOUT WHAT THEY DO SO I CAN BE A BETTER COMMUNICATOR TO THE PEOPLE OF CALIFORNIA OF WHAT WE ARE AND WHAT WE ARE ABOUT.

SO IT'S BEEN A VERY, VERY BUSY MONTH. I'VE STILL GOT A FEW MORE SITES TO VISIT. I THINK THERE ARE A NUMBER OF PEOPLE IN THIS ROOM, I THINK, THAT ARE NEXT ON THE LIST.

I WOULD LIKE NEXT TO TELL YOU -- HE'S NOT HERE -- WE HAVE A NEW BOARD MEMBER. HIS NAME IS KEVIN XU. LAST NAME IS SPELLED X-U. HE WAS NOMINATED BY THE SPEAKER OF THE CALIFORNIA ASSEMBLY. AND I'LL TELL YOU SOMETHING ABOUT HIM. HE'S GOING TO JOIN US FOR THE FIRST TIME IN OUR SEPTEMBER BOARD MEETING. HE RECEIVED A BACHELOR OF ARTS IN NEUROSCIENCE IN 2011 FROM THE UNIVERSITY OF SOUTHERN CALIFORNIA. HE'S VERY, VERY INVOLVED IN A NUMBER OF NATIONAL AND INTERNATIONAL BOARDS. I'LL JUST NAME A FEW OF THEM.

HE WAS APPOINTED FIRST TO SERVE BY CALIFORNIA GOVERNOR JERRY BROWN TO THE CALIFORNIA CHINA TRADE AND INVESTMENT ADVISORY GROUP. HE'S A MEMBER OF THE LOS ANGELES COUNTY MEDICAL HEALTH

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COMMISSION, AND I THINK THAT THAT'S WHAT -- IT'S THAT CREDENTIAL THAT CAUGHT THE SPEAKER'S ATTENTION IN APPOINTING HIM TO BE THE PATIENT ADVOCATE TO THE MENTAL HEALTH COMMUNITY. WE SHOULD KNOW THAT. HE'S INVOLVED IN THE CLINTON GLOBAL INITIATIVE. I'M ONLY GIVING YOU A VERY HIGHLY SELECT RENDERING OF HIS CV. HE'S THE DIRECTOR IN BEIJING OF THE, AND I THINK THIS IS -- WHAT'S THE WORD? -- EPONYMOUS WHEN THE INSTITUTE IS NAMED AFTER YOURSELF, THE RONGXIANG REGENERATIVE MEDICINE LABORATORY, WHICH IS UNDER THE UNITED NATIONS ACADEMIC IMPACT PROGRAM. PRESIDENT OF THE INTERNATIONAL SOCIETY OF REGENERATIVE MEDICINE AND WOUND REPAIR.

HE'S ALSO ON MANY ADVISORY BOARDS, INCLUDING THE RONGXIANG XU CENTER FOR REGENERATIVE THERAPEUTICS AT BETH ISRAEL AT HARVARD, CALIFORNIA INSTITUTE OF TECHNOLOGY NEURO TECHNOLOGY CENTER, CALIFORNIA STATE UNIVERSITY LOS ANGELES, THE PRESIDENTIAL COUNCIL, THE HARRIS SCHOOL OF PUBLIC POLICY AT THE UNIVERSITY OF CHICAGO, AND THE KEVIN XU INITIATIVE AT THE ROSE TRUST OF OXFORD UNIVERSITY.

IN 2014 HE RECEIVED AN IMPACT 100 RECOGNITION AT THE UNITED NATIONS AND A FEW YEARS AGO WAS AWARDED USC'S YOUNG ALUMNI MERIT AWARD. SO

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A VERY ACCOMPLISHED YOUNG ADDITION DO THIS BOARD OF DIRECTORS. WE'LL MEET HIM IN PERSON IN SEPTEMBER.

THIRD OF MY FOUR POINTS, I VERY CAREFULLY LISTENED TO A NUMBER OF THE COMMENTS MADE OVER THE LAST THREE BOARD MEETINGS BY MEMBERS OF THE BOARD. THESE ARE QUESTIONS THAT AROSE ABOUT OUR BUDGETING PROCESS AND HOW IT SUPPORTS, HIGHLIGHTS, AND SELECTS, IF YOU WILL, AREAS OF SCIENTIFIC FOCUS. THAT'S A FANCY WAY OF SAYING HOW DO WE PRIORITIZE APPLICATIONS THAT ARE WORTHY OF SUPPORT HERE AT THE BOARD. HOW DO WE PRIORITIZE, SHOULD WE PRIORITIZE ONE AREA OF INQUIRY OVER ANOTHER? HOW DO WE IMPLEMENT THE MANDATE OF PROP 14, SPECIFICALLY THE $1.5 MILLION THAT ARE EARMARKED, IF YOU WILL, FOR NEUROSCIENCE?

THE NEURO TASK FORCE OF THIS BOARD IS PRESENTLY INVOLVED IN EXACTLY THAT ACTIVITY, A VERY PRECISE AND DEEP ANALYSIS THAT IS ESSENTIALLY AN EXERCISE IN PRIORITIZATION. AND THEY WILL BE REPORTING ON THAT AT TODAY'S MEETING. I AM GOING TO SHORTLY WHEN I'M DONE TURN OVER TO PRESIDENT MILLAN WHO IS GOING TO ELABORATE ON THIS VERY TOPIC IN HER REPORT. AND I AM TAKING THE PREROGATIVE OF ASKING THE SCIENCE SUBCOMMITTEE TO FORMALLY TAKE UP THIS ISSUE OF PRIORITIZATION BASED ON COMMENTS MADE BY

MANY OF THE MEMBERS OF THIS BOARD, TAKE IT UP AND AT THEIR OWN PACE STUDY IT AND PLEASE REPORT BACK.

AND FINALLY, IN ADVANCE -- WE ARE IN OUR 19TH YEAR AT CIRM. IN LIGHT OF THE ADVANCES MADE IN BASIC SCIENCE AND CLINICAL MEDICINE, I HAVE A THOUGHT, THAT IT IS NOW AN OPPORTUNE TIME TO CONSIDER EXPANDING OUR GOVERNMENT RELATIONS ACTIVITY, WHICH AT PRESENT ARE LIMITED TO SACRAMENTO, SPEARHEADED BY, AS IT HAS BEEN FOR YEARS, BY OUR NOW FORMER VICE CHAIR ART TORRES. I'M THINKING WE WOULD PROFIT FROM HAVING A WORKING RELATIONSHIP IN THE WASHINGTON, D.C. AREA WITH CLOSER PROXIMITY TO THE WORK OF CONGRESS AS WELL AS THE FEDERAL AGENCIES, INCLUDING THE FDA AND THE NIH.

IN TOURING AROUND THE STATE AS PART OF ALL THE ACTIVITIES I'VE MENTIONED EARLY ON, I'VE IDENTIFIED AT ALMOST EVERY CENTER A GOOD NUMBER OF INTERESTED AND ENGAGED STAKEHOLDERS WITH EXPERTISE IN THIS AREA WHO MIGHT LIKE TO CONTRIBUTE TO THAT EFFORT AND WHO CONCUR IN THIS IDEA THAT THE TIME IS RIGHT TO HAVE A MORE ACTIVE INVOLVEMENT IN GOVERNMENT RELATIONS.

SO I'LL LEAVE IT AT THAT. THANK YOU VERY MUCH. AND I'M GOING TO PASS THE GAVEL TO PRESIDENT MILLAN.

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MS. DURON: MR. CHAIR.

CHAIRMAN IMBASCIANI: YSABEL, SORRY.

MS. DURON: WHILE SHE APPROACHES THE BENCH, I WOULD LIKE TO ACKNOWLEDGE THE WELCOMING OF MR. XU, BUT AT THE SAME TIME WOULD LIKE TO SAY THANK YOU VERY MUCH FOR THE SERVICE OF AL ROWLETT, WHO HAS BEEN A CALM, SMART, AND ENGAGED PRESENCE FOR 11 YEARS. AND I'M GOING TO MISS HIM DEARLY AS I THINK A LOT OF US WILL, AND I THINK I WOULD LIKE HIM TO KNOW THAT WE APPRECIATED HIS SERVICE. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU.

(APPLAUSE.)

CHAIRMAN IMBASCIANI: YSABEL, WE DID REACH OUT TO AL. WE WOULD LIKE TO HAVE MORE FORMALLY HONORED HIM AT THIS PARTICULAR BOARD MEETING. HE'S ASKED THAT WE HOLD OFF ON THAT FOR A LITTLE WHILE. SO IT WILL COME UP AT ANOTHER MEETING. THANK YOU VERY MUCH.

DR. MILLAN: THANK YOU SO MUCH. MAY I PLEASE HAVE MY SLIDES OR DO I JUST CLICK? PERFECT.

THANK YOU, CHAIR IMBASCIANI, MEMBERS OF THE BOARD, MEMBERS OF THE PUBLIC, AND DEAR COLLEAGUES. TODAY I'LL BE PROVIDING A YEAR-ONE UPDATE ON CIRM'S FIVE-YEAR STRATEGIC PLAN THAT WAS LAUNCHED SHORTLY AFTER THE PASSAGE OF PROPOSITION

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14. AS A REMINDER AND A VERY IMPORTANT REMINDER, CIRM'S MISSION IS TO ACCELERATE WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD. THIS REMAINS OUR NORTH STAR, AND EVERYTHING WE DO REALLY LEVERAGES ON THIS MISSION.

SINCE ITS FORMATION, CIRM HAS BEEN AT THE LEADING EDGE OF CREATING A WHOLE NEW FIELD IN REGENERATIVE MEDICINE. AND THIS FIELD IS NOW COMING OF AGE. THERE ARE MORE AND MORE PROGRAMS MAKING IT TO THE CLINICS. THERE ARE NOW THOUSANDS OF CLINICAL TRIALS WORLDWIDE. MOST OF THEM ARE STILL IN EARLY STAGES AS THEY ARE IN CIRM'S PORTFOLIO WHERE WE FUNDED 91 CLINICAL TRIALS, 58 OF THEM STILL ACTIVE. THE MAJORITY ARE STILL IN EARLY DEVELOPMENT PHASE 1 AND PHASE 2. HOWEVER, OVER THE PAST SEVERAL YEARS, WE HAVE SEEN AN INCREASE IN PROGRAMS THAT HAVE MADE IT ALL THE WAY TO FDA APPROVAL TO MAKE IT TO THE MARKETPLACE. AND TO DATE 29 CELL AND GENE THERAPIES, ACTUALLY 30 AS OF LAST WEEK, HAVE BEEN APPROVED BY THE FDA. I'LL GO INTO THAT IN A LITTLE BIT.

AS SHOWN IN THAT PIE CHART THAT REPRESENTS WHAT THE FIELD LOOKED LIKE IN 2022, JUST A YEAR AGO,

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CELL AND GENE THERAPY DOES STILL COMPOSE A SMALL PROPORTION OF BIOLOGICS THAT HAVE BEEN APPROVED BY THE FDA. SO IT IS STILL A VERY EARLY FIELD. TODAY I'D LIKE TO GIVE A STATUS UPDATE ON WHERE WE ARE IN THE FIELD, THE CHALLENGES THAT ARE BEFORE US, AND WHAT CIRM IS DOING TO ADDRESS THOSE CHALLENGES IN ITS MISSION.

SO TO SPEAK TO RECENT ANNOUNCEMENTS, LAST WEEK SAREPTA, WHICH IS A GENE THERAPY FOR DUCHENNE MUSCULAR DYSTROPHY, WAS THE FIRST GENE THERAPY THAT WAS APPROVED BY THE FDA. WHAT'S REMARKABLE ABOUT THIS EVENT IS THAT PETER MARKS, WHO IS THE HEAD OF THE DIVISION, CBER, THE BIOLOGIC DIVISION, OVERTURNED HIS OWN REVIEWERS' RECOMMENDATION NOT TO APPROVE THIS. WHY IS THIS SIGNIFICANT? HE SIDED WITH THE ADVISORY COUNCIL, WHICH LOOKED AT THE DATA MUCH MORE CLOSELY AND TOOK INTO ACCOUNT THE NATURE OF THIS DISEASE. IT AFFLICTS THE YOUNG. IT IS DEVASTATING. THERE IS NO TREATMENT.

SO THEY LOOKED AT THE DATA DESPITE THE FACT THAT THE STUDY INITIAL DESIGNED ENDPOINTS WERE NOT MET AND LOOKED AT THE POST HOC ANALYSIS AND SAW THAT IN FOUR- AND FIVE-YEAR-OLDS THERE WAS AN EFFICACY SIGNAL THAT MATCHED BIOLOGICAL SURROGATES OR ACTUALLY NOT EVEN SURROGATES, REAL MARKERS. IN

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GENE THERAPY THERE IS THE ENCODING OF A PROTEIN THAT HELPS TO REVERSE THIS DISEASE. AND THEY COULD SEE THAT THE EXPRESSION OF THIS PROTEIN CORRELATED WITH IMPROVEMENT AND FUNCTION IN THE HEALTH OF THESE FOUR- AND FIVE-YEAR-OLDS.

SO BECAUSE THIS WAS UNDER ACCELERATED PATHWAY DESIGNATION, DR. MARKS HAD MOVED FORWARD WITH THE APPROVAL OF THIS THERAPY WITH THE PROVISION THAT THERE WOULD BE POST-APPROVAL CONFIRMATORY STUDIES. SO THIS IS CALLED THE ACCELERATED PATHWAY. JUST TO REMIND YOU, DR. ABLA CREASEY, THE HEAD OF THE THERAPEUTICS PROGRAM, HAD UPDATED THE BOARD THAT 11 OF OUR PROGRAMS HAVE EXPEDITED PATHWAY DESIGNATIONS THAT WOULD FOLLOW THIS TYPE OF PARADIGM.

SO WE KNOW THAT THE REGULATORY PARADIGM IS SHIFTING. SO THE PIPELINE IS GROWING. WE ARE SEEING INNOVATION IN THE REGULATORY ARENA. THIS IS GREAT. FURTHERMORE, OUR PROGRAMS CONTINUE TO MAKE PROGRESS. FOR INSTANCE, ONE OF OUR PROGRAMS, WHICH WAS A SPINOUT OF UCSF, WHICH IS A PLURIPOTENT STEM CELL-DERIVED NEURAL PRODUCT THAT'S BEEN USED TO TREAT INTRACTABLE FOCAL EPILEPSY THAT IS NOT AT ALL RESPONSIVE TO ANY MEDICATION. IT'S BEING CARRIED OUT BY NEURONA, WHICH IS A SPINOUT OF THE UCSF

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PROGRAM FUNDED BY CIRM. WE FUNDED IT AND SUPPORTED IT THROUGH EARLY STAGES AND TRANSLATION. IT'S NOW IN CLINICAL TRIALS. AND THAT THEY JUST REPORTED AT THE INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH A COUPLE OF WEEKS AGO IN BOSTON A ONE-YEAR FOLLOW-UP ON ONE OF THEIR PATIENTS, AND THERE'S MORE COMING THROUGH, WHERE THERE WAS A 90-PERCENT REDUCTION IN SEIZURE ACTIVITY AND ALL OF THE KIND OF ASSOCIATED STUDIES TO GO WITH THIS.

THIS IS JUST THE START. AND WITH CELL THERAPIES, WHICH IS CELL AND GENE THERAPIES, THAT IS WHAT DISTINGUISHES IT FROM TRADITIONAL DRUG DEVELOPMENT. THERE'S EARLY SIGNALS, SMALL STUDIES, EFFECT SIZES LARGE, THE IMPACT IS HUGE, AND IT'S ONE-TIME TREATMENT. JUST BEAR THAT IN MIND. IT'S A COMPLETELY DIFFERENT MODEL THAN WHAT IS OUT THERE FOR TRADITIONAL EVEN BIOLOGICS.

SO WITH THAT, WE OURSELVES HAVE BUILT A VERY ROBUST PORTFOLIO AND PIPELINE. DR. IMBASCIANI, CHAIR IMBASCIANI, HAD REFERRED TO THE BOARD'S DISCUSSION OF POTENTIAL PRIORITIZATION WITHIN THIS BROAD PORTFOLIO. SO IT'S A VERY IMPORTANT TOPIC GIVEN THAT THERE IS A MASSIVE INCREASE IN THE TYPES OF PROGRAMS COMING THROUGH OUR PROGRAMS. BUT THE SNAPSHOT OF WHERE WE ARE TODAY, THE CUMULATIVE

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PROGRAMS THAT HAVE RESULTED FROM OUR GRANTMAKING PROCESS IS THAT BETWEEN 30 AND 35 PERCENT ARE IN THE NEURO FIELD IN GENERAL. YOU'LL HEAR A MUCH MORE PRECISE ANALYSIS OF THIS IN UPCOMING MEETINGS AS LED BY THE NEURO TASK FORCE AND DR. ROSA AVILES, WHO'S OUR VP OF SCIENTIFIC PROGRAMS. BUT ABOUT 10 PERCENT IN CARDIAC, 18 PERCENT IN MALIGNANCIES, 10 PERCENT IN MUSCULOSKELETAL, AND QUITE A BIT IN OTHER DISEASES WITH LARGE TARGETS SUCH AS DIABETES.

AND THIS IS DONE THROUGH A PREDICTABLE AND RECURRING PROGRAM ANNOUNCEMENT, PROGRAM OPPORTUNITIES, WHICH DR. GIL SAMBRANO, OUR HEAD OF PORTFOLIO AND GRANTS REVIEW, WILL BE HIGHLIGHTING IN HIS TALK FOLLOWING MINE. BUT HERE IS WHAT WE HAVE DONE, WHAT CIRM HAS DONE, WHAT THIS BOARD HAS APPROVED TO DATE. SO IN TOTAL, BETWEEN PROPOSITION 71 AND THE CURRENT PROPOSITION 14 FUNDS, YOU SEE IN THE TOP ROW, THE CUMULATIVE INVESTMENT INTO DISCOVERY IS OVER $1 BILLION, SAME WITH CLINICAL STAGE PROGRAMS, OVER HALF A BILLION DOLLARS IN TRANSLATION, WHICH, AGAIN, DISTINGUISHES CIRM FROM OTHER FUNDING AGENCIES. OUR BRAND IS A TRANSLATIONAL FUNDING AGENCY. BUT ALSO SIGNIFICANT INVESTMENT IN EDUCATION NEARING A HALF A BILLION AND OVER HALF A BILLION DOLLARS IN INFRASTRUCTURE, BOTH

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BUILDING INFRASTRUCTURE, BUT ALSO MAJOR PROGRAMMATIC INFRASTRUCTURE, WHICH ARE MOST OF THE PROGRAMS YOU HAVE BEEN SEEING COME THROUGH TO YOU RECENTLY.

AND IN THE PROPOSITION 14 ERA, THIS CONTINUES, VERY ROBUST FUNDING ACROSS ALL FIVE PILLARS. AND THEN THE FISCAL YEAR 22/23 WHERE YOU WILL SEE IN MORE DETAIL WHERE POUNEH SIMPSON, OUR HEAD OF FINANCE, WILL GIVE AN UPDATE ON OUR EXPENDITURES WITH WHAT THE BOARD ALLOCATED FOR THIS FISCAL YEAR. BUT YOU WILL SEE THAT THERE HAS ALSO BEEN A SIGNIFICANT AMOUNT OF INVESTMENT IN ALL THE FIVE PILLARS. I WON'T READ THE NUMBERS. YOU ALL HAVE THEM, BUT HAPPY TO ANSWER ANY QUESTIONS RELATED TO ANY OF THESE.

SO WE ARE FUNDING ALL THESE PROGRAMS. THIS IS AN INTEGRATED APPROACH. WHAT WE STRIVE FOR AT CIRM IS AN END-TO-END SOLUTION, FUNDING PROGRAMMATIC, INFRASTRUCTURE, BUILDING FOR THE FUTURE. WHY? BECAUSE WE KNOW THAT CELL AND GENE THERAPY IS A NEW FIELD. THERE ARE SO MANY PLACES WHERE IT CAN FAIL EVEN IF IT'S USEFUL. I'LL GIVE YOU A USE CASE OF THAT OR A DEMONSTRATION OF THAT SHORTLY. IT'S BEEN CALLED VALLEY OF DEATH WHERE PROGRAMS, EVEN WITH PROMISE, JUST FALL THROUGH THE CRACKS AND ARE NOT ABLE TO MAKE IT TO THE NEXT

STAGE. THERE ARE TWO VALLEY OF DEATHS ACTUALLY. THERE'S ONE GOING FROM VERY IMPORTANT AND PROMISING SCIENCE AND DISCOVERIES TO BE ABLE TO TRANSLATE THIS INTO SOMETHING WHERE YOU CAN CREATE PREDICTABLY A THERAPEUTIC PRODUCT CANDIDATE. THIS IS A LIVING MEDICINE. SO IT'S A VERY VARIABLE NEW SYSTEM. COMPLETELY NEW TYPES OF TECHNOLOGIES NEED TO BE DEVELOPED. SO IT CAN FALL THROUGH THE CRACKS THERE.

IF YOU GET THROUGH THAT PART, YOU CAN GET INTO CLINICAL TRIALS, WHICH IS FANTASTIC. AND WE ARE STARTING TO SEE THAT AS INDICATED BY SOME OF THE PROGRESS REPORTS WE HAVE BEEN PROVIDING. HOWEVER, IT CAN STILL FALL THROUGH THE CRACKS IN MAKING IT ALL THE WAY, EVEN IF IT'S VERY NEAR BEING APPROVED, INTO THE CLINICS. AND THEN, EVEN ONCE APPROVED AND INITIALLY IN THE CLINICS, IT CAN STILL FAIL TO REACH THE PATIENTS IN NEED, ESPECIALLY THE DISPROPORTIONATELY AFFECTED COMMUNITIES THAT ARE UNDERSERVED. SO THESE ARE HUGE CHALLENGES.

AND THERE ARE MANY STAKEHOLDERS AND INTERESTED PARTIES IN THIS, BUT WHAT IS CIRM DOING? CIRM LAUNCHED THE STRATEGIC PLAN THAT THIS BOARD HAD APPROVED IN DECEMBER OF 2021, SHORTLY AFTER PROPOSITION 14 WAS PASSED. AND WE ORGANIZED OUR STRATEGIC THINKING AROUND THREE THEMATIC PILLARS OR

THREE THEMES: ADVANCE WORLD-CLASS SCIENCE, DELIVER REAL-WORLD SOLUTIONS, AND PROVIDE OPPORTUNITY FOR ALL. THERE ARE VERY DELIBERATE AND CONCRETE TACTICAL OBJECTIVES UNDER EACH OF THESE PILLARS. AND I'M JUST GOING TO GIVE A VERY HIGH LEVEL ACCOUNTING FOR WHAT WE'VE DONE THIS YEAR TO OPEN UP DISCUSSIONS.

SO IN TERMS OF ADVANCING WORLD-CLASS SCIENCE, THERE IS AN OPEN RFA FOR SHARED RESOURCE LABS. YOU'VE HEARD ABOUT THAT FROM DR. UTA GREISHAMMER AND ROSA AVILES IN PAST MEETINGS TO DISCUSS HOW THIS REALLY CAN EMPOWER THE SCIENTIFIC COMMUNITY FOR COLLABORATIVE SCIENCE AND TO BE ABLE TO PROVIDE THOSE RESOURCES TO MORE LABS AND, THEREFORE, ACCELERATE THE SCIENCE THROUGH SYNERGIES.

WE FUNDED THE FIRST PROGRAMS IN THE MANUFACTURING NETWORK PARTNERSHIP PROGRAM LED BY DR. SHYAM PATEL WITH HUGE ASSISTANCE FROM DR. SOHEL TALIB FROM THE THERAPEUTICS DEVELOPMENT TEAM AND DR. ROSS OKAMURA. AND THAT PROGRAM IS JUST ABOUT TO LAUNCH. THIS BOARD'S FUNDED THE FIRST OF THOSE, AND THE DESCRIPTION AND THE OBJECTIVES OF THAT WERE DESCRIBED AT PRIOR MEETINGS, BUT HAPPY TO ANSWER ANY QUESTIONS ON THAT. AND YOU WILL GET UPDATES, BY THE WAY, ON ALL PROGRAMS AS THEY LAUNCH AND PROGRESS.

AS YOU KNOW, THE ALPHA CLINICS DR. IMBASCIANI HAD REFERRED TO, THE EXPANSION OF THAT IS NOW ACROSS CALIFORNIA WITH NINE CENTERS. AND THE PROMISE OF THAT IS NOT JUST THAT THERE ARE FACILITIES AND THERE ARE PEOPLE, BUT IT'S THE AMAZING POTENTIAL THAT CORE COMPETENCIES AND RESOURCES ACROSS THESE PROGRAMS WILL REALLY PROVIDE OPPORTUNITIES TO ADDRESS THESE BARRIERS THAT ARE REPRESENTED IN THE SCHEMATIC DIAGRAM ABOVE.

AS YOU KNOW, SOME OF THE FIRST PROGRAMS WE LAUNCHED WERE EDUCATION PROGRAMS TO TRAIN THE WORKFORCE OF TOMORROW, TO BUILD THE DIVERSE CULTURALLY SENSITIVE AND SKILLFUL WORKFORCE IN ALL ASPECTS OF DEVELOPMENT OF EDUCATION AND OF MEDICINE AND HEALTHCARE ADVOCACY, ALL ASPECTS.

SO WHAT ELSE IS BEING SET UP THIS YEAR? THE PATIENT SUPPORT PROGRAM, WHICH YOU HEARD DESCRIBED IN PRIOR MEETINGS, THE RFA FOR THAT IS NOW OPEN. THAT'S UNDER DEVELOPMENT BY THE TEAM. AND YOU WILL HEAR MORE ABOUT SOME OF THIS IN THE ROADMAP PRESENTATION BY SEAN TURBEVILLE.

THE COMMUNITY CARE CENTERS CONCEPT DEVELOPMENT HAS BEEN UNDER WAY. AND AS PARTNER TO THAT, THERE HAVE BEEN A SERIES OF LISTENING SESSIONS WHICH MANY OF YOU HAVE BEEN PARTICIPATING IN. THANK

YOU VERY MUCH. AND THE MOST RECENT CULMINATED IN A STATEWIDE LISTENING SESSION IN SACRAMENTO LAST WEEK WHICH WAS AMAZINGLY SUCCESSFUL, JUST SO RICH WITH INSIGHT AND PROBLEM SOLVING AND DISCUSSION. MEMBERS OF THE BOARD WERE THERE, AND I'M SURE THAT AT SOME POINT THEY WILL BE ABLE TO SHARE. WE WERE VERY FORTUNATE THAT WE HAD MEMBERS ALSO LEAD THE PANEL, SUCH AS MARIA BONNEVILLE, YSABEL DURON. AND SO WE'RE REALLY FORTUNATE FOR THAT LEVEL OF ENGAGEMENT. FANTASTIC.

SO LATER ON YOU WILL HEAR THE INITIAL DRAFT OF THE ROADMAP FOR ACCESSIBILITY AND AFFORDABILITY, WHICH WILL BE INTRODUCED BY THE CHAIR OF OUR AAWG WORKING GROUP AND THEN PRESENTED BY SEAN TURBEVILLE.

ALL RIGHT. SO HERE'S A LITTLE BIT MORE KIND OF DEMONSTRATION CASES. WE'VE PRESENTED, SHYAM PATEL, OUR HEAD OF BUSINESS DEVELOPMENT AND ALLIANCE MANAGEMENT, HAS PRESENTED AT MANY PRIOR BOARD MEETINGS AND ALSO AT BIO. HE AND I AND MEMBERS OF THE LEADERSHIP TEAM HAVE PRESENTED ALL AROUND THE COUNTRY, DESCRIBING THE CIRM FUNDING MODEL AND HOW IT DERISKS PROGRAMS AND ARE ABLE TO GET THEM THROUGH THIS VALLEY OF DEATH. AND IT'S SOMETHING THAT, AS DR. IMBASCIANI HAD POINTED OUT, IS THE ENVY OF MANY

AND ALSO A DESIRE TO PARTNER WITH US BECAUSE OF THIS OPPORTUNITY.

THE MOST RECENT OF THESE, ESPECIALLY NOTABLE IN THIS CURRENT FINANCIAL CLIMATE, IS A PROGRAM OUT OF UCSD LED BY DR. STEPHANIE CHERQUI AS THE PI IN A RARE DISEASE CALLED CYSTINOSIS. AND IT UTILIZES A GENE THERAPY PLATFORM WHICH WAS DEVELOPED BY DR. DON KOHN AT UCLA. SO IT WAS A COLLABORATION THAT WAS ACTUALLY ENABLED BY THE ALPHA CLINICS NETWORK AND JUST THIS ECOSYSTEM THAT WE HAVE. AND DR. CHERQUI WAS ABLE TO BRING IT TO A POINT THAT IT RECEIVED INDUSTRY ATTENTION. AVROBIO HAS LICENSED IT, AND MOST RECENTLY NOVARTIS HAD ACQUIRED IT FOR $88 MILLION SUBJECT TO MILESTONES, ET CETERA. THIS ADDS TO THE TOTAL OF OVER $24 BILLION IN INDUSTRY INVESTMENT INTO OUR PROGRAMS. SO, AGAIN, JUST HIGHLIGHTING CIRM'S VALUE PROPOSITION AND ROLE. EVEN IN TIMES OF ECONOMIC CHALLENGES, IT'S A SOURCE OF RELIABLE SUPPORT AND FUNDING FOR HIGH IMPACT, SCIENTIFICALLY MERITORIOUS PROGRAMS SUCH AS THIS.

NEXT SLIDE PLEASE. HOWEVER, AGAIN SPEAKING TO THE POINT THAT WE CAN OVERCOME ALL THESE THINGS BUT THEN REALITY SETS IN, WE STILL HAVE MANY CHALLENGES AHEAD OF US. AND THIS IS SOMETHING I PUT AS INITIAL SUCCESS IS ALSO A PROBLEM STATEMENT.

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THIS IS A VERY LOUD, UNDERLINED, BOLD PROBLEM STATEMENT. YOU WILL RECOGNIZE EVIE ON THIS SLIDE. SHE'S NOW OVER TEN YEARS OLD YEAR. THIS IS JUST A YEAR OR TWO AGO. SHE AS AN INFANT WAS TREATED WITH DR. KOHN'S -- UNDER DR. KOHN'S TRIAL FOR THIS CONDITION CALLED ADA-SCID, ADENOSINE DEAMINASE DEFICIENCY, AN ENZYME THAT LEADS TO INABILITY TO FORM AN IMMUNE SYSTEM, ALSO CALLED BUBBLE BABY DISEASE. SHE'S BEEN CURED OF THIS FOR OVER TEN YEARS.

