BEFORE THE
ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: MAY 17, 2022
3 P.M.

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

FILE NO.: 2022-20

I N D E X

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MAY 17, 2022; 3 P.M.

(THE MEETING WAS DULY CALLED TO ORDER BY THE CHAIR AND THE ROLL WAS TAKEN AS FOLLOWS:)

MS. BONNEVILLE: JAMES BENEDETTI.

MR. TORRES: ART TORRES HERE. GO AHEAD.

MS. BONNEVILLE: JAMES BENEDETTI.

MR. BENEDETTI: HERE.

MS. BONNEVILLE: DAN BERNAL. ANN BOYNTON.

MS. BOYNTON: HERE.

MS. BONNEVILLE: DANA DORNSIFE.

DR. DORNSIFE: HERE.

MS. BONNEVILLE: DANA GOLDMAN.

DR. GOLDMAN: HERE.

MS. BONNEVILLE: TED GOLDSTEIN. DAVID HIGGINS. HARLAN LEVINE.

DR. LEVINE: HERE.

MS. BONNEVILLE: PAT LEVITT. ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: AMMAR QADAN.

DR. QADAN: YES, I'M HERE.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: MAHESWARI SENTHIL.

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DR. SENTHIL: HERE.

MS. BONNEVILLE: DAVID SERRANO-SEWELL. ADRIENNE SHAPIRO.

MS. SHAPIRO: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN TORRES: HERE.

MS. BONNEVILLE: THANK YOU. THERE IS QUORUM.

CHAIRMAN TORRES: ALL RIGHT. THANK YOU. WE HAVE A QUORUM.

SO I WANT TO WELCOME ALL OF OUR MEMBERS OF OUR WORKING GROUP. WE SHOULD HAVE A PRETTY EFFICIENT MEETING TODAY AS I DON'T WANT TO TAKE TOO MUCH OF YOUR TIME BECAUSE I REALLY KNOW HOW BUSY EACH OF YOU ARE.

WHAT I WANTED TO DO WAS TO PROCEED FOR AN UPDATE ON OUR PATIENT ASSISTANCE FUND BUDGET REQUEST WHICH IS NOW BEING CONSIDERED ON THURSDAY BY THE SENATE SUBCOMMITTEE NO. 2 OF OUR SENATE BUDGET REVIEW COMMITTEE. AS YOU WILL FIND OUT, IT IS NOT AN APPROPRIATION; SO, THEREFORE, IT MERELY REQUIRES A VOTE OF THE SUBCOMMITTEE OF THE ENTIRE SECTION WHICH DEALS WITH HEALTHCARE ALL OVER THE STATE OF CALIFORNIA AND THE STATE BUDGET AND, THEREFORE, WILL MOVE FORWARD WITH THE DEPARTMENT OF FINANCE AS WE

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TAKE THE STEPS TO MAKE THIS A REALITY FOR PATIENTS.

SO I'D LIKE TO CALL UPON OUR VICE PRESIDENT OF MEDICAL AFFAIRS AND POLICY, SEAN TURBEVILLE, TO PLEASE PROCEED.

DR. TURBEVILLE: ALL RIGHT. THANK YOU, SENATOR TORRES. AS SENATOR TORRES SAID, MY NAME IS SEAN TURBEVILLE. I'M THE VICE PRESIDENT OF MEDICAL AFFAIRS, AND I AM HERE TO REPORT ON A NUMBER OF PATIENT ASSISTANCE PROGRAM PATHWAYS THAT I WILL PRESENT TO THE TEAM AND THEN HOPEFULLY AT THE END GET SOME GUIDANCE FROM YOU IN TERMS OF WHICH TRAJECTORY WE'D LIKE TO TAKE.

SO SOME BACKGROUND FIRST. SO PROPOSITION 14 SPECIFICALLY DIRECTED THAT REVENUE SPECIFIED RECEIVED SHALL BE DEPOSITED INTO AN INTEREST BEARING ACCOUNT IN THE GENERAL FUND LICENSING AND REVENUE FUND WITH THOSE AMOUNTS TO BE SPENT ON OFFSETTING THE COST OF PROVIDING TREATMENTS AND CURES ARISING FROM INSTITUTE-FUNDED RESEARCH TO CALIFORNIA PATIENTS WHO HAVE INSUFFICIENT MEANS TO PURCHASE SUCH TREATMENT OR CURE, INCLUDING THE REIMBURSEMENT OF PATIENT-QUALIFIED COSTS FOR RESEARCH PARTICIPANTS.

AT THE FEBRUARY 9TH AAWG MEETING, WHICH MANY OF YOU ATTENDED, THE GROUP RECOMMENDED THAT

CIRM REQUEST ALLOCATION OF THE EXISTING REVENUES IN THE LICENSING AND REVENUE FUND TO DEVELOP A CIRM PATIENT ASSISTANCE PROGRAM. YOU RECOMMENDED TWO THINGS. ONE, CIRM STAFF TO BRING PROPOSED OPTIONS FOR THE CIRM'S PATIENT ASSISTANCE PROGRAM TO THE AAWG AND CAN BE DEVELOPED INTO A CONCEPT PLAN; AND, TWO, THAT CIRM PURSUE THE BEST PROCESS TO ASSESS THE FUNDS FOR THE 2022-2023 FISCAL YEAR IN ORDER TO INITIATE A PROGRAM ONCE THE AAWG RECOMMENDED THE CONCEPT AND HAS BEEN APPROVED BY THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE, ICOC.

SO AN UPDATE. IN APRIL CIRM SUBMITTED A BUDGET CHANGE PROPOSAL, BCP, TO THE DEPARTMENT OF FINANCE TO AUTHORIZE THE 15.6 MILLION FOR THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE LICENSING REVENUES AND ROYALTIES FUND FOR PATIENT ASSISTANCE PROGRAM TO BE SPENT OVER FIVE YEARS. THE DEPARTMENT OF FINANCE APPROVED THE BCP FOR INCLUSION IN THE GOVERNOR'S REVISED BUDGET WHICH IS UNDER REVIEW AS OF TODAY. AND CIRM HAS IDENTIFIED THREE OPTIONS WHICH I'LL TALK ABOUT IN A FEW MINUTES.

CHAIRMAN TORRES: ALL RIGHT. I JUST WANT TO MAKE SURE THAT ALL MEMBERS OF THE COMMITTEE UNDERSTAND WHERE THIS MONEY IS COMING FROM.

DR. TURBEVILLE: YEAH. CERTAINLY. I

THOUGHT THAT WAS --

MR. TORRES: JUST EXPLAIN WHERE THE 15.6 MILLION IS COMING FROM.

