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: VIA ZOOM

DATE: MARCH 23, 2021
9 A.M.

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

FILE NO.: 2021-07

I N D E X

MARCH 23, 20/21; 9 A.M.

CHAIRMAN THOMAS: THANK YOU. WELCOME, EVERYBODY, TO THE MARCH 2021 MEETING OF THE APPLICATION REVIEW SUBCOMMITTEE AND THE ICOC. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: HAIFAA ABDULHAQ.

DR. ABDULHAQ: HERE.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: HERE.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: PRESENT.

MS. BONNEVILLE: ALLISON BRASHEAR.

DR. BRASHEAR: HERE.

MS. BONNEVILLE: DEBORAH DEAS.

DR. DEAS: HERE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON. MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: HERE.

MS. BONNEVILLE: ELENA FLOWERS.

DR. FLOWERS: PRESENT.

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MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: HERE.
MS. BONNEVILLE: LARRY GOLDSTEIN.
DR. GOLDSTEIN: HERE.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: HERE.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: HERE.
MS. BONNEVILLE: PAT LEVITT.
DR. LEVITT: HERE.
MS. BONNEVILLE: LINDA MALKAS.
DR. MALKAS: HERE.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: HERE.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: HERE.
MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: HERE.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: HERE.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: HERE.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: HERE.
MS. BONNEVILLE: AL ROWLETT.

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MR. ROWLETT: HERE.
MS. BONNEVILLE: MICHAEL STAMOS.
DR. STAMOS: HERE.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: HERE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: HERE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: HERE.
MS. BONNEVILLE: KAROL WATSON.
DR. WATSON: HERE.
MS. BONNEVILLE: DIANE WINOKUR. KEITH YAMAMOTO.
THANK YOU.
CHAIRMAN THOMAS: OKAY. THANK YOU VERY MUCH, EVERYBODY. TODAY'S MEETING IS GOING TO BE BROKEN DOWN INTO THREE SECTIONS. WE'VE GOT A FEW ACTION ITEMS THAT ARE GOING TO BE RELATIVELY QUICK WHICH WILL BE FOLLOWED BY A PRESENTATION OF A REPORT ON THE SCIENTIFIC STRATEGIC ADVISORY PANEL THAT WE HAD IN FEBRUARY, AND THAT, IN TURN, WILL BE FOLLOWED BY A BOARD RETREAT-LIKE DISCUSSION OF CIRM POLICIES AND PROCEDURES TO GIVE EVERYBODY AN UPDATE ON ALL

YOU NEED TO KNOW ABOUT CIRM AND HOW IT WORKS. PARTICULARLY FOR THE NEWER MEMBERS, I THINK IT WILL BE SOMETHING THAT'S VERY HELPFUL.

SO TO BEGIN WITH, WE HAVE FOUR NEW MEMBERS ON THE PHONE TODAY, THREE OF WHICH NEED TO BE SWORN IN, TWO OF WHICH NEED TO INTRODUCE THEMSELVES TO THE REST OF THE BOARD. THE FIRST TWO, CAROL AND MARK, HAVING DONE, I BELIEVE, AT THE LAST MEETING. SO WE START WITH, CHRISTINE, IF YOU COULD INTRODUCE YOURSELF TO THE BOARD PLEASE.

DR. MIASKOWSKI: THANKS, J.T. GOOD MORNING. I'M CHRIS MIASKOWSKI. I AM A PROFESSOR IN THE SCHOOL OF NURSING AT THE UNIVERSITY OF CALIFORNIA SAN FRANCISCO, AND I HOLD A JOINT APPOINTMENT IN THE DEPARTMENT OF ANESTHESIA AS WELL WHERE I HEAD UP A PAIN AND ADDICTION RESEARCH CENTER WITH AN ANESTHESIOLOGY COLLEAGUE.

I'VE BEEN AN ONCOLOGY NURSE FOR 45 YEARS, DID MY INITIAL TRAINING AND WORK IN NEW YORK CITY, CAME TO UCSF IN 1988 TO DO A POST-DOC AND BECAME IN LOVE, FELL IN LOVE WITH THE BAY AREA AND STAYED. I WORK IN THE AREA OF SYMPTOM MANAGEMENT IN PATIENTS WITH CANCER. AND OUR GROUP IS REALLY TRYING TO UNDERSTAND COMMON SYMPTOMS THAT OCCUR IN PATIENTS WITH CANCER AND TRYING TO UNDERSTAND WHY THERE'S A

LARGE AMOUNT OF INTERINDIVIDUAL VARIABILITY IN THE SYMPTOMS THAT PATIENTS EXPERIENCE. SO WE'RE TRYING TO DO THAT BOTH FROM A PHENOTYPIC PERSPECTIVE AS WELL AS LOOKING AT UNDERLYING MECHANISMS THROUGH MEASURES OF GENE EXPRESSION, GENETIC VARIABILITY, DNA METHYLATION. AND I'M REALLY, REALLY PLEASED TO BE JOINING THIS BOARD.

MR. TORRES: MR. CHAIRMAN.

CHAIRMAN THOMAS: YES, SENATOR TORRES.

MR. TORRES: YOU ARE THE REASON WHY BOB KLEIN AND I MADE SURE THAT WE HAD TWO NURSES NEWLY APPOINTED TO THIS BOARD. WE ARE SO GRATEFUL THAT YOU AGREED TO PARTICIPATE GIVEN, I KNOW IN TALKING TO SAM AND OTHERS, YOUR SCHEDULE, AND CHRISTINE DODD, BUT WE ARE SO FORTUNATE TO HAVE YOU AND ESPECIALLY NOW AS WE MOVE INTO TO A NEW EPIC AREA FOR CIRM TO HAVE YOUR PERSPECTIVE AS A NURSE, AS A PROFESSOR, AS A CAREGIVER WHO UNDERSTANDS THE FIELD. THANK YOU SO MUCH, CHRISTINE.

DR. MIASKOWSKI: I REALLY APPRECIATE YOUR COMMENTS, AND I'M EAGER TO CONTRIBUTE IN THAT REALM. SO THANK YOU, SIR.

CHAIRMAN THOMAS: THANK YOU VERY MUCH, CHRISTINE.

NEXT LET'S MOVE ON TO PAT. IF YOU COULD

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INTRODUCE YOURSELF.

DR. LEVITT: THANKS, J.T. I'M PAT LEVITT. I'M THE CHIEF SCIENTIFIC OFFICER AT CHILDREN'S HOSPITAL LOS ANGELES AND A PROFESSOR OF PEDIATRICS, PHARMACEUTICAL SCIENCES, AND PSYCHOLOGY AT USC.

I'M A DEVELOPMENTAL NEUROSCIENTIST AND HAVE PROBABLY WHAT'S AN UNUSUAL RESEARCH PROGRAM THAT INCLUDES BOTH VERY BASIC RESEARCH AND UNDERSTANDING GENETIC AND ENVIRONMENTAL CONTRIBUTIONS TO CIRCUIT FORMATION, MATURATION IN THE BRAIN, AND ALSO CLINICAL RESEARCH PARTICULARLY RELATED TO NEURODEVELOPMENTAL DISORDERS AND THE INFLUENCE OF EARLY LIFE STRESS ON INCREASED RISK FOR LIFE SPAN DISEASE, INCLUDING BRAIN DISEASES AND DISEASES THAT INVOLVE PERIPHERAL ORGANS.

WE DO IN INFANTS AND TODDLERS AND YOUNG CHILDREN MEASURES OF BRAIN WAVE ACTIVITY WITH EEG AND OTHER SORTS OF MEASURES AND PARTICULARLY FOCUSED ON MITOCHONDRIAL FUNCTION AND METABOLIC MEASURES. I THINK I'M PLEASED TO BE ON THE BOARD. J.T. PROMISED IT WOULDN'T BE A HEAVY LIFT, BUT I'M SUSPECTING THAT HE WAS BEING KIND WHEN HE TALKED TO ME ABOUT THIS. SO I'M HAPPY TO BE HERE.

CHAIRMAN THOMAS: THANK YOU, CHRISTINE AND PAT. AND ALONG WITH KAROL AND MARK, WE ARE

DELIGHTED THAT YOU HAVE JOINED US. SO WELCOME HERE. WE NEED TO SWEAR IN KAROL, MARK, AND CHRISTINE, PAT HAVING ALREADY BEEN SWORN IN. SO IF THE THREE OF YOU COULD RAISE YOUR RIGHT HANDS AND REPEAT AFTER ME.

(MEMBERS MIASKOWSKI, WATSON, AND FISCHER-COLBRIE WERE THEN DULY SWORN IN AS MEMBERS OF THE ICOC.)

CHAIRMAN THOMAS: CONGRATULATIONS TO YOU ALL AND WELCOME ALL FOUR TO THE BOARD. THANK YOU VERY MUCH.

OKAY. WE ARE GOING TO NOW PROCEED TO THE ACTION ITEMS, WHICH WE WILL START WITH NO. 4, WHICH IS CONSIDERATION OF APPOINTMENT OF PATIENT ADVOCATE MEMBERS TO THE GRANTS WORKING GROUP. WE HAVE ONE FOR TODAY WHICH IS MARK FISCHER-COLBRIE, AND WE WOULD LIKE TO HAVE HIM UP FOR CONSIDERATION. SO DO I HAVE A MOTION THAT HE BE SO APPOINTED?

MR. ROWLETT: SO MOVED.

CHAIRMAN THOMAS: THANK YOU, AL. IS THERE A SECOND?

DR. DULIEGE: I SECOND.

CHAIRMAN THOMAS: THANK YOU, ANNE-MARIE. IS THERE ANY BOARD DISCUSSION? HEARING NONE, IS THERE ANY PUBLIC COMMENT? HEARING NONE, MARIA, WILL

YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: HAIFAA ABDULHAQ.

DR. ABDULHAQ: PRESENT.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: YES.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: ALLISON BRASHEAR.

DR. BRASHEAR: YES.

MS. BONNEVILLE: DEBORAH DEAS.

DR. DEAS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON. ELENA FLOWERS.

DR. FLOWERS: PRESENT.

MS. BONNEVILLE: JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: LARRY GOLDSTEIN.

DR. GOLDSTEIN: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

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MR. JUELSGAARD: YES.
MS. BONNEVILLE: PAT LEVITT.
DR. LEVITT: YES.
MS. BONNEVILLE: LINDA MALKAS.
DR. MALKAS: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: MICHAEL STAMOS.
DR. STAMOS: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.

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MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: KAROL WATSON.
DR. WATSON: YES.
MS. BONNEVILLE: DIANE WINOKUR. KEITH YAMAMOTO.
THE MOTION CARRIES. THANK YOU.
CHAIRMAN THOMAS: OKAY. THANK YOU. WE'RE GOING TO NOW GO ON TO ITEM NO. 5, WHICH IS CONSIDERATION OF APPOINTMENT OF MEMBERS TO THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP. AS YOU WILL RECALL, AMONGST THE MANY NEW ELEMENTS IN PROPOSITION 14 WAS THE MANDATE TO ESTABLISH THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP TO DEAL WITH ALL THE MANY ISSUES THAT ARE GOING TO ARISE AS CIRM-FUNDED PRODUCTS WORK THEIR WAY THROUGH THE RESEARCH CONTINUUM AND ULTIMATELY END UP OUT IN THE MARKETPLACE.
WE ARE IN THE PROCESS OF PUTTING THAT WORKING GROUP TOGETHER. I'VE ASKED SENATOR TORRES TO CHAIR THAT WORKING GROUP, AND WE HAVE SOME MEMBERS WE WANT TO APPOINT TO IT TODAY.
BUT BEFORE WE GET TO THAT ACTUAL VOTE AND

MOTION, I WANTED TO READ YOU A LITTLE BIT OF BACKGROUND, GIVE YOU MORE OF A FLAVOR FOR THE, AS WE CALL IT, AAWG AND SOME OF THE MEMBERS WHICH WE HAVE ALREADY APPOINTED. SO IF YOU WILL BEAR WITH ME, I'M GOING TO BE READING THIS MEMO TO YOU. THIS IS FROM ME AND SENATOR TORRES.

"AS YOU KNOW, PROPOSITION 14 CREATED THE TREATMENTS AND CURES ACCESSIBILITY AND AFFORDABILITY WORKING GROUP, OR AAWG, TO RECOMMEND POLICIES AND PROGRAMS TO THE BOARD TO ENHANCE ACCESS TO AND THE AFFORDABILITY OF TREATMENTS AND CURES ARISING FROM CIRM-FUNDED RESEARCH FOR CALIFORNIA PATIENTS.

"THE AAWG IS COMPOSED OF 17 MEMBERS: SEVEN MEMBERS OF THE BOARD, INCLUDING THE CHAIR AND VICE CHAIR, AND TEN OUTSIDE EXPERTS. PURSUANT TO HEALTH AND SAFETY CODE SECTION 125290.75 -- BY THE WAY, IDENTIFIES THIS AS A MEMO WRITTEN BY JAMES -- THE CHAIR AND VICE CHAIR OF THE BOARD ARE REQUIRED TO NOMINATE MEMBERS OF THE AAWG FOR APPROVAL BY THE BOARD. TO DATE THE BOARD HAS APPOINTED THE FOLLOWING BOARD MEMBERS TO THE AAWG: DAN BERNAL, ALLISON BRASHEAR, DAVID HIGGINS, ADRIANA PADILLA, AND AL ROWLETT. IN ADDITION, THE BOARD APPOINTED JAMES DEBENEDETTI, THE DIRECTOR OF PLAN MANAGEMENT AT COVERED CALIFORNIA, WHO FILLS THE SEAT FOR AN

EXPERT IN CALIFORNIA'S PUBLIC INSURANCE PROGRAM; DANA DORNSIFE, THE FOUNDER OF LAZEREX CANCER FOUNDATION, WHO FILLS THE SEAT FOR A REPRESENTATIVE FROM A PHILANTHROPIC ORGANIZATION WHO HAS EXPERIENCE ASSISTING PATIENTS IN CLINICAL TRIAL ACCESS AND AFFORDABILITY OR WITH ACCESS TO AND THE AFFORDABILITY OF INNOVATIVE THERAPIES; DANA GOLDMAN, INTERIM DEAN OF THE USC SOL PRICE SCHOOL OF PUBLIC POLICY WHERE HE HOLDS THE LEONARD SCHAEFFER CHAIR AND IS A DISTINGUISHED PROFESSOR OF PUBLIC POLICY, PHARMACY, AND ECONOMICS, TO FILL THE SEAT FOR A HEALTHCARE ECONOMIST WITH EXPERIENCE IN ADVISING OR NEGOTIATING WITH PRIVATE INSURERS, GOVERNMENT INSURERS, OR CORPORATE SELF-INSURANCE PROGRAMS ON COVERAGE FOR INNOVATIVE THERAPIES FOR HUMAN TRIALS, INCLUDING EXPERIENCE IN ASSISTING HOSPITALS AND CLINICS IN COVERING FINANCIAL GAPS IN COVERAGE OF THE DIRECT AND INDIRECT COSTS OF INNOVATIVE THERAPIES. SO WE HAVE THOSE THREE MEMBERS CURRENTLY.

"TODAY WE WISH TO NOMINATE THREE OTHERS. THEY ARE ANN BOYNTON, EXECUTIVE DIRECTOR OF STRATEGIC PLANNING AT THE UC DAVIS MEDICAL CENTER, WHO FILLS THE SEAT FOR A REPRESENTATIVE FROM HOSPITALS IN CALIFORNIA THAT ARE PARTICIPATING IN

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STEM CELL CLINICAL TRIALS OR FDA-APPROVED STEM CELL OR GENETIC THERAPY; ADRIENNE SHAPIRO, PATIENT ADVOCATE FOR SICKLE CELL DISEASE, WHO FILLS THE SEAT FOR A REPRESENTATIVE FROM A PATIENT ADVOCACY ORGANIZATION WHO HAS TECHNICAL EXPERTISE OR EXPERIENCE IN COVERAGE, QUALIFICATIONS, AND THE PROCESS FOR REIMBURSEMENT OF INNOVATIVE THERAPIES; AMMAR QADAN, VICE PRESIDENT AND GLOBAL HEAD OF MARKET ACCESS AT ILLUMINA INC., WHO FILLS THE SEAT FOR AN EXPERT FOR A HIGHLY KNOWLEDGEABLE INDIVIDUAL WITH EXPERIENCE IN FEDERAL THERAPY COVERAGE, QUALIFICATIONS, AND PROCESS FOR REIMBURSEMENT, INCLUDING, IF POSSIBLE, EXPERIENCE WITH THE CENTERS FOR MEDICARE AND MEDICAID SERVICES. BIOS WERE ATTACHED IN YOUR MATERIALS."

SO DO WE HAVE A MOTION TO NOMINATE FOR THE AAWG ANN BOYNTON, ADRIENNE SHAPIRO, AND AMMAR QADAN PLEASE?

DR. HIGGINS: SO MOVED.

MS. BONNEVILLE: I THINK DAVID HIGGINS GAVE ME THE FIRST.

DR. STAMOS: SECOND.

CHAIRMAN THOMAS: THANK YOU. IS THERE DISCUSSION BY ANY MEMBERS OF THE BOARD?

MS. BONNEVILLE: THERE ARE NO HANDS

RAISED.

CHAIRMAN THOMAS: I'LL NOTE FOR THE BOARD MEMBERS THAT IF WE DO VOTE TO APPROVE THESE THREE INDIVIDUALS GOING ON THE AAWG, THAT STILL LEAVES AN ADDITIONAL FOUR SLOTS THAT SENATOR TORRES AND I AND MARIA BONNEVILLE ARE WORKING ON FILLING, AND WE'LL BE BRINGING ADDITIONAL NOMINEES TO LATER BOARD MEETINGS.

IS THERE ANY COMMENT FROM MEMBERS OF THE PUBLIC?

MS. BONNEVILLE: I DO NOT SEE ANY HANDS RAISED.

CHAIRMAN THOMAS: HEARING NONE, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: HAIFAA ABDULHAQ.

DR. ABDULHAQ: YES.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: YES.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: ALLISON BRASHEAR.

DR. BRASHEAR: YES.

MS. BONNEVILLE: DEBORAH DEAS.

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DR. DEAS: YES.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MS. BONNEVILLE: MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: YES.
MS. BONNEVILLE: ELENA FLOWERS.
DR. FLOWERS: YES.
MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: YES.
MS. BONNEVILLE: LARRY GOLDSTEIN.
DR. GOLDSTEIN: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: PAT LEVITT.
DR. LEVITT: YES.
MS. BONNEVILLE: LINDA MALKAS.
DR. MALKAS: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.

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MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: MICHAEL STAMOS.
DR. STAMOS: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: KAROL WATSON.
DR. WATSON: YES.
MS. BONNEVILLE: DIANE WINOKUR. KEITH YAMAMOTO.
THE MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU, MARIA. ON TO ITEM 6, CONSIDERATION OF APPOINTMENT OF ICOC MEMBERS

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TO THE APPLICATION REVIEW SUBCOMMITTEE. JAMES.

MR. HARRISON: GOOD MORNING, MEMBERS. AS I THINK ALL OF YOU WILL RECALL, AND WE'VE HAD A CHANCE TO DESCRIBE THIS TO THE NEW MEMBERS, IN 2013 THE BOARD AMENDED ITS BYLAWS TO CREATE WHAT'S CALLED THE APPLICATION REVIEW SUBCOMMITTEE, WHICH IS COMPRISED OF THE ENTIRE BOARD, BUT THE 13 MEMBERS WHO ARE APPOINTED FROM ACADEMIC AND NONPROFIT RESEARCH INSTITUTIONS ARE NONVOTING MEMBERS. AND THE APPLICATION REVIEW SUBCOMMITTEE, AS YOU KNOW, MAKES ALL FINAL DECISIONS WITH RESPECT TO RESEARCH AWARDS.

GIVEN THE FACT THAT PROP 14 EXPANDED THE BOARD TO ADD SIX NEW MEMBERS, INCLUDING TWO MEMBERS APPOINTED FROM UC RIVERSIDE AND UCSF FRESNO-CLOVIS, RESPECTIVELY, TWO NURSES AND TWO PATIENT ADVOCATES FROM MENTAL HEALTH CONDITIONS, WE NEED TO TAKE FORMAL ACTION TO ADD THOSE MEMBERS TO THE APPLICATION REVIEW SUBCOMMITTEE. SO WE WOULD REQUEST THAT THE BOARD APPROVE A MOTION TO APPOINT THE NURSE AND PATIENT ADVOCATE MEMBERS AS VOTING MEMBERS OF THE APPLICATION REVIEW SUBCOMMITTEE AND APPOINT THE UC RIVERSIDE AND UCSF FRESNO-CLOVIS MEMBERS AS NONVOTING MEMBERS OF THE APPLICATION REVIEW SUBCOMMITTEE. AND I'D BE HAPPY TO ANSWER ANY

QUESTIONS ANYONE HAS.

MR. TORRES: SO MOVED.

CHAIRMAN THOMAS: IS THERE A SECOND?

DR. MARTIN: SECOND.

CHAIRMAN THOMAS: THANK YOU, DAVE. IS THERE ANY DISCUSSION BY MEMBERS OF THE BOARD?

MS. BONNEVILLE: NO HANDS RAISED.

CHAIRMAN THOMAS: ANY COMMENT FROM MEMBERS OF THE PUBLIC? JAMES, THANKS VERY MUCH FOR THAT PRESENTATION. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: HAIFAA ABDULHAQ.

DR. ABDULHAQ: YES.

MS. BONNEVILLE: DAN BERNAL.

MR. BERNAL: YES.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: ALLISON BRASHEAR.

DR. BRASHEAR: YES.

MS. BONNEVILLE: DEBORAH DEAS.

DR. DEAS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

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DR. FISCHER-COLBRIE: YES.
MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: YES.
MS. BONNEVILLE: LARRY GOLDSTEIN.
DR. GOLDSTEIN: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: PAT LEVITT.
DR. LEVITT: YES.
MS. BONNEVILLE: LINDA MALKAS.
DR. MALKAS: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.

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MS. BONNEVILLE: MICHAEL STAMOS.
DR. STAMOS: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: KAROL WATSON.
DR. WATSON: YES.
MS. BONNEVILLE: DIANE WINOKUR. KEITH YAMAMOTO.
THE MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU, MARIA. ON TO ITEM NO. 7, CONSIDERATION OF SUPPLEMENTAL FUNDING FOR EXISTING BRIDGES AWARDEES. WE HAVE JENNIFER AND GIL.
MS. BONNEVILLE: YIMI, CAN YOU GO TO PRESENTATION AND SHARE THE SCREEN PLEASE.
MS. LEWIS: MORNING, EVERYONE. MY NAME IS JENNIFER LEWIS. I'M THE DIRECTOR OF GRANTS MANAGEMENT. AND TODAY I'M GOING TO BRIEFLY JUST SHARE AN UPDATE ON THE BUDGET FOR THE EDUC PROGRAMS.

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NEXT SLIDE PLEASE.

AS THE MEMBERS OF THE BOARD MAY RECALL, AT THE FEBRUARY BOARD MEETING, THE BOARD APPROVED TWO PROGRAMS IN THE -- TWO EDUCATION CONCEPTS IN THE BRIDGES PROGRAM AND THE RESEARCH TRAINING GRANT PROGRAM. AND DURING THAT DISCUSSION, THERE WERE SOME QUESTIONS REGARDING THE BUDGET. AND SO I WANTED BRIEFLY JUST TO PROVIDE SOME SUPPLEMENTAL INFORMATION TO THE FULL BOARD AND HAPPY TO TAKE ANY QUESTIONS.

SO AS YOU WILL SEE HERE IN THE TWO COLUMNS LISTED, THE TOTAL INVESTMENT THAT WAS APPROVED LAST MONTH FOR THE BRIDGES PROGRAM WAS $65 MILLION AND $100 MILLION FOR THE RESEARCH TRAINING GRANT PROGRAM. AND THE TOTAL AWARD AMOUNT FOR EACH OF THESE PROGRAMS IS UP TO 3.6 MILLION FOR THE BRIDGES PROGRAM AND FIVE MILLION FOR THE RESEARCH TRAINING GRANT PROGRAM.

BASED ON THIS, THE ESTIMATED NUMBER OF TRAINEES TO COME OUT OF EACH OF THESE PROGRAMS WOULD BE 900 FOR THE BRIDGES PROGRAM AND 530 FOR THE RESEARCH TRAINING GRANT PROGRAM. AND THE DURATION FOR THESE APPOINTMENT PERIODS FOR THESE TRAINEES IS ONE YEAR FOR BRIDGES AND TWO YEARS FOR THE RESEARCH TRAINING.

FROM THIS WE BROKE DOWN THE COSTS THAT ARE GOING DIRECTLY TO STUDENTS AND THE OVERHEAD. AND SO DIRECT STUDENT COST, WHICH INCLUDES THINGS LIKE STIPENDS, TUITION AND FEES, HEALTH INSURANCE AS IN THE RESEARCH TRAINING PROGRAM. IN THE BRIDGES PROGRAM THIS IS ABOUT $51,000 PER STUDENT, AND RESEARCH TRAINING IS ABOUT $79,000 PER TRAINEE.

AND THEN THE PROGRAM ADMINISTRATION AND OVERHEAD COSTS ARE A BUDGET LINE ITEM THAT'S ALL ENCOMPASSING OF EACH YEAR. HOWEVER, IF WE BREAK IT DOWN BY EACH TRAINEE PER YEAR, IT'S $20,000 PER TRAINEE FOR THE BRIDGES PROGRAM AND $14,000 FOR THE RESEARCH TRAINING GRANT PROGRAM, WHICH GIVES US A TOTAL COST PER STUDENT PER YEAR OF 72,000 FOR THE BRIDGES TRAINEE PROGRAM AND $94,000 FOR THE RESEARCH TRAINING GRANT PROGRAM.

SO THE LAST TWO LINE ITEMS HERE ARE JUST TO GIVE YOU AN IDEA OF SOME OF THE BENCHMARKING COMPARATORS WE DID JUST AS A SUMMARY. SO BOTH OF THESE PROGRAMS, THE INITIAL RFA'S WERE LAUNCHED IN 2008 UNDER PROP 71. AND ALL THE BUDGET CATEGORIES IN BOTH OF THESE PROGRAMS HAVE NOT BEEN INCREASED SINCE THAT TIME. SO THERE IS A 16-PERCENT INCREASE IN THE BUDGET LINE ITEMS FOR EACH OF THESE PROGRAMS. AND WHEN COMPARING TO THE NIH, THE RESEARCH TRAINING

GRANT PROGRAM IS ABOUT AN 8-PERCENT INCREASE IN THE PER TRAINEE'S COST PER PROGRAM.

SO, J.T., I WANTED TO PAUSE FOR JUST ONE MOMENT TO SEE IF ANYONE HAD ANY QUESTIONS REGARDING THIS DISCUSSION ITEM, AND THEN I'LL HAND IT OFF TO GIL.

CHAIRMAN THOMAS: OKAY. ANY COMMENTS BY MEMBERS OF THE BOARD?

DR. MARTIN: COULD YOU REMIND ME AGAIN THE STATUS OF EDUCATION OF THE BRIDGES VERSUS THE RESEARCH TRAINING GRANTS?

MS. LEWIS: SURE. SO BRIDGES TRAINING PROGRAMS ARE UNDERGRADUATE. SOME OF THEM ARE MASTER'S LEVEL, BUT THESE HAPPEN AT COMMUNITY COLLEGES. AND THE RESEARCH TRAINING PROGRAM IS PRE-DOC, POST-DOC, AND CLINICAL FELLOWS. SO THIS PER TRAINEE NUMBER IS BASED ON THE POST-DOC, KIND OF THE MIDDLE AVERAGE OF PER TRAINEE DOLLARS. THAT GIVES YOU KIND OF A COMPARATOR BETWEEN THE TWO PROGRAMS.

DR. MARTIN: THANK YOU.

CHAIRMAN THOMAS: ANY OTHER QUESTIONS FOR JENN? ANNE-MARIE.

DR. DULIEGE: IT'S RATHER COMMENT. I JUST WANT TO THANK YOU, JENN, AS WELL AS YOUR TEAM AND

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MARIA FOR PROVIDING THESE NUMBERS. THEY ARE CRYSTAL CLEAR, VERY EASILY UNDERSTANDABLE, AND MAKES A LOT OF SENSE. THANK YOU SO MUCH.

MS. LEWIS: THANK YOU, ANNE-MARIE.

CHAIRMAN THOMAS: ANY OTHER COMMENTS OR QUESTIONS FROM MEMBERS OF THE BOARD FOR JENN AT THIS POINT? HEARING AND SEEING NONE, WE'LL GO ON TO PART 2 OF THE PRESENTATION FOR THIS ITEM WHICH IS FROM GIL.

DR. SAMBRANO: THANK YOU. GO ON TO THE NEXT SLIDE. GOOD MORNING, EVERYONE.

SO AT THE JANUARY 28TH MEETING OF THE GOVERNING BOARD, THERE WAS A REQUEST THAT CIRM BRING A PROPOSAL FOR A SUPPLEMENTAL AWARD AS A POSSIBLE SOLUTION TO ENSURE THE CONTINUITY OF EXISTING BRIDGES TRAINING PROGRAMS THAT MAY REQUIRE IMMEDIATE INFUSION OF FUNDS IN ORDER TO ENABLE THEIR NEXT COHORT OF TRAINEES. NEXT SLIDE PLEASE.

SO SEVERAL OF THE EXISTING BRIDGES TRAINING PROGRAM AWARDEES ARE NOW REACHING THE END OF THEIR CURRENT FIVE-YEAR AWARD IN JUNE OR JULY OF THIS YEAR. HOWEVER, IN MANY CASES THE RECRUITMENT AND APPOINTMENT ACTIVITIES REQUIRED TO ESTABLISH WHAT WOULD BE THE NEXT YEAR'S TRAINEE COHORT WILL OFTEN BEGIN SIX TO 18 MONTHS AHEAD OF THE INTERNSHIP

PERIOD. AND ALTHOUGH WE HAVE ISSUED AN RFA NOW TO RENEW THE BRIDGES TRAINING PROGRAM AND PROVIDE NEW AWARDS TO MERITORIOUS INSTITUTIONS, MANY OF THOSE EXISTING AWARDEES ARE GOING TO EXPERIENCE AN INTERRUPTION WHERE THEIR NEXT COHORT IS GOING TO SKIP A YEAR DUE TO THE TIMING OF THAT NEW OPPORTUNITY. SO NEXT SLIDE PLEASE.

SO A POSSIBLE SOLUTION FOR THESE EXISTING AWARDEES IS TO PROVIDE A SUPPLEMENT THAT WOULD COVER PROGRAM ADMINISTRATION COSTS FROM MARCH, BASICALLY NOW, THROUGH A NEW AWARD START DATE WHICH WE ANTICIPATE WOULD BE IN AUGUST OF THIS YEAR. SO BASICALLY A FIVE-MONTH PERIOD. AND ALTHOUGH A FEW HAVE ALREADY LOST THEIR NEXT COHORT, THERE ARE SEVERAL THAT COULD BEGIN ACTIVITIES NOW TO AVOID A DISRUPTION IN STARTING THAT NEXT TRAINEE COHORT.

SO WE PROPOSE THAT EXISTING AWARDEES WHO WILL BE APPLYING FOR A NEW AWARD THIS YEAR AND THAT CAN'T CONDUCT ACTIVITIES THAT ARE NECESSARY TO AVOID INTERRUPTION IN APPOINTING THEIR NEXT TRAINEE COHORT COULD REQUEST A SUPPLEMENT AWARD TO ENABLE THE CONTINUITY OF THE PROGRAM. AND THE COSTS COVERED BY THE SUPPLEMENT, WE FEEL, MUST BE NECESSARY FOR THE PROGRAM CONTINUITY IN ORDER TO QUALIFY AS WELL AS OBVIOUSLY APPLYING FOR A NEW AWARD.

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IF A SUPPLEMENT AWARDEE IS SUCCESSFUL IN EARNING A NEW BRIDGES TRAINING AWARD, THEN THAT AWARD AMOUNT WILL BE REDUCED FROM THE SUPPLEMENTED AMOUNT OR BY THE SUPPLEMENTED AMOUNT. EXCUSE ME.

AND THEN IF A SUPPLEMENT AWARDEE IS NOT SUCCESSFUL, ANY REMAINING AMOUNT WOULD BE ALLOWED TO BE USED FOR WIND-DOWN ACTIVITIES AND AWARD CLOSEOUT. NEXT SLIDE PLEASE.

AND SO THIS IS BASICALLY THE ALLOCATION THAT WE PROPOSE FOR THE SUPPLEMENT. THE MAXIMUM AWARD AMOUNT FOR EACH WOULD BE 50,000, WHICH ALIGNS WITH THE PROGRAM ADMINISTRATION COSTS OVER A FIVE-MONTH PERIOD. AND JENN WILL PROVIDE MORE DETAIL ON THE NEXT SLIDE ABOUT THAT. WE SUGGEST THAT THE SUPPLEMENT MAY ONLY BE USED FOR THE PROGRAM ADMINISTRATION COSTS THAT ARE DIRECTLY ATTRIBUTED TO AND NECESSARY FOR AVOIDING AN INTERRUPTION IN APPOINTING THE NEXT TRAINEE COHORT.

IN ORDER TO REQUEST A SUPPLEMENT, THE QUALIFYING AWARDEES WOULD PROVIDE A DETAILED BUDGET TO CIRM THAT ADEQUATELY JUSTIFIES THE PROPOSED COSTS AND MAKE IT CLEAR THAT THEY ARE SPECIFICALLY FOR THIS PURPOSE.

AND SO OVERALL CIRM PROPOSES A TOTAL ALLOCATION OF 500,000 FOR APPROXIMATELY TEN

SUPPLEMENT AWARDS. THERE ARE CURRENTLY 14 BRIDGES PROGRAMS ACTIVE, BUT WE BELIEVE AT MAXIMUM ONLY TEN WOULD QUALIFY FOR THIS AWARD.

SO IN THE NEXT SLIDE, JENN IS GOING TO GO OVER THE SPECIFIC DETAILS OF THAT BUDGET ALLOCATION.

MS. LEWIS: THANKS, GIL. SO THIS IS JUST A SNAPSHOT OF THE PROPOSED ALLOCATION THAT WE ARE REQUESTING TODAY WHICH IS $500,000. AS GIL MENTIONED, THERE WOULD BE TEN AWARDS OF THE 14 ACTIVE AWARDS WHICH WOULD BE FOR A PERIOD OF FIVE MONTHS. THE BUDGET IN THE PROGRAM IS UP TO 125,000 FOR PROGRAM ADMINISTRATION. SO WE ESTIMATED THE SUPPLEMENT BASED ON A MONTHLY COST OF $10,000 PER MONTH FOR THESE ACTIVITIES, WHICH WOULD BE THE $50,000 PER AWARDEE.

AND THEN NEXT SLIDE. AND SO OUR REQUESTED ACTION FOR TODAY IS WE ARE REQUESTING THE BOARD TO APPROVE THIS PROPOSED SUPPLEMENT CONCEPT WITH AN ALLOCATION OF $500,000.

CHAIRMAN THOMAS: SO THANK YOU, GIL AND JENN. BEFORE I ASK FOR A MOTION AND SECOND, I JUST WANT TO REMIND EVERYBODY THIS PARTICULAR ITEM PLEASE ONLY MOVE OR SECOND IF YOU ARE NOT IN CONFLICT. DO I HEAR A MOTION TO APPROVE?

DR. HIGGINS: SO MOVED.

CHAIRMAN THOMAS: THANK YOU, DAVID. IS THERE A SECOND?

MR. BERNAL: SECOND.

CHAIRMAN THOMAS: THANKS, DAN. ANY COMMENTS OR QUESTIONS FOR EITHER JENN OR GIL FROM MEMBERS OF THE BOARD?

DR. MARTIN: CAN YOU EXPLAIN TO US OR JUST DESCRIBE TO US WHAT THE USES OF THE $10,000 PER MONTH SUPPLEMENT WOULD BE? WHAT IS THAT COVERING?

DR. SAMBRANO: SURE. SO THAT MAY COVER PERSONNEL COSTS OR COSTS THAT ARE RELATED TO IDENTIFYING AND RECRUITING NEW STUDENTS. SO IN SOME CASES IT MAY BE SOME OF THE PREPARATORY COURSEWORK THAT THEY HAVE IN ORDER TO BEGIN THE PROCESS OF BOTH IDENTIFYING AND PREPARING THE STUDENTS FOR THEIR INTERNSHIP PERIOD.

DR. MARTIN: THANK YOU.

CHAIRMAN THOMAS: OTHER QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD?

MS. BONNEVILLE: ANNE-MARIE HAS A QUESTION.

DR. DULIEGE: MORE CLARIFICATION. I ASSUME THAT IN EACH INSTANCE THIS IS A MAXIMUM AMOUNT AND THAT THE CIRM WILL OBVIOUSLY PROVIDE OVERSIGHT AND NEGOTIATE AS APPROPRIATE TO MAKE SURE

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THAT IT'S THE RIGHT AMOUNT. YOU'RE ASKING US TO BLESS A MAXIMUM AMOUNT; IS THAT RIGHT?

DR. SAMBRANO: YES, THAT'S CORRECT.

DR. DULIEGE: THANK YOU.

CHAIRMAN THOMAS: OTHER QUESTIONS OR COMMENTS?

MS. BONNEVILLE: I DON'T SEE ANY OTHERS.

CHAIRMAN THOMAS: THANK YOU. QUESTIONS OR COMMENTS FROM -- COMMENTS FROM MEMBERS OF THE PUBLIC? HEARING NONE, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: SURE. DAN BERNAL.

MR. BERNAL: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: MARK FISCHER-COLBRIE.

DR. FISCHER-COLBRIE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: DAVE MARTIN. WE'LL COME BACK TO DAVE. LAUREN MILLER-ROGEN.

MS. MILLER-ROGEN: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

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DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: DIANE WINOKUR. DAVE MARTIN, CAN I COME BACK TO YOU? ARE YOU THERE?
DR. MARTIN: YES.
MS. BONNEVILLE: IS THAT A YES FOR THE VOTE?
DR. MARTIN: YES.
MS. BONNEVILLE: THE MOTION CARRIES. THANK YOU.
CHAIRMAN THOMAS: THANK YOU, MARIA. ON TO ITEM NO. 8, CONSIDERATION OF THE SELECTION PROCESS FOR REVIEWERS ON THE GRANTS WORKING GROUP. PRESENTATION BY GIL.
DR. SAMBRANO: GOOD MORNING AGAIN. AND TODAY WHAT I WANT TO DO IS PRESENT AN OVERVIEW OF THE GRANT'S WORKING GROUP RECRUITMENT AND NOMINATION PROCESS. I'M GOING TO BEGIN WITH A BRIEF BACKGROUND ABOUT THE GRANTS WORKING GROUP ITSELF AND WHAT ITS RESPONSIBILITIES ARE.

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SO THE GRANTS WORKING GROUP, OR THE GWG, AS WE AFFECTIONATELY CALL IT, IS RESPONSIBLE FOR EVALUATING THE SCIENTIFIC MERIT OF ALL APPLICATIONS THAT ARE SUBMITTED TO CIRM AND ALSO WITH PROVIDING FUNDING RECOMMENDATIONS TO THE ICOC.

BY STATUTE, THE GRANTS WORKING GROUP IS COMPOSED OF 15 SCIENTIFIC MEMBERS WHO ARE NOT FROM CALIFORNIA OR NOT RESIDING IN CALIFORNIA, SEVEN PATIENT ADVOCATE MEMBERS OF THE BOARD, AND THE CHAIR OF THE ICOC IN AN EX OFFICIO CAPACITY.

THE GRANTS WORKING GROUP MEETS TO EVALUATE ALL THE PROPOSALS FOR SCIENTIFIC MERIT ACROSS ALL FIVE OF OUR FUNDING OPPORTUNITY PILLARS, SUCH AS DISCOVERY, TRANSLATION, CLINICAL, EDUCATION, AND INFRASTRUCTURE. AND SO, AS YOU MIGHT IMAGINE, THE BREADTH OF EXPERTISE THAT REQUIRES IS GOING TO BE NECESSARILY VERY LARGE.

IN ORDER TO HAVE AVAILABLE THAT BROAD EXPERTISE REQUIRED TO ASSEMBLE GRANTS WORKING GROUP PANELS FOR ALL OF OUR DIFFERENT FUNDING OPPORTUNITIES, CIRM HAS MAINTAINED AND WE INTEND TO GROW A LARGE POOL OF EXPERTS ON THE ORDER OF 250 TO 300 MEMBERS CURRENTLY WHICH WE'LL LIKELY NEED TO INCREASE IN SIZE. NOW, SINCE A PANEL CANNOT HAVE MORE THAN 15 SCIENTIFIC MEMBERS, WE DRAW THE MOST

RELEVANT EXPERTS FROM OUR POOL TO COMPOSE A GROUP THAT BEST MATCHES THE EXPERTISE NEEDS OF THE PORTFOLIO OF PROPOSALS THAT ARE SUBMITTED WITHIN A GIVEN CYCLE.

NOW, IT'S IMPORTANT TO NOTE THAT WE HAVE MULTIPLE CYCLES RUNNING IN PARALLEL AND, THEREFORE, MULTIPLE PANELS THAT NEED TO BE ASSEMBLED AT ANY GIVEN TIME. WE ALSO NEED TO ACCOUNT FOR THE AVAILABILITY OF MEMBERS, ANY POSSIBLE CONFLICTS OF INTEREST, AND THE OVERALL WORKLOAD THAT IS REQUIRED TO ASSEMBLE THESE AND MANAGE THE APPLICATIONS. JUST AS AN EXAMPLE OF HOW WE MAY CHOOSE EXPERTS FOR OUR CLINICAL PANEL, FOR INSTANCE, WE WILL TYPICALLY INCLUDE REVIEWERS THAT HAVE EXPERTISE IN REGULATORY AFFAIRS, MANUFACTURING, PRODUCT DEVELOPMENT, AND THE RELEVANT CLINICAL DISEASE EXPERTISE. AND WE ALSO ENSURE THAT WE HAVE MULTIPLE EXPERTS IN THESE AREAS THAT CAN CONTRIBUTE TO A GIVEN TOPIC OR SPECIALTY SO THAT WE ARE HEARING FROM MULTIPLE PERSPECTIVES AND VIEWS ON THIS.

NOW, IN ASSEMBLING THESE PANELS, WE WANT TO ENSURE THAT WE HAVE ENOUGH EXPERTS TO DRAW FROM FROM THAT POOL THAT WILL BE ABLE TO ADDRESS ALL OF OUR NEEDS. SO BASICALLY WE ARE LOOKING FOR GAPS IN THE POOL, WHICH FOR US IS AN ONGOING PROCESS. AND

SO THIS INCLUDES HAVING A PANEL THAT INCLUDES MEMBERS WITH DIVERSE BACKGROUNDS AND EXPERIENCES AS WELL AS MULTIPLE SCIENTIFIC PERSPECTIVES, SUCH AS EXPERIENCE FOR THE RELEVANT STAGE OF THERAPY DEVELOPMENT, DISEASE INDICATION, THE THERAPEUTIC APPROACH, THE SPECIFIC ACTIVITIES THAT ARE PROPOSED, AND/OR THE TECHNOLOGIES THAT ARE BEING UTILIZED. AND AS IN SOME CASES, WE HAVE A LARGE NUMBER OF PROPOSALS WITHIN A GIVEN AREA, ENSURING THAT WE HAVE SEVERAL AVAILABLE EXPERTS IN THAT AREA IS ALSO IMPORTANT TO MANAGE THAT WORKLOAD AS WAS MENTIONED BEFORE.

SO THIS DIAGRAM IS PRESENTING AN OVERVIEW OF OUR PROPOSED GWG RECRUITMENT PROCESS WHICH I'M GOING TO GO OVER IN MORE DETAIL ON SUBSEQUENT SLIDES. JUST BRIEFLY, WHEN WE IDENTIFY A NEED OR A GAP IN EXPERTISE, WE HAVE TO FIRST DETERMINE WHO CAN FILL THOSE EXPERTISE NEEDS. WE CAN GO ABOUT THIS IN A VARIETY OF WAYS THAT I'LL DISCUSS ON THE NEXT SLIDE, INCLUDING RECOMMENDATIONS FROM EXPERTS AND OUR PARTNERS.

ONCE WE IDENTIFY AN INDIVIDUAL OR INDIVIDUALS WITH RELEVANT EXPERTISE, AN ASSESSMENT IS MADE OF THEIR LEVEL OF COMMITMENT TO CIRM AS WELL AS THEIR RELEVANT KNOWLEDGE AND PROFICIENCY. AN

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IMPORTANT PART OF THIS ASSESSMENT IS PARTICIPATION IN THE REVIEW PROCESS ITSELF AS A SPECIALIST REVIEWER THAT DOES NOT VOTE OR SCORE, BUT CONTRIBUTES TO THE DISCUSSION AND EVALUATION OF PROPOSALS. AND I WILL MENTION THAT IN MORE DETAIL AGAIN.

NOW, INDIVIDUALS THAT SHOW COMMITMENT TO CIRM WITH DEMONSTRATED KNOWLEDGE AND PROFICIENCY MAY THEN BE NOMINATED FOR MEMBERSHIP INTO THE GWG. NOMINEES ARE FIRST PROPOSED TO THE CIRM LEADERSHIP TEAM TO DETERMINE IF THEY AGREE THAT THE NOMINEES WILL SERVE THE NEEDS OF CIRM AND WILL ADDRESS OUR EXPERTISE NEEDS AND GAPS. AND ONCE WE HAVE AGREEMENT FROM THE CIRM PRESIDENT, NOMINATIONS ARE BROUGHT TO THE ICOC FOR FINAL APPROVAL. AND AS A NOTE, GWG MEMBERS ARE APPOINTED INITIALLY TO A SIX-YEAR TERM AND THEN ARE REAPPOINTED EITHER TO A TWO-, FOUR-, OR SIX-YEAR SUBSEQUENT TERM, AND THEN ADDITIONAL TERMS AFTER THAT ARE SIX YEARS. AND THESE TERMS ARE AS LAID OUT IN PROP 14.

SO LET'S GO INTO A LITTLE MORE DETAIL. SO FIRST LET ME EXPLAIN HOW WE GO ABOUT IDENTIFYING EXPERTS AND GETTING RECOMMENDATIONS. FIRST, WE MAY IDENTIFY A RECOGNIZED EXPERT IN THE FIELD OF INTEREST THROUGH THE SCIENTIFIC LITERATURE, THROUGH

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PARTICIPATION OR THEIR PARTICIPATION IN RELEVANT SCIENTIFIC MEETINGS, AND THEIR MEMBERSHIP IN SCIENTIFIC SOCIETIES OR ORGANIZATIONS WHICH HIGHLIGHT THEIR EXPERTISE. WE LOOK FOR AN INDICATION THAT THE SCIENTIST IS A LEADER AND WELL VERSED IN THE FIELD BY THE NUMBER AND NATURE OF THE PUBLICATIONS, THEIR INVITATIONS TO SPEAK ON THAT TOPIC OF INTEREST AT A RELEVANT MEETING, AND THEN THE ROLE THAT THEY MIGHT HAVE WITHIN THOSE ORGANIZATIONS.

