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: CIRM
1999 HARRISON STREET, SUITE 1650
OAKLAND, CALIFORNIA

DATE: FEBRUARY 6, 2020
10 A.M.

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

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FEBRUARY 6, 2020; 10 A.M.

CHAIRMAN THOMAS: MORNING, EVERYBODY, HIGH ATOP 1999 HARRISON. IT IS A GORGEOUS DAY IN OAKLAND. I'D LIKE TO WELCOME EVERYBODY AND CALL THIS MEETING TO ORDER. MARIA, WILL YOU PLEASE LEAD US IN THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

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

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MS. BONNEVILLE: LINDA BOXER. KEN BURTIS. DEBORAH DEAS.

DR. DEAS: HERE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE. YSABEL DURON.

MS. DURON: HERE.

MS. BONNEVILLE: LEON FINE.

DR. FINE: HERE.

MS. BONNEVILLE: JUDY GASSON.

DR. GASSON: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

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MR. JUELSGAARD: HERE.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: HERE.
MS. BONNEVILLE: LAUREN MILLER. ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA. FRANCISCO PRIETO.
DR. PRIETO: PRESENT.
MS. BONNEVILLE: ROBERT QUINT. AL ROWLETT. SUZANNE SANDMEYER.
DR. SANDMEYER: YES.
MS. BONNEVILLE: JEFF SHEEHY. OS STEWARD. JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: HERE.
MS. BONNEVILLE: CARL WARE.
DR. WARE: HERE.
MS. BONNEVILLE: DIANNE WINOKUR.
MS. WINOKUR: HERE.
MS. BONNEVILLE: KEITH YAMAMOTO.
DR. YAMAMOTO: HERE.
MS. BONNEVILLE: DOUG ZIEDONIS.
DR. ZIEDONIS: I'M HERE. ALSO I'M ON THE

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LINE AND IT'S HARD TO HEAR YOU.

MS. BONNEVILLE: I WAS CLEARLY NOT SPEAKING INTO THE MIC. SORRY ABOUT THAT. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, MARIA. SO THE ORDER TODAY, WE'RE GOING TO START WITH THE CHAIR'S REPORT. FOLLOWING THAT WE'RE GOING TO SKIP TO THE ACTION ITEM NO. 6 JUST TO MAKE SURE WE HAVE EVERYBODY AVAILABLE FOR THAT DISCUSSION. AND THEN WE'LL PROCEED TO THE PRESIDENT'S REPORT AFTER THAT ITEM.

SO STARTING THE CHAIR'S REPORT, TO BEGIN, WOULD LIKE TO INTRODUCE TO YOU OUR NEWEST MEMBER OF THE ICOC, WHICH IS YSABEL DURON, WHO IS OUR NEW PATIENT ADVOCATE FOR CANCER, REPLACING LONGTIME AND ORIGINAL BOARD MEMBER SHERRY LANSING. YSABEL, COULD YOU PLEASE SAY A FEW WORDS ABOUT YOUR BACKGROUND TO THE BOARD?

MS. DURON: THANK YOU VERY MUCH, JONATHAN. IT IS A PLEASURE TO BE HERE WITH ALL OF YOU. IT'S AN HONOR TO SERVE ON THIS ESTEEMED ORGANIZATION. AND I WANT TO THANK ART FOR DRAGGING ME IN.

I AM BY TRAINING FOR 43 YEARS A JOURNALIST, TELEVISION, BROADCASTING, BUT I AM A SCIENTIST AT HEART. WE DO BELIEVE IN DATA AND

FACTS. AND IN THE LAST 20 YEARS, MUCH OF MY FOCUS HAS BEEN ON HEALTH SINCE I WAS DIAGNOSED MYSELF WITH CANCER, HODGKIN'S LYMPHOMA, AT THE AGE OF 50. AND THAT'S WHEN I STARTED TO LOOK INTERNALLY AT THE LATINO COMMUNITY AND THE IMPACT OF CANCER ON IT AND STARTED RECOGNIZING AND REALIZING PROGRAMS THAT WERE GOING TO ACTUALLY ADDRESS THE BURDEN OF CANCER IN THE LATINO COMMUNITY.

AND WHAT I DISCOVERED OVER TIME IS THAT IT IS MORE A SYSTEMS PROBLEM THAN IT IS AS MUCH A SERVICE PROBLEM. AND SO IN THIS PAST 20 YEARS, AS I'VE BUILT SEVERAL ORGANIZATIONS AND CURRENTLY ESTABLISHED THE LATINO CANCER INSTITUTE, MY GOAL HAS ALWAYS BEEN TO MOVE TO BRING THE TWO THINGS TOGETHER SO THAT WE CAN WORK EQUALLY TOWARDS DIMINISHING, IN FACT, ERADICATING THE LATINO CANCER BURDEN, WHICH, IN FACT, IS THE NO. 1 CAUSE OF DEATH OF LATINOS AROUND THIS COUNTRY. AND SINCE THERE ARE ALMOST 60 MILLION OF US, WE NEED TO BE VERY PREPARED THAT PERHAPS ONE IN FIVE OF LATINO DEATHS ARE DUE TO CANCER.

SO THIS IS NOT SOMETHING OF SMALL CONCERN TO THE COMMUNITY. AND WHEN THEY DON'T HAVE EQUAL ACCESS, WHEN THEY DON'T UNDERSTAND THE LANGUAGE, WHEN THE SYSTEMS THEMSELVES ARE NOT PREPARED TO DEAL

WITH THE COST OF TREATING SOMEONE AND THEN PROVIDING THE OPPORTUNITIES FOR ADVANCED CANCER TREATMENT, THESE BECOME REAL BARRIERS AND SYSTEMS PROBLEMS. SO THAT'S WHAT I'M WORKING ON NOW.

STEM CELLS IS INTEREST -- I SPENT A LOT OF TIME IN THE LAST DECADE WORKING ON PRECISION MEDICINE ISSUES AND STILL TRYING TO WRAP MY HEAD AROUND THAT SCIENCE. SO THIS IS ALSO A NEW TURN FOR ME, BUT I THINK IT ALL ULTIMATELY MEANS THE SAME THING. WE NEED TO ENGAGE COMMUNITY, WE NEED THEM TO BE AWARE OF WHAT'S OUT THERE, WE NEED THEM NOT TO BE AFRAID OF THE SCIENCE, AND WE NEED, AS SCIENTISTS, RESEARCHERS, ALL OF THE OTHER WONDERFUL PEOPLE WHO ARE ENGAGED, WE NEED TO BRING THIS TO THEM AND NOT BE AFRAID TO ENGAGE COMMUNITY. WE CANNOT STAY IN OUR SILOS. WE NEED TO OPEN THIS UP TO EVERYBODY AND MAKE SURE THAT EVERYBODY IS AWARE AND CAN AND WILL TAKE ADVANTAGE, BE SUPPORTIVE, AND ACTUALLY, I THINK, BE SUPPORTED AND HELPED BY ANY NEW ADVANCES IN THIS DISEASE OR IN ANY DISEASES THEY HAVE TO FACE, THEIR FAMILIES HAVE TO FACE, OR THE COMMUNITIES HAVE TO FACE.

THANK YOU VERY MUCH, JONATHAN, FOR GIVING ME THE OPPORTUNITY TO SPIEL. I'M KIND OF AN A TO Z CINEMA VERITE KIND OF A PERSON. BE GLAD TO TALK TO

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ALL OF YOU ABOUT ANYTHING.

MR. TORRES: I CAN ATTEST TO THAT.

CHAIRMAN THOMAS: SENATOR TORRES.

MR. TORRES: I JUST WANT TO THANK MY FELLOW CANCER SURVIVOR TO AGREE TO SERVE WITH US. AND I'VE KNOWN YSABEL FOR, GOD, MORE THAN 35 YEARS. AND SHE WAS A TOUGH REPORTER IN THE BAY AREA AND VERY INQUISITIVE, AND CLEARLY SHE'S GOING TO BRING THAT SAME VALUE, SAME DETERMINATION, AND SAME COURAGE YOU'VE SHOWN OVER THE YEARS TO THIS BOARD. SO WELCOME ABOARD.

CHAIRMAN THOMAS: THANK YOU. AND LIKEWISE, WE LOOK FORWARD TO A GREAT WORKING RELATIONSHIP GOING FORWARD.

MOVING ON, TODAY WILL BE THE FIRST, AS WE TALKED ABOUT AT THE OCTOBER BOARD MEETING, THE FIRST IN A SERIES OF REPORTS BACK TO THE PUBLIC. DR. MILLAN IN HER PRESIDENT'S REPORT HAS A DETAILED REVIEW OF A NUMBER OF ASPECTS OF OUR PROGRAMS AND PORTFOLIO, WHICH SHE WILL BE GIVING SHORTLY.

WITH RESPECT TO THE INITIATIVE, AS YOU RECALL, WE'VE BEEN ADMONISHED BY COUNSEL, MR. HARRISON, THAT WE CANNOT ADVOCATE FOR IT AND HAVE TO BE VERY STEADFAST IN THAT. I CAN, HOWEVER, FACTUALLY REPORT A NUMBER OF THINGS WITH RESPECT TO

IT JUST TO GIVE THE BOARD AN UPDATE ON WHERE WE STAND.

FOLLOWING OUR NOVEMBER MEETING WITH MR. KLEIN WHERE WE DISCUSSED THE NEW INITIATIVE IN CONSIDERABLE DETAIL, HE FILED THE FINAL VERSION OF THE MEASURE THE FOLLOWING MONDAY. SINCE THAT TIME, THE ATTORNEY GENERAL'S OFFICE HAS ISSUED WHAT THEY CALL "TITLE AND SUMMARY," WHICH IS SOMETHING THEY DO FOR ALL MEASURES THAT ARE CONSIDERED TO BE PUT ON THE BALLOT. AND THAT TRIGGERED A SIX-MONTH PERIOD FOR BOB TO COLLECT SIGNATURES TO QUALIFY IT FOR THE BALLOT. THE NUMBER OF SIGNATURES IS A FUNCTION OF THE TOTAL VOTE IN THE PREVIOUS GENERAL ELECTION, WHICH WAS THE NOVEMBER 2018 GUBERNATORIAL ELECTION. AND LOOKING AT THAT PARTICULAR VOTE TOTAL, BOB NEEDS 623,000 AND CHANGE SIGNATURES TO QUALIFY THE NEW INITIATIVE FOR THE BALLOT.

BECAUSE THERE ARE ALWAYS ISSUES WITH THE VALIDITY OF SIGNATURES IN ANY SIGNIFICANT GATHERING EFFORT, IT IS ALWAYS BEST TO EXCEED THE AMOUNT TO MAKE SURE THAT YOU'RE COVERED. AND SO BOB'S GOAL IS TO GET A MILLION SIGNATURES FOR THE INITIATIVE AS A CUSHION, WHICH NUMBER, I BELIEVE, SENATOR TORRES, IS SIMILAR TO WHAT HE GOT FOR PROP 71; IS THAT CORRECT?

MR. TORRES: YES.

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CHAIRMAN THOMAS: THANK YOU. SO HE'S IN THE PROCESS NOW OF SIGNATURE GATHERING. AS MR. JENSEN REPORTED, I BELIEVE, YESTERDAY, IN AN INTERVIEW WITH BOB, HE'S THROUGH 250,000 SIGNATURES TO DATE AND IS CONTINUING ALONG.

ONCE YOU REACH THE 25-PERCENT FIGURE OF SIGNATURES NEEDED, THEN THE LEGISLATURE CAN HOLD HEARINGS NO LATER THAN 131 DAYS IN ADVANCE OF THE VOTE, WHICH IS NOVEMBER OBVIOUSLY. AND THE END OF THE PROCESS IS IF THE SIGNATURES ARE COLLECTED AND VERIFIED, THIS INITIATIVE AND ANY OTHER INITIATIVE THAT'S TRYING TO QUALIFY SIMILARLY WILL BE CERTIFIED FOR THE BALLOT BY THE SECRETARY OF STATE. AND IF THAT HAPPENS, WHICH HAS TO HAPPEN AT THE END OF JUNE, JUNE 25TH, THEN THE MEASURE WILL GO ON THE BALLOT IN NOVEMBER. SO THAT IS AN UPDATE ON WHERE THAT STANDS.

THE OTHER POINT I WOULD MAKE IS THE BOARD, OF COURSE, HAS TAKEN NO POSITION ON THE INITIATIVE AT THIS POINT. WE, IN DISCUSSIONS WITH MR. HARRISON, HAVE DECIDED TO BRING THE TOPIC OF THE BOARD'S THOUGHTS ON THE MEASURE TO THE MEETING THAT WE WILL BE HAVING IN MAY. SO THAT WILL BE AN AGENDA ITEM FOR THAT BOARD MEETING.

ON OTHER FRONTS, ON THE BRIDGE FUNDING

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FRONT, WE HAVE CONTINUED TO HAVE A NUMBER OF DIFFERENT EFFORTS GOING ON. I DO NOT HAVE ANY NEWS TO REPORT ON THAT AT THIS TIME. AT SUCH TIME AS WE DO HAVE SOME POSITIVE NEWS, I WILL BRING IT TO THE BOARD POSTHASTE.

MOVING ON NOW, WE HAVE AN AGENDA ITEM ON HERE, MR. PANETTA WAS GOING TO DO AN INDUSTRY UPDATE. HE'S HAD A CONFLICT WITH HIS BOARD DOWN IN SAN DIEGO AND WILL BE JOINING BY PHONE. SO WE HAVE POSTPONED THAT UNTIL THE MAY BOARD MEETING AS WELL. IN ITS PLACE, THERE ARE A FEW STATS I WANTED TO GIVE TO THE BOARD.

AS YOU KNOW, A COUPLE WEEKS AGO WE HAD THE JP MORGAN CONFERENCE HERE, WHICH IS THE MAJOR GATHERING OF THE BIOTECH INDUSTRY AND INVESTORS NATIONALLY. AND AT THAT THE ALLIANCE FOR REGENERATIVE MEDICINE ALWAYS GIVES ITS STATE OF THE INDUSTRY TALK TO DISCUSS HOW THINGS HAVE GONE THE PAST YEAR AND WHAT THE TRENDS ARE, ET CETERA.

THERE ARE A FEW SLIDES FROM THEIR PRESENTATION I DISTILLED DOWN THAT I THINK WOULD BE OF INTEREST TO THE BOARD, SPEAKING TO THE GENERAL NOTION THAT THE INDUSTRY IS FLOURISHING, THAT RESEARCH CONTINUES TO ACCELERATE AT A DRAMATIC PACE AS REFLECTED BY THE NUMBER OF COMPANIES, THE FUNDS

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RAISED, THE PRODUCTS THAT ARE IN THE PIPELINE IN CLINICAL TRIALS, ET CETERA. SO, DOUG, THIS IS THE SLIDES UP ON THE SCREEN.

NOTICE HERE THERE ARE NOW CLOSE TO A THOUSAND REGENERATIVE MEDICINE COMPANIES WORLDWIDE, WHICH IS A VERY IMPRESSIVE STAT. YOU CAN SEE ON THE SCREEN HALF OF THOSE ROUGHLY ARE IN NORTH AMERICA, BUT THEY ARE SPREAD ACROSS A NUMBER OF DIFFERENT CONTINENTS, AND THAT IS REFLECTIVE OF THE FACT THAT THE SPACE CONTINUES TO GROW.

OF THE PROJECTS THAT ARE BEING IN CLINICAL TRIALS RIGHT NOW, THEY'RE GETTING ACCELERATED STATUS. YOU SEE 17 OF THOSE ARE GETTING VARIOUS DESIGNATIONS TO ACCELERATE. OVER A THOUSAND CLINICAL TRIALS WORLDWIDE ARE IN PLACE, AND $9.8 BILLION WAS RAISED IN FINANCINGS FOR REGENERATIVE MEDICINE COMPANIES, WHETHER IT WAS PRIVATE EQUITY RAISES OR MERGERS AND ACQUISITIONS OR IPO'S OR WHATEVER IN 2019.

SO YOU'VE READ IN THE NEWS THERE HAVE BEEN A NUMBER OF PRODUCTS THAT WERE APPROVED IN 2019. THIS IS A SLIDE REFLECTIVE OF SOME OF THE HIGHER PROFILE PRODUCTS. AND YOU CAN SEE, READING DOWN THERE ON THE RIGHT, WHAT RESPONSE THE TREATMENTS AT ISSUE HAVE GOTTEN FROM THE PATIENTS. IT'S QUITE

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IMPRESSIVE AND REFLECTIVE OF THE SUCCESS OF THOSE COMPANIES.

THERE ARE LIKEWISE, IN A VARIETY OF SPACES WITHIN REGENERATIVE MEDICINE, A NUMBER OF COMPANIES THAT ARE ANTICIPATING PRODUCT APPROVALS IN 2020. YOU MIGHT NOTICE A COUPLE FAMILIAR NAMES ON THERE. ONE, FOR EXAMPLE, ORCHARD THERAPEUTICS, WHICH IS THE COMPANY WHICH WAS THE IN-LICENSED TECHNOLOGY OF DON KOHN'S AT UCLA IN CONNECTION, STARTING WITH EVIE AND HIS SCID WORK, THAT THEY'VE SINCE ADDED A VERY LARGE NUMBER OF RARE DISEASE TARGETS AND PRODUCTS THAT ARE IN THE PIPELINE. THEY WENT PUBLIC, AS YOU KNOW, LAST YEAR, AND THEY ARE EXPECTED TO HAVE IN 2020 AN APPROVAL FOR THE REFERENCED PRODUCT UP THERE.

BUT YOU CAN SEE IN THE DIFFERENT FIELDS OF REGENERATIVE MEDICINE, GENE THERAPY, CELL THERAPY, CELL-BASED IMMUNO-ONCOLOGY AND TISSUE ENGINEERING, THERE ARE EXPECTED TO BE A NUMBER OF THINGS APPROVED. AND AS YOU SEE IN THE LOWER RIGHT HAND OF THE SCREEN, THERE ARE A BUNCH OF PRODUCTS EXPECTING TO GET IND'S IN 2020 AND GO INTO CLINICAL TRIALS.

JUST A BIT OF A BREAKDOWN OF THE OVER A THOUSAND PROJECTS THAT ARE IN CLINICAL TRIALS RIGHT NOW. YOU CAN SEE HERE THIS BREAKS IT DOWN TO PHASES 1, 2, AND 3 FOR THE FOUR CATEGORIES WE JUST

DESCRIBED TO GIVE YOU A FLAVOR FOR HOW EACH OF THOSE SUBFIELDS WITHIN REGENERATIVE MEDICINE ARE FARING.

AND THEN THIS IS MEANT TO SHOW THE CLINICAL ACTIVITY FOR SO-CALLED LARGER INDICATIONS. AND THAT, IF YOU NOTICE, IT GIVES YOU THE NUMBER OF CLINICAL TRIALS, BUT IT ALSO GIVES YOU A FEEL FOR THE FACT THAT WITH THE LARGER INDICATIONS, A LOT OF THE DIFFERENT CONDITIONS ARE SEEING AN INCREASED NUMBER OF CLINICAL TRIALS AT AN INCREASED PACE.

THIS IS SORT OF AN INTERESTING SLIDE. THIS IS THE 9.8 BILLION IN TOTAL FINANCINGS FOR NEW INDUSTRY IN 2019. IF YOU LOOK AT THE MATH ON THE RIGHT, IT DOESN'T QUITE ADD UP UNTIL YOU'VE NOTICED THE FOOTNOTE AT THE BOTTOM, WHICH IS VERY DIFFICULT TO READ, WHICH HAS A COUPLE OF THE GENE-BASED AND CELL THERAPIES ARE DOUBLE-COUNTED, WHICH SORT OF, AT THE END OF THE DAY, ALL IN THE WASH WORKS OUT TO 9.8 BILLION. BUT, AGAIN, YOU GET A SENSE THAT THERE ARE VERY MATERIAL AMOUNTS OF MONEY BEING PUT INTO THIS. IT'S A VERY NOTEWORTHY TREND.

INTERESTINGLY, 2018 WAS THE LARGEST YEAR IN TERMS OF MONEY RAISED FOR REGENERATIVE MEDICINE COMPANIES. 2019 WAS THE SECOND HIGHEST. AND I THINK IN 2018 YOU HAD SOME NOTABLE IPO'S THAT BOOSTED THE TOTAL. BUT YOU GET THE NOTION THAT

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THERE'S A CONSISTENT AMOUNT OF LARGE AMOUNTS OF MONEY BEING PUT IN HERE.

LOOKING FORWARD BY 2020, NEXT SLIDE, THIS IS KIND OF INTERESTING. IT LOOKS LIKE A BUSY SLIDE, BUT THIS GETS TO A VERY IMPORTANT TOPIC, WHICH IS PATIENT ACCESS AS A FUNCTION OF POSITIVE REIMBURSEMENT DECISIONS FOR SELECT REGENERATIVE MEDICINE PRODUCTS. OBVIOUSLY THIS WHOLE NOTION OF REIMBURSEMENT FOR THE PRODUCTS IS A HUGE ISSUE. AND YOU CAN SEE FOR A NUMBER OF THESE HIGH PROFILE PRODUCTS THAT ARE OUT ON THE MARKET NOW, JUST EXACTLY THE TREND AND WHERE THINGS HAVE BEEN APPROVED AND GOTTEN THROUGH THE REGULATORY PROCESS AND GOTTEN THE PAYERS TO AGREE TO COVER THEM.

AND SO THIS IS AN EVOLVING STORY OF WHICH THERE IS GOING TO BE A GREAT DEAL OF TALK IN 2020 AND BEYOND TO GET THESE PRODUCTS INTO THE MAINSTREAM IN TERMS OF REIMBURSEMENT AND REGULATORY APPROVAL.

THIS I PUT UP, THIS IS KIND OF INTERESTING, THERE ARE STUDIES DONE TO DETERMINE WHAT THE SAVINGS MIGHT BE FOR PARTICULAR THERAPIES ABOVE AND BEYOND THE CURRENT COST UNDER STANDARD OF CARE. AND THERE WAS A STUDY DONE BY ARM IN CONNECTION WITH RARE BLOOD DISEASES, PARTICULARLY SICKLE CELL, HEMOPHILIA, AND MULTIPLE MYELOMA. AND

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THAT STUDY DETERMINED THAT THERAPIES COULD PROVIDE COST SAVINGS OF 18 TO 30 PERCENT OVER A TEN-YEAR PERIOD, WHICH IS MATERIAL. AND I DARE SAY THAT YOU WILL BE SEEING A LOT OF STUDIES LIKE THIS COME OUT AS PRODUCTS GET CLOSER TO ACTUALLY MATERIALIZING.

BIT OF A BUSY SLIDE HERE, BUT THIS IS SORT OF PROJECTING INTO 2020. JUST INVITE YOU TO READ THIS WITH RESPECT TO A LOT OF THE BIG TOPICS THAT FACE THE INDUSTRY. I THINK THIS IS A GOOD SUMMARY OF WHAT'S PROJECTED FOR THE COMING YEAR.

SO IN SUMMARY, 2019 WAS A YEAR OF SIGNIFICANT GROWTH IN THE REGENERATIVE MEDICINE SECTOR. WE ENTER 2020 POISED FOR CONTINUED EXPANSION. MANY PATIENTS ARE ALREADY BENEFITING FROM REGENERATIVE MEDICINES, AND THE CLINICAL RESULTS ARE DRAMATIC. THE PIPELINE IS ROBUST WITH SEVERAL NEXT GEN TECHNOLOGIES ENTERING THE CLINIC AND AN INCREASE IN CLINICAL TRIALS FOR INDICATIONS WITH LARGE PATIENT POPULATIONS.

CONSIDERABLE EFFORT AND PROGRESS HAS BEEN MADE IN ADDRESSING VARIOUS MANUFACTURING CHALLENGES, WHICH WE DIDN'T REALLY GET INTO, BUT THERE HAVE BEEN SOME SIGNIFICANT DEVELOPMENTS THERE. AND WHILE FINANCING DIPPED IN 2019 VERSUS 2018, FINANCING REMAINS STRONG ACROSS VENTURE CAPITAL AND

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PARTNERSHIPS WITH M&A ACTIVITY SHOWCASING LARGE AND MIDDLE CAP PHARMA'S INTEREST IN THE CELL AND GENE THERAPY SPACE.

THAT LAST POINT IS VERY IMPORTANT BECAUSE, AS YOU KNOW, IT'S TAKEN PHARMA QUITE A BIT OF TIME TO WARM UP TO THE FIELD. THERE WAS A LOT OF THOUGHT THAT YOU NEEDED TO ESTABLISH PROOF OF CONCEPT FOR CELL AND GENE THERAPIES WHICH GENERALLY GO INTO THE END OF PHASE 1 OR 2 DEPENDING ON THE PROJECTS. YOU'RE NOW SEEING PHARMA GETTING INTO THINGS EARLIER WHICH IS A REFLECTION ON THE FACT THAT THEY ARE SEEING THE VIABILITY OF REGENERATIVE MEDICINE IN GENERAL, AND I THINK THAT'S MOST DEFINITELY A TREND THAT'S GOING TO CONTINUE.

SO THAT IS THE END OF THE SLIDES FROM THE STATE OF THE INDUSTRY TALK AT ARM. ARE THERE ANY QUESTIONS ON THAT AT ALL? YES, DR. HIGGINS.

DR. HIGGINS: FOR A LONG TIME NOW, WE'VE SORT OF AVOIDED THE ISSUE OF AFFORDABILITY AND VIABILITY FROM THE FINANCIAL POINT OF VIEW. AND IT SEEMS IT JUST CHANGED OVERNIGHT, THAT THERE'S INTEREST IN THAT FOR OBVIOUS REASONS.

YOU GAVE TWO POSSIBLE REASONS THAT THAT'S BECOME UNFEASIBLE TO FEASIBLE, THE INTEREST OF PHARMA, FOR EXAMPLE, CLOSE TO BEING FURTHER ALONG IN

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DEVELOPMENT. BUT WHAT WOULD YOU SAY WAS THE ONE OR TWO MAJOR REASONS THAT THE MOOD HAS CHANGED FROM BEING UNFRIENDLY TO REGENERATIVE MEDICINE TO BEING ECONOMICALLY VIABLE?

CHAIRMAN THOMAS: SO I THINK FIRST AND FOREMOST A FUNCTION OF THE TIMELINE OF DEVELOPMENT OF PRODUCTS. SO EARLIER WHEN THINGS WEREN'T QUITE INTO CLINICAL TRIALS OR THEY WERE EARLY ON IN CLINICAL TRIALS AND THERE HADN'T BEEN ENOUGH EXAMPLES OF VIABILITY, THAT THERE WAS VERY MUCH A WAIT AND SEE SORT OF THING, WHICH I DARE SAY WAS PROBABLY THE SAME BACK IN THE '90S WHEN MONOCLONAL ANTIBODIES FIRST CAME ON THE SCENE. IT'S A WHOLE NEW APPROACH. AND UNTIL YOU ESTABLISH THAT, BIG PHARMA IS RELUCTANT TO GET INTO THE GAME.

I THINK YOU'RE NOW SEEING PRODUCTS APPROVED, YOU'RE SEEING DRAMATIC RESULTS. I THINK THERE'S A DEVELOPING SENSE IN BIG PHARMA THAT, IN MY OPINION, I DON'T KNOW, WELCOME OTHERS, THAT THE TRAIN IS GOING TO LEAVE THE STATION IF IT HASN'T STARTED TO ALREADY, AND THERE'S A REAL NEED TO GET INTO THE FIELD IN A BIGGER WAY LEST YOU GET LEFT BEHIND. SO I THINK THAT'S PROBABLY THE SINGLE BIGGEST THING.

DR. HIGGINS: ONE COMMENT. THAT

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UNDERSCORES TO ME THE IMPORTANCE OF CIRM'S ALPHA CLINICS.

CHAIRMAN THOMAS: YES. THERE ARE A LOT OF THINGS THAT UNDERSCORE THE IMPORTANCE. THERE'S THAT. THERE IS THE ALPHA CLINICS AS THE SHINING EXAMPLE OF THE RIGHT WAY TO DO THINGS AS OPPOSED TO STEM CELL CLINICS THAT ARE PROLIFERATING OUT THERE THAT ARE INCREASINGLY A PROBLEM. THAT IS THE WRONG WAY TO GO ABOUT IT WITH NO SORT OF APPROVAL MECHANISM, NO BACKING, WHATEVER. BUT, YES, I ABSOLUTELY AGREE WITH THAT.

DR. DULIEGE: THANK YOU, J.T., FOR THIS GREAT OVERVIEW, VERY COMPREHENSIVE, AND ACTUALLY VERY ENCOURAGING. YOU MENTIONED THE POINT ABOUT MANUFACTURING CHALLENGES. BUT MY QUESTION IS WERE THERE ANY REFERENCES TO HOW WE HAVE IMPROVED ON ADDRESSING THE REGULATORY CHALLENGES GLOBALLY? AND I RECALL THAT THIS WAS VERY MUCH AN EFFORT OF THE CIRM. ACTUAL CIRM WAS THE LEADER IN ADDRESSING REGULATORY CHALLENGES. SO ANY UPDATE ON THAT?

CHAIRMAN THOMAS: DR. MILLAN, WOULD YOU WANT TO COMMENT ON THAT BECAUSE YOU'VE BEEN INVOLVED DEALING BACK THERE WITH THE FDA?

DR. MILLAN: ABSOLUTELY. AND I'LL TOUCH A LITTLE BIT ON THAT WHEN WE GIVE OUR PRESENTATION

BECAUSE WE HAVE A DEMONSTRATION OF HOW, ESPECIALLY WITH THE 21ST CENTURY CURES ACT THAT WAS PASSED IN DECEMBER 2016 THAT PROVIDED A PATHWAY FOR, NO. 1, MODERNIZATION OF HOW THE FDA IS LOOKING AT REGENERATIVE MEDICINE PRODUCTS AND, TWO, CREATING A FORMAL PATHWAY, AN EXPEDITED PATHWAY, THAT ALLOWS FOR MORE INTERACTIVE PARTNERSHIPS WITH THE FDA. AND WE'VE SEEN THAT THAT HAS WORKED OUT VERY WELL FOR OUR PROJECTS SPECIFICALLY, BUT WE AS AN AGENCY HAVE HAD VERY COLLEGIAL AND COLLABORATIVE CONVERSATIONS WITH THE FDA TO TACKLE ISSUES. AND THEY'VE ATTENDED OUR WORKSHOPS. SO JUST THAT EXCHANGE OF INFORMATION AS THE FIELD IS GROWING IS AMAZING.

BUT MORE TANGIBLY THEY'VE PUT OUT SPECIFIC GUIDANCE DOCUMENTS NOW THAT HAVE CREATED CLARITY IN THE FIELD AND GUIDANCE DOCUMENTS EVEN IN TERMS OF CLINICAL TRIAL DESIGN, SUCH AS ADAPTIVE TRIAL DESIGN, FOR INSTANCE, WHICH TAKES INTO ACCOUNT, AND I'LL MENTION THIS, THAT FOR MANY OF THE DISORDERS THAT WE ARE TACKLING WITH REGENERATIVE MEDICINE PRODUCTS, THEY ARE RARE CASES, SMALL NUMBERS. SO THE CLASSIC PHASE 1, 2, 3 TRIAL DESIGN THAT WE ARE USED TO IN THE PAST THAT REQUIRED LARGE NUMBERS AND LONG TIMELINES IS SOMETHING THAT'S BEING CHALLENGED RIGHT NOW. AND YOU WILL SEE DEMONSTRATION OF THIS

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MORE, I WOULD SAY, NIMBLE WAY OF LOOKING AT DATASETS AND DETERMINING THE BEST WAY TO REALLY FIGURE OUT IF SOMETHING IS WORKING OR NOT. AND SO THE FDA IS WORKING WITH INVESTIGATORS ON THAT.

IN TERMS OF MANUFACTURING, THERE'S A LONG WAY TO GO. THAT IS A MAJOR CHALLENGE, BUT THERE'S PROGRESS IN TERMS OF, FOR EXAMPLE, STARTING TO THINK ABOUT HOW THEY CAN -- WHAT ROLE THEY CAN PLAY IN TACKLING THAT. WE'VE BEEN HAVING CONVERSATIONS WITH MULTIPLE STAKEHOLDERS IN THAT AS WELL.

CHAIRMAN THOMAS: THANK YOU. DR. SANDMEYER.

DR. SANDMEYER: GIVEN THE VALUE-ADDED DATA THAT YOU INDICATED, COULD YOU COMMENT ON THE REIMBURSEMENT LANDSCAPE GOING FORWARD?

CHAIRMAN THOMAS: SO THAT'S VERY MUCH A WORK IN PROGRESS. I THINK IT'S AT ITS EARLIEST STAGES. I THINK THERE ARE A LOT OF COMPETING ISSUES HERE. THERE'S THE NEED TO GET ACROSS THE FACT THAT IF YOU HAVE SOMETHING THAT'S A ONE-TIME CURE THAT HAPPENS TO HAVE A HIGH PRICE TAG, THAT COULD BE VIEWED AS EXCESSIVE. THERE'S AN EDUCATIONAL PROCESS TO EXPLAIN THAT IF YOU COMPARE THAT TO THE COST OF CHRONIC TREATMENT OVER TIME, IT'S ACTUALLY A REAL COST SAVER, WHICH I THINK IS THE POINT OF THAT ONE

SLIDE, THAT THAT WAS WHAT THEY WERE TRYING TO MAKE.

I THINK THERE'S ALSO THE POLITICAL ISSUES BACK THERE HEAVILY WEIGHING AGAINST THE COST OF PRESCRIPTION DRUGS AND SORT OF SETTING THE TONE FOR THERE BEING AN ISSUE WITH HIGH COST TREATMENTS, WHICH MANY OF OUR PRODUCTS ARE GOING TO HAVE JUST BY THE VERY NATURE OF THE AMOUNT THAT IT HAS COST TO DEVELOP, ET CETERA. SO I THINK THAT SOME OF THE PROJECTS HAVE REACHED A POINT WHERE REIMBURSEMENT HAS BEEN AGREED TO, BUT THERE ARE A LOT OF THINGS THAT ARE IN PRODUCT DEVELOPMENT RIGHT NOW WHERE THAT'S NOT YET THE CASE. AND IT'S GOING TO BE A CONTINUING PROCESS OF EDUCATION. AND AS THE FIELD MATURES AND MORE AND MORE PRODUCTS COME TO MARKET, IT'S GOING TO BE A VERY BIG ISSUE.

SENATOR TORRES.