DR. TURBEVILLE: YEAH. SO THE 15.6 MILLION IS A RESOURCE THAT WAS GENERATED FROM, TO BE GRANULAR, THE SALE OF ONE PARTICULAR BIOTECH ASSET FROM STANFORD OUT TO A PRIVATE INDUSTRY. AND SO THAT WAS ON THE BACK, AND THOSE ROYALTIES WERE CONSIDERED THE ROYALTIES THAT WE ARE DISCUSSING NOW.

CHAIRMAN TORRES: AS AUTHORIZED BY THE PROPOSITION OR THE INITIATIVE SO THAT WHENEVER THOSE KINDS OF ROYALTIES ARE AVAILABLE, THEY HAVE TO BE TRANSFERRED TO THE GENERAL FUND OF THE STATE OF CALIFORNIA UNDER THE PROVISIONS OF OUR ACT AND NEGOTIATIONS. ALL RIGHT. THANK YOU.

DR. TURBEVILLE: THANK YOU. I HOPE WE HAVE MORE OF THEM.

CHAIRMAN TORRES: WE WILL. WE WILL.

DR. TURBEVILLE: VERY GOOD. OKAY.

SO THE PATIENT ASSISTANCE PROGRAM IS ONE COMPONENT OF A FIVE-YEAR STRATEGIC PLAN. I CONSIDER THIS SORT OF LOW HANGING FRUIT TO BE HONEST WITH YOU. THERE'S A MUCH LARGER PLAN THAT MARIA AND SENATOR TORRES AND THE TEAM WILL PRESENT DOWN THE ROAD; BUT THIS, WHEN I FIRST CAME ON BOARD, WHAT,

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THREE MONTHS DEEP, THERE ARE SOME THINGS THAT WE DO IN INDUSTRY, BACK WHEN I WAS IN THE INDUSTRY DAYS, THAT I THINK WOULD RESONATE WITH CIRM, WOULD RESONATE WITH CALIFORNIANS. AND THAT'S WHY I WANT TO PRESENT SOME OF THESE METHODS TO YOU TODAY.

SO I AM GOING TO DESCRIBE THREE SUPPORT PROGRAM OPTIONS FOR PATIENTS WITH FINANCIAL HARDSHIPS OR BARRIERS TO PARTICIPATING IN CIRM-SUPPORTED CLINICAL TRIALS. AND AFTER I PRESENT THIS, I'M HOPING THAT THE AAWG WILL RECOMMEND A LEAD, ONE OF THE THREE, OPTIONS FOR FURTHER SCOPING AND DEVELOPMENT AND SUBSEQUENT PRESENTATION FOR FINAL APPROVAL BY THE ICOC.

SO LET'S BACK UP A LITTLE BIT. WHEN WE TALK ABOUT ACCESSIBILITY AND AFFORDABILITY ISSUES IN CLINICAL TRIALS, THERE'S A NUMBER OF WAYS THAT WE CAN APPROACH THIS. AND THIS IS SPECIFICALLY FOR CLINICAL TRIALS. SO I KNOW ACCESSIBILITY AND AFFORDABILITY COVERS A WIDE GAMUT, ALL THE WAY FROM WHO GETS INTO OUR CLINICAL TRIALS, WHO STAYS IN OUR CLINICAL TRIALS, WHO GETS ACCESS TO A COMMERCIAL THERAPY, ET CETERA.

I WANT TO START ALL THE WAY AT THE BEGINNING. AND, IN FACT, WHAT YOU'RE SEEING IN THE LITERATURE RIGHT NOW IS A LOT OF DISCUSSION ABOUT

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PATIENT SUPPORT SERVICES STARTING MUCH EARLIER, SORT OF THAT DRUG DEVELOPMENT PROCESS, PHASE 1, PHASE 2, AS OPPOSED -- AND GIVING GUIDANCE AND INSIGHT AS OPPOSED TO STARTING MUCH LATER WHEN YOU'RE ALMOST AT THAT COMMERCIAL SORT OF LINE WHERE YOU GET THE LACK PRICE, AND ALL OF A SUDDEN THERE YOU'RE STARTING TO NEGOTIATE WITH PAYORS. IT'S A LITTLE TOO LATE. THERE'S LOTS OF DIFFERENT METHODOLOGIES.

AND ONE OF THE METHODOLOGIES THAT I WANT TO PRESENT TODAY IS HOW, ONE, CAN WE GET UNDERSERVED PATIENTS ENROLLED INTO CIRM-FUNDED TRIALS; AND, TWO, HOW CAN WE HELP THEM STAY ENROLLED. NOW, THIS IS AN ISSUE THAT'S JUST NOT NEW TO CIRM. IT'S BEEN AN ISSUE WITH INDUSTRY. IT'S AN ISSUE WITH ACADEMIA. IT'S VERY COMPETITIVE WITH CLINICAL TRIALS. MANY OF YOUR CLINICIANS KNOW THAT. YEAH, SO IT'S SOMETHING THAT'S REALLY COME TO THE FOREFRONT OF A LOT OF INDUSTRY AS WELL AS ACADEMIA.

SO WHEN WE THINK ABOUT RECRUITMENT ISSUES, RIGHT, IF WE GO TO THE UNDERSERVED POPULATION, THE RECRUITMENT CHALLENGES, THERE'S MULTIPLE, MULTIPLE RECRUITMENT CHALLENGES. A LITTLE STATISTIC. NINETEEN PERCENT OF REGISTERED CLINICAL TRIALS ARE TERMINATED DUE TO THE FAILURE TO REACH EXPECTED ENROLLMENTS.

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WHEN WE MOVE ON TO THE RETENTION SIDE, 80 PERCENT OF TRIALS FAIL TO FINISH ON TIME DESPITE SUBJECT RECRUITMENT AND RETENTION EFFORTS. FURTHERMORE, 85 PERCENT OF CLINICAL TRIALS FAIL TO RECRUIT AND RETAIN ENOUGH SUBJECTS TO MEET ENROLLMENT TIMELINES.

SO THIS IS A CHALLENGE OF THE WHOLE INDUSTRY, ALL RESEARCHERS. I THINK CIRM CAN PROPOSE ONE OR TWO CONCEPTS THAT MIGHT IMPACT THIS DIRECTLY WITH THE PROPOSALS THAT I'M GOING TO TALK TO IN A FEW MINUTES.