FURTHERMORE, IN THAT SAME TRIAL, 50 BABIES HAVE BEEN TREATED WITH A HUNDRED PERCENT SURVIVAL AND 90-PERCENT EFFICACY. ONE-TIME TREATMENT. PARADIGM SHIFTING. REMARKABLE.

ORCHARD THERAPEUTICS WAS FORMED WITH THIS AS THEIR LEAD PROGRAM. THEY SHELVED THIS PROGRAM IN JUNE 2021. BECAUSE OF CIRM FUNDING AND PATIENT ADVOCACY AND ALL THE EFFORTS TOWARD IT, THERE WAS AGREEMENT BY THE COMPANY TO RETURN THE PROGRAM TO UCLA SO DR. KOHN CAN CONTINUE THIS PROGRAM. THERE'S NOW AN ACTIVE IND THAT THEY WERE ABLE TO PROVIDE UNDER PREAPPROVAL PATHWAYS THROUGH THE FDA. AND THE FIRST FEW PATIENTS HAVE NOW BEEN TREATED UNDER A TREATMENT PROTOCOL. THE PROBLEM IS STILL NOT SOLVED, BUT ONE OF THE THINGS, A KEY THEME THAT WE

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ARE HEARING, AND WE'VE HEARD IT AT AAWG MEETINGS AND ELSEWHERE, IS THAT FOR CONDITIONS SUCH AS THIS THERE IS NO OTHER TREATMENT, THERE IS NO OTHER CURE. WELL, THERE'S TREATMENT, BUT IT'S SYMPTOMATIC, AND IN SOME CASES THERE ARE NO TREATMENTS. WHAT DO YOU DO?

SOMETIMES THESE ARE THE BEST TREATMENTS THAT EVEN INVOLVEMENT IN A CLINICAL TRIAL, IN THIS CASE, IT'S AN EXTREME CASE WHERE ACTUALLY THEY ALREADY HAD BENEFIT FROM IT DURING THE TRIAL. NOT SAYING THAT'S IN EVERY TRIAL. BUT IF THEY'RE NOT ACCESSIBLE, THEN THERE'S NO CHANCE OF THAT.

SO WHAT ARE WE GOING TO DO ABOUT THAT? FIRST OFF, JUST A REMINDER, THAT OVER HALF OF OUR DEVELOPMENT PORTFOLIO IS IN RARE DISEASE. IT'S IN VERY CONDITION THAT IS PROBABLY THE MOST CHALLENGING OF THE CELL AND GENE THERAPY. CELL AND GENE THERAPY AS A SPACE HAS A CONSIDERABLE AMOUNT OF CHALLENGES. EVEN CAR-T THERAPIES THAT HAD BEEN LICENSED TO BIOPHARMA, IT'S BEEN RECOGNIZED THAT THERE WERE CHALLENGES IN MANUFACTURING AND EVERYTHING ELSE, AND IT'S STILL UNDER CONSIDERATION AS TO WHETHER THE BIOPHARMA MODEL IS THE APPROPRIATE PLACE IN GENERAL, AT LEAST IN THE EARLY PHASES, FOR THESE THERAPIES TO BE DEVELOPED AND DISTRIBUTED. HOWEVER, ONE OF THE

PROBLEMS IS, BECAUSE FOR EACH INDICATION THERE ARE SO FEW PATIENTS, THE FINANCES DON'T WORK OUT. IT DOESN'T FIT INTO BUSINESS PLANS. IT DOESN'T FIT INTO THE TYPICAL COMMERCIALIZATION MODELS AND PATHWAY. WHAT DO WE DO?

RARE DISEASE IN AGGREGATE IS SIGNIFICANT IN TERMS OF DISEASE BURDEN. AS YOU CAN SEE THE NUMBERS HERE, EVEN THOUGH EACH ONE MAY AFFECT LESS THAN 200,000, IN ULTRA CASES EVEN FEWER, CUMULATIVELY IN AGGREGATE RARE DISEASES AFFECTS 30 MILLION AMERICANS. IT'S SIGNIFICANT. SO ONE OF THE OPPORTUNITIES WITH CELL AND GENE THERAPY, ESPECIALLY THESE TECHNOLOGY PLATFORMS, IS THAT, ALTHOUGH YOU'RE DEVELOPING A PROGRAM FOR A SPECIFIC RARE DISEASE, FOR INSTANCE, ONE CAN IMAGINE AN APPROACH WHERE IT ACTUALLY COULD BE APPLIED IN A PLATFORM TECHNOLOGY ACROSS DISEASES AND EVEN INTO MORE COMMON DISEASES. SO THOSE ARE THE OPPORTUNITIES. NOT ONLY COULD THEY ADDRESS UNMET MEDICAL NEED, BUT DEVELOP TECHNOLOGY PLATFORMS THAT CAN BE APPLIED MORE BROADLY AS WELL AS DEVELOP THE PARALLEL NEEDS IN TERMS OF THE HEALTHCARE DELIVERY, COVERAGE, AND INFRASTRUCTURE THAT'S NEEDED FOR CELL AND GENE THERAPY IN GENERAL. SO IT'S ALMOST LIKE THE FIRST CHILD GOING OUT THERE IN THE WORLD.

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SO MUCH OF WHAT OUR DISCUSSIONS AND OUR ACTIVITIES, IN THIS PAST YEAR ESPECIALLY, BUT HAS BEEN PERCOLATING THROUGHOUT HAVE BEEN IN LARGE STAKEHOLDER ENGAGEMENT IN POTENTIAL SOLUTIONS. WE'VE SPOKEN TO THOSE FOUNDATIONS AND PATIENT-DRIVEN INITIATIVES THAT HAVE ACTUALLY RUN N OF 1 TRIALS WITH REGULATORY SUPPORT. BECAUSE IN THOSE CASES SOMETIMES THAT'S THE ONLY CHILD THAT HAS BEEN IDENTIFIED. AND SO THAT PLATFORM IS SOMETHING THAT IS NOT GOING TO GO INTO A COMMERCIAL MODEL. HOWEVER, A LOT HAS BEEN LEARNED FROM THAT, AND THERE'S A NEED FOR IT.

FYODOR URNOV, WHO'S ONE OF THE PIONEERS IN THE FIELD OF CELL AND GENE THERAPY, HAD WRITTEN AN OPINION PIECE IN THE *NEW YORK TIMES* AT THE END OF LAST YEAR SPEAKING TO THIS PROBLEM STATEMENT OF WE HAVE INCREDIBLE POTENTIAL, ESPECIALLY WITH CRISPR EDITING AND NEXT GENERATION BASE EDITING, ET CETERA, FOR ACTUALLY CURING DISEASE. AGAIN, SINGLE TREATMENTS, SIMILAR TO THE SCENARIOS WE MENTIONED. HOW DO YOU DO THAT THOUGH?

SOME OF THE INVOLVEMENT THAT WE HAVE IN PARTNERSHIPS, ABLA CREASEY AND SHYAM PATEL ARE PICTURED HERE. THEY ARE OUR REPRESENTATIVES TO THE BESPOKE GENE THERAPY CONSORTIA, WHICH INVOLVES THE

FDA, THE FOUNDATION FOR THE NIH, AND THE NIH, NCATS, MAJOR GROUPS TRYING TO DETERMINE WHETHER A BESPOKE PLATFORM-BASED APPROACH COULD ADDRESS BROADLY ACROSS INDICATIONS. AND ABLA AND SHYAM LED A DISCUSSION AT THE RECENT AMERICAN SOCIETY FOR CELL AND GENE THERAPY IN L.A.

AND THEN WE WERE INVITED TO A THINK TANK IN WASHINGTON, D.C. CONVENED BY CONCERNED SCIENTISTS WHO SEE THE PROMISE OF THEIR WORK, BUT KNOW THAT THERE'S NOWHERE TO KIND OF RECEIVE IT ON THE DOWNSTREAM. AND WE, ALONG WITH NIH, THE DIRECTOR OF ARPA-H AND CIRM, SCIENTISTS, FDA, WE DISCUSSED NOVEL REGULATORY APPROACHES, COLLABORATIONS THAT COULD ENABLE PLATFORM APPROACHES. DISCUSSED MODELS SUCH AS POINT-OF-CARE MANUFACTURING, WHICH IS SOMETHING THAT CAN BE SUPPORTED BY OUR MANUFACTURING INITIATIVE, FOR INSTANCE. AND EVEN NONPROFIT MODELS AND ACADEMIC-BASED MODELS THAT MAY SUPPLANT A BIOPHARMA TYPE MODEL AT LEAST INITIALLY. SO THOSE ARE STILL UNDER DISCUSSION, AND WE HOPE TO BE ABLE TO BRING BACK MORE INFORMATION ON SOME OF THESE FOR CONSIDERATION.

ONE OF THE THINGS THAT I WANTED TO SAY IS THAT CIRM IS UNIQUELY POSITIONED. WE GET INVITED TO ALL THESE DISCUSSIONS BECAUSE OUR FUNDING MODEL, OUR

INFRASTRUCTURE, OUR ECOSYSTEM, OUR PROJECTS THEMSELVES, WE HAVE A VERY UNIQUE OPPORTUNITY TO, AGAIN, REMAIN ON THE LEADING EDGE OF WHERE WE ARE IN THE CHALLENGES WITH CELL AND GENE THERAPY.

AND WE DO THIS IN PARTNERSHIP. SO I WANTED TO ACKNOWLEDGE NOT EVERYBODY IS UP HERE BECAUSE WE'VE HEARD ABOUT SOME OTHER ACCOLADES AND AWARDS, BUT OUR BOARD, OUR PATIENT ADVOCATES, OUR GWG REVIEWERS, AND OUR SCIENTISTS ARE ALL WORLD-RENOWNED LEADERS IN THE FIELD. SO I JUST WANTED TO HIGHLIGHT A FEW. DAVID WILLIAMS, WHO WAS FUNDED UNDER OUR SICKLE CELL CURE PARTNERSHIP WITH THE NIH FROM BOSTON CHILDREN'S, WHO PARTNERS WITH UCLA AND UCSF IN OUR ALPHA CLINICS ON THE SICKLE CELL PROGRAM, WAS AWARDED THE ASGCT FOUNDERS AWARD SEVERAL WEEKS AGO. RAYNE ROUCE WHO'S AN INCREDIBLE GWG MEMBER, KUDOS TO GIL AND TEAM FOR BUILDING SUCH AN AUGUST GWG TEAM REALLY TO REVIEW OUR PROGRAMS THAT CAN BE BROUGHT TO YOU. RAYNE HAS BEEN A LEADER IN ADVANCING DEI BROADLY ACROSS THE COMMUNITY. SHE'S A PEDIATRIC ONCOLOGIST AT BAYLOR AND TEXAS CHILDREN'S. AND, OF COURSE, YOU RECOGNIZE RIGHT UNDERNEATH THE PICTURE, OUR BELOVED BOARD MEMBER AND LEADER, YSABEL DURON, WHO BASICALLY WAS THE REASON FOR THE CALL TO ACTION DURING THE COVID

TIMES THAT LED TO WHERE WE ARE WITH OUR DEI INITIATIVE, AGAIN WITH THE LEADERSHIP FROM FORMER BOARD MEMBER AL ROWLETT. WE'RE GREATLY INDEBTED TO YOUR LEADERSHIP FOR THAT.

SO YSABEL, AS YOU KNOW, HAS BEEN APPOINTED TO THE NATIONAL CANCER ADVISORY BOARD BY PRESIDENT BIDEN. THIS HAS BROUGHT A WEALTH OF INFORMATION AND CONNECTIVITY TO US AS WE CONSIDER OUR PROGRAMS.

JOY CAVAGNARO, WHO'S BEEN A LONG-TERM, AGAIN, GWG MEMBER IN THE ARENA OF REGULATORY SCIENCES AND DEVELOPMENT, RECEIVED THE ASGCT CATALYST AWARD. AND OTHER CALIFORNIA SCIENTISTS SUCH AS HELEN BLAU, CRYSTAL MACKALL AND OTHERS WERE FEATURED SPEAKERS AT THE ASGCT, AND IN THIS CASE HELEN BLAU AT THE ISSCR PRESIDENTIAL PLENARY WHERE SHE REPORTED ON THE REGENERATIVE MEDICINE PROGRAM SHE HAD FUNDED BY CIRM FOR MUSCLE REGENERATION.

SO JUST TO RECAP, CIRM'S FUNDING MODEL HAS BUILT A ROBUST AND DIVERSE PORTFOLIO AND PIPELINE, THERAPEUTICS DEVELOPMENT, INFRASTRUCTURE AND EDUCATION PROGRAMS. OUR FIVE-YEAR STRATEGIC PLAN HAS KICKED OFF. WE'VE BEEN VERY HAPPY WITH HOW WE'VE DONE ON THIS PLAN FOR THE FIRST YEAR. THAT'S ALL SEEDING THE PIECES, PUTTING THE PIECES IN PLACE, WITH THE MISSION OF ADVANCING -- WITH THE OBJECTIVE

OF ADVANCING OUR MISSION OF DELIVERING TRANSFORMATIVE SCIENCE TO CLINICAL TRIALS AND THERAPIES AND MAKING THEM ACCESSIBLE.

AND THIS FUNDING MODEL AND STRATEGY ARE ADAPTABLE TO REAL-TIME ADVANCEMENTS IN THE FIELD, EMERGING PRIORITIES, PROGRAMMATIC DIRECTION FROM THIS BOARD, AND OPPORTUNITIES TO ADVANCE CIRM'S MEETINGS IN AREAS SUCH AS RARE DISEASE, CNS, TOPICS THAT WILL BE DISCUSSED TODAY, AS WELL AS OTHER POTENTIAL PRIORITIES. AND SO I'LL TAKE QUESTIONS, AND THEN I'D LIKE TO HAND IT OVER TO DR. GIL SAMBRANO WHO WILL LAY DOWN KIND OF THE HOW WE DO IT IN TERMS OF THE FUNDING, WHAT THE ELIGIBILITY IS, HOW THIS PIPELINE WAS BUILT THROUGH OUR MACHINERY, AND THAT HOPEFULLY WILL PROVIDE SOME INITIAL PERSPECTIVE IN TERMS OF WHAT IS POSSIBLE AS THE BOARD ENGAGES IN CONTINUED PROGRAMMATIC CONSIDERATIONS.

SO WITH THAT, CHAIR IMBASCIANI, I'LL TURN IT OVER TO YOU. AND I'M HAPPY TO TAKE ANY QUESTIONS. THANK YOU.

CHAIRMAN IMBASCIANI: MEMBER JUELSGAARD.

MR. JUELSGAARD: YES, MARIA. I'D LIKE TO TALK A LITTLE BIT ABOUT THE SLIDE THAT'S HEADED INITIAL SUCCESS IN CGT IS ALSO OUR PROBLEM

STATEMENT, AND THAT'S THE DON KOHN THERAPEUTIC AREA OF SCID.

SO LET'S ASSUME FOR A MOMENT THAT THERE'S NEVER A COMMERCIAL PARTNER TO BE FOUND FOR THAT PARTICULAR DISEASE, YET WE HAVE A VERY SUCCESSFUL TREATMENT. WHAT'S OUR THOUGHT PROCESS ABOUT WHERE WE GO IN THAT SET OF CIRCUMSTANCES? AND I WANT TO USE THAT AS A POTENTIAL MODEL FOR OTHERS THAT MAY FIT THAT BECAUSE THERE ARE A NUMBER OF COMMERCIAL ISSUES THAT COME UP WITH THESE SORTS OF DISEASES. THE FIRST ARE THE NUMBER OF PATIENTS THAT ARE INVOLVED. THE SMALLER THE NUMBER, THE MORE DIFFICULT IT IS COMMERCIALLY FOR WHAT IT IS THAT IS INVOLVED IN THE TREATMENT, THE COST OF ACTUALLY PREPARING THE TREATMENT FOR ADMINISTRATION, A NUMBER OF OTHER ISSUES. LET'S JUST ASSUME FOR A MOMENT THERE IS NO COMMERCIAL PARTNER. HOW HAVE WE THOUGHT ABOUT THAT?

DR. MILLAN: SO THOSE ARE -- IT'S A VERY IMPORTANT TOPIC. AND NOT ONLY IS IT IMPORTANT, IT'S ACTUALLY IN FRONT OF US, THAT WE ARE -- IN ORDER FOR US TO ACTUALLY CONTINUE TO BRING THESE PROGRAMS FORWARD, WE NEED TO ACTUALLY COME UP WITH SOLUTIONS TO THAT IN REAL TIME BECAUSE WE ACTUALLY HAVE THEM IN FRONT OF US TODAY.

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ONE OF THE THINGS I SHOULD POINT OUT IS THAT I MENTIONED THERE ARE SOME PROGRAMS THAT ARE ALREADY ON THE DOCKET FOR APPROVAL THIS YEAR IN SICKLE CELL, FOR INSTANCE. THERE ARE TWO PROGRAMS, ONE OUT OF VERTEX, ONE OUT OF BLUEBIRD, THAT ARE FOR CONSIDERATION IN DECEMBER. MENTIONED THE ONE FOR DUCHENNE MUSCULAR DYSTROPHY. ONE IN HEMOPHILIA IS COMING UP, I THINK ANOTHER ONE IN DUCHENNE MUSCULAR DYSTROPHY. SO SOME OF THESE ARE ACTUALLY BEING BROUGHT FORWARD BY COMMERCIAL ENTITIES. SO WE WILL LEARN FROM THAT. WE'RE ALSO LEARNING FROM NOVARTIS, GILEAD, KITE IN TERMS OF WHAT THEY'VE DONE WITH CAR-T'S THAT WILL INFORM WHAT INNOVATIVE SOLUTIONS HAVE BEEN CREATED IN THAT CONTEXT. AND SO THAT IT NEEDS TO BE DETERMINED WHETHER THERE IS AN ADAPTOR SOLUTION THAT WILL BE ABLE TO TAKE OUR ACADEMIC PROGRAMS AND THEN BE ABLE TO MAKE THEM READY FOR THIS. SOME OF THE THINGS WE'RE PUTTING IN PLACE SUCH AS THE MANUFACTURING NETWORK AND THE PARTNERSHIPS ARE INTENDED TO HELP CREATE THAT ADAPTOR.

THERE ARE SOME CASES, AND MANY HAVE TALKED ABOUT IT, WHERE IT MAY BE THAT THEY NEVER GO INTO THESE PROGRAMS. SPEAKING WITH THE HEAD OF THE RARE DISEASE PROGRAMS AT MANY OF THESE COMPANIES,

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NOVARTIS INCLUDED, WHICH THEY DID TAKE UP OUR PROGRAM, THEY HAVE SAID THERE ARE SOME PROGRAMS THEY WOULD LIKE TO PURSUE. THEY HAVE IN-HOUSE PEOPLE WORKING ON IT, BUT THEY'RE NOT GOING TO TAKE IT TO COMMERCIALIZATION. I ASSUME THEY'RE ALSO WORKING ON SOLUTIONS, AND WE WILL CONTINUE TO BE IN TOUCH WITH THEM.

SO WHERE DOES THAT LEAVE US? IT LEAVES US WITH A PARADIGM THAT'S VERY SIMILAR, NOT EXACTLY THE SAME, TO SOMETHING I'M FAMILIAR WITH, WHICH IS ORGAN TRANSPLANTATION WHERE IT WAS A LIFESAVING ADVANCEMENT WHERE INFRASTRUCTURE AND POLICY, NATIONAL INFRASTRUCTURE NEEDED TO BE PUT BEHIND BEING ABLE TO MAKE THIS HAPPEN. IT REMAINED WITHIN THE PRACTICE OF MEDICINE WITH STANDARDS PUT IN PLACE, BUT IT'S VERY MUCH ACADEMIC BASED. THERE ARE INFRASTRUCTURE PROGRAMS FUNDED BY THE HHS FOR THE ORGAN PROCUREMENT ORGANIZATIONS AND HOW THAT'S RUN THROUGH THE UNOS, FOR INSTANCE, AND THEN LOCAL PROCUREMENT ORGANIZATIONS. INDUSTRY HAS BEEN BUILT UP FOR IMMUNOSUPPRESSION MEDICATIONS, ORGAN PRESERVATION SOLUTIONS. SO THERE'S KIND OF THE SO-CALLED PICKS AND SHOVELS INDUSTRY THAT GO AROUND THAT TO SUPPORT IT. THAT'S ANOTHER POTENTIAL MODEL.

WE DON'T HAVE THE ANSWER YET, BUT WE ARE

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ENGAGED ACTIVELY WITH TESTING SOME OF THESE MODELS. ONE OF THEM IS THIS BESPOKE GENE THERAPY NETWORK, FOR INSTANCE. ABLA AND SHYAM IN UPCOMING MEETINGS WILL DESCRIBE SOME PROGRESS ON THAT. THE IDEA BEHIND THAT IS THAT NIH, FDA, CIRM, OTHER COMPANIES, PATIENT GROUPS ARE TRYING TO DETERMINE WHETHER WE CAN BRING IN EFFICIENCY TO EVEN THE NUTS AND BOLTS OF HOW YOU BRING THESE THERAPIES FORWARD. SO, FOR INSTANCE, BUILDING THE BEST PLATFORM FOR THE VECTOR, FOR THE GENE DELIVERY VECTOR, THAT THEN LINKS WITH IT AN EVIDENCE BASE THAT THE FDA CAN BE VERY COMFORTABLE WITH TO FACILITATE ACCELERATED APPROVAL OR EXPEDITED PATHWAYS, BUT THEN HAVING AN AGREEMENT FROM THE COMMUNITY WE WILL USE THAT PLATFORM. IT KIND OF TAKES OUT SOME OF THE COMPETITIVE ASPECTS OF WHAT TYPICAL DRUG DEVELOPMENT IS, THE SECRET SAUCE. NO. EVERYBODY GETS THE SAUCE BECAUSE THAT'S GOING TO ALLOW YOU TO COME UP WITH YOUR END RESULT.

AND SO THERE'S A WHOLE NEW PARADIGM THAT'S GOING TO NEED TO FORM IN A COMPANY FOR THAT TO TAKE HOLD, BUT THERE IS PROGRESS. AND WE'LL CONTINUE TO BRING FORWARD JUST KIND OF THE HOW-TOS IN THAT. AND WE DO HAVE OPPORTUNITIES BETWEEN CIRM FUNDING MODELS, OUR REQUIREMENTS, OUR ABILITY TO CONVENE, AND TO PROMOTE THIS TYPE OF COLLABORATIVE APPROACH.

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IT'S NOT AN ANSWER BECAUSE NOBODY HAS AN ANSWER YET, BUT IT'S THE APPROACH THAT I HOPE I BROUGHT SOME LIGHT TO. THANK YOU.

CHAIRMAN IMBASCIANI: MEMBER CHOU.

DR. CHOU: I HAVE A RELATED FOLLOW-UP QUESTION ON THIS. SO I THINK YOU MENTIONED ABOUT FOR BIG PHARMA THE MODEL OF CELL/GENE THERAPY ACTUALLY MAY NOT BE THE RIGHT FIT. FROM WHAT I CAN SEE IN THE INDUSTRY, I THINK THIS TREND IS COMING THAT WAY. AND I USED TO RUN ALSO A BIG ORGANIZATION, HELD THE P&L RESPONSIBILITY. I WOULD SAY THAT'S REALLY HARD TO INCORPORATE THE CELL/GENE THERAPY MODEL.

SO IN A SENSE, ALSO, I THINK THE THOUGHT HAS BEEN FROM THE INDUSTRY POINT OF VIEW GOING MORE TOWARDS THIS IS GOING TO BE THE MEAT OF MORE SITES OF THE PHARMA COMPANY MODEL MAY FIT BETTER. SO MY QUESTION, THEN, IS FROM CIRM ANGLE, ARE WE -- ARE WE DOING SOMETHING TO BUILD THAT PARTNERSHIP WITH THE BIG PHARMA? AND ARE WE CHANGING THAT TO MORE LIKE TARGET MID-SIZE OR SMALL SIZE OF COMPANY TO MAKE SURE THERE'S A WAY TO GET THE MEDICINES TO THE PATIENTS?

DR. MILLAN: THANK YOU SO MUCH. SHYAM PATEL IS OUR HEAD OF BUSINESS DEVELOPMENT, AND HE'S

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BUILT QUITE A SIGNIFICANT INDUSTRY ALLIANCE PROGRAM WHERE WE DO HAVE PARTNERSHIPS WITH DEVELOPERS AS WELL AS MANUFACTURERS AND OTHER INTERESTED PARTIES IN THIS SPACE FOR THAT VERY REASON. THEY SEE THE VALUE IN THE CIRM DERISKING. THEY SEE THE VALUE IN OUR ROBUST PORTFOLIO. PART OF THE -- ONE OF THE BASIC PRINCIPLES INFORMING THE MANUFACTURING NETWORK IS THAT THIS WOULD PROVIDE AN OPPORTUNITY FOR EARLY ENGAGEMENT AND INFLUENCE BY INDUSTRY PARTNERS ALONG THE WAY SO THAT, WHEN POTENTIAL PROGRAMS ARE READY TO BE PICKED UP, EITHER WITH MANUFACTURERS AS A PARTNER, OR EVEN TAKE IT UP ALTOGETHER, THAT THOSE PROGRAMS ARE MORE READY FOR THAT. SO IT'S BOTH COST EFFICIENCIES AND THE SUITABILITY FOR TRANSFERRING.

AND I'M SORRY. I DON'T KNOW IF THAT ANSWERED YOUR QUESTION, JUDY.

DR. CHOU: I THINK MY QUESTION IS THEN SO WHEN YOU MENTIONED ABOUT THE RELATIONSHIP WE ARE BUILDING, I WOULD ASSUME THAT'S PROBABLY WITH MUCH MORE ESTABLISHED BIG PHARMA CURRENTLY; IS THAT CORRECT?

DR. MILLAN: ACTUALLY NO. WE HAVE A LOT OF RELATIONSHIPS WITH INVESTORS WITH SMALLER COMPANIES AS WELL AS LARGER COMPANIES. SO SOME OF THE LARGER COMPANIES THAT ARE IN OUR INDUSTRY

ALLIANCE PROGRAM ARE BAYER, FOR INSTANCE, WHICH HAS WITH IT ASKBIO AND BLUEROCK WHICH RECENTLY REPORTED ON THEIR PARKINSON'S PHASE 1 ENCOURAGING PROGRAM, AND NOVO NORDISK. THEIR ENGAGEMENT WITH US IS NOT ONLY ON THE PROGRAMS, BUT IN CAPACITY AND INFRASTRUCTURE. AND THEY SEE THE VALUE IN PARTNERSHIP. AND SO SHYAM HAD PRESENTED SEVERAL MONTHS AGO, AND HE'LL BE READY TO GIVE AN UPDATE ON MANY ASPECTS OF THESE BUSINESS ALLIANCES, BUT WE'RE ALSO HAPPY TO HAVE KIND OF A SMALLER GROUP RECAP. AND I KNOW THEY'RE EXTREMELY BUSY, BUT WHEN YOU HAVE TIME, WE CAN SCHEDULE THAT.

DR. CHOU: THANK YOU. IF I CAN ASK A TOTALLY SEPARATE QUESTION JUST FOR CLARIFICATION. YOU MENTIONED ABOUT CIRM, WE BRAND YOURSELF AS A TRANSLATIONAL INSTITUTE TO GET THE SCIENCE TO THE BENCH. I JUST WANT TO CLARIFY ABOUT WITH THAT KIND OF BRANDING, WHEN WE LOOK AT THE FIVE PILLAR OF THE FUNDING DISTRIBUTION, IS THAT HAVING THE IMPACT OF ANYTHING WE PREFER TO FUND, OR WE'RE STILL KIND OF ACROSS THE BOARD FOR ALL THE FIVE PILLARS?

DR. MILLAN: SO I THINK THAT THAT IS GOING TO BE THE SUBJECT OF WHAT DR. IMBASCIANI HAD RECOMMENDED, THAT THE SCIENCE SUBCOMMITTEE LEAD A DISCUSSION IN TERMS OF PRIORITIZATION, WHETHER IT BE

TYPES OF PROGRAMS, BY DISEASE AREAS, OR OTHER PROGRAMMATIC DISCUSSION. THE CIRM FUNDING MODEL AND ALL OF THE INFRASTRUCTURE AND EVERYTHING WE SET UP IS ADAPTABLE TO THE DIRECTION, WHETHER IT BE BY PRIORITIES OR PROGRAMS, WHICH IS -- I THINK WE HAVE REALLY PROBABLY AN OPPORTUNE TIME AND IMPORTANT TIME BECAUSE GIL WILL PROBABLY TELL YOU THAT THERE'S BEEN A HUGE INFLUX OF GRANT APPLICATIONS IN ALL THE PILLARS. SO IT'S VERY TIMELY TO HAVE THAT TYPE OF DISCUSSION AT THE BOARD. THANK YOU SO MUCH, DR. CHOU.

CHAIRMAN IMBASCIANI: MEMBER ABOUSALEM.

DR. ABOUSALEM: GOOD MORNING AND THANK YOU FOR THE PRESENTATION. JUST AN OPERATIONAL QUESTION. SO I APPRECIATE ALL THESE EFFORTS, FORWARD LOOKING SORT OF CONVERSATIONS, EXPLORATORY CONVERSATIONS FOR NEW OPPORTUNITIES AND NEW WAYS TO EXPAND CIRM'S IMPACT IN AREAS THAT WE MIGHT HAVE NOT BEEN ALREADY. THE QUESTION IS DO YOU HAVE PROVISIONS IN THE 23/24 BUDGET THAT WE'RE GOING TO BE LOOKING AT TODAY FOR ANY OF THESE SORTS OF CONVERSATIONS BECOMING -- GETTING TO A CONCLUSIVE PROGRAM OR A PROCESS OR EXPANDING EXISTING PROGRAMS TO ACCOMMODATE THE FINDINGS FROM THIS?

DR. MILLAN: THANK YOU VERY MUCH.

REGARDING OUR ABILITY WITH THE PROPOSED 23/24 BUDGET TO BE ABLE TO ACCOMMODATE DIRECTION FROM THE BOARD, FOR INSTANCE, OR ANY OPPORTUNITIES THAT MAY ARISE FROM THESE DISCUSSIONS, WE DO BELIEVE WE HAVE, JUST KIND OF LOOKING AT WHAT THOSE COULD LOOK LIKE, WE DO BELIEVE THAT WITHIN THE PILLAR BUDGETARY REQUESTS, THOSE COULD BE SHAPED TO SUPPORT SOME OF THE OPPORTUNITIES. AND THEN WE WOULD BRING, OF COURSE, THE RATIONALE BEHIND THAT AND WHAT THE SHAPING INITIATIVES WOULD BE IN UPCOMING MEETINGS. THANK YOU SO MUCH.