MR. TORRES: YES. AS SOME OF YOU MAY KNOW, I'M A MEMBER OF THE FIVE-MEMBER BOARD WHICH OVERSEES OBAMACARE HERE IN CALIFORNIA. IT'S CALLED COVER CALIFORNIA. AND WE'VE BEEN VERY PROUD OF THE FACT THAT ACROSS THE NATION WE'VE KEPT OUR PREMIUMS $1500 BELOW ANY OTHER PREMIUM IN THE NATION BECAUSE OF VERY TOUGH NEGOTIATIONS. AND AS A RESULT OF THAT, I BROUGHT IN TO MEET WITH MARIA OUR NEGOTIATORS FROM COVER CALIFORNIA WHO BASICALLY

BROUGHT IN THIRD-PARTY PAYERS, BLUE SHIELD, BLUE CROSS, KAISER, HERE IN THIS VERY ROOM TO START TALKING ABOUT THE FUTURE, TO START TALKING ABOUT TREATMENT REIMBURSEMENT, TO START TALKING, ESPECIALLY MY CONVERSATIONS WITH THE HEADS OF THESE THIRD-PARTY PAYERS, ABOUT THE ECONOMIC BENEFITS OF THE INSURERS IN TERMS OF, YES, THE COST WILL BE HIGH INITIALLY, BUT IN THE LONG TERM THINK OF ALL THE OTHER FACTORS THAT YOU'RE NOT GOING TO BE CHARGED FOR OR BE ABLE TO CHARGE PEOPLE FOR.

WE ARE ALSO IN THE PROCESS NOW OF MAKING SURE THAT THAT PROVISION WITHIN THE NEW INITIATIVE WHICH TALKS ABOUT ACCESSIBILITY AND THE ESTABLISHMENT OF AN ACCESSIBILITY COMMITTEE IS GOING TO BE SO KEY. I'VE BRIEFED COVER CALIFORNIA ON THAT AS WELL TO MAKE SURE THAT WE COORDINATE AS MUCH AS WE CAN BECAUSE WE ARE NOW AT THE NEXT LEVEL. WE'VE DONE OUR HOMEWORK. NOW, GOD WILLING, THIS INITIATIVE WILL PASS. THAT'S NOT A POLITICAL STATEMENT. THAT'S A PRAYER. GOD WILLING, THIS INITIATIVE WILL PASS AND THAT WILL HELP US CONTINUE ON THAT ROAD. BUT WHAT IS KEY TO ME IS THAT THESE INSURERS ARE NOW AT THE TABLE REALIZING WHAT'S AHEAD AND REALIZING THE POTENTIAL BENEFITS TO THEM.

CHAIRMAN THOMAS: DR. MARTIN.

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DR. MARTIN: JUST A COMMENT ON A THIRD-PARTY PAYER. THE MAJOR POLITICAL HURDLE WAS THAT THE CMS AGREED LAST FALL TO PAY FOR CAR-T THERAPY THAT WAS APPROVED BY THE FDA. THAT WAS MAJOR. AND THE STUDY WAS DONE BY AN ORGANIZATION OUT OF THIS COUNTY. AND IT'S A VERY CONVINCING ECONOMIC ANALYSIS. AND IT ENDS UP THAT THE MOST ECONOMICALLY BENEFICIAL ANALYSIS IS ON CHILDREN WITH CHIMERA BECAUSE THE EFFECT EXTENDS SO LONG THAT IT ALSO WAS APPROVED FOR THOSE OF US OVER 65. THAT WAS A MAJOR HURDLE.

CHAIRMAN THOMAS: DR. MILLAN AND THEN YSABEL.

DR. MILLAN: THANK YOU SO MUCH. I JUST WANTED TO MAKE A PITCH FOR OUR ALPHA CLINICS SYMPOSIUM WHERE WE WILL HAVE ICER THERE ON A PANEL. GEOFF LOMAX IS HELPING OUR ALPHA CLINICS ORGANIZE THIS MEETING. AND WE'VE BEEN, ABLA CREASEY AND THE TEAM, HAVE BEEN DISCUSSING WITH ICER AND I'VE BEEN IN MEETINGS WITH CMS AND THE FDA, AND THERE IS A LOT OF MOTIVATION TOWARD ALIGNING REGULATORY APPROVALS AND THE TYPES OF DATASETS AND EVIDENCE GENERATION FROM THE CLINICAL TRIALS THAT COULD BE USEFUL FOR SUPPORTING CURRENTLY.

AND ANOTHER STATEMENT IS WE DON'T HAVE

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MANY PRODUCTS OUT THERE THAT HAVE BEEN MARKETED, BUT EVEN THE NON-CAR-T PROGRAMS, THE SPARK THERAPEUTICS PROGRAM FOR BLINDING EYE DISEASE, AND THE PROGRAM, AVEXIS PROGRAM, FOR SMA THAT IS NOW BEING MARKETED BY NOVARTIS. WE'VE HAD PUBLICLY REPORTED INTERIM KIND OF MARKET UPDATES. AND SURPRISINGLY THE PRIVATE INSURERS ARE COVERING. THEY HAVE BEEN GETTING A LOT OF TRACTION WITH PRIVATE INSURERS AT THIS POINT. SO IT'S A RARE DISEASE. THERE'S NO OTHER CURE. THERE DEFINITELY IS A MOTIVATION. IT'S JUST FINDING THE BEST MODEL.

AND ONE OF THE THINGS IN ALL OUR CONVERSATIONS AND THE MULTIPLE WORKSHOPS THAT WE HAVE HAD WITH CMS, FDA, AND OTHER POLICY FOLKS IS THAT IT HAS TO BE DATA DRIVEN. AND SO THAT IS KIND OF THE KEY THINGS THAT WE ARE HEARING ALL THE TIME IS DATA. AND SO THAT'S AN IMPORTANT THING TO KEEP IN MIND AS WE DO ALL OUR RESEARCH.

DR. MARTIN: LET ME JUST ADD QUICKLY, THAT THAT DOES NOT INFER THAT THE INDUSTRY AND ACADEME DOES NOT HAVE TO CONTINUE TO TRY TO REDUCE COST OF MANUFACTURING. AND THERE ARE ONGOING PRESSURES THERE, PARTICULARLY TO MAKE IT SCALABLE.

CHAIRMAN THOMAS: MS. DURON.

MS. DURON: THANK YOU, JONATHAN. I MAY BE

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TOTALLY OFF BASE HERE, BUT I'M ALWAYS THINKING ABOUT LIKE NO. 2, THE PATIENTS BENEFITING, BUT WHO'S PAYING? HOW ARE THEY PAYING? CAN THEY AFFORD? THIS IS THE FIRST THING THAT STOPS MANY LOW-INCOME PEOPLE FROM EVEN HEADING TOWARDS CARE BECAUSE THEY'RE PUTTING THEIR DOLLAR INTO THIS INSTEAD OF THAT. I'M SURE ART KNOWS THIS FROM EVEN THE ACA.

I MAY HAVE MENTIONED -- I MAY NOT HAVE MENTIONED TO YOU THAT I SIT ON THE INSTITUTIONAL REVIEW BOARD FOR THE ALL OF US RESEARCH PROGRAM. AND EVEN AS THEY'RE RAMPING UP ON GETTING, I THINK THEY'RE NOW AT 330,000 AT LEAST, PARTICIPANTS, THE QUESTIONS COMING BACK IS SORT OF LIKE WHAT'S IN IT FOR US? WE'VE NOW GIVEN YOU ACCESS TO IT, WHAT'S IN IT FOR US? WHAT ARE WE GETTING BACK? SO THERE WILL BE RETURN OF RESULTS. THEY'RE DOING SOME SEQUENCING AND SO ON AND SO FORTH.

BUT I THINK THAT, IN GENERAL, THIS KIND OF AN INITIATIVE, THIS KIND OF MEDICINE IN ALL OF ITS WONDERFUL MEDICAL DISCOVERIES THAT CAN IMPACT PATIENTS, IN SOME WAYS THERE OUGHT TO BE PAYBACK FOR THE INVESTMENT OF TAXPAYERS IN CALIFORNIA PUTTING MONEY INTO THESE DISCOVERIES.

SO HOW DO THEY GET PAID BACK? WHERE DO THEY GET SOME BENEFIT FROM THIS BESIDES, OF COURSE,

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THESE PATIENTS, WHICH IS FABULOUS, BUT THE SENSE THAT I'M PUTTING IN A DOLLAR AND I GET BACK A PENNY. I WOULD LOVE TO SEE, AND I DON'T KNOW IF THIS IS SOME KIND OF AN ISSUE THAT HAS TO BE TAKEN UP IN THE LEGISLATURE, I WOULD LOVE TO SEE THAT WHENEVER WE PUT UP -- WELL, YOU NEVER KNOW WHAT IT'S GOING TO ENTAIL, RIGHT? IT'S PROBABLY GOT 5,000 RULES THAT GO WITH IT, BUT I WOULD LOVE TO SEE THAT, EVEN AS YOU'RE PUTTING OUT RFA'S, THAT YOU'RE ALSO SAYING FOR EVERY -- AND WE'VE GOT THE CALIFORNIA BREAST CANCER RESEARCH PROGRAM WHICH IS BASED ON A TAX INITIATIVE IN WHICH DOLLARS GO BACK INTO RESEARCH AND SUPPORT, BUT IT'S ALSO SUPPORTING COMMUNITY-BASED ENGAGEMENT IN RESEARCH.

SO THERE'S A LINE ITEM THERE THAT IS VERY IMPORTANT THAT'S HELPING CBO'S GET ENGAGED IN RESEARCH AND PAYING THEIR BILLS AND NOT JUST ASKING THEM TO DO IT VOLUNTARILY. WHAT I'D LIKE TO SEE IS SOMETHING CALLED A PEOPLE FUND. CAN WE TAKE FOR EVERY DOLLAR WE ARE PUTTING INTO AN INVESTMENT IN A PRODUCT, EVENTUAL PRODUCT OR RESEARCH, WE CAN PUT A PENNY INTO IT? BY THE TIME YOU GATHER A LOT OF PEOPLE'S PENNIES, IT TURNS INTO, I THINK, I WOULD HOPE, A SIZABLE FUND TO BE PUT ASIDE TO PAY FOR PEOPLE OR PAY FOR OPPORTUNITIES FOR PEOPLE TO ENGAGE

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IN THESE CLINICAL TRIALS BECAUSE IT TAKES TIME AND MONEY AND EFFORTS, AND A LOT OF PEOPLE DON'T ENGAGE OR CAN'T ENGAGE BECAUSE OF THE COST OR IT GOES TO CLINICS, IT GOES INTO THE ACA TO SUPPORT PEOPLE'S ABILITY TO GET THIS KIND OF HEALTHCARE WHEN AND WHERE NEEDED AS THE DISCOVERIES ARE FOUND. BECAUSE TO ME THIS IS -- PEOPLE INVESTING IN OPPORTUNITIES AND AS STAKEHOLDERS, WHAT ARE THEY GETTING BACK FOR THEIR DOLLAR?

MR. TORRES: I THINK IT'S IMPORTANT FOR YOU TO BE EDUCATED BY JAMES HARRISON WHO'S EDUCATED ME FROM THE BEGINNING. I THINK IT'S IMPORTANT TO LAY OUT WHAT IS THE CURRENT INITIATIVE LANGUAGE AND WHAT'S THE PROPOSED INITIATIVE LANGUAGE IF YOU WOULD BE SO KIND.

MR. HARRISON: CERTAINLY. SO THE ORIGINAL LAW REQUIRES THIS GOVERNING BOARD TO ESTABLISH INTELLECTUAL PROPERTY REGULATIONS TO ENSURE THAT THE DESIRE FOR THE STATE TO BENEFIT FROM ANY ROYALTIES EARNED FROM THE RESEARCH IT'S FUNDING IS BALANCED AGAINST THE DESIRE NOT TO UNNECESSARILY IMPEDE MEDICAL RESEARCH AND DISCOVERY. SO THIS BOARD HAS ADOPTED AND AMENDED MANY TIMES EXTENSIVE INTELLECTUAL PROPERTY REGULATIONS, WHICH MR. JUELSGAARD CAN DESCRIBE TO YOU IN DETAIL AS THE

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CHAIR OF THE IP TASK FORCE, BUT THEY DO PROVIDE FOR A RETURN TO THE STATE. AND UNDER CURRENT LAW, THOSE FUNDS GO DIRECTLY TO THE STATE GENERAL FUND TO BENEFIT THE STATE AT LARGE.

HOWEVER, UNDER THE PROPOSED MEASURE THAT MR. KLEIN HAS SUBMITTED, THOSE FUNDS WOULD BE EARMARKED TO HELP DEFRAY THE COST OF THERAPIES AND CURES THAT ARISE FROM CIRM-FUNDED RESEARCH FOR THOSE CALIFORNIANS WHO DON'T HAVE SUFFICIENT FUNDS TO OBTAIN THEM.

MS. DURON: OKAY. I DON'T KNOW IF IT'S QUITE GOOD ENOUGH, BUT I'LL START THERE.

CHAIRMAN THOMAS: DR. PRIETO.

DR. PRIETO: YES. I KNOW SOME OF THESE ARE PERHAPS BRANCHES OF LARGER COMPANIES, BUT HOW MANY OF THE REGENERATIVE MEDICINE COMPANIES HAVE SHOWN A PROFIT? DO WE HAVE ANY IDEA OF THAT?

CHAIRMAN THOMAS: I DON'T. DR. MILLAN, DO YOU?

DR. MILLAN: WELL, THERE WAS -- I DON'T KNOW IF SHYAM PATEL IS HERE. SHYAM, DO YOU WANT TO COMMENT ON THE REPORTS THAT THEY HAD WITH THE SMA PRODUCT BECAUSE THAT JUST CAME OUT?

DR. PATEL: SO THE APPROVED MEDICINES ARE KYMRIAH, ESCARDA, LUXTURNA, AND ZOLGENSMA, AS MARIA

ALLUDED TO.

SO KYMRIAH, WHICH IS THE NOVARTIS ONE, WAS THE FIRST CAR-T PRODUCT TO BE COMMERCIALLY VIABLE. AND THAT WAS -- BECAUSE OF MANUFACTURING ISSUES, THE REVENUE HAS BEEN SLOW, THE GROWTH HAS BEEN SLOW.

ESCARDA IS DOING BETTER. THEY HAD BETTER MANUFACTURING IN PLACE.

LUXTURNA IS A VERY SMALL POPULATION, SO THE REVENUE THERE IS NOT GOING TO BE VERY LARGE.

BUT ZOLGENSMA, WHICH IS THE SMA GENE THERAPY PRODUCT, HAS SHOWN REALLY GREAT REVENUE GROWTH OVER THE PAST FEW QUARTERS. AND IT'S GROWING BEYOND WHAT THEY ORIGINALLY PROPOSED AND EXPECTED. SO THAT ONE IS TAKING A LOT OF MARKET SHARE FROM SPINRAZA. IT'S GOT GOOD COVERAGE BOTH THROUGH MEDICAID AS WELL AS THROUGH PRIVATE INSURERS, AND IT'S GETTING SOLID REVENUE GROWTH QUARTER OVER QUARTER.

SO NOW I CANNOT SAY THAT BECAUSE IT'S OWNED BY NOVARTIS, IT DOESN'T REALLY SHOW HOW MUCH PROFIT THEY'RE MAKING OFF OF IT, BUT IT IS DEFINITELY A SUCCESS STORY SO FAR IN TERMS OF CELL AND GENE THERAPIES.

CHAIRMAN THOMAS: THANK YOU. ANY OTHER QUESTIONS OR COMMENTS? OKAY.

THE NEXT ITEM, WANT TO TALK A BIT, SET THE STAGE FOR DR. MILLAN'S PRESENTATION ON THE STRATEGIC PLAN. SO AS YOU WILL RECALL, IN OUR LAST BOARD MEETING, WE HAD TALKED ABOUT DEVELOPING A NEW STRATEGIC PLAN. THAT STRATEGIC PLAN FOLLOWS ON THE CURRENT PLAN, WHICH HAS BEEN IN PLACE SINCE 2016 AND RUNS THROUGH THIS YEAR, AND THE IDEA WAS TO HAVE THE TEAM PUT TOGETHER A STRATEGIC PLAN OVER THE COURSE OF THIS YEAR FOR CONSIDERATION BY THE BOARD IN THE EVENT THE NEW INITIATIVE PASSES IN NOVEMBER.

GENERAL GAME PLAN HERE IS SEVERAL FOLD. FIRST, DR. MILLAN TODAY WILL BE LOOKING BACK AT THE 2016-2020 STRATEGIC PLAN TO SEE HOW WE'VE DONE REACHING ITS GOALS. THEN SHE WILL PRESENT AND OUTLINE FOR THE NEW STRATEGIC PLAN FOR BOARD DISCUSSION THAT FACTORS IN LANGUAGE IN THE NEW INITIATIVE. I HAVE CONFERRED WITH HER AND MEMBERS OF THE TEAM ON THIS OUTLINE. MEMBERS OF THE BOARD ARE ENCOURAGED TO ENGAGE FOLLOWING TODAY'S DISCUSSION IN THE VARIOUS PARTS OF THE PLAN OUTLINE THAT WILL BE FLESHED OUT IN THE COMING MONTHS.

DR. MILLAN WILL NEXT BRING THE REVISED PLAN TO THE BOARD FOR FURTHER REVIEW AT OUR MAY MEETING. THAT WILL TRIGGER ADDITIONAL WORK FOR THE NEXT FEW MONTHS THEREAFTER CULMINATING IN ITS FINAL

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REVIEW AT OUR OCTOBER MEETING. IF THE MEASURE PASSES, THE FINAL VERSION OF THE PLAN, WHICH WILL STILL BE IN DRAFT FORM, WILL GO TO THE NEW BOARD AFTER THE PASSAGE OF THE MEASURE FOR ITS REVIEW AND ADOPTION AT THE FIRST MEETING AFTER THAT ELECTION. AND THE DATE FOR THAT BOARD MEETING IS YET TO BE DETERMINED.

IN ADDITION TO WORKING ON THE STRATEGIC PLAN, BOARD MEMBERS ARE ENCOURAGED TO BE AMBASSADORS FOR CIRM IN THE COMING MONTHS BY SPEAKING AT CONFERENCES, SERVING ON PANELS, DOING INTERVIEWS WITH THE PRESS WHEN COORDINATED THROUGH OUR COMMUNICATIONS GROUP, TALKING TO EDITORIAL BOARDS, ET CETERA. I'LL BE DOING MUCH OF THAT DURING THAT TIME FRAME AS A WAY TO EDUCATE THE PUBLIC ABOUT CIRM AND OUR PROGRAMS AND PORTFOLIO, MUCH AS I'VE BEEN DOING IN THE PAST.

LAST WEEK, JUST FOR EXAMPLE, I SPOKE TO THE ROTARY CLUB IN THE SOUTH BAY DOWN IN LOS ANGELES AND AT THE STEM CELL CONFERENCE DOWN AT UC IRVINE. TOMORROW I'M SPEAKING TO THE L.A. CHAMBER OF COMMERCE.

SO I THINK WHEN WE GET INTO THIS DISCUSSION THAT DR. MILLAN WILL LEAD, YOU WILL GET A GOOD FEEL FOR WHAT AN OPENING OUTLINE FOR PURPOSES

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OF DISCUSSION WILL BE.

FINALLY, A COUPLE OF THINGS. WANTED TO NOTE, DON WANTED TO SAY THAT -- DON'S WIFE GLORIA STARTED CHEMO LAST WEEK FOR CANCER. AND I WANTED TO SAY THAT OUR THOUGHTS ARE VERY MUCH, AS ALWAYS, WITH YOU AND THE FAMILY, AND TO PLEASE PASS THAT ALONG TO GLORIA. WE KNOW THAT SHE WILL BEAT THIS, AND WE LOOK FORWARD TO POSITIVE NEWS IN THE VERY SHORT NEAR FUTURE. IF WOULD YOU LIKE TO SAY SOMETHING, PLEASE DO.

MR. REED: JUST THAT THE WORK THAT YOU DO IS IMPORTANT TO NOT ONLY EVERY INDIVIDUAL WHO SUFFERS CHRONIC, BUT THE ENTIRE COUNTRY AND THE WORLD. MY WIFE IS MY HEART. I DREAD THE THOUGHT IF SHE DOESN'T MAKE IT. BUT NO MATTER WHAT, FIGHT GOES ON. THANK YOU SO MUCH.

CHAIRMAN THOMAS: THANK YOU. AND LAST, SO AN ADDITIONAL TOUGH NOTE. VERY SORRY TO REPORT THAT LAUREN MILLER'S MOTHER PASSED AWAY THIS WEEK AFTER A LONG BATTLE WITH EARLY ONSET ALZHEIMER'S WHICH LAUREN SO ELOQUENTLY DESCRIBED AT OUR LAST BOARD MEETING IN OCTOBER. WE SEND OUR DEEPEST CONDOLENCES TO HER AND THE FAMILY AT THIS MOST DIFFICULT TIME AND LOOK FORWARD TO THE DAY WHEN THIS TERRIBLE DISEASE IS CURED. WE WILL BE OBSERVING A MOMENT OF

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SILENCE IN HER MEMORY AT THE END OF THIS MEETING.

SO THAT CONCLUDES THE CHAIRMAN'S REPORT. WHERE IS BETH? GREAT. LET'S GO TO ONE MORE ITEM AND THEN WE'LL TAKE A BREAK. GOING TO GO NOW, PLEASE, TO ITEM NO. 6, CONSIDERATION OF ALLOCATION OF RECOVERED FUNDS TO RESEARCH PROGRAMS. WE'LL HAVE DR. SAMBRANO PRESENTING HERE.

DR. SANDMEYER JUST ASKED IF IT'S POSSIBLE TO GET THE JP MORGAN SLIDES. THE ANSWER IS YES. I WILL SEND IT OUT TO EVERYBODY.

MS. BONNEVILLE: I JUST WANT TO CHECK TO SEE IF BOARD MEMBERS HAVE JOINED. LINDA BOXER, ARE YOU ON THE LINE?

DR. BOXER: YES. I'VE BEEN ON SINCE THE BEGINNING.

MS. BONNEVILLE: GREAT. THANK YOU. ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: THANK YOU. AL ROWLETT.

MR. ROWLETT: YES. I'VE BEEN ON SINCE THE BEGINNING.

MS. BONNEVILLE: THANK YOU. OS STEWARD. OKAY. THANK YOU.

CHAIRMAN THOMAS: DR. SAMBRANO.

DR. SAMBRANO: OKAY. THANK YOU, MR.

CHAIRMAN. GOOD MORNING, EVERYBODY. SO MANY OF YOU MAY RECALL THAT THE LAST TIME THIS BOARD MET TO TALK ABOUT FUNDING OF APPLICATIONS, WE REACHED A BALANCE OF ZERO OTHER THAN THE SICKLE CELL PROGRAM FOR WHICH WE HAD RESERVED 27 MILLION. SO IN THE COURSE OF MANAGING OUR PORTFOLIO OF EXISTING AWARDS, WHAT HAPPENS IS WE RECOVER FUNDS. SO USUALLY THESE ARE FUNDS THAT ARE UNUSED, UNDER CERTAIN AWARDS, CUTS THAT ARE MADE DURING THE LAUNCHING OF NEW AWARDS, AND SO THOSE CONTINUE TO ADD UP, AND THIS HAPPENS ON AN ONGOING BASIS.

SO THOSE ARE CALLED UNALLOCATED RECOVERED FUNDS. AND SO AS OF THE END OF JANUARY, WE HAD $2.28 MILLION THAT ARE AWAITING ALLOCATION. AND SO TODAY'S PRESENTATION IS BASICALLY A COUPLE OF SUGGESTIONS AND RECOMMENDATIONS OF WHAT TO DO WITH THOSE FUNDS.

AND SO THOSE COVER TWO MAIN AREAS. SO ONE IS THE CIRM PROGRESSION AWARDS, WHICH I WILL DISCUSS AND EXPLAIN TO YOU, AS WELL AS A PROPOSED CIRM GRANTEE MEETING.

SO LET'S FIRST TALK ABOUT THE PROGRESSION AWARDS AND WHAT THESE ARE. SO THIS IS PART OF AN INCENTIVE MECHANISM THAT WAS BUILT INTO THE QUEST AWARD PROGRAM. SO THAT'S ONE OF OUR DISCOVERY EARLY

RESEARCH AWARDS. GOAL OF THOSE AWARDS IS TO DEVELOP A DEVELOPMENT CANDIDATE THAT WILL ULTIMATELY GO INTO TRANSLATION. AND SO WE KNOW THAT THERE ARE A LOT OF SCIENTISTS, ESPECIALLY IN ACADEMIA, WHO ARE VERY GOOD AT DEVELOPING, DOING A LOT OF THE BASIC SCIENCE THAT WILL GET WORK TO THAT POINT. AND SO THE PROGRAM CREATES AN INCENTIVE TO THEN HAVE THAT WORK TRANSITION INTO TRANSLATIONAL TYPE ACTIVITIES WHETHER THE INVESTIGATOR DOES THEM THEMSELVES OR THEY TRANSITION IT ON TO SOMEBODY ELSE TO DO IT.

AND SO THAT INCENTIVE IS $150,000 IN DIRECT PROJECT COSTS THAT WILL ALLOW THE INVESTIGATOR TO CONTINUE TO DO WHAT THEY DO BEST AND DO MORE DISCOVERY WORK. SO THE QUEST AWARDEES WHO THEN ACHIEVE A PROGRESSION EVENT, MEANING THEY'VE TRANSITIONED ONE OF OUR PROJECTS INTO TRANSLATION WITHIN ONE YEAR OF COMPLETING THE QUEST AWARD, ARE THEN ELIGIBLE TO RECEIVE THIS AWARD TO CONDUCT STEM CELL RESEARCH AS LONG AS IT ALIGNS WITH THE OVERALL CIRM MISSION.

AND SO JUST MORE SPECIFICALLY, THE PROGRESSION EVENT, AS WE CALL IT, OCCURS WHEN NEW FUNDS FROM ANY SOURCE HAVE THEN BEEN COMMITTED TO ADVANCE THE RESEARCH PROJECT TO THE NEXT STAGE OF TRANSLATIONAL ACTIVITIES.

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AND SO HOW IT WORKS IS A QUEST AWARDEE WHO REACHES THE END OF THEIR AWARD AND HAS ACHIEVED A PROGRESSION EVENT WILL SUBMIT AN APPLICATION TO US. CIRM ASSESSES WHETHER IT IS ELIGIBLE IN TERMS OF THE ACTIVITIES THAT ARE PROPOSED AND IF THERE IS EVIDENCE THAT SHOWS THAT THEY HAVE ACTUALLY ADVANCED THE PROJECT TO THE DESIRED TRANSLATIONAL ACTIVITIES. SO CIRM ASSESSES THAT. AND IF THEY ARE ELIGIBLE, THEN AN AWARD IS MADE.

AND SO THE CURRENT STATISTICS FOR THESE. WE HAVE NOW SEVERAL QUEST AWARDS THAT HAVE REACHED THE POINT OF COMPLETION. SO USUALLY IT'S 24 TO 30 MONTHS THAT THEY ARE GIVEN. AND SO THE FIRST COHORTS OF QUEST AWARDS ARE REACHING THEIR END. AND SO WE HAVE NOW RECEIVED TWO APPLICATIONS FOR PROGRESSION AWARDS THAT, IF ELIGIBLE, WOULD REQUIRE APPROXIMATELY 460,000 TO ISSUE A PROGRESSION AWARD. WE ALSO EXPECT THAT WE COULD RECEIVE UP TO SIX ADDITIONAL APPLICATIONS BY MIDYEAR THAT WOULD CALL FOR ANOTHER 1.38 MILLION.

AND SO OUR REQUEST IS TO ALLOCATE 1.84 MILLION INTO THE PROGRESSION AWARD PROGRAM BUCKET OUT OF THE AVAILABLE 2.28 MILLION IN ORDER TO ALLOW FUNDING FOR UP TO EIGHT ELIGIBLE PROJECTS. WE WILL BE PROVIDING AN UPDATE AT THE NEXT BOARD MEETING IN

MAY ON THE NUMBER OF APPLICATIONS THAT COME IN AS WELL AS THE STATUS OF RECOVERED FUNDS THAT AT THAT TIME WE EXPECT WILL BE HIGHER AND MAY BE AVAILABLE FOR ADDITIONAL PROJECTS.

SO I CAN PAUSE HERE FOR ANY QUESTIONS BEFORE I GO INTO THE SECOND ITEM. MR. JUELSGAARD.

MR. JUELSGAARD: YES. I'M TRYING TO SQUARE THE $150,000 PER PROGRESSION AWARD EVENT WITH THE $460,000 FOR TWO.

DR. SAMBRANO: RIGHT. SO THE ESTIMATE IS ACTUALLY FOR 230,000 PER AWARD TO ALLOW FOR THE FACILITIES AND INDIRECT COST RATE THAT IS ADDED. AND SO THAT'S VARIABLE DEPENDING ON THE INSTITUTION THAT RECEIVES IT.

MR. JUELSGAARD: ONE OTHER QUESTION. IS THERE A MINIMUM OF FUND RAISE FOR ELIGIBILITY FOR A PROGRESSION AWARD?

DR. SAMBRANO: SO FOR THE COMMITMENT, I BELIEVE WE HAVE A MINIMUM AMOUNT, I THINK. SO WHAT WE LOOK FOR IS EVIDENCE THAT THEY HAVE EITHER RECEIVED A GRANT, THEY HAVE DEVELOPED A PARTNERSHIP WITH SOMEBODY WHERE THERE IS CLARITY THAT THEY'RE GOING TO MOVE AND HAVE STARTED TRANSLATIONAL ACTIVITIES.

MR. JUELSGAARD: BUT IS IT SAFE TO ASSUME

THAT THAT COMMITMENT IS A SUBSTANTIAL COMMITMENT AND NOT JUST $10,000 IN ADDITIONAL FUNDS?

DR. SAMBRANO: SO WE NEED TO KNOW THAT THEY'RE ACTUALLY MOVING IT FORWARD. BUT IN TERMS OF THE SPECIFIC REQUIREMENT, I DON'T THINK BY THE LETTER WE HAVE ANY SPECIFIC MINIMUM STATED.

MS. WINOKUR: THESE PROGRESSION AWARDS GO THROUGH THE SAME PROCESS OF APPROVAL?

DR. SAMBRANO: SO THE AWARDS ARE PART OF THE QUEST PROGRAM ITSELF. AND SO THE WAY THESE ARE APPROVED ARE BY THE CIRM PRESIDENT. SO THEY GO THROUGH AN ELIGIBILITY REVIEW. THEY DON'T GO THROUGH A SCIENTIFIC REVIEW. THE REVIEW IS BASICALLY FOR ISSUING FUNDS FOR THOSE PROJECTS THAT MEET THE BASIC ELIGIBILITY CRITERIA.

MS. WINOKUR: OKAY.

MS. DURON: NOT HAVING READ THE RFA, NOT KNOWING WHAT IT REQUIRES IN ORDER TO GET AN AWARD, DOES IT REQUIRE A DISSEMINATION REPORT TO THE PUBLIC ABOUT WHAT THEY'VE DONE, HOW THEY'VE USED THE MONEY, AND WHAT THEY'VE DISCOVERED IN TIME? I ASK THAT BECAUSE, GOING BACK TO THIS PERHAPS ONE OF THE THINGS, IF YOU POSSIBLY REQUEST, IS ASK THEM IN RECEIVING THE AWARD, J.T., THAT THEY DISSEMINATE TO THE PUBLIC IN SOME WAY, SHAPE, OR FORM, HOLD A

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CONFERENCE FOR PEOPLE OF INTEREST IN THEIR COMMUNITY.

I THINK THAT PART OF THE PROBLEM, ONCE AGAIN, WITH SILOING AND LOOKING INWARD AT HOW SUCCESSFUL WE ARE, WE FAIL TO LET THE PUBLIC KNOW WHAT'S GOING ON IN A VERY BROAD WAY. I WOULD LOVE TO SEE THEM DISSEMINATE WHAT THEY'VE LEARNED AND HOW IMPORTANT IT IS TO ADVANCE THE MEDICINE IN THIS PARTICULAR ARENA AND WHAT THEY SEE FOR THE FUTURE AND HOW IT IMPACTS THE PUBLIC BECAUSE I THINK THE PUBLIC NEEDS TO UNDERSTAND THIS IN ORDER TO BE ABLE TO SUPPORT AN INITIATIVE WHERE THEY'RE SPENDING THEIR TAXPAYER DOLLARS. CAN YOU ATTACH THAT? CAN YOU MAKE IT PART OF -- IS IT PART OF THEIR UNDERSTANDING ANYWAY?

DR. SAMBRANO: SO THAT'S A GREAT QUESTION. AND SO WE DO MAKE AN EFFORT TO ENSURE THAT THE WORK WE FUND AND THE PROGRESS THAT IS MADE IS AVAILABLE TO THE PUBLIC. SO PART OF IT IS THROUGH HAVING A PUBLIC VERSION OF AN ABSTRACT THAT SUMMARIZES THE PROGRESS OVER THE COURSE OF AN AWARD. AND SO THAT IS PART OF OUR WEBSITE. AND SO GRANTEES ARE ASKED TO UPDATE THAT.

THE OTHER MECHANISM THAT IS USED IS THAT WE PERIODICALLY TRY TO HAVE MEETINGS OF OUR GRANTEES

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IN ORDER TO HAVE THEM SHARE THAT INFORMATION WITH OTHER SCIENTISTS BUT AS WELL AS MEMBERS OF THE PUBLIC. SO THERE ARE EFFORTS. NOW, WHETHER THAT IS SUFFICIENT AND WHETHER THERE ARE ADDITIONAL THINGS WE CAN DO, I THINK THAT IS CERTAINLY WORTH CONSIDERING.

DR. BLUMENTHAL: YOU MENTIONED THE POSSIBILITY OF SIX ADDITIONAL APPLICATIONS FOR THESE AWARDS. HOW FIRM IS THAT EXPECTATION? COULD IT BE LARGER? COULD IT BE A SMALLER NUMBER? AND IF IT'S DIFFERENT THAN SIX, HOW WOULD YOU PROPOSE THAT WE ADDRESS THAT DIFFERENCE?

DR. SAMBRANO: RIGHT. SO THIS IS OUR BEST GUESS ESTIMATE BASED ON AWARDS THAT ARE COMING TO COMPLETION AT THAT TIME. SO WE ANTICIPATE THAT ABOUT 50 PERCENT OR MORE WOULD COME IN WITH AN APPLICATION, AND THAT'S WHAT THE ESTIMATE IS BASED ON. THE LIKELIHOOD THAT IT WOULD BE MORE IS PROBABLY PRETTY LOW, BUT THAT IS ALSO WHY I GAVE THE CAVEAT THAT IN MAY WE WILL REPORT TO YOU IN TERMS OF THE NUMBER OF APPLICATIONS THAT ARE ACTUALLY RECEIVED AND IF THERE ARE ADDITIONAL FUNDS THAT MIGHT BE REQUIRED IN ORDER TO MEET THAT THRESHOLD.