SO WHEN WE TALK ABOUT BARRIERS THAT MUST BE OVERCOME TO ACHIEVE BROAD, EQUITABLE ACCESS TO REGENERATIVE MEDICINES, THERE'S NUMEROUS. BUT IF YOU REVIEW THE LITERATURE, I THINK MOST OF YOU WOULD, INCLUDING MYSELF, CATEGORIZE IT INTO FIVE MAJOR BARRIERS. THERE'S CULTURAL AND SOCIAL DETERMINANTS, THERE'S INFORMATIONAL DETERMINANTS, THERE'S LOGISTICAL BARRIERS, THERE'S FINANCIAL BARRIERS, AND THERE'S ABILITY-BASED BARRIERS. AND WHEN I TALKED ABOUT EARLIER SORT OF THE LOW HANGING FRUIT OF WHERE WE CAN MAKE A DELTA FOR PATIENTS RIGHT OUT OF THE GATE, THERE'S THREE OF THESE.

BUT TO BACK UP, WHEN WE TALK ABOUT CULTURAL AND SOCIAL DETERMINANTS, AS YOU PROBABLY

ALREADY KNOW, JUST TO REVIEW REAL QUICKLY, LOWER ENROLLMENT FOR MINORITIES, SOCIOECONOMIC STATUS, UNEMPLOYMENT, EDUCATION, POPULATION SIZE, THE STIGMA OF DISEASE WE ALL KNOW UNIVARIATELY AND MULTIVARIATELY IMPACT ACCRUAL.

INFORMATIONAL: PHYSICIAN LOW REFERRAL RATE. THEY'RE NOT GETTING ALL THE INFORMATION. AND THAT'S PARTICULARLY TRUE FOR GENE THERAPY OR GENE-EDITED TRIALS. AND THERE'S STILL THIS MEDICAL MISTRUST ABOUT MISINFORMATION, WHICH IS A MUCH BIGGER OBSTACLE, TO BE HONEST WITH YOU, IN THIS DISCUSSION HERE.

LOGISTICAL: BELIEVE IT OR NOT, LACK OF RELIABLE TRANSPORTATION IS STILL A MAJOR ISSUE.

LANGUAGE BARRIERS. WORK OR CHILDCARE REQUIREMENTS. I MEAN WE DIDN'T THINK IT WAS SUCH A BIG ISSUE UNTIL WE SAW COVID, RIGHT? THAT WAS A BIG IMPACT FACTOR FOR PATIENTS JUST TRYING TO GO OUT AND GET THEIR VACCINE, LET ALONE CONTRIBUTE TO A CLINICAL TRIAL.

FINANCIAL: COST OF REGENERATIVE MEDICINES, GENE AND CELL THERAPIES, INSURANCE BENEFITS MAY INCLUDE HIGH COPAYS AND LIFETIME BENEFITS.

NOW, THIS IS JUST STARTING TO PLAY OUT ON

THE PAYOR SIDE. AND I KNOW I HAVE SOME PAYOR EXPERTS ON THE CALL. WE ARE STILL LEARNING ABOUT THE PAY FOR PERFORMANCE MODELS. I'M NOT GOING TO ADDRESS HOW WE CAN IMPACT THAT TODAY, BUT DOWN THE ROAD WE WILL HAVE SOME GUIDANCE ON THE POLICY SIDE ON WHICH WE MAY BE ABLE TO MAKE AN IMPACT FOR PATIENTS IN THAT PARTICULAR AREA.

AND THEN THERE'S ABILITY BASED: PARTICIPATION FOR THE LIMITED, FOR ELDERLY, THE ADOLESCENTS, YOUNG ADULTS, DISABLED, ET CETERA.

SO I THINK THIS IS A GOOD REPRESENTATION OF THE FACTORS THAT DO CONTRIBUTE THAT MUST BE OVERCOME TO ACHIEVE BROAD, EQUITABLE ACCESS TO REGENERATIVE MEDICINES.

NOW, WHAT CAN WE DO? THERE'S THREE AREAS WHERE I WANT TO FOCUS ON: INFORMATIONAL, LOGISTICAL, AND FINANCIAL. I MENTION THE LOW HANGING FRUIT, AND FOR SOMEBODY WHO HAS BEEN IN THE INDUSTRY AS LONG AS I HAVE, THIS ACTUALLY GETS ME PRETTY FIRED UP BECAUSE I DON'T THINK PEOPLE HAVE APPROACHED THESE THREE VARIABLES WITH ENOUGH HORSEPOWER TO THE POINT WHERE YOU ACTUALLY CAN MAKE A DIFFERENCE FOR PATIENTS, PARTICULARLY THOSE IN THE UNDERSERVED COMMUNITIES.

SO LET'S TALK ABOUT THIS IN A LITTLE BIT

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MORE DETAIL. FOR BACKGROUND, THERE ARE A NUMBER OF ITEMS TYPICALLY REIMBURSED OR SUPPORTED TODAY IN CLINICAL TRIALS. AND MANY OF YOU ARE FAMILIAR WITH THIS. SO TRAVEL EXPENSES ARE REIMBURSABLE, RIGHT. THE ACCOMMODATIONS ARE REIMBURSABLE. MEALS, CHILDCARE, OUT-OF-POCKET HEALTHCARE EXPENSES, ANCILLARY HEALTHCARE EXPENSES. I'LL COME BACK TO THIS BECAUSE WE ARE FINDING SOME NEW INFORMATION JUST RECENTLY ON GENE THERAPY, CAR-T THERAPIES, WHERE THAT'S STARTING TO BE AN OUTLIER WITH RESPECT TO THE AMOUNT OF MONEY THAT'S REQUIRED FOR THOSE ANCILLARY CARES.

AND THEN I DID PUT COMMERCIAL COPAY ASSISTANCE HERE. WE ARE NOT GETTING INTO THAT SPACE RIGHT NOW. I'M SUGGESTING PATIENT SUPPORT SERVICES THAT WOULD OBVIOUSLY PROVIDE SUPPORT MUCH EARLIER IN THAT DRUG DEVELOPMENT PROCESS. WE WOULD, I JUST WANT YOU TO PUT THIS IN YOUR BACK POCKET, WE WOULD HAVE THE ABILITY SOMEHOW, WHEN WE ARE READY, TO TURNKEY AND AT LEAST PROVIDE SOME GUIDANCE, EVEN INSIGHTS, EVEN RESEARCH INTO WHAT ARE THE PITFALLS FOR THE PATIENTS WHO ARE ACTUALLY TRANSITIONING OVER TO COMMERCIAL DRUGS. RIGHT.