DR. ABOUSALEM: THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU. I CANNOT THINK OF A BETTER SCRIPTED SEGUE, CONSIDERING BUDGET.

DR. MILLAN: I THINK THAT DR. YAMAMOTO.

CHAIRMAN IMBASCIANI: SORRY. DR. YAMAMOTO.

DR. YAMAMOTO: I JUST WANT TO EXTEND THE QUESTION AND POINT THAT STEVE JUELSGAARD RAISED ABOUT THE CHALLENGE THAT WE ARE FACING, TWO POINTS. THE FIRST IS THAT THE VERY FACT THAT WE ARE FACING THIS PROBLEM IS A CREDIT TO WHAT CIRM HAS DONE. NO ONE ELSE HAS GOTTEN THE COUNTRY'S ATTENTION TO THIS PROBLEM BECAUSE NOBODY ELSE HAS CARRIED THE BALL FAR

ENOUGH THAT IT'S REALLY BECOME EVIDENT. AND SO WHILE IT'S PART OF THE PROBLEM STATEMENT NOW, IT SHOULD ALSO BE SOMETHING THAT WE RECOGNIZE IS A REALLY UNIQUE CONTRIBUTION, ONE OF MANY, BUT CERTAINLY A UNIQUE CONTRIBUTION THAT CIRM IS MAKING.

THE SECOND IS THAT I THINK AT THE END OF THE DAY, THERE'S GOING TO BE NOTHING THAT CAN REPLACE THE FEDERAL GOVERNMENT STEPPING IN TO CARRY THE BALL TO THE NEXT STEP. I THINK IT'S THE REASON I WAS REALLY HAPPY TO HEAR THE CHAIRMAN CALL FOR CIRM'S INCREASED PRESENCE ON THE FEDERAL GOVERNMENT RELATION STAGE TO REALLY DRIVE THESE MESSAGES HOME. SO THIS IS THE FIRST EXAMPLE, BUT ONE OF MANY IF CIRM CAN CONTINUE TO DRIVE SUCCESSES TO THIS POINT WHERE THE ISSUE BECOMES REALLY EVIDENT. WE ALL KNOW THAT, AT THE END OF THE DAY, THERE WOULD HAVE BEEN NO COMPANY THAT WOULD HAVE STARTED MANUFACTURING HUNDREDS OF MILLIONS OF DOSES OF THE VACCINE BEFORE APPROVAL WITHOUT THE GOVERNMENT STEPPING IN AND SAYING, HERE'S A BUNCH OF MONEY. GO AHEAD.

SO MAKING THAT -- I THINK AT THE END OF THE DAY, THE GOVERNMENT IS GOING TO HAVE TO MAKE THESE KINDS OF BETS. AND A PART OF IT WILL BE TO RECOGNIZE THAT WHAT CIRM IS DOING IS MOVING THE BALL TO MAKING THESE PROBLEMS EVIDENT AND DOING IT IN A

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WAY THAT HAS A CHANCE OF BEING ABLE TO ESTABLISH PLATFORM APPROACHES THAT WILL BE RELEVANT TO MULTIPLE DISEASES. AND I THINK IF THE FEDERAL GOVERNMENT CAN RECOGNIZE THAT, THERE WILL INCREASINGLY BE EXAMPLES IN WHICH THEY WILL STEP IN AND SAY, OKAY. WE'LL LET YOU CARRY THE BALL TO THE NEXT ENABLING STEP. NO COMPANY CAN TAKE THIS ON, BUT WE'RE GOING TO ENABLE IT TO HAPPEN. SO I THINK THAT'S PROBABLY HOW THIS PROBLEM IS GOING TO BE SOLVED, AND IT'S THE REASON THAT CIRM REALLY NEEDS TO BE IN WASHINGTON MAKING THESE POINTS VERY STRONGLY.

DR. MILLAN: THANK YOU VERY MUCH.

CHAIRMAN IMBASCIANI: THANK YOU. THANK YOU FOR THOSE COMMENTS.

TYING TOGETHER A BUDGET PORTFOLIO AND THE FUNDING TO ACHIEVE OUR STRATEGIC GOALS, THE BOARD WILL NOW HEAR FROM DR. SAMBRANO. THANK YOU.

DR. SAMBRANO: THANK YOU, DR. IMBASCIANI, DR. MILLAN. IT'S ALWAYS A PRIVILEGE TO STAND BEFORE YOU AND HAVE THE OPPORTUNITY TO PRESENT. TODAY I WANT TO TALK ABOUT OUR CIRM FUNDING MODEL. AND WHAT WE MEAN BY THAT IS WHAT THE PROCESS AND THE PRINCIPLES ARE THAT UNDERLIE THIS AND HOW IT IS THAT WE'VE GOTTEN TO DEVELOP THE PORTFOLIO OF GRANTS THAT

WE CURRENTLY HAVE. SO I'M GOING TO TALK ABOUT THAT IN A FEW SLIDES.

YOU'VE SEEN THIS ALREADY. WE KNOW THAT EVERYTHING THAT WE FUND AT CIRM IS CATEGORIZED WITHIN THESE FIVE PILLARS OF INFRASTRUCTURE, EDUCATION, DISCOVERY, TRANSLATION, AND CLINICAL. BUT WE CAN LOOK AT THESE A LITTLE DIFFERENTLY BECAUSE THEY ARE INTENDED TO BE CONNECTED, AND THERE ARE RELATIONSHIPS AMONG THEM THAT ARE VERY IMPORTANT TO SEE. IN SOME OF THESE SCREENS YOU CAN SEE IT BETTER THAN IN OTHERS.

THE DISCOVERY, TRANSLATION, AND CLINICAL PILLARS ARE CONNECTED ALONG THE THERAPEUTIC DEVELOPMENT PIPELINE. THE IDEA BEHIND THIS IS THAT WE WANT TO SUPPORT PROJECTS THAT COME AT ANY STAGE BETWEEN GENERATING A NEW IDEA AND SUPPORTING A CLINICAL TRIAL THAT ULTIMATELY GETS TO AN APPROVED THERAPY, THAT A PROJECT CAN COME IN AT ANY OF THESE TIME POINTS AND MOVE FORWARD.

WE HAVE ALSO VERY SPECIFICALLY SET UP MILESTONES ALONG THAT PATH. SO IDENTIFY THINGS SUCH AS ACHIEVING A SINGLE PRODUCT CANDIDATE. SO A DISCOVERY AWARD WOULD LEAD AN APPLICANT TO ACHIEVE AND CHARACTERIZE A CANDIDATE THAT THEN IS THE PREREQUISITE FOR GETTING A TRANSLATION AWARD. THE

TRANSLATION AWARD WOULD ALLOW AN APPLICANT TO MOVE FORWARD THROUGH -- AWARDEE, EXCUSE ME, THROUGH THE STAGES OF TRANSLATION TO ACHIEVE A PRE-IND MEETING OR OTHER PRESUBMISSION MEETING. AND THEN THAT IS THE PREREQUISITE FOR A CLINICAL PROGRAM.

THE IDEA BEHIND THIS IS THAT WE'VE CREATED THE RUNGS ON A LADDER THAT ALLOW A PROJECT TO PROCEED IN AN APPROPRIATE WAY THROUGH THIS PATH. BUT THEN WE ALSO HAVE OUR INFRASTRUCTURE PROGRAMS, SUCH AS ALPHA CLINICS, LET'S SAY, THAT SUPPORTS OUR CLINICAL PROGRAMS. SO THE ALPHA CLINICS PROVIDES CLINICAL TRIAL SUPPORT THROUGH CLINICAL TRIAL COORDINATION, THROUGH ENROLLMENT AND RECRUITMENT HELP. AND SO THAT HELPS SUPPORT THE ACTIVITIES THAT HAPPEN IN THE CLINICAL PROGRAM. WE HAVE OTHER INFRASTRUCTURE PROGRAMS SUCH AS THE MANUFACTURING, SHARED LABS, AND SO ON THAT ARE INTENDED TO DO THE SAME THING.

WE HAVE OUR EDUCATION PROGRAM THAT PROVIDES IN MANY WAYS THE WORKFORCE THAT IS UTILIZED WITHIN ALL OF THE RESEARCH PROGRAMS WE HAVE, BUT WITH THE INTENT TO CREATE A DIVERSE COHORT OF INDIVIDUALS THAT ARE ALSO SKILLED AND KNOWLEDGED IN CELL AND GENE THERAPY.

SO LOOKING AT IT THIS WAY, WE SEE THE

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CONNECTIONS AND CAN APPRECIATE THE RELATIONSHIPS BETWEEN THEM A LITTLE BETTER.

THE FUNDING OPPORTUNITIES THAT ARE TIED, THEN, TO EACH OF THESE PILLARS HAPPEN THROUGH A VERY SPECIFIC APPLICATION AND REVIEW PROCESS, AND I'LL DESCRIBE THAT BRIEFLY. EVERYTHING THAT WE ISSUE REQUIRES APPLICANTS TO APPLY, TO SUBMIT A PROPOSAL TO CIRM THAT WE CAN LOOK AT AND ASSESS FOR MERIT. SO OUR FUNDING OPPORTUNITIES ARE DESCRIBED IN WHAT WE CALL EITHER A REQUEST FOR APPLICATIONS, AN RFA, OR A PROGRAM ANNOUNCEMENT, A PA. SO THESE DOCUMENTS PROVIDE ALL THE REQUIREMENTS AND ALL OF THE NECESSARY ELEMENTS THAT ARE APPROPRIATE FOR THAT PROGRAM INCLUDING WHAT'S ELIGIBLE AND WHAT'S NOT.

AND JUST TO GIVE YOU A BETTER SENSE OF THE TWO TYPES OF SOLICITATIONS THAT WE ISSUE, ONE IS A RECURRING FUNDING OPPORTUNITY WHICH WE CALL PROGRAM ANNOUNCEMENTS. AND SO THAT USUALLY IS APPLIED TO OUR CORE RESEARCH FUNDING. AND THE IDEA BEHIND A RECURRING FUNDING OPPORTUNITY IS THAT IT IS ESSENTIALLY THE SAME OPPORTUNITY THAT'S AVAILABLE MULTIPLE TIMES PER YEAR. AND EACH CYCLE IS LARGELY THE SAME AS THE PREVIOUS ONE. AND SO ONE GOOD EXAMPLE OF THAT IS OUR CLINICAL PROGRAM. THE CLINICAL PROGRAM HAS 12 CYCLES THAT WE RUN PER YEAR,

AND THERE'S AN APPLICATION DEADLINE AT THE END OF EVERY MONTH. AND SO IT IS ONGOING AND CONTINUES TO ACCEPT PROJECTS INTO OUR CLINICAL PROGRAM.

WE ALSO HAVE NONRECURRING FUNDING OPPORTUNITIES WHICH WE GENERALLY APPLY TO THOSE OPPORTUNITIES THAT WE MAY OFFER ONLY ONCE. SO THE ALPHA CLINICS, MANUFACTURING NETWORK ARE SOMETHING THAT WE WILL RUN ONCE, HOPE TO ESTABLISH THESE PROGRAMS, PUT THEM IN PLACE, BUT IT IS NOT AN OPPORTUNITY THAT WE WOULD NECESSARILY BRING UP AGAIN.

WE ALSO DO THIS FOR OUR EDUCATION PROGRAMS SIMPLY BECAUSE THOSE HAVE A TIME SPAN OF ABOUT FIVE YEARS. WE ISSUE FUNDING FOR A COHORT OF PROGRAMS, AND WE WON'T DO IT AGAIN FOR FOUR OR FIVE YEARS. AND TYPICALLY THOSE ARE A LITTLE DIFFERENT EACH TIME WE OFFER THE OPPORTUNITY.

AND SO THE RECURRING AND NONRECURRING OPPORTUNITIES ARE BOTH PART OF OUR TOOLKIT THAT WE CURRENTLY USE IN ORDER TO MAKE THESE SOLICITATIONS AND GET APPLICATIONS TO COME IN.

NOW, REGARDLESS OF THE PROGRAM TYPE, WHAT PILLAR IT BELONGS TO, THEY ALL HAVE TO GO THROUGH A VERY SPECIFIC APPLICATION AND REVIEW PROCESS. AND THAT IS BEST DESCRIBED IN THIS IMAGE, WHICH IS A

THREE-STEP PROCESS. SO APPLICATIONS THAT COME TO CIRM FIRST GO THROUGH AN ELIGIBILITY ASSESSMENT. AND THE ELIGIBILITY IS DONE INTERNALLY BY THE CIRM TEAM. WE LOOK AT VERY SIMPLE THINGS, OBJECTIVE, CRITERIA, IF YOU WILL, OF WHETHER AN APPLICATION IS COMPLETE, IF IT'S A COMPANY, WHETHER IT'S SOLVENT, WHETHER IT MEETS THE CRITERIA THAT WE HAVE ESTABLISHED IN THE PA OR RFA FOR A THERAPEUTIC CANDIDATE. AND THOSE THAT ARE APPROPRIATE AND ACCEPTED FOR REVIEW THEN GO ON TO THE MERIT REVIEW, WHICH IS TYPICALLY CONDUCTED BY THEY GRANTS WORKING GROUP.

AND SO THE GRANTS WORKING GROUP'S TASK IS TO ASSESS THE APPLICATIONS BASED ON THE SCIENTIFIC MERIT, AND THOSE CRITERIA ARE LAID OUT IN OUR RFA'S AND PA'S SO THAT IT IS CLEAR TO THE APPLICANTS WHAT IT IS THE GRANTS WORKING GROUP REVIEWERS WILL LOOK AT. AND BEYOND THE SCIENTIFIC ASSESSMENT, WE ALSO DO, AS YOU KNOW, THE DEI ASSESSMENT AT THIS STAGE. SO OUR PATIENT ADVOCATE MEMBERS OF OUR GRANTS WORKING GROUP PARTICIPATE IN SCORING FOR THOSE THAT ARE TRANSLATIONAL AND CLINICAL APPLICATIONS, PARTICIPATING IN DISCUSSION THAT HELPS US BETTER ASSESS THE DEI ELEMENTS AS WELL.

AND THEN THE OUTCOME OF THESE REVIEWS IS A

RECOMMENDATION TO THE CIRM BOARD. IN MOST CASES IT IS TO THE APPLICATION REVIEW SUBCOMMITTEE THAT MAKES THE FINAL DETERMINATION, BUT IN SOME CASES, SUCH AS WITH THE AAWG, THE ACCESS AND AFFORDABILITY WORKING GROUP, IT IS THE FULL BOARD. THE IDEA IS THESE RECOMMENDATIONS THAT ARE COMING TO THE BOARD ARE ONLY PART OF THE EQUATION THAT THE ICOC OR THE APPLICATION REVIEW SUBCOMMITTEE MAY USE IN MAKING THAT FUNDING DECISION. SO THERE'S THOSE RECOMMENDATIONS, BUT THERE ARE ALSO CIRM TEAM RECOMMENDATIONS THAT MAY COME TO YOU. THERE ARE ALSO PUBLIC COMMENT AND OTHER FACTORS THAT MAY CONTRIBUTE TO DETERMINING WHETHER CIRM SHOULD FUND A GIVEN PROJECT OR SET OF PROJECTS. AND PART OF THAT MAY BE STRATEGY, PORTFOLIO, OTHER ELEMENTS THAT COME INTO PLAY. AND SO THESE THREE STEPS IS SOMETHING THAT WE UTILIZE FOR ALL OUR PROGRAMS.

NOW, WHAT WE FUND, WHAT ACTUALLY COMES IN AND GOES THROUGH THIS PROCESS IS LARGELY DETERMINED BY THE MANDATE UNDER PROP 71 AND/OR PROP 14. AND IT'S PRETTY STRAIGHTFORWARD AND SIMPLE, AND I'VE ACTUALLY ATTEMPTED TO SUMMARIZE THAT IN FOUR BULLETS. THE MAIN ONE BEING RESEARCH USING STEM AND PROGENITOR CELLS AND NOW UNDER PROP 14 WHAT WE DEFINE AS GENETIC THERAPIES. AND SO THAT HAS BEEN

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FROM THE ONSET AN IMPORTANT ELEMENT. BUT ALSO RESEARCH THAT GENERALLY THE NIH AND THE FEDERAL GOVERNMENT DO NOT SUPPORT OR DOES NOT SUPPORT SUFFICIENTLY.

AND SO THE CASE THAT WE HAVE MADE, EVEN THOUGH IT IS TRUE THAT NIH FUNDS STEM CELL RESEARCH, THEY CERTAINLY HAVE REGENERATIVE MEDICINE PROGRAMS AND RESEARCH THAT INVOLVES STEM CELLS, IS THAT WE HAVE A VERY UNIQUE FUNDING MODEL. SO WE TEND TO FUND RESEARCH AT LATER STAGES, PARTICULARLY THAT VALLEY OF DEATH, THE TRANSLATIONAL AND CLINICAL STAGES. WE TEND TO SUPPORT RESEARCH AND ACTIVITIES THAT THE FEDERAL GOVERNMENT AND NIH DO NOT. AND WE ALSO PROVIDE A LEVEL OF SUPPORT FOR AWARDEES THAT GENERALLY IS UNPRECEDENTED IN OTHER FUNDING AGENCIES. AND SO THOSE ARE OUR KEY ELEMENTS THAT DO DISTINGUISH US FROM NIH AND THE FEDERAL GOVERNMENT.

ALSO IMPORTANTLY PART OF OUR MANDATE IS THE DEVELOPMENT OF THERAPIES AND CURES. SO ALL OF OUR WORK, ALL OF THE RESEARCH THAT WE DO, ALL OF OUR PROGRAMS ARE DIRECTED IN SOME WAY TOWARDS THAT GOAL. NOW, UNDER PROP 14 TO ALSO MAKE THEM AFFORDABLE AND ACCESSIBLE, AND THAT'S SOMETHING THAT WE STILL HAVE TO TACKLE.

AND THEN, FINALLY, SOMETHING THAT WE'VE

TALKED ABOUT EARLIER TODAY AND IN OTHER MEETINGS IS THE ALLOCATION THAT HAS BEEN SPECIFICALLY SET FOR DISEASES OF THE BRAIN. AND SO HOW THAT IS INCLUDED AND ACCOUNTED FOR WITHIN THE MANDATE IS SOMETHING THAT WE WILL ALSO CONTINUE TO TALK ABOUT.

BUT OTHER THAN THAT, THERE IS NO SPECIFIC DIRECTIVE TOWARDS A SPECIFIC DISEASE, CONDITION, ANY SCIENTIFIC DISCIPLINES THAT MUST BE ACCOUNTED FOR OR ANY STAGE OF RESEARCH THAT WE MUST TAKE ON. SO THERE IS STILL WITHIN OUR MANDATE QUITE A BIT OF FLEXIBILITY IN WHAT WE DO.

AND I'LL SHOW YOU ONE MORE SLIDE AS IT RELATES TO THE SCOPE OF WHAT IT IS THAT WE DO JUST BECAUSE IT'S A GOOD EXAMPLE OF HOW IT IS THAT WE DETERMINE WHAT COMES IN AS AN APPLICATION. AND OFTENTIME THIS RELATES TO THE SUPPORT OF DIFFERENT THERAPEUTIC CANDIDATE TYPES. SO OVER THE YEARS THIS HAS CHANGED A LITTLE BIT HERE AND THERE, BUT GENERALLY WE HAVE SUPPORTED CELL THERAPIES WHERE A STEM OR PROGENITOR CELL IS A COMPONENT OF THAT THERAPY OR IS USED TO MANUFACTURE IT. WE ALSO, BEYOND THE ACTUAL CELL THERAPY, WHICH IS WHAT MOST PEOPLE THINK ABOUT WITH RESPECT TO REGENERATIVE MEDICINE, ARE SMALL MOLECULES OR BIOLOGICS. THESE ARE JUST SMALL MOLECULE DRUGS THAT ACT ON A STEM

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CELL, WHETHER IT'S AN ENDOGENOUS STEM CELL OR A CANCER STEM CELL, TO EXERT A THERAPEUTIC EFFECT. WE ALSO ALLOW FOR, FOR EXAMPLE, ANY BIOLOGIC THAT CAN MODIFY A STEM CELL THERAPY, SO AN IMAGING AGENT, FOR EXAMPLE, OR WHERE A STEM CELL IS NECESSARY TO MANUFACTURE IT. SO THESE ARE EXTRACELLULAR VESICLES, FOR EXAMPLE, THAT CAN BE GENERATED.

SO ALL OF THOSE DIFFERENT TYPES OF THERAPEUTIC CANDIDATES AND MODALITIES QUALIFY FOR CIRM FUNDING. SO IT IS A PRETTY BROAD WINDOW. AND NOW UNDER PROP 14 WE HAVE ALSO ADDED THE GENETIC THERAPY. AND SO THIS WE HAVE DEFINED QUITE BROADLY AS WELL. THIS IS BEYOND JUST THE GENE THERAPY THAT MANY PEOPLE KNOW, WHICH IS ENCOMPASSED UNDER ANYTHING THAT ALTERS THE GENOMIC SEQUENCE OF CELLS. IT IS ALSO ANY THERAPEUTIC THAT INTRODUCES OR DIRECTLY MANIPULATES NUCLEIC ACIDS. SO NOW WE HAVE M-RNA'S, ANTISENSE OLIGOS, AND SO ON THAT ARE PART OF THE SCOPE OF WHAT WE CAN FUND.

AND SO ALL OF THIS BACKGROUND I'M GIVING TO YOU IS PART OF A WAY OF INFORMING YOU WHAT IT IS THAT WE DO, BUT ALSO HOPING TO INSPIRE YOU TO THINK ABOUT, AS WE MOVE FORWARD, AND THINK ABOUT PRIORITIZATION, HOW THAT MODEL THAT WE HAVE BEEN USING EITHER COULD BE TWEAKED, CHANGED, MODIFIED, OR

CONTINUE TO BE USED IN A WAY THAT IS BETTER FOCUSED ON US ACCOMPLISHING OUR MISSION. SO TOWARDS THAT END, THERE'S A SERIES OF QUESTIONS THAT I'LL GO OVER VERY BRIEFLY, BUT ARE NOT INTENDED FOR US TO DISCUSS HERE, BUT MAYBE ARE AN INSPIRATION FOR WHAT THE SCIENCE SUBCOMMITTEE AND DR. IMBASCIANI WAS REQUESTING THAT COULD BE TAKEN ON.

AND ONE OF THE MOST IMPORTANT QUESTIONS IS HOW IS IT THAT CIRM CAN MAKE THE GREATEST IMPACT ON ITS MISSION? NOW, THIS QUESTION, AS WELL AS ALL THESE OTHER QUESTIONS THAT ARE I'M GOING TO GO THROUGH ARE ONES THAT WE'RE NOT JUST ASKING NOW. WE'VE BEEN ASKING THESE ALL ALONG THE WAY. THIS HAS BEEN ESSENTIAL IN DEVELOPING THE STRATEGIC PLAN THAT WE HAVE AS WELL AS THE STRATEGIC PLANS THAT WE HAVE THAT HAVE COME BEFORE THAT. BUT IT IS SOMETHING THAT IS AN ONGOING PROCESS. WE NEED TO CONTINUOUSLY BE ASKING THESE QUESTIONS TO SEE WHETHER WE ARE STILL ON TASK.

AND SO HOW IS IT THAT WE CAN MAKE THE GREATEST IMPACT? WE HAVE A VERY GENEROUS AMOUNT OF FUNDS TO WORK WITH, BUT IT'S ALSO NOT UNLIMITED. AND SO HOW WE CHOOSE TO FOCUS AND BRING THAT TOGETHER IN ORDER TO MAKE AN IMPACT IS A KEY QUESTION. HOW NARROW OR HOW BROAD SHOULD OUR

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PORTFOLIO BE AS IT RELATES TO DIFFERENT ELEMENTS? DISEASE REPRESENTATION, FOR EXAMPLE, IS ONE THAT OFTEN COMES UP. SHOULD WE SEEK TO HAVE AS MANY DISEASES AS POSSIBLE REPRESENTED WITHIN OUR PORTFOLIO? OR IS IT OKAY TO MAYBE FOCUS IN ON THOSE THAT ARE MOST LIKELY TO BE IMPACTED BY CELL AND GENE THERAPY APPROACHES?

QUALIFYING CANDIDATES. AS I SHOWED YOU, WE HAVE A VERY BROAD ARRAY OF WHAT QUALIFIES FOR CIRM FUNDING. IN SOME CASES THE LINE CAN GET A LITTLE BIT BLURRY EVEN AT THE ELIGIBILITY STAGE. FOR EXAMPLE, WHAT DETERMINES WHAT IS A CANCER STEM CELL? EVEN IN THE FIELD, IT ISN'T ALWAYS ACCEPTED THAT A GIVEN CELL TYPE IS A CANCER STEM CELL OR WHAT MAY BE A PROGENITOR CELL OR WHAT SHOULD BE INCORPORATED WITHIN THE DEFINITION OF A GENETIC THERAPY. WE CREATED A DEFINITION, BUT THAT CAN CHANGE DEPENDING ON WHAT WE THINK OUR PRIORITIES MIGHT BE. OR HOW DO WE ADDRESS HAVING SIMILAR THERAPEUTIC APPROACHES? CAR-T COMES UP AS AN EXAMPLE BECAUSE WE SEE THAT A LOT. THAT COMES QUITE OFTEN, BUT THERE ARE OTHERS. IS IT OKAY TO TAKE ON THE SAME APPROACH? AND HOW MANY PROJECTS ARE SUFFICIENT TO SAY THAT WE'VE COVERED THAT ARENA?

WHICH LEADS TO THE NEXT QUESTION: HOW

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MUCH FUNDING SUPPORT IS ACTUALLY NECESSARY WITHIN A GIVEN THERAPEUTIC APPROACH OR WITHIN A STAGE OF RESEARCH OR A DISEASE FOR US TO HAVE A MEANINGFUL IMPACT? AND THAT IS IMPORTANT BECAUSE THERE MAY BE CASES WHERE WE MAY HAVE ONLY TWO PROJECTS IN A GIVEN DISEASE AREA OR THAT USE AN APPROACH. HOW MUCH OF AN IMPACT OVER OUR TIME FRAME WILL THAT MAKE?

AND THEN, LASTLY, WHAT IS OR WHAT ARE THE MOST IMPORTANT OUTCOMES FOR CIRM IN TEN YEARS? LOOKING INTO THE FUTURE AND THINKING OF WHAT WE'D LIKE TO ACCOMPLISH, WHERE WE WOULD LIKE TO BE, WHAT WOULD WE HAVE TO DO TODAY IN ORDER TO ACCOMPLISH THOSE ELEMENTS? AND, AGAIN, THESE ARE QUESTIONS NOT FOR TODAY, BUT HOPEFULLY TO INSPIRE YOUR THINKING AND HOPEFULLY THAT IT DOES. SO THAT IS MY PRESENTATION, AND I THANK YOU VERY MUCH.

(APPLAUSE.)

CHAIRMAN IMBASCIANI: WE'RE GOING TO START WITH LEONDRA.

DR. CLARK-HARVEY: THANK YOU FOR YOUR PRESENTATION. I REALLY APPRECIATE IT. AND I KNOW YOU SAID THE QUESTIONS AREN'T FOR TODAY, BUT I'M DYING TO HAVE A FEW COMMENTS TODAY. IS THAT OKAY? IS THAT OUT OF ORDER?

I LOVE THE SLIDE THAT YOU HAD THAT

REMINDED US OF OUR SCOPE. AND I THINK ONE OF THE STRENGTHS OF CIRM IS THE ABILITY TO GO OUTSIDE WHAT'S TYPICALLY FUNDED AND TYPICALLY SUPPORTED. I THINK THAT JUST LEADS TO DIVERSITY AND THOUGHT AND INNOVATION. AND THAT'S REALLY, I THINK, A VALUE OF CIRM.

AND IN LINE WITH THAT, YOUR QUESTION AROUND SHOULD WE STAY NARROW, SHOULD WE GO BROAD, I KNOW GOING NARROW MAY SEEM MORE FOCUSED AND STRATEGIC IN SOME WAYS, BUT I THINK THE ABILITY TO STAY BROAD IN SOME WAYS DOES CORRELATE WITH THE SCOPE OF THINKING OUTSIDE THE BOX AND INNOVATION IN DIFFERENT WAYS AND ALSO REALLY VALUING THE DIVERSITY. I THINK ABOUT THE STORIES THAT WERE SHARED THIS MORNING BY MARIA AND THE FACT THAT THESE INNOVATIONS WERE SUPPORTED AND CONTINUE TO BE SUPPORTED.

SO I WOULD HATE TO DO SOMETHING THAT WOULD POTENTIALLY PUT US IN A SPACE WHERE WE'RE NOT ABLE TO FUND SOMETHING THAT COMES UP THAT IS REALLY INNOVATIVE AND IMPORTANT WORK. AND SO I WOULD, EVEN THOUGH YOU DIDN'T ASK FOR QUESTIONS AND RESPONSES RIGHT NOW, I REALLY AM LEANING INTO WHAT'S ATYPICAL, WHICH IS BEING PRETTY BROAD AND OPEN TO THE DIVERSITY OF DIFFERENT APPROACHES. WANTED TO SHARE

THAT.

AND IN TEN YEARS, I REALLY DO HOPE THAT WE'RE ABLE TO SAY THAT WE DID THAT. JUST TODAY AS FOLKS ARE REPORTING ON THE WONDERFUL THINGS THAT WE DID BECAUSE WE STEPPED OUTSIDE THE BOX, I WANT TO BE ABLE TO SAY THAT IN TEN YEARS AS WELL. UNSOLICITED INPUT.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH. I THINK NEXT IS MEMBER DULIEGE.

DR. DULIEGE: THANK YOU. WE'RE ALL GOING TO AGREE, PROBABLY NOT ALL. I SHOULDN'T SAY THAT, BUT I DO AGREE. GREAT PRESENTATION.

CAN YOU GIVE US A FEW EXAMPLES OF SOME OF THE CHALLENGES THAT THE CIRM TEAM HAS ALREADY FACED WHEN REVIEWING THE APPLICATION INITIALLY, THE FIRST SCREEN BEFORE IT GOES TO GWG, AND SPECIFICALLY ABOUT THE DEFINITION, NOT SO MUCH ABOUT THE QUALITY, THE DEFINITION.

AND YOUR SECOND POINT HERE, HOW HAS THE TEAM ADDRESSED THAT, FACED THAT BECAUSE IT'S A REAL CHALLENGE. YOU REALLY ELOQUENTLY DESCRIBED HOW DEFINITIONS CAN BE BLURRIER THAN WHAT WE THINK.

