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:	MARRIOTT WATERFRONT HOTEL BAYSIDE II & III 1800 OLD BAYSHORE HIGHWAY BURLINGAME, CALIFORNIA
DATE:	JANUARY 29, 2026 9 A.M.
REPORTER:	BETH C. DRAIN, CA CSR CSR. NO. 7152
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I N D E X

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I N D E X (CONT'D.)

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JANUARY 29, 2026; 9 A.M.

CHAIRMAN IMBASCIANI: GREAT. NOW I CAN CALL THIS MEETING OF THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE OF THE CIRM BOARD TO ORDER HERE IN BURLINGAME, CALIFORNIA. MEETING IS CALLED TO ORDER. WE'RE GOING TO START WITH THE PLEDGE OF ALLEGIANCE. IF YOU ARE ABLE, PLEASE STAND, PUT YOUR RIGHT HAND ON YOUR HEART, AND FACE THE FLAG. SCOTT, WOULD YOU LEAD US? THANK YOU.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN IMBASCIANI: THANK YOU. SCOTT, WE NEED TO START WITH THE TAKING OF THE ROLL.

MR. TOCHER: THANK YOU. EYAD ALMASRI.

KIM BARRETT.

DR. BARRETT: PRESENT.

MR. TOCHER: DAN BERNAL. GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MR. TOCHER: MARIA BONNEVILLE.

VICE CHAIR BONNEVILLE: PRESENT.

MR. TOCHER: LINDA BOXER. JOHN CARETHERS.

DR. CARETHERS: PRESENT.

MR. TOCHER: MARGUERITE CASILLAS.

MS. CASILLAS: PRESENT.

MR. TOCHER: JUDY CHOU.
DR. CHOU: PRESENT.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: PRESENT.
MR. TOCHER: SHANNON DAHL.
DR. DAHL: PRESENT.
MR. TOCHER: DEBORAH DEAS. ANNE-MARIE DULIEGE.
DR. DULIEGE: PRESENT.
MR. TOCHER: YSABEL DURON.
MS. DURON: HERE.
MR. TOCHER: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: HERE.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: PRESENT.
MR. TOCHER: JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: JEFF GOLDEN FOR SHLOMO MELMED.
DR. GOLDEN: PRESENT.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: PRESENT.
MR. TOCHER: RICH LAJARA. PAT LEVITT.
DR. LEVITT: HERE.
MR. TOCHER: HALA MADENAT.

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DR. MADENAT: HERE.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: HERE.
MR. TOCHER: CAROLYN MELTZER.
DR. MELTZER: PRESENT.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: PRESENT.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: HERE.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: HERE.
MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: HERE.
MR. TOCHER: SHAUNA STARK.
DR. STARK: HERE.
MR. TOCHER: KAROL WATSON. YAEL WYTE.
DR. WYTE: HERE.
MR. TOCHER: KEVIN XU. KEITH YAMAMOTO.
DR. YAMAMOTO: HERE.
MR. TOCHER: THANK YOU VERY MUCH, MR. CHAIR. WE HAVE A QUORUM.
CHAIRMAN IMBASCIANI: GREAT. THANK YOU. WE WILL PROCEED TO ITEMS 3 AND 4 TAKEN TOGETHER, WHICH ARE DISCUSSIONS OF PERSONNEL ITEMS RELATED TO THE CHAIR AND THE VICE CHAIR. AND FOR THIS I WILL

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HAND OVER THIS PART OF THE MEETING TO THE CHAIRS OF THE GOVERNANCE SUBCOMMITTEE, JUDY GASSON AND PAT LEVITT.

DR. GASSON: THANK YOU VERY MUCH, VITO. AT THIS POINT IN TIME, WE WOULD -- SCOTT, WOULD YOU PLEASE READ THE LANGUAGE THAT TAKES US INTO CLOSED SESSION.

MR. TOCHER: YES. SO FOR THESE TWO AGENDA ITEMS, THE BOARD WILL BE ADJOURNING TO CLOSED SESSION FOR A DISCUSSION OF PERSONNEL RELATED TO ITEMS 3 AND 4 OF THIS AGENDA PURSUANT TO HEALTH AND SAFETY CODE 125290.30(F)(3)(D).

SO FOR THOSE BOARD MEMBERS ON THE ZOOM, YOU SHOULD SEE A CUE ON YOUR SCREEN TO JOIN THE BREAKOUT ROOM. PLEASE CLICK JOIN, AND WE WILL SEE YOU ALL THERE MOMENTARILY. AND FOR THOSE IN THE ROOM, EVERYONE WILL CLEAR OUT EXCEPT FOR RAPHAEL AND MYSELF.

DR. GASSON: AND MARIA BONNEVILLE IS EXCUSED FOR THIS PART OF THE MEETING. THANK YOU.

(THE BOARD THEN WENT INTO CLOSED SESSION, NOT REPORTED NOR HEREIN TRANSCRIBED. AT THE CONCLUSION, THE BOARD THEN MET IN OPEN SESSION AND WAS THEN HEARD AS FOLLOWS.)

MR. TOCHER: YOU'RE GOOD TO GO.

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CHAIRMAN IMBASCIANI: THANK YOU. THANKS, SCOTT. WE ARE NOW ON AGENDA ITEM NO. 3, WHICH IS AN OPEN SESSION CONSIDERATION REGARDING THE FIRST ITEM WHICH INVOLVES THE VICE CHAIR.

MR. TOCHER: AND JUDY HAS AN ANNOUNCEMENT TO MAKE.

CHAIRMAN IMBASCIANI: OKAY. AND I WAS JUST ABOUT TO PASS THE GAVEL, METAPHORICALLY, TO JUDY.

DR. GASSON: THANK YOU, VITO. AND I WANT TO REPORT THAT NO ACTION WAS TAKEN IN THE CLOSED SESSION.

CHAIRMAN IMBASCIANI: THANK YOU, JUDY. CONTINUE.

DR. GASSON: THANK YOU VERY MUCH. WE'RE NOW CONSIDERING AND I WILL NOW ENTERTAIN A MOTION TO APPROVE THE 3-PERCENT MERIT INCREASE FOR THE VICE CHAIR. I'D LIKE TO REQUEST A MOTION PLEASE.

DR. BARRETT: SO MOVED.

DR. YAMAMOTO: SECOND.

DR. GASSON: AND IS THERE ANY DEBATE ON THIS MATTER?

KIM, DID YOU RAISE YOUR HAND?

MR. TOCHER: NO. SORRY. I WAS SPEAKING AS TO WHO MADE THE MOTION. MAY I JUST CLARIFY FOR

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THE MAKER AND SECOND OF THE MOTION, THAT THIS IS 3 PERCENT RETROACTIVE TO JULY 1ST, 2025.

DR. BARRETT: PRECISELY.

DR. GASSON: THANK YOU. OKAY. HEARING NO FURTHER DISCUSSION, MAY WE TAKE THE ROLL CALL PLEASE.

MR. TOCHER: ONE MOMENT TO CHECK IF THERE IS PUBLIC COMMENT. DOESN'T APPEAR SO.

KIM BARRETT.

DR. BARRETT: AYE.

MR. TOCHER: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MR. TOCHER: JOHN CARETHERS.

DR. CARETHERS: YES.

MR. TOCHER: MARGUERITE CASILLAS.

MS. CASILLAS: YES.

MR. TOCHER: JUDY CHOU.

DR. CHOU: YES.

MR. TOCHER: LEONDRA CLARK-HARVEY.

DR. CLARK-HARVEY: YES.

MR. TOCHER: SHANNON DAHL.

DR. DAHL: YES.

MR. TOCHER: DEBORAH DEAS.

DR. DEAS: YES.

MR. TOCHER: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.
MR. TOCHER: YSABEL DURON.
MS. DURON: YES.
MR. TOCHER: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: YES.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: JUDY GASSON.
DR. GASSON: YES.
MR. TOCHER: JEFF GOLDEN FOR SHLOMO MELMED.
DR. GOLDEN: YES.
MR. TOCHER: VITO IMBASCIANI.
CHAIRMAN IMBASCIANI: YES.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: YES.
MR. TOCHER: HALA MADENAT.
DR. MADENAT: YES.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: YES.
MR. TOCHER: CAROLYN MELTZER.
DR. MELTZER: YES.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.

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DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: SHAUNA STARK.
DR. STARK: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: YAEL WYTE.
DR. WYTE: YES.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: THANK YOU VERY MUCH. AND THAT MOTION CARRIES. JUDY.
DR. GASSON: THANK YOU VERY MUCH. WE WILL NOW TAKE UP THE CHAIR'S REQUEST AND TURN IT OVER TO VITO FOR A SHORT PRESENTATION TO OPEN THIS ITEM.
CHAIRMAN IMBASCIANI: THANK YOU, JUDY, AND THANK YOU, PAT, AND MEMBERS OF THE GOVERNANCE SUBCOMMITTEE AND THE FULL BOARD FOR CONSIDERING THE REQUEST.
THE FIRST THOUGHT THAT YOU PROBABLY SHOULD HAVE HAD WHEN YOU READ MY MEMO, WHAT ARE THE RESPONSIBILITIES OF THE CHAIR AND HOW WOULD THEY BE

COVERED IF THIS REQUEST WERE TO BE HONORED.

SO I WANT TO TELL YOU THAT, WITH SCOTT'S HELP AND DIRECTION, I SCOURED PROPOSITION 14 AND THE INTERNAL GOVERNANCE POLICY OF THE ICOC AND CAME UP WITH 14 RESPONSIBILITIES OF THE CHAIR AND HAVE DIVIDED THEM EFFECTIVELY IN HALF SO THAT I WOULD MAINTAIN RESPONSIBILITY AND FOCUS ON SIX OF THEM, WHICH I HAVE LISTED IN THE MEMO. THAT INCLUDES MANAGING THE ICOC MEETING AGENDAS AND WORKFLOW, AND THAT INCLUDES WEEKLY MEETINGS WITH OUR CEO AND PRESIDENT, WITH OUR CHIEF COUNSEL, AND WITH BOARD GOVERNANCE; EX OFFICIO MEMBER AND PARTICIPATING MEMBER OF ALL BOARD SUBCOMMITTEES; OVERSEE THE ANNUAL AUDIT; AND THE BUDGET CREATION FOR THE OFFICE OF THE CHAIR; AND TO APPOINT ADVISORY TASK FORCES AS NEEDED. THE LAST TIME THAT WAS DONE WAS OVER TWO YEARS AGO WITH THE CREATION OF THE NEURO TASK FORCE.

THAT LEAVES EIGHT OTHER ACTIVITIES, TWO OF WHICH, NOS. 4 AND 7, ARE REALLY RARE. AND I AM ASSURED IN CONVERSATIONS WITH THE GOVERNANCE SUBCOMMITTEE AND WITH OUR PRESIDENT AND CEO THAT DEVOLVING THESE RESPONSIBILITIES, IN PART, TO MEMBERS OF THE CIRM TEAM WILL NOT OVERLY BURDEN ANYONE. AND I SAY THAT WITH EXPERIENCE BECAUSE THE VARIOUS TEAMS, FOR EXAMPLE, THE COMMUNICATIONS TEAM

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THAT DOES SO MUCH WORK IN DATA COLLECTION AND PATIENT SELECTION AND OTHER ACTIVITIES RELATED TO THE CREATION OF THE ANNUAL AUDIT, THEY'RE ALREADY DOING THIS WORK. AND I PARTICIPATE IN AN EDITORIAL AND A GUIDANCE WAY AND GIVING FINAL APPROVAL. THE SAME WITH THE PREPARATION OF THE BUDGET AND PREPARING FOR THE BOND SALES TWICE A YEAR. SO I'M ASSURED THAT THIS IS COVERED.

AND I GUESS IF YOU HAVE ANY QUESTIONS, THIS WOULD BE A GOOD TIME FOR THAT.

DR. GASSON: NOT HEARING --

MR. TOCHER: JUDY, WE DO NOT YET HAVE A MOTION ON THE TABLE.

DR. GASSON: I WAS GOING TO -- I WILL ENTERTAIN A MOTION TO APPROVE THE CHAIR'S REQUEST.

VICE CHAIR BONNEVILLE: SO MOVED.

DR. GASSON: SECOND PLEASE.

DR. MIASKOWSKI: SECOND.

MR. TOCHER: THANK YOU, CHRIS.

DR. GASSON: AND IS THERE ANY DISCUSSION UPON THIS MOTION REGARDING THE MECHANICS AND THE MERITS OF THIS PROPOSAL? I'M NOT HEARING ANYTHING. SCOTT, ARE THERE HANDS RAISED?

MR. TOCHER: THERE ARE NOT. SO WE CAN MOVE TO --

DR. GASSON: A VOTE THEN.
MR. TOCHER: PUBLIC COMMENT. LET US PAUSE. DOESN'T APPEAR THERE'S ANY PUBLIC COMMENT.
KIM BARRETT.
DR. BARRETT: AYE.
MR. TOCHER: GEORGE BLUMENTHAL.
DR. BLUMENTHAL: YES.
MR. TOCHER: MARIA BONNEVILLE.
VICE CHAIR BONNEVILLE: YES.
MR. TOCHER: JOHN CARETHERS.
DR. CARETHERS: YES.
MR. TOCHER: MARGUERITE CASILLAS.
MS. CASILLAS: YES.
MR. TOCHER: JUDY CHOU.
DR. CHOU: AYE.
MR. TOCHER: LEONDRA CLARK-HARVEY.
DR. CLARK-HARVEY: AYE.
MR. TOCHER: SHANNON DAHL.
DR. DAHL: YES.
MR. TOCHER: DEBORAH DEAS.
DR. DEAS: YES.
MR. TOCHER: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MR. TOCHER: YSABEL DURON.
MS. DURON: YES.

MR. TOCHER: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: YES.
MR. TOCHER: ELENA FLOWERS.
DR. FLOWERS: YES.
MR. TOCHER: JUDY GASSON.
DR. GASSON: YES.
MR. TOCHER: JEFF GOLDEN.
DR. GOLDEN: YES.
MR. TOCHER: PAT LEVITT.
DR. LEVITT: YES.
MR. TOCHER: HALA MADENAT.
DR. MADENAT: YES.
MR. TOCHER: LINDA MALKAS.
DR. MALKAS: YES.
MR. TOCHER: CAROLYN MELTZER.
DR. MELTZER: AYE.
MR. TOCHER: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MR. TOCHER: ADRIANA PADILLA.
DR. PADILLA: YES.
MR. TOCHER: JOE PANETTA.
MR. PANETTA: YES.
MR. TOCHER: MARVIN SOUTHARD.
DR. SOUTHARD: YES.
MR. TOCHER: SHAUNA STARK.

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DR. STARK: YES.
MR. TOCHER: KAROL WATSON.
DR. WATSON: YES.
MR. TOCHER: YAEL WYTE.
DR. WYTE: YES.
MR. TOCHER: AND KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MR. TOCHER: THANK YOU VERY MUCH. JUDY, THAT MOTION CARRIED.
DR. GASSON: THANK YOU ALL. BACK TO THE CHAIR.
CHAIRMAN IMBASCIANI: THANKS, JUDY, AND THANKS, PAT, TOO FOR GUIDANCE IN ALL OF THIS.
OKAY. WE'RE NOW MOVING ON HAPPILY TO AGENDA ITEM NO. 6, A DISCUSSION REGARDING THE PROCESS CIRM IS USING FOR PREFERENCE SETTING. I'M GOING TO INTRODUCE OUR PRESIDENT AND CEO, JONATHAN THOMAS, TO LEAD THE DISCUSSION AND MAKE NECESSARY INTRODUCTIONS. THANK YOU, J.T.
DR. THOMAS: THANK YOU, MR. CHAIR. JUST VERY BRIEFLY, AS THE BOARD WELL KNOWS, THE CONCEPT PLANS ADOPTED FOR THE NEW PDEV AND CLIN2 PROGRAMS UNDER THE SAF INCLUDE PREFERENCES AS AN IMPORTANT PART OF THE PROCESS. THERE HAVE BEEN A NUMBER OF QUESTIONS ABOUT HOW THE PREFERENCES HAVE BEEN

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WORKING, WHAT'S APPROPRIATE, WHAT'S NOT, ET CETERA. AND WE'RE PLEASED THAT, NOW THAT WE HAVE TWO FULL ROUNDS OF PRESUBMISSION ANALYSIS FOR PDEV AND QUALIFICATION ANALYSIS FOR CLIN IN THE BOOKS, THAT WE NOW HAVE DATA THAT MAKES IT APPROPRIATE FOR US TO GIVE THE BOARD AND THE PUBLIC A FULL ACCOUNTING OF RETROSPECTIVELY HOW PREFERENCES HAVE PLAYED OUT OVER THIS INITIAL PHASE OF IMPLEMENTATION UNDER THE SAF.

AND TO DO THAT, WE HAVE OUR ESTEEMED CHIEF SCIENCE OFFICER, ROSA CANET-AVILES, WHO'S GOING TO GIVE THE BOARD A PRESENTATION ON THIS TOPIC IN DETAIL. ROSA.

DR. CANET-AVILES: THANK YOU, J.T. AND THANK YOU, MR. CHAIRMAN, MADAM VICE CHAIR, DISTINGUISHED MEMBERS OF THE BOARD, AND THE PUBLIC. I'M HAPPY TO COME HERE WITH AN UPDATE ON THE FUNDING PREFERENCES.

JUST BEFORE I GET STARTED, CAN ANYONE TELL ME IF YOU CAN SEE THE PRESENTATION WELL?

MR. TOCHER: WE CAN.

DR. CANET-AVILES: OKAY. WONDERFUL. SO AS J.T. WAS SAYING, OVER THE LAST YEAR, WE INTRODUCED THESE PREFERENCES TO HELP TRANSLATE THE PUBLIC INVESTMENT THAT WE ARE GIVEN THROUGH PROPOSITION 14 INTO WHAT WE ARE EXPECTING TO BE THE

REAL PATIENT IMPACT WITHIN OUR REMAINING RUNWAY. SO WHAT WE ARE BRINGING TODAY TO THE BOARD ARE THE RESULTS OF THE FIRST CYCLES TO GIVE US ALL A CHANCE, AS J.T. WAS SAYING, TO PAUSE AND TO ASSESS HOW THIS IS WORKING IN PRACTICE.

AND I'D LIKE TO START WITH THE END OF WHAT WE INTEND TO ACHIEVE TODAY SO THAT THERE IS A FOCUS IN TODAY'S DISCUSSION. TODAY IS ABOUT THE INTENT, IT'S ABOUT THE EARLY SIGNALS THAT WE'VE SEEN, AND WHAT WE ARE LEARNING, NOT ABOUT FINAL CONCLUSIONS. SO THE GOAL AT THE END OF TODAY IS TO DISCUSS AND LEARN FROM THE BOARD, FROM YOU, WHAT TYPES OF DATA YOU WOULD LIKE TO SEE AT OUR NEXT MARCH ICOC MEETING TO BE ABLE TO MAKE DECISIONS MOVING FORWARD.

SO WITH THAT, I'M JUST GOING TO MOVE INTO TODAY'S LAYOUT OF THE PRESENTATION. THE OVERVIEW HAS THE CONTEXT AND OBJECTIVES OF WHY ARE WE DOING THIS, WHERE ARE WE; THE GUIDING PRINCIPLES THAT MOVED US, AND WE WILL GO THROUGH THOSE GUIDING PRINCIPLES; AND THEN THE RESULTS OF THE FIRST CYCLES FOR THE THREE PROGRAMS, THE PRECLINICAL DEVELOPMENT AND THE CLINICAL DEVELOPMENT, CLIN2, AND THEN DISC4, WHICH ALSO HAS HAD ONE REVIEW -- ONE CYCLE WHERE PREFERENCES WERE APPLIED AND THE REVIEW IS HAPPENING SOON. AND THEN CLOSING, WHAT ARE THE NEXT STEPS.

AND THEN WE CAN OPEN FOR DISCUSSION.

SO THIS SLIDE IS MEANT TO GROUND THE REST OF TODAY'S DISCUSSION IN THE REALITY, IN THE OPERATING REALITY THAT WE ARE ALL WORKING WITHIN. SO WE ARE WORKING WITHIN PROPOSITION 14, WHICH SIGNIFICANTLY EXPANDED OUR MANDATE, BOTH IN TERMS OF SCIENTIFIC AMBITION, BUT ALSO IN THE EXPECTATIONS AROUND PATIENT IMPACT. CELL AND GENE THERAPIES HAVE MOVED FORWARD. WHEN WE STARTED IN 2004, IT WAS A VERY DIFFERENT FIELD THAN WE ARE NOW, RIGHT.

SO IN PARTICULARLY IT REINFORCED PRIORITIES AROUND DISEASES OF THE CENTRAL NERVOUS SYSTEM AND MADE ACCESS AND AFFORDABILITY AN EXPLICIT PART OF OUR RESPONSIBILITY, NOT SOMETHING TO CONSIDER DOWNSTREAM. AT THE SAME TIME OUR FUNDING REMAINS FINITE AND TIME BOUND. SO WE HAVE A DEFINED REMAINING RUNWAY, AND THE AMOUNT OF STRONG APPLICATIONS SCIENTIFICALLY THAT WE RECEIVE CONSISTENTLY IS MUCH LARGER THAN WHAT WE COULD SUPPORT. AND THIS HAPPENS TO ALL FUNDING AGENCIES. IT'S NOT A UNIQUE PROBLEM TO CIRM. SO THIS IS NOT A REFLECTION OF DECLINING QUALITY. IT'S A REFLECTION OF THE DEMANDING OUTPACING CAPACITY THAT WE CAN TAKE.

SO TAKEN TOGETHER, THESE TWO REALITIES,

THE FINITE FUNDS AND THE EXPANDED MANDATES AND THE INCREASED AMOUNT OF APPLICATIONS, CREATE A CENTRAL TENSION THAT WE ARE TRYING TO MANAGE.

SO THE EXPANDED EXPECTATIONS FOR IMPACT WITHIN FIXED RESOURCES AND FINITE TIME FRAME, AND ULTIMATELY THE GOAL IS TO TRANSLATE ALL OF THIS INVESTMENT INTO THERAPIES THAT REACH PATIENTS, BUT THERAPIES THAT REACH PATIENTS THAT COULD NOT OTHERWISE BE REACHED IN CALIFORNIA. SO TO THAT END, THE BOARD APPROVED THE STRATEGIC FRAMEWORK AND THE IMPACT GOALS AS THE ROADMAP TO ACHIEVE THAT BACK IN SEPTEMBER OF 2024.

SO PREFERENCES ARE THE MECHANISM BY WHICH WE INTRODUCE TO HELP NAVIGATE THIS CHALLENGE. AND THE REST OF THE PRESENTATION BUILDS FROM THIS REALITY. HOW WE ATTEMPTED TO OPERATIONALIZE ALL OF THIS, WHAT ARE WE SEEING FROM THE INITIAL CYCLES, AND WHAT ELSE DO WE NEED TO BRING TO THE BOARD SO THAT YOU CAN MAKE INFORMED DECISIONS BEFORE CONSIDERING ANY NEXT STEPS.

SO STARTING FROM THIS CONTEXT AND REALITY, THE PRACTICAL QUESTION IS HOW DO WE MOVE FORWARD FROM MANY STRONG APPLICATIONS, THE PORTFOLIO THAT HAS THE HIGHEST LIKELIHOOD OF DELIVERING REAL PATIENT IMPACT WITHIN OUR LIFETIME?

THIS SLIDE SHOWS THE ROLE OF THE PREFERENCES, THE ROLE THAT THEY ARE INTENDED TO PLAY. AND IS IT'S NOT A SUBSTITUTE OF SCIENTIFIC REVIEW, BUT A WAY TO FOCUS LIMITED RESOURCES TOWARDS APPLICATIONS THAT ARE MOST ALIGNED WITH OUR IMPACT GOALS.

ON THE LEFT WE START WITH A VERY HIGH VOLUME OF APPLICATIONS. MANY OF THESE ARE SCIENTIFICALLY STRONG, BUT THEY, IN TERMS OF READINESS, ALIGNMENT WITH STATUTORY MANDATES, AND THE LIKELIHOOD OF TRANSLATING INTO THERAPIES WITHIN THE TIME FRAME THAT WE HAVE. THE STARS HERE IN THIS SLIDE REPRESENT APPLICATIONS THAT MOST STRONGLY ALIGN WITH OUR GUIDING PRINCIPLES. DOESN'T MEAN THAT THE OTHERS ARE NOT SCIENTIFICALLY STRONG. IT'S JUST THAT THE ONES WITH THE STARS ARE MORE ALIGNED WITH THOSE GUIDING PRINCIPLES. AND SO IMPORTANTLY, THE ABSENCE OF THE STAR DOESN'T MEAN THAT THEY ARE NOT STRONG SCIENTIFICALLY AS I WAS SAYING.

SO THE PREFERENCES HELP REACH THE POOL BY BRINGING FORWARD APPLICATIONS THAT ARE MORE LIKELY TO CONTRIBUTE TO NEAR OR MIDTERM IMPACT GIVEN OUR CONSTRAINTS. SO THAT'S WHAT THE PREFERENCES ROLE HAS BEEN. AND THAT ENRICHED POOL THEN MOVES INTO SCIENTIFIC AND TECHNICAL REVIEW WHERE THE MERIT, THE

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RIGOR, AND THE READINESS ARE EVALUATED IN-DEPTH. THE KEY POINT IS THAT PREFERENCES SHAPE WHICH APPLICATIONS RISE FOR REVIEW WHILE THE PEER REVIEW DETERMINES WHICH OF THOSE WILL GET FUNDED.

NOW, I WANT TO PAUSE HERE AND ACKNOWLEDGE WHAT WE'VE BEEN HEARING BECAUSE THIS FEEDBACK IS AN IMPORTANT PART OF WHY WE ARE HAVING TODAY'S DISCUSSIONS. ALSO, I WANT TO MAKE SURE THAT EVERYBODY KNOWS THAT THERE IS A MEMO AS WELL THAT CONTAINS ALL OF THIS PRESENTATION AND A LOT OF THE DETAILS THAT WE HAVE BEEN ASKED THROUGH THE SCIENCE SUBCOMMITTEE IN TERMS OF DATA. SO IF YOU WANT TO REFER TO THAT WHILE I'M PRESENTING, THAT'S ALSO AVAILABLE.

SO SOME OF THE CONCERNS REFLECT UNCERTAINTY ABOUT HOW THE PREFERENCES OR THESE PRESUBMISSION/QUALIFICATION PROCESS INTERACTS WITH THE SCIENTIFIC REVIEW AND WHETHER THE PROPOSALS THAT DIDN'T ADVANCE WERE FULLY CONSIDERED ON SCIENTIFIC GROUNDS. OTHERS REFLECT QUESTIONS ABOUT WHETHER PREFERENCES MIGHT UNINTENTIONALLY FAVOR CERTAIN MODALITIES OR PATHWAYS OR WHETHER PROGRESSION WITHIN THE CIRM PORTFOLIO IS BEING APPROPRIATELY RECOGNIZED. WE HAVE ALSO HEARD A DESIRE FOR MORE CLARITY AROUND HOW QUALIFICATION, SCORING, AND

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PREFERENCES AND INTENT FIT TOGETHER AND WHAT THE PREFERENCES ARE DESIGNED TO DO VERSUS WHAT THEY ARE NOT DESIGNED TO DO.

MORE IMPORTANTLY, A LOT OF THIS FEEDBACK IS LESS ABOUT DISAGREEMENT WITH THE GOALS AND MORE ABOUT UNDERSTANDING THE LOGIC; IN OTHER WORDS, HOW THE PIECES FIT TOGETHER, HOW DECISIONS WERE SEQUENCED, AND HOW THIS ULTIMATELY CONNECTS TO DELIVERING THERAPIES FOR PATIENTS. AND THAT FEEDBACK HAS HELPED US UNDERSTAND THAT WE NEED TO BE CLEARER AND MORE EXPLICIT IN HOW WE COMMUNICATE THE RATIONALE BEHIND THESE DECISIONS, AND HOW WE SHOW THE LINK BETWEEN PRIORITIZATION DECISIONS AND THE OUTCOMES OF PATIENT IMPACT. AND ALSO ABOUT THE FACT THAT, IF WE WANT TO MAKE AN IMPACT WITH THE CONSTRAINTS THAT WE HAVE OF TIME AND FUNDING, WE NEED TO MAKE HARD CHOICES. AND THAT WE NEED TO BE MORE CLEAR ABOUT IT, TO MAKE VERY CLEAR WHAT THE CHOICES ARE IN ALIGNMENT WITH THE BOARD, OBVIOUSLY.

TAKING ALL OF THAT TOGETHER, THE CONTEXT THAT WE ARE OPERATING IN, THE ROLE OF THE PREFERENCES ARE MEANT TO PLAY, AND THE FEEDBACK WE'VE BEEN HEARING, THIS BRINGS US TO WHAT WE ARE TRYING TO ACCOMPLISH IN TODAY'S DISCUSSION.

WE HAVE THREE OBJECTIVES. I JUST WANT TO

MAKE SURE THAT THE OBJECTIVE TODAY IS NOT TO DEBATE INDIVIDUAL OUTCOMES OR TO MAKE DECISIONS ABOUT CHANGING PREFERENCES. THAT'S GOING TO HAPPEN IN MARCH. I JUST WANT TO MAKE THIS VERY CLEAR.

THE OBJECTIVES TODAY ARE ABOUT REVIEWING THE RATIONALE FOR THESE PREFERENCES. HOW DID WE SET THEM UP? HOW DO THEY CONNECT TO OUR PROPOSITION 14 MANDATE AND TO THE STRATEGY THAT THE BOARD APPROVED BACK IN SEPTEMBER OF '24, AND TO THE PRACTICAL CONSTRAINTS THAT WE ARE WORKING WITHIN. THAT'S A VERY IMPORTANT POINT, AND WE HOPE THAT THIS WILL BE CLEAR AFTER TODAY'S PRESENTATION.

THE SECOND IS THAT WE WANT TO SHARE WHAT WE ARE LEARNING FROM THE FIRST FUNDING CYCLES. THESE ARE SIGNALS, NOT CONCLUSIONS, BUT THEY WILL HELP US UNDERSTAND WHETHER THE APPROACH IS FUNCTIONING IN THE WAY THAT IT WAS INTENDED. AND PART OF OUR QUESTIONS TODAY TO THE BOARD ARE ARE THERE ANY SPECIFIC ANALYSIS OF THESE FIRST FUNDING CYCLES THAT YOU NEED -- THAT YOU WOULD LIKE TO SEE MORE GRANULARITY IN THE DATA SO YOU CAN UNDERSTAND THIS BETTER AT THE MARCH MEETING TO MAKE YOUR DECISIONS. SO THAT WOULD BE THE SECOND PART.

AND THE LAST OBJECTIVE TODAY IS THAT WE WANT TO USE THE COMMITTEE'S PERSPECTIVE TO IDENTIFY

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WHAT PORTFOLIO ANALYSIS LEVELS ARE NEEDED BEFORE WE COME BACK IN MARCH TO HAVE A MORE SUBSTANTIVE DISCUSSION ABOUT THESE NEXT STEPS. SO THE SECOND AND THE THIRD KIND OF GO TOGETHER.

SO NOW WE ARE GOING TO GO -- WITH THAT FRAMING, BEFORE GETTING INTO ANY SPECIFIC PREFERENCES OR SCORING MECHANICS, IT IS IMPORTANT THAT WE GO BACK AND MAKE EXPLICIT WHAT WERE THE PRINCIPLES THAT GUIDED HOW THESE PREFERENCES WERE DEVELOPED IN THE FIRST PLACE BECAUSE THAT DOESN'T SEEM -- WE DIDN'T DO A GOOD JOB EXPLAINING THIS. SO I'M GOING TO SPEND QUITE A BIT OF TIME IN THIS SLIDE.

THESE PRINCIPLES ARE NOT THEORY. THEY ARE BASICALLY THE BACKBONE ON HOW WE DESIGN ALL OUR PROGRAMS, BUT SPECIFICALLY WE ARE TALKING NOW ABOUT THE PRECLINICAL DEVELOPMENT AND THE CLIN2. AND THEY REFLECT THE REALITIES ALSO OF WHAT WE'VE LEARNED OVER THE YEARS OF FUNDING PROGRAMS THAT EITHER DID OR DIDN'T TRANSLATE INTO THERAPIES THAT REACH PATIENTS.

THE FIRST PRINCIPLE IS THAT THEY NEED TO OFFER POTENTIAL FOR TRANSFORMATIVE CLINICAL IMPACT. WHAT DO WE MEAN BY CLINICAL IMPACT? WE ARE NOT USING THAT AS A SYNONYM FOR SCIENTIFIC NOVELTY OR

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DISEASE IMPORTANCE. IN THE CONTEXT OF PRECLINICAL AND CLINICAL PROGRAMS, CLINICAL IMPACT MEANS THE REALISTIC POTENTIAL FOR A THERAPY TO MEANINGFULLY CHANGE OUTCOMES FOR PATIENTS IN TERMS OF EFFICACY, DURABILITY, SAFETY, OR BURDEN OF CARE COMPARED TO WHAT EXISTS OR IS POTENTIALLY COMING DOWN THE PIPELINE.

THIS PRINCIPLE FORCES US TO ASK IS THE SCIENCE INTERESTING. IT DOESN'T FORCE US TO ASK IS THE SCIENCE INTERESTING. WHAT IT'S ASKING IS IF THIS WORKS, DOES IT ACTUALLY MATTER FOR PATIENTS.

THE SECOND GUIDING PRINCIPLE IS THAT IT ADDRESSES BOTTLENECKS TO ACCESS, AFFORDABILITY, AND TRANSLATIONAL FEASIBILITY. THIS PRINCIPLE REFLECTS ONE OF THE MOST IMPORTANT LESSONS EMBEDDED IN CIRM'S STRATEGY. EARLY DECISIONS THAT WE MAKE AFFECT DOWNSTREAM ACCESS. IN BOTH THE PRECLINICAL AND THE CLIN2, WE HAVE SEEN THAT CHOICES AROUND MODALITY, DELIVERY, MANUFACTURING STRATEGY, AND THE CLINICAL IMPLEMENTATION CAN MAKE THE DIFFERENCE BETWEEN A THERAPY THAT'S TECHNICALLY SUCCESSFUL AND ONE THAT IS ACTUALLY USABLE AT SCALE. SO THIS PRINCIPLE IS NOT ABOUT PRICING POLICY OR REIMBURSEMENT DEBATE. IT'S ABOUT WHETHER THE PROPOSED APPROACH ACKNOWLEDGES AND BEGINS TO ADDRESS KNOWN BOTTLENECKS

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TO ACCESS.

THE THIRD PRINCIPLE IS THAT IT FILLS CRITICAL FUNDING GAPS AND ADVANCE CIRM'S STATUTORY MANDATES. THIS IS A VERY IMPORTANT PRINCIPLE. SO CIRM'S ROLE IS NOT TO FUND EVERYTHING. IT'S TO FUND WHAT OTHERS CANNOT OR WILL NOT, WHICH WAS PART OF THE REASON OUR RAISON D'ETRE WHEN WE WERE ESTABLISHED IN 2004. THIS PRINCIPLE REFLECTS THE REALITY THAT SOME DISEASES, MODALITIES, OR STAGES OF DEVELOPMENT ARE PERSISTENTLY UNDERFUNDED BY FEDERAL AGENCIES OR BY THE PRIVATE SECTOR DESPITE THEIR POTENTIAL IMPACT AND IMPORTANCE.

IN PRECLINICAL DEVELOPMENT, THIS SHOWS UP IN HOW WE THINK ABOUT ENABLING TRANSLATIONAL WORK THAT COULD OTHERWISE STALL. IN THE CLIN2 PROGRAM IT SHOWS UP IN SUPPORTING TRIALS THAT CARRY SCIENTIFIC OR OPERATIONAL RISK, BUT THAT ALIGN STRONGLY WITH CIRM'S MISSION. THIS PRINCIPLE ALSO EXPLICITLY INCORPORATES PROP 14 MANDATES, INCLUDING CNS AND PLURIPOTENT STEM CELL APPROACHES AS PART OF OUR PRIORITIZATION LOGIC, NOT AS EXCLUSIONS, BUT AS AREAS THAT CIRM HAS A STATUTORY OBLIGATION TO LEAD.

THE FOURTH PRINCIPLE IS THAT IT CAN REALISTICALLY ACHIEVE KEY REGULATORY AND DEVELOPMENT PATHS WITHIN CIRM'S FINITE RUNWAY. THIS PRINCIPLE

IS ONE OF THE HARDEST AND ALSO A VERY IMPORTANT ONE. IT DOESN'T MEAN THAT AMBITIOUS SCIENCE IS DISCOURAGED. IT MEANS THAT WE HAVE TO BE HONEST ABOUT TIMELINES, THE TENDENCIES, AND WHAT CIRM FUNDING CAN REASONABLY ENABLE WITHIN THE YEARS THAT WE HAVE LEFT.

IN THE CLIN2 PROGRAM, THIS IS WHY READINESS, REGULATORY CLARITY, AND OPERATIONAL FEASIBILITY MATTERS SO MUCH. IN PRECLINICAL DEVELOPMENT IN THE PDEV PROGRAM IS WHY WE FOCUS ON WHETHER A PROGRAM IS POSITIONED TO MAKE A MEANINGFULLY INFLECTION SUCH AS ENABLING AN IND. THIS PRINCIPLE -- RATHER THAN ACCUMULATING MORE EXPLORATORY DATA, FOR EXAMPLE. AND THIS PRINCIPLE PROTECTS BOTH CIRM AND APPLICANTS FROM INVESTING HEAVILY IN PROGRAMS THAT, EVEN IF SCIENTIFICALLY SOUND, ARE UNLIKELY TO REACH MEANINGFUL MILESTONES WITHIN CIRM'S LIFETIME.

THE FIFTH PRINCIPLE IS THAT IT ADDRESSES DISEASES AFFECTING CALIFORNIANS. AS A PUBLIC FUNDED AGENCY, CIRM HAS A RESPONSIBILITY TO ENSURE THAT ITS PORTFOLIO REFLECTS DISEASES AND CONDITIONS THAT MEANINGFULLY AFFECT CALIFORNIANS. THIS DOESN'T MEAN FUNDING ONLY COMMON DISEASES, NOR DOES IT EXCLUDE RARE DISEASES. WHAT IT DOES IS REQUIRES US TO BE

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THOUGHTFUL ABOUT THE OVERALL BALANCE OF THE PORTFOLIO AND THE POPULATIONS ULTIMATELY SERVED IN THAT. AND THAT'S SOMETHING ALSO THAT, AS PART OF THE PORTFOLIO THAT WE BRING IN MARCH, IF YOU HAVE QUESTIONS ABOUT THIS, WE WANT TO MAKE SURE THAT WE INCORPORATE THEM.