NOW, INDUSTRY TYPICALLY DOES A REALLY GOOD JOB OF THAT; BUT IN FACT, IF ONE OF THESE PROGRAMS

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DOES GO IN PLAY, YOU CAN IMAGINE THE AMOUNT OF DATA THAT WE GET TO COLLECT UP AND TO THE POINT OF MARKETING AUTHORIZATION. THAT CAN BE USED IN A REALLY CREATIVE LIGHT.

THERE ARE TWO CONCEPTS HERE THAT I'VE NOT LISTED THAT ARE SLIGHTLY CONTROVERSIAL, AND I'M GOING TO BRING THEM UP BECAUSE THEY'RE USED. ONE IS THERE IS A LOSS OF INCOME REIMBURSEMENT THAT IS TAKING PLACE. AND THIS ISN'T JUST IN THE UNITED STATES. IF YOU THINK ABOUT MANY OF THESE TRIALS, THEY ASK A LOT. THEY ASK A LOT OF PARENTS. THEY ASK A LOT OF CHILDREN. MANY OF THEM ARE A NUMBER OF DIFFERENT LINES OF THERAPY, AND MANY OF THEM ARE CARE PROVIDERS FOR THE FAMILY. SO SURPRISINGLY THIS IS STARTING TO COME UP. IT IS A LITTLE BIT CONTROVERSIAL. THERE ARE MANY ORGANIZATIONS THAT ARE COMPENSATING FOR LOST REVENUE ON THE WORK SIDE. AND IF YOU BENCHMARK THIS TO EUROPE, IT IS ACTUALLY MANDATED IN MANY COUNTRIES WHERE THOSE FAMILIES OR THAT PARTICIPANT DOES GET COMPENSATED FOR THE LOSS OF WORK IN PARTICIPATING IN A TRIAL.

CHAIRMAN TORRES: LET ME BE VERY CLEAR ON THAT POINT. THE INITIATIVE SPECIFICALLY PROHIBITS EXPRESS COMPENSATING FOR RESEARCH PARTICIPANTS. WE CANNOT DO THAT.

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DR. TURBEVILLE: FAIR ENOUGH. WANTED TO JUST THROW IT OUT THERE SO THAT IT IS IN THE PUBLIC DOMAIN. SO THANK YOU, SENATOR.

DR. GOLDMAN: CAN YOU CLARIFY, ART, WHY THE INITIATIVE PREVENTS THAT?

CHAIRMAN TORRES: THE LANGUAGE OF THE BALLOT INITIATIVE PASSED BY THE VOTERS IN NOVEMBER 2020 SPECIFICALLY PROHIBITS COMPENSATING RESEARCH PARTICIPANTS. EXPENSES ARE FINE. ALL THE EXPENSES THAT ARE LISTED HERE ARE FINE. GENERAL COUNSEL HAS OPINED WITH ME AS LATE AS LAST WEEK, BECAUSE I WANTED TO CHECK ON IT TO MAKE SURE, AND THAT IS THE PROHIBITION THAT IS IN THE CONSTITUTION AND THEREFORE IN THE INITIATIVE.

DR. GOLDMAN: I SEE. I JUST WANT TO POINT OUT WE RELEASED OUR NATIONAL ACADEMY OF MEDICINE REPORT TODAY ON IMPROVING REPRESENTATION IN CLINICAL TRIALS. AND ONE OF THE THINGS WE ARGUED AS A RECOMMENDATION THERE WAS TO IMPROVE REMUNERATION. AND IT'S NOT CLEAR TO ME WHICH WAY SOMETHING LIKE LOST WAGES FALLS IN TERMS OF THAT. BUT THAT PART OF THE INITIATIVE IS BEHIND WHERE THE SCIENCE IS ACCORDING TO OUR NATIONAL ACADEMY.

CHAIRMAN TORRES: YES. THE VOTERS ARE BEHIND, RIGHT.

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MS. BONNEVILLE: ART, ADRIENNE HAS HER HAND RAISED.

CHAIRMAN TORRES: I'M SORRY. ADRIENNE.

MS. SHAPIRO: BASED ON THAT, THERE'S A REAL PROBLEM FOR THE CAREGIVER. WOULD CAREGIVER FINANCING BE A PART OF THIS?

CHAIRMAN TORRES: YES. WE ANTICIPATE THAT THOSE KINDS OF EXPENSES WOULD BE INCLUDED TO BE REIMBURSED, LIKE TRAVEL, LIKE ACCOMMODATION, LIKE MEALS, AND CHILDCARE, WHICH IS AN IMPORTANT ISSUE AS WELL AS MANY OF OUR PATIENTS NEED CHILDCARE, THAT WOULD BE ALSO OUT-OF-POCKET HEALTHCARE EXPENSES WHICH WOULD INCLUDE THE CAREGIVER.

MS. SHAPIRO: SO JUST TO BE CLEAR, ARE WE PAYING FOR THE CAREGIVER'S TIME WHICH THEY ARE LOOKING AFTER THE SUBJECT?

CHAIRMAN TORRES: WE REALLY CAN'T ANSWER THAT SPECIFICALLY YET.

MS. SHAPIRO: OKAY.

CHAIRMAN TORRES: OKAY. HAVE TO WAIT A LITTLE BIT. BUT ALL I CAN SAY WITH CERTAINTY IS THAT THE RESEARCH PARTICIPANTS CANNOT BE REIMBURSED FOR LOST WAGES.

MS. SHAPIRO: I UNDERSTAND THAT. THANK YOU.

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CHAIRMAN TORRES: THANK YOU.

DR. TURBEVILLE: AND AGAIN, I BRING IT UP. I KNOW IT'S SENSITIVE, BUT IT IS OUT THERE AND IT'S GOT QUITE A BIT OF MOMENTUM, AT LEAST IN THE PUBLIC DOMAIN. SO THANK YOU.

ONE OF THE THINGS THAT'S ALSO INTERESTING THAT WE ARE LEARNING ABOUT, AND MANY OF YOU ON HERE MAY HAVE LAUNCHED A GENE THERAPY TRIAL OR ACTUALLY AN APPROVED PRODUCT, THE AMOUNT OF TIME THAT -- IF YOU TALK TO SOMEBODY FROM CLINICAL OPERATIONS, WHAT WE ARE HEARING FROM COMPANIES OUT THERE WHO DO HAVE A GENE THERAPY IS THEY WAY UNDERESTIMATED THE COST OF RUNNING A TRIAL BY AS MUCH AS 50 PERCENT. AND THAT'S NOT NECESSARILY BECAUSE OF COG'S. IT'S BECAUSE OF THE ANCILLARY SERVICES THAT ARE REQUIRED TO TAKE CARE OF THE PATIENTS.