CHAIRMAN THOMAS: MR. JUELSGAARD.

MR. JUELSGAARD: GIL, DO YOU HAVE ANY

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ESTIMATE OF ADDITIONAL UNALLOCATED RECOVERED FUNDS THAT MIGHT BE RECEIVED BETWEEN NOW AND THE MAY MEETING? SO WE ARE AT, WHAT, 2.3 MILLION NOW. DO YOU EXPECT MORE TO COME IN? DO YOU HAVE ANY IDEAS? IF SO, WHAT THAT AMOUNT MIGHT ENTAIL?

DR. SAMBRANO: SO I'M GOING TO SEE IF JENN IS WILLING TO GET A NUMBER. BUT I'LL JUST SAY THAT ON AN ONGOING BASIS WE RECEIVE FUNDS. IN THE PAST WE HAVE RECEIVED IN A YEAR SOMEWHERE BETWEEN 20 TO 30 MILLION. BUT WHETHER WE ACTUALLY RECEIVE THAT THIS YEAR IS DEPENDENT ON A LOT OF FACTORS. SO IN SOME WAYS IT'S DIFFICULT TO PREDICT; ON THE OTHER HAND, IT IS LIKELY WE WILL RECEIVE MORE.

MR. JUELSGAARD: SO ONE FOLLOW-UP QUESTION ON THAT. LET'S ASSUME JUST FOR THE SAKE OF THIS DISCUSSION FOR A MOMENT THAT IN MAY, LET'S SAY WE DON'T ALLOCATE THESE FUNDS FOR ANYTHING, BUT SIMPLY PUT THEM ASIDE, AND IN MAY WE HAVE FIVE OR SIX MILLION OR SOME AMOUNT MORE THAN THAT. WOULD WE BE LOOKING AT SPENDING THE MONEY IN THE SAME WAY THAT WE ARE SPENDING IT NOW? WOULD WE LOOK AT THESE SORTS OF AWARDS, OR WOULD WE LOOK AT CLINICAL DEVELOPMENT OR SOMETHING ELSE?

DR. SAMBRANO: RIGHT. SO THAT'S A GREAT QUESTION. SO IF YOUR DESIRE IS TO CONTINUE ISSUING

PROGRESSION AWARDS, WE WOULD EXPECT THAT BY THE END OF THE YEAR WE WOULD HAVE MAYBE A DOZEN OR MORE APPLICATIONS. SO WE MIGHT BE DOUBLING UP ON THE REQUEST FOR THOSE. IF THERE ARE SUFFICIENT FUNDS, IT REALLY IS UP TO THIS BOARD WHETHER WE SHOULD USE THOSE FOR OUR CLINICAL PROGRAM OR OTHER PROGRAM WHERE IT MIGHT BE APPROPRIATE. BUT AT THE MOMENT WE DON'T HAVE ANY SPECIFIC RECOMMENDATION FOR THOSE ADDITIONAL FUNDS.

CHAIRMAN THOMAS: ANY OTHER QUESTIONS OF DR. SAMBRANO? DO WE HAVE A MOTION TO APPROVE? MOVED BY DR. BLUMENTHAL, SECONDED BY SENATOR TORRES. ANY FURTHER DISCUSSION BY MEMBERS OF THE BOARD?

DR. DULIEGE: CAN YOU REPEAT EXACTLY THE MOTION?

CHAIRMAN THOMAS: MR. HARRISON.

MR. HARRISON: TO APPROVE THE ALLOCATION OF 1,840,000 OF RECOVERED FUNDS FOR PROGRESSION AWARDS.

DR. DULIEGE: IS IT TO APPROVE THIS SPECIFIC PROJECT OR TO HAVE AN ENVELOPE OF MONEY OF THAT AMOUNT TO FUTURE PROJECTS BASED ON SUBMISSIONS?

DR. SAMBRANO: YES. IT'S THE LATTER.

DR. DULIEGE: SO WE ARE NOT HAVING TO APPROVE SPECIFIC PROJECTS?

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DR. SAMBRANO: CORRECT.

DR. DULIEGE: JUST A CONCEPT.

DR. SAMBRANO: CORRECT. SO THE CONCEPT HAS BEEN APPROVED, AND YOU'RE PUTTING MONEY INTO THE BUCKET THAT ALLOWS US TO APPROVE THOSE.

DR. DULIEGE: THANK YOU.

CHAIRMAN THOMAS: ANY MORE COMMENTS BY MEMBERS OF THE BOARD EITHER HERE OR ON THE PHONE? ANY COMMENTS BY MEMBERS OF THE PUBLIC EITHER HERE OR ON THE PHONE? MR. REED.

MR. REED: SOUNDS GREAT, BUT DOES THAT MEAN THERE WILL BE LESS MONEY FOR THE CONFERENCE TO EXPLAIN THE PURPOSE OF CIRM? IS THAT SEPARATE? AND THERE WILL BE SUFFICIENT MONIES FOR THAT BECAUSE THAT'S IMPORTANT?

CHAIRMAN THOMAS: THAT'S A SEPARATE ITEM.

MR. REED: OKAY. THANK YOU.

CHAIRMAN THOMAS: ANY OTHER COMMENTS BY MEMBERS OF THE PUBLIC? HEARING NONE, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: DEBORAH DEAS.

DR. DEAS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.
MS. BONNEVILLE: YSABEL DURON.
MS. DURON: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: CARL WARE.

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DR. WARE: AYE.
MS. BONNEVILLE: DIANNE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU, DR. SAMBRANO. ON TO THE SECOND ITEM.
DR. SAMBRANO: OKAY. THANK YOU, MR. CHAIRMAN. SO THE SECOND ITEM IS A PROPOSED CIRM GRANTEE MEETING. AND SO WHAT WE ARE PROPOSING HERE IS TO USE OUR EXISTING CONFERENCE GRANT MECHANISM TO SOLICIT APPLICATIONS TO ORGANIZE AND EXECUTE A MEETING OF GRANTEES SOMETIME LATER THIS YEAR. THE MEETING WOULD INVITE, OF COURSE, CIRM GRANTEES, MEMBERS OF THE GOVERNING BOARD, PATIENT ADVOCATES, INTERESTED FUNDING ORGANIZATIONS, AND OTHER STAKEHOLDERS, AS WELL AS THE PUBLIC TO DISCUSS AND HEAR ABOUT ADVANCES IN PROGRESS IN THE FIELD OF STEM CELL RESEARCH IN THE STATE.
AND SO WE SUMMARIZE THE MEETING GOALS WITH THE FOLLOWING FOUR BULLETS. ONE, TO PROVIDE A PUBLIC FORUM TO LEARN ABOUT THE MOST RECENT ADVANCES IN STEM CELL RESEARCH, TO ENCOURAGE THE SHARING OF INFORMATION AND DATA AMONG CIRM GRANTEES AND FOSTER COLLABORATION AND LEARNING, TO HAVE TIMELY PRESENTATIONS THAT ADDRESS AND OVERCOME KEY

BOTTLENECKS. AND THAT'S IMPORTANT ESPECIALLY TO PROJECTS THAT WE ARE CURRENTLY FUNDING THAT MAY BE MEETING CHALLENGES. AND SO HELP WITH THAT IS ALWAYS WELCOME. AND THEN SHOWCASING PROMISING STEM CELL-BASED PROJECTS FOR POSSIBLE PARTNERSHIP OPPORTUNITIES WITH INVESTIGATORS, FUNDERS, AND OTHER COMPANIES.

SO THESE ALIGN VERY MUCH WITH THE GRANTEE MEETINGS THAT WE HAVE HAD IN PAST YEARS BETWEEN 2008 AND 2013 WHERE WE BROUGHT OUR GRANTEES TOGETHER TO SHOW US AND OTHER SCIENTISTS AND THE PUBLIC MANY OF THESE ADVANCES. AND IT WAS SOMETHING THAT WAS VERY WELL RECEIVED. WE HAVE NOT HAD ONE SINCE THAT TIME, BUT WE CERTAINLY THOUGHT THAT, GIVEN THAT WE'VE REACHED A POINT WHERE WE NOW ARE CULMINATING ALL OF THE PROJECTS AND ADVANCES, THAT IT MIGHT BE A GOOD TIME TO DO THAT.

SO THE FORMAT WOULD BE A TWO-DAY MEETING THAT WOULD INCLUDE SCIENTIFIC PRESENTATIONS BY NOTABLE KEY SPEAKERS INCLUDING CIRM INVESTIGATORS. WE ESTIMATE APPROXIMATELY THREE TO 400 ATTENDEES AND THAT THIS WOULD BE HELD SOMETIME IN THE LATTER HALF OF 2020, LIKELY IN THE FALL. AND THE COST ESTIMATE, BASED ON PREVIOUS MEETINGS OF A SIMILAR TYPE, IS ABOUT 250,000 THAT WE WOULD CONTRIBUTE TO THIS.

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AND SO OUR REQUEST IS FOR AN ALLOCATION OF THAT AMOUNT INTO THE CONFERENCE GRANT PROGRAM SO THAT WE MAY ISSUE AN RFA AND NOW ALLOW FUNDING OF A GRANT THAT COULD REALIZE THIS MEETING.

CHAIRMAN THOMAS: DR. DULIEGE.

DR. DULIEGE: I THINK IT'S A TERRIFIC IDEA TO RESUME SUCH MEETINGS. THERE'S NOTHING LIKE BRAINSTORMING CONFERENCES. AND I JUST HOPE THAT ICOC MEMBERS MIGHT BE ALLOWED TO ATTEND AS WELL.

DR. SAMBRANO: YES, ABSOLUTELY.

MS. DURON: DO PATIENT ADVOCATES OR PATIENT FAMILIES AND PUBLIC ADVOCATES GET TO HELP PLAN THE CONFERENCE? AND IS THERE A SEPARATE TRACK FOR THE PUBLIC WHO -- SO THAT THERE'S OPPORTUNITIES TO HEAR IN ENGLISH WHAT THIS IS ALL ABOUT? SOMETIMES THE SCIENCE IS WAY ABOVE THEM. I JUST THINK YOU COULD EITHER TRACK IT, BUT IT HELPS TO SERVE THE PUBLIC AS WELL AS THE SCIENTISTS.

I SIT THROUGH A LOT OF SCIENTIFIC PRESENTATIONS, AND I PROBABLY GET A SMIDGEON, BUT IT'S ENOUGH FOR ME TO GO BACK AND TALK TO PEOPLE. BUT I THINK THE PATIENT FAMILIES ALSO NEED TO SHOW THEIR SIDE OF THE ISSUE AND ITS IMPACT AND WHAT IT MEANS TO THEM. AND THIS RESONATES MORE WITH THE PUBLIC, I THINK, THAN A SCIENTIFIC PRESENTATION. SO

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CAN YOU PLAN TWO TRACKS, OR INSERT PATIENT FAMILIES AS PART OF THE PRESENTATION AND NOT JUST FOCUS ON THE SCIENCE PER SE?

DR. SAMBRANO: YES, WE CAN. SO IT IS -- THE SPECIFIC DETAILS OF THE MEETING ITSELF HAVE NOT BEEN YET DEVELOPED. SO THE GOAL IS TO HAVE AN AWARD THAT WOULD ALLOW SOMEBODY TO TAKE ON THE LOGISTICS OF PUTTING THIS TOGETHER AND THEN BRING IDEAS FROM CIRM, FROM THE BOARD AS WELL, TO INCLUDE ALL OF US IN HELPING DEVELOP WHAT THE MEETING WOULD LOOK LIKE.

CHAIRMAN THOMAS: DR. MILLAN AND DR. HIGGINS.

DR. MILLAN: JUST TO ADD A LITTLE BIT MORE TO THAT. WE ENVISION THAT ONE OF THE REQUIREMENTS WILL BE THAT THE PRESENTATIONS, THAT THE REQUIREMENTS OF THE SCIENTIFIC PRESENTATIONS WILL BE GEARED TOWARD THE PUBLIC. SO THAT IT WILL BE DISSEMINATION OF SCIENTIFIC KNOWLEDGE, BUT IN A WAY THAT WOULD BE DIGESTIBLE BY THE PUBLIC. AND I THINK THAT THAT SERVES TWO PURPOSES.

ONE IS THAT SCIENTISTS HAVE FOUND IT HELPFUL TO LEARN THE SKILLS OF BEING ABLE TO SPEAK IN THAT WAY BECAUSE THEY GAIN MORE TRACTION ON THEIR RESEARCH AND THEY DON'T BORE PEOPLE AT PARTIES. BUT

SECONDLY, ON THE OTHER SIDE, FOR SURE WE HAVE SOME AMAZING PATIENTS AND ADVOCATES WHO ATTEND THESE MEETINGS TIRELESSLY. AND WE REALLY WANT TO MAKE SURE IT'S WORTH THEIR WHILE.

AND THE SECOND POINT I WANT TO MAKE IS WE DO HAVE A FORUM THAT WE HAVE EVERY YEAR. IT'S CALLED THE ALPHA STEM CELL CLINICS SYMPOSIUM THAT'S HOSTED BY ONE OF THE ALPHA CLINICS EVERY YEAR. AND IN THAT IT'S COMPLETELY EMBEDDED THAT THE PATIENT TRACK IS EMBEDDED WITHIN EACH OF THE PANELS. SO IF THERE'S A TOPIC, WHAT HAPPENS IS WE EVALUATE IT FROM THE SCIENTIFIC, THE HEALTHCARE, THE CLINICAL PROVIDER, AS WELL AS THE PATIENT AND POLICY ISSUES. AND SO THAT IS SOMETHING THAT'S A MODEL THAT WE'VE BEEN FOLLOWING FOR THE ALPHA CLINICS SYMPOSIUM. AND THE NEXT ONE IS IN MAY UP IN SACRAMENTO.

CHAIRMAN THOMAS: I'D JUST LIKE TO PUT OUT A SHOUT OUT TO THESE ALPHA CLINIC MEETINGS. THEY'RE ABSOLUTELY OUTSTANDING. AND IF BOARD MEMBERS HAVE SOME TIME TO ATTEND, IT IS REALLY, REALLY INTERESTING, AND YOU GET A GREAT FEEL FOR WHERE THE SCIENCE IS, A VIEW FROM THE PATIENT COMMUNITY, ET CETERA. THEY'RE JUST GREAT. AND WE HISTORICALLY HAVE NOT HAD A LOT OF BOARD MEMBERS THERE, SO WE'LL MAKE A REAL EFFORT TO MAKE SURE EVERYBODY KNOWS

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EXACTLY WHEN IT IS. AND THOSE THAT CAN MAKE IT, PLEASE DO. IT'S REALLY WORTHWHILE.

DR. HIGGINS.

DR. HIGGINS: COUPLE OF QUICK QUESTIONS. IS THIS, YOU SAID, FOR THE FALL, PLANNED FOR THE FALL? IS IT BEFORE NOVEMBER 3D?

DR. SAMBRANO: WE AREN'T SPECIFYING ONE WAY OR THE OTHER. SO IT WILL BE UP TO, MOST LIKELY, THE AVAILABILITY OF THE VENUE AND WHERE IT CAN BE HOSTED.

DR. HIGGINS: OKAY. AND THE SECOND QUESTION COMES OFF OF YSABEL'S COMMENTS ABOUT INVOLVING PATIENTS AND THE PUBLIC, WHICH I THINK IS A FANTASTIC IDEA. BUT IT'S REALLY A QUESTION FOR HER. DO YOU THINK THERE WOULD BE ENOUGH OF AN INTEREST AND A NEED TO HAVE A PARALLEL TRACK IN SPANISH?

MS. DURON: I THINK THAT EVEN IF YOU WERE ABLE TO AT LEAST PROVIDE ONE IN SPANISH, THAT MIGHT BE OF BROAD INTEREST. LIKE, WHAT IS STEM CELL? AND THEN HAVE SOME FAMILIES WHO HAVE ACTUALLY BEEN IMPACTED BY IT TO TALK ABOUT IT. THEN I THINK THAT THERE'S AN OPPORTUNITY. I DON'T KNOW THAT I'D SATURATE IT. I DO BILINGUAL CONFERENCES ALL THE TIME BECAUSE I WORK WITH COMMUNITY HEALTH WORKERS AS

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WELL AS WITH THE SCIENTISTS. SO I LIKE THAT COLLABORATION. BUT I THINK THAT EVEN IF YOU DID ONE, WHAT THAT SAYS TO A LARGE SPANISH SPEAKING COMMUNITY IN CALIFORNIA IS THAT WE ARE INCLUDED. THIS IS ALSO ABOUT US. AND SO I THINK AT LEAST ONE WOULD BE VERY LOVELY. THANK YOU FOR THINKING ABOUT IT.

MR. TORRES: UNDER THE OTHER HAT, PRO BONO HAT, I WEAR AS WELL, WHICH IS THE ONE LEGACY FOUNDATION, THE ORGAN TRANSPLANT FOUNDATION, WE'VE CONTINUALLY DONE ENGLISH AND SPANISH, DONE MORE REMEMBRANCES WHERE FAMILIES COME TOGETHER. AND IT'S VERY POIGNANT AND VERY INSPIRATIONAL BECAUSE PARENTS WILL LISTEN TO A RECIPIENT'S HEART AND SAY MY SON IS STILL ALIVE. AND THOSE FAMILIES COMING TOGETHER HAVE BEEN VERY, VERY IMPORTANT IN TERMS OF OUTREACH BECAUSE IT WAS VERY DIFFICULT TO EDUCATE AFRICAN-AMERICAN AND LATINO FAMILIES TO THINK ABOUT ORGAN DONATION, BUT IT WAS BECAUSE OF THOSE BILINGUAL CONFERENCES THERE WAS AN INCREASE IN ORGAN DONATION FROM THE LATINO COMMUNITY, AT LEAST IN SOUTHERN CALIFORNIA. SO, YEAH, IT'S VERY IMPORTANT.

MS. WINOKUR: THE PACKARD FOUNDATION FOR ALS RESEARCH AT JOHNS HOPKINS DOES THE SAME KIND OF THING TWICE A YEAR WHEN ALL OF THEIR GRANTEES MAKE A

PRESENTATION ABOUT THEIR RESEARCH, WHAT PROGRESS THEY'VE MADE, WHAT STATE IT'S AT. AND THERE IS THEN CONVERSATION THAT GOES ON BETWEEN GRANTEES AND THE GRANTEES SITTING IN THE ROOM AND OTHERS ABOUT THAT RESEARCH. AND IT HAS BEEN VERY EFFECTIVE AND HELPFUL AND POSITIVE.

CHAIRMAN THOMAS: THANK YOU, DIANE. DR. YAMAMOTO.

DR. YAMAMOTO: THE CHALLENGE HERE IT SEEMS IS THAT THERE ARE TWO, MAYBE EVEN MORE THAN TWO, COMPLETELY JUSTIFIED TARGET AUDIENCES. THE SCIENTISTS AND THE PUBLIC, MAYBE COMPANIES AS WELL, THAT WOULD BE INTERESTED OR ASPIRE TO DO WORK IN THIS AREA. AND I REALLY SUPPORT THE IDEA OF HAVING A MEETING THAT SPEAKS TO ALL OF THOSE AUDIENCES, BUT I DO THINK THERE NEEDS TO BE -- I LIKE THE SEPARATE TRACK IDEA THAT YSABEL HAS PUT FORWARD. IT'S REALLY IMPORTANT THAT THE SCIENCE BE PRESENTED AT A HIGH LEVEL SO THAT OTHERS CAN REALLY, OTHER SCIENTISTS, AND, AS I SAID, ASPIRING COMPANIES, COULD THINK ABOUT HOW THEIR WORK INTERRELATES, HOW COLLABORATIONS COULD ADVANCE THE WORK BEYOND THAT OF EITHER THE GRANTEE THAT'S TALKING OR THE ASPIRANTS.

AND THAT REALLY NEEDS TO BE AT A HIGH LEVEL WHERE WE REALLY GET INTO THE DETAILS OF THE

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SCIENCE AND THE DATA. THAT RUNS A RISK, OF COURSE, OF AT LEAST BORING, IF NOT JUST GOING OVER THE HEADS, OF THE PUBLIC IN A WAY THAT REALLY SHOULDN'T HAPPEN. I THINK THERE'S A REALLY JUSTIFIED AND ESSENTIAL ELEMENT OF BEING ABLE TO CONVEY THE INTERESTING AND EXCITING ASPECTS OF THE WORK IN A WAY THAT THE PUBLIC CAN UNDERSTAND. BUT IF IT'S ONLY PRESENTED AT THAT LEVEL, THEN THE RISK IS THAT THE SCIENTISTS WON'T BE ABLE TO GRASP THE DETAILS SUFFICIENTLY TO BE ABLE TO EXTEND THEIR THINKING TO WHAT COULD HAPPEN.

SO I THINK PRESENTING ALL THIS INFORMATION IN ONE MEETING, I THINK, IS PROBLEMATIC; BUT IF WE'RE GOING TO TRY TO ACHIEVE THOSE GOALS OF REALLY BEING ABLE TO EFFECTIVELY COMMUNICATE TO THESE DIFFERENT TARGET AUDIENCES, I THINK IT NEEDS TO BE DONE AT LEAST IN SEPARATE TRACKS, IF NOT IN SEPARATE MEETINGS.

CHAIRMAN THOMAS: THANK YOU FOR THAT COMMENT. I WOULD ALSO SAY THAT ANOTHER TARGET AUDIENCE, AS FURTHER TO DR. PATEL'S COMMENTS AND THE EXCELLENT WORK HE'S DOING IN DEVELOPING COLLABORATIONS WITH OUR GRANTEES AND MONEY SOURCES, THAT THIS WOULD BE SOMETHING THAT WE WOULD WANT TO INVITE VENTURE FIRMS TO AND PHARMA, ET CETERA, SO

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THEY CAN SEE WHAT'S GOING ON BECAUSE A LOT OF THEM DON'T KNOW THE FULL EXTENT OF WHAT THE PORTFOLIO IS OR THE STATE OF THE SCIENCE.

SO I THINK THERE ARE A LOT OF RICH TARGET AUDIENCES FOR THIS THING, AND THE CHALLENGE WILL BE TO PULL IT TOGETHER IN A WAY THAT SPEAKS TO ALL OF THEM.

SO DO I HEAR A MOTION TO APPROVE? MOVED BY DR. BURTIS. WHO WAS THE SECOND THERE?

MS. WINOKUR: DIANE.

CHAIRMAN THOMAS: THANK YOU. SECONDED BY MS. WINOKUR. ANY FURTHER DISCUSSION BY MEMBERS OF THE BOARD?

UNIDENTIFIED SPEAKER: ON THE DIVERSITY OF DISSEMINATING THIS INFORMATION, FOR RURAL AND REMOTE AREAS, IF THERE CAN BE SOME SORT OF A SCALED DOWN, SHORTER VERSION SO PEOPLE CAN PARTICIPATE BECAUSE TRAVEL TO THESE CONFERENCES CAN BE SOMEWHAT ONEROUS. THAT WOULD BE REALLY HELPFUL.

CHAIRMAN THOMAS: THANK YOU FOR THAT SUGGESTION. ANY OTHER COMMENTS BY MEMBERS OF THE BOARD? ANY COMMENTS BY MEMBERS OF THE PUBLIC? HEARING NONE, MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.
DR. BOXER: YES.
MS. BONNEVILLE: KEN BURTIS.
DR. BURTIS: YES.
MS. BONNEVILLE: DEBORAH DEAS.
DR. DEAS: YES.
MS. BONNEVILLE: ANNE-MARIE DULIEGE.
DR. DULIEGE: YES.
MS. BONNEVILLE: YSABEL DURON.
MS. DURON: YES.
MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: YES.
MS. BONNEVILLE: DAVID HIGGINS.
DR. HIGGINS: YES.
MS. BONNEVILLE: STEVE JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: LINDA MALKAS.
DR. MALKAS: YES.
MS. BONNEVILLE: DAVE MARTIN.
DR. MARTIN: YES.
MS. BONNEVILLE: LEON FINE.
DR. FINE: YES.
MS. BONNEVILLE: ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.

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MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: SUZANNE SANDMEYER.
DR. SANDMEYER: YES.
MS. BONNEVILLE: JEFF SHEEHY.
SUPERVISOR SHEEHY: YES.
MS. BONNEVILLE: OS STEWARD. JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: CARL WARE.
DR. WARE: AYE.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MS. BONNEVILLE: DOUG ZIEDONIS.
DR. ZIEDONIS: YES.
MS. BONNEVILLE: AND OS, ARE YOU THERE?

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MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU. THANK YOU, DR. SAMBRANO. LET'S TAKE A TEN-MINUTE BREAK AT THIS POINT. WE'VE GOT REFRESHMENTS IN THE KITCHEN, AND WE WILL RECONVENE SHORTLY. THANK YOU.

DR. STEWARD: MARIA, ARE YOU STILL ON?

MS. BONNEVILLE: YES.

DR. STEWARD: THIS IS OS. I HAVE BEEN HERE, I AM HERE, BUT APPARENTLY TECHNOLOGICALLY INCOMPETENT TODAY. I FINALLY GOT MY PHONE OFF MUTE.

MS. BONNEVILLE: THOSE THINGS HAPPEN. SO WAS THAT A YES FOR YOU?

DR. STEWARD: THAT WAS A YES.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: EVERYBODY PLEASE TAKE YOUR SEATS. THOSE ON THE PHONE, WE ARE ABOUT TO RECONVENE. THANK YOU VERY MUCH.

OKAY. NOW WE ARE ON TO THE PRESIDENT'S REPORT, WHICH IS MULTIFACETED AND COMPREHENSIVE, ALL FURTHER TO OUR STATED PURPOSE OF REPORTING BACK TO THE PUBLIC AT EACH OF THE BOARD MEETINGS. SO WITHOUT FURTHER ADO, TURN IT OVER TO DR. MILLAN.

DR. MILLAN: THANK YOU VERY MUCH. AND GOOD MORNING, CIRM BOARD, MEMBERS OF THE PUBLIC. THE CIRM TEAM AND I THANK YOU FOR THIS OPPORTUNITY

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TO PROVIDE AN UPDATE AND A LOOK BACK. AND I HAVE TO SAY WE ARE VERY EXCITED ABOUT WHERE OUR PROGRAMS ARE AT THIS TIME. FOR THOSE OF YOU WHO HAVE NOT HEARD SOME OF THESE, ABOUT SOME OF THESE PROGRAMS, FEEL FREE TO ASK QUESTIONS ABOUT THEM. BUT I WILL BE GIVING A VERY BROAD OVERVIEW.

I WILL START THE PRESENTATION BY GIVING AN UPDATE ON OUR CLINICAL PROGRAMS. I'LL BE FOLLOWED BY PAUL WEBB, WHO MANAGES OUR CLINICAL ADVISORY PANEL, TO GIVE AN UPDATE ON THE HOW-TOS. HOW DO WE HELP THESE PROGRAMS ACHIEVE THEIR GOALS, WHICH WILL THEN BE FOLLOWED BY KENT FITZGERALD WHO IS THE DIRECTOR OF DISCOVERY AND TRANSLATION, WHO WILL DESCRIBE OUR TRANSLATIONAL PROGRAM. AND THEN FOLLOWED BY KELLY SHEPARD, ASSOCIATE DIRECTOR FOR DISCOVERY, WHO WILL THEN GIVE YOU AN UPDATE ON A VERY EXCITING PROGRAM, OUR EDUCATION PROGRAM.

JUST FOR A BROAD OVERVIEW OF CIRM INVESTMENTS SINCE ITS FORMATION IN 2004. $2.7 BILLION IN AWARDS OF OVER A THOUSAND AWARDS HAVE BEEN SO FAR ALLOCATED. THE LARGEST HAS GONE INTO BASIC AND DISCOVERY RESEARCH OF 900 MILLION. ESPECIALLY OVER THE PAST THREE TO FOUR YEARS, WE HAVE HAD AN INCREASING INVESTMENT IN CLINICAL STAGE PROGRAMS. IT'S NOW UP TO 744 MILLION, AND THE

AVAILABLE BUDGET IS 27 MILLION FOR SICKLE CELL PROGRAMS.

THE TRANSLATIONAL PORTFOLIO HAS ALSO BEEN GROWING, AND RIGHT NOW WE HAVE QUITE A FEW JUST GETTING STARTED. AND IT'S A VERY UNIQUE ASPECT OF CIRM TO FUND TRANSLATIONAL PROGRAMS; THAT IS, TAKING THE DISCOVERY, GETTING IT PREPARED SO THAT IT CAN BE TESTED IN THE CLINIC. AND THEN WE HAVE 480 MILLION IN INFRASTRUCTURE. THAT'S BOTH BUILDING INFRASTRUCTURE AS WAS INVESTED EARLY ON AND PROGRAMMATIC INFRASTRUCTURE, SUCH AS THE ALPHA CLINICS NETWORK, AND ALL OF THE DIFFERENT PROGRAMS TO ASSIST OUR PROGRAMS IN ACHIEVING THEIR GOALS AND MAKING IT THROUGH THE DEVELOPMENT PATH. AND 220 MILLION IN EDUCATION PROGRAMS, AND YOU WILL HEAR A LITTLE BIT MORE ABOUT THAT LATER.

SO AS CHAIRMAN THOMAS HAD STATED EARLIER, WE CAN NOW HAVE A LOOK BACK ON HOW WE ARE DOING AGAINST OUR FIVE-YEAR STRATEGIC PLAN, WHICH WAS LAUNCHED BY MY PREDECESSOR RANDY MILLS, AND AT THAT TIME WITH THIS TEAM WE SET EXTREMELY BOLD GOALS, AND ONE COULD SAY THEY WERE STRETCH GOALS. AND WE CENTERED THEM AROUND THREE BIG SIX GOALS. AND I'M JUST GOING TO GO THROUGH THE PROGRESS OF WHERE WE ARE TODAY. WE ARE JUST ENTERING YEAR FIVE OF THIS

FIVE-YEAR STRATEGIC PLAN.

BY CATEGORY, WE AIM TO BRING IN 50 NEW PROGRAMS INTO OUR PIPELINE OF DEVELOPMENT CANDIDATES, AND WE'VE ACHIEVED 45. AND THAT'S WHERE IT'S GOING TO HOLD BECAUSE WE, AT THIS TIME AT LEAST, DON'T HAVE ANY ADDITIONAL FUNDS FOR TRANSLATIONAL. OF COURSE, THERE COULD BE CLIN1 PROGRAMS THAT STILL COUNT TOWARD THAT, BUT THAT IS A VERY, I THINK, IMPRESSIVE PROGRESS TO THE GOAL.

ADVANCE IS WE PUT REFINEMENTS AND ACCELERATION PROGRAMS IN PLACE OPERATIONALLY IN CIRM TO INCREASE THE PROBABILITY OF PROGRAMS EXCEEDING AND MEETING THEIR MILESTONES, MEETING THEIR PROGRESS, AND THEN THAT'S REFLECTED BY HOW THEY CAN MOVE FROM ONE STAGE OF RESEARCH TO THE NEXT, FROM DISCOVERY, TRANSLATIONAL; FROM TRANSLATIONAL TO CLINICAL.

WE'VE DOUBLED THOSE TYPES OF PROGRESSIONS SINCE WE HAVE LAUNCHED THIS STRATEGIC PLAN, AND WE HAVE NOW CLOCKED IN 72 PROGRESSION EVENTS.

IN TERMS OF REFINING THE REGULATORY PARADIGM, WE TOUCHED ON THIS DURING THE EARLIER DISCUSSION ABOUT HOW THE REGULATORY PATHWAY FOR REGENERATIVE MEDICINE IS NOW STARTING TO MATURE. AND CIRM HAS BEEN A VERY BIG PLAYER IN THIS WHOLE

THING. IN FACT, I MENTIONED THAT THE 21ST CENTURY CURES ACT, WHICH WAS PASSED IN DECEMBER 2016, CREATED A NEW PATHWAY CALLED THE REGENERATIVE MEDICINE ADVANCED THERAPIES PATHWAY FOR A VERY INTERACTIVE AND COLLABORATIVE RELATIONSHIP WITH THE FDA AND FEATURES THAT WOULD ACCELERATE DEVELOPMENT.

THE CIRM PROGRAMS WERE AMONG THE FIRST TO ACHIEVE RMAT. 129 RMAT APPLICATIONS HAVE BEEN PRESENTED TO THE FDA. 47 RMATS HAVE BEEN APPROVED BY THE FDA, AND OF THOSE, SIX ARE CIRM. SO ALMOST 13 PERCENT OF RMATS THAT HAVE BEEN GIVEN OUT BY THE FDA ARE CIRM PROGRAMS. SO THAT'S QUITE REMARKABLE. IT'S NOT JUST THE NUMBERS THAT MATTER. IT'S THAT OPPORTUNITIES FOR ADVANCING THE REGULATORY SCIENCE TO ACCOMPANY THE SCIENCE OF THESE TRANSFORMATIVE TREATMENTS.

THE NEXT GOAL WAS TO SHORTEN THE TIME TO CLINICAL TESTING, TO CUT IT IN HALF. AND AS WE DID WITH THOSE REFINEMENTS THAT WE INTRODUCED ALONG WITH THE STRATEGIC PLAN, WE THEREFORE DESIGNED AN APPLICATION PROCESS READINESS CRITERIA AND REVIEW CRITERIA THAT MADE SURE THAT THE APPLICANTS COULD ACHIEVE ACTIVITIES WITHIN A GIVEN TIME FRAME.

SO WE SET TRANSLATIONAL PROGRAMS TO A 30-MONTH TIME PERIOD, AND CLIN1, WHICH ARE

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IND-ENABLING, WHICH ARE THE STUDIES THAT ARE NECESSARY TO GET THE FDA TO APPROVE YOU GOING TO CLINICAL TRIALS, TO 18 MONTHS. AND ABOUT HALF THE PROGRAMS SO FAR ARE ACHIEVING IT. 55 PERCENT OF CLIN1S HAVE ACHIEVED THEIR IND IN LESS THAN 18 MONTHS, BUT ACTUALLY IT'S VERY IMPRESSIVE THAT 72 PERCENT ACTUALLY HAVE ACHIEVED THIS WITHIN TWO YEARS. AND THOSE WHO HAVE BEEN IN DRUG DEVELOPMENT CAN APPRECIATE THAT THAT IS VERY RAPID.

THE FIFTH OF THE BIG SIX IS TO EXPAND OUR CLINICAL PORTFOLIO. YOU MAY RECALL WHEN WE STARTED THE STRATEGIC PLAN, CIRM HAD FUNDED ABOUT 17 PROGRAMS. TO DATE WE HAVE NOW FUNDED 60 PROGRAMS. WE'VE ADDED 43 NEW CLINICAL PROGRAMS TO OUR PORTFOLIO, AND SOME OF WHICH I'LL BE DESCRIBING IN A LITTLE BIT MORE DETAIL TODAY.