AND THE LAST PRINCIPLE IS DIVERSIFICATION OF CIRM'S ACTIVE AWARD PORTFOLIO. THIS FINAL PRINCIPLE IS PARTICULARLY IMPORTANT GIVEN THE CONCERNS THAT HAVE BEEN RAISED ABOUT PREFERENCES BECOMING RESTRICTIVE. DIVERSIFICATION IS A GUARDRAIL. IT EXISTS TO PREVENT OVERCONCENTRATION IN A SINGLE DISEASE AREA OR MODALITY OR DEVELOPMENT PATHWAY EVEN IF THAT AREA IS POPULAR OR WELL REPRESENTED AMONG APPLICATIONS. IN PRACTICAL TERMS, THIS PRINCIPLE IS WHY NOVELTY, UNDERREPRESENTED DISEASE AREAS, AND THEIR POSITION RELATIVE TO THE ACTIVE PORTFOLIO ARE EXPLICITLY CONSIDERED IN THE PDEV AND CLIN2 SCORING. IT IS ALSO WHY PREFERENCES ARE NOT BINARY GATES. AND IT ENSURES THAT GENERALLY NOVEL OR NONOBVIOUS APPROACHES, INCLUDING OUTLIERS, HAVE A PATHWAY FORWARD RATHER THAN BEING CROWDED OUT BY PROGRAMS THAT SIMPLY ALIGN WITH THE MOST COMMON PREFERENCES.

WITH THOSE GUIDING PRINCIPLES IN MIND, I

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WANT TO SHOW NOW HOW THEY WERE TRANSLATED INTO PRACTICAL PROGRAM-SPECIFIC PREFERENCE RUBRICS. AND IN THE NEXT SLIDES, I WILL WALK THROUGH BOTH THE PDEV AND THE CLIN2 SLIDES RUBRICS WHICH WERE INTENTIONALLY DESIGNED AS COMPLEMENTARY TOOLS AT DIFFERENT POINTS ALONG THE TRANSLATIONAL PATHWAY. IN BOTH CASES THE KEY THING TO KEEP IN MIND HERE IS THAT THESE ARE ALIGNMENT AND QUALIFICATION TOOLS, NOT SUBSTITUTES OF SCIENTIFIC PEER REVIEW.

SO THE PDEV PROGRAM IS INTENDED TO ENRICH CIRM'S CLINICAL PIPELINE. COMPARED TO THE EXISTING PORTFOLIO, IT SHOULD ADVANCE STATE-OF-THE-ART THERAPEUTIC TECHNOLOGIES THAT ADDRESS A BROAD RANGE OF DISEASES AFFECTING CALIFORNIANS. THE FIRST LINE HERE REFLECTS ALIGNMENT WITH CORE AREAS WHERE CIRM HAS A CLEAR ROLE AND RESPONSIBILITY, EITHER BECAUSE OF OUR STATUTE OR BECAUSE OF DOWNSTREAM ACCESS AND FEASIBILITY CONSIDERATIONS.

APPLICANTS IN THE FIRST LINE OF PREFERENCE RECEIVE UP TO THREE POINTS IF THEIR PROJECT ALIGNS WITH AT LEAST ONE OF THESE AREAS, EITHER PLURIPOTENT STEM CELL-DERIVED THERAPIES, DISEASES OF THE CNS, OR IN VIVO GENE THERAPIES. IMPORTANTLY, IN THIS CASE THIS IS NOT AN ADDITIVE POINT. MEETING ONE CRITERION IS ENOUGH. AND IF YOU MEET TWO, YOU GET

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THE SAME. THIS WAS DESIGNED DELIBERATELY TO AVOID STACKING MODALITY BIAS OR FORCING PROJECTS TO FIT MULTIPLE BOXES.

THE NEXT SET OF PREFERENCES CAPTURES READINESS AND TRANSLATIONAL MOMENTUM. THESE INCLUDE NONVIRAL NUCLEIC ACID DELIVERY, EVIDENCE OF EARLY FDA ENGAGEMENT THROUGH A PRE-IND OR INTERACT MEETING, AND PROGRESSION FROM EARLIER CIRM PROGRAMS SUCH AS DISC2 OR TRAN1. THESE SIGNALS HELP US UNDERSTAND WHERE A PROJECT SITS ON THE DEVELOPMENT PATH AND WHETHER CIRM FUNDING IS LIKELY TO BE CATALYTIC AT THIS STAGE. AGAIN, THESE PREFERENCES ARE NOT REQUIREMENTS. AND YOU GET A POINT FOR EACH ONE OF THESE IF YOU GET THIS -- IF YOU CLICK THAT BOX.

UNDERREPRESENTED DISEASE AREAS, THIS CATEGORY IS ABOUT PORTFOLIO BALANCE. WE EXPLICITLY LOOK AT HOW REPRESENTATIVE A DISEASE AREA ALREADY IS WITHIN CIRM'S ACTIVE AWARDS AND GIVE MODEST ADDITIONAL WEIGHT TO AREAS THAT ARE UNDERREPRESENTED. THE INTENT HERE IS DIVERSIFICATION, NOT PRIORITIZATION OF RARITY OR EXCLUSION OF WELL-REPRESENTED DISEASES.

AND THE LAST ONE IS THE NOVELTY CRITERIA WHICH EXISTS SPECIFICALLY TO PREVENT PREFERENCES

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FROM BECOMING EXCLUSIONARY AND TO ENSURE THAT STRONG OUTLIER IDEAS STILL HAVE A WAY TO MOVE FORWARD EVEN WHEN THEY DON'T SCORE POINTS ON MULTIPLE PREFERENCES. AT THE SAME TIME IT'S IMPORTANT TO BE EXPLICIT THAT NO SINGLE PREFERENCE OPERATES IN ISOLATION. PROJECTS STILL NEED TO TOUCH OTHER ASPECTS OF PROGRAM INTENT, AND PREFERENCES INEVITABLY WILL INVOLVE TRADE-OFFS.

SETTING PREFERENCES MEANS MAKING CHOICES ABOUT WHAT THE PORTFOLIO IS OPTIMIZED TO DO. AND THAT DOESN'T EXCLUDE SOME THINGS EVEN WHEN THE SCIENCE IS STRONG.

THE NEXT ONE IS THE CLIN2 RUBRIC, AND THIS IS AT THE QUALIFICATION. SO THIS SLIDE SUMMARIZES WHAT WE'VE USED FOR THE CLIN2 QUALIFICATION RUBRIC WHICH IS USED AS AN INTERNAL SCREENING TOOL BY THE REVIEW TEAM TO DETERMINE WHICH APPLICATIONS AND DISC4 APPLICATIONS THAT PDEV WAS FOR PRESUBMISSIONS. SO THERE IS A DIFFERENCE BETWEEN THE PDEV AND CLIN2. SO THE REVIEW TERM DETERMINES WHICH APPLICATIONS MOVE FORWARD BASED ON THIS RUBRIC TO THE GRANTS WORKING GROUP. IT'S NOT A SCIENTIFIC SCORING RUBRIC AND IT DOESN'T REPLACE PEER REVIEW.

EACH ITEM HERE REFLECTS A DISCRETE PREFERENCE DESIGNED TO ASSESS ALIGNMENT WITH THE

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GUIDING PRINCIPLES THAT I MENTIONED A FEW SLIDES AGO. THE FIRST SET OF PREFERENCES INCLUDES PLURIPOTENT STEM CELL-DERIVED THERAPIES AND DISEASES OF THE CNS WHICH ARE BOTH EXPLICIT PROP 14 PRIORITIES. THIS IS ALIGNED WITH THE PDEV PREFERENCES AS WELL.

IN VIVO GENE THERAPY IS INCLUDED HERE INDIRECTLY, RESPONDING TO A STATUTORY MANDATE BECAUSE OF ITS POTENTIAL FOR SCALABLE DELIVERY AND BROADER PATIENT ACCESS.

NONVIRAL GENETIC THERAPIES ARE INCLUDED TO RECOGNIZE EMERGING APPROACHES THAT MAY REDUCE SAFETY OR MANUFACTURING CONSTRAINTS. WE ALSO ACCOUNT FOR ACCELERATED REGULATORY DESIGNATIONS SUCH AS RMAT, BREAKTHROUGH, OR FAST TRACK BECAUSE THESE MATERIALLY CHANGE DEVELOPMENT TIMELINES AND SIGNAL REGULATORY ALIGNMENT. PROGRESSION FROM EARLIER CIRM AWARDS REFLECTS STEWARDSHIP OF PRIOR INVESTMENTS, AND CALIFORNIA ORGANIZATIONS REFLECT THE TAXPAYER FUNDED NATURE OF THE PROGRAM.

FINALLY, PIVOTAL TRIALS RECEIVE ADDITIONAL WEIGHT BECAUSE THEY REPRESENT THE FASTEST AND MOST DIRECT PATH TO POTENTIAL LICENSURE AND PATIENT IMPACT. SOMETHING THAT IS NOT HERE -- WELL, I'LL TALK ABOUT THIS LATER.

SO WITH THAT FRAMEWORK IN MIND, WE'LL SHOW HOW THE RESULTS FROM THE FIRST TWO CYCLES OF PDEV AND CLIN2 ILLUSTRATE HOW THESE PREFERENCES PLAYED OUT IN PRACTICE. AND WE'LL START WITH THE PDEV AND THE FIRST CYCLE. THIS SLIDE SUMMARIZES HOW THE PREFERENCES FRAMEWORK PLAYED IN THE PDEV CYCLE FIRST CYCLE.

WE RECEIVED A TOTAL OF 168 PRESUBMISSIONS REFLECTING WHAT I WAS SAYING AT THE VERY BEGINNING, A VERY STRONG DEMAND AND HIGH VOLUME OF APPLICATIONS.

USING THE PRESUBMISSION RUBRIC, WE INVITED 33 APPLICATIONS FORWARD FOR FULL APPLICATION AND REVIEW, WHICH IS ROUGHLY THE TOP 20 PERCENT. WHAT'S IMPORTANT HERE IS THE SEPARATION SIGNAL. AMONG THE INVITED GROUP, 97 PERCENT MET THREE TO FOUR OF THE STATED PREFERENCES. WHEREAS, 42 PERCENT OF THE NONINVITED PROPOSALS MET ZERO OR ONE PREFERENCES. THAT TELLS US THE RUBRIC WAS FUNCTIONING AS INTENDED, NOT EXCLUDING IDEAS ARBITRARILY, BUT HELPING DISTINGUISH WHICH PROPOSALS WERE MOST ALIGNED WITH THE PRIORITIES THAT THE BOARD SET.

AND DURING THE SCIENCE SUBCOMMITTEE PRESENTATIONS, WE HAD QUESTIONS ABOUT HOW THE PREFERENCES WERE DISTRIBUTED BY THE APPLICATIONS.

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THOSE DETAILS ARE ACTUALLY IN THE MEMO. SO IF YOU ARE THINKING ABOUT THESE, PLEASE REFER TO THE MEMO FOR THOSE DETAILS.

NOW, OF THOSE 33 INVITED TO FULL APPLICATION AND REVIEW, 12 WERE ULTIMATELY FUNDED AWARDS. AND WE SEE SEVERAL CONSISTENT THEMES HERE. THERE WAS A CLEAR INCREASE IN PROPOSALS WITH STRONGER TRANSLATIONAL READINESS, INNOVATION, AND SCALABILITY. THIS IS ALL ALIGNED WITH THE GUIDING PRINCIPLES. MORE THAN HALF REPRESENTED PROGRESSIONS OF PRIOR CIRM-FUNDED PROGRAMS. AND THE FUNDED SET IS MORE ENRICHED FOR DISEASE AREAS THAT HAVE BEEN UNDERREPRESENTED IN OUR ACTIVE PORTFOLIO.

TAKEN TOGETHER, THIS CYCLE SUGGESTS THAT THE PREFERENCES ARE NOT NARROWING THE SCIENCE, BUT REBALANCING THE PRECLINICAL PORTFOLIO ACROSS MODALITY, DISEASE AREA, AND PROP 14 PRIORITIES IN A WAY THAT'S INTENTIONAL AND ALIGNED WITH THE STRATEGY THAT THE BOARD APPROVED.

THIS SLIDE IS GOING TO NOW SHOW THE DATA FOR THE SECOND CYCLE OF THE PRECLINICAL DEVELOPMENT. AN IMPORTANT CAVEAT HERE IS THAT THESE ARE PRESUBMISSION RESULTS ONLY. WE HAVE NOT YET COMPLETED FULL APPLICATION REVIEW OR GRANTS WORKING GROUP ASSESSMENT. WHAT WE SEE, HOWEVER, IS THAT THE

SAME PATTERN FROM THE FIRST CYCLE IS HOLDING. WE RECEIVED 126 PRESUBMISSIONS AND INVITED 23 FOR FULL APPLICATION, REPRESENTING APPROXIMATELY 18 PERCENT OF THE TOTAL. IMPORTANTLY, A HUNDRED PERCENT OF THE INVITED APPLICATIONS MET THREE TO FIVE PREFERENCES WHILE ABOUT A THIRD OF UNINVITED APPLICATIONS MET ZERO TO ONE PREFERENCES. SO THE SIGNAL HERE REMAINS VERY CLEAN.

TWO ADDITIONAL POINTS RESPOND DIRECTLY TO QUESTIONS THAT WE'VE BEEN HEARING. FIRST, THE INVITED POOL SPANS BROADER DISEASE AREAS, INCLUDING MORE CANCER AND IMMUNOLOGY PROGRAMS THAN IN CYCLE 1, AND, SECOND, NEARLY 40 PERCENT OF INVITED APPLICATIONS COULD REPRESENT PROGRESSIONS WITHIN THE EXISTING CIRM PORTFOLIO IF FUNDED, WHICH IS EXACTLY WHAT WE INTENDED AS WELL. SO WHILE FINAL FUNDING DECISIONS ARE STILL AHEAD, THE TAKEAWAY, THE PRELIMINARY TAKEAWAY IS THAT THE PREFERENCE FRAMEWORK CONTINUES TO DO WHAT IT WAS DESIGNED TO DO, WHICH IS TO IDENTIFY THE STRONGEST, MOST ALIGNED PROGRAMS EARLY WHILE ALLOWING THE PORTFOLIO TO BROADEN ACROSS DISEASE AREAS WHERE THE SCIENCE IS READY.

I'M HAVING TROUBLE TODAY WITH THE CLICKS. OKAY.

SO NOW I'M GOING TO TURN THE CLIN2 CYCLE 1. WE RECEIVED 23 TOTAL APPLICATIONS, ALL OF WHICH WERE RANKED USING THE PREFERENCE POINTS AS PART OF THE QUALIFICATION. FROM THOSE, SEVEN ADVANCED TO FULL REVIEW AND FOUR WERE ULTIMATELY FUNDED. A FEW THINGS ARE WORTH HIGHLIGHTING HERE.

FIRST, ALL THE SEVEN APPLICATIONS THAT ADVANCED TO FULL REVIEW MET THREE TO FOUR PREFERENCE POINTS. SO THE FRAMEWORK THAT WE PUT TOGETHER WITH THE PREFERENCES CLEARLY DISTINGUISHED THE TOP TIER. ALL SEVEN TARGETED CNS INDICATIONS, WHICH IS CONSISTENT WITH ONE OF THE PROP 14 PRIORITIES. THERE'S BEEN SOME QUESTIONS HERE ABOUT WHETHER, IF WE REMOVE CNS, IT COULD CHANGE THE POOL OF WHAT ADVANCED. WE'VE DONE THAT, AND WE COULD BRING THIS IN MARCH. IT DIDN'T CHANGE THE NATURE. IT ACTUALLY CHANGED -- IN TERMS OF ONCOLOGY, IT CHANGED WHICH APPLICATION OF ONCOLOGY MOVED FORWARD, BUT IT DIDN'T CHANGE THE PICTURE BECAUSE ALL THE CNS INDICATIONS ARE ALSO CLICKING OTHER PREFERENCE CRITERIA IN THE QUALIFICATION PROCESS.

THE SECOND CONCLUSION HERE IS THAT SIX OF THE SEVEN INVOLVED EITHER PLURIPOTENT STEM CELL-DERIVED THERAPIES OR IN VIVO GENETIC THERAPIES, AND FOUR ALREADY HAD ADVANCED REGULATORY

DESIGNATIONS, WHICH SPEAKS TO DEVELOPMENT MATURITY. LOOKING AT THE FUNDED PROGRAMS, ALL FOUR HAVE A FEASIBLE DELIVERY PATH ALIGNED WITH OUR ACCESS AND AFFORDABILITY STRATEGY. AS YOU KNOW, WE'VE DEVELOPED A RUBRIC, WE HAVE CONSULTANTS EVALUATING THIS, AND THAT'S A VERY STRONG PART OF OUR REVIEW PROCESS AS WELL. AND THREE REPRESENT PROGRESSIONS OF PRIOR CIRM-FUNDED PROGRAMS. AND THIS TELLS US THAT THE SYSTEM IS REINFORCING BOTH INNOVATION AND DISCIPLINED PORTFOLIO ADVANCEMENT.

THE KEY TAKEAWAY IS THAT THE SYSTEM HAS BEEN WORKING DIRECTIONALLY AS INTENDED, AND IT ELEVATED PROGRAMS THAT ARE ALIGNED WITH THE STATUTORY -- IT HAS ELEVATED PROGRAMS THAT ALIGN WITH THE STATUTORY PRIORITIES, CLINICAL READINESS, AND DELIVERY FEASIBILITY. THAT SAID, THIS FIRST CYCLE ALSO MADE CLEAR THAT THE RELATIVE WEIGHING OF PREFERENCE MATTERS. AND THAT'S WHERE REFINEMENT MIGHT BE NEEDED TO ENSURE WE ARE NOT OVERCONCENTRATED SIGNALS AS THE PORTFOLIO GROWS.

THIS IS THE SECOND CYCLE. THIS SLIDE SHOWS WHERE WE ARE FOR THE SECOND CYCLE, RECOGNIZING THAT THESE ARE INTERIM RESULTS PENDING THE APPLICATION REVIEW SUBCOMMITTEE APPROVAL OF THE GRANTS WORKING GROUP REVIEW THAT HAPPENED TWO DAYS

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AGO. WE RECEIVED 21 APPLICATIONS, ALL OF WHICH WERE RANKED USING THE SAME PREFERENCE-BASED FRAMEWORK. FROM THOSE SEVEN, SEVEN ADVANCED TO FULL REVIEW, AND EVERY ADVANCING APPLICATION SCORED, AGAIN, THREE TO FOUR PREFERENCE POINTS, WHICH IS CONSISTENT WITH WHAT WE SAW IN THE FIRST CYCLE.

IN TERMS OF COMPOSITION, FOUR TARGETED CNS, AND THOSE FIVE REPRESENT PROGRESSION FROM THE EXISTING CIRM PORTFOLIO, AND FIVE ARE EITHER IN VIVO GENETIC THERAPIES OR PLURIPOTENT STEM CELL-DERIVED THERAPIES, AGAIN, REFLECTING STRONG ALIGNMENT WITH THE PREFERENCES THAT THE BOARD SET. AND THE FINAL FUNDING RECOMMENDATIONS WILL FOLLOW THE APPLICATION REVIEW SUBCOMMITTEE APPROVAL, WHICH I BELIEVE THIS ONE IS MARCH 1, BUT SCOTT WILL CONFIRM.

SO STEPPING BACK, WHEN WE LOOK ACROSS THE PRECLINICAL DEVELOPMENT AND THE PDEV AND CLIN2 FIRST CYCLE TOGETHER, THE OVERALL PATTERN IS CONSISTENT AND DIRECTIONALLY ALIGNED WITH WHAT THE BOARD ASKED US TO DO WHEN WE SET THE STRATEGY. AWARDS IN BOTH PROGRAMS REFLECT THE INNOVATION, READINESS, ACCESS AND AFFORDABILITY, AND CNS CRITERIA THAT WERE EXPLICITLY LAID OUT IN THE PROGRAM ANNOUNCEMENT, NOT INFORMALLY, BUT OPERATIONALLY THROUGH THE QUALIFICATION AND RANKING PROCESS.

THE APPLICATIONS THAT ADVANCED WERE LARGELY CIRM PORTFOLIO PROGRESSIONS, BUT IMPORTANTLY THEY WERE NOT ADVANCING BECAUSE THEY WERE LEGACY PROJECTS. THEY ADVANCED BECAUSE THEY ALSO MET MULTIPLE STATED PREFERENCES, SAME WITH THE CNS.

AS A RESULT, THE PORTFOLIO NOW INCLUDES MORE FEASIBLE AND SCALABLE MODALITIES WHICH STRENGTHENS DOWNSTREAM ACCESS AND AFFORDABILITY POTENTIAL WITHOUT SACRIFICING SCIENTIFIC RIGOR.

THAT SAID, I JUST WANT TO MAKE SURE THAT WE ARE CLEAR ABOUT THE CAVEATS HERE. THESE ARE EARLY SIGNALS, AND IT'S TOO SOON TO ASSESS PORTFOLIO LEVEL IMPACT. WHAT WE CAN SAY AT THIS STAGE IS THAT THE SYSTEM IS BEHAVING DIRECTIONALLY AS INTENDED.

I'M NOW GOING TO MOVE INTO THE DISC4 RESULTS. AND AS YOU ALL RECALL, THE DISC4 PREFERENCES WERE SET DIFFERENT THAN WHAT WE DID FOR PDEV AND CLIN4 -- CLIN2. THIS WAS DONE THROUGH THE NEURO TASK FORCE/SCIENCE SUBCOMMITTEE. AND IT'S A BRIEF REMINDER THAT THE STAFF PROPOSED ALTERNATING PREFERENCE CYCLES FOR DISC4 WITH NEURO EVERY OTHER YEAR. AND THE BOARD APPROVED NEUROLOGICAL DISEASE AS A PREFERENCE FOR FISCAL YEAR '25/'26 FOR THE DISC4 CYCLE.

THE PROGRAM WAS OPEN TO ALL COMERS, BUT

THERE WAS THIS PREFERENCE. AND WHEN WE SAY NEUROLOGICAL DISEASE, IT WAS IN THE WIDE -- IN THE WIDE UNDERSTANDING INCLUDING NEURODEGENERATIVE, NEUROPSYCHIATRIC, AND NEURODEVELOPMENTAL DISEASES.

THIS SLIDE SHOWS HOW THE ALTERNATING STRUCTURE IS INTENDED TO WORK OVER TIME. SOME CYCLES ARE DRIVEN BY NEURO TASK FORCE/SCIENCE SUBCOMMITTEE IDENTIFIED NEEDS, SUCH AS THE FIRST ROUND THAT WE HAD IN NEUROPSYCHIATRIC OR NEURODEVELOPMENTAL PRIORITIES, WHILE OTHERS REFLECT THE BOARD SET PREFERENCES. AND IT WAS PROP 14 NEURO-WIDE UNDERSTANDING OF THE PREFERENCE THAT THE BOARD SET BACK THIS YEAR. SO CRUCIALLY EVERY CYCLE REMAINS OPEN TO ALL COMERS, BUT THE PREFERENCE DOES DETERMINE WHAT WE WILL MOSTLY BE REVIEWING.

THIS STRUCTURE GIVES THE BOARD A REPEATABLE, TRANSPARENT WAY TO SET DIRECTION YEAR OVER YEAR WHILE STILL PRESERVING SCIENTIFIC BREADTH AND FLEXIBILITY.

SO NOW I'M GOING TO SHOW WHERE THE PREFERENCE SCORING FOR DISC4 IN THIS YEAR. THESE ARE HOW WE OPERATIONALIZE THE PREFERENCES CONSISTENT WITH WHAT WAS APPROVED IN THE PROGRAM ANNOUNCEMENT. SO THE NEUROLOGICAL DISEASE PREFERENCE CARRIED A VERY LARGE WEIGHT. YOU CAN SEE HERE THAT IF YOU

DIDN'T APPLY NEURO, YOU COULD STILL MAKE IT THROUGH, BUT IT WAS HARD. SO THE NEUROLOGICAL DISEASE CARRIED 36 PERCENT OF THE TOTAL SCORING WEIGHT. AND THAT WAS INTENTIONAL AND TRANSPARENT, WHICH REFLECTED THE BOARD DECISION TO CLEARLY SIGNAL A PRIORITY FOR THIS CYCLE WHILE STILL KEEPING THE PROGRAM OPEN TO ALL APPLICANTS.

IMPORTANTLY, THE PREFERENCE ALIGNMENT WAS NOT THE SOLE DRIVER OF THE RANKING. 64 PERCENT OF THE SCORE CAME FROM SCIENTIFIC SUBSTANCE WHICH WAS REPRESENTED BY RELEVANCE TO HUMAN DISEASE BIOLOGY, CROSS-DISCIPLINARY AND SYSTEM LEVEL APPROACHES, AND INNOVATION IN STEM CELL OR GENETIC RESEARCH. IN OTHER WORDS, AS I WAS SAYING, PROJECTS STILL HAD TO BE STRONG SCIENCE FIRST, AND THE PREFERENCE WEIGHT DID NOT REPLACE SCIENTIFIC MERIT, BUT IT SHAPED WHICH STRONG PROJECTS ROSE TO THE TOP WHEN TRADE-OFFS WERE NECESSARY.

THIS STRUCTURE IS DOING WHAT IT WAS DESIGNED TO DO, WHICH IS TO TRANSLATE THE PRIORITIES THAT THE BOARD GAVE US WITHOUT COLLAPSING DISC4 INTO A SINGLE DISEASE PROGRAM OR EXCLUDING HIGH QUALITY WORK OUTSIDE OF THE PREFERENCE AREA.

NOW I'M GOING TO SHOW WHAT DID WE GET AS RESULTS OF SETTING THESE PREFERENCES IN THIS FIRST

CYCLE. WE RECEIVED 138 PRESUBMISSIONS AND 86 PERCENT ALIGNED WITH THE NEURO PREFERENCE. THAT TELLS US THAT THE SIGNAL WAS CLEARLY HEARD BY THE COMMUNITY. FROM THAT POOL, 24 APPLICATIONS WERE INVITED TO FULL APPLICATION AND REVIEW. AND, IMPORTANTLY, HUNDRED PERCENT OF THOSE INVITED MET THE NEURO PREFERENCE, BUT THEY SPAN A BROAD RANGE OF NEUROLOGICAL DISEASES AND REPRESENT A WIDE DIVERSITY OF MECHANISMS AND SCIENTIFIC APPROACHES. AND THAT PART WE WILL BE HAPPY IN MARCH TO PROVIDE A DOWNLOAD OF -- GRANULAR DOWNLOAD OF THAT DATA.

SO WHAT WE ARE SEEING HERE IS NOT CONVERGENCE ON A SINGLE DISEASE OR MODALITY. IT'S ENRICHMENT WITHIN A PRIORITY AREA WHILE PRESERVING SCIENTIFIC BREADTH. FUNDING DECISIONS, AS I MENTIONED EARLIER, ARE STILL PENDING. AND WE'LL HAVE A REVIEW IN 2026 IN FEBRUARY, BUT AT THIS STAGE THE PREFERENCE IS DOING EXACTLY WHAT THE BOARD DESIGNED TO DO, WHICH IS TO SHAPE THE POOL WITHOUT NARROWING THE SCIENCE.

SO I'M JUST GOING TO CLOSE WITH TWO SLIDES. STEPPING BACK, THESE ARE THE SIGNALS THAT WE ARE SEEING FROM PREFERENCE SETTING ACROSS THE PROGRAMS. FIRST, APPLICATIONS THAT ADVANCE TO GRANTS WORKING GROUP REVIEW CONSISTENTLY MET

MULTIPLE PREFERENCES. THIS TELLS US THAT THE RUBRIC IS DOING REAL TRIAGE AND IS NOT ADVANCING PROJECTS ON A SINGLE ATTRIBUTE ALONE.

THE SECOND IS THAT IN CLIN2 WE SEE HIGH PROPORTION OF CNS PROJECTS FUNDED, WHICH IS CONSISTENT WITH THE STATED PREFERENCE AND CONFIRMS THAT, WHEN WE WEIGH A PRIORITY, IT SHOWS UP CLEARLY AT THE OUTCOME LEVEL, BUT IT ALSO SHOWS THAT, FOR THOSE CNS PROJECTS, THEY ARE KEEPING OTHER MULTIPLE PREFERENCES. SO THEY ARE NOT COMING IN SIGNALING THAT THE FIELD IS READY FOR CNS PROJECTS.

IN CONTRAST, FOR PDEV, IT SHOWS A MUCH WIDER SPREAD ACROSS DISEASE AREAS AND MODALITIES, WHICH REFLECTS BOTH THE EARLIER STAGE OF THE SCIENCE AND THE WAY THAT PREFERENCES WERE DESIGNED TO GUIDE, NOT CONSTRAIN THE PORTFOLIO.

AND FINALLY, ACROSS BOTH PROGRAMS, A LARGE FRACTION OF FUNDED PROJECTS ARE CIRM PORTFOLIO PROGRESSIONS. OVER 50 PERCENT IN THE CASE OF THE PDEV PROGRAM AND ROUGHLY 75 PERCENT IN THE CLIN2, SUGGESTING THAT WHAT WE SET UP IS REINFORCING CONTINUITY WHILE STILL APPLYING DIRECTIONAL FILTERS.

IMPORTANTLY, THESE ARE EARLY SIGNALS, NOT FINAL CONCLUSIONS. AND THIS PRESENTATION, WHAT WE ARE INTENDING TO DO IS KEY UP KEY QUESTIONS FOR THE

BOARD. AND IN MARCH WE COULD BRING PORTFOLIO ANALYSIS AND OPTIONS INFORMED BY YOUR GUIDANCE.

NOW, BASED ON WHAT WE'VE SHOWN TODAY, WHAT ARE WE GOING TO BRING IN MARCH? THE FIRST THING IS WE WILL PROPOSE PATHS IN MARCH TO MOVE FORWARD THAT WILL BE INFORMED BY, A, WHAT SORT OF PREFERENCES COULD THE BOARD LIKE TO SEE; AND, B, WHERE IN THE PROCESS DOES THE BOARD WANT TO SEE THE PREFERENCES? SO THOSE ARE TWO VERY IMPORTANT THINGS, RIGHT. THE SORT OF PREFERENCES AND WHERE IN THE PROCESS DO WE PUT THOSE -- DO WE HAVE THESE PREFERENCES.

IN ORDER TO HAVE THAT DISCUSSION, WE WILL PROVIDE PORTFOLIO ANALYSIS THAT ALLOWS US TO VISUALIZE HOW PREFERENCES ARE SHAPING WHAT'S MOVING FORWARD IN TERMS OF THE PORTFOLIO. DURING OUR PRE-CALLS THAT WE HAD WITH THE SCIENCE SUBCOMMITTEE, WE GOT FEEDBACK ON THOSE ANALYSES ALREADY. AND THOSE ARE REFLECTED HERE.

FIRST, WE WILL BRING ILLUSTRATIVE PORTFOLIO CUTS THAT SHOW HOW CIRM-FUNDED PROJECTS MAP ACROSS INNOVATION, PROGRESSION, AND DISEASE FOCUS. THAT INCLUDES COMPLETE EXAMPLES OF WHAT WE ARE CATEGORIZING AS INNOVATION, HOW PROJECTS ADVANCE THROUGH SUCCESSIVE STAGES OF CIRM FUNDING, AND HOW DISEASES ARE REPRESENTED ACROSS RECENT CYCLES.

SECOND, WE WILL PRESENT A CLEAR PICTURE OF THE CURRENT AND EMERGING PORTFOLIO, LOOKING AT BOTH ACTIVE AWARDS AND RECENT APPLICATION CYCLES BROKEN DOWN BY DISEASE AREA, MODALITY, STAGE OF DEVELOPMENT, AND HOW PREFERENCES IN THE FIRST CYCLE HAVE BEEN SHAPING THE PIPELINE. WITH ALL OF THIS, THE PROPOSED ANALYSIS INTENT IS TO MOVE THE CONVERSATION FROM INDIVIDUAL APPLICATIONS TO PORTFOLIO LEVEL EFFECTS.

THE SECOND THING THAT -- AND PLEASE LET US KNOW IF THERE'S ANYTHING THERE THAT WE ARE MISSING FROM THE SCIENCE SUBCOMMITTEE FEEDBACK OR FROM QUESTIONS THAT YOU MIGHT HAVE NOW.

THE SECOND THING THAT WE PLAN ON BRINGING ARE OPTIONS FOR WHERE PREFERENCES COULD OPERATE IN THE FUNDING PROCESS. FOR EXAMPLE, SHOULD WE HAVE THEM AT PRESUBMISSION, AT QUALIFICATION, OR LATER AT THE APPLICATION REVIEW SUBCOMMITTEE AS PROGRAMMATIC CONSIDERATIONS. AND WHAT EACH OPTION IMPLIES FOR SCIENTIFIC REVIEW, FOR TRANSPARENCY, AND BOARD OVERSIGHT. THIS WILL BE FRAMED AS OPTIONS, NOT RECOMMENDATIONS, TO SUPPORT THE DISCUSSION IN MARCH.

AND WITH THIS, I WOULD LIKE TO THANK YOU ALL, THE BOARD AND THE PUBLIC, FOR THE ATTENTION AND ALL THE QUESTIONS AS WELL THAT HAVE HELPED US SHAPE

THESE PRESENTATIONS, WHICH WE HOPE THAT IT BROUGHT SOME CLARITY AROUND THE PROCESS AND THE STAGE THAT WE ARE IN AS WE ARE TRYING TO REACH OUR GOALS. WITH THIS, I WOULD LIKE TO BRING IT BACK TO OUR -- BACK TO YOU, MR. CHAIRMAN.

CHAIRMAN IMBASCIANI: THANK YOU, ROSA. THANKS FOR THE COMPREHENSIVE PRESENTATION. ALSO, I WANT TO THANK YOU FOR THE CARE AND THE BREADTH AND THE SCOPE OF THAT MEMO THAT YOU AND VICE PRESIDENT FOR REVIEW, GIL SAMBRANO, SUPPLIED THE BOARD WITH. IT WAS A GREAT DOCUMENT TO HELP FRAME THE DISCUSSION.

SO I EXPECT SORT OF BROAD AND ROBUST DISCUSSION FROM BOARD MEMBERS BEFORE WE GO TO THE PUBLIC. SO I'D LIKE TO OPEN THE FLOOR TO DISCUSSION ON THIS ITEM.

MR. TOCHER: JUDY CHOU.

CHAIRMAN IMBASCIANI: THIS IS NOT AN ACTION ITEM.

MR. TOCHER: JUDY CHOU HAS HER NAME RAISED AS WELL.

CHAIRMAN IMBASCIANI: LET'S START WITH JUDY THEN AND GEORGE WILL FOLLOW.

DR. CHOU: AGAIN, I WILL ECHO VITO'S COMMENT. VERY NICE PRESENTATION. AND I

PARTICULARLY ALSO APPRECIATE THE MEMO BECAUSE THAT REALLY HELP TO FRAME THE WHOLE DISCUSSION.

I DO THINK, WHEN WE LOOK AT THE PDEV AND ALSO CLIN2, I AM A LITTLE BIT SURPRISED HOW WE DIDN'T MENTION ANYTHING ABOUT THE MANUFACTURABILITY. IF YOU LOOK AT TODAY'S CELL/GENE THERAPY, THE BIGGEST BOTTLENECK TO BECOME A FEASIBLE PRODUCT, NO MATTER FOR INDIVIDUAL PATIENT OR THE BROADER PATIENT POPULATION, THE BIGGEST ISSUE IS THERE. AND I KNOW CIRM, WE HAD TO PUT IN QUITE A BIT OF EFFORT AND ALSO INVESTMENT IN SOME SENSE TO THIS AREA. BUT I DO THINK WHEN WE SET UP THE CRITERIA, PARTICULARLY IN THE LATER PHASE, IT SHOULD HAVE SOME MANUFACTURABILITY TO MAKE SURE IT TRULY CAN BENEFIT THE PATIENT AND ALSO GUARANTEE ROBUSTNESS.

AGAIN, I HEARD YOU. ROSA, YOU'VE BEEN SAYING THOSE WORDS LIKE SCALABILITY, THE MANUFACTURABILITY, BUT I FEEL WE NEED TO FORMALIZE THAT BECAUSE IT IS SO IMPORTANT.

DR. CANET-AVILES: VERY GOOD POINT, DR. CHOU. AND THE MANUFACTURABILITY IS TAKEN INTO ACCOUNT IN THE REVIEW CRITERIA OF THE APPLICATIONS. WHAT I WAS TRYING TO CONVEY IN THE GUIDING PRINCIPLES WAS THE ACCESS AND AFFORDABILITY. BUT YOU'RE OUR ABSOLUTELY RIGHT, THAT MANUFACTURABILITY

IS ESSENTIAL IN TERMS OF BEING ABLE TO ACCESS AND AFFORD, RIGHT, IN THE ACCESS AND AFFORDABILITY. SO THANK YOU VERY MUCH FOR THAT POINT.

CHAIRMAN IMBASCIANI: THANK YOU, JUDY. GEORGE.

DR. BLUMENTHAL: THANK YOU SO MUCH, ROSA. I THINK THAT WAS AN EXCELLENT PRESENTATION, AND I THINK THIS IS A REALLY IMPORTANT TOPIC FOR THE BOARD, PARTICULARLY IN VIEW OF THE VOLUME OF APPLICATIONS THAT WE ARE GETTING AND WILL CONTINUE TO GET IN THE FUTURE. AND IT WILL BE AN IMPORTANT TOOL IN HELPING US DISTINGUISH WHICH APPLICATIONS CAN MOVE FORWARD. SO I THINK THAT'S REALLY GOOD.

I ALSO THINK IT'S REALLY GOOD THAT THIS AFFORDS THE OPPORTUNITY OF GREATER TRANSPARENCY TO THOSE WHO ARE APPLYING FOR GRANTS TO HAVE A BETTER IDEA OF WHAT THE CRITERIA THAT THE BOARD WILL BE USING IN TERMS OF DECISION MAKING.

MY QUESTION, AND THIS MAY REALLY BE A QUESTION FOR OUR DISCUSSION IN MARCH, IS HOW DO YOU ENVISION US APPROVING A FINAL LIST OF PREFERENCES FOR EACH OFFERING? IS THIS SOMETHING THAT WOULD BE DONE AT A BOARD LEVEL, OR WILL THIS BE DONE AT A CIRM LEVEL BEFORE EACH OFFERING?

DR. CANET-AVILES: AS ALWAYS, VERY GOOD

QUESTION, DR. BLUMENTHAL. AND BEFORE I ANSWER THAT QUESTION, I JUST WANT TO MENTION THAT WE HAVE HEARD LOUD AND CLEAR WE DID NOT DO A GOOD JOB IN COMMUNICATING AND BEING TRANSPARENT, AND WE ARE REALLY MAKING A BIG CHANGE. THAT'S WHY THE MEMO, BUT ALSO IT'S GOING TO BE IN THE PROGRAM ANNOUNCEMENTS AND WILL BE VERY CLEAR IN OUR READINESS AS WELL.

SO I THINK MORE THAN TWO WAYS I WOULD ANSWER THE QUESTION. THE FIRST ONE IS FOR MARCH THERE COULD BE -- THE DECISIONS THAT I THINK COULD HELP US AS A TEAM FROM THE BOARD COULD BE WHERE COULD THE BOARD LIKE TO SET THE PREFERENCES? WHERE IS THE PLACEMENT? SHOULD THE PREFERENCES CONTINUE TO BE APPLIED UPSTREAM AT THE PRESUBMISSION OR QUALIFICATION? OR DO WE WANT THE PREFERENCES TO BE SHIFTED LATER IN THE PROCESS? THAT'S ONE QUESTION.