SO JUST TO GIVE YOU AN EXAMPLE, IN A CAR-T INVESTIGATIONAL THERAPY, EVERY INSTITUTION REQUIRES A DIFFERENT PROTOCOL, RIGHT. EVEN THOUGH THERE MAY BE SOMETHING IN THE MANUFACTURER'S PROTOCOL THAT SAYS, HEY, THREE DAYS IS SUFFICIENT AND AFTER THREE DAYS YOU CAN MONITOR FROM X, Y, AND Z. EVERY ORGANIZATION'S INSTITUTIONAL PROTOCOL MAY SAY 15 DAYS IN-HOUSE WITH THE HOSPITAL, MONITORED, RIGHT, WITH A FAMILY MEMBER, AND THEN A SUBSEQUENT 15 DAYS

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AFTER THAT BEING MONITORED WITH A FAMILY MEMBER TWO HOURS FROM THE ORIGINAL POINT OF ADMINISTRATION. AND I THINK ITEMS LIKE THAT THAT ARE JUST NOW COMING TO FRUITION ARE WHAT ARE STARTING TO INCREMENTALLY INCREASE THOSE COSTS. THOSE ARE EXAMPLES AS WELL.

CHAIRMAN TORRES: THANK YOU, SEAN. I KNOW THAT DANA DORNSIFE WANTED TO COMMENT ON ISSUES REGARDING THIS AREA; ISN'T THAT CORRECT, DANA?

DR. DORNSIFE: YEAH. SO LAZAREX CANCER FOUNDATION HAS BEEN INVOLVED IN REIMBURSING PATIENTS TO THE TUNE OF LIKE 7,000 PATIENTS SINCE 2006. I WOULD SAY, IN THIS PARTICULAR SLIDE, THE ITEMS THAT ARE TYPICALLY REIMBURSED, SOME TRAVEL EXPENSES, SOME ARE, BUT THEY'RE NOT TYPICALLY REIMBURSED. THE OTHER THINGS YOU HAVE LISTED HERE, YES, ABSOLUTELY ONE OF THE BIGGEST BARRIERS WE FACE IS COMPROMISED PERFORMANCE STATUS FROM THE PATIENT PERSPECTIVE. AND SO THEY REALLY DO REQUIRE A TRAVEL COMPANION IN MANY INSTANCES IN ORDER TO BE ABLE TO PARTICIPATE IN A CLINICAL TRIAL.

IN ADDITION TO CHILDCARE NOW, WE ALSO HAVE ISSUES AROUND ELDER CARE IF SOMEONE IS RESPONSIBLE TO TAKE CARE OF THEIR ELDERLY PARENTS. AND THEN WE ALSO HAVE AN ISSUE WITH THE DIGITAL DIVIDE AS WELL WHERE, IF WE ARE USING TELEMEDICINE AND IF

TECHNOLOGY IS REALLY REQUIRED FOR A PATIENT TO BE COMPLIANT AND PARTICIPATE FOR MANY OF OUR RESIDENTS OF COMMUNITIES OF COLOR, THEY SIMPLY DON'T HAVE ACCESS. AND SO WE ARE TAKING A LOOK NOW AT PROVIDING WI-FI OR HOT SPOTS TO GET THEM THE ACCESS THAT THEY NEED TO TECHNOLOGY SO THAT THEY CAN PARTICIPATE.

THE OTHER THING I WILL SAY IS THAT MORE -- THE TYPE OF INSURANCE OR LACK OF INSURANCE THAT PATIENTS HAVE, ESPECIALLY WHEN YOU'RE TRYING TO INCREASE DIVERSITY, IS REALLY IMPORTANT BECAUSE THE TYPE OF INSURANCE YOU HAVE IN MANY INSTANCES RELEGATES YOU TO BEING SEEN AT A PARTICULAR INSTITUTION. AND THE VAST MAJORITY OF THOSE INSTITUTIONS DO NOT OFFER CLINICAL TRIALS. THEY DO NOT. AND SO THAT IS AN ABSOLUTE DETERMINANT FOR A PATIENT WHO IS IN NEED OF OR WOULD BENEFIT BY PARTICIPATING IN A CLINICAL TRIAL.

CHAIRMAN TORRES: THANK YOU, DANA.

TO GIVE YOU ALL THE ORIGIN OF THIS LANGUAGE, IT CAME FROM MY EXPERIENCE AS VICE CHAIR OF THE ONE LEGACY ORGAN TRANSPLANT FOUNDATION. AND SO WHEN BOB KLEIN AND I AND JAMES HARRISON PUT OUR HEADS TOGETHER AS TO THE FACT THAT I REALLY FELT THIS WAS A NEED THAT NEEDED TO BE INCORPORATED INTO

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THE INITIATIVE, IT CAME FROM WHAT WE DO THERE. ONE OF THE ORGANIZATIONS THAT WE FUND IS THE AVA FOUNDATION FOR HEART TRANSPLANT PATIENTS. AND SO ONE LEGACY PROVIDES FUNDING FOR THAT FOUNDATION, WHICH WAS JUST NAMED A CNN HERO, TO MAKE SURE THAT HEART TRANSPLANT PATIENTS THAT NEED TO COME TO LOS ANGELES FOR A HEART ORGAN TRANSPLANT HAVE THE NEEDED SUPPORT.

SO I THINK THOSE ARE VERY IMPORTANT POINTS THAT YOU RAISE, DANA.

AND I KNOW THAT ERIC KENTOR FROM ALS WANTED TO MAKE A COMMENT AS WELL. ERIC. NANCY RENICK.

MR. KENTOR: SORRY, SENATOR TORRES, THIS IS ERIC. I WAS TRYING TO UNMUTE.

A LOT OF WHAT YOU GUYS ARE TALKING ABOUT RESONATES NOT NECESSARILY MY PERSONAL SITUATION, BUT MY OBSERVATIONS. I THINK -- FIRST OF ALL, THANK YOU FOR THIS OPPORTUNITY. AND I'D LIKE TO JUST BEGIN WITH A LITTLE SNIPPET.

IN THE SPRING OF 2020, I WAS DIAGNOSED WITH AMYOTROPHIC LATERAL SCLEROSIS, WHICH IS ALS OR LOU GEHRIG'S DISEASE. AND LIKE 90 PERCENT OF THE PATIENTS, I HAVE NO FAMILY HISTORY. SO DIAGNOSIS WAS REALLY A SHOCK, AND IT IS A BRUTAL NEUROMUSCULAR

DISEASE --

CHAIRMAN TORRES: YES.