WE ALSO SOLICIT RECOMMENDATIONS FROM OUR CURRENT GRANTS WORKING GROUP MEMBERS. THEY ARE A GREAT RESOURCE FOR FOLKS THAT WE MAY NOT KNOW ABOUT AS WELL AS OUR OWN CIRM SCIENTIFIC TEAM. AS YOU MIGHT IMAGINE, CIRM PARTICIPATES IN MANY SCIENTIFIC MEETINGS. WE HOLD WORKSHOPS AND CONFERENCES AND ALSO ASSEMBLE ADVISORY PANELS; FOR EXAMPLE, OUR CLINICAL ADVISORY PANELS THAT HELP OVERSEE AND SUPPORT OUR CLINICAL GRANTS AND TRANSLATIONAL GRANTS. AND SO ALL OF THAT INTRODUCED US TO A VARIETY OF EXPERTS AS WELL. SO WE CAN OFTEN GET RECOMMENDATIONS FROM OUR OWN INTERNAL COLLEAGUES.

WE ALSO TAKE RECOMMENDATIONS FROM APPLICANTS OR GRANTEES AND CERTAINLY INVITE ICOC MEMBERS TO CONTRIBUTE RECOMMENDATIONS ANY TIME THEY

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HAVE THEM.

NOW, LASTLY, WE ARE ALSO EXPLORING THE POSSIBLY OF PARTNERSHIPS WITH SCIENTIFIC ORGANIZATIONS AND SOCIETIES WHO CAN SHARE THEIR KNOWLEDGE OF EXPERTS OR RECOMMEND THEIR OWN MEMBERS TO INCREASE OUR OVERALL REACH. OTHER FUNDERS AND ORGANIZATIONS ALSO ARE LOOKING FOR EXPERTS THEMSELVES, AND SO SHARING IN THIS EFFORT WOULD CERTAINLY BE MUTUALLY BENEFICIAL. AND WE ARE ACTUALLY QUITE EXCITED ABOUT THIS IDEA AS IT COULD HELP US IDENTIFY AND GET INSIGHTS ON EXPERTS THAT MIGHT NOT OTHERWISE BE AVAILABLE TO US OR THAT MAY NOT KNOW ABOUT US. AND SO WE HAVE ALREADY BEGUN DISCUSSIONS WITH AT LEAST TWO DIFFERENT ORGANIZATIONS THAT HAVE EXPRESSED INTEREST IN PARTNERING IN THIS IDEA.

SO ONCE WE IDENTIFY A POTENTIAL EXPERT, HOW DO WE GO ABOUT ASSESSING THEM FOR POSSIBLE GWG NOMINATION? SO AS MENTIONED, WE WILL LOOK AT ELEMENTS SUCH AS THEIR PUBLICATION RECORD, INVITATIONS TO SPEAK, BUT IN ADDITION THEIR ACADEMIC COMPANY OR GOVERNMENT POSITION THAT DEMONSTRATES LEADERSHIP AND EXPERIENCE IN THE FIELD. WE ALSO LOOK AT ANY AWARDS AND HONORS THAT HIGHLIGHT THEIR SCIENTIFIC ACCOMPLISHMENTS OR RECOMMENDATIONS THAT

COME TO US FROM EITHER A FUNDING AGENCY OR SOCIETY.

IT IS IMPORTANT TO NOTE THAT NOT ALL EXPERTS CAN BE ASSESSED BY THE SAME CRITERIA OR ALL OF THE THINGS I LISTED HERE. SO, FOR EXAMPLE, AN ACADEMIC SCIENTIST CAN BE ASSESSED THROUGH THEIR PUBLICATION RECORD AND ACADEMIC ACHIEVEMENTS; HOWEVER, EXPERTS WITH COMPANY OR GOVERNMENT BACKGROUNDS WOULD NOT NECESSARILY HAVE AN EXTENSIVE PUBLICATION RECORD. THEREFORE, WE LOOK FOR OTHER INDICATORS OF THEIR KNOWLEDGE AND EXPERIENCE, SUCH AS HAVING TAKEN THERAPEUTIC PRODUCTS TO MARKET, HAVING SUCCESSFULLY SUBMITTED IND'S, OR HAVING LED CLINICAL TRIALS, HAVING DEVELOPED BROADLY USED MANUFACTURING PROTOCOLS, OR PERHAPS HAVING REVIEWED SUBMISSIONS TO THE FDA IF THEY WORKED FOR A REGULATORY -- FOR THE FDA ITSELF OR OTHER REGULATORY AGENCY.

WE ALSO LOOK TO SEE IF AN EXPERT HAS EXPERIENCE WITH GRANTS OR OTHER SIMILAR REVIEWS FOR NIH, THE DEPARTMENT OF DEFENSE, NONPROFIT FOUNDATIONS, OR OTHER SIMILAR ORGANIZATIONS. AND FOR US THIS IS AN INDICATOR THAT THE EXPERT WILL BE RELATIVELY FAMILIAR WITH THE GRANTMAKING PROCESS AND PEER REVIEW, AND IT MAY ALSO BE AN INDICATOR OF JUST THEIR GENERAL WILLINGNESS TO CONTRIBUTE TO THE

SCIENTIFIC REVIEW PROCESS IN GENERAL.

AND AS MENTIONED BEFORE, A CRITICAL STEP FOR US IN ASSESSING AN EXPERT REVIEWER FOR NOMINATION IS TO FIRST INVITE THEIR PARTICIPATION AS A NONVOTING, NONSCORING SPECIALIST REVIEWER FOR CIRM. THIS WILL ALLOW US TO ASSESS THEIR FOLLOW-THROUGH AND UNDERSTANDING OF THE REVIEW PROCESS, INCLUDING THE REVIEW OF ASSIGNED APPLICATIONS, THE COMPLETION OF CRITIQUES AND FULL PARTICIPATION IN GRANT WORKING GROUP MEETINGS. WE ALSO LOOK TO SEE IF THE EXPERT DEMONSTRATES KNOWLEDGE, THOUGHTFULNESS, AND THOROUGHNESS WHEN EVALUATING AND DISCUSSING THE PROPOSALS THAT WE ASSIGN TO THEM.

WHEN WE BELIEVE WE HAVE A CANDIDATE OR CANDIDATES THAT HAVE BEEN ASSESSED AS I JUST DESCRIBED AND THAT SHOULD BE NOMINATED FOR GWG MEMBERSHIP, WE PROPOSE HAVING THEM VETTED BY THE CIRM LEADERSHIP TEAM. THE LEADERSHIP TEAM HAS A PRETTY CLEAR UNDERSTANDING OF CIRM NEEDS; AND THE TEAM, WHICH INCLUDES DR. MILLAN AND THE LEADERS OF OUR VARIED DEPARTMENTS, IS PRESENT AT GWG REVIEWS. SO THEY GET TO HEAR THE DELIBERATIONS AND BE WITNESS TO THE COMPETENCY OF OUR REVIEWERS. AS SUCH, THEY'RE PRETTY WELL POISED TO CONTRIBUTE AND VET

NOMINATIONS TO THE GWG.

THE CIRM REVIEW TEAM IN THIS CAPACITY WILL THEN PRESENT THE BACKGROUND, QUALIFICATIONS, AND OVERALL PERFORMANCE OF EXPERT REVIEWERS TO THE LEADERSHIP TEAM TO CONFIRM THEIR AGREEMENT ON NOMINATING THEM FOR SERVICE. AND WITH THAT LEADERSHIP TEAM ADVICE, THE FINAL LIST OF NOMINEES WOULD THEN BE DETERMINED BY DR. MILLAN AND MYSELF.

AND THEN, FINALLY, ONCE WE HAVE A VETTED LIST OF NOMINEES, WE'RE GOING TO BRING THOSE NAMES TO THE ICOC FOR FINAL APPROVAL. IN THE PAST WE HAVE PROVIDED A BIOGRAPHY OF EACH NOMINEE THAT INCLUDES A DESCRIPTION OF THEIR EXPERTISE, THEIR TRAINING, THEIR AFFILIATIONS, HONORS AND ACCOMPLISHMENTS, AND WE WILL CONTINUE TO DO THAT. BUT, IN ADDITION, JUST TO PROVIDE MORE CONTEXT, WE WILL ALSO PROVIDE INFORMATION ON THEIR SPECIFIC EXPERTISE, GAPS OR NEEDS THAT THE NOMINEE FULFILLS, HOW IT IS THAT THE NOMINEE WAS IDENTIFIED, FOR EXAMPLE, IF THEY WERE RECOMMENDED BY A SOCIETY OR BY A GWG MEMBER, AND WHAT THEIR HISTORY OF SERVICE TO CIRM HAS BEEN. AND THEN WE ARE ALSO HAPPY TO PROVIDE JUST OUR RUNNING TOTAL OF EXPERTS IN OUR POOL AND THE NUMBER OF ACTIVE MEMBERS THAT WE HAVE.

SO, MR. CHAIRMAN, THAT CONCLUDES MY

PRESENTATION AND HAPPY TO TAKE ANY QUESTIONS.

CHAIRMAN THOMAS: OKAY. ARE THERE ANY QUESTIONS FROM MEMBERS OF THE BOARD ABOUT THIS PRESENTATION? ACTUALLY WOULD LIKE -- OS, CAN YOU HEAR ME?

DR. STEWARD: YES, I HEAR.

CHAIRMAN THOMAS: IF YOU COULD, AS CHAIRMAN OF THE SCIENCE SUBCOMMITTEE AND THE LONGEST STANDING PATIENT ADVOCATE BOARD MEMBER WHO'S BEEN ON THE GWG SINCE INCEPTION, IF YOU COULD SPEAK TO GIL'S PRESENTATION, BUT MORE BROADLY TO YOUR THOUGHTS FOR THE REST OF THE BOARD ON THE EXCEPTIONAL JOB THAT MEMBERS OF THE GWG HAVE DONE ON BEHALF OF CIRM OVER THE YEARS.

DR. STEWARD: SURE. OKAY. OOPS. WAIT. OKAY. AM I NOT ECHOING NOW?

CHAIRMAN THOMAS: NOT ECHOING. WE LOST YOUR PICTURE.

DR. STEWARD: I'M ON TWO DEVICES, SO YOU'RE HEARING ME ON MY IPHONE, BUT SEEING ME ON THE REGULAR. I HOPE EVERYBODY CAN SEE ME. SO THANK YOU, J.T.

I JUST WANT TO SAY THAT I HAVE BEEN INVOLVED IN THE GWG FOR A NUMBER OF YEARS NOW. AND JUST TO SAY I HAVE BEEN COMPLETELY IMPRESSED WITH

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THE WAY THAT THE ENTIRE PROCESS HAS BEEN HANDLED, HAS COME TOGETHER. WHAT GIL DESCRIBED IS NOT REALLY VERY MUCH DIFFERENT THAN WHAT HAS BEEN DONE IN THE PAST. IT'S JUST SORT OF SETTING DOWN IN DETAIL FOR OUR NEW BOARD REALLY HOW THE WHOLE THING WORKS.

THE EXPERTS ON THE PANEL ARE HIGHLY DIVERSE. THE PROCESS OF, I THINK SORT OF THE TRY-OUT PERIOD THAT GIL DESCRIBED, I BELIEVE WORKS VERY WELL BECAUSE REVIEWERS COME ON, GET A CHANCE TO -- GIL GETS A CHANCE TO ASSESS THEIR INTEREST AND EXPERTISE, BUT MORE IMPORTANTLY REALLY HOW THEY THINK BROADLY ABOUT WHAT CIRM IS ALL ABOUT. I LOVE THE TERM THAT EVOLVED OVER THE YEARS WHEN REVIEWERS WOULD START SAYING, WELL, THIS PROJECT IS CIRMY OR NOT CIRMY OR WHATEVER. THEY REALLY THOUGHT DEEPLY ABOUT ALL ASPECTS OF THE REVIEW, NOT JUST THE SCIENCE, BUT THE BROAD IMPACT, THE ECONOMIC BENEFITS, AND REALLY WHAT THIS PROJECT MIGHT BRING IN TERMS OF NEW THERAPIES AND CURES AND BROAD IMPACT FOR PEOPLE LIVING WITH THE VARIOUS DISORDERS THAT ARE THE TOPIC OF OUR RESEARCH ENTERPRISES.

SO I THINK THAT THE GWG STANDS OUT, IN MY OPINION, AS A REVIEWING ENTITY BECAUSE IT CONSIDERS EVERY APPLICATION. IT GIVES THE SAME AMOUNT OF TIME TO APPLICATIONS THAT INITIALLY SCORE LOW AND ONES

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THAT SCORE HIGH. AND AT THE END OF THAT PROCESS, ONE OF THE THINGS THAT HAPPENS IS THAT THERE'S A VOTE ON WHETHER ADEQUATE TIME WAS GIVEN FOR CONSIDERATION. AND THAT'S JUST A WONDERFUL PROCESS THAT WAS SORT OF BUILT IN.

THE SCIENCE SUBCOMMITTEE DID REVIEW GIL'S PROPOSAL. WE HAD SEVERAL COMMENTS AND SUGGESTIONS THAT HAVE BEEN INCORPORATED. I WOULD SAY ONE OF THE THINGS THAT WAS ASKED AT THAT SCIENCE SUBCOMMITTEE WAS WHETHER THERE WAS DIVERSITY ACROSS THE CAREER SPECTRUM, AND ACTUALLY I CAN SAY FROM MY EXPERIENCE THAT THERE IS. AND THAT WAS AN IMPORTANT WAY TO BRING IN BOTH PEOPLE WHO ARE ESTABLISHED EXPERTS, BUT ALSO ONES THAT ARE EARLIER IN THEIR CAREER WHO BRING IN THE REALLY INTERESTING AND IMPORTANT NEW IDEAS.

SO I'M A FAN, AS YOU CAN TELL, OF THE WAY THE GWG HAS OPERATED. AND FOR THE NEW MEMBERS OF THE BOARD I'LL JUST SAY THIS WHOLE PROCESS HAS BEEN COMMENTED UPON BY NIH. I THINK THAT IT'S SAFE TO SAY THAT NIH IN SOME WAYS ENVIES THE HARD WORK THAT CIRM HAS DONE AND THE WAY THE PROCESS ACTUALLY WORKS AT CIRM.

SO WITH THAT, I'M HAPPY TO ANSWER ANY QUESTIONS, BUT JUST TO SAY THAT THIS WHOLE THING HAS BEEN REVIEWED BY QUITE A NUMBER OF PEOPLE. AND GIL

HAS BEEN GREAT ABOUT INCORPORATING ALL THOSE SUGGESTIONS. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, OS. SO LET'S SEE. WHY DON'T WE GET A MOTION TO APPROVE FIRST AND THEN WE'LL GO TO MORE DISCUSSION. SO DO WE HAVE A MOTION TO APPROVE THIS PROCESS AS SET FORTH BY GIL AND HIS PRESENTATION?

DR. STEWARD: I'LL DO THAT. SO MOVED.

DR. BRASHEAR: SECOND.

CHAIRMAN THOMAS: ARE THERE FURTHER COMMENTS OR QUESTIONS BY MEMBERS OF THE BOARD?

MS. BONNEVILLE: DEBORAH HAS A QUESTION.

DR. DEAS: MAYBE IT'S NOT A SPECIFIC QUESTION, BUT MORE COMMENTS AND CONCERN. I REALLY FEEL THAT THIS WAS WELL THOUGHT THROUGH, AND THE GWG HAS DONE AN EXTRAORDINARY JOB. AS I LOOK AT AND LISTEN TO THE RUBRIC IN SELECTING THE MEMBERS, I REALLY THINK THAT TO SOME EXTENT THE RUBRIC INTRODUCES BIASES AND EXCLUSION AS IT RELATES TO UNDERREPRESENTED MINORITIES. AND I KNOW THAT IT WAS MENTIONED THAT THIS HAS BEEN LOOKED AT NIH AS WELL. AND NIH IS NOW HAVING A RECKONING THAT INHERENT IN THEIR PROCESSES THERE HAVE BEEN AND STILL IS BIAS.

SO WHEN WE LOOK AT SELECTING INDIVIDUALS WHO HAVE EXCELLED IN SCIENTIFIC LITERATURE, WE KNOW

THAT MINORITIES WHO MAY BE ON PROJECTS, THEY MAY NOT BE THE FIRST AUTHOR; HOWEVER, THEY PARTICIPATE ON THE PROJECT. PEOPLE WHO ARE HEAD OF MAJOR LABS THAT ARE VERY PRODUCTIVE MAY HAVE MINORITIES IN THOSE LABS, BUT THEY MAY NOT RISE TO THE TOP IN TERMS OF BEING RECOGNIZED. WHEN YOU LOOK AT INVITATIONS TO SPEAK, THOSE WHO ARE SENIOR ARE MORE LIKELY TO BE ASKED TO SPEAK, AGAIN, EXCLUDING MANY TIMES SOME OF THE MINORITIES WHO WORK ON THESE PROJECTS.

WHEN WE LOOK AT HAVING GRANTS, ESPECIALLY RO1, YOU MAY KNOW THE DATA OF THE FEWNESS OF MINORITIES WITH RO1S AS WELL AS SERVING ON REVIEW PANELS.

SO WHILE THIS IS WELL THOUGHT OUT, AND WHILE IT'S A RUBRIC THAT HAS BEEN COMMONLY USED, IT IS AN EXCLUSIVE RUBRIC, AND IT DOES HAVE SOME BIASES. I REALLY THINK THAT WHEN WE THINK ABOUT IT WAS MENTIONED THAT THE EXPERTS ARE HIGHLY DIVERSE. THEY MAY BE HIGHLY DIVERSE IN THEIR SPECIALTIES, THE WAY THEY THINK, ET CETERA, BUT I REALLY THINK THAT WE HAVE TO TAKE A HARD LOOK AND REIMAGINE HOW WE MAKE SELECTIONS, AND WE MAY HAVE TO DO IT DIFFERENTLY EVEN IF WE HAVE TO ENLIST SOMEONE OR A CONSULTANT TO HELP US TO DIVERSIFY BECAUSE THOSE PEOPLE ARE REALLY THERE. THEY'RE OUT THERE, THE

MINORITIES IN THESE AREAS, BUT WE HAVE TO MAKE AN EFFORT TO FIND THEM. AND FINDING THEM IS NOT BY HAVING RECOMMENDATIONS FROM OTHERS WHO ARE EXCELLING BECAUSE LIKENESS WILL RECOMMEND LIKENESS.

SO I WOULD LIKE US TO THINK ABOUT HOW WE UTILIZE THIS RUBRIC, IF WE DECIDE ON IT, BUT YET HOW WE ENLIST ANOTHER RUBRIC SO THAT WE CAN BRING MORE PEOPLE INTO THE FOLD. AND I THINK WHEN I USE DIVERSITY, I'M NOT TALKING ABOUT DIVERSITY OF THOUGHT, DIVERSITY OF EXPERIENCE. I THINK WE NEED TO LOOK POINTEDLY AT RACIAL AND ETHNIC DIVERSITY IN THIS.

CHAIRMAN THOMAS: THANK YOU VERY MUCH FOR THOSE VERY IMPORTANT OBSERVATIONS, DEBORAH.

MS. BONNEVILLE: J.T., AL HAD HIS HAND RAISED AS WELL.

MR. ROWLETT: ONE OF THE THINGS THAT SEEMS OBVIOUS TO ME IS THAT DR. DEAS, IF SHE'S NOT ON THIS SUBCOMMITTEE, SHOULD BE CONSIDERED AS A MEMBER OF THIS SUBCOMMITTEE, THAT HER EXPERTISE AND PERSPECTIVE WOULD NOT ONLY ADD VALUE, BUT IMMEDIATELY IMPROVE WHAT IS BEING RECOMMENDED. AND SO I WOULD HOPE, NOT KNOWING WHAT THE FORMAL PROCESS IS, IF DR. DEAS HAS NOT ASKED TO BE ON THE SUBCOMMITTEE AND IT IS APPROPRIATE GIVEN CIRM'S

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PROCESS, THAT SHE WOULD BE CONSIDERED FOR MEMBERSHIP AND THAT SHE WOULD SAY YES.

DR. DEAS: WELL, I DON'T HAVE THE BANDWIDTH, BUT WE CALL THAT MINORITY TAX AS WELL. BUT I MAKE A SUGGESTION AND THEN I GET TO DO THE JOB AS WELL. SO I WOULD REALLY LIKE SOMEONE WHO IS NOT MINORITY WHO HAVE SIMILAR THOUGHTS TO REPRESENT.

CHAIRMAN THOMAS: AL, JUST FOR THE RECORD HERE, AS YOU HEARD FROM OS, THE GWG COMES UNDER THE DIRECTION OF THE SCIENCE SUBCOMMITTEE, OF WHICH DEBORAH IS A MEMBER AND GIVES GREAT GUIDANCE IN OUR DISCUSSIONS. I THINK THIS IS SORT OF -- GIL, COULD YOU RESPOND TO THESE COMMENTS?

MR. ROWLETT: J.T., IF I MAY, POINT OF CLARIFICATION FOR DR. DEAS. I WAS NOT RECOMMENDING THAT SHE BE PART OF THE GWG, BUT THE SCIENCE SUBCOMMITTEE. AND YOUR CONFIRMATION OF THAT IS DULY NOTED. SO THANK YOU.

MS. BONNEVILLE: ALLISON HAS HER HAND UP.

DR. BRASHEAR: I AGREE WITH DEBORAH'S COMMENTS. ONE THING I WOULD SUGGEST IS THAT WE MAKE A BIG, MAJOR EFFORT TO WIDELY SOURCE FROM A VARIETY OF AREAS FOR MEMBERSHIP. SO THERE ARE A MYRIAD OF PLACES TO LOOK OTHER THAN JUST NIH. AND THERE'S THE HAROLD AMOS FOUNDATION THAT FUNDS A DIVERSE GROUP OF

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INVESTIGATORS. I THINK THAT'S AN ACTION ITEM THAT GIL COULD TAKE BACK, AND WE CAN BE VERY DATA DRIVEN ABOUT MAKING SURE THAT WE ARE VERY INCLUSIVE IN THAT GROUP. I THINK DEBORAH HAS AN EXCELLENT POINT.

CHAIRMAN THOMAS: THANK YOU. ANY OTHER COMMENTS FROM MEMBERS OF THE BOARD?

DR. STEWARD: IF I COULD, JUST ONE. I THINK YOU ALREADY ASKED, BUT MAYBE GIL CAN ACTUALLY TALK A LITTLE BIT ABOUT HOW CIRM DOES CONSIDER ASPECTS OF DIVERSITY. AGAIN, I CAN TELL THAT THAT IS SOMETHING THAT THEY ARE DOING BASED ON THE COMPOSITION OF THE DIFFERENT REVIEW GROUPS OVER THE YEARS. BUT MAYBE GIL CAN EXPLAIN A LITTLE BIT MORE ABOUT IT AND HOW THAT CONSIDERATION DOES PLAY A ROLE. THANK YOU.

DR. SAMBRANO: SURE. I'M HAPPY TO. IT IS SOMETHING THAT IS PRESENT IN OUR MINDS WHEN WE PUT TOGETHER PANELS. AND WE DO ATTEMPT TO BALANCE. PARTICULARLY WE HAVE BEEN PAYING ATTENTION TO GENDER BALANCE; BUT IN TERMS OF THINKING ABOUT RACE AND ETHNICITY, IT HAS ALSO BEEN CHALLENGING BECAUSE, AS MENTIONED, THE APPROACH THAT WE TAKE IN IDENTIFYING EXPERTS IS ONE THAT MAY NOT NECESSARILY HIGHLIGHT MINORITY MEMBERS IN THE SCIENTIFIC COMMUNITY. AND SO WE ARE LOOKING FOR WAYS AND APPRECIATE YOUR

THOUGHTS AND SUGGESTIONS FOR HOW WE CAN INCREASE OUR REACH.

WE HAVE THOUGHT OF APPROACHING SCIENTISTS. FOR EXAMPLE, THERE ARE SOCIETIES, SUCH AS SACHNAS, WHICH SOME OF YOU MAY BE FAMILIAR WITH, OR THE FORD FOUNDATION, WHICH MAY ALSO BE HELPFUL IN IDENTIFYING SCIENTIFIC MEMBERS WHO CAN HELP US. SO ALTHOUGH WE DO MAKE AN EFFORT, I DO AGREE THAT WE CAN AND SHOULD IMPROVE OUR WORK IN TRYING TO DO THIS. SO I AM HAPPY TO TAKE THIS AND PUT CERTAINLY MORE EFFORT AND THOUGHT INTO HOW TO DO IT AND HAPPY TO TAKE ADDITIONAL SUGGESTIONS FOR STRATEGIES THAT WE CAN IMPLEMENT TO MAKE IT WORK.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS BY MEMBERS OF THE BOARD?

MS. BONNEVILLE: DAVID HIGGINS HAS A COMMENT.

DR. HIGGINS: CAN I JUST MAKE A SUGGESTION? I WAS JUST INSPIRED BY GIL'S COMMENTS. THAT INSTEAD OF -- I THINK THAT I HEARD THIS, THAT BASICALLY EVERYTHING GIL LAID OUT AS THE PROCESS IS US GOING OUT AND ASKING PEOPLE TO JOIN OUR COMMITTEES, BOARDS, WHATEVER BASED ON THEIR QUALIFICATIONS. WHAT ABOUT IF WE JUST SORT OF HAVE AN OPEN HOUSE? WE DON'T KNOW WHO'S OUT THERE, BUT

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INVITE STRANGERS INTO OUR HOUSE AND THEN PUT THEM INTO THE QUEUE, SO TO SPEAK. WE MAY GET A LOT MORE DIVERSITY, MAYBE, AND WE MIGHT GET A LOT MORE PEOPLE THAT WE JUST DIDN'T EVEN KNOW EXISTED, AS DEBORAH IS SORT OF POINTING OUT TO ME IS THAT YOU DON'T NECESSARILY WANT THE PEOPLE THAT YOU KNOW BECAUSE THEY'RE GOING TO BE JUST LIKE THE PEOPLE YOU KNOW. AND SO INSTEAD OF GOING OUT AND FINDING THEM, LET THEM FIND US, HOWEVER THAT'S DONE. ANYWAY.

CHAIRMAN THOMAS: THANK YOU, DAVID. OTHER COMMENTS BY MEMBERS OF THE BOARD?

DR. LEVITT: J.T., IT'S PAT. ONE SOURCE OF INFORMATION AT NIH, WHICH DOESN'T SOUND LIKE IT'S BEEN TAPPED INTO, MOST INSTITUTES HAVE AN R25 PROGRAM FOR SUPPORTING UNDERREPRESENTED MINORITY RESEARCH OPPORTUNITIES AND ALSO ARE AWARDED TO INSTITUTIONS THAT HAVE LARGE STUDENT BODIES OF UNDERREPRESENTED MINORITY REPRESENTATION. AND MANY OF THE PI'S OR CO-PI'S OR OTHERS WHO ARE RUNNING THOSE PROGRAMS, SCIENTISTS AND RESEARCHERS THEMSELVES, ALSO ARE HIGHLY REPRESENTATIVE, PARTICULARLY IN HISPANIC AND AFRICAN-AMERICAN AREAS, AND WOULD BE SOMETHING THAT GIL AND OTHERS WHO ARE CONSIDERING THIS COULD LOOK AT CONTACTING THEM. YOU CAN SEARCH AND IDENTIFY ALL THOSE R25S, AND THEY

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TEND TO BE CONNECTED TO MAJOR UNIVERSITIES WHERE THEY HAVE BROADER OPPORTUNITIES FOR GETTING INTERNSHIPS, ET CETERA. BUT IT MIGHT BE A RESOURCE THAT TRADITIONALLY IS NOT LOOKED AT IN TERMS OF IDENTIFYING PEOPLE WHO MAY BE AFFORDED THE OPPORTUNITY TO JOIN THE REVIEW PANELS.

CHAIRMAN THOMAS: THANK YOU, PAT. OTHER COMMENTS FROM MEMBERS OF THE BOARD?

MS. BONNEVILLE: ANNE-MARIE'S HAND IS RAISED.

DR. DULIEGE: JUST AS WE DON'T HAVE A CHANCE TO USE THE CHAT ROOM FOR MINOR COMMENTS, BUT I JUST WANTED TO SAY THAT I FULLY SUPPORT THE DISCUSSION AND THE COMMENTS FROM DEBORAH.

CHAIRMAN THOMAS: THANK YOU, ANNE-MARIE. OTHER COMMENTS FROM MEMBERS OF THE BOARD? OKAY. COMMENTS FROM MEMBERS OF THE PUBLIC? HEARING NONE, I THINK THIS HAS BEEN A VERY IMPORTANT DISCUSSION. DEBORAH, AGAIN, THANK YOU FOR RAISING THESE POINTS VERY ELOQUENTLY AND PERSUASIVELY. AND GIL WILL TAKE THAT AND ADDRESS THESE ISSUES AND REPORT BACK TO US ON THE PROGRESS TO BE MADE IN THIS AREA.

WITH THAT, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: HAIFAA ABDULHAQ.

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DR. ABDULHAQ: YES.
MS. BONNEVILLE: DAN BERNAL.
MR. BERNAL: YES.
MS. BONNEVILLE: GEORGE BLUMENTHAL.
DR. BLUMENTHAL: YES.
MS. BONNEVILLE: LINDA BOXER.
DR. BOXER: YES.
MS. BONNEVILLE: ALLISON BRASHEAR.
DR. BRASHEAR: YES.
MS. BONNEVILLE: DEBORAH DEAS.
DR. DEAS: YES.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MS. BONNEVILLE: YSABEL DURON. MARK FISCHER-COLBRIE.
DR. FISCHER-COLBRIE: YES.
MS. BONNEVILLE: ELENA FLOWERS.
DR. FLOWERS: YES.
MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: YES.
MS. BONNEVILLE: LARRY GOLDSTEIN.
DR. GOLDSTEIN: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: YES.
MS. BONNEVILLE: PAT LEVITT.
DR. LEVITT: YES.
MS. BONNEVILLE: LINDA MALKAS.
DR. MALKAS: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: SHLOMO MELMED.
DR. MELMED: YES.
MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
DR. MIASKOWSKI: YES.
MS. BONNEVILLE: LAUREN MILLER-ROGEN.
MS. MILLER-ROGEN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: MICHAEL STAMOS.
DR. STAMOS: YES.
MS. BONNEVILLE: OS STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.

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MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: KAROL WATSON.
DR. WATSON: YES.
MS. BONNEVILLE: DIANE WINOKUR. KEITH YAMAMOTO.
MOTION CARRIES.
CHAIRMAN THOMAS: OKAY. THANK YOU. THAT CONCLUDES THE ACTION ITEMS. WE'RE GOING TO TAKE A FIVE-MINUTE BREAK NOW BEFORE WE GET TO THE DISCUSSION ITEMS, THE FIRST OF WHICH IS THE REPORT ON THE SCIENTIFIC STRATEGIC ADVISORY PANEL. FIVE-MINUTE BREAK. WE'LL SEE YOU IN A FEW.
(A RECESS WAS TAKEN.)
MS. BONNEVILLE: I THINK WE ARE GOOD TO GO. J.T., IF I COULD READ ONE COMMENT INTO THE PUBLIC RECORD. I JUST GOT IT FROM A MEMBER OF PUBLIC WHO HAD TROUBLE COMING ONTO THE LINE. IT'S FROM JAMES STUART.
"HI. MY NAME IS JAMES STUART, AND I AM WITH THE NATIONAL MULTIPLE SCLEROSIS SOCIETY. THANK YOU FOR TAKING MY COMMENTS. JUST CAST THE NET WIDER TO FIND GWG SCIENTIST AND PATIENT ADVOCATE

PARTICIPANTS. MR. SAMBRANO MAY CONSIDER INVOLVING PATIENT ADVOCACY ORGANIZATIONS THAT WOULD BE THRILLED TO ASSIST IN IDENTIFYING DIVERSE CANDIDATES WHO ARE WELL QUALIFIED AND EAGER TO PARTICIPATE IN THESE ROLES. THANK YOU. JAMES."

CHAIRMAN THOMAS: THANK YOU. THANK YOU FOR THAT COMMENT. SO BEFORE I TURN THIS OVER TO MARIA, JUST A BRIEF INTRODUCTION, COUPLE COMMENTS HERE.

SO PROP 14, IN ADDITION TO PROVIDING FOR THE ADVENT OF THE AAWG AND A VARIETY OF OTHER THINGS, HAD IN IT A PROVISION WHEREBY THE CHAIR AND CEO COULD CONVENE PANELS TO ADVISE CIRM FROM TIME TO TIME ON THINGS OF INTEREST TO THE AGENCY. AND SO A NUMBER OF MONTHS AGO MARIA MILLAN AND I WERE TALKING AND THOUGHT THAT, AS THE STRATEGIC PLAN WAS IN DEVELOPMENT NOW AND AS THE FIELD OF REGENERATIVE MEDICINE WAS PROGRESSING VERY RAPIDLY WITH CIRM BEING A KEY PLAYER AND ACCELERATOR IN ALL OF THAT, THAT IT WOULD MAKE SENSE TO CONVENE AN ADVISORY PANEL TO TALK TO US ABOUT THE STATE OF PLAY IN THE INDUSTRY IN THE CONTEXT OF IDEAS THAT WE ARE CONTEMPLATING FOR STRATEGIC PLAN DEVELOPMENT.

SO IN FEBRUARY WE CONVENED THAT PANEL. MARIA AND I INVITED A NUMBER OF DISTINGUISHED FOLKS

FROM VARIOUS PARTS OF THE INDUSTRY THAT BEAR ON REGENERATIVE MEDICINE AND, I THINK, WERE ABLE TO PULL TOGETHER A REALLY STELLAR GROUP OF PEOPLE TO COME AND SERVE ON THIS INITIAL ADVISORY PANEL.

WE HAD THE MEETING, WHICH MARIA WILL DESCRIBE IN GREAT DETAIL, WHICH SHE VERY ARTFULLY ORCHESTRATED WITH, NOT JUST THE PANEL, BUT A NUMBER OF CIRM GRANTEES WHO GAVE PRESENTATIONS THAT WERE ALL GEARED TOWARDS SPURRING DISCUSSION ON PARTICULAR ITEMS OF INTEREST.

A NUMBER OF THE BOARD MEMBERS WERE ON THAT CALL. AND I THINK BEFORE I TURN IT OVER TO MARIA, WOULD ANY MEMBERS OF THE BOARD THAT WERE ON THAT CARE TO COMMENT ON THE PANEL BEFORE WE GET STARTED HERE WITH A REVIEW OF IT?

MR. ROWLETT: MY COMMENT WOULD BE THAT, AGAIN, AS A PATIENT ADVOCATE IN THE AREA OF BEHAVIORAL HEALTH/MENTAL HEALTH, I WAS HEARTENED BY THE EMPHASIS PLACED ON DIVERSITY, EQUITY, AND INCLUSION BY SEVERAL OF THE PROMINENT MEMBERS WHO WERE PRESENTING. AND THEY SPOKE VERY ELOQUENTLY AND EVEN DIRECTLY TO SOME OF DR. DEAS' CONCERNS RELATED TO HOW TO MAKE SURE THAT INDIVIDUALS WHO WERE UNDERSERVED AND NOT SERVED IN VARIOUS REGIONS OF OUR STATE HOW WE COULD BETTER PERFORM IN TERMS OF OUR

OUTREACH AND ENGAGEMENT WITH THEM.

IN ADDITION, FROM MY PERSPECTIVE, NEUROPHYSIOLOGY IS SOMETIMES AN ADD-ON IN TERMS OF CIRM AND LOOKING AT THE IMPACT OF MENTAL HEALTH AND BEHAVIORAL HEALTH ON A PERSON'S ABILITY TO ADHERE TO THE SOMEWHAT COMPLICATED SOMETIMES CRITERIA ASSOCIATED WITH A TRIAL. AND THEY ALSO SPOKE VERY ELOQUENTLY REGARDING THAT.

I PROVIDE THOSE TO SPECIFIC EXAMPLES, AND I THINK THAT IT WAS A GREAT PANEL AND IT UNDERSCORED THE GOALS THAT WERE IDENTIFIED BY J.T. IN HIS INTRODUCTION.

CHAIRMAN THOMAS: OTHER COMMENTS?

DR. MELMED: I WOULD ECHO THAT. I THINK IT WAS A VERY, VERY COMPREHENSIVE ASSESSMENT, TWO THEMES OF WHICH, ONE WAS, TO REPEAT THE PREVIOUS SPEAKER AGAIN, THE CLEAR RECOGNITION OF THE SOCIETAL RESPONSIBILITY WHICH CIRM HAS TO ALL THE CITIZENS OF CALIFORNIA. AND THAT CAME THROUGH VERY LOUD AND CLEAR. BUT THIS WAS COUPLED WITH A VERY, VERY STRONG SCIENTIFIC ASSESSMENT AND ALMOST AN ENVY, THAT WE WERE THE ENVY OF THE REST OF THE COUNTRY AND THE REST OF THE WORLD. AND TO CONGRATULATE MARIA AND HER TEAM BECAUSE THEY PERFORMED EXEMPLARILY AND WERE WONDERFUL AMBASSADORS FOR US. SO OVERALL I

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THINK IT WAS A VERY POSITIVE DAY, AND I LOOK FORWARD TO OUR ANALYSIS LATER ON THIS MORNING.

CHAIRMAN THOMAS: OTHER COMMENTS? THANK YOU, SHLOMO.

DR. MARTIN: AS I COMMENTED TO BOTH J.T. AND MARIA, I FOUND IT ALSO A VERY INTERESTING AND FOR ME IMPORTANT DISCUSSIONS, SERIES OF DISCUSSIONS. AND I TOOK PRETTY EXTENSIVE NOTES, WHICH I DON'T NORMALLY DO, AND I DID NOT EXPECT TO DO, BUT THERE WAS SO MUCH KNOWLEDGE BEING FOCUSED ON THE STRATEGY OF CIRM. AND IT WAS AN EVOLUTION, I THINK, OF CIRM THAT WAS LAID OUT FOR US. SO I WAS VERY PLEASED. AND I HAVE, SINCE IT WAS PUBLIC INFORMATION, I HAVE CERTAINLY CONVEYED A NUMBER OF THE CONCEPTS TO MY PROFESSIONAL COLLEAGUES WITHIN ZYCOS AND ASTELLAS. SO THANKS FOR DOING IT. IT WAS JUST WELL DONE.

CHAIRMAN THOMAS: THANKS, DAVE.

DR. MARTIN: AND GIL DID A GREAT JOB AS WELL I HAVE TO SAY.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS BY MEMBERS OF THE BOARD?

MS. BONNEVILLE: J.T., HAIFAA HAS HER HAND RAISED.

DR. ABDULHAQ: HI. SO AS A NEW MEMBER OF THE BOARD, I FELT THAT THE ADVISORY PANEL WAS

OUTSTANDING. THE COMMENTS WERE ACTUALLY VERY INFORMATIVE AND WERE EYE-OPENING FOR ME. AND I THINK PART OF WHAT STUCK WITH ME IS THE EMPHASIS ON DIVERSITY, THE EMPHASIS ON REACHING ALL THE PEOPLE OF CALIFORNIA, AND ALSO MAYBE CONSIDERATION OF EXPANDING ALSO MORE TO CELLULAR THERAPY IN ADDITION TO STEM CELL RESEARCH. BUT I WAS VERY IMPRESSED. THANK YOU.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS?

MR. ROWLETT: J.T., I WAS REMISS IN NOT ACKNOWLEDGING, AND THANK YOU, FELLOW BOARD MEMBERS, THE STAFF DID A TREMENDOUS JOB, MARIA, GIL, DR. MILLAN. IT WAS VERY ORGANIZED. AND CERTAINLY I'M, AS YOU KNOW, A BIG PROPONENT OF AN IMPROVEMENT IN OUR OVERALL BOARD ORIENTATION PROCESS, ESPECIALLY GIVEN THE NUMBER OF MEMBERS OF THIS BOARD. AND IT SHOULD BE ARCHIVED, AND FOR NEW BOARD MEMBERS THERE ARE CERTAINLY RELEVANT SECTIONS OF THE DISCUSSION THAT WOULD BE HELPFUL IN APPRECIATING THE WORK THAT CIRM DOES.

CHAIRMAN THOMAS: THANK YOU, AL. I SHOULD NOTE, EVERYBODY, THAT WE HAVE A LINK TO THE SESSION WHICH I BELIEVE YOU'VE ALL GOTTEN, AND IF NOT, WE'LL SEND IT OUT AGAIN. IT WAS A LONG PANEL. THERE WAS

A GREAT DEAL OF MATERIAL COVERED. BUT IF YOU WERE NOT ABLE TO ATTEND THAT DAY AND HAVE SOME SPARE TIME, I THINK IT'S WELL WORTH WATCHING BECAUSE THERE WAS A TREMENDOUS AMOUNT OF MATERIAL PACKED INTO THE FIVE AND A HALF HOURS OR SO. SO OTHER COMMENTS?

DR. MARTIN: MARIA, COULD YOU SEND THAT AGAIN, THAT LINK?

MS. BONNEVILLE: I SURE WILL. AND I'LL ALSO INCLUDE THE REPORT THAT WAS GENERATED AS A CONSEQUENCE OF THAT MEETING. SO I'LL SEND THEM BOTH.

DR. MARTIN: THANK YOU.

CHAIRMAN THOMAS: JUST A COMMENT ON THE REPORT. AS DR. MILLAN WILL GET INTO IN MUCH GREATER GREAT DETAIL, IT WAS AN OUTSTANDING JOB OF COMPILING AND ANALYZING THE DISCUSSION. AND IT'S, I THINK, QUITE A FASCINATING READ AND WELL WORTH EVERYBODY'S TIME. IT WILL TAKE YOU MUCH LESS TIME TO READ THE REPORT THAN TO WATCH THE ENTIRE SESSION, BUT IT'S A TREMENDOUS DOCUMENT FOR US TO HAVE. AND I DO HIGHLY RECOMMEND IT TO YOU.

ANY OTHER COMMENTS FROM MEMBERS OF THE BOARD?

DR. GOLDSTEIN: I JUST WANT TO MAKE IT CLEAR THAT I THOUGHT THAT THE QUALITY OF THE

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SCIENTIFIC AND CLINICAL INPUT WE GOT WAS REALLY OUTSTANDING. HAVING WORKED IN THIS FIELD FOR A LONG TIME, I KNOW THE PEOPLE, AND THESE WERE AMONG THE VERY BEST PEOPLE IN THE FIELD GIVING THEIR BEST PREDICTIONS AND ADVICE ABOUT WHERE TO PUT OUR RESOURCES MOVING FORWARD.

CHAIRMAN THOMAS: THANK YOU, LARRY. OTHER COMMENTS? OKAY. THANK YOU, EVERYBODY, FOR YOUR INPUT.

BEFORE WE GO, ONE LAST HOUSEKEEPING THING BEFORE I TURN IT OVER TO MARIA. OVER THE COURSE OF HER PRESENTATION, THERE ARE GOING TO BE A NUMBER OF INSTANCES THAT ASK FOR BOARD THOUGHT AND APPROVAL. SO THIS IS MEANT TO BE A DISCUSSION PIECE AND WELCOME ALL THOUGHTS AND COMMENTS THAT YOU WOULD HAVE AS MARIA IS GOING THROUGH. SO WITH THAT, LET ME TURN IT OVER TO MARIA FOR A REPORT ON THE DAY. THANK YOU.

DR. MILLAN: THANK YOU VERY MUCH, CHAIRMAN THOMAS. AND THANK YOU TO ALL THE BOARD MEMBERS FOR PARTICIPATING IN THIS SCIENTIFIC STRATEGY ADVISORY PANEL. IT WAS A VERY FULL DAY. THE SUMMARY THAT YOU WILL BE RECEIVING KIND OF HIGHLIGHTS SOME THEMES AND AREAS OF OPPORTUNITY THAT AROSE FROM THAT PANEL, THAT, AS MENTIONED, THERE'S A MUCH MORE COMPLETE

CHRONICLE OF THIS IN THE YOUTUBE VIDEO THAT'S POSTED ON OUR SITE AND WILL BE CIRCULATED, IF NOT ALREADY, AS WELL AS A FULL TRANSCRIPT. SO EVERY WORD WAS CAPTURED. THANK YOU SO MUCH.

I'M REALLY LOOKING FORWARD TO HAVING THIS DISCUSSION TODAY. WE WILL NOT BE ASKING FOR ANY VOTING ITEMS OR ACTION ITEMS, BUT WE REALLY WOULD VERY MUCH APPRECIATE YOUR INPUT DURING THIS PRESENTATION. NEXT SLIDE PLEASE.

SO WELCOME, NEW MEMBERS OF THE BOARD. AND TO THOSE WHO HAVE BEEN WITH US THROUGH THIS JOURNEY, YOU WILL NOTE THAT WE COMPLETED A FIVE-YEAR STRATEGIC PLAN UNDER PROP 71 THAT BY ALL MEASURES WE FELT VERY PROUD OF AND WAS SUCCESSFUL. THE BIG SIX GOALS WERE TO INCREASE OUR PIPELINE, MAKE SURE TO BRING THESE IN THE MOST ACCELERATED AND SAFE FASHION THROUGH DEVELOPMENT, BUILD A CLINICAL PORTFOLIO, AND THEN THIS IS THE QUALITY AND VALUE OF THIS PORTFOLIO HAS BEEN VALIDATED BY INDUSTRY PARTNERSHIP. SO WE CALL THESE THE BIG SIX, AND WE EXCEEDED THE METRICS ASSOCIATED WITH THAT STRATEGIC PLAN IN EVERY CATEGORY LIMITED ONLY BY FUNDING. SO WE ARE VERY PLEASED THAT PROP 14 WAS PASSED. SO NOT ONLY CAN WE COMPLETE THE WORK THAT WE STARTED UNDER PROP 71, BUT HAVE NEW AREAS OF OPPORTUNITY, MUCH OF WHICH WAS

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DISCUSSED AND HIGHLIGHTED AT THE STRATEGIC ADVISORY PANEL. NEXT SLIDE PLEASE.

SO TO DATE WITH THE LEGACY FUNDING AND THE PREVIOUS PROGRAM ANNOUNCEMENTS, WE STILL HAD EVEN AT THE END OF LAST YEAR 130 PROGRAMS THAT WERE UNDER MANAGEMENT. AND SO A SNAPSHOT OF WHERE WE ARE TODAY IS SHOWN IN THIS PIE CHART. AS YOU CAN SEE, WE HAVE DIVERSITY IN TERMS OF DISEASE AREAS, THERAPEUTIC MODALITIES, AND STAGES IN DEVELOPMENT FROM DISCOVERY, TRANSLATIONAL STAGE, AND TO THE CLINICAL STAGE. NEXT SLIDE PLEASE.

THIS HAS GIVEN RISE AND SUPPORTED PROGRAMS MOVING TO THE CLINICAL STAGE TOTALING NOW 68 CLINICAL TRIALS DIRECTLY FUNDED BY CIRM AND MANY MORE THAT HAVE ARISEN FROM INITIAL CIRM FUNDING ACROSS 35 INDICATIONS, UNMET MEDICAL NEED WITHOUT ANY THERAPIES OR CURES. SO 51 TRIALS WERE FUNDED IN THE FIVE-YEAR STRATEGIC PERIOD. NEXT SLIDE PLEASE.