THE SECOND ONE IS DOES THE BOARD HAVE -- WHEN WE'VE LOOKED AT THE PRINCIPLES, I THINK IT'S NOT SO MUCH ABOUT THE PREFERENCES. IT'S ABOUT THE PRINCIPLES THAT WE ARE APPLYING TO SET THOSE PREFERENCES. IS THERE A DISAGREEMENT WITH THOSE PRINCIPLES FROM THE BOARD? BECAUSE THOSE ARE THE CORE -- I MEAN THE WAY WE TRANSLATE THOSE PRINCIPLES TO THE PREFERENCES IS KIND OF -- IS MORE SCIENTIFIC.

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DOESN'T REALLY HAVE A LOT OF LEEWAY, BUT IT'S THE PRINCIPLES THAT WE ALL NEED TO BE ADHERING AND IN AGREEMENT.

SO PERHAPS A DISCUSSION COULD BE ARE THESE THE PRINCIPLES THAT WE ALL ADHERE TO AND THAT COULD HELP US BECAUSE THE PREFERENCES ARE MORE OF A MATHEMATIC TRANSLATION OF THOSE PRINCIPLES. THANK YOU, DR. BLUMENTHAL.

CHAIRMAN IMBASCIANI: THANK YOU, ROSA AND GEORGE. BEFORE PAT ASKS A QUESTION, SCOTT HAS AN ISSUE OF CLARIFICATION.

MR. TOCHER: SURE. JUST FOR A PROCESS POINT, FOR THOSE MEMBERS OF THE PUBLIC PARTICIPATING ON THE ZOOM, I WANT TO REMIND YOU THAT IF YOU WISH TO MAKE PUBLIC COMMENT, PLEASE REFER TO THE PROCESS DESCRIBED ON THE AGENDA BECAUSE IT'S SLIGHTLY DIFFERENT FROM HOW WE'VE INVITED PARTICIPATION IN THE PAST. WE WON'T CALL ON YOU FROM THE ZOOM, BUT INSTEAD THROUGH THE DIAL-IN INFORMATION THAT IS AT THE TOP OF THE AGENDA POSTED ON OUR WEBSITE. SO WANTED TO GIVE THAT REMINDER WHILE THE BOARD CONTINUES ITS DISCUSSION.

DR. CANET-AVILES: SCOTT, COULD I SAY SOMETHING TO FINISH DR. BLUMENTHAL'S QUESTION THAT I FORGOT AND DR. PATEL JUST REMINDED ME?

MR. TOCHER: SURE.

DR. CANET-AVILES: SO I SHOULD HAVE SPECIFIED THAT THE PREFERENCES ARE APPROVED BY THE BOARD WHEN WE PRESENT OUR CONCEPTS. SO I THINK THAT IF THERE IS A REVISION OR IF THE BOARD DESIRES A CHANGE IN THE PREFERENCES, WE WOULD HAVE TO COME BACK WITH A REVISED OR AMENDED CONCEPT FOR THE BOARD TO DISCUSS THAT. SO THAT COULD BE THE PROCEDURE, BUT I THINK WHAT I WAS SAYING EARLIER ON IS THE GUIDING PRINCIPLES IS WHAT WE ALL NEED TO ADHERE TO. AND IF THERE ARE DISCUSSIONS ABOUT THAT, THEN THAT DEEMS A DISCUSSION ABOUT THE PREFERENCES FOR THE PROGRAMS.

CHAIRMAN IMBASCIANI: OKAY. THANK YOU. NEXT WILL BE PAT FOLLOWED BE MARIA AND THEN KIM AND KEITH.

DR. LEVITT: SO THANKS, ROSA. THE GREAT THING ABOUT PREFERENCES IS THAT YOU DON'T KNOW UNTIL YOU INSTITUTE THEM WHETHER THEY HAVE UNINTENDED CONSEQUENCES. AND THEN IF THEY DO, THEN YOU CAN ADAPT AND ADJUST TO THEM. SO THEY'RE NOT SUPER GLUED. SO I HAVE TWO COMMENTS.

ONE IS ABOUT THE GUIDING PRINCIPLES. IF YOU READ THE GUIDING PRINCIPLES, NO. 1, OFFER POTENTIAL FOR TRANSFORMATIVE CLINICAL IMPACT AND,

NO. 4, CAN REALISTICALLY ACHIEVE KEY REGULATORY DEVELOPMENTAL PATH WITHIN CIRM'S FINITE RUNWAY. THOSE ARE REALLY HIGH. THEY'RE RELATED TO EACH OTHER. THEY GO HAND IN HAND. CAN YOU HEAR ME?

DR. CANET-AVILES: YES, I CAN HEAR YOU.

DR. LEVITT: WELL, IT'S PRETTY CLEAR THEY'RE TRYING TO SILENCE ME.

SO 1 AND 4 ARE BASICALLY -- I'M NOT SAYING THEY'RE IDENTICAL, BUT THEY'RE BASICALLY VERY COMPLEMENTARY. LIKE YOU CAN'T HAVE POTENTIAL TRANSFORMATIVE CLINICAL IMPACT WITHOUT REALISTICALLY ACHIEVING KEY REGULATORY, ET CETERA, ET CETERA.

AND THEN YOU HAVE 3 AND 6. FILL CRITICAL FUNDING GAPS AND ADVANCE STATUTORY MANDATES. THERE'S NO ISSUES WITH CIRM'S ADVANCING STATUTORY MANDATES. THAT'S OUR CHARGE. FILLING CRITICAL FUNDING GAPS AND DIVERSIFY CIRM'S ACTIVE AWARD PORTFOLIO, BASICALLY THE SAME THING.

SO, IN FACT, I THINK WE HAVE THREE GUIDING PRINCIPLES. ONE IS ABOUT TRANSFORMATIVE CLINICAL IMPACT. THE SECOND IS ABOUT BOTTLENECKS, ACCESS AND AFFORDABILITY, EXTREMELY IMPORTANT. AND THE THIRD IS ABOUT DEBATING WHERE WE ARE NOW IN TERMS OF RUNWAY ABOUT DIVERSIFYING THE PORTFOLIO. WHAT DOES THAT MEAN? WHAT DOES THAT HAVE AN IMPACT ON IN

TERMS OF THOSE OPPORTUNITIES THAT MAY BE MORE ADVANCED, BUT YET ARE CONTINUING TO BE PART OF OUR PORTFOLIO?

SO THAT WILL BE MAYBE A CONVERSATION FOR MARCH. I DON'T WANT TO BELABOR THAT.

THE OTHER IS THAT THERE'S A CIRCULAR ARGUMENT THAT IF YOU HAVE PREFERENCES AND YOU USE THOSE PREFERENCES TO EVALUATE A SUBSET OF GRANTS GOING FORWARD, OF COURSE, THOSE GRANTS ARE GOING TO MEET THE PREFERENCES BECAUSE YOU USE THE PREFERENCES TO MAKE THE DECISIONS. RIGHT? SO IT'S ALWAYS A CIRCULAR ARGUMENT. THE QUESTION IS WHETHER THE PREFERENCES NEED TO BE REEXAMINED.

SO FOR ME THERE'S -- AND THERE'S ISSUES AROUND TWO THINGS. ONE IS WHAT WOULD SEEM TO BE A BIAS AGAINST CELL-BASED THERAPIES WHICH CAN'T GET SCORED. IT DOESN'T GET A POINT. AND THEN THE OTHER IS NONVIRAL NUCLEIC ACID DELIVERY WHICH I THINK IS A VERY IMPORTANT PLATFORM. IN FACT, WE'RE GOING TO HEAR LATER ABOUT A NEW INITIATIVE, WHICH IS VERY EXCITING, THAT IS ESSENTIALLY NONVIRAL NUCLEIC ACID DELIVERY IN MOST WAYS. AND SO WE HAVE TWO COMPONENTS NOW THAT ARE BASICALLY PUSHING NONVIRAL DELIVERY WHEN WE KNOW THAT THERE ARE STILL MAJOR OPPORTUNITIES FOR VIRAL DELIVERY. THE VAST MAJORITY

OF APPROVED FDA THERAPIES ARE VIRAL DELIVERY. FOLKS ARE WORKING HARD IN THIS AREA AS WELL TO MODIFY SO THAT THERE'S GREATER SUCCESS JUST LIKE THEY ARE IN NONVIRAL DELIVERIES, WHICH IS VERY EXCITING.

SO I'M SUGGESTING THAT CIRM INVEST IN NONVIRAL DELIVERY PLATFORMS, RIGHT. BUT WE HAVE TWO COMPONENTS NOW THAT ARE FAVORING THAT. AND BASICALLY, IF YOU'RE DOING VIRAL DELIVERY, YOU'RE BEHIND THE EIGHT BALL.

SO THIS IS ALL TO SAY, I'LL STOP THERE, THAT I THINK REVISITING THE PREFERENCES BASED ON THE INITIAL OUTCOMES, I THINK, IS WORTH SOME SIGNIFICANT PERIOD OF TIME DURING THE MARCH MEETING. WE'RE NOT GOING TO HAVE ENOUGH TIME THIS MEETING TO GO THROUGH ALL THIS, BUT I JUST RAISE THOSE TWO POINTS. THANKS.

CHAIRMAN IMBASCIANI: MARIA.

VICE CHAIR BONNEVILLE: AS SOMETHING ROSA MENTIONED ABOUT IF WE CHANGE PREFERENCES, IT'S A CHANGE IN THE CONCEPT PLAN AND THAT HAS TO COME BACK TO THE BOARD. I WANT TO UNDERSTAND A LITTLE BIT, SCOTT OR J.T. IS THE TEAM GOING TO -- THE TEAM WILL MAKE RECOMMENDATIONS IN MARCH FOR PERHAPS WHAT PREFERENCES MIGHT LOOK LIKE. IF THERE'S MORE CONVERSATION AT THAT MEETING, WILL WE BE ABLE -- I

ASSUME THERE WOULD BE A CONCEPT PLAN THAT WOULD COME IN ORDER TO ALLOW FOR TIMING BECAUSE I THINK THAT'S WHY WE WANTED TO HAVE THIS CONVERSATION EARLIER BECAUSE OF THE CONCEPT PLANS AND WHETHER OR NOT JUNE IS SOON ENOUGH. I'D HEARD SOME CONVERSATION AROUND THAT. SO I JUST WANT TO MAKE SURE THAT IF THERE ARE CHANGES TO THE CONCEPT PLAN THAT ARE DECIDED AT THE MARCH MEETING THAT ARE OUTSIDE OF RECOMMENDATIONS THAT HAVE COME FROM THE TEAM, THAT ALL OF THAT TIMING WORKS.

DR. THOMAS: SO, YES, THAT'S THE IDEA.

VICE CHAIR BONNEVILLE: WHICH PART? I'M SORRY. WHICH PART?

DR. THOMAS: YOU'RE ASKING WILL YOU BE ABLE TO MAKE ADJUSTMENTS TO THE CONCEPT PLAN AT THE MARCH MEETING AS OPPOSED TO WAITING TILL JUNE. IS THAT SORT OF THE CRUX OF THE QUESTION?

VICE CHAIR BONNEVILLE: YEAH.

DR. THOMAS: SO I THINK, ROSA, IF YOU WANT TO STEP IN HERE, BUT I THINK THE OBJECT HERE IS GET THE NEW PREFERENCES IN PLACE AS SOON AS WE POSSIBLY CAN. AND IF THAT CAN BE DONE IN MARCH, THAT'S A PREFERABLE WAY TO GO.

DR. CANET-AVILES: THEY WOULD NEED TO BE IN MARCH BECAUSE OF THE TIMELINE FOR THE DIFFERENT

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PROGRAMS THAT ARE COMING IN. SO THE IDEA WAS TO HAVE KIND OF A BLANKET APPROVAL, LIKE IF WE HAVE A DISCUSSION AROUND PREFERENCES AND PROCESS, BECAUSE THE SECOND THING IS WHERE DO PREFERENCE COME IN. AND I THINK THAT THERE ARE SOME TRADE-OFFS ABOUT HAVING THE PREFERENCES EARLIER OR LATER, RIGHT. BUT SO THAT WOULD BE ONE QUESTION.

AND THE OTHER COULD BE, IF WE DISCUSS THE PREFERENCES, AND YOU CAN SEE PDEV AND CLIN2 ARE ALIGNING PREFERENCES, THEN WE WERE GOING TO DO THIS EVERY YEAR, RIGHT, REVISE THE PREFERENCES. THAT COULD BE LIKE A BLANKET APPROVAL THAT COULD THEN FLOW INTO THE CONCEPT. WE DON'T HAVE TO PRESENT THE WHOLE CONCEPT AGAIN. IT'S JUST THAT BOARD HAS SET THESE PREFERENCES FOR THIS UPCOMING YEAR BASED ON THIS DATA, AND THAT'S NOW TRANSLATED INTO THE CONCEPTS. THAT'S HOW I WAS CONCEIVING THIS, AND I DON'T KNOW IF SCOTT AND YOU, J.T., AGREE WITH THAT.

DR. THOMAS: THAT'S ENTIRELY IN LINE WITH WHAT I JUST SAID. SO THANK YOU, ROSA.

VICE CHAIR BONNEVILLE: AND THE SECOND THING I WANTED TO MENTION, JUST IN CONVERSATIONS, WE'VE HAD A LOT OF CONVERSATIONS ABOUT THIS, BUT SOMETHING THAT I THINK WE MISS IS, AND IT'S SOMETHING THAT PAT MENTIONED, WHAT ARE THE OUTCOMES

WE WANT BECAUSE THAT REALLY DRIVES WHAT OUR PREFERENCES ARE. AND SO A CLEAR ALIGNMENT AROUND AN OUTCOME OR THE OUTCOMES THAT WE BELIEVE ARE IMPORTANT IS REALLY THE CONVERSATION WE NEED TO GET TO. AND I THINK THEN EVERYONE IS MORE CLEAR ON WHAT THE PREFERENCES MEAN AND WHY THEY'RE THERE. SO THANK YOU, PAT, FOR BRINGING THAT UP.

CHAIRMAN IMBASCIANI: THAT WASN'T A RHETORICAL QUESTION.

NEXT IS KIM FOLLOWED BY KEITH.

DR. BARRETT: ROSA, THANK YOU SO MUCH FOR A REALLY CAREFUL EXPOSITION OF WHERE WE'VE BEEN AND WHERE WE ARE RIGHT NOW. I APPRECIATE THAT. I ALSO AGREE WITH YOU, THAT THE RESPONSE THAT WE'VE RECEIVED FROM THE COMMUNITY ILLUSTRATES THAT WE HAVE TO DO MORE TO COMMUNICATE. AND I'M GLAD THAT THAT'S IN THE PLANS.

I THINK WE CAN ALL AGREE THAT, IN A PERFECT WORLD, WE WOULD HAVE ENOUGH RESOURCES TO FUND EVERY PROJECT THAT WAS SCIENTIFICALLY MERITORIOUS. BUT CLEARLY NEITHER, BOTH IN AMOUNT NOR TIME FRAME, WE DON'T HAVE THAT. SO I PERSONALLY BELIEVE THAT WE HAVE A NEED FOR PREFERENCES AND THAT THEY NEED TO BE APPLIED EARLY BECAUSE OTHERWISE WE LOSE THE EFFICIENCY OF THE REVIEW PROCESS AND THE

ABILITY TO FOCUS ON THE PROPOSALS THAT ARE MOST ALIGNED WITH OUR PRIORITIES.

SO THE REQUEST I HAVE FOR MARCH, I'M A SCIENTIST. I LIKE DATA. IN THE SCIENTIFIC LITERATURE IN MY OWN FIELD AND MANY OTHERS, THERE'S BEEN A REVOLUTION OVER THE LAST FIVE TO TEN YEARS TO BE MUCH MORE EXPLICIT ABOUT INDIVIDUAL DATA POINTS. AND SO WITH THE UNDERSTANDING THAT AVERAGES AND PROPORTIONS CAN HIDE DETAILS OF THE DATA INFORMATION. SO I WOULD REALLY HOPE IN MARCH THAT YOU CAN PROVIDE US WITH THE ACTUAL DISTRIBUTION OF PREFERENCE POINTS FOR THE FULL APPLICATION POOL AND THOSE THAT WERE MOVED FORWARD FOR FUNDING.

I KNOW IT'S EXPEDIENT IN A SHORT MEMO TO SUMMARIZE THOSE DATA, BUT I, FOR ONE, WOULD LIKE TO SEE THE ACTUAL DATA OF EVERY SINGLE PROPOSAL, HOW MANY POINTS IT RECEIVED, AND WHAT THE DISTRIBUTION WAS FOR BOTH THE ONES THAT WERE PUT FORWARD AND THE ONES THAT WERE NOT REVIEWED.

DR. CANET-AVILES: WE WILL BE HAPPY TO PROVIDE THAT. FOR CLIN2 IT'S GOING TO BE EASY BECAUSE THERE'S LIKE 44 TOTAL APPLICATIONS THAT CAME IN. FOR PDEV IT WILL BE COMPLEX AND FOR DISC4, BUT WE WILL FIGURE OUT A WAY TO DO IT. AND IF NOT, IT WILL BE PRESENTED AND IT NEEDS TO BE ANONYMIZED, BUT

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IT WILL BE PRESENTED IN THE FORM OF A MEMO. I WANT TO MAKE SURE THAT THAT'S POSSIBLE AS WELL.

DR. BARRETT: I'M HAPPY TO TALK TO YOU OFFLINE ABOUT WAYS THAT THE DATA MIGHT BE DEPICTED. AND IT CERTAINLY CAN BE ANONYMIZED. I'M ONLY LOOKING FOR THE DISTRIBUTION HERE.

DR. CANET-AVILES: THAT WOULD BE VERY HELPFUL. THANK YOU SO MUCH, DR. BARRETT.

CHAIRMAN IMBASCIANI: THANKS, KIM AND ROSA. KEITH.

DR. YAMAMOTO: THANKS, ROSA, FOR THE PRESENTATION. AND THANK YOU FOR -- MORE IMPORTANTLY, THANK YOU FOR ALL THE WORK THAT YOU HAVE DONE IN FRAMING THIS IDEA OF FINDING WAYS TO KIND OF PRE-ASSESS WHETHER APPLICATIONS QUALIFY GIVEN THE FACT THAT WE'RE GOING TO BE FACED ACTUALLY WITH AN INCREASING LOAD OF APPLICATIONS.

HAVING SAID ALL THAT, I'M ACTUALLY DEEPLY CONCERNED ABOUT THIS PROGRAM. YOU MIGHT ASK WHY I DIDN'T RAISE THIS EARLIER. PAT AND I AND MAYBE OTHERS AROUND THIS TABLE WHO ARE ON THE SCIENCE COMMITTEE HAVE HEARD THIS PRESENTED BEFORE, AND WE HAPPILY PASSED IT ON TO BE PRESENTED AT THIS MEETING.

BUT HAVING THOUGHT MORE ABOUT IT AND ALSO

READ AND THOUGHT ABOUT THE PUBLIC COMMENTS THAT WE RECEIVED, I'M DEEPLY CONCERNED. AND MY CONCERNS START WITH THREE OF THE SIX GUIDING PRINCIPLES. PAT TALKED A BIT ABOUT THE GUIDING PRINCIPLES, BUT I HAVE CONCERNS ABOUT THREE OF THEM.

ONE IS THE NEED TO OFFER THE POTENTIAL FOR CLINICAL IMPACT. I THINK FOR FUNDAMENTAL BASIC STUDIES THAT'S A HARD CALL. AND THE CONSEQUENCE OF THAT, OF ENFORCING THAT, IS TAKING A RATHER SHORT-TERM PERSPECTIVE ON THE WAYS THAT WE THINK ABOUT AN APPLICATION. AND THAT WOULD NECESSARILY LEAD TO MORE SUPPORT FOR MORE CONSERVATIVE WORK, WORK THAT IS KIND OF HIGH ON THE FEASIBILITY SCORE, BUT MAYBE NOT VERY DEEPLY CONSIDERING ITS POTENTIAL IMPACT IF IT'S NOT APPARENT AT THE POINT OF APPLICATION.

THE SECOND GUIDING PRINCIPLE I'M CONCERNED ABOUT IS WHETHER THE WORK ADDRESSES BOTTLENECKS IN ACCESS, AFFORDABILITY, AND FEASIBILITY. THESE THREE ALSO REALLY DRIVE CONSERVATIVE THINKING AND EVALUATION OR CHOOSING TO EVALUATE CONSERVATIVE APPLICATIONS, THINGS WHERE IT IS IMMEDIATELY APPARENT. AND HERE AFFORDABILITY IS -- ASSESSMENT OF AFFORDABILITY IS A PARTICULARLY FLAWED CRITERION. ALL NEW TECHNOLOGIES ARE NOT AFFORDABLE AT THE

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OUTSET. EVERYBODY REMEMBERS, BUT I'LL JUST SAY IT, THAT THE FIRST HUMAN GENOME SEQUENCE COST $3 BILLION, AND THAT COST HAS COME DOWN 10 MILLION-FOLD. SO TRYING TO MAKE A GUESS ABOUT AFFORDABILITY AT THE OUTSET IS FLAWED.

THIRD, ACHIEVING REGULATORY AND DEVELOPMENTAL PATHWAY WITHIN CIRM'S FINITE RUNWAY. THE PROBLEM I HAVE WITH THIS ONE IS THAT SCIENCE CAN'T BE ACTUALLY SCALED OR ASSESSED OR EVALUATED ON THE BASIS OF WHETHER IT FITS INTO THIS ARTIFICIAL TIMELINE THAT WE ARE STUCK WITH IF YOU WANT TO PUT IT THAT WAY. FIRST OF ALL, WE DON'T KNOW THAT WE'RE STUCK WITH THAT, A TRUE END POINT. BUT MORE IMPORTANTLY, THERE'S REALLY NOTHING WRONG WITH GETTING WORK STARTED AND DOING SOMETHING SIGNIFICANT WHEN YOU CAN AND THEN MAKING IT APPARENT TO THE REST OF THE WORLD, THAT IS TO SAY OTHER FUNDERS, THAT THERE'S VALUE IN BEING ABLE TO EXTEND THAT WORK. SO IF IT'S NOT DONE INSIDE OF THE CIRM PATHWAY, BUT CIRM GETTING SOMETHING STARTED THAT ENDS UP BEING HIGHLY SIGNIFICANT, IT'S NOT A BAD THING.

SO I'M CONCERNED ABOUT HALF OF THE GUIDING PRINCIPLES ON WHICH THIS IDEA IS FOUNDED.

SECONDLY, I THINK WE LEARNED SOMETHING, LEARNED MORE THAN WHAT YOU PRESENTED, ROSA, IN THOSE

FIRST TWO CYCLES OF EXPERIMENTING WITH THIS PROGRAM. AS PAT SAID, IT'S NO SURPRISE THAT THE APPLICATIONS THAT MOVED FORWARD FOR REVIEW AND WERE ULTIMATELY FUNDED FIT THE PATHWAY, THE PROGRAM, WELL BECAUSE OF THE CIRCULARITY THAT PAT TALKED ABOUT. BUT WHAT WASN'T CONSIDERED -- SO THE FACT THAT THE APPLICATIONS THAT WENT FORWARD FOR REVIEW AND THEN THOSE THAT WERE ULTIMATELY FUNDED SCORED WELL ON THE PREFERENCE LIST THAT WAS CONSTRUCTED IS NOT VERY SURPRISING.

WHAT WASN'T CONSIDERED, BUT I THINK WE HEARD ABOUT IN SOME OF THE PUBLIC COMMENTS, MAYBE ALL OF THEM, IS WERE THERE APPLICATIONS THAT WERE HIGHLY MERITORIOUS THAT DID NOT SCORE WELL AND, THEREFORE, WERE TRIAGED. THAT'S NOT SO GOOD IF THAT HAPPENS. AND I THINK WHAT WE HEARD IN THE PUBLIC COMMENTS IS THAT IT DID HAPPEN.

AND WE DON'T WANT TO BEGIN TO BUILD A SYSTEM WHICH IS SORT OF RIGGED IN THE SENSE THAT HIGHLY MERITORIOUS PROPOSALS DON'T EVEN GO FORWARD TO REVIEW. AND I THINK THAT'S THE SITUATION THAT WE'RE IN. SO CONSIDERING THAT DENOMINATOR, AS IT WERE, NOT JUST THE ONES THAT WENT FORWARD AND THEREFORE QUALIFIED VERY WELL, BUT ALSO ASKING OURSELVES A VERY MUCH MORE DIFFICULT QUESTION OF

WHETHER THERE ARE APPLICATIONS THAT ARE HIGHLY MERITORIOUS THAT ARE BEING ELIMINATED BECAUSE OF THE WAY THAT THE SYSTEM IS SET UP. AND I THINK WE NEED TO BE VERY CAREFUL AND THOUGHTFUL ABOUT THAT.

AND SO MY FINAL POINT IS THAT WE HEARD IN THE PUBLIC COMMENTS THAT, AT LEAST IN THE VIEW OF CERTAIN APPLICANTS, THERE WERE HIGHLY QUALIFIED PROPOSALS THAT WERE PUT FORTH AND SUBJECTED TO THIS EXPERIMENT -- I THINK IT'S FINE THAT WE DID THE EXPERIMENT -- SUBJECTED TO THE EXPERIMENT THAT WERE TRIAGED. AND I THINK THAT THOSE PEOPLE NEED OUR ATTENTION AND THAT WE NEED TO GO BACK AND LOOK AT THOSE AND CONSIDER THEM. AND IT'S NOT LIMITED TO JUST TO THOSE THAT WE HEARD FROM. SO THERE'S GOING TO BE A FAIR AMOUNT OF WORK IN DOING THAT, BUT I THINK WE OWE THAT TO THE APPLICANTS. IT'S FINE TO DO AN EXPERIMENT. IT'S IMPORTANT TO DO EXPERIMENTS. WE'RE SCIENTISTS. BUT WE NEED TO BE ABLE TO LOOK AT OUTCOMES IN WAYS THAT WE CAN ASSURE OURSELVES AND THE APPLICANTS THAT WE ARE BEING AS EQUITABLE AND JUST ABOUT MAKING THESE JUDGMENTS AS WE CAN.

CHAIRMAN IMBASCIANI: THANKS, KEITH, FOR THOSE REMARKS.

DR. CANET-AVILES: DR. IMBASCIANI, COULD I RESPOND OR MAKE SOME CLARIFICATIONS?

CHAIRMAN IMBASCIANI: OKAY. ROSA, SURE.

DR. CANET-AVILES: THANK YOU. THANK YOU, DR. YAMAMOTO. AS ALWAYS, VERY EXCELLENT POINTS AND ASSESSMENTS. I WOULD JUST LIKE TO TAKE THE OPPORTUNITY TO MAKE A FEW CLARIFICATIONS IF I MAY.

SO WITH THE -- HOPEFULLY I TOOK GOOD NOTES. THE FIRST POINT WAS ABOUT CLINICAL IMPACT IN TERMS OF THE GUIDING PRINCIPLES THAT IS HARD FOR FUNDAMENTAL, BASIC STUDIES. BUT THESE PROGRAMS WE WERE TALKING ABOUT IN TERMS OF THE GUIDING PRINCIPLES ARE NOT FUNDING FUNDAMENTAL BASIC STUDIES. WE ARE TALKING ABOUT THE PRECLINICAL DEVELOPMENT, THE CLINICAL DEVELOPMENT PROGRAMS. SO WHEN WE SAY CLINICAL IMPACT, WE ARE NOT ASKING TO PREDICT DOWNSTREAM VALUE OF DISCOVERY SCIENCE. WE ARE ASKING ABOUT THE DEVELOPMENT STAGE OF PROPOSALS THAT WE ARE EVALUATING. I JUST WANTED TO MAKE THAT AS A CLARIFICATION.

THE SECOND POINT IN TERMS OF ACCESS AND AFFORDABILITY, WE ARE NOT TALKING ABOUT PRICE PREDICTION. IT'S ABOUT FEASIBILITY OF THE DELIVERY AND THE SCALABILITY AND, AS DR. CHOU ALSO MENTIONED, MANUFACTURABILITY AND AVOIDABLE BARRIERS, THE DOWNSTREAM DELIVERABILITY OF THESE THERAPIES. RIGHT?

THERE WAS SOMETHING ELSE ABOUT -- THERE WAS A THIRD POINT WAS ABOUT -- THE ONE I WANTED TO -- THERE WAS ONE POINT -- THERE'S A THIRD POINT AND I CAN'T REMEMBER BECAUSE I DIDN'T TAKE NOTES. I WAS TRYING TO THINK ABOUT THE RESPONSE. BUT THE LAST ONE IS ABOUT APPLICATIONS THAT ARE DEEMED HIGHLY MERITORIOUS. WELL, WITHOUT PEER REVIEW, WE DON'T KNOW IF THEY ARE HIGHLY MERITORIOUS, RIGHT. SO THE PREFERENCES ARE CLASSIFYING BASED ON OBJECTIVE QUALIFICATION OR PREFERENCE CRITERIA THAT, IF YOU CLICK IT, THEN YOU GET TO BE ABLE TO FIGURE OUT IF THERE IS A HIGHLY MERITORIOUS.

NOW, ARE THERE GUARDRAILS? SO THAT'S ONE OF THE QUESTIONS FOR THE BOARD. IS THERE AN EXPLICIT PATHWAY FOR HIGH NOVELTY OR TRANSFORMATIVE APPLICATIONS THAT HAVE NOT MET THE STANDARD PREFERENCES? AND I KNOW I'M GETTING MYSELF INTO A BIT OF POTENTIALLY TROUBLE HERE. ARE THERE GUARDRAILS THAT THE BOARD WOULD LIKE US TO HAVE TO FIGURE OUT IF THERE ARE SOME THAT DON'T MEET THE PREFERENCES THAT COULD NEED TO GO TO REVIEW? WE CANNOT MAKE EVERYBODY HAPPY. I THINK THAT'S ONE OF THE PROBLEMS THAT WE'VE HAD. WE'VE NOT BEEN CLEAR ABOUT WHAT WE COULD NOT BE FUNDING. AND I THINK AS A BOARD OF 35 MEMBERS, THERE IS A DECISION THAT

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NEEDS TO BE MADE BECAUSE WE CANNOT FUND IT ALL. RIGHT?

SO I JUST WANTED TO MAKE THOSE POINTS. BUT I REALLY APPRECIATE THE THINKING BECAUSE THAT'S THE KIND OF DISCUSSION THAT WE SHOULD HAVE HAD. THANK YOU.

CHAIRMAN IMBASCIANI: I HAVE A LIST OF FIVE SPEAKERS, BUT, KEITH, I'M GOING TO OFFER YOU THE OPPORTUNITY TO REBUT IF YOU WOULD LIKE.

DR. YAMAMOTO: WELL, SO LET ME KEEP THIS BRIEF. THANKS, ROSA. I APPRECIATE THAT. AND I'M NOT SAYING THAT EVERY APPLICANT WHO FEELS THAT THIS TRIAGE SYSTEM HAS ELIMINATED THE POTENTIAL TO COMPETE WITH -- EVERY APPLICANT CONSIDERS THEIR WORK TO BE HIGHLY MERITORIOUS. SO I'M NOT SAYING THAT THAT DENOMINATOR, AS I REFERRED TO IT, IS A FIRM NUMBER, THAT EVERYBODY THAT WAS TRIAGED AND FEELS THAT IT WASN'T FAIR SHOULD HAVE BEEN FUNDED.

BUT I WOULD ARGUE THAT MANY -- BASED ON THE LETTERS THAT WE RECEIVED AND READING THEM FAIRLY CAREFULLY, IT SEEMED APPARENT TO ME THAT WHAT THE AUTHORS OF THE LETTERS WERE ARGUING IS THAT THE WAYS THAT THE PREFERENCES WERE STRUCTURED AND MAYBE EVEN THE POINT SYSTEMS ASSIGNED TO THE PREFERENCES WERE STRUCTURED ELIMINATED THEIR WORK KIND OF IN A

PREEMPTIVE WAY THAT DIDN'T EVEN ALLOW THE EVALUATION TO GO FORWARD.

AND I THINK THAT'S WHAT WE NEED TO BE CAUTIOUS ABOUT. DON'T MISUNDERSTAND. I THINK THAT'S COMPLICATED AND DIFFICULT TO DO, BUT I THINK WE OWE IT TO APPLICANTS NOT TO CONSTRUCT A SYSTEM THAT PREEMPTIVELY ELIMINATES THEM FOR REASONS THAT AREN'T DIRECTLY ASSOCIATED WITH THE QUALITY OF THE APPLICATION.

CHAIRMAN IMBASCIANI: THANK YOU, KEITH. SO HERE'S WHAT I HAVE FOR A LIST: JUDY GASSON, YSABEL, SHANNON DAHL, MARGUERITE CASILLAS, AND YAEL, BUT I'M AFRAID WE LOST JUDY. WE DID. OKAY. SO, YSABEL, YOU'RE NEXT.

MS. DURON: THANK YOU. ROSA, THANK YOU VERY MUCH FOR THE REFRESHER COURSE. WE'VE BEEN DISCUSSING THIS A LOT, AND I'M VERY PLEASED TO HEAR AND LEARN MORE SO I CAN KEEP CHEWING ON THIS.

AS A PATIENT ADVOCATE FOR ONCOLOGY, A CANCER SURVIVOR MYSELF, AND A CONCERNED VOICE, LOUD VOICE, FOR THE LATINO COMMUNITY WHERE CANCER IS THE SECOND LEADING CAUSE OF DEATH, I ALWAYS WANT TO SUPPORT NEW, EMERGING, AND ADVANCED CANCER RESEARCH WITH THE HOPES THAT IT'S ULTIMATELY GOING TO REACH AND SERVE MY UNDERSERVED COMMUNITY.

AS 40 PERCENT OF THE CALIFORNIA POPULATION, MAJOR CONTRIBUTORS TO THE ECONOMIC BACKBONE OF THIS STATE, AND TAXPAYERS TO BOOT, THE LATINO COMMUNITY IS AS ANXIOUS AS ANYONE TO BE HEALTHY AND HAVE THEIR CHILDREN SURVIVE.

SO I'M VERY EMPATHETIC TO THE LETTERS THAT POURED IN FROM OUR CANCER RESEARCHERS. THANKS, KEITH, FOR YOUR WRAP-UP. I APPRECIATED THAT AS WELL. HAVE WE, CIRM, BEEN FAIR IN FUNDING ACROSS DISEASES AS WE TRY TO STRUGGLE TO MEET OUR GOALS AND USE TAXPAYER FUNDS WISELY? I CAN'T HELP BUT THINK AND REMEMBER AND EVEN CRY WITH AND FOR THE NUMBERS OF PARENTS WHO HAVE STOOD BEFORE US IN THESE PRIOR PUBLIC HEARINGS AND SHARED PRIVATE STRUGGLES AND FEAR AND HOPES IN RESEARCH MOST OFTEN FOR THEIR CHILDREN SUFFERING FROM THESE RARE DISEASES. HOW OFTEN? I WANTED TO FUND THEM ALL, TO GIVE THEM HOPE, TO LET THEM KNOW WE HEAR THEIR PAIN. AND YET, AFTER LISTENING TO THE RATIONALE FROM MY MOST LEARNED SCIENTIFIC COLLEAGUES, HAVE CHOSEN TO SAY NO.

FOR THOSE RESEARCHERS WHO WROTE US, WE DID NOT CHOOSE NOT TO HONOR AND RESPECT YOUR WORK. IT'S VERY CRITICAL. FOR ANY REASON WE VOTED, I THINK, OUR BEST INTENTIONS, OUR CONCERNS, KNOWLEDGE, AND,

OF COURSE, I FROM GUIDANCE FROM EXPERTS IN THE FIELD. SO I THANK ROSA ONCE AGAIN FOR HER REFRESHER COURSE. BUT REST ASSURED, AT LEAST FROM MY PERSPECTIVE, NOTHING IS SET IN STONE. AND CONSISTENTLY REVIEWING OURSELVES AND HOW WE DETERMINE DECISIONS COMES BACK TO US TIME AND TIME AGAIN. AND I KNOW THAT THE PEOPLE I SIT WITH HERE TODAY ARE ALWAYS WELL INTENTIONED WITH THE BEST FOR COMMUNITY HEALTH, BUT ALSO FOR GREAT SCIENCE.

SO KNOW THAT WE HAVE HEARD THE CONCERNS FROM THE ONCOLOGY COMMUNITY. AND ONCE AGAIN, WE WILL LOOK INWARD TO SEE IF AND HOW WE CHANGE IF IT'S ONCE AGAIN REQUIRED. SO THANK YOU VERY MUCH FOR SENDING IN ALL OF YOUR LETTERS, FOR YOUR CONCERNS, FOR YOUR ENGAGEMENT. AND MAY I ASK YOU TO USE THAT FORCE AND THAT CONCERN IN, I THINK, ENGAGING ALL MEMBERS OF OUR COMMUNITIES IN CALIFORNIA SO THAT WE CAN SEE EQUITY AND DIVERSITY IN CARE AND TREATMENT AND RESEARCH. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, YSABEL. SHANNON.

DR. DAHL: THANK YOU, ROSA, FOR A GREAT SUMMARY AND FOR ALSO SETTING THE STAGE OF GUIDING US TO ASK FOR WHAT WE SHOULD BE THINKING ABOUT FOR THE DISCUSSION IN MARCH SO WE CAN ALL CONTINUE TO

PERCOLATE ON THE TOPIC.

ONE OF THE THINGS THAT STUCK OUT TO ME ABOUT THE PORTFOLIO, WE'VE HEARD ABOUT DIFFERENT DISEASES, AND I'M GOING TO SET THAT ASIDE FOR NOW, AND INSTEAD THINK ABOUT DIFFERENT STAGES OF DEVELOPMENT. EARLIER STAGE, THERE'S OFTEN MORE INNOVATION IN MODALITY. AND WHEN WE GET TO A LATER STAGE, IT BECOMES MORE ABOUT FEASIBILITY. CAN WE GET TO COMMERCIALIZATION? ARE WE GOING TO REALLY SERVE THE PATIENTS OF CALIFORNIA BY DELIVERING SOMETHING OVER THE FINISH LINE?

AND SO AS WE THINK ABOUT PREFERENCES, I WONDER IF IT MIGHT BE HELPFUL TO CONSIDER DIFFERENT PREFERENCES AT DIFFERENT STAGES. AND I KNOW THEY ARE SLIGHTLY DIFFERENT, BUT EVEN PERHAPS SEPARATING THE PDEV AND THE CLINICAL MORE SO TO ALIGN WITH DIFFERENT PRINCIPLES THAT RESONATE FOR DIFFERENT STAGES OF DEVELOPMENT.

AND THEN WITH RESPECT TO INFORMATION THAT MIGHT HELP US CONSIDER HOW THAT WOULD PAN OUT, I WAS STRUCK ESPECIALLY IN THE CLINICAL GROUP IN OUR LAST MEETING THAT WE DID END UP WITH ALMOST TOO FEW APPLICATIONS. AND SO WE DID HAVE A FUNDING LEVEL OF ONE THAT WAS BELOW THE TYPICAL FUNDING LINE. AND SO LOOKING AT HOW THOSE PREFERENCES ARE SET UP AT THAT

STAGE TO ENSURE THAT WE'RE THINKING ABOUT MAYBE MORE ABOUT CLINICAL IMPACT THERE AND WHAT'S FEASIBLE TO GET ALL THE WAY TO THE FUNDING LINE. JUST CONSIDERING DIFFERENT STAGES FOR DIFFERENT PREFERENCES. THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, SHANNON. MARGUERITE CASILLAS.