MR. KENTOR: -- AS YOU, FOLKS, I'M SURE, ALL WELL NO, CHARACTERIZED BY PROGRESSIVE DEGENERATION OF THE NERVE CELLS IN THE BRAIN. SPINAL CORD RAVAGES THE BODY. AND WE ARE TYPICALLY NOT DIAGNOSED FOR BETWEEN SIX AND 18 MONTHS THAT IT TAKES TO ACTUALLY DIAGNOSE IT. BEING DIAGNOSED WITH ALS IS A DEATH SENTENCE AS IT IS TODAY 100 PERCENT FATAL, AND THERE'S NO ONE CURE WITH THE LIFE EXPECTANCY BEING TWO TO FIVE YEARS. SO THERE'S A PARTICULAR URGENCY, I THINK, THAT ALS PATIENTS FEEL.

AND ALS, AT LEAST THIS ALS PATIENT, DESPERATELY WANTED TO PARTICIPATE IN A CLINICAL TRIAL FOR ME TO PARTICIPATE IN, AND I THINK FOR SEVERAL OTHER FOLKS IN MY SITUATION IS OFTEN A MOST DIFFICULT CHALLENGE.

CHAIRMAN TORRES: YES.

MR. KENTOR: AND I THINK FURTHER TO THE COMMENTS THAT ALL OF YOU HAVE BEEN MAKING, I AM AN UPPER CLASS, EDUCATED PROFESSIONAL WHO ACTIVELY SOUGHT OUT AND SWITCHED INSTITUTIONS FROM WHERE I WAS ORIGINALLY BEING TREATED FOR THE SPECIFIC PURPOSE OF TRYING TO SEEK OUT A CLINICAL TRIAL. I LOOKED AT OTHER OPPORTUNITIES AND ACTUALLY STARTED

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DOWN THE ROUTE OF ONE PROMISING THERAPEUTIC FOR WHICH, REGRETTABLY, THE FDA IS AGONIZINGLY SLOW IN APPROVING, BUT HAS TWO COMPOUNDS THAT ARE OTHERWISE COMMERCIALLY AVAILABLE. AND SOME ALS PATIENTS ARE ACTUALLY MIXING THEIR OWN COCKTAIL, TAKING THAT, AND PAYING OUT OF POCKET FOR IT.

I WAS FORTUNATELY ABLE TO PARTICIPATE IN A CLINICAL TRIAL, AND I'M GOING DOWN THAT ROAD. BUT PARTICIPATION DOES REQUIRE A CONSIDERABLE COMMITMENT OF MY TIME AND THAT OF MY WIFE WHO IS MY PRIMARY CAREGIVER. SO I THINK ALL OF THE COMMENTARY THAT HAS BEEN MADE ALREADY RESONATES WITH ME. IN OUR SITUATION, WE ARE ABLE TO HANDLE THAT, BUT I'M SURE IT'S A CHALLENGE THAT OTHER PEOPLE WHO AREN'T AS FORTUNATE HAVE TROUBLE WITH.

SO I THINK THE EFFORT TO AGGRESSIVELY PURSUE A DIVERSE SOCIOECONOMIC PROFILE OF PATIENTS TO GIVE THEM A CHANCE TO PARTICIPATE IN THESE TRIALS WOULD BE A GREAT SERVICE TO THE ENTIRE COMMUNITY OF CALIFORNIA, THE MEDICAL COMMUNITIES, AND OBVIOUSLY THOSE COMMUNITIES. AND I WOULD ENCOURAGE YOU TO DO THAT, PROVIDING AS MUCH SUPPORT AS YOU CAN. ALS, AGAIN ON MY SIDE OF THE WORLD, IT'S RARE, BUT IT'S NOT AS RARE AS I HAD ORIGINALLY THOUGHT.

CHAIRMAN TORRES: RIGHT.

MR. KENTOR: AND WE DON'T HAVE A LOT OF TIME. WE USUALLY DON'T SURVIVE LONG ENOUGH TO ADVOCATE AGGRESSIVELY FOR RESEARCH. SO I'M REALLY GRATEFUL THAT I HAVE THAT OPPORTUNITY TODAY, BUT MUCH, MUCH MORE NEEDS TO BE DONE. IT'S AN EMOTIONAL, PHYSICAL, AND SOMETIMES HIDDEN FINANCIAL BURDEN AND CHALLENGE UNLIKE ANYTHING I'VE EVER SEEN BEFORE. AND THE EXTENT TO WHICH YOU CAN TAKE INTO ACCOUNT THE FINANCIAL BURDEN THAT COMES WITH THAT IN THOSE COMMUNITIES THAT HAVE MUCH LESS AS I AM FORTUNATE TO HAVE, I THINK THAT WOULD ENDOW TO EVERYONE'S BENEFIT.

CHAIRMAN TORRES: THANK YOU.

MR. KENTOR: THANK YOU FOR LISTENING TO ME. MORE IMPORTANTLY, THANK YOU FOR THE WORK YOU'RE DOING FOR CALIFORNIA AND FOR THE WORLD ACTUALLY.

CHAIRMAN TORRES: I'M GOING TO LISTEN TO YOU MORE, ERIC, BECAUSE I HAVE BEEN, AS A CANCER SURVIVOR, COLON CANCER SURVIVOR, BUT ALSO AS A VERY, VERY CLOSE FRIEND. I HAVE BEEN INTIMATELY INVOLVED WITH TWO FRIENDS WHO HAVE BEEN DIAGNOSED WITH ALS. SO I PERSONALLY KNOW WHAT YOU'VE BEEN, NOT YOU HAVE BEEN GOING THROUGH, BUT WHAT SOMEONE DOES HAVE TO GO THROUGH WITH THIS DISEASE. SO YOU WILL HAVE AN ADVOCATE IN ME.

WE WANT TO HEAR NOW FROM NANCY RENICK FROM SICKLE CELL. IS SHE AVAILABLE? THANKS AGAIN, ERIC.

MR. KENTOR: THANK YOU, SIR.

CHAIRMAN TORRES: NANCY RENICK.

MS. BONNEVILLE: I THINK SHE'S ON MUTE.

CHAIRMAN TORRES: OKAY. WE'LL COME BACK TO HER.

MS. BONNEVILLE: OKAY. GREAT.

DR. TURBEVILLE: OKAY. I WILL CONTINUE. SO NOW WE'RE GOING TO GET INTO SOME MODELS, PROPOSALS FOR YOU GUYS. SO I AM GOING TO PROPOSE THREE PATHWAYS TO SUPPORT PATIENT ASSISTANCE FUND. AND THIS REALLY DOES COME OUT OF A COMBINATION OF INDUSTRY, HAVING LAUNCHED MANY OF THESE PROGRAMS IN INDUSTRY AND INCLUDING IN ALS, BELIEVE IT OR NOT, ALL THE WAY TO PATIENT ADVOCACY AS WELL ON THAT SIDE.