THAT'S REMARKABLE, AND WE ACTUALLY ARE NOT DONE WITH THIS GOAL BECAUSE WE DO HAVE A SET ASIDE FOR CURE SICKLE CELL, THE CURE SICKLE CELL INITIATIVE, IN PARTNERSHIP WITH THE NHLBI. SO WE EXPECT SOME TO COME IN VIA THAT PROGRAM ANNOUNCEMENT.

AND THEN A SURROGATE MARKER FOR THE MATURATION OF THE FIELD THAT J.T. DID A NICE EXTENSIVE REVIEW AT THE BEGINNING OF THIS MEETING IN

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TERMS OF THE INDUSTRY PULL REALLY INCREASING INVESTMENTS GOING INTO THIS. CIRM PROGRAMS HAVE BROUGHT IN $3.4 BILLION IN INVESTMENTS INTO OUR PROGRAMS, 1.2 BILLION IN 2018 AND 1.4 BILLION JUST LAST YEAR. THIS INCREASES THE LEVERAGE ON THE 2.7 BILLION THAT WE'VE ALLOCATED, THAT $4.9 BILLION HAVE COME IN AS AN AGGREGATE FROM CO-FUNDING, OTHER SOURCES OF FUNDING, AS WELL AS INDUSTRY INVESTMENT. SO BY ALL MEASURES WE ARE EITHER ON TARGET OR EXCEEDING TARGETS FOR THE FIVE-YEAR STRATEGIC PLAN, AND OVER 50 PERCENT OF OUR PROGRAMS NOW HAVE INDUSTRY PARTNERSHIPS.

SO NOW FOR THE CLINICAL UPDATE. WE HAVE THE GREAT PROBLEM OF HAVING SO MANY CLINICAL PROGRAMS THAT TODAY WE'LL FOCUS ON TWO CATEGORIES. ONE ARE THOSE THAT ARE IN PIVOTAL PHASE OR NEAR PIVOTAL PHASE, WHICH MEANS CLOSE TO BEING APPROVED BY THE FDA TO BE MORE WIDELY AVAILABLE THROUGH A MARKETING APPROVAL, AND THE OTHER CATEGORY PROGRAMS WHERE WE HAVE SOME INTERIM DATA THAT'S BEEN REPORTED. AND THEN I'LL TOUCH UPON SOME OF THE NEW PROGRAMS THAT JUST RECEIVED THEIR IND, PERMISSION TO GO TO CLINICAL STAGE.

SO FOR THE FIRST GROUP OF PROJECTS, I'VE LISTED HERE PROGRAMS THAT ARE IN THE PIVOTAL PHASE.

CLASSICALLY PIVOTAL PROGRAMS ARE IN PHASE 3. CLASSICALLY THEY'RE VERY LARGE, USUALLY RANDOMIZED CONTROLLED STUDIES. AND ONE OF THE THINGS THAT YOU WILL START TO SEE WITH REGENERATIVE MEDICINE AND THE MODERNIZATION OF THE FDA APPROACH TO REGENERATIVE MEDICINE TRIALS THAT TARGET RARE AND SMALL POPULATIONS IS THAT THE TRIALS ARE SMALLER BECAUSE THEY EXPECT THE EFFECT SIZE TO BE LARGER.

AND ANOTHER TREND IS THAT THE FDA IS BECOMING MORE RECEPTIVE TO WHAT'S CALLED ADAPTIVE TRIAL DESIGN. SO AS A TRIAL IS GOING ALONG, THEY CAN BE PRESENTED WITH CLINICAL DATA THAT MAY SUPPORT A CHANGE IN THE PROTOCOL THAT ALLOWS THE INVESTIGATORS TO SEE THE TRUE EFFECT. AND THAT REALLY IS WELL-SUITED FOR SMALL TRIALS.

AND ANOTHER THING WITH REGENERATIVE MEDICINE TRIALS IS A MECHANISM OF ACTION IS REALLY BASED ON BIOLOGY, SO IT ALLOWS ONE TO DO THAT. AND I'LL DESCRIBE EXAMPLES OF THAT IN A LITTLE BIT.

WE ALSO HAVE TWO POTENTIAL REGISTRATION-ENABLING TRIALS. THIS SPEAKS TO THE CONCEPT OF ADAPTIVE TRIAL DESIGN AND MODERNIZATION WHERE EVEN PHASE 1 TRIALS ARE NOW SPEAKING TO THE FDA AND HAVING AN IDEA THAT THE DATA THEY'RE GETTING FROM PHASE 1 TRIALS, WHICH IN THE PAST WERE JUST

CONSIDERED SAFETY TRIALS, NOW THERE'S MORE AND MORE OF A TREND TOWARD DESIGNING THE CLINICAL TRIAL SO THEY CAN ACTUALLY GET EFFICACY DATA BENEFIT OR EARLY SIGNS OF CLINICAL BENEFIT THAT CAN SUPPORT REGISTRATION. SO THAT, AGAIN, IS A POTENTIAL WAY OF ACCELERATING DEVELOPMENT AND GETTING THESE TO PATIENTS.

SO THE FIRST EXAMPLE OF A PIVOTAL TRIAL IS THE ADA-SCID TRIAL THAT J.T. ALSO MENTIONED. IT ORIGINATED FROM UCLA WITH DON KOHN. IT'S A CELL GENE THERAPY TRIAL WHERE THE, IN THIS CASE, ADA-SCID, ALSO CALLED BUBBLE BABY DISEASE, IS A CONDITION WHERE BABIES ARE BORN WITHOUT IMMUNE SYSTEMS BECAUSE OF A MISSING ENZYME CALLED ADENOSINE DEAMINASE ADA. AND THIS APPROACH TAKES THE CHILDREN'S OWN BLOOD STEM CELLS THAT'S RETRIEVED THROUGH KIND OF A PHORESIS, JUST COLLECTING BLOOD, SELECTING OUT THE BLOOD STEM CELLS. THEY'RE ENGINEERED TO NOW EXPRESS ADA, AND THESE BLOOD STEM CELLS ARE GIVEN BACK TO THE AFFECTED CHILDREN WHERE THEY HOME INTO THE BONE MARROW, THE PLACE WHERE THEY GIVE RISE TO ALL THE BLOOD CELLS OF THE BODY INCLUDING THE IMMUNE CELLS.

I WAS TALKING ABOUT EFFECT SIZE BEING VERY LARGE FOR THIS. THIS IS A PRIME EXAMPLE OF THIS

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BECAUSE, IF THIS WORKS, NO. 1, YOU COULD DETECT IF THE ENZYME IS NOW THERE. SO THAT WASN'T THERE BEFORE. AND, TWO, YOU COULD ACTUALLY MEASURE THE IMMUNE CELLS THAT ARE NOW CIRCULATING IN THE BLOOD THROUGH A BLOOD TEST SO THAT IT'S RETRIEVABLE. BECAUSE OF THIS, YOU WILL NOTE THAT THIS IS A PHASE 2 REGISTRATION TRIAL WITH A SMALL NUMBER OF PATIENTS, 20 PATIENTS. AND THE INTERIM DATA IS THAT THERE'S BEEN A HUNDRED PERCENT EVENT FREE SURVIVAL AT TWO YEARS AND 20 PATIENTS. AND THEN THERE'S ACTUALLY BEEN DATA ON MORE PATIENTS THAT HAVE GONE OUT EVEN LONGER, FIVE OR SIX YEARS, SUCH AS EVIE WHO YOU SEE IN THIS PICTURE, WHERE THEY STILL HAVE THEIR FULL IMMUNE SYSTEM AND HAVE A DURABLE EFFECT. SO THIS IS AN EXAMPLE OF CURATIVE THERAPY.

THIS PARTICULAR PROGRAM IS UP FOR A BLA. IT'S A ROLLING BLA, I BELIEVE. AND SO WE EXPECT TO HEAR THE FDA FINAL AWARD ON THAT THIS YEAR.

WE HAVE HEARD ABOUT THE RECENT PARTNERING HIGHLIGHTS THAT HAS ALLOWED THIS PROGRAM TO GO THIS FAR, INCLUDING AN IPO AND FOLLOW-ON PUBLIC OFFERINGS.

THE NEXT PIVOTAL TRIAL IS IN ALS OR LOU GEHRIG'S DISEASE WHERE THERE'S A DESTRUCTION OF MOTOR NEURONS THAT LEADS TO PROGRESSIVE LOSS OF

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MUSCLE FUNCTION, AND IT IS A FATAL CONDITION AND IS VERY DEBILITATING ALONG THE WAY.

THIS TRIAL IS A PHASE 3 RANDOMIZED PLACEBO CONTROLLED MULTICENTER STUDY. THIS WAS APPROVED BY OUR CIRM BOARD AFTER GWG APPROVAL BASED ON EARLIER TRIALS, MULTICENTER TRIALS, DATA THAT SUGGESTED CLINICAL EFFECT.

SO THE PRODUCT HERE ARE MESENCHYMAL STEM CELLS THAT ARE INDUCED TO EXPRESS OR SECRETE GROWTH FACTORS AND IMMUNE MODULATORS THAT, ONCE IMPLANTED INTO THE SPINAL FLUID, COULD THEN IMPACT THE NEURONS TO PROTECT THEM FROM DESTRUCTION THAT LEADS TO THEIR DEMISE IN ALS.

THEY HAVE ENROLLED THEIR LAST PATIENT OF A 196, AND THE TOP-LINE DATA IS EXPECTED. THEY'RE IN ANALYSIS AND FOLLOW-UP RIGHT NOW, AND WE EXPECT DATA FROM THIS TRIAL BY THE END OF THIS YEAR.

I PRESENTED THIS TO THIS BOARD IN THE PAST. THIS IS A SLIGHTLY DIFFERENT TYPE OF PRODUCT. THIS IS A DECELLULARIZED PRODUCT THAT IS BIOLOGICAL STILL. IT'S IMPLANTED INTO THE HOST AND GETS SEEDED WITH THE HOST'S OWN BLOOD STEM CELLS THAT AFTER A BIT REMODEL AND LOOK JUST LIKE A NATIVE BLOOD VESSEL. IT'S QUITE REMARKABLE.

SO THE FIRST INDICATION THAT THIS COMPANY,

HUMACYTE, HAS APPLIED THIS TO IS FOR AV FISTULAS FOR -- A REPLACEMENT FOR AV FISTULAS FOR KIDNEY FAILURE. SO THIS IS A LIVE LINE. DIALYSIS IS THE LIFELINE FOR PATIENTS EITHER AWAITING TRANSPLANT OR WHO ARE CANDIDATES FOR TRANSPLANT, AND DIALYSIS ACCESS IS A HUGE PROBLEM. USUALLY YOU TRY WITH NATIVE VESSELS. THEY EVENTUALLY FAIL. YOU RUN OUT OF VESSELS. YOU GO TO THE SYNTHETIC GRAFT LIKE PTFE. THOSE HAVE ALL SORTS OF POTENTIAL COMPLICATIONS WITH IT.

SO IN THIS TRIAL THERE ARE TWO PHASE 3 RANDOMIZED COMPARISON TRIALS THAT THIS COMPANY IS DOING TO COMPARE IT TO THOSE TWO DIFFERENT TYPES OF AV ACCESS. AND THEY'RE COMPLETING ANALYSES IN THE FIRST OF THOSE TRIALS AND COMPLETING ENROLLMENT IN THE SECOND AND THEIR ONGOING EFFORTS WITH THE FDA DURING ENROLLING BLA SUBMISSION. THEY ALREADY HAVE A PARTNERSHIP WITH ONE OF THE LARGEST GLOBAL DIALYSIS ACCESS COMPANIES IN TERMS OF AN EQUITY INVESTMENT AND FUTURE GLOBAL MARKETING AND SALES, AGAIN SPEAKING TO THE PROMISE OF THIS TECHNOLOGY.

I'M GOING TO PAUSE THERE BECAUSE I'M KIND OF ROLLING THROUGH EVERYTHING. DOES ANYBODY HAVE ANY QUESTIONS RIGHT NOW ABOUT THE TECHNOLOGY SO FAR? OKAY.

SO NOW SHIFTING GEARS TO ANOTHER TYPE OF TRIAL THAT CIRM UNIQUELY FUNDS, AND THIS WAS ACTUALLY A TRIAL THAT WE PARTNERED WITH THE NIH IN THAT THEY INITIALLY DID SOME OF THE STUDIES AND THEN IT WENT TO CIRM AS IT WAS PROGRESSING IN THE ACADEMIC SETTING. AND THIS IS A COMPANY THAT'S RELATED TO THAT TRIAL.

SO THIS TRIAL SEEKS TO INDUCE IMMUNE TOLERANCE TO A TRANSPLANTED ORGAN BY DOING A COMBINED BLOOD STEM CELL AND ORGAN TRANSPLANT. THE IDEA IS BASED ON THE CLASSIC IMMUNOLOGIC PHENOMENON OF IMMUNE TOLERANCE WHERE DOING THIS, GETTING THE HEMATOPOIETIC STEM CELLS OF THE SAME DONOR TYPE AS THE KIDNEY ALLOWS THE HOST TO VIEW THE KIDNEY AS ITSELF AND DOESN'T REJECT IT.

AND SO THIS TRIAL IS ONGOING. IT'S A PHASE 3 REGISTRATION TRIAL WITH 30 HLA-MATCHED LIVING DONOR TRANSPLANTS. THE ENROLLMENT IS ONGOING. WE EXPECT THAT THEY'LL BE REPORTING THEIR RESULTS IN AN ACADEMIC SOCIETY SOMETIME MIDYEAR. AND I'LL COME BACK WITH AN UPDATE ON THAT.

THIS TRIAL THAT'S BEING -- THAT CIRM HAS FUNDED THAT'S BEING CARRIED OUT BY ROCKET PHARMA IS AN EXAMPLE OF THE KIND OF UNIQUE ASPECT OF THESE CELL AND GENE THERAPY TRIALS. IT'S A GENE THERAPY

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FOR A FATAL PEDIATRIC CONDITION CALLED LEUKOCYTE ADHESION DEFICIENCY 1. ESSENTIALLY THE BLOOD CELLS DON'T WORK THE WAY THEY SHOULD TO AVOID INFECTION AND PROTECT THE KIDNEYS. AND SO IT'S FATAL.

WHAT'S REMARKABLE ABOUT THIS TRIAL, IT'S A PHASE 1/2 TRIAL, BUT IT'S DESIGNED SO THAT IT'S REGISTRATION ENABLING, MEANING THAT EVEN WITH A SMALL NUMBER OF PATIENTS, NINE PATIENTS, THAT POSITIVE DATA WITH THIS, THE IDEA IS THAT THE COMPANY HOPES THAT THIS IS ENOUGH TO GO TO THE FDA AND THAT THE EFFECT IS SOMETHING THAT COULD SUPPORT GOING STRAIGHT TO REGISTRATION EITHER MAYBE BY ADDING MORE PATIENTS BUT ACCELERATING THE DEVELOPMENT OF THIS VERY NEEDED THERAPY FOR A HUGE UNMET FATAL CONDITION IN A SMALL NUMBER OF PATIENTS.

THIS HAS BEEN ABLE TO, IN ADDITION TO CIRM FUNDING, RAISE MONEY IN THE PUBLIC MARKET AS WELL AS LICENSE OTHER GENE THERAPY PROGRAMS FROM THE CIRM PORTFOLIO.

I WANTED TO SAY THAT WE'RE GOING THROUGH THESE, AND IT SEEMS LIKE A LOT AND IT IS A LOT. THIS IS QUITE REMARKABLE AT THIS PHASE, THAT OUR PROGRAMS HAVE GOTTEN TO THIS MATURATION. YOU'VE HEARD DR. MARK CHAO FROM FORTY SEVEN INC., WHICH IS A SPIN-OUT FROM STANFORD FROM DR. IRV WEISSMAN'S

TECHNOLOGY, AT THIS BOARD MEETING PRESENT ON THE PROGRESS AND THE PART OF THEIR PROGRAM AND THE PARTNERSHIP WITH CIRM ON THIS.

SO THIS IS AN UPDATE ON THEIR PHASE 1B TRIAL OF A COMBINATION THERAPY OF THEIR PRODUCT, WHICH IS AN ANTIBODY, TO CD 47 AND CHEMOTHERAPY. THE IDEA BEHIND THIS COMBINATION IS THE ANTIBODY THAT BLOCKS CD 47 ESSENTIALLY UNMASKS THE TUMOR TO SOMETHING THAT IT DOES TO AVOID IMMUNE DESTRUCTION. IN THIS CASE, BY COMBINING IT WITH CHEMOTHERAPY, IT RENDERS THOSE CANCER STEM CELLS MORE SUSCEPTIBLE TO IMMUNE DESTRUCTION.

IT'S AN ONGOING PHASE 1B TRIAL, AND THE REPORT FROM THE COMPANY IS THAT THEY HAVE REASON TO BELIEVE THAT IT'S POTENTIALLY REGISTRATION ENABLING ALREADY. IN ADDITION, THEY'RE ALSO LAUNCHING A PHASE 3 TRIAL WITH SOME REFINEMENTS TO THE PROTOCOL. IT HAS FAST-TRACKED AN ORPHAN DRUG DESIGNATION. THIS COMPANY WENT PUBLIC, AS YOU HEARD, IN 2018 AND HAS SUCCESSFULLY RAISED MONEY IN THE PUBLIC MARKET AND IS CREATING STRATEGIC PARTNERSHIPS FOR NEXT GENERATION APPROACHES TO THERAPY.

OKAY. SO THAT'S IT FOR PIVOTAL. I THINK THAT, EVEN IN THE COURSE OF A YEAR, THIS IS THE TYPE OF PRESENTATION WE WOULDN'T HAVE BEEN ABLE TO

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PROVIDE THE BOARD BECAUSE IT JUST SPEAKS TO KIND OF THE PACE BY WHICH THESE PROGRAMS ARE PROGRESSING.

AND I WANT TO SAY, I WANT TO ACKNOWLEDGE, WHICH I SHOULD HAVE DONE IN THE BEGINNING, THE THERAPEUTICS TEAM AND THE SCIENCE OFFICERS WHO WORKED TIRELESSLY WITH EACH OF THESE PROGRAMS AS IF THEY WERE THEIR OWN TO MAKE SURE THEY STAY ON TRACK AND GET ALL THE HELP THEY NEED ALONG THE WAY.

SO TO JUST CONTINUE, I'LL BE PRESENTING SOME INTERIM CLINICAL DATA FROM SOME OTHER CLINICAL PROGRAMS THAT WE HAVE IN OUR CIRM PORTFOLIO.

YOU MAY HAVE HEARD OF THE CAR-T TECHNOLOGY WHICH HAS TAKEN THE WORLD BY STORM. BUT I WANTED TO JUST DESCRIBE THAT FOR THOSE WHO MAY NOT BE AS FAMILIAR. THIS IS A REVOLUTIONARY NEW APPROACH TO CANCER THERAPY WHICH USES THE BODY'S OWN IMMUNE CELLS, WHICH IS THE NORMAL HEALTHY STATE, CIRCULATES AROUND AND DESTROYS ANY KIND OF ABERRANT CELLS THAT MAY EXIST IN OUR BODIES. BUT FOR ONE REASON OR ANOTHER, A TUMOR CANCER WOULD EVADE THESE T-CELLS, OR THE T-CELLS THEN BECOME KIND OF INCAPACITATED TO DESTROY THOSE CANCER CELLS.

SO THE CAR-T TECHNOLOGY IS A TECHNOLOGY WHERE T-CELLS FROM THE PATIENTS, THE IMMUNE CELLS, THESE CANCER DESTROYING CELLS, ARE EXTRACTED, THEN

ARE ENGINEERED TO EXPRESS WHAT WE CALL A SEEK-AND-DESTROY RECEPTOR, CHIMERIC ANTIGEN RECEPTORS, SO THAT THEY CAN SPECIFICALLY HOME TO THE CANCER. THEY CAN RECOGNIZE THESE CANCERS AND THEN INITIATE DESTRUCTION OF THOSE CANCERS. AND IT SEEMS KIND OF LIKE SCIENCE FICTION IF I DESCRIBE IT THAT WAY, BUT THE AMAZING THING ABOUT IT IS THE INITIAL RESULTS FOR THIS WITH LEUKEMIA AND THEN WITH LYMPHOMA WITH PATIENTS WHO WERE RESISTANT TO ALL CHEMOTHERAPY. ESSENTIALLY THEY WERE GIVEN SIX MONTHS BECAUSE THEY HAD NO OTHER REGIMEN. SO IT WAS REALLY SALVAGE THERAPY. BUT THEY WERE GETTING 70 TO 80 PERCENT COMPLETE RESPONSE RATE. AND THEN YOU SAW FROM THE SLIDE THAT J.T. HAD SHOWN SOME LONGER TERM, TWO YEARS, OF ABOUT 60, 70 PERCENT RESPONSE DEPENDING ON THE DIFFERENT BLOOD CANCERS. SO IT'S A REMARKABLE TECHNOLOGY. AND THEN, OF COURSE, THE FIELD HAS EXPLODED WITH MANY DIFFERENT COMPANIES TARGETING THIS APPROACH.

BUT CIRM HAS BEEN FUNDING NEXT GENERATION APPROACHES, AND POSEIDA THERAPEUTICS IS ONE OF THESE WHERE THIS TECHNOLOGY ENRICHES FOR T-STEM CELL MEMORY CELLS BECAUSE WHEN THESE CAR-TS EVENTUALLY FAILED, IT COULD BE BECAUSE THE T-CELLS CAN GET EXHAUSTED OR THEY'RE KIND OF GONE. AND THESE T-CELL

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STEM CELL MEMORY CELLS ARE KIND OF LIKE A RESERVE ARMY THAT ARE STICKING AROUND. AND THEN ONCE THERE'S EITHER A RESIDUAL TUMOR OR SOMETHING THAT STARTS TO BLOSSOM AGAIN, THEY ESSENTIALLY RAMP UP, EXPAND, AND THEN CAN CONTACT THOSE. THAT'S THE IDEA BEHIND IT, AND THAT'S BEING TESTED.

IN ADDITION, THESE CAR-T CELLS BEING DEVELOPED BY POSEIDA ARE ENGINEERED USING NONVIRAL VECTORS. SO OTHER TYPES OF CAR-T CELLS USE A VIRAL, A NAKED VECTOR, OR SOMETHING THAT'S INCAPACITATED, BUT STILL USE A VECTOR TO BE ABLE TO DELIVER THE GENE IN THERE TO EXPRESS THESE SEEK AND DESTROY. AND THEY USE A NONVIRAL METHOD AS WELL AS ENCODE WHAT'S CALLED A SAFETY SWITCH. SO THEY ENCODE IN, WHEN THEY ENGINEER THESE CELLS, SOMETHING SO THAT THEY CAN BE GIVEN A PILL TO TURN THEM OFF IF NEEDED.

SO THAT TRIAL IS ONGOING. THE PHASE 1 TRIAL HAS BEEN COMPLETED AND HAS ACHIEVED CLINICAL DATA TO SUPPORT A PHASE 2 REGISTRATION TRIAL THAT'S BEING INITIATED NOW. THE COMPANY HAS BEEN ABLE TO SUCCESSFULLY RAISE IN THE PUBLIC MARKET AS WELL AS GET A SERIES C INVESTMENT LED BY NOVARTIS JUST LAST YEAR.

AND THEN VIACYTE, WHICH THIS BOARD IS VERY FAMILIAR WITH BECAUSE THIS COMPANY HAS BEEN FUNDED

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BY CIRM FROM THE VERY BEGINNING IN MULTIPLE CAPACITIES TO DEVELOP A CELL REPLACEMENT APPROACH FOR TYPE 1 DIABETES. AND, AGAIN, UNIQUELY CIRM IS THAT THESE ARE EMBRYONIC STEM CELL DERIVED, AND THE COMPANY NOW HAS CLINICAL DATA TO REPORT. THEY REPORTED THAT IN EIGHT PATIENTS IMPLANTED WITH THESE EMBRYONIC STEM CELL-DERIVED PANCREATIC PROGENITOR CELLS IN A CASSETTE THAT'S LIKE A THIN LITTLE CREDIT CARD, THEY WERE ABLE TO DETECT IN EIGHT PATIENTS EVIDENCE OF BIOLOGIC ACTIVITY. THEY WERE ABLE TO DETECT C-PEPTIDE WHICH IS A FRAGMENT OF NOVEL INSULIN PRODUCTION AS WELL AS STAIN FOR INSULIN IN EXPLANTS OR MINI BIOPSIES THAT THEY IMPLANT AT THE SAME TIME.

THEY'VE ALSO HAD PARTNERING WITH W. L. GORE, WHICH IS A DEVICE AND MATERIALS COMPANY, TO IMPROVE ON THIS AS WELL AS WITH CRISPR TO ENGINEER THESE CELLS SO THAT THEY COULD EVADE IMMUNE ATTACK. AND SO THAT IS SOMETHING THAT IS NEW FROM THIS YEAR BECAUSE UP UNTIL NOW WE HAVE NOT HAD CLINICAL DATA.

THE NEXT TRIAL, WHICH ALSO HAS AN RMAT DESIGNATION THAT I SPOKE OF EARLIER, IS FOR ANOTHER FORM OF SCID, ANOTHER FORM OF BUBBLE BABY DISEASE CALLED X-LINKED SCID. IT'S A COLLABORATION BETWEEN ST. JUDE HOSPITAL AND UCSF. AND THIS TRIAL USES

VIRAL DELIVERY OF THE MISSING IL 2 RECEPTOR GAMMA CHAIN. THAT'S WHAT'S MISSING AND LEADING TO THAT IMMUNE DEFICIENCY IN THESE CHILDREN.

THEY'VE REPORTED ON EIGHT PATIENTS AT 16-MONTH FOLLOW-UP WHO NOW HAVE NORMAL T-CELL AND NK CELL; WHEREAS, THEY DID NOT HAVE THAT PRIOR TO TREATMENT BECAUSE THAT WAS THE BASIS OF THEIR DISEASE. AND THAT THESE CELLS AND THEIR BLOOD CELLS RECONSTITUTED WITHIN FOUR MONTHS AFTER TRANSPLANT. THIS HAS BEEN RECENTLY PARTNERED WITH ADDITIONAL INVESTMENTS BY A COMPANY, MUSTANG BIO.

AND THEN ARE THERE ANY QUESTIONS AT THIS POINT? OKAY.

THE NEXT TRIAL IS A TRIAL WITH JCYTE, WHICH WAS A COMPANY THAT WAS SPUN OUT OF UC IRVINE. DR. HENRY KLASSEN IS STILL THE PI WHO HAD DISCOVERED THIS TECHNOLOGY. IT'S A CLINICAL STUDY FOR RETINITIS PIGMENTOSA WHICH IS A BLINDING EYE DISEASE. AND THE COMPANY HAS NOW COMPLETED ITS PHASE 2B TRIAL. AND THAT'S SUPPORTING THE NEXT PHASE OF DEVELOPMENT. AND THIS IS A VERY INTERACTIVE KIND OF CLINICAL DEVELOPMENT DESIGN ALONG WITH THE FDA AND WITH OUR CIRM TEAM BEING VERY INVOLVED IN THAT.

SO THE PHASE 1/2A TRIAL SHOWED FAVORABLE

SAFETY PROFILE AND INDICATIONS OF BIOLOGIC ACTIVITY. AND THE PHASE 2B DATA IS EXPECTED IN THE SECOND HALF OF THIS YEAR.

TO TELL YOU THE TRUTH, I DON'T KNOW HOW MUCH LONGER THIS IS. WE HAVE MAYBE THREE MORE PROGRAMS. THIS IS A LOT. AGAIN, IF WE THINK BACK TO WHEN I JOINED CIRM, WE WERE THINKING HOW MANY CLINICAL TRIALS CAN WE ACTUALLY INITIATE. AND SO TO HAVE CLINICAL DATA ON THESE TRIALS, I JUST WANT TO REEMPHASIZE IS AMAZING.

THIS IS A TRIAL THAT HAS BEEN BROUGHT TO THIS BOARD RECENTLY BY DR. JUDY SHIZURU FROM STANFORD. THIS TRIAL IS USING A MONOCLONAL ANTIBODY TO CREATE A NEW WAY OF WHAT'S CALLED MAKING ROOM. SO WHEN YOU DO A BONE MARROW TRANSPLANT OR EVEN AN ENGINEERED BLOOD STEM CELL TRANSPLANT, YOU NEED TO MAKE ROOM IN THE BONE MARROW. OTHERWISE, IT GETS CROWDED OUT BY THE PATIENT'S OWN OTHER CELLS. AND TO DO THAT, OFTEN YOU NEED TO USE CHEMOTHERAPY TO KIND OF KNOCK DOWN THE OTHER CELLS OR EVEN RADIATION, BUT THAT'S VERY TOXIC. AND SO DR. SHIZURU AND HER TEAM ARE DEVELOPING A WAY BY TARGETING C-KIT, WHICH IS A BLOOD STEM CELL MARKER, TO KIND OF KNOCK OUT THE PATIENT'S OWN STEM CELLS SO THAT IT MAKES ROOM FOR THE NEW STEM CELLS THAT ARE

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SUPPOSED TO BE THERAPEUTIC.

AND THEY HAVE SOME POSITIVE INTERIM RESULTS AT SIX MONTHS, THAT FOUR OF SIX PATIENTS REACHED THE ENDPOINT OF CHIMERISM. CHIMERISM MEANS THAT THEY COULD SEE THAT THE PATIENT WAS ABLE TO ENGRAFT WITH THE NEW CELLS THAT THEY WERE TRANSPLANTED WITH. AND THIS IS A FIRST DEMONSTRATION OF ENGRAFTMENT USING THIS TYPE OF PROTOCOL THAT AVOIDS CHEMOTHERAPY AND RADIATION ALTOGETHER.

OTHERS ARE WATCHING THIS, OTHER OF OUR PROGRAMS WHO ARE DEVELOPING GENE-ENGINEERED BLOOD STEM CELLS AND OTHER BONE MARROW PROTOCOLS BECAUSE THEY WOULD LOVE TO BE ABLE TO GET RID OF THE CHEMOTHERAPY BECAUSE THESE PATIENTS, THEY MAY HAVE BENEFIT ON THE OTHER SIDE, BUT THEN THEY HAVE TO DEAL WITH ALL THE COMPLICATIONS AND EVERYTHING ELSE OF A TOXIC REGIMEN.

I THINK ONE OF THE THINGS THAT IS NEW IS THAT THIS PROGRAM WAS RECENTLY SPUN OUT OF STANFORD AND PARTNERED WITH JASPER THERAPEUTICS WHICH LICENSES THE TECHNOLOGY. AND THERE WAS A $50 MILLION SUCCESSFUL SERIES A LED BY ROCHE VENTURE AS WELL AS OTHER PROMINENT INVESTORS. SO THAT IS SOMETHING I KNOW THAT THE BOARD WAS LOOKING AT WHEN

WE APPROVED THIS PROGRAM FOR FUNDING.

THE NEXT TRIAL IS ANOTHER IMMUNE TOLERANCE. THIS IS KIND OF THE ACADEMIC GENESIS OF THE MEDEOR TRIAL, BUT THIS IS WITH A SLIGHTLY DIFFERENT PROTOCOL BY DR. SAM STROBER AT STANFORD USING COMBINED KIDNEY AND HEMATOPOIETIC BLOOD STEM CELL TRANSPLANT. AND THEY HAVE DEMONSTRATED PERSISTENT MIXED CHIMERISM, MEANING THAT THEY SHOWED THAT IN THAT APPROACH THAT I MENTIONED WHERE YOU TAKE THE BLOOD STEM CELL FROM THE DONOR OF THE KIDNEY, TRANSPLANT BOTH AT THE SAME TIME SO THAT THAT BLOOD STEM CELL ALLOWS THE HOST TO THINK THAT THE KIDNEY IS THEIR OWN.

SO THEY'VE SHOWN THAT THESE BLOOD STEM CELLS THAT ENABLE THIS TOLERANCE ARE PERSISTENT AND ARE FLOATING AROUND SAYING THAT'S YOUR KIDNEY. SO THAT IS SOMETHING THAT THEY'VE DEMONSTRATED IN PATIENTS WITHOUT REJECTION AFTER WITHDRAWAL OF IMMUNOSUPPRESSION. THAT WAS JUST RECENTLY PUBLISHED IN JANUARY.

AND THEN ANOTHER CELL GENE THERAPY, AND BY THE WAY, CHAIRMAN THOMAS DID ASSURE ME THAT YOU WANTED THIS VERY FULL UPDATE. SO THIS IS ANOTHER PROGRAM WHICH IS A CELL GENE THERAPY FOR X-LINKED CGD. YOU'VE HEARD ABOUT BRANDON BEFORE, BUT NOW

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THERE ARE FIVE OTHER PATIENTS. THERE'S SIX PATIENTS WITH SUSTAINED LEVEL OF CORRECTED CELLS. THIS HAS BEEN PUBLISHED IN *NATURE MEDICINE* JUST IN JANUARY OF THIS YEAR, VERY PROMINENT JOURNAL. AND, AGAIN, IT'S BEING CARRIED OUT BY ORCHARD, THE SAME COMPANY THAT'S DEVELOPING THE ADA-SCID PROGRAM.

STILL GOING. ONCTERNAL, WHICH IS A THERAPY THAT WAS DEVELOPED FOR TARGETING LEUKEMIA AND LYMPHOMA, OUT OF UCSD IS SHOWING INITIAL FAVORABLE OUTCOME, AND NOW THE INTERIM PHASE 1 RESULTS HAVE SUPPORTED A PHASE 2 PROGRAM. SO THAT'S ENROLLING. SO, AGAIN, SIGNS OF PROGRESS.

AND WE'VE FUNDED SANGAMO FOR A GENE-EDITED CELL THERAPY FOR BETA THALASSEMIA WHICH IS A FORM ANEMIA. THEY'VE HAD PRELIMINARY RESULTS FROM THREE PATIENTS SHOWING PROMPT RECONSTITUTION, MEANING THAT AFTER THE CONDITIONING THAT THEY WERE ABLE TO RECONSTITUTE OR HAVE RECOVERY OF THEIR BLOOD SYSTEM WITH NOW EDITED CELLS THAT ARE THE THERAPEUTIC CELLS CIRCULATING, AND EVIDENCE OF WHAT THEIR THERAPEUTIC DOES IS EXPRESSION OF HEMOGLOBIN F, FETAL HEMOGLOBIN, TO REVERSE THE DISEASE. SO THEY HAVE DEMONSTRATED THAT THEIR GENE THERAPY IS WORKING. LONGER-TERM FOLLOW-UP IS ONGOING TO DEMONSTRATE WHETHER THIS IS DURABLE AND WHETHER IT IMPACTS ALL

THE CLINICAL OUTCOMES.