MS. CASILLAS: WELL, I'M REALLY HEARTENED BY THE CONVERSATION HERE TODAY. AND AGAIN WANT TO THANK YOU, ROSA, FOR YOUR PRESENTATION. IT'S GREAT TO HEAR THAT PEOPLE ARE REALLY THINKING CAREFULLY ABOUT THIS SYSTEM THAT WAS POSSIBLY WITH GOOD INTENTION, BUT CONSTRUCTED IN A WAY THAT IS NOW ELIMINATING SOME GOOD SCIENCE. I'M REALLY THINKING ABOUT THE COMMS TEAM, AND ONE OF THE KEY AUDIENCES BEING SCIENTISTS AND INDUSTRY AND US WANTING TO FEEL THAT THEY'RE CONFIDENT IN CIRM PROGRAMS AND PROUD OF CALIFORNIA AND SUPPORTED BY CIRM. SO I THINK WE SAW IN THOSE LETTERS THAT THERE ARE DEFINITELY SOME QUESTIONS THERE.

I DON'T KNOW HOW THE EARLIER PREFERENCES MIGHT HAVE BEEN COMMUNICATED TO THOSE FOLKS. SOUNDS LIKE THERE'S WEBINARS AND OTHER THINGS. BUT I THINK IT'S A POINT, IF WE MAKE CHANGES OR REFINEMENTS, THAT WE REALLY NEED TO BE TRANSPARENT AND PROBABLY

OVERCOMMUNICATE WHAT'S HAPPENING THERE. THAT'S MY COMMENT.

CHAIRMAN IMBASCIANI: THANK YOU, MARGUERITE. YAEL WYTE.

MS. WYTE: I'M DEBATING. ANYWAY --

CHAIRMAN IMBASCIANI: SO ARE WE ALL.

MS. WYTE: I ALSO WANT TO THANK ROSA FOR HER PRESENTATION. AND WHILE I THINK OBVIOUSLY WE WANT TO HAVE MORE MERITORIOUS APPLICANTS AND WE WANT TO BE TRANSPARENT WITH OUR DECISIONS AND WE WANT TO HAVE GREAT COMMUNICATION AND WE CAN'T FUND IT ALL, I FEEL LIKE YOU ALSO CAN'T BE SURPRISED WHEN YOU'RE APPLYING FOR AN APPLICATION, FOR A GRANT, TO BE FUNDED AND YOU DON'T QUALIFY WITH ALL THE PREDETERMINED EXPECTATIONS OF WHAT WE'RE LOOKING FOR. SO, AGAIN, THERE'S ALWAYS ROOM FOR REEVALUATION ON OUR PART OF DO WE NEED TO BE MORE INCLUSIVE? HAVE WE OVERLOOKED SOMETHING? HAVE WE NOT? BUT IF THE GUIDELINES ARE STATED ACCURATELY, I DON'T KNOW, I FEEL YOU CAN'T BE DISAPPOINTED -- WELL, YOU CAN BE -- YOU CAN ALWAYS BE DISAPPOINTED, BUT IT SHOULDN'T BE, I GUESS, A BIG SURPRISE. AND MAYBE YOU NEED TO REEVALUATE THE SCOPE OF YOUR RESEARCH. IT'S A TWO-WAY STREET.

CHAIRMAN IMBASCIANI: I'M SORRY. WE'RE

HAVING A LITTLE LOGISTICAL DISCUSSION HERE THAT INVOLVES LUNCH. AND WE HAVE SPEAKERS THAT HAVE HARD STOPS THAT MUST GET BACK TO THEIR RESPECTIVE INSTITUTIONS AT A CERTAIN TIME. DID WE SOLVE THAT? OKAY. I'M REALLY SORRY FOR THAT INTERRUPTION, YAEL. THANK YOU FOR YOUR REMARKS. FOR YOUR REMARKS, I'M GOING TO HAVE TO GO BACK ON THE TRANSCRIPT, BUT THANK YOU.

I DON'T SEE ANY OTHER HANDS. I DO, YES.

DR. MIASKOWSKI: I WANT GET BACK TO ROSA'S REQUEST, THANKING HER FOR HER PRESENTATION. AND I WANT TO AGREE WITH KIM BARRETT. I THINK IF WE'RE GOING TO APPLY PREFERENCES, WE HAVE TO DO IT AT THE BEGINNING OF THE PROCESS. OTHERWISE, WE DON'T DEAL WITH THE HUGE NUMBER OF GRANTS THAT WE RECEIVE.

I, LIKE KIM, LIKE DATA. AND I AGREED WITH HER SUGGESTION, THAT WE NEED TO SEE, NOT ONLY THE APPLICATION OF THE PREFERENCES TO THE GRANTS THAT GOT CHOSE, BUT I WANT TO SEE THE PREFERENCE APPLICATIONS TO THE ONES THAT DIDN'T MOVE FORWARD. AND THAT MAY ADDRESS SOME OF KEITH'S COMMENTS.

THE OTHER THING, I'M GOING TO OFFER A SUGGESTION TO MARIA. I JUST WAS ON THE LAST GRANTS WORKING GROUP FOR CLIN. AND WHAT OCCURRED TO ME IS KEITH WAS TALKING ABOUT ACCESS AND AFFORDABILITY. I

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WAS ASTOUNDED BY THE APPLICATIONS AND HOW THEY RESPONDED TO OUR CRITERIA AROUND ACCESS AND AFFORDABILITY FOR THE CLINICAL PROJECTS BECAUSE THESE PROJECTS HAD RECEIVED FDA APPROVAL TO MOVE FORWARD LARGELY TO A PHASE 1. AND I THINK THE BOARD WOULD BENEFIT FROM GETTING SOME EXEMPLARS. YOU AND I TALKED ABOUT ONE THAT WAS ABSOLUTELY OUTSTANDING IN TERMS, WITHOUT DIVULGING ANY CONFIDENTIAL INFORMATION, IN TERMS OF HOW THEY ENGAGED WITH A COMPANY THAT KNOWS HOW TO DO AN ACCESS AND AFFORDABILITY EVALUATION FOR A PRODUCT THAT'S POTENTIALLY, IF IT'S SUCCESSFUL, WILL MOVE TO THE CLINICAL ARENA, AND THE PRODUCT WAS NOT CHEAP. AND THE EVALUATION FROM THE COMPANY, THE INSURANCE COMPANIES, THAT WERE LOOKING AT THESE WAS REALLY, REALLY INTERESTING.

I'LL STOP THERE BECAUSE I DON'T KNOW WHAT'S GOING TO HAPPEN WITH THAT APPLICATION, BUT I DO THINK BOARD IT WOULD BE, IF THE BOARD AGREES, INFORMATIVE TO KIND OF SEE OUR RUBRIC AND HOW SOME EXAMPLES ARE BEING PRODUCED. AND SOME DIDN'T DO ANYTHING AND OTHERS DID EXCEPTIONAL JOB. OTHERS THAT WERE ON THE GRANTS REVIEW RECENTLY MAYBE WANT TO COMMENT ON THAT. SO THOSE ARE MY POINTS. I WOULD SUPPORT, IN TERMS OF ADDITIONAL EVALUATIONS,

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WHAT KIM SAID AND THEN PERHAPS AT ANOTHER MEETING WHERE THERE'S TIME TO TALK ABOUT OUR CRITERIA AND HOW WE'RE SEEING RESPONSES.

VICE CHAIR BONNEVILLE: I'LL DEFINITELY WORK WITH THE INTERNAL TEAM TO SEE WHAT SORT OF INFORMATION WE CAN BRING BACK AT A HIGH LEVEL THAT ILLUSTRATES WHAT YOU ARE REFERRING TO. SO THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU, CHRIS. NO OTHER HANDS. SO WE CAN INVITE MEMBERS OF THE -- DO YOU WANT TO SAY SOMETHING ABOUT OUR TIME SCHEDULE?

MR. TOCHER: YES. THANK YOU, VITO. WE HAVE IMPORTANT PUBLIC COMMENT THAT WE WANT TO GET TO ON THIS ITEM AS HAS BEEN ALREADY REFLECTED BY MEMBERS OF THE BOARD. WE ARE RUNNING UP AGAINST SOME CONFLICTING SCHEDULES. OUR TWO PRESENTERS FOR CLOSER TO CURES HAVE HARD STOPS AT 12:30 AND 1:15. YOU ALSO HAVE LUNCH THAT IS CONSTRAINED BETWEEN 12 AND 1:30. THIS IS NOT AN ACTION ITEM. MY PROPOSAL IS THAT, ONCE BOARD COMMENT HERE FOR THIS FIRST ROUND IS COMPLETE, THAT WE TABLE THE ITEM, GO TO THE CLOSER TO CURES PRESENTATIONS TO YOU, TAKE LUNCH, BRING IT BACK, IF NECESSARY, TO THE DAIS. AND THEN, ONCE THAT IS COMPLETED, COME BACK TO THIS ITEM TO

HEAR PUBLIC COMMENT AND CONTINUE ANY FURTHER BOARD DISCUSSION IF THAT SOUNDS AMENABLE TO FOLKS.

CHAIRMAN IMBASCIANI: ANY OBJECTION TO THAT? THANK YOU. IF THERE WAS, I WOULDN'T KNOW HOW TO HANDLE IT.

MR. TOCHER: ALL RIGHT. FOR MEMBERS OF THE PUBLIC, PLEASE PLAN TO PARTICIPATE VIA THE PHONE NUMBERS THAT ARE INDICATED ON THE AGENDA AS I SAID EARLIER. IS THERE ANY MORE BOARD COMMENT AT THIS TIME? PLEASE FEEL FREE TO CONTINUE WITH THIS BEFORE WE HIT PAUSE. ALL RIGHT.

SO THEN WITH THAT, I WOULD PROPOSE THAT WE MOVE TO THE FIRST PRESENTATION AND AMY ADAMS.

CHAIRMAN IMBASCIANI: I'M SORRY. I'M GOING TO INTRODUCE OUR SENIOR DIRECTOR FOR COMMUNICATIONS, AMY ADAMS, WHO'S GOING TO MAKE SOME INTRODUCTIONS TO TWO SPEAKERS FOR THIS NOVEL ENTRY IN OUR AGENDA. AMY.

MS. ADAMS: THANK YOU, EVERYONE. MY APOLOGIES FOR INTERRUPTING THIS REALLY FANTASTIC CONVERSATION. WE DO HAVE TERRIFIC SPEAKERS WITH A HARD STOP. SO CONSIDER THIS US GIVING YOU TIME TO THINK ABOUT EVERYTHING THAT'S HAPPENED AND RUMINATE.

OKAY. I'D LIKE TO INTRODUCE A NEW STANDING AGENDA ITEM OF IN-PERSON BOARD MEETINGS.

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AT EACH MEETING WE WILL INVITE CIRM AWARDEES TO SPEAK IN THEIR OWN WORDS ABOUT HOW CIRM SUPPORT IS MAKING A DIFFERENCE IN THEIR WORK TO BRING CALIFORNIANS CLOSER TO CURES.

TODAY WE'LL HEAR FROM TWO SPEAKERS. AND I'M GOING TO INTRODUCE THEM BOTH NOW. MY NOTES SAY IT'S SO I DON'T INTERRUPT THE FLOW, BUT I THINK IT'S SO THAT I DON'T INTERRUPT YOUR LUNCH.

FIRST WE'RE GOING TO HEAR FROM CORY NICHOLAS. HE'S THE CEO AND CO-FOUNDER OF NEURONA THERAPEUTICS. HE WILL PRESENT RESULTS OF TWO CLINICAL TRIALS TESTING STEM CELL-BASED THERAPIES FOR EPILEPSY. HIS STORY SHOWS THE POWER OF CIRM FUNDING OVER MANY YEARS WITH CIRM SUPPORT FOR THIS PROJECT STARTING AT THE BENCH AND CONTINUING TO THE RESULTS THAT HE'LL SHOW YOU TODAY.

NEXT, AFTER LUNCH, WE'LL HEAR FROM CRYSTAL MACKALL, WHO'S A PROFESSOR OF BOTH PEDIATRICS AND MEDICINE AT STANFORD SCHOOL OF MEDICINE. SHE'S ALSO THE FOUNDING DIRECTOR OF THE STANFORD MEDICINE CENTER FOR CANCER CELL THERAPY AND THE DIRECTOR OF THE PARKER INSTITUTE FOR CANCER IMMUNOTHERAPY AT STANFORD.

SHE'LL DISCUSS RESULTS OF A CLINICAL TRIAL TESTING A NEW APPROACH FOR TREATING A DEADLY FORM OF

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BRAIN CANCER THAT INVOLVES MODIFYING A PATIENT'S OWN IMMUNE STEM CELLS SO THEY'LL IDENTIFY AND DESTROY CANCER CELLS. IT'S AN APPROACH KNOWN AS CAR-T. SO WITH THAT, I'M GOING TO INVITE COREY UP.

(THE CLOSER TO CURES PRESENTATIONS WERE THEN HEARD, NOT REPORTED NOR HEREIN TRANSCRIBED. AT THE CONCLUSION OF THE CLOSER TO CURES PRESENTATIONS, THE FOLLOWING WAS THEN HEARD.)

CHAIRMAN IMBASCIANI: OKAY. WE'RE GOING TO MOVE ON. THERE'S NOT GOING TO BE A CHAIR'S REPORT. THE BOARD MET ONLY A MONTH AGO. I WAS JUST GOING TO PASS OVER THIS AGENDA. GIVE ME A SECOND, SCOTT. BECAUSE IT'S ONLY BEEN A MONTH SINCE THE LAST BOARD MEETING, THE TIME OF HOLIDAYS WHEN NOT MUCH HAPPENED, THERE WAS THE NUCLEUS FORUM, BUT OUR PRESIDENT AND CEO IS GOING TO REPORT ON THAT. SO WE'LL SKIP OVER THE CHAIR'S REPORT. NOW SCOTT.

MR. TOCHER: SURE. WE'RE NOW GOING TO ACTUALLY RETURN BACK TO ITEM 6, THE DISCUSSION OF THE PROCESS FOR PREFERENCE SETTING TO RESUME IN A CONTINUED BOARD DISCUSSION AND THEN TAKE PUBLIC COMMENT AS WELL.

SO I KNOW THAT WE STILL HAVE ROSA ON THE LINE. WE HAVE J.T. HERE AT THE MIC READY AS WELL. SO I GUESS THE FIRST WOULD BE TO -- IF THE BOARD HAS

ANY --

CHAIRMAN IMBASCIANI: ANY RESIDUAL OR DE NOVO QUESTIONS ARISE FROM ANY OF THE BOARD MEMBERS RELATED TO ROSA'S PRESENTATION ON PREFERENCES? OKAY. SO SEEING NONE, YOU CAN ASK IF THERE'S ANY, LANA, RIGHT, IF THERE'S ANYONE IN THE PUBLIC.

MS. MORALEZ: ALL RIGHT. WE WILL NOW OPEN THE FLOOR TO PUBLIC COMMENT. SO YOU'RE JOINING US IN PERSON, PLEASE APPROACH THE PODIUM, STATE YOUR NAME FOR THE RECORD WHEN READY, AND KEEP YOUR REMARKS WITHIN TWO MINUTES. FOR THE PUBLIC PARTICIPANTS ON THE PHONE, PRESS STAR NINE TO RAISE YOUR HAND. WHEN CALLED ON, PRESS STAR SIX TO UNMUTE YOURSELF. PLEASE STATE YOUR NAME FOR THE RECORD AND KEEP YOUR COMMENT WITHIN TWO MINUTES AS WELL.

IS THERE ANYBODY IN THE PUBLIC HERE WITH US TO MAKE A COMMENT? ALL RIGHT. WE'RE GOING TO GO TO THE PHONE. THE PHONE NUMBER THAT ENDS IN 6596, WOULD YOU PLEASE UNMUTE YOURSELF. YOU HAVE TWO MINUTES.

DR. CHEN: GOOD AFTERNOON. MY NAME IS YVONNE CHEN. I AM A PROFESSOR OF IMMUNOLOGY AT UCLA. I'D LIKE TO THANK YOU FOR THIS OPPORTUNITY TO SPEAK.

I'M VERY GRATEFUL THAT THE BOARD HAS

ALREADY READ THE PUBLIC COMMENTS THAT WERE SUBMITTED PRIOR TO THE MEETING. SO I WILL NOT REPEAT THOSE POINTS HERE.

I JUST WANT TO UNDERSCORE THAT THE MAIN ISSUE REALLY IS NOT JUST A LACK OF CLARITY IN COMMUNICATION, BUT THE ACTUAL CONSEQUENCES OF THE PDEV AND CLIN2 PREFERENCE SYSTEM. THE LIST OF FUNDED GRANTS SHOW A COMPLETE ABSENCE OF WELL-PROVEN MODALITIES, SUCH AS CAR-T CELL THERAPIES, WHICH POTENTIAL DR. MACKALL JUST BEAUTIFULLY ILLUSTRATED FOR US. THE LIST OF FUNDED GRANTS ALSO SHOWS A COMPLETE ABSENCE OF THERAPIES TARGETING CANCER ALTOGETHER. I THINK THIS CLEARLY DEMONSTRATES THE EXCLUSIONARY NATURE OF THE SYSTEM.

AS AN EXAMPLE, I SUBMITTED A PDEV OF MY PATIENT FOR A CAR-T CELL THERAPY FOR GLIOBLASTOMA. THAT'S A CNS DISEASE THAT'S CURRENTLY INCURABLE. BY ROSA'S RUBRIC, THIS GRANT SHOULD HAVE RECEIVED A SCORE OF 4 BECAUSE IT ALSO COMPLETED A PRE-IND MEETING, AND YET IT HAS BEEN TRIAGED TWICE IN THE PDEV SYSTEM WITHOUT REVIEW.

I THINK IT'S IMPORTANT TO NOTE THAT, EVEN THOUGH THE PREFERENCE SYSTEM IS NOT DESIGNED TO EXCLUDE, THE EFFECTIVE CONSEQUENCE IS THAT IT NOW EXCLUDES POTENTIALLY LIFESAVING MODALITIES FOR HIGH

UNMET MEDICAL NEED FROM HAVING A CHANCE TO REACH PATIENTS.

I THANK YOU VERY MUCH FOR THIS OPPORTUNITY TO SHARE MY OPINION. AND I THANK YOU AGAIN YOUR TIME IN GUIDING CIRM'S TRAJECTORY.

CHAIRMAN IMBASCIANI: THANK YOU, DR. CHEN.

MS. MORALEZ: THANK YOU VERY MUCH. ALL RIGHT. THE PHONE NUMBER THAT ENDS IN 2019, WOULD YOU PLEASE UNMUTE YOURSELF.

DR. NOWICKI: GOOD AFTERNOON. MY NAME IS DR. THEODORE NOWICKI. I'M A CALIFORNIA RESIDENT AND A PEDIATRIC ONCOLOGIST AT UCLA, AND I'M ALSO A PHYSICIAN SCIENTIST WHO TREATS CHILDREN AND YOUNG ADULTS WITH AGGRESSIVE SARCOMAS USING CELL AND GENE THERAPIES, MANY OF WHICH HAVE BEEN MADE POSSIBLE THROUGH CIRM SUPPORT. I THANK EVERYONE FOR THE OPPORTUNITY TO SPEAK TODAY.

I'D JUST LIKE TO REITERATE A POINT THAT I MADE IN MY SUBMITTED COMMENTS WHICH IS THAT WITH THE PATIENT'S THAT I CARE FOR, I RECENTLY TREATED A TEENAGER WITH A RELAPSE SARCOMA WHOSE FAMILY SIMPLY ASKED THE QUESTION: IS THERE ANYTHING LEFT FOR TREATMENT? AND THE ONLY HONEST ANSWER THAT WE COULD GIVE WAS THE TYPES OF CELL THERAPIES THAT HAVE BEEN MADE POSSIBLE BY YEARS OF CIRM-FUNDED ACADEMIC WORK.

AND I JUST WANTED TO REITERATE THAT POINT THAT MY COLLEAGUE DR. CHEN MADE, WHICH IS THAT UNDER THE CURRENT SCORING GUIDELINES, IT BECOMES HIGHLY MATHEMATICALLY UNFEASIBLE TO HAVE ANY CELL THERAPY FOR CANCER FUNDED UNDER THE CURRENT SCORING RUBRIC.

AND I JUST WANTED TO OFFER THREE OBSERVATIONS REGARDING THE CURRENT RUBRIC. FIRST, THE CURRENT PREFERENCE-BASED SELECTION APPEARS, AS WAS MENTIONED BEFORE, INTENTIONALLY OR OTHERWISE, TO EXCLUDE THESE KINDS OF PROVEN TRACK RECORD CELL AND GENE THERAPIES. AND I KNOW THE POINT WAS MADE ABOUT PATIENT OUTCOMES, NEITHER TREATMENTS THAT HAVE BEEN REACHING PATIENTS AND CONTINUE TO REACH PATIENTS FOR ALL OF THOSE OF US THAT HAVE BEEN INVOLVED IN THIS.

SECOND OF ALL, THE PRACTICAL REALITY THAT DESERVES CONSIDERATION IS THAT ACADEMIC CELL THERAPY PROGRAMS THAT HAVE BEEN MEETING MILESTONES OFTEN DON'T REALLY HAVE ANY VIABLE ALTERNATIVE FUNDING PATHWAYS OUTSIDE OF CIRM TO ADVANCE THESE INTO CLINICAL PRACTICE WITH OUR PATIENTS. AND THIS IS ESPECIALLY POIGNANT IN THE CURRENT NATIONAL FUNDING ENVIRONMENT WHICH HAS BECOME MUCH MORE CONSTRAINED AND FRAUGHT WITH LACK OF STABILITY.

AND FINALLY, THE OTHER ISSUE THAT WAS IN THE CLIN2, THERE HAVE BEEN -- A LOT OF THE WEIGHTING

HAS BEEN SHIFTED THE FUNDING TOWARDS PRIVATE ENTITIES RATHER THAN --

MS. MORALEZ: THANK YOU SO MUCH. YOUR TIME IS UP. AND THEN PHONE NUMBER 6063, IF YOU WOULD UNMUTE YOURSELF, YOU HAVE TWO MINUTES. 6063, IF YOU WOULD PRESS STAR 6.

DR. RIBAS: YEAH. CAN YOU HEAR ME?

MS. MORALEZ: I CAN HEAR YOU.

DR. RIBAS: OKAY. THANK YOU. MY NAME IS ANTONI RIBAS. I'M A PROFESSOR OF MEDICINE AT UCLA ALSO. AND I WANT TO THANK THE CIRM BOARD FOR THE OPPORTUNITY TO TALK ON THE CIRM LEADERSHIP AND DR. CANET-AVILES FOR THE DISCUSSION TODAY.

I SENT WRITTEN REPORT, WRITTEN SCRIPT, BUT IT'S ABOUT THE CLIN2 THAT WE HAVE SUBMITTED TWICE WITH 82 PAGES. WE KNEW ABOUT THE PRIORITIES, BUT IT CALLED FOR FULL APPLICATIONS AND IT'S NOT BEEN REVIEWED SCIENTIFICALLY TWICE.

IT'S FOR A GEL TO REGENERATE THE SKIN STEM CELLS FOR WOUND HEALING, WHICH HAS AN INCIDENCE OF 1 PERCENT OF CALIFORNIANS, MORE COMMON IN MARGINALIZED POPULATIONS, BUT HAS LIMITED INTEREST OF COMMERCIAL DEVELOPMENT. THERE'S NO EXISTING DRUG THERAPY FOR THIS CONDITION. WE DESIGNED A CLINICAL TRIAL THAT WOULD GO FROM PHASE 1 TO PHASE 2 RANDOMIZED TO MOVE

THE THERAPY FORWARD AND BRING IT TO CALIFORNIA AS SOON AS POSSIBLE.

WE ALSO ADDRESSED THE AFFORDABILITY AND COMMERCIALIZATION REQUEST. WE WORK WITH COLLEAGUES AT THE UCLA ANDERSON SCHOOL OF MANAGEMENT FOR THIS. NONE OF THIS WAS SCIENTIFICALLY REVEALED BY CIRM. IF THE GOAL OF CIRM IS TO DEVELOP REGENERATIVE MEDICINES FOR DISEASES THAT AFFECT CALIFORNIANS, WHY DID THE GRANT LIKE OURS ONLY CHECK TWO PREFERENCES, ONE BEING IN CALIFORNIA AND TWO HAVING A PRIOR CIRM GRANT? THANK YOU.

MS. MORALEZ: OKAY. THANK YOU SO VERY MUCH FOR YOUR COMMENT. ALL RIGHT. THE PHONE NUMBER 6583, IF YOU WOULD PLEASE UNMUTE YOURSELF.

DR. BROWN: GOOD AFTERNOON. MY NAME IS CHRISTINE BROWN. I'M A PROFESSOR AT CITY OF HOPE, AND I LEAD A TRANSLATIONAL RESEARCH PROGRAM FOCUSED ON CLINICALLY ADVANCING CAR-T CELL THERAPIES FOR INCURABLE BRAIN TUMORS. AND I THINK IT'S VERY TIMELY AFTER DR. MACKALL'S PRESENTATION TODAY.

I WANTED TO MAKE AND SHARE SORT OF THREE POINTS BASED ON RECENT EXPERIENCES. FIRST, I'D LIKE TO COMMENT ON THE NEW PRESUBMISSION REVIEW PROCESS. I RECENTLY SUBMITTED A DISC4 PREAPPLICATION THAT STRONGLY ALIGNED WITH ALL PUBLISHED CIRM PREFERENCE

TOPICS, INCLUDING NEUROLOGICAL DISEASES. THE PROJECT PROPOSED A CROSS-DISCIPLINARY SYSTEMS BIOLOGY APPROACH TO UNDERSTAND THE COMPLEX BIOLOGY OF BRAIN TUMORS BY INTERROGATING UNIQUE PATIENT SAMPLES FROM MULTIPLE BRAIN TUMOR CAR-T CELL CLINICAL TRIALS, INCLUDING THOSE DEVELOPED AND EXECUTED WITH CIRM FUNDING.

DESPITE THIS ALIGNMENT, OUR PRESUBMISSION APPLICATION WAS ADMINISTRATIVELY TRIAGED WITHOUT EVALUATION COMMENTS. THIS RAISES QUESTIONS AS TO THE ADMINISTRATIVE CRITERIA USED WITHOUT INDEPENDENT SCIENTIFIC REVIEW TO SELECT ONLY 17 PERCENT OF THE SUBMITTED APPLICATIONS. AND I AND OUR COLLEAGUES WOULD ADVOCATE FOR GREATER TRANSPARENCY AROUND THE ADMINISTRATIVE TRIAGE CRITERIA, ALLOWING TEAMS TO BETTER ALIGN PRIORITIES WITH CIRM GOALS.

SECOND, I'D LIKE TO COMMENT REALLY ON THE IMPORTANT CLINICAL IMPACT CIRM HAS ACHIEVED. OUR SUCCESS IN ADVANCING CAR-T CELLS FOR INCURABLE BRAIN TUMORS, AS YOU ALSO HEARD FROM CRYSTAL MACKALL, WOULD NOT BE POSSIBLE WITHOUT CIRM'S PARTNERSHIP.

OUR PROJECT AT CITY OF HOPE WAS THE FIRST CAR-T CELL THERAPY SUPPORTED BY CIRM. WE TREATED OUR FIRST PATIENT WITHIN THREE YEARS OF A TRAN1 AWARD. WE DEMONSTRATED THAT CAR-T CELLS CAN MEDIATE

A COMPLETE RESPONSE AGAINST RECURRENT GLIOBLASTOMA, AND WE HAVE PATIENTS LIVING YEARS...

MS. MORALEZ: THANK YOU FOR YOUR COMMENT. I DON'T SEE ANY OTHER HANDS RAISED.

CHAIRMAN IMBASCIANI: OKAY. YES. YSABEL, YOU WANT TO ADD SOMETHING?

MS. DURON: I WAS IN PAIN FOR HER.

CHAIRMAN IMBASCIANI: OKAY. SO I WANT TO THANK ALL THE MEMBERS OF THE PUBLIC WHO SPOKE AND ESPECIALLY THE AUTHORS OF THE LETTERS. YOU CAN TELL FROM THE TESTIMONY HERE THAT THE BOARD MEMBERS HAVE READ YOUR LETTERS. THEY WERE CAREFULLY WRITTEN. THEY WERE VERY INFORMATIVE. AND I HOPE YOU ARE LEFT WITH THE IMPRESSION THAT YOUR COMMENTS WILL BE SERIOUSLY CONSIDERED IN THE NEXT COUPLE OF MONTHS.

DID YOU WANT TO SAY SOMETHING?

DR. OKADA: EXCUSE ME.

CHAIRMAN IMBASCIANI: AS PART OF PUBLIC COMMENT?

DR. OKADA: YEAH. ON BEHALF OF MY COLLEAGUES, IT'S NOT THAT WE ARE TRYING TO SKEW ALL THE GRANTS TOWARDS CANCER RESEARCH.

CHAIRMAN IMBASCIANI: START BY IDENTIFYING YOURSELF FOR THE RECORD.

DR. OKADA: EXCUSE ME. I'M HEDEHO OKADA,

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PROFESSOR AT UCSF. THANK YOU. I PROVIDED LETTERS.

SO IT'S NOT THAT WE ARE TRYING TO SKEW ALL THE GRANTS GOING TO THE FIELD OF CANCER. ALL DISEASE IS IMPORTANT. THERE ARE MANY WAYS TO HELP PEOPLE.

I THINK MY CLEAR POINT IS THAT IMPLEMENTATION OF THOSE NEW PRIORITIES IN PRECLINICAL AND THE CLINICAL STAGE, MY OPINION IS THE ISSUE BECAUSE EVERY PROJECT HAS A DEVELOPMENTAL STAGE. AND AS CLEARLY DR. MACKALL PRESENTED, THE AUTOLOGOUS CELL THERAPY IS STILL PLATFORM. IMPORTANT THING IS FOR US TO DEMONSTRATE REPRODUCIBLE SAFETY AND EFFICACY USING THE RELIABLE PLATFORM. CLINICAL TRIALS HAS INCREMENTAL NATURE THAT WE ASK ONE NEW QUESTION EACH TIME.

SO WE HAVE TO RELY ON RELIABLE EXISTING PLATFORM TO ASK ONE IMPORTANT NOVEL QUESTION. THAT'S HOW CLINICAL TRIAL MOVES. SO, THEREFORE, IF YOU IMPLEMENT IN VIVO GENE THERAPY NONVIRAL IPSC IN PRECLINICAL PDEV AND CLIN2, THAT CAN BE A BIT DISRUPTIVE RATHER THAN CONSTRUCTIVE.

THAT IS MY QUESTION, AND I REALLY APPRECIATE IF THE BOARD CAN CONSIDER THIS ASPECT IN POTENTIAL REEXAMINATION OF THE PRIORITIES.

CHAIRMAN IMBASCIANI: THANK YOU VERY MUCH,

DOCTOR. I APPRECIATE YOUR COMMENTS.

OKAY. I THINK WE HAVE REACHED THE END OF THIS AGENDA ITEM THEN. CORRECT? GOOD. OKAY.

WE'RE MOVING TO AGENDA ITEM NO. 12. OKAY. SO I'M GOING TO INTRODUCE OUR ASSOCIATE VICE PRESIDENT FOR PRECLINICAL DEVELOPMENT, DR. SHYAM PATEL, TO COME TO THE PODIUM. THIS IS GOING TO BE AN EXCITING PRESENTATION -- I HOPE YOU ALL FIND SO -- ON OUR RARE DISEASE PLATFORM PROPOSAL.

DR. PATEL: THANK YOU, DR. IMBASCIANI. WHILE I'M WAITING FOR THE SLIDES TO COME UP, SO I'M SHYAM PATEL. AND THANK YOU TO THE ICOC FOR THIS OPPORTUNITY TO PRESENT THE RAPID FUNDING OPPORTUNITY TO YOU TODAY. AND THANK YOU TO THE SCIENCE SUBCOMMITTEE FOR YOUR ENDORSEMENT A COUPLE WEEKS AGO.

I'M PRESENTING THIS FUNDING OPPORTUNITY CONCEPT ON BEHALF OF MY COLLEAGUES, DR. JIM CAMPANELLI, WHO'S IN THE AUDIENCE TODAY, AND DR. LISA MCGINLEY, WHO'S ON ZOOM. AND THE RAPID FUNDING OPPORTUNITY STANDS FOR RARE DISEASE ACCELERATION THROUGH PLATFORM INNOVATION AND DELIVERY. FULL DISCLOSURE, I WILL BE MAKING A REFERENCE TO CARS, BUT THEY'RE OF THE BORING DRIVING VARIETY. AND ADVANCE APOLOGY TO THE SCIENCE

SUBCOMMITTEE TO HAVE TO HEAR THAT ANALOGY YET AGAIN.

OKAY. SO THIS PRESENTATION IS GOING TO FOCUS QUITE A BIT ON THE BACKGROUND AND MOTIVATION FOR THIS FUNDING CONCEPT. AND THEN I WILL GO INTO THE STRUCTURE AND SCOPE OF THE PROGRAM, ENDING WITH THE TIMELINE.

SO THE RAPID FUNDING OPPORTUNITY IS RESPONSIVE TO THE SAF GOAL 3, WHICH WAS TO ADVANCE FOUR TO SEVEN RARE DISEASE PROJECTS TO BLA. IN THAT GOAL WE HAD TWO RECOMMENDATIONS. AND THIS IS FOR THE SECOND RECOMMENDATION, WHICH WAS TO ADVANCE A NEW MODEL FOR RARE DISEASE THERAPY DEVELOPMENT THAT IS BASED ON PLATFORMS. AND I WILL SAY PLATFORMS AND RAPID A HUNDRED TIMES, AND WE'LL GET THROUGH THIS ONE STEP AT A TIME.

OKAY. SO, AS YOU ALL KNOW, THERE ARE OVER 10,000 UNIQUE RARE DISEASES THAT AFFECT THE WORLD POPULATION TODAY. WHILE EACH RARE DISEASE AFFECTS A SMALL GROUP OF PEOPLE, COLLECTIVELY OVER 30 MILLION AMERICANS ARE LIVING WITH RARE DISEASE TODAY. OVER 50 PERCENT OF THOSE RARE DISEASES MANIFEST THEMSELVES IN CHILDHOOD, AND 80 PERCENT OF THEM HAVE A GENETIC BASIS.

NOW, THE VAST MAJORITY OF CELL AND GENE THERAPIES THAT HAVE BEEN APPROVED AND ARE IN THE

MARKET TODAY ARE FOR RARE DISEASES, BUT 95 PERCENT OF RARE DISEASES HAVE NO APPROVED THERAPY. WHY IS THAT? AND WE ALL KNOW THAT. IT'S BECAUSE THE DRUG DEVELOPMENT PROCESS, PARTICULARLY FOR ADVANCE MODALITIES, IS TIME, RESOURCE, AND COST INTENSIVE. AND IT MAKES IT VERY DIFFICULT TO BE ABLE TO DEVELOP THERAPIES WHEN YOU'RE LOOKING AT THOUSANDS OF DISEASES.

SO THIS GETS US TO THE POINT OF -- THIS IS REINFORCED HERE AGAIN IN THIS SLIDE, WHICH IS THAT EVEN FOR GENE THERAPIES WHERE THE DEVELOPMENT PATHWAY IS A LITTLE BIT ACCELERATED COMPARED TO SMALE MOLECULES AND BIOLOGICS, IT COULD STILL TAKE FIVE TO TEN YEARS TO GET THESE THERAPIES THROUGH THE DEVELOPMENT LIFE CYCLE FROM CANDIDATE DISCOVERY THROUGH PRECLINICAL DEVELOPMENT TO CLINICAL TRIALS AND FDA APPROVAL. AS I MENTIONED, BECAUSE YOU'RE LARGELY REPEATING THE TESTING PROCESS WHOLESALE FOR EACH CANDIDATE, IT'S VERY DIFFICULT TO DEVELOP THESE THERAPIES IN ANY PARALLEL FORMAT. AND YOU OFTEN SEE THESE TYPES OF STAGGERED OR SERIAL DEVELOPMENT OF GENE THERAPIES ACROSS ACADEMIA AND INDUSTRY BECAUSE YOU JUST CANNOT COMMIT THE AMOUNT OF TIME, RESOURCES, AND FUNDING TO BE ABLE TO DO IT IN PARALLEL.

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WHAT IF YOU COULD SPEED UP THE DEVELOPMENT OF A GENETIC THERAPY? WE SAW AN EXAMPLE OF THIS, AND WOULD THIS ACTUALLY RESULT IN A SCALABLE SOLUTION? SO WE SAW AN EXAMPLE OF THIS RECENTLY WHERE THE CHILDREN'S HOSPITAL OF PHILADELPHIA TEAM DEVELOPED A BASE EDITING GENETIC THERAPY FOR BABY KJ WITHIN SIX MONTHS OF DIAGNOSIS. WHILE THAT WAS A VERY REMARKABLE ACHIEVEMENT BECAUSE THEY HAD TAKEN A NOVEL GENE EDITING TECHNOLOGY AND DROVE IT TO THE CLINIC IN SIX MONTHS, IF YOU LOOK AT THEIR TESTING TIMELINE, THEY HAD TO DO THE LARGE MAJORITY OF THE TESTING YOU NORMALLY WOULD DO FOR A GENE THERAPY. THIS INCLUDES TESTING IN SMALL AND LARGE ANIMAL MODELS AND ALL THE MANUFACTURING FOR THIS THERAPY. AND BECAUSE IT WAS AN N OF 1 THERAPY FOR A SINGLE PATIENT UNDER A SINGLE ADMINISTRATION, YOU HAVE TO REPEAT ALL OF THAT TESTING AGAIN FOR THE NEXT BABY KJ. SO WHILE IT WAS SPED UP IN TIME, IT WAS NOT EFFICIENT IN THE USE OF RESOURCES AND DOLLARS.

SO THIS IS WHERE I'M GOING TO PAUSE TO TALK A LITTLE BIT ABOUT CARS. AND SO IMAGINE IN YOUR MIND TWO CARS. ONE IS -- I'M NOT SURE I CAN DO THIS WITH A STRAIGHT FACE. ONE IS A HONDA CRV, WHICH IS AN SUV THAT I DRIVE. AND THE OTHER IS A

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HONDA CIVIC, A COMPACT SEDAN. THESE LOOK LIKE TWO COMPLETELY DIFFERENT CARS. THEY HAVE DIFFERENT FUNCTIONS. THEY'RE MEANT FOR DIFFERENT LIFESTYLES, BUT THEY'RE IN FACT BASED ON EACH OTHER. THE HONDA CRV WAS DESIGNED AND BUILT ON THE CHASSIS OF THE HONDA CIVIC. AND THAT WAS A DELIBERATE STRATEGY WHERE EVERY SINGLE GENERATION OF THE CRV IS BUILT ON THE SAME GENERATION OF THE CIVIC AS A DELIBERATE STRATEGY TO APPLY PLATFORM EFFICIENCIES TO EVERY SINGLE STAGE OF PRODUCT DEVELOPMENT AND PRODUCT LIFE CYCLE STARTING WITH DESIGN, TESTING, AND GETTING INTO MANUFACTURING, AND MAINTENANCE OF THOSE VEHICLES. SO EVERY GENERATION OF THOSE CARS.