SO THE THREE PATHWAYS I WANT TO TALK ABOUT ARE AN INDUSTRY MODEL -- I'LL TALK ABOUT THAT IN MORE DETAIL -- AN ADVOCACY/CHARITABLE ORGANIZATION MODEL, AND AN ACADEMIC INSTITUTIONAL SUPPORT MODEL. AND, AGAIN, THESE ARE THREE PATHWAYS WHERE WE COULD START PICKING AWAY, IF YOU WILL, AT THE ACCESSIBILITY AND AFFORDABILITY WHEN IT COMES TO PARTICIPATING IN CLINICAL TRIALS.

SO THE FIRST PATHWAY IS THE ESTABLISHED INDUSTRY SUPPORT MODEL. NOW, WHAT DO I MEAN BY THAT? SO I WANT YOU -- WE ARE TALKING SMALL BIOTECH, AND THERE'S A STORY HERE. SO WE ARE NOT TALKING ABOUT THE PFIZERS OF THE WORLD OR THE SANOFIS OF THE WORLD. WE ARE TALKING ABOUT REALLY NICHEY BIOTECHS HERE IN THE BAY AREA, BOSTON, GLOBALLY WHO HAVE ESTABLISHED OR CONTRACTED OUT WITH CALL CENTERS WITH HIGHLY TRAINED NURSES TO SUPPORT PATIENTS ACROSS, NOT ONLY THE CLINICAL, BUT COMMERCIAL JOURNEY. THEY PROVIDE SERVICES TO PATIENTS NOT ONLY ON THE CLINICAL SIDE, SUCH AS TRIAL TRIAGE, INFORMATION AND ELIGIBILITY, FINANCIAL SUPPORT, INCLUDING TRANSPORTATION, ALL OF THOSE THINGS THAT WE TALKED ABOUT, INCLUDING ANCILLARY EXPENSES, BUT THERE'S ADDITIONAL LAYERS OF SUPPORT THAT ARE PROVIDED BY THESE SORT OF CONCIERGE PATIENT SUPPORT SERVICES.

AND GENERALLY THEY STARTED OUT WITH MORE OF THE RARE, ULTRA ORPHAN SPACE, BUT NOW 20 YEARS LATER, I STILL USED THEM PREVIOUSLY IN MY INDUSTRY TO MORE LARGER, MORE PREVALENT DISEASES THAT ARE OUT THERE. SO IT USED TO BE VERY BOUTIQUE, NOW CAN BE SCALED TO MORE PREVALENT DISEASES.

THERE'S A NUMBER OF THINGS YOU CAN DO. I

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DO HAVE TO SAY THIS IS THE CADILLAC VERSION. SO THERE'S A NUMBER OF STRENGTHS AND WEAKNESSES. ONE, EVERY PATIENT WOULD GET A CASE NAVIGATOR APPROACH. AND MANY OF YOU PROBABLY HAVE EXPERIENCED THAT. THEY ARE SCALABLE, TURNKEY OPERATIONS. THESE ARE STATE OF THE ART TELEHEALTH SOFTWARE. MOST OF THE NURSES HAVE BEEN TRAINED IN CLINICAL TRIALS AT LEAST FIVE TO TEN YEARS. SO THEY UNDERSTAND THAT PATIENT JOURNEY ALL THE WAY FROM PHASE 1 TO PHASE 3 AND THEN OVER TO COMMERCIALIZATION. THEY'RE COMPLIANT, OF COURSE, WITH STATE AND FEDERAL REGULATIONS. THE SPEED, WHAT WE CALL THE SPEED OF CASE HANDLING AND PROCESSING IS REALLY TO BE UNMATCHED WHEN IT COMES TO ANYTHING ELSE THAT'S OUT THERE. THEY PROVIDE ROBUST ANALYTICS, SO SOMEBODY WHO'S AS GEEKY AS MYSELF WHO IS CONSTANTLY WATCHING CALL CENTERS THROUGHOUT THE WORLD, JUST CONSTANTLY MONITORING CHANGE AND SEEING HOW WE CAN IMPROVE THE PROCESS, RIGHT. HOW CAN WE IMPROVE PATIENTS, WHETHER IT'S SIMPLY THE SPEED AT WHICH WE CAN GET THEM REIMBURSED BY SOME OF THOSE COSTS OR THE ADDITIONAL INFORMATION THAT THEY NEED FROM THE CLINICIAN, ET CETERA.

THE WEAKNESSES ARE, AND I DON'T KNOW IF IT'S A WEAKNESS. THIS IS PROBABLY MORE OF A CHALLENGE. ONE IS THERE'S A RAMP-UP TIME. SO

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THERE'S A BIG DEMAND FOR EVERY BIOTECH COMPANY. AND LET ME PAUSE HERE. NO BIOTECH COMPANY NOW WILL LAUNCH A MARKETED AUTHORIZED PRODUCT IN THE UNITED STATES WITHOUT PATIENT SUPPORT SERVICES. AND WHAT YOU'RE SEEING, NO DIFFERENT THAN WHAT I'M PROPOSING HERE, IS COMPANIES ARE TAKING THESE PROGRAMS AND THEY'RE STARTING THEM EARLIER IN THE DRUG DEVELOPMENT PROCESS, ALL THE WAY, AGAIN, TO PHASE 1, PHASE 2. SO THAT WHOLE PATIENT JOURNEY THEY UNDERSTAND. RIGHT.

THERE IS A HIGH DEMAND. THERE'S RAMP-UP TIME. NOTHING I HAVEN'T DONE IN THE PAST. THERE ARE SOME COSTS ASSOCIATED. BUT THIS WOULD BE CONSIDERED ONE OF THE CADILLAC PROPOSALS THAT WE WOULD PRESENT TO THE TEAM TODAY.

LET ME PAUSE THERE JUST TO SEE IF THERE'S ANY QUESTIONS BEFORE I GO INTO CURTAIN NO. 2.

CHAIRMAN TORRES: SEEING NONE.