ALL RIGHT. THAT'S IT FOR THE CLINICAL UPDATES IN TERMS OF DATA. THIS LIST IS NOW THE LIST OF NEW IND'S JUST IN 2019. SO IT'S QUITE A VERY IMPRESSIVE LIST. FATE THERAPEUTICS FOR ENGINEERED INDUCED PLURIPOTENT STEM CELL-DERIVED NK CELLS FOR SOLID TUMORS. THIS IS ONE OF THE FIRST INDUCED PLURIPOTENT STEM CELL-DERIVED PRODUCTS. SO IT'S A VERY EXCITING TREND IN THIS FIELD. WE EXPECT IN THE FUTURE THAT THE FUTURE WILL GO TOWARD IPSC AND ENGINEERED CELLS.

UCLA, SOPHIE DENG, AUTOLOGOUS LIMBAL STEM CELLS FOR CORNEAL DAMAGE. POSEIDA, I MENTIONED THEIR MULTIPLE MYELOMA PROGRAM. THEIR CAR-T PROGRAM FOR CASTRATE RESISTANT METASTATIC PROSTATE CA HAS NOW ACHIEVED A SUCCESSFUL IND. SO THAT WILL BE INITIATING THE TRIAL.

THE CITY OF HOPE'S CHEMO TOXICITY RESISTANT MODIFIED HEMATOPOIETIC STEM CELLS FOR GLIOBLASTOMA, DR. STEINBERG'S TRIAL FOR EMBRYONIC STEM CELL STEM CELL-DERIVED NEURAL STEM CELLS FOR CHRONIC SUBCORTICAL STROKE. AND DR. WU WITH EMBRYONIC STEM CELL-DERIVED CARDIOMYOCYTES FOR END STAGE HEART FAILURE.

ARE THERE ANY QUESTIONS ON THE CLINICAL

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PROGRAM? THE DATA REALLY SPEAK AND THE PROGRESS IS REAL IN THE DATA. I THINK THAT ONE OF THE KEY THINGS, AND NOW I'M GOING TO INTRODUCE PAUL WEBB, IS THAT THE CIRM TEAM WORK IN PARTNERSHIP. IT STARTS FROM THE BEGINNING, CHOOSING THE BEST PROGRAMS, HAVING THE BOARD LOOK AT IT AND SAY THIS IS SOMETHING WE WANT TO DERISK AND TAKE AND MAKE SURE TO SUPPORT EARLY ON. AND THEN IT GOES THROUGH AND GETS INDUSTRY FUNDING LATER. SO THIS MODEL HAS BEEN WORKING WELL, BUT ALONG THE WAY IT'S EXECUTION. AND SO OUR TEAM, NOT ONLY FROM THE BEGINNING IN HELPING MAKE SURE THAT THE PROGRAMS ARE TEED UP TO BE ON A GOOD PATH FORWARD ARE ACTUALLY WITH THEM ALONG THE WAY. SO PAUL WEBB, PROGRAM MANAGER FOR THE CLINICAL ADVISORY PANEL, IS GOING TO DESCRIBE THE HOW-TOS.

ARE THERE ANY QUESTIONS PRIOR TO PAUL?

DR. MARTIN: MAY WE HAVE A COPY OF THIS DECK?

DR. MILLAN: ABSOLUTELY. IT'S ACTUALLY POSTED, AND WE'LL GIVE YOU A -- ACTUALLY YOU MAY HAVE A PAPER COPY RIGHT THERE. OKAY. I'LL GIVE YOU ONE. THANK YOU VERY MUCH.

SO REALLY WANT TO THANK THE BOARD BECAUSE WITHOUT YOU THESE PROGRAMS WOULDN'T HAVE GOTTEN THEIR START, AND I KNOW THAT THROUGH THE PROCESS OF

THE GRANTS WORKING GROUP, THE SUBCOMMITTEES, AND THEN THE BOARD THAT A LOT OF THOUGHT HAS GONE INTO CHOOSING THESE PROGRAMS. SO IT'S REALLY GREAT TO HAVE THEM PROGRESS TO THIS POINT. THANK YOU.

I WANTED TO GIVE YOU AN UPDATE. SO AS YOU KNOW, WE HAVE A LANDMARK PARTNERSHIP WITH NHLBI WHO DECLARED THAT WE NEED TO CURE SICKLE CELL. SO THIS IS THE CURE SICKLE CELL INITIATIVE. WE HAD MEETINGS WITH THE NIH AND THE NHLBI, AND THEY REALLY RECOGNIZE THE ACCELERATION TRANSLATIONAL MACHINERY THAT CIRM IS. AND, THEREFORE, WE HAVE A JOINT MOU WHERE WE ARE USING THE CIRM APPLICATION AND REVIEW PROCESS, AND THEN NHLBI'S EXECUTIVE COMMITTEE THEN, BASED ON THAT REVIEW, MAKES THEIR OWN DETERMINATION, AND WE THEN AGREE TO CO-FUND.

WE DO THIS ALL WITHOUT SLOWING DOWN OUR INCREDIBLY IMPRESSIVE ACCELERATION PROCESS WHERE WE CAN GET FROM APPLICATION TO APPROVAL ANYWHERE FROM A HUNDRED, MAYBE SOMETIMES 95 DAYS TO 125 DAYS THEY GET FUNDED. SO WE DIDN'T WANT TO SLOW THAT DOWN; AND WHILE WE CRAFTED EVERYTHING THAT WENT INTO THIS, AND JENN LEWIS IS HERE, AND HER PREDECESSOR, GABE THOMPSON, MADE SURE THAT WE OPERATIONALIZE IT IN A WAY THAT WE DIDN'T SLOW DOWN OUR PROCESSES. AND I'M PLEASED TO REPORT ON BEHALF OF THE TEAM THAT WE

FUNDED OUR FIRST AWARD GOING THROUGH THIS WHOLE PROCESS, MARK WALTERS' PROGRAM, UCSF, BENIOFF CHILDREN'S. AND WE ARE DOING A HALF/HALF FUNDING OF THIS PROGRAM. AT LEAST SIX OTHER APPLICANTS ARE PREPARING, THAT WE KNOW OF, THERE MAY BE OTHERS, ARE PREPARING FOR A SUBMISSION TO THIS JOINT PROGRAM THIS YEAR, THREE INDUSTRY AND THREE ACADEMIC.

AND JUST A VERY BRIEF DESCRIPTION OF WHAT THIS SICKLE CELL PROGRAM DOES. DR. WALTERS' PROGRAM, THE ONE THAT'S BEING FUNDED BY THIS MOU, IS A GENE CORRECTION PROGRAM USING CRISPR-CAS9, WHICH IS A VERY SPECIFIC BASE EDITING TOOL. AND BY DOING THAT, IT CORRECTS THE ONE SINGLE ERROR THAT GIVES RISE TO THIS HORRENDOUS DISEASE. AND SO DR. WALTERS IS NOW IN THE IND-ENABLING PHASE, AND THAT'S AN 18-MONTH TIME PERIOD THAT WE ARE TALKING ABOUT. SO ANTICIPATING SUCCESS, HE WOULD THEN BE ELIGIBLE TO COME IN FOR A CLINICAL -- FOR THE CLINICAL PORTION OF THAT AWARD.

SENATOR TORRES.

MR. TORRES: ON THE SICKLE CELL DISEASE, IT'S ALSO IMPORTANT TO KNOW THAT IT AFFECTS LATINOS AS WELL, NOT JUST AFRICAN-AMERICANS. AND I BRIEFED THE CHAIR OF THE LEGISLATIVE BLACK CAUCUS LAST WEEK IN TERMS OF WHAT WE WERE DOING. SHE INFORMED ME

THIS ISSUE WAS DISCUSSED AT THE NATIONAL CONFERENCE OF STATE LEGISLATURES AS WELL.

HOW DOES THIS COINCIDE WITH DR. KOHN'S RESEARCH AT UCLA?

DR. MILLAN: ABSOLUTELY. SO DR. KOHN ALSO HAS A PROGRAM THAT'S ACTUALLY IN CLINICAL STAGE OF USING A DIFFERENT APPROACH, A LENTIVIRAL, A VIRAL VECTOR GENE ADDITION. SO DR. WALTERS' APPROACH IS USING CRISPR-CAS9 TO FIX A SINGLE BASE PAIR. DR. KOHN'S APPROACH IS USING A VIRAL VECTOR TO DELIVER A GENE FOR A MORE FUNCTIONAL FORM OF WHAT'S MISSING IN SICKLE CELL. AND THAT'S STILL ONGOING. THERE'S SIX PATIENTS, THAT'S A TARGET ENROLLMENT, AND THAT'S ONGOING.

THE CHALLENGE WITH THAT IS MAKING SURE THEY HAVE THE RIGHT VECTOR, HAVING THE RIGHT TRANSDUCTION EFFICIENCY SO THAT YOU CAN HAVE ENOUGH OF FOR YOUR THERAPEUTIC EFFECT.

BUT I JUST WANTED TO JUST SAY BROADLY WHAT THIS PARTNERSHIP IS ABOUT. IT'S NOT JUST CO-FUNDING. WHAT HAPPENS, AND WE TALKED ABOUT THIS EARLIER, IS THE PATIENT SIDE OF IT. SO WE ARE PARTNERING ALSO WITH THE AMERICAN SOCIETY FOR HEMATOLOGY, WHICH IS A BROAD NATIONAL ORGANIZATION, WHICH IS ALSO PART OF THE CURE SICKLE CELL NHLBI

EFFORT. AND OUR ALPHA CLINICS NETWORK WAS CHOSEN AS ONE OF THE COMPONENTS OF THE BROAD CLINICAL TRIAL NETWORK FOR SICKLE CELL. AND THEN THE IDEA IS THE PATIENTS' INTERACTIONS AND TRYING TO GET THOSE ALTOGETHER AND A DATA HUB, INFORMATION ACCESS, SOCIAL DETERMINANTS, ALL THESE THINGS ARE KIND OF BROUGHT INTO THE CONVERSATION.

SO, YES, IT'S FUNDING. IT'S BRINGING THE SCIENCE FORWARD, BUT IN PARALLEL IT REALLY TAKES INTO ACCOUNT THE PATIENT SIDE. THIS IS A VERY COMPLICATED THING. IT'S NOT JUST ONE BASE PAIR TO FIX IT. THERE ARE SO MANY OTHER ASPECTS FOR THE CARE AND THE EXPERIENCE OF THESE PATIENTS, WHICH WE CAN GO INTO IN MORE DEPTH AT ANOTHER TIME. BUT I JUST WANTED TO UPDATE THE BOARD THAT WE DID SUCCESSFULLY USE THIS MODEL, AND SO THAT'S A GREAT START, AND WE EXPECT THAT WE'LL BE BRINGING MORE PROPOSALS TO OUR REVIEW PROCESS AND TO YOU IN THE NEAR FUTURE.

CHAIRMAN THOMAS: DR. YAMAMOTO.

DR. YAMAMOTO: CAN YOU SAY SOMETHING ABOUT HOW MATTHEW PORTEUS' APPROACH DIFFERS FROM THE WALTERS' STRATEGY?

DR. MILLAN: I HAVE DR. SOHEL TALIB HERE WHO CAN MAYBE GIVE A LITTLE BIT MORE GRANULARITY ON

THAT BECAUSE I DON'T WANT TO MESS THAT UP.

DR. TALIB: THANK YOU, MARIA.

SO I THINK THE PROGRAM WHICH DR. PORTEUS IS DOING AND THE PROGRAM WHICH DR. WALTERS IS DOING IS VERY SIMILAR. BOTH APPROACHES ARE THE SAME USING CRISPR APPROACH TO REMOVE THE BASE WHICH IS MISSING AND REPLACE IT WITH A CORRECT BASE. AND THAT APPROACH IS A LITTLE BIT DIFFERENT IN TERMS OF OPTIMIZATION, HOW THEY ARE DOING IT.

IN ONE CASE THEY ARE USING AN ENZYME TO DO THE GENE CORRECTION AND AN RNA TO DO IT. THE SECOND IS A KNOWN VIRAL APPROACH. SO THE APPROACH IS VERY SIMILAR, BUT IT'S THE WAY IT IS DONE IS A LITTLE BIT DIFFERENT.

BUT I THINK AT THIS TIME IT'S MORE SHOTS ON GOAL TO SEE WHICH PART OF THE PROGRAM WILL GIVE THE BENEFIT. SO THESE PROGRAMS BOTH ARE VERY MATURE AND THEY ARE PROGRESSING VERY WELL.

CHAIRMAN THOMAS: THANK YOU, DR. TALIB. DR. SANDMEYER.

DR. SANDMEYER: I THINK YOU PROBABLY HAVE COMMENTED ON THIS PREVIOUSLY, BUT COULD YOU JUST EXPLAIN HOW THE FUNDS FLOW FROM THE CIRM PROGRAM AND THE FEDERAL GOVERNMENT FLOW? I UNDERSTAND THAT MORE PEOPLE IN THE CLINICAL TRIALS BENEFITS EVERYONE

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BROADLY, BUT I'M JUST CURIOUS HOW THOSE FUNDS ARE DIFFERENTIATED.

DR. MILLAN: OKAY. I'LL TAKE A STAB AT IT FROM A BROAD SENSE, AND THEN I'LL HAVE JENN LEWIS, WHO IS OUR DIRECTOR OF GRANTS MANAGEMENT, IF THE BOARD DESIRES MORE DETAIL.

SO IF BOTH CIRM, THIS BOARD, AND THE NHLBI EXECUTIVE COMMITTEE DECIDE THAT THEY WILL CO-FUND A PROGRAM, IT'S NEGOTIATED WHAT PERCENTAGE THEY'LL CO-FUND. THE BROAD SENSE IS FOR CALIFORNIA APPLICANTS, WHICH GENERALLY CIRM WOULD FUND A HUNDRED PERCENT OF THEM BECAUSE THEY'RE ELIGIBLE FOR A HUNDRED PERCENT -- WELL, OF WHAT'S CALLED ELIGIBLE COSTS. WHAT ARE THEY CALLED? CIRM WOULD COVER ALL OF IT. IN THIS CASE FOR THAT TYPE OF APPLICANT, THE NHLBI WOULD COVER HALF OF IT. THAT'S WHAT HAPPENED WITH DR. WALTERS' CASE.

IN PROGRAMS THAT ARISE OUTSIDE OF CALIFORNIA, WE HAVEN'T CHANGED OUR REQUIREMENTS, THAT CIRM FOR PROGRAMS WHERE THE PI IS OUTSIDE, THE IND HOLDER IS OUTSIDE OF CALIFORNIA, THE CIRM ELIGIBLE COSTS ARE ONLY THE COSTS INCURRED WITHIN CALIFORNIA. SO CLINICAL TRIAL SITES WITHIN CALIFORNIA OR IF THEY USE LABORATORIES WITHIN CALIFORNIA, RESOURCES WITHIN CALIFORNIA, THAT'S

ELIGIBLE. THE BALANCE OF THAT WOULD THEN BE SOMETHING THAT THE NHLBI WOULD DECIDE WHETHER THEY WOULD COVER THAT PLUS WHATEVER CO-FUNDING THE APPLICANT WOULD BRING IN. DOES THAT ANSWER THAT QUESTION?

DR. SANDMEYER: THANK YOU. THAT'S PLENTY OF DETAIL.

CHAIRMAN THOMAS: OKAY. DR. MILLAN, THANK YOU VERY MUCH FOR THAT PRESENTATION. I HOPE THE BOARD IS REALLY IMPRESSED WITH THE STATUS OF THE PORTFOLIO AND WHAT OUR WONDERFUL SCIENTISTS STATEWIDE HAVE BEEN ABLE TO ACCOMPLISH. IT REALLY IS A TESTAMENT TO EXACTLY WHAT THIS PROGRAM IS ALL ABOUT. I THANK YOU FOR THAT. I THINK IT WAS IMPORTANT THAT EVERYBODY GET A FEEL FOR WHERE WE STAND AT THE MOMENT.

WE'RE GOING TO TAKE A BREAK TO GET LUNCH. PLEASE BRING IT BACK. IT'S A WORKING LUNCH. AND THEN WE'LL GO TO PAUL AS SOON AS EVERYBODY HAS GOTTEN THEIR SEATS BACK. SO THOSE ON THE PHONE, IT WILL BE FIVE TO EIGHT MINUTES, SOMETHING LIKE THAT. THANK YOU.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: THOSE ON THE PHONE, WE'RE GOING TO RECONVENE. WE ARE ON TO THE NEXT

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PRESENTATION. PAUL IS GOING TO WALK US THROUGH ON THE CLINICAL ADVISORY PANELS AND A VARIETY OF OTHER ITEMS. SO, PAUL, WITHOUT FURTHER ADO.

DR. WEBB: THANKS FOR THE OPPORTUNITY TO TALK TO YOU ALL TODAY. WHAT I'M GOING TO DO IS EXPLAIN A CIRM INTERNAL MECHANISM THAT WE THINK HELPS ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. AND THAT'S THE CLINICAL ADVISORY PANEL.

SO I'LL START BY JUST BRIEFLY EXPLAINING WHAT A CLINICAL ADVISORY PANEL ACTUALLY IS. AND PERHAPS IT'S WELL DEFINED, FROM THE DEFINITION YOU CAN LEARN A LOT.

BUT IT'S A GROUP OF EXPERTS THAT HELP THE CLINICAL PROGRAMS AS THEY NAVIGATE SOME VERY CHALLENGING STUDIES AND ENCOUNTER SOME, PERHAPS, DIFFICULTIES, ROADBLOCKS, CHALLENGES, HELP THEM GET THROUGH THAT CHALLENGE. ESSENTIALLY IT'S AN EXTENSION OF THE PROJECT TEAM.

SO ONE CAP IS ASSEMBLED BY CIRM FOR EVERY CLINICAL STAGE AWARD. AND IT'S COMPOSED OF THE FOLLOWING THAT'S LISTED ON THE DIAGRAM. SO INTERACTING WITH THE PROGRAM, THERE'S EXTERNAL SCIENCE ADVISORS. THESE CAN BE EITHER SCIENTISTS OR DOCTORS. THEY'RE EXPERIENCED IN THE PARTICULAR

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DISEASE INDICATION, USUALLY A KEY OPINION LEADER, AND THEY, OF COURSE, ARE EXCELLENT IN ADVISING HOW THE PROGRAM IS GOING. THEY'LL OFTEN HAVE SOME BACKGROUND IN STEM CELLS. THERE'S A PATIENT REPRESENTATIVE, AND THIS IS SOMEBODY WHO'S GOT BOTH AN EXTENSIVE KNOWLEDGE OF THE DISEASE AND, IN PARTICULAR, SOMEONE WHO CAN REALLY HELP US UNDERSTAND HOW THE DISEASE IMPACTS THE PATIENTS. AND ALSO CIRM TEAM. IN-HOUSE IN CIRM WE HAVE A LOT OF VERY EXPERIENCED PEOPLE WHO HAVE BEEN THERE, DONE THAT. THEY'VE BEEN THROUGH THE PRODUCT DEVELOPMENT, CLINICAL TRIALS, STEM CELL TECHNOLOGIES, AND THEY CAN BOTH WEIGH IN WITH ADVICE BUT ALSO CAN HELP TO DEPLOY EXTRA TYPES OF CIRM ASSISTANCE THAT WE CAN PROVIDE.

SO THE CAP STAYS WITH THE PROGRAM THROUGHOUT. IT WILL MEET MULTIPLE TIMES OVER THE LIFETIME OF A PROGRAM AWARD, AND IT CAN EVOLVE. SO IF, FOR EXAMPLE, THE TEAM'S EXPERIENCING A PARTICULAR CHALLENGE, WE CAN BRING IN AN AD HOC EXPERT TO HELP THE TEAM DEAL WITH THAT CHALLENGE AND ADVISE THEM.

SO WHAT WE THINK IS THAT THE CAP'S HAVE EVOLVED TO BECOME A KEY TOOL IN CIRM'S KIND OF ACTIVE MANAGEMENT APPROACH. I'LL TELL YOU ON THIS

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SLIDE WHAT THE CAP'S ARE ACTUALLY DOING. WE ARE WORKING WITH CLINICAL STAGE AWARDS WHICH ENCOMPASS BOTH THE CLIN1, AND THAT'S OUR SHORTHAND FOR THE KIND OF FINAL IND-ENABLING STUDIES REQUIRED TO SUBMIT AN IND. WE ALSO WORK WITH THE CLIN2 AWARDS. THAT'S OUR SHORTHAND FOR THE CLINICAL TRIAL AWARDS, THE GOAL OF WHICH IS TO COMPLETE A CLINICAL TRIAL. AND, OF COURSE, WE ARE COVERING THE WIDE RANGE OF INDICATIONS THAT CIRM'S INVOLVED WITH. THERE'S INFECTIOUS DISEASE, VARIOUS FORMS OF CANCER, METABOLIC DISEASES, BLINDING DISEASES, NEURO, ET CETERA, ET CETERA.

SO IT'S AN ACTIVE EFFORT, AND THAT'S REFLECTED IN SOME OF THE STATISTICS YOU'RE SEEING UP HERE. SO THE PROGRAM BEGAN IN 2015; AND SINCE INCEPTION, BY THE END OF 2019, WE STAGED 250 INDIVIDUAL CAP MEETINGS. THAT INVOLVED 78 EXTERNAL ADVISORS AND 57 DIFFERENT PATIENT REPS. AND I WILL SAY THAT MANY OF THESE ARE DOING DOUBLE OR TRIPLE DUTY. I'M TRYING TO THINK IF THERE'S A QUADRUPLE. I THINK THE MOST IS TRIPLE, BUT THERE'S SOME EXCELLENT CONTRIBUTIONS HERE.

AND YOU CAN ALSO, IF YOU LOOK AT THE BAR GRAPH ON THE LEFT, YOU CAN SEE THE WAY THIS HAS EXPANDED YEAR BY YEAR. SO WE BEGAN WITH SEVEN IN

2015 GOING TO 28 IN 2016, HEADING UP TO 67, AND NOW IN THE 70S THROUGH THE LAST TWO YEARS. AND THE REASON FOR THAT IS QUITE SIMPLE. IT REFLECTS CIRM'S SUCCESS IN BRINGING IN CLINICAL TRIALS AND, OF COURSE, THE CONTRIBUTION TO THE BOARD FUNDING THESE CLINICAL TRIALS. SO THE MORE CLINICAL TRIALS WE HAVE, THE MORE CAP'S.

SO GIVEN THAT EFFORT, ARE THESE USEFUL? AND WHAT I'LL SAY IS THAT ANECDOTALLY CIRM STAFF AND THE GRANTEES FELT THEY WERE. AND I THINK YOU'VE HEARD SOME OF THE INDIVIDUAL ANECDOTES OF HOW CAP'S HAVE REALLY HELPED TEAMS AT ICOC MEETINGS IN THE PAST. BUT WHAT I'M GOING TO SHARE WITH YOU TODAY IS THE WAY WE TRY AND PUT A QUANTITATION ON THAT AND TRY AND TRACK IT INTERNALLY.

THE WAY THAT'S DONE IS TO TRACK THE NUMBER OF INDIVIDUAL IMPACTS. AND THAT'S DEFINED UP IN THE TOP LEFT. SO WHAT THAT IS IS AN INSTANCE OF CAP FEEDBACK FROM THE ORGANIZATION WORKING WITH THE TEAM THAT HELP THE TEAM ADVANCE ITS GOALS TOWARDS WHETHER IT'S IND SUBMISSION OR CLINICAL TRIALS. AND SOME OF THE TYPES OF THINGS WE'VE ENCOUNTERED ARE LISTED ON THE LEFT. WE MIGHT HELP THE TEAM RESOLVE A SPECIFIC CHALLENGE THAT THEY COME TO THE CAP WITH. AND THAT COULD DO SOMETHING, FOR EXAMPLE, LIKE HELP THEM

OVERCOME A MANUFACTURING CHALLENGE. THERE CAN BE ADVICE THAT EMERGES DURING THE CAP THAT HELP THE TEAM OPTIMIZE THE PROJECT EXECUTION. SO, FOR EXAMPLE, THERE COULD BE SUGGESTIONS ABOUT HOW TO IMPROVE AND ACCELERATE ENROLLMENT. AND WE COULD DISCOVER CRITICAL INFORMATION THAT MAY NOT BE APPARENT UNTIL WE ARE ALL SITTING IN A ROOM OR ON THE PHONE TOGETHER TALKING ABOUT IT. AND THAT CAN LEAD TO THINGS LIKE THE NECESSITY FOR REGULATORY ADVICE OR DELINEATION OF THE DEVELOPMENTAL PATH FOR THE NEXT STAGE.

SO WHEN WE ADD ALL THOSE THINGS UP, TO DATE WE CAN SAY THAT THE CAP'S HAVE HAD A POSITIVE INFLUENCE ON 74 PERCENT OF THE CLIN STAGE AWARDS. I'LL SAY MANY OF THESE CLIN AWARDS ARE AT EARLY STAGE. I'LL COME BACK TO THAT.

SO WHERE IS THE ADVICE GOING? WHAT WE'VE DONE HERE IS TO TRY AND QUANTITATE THE DEVELOPMENTAL FUNCTIONS. THAT'S THE KIND OF KEY AREAS THAT A TEAM NEEDS TO WORK ON TO ADVANCE THE STUDY. I'VE DIVIDED IT HERE INTO CLIN1 AND CLIN2. SO CLIN1 IS THE IND-ENABLING, CLIN2 THE CLINICAL TRIAL. AS YOU CAN SEE, CLIN1 WE'VE COUNTED 77 INDIVIDUAL IMPACTS OVER THE LIFETIME OF THE PROGRAM, AND CLIN2 WE COUNTED 161. AND ON THE BOTTOM IN THE BAR CHART, WE'VE

BUCKETED THESE ACCORDING TO THE DEVELOPMENTAL FUNCTION.

SO WHAT YOU CAN SEE FOR CLIN1, THERE'S A LOT OF ADVICE GOING TO DIFFERENT AREAS THAT HELP THE TEAM. CMC IS THE ACRONYM THAT'S USED FOR JUST MANUFACTURING ISSUES. PHARM-TOX ARE THE FINAL SAFETY. CLINICAL, THAT REFLECTS THE NEED TO PUT TOGETHER THE CLINICAL PROTOCOL WITH THE IND. REGULATORY AND DEVELOPMENT, THAT'S THINKING ABOUT THE NEXT STAGE, REGULATORY INTERACTIONS WITH THE FDA AND SO FORTH. THE CLIN2, THE CLINICAL STAGE, PERHAPS NOT SURPRISINGLY MUCH OF THE HELP IS GOING TO THE CLINICAL TRIAL. IT'S REFINING THE DESIGN, HELPING WITH THE EXECUTION. BUT WHAT YOU ALSO SEE IS THAT WE ARE STILL GIVING SIGNIFICANT AMOUNTS OF ADVICE IN OTHER AREAS LIKE MANUFACTURING, REGULATORY, AND DEVELOPMENT.

SO HOW DID THIS GO BY INDIVIDUAL PROJECT? AND THIS IS, AGAIN, THIS BAR CHART REFLECTS THE IMPACTS, BUT THIS TIME WE ARE LOOKING AT IT BY AWARD. SO, AGAIN, TO WALK YOU THROUGH IT. IT'S A RATHER BUSY SLIDE. WE HAVE ON THE LEFT THE CLIN1, THE IND-ENABLING, AND WHAT WE'VE DONE ON THE Y AXIS IS TO COUNT THE NUMBER OF PROGRAMS SINCE INCEPTION. THERE'S 22 AWARDS AND GIVE THEM A NUMBER. AND

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THERE'S A SIMILAR PRESENTATION FOR THE CLIN2 ON THE RIGHT WHERE THERE'S 56 AWARDS SINCE INCEPTION OF THE CAP PROGRAM.

NOW, A COUPLE OF THINGS JUMP OUT AT YOU WHEN YOU SEE THE CAP IMPACTS PLOTTED BY THE NUMBER OF PROGRAMS IS THAT MOST OF THE PROGRAMS HAVE GOT TANGIBLE HELP THAT'S GONE TOWARDS ACCELERATION OF THEIR PROGRAM.

THE SECOND THING THAT JUMPS OUT AT YOU IS THERE'S VARIABILITY. SOME PROGRAMS ASKED FOR, GET A LOT OF HELP, OTHER PROGRAMS LESS SO. THE REASON FOR THE VARIABILITY IS TWOFOLD. PARTLY IT'S PROGRAM NEEDS, VARIOUS CHALLENGES THAT DIFFERENT PROGRAMS ENCOUNTER. I THINK THE REASON THAT SOME OF THE PROGRAMS HAVE RECEIVED LOWER AMOUNTS OF ASSISTANCE IS ACTUALLY SIMPLER. IT'S THAT MANY OF THEM IN THE LOWER PART OF THE GRAPH HAVE ONLY JUST STARTED. AND WHAT WE THINK IS THAT PERHAPS THEY'LL NEED HELP IN THE FUTURE. WE'LL WAIT AND SEE. BUT AT THE MOMENT, WHAT WE CAN SAY IS THAT ON AVERAGE THERE'S ABOUT THREE INSTANCES OF HELP PER AWARD DRIVEN BY THIS CAP PROGRAM.

SO WE THINK IT'S A GREAT VALUE ADD TO THE GRANTEES, AND HOPEFULLY -- WE'VE RECEIVED GOOD FEEDBACK FROM CERTAIN GRANTEES THAT THIS IS INDEED

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THE CASE. SO I'LL PAUSE BRIEFLY TO TAKE ANY QUESTIONS YOU MAY HAVE.

DR. MARTIN: HOW DO YOU INTEND TO FUND THIS GOING FORWARD?

DR. WEBB: THIS IS FUNDED INTERNALLY FROM THE CIRM BUDGET.

DR. MARTIN: AND WE HAVE THE BUDGET FOR THAT OVER THE NEXT HOW LONG OF A PERIOD?

DR. WEBB: THAT'S A BUDGET QUESTION I'LL HAND OVER TO JENN. BUT THE ANSWER IS YES.

DR. MARTIN: THE ADMINISTRATIVE BUDGET.

DR. WEBB: ADMINISTRATIVE BUCKET, AND WE CAN CERTAINLY BE TAKEN OUT FOR THE LIFETIME OF THESE AWARDS.

DR. MARTIN: AND MOST OF THESE ADVISORS ARE RESIDENTS OF CALIFORNIA? ARE THEY ALL OVER THE COUNTRY?

DR. WEBB: THEY'RE ALL OVER THE PLACE. SOME OF THEM ARE EAST COAST. THERE'S SEVERAL WHO ARE INTERNATIONAL AND TAKE PART BY PHONE.

DR. MARTIN: THANK YOU.

MS. DURON: I WAS JUST INTERESTED WHETHER YOU FIND INCREASINGLY COMMON WISDOM ABOUT THE REGULATIONS IS MITIGATING THE DEMAND AT ALL FOR EXPERT ADVICE THAT MIGHT AMELIORATE SOME OF THE

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EFFECTS OF THE EXPANDED CLINICAL TRIALS ON DEMAND FOR YOUR EXPERTS.

DR. WEBB: HAVE TO BE REALLY CAREFUL IN WHAT I SAY BECAUSE THIS IS ALL UNDER -- IT'S ALL HIGHLY CONFIDENTIAL. BUT WE HAVE A VARIETY OF DIFFERENT TEAMS IN THE PORTFOLIO. WE HAVE ACADEMIC GROUPS, SMALL BIOTECHS, SOME LARGER BIOTECHS, AND THE AMOUNT OF IN-HOUSE EXPERTISE VARIES. SO THE SHORT ANSWER IS NO. AND THEN THE SECOND PART I'LL BRING UP FOR THAT, WHICH I THINK ABLA CREASEY COULD HELP ATTEST TO, IS THAT THE REGULATORY ENVIRONMENT IS CHANGING ALL THE TIME. CIRM HAS STAFF THAT KEEP UP WITH THAT. THAT WISDOM DOESN'T NECESSARILY PERCOLATE INTO EVERY CORNER OF RESEARCH.

UNIDENTIFIED SPEAKER: DO GRANTEES GENERALLY COME TO THE CAP ASKING FOR HELP, OR IS IT A REGULARLY --

DR. WEBB: IT'S A MIX. I PERHAPS DIDN'T SPECIFY THIS EXACTLY, BUT WE HAVE QUARTERLY INTERACTIONS WITH EVERY TEAM THAT TAKE A VARIETY OF FORMS. THAT SAID, OFTEN THE GRANTEES COME TO US WITH HELP. THEY SAY THERE'S AN ISSUE WE'D LIKE TO DISCUSS. WE JUST HAD ONE ISSUE EXACTLY LIKE THAT IN THE BEGINNING OF JANUARY WHERE THE GRANTEES REQUESTED A CAP, AND IT'S A FAIRLY COMMON

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OCCURRENCE.

DR. YAMAMOTO: WHEN I HEAR WHAT YOU'VE SAID, I THINK OF IT AS SORT OF ADVISING, ACTIVE ADVISING MAYBE; WHEREAS, IN INDUSTRY, ACTIVE MANAGEMENT AND A COUPLE OF GOVERNMENT AGENCIES, DARPA COMES TO MIND, ACTIVE MANAGEMENT IS REALLY AGGRESSIVELY ACTIVE. SPECIFIC MILESTONES ARE SET OUT; AND IF YOU DON'T HIT THEM, YOU LOSE YOUR MONEY. IT'S OVER.

SO IS THERE -- ARE THERE CONSEQUENCES LIKE THAT WHERE THEIR EXPECTATIONS FROM CIRM IN GETTING FUNDING ARE EXPLICIT ENOUGH THAT EITHER ON A TEMPORAL BASIS OR OVERALL SCOPE THAT THE PROGRAMS ARE MANAGED TO THAT EXTENT THAT THE INVESTIGATORS FEEL THAT IF THEY DON'T PERFORM OR IF THEY DON'T HIT THEIR MILESTONES, THEN THE FUNDING ENDS? DOES THAT EVER HAPPEN?

DR. WEBB: ABSOLUTELY. AND THAT'S PART OF THE OPERATIONAL MILESTONE SETTING. GRANTEES' PAYMENTS ARE BASED ON OPERATIONAL MILESTONES, AND IT HAS HAPPENED. I THINK THAT'S PUBLIC. BUT THE -- ONE THING I'LL SAY ABOUT THE CAP'S IS THAT THE CAP IS WORKING TO TRY TO STOP THAT HAPPENING. AND THIS IS -- IT'S ACTUALLY A COLLEGIAL, HELPFUL ENVIRONMENT IN WHICH WE ARE TRYING TO ANTICIPATE ISSUES THAT THE

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GRANTEE MAY FACE IN TERMS OF COMPLETING THEIR OPERATIONAL MILESTONES ON TIME AND HELPING THEM GET AROUND THAT PROCESS. WE WANT TO GIVE THEM MONEY, AND WE WANT THESE STUDIES TO SUCCEED.