WHAT WOULD HAPPEN IF WE TOOK THAT SORT OF AN APPROACH WHERE YOU ARE REALIZING PLATFORM EFFICIENCIES AT EVERY SINGLE STAGE YOU SEE HERE FROM DISCOVERY THROUGH PRECLINICAL TESTING TO CLINICAL TESTING TO APPROVAL? WHAT WOULD THAT LOOK LIKE? AND SO THAT IS THE CONCEPT OF PLATFORM-BASED THERAPIES WHERE YOU WOULD HAVE MULTIPLE RELATED THERAPIES FOR MULTIPLE INDICATIONS THAT ARE RAPIDLY ADVANCED TO PATIENTS BY LEVERAGING COMMON COMPONENTS, TECHNOLOGIES, DATA, AND RESOURCES. THIS IS DONE TO A CERTAIN EXTENT TODAY, BUT WHAT I'M GOING TO DESCRIBE IN THE NEXT COUPLE SLIDES IS HOW

TO DO THAT EFFICIENTLY ACROSS THE ENTIRE LIFE CYCLE.

SO HERE ARE A FEW ILLUSTRATIVE EXAMPLES THAT ARE NOT MEANT TO BE LIMITING, BUT TO JUST GIVE YOU AN IDEA OF POTENTIALLY PLATFORMIZABLE GENETIC THERAPIES. THERE IS NONVIRAL GENE EDITING RNA-BASED THERAPIES AND AAV GENE DELIVERY. WE'RE GOING TO KEY IN ON THE GENE EDITING. I'M GOING TO CARRY FORWARD THAT BABY KJ EXAMPLE A COUPLE MORE TIMES HERE.

SO IF WE LOOK AT CRISPR GENE EDITING, THERE ARE THREE BASIC COMPONENTS TO THAT TYPE OF A THERAPY. THERE IS A DELIVERY VEHICLE. IT COULD BE A NONVIRAL LIPID NANOPARTICLE; AN EDITOR ENZYME, WHICH DOES THE JOB OF MODIFYING THE DNA; AND AS WELL AS A GUIDE RNA. THE GUIDE RNA'S FUNCTION IS TO GUIDE THE ENZYME TO THE APPROPRIATE SEQUENCE IN THE GENE. BY VARYING JUST THAT GUIDE RNA, YOU CAN ACTUALLY CREATE HUNDREDS OF DIFFERENT THERAPIES THAT TARGET DIFFERENT MUTATIONS.

AND SO WITH THAT, I'M GOING TO WALK THROUGH WHAT IS AN IDEAL STATE OF PLATFORM-BASED THERAPY DEVELOPMENT AND APPROVAL AND WHERE WE'RE AT AT THE MOMENT.

AS I JUST DESCRIBED, IT'S RELATIVELY STRAIGHTFORWARD TO USE A PLATFORM LIKE CRISPR TO DISCOVER A LARGE NUMBER OF CANDIDATES. SO LET'S GO

BACK TO THE BABY KJ EXAMPLE. BABY KJ HAS A UREA CYCLE DISORDER WHERE IT HAD A MUTATION IN ONE GENE. THERE ARE SIX OTHER KNOWN GENES WHERE A MUTATION CAUSES A DISRUPTION TO THE UREA CYCLE PROCESS. WHAT IF, INSTEAD OF DEVELOPING A THERAPY ONE AT A TIME, YOU DEVELOPED A THERAPY FOR ALL SEVEN OF THOSE GENETIC MUTATIONS AT THE SAME TIME. SO EFFECTIVELY YOU'RE LOOKING AT SEVEN DIFFERENT CANDIDATES OR MORE ACTUALLY FOR SEVEN RELATED INDICATIONS AND SEVEN PATIENT POPULATIONS.

OKAY. SO IN THIS SIMPLIFIED EXAMPLE, LET'S JUST ASSUME THAT BY VARYING THE GUIDE RNA, YOU COULD CREATE A BASE EDITING THERAPY FOR EACH OF THOSE SEVEN MUTATIONS. PLEASE PARDON THE FACT THAT I STOPPED AT THREE GRAPHICS HERE. AND THEN YOU CAN DEVELOP THOSE THERAPIES RELATIVELY -- YOU CAN DISCOVER THOSE THERAPIES RELATIVELY QUICKLY. WHERE IT GETS CHALLENGING IS WHEN YOU GET TO THE PRECLINICAL TESTING PHASE. SO HERE WHAT YOU WOULD DO IN THIS IDEAL STATE IS RESERVE THE BULK OF YOUR PRECLINICAL TESTING, YOUR ANIMAL TESTING, YOUR IN VITRO ASSAYS, A LOT OF YOUR MANUFACTURING FEASIBILITY, TO ONE CANDIDATE. AND THEN YOU WOULD DO THE NECESSARY IN VITRO TESTING FOR THE REST OF THOSE CANDIDATES.

SO HERE YOU'RE BASICALLY LIMITING AND USING THE DATA FROM ONE CANDIDATE TO JUSTIFY THE PLATFORM, BUT YOU'RE SUPPLEMENTING THAT WITH DATA FROM ADDITIONAL CANDIDATES THAT'S MAYBE ONLY IN VITRO TESTING. THEN WHEN IT GETS TO THE IND AND CLINICAL TRIAL STAGE, INSTEAD OF SUBMITTING A SINGLE IND FOR EACH OF THOSE CANDIDATES TO DO A SINGLE CANDIDATE TRIAL, THE FDA WILL ALLOW YOU TO SUBMIT A MASTER CLINICAL PROTOCOL DRIVEN BY A MASTER CLINICAL IND, WHICH WOULD ALLOW YOU TO DO AN EFFICIENT UMBRELLA TRIAL DESIGN WHERE YOU CAN TEST ALL OF THESE CANDIDATES AT THE SAME TIME IN AN UMBRELLA TRIAL. AND YOU CAN ALSO ADD ADDITIONAL CANDIDATES AS NEW MUTATIONS ARISE IN THOSE PATIENT POPULATIONS.

FINALLY, INSTEAD OF SUBMITTING A BLA FOR EVERY SINGLE CANDIDATE, THE FDA WOULD ALLOW YOU -- FDA WOULD APPROVE THE PLATFORM. SO THEY'RE APPROVING THE PLATFORM WHICH WOULD ALLOW FOR ADDITIONAL CANDIDATES TO RAPIDLY BE DEVELOPED AND APPROVED. SO THAT WOULD BE THE IDEAL STATE OF APPLYING PLATFORM-BASED APPROACHES ACROSS THE ENTIRE LIFE CYCLE OF DRUG DEVELOPMENT IF YOU WERE TO CREATE HONDAS AND CRV'S.

SO WITH THAT IN MIND, THE PREVAILING THOUGHT SO FAR HAS BEEN TO GET TO THIS SORT OF AN

IDEAL STATE WOULD REQUIRE A LOT OF ITERATIVE STEPS WHERE YOU REALIZE PLATFORM EFFICIENCIES AT ONE STEP IN THE PROCESS AND YOU STACK ALL THOSE EFFICIENCIES TO GET WHERE YOU NEED TO BE. FOR EXAMPLE, RIGHT NOW I'M WORKING ON MANAGING AN AWARD THAT IS A GENE THERAPY. AND WHAT -- THAT COMPANY ACTUALLY HAS ANOTHER GENE THERAPY THAT HAS SIMILAR STRUCTURAL ELEMENTS THAT'S ALREADY IN THE CLINIC. AND THEY'RE ABLE TO LEVERAGE SOME OF THE DATA FROM THAT CLINICAL CANDIDATE TO REDUCE SOME OF THE ANIMAL TESTING FOR THEIR EXISTING CANDIDATE. HOWEVER, TO REALIZE THIS SORT OF A STRATEGY WOULD REQUIRE A DELIBERATE APPROACH.

SO I MENTIONED THE CHOP TEAM BEFORE AND THE UREA CYCLE DISORDER IN THE BABY KJ EXAMPLE. THE CHOP TEAM IS, IN FACT, EXECUTING ON THIS STRATEGY. THEY HAVE GONE TO THE FDA IN A PRE-IND MEETING PROPOSING THIS EXACT APPROACH, WHICH IS PARALLEL DEVELOPMENT OF GENETIC THERAPIES FOR ALL SEVEN UREA CYCLE GENES TO DO A MASTER PROTOCOL CLINICAL TRIAL. AND BY RESERVING THE TESTING, THE BULK OF THE TESTING ON A SUBSET OF THOSE CANDIDATES. THEY HAVE PRE-IND BUY-IN. THE PRE-IND MEETING MINUTES HAVE BEEN PUBLISHED AND SHARED WITH THE PUBLIC.

AND ON TOP OF THAT, A COUPLE MONTHS AGO

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THE FDA, PARTLY INSPIRED BY THE BABY KJ EXAMPLE, PUT OUT A VERY PRELIMINARY BLUEPRINT THAT THEY CALL THE PLAUSIBLE MECHANISM PATHWAY. THE PLAUSIBLE MECHANISM PATHWAY DESCRIBES HOW PLATFORM-BASED GENETIC THERAPIES FOR RARE DISEASES CAN BE RAPIDLY DEVELOPED AND APPROVED AS A PLATFORM, EFFECTIVELY WHAT IS DESCRIBED IN THIS SLIDE. AND SO AT THIS POINT, WHILE A LOT STILL NEEDS TO BE DONE, MUCH STILL NEEDS TO BE WORKED OUT AND PROVEN, THERE APPEARS TO BE A POSITIVE FEEDBACK LOOP BETWEEN REGULATORS AND THERAPY DEVELOPERS ON HOW TO GET TO THIS VISION OF A PLATFORM-BASED APPROACH FOR RARE DISEASE THERAPIES.

SO I'M GOING TO TAKE A MINUTE TO STEP BACK AND TALK ABOUT HOW WE GOT TO THIS STAGE. SO THE CHOP TEAM'S WORK HAS BEEN ENTIRELY SUPPORTED BY A VISIONARY SET OF NIH FUNDING OPPORTUNITIES THAT WERE ISSUED THREE YEARS AGO. SO THE NIH ISSUED A COUPLE OF FUNDING OPPORTUNITIES THAT ASKED A VERY SIMPLE QUESTION FOR PROPOSALS. BRING US MULTIPLE GENE EDITING THERAPIES FOR MULTIPLE DISEASES, AND WE WILL FUND YOU TO IND. AND SO THAT WAS THEIR APPROACH. SO BABY KJ IS ACTUALLY A STEPPING STONE IN THAT BROADER CHOP PROGRAM APPROACH TO BRING THOSE -- ALL THOSE GENE THERAPIES AT THE SAME TIME TO THE CLINIC AND AN

IMPORTANT VALIDATION.

ON THE REGULATORY SIDE, AS MANY OF YOU KNOW, A COUPLE YEARS AGO THE FDA PUBLISHED PLATFORM DESIGNATION DRAFT GUIDANCE. THIS IS DRIVEN BY THE 21ST CENTURY CURES ACT. UNFORTUNATELY THAT PLATFORM DESIGNATION GUIDANCE IS NOT ACCESSIBLE TO MOST CELL AND GENE THERAPY DEVELOPERS BECAUSE IT REQUIRES YOU TO HAVE AN APPROVED PRODUCT IN THE FIRST PLACE. HOWEVER, THAT HAS SPURRED A LOT OF DIRECT INTERACTION BETWEEN THERAPY DEVELOPERS, PATIENT ADVOCATES, AND THE FDA ON HOW YOU CAN HAVE EFFICIENT REGULATORY PATHWAYS FOR RARE DISEASE DRUG DEVELOPMENT. AND THAT'S WHAT LED TO THE PLAUSIBLE MECHANISM PATHWAY PUBLICATION FROM THE FDA.

SO YOU CAN SEE HOW ALL THE PIECES ARE FITTING TOGETHER. AND THE RAPID PROGRAM AT THIS POINT IN TIME, IF APPROVED BY THE BOARD TODAY, WOULD BE POSITIONED TO ADVANCE PLATFORM-BASED THERAPIES FROM PROMISE TO PRACTICE BY BUILDING ROBUST EVIDENCE ACROSS RARE DISEASE AND TECHNOLOGY.

SO THE GOAL FOR THIS PROGRAM IS TWOFOLD, AND THAT'S DESCRIBED IN THIS SLIDE. SO THE FIRST IS SCIENTIFIC AND REGULATORY INNOVATION AND SECOND IS PATIENT IMPACT. SO FOR THAT FIRST GOAL OF SCIENTIFIC AND REGULATORY INNOVATION, THE IDEA HERE

IS THAT THIS PROGRAM WOULD SUPPORT MULTIPLE APPROACHES FOR MULTIPLE DISEASE AREAS AND BUILD A STRONG EVIDENCE BASE OF SAFETY AND EFFICACY FOR THESE PLATFORM-BASED APPROACHES ACROSS THESE DIFFERENT APPROACHES. HOWEVER, IF IT'S GOING TO DO THAT, IT ALSO NEEDS TO ENSURE THAT IT CAN DEMONSTRATE RAPID PROGRESSION OF PLATFORM-BASED THERAPIES TO PATIENTS WHERE THERE IS DIRECT CLINICAL IMPACT. AND THAT'S THE SECOND GOAL OF PATIENT IMPACT. ULTIMATELY ALL THIS WOULD RESULT IN BLAZING A PATHWAY THAT OTHERS CAN FOLLOW.

SO WITH THAT IN MIND, THE RAPID PROGRAM HAS AN OBJECTIVE OF CREATING A SCALABLE MODEL TO RAPIDLY DELIVER TRANSFORMATIVE PLATFORM-BASED GENETIC THERAPIES TO PATIENTS WITH RARE DISEASE.

I'M GOING TO SPEND THE NEXT FEW SLIDES TALKING ABOUT THE SCOPE AND STRUCTURE OF THE PROGRAM AS WELL AS THE BUDGET ASK. AND THEN I'LL END WITH A COUPLE OF SLIDES ABOUT THE LIFE CYCLE OF THE AWARD.

SO AS YOU KNOW, WE HAVE A SET OF FUNDING OPPORTUNITIES THAT DO SPAN PRECLINICAL TO CLINICAL DEVELOPMENT. THESE INCLUDE LEGACY PROGRAMS LIKE TRANSLATIONAL AND CLIN1 AS WELL AS OUR NEWER PROGRAMS LIKE PDEV AND THE MODIFIED CLIN2. ALL OF THESE PROGRAMS HAVE SUPPORTED RARE DISEASE THERAPIES

AND WILL CONTINUE TO DO SO AS WE GO FORWARD. HOWEVER, THESE PROGRAMS ARE NOT CURRENTLY DESIGNED TO ACCELERATE INNOVATIVE, HIGH RISK PLATFORM APPROACHES.

SO THESE PROGRAMS ARE DESIGNED TO SUPPORT THE TRIED AND TRUE REGULATORY PATHWAY OF FOCUSING ON A SINGLE CANDIDATE FOR A SINGLE INDICATION DOING ALL THE PRECLINICAL TESTING AND MANUFACTURING AND THEN CONDUCTING A SINGLE CANDIDATE TRIAL UNDER A SINGLE IND. LOTS OF SINGLES THERE. THIS SHOULD COME AS NO SURPRISE TO YOU, BUT THE RAPID PROGRAM WILL DO EVERYTHING IN MULTIPLES. AND SO THE IDEA HERE IS THAT THIS PROGRAM WILL SUPPORT THE DEVELOPMENT OF MULTIPLE CANDIDATES FOR MULTIPLE RELATED INDICATIONS IN A MASTER PROTOCOL TRIAL WHERE THE PLATFORM EFFICIENCIES ARE REALIZED AT BOTH THE PRECLINICAL, MANUFACTURING, AND CLINICAL STAGES.

SO IN ORDER TO SUPPORT THE GOALS THAT I MENTIONED EARLIER ABOUT REGULATORY AND TECHNICAL INNOVATION AND PATIENT IMPACT, WE'RE PROPOSING TWO TYPES OF AWARDS FOR THE RAPID PROGRAM. THE FIRST IS THE RAPID VALIDATION AWARD. THIS IS MEANT TO SERVE THAT PATIENT IMPACT GOAL. AND THE IDEA HERE IS THAT THERE WILL BE A SUBSET OF PROJECTS THAT HAVE PRE-IND FEEDBACK FROM THE FDA ON A PLATFORM-BASED APPROACH.

AND THEY WOULD BE ABLE TO APPLY TO CIRM FOR FUNDING FOR A VALIDATION AWARD, WHICH WOULD TAKE THEM THROUGH ALL THE IND-ENABLING STUDIES, THE IND CLEARANCE, AS WELL AS COMPLETION OF THAT FIRST-IN-HUMAN MASTER PROTOCOL TRIAL. SO THIS EFFECTIVELY SPANS IND-ENABLING STAGE AS WELL AS CLINICAL STAGE.

WE COULD ENVISION SOME NONLIMITING EXAMPLES OF TYPES OF PROJECTS THAT MIGHT COME IN. THIS COULD INCLUDE NONVIRAL LIVER TARGETED BASED EDITING THERAPIES FOR METABOLIC DISORDERS AS WHAT I'VE BEEN SPEAKING ABOUT WITH RESPECT TO WHAT THE CHOP TEAM HAS BEEN DOING. BUT THERE'S ANOTHER BROAD ARRAY OF METABOLIC DISORDERS THAT COULD BE LIVER TARGETED OR TARGETING SPECIFIC ORGANS. YOU COULD ALSO HAVE AAV-BASED GENE DELIVERY FOR NEURODEVELOPMENTAL DISEASES WHERE THERE HAS BEEN SIGNIFICANT CLINICAL PROGRESS TO DATE, BUT CANNOT BE PLATFORMIZED. AND THESE AWARDS WILL ACHIEVE THE PROGRAM OBJECTIVE BY DEMONSTRATING THAT YOU CAN RAPIDLY BRING THESE THERAPIES TO PATIENTS AS WELL AS BUILDING THAT EVIDENCE BASE OF SAFETY AND EFFICACY FOR THESE TYPES OF APPROACHES.

AND I'M GOING TO BRIEFLY TALK ABOUT THE STRUCTURE OF THE AWARDS. SO THE CANDIDATES THAT

WOULD BE THE ELIGIBLE FOR A RAPID VALIDATION AWARD WOULD BE IN VIVO GENETIC THERAPIES FOR RARE GENETIC DISEASES. THE APPLICANT WOULD HAVE TO HAVE CONDUCTED THAT PRE-IND MEETING, AS I MENTIONED. AND THE OUTCOME FOR THESE AWARDS WOULD BE COMPLETION OF THE CLINICAL TRIAL FOR AT LEAST THREE CANDIDATES. AND THIS PA, UNLIKE SOME OF OUR OTHER PROGRAMS, WILL NOT SPECIFY AN AWARD CAP AND IT WILL NOT HAVE A MINIMUM CO-FUNDING REQUIREMENT.

THIS IS SPELLED OUT IN THE MEMO, BUT BRIEFLY, WHAT WE'RE INTENDING TO DO HERE IS TO ALLOW FOR A RANGE OF PROJECTS WHERE CO-FUNDING IS NOT A BARRIER, BUT ALSO PUT THE ONUS ON THE APPLICANT TO PROPOSE A WELL-JUSTIFIED BUDGET THAT CLEARLY DEMONSTRATES TIME, COST, AND RESOURCE EFFICIENCIES. AND LIKE ALL OF OUR PDEV PROGRAM, THE RAPID PROGRAM WILL BE LIMITED TO CALIFORNIA AWARDEES.

THE SECOND AWARD TYPE IS THE RAPID INNOVATION AWARDS. THIS SPEAKS TO THE FIRST GOAL OF REGULATORY AND TECHNICAL INNOVATION. SO THE INTENT HERE WITH THE RAPID INNOVATION AWARDS IS TO REALLY PUSH THE BOUNDARIES OF WHAT CONSTITUTES A PLATFORM. SO WHAT WE EXPECT HERE IS THAT, AS NOVEL TECHNOLOGIES ARE DEVELOPED, THEY'RE DEVELOPED WITH PLATFORM-BASED APPROACH IN MIND, AND THAT THEY ARE

USING THAT TO EXPAND THE REACH OF PLATFORM-BASED GENETIC THERAPIES TO ADDITIONAL TYPES OF RARE DISEASES. AND SO WE WILL SUPPORT THESE PROJECTS THROUGH THAT EARLY OPTIMIZATION OF THE CANDIDATES THROUGH IND CLEARANCE. SO THIS IS VERY SIMILAR IN SCOPE TO THE PDEV PROGRAM, BUT IT WILL NOT SUPPORT CLINICAL TRIALS.

SO WE CAN ENVISION SOME NONLIMITING EXAMPLES THAT COULD INCLUDE NONVIRAL GENE DELIVERY TECHNOLOGIES TO THE CNS. IT COULD INCLUDE NEXT GENERATION GENE EDITING THERAPIES DEVELOPED WITH NOVEL IN VITRO MODELS. AND THESE SERVE THE PLATFORM GOAL BY REALLY ADVANCING NOVEL TECHNOLOGIES IN A PLATFORM-BASED STRATEGY AND CONTINUING TO ADD TO THE EVIDENCE BASE FOR WHAT WOULD CONSTITUTE EFFECTIVE PLATFORMS.

AN INNOVATION AWARD WOULD, AGAIN, BE FOR CANDIDATES THAT ARE IN VIVO GENETIC THERAPIES FOR RARE GENETIC DISEASES. WE WOULD REQUIRE THAT THE APPLICANTS HAVE AT A MINIMUM REQUESTED AN FDA INTERACT MEETING. THIS IS IMPORTANT BECAUSE YOU HAVE TO HAVE ALIGNMENT WITH THE FDA FOR THESE TYPES OF NOVEL APPROACHES. AND THE OUTCOME FOR THIS AWARD WOULD BE A MASTER PROTOCOL IND CLEARED FOR AT LEAST THREE CANDIDATES. LIKE THE VALIDATION AWARD, THERE

WOULD BE NO AWARD CAP SPECIFIED IN THE PA AND NO MINIMUM REQUIRED CO-FUNDING. AND LIKE THE VALIDATION AWARD AND OUR PDEV PROGRAM, THE AWARDEE WOULD HAVE TO BE A CALIFORNIA ORGANIZATION.

TO SUPPORT THESE TYPES OF PROJECTS, WE ARE REQUESTING THAT THE BOARD AUTHORIZE A $100 MILLION BUDGET FOR THIS PROGRAM THAT WOULD BE SPREAD ACROSS TWO ANNUAL FUNDING CYCLES. I'LL DESCRIBE HOW WE MAY COME BACK TO THE BOARD DOWN THE ROAD FOR APPROVAL TO REINVEST ADDITIONAL FUNDS IF THEY'RE RECOVERED FROM RAPID PROJECTS.

GIVEN THE DYNAMIC NATURE OF THESE PROJECTS, WE WOULD LIKE TO REQUEST FROM THE BOARD THE AUTHORIZATION TO HAVE A SUPPLEMENT BUDGET. THIS WILL BE A PROGRAM SUPPLEMENT BUDGET THAT COULD BE DEPLOYED BY CIRM IN A DEFINED REQUEST AND APPROVAL PROCESS TO HELP ACCELERATE FUNDED PROJECTS THAT ARE OTHERWISE MOVING AND EXECUTING ON THEIR OM'S.

SO TO DESCRIBE WHAT THAT WOULD LOOK LIKE OVER A TWO-YEAR PERIOD, IN FISCAL YEAR 26/27, CIRM WOULD REQUEST THAT THE BOARD AUTHORIZE $55 MILLION TO THE RAPID PROGRAM, $50 MILLION OF WHICH WOULD BE DEPLOYED TO FUND UP TO TWO OR THREE AWARDS OR POSSIBLY MORE, AND $5 MILLION WILL BE RESERVED FOR THE PROGRAM SUPPLEMENT THAT COULD BE DEPLOYED OVER

THE LIFETIME OF THE PROGRAM.

IN FISCAL YEAR 27/28, WE WOULD REQUEST THAT THE BOARD AUTHORIZE $45 MILLION THAT COULD BE DEPLOYED TO FUND ADDITIONAL AWARDS IN THE RAPID PROGRAM.

CIRM ROUTINELY RECOVERS FUNDS FROM PROJECTS. AND IF ENOUGH FUNDS ARE RECOVERED FROM RAPID PROJECTS THEMSELVES, WE MAY IN FUTURE YEARS ASK THE BOARD FOR APPROVAL TO EITHER REPLENISH THE SUPPLEMENT BUDGET AND/OR OPEN UP THE PROGRAM FOR ADDITIONAL RAPID APPLICATIONS. THAT BE WOULD BE PART OF OUR RESEARCH BUDGET APPROVAL PROCESS.

SO IN THE NEXT COUPLE SLIDES, I'M GOING TO TALK ABOUT THE LIFE CYCLE OF THE AWARD. THIS IS RELATIVELY SIMILAR TO OUR OTHER PROGRAMS. SO GIVEN THE NATURE OF THIS PROGRAM AND THE SCOPE OF IT, WE WANT TO ENSURE THAT EVERY APPLICANT HAS HAD A CONSULTATION WITH THE CIRM TEAM BEFORE THEY SUBMIT THEIR APPLICATION. WE DON'T WANT THEM TO SPEND A LOT OF TIME ON THE PROPOSAL MAKING PROCESS WITHOUT MAKING SURE THAT THE PROGRAM IS ALIGNED WITH THE GOALS.

SO WHAT WE WOULD EXPECT HERE IS THAT WE ARE GOING TO REQUIRE THAT EVERY APPLICANT HAVE A CONSULTATION WITH CIRM BEFORE THEY CAN SUBMIT THAT

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APPLICATION.

THE APPLICATION REVIEW PROCESS WILL BE SIMILAR TO OUR OTHER PROGRAMS. IT WILL REQUIRE SUBMISSION OF A COMPLETE APPLICATION. THERE IS NO PRESUBMISSION FOR THIS PROGRAM. IF NECESSARY, AND THE VOLUME EXCEEDS THE AMOUNT OF APPLICATIONS THE GWG CAN REVIEW, WE WOULD DO A POSITIVE SELECTION MECHANISM. THIS IS WHERE THE GRANTS WORKING GROUP MEMBERS SELECT APPLICATIONS THAT THEY WANT TO FORWARD TO SCIENTIFIC REVIEW. AND LIKE ALL OF OUR OTHER PROGRAMS, ALL OF THE APPLICATIONS WOULD BE SCORED BY THE GWG ON A 1 TO 100 SCORE.

WE'LL ALSO UTILIZE OUR EXISTING MANAGEMENT MECHANISMS TO ENSURE THAT RAPID PROJECTS ADHERE TO THE PROGRAM OBJECTIVE AND EXPECTED OUTCOME. SO WE HAVE BEEN DEPLOYING A PROACTIVE AWARD MANAGEMENT STRATEGY ACROSS OUR ENTIRE PORTFOLIO. THIS GOES BEYOND QUARTERLY REPORT REVIEW TO HAVE ONE-ON-ONE DISCUSSIONS WITH THE AWARDEE TO MAKE SURE THAT CIRM IS INCLUDED ALL FDA MEETINGS AND TO CREATE A PROACTIVE AND COLLABORATIVE ENVIRONMENT WITH THE AWARDEE TO MOVE THAT PROJECT FORWARD.

TO ENSURE THAT THE PROJECT IS OPERATING ON ITS OBJECTIVE, ALL AWARDS WILL USE THE CIRM PERFORMANCE DRIVEN OPERATIONAL MILESTONE STRUCTURE.

HERE FUNDS ARE ONLY DISBURSED IF THAT PROJECT MEETS THE OPERATIONAL MILESTONE SUCCESS CRITERIA DEFINED IN THE NOTICE OF AWARD. THIS HELPS US ALSO ENSURE THAT THE PROJECTS ARE REALIZING PLATFORM EFFICIENCIES AND CONTINUOUSLY PROGRESSING CANDIDATES, THE MINIMUM NUMBER REQUIRED, FOR EACH OF THOSE AWARDS.

A REALLY CRITICAL COMPONENT OF THIS PROGRAM IS TO BOLSTER THE KNOWLEDGE AND DATA SHARING REQUIREMENTS BECAUSE THERE'S TWO GOALS THAT WE HAVE FOR THIS PROGRAM. ONE IS TO ENSURE THAT THE RAPID AWARDS CAN LEVERAGE THE COLLECTIVE EXPERIENCE AND KNOWLEDGE OF OUR VAST AWARDEE NETWORK. WE HAVE A LARGE, ACTIVE AWARD PORTFOLIO OF PRECLINICAL PROGRAMS AS WELL AS CLINICAL PROGRAMS. SO HERE, IF YOU HAVE THESE RAPID AWARDEES WHO ARE CREATING A NEW PATHWAY HERE, THEY CAN LEVERAGE A LOT OF THE EXPERIENCE AND KNOWLEDGE FROM OUR EXISTING AWARDEES.

SO IN THAT INSTANCE, WHAT WE EXPECT IS TO CREATE AN INTERNAL KNOWLEDGE NETWORK WHERE THE RAPID AWARDEES AND OUR OTHER AWARDEES ARE FACILITATING REAL-TIME SHARING OF STUDY DESIGNS, DATA, RESOURCES, AND REGULATORY EXPERIENCE. AT THE SAME TIME, BECAUSE THIS PROGRAM IS MEANT TO BLAZE A NEW PATHWAY FOR OTHERS TO FOLLOW, IT'S IMPORTANT THAT WE REQUIRE

PUBLIC DATA SHARING.

SO THE PA AND THE NOA WILL SPELL OUT WHAT CAN BE SHARED, WHEN IT IS SHARED, AND HOW, AND TO WHOM. SO ON THE PUBLIC DATA SHARING SIDE, THE INTENT HERE IS TO BUILD AN EVIDENCE BASE AND ADVANCE BEST PRACTICES IN THE BROADER COMMUNITY AND TO REQUIRE SHARING OF STUDY DESIGNS, FDA INTERACTIONS, AND APPLICABLE DATA DURING THE LIFE CYCLE OF THE AWARD. SO SHORTLY AFTER -- I'LL GIVE YOU AN EXAMPLE OF WHAT THIS MEANS.

SO ON THE AWARDEE KNOWLEDGE NETWORK SIDE, PRIOR TO AN FDA INTERACTION, THE AWARDEE MIGHT SHARE ITS STRATEGY WITH THE RELEVANT CIRM AWARDEES WHO HAVE SIMILAR PROJECTS WHO CAN OFFER SOME GUIDANCE ON HERE. AFTER THE FDA INTERACTION, THEY WOULD MAKE THEIR REGULATORY EXPERIENCE AND LEARNINGS AVAILABLE TO THE CIRM AWARDEES TO BENEFIT FROM THAT AND THEY WOULD PUBLISH REDACTED FDA MEETING MINUTES FOR THE PUBLIC SO THAT THE PUBLIC CAN LEARN FROM THAT AS WELL.

AND LASTLY, SHOULD THE BOARD APPROVE THIS CONCEPT TODAY, THE CIRM TEAM WILL EMBARK ON EARLY OUTREACH TO APPLICANTS. AND THE INTENT HERE IS TO PROMOTE THE PROGRAM, TO RESPOND TO MOMENTUM IN THE FIELD BY HAVING A CLEAR CONVERSATION ABOUT PLATFORM

APPROACHES, AND TO FACILITATE COLLABORATIONS THAT WILL INFORM THE BEST PROPOSALS THAT WE CAN GET FOR THIS PROGRAM.

SO WE'RE PLANNING TO DO THIS BY HAVING EARLY INTERACTIONS WITH PROSPECTIVE APPLICANTS, BY ENGAGING WITH EXPERTS AND PATIENT ADVOCACY ORGANIZATIONS, AS WELL AS OTHER FUNDING AGENCIES, AND, LASTLY, TO CONVENE FORUMS OR WORKSHOPS THAT BRING TOGETHER KEY STAKEHOLDERS TO TALK ABOUT AND DISCUSS WHAT PLATFORM APPROACHES HAVE BEEN TRIED, WHAT CAN BE LEVERAGED GOING FORWARD, AND WHAT RESOURCES ARE AVAILABLE TO THEM.

SO IF THE BOARD APPROVES THIS CONCEPT TODAY, WE WOULD AIM FOR AN APPLICATION TIMELINE THAT WOULD OPEN THE APPLICATIONS MID-YEAR. WE'RE LOOKING AT A NINE-MONTH CYCLE FROM APPLICATION OPEN TO AWARD START, WHICH WOULD MEAN THAT THE FIRST SET OF RAPID AWARDS COULD BE UNDER WAY IN EARLY 2027.

SO WITH THAT, THE CIRM TEAM REQUESTS ICOC APPROVAL OF THE PROPOSED RAPID PROGRAM CONCEPT WITH AN INITIAL ALLOCATION OF $100 MILLION IN THE FIRST TWO FUNDING CYCLES, FISCAL YEAR 26/27 AND FISCAL YEAR 27/28. THANK YOU.

MR. FISCHER-COLBRIE: SO MOVED.

CHAIRMAN IMBASCIANI: YOU JUMPED THE GUN,

BUT I SO MUCH APPRECIATE IT. THANK YOU. SO WE HAVE A MOTION ON THE FLOOR TO ACCEPT THE RECOMMENDATION.

MR. TOCHER: AND A SECOND BY MARV.

CHAIRMAN IMBASCIANI: IT WAS SECONDED? THANK YOU, MARV. OKAY. THE FLOOR IS OPEN FOR DISCUSSION ON THE RAPID PLATFORM INITIATIVE TO BOARD MEMBERS. WE'LL START WITH THE MOVER.

MR. FISCHER-COLBRIE: I JUST WANT TO COMPLIMENT SHYAM AND THE ENTIRE CIRM TEAM FOR CONTINUATION OF DEVELOPING NOVEL APPROACHES THAT ARE INNOVATIVE AND ACCELERATIVE. SO THIS HAS AN OPPORTUNITY TO BE FANTASTIC PROGRAM. SO THANK YOU.

CHAIRMAN IMBASCIANI: THANK YOU. ANNE-MARIE.

DR. DULIEGE: THANK YOU. GREAT. GREAT SENSE OF INNOVATION. HAVE YOU HAD A CHANCE TO DISCUSS THIS CONCEPT WITH POTENTIAL AWARDEES, PEOPLE WHO WOULD BE INTERESTED? AND CAN YOU GIVE US ONE OR TWO EXAMPLES OF HOW IT WOULD LOOK LIKE?

DR. PATEL: SO POTENTIAL AWARDEES, WE'VE HAD SOME CONVERSATIONS WITH SOME OF OUR AWARDEES WHO ARE TRYING THESE TYPES OF APPROACHES. WE DO TEND TO LIMIT DISCUSSIONS WITH POTENTIAL APPLICANTS WHEN WE DO THAT. WE'VE HAD A LOT OF THE CONVERSATIONS WITH THE NIH AND ARPA-H, WHO HAVE SIMILAR EFFORTS UNDER

WAY. WE'VE HAD ONGOING DISCUSSIONS WITH THE CHOP TEAM ON WHAT THEY WERE DOING, AND THEY WERE VERY CANDID WITH US EVEN BEFORE THEIR PRE-IND MEETING AS TO WHAT WAS HAPPENING. SO ALL THAT HAS INFORMED OUR APPROACH HERE.

AND SO WITHIN OUR OWN AWARDEE NETWORK, WE DO KNOW THAT THERE ARE AT LEAST A FEW APPLICANTS THAT COULD BE SUBMITTING APPLICATIONS THAT MIGHT INVOLVE CRISPR GENE EDITING PROJECTS AS WELL AS AAV PROJECTS.

DR. SOUTHARD: I WONDER IF YOU'VE THOUGHT OF WAYS OF PUBLICIZING THIS BECAUSE I THINK THIS AND OTHER THINGS WE'VE TALKED ABOUT TODAY REALLY NEED TO BE OUT TO THE PUBLIC SO THAT THE PUBLIC BECOMES MORE APPRECIATIVE OF WHAT CIRM IS CAPABLE OF AND MAYBE MORE CAPABLE OF IN THE FUTURE.

DR. PATEL: YES. SO THAT -- AS YOU KNOW, AMY ADAMS IS OUR DIRECTOR OF COMMUNICATIONS. SO WE'RE WORKING CLOSELY WITH HER ON THAT, AS WELL AS WE HAVE REACHED OUT TO SEVERAL OTHER STAKEHOLDERS LIKE ALLIANCE FOR REGENERATIVE MEDICINE, REACHING OUT TO ASCGT AND OTHERS WHERE THEY CAN ALSO RAISE AWARENESS OF THIS PROGRAM.

ONE OF THE THINGS THAT WE REALLY WANT IS FOR THIS TO START A CONVERSATION ABOUT WHAT SORT OF

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PLATFORM APPROACHES HAVE ACTUALLY BEEN TRIED BEYOND WHAT WE KNOW ABOUT, AND THAT WOULD BEST INFORM THIS PROJECT. WE WOULD ALSO REALLY GREATLY APPRECIATE OUR WONDERFUL 35-MEMBER BOARD TO BE ABLE TO PROMOTE THIS OPPORTUNITY AS WELL.

CHAIRMAN IMBASCIANI: ANY OTHER BOARD MEMBERS? IM' SORRY. PAT, YES.

DR. LEVITT: SO A FEW QUESTIONS. CONGRATULATIONS. IT'S GREAT. YOU KNOW ME. I'M ALL CHIPS IN. SO I'M VERY MUCH IN FAVOR OF THIS, BUT I HAVE A FEW QUESTIONS.

THE FIRST IS SO THERE ARE RARE DISEASE PROJECTS COMING IN THROUGH OTHER MECHANISMS WITH OTHER APPROACHES. HOW DOES THIS PROGRAM AFFECT THOSE? AND IF YOU ARE GOING USE A RUBRIC TO MAKE DECISIONS IF, FOR WHATEVER REASON, YOU HAVE MORE APPLICATIONS THAN YOU THINK YOU ARE GOING TO BE ABLE TO REVIEW, WHAT'S THE RUBRIC GOING TO LOOK LIKE?

SO IS IT GOING TO IMPACT THE OTHERS COMING IN THROUGH OTHER MECHANISMS AT CIRM? AND HOW? AND WHAT'S THE RUBRIC?

DR. PATEL: WONDERFUL QUESTIONS AS ALWAYS, PAT. AND SO I'LL TALK ABOUT THE FIRST ONE. SO IT REALLY DEPENDS ON WHAT STRATEGY THEY'RE TAKING, RIGHT. IF THEY'RE TAKING A PLATFORM-BASED STRATEGY

AND THEY THINK THEY CAN DEVELOP MULTIPLE CANDIDATES, THIS WOULD BE THE RIGHT PROGRAM FOR THEM. IF THEY'RE TAKING A MORE TRADITIONAL APPROACH, THEN THE OTHER PROGRAMS WOULD BE APPROPRIATE FOR THAT.