DR. SAMBRANO: THAT'S RIGHT. IT CONTINUES TO BE CHALLENGING BECAUSE IT SEEMS ANYWHERE WE TRY TO DRAW A LINE, THERE IS ALWAYS GOING TO BE A

PROJECT THAT JUST STRADDLES THAT LINE. AND WHAT WE DO IS WE HAVE GROUP DISCUSSIONS ABOUT THESE, AND WE ATTEMPT TO BE CONSISTENT IN OUR INTERPRETATION. AND SO WE MAKE SURE THAT IF WE SAY, OKAY, SOMETHING THAT WAS STRADDLING THE LINE THAT WE DECIDED WAS ELIGIBLE, THAT IF WE SEE ANYTHING THAT LOOKS LIKE THAT AGAIN, THAT WE TREAT IT THE SAME WAY. AND IT DOES TAKE EFFORT AND TIME, AND I THINK THAT'S THE CHALLENGE.

IN AN IDEAL WORLD, WE WOULD LIKE TO HAVE A VERY CLEAR DELINEATION THAT ALLOWS US TO SAY, OKAY, THIS PROJECT IS IN, THIS PROJECT IS OUT, BUT IT JUST HAS BEEN THE CASE THAT IT'S NOT THAT EASY. FOR SOME THINGS IT IS SIMPLE; BUT WHERE A FIELD CONTINUES TO MOVE AND EVOLVE AND DEFINITIONS WITHIN A FIELD CHANGE AND OPINIONS CHANGE, IT IS SORT OF THE MOVING TARGET THAT WE JUST HAVE TO KEEP UP WITH.

AND I'M NOT SURE, OTHER THAN WHAT WE ARE DOING, WHAT ELSE WE CAN DO.

DR. DULIEGE: I WAS ASKING IF YOU HAD ONE OR TWO SPECIFIC EXAMPLES.

DR. SAMBRANO: I'M SORRY. SO THE ONES THAT OFTEN COME UP ARE A SMALL MOLECULE THAT TARGETS A CANCER STEM CELL OF SOME TYPE. AND THERE WE OFTEN LOOK TO SEE IS THERE EVIDENCE THAT THIS TUMOR TYPE

ACTUALLY INVOLVES OR HAS CANCER CELLS, WHAT DATA DOES THE APPLICANT PROVIDE AND SHOW TO SAY THAT THEY HAVE AN ACTUAL CANCER STEM CELL THAT THEY ARE TARGETING. SO THAT'S ONE EXAMPLE OF WHAT WE DO. AND IT'S SIMILAR WITH PROGENITOR CELLS. SOMETIMES IN CERTAIN DISCIPLINES SOMEBODY IDENTIFIES AN ENDOGENOUS STEM CELL TYPE THAT ARGUABLY MAY OR MAY NOT BE ONE. WE ALSO HAVE A VERY BROAD DEFINITION OF WHAT A PROGENITOR IS. THE QUALIFIER IS THAT IT MUST BE NOT A COMPLETELY MATURE CELL IN THAT IT HAS THE CAPACITY TO DIVIDE. AND THERE ARE CELLS THAT MAYBE IN THE FIELD IT WOULD NOT BE ACCEPTED AS A PROGENITOR, BUT IT STILL MEETS THE DEFINITION. SO IN SOME CASES WE WOULD ALLOW IT.

CHAIRMAN IMBASCIANI: MEMBER YAMAMOTO.

DR. YAMAMOTO: STEPPING BACK FROM THESE CHALLENGES OF HAVING TO MAKE CHOICES ABOUT SPECIFIC DISEASE AREAS OR PROJECTS, I THINK ONE OF THE STRIKING THINGS ABOUT WHAT CIRM HAS DONE HISTORICALLY IS THE BALANCE THAT IT HAS REALLY EXERCISED IN SUPPORTING THE DIFFERENT RESEARCH APPROACHES. I DON'T THINK THERE'S ANY REASON TO TRY TO BE SLAVISH ABOUT THIS. DIFFERENT KINDS OF RESEARCH COST DIFFERENT AMOUNTS OF MONEY. BUT NEVERTHELESS, IT IS REALLY INTERESTING, AS MARIA

SHOWED IN ONE OF HER GRAPHICS, THAT HISTORICALLY CIRM HAS REALLY SUPPORTED BASIC RESEARCH, TRANSLATIONAL, AND CLINICAL REALLY ACROSS THE BOARD ROBUSTLY.

THAT'S NOT TRUE IN THE RECENT EXPENDITURES. I THINK THAT WAS THE OTHER STRIKING THING THAT I TOOK AWAY FROM THAT SLIDE IS THAT IN THE REALLY RECENT HISTORY, WHAT WE'VE SEEN IS A MUCH STRONGER LEVEL OF SUPPORT IN TERMS OF DOLLARS THAT HAVE GONE TO CLINICAL RESEARCH. I'M ASSUMING THAT DOESN'T REPRESENT A TREND OR A DECISION. IT'S JUST A POINT IN TIME. BUT IF YOU COULD SPEAK TO THAT POINT SPECIFICALLY, I THINK WOULD BE HELPFUL.

DR. SAMBRANO: IN MANY WAYS THE DEMAND, IF YOU WILL, THAT IS OUT THERE, AS WAS MENTIONED, HAS INCREASED OVERALL FOR ALL PROJECTS. BUT AS YOU ALSO INDICATED, FOR SOME PROJECTS IT'S GREATER COST, PARTICULARLY WHEN YOU'RE LOOKING AT CLINICAL TRIALS. SO WE ARE FACED WITH THE QUESTION OF HOW MUCH CAN CIRM ACTUALLY HANDLE WHEN WE DEAL WITH THIS DEMAND. IN SOME AREAS IT IS REASONABLE, WE HAVE MECHANISMS IN PLACE TO DO IT, BUT WE HAVE A CONTINUINGLY GROWING NUMBER OF APPLICATIONS THAT CONTINUE TO COME TO US THAT WOULD BENEFIT FROM US HAVING A BETTER UNDERSTANDING OF WHAT WE WANT TO EITHER PRIORITIZE,

AS WE'VE BEEN TALKING ABOUT, OR CHOOSE TO FUND OVER OTHERS. BECAUSE IT'S NOT AN ISSUE OF MERIT WHERE I THINK WHERE WE STARTED IT WAS LET THE SCIENCE DETERMINE WHAT WE FUND BECAUSE THE MERIT ALONE WAS ENOUGH TO KEEP THE NUMBER OF PROJECTS AND THE AMOUNT OF FUNDS THAT WE WOULD ISSUE TO THEM TO BE ALIGNED.

NOW WE MAY BE GETTING TO A POINT WHERE THE NUMBER OF MERITORIOUS PROJECTS EXCEEDS WHAT WE MAY WANT TO ACTUALLY EXPEND ON AN ANNUAL BASIS. AND SO THEN COMES THE QUESTION OF THEN WHICH ONES DO WE CHOOSE. AND AMONG A SET OF ALL MERITORIOUS PROJECTS, WHICH ONES ARE THE MOST LIKELY TO HELP US ACHIEVE OUR MISSION OR HAVE AN IMPACT? AND SO I KIND OF TWIRLED AROUND TRYING TO ANSWER YOUR QUESTION, BUT IT MAYBE GIVES A LITTLE CONTEXT AS TO HOW WE'RE THINKING ABOUT IT IN TERMS OF THAT PERSPECTIVE.

CHAIRMAN IMBASCIANI: THANK YOU. MEMBER JUELSGAARD AND THEN WE'LL JUST CONTINUE AROUND THE TABLE.

MR. JUELSGAARD: THANKS, AGAIN, GIL, FOR THE PRESENTATION. SO THE LAST SLIDE POSED FOUR STRATEGIC QUESTIONS. I ASSUME THE REASON FOR POSING THE QUESTIONS IS TO DEVELOP ANSWERS, AND THOSE ANSWERS WILL BE DISCUSSED HERE IN THIS ROOM OR A

ROOM LIKE THIS AT SOME POINT.

I'M GOING TO FOCUS FOR A MOMENT ON THE THIRD ONE BECAUSE THAT'S THE ONE THAT FOR ME, ANYWAY, BASED UPON BEING ON THE NEURO TASK FORCE AND SOME OF THE THINGS THAT WE'VE HEARD, PARTICULARLY ANECDOTALLY, IS WHETHER WE HAVE ENOUGH FUNDING SUPPORT. SO OUR FUNDING SUPPORT, IF YOU GO BACK, I LOOKED BACK, WHAT, IN 2016 I THINK THE AWARD LEVELS WERE THE SAME IN 2016 AS THEY ARE TODAY. WE HAVEN'T CHANGED THE AMOUNT OF AWARDS WE'RE MAKING, AND YET I'M SURE MANY OF US ARE AWARE OF THE IMPACT OF INFLATION AND PARTICULARLY MORE RECENTLY.

AND SO IS THERE A -- HOW MUCH THOUGHT IS BEING GIVEN TO REALLY LOOK AT OUR FUNDING LEVELS? AND THIS FOLLOWS DR. YAMAMOTO'S QUESTION PARTICULARLY IN THE AREA OF DISCOVERY AND OF TRANSLATIONAL WORK TO SAY WHETHER OR NOT THEY'RE SUFFICIENT AND EVEN WITH SPECIFIC AREAS THE ANECDOTAL ISSUE I REFERRED TO IS NEUROPSYCHIATRIC RESEARCH WHICH INVOLVES A LOT OF GENETIC RESEARCH WHICH IS NOT SIMPLE AND NOT INEXPENSIVE.

AND SO, ANYWAY, I'M JUST HOPEFUL THAT WE TAKE A GOOD LOOK AT THAT AND WHETHER WE OUGHT TO THINK ABOUT MAKING SOME CHANGES AT LEAST IN SOME SPECIFIC AREAS. THANK YOU.

DR. SAMBRANO: YES. AND WE ARE SPECIFICALLY LOOKING AT THE BUDGET CAPS THAT WE HAVE FOR EACH OF THE PROGRAMS TO ENSURE THAT THEY'RE APPROPRIATE. BUT AS YOU KNOW, THERE IS QUITE A BIT OF VARIABILITY AMONG PROJECTS AND THE DIFFERENT ACTIVITIES THAT THEY CONDUCT, THAT IN SOME CASES JUSTIFY A GREATER AMOUNT AND IN OTHER CASES MAYBE NOT.

CHAIRMAN IMBASCIANI: THANK YOU, GIL. MEMBER BARRETT.

DR. BARRETT: THANK YOU, GIL, VERY MUCH FOR YOUR PRESENTATION. I REALLY WANTED IN SOME WAYS TO ECHO WHAT LEONDRA SAID, THAT IT IS IMPORTANT WITHIN THE CONSTRAINTS OF WHAT THE AGENCY WAS SET UP TO DO TO REMAIN AS BROAD AS POSSIBLE BECAUSE HISTORY HAS SHOWN US THAT WE ARE PRETTY FOOLISH IF WE THINK THAT WE CAN TRULY PREDICT WHAT IS GOING TO BE THE MOST IMPACTFUL. LETTING THINGS BUBBLE UP FROM THE SCIENTIFIC COMMUNITY, MAKING SURE THAT WE DO CONTINUE TO SUPPORT DISCOVERY RESEARCH EVEN THOUGH THE IMPACT OF THAT MAY BE A LONG WAY DOWN THE ROAD AND PERHAPS BEYOND MANY OF OUR LIFE SPANS DOESN'T MEAN THAT WE SHOULDN'T BE SUPPORTING IT.

SO A BALANCE BETWEEN THE QUICK WINS AND THE BLUE SKY RESEARCH THAT MAY BE EXTREMELY

IMPACTFUL IF JUDGED TO BE HIGHLY MERITORIOUS. BUT I DO NOT PERSONALLY SEE, OTHER THAN THE CONSTRAINTS OF THE PROPOSITION LEGISLATION, THAT WE SHOULD BE TARGETING SPECIFIC DISEASE STATES. THERE'S A LOT OF SUFFERING TO GO AROUND.

CHAIRMAN IMBASCIANI: I'LL TAKE THAT AS A COMMENT RATHER THAN A QUESTION. SO MEMBER SOUTHARD.

DR. SOUTHARD: I ALSO WANTED TO BUILD ON THE REMARKS ALREADY MADE ABOUT THE THINGS THAT WE'VE BEEN TALKING ABOUT IN THE NEURO TASK FORCE PARTICULARLY ON NEUROPSYCH WHERE IT'S CLEARLY AN AREA THAT WE HEAR. WE DON'T GET PROPOSALS BECAUSE THE PROPOSALS TO DO REAL ACTION WOULD BE VERY EXPENSIVE, AND YET THEY'RE AT THE VERY BEGINNING STAGES. SO IN THE TEN-YEAR AREA, I WOULD HOPE THAT WE ARE ABLE TO AT LEAST BEGIN TO START TO MAKE AN EFFECT ON THE ISSUES OF SEVERE MENTAL ILLNESS AND ADDICTION AS ONE OF THE THINGS THAT BECOMES OUR HALLMARK. THAT WOULD BE THE HOPE OF MANY OF US HERE.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH. ANY OTHER COMMENTS IN THE ROOM? VICE CHAIR.

VICE CHAIR BONNEVILLE: I ALSO WANTED TO COMMENT ON CAPACITY FOR OUR REVIEW TEAM AND HOW MANY REVIEWS WE CAN HAVE A YEAR. THAT REALLY ALSO

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DETERMINES HOW MUCH MONEY IS PUT OUT IN DIFFERENT AREAS. SO IT ALSO -- FOR DISCOVERY, HOW MANY ROUNDS DO WE HAVE OF DISCOVERY VERSUS HOW MANY ROUNDS DO WE HAVE OF CLIN VERSUS HOW MANY ROUNDS WE HAVE OF TRANSLATION. SO THAT'S ALSO SOMETHING TO TAKE INTO CONSIDERATION, KEITH, WITH YOUR QUESTION. SO IT'S NOT JUST DOLLARS ALLOCATED, BUT IT'S WHAT THE CAPACITY IS AND WHAT THE BOARD THINKS IS BEST.

CHAIRMAN IMBASCIANI: MEMBER DURON.

MS. DURON: GIL, YOU SAID IT'S NOT ALWAYS EASY, BUT I THINK THAT'S WHAT CIRM IS ALL ABOUT. IT IS A MAVERICK. IT WAS MADE TO EXIST BECAUSE THE FEDS WOULDN'T DO IT. AND SO WE ARE ALWAYS REACHING HIGHER THAN PERHAPS PEOPLE THINK IS REASONABLE. WE'RE SHOOTING FOR THE STARS HERE. WE ARE SHOOTING FOR THE HOPES AND DREAMS OF PEOPLE WHO ARE ILL, AS KIM SAID. TO EVERY PERSON WHO'S ILL LOOKING FOR AN ANSWER, THIS IS WHAT WE ARE ABOUT. SO I DON'T -- I NEVER -- I ALWAYS WANT TO DO RISK, AND I ALWAYS WANT TO SHOOT AS HIGH AS WE CAN. AND, YES, THERE ARE REASONABLE PEOPLE WHO MIGHT HELP US KEEP SOME FEET ON THE GROUND, BUT I THINK THAT WHAT CIRM IS ALL ABOUT IS ABOUT SHOOTING FOR THE HIGHEST AND HOPING FOR THE BEST RESULTS WE CAN GET AND THEN LEADING, HELPING LEAD THE SCIENCE. AND SO I'M NOT

FOR CLIPPING WINGS. I'M FOR ADDING NEW OPPORTUNITY. SO THANK YOU. PERHAPS WITHIN THE WORK WE'VE ALREADY DONE, THEY'RE STARTING TO SHOW US SOME ANSWERS THAT WE CAN LOOK AT TO SEE WHAT ARE THE GOOD OUTCOMES, HOW LONG IT TAKES TO GET TO THESE GOOD OUTCOMES, ET CETERA, ET CETERA, SO WE CAN START THERE WITH SOME BASELINE DATA.

CHAIRMAN IMBASCIANI: THANK YOU, BOARD MEMBERS, FOR YOUR COMMENTS AND QUESTIONS. GIL, THANK YOU VERY MUCH FOR A GREAT PRESENTATION. I HAVE A FEELING, WHEN THE BOARD DISCUSSES THIS TOPIC IN THE MONTHS AND MONTHS TO COME, THEY'RE GOING TO REFER BACK. REMEMBER WHAT GIL SAID ON JUNE 29TH. SO THIS WAS VERY IMPORTANT FOR US TO HEAR. I THINK IMPORTANT FOR BOARD MEMBERS, REGARDLESS OF HOW MANY YEARS OF TENURE ON THE BOARD, ESPECIALLY IF YOU'RE NEW, TO HAVE HAD A REALLY FUNDAMENTAL REVIEW OF OUR WHOLE FUNDING PROCESS. SO IT WAS A DOUBLE WHAMMY. THANK YOU VERY MUCH.

I AM GOING TO DO ONE MORE THING AND PROCEED TO THE CONSENT CALENDAR AND THEN WE'LL TAKE A SHORT BREAK. BEFORE WE GO TO THE CONSENT, LET ME ADD AN ADDENDUM TO THE CHAIR'S REPORT. I STARTED BY SAYING I HAD TOURED THE STATE AND VISITED SIX OF OUR NINE ALPHA CLINICS. AND THEN WHEN I WAS DONE

SPEAKING, I ONLY TICKED OFF FIVE ON MY FINGERS. I CREDIT IT TO THE NERVOUSNESS OF A MAIDEN VOYAGE, IF YOU WILL. I THINK I LEFT OUT ONE, AND I THINK IT WAS UC IRVINE. I DID NOT MEAN TO SLIGHT ANYONE BY OVERSIGHT. SO I APOLOGIZE. BUT THE RECEPTION THERE WAS EQUAL IN ENTHUSIASM AND COMPLETENESS AS ALL THE OTHERS. SO THANK YOU.

SO THE CONSENT CALENDAR, YOU KNOW HOW THIS WORKS. THIS IS SOMETHING THE BOARD LEADERSHIP HAS DETERMINED IT PROBABLY CONTAINS NONCONTROVERSIAL ITEMS WHICH CAN BE VOTED ON UNLESS ANYONE AT THE TABLE, ANY BOARD MEMBER, WHETHER YOU'RE HERE IN THE ROOM OR NOT, HAS AN ISSUE WITH ANY ONE, THEN YOU WOULD EXCERPT IT. AND IF YOU DO TAKE IT OUT OF CONSENT, WE WILL DISCUSS THE REASONS WHY YOU WANT TO CONSIDER IT SEPARATELY AT A SLIGHTLY LATER POINT IN THE AGENDA.

SO UNDERSTANDING THAT, I WOULD LIKE TO KNOW ARE THERE ANY -- DOES ANY BOARD MEMBER HAVE ANY DESIRE TO REMOVE ANY ITEM FROM THE CONSENT AGENDA? HEARING NONE, I WOULD LIKE A MOTION AND A SECOND TO APPROVE ALL THE REMAINING ITEMS ON THIS CONSENT CALENDAR WHICH ARE ALL OF THEM.

DR. BARRETT: SO MOVED.

DR. SOUTHARD: SECOND.

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CHAIRMAN IMBASCIANI: WE HAVE A MOVE AND A SECOND. SO IS THERE ANY PUBLIC COMMENT ON THIS BEFORE WE PROCEED TO A VOTE?

MS. DEQUINA-VILLABLANCA: THERE ARE NONE.

CHAIRMAN IMBASCIANI: OKAY. THEN, SCOTT, I CAN GO TO A VOTE THEN, I PRESUME. ALL THOSE IN FAVOR PLEASE SAY AYE. THOSE OPPOSED SAY NAY.

SCOTT, WOULD YOU TAKE A ROLL CALL OF THOSE MEMBERS ON THE PHONE?

MR. TOCHER: HAIFAA ABDULHAQ. I'LL COME BACK. DAN BERNAL. I'LL COME A BACK. GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MR. TOCHER: LINDA BOXER.

DR. BOXER: YES.

MR. TOCHER: FRED FISHER. JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: LARRY GOLDSTEIN.

DR. GOLDSTEIN: YES.

MR. TOCHER: RICH LAJARA.

MR. LAJARA: YES.

MR. TOCHER: DAVID LO.

DR. LO: YES.

MR. TOCHER: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: YES.

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MR. TOCHER: MICHAEL STAMOS.
DR. STAMOS: YES.
MR. TOCHER: I'LL CALL THE OTHERS AGAIN. HAIFAA.
DR. ABDULHAQ: YES.
MR. TOCHER: DAN BERNAL. FRED FISHER. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANKS VERY MUCH. OKAY. THE BOARD WILL NOW ENJOY A SHORT RECESS.
(A RECESS WAS TAKEN.)
CHAIRMAN IMBASCIANI: I THINK WE ARE ABOUT TO CONVENE BACK INTO REGULAR ORDER HERE. THANK YOU VERY MUCH.
SO CHAIR'S DISCRETION, BECAUSE OF SOME OF THE EXIGENCIES OF SOME OF OUR BOARD MEMBERS, I'M GOING TO MOVE UP ITEM NO. 12 IN THE AGENDA. EVERYTHING ELSE WILL KEEP ITS ORDER. THIS IS THE CONSIDERATION OF FROM THE GOVERNANCE SUBCOMMITTEE, AND I'M GOING TO ASK DR. LEVITT TO MY LEFT TO TAKE IT FROM HERE.
DR. LEVITT: I WAS GOING TO ASK DR. GASSON ON MY RIGHT TO DO IT, BUT SHE'S NOT HERE AND YOU'RE SILENCED AS WELL.
SO LET ME PREFACE A FEW REMARKS ABOUT THE PROCESS. THIS IS TO TAKE UP THE CORE OF THE REVIEW

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OF THE PRESIDENT AND CEO. AND YOU HAD IN YOUR BRIEFING BOOK THE SURVEY, WHICH WILL BE THE ITEM TO VOTE ON.

JUST TO PREFACE, THE GOVERNANCE SUBCOMMITTEE MET ON JUNE 19TH. PRIOR TO JUNE 19TH, THE BOARD CHAIR, VICE CHAIR, AND THE CO-CHAIRS OF THE GOVERNANCE COMMITTEE MET TO DISCUSS A PROCESS THAT WE WOULD USE FOR THE RETROSPECTIVE ASSESSMENT OF DR. MILLAN THAT WOULD ENCOMPASS FY '23. SO THIS IS A RETROSPECTIVE REVIEW.

I DO WANT TO SAY THAT WE'VE HAD REALLY PRODUCTIVE CONVERSATIONS ABOUT THE GOVERNANCE COMMITTEE TAKING UP, AFTER THIS REVIEW, TO REVIEW THE PROCESS OF THE REVIEW AND TO WORK WITH THE PRESIDENT AND CEO AND THE CHAIR AND VICE CHAIR OF THE BOARD ABOUT MODIFYING THE PROCESS IN A VERY PRODUCTIVE WAY. SO WE HAVE HAD SOME VERY EXCITING CONVERSATIONS. AND SPEAKING ON BEHALF OF THE GOVERNANCE SUBCOMMITTEE, I THINK THEY'RE EXCITED ABOUT THIS AS WELL. HOPEFULLY I'M NOT EXAGGERATING. MARIA IS VERY EXCITED ABOUT THIS.

AND SO THE REVIEW PERIOD I'VE ALREADY MENTIONED. THE STAKEHOLDERS THAT ARE GOING TO COMPLETE THE SURVEY ARE THE BOARD CHAIR AND VICE CHAIR, THE CO-CHAIRS OF GOVERNANCE, THE CO-CHAIRS OF

THE OTHER BOARD SUBCOMMITTEES, AND THE DIRECT REPORTS TO THE PRESIDENT AND CEO. THERE WAS AN INDEPENDENT CONSULTANT WHO WAS ENGAGED, SUSAN WHITE, TO LOOK AT -- THE DECISION WAS MADE TO BRING TO THE GOVERNANCE SUBCOMMITTEE ESSENTIALLY THE SAME SURVEY THAT WAS DONE IN THE LAST REVIEW WITH SOME MINOR MODIFICATIONS THAT WERE MADE. IT'S NOT A 360. I WANT TO POINT THAT OUT. IT'S A SURVEY, AND WE'RE GOING TO TAKE UP A NUMBER OF THESE ISSUES PROBABLY AROUND SEPTEMBER.

SO WE HAD THE SUBCOMMITTEE MEETING TO DISCUSS THE PROCESS SURVEY AND THE TIMELINE, AND THAT WAS ALL APPROVED. THE PROCESS INVOLVES THE SURVEY, IT ALSO INVOLVES VIRTUAL INDIVIDUAL INTERVIEWS WITH THE BOARD CHAIR AND VICE CHAIR AND THE CO-CHAIRS OF THE MANY SUBCOMMITTEES FOR THIS BOARD, AND THEN SOME OF THE DIRECT REPORTS THAT WERE INVITED TO DO A VIRTUAL INTERVIEW. I THINK IT'S UP TO THEM TO DO THAT. THERE WILL BE THE SAME, IF YOU READ IT BEFORE THIS MEETING, THE COMPETENCY AREAS, THE REVIEW AREAS. WE ARE HAVING THIS MEETING TODAY ON THE 29TH TO APPROVE THAT SURVEY. THE BOARD CHAIR WILL COMMUNICATE TO DR. MILLAN, THE BOARD, AND THE DIRECT REPORTS TO INTRODUCE SUSAN WHITE AS THE INDEPENDENT CONSULTANT. THERE WILL BE AN EMAIL THAT

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GETS SENT OUT JULY 11TH WITH REQUESTS FOR RESPONSE BY THE 25TH. GIVEN THAT DR. YAMAMOTO IS ALWAYS LATE, WE'RE GOING TO ADD ANOTHER DAY OR TWO TO MAKE SURE THAT YOU GET YOUR SURVEY IN. THAT WAS JUST SPONTANEOUS. MOST BASIC SCIENTISTS ARE ALWAYS LATE. ABSOLUTELY.

SO THERE WILL BE A LATE RESPONSE WINDOW, AND THEN THE CONSULTANT WILL -- YOU ASKED ME TO DO THIS. THE CONSULTANT WILL COMPILE THE RESULTS, CREATE A PERFORMANCE REVIEW SUMMARY. WRITTEN PERFORMANCE SUMMARY WILL GO TO THE BOARD CHAIR AND VICE CHAIR AND THE GOVERNANCE COMMITTEE'S CO-CHAIRS. SUSAN WHITE WILL BE AVAILABLE TO MEET WITH US TO DISCUSS THE PERFORMANCE SUMMARY SOMETIME IN AUGUST LIKELY. AND THEN THERE WILL BE A BOARD MEETING IN SEPTEMBER IN WHICH THE PERFORMANCE REVIEW SUMMARY WILL BE DISCUSSED. SO THAT'S THE TIMELINE.

JUDY, DID I LEAVE ANYTHING CRITICAL OUT?

DR. GASSON: YOU DID NOT. IT WAS PERFECT.

DR. LEVITT: PERFECT. TELL MY FAMILY THAT. I NEVER HEAR THAT.

SO I THINK THAT WAS MY PREFACE, THAT WE ARE NOT GOING TO REVIEW THE QUESTIONS. WE HAVE TO HAVE A MOTION AND A SECOND IN ORDER TO DISCUSS.

CHAIRMAN IMBASCIANI: THAT'S RIGHT. OKAY.

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THANK YOU FOR THAT INTRODUCTION. MAY I HAVE A MOTION TO APPROVE THE FORM RECOMMENDED FOR APPROVAL BY THE GOVERNANCE SUBCOMMITTEE?

VICE CHAIR BONNEVILLE: SO MOVED.

DR. ABOUSALEM: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A SECOND. COMMENTS IN THE BOARD? GOING ONCE. IS THERE ANY PUBLIC COMMENT ON THIS TOPIC?

MS. DEQUINA-VILLABLANCA: THERE ARE NO PUBLIC COMMENTS.

CHAIRMAN IMBASCIANI: THERE ARE NO COMMENTS. ALL RIGHT. SO OKAY. ALL THOSE IN FAVOR OF THIS RECOMMENDATION FROM THE GOVERNANCE SUBCOMMITTEE PLEASE SAY AYE. THOSE OPPOSED SAY NO. SCOTT, WILL YOU PLEASE POLL THE PEOPLE ON THE LINE.

MR. TOCHER: HAIFAA ABDULHAQ. I'LL COME BACK. DAN BERNAL. I'LL COME A BACK. GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MR. TOCHER: LINDA BOXER.

DR. BOXER: YES.

MR. TOCHER: FRED FISHER. JUDY GASSON.

DR. GASSON: YES.

MR. TOCHER: LARRY GOLDSTEIN.

DR. GOLDSTEIN: YES.

MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: DAVID LO.
DR. LO: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: MICHAEL STAMOS.
DR. STAMOS: YES.
MR. TOCHER: I'LL CALL THE OTHERS AGAIN. HAIFAA.
DR. ABDULHAQ: YES.
MR. TOCHER: DAN BERNAL. FRED FISHER. THE MOTION CARRIES UNANIMOUSLY.
CHAIRMAN IMBASCIANI: THANK YOU, MR. TOCHER. OKAY. WE'RE GOING TO MOVE ON NOW TO REGULAR ORDER HERE. ITEM NO. 10, WE HAVE TWO BUDGET ITEMS TO CONSIDER TODAY. THIS IS THE FIRST, CONSIDERATION OF CIRM'S ADMINISTRATIVE BUDGET FOR FISCAL YEAR 23/24. I'M GOING TO INVITE POUNEH SIMPSON TO PRESENT THE ADMINISTRATIVE BUDGET.
MS. SIMPSON: GOOD MORNING, CHAIR AND BOARD MEMBERS. I AM POUNEH SIMPSON, THE SENIOR DIRECTOR OF FINANCE, AND, LIKE THE CHAIR SAID, I WILL BE MAKING TWO PRESENTATIONS TODAY.
THE FIRST WILL BE THE ADMINISTRATIVE

BUDGET. AND IN OUR PRESENTATIONS, WE ALWAYS START WITH OUR MISSION. AS DR. MILLAN SAID, OUR MISSION IS THE NORTH STAR, AND WE BUILT OUR BUDGET BASED ON THE MISSION AND OUR GOALS FOR THIS NEXT YEAR.

TO GO OVER THE AGENDA FOR THE FIRST PRESENTATION, I'M GOING TO ADD SOMETHING THAT I HAVEN'T IN PREVIOUS YEARS, WHICH IS THE OVERVIEW OF PROP 14. THEN I WILL SHARE WITH YOU WHERE WE ARE AT IN THIS FISCAL YEAR, FISCAL YEAR 22/23, AND THEN PRESENT THE 23/24 PROPOSED BUDGET FOR YOUR APPROVAL.