WITH THIS AS A STARTING POINT, CIRM IS VERY WELL POSITIONED BECAUSE NOW WE HAVE A VALIDATED FUNDING MECHANISM THAT HAS DEMONSTRATED THE ABILITY TO ACCELERATE THE RESEARCH WHILE STILL MAINTAINING RIGOR AND SAFETY, IS PATIENT CENTRIC, AND WE'RE BUILDING ON THIS. AT THE END OF LAST YEAR, WE BUILT IN DIVERSITY, EQUITY, AND INCLUSION CONSIDERATIONS

INTO OUR APPLICATIONS THEMSELVES. SO THOSE WILL BE -- AS YOU START TO SEE THOSE APPLICATIONS GO THROUGH, THAT WILL BE PART OF ALL RESEARCH PROPOSALS. WE HAVE SERVED AS A FUNDER, A DERISKER SO THAT WE FUND PROGRAMS EARLY ON THAT ARE NOT NECESSARILY ABLE TO OBTAIN FUNDING BECAUSE THEY'RE HIGH RISK, BUT, OF COURSE, HIGH REWARD AND BEEN ABLE TO BRING THEM THROUGH THE STAGES FROM BASIC, TRANSLATIONAL, AND CLINICAL RESEARCH.

WE'VE ALSO FUNDED MAJOR INFRASTRUCTURE SUCH AS THE ALPHA CLINICS NETWORK, CREATION OF GENOMICS CENTERS OF EXCELLENCE, AS WELL AS THE CREATION OF THE LARGEST BANK OF WHAT'S CALLED THE INDUCED PLURIPOTENT STEM CELLS THAT'S USED FOR DRUG DISCOVERY AND SCIENTIFIC RESEARCH. THAT'S JUST A MAJOR OVERVIEW, AND WE HOPE TO BE ABLE TO BRING SOME OF THOSE PROGRAMS WITH MORE DETAIL, BUT REALLY THE FOCUS OF THE ADVISORY PANEL WAS TO TAKE WHERE WE ARE TODAY WITH THIS VALUE PROPOSITION AND DETERMINE WHERE WE CAN GO FOR THE FUTURE.

WE HAVE ALONG WITH THE BOARD BEEN CONSIDERING FOUR MAJOR THEMES AS WE THINK ABOUT THE STRATEGIC PLAN, WHICH WE PLAN TO HAVE IN FINAL FORM BY THE END OF THIS YEAR AND BROUGHT TO THE BOARD FOR FINAL APPROVAL. IN THE PAST ONE AND A HALF YEARS,

WE HAVE BEEN GOING THROUGH A PROCESS OF BRINGING CONCEPTS, DEVELOPING THEM ALONG WITH THE BOARD AND EXTERNAL STAKEHOLDERS AND EXTERNAL TO OUR SYSTEMS IN FOUR MAJOR AREAS, WHICH ARE ADVANCING WORLD-CLASS SCIENCE, DETERMINING WHAT THE HURDLES ARE TO BRING THEM TO COMMERCIALIZATION AND TO BROADER ACCESS TO THE PATIENT COMMUNITIES, INCREASING EQUITABLE PATIENT ACCESS TO THESE INNOVATIVE TREATMENTS, AND MAXIMIZING OUR IMPACT FOR CONTINUALLY IMPROVING ON OPERATIONAL EXCELLENCE, ALL WITH THE CONTINUED GOAL OF ACCELERATING THE SCIENCE AND BRINGING THERAPEUTIC OPTIONS TO PATIENTS WITH UNMET MEDICAL NEEDS.

SO THE FOCUS OF THE PANEL WAS ON ADVANCE WORLD-CLASS SCIENCE AS A SUBJECT MATTER, BUT THESE ARE ALL INTERLINKED AND INTERRELATED. NEXT SLIDE PLEASE.

THERE WERE 14 SCIENTIFIC LEADERS WHO SERVED AS A PANEL, AND WE ALSO INVITED SOME CIRM GRANTEES AS WELL AS SCIENTIFIC EXPERTS WHO ARE MEMBERS OF OUR GWG TO PRESENT SHORT, KIND OF, I WOULD SAY, EITHER POSITION STATEMENTS OR FRAMING OF TOPICS THAT ALLOWED THE PANEL, WITH MUCH INTERACTION, TO ADDRESS FIVE MAJOR OVERARCHING QUESTIONS AND THEY'RE LISTED HERE. WHAT IS THE GREATEST IMPACT THAT CIRM COULD MAKE IN THE NEXT TEN

YEARS FOR STEM CELL AND REGENERATIVE MEDICINE RESEARCH? WHAT TYPES OF RESEARCH OPPORTUNITIES AND VITAL RESEARCH OPPORTUNITIES ARE IN NEED OF FUNDING WITHIN THE FIELD? AND WHAT TYPES OF OPPORTUNITIES FALL OUTSIDE OF WHAT'S CURRENTLY FUNDED BY CIRM?

WE HAVE BUILT INTO IT THE IDEA THAT A CONSORTIA MODEL, WHICH HAS BEEN UNDER CONSIDERATION AND MUCH DISCUSSION WITH STRONG SUPPORT IN OUR PREVIOUS BOARD MEETINGS AS WELL AS EXTERNAL WORKSHOPS. SO THE IDEA WAS TO DETERMINE -- TO TEST THAT ASSUMPTION. ARE CONSORTIA MODELS THE BEST WAY TO ACCOMPLISH THIS? AND WHAT ARE THE LARGEST GAPS IN BASIC TRANSLATIONAL RESEARCH THAT STILL NEED TO BE OVERCOME AS WELL AS KEY INFRASTRUCTURE GAPS? WITH THIS FORMAT, WE WERE ABLE TO HAVE A VERY ROBUST AND FULL DISCUSSION, BUT THE TOPICS THAT I'LL BE RAISING TODAY REALLY SPEAK MORE TOWARD EITHER AREAS THAT ARE NOT FUNDED BY CIRM OR AREAS THAT ARE OF QUESTION, AND WE WELCOME THE BOARD TO PLEASE GIVE US AS MUCH INPUT AS YOU FEEL APPROPRIATE AND ALSO FOLLOW-UP ITEMS AS YOU FEEL APPROPRIATE SO THAT WE CAN CONTINUE TO DEVELOP THE STRATEGIC PLAN IN THE BEST INFORMED FASHION POSSIBLE.

SINCE NEUROSCIENCE IS SPECIFICALLY HIGHLIGHTED IN PROP 14, $1.5 BILLION OF THE $5.5

BILLION IS EARMARKED FOR DISEASES OF THE BRAIN AND CNS. MUCH OF THE AGENDA AND THE TYPE OF TOPICS, WE USED NEUROSCIENCE AS A DEMONSTRATION CASE OR A TOPIC, ANCHORING TYPE TOPIC, BUT THE SCIENTIFIC DISCUSSIONS REALLY APPLIED BROADLY, BUT THERE WAS DEFINITELY AN EMPHASIS ON NEUROSCIENCE RESEARCH. NEXT SLIDE PLEASE.

TO MANY OF YOU, THIS SUMMARY IS FAMILIAR IN TERMS OF OUR CURRENT THINKING. WE'VE BEEN ADVANCING WORLD-CLASS SCIENCE AND ACCELERATING SCIENTIFIC ADVANCEMENTS THROUGH TEAM SCIENCE AND CONSORTIA APPROACH, BUILDING INTO IT SHARED TECHNOLOGY CORES AND INFRASTRUCTURE, AND EMBEDDING AND MAKING IT AN INTEGRAL PART OF THE SCIENTIFIC AND FUNDING STRATEGY, THE CREATION OF DATA SHARING, WHICH THEN SPURS ON KNOWLEDGE NETWORKS, AND EMBEDDING AND MAKING PART OF THE ENTIRE, NOT ONLY RESEARCH PROCESS, BUT ALL OF THE CONSIDERATIONS THAT WERE BROUGHT FORWARD IN TERMS OF HOW WE EVEN DO BUSINESS, OUR REVIEWERS, AND WHO WE TRAIN TO BRING IN THE DEI PRINCIPLES IN ORDER TO STRENGTHEN ALL OF THESE EFFORTS.

OTHER CONSIDERATIONS ARE CLINICAL PARADIGMS ESPECIALLY AS RELATED TO THESE NOVEL TYPES OF APPROACHES AND STRATEGIC PARTNERSHIPS. WE'VE HAD

SOME GOOD DEMONSTRATION CASES WHERE PARTNERSHIPS, SUCH AS WITH THE HEART LUNG BLOOD INSTITUTE AT THE NIH, ALONG WITH CIRM. THEY'VE BEEN ABLE TO PARTNER WITH US. WE'VE LEVERAGED THE CIRM FUNDING MODEL AND HAVE BEEN ABLE TO CO-FUND VERY PROMISING CELL AND GENE THERAPY PROGRAMS. WE ALSO HAVE DEMONSTRATION PROJECTS WITH THE CHAN ZUCKERBERG INITIATIVE IN SINGLE CELL ANALYSIS WITH SOME OF OUR PROGRAMS IN THE BASIC AND SOME CLINICAL ARENA RELATED TO COVID.

AND THEN, FINALLY, PROVIDING ONRAMPS ALONG THE WAY, EDUCATION AND CAREER, FOR A DIVERSE AND WELL-TRAINED FUTURE WORKFORCE AND LEADERSHIP.

AND NEXT SLIDE PLEASE. AND THAT LAST TOPIC IS SOMETHING WE'VE ALREADY BEEN TAKING TO YOU FOR APPROVAL, WHICH ARE SOME OF THE EDUCATION PROGRAMS, AGAIN, WITH DIVERSITY, EQUITY, AND INCLUSION AS PART OF THE EDUCATIONAL PROGRAM. SO YOU HAVE RECENTLY APPROVED THE BRIDGES PROGRAM AND THE TRAINING PROGRAM. SO WE WILL CONCENTRATE ON MORE OF THE OTHER TOPIC AREAS.

SO TO START OFF WITH, THERE WAS BROAD AND ALMOST, I WOULD SAY, UNIFORM SUPPORT FOR THIS IDEA OF THE CONSORTIUM APPROACH. IN FACT, IT WAS THE BASIS FOR A LOT OF THE DISCUSSION THAT DAY IN TERMS OF THE FORMAT, THE BEST FORMAT TO BRING FORWARD

THESE AMBITIOUS GOALS, ESPECIALLY DISEASES OF THE CNS. THE PANEL DID DISCUSS DIFFERENT TYPE OF CONSORTIA MODELS. SHOULD IT BE DISEASE FOCUSED, PATHWAY, OR COMMON BIOLOGIC MECHANISM FOCUSED? WE DIDN'T SPECIFICALLY PICK A WINNER IN TERMS OF THE BEST TYPE OF THEME FOR CONSORTIA; BUT WHATEVER IT IS, IT NEEDS TO MAKE SENSE AND BE ABLE TO LEVERAGE OTHER ASPECTS SUCH AS THE CORE TECHNOLOGY AND DATA SHARING.

SO THERE ARE DEMONSTRATIONS AND EXAMPLES OF WHERE DISEASE-TARGETED CONSORTIA HAVE SHOWN SOME PROMISE. AND, IN FACT, SOME OF THEM ARE ALREADY IN PLACE IN CALIFORNIA SUCH AS THE ANSWER ALS CONSORTIA WHICH CLIVE SVENDSEN AND LESLIE THOMPSON, BOTH OF OUR SCIENTISTS WITHIN THE CIRM ECOSYSTEM, HAVE BEEN LEADERS IN THAT CONSORTIA THAT REALLY INTEGRATE OMICS DATA WITH PHENOTYPE AND RESEARCH MODELING FOR ALS. THAT IS AN EXCELLENT STARTING POINT FOR SOME OF WHAT WE ARE TALKING ABOUT. SO THAT'S ONE OF THE MODELS THAT WAS DISCUSSED. ALSO STEM CELLS FOR HUNTINGTON'S DISEASE AND MANY MORE.

CIRM HAS FUNDED INFRASTRUCTURE, INCLUDING THE ALPHA CLINICS NETWORK AND OTHER CIRM INFRASTRUCTURE THAT PROVIDE REGULATORY ASSISTANCE AS WELL AS PROCESS DEVELOPMENT AND EARLY MANUFACTURING

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SUPPORT. THESE ARE EXCELLENT STARTING POINTS THAT WOULD ENABLE DISEASE-FOCUSED CONSORTIA.

ANOTHER ADVANTAGE OF A CONSORTIA-BASED MODEL IS IT WOULD ENABLE NEW GENERATION OF REGULATORY PATHWAYS. AND ONE OF THE SPEAKERS HIGHLIGHTED THE IMPORTANCE OF THIS, ESPECIALLY AS WE EMBARK ON A NEW ERA WHERE GENE EDITING WITH CRISPR-CAS9, FOR INSTANCE, AS WELL AS OTHER MODALITIES, HAVE REALLY OPENED UP THE FIELD. WE'VE SEEN THAT GENE EDITING AND GENE THERAPY AND EVEN THE CIRM PROGRAMS THAT ARE NOW IN THE FINAL STAGES OF APPROVAL HAVE SHOWN CURATIVE OUTCOMES WITH 50 PATIENTS, FOR INSTANCE, CURED OF ADA, SEVERE COMBINED IMMUNODEFICIENCY, ADENOSINE DEAMINASE DEFICIENCY, LEADING TO COMPLETE IMMUNODEFICIENCY. ONCE THAT IS RETURNED BY A GENE THERAPY APPROACH TO THE HEMATOPOIETIC STEM CELLS, THE PATIENTS WHO HAVE BEEN ENROLLED IN THAT TRIAL HAD RESTORATION OF THE ENZYME AND FULL REPOPULATION OF THE IMMUNE SYSTEM. SO THERE ARE DEMONSTRATION CASES ALREADY. WE HAVE PROGRAMS, AGAIN, WITH THE CURE SICKLE CELL INITIATIVE FOR BOTH CRISPR-CAS9 BASED AS WELL AS OTHER GENE THERAPIES.

THE SPEAKER HAD BROUGHT UP THAT THERE ARE SO MANY ULTRA RARE AND N = 1 DISEASE INDICATIONS

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THAT CAN ONLY BE SERVED PROBABLY IN ACADEMIC CENTERS OR ACADEMIC NETWORKS. AND TECHNOLOGIES SUCH AS THESE GENE EDITING TECHNOLOGIES COULD PROVIDE A PLATFORM WHERE THEN SIMPLY AN N OF 1 DISEASE COULD BE N OF A HUNDRED BECAUSE THERE COULD BE DIFFERENT TYPES OF GENETIC INTERVENTIONS, BUT USING THE SAME TECHNIQUE AND THEN HAVING KIND OF AN AGGREGATE SAFETY PACKAGE AND EXPERIENCE THAT'S BEEN GAINED BY THAT PLATFORM. AND SO THOSE ARE THE TYPE OF THINGS THAT ACADEMIC NETWORKS AND AN AGENCY ORGANIZATION SUCH AS CIRM WOULD BE ABLE TO BRING FORWARD THAT MAY NOT NECESSARILY FIT INTO THE INDUSTRY MODEL. SO THIS REALLY DOES SPEAK TO THE VALUE OF A CONSORTIA APPROACH IN THAT REGARD.

ALSO, FOR INSTANCE, WITH CRISPR-CAS9 WE JUST HAPPENED TO BE IN THE STATE WHERE JENNIFER DOUDNA, THE NOBEL LAUREATE, HAD FORMED THE IGI WHICH SPECIFICALLY HAS A GOAL OF BRINGING THESE TYPE OF THERAPIES TO UNDERSERVED AND PATIENTS WITH UNMET MEDICAL NEEDS THAT MAY NOT BE SERVED BY THE STANDARD INDUSTRY MODELS.

SO THE PANEL ENCOURAGES CIRM THROUGH ITS EXISTING AND FUTURE COLLABORATORS ALSO PURSUE INTERNATIONAL ALLIANCES TO CREATE PATIENT REGISTRIES AND CENTRAL DATA REPOSITORIES BECAUSE THERE'S A LOT

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OF DATA OUT THERE, GENOMICS AND OTHERWISE, IN SILOS, AND THERE IS AN INTERNATIONAL AND NATIONAL INTEREST IN BEING ABLE TO TURN THAT DATA, THOSE TERABYTES OF DATA THAT WE EACH HAVE ON US, TO KNOWLEDGE, AND THAT THAT IS SOMETHING THAT IS GOING TO BE THE KEY IN TERMS OF ENABLING SOME OF THESE EFFORTS. BUT IT'S SOMETHING THAT'S REALLY, REALLY, I WOULD SAY, CHALLENGING AS AN UNDERSTATEMENT. BUT CIRM BEING FOCUSED ON REGENERATIVE MEDICINE CELL THERAPY AND HAVING THIS ECOSYSTEM IS VERY WELL POSITIONED TO LEAD THIS TYPE OF EFFORT. NEXT SLIDE PLEASE.

SO I'LL JUST PAUSE THERE MAYBE FOR A SECOND TO HEAR IF THERE ARE ANY QUESTIONS OR COMMENTS ON THE IDEA OF CONSORTIA. OKAY. I'LL GO ON.

SO WITH REGARD TO DATA SHARING AND KNOWLEDGE NETWORKS, THIS IS A TOPIC THAT WAS BROUGHT FORWARD. DR. KEITH YAMAMOTO LED A PANEL AT OUR GRANTEE MEETING, BROUGHT IN EXPERTS FROM INDUSTRY AND ACADEMIA AND NATIONAL/INTERNATIONAL ORGANIZATIONS TO DISCUSS THIS. THE IDEA IS NOT SHOULD WE DO THIS. THE IDEA IS HOW TO DO THIS. EVERYBODY IS MOTIVATED TO FIGURE OUT THE BEST WAY TO FEASIBLY, IN PARTNERSHIP WITH THE PATIENT COMMUNITY, PUT THE DATA TO WORK FOR PATIENTS. THE IDEAS OF

DATA OWNERSHIP, PRIVACY CONCERNS, REGULATORY ISSUES, ALL OF THAT ARE ALL THE REASONS IT HASN'T REALLY HAPPENED TO THE EXTENT THAT EVERYBODY WANTS IT TO. HOWEVER, THE PANEL DID FEEL THAT IF ITS BUILT INTO HOW WE FUND PROGRAMS AND HOW WE STRUCTURE THEM, THEY DID AGREE THAT STANDARDIZED APPROACHES WOULD ENABLE THIS TYPE OF DATA AND KNOWLEDGE NETWORKS. AND ESPECIALLY IF IT'S PART OF A SPECIFIC CONSORTIUM-BASED APPROACH WITH TANGIBLE GOALS.

AND, ADDITIONALLY, LINKAGES IN THESE NETWORKS WOULD EMPOWER CROSSCUTTING MECHANISMS. SO IF YOU WERE TO -- SO LOOKING AT THINGS THAT SEEM OBSCURE LIKE SUCH AS IMMUNOLOGY AND HOW IT IMPACTS DISEASES OF THE BRAIN, FOR INSTANCE, IF THIS WAS BUILT INTO THE CONSORTIA, LET'S SAY FOR CNS AS WELL AS OTHER TYPES OF DISEASE INDICATIONS AND THERE WERE IMMUNOLOGIC MECHANISMS THAT WORK, THE DATA COULD BE EMPOWERED IF WE WERE ABLE TO KIND OF LINK THOSE DATASETS ACROSS DIFFERENT TYPES OF CONSORTIA.

CIRM HAS ALREADY FORMED ONE OF THE LARGEST OR THE LARGEST IPSC BANK WITH 2600 LINES. THE IDEA OF ORGANOIDS, WHICH ARE SAMPLE MINI ORGANS AS YOU CALL IT CREATED WITH STEM CELL MODELS IS HIGHLY LOOKED ON AS A VERY POWERFUL DISEASE MODELING AND RESEARCH TOOL AND DRUG DISCOVERY TOOL. AND ONE OF

THE MAJOR, I'D SAY, EXCITEMENT OF THIS PANEL IS THAT THE IDEA OF HAVING THE ABILITY TO HAVE CORE RESOURCES FOR ORGANOID AND IPSC MODELING THAT COULD BE SHARED WHERE THE DATA COULD INFORM, NOT JUST THAT ONE RESEARCHER, BUT ACROSS RESEARCHERS THAT COULD THEN BE ALSO A HUB FOR PARTNERSHIP WITH OTHER ENTITIES THAT HAVE IPSC AND ORGANOID MODELS, INCLUDING THE NEW YORK STEM CELL FOUNDATION AND ALLEN INSTITUTE AS WELL AS THE NIH, FOR INSTANCE, THIS COULD HAVE A HIGH IMPACT.

THE IDEA, ESPECIALLY WITH NEURODEGENERATION AND CNS RESEARCH, THE MAJOR HURDLE THAT THIS PANEL AS WELL AS OTHERS HAVE POINTED OUT IS THAT WE JUST DON'T UNDERSTAND WELL ENOUGH THE BASIC AND FOUNDATIONAL AND BASIC MECHANISMS OF DISEASE. BUT HAVING RELEVANT CELL MODELS AND HAVING THIS BE EMPOWERED BY THESE TYPE OF NETWORKS, REALLY WE HAVE A GREAT PROMISE IF WE CAN MAKE SOME PROGRESS IN THE FUTURE.

THERE WAS A STRONG FEELING THAT A CONSORTIUM THAT MARRIES THESE TYPE OF CELL-BASED MODELS WITH GENOMICS AND MULTIOMICS THAT COULD SYSTEMATICALLY INTERROGATE ASSOCIATIONS BETWEEN BIOLOGIC AND GENOMIC VARIATIONS AND LAYER ON TOP OF THAT, FOR INSTANCE, SOME THINGS SUCH AS SOCIAL

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DETERMINANTS, IF WE WERE TO GO THERE, WOULD BE EXTREMELY POWERFUL. AND THEY RECOMMENDED THAT WE BRING OUR STAKEHOLDERS, INCLUDING SOME OF THE VALUABLE RESOURCES THAT CIRM HAS ALREADY CREATED, SUCH AS THE CIRM STEM CELL HUB GENOMICS CENTERS OF EXCELLENCE AND ORGANOID AND IPSC MODEL CORES, BRING THEM TOGETHER TO DETERMINE THE BEST WAY TO EXECUTE ON SUCH A CONSORTIUM. NEXT SLIDE PLEASE.

AS YOU RECALL, PROP 14 HAS FUNDING FOR WHAT'S CALLED SHARED LABS. SHARED LABS IN THE PAST DEALT WITH EMBRYONIC STEM CELL CULTURE AND RELATED TYPES OF SERVICES AS WELL AS TRAINING. THE STRATEGIC ADVISORY PANEL WAS VERY SUPPORTIVE OF THE IDEA OF CORE SHARED FACILITIES, BUT BRINGING IT TO THE 21ST CENTURY IN TERMS OF THESE CORE RESOURCES AND ORGANOID MODELS AND IPSC SPECIALIZED GENE THERAPY CORES. AND BY DOING THAT, WE ARE ABLE TO PROVIDE ACCESS TO THE ENTIRE SCIENTIFIC STAKEHOLDER COMMUNITY TO THESE HIGH COST, HIGHLY SPECIALIZED TECHNOLOGIES. FOR INSTANCE, SOME OF THE TECHNOLOGIES AND SPECIALIZATION RELATED TO REPROGRAMMING CELLS TO BECOME INDUCED PLURIPOTENT STEM CELLS. THERE'S NO REASON THAT EVERY LAB NEEDS TO BE ABLE TO HAVE THAT SPECIALTY, THAT ABILITY TO DO THAT IF THEY COULD HAVE A CORE BANK TO PRODUCE

THOSE IPSC'S SO THAT THEY CAN FURTHER DO RESEARCH ON THAT DOWNSTREAM. SAME THING WITH CRISPR-CAS9 AND ALL OF THE NEXT GENERATION GENOME EDITING TECHNIQUES.

THESE CORE FACILITIES WOULD BUILD INTO THIS CONSORTIA MODEL BY HAVING THE DATA SHARING PROVISIONS, WHICH CIRM HAS ALREADY EMBEDDED IN THEIR RESEARCH PROGRAMS, AND WE PLAN TO BUILD ON THAT AS WE GAIN MORE AND MORE KNOWLEDGE AND AS THE BEST TYPES OF DATA SHARING INFRASTRUCTURE BECOME CLEARER TO US, THERE'S SUCH GREAT OPPORTUNITIES TO REALLY LEVERAGE THIS KNOWLEDGE. EXAMPLES BY HOW THESE COULD BE USED OR HAVING BIO VALIDATION CORES, VERY WELL DESIGNED BIOMARKERS THAT ARE DEVELOPED ALONG WITH THE RESEARCH PROGRAMS THAT COULD THEN HAVE A REVERSE TRANSLATION AS WELL AS BENCH TO BEDSIDE APPLICATION FOR CLINICAL DEVELOPMENT. NEXT SLIDE PLEASE.

CHAIRMAN THOMAS: MARIA, I'D JUST SAY, FOR THOSE WHO ARE ON THE CALL, ALL THAT CORE DISCUSSION, SOMEBODY DUBBED IT TO BUILD THE HOTEL CALIFORNIA, WHICH WOULD BE SORT OF THE CENTRAL FOCUS OF ALL OF THESE CORE ELEMENTS AND BE SOMETHING THAT REALLY FURTHER DISTINGUISHES WHAT CIRM IS ABLE TO PROVIDE, NOT JUST FOR CALIFORNIA, BUT SOMETHING THAT WOULD BE

USABLE BY THE REST OF THE COUNTRY AND THE WORLD. THAT HOTEL CALIFORNIA IDEA SORT OF CAUGHT ON, OBVIOUSLY FAIRLY CATCHY PHRASE, AND GENERATED A GREAT DEAL OF ENTHUSIASTIC COMMENT.

DR. MILLAN: AS WELL AS THAT SONG BEING STUCK IN OUR HEADS FOR DAYS BECAUSE IT REALLY WAS MENTIONED QUITE A BIT DURING THAT MEETING.

THERE WAS DEFINITELY A VERY STRONG SUPPORT FOR -- AND IT'S NOT -- DR. DEAS BROUGHT UP ALL OF AND DR. BRASHEAR AND EVERYBODY ELSE WHO BROUGHT IN ALL THOSE RECOMMENDATIONS, THANK YOU SO MUCH. THIS IS A WORK IN PROGRESS. IT IS BY NO MEANS A DONE DEAL JUST BECAUSE WE WORKED IT INTO OUR APPLICATION PROCESS. AND WE ARE VERY EXCITED ABOUT REALLY BEING IMPACTFUL. CALIFORNIA IS VERY WELL POSITIONED FOR THIS. WE ARE THE MOST DIVERSE STATE IN THE NATION. AND THERE IS SO MUCH OPPORTUNITY TO INCREASE OUR DIVERSITY IN TERMS OF OUR GENOMICS DATASETS, WHICH ARE SHOCKINGLY NORTHERN EUROPEAN PREDOMINANTLY NOW; WHEREAS, IT'S DISPROPORTIONATE TO WHAT WE ARE REALLY DEALING WITH. SO HOW CAN WE REALLY PURSUE AND FUND THIS RESEARCH AND TRY TO DEVELOP PROGRAMS WHEN WE DON'T REALLY HAVE A FULLY REPRESENTATIVE RESEARCH BASE TO WORK FROM? SO IT'S A VERY EXCITING TIME. AS WELL AS THEY ARE EXTREMELY SUPPORTIVE OF AND WE

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ALL BELIEVE THAT EDUCATION AND WORKFORCE DEVELOPMENT IS KEY TO THE SUSTAINABILITY OF ALL THESE IDEAS. NEXT SLIDE PLEASE.

SO IF THERE ARE NO QUESTIONS IN TERMS OF THAT SUMMARY, NOW WE GET TO THE SECTION ON WHICH WE HOPE TO BE MUCH MORE INTERACTIVE FOR YOUR INPUT IN TERMS OF SPECIFIC QUESTIONS THAT AROSE FROM THIS PANEL. J.T., DID YOU WANT TO LEAD A DISCUSSION AT THIS POINT, OR SHOULD WE JUST GO ON TO THIS SECTION?

MS. BONNEVILLE: MARK FISCHER-COLBRIE HAS A QUESTION.

DR. FISCHER-COLBRIE: YES. ACTUALLY A QUICK COMMENT. AND I JUST WANT TO REINFORCE THE OUTSTANDING WORK OF THINKING ABOUT CONSORTIA IN CORE LABS. THE JUVENILE DIABETES RESEARCH FOUNDATION'S HAD GREAT SUCCESS WITH BOTH THOSE. SO THERE ARE REAL-WORLD EXAMPLES OF THAT AS WELL AS IN OTHER AREAS. SO THERE'S GREAT VALIDATION THAT'S OUT THERE. SO I THINK THIS IS FANTASTIC. SO THANK YOU.

DR. MILLAN: THANK YOU SO MUCH.

CHAIRMAN THOMAS: THANK YOU, MARK. SO WITH RESPECT TO ITEMS FOR DISCUSSION, SO OBVIOUSLY WE WERE FOCUSED PRIMARILY ON CELLULAR THERAPIES AND POTENTIAL CURES WITH THE CELLS THEMSELVES AS LIVING DRUGS, BUT THERE ARE OTHER WAYS TO EFFECT CELLS

DOING THINGS THROUGH THE USE OF SMALL MOLECULES AND BIOLOGICS. AND WE HAVE HAD A NUMBER OF INSTANCES IN THE PAST WHERE WE'VE HAD PROJECTS WHERE THESE THINGS WOULD TRIGGER REACTIONS IN CELLS THAT WERE PART OF THE MECHANISM OF ACTION TO ACCOMPLISH WHATEVER THE PARTICULAR GOAL WAS.

BUT THE FIRST QUESTION FOR THE BOARD IS WOULD WE CONTINUE TO ENCOURAGE FUNDING PROJECTS THAT ARE SMALL MOLECULE OR BIOLOGIC BASED AS PART OF THE OVERALL PROGRAM? BECAUSE WE RECENTLY TENDED MORE JUST TO STICK TO THE STRAIGHT CELLULAR THERAPY APPROACH. SO THAT'S QUESTION NO. 1.

QUESTION NO. 2 IS PROP 14 -- AS YOU MAY RECALL, UNDER PROP 71 WE DID HAVE A PROJECT THAT WAS IN THE GENE THERAPY SPACE, DID NOT UTILIZE STEM CELLS PER SE, WAS DEEMED A VITAL RESEARCH OPPORTUNITY. I THINK WE HAD TWO ACTUALLY, MOST RECENT OF WHICH WAS CONVALESCENT PLASMA FOR COVID. BUT PROP 14 EXPANDS SORT OF THE DEFINITION OF WHAT WE ARE ABLE TO DO IN THE GENE THERAPY SPACE AND CARVES IT OUT AS AN ACTUAL FIELD TO FUND. SO THE QUESTION FOR THE BOARD IS HOW EXPANSIVE DO WE WANT THAT TO BE?

AND THEN THE THIRD ITEM IS WE HAD, AS I JUST NOTED, VERY SPARINGLY UTILIZED VITAL RESEARCH

OPPORTUNITIES IN THE PAST, BUT PROP 14 HIGHLIGHTS THAT AS SOMETHING THAT CAN BE USED TO PROVIDE FUNDING FOR PROJECTS THAT DON'T COME UNDER OTHER CATEGORIES THAT ARE SPECIFICALLY DEFINED BY THE PROPOSITION. AND SO THE QUESTION THERE IS WHAT ARE SORT OF THE BOUNDS OF THE VITAL RESEARCH OPPORTUNITY IDEA THAT THE BOARD WOULD LIKE TO PURSUE?

NOW, AGAIN, THIS IS ALL UNDER THE CONTEXT OF STRATEGIC PLAN DEVELOPMENT. WE ARE NOT LOOKING FOR ANY PARTICULAR ANSWERS AT THIS POINT, BUT AS A MEANS OF DISCUSSION WOULD LOVE TO GET THE BOARD'S INPUT. AND BEFORE WE GET TO THAT, JUST THE LAST POINT IS ONE OF THE EARLY PARTS OF THE CIRM MANDATE UNDER PROP 71 WAS FUNDING PROJECTS THAT NOBODY ELSE WOULD, PARTICULARLY IN THE VALLEY OF DEATH, ET CETERA. AND THAT SORT OF NOTION HAS BEEN BROUGHT FORWARD INTO PROP 14 TO CONTEMPLATE FUNDING FOR PROJECTS THAT ARE UNLIKELY TO RECEIVE FUNDING FROM ANY OTHER SOURCES.

SO WITH THOSE FOUR CATEGORIES FOR BOARD COMMENT, WOULD LOVE TO OPEN IT UP TO ANYBODY'S THOUGHTS ON ANY ONE OR MORE OF THE FOUR.

MS. BONNEVILLE: LARRY HAS HIS HAND RAISED.

DR. GOLDSTEIN: I'M TRYING TO BE POLITE.

SO I THINK THAT ONE WAY TO LOOK AT THIS IS THAT WE'RE AT THE BEGINNING OF A TEN-YEAR FUNDING CYCLE OR SCIENTIFIC AND CLINICAL CYCLE. AND THE TENDENCY TO EXPAND BROADLY TO TRY TO ADDRESS EVERYTHING AS WE LAUNCH IS GOING TO BE PRETTY STRONG BECAUSE THERE IS SO MUCH UNMET NEED AND THERE ARE A LOT OF GREAT IDEAS ALL THROUGH BIOLOGIC AND CLINICAL SCIENCE. BUT I THINK IT WOULD MAKE SENSE AT THE BEGINNING TO FOCUS ON THESE AREAS AS THEY RELATE TO THE USE OF STEM CELLS AND CELL THERAPY. EVEN WITHIN THAT AREA, THERE IS A HUGE SET OF OPPORTUNITIES, AND WE CAN ALWAYS EXPAND LATER IF WE FIND THAT WE ARE MISSING VITAL OPPORTUNITIES OF VARIOUS SORTS. BUT EACH OF THOSE IN AND THE ABSENCE OF STEM CELLS OR CELL THERAPIES ARE JUST VOLUMINOUS. THEY'RE ENORMOUS.

SO I'M MAKING A RECOMMENDATION THAT, AT LEAST AT THE OUTSET, WE MAINTAIN SOME STRATEGIC FOCUS IN THE AREA OF STEM CELLS AND CELL THERAPY. AND THAT'S FINE. SMALL MOLECULES CAN BE SCREENED ON STEM CELLS TO LOOK FOR NEW DRUGS. THAT'S A VERY IMPORTANT APPROACH. AND SIMILARLY FOR EACH OF THOSE AREAS, YOU CAN IDENTIFY SUCH TOPICS. I'M SURE THE STAFF KNOWS THIS PRETTY WELL.

MS. BONNEVILLE: ALLISON HAS HER HAND RAISED, J.T.

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DR. BRASHEAR: SO SOME OF YOU MAY NOT KNOW I'M A NEUROLOGIST. SO THIS DISCUSSION HITS CLOSE TO HOME, AND I STUDY A RARE DISEASE. I WOULD BE CAUTIOUS. I WOULDN'T EXPAND TO THIS, BUT MAYBE THINK ABOUT SOME PILOT PROJECTS, THE CONNECTION TO STEM CELL THAT WAS JUST MENTIONED, BUT I WOULDN'T WANT THE MESSAGING TO BE THAT WE ARE ONLY INTERESTED IN THIS CORE AREA BECAUSE THE SMALL MOLECULES, BIOLOGICS, ALL OF THESE THINGS ARE MOVING VERY RAPIDLY. AND I THINK WE WANT TO BE THE GO-TO PLACE FOR THIS IN THE COUNTRY. AND THIS IS JUST A PERFECT TIME TO DO THAT. SO MAYBE PILOT PROJECTS, GO BACK TO THE ADVISORY GROUPS AND GET HOW CAN WE REALLY EXPLORE THESE THINGS.

DR. MILLAN: THANK YOU SO MUCH. J.T., SHOULD WE GO ON BECAUSE --

CHAIRMAN THOMAS: LET'S JUST SEE IF WE HAVE -- LOOKS LIKE OS HAS HIS HAND RAISED. KRISTINA DOES AS WELL IF I'M READING THIS CORRECTLY. OS.

DR. STEWARD: THANK YOU. I WONDER -- WE TALKED A LITTLE BIT ABOUT THIS AT THE MEETING, AND THIS IDEA OR, RATHER, THE EXISTENCE OF THE OPPORTUNITY TO LOOK AT VITAL RESEARCH OPPORTUNITIES WAS THERE IN PROP 71 AS WELL ALTHOUGH IT WASN'T SOMETHING THAT WAS UTILIZED EXTENSIVELY AT ALL. IN

FACT, I THINK MAYBE TWICE IF I REMEMBER RIGHT. AND ONE OF THOSE WAS ACTUALLY THE EXPANSION INTO GENE THERAPY APPLICATIONS.

SO AS IT'S LAID OUT RIGHT NOW, AND, MARIA, IF YOU COULD EXPAND ON THIS, THE FOCUS AS DEFINED IN PROP 14 IS REALLY THE STEM CELL THERAPIES AND ALSO GENE THERAPIES AND NOT BEYOND THAT. AND WHILE THERE IS NOW SORT OF A SPECIFIC CATEGORY FOR VITAL RESEARCH OPPORTUNITIES, IT ISN'T WIDE OPEN IN ANY SENSE. THIS IS SOMETHING THAT ACTUALLY WOULD BE BROUGHT TO THE BOARD FOR CONSIDERATION. BUT WHAT I'D LIKE TO ACTUALLY ASK MARIA TO DO IS OUTLINE HOW THAT WOULD ACTUALLY TAKE PLACE GOING FORWARD IN CONSIDERING OTHER THINGS AS VITAL RESEARCH OPPORTUNITIES. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, OS. KRISTINA.

DR. VUORI: I AGREE WITH WHAT OTHERS HAVE STATED SO FAR. I THINK THE KEY FOR CIRM, GIVEN BOTH THE BROAD NEED AND OPPORTUNITY THAT WE HAVE IN THE STATE OF CALIFORNIA OF PROVIDING CURES AND TREATMENTS, WE NEED TO BE ALSO STRATEGIC, OTHERWISE WE'LL PROBABLY GET DROWNED IN THE VARIOUS THINGS. HOWEVER, I THINK WE ALSO NEED TO BE, AS WAS SAID BEFORE, REALLY IN THE CUTTING EDGE. I THINK IT

WOULD BE MORE PRUDENT, I THINK, RATHER THAN A PRIORI MAKING STRONG DECISIONS ABOUT, LET'S SAY, SMALL MOLECULES OR BIOLOGICS IS TO, IN THE CONTEXT OF RFA'S WHEN WE ISSUE SPECIFIC GRANT APPLICATION INITIATIVES, TO REALLY STATE IN THAT CONTEXT WHAT WE ARE LOOKING FOR. FOR EXAMPLE, JUST GIVEN THE EMPHASIS ON CNS BRAIN DISORDERS, TODAY REMAINS THAT IT'S ONLY SMALL MOLECULES THAT REALLY RELIABLY WILL GO THROUGH THE BLOOD BRAIN BARRIER. SO IF YOU WANT TO EFFECT REGENERATIVE OR DEGENERATIVE PROCESS IN THE BRAIN, THAT WILL BE MOST LIKELY THE BEST APPROACH.

SO I DON'T THINK WE SHOULD STICK TO THINKING THAT AT ANY COST WE NEED TO USE A CERTAIN PLATFORM, BUT RATHER REALLY THINK WHAT IS THE BEST APPLICATION AT ANY GIVEN INSTANCE WE WANT TO REALLY HAVE THE GRANTEES TO FOCUS ON.

CHAIRMAN THOMAS: THANK YOU, KRISTINA.

ARE THERE OTHER COMMENTS ON THIS SLIDE FOR MEMBERS OF THE BOARD?

DR. MALKAS: I WANT TO ECHO KRISTINA'A COMMENTS. ACTUALLY HER POINT OF VIEW THERE IS VERY THOUGHTFUL, AND I DO AGREE WITH IT.

CHAIRMAN THOMAS: THANK YOU, LINDA. OTHER COMMENTS FROM MEMBERS OF THE BOARD? THANK YOU.

MARIA, DO YOU WANT TO GO TO THE NEXT -- WAIT. WE HAVE OS HAS HIS HAND UP AGAIN. OS, WAS THAT A NEW HAND OR AN OLD HAND?

DR. VUORI: HIGH FIVE.

CHAIRMAN THOMAS: HIGH FIVE.

DR. STEWARD: CAN YOU HEAR ME? I WAS STRUGGLING TO GET MY MUTE OFF. WOULD IT BE OKAY FOR MARIA TO TAKE A FEW MINUTES TO JUST SORT OF EXPLAIN NOW WHAT THE PROCESS IS GOING FORWARD FOR THE STRATEGIC -- FOR CONSIDERATION OF STRATEGIC OPPORTUNITIES? THANK YOU.

DR. MILLAN: J.T.

CHAIRMAN THOMAS: YES, PLEASE.

DR. MILLAN: OS, WHAT WE ARE DOING TODAY IS GAINING MORE, I THINK, DEEPER BOARD INPUT TO SOME OF THE TOPICS, THEMATIC AREAS, AND ACTUAL QUESTIONS. THAT'S WHAT I'LL BE ADDRESSING IN THE NEXT FEW SLIDES. WE'LL BE TAKING THAT BACK AND INCORPORATING IT INTO, I WOULD SAY, A COUPLE OF DIFFERENT BUCKETS. ONE BUCKET IS BASED ON THIS INPUT. WE ACTUALLY COULD BRING TO THE BOARD IN THE SHORTER TERM SOME REFINEMENTS TO OUR PILLAR PROGRAMS, OUR DISC, TRAN, AND CLINICAL OFFERINGS THAT ARE ALREADY OPEN. AND THAT COULD BE RELATED TO SOME OF THE QUESTIONS ABOUT SCOPE AND AREAS OF RESEARCH THAT WE DON'T CURRENTLY

FUND OR AREAS THAT THE BOARD MAY FEEL LIKE MAYBE WE SHOULD LIMIT THE FUNDING, FOR INSTANCE. SO CHANGES TO SCOPE, ELIGIBILITY, ET CETERA TO EXISTING PROGRAMS.

OTHER TYPES OF INPUT THAT WOULD COME FROM TODAY AS WELL AS OTHER KIND OF FOLLOW-ON DISCUSSIONS WOULD FEED INTO THE STRATEGIC PLAN CONCEPTS WHICH WILL BE CONTINUALLY BROUGHT TO THE BOARD FOR INPUT. BY THE END OF THE YEAR, WE HOPE TO HAVE A FULL STRATEGIC PLAN WITH A PLAN FOR CONCEPTS RELATED TO THAT THAT WOULD THEN BE SUBSEQUENTLY ROLLED OUT AND EACH CONCEPT BEING BROUGHT ALONG WITH A BUDGET BEING BROUGHT TO THE BOARD FOR APPROVAL.

WE HOPE THROUGH THIS PROCESS THAT WE ARE CONTINUING TO CO-DEVELOP THESE IDEAS AND VET SOME ASPECTS AND REALLY DEFINE THE CONTOURS OF WHERE WE COULD GO FORWARD WITH STRATEGIC ELEMENTS.

IN TERMS OF YOUR QUESTION RELATED TO VITAL RESEARCH OPPORTUNITIES, WE DON'T HAVE A PROCESS TODAY. SOME OF THE -- EXCEPT FOR THE FACT THAT WE ARE BRINGING FORWARD SOME QUESTIONS REGARDING SCOPE AND POTENTIAL VITAL RESEARCH OPPORTUNITIES FOR BOARD INPUT. HOW WE'VE DONE IT IN THE PAST IS THAT WHEN CERTAIN TYPES OF OPPORTUNITIES PERCOLATE EITHER THROUGH OUR ATTENTION IS BROUGHT TO IT THROUGH THE

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BOARD OR THROUGH THE SCIENTIFIC COMMUNITY BRINGING IT TO US FOR A QUESTION, WE BRING IT FOR DISCUSSION WITH THE BOARD MEMBERS, AND THEN FINALLY TO THE FULL BOARD IF WE DECIDE TO BRING IT FOR CONSIDERATION FOR FUNDING.

AND WHAT VITAL RESEARCH OPPORTUNITIES REALLY MEANS IS THAT THE BOARD, WHEN THEY HAVE APPROVED THE IDEA OF A PARTICULAR TOPIC AREA SUCH AS GENE THERAPY AS A VITAL RESEARCH OPPORTUNITY, THAT ALLOWS OUR REVIEW TEAM TO RENDER THOSE TYPES OF PROGRAMS ELIGIBLE SO THEY CAN GO THROUGH THE REVIEW PROCESS. HOWEVER, AT THE END OF THE REVIEW PROCESS, THERE'S STILL A VOTE AS TO WHETHER IT'S CONSIDERED A VITAL RESEARCH OPPORTUNITY, THEN THAT'S BROUGHT TO THE BOARD FOR FINAL APPROVAL FOR FUNDING.

UNDER PROP 14, THE AREA OF GENE THERAPY AND IN ADDITION THIS OTHER AREA CALLED GENETIC RESEARCH ARE NOW CONSIDERED ELIGIBLE. SO IT WILL NOT REQUIRE A VITAL RESEARCH OPPORTUNITY VOTE. THEY WILL NOW AUTOMATICALLY BE CONSIDERED ELIGIBLE FOR REVIEW AND POTENTIAL FUNDING. SO WE DON'T, ASIDE FROM WHAT'S ALREADY BEEN PUT FORTH BY PROP 14 REGARDING SOME SUBJECT AREAS AND BRINGING SOME OTHER TOPICS FOR CONSIDERATION TODAY, WE DON'T HAVE ANY OTHER PLANS TODAY, BUT WE CAN CERTAINLY FOR FUTURE

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BOARD MEETINGS BRING FORWARD A POTENTIAL PROCESS FOR CONSIDERING VITAL RESEARCH OPPORTUNITIES.

OS, IS THAT OKAY FOR NOW? I CAN GO ON TO MORE SPECIFIC DETAIL.

DR. STEWARD: NO. THAT WAS PERFECT. I JUST ACTUALLY WANTED FOR REALLY ALL THE BOARD, BUT ESPECIALLY THE NEW MEMBERS, TO HAVE AN UNDERSTANDING OF HOW THAT WHOLE PROCESS OF CONSIDERATION OF VITAL RESEARCH OPPORTUNITIES ACTUALLY WOULD TAKE PLACE GOING FORWARD. THAT WAS PERFECT. THANK YOU, MARIA. MUCH APPRECIATED.

DR. MILLAN: YOU'RE WELCOME. AND IT REALLY DOES POINT TO THE FACT THAT WE ARE IN A VERY EXCITING TIME WHERE THE FIELD CAN MOVE VERY, VERY QUICKLY. WE CANNOT ANTICIPATE WHAT COULD POTENTIALLY PRESENT TO US AS ON OPPORTUNITY ALONG THE WAY. AND SO THAT ALLOWS OUR SCIENTIFIC REVIEWERS, OUR BOARD TO CONSIDER THESE ADVANCEMENTS AND DETERMINE HOW TO IT CAN BE INCORPORATED INTO OUR PROGRAMS.

IF IT'S OKAY, J.T., I'LL JUST GO AHEAD AND PROCEED.

CHAIRMAN THOMAS: PLEASE.

DR. MILLAN: NEXT SLIDE PLEASE. SO BY WAY OF REVIEW, THIS IS THE CURRENT SCOPE FOR OUR CIRM

FUNDING OPPORTUNITIES, INCLUDING THE OPEN PROGRAM ANNOUNCEMENTS FOR DISCOVERY 2, WHICH IS CANDIDATE DISCOVERY; TRANSLATIONAL PROGRAMS, AS WELL AS CLINICAL, IND-ENABLING AND CLINICAL TRIALS. THEY'RE LISTED HERE. FOR STEM-CELL OR PROGENITOR-CELL BASED PROJECTS, IT'S EITHER CELL THERAPY FOR DEVELOPMENT, VARIOUS PLURIPOTENT STEM-CELL DERIVED AS WELL AS MESENCHYMAL, STROMAL CELL OR STEM CELLS THAT DIFFERENTIATE INTO OTHER CELL TYPES, AND HEMATOPOIETIC STEM CELLS ARE ALL ELIGIBLE TO COME IN FOR CONSIDERATION FOR FUNDING.