YOUR QUESTION ABOUT THE RUBRIC --

DR. LEVITT: WE HAVE PART OF THE DECISION-MAKING EARLY, BEFORE IT GETS REVIEWED, IS IT FILLING A GAP. THIS IS A $100 MILLION INVESTMENT IN FILLING A GAP, RIGHT, WITH REALLY EXCITING ADVANCED TECHNOLOGIES. SO IS IT NOT GOING TO IMPACT THE CHECK BOX THAT OCCURS WITH THE OTHER BECAUSE LIKE, WELL, WE HAVE THIS OTHER PROGRAM AND THIS IS NOT USING THE MOST ADVANCED APPROACHES. SO THUMBS DOWN. I DON'T KNOW IF THAT WOULD HAPPEN. I'M JUST WONDERING WHETHER IT WOULD HAPPEN.

DR. PATEL: IT DEPENDS ON THE TYPES OF APPROACHES AND THE MATURITY OF THOSE APPROACHES AS WELL AS TO WHAT'S POSSIBLE HERE. SO YOU CAN HAVE AN INSTANCE WHERE YOU HAVE A PROJECT HERE WHERE IT'S LOOKING AT LIPID NANOPARTICLE DELIVERY, FOR EXAMPLE, WHICH YOU COULD POTENTIALLY PLATFORMIZE, RIGHT, AND THAT MAY MAKE SENSE FOR THE VALIDATION PROJECT. OR IF THEY'RE DEVELOPING A SINGLE CANDIDATE AND THEY CAN'T ACTUALLY PLATFORMIZE THAT FOR WHATEVER REASON, THEY COULD POTENTIALLY USE THAT AS PART OF A PDEV

AWARD. IF YOU HAVE SOMETHING THAT'S VERY NOVEL LIKE A BRAND NEW DELIVERY TECHNOLOGY, THE INNOVATION APPROACH MIGHT BE THE WAY TO GO RATHER THAN GOING FOR A PDEV AWARD WHERE YOU COULD DO IT AT A BIGGER SCALE.

TO GET TO YOUR QUESTION ABOUT TRIAGING AND PREFERENCES. SO FOR THIS PARTICULAR PROGRAM, IF WE GOT MORE APPLICATIONS THAN THE GWG CAN REVIEW, THEY WOULD DO A POSITIVE SELECTION PROCESS. SO WHAT THAT MEANS IS THAT ALL THE APPLICATIONS ARE VIEWABLE BY GWG REVIEWERS AND THEY WILL PICK. SO IT WOULD NOT HAVE ANY CHECKLIST CRITERIA.

NOW, IF THE BOARD WOULD LIKE FOR US TO REVISE THE PDEV PREFERENCES BASED ON WHAT THEY EXPECT TO COME IN FOR THE RAPID PROGRAM, WE CAN DEFINITELY HAVE THAT CONVERSATION IN MARCH.

DR. LEVITT: I THINK THOSE CRITERIA ARE GOING TO BE DISCUSSED IN MARCH, AND WHAT YOU'VE DESCRIBED IS OVERLAPPING, BUT DEFINITELY NOT IDENTICAL. SO I THINK SOME CONSIDERATION.

THE SECOND QUESTION IS REAL-TIME DATA SHARING, REAL-TIME PROTOCOL SHARING, WHICH IS GREAT, HOW DOES IT AFFECT INSTITUTIONAL COMMERCIALIZATION?

DR. PATEL: GOOD QUESTION. SO THAT'S A VERY RELEVANT QUESTION IF SOME OF THESE HAVE

COMMERCIAL POTENTIAL. AND SO PART OF THAT IS GOING TO BE -- WHAT WE'RE THINKING ABOUT RIGHT NOW IS WE'RE ACTUALLY IMPLEMENTING A VERSION OF THE KNOWLEDGE SHARING INTO THE PDEV PROGRAM AS WELL, WHICH YOU KNOW FROM LAST YEAR. AND SO IT'S GOING TO BE CRITICAL TO DO SO IN -- THEY CAN REDACT REALLY PROPRIETARY INFORMATION THAT DOESN'T HAVE IP PROTECTION WOULD BE ONE WAY TO START THAT.

IN THE RAPID PROGRAM, WE COULD POTENTIALLY EVEN THINK ABOUT CREATING A CONFIDENTIAL SPACE, IF NEEDED, TO BE ABLE TO SHARE THAT TYPE OF INFORMATION IF IT'S NECESSARY. BUT AT A MINIMUM, BEING ABLE TO REDACT IMPORTANT INFORMATION WOULD BE ONE WAY TO GO.

SO, FOR EXAMPLE, WHEN THE CHOP TEAM SHARED THEIR PRE-IND PACKAGE AND THEIR PRE-IND MEETING MINUTES, THE PROPRIETARY ELEMENTS IN THERE WERE SOME OF THE MANUFACTURING COMPONENTS BECAUSE THEY WERE USING A PRIVATE PARTY FOR THAT. AND SO THOSE WERE REDACTED. BUT THE BULK OF THE INFORMATION IN TERMS OF THE QUESTIONS THEY WERE ASKING AND SOME OF THE DATA THEY WERE PROVIDING ON THEIR ASSAYS AND THEIR OWN STUDIES WAS NOT REDACTED. AND THAT IS STILL REALLY INFORMATIVE.

CHAIRMAN IMBASCIANI: YSABEL.

MS. DURON: THANK YOU. SHYAM, I KNOW

YOU'RE NOT GOING TO BE ABLE TO ANSWER THIS. I'M GOING TO START WITH HOPE ASKING FOR COLD, HARD FACTS. WE TALK ABOUT REINVESTING ANY MONIES THAT COMES BACK TO US, RIGHT?

DR. PATEL: YES.

MS. DURON: I WOULD LIKE TO KNOW WHAT COMES BACK TO US. SO I'M GOING TO ASK, AND I DON'T KNOW IF THAT'S THE CHAIR OR MR. PRESIDENT, BUT I WOULD LIKE REPORT BACK TO US BY MARCH OF HISTORICALLY THE AMOUNT OF MONEY THAT HAS COME BACK TO CIRM, FROM WHICH PROGRAMS HAVE PROVED TO BE, I GUESS, SUCCESSFUL IN ORDER TO GIVE US MONEY BACK INTO OUR TREASURY, AND THEN WHAT AND WHERE HAVE WE DECIDED TO REINVEST THAT MONEY? SO YOU'RE SAYING IT'S A LONGSHOT THAT WE'LL GET MONEY, THAT'S WE'LL SUCCEED.

DR. PATEL: SO I'M GOING TO MAKE A DISTINCTION HERE. AND SO THERE'S TWO WAYS THAT WE GET MONEY BACK. SO MULTIPLE WAYS. LET'S FOCUS ON THERE'S THE REVENUE SHARING COMPONENT WHICH YOU ARE REFERRING TO, WHICH WOULD BE REVENUE COMING BACK TO CIRM BASED ON THE REVENUE SHARING PROVISIONS IN OUR AWARDS.

THE OTHER PART IS THAT THROUGH NORMAL AWARD MANAGEMENT PROCESSES, AWARDS MIGHT END EARLY,

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THEY MAY GET TERMINATED. AND SO BECAUSE WE COMMIT FUNDS UP FRONT, WE COMMIT, LET'S SAY, $10 MILLION UP FRONT, BUT THE AWARD ENDS EARLY OR IS TERMINATED AND WE DIDN'T DEPLOY FIVE MILLION OF THAT. THAT FIVE MILLION COMES BACK INTO THE RESEARCH BUDGET TO BE REDEPLOYED.

FOR THIS PROGRAM, WHAT WE'RE SAYING IS THAT WE'LL ONLY DO THAT IN THE EVENT THAT RAPID AWARD FUNDS ARE RECOVERED AND THAT WE CAN REDEPLOY IT.

MS. DURON: OKAY. THANK YOU FOR THE CLARIFICATION. I THINK THIS IS WHERE SOME OF OUR SKEPTICISM, AT LEAST FOR THE PUBLIC AND THE TRANSPARENCY FOR THE PUBLIC, HAS TO BE THE CLARITY AND THE CLARIFICATION ABOUT BECAUSE I'M ONLY HEARING ONE THING. TAKE MONEY OUT, PUT IT OUT THERE, PULL IT BACK IN TO REWARD CIRM FOR ITS INVESTMENT. THAT'S WHAT I HEAR. WHAT I HOPE FOR, WHICH I HAVEN'T SEEN ANY REPORTS ABOUT WHETHER WE HAVE BEEN SUCCESSFUL AT ALL. I UNDERSTAND WHAT YOU'RE TALKING ABOUT ON THE OTHER BECAUSE THOSE, I'M SURE, WE'VE SEEN ANY NUMBER OF TIMES. SO I'M STILL WANTING TO ASK FOR A REPORT IF SOMEONE CAN DETERMINE WHAT THAT REPORT'S GOING TO LOOK LIKE AND HOPE IT'S NOT GOING TO BE SO DE FECI GO BACK 20 YEARS.

DR. THOMAS: YSABEL, WE'LL BE HAPPY TO COME BACK AND REPORT ON THAT QUESTION.

MS. DURON: THANK YOU.

CHAIRMAN IMBASCIANI: GOOD. THAT'S A NICE ANSWER. I DON'T SEE ANY OTHER HANDS IN THE ROOM. IS THERE ANY BOARD MEMBER ON THE ZOOM THAT WANTS -- NO. GOOD. THEN I WOULD LIKE TO INVITE MEMBERS OF THE PUBLIC. CAN'T OFFER YOU A PLATFORM, BUT WE CAN OFFER YOU A MICROPHONE TO MAKE PUBLIC COMMENTS. OR ON THE TELEPHONE. I'M BEING TOLD THERE ARE NO HANDS. OKAY. IF THERE ARE NO OTHER COMMENTS FROM BOARD MEMBERS, WE CAN PROCEED TO A VOTE ON THE MOTION MADE BY MARK FISCHER-COLBRIE TO ACCEPT THE RAPID PROGRAM.

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

JUDY CHOU.

DR. CHOU: AYE.

MR. TOCHER: DEBORAH DEAS.

DR. DEAS: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: JEFF GOLDEN. JEFF, YOU MAY BE MUTED. I'LL COME BACK.

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DR. GOLDEN: YES. SORRY. I'M THERE. YES.

MR. TOCHER: THANK YOU, JEFF.

LINDA MALKAS. LINDA, PERHAPS YOU'RE MUTED AS WELL. I'LL COME BACK.

JOE PANETTA.

MR. PANETTA: YES.

DR. MALKAS: LINDA IS YES. SORRY. THE LAPTOP WAS BEING A PAIN.

MR. TOCHER: NO PROBLEM. THANK YOU, LINDA.

AND KAROL.

DR. WATSON: YES.

MR. TOCHER: THANK YOU VERY MUCH. THANK YOU, MR. CHAIR. THE MOTION CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU. LOOKING OUT TO AGENDA ITEM NO. 13.

MR. TOCHER: REQUESTING A FIVE-MINUTE BIO BREAK.

CHAIRMAN IMBASCIANI: UH-HUH. GRANTED.

(A RECESS WAS TAKEN.)

CHAIRMAN IMBASCIANI: OKAY. WELCOME BACK FROM YOUR BREAK. WERE ARE NOW UP TO AGENDA ITEM NO. 13. AND TO INTRODUCE THIS ITEM, I'M GOING TO HAVE THE CHAIRMAN OF OUR SCIENCE SUBCOMMITTEE, BOARD

MEMBER MARK FISCHER-COLBRIE, WILL HAVE SOME REMARKS AND MAKE AN INTRODUCTION. THANK YOU, MARK.

MR. FISCHER-COLBRIE: THANK YOU. I'M PLEASED TO INTRODUCE THE DIRECTOR OF GRANTS MANAGEMENT, DOUG KEARNEY, TO DISCUSS A MINOR MODIFICATION WITH RESPECT TO OUR AWARDS MANAGEMENT POLICY THAT COVERS ELEMENTS AROUND RATES FOR FACILITIES OVERHEAD. SO WITH THAT, DOUG, TAKE IT AWAY.

MR. KEARNEY: THANK YOU, DR. FISCHER-COLBRIE. SO I DID NOTICE THEY JUST BROUGHT OUT POPCORN, BUT I SERIOUSLY DOUBT IT'S GOING TO BE THAT EXCITING. GOOD AFTERNOON, ESTEEMED MEMBERS OF THE BOARD AND PUBLIC. MY NAME IS DOUG KEARNEY. I'M THE DIRECTOR OF GRANTS MANAGEMENT HERE AT CIRM. AND I'M HERE TODAY TO REQUEST APPROVAL FOR A MODIFIED FACILITIES RATE POLICY.

IN DECEMBER OF LAST YEAR, THE BOARD APPROVED THE ADOPTION OF A NEW AWARD MANAGEMENT POLICY WHICH WE CALL THE AMP. WHILE CIRM'S ALLOWABLE FACILITIES COST POLICY WAS ARTICULATED IN OUR PREVIOUS GRANTS ADMINISTRATION POLICIES, THE AMP RELIES ON THE BOARD TO SET ALLOWABLE FACILITIES RATES OUTSIDE OF THAT DOCUMENT. THIS METHOD PROVIDES FLEXIBILITY TO THE BOARD TO MAKE FUTURE

ADJUSTMENTS TO OUR FACILITIES RATE POLICY IN AN UNCERTAIN NATIONAL LANDSCAPE.

WHEN THE AWARD MANAGEMENT POLICY GOES INTO EFFECT LATER THIS QUARTER, CIRM NEEDS TO HAVE A POLICY IN PLACE. AS I JUST DESCRIBED, THE PURPOSE OF THIS PROPOSAL IS TO -- WE HAVE THE OPPORTUNITY TO SIMPLIFY AND CLARIFY THE POLICY AROUND ALLOWABLE FACILITIES RATES FOR AWARDEES AND THE CIRM TEAM.

OUR CURRENT POLICY, WHICH I WILL DESCRIBE IN A MOMENT, HAS WORKED WELL FOR CIRM OVER THE YEARS AND CAN CONTINUE TO DO SO FOR THE FORESEEABLE FUTURE, BUT WE BELIEVE SOME MODIFICATIONS MAY BE BENEFICIAL. THESE MODIFICATIONS ARE LIMITED TO THE ALLOWABLE FACILITIES RATES FOR INSTITUTIONS THAT DO NOT HAVE A FEDERALLY NEGOTIATED RATE.

THE IMPACT OF THESE MODIFICATIONS WOULD AFFECT A LIMITED NUMBER OF FUTURE APPLICANTS, AND I'LL TALK MORE ABOUT THAT IN A MOMENT.

BOTH CIRM AND THE FEDERAL GOVERNMENT PROVIDE TWO TYPES OF SUPPORT TO SUBSIDIZE THE UNDERLYING COSTS OF DOING RESEARCH, FACILITIES COSTS AND ADMINISTRATIVE COSTS. FACILITIES COSTS COVER GENERAL OPERATING COSTS OF THE FACILITIES AND ADMINISTRATIVE COSTS COVER GENERAL ADMINISTRATION EXPENSES.

WE RELY ON FEDERALLY NEGOTIATED RATE AGREEMENTS TO ESTABLISH HOW MUCH TOTAL OVERHEAD OUR AWARDEES CAN REQUEST FROM CIRM. ALTHOUGH CIRM ARRANGES COMPONENTS OF THESE NEGOTIATED RATES DIFFERENTLY BY SEPARATING OUT FACILITIES AND ADMINISTRATIVE RATES, THE RESULT OF OUR CALCULATION METHOD PROVIDES AN EQUIVALENT AMOUNT OF FUNDING TO THE FEDERAL POLICY.

AGAIN, WE ARE ONLY TALKING ABOUT FACILITIES COSTS IN THIS PRESENTATION.

WHERE OUR POLICY DIFFERS FROM THE FEDERAL POLICY IS WHEN NO RATE AGREEMENT HAS BEEN NEGOTIATED. IN THE FEDERAL SYSTEM, AWARDEES ARE LIMITED TO 15 PERCENT TOTAL FACILITIES IN ADMINISTRATIVE COSTS UNTIL NEGOTIATIONS HAVE BEEN COMPLETED. AT CIRM WE LIMIT FOR-PROFIT AWARDEES AND NONPROFIT AWARDEES WITHOUT ESTABLISHED RATES TO 35 PERCENT FACILITIES. THE 35 PERCENT MUST BE NEGOTIATED AND SUPPORTED BY A DEMONSTRATION OF NEED, CREATING ADMINISTRATIVE BURDEN FOR BOTH PARTIES WHEN LAUNCHING AN AWARD.

LET'S WALK THROUGH OUR CURRENT PROCESS. SO WE START WITH AN AWARDEE. THAT AWARDEE IS EITHER A FOR-PROFIT OR A NONPROFIT ORGANIZATION. A FOR-PROFIT ORGANIZATION CAN REQUEST UP TO 35 PERCENT

FACILITIES SUBJECT TO NEGOTIATION WITH CIRM. A NONPROFIT ORGANIZATION EITHER HAS A FEDERALLY NEGOTIATED RATE OR THEY DO NOT. WHEN THEY HAVE A FEDERALLY NEGOTIATED RATE, CIRM WILL HONOR THAT RATE TO ESTABLISH THE ALLOWABLE CIRM FACILITIES RATES. IF THEY DO NOT HAVE A FEDERALLY NEGOTIATED RATE, THEY CAN REQUEST UP TO 35 PERCENT SUBJECT TO NEGOTIATION WITH CIRM.

AND, AGAIN, THE ITEMS HIGHLIGHTED IN GOLD ARE THE ONLY ITEMS THAT WE'RE PROPOSING TO CHANGE IN THIS PROPOSAL.

WE PROPOSE THAT CIRM CONTINUE TO ACCEPT FEDERALLY NEGOTIATED RATES PER OUR LONG-STANDING POLICY. FOR NONPROFIT AWARDEES WITHOUT A PREVIOUS RATE AGREEMENT AS WELL AS FOR-PROFIT AWARDEES, THE CIRM FACILITIES RATE WOULD BE LIMITED TO A 15-PERCENT FLAT RATE ALIGNING WITH CURRENT FEDERAL POLICY.

LET'S WALK THROUGH WHAT THAT PROCESS WOULD LOOK LIKE. AGAIN, WE START WITH AN AWARDEE WHO'S EITHER A FOR-PROFIT OR A NONPROFIT. A FOR-PROFIT APPLICANT CAN REQUEST UP TO 15 PERCENT FACILITIES WITHOUT THE REQUIREMENT FOR NEGOTIATIONS WITH CIRM. A NONPROFIT APPLICANT HAS A CURRENT PROVISIONAL OR PREVIOUSLY NEGOTIATED FEDERAL RATE OR THEY DO NOT.

IF THE FORMER, THEN WE WOULD CONTINUE TO HONOR THOSE FEDERALLY NEGOTIATED RATES. IF THEY DON'T HAVE ANY OF THOSE, THEN THEY COULD REQUEST UP TO 15 PERCENT FACILITIES AGAIN WITHOUT THE NEED FOR NEGOTIATIONS WITH CIRM.

HIGHLIGHTING IN GOLD THE CHANGES FROM THE PREVIOUS SLIDE. SO WHAT'S THE IMPACT OF THIS PROPOSAL? WHILE 96 PERCENT OF OUR NONPROFIT AWARDEES DO HAVE FEDERALLY NEGOTIATED RATES AND CIRM CAN CONTINUE TO HONOR THOSE. FOR NONPROFITS WITHOUT RATE AGREEMENTS, CIRM WILL STILL PROVIDE OVERHEAD FUNDING, BUT WITH LESS ADMINISTRATIVE BURDEN. FOR FOR-PROFIT APPLICANTS, THE MAJORITY OF FOR-PROFIT AWARDEES DON'T REQUEST FACILITIES FROM US AT ALL, OPTING TO MAXIMIZE DIRECT PROJECT COSTS WITHIN OUR TOTAL COST CAPPED AWARDS. SO ALTHOUGH THIS IS LOWERING THE LIMIT FROM 35 TO 15 PERCENT, IT DOES AFFECT A MINORITY OF OUR APPLICANTS, FOR-PROFIT APPLICANTS.

THE BENEFITS THAT WE SEE FROM THIS PROPOSAL ARE THAT IT SIMPLIFIES AWARD LAUNCH AND PROVIDES A CLEARLY DEFINED POLICY THAT MORE CLOSELY ALIGNS WITH FEDERAL PRACTICE. IT ELIMINATES HIGHER THAN AVERAGE FACILITIES RATES TO ORGANIZATIONS WHO HAVE NOT GONE THROUGH RIGOROUS FEDERAL RATE

NEGOTIATION. AND I SKIPPED OVER SOMETHING THAT I'M GOING TO TALK ABOUT RELATED TO THAT.

SO UNDER OUR EXISTING POLICY, A NONPROFIT WITHOUT FEDERALLY NEGOTIATED RATES CAN REQUEST UP TO 35 PERCENT FACILITIES RATES. AND ENTITIES THAT HAVE UNDERGONE THAT FEDERAL RATE SETTING PROCESS AVERAGE AROUND 30 PERCENT. SO, THEREFORE, IT'S POSSIBLE TO POTENTIALLY GET MORE FACILITIES RATES WITHOUT HAVING GONE THROUGH THAT FEDERAL RATE SETTING PROCESS, WHICH IS SOMETHING THAT WE'RE HOPING TO CORRECT WITH THIS. MOST IMPORTANTLY, IT RETAINS THE FLEXIBILITY TO ADOPT A NEW MODEL AS NEEDED TO ADEQUATELY SUPPORT CALIFORNIA INSTITUTIONS.

SO THE CIRM TEAM REQUESTS THE ICOC APPROVE THE ALLOWABLE FACILITIES RATE STRUCTURE AS PRESENTED TODAY.

MR. FISCHER-COLBRIE: SO MOVED.

CHAIRMAN IMBASCIANI: THERE WE GO. WE HAVE A MOVEMENT TO ACCEPT THE RECOMMENDATION.

DR. DULIEGE: SECOND.

CHAIRMAN IMBASCIANI: ANNE-MARIE SECONDED. YES. THANK YOU. SO COMMENTS FROM BOARD MEMBERS. WE'LL START WITH KIM BARRETT. THANKS. AND JOHN.

DR. BARRETT: SO THANK YOU VERY MUCH FOR YOUR PRESENTATION. I WONDERED, AS OF RIGHT NOW, IT

LOOKS LIKE THE FEDERAL GOVERNMENT'S EFFORTS TO REDUCE F AND A TO 15 PERCENT HAS BEEN AT LEAST STYMIED, IF HOPEFULLY RETIRED. BUT WHAT WOULD BE THE IMPACT IF AT SOME FUTURE POINT CALIFORNIA INSTITUTIONS ARE VERY MUCH UNDERSUPPORTED BY THE FEDERAL GOVERNMENT?

MR. KEARNEY: RIGHT. SO GOING BACK TO THE AWARD MANAGEMENT POLICY, IT GIVES THE BOARD THE AUTHORITY TO SET OUR FACILITIES RATE, OUR OVERHEAD RATE POLICIES. SO IF SOMETHING HAPPENED ON THE NATIONAL SCALE THAT REQUIRED A CHANGE IN US RELYING ON THESE FEDERALLY NEGOTIATED RATES, THE BOARD CAN ASK US TO COME BACK WITH PROPOSALS FOR AN ALTERNATE FUNDING STRATEGY.

DR. CARETHERS: ALSO THANK YOU FOR THIS PRESENTATION. THIS IS ONLY THE FACILITY PIECE OF THE F AND A. SO I THINK IN THE FEDERAL, IT WAS BOTH F AND A THAT WAS GOING TO GO DOWN. I GUESS MY QUESTION, IF THIS IS PEGGED AT THE FEDERAL RATES, ARE THE -- IS THE ADMINISTRATION COMPONENT, I KNOW YOU DIDN'T TALK ABOUT THAT, IS THAT ALSO PEGGED AT A NEGOTIATED RATE OR A FEDERAL RATE?

MR. KEARNEY: WE HAVE AN INDIRECT COST POLICY OF 20 PERCENT. SO I REFERRED THAT WE SORT OF CALCULATE THINGS DIFFERENTLY, BUT IT COMES OUT TO

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AROUND THE SAME AMOUNT OF FUNDING. WE'RE NOT PROPOSING ANY CHANGES TO OUR ADMINISTRATIVE OVERHEAD RATES AT THIS TIME. SO YOU'RE RIGHT. I DIDN'T TALK ABOUT THAT IN THIS BECAUSE WE'RE TALKING ABOUT FACILITIES, BUT THAT DOES IMPACT THE OVERALL OVERHEAD THAT OUR AWARDEES CAN RECEIVE.

CHAIRMAN IMBASCIANI: GEORGE.

DR. BLUMENTHAL: THANK YOU. YOU ALLUDED TO THE FACT THAT PRIVATE ENTITIES HAVE MORE FLEXIBILITY WITH REGARD TO DIRECT CHARGES. COULD YOU SAY A LITTLE BIT MORE ABOUT THAT?

MR. KEARNEY: SURE. SO OUR AWARD MECHANISMS ARE ALL TOTAL COST CAPPED AWARDS. SO EVERY APPLICANT CAN ASK FOR THE SAME LIMIT, TOTAL LIMIT. OUR NONPROFIT AWARDEES GENERALLY HAVE OVERHEAD RATES THAT THEY MUST CHARGE TO ALL SPONSORED RESEARCH PROJECTS TO STAY IN BUSINESS. WHEREAS, WHAT WE FOUND WITH FOR-PROFIT APPLICANTS IS MANY OF THEM WILL NOT ASK US FOR OVERHEAD SUPPORT AND INSTEAD MAXIMIZE UP TO THE AWARD CAP AND ASK FOR DIRECT PROJECT COSTS AND NOT ASK CIRM FOR THOSE OVERHEAD COSTS. SO THAT'S BEEN A VERY CLEAR TRAJECTORY WHERE NONPROFITS ALWAYS ASK FOR IT. FOR-PROFITS USUALLY DON'T.

DR. BLUMENTHAL: IS THERE A DIFFERENCE IN

THE WAY THAT DIRECT COSTS ARE CALCULATED BETWEEN THOSE TWO GROUPS?

MR. KEARNEY: NO.

CHAIRMAN IMBASCIANI: OKAY. ANY OTHER COMMENT FROM BOARD MEMBERS IN THE ROOM? HOW ABOUT ONLINE? NO COMMENTS. OKAY. SO ANY MEMBER OF THE PUBLIC WANT TO COMMENT ON THE MOTION ON THE FLOOR? AND THERE ARE NO HANDS RAISED. IN THAT CASE WE CAN PROCEED TO A VOTE THEN. VOICE VOTE.

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

JUDY CHOU.

DR. CHOU: AYE.

MR. TOCHER: DEBORAH DEAS.

DR. DEAS: YES.

MR. TOCHER: ELENA FLOWERS.

DR. FLOWERS: YES.

MR. TOCHER: JEFF GOLDEN.

DR. GOLDEN: YES.

MR. TOCHER: LINDA MALKAS.

DR. MALKAS: YES.

MR. TOCHER: JOE PANETTA. KAROL WATSON.

DR. WATSON: YES.

MR. TOCHER: THANK YOU VERY MUCH. THE

MOTION CARRIES.

CHAIRMAN IMBASCIANI: THANK YOU. ADVANCING NOW TO ITEM 15 OF THE AGENDA, THIS IS A DISCUSSION ON OUR 2023 TO 24 FINANCIAL AUDIT. OUR VICE PRESIDENT FOR OPERATIONS, JENN LEWIS, WILL LEAD THE DISCUSSION AND INTRODUCE OUR AUDITOR.

MS. LEWIS: THANK YOU, CHAIR IMBASCIANI AND MEMBERS OF THE BOARD. THANK YOU FOR GIVING ME THE OPPORTUNITY TO INTRODUCE THE FISCAL YEAR 23/24 FINANCIAL AUDIT.

AS BACKGROUND, PER PROPOSITION 14, CIRM IS REQUIRED TO HAVE AN INDEPENDENT AUDIT OF OUR FINANCIAL STATEMENTS ON AN ANNUAL BASIS, WHICH IS THEN REVIEWED AND AUDITED BY THE STATE CONTROLLER'S OFFICE FOR A QUALITY REVIEW THEY CALL IT.

FOR 23/24 FISCAL YEAR, CIRM ENGAGED MACIAS, GINI & O'CONNELL FOR THAT INDEPENDENT AUDIT, AND WE REFER TO THEM AS MGO, TO COMPLETE THE INDEPENDENT AUDIT. THIS AUDIT TESTED THE FAIR REPRESENTATION OF OUR FINANCIAL DATA, LOOKED AT OUR INTERNAL CONTROLS TO ENSURE THAT WE WERE NOT MISREPRESENTING ANY FINANCIAL DATA DUE TO ERROR OR FRAUD.

AND ON BEHALF OF THE CIRM'S FINANCE TEAM, I'M HAPPY TO REPORT THAT, ONCE AGAIN, THERE WERE NO

FINDINGS IN THIS AUDIT.

THE AUDIT WAS CERTIFIED BY THE STATE CONTROLLER'S OFFICE SUBSEQUENT TO THE COMPLETION BY MGO. AND THEN IN DECEMBER OF LAST YEAR, IT WAS PRESENTED TO THE CITIZENS' FINANCIAL ACCOUNTABILITY AND OVERSIGHT COMMITTEE THAT IS HEAD BY THE STATE CONTROLLER.

I WANT TO THANK DIRECTOR OF FINANCE MICHELE LEWIS, WHO'S ON THE LINE, AS WELL AS HER TEAM, SENIOR FINANCE OFFICER SUMI THOMASIN WHO LED THAT PROCESS.

AND NOW I'D LIKE TO INTRODUCE OUR AUDITORS, RUSSELL ROBERTSON, WHO IS THE ASSURANCE DIRECTOR AT MGO, AND KATHLEEN FOSTER, WHO IS THE ASSURANCE MANAGER AT MGO, WHO WILL REVIEW THE RESULTS OF THAT AUDIT ANALYSIS AND ANY CONCLUSIONS. AND HAPPY TO ANSWER ANY QUESTIONS.

MR. ROBERTSON: THANKS, JENN. THANKS, BOARD, FOR ALLOWING US TO DO A QUICK OVERVIEW OF THE 23/24 AUDIT RESULTS. JENN DID A GREAT SUMMARY OF WHY YOU'RE HAVING THIS AUDIT AS A REQUIREMENT. AND I WILL GO THROUGH BRIEFLY SOME OF THE RESULTS AND HIGHLIGHT SOME OF THE OPERATIONS FOR THE PREVIOUS YEAR. NEXT SLIDE PLEASE.

HERE'S THE QUICK AGENDA. I'M GOING TO

BRIEFLY GO OVER THE SCOPE AND THE SERVICES AND DELIVERABLES THAT WERE PRESENTED FOR FISCAL YEAR 23/24, AGAIN GIVE YOU THE AUDIT RESULTS, SOME OPERATIONAL HIGHLIGHTS. AND THERE'S -- I'LL GO INTO A SECONDARY REPORT CALLED THE REQUIRED COMMUNICATION REPORT THAT'S PRESENTED TO THE BOARD AS WELL THAT YOU SHOULD HAVE BOTH THE INDEPENDENT AUDIT REPORT AND THIS COMMUNICATION REPORT. I'LL GO OVER THAT BRIEFLY AND GO OVER SOME OF THE HIGHLIGHTS IN THAT REPORT AS WELL. NEXT SLIDE PLEASE.

AS INDICATED, THE SCOPE OF OUR SERVICES FOR THIS AUDIT WAS FOR THE BASIC FINANCIAL STATEMENTS FOR FISCAL YEAR 24. THE AUDIT WAS CONDUCTED LAST YEAR AND ISSUED SOMETIME IN LATE SUMMER, AND NOW WE ARE GETTING TO THE RESULTS. WITH THOSE DELIVERABLES, WE HAVE WHAT IS CALLED INDEPENDENT AUDIT REPORT. IN THAT REPORT IS THE MAIN PIECE OF THE AUDIT WHERE WE PROVIDE OUR OPINION OVER THE FINANCIAL STATEMENTS AND THE MATERIAL ASPECTS OF THOSE FINANCIAL STATEMENTS.

WE ALSO HAVE A SECONDARY REPORT IN THERE, AND THAT REPORT IS ON THE INTERNAL CONTROL OVER FINANCIAL REPORTING. I ALWAYS LIKE TO SAY IN THIS REPORT WE ASSESS INTERNAL CONTROL, AND WE DO TEST THOSE CONTROLS. WE DON'T PROVIDE AN OPINION OVER

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THOSE INTERNAL CONTROLS. SO YOU WON'T SEE THAT IN THAT REPORT. BUT IF THERE WERE ANY ISSUES THAT POPPED UP THROUGH THOSE TESTS THAT WE DID, WE WOULD IDENTIFY THOSE AND COMMUNICATE THOSE AS WELL. AND THEN THE SECONDARY REPORT THAT I'LL BE TALKING ABOUT IS THAT COMMUNICATIONS AT THE CONCLUSION OF THE AUDIT. NEXT SLIDE PLEASE.

SO AS JENN WAS INDICATING, FOR THE FISCAL YEAR 24, WE PROVIDED MODIFIED OPINIONS OVER THE FINANCIAL STATEMENTS. AND WHAT THAT REALLY MEANS IN A NUTSHELL IS THAT THE FINANCIAL STATEMENTS PRESENT FAIRLY IN ALL MATERIAL RESPECTS OF CIRM'S FINANCIAL POSITION AND THE RESULTS OF OPERATIONS. AND THOSE ARE IN ACCORDANCE WITH GENERALLY ACCEPTED ACCOUNTING PRINCIPLES. THERE WERE NO MATERIAL MISSTATEMENTS, NO SCOPE LIMITATIONS. WE WERE ABLE TO AUDIT EVERYTHING. OUR FOCUS IS ON MATERIAL AREAS, LOOK AT THE EXPENDITURES, ANY OF THE GRANTS THAT WERE PROVIDED TO CIRM DURING THE YEAR, THE COLLECTIONS OF MONIES RECEIVED. SO WE LOOK AT MATERIAL AREAS IN THE OPERATIONS OF CIRM. SO THERE WERE NO SCOPE LIMITATIONS. WE WERE ABLE TO TEST EVERYTHING WE COULD. NO DISAGREEMENTS WITH MANAGEMENT DURING THAT AUDIT.

AND UNDER GOVERNMENTAL AUDITING STANDARDS,

AS I INDICATED, WE TESTED CONTROLS AND THERE WAS NO FINDINGS IDENTIFIED. AND THERE WERE NO INSTANCES OF NONCOMPLIANCE WITH LAWS AND REGULATIONS.

SO OVERALL A VERY CLEAN, EFFICIENT AUDIT, NO PROBLEMS, AS JENN WAS INDICATING. SO VERY EASY TO GET THROUGH THE AUDIT. AND WE WERE ABLE TO GET ALL THE INFORMATION WE NEEDED TO CONDUCT THAT AUDIT. SO EVERYTHING WAS GOOD ON THAT FRONT. NEXT SLIDE PLEASE.

SO IN THE NEXT COUPLE SLIDES, I'LL BRIEFLY GO OVER SOME VERY HIGH LEVEL OPERATIONAL HIGHLIGHTS. THAT WAS THE FOCUS OF OUR AUDIT. IT WAS THE REVENUE COMING IN OBVIOUSLY AND THE EXPENDITURES GOING OUT. AS WE IDENTIFIED AND YOU WILL SEE IN THE REPORT, THE CHANGE IN FINANCIAL POSITION AND LIQUIDITY INCREASED BY 124 MILLION FROM 213 TO 337. THE MAIN DRIVER OF THIS WAS PROP 14 GO BONDS, GENERAL OBLIGATION BONDS PROCEEDS OF 383 MILLION AND PROPOSITION 71 COMMERCIAL PAPER OF 52.8 MILLION. AND THERE WAS SOME HIGHER INVESTMENT EARNINGS, ROUGHLY ABOUT SIX OR SEVEN -- 9 MILLION INCREASE IN INVESTMENT EARNINGS BECAUSE OF THE INFLUX OF CASH DURING THE YEAR THAT WAS HELD BY CIRM. NEXT SLIDE PLEASE.

OUR FOCUS WAS, OF COURSE, ON THE MAJOR PROGRAMS. WE IDENTIFY HERE RESEARCH GRANTS TOTAL

NEARLY $300 MILLION. THAT REPRESENTED A MAJORITY OF THE EXPENSES FOR THE YEAR. THIS WAS AN INCREASE OF 104 MILLION YEAR OVER YEAR FROM '23. WE HAVE IDENTIFIED THE THREE MAJOR FUND AREAS HERE. FOR THE STEM CELL RESEARCH AND CURES FUND, GRANT EXPENDITURES INCREASED SIGNIFICANTLY AS THE FUND WORKS TO BE FULLY EXPENDING THE PROP 71 AUTHORIZED FUNDING.

THE STEM CELL RESEARCH AND CURES FUND, THE INCREASED PAYMENTS WAS BECAUSE OF OVERALL INCREASED ACTIVITY WHILE NEW GRANTS WERE AWARDED DURING THE YEAR, AND SOME MILESTONES WERE MET AS THE COMPLETION OF THE GRANTS FROM THE PRIOR YEAR. AND THE REVENUES AND ROYALTIES, NO ACTIVITY DURING THE YEAR, BUT CIRM IS WORKING TOWARDS DEVELOPING A PLAN. AND PROBABLY BY FISCAL YEAR '25 THAT'S ALREADY ROLLING OUT BECAUSE WE ARE A YEAR -- REPORTING ON A YEAR AND BACK. SO THAT'S PROBABLY ALREADY IN THE WORKS AND ENROLLING ELIGIBLE PATIENTS FOR THE AWARDS. NEXT SLIDE PLEASE.

THIS SLIDE FOCUSES ON THE REQUIRED COMMUNICATION REPORT. IN THIS REPORT THIS IS REALLY FOR YOU AS A GOVERNING BODY. THIS REALLY HIGHLIGHTS ANY CHANGES YEAR OVER YEAR, ANY NEW ACCOUNTING POLICIES THAT ARE INITIATED, ANY NEW OR SIGNIFICANT

ACCOUNTING ESTIMATES. THERE WERE SOME NEW ACCOUNTING STANDARDS; HOWEVER, THEY DIDN'T HAVE AN IMPACT ON CIRM FOR FISCAL YEAR '24. THERE WAS A COUPLE THAT DIDN'T REALLY MATERIALLY AFFECT THE OPERATIONS OF CIRM. THERE IS NO MISSTATEMENTS AS INDICATED EARLIER. IF THERE WAS, THEY WOULD BE IN THIS REPORT. NO DISAGREEMENTS, AS I INDICATED BEFORE, AND NO SUBSEQUENT MATTERS TO REPORT ON.

SO OVERALL, AS YEAR TO YEAR GOES, THERE WAS AN INCREASE OF EXPENDITURES, BUT REALLY A SMOOTH TRANSITION FROM '23 TO '24. NO SIGNIFICANT CHANGES ON HOW THE FINANCE TEAM CONDUCTS OPERATIONS. SO VERY CLEAN. AND REALLY APPRECIATE WORKING WITH CIRM'S STAFF TO GET THIS AUDIT COMPLETED. I THINK THAT'S THE LAST SLIDE FOR MY PRESENTATION, BUT I'M HERE TO ANSWER ANY QUESTIONS IF THERE ARE ANY.