SO TO START WITH THE OVERVIEW OF PROP 14, WE HAVE SHOWN IN THIS GRAPH EVERYTHING THAT'S IN THAT $5.5 BILLION PROPOSITION. AND WE'VE BROKEN IT OUT INTO FOUR DIFFERENT BUCKETS, THE LARGEST BUCKET BEING THE RESEARCH AT $4.9 BILLION. THE DISCUSSION ON THAT BUCKET WILL BE LATER IN THE SECOND PRESENTATION. THE OTHER THREE BUCKETS ARE THE GRANT ADMINISTRATION AND COMPLIANCE, WHICH EQUAL $320 MILLION, THE ADMINISTRATION AND OVERHEAD, WHICH IS $192.5 MILLION, AND A BUCKET THAT'S CONTROLLED BY THE TREASURER'S OFFICE FOR THE SALE OF OUR BONDS FOR $100 MILLION.

SO I WANT TO BREAK OUT THE THREE BUCKETS ON THE RIGHT IN THE NEXT SLIDE AND SHOW YOU WHERE WE ARE AT AS IT RELATES TO EXPENDITURES IN THE LAST

THREE YEARS THAT WE HAVE BEEN OPERATING WITH PROP 14 FUNDS.

SO THE LARGEST OF THOSE IS THE 3.5 PERCENT THAT'S ALLOWED FOR GENERAL ADMINISTRATION. THE OTHER THREE BUCKETS THAT I HAD COMBINED INTO GRANT ADMINISTRATION AND COMPLIANCE ARE REALLY THREE INDIVIDUAL SECTIONS CALLED OUT IN THE PROPOSITION. THE FIRST BEING 3 PERCENT FOR GRANT ADMINISTRATION, THE SECOND BEING 1 PERCENT FOR ACCESS AND AFFORDABILITY, AND THE LAST BEING A POT OF $100 MILLION SET ASIDE FOR GRANT COMPLIANCE. AND FINALLY, THE HUNDRED MILLION THAT THE TREASURER'S OFFICE CONTROLS.

SO HAVING SHARED THAT OVERVIEW OF THE PROPOSITION AND WHERE THE ADMINISTRATIVE BUCKETS ARE, I WANT TO TALK ABOUT WHERE WE'VE BEEN IN THIS FISCAL YEAR, IN FISCAL YEAR 22/23. THIS WAS ANOTHER YEAR OF RAMPING FOR US, AND WE INCREASED OUR STAFFING LEVELS DUE TO THE INCREASED WORKLOAD. AS A RESULT OF THE HARD WORK OF OUR HR EXPERTS AND THE LEADERSHIP TEAM, WE WELCOMED 16 NEW MEMBERS THAT ARE TALENTED AND HAVE BEEN CONTRIBUTING TO THE NEW MISSIONS OF OUR ORGANIZATION.

WE STILL HAVE FOUR POSITIONS IN RECRUITMENT, ONE OF WHICH WILL LIKELY GET FILLED

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THIS FISCAL YEAR. SO WE WILL BE REQUESTING THREE IN MY PRESENTATION LATER WHEN WE TALK ABOUT THE 23/24 BUDGET. AND THE REASON WE DO THAT IS IF POSITIONS ARE LEFT VACANT, WE EVALUATE THEIR NEED AND WHETHER WE NEED TO CONTINUE THEM OR RETURN THE FUNDS TO THE BIG BUCKET. SO YOU WILL SEE THOSE THREE IN A FEW SLIDES.

WE ALSO COMPLETED OUR MOVE TO THE SOUTH SAN FRANCISCO OFFICE, AND WE HAVE HAD PARTIAL RESUMPTION OF OUR TRAVEL AND PRE-PANDEMIC ACTIVITIES THAT HAVE SHAPED SOME OF THE EXPENDITURES FOR THIS FISCAL YEAR.

IN THE NEXT CHART WE KIND OF SUMMARIZE WHAT WAS APPROVED BY THE BOARD AND HOW MUCH WE SPENT. SO IN THE SECOND COLUMN WE HAD A BUDGET APPROVED BY THE ICOC OF $26.2 MILLION. WE ESTIMATE THAT WE'RE GOING TO FINISH THIS YEAR AT $21.7 MILLION, AND THE VARIANCE IS 4.5 MILLION.

I WANT TO TALK A LITTLE BIT ABOUT THAT VARIANCE IN THE NEXT FEW SLIDES AND EXPLAIN SOME OF THE FACTORS THAT CONTRIBUTED TO IT. BEFORE I MOVE ON, I WANTED TO REMIND EVERYBODY. FUNDS NOT SPENT IN A GIVEN YEAR ARE NOT LOST. THEY'RE RETURNED TO THE BIG BUCKET OF AVAILABLE FUNDS FOR FUTURE USE.

THERE WERE FOUR CATEGORIES THAT

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CONTRIBUTED TO THAT $4.5 MILLION VARIANCE, THE LARGEST ONE BEING EMPLOYEE EXPENSE. WE WERE UNDER BUDGET BY THREE MILLION, AND THAT WAS MAINLY BECAUSE OF THE DELAYS IN HIRING THOSE 16 POSITIONS AND THE FOUR VACANT ONES THAT ARE STILL BEING WORKED ON ACTIVELY, SOME STAFF TURNOVER, AND SOME TRANSIT AND PER DIEM SAVINGS. WE HAD BUDGETED MORE THAN WHAT ACTUALLY HAPPENED.

WE ALSO HAD SAVINGS IN THE AREA OF REVIEWS, MEETINGS, AND WORKSHOPS. WE WERE UNDER BUDGET BY $551,000. THIS WAS PRIMARILY BECAUSE IN-PERSON MEETINGS BECAME VIRTUAL OR WERE POSTPONED. WE HAD SOME SAVINGS IN OFFICE EXPENSES, AND THAT HAD TO DO WITH SOME OF OUR MOVE COSTS BEING LOWER DUE TO THE DILIGENT WORK OF THE STAFF TO BRING IN COMPETITIVE BIDS FOR THE VARIOUS ASPECTS OF OUR MOVE.

FINALLY, WE HAD SOME SAVINGS IN RENT BECAUSE WE DIDN'T MOVE INTO THIS BUILDING UNTIL THE FIFTH MONTH OF THE FISCAL YEAR. SO WE HAD A SAVINGS OF $600,000. ALTOGETHER THESE COST SAVINGS ARE A RESULT OF THE HARD WORK OF THE TEAM MANAGING EXPENSES AND KEEPING COSTS DOWN WHILE ADDRESSING THE CHANGING NEEDS OF OUR PROGRAM.

I WANT TO TALK A LITTLE BIT MORE ABOUT

EMPLOYEE EXPENSES BECAUSE IT IS A LARGE NUMBER, AND I WANT TO BREAK THAT DOWN A LITTLE BIT MORE. THE VACANCIES AND THE DELAYED HIRING ATTRIBUTED TO 2.3 MILLION OF THE VARIANCE THAT WE HAD. A LOT OF THOSE POSITIONS ARE FILLED NOW. SO WHEN I PRESENT THE 23/24 BUDGET, I'M ACCOUNTING FOR THE FULL-YEAR COSTS NOW THAT THEY'RE ON BOARD. BUT I HAD TO SHOW THE SAVINGS HERE BECAUSE IT WAS DOLLARS NOT SPENT.

THERE WAS ALSO SOME UNDER-UTILIZATION OF TEMP HELP AND THE ACTUALS FOR OUR PATIENT ADVOCATE BOARD MEMBER PER DIEM COMING IN LOWER THAN WE HAD BUDGETED.

FINALLY, I MENTIONED THE TRANSIT SAVINGS. ALTOGETHER THERE WAS A $3 MILLION VARIANCE BETWEEN WHAT WE HAD REQUESTED AND WHAT WE HAD SPENT. THIS $3 MILLION IS GOING TO COME UP IN A LATER SLIDE. SO I WANT YOU TO REMEMBER THAT BECAUSE IT WILL COME UP WHEN WE TALK ABOUT THE 23/24 BUDGET.

I ALSO WANTED TO POINT OUT THE HIGHER EXPENSES. SO THERE WAS LOT OF SAVINGS IN DIFFERENT CATEGORIES. THERE WAS A CATEGORY WHERE WE HAD HIGHER EXPENSES. SO THIS HAD TO DO WITH EXTERNAL SERVICES, AND THERE'S TWO REASONS WHY WE HAD HIGHER EXPENSES IN THIS CATEGORY. THE FIRST WAS WE NEEDED CONSULTANTS FOR SOME OF OUR NEW INITIATIVES. THEY

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INCLUDED THE IP AND INDUSTRY ACTIVITIES FOR BUSINESS DEVELOPMENT, THE ROADMAP DISCUSSION FOR ACCESS AND AFFORDABILITY, THE FACILITIES WORKING GROUP CONSULTANT TO HELP US GET THOSE GRANTS UNDER WAY. AND, FINALLY, IN FINANCE WE HAD A CONSULTANT THAT HELPED US WITH THE AUTOMATION OF FINANCIAL PROCESSES.

THERE WAS ALSO ANOTHER REASON FOR THIS INCREASE, AND IT HAD TO DO WITH A CORRECTION WE MADE IN THE BUDGET. WE FELT THERE WERE SOME ITEMS IN OFFICE EXPENSES THAT WERE MORE ACCURATELY PRESENTED AS EXTERNAL SERVICES. THEY WERE MORE CONTRACTS THAN THEY WERE SERVICES. SO WE MOVED THEM UP. AND AN EXAMPLE IS A CONTRACT FOR $225,000 WHICH WAS FOR THE DIAGRAMS AND THE CONSULTING FOR OUR AV SYSTEM. SO ALTOGETHER THERE WAS AN INCREASE HERE OF 535, BUT WE SHOWED THE SAVINGS IN OFFICE EXPENSES AND WERE ABLE TO MANAGE THE OVERALL BUDGET WITHIN WHAT THE BOARD HAD APPROVED.

HAVING SUMMARIZED WHAT WE DID IN 22/23, I WANT MOVE ON TO 23/24 AND TALK ABOUT WHAT WE'RE ASKING FOR. IN THE SECOND COLUMN, I, AGAIN, PRESENT TO YOU WHAT THE BOARD APPROVED IN 22/23 AND IN THE THIRD COLUMN THE ESTIMATE TO FINISH THAT WE JUST LOOKED AT. IN THE FOURTH COLUMN I PRESENT THE 23/24

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PROPOSED BUDGET FOR ADMINISTRATION. RIGHT OFF THE BAT THE TOP NUMBER, $19.7 MILLION, AGAIN, THAT'S THE FULL-YEAR COST OF ALL THE POSITIONS THAT WERE APPROVED AND FILLED THIS YEAR PLUS THE ADDITIONAL POSITIONS I WILL BE REQUESTING IN A FEW SLIDES.

ALTOGETHER WE'RE ASKING FOR A BUDGET OF $28.9 MILLION IN FISCAL YEAR 23/24. AND WE ALWAYS SHOW YOU THE COMPARISON OF WHAT WE ARE ASKING FOR VERSUS WHAT WE SPENT THIS YEAR. SO THE LAST COLUMN, THE $7.2 MILLION, IS THE DIFFERENCE BETWEEN WHAT WE ARE ASKING FOR NEXT YEAR VERSUS WHAT WE ACTUALLY THINK WE SPENT THIS YEAR.

SO I WANT TO DIG INTO THAT $7.2 MILLION A LITTLE BIT AND MAINLY FOCUS ON THE TOP THREE CATEGORIES WHICH ARE THE LARGEST DOLLAR AMOUNTS.

THOSE THREE CATEGORIES ARE EMPLOYEE EXPENSE. IT HAS TO DO WITH NINE ADDITIONAL POSITIONS. REMEMBER THREE ARE IN RECRUITMENT NOW. SO REALLY WE'RE ASKING FOR SIX NEW POSITIONS AND CONTINUATION OF THREE THAT ARE IN RECRUITMENT. SO ADDITIONAL REVIEWS, MEETINGS, AND WORKSHOPS THAT WILL TAKE PLACE IN PERSON, WHICH IS A HIGHER COST THAN VIRTUAL. AND THEN SOME MEMBERSHIP AND TRAINING, BOTH BECAUSE WE HAVE INCREASED NUMBER OF STAFF AND BECAUSE WE'RE RESUMING THE PRE-PANDEMIC

LEVELS OF ACTIVITY.

SO TO DIG A LITTLE BIT MORE INTO THE EMPLOYEE COSTS, WHICH ARE THE LARGEST COMPONENT OF THE BUDGET, WE ARE REQUESTING NINE NEW POSITIONS WHICH EQUALS $1.6 MILLION. WE ARE ALSO ACCOUNTING FOR A SALARY INCREASE CALLED A PERFORMANCE-BASED MERIT SALARY INCREASE. THIS IS BUDGETED AT 3 PERCENT. SO THE BUDGET INCLUDES $290,000 FOR A MERIT INCREASE FOR THOSE WHO ARE ELIGIBLE FOR IT. I HAVE NOT BUDGETED ANYTHING FOR COST OF LIVING. SO NOTHING IN THE BUDGET FOR THAT. AND THERE'S ALSO BEEN AN ADJUSTMENT HERE WHERE WE HAVE TO ADJUST THE CONTRIBUTIONS TO RETIREMENT WAS AT 34 PERCENT AND IT'S BEEN DECREASED TO 33 PERCENT. THIS IS SET BY THE CONTROL AGENCIES. IT'S NOT ANYTHING WE CONTROL, BUT IT RESULTED IN A SAVINGS. SO THE NET IMPACT IS $4.5 MILLION. THREE MILLION BEING THE SAVINGS FROM LAST YEAR, WHICH I SHOWED YOU A FEW SLIDES AGO, AND THEN 1.4 MILLION INCREASE THIS YEAR.

THE NEXT SLIDE GOES INTO THE NEXT CATEGORY WHERE WE HAD A HIGH VARIANCE, EXTERNAL SERVICES. THERE WAS SOME ONE-TIME CONSULTING THAT I MENTIONED NEEDED TO DEVELOP OUR NEW INITIATIVES AND PROGRAMS. THERE WAS SOME CONTINGENT CONTRACTS IN PLACE FOR THE MOVE WHICH WE NOW CAN TAKE OUT OF OUR BUDGET BECAUSE

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WE HAVE MOVED AND DON'T NEED THOSE CONTINGENT CONTRACTS ANYMORE. ALSO THERE WAS THAT REALIGNMENT WHERE WE'RE TRYING TO SHOW SERVICES UNDER EXTERNAL SERVICES VERSUS OTHER CATEGORIES. SO THIS ATTRIBUTED TO $996,000 BETWEEN WHAT WE SPENT THIS YEAR AND WHAT WE ANTICIPATE SPENDING NEXT YEAR.

FINALLY, IN THE LAST CATEGORY, WHICH IS REVIEWS, MEETINGS, AND WORKSHOPS, WE HAD HIGHER COST OF REVIEWS. WE ARE INCREASING TO FIVE IN-PERSON MEETINGS VERSUS THE VIRTUAL ONES WE WERE HAVING. WE ARE CONTINUING OUR SCIENTIFIC WORKSHOPS AND ADVISORY MEETINGS. AND WE ARE CONTINUING THE CLINICAL AND TRANSLATIONAL ADVISORY PANELS. SO THE DIFFERENCE BETWEEN WHAT WE SPENT THIS YEAR AND WHAT WE'RE ASKING FOR NEXT YEAR IS $845,000.

IN BUILDING THE BUDGET, WE TRY TO ACTIVELY MANAGE ALL OF THE ASPECTS OF THE BUDGET, BUT THERE ARE THINGS THAT ARE OUTSIDE OUR CONTROL. THOSE INCLUDE RECRUITMENT AND PERSONNEL GROWTH, ECONOMIC INSTABILITY, AND POST-PANDEMIC RECOVERY OF MEETINGS, TRAVEL, AND WORK ACTIVITIES.

WITH THOSE CONSTRAINTS, WE HAVE PREPARED THE BUDGET OF 28.9 MILLION THAT WE ARE ASKING THE BOARD TO APPROVE. SO I CAN STOP HERE AND TAKE ANY QUESTIONS BEFORE THE VOTE.

CHAIRMAN IMBASCIANI: BEFORE WE GO TO QUESTIONS, MAY I HAVE A MOTION TO APPROVE THE FORM RECOMMENDED BY THE FINANCE COMMITTEE AND A SECOND PLEASE?

DR. SOUTHARD: MOVE.

DR. CLARK-HARVEY: SECOND.

CHAIRMAN IMBASCIANI: WE HAVE A MOVEMENT AND A SECOND. OKAY. ANY BOARD COMMENT? MOHAMED.

DR. ABOUSALEM: THANK YOU VERY MUCH, POUNEH, FOR THE VERY CLEAR MATERIAL AND VERY CLEAR AND SUCCINCT PRESENTATION. I HAVE ONE QUESTION REGARDING COST OF LIVING. SO YOU DON'T HAVE IN THE BUDGET, I'M ASSUMING, WHAT I UNDERSTOOD, YOU DON'T HAVE A PROVISION FOR COST OF LIVING INCREASE, BUT IT IS A FACT, INFLATION IS AN ACTUAL MATTER. AND STATE AGENCIES, A NUMBER OF STATE AGENCIES ARE EXPECTED TO HAVE RAISES FOR COST OF LIVING OVER THE NEXT FEW MONTHS RETRO TO JULY 1ST JUST BASED ON THE DYNAMICS AND WHAT'S GOING ON.

CAN YOU JUST SPEAK TO WHY NOT HAVING AT LEAST A PROVISION IN THERE IN CASE YOU NEED IT?

MS. SIMPSON: ABSOLUTELY. THANK YOU FOR THE QUESTION.

SO THE GOVERNOR NEGOTIATES THE COST OF LIVING ADJUSTMENT PERCENTAGE WITH THE DIFFERENT

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BARGAINING UNITS. WE ARE ALL EXEMPT EMPLOYEES AT CIRM. WE HAVE NO BARGAINING, BUT WE DO FOLLOW WHAT THE GOVERNOR RECOMMENDS AS A COST OF LIVING ADJUSTMENT. BECAUSE THAT HASN'T BEEN DETERMINED, WE DIDN'T WANT TO PUT ANY IN MONEY IN THE BUDGET FOR IT. AGAIN, PARTIALLY BECAUSE WE'RE TRYING TO PUT THINGS IN THE BUDGET THAT WE'RE NOT SURE MIGHT MATERIALIZE, WHICH LEADS TO THOSE REALLY BIG VARIANCE GAPS OF WHAT WE SPENT VERSUS WHAT WE'RE ASKING FOR.

SO NOTHING HAS BEEN PUT IN THE BUDGET. BUT SHOULD THE GOVERNOR APPROVE A COST OF LIVING ADJUSTMENT, WE WILL EVALUATE IT AND DECIDE IF IT IS SOMETHING THAT CIRM WANTS TO INCLUDE IN OUR BUDGET. WE WILL ADDRESS THAT EITHER BY REDIRECTING SAVINGS IF WE HAVE ANY IN THE FISCAL YEAR OR THAT ADJUSTMENT WON'T TAKE PLACE, OR WE WILL COME BACK TO THE BOARD IF WE DON'T HAVE ENOUGH FUNDS AND ASK FOR THOSE DOLLARS.

DR. ABOUSALEM: THANK YOU.

CHAIRMAN IMBASCIANI: MEMBER JUELSGAARD IS NEXT FOLLOWED BY MEMBER HIGGINS.

OKAY. DAVID.

DR. HIGGINS: MOHAMED ASKED, I THINK, A VERY GOOD QUESTION ABOUT IF THIS NUMBER CHANGES.

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CHAIRMAN IMBASCIANI: I THINK HE SAID THAT MOHAMED ASKED HIS QUESTION. ANY OTHER BOARD COMMENT? IS THERE ANY PUBLIC COMMENT ON THE 23/24 BUDGET?

MS. DEQUINA-VILLABLANCA: NO PUBLIC COMMENT.

CHAIRMAN IMBASCIANI: NONE. OKAY. THEN WE'RE GOING TO VOTE ON CIRM -- MR. TOCHER IS CLEARLY PLURIPOTENT IN HIS ABILITIES. THEN WE'RE GOING TO MOVE TO A VOTE ON ACCEPTING THE BUDGET FOR THE NEXT FISCAL YEAR. ALL THOSE IN FAVOR PLEASE SAY AYE. AND THOSE OPPOSED SAY NAY. NO OPPOSITION. SCOTT, WOULD YOU PLEASE CALL THE ROLL OF THE MEMBERS ON THE PHONE.

MR. TOCHER: HAIFAA ABDULHAQ.

DR. ABDULHAQ: YES.

MR. TOCHER: DAN BERNAL.

MR. BERNAL: AYE.

MR. TOCHER: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MR. TOCHER: LINDA BOXER.

DR. BOXER: YES.

MR. TOCHER: FRED FISHER.

DR. FISHER: YES.

MR. TOCHER: JUDY GASSON.

DR. GASSON: YES.
MR. TOCHER: LARRY GOLDSTEIN.
DR. GOLDSTEIN: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: DAVID LO.
DR. LO: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: MICHAEL STAMOS.
DR. STAMOS: YES.
MR. TOCHER: THANK YOU. THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH. SO WE'RE GOING TO NOW MOVE TO -- MEMBER DURON.
MS. DURON: MR. CHAIR, I JUST WANTED TO COMMENT BECAUSE I'D ASKED THIS LAST YEAR. I HOPE IT'S BEING CONSIDERED. CONCERN ABOUT HAVING A ROBUST, DECENT COMMS BUDGET. AFTER ALL, WE ARE NOW PROMOTING NEW ISSUES, NEW ACTIVITIES, NEW OPPORTUNITIES FOR OUR DIVERSE COMMUNITIES TO ENGAGE. AND THAT TAKES A REAL LIFT FOR OUR COMMS TEAM TO MAKE SURE THAT THEY'RE WELL SUPPORTED, THEY HAVE ENOUGH PEOPLE TO DO THE WORK, AND WE ARE OUTREACHING IN THE MULTIPLE WAYS ONE NEEDS TO IN ORDER TO GET

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THE MESSAGE OUT AND TO ENGAGE, NOT JUST OUR BRIDGES TEAMS AND OUR SPARKS KIDS AND SO ON AND SO FORTH, BUT TO MAKE SURE THAT OUR PUBLIC IS REALLY BEGINNING TO HEAR, SEE, AND KNOW WHAT THE HECK WE'RE ALL ABOUT.

AND SO I JUST REALLY WANT TO CONTINUE TO SUPPORT THAT SOMEHOW OR ANOTHER BUILT WITHIN THIS IS A DECENT AMOUNT OF DOLLARS FOR OUR COMMS TEAM. AND WELCOME ABOARD KOREN WHO'S JUST IN THE BACK OF THE ROOM. SORRY, MR. CHAIR, DIDN'T MEAN TO STEEL ANY THUNDER HERE, BUT JUST WANTED TO WELCOME KOREN.

CHAIRMAN IMBASCIANI: CERTAINLY CONSTANT WITH ONE OF MY IMPERATIVES, IF YOU WILL. I CERTAINLY SUPPORT YOUR COMMENT, AND I DON'T THINK THERE'S A WORRY ON THAT.

MS. DURON: SHOW ME THE MONEY.

CHAIRMAN IMBASCIANI: I DON'T THINK IT'S CALLED OUT AS A SEPARATE LINE ITEM.

MS. DURON: I THINK IT SHOULD BE.

CHAIRMAN IMBASCIANI: OKAY. FINANCE CAN TAKE THAT UNDER ADVISEMENT. GOOD SUGGESTION. THANK YOU.

SO PLEASE, MS. SIMPSON, STAY THERE AT THE PODIUM. WE'RE GOING TO CONSIDERATION OF CIRM'S SCIENTIFIC RESEARCH BUDGET FOR FISCAL YEAR 23/24.

SO MAY I HAVE A MOTION TO APPROVE THE FORM RECOMMENDED IN YOUR PACKET BY THE FINANCE SUBCOMMITTEE AND A SECOND?

DR. HIGGINS: SO MOVED.

DR. YAMAMOTO: SECOND.

CHAIRMAN IMBASCIANI: MEMBER HIGGINS HAS MOVED IT; MEMBER YAMAMOTO HAS SECONDED. POUNEH, YOU MAY PROCEED.

MS. SIMPSON: SO TO PRESENT THE RESEARCH BUDGET, WE BROUGHT BACK A COUPLE OF SLIDES THAT YOU MAY REMEMBER SEEING IN THE PRE-PANDEMIC ERA, PRE-PROP 14 ERA. SO THIS IS TO SUMMARIZE THE 5.5 BILLION OF PROP 14 AGAIN. SO TO CALL OUT WHAT IS IN THE RESEARCH BUCKET, THE 4.9 BILLION.

IN THE NEXT SLIDE I BREAK OUT THAT RESEARCH BUCKET INTO COMMITTED AND UNCOMMITTED. SO FAR THE BOARD HAS COMMITTED $811.4 MILLION OF THE RESEARCH BUCKET. SO TODAY I'M GOING TO BE PRESENTING THE 23/24 BUDGET FOR ADDITIONAL COMMITMENTS IN THE FUTURE FOR RESEARCH.

TO GO OVER THE AGENDA, I WILL TELL YOU WHERE WE ARE AT WITH THIS YEAR WITH WHAT THE BOARD APPROVED AND WHAT WE'VE BEEN ABLE TO DO WITH IT BEFORE PRESENTING THE 23/24 BUDGET FOR YOUR APPROVAL.

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SO IN 22/23 IN THIS CHART WE SUMMARIZE THE AMOUNT THAT THE BOARD APPROVED, $426.7 MILLION. THE BOARD HAS BEEN VERY BUSY IN COMMITTING GRANTS TO VARIOUS PROJECTS. AND IN TOTAL WE HAVE COMMITTED $293.6 MILLION. THERE'S PENDING COMMITMENTS OF $26.2 MILLION, AND THIS HAS TO DO WITH THE TIMING OF HOW WE PUT OUR GRANTS OUT. SOME OF THEM CAN'T FIT IN THE CALENDAR BEFORE JUNE 30TH AND FALL INTO SUBSEQUENT MONTHS. THIS IS ACTUALLY SOMETHING THAT WE ARE PROPOSING A CHANGE TO IN FISCAL YEAR 23/24, WHICH I WILL TALK ABOUT IN FEW SLIDES.

SO THE COMBINED ESTIMATED TO FINISH COMMITMENTS IN RESEARCH WILL BE $330.4 MILLION THIS YEAR WITH A SAVINGS OF 96.3 MILLION. I WANT TO TALK A LITTLE BIT ABOUT THE LARGEST CATEGORY OF SAVINGS THERE, THE 70 MILLION. THIS IS MOSTLY ATTRIBUTED TO OUR INABILITY TO FIND A CONTRACTOR QUICKLY ENOUGH FOR THE FACILITIES WORKING GROUP AND SOME DELAYS THAT CAME FROM THAT FOR THE SHARED LABS. WE NOW HAVE THE CONTRACTOR IN PLACE AND THEY WILL HELP US WITH DESIGNING THE REVIEW REQUIREMENTS FOR THE APPLICATIONS THAT WE WILL BE REVIEWING.

SO MOVING ON TO THE 23/24 BUDGET, THERE'S SOME MAJOR DRIVERS THAT HAVE LED TO THE BUDGET WE ARE PROPOSING. WE PLAN ON HAVING 18 GRANTS WORKING

GROUPS, ONE FACILITIES WORKING GROUP, ONE ACCESS AND AFFORDABILITY WORKING GROUP IN A 12-MONTH PERIOD. WE WILL CONTINUE FUNDING OUR DISCOVERY, TRANSLATIONAL, AND CLINICAL PILLARS. AND WE WILL CONTINUE FUNDING CONFERENCE GRANTS IN THE EDUCATION PILLAR.

WE HAVE SOME NEW INITIATIVES THAT WE'RE PROPOSING THIS YEAR, WHICH INCLUDE THE SHARED LABS, THE ACCESS AND AFFORDABILITY IN THE PATIENT SUPPORT PROGRAM, AND THE DISC NEURO CONCEPT WILL BE PRESENTED IN THE FALL OF THIS COMING YEAR.

SO TO DIG A LITTLE BIT DEEPER INTO OUR METHODOLOGY BY PILLAR, I WANT TO START BY SAYING THAT, WHEN WE PREPARE THE RESEARCH BUDGET, WE WANT TO MAKE SURE THERE'S ENOUGH FUNDING SO THAT IF OUR PERFORMANCE IN A GIVEN YEAR IS THE SAME AS PREVIOUS YEARS, THAT WE HAVE THE FUNDS AVAILABLE FOR THE BOARD SO THAT THEY CAN MAKE COMMITMENTS.

SO WITH REGARDS TO THE CLINICAL BUDGET, WE HAVE A NEW PARADIGM THIS YEAR WITH INCREASES IN THE VOLUME OF APPLICATIONS. THIS IS PRIMARILY DUE TO TWO THINGS: THE SUCCESSFUL RECRUITMENT OF GRANTEES AND ALSO THE CHANGE IN THE ECONOMY. SO WE ARE REQUESTING $250 MILLION, WHICH IS BASED ON THE MAXIMUM NUMBER OF AWARDS FUNDED IN A YEAR TIMES THE

AVERAGE AWARD AMOUNT. AND THIS SPACE HAS BEEN NOW ADJUSTED TO REFLECT THE HIGH THAT WE HAD IN FISCAL YEAR 22/23.

FOR TRANSLATIONAL BUDGET, WE'RE REQUESTING $84.6 MILLION. THIS IS BASED ON THE AVERAGE NUMBER OF AWARDS FUNDED PER REVIEW TIMES THE NUMBER OF REVIEWS TIMES THE AVERAGE AMOUNT. WE ARRIVED AT THIS METHODOLOGY BASED ON THE INPUT WE GET FROM THE STAFF. AND THIS ALSO INCLUDES AN INCREASE OF TWO EXTRA GRANTS GOING OUT IN 23/24.

FOR THE DISCOVERY BUDGET, WE INITIALLY REQUESTED $62.5 MILLION, BUT IN A LATER SLIDE I WANT TO COME BACK TO THIS BECAUSE WE HAVE SOME ADDITIONAL NUMBERS THAT WE WANT TO UPDATE YOU ON. WITH REGARDS TO EDUCATION, WE'RE GOING TO CONTINUE WITH 2.5 MILLION IN FUNDING FOR CONFERENCE GRANTS. AND, FINALLY, IN THE CATEGORY OF INFRASTRUCTURE, WE ARE REQUESTING 62.5 MILLION TO COVER THE SHARED LABS, THE PATIENT SUPPORT GRANTS, AND THE MANUFACTURING POTENTIAL FOR POSSIBLE RESUBMISSION OF APPLICATIONS.