THOSE PROJECTS THAT MAY NOT BE THE STEM CELLS, BUT THEY STUDY STEM PROGENITOR CELLS, SUCH AS MECHANISTIC STUDIES, ARE ELIGIBLE AS WELL AS PROGRAMS WHERE THE STEM PROGENITOR CELLS DISEASE IN A DISH, IPSC ORGANOID MODELS, THOSE ARE ELIGIBLE FOR CONSIDERATION FOR FUNDING. DIRECTLY REPROGRAMMED CELLS, THAT MEANS THAT CERTAIN FACTORS OR CERTAIN MANIPULATIONS ARE DONE TO SOMATIC CELLS OR TO FULLY DIFFERENTIATED CELLS AND REPROGRAM THEM TO A DIFFERENT DIFFERENTIATION STATE OR INTO A DIFFERENT CELL TYPE ARE CURRENTLY ELIGIBLE FOR FUNDING. AND SMALL MOLECULES AND OTHER BIOLOGICS IN A LIMITED FASHION, AND THE CONDITIONS FOR THAT ARE VERY MUCH RELATED TO STAGE OF PROGRAM AND PRIOR FUNDING BY

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CIRM, BUT THEY ARE IN SOME CASES ELIGIBLE FOR FUNDING AS LONG AS THEY ACT ON OR DEPEND ON STEM CELLS. GIL, WHO WILL BE PRESENTING AT THE END OF THIS DISCUSSION, CAN GIVE MORE DETAIL IN TERMS OF WHAT THE LIMITATIONS ARE ON SMALL MOLECULE FUNDING.

THE OTHER TOPIC THAT I BROUGHT UP EARLIER IS THIS IDEA OF GENETIC RESEARCH. IT IS NOTED IN PROP 14. IT IS A BROAD TERM, AND THAT IS SOMETHING THAT WE'D LIKE TO DISCUSS WITH THE BOARD TODAY. GENE THERAPY IS CURRENTLY ELIGIBLE FOR FUNDING, AND WE DO HAVE AN EXISTING DEFINITION OF GENE THERAPY IN THAT IT'S INTENDED TO REPLACE, REGENERATE, OR REPAIR THE FUNCTION OF AGED, DISEASED, DAMAGED, OR DEFECTIVE CELL TISSUES AND/OR ORGANS. GIL, AGAIN, WILL HAVE EVEN A MORE DETAILED DEFINITION OF THAT.

NEXT SLIDE PLEASE. SO I THINK THIS IS WHAT DR. BRASHEAR, DR. VUORI, DR. MALKAS HAVE JUST BROUGHT UP EARLIER. SINCE $1.5 BILLION OF THE $5.5 BILLION THAT'S EARMARKED FOR CNS RESEARCH, WE ARE FACED WITH REALITY AS MUCH AS THERE'S PROMISE WITH REGENERATIVE MEDICINE AND EVEN GENE THERAPY. WE'RE STILL AT THE VERY START OF THAT JOURNEY. AND THE MAJOR FEELING FROM ALL THE EXPERTS IN THE FIELD IS WE JUST NEED TO UNDERSTAND MORE WHAT WE ARE TARGETING IN TERMS OF REALLY EXPLORING DISEASE

MECHANISMS AND FOUNDATIONAL RESEARCH, WHICH, OF COURSE, CAN BE SUPPORTED THROUGH OUR DISCOVERY PROGRAM.

THE PANELISTS DID FEEL THAT IF WE WERE DEVOTED TO BRINGING THE CNS FIELD FORWARD, THAT WE CONSIDER A BROADER INVESTMENT HELP, THEREFORE, IN THIS AREA SO THAT IT WOULD ENABLE RATIONAL DEVELOPMENT OF STEM CELL AND GENE THERAPIES. IF NOT INITIALLY, TO GIVE RISE DIRECTLY TO STEM CELL GENE THERAPY, ENABLE THE DEVELOPMENT OF STEM CELL AND GENE THERAPY. AND THAT MAY INVOLVE SMALL MOLECULES, IT MAY INVOLVE BIOLOGICS IN THAT REGARD; BUT IT ALSO MAY INVOLVE THINGS SUCH AS EPIGENETICS, EPIGENOMIC REPROGRAMMING, STUDIES OF THE MICRO ENVIRONMENT, MITOCHONDRIAL STATES, FOR INSTANCE, AND STUDIES OF NON-NEURONAL CELLS, SUCH AS MICROGLIA OR OTHER IMMUNE AND INFLAMMATORY CELLS AS WELL AS VASCULAR EVENTS AND CELL-CELL INTERACTIONS THAT ARE ALL INVOLVED IN PATHOLOGY AND DISEASE PROGRESSION.

MANY OF THESE AREAS ARE NOT CURRENTLY IN SCOPE FOR CIRM DISCOVERY RFA'S EVEN UNLESS THEY INCLUDE STEM CELLS. WE ALREADY KIND OF HAD A PREVIEW TO THAT TOPIC. SO THIS WAS SPECIFICALLY DISCUSSED.

IN ADDITION, WE NEED A BETTER

UNDERSTANDING OF DISEASE PROGRESSION. SO I'M GOING TO -- MAYBE I'LL PRESENT ALL OF THIS AND THEN THE BOARD CAN KIND OF WEIGH IN.

SO THIS IS ON THE OTHER END OF THE IDEA IS SO, IN ADDITION TO BASIC RESEARCH, REALLY UNDERSTANDING NATURAL HISTORY, THE ROLE OF ETHNIC DIVERSITY, GENOMIC BACKGROUND, EPIGENOMIC PROCESSING, AND THE HETEROGENEITY OF THAT. THOSE ARE STUDIES THAT ARE NOT CURRENTLY IN CIRM FUNDING PILLARS. WE DON'T FUND NATURAL HISTORY STUDIES. WE DON'T FUND THESE TYPES OF STUDIES, LET ALONE FUNDING THINGS SUCH AS IMPACT OF SOCIAL DETERMINANTS AND ENVIRONMENTS AND HOW IT INTERACTS WITH THE GENOMICS AND THE CELL BIOLOGY OF EARLY-ON DISEASE PROGRESSION. SO THAT'S THE SECOND POINT.

ALSO NEUROPSYCHIATRIC DISEASE, WHICH IS ALSO NOTED IN PROP 14 AS AN AREA OF RESEARCH, THERE ARE GREAT OPPORTUNITIES TO ADDRESS THIS IN ORGANOID MODELS AND IPSC AND SO-CALLED DISEASE IN A DISH MODEL, BUT THEY ALSO MAY INVOLVE AND GIVE RISE TO CANDIDATES SUCH AS SMALL MOLECULES WHICH ADDRESS THESE MECHANISMS THAT ARE THEN DELINEATED. AND SHOULD WE THEN ONLY FUND THAT TO A CERTAIN POINT AND THEN ALLOW IT TO GO ON? IS IT SUFFICIENTLY DERISKED, THAT OTHERS WOULD BE ABLE TO TAKE IT ALL

THE WAY THROUGH BECAUSE IT IS A TORTUROUS ROUTE TO GET ALONG THE DEVELOPMENT PATH. SO SOME PROMISING PROGRAMS MAY STILL NOT MAKE IT THROUGH FOR CNS.

AND THEN THE IDEA OF REVERSE TRANSLATION, ACTUALLY LEARNING FROM CLINICAL TRIALS. SO DRAWING FROM THE EARLIER THEMES OF CONSORTIA AND DATA SHARING AND KNOWLEDGE NETWORKS, THERE WAS GREAT VALUE THAT WAS SEEN BY EVEN THE BASIC SCIENTISTS IN BEING ABLE TO TAKE LARGE SCALE DATASETS BOTH FROM LATE STAGE KIND OF CLINICAL RESEARCH AS WELL AS DATASETS FROM BASIC RESEARCH AND THAT BEING THE RESEARCH PROJECT ON ITS OWN. THIS IS NOT CURRENTLY FUNDED BY CIRM. DATA SCIENCE JUST AS A PROJECT ON ITS OWN IS NOT. HOWEVER, WE DO HAVE PROGRAMS THAT EMBED THAT WITHIN THE PROJECT ITSELF. THOSE GIVE RISE TO EITHER LIMITED DATASETS OR MAYBE THEY LINK TO OTHER DATASETS, BUT IT'S NOTHING THAT'S REALLY BROUGHT INTO THE CIRM FOLD PER SE.

AND ALL OF THESE COULD BE ACCOMPLISHED VIA THE CONSORTIA MODEL. ALL OF THESE WOULD REQUIRE AN INTEGRATED APPROACH, AND SOME OF THESE ARE NOT ELIGIBLE FOR FUNDING. SO I THINK I'LL LEAVE IT THERE SO THAT WE CAN HAVE THE OPPORTUNITY FOR THE BOARD TO CONSIDER THESE DIFFERENT TOPICS. J.T., I'LL TURN IT BACK TO YOU.

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CHAIRMAN THOMAS: OKAY. THANK YOU, MARIA. SO MARIA HAS HIGHLIGHTED IN RED THERE THE DIFFERENT IDEAS OF APPROACHES, MANY OF WHICH SHE SAID AREN'T CURRENTLY FUNDED. THEY'RE OUTSIDE OF SCOPE, ALTHOUGH THEY OBVIOUSLY ARE TANGENTIAL TO WHAT WE ARE DOING. SO THE QUESTION IN FRONT OF THE BOARD IS, FOR THESE DIFFERENT AREAS, WHAT'S THE BOARD'S THINKING ON WHETHER OR NOT WE SHOULD SOMEWHAT EXPAND WHAT WE DO TO TAKE INTO ACCOUNT THESE QUESTIONS AND FIELDS?

ALLISON, WHY DON'T WE START WITH YOU SINCE THIS IS SORT OF SQUARELY IN YOUR BAILIWICK?

DR. BRASHEAR: WELL, I'M TREMENDOUSLY ENTHUSIASTIC ABOUT THIS. I HAVE TO SAY I'M NEW TO THE BOARD. SO I'M NOT FAMILIAR WITH HOW MUCH SCOPE WE CAN GET OUT OF RANGE, BUT THESE ARE THE KEY AREAS THAT I THINK ARE GOING TO BE JUST CRITICAL FOR NEW DISCOVERY. AND I'M THINKING OF NEUROPSYCHIATRIC DISEASE, AUTISM, MULTIPLE GENETIC DISEASES. AND I JUST THINK THAT THERE'S SO MUCH OUT THERE THAT IS IN THE BROAD DEFINITION OF THE STEM CELL AND CIRM. SO, AGAIN, I'M ENTHUSIASTIC. FOR NEUROSCIENCES THIS IS A LONG TIME COMING.

AND I ALSO WILL JUST SHARE WITH THE BOARD A LITTLE TIDBIT, THAT PSYCHIATRY IS THE TOP SOUGHT

AFTER RESIDENCY PROGRAM IN THE COUNTRY FOR THIS VERY REASON. SO NO LONGER IS IT DERMATOLOGY OR ORTHOPEDIC SURGERY. IT IS PSYCHIATRY.

CHAIRMAN THOMAS: VERY INTERESTING. I'M SURE AS GREATLY INFLUENCED BY THE PAST YEAR AND THE INCREASE IN ISSUES, ET CETERA. THANK YOU. JUDY, YOU WERE NEXT.

DR. GASSON: THANK YOU VERY MUCH. I FULLY AGREE WITH WHAT ALLISON SAID. AND, MARIA MILLAN, YOU DID A WONDERFUL JOB OF PUTTING THIS ALTOGETHER IN ONE SLIDE FOR US.

YESTERDAY AT UCLA WE HAD A TWO-HOUR SYMPOSIUM ON NEUROPSYCHIATRIC DISORDERS FROM THE BENCH TO THE POPULATION. AND ONE OF THE THINGS THAT REALLY CAME THROUGH THAT IS THAT THE STUDIES THAT HAVE BEEN DONE IN MANY TYPES OF NEUROPSYCHIATRIC DISORDERS HAVE BEEN DONE IN BASICALLY EUROPEAN POPULATIONS AND THAT THEY DON'T EXTEND TO OTHER POPULATIONS. AND THERE'S PROBABLY LOTS OF PATHWAYS THAT WE ARE MISSING BECAUSE WE HAVEN'T DONE A MORE COMPLETE WAY OF COLLECTING SAMPLES AND COHORTS. AND MANY OF THESE STUDIES ARE BEING DONE OUTSIDE THE UNITED STATES IN ORDER TO GET THIS ADDITIONAL INFORMATION.

SO I FULLY SUPPORT EXPANDING THE SCOPE AND

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THE CHALLENGES IN THE CNS RESEARCH GIVEN WHERE THE FIELD IS TODAY, GIVEN THE INCREDIBLE IMPACT IT HAS ON FAMILIES AND PATIENTS AND COMMUNITIES. AND WE HAVE A 10- TO 16-YEAR TIME FRAME HERE, WHICH IS A REASONABLE AMOUNT OF TIME TO REALLY TRY TO HAVE AN IMPACT. AND SO I'M REALLY VERY ENTHUSIASTIC ABOUT THIS AREA OF RESEARCH.

CHAIRMAN THOMAS: THANK YOU. HAIFAA.

DR. ABDULHAQ: THANK YOU. SO AS A HEMATOLOGIST ONCOLOGIST, I JUST WANTED TO FOCUS ON THE ASPECTS RELATED TO CNS TUMORS, INCLUDING CNS LYMPHOMA. I THINK FOR THAT ENTITY, IT WOULD BE REALLY IMPORTANT TO EXPAND JUST TO EPIGENETICS AS WELL AS STUDYING THE MICROENVIRONMENT BECAUSE WE KNOW THAT IN THOSE DISEASES, IT'S NOT ONLY ABOUT THE STEM CELLS, AND REALLY A LOT OF THE ADVANCES AND THE WORK THAT IS BEING DONE IN TERMS OF TREATMENT IS RELATED TO THE MICROENVIRONMENT.

SO I WOULD BE SUPPORTIVE -- I CAN'T COMMENT ON ALL THE CNS DISEASES AS I DON'T REALLY HAVE KNOWLEDGE IN THOSE; BUT WHEN IT COMES TO TUMORS, I WOULD BE SUPPORTIVE OF EXPANDING THE FOCUS.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS? CHRISTINE.

DR. MIASKOWSKI: BEING NEW TO THE BOARD, I'D LIKE TO ASK A QUESTION TO MARIA. I WAS INTERESTED IN YOUR COMMENTS ON ONE OF YOUR SLIDES WHERE YOU TALKED ABOUT CIRM'S FOCUS ON PATIENT CENTRIC END POINTS. I'D LIKE TO HEAR A LITTLE BIT MORE ABOUT WHAT'S CONSIDERED IN THAT TERMINOLOGY, AND THEN COMMENT ON WHAT OTHERS HAVE SAID RELATED TO THE CHALLENGES IN CNS DISORDERS.

DR. MILLAN: THANK YOU SO MUCH. I THINK THAT YOU MAY HAVE SEEN THAT THE ENTIRE CIRM AS AN AGENCY AND HOW WE DO THINGS IS PATIENT CENTRIC, AND SO OPERATIONALLY OR LOGISTICALLY, ALL OF OUR MAJOR COMMITTEES, OUR BOARD, OUR CLINIC ADVISORY PANEL, OUR TRANSLATIONAL ADVISORY PANEL ALL HAVE PATIENT REPRESENTATIVES. SO WE CAN LOOK AT THINGS FROM THE VIEW OF PATIENTS AND PATIENT REPRESENTATIVES AND INFORMED CONSENTS. EDUCATIONAL MATERIALS, COMMUNICATION, KIND OF THE INTANGIBLES THAT MAYBE WE DON'T TAKE INTO ACCOUNT WELL ENOUGH IN TERMS OF HOW TRIALS ARE EITHER CONSTRUCTED OR CARRIED OUT. THINGS RELATED TO THE SOCIAL ASPECTS OF THE DISEASE AS WELL AS THE CLINICAL TRIAL AND HOW THAT IMPACTS.

IN TERMS OF PATIENT CENTRIC OUTCOMES, WE HAVE NOT YET -- THAT IS NOT YET PART OF OUR PROGRAMS PER SE BECAUSE THERE ARE VERY FEW CLINICAL TRIALS

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THAT DO THAT. THAT IS BEING PILOTED IN FDA-FUNDED PROGRAMS TO DETERMINE HOW WE CAN BEST INCORPORATE PATIENT CENTRIC OUTCOMES IN TERMS OF EVEN HOW WE LOOK AT OUR -- EVEN HOW WE CONDUCT OUR CLINICAL RESEARCH.

THOSE ARE AREAS THAT IN THE FUTURE, AS THEY MATURE AND CAN GET AN IND, WOULD BE ELIGIBLE FOR FUNDING, AGAIN, PROVIDED THEY'RE WITHIN SCOPE.

I HOPE THAT CLARIFIES USE OF THAT TERM.

DR. MIASKOWSKI: THANKS VERY MUCH. I THINK THE POINT I'D LIKE TO MAKE IS, IN THINKING THROUGH PARTICULARLY THE CHALLENGES IN CNS RESEARCH AND THINKING ABOUT CLINICAL TRIALS AND STUDYING DISEASE PROGRESSION, IT WOULD BE REALLY, REALLY IMPORTANT TO MEASURE PATIENT-REPORTED OUTCOMES. THERE'S ENOUGH LITERATURE NOW, LARGELY IN, I THINK, THE CANCER, THE NEURO, THE PSYCHIATRIC WORLD THAT THESE ARE CRITICALLY IMPORTANT AND MAYBE EVEN MORE IMPORTANT THAN THE DISEASE PROCESS ITSELF. I THINK IT'S A REAL OPPORTUNITY TO THINK CRITICALLY ABOUT THE ONES THAT ARE MOST IMPORTANT IN TERMS OF MOOD, FUNCTIONAL STATUS, AS WELL AS SOCIAL DETERMINANTS OF HEALTH. I REALLY BELIEVE THAT THOSE NEED TO BE CONSIDERED AS FUNDAMENTAL COVARIATES IN CLINICAL TRIALS LIKE THIS.

AND I DON'T KNOW WHETHER CIRM HAS DONE WORK IN LOOKING AT, PARTICULARLY WITH THESE PROGRESSIVE DISORDERS, THE RESOURCE NEEDS OF PATIENTS THAT INFLUENCE OUTCOMES AS WELL AS THE IMPACT ON FAMILY MEMBERS THAT CARE FOR THESE PATIENTS. I MAY BE SPEAKING TOTALLY OUT OF TURN IN TERMS OF SCOPE, BEING A NEW PERSON ON THE BOARD, BUT I THINK THESE ARE CRITICALLY IMPORTANT FACTORS TO CONSIDER AS WE MOVE INTO CLINICAL TRIALS. THERE'S SO MUCH DIVERSITY IN MOST OF THESE CLINICAL CONDITIONS, THAT THE ENVIRONMENT, THE MILIEU THAT THE PATIENT IS IN CAN INFLUENCE THE THERAPIES THAT WILL BE ADMINISTERED TO THEM. SO THINKING ABOUT THAT, I THINK, WOULD PUT US ON A DIFFERENT PLANE AS WELL IN TERMS OF SEEING THE WHOLE PATIENT.

DR. MILLAN: THANK YOU SO MUCH. THE IDEA OF PATIENT-REPORTED OUTCOMES, REAL-WORLD EVIDENCE, RELEVANT COVARIATE ANALYSIS, THOSE ARE TOPICS THAT HAVE BEEN RAISED. THEY'RE NOT CURRENTLY FUNDED AS INDEPENDENT PROGRAMS PER SE. THERE MAY BE SOME OF OUR CLINICAL RESEARCH PROGRAMS THAT HAVE THAT IN THEIR PROTOCOLS; BUT FOR THE MOST PART, I WOULD SAY THAT THE RULE RATHER THAN THE EXCEPTION IS THEY ARE NOT IN THERE BECAUSE THEY'RE NOT NECESSARILY REQUIRED BY THE FDA AT THIS TIME. SO WHAT HAPPENS

IS THEY'RE NOT NECESSARILY EMBEDDED WITHIN THOSE PROGRAMS.

FOR CONSIDERATION FOR THE BOARD FOR DISCUSSION IS THIS IDEA OF SHOULD WE BE FUNDING PUBLIC HEALTH AND SOCIAL SCIENCE RESEARCH AND ALL THESE OTHER RELATED MATTERS LAYERED ON TOP OF THE TYPE OF RESEARCH WE ARE DOING? AGAIN, POTENTIALLY EVEN BRINGING IN KIND OF THE DATA SCIENCE DRIVEN ASPECT OF THIS.

DR. MIASKOWSKI: AGAIN, BEING NEW, MAYBE A CONSIDERATION WOULD BE RELATED TO THE CLINICAL TRIALS THAT CIRM IS GOING TO SUPPORT, THAT THERE BE SOME COMMON DATA ELEMENTS THAT INVESTIGATORS NEED TO INCLUDE AS PART OF THE PROCESS OF GATHERING DATA. NOT PRIMARY DATA COLLECTION PER SE, BUT IS THERE A WAY IN YOUR CLINICAL TRIALS NETWORK OR IF YOU ARE GOING TO BUILD A CONSORTIUM, THAT THERE BE SOME COMMON DATA ELEMENTS? THERE'S SOME OF THIS BEING DONE AT THE NCI WITH PATIENT-REPORTED ADVERSE EFFECTS IN CLINICAL TRIALS. SO THERE ARE SOME PROTOTYPES FOR THIS, AND IT MIGHT BE INTERESTING TO HAVE A DISCUSSION ABOUT THAT.

DR. MILLAN: I THINK THAT'S AN EXCELLENT RECOMMENDATION. AND IF WE ARE ABLE TO LAUNCH CONSORTIA, THAT WOULD BE A WAY TO BE ABLE TO EMBED

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THAT IN TERMS OF WHAT PARTICIPATING IN A CONSORTIA WOULD MEAN SO THAT THAT IS A WAY TO KIND OF HAVE THAT CENTRALIZED, STANDARDIZED WAY OF COLLECTING THAT TYPE OF DATASET ACROSS THE VARIOUS PROGRAMS. SO THAT IS SOMETHING THAT WE WILL BRING AND BRING IN AND SEE HOW IT COULD FIT INTO A CONCEPT. THANK YOU.

CHAIRMAN THOMAS: LINDA BOXER, YOU'VE GOT YOUR HAND UP.

DR. BOXER: THANK YOU. I THINK THESE CHALLENGES ARE REALLY IMPORTANT, AND I THINK IT'S A GREAT DISCUSSION. THIS IS CLEAR. I MEAN I KNOW THE INTEREST IN PSYCHIATRY AS WELL. WE SEE THAT. BUT I DO WANT TO GO BACK TO SOME OF THE COMMENTS MADE BY SOME OF THE BOARD MEMBERS EARLIER ABOUT WE HAVE TO BE A LITTLE CAREFUL ABOUT BEING TOO BROAD, AND I WOULD ADD TRYING TO BOIL THE OCEAN.

I WONDER IF THERE ISN'T A MIDDLE GROUND WHERE WE COULD SAY THAT WE'RE GOING TO ADOPT A VERY FLEXIBLE APPROACH AND BE WILLING TO CHANGE AND ADD NEW DIRECTIONS SUCH AS THIS. I'M JUST A LITTLE CONCERNED IN TERMS OF STARTING OUT HOW FAR AWAY WE MIGHT GET FROM THE ORIGINAL MISSION AND WHAT I THINK THE VOTERS OF CALIFORNIA APPROVED.

NOW, ADDING, I THINK IT'S GREAT, THAT CNS DISEASE IS NOW PART OF THAT, AND I THINK THAT'S

FANTASTIC. SO WHILE I'M VERY ENTHUSIASTIC ABOUT ALL OF THESE AREAS, I JUST DO WONDER IF WE ARE GOING BECOME TOO DILUTE TO HAVE IMPACT. AND I THINK THAT WOULD OBVIOUSLY NOT BE SOMETHING THAT WE WANT TO SEE.

MR. TORRES: MR. CHAIRMAN.

CHAIRMAN THOMAS: SENATOR TORRES.

MR. TORRES: I WANT TO ECHO LINDA'S COMMENTS BECAUSE DURING THE CAMPAIGN IT WAS VERY CLEAR WHAT PEOPLE WERE VOTING FOR. AND THE TAXPAYERS MADE IT VERY CLEAR WHAT THEIR INTENT WAS IN TERMS OF OUR SCOPE. SO WE JUST HAVE TO BE CAREFUL TO ADHERE TO THAT BECAUSE IT GOES BACK TO WHAT'S CALLED LEGISLATIVE INTENT. MANY COURTS, WHETHER IT'S THE SUPREME COURT OR APPELLATE COURTS, WHEN REVIEWING LEGISLATION ALWAYS GO BACK TO THE LEGISLATIVE HISTORY TO DETERMINE WHAT THE INTENT OF THE LEGISLATURE WAS IN DRAFTING AND PASSING A LAW WHICH IS NOW SUBJECT TO LEGAL REVIEW.

THE SAME THING HAS TO APPLY HERE. WHAT WAS THE INTENT OF THE VOTERS IN SUPPORTING US FOR ANOTHER 5.5 BILLION? I DON'T THINK IT WAS TO BE TOO EXPANSIVE, BUT AT LEAST REMAIN SOMEWHAT WITHIN THE CONFINES OF THE INTENT OF THE STEM CELL RESEARCH THAT WE HAVE BEEN OPERATING UNDER FOR THE LAST

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ALMOST 12 YEARS.

SO I THINK IT'S VERY IMPORTANT BECAUSE THEN, IF WE DO TRAVERSE BEYOND THE INTENT OF THE VOTERS, WE ALSO RUN INTO THE INTENT OF LEGISLATIVE HEARINGS AND OVERSIGHT WHICH MAY BE NOT APPROPRIATE, BUT STILL MAY CAUSE DELAYS OR OTHER KINDS OF MISUNDERSTANDINGS THAT WE NEED TO AVOID.

CHAIRMAN THOMAS: MARK. THANK YOU, ART. MARK.

DR. FISCHER-COLBRIE: THOSE ARE GREAT COMMENTS FROM ART. THE OTHER VARIABLE HERE OBVIOUSLY IS THE STAGE OF DEVELOPMENT IN THE CONTEXT OF INTENT RELATED TO PUSHING MORE TOWARDS CLINICAL TRIALS RATHER THAN EARLY STAGE RESEARCH. THAT'S AN OPEN QUESTION. I DON'T HAVE A PARTICULAR PERSPECTIVE ON THAT, BUT OBVIOUSLY EVERYBODY KNOWS THAT, BUT THAT'S ANOTHER FACTOR FOR CONSIDERATION HERE ABOUT HOW WE THINK THAT SHOULD BE DIALED IN.

CHAIRMAN THOMAS: OKAY. OTHER COMMENTS FROM MEMBERS OF THE BOARD?

DR. GOLDSTEIN: LET ME JUST MAKE A BRIEF COMMENT HERE, J.T. I THINK SOME OF THE MOST RECENT COMMENTS HERE I REALLY RESONATE WITH. REMEMBER THAT THE NIH HAS AN APPROPRIATION AT THE MOMENT OF OVER $40 BILLION PER YEAR. WE CAN'T HOPE TO MATCH THAT;

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HOWEVER, WE CAN LEVERAGE OFF OF IT. AND PART OF LEVERAGING OFF OF IT IS ENSURING THAT WHEN WE DECIDE TO DO SOMETHING, IT'S NOT ALREADY BEING DONE BY A LARGER AGENCY. AND IF IT'S JUST LAUNCHING, PERHAPS WE CAN ADD A DIMENSION IN A PARTNERSHIP OR CONSORTIUM APPROACH WITH THOSE EFFORTS.

TO THE EXTENT WE CAN LEVERAGE THAT 43 BILLION A YEAR, THAT ACTUALLY EXTENDS OUR MISSION AND OUR REACH QUITE DRAMATICALLY.

CHAIRMAN THOMAS: THANK YOU, LARRY. OTHER COMMENTS FROM MEMBERS OF THE BOARD?

IF I CAN ASK AS REGARDS THE SEVERAL ITEMS UP HERE FOR DISCUSSION ON THIS SLIDE, DO BOARD MEMBERS HAVE A PARTICULAR FEEL ON WHICH OF THESE, IF ANY, YOU THINK WE SHOULD DEVOTE FUNDING TO? WHILE I TAKE ART'S COMMENTS, VERY GOOD COMMENTS, SERIOUSLY EACH OF THESE ARE SORT OF ON THE FRINGES OF WHAT IS SET FORTH IN PROP 14. THESE ARE NOT TOPICS OUT OF THE BLUE. SO ARE THERE ANY IN HERE THAT PEOPLE THINK ARE MORE IMPORTANT THAN OTHERS?

MS. DURON: MR. CHAIR.

CHAIRMAN THOMAS: YES, YSABEL.

MS. DURON: THANK YOU. I'M SORRY I'M LATE.

TO LAWRENCE'S POINT AND TO MY CONCERN ON

POINT 1, BETTER UNDERSTANDING OF DISEASE PROGRESSION, NATURAL HISTORY, RACIAL AND ETHNIC DIVERSITY IS CRITICAL, AND THIS IS SORT OF NOT CURRENTLY IN THE FUNDING PILLAR. YET WE LEARNED AND SAW OVER THIS PAST YEAR HOW CRUCIAL AND IMPORTANT INCLUSION OF RACIAL AND ETHNIC MINORITIES ARE IN RESEARCH BECAUSE OF THE IMPACTS OF COVID AND BECAUSE OF THE FACT THAT THEY'VE BEEN TRADITIONALLY UNDERREPRESENTED IN RESEARCH. I DON'T THINK THEY SHOULD BE ON THE FRINGE OR NOT IN FUNDING.

BUT TO LAWRENCE'S POINT ABOUT THE BILLIONS BEING INVESTED BY NIH, THEY ARE VERY FOCUSED ON ISSUES AROUND RACIAL AND ETHNIC DIVERSITY, REPRESENTATION, AND INCLUSION. SO THERE MIGHT BE OPPORTUNITIES TO LEVERAGE THE FUNDING AROUND THAT. I JUST THINK THAT NOW IS THE MOMENT IN WHICH WE HAVE TO BE CRITICALLY AWARE OF INCLUSION JUST TO MOVE IT DOWN THE REGULAR RESEARCH PATH, BUT ALSO TO TAKE ADVANTAGE OF THE FACT THAT EVERYBODY SEEMS TO BE LOOKING AT THE ISSUES OF RACIAL AND ETHNIC DIVERSITY UNDERREPRESENTATION AND THE NEED TO KNOW MORE IN ORDER TO MOVE THEM TOWARDS EQUAL HEALTH.

SO I WOULD PUSH FOR THE FACT THAT IF WE CAN AND DO ANYTHING ABOUT CIRM FUNDING FOR RACIAL AND ETHNIC DIVERSITY ISSUES, I WOULD HIGHLY SUPPORT

THAT AND ASK EVERYBODY ELSE TO DO SO.

CHAIRMAN THOMAS: THANK YOU, YSABEL. OTHER COMMENTS? OKAY. THANK YOU FOR ALL OF YOUR INPUT ON THIS PAGE. MARIA, IF YOU'D LIKE TO PROCEED.

DR. MILLAN: THANK YOU, CHAIRMAN THOMAS.

JUST TO ADDRESS SOME OF THE QUESTIONS OR POINTS THAT WERE BROUGHT UP, ONE OF THE THINGS TO CONSIDER IS, FOR INSTANCE, WHEN WE DO CLINICAL TRIALS OR WE DO OUR RESEARCH, THERE IS ALREADY DATA BEING GENERATED BY THIS RESEARCH. SO SOME OF THE THINGS WE ARE TALKING ABOUT AS BEING OUT OF SCOPE, ET CETERA, IT'S A FUNCTIONAL THING RATHER THAN SOMETHING THAT'S NOT ALREADY -- IT'S ALREADY PRESENT IN TERMS OF THE SUBSTRATE FOR BEING ABLE TO DO THIS. WE JUST DON'T HAVE THE MECHANISM BY HOW TO KIND OF GATHER INFORMATION ACROSS OUR PROGRAMS, FOR INSTANCE, THAT WOULD SHED LIGHT ON SOME OF THE COVARIATES THAT WERE BROUGHT UP EARLIER.

SO I GUESS I'D LIKE TO REALLY JUST CENTER IT AND MAKE SURE THAT WE DON'T TRY TO BOIL THE OCEAN. WE ACTUALLY HAVE A VERY DELIBERATE AND FOCUSED AREA THAT WE ARE LEADING; BUT WITHIN THAT AREA, WE CAN BRING VALUE BY STRUCTURING IT IN A WAY THAT WE COULD REALLY HARNESS BOTH THE STRUCTURE, THE

MATERIAL, THE DATA, AND THE KNOWLEDGE THAT'S GAINED FROM THIS AND CREATE A WAY TO BRING THEM TOGETHER.

I HOPE THAT'S NOT TOO ABSTRACT. FOR INSTANCE, AS ONE OF THE HEAD OF THERAPEUTICS REMINDS ME, THAT QUALITY OF LIFE AND SOME OF THESE THINGS ARE ALREADY COLLECTED WITHIN THEIR CLINICAL TRIALS PER SE. SO IF IN A CONSORTIUM THERE'S A WAY TO BRING SOME OF THOSE FORWARD AND WE ARE ABLE TO DO MORE DEEP ANALYSIS OR SOMEBODY IS ABLE TO, THERE IS A WAY TO DO THAT WITHOUT BEING OUT OF SCOPE BECAUSE THESE ARE PROGRAMS THAT WOULD OTHERWISE BE FUNDED ANYWAY.

SO THAT'S THE ONE POINT I WANTED TO BRING TO THE BOARD TO CONSIDER. AND THE OTHER POINT IS ABOUT BASIC RESEARCH. THE STRATEGIC PLAN AS WE'VE BEEN DISCUSSING IT WITH THE BOARD DOES EMBED WITHIN A COMMITMENT TO BASIC RESEARCH AS WELL AS TRANSLATIONAL AND CLINICAL. IN THE FINAL ESPECIALLY FIVE YEARS OF THE CIRM UNDER PROP 71, WE REALLY DID FOCUS ON LATER STAGE AND CLINICAL RESEARCH WITH THE REMAINING FUNDS. I BELIEVE THE INTENT OF PROP 14, AT LEAST AS TO HOW WE'VE BEEN DISCUSSING IT AT THIS MEETING, IS THAT WE SUPPORT THE FULL COMPLEMENT OF RESEARCH, THAT WE CAN ONLY DO SO MUCH BY JUST PUSHING FORWARD LATER STAGE PROGRAMS IN A SELECTION

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BIAS AND NOT GIVING RISE TO THE PIPELINE AND NEW KNOWLEDGE THAT WILL ENABLE US TO TACKLE TOUGH INDICATIONS, SUCH AS DISEASES OF THE BRAIN.

SO I WANTED TO BRING THOSE TWO POINTS UP IN TIME TO HAVE IN THE STRATEGIC PLAN, THAT BASIC RESEARCH WILL ALSO BE AS EQUALLY VALUED AS TRANSLATIONAL AND CLINICAL BECAUSE IT'S ESSENTIAL IN BEING ABLE TO DEVELOP THE DOWNSTREAM THERAPIES. NEXT SLIDE PLEASE.

CHAIRMAN THOMAS: MARIA, PAT HAS A COMMENT.

DR. LEVITT: THANKS, J.T. IT ACTUALLY RELATES TO WHAT MARIA JUST SAID. PEOPLE HAVE SAID THINGS THAT ARE VERY CLEAR AND POINTED, AND I AGREE WITH THEM. I THINK OUT OF ANYTHING, EVERYTHING ON THIS LIST, INSTITUTIONS ARE RECOGNIZING THAT IF THEY DON'T BECOME DATA DRIVEN, THEY'RE GOING TO BE ON THE OUTSIDE LOOKING IN. I THINK CIRM AND, MARIA, YOU COMMENTED ON THIS, NEEDS THE SAME APPROACH. WE HAVE SOME OF THE BEST PRIVATE SECTOR EFFORTS IN THE WORLD FIGURING OUT HOW TO USE DATA TO MAKE DISCOVERY. I THINK THIS IS NOT OUTSIDE THE SCOPE OF CIRM. AND SO JUST AS INCLUSION NEEDS TO BE A PART OF EVERY STUDY THAT'S PROPOSED THAT INVOLVES HUMAN BEINGS, DATA ANALYTICS AND BEING DATA DRIVEN IN THE APPROACHES

THAT CIRM INVESTIGATORS USE HAS TO BE, IN MY OPINION, NEEDS TO BE A SIGNIFICANT PART OF THAT.

SO I'M IN FAVOR OF FIGURING OUT HOW TO REALLY BECOME DATA DRIVEN WHERE WE NOW HAVE GREAT OPPORTUNITIES TO WORK WITH OUR COLLEAGUES IN COMPUTER SCIENCE AND DEEP LEARNING AND OTHER AREAS THAT REALLY PROVIDE MUCH GREATER INSIGHT THAN WE'VE HAD IN THE PAST, PARTICULARLY WHEN IT RELATES TO BRAIN DISEASES.

CHAIRMAN THOMAS: KRISTINA. THANK YOU, PAT. KRISTINA.

DR. VUORI: I FULLY ENDORSE WHAT PAT WAS JUST SAYING ABOUT THE DATA. AND AS IT COMES TO THIS SLIDE, AND I THINK MARIA WAS ADDRESSING THIS AS WELL, REALLY LEARNING FROM THE CLINICAL TRIALS, I THINK, IS REALLY A GREAT OPPORTUNITY FOR CIRM. WE NOW HAVE QUITE A FEW CLINICAL TRIALS OBVIOUSLY GOING ON, SOME OF WHICH HAVE BEEN SUCCESSFUL, OTHERS WHICH HAVE NOT AND PROGRESS HAS NOT BEEN MADE. I THINK IN THE FIELD OF CELL THERAPIES IN GENERAL, I THINK IT'S VERY IMPORTANT TO UNDERSTAND ALSO WHY FAILURE TOOK PLACE. BROADLY SPEAKING, I THINK WE HAVE VERY LITTLE UNDERSTANDING EVENTUALLY THAT WE WERE ABLE TO REALLY TEST THE HYPOTHESIS IN HUMAN BEINGS THAT SOMETIMES IN THESE CLINICAL TRIALS COMES WITH WAS

THE BIODISTRIBUTION CORRECT? DID THE CELLS SURVIVE THE PROCESS? THERE ARE VERY FEW BIOMARKERS AND WAYS TO EVEN IMAGE CELLS WHAT THE ACTUAL FATE IS IN CLINICAL TRIALS. I THINK LEARNING FROM THOSE CLINICAL TRIALS THAT HAVE ALREADY TAKEN PLACE, TAKING THE DATA, THERE'S A LOT OF DATA THAT IS GENERATED BY DEFINITION WHETHER IT'S SPECIFICALLY FUNDED OR NOT, I THINK IS A FANTASTIC OPPORTUNITY FOR CIRM GOING FORWARD.

CHAIRMAN THOMAS: THANK YOU, KRISTINA.

OTHER COMMENTS ON THIS SLIDE BY MEMBERS OF THE BOARD? OKAY. NEXT, MARIA.

DR. MILLAN: THANK YOU SO MUCH. NEXT SLIDE PLEASE.

ANOTHER TOPIC, IT DOESN'T HAVE AS MUCH ORANGE, BUT I THINK IT WILL GENERATE AS MUCH DISCUSSION. SO GENE THERAPY IS CURRENTLY WITHIN SCOPE FOR CIRM. AND IT WAS THE DEFINITION THAT I POSED EARLIER -- THAT I PROVIDED EARLIER. THE ADVISORS ENCOURAGED FROM THE SCIENTIFIC STRATEGY PANEL FOCUSED INVESTMENT IN THE INTERSECTION BETWEEN GENE THERAPY AND STEM CELL REGENERATIVE MEDICINE, TO TARGET BOTH LARGE INDICATIONS AS WELL AS SMALL INDICATIONS, ORPHAN AND ULTRA RARE, BROUGHT UP THE IDEA THAT SOME OF THE ULTRA RARE AND SMALL

INDICATIONS MAY NEED THE ACADEMIC PARTIES TO CONTINUE TO BRING THAT FORWARD THAT MAY NOT NECESSARILY FIT INTO THAT MODEL OF DERISKING FROM A COMMERCIALIZATION BY INDUSTRY PARTNERS. THAT IS THE TOPIC THAT WAS BROUGHT UP.

AND THERE WAS AN ENCOURAGEMENT THAT CIRM SHOULD PURSUE IN VIVO GENE THERAPY PROJECTS. BY THE WAY, THAT IS CURRENTLY IN SCOPE. IT DOESN'T NEED TO GO FOR A VITAL RESEARCH OPPORTUNITY VOTE. WE DON'T CURRENTLY HAVE IN VIVO GENE THERAPY PROJECTS AT THE CLINICAL STAGE IN OUR PORTFOLIO; HOWEVER, THE PANEL ENCOURAGED THAT THIS SHOULD BE PURSUED BOTH FOR PROJECTS THAT ARE MORE LIKELY TO SUCCEED, I.E., THE PROVERBIAL LOW HANGING FRUIT AS WELL AS HARD PROBLEMS.

CIRM COULD SUPPORT BASIC RESEARCH THAT ADDRESSES GENOTOXIC EFFECTS WITH GENE THERAPY, LOOKING AT IN-AND-OUT APPROACHES THAT ALLOW GENES TO BE INTRODUCED INTO HUMANS THAT CAN BE TURNED OFF OR REMOVED. SO THOSE ARE KIND OF SOME MORE DETAILED AREAS OF WHAT COULD BE PURSUED.

ALSO ANOTHER TOPIC THAT'S ARISEN ESPECIALLY RECENTLY WITH THE EXPERIENCE IN LENTIVIRAL THAT'S UNDER INVESTIGATION WITH LENTIVIRAL GENE DELIVERY IS SOME OF THE THINGS WE

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WERE TALKING ABOUT IN TERMS OF WHAT IS THE BASELINE GENOMIC GENETIC BACKGROUND UPON WHICH WE ARE HAVING INTERVENTION? SO SOME OF THOSE TYPES OF STUDIES TO REALLY CHARACTERIZE, FOR INSTANCE, SICKLE CELL, SOME BASELINE INSERTIONAL MUTAGENESIS THAT ALREADY -- NOT INSERTIONAL MUTAGENESIS, BUT MUTAGENESIS THAT ALREADY OCCURS AT BASELINE VERSUS WHAT IS THE IMPACT OF THE CELL THERAPY. SO THOSE ARE KIND OF SPECIALIZED TOPICS THAT ON ITS OWN MAY NOT BE PURSUED AS A CLINICAL PROJECT PER SE, BUT ARE RELEVANT TO BRINGING FORWARD THE AREA OF GENE THERAPY.

AND ONE OF THE ADVISORS RAISED A NEED FOR FUNDING FOR NONHUMAN PRIMATE STUDIES WHICH THEY BELIEVE ARE GOING TO BE CRITICAL TO BRINGING FORWARD THESE TYPES OF INTERVENTIONS. NONHUMAN PRIMATE STUDIES THAT ARE PART OF THE PROJECT ARE CURRENTLY WITHIN SCOPE. WE HAVEN'T FUNDED A NONHUMAN PRIMATE FACILITY PER SE. IT COULD BE CONSIDERED IN THE CONTEXT OF CREATING A CORE FACILITY, FOR INSTANCE, FOR A CONSORTIUM MODEL. SO THERE'S KIND OF A STANDARD COLONY OR STANDARD MODELS THAT CAN EVENTUALLY BE USED IN THE CONSORTIUM. SO THAT IS -- MAYBE THE NEXT SLIDE IS WHERE IT REALLY IS GOING TO GENERATE MORE OF A DISCUSSION. BUT IF THERE ARE ANY

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QUESTIONS REGARDING THESE STATEMENTS, J.T., I'M HAPPY TO PAUSE FOR A SECOND.

CHAIRMAN THOMAS: THANK YOU. I THINK WITH RESPECT TO THERE WAS A LOT OF DISCUSSION ABOUT IN VIVO GENE THERAPIES, AS MARIA NOTES. I THINK THE MORE LIKELY TO SUCCEED WAS CENTERED AROUND THE MONOGENIC DISORDERS, NOT THAT ANY OF IT IS MORE LIKELY TO SUCCEED. THIS IS TOUGH STUFF. BUT THIS IS ALL THE GREAT ENTHUSIASM ON THAT AS WELL AS ALL THE OTHER TOPICS.

KRISTINA, YOU HAVE YOUR HAND UP?

DR. VUORI: SORRY. IT'S FROM THE PREVIOUS.

CHAIRMAN THOMAS: PAT.

DR. LEVITT: THERE ARE FEDERALLY FUNDED, AS MANY PEOPLE KNOW ON THIS, CALLED FEDERALLY FUNDED NONHUMAN PRIMATE CENTERS, AND PART OF THEIR CHARGE IS TO COLLABORATE. THERE ARE CONSORTIA. THERE'S ONE AT UC DAVIS, OBVIOUSLY, AND THERE ARE TWO OTHERS ON THE WEST COAST. PART OF THEIR CHARGE IS TO COLLABORATE WITH NOT JUST INSTITUTIONS, BUT ORGANIZATIONS LIKE THIS THAT CAN'T INVEST IN SUPPORTING A NONHUMAN PRIMATE CENTER, BUT CAN SUPPORT RESEARCH THAT WOULD INVOLVE NONHUMAN PRIMATE MODELS FOR GENE THERAPY, FOR EXAMPLE. SO THAT'S

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SOMETHING TO CONSIDER. STARTING WITH JOHN MORRISON, WHO'S THE DIRECTOR AT UC DAVIS, WOULD BE ONE PLACE TO START IF THIS IS AN INTEREST OF THE BOARD.

CHAIRMAN THOMAS: THANK YOU, PAT. I WAS JUST GOING TO ASK ALLISON ABOUT THAT VERY FACILITY.

DR. BRASHEAR: YES. VERY ENTHUSIASTIC AND ACTUALLY THE WORD FROM NIH, I'M NOT HEARING MYSELF, BUT GETTING FEEDBACK FROM OTHERS IS THAT THEY ARE ALSO VERY EXCITED ABOUT EXPANDING NONHUMAN PRIMATE RESEARCH IN TERMS OF THE PANDEMIC AND OTHER THINGS. AND SO I WOULD SEE THERE'D BE PARALLEL PROCESSES WITH CIRM'S INTEREST IN NONHUMAN PRIMATE, NIH INTEREST IN NONHUMAN PRIMATE, LOTS OF EXCITEMENT. WE RECENTLY HAD AN EXTERNAL REVIEW, AND IT WENT VERY WELL, AND STILL WAITING FOR THE DOCUMENT. SO WE ARE ENTHUSIASTIC ABOUT THIS MODEL FOR THE FUTURE OF MANY DISEASES AND PARTICULARLY, TO BE HONEST, NEUROSCIENCE.

CHAIRMAN THOMAS: THANK YOU, ALLISON. COMMENTS MORE GENERALLY ON THE TOPIC. WE'VE HAD SOME EARLIER ABOUT GENE THERAPY AND RECALL THAT PROP 14 SPECIFICALLY EXPANDS THE SCOPE OF WHAT CIRM CAN FUND AND INCLUDES GENE THERAPY AS A CATEGORY AND NOT JUST AS SOMETHING ONE MIGHT CONSIDER UNDER VITAL RESEARCH OPPORTUNITIES. SO COMMENTS ON THAT,

MEMBERS OF THE BOARD? KRISTINA.