MR. TOCHER: MARK.

MR. FISCHER-COLBRIE: JUST HAD A QUESTION. I ASSUME THAT ONE OF THE STEPS IN THE PROCESS WILL BE A REVIEW BY THE CITIZENS FINANCIAL ACCOUNTABILITY OVERSIGHT COMMITTEE. I THINK THAT'S GOING TO HAPPEN AFTER THIS; IS THAT CORRECT? JUST WANTED TO CONFIRM THAT.

MS. LEWIS: FOR FISCAL YEAR 23/24, THE CONTROLLER SCHEDULED THAT MEETING IN LATE DECEMBER.

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SO ACTUALLY DUE TO THE TIMING, UNFORTUNATELY WE HAD TO BRING THAT TOO, BUT THAT HAS BEEN REVIEWED BY THE CFAOC AS WELL IN LATE DEC EMBER AND THEN SUBSEQUENTLY HERE AT THE BOARD MEETING. AND THEN NEXT YEAR, OBVIOUSLY FISCAL YEAR 24/25, WE'VE COMPLETED THAT AUDIT. WE'VE SUBMITTED IT TO THE STATE CONTROLLER'S OFFICE FOR QUALITY REVIEW. ONCE WE GET THAT COMPLETED, THEN WE WILL BRING IT TO THE BOARD.

MR. FISCHER-COLBRIE: THANK YOU.

CHAIRMAN IMBASCIANI: ANY OTHER QUESTIONS OF THE AUDITOR OR OF JENN OR ON ZOOM?

MS. FOSTER: THIS IS KATHLEEN FOSTER. JUST BRIEFLY, THE STATE CONTROLLER'S OFFICE IS CURRENTLY IN THE MIDDLE OF THEIR REVIEW FOR 24/25'S AUDIT. SO HOPEFULLY WE'LL BE ABLE TO PRESENT IT SOONER TIMEWISE FROM THE END OF THE PERIOD.

CHAIRMAN IMBASCIANI: SURE. OKAY. WE'LL LOOK FORWARD TO THAT. THANK YOU. JENN, GOOD REPORT. IT'S ALWAYS GOOD NEWS AS USUAL. THANK YOU SO MUCH.

SENIOR DIRECTOR OF COMMUNICATIONS, AMY ADAMS, IS GOING TO BRING US UPDATE ON COMMUNICATIONS, ITEM NO. 16.

MS. ADAMS: THANK YOU, MEMBERS OF THE

BOARD, CIRM TEAM, AND MEMBERS OF THE PUBLIC LISTENING IN. I WANT TO START THIS PRESENTATION, I'M ALWAYS UP HERE BABBLING AWAY AT YOU GUYS WHILE MY TEAM WORKS VERY HARD. I WANT TO SAY RIGHT NOW AS I TELL YOU ABOUT WHAT WE'VE HAVE DOING AND WILL DO IN THE FUTURE, THEY'RE WORKING VERY HARD GETTING A PRESS RELEASE OUT ABOUT THE RAPID PROGRAM, POSTING A STORY ABOUT THE BOARD MEETING SO THAT EVERYONE IN THE CALIFORNIA PUBLIC CAN KNOW WHAT'S BEEN GOING ON. THERE'S A RAPID BLOG ITEM GOING UP. THERE'S TWO STORIES BEING WRITTEN ABOUT THE TWO PRESENTATIONS THAT HAPPENED, AND ALL OF THIS IS HAPPENING WHILE I STAND HERE -- I'M IGNORING ALL THE SLACKS THAT THEY'RE SENDING ME RIGHT NOW. SO THINGS ARE DELAYED, IT'S BECAUSE OF THIS. I THINK IT'S REALLY IMPORTANT TO ACKNOWLEDGE THE PEOPLE WHO ARE DOING SO MUCH HARD WORK.

WITH THAT, TODAY I'M GOING TO INTRODUCE A COMMUNICATIONS TOOLKIT THAT I'VE DEVELOPED TO HELP PEOPLE TALK ABOUT CIRM. DEVELOPING THIS TOOLKIT AND TRAINING PEOPLE TO USE IT WERE CALLED OUT AS SPECIFIC TACTICS IN THE STRATEGY THAT I PRESENTED AT THE LAST MEETING. TODAY I'LL ALSO UPDATE YOU ON A FEW OF THE ACTIVITIES THE TEAM HAS BEEN ENGAGED IN IN ADDITION TO WHAT THEY'RE DOING TODAY.

AS ALWAYS, I START WITH CIRM'S MISSION OF TRANSFORMATIVE TREATMENTS AND THE SCIENTISTS, STUDENTS, AND PATIENTS WHO ARE TOP OF MIND IN ALL OF OUR ACTIVITIES. AND A REMINDER OF THE COMMUNICATIONS AND OUTREACH TEAM MISSION WHICH DEFINES OUR ROLE IN HELPING CIRM ACHIEVE ITS MISSION.

AT THE LAST MEETING I PRESENTED OUR COMMUNICATIONS STRATEGY, COMMUNICATIONS AND OUTREACH STRATEGY. IT CONSISTS OF FOUR PARTS. CREATE THE STORY. TELL THE STORY. DELIVER THE STORY. AND MEASURE THE IMPACT.

THE TOOLKIT I'M GOING TO TALK ABOUT TODAY MOSTLY ADDRESSES THE FIRST TWO PARTS OF THAT STRATEGY, CREATE THE STORY AND TELL THE STORY. FIRST, HIGHLIGHTED IN RED HERE, THE NARRATIVE AND DECK. THAT WAS WHAT J.T. PRESENTED AT THE LAST BOARD MEETING. IT IS NOW PART OF THE TOOLKIT. IT IS AVAILABLE TO ALL OF YOU. IT IS POSTED TO THE AGENDA. YOU CAN REACH OUT ANY TIME AND WE CAN GIVE YOU A COPY OF THAT DECK WITH THE ASSOCIATED SCRIPT. AND JUST TEEING UP SOMETHING THAT'S NOT QUITE DONE YET, BUT WILL BE. WE'RE CREATING SOME VARIATIONS ON THAT DECK JUST SO THAT PEOPLE HAVE SOME DIFFERENT VERSIONS THAT MIGHT FEEL MORE APPROPRIATE FOR THEM

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OR THEIR AUDIENCES.

JUST A REMINDER ABOUT THAT NARRATIVE AND DECK FOR THOSE OF YOU WHO HAVE FORGOTTEN IT IN THE BUSY LAST MONTH. MIXED CIRM'S MISSION PERSONAL. IT FOCUSES ON REAL PATIENTS WHOSE LIVES HAVE BEEN IMPACTED BY CIRM'S WORK. IT'S ALSO VERY BEAUTIFUL. I THINK THE VISUAL ELEMENT OF IT REALLY HELPS HIGHLIGHT THE EMOTIONS IN THE STORY.

IT ALSO, CONVENIENTLY, HITS ALL FOUR OF CIRM'S KEY MESSAGES WHICH I'M GOING TO TALK ABOUT NEXT.

OKAY. SO THE NEXT PART OF MY STRATEGY IS TELLING CIRM'S STORY. AND WE'RE GOING TO FOCUS THERE FOR A LITTLE BIT TODAY. JUST A REMINDER. HERE'S THE TOOLKIT. WE'RE GOING TO START BY TALKING ABOUT SOME MESSAGING. THE MESSAGING IS ATTACHED TO THE MEETING AGENDA, AND YOU'RE ALL WELCOME TO TAKE A LOOK AT IT. I'M HAPPY TO TAKE QUESTIONS NOW OR LATER ABOUT EVERYTHING IN THE MESSAGING. I'M NOT GOING THROUGH EVERY WORD OF THAT MESSAGING DOCUMENT UP HERE BECAUSE IT'S BEEN A LONG DAY. I'M GOING TO GO THROUGH SOME KEY POINTS THOUGH JUST SO WE ALL KIND OF GET OUR HEADS AROUND HOW TO USE THAT MESSAGING.

TO BE CLEAR, THIS MESSAGING DOESN'T

NECESSARILY SAY ANYTHING NEW. WE'RE THE SAME ORGANIZATION WITH THE SAME MISSION, BUT IT HELPS US TALK ABOUT THE ORGANIZATION IN A WAY THAT MIGHT RESONATE MORE WITH OUR VARIOUS AUDIENCES. SOME OF YOU WHO WERE HERE MIGHT RECALL THAT IN JUNE AT THIS VERY PODIUM I SAID ONE REASON I THOUGHT CIRM WAS STRUGGLING TO BE BETTER KNOWN IN THE STATE WAS BECAUSE SOME OF THE WORDS WE USE IN TALKING ABOUT OURSELVES, INSTITUTE, REGENERATIVE MEDICINE, STEM CELLS. THESE ARE KIND OF BIG, COMPLEX WORDS AND AREN'T GOING TO RESONATE WITH EVERYONE.

THIS IS A REAL WORD CLOUD I MADE FROM OUR NEW MESSAGING. IT'S GOT SOME OF THE SAME WORDS IN THERE. YOU CAN'T GET AWAY FROM THE WORD STEM CELL AND REGENERATIVE MEDICINE, BUT WE'VE GOT SOME NEW WORDS IN THERE TOO, THERAPIES, CURES, ACCESS, MEDICINE, AND SOME OTHER WORDS THAT I THINK WILL HELP US TALK ABOUT OURSELVES IN TERMS OF THAT ARE A LITTLE MORE REAL TO PEOPLE.

I'LL GO THROUGH A FEW SECTIONS OF THE MESSAGING TODAY. IT INCLUDES FOUR KEY MESSAGES SHOWN HERE. AND LATER IN MY PRESENTATION, I'M GOING TO GIVE YOU EXAMPLES OF HOW WE CAN USE THESE MESSAGES. HANG ON. THERE'S AN ANIMATION THAT IS NOT WORKING. THAT'S OKAY. THESE FOUR MESSAGES COME

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DOWN TO THE FOLLOWING CONCEPTS. OUR FUNDING FOCUSES ON CURES OR THERAPIES. WE'RE GOING TO TALK ABOUT THAT IN A MINUTE. WE WORK TO MAKE SURE CALIFORNIANS FROM ACROSS THE ENTIRE STATE CAN BENEFIT FROM OUR CLINICAL TRIALS AND EVENTUAL THERAPIES. WE BRING ADDITIONAL EDUCATIONAL AND ECONOMIC BENEFITS TO THE STATE. AND WE'RE ADVANCING ALL OF THIS TO BENEFIT CALIFORNIANS AT A TIME WHEN FEDERAL FUNDING IS LESS SECURE. AND I'VE HIGHLIGHTED SOME KEYWORDS HERE THAT KIND OF TOUCH ON THOSE KEY MESSAGES.

SO REALLY IF YOU USE SOME HANDFUL OF THESE WORDS IN A SENTENCE, YOU'RE PRETTY MUCH ON MESSAGE. I'M TRYING TO MAKE IT EASY FOR YOU.

SO THE MESSAGING DOCUMENT INCLUDES SOME TALKING POINTS TO HELP YOU ADDRESS THESE KEY MESSAGES IN CONVERSATIONS AND PRESENTATIONS. I THINK THE SECOND PAGE HAS EACH OF THESE KEY MESSAGES AND SOME PROOF POINTS AND LANGUAGE THAT YOU CAN USE TO TALK ABOUT THESE MESSAGES. I'M NOT GOING TO GO THROUGH THEM NOW, BUT I ENCOURAGE YOU TO LOOK AT THEM. WE TRIED TO WRITE THOSE IN LANGUAGE THAT FELT VERY NATURAL, LANGUAGE THAT YOU COULD WORK INTO AN EMAIL OR A PRESENTATION OR ANY PIECE OF WRITING TO HELP YOU BE ON MESSAGE AND ALSO SOUND COMFORTABLE.

THE DOCUMENT ALSO INCLUDES THESE PHRASES.

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BEHIND EVERY NUMBER IS A NAME. BEHIND EVERY DISEASE, CONDITION, OR INJURY IS A PERSON. WE HAVE THE POWER TO CREATE CURES THAT CHANGE LIVES. ALL THIS BECAUSE CALIFORNIANS CHOSE TO INVEST IN WORLD-CLASS SCIENCE. AND THOSE ARE THEMES THAT WERE IN THE PRESENTATION THAT J.T. DELIVERED.

THESE ARE OBVIOUSLY NOT WORDS THAT FLOW OFF THE TONGUE. YOU'RE PROBABLY NOT GOING TO WEAVE THIS INTO A CONVERSATION WITH YOUR NEIGHBOR, BUT THEY ARE THEMES THAT I THINK ARE VERY IMPORTANT AND ARE WORTH KEEPING IN MIND. FOR THE FIRST ONE, ANYTIME WE TALK ABOUT NUMBERS OF AWARDS OR THE NUMBER OF CLINICAL TRIALS WE HAVE FUNDED, WHICH THESE ARE NUMBERS WE USE QUITE A BIT, WE ALWAYS NEED TO TALK ABOUT THE PATIENTS WHO STAND TO BENEFIT FROM THAT WORK. WE'RE NOT JUST AN AGENCY THAT GIVES OUT AWARDS OR AN AGENCY THAT TRIES TO HELP PATIENTS.

WHEN WE TALK ABOUT DISEASES OR CONDITIONS OUR RESEARCHERS FOCUS ON, ALSO TALK ABOUT PEOPLE LIVING WITH THOSE CONDITIONS. WHAT IS IT LIKE TO HAVE THAT CONDITION, AND WHY DO WE WANT TO HELP THEM? FOCUS ON HOW YOUR WORK AND CIRM'S ACTIVITIES WILL DELIVER CURES OR THERAPIES AND BENEFIT CALIFORNIANS ACROSS THE STATE. AND REMIND PEOPLE THAT CALIFORNIA IS INVESTING IN THIS WORK AT A TIME

WHEN THE FUNDING LANDSCAPE IS UNCERTAIN.

THE FINAL PAGE OF THE MESSAGING, IT'S CALLED OUR MISSION IN MOTION. THE MISSION IN MOTION, THAT'S OUR STRATEGIC ALLOCATION FRAMEWORK THAT GUIDES OUR FUNDING PROGRAMS. THE SAF IS HOW WE'RE GOING TO MAKE GOOD ON THE PROMISE IN OUR KEY MESSAGES. THE SAF IS DEEPLY CONSIDERED AND THOUGHTFULLY OUTLINED; AND IT'S, THEREFORE, A LOT TO TAKE IN, WHICH HAS MADE IT HARD FOR US TO TALK ABOUT IT IN WAYS THAT REALLY EXPLAIN ITS IMPORTANCE TO THE PEOPLE OF CALIFORNIA.

SO THE LAST PAGE OF YOUR MESSAGING DOCUMENT BREAKS THE SIX GOALS OF THE SAF DOWN INTO WHAT I CALL A BITE, SNACK, MEAL APPROACH TO COMMUNICATION. AND TO BE CLEAR, I DON'T JUST CALL IT THAT. I DIDN'T MAKE THAT UP. I THINK IT'S SUPER SMART, AND I BORROWED IT FROM OTHER PEOPLE. THE BITE IS IF YOU'RE NOT SURE HOW MUCH TIME YOU HAVE OR THE PERSON'S APPETITE TO LEARN ABOUT THE SAF OR ABOUT CIRM, IN THAT CASE FOR EVERY GOAL, WE HAVE A SHORT SNAPSHOT OF WHAT THAT GOAL MEANS.

IF THE PERSON SEEMS INTERESTED OR YOU HAVE A LITTLE TIME, YOU CAN GIVE THEM THE SNACK. IN HERE I HAVE THE SNACK FOR GOAL ONE. IT'S A FULL SENTENCE.

AND IF PEOPLE ARE REALLY INTERESTED, WELL, YOU KNOW WHAT, OUR WEBSITE HAS, I THINK, NOT JUST A MEAL. I THINK IT HAS AN ENTIRE BUFFET ON THE SAF SO WE CAN GO QUITE DEEP. THIS IS JUST A WAY TO HELP PEOPLE GET INTO CONCEPTS THAT MIGHT BE HARD TO UNDERSTAND, BUT I THINK ARE INCREDIBLY IMPORTANT TO US.

OKAY. SO I'M GOING TO MOVE ON TO ANOTHER DOCUMENT THAT IS ATTACHED TO THE BOARD AGENDA AND IS AVAILABLE TO YOU ANYTIME IF YOU DON'T MEMORIZE THE URL FOR THE BOARD AGENDA AND JUST WANT TO REACH OUT TO ME. AND THAT IS AN ELEVATOR PITCH AND FAQ. SO AT THE SAME MEETING WHERE I STOOD HERE AND TALKED TO YOU ABOUT THE WORDS CIRM USES, I SAID I THOUGHT WE NEEDED A CONSISTENT WAY OF TALKING ABOUT CIRM. A DESCRIPTION OF CIRM THAT ALL OF US COULD USE AND THAT WOULD HELP US BE TALKING ABOUT SAME ORGANIZATION. BECAUSE WHEN I TALK TO -- WHEN I ASK PEOPLE HOW THEY TALK ABOUT CIRM, THEY MIGHT HAVE BEEN TALKING ABOUT 20 DIFFERENT ORGANIZATIONS. SO I GOT FEEDBACK. THANK YOU. FEEDBACK IS A GIFT.

YOU WILL NOT BE SURPRISED TO KNOW THAT THE FEEDBACK I GOT DEPENDED ON WHO IT CAME FROM. PEOPLE HAD VERY, VERY DIFFERENT IDEAS OF WHAT WAS IMPORTANT ABOUT CIRM. AND FROM THAT, I REALIZED THERE'S NEVER

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GOING TO BE A DESCRIPTION OF CIRM THAT ALL OF US CAN USE AND ALL OF US WILL FEEL COMFORTABLE WITH AND THAT WILL BE APPROPRIATE FOR ALL OF OUR AUDIENCES.

SO THIS IS WRITTEN AS AN ELEVATOR PITCH IN THE SINGULAR, AND IT'S REALLY ELEVATOR PITCH IN THE PLURAL. AND IT'S SORT OF A CHOOSE YOUR OWN ADVENTURE ELEVATOR PITCH. SO I'M GOING TO GO THROUGH THAT A LITTLE BIT SO YOU CAN THINK ABOUT HOW TO USE IT.

THIS ANIMATION IS WORKING. HERE'S A PROPOSED SENTENCE THAT YOU COULD USE. YOU'RE TALKING TO SOMEONE YOU DON'T KNOW. SO YOU'RE AT A DINNER PARTY, YOU'VE GOT NO IDEA WHO THIS PERSON IS. SO A GOOD SENTENCE MIGHT BE CIRM IS A CALIFORNIA AGENCY THAT FUNDS RESEARCH INTENDED TO PRODUCE THERAPIES FOR PEOPLE WITH INCURABLE DISEASES. AND I'VE HIGHLIGHTED THE WORDS THAT MIRROR OUR MESSAGING. SO WHATEVER QUESTIONS THE PERSON COMES BACK WITH, THEY'RE PROBABLY GOING TO BE QUESTIONS THAT ARE ON MESSAGE AND WILL ALLOW YOU TO TALK ABOUT THINGS THAT ARE CRITICAL FOR CIRM.

OKAY. I'M GOING TO GIVE YOU A LONGER EXAMPLE, AND THIS IS AN ACTUAL SCRIPT THAT I USE. I KNOW YOU'RE NOT SUPPOSED TO READ A LOT OF TEXT ON THE SLIDE OUT LOUD, BUT I'M GOING TO BREAK THAT RULE

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ONLY BECAUSE I WANT YOU TO HEAR WHAT IT SOUNDS LIKE CONVERSATIONALLY.

SO THIS IS ACTUALLY WHAT I WOULD SAY. CIRM IS A CALIFORNIA AGENCY THAT FUNDS INTENDED TO PRODUCE THERAPIES FOR PEOPLE WITH INCURABLE DISEASES. YOU MIGHT REMEMBER THAT IN 2004 THERE WAS A PROPOSITION TO FUND STEM CELL RESEARCH IN THIS STATE. THAT'S HOW WE WERE CREATED. IN 2020 ANOTHER PROPOSITION EXTENDED OUR FUNDING TO INCLUDE GENE THERAPY AND TO INCLUDE A FOCUS ON NEUROLOGICAL DISEASES. WE FUND SCIENCE FROM RESEARCH BREAKTHROUGHS, THROUGH CLINICAL TRIALS, WE TRAIN STUDENTS TO WORK IN REGENERATIVE MEDICINE LABS, AND MAKE SURE CALIFORNIANS ALL OVER THE STATE CAN ACCESS OUR CLINICAL TRIALS.

THIS ONE WORKS FOR ME AND HERE'S WHY. I'M OLD. SO A LOT OF THE PEOPLE I TALK TO, THEY REMEMBER PROP 71. AND SO IF YOU CAN JOG SOMEONE'S MEMORY, YOU CAN KIND OF PULL THEM ALONG FROM THERE TO TALK ABOUT WHO WE ARE NOW. OKAY. I WAS INTRODUCED TO A FRIEND'S KID THE OTHER DAY WHO JUST GRADUATED FROM GRAD SCHOOL IN THE FIELD OF SCIENCE, BUT SHE'S NOT AS OLD AS ME AND HAS PROBABLY NEVER VOTED. SO I DIDN'T USE THIS. I USED A VARIANT OF THIS BUT WITHOUT THE PROPOSITIONS BECAUSE IT WASN'T

GOING TO RESONATE FOR HER.

SO THIS IS ONE EXAMPLE BUILT ON OUR MESSAGING. IT'S NOT A MANDATE, BUT I HOPE IT'S HELPFUL TO PEOPLE. HERE'S MY ANIMATION WORKING WHERE I HIGHLIGHT HERE'S OUR KEY MESSAGES EMBEDDED WITHIN THAT ELEVATOR PITCH.

LET'S GO BACK TO THE BITES. HOW DO YOU TAKE THAT FIRST BITE, THE UNKNOWN AUDIENCE AND SAY, OKAY. I'M PRETTY SURE I'M AT A DINNER PARTY WITH A BUNCH OF SCIENTISTS. I DON'T KNOW EXACTLY WHAT KIND, BUT MAYBE I'LL WORK IN CIRM IS A CALIFORNIA AGENCY THAT FUNDS STEM CELL AND GENE THERAPY RESEARCH INTENDED TO PRODUCE THERAPIES. IT MIGHT BE INFORMATION THAT'S USEFUL TO A LOT OF AUDIENCES.

OR THIS ONE. YOU CAN SEE IN RED I ADDED FROM DISCOVERY RESEARCH THROUGH CLINICAL TRIALS. IF YOU'RE SOMEWHERE WHERE YOU THINK YOU PROBABLY ARE TALKING TO SOMEONE WHO KNOWS A LITTLE BIT ABOUT BIOMEDICAL RESEARCH, THEY MIGHT BE INTERESTED TO KNOW IT'S DISCOVERY THROUGH CLINICAL TRIALS BECAUSE THAT'S NOT WHAT EVERYONE DOES.

AND I WANT TO GIVE ANOTHER EXAMPLE, AND THIS IS MARIA BONNEVILLE DELIVERED, RIGHT OVER THERE, AND I'M GOING TO SAY SOMETHING GOOD, MARIA. SO YOU WANT TO LISTEN. MARIA DELIVERED A MASTER

CLASS THE OTHER DAY AND HAD TO USE OUR MESSAGING. IT WAS IN A MEDIA INTERVIEW. AND SHE WAS ON THE INTERVIEW TO TALK ABOUT THE CCCE'S AND MORE GENERALLY ABOUT ACCESS. MARIA IS THE HEAD OF THE WORKING GROUP FOR ACCESS AND AFFORDABILITY. SO THAT WAS HER ROLE ON THIS CALL.

SO SHE SAID, CIRM IS A CALIFORNIA AGENCY THAT FUNDS RESEARCH INTENDED TO PRODUCE THERAPIES, AND THEN SHE PULLED A LINE FROM THE MESSAGING AND SAID, AND PUT THOSE THERAPIES WITHIN REACH OF PEOPLE IN CALIFORNIA, WHICH TEES UP ACCESS AND AFFORDABILITY. AND I DIDN'T ACTUALLY JUMP UP AND HUG HER IN THE INTERVIEW BECAUSE I WAS ON ZOOM, BUT AFTER -- IT WAS A PERFECT WAY OF TAKING OUR MESSAGING AND MIXING IT UP FOR AN APPROPRIATE AUDIENCE BUT STAYING RIGHT ON MESSAGE. AND SHE TEED UP THE CONVERSATION PERFECTLY. SHYAM PATEL, IF HE'S STILL IN THE ROOM, WAS ON THAT CALL TOO. I THINK THEY DID A TERRIFIC JOB TOGETHER.

I DIDN'T REALLY TALK -- I'M NOT GOING TO TALK ABOUT THIS IN THE PRESENTATION, BUT THAT ELEVATOR PITCH DOCUMENT ALSO HAS SOME FAQ'S. THESE ARE VERY LIGHT, VERY HIGH LEVEL. THEY'RE THE KINDS OF FAQ'S THAT ANYONE MIGHT GET IN A FAIRLY CASUAL SETTING. THEY ARE NOT INTENDED TO GET YOU THROUGH

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AN ENTIRE CONVERSATION. I CAN'T HELP YOU WITH A WHOLE DINNER PARTY, BUT I CAN PROBABLY GET YOU THROUGH THE FIRST COUPLE QUESTIONS THAT COME UP IN A CONVERSATION IN A WAY THAT SORT OF KEEPS YOU ON MESSAGE AND KEEPS THE LEVEL RIGHT. SO PLEASE READ THOSE FAQ'S. THEY'RE THE FIRST DRAFT. I DON'T THINK THEY PROBABLY ARE COMPLETE. THERE'S SOME QUESTIONS THAT YOU ARE GOING GET THAT I DON'T KNOW ABOUT. SO PLEASE REACH OUT TO ME. PLEASE GIVE ME FEEDBACK. IF YOU USE MY FAQ'S AND IT GOES HORRIBLY AWRY, I WANT TO KNOW ABOUT THAT.

NOW I'M GOING TO CATCH UP WITH MY SCRIPT TO MAKE SURE I SAID EVERYTHING I WANTED TO SAY. OKAY. SO ANOTHER PART OF THE TOOLKIT, AND THIS IS SOMETHING THAT IS NOT COMPLETE. SO I CAN'T GIVE THIS TO YOU NOW, BUT IT WILL BE COMPLETE. SO I WANT TO TALK TO YOU ABOUT IT A LITTLE BIT. SO WE'RE CALLING THIS A PATIENT AND STUDENT STORY COMPENDIUM. SO WE HAVE LOTS AND LOTS AND LOTS AND LOTS OF STORIES ABOUT VARIOUS PATIENTS. AND WE HAVE LOTS OF STORIES ABOUT OUR INCREDIBLE STUDENTS. THEY'RE A LITTLE BURIED AND THEY'RE HARD FOR THE PEOPLE OF CIRM TO TALK ABOUT IF WE DON'T SURFACE THEM FOR YOU.

SO WE'RE GOING TO HAVE A SERIES OF I BELIEVE THEY'LL BE SLIDES. EACH SLIDE WILL HAVE A

PICTURE OF THAT PATIENT OR THAT PERSON AND SOME INFORMATION: THE PERSON'S NAME, THE DISEASE, DETAILS ABOUT THE TRIAL, LINKS TO AWARD INFORMATION, LINKS TO A BLOG ENTRY WE'VE WRITTEN, PREVALENCE OF THAT DISEASE, DIFFERENT ETHNIC GROUPS THAT MIGHT BE MORE IMPACTED BY THAT DISEASE. WE'LL PUT WHATEVER INFORMATION IN THERE WE HAVE. YOU CAN PULL THAT OUT AND THAT ALLOWS YOU TO USE THESE STORIES AND THESE SLIDES IN WHATEVER CONTEXT YOU WANT. MAYBE YOU DON'T REALLY WANT TO TALK ABOUT THAT PARTICULAR PATIENT. YOU JUST WANT AN IMAGE THAT REPRESENTS A FIELD OF RESEARCH YOU ARE GOING TO BE TALKING ABOUT. THAT'S FINE. WE'VE GOT A SLIDE FOR YOU. SO THIS IS COMING.

AND THEN FINALLY, I MENTIONED NUMBERS. BEHIND EVERY NUMBER THERE'S A NAME. WE USE A LOT OF NUMBERS. I THINK I'M ON SIX MONTHS HERE AT CIRM. I WILL TELL YOU WE USE THE NUMBERS, VERY DIFFERENT NUMBERS. THEY'RE DIFFERENT IN DIFFERENT PLACES. SO ONE OF THE THINGS I'VE BEEN DOING, AND I WANT TO SAY I'M WORKING VERY CLOSELY WITH PEOPLE ON ROSA'S TEAM WHO ARE EXCEPTIONALLY PICKY, AND WE'RE TRYING TO PULL TOGETHER NUMBERS IN A WAY THAT WE'RE ACTUALLY USING THE SAME ONES. WE'LL HAVE DATES ON THEM. SO IF YOU WANT TO GIVE A PRESENTATION AND YOU WANT SOME

NUMBERS ABOUT CIRM, YOU'VE GOT IT AT YOUR DISPOSAL. YOU DON'T HAVE TO EMAIL US.

WE'LL BE STARTING WITH NUMBERS THAT WE HAVE AT OUR DISPOSAL AND THEN HOPING TO EXPAND WHAT WE CAN PROVIDE. SO LOOK FOR THIS. I TELL YOU IF WE GET THIS ONE DONE, THAT'S BLOOD, SWEAT, AND TEARS.

OKAY. THE ROLLOUT. THIS IS A HAPPY PHOTO OF SOME OF OUR BOARD MEMBERS AND THEN JACQUELINE HANTGEN WHO DOES OUTREACH FOR US IN SOUTHERN CALIFORNIA AT AN EVENT. THIS IS TO MAKE THE POINT ALL OF THIS IS AVAILABLE TO YOU TO SPEAK ABOUT CIRM, WHICH TEES ME UP TO SAY I'VE BEEN WARNING YOU OF THIS, AND WE WANT BOARD MEMBERS TO GET OUT AND TALK ABOUT CIRM, AND WE'RE GOING TO MAKE IT EASY FOR YOU.

ADITI DESAI ON MY TEAM IS TASKED WITH HELPING BOARD MEMBERS FIND OPPORTUNITIES TO SPEAK. SHE WILL NOW BE REACHING OUT TO YOU. OVER TIME WE'LL FIGURE OUT WHAT KINDS OF OPPORTUNITIES PEOPLE LIKE, WHAT YOU DON'T, WHAT ARE APPROPRIATE OPPORTUNITIES FOR EACH OF YOU, BUT I THINK WE CAN DO A BETTER JOB OF GETTING ALL OF US OUT TALKING MORE, AND WE WILL TRY TO MAKE IT EASY FOR YOU.

AND A PRESENTATION FROM COMMUNICATIONS WOULD BE INCOMPLETE IF I DIDN'T TALK A LITTLE BIT ABOUT WHAT WE'VE ACTUALLY BEEN DOING BECAUSE ALL OF

THIS HAS BEEN ABOUT WHAT WE'RE TRYING TO DO IN THE FUTURE, AND WE'RE KIND OF TIRED OF LOOKING TOWARDS THE FUTURE. WHAT ARE WE REALLY DOING?

HERE'S SOME OF THE STUFF WE'RE DOING. I'M GOING TO TALK ABOUT -- I'M MOSTLY GOING TO TALK ABOUT OUTREACH TODAY. WE DO OTHER THINGS, BUT I'M JUST REALLY EXCITED ABOUT SOME OF THIS. SO OUR COMMUNITY OUTREACH TEAM WILL BE AT A STUDENT-FOCUSED EVENT THIS WEEKEND, AND THEY WILL BE ACCOMPANIED BY THREE OF OUR EDUCATION PROGRAM STUDENTS.

MARIA BONNEVILLE AND ADITI SPOKE AT A ROTARY CLUB MEETING. I THINK THAT WAS LAST MONTH. JACQUELINE WHO ASSISTS IN SOUTHERN CALIFORNIA REPRESENTED CIRM AT AN ALS SUMMIT RECENTLY WHICH ATTRACTED ABOUT 200 PEOPLE. SHE REPORTS THAT THE PROGRAM FEATURED A DEDICATED PAGE RECOGNIZING THE IMPORTANCE OF CIRM TO THE ALS NETWORK.

IN ADDITION, ADITI RECENTLY SPOKE TO A SACRAMENTO AREA ROTARY CLUB WHERE SHE GAVE THE PRESENTATION THAT J.T. PREVIEWED AT THE LAST MEETING. SO WE'RE STARTING TO ROLL THAT OUT, AND SHE SAID IT WAS VERY WELL RECEIVED. PARTICIPANTS HAD QUESTIONS ABOUT ACCESS, SPECIFIC DISEASE AREAS, AND LONG-TERM IMPLICATIONS OF CELL AND GENE THERAPIES. SO THEY WERE VERY ENGAGED. WE'VE DONE

MORE, BUT I'M GOING TO LEAVE IT THERE ON THIS VERY LONG DAY.

MEASURE THE IMPACT. I'M NOT PREPARED TO GIVE YOU A FULL METRICS REPORT TODAY, BUT I AM GOING TO BRING IN ONE OF MY TEAM MEMBERS AT AN UPCOMING MEETING AND TALK IN MUCH MORE DETAIL ABOUT METRICS BECAUSE I THINK IT'S INCREDIBLY IMPORTANT.

THE ONE THING I'LL TOUCH ON LIGHTLY HERE IS AT PREVIOUS MEETINGS I MENTIONED WE'VE STARTED DOING BLOG ENTRIES ON OUR BOARD MEMBERS. AND WE'RE DOING THAT AS A WAY OF HUMANIZING WHAT CAN LOOK LIKE KIND OF A BUREAUCRACY. THESE HAVE BEEN DOING INCREDIBLY BRING WELL. PEOPLE SEEM TO REALLY RESONATE WITH THESE. AND THE OTHER IS A BLOG ENTRY WE DID AWHILE AGO ON OUR EDUCATION PROGRAMS OVER THE PAST 20 YEARS, AND IT CONTINUES TO DO WELL. I THINK THOSE PROGRAMS REALLY RESONATE WITH PEOPLE.

WHILE I HAVE THE FLOOR, THANK YOU. AND RIGHT BEFORE I TAKE QUESTIONS, I WANT TO SAY EARLIER TODAY SOMEONE CAME UP AND ASKED ME ABOUT SOCIAL MEDIA STRATEGY AND HOW PEOPLE -- IF YOU ARE COMFORTABLE ON SOCIAL MEDIA COULD AMPLIFY CIRM. I WILL JUST SAY THAT IN THE NEXT WEEK OR TWO, THOSE CLOSER TO CURES PRESENTATIONS WILL BE ON OUR LINKED-IN. SO IF ANY OF YOU ARE LINKED-IN USERS AND

WANT TO LOOK FOR THEM, I'M NOT INSISTING THAT PEOPLE PROMOTE THEM; BUT IF YOU LIKED THE TALKS, WE WOULD NOT MIND IT IF YOU SAID SOMETHING.

WITH THAT, I'M GOING TO COME BACK TO SOMETHING THAT I PROMISED I WAS GOING TO TEE UP. AND THAT WAS AT THE LAST COMMUNICATION SUBCOMMITTEE MEETING, WE HAD AN OUTSTANDING CONVERSATION, I THOUGHT, ABOUT SOME OF THE WORDS WE USE TO TALK ABOUT THERAPIES, CURES, OR MAYBE TREATMENTS, SOME COMBINATION OF THOSE. JUST HOW WE'RE TALKING ABOUT WHAT IT IS THAT WE'RE DOING. YOU'LL NOTICE IN A LOT OF MY WORK I'M USING THE WORD "CURES." THAT'S BECAUSE IT'S SHORT AND A LOT OF WHAT I DO IS SHORT.

I THINK IN SOME WAYS CURES ALSO DOES -- IS AN IMPORTANT POINT OF REGENERATIVE MEDICINE. IT IS A FIELD OF MEDICINE WHERE WE COULD HOPE FOR CURES AND WE WANT TO LEAN INTO THAT. IN OTHER CONTEXTS I KNOW FROM TALKING TO ALL OF YOU THAT IT'S NOT A COMFORTABLE WORD TO USE. AND I KNOW THAT. MY TAKEAWAY FROM THE CONVERSATION WAS THAT I THINK WE ALL REALLY NEED TO THINK ABOUT OUR WORDS AND USE WORDS THAT ARE RELEVANT IN OUR CONTEXT. I DON'T HAVE A MANDATE, AND I'M NOT GOING TO TELL PEOPLE WHICH WORD THEY HAVE TO USE. I KIND OF TRUST ALL OF YOU TO BE GROWNUPS AND CHOOSE YOUR WORDS. BUT I

WOULD WELCOME MORE THOUGHTS ON THAT TOPIC NOW OR ANY OTHER TIME. WITH THAT, I'M DONE. THANK YOU.

(APPLAUSE.)

CHAIRMAN IMBASCIANI: THANK YOU, AMY. ANY FURTHER COMMENTS? YES, YAEL.

MS. WYTE: I'M SURE I SHOULD KNOW THIS, BUT WHERE DOES THE TOOLKIT LIVE SO THAT WE CAN REFERENCE IT?

MS. ADAMS: WELL, RIGHT NOW IT LIVES ATTACHED TO THE BOARD AGENDA, BUT IN A SLIGHTLY DRAFT FORM. YOU CAN GRAB IT. THERE'S LITTLE UPDATES ALONG THE WAY THAT PEOPLE HAVE COMMENTED ON. SO I WILL BE AT SOME POINT SENDING YOU GUYS A PACKET THAT HAS THE FINAL. YOU'RE WELCOME TO REACH OUT TO ME ANYTIME ALSO.

ONE THING I THINK I FORGOT TO MENTION IS I AM GOING TO BE HOLDING SOME TRAININGS ON THE TOOLKIT IN FEBRUARY. THEY'LL BE FOR STAFF, BUT WE'LL INVITE -- I'M LOOKING AT SCOTT -- WE'LL INVITE THE BOARD IN A WAY THAT IS OKAY ACCORDING TO BAGLEY-KEENE, AND SCOTT IS GOING TO MAKE THAT POSSIBLE. SO WE'LL BE TALKING ABOUT HOW TO USE THE DECK, HOW TO USE SOME OF THE IMAGES THAT WE'VE BEEN DEVELOPING. SO WE'LL DO THAT AS WELL.

DR. SOUTHARD: SO I WAS WONDERING IF WE DO

COMMUNICATIONS AND TELL OUR STORY IN LANGUAGES OTHER THAN ENGLISH.

MS. ADAMS: OH, WELL. YOU BEAT YSABEL TO THAT QUESTION. SO CONGRATULATIONS. SO I'LL ANSWER TO BOTH OF YOU. YEAH. I THINK THAT'S AN OUTSTANDING QUESTION. RIGHT NOW I WILL SAY WE HAVE NO MATERIALS TO HELP YOU. I THINK IT'S AN IMPORTANT QUESTION THOUGH, AND I THINK IT'S A PLACE WHERE WE NEED TO FOCUS IN THE FUTURE. WE ARE STARTING TO TRY TO GET THINGS LIKE PRESS RELEASES TRANSLATED, AND WE'RE REACHING OUT TO SPANISH SPEAKING MEDIA, BUT IT'S LIMITED AT THIS TIME. BUT I THINK OTHER LANGUAGE -- WE'RE A DIVERSE STATE. THAT'S NOT THE ONLY LANGUAGE IN THE STATE. SO AT THIS POINT I CAN'T HELP YOU, BUT I'M HAPPY TO HAVE A CONVERSATION IF THAT'S USEFUL TO YOU.