IN A SITUATION WHERE PERFORMANCE EXCEEDS OUR BUDGET, WE CAN ALWAYS COME BACK TO THE BOARD AS PART OF THE MID-YEAR BUDGET TO REQUEST ADDITIONAL FUNDS SO THAT ALL MERITORIOUS GRANTS AND NEEDS OUT THERE ARE MET.

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UP TO NOW THE BUDGET INCLUDED THE START OF ALL OF OUR INITIATIVES, BUT NOT NECESSARILY WHEN THAT INITIATIVE WOULD BE PRESENTED FOR AWARD. SO AN INITIATIVE MIGHT HAVE STARTED MID-YEAR AND IT WOULD SPILL INTO THE FOLLOWING YEAR BECAUSE OF THE CALENDARING OF THE REVIEW AND AWARD PROCESS.

ONE OF THE FISCAL CHANGES WE'RE PROPOSING IS STARTING IN FISCAL YEAR 23/24, ALL THE REQUESTS IN ALL THE PILLARS THAT WE'RE PRESENTING WILL BE COMMITTED IN THAT FISCAL YEAR. SO BARRING ANY UNFORESEEN CIRCUMSTANCES, ALL THE FUNDS WE ARE ASKING FOR IN THIS NEXT FISCAL YEAR WILL ACTUALLY COME TO THE BOARD FOR A DECISION BEFORE JUNE 30TH.

THIS NEXT SLIDE IS WHAT I PRESENTED TO THE SCIENCE SUBCOMMITTEE. AND SINCE THEN WE HAVE HAD ADDITIONAL INFORMATION THAT IS ADJUSTING THE TOTAL ASK. SO THE FOLLOWING SLIDE SHOWS THE ADJUSTMENT THAT WE'RE GOING TO BE ASKING FOR. SO IN THE LAST NEURO TASK FORCE, THE CIRM STAFF WAS ASKED TO REEVALUATE THE GRANT AMOUNTS FOR THE DISCOVERY PROGRAM. AND SO FOR THAT REASON, WE HAD BEEN PROPOSING A REDUCTION IN DISCOVERY OF $22.2 MILLION; BUT NOW WE'VE REVISED OUR REQUEST AND ARE ASKING THAT YOU ALLOW US TO STAY AT THAT 84.7 MILLION THAT WAS APPROVED IN 22/23 SO THAT THERE WON'T BE ANY

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CHANGES FROM THIS FISCAL YEAR TO NEXT IN THAT CATEGORY.

AS A RESULT, WE ARE ASKING FOR A TOTAL OF $486.3 MILLION FOR THE 23/24 FISCAL YEAR.

AND THAT IS THE PRESENTATION. I'M ASKING FOR APPROVAL FOR THAT AMOUNT. IF THERE'S ANY QUESTIONS, I'M HAPPY TO TAKE IT.

CHAIRMAN IMBASCIANI: NOW PROCEED TO BOARD QUESTIONS AND COMMENTS. KIM BARRETT.

DR. BARRETT: THANK YOU VERY MUCH FOR YOUR CLEAR PRESENTATION. IF I'M READING THE NUMBERS RIGHT, IN 22/23 THERE WAS A SIGNIFICANT UNDER-SPEND IN THE DISCOVERY CATEGORY OF AROUND 20 PLUS MILLION.

MS. SIMPSON: THAT WAS ACTUALLY A RESULT OF A POSTPONEMENT OF ONE OF OUR AWARDS. SO IT WAS JUST POSTPONED OUT.

DR. BARRETT: BUT YOU WERE BUDGETED LAST YEAR A HUNDRED MILLION; AND EVEN WITH THE INCREASE OF 22.2 MILLION, YOU WOULD STILL GO UP TO 84?

MS. SIMPSON: THAT'S CORRECT. THAT'S WHAT WE'RE ASKING FOR.

DR. BARRETT: SO THAT DOES REFLECT AN OVERALL REDUCTION IN INVESTMENT IN THE DISCOVERY CATEGORY. AND APROPOS OF THE CONVERSATION THAT WE HAD EARLIER WITH GIL ABOUT HAVING TO PRIORITIZE AND

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HAVE MORE MERITORIOUS APPLICATIONS THAN CAN BE SUPPORTED, I WONDERED WHETHER THAT WAS PERHAPS SHORTSIGHTED.

MS. SIMPSON: MY COLLEAGUE WILL ADDRESS THAT QUESTION.

DR. CANET-AVILES: THERE ARE TWO REASONS. SO YOU HAVE ACTUALLY VERY CORRECTLY IDENTIFIED $22 MILLION, THAT WAS ONE OF DISCOVERY, THAT DUE TO CAPACITY FROM REVIEW AND ALSO FROM A STATUS YOU CAN SEE WE WERE NOT ABLE HIRE ON TIME, WE HAD TO REMOVE ONE OF THE CALLS. ALSO WE WERE DEVELOPING NEW INITIATIVES. SO WE WERE BEING VERY MINDFUL.

THE SECOND REASON WAS THAT WE ACCOUNTED FOR ONE OF THE DISC2S FROM LAST YEAR IN THE BUDGET OF 22/23, BUT IT HAD ACTUALLY COME IN 2021. WE HAD THE REVIEW, BUT WE ACCOUNTED -- WE HAD PAID FOR IT ALREADY IN THE YEAR BEFORE. AND THAT WAS A FISCAL YEAR ACCOUNTING TIMELINE MISTAKE THAT WE MADE AS NEW THAT WE DIDN'T REALIZE. SO THAT WAS THE REASON, BUT WE HAD THE AMOUNT OF THE THREE REVIEWS ACTUALLY. HOPEFULLY THAT ANSWERS.

AND THEN IN TERMS --

DR. BARRETT: IF I MAY BE ALLOWED JUST TO FOLLOW UP, I THINK THIS MUST BE CAREFULLY MESSAGED BECAUSE THE COMMUNITY WILL SEE THIS AS A REDUCTION

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IN SUPPORT FOR DISCOVERY GRANTS.

DR. CANET-AVILES: THANK YOU. WE WILL.

CHAIRMAN IMBASCIANI: FURTHER COMMENTS OR QUESTIONS FROM THE BOARD? MEMBER SOUTHARD.

DR. SOUTHARD: IN THIS AREA OF DISCOVERY, I THINK IT'S REALLY IMPORTANT FOR US TO KEEP OUR EYE ON IT FOR THE MIDTERM BUDGET ADJUSTMENT BECAUSE IF WE ARE SUCCESSFUL IN DOING THE SEEK AND FIND FOR THE NEUROPSYCH AREAS, IT WILL BE QUITE EXPENSIVE. AND SO IN SOME WAYS WE SHOULD PREPARE OUR MINDS AND OUR EFFORTS TOWARDS A BUDGET CORRECTION AT MID TERM.

DR. CANET-AVILES: THANK YOU, DR. SOUTHARD. WE ARE ACTUALLY TAKING THAT INTO ACCOUNT ALREADY, AND THAT'S WHY WE ADDED THE $22.2 MILLION. AND WE ARE GOING TO BE STAGING THE NEURO DISCOVERY STRATEGY. SO THAT WILL COME AT THE JUNE MEETING OF NEXT YEAR, BUT WE HAVE A LARGE INITIATIVE THAT HAS BEEN TAKEN INTO ACCOUNT HERE. SO THANK YOU. AND IT WILL COME IN SEPTEMBER.

CHAIRMAN IMBASCIANI: MEMBER LEVITT.

DR. LEVITT: I'LL SAVE IT FOR LUNCH. SO WHEN YOU LOOK AT THE VARIANCE, CAN YOU -- YOU'VE DONE YOUR CALCULATIONS. IS THIS INCREASE IN NUMBER OF GRANTS OR AN INCREASE OF THE SIZE OF EACH GRANT OR BOTH GIVEN THE CONVERSATIONS THAT HAVE OCCURRED

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IN VARIOUS FORMS ABOUT THE CHALLENGES OF CONTINUING TO DO THIS RESEARCH ON BUDGET LEVELS THAT WERE SET SOME YEARS AGO?

DR. CANET-AVILES: I'LL JUST STAY HERE NOW FOR A BIT. IT'S AN INCREASE IN THE SIZE OF THE GRANTS, A SUBSTANTIAL INCREASE THAT YOU HAVE TO REVISE AND APPROVE AND AN INCREASE IN NUMBERS AS WELL.

DR. LEVITT: SO IT'S AN INCREASE IN BOTH.

DR. CANET-AVILES: IN BOTH. WE ARE TALKING ABOUT DISCOVERY RIGHT NOW. I WILL DEAL WITH DISCOVERY AND SHARED LABS AND EDUCATION, AND MY COLLEAGUE, DR. CREASEY, CAN DEAL WITH THE TRANSLATION ON CLINICAL.

DR. LEVITT: OKAY.

CHAIRMAN IMBASCIANI: THANK YOU, ROSA.

IS THERE ANY PUBLIC COMMENT? I'M BEING TOLD THERE'S NO PUBLIC COMMENT. SO WE'RE GOING TO PROCEED TO A VOTE TO ACCEPT THE FORM RECOMMENDED FOR APPROVAL BY THE SCIENCE SUBCOMMITTEE. I MISAPPROPRIATED THEM. I SAID FINANCE SUBCOMMITTEE. SO PROCEEDING, ALL THOSE IN FAVOR OF ACCEPTING THE PROPOSED FISCAL YEAR 23/24 RESEARCH BUDGET, PLEASE SAY AYE. THOSE OPPOSED SAY NO. MR. TOCHER, IF YOU WOULD POLL THE MEMBERS ONLINE.

MR. TOCHER: HAIFAA ABDULHAQ.
DR. ABDULHAQ: YES.
MR. TOCHER: DAN BERNAL.
MR. BERNAL: AYE.
MR. TOCHER: GEORGE BLUMENTHAL.
DR. BLUMENTHAL: YES.
MR. TOCHER: LINDA BOXER.
DR. BOXER: YES.
MR. TOCHER: FRED FISHER.
DR. FISHER: AYE.
MR. TOCHER: JUDY GASSON.
DR. GASSON: YES.
MR. TOCHER: LARRY GOLDSTEIN.
DR. GOLDSTEIN: YES.
MR. TOCHER: RICH LAJARA.
MR. LAJARA: YES.
MR. TOCHER: DAVID LO.
DR. LO: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: MICHAEL STAMOS.
DR. STAMOS: YES.
MR. TOCHER: GREAT. THANKS VERY MUCH.
THE MOTION CARRIES.
CHAIRMAN IMBASCIANI: WE'RE GOING TO

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PROCEED TO AGENDA ITEM NO. 13, WHICH IS CONSIDERATION OF AN UPDATE FROM THE NEURO TASK FORCE OF THE BOARD. THIS WILL BE PRESENTED BY BOARD MEMBER LARRY GOLDSTEIN.

DR. GOLDSTEIN: OKAY. LET ME GET ACTIVATED HERE. MARIANNE, IF YOU COULD BRING UP THE FIRST SLIDE PLEASE.

MS. DEQUINA-VILLABLANCA: WE ARE WORKING ON IT, LARRY.

DR. GOLDSTEIN: GREAT. SO LET ME JUST GIVE YOU A SUMMARY OF WHERE WE ARE AFTER HALF A DOZEN OR SO MEETINGS. WE'VE BEEN MEETING MONTHLY SINCE FEBRUARY, AND THOSE MEETINGS HAVE BEEN DEVOTED TO A REVIEW OF THE CURRENT PORTFOLIO OF GRANTS FROM CIRM IN A VARIETY OF AREAS OF NEURO, A DISCUSSION OF PRIORITIES, AND A DISCUSSION OF REALLY WHERE WE WANT TO BE MOVING FORWARD.

THIS SLIDE JUST SUMMARIZES THE BULK OF OUR CONCLUSIONS. FIRST, WHEN WE LOOK AT THE FRACTION OF THE BUDGET THAT IS BEING SPENT IN THE NEURO AREA, IT IS RUNNING AT ABOUT THE SAME PERCENTAGE AS THE 1.5 BILLION SET ASIDE OUT OF THE TOTAL 5.5 BILLION. SO THAT'S -- WE WOULD EXPECT SLASH HOPE IN ORDER TO HIT THAT MARK, THAT IT OUGHT TO BE ABOUT 30 PERCENT, AND THAT'S ABOUT WHAT IT'S BEEN RUNNING AT. SO THERE'S

NO, IN A SENSE, EMERGENCY TO BE SURE THAT WE EITHER DECREASE OR INCREASE THE RATE OF SPENDING IN THE NEURO AREA BECAUSE THE GRANTS WORKING GROUP IS DOING AN APPROPRIATE JOB OF SORTING THROUGH THE APPLICATIONS.

NONETHELESS, WHEN WE THINK ABOUT HOW MUCH OF THAT ONE AND A HALF BILLION SHOULD WE TRY TO PROGRAM, AT PRESENT THERE'S NOT A LOT OF SENTIMENT IN FAVOR OF TRYING TO SPECIFY ALL OF THAT ONE AND A HALF BILLION. WE THINK THAT THE GRANT REVIEW SYSTEM IS DOING JUST FINE.

BUT PORTFOLIO REVIEW HAS SUGGESTED A COUPLE THINGS WE SHOULD THINK ABOUT. AND, MARIANNE, COULD WE HAVE THE NEXT SLIDE PLEASE. SO THIS IS ONE OF SEVERAL SLIDES THAT THE CIRM TEAM CREATED FOLLOWING A REALLY EXCELLENT REVIEW OF THE PORTFOLIO. AND IT'S A MEASURE OF SPENDING IN DIFFERENT AREAS OF NEURO DISEASE RELATIVE TO THE DISABILITY INDEX. DALY, DISABLED ADJUSTED LIFE YEARS, IS ONE OF SEVERAL MEASURES THAT CAN BE USED TO MEASURE THE IMPACT OF A DISEASE ON THE AMERICAN POPULATION. AND ALTHOUGH THE FUNDING DOESN'T NECESSARILY FOLLOW THE DISABILITY INDEX VERY CLOSELY, THERE'S NO REASON AT THE MOMENT TO SUSPECT WITH AN EXCEPTION OR TWO THAT THE GRANT REVIEW

SYSTEM IS NOT DOING AN ADEQUATE JOB OF ALLOCATING BASED ON THE MERIT OF THE APPLICATIONS IN THE AREA.

ONE MAJOR EXCEPTION YOU CAN SEE AT THE BOTTOM THERE, WHICH ARE GRANTS IN THE NEUROPSYCHIATRIC DISEASE AREA, WHERE YOU CAN SEE THE DISABILITY INDEX IS ENORMOUS COMPARED TO MOST OTHER DISEASES. AND YOU CAN SEE THAT OUR CURRENT COMMITMENT IN THIS AREA IS ZERO, AND WE FELT THAT THAT WAS ULTIMATELY INAPPROPRIATE. THERE'S ALSO A DISCUSSION ENSUING ABOUT STROKE ALTHOUGH IT'S PROBABLY LESS URGENT IN THE NEUROPSYCHIATRIC AREA.

MARIANNE, IF YOU CAN GO BACK TO THE PREVIOUS SLIDE. SO CONCLUSION NO. 2 THERE, WE ARE RECOMMENDING AN INCREASED INVESTMENT IN NEUROPSYCHIATRIC DISORDERS WHERE I'LL COME TO WHAT OUR PLANS ARE IN A MOMENT AND POSSIBLY IN STROKE.

NOW, THE OTHER THING THAT HAS COME UP IS SOMETHING THAT THE BOARD JUST DISCUSSED EARLIER IN THIS MEETING, WHICH IS SIZE AND DURATION OF GRANT AWARDS. WE HEARD FROM SOME FOLKS IN THE NEUROPSYCHIATRIC COMMUNITY IN PARTICULAR THAT THE GRANT AMOUNTS ARE REALLY NOT LARGE ENOUGH TO SUPPORT WHAT THEY REGARD AS APPROPRIATE SCIENTIFIC AND MEDICAL INVESTMENTS IN THIS AREA. AND I KNOW THAT THERE'S GOING TO BE CONTINUED BOARD DISCUSSION OF

THIS AND PROBABLY SOME DISCUSSION IN THE TASK FORCE.

ITEM 4 IS, IN PARTICULAR, FOR NEW WORK IN NEUROPSYCHIATRY, PSYCHIATRIC DISEASE, THAT WE HOPE WILL BE FUNDED. WE REALLY THINK THERE OUGHT TO BE A STRONG EFFORT TO PUT MULTIDISCIPLINARY TEAMS TOGETHER. THE REASON FOR THAT IS THAT IT'S VERY CLEAR THAT THERE ARE STRONG GENETIC INFLUENCES ON THE DEVELOPMENT OF NEUROPSYCHIATRIC DISEASE AND AT THE VERY LEAST A TEAM WITH STEM CELL BIOLOGISTS AND BIOCHEMISTS OUGHT TO INCLUDE GENETICISTS TO HELP FIGURE OUT WHAT SORTS OF INDIVIDUALS TO GENERATE STEM CELL LINES FROM FOR DIFFERENT NEUROPSYCHIATRIC DISORDERS. THERE'S A MIX IN THAT 50 PERCENT HERITABILITY OF SINGLE LARGE EFFECT RARE FACTORS COMBINED WITH MUCH MORE COMMON LOW EFFECT INDIVIDUALLY GENETIC VARIANTS.

AND THEN, FINALLY, AGAIN, THERE WAS A DISCUSSION THAT CAME UP IN THIS AREA ABOUT FUNDING OF SMALL MOLECULES. I KNOW GIL ADDRESSED THAT EARLIER IN THE MEETING. I'LL JUST POINT OUT THAT IN THE NEUROPSYCHIATRIC AREA ONE HOPE WOULD BE THAT USING STEM CELL MODELS, IT MAY BE POSSIBLE, FOR EXAMPLE, TO FIND FDA-APPROVED DRUGS THAT HAVE SOME INFLUENCE ON THE BEHAVIOR OF NEURONS AND GLIA DERIVED FROM INDIVIDUALS WITH, FOR EXAMPLE,

SCHIZOPHRENIA OR DEPRESSION OR WHAT HAVE YOU. EXACTLY HOW THOSE WOULD BE FUNDED TO GET THEM TO CLINICAL TRIALS AND THEN APPROVAL MAY REQUIRE AT SOME POINT A DISCUSSION OF FUNDING OF SMALL MOLECULE PROPOSALS, IN PARTICULAR, THOSE THAT DON'T NECESSARILY DEPEND ON STEM OR PROGENITOR CELLS FOR THEIR EVALUATION.

I THINK THAT THIS IS NOT HIGHLY LIKELY, BUT IT MAY WELL HAPPEN AND WE SHOULD PREPARE OURSELVES AT SOME POINT TO DISCUSS THIS ISSUE.

SO, MR. CHAIRMAN, THAT'S THE SUMMARY I WANTED TO PROVIDE. AND I'D BE HAPPY TO TAKE QUESTIONS FROM BOARD MEMBERS IF THERE ARE ANY.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH FOR THAT PRESENTATION. THE FLOOR IS NOW OPEN FOR COMMENTS AND QUESTIONS STARTING WITH SHLOMO.

DR. MELMED: THANKS, LARRY. THAT WAS REALLY A TERRIFIC ASSESSMENT AND VERY HELPFUL FOR UNDERSTANDING THE LANDSCAPE AND ALSO BE IMPORTANT FOR GOING FORWARD.

I WAS STRUCK BY ANOTHER INCONSISTENCY IN THE DALY VERSUS WHAT WE ARE FUNDING, WHICH ALSO INDIRECTLY AND DIRECTLY LEADS TO STROKE AND ALZHEIMER'S IN YOUR PURVIEW, AND THAT IS DIABETES. IS THERE REALLY ZERO IN DIABETES? I RECALL THERE

WERE SOME DIABETES GRANTS. IF IT IS ZERO, I THINK THAT SHOULD APPEAR AS A TRIGGER FOR STROKE AND CERTAINLY SHOULD BE CONSIDERED BECAUSE THE DALY IS VERY HIGH.

DR. GOLDSTEIN: THANK YOU, SHLOMO. THAT'S AN EXCELLENT POINT. I DON'T THINK WE CALLED OUT DIABETES IN THE NEURO AREA SPECIFICALLY IN THE PORTFOLIO ANALYSIS. SOMEBODY FROM THE CIRM TEAM CAN CORRECT ME IF I'M WRONG ABOUT THAT. YOU'VE RAISED AN INTERESTING POINT THOUGH ABOUT WHETHER WE SHOULD INCLUDE IT IN OUR THINKING ABOUT STROKE. AND I'LL BRING THAT TO OUR NEXT TASK FORCE MEETING.

DR. CANET-AVILES: THE ANALYSIS THAT DR. CREASEY AND MY TEAM DID ONLY WAS FOR NEUROSCIENCE BECAUSE WE WERE -- THIS WAS IN CONTEXT OF THE NEURO TASK FORCE.

DR. MELMED: BECAUSE IT WOULD BE INTERESTING TO COMPARE THE DALY TO THAT AS WELL AND WHAT OUR SUPPORT IS BECAUSE THE DALY IS MUCH HIGHER THAN MANY OF THOSE THERE FOR DIABETES. IT'S 14 PERCENT OF THE HEALTHCARE GMP.

CHAIRMAN IMBASCIANI: THANK YOU, SHLOMO. NEXT WE HAVE BOARD MEMBER FRED FISHER.

DR. FISHER: HI. I APOLOGIZE FOR MISSING THE LAST TASK FORCE MEETING. SO MY QUESTION

PROBABLY COULD HAVE BEEN ASKED AND ANSWERED IN THE LAST MEETING.

I'M NOT FAMILIAR WITH THE DALY. AND THE WAY I HEARD YOU SPEAK OF IT, WHICH I MIGHT HAVE MISHEARD YOU, IT'S SOME REFLECTION OF EITHER DISEASE BURDEN OR BURDEN -- SHLOMO'S COMMENTS SUGGEST TO ME MAYBE IT'S NOT, NOT ABOUT DISEASE BURDEN, BUT IT'S ABOUT HOW MUCH BURDEN IT PUTS ON THE HEALTHCARE SYSTEM.

SO COULD YOU CLARIFY FOR ME WHAT THE DALY MEANS?

DR. GOLDSTEIN: YEAH. SO I'M NOT AN EPIDEMIOLOGIST EXPERT, BUT MY UNDERSTANDING OF IT, FRED, IS THAT IT IS THE BURDEN OF DISEASE ON THE INDIVIDUALS, NOT NECESSARILY THE HEALTHCARE SYSTEM. I THINK THE BURDEN ON THE HEALTHCARE SYSTEM IS A DIFFERENT MEASURE THAT'S NOT SHOWN THERE. SO THE NEUROPSYCHIATRIC DISEASE BURDEN, FOR EXAMPLE, MEASURES OR ESTIMATES HOW MUCH DOES DEPRESSION OR MANIA OR OTHER OR SCHIZOPHRENIA BURDEN PEOPLE'S PRODUCTIVE LIVES. IT'S A VERY IMPORTANT WAY OF LOOKING AT DISEASE.

COST OBVIOUSLY IS IMPORTANT, BUT IT DOESN'T MEASURE THE HUMAN IMPACT NECESSARILY. AND I THINK THAT'S WHAT WE'RE LOOKING AT THERE.

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DR. FISHER: IT MAY BE THAT FOR NEUROPSYCH IT'S AN EXCELLENT MEASURE OF BURDEN AND CERTAINLY SOMETHING THAT WE SHOULD BE LOOKING AT. IF YOU CAN PUT THAT CHART BACK UP. AS THE ALS/MMD PATIENT ADVOCATE, THE DALY FOR ALS AND NEURODEGENERATIVE DISEASES IS AMONG THE LOWEST HERE, BUT FEW WOULD ARGUE THAT THE BURDEN OF HAVING ALS IS SMALL. SO IT MIGHT BE THAT WHAT WE USE TO EVALUATE THE BURDEN OF DISEASE, WE MAY NEED DIFFERENT TOOLS BECAUSE THIS ONE, IN MY MIND, CERTAINLY DOES NOT CAPTURE IN ANY ADEQUATE WAY THE BURDEN OF DISEASE THAT ALS AND MOTOR NEURON DISEASE AND MS FOR THAT MATTER WHICH I AM ALSO THE PATIENT ADVOCATE FOR.

DR. MELMED: I THINK IT'S THE NOMINATOR. IT'S DALY PER 100,000. BECAUSE ALS IS SO RARE, THAT'S WHY IT COMES OUT 4.7 OR 47. CAN'T SEE.

DR. GOLDSTEIN: IF I MIGHT ADD TO THAT, SHLOMO, THE OTHER THING THAT YOU POINT OUT, FRED, IS I THINK COMPLETELY CORRECT. AND THAT IS THAT A DISORDER SUCH AS ALS THAT IS RAPIDLY LETHAL IS GOING TO UNDERESTIMATE THE DISEASE BURDEN OVER TIME BECAUSE THE TIME THAT PEOPLE HAVE THESE SORTS OF THINGS IS SO SHORT.

SO A GOOD QUESTION MIGHT BE, AND WE CAN TAKE THIS UP AT ANOTHER TASK FORCE MEETING, WHAT

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DOES THE GRANT PORTFOLIO LOOK LIKE AND ARE GRANTS MISSING SOMETHING OBVIOUS IN THE AREA OF ALS. SO I WOULDN'T SAY THAT WE'VE NECESSARILY CUT OFF FURTHER DISCUSSION OF THAT. AND YOUR POINT IS, I THINK, PRETTY REASONABLE FOR THESE DISORDERS THAT ARE SO RAPIDLY LETHAL.

DR. FISHER: AND REPRESENT PERHAPS A SMALLER PERCENTAGE OF THE PATIENT POPULATION. SO WE NEED A DIFFERENT TOOL TO LOOK AT WHAT WE ARE INVESTING AND THE BURDEN OF THE DISEASE ON THOSE POPULATIONS SUFFERING FROM WHAT ARE CONSIDERED RARE DISEASES.

DR. GOLDSTEIN: FAIR POINT.

DR. CANET-AVILES: DR. GOLDSTEIN, CAN I ADD A COMMENT?

DR. GOLDSTEIN: OH, YES. PLEASE, ROSA.

DR. CANET-AVILES: I JUST WANTED TO READ HOW WE CALCULATED THESE. THE DALY ACTUALLY REFLECTS A TIME-BASED MEASURE THAT COMBINES YEARS OF LIFE LOST DUE TO PREMATURE MORTALITY AND YEARS OF LIFE LOST DUE TO TIME IN STATES OF LESS THAN FULL HEALTH OR HEALTH. SO I JUST WANTED TO -- AND WE DID THIS PER 100,000, AND WE TOOK VALUES THAT WERE FROM THE WORLD HEALTH ORGANIZATION AND THE GATES FOUNDATION THAT HAS BEEN CALCULATING THESE OVER THE YEARS, AND

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THESE ARE THE MOST RECENT VALUES.

DR. FISHER: I WOULD JUST SUGGEST THAT USING THE DALY WHEN IT COMES TO FAST PROGRESSING, LETHAL DISEASES, THAT THIS IS NOT THE BEST ILLUSTRATION OF INVESTMENT VERSUS IMPACT BECAUSE WHEN YOU GO FROM BEING PERFECTLY FUNCTIONING TO LOSING THE ABILITY TO EAT, SWALLOW, MOVE, TALK, AND BREATHE WITHIN TYPICALLY A TWO- TO FIVE-YEAR PERIOD AND IT'S A RARE DISEASE, YOU'RE GOING TO BE UNDERREPRESENTED IN THE WAY THAT ROSA JUST DESCRIBED. AND SO WE NEED A VARIETY OF TOOLS TO EXPRESS AND UNDERSTAND HOW WE ARE INVESTING FUNDS AND THE IMPACT OF THOSE DISEASES ON THOSE COMMUNITIES AS THIS ONE REALLY IS INADEQUATE WHEN IT COMES TO ALS AND MND AND MS.

DR. GOLDSTEIN: I THINK THIS IS SOMETHING WE CAN TAKE UP AT A FUTURE MEETING, FRED. I DON'T DISPUTE THAT THERE'S VALUE IN CONTINUING THAT DISCUSSION. UNFORTUNATELY FOR MANY OF THESE DISEASES, ADVOCATES CAN MAKE VERY STRONG ARGUMENTS ABOUT WHAT THE RIGHT LEVEL OF ALLOCATION IS. AND AS YOU KNOW, THAT'S ALWAYS A TRICKY BUSINESS. I THINK HITTING NEUROPSYCH FIRST IS SOMETHING WHERE IT'S REALLY BEEN ALMOST COMPLETELY IGNORED IN OUR PORTFOLIO AND, THEREFORE, CONSTITUTES A HIGH

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PRIORITY. AND THERE WILL BE A CONCEPT COMING FROM VICE PRESIDENT CANET-AVILES SOON.

DR. FISHER: I DON'T WANT TO BE MISUNDERSTOOD. I'M NOT BEING CRITICAL OF THE PRIORITY OF NEUROPSYCH. I'M BEING CRITICAL OF USING DALY WHEN IT COMES TO UNDERSTANDING OUR INVESTMENT RELATED TO THE IMPACT OF DISEASE BECAUSE IT SEVERELY UNDERREPRESENTS THE BURDEN OF DISEASE.

CHAIRMAN IMBASCIANI: VERY GOOD POINT. MEMBER MELMED.

DR. MELMED: ANOTHER NUANCE, LARRY. I DON'T KNOW IF YOU CONSIDERED FOR EPILEPSY, FOR EXAMPLE, DID YOU CALL OUT PEDIATRICS? BECAUSE PEDIATRIC EPILEPSY AND NEONATAL EPILEPSY IS SO MUCH MORE COMMON IN ADULTS. I WONDER IF THAT SHOULDN'T BE EMPHASIZED. THAT'S A VERY SIGNIFICANT COMPONENT OF THE NEONATAL MORBIDITY POPULATION.

DR. GOLDSTEIN: ROSA OR ABLA, CAN YOU ADDRESS THAT PLEASE?

DR. MELMED: DO WE HAVE ANYTHING IN PEDIATRIC EPILEPSY? IF WE DON'T, WE SHOULD. I WOULD ARGUE THAT'S A VERY IMPORTANT DALY FOR PEDIATRIC PATIENTS.

DR. CANET-AVILES: WE WILL HAVE TO LOOK INTO THIS. WELL, WE HAVE EPILEPSY. YOU WERE

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TALKING ABOUT PEDIATRIC EPILEPSY?

DR. MELMED: DID WE CALL IT OUT SEPARATELY OR IN ADDITION?