DR. VUORI: SO I'M REALLY A VERY STRONG SUPPORTER OF THE GENE THERAPY APPROACH. I THINK IT ULTIMATELY IS AN EXCELLENT WAY TO LEVERAGE THE GENETIC BASE KNOWLEDGE OF DISEASES THAT WE HAVE, ESPECIALLY IN THE CASE OF MONOGENIC DISEASES. CLEARLY IN MORE CHRONIC DISEASES AND POLYGENIC DISEASES GENE THERAPY APPROACH MAY BE A LITTLE BIT MORE COMPLICATED, BUT I REALLY LIKE THE IDEA THAT THE ADVISORY BOARD CAME UP AS IT COMES TO REALLY MAKING A MARK AS IT COMES TO MONOGENIC DISEASES AS THOSE ARE LIKELY TO BE ADDRESSED BY ACADEMICS ONLY. SO I THINK THAT'S A GREAT OPPORTUNITY FOR CIRM.

I THINK THE OTHER AREA THAT WE SHOULD REALLY CONSIDER PURSUING IS THE CONCEPT OF IN VIVO GENE THERAPY. I THINK DOWN THE ROAD OUR OBLIGATION IS TO DEMOCRATIZE BOTH CELL AND GENE THERAPY APPROACHES. AND THE ONLY WAY REALLY TO HAVE GENE THERAPY WIDELY USED GLOBALLY IN UNDERSERVED AREAS, POPULATIONS IS TO GO THE IN VIVO ROUTE. THERE'S NO OTHER WAY OF DOING THAT. I THINK AS WE SEE IN THE COVID VACCINATION SAGA, UNDERSTANDING REALLY THE DELIVERY OF THE TREATMENTS TO PATIENTS IS EXTREMELY IMPORTANT. AND I THINK THAT IS AN AREA THAT I BELIEVE CIRM AND CALIFORNIA CAN REALLY UNIQUELY

TACKLE.

CHAIRMAN THOMAS: THANK YOU, KRISTINA. OTHER COMMENTS?

OS, I'M GOING TO PUT YOU ON THE SPOT HERE AS CHAIR OF THE SCIENCE SUBCOMMITTEE. YOU'VE HAD COMMENTS IN THE PAST ON GENE THERAPY. WHAT ARE YOUR THOUGHTS ON THIS TOPIC BEYOND WHAT YOU'VE SAID BEFORE?

DR. STEWARD: THANKS, J.T. I THINK THAT ONE OF THE CONSIDERATIONS GOING FORWARD IS REALLY THE DEFINITION OF GENE THERAPY. THAT WOULD BE THE ONLY COMMENT THAT I WOULD KIND OF HIGHLIGHT HERE. TO WHAT EXTENT WE WOULD CONSIDER EXTENDING TO GENE MODIFICATIONS THAT AREN'T CORRECTING MONOGENIC DISORDERS OR OTHER TYPES OF DISORDERS. I DON'T KNOW WHETHER PAT WANTS TO COMMENT ON THIS. PAT IS VERY MUCH AN EXPERT IN DISORDERS THAT ARE COMPLICATED, COMPLEX THINGS RELATED TO NEURODEVELOPMENT. SO THERE MIGHT BE POSSIBILITIES, ESPECIALLY IN THE NEURODEVELOPMENTAL END OF THINGS, WHERE IT ISN'T SO MUCH CORRECTING AN ERROR OF GENES, BUT IT WOULD BE INTERVENING TO ACTUALLY CORRECT THE DISORDER IN SOME OTHER WAY.

AGAIN, THERE ARE ALL KINDS OF POSSIBILITIES HERE, BUT THAT WOULD BE THE ONE THING

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THAT I WOULD MAYBE BRING UP AS A POSSIBILITY FOR CONSIDERATION IN THE GENE THERAPY DOMAIN. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, OS.

OTHER COMMENTS FROM MEMBERS OF THE BOARD?

ALLISON, A QUESTION FOR YOU. I'M SURE THERE ARE A NUMBER OF MEMBERS OF THE BOARD WHO HAVE ACTUALLY NEVER SEEN A PRIMATE FACILITY. AND I KNOW THAT I AND MARIA BONNEVILLE WENT AND SAW THE UC DAVIS FACILITY. SEEMS LIKE EIGHT OR NINE YEARS AGO NOW. WOULD IT BE POSSIBLE, IF THERE WERE MEMBERS OF THE BOARD, WHEN IT GETS AROUND TO WHERE PEOPLE CAN ACTUALLY LEAVE THEIR HOUSES AGAIN, TO ARRANGE FOR A TOUR? I THINK IT WOULD BE VERY INSTRUCTIVE FOR EVERYBODY.

DR. BRASHEAR: ABSOLUTELY. WE CAN DEFINITELY DO THAT, AND WE MIGHT EVEN THROW A FEW TALKING POINTS ABOUT AGGIE SQUARE IN THAT MIX TOO.

CHAIRMAN THOMAS: GREAT. I THINK PEOPLE WOULD FIND IT MOST INTERESTING, AS MARIA AND I DID WHEN WE WENT.

OTHER COMMENTS ON THIS TOPIC? THANK YOU. MARIA, PLEASE PROCEED.

DR. MILLAN: THANK YOU. NEXT SLIDE PLEASE.

HERE IS ANOTHER AREA THAT I THINK WILL BE A GREAT OPPORTUNITY FOR DISCUSSION. THE SSAP DISCUSSED PROMISING APPROACHES SPECIFICALLY FOR CNS, BUT ALSO FOR OTHER INDICATIONS, THAT DON'T CURRENTLY MEET CIRM'S ELIGIBILITY FOR GENE THERAPY. HERE'S THE MORE EXPANSIVE DEFINITION, OS. AND I'LL JUST READ IT OUT LOUD THAT CIRM CURRENTLY USES FOR ITS ELIGIBILITY CRITERIA. "A GENE THERAPY APPROACH THAT TARGETS A STEM CELL FOR ITS THERAPEUTIC EFFECT OR ANY SOMATIC CELL AND IS INTENDED TO REPLACE, REGENERATE, OR REPAIR THE FUNCTION OF AGED, DISEASED, DAMAGED, OR DEFECTIVE CELL TISSUES AND/OR ORGANS, AND IS BEING DEVELOPED FOR A RARE OR UNMET MEDICAL NEED UNLIKELY TO RECEIVE FUNDING FROM OTHER SOURCES.

"GENE THERAPY MEANS A HUMAN THERAPY INTERVENTION INTENDED TO, NO. 1, ALTER THE GENOMIC SEQUENCE OF CELLS OR, TWO, ALTER THE CELLULAR LINEAGE VIA GENE DELIVERY, EXAMPLE BEING DIRECT LINEAGE REPROGRAMMING. THE INTERVENTION MAY INCLUDE STRATEGIES TO REPAIR A DISEASE CAUSING GENE SEQUENCE, REMOVE OR INACTIVATE A DISEASE CAUSING GENE, INTRODUCE NEW OR MODIFIED GENES THAT AUGMENT THE THERAPEUTIC POTENTIAL OF THE TARGET CELLS."

AS NOTED EARLIER, NOT ONLY DOES PROP 14

PROVIDE FOR GENE THERAPY AS ELIGIBLE FOR FUNDING WITHIN SCOPE UNDER PROP 14, BUT ALSO GENETICS RESEARCH. AND HERE'S AT LEAST ONE DEFINITION THAT I TOOK FROM THE JOURNAL *NATURE* AS A DEFINITION FOR GENETIC RESEARCH. "GENETIC RESEARCH IS THE SCIENTIFIC DISCIPLINE CONCERNED WITH THE STUDY OF THE ROLE OF GENES AND TRAITS SUCH AS THE DEVELOPMENT OF DISEASE. IT HAS A KEY ROLE IN IDENTIFYING POTENTIAL TARGETS FOR THERAPEUTIC INTERVENTION AND ALSO IN UNDERSTANDING GENETICALLY BASED VARIATIONS IN RESPONSE TO THERAPEUTIC INTERVENTIONS."

WE ARE SEEKING GUIDANCE FROM THE ICOC. THIS HAS BEEN DISCUSSED EARLIER, BUT MAYBE MORE DISCUSSION ON THIS. SHOULD APPROACHES SUCH AS THOSE EXAMPLES THAT WERE IDENTIFIED AS PROMISING APPROACHES BY THE ADVISORY PANEL, SPECIFICALLY FOR CNS, BUT OTHER DISEASES SUCH AS EPIGENETICS, EPIGENOMIC EDITING, ANTISENSE OLIGONUCLEOTIDE, SHRNA, M-RNA, POST TRANSCRIPTIONAL OR TRANSCRIPTIONAL REGULATION-BASED TECHNOLOGY BE CONSIDERED ELIGIBLE FOR CIRM FUNDING UNDER THIS CATEGORY OF GENETIC RESEARCH WHICH IS CONSIDERED IN SCOPE AS STIPULATED IN PROPOSITION 14? J.T., I'LL TURN BACK TO YOU FOR DISCUSSION.

CHAIRMAN THOMAS: OKAY. AGAIN, THIS IS

SOMETHING THAT COULD DRAMATICALLY INCREASE SCOPE, BUT IT IS A CONCEPT CONTEMPLATED BY THE PROPOSITION SPECIFICALLY, WHICH, ALTHOUGH IT DIDN'T GET INTO NEARLY THE AMOUNT OF DETAIL OR EXAMPLES THAT MARIA JUST GAVE, IT CLEARLY IS SOMETHING CONTEMPLATED TO ENLARGE THE SCOPE BEYOND WHAT WE ARE DOING. AND A NUMBER OF THESE THINGS OBVIOUSLY BEAR, AGAIN, ON CIRM PROJECTS IN ONE WAY OR ANOTHER, THERE ARE ELEMENTS OF IT, AND CAN INFORM THOSE PROJECTS.

SO THE QUESTION FOR THE BOARD IS WHAT DO YOU THINK OF THIS NEW CATEGORY AND HOW EXPANSIVE OR NOT SHOULD IT BE? OS, YOU'VE GOT YOUR HAND UP.

DR. STEWARD: THANKS, J.T. SO I WANTED TO JUST GIVE AN EXAMPLE OF AN APPROACH THAT ACTUALLY I THINK FALLS INTO THIS CATEGORY THAT HAS BECOME QUITE FAMOUS, I GUESS. AND IT'S THE TREATMENTS FOR SPINAL MUSCULAR ATROPHY. YOU MAY KNOW THAT ABOUT THREE YEARS AGO TWO TREATMENTS WENT FORWARD THAT QUITE LITERALLY CREATED VIRTUAL CURE FOR THIS HORRIBLE DISORDER THAT AFFECTS KIDS PRIMARILY, BUT ALSO HAS AN ADULT ONSET PHENOTYPE. KIDS WITH SPINAL MUSCULAR ATROPHY ARE BORN NORMALLY, DEVELOP FOR THE FIRST YEAR, AND THEN BEGIN TO EXHIBIT MOTOR PARALYSIS AND EVENTUALLY DIE BECAUSE THEY CAN'T BREATHE.

THE TREATMENT THAT WAS DEVELOPED, ONE OF

THE TREATMENTS, IS SOMETHING CALLED SPINRAZA. AND SPINRAZA IS ACTUALLY AN ANTISENSE OLIGONUCLEOTIDE TREATMENT. SO IT WOULD OFFICIALLY FALL OUT OF THE GENE THERAPY DEFINITION BECAUSE IT ISN'T CORRECTING THE GENE THAT'S DEFICIENT IN SPINAL MUSCULAR ATROPHY. IT'S ACTUALLY SOMETHING THAT IS MODIFYING THE ACTION OF THAT GENE. SO JUST AS AN EXAMPLE, THIS WOULD BE ONE WHERE SLIGHTLY EXPANDING THE SCOPE OF THE DEFINITION OF GENE THERAPY, I THINK, WOULD BRING US INTO A DOMAIN THAT HAS ALREADY PROVEN TO BE HIGHLY SUCCESSFUL. AGAIN, I THINK WE CAN IMAGINE OTHER THINGS GOING FORWARD WHERE THIS KIND OF AN APPROACH MIGHT BE QUITE POWERFUL. THANK YOU.

CHAIRMAN THOMAS: THANKS, OS. I WOULD ADD AS ANOTHER EXAMPLE, ONE OF THE BOARD MEMBERS OR ONE OF THE PANEL MEMBERS, RATHER, WE HAD WAS DERRICK ROSSI, WHO WAS A CIRM GRANTEE IN 2006 IN IRV WEISSMAN'S LAB UP AT STANFORD WHO WAS WORKING ON MANIPULATING M-RNA AND LATER WENT ON, MOVED BACK TO HARVARD, AND THEN USING DIFFERENT ASPECTS OF HIS RESEARCH, NOT NECESSARILY WHAT WAS FUNDED AT STANFORD, TOOK THE M-RNA CONCEPT AND TECHNOLOGY AND CO-FUNDED MODERNA, WHICH I MENTIONED BEFORE. JUST FOR THOSE NEWEST MEMBERS OF THE BOARD WHO DIDN'T HEAR THAT, OBVIOUSLY WHEN YOU FUND PEOPLE, YOU NEVER

KNOW WHERE THINGS MIGHT LEAD. AND SO THERE ARE LOTS OF THINGS THAT ARE IN THIS GENETIC SPACE THAT DO BEAR DIRECTLY ON WHAT WE WOULD FUND, ET CETERA.

SO OTHER COMMENTS BY MEMBERS OF THE BOARD? ALLISON'S SHAKING HER HEAD.

DR. BRASHEAR: THERE WAS A GREAT TALK ON THE SCHOOL OF MEDICINE FACEBOOK PAGE WITH KATIE KERICO (PHONETIC) TALKING ABOUT ALL THE M-RNA TECHNOLOGY. WE TALKED -- WE ASKED HER SPECIFICALLY ABOUT THIS GENE THERAPY AND THE APPLICABILITY, AND SHE SAID THAT IT'S BEING EXPLORED.

CHAIRMAN THOMAS: ARE THERE ANY MEMBERS OF THE BOARD WHO -- BEFORE I ASK THAT, PAT.

DR. LEVITT: SO THERE ARE TWO DESCRIPTORS ON HERE. ONE IS GENETIC RESEARCH. AND THE TEXT IN ORANGE OR RED, I CAN'T TELL ON MY SCREEN, THAT'S ALL PART OF GENETIC RESEARCH. BUT THEN THERE'S THE VERY SPECIFIC FOCUS ON GENE THERAPY. RIGHT? AND THAT IS ENCOMPASSED WITHIN GENETIC RESEARCH. AND SO IT'S VERY CLEAR JUST VERY RAPIDLY OVER THE LAST FIVE YEARS THAT GENE THERAPY HAS NOW ENCOMPASSED THE ABILITY TO MANIPULATE THE FUNCTION OF GENES THROUGH THERAPEUTIC APPROACHES THAT COULD EXPAND INTO SMALL MOLECULES IF ONE WANTED TO DO THAT, BUT CERTAINLY THE COMPONENTS THAT ARE LISTED HERE ARE ALREADY

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BEING USED THERAPEUTICALLY IN VARIOUS WAYS. IT WOULD SEEM THAT CIRM WOULD SHOOT ITSELF IN THE FOOT IF IT DIDN'T INCLUDE THOSE AND HOLD TO THE OLDER DEFINITION OR THE MORE STRINGENT DEFINITION. BUT IN TERMS OF GENETIC RESEARCH SUPPORT, THOSE ALL FALL UNDER THAT CATEGORY.

CHAIRMAN THOMAS: I COMPLETELY AGREE WITH THAT. OTHER COMMENTS BY MEMBERS OF THE BOARD?

MARIA, I THINK YOU CAN TAKE FROM THAT ENTHUSIASTIC COMMENTARY ON THIS PARTICULAR TOPIC AND INCLUSION OF THESE SORTS OF THINGS GOING FORWARD IS PROJECTS THAT WE COULD FUND. SO THANK YOU. NEXT SLIDE PLEASE.

DR. MILLAN: THANK YOU SO MUCH. THAT'S VERY USEFUL. NEXT SLIDE. AND HERE'S WHERE I TURN IT OVER TO DR. GIL SAMBRANO TO TALK ABOUT SOME OTHER SPECIFIC INPUT WE WOULD HOPE TO GET FROM THE BOARD TODAY. THANK YOU SO MUCH FOR TODAY'S DISCUSSION.

DR. SAMBRANO: THANK YOU, MARIA. I THINK THIS WAS ALREADY DISCUSSED, AND THE POINT OF THIS WAS JUST TO HIGHLIGHT THE MECHANISM THAT IS AVAILABLE THROUGH PROP 14 AND WAS AVAILABLE THROUGH PROP 71 OF THE VITAL RESEARCH OPPORTUNITY. AND REALLY JUST TO SAY THAT IT EMPOWERS US WITH SOME LEVEL OF FLEXIBILITY IN THE PROCESS THAT WE WOULD

CREATE AROUND IT. AND ONE OF THE NEW ELEMENTS RELATED TO THIS IS THAT THE BOARD ITSELF CAN MAKE A RECOMMENDATION FOR A VITAL RESEARCH OPPORTUNITY THAT WE WOULD INCLUDE WITHIN OUR PROGRAMS WITHOUT NECESSARILY HAVING GRANTS WORKING GROUP SUPPORT. SO IT MAY STREAMLINE HOW WE GO ABOUT IT, BUT IN GENERAL I THINK WE'VE DISCUSSED THIS ALREADY.

NEXT SLIDE. SO AS EXAMPLES OF VITAL RESEARCH OPPORTUNITIES, ONE OF THEM THAT WAS ALREADY DISCUSSED, AND THERE'S A SLIDE AFTER THIS RELATED TO THE CURRENT SMALL MOLECULE ALLOWANCES IN OUR ELIGIBILITY, IS THAT YOU COULD ENVISION THE USE OF SMALL MOLECULES THAT EXPAND BEYOND HAVING THEM ACTUALLY ACT ON STEM CELLS DIRECTLY. AND IN THE ADVISORY PANEL MEETING, THERE WERE DIFFERENT TAKES ON IT. CERTAINLY VARIED OPINION IN TERMS OF SOME ADVOCATING FOR BROADENING THE APPROACH TO INCLUDE SMALL MOLECULES THAT WOULD HAVE SOME REGENERATIVE CAPACITY REGARDLESS OF WHETHER THEY ACT ON STEM CELLS, OTHERS SUGGESTING THAT WE DO STAY FOCUSED ON STEM CELL-BASED APPROACHES AS PART OF CIRM'S IDENTITY.

ONE OTHER AREA COULD BE THE APPROACH TO DISEASE PREVENTION. JUST MORE GENERALLY, WHEN WE THINK ABOUT THE TYPES OF PROJECTS WE FUND, THAT IN

PARTICULAR MAY NOT NECESSARILY BE A VITAL RESEARCH OPPORTUNITY, BUT SOMETHING THAT COULD ALSO BE CONSIDERED.

NEXT SLIDE.

CHAIRMAN THOMAS: GIL, CAN I JUST HOLD ON THAT SLIDE? LET'S GO TO THIS BECAUSE IT'S A SMALL MOLECULE COMMENT ONCE YOU GO TO THIS PAGE.

DR. SAMBRANO: SURE. SO THIS ONE EXPANDS ON THE QUESTION OF THE SMALL MOLECULES THAT COULD BE UTILIZED JUST BROADLY IN REGENERATIVE MEDICINE. SO THERE ARE CURRENT ELIGIBILITIES SOMEWHERE IN THE MIDDLE OF THE SLIDE, CURRENT ELIGIBILITY FOR SMALL MOLECULE. SO WHAT WE REQUIRE RIGHT NOW IS THAT THE PUTATIVE DRUG SMALL MOLECULE ACTS ON OR IS DEPENDENT ON AN ENDOGENOUS STEM CELL FOR ITS THERAPEUTIC EFFECT, THAT IT IS DEPENDENT ON TARGETING CANCER STEM CELLS, OR THAT IT MODIFY THE STEM CELL PRODUCT, OR WHERE A STEM CELL IS NECESSARY TO MANUFACTURE IT. AND THAT WOULD BE IN THE CASE OF A BIOLOGIC AND, OF COURSE, WHETHER IT'S BEING DEVELOPED FOR A RARE UNMET NEED UNLIKELY TO RECEIVE FUNDING FROM OTHER SOURCES.

IN GENERAL, THE WAY WE'VE APPROACHED SMALL MOLECULES IS THAT, BASED ON THAT DEFINITION, THERE HAS TO BE A STEM CELL CONNECTION IN SOME WAY,

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WHETHER IT'S CANCER STEM CELLS OR ENDOGENOUS STEM CELLS OR WHATEVER IT MAY BE. AND HISTORICALLY WE HAVE ALSO HAD LIMITATIONS ON THE FUNDING BASED ON THE DEVELOPMENT PHASE. SO, FOR EXAMPLE, CURRENTLY WE DO NOT ALLOW SMALL MOLECULES BEYOND THE PHASE 1 CLINICAL TRIAL, AND THAT HAS BEEN FOR SEVERAL REASONS. WHEN WE WERE SORT OF AT THE END OR AT THE TAIL END OF OUR FUNDING AND THINKING ABOUT WHERE WE WANTED TO MAKE THE MOST IMPACT, I THINK THE IDEA WAS THAT CELL THERAPY WAS THE MOST LIKELY PLACE AND KIND OF THE CORE ELEMENT OF OUR MANDATE. BUT ALSO BECAUSE I THINK THE REGULATORY PATH AND THE FUNDING THAT'S AVAILABLE FOR THE DEVELOPMENT OF SMALL MOLECULES IS ALREADY MORE ESTABLISHED, FUNDING IS MORE READILY AVAILABLE. SO IN TERMS OF THINKING OF WHERE CIRM CAN MAKE A DIFFERENCE, WE THOUGHT THAT MAYBE LIMITING ELIGIBILITY OR CUTTING THEM OFF AT THAT POINT WAS SOMETHING THAT WE WOULD DO. BUT, AGAIN, THAT'S SOMETHING THAT HAS EVOLVED OVER TIME, AND THERE HAVE BEEN DIFFERENT CONSIDERATIONS THAT HAVE GONE INTO IT.

SO AS WE REFLECT ON WHERE WE ARE TODAY AND WHAT MIGHT MAKE THE MOST SENSE FOR TODAY, HERE I THINK WE'RE LOOKING FOR JUST SOME GUIDANCE ON WHERE YOU MAY FEEL THE ELIGIBILITY OF SMALL MOLECULE

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PROJECTS MAY FALL. SO I'LL STOP THERE IN TERMS OF DISCUSSION AND YOUR QUESTIONS.

CHAIRMAN THOMAS: THANKS, GIL. YOU ANSWERED WHAT I WAS GOING TO ASK.

ARE THERE COMMENTS ON THIS PARTICULAR TOPIC? TAKE NOTE OF GIL'S COMMENTS, THAT SINCE SMALL MOLECULE DEVELOPMENT HAS BEEN AROUND MANY, MANY YEARS, THERE ARE A LOT OF DIFFERENT SOURCES OF FUNDING THAT ARE TRIED AND TRUE FOR THIS PARTICULAR CATEGORY OF WORK.

HAVING SAID THAT, THERE'S VERY INTERESTING PRODUCTS BEING DEVELOPED OUT THERE THAT ARE TRIGGERED BY SMALL MOLECULES. WE HAVE, JUST AS AN EXAMPLE, ONE OF OUR INDUSTRY ADVISORY PARTNER MEMBERS IS FREQUENCY THERAPEUTICS, WHICH IS A BOSTON SUBURBAN COMPANY THAT'S USING SMALL MOLECULES TO TRIGGER PROGENITOR CELLS TO MATURE INTO FULL ACTIVE CELLS TO TREAT DEGENERATIVE DISEASE. AND THEY'RE LOOKING AT USING THAT FOR HEARING DEGENERATIVE PROBLEMS. SO THERE ARE THINGS LIKE THAT THAT THERE'S REAL USES FOR SMALL MOLECULE. WE'VE USED IT IN THE PAST IN FUNDING A NUMBER OF CANCER-BASED PROJECTS, ET CETERA.

BUT IN TERMS OF USING IT FOR DISC AND/OR LATE STAGE AND REGISTRATION, WHAT IS EVERYBODY'S

THOUGHTS? MARK.

DR. FISCHER-COLBRIE: IF IT'S FOR LATE STAGE LIKE PHASE 3 IN PARTICULAR, I WOULD LIKE TO THINK THERE ARE OTHER GROUPS AND PARTIES THAT CAN CERTAINLY BE ENTICED TO TAKE THAT ON. TYPICALLY THOSE HAVE HUGE COSTS ASSOCIATED WITH THOSE. AND IN THAT CONTEXT AND ALSO TO SOME EXTENT FOR PHASE 2 TRIALS, ALTHOUGH LESSER SO, I WOULD CERTAINLY ENCOURAGE TRYING TO GET EXTERNAL PARTIES TO TAKE ON THAT WORK RATHER THAN THAT BE THE FUNDING FOCUS FOR CIRM.

CHAIRMAN THOMAS: HOW ABOUT THE DISCOVERY WORK?

DR. FISCHER-COLBRIE: YEAH. I THINK THE DISCOVERY WORK IS IN EFFECT TIED TO ADVANCEMENTS IN OTHER AREAS. AND THESE ALL INTERRELATE, AND WHAT WE ARE GOING TO CONTINUE TO SEE GOING IN THE FUTURE IS SORT OF THE PHENOMENON OF WHAT SMALL MOLECULE, LARGE MOLECULE, WHAT IS CRISPR, WHAT IS THESE VARIOUS TOOLS AND MODALITIES, THEY'RE ALL GOING TO INTERACT WITH EACH OTHER IN ONE WAY, SHAPE, OR FORM. SO I THINK WE NEED A CERTAIN AMOUNT OF FLEXIBILITY TO BE ABLE TO ACCOMMODATE THOSE INTERRELATIONSHIPS THAT ARE INCREASINGLY OCCURRING AS WE GO FORWARD.

CHAIRMAN THOMAS: SO THAT SOUNDS LIKE

SUPPORT, MORE SUPPORT FOR USING SMALL MOLECULE IN THE DISC STAGE, MUCH LESS SO IN THE LATER STAGES. OTHER COMMENTS FROM MEMBERS OF THE BOARD?

DR. MARTIN: I WOULD ALSO, I GUESS, FEEL THAT THE LIMITATION OF CURRENT USE ANYWAY OF SMALL MOLECULES SHOULD BE IN THE INVOLVED STEM CELLS OR GENE THERAPY RATHER THAN, FOR INSTANCE, A SMALL MOLECULE TO TREAT A CANCER STEM CELL. I'D BE A LITTLE RELUCTANT TO PULL A THERAPEUTIC LIKE THAT IN ALTHOUGH IT'S A SHADY AREA. IT'S NOT BLACK OR WHITE. I THINK PUTTING THE GUIDELINES FOR ELIGIBILITY FOR CIRM FUNDING AT INVOLVEMENT OF STEM CELLS OR GENE THERAPY IS A PRETTY SAFE PLACE TO START NOW AND NOT GO FAR BEYOND THAT NOW. AND THEN PEOPLE CAN USE THEIR IMAGINATION AS TO WHAT THAT MEANS.

CHAIRMAN THOMAS: OKAY. HAIFAA.

DR. ABDULHAQ: I JUST WANTED TO SAY THAT I AGREE WITH THE PREVIOUS COMMENTS. I WOULD BE IN SUPPORT OF UTILIZING -- SUPPORTING RESEARCH OF SMALL MOLECULES IN EARLY PHASE TRIALS RATHER THAN THE PHASE 2 OR 3 BECAUSE THOSE HAVE MANY OTHER SOURCES OF FUNDING.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS BY MEMBERS OF THE BOARD? OKAY. THANK YOU.

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MARIA.

DR. MILLAN: I THINK IT'S STILL GIL. BUT JUST A CLARIFICATION QUESTION. SO IN TERMS OF THOSE TYPES OF STUDIES THAT MAY INVOLVE SMALL MOLECULE ALONG WITH GENE THERAPY AND CELL THERAPY, DOES THE BOARD FEEL THAT THE IDEA OF STILL LIMITING THAT TO EARLY STAGE RESEARCH AND PHASE 1 TRIALS WOULD STILL BE APPROPRIATE FOR THOSE THAT INVOLVE -- THAT ARE PARTNER APPROACHES WITH GENE THERAPY AND CELL THERAPY? I GUESS CELL THERAPY AND GENE THERAPY WOULD MAKE THEM ELIGIBLE ANYWAY.

DR. MELMED: MARIA, CAN YOU REPEAT THE QUESTION IN A MORE RESOLUTION FOCUSED FASHION?

DR. MILLAN: YES. I ANSWERED MY OWN QUESTION BECAUSE IF IT INVOLVES GENE THERAPY AND CELL THERAPY IN LATE STAGE, THEY WOULD BE ELIGIBLE UNDER GENE THERAPY AND CELL THERAPY. I THINK I DON'T HAVE A QUESTION. THANK YOU.

CHAIRMAN THOMAS: ANY OTHER COMMENTS?

DR. MILLAN: BUT I DO WANT TO MENTION SOMETHING ON THE PREVIOUS SLIDE WHICH IS, I THINK, IMPORTANT. IF WE CAN JUST BACK UP FOR US TO GET SOME GUIDANCE ON FROM THE BOARD, WHICH IS THIS IDEA OF EARLIER STAGE PROGRAMS THAT ARE RELATED TO DISEASE PREVENTION AND LONG-TERM STUDIES THAT MAY

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ALSO BE RELATED TO LONG-TERM FOLLOW-UP STUDIES AND GENOMIC STUDIES WITH THESE TOP INDICATIONS. SOME OF THE ADVISORS, ESPECIALLY RELATED TO CNS DISEASE, FELT THAT SOME OF THE REASON THAT WE ARE FAILING AS A SCIENTIFIC COMMUNITY IS THAT THE INTERVENTION IS JUST TOO LATE AND THE CAT'S OUT OF THE BAG AND THAT WE'RE NOT REALLY IMPACTING ESPECIALLY THE STEM CELL OR REGENERATIVE ASPECTS OF WHAT COULD BE PUT INTO PLAY BECAUSE WE'RE NOT INTERVENING EARLY ENOUGH.

OF COURSE, IT WOULD ALSO, IN ORDER FOR THIS TO GO FORWARD, IT WOULD HAVE TO THEN GET FDA BUY-IN IN TERMS OF BEING ABLE TO COME IN AT AN EARLIER STATE. BUT IN PRINCIPLE, IF THERE IS ANY INPUT FROM THE BOARD AND FEELING REGARDING THIS IDEA OF FUNDING PREVENTION TRIALS OR EARLIER STAGE TRIALS THAT REQUIRE VERY LONG FOLLOW-UP.

CHAIRMAN THOMAS: THANK YOU FOR BRINGING THAT UP, MARIA. IT IS A VERY IMPORTANT QUESTION. ANNE-MARIE.

DR. DULIEGE: SO I COMPLETELY AGREE. I THINK WE KNOW IN MANY OF THE EXAMPLES THAT WERE QUOTED THIS MORNING THAT WHENEVER APPROPRIATE PREVENTION OF DISEASE IS AS IMPORTANT, IF NOT MORE SO, THAN TREATMENT OF THAT DISEASE. AND THAT, AGAIN, THIS LONG-TERM FOLLOW-UP IS SO EXPENSIVE,

THAT THIS TYPE OF RESEARCH ISN'T LIKELY TO FIND OTHER SOURCES OF FUNDING. SO I SUPPORT IT. I ALSO SUPPORT A BREAK IN A FEW MINUTES SHORTLY. THAT'S A SEPARATE TOPIC. THANK YOU.

CHAIRMAN THOMAS: MARK.

DR. FISCHER-COLBRIE: I'D LIKE TO PARSE THE TERM "PREVENTION" BECAUSE I THINK IT'S EXTREMELY IMPORTANT IN THE CONTEXT THAT, IF THERE ARE BIOMARKERS INITIATION OF DISEASE, THERE'S A MUCH BETTER OPPORTUNITY FOR UNDERSTANDING THE INTERVENTION AND THE SUCCESS OF A TRIAL AND OTHER ELEMENTS. AND CLEARLY IN MANY DISEASE PROCESSES TODAY THERAPIES ARE BEING APPLIED. AND CLINICAL TRIALS ARE, BOY, THE HORSE IS ALREADY OUT OF THE BARN. SO I THINK THERE'S DIRECT RELEVANCE THERE. BUT RELATED TO PREVENTION, IF THERE'S A WAY TO THINK ABOUT THAT DISEASE ONSET CONCEPT WITH A BIOMARKER, I THINK THAT'S EXTREMELY RELEVANT. SO I THINK THAT'S A DIFFERENT DEFINITION OF PREVENTION.

CHAIRMAN THOMAS: THANK YOU. PAT.

DR. LEVITT: I'M NOT QUITE CLEAR ABOUT WHERE THE BOUNDARIES ARE, TO BE HONEST, BECAUSE THE SECOND BULLET IS REALLY DESCRIBING SMALL MOLECULE USE FOR ALTERING PATHOPHYSIOLOGY. PREVENTING NEURAL LOSS, THAT'S A PATHOPHYSIOLOGICAL PROCESS WHICH MAY

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OR MAY NOT BE CAUSED BY A SPECIFIC GENE MUTATION. SO THERE'S STUDIES NOW IN AUTISM THAT ARE USING SMALL MOLECULE ANTAGONISTS TO DIFFERENT KINDS OF RECEPTORS THAT I'M CERTAIN CHANGE CELLULAR PROCESSES AND WOULD PROBABLY FIT INTO BULLET TWO OR MAYBE PART OF BULLET ONE. I DON'T KNOW. BUT I'M JUST CONFUSED ABOUT WHERE THE BOUNDARIES ARE BECAUSE IF IT'S THIS BROAD SMALL MOLECULE INCLUSION, IT'S GOING TO OPEN UP A LOT MORE OPPORTUNITIES FOR APPLICATIONS IN THIS AREA THAT MAY OR MAY NOT HAVE ANYTHING TO DO WITH REGENERATIVE MEDICINE PER SE.

DR. MILLAN: JUST TO CLARIFY, THESE ARE TWO SEPARATE BULLET POINTS. THEY'RE NOT RELATED TO EACH OTHER. THEY'RE TWO EXAMPLES OF POTENTIAL VITAL RESEARCH OPPORTUNITIES.

DR. LEVITT: SO USING SMALL MOLECULES FOR DISEASE PREVENTION, DOES THAT COUNT?

DR. MILLAN: SO THE WHOLE IDEA OF DISEASE PREVENTION COULD BE WITH ANY INTERVENTION, NOT NECESSARILY JUST SMALL MOLECULES BECAUSE EVEN WITH OTHER INTERVENTION, SMALL MOLECULES ASIDE, WE HAVEN'T FUNDED EARLY ONSET.

DR. LEVITT: I UNDERSTAND THAT. SO THE EXAMPLE IN BULLET ONE OF SMALL MOLECULE, THEY GIVE SOME EXAMPLES, RIGHT, REPAIR, REPLACE DAMAGED

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TISSUE. IS THAT GOING TO BE -- IS THAT THE BOUNDARY, SMALL MOLECULES TO REPLACE DAMAGED CELLS OR TISSUES?

DR. MILLAN: NO. THOSE ARE JUST EXAMPLES. I THINK THESE TWO SLIDES, THESE TWO THINGS ACTUALLY ARE TWO SEPARATE TOPICS. BUT REGARDING SMALL MOLECULE, THAT'S JUST AN EXAMPLE OF HOW SMALL MOLECULES COULD IMPACT REGENERATION.

DR. LEVITT: OKAY. I'M JUST RAISING IT. IF THE DEFINITIONS ARE REALLY CLEAR, BECAUSE I THINK RESEARCHERS WILL READ THE ACCEPTABLE DOMAINS OF RESEARCH SUPPORT BY CIRM, AND THEY'LL -- THERE ARE MANY WAYS TO INTERPRET.

DR. MILLAN: OKAY. I THINK I UNDERSTAND. SO CURRENTLY SMALL MOLECULES WOULD NOT BE ELIGIBLE IF THEY HAD NO CONNECTION AT ALL TO STEM CELLS. AFTER THE LAST DISCUSSION, THERE DID NOT SEEM TO BE ANY SUPPORT FOR EXPANDING IT BEYOND THAT. SO WE'VE ADDRESSED QUESTION ONE.

I JUST RETURNED TO THIS SLIDE BECAUSE WE REALLY DID NOT ADDRESS QUESTION TWO IN TERMS OF EARLIER INTERVENTION.

DR. LEVITT: OKAY. THANKS.

DR. MILLAN: I APOLOGIES FOR THAT CONFUSION.

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CHAIRMAN THOMAS: ALLISON.

DR. BRASHEAR: I APOLOGIZE IF THERE'S SOMEONE ON THE BOARD HERE THAT NEEDS THIS, BUT WE TALKED ABOUT BIOMARKERS, PATIENT-RELATED OUTCOMES. AND AT SOME TIME WE MIGHT WANT SOMEONE WITH FDA EXPERIENCE PARTICULARLY WITH THE SMA DRUG AND HOW THAT GOT THROUGH AND THESE OTHER PIECES BECAUSE THAT'S A PART OF THE GETTING IT OUT TO THE -- NOT ONLY FUNDING THE RESEARCH, BUT GETTING IT OUT TO THE PATIENTS WHICH IS OUR EARLIER DISCUSSION FROM THIS MORNING. SO UNDERSTANDING EXACTLY WHAT THEY'RE GOING TO WANT WHEN SOMETHING GETS IN FRONT OF THEM. AND THE STUDY THAT BROUGHT THE SMA DRUG TO LIGHT WAS VERY DELIBERATE IN GETTING THE NATURAL HISTORY AND THEN DOING THE STUDY AND THE INTERVENTION.

CHAIRMAN THOMAS: THANK YOU. WE DO NOT HAVE ANYBODY, ANY PAST FDA TYPES ON THE BOARD. WE DO, HOWEVER, HAVE THAT QUITE WELL COVERED IN THE GWG AS PART OF THE ANALYSIS AND HAVE ALWAYS SINCE THAT GROUP STARTED. SO I THINK WE ARE IN GOOD SHAPE THERE.

OTHER COMMENTS FROM MEMBERS OF THE BOARD?

DR. MILLAN: I JUST WANTED TO MENTION, J.T., THAT PETER MARKS, WHO WAS ON OUR SCIENTIFIC STRATEGY ADVISORY PANEL, AND THERE ARE DEFINITELY

WAYS THAT WE CAN FOLLOW UP, DR. BRASHEAR, AS WE LOOK THROUGH KIND OF THE CONSORTIUM APPROACHES AND WHAT TYPES OF COMMON DATA ELEMENTS AND DATASETS THEY WOULD FEEL WOULD BE RELEVANT AND IMPORTANT TO INCORPORATE. DR. MARKS IS A HUGE FAN OF THE IDEA OF, AS YOU KNOW, CONSORTIUM AND PLATFORM APPROACHES BECAUSE IT HELPS THEM TO DETERMINE THE SIGNAL VERSUS NOISE WHEN THEY EVALUATE DATA PACKAGES THAT ARE BROUGHT TO THEM.

CHAIRMAN THOMAS: YES. THANK YOU, MARIA.

DR. MARTIN: I'D JUST COMMENT ON THE DISEASE PREVENTION DISCUSSION. DISEASE PREVENTION IS TERRIFIC SO LONG AS, AS SOMEONE HAS SAID, YOU CAN RECOGNIZE WHETHER IT'S SUCCESSFUL OR NOT WITHIN A LIFETIME AND, IN FACT, WITHIN CIRM'S LIFETIME. AND SO ONE WAY TO DO THAT IS SIMPLY PUT IN SOME QUALIFICATION FOR WHAT'S INCLUDED WOULD BE PREVENTION OF DISEASES OR INTERVENTION FOR PREVENTION OF DISEASES FOR WHICH AN ENDPOINT OR IN PROCESS ENDPOINT, IF YOU WILL, WOULD BE FEASIBLE WITHIN SOME FIVE-YEAR PERIOD OR TEN-YEAR PERIOD, WHATEVER IS APPROPRIATE, AND EMPHASIZE THE USE OF INDICATIVE BIOMARKERS OR PREDICTIVE BIOMARKERS BECAUSE THAT SHOULD BE PART OF THEIR PROPOSAL IF SUCH DOES NOT EXIST AT THE TIME OF THE PROPOSAL.

CHAIRMAN THOMAS: THANK YOU, DAVE. OTHER COMMENTS? KRISTINA.

DR. VUORI: ALSO COMMENTING ON THE DISEASE PREVENTION. I THINK WHAT WAS JUST SAID IS A VERY GOOD POINT WITHIN AT LEAST IN CIRM'S LIFE SPAN. ALSO, I THINK THAT CONSISTENT WITH THE MISSION OF CIRM, WE SHOULD FOCUS ON DISEASES, I THINK, THAT EVENTUALLY TAKE PLACE DUE TO LOSS OF STEM CELLS, FOR EXAMPLE, DUE TO REGENERATIVE CAPABILITY OF CELLS AND TISSUES, ET CETERA, SO THAT IT'S NOT REALLY ALL OVER THE PLACE. THIS WOULD BE A VERY, AGAIN, BOIL THE OCEAN, VERY, VERY BROAD TOPIC.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS? WE'LL GO BACK TO GIL AND CONTINUE WITH YOUR PRESENTATION.

DR. SAMBRANO: IF YOU COULD GO AHEAD A COUPLE OF SLIDES. THANK YOU.

ALL OF THESE QUESTIONS FOR WHICH WE REALLY APPRECIATE YOUR FEEDBACK IS HELPING US UNDERSTAND AND GET A HANDLE ON HOW TO PRIORITIZE BOTH OUR ELIGIBILITY AND HOW WE APPROACH THESE TYPES OF PROJECTS.

AND SO ANOTHER AREA THAT HAS HAD AN EVOLUTION THROUGH CIRM IS HOW WE APPROACH MINIMALLY MANIPULATED CELLS. AND SO THE CURRENT ELIGIBILITY

FOR WHERE THESE ARE ALLOWED IS THAT THEY ARE ELIGIBLE ONLY IF THEY'RE BEING DEVELOPED AS A NOVEL METHOD OF ADDRESSING A RARE OR UNMET NEED UNLIKELY TO RECEIVE FUNDING FROM OTHER SOURCES. AND THE RATIONALE FOR LIMITING THESE IS THE WEALTH OF PROJECTS THAT ARE ALREADY IN CLINICAL TRIALS THAT USE MINIMALLY MANIPULATED CELLS AND WHICH, IN GENERAL, DON'T OFFER A NOVEL APPROACH AND, THEREFORE, ALSO MORE LIKELY TO HAVE FINANCIAL SUPPORT.

SO THESE ARE FOR THAT REASON NOT ACTUALLY ELIGIBLE AT ALL FOR OUR TRANSLATIONAL OPPORTUNITIES. AND THEN THERE'S THIS CAVEAT IN TERMS OF THE ELIGIBILITY THAT I JUST READ FOR OUR CLINICAL STAGE PROJECTS. AND SO THE QUESTION HERE IS IS THIS SOMETHING THAT CIRM SHOULD CONTINUE TO HIGHLIGHT AS SOMETHING THAT IS GOING TO REQUIRE A HIGHER THRESHOLD TO QUALIFY, OR SHOULD WE SIMPLY ALLOW IT LIKE WE DO ALL OTHER STEM CELL PROJECTS? AND I'LL STOP THERE.

CHAIRMAN THOMAS: THANK YOU, GIL. THOUGHTS ON THIS PARTICULAR TOPIC?

DR. MARTIN: THAT SOUNDS APPROPRIATE TO ME. THAT MAKES A LOT OF SENSE TO ME.

CHAIRMAN THOMAS: THANK YOU, DAVE.

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OTHER COMMENTS? GIL, THAT ONE DOESN'T SEEM TO BE TOO CONTROVERSIAL.

DR. SAMBRANO: OKAY. SO WE CAN GO ON MAYBE TO THE NEXT SLIDE. THERE'S, I THINK, JUST TWO MORE AND THEN THAT'S IT.

SO THIS IS THE AREA THAT HAS BEEN HIGHLIGHTED ALREADY IN PART WITH RESEARCH THAT'S UNLIKELY TO BE FUNDED BY OTHERS. AND SO, AS YOU KNOW, CIRM'S MANDATE IN PART IS A CALL FOR FUNDING RESEARCH THAT OTHERS CAN'T FUND OR WHERE CIRM CAN MAKE A DIFFERENCE. AND SO WE CERTAINLY HAVE DONE THAT WITH EXISTING AND FEDERAL RESTRICTIONS ON HUMAN EMBRYONIC STEM CELL RESEARCH. BUT AS WE ALL KNOW, THOSE ARE SUBJECT TO CHANGE WITH POLITICAL WINDS. AND SO ONE OF THE THINGS THAT THE SSAP MENTIONED WAS CIRM'S ABILITY TO PROVIDE STABILITY TO THE FIELD AS A RESULT OF BEING ABLE TO FUND A LOT OF THESE AREAS.

SO MANY OF THEM, INCLUDING THINGS SUCH AS HUMAN FETAL TISSUE RESEARCH, RESEARCH ON HUMAN EMBRYOS WHERE THOSE ARE CRITICAL FOR UNDERSTANDING HUMAN REPRODUCTION, PREGNANCY LOSS, BIRTH DEFECTS, AND OTHER THINGS, RESEARCH WITH THE USE OF HUMAN GAMETES, AND HUMAN MITOCHONDRIAL REPLACEMENT AS POTENTIAL CURATIVE APPROACHES FOR SOME DISEASE AREAS. SO WE CERTAINLY REMAIN WELL POSITIONED TO

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PROVIDE THOSE PLATFORMS FOR POLICY DISCUSSION RELATED TO STEM CELL RESEARCH AND THESE OTHER AREAS. SO THIS IS SOMETHING THAT WAS THOUGHT TO BE IMPORTANT.

IF YOU COULD GO ON TO THE NEXT SLIDE PLEASE.

CHAIRMAN THOMAS: GIL, CAN I COMMENT ON THAT?

DR. SAMBRANO: SURE.

CHAIRMAN THOMAS: THIS IS VERY MUCH IN KEEPING WITH THE SPIRIT OF CIRM GOING BACK TO THE VERY BEGINNING, WHICH IS TO FUND AREAS OF GREAT IMPORTANCE THAT ARE UNLIKELY TO BE FUNDED FOR A VARIETY OF REASONS. AND WE'VE BEEN FORTUNATE IN CALIFORNIA TO BE ABLE TO DO JUST THAT FROM INCEPTION.

SO MY THOUGHT ON THIS WOULD BE THAT THESE ARE ALL AREAS THAT SHOULD BE FAIR GAME BECAUSE WORK BEING DONE ON THESE THINGS CAN ABSOLUTELY BE TRANSFORMATIVE AND ADVANCE THE FIELD. WHY DON'T YOU GO ON TO THIS LAST NEXT SLIDE, THEN WE'LL TAKE COMMENTS ON THE OTHER SIDE.