MARIA MAKES A GOOD POINT. WE HAVE ANNUAL REPORTS IN SPANISH. WE ALSO HAVE A SERIES OF PATIENT-FOCUSED FLIERS. AND SOMEONE ON MY TEAM IS GOING TO SLACK ME IN JUST A SECOND IF I SAY THIS WRONG, BUT I'M PRETTY SURE SEVERAL OF THOSE ARE ALSO TRANSLATED INTO SPANISH. OKAY. MARIA SAYS YES. SO WE HAVE SOME TRANSLATION.

DR. DULIEGE: THANK YOU VERY MUCH. EXCELLENT PRESENTATION THAT WILL HELP US TALK MORE

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ABOUT CIRM IN OUR DAILY LIVES.

GENERAL QUESTION, NOT NECESSARILY JUST FOR YOU. WHEN WE'RE ASKED THE QUESTION HOW MUCH FUND IS THERE STILL TO BE ALLOCATED FROM NOW ON, I'M TOLD 3.1. I JUST WANTED TO MAKE SURE THAT WE ALL HAVE THE SAME RESPONSE THERE.

MS. ADAMS: THAT IS A NUMBER -- I'M LOOKING AT JENN RIGHT NOW. THAT IS A NUMBER WE'RE CURRENTLY UPDATING ONCE A YEAR IN THE ANNUAL REPORT. AND IT WILL BE IN THE PROOF POINTS DOCUMENT WITH A DATE ON IT. JENN, IS THAT RIGHT? ARE WE DOING THAT ONCE A YEAR?

MS. LEWIS: YEAH.

MS. ADAMS: WE'RE DOING THE REVERSE. WE'RE TALKING ABOUT HOW MUCH HAS BEEN SPENT, NOT HOW MUCH IS LEFT.

DR. DULIEGE: HOW MUCH IS STILL TO BE ALLOCATED?

MS. LEWIS: SO 3.4 BILLION AS OF THE START OF THIS YEAR IS WHAT WE HAVE FOR THE NEXT SIX YEARS. BUT THAT IS A NUMBER WE WILL REPORT ON EVERY YEAR AS WE COME WITH THE NEW BUDGET. AND THEN WE'LL MAKE SURE THAT'S IN YOUR MATERIALS SO YOU HAVE THAT AS WELL.

DR. DULIEGE: GREAT. THANK YOU.

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CHAIRMAN IMBASCIANI: THANKS, JENN.

DR. MIASKOWSKI: AMY, THAT WAS A GREAT PRESENTATION. AND IN REFERENCE TO THE TRANSLATION OF PRODUCTS, BEING ON THE GRANTS WORKING GROUP, VIRTUALLY EVERY GRANT THAT GOES TO A CLINICAL TRIAL, THE INVESTIGATORS SAY WE ARE TRANSLATING OUR INSTRUMENTS, OUR CALL FOR STUDY. I'M IMAGINING SOME OF THAT MATERIAL MIGHT BE USEFUL TO US. CAN WE ACCESS THAT? HAVE YOU THOUGHT ABOUT THAT?

MS. ADAMS: OKAY. SO I'M GOING TO DIG BACK IN TIME NOW TO MY LAST STINT AT CIRM. I WOULD SAY RIGHT NOW NOT SO MUCH. IS IT AVAILABLE AND SHOULD IT BE USED IN THE FUTURE? I THINK IT'S WORTH MINING FOR SURE. IN THE PAST WE MADE THE PUBLIC SUMMARIES. WE DID THINGS WITH THEM. IS THAT DIFFERENT?

VICE CHAIR BONNEVILLE: YEAH. WHEN THEY TALK ABOUT ACCESS TO THE TRIALS, IT'S POPULATION IMPACT.

MS. ADAMS: SORRY. I WAS THINKING ABOUT THE PUBLIC -- I'M SORRY. I WAS RESPONDING ABOUT THE PUBLIC STATEMENT. NO. ACTUALLY I THINK I'M PRETTY SURE THAT RIGHT NOW WE DO NOTHING WITH THAT.

DR. MIASKOWSKI: I'M WONDERING IF OUR ALPHA CLINICS ARE PREPARING DOCUMENTS THEY'RE USING

TO EDUCATE PATIENTS IN DIFFERENT LANGUAGES. WE MIGHT BE ABLE TO ACCESS THOSE AS WELL AS A STARTING POINT ANYWAY.

MS. ADAMS: I THINK THE ALPHA JUST AS A GENERAL STATEMENT. I THINK THE ALPHA CLINICS ARE DOING LOTS OF AMAZING THINGS TO GET THE WORD OUT, AND IT'S SOMETHING THAT WE'RE WANTING TO EXPAND.

MS. DURON: MR. CHAIR.

CHAIRMAN IMBASCIANI: YES.

MS. DURON: YOU HAVE A LEFT BIAS. ACTUALLY WHAT I'M GOING TO BE DOING WITH THE OAKLAND ROTARY AND WHAT I ALWAYS SUGGEST IS, DEPENDING ON WHERE YOU'RE PRESENTING, YOU THINK LOCALLY. SO MY IMMEDIATE QUESTIONS, AMY, AND PUT THE TEAM TO WORK, WAS HOW MANY BRIDGE PROGRAMS DO WE HAVE IN THIS AREA THAT WE CAN POINT AT? HOW MANY COMPANIES IN THIS AREA WHO HAVE GOTTEN CIRM FUNDING AND ARE DOING WHAT? SO THAT WE CAN POINT TO THE ACTIVITIES WITHIN THEIR SPHERE OF KNOWLEDGE AND INFLUENCE AND SAY, OH, WE ARE GETTING SOMETHING OUT OF THIS. THIS IS BUILDING JOBS, BUILDING TEAMS OF SCIENTISTS GOING FORWARD. I THINK THAT'S ALWAYS CRITICAL. WHAT IS IT, POLITICS IS LOCAL. I THINK IT'S REALLY CRITICAL. I KNOW THAT CREATES MORE WORK.

MS. ADAMS: MY TEAM IS HAPPY TO DO THE

WORK FOR YOU, YSABEL.

MS. DURON: IN LOOKING FOR THE DATA, BUT I ALWAYS BELIEVE THAT'S KIND OF A WHAT ABOUT ME RESPONSE. AND SO I LOVE THE -- SO I WOULD SUGGEST THAT ANYTIME THEY ASK YOU TO SPEAK, ASK THEM TO GIVE YOU THAT LOCALIZED IMPACT THAT'S ALREADY HAPPENED WITHIN THEIR COMMUNITIES.

CHAIRMAN IMBASCIANI: YSABEL. ANYONE ELSE? IF NOT, THANK YOU, AMY, FOR A GREAT PRESENTATION.

MS. ADAMS: THANK YOU, EVERYONE.

CHAIRMAN IMBASCIANI: SO WE SKIPPED AROUND A LITTLE BIT TO ACCOMMODATE VARIOUS EXIGENCIES IN THE SCHEDULE. GOING TO GO BACK NOW TO ITEM NO. 9 IS THE REPORT FROM THE VICE CHAIR. MARIA.

VICE CHAIR BONNEVILLE: AS MANY OF YOU HAVE HEARD, NIH IS ISSUING A REQUEST FOR INFORMATION ON REDUCING RELIANCE ON HUMAN EMBRYONIC STEM CELLS IN NIH-SUPPORTED RESEARCH. AND WHILE THEY AWAIT THESE RESPONSES, HHS IS PAUSING NEW SUBMISSIONS TO THE NIH HUMAN EMBRYONIC STEM CELL REGISTRY.

AND OUR TEAMS HAVE BEEN IN CONTACT WITH SOME OF OUR PARTNERS, ISSCR, ASGCT. AND IN ADDITION, THAT TEAM IS ALREADY WORKING ON A PLAN TO COORDINATE A RESPONSE TO THE RFI WITH OUR CALIFORNIA

INSTITUTIONS. AND SO I'LL KEEP YOU POSTED AND UPDATED AS THINGS UNFOLD BECAUSE THAT'S A BIG -- THAT'S A NEW BIG DEVELOPMENT.

AND IN ADDITION TO THAT, THERE WAS ALSO NEWS OUT OF NIH THAT THEY WERE WILL STOP FUNDING RESEARCH INVOLVING FETAL TISSUE. AND I'VE HAD A LOT OF QUESTIONS ON HOW THIS WILL AFFECT CIRM. AND THE SHORT ANSWER IS IT DOESN'T BECAUSE WE WILL CONTINUE TO FUND THIS WORK. IT WILL, OF COURSE, AFFECT SOME OF OUR PARTNERS. AND SO WE'LL ALSO MONITOR THE SITUATION AND PROVIDE ANY UPDATES AS WE GET THEM.

THE SENATE HEALTH COMMITTEE IS HOLDING A HEARING ON FEBRUARY 3D ON MODERNIZING THE NATIONAL INSTITUTES OF HEALTH, FASTER DISCOVERIES, MORE CURES. AND THE MAHA INSTITUTE IS HOSTING AN EVENT ON FRIDAY ON RECLAIMING SCIENCE, THE PEOPLE'S NIH, FEATURING PRESENTATIONS FROM NIH LEADERSHIP. AND BASED ON THE AGENDAS ITEMS, IT LOOKS LIKE IT'S FOCUSED ON NIH REORGANIZATION, CRITICISM OF COVID RESPONSES, GOLD STANDARD SCIENCE, ET CETERA.

AND SO AS SOON AS WE HEAR BACK ON HOW THOSE GO, I'LL SEND SOMETHING OUT TO THE BOARD.

WE'VE BEEN TRACKING SENATOR WIENER'S BILL, AND THAT WAS RESUBMITTED AND IS NOW SB 895. THAT'S A 23 BILLION BOND MEASURE, AND WEINER HAS ASKED THE

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LEGISLATURE TO PUT IT ON THE NOVEMBER BALLOT SO IT AVOIDS SIGNIFICANT COLLECTION, WHICH AS WE KNOW CAN BE VERY WE COSTLY. AND IT COVERS A WIDE RANGE OF SCIENTIFIC RESEARCH, INCLUDING BIOMEDICAL, NEW AND EMERGING HEALTH THREATS, DISEASE PREVENTION, STROKE, HEART DISEASE, CHILD AND ADULT LEUKEMIA, INFECTIOUS DISEASE, AND HIV/AIDS, WILDFIRE PREVENTION, PROMOTION OF HEALTHY AND SAFE BEHAVIORS, COMMUNITIES AND ENVIRONMENTS, ADDICTION AND SUBSTANCE ABUSE, BEHAVORIAL, CLIMATE, WEATHER, AND OCEANS, COASTAL AND MARINE ECOSYSTEMS, AGRICULTURE AND WATER, EMERGING TECHNOLOGIES, SAFETY, EFFICACY, AND SECURITY OF DRUGS. SO IT'S BROAD REACH.

THE BILL IS CURRENTLY SITTING IN THE SENATE RULES COMMITTEE PENDING REFERRAL TO THE SENATE HEALTH COMMITTEE. THE HEALTH COMMITTEE WILL BEGIN TO HEAR NEWLY INTRODUCED SENATE BILLS IN MID- TO LATE MARCH. IF IT'S APPROVED, HEARD AND APPROVED BY THE HEALTH COMMITTEE, THE BILL WILL BE REFERRED TO THE APPROPRIATIONS HEARING FOR CONSIDERATION. IF APPROVED BY THE APPROPRIATIONS COMMITTEE, THE BILL WILL MOVE TO THE SENATE FLOOR FOR APPROVAL BY THE FULL HOUSE. ONCE APPROVED BY THE SENATE, THE MEASURE WILL GO TO THE ASSEMBLY WHERE IT WILL BE HEARD IN THE ASSEMBLY HEALTH AND APPROPRIATIONS

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COMMITTEE BEFORE GOING TO THE ASSEMBLY FLOOR FOR A FULL VOTE. IF IT'S AMENDED IN THE ASSEMBLY, IT HAS TO GO BACK TO THE SENATE FOR A CONCURRENCE VOTE BEFORE THAT GOES TO THE GOVERNOR FOR SIGNATURE TO BE PLACED ON THE BALLOT, AND THAT HAS TO HAPPEN BY AROUND JUNE 25TH UNLESS THAT DATE IS EXTENDED, BUT NO LATER THAN JULY 2D WHEN THEY RECESS. SO THAT'S WHERE THAT STANDS. SO THERE'S A LOT OF HURDLES BETWEEN NOW AND THEN.

THEN THERE'S ALSO A POTENTIAL BOND MEASURE FOCUSING ON IMMUNOLOGY. THIS PROPOSED BOND MEASURE IS CURRENTLY OUT IN THE FIELD FOR SIGNATURES AND MUST QUALIFY BY THE END OF JUNE IN ORDER TO MAKE IT TO THE NOVEMBER BALLOT. AND IT PROPOSES 8.4 BILLION IN BONDS TO FUND CUTTING EDGE MEDICAL RESEARCH FOCUSED ON IMMUNOLOGY AND IMMUNE THERAPY. ABOUT HALF THE FUNDING WOULD GO TO ONE MAJOR NONPROFIT RESEARCH INSTITUTE AFFILIATED WITH THE UNIVERSITY OF CALIFORNIA. THE OTHER HALF WOULD BE AWARDED AS COMPETITIVE GRANTS TO CALIFORNIA PUBLIC AND NONPROFIT UNIVERSITIES AND RESEARCH INSTITUTIONS. AND AT LEAST 4.2 BILLION MUST BE SPENT SPECIFICALLY ON CANCER, HEART DISEASE, AND ALZHEIMER'S DISEASE RESEARCH.

THAT'S MY REPORT. IF YOU HAVE ANY

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QUESTIONS.

CHAIRMAN IMBASCIANI: I SEE A HAND. YES, GEORGE.

DR. BLUMENTHAL: THANK YOU, MARIA, FOR THAT COMPREHENSIVE REPORT. A COUPLE OF QUICK QUESTIONS ABOUT GOVERNANCE. BOTH THE WEINER BILL AND THE OTHER BILL THAT YOU MENTIONED, WHAT MECHANISMS ARE BEING CONSIDERED IN ORDER TO DISBURSE FUNDS? IS THERE AN EQUIVALENT OF THE ICOC?

VICE CHAIR BONNEVILLE: I'D HAVE TO GO BACK TO THE IMMUNOLOGY. FOR THE SENATOR'S BILL THAT'S GOING THROUGH RIGHT NOW, LET ME JUST BRING THAT UP, IT DOES ESTABLISH THE CALIFORNIA FOUNDATION FOR SCIENCE AND HEALTH RESEARCH FOUNDATION. THAT LIVES UNDER THE GOVERNMENT OPERATIONS AGENCY. AND THEIR ROLE IS TO FACILITATE THE SCIENTIFIC RESEARCH BY AWARDING GRANTS AND MAKING LOANS TO PUBLIC OR PRIVATE RESEARCH COMPANIES, UNIVERSITIES, INSTITUTES, ET CETERA.

IT'S NOT COMPLETELY CLEAR HOW THE OVERSIGHT IS HANDLED IN THAT INSTANCE. WHAT I DO KNOW IS THAT THEY DID GO BACK AND ADD LANGUAGE TO THE BILL THAT HAS A LOT OF SIMILARITIES WITH CIRM IN SOME OF THE INSTANCES AROUND CLOSED SESSION AND OTHERWISE. SO I CAN GET BACK TO YOU WITH MORE

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INFORMATION ON THAT.

DR. BLUMENTHAL: THANK YOU.

CHAIRMAN IMBASCIANI: ANY OTHER QUESTIONS FOR MARIA? ANY OTHER BOARD MEMBERS ONLINE? NO. OKAY. MARIA, THANK YOU. GREAT.

OUR CEO AND PRESIDENT JON THOMAS, PRESIDENT'S REPORT IS NEXT.

DR. THOMAS: LAST AND PROBABLY LEAST, BUT MAYBE NOT, WANTED TO GIVE YOU AN UPDATE ON A NUMBER OF THINGS. TWO, VERY BRIEFLY, ON EVENTS THAT HAVE HAPPENED, TWO ON THINGS THAT ARE GOING TO HAPPEN, AND ONE ON A PRESENTATION WHICH I'VE STREAMLINED AND HAVE CULLED OUT SOME INTERESTING FACTS THAT I THINK YOU GUYS WILL LIKE AS YOU HEAD OUT INTO THE NIGHT AFTER TODAY'S VERY BUSY SESSION.

SO WITH RESPECT TO THINGS THAT HAVE HAPPENED SO FAR, AS JENN NOTED, ON DECEMBER 30TH THE CFAOC MET, AS IT DOES ANNUALLY, TO HEAR THE STORY OF OUR AUDIT, TO HEAR THE STORY OF OUR BUDGET. THIS WAS A VIRTUAL MEETING. MARIA, MICHELLE LEWIS, AND I DID THE CALL FOR CIRM. IT WENT VERY WELL. IN THE PAST WE'VE HAD DISCUSSIONS ABOUT THE COOL THINGS THAT WE'RE DOING. AND, BOY, DID WE HEAR SOME TODAY. AND THIS PARTICULAR INSTANCE, GIVEN THE LATE DAY IN THE YEAR, WE DID NOT GET INTO THAT, BUT PRESUMABLY

IT WILL BE RECONVENING WITH THE CFAOC SOMETIME IN THE COMING MONTHS TO GIVE THEM AN UPDATE ON THAT.

VITO ALLUDED TO AN ANNUAL EVENT THAT PRECEDES JP MORGAN WEEK. THE ISSCR SPONSORS SOMETHING CALLED THE NUCLEUS FORUM, WHICH IS A VERY UNIQUE COMBINATION OF ACADEMIA, INDUSTRY, AND FINANCE THAT CONVENES IN PALO ALTO FOR A KEYNOTE FIRESIDE CHAT ON SATURDAY NIGHT AND THEN A FULL DAY OF PANELS. THIS ENTITY HAS BEEN AROUND TEN YEARS. IT'S PUT TOGETHER BY A CIRM GRANTEE, DEEPAK SHRIVASTAVA OF HARVARD MED SCHOOL, DEAN GEORGE DALY, AND HARVARD RESEARCHER LEN ZON FOR THOSE OF YOU WHO MAY KNOW THE TWO OF THEM. AND IT PULLS TOGETHER EVERY YEAR A REALLY INTERESTING GROUP OF PEOPLE.

THE FIRESIDE CHAT THIS TIME WAS THE GUY AT META IN CHARGE OF HEALTHCARE AI, WHICH WAS INTERESTING. ALTHOUGH JUST AS CIRM HAS AND LIFE SCIENCE HAS ITS OWN SET OF IMPENETRABLE ACRONYMS, SO DOES AI. SO JUST WHEN YOU THOUGHT YOU KNEW WHAT HE WAS TALKING ABOUT, HE'D SORT OF LAPSE INTO SOME ACRONYM. SO YOU GOT A BIT LOST, BUT NONETHELESS IT WAS A VERY ENTERTAINING TALK.

THE PANELS WERE VARIOUSLY IN ACADEMIA, INDUSTRY LEADERS, AND FINANCE. THE PRINCIPAL BENEFIT OF THIS, VITO AND I AND MARIA WERE THERE

THIS TIME. IT'S ALWAYS THE NETWORKING THAT YOU ARE ABLE TO DO. THERE ARE ALWAYS NEW PEOPLE THERE THAT CAN FORM A VERY GOOD GROUP OF PEOPLE TO KNOW TO HELP ADVANCE CIRM'S AGENDA ON BEHALF OF THE PEOPLE OF CALIFORNIA. SO THOSE WERE TWO EVENTS THAT HAVE HAPPENED.

COMING UP, YOU MAY RECALL IN OCTOBER THE BOARD APPROVED THE CCCE DELIVERY SITES, ONE IN CENTRAL CALIFORNIA, ONE IN THE INLAND EMPIRE, ONE IN SOUTHERN CALIFORNIA. CONSPICUOUSLY MISSING WAS ONE IN NORTHERN CALIFORNIA. AND I JUST WANT TO LET THE BOARD KNOW THAT WE'VE BEEN DOING A LOT OF RECONNAISSANCE AND INTELLIGENCE ON POTENTIAL SITES IN THE NORTHERN PART OF THE STATE THROUGH A VARIETY OF CONVERSATIONS WITH STAKEHOLDERS IN THE KNOW. AND WE ARE GOING TO BE COMING BACK TO YOU IN MARCH WITH A CONCEPT PLAN FOR THE SELECTION OF THAT FINAL SITE TO ROUND OUT THE GEOGRAPHIC DIVERSITY OF THE PROGRAM.

SIMILARLY, I WANTED LET YOU KNOW FURTHER TO DOWN THE ROAD ON THE SUBJECT OF ALPHA CLINICS, THE DISCUSSIONS ON VARIOUS FRONTS IN CONNECTION WITH THAT, THE CIRM TEAM HAS BEEN EVALUATING HOW THE PROGRAMS ARE GOING AROUND THE STATE. AND AT THE APPROPRIATE TIME LATER IN THE YEAR, WE'LL BE COMING

BACK TO THE BOARD WITH RECOMMENDATIONS FOR NEXT STEPS IN CONNECTION WITH ALPHA CLINICS.

SO THAT CONCLUDES MY VERY BRIEF RUN-THROUGH OF THE FOUR ITEMS.

NOW, IF I MIGHT, SO OVER THE COURSE OF THE YEAR, I'VE ASKED AT VARIOUS TIMES ABOUT, AND OTHERS HERE AS WELL, ABOUT THE STATE OF THE FIELD, WHERE THE DEVELOPMENT OF CGT AND INDUSTRY, THE INTERNATIONAL COMPETITIVE LANDSCAPE, THE REGULATORY ENVIRONMENT, ALL THAT STUFF. AND AS IT HAPPENS EVERY YEAR, THAT AND MORE IS ALWAYS ENCAPSULATED IN AN EXTREMELY, HIGHLY ATTENDED SPEECH AND PANEL GIVEN BY THE ALLIANCE FOR REGENERATIVE MEDICINE. THE SPEECH GIVEN BY TIM HUNT, THE CEO, AND IT COVERS A WIDE RANGE OF TOPICS.

I'VE REDUCED THEIR SLIDES TO A MANAGEABLE AMOUNT AND IN THE INTEREST OF GETTING EVERYBODY OUT OF HERE EVEN SOONER, I'M GOING REDUCE IT EVEN FURTHER TO SCORE POINTS WITH ALL OF YOU.

SO, SORT OF THE BOOKEND STORY THAT STARTED TIM'S SPEECH WAS ABOUT PATIENTS THAT DEMONSTRATE THE POTENTIAL FOR CELL AND GENE THERAPY. YOU'VE HEARD A LOT, PARTICULARLY FROM SHYAM TODAY, ABOUT BABY KJ AND WHAT HAPPENED WITH HIM. ALSO THEY TALKED ABOUT A WOMAN, MARCI MCCUE, WHO IS THE FIRST PERSON EVER

TO GET CAR-T CLINICAL TRIAL TREATMENT FOR MULTIPLE SCLEROSIS, DEMONSTRATING THE BRANCHING OUT EFFECT OF WHAT CAR-T TREATMENTS CAN REACH TO.

I'M GOING TO SKIP OVER THIS BECAUSE WE DON'T NEED TO GET THROUGH THIS. NOW, THIS IS INTERESTING AND FRANKLY DISTURBING. GLOBAL COMPETITION, WE HAD A SIDEBAR OVER HERE ABOUT THIS VERY ISSUE. IF YOU WILL NOTICE HERE, IN THE CGT SPACE, THE U.S., WHICH HAS ALWAYS SORT OF LED THE FIELD, IS STARTING TO LOSE SOME GROUND IN WHAT COULD UNFORTUNATELY BE THE START OF A TREND. YOU SEE THAT CHINA MADE VERY SIGNIFICANT STRIDES OVER THE COURSE OF THE LAST YEAR LARGELY DUE TO THEIR STREAMLINED REGULATORY PROCESS, NOT TO MENTION ALL THE MONEY THEY'RE PLOWING INTO THE REGENERATIVE MEDICINE SPACE.

THE MIDDLE EAST IS BECOMING MORE AND MORE OF A FACTOR AS THEY LOOK TO DEVELOP THE BIOTECH INDUSTRY AND INCREASE THE ROLE OF THAT AREA OF THE WORLD IN THAT FIELD. AND THE EU PASSED AN ACT WHICH WAS MEANT TO ACCELERATE CLINICAL TRIALS. IT CREATED AN ADVANCED THERAPY MEDICAL PRODUCT CENTER OF EXCELLENCE, EXTENDED PATENT RIGHTS, AND PROVIDES 10 BILLION IN EURO TO JUMP-START A BUNCH OF COMPANIES.

SO THINGS ARE HAPPENING IN OTHER PARTS OF

THE WORLD. AND IF WE'RE NOT CAREFUL, WE'RE GOING TO SORT OF PROGRESSIVELY FIND OURSELVES WITH MORE COMPETITION AT A MINIMUM AND FALLING BEHIND IN SOME AREAS AT WORST.

OKAY. NOW THIS IS INTERESTING. SO BABY KJ HIT EARLY IN 2025, AND WHAT IT DID WAS IT GENERATED, WHEN THE NEW ADMINISTRATION WAS STARTING AND THE NEW HHS HIERARCHY WAS IN PLACE, THEY'RE LOOKING FOR WINS. AND THIS WAS LIKE A REALLY EARLY WIN. AND IT LED TO A MOST UNUSUAL EVENT WHICH WAS IN MARCH THEY CONVENED 27 STAKEHOLDERS IN THE CELL AND GENE THERAPY SPACE AT A SITE IN D.C. TO GIVE BASICALLY TESTIMONY -- AND THIS IS RESEARCHERS, PATIENT ADVOCATES, INDUSTRY, ET CETERA -- GIVE TESTIMONY TO MEMBERS OF THE NEW HHS TEAM ABOUT THE BENEFITS OF CELL AND GENE THERAPY.

INCLUDED IN THE 27 WERE CRYSTAL MACKALL, INTERESTINGLY, DON KOHN, AND A NUMBER OF OTHER NAMES THAT YOU ALL WOULD RECOGNIZE. IT WAS CONVENED OVER BY THE NEW HEAD OF THE FDA AND THE NEW HEAD OF CBER. AND THEY WENT THROUGH ALL 27 -- HOW MANY HERE HAPPENED TO WATCH THIS? IT WAS ON YOUTUBE. A NUMBER PEOPLE WATCHED. IT WAS INTERESTING TO SAY THE LEAST. ALL THE THINGS THAT WERE SAID WERE GREAT.

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ABOUT 45 MINUTES BEFORE THE END OF IT, THEY TOOK A BREAK, AND THE TWO OF THEM WERE JOINED BY RFK, JR., BY DR. OZ, AND BY DR. BHATTACHARYA. SO THE FIVE NOW, EVERYBODY INVOLVED, LEADERS OF HEALTHCARE, WERE LISTENING TO WHAT'S GOING ON IN THE FIELD THAT LED TO A NUMBER OF SIDEBAR, AS I'VE BEEN TOLD, SIDEBAR DISCUSSIONS THAT DEMONSTRATED INTEREST IN CELL AND GENE THERAPY BY THE LEADERSHIP THERE.

YOU CAN SEE ON THE SLIDE A NUMBER OF THE THINGS THEY'RE DOING TO MAKE IT EASIER TO GET THINGS THROUGH THE FDA IN OUR FIELD. YOU CAN SEE THOSE ON THE RIGHT. I WON'T GO THROUGH THEM. THE SECRETARY HIMSELF IS A FAN OF CELL AND GENE THERAPY BECAUSE IT DEALS WITH TREATING THE CURES AS OPPOSED TO CHRONIC DISEASES, WHICH IS WHAT HE HAS A LITTLE BIT LESS FOCUS ON. BUT THIS IS ONE OF THE THINGS, REGULATORY FLEXIBILITY IN CMC. YOU CAN SEE MARTY MAKARY'S COMMENT, THE ACTING DIRECTOR OF CBER, ET CETERA. SO THAT WAS INTERESTING.

NOW, THIS WOULD HAVE BEEN A GREAT ENTRE TO SHYAM HAD I GONE BEFORE HIM. BUT GOING BEHIND HIM, THIS DEMONSTRATES THE INTEREST THAT HE OUTLINED IN PLATFORM APPROACHES TO TREATING RARE DISEASE. AND IT'S NOT JUST US, BUT IN EUROPE THEY'RE VERY INTERESTED IN THE SAME THING. SO I THINK YOU ARE

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GOING TO START SEEING THAT AS AN AREA OF MAJOR EMPHASIS. AND I'M VERY PROUD TO SAY THAT I BELIEVE CIRM WITH OUR RAPID PROGRAM IS GOING TO BE ON THE FOREFRONT OF DEVELOPMENTS IN THAT AREA.

THIS YOU MIGHT FIND INTERESTING AS WELL. THIS IS A SCORECARD ON HOW THE OFFICE OF THERAPEUTIC PRODUCTS AT THE FDA IS TREATING COMPANIES THAT HAVE PRODUCTS THAT ARE COMING UP TO MARKET. AND YOU CAN SEE SOME OF THEM HAVE PDUFA DATES. SOME OF THEM HAVE COMPLETE RESPONSE LETTERS WHICH, AS YOU KNOW, ARE DOCUMENTS THAT BASICALLY SAID YOU'VE GOT MORE WORK TO DO IN DEFINING WHAT YOU HAVE TO DO TO COME BACK TO THEM, AND VARIOUS BLA-REFERENCED ITEMS HERE. SO THERE A NUMBER OF THINGS COMING UP.

ARM, THIS IS A SCORECARD THAT ARM HAS PUT TOGETHER. SO THEY'RE KEEPING TRACK OF WHAT'S HAPPENING IN THE INDUSTRY AND CAN UPDATE EVERYBODY ON HOW THE FDA IS HANDLING THINGS.

THIS IS, I THINK, PRETTY INTERESTING. SO BIG PHARMA IS PROGRESSIVELY MORE AND MORE GETTING INTO THE CELL AND GENE THERAPY SPACE. I WILL SAY IT TOOK AWHILE; BUT, AS YOU CAN SEE HERE, 20 OF THE 30 LARGEST NOW HAVE EITHER INDIVIDUAL PRODUCTS OR IN MANY CASES MULTIPLE PRODUCTS THAT THEY'RE PURSUING. AND I THINK THAT THAT'S A GREAT SIGN FOR THE FIELD.

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IT'S A GREAT SIGN FOR, AMONG OTHER THINGS, OUR EFFORTS TO TRY TO HELP MATCH OUR AWARDEES WITH INDUSTRY IN ONE FASHION OR ANOTHER.

AND SO YOU SAW THAT BY, AT THIS NUCLEUS FORUM I REFERENCED EARLIER, IF YOU LOOKED AT THE PANEL OF WHO'S THERE ON INDUSTRY, IT'S THE EVP OF PRODUCT DEVELOPMENT AT AMGEN, IT'S PEOPLE FROM LILLY, PEOPLE FROM J & J. A LOT OF THE COMPANIES REPRESENTED HERE ARE IN THAT GROUP.

NOW, THIS IS A FINANCIAL SLIDE WHICH SHOWS THAT IN THE PAST FOUR YEARS, '21 THROUGH '24, YOU HAD TWO BLOCKBUSTERS, WHICH ARE DEFINED AS BILLION IN REVENUE, ONE OF WHICH ZOLGENSMA IN SMA WITH NOVARTIS AND YOU HAD YESCARTA, WHICH, OF COURSE, IS KITE'S CAR-T PRODUCT IN LARGE B-CELL LYMPHOMA. AND THEN YOU LOOK AND THEY PROJECT TWO MORE CAME INTO THE MIX LAST YEAR, WHICH IS, AS YOU CAN SEE, ARE CARVYKTI, WHICH IS MULTIPLE MYELOMA PRODUCT BY JOHNSON, AND BREYANZI, WHICH IS ANOTHER CAR-T PRODUCT IN LARGE B-CELL LYMPHOMA BY BMS. AND THEN YOU CAN SEE WHAT THEY EXPECT OVER THE COURSE OF THE NEXT FEW YEARS.

SO THE FIELD IS, IN TERMS OF BIG WINNERS, THIS IS NOT MANY, BUT IT'S A START, AND IT'S IMPROVING YEAR OVER YEAR. AND IT IS EVIDENCE OF THE

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FIELD FURTHER MATURING. YOU CAN SEE THERE AT THE BOTTOM TEN TOTAL BLOCKBUSTERS EXPECTED THE NEXT FIVE YEARS.

THIS IS -- IF YOU'RE WONDERING WHO'S INVESTING IN THE SECTOR, SO WE HAD 11.1 BILLION LAST YEAR. AND YOU CAN SEE HOW THAT BREAKS DOWN BETWEEN VENTURE, EQUITY, DEBT, ET CETERA. LOTS OF -- A NUMBER OF VERY BIG TICKET M AND A AND PARTNERSHIPS. AGAIN, YOU CAN JUST READ THE SLIDE THERE. THE INVESTORS MAKING VENTURE FINANCINGS IN INDIVIDUAL COMPANIES, YOU CAN SEE HERE ON THIS LIST A NUMBER OF DIFFERENT PLAYERS IN THE FIELD AND WHAT THEY GOT OVER THE COURSE OF LAST YEAR.

THIS IS KIND OF INTERESTING. YOU WOULDN'T HAVE THOUGHT THIS IS NECESSARILY THE CASE THAT OUR SECTOR COMPRISED A HIGHER PERCENTAGE OF BIOTECH VENTURE LAST YEAR THAN THE YEAR BEFORE, WHICH IS A GOOD SIGN FURTHER. THEN YOU'VE GOT PUBLIC OFFERINGS OF WHICH THERE WERE QUITE A FEW OF A HUNDRED MILLION OR MORE, WHICH IS NOTEWORTHY BECAUSE THE PUBLIC OFFERING MARKET IN GENERAL WAS WAY DOWN LAST YEAR. YOU WILL NOTICE THE TOP RIGHT TWO, CAPRICOR AND TENAYA, AND THE BOTTOM LEFT, 4DMT, THOSE ARE THREE OF THE COMPANIES THAT WE HAVE HELPED FUND OVER THE YEARS. SO THIS IS EVIDENCE OF CIRM PLAYERS GETTING

INTO THE GAME IN BIG-TICKET FINANCIAL MANNER.

THEN YOU HAVE -- THIS IS SORT OF WHAT THEY EXPECT COMING UP HERE. SO IN 2026 THEY EXPECT FOUR MORE COMPANIES MAKING IT TO MARKET IN THE U.S., TWO IN EUROPE, AND A NUMBER OF OTHER INDICATIONS THAT ARE WORKING THEIR WAY UP AND GETTING CLOSE TO THE FINISH LINE, WHICH YOU CAN SEE ON THE RIGHT-HAND SIDE THERE.

POTENTIAL CLINICAL MILESTONES THAT ADVANCE THE SECTOR, I'M NOT GOING TO GO THROUGH THESE. BY THE WAY, THIS IS ALL ON THE SLIDE ON THE AGENDA. WELCOME YOU TO TAKE A LOOK AT THAT. SO THEY SORT OF END BY SAYING -- I MISSED THAT. THEY HAD A LITANY OF REASONS WHY THEY FELT THAT THIS DEMONSTRATES THAT THE SECTOR IS FURTHER DEVELOPING, WHICH YOU CAN JUST READ HERE. SCIENCE IS GREAT. PATIENT IMPACT UNDENIABLE. COMPETITION INCREASING. COMMERCIAL OPPORTUNITY AND INVESTMENT INCREASING. STRATEGIC BIOPHARMA RELATIONSHIPS INCREASING. DON'T WANT TO SAY THAT THIS DEPICTS SOMETHING THAT'S LIKE ANYWHERE NEAR WHAT THIS IS GOING TO BE IN FIVE TO TEN YEARS. IT'S, AGAIN, JUST GETTING STARTED.

THE FINANCIAL ATMOSPHERE CONTINUES TO BE TOUGH IN LIFE SCIENCE AS YOU ALL KNOW, BUT THERE ARE INDICATIONS HERE THAT THINGS ARE CONTINUING APACE.

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TIM HUNT SORT OF ENDED BY SAYING THAT THIS IS VERY REMINISCENT, THOSE OF YOU WHO TRACK THE DEVELOPMENT OF MONOCLONAL ANTIBODIES AND THAT INDUSTRY WHEN IT FIRST GOT STARTED WITH THE CHALLENGES IT FACED AND THE SORT OF MIDLIFE OFF-AND-ON DEVELOPMENTS AS THE FIELD MATURED, AND NOW WELL INTO 30 YEARS LATER TO $250 BILLION MARKET. AND THERE'S EVERY INDICATION THAT AT THE END OF THE DAY THIS IS GOING TO END UP SOMETHING SIMILAR. SO THOUGHT THOSE NUMBERS WOULD BE INTERESTING FOR PEOPLE.

AND WITH THAT, THANK YOU VERY MUCH. AND ANY QUESTIONS HAPPY TO ANSWER.

CHAIRMAN IMBASCIANI: THANK YOU, J.T. GREAT ANALYSIS OF THE LANDSCAPE. ANY COMMENTS OR QUESTIONS FROM BOARD MEMBERS?

DR. THOMAS: THANK YOU, MR. CHAIR.

CHAIRMAN IMBASCIANI: THANK YOU, MR. PRESIDENT.

I HAVE ONE ITEM THAT WE PASSED OVER I NEED TO TAKE CARE OF. IT TAKES YOUR VOTE.

MR. TOCHER: WE'RE JUST GOING TO PUNT TO MARCH.

CHAIRMAN IMBASCIANI: WE WILL? THE CONSENT AGENDA?

MR. TOCHER: IT'S JUST THE MINUTES.

CHAIRMAN IMBASCIANI: IT'S JUST THE MINUTES. OKAY. FINE. WE'RE HAPPY TO DO THAT.

SO IS THERE ANY MEMBER OF THE PUBLIC THAT WOULD LIKE TO MAKE ANY COMMENT ON ANY ITEM ON TODAY'S AGENDA OR ON ANY ITEM THAT WAS NOT ON TODAY'S AGENDA? ARE YOU SEEING ANY HANDS? NO. OKAY. THEN I CAN ADJOURN THE MEETING. WE WILL NEXT CONVENE AT 9 O'CLOCK IN THE MORNING ON THURSDAY, MARCH 26TH AT THE WESTIN HOTEL IN SACRAMENTO.

VICE CHAIR BONNEVILLE: AND I JUST WANTED TO THANK BOARD GOVERNANCE FOR A REALLY GREAT MEETING. SO THANK YOU. AND FOR THE CLOSER TO CURES, THANKS FOR INTRODUCING THAT AND MAKING IT A GREAT ADDITION TO OUR BOARD MEETING.

CHAIRMAN IMBASCIANI: YES. THANK YOU, EVERYONE, FOR BEING HERE.

(APPLAUSE.)

(THE MEETING WAS THEN CONCLUDED AT 3:26 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 JANUARY 29, 2026, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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