DR. MILLAN: JUST IN TERMS OF THE PORTFOLIO, IN THE PRESIDENT'S REPORT, I REPORTED ON AT LEAST ONE PROGRAM THAT'S IN CLINICAL STAGE FOR PEDIATRIC FOCAL EPILEPSY THAT'S RESISTANT TO DRUGS, WHICH IS WHERE WE ARE FINDING --

DR. MELMED: ONLY ONE.

DR. MILLAN: THERE MAY BE MORE IN THE TRANSLATIONAL PORTFOLIO, BUT I'LL DEFER TO DR. CREASEY FOR ADDITIONAL.

DR. CREASEY: THERE'S ONLY ONE, THAT'S THE NEURONA PROGRAM IN CLINICAL CURRENTLY. WE DON'T HAVE PEDIATRICS IN CLINICAL YET.

DR. MELMED: I WOULD SUGGEST THAT THE TASK FORCE CONSIDER THAT WE CALL THAT OUT SEPARATELY BECAUSE IT'S SO IMPORTANT.

CHAIRMAN IMBASCIANI: MEMBER DURON.

MS. DURON: I WANTED TO PULL OUT, LARRY, A WRINKLE AND PERHAPS EVEN FROM LEFT FIELD. BUT I WOULD LIKE TO SEE SOME DATA THAT REPRESENTS THE IMPACT OF THESE DISEASES ON COMMUNITIES OF COLOR WHICH SOMETIMES THE IMPACT IS EVEN GREATER AS A RESULT OF SOCIAL DETERMINANTS OF HEALTH. THEREFORE,

I WOULD LIKE TO SEE IF THEY'RE ACTUALLY RECEIVING OR BEING INCLUDED. THIS GETS REALLY COMPLEX, BUT ARE THEY BEING EQUALLY INCLUDED SO THAT THEY'RE GETTING THE BENEFIT OF THE RESEARCH, THE TRIALS, ET CETERA, BECAUSE THEY MIGHT BE DISPROPORTIONATELY IMPACTED BY SOME OF THESE DISEASES.

ONE OF THE THINGS WE SAW PARTICULARLY DURING COVID WAS THE MENTAL, EMOTIONAL IMPACT ON MANY OF OUR COMMUNITIES; BUT FOR THIS FIRST TIME, IN A RESPONSE FROM THE LATINO COMMUNITY WAS THEY ARE ACTUALLY ADMITTING TO THE NEED FOR EMOTIONAL HELP, THAT THEY WERE ACTUALLY ADMITTING THAT THERE WAS AN ISSUE IN TERMS OF MENTAL HEALTH. SO THAT'S A MESSAGING ISSUE. IT'S AN INVESTMENT ISSUE. IT'S A WAY TO BRING THEM TO THE TABLE FOR CLINICAL TRIALS THROUGH OUR CANCER CENTERS OF EXCELLENCE. I KEEP SAYING THAT. I'M GOING TO HAVE TO WIPE IT OFF MY TONGUE.

AND SO IF WE DON'T SEE IT REFLECTED IN THE DATA, IT'S JUST THIS MASS STUFF, THEN I DON'T KNOW HOW TO MESSAGE BACK TO MY COMMUNITY IF THIS IS HELPING THEM, IF THEY'RE BEING IMPACTED, IF THEY'RE ENGAGED, AND WHAT THEY NEED TO DO IN ORDER TO DO AND ADDRESS ISSUES THAT THEY'RE FINALLY ADMITTING ARE PART OF THE COMMUNITY IMPACT. SO I DON'T KNOW IF

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YOU CAN PULL THAT DATA OUT, IF IT EXISTS, IF ANYBODY'S TRIED TO LOOK AT IT, BUT I THINK IT IS REALLY CRITICAL IF WE'RE, IN FACT, GOING TO BEGIN MESSAGING TO THESE VULNERABLE POPULATIONS AS WELL.

DR. GOLDSTEIN: THANK YOU FOR THAT COMMENT, YSABEL. I THINK I'M SURE THAT THE NUMBERS EXIST SOMEWHERE. WE DID NOT DISCUSS THE DETAILS OF THOSE NUMBERS THUS FAR, BUT I WILL TELL YOU THAT, AS A GENERAL MATTER, THE TASK FORCE IS AWARE THAT UNDERSERVED COMMUNITIES AND COMMUNITIES OF COLOR ARE, IN FACT, VERY HIGHLY IMPACTED BY THESE SORTS OF DISORDERS AND ABSOLUTELY NEED TO BE INCLUDED MOVING FORWARD.

THE MESSAGING WILL BE CRITICAL, TO BE SURE THAT, AS GENETIC STUDIES NOT SUPPORTED BY CIRM AND PERHAPS THOSE THAT WE PARTNER ON, ARE CONTINUED IN THE COMING YEARS. I'M RELATIVELY SURE THAT SOME OF THEM ARE TRYING TO GET INTO COMMUNITIES OF COLOR, AND IT'S CERTAINLY A COMMUNITY THAT WE ABSOLUTELY HAVE TO ENGAGE MOVING FORWARD HERE.

CHAIRMAN IMBASCIANI: THANK YOU. MEMBER MALKAS.

DR. MALKAS: ACTUALLY I WOULD LOVE TO ECHO THAT AND ALSO DRAW A POINT TO THE CHILDREN HAVE BEEN SO PROFOUNDLY AFFECTED IN THOSE COMMUNITIES BY THIS.

SO I WANT TO ECHO YOUR POINT.

CHAIRMAN IMBASCIANI: PAT LEVITT.

DR. LEVITT: SO THERE IS DATA ON SELECTIVE DSM-V DISORDERS THAT SPEAK TO YOUR POINT DIRECTLY. AND PARTICULARLY IN PEDIATRIC POPULATIONS, IT HAS A VERY LARGE IMPACT ON TIME TO FIRST DIAGNOSIS, WHICH, OF COURSE, THEN AFFECTS TIME TO FIRST INTERVENTION. SO AFRICAN-AMERICAN CHILDREN HAVE THE LARGEST GAP BETWEEN THE MEAN, WHICH IS ABOUT 3.2 YEARS FOR AUTISM SPECTRUM DISORDER, FOR EXAMPLE, AND FIRST DIAGNOSIS FOR CHILDREN WHO ARE IN THOSE FAMILIES, WHICH IS ABOUT SIX YEARS OLD. SO IT'S SCHOOL AGE. THE GAP IS CLOSING, BUT SLOWLY.

THERE'S ALSO NOW A LARGE NIH-FUNDED STUDY OF GENETICS THAT INCLUDES LARGE LATINO POPULATIONS. ALMOST ALL OF GENETICS AND IDENTIFYING MUTATIONS ARE BASED ON NORTHERN EUROPEAN DATA. SO THAT'S CHANGING AS WELL. BUT, AS YOU KNOW, IT'S REALLY A HEAVY LIFT TO WORK WITH COMMUNITIES, PARTICULARLY WITH ORGANIZATIONS THAT ARE IN COMMUNITIES, TO TALK ABOUT WHY IT'S IMPORTANT TO PARTICIPATE IN RESEARCH. SO THERE IS NOT JUST A GROWING AWARENESS, BUT THERE'S A LARGE EFFORT ON THE PART OF THE RESEARCH COMMUNITY TO BE VERY INCLUSIVE. BUT THE RESEARCH COMMUNITY FOLKS NEED HELP IN DOING THIS THE RIGHT WAY. BUT

THE POINT YOU MAKE IS ABSOLUTELY SPOT ON.

MS. DURON: MAY I JUST ADD BUT WE NEED TO SEE THE DATA BECAUSE OTHERWISE WE DON'T BUY IT, RIGHT. THERE'S JUST TOO MANY PEOPLE WHO DON'T BELIEVE IT. AND SO WE NEED TO SEE THE DATA. AND I KNOW THAT PULLING THAT OUT MIGHT BE DIFFICULT, WHETHER STAFF CAN HELP WITH THAT, BUT I JUST THINK OVERARCHINGLY WE JUST NEED TO SEE IT SO I CAN GO BACK AND USE THAT. ALL OF US RESEARCH PROGRAM IN WHICH THEY CLAIM NOW TO HAVE THE LARGEST GENOMIC DATABASE, DIVERSE DATABASE, SHOWED THAT 16 PERCENT OF THE ENROLLEES ARE LATINO. SO WHEN YOU SAY YOU CAN'T GET THEM TO GET ENGAGED, YOU CAN, BUT WHO'S CALLING THEM OUT AND WHAT ARE THEY TELLING THEM AND HOW ARE THEY LISTENING TO THEM AND IN WHAT LANGUAGE ARE THEY TALKING?

SO I THINK, AS YOU SAY, PAT, IT'S THE DEVIL'S IN THE DETAILS OF HOW WE'RE GOING TO DO THIS, BUT WE NEED THE DATA. SO IT HAS TO BE CALLED OUT AND PULLED OUT.

DR. CREASEY: YSABEL, I JUST WANTED TO MENTION TO YOU THAT WE ARE COMMITTED TO DOING THAT. WE'RE IN THE PROCESS OF COLLECTING THAT KIND OF DATA FROM THE CLINICAL TRIALS. AND SO AS SOON AS WE HAVE CRITICAL AMOUNTS THAT ARE WORTHY OF ANALYSIS, WE

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WILL BE DOING THAT. SO WE HEARD YOU.

MS. DURON: THAT'S SAD, ABLA, THAT ARE WORTHY OF CALLING OUT.

DR. CREASEY: NUMBERS-WISE.

MS. DURON: YOU KNOW. BUT I APPRECIATE IT. THANK YOU.

DR. CREASEY: ALL I'M SAYING IS THAT IF WE HAD ONLY FIVE PATIENTS, WHAT DO THESE DATA MEAN; BUT IF WE HAVE 25, I CAN THEN DESCRIBE TRENDS FOR YOU THE WAY WE DID HERE.

DR. GOLDSTEIN: LET ME JUST ADD A TECHNICAL POINT. SO FIRST OF ALL, YSABEL, I AGREE. WE SHOULD HAVE A LOOK AT THOSE DATA. I WANT TO REMIND EVERYBODY THAT IN ORDER FOR STEM CELL PROJECTS TO BE INITIATED IN SOME OF THESE AREAS, IN PARTICULAR NEUROPSYCHIATRY, WE DEPEND VERY HEAVILY ON THE GENETIC ANALYSES DONE BY THE GENETICS COMMUNITY. AT PRESENT CIRM IS NOT SUPPORTING GENOMEWIDE SCREENS IN ANY OF THESE COMMUNITIES. IT'S AN IMPORTANT QUESTION, TO WHAT EXTENT SHOULD WE BECOME INVOLVED IN STIMULATING THOSE PROJECTS? AND I THINK AS WE START TO DEVELOP SOME PILOT PROJECTS IN THE PORTFOLIO, WE'LL START TO LEARN TO WHAT EXTENT THE STEM CELL COMMUNITY IS ENGAGED WITH THE GENETICS COMMUNITY AND TO WHAT EXTENT WE CAN

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ENCOURAGE THAT.

DR. CANET-AVILES: I'D LIKE TO ADD. SO THIS CONVERSATION ABOUT ANCESTRAL DIVERSITY HAD COME UP EARLIER ON. AS WE WERE DEVELOPING AND BRAINSTORMING ABOUT THE NEURO DISCOVERY INITIATIVE, ONE OF THE THINGS THAT THE CIRM TEAM DID WAS START DISCUSSING WHAT'S OUT THERE. WHAT IS THE NATIONAL INSTITUTES OF MENTAL HEALTH FUNDING? WHAT ARE OTHER ORGANIZATIONS FUNDING? SO THERE'S ACTUALLY A VERY LARGE COHORT WITH ANCESTRAL DIVERSITY, GENOTYPING AND CLINICAL PHENOTYPING OF DIVERSE POPULATIONS ACROSS THE WORLD, THOUSANDS OF SCHIZOPHRENIA AND BIPOLAR DISEASE. AND THEY ARE ACTUALLY CURRENTLY LOOKING FOR A PARTNER TO DERIVE SOME LINES, IPS LINES, SO THAT WE COULD HAVE -- ACTUALLY THIS COULD BE SOMETHING THAT, THIS IS A PROPOSAL FOR LATER. JUST WANTED TO BRING IT UP TO THE BOARD, THAT THIS MIGHT COME UP AT THE TASK FORCE LEVEL, BUT THIS COULD BE A VERY GOOD RESOURCE FOR US TO PARTNER AND ANSWER SOME OF THE QUESTIONS AND VOIDS THAT WE ARE IDENTIFYING IN THIS DISCUSSION. JUST WANTED TO BRING IT UP. I'M HAPPY TO PRESENT IT AT A LATER TIME.

DR. GOLDSTEIN: THANK YOU, ROSA.

CHAIRMAN IMBASCIANI: ANY OTHER COMMENTS

FROM BOARD MEMBERS IN THE ROOM OR ONLINE OR FROM THE PUBLIC? OKAY. THIS WAS A VERY GOOD CONVERSATION. I'M SURE THE NEURO TASK FORCE IS GOING TO TAKE THIS BACK FOR CONSIDERATION, AND THEY ARE GOING TO MAKE A PRESENTATION, I THINK, MORE FORMALLY AT THE NEXT BOARD IN SEPTEMBER.

WITH THAT, I WOULD LIKE TO HAVE A TEMPORARY RECESS FOR LUNCH, AND THEN WE WILL COME BACK AND LISTEN TO DR. TURBEVILLE'S REPORT ON AAWG.

MR. TOCHER: WE'LL COME BACT AT 12:40, SO HALF AN HOUR.

CHAIRMAN IMBASCIANI: PERFECT. THANK YOU.

(A RECESS WAS TAKEN.)

CHAIRMAN IMBASCIANI: IF EVERYONE CAN PLEASE RESUME THEIR SEATS. WE'LL TAKE UP THE FINAL ITEM ON THE AGENDA. GIVE EVERYONE A FEW SECONDS TO GET SETTLED. OKAY. THANK YOU, EVERYONE. HOPE YOU ENJOYED YOUR LUNCH.

WE HAVE ONE ITEM ON THE FORMAL AGENDA REMAINING, AND THAT IS AN UPDATE ON ACCESSIBILITY AND AFFORDABILITY WORKING GROUP. AND THE PRESENTATION WILL BE LED BY DR. SEAN TURBEVILLE, OUR VICE PRESIDENT FOR MEDICAL AFFAIRS. THANK YOU.

DR. TURBEVILLE: OKAY. THANK EVERYBODY AND GOOD AFTERNOON. I WANT TO THANK THE CHAIRMAN,

OF COURSE, AND VICE CHAIR, MEMBERS OF THE ICOC, AND MEMBERS OF THE PUBLIC. I THINK IT'S FIRST TO SAY THAT THIS IS PROBABLY MY LAST PRESENTATION TO THE ICOC. AND I WANT TO TAKE THIS OPPORTUNITY TO EXPRESS MY GRATITUDE AND APPRECIATION FOR THE OPPORTUNITY TO WORK FOR CIRM. CIRM IS AN AMAZING PLACE, PARTICULARLY THE EXTRAORDINARY ORGANIZATION WITH RESPECT TO THE TIRELESS WORK THAT I SEE FROM THE CIRM EMPLOYEES, THE STAFF. THE GROUNDBREAKING INVESTIGATIVE THERAPIES FOR CALIFORNIA PATIENTS DESERVES IMMENSE RECOGNITION, AND SOMETIMES I HEAR, TALKING TO COLLEAGUES, THAT PEOPLE STILL DON'T KNOW WHO CIRM IS. AND IT'S JUST QUITE SURPRISING TO ME GIVEN ALL THE WORK THAT I SEE INTERNALLY AS WELL AS EXTERNALLY, BUT I'M CERTAIN THAT THAT WILL CHANGE OVER TIME. SO THE DEDICATION AND REMARKABLE ACHIEVEMENTS OF CIRM IN THIS FIELD IS TRULY INSPIRING AND CERTAINLY APPRECIATE THE OPPORTUNITY TO BUILD THE MEDICAL AFFAIRS ORGANIZATION. WE DID A LOT OF WORK IN 14 MONTHS. AND I'D LIKE TO NOW MOVE TO THE PRESENTATION TODAY.

AND WHAT I'LL BE SPEAKING TO IS OUR INTRODUCTION TO OUR PROPOSED ROADMAP TO ACCESS AND AFFORDABILITY. IN THE LAST FOUR TO FIVE MONTHS, WE'VE BEEN ENGAGING WITH THE AAWG ON DIFFERENT

CONCEPTS THAT SHOULD BE CONSIDERED FROM ICOC, THE OPPORTUNITY TO BE IN A ROADMAP FOR ACCESS AND AFFORDABILITY. SO I'M GOING TO FOCUS ON WHY WE ARE CREATING THE ROADMAP, REVIEW THE POTENTIAL PROBLEM STATEMENT, AND THE OPPORTUNITY AREAS TO ADDRESS BARRIERS TO ACCESS AND AFFORDABILITY. AND THEN AT THE END OF THIS PRESENT A COUPLE OF CONCEPTS THAT I'D LIKE TO GET FEEDBACK ON THAT WE CAN CONSIDER FOR NEAR-TERM OPPORTUNITY WITHIN THE ROADMAP.

SO IT'S CRITICAL TO TAKE A MOMENT TO REFLECT ON THE PURPOSE BEHIND THE DEVELOPMENT OF THE PROPOSED ROADMAP. SO WHY ARE WE DOING THIS? SO PROPOSITION 14 AND THE FIVE-YEAR STRATEGIC PLAN STATE THAT CIRM WILL SUPPORT THE DEVELOPMENT OF A ROADMAP FOR ACCESS AND AFFORDABILITY IN CONCORDANCE WITH CIRM'S ACCESSIBILITY AND AFFORDABILITY WORKING GROUP, THE AAWG.

THE ROADMAP WILL INCLUDE A STRATEGY FOR GATHERING DATA TO SUPPORT REIMBURSEMENT, ENGAGING POLICYMAKERS AND REGULATORS, AND DEVELOPING NOVEL HEALTHCARE DELIVERY MODELS. IT WILL ALSO MANAGE FUTURE INITIATIVES INVOLVING POST-MARKETING RESEARCH, FOLLOW-UP AND OUTCOME DATABASES, REGISTRY DEVELOPMENT, REAL-WORLD EVIDENCE RESEARCH, HEALTHCARE ECONOMICS, AND PATIENT-REPORTED OUTCOMES.

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AS WE DIVE INTO VARIOUS RECOMMENDATIONS, YOU WILL NOTICE THAT THESE SUGGESTIONS ARE IN LINE WITH THE LANGUAGE OUTLINED IN THE PROPOSITION 14 AND OUR FIVE-YEAR STRATEGIC PLAN THAT I JUST DESCRIBED.

SO NO DOUBT ABOUT IT, CELL AND GENE THERAPIES HAVE A SIGNIFICANT IMPACT ON PATIENTS, AND WE'VE SEEN IT TIME AND TIME AGAIN OVER A NUMBER OF DIFFERENT THERAPEUTIC AREAS; HOWEVER, THERE ARE ALSO SOME CHALLENGES. AND WE COULD PERHAPS START WITH A PROBLEM STATEMENT, BUT ALSO SOME OPPORTUNITIES. ONE OF THE PROBLEM STATEMENTS SAYS THERE ARE SEVERAL LOGISTICAL AND FINANCIAL BARRIERS TO CLINICAL TRIALS AND APPROVED THERAPIES FOR CELL AND GENE THERAPIES. WE'VE SEEN OVER AND OVER AGAIN THE CHALLENGES FOR PATIENTS AND FAMILY MEMBERS TO PARTICIPATE IN MANY OF THESE TRIALS.

THE OPPORTUNITY THAT WE HAVE IS IN PROPOSITION 14, WHICH PROVIDES DEDICATED FUNDING AND THE FORMATION OF THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP TO ADDRESS THESE BARRIERS. THE GOAL OF THE ROADMAP IS TO IDENTIFY NEAR-TERM AND LONGER-TERM INITIATIVES TO HELP PATIENTS OVERCOME SOME OF THESE BARRIERS TO ACCESS AND AFFORDABILITY.

SO I WANT TO TAKE A LITTLE BIT OF TIME TO FOCUS ON THIS SLIDE. SO WE'VE DONE A LOT OF DUE

DILIGENCE ON BARRIERS THAT PREVENT PATIENTS FROM HAVING ACCESS TO CLINICAL TRIALS. AND THERE ARE A NUMBER OF OPPORTUNITIES AND A NUMBER OF PROGRAMS WITHIN CIRM THAT ARE ALREADY IN PLAY AND OTHERS THAT WE WANT TO RECOMMEND THAT WILL MITIGATE SOME OF THE BARRIERS.

SO IF WE THINK ABOUT INITIATIVES THAT MITIGATE NEGATIVE SOCIAL AND CULTURAL DETERMINANTS OF HEALTH, ONE, WE ALREADY HAVE THE EXPANSION OF THE ALPHA CLINICS THAT WENT FROM SIX TO NINE, AND THERE ARE A NUMBER OF OFFERINGS WITHIN THOSE AWARDS THAT ACTUALLY ADDRESS AND SOME OF THEM MITIGATE THE NEGATIVE SOCIAL AND CULTURAL DETERMINANTS OF HEALTH. AND I'LL SPEAK TO THOSE IN A FEW MINUTES.

WE ALSO HAVE THE COMMUNITY OUTREACH IN EDUCATION. THIS IS A NEW DEPARTMENT THAT'S JUST STARTING TO GEAR UP, STARTING TO THINK THROUGH OUTREACH PROGRAMS THAT WOULD HELP WITH EDUCATION AND OTHER OPPORTUNITIES.

WE ALSO HAVE THE FUTURE COMMUNITY CARE CENTERS OF EXCELLENCE. THIS IS A BIG INITIATIVE I'LL SPEAK TO IN A FEW MINUTES. AND THEN COMMUNITY PARTNERS. I'VE LEARNED RECENTLY THROUGH THIS JOURNEY HOW IMPORTANT COMMUNITY-BASED ORGANIZATIONS ARE IN INTERACTING WITH PATIENTS, GETTING THE WORD

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ACROSS, EDUCATING ON CELL AND GENE THERAPIES, ET CETERA.

WHEN WE THINK ABOUT CIRM PROGRAMS TO ADDRESS INFORMATIONAL BARRIERS, THIS IS WHERE OUR PATIENT SUPPORT PROGRAM SITS. AND SO THE PATIENT SUPPORT PROGRAM PROVIDES A NUMBER OF SERVICES. ONE, NAVIGATING PATIENTS TO THE RIGHT CLINICAL TRIAL. SO CIRM HAS, WHAT, ABOUT 91 TRIALS CURRENTLY ENROLLED. THE OTHER THING IS INFORMATION, INFORMATION ABOUT THE TRIAL, INFORMATION FOR HEALTHCARE PROVIDERS AND PATIENTS IS ABSOLUTELY KEY.

WHEN WE THINK ABOUT PROGRAMS TO HELP PATIENTS NAVIGATE THE LOGISTICAL BARRIERS, AND THIS IS ONE OF THE VARIABLES THAT CONSISTENTLY COMES UP IN PARTICIPATING IN TRIALS, IS HOW CAN I GET TO THE SITE, THE EXPENSES THAT TAKE PLACE, FAMILY, CHILDCARE, ET CETERA. THIS TOO IS WHERE IT CAN BE SUPPORTED BY THE PATIENT SUPPORT PROGRAM. AND WHEN WE THINK ABOUT LOGISTICS, THERE'S AN OPPORTUNITY FOR THE PATIENT SUPPORT PROGRAM TO HELP THE SITE ORGANIZE THE PATIENT IN TERMS OF LOGISTICS TO THE SITE, GOING BACK AND FORTH HOME, ET CETERA.

THE OTHER THING WITH RESPECT TO FINANCIAL, WITHIN THE PATIENT SUPPORT PROGRAM THERE'S ALSO THE PATIENT ACCESS FUND. AND THIS IS AN RFA THAT'S

POSTED RIGHT NOW. THAT PATIENT ACCESS FUND SITS WITHIN THE PATIENT SUPPORT PROGRAM. THIS IS $15.6 MILLION THAT IS DEDICATED DIRECTLY TO SUPPORTING PATIENTS THROUGH TRIALS. AND, AGAIN, WE KNOW THOSE OUT-OF-POCKET PATIENT EXPENSES CAN BE HIGH. IN FACT, THERE'S RECENT DATA THAT SUGGESTS THAT OUT-OF-POCKET PATIENT EXPENSES CAN BE ANYWHERE BETWEEN FIVE TO EIGHT HIGHER THAN WHAT YOU WOULD SEE IN PATIENTS WHO ARE PARTICIPATING IN NON-CELL AND GENE THERAPY TRIALS.

SO WHILE CIRM'S EFFORT PRIMARILY FOCUSES ON ADDRESSING BARRIERS TO CLINICAL TRIALS, IT IS CRUCIAL TO ACKNOWLEDGE THAT REMOVING ALL BARRIERS, EVEN IF WE HAD THE OPPORTUNITY, DOES NOT NECESSARILY MEAN PATIENTS ARE ALWAYS GOING TO GET ACCESS TO DRUGS. MARIA MILLAN JUST GAVE A PRESENTATION TODAY ABOUT CANDIDATES, DRUG CANDIDATES, THAT DEMONSTRATED EFFICACY THAT STILL CAN'T GET TO THE MARKETPLACE. SO FDA APPROVAL AND REIMBURSEMENT FOR A THERAPY ARE ESSENTIAL ASPECTS TO ENSURE THAT ALL CALIFORNIA PATIENTS HAVE MEANINGFUL ACCESS TO CELL AND GENE THERAPIES BEYOND JUST THE CLINICAL TRIAL STAGE.

SO I'LL TALK A LITTLE BIT ABOUT SUPPORTING BROAD AND FAIR COVERAGE FOR CELL AND GENE THERAPIES. A COUPLE OF COMPONENTS I'LL GET BACK INTO IN MORE

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DETAIL LATER. ONE IS THINKING ABOUT THE RESEARCH WITH RESPECT TO REAL-WORLD EVIDENCE AND HEALTH OUTCOMES AND OPPORTUNITIES AND THAT IMPACT ON ACCESS AND AFFORDABILITY. ANOTHER IS THE ENGAGEMENT WITH PAYERS. AND THIRD IS OUTCOMES-BASED PERFORMANCE MODELS, WHICH ARE ABSOLUTELY CRITICAL WITH RESPECT TO REIMBURSEMENT, ET CETERA.

SO I'D LIKE TO DIRECT YOU TO THIS SLIDE. THIS IS OUR PROPOSED ROADMAP TO ACCESS AND AFFORDABILITY, AND IT IS COLOR CODED. SO THE ORANGE TO THE LEFT OF THE SLIDE REPRESENTS APPROVED CIRM-FUNDED PROGRAMS. SO RIGHT NOW WE HAVE EXPANSION OF THE ALPHA CLINICS AND WE HAVE THE PATIENT SUPPORT PROGRAM. THE NAVY BLUE DEPICTS THREE PROPOSED STRATEGIES IN THE MIDDLE THAT I WILL FOCUS ON TODAY FURTHER ON WITH MY DISCUSSION. AND THEN THE GRAY COMPONENT INDICATES AN IMPORTANT PROGRAM THAT IS CURRENTLY IN PROGRESS. AND, OF COURSE, THAT'S THE COMMUNITY CARE CENTERS OF EXCELLENCE. AND THE WAY WE DESIGNED THIS IS ALSO THINKING THROUGH MUCH MORE LONG-TERM FUTURE INITIATIVES.

SO FOR THE PURPOSE FOR THIS PRESENTATION IS REALLY TO THINK ABOUT SHORT-TERM, NEAR-TERM OPPORTUNITIES THAT WE CAN HELP PATIENTS WITH RESPECT

TO ACCESS AND AFFORDABILITY.

SO LET'S FIRST TALK ABOUT APPROVED PROGRAMS, SO THE EXPANSION OF THE ALPHA CLINICS. THIS PROGRAM ALIGNS WITH PROP 14 AND INVOLVES EXPANDING THE EXISTING NETWORK OF ALPHA CLINICS. THE NINE CENTERS OF EXCELLENCE OFFER VARIOUS CLINICAL SERVICES, RESOURCES THAT ALLOW CIRM TO GATHER ADDITIONAL INFORMATION FOR FUTURE CONSIDERATIONS RELATED TO ACCESS AND AFFORDABILITY. AS PART OF THE EXPANSION, THERE ARE SPECIFIC OFFERINGS WITHIN THE AWARDS, SUCH AS PATIENT NAVIGATION, COVERAGE ANALYSIS, NEW FINANCIAL MODELS, DEI INITIATIVES, AND OTHER OFFERINGS THAT ARE INCORPORATED TO ENHANCE THE PATIENT SUPPORT AND ACCESS.

SO AS THESE STUDIES CONTINUE TO ENROLL, WE'LL BE ABLE TO GET INFORMATION FROM THE ALPHA CLINICS ON THE REPORTING THAT WILL GIVE US GUIDANCE IN TERMS OF WHERE THERE MAY BE ADDITIONAL OPPORTUNITIES FOR ACCESS AND AFFORDABILITY RELATED TO THESE VARIABLES.

THE OTHER IS THE PATIENT SUPPORT PROGRAM. AND THIS IS OFFSETTING THE COST OF PROVIDING TREATMENTS AND CURES ARISING FROM INSTITUTE FUNDING RESEARCH. SO THE ACTIVITY HERE IS TO CREATE

CONSISTENT, EFFICIENT, STREAMLINED, AND RELIABLE ACCESS TO RESOURCES AND SUPPORT ACROSS ALL THE DIFFERENT TYPES OF CIRM-FUNDED PROGRAMS. AGAIN, THESE ARE TWO PROGRAMS THAT ARE PROGRESSING AND ARE PART OF THE PROPOSED ROADMAP AND DIRECTLY ALIGN WITH THE PROPOSITION 14.

NOW I WANT TO TALK ABOUT THE PROGRAM IN PROGRESS, AND THIS IS THE COMMUNITY CARE CENTERS OF EXCELLENCE. SO THIS ALIGNS WITH PROPOSITION 14, IN THAT IT ENHANCES THE GEOGRAPHICAL DISTRIBUTION TO PROMOTE PATIENT ACCESS TO TRIALS AND CREATE NOVEL HEALTHCARE DELIVERY MODELS. SO THIS IS AN ONGOING PROGRAM. THE MEDICAL AFFAIRS TEAM WORKED TIRELESSLY. MANY PEOPLE HERE IN THIS ROOM GAVE A LOT OF GUIDANCE AND ATTENDED NOT ONLY THE THREE LISTENING SESSIONS, BUT JUST RECENTLY THE PUBLIC SESSION THAT WE HAD LAST WEEK. AND THESE COMMUNITY CARE CENTERS OF EXCELLENCE ARE QUALIFIED SITES WITH CLINICAL, OPERATIONAL, AND EDUCATIONAL EXPERTISE TO PROVIDE RURAL COMMUNITIES ACCESS TO INVESTIGATIONAL CELL AND GENE THERAPY TRIALS.