DR. YAMAMOTO: OF COURSE. I DIDN'T MEAN THAT THIS IS SORT OF A WAY TO TERRIFY THE INVESTIGATORS. BUT THE PUBLIC COULD VIEW THIS, THE USE OF THEIR FUNDS IN THIS CONTEXT OF BEING ABLE TO BE EFFICIENT AND USE THE JUDGMENT, THE EXPERTISE, WITHIN CIRM TO BE ABLE TO SORT OF EXERCISE THAT IN A SPECIFIC WAY. NIH FUNDS, FOR EXAMPLE, ARE NOT MANAGED AT ALL, NOT EVEN INACTIVE MANAGEMENT. NOW, IF YOU GET A FIVE-YEAR NIH GRANT, YOU HAVE FIVE YEARS OF MONEY, AND THAT'S JUST THE WAY IT IS. BUT THAT IN A WAY REFLECTS MORE THE DIFFERENCE IN THE MISSION AND GOALS OF ACADEMIC RESEARCH WHERE THE CHARGE IS TO KIND OF KEEP YOUR EYES OPEN. AND IF YOU DISCOVER SOMETHING THAT LEADS YOU ON A DIFFERENT PATHWAY, YOU TAKE IT. IT'S YOUR JUDGMENT TO DO THAT. AND THIS IS REALLY DIFFERENT. THE GOALS HERE ARE TO REALLY ACCOMPLISH A SPECIFIC TASK. AND IT COULD BECOME EVIDENT HALFWAY THROUGH A PROJECT THAT IT'S NOT GOING TO HAPPEN. THE BOLD IDEAS ARE BOLD BECAUSE THEY MIGHT BE WRONG. AND SHOULD SOMEBODY BE STEPPING IN TO EXERCISE THAT KIND OF JUDGMENT?

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DR. MILLAN: SO WE DO. IN FACT, YOU'VE HEARD ABOUT THE RETURN FUNDS. AND SOME OF THEM COME FROM WHERE, DESPITE ALL THE BEST EFFORTS TO PUT -- SOME THINGS DON'T WORK OUT. SO WE PUT THE BEST EXPERTISE BEHIND IT TO OVERCOME THIS, BUT THERE ARE SPECIFIED TIME PERIODS AND CONDITIONS AS WELL AS THE IDEA THAT THEY DON'T GET ANY ADDITIONAL FUNDS UNLESS IT'S OVERCOME. AND THERE'S ALWAYS THE ABILITY TO CLAW BACK FUNDS IF THERE ARE ACTIVITIES THAT WERE SUPPOSED TO HAVE BEEN COMPLETED AND ARE NOT. SO THAT'S ALL EMBEDDED WITHIN THE CONTRACTING.

CHAIRMAN THOMAS: SO I'D JUST LIKE TO MAKE A COUPLE OF COMMENTS. ONE, DR. YAMAMOTO, YOU HIT ON A KEY POINT, THAT THE WAY CIRM STAYS INVOLVED IS REALLY UNIQUE AND IT REALLY SPEAKS TO THE MODEL AND THE LENGTHS TO WHICH THE AGENCY GOES TO TRY TO ACHIEVE SUCCESS FOR OUR INVESTIGATORS. AND THAT'S ONE OF MANY FEATURES THAT PEOPLE LOOKING AT IT FROM THE OUTSIDE FIND VERY VALUABLE AND A GREAT VALUE ADD.

ON THE SUBJECT OF THE MILESTONES, THERE ARE INSTANCES ABSOLUTELY WHERE WE RECALL FUNDING, BUT THERE ARE OTHER INSTANCES WHERE THERE ARE DEEMED TO BE REASONS FOR PERHAPS ADJUSTING MILESTONES ALONG THE WAY. AND PERHAPS AT A FUTURE MEETING IT WOULD

BE WORTH DISCUSSING THAT BECAUSE THAT'S SOMETHING THAT YOU DO NEED TO MODIFY UNDER CERTAIN FACTS GOING FORWARD. SO IT'S NOT A COMPLETELY BLACK-AND-WHITE THING. IT ALLOWS FOR SUBJECTIVE ANALYSIS AS TO HOW YOU CAN FURTHER THE PROJECT IF YOU NEED TO MODIFY IT IN SOME RESPECTS.

I THINK MAYBE AT THE NEXT BOARD MEETING WE'LL GET INTO THAT IN MORE DETAIL. THAT'S A VERY IMPORTANT QUESTION. I'M VERY GLAD YOU RAISED THAT. SO THANK YOU.

DR. MALKAS.

DR. MALKAS: ARE YOU GOING TO PUBLISH THIS? THIS IS A REALLY GREAT TOOL. YOU BUILT A TEMPLATE HERE AND GREAT METRICS AROUND GUIDING THAT. ONE, BY PUBLISHING IT, YOU HIGHLIGHT THE SUCCESS OF THIS PROGRAM, BUT ALSO YOU ENABLE OTHER INSTITUTIONS AND OTHER AGENCIES TO START THINKING ABOUT HOW TO EMULATE THIS. SO THERE PROBABLY COULD BE A PUBLICATION ESPECIALLY BECAUSE YOU HAVE OUTCOME AND YOU HAVE MEASURES. AND OBVIOUSLY METRICS IS SO IMPORTANT. I WOULD ENCOURAGE YOU TO ACTUALLY THINK ABOUT THAT.

DR. WEBB: WE CERTAINLY HAVE INTERNALLY THOUGHT ABOUT THAT. IT HAS TO BE ANONYMOUS OBVIOUSLY BECAUSE THERE'S CONFIDENTIALITY CONCERNS,

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BUT THE OVERALL METRICS ARE ANONYMIZED. AND, MARIA, I THINK YOU WERE GOING TO SAY SOMETHING.

CHAIRMAN THOMAS: DR. MILLAN.

DR. MILLAN: THANK YOU. ON THAT TOPIC, DR. MALKAS, THE CIRM TEAM HAS ACTUALLY SUCCESSFULLY PUBLISHED SEVERAL DIFFERENT PERSPECTIVE ARTICLES IN A VARIETY OF DIFFERENT JOURNALS INCLUDING *STEM CELL TRANSLATIONAL MEDICINE* HAS BEEN INVITED TO ACTUALLY ALSO SUMMARIZE KIND OF OUR SYSTEMS FOR OTHER PROMINENT JOURNALS. AND SO MORE OF THAT WILL BE COMING OUT, AND WE WILL BRING IT UP AT THE NEXT MEETING. SOME OF THEM ARE DISEASE FOCUSED, SOME OF THEM ARE NOVEL APPROACH BASED, SOME OF THEM ARE ACTUALLY OPERATIONAL, AND SOME OF THEM ARE POLICY. AND SO YOU WILL BE HEARING MORE ABOUT THAT. AND SO THIS IS EMBEDDED IN ONE OF THOSE REPORTS, BUT, YEAH, SO WE'LL BRING THAT.

CHAIRMAN THOMAS: OKAY. PAUL, THANK YOU. ON TO TAP'S.

DR. FITZGERALD: PAUL DID AN EXCELLENT JOB OF INTRODUCING KIND OF SOME OF THE FUNDAMENTAL IDEAS BEHIND THE TRANSLATIONAL ADVISORY PANEL THAT WE'VE PUT IN PLACE RECENTLY. I WANTED TO BRIEFLY GIVE YOU AN OVERVIEW OF THE TRANSLATIONAL PROGRAM. I KNOW THE CLINICAL PROGRAM IS AT THE FRONT OF EVERYONE'S

MIND, AND MARIA ELABORATED ON A NUMBER OF THE CLINICAL STAGE PROGRAMS THAT WE ARE FUNDING.

THE TRANSLATIONAL PROGRAM, AS WAS MENTIONED EARLIER, IS UNIQUE IN TERMS OF THE SPACE IT OCCUPIES AND THE DEVELOPMENT TIMELINE. FOR CIRM THE TRANSLATIONAL PROGRAM COMES AFTER WHAT WE CALL OUR DISC2 PROGRAM, WHICH IS CANDIDATE DECLARATION STAGE, AND IMMEDIATELY PRECEDING THE CLIN1 OR THE IND-ENABLING PROGRAMS THAT PAUL JUST DESCRIBED.

SO FOR THE TRANSLATIONAL PROGRAM, THE EXPECTED OUTCOME OVER A 30-MONTH TIME FRAME IS THAT THE PROJECT TEAM WILL BRING AN ELIGIBLE, CLINICALLY ELIGIBLE CANDIDATE TO A PRE-IND MEETING WITH THE FDA AND THAT THE FDA WILL GIVE THEM FEEDBACK, AGREEING WITH THEIR IND-ENABLING PRECLINICAL PLAN.

THE BUDGET FOR THE TRANSLATIONAL PROGRAM IS FOUR MILLION FOR CELL THERAPY AND TWO MILLION FOR A SMALL MOLECULE. AND AS I ALLUDED TO, THE OUTPUT OF OUR DISC2 CANDIDATE DECLARATION STAGE PROGRAM ENABLES ENTRY INTO THE TRAN PROGRAM, WHICH IS A SINGLE ELIGIBLE HUMAN CLINICALLY COMPATIBLE CANDIDATE WITH REPRODUCIBLE DISEASE MODIFYING ACTIVITY RELEVANT TO THE PROPOSED TARGET CLINICAL INDICATION, WHICH HAS BEEN CONSENTED FOR BOTH RESEARCH AND COMMERCIAL USE, AND IT MEETS THE FDA

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DONOR ELIGIBILITY REQUIREMENTS.

SO THE TRAN PROGRAM ACTIVITIES REALLY ARE DESIGNED TO BE ALONG THE CRITICAL PATH TO MEETING THE EXPECTED OUTCOME, WHICH IS THE PRE-IND MEETING. BOTH OF THE ACTIVITIES ARE IN THE C-GMP PROCESS DEVELOPMENT PROCESS SCALE-UP STAGE. SO I'LL TALK A LITTLE BIT ABOUT THAT WHEN WE GET INTO THE TRANSLATIONAL ADVISORY OUTCOMES.

THE PROJECTS SPEND A SIGNIFICANT AMOUNT OF TIME AT HEARINGS. YOU CAN IMAGINE THERE'S A LOT OF RISK ASSOCIATED WITH THIS. OFTENTIMES THESE ARE CANDIDATES THAT ARE COMING FROM A LAB BENCH, AND THEY NEED TO DEMONSTRATE THAT THEY CAN BE MADE REPRODUCIBLY AT A SCALE THAT IS COMPATIBLE WITH CLINICAL DEVELOPMENT. OTHER ASSOCIATED ACTIVITIES WOULD INCLUDE ASSAY DEVELOPMENT FOR RELEASE, IN-PROCESS ASSAYS, BIOMARKER DEVELOPMENT, CONDUCT OF NONCLINICAL STUDIES, INCLUDING PK AND PD STUDIES, IMMUNOGENICITY, PILOT SAFETY, AND MECHANISM OF ACTION STUDIES. FINALLY, STUDIES TO SELECT DOSE AND ROUTE OF ADMINISTRATION, WHICH ALL SORT OF CULMINATE IN SELECTION OF THE INDICATION AND DEVELOPMENT OF A CLINICAL PLAN WHICH IS PRESENTED IN THE PRE-IND FILING.

SO THE TRAN PROGRAM STATISTICS, THIS IS A

PROGRAM THAT WAS AN EVOLUTION OF SOME OF OUR EARLIER FUNDING PROGRAMS; BUT THE TRAN PROGRAM, AS IT STANDS NOW, BEGAN IN JUNE OF 2016. TO DATE WE HAVE FUNDED 31 OR YOU ALL HAVE FUNDED 31 PROGRAMS. THESE ARE ALSO ADMINISTERED THROUGH OPERATIONAL MILESTONES. SO THESE 31 PROGRAMS ARE COMPRISED OF 83 OPERATIONAL MILESTONES. TO DATE 100 PERCENT OF THE TRAN PROGRAMS THAT HAVE CONCLUDED HAVE CULMINATED IN A SUCCESSFUL PRE-IND SUBMISSION. SO THE N ON THAT IS FIVE, AND TWO OF THOSE FIVE HAVE ACTUALLY PROGRESSED INTO A CLIN1 FUNDING PROGRAM. AND THOSE WERE THE ANKASA PROGRAM AND THE MARK WALTERS PROGRAM.

SO PAUL DID A NICE SUMMARY OF THE COMPOSITION OF THE CAP'S. AS WE STARTED SEEING THESE TRAN PROGRAMS MATURE, WE SIMULTANEOUSLY WERE WATCHING SOME OF THE BENEFITS THAT THE CLINICAL ADVISORY PANEL WAS PROVIDING FOR THE CLINICAL PROGRAMS, WE STARTED THINKING OF IF THERE WAS A POSSIBLE WAY THAT WE COULD EVOLVE THE CLINICAL ADVISORY PANEL INTO SOMETHING THAT WOULD BE SUITABLE FOR THE TRANSLATIONAL PROGRAM.

THE TRANSLATIONAL STAGE IS SOMEWHAT DIFFERENT. THE TEAMS ARE NOT LOCKED INTO A SIMILAR PATH THAT THE CLINICAL PROGRAMS ARE; HOWEVER, THEY DO HAVE A NUMBER OF GOALS THAT THEY NEED TO ACHIEVE

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IN ORDER TO FILE THE PRE-IND. SO THE TAP PROGRAM IS MADE UP OF THE SAME DIAGRAM WHERE THE FUNDED PROGRAM IS AT THE CORE. THE CIRM TEAM INTERACTS WITH THAT PROGRAM LEVERAGING INTERNAL CIRM EXPERTISE AS WELL AS A BESPOKE PANEL OF EXTERNAL ADVISORS THAT ARE ASSEMBLED SPECIFICALLY TO WORK WITH THE PROGRAM AND THE TYPE OF PROGRAM THAT'S UNDER CONSIDERATION.

ANOTHER REALLY IMPORTANT COMPONENT OF THIS THAT WE'VE SEEN GREAT BENEFIT IN THE TAP PROGRAM IS THE INCLUSION OF A PATIENT REPRESENTATIVE. SO OFTENTIMES, AS I MENTIONED, THESE ARE PROGRAMS THAT ARE SORT OF GRADUATING FROM THE LAB BENCH IN BASIC SCIENCE AND MOVING INTO DEVELOPMENT. THIS MAY BE ONE OF THE FIRST TIMES THAT THEY'VE HAD FACE-TO-FACE CONTACT WITH A PATIENT AFFLICTED BY THE DISEASE OR INDICATION THAT THE TEAM IS LOOKING TO ADDRESS. SO THEY GET FEEDBACK FROM THE PATIENT REPRESENTATIVE AS WELL AS IT GIVES EARLY PATIENT REPRESENTATIVES AN INSIGHT ABOUT WHAT GOES INTO DEVELOPMENT OF A THERAPEUTIC. AND THAT'S SOMETHING THAT THEY'RE ABLE TO TAKE BACK TO THEIR COMMUNITIES AND GAIN AN APPRECIATION FOR SOME OF THE COMPLEXITIES OF CAN A CELL THERAPY BE MADE AND HOW ARE THESE EARLY RESEARCH DISCOVERIES TRANSLATED INTO SOMETHING THAT THEY MAY ULTIMATELY SEE IN THE CLINIC.

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MUCH LIKE THE CAP PROGRAM, WE HAVE MULTIPLE TAP MEETINGS OVER THE COURSE OF A TRAN PROJECT. WE HAVE MEASURED IMPACTS AS WELL, WHICH ARE FEEDBACKS, SIMILARLY, FEEDBACKS AND RECOMMENDATIONS THAT RESULT IN A POSITIVE IMPACT AND ACHIEVEMENT OF THE PROJECT OBJECTIVE. AND, AGAIN, THE TAP PROGRAM CAN HAVE MULTIPLE IMPACTS ON A TRAN PROGRAM THROUGH THE COURSE OF THE PROGRAM.

NOW, OUR NUMBERS ARE MUCH SMALLER THAN PAUL'S. I WAS SORT OF HOPING I WOULD GO BEFORE PAUL, BUT HERE WE HAVE IT. SO IT'S A YOUNGER PROGRAM. AND SO THIS PROGRAM STARTED IN JULY OF 2018. AND IT WAS INITIATED AS A PILOT PROGRAM TO SEE WHAT SORT OF AN EFFECT WE MAY HAVE ON THE TRANSLATIONAL PROGRAM AS A WHOLE.

SO SEVEN TRAN PROJECTS HAVE HAD TRANSLATIONAL PATHS INSTALLED TO WORK WITH THEM. WE HAVE HAD NINE MEETINGS. WE HAVE 16 ADVISORS, SOME OF THEM ARE SERVING ON MULTIPLE PROGRAMS, SIX PATIENT REPRESENTATIVES, AND WE HAVE 64 DOCUMENTED IMPACTS.

NOW, THE OUTCOMES, AS YOU MIGHT EXPECT FOR PROGRAMS AT THIS STAGE, HAVE CENTERED AROUND GMP PROCESS DEVELOPMENT CHALLENGES, OF WHICH THERE ARE MANY AS THESE PROJECTS MOVE FORWARD, PRECLINICAL

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STUDY DESIGN OPTIMIZATION. THE TEAMS ARE OFTEN LOOKING FOR TARGETED REGULATORY ADVICE. AND THE REGULATORY ENVIRONMENT IS CONSTANTLY EVOLVING. WE HAVE EMPLOYED ADVISORS THAT ARE EX-FDA OR ADVISORS THAT HAVE ROUTINE INTERACTION WITH THE FDA. SO THEY DO HAVE THEIR FINGER ON THE PULSE OF WHAT THE CURRENT EXPECTATIONS ARE AROUND REGULATORY FILING. REFINEMENT OF THE DEVELOPMENT PATH AND OCCASIONALLY FACILITATED PARTNERING FOR THESE PROJECTS.

SO THE INFLUENCES THAT WE'VE SEEN HAVE BEEN ACROSS ALL KEY TRANSLATIONAL ACTIVITIES. YOU WILL SEE THE BULK OF THE 64 IMPACTS THAT WE'VE MEASURED HAVE BEEN IN THE CMC MANUFACTURING PROCESS DEVELOPMENT AREA OF THE PROJECT. AGAIN, THAT AREA REPRESENTS SIGNIFICANT TECHNICAL HURDLES FOR MANY PROJECTS, AND WE'VE BEEN ABLE TO USE ADVISORY PANEL MEMBERS WITH EXPERTISE ON A LARGER SCALE THAT HAVE BEEN ABLE TO NAVIGATE THROUGH SOME OF THESE PROBLEMS AND ADVANCE THROUGH THE MILESTONES.

DEVELOPMENT PATH, AGAIN, IS SOMETHING THAT IS BEING REFINED AT THIS STAGE. SO WE'VE SEEN A LOT OF RECOMMENDATIONS AND IMPACTS IN THAT SPACE.

REGULATORY ADVICE IN THIS CONTEXT CAN TAKE THE FORM OF HELPING THE PROJECTS CRAFT EITHER THEIR PRE-IND PACKAGE OR THEIR INTERACT PACKAGE. SO THE

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INTERACT IS ESSENTIALLY WHAT THE PRE, PRE-IND USED TO BE CALLED, AND THAT HAS BEEN IMPORTANT FOR A NUMBER OF OUR PROJECTS TO GET EARLY REGULATORY INPUT TO HELP DERISK THE PROGRAM AS IT MOVES FORWARD.

AND, AGAIN, MIRRORING WHAT PAUL PRESENTED WITH SMALLER NUMBERS, THE NUMBER OF IMPACTS PER AWARD IS SOMEWHAT VARIABLE. WE HAVE A FEW PROJECTS THAT HAVE HAD MORE THAN ONE MEETING, AND THOSE OBVIOUSLY HAVE HAD HIGHER NUMBERS OF IMPACTS ASSOCIATED WITH THEM. AND TO ECHO WHAT PAUL SAID, WE HAVE SOME PROJECT TEAMS THAT ACTIVELY SEEK RECOMMENDATIONS AND ADVICE AND ARE REALLY LOOKING TO LEVERAGE THIS EXTERNAL PANEL TO STRENGTHEN THEIR OWN INTERNAL TEAM. AND THEY'RE EAGER FOR ADVICE. OTHER TEAMS ARE PLUGGING ALONG FINE, AND THEY RECEIVE MINIMAL INPUT FROM THE TAP'S, JUST MORE OF KIND OF KEEPING THEM ON COURSE.

SO WE EXPECT THESE NUMBERS TO EVOLVE OVER TIME, AND WE WILL PROVIDE ADDITIONAL UPDATES AS THESE NUMBERS GROW. BUT SO FAR THE PROGRAM HAS BEEN PRETTY SUCCESSFUL. AND I WOULD SAY UNANIMOUSLY WITH THE TEAMS THAT HAVE HAD TAP'S ASSOCIATED WITH THEM, WE'VE GOTTEN POSITIVE FEEDBACK FROM THE PI'S. I THINK THAT, AGAIN, THESE ARE TEAMS THAT AREN'T USED TO WORKING WITH EXTERNAL ADVISORS AND PANELS THAT

HAVE AN INFLUENCE OVER THEIR PROJECT. AND SO THERE CAN OCCASIONALLY BE SOME HESITANCE, BUT UNANIMOUSLY AFTER THE FIRST MEETING THEY SEE THE VALUE, AND IT'S REALLY HELPED ACCELERATE AN INCREASE IN THE PROBABILITY OF SUCCESS FOR THE PROJECTS AS A WHOLE.

I'LL TAKE ANY QUESTIONS.

DR. SANDMEYER: AT FIRST I THOUGHT, WELL, MAYBE THESE TAP TEAMS WOULD WANT TO GRADUATE AND REMAIN THE CAP TEAMS, BUT THE DISTRIBUTION OF INPUT IS QUITE DIFFERENT BETWEEN THE TAP AND THE CAP. SO IS THE IDEA TO GET REAL MANUFACTURING EXPERTS NOW BASED ON -- I MEAN IT'S A SMALL N, BUT IS THAT YOUR INTENT NOW?

DR. FITZGERALD: SO THAT REALLY IS THE BULK OF THE ACTIVITY THAT'S HAPPENING IN A TRAN AWARD. AND SO AS A RESULT, THE TYPES OF ADVISORS WE'LL USE HAVE EXPERTISE IN THAT AREA. AND I THINK THAT THE NEEDS AND THE TYPES OF IMPACTS THAT WE HAVE HAD IN THE TRAN PROGRAM REFLECT WHAT THE GOAL OF THE TRAN PROJECT IS FOR AND THE NEEDS OF A PRE-IND FILING VERSUS AN IND.

CHAIRMAN THOMAS: OKAY. KENT. GREAT WORK. AGAIN, I REITERATE WHAT I SAID ABOUT THE CAP'S. THESE ARE VERY UNIQUE PROGRAMS AND SETS OF INPUT THAT POSITION OUR PROJECTS TO BE AS SUCCESSFUL

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AS THEY POSSIBLY CAN BE. SO EXCELLENT WORK ON ALL OF THIS STUFF. THANK YOU.

DR. MARTIN: I THINK YOU COULD GENERATE REVENUES BY RENTING THESE OUT.

CHAIRMAN THOMAS: EXCELLENT IDEA. DR. SHEPARD.

DR. SHEPARD: GOOD AFTERNOON, EVERYBODY. IT'S MY PLEASURE TO COME HERE BEFORE YOU TODAY TO GIVE YOU AN UPDATE ON OUR EDUCATIONAL AND TRAINING GRANT PROGRAMS.

SO I'M GOING TO BEGIN BY RESTATING YOUR MISSION OF CIRM, WHICH IS ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. AND YOU ALL KNOW, CIRM HAS, AND AS ALLUDED TO BY DR. MILLAN EARLIER TODAY, WE'VE INVESTED IN FIVE KEY AREAS IN ORDER TO ACHIEVE THIS MISSION, WHICH IS ESSENTIALLY TO TURN IDEAS INTO MEDICINES.

NOW, WE JUST HEARD A DISCUSSION OF SOME UPDATES OF SOME OF OUR PROGRAMS THAT REPRESENT THESE KEY PILLARS, INCLUDING, FIRST, THE CLINICAL STAGE PROGRAMS, AND BY DR. FITZGERALD THE TRANSLATIONAL STAGE PROGRAMS. BUT I'M HERE TO TELL YOU TODAY ABOUT THE RIGHT-MOST PILLAR THAT YOU SEE THERE, THE EDUCATIONAL PILLAR, WHICH IS JUST AS IMPORTANT AS EVERYTHING ELSE BECAUSE HUMAN RESOURCES AND TALENTED

WORKFORCE IS ESSENTIAL TO DO THE WORK THAT IS REPRESENTED IN THIS GRAPHIC.

SO QUITE SIMPLY STATED, THE GOALS OF EDUCATIONAL PROGRAMS ARE TO CREATE A DIVERSE AND WELL-TRAINED WORKFORCE, SCIENTISTS, AND TECHNICIANS TO HELP REALIZE THE FULL POTENTIAL OF STEM CELLS TO TREAT PATIENTS WITH UNMET MEDICAL NEEDS.

CIRM HAS BEEN SUPPORTING TRAINING PROGRAMS IN ONE FORM OR ANOTHER SINCE OUR INCEPTION. THE PROGRAMS I'M GOING TO FOCUS ON TODAY ARE OUR TWO ACTIVE TRAINING GRANT PROGRAMS, WHICH I'LL GO OVER INDIVIDUALLY IN A LITTLE BIT MORE DETAIL IN MY FOLLOWING SLIDES: THE BRIDGES PROGRAM AND THE SPARK PROGRAM.

SO LET'S BEGIN WITH THE BRIDGES PROGRAM. SO THE OBJECTIVE OF THE BRIDGES PROGRAM IS TO PREPARE CALIFORNIA'S UNDERGRADUATE AND MASTER'S LEVEL STUDENTS FOR HIGHLY PRODUCTIVE CAREERS IN STEM CELL RESEARCH AND THERAPY DEVELOPMENT. THESE PROGRAMS ARE INTEGRATED INTO EXISTING BACHELOR'S, MASTER'S, OR EVEN CERTIFICATE GRANTING PROGRAMS BASED AT HOME INSTITUTIONS AROUND THE STATE OF CALIFORNIA.

SO BY CERTIFICATE GRANTING PROGRAMS, SOME OF THESE CAN BE AFFILIATED WITH UNDERGRADUATE LEVEL

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OR MASTER'S LEVEL STUDENTS ENROLLED AT COMMUNITY COLLEGE OR CALIFORNIA STATE UNIVERSITY PROGRAMS. IT CAN ALSO INCLUDE INDIVIDUALS WHO HAVE HAD CAREERS IN OTHER FIELDS WHO WOULD LIKE TO COME BACK TO SCHOOL AND GAIN NEW EXPERTISE IN STEM CELL BIOLOGY.

SO THE HOME INSTITUTIONS THAT OFFER THESE BRIDGES PROGRAMS ARE INDICATED ON THE FOLLOWING SLIDE. THIS PROGRAM HAS BEEN OPERATING FOR TEN YEARS NOW; AND OVER THE COURSE OF THE TEN YEARS, BRIDGES PROGRAMS HAVE BEEN OFFERED AT 16 DIFFERENT INSTITUTIONS CROSS THE STATE. CURRENTLY 14 OF THESE PROGRAMS ARE ACTIVE. AND I LIKE TO SHOW THIS SLIDE BECAUSE IT SHOWS THAT GEOGRAPHICALLY THESE PROGRAMS ARE DISTRIBUTED FROM THE SOUTHERN PART OF CALIFORNIA. THE SOUTHERNMOST PROGRAM IS SAN DIEGO STATE UNIVERSITY, ALL THE WAY UP TO THE NORTHWEST CORNER IN ARCATA, WHICH IS WHERE HUMBOLDT STATE UNIVERSITY IS LOCATED.

IN ADDITION TO THESE INSTITUTES THAT OFFER THESE PROGRAMS, MANY OF THEM HAVE RELATIONSHIPS WITH LOCAL COMMUNITY COLLEGES IN WHICH STUDENTS ARE RECRUITED INTO THESE BRIDGES PROGRAMS.

NOW, WHAT MAKES THESE BRIDGES PROGRAMS SPECIAL? I'VE JUST TOLD YOU THAT SOME OF THEM OFFER MASTER'S DEGREE, SOME OF THEM OFFER CERTIFICATES,

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AND SOME OF THEM ARE INCORPORATED INTO A BACHELOR DEGREE PROGRAM. HOWEVER, THEY ALL SHARE SOME CORE FEATURES IN COMMON. OF COURSE, THERE IS COURSEWORK AND LABORATORY TECHNIQUE TRAINING TO HELP GIVE THEM A STRONG FOUNDATION IN STEM CELL BIOLOGY AND REGENERATIVE MEDICINE. AND IN THE PAST FIVE YEARS, A FORMAL COURSE IN REGULATORY AFFAIRS HAS ALSO BEEN A PART OF THIS COURSEWORK TO REALLY HELP THEM UNDERSTAND THE DRUG DEVELOPMENT PROCESS AND HOW THE WORK THAT THEY'RE DOING CAN FIT INTO THE DEVELOPMENT OF MEDICINES FOR PATIENTS WITH UNMET MEDICAL NEEDS.

THE SECOND PANEL HERE, I'VE LISTED SOME CORE ACTIVITIES THAT ARE AN ADDITIONAL PART OF THE PROGRAM ON TOP OF THE TRADITIONAL COURSEWORK AND LABORATORY TRAINING. THEY HAVE FORMAL STRUCTURED ACTIVITIES IN WHICH THEY ENGAGE WITH PATIENTS SO THEY CAN LEARN ABOUT THE PATIENT PERSPECTIVES AND HOW THAT IMPACTS THEIR WORK AND HOW THEIR WORK IMPACTS PATIENTS. ANOTHER FORMAL PART OF THEIR CURRICULUM IS COMMUNITY OUTREACH, LEARNING TO COMMUNICATE THE IMPORTANCE OF WHAT THEY DO BOTH TO THE PUBLIC AND TO MEMBERS OF THEIR COMMUNITY AS WELL AS TO OTHER SCIENTISTS.

AND, FINALLY, A THIRD KEY AND CRITICAL COMPONENT OF EVERY BRIDGES PROGRAM IS A PAID

RESEARCH INTERNSHIP AT A HOST INSTITUTION. THESE STUDENTS TRAVEL FROM THEIR HOME INSTITUTION, WHEREVER THAT IS BASED, TO PERFORM INTERNSHIPS, DEPENDING ON THE PROGRAM, RANGING FROM 6 TO 12 MONTHS IN WORLD-CLASS STEM CELL LABORATORIES, WHICH ARE FAMILIAR TO ALL OF US, PERFORMING STEM CELL RESEARCH, MEDICAL SCHOOLS, THE MAJOR UNIVERSITIES AND RESEARCH INSTITUTES AROUND THE STATE, AS WELL AS A SIGNIFICANT NUMBER OF BIOTECH COMPANIES RANGING FROM THE START-UP ENVIRONMENT TO MORE SUSTAINED COMPANIES.

AT THE END OF THEIR EDUCATIONAL EXPERIENCE, STUDENTS ARE ALL INVITED TO CONVENE TO THE ANNUAL BRIDGES CONFERENCE WHERE THEY HAVE AN OPPORTUNITY TO PRESENT THEIR RESEARCH TO ONE ANOTHER IN THE FORM OF POSTERS, LISTENING TO INSPIRING TALKS. FOR THE PAST COUPLE OF YEARS, THESE ANNUAL CONFERENCES ARE ORGANIZED IN THE FORMAT WHERE THEY HEAR FROM BASIC RESEARCH, STEM CELL BIOLOGISTS IN A PARTICULAR DISEASE AREA, AS WELL AS A CLINICIAN WHO IS RUNNING A CLINICAL TRIAL IN THAT DISEASE AREA, AND FROM A PATIENT WHO EITHER HAS SUFFERED FROM THAT DISEASE AND SHARES THEIR EXPERIENCE AND IN SOME CASES HAS EVEN BEEN A PARTICIPANT IN ONE OF THOSE CLINICAL TRIALS AND CAN SHARE THEIR STORIES WITH THE

STUDENTS.

SO AS I MENTIONED, THIS PROGRAM HAS BEEN OPERATING CONTINUOUSLY FOR TEN YEARS NOW. IT'S IN ITS ELEVENTH YEAR. AND I JUST WANTED TO SHARE A LITTLE BIT OF WHAT WE LEARNED ABOUT THE OUTCOMES OF THE ALUMNI OF THESE PROGRAMS IN THE FIRST TEN YEARS.

THERE'S BEEN NEARLY 1400 OF THEM. FORTY-EIGHT PERCENT OF THESE STUDENTS ARE FIRST GENERATION COLLEGE STUDENTS, THE FIRST PERSON IN THEIR FAMILY TO ATTEND COLLEGE. AT THIS TIME, BASED ON THE MOST RECENT INFORMATION PROVIDED FROM SOME OF THESE COHORTS WHICH GO BACK FOR QUITE SOME TIME NOW, THERE ARE A LITTLE MORE THAN 60 PERCENT WHO ARE EMPLOYED IN RESEARCH AND DEVELOPMENT POSITIONS IN LABORATORIES. A LITTLE MORE THAN HALF OF THOSE ARE ACADEMIC LABORATORIES, AND A LITTLE LESS THAN HALF ARE BIOTECH OR PHARMA LABORATORIES OR OTHER INDUSTRY POSITIONS.

ABOUT A THIRD OF THESE STUDENTS DECIDE TO CONTINUE THEIR CAREERS IN SCIENCE BY PURSUING HIGHER EDUCATION, MANY OF THEM IN PH.D. PROGRAMS OR OTHER FORMS OF PROFESSIONAL HEALTH SCIENCE SCHOOLS, SUCH AS MEDICAL SCHOOL. AND ALTHOUGH THEIR RESEARCH INTERNSHIPS ARE TYPICALLY A YEAR AT MOST IN THE LABORATORY, THESE TRAINEES ARE CONTRIBUTING TO

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PUBLICATIONS IN HIGH IMPACT JOURNALS FROM THEIR TIME THERE.

AND I'VE JUST GIVEN YOU QUITE A FEW NUMBERS ABOUT OUTCOMES, BUT VERY BRIEFLY I WANTED TO GIVE YOU SOME FACES TO GO WITH THOSE NUMBERS. SO HERE ARE THREE RECENT EXAMPLES. I KNOW IN THE PAST YOU'VE BEEN UPDATED ABOUT THIS PROGRAM, AND I WANTED TO GIVE YOU SOME NEW EXAMPLES BECAUSE WE ARE CONTINUING TO HAVE STUDENTS GRADUATE AND SUCCEED IN THIS FIELD.