DR. SAMBRANO: SURE. AND SO THE CURRENT REQUIREMENT THAT WE PUT INTO, AS YOU'VE SEEN ALREADY, OUR RFA'S AND PROGRAM ANNOUNCEMENTS IS THAT

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OF HAVING A RARE OR UNMET NEED THAT'S UNLIKELY TO RECEIVE FUNDING FROM OTHER SOURCES. AND SO THIS EMANATES FROM BOTH PROP 71 AND PROP 14, THAT STATES THE FOLLOWING, THAT IN ORDER TO ENSURE THAT THE INSTITUTE FUNDING DOES NOT DUPLICATE OR SUPPLANT EXISTING FUNDING, A HIGH PRIORITY SHALL BE PLACED ON FUNDING PLURIPOTENT STEM CELL AND PROGENITOR CELL RESEARCH THAT CANNOT OR IS UNLIKELY TO RECEIVE TIMELY OR SUFFICIENT FEDERAL FUNDING UNENCUMBERED BY LIMITATIONS THAT WOULD IMPEDE THE RESEARCH.

SO IN THIS REGARD, OTHER RESEARCH CATEGORIES FUNDED BY THE NATIONAL INSTITUTES OF HEALTH SHALL NOT BE FUNDED BY THE INSTITUTE UNLESS SUCH RESEARCH FUNDING IS NOT TIMELY OR SUFFICIENT. AND SO IN ATTEMPTING TO ADDRESS THAT CALL, WHERE IT IS PRETTY STRAIGHTFORWARD AND EASY FOR MUCH OF THE HUMAN EMBRYONIC STEM CELL RESEARCH OR FETAL TISSUE WORK, IT HAS PROVEN TO BE DIFFICULT TO FIND OBJECTIVE CRITERIA IN ORDER FOR US TO OBJECTIVELY SAY HERE IS A PROJECT THAT WOULDN'T GET TIMELY OR SUFFICIENT FEDERAL FUNDING NECESSARILY OTHER THAN TO JUST INCLUDE IT AS AN ELIGIBLE TYPE OF PROJECT VERY BROADLY. BUT WHEN IT COMES TO USING IT AS A SPECIFIC ELIGIBILITY CRITERION OR EVEN A REVIEW CRITERION, IT BECOMES DIFFICULT.

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IT IS ALSO SOMETHING THAT CAN COME TO THE ICOC OR THE APPLICATION REVIEW SUBCOMMITTEE DURING THEIR PROGRAMMATIC REVIEW AND DISCUSSION. AND I THINK THE QUESTION HERE IS HOW WOULD YOU SEE US APPROACHING THIS REQUIREMENT IN OUR PROGRAMS GOING FORWARD? I'LL LEAVE IT THERE.

CHAIRMAN THOMAS: COMMENTS FROM MEMBERS OF THE BOARD? THANK YOU, GIL. OS, WHAT DO YOU THINK ON THIS ONE?

DR. STEWARD: THANK YOU. I'VE COMMENTED ON SOME OF THE OTHER ONES. I DON'T REALLY HAVE ANYTHING PARTICULARLY DRAMATICALLY THOUGHTFUL TO ADD HERE, I GUESS. SO I'M JUST GOING TO PASS AND SEE IF OTHERS HAVE COMMENTS. THANK YOU.

CHAIRMAN THOMAS: FAIR ENOUGH. LARRY.

DR. GOLDSTEIN: I GUESS I'D JUST POINT OUT THAT, FROM SEEING REVIEW PROCESSES IN OTHER CONTEXTS, IT'S NOT UNCOMMON, IN FACT, IT IS VERY COMMON, TO DIRECT REVIEWERS TO EVALUATE POTENTIAL IMPACT. AND IMPACT IS PARTLY THE QUALITY OF THE SCIENTIFIC OR CLINICAL DISCOVERIES BEING PROPOSED, BUT IT IS ALSO PARTLY IDENTIFYING WHAT ARE OTHER GROUPS DOING TO IDENTIFY IT, AND WHY IS THE PROPOSED APPROACH HERE BETTER, OR WHY IS IT GOING TO MAKE AN IMPACT THAT THE OTHERS WON'T. I THINK REVIEWERS ARE

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ACCUSTOMED TO MAKING THOSE JUDGMENTS.

CHAIRMAN THOMAS: THANK YOU. OTHER COMMENTS?

DR. STEWARD: I'M SORRY. I GUESS I WILL MAKE JUST ONE COMMENT IF I COULD. AND THAT IS THAT THIS ACTUALLY, I THINK, IS SORT OF LEFT OVER FROM THE DAYS WHEN THERE WERE SPECIFIC EXCLUSIONS ON NIH FUNDING IN THIS CASE SPECIFICALLY FOR EMBRYONIC STEM CELL RESEARCH. AND BEYOND THAT, JUST TO HIGHLIGHT DR. GOLDSTEIN'S COMMENT, I THINK THAT REVIEW GROUPS ARE VERY COMFORTABLE IN MAKING AT LEAST AN ESTIMATE OF WHETHER X, Y, OR Z IS LIKELY TO BE FUNDED ELSEWHERE.

SO IT'S ALMOST UNNECESSARY, BUT I GUESS STILL IMPORTANT IN SOME RESPECTS. I DON'T KNOW QUITE HOW TO WRAP THE DEFINITION AROUND IT, I GUESS, WHICH IS WHY I PASSED ON COMMENTING THE FIRST TIME, BUT JUST TO GIVE A LITTLE BIT OF THE PERSPECTIVE OF THE HISTORY OF THIS THING. THANK YOU.

CHAIRMAN THOMAS: THANK YOU. ALLISON.

DR. BRASHEAR: WHAT IF THERE WAS SOME CRITERIA IN THE REVIEW THAT DEEMED IT HIGH RISK OR EMERGING OR SOMETHING ALONG -- THERE'S SOME CRITERIA, WORDS LIKE THAT BECAUSE IT'S IMPOSSIBLE TO LOOK INTO WHAT NIH WILL OR WON'T FUND. BUT FOR

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THOSE OF US WHO HAVE BEEN ON THESE REVIEWS, YOU HAVE TO HAVE CERTAIN GOALS, CERTAIN THINGS ALREADY ACHIEVED. SO MAYBE THAT'S THE WAY AROUND THIS. OTHERWISE, I WOULDN'T KNOW HOW TO REVIEW FOR THIS BECAUSE I WOULDN'T KNOW HOW TO ANSWER WHETHER OR NOT NIH WOULD FUND IT OR NOT. SO MAYBE THERE'S JUST SOME WAYS THAT THE REVIEW PROCESS COULD USE SOME KEYWORDS.

CHAIRMAN THOMAS: THANK YOU.

DR. BRASHEAR: JUST A THOUGHT.

CHAIRMAN THOMAS: STEVE.

MR. JUELSGAARD: IS JAMES HARRISON STILL ON THE LINE?

MR. HARRISON: I AM, STEVE.

MR. JUELSGAARD: JAMES, THIS LANGUAGE IS BOTH PRESCRIPTIVE AND PROSCRIPTIVE IN NATURE. AND SO THE QUESTION GETS TO BE, THEN, HOW SERIOUSLY SHOULD WE TAKE THIS LANGUAGE? IN OTHER WORDS, WHAT STEPS DO WE NEED TO GO TO IN ORDER TO VERIFY THAT SOMETHING THAT IS HIGH PRIORITY ON THE ONE HAND OR SOMETHING THAT SHALL NOT BE FUNDED ON THE OTHER IN TERMS OF HOW WE THINK ABOUT THIS? I'VE ALWAYS WONDERED ABOUT THE LEGAL RAMIFICATIONS OF THIS LANGUAGE BECAUSE IT'S THERE AND, AS I SAID, IT HAS SOME TEETH TO IT AT LEAST IN THE LANGUAGE SENSE.

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MR. HARRISON: STEVE, I THINK THE GENERAL INTENT BEHIND THIS LANGUAGE WAS THAT THE GOAL OF PROP 71 AND PROP 14 WASN'T SIMPLY TO DUPLICATE WHAT NIH DID. BUT AT THE SAME TIME TO RECOGNIZE THAT THERE MAY BE INSTANCES WHERE NIH IS FUNDING A CATEGORY OF RESEARCH, BUT IT'S EITHER SUCH HIGH PRIORITY RESEARCH OR SUCH HIGH RISK RESEARCH THAT WHAT NIH IS FUNDING IS NOT SUFFICIENT OR TIMELY IN THE JUDGMENT OF THE BOARD. SO I THINK THE GOAL WAS SIMPLY TO PROVIDE CIRM WITH A LITTLE BIT OF FLEXIBILITY HERE TO FUND CATEGORIES OF RESEARCH THAT NIH FUNDED WHEN THE BOARD DETERMINES THAT IT'S SUFFICIENTLY IMPORTANT TO DO SO.

MR. JUELSGAARD: SO IF I UNDERSTAND WHAT YOU ARE SAYING IS THAT THE BOARD ACTUALLY NEEDS TO MAKE A FINDING IN THIS CASE?

MR. HARRISON: NO. I THINK WHEN THE BOARD ISSUES REQUESTS FOR PROPOSALS OR RATHER APPROVES CONCEPT PLANS DESIGNATING WHAT RESEARCH CATEGORIES IT WILL FUND, IT'S TAKING INTO CONSIDERATION IMPLICITLY, AT LEAST, WHAT NIH IS ALREADY FUNDING.

MR. JUELSGAARD: THAT MAY BE TRUE ON LARGE CATEGORIES OF THINGS, BUT NOT ON SPECIFIC PROJECTS. WE MIGHT SEE A SPECIFIC PROJECT COMING IN THAT THE NIH MIGHT WELL DECIDE TO FUND, BUT FOREVER WHATEVER

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REASON COMES TO CIRM INSTEAD.

MR. HARRISON: YES. WHICH IS, I THINK TO THE POINT OF THIS DISCUSSION, IS HOW WE ARRIVE AT REVIEW CRITERIA THAT PROVIDE SUFFICIENT GUIDANCE TO THE REVIEWERS TO EVALUATE THIS. I THINK SOME OF THE SUGGESTIONS MADE BY MEMBERS OF THE BOARD, SUCH AS LOOKING AT WHETHER THE RESEARCH IS HIGH RISK, WHAT ELSE IS BEING FUNDED IN THE FIELD, ARE ASPECTS OF THE REVIEW THAT CAN BE USED TO MAKE A DETERMINATION ON A CASE-BY-CASE BASIS.

MR. JUELSGAARD: I HAVE A SUGGESTION TO MAKE ON THIS ONE, WHICH IS THAT WE COME BACK TO IT AT A SUBSEQUENT MEETING AND ASK THE STAFF AT CIRM, MARIA AND PEOPLE TO WORK WITH HER, TO TRY AND PUT SOME SORT OF METHODOLOGY TOGETHER, A PROCESS THAT REALLY CAN ADDRESS THIS WHEN WE GET THERE.

DR. MELMED: J.T., I WOULD AGREE WITH THAT. I WOULD ADD THAT THE LANGUAGE SHOULD REFLECT ALSO THE FACT THAT WE WOULDN'T WANT CIRM TO BE THE RECIPIENT OF EVERY REJECTED NIH GRANT BECAUSE THIS COULD BE INTERPRETED THAT WAY, THAT IF NIH DOESN'T FUND IT FOR WHATEVER REASON, THEY'LL JUST SEND IT TO CIRM.

CHAIRMAN THOMAS: I THINK THAT, JAMES, I BELIEVE THAT THAT WAS REFERRING TO SOMETHING OUTSIDE

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THE SCOPE OF WHAT NIH WOULD FUND AS OPPOSED TO REJECTED PROJECTS, BUT I COULD BE WRONG.

DR. MELMED: I APPLAUD THE SUGGESTION JUELSGAARD MADE TO RELOOK AT THE LANGUAGE, BUT I THINK WE SHOULD DEFINITELY INCLUDE THAT PRECLUSION.

CHAIRMAN THOMAS: YES. THANK YOU, SHLOMO. PAT.

DR. LEVITT: SO NIH HAS A DEFINITION FOR SOME OF THEIR R GRANT AWARDS THAT THEY ACTUALLY DON'T FOLLOW IN TERMS OF REVIEWS. SO WHAT WOULD FALL UNDER THIS CATEGORY WOULD BE HIGH RISK STUDIES THAT DON'T NEED PRELIMINARY DATA, BUT THOSE R GRANTS ARE REVIEWED BY AND LARGE REQUIRING PRELIMINARY DATA. THEY'RE CONSIDERED TO BE INNOVATIVE AND HIGH RISK, BUT THEY DON'T HAVE PRELIMINARY DATA OR THEIR SAMPLE SIZES ARE SMALL AND THE IDEA IS EXCITING. IT SEEMS TO ME IF IT FALLS IN THE CATEGORY OF UNMET NEED, UNLIKELY TO RECEIVE FUNDING, AND CIRM DEFINES WHAT THE CRITERIA ARE FOR THE REVIEWERS IN TERMS OF WHAT THEY SHOULD OR SHOULDN'T CONSIDER AND THEY FOLLOW THAT STRICTLY, THEN YOU WOULD HAVE A DEFINITION FOR THE PROCESS. IT'S UNFORTUNATE NIH DOESN'T FOLLOW THEIR OWN DEFINITIONS. THAT'S PART OF THE PROBLEM.

CHAIRMAN THOMAS: THANK YOU, PAT. SOUNDS

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LIKE YOU'RE IN AGREEMENT WITH THE PREVIOUS SUGGESTIONS.

DR. LEVITT: YES.

DR. MILLAN: J.T., MAY I MAKE A COMMENT?

CHAIRMAN THOMAS: CERTAINLY. PLEASE.

DR. MILLAN: SO, ESTEEMED BOARD, THE REASON WE BRING THIS UP IS THROUGH ALL THE YEARS THAT THE REVIEW TEAM AND THIS TEAM HAS HAD TO TRY TO RESOLVE HOW WE DEAL WITH THIS, WE HAVEN'T FOUND A WAY TO FIGURE OUT WHAT TYPE OF METHODOLOGY TO APPLY TO THIS. IF YOU THINK ABOUT IT, WE DISCUSS SCOPE AND TYPES OF PROGRAMS AND EVERYTHING ELSE THAT WE DISCUSSED EARLIER, IF THE BOARD SAYS THAT THOSE ARE THE TYPE OF PROGRAMS WE SHOULD SUPPORT, IT WOULD BE REALLY KIND OF COUNTERINTUITIVE THEN TO TRY TO TAKE THAT TO THINNER PIECES AND SAY OF THOSE WHAT DO YOU THINK THE NIH IS -- DR. BRASHEAR SAID, WE WON'T KNOW IF NIH WILL FUND IT OR NOT. OR AS DR. MELMED SAID, WE KNOW THEY WON'T BECAUSE THEY GOT REJECTED AND THEY'LL NEVER GET FUNDED. WE REALLY DON'T WANT THOSE TYPE OF PROGRAMS EITHER.

SO THE REASON THAT WE BRING THIS TO YOU TODAY IS BECAUSE WE HAVE BEEN TRYING TO DEAL WITH THIS AND TRYING TO FIGURE OUT HOW TO DEAL WITH THIS PARTICULAR WORDING. AND I THINK TO WHAT STEVE

JUELSGAARD HAS SAID, I GUESS WE WANT TO KNOW WHAT KIND OF REQUIREMENTS -- I MEAN EVEN SOME FORMS OF EMBRYONIC STEM CELL RESEARCH COULD POTENTIALLY BE FUNDED BY THE NIH. RIGHT? BUT THERE'S A BROAD NUMBER THAT ARE NOT. FETAL CELL RESEARCH GOES IN AND OUT OF FAVOR IN TERMS OF WHAT, EVEN DOING FETAL TYPE OF RESEARCH IN LIVE FETUSES SOMETIMES MAY NOT BE AS ATTRACTIVE AS A PROJECT. IT'S REALLY, REALLY DIFFICULT FOR US TO TRY TO GUESS WHAT ANYBODY ELSE, WHETHER VENTURE CAPITAL OR NIH, WILL FUND.

SO WE ARE BRINGING THIS TO YOU BECAUSE WE DON'T THINK WE CAN DO ANYTHING ABOUT THIS ASIDE FROM KIND OF A BROADER MANDATE OF WHAT WE BELIEVE AS AN AGENCY WE SHOULD BE FUNDING. AND SO HOW DO YOU RESOLVE THAT WITH THIS SECTION? AND I GUESS I THINK THAT IT IS RELEVANT IN TERMS OF WHAT ARE THE LEGAL IMPLICATIONS OF THIS AND WHAT IS THE ACTUAL FEASIBLE AND PRACTICAL WAY THAT WE CAN PUT THIS INTO PRACTICE. WE HAVE NOT BEEN ABLE TO DO THIS SINCE 2004. I WOULD SAY THIS TEAM HAS BEEN TRYING TO KIND OF GO ABOUT THIS, AND THEN THERE WAS ALSO A TIME WHEN WE WERE THINKING ABOUT SHOULD WE -- THERE WAS AN ATTEMPT TO DO KIND OF A COMPETITIVE LANDSCAPE ANALYSIS AND TRY TO BRING THOSE PIECES IN, BUT THE FIELD MOVED SO QUICKLY, AND THEN THE COST OF JUST

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EVEN DOING THAT IS PROHIBITIVE.

SO I WANTED TO REALLY JUST PUT THAT FORWARD BECAUSE I DON'T WANT TO BRING FORWARD AN ARTIFICIAL PROPOSAL TO YOU BECAUSE -- AND THIS IS THE VERY REASON WHY THIS IS IN FRONT OF US TODAY. I JUST WANTED TO MAKE THAT POINT.

CHAIRMAN THOMAS: THANK YOU. WE'VE GOT OS FIRST, THEN STEVE.

DR. STEWARD: AS I MENTIONED, AND JAMES CAN EITHER CORRECT ME OR EXPAND, REALLY THE INITIAL REASON FOR HAVING THIS IN THERE IN THE FIRST PLACE WAS BECAUSE IN THE BEGINNING STEM CELL RESEARCH WAS VERY STRICTLY LIMITED DURING THE BUSH ERA. AND A LOT OF THOSE PROHIBITIONS DON'T EXIST ANYMORE. AS MARIA SAID, A LOT OF THINGS THAT ARE STEM CELL RELATED, HUMAN EMBRYONIC STEM CELL RELATED NOW CAN BE FUNDED THROUGH NIH. SO WHERE I'M GOING. I WONDER IF WE REALLY OUGHT TO GO BACK TO WHAT WAS THE ORIGINAL PURPOSE OF THIS LANGUAGE AND SIMPLY SAY IF THERE ARE AREAS OF RESEARCH THAT END UP BEING PROHIBITED IN THE FUTURE, THEN CIRM COULD CONSIDER FUNDING THOSE RATHER THAN TRYING TO GO THROUGH THIS THING OF MAKING THESE JUDGMENTS OF, YEAH, MAYBE IT'S GOING TO GET FUNDED BECAUSE NIH DID NOT LIKE IT OR ALL OF THESE OTHER THINGS WHICH WERE ORIGINALLY NOT

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PART OF THE ORIGINAL PURPOSE OF THIS LANGUAGE. JUST ONE POSSIBLE WAY TO THINK ABOUT THIS GOING FORWARD. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, OS. STEVE.

MR. JUELSGAARD: WHAT I FIND INTERESTING, AND THIS IS SORT OF DIRECTED TO JAMES, I GUESS, IS THAT THIS LANGUAGE SURVIVED OUT OF 71 AND INTO 14. AND I GUESS I DON'T KNOW IF IT GOT ANY ATTENTION OR NOT WHEN IT WAS BEING -- WHEN 14 WAS BEING WRITTEN, BUT IT'S CARRIED OVER. SO IT STILL STANDS EVEN THOUGH IT WAS ALL ABOUT ORIGINAL INTENT.

ONE WAY TO TRY AND SOLVE THIS, AND IT'S NOT PERFECT BY ANY MEANS, IS TO SIMPLY HAVE AN APPLICANT MAKE A STATEMENT, I WON'T SAY UNDER PENALTY OF PERJURY, BUT BASICALLY AN AFFIRMATIVE STATEMENT THAT THEIR RESEARCH CANNOT OR IS UNLIKELY TO RECEIVE TIMELY OR SUFFICIENT FEDERAL FUNDING UNENCUMBERED BY LIMITATIONS, ET CETERA, JUST BASICALLY TO TAKE THIS LANGUAGE THAT'S THERE AND HAVE THEM MAKE THAT AS AN AFFIRMATIVE STATEMENT THAT THEY HAVE TO STAND BEHIND AS THEY PUT THEIR NAME TO BECAUSE I AGREE WITH MARIA MILLAN. THIS IS GOING TO BE REALLY DIFFICULT TO FIGURE OUT IF WE TRY TO PULL IT APART. I CAN'T THINK OF ANY GOOD WAY TO DO THAT. AND I ASKED JAMES THIS. IF WE FULFILLED OUR

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STATUTORY DUTY OR EVEN A CONSTITUTIONAL DUTY, BECAUSE I THINK THIS PART OF THE CONSTITUTION, THAT THAT WILL SUFFICE.

MR. HARRISON: YEAH, STEVE. I THINK THAT WOULD SUFFICE. I WANT TO RETURN TO THE POINT I MADE EARLIER, WHICH IS IN EVALUATING WHAT RESEARCH CIRM SHOULD FUND, THE AGENCY HAS BEEN AND SHOULD CONTINUE TO BE COGNIZANT OF WHAT CATEGORIES OF RESEARCH NIH IS FUNDING AND TO WHAT DEGREE. WE JUST HAD A LONG CONVERSATION ABOUT SMALL MOLECULE RESEARCH. I THINK IN CONSIDERING CONCEPT PLANS AND DEVELOPING CIRM'S STRATEGIC PLAN, CIRM SHOULD BE GUIDED BY THE GOAL OF, AGAIN, NOT SIMPLY SUPPLANTING OR REPLACING NIH, BUT TRYING TO FILL HOLES IN THE RESEARCH SPECTRUM AND TO ADDRESS OPPORTUNITIES THAT ARE HIGH RISK AND HIGH PRIORITY.

DR. MELMED: JAMES, I LIKE YOUR ANSWER. THE PROBLEM IS IT'S A VERY SLIPPERY SLOPE FOR US BECAUSE MANY OF US KNOW CIRM-FUNDED PROJECTS WHICH COULD DEFINITELY HAVE BEEN FUNDED BY NIH BASED ON THE QUALITY OF THE SCIENCE. WE ARE IN BIT OF A CATCH 22 THERE.

DR. MILLAN: J.T., MAY I ASK A QUESTION OR MAYBE MAKE A STATEMENT?

CHAIRMAN THOMAS: SURE.

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DR. MILLAN: SO, JAMES, WHEN THE BOARD HAS THESE PROGRAMMATIC DISCUSSIONS AND WHEN WE HAVE THESE VERY FULL DISCUSSIONS OF WHAT THEY BELIEVE ARE WORTHWHILE FUNDING REGARDING SCOPE, ET CETERA, SIMILAR TO DISCUSSIONS WE HAD TODAY, THE DISCUSSIONS THAT LED TO OUR CURRENT PROGRAM ANNOUNCEMENTS, THEIR ELIGIBILITY AND SCOPE, IS IT POSSIBLE THAT BY VOTING, BY THE BOARD HAVING THESE DISCUSSIONS AND SAYING THESE ARE ELIGIBLE FOR FUNDING, THAT THAT MEETS THE CRITERIA BECAUSE OTHERWISE WE ARE QUESTIONING THE ORIGINAL -- OTHERWISE, BY HAVING THIS BE PART OF THE REVIEW, IT'S ALMOST QUESTIONING WHETHER ALL THOSE CATEGORIES THAT THE BOARD SAY ARE IMPORTANT AREAS TO FUND AS BROAD CATEGORIES ARE BEING QUESTIONED AT EACH REVIEW. THAT'S WHERE WE HAVE THIS FUNDAMENTAL ISSUE.

AND IT WOULD BE -- AND THE OTHER THING IS NIH CAN PRETTY MUCH FUND ANYTHING. THEY FUND SO MANY THINGS WE DON'T EVEN KNOW ABOUT. THEY DO. AND SO THAT'S THE PROBLEM IS THEY MIGHT ACTUALLY -- EVEN IF WE HAD SOMEBODY DOING A FULL -- THE NIH IN ADDITION TO OTHER FUNDING AGENCIES HAVE SUCH BROAD PROGRAMS THAT THEIR OWN INSTITUTIONS DON'T EVEN KNOW SOMETIMES WHAT THEY'RE FUNDING WITHIN THEIR INSTITUTES. SO IT WOULD BE REALLY DIFFICULT TO WORK

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THAT IN AND ALSO UNREALISTIC TO EXPECT OUR REVIEWERS TO KNOW THE FULL BREADTH OF WHAT'S AVAILABLE OUT THERE FOR FUNDING SOURCES.

SO I GUESS I RETURN TO MY ORIGINAL QUESTION. BY THE BOARD SAYING THAT THESE ARE AREAS THAT ARE IMPORTANT, THAT THEY HAVE SIGNIFICANCE AND IMPACT, SIMILAR TO GENE THERAPY, WHICH, BY THE WAY, THE NIH FUNDS, JUST BY SAYING THAT, WOULD THAT QUALIFY AS MEETING THIS REQUIREMENT? AND THEN OUR REQUEST IS TO ASK THE BOARD WHETHER WE CAN JUST THEN REMOVE IT FROM -- RIGHT NOW THE REVIEW TEAM HAS BEEN TRYING TO EMBED IT INTO THE REVIEW; HOWEVER, IT'S NOT EFFECTIVELY SOMETHING THAT ACTUALLY CAN BE REVIEWED IN ALL DIFFERENT ATTEMPTS. THAT'S JUST MY QUESTION.

MR. HARRISON: YES. THAT WAS THE POINT I WAS TRYING TO MAKE ABOUT THE DEVELOPMENT OF CONCEPT PLANS. IN PRESENTING CONCEPT PLANS, THERE'S A VALUE PROPOSITION AT STAKE. IN OTHER WORDS, CIRM ISN'T PROPOSING TO FUND RESEARCH JUST FOR THE SHEER PURPOSE OF FUNDING RESEARCH THAT MAY BE SUFFICIENTLY FUNDED BY NIH OR THAT DOESN'T ADDRESS A PARTICULAR NEED OR IT ISN'T PARTICULARLY HIGH RISK. SO I THINK THAT CAN BE PART OF THE VALUE PROPOSITION AT THE STAGE WHEN THE BOARD CONSIDERS CONCEPT PLANS FOR

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WHAT CIRM SHOULD FUND.

CHAIRMAN THOMAS: I THINK THAT MAKES A LOT OF SENSE, JAMES. IS THAT HELPFUL, MARIA?

DR. MILLAN: LIKE THEY SAY, WHEN YOU GET THE ANSWER THAT YOU WANT, JUST HANG UP. SO I'M JUST GOING TO MUTE MYSELF NOW.

CHAIRMAN THOMAS: I SEE STEVE LAUGHING IN THE BACKGROUND.

ARE THERE ANY OTHER COMMENTS ON THIS PARTICULAR TOPIC? OTHER THAN TO NOTE THAT WE'VE BEEN GOING FOR 15 YEARS AND THINGS HAVE WORKED OUT VERY WELL WITHIN THE SCOPE OF THIS LANGUAGE AND CONCEPT. I DON'T THINK THIS IS SOMETHING THAT HAS BEEN PROBLEMATIC OVER TIME, BUT I THINK THIS HAS BEEN VERY HELPFUL NONETHELESS.

DR. MILLAN: WE APPRECIATE IT. SO WE'LL REMOVE IT FROM THE REVIEW CRITERIA BECAUSE, AGAIN, WHAT JAMES HAD PUT FORWARD, THAT THAT WOULD BE ACCEPTABLE, THAT WE'RE CONSIDERING THIS AT THE TIME OF THE CONCEPT APPROVAL.

CHAIRMAN THOMAS: OKAY. GIL, DOES THAT CONCLUDE YOUR SLIDES?

DR. SAMBRANO: YES, IT DOES. THANK YOU VERY MUCH.

CHAIRMAN THOMAS: MARIA, WOULD YOU LIKE

ANY -- THANK YOU, GIL, VERY MUCH. WOULD YOU LIKE ANY CLOSING THOUGHTS ON THIS PARTICULAR SEGMENT OF THE MEETING HERE?

DR. MILLAN: JUST WANTED TO SAY THAT WE ARE SO APPRECIATIVE AND ARE SO EXCITED. THIS BOARD IS A REALLY SPECIAL COMPILATION OF AN AMAZING BREADTH AND DEPTH OF EXPERTISE ALONG THE VARIOUS ASPECTS OF RESEARCH AND EVERYTHING THAT'S IMPORTANT TO IT, INCLUDING DIVERSITY, INCLUDING ALL OF THE OTHER THINGS THAT WE HAVEN'T EVEN STARTED TO THINK ABOUT. SO THE TEAM AND I ARE VERY APPRECIATIVE OF THE OPPORTUNITY TO PRESENT IDEAS AND GET YOUR INPUT, AND WE LOOK FORWARD TO COMING BACK TO YOU INTERMITTENTLY AS WE DEVELOP THIS STRATEGIC PLAN.

CHAIRMAN THOMAS: THANK YOU, MARIA. AND THANK YOU AND THE TEAM FOR ALL THE GREAT WORK ON THIS PANEL DISCUSSION, THE REPORT, THE ANALYSIS TODAY. I THINK IT'S BEEN AN OUTSTANDING DISCUSSION AND ONE THAT IS PROPERLY BEFORE THE BOARD AND GOT LOTS OF PARTICIPATION. SO THANK YOU ALL, MEMBERS OF THE BOARD, FOR THAT.

AS REGARDS THE PANEL ITSELF, I WOULD, IN ADDITION TO READING THE REPORT, JUST TAKE A LOOK AT WHO THE MEMBERS WERE OF THIS PANEL. THIS REALLY WAS AN A-TEAM GROUP OF EXTRAORDINARY INDIVIDUALS. AND

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WE WERE FORTUNATE. IT WAS NICE TO SEE OUR CONVENING POWER WAS PRETTY GOOD. WITH THE EXCEPTION OF FRANCIS COLLINS, WHO WAS OTHERWISE ENGAGED, WE GOT EVERYBODY THAT WE ASKED TO JOIN, AND ALL OF THEM WERE LEADING EXPERTS IN THE FIELD. WE ACTUALLY RAN OUT OF TIME. THERE WERE A NUMBER OF THINGS WE'D LOVED TO HAVE ASKED. FOR EXAMPLE, BACK IN 2004 THERE WERE NO IPS CELLS, THERE WAS NO CRISPR, SORT OF WHAT THE PANEL MIGHT VIEW AS THE NEW, NEW THING COMING DOWN THE ROAD OF THAT MAGNITUDE BECAUSE THERE CERTAINLY WILL BE THINGS AS THE FIELD PROGRESSES.

SIMILARLY, WE'D LIKE TO ASK THEM AS A FOLLOW-UP. WE HAVE THESE GREAT INFRASTRUCTURE PROJECTS, WHETHER IT'S THE IPS CELL BANK OR THE ALPHA STEM CELL CLINICS OR THE GENOMIC CENTERS OF EXCELLENCE OR WHATEVER, AND WOULD LOVE TO GET THEIR INPUT ON MACRO INFRASTRUCTURE PROJECTS OF THAT MAGNITUDE THAT WE MIGHT ADD AS WE DEPLOY THIS $5.5 BILLION TO FURTHER BENEFIT THE PROGRAM. A LOT OF FOLLOW-UP TO HAVE. AND THIS GROUP WAS VERY NICE ABOUT WANTING TO BE KEPT ABREAST AND TO GET BACK WITH ADDITIONAL FEEDBACK. SO I DO THINK WE WILL BE GOING BACK.

AND I THINK JUST THE FINAL COMMENT IS THAT THE CONCEPT OF THE PANEL, I THINK, WAS A GREAT

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SUCCESS AS EVIDENCED BY THEIR SUGGESTIONS, YOUR DISCUSSION HERE. AND I'M SURE THAT MARIA AND I WILL HAVE OTHER PANELS ON OTHER TOPICS DOWN THE ROAD; BUT AS AN INAUGURAL PANEL UNDER THIS NEW CONCEPT IN PROP 14, WE WERE DELIGHTED WITH HOW THIS WORKED OUT. SO THANK YOU TO ALL CONCERNED.

IT'S TIME TO GET SOME LUNCH. IF EVERYBODY -- WE WANT TO KEEP THE MOMENTUM GOING HERE -- GRAB SOMETHING AND BE BACK WITHIN ABOUT 15 MINUTES, WE'RE GOING TO START BACK UP AT 1:20. WE HAVE THIS ONE MAJOR ITEM LEFT ON THE DISCUSSION AGENDA, WHICH IS TO REVIEW A NUMBER OF THE POLICIES AND PROCEDURES FOR THE BOARD SO THAT EVERYBODY IS ON THE SAME PAGE. THERE'S LOTS OF GOOD STUFF IN THERE TOO. SO WE'LL SEE EVERYBODY BACK HERE AT 1:20. THANK YOU.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: OKAY, EVERYBODY. IF WE COULD RECONVENE HERE. HOPE EVERYBODY HAD SOMETHING GOOD, ALBEIT QUICK, TO HAVE FOR LUNCH.

SO WHAT WE'RE GOING TO DO NOW IS GO THROUGH A NUMBER OF BRIEF PRESENTATIONS ON DIFFERENT ELEMENTS DEALING WITH CIRM POLICIES AND PROCEDURES. THE PURPOSE OF THIS IS JUST TO, FOR THE OLDER MEMBERS, THAT'S OLDER IN TENURE, NOT AGE, OF COURSE,

THE OLDER MEMBERS JUST TO GIVE A BIT OF A REFRESHER ON CERTAIN THINGS AND FOR THE NEWER MEMBERS TO TRY TO LAY OUT ALL THE RELEVANT TOPICS FOR THE PURPOSES OF THIS DISCUSSION THAT GETS EVERYBODY SORT OF UP TO SPEED ON WHAT CIRM IS DOING WITH RESPECT TO DIFFERENT THINGS. GET EVERYBODY ON KIND OF A LEVEL PLAYING FIELD. SO WE THOUGHT THIS WOULD BE A GOOD THING TO DO. AND AS PART OF THIS, WE HAVE A NUMBER OF PRESENTATIONS BY DIFFERENT PEOPLE WITH YIMI ORCHESTRATING IN THE BACKGROUND. THANK YOU, YIMI, FOR YOUR HELP ON ALL THE SLIDES.

SO WITHOUT FURTHER ADO, MARIA, DO YOU WANT TO EMCEE THIS?

MS. BONNEVILLE: SURE. YOU'RE FIRST UP. SO I'M GOING TO PASS IT BACK TO YOU.

CHAIRMAN THOMAS: COULD YOU GET THE FIRST SLIDE. OF COURSE, WE START EVERYTHING ACKNOWLEDGING OUR MISSION, ACCELERATING STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. THAT'S WHAT THIS IS ALL ABOUT. NEXT SLIDE PLEASE.

ONE OF THE THINGS I THOUGHT WOULD BE INTERESTING WE GET OUR MONEY, WE, OF COURSE, BENEFITED FROM THE GENEROSITY OF THE VOTERS IN VOTING TO PASS PROP 71 AND THEN PROP 14, BUT THE MECHANICS OF HOW WE ACTUALLY GET IT IS SOMETHING

THAT NOT EVERYBODY MAY BE FAMILIAR WITH. SO I THOUGHT IT WOULD BE A GOOD IDEA TO START OFF THIS STRETCH OF THE MEETING BY REVIEWING THAT PROCESS SO THAT EVERYBODY UNDERSTANDS WHERE WE GET OUR DOLLARS. NEXT SLIDE PLEASE.

OKAY. IT'S A LITTLE PROBLEMATIC BECAUSE THE SLIDE IS BEHIND EVERYBODY ON THE RIGHT SIDE OF MY LAPTOP, SO I CAN'T READ EXACTLY THE FULL TEXT HERE. BUT THE IDEA HERE IS EVERY SIX MONTHS WE TAKE STOCK OF WHAT WE EXPECT THE FOLLOWING SIX MONTHS TO ENTAIL IN TERMS OF PROGRAMS AND COSTS BEHIND THOSE PROGRAMS. AND WE DEVELOP WHAT WE THINK IS AN AMOUNT WE WILL NEED TO BE ABLE TO EXECUTE FOR THAT FOLLOWING SIX-MONTH PROGRAM BOTH IN TERMS OF THE PROJECTS THAT WE FUND AND OUR ADMINISTRATIVE EXPENSES. NEXT SLIDE PLEASE.

ONCE WE HAVE THAT NUMBER IN HAND, THE PROCESS IS AS FOLLOWS. I, OR THE CHAIR, RATHER, AND THE DIRECTOR OF FINANCE WILL GO TO SACRAMENTO AND SIT DOWN WITH REPRESENTATIVES FROM THE DEPARTMENT OF FINANCE IN THE GOVERNOR'S OFFICE, AND WE WILL WALK THEM THROUGH OUR NEEDS ASSESSMENT AND THE RATIONALE FOR HOW WE ARRIVED AT A PARTICULAR NUMBER. THROUGH THE COURSE OF THAT DISCUSSION, THE DEPARTMENT OF FINANCE WILL THEN ACCEPT OR AMEND OUR

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RECOMMENDATIONS TO COME UP WITH A RECOMMENDATION IN TURN TO PASS ALONG TO THE STATE TREASURER INFORMING THE TREASURER OF HOW MUCH WE SHOULD BE ENTITLED TO FOR THAT NEXT SIX-MONTH PERIOD. NEXT SLIDE PLEASE.

THEN THE STATE TREASURER CONVENES A MEETING OF -- AGAIN, MY SCREEN IS BLOCKED HERE SO I CAN'T SEE ALL THIS. BUT IT'S A GROUP THAT IS COMPRISED OF THE STATE TREASURER AND REPRESENTATIVES FROM THE DEPARTMENT OF FINANCE AND THE STATE CONTROLLER'S OFFICE. IT CONVENES IT AS PART OF A -- PLUS, ALSO, SORRY, THE CHAIR, VICE CHAIR, AND ONE OTHER ADDITIONAL CIRM BOARD MEMBER. THIS MEETING IS CONVENED AS PART OF A GROUP OF MEETINGS THAT THE STATE TREASURER HAS IN CONNECTION WITH A NUMBER OF AGENCIES THAT ARE GOING TO BE FUNDED OUT OF THE STATE GENERAL OBLIGATION BOND MEASURE. AND THESE DIFFERENT AGENCIES MEET IN SEQUENCE AT THIS MEETING, AND IT MEETS TWICE A YEAR. IT'S TIMED TO BE IN ADVANCE OF A STATE TREASURER BOND ISSUE IN THE SPRING AND THE FALL.

WE ARE ONE, AS I SAY, OF NUMEROUS AGENCIES THAT ARE INCLUDED IN THAT ISSUE. AND AT THE CONCLUSION OF THIS MEETING, WHICH IS USUALLY QUITE BRIEF WITH RESPECT TO US, THE COMMITTEE AUTHORIZES THE ISSUANCE OF EITHER BONDS OR COMMERCIAL PAPER IN

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ACCORDANCE WITH THE DEPARTMENT OF FINANCE'S INSTRUCTION AS TO THE DOLLAR AMOUNT. NEXT SLIDE PLEASE.

THEN ONCE THAT HAPPENS, USUALLY TWO TO THREE WEEKS LATER OR SO, YOU HIT THIS SEMIANNUAL BOND ISSUANCE BY THE STATE TREASURER ON BEHALF OF STATE AGENCIES OF WHICH OUR PIECE IS INCLUDED IN THAT. AND THAT THEN OBVIOUSLY GOES OUT SUBJECT TO MARKET CONDITIONS, AND THE PROCEEDS FOR CIRM ARE HELD IN A SEGREGATED ACCOUNT BY THE STATE CONTROLLER. NEXT SLIDE PLEASE.

AS YOU KNOW FROM OUR BUDGET DISCUSSIONS, WE HAVE A BIG BUCKET, WHICH IS THE MONEY THAT GOES TOWARDS CIRM PROJECTS, AND A LITTLE BUCKET, WHICH GOES TOWARDS ADMINISTRATIVE EXPENSES. AS WE NEED EITHER BIG BUCKET OR LITTLE BUCKET FUNDS, WE NOTIFY THE STATE CONTROLLER OF THE AMOUNT. THE STATE CONTROLLER THEN DISBURSES THE BIG BUCKET FUNDS DIRECTLY TO SPECIFIED RECIPIENTS, FOR EXAMPLE, GRANTEES, OR IT DISBURSES SMALL BUCKET FUNDS TO PAY VENDORS AND MEET PAYROLL. AND THE WAY THAT WORKS IS IT'S GENERALLY SOMETHING THAT'S PREDISCUSSED WITH THE CONTROLLER'S OFFICE, AND EITHER THEY GET AN INVOICE THAT TRIGGERS THE VENDOR PAYMENT OR, WITH RESPECT TO SALARIES, IT'S SOMETHING THAT'S

AUTOMATICALLY PAID OUT AS PART OF PAYROLL, FOR EXAMPLE.

SO THAT MECHANISM TAKES CARE OF ALL OF THE FUNDING EITHER FOR THE PROJECTS THAT WE DO AND FOR THE ADMINISTRATIVE EXPENSE.

LAST SLIDE. THIS IS SOMETHING THAT GOES ON LIKE CLOCKWORK EVERY SIX MONTHS AND HAS BEEN SOMETHING THAT HAS VERY SUCCESSFULLY KEPT CIRM AND ITS PROJECTS AND ADMINISTRATION WELL FUNDED SINCE INCEPTION AND FIGURES TO DO THE SAME GOING FORWARD UNDER THE SAME SEQUENCE WITH PROP 14.

ANY QUESTIONS ON HOW WE GET OUR MONEY? OKAY. AND I SHOULD NOTE, JUST SINCE I'M THE FIRST UP ON THE PRESENTATIONS, FOR PUBLIC COMMENT WE'RE GOING TO HOLD TILL THE END OF THE PRESENTATIONS. IF BOARD MEMBERS WANT TO COMMENT ON ANY OF THE PRESENTATIONS IN TURN, PLEASE FEEL FREE TO. PUBLIC COMMENT AT THE END. THANK YOU. MARIA, BACK TO YOU.

MS. BONNEVILLE: THANK YOU. YIMI, I THINK I MAY BE NEXT. I AM. SO WE'LL BE TALKING ABOUT ICOC SUBCOMMITTEES, HOW FREQUENTLY WE MEET WITH THE BOARD, AND SCHEDULE FOR THE REMAINDER OF THE YEAR. NEXT SLIDE PLEASE.

SO COMPOSITION OF THE BOARD. WE HAVE 35 BOARD MEMBERS: CHAIR, VICE CHAIR, 12 PATIENT

ADVOCATE MEMBERS, TWO NURSES, 15 EXECUTIVE OFFICERS FROM RESEARCH INSTITUTIONS, MEDICAL SCHOOLS, AND UNIVERSITIES, AND FOUR CALIFORNIA LIFE SCIENCE COMMERCIAL ENTITY MEMBERS. NEXT SLIDE.

ICOC MEETING SCHEDULE. WE HAVE FULL BOARD MEETINGS ONCE A QUARTER ALTHOUGH I REALIZE THIS YEAR HAS BEEN A LITTLE DIFFERENT WITH THAT SCHEDULE. AND APPLICATION REVIEW SUBCOMMITTEE MEETINGS ONCE A MONTH.

SO RIGHT NOW ON THE SLIDE ARE THE REMAINING MEETINGS FOR THE YEAR. AS YOU WILL SEE, WE WERE TRYING TO GET A FULL BOARD MEETING SCHEDULED FOR APRIL. I'M NOT SURE THAT'S GOING TO WORK. ON OCCASION, THINGS COME UP THAT NEED FULL BOARD CONSIDERATION AND DOESN'T FALL INTO A REGULARLY SCHEDULED FULL BOARD MEETING. SO WE TRY AND, IF IT'S NOT POSSIBLE, IT'S NOT POSSIBLE. SO JUST KNOW IF WE SEND YOU A DOODLE FULL REQUEST, IT'S FOR THAT REASON.

SO IN MAY THERE'S AN ARS MEETING, JUNE IS FULL BOARD MEETING, SEPTEMBER IS FULL BOARD MEETING, AND DECEMBER IS FULL BOARD MEETING. NEXT SLIDE PLEASE.

SO AS YOU KNOW, WE HAVE SEVERAL SUBCOMMITTEES. THEY ARE THE APPLICATION REVIEW

SUBCOMMITTEE, THE SCIENCE SUBCOMMITTEE, COMMUNICATIONS SUBCOMMITTEE, LEGISLATIVE, GOVERNANCE, EVALUATION, TRANSITION, AND INTELLECTUAL PROPERTY AND INDUSTRY ENGAGEMENT.

MOVING FORWARD, WE ARE GOING TO CONSOLIDATE THE EVALUATION AND GOVERNANCE SUBCOMMITTEE INTO ONE COMMITTEE. WE WILL RETIRE THE LEGISLATIVE SUBCOMMITTEE, AND MATTERS WILL BE BROUGHT STRAIGHT TO THE BOARD. AND WE WILL RETIRE THE TRANSITION SUBCOMMITTEE. WE DON'T NEED THIS ONE ANY LONGER. IF THERE ARE OTHER SUBCOMMITTEES THAT NEED TO BE FORMED AS A CONSEQUENCE OF SPECIFIC SUBJECT MATTER, WE CAN DO THAT. J.T. WILL ASK THE BOARD TO FORM A SUBCOMMITTEE, AND THEN IT WILL BE FORMED. BUT FOR NOW WE THINK THAT, WITH THE CHANGES MOVING FORWARD, WE THINK THAT THAT SHOULD COVER THE DIFFERENT AREAS THAT WE ARE TALKING ABOUT MOVING FORWARD.

I WILL SAY THAT WE HAVE NOT USED SUBCOMMITTEES AS MUCH AS THE BOARD DID AT THE BEGINNING OF THE AGENCY'S HISTORY. WE UNDERSTAND THAT NOW WITH A BOARD THAT'S 35 MEMBERS, IT'S A BIG BOARD, AND SO WE WILL BE USING SUBCOMMITTEES MORE NOW TO BRING DIFFERENT SUBJECTS TO THEM TO DISCUSS AND GIVE OPINIONS ON, AND THEN MOVE IT TO THE BOARD

ONCE THERE'S BEEN TIME TO REVIEW IT THERE. NEXT SLIDE PLEASE.

SO THIS IS THE CURRENT SUBCOMMITTEE MEMBERSHIP. I KNOW IT'S VERY SMALL. IT'S ON OUR WEBSITE AS WELL. NEXT SLIDE.

PROCESS FOR APPOINTMENT TO OUR SUBCOMMITTEES. THE BYLAWS STATE THAT THE ICOC SHALL APPOINT THE CHAIRPERSON OF EACH SUBCOMMITTEE BASED UPON THE RECOMMENDATIONS OF THE MEMBERS OF THE ICOC. AND THEN THE CHAIRPERSON OF THE SUBCOMMITTEE SHALL THEN APPOINT THE OTHER MEMBERS OF THE SUBCOMMITTEE WITH THE CONCURRENCE OF THE CHAIRPERSON OF THE ICOC. AND THEN ONCE SUBCOMMITTEES ARE SET, WE WILL WORK ON UPDATING THE MISSION AND SCOPE OF EACH.

SO MY ASK TO ALL OF YOU IS IF YOU ARE INTERESTED IN CHAIRING A SUBCOMMITTEE OR PARTICIPATING IN A SUBCOMMITTEE, PLEASE LET J.T. KNOW OR ME KNOW, AND WE WILL BRING IT THROUGH THE PROCESS.