THE CCE HOLDS SIGNIFICANT IMPORTANCE AS IT WILL SERVE AS A CRUCIAL COMPONENT OF THE ROADMAP PARTICULARLY IN SUPPORTING CLINICAL TRIALS IN RURAL COMMUNITIES. SO AT THIS STAGE, AS DR. MILLAN

MENTIONED EARLIER TODAY, WE ARE NOW STARTING TO DEVELOP THE CONCEPT PLAN. THAT CONCEPT PLAN WILL BE PRESENTED TO THE ACCESS AND AFFORDABILITY WORKING GROUP, TO THE SCIENTIFIC COMMITTEE, AND THEN HOPEFULLY TO THE ICOC FOR FINAL CONSIDERATION INTO AN RFA. AND OUR EXPECTATION IS THAT THROUGH THAT PROCESS AN RFA COULD BE POSTED AS EARLY AS Q2 OF THE FIRST HALF OF 2024.

SO THIS IS A SLIDE THAT WAS DEVELOPED BY MY COLLEAGUE GEOFF. AND BY INTEGRATING THE ALPHA CLINICS, THE COMMUNITY CARE CENTERS OF EXCELLENCE, THE CIRM-FUNDED TRIALS, AND THE PATIENT SUPPORT PROGRAM, THIS COLLABORATIVE APPROACH WILL ALLOW THE CREATION OF MORE ROBUST STRATEGIES AND INITIATIVES THAT ADDRESS THE SPECIFIC NEEDS OF DIVERSE COMMUNITIES, ENHANCE ACCESSIBILITY TO INNOVATIVE THERAPIES, AND PROMOTE AFFORDABILITY FOR PATIENTS ACROSS DIFFERENT REGIONS.

SO IF YOU THINK ABOUT THIS, OF COURSE, WE'VE GOT THE ALPHA CLINICS. THOSE ARE THE NINE LEAD SITES AND CENTERS, CENTERS OF EXCELLENCE. THE COMMUNITY CARE CENTERS OF EXCELLENCE BRING THE CLINICAL CAPACITY TO THE COMMUNITY. THE CIRM CLINICAL TRIALS, NOW 91 CIRM-FUNDED TRIALS, ARE IN PLAY. AND THEN YOU TACK ON BOARD THE PATIENT

SUPPORT PROGRAM THAT WILL PROVIDE THE ADDITIONAL FINANCIAL AND LOGISTICAL BARRIERS.

SO NOW WHAT I'D LIKE TO DO IS DISCUSS THE PROPOSED INITIATIVES FOR CONSIDERATION. SO POSSIBLE STRATEGY NO. 1 IS SUPPORTING FUNDING OF CALIFORNIA DISEASE REGISTRIES AND OTHER REAL-WORLD DATA COLLECTION. WE KNOW THAT THE FDA AND PAYERS HAVE REQUIREMENTS NOW FOR REAL-WORLD DATA. THEY HAVE A SIGNIFICANT IMPACT ON CLINICAL DOSSIERS THAT GO TO THE FDA, AND THEY HAVE EVEN MORE IMPORTANCE WITH RESPECT TO REIMBURSEMENT. SO THE BENEFIT HERE IS IT ENHANCES OPPORTUNITY FOR APPROVED AND PAYER REIMBURSEMENT WHEN DATA IS APPROPRIATELY SUBSTANTIATED ACCORDING TO FDA GUIDANCE AND PAYER MANDATES. PATIENTS WILL HAVE ACCESS TO THE TREATMENT IF APPROVED AND REIMBURSED BY PAYERS.

AS AN EXAMPLE, DR. MILLAN, AND THERE ARE OTHERS, JUST RECENTLY WE HEARD ABOUT THE MOST RECENT GENE THERAPY THAT WAS APPROVED FOR DND. AND IN THAT CLINICAL PACKAGE THAT WENT TO THE FDA, THAT BLA, NOT ONLY DID IT INCLUDE OPEN LABEL PHASE 2 TRIAL DATA, BUT IT ALSO INCLUDED REAL-WORLD EVIDENCE AND DATA FROM DISEASE REGISTRY. AND THAT WAS IMPORTANT BECAUSE IT DID PROVIDE SUBANALYSES THAT WERE ASKED OF THE COMMITTEE ON A NUMBER OF DIFFERENT VARIABLES.

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AND WE ARE SEEING THIS OVER AND OVER AGAIN WITH OTHER PRODUCTS THAT ARE BEING PRESENTED TO THE FDA THROUGH BLA OR EVEN AN NDA FOR THAT MATTER.

SO PAYERS ARE ALSO BEGINNING TO SET UP THEIR INFRASTRUCTURE, WHAT THE REQUIREMENTS ARE, WITH REAL-WORLD DATA. THE AMCP DOSSIER THAT YOU MAY BE FAMILIAR WITH, THAT IS THE GOLD STANDARD FORMULARY SUBMISSION THAT GOES TO ALL THE PAYERS. THAT INCLUDES PUBLIC AS WELL AS PRIVATE. THEY HAVE GUIDELINES ON HOW YOU CAN USE REAL-WORLD DATA TO SUPPORT THE CLINICAL EFFICACY, MORE IMPORTANTLY EFFECTIVENESS OUT THERE IN THE REAL WORLD.

SO ONE HAS TO START THINKING THROUGH IN THE ABSENCE OF REAL-WORLD DATA AND -- LET ME BACK UP. MY POINT BEING IS SO NOW WE MUST CONSIDER THE POTENTIAL CONSEQUENCES FOR PATIENTS IF DISEASE REGISTRIES AND OTHER REAL-WORLD DATA SOURCES ARE NOT UTILIZED FOR REGULATORY AND PAYER SUBMISSION IN APPROVING ACCESS. SO THERE ARE A COUPLE OF RECOMMENDATIONS HERE.

ONE, WE RECOMMEND ADDITIONAL RESEARCH. WHERE HAVE DISEASE REGISTRIES BEEN IMPACTFUL FOR REGULATORY APPROVAL? TWO, WHERE HAVE DISEASE REGISTRIES AND OTHER REAL-WORLD DATA BEEN SUCCESSFULLY SUBMITTED TO PAYERS? AND HOW CAN THIS

KNOWLEDGE BE APPLIED FOR CIRM-FUNDED TRIALS, PARTICULARLY WHEN WE START ASKING THE QUESTIONS ABOUT PATIENT AND ECONOMIC OUTCOMES?

BY CONDUCTING SUCH RESEARCH AND UTILIZING THESE DISEASE REGISTRIES AND OTHER REAL-WORLD DATA SOURCES EFFECTIVELY, CIRM CAN PROVIDE A NEW FUNDING MECHANISM TO PROVIDE AWARDEES THE BEST CHANCE FOR SUCCESS FOR REGULATORY APPROVAL, THEREBY FACILITATING ACCESS TO APPROVED NOVEL THERAPIES. SO THAT IS POSSIBLE STRATEGY NO. 1, SUPPORT THE FUNDING OF REAL-WORLD DATA AND DISEASE REGISTRIES.

A POSSIBLE SECOND STRATEGY IS ENGAGING WITH PAYERS. SO THE BENEFIT HERE IS IT CREATES PROACTIVE UNDERSTANDING OF PAYER ISSUES, NECESSARY DATA NEEDED FOR APPROPRIATE PAYMENT MODELS. AND THERE'S A COUPLE OF RECOMMENDATIONS BY THE AAWG. ONE, LET'S PUT OUT A PAYER SURVEY, A ROBUST SURVEY THAT ASKS A NUMBER OF QUESTIONS AMONG PRIVATE AS WELL AS PUBLIC PAYERS TO UNDERSTAND WHAT THEIR CHALLENGES ARE RELATED TO CELL AND GENE THERAPY REIMBURSEMENT. THE SURVEY COULD PROVIDE VALUABLE INFORMATION ON PAYER EXPECTATIONS AND DATA REQUIREMENTS AIDING IN THE DEVELOPMENT OF APPROPRIATE REIMBURSEMENT STRATEGIES. THAT WOULD BE RECOMMENDATION NO. 1.

AFTER THAT THERE WAS A RECOMMENDATION TO ACTUALLY HAVE A PAYER ADVISORY BOARD, ESTABLISHING A ROBUST PAYER ADVISORY BOARD LED BY THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP. THIS BOARD COULD BRING TOGETHER PAYERS AND OTHER RELEVANT STAKEHOLDERS TO PROVIDE ONGOING GUIDANCE, ADVICE, AND FEEDBACK ON REIMBURSEMENT STRATEGIES, POLICY CONSIDERATIONS, AND PAYER ENGAGEMENT.

BY UNDERTAKING THESE RESEARCH OPPORTUNITIES AND ACTIVELY ENGAGING WITH PAYERS, CIRM COULD GAIN INSIGHTS INTO THE PAYER LANDSCAPE, ADDRESS PAYER CONCERNS, FOSTER COLLABORATIVE RELATIONSHIPS. THIS PROACTIVE APPROACH CAN HELP GUIDE APPROPRIATE REIMBURSEMENT STRATEGIES, ANTICIPATE POTENTIAL POLICY RESTRICTIONS, AND ENSURE THAT CIRM-FUNDED THERAPIES HAVE ACCESS TO FAVORABLE REIMBURSEMENT FRAMEWORKS. SO THAT'S POSSIBLE STRATEGY NO. 2.

POSSIBLE STRATEGY NO. 3 FOCUSES ON THE FEDERAL AND STATE POLICY ISSUES. SO THE BENEFIT OF THIS IS DEVELOPING AN UNDERSTANDING OF THE STATE POLICY TO SUPPORT PROACTIVE COMMUNICATION AND DEVELOPMENT OF CIRM POLICIES WITH KEY CALIFORNIA AGENCIES. ONE PARTICULAR OPPORTUNITY IS TO WORK WITH CMS. SO CMS, PARTICULARLY THE CENTER FOR

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MEDICARE/MEDICAID INNOVATION THAT'S CALLED CMMI, HAS NOW REACHED OUT TO STATES AND REACHED OUT TO STATES TO GET GUIDANCE ON WHAT THE PAYER OUTCOME-BASED MODELS SHOULD LOOK LIKE.

SO THIS IS A VOLUNTARY OPPORTUNITY. YOU DON'T HAVE TO DO IT, BUT WHAT WE WERE THINKING IS THAT THIS WOULD BE AN OPPORTUNITY FOR CIRM TO COLLABORATE WITH OTHER STATE ORGANIZATIONS WITHIN CALIFORNIA TO PROVIDE FEEDBACK OF WHAT WE THINK ARE IMPORTANT WHEN IT COMES TO VALUE, PARTICULARLY VALUE OF CELL AND GENE THERAPIES. SO THIS WOULD BE A GREAT OPPORTUNITY TO INTERACT WITH CMS, PROVIDE GUIDANCE PARTICULARLY WHEN IT COMES TO THOSE OUTCOMES-BASED MODELS.

JUST TO BRIEFLY SPEAK ABOUT OUTCOMES-BASED MODELS, VALUE-BASED CONTRACTS, THEY'RE NOT ALL THE SAME. AND SOME OF THEM WORK REALLY WELL IN ONCOLOGY, SOME OF THEM WORK REALLY WELL IN GENE THERAPY, BUT FOR NEUROMUSCULAR DISEASES, FOR EXAMPLE, THEY'RE A LITTLE BIT DIFFICULT. AND SO IT GIVES US AN OPPORTUNITY TO TAKE THE LEAD AND PROVIDE SOME GUIDANCE TO THE CMS IN TERMS OF WHAT CALIFORNIA APPRECIATES WITH RESPECT TO VALUE.

ANOTHER OPPORTUNITY THAT WAS RECOMMENDED TO US IS TO FURTHER EXPLORE THE CANCER CARE EQUITY

ACT. NOW, THERE'S AN ONGOING DISCUSSION ON THE CANCER CARE EQUITY ACT AMONG OTHER STAKEHOLDERS WITH RESPECT TO EXPLORING OPPORTUNITIES TO EXPAND THE LANGUAGE OF THIS LAW. AND BASICALLY HOW THIS LAW WAS SET UP IS THAT IT MANDATES -- WELL, IT DOESN'T REALLY MANDATE. WHAT IT DOES IS A GOOD FAITH PRINCIPLE, AND THAT IS ANY CANCER PATIENT RECENTLY DIAGNOSED, THEY HAVE THE RIGHT TO BE TREATED AT AN NCI CERTIFIED SITE, MUCH LIKE ALL THE ALPHA CLINICS.

ONE OF THE DRAWBACKS TO THIS IS IT'S NOT MANDATED. THAT IS, IF YOU DON'T HAVE TO TELL THE PATIENT, IT'S WITH A GOOD FAITH PRINCIPLE. AND SO THE AAWG AND A NUMBER OF OTHER COLLEAGUES THOUGHT IT MAY BE A GOOD OPPORTUNITY FOR CIRM TO GET INVOLVED WITH PERHAPS UPDATING THIS LEGISLATION TO ACTUALLY HAVE IT MANDATED. THAT IS, ANY CANCER PATIENT THAT'S DIAGNOSED, THEY GET THE OPPORTUNITY TO NOT ONLY BE TREATED AT THE COMMUNITY CENTER, BUT ALSO HAVE A MUCH MORE ROBUST 360 CARE AT ONE OF THE NCI CERTIFIED SITES.

AND THEN, FINALLY, ANOTHER OPPORTUNITY ON THE PAYER SIDE IS TO WORK WITH THE OFFICE OF HEALTH AND AFFORDABILITY. AND SENATOR ART TORRES GOT US CONNECTED WITH THIS GROUP. IT'S PART OF THE GOVERNOR'S TEAM. IT IS A BIG INITIATIVE. MANY OF

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YOU WERE ON THAT CALL WITH ME. THERE IS INTEREST IN COLLABORATION. RIGHT NOW THEY ARE JUST SETTING UP THE INFRASTRUCTURE. CELL AND GENE THERAPY FOR THEM RIGHT NOW IS NOT A BIG BUDGET IMPACT MODEL OR IMPACTS THE BUDGET FRAMEWORK, BUT THERE IS INTEREST FOR US TO GIVE GUIDANCE TO THEM IN TERMS OF WHAT'S IN THE PIPELINE, WHAT THAT LOOKS LIKE. RIGHT NOW THE FDA IS EXPECTING ANYWHERE FROM 15 TO 20 NEW APPROVALS A YEAR INTO THE FUTURE ON CELL AND GENE THERAPIES. AND WHEN YOU START THINKING ABOUT THE COST OF THOSE THERAPIES, EVEN THOUGH THEY'RE NOT LARGE FROM A PATIENT POPULATION STANDPOINT, CUMULATIVELY IT WILL HAVE A LARGE IMPACT ON BUDGET IMPACTS FOR PAYERS. SO THERE'S A GOOD OPPORTUNITY, AND THAT HAS ALREADY KICKED OFF. SO LOOK FORWARD TO POTENTIALLY FUTURE COLLABORATIONS WITH THAT GROUP ON BEHALF, OF COURSE, OUR VICE CHAIR AS WELL.

SO THOSE ARE THREE POSSIBLE STRATEGIES FOR NEAR-TERM OPPORTUNITIES. WHEN YOU THINK ABOUT ROADMAP ELEMENTS, THIS IS NOT NECESSARILY A TIMELINE, BUT JUST GIVES YOU AN EXAMPLE OF WHAT WE ARE THINKING FROM A NEAR-TERM STANDPOINT. AGAIN, WE HAVE THE APPROVED PRODUCTS. THAT'S THE EXPANSION OF THE ALPHA CLINICS THAT KICKED OFF IN JANUARY OF THIS YEAR. THE PATIENT SUPPORT PROGRAM, THAT RFA IS

POSTED. WE ARE HOPING THAT WE'LL BE ABLE TO LAUNCH THAT IN THE SECOND HALF OF NEXT YEAR. IN PROGRESS, OF COURSE, IS THE COMMUNITY CARE CENTERS OF EXCELLENCE. THAT'S GOING TO GIVE THAT OPPORTUNITY FOR CLINICAL TRIAL ACTIVITIES OUT IN THE RURAL COMMUNITIES, EDUCATION, ETC. THAT IS A VERY BIG INITIATIVE.

AND THEN WE HAVE THE POSSIBLE STRATEGIES. SO DISEASE REGISTRIES AND REAL-WORLD EVIDENCE. IF, IN FACT, THAT'S SOMETHING WE WANT TO PURSUE, THAT COULD BE KICKED OFF AS EARLY AS SEPTEMBER OF THIS YEAR. A PAYER ADVISORY GROUP MEETING, WHICH WAS RECOMMENDED, COULD KICK OFF IN DECEMBER OF THIS YEAR. AND THEN POLICY OPPORTUNITIES, WE HAVE TO REALLY THINK THROUGH SOME OF THE STRATEGIES, WHO WE WANT TO ENGAGE WITH, AND THE DELIVERABLE, BUT THAT COULD EASILY BE KICKED OFF IN JANUARY OF 2024.

AND THEN THROUGH THESE LEARNING SESSIONS, WE'LL BE ABLE TO IDENTIFY NEW FUTURE STRATEGIES. ONE OF THE CHALLENGES WITH CELL AND GENE THERAPY IS THE FRAMEWORK IS CHANGING DAILY. THE PAYER PATHWAYS ARE CHANGING CONSTANTLY. MANUFACTURING IS CHANGING. DISTRIBUTION IS CHANGING. AND SO IT'S TOUGH TO GET A HANDLE ON A TRAJECTORY OF WHERE YOU WANT TO GO FOUR OR FIVE YEARS FROM NOW. SO IT'S REALLY ABOUT

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BABY STEPS AND REALLY THE NEAR-TERM OBJECTIVES THAT WE MIGHT BE ABLE TO HAVE AN IMPACT FOR PATIENTS WITH RESPECT TO ACCESS AND AFFORDABILITY.

AND SO WITH THAT, I WANT TO SAY THANK YOU FOR THE OPPORTUNITY TO PRESENT WHAT WE HAVE TO DATE ON NEAR-TERM OPPORTUNITIES. AND DO WANT TO OPEN IT UP TO A SPECIFIC QUESTION. AND THAT IS, BASED ON WHAT I REPORTED TODAY, ARE THE PROPOSED RESEARCH ACTIVITIES APPROPRIATE AS INITIAL STEPS OF IMPLEMENTATION FOR THE ROADMAP TO ACCESS AND AFFORDABILITY? CHAIRMAN, I'LL HAND IT OVER TO YOU.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH, DR. TURBEVILLE. LEONDRA, DID YOU WANT TO START THE CONVERSATION?

DR. CLARK-HARVEY: VERY QUIET. I HAVEN'T TALKED MUCH. THANK YOU. GREAT REPORT. AND CONGRATULATIONS ON YOUR TENURE HERE AT CIRM.

ONE OF THE THINGS THAT YOU MENTIONED THAT I THOUGHT WAS REALLY GREAT WAS THE IDEA OF A PAYER ADVISORY BOARD. I JUST WONDER, IT MADE ME THINK ABOUT, I KNOW THAT THERE ARE -- MY UNDERSTANDING IS THAT THERE ARE SOME PATIENT KIND OF ADVISORY BOARDS AND GROUPS THAT YOU ALL WORK WITH IN OTHER WAYS, BUT WONDERING IF IT MIGHT MAKE SENSE TO ALSO THINK ABOUT THAT AS PART OF THIS DISCUSSION, EVEN NOT JUST

PATIENTS BECAUSE IT MIGHT MAKE SENSE TO HAVE SPECIFIC PATIENTS FOR SPECIFIC AREAS WHERE YOU NEED THAT FEEDBACK, BUT ALSO INCLUDING, LIKE, COMMUNITY OR STAKEHOLDERS, PARTICULARLY CULTURAL INFORMANTS. I KNOW WE TALK ABOUT THAT A LOT IN THE COMMUNICATIONS SUBGROUP, THE IMPORTANCE OF, LIKE, WHO YOU'RE WORKING WITH TO GET THE MESSAGE ABOUT EVERYTHING OUT TO THE COMMUNITY. SO EVEN IF THOSE KEY CULTURAL INFORMANTS SAT ON SOME TYPE OF COMMUNITY ADVISORY BOARD AS WELL WHEREVER IT MAKES SENSE. IT'S JUST SOMETHING THAT'S GOING AROUND IN MY HEAD RIGHT NOW AS YOU TALKED ABOUT THE PAYER BOARD, A NICE BALANCE TO IT, I THINK.

DR. TURBEVILLE: YEAH. THAT'S GOOD. THANK YOU. YEAH. I THINK THAT PROVIDES A MUCH MORE ROBUST INTERACTION. THANK YOU.

CHAIRMAN IMBASCIANI: BOARD MEMBER BERNAL IS NEXT.

MR. BERNAL: FIRST OF ALL, SEAN, THANK YOU SO MUCH FOR THIS PRESENTATION. THERE'S A LOT OF INNOVATIVE WORK IN THERE. IT'S BEEN A PLEASURE WORKING WITH YOU OVER THESE YEARS, AND YOU'LL CERTAINLY BE MISSED HERE AT CIRM.

I WANTED TO ASK SPECIFICALLY ABOUT THE STRATEGY THAT RELATES TO ENGAGING WITH THE CENTER

FOR MEDICARE AND MEDICAID SERVICES. THAT SEEMS TO BE A REALLY GOOD IDEA WITH REGARD TO MEDICAID SINCE THAT'S A POPULATION THAT WE ARE HOPING TO TARGET IN MAKING OUR TRIALS AND TREATMENTS AVAILABLE. HOW WOULD THAT FIT IN WITH CHAIR IMBASCIANI'S STATEMENTS EARLIER ABOUT OUR SORT OF HAVING A LACK OF OR NOT HAVING ENOUGH PRESENCE AND ENGAGEMENT WITH FEDERAL LAWMAKERS? AND HOW WOULD WE GO ABOUT IMPLEMENTING THAT STRATEGY GIVEN OUR CURRENT RESOURCES, OR WOULD IT REQUIRE MORE STAFF?

DR. TURBEVILLE: YEAH. CERTAINLY. SO, DR. IMBASCIANI, IT WOULD CERTAINLY PIGGYBACK YOUR VISION OF GETTING INTO THE BELTWAY FOR THE MOST PART AND INTERACTING ON THE FEDERAL LEVEL. THAT'S A STRATEGY THAT CERTAINLY CAN BE PUT IN PLAY. BUT CERTAINLY ENCOURAGE, WHEN THEY'RE ASKING US TO COME OUT AND GIVE GUIDANCE, THAT'S ANALOGOUS TO PAYERS REACHING OUT TO, LET'S SAY, A BIOPHARMA COMPANY, WHICH HAPPENS RARELY. WHEN THEY DO ASK US FOR GUIDANCE, WE LISTEN. SO IT'S A UNIQUE OPPORTUNITY. I THINK THAT WOULD BE GREAT SYNERGY.

CHAIRMAN IMBASCIANI: YES. RESPONDING WHEN THEY ASK US, BUT I HAD IN MIND US ASKING THEM TO ASK US.

DR. TURBEVILLE: WE CAN DO THAT TOO.

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MR. BERNAL: THANK YOU.

CHAIRMAN IMBASCIANI: ABLA, DID YOU WANT TO MAKE A COMMENT?

DR. CREASEY: JUST A COMMENT REGARDING ADVISORY PANELS. SO WE ACTUALLY HAVE IN OUR STRATEGIC PLAN MARKETING APPROVAL ADVISORY PANELS. AND WE ARE IN THE PROCESS OF GETTING THOSE STARTED, AND WE WILL INCLUDE PEOPLE LIKE PAYERS IN THOSE PANELS. SO IT'S ALONG THE LINES OF WHAT YOU WERE SUGGESTING, AND THANK YOU FOR MAKING THAT.

CHAIRMAN IMBASCIANI: MEMBER LEVITT.

DR. LEVITT: SO, SCOTT, WE'VE TALKED ABOUT THIS OFTEN. IN EACH OF THOSE DOMAINS AND WHAT YOU PROPOSE THERE ARE UNIQUE CHALLENGES IN EACH OF THOSE DOMAINS FOR AFFORDABILITY AND ACCESSIBILITY FOR PEDIATRIC POPULATIONS. SO AS YOU'VE GONE THROUGH THIS, I'D BE INTERESTED IN YOUR VIEW OF HOW TO DIFFERENTIATE THAT IN A WAY OR A POSITIVE WAY THAT THOSE ISSUES CAN BE ADDRESSED SPECIFICALLY BECAUSE THEY WON'T BE ADDRESSED FULLY OR MAYBE NOT AT ALL IF IT'S A VERY ADULT DISEASE-CENTRIC SET OF ACTIVITIES THAT GOES ON. I DON'T HAVE TO BELABOR IT. YOU KNOW WHAT I'M TALKING ABOUT.

DR. TURBEVILLE: CERTAINLY. IT IS SORT OF AN OVERLOOKED ISSUE, TO BE QUITE HONEST WITH YOU.

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THERE ARE OPPORTUNITIES WITH THE STATE-FUNDED PROGRAMS THAT ARE TRYING TO IMPROVE EXACTLY WHAT YOU JUST DISCUSSED AND WHAT WE DISCUSSED IN THE PAST. MEDICAID IS MEDICAID. AND TO BE HONEST WITH YOU, I THINK WE'D HAVE TO DO A LITTLE BIT MORE DUE DILIGENCE IN IDENTIFYING WHAT OPPORTUNITIES ARE AVAILABLE ON THE PEDIATRIC SIDE.

DR. LEVITT: HAVE YOU HAD CONVERSATIONS WITH, MAYBE OTHERS HAVE HAD CONVERSATION AT THE STATE LEVEL FOR THOSE WHO SORT OF SEE THIS AS CARRYING A TORCH ON THE LEGISLATIVE SIDE TO TRY TO DEAL WITH THIS BECAUSE YOU COULD -- I CAN IMAGINE, I DON'T EVEN HAVE TO IMAGINE BECAUSE IT EXISTS NOW, THAT THE IDENTICAL TREATMENT THAT WOULD BE REIMBURSED DIFFERENTLY IF IT'S A CHILD VERSUS IF IT'S AN ADULT. SO ARE THERE CHAMPIONS THAT CAN BE ENGAGED IN SOME WAY BECAUSE OTHERWISE, FROM MY PERSPECTIVE, IT'S LIKE SPEAKING INTO THE WIND THAT'S BLOWING AT YOU. SO IT DOESN'T GO VERY FAR.

DR. TURBEVILLE: CERTAINLY. WHAT YOU'RE SPECIFICALLY GETTING AT IS REALLY THOSE REIMBURSEMENT RATES FOR CERTAIN ORGANIZATIONS, CERTAIN HOSPITALS. AND I THINK THAT WOULD BE AN INITIATIVE THAT, AND I CAN'T SPEAK FOR CIRM SPECIFICALLY, BUT CERTAINLY TAKE IT BACK TO THE

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ACCESSIBILITY AND AFFORDABILITY WORKING GROUP AND SEE IF THERE'S ANY OPPORTUNITY THERE WHERE WE COULD PERHAPS CHAMPION SOME NEW LANGUAGE THAT WE COULD TAKE TO THE LEGISLATURE.

DR. LEVITT: AND THE OTHER THING IS THAT THERE'S ALSO DIFFERENT NEEDS FOR INFRASTRUCTURE AT THE ALPHA CLINICS AND OTHER AREAS BECAUSE A FAMILY, A CAREGIVER BRINGING A CHILD TO A TREATMENT VISIT IS DIFFERENT THAN EVEN A CAREGIVER BRINGING AN ELDERLY ADULT TO TREATMENT. AND SO WHETHER THERE'S GOING TO BE APPROPRIATE INFRASTRUCTURE TO DEAL WITH THAT SO THAT ACCESSIBILITY WILL BE ACTUALLY BALANCED, I THINK, WILL BE IMPORTANT TO DO AS WELL. I DON'T HAVE ANY SOLUTIONS TO THIS.

DR. TURBEVILLE: IT'S A PRESSING ISSUE.

CHAIRMAN IMBASCIANI: OKAY.

DR. CLARK-HARVEY: I WAS GOING TO SAY I THINK YOU DO HAVE A SOLUTION. I THINK YOU PROPOSED ONE AROUND FINDING LEGISLATIVE CHAMPIONS AND OTHERS. I THINK IF THAT'S APPROPRIATE OR THAT'S NEEDED, THAT SHOULD BE LOOKED AT. AND IF THERE'S OTHER WAYS OF DOING THAT WITHOUT HAVING TO TAKE THAT STEP, I THINK THAT THAT'S WORTH FURTHER DISCUSSION AS WELL.

DR. TURBEVILLE: THANK YOU.

CHAIRMAN IMBASCIANI: I DON'T SEE

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ADDITIONAL BOARD COMMENT EITHER OUTSIDE THE ROOM OR INSIDE THE ROOM. SO THIS IS NOT AN ACTION ITEM. WE'RE GOING TO PROCEED TO OUR LAST ITEM ON THE AGENDA. IS THERE ANY MEMBER OF THE PUBLIC THAT WOULD LIKE TO MAKE COMMENT ON ANY ITEM WHETHER ON THE AGENDA OR NOT?

MS. DEQUINA-VILLABLANCA: THERE ARE NO PUBLIC.

CHAIRMAN IMBASCIANI: NO PUBLIC COMMENTS. THEN LET ME GIVE MY PERSONAL THANKS TO ALL THE BOARD MEMBERS FOR MAKING THIS A VERY SWEET AND PRODUCTIVE MEETING, BUT VERY NICE FOR ME. THANK YOU VERY MUCH. AND I THINK WE ARE ADJOURNED.

MR. TOCHER: HOUSEKEEPING, LITTLE HOUSEKEEPING JUST QUICK. YOUR NEXT IN-PERSON, WE WILL WELCOME YOU BACK HERE ON THE LAST THURSDAY OF SEPTEMBER, SEPTEMBER 28TH, SAME TIME. AND THE APPLICATION REVIEW SUBCOMMITTEE WILL RESUME ITS REGULAR PROGRAMMING ON JULY 27TH. THAT'S ALSO THE LAST THURSDAY, AS WELL AS AUGUST 31ST. SO THOSE ARE YOUR NEXT MEETINGS COMING UP IN THE NEXT QUARTER. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, SCOTT. WE ARE ADJOURNED. THANK YOU SO MUCH, EVERYONE.

(THE MEETING WAS THEN CONCLUDED AT 1:25 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 OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JUNE 29, 2023, 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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