SO MICHAEL SILVA ON THE LEFT BEGAN HIS EDUCATION AT SOLANO COMMUNITY COLLEGE AFTER WHICH HE TRANSFERRED TO UC SANTA BARBARA. HE ENTERED IN THE BRIDGES PROGRAM AT CAL STATE UNIVERSITY CHANNEL ISLANDS AND DID HIS RESEARCH INTERNSHIP AT THE CITY OF HOPE. AFTER HIS TRAINING WAS COMPLETE, HE TOOK A JOB AT GENENTECH AT THEIR VACAVILLE MANUFACTURING FACILITY. AND TODAY HE'S A PROFESSOR OF BIOTECHNOLOGY BACK AT SOLANO COMMUNITY COLLEGE WHERE HE STARTED BRINGING BACK THE LESSONS HE'S LEARNED AND SHARING HIS PAST WITH OTHER STUDENTS AROUND HIM.

THE SECOND STORY, VAHID, WAS BROUGHT TO ME BY DR. TREVOR CARDINAL WHO MANAGES THE CAL POLY BRIDGES PROGRAM. VAHID HAD TO DROP OUT OF UC BERKELEY DUE TO A FINANCIAL SITUATION WITH HIS

FAMILY THAT HE NEEDED TO HELP THEM RECOVER FROM. DURING THAT TIME HE WAS ABLE TO TAKE COURSES AT COMMUNITY COLLEGE, AND EVENTUALLY HE WAS ABLE TO TRANSFER TO CAL POLY INTO THE BRIDGES PROGRAM THERE. HIS RESEARCH INTERNSHIP WAS AT A COMPANY CALLED VIACYTE, WHICH YOU HEARD FROM DR. MILLAN'S LATER STAGE CLINICAL TRIAL PROGRAMS THAT SHE WAS DISCUSSING TODAY THAT HAVE RESULTS THAT ARE BEING REPORTED. AND THEY ARE ALSO ONE OF THE FIRST COMPANIES TO RUN A PLURIPOTENT STEM CELL THERAPY TRIAL IN THE WORLD.

HE'S CURRENTLY -- HE GRADUATED FROM HIS PROGRAM. HE'S CURRENTLY EMPLOYED AT VIACYTE AS A MANUFACTURING ENGINEER.

AND MY THIRD EXAMPLE IS LAUGHING BEAR TORREZ, AND SHE WAS ACTUALLY FEATURED IN A PREVIOUS UPDATE WE DID ABOUT FIVE YEARS AGO FOR THE BRIDGES PROGRAM, BUT I WANTED TO BRING HER TO YOUR ATTENTION AGAIN TO SHARE HOW HER STORY HAS EVOLVED. SHE CAME INTO THE BRIDGES PROGRAM FROM SAN BERNARDINO CAL STATE PROGRAM, AND DID HER RESEARCH INTERNSHIP AT UC RIVERSIDE. AFTER HER GRADUATING FROM THERE, SHE BECAME ONE OF THE INAUGURAL PH.D. STUDENTS IN THE STANFORD STEM CELL TRAINING GRANT PROGRAM. AND JUST LAST SUMMER SHE GRADUATED WITH HER PH.D. FROM THAT

PROGRAM AND IS NOW EMPLOYED AS A SCIENTIST AT BOLT BIOTHERAPEUTICS.

MR. TORRES: I'M SO PROUD OF THIS PROGRAM BECAUSE IT'S ONE THAT I ATTACHED MYSELF TO WHEN I FIRST CAME TO CIRM, BUT ALSO BECAUSE OF WHAT THE STUDENTS HAVE BEEN DOING. AND IF ANY BOARD MEMBER HAS AN OPPORTUNITY TO GO TO ONE OF THESE PRESENTATIONS, YOU WILL BE OVERWHELMED. THEY ARE SO INSPIRING AND SO DEDICATED TO THE WORK THEY DO, AS YOU WELL KNOW, AND FOLKS, THE STAFF, GILBERT AND OTHERS HERE AND MARIA KNOW IN DEALING WITH MANY OF THESE STUDENTS.

I ALSO HAVE TO NOTE AT SOLANO COMMUNITY COLLEGE, THE LEGISLATURE PASSED IN 2014 LEGISLATION TO ALLOW COMMUNITY COLLEGES TO GIVE BACCALAUREATE DEGREES IN SPECIFIC AREAS OF EXPERTISE. ONE OF THEM IS BIOMANUFACTURING. AND SOLANO COMMUNITY COLLEGE HAS SUCH A PROGRAM, JUST DOWN THE ROAD UP HERE, AND ALSO ONE IN SAN DIEGO. SO THERE'S A LOT OF EFFORT THAT IS GOING ON.

SECONDLY, THE LEGISLATURE AND THE CONSTITUTIONAL OFFICERS ALWAYS RELATE TO THIS PROGRAM AND THE SPARKS PROGRAM, THE HIGH SCHOOL PROGRAM, BECAUSE THEY SEE THE IMPACT WE ARE MAKING ON THE FUTURE OF CALIFORNIA AND FUTURE STEM CELL

SCIENTISTS THAT REFLECT THE DIVERSITY OF THIS STATE. AND I THINK THAT'S SO IMPORTANT. AND THESE YOUNG PEOPLE ARE REALLY GOING TO BE OUR ROLE MODELS THAT WE'VE INVESTED IN EARLY ON THAT WILL HELP IN SO MANY AREAS, NOT TO MENTION THE DIVERSITY OF CLINICAL TRIAL PATIENTS WHICH WILL HAVE THAT IMPACT. THANK YOU, KELLY.

DR. SHEPARD: YEAH. YOU'RE WELCOME. AND I JUST WANT TO SAY THAT WHEN I LOOKED FOR A COUPLE OF ANECDOTES TO PUT FACES BEHIND THE NUMBERS, I DID NOT HAVE TO LOOK HARD. THAT'S THE JOY OF HELPING TO ADMINISTER THIS PROGRAM IS SEEING HOW SUCCESSFUL SOME OF THE STUDENTS ARE THAT ARE COMING OUT OF IT. NOT SOME, BASICALLY ALL, AS YOU CAN SEE FROM THOSE NUMBERS, ARE VERY SUCCESSFUL.

DR. FINE: THIS IS LEON FINE. I JUST WANTED TO SAY THAT I THINK THIS IS ONE OF THE GREAT ACHIEVEMENTS OF CIRM AND REALLY SHOULD RECEIVE THE WIDEST POSSIBLE COVERAGE. IT'S SO ADMIRABLE.

DR. SHEPARD: THANK YOU.

DR. DULIEGE: AND, INDEED, I WANT TO ADD MY VOICE AND MY APPLAUDS TO THIS PROGRAM, PARTICULARLY FOR THE PAID RESEARCH INTERNSHIP PROGRAM. AND THE MOST IMPORTANT WORD HERE IS PAID BECAUSE IT IS VERY DIFFERENT TO SO MANY OTHER

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PROGRAMS WE KNOW ABOUT THAT GOT INTERNSHIPS THAT ARE UNPAID AND THAT CREATES UPFRONT FROM THE GET-GO AN UNACCEPTABLE INEQUALITY IN TERMS OF OPPORTUNITIES TO IMPORTANT PROGRAMS THAT COULD BE REALLY PROFESSIONAL LIFE-CHANGING AS MANY OF THESE INTERNS COULD NOT AFFORD TO NOW BE PAID. SO CONGRATULATIONS FOR THIS.

MS. DURON: I THINK THIS IS FABULOUS. THERE'S NOTHING LIKE CREATING A PIPELINE INTO UNIVERSITY AND FOR A DIVERSE COMMUNITY OF SCIENTISTS. I WOULD LOVE TO SEE THIS PROGRAM SPOTLIGHTED AT THE CONFERENCE THAT WE'VE JUST VOTED ON, ALLOWING NUMBERS OF THESE PEOPLE TO DESCRIBE THAT EXPERIENCE, WHY IT'S CRUCIAL. SO IF YOU ARE GOING TO HAVE INVESTORS AND OTHER PEOPLE IN THE ROOM BESIDES SCIENTISTS WHO CAN BECOME MENTORS, IT GIVES AN OPPORTUNITY TO SHOW THIS PIPELINE AND WHY IT'S SO CRUCIAL BECAUSE THIS IS THE FUTURE. AND WE NEED TO MAKE SURE THAT IT IS DIVERSE. AND I REALLY LOVE THAT THEY ALSO DEAL IN COMMUNITY ENGAGEMENT BECAUSE THAT'S WHERE IT'S AT. THAT'S GOT TO HAPPEN THAT WAY. SO THANK YOU. AND CONGRATULATIONS.

DR. SHEPARD: THAT'S A GOOD IDEA. AND MY OWN INTERACTION WITH ALUMNI FROM THIS PROGRAM IS THEY'RE VERY ENGAGED AND EAGER TO HELP TOO. IN FACT, A FEW MONTHS AGO DURING THE DISCOVERY DAY AT

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AT&T PARK, I WAS GOING TO SAY WHERE THE GIANTS PLAY, IN SAN FRANCISCO, ORACLE, OH, SORRY. YOU CAN TELL I DON'T FOLLOW SPORTS. BUT ANYWAY --

CHAIRMAN THOMAS: I DON'T FOLLOW THE GIANTS EITHER, FOR THE RECORD.

MR. ROWLETT: THOSE OF US ON THE PHONE ARE STILL LISTENING.

DR. SHEPARD: I BROUGHT MY DAUGHTER WITH ME AND WE VOLUNTEERED, AND WE SPOKE TO MANY STUDENTS. AND SOME OF THE OTHER PEOPLE WHO VOLUNTEERED TO COME HELP CIRM WERE BRIDGES ALUMNI IN THE SAN JOSE STATE PROGRAM. ONE OF THEM, I FOUND OUT, EVEN HAD GONE TO THE SAME HIGH SCHOOL AS MY DAUGHTER. AND I JUST THOUGHT THAT WAS WONDERFUL. THEY'RE AROUND, THEY'RE ENGAGED, AND THEY'RE EAGER TO SHARE WHAT THEY EXPERIENCED WITH UP AND COMING STUDENTS. SO THE PROGRAM HAS BEEN VERY REWARDING TO BE A PART OF.

DR. YAMAMOTO: I WAS JUST GOING TO ADD THAT YOU GOT TO BE CAREFUL. THESE ARE THE DOCTORS THAT ARE GOING TO BE TAKING CARE OF US IN A FEW YEARS. SO GOT TO TRAIN THEM WELL AND TREAT THEM WELL. THEY WILL REMEMBER.

DR. SHEPARD: SO IF THERE ARE NO QUESTIONS ABOUT THE BRIDGES PROGRAM, I'LL MOVE ON TO THE

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SECOND TRAINING PROGRAM, WHICH ARE THE SPARK AWARDS. AND, OF COURSE, IF ANY OTHER QUESTIONS COME TO MIND AT THE END OF MY TALK, I'M HAPPY TO TAKE THEM.

SO THE NEXT PROGRAM I'M GOING TO TELL YOU ABOUT ARE THE SPARK AWARDS. AND THIS IS OUR HIGH SCHOOL LEVEL TRAINING PROGRAM. SO THE OBJECTIVE OF THESE AWARDS IS TO PROVIDE HIGH SCHOOL STUDENTS WITH HANDS-ON TRAINING IN STEM CELL RESEARCH THROUGH SUMMER INTERNSHIPS AND TO INSPIRE THEIR INTEREST IN REGENERATIVE MEDICINE AS A SECONDARY GOAL.

THESE PROGRAMS SUPPLEMENT AND INTEGRATE WITHIN EXISTING SUMMER PROGRAMS THAT ARE SPONSORED BY ELIGIBLE CALIFORNIA INSTITUTIONS. NOW, I HAVE A SLIDE THAT'S SIMILAR TO THE ONE I SHOWED YOU FOR BRIDGES. THE SPARK PROGRAM AND ITS PREDECESSOR, THE CREATIVITY AWARDS, HAVE BEEN OPERATING SINCE 2012. HISTORICALLY, TEN DIFFERENT PROGRAMS WERE FUNDED ACROSS THE STATE. CURRENTLY SEVEN OF THESE PROGRAMS ARE ACTIVE, AND THEY'RE OFFERED BY THE INSTITUTIONS SHOWN ON THE SLIDE.

NOW, THE SPARK PROGRAMS ALL HAVE CERTAIN FEATURES IN COMMON, SOME OF WHICH WILL BE FAMILIAR TO YOU BECAUSE THEY'RE SHARED WITH OUR BRIDGES TRAINING PROGRAMS. BUT SINCE THESE ARE HIGH SCHOOL LEVEL STUDENTS AND THEY'RE IN HIGH SCHOOL FOR MOST

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OF THE YEAR, THEIR RESEARCH INTERNSHIPS ARE DONE DURING THE SUMMER, DURING A 12-WEEK PERIOD OF TIME. BEFORE THEY START THEIR INTERNSHIPS, THEY DO HAVE SOME PREPARATORY COURSES AND WORKSHOPS TO HELP THEM BE READY TO HIT THE GROUND RUNNING WHEN THEY GO TO THOSE RESEARCH LABORATORIES WHICH ARE AT PLACES LIKE STANFORD AND UCSF, AS YOU SAW IN THAT SLIDE. SO WORLD-CLASS RESEARCH LABORATORIES, OPPORTUNITIES TO WORK WITH PEOPLE WHO ARE LEADERS IN THAT FIELD.

THEY ALSO HAVE PATIENT ENGAGEMENT ACTIVITIES WHERE THEY WORK DIRECTLY IN A STRUCTURED ACTIVITY WITH PATIENTS IN ORDER TO HELP THEM UNDERSTAND THE PERSPECTIVE OF THOSE PATIENTS AND WHY THEIR WORK IS IMPORTANT TO THEM AND TO OUR COMMUNITY. AND ALSO THERE'S A FORMAL COMMUNITY OUTREACH COMPONENT. AND SPECIFICALLY WITH THIS PROGRAM, IT INVOLVES SOCIAL MEDIA. AND WE ALL KNOW HIGH SCHOOL STUDENTS ARE GREAT AT SOCIAL MEDIA. SO LET'S TAKE ADVANTAGE OF THAT AND HAVE THEM USE THAT AS A PLATFORM TO REACH OUT AND SHARE WITH THE COMMUNITY THE VALUE OF WHAT THEY DO. YOU MIGHT HEAR A LITTLE BIT MORE ABOUT THIS LATER.

IF YOU READ CIRM'S BLOG, YOU CAN READ ACTUALLY SOME OF THE BLOG AND INSTAGRAM POSTS THAT THESE STUDENTS HAVE PUT OUT OVER THE YEARS, WHICH

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ARE VERY INSPIRING.

AT THE CULMINATION OF THEIR SUMMER INTERNSHIP, WE DO CONVENE ALL THE STUDENTS FROM ALL THE PROGRAMS ACROSS THE STATE FOR AN ANNUAL SPARK POSTER DAY WHERE THEY GET TOGETHER AND THEY SHARE THEIR RESEARCH PROJECTS WITH ONE ANOTHER ON POSTERS. SOME OF THEM ARE SELECTED TO GIVE FORMAL PRESENTATIONS, AND WE CELEBRATE THEIR BLOGS AND THEIR SOCIAL MEDIA ACTIVITIES. AND PARENTS ARE INVITED, AND IT'S A VERY INSPIRING DAY FOR EVERYONE INVOLVED, INCLUDING THE CIRM TEAM.

SO THIS PROGRAM HASN'T BEEN GOING ON QUITE AS LONG AS THE BRIDGES PROGRAM, BUT WHAT I CAN TELL YOU NOW IS THAT TO DATE WE HAVE HAD 482 STUDENTS COMPLETING THEIR INTERNSHIPS SINCE 2012. MANY OF THE TRAINEES ARE STILL IN HIGH SCHOOL BECAUSE THEY DO THEIR INTERNSHIPS A COUPLE YEARS BEFORE THEY GRADUATE IN SOME CASES. BUT OF SOME 76 RECENT ALUMNI WHO HAVE REPORTED THEIR COLLEGE ATTENDANCE TO US SO FAR, I CAN TELL YOU THAT ABOUT 50 PERCENT OF THEM ARE ATTENDING A UC, ABOUT 18 PERCENT ARE ATTENDING ANOTHER SCHOOL IN CALIFORNIA, AND ABOUT A THIRD OF THEM ARE ATTENDING SCHOOLS OUTSIDE OF CALIFORNIA, INCLUDING SOME OF THE VERY WELL RECOGNIZED AND PRESTIGIOUS SCHOOLS THAT YOU SEE

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LISTED ON THE SLIDE.

ALTHOUGH SOME OF THEM ARE PURSUING OTHER TYPES OF STEM CAREERS, MANY OF THEM ARE PURSUING BIOLOGY AS THEIR FIRST CHOICE OF A MAJOR. AND SO HOPEFULLY THE NEXT TIME I PRESENT AN UPDATE ON THIS, I'LL HAVE MORE INFORMATION TO SHARE WITH YOU ABOUT THIS. WE MAY ALSO HAVE SOME INSPIRING STORIES TO SHARE WITH YOU, ONE OF WHICH IS ABIGAIL MORA WHO'S SHOWN ON THIS SLIDE. SHE WAS IN THE SUMMER INTERNSHIP PROGRAM LAST SUMMER, AND THERE SHE IS HOLDING AN AWARD SHE RECEIVED FOR THE MOST INSPIRING BLOG. SHE DESCRIBED HOW, AS A CHILD IN MEXICO, THE EXPERIENCE OF HER BROTHER, WHO WAS BORN PREMATURE, INSPIRED HER TO LEARN MORE ABOUT WHAT HAPPENS DURING DEVELOPMENT AND WHAT HAPPENS DURING DEVELOPMENT WHEN A BABY IS BORN PREMATURE. AND SHE WAS ABLE TO DO AN INTERNSHIP IN A LABORATORY AT UCSF TO STUDY THIS VERY ISSUE.

SO THAT CONCLUDES MY BRIEF UPDATE ON THE STATUS OF THESE PROGRAMS AND OUTCOMES. I'VE INCLUDED A LINK TO OUR WEBSITE WHERE MORE INFORMATION ABOUT THE INDIVIDUAL PROGRAMS CAN BE FOUND IF YOU'RE INTERESTED IN A SPECIFIC ONE. AND I'M HAPPY TO TAKE ANY QUESTIONS NOW IF YOU HAVE ANY.

CHAIRMAN THOMAS: KELLY, I'M JUST GOING TO

POINT OUT, I HAVE IN THE PAST, THAT THE SPARK PROGRAM IS ONE OF MY PERSONAL FAVORITES. THESE KIDS, MOST OF THEM ARE AP BIO STUDENTS THAT GO INTO THESE SUMMER PROGRAMS. AP BIO COVERS A LOT OF TERRITORY, A SMALL PERCENTAGE OF WHICH IS STEM CELL RELATED. SO THEY GO INTO THIS WITH NOT A LOT OF BACKGROUND.

AND WHEN YOU GO TO THIS POSTER DAY, AND YOU LISTEN TO THESE KIDS, IT IS UNBELIEVABLE. THEY SOUND LIKE PH.D. STUDENTS. AND THE ONES THEY SELECT TO GIVE THE PRESENTATIONS, YOU JUST SIT THERE AND YOU'RE SHAKING YOUR HEAD AND YOU'RE SAYING YOU GOT TO BE KIDDING ME. THESE KIDS ARE SO TALENTED, THEY'RE SO PASSIONATE, THEY'RE SO INTO THIS, IT BODES VERY WELL FOR THEM GOING ON TO PURSUE THIS IN SOME FASHION IN COLLEGE AND BEYOND THAT INTO THE WORKFORCE.

AND I THINK THAT THE FACT THAT WE PROVIDE THIS PROGRAM IS ANOTHER GREAT FEATURE OF WHAT WE DO, WHICH IS UNIQUE, TO GO ALONG WITH THE BRIDGES PROGRAM, WHICH I ECHO SENATOR TORRES' COMMENTS ON, WHICH IS JUST A HUGE SUCCESS. AND TO THE EXTENT, WITH RESPECT TO SPARK, ANY OF YOU HAPPEN TO BE AROUND, THE POSTER DAY IS USUALLY IN ABOUT THE SECOND WEEK OF AUGUST ROUGHLY, SHOULD CHECK IT OUT.

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THESE KIDS ARE REALLY AMAZING. CONGRATULATIONS TO YOU FOR THIS.

DR. SHEPARD: GOING TO BE IN SACRAMENTO THIS COMING SUMMER.

CHAIRMAN THOMAS: OKAY. THANK YOU VERY MUCH.

DR. SHEPARD: THANK YOU. DR. MILLAN.

DR. MILLAN: SO ON BEHALF OF THE CIRM TEAM AND CHAIRMAN THOMAS, WHAT WE'D LIKE TO DO TODAY IS INTRODUCE SOME STRATEGIC THEMES FOR THE BOARD TO CONSIDER. AS CHAIRMAN THOMAS HAS MENTIONED IN THE BEGINNING OF THE MEETING, THERE WAS A, I DON'T KNOW IF YOU CALL IT A FORMAL REQUEST, BUT I THINK AN INTEREST IN THE IDEA OF BEGINNING OUR STRATEGIC PLANNING SO THAT, IN THE EVENT THAT THERE IS A NEXT INITIATIVE, WE ARE REALLY NOT CAUGHT WITH ANY DOWNTIME.

WE ARE FORTUNATE IN THAT THIS BOARD HAS SUPPORTED THE MAINTENANCE OF A VERY STRONG CORE OF THE CIRM TEAM, WHICH HAVE CONTINUED TO MANAGE THEIR PROJECTS AS YOU CAN SEE. THERE'S ACTIVE MANAGEMENT A LOT GOING ON WITH THESE PROGRAMS. BUT IN ADDITION, WE CAN USE THAT KNOWLEDGE AND THE EXPERTISE OF THAT TEAM TO HELP DEVELOP DRAFT PLANS THAT WE CAN ENGAGE THE BOARD IN AND DEVELOP A DRAFT

PLAN THAT WE CAN PRESENT IN OCTOBER AND THEN BRING FOR FORMAL DISCUSSION AND APPROVAL EARLY NEXT YEAR SHOULD THERE BE AN INITIATIVE THAT GOES THROUGH.

SO WITHOUT ANY FURTHER DELAY, THE BROAD OUTLINE IN THE PROCESS, AND I SHOULD SAY THAT OVER THE COURSE OF THE YEARS THAT CIRM HAS BEEN IN EXISTENCE AS WELL AS ALL THE RECENT TYPES OF CONFERENCES, WORKSHOPS, AND CONSIDERATIONS THAT THE CIRM TEAM HAS BEEN INVOLVED IN, WE HAVE QUITE A BIT OF INFORMATION TO BRING TO THIS PROCESS. THIS HELPED US IDENTIFY CRITICAL GAPS AND OPPORTUNITIES AND WHAT THE NEXT CIRM COULD LOOK LIKE. AND THAT WILL PROVIDE OPPORTUNITIES TO ENGAGE WITH OUR BOARD AND THE VARIOUS TOPICS, SOME OF WHICH WE ALREADY TOUCHED ON TODAY, CONTINUE ADDITIONAL OUTREACH, AND DRAW FROM THE KNOWLEDGE GAINED FROM THE PREVIOUS INPUT AS WELL AS PERHAPS CONTINUE OUTREACH TO INFORM THE PROCESS.

THE OUTCOME, THIS IS THEN TO DEVELOP KIND OF A GAP ANALYSIS AS WELL AS A LIST OF THINGS OR REFINEMENTS OR IMPROVEMENTS WE CAN BRING TO OUR CURRENT PROGRAMS. AND THAT WE WOULD THEN ENGAGE IN A PROCESS AFTER THE NEW BOARD APPROVES A FORMAL PLAN, THAT WE'D ALREADY BE TEED UP TO BE BRINGING CONCEPT PROPOSALS TO THE BOARD TO SUPPORT THE

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STRATEGIC PLAN.

SO THE FIRST STEP OF THIS IS FIRST GETTING AGREEMENT IN TERMS OF WHAT THE STRATEGIC THEMES WOULD BE, WHAT TYPES OF INFORMATION AND GAP ANALYSIS AND KNOWLEDGE WOULD WE BRING TOGETHER TO INFORM POTENTIAL NEW CONCEPTS AND NEW PROGRAMS.

SO OUR MISSION IS CURRENTLY ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS. WE'VE EXPANDED THAT TO GENE THERAPIES AS WELL. SO I'VE JUST, IN THIS SLIDE, JUST FOR CONSIDERATION, WE HAVE THE OPPORTUNITY TO RELOOK AT THAT MISSION. SO THAT'S SOMETHING THAT WE WOULD ALSO BRING TO THE BOARD. RIGHT NOW, TO BE CONSISTENT WITH WHAT WE ARE FUNDING, IT'S STEM CELL AND REGENERATIVE MEDICINE TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS.

THE FOUR THEMES THAT WE'D LIKE TO DISCUSS TODAY ARE ADVANCING WORLD-CLASS SCIENCE AND DEVELOPMENT OF DEFINITIVE AND CURATIVE THERAPIES, BACKGROUND PATHWAYS TO COMMERCIALIZATION, INCREASING ACCESS TO PATIENTS, AND MAXIMIZING FUNDING THROUGH OPERATIONAL EXCELLENCE. YOU'VE ALREADY HEARD EXAMPLES OF HOW CIRM IS UNIQUE AND HOW WE STRIVE FOR OPERATIONAL EXCELLENCE, BUT WE BELIEVE THAT WE CAN EVEN DO MORE.

AND SO WHAT I'D LIKE TO DO, THEN, IS TAKE THEM ONE BY ONE SO THAT THE BOARD HAS THE OPPORTUNITY TO DISCUSS THESE TOPICS AND PROVIDE INPUT OR HAVE FOLLOW-UP CONVERSATIONS WITH US REGARDING THESE CONCEPTS.

IN TERMS OF ADVANCING WORLD-CLASS SCIENCE, OUR MECHANISM FOR DOING THIS IS THROUGH OUR REVIEW AND FUNDING MECHANISM WHERE WE HOLD THE PROJECTS ACCOUNTABLE THROUGH MILESTONES BASED ON OPERATIONAL EXPECTATIONS AND A CONTINUOUS AND PREDICTABLE FUNDING STREAM SO THAT PROGRAMS CAN GO FROM ONE STAGE TO THE NEXT. AND WE BELIEVE THAT THAT IS SOMETHING THAT IS WORTHWHILE RETAINING.

THERE ARE FIVE FUNDING PILLARS WHICH YOU'VE HEARD ABOUT: DISCOVERY, TRANSLATION, CLINICAL, EDUCATION, AND INFRASTRUCTURE. OUR BASELINE EXPECTATION IS WE WOULD WANT TO RETAIN ALL THESE FIVE PILLARS.

DISCOVERY, WE THINK, IS ABSOLUTELY IMPORTANT AND FUNDAMENTAL AND NECESSARY JUST ON ITS OWN, BUT IT ALSO GIVES RISE TO THE DEVELOPMENT CANDIDATES THAT ARE THEN BROUGHT FORWARD THROUGH THE OTHER PROGRAMS.

YOU HEARD ABOUT THE EDUCATIONAL PROGRAM. WE BELIEVE THAT THERE IS EVEN MUCH MORE WE COULD DO

WITH THAT.

AND INFRASTRUCTURE, WE ARE THINKING PRIMARILY OF PROGRAMMATIC INFRASTRUCTURE LIKE CLINICAL NETWORKS, PERHAPS PATIENT NAVIGATION, AND DIFFERENT WAYS THAT WE CAN INTEGRATE THE PROGRESS OF THE SCIENCE ALONG WITH MAKING SURE THAT THE COMMUNITY'S IN STEP WITH US AND UNDERSTAND WHAT'S GOING ON, NOT ONLY JUST UNDERSTANDING IT, BUT ACTUALLY HAVE A SAY AND INPUT BECAUSE THIS IS EXTREMELY IMPORTANT.

SO THOSE ARE JUST SOME EXAMPLES. WE WOULD IDENTIFY AREAS THAT DON'T NECESSARILY FIT INTO THE FIVE PILLARS; FOR INSTANCE, ACCESS IN TERMS OF REIMBURSEMENT, DATA-DRIVEN SOLUTIONS TO SOME OF THE THINGS THAT WE ARE TALKING ABOUT, BEING ABLE TO SUPPLY THE HEALTHCARE ECONOMICS VALUE EVIDENCE. THAT'S A POSSIBILITY. IDENTIFY PRIOR PROGRAM AND INFRASTRUCTURE INVESTMENTS THAT COULD BE LEVERAGED FOR FUTURE PROGRAMS. WE BELIEVE THE ALPHA CLINIC NETWORK AND THEIR PARTNER COMMUNITY HOSPITALS WILL BE CRITICAL IN BRINGING THE NEW TECHNOLOGIES FORWARD, AGAIN, IN PARTNERSHIP WITH THE COMMUNITIES. AND SO THAT'S GOING TO REQUIRE NOT ONLY WORKFORCE DEVELOPMENT, BUT EVOLUTION OF A TYPE OF CARE DELIVERY AND TOOLS WE HAVE. AND, FINALLY, THE IDEA

OF A CONSORTIA OR MOONSHOT APPROACHES, AND THIS CONCEPT WAS BROUGHT FORWARD BY THE GWG DURING THAT RETREAT THAT DR. SAMBRANO SUMMARIZED AT THE LAST BOARD MEETING.

OUR REVIEWERS FELT THAT THIS WAS AN IMPORTANT MODEL TO CONSIDER BECAUSE CIRM FUNDS HIGHLY RIGOROUS SCIENCE, BUT TO DO IT IN A COORDINATED FASHION WOULD POTENTIALLY BRING EVEN MORE ACCELERATION AND VALUE PER DOLLAR OF WHAT WE INVEST INTO THE SCIENCE.

SO I THINK I'M GOING TO JUST STOP RIGHT THERE AND TAKE QUESTIONS. AND THIS REALLY IS THE OPPORTUNITY FOR THE BOARD TO DISCUSS, ASK QUESTIONS ABOUT THESE VARIOUS TOPIC AREAS.

CHAIRMAN THOMAS: MS. DURON.

MS. DURON: GRACIAS. WHY HAVE YOU NOT CONSIDERED THE COMMUNICATIONS AND DISSEMINATION AS A VERY STRATEGIC PILLAR?

DR. MILLAN: IT IS. IT'S IN THEME FOUR -- THEME THREE, ACCESS. AND WE CAN DISCUSS THAT NOW BECAUSE ONE OF THE CONCEPTS IS THAT THESE FOUR THEMES WILL ACTUALLY OVERLAP. SO SOME OF THE -- KIND OF THE TOPICS THAT ARISE HERE, FOR INSTANCE, WILL BE BY NATURE AND BY NECESSITY LINKED TO OTHER ASPECTS OF HOW YOU DISSEMINATE THE

INFORMATION, HOW THEY NAVIGATE PATIENTS THROUGH CLINICAL TRIALS, NOVEL THERAPIES, HOW THEY'RE ENGAGED AND INVOLVED IN DATA. YOU MENTIONED DATA. THAT IS THE NEW OIL OR THE GOAL THAT SOME HAVE TALKED ABOUT. THESE ARE ALL INTERLINKED AND INTERRELATED.

PATIENT ACCESS IN TERMS OF JUST THE PRACTICE ASPECTS OF ACTUALLY KNOWING THAT THERE ARE THESE THERAPIES OUT THERE. ACCESS IN TERMS OF PAYMENT THAT'S GOING TO BE HEALTHCARE ECONOMICS AND VALUE DRIVEN. ACCESS IN TERMS OF THE CARE DELIVERY SYSTEM BEING ABLE TO ACCOMMODATE THESE NEW THERAPIES. SO THEY ALL ARE INTERLINKED.

BUT TO MAKE IT, TO BE ABLE TO APPROACH THIS FROM KIND OF AN ORGANIZED FASHION, THEY'RE ORGANIZED INTO THESE FOUR THEMES. AND WHAT YOU'RE SPECIFICALLY TALKING ABOUT IS IN THE ACCESS.

MS. DURON: CAN I INTERPRET, THOUGH, THAT WHAT YOU SAID IS THAT UNDER EACH ONE OF THOSE, LET'S CALL IT A BUCKET OR A PILLAR, THERE IS VERY STRONG EMPHASIS ON COMMUNICATION AND DISSEMINATION FOR EACH OF THOSE AT ALL OF THOSE LEVELS AND, THEREFORE, THAT REQUIRES SOME LINE ITEM DOLLARS FOR COMMUNICATION AND DISSEMINATION --

DR. MILLAN: YES.

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MS. DURON: -- AT EVERY LEVEL? AND THAT HELPS DEFINE THE OVERARCHING TRANSPARENCY AS WELL AS UNDERSTANDING IN THE PUBLIC AND NOT JUST BUCKETS OF INTERESTED PARTIES? I JUST THINK IF YOU DEPEND ON A WEBSITE, IF YOU LOOK AT HOW MANY PEOPLE IN CALIFORNIA VERSUS HOW MANY ACTUALLY VISIT A WEBSITE, YOU'RE NEVER GOING TO GET YOUR MESSAGE OUT. SO HOW DO YOU BEGIN TO USE --

DR. MILLAN: ABSOLUTELY.

MS. DURON: -- MULTIPLE WAYS TO GET THE MESSAGE OUT, BUT AT EACH LEVEL, BECAUSE I THINK EACH OF THOSE ARE IMPORTANT, BUT WE ALL NEED TO UNDERSTAND THEM AND HAVE THEM DISSEMINATED.

DR. MILLAN: ABSOLUTELY. SO JUST TO GIVE A SPECIFIC ON THAT, YOU JUST HEARD ABOUT THE EDUCATION PROGRAM, WHICH IS ACTUALLY ONE OF THE PILLARS. SO IN TERMS OF ENGAGEMENT AND COMMUNICATION, THOSE ARE THE AMBASSADORS AS WELL AS THE FUTURE PROFESSIONALS IN THE FIELD, FOR INSTANCE.

ONE OF THE KEY, I THINK, GLUES TO THIS WHOLE THING IS HAVING THE MOST SOLID EVIDENCE-BASED SOURCES BY WHICH WE CAN EDUCATE, COMMUNICATE, AND INFORM BOTH THE RESEARCH, THE COVERAGE OF THE TREATMENTS, BUT ALSO HOW THESE TREATMENTS ARE APPLIED. PATIENTS SHOULD BE AWARE OF THEIR

DIFFERENT TREATMENT OPTIONS. HEALTHCARE PROVIDERS SHOULD BE AWARE OF THESE NOVEL TREATMENTS COMING OUT THERE. SO THESE ARE ALL TOPIC AREAS THAT WE'VE ALREADY STARTED TO BE INVOLVED IN CONVERSATIONS WITH VARIOUS STAKEHOLDERS THAT ARE GOING TO LEAD EVEN NATIONAL-BASED EFFORTS.