ONE THING TO HIGHLIGHT THAT I DID NOT IN ONE OF THE FIRST SLIDES. WITH A 35-MEMBER BOARD, OUR QUORUM IS 23 MEMBERS. SO JUST KEEP THAT IN MIND IF WE ASK YOU OVER AND OVER IF YOU'RE AVAILABLE FOR MEETINGS. IT MIGHT JUST BE THAT WE HAVEN'T QUITE HIT OUR QUORUM YET. NEXT SLIDE.

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NEXT UP IS GIL, AND HE WILL BE WALKING YOU THROUGH THE GWG, AND IT SHOULD BE QUITE EXCITING.

DR. SAMBRANO: THANK YOU, MARIA. SO YOU CAN GO ON TO THE NEXT SLIDE. I'VE SHOWN YOU THIS BEFORE ESSENTIALLY. THIS IS JUST WHAT THE GRANTS WORKING GROUP IS OR THE GWG. AS MENTIONED EARLIER TODAY, THIS IS THE GROUP THAT IS RESPONSIBLE FOR EVALUATING THE SCIENTIFIC MERIT OF ALL OF OUR APPLICATIONS AND PROVIDING FUNDING RECOMMENDATIONS TO THE ICOC.

AND SO IN THIS CAPACITY, IT IS AN ADVISORY GROUP MUCH LIKE OTHER ADVISORY GROUPS. YOU WILL HEAR ABOUT THE STANDARDS WORKING GROUP AND FACILITIES WORKING GROUP AND SO ON. THIS ONE IN PARTICULAR IS COMPOSED OF 15 SCIENTIFIC MEMBERS NOT IN CALIFORNIA, SEVEN PATIENT ADVOCATE MEMBERS OF THE ICOC, AND THE CHAIR OF THE ICOC.

THE GRANTS WORKING GROUP PANELS ARE ASSEMBLED AND TAILORED WITH EXPERTS TO EVALUATE THE PROPOSALS, AS I DISCUSSED EARLIER, ACROSS OUR DIFFERENT FUNDING OPPORTUNITIES. NEXT SLIDE PLEASE.

AND SO THIS IS JUST AN OVERVIEW OF THE REVIEW PROCESS ITSELF. SO APPLICATIONS THAT ARE SUBMITTED TO CIRM GO THROUGH ESSENTIALLY A THREE-STAGE PROCESS. THE FIRST STAGE BEING AN

ELIGIBILITY ASSESSMENT, ASKING THE QUESTION CAN THE APPLICATION BE REVIEWED. AND SO THERE WE ASSESS WHETHER THE APPLICATION IS COMPLETE, WHETHER IT HAS ALL THE ELEMENTS THAT ARE REQUIRED AND NECESSARY TO MOVE IT ON TO THE NEXT STAGE. THOSE THAT ARE ACCEPTED FOR REVIEW GO TO THE GRANTS WORKING GROUP ITSELF WHERE WE MAKE SPECIFIC ASSIGNMENTS AND HAVE A REVIEW MEETING TO DISCUSS THE APPLICATIONS AND DETERMINE WHETHER THEY ARE SCIENTIFICALLY MERITORIOUS.

THE SCORES AND RECOMMENDATIONS FROM THE GRANTS WORKING GROUP ARE THEN FORWARDED TO THE ICOC, SPECIFICALLY THE APPLICATION REVIEW SUBCOMMITTEE, THAT ASSESSES WHETHER THIS IS THE KIND OF PROJECT THAT CIRM SHOULD FUND. AND THE FINAL APPROVAL MADE BY THE APPLICATION REVIEW SUBCOMMITTEE AT THEIR MEETING. AND THIS PROCESS, IN GENERAL, TAKES, DEPENDING ON THE FUNDING OPPORTUNITY, 80 TO 90 DAYS FOR OUR CLINICAL PROGRAM AND BETWEEN A HUNDRED AND 120 DAYS FOR OUR OTHER PROGRAMS. NEXT SLIDE PLEASE.

SO IN LOOKING A LITTLE CLOSER AT THE MERIT REVIEW BY THE GRANTS WORKING GROUP, THERE ARE FOUR QUESTIONS THAT HISTORICALLY HAVE BEEN POSED TO REVIEWERS IN TERMS OF ASSESSING THE MERIT. AND THESE BASICALLY WORKING ACROSS ALL OUR DIFFERENT

FUNDING OPPORTUNITIES. THERE IS MORE DETAIL PROVIDED IN TERMS OF EACH ONE DEPENDING ON THAT FUNDING OPPORTUNITY. BUT JUST GENERALLY SPEAKING, THE QUESTIONS ARE: DOES THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT? IS THE RATIONALE SOUND? AND THAT RELATES TO DATA THAT THEY HAVE AND THE PREMISE FOR WHAT THEY ARE PROPOSING TO DO. WHETHER THE PROJECT IS WELL PLANNED AND DESIGNED? AND WHETHER THE PROJECT IS FEASIBLE, MEANING DO THEY HAVE THE APPROPRIATE TEAM MEMBERS IN PLACE? DO THEY HAVE ALL THE RESOURCES TO CARRY IT OUT IN THE TIME THAT THEY DESIRE?

AND THEN FINALLY WE HAVE ADDED A NEW CRITERION WHICH WE ARE MOVING FORWARD NOW IN OUR UPCOMING REVIEWS. AND THAT IS DOES THE PROJECT ADDRESS THE NEEDS OF THE UNDERSERVED? AND THIS WILL COME IN PLACE IN A COUPLE OF WAYS. SO FOR CLINICAL TRIALS, FOR EXAMPLE, IT IS LOOKING AT THE ENROLLMENT OF THE PATIENTS TO BE INCLUDED IN THE TRIAL, ENSURING THAT IT'S A DIVERSE COHORT, LOOKING AT THE PLAN FOR DOING THE OUTREACH IN ORDER TO INCLUDE THE UNDERSERVED POPULATIONS. AND ALSO PROVIDING JUSTIFICATION FOR WHERE A TRIAL MAY FOCUS ON A PARTICULAR SUBPOPULATION TO ADDRESS AN UNMET NEED. NEXT SLIDE PLEASE.

AND IN SOME CASES, SO WE WILL HAVE MANY APPLICATIONS THAT WILL COME TO US, PARTICULARLY FOR BASIC BIOLOGY OR OUR DISCOVERY OPPORTUNITIES, IN THE HUNDRED OR MORE RANGE. AND SO WHAT WE DO THEN IS CONDUCT THE REVIEW IN TWO STAGES. SO THE FIRST STAGE IS WHERE THE GRANTS WORKING GROUP MEMBERS, INCLUDING THE PATIENT ADVOCATE MEMBERS, CONDUCT A PRE-REVIEW OF THE APPLICATIONS AND SELECT WHICH ONES TO ADVANCE TO A FULL REVIEW. AND SO THIS PROCESS WE CALL POSITIVE SELECTION. AND THE CIRM PRESIDENT AND CIRM TEAM WILL EXAMINE NONSELECTED APPLICATIONS TO DETERMINE IF ANY OF THOSE THAT WERE NOT SELECTED BY THE GRANTS WORKING GROUP MIGHT MERIT A FULL REVIEW AND INCLUDE THOSE IN THAT POOL. AND THEN THE REMAINDER ARE NOT CONSIDERED FURTHER.

AND THEN THE SECOND STAGE IS WHERE THEN THE GRANTS WORKING GROUP MEMBERS REVIEW THE SELECTED APPLICATIONS IN THE USUAL MANNER AND MAKE THEIR SCORING AND FUNDING RECOMMENDATIONS TO THE BOARD. NEXT SLIDE PLEASE.

AND THEN JUST TO NOTE THAT WE HAVE A SCORING THAT WE'VE TAILORED TO OUR DIFFERENT FUNDING OPPORTUNITIES. SO WITH THE CLINICAL PROGRAM, THE WAY THE GRANTS WORKING GROUP SCORES THESE APPLICATIONS IS ON A ONE, TWO, OR THREE BASIS. WITH

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A ONE MEANING THIS IS A GREAT APPLICATION, WARRANTS FUNDING. A TWO MEANS IT IS ONE THAT NEEDS IMPROVEMENT AND HAS CONCERNS THAT SHOULD BE ADDRESSED. AND SO THAT SCORE OF A TWO ALLOWS THE APPLICANT TO GET COMMENTS FROM REVIEWERS AND ALSO ADDRESS THEM WITHOUT HAVING TO GO BACK AND RESTART THE APPLICATION PROCESS. AND SO MANY OF THE APPLICANTS WHO GO THROUGH THIS PROCESS GENERALLY END UP SUCCEEDING AND THEN GETTING A POSITIVE RECOMMENDATION BY ADDRESSING AND/OR FIXING OR PROVIDING ADDITIONAL DATA AS REQUESTED FROM REVIEWERS. AND, OF COURSE, A THREE MEANING THAT IT DOES NOT WARRANT FUNDING.

FOR OUR OTHER APPLICATION TYPES, WE HAVE A MORE FAMILIAR SYSTEM, WHICH IS A SCORE OF ONE TO A HUNDRED WHERE WE CREATE A CUTOFF AT 85. ANYTHING THAT SCORES 85 OR ABOVE, IT'S RECOMMENDED FOR FUNDING WHILE THOSE THAT DON'T ARE NOT RECOMMENDED. AND SO THOSE ARE RANKED BASED ON THE SCORE, AND WHAT WE PROVIDE TO THE BOARD IS A RANKING OF THE ENTIRE PORTFOLIO OF THOSE APPLICATIONS. NEXT SLIDE PLEASE.

AND SO THEN AT THE STAGE OF PROVIDING THOSE RECOMMENDATIONS TO THE APPLICATION REVIEW SUBCOMMITTEE, WE ASK THE QUESTION SHOULD CIRM FUND THESE PROJECTS? AND SO THESE MEETINGS OCCUR, AS

MARIA POINTED OUT, ON A MONTHLY BASIS, OFTEN BY TELECONFERENCE, AND WE PROVIDE THE SCORES AND SUMMARY OF KEY STRENGTHS AND WEAKNESSES FOR EACH OF THE APPLICATIONS. AND THE BOARD AT THAT POINT CONDUCTS A PROGRAMMATIC REVIEW. NEXT SLIDE PLEASE.

AND SO THE PROGRAMMATIC REVIEW IS LOOKING AT THE SET OF APPLICATIONS FROM A SLIGHTLY DIFFERENT PERSPECTIVE. SO WITH THE SCIENTIFIC SCORE AND OVERALL RANKING OF APPLICATIONS IN HAND AND SUMMARY OF SCIENTIFIC WEAKNESSES, THE BOARD CAN THEN, IN ADDITION, LOOK AT THE ALIGNMENT OF THE PROPOSALS WITH CIRM MISSION AND/OR OBJECTIVES OF THE SPECIFIC FUNDING OPPORTUNITY, LOOK AT THEIR POTENTIAL IMPACT ON PATIENTS, THE OVERALL PORTFOLIO OF PROJECTS THAT WE HAVE. FOR EXAMPLE, IF WE DON'T HAVE MANY PROJECTS IN A PARTICULAR AREA, WHETHER SOME OF THE PROJECTS WOULD DESERVE FUNDING AS A RESULT OF OUR PORTFOLIO MAKEUP, THE DEI SCORE, WHICH IS A NEW ELEMENT THAT WE ARE NOW INCORPORATING, WHICH WILL BE PROVIDED BY OUR PATIENT ADVOCATE MEMBERS, AND, OF COURSE, THE AVAILABILITY OF FUNDS. AND, OF COURSE, ALL OF THESE ELEMENTS COMING TOGETHER IN ORDER FOR THE BOARD TO MAKE ITS FINAL DECISIONS ON WHETHER TO APPROVE AN APPLICATION OR NOT. AND THAT, I BELIEVE, CONCLUDES THE PRESENTATION.

MS. BONNEVILLE: THANKS.

CHAIRMAN THOMAS: ANY QUESTIONS? GEORGE.

DR. BLUMENTHAL: THANK YOU. THANK YOU FOR THAT PRESENTATION, GIL. IT WAS VERY CLEAR AS TO PROCESS. ONE QUESTION I HAD WAS ABOUT THE NUMBERS. FOR EXAMPLE, WHAT FRACTION OF PROPOSALS THAT COME IN ARE DEEMED NOT WORTHY OF EVEN BEING REVIEWED? AND IF YOU HAVE AN OVERABUNDANCE OF PROPOSALS, WHAT FRACTION OF THOSE PROPOSALS ARE DEEMED NOT ACTUALLY GOING TO REVIEW? SO I DON'T HAVE A REAL SENSE OF THOSE NUMBERS. DO YOU HAVE A ROUGH IDEA WHAT THOSE ARE?

DR. SAMBRANO: ABSOLUTELY. PROJECTS THAT ARE DEEMED NOT ELIGIBLE ARE GENERALLY VERY FEW. SO OUT OF, SAY, A HUNDRED APPLICATIONS THAT WE MIGHT GET IN OUR DISCOVERY OPPORTUNITY, THERE MAY BE FIVE OR SO THAT WON'T MEET ELIGIBILITY, AND SO THOSE ARE TURNED DOWN. THE REMAINDER WOULD GO TO REVIEW.

THE FRACTION THAT ULTIMATELY GETS SELECTED WOULD BE IN THE ORDER OF ABOUT 50 OR 60 TO GO TO FULL REVIEW, AND THEN OF THOSE ABOUT 10 TO 20 ARE RECOMMENDED FOR FUNDING. SO FOR DISCOVERY, THE FRACTION THAT MIGHT ULTIMATELY GET FUNDED IS ANYWHERE FROM 10 TO 20 PERCENT.

IN OUR CLINICAL PROGRAM, IT'S A LITTLE

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DIFFERENT. THE FUNDING CAN BE AS HIGH AS 50 PERCENT OF THE PROJECTS THAT WE GET. BUT THE PROJECTS THAT WE RECEIVE USUALLY HAVE HAD MORE GUIDANCE AND ADVICE AT THE ONSET BEFORE WE EVEN GET AN APPLICATION. SOMETIMES WE DON'T. AND SO SOMETIMES A PROJECT MAY BE ELIMINATED EARLY. BUT, IN GENERAL, IF THEY GO THROUGH A REVIEW OF A CLINICAL PROJECT THROUGH THAT PROCESS THAT ALLOWS THEM TO RESPOND TO REVIEWER COMMENTS WILL END UP GIVING US ABOUT A 50-PERCENT FUNDING RATE.

DR. BLUMENTHAL: (NODS.)

CHAIRMAN THOMAS: ANY OTHER QUESTIONS OR COMMENTS? THANK YOU, GIL. MARIA.

MS. BONNEVILLE: SO WE'LL JUST GO ON TO THE NEXT PRESENTATION, AND THAT IS GEOFF LOMAX.

DR. LOMAX: GREAT. THANKS, EVERYONE. I'M GEOFF LOMAX. I ACTUALLY JOINED THE CIRM TEAM BACK IN 2005, AND AT THAT TIME I WAS LEADING UP CIRM'S EFFORT TO DEVELOP THE MEDICAL AND ETHICAL STANDARDS WORKING GROUP. SO I'M GOING TO TELL YOU A LITTLE BIT ABOUT THAT EXPERIENCE. COULD WE GET THE FIRST SLIDE, PLEASE.

SO THE MEDICAL AND ETHICAL STANDARDS WORKING GROUP, WE REFER TO IT COLLOQUIALLY AS THE SWG. THE WORKING GROUP IS CHARGED WITH PROVIDING

RECOMMENDATIONS TO THE ICOC ON HOW CIRM CAN DELIVER ON ITS MISSION WHILE ADVANCING HIGH ETHICAL STANDARDS FOR RESEARCH. THE SWG'S RECOMMENDATIONS ENCOMPASS MEDICAL AND FINANCIAL ASPECTS OF OUR RESEARCH, ETHICAL PROCEDURES FOR OBTAINING TISSUE FROM RESEARCH DONORS, PARTICULARLY WHEN THESE DONATIONS -- PARTICULARLY WHEN THE TISSUE DONATION IS INTENDED FOR THE DERIVATION OF PLURIPOTENT STEM CELL LINES. AND WE ALSO MAKE RECOMMENDATIONS FOR THE INSTITUTIONAL OVERSIGHT OF RESEARCH BY OUR AWARDEES.

THE WORKING GROUP IS COMPRISED OF THE ICOC CHAIRPERSON, PATIENT ADVOCATES, STEM CELL SCIENTISTS, AND MEDICAL ETHICISTS. HISTORICALLY THE STANDARDS WORKING GROUP HAS FOCUSED ON A COMPARATIVELY NARROW SET OF CONSIDERATIONS RELATED TO THE INSTITUTIONAL REVIEW AND OVERSIGHT OF CIRM-FUNDED RESEARCH PROTOCOLS AND BEST PRACTICES FOR THE PROTECTION OF RESEARCH DONORS WITH REGARD TO PAYMENTS AND INFORMED CONSENT.

SO WHAT I'LL DO IS I'LL HIGHLIGHT A COUPLE OF EXAMPLES OF THESE ACTIVITIES. NEXT SLIDE PLEASE.

IN 2005, BECAUSE OF THE BUSH ADMINISTRATION'S BAN ON THE DERIVATION OF EMBRYONIC STEM CELL LINES, THERE WAS A GAP IN FEDERAL

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LEGISLATION. SPECIFICALLY, GUIDELINES DID NOT EXIST FOR THE DERIVATION AND USE OF HUMAN EMBRYONIC STEM CELL LINES. TO ADDRESS THIS GAP, THE NATIONAL ACADEMIES DEVELOPED A FRAMEWORK FOR THE OVERSIGHT OF HUMAN EMBRYONIC STEM CELL RESEARCH. THE STANDARDS WORKING GROUP USED THE NATIONAL ACADEMIES' GUIDELINES TO DEVELOP A MORE COMPREHENSIVE FRAMEWORK FOR BROAD RESEARCH OVERSIGHT WHICH WAS SUBSEQUENTLY THEN ADOPTED BY THE ICOC.

THE CIRM REQUIREMENTS INCLUDE REVIEW AND APPROVAL OF PROTOCOLS BY A STEM CELL RESEARCH OVERSIGHT COMMITTEE, INFORMED CONSENT REQUIREMENTS FOR GAMETE AND EMBRYO RESEARCH, AND CRITERIA FOR DETERMINING THAT CELL LINES ARE ACCEPTABLE FOR USE IN CIRM-FUNDED RESEARCH. NEXT SLIDE PLEASE.

SO KEEP IN MIND CIRM WAS AMONG THE FIRST FUNDING AGENCIES TO REQUIRE THE CREATION OF A STEM CELL RESEARCH OVERSIGHT COMMITTEE. SO WE EMBARKED ON A PROCESS TO SUPPORT THE EFFECTIVE IMPLEMENTATION OF THIS OVERSIGHT MECHANISM. AND BETWEEN 2008 AND 2010, WE HAD A NUMBER OF WORKSHOPS TO FACILITATE IMPLEMENTATION. AND IN THESE WORKSHOPS REPRESENTATIVES FROM AWARDEE INSTITUTIONS SHARED IMPLEMENTATION PROTOCOLS WITH EACH OTHER IN A VERY SORT OF COLLABORATIVE AND DISCURSIVE WAY, DESCRIBED

THE INTERACTIONS BETWEEN STEM CELL RESEARCH OVERSIGHT COMMITTEES AND OTHER REVIEW COMMITTEES WITHIN THEIR INSTITUTIONS; FOR EXAMPLE, THE INSTITUTIONAL REVIEW BOARDS OR IRB'S OR THE ANIMAL CARE COMMITTEES, THE IACOC'S.

IN ADDITION, THEY PROVIDED FEEDBACK BACK TO CIRM FOR HOW WE COULD ENHANCE THE EFFECTIVENESS OF OUR REGULATIONS. SO IT WAS VERY MUCH A TWO-WAY CONVERSATION, AND I THINK IT RESULTED IN A MORE EFFECTIVE REGULATORY FRAMEWORK. NEXT SLIDE PLEASE.

IN 2011 THE STANDARDS WORKING GROUP INITIATED A PROCESS DESIGNED TO SUPPORT THE CREATION OF CIRM'S INDUCED PLURIPOTENT STEM CELL BANK. DR. MILLAN ALLUDED TO THIS INTERNATIONALLY RECOGNIZED BANK IN HER REVIEW OF THE SCIENTIFIC SYMPOSIUM. AND THE WORKING GROUP DEVELOPED A SET OF RECOMMENDATIONS FOR EDUCATING AND CONSENTING PROSPECTIVE DONORS. THIS WAS THEIR PRIMARY FOCUS AS THE BANK WAS INTENDED TO COLLECT THOUSANDS OF SKIN AND BLOOD SAMPLES FROM DONORS THAT WOULD BE CONVERTED INTO PLURIPOTENT STEM CELLS.

CIRM THEN PRODUCED A NUMBER OF SPECIFIC OUTPUTS DESIGNED TO SUPPORT THE BANKING INITIATIVE. THESE OUTPUTS INCLUDE A MODEL INFORMED CONSENT TEMPLATE SPECIFICALLY TAILORED TO THE AIMS AND

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OBJECTIVES OF THE CIRM BANK, DONOR EDUCATION MATERIALS EXPLAINING THE POTENTIAL OF INDUCED PLURIPOTENT STEM CELLS, AND HOW THE DERIVED LINES WOULD BOTH BE USED IN RESEARCH AND DISTRIBUTED BECAUSE IT'S A GLOBAL RESOURCE, SO IT WAS IMPORTANT FOR THE DONORS TO REALLY UNDERSTAND WHERE THEIR CELLS WOULD BE GOING. IN ADDITION, THERE WERE VERIFICATION PROCEDURES DEVELOPED TO SUPPORT THE USE OF DERIVED LINES IN RESEARCH BROADLY. NEXT SLIDE PLEASE.

MOST RECENTLY THE STANDARDS WORKING GROUP HAS RECOMMENDED CIRM ABIDE BY THE NATIONAL ACADEMIES' RECOMMENDATIONS ON GENOME EDITING. AND THE WORKING GROUP ITSELF HAS PROVIDED ADDITIONAL RECOMMENDATIONS FOR CONSENTING DONORS PARTICULARLY WHEN THEY'RE PROVIDING EMBRYOS FOR RESEARCH THAT MAY BE USED IN GENOME EDITING STUDIES.

AND AS WE NOW EMBARK ON THE PROPOSITION 14 ERA, ETHICS POLICY ISSUES CONTINUE TO EVOLVE, AND THERE ARE A NUMBER OF AREAS FOR FUTURE CONSIDERATION. THESE AREAS INCLUDE ONGOING CONSENT FOR CLINICAL TRIALS, CONTINUED OVERSIGHT OF EMBRYO RESEARCH AS SUCH ACTIVITIES CONTINUE TO BE INELIGIBLE FOR FEDERAL FUNDING. THUS, THERE'S NO NATIONAL STANDARDS FOR HOW THIS RESEARCH SHOULD BE

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CONDUCTED.

IN ADDITION, STANDARDS INVOLVING GENETIC MEDICAL TREATMENTS, WHICH ARE CALLED OUT IN PROPOSITION 14, IS ANOTHER TOPIC. WHILE WE ARE NOT AWARE OF ANY SPECIFIC REGULATORY GAPS AT THIS TIME, WE REMAIN VIGILANT IN THIS EVOLVING AREA OF RESEARCH. AND POLICIES FOR THE REIMBURSEMENT OF RESEARCH PARTICIPANTS, CAREGIVERS, AND THEIR FAMILIES AS THIS IS ANOTHER AREA THAT'S CALLED OUT IN PROPOSITION 14. SO THESE ARE FUTURE CONSIDERATIONS THAT, AGAIN, THE BOARD MAY WISH TO CONVENE THE STANDARDS WORKING GROUP TO DEVELOP RECOMMENDATIONS WHICH THEY CAN THEN TAKE UNDER CONSIDERATION. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, GEOFF. QUESTIONS OR COMMENTS FROM MEMBERS OF THE BOARD?

I WILL NOTE THAT, AS GEOFF LAID OUT, THAT THIS WORKING GROUP DOES HAVE ROOM FOR BOARD PARTICIPATION. AND THOSE OF YOU WHO ARE PARTICULARLY INTERESTED IN ETHICAL ISSUES, PLEASE LET US KNOW. AS THE FIELD CONTINUES TO DEVELOP AND ACCELERATE, THERE ARE GOING TO BE MORE AND MORE ISSUES OF NOTE. GO BACK THE LAST COUPLE OF YEARS, YOU HAD THE DESIGNER BABIES IN CHINA, YOU HAD THE HUMAN THERAPEUTIC CLONING AT THE OREGON HEALTH AND

SCIENCE UNIVERSITY, BOTH OF WHICH GENERATED A CONSIDERABLE AMOUNT OF DISCUSSION AND POSITION PAPERS INTERNATIONALLY. THESE SORTS OF THINGS ARE GOING TO BE RECURRING AT A MORE FREQUENT RATE THAN LESS. SO PLEASE, IF YOU ARE INTERESTED, LET US KNOW. LARRY.

DR. GOLDSTEIN: THANK YOU, J.T. SO, GEOFF, THAT WAS VERY HELPFUL. ARE YOU GOING TO SOON UNDERTAKE THE PROBLEM OF SO-CALLED I-BLASTOIDS OR THESE EMBRYO-LIKE STRUCTURES THAT HAVE JUST BEEN REPORTED?

DR. LOMAX: WE'VE BEEN TRACKING THE LITERATURE THERE AND HAVE SORT OF BEEN BUILDING THE BACKGROUND IF THAT IS A CONVERSATION WHICH IT BECOMES APPARENT WE NEED TO TAKE UP BECAUSE THERE'S SOME SORT OF GAP IN OUR EXISTING PROCEDURES AND POLICIES, THEN OBVIOUSLY WE ARE WELL POSITIONED TO DO SO. BUT AT THE MOMENT, I'M NOT AWARE OF ANY GAP IN OUR EXISTING REGULATIONS THAT IS CREATING ANY SORT OF BARRIER TO EXISTING RESEARCH PROTOCOLS.

DR. GOLDSTEIN: SO ARE YOU SAYING THAT EXISTING REGULATIONS ALLOW THAT KIND OF RESEARCH BECAUSE THE NIH IS GETTING VERY TANGLED UP IN THIS AND HAVE NOT MADE VERY CLEAR STATEMENTS. AND SO WE MAY BE THE CLEANEST GAME IN TOWN TO DO THIS, BUT

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THERE NEEDS TO BE SOME ETHICAL OVERSIGHT, DOESN'T THERE?

DR. LOMAX: AGAIN, I WOULD DEFER TO OUR EXISTING FRAMEWORK TAKES THESE TYPES OF PROTOCOLS INTO ACCOUNT. BUT IF WE FEEL THERE'S A NEED TO KIND OF REVISIT THOSE GUIDELINES IN LIGHT OF THE EVOLVING SCIENCE, THEN WE COULD CONVENE THE WORKING GROUP TO TAKE THAT UNDER CONSIDERATION.

CHAIRMAN THOMAS: LARRY, I THINK IT'S VERY HELPFUL THAT YOU RAISE THIS AND ANY OTHER ISSUES BECAUSE YOU'RE SO OBVIOUSLY PLUGGED INTO THE FRONT LINE ON WHAT'S GOING ON. THAT'S VERY HELPFUL.

DR. GOLDSTEIN: THANK YOU, J.T.

CHAIRMAN THOMAS: IF YOU WOULD LIKE TO BE ON THIS WORKING GROUP, THAT WOULD BE GREAT.

MS. BONNEVILLE: IT IS JUST FOR PATIENT ADVOCATE MEMBERS, J.T.

CHAIRMAN THOMAS: I'M SORRY. THANK YOU. SORRY ABOUT THAT, LARRY.

DR. GOLDSTEIN: NO SWEAT.

CHAIRMAN THOMAS: ANY OTHER COMMENTS OR QUESTIONS? THANKS VERY MUCH, GEOFF.

DR. LOMAX: THANK YOU.

CHAIRMAN THOMAS: MARIA.

MS. BONNEVILLE: JAMES IS NEXT.

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MR. HARRISON: THANKS, MARIA. YIMI, IF YOU COULD MOVE ON TO THE NEXT SLIDE.

SO I'M GOING TO BE BRIEFLY DISCUSSING THE THIRD OF CIRM'S WORKING GROUPS WHICH WERE ESTABLISHED BY PROP 71. BY THE WAY, THE COMPOSITION AND THE FUNCTIONS OF EACH OF THESE WORKING GROUPS IS PRESCRIBED BY STATUTE. SO WE DO HAVE CERTAIN LIMITATIONS WITHIN WHICH WE NEED TO WORK.

THE FACILITIES WORKING GROUP IS COMPOSED OF 11 MEMBERS. THEY INCLUDE THE CHAIR OF THE BOARD, SIX MEMBERS OF THE GRANTS WORKING GROUP WHO HAVE HISTORICALLY BEEN DRAWN FROM AMONG THE PATIENT ADVOCATE MEMBERS OF THE GRANTS WORKING GROUP, AND THEN FOUR SPECIALISTS IN REAL ESTATE IN THE STATE OF CALIFORNIA.

THE FUNCTIONS OF THE FACILITIES WORKING GROUP ARE REALLY THREEFOLD. THEY ARE CHARGED WITH RECOMMENDING STANDARDS FOR APPLICATIONS AND REVIEW OF AWARDS FOR FACILITIES FUNDING FOR NONPROFIT INSTITUTIONS IN CALIFORNIA. THEY'RE ALSO CHARGED WITH THE OVERSIGHT OF EXISTING FACILITY AWARDS, AND THEY'RE CHARGED WITH REVIEWING AND RECOMMENDING APPLICATIONS FOR FACILITIES FUNDING. PROP 71 EARMARKED UP TO 286.5 MILLION FOR FACILITIES. NEXT SLIDE PLEASE.

THE FACILITIES WORKING GROUP WAS FIRST ESTABLISHED IN 2005. AND BECAUSE PROP 71 PUT A PRIORITY ON BUILDING FACILITIES THAT WERE FREE OF FEDERAL FUNDING TO ENSURE THAT RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS COULD PROCEED UNIMPEDED, THE WORKING GROUP WAS EXTRAORDINARILY BUSY IN THE EARLY YEARS BETWEEN 2005 AND 2007. IT MET 16 TIMES. THE WORKING GROUP DEVELOPED STANDARDS FOR APPLICATIONS FOR AWARDS AND FOR THE OVERSIGHT OF FACILITIES FUNDING, AND THEY ALSO PARTICIPATED IN THE REVIEW OF APPLICATIONS FOR TWO PROGRAMS FUNDED UNDER PROP 71. THE FIRST WAS A SHARED LABS PROGRAM, AND THE FACILITIES WORKING GROUP REVIEWED AND MADE RECOMMENDATIONS WITH RESPECT TO THOSE AWARDS IN 2007 WITH THE SCIENTIFIC MERIT OF THE APPLICATIONS BEING SUBJECT TO REVIEW BY THE GWG.

THE CRITERIA THAT THE FACILITIES WORKING GROUP FOCUSED ON INCLUDED FEASIBILITY, COST, TIMELINE, AND INSTITUTIONAL COMMITMENT. AND ULTIMATELY CIRM FUNDED 17 SHARED LAB PROGRAMS. THIS, OF COURSE, WILL BE THE STARTING POINT FOR SHARED LABS 2.0, WHICH IS A PROGRAM THAT MARIA MILLAN MENTIONED EARLIER TODAY, WHICH WILL BE FORTHCOMING AT SOME POINT IN THE FUTURE. NEXT SLIDE PLEASE.

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IN ADDITION TO THE SHARED LABS, THE FACILITIES WORKING GROUP REVIEWED AND RECOMMENDED APPLICATIONS FOR CIRM'S MAJOR FACILITIES PROGRAMS. THIS OCCURRED IN 2007 AND 2008. AND ONCE AGAIN, THE GRANTS WORKING GROUP TOOK THE LABORING ROLE WITH RESPECT TO THE REVIEW OF THE SCIENTIFIC MERIT OF APPLICATIONS FOR MAJOR FACILITIES. BUT THE FACILITIES WORKING GROUP REVIEWED THE APPLICATIONS FOR TECHNICAL FACILITIES ISSUES, AND THEY USED CRITERIA INCLUDING URGENCY; VALUE, WHICH ENCOMPASSED EXCELLENCE, INNOVATION, AND COST, FUNCTIONALITY, SHARED RESOURCES, AND LEVERAGE. AND FOR THIS PROGRAM, THE LEVEL OF FUNDING VARIED BASED ON THE COMBINATION OF USES THAT WERE PROPOSED FOR THE FACILITY. SO INSTITUTES INCLUDED RESEARCH INVOLVING DISCOVERY, TRANSLATIONAL, AND CLINICAL PROGRAMS; WHEREAS, CENTERS OF EXCELLENCE WERE PROPOSED FOR TWO OF THE THREE ELEMENTS OF RESEARCH, AND SPECIAL PROGRAMS HAD ONLY ONE ELEMENT OF RESEARCH. NEXT SLIDE PLEASE, YIMI.

ULTIMATELY CIRM FUNDED 12 NEW RESEARCH FACILITIES IN CALIFORNIA AT A TOTAL COST OF $271 MILLION. THIS INCLUDED BOTH FUNDING FOR FACILITIES AS WELL AS RESEARCH EQUIPMENT WHICH WAS, IN PART, FUNDED USING RESEARCH DOLLARS. CIRM FUNDED A NUMBER

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OF CIRM INSTITUTES. I WILL NOT READ THE LIST, BUT YOU CAN SEE THEM IDENTIFIED THERE.

AND ON THE NEXT SLIDE, YIMI, PLEASE, CIRM ALSO FUNDED TWO CENTERS OF EXCELLENCE AND THEN SPECIAL PROGRAMS AT SANTA CRUZ, MERCED, AND SANTA BARBARA. NEXT SLIDE PLEASE, YIMI.

ULTIMATELY THESE FACILITIES GENERATED MORE THAN $543 MILLION IN MATCHING FUNDS, 13,000 JOB YEARS FOR CONSTRUCTION, AND BROUGHT IN AN ESTIMATED $100 MILLION IN STATE TAX REVENUES. AND I THINK ALL WILL CONCUR THAT THIS WAS AN EXTRAORDINARILY SUCCESSFUL PROGRAM IN ESTABLISHING THE INFRASTRUCTURE NECESSARY TO CARRY OUT THE RESEARCH THAT CIRM CONTINUES TO FUND TODAY. NEXT SLIDE PLEASE.

THE FACILITIES WORKING GROUP HAS NOT MET SINCE 2010. AND BECAUSE PROP 14 PROVIDES ADDITIONAL FUNDING FOR FACILITIES AWARDS, THE WORKING GROUP NEEDS TO BE RECONSTITUTED IN THE FUTURE. IT'S CHARGED WITH REVIEWING AND RECOMMENDING APPLICATIONS FOR FACILITIES AWARD BOTH FOR A NEW SHARED LAB PROGRAM WHICH HAS BEEN ALLOCATED UP TO $26 MILLION, AND THEN A SECOND PROGRAM FOR COMMUNITY CARE CENTERS OF EXCELLENCE WHICH ARE KIND OF COMPARED TO SATELLITES OF THE EXISTING ALPHA CLINICS FOR UP TO

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$78 MILLION. J.T., BACK TO YOU.

CHAIRMAN THOMAS: THANK YOU, JAMES. ANY QUESTIONS OR COMMENTS FOR JAMES? VERY CLEAR AND CONCISE IN A TYPICAL JAMES FASHION. THANK YOU. MARIA.

MS. BONNEVILLE: LET'S SEE WHO'S UP NEXT. YIMI, WHAT'S THE NEXT SLIDE. OH, IT'S JAMES AGAIN. JAMES, TAKE IT AWAY.

MR. HARRISON: MORE FUN. SO I'M JUST GOING TO BRIEFLY WALK YOU THROUGH THE VARIOUS BOARD POLICIES THAT APPLY TO YOU AS BOARD MEMBERS AND TO THE BOARD GENERALLY. NEXT SLIDE PLEASE, YIMI.

FIRST I'D LIKE TO FIRST BRIEFLY TOUCH ON THE CONFLICT OF INTEREST POLICIES OF WHICH THERE ARE MANY, AND I'M SURE YOU ALL KNOW THEM WELL. NEXT SLIDE PLEASE, YIMI.

AS YOU KNOW, ONE OF THE SOMEWHAT UNIQUE FEATURES OF PROP 71 AND PROP 14 IS THAT BOARD MEMBERS ARE APPOINTED BASED ON THEIR EXPERTISE. AND I THINK AS THE BOARD SELF-EVALUATION ILLUSTRATES, CIRM HAS BENEFITED TREMENDOUSLY FROM THE DIVERSE EXPERTISE AND EXPERIENCE OF BOARD MEMBERS FROM THOSE WITH EXPERIENCE AS LEADERS OF RESEARCH INSTITUTIONS TO PATIENT ADVOCATES TO MEMBERS OF INDUSTRY APPOINTED FROM LIFE SCIENCE COMMERCIAL COMPANIES.

THE BROAD ARRAY OF VIEWPOINTS HAS DEFINITELY ENRICHED THE DEBATE AS WAS CLEAR TODAY.

ONE OF THE REALLY IMPORTANT THINGS THAT WE ALL NEED BEAR IN MIND IS THAT, EVEN THOUGH MEMBERS ARE APPOINTED BASED ON THEIR EXPERTISE AS LEADERS, FOR EXAMPLE, AT RESEARCH INSTITUTIONS, ALL OF YOU ULTIMATELY REPRESENT THE INTERESTS OF ALL CALIFORNIANS, NOT JUST THOSE OF YOUR RESEARCH INSTITUTION. AND WHILE WE OBVIOUSLY BENEFIT FROM YOUR EXPERIENCE, ULTIMATELY OUR FOCUS IS ON DECISIONS THAT BENEFIT ALL CALIFORNIANS. NEXT SLIDE PLEASE.

THERE ARE A NUMBER OF CONFLICT OF INTEREST POLICIES THAT APPLY TO YOU AS BOARD MEMBERS. YOU ARE PUBLIC OFFICIALS FOR PURPOSES OF CALIFORNIA LAW. THAT MEANS YOU'RE SUBJECT TO A PANOPLY OF CONFLICT RULES INCLUDING THE POLITICAL REFORM ACT, WHICH PROHIBITS OFFICIALS FROM PARTICIPATING IN DECISIONS IF IT'S REASONABLY FORESEEABLE THAT THE DECISION WILL HAVE A MATERIAL FINANCIAL EFFECT ON ONE OF YOUR OWN FINANCIAL INTERESTS. THE POLITICAL REFORM ACT ALSO IMPOSES A REQUIREMENT THAT YOU DISCLOSE YOUR ECONOMIC INTERESTS, WHICH IS EMBODIED IN FORM 700, WHICH YOU HAVE A WEEK LEFT TO COMPLETE. THOSE ANNUAL FORMS ARE DUE ON APRIL 1ST, AND THEY REFLECT

YOUR INTERESTS IN CALENDAR YEAR 2020. YOU'RE ALSO REQUIRED TO TAKE THE ATTORNEY GENERAL'S ETHNICS COURSE ONCE EVERY TWO YEARS, AND WE TRACK THAT TO ENSURE THAT YOU COMPLY.

THERE ARE ADDITIONAL CONFLICT OF INTEREST RULES, JUST TO MAKE THINGS COMPLEX. ONE IS GOVERNMENT CODE SECTION 1090 WHICH IS SPECIFIC TO CONFLICTS OF INTEREST IN CONTRACTS. THE PENALTIES FOR VIOLATING THIS PARTICULAR PROVISION CAN BE QUITE SEVERE, INCLUDING CRIMINAL PENALTIES. AND THEY ALSO CAN RESULT IN WHATEVER CONTRACT HAS BEEN MADE IN VIOLATION OF GOVERNMENT CODE SECTION 1090 BEING VOIDED. IN ESSENCE, THE LAW PROHIBITS A PERSON FROM BEING FINANCIALLY INTERESTED IN A CONTRACT BOTH IN THE PERSON'S OFFICIAL CAPACITY AND IN THE PERSON'S PRIVATE CAPACITY.

AND THEN JUST TO MAKE MATTERS A LITTLE BIT MORE COMPLICATED, IF THE COURTS OR THE ATTORNEY GENERAL CAN'T FIND A VIOLATION OF A CONFLICT RULE IN GOVERNMENT CODE SECTION 1090 OR THE POLITICAL REFORM ACT, THEY CAN ALWAYS TURN TO THE COMMON LAW OF CONFLICTS, WHICH THEY DO ON OCCASION. AND THE COMMON LAW OF CONFLICTS IS ESSENTIALLY A BODY OF LAW WHICH PROVIDES THAT EVEN IF YOU DON'T HAVE A FINANCIAL INTEREST, IF YOU HAVE A PARTICULAR BIAS OR

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ARE UNABLE TO MAKE A FAIR DECISION, YOU CAN BE DEEMED TO VIOLATE THE COMMON LAW CONFLICT OF INTEREST, THE MOST FAMOUS CASE OF WHICH WAS A CITY PLANNING COMMISSIONER WHO WAS VEHEMENTLY OPPOSED TO A PROJECT THAT WOULD HAVE OBSTRUCTED THE VIEW OF THE OCEAN FROM HIS OWN HOME AND WHO WAS HELD TO HAVE VIOLATED THE COMMON LAW CONFLICTS OF INTEREST BECAUSE HE DIDN'T VIOLATE EITHER THE POLITICAL REFORM ACT OR GOVERNMENT CODE SECTION 1090.

SO THESE LAWS ARE QUITE EXTENSIVE AND IMPORTANT TO BEAR IN MIND AS YOU'RE CALLED TO MAKE DECISIONS ON THE BOARD. NEXT SLIDE PLEASE, YIMI.

IT'S IMPORTANT TO NOTE THAT THE BOARD HAS ADOPTED CONFLICT RULES THAT GO BEYOND THE REQUIREMENTS OF STATE LAW. AND THESE INCLUDE A PROHIBITION ON MEMBERS PARTICIPATING IN OR ATTEMPTING TO INFLUENCE A DECISION REGARDING AN APPLICATION SUBMITTED BY THEIR OWN EMPLOYER. THEY ALSO INCLUDE A RULE PROHIBITING MEMBERS FROM APPLYING FOR CIRM FUNDING, ACTING AS A PI ON A CIRM APPLICATION, OR RECEIVING SALARY SUPPORT THROUGH A CIRM AWARD.

IN ADDITION, MEMBERS ARE PRECLUDED FROM ACCEPTING GIFTS FROM A PERSON OR ENTITY THAT IS EITHER DOING BUSINESS WITH CIRM OR SEEKING TO DO

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BUSINESS WITH CIRM IF THE GIFT IS INTENDED TO INFLUENCE OR REWARD THE MEMBER FOR OFFICIAL ACTION. NEXT SLIDE PLEASE, YIMI.

SO I ALSO WANTED TO BRIEFLY TOUCH ON THE BOARD BYLAWS. WE DISCUSSED SEVERAL ISSUES TODAY, INCLUDING THE COMPOSITION OF THE APPLICATION REVIEW SUBCOMMITTEE, AS WELL AS SEVERAL SUBCOMMITTEES OF THE BOARD. THE BOARD BYLAWS DEFINE THE FUNCTIONS OF THE BOARD, INCLUDING DEFINING CERTAIN STANDING SUBCOMMITTEES, WHICH INCLUDE THE APPLICATION REVIEW SUBCOMMITTEE, THE GOVERNANCE SUBCOMMITTEE, AND THE LEGISLATIVE SUBCOMMITTEE.

IN JUNE WE WILL BE BRINGING AMENDMENTS TO YOU FOR YOUR CONSIDERATION TO DEAL WITH BOTH SOME OF THE CHANGES MADE BY PROP 14 AS WELL AS SOME OF THE OTHER CHANGES WE DISCUSSED TODAY, INCLUDING EXPANDING THE COMPOSITION OF THE APPLICATION REVIEW SUBCOMMITTEE, ELIMINATING THE LEGISLATIVE SUBCOMMITTEE, AND CONSOLIDATING THE GOVERNANCE AND EVALUATION SUBCOMMITTEE. NEXT SLIDE PLEASE, YIMI.

THE BOARD HAS ALSO ADOPTED A CODE OF CONDUCT. THIS ESTABLISHES AN EXPECTATION THAT MEMBERS REGULARLY ATTEND AND PARTICIPATE IN BOARD MEETINGS AND ANY SUBCOMMITTEES OF WHICH THEY ARE MEMBERS. IMPORTANTLY, BECAUSE THE BOARD DOES HAVE

ACCESS TO CONFIDENTIAL INFORMATION, THE CODE OF CONDUCT EXPRESSLY REQUIRES MEMBERS TO PROTECT THE CONFIDENTIALITY OF INFORMATION PROVIDED TO THEM AS MEMBERS OF THE BOARD, INCLUDING IN THEIR CAPACITY AS MEMBERS OF THE WORKING GROUPS OR BOARD SUBCOMMITTEES.

AND THE CODE OF CONDUCT ALSO REQUIRES THAT ANY REQUESTS BY MEMBERS OF THE BOARD TO THE CIRM TEAM TO PERFORM SPECIFIC TASKS BE COORDINATED THROUGH THE CHAIR AND THE PRESIDENT SO THAT THEY CAN ENSURE THAT THE REQUESTS ARE BOTH PROMPTLY RESPONDED TO AND THAT THE RIGHT TEAM MEMBERS ARE HANDLING THEM. NEXT SLIDE PLEASE.

FINALLY, THE BOARD HAS AN INTERNAL GOVERNANCE POLICY, WHICH WE WILL ALSO BE BRINGING BACK TO THE BOARD CONSIDERATION IN JUNE. THIS DEFINES THE RESPONSIBILITIES OF THE CHAIR, THE VICE CHAIR, AND THE PRESIDENT AND PROVIDES FOR THE ADMINISTRATIVE AND ORGANIZATIONAL STRUCTURE OF CIRM. NEXT SLIDE PLEASE, YIMI. AND NOW BACK TO YOU, MARIA.

MS. BONNEVILLE: DOES THE BOARD HAVE ANY QUESTIONS ON THE PRESENTATION JAMES JUST MADE? IT DOES NOT LOOK LIKE IT. BEN, YOU'RE NEXT.

MR. HUANG: GOOD AFTERNOON, BOARD MEMBERS.

I'M NOT AS WELL SPOKEN AS JAMES, NOR IS MY GARAGE OFFICE BACKGROUND AS NICE, BUT PLEASE BEAR WITH ME. NEXT SLIDE.

SO THE BASIS FOR THE CIRM INTELLECTUAL PROPERTY REGS DERIVES FROM THIS CLAUSE IN PROPOSITION 71, WHICH STATES THAT THE ICOC SHALL ESTABLISH STANDARDS THAT REQUIRE ALL GRANTS AND LOAN AWARDS BE SUBJECT TO INTELLECTUAL PROPERTY AGREEMENTS THAT BALANCE THE OPPORTUNITY OF THE STATE OF CALIFORNIA TO BENEFIT FROM THE PATENTS, ROYALTIES, AND LICENSES THAT RESULT FROM BASIC RESEARCH, THERAPY DEVELOPMENT, AND CLINICAL TRIALS WITH THE NEED TO ASSURE THAT ESSENTIAL MEDICAL RESEARCH IS NOT UNREASONABLY HINDERED BY THESE INTELLECTUAL PROPERTY AGREEMENTS.

ALL REVENUES RECEIVED THROUGH THE INTELLECTUAL PROPERTY AGREEMENTS ESTABLISHED PURSUANT TO THIS SUBDIVISION SHALL BE DEPOSITED INTO THE STATE'S GENERAL FUND. NEXT SLIDE PLEASE.