SO WE IN LOOKING AT THE LANDSCAPE ARE LOOKING AT ALL THOSE MAJOR TIDES AND MAKING SURE WE ALIGN IN A WAY THAT WILL BENEFIT THE STAKEHOLDERS THAT WE WOULD SERVE THROUGH CIRM FUNDING AND DEVELOPMENT OF THESE TREATMENTS.

MS. DURON: MAY I HAVE THE PRIVILEGE OF THE FLOOR FOR ONE MORE THING JUST BECAUSE IT'S A THEME? I THINK WE ARE ALL PATIENTS AT ONE POINT OR TIME OR ANOTHER. SO TO ME WE ARE SORT OF A COMMUNITY OF PATIENTS. AND SO THE IDEA OF DISSEMINATING OUT TO THE PUBLIC AND NOT JUST THE PATIENTS, TO ME, IS A BROADER WAY --

DR. MILLAN: ABSOLUTELY.

MS. DURON: -- OF ADDRESSING THAT ISSUE. BECAUSE AT ONE POINT IN TIME, SOMEONE IN THEIR FAMILY MAY, OF COURSE, BE BORN WITH OR NEED AND TO ACCESS THIS. SO YOU WANT THEM AWARE OF IT INSTEAD OF THEM SUDDENLY STUMBLING INTO THE DOCTOR'S OFFICE, YOUR CHILD HAS THIS, OR YOU HAVE THIS, HELP YOU

UNDERSTAND IT.

SO I THINK IT'S JUST BOTTOM LINE WHAT I THINK JOURNALISTS DO IS EDUCATE THE PUBLIC, PERIOD. AND MAYBE I'M OVERREACHING HERE, BUT I'M WANTING TO EDUCATE CALIFORNIA AND NOT JUST PATIENTS OR SILOS OF PEOPLE. SO WHEN I TALK ABOUT DISSEMINATION, I TALK ABOUT A BROAD WAY OF FIGURING OUT HOW TO DO THAT, BUT MAKING SURE THAT IT'S ADEQUATELY FUNDED AT EACH LEVEL OF THOSE SO THAT WE ARE ALL WORKING IN CONCERT AND TANDEM TOGETHER AND UTILIZING THE MOST OF OR ALL OF THESE RESOURCES, BUT BEING ABLE TO MAKE SURE THAT THE PUBLIC IS GOING TO HEAR ABOUT IT SOME WAY, SOMEHOW AND BE ABLE TO SAY, "OH, I HEARD ABOUT THAT. WHAT ABOUT THAT? OH, I'M GOING TO LOOK THAT UP." SO YOU MAY ALREADY BE THINKING ABOUT THIS.

DR. MILLAN: THESE ARE VERY IMPORTANT ISSUES. IN FACT, WE HAD A VERY SMALL CONVERSATION THAT WE HAD RECENTLY AT THE JP MORGAN CONFERENCE. DR. MALKAS WAS INVOLVED IN THAT MEETING AS A REPRESENTATIVE.

DR. MALKAS: IT WAS A FANTASTIC WORKSHOP THAT CIRM PUT TOGETHER AND HOSTED WHICH REALLY BROUGHT ALL KINDS OF MEMBERS OF THE COMMUNITY FROM THE MEDICAL PROFESSIONALS TO SCIENTISTS TO THE INSURANCE TO ACTUALLY A NUMBER OF FOUNDATION,

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DISEASE FOUNDATIONS WERE INVOLVED. AND THE WORKSHOP WAS PHENOMENAL. IT WAS CLOSED DOOR, BUT YOU BROUGHT ALL THESE DIFFERENT MINDS TOGETHER AND CAME IN LOOKING AT A PROBLEM AND IDENTIFYING THE GAPS. IT WAS SUCH AN AMAZING MEETING, THAT I SAID TO MARIA, "YOU GOT TO PUT A WHITE PAPER TOGETHER ON THIS" BECAUSE THEY REALLY HIT WHERE WE ARE GETTING IT RIGHT AND WHERE THERE IS ROOM FOR IMPROVEMENT. BUT IT WAS REALLY VERY WELL DONE BECAUSE SO MANY DIFFERENT VOICES WERE AT THE TABLE, AND THEY HAD THE ABILITY TO ARTICULATE.

SO THAT IS PART OF DISSEMINATION OF INFORMATION AS WELL. IF YOU WANT TO ADD TO THAT.

DR. MILLAN: IT WAS MEANT BY NATURE BECAUSE OF THE -- YOU CAN ONLY DO SO MUCH IN THE FIRST. IT WAS AN INTRODUCTION TO THIS CONCEPT AND TO GET BUY-IN FROM DIFFERENT -- SO WE HAD THE FDA THERE, WE HAD FOLKS WHO LED POLICY INITIATIVES, FORMER CMS ADMINISTRATOR, FOUNDATIONS, PATIENT ADVOCATES, OUR BOARD MEMBERS WHO ARE ALSO PATIENT ADVOCATES TALKING ABOUT THE CONVERSATION ABOUT WHERE WE DON'T HAVE IT RIGHT YET IS COMMUNICATING WELL, AND THAT'S WHY IT'S TEEING US UP FOR SOME OF THE DISTRACTIONS OF STEM-CELL-DIRECT-TO-CONSUMER TOURISM THAT ARE PREYING ON THE HOPES OF PATIENTS. BUT ALSO

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ON THE OTHER SIDE, IT'S BECAUSE IT'S JUST STARTING TO MATURE, SO THERE'S AN OPPORTUNITY WHERE WE ARE A FIELD THAT CAN BE THE FIRST-USE CASE FOR THE MODERN ERA OF INFORMATION DISSEMINATION JUST GENERALLY.

AND SO THERE IS A LOT OF INTEREST IN THAT CONCEPT FROM KEY STAKEHOLDERS. THE REASON WE BROUGHT THESE FOLKS TOGETHER IS BECAUSE WE KNOW SOME THINGS ARE GERMINATING NOW IN TERMS OF POTENTIAL INITIATIVES, AND WE WANTED TO MAKE SURE WE WERE INFORMED. WE WANTED TO MAKE SURE OUR VOICES WERE HEARD AS WELL. AND THERE'S MUCH MORE DOWNSTREAM. SENATOR TORRES HAS OTHER THINGS THAT HE HAS BEEN REALLY TEEING UP TO MAKE SURE FROM ALL DIFFERENT SECTORS THAT THE FOLKS ARE INFORMED ABOUT THE PROGRESS OF THE FIELD.

AND SO IT'S TOO MUCH TO GET INTO TODAY, BUT WE HOPE THAT WE CAN ENGAGE YOU AND OTHER BOARD MEMBERS IN THIS DISCUSSION BECAUSE IT WILL BE REALLY VALUABLE TO BRING YOUR EXPERTISE AND YOUR INPUT INTO THIS.

CHAIRMAN THOMAS: DR. BLUMENTHAL.

DR. BLUMENTHAL: I THINK IT'S GREAT THAT WE ARE DOING THIS PROCESS. I WAS REALLY GOING TO ASK YOU TO REMIND US WHAT THE TIME FRAME IS AND WHEN WE WILL HAVE FURTHER DISCUSSION OF A MORE REFINED

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PLAN. IS THAT SOMETHING WE WILL BE DISCUSSING IN GREATER DETAIL AT OUR NEXT BOARD MEETING?

DR. MILLAN: SO TODAY WHAT WE HOPE TO BRING TO YOU IS THESE THEMES AND A GENERAL SENSE FROM THE BOARD AS TO WHETHER WE ARE ON THE RIGHT TRACK. ONCE WE HAVE KIND OF YOUR DIRECTION ON THIS, WHAT WE WILL DO IS INTERNALLY WE ARE ALREADY POISED AND ORGANIZED TO START WORKING THROUGH THE PROCESS OF BRINGING TANGIBLE MATERIALS TO SHARE WITH THE BOARD SO THAT IN MAY WE CAN GIVE YOU AN UPDATE OF WHERE THINGS ARE SHAPING UP AND POTENTIAL PRIORITY AREAS AND MODELS AND THINGS TO CONSIDER FOR THE VARIOUS THEMES. AND THEN IN OCTOBER WE WOULD BRING A DRAFT STRATEGIC PLAN TO THE BOARD FOR DISCUSSION. AND THEN I BELIEVE IN 2021, SHOULD THERE BE A NEW INITIATIVE, IT WOULD BE BROUGHT TO THE NEW BOARD FOR CONSIDERATION.

CHAIRMAN THOMAS: I WOULD JUST ADD TO THAT THAT AS YOU LISTEN TO THESE THEMES AND THE TOPICS DISCUSSED, TO THE EXTENT THAT THERE ARE PARTICULAR SUBJECT MATTERS THAT YOU FIND INTERESTING AND WANTED TO WEIGH IN ON AND HELP WITH THE DEVELOPMENT OF, PLEASE LET US KNOW BECAUSE THE PURPOSE OF THIS IS TO GET AS MUCH BOARD ENGAGEMENT AS POSSIBLE ON THESE THINGS, SIMILAR, FOR EXAMPLE, TO MS. DURON'S

INTEREST IN THE COMMUNICATIONS. I HEAVILY SUSPECT SHE WILL BE INVOLVED IN THAT GOING FORWARD. BUT OTHERS OF YOU, AS YOU HEAR TOPICS, PLEASE LET US KNOW. DR. MILLAN.

DR. MILLAN: MS. DURON HAS BEEN TAGGED AS IN THE ACCESS AREA, FOR INSTANCE, BECAUSE THE IDEA OF EDUCATION AND COMMUNICATION AND ALL THAT IS SOMETHING THAT'S GOING TO BE A HEAVY TOPIC IN THAT AREA. THANK YOU.

DR. DULIEGE: MAYBE WE CAN DISCUSS IT OFFLINE DEPENDING ON TIME, BUT COULD YOU GIVE US A FEW EXAMPLES OF WHAT SPECIFICALLY YOU WOULD LIKE THE BOARD MEMBERS TO DO MORE OR DIFFERENTLY COMPARED TO WHAT WE HAVE BEEN DOING SO FAR TO FULFILL YOUR GOALS HERE? A FEW SPECIFIC IDEAS.

DR. MILLAN: SO FOR THIS PARTICULAR --

DR. DULIEGE: FOR ANY OF THE PILLARS.

DR. MILLAN: IF THERE IS SOMETHING THAT SHOWS UP ON THE SCREEN WHERE YOU THINK THIS IS TOTALLY OFF, IT WOULD BE GREAT IF YOU COULD SHARE THAT WITH US. AND IF THERE'S SOMETHING ON THE SCREEN THAT CAPTURES YOUR INTEREST WHERE YOU HAVE HAD IDEAS OF THIS WILL BE SPECTACULAR, BE ABLE TO FIT THIS IN, WE'D LOVE TO HEAR ABOUT IT. AND THEN THE THIRD THING IS IF, IN GENERAL, IT'S A TOPIC OF

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INTEREST TO YOU, PLEASE LET CHAIRMAN THOMAS KNOW BECAUSE HE AND I WILL BE WORKING VERY CLOSELY IN ASSEMBLING INFORMATION TO A POINT THAT WE CAN HAVE THE BOARD INPUT ON THE VARIOUS TOPICS. THANK YOU.

SO IF THERE ARE NO ADDITIONAL, ONE OF THE THINGS, AN EXAMPLE OF A MOONSHOT IS, FOR INSTANCE, WE RAN A NEURODEGENERATION WORKSHOP IN APRIL THIS YEAR WHERE WE HAD SOME REAL KEY PLAYERS, FOUNDATIONS, ET CETERA, INVOLVED. AND THERE'S A LOT GOING ON IN THE FIELD, BUT IT'S STILL AN AREA WHERE THERE HAS BEEN LITTLE PROGRESS IN TERMS OF GETTING TREATMENTS FOR ALZHEIMER'S, PARKINSON'S, AND ALS. WE DO HAVE SOME CLINICAL TRIALS.

AND THERE IS AN IDEA THAT THERE ARE SOME KIND OF SHARED COMPONENTS SCIENTIFICALLY AS WELL AS RESOURCEWISE WHERE IT MAY BE USEFUL TO HAVE SOMETHING THAT'S MORE COLLABORATIVE. AND IT COULD SPAN THE GAMUT FROM THE BASIC RESEARCH, GENOMICS, TO CLINICAL DATASETS TO REAL-WORLD EVIDENCE, PATIENT EXPERIENCE. IT COULD SPAN THE WHOLE GAMUT, BUT IT WOULD REQUIRE A STRUCTURE BEHIND IT AND WOULD NEED TO BE DELIBERATE, AND IT WOULD NEED TO CREATE KEY PARTNERSHIPS WITH VISIBLE PLAYERS WHO HAVE ALREADY INVESTED QUITE A BIT INTO THIS FIELD AND CREATE PARTNERSHIPS SIMILAR TO WHAT WE'VE DONE WITH NHLBI

FOR CURE SICKLE CELL, FOR INSTANCE, BUT, AGAIN, WITH DIFFERENT TYPES OF DISEASE AREAS.

CHAIRMAN THOMAS: DR. HIGGINS.

DR. HIGGINS: FOR DR. MILLAN, DOES THAT FIT IN WITH THE LANGUAGE IN THE NEW PROPOSAL IS $1.5 BILLION OF THE 5.5 BILLION GOES SPECIFICALLY TO NEURO PROGRAMS? IS THAT HOW YOU SEE THAT MONEY BEING SPENT OR TARGETED, TO SORT OF GROUP GRANTS OR CENTER GRANTS OR COLLABORATIVE GRANTS?

DR. MILLAN: SO THIS IS WHERE -- IT'S KIND OF TRICKY BECAUSE WE CAN'T DEPEND ON -- SO WE ARE GOING THROUGH THIS EXERCISE PLANNING FOR SUCCESS. AND IT'S TRUE THAT THE NEW INITIATIVE EARMARKS $1.5 BILLION IN NEURO, SO THAT'S VERY VISIBLE. EVEN PRIOR TO THE INITIATIVE COMING OUT, WE DID IDENTIFY NEURODEGENERATION AS AN AREA OF NEED THAT WE HAVEN'T SUCCESSFULLY REALLY MADE SUFFICIENT PROGRESS IN. SO THAT IS THE REASON WE LAUNCHED THE WORKSHOP.

SO JUST BECAUSE FOR THE SAME REASON PROBABLY THAT THAT WAS EARMARKED, WE WERE ALREADY THINKING INTERNALLY ABOUT HOW CAN WE BEST LEVERAGE THE RESEARCH THAT'S ALREADY BEEN DONE, THINK ABOUT FUTURE APPROACHES TO THIS THAT CAN EVEN IMPROVE OUR CHANCES OF MAKING PROGRESS.

DR. GASSON: IN TERMS OF CONSORTIA, I'M

SURE YOU'RE PROBABLY AWARE OF THIS, BUT THERE'S A CONSORTIUM OF UNIVERSITIES AND BIOTECH THAT'S CALLED NATIONAL INSTITUTE FOR INNOVATION IN MANUFACTURING AND BIOPHARMACEUTICALS, AND IT GOES BY THE ACRONYM NIIMBL. AND I NOTICED IN A LOT OF YOUR CAP'S -- IT'S UNDER THE NATIONAL INSTITUTE OF STANDARDS IN TECHNOLOGY. AND I NOTICED IN A LOT OF YOUR CAP'S, THEY HAD TO DO WITH MANUFACTURING BOTTLENECKS. SO PERHAPS AN INTERACTION OR AT LEAST A CONVERSATION WITH THAT ORGANIZATION WOULD BE USEFUL.

DR. MILLAN: THAT IS ABSOLUTELY TRUE. AND WE HAVE INTERACTED WITH NIST AND WITH NIIMBL.

DR. GASSON: OH, GOOD.

DR. MILLAN: WELL, WE HAVEN'T HAD ANY FORMAL COLLABORATIONS, BUT WE ARE IN THE SAME MEETINGS. WE BOTH ATTEND THE NATIONAL ACADEMY OF SCIENCES, THEY'RE STEM CELL FORUM. DR. SOHEL TALIB IS OUR REPRESENTATIVE THERE, AND MEMBERS OF THE TEAM ATTEND AS WELL. SO WE ARE FAMILIAR WITH THE INITIATIVES AND ALSO OTHER ORGANIZATIONS SUCH AS ARMY. AND SO WE ARE IN CONVERSATIONS WITH ALL OF THESE STAKEHOLDERS, AND WE ARE THINKING THROUGH HOW WE CAN DO THINGS BETTER.

DR. GASSON: THAT'S GREAT. THAT WAS MY ONLY POINT.

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DR. MILLAN: THE KEY THING IS STANDARDIZATION, BUT IT'S NOT OFTEN REALISTIC, BUT THERE ARE PRECOMPETITIVE AREAS WHERE WE SEE THAT WE HAVE OPPORTUNITIES. SO ABSOLUTELY. THANK YOU.

CHAIRMAN THOMAS: OKAY. PERHAPS ON TO THEME TWO.

DR. MILLAN: SO THEME TWO IS BUILD PATHWAYS TO COMMERCIALIZATION. WHILE WE ARE SEEING PROGRESS, AND AS YOU SAW FROM THE CLINICAL REVIEW, WE REALLY DO RELY ON INDUSTRY PARTNERSHIPS TO TAKE IT FROM THE EARLY STAGE WHERE WE DERISK AND SUPPORT THE EARLY SCIENCE TO TAKE IT TOWARD COMMERCIALIZATION BECAUSE THAT'S A HUGE FINANCIAL INVESTMENT AS WELL AS A DIFFERENT SET OF EXPERTISE. SO WE HAVE ALREADY ESTABLISHED AN INDUSTRY ALLIANCE PROGRAM, AND WE HAVE SIX OR SEVEN PARTNERSHIPS WITH SOME KEY STRATEGIC PARTNERS WHO HAVE INVESTED IN THE FIELD AND ARE INTERESTED IN HELPING OUR PROGRAM.

BUT WE ALSO SEE INFRASTRUCTURE AND POTENTIAL NEEDS IN AREAS SUCH AS MANUFACTURING IN WAYS WHERE IN AN -- SO CIRM IN A WAY SERVES AS AN INCUBATOR. WE ACCELERATE, WE BRING RESOURCES TO IMPROVE THE CHANCES OF SUCCESS.

SO THIS BUILD PATHWAY TO COMMERCIALIZATION IS INTENDED TO BUILD UPON THAT, BUT ALSO TO INCREASE

THE PROBABILITY OF OUR PROGRAMS MAKING IT OUT THERE. SO WE'VE ALSO DONE, ALREADY STARTED MEETING WITH THE OFFICE OF TECHNOLOGY AND LICENSING FROM THE MAJOR INSTITUTIONS THAT WE FUNDED. I THINK WE HAVE HAD SIX OF THOSE MEETINGS. WE'VE IDENTIFIED AREAS WHERE THINGS ARE SLUGGISH AND, IF WE WORK TOGETHER IN A STRUCTURED WAY WITH THOSE OFFICES, WE BELIEVE THAT WE COULD IMPROVE THE CHANCES OF OUR PROGRAMS MAKING IT OUT THERE AND MAKING IT TO PATIENTS.

ANY QUESTIONS ON THAT ONE?

CHAIRMAN THOMAS: MARIA, THE NOTION OF TRYING TO HELP FOSTER ACCELERATED REGULATORY APPROVALS, WHERE DOES THAT FIT IN?

DR. MILLAN: IT WOULD BE IN THEME ONE BECAUSE IT'S EMBEDDED WITHIN ADVANCING THE SCIENCE. SO THE REGULATORY SCIENCE IS KIND OF RIGHT NOW WITHIN THE DEVELOPMENT PROGRAMS, TYPICALLY THE TRANSLATION AND CLINICAL, BUT IT ALSO IS THROUGHOUT. I THINK THAT ONE OF THE THINGS THAT WILL BECOME APPARENT AS WE GO THROUGH THIS EXERCISE IS WE'LL BE ABLE TO MAKE THOSE LINKAGES MORE VISIBLE IN TERMS OF HOW DOES ONE PLAY INTO THE NEXT WHEN WE CRAFT THE STRATEGIC PLAN. IS THERE SOMETHING SPECIFIC?

CHAIRMAN THOMAS: NO. EXCEPT THAT THE PATHWAY TO COMMERCIALIZATION, BY DEFINITION,

INVOLVES REGULATORY APPROVALS. I JUST THOUGHT THAT IT MIGHT BE SOMETHING THAT WOULD BE WITHIN THIS THEME AS WELL.

DR. MILLAN: WELL, THAT'S A REALLY GOOD POINT BECAUSE ONE OF THE REASONS I THINK OUR PROGRAMS HAVE RECEIVED SO MUCH INDUSTRY INVESTMENT IS BECAUSE OF WHAT CIRM HAS DONE FROM DERISKING IT, NOT JUST FROM FINANCIALLY, BUT PUTTING EXPERTISE TOWARD IT AS WELL AS HAVING A TRANSLATIONAL MACHINERY THAT IS DIFFERENT FROM OTHER PLACES. SO THEY KNOW THAT BY THE TIME THEY'RE READY TO MAKE A DECISION TO BRING IT FORWARD THAT SO MUCH OF THIS HAS BEEN DONE. SO BY NATURE, AGAIN, THEY'RE LINKED. BUT THIS IS MORE OF KIND OF THE BUSINESS SIDE OF IT AND HOW WE STRUCTURE. THEY'RE ALL GOING TO BE INTERRELATED. THESE AREN'T MEANT TO BE IMPERMEABLE SILOS BY ANY STRETCH. IN FACT, IT FREE-FLOWS BETWEEN THE DIFFERENT THEMES.

SO THE THIRD THEME, THIS IS A THEME THAT WE HAD ALREADY TOUCHED ON EARLIER, INCREASE ACCESS TO PATIENTS. AND SO, OKAY, INCREASING PATIENT AWARENESS, INCREASING COMMUNITY AWARENESS IS A POINT WELL TAKEN. AND ACCESS TO FDA REGULATED AS WELL AS NEWLY APPROVED REGENERATIVE MEDICINE THERAPIES AND REALLY KNOWING WHERE IT FITS INTO THE SCHEME OF THE

CONTINUUM OF CARE FROM PREVENTIVE TO INTERVENTIONAL AND ONWARD.

AND EVIDENCE GENERATION TO SUPPORT REGENERATIVE MEDICINE ADOPTION, THE HEALTHCARE ECONOMICS, AS WELL AS ALL OF THE OTHER THINGS THAT GO INTO IT, HOW DOES IT IMPACT THE LIVES OF PEOPLE? HOW DO YOU CAPTURE THAT? AND HOW IS THAT BROUGHT INTO THE EQUATION? AND ALL OF THIS, BY NECESSITY, WILL NEED DATA AND KNOWLEDGE PLATFORMS TO SUPPORT ACCESS. ONE COULD THINK THIS IS A HUGE THING TO OVERCOME BECAUSE TRYING TO CENTRALIZE DATA IS NOT FOR THE FAINT HEARTED. HOWEVER, WE DO KNOW THAT THERE ARE ALREADY AGGREGATES OF VERY SOPHISTICATED PLATFORMS THAT ARE BEING DEVELOPED. AND THE IDEA IS HOW DO WE BUILD UPON THAT? AND OUR TEAM OFTEN TALKS ABOUT HOW CIRM COULD BE THE CONNECTOR. WE ARE NEVER GOING TO GET EXACTLY STANDARDIZED ANYTHING, BUT THERE NEEDS TO BE A WAY, AND THE TECH WORLD ALREADY KNOWS HOW TO DO THIS, HOW TO BRING DATASETS DOWN TO ITS SMALLEST, RIGHT, SUBCOMPONENTS SO THAT IT CAN BE USEFUL.

BUT CIRM, BY NECESSITY, BECAUSE WE ARE DOING IT FOR A SPECIFIC PURPOSE, COULD BE THE CONNECTOR TO BRING IN THE KEY SETS AND BY NATURE THEN CREATES A VALUE THERE. AND THEN THAT IN ITSELF

BECOMES A NEW KIND OF HUB WHICH THEN COULD BE A SPOKE FOR SOMETHING ELSE. SO THAT'S HOW WE WILL CONNECT WITH THE WORLD. WE ARE NOT HERE IN ISOLATION. THAT'S VERY ABSTRACT, BUT WE HOPE TO BRING SOME MORE CONCRETE STRUCTURE TO THAT AS WE DEVELOP THE PLAN.

MS. DURON: CAN I SUGGEST ALSO THE OFFICE OF PLANNING AND RESEARCH IN THE GOVERNOR'S OFFICE WHICH GIVES OUT THE PRECISION MEDICINE AWARDS IS TRYING TO ESTABLISH CONNECTED DATASETS.

DR. MILLAN: ABSOLUTELY.

MS. DURON: THEY MIGHT BE A PARTNER.

DR. MILLAN: WE ACTUALLY HAD INTERACTED WITH SHANNON OR SHARON? SHANNON. SHE AND I WERE BOTH AT A CONFERENCE TOGETHER TO SERVE ON A PANEL. WE INVITED HER TO THAT PANEL THAT WE SPOKE OF. SHE WAS VERY TITILLATED BY THAT EVENING, BY THE WAY, AS WELL AS THE WORLD ECONOMIC FORUM. OKAY. EXCITED.

MS. DURON: WORD POLICE.

DR. MILLAN: I MEANT REALLY EXCITED ABOUT WHAT SHE HEARD. AND THE WORLD ECONOMIC FORUM PRECISION MEDICINE INITIATIVE WAS THERE AS WELL, AND THEY WERE ALSO EXTREMELY EXCITED. IN FACT, THE REPRESENTATIVE HAD SAID THAT THAT WAS THE BEST EVENT SHE'S EVER ATTENDED AT THE JP MORGAN CONFERENCE IN

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THE PAST TWO YEARS. I'M SURE SHE WAS FINE WITH US SHARING THAT JUST BECAUSE SHE FELT IT WAS SO RELEVANT IN TERMS OF WHAT THEY'RE ALL ABOUT. HOW DO YOU REALLY BRING THIS OUT MORE GLOBALLY? SO THE PROBLEM SETS THAT WE ARE TRYING TO ADDRESS IN THE SMALLEST -- IN OUR CIRCLE IS SOMETHING THAT'S REALLY SCALABLE AND IMPORTANT MORE GLOBALLY.

DR. YAMAMOTO: THIS IS GREAT TO HEAR. LET ME JUST SUGGEST THAT BUILDING THIS KIND OF KNOWLEDGE NETWORK THAT YOU'RE TALKING ABOUT IS A PRETTY COMPLEX COMPUTATIONAL UNDERTAKING AND SOMETHING THAT WE'VE INVESTED HEAVILY IN AT UCSF BUILDING A PRETTY ROBUST KNOWLEDGE BASE. AND THE GOOD NEWS ABOUT THIS IS THAT THE WAY THAT I THINK IT NEEDS TO BE BUILT, CERTAINLY THE WAY WE ARE BUILDING IT, IS TO BEGIN WITH SORT OF POCKETS OF EXCELLENCE AND EXISTING DATA AND ALLOW THOSE TO BUILD OUT TO LITTLE NETWORKS USING THE PRINCIPLE THAT WE'VE ESTABLISHED COMPUTATIONALLY, AND THEN CONNECT THOSE TO THE OTHER PROGRAMS THAT WE'VE ALREADY BUILT.

SO THERE'S A BIG HEAD START ON THIS NOW. WE MIGHT TALK ABOUT HOW TO JOIN FORCES WITH THE UCSF SIDE.

DR. MILLAN: ABSOLUTELY.

DR. YAMAMOTO: AND THE CALIFORNIA

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INITIATIVE FOR PHYSICIAN MEDICINE IS JUST BEING REBUILT NOW OUT OF THE OPR. AND I'M ON THE ADVISORY -- JUST PUT ON THE ADVISORY COUNCIL. SO I THINK THIS WOULD BE AN OPPORTUNE TIME TO BE CONNECTING WITH THEM AS WELL. BUT THE UCSF EFFORT IS REALLY UNDER WAY. I THINK THE CURRENT KNOWLEDGE BASE THAT WE HAVE HAS OVER FIVE MILLION INFORMATION DATA NODES OR THREE MILLION DATA NODES AND FIVE MILLION EDGES CONNECTING THEM. SO THERE'S A LOT OF STUFF THERE ALREADY WHICH YOU COULD MOUNT THE CIRM INFORMATION.

CHAIRMAN THOMAS: OKAY. PERHAPS WE COULD WRAP UP WITH THEME FOUR.

DR. MILLAN: SO THEME FOUR IS MAXIMIZE FUNDING THROUGH OPERATIONAL EXCELLENCE. THAT'S REALLY THE CIRM ENGINE THAT YOU'VE HEARD SO MUCH ABOUT IN TERMS OF BEING ABLE TO ACCELERATE THE WAY WE HAVE AND INCREASE THE PROBABILITY OF PROJECTS MOVING FORWARD AND FUNDING THEM EFFICIENTLY. AND SO THE IDEA -- THIS IS KIND OF A MIXTURE OF STRATEGY, BUT ALSO OPERATIONAL. IF THE NEXT INITIATIVE DOES GO THROUGH, THE INTENT WOULD BE TO REVIVE THE DISCOVERY, TRANSLATIONAL, AND CLINICAL RFA'S AS ONE OF THE FIRST STEPS. AND THEN TO BRING IN THE CONCEPT PROPOSALS TO EITHER REFINE THOSE PROGRAM

ANNOUNCEMENTS OR ADD TO THEM AND THEN BRING IN ADDITIONAL AS THINGS GO FORWARD.

SO WE JUST WANTED TO BRING THAT TO YOU TO MAKE SURE THAT YOU AGREE THAT THAT WOULD BE ONE OF THE FIRST THINGS TO DO.

AND THEN THEREAFTER, THE IDEA IS THAT WE WOULD LOOK AT WHAT OUR CURRENT PROGRAM ANNOUNCEMENT RFA STRUCTURE LOOKS LIKE AND SCHEDULING JUST KIND OF THE OPERATIONS BEHIND THAT AND LOOK FOR HOW THIS COULD FIT A CONSORTIUM APPROACH. SO THINGS LIKE WHAT KIND OF REQUIREMENTS WOULD WE HAVE, OUR DATA SHARING REQUIREMENTS, FOR INSTANCE, OR HOW DO WE EMBED IN IT CONNECTIVITY BETWEEN THE DIFFERENT PROGRAMS, HOW WOULD THE PROGRAM ANNOUNCEMENTS CHANGE TO ACCOMMODATE THAT.

OPERATIONALIZE FUNDING PARTNERSHIPS. WE ALREADY HAVE HAD THE BENEFIT OF A PILOT PROGRAM WITH THE NHLBI CURE SICKLE CELL. HOW ADAPTABLE IS THAT TO DIFFERENT TYPES OF PARTNERSHIPS WITH OTHER FOUNDATIONS? SHOULD THAT BE SOMETHING THAT WE THINK COULD BE USEFUL FOR THE STRATEGIC PLAN?

AND THEN THE OTHER PARTS OF IT ARE JUST REALLY REFINING OUR OWN INTERNAL OPERATIONS TO SCALE UP FOR WHAT WOULD BE REQUIRED FOR A NEW INITIATIVE AND FOR THE NEW PROGRAMS. AND THAT, OF COURSE,

WOULD INVOLVE THE I.T. ENHANCEMENTS WHERE I'M TOLD WE ARE 100 PERCENT IN THE CLOUD NOW. WE ARE NOT IN THE CLOUDS, BUT OUR I.T. IS IN THE CLOUD. AND THAT IS SOMETHING THAT COULD BE EXPANDED, BUT HOW DOES THAT PLAY INTO HOW WE ARE VIEWING OTHER INITIATIVES SUCH AS THE DATA COMPONENTS OR THE COMMUNICATION AND EDUCATION COMPONENTS? HOW DO WE BUILD THAT IN SO THAT IT'S SEAMLESS AND IT ACTUALLY FLOWS THROUGH A PROCESS SO THAT IT'S NOT DISJOINTED DIFFERENT PROGRAMS? SO THIS IS A PERFECT OPPORTUNITY TO START LOOKING AT THOSE COMPONENTS.

ANY COMMENTS OR QUESTIONS ON THAT? THOSE ARE KIND OF THE NUTS AND BOLTS ACTUALLY, THIS THEME FOUR, BUT IT'S EXTREMELY IMPORTANT. THAT'S HOW WE'VE BEEN ABLE TO DELIVER ON SOME OF THE PROJECTS AS WE TALKED ABOUT TODAY. OKAY. CHAIRMAN THOMAS.

CHAIRMAN THOMAS: THANK YOU, DR. MILLAN. SO WE MAY, IN ADDITION TO YOU DECIDING THERE'S CERTAIN THINGS OF INTEREST THAT YOU'D LIKE TO VOLUNTEER ON TO DISCUSS GOING FORWARD BETWEEN NOW AND MAY, WE MAY REACH OUT TO YOU TO ASK YOU TO FOCUS ON SPECIFIC ELEMENTS HERE. I THINK THERE'S A LOT OF EXPERTISE HERE, OBVIOUSLY, THAT COULD BE VERY USEFUL IN THE FORMULATION OF THIS PLAN. SO STAY TUNED.

OKAY. THAT BRINGS US TO THE END OF OUR

AGENDA. WE ARE NOW AT PUBLIC COMMENT. IS THERE ANY PUBLIC COMMENT ON ANY TOPIC OF ANY NOTE EITHER HERE OR MEMBERS OF THE PUBLIC ON THE PHONE? HEARING NONE, I THINK WE HAVE CONCLUDED THIS MEETING. THANK YOU FOR ALL THE MEMBERS OF THE TEAM WHO HAVE WORKED VERY HARD TO PREPARE TODAY'S PRESENTATION AND WHO DELIVERED -- DR. BURTIS.

DR. BURTIS: YOU MENTIONED EARLIER YOU WERE GOING TO TAKE A BRIEF MOMENT OF SILENCE TO REMEMBER LAUREN'S MOTHER.

CHAIRMAN THOMAS: I WAS GOING TO DO THAT AFTER THE PUBLIC COMMENT. VERY TAIL END HERE.

MS. BONNEVILLE: OUR NEXT BOARD MEETING IS MAY 7TH, AND IT'S IN PERSON HERE. CAN'T WAIT TO SEE YOU ALL AGAIN.

CHAIRMAN THOMAS: YES. THAT'S VERY IMPORTANT. THE IN-PERSON ELEMENT OF THIS, TO THE FULL EXTENT POSSIBLE, IS EXTREMELY IMPORTANT. SO THANK YOU, MARIA.

NO PUBLIC COMMENTS. WITH THAT, THEN WE'D LIKE TO ADJOURN TODAY'S MEETING IN MEMORY OF LAUREN MILLER'S MOTHER. THANK YOU VERY MUCH. WE ARE ADJOURNED.

(THE MEETING WAS THEN ADJOURNED.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

1999 HARRISON STREET
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OAKLAND, CALIFORNIA
ON
FEBRUARY 6, 2020

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
133 HENNA COURT
SANDPOINT, IDAHO 83864
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