THE IP REGULATIONS COVER THE FOLLOWING TOPICS: THE REPORTING TO CIRM OF ALL INVENTIONS AND LICENSES; PUBLICATION REQUIREMENTS, WHICH COVERS THE SUBMITTAL OF PUBLICATION DISCLOSURE FORMS TO CIRM; AND IT ALSO REQUIRES INSERTING LANGUAGE CREDITING CIRM.

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PATENT OWNERSHIP. THIS IS IMPORTANT. IT EXPLICITLY STATES THAT CIRM DOES NOT HAVE AN OWNERSHIP INTEREST IN INVENTIONS AND PATENTS THAT ORIGINATE FROM THE GRANTEES. LICENSING AND ASSIGNMENT OF CIRM-FUNDED INVENTIONS AND TECHNOLOGY, THESE REQUIREMENTS STATES THE DUE DILIGENCE THAT GRANTEES HAVE IN ORDER TO LICENSE.

ACCESS REQUIREMENTS FOR PRODUCTS. FOR DRUG PRODUCTS, GRANTEES OR THE EVENTUAL COMMERCIALIZING ENTITY WILL NEED TO SUBMIT TO CIRM AN ACCESS PLAN FOR CALIFORNIANS UNDER A CERTAIN INCOME LEVEL.

REVENUE SHARING I'LL DISCUSS IN THE NEXT TWO SLIDES.

AND MARCH-IN RIGHTS, WHICH IS SIMILAR TO THE NIH IN CONCEPT, AND ALLOWS CIRM TO STEP IN TO LICENSE INVENTIONS AND TECHNOLOGY UNDER VERY CERTAIN CIRCUMSTANCE. NEXT SLIDE PLEASE.

HERE ARE THE VERSIONS OF THE CIRM IP REGULATIONS. MOST OF THE SIGNIFICANT CHANGES HAVE A REVENUE SHARING FOCUS. THE INITIAL 2006 VERSION ESTABLISHED FORMULAS FOR LICENSING REVENUE FROM PATENTS FOR NONPROFITS AND FOR-PROFITS AS WELL AS ESTABLISHING A FORMULA FOR ROYALTIES FROM FOR-PROFIT SELF-COMMERCIALIZATION.

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THE 2009 VERSION ADDRESSED THE LAUNCH OF CIRM'S DISEASE TEAM PROGRAM WHICH FUNDED CLINICAL RESEARCH. IT ADDRESSED IT BY ADDING CIRM-FUNDED TECHNOLOGY LICENSING OBLIGATIONS WHICH WOULD COVER SUCH THINGS AS CLINICAL DATA. THIS VERSION ALSO TWEAKED THE FORMULAS FOR REVENUE SHARING.

THE 2014 VERSION REVISED THE REVENUE SHARING FORMULA FOR NONPROFITS AND CHANGED THE FOR-PROFIT ROYALTY FORMULA.

AND THE CURRENT 2018 VERSION CHANGED THE NONPROFIT LICENSING FORMULA INTO A ROYALTY FORMULA. SO NOW ALL GRANTEES ARE TREATED THE SAME.

I WOULD LIKE TO POINT OUT THAT THESE REVENUE SHARING TERMS ARE NOT RETROACTIVE. SO CIRM STILL NEEDS TO ENGAGE GRANTEES UNDER ALL OF THESE VARIOUS REGULATIONS. FOR EXAMPLE, FOR OUR CLINICAL LEVEL AWARDS, WHICH ARE DISEASE TEAM AND CLINICAL GRANTS, CIRM HAS APPROXIMATELY 33 UNDER THE 2009 VERSION, 54 UNDER THE 2014 VERSION, AND 26 UNDER THE CURRENT VERSION WHICH WE NEED TO TRACK. NEXT SLIDE.

AND HERE'S CIRM'S CURRENT REVENUE SHARING FORMULA. LOOKING AT THE SECOND PARAGRAPH, I'LL JUST KIND OF READ OUT THE ROYALTY AND GIVE AN EXAMPLE. WE CALCULATE A ROYALTY AT THE RATE OF .1 PERCENT PER MILLION DOLLARS OF THE CIRM AWARD. AND THIS ROYALTY

WILL EXIST FOR THE EARLIER OF TEN YEARS FROM THE DATE OF FIRST COMMERCIAL SALE OR UNTIL RECEIPT OF 9X OF THE GRANT AMOUNT BY THE STATE. FOR EXAMPLE, AN AWARD TOTALING $15 MILLION WILL RESULT IN ROYALTY PAYMENTS OF 1.5 PERCENT OF NET COMMERCIAL REVENUES LASTING UNTIL THE EARLIER OF TEN YEARS AFTER FIRST SALE OR UNTIL $135 MILLION IS DEPOSITED IN THE GENERAL FUND.

AFTER FULFILLMENT OF THE ROYALTY ABOVE AND UNDER CERTAIN OTHER REQUIREMENTS, THERE'S ALSO AN ADDITIONAL 1 PERCENT ON ROYALTY IN EXCESS OF $500 MILLION PER YEAR UNTIL THE LAST TO EXPIRE PATENT WHICH COVERS A CIRM-FUNDED INVENTION. SO THE LAST SECTION JUST COVERS THOSE GRANTS THAT ORIGINATED A CIRM-FUNDED INVENTION. NEXT SLIDE.

HERE'S A FINAL NOTE. UNDER PROPOSITION 14, THERE'S ADDED LANGUAGE THAT NOW ALLOCATES THE DEPOSITED FUNDS IN THE GENERAL FUND WHICH STATES, GOING TO THE BOLD LANGUAGE, THAT SUCH FUNDS SHALL BE APPROPRIATED FOR THE PURPOSE OF OFFSETTING THE COSTS OF PROVIDING TREATMENTS AND CURES ARISING FROM CIRM-FUNDED RESEARCH TO CALIFORNIA PATIENTS WHO HAVE INSUFFICIENT MEANS TO PURCHASE SUCH TREATMENT OR CURES, INCLUDING THE REIMBURSEMENT OF PATIENT-QUALIFIED COSTS FOR RESEARCH PARTICIPANTS.

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SO THAT'S WHERE WE ARE, AND I'M AVAILABLE TO TAKE QUESTIONS.

CHAIRMAN THOMAS: THANKS, BEN. QUESTIONS OR COMMENTS FOR BEN? BEN, YOU WERE OBVIOUSLY EXCEPTIONALLY CLEAR IN YOUR PRESENTATION.

MR. HUANG: THANK YOU. I THINK JAMES IS NEXT.

MS. BONNEVILLE: HE SURE IS.

MR. HARRISON: ALL RIGHT. SO I'M GOING TO BRIEFLY TAKE YOU THROUGH THE BOARD SELF-EVALUATION. NEXT SLIDE PLEASE, YIMI.

AT A HIGH LEVEL WE SENT THE BOARD TO -- EXCUSE ME -- WE SENT THE SURVEY TO ALL BOARD MEMBERS AND ALTERNATES. THE LAST TIME WE CONDUCTED A SIMILAR SURVEY WAS IN 2011. THE BOARD WAS AT A FAIRLY STEADY STATE AT THAT POINT IN TIME. GIVEN THE BOARD TURNOVER AND THE EXPANSION OF THE SIZE OF THE BOARD, INCLUDING A NUMBER OF NEW MEMBERS WHO WE DID NOT ANTICIPATE WOULD RESPOND, WE RECEIVED FEWER RESPONSES THAN WE DID IN 2011, BUT NONETHELESS HAD A FAIRLY ROBUST PARTICIPATION.

THE SURVEY RESULTS SUGGEST THAT THERE IS AN INTEREST IN REINVIGORATING THE ROLE OF THE SUBCOMMITTEES, WHICH, AS MARIA DISCUSSED, WE INTEND TO DO, PROVIDING MORE INPUT INTO THE DEVELOPMENT OF

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THE AGENDA, AND ALSO RECEIVING MORE ROBUST INFORMATION REGARDING MATTERS PRESENTED TO THE BOARD. I'M JUST GOING TO BRIEFLY WALK YOU THROUGH THE QUESTIONS. NEXT SLIDE PLEASE.

SO THE FIRST QUESTION WAS WHETHER CIRM LIVES UP TO ITS MISSION. AS YOU WILL SEE, WE HAD A FAIRLY UNANIMOUS RESPONSE IN THE POSITIVE. NEXT SLIDE PLEASE, YIMI.

THE NEXT QUESTION WAS WHETHER THE BOARD FOCUSED ON THE APPROPRIATE STRATEGIC, FIDUCIARY, AND OVERSIGHT ISSUES THAT GUIDE CIRM'S WORK. AND, AGAIN, WITH ONE EXCEPTION, THERE WAS BROAD UNANIMITY THAT THE FOCUS WAS IN THE RIGHT PLACE. NEXT SLIDE PLEASE.

MEMBERS ALSO LARGELY AGREED THAT THE BOARD ATTENDS TO POLICY-RELATED ACTIVITIES THAT GUIDE THE WORK OF MANAGEMENT STAFF. NEXT SLIDE.

AND NOT SURPRISINGLY, GIVEN THAT LAST QUESTION, MEMBERS ALSO AGREED THAT THE BOARD GENERALLY AVOIDS GETTING INTO EXCESSIVE ADMINISTRATIVE OR MANAGEMENT DETAILS. NEXT SLIDE PLEASE.

THE MEMBERS WERE ALSO SUPPORTIVE OF THE STATEMENT THAT THE BOARD ENGAGES IN THE APPROPRIATE LEVEL OF OVERSIGHT OF THE CIRM TEAM. NEXT SLIDE

PLEASE.

AND THAT THE BOARD IS INDEPENDENT MINDED AND ASKS PENETRATING QUESTIONS REQUIRED TO UNCOVER ISSUES, WHICH I THINK WE CAN ALL AGREE WAS CERTAINLY THE CASE TODAY. NEXT SLIDE PLEASE.

THIS, I THINK, IS AN IMPORTANT ONE AND GOES TO A COMMENT I MADE EARLIER ABOUT THE DIVERSITY OF EXPERIENCE AND EXPERTISE ON THE BOARD. MEMBERS WERE UNANIMOUS IN AGREEING THAT BOARD MEMBERS OFFERED A DIVERSITY OF OPINIONS AND ADDRESS ISSUES IN A RESPECTFUL MANNER. NEXT SLIDE PLEASE.

THERE WAS GENERAL AGREEMENT WITH ONE EXCEPTION TO THE STATEMENT THAT THE BOARD'S LEVEL OF RELIANCE ON THE VIEWS OF THE PRESIDENT AND/OR OTHER MANAGEMENT STAFF IS APPROPRIATE. NEXT SLIDE.

AND ALSO THAT THE BOARD PLAYS AN APPROPRIATE ROLE IN CIRM'S FINANCES. NEXT SLIDE PLEASE.

THIS IS THE SLIDE I REFERRED TO AT THE OUTSET WHICH POSES A QUESTION AS TO WHETHER OR NOT THE BOARD MAKES APPROPRIATE USE OF SUBCOMMITTEES TO PROVIDE INPUT AND RECOMMENDATIONS. AS YOU WILL SEE, THERE WAS A MIXED VIEW HERE AND ILLUSTRATES, I THINK, AN INTEREST IN MAKING BETTER USE OF SUBCOMMITTEES, PARTICULARLY GIVEN THE EXPANDED SIZE

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OF THE BOARD. NEXT SLIDE PLEASE.

AND THIS QUESTION ALSO REFLECTS A SPLIT VIEW ON WHETHER BOARD MEMBERS HAVE APPROPRIATE INPUT INTO THE PREPARATION OF AGENDAS FOR BOARD MEETINGS. NEXT SLIDE PLEASE.

THE BOARD GENERALLY AGREED WITH ONE EXCEPTION THAT THE BOARD MEETS WITH APPROPRIATE FREQUENCY TO CARRY OUT CIRM'S MISSION. NEXT SLIDE.

AND FOR THE MOST PART THERE WAS AGREEMENT THAT BOARD MEETINGS ARE CONDUCTED IN A MANNER THAT ENSURES OPEN COMMUNICATION AND MEANINGFUL PARTICIPATION BY BOARD MEMBERS. NEXT SLIDE.

BOARD MEMBERS ALSO AGREED THAT THEY GRASP AND DELIBERATE IMPORTANT ISSUES AND BRING DECISION TOPICS TO CLOSURE IN A TIMELY WAY. NEXT SLIDE.

HERE THERE WAS A BIT OF A DIVIDED VIEW ABOUT WHETHER THE BOARD RECEIVES ADEQUATE INFORMATION TO UNDERSTAND THE ISSUES PRESENTED AND TO MAKE GOOD DECISIONS WITH SOME MEMBERS EXPRESSING THE BELIEF THAT THAT IS NOT ALWAYS TRUE. NEXT SLIDE PLEASE.

BOARD MEMBERS GENERALLY AGREED THAT INFORMATION RECEIVED PRIOR TO AND DURING MEETINGS IS CLEAR AND CONCISE AND DELIVERED IN A TIMELY FASHION. AGAIN, SOME MEMBERS FELT THAT THIS WAS NOT ALWAYS

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TRUE, AND ONE MEMBER TOOK EXCEPTION TO THAT STATEMENT. NEXT SLIDE PLEASE.

THERE WAS WIDESPREAD AGREEMENT THAT THE BOARD HAS AN EFFECTIVE COOPERATIVE AND COLLABORATIVE CULTURE. NEXT SLIDE.

AND THERE WAS UNANIMOUS SUPPORT AMONG BOARD MEMBERS THAT THEY UNDERSTAND AND SUPPORT CIRM'S MISSION. NEXT SLIDE.

BOARD MEMBERS ALSO AGREED THAT THEY UNDERSTAND THE RESPONSIBILITIES AS BOARD MEMBERS. NEXT SLIDE.

AND THAT THEY COME TO BOARD MEETINGS FULLY PREPARED TO PARTICIPATE. NEXT SLIDE.

BOARD MEMBERS GENERALLY AGREED WITH THE STATEMENT THAT THEY FEEL COMFORTABLE RAISING AND DISCUSSING DISSENTING OR CONTRARY OPINIONS ALTHOUGH SOME MEMBERS EXPRESSED THE VIEW THAT THAT WAS NOT ALWAYS THE CASE. NEXT SLIDE PLEASE.

SOME BOARD MEMBERS, BUT NOT ALL, THINK ABOUT THE WORK OF CIRM BETWEEN BOARD CALLS AND MEETINGS. NEXT SLIDE.

THIS ONE REALLY WARMED MY HEART. YOU ALL STATED THAT YOU UNDERSTOOD THE CONFLICT OF INTEREST ISSUES. NEXT SLIDE.

AND THE BOARD WAS UNANIMOUS IN STATING

THAT MEMBERS RECEIVED PERSONAL SATISFACTION FROM THEIR ROLE AS MEMBERS OF THE BOARD. NEXT SLIDE PLEASE.

BACK TO YOU, J.T.

CHAIRMAN THOMAS: SO WANT TO OPEN THIS UP FOR DISCUSSION. THANK YOU, JAMES, FIRST OF ALL, FOR PUTTING TOGETHER THE SURVEY AND FOR COLLATING THE RESULTS AND ANALYZING AND GIVING THE PRESENTATION YOU JUST GAVE TO THE BOARD.

I THINK BY AND LARGE THE BOARD RESPONSES TO THE VARIOUS QUESTIONS WERE VERY POSITIVE. THERE WERE A COUPLE THINGS THAT NEED ADDITIONAL ATTENTION ON THE SUBCOMMITTEE FRONT. AS MARIA SUGGESTED, WE'RE GOING TO DO A BETTER JOB OF GEARING UP THE SUBCOMMITTEES AS WE HEAD INTO THIS NEW STAGE HERE. AND I'M IN THE PROCESS WITH MARIA AND WITH ART IN DETERMINING THE ROSTERS FOR THE SUBCOMMITTEES BASED ON EVERYBODY'S PARTICULAR INTEREST LEVEL. AND I THINK YOU WILL SEE THAT WE STEP THAT -- WE WILL BE STEPPING THAT UP GOING FORWARD.

ON THE ISSUE OF BOARD MEMBERS HAVING INPUT TO BOARD AGENDAS, HISTORICALLY WE HAVE, I AND ART AND MARIA AND JAMES, HAVE SORT OF SET THE AGENDA IN WORKING WITH MARIA MILLAN AND HAVE NOT DONE, AS WE SEE AS EVIDENCED BY THAT PARTICULAR RESPONSE, A GOOD

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ENOUGH JOB SEEKING INPUT FROM THE BOARD ITSELF AS TO PARTICULAR MATTERS THAT WOULD GO ON THE AGENDA. SO I WILL TAKE FULL RESPONSIBILITY FOR THAT AND GOING FORWARD WILL BE SORT OF ON A ROUTINE BASIS SEEKING INPUT FROM ALL OF YOU ON POTENTIAL AGENDA TOPICS. I WOULD ALSO ENCOURAGE YOU, AS ANY SUCH TOPICS OCCUR TO YOU ALONG THE WAY, YOU NEEDN'T WAIT TO BE ASKED. PLEASE FEEL FREE TO GET IN TOUCH WITH ME OR MARIA TO SUGGEST TOPICS, AND WE WILL MAKE SURE THAT THAT GETS ADDRESSED.

WITH RESPECT TO GETTING ADEQUATE INFORMATION TO UNDERSTAND THE ISSUES, I THINK THAT WE WILL -- MARIA MILLAN SORT OF HEARS THAT RESPONSE. I THINK WE'RE GOING TO TRY AS A TEAM TO DO A BETTER JOB IN GETTING INFORMATION OUT EARLIER TO BOARD MEMBERS. THAT WILL ALLOW FOR ANALYZING ISSUES AND QUESTIONS FURTHER IN ADVANCE SO THAT, WHEN WE GET TO THE BOARD MEETING ITSELF, TO THE EXTENT THERE WERE ANY QUESTIONS ON PARTICULAR ITEMS, THEY WILL HAVE BEEN FLUSHED OUT AND DISCUSSED AND SORTED OUT PRIOR TO THAT.

AND THEN I THINK THOSE WERE THE THREE MAJOR ISSUES. JAMES, WHAT WERE THE ONES YOU HIGHLIGHTED OFF THE TOP? ARE THOSE THE THREE OR AM I MISSING ONE HERE?

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MR. HARRISON: YOU'VE GOT ALL OF THEM, J.T.

CHAIRMAN THOMAS: OKAY. SO THAT WOULD BE MY COMMENT ON THE SURVEY. I THINK THE GENERAL MESSAGE IS COLLECTIVELY WE'RE DOING A VERY GOOD JOB IN SHEPHERDING THE TAXPAYERS' DOLLARS AND DOING WHAT WE WERE PUT ON THE BOARD TO DO. I'D LIKE TO OPEN IT NOW TO ANY COMMENTS OR QUESTIONS FROM MEMBERS OF THE BOARD.

MS. DURON: J.T., YSABEL HERE.

CHAIRMAN THOMAS: YES, YSABEL.

MS. DURON: TWO THINGS THAT STRUCK ME, EITHER FOR THE LACK OF INFORMATION OR FOR SOME TIDBITS OF INFORMATION. I'M WONDERING IF YOU EVER PULLED OUT THE SURVEY TO REFLECT SOME OF THE IMPACT FOR THE PATIENT ADVOCATES OR THE IMPORTANCE OF THE PATIENT ADVOCATES AND WHETHER OR NOT THEY FEEL APPROPRIATELY REPRESENTED IN TERMS OF TOPIC MATTER. SOMETIMES I THINK THE SCIENCE CAN BECOME, FOR ME TRYING TO LEARN FROM A TO Z VERY QUICKLY, SOMETIMES BECAUSE IT'S NOT OUR PARTICULAR SILOED SITE, INCIDENCE, WHATEVER YOU WANT TO CALL IT, WE MAY HAVE LESS THAN THE APPROPRIATE AMOUNT OF INFORMATION.

SO I WAS JUST VERY CURIOUS IF WE UNDERSTAND WHERE PATIENT ADVOCATES STAND, HOW THEY

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FEEL, DO THEY FEEL COMFORTABLE. AND THAT GOES TO THE SECOND QUESTION ABOUT I THINK THERE WERE AT LEAST FOUR COMMENTS FROM PEOPLE SAYING WEREN'T ALWAYS COMFORTABLE IN THE DISCUSSION. AND I WONDER WHY AND WHAT CAN BE DONE ABOUT THAT.

AND PERHAPS THERE ARE TWO OF THOSE THINGS GO TOGETHER, AND I'D CERTAINLY LOVE TO HEAR INPUT FROM OTHER PATIENT ADVOCATES BECAUSE PART OF THE PROBLEM WITH OUR VIRTUAL IS WE REALLY DON'T HAVE A CHANCE TO SEE EACH OTHER FACE TO FACE, TO GET TO KNOW EACH OTHER BETTER, TO DEVELOP A RAPPORT, AND SO ON AND SO FORTH. OBVIOUSLY I'M ALL IN FAVOR OF A NEW FACE-TO-FACE, BUT THOSE ARE SOME OF THE COMMENTS AND THE THOUGHTS THAT I HAVE IN LISTENING AND WATCHING THE SURVEY RESPONSES.

CHAIRMAN THOMAS: THANK YOU, YSABEL. YOU SUGGESTED WHAT I WAS GOING TO SUGGEST ON THE QUESTION AS TO PATIENT ADVOCATES FEELING COMFORTABLE WITH BOTH THEIR ROLE, WHICH IS VERY SIGNIFICANT. PATIENT ADVOCATES, IN ADDITION TO BEING ON THE BOARD, ARE MEMBERS OF THE GWG, MEMBERS OF THE SWG, MEMBERS OF THE FACILITIES WORKING GROUP, MEMBERS OF THE CLINICAL AND TRANSLATIONAL ADVISORY PANELS. PATIENT ADVOCATES PLAY A CENTRAL ROLE IN ALL OF WHAT CIRM DOES.

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AND SO A QUESTION FOR THE OTHER PATIENT ADVOCATES PER YSABEL'S COMMENT, DO YOU FEEL COMFORTABLE IN THAT ROLE AND/OR WITH THE SUBJECT MATTER?

DR. HIGGINS: SPEAKING JUST FOR MYSELF, I FEEL VERY COMFORTABLE. OBVIOUSLY I'M A SCIENTIST AND THAT TAKES AWAY SOME OF THE INTIMIDATION OF THE SCIENCE. BUT I THINK MORE IMPORTANTLY IS HOW WE ARE INVITED TO FEEL, NOT JUST HOW WE ARE MADE TO FEEL. AND I THINK THE BOARD AND THE STAFF, IN PARTICULAR, DOES A PHENOMENAL JOB OF TAKING CARE OF A BUNCH OF BIG, ADULT, WHINING BABIES. THAT'S ME ANYWAY. SO I'M TOTALLY THRILLED AND BLOWN AWAY BY THE STAFF.

CHAIRMAN THOMAS: THANK YOU, DAVID.

DR. DULIEGE: DAVID, WHO ARE YOU REFERRING TO WITH YOUR BIG ADULT WHINING BABIES? YOUR COLLEAGUES ON THE ICOC OR YOUR COLLEAGUES AS PATIENT ADVOCATES? PLEASE CLARIFY.

MS. DURON: THANK YOU FOR THAT.

MS. BONNEVILLE: J.T., LAUREN HAS A COMMENT.

MS. MILLER-ROGEN: I'LL CHIME IN AS SOMEONE WHO HAS, I FEEL LIKE, BEEN VERY HONEST ABOUT HAVING A BRAIN THAT DOES NOT AT ALL UNDERSTAND SCIENCE BEYOND A VERY BASIC LEVEL. AND SO MY ROLE

AS A PATIENT ADVOCATE IS TO LISTEN AS MUCH AS I CAN, BUT KNOW THAT THERE ARE PEOPLE WHO DO UNDERSTAND THE SCIENCE, AND THEN TO ANALYZE WHAT THOSE PEOPLE ARE SAYING AND LET THAT INFORM MY DECISION WHILE MY MAIN GOAL, OF COURSE, IS ALWAYS LOOKING OUT FOR WHAT CAN I DO AS THE ALZHEIMER'S ADVOCATE? WHAT TYPE OF THINGS ARE WE TALKING ABOUT THAT CAN AFFECT PEOPLE WITH ALZHEIMER'S? AND THAT IS MY ROLE, AND THAT IS SOMETHING THAT I FEEL COMFORTABLE WITHIN MY ROLE.

IF YOU ASK ME TO SPEAK SPECIFICALLY TO OUR SCIENCE, I CAN GIVE A VERY BASIC OVERVIEW AND THEN WHEN IT GOES FURTHER, IT'S HARD. THERE ARE SO MANY DETAILS THAT ARE GIVEN IN THESE MEETINGS THAT ARE PRESENTED IN A VERY, VERY -- I DON'T EVEN KNOW THE RIGHT WORD -- CLINICAL WAY. AND I THINK THAT SOMETIMES IF THERE WAS PERHAPS A WAY TO TRANSLATE SOME OF THESE VERY SCIENTIFIC THINGS THAT ARE SO ABSTRACT FOR SOMEONE LIKE ME TO UNDERSTAND, TO TRANSLATE IT. HOW WILL THIS STUDY AFFECT PATIENTS, TO REALLY HIGHLIGHT THAT MORE IS HELPFUL. BUT AT THE SAME TIME, AGAIN, I KNOW THAT MY ROLE IS TO LISTEN FOR THE ALZHEIMER'S THINGS, TO LISTEN TO THE OTHER SMART PEOPLE WHO ARE AROUND, AND BRING SUPPORT FOR THE ALZHEIMER'S COMMUNITY WHENEVER I CAN. SO THAT'S MY COMMENT ON THAT.

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CHAIRMAN THOMAS: THANK YOU, LAUREN.

OTHER COMMENTS?

MS. BONNEVILLE: AL HAS HIS HAND RAISED AS DOES DAVID HIGGINS.

MR. ROWLETT: I'LL LET DAVID GO FIRST SO HE CAN FOLLOW UP ON HIS FIRST COMMENT.

DR. HIGGINS: THANK YOU, AL. I JUST WANTED TO FOLLOW UP. ACTUALLY LAUREN, I THINK, JUST PLANTED A SEED I THINK IS A REALLY GOOD IDEA. AND I THINK AMONG US WE COULD GENERATE THE KINDS OF DOCUMENTS, THE KINDS OF INFORMATION THAT YOU ARE TALKING ABOUT, LAUREN, AND HAVE IT CUSTOMIZED FOR OUR PATIENT ADVOCATES WHO MAY NOT UNDERSTAND THE SCIENCE AT THE HIGHEST LEVEL. AND THE GOAL IS NOT FOR THEM TO UNDERSTAND THE SCIENCE, BUT THE GOAL IS FOR THEM TO UNDERSTAND THE SIGNIFICANCE OF THE SCIENCE ON WHAT THEY DO UNDERSTAND, WHICH I THINK YOU JUST ARTICULATED PERFECTLY. LAUREN, I WOULD LOVE TO WORK ON THAT PROJECT WITH YOU IF THAT'S SOMETHING YOU'D BE INTERESTED IN.

MS. MILLER-ROGEN: OH, SURE. I THINK THAT I'M GOING TO BE PART OF COMMUNICATIONS IN SOME WAY, SUBCOMMITTEE AND ALL OF THAT. AND I THINK THAT, AGAIN, OUR ROLE AS A PATIENT ADVOCATE IS TO JUST MAKE SURE THAT PEOPLE UNDERSTAND WHAT REMARKABLE

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WORK WE ARE DOING. WHAT I'M CONSTANTLY TELLING PEOPLE, I'M LIKE I KNOW IT SOUNDS HARD FOR US TO UNDERSTAND, BUT IT'S TRULY INCREDIBLE AND MOVING THE NEEDLE IN SO MANY IMPORTANT WAYS. AND ALL I WANT TO DO IS TRANSLATE THAT TO EVERYONE ELSE AND TO MYSELF, TO BE COMPLETELY SELFISH. I WANT TO UNDERSTAND IT TOO.

DR. HIGGINS: WE CAN DO IT. WE CAN DO IT.

MR. ROWLETT: MY PERSPECTIVE ON YOUR QUESTION IS, METAPHORICALLY SPEAKING, WHEN I STARTED AS A PATIENT ADVOCATE ON THE BOARD, ONE OF MY PATIENT ADVOCATE COLLEAGUES COMMENTED, "WELL, WE KIND OF THREW YOU IN THE DEEP END OF THE POOL AND NOBODY ASKED YOU IF YOU COULD SWIM." AND IT WAS FORTUNATELY AND UNFORTUNATELY A BIT LIKE THAT. AND I TOOK IT UPON MYSELF TO ENGAGE PATIENT ADVOCATES WHO ARE ALL VERY RECEPTIVE AND EXTRAORDINARILY RESPONSIVE TO MY QUESTIONS ABOUT BOARD PROCESS, THE CIRM PORTFOLIO, AND THEN, LASTLY, SCIENCE.

AND I WAS SOMEWHAT RETICENT TO, AND J.T. CAN CERTAINLY ATTEST TO THIS, TO BE CONSIDERED AS A MEMBER OF THE GRANTS WORKING GROUP BECAUSE, AS LAUREN ARTICULATED FAR BETTER THAN I COULD, MY UNDERSTANDING OF THE CLINICAL APPLICATIONS AND STEM CELL SCIENCE WAS, AGAIN, PROBABLY AKIN TO PROBABLY

WHAT LAUREN IS EXPERIENCING AT TIMES RIGHT NOW AND WANTED AN OPPORTUNITY OR AT LEAST A SOURCE DOCUMENT THAT I COULD APPRECIATE WHAT WE WERE DOING BETTER SCIENTIFICALLY FROM THE PERSPECTIVE OF A PATIENT ADVOCATE. AND THERE WAS AND STILL IS NO REAL SOURCE DOCUMENT FOR US AS PATIENT ADVOCATES.

AND THAT WOULD BE A POINT OF IMPROVEMENT, I THINK, AS WELL AS AN INTERSECTION OF THAT DOCUMENT WITH AN UNDERSTANDING OF THE PORTFOLIO BECAUSE WHEN I'M ASKED ABOUT WHAT I DO AS A PATIENT ADVOCATE BY INDIVIDUALS WHO RESIDE IN OUR STATE, I OFTEN REFLECT ON OUR STRATEGIC PLAN, WHICH I DO THINK IS A WONDERFUL DOCUMENT AND VERY WELL WRITTEN, BUT IT IS MISSING SOME OF THOSE ESSENTIAL POINTS THAT A LAYPERSON WOULD APPRECIATE AS ARTICULATED BY LAUREN. AND IT IS THOSE FOLKS WHO VOTED FOR THIS, AND WE HAVE A RESPONSIBILITY TO THEM, AS ART TORRES WOULD PASSIONATELY ADVOCATE, TO BE ABLE TO EXPLAIN WHAT WE DO AND THE IMPACT IT IS HAVING ON THEIR LIVES. AND THAT SOMETIMES IS MISSING FOR ME AND BEING ABLE TO TAKE -- IT'S THE JUXTAPOSITION OF TAKING THE SCIENCE TO THE EVERYDAY FOLKS IN THE STATE OF CALIFORNIA WHO VOTED FOR THIS. AND THAT'S MY ROLE AS A PATIENT ADVOCATE.

TODAY I AM, YSABEL, VERY EXCITED ABOUT THE

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WORK THAT WE ARE DOING AROUND DIVERSITY, EQUITY, AND INCLUSION. THAT WAS SOMETHING THAT WHEN IT WAS RAISED EARLY ON ABOUT PATIENT ACCESS AND UNDERREPRESENTED GROUPS OF PEOPLE, AS A PATIENT ADVOCATE I DIDN'T FEEL LISTENED TO IN REGARDS TO THAT. AND, IN FACT, ARTICULATED THAT AND CERTAINLY THINK THAT SOME OF MY EARLY COMMENTS, YSABEL, RESULTED IN SOME TRANSITION AND CHANGE IN LEADERSHIP AND A COMPLETE ENDORSEMENT OF MARIA AND WHAT SHE'S DOING FOR CIRM.

AND THAT WOULD BE MY LAST POINT. I THINK PATIENT ADVOCATES DO HAVE INFLUENCE REGARDING LEADERSHIP IN THE ORGANIZATION. AND NOT THAT I'M TRYING TO ORALLY ARTICULATE SORT OF THE EVALUATION OR TALK ABOUT THE EVALUATION PROCESS, BETTER SAID, BUT AS A PATIENT ADVOCATE, WE REPRESENT SO MANY CONSTITUENTS. AND WHEN WE TALK ABOUT THEIR EXPERIENCE IN THE ORGANIZATION AND THE IMPACT THAT LEADERSHIP HAS, THAT I THINK HAS SIGNIFICANT VALUE AND MAKES A DIFFERENCE IN THE TRAJECTORY OF THE ORGANIZATION. AND THAT'S WHERE, AFTER I LEARN HOW TO SWIM, IF I WAS DROPPED IN THE DEEP END OF THE POOL, THAT'S WHERE I HAD A LOT OF IMPACT.

CHAIRMAN THOMAS: THANKS, AL. THAT WAS GREAT.

OTHER COMMENTS FROM MEMBERS OF THE BOARD? OTHER PATIENT ADVOCATES LIKE TO WEIGH IN HERE?

MS. BONNEVILLE: YSABEL AND MARK BOTH HAVE THEIR HANDS RAISED.

MS. DURON: I'LL LET MARK GO FIRST.

DR. FISCHER-COLBRIE: JUST A QUICK COMMENT. I THINK LAUREN'S COMMENTS, AL'S ARE TERRIFIC AS OTHERS, GETTING REALLY DOWN TO THE FUNDAMENTAL SOUND BITE OF WHAT DOES THIS MEAN FOR PATIENTS OR AT LEAST THE POTENTIAL FOR WHAT IT MEANS FOR PATIENTS. SO IF WE CAN SORT OF KEEP THAT IN THE FOREFRONT OF OUR COMMUNICATIONS MORE BROADLY INTERNALLY, THAT WILL HELP US EXTERNAL AS WELL. SO GREAT COMMENTS.

MS. DURON: THANKS, AL. I APPRECIATE YOUR COMMENTS AND THAT OF LAUREN'S BECAUSE I THINK IN REALITY OVER TIME, IT'S POSSIBLY BEEN SOME OF THE FIRST TIME WHERE I'VE HEARD COMMENTS FROM PATIENT ADVOCATES AT THIS LEVEL THAT IS SO IMPORTANT BECAUSE YOU HAVE STATED SPECIFICALLY WHAT IS ALWAYS THE ISSUE. YOU CAN CALL IT TRANSLATIONAL SCIENCE. I CALL IT COMMUNICATION SCIENCE. AND THAT IS, IF WE'RE GOING BACK TO THE PUBLIC AND ASKING THEM TO POUR THEIR HARD-EARNED DOLLARS INTO SOMETHING THAT THEY DON'T QUITE UNDERSTAND, THEN WE NEED TO BE ABLE

TO TRANSLATE IT FOR THEM. SO TRYING TO UNDERSTAND THIS FABULOUS, WONDERFUL, MIRACULOUS THING CALLED SCIENCE AND TRANSLATE IT INTO A WAY THAT THE PEOPLE FEEL, WOW, IT IS A MIRACLE AND IT COULD MEAN SOMETHING FOR ME, MY FAMILY, OR MY COMMUNITY OVER TIME, THAT'S WHERE WE NEED TO BE TALKING AT THAT LEVEL.

SO I TOTALLY AGREE WITH YOU. I TRY VERY HARD, LIKE LAUREN SAYS, TO UNDERSTAND THE SCIENCE, DABBLE AROUND THE EDGES, HOPE I GOT THE BASICS, AND THEN I CAN GO BACK OUT AND SAY TO FOLKS THIS IS WHAT THEY'RE DOING. I THINK THE SUBCOMMITTEE, THE COMMUNICATIONS SUBCOMMITTEE WHERE WE'RE HOPING REALLY TO MAKE THAT TRAJECTORY FROM THE SCIENCE INTO THE ENGLISH TO THE PEOPLE. AND SO I'M SO GLAD WE HAD THIS LITTLE CONVERSATION. THANK YOU.

MS. BONNEVILLE: DAN HAS HIS HAND RAISED, J.T.

MR. BERNAL: THANK YOU. I'D LIKE TO THANK YSABEL AND LAUREN AND AL AND DAVID FOR ALL YOUR COMMENTS. THIS IS A RELATIVELY NEW (INAUDIBLE) FOR ME SHARPEN MY UNDERSTANDING OF OUR ROLE AS BRIDGES TO THE PUBLIC TO WHOM WE ARE ALL ACCOUNTABLE. THAT'S, I THINK, A VERY IMPORTANT ROLE THAT WE CAN PLAY. SO I LOOK FORWARD TO LEANING INTO THAT AND

LOOK FORWARD TO THE REST OF THE BOARD UTILIZING US IN THAT WAY AS WELL.

CHAIRMAN THOMAS: THANK YOU, DAN.

OTHER COMMENTS? ARE THERE OTHER COMMENTS IN ADDITION TO THE PATIENT ADVOCATE PERSPECTIVE IN GENERAL ON THE SURVEY?

OKAY. I THINK, AGAIN, THE OVERRIDING MESSAGE IS WE'RE DOING A GOOD JOB. THE ENTIRE CIRM FAMILY, I BELIEVE, IS DOING A GREAT JOB. AND WE WILL TWEAK THE ITEMS THAT NEED TO BE DEALT WITH AND PROCEED ACCORDINGLY HERE.

SO, MARIA, IS THAT OUR LAST PRESENTATION?

MS. BONNEVILLE: IT IS.

CHAIRMAN THOMAS: OKAY. SO AFTER ALL OF THIS TODAY, WE ARE NOW AT THE LAST ITEM, WHICH IS GENERAL PUBLIC COMMENT. I HAVE ONE FROM MR. JENSEN, WHICH IS ADDRESSED TO US, I THINK, IN RESPONSE TO MY PRESENTATION ON WHERE WE GET OUR MONEY FROM AND HOW. AND THE QUESTION IS ONE OF THE GOALS OF THE INITIATIVE THAT CREATED CIRM WAS TO REMOVE STEM CELL RESEARCH FINANCING FROM THE POLITICAL FRAY. ALSO, THE MEASURE, PROP 71, ISOLATED CIRM SPECIFICALLY FROM LEGISLATIVE AND GUBERNATORIAL ACTION. HOWEVER, TODAY'S BRIEFING ON THE NUTS AND BOLTS OF CIRM'S ACCESS TO BOND FUNDS SHOWS CONSIDERABLE INVOLVEMENT

BY THE GOVERNOR OR HIS APPOINTEES.

GOVERNOR NEWSOM HAS BEEN A GOOD FRIEND OF CIRM. OTHER GOVERNORS MAY NOT FEEL THE SAME. DOESN'T THE HEAVY CONSULTATION WITH THE GOVERNOR'S OFFICE AND HIS FINANCE OFFICIALS FLY IN THE FACE OF WHAT WAS SUPPOSED TO BE ONE OF THE MAJOR VIRTUES OF THE MEASURE THAT CREATED CIRM?

OUR RESPONSE TO THAT IS WHILE PROPOSITION 71 WAS DESIGNED TO PROTECT CIRM FUNDING, CIRM FITS SQUARELY IN STATE GOVERNMENT. AS A STATE AGENCY, WE ARE STILL SUBJECT TO OVERSIGHT BY CONTROL AGENCIES SUCH AS THE DEPARTMENT OF FINANCE, AND WE ARE SUBJECT TO AN ANNUAL REVIEW BY THE CONTROLLER THROUGH THE CFAOC. AS A STATE AGENCY, WE KNOW THAT OUR SUCCESS IS DEPENDENT ON HAVING STRONG WORKING RELATIONSHIPS WITH THE STATE AND BEING AS OPEN AND TRANSPARENT AS POSSIBLE IN KEEPING THE GOVERNOR AND LEGISLATURE INFORMED ON THE WORK WE DO.

TALKING WITH THE GOVERNOR AND HIS FINANCE TEAM AND OTHER STATE OFFICIALS IS SIMPLY A MATTER OF HAVING AN OPEN RELATIONSHIP REGARDLESS OF SPECIFIC REPORTING STRUCTURES.

ARE THERE OTHER PUBLIC COMMENTS? OKAY. HEARING NONE, I WANT TO THANK EVERYBODY. THIS HAS BEEN AN EXTRAORDINARY DAY. WE'VE COVERED A LOT OF

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GROUND. WE HAD MAJOR CONTRIBUTIONS FROM MANY PEOPLE, BOTH DR. MILLAN AND HER TEAM, ALL OF THE CIRM BOARD MEMBERS. I WANT TO A SPECIAL THANKS, IN ADDITION TO DR. MILLAN, GO TO GIL TO MARIA B FOR ORCHESTRATING ALL OF THIS AS SHE ALWAYS DOES, TO YIMI FOR HIS EXCELLENT WORK ON THE SLIDE PRESENTATIONS, TO GIL FOR HIS NUMEROUS CONTRIBUTIONS AND PRESENTATIONS, LIKEWISE TO JENN AND TO DOUG FOR ALL HIS HELP. SO YOU GUYS ALL PUT TOGETHER A TERRIFIC MEETING HERE. I HOPE THIS HAS BEEN INSTRUCTIVE AND INFORMATIONAL FOR THE BOARD AS IT WAS MEANT TO BE.

AND SO I THINK WE ARE AT THE END OF OUR MEETING HERE. MARIA, AS FAR AS NEXT MEETING, WE DON'T KNOW WHAT THE DATE IS.

MS. BONNEVILLE: NO, WE DON'T. I'M NOT SURE APRIL WILL WORK UNLESS SOME BOARD MEMBERS CAN MOVE CALENDARS. I'LL REACH OUT ABOUT APRIL. I THINK YSABEL HAS A COMMENT BECAUSE HER HAND IS RAISED.

MS. DURON: THANK YOU, J.T., MR. CHAIR. I JUST WANTED TO ADD MY THANKS TO THE WORK THAT'S BEEN DONE FOR THIS RETREAT. HARD WORK, HEAVY LIFTING, EVERYBODY WAS WONDERFUL TO TAKE THE TIME. IT WAS REALLY TRULY A HEAVY LIFT. IN FACT, IT ACTUALLY

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BACKTRACKED FOR ME SOME THINGS I DON'T THINK I LEARNED THE FIRST TIME AROUND. SO I REALLY APPRECIATE THE REFRESHER COURSE.

AND I WANT TO WELCOME ALL THE NEW MEMBERS ABOARD. I HOPE THAT YOUR FIRST EXPERIENCES WITH US ARE EXCELLENT, IF YOU WILL. AND I'M PRAYING THAT AT SOME POINT VERY NEAR, MR. CHAIR, THAT WE WILL, IN FACT, GET TO HAVE A FACE-TO-FACE MEETING. I MYSELF CAN ANNOUNCE THAT I AM DOUBLY DOSED AND READY TO GO.

CHAIRMAN THOMAS: THERE YOU GO. I THINK WE ALL SHARE THAT SENTIMENT. WE CAN'T REALLY SPEAK TO WHEN THAT'S GOING TO BE. IN THE MEANTIME I THINK WE ARE MAKING GOOD DO WITH OUR ZOOM APPROACH AND GETTING VERY GOOD ATTENDANCE.

AND I JUST WANT TO SAY THE LAST THREE MEETINGS, STARTING WITH THE JANUARY MEETING AND THE SPECIAL MEETING WITH THE ADVISORY PANEL AND TODAY, THE LEVEL OF BOARD PARTICIPATION HAS BEEN EXCEPTIONAL. AND A SPECIAL SHOUT-OUT GOES TO ALL OF OUR NEW BOARD MEMBERS WHO REALLY PLAYED A BIG ROLE IN THE DISCUSSION TODAY. SO THANK YOU TO ALL OF YOU. I THINK WITH AN EXPANDED BOARD AND AN ENERGIZED BOARD, WE'RE WELL SET UP TO MEET THE CHALLENGES OF THE FUTURE GOING FORWARD.

LAST, AGAIN, JUST FOR TODAY, THANK YOU

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GOES TO GEOFF LOMAX, TO BEN, AND LAST, BUT NOT LEAST, TO JAMES WHO ALWAYS IS OUR RUDDER ON EVERYTHING. MANY OF YOU HEARD ME SAY THIS, BUT WHEN I STARTED THE JOB AT CIRM, BOB KLEIN'S FIRST THING HE ADMONISHED ME ON WAS NOT TO BRUSH MY TEETH WITHOUT CHECKING WITH JAMES FIRST. AND THAT HAS BEEN BORNE OUT OVER TIME. SO, JAMES, THANK YOU FOR ALL THE CONTINUED EXTRAORDINARY WORK YOU DO FOR THE AGENCY.

I THINK THAT ABOUT DOES IT. NO MEETING --

MS. BONNEVILLE: ANNE-MARIE HAS A COMMENT.

DR. DULIEGE: SO OBVIOUSLY DITTO ON EVERYTHING THAT YOU SAID. I COULDN'T SAY IT BETTER. BUT MY QUESTION IS DO YOU KNOW WHAT YOU'RE THINKING IN TERMS OF THIS BALANCE BETWEEN RECREATING OR RESUMING THE FACE-TO-FACE, MEETINGS WHICH ARE ESSENTIAL, WE KNOW THAT, NOTHING CAN REPLACE THAT. ON THE OTHER HAND, HAVING AT TIMES MEETING ON ZOOM AT THE DISTANCE WHEN THEY'RE NOT THAT LONG, MAYBE AN HOUR AND A HALF, TWO HOURS, MAKE IT MUCH EASIER FOR MORE PEOPLE TO PARTICIPATE. SO WHAT'S THE DISCUSSION AROUND THAT, IF ANY?

CHAIRMAN THOMAS: RIGHT. SO THE DISCUSSION IS -- MARIA, DO YOU WANT TO ANSWER THAT QUESTION?

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MS. BONNEVILLE: SURE. YES. ANNE-MARIE, WHAT WE HOPE TO DO IS, WHEN WE CAN SAFELY RECONVENE IN PERSON, WE THINK MAYBE A COUPLE OF TIMES A YEAR WE CAN BRING EVERYONE TOGETHER IN PERSON. IF PEOPLE WANTED TO JOIN IN PERSON, THEY COULD, BUT THERE WOULD ALWAYS BE A ZOOM OPTION SO THAT WE COULD CONTINUE TO MAKE IT CONVENIENT FOR EVERYONE TO PARTICIPATE IN WHATEVER MANNER THEY CAN PARTICIPATE.

CHAIRMAN THOMAS: OKAY. ANY OTHER COMMENTS OR QUESTIONS? SO I, OF COURSE, WOULD BE REMISS AT THIS TIME OF YEAR IF I DIDN'T -- LOOK AT MARIA. FOR THOSE OF YOU WHO DIDN'T CATCH MY SUBTLE MESSAGE, YOU MAY NOTICE BABY YODA SITTING OVER MY SHOULDER HERE WEARING HIS L.A. DODGER CAP. SO I'D LIKE TO CLOSE WITH GO BLUE AS THE SEASON IS ABOUT TO START.

WITH THAT, THANK YOU SO MUCH TO EVERYBODY, AND WE LOOK FORWARD TO OUR NEXT MEETING.

DR. DULIEGE: AND THANK YOU TO YOU, J.T., ALSO. GREAT WAY TO MODERATE AND LEAD THE DIALOGUE AS ALWAYS. THANK YOU VERY MUCH.

CHAIRMAN THOMAS: THANK YOU. ALL RIGHT, FOLKS.

(THE MEETING WAS THEN CONCLUDED AT 2:51 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 ZOOM PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MARCH 23, 2021, 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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