DR. TURBEVILLE: SEEING NONE. OKAY. THANK YOU. BEFORE I DO THAT, LET ME JUST SHOW YOU SOME OF THE METRICS THAT WOULD BE REPORTED ON THESE CALL CENTERS. SO THIS IS REAL-TIME STUFF. AS I MENTIONED, AT LEAST IN MEDICAL AFFAIRS, WE METRIC EVERYTHING, RIGHT. WHO IS CALLING, WHY THEY'RE CALLING, HOW IMPACTFUL IS OUR PROGRAM, WHERE CAN WE

IMPROVE THINGS? SO WHAT'S NICE ABOUT THESE PROGRAMS IS THEY HAVE PUT LOTS OF CFR 21 VALIDATED SYSTEMS IN THESE INSTITUTIONS, WHICH PROBABLY MEANS NOT A WHOLE LOT TO THIS TEAM, BUT FOR SOMEBODY WHO USED TO BE IN THE INDUSTRY, IT'S REALLY IMPORTANT. BUT IT ALLOWS US TO BENCHMARK. IT ALLOWS US TO TEST THINGS. IT ALLOWS US TO HAVE THE METRICS TO ACTUALLY MAKE IMPROVEMENT AND COME BACK TO YOU GUYS SAYING, HEY, LOOK. HERE'S BENCH LINE, RIGHT, HERE'S T ZERO, AND HERE'S WHERE WE ARE NOW SIX, SEVEN MONTHS LATER. HERE'S THE IMPACT. OR, TO BE FAIR, HERE'S WHERE WE MISSED THE MARK. RIGHT? SO THAT'S WHAT'S UNIQUE ABOUT THESE PARTICULAR PROGRAMS.

MS. BONNEVILLE: ART, HARLAN HAS HIS HAND RAISED.

CHAIRMAN TORRES: ALL RIGHT. HARLAN, NICE TO HAVE YOU WITH US. WE APPRECIATE IT.

DR. LEVINE: OF COURSE, HAPPY TO BE HERE, SENATOR. SO THANK YOU.

I THINK, IF I'M UNDERSTANDING THE DESCRIPTION, THESE ARE THE TYPES OF PROGRAMS THAT SPECIALTY PHARMACY COMPANIES STARTED HAVING TO MAKE SURE THEIR DRUGS WERE TAKEN, PEOPLE KNEW HOW TO DEAL WITH SIDE EFFECTS, AND THEN COMPLIANCE. IT'S SPANNED OUT SIGNIFICANTLY. SO ANOTHER WAY TO LOOK

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AT THIS IS THERE ARE DISEASE MANAGEMENT AND CARE MANAGEMENT PROGRAMS WITHIN THE HEALTHPLANS AND BOUTIQUE COMPANIES. AND ONE IN PARTICULAR, AND I DON'T KNOW THIS FIELD AS WELL AS I KNOW THE REST OF THE PAYOR INDUSTRY, BUT THE MEDI-CAL PROGRAMS WILL HAVE PATIENT SUPPORT PROGRAMS TOO. AND IT MAY BE ANOTHER OPTION OTHER THAN GOING TO BIOTECH, BUT GIVEN THE POPULATION THAT WE ARE TRYING TO SERVE, THEY MAY HAVE A BETTER UNDERSTANDING OF THE SOCIAL DETERMINANTS OF HEALTH AND ALSO THE INSURANCE PARAMETERS AND HOOPS THAT PEOPLE HAVE TO HOP THROUGH TO GET ON THESE PROGRAMS.

SO I WANTED TO JUST AUGMENT THAT THIS MAY NOT HAVE TO BE THE BIOTECH INDUSTRY. IT COULD BE THE HEALTH SERVICES INDUSTRY AND MEDI-CAL PROGRAMS THAT MIGHT HAVE FOUNDATIONAL PROGRAMS THAT COULD BE MODIFIED TO SUPPORT THE PATIENTS THROUGH THIS JOURNEY.

CHAIRMAN TORRES: EXCELLENT POINT.

DR. TURBEVILLE: I'M GOING TO RESPOND TO THAT IF THAT'S OKAY. SO I APOLOGIZE. THIS IS NOT OWNED BY BIOTECH. THESE ARE THIRD-PARTY SERVICE PROVIDERS WHO BIOTECH CONTRACTS WITH. SO THEY'RE NOT IN-HOUSE BY ANY MEANS. THESE ARE EXTERNAL COMPANIES. AND QUITE FRANKLY, THE SMALL GUYS ARE

GETTING BOUGHT UP SO QUICK BY THE BIG AMERISERVES BECAUSE THIS STUFF REALLY DOES MOVE MOUNTAINS FOR PATIENTS. YEAH. LET ME MAKE THAT REALLY CLEAR, THAT THIS IS NOT OWNED BY BIOTECHS. SOMETIMES THEY DO TRY TO INTERNALIZE THE SYSTEMS, AND I'VE TRIED TO DO THAT, BUT MOSTLY THEY'RE CONTRACTING OUT TO THIRD PARTIES.

DR. LEVINE: SEAN, LET ME JUST COMMENT TO CLARIFY. I AGREE WITH YOUR SECOND POINT, THAT THEY'RE GETTING BOUGHT UP SO THERE WOULD BE FEWER AND HARDER TO FIND. MY POINT IS THAT THERE ARE ALSO -- I DID UNDERSTAND THAT FOR THE MOST PART THEY'RE THIRD PARTY. THEY STARTED INTERNAL AND THEN HAVE MOVED OUT, BUT THERE ARE THIRD PARTIES THAT FOCUS NOT ON BIOTECH, BUT FOCUS ON THE HEALTH SERVICES INDUSTRY THAT MIGHT ALSO BE PART OF THE POOL THAT WE LOOK AT IF WE GO THAT DIRECTION.

DR. TURBEVILLE: FAIR ENOUGH. THAT'S HELPFUL. THANK YOU.

CHAIRMAN TORRES: WE GOT TO MOVE ALONG HERE.

DR. TURBEVILLE: OKAY. SO THE SECOND CURTAIN, IF YOU WILL, IS THE ADVOCACY/CHARITABLE ORGANIZATION MODEL. AND I'VE WORKED WITH THEM AS WELL. MANY OF YOU HERE ARE ADVOCACY GROUPS WHO ARE

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FAMILIAR WITH THIS. BASICALLY IT'S THE SAME SERVICES, RIGHT. THEY PROVIDE A NUMBER OF SERVICES TO PATIENTS WHO ARE INVOLVED IN PARTICULAR CLINICAL TRIALS, WHETHER IT'S DISEASE EDUCATION, TRANSPORTATION. I'VE LISTED JUST A RANDOM SAMPLE OF ONES, RIGHT, THAT I'VE WORKED WITH IN THE PAST. NO DISRESPECT TO ANYBODY ON THE CALL THAT I DIDN'T LIST. IT TRULY IS A RANDOM SAMPLE.

THEY DO HAVE THEIR STRENGTHS AND WEAKNESSES. I WOULD POINT OUT ONE, FOR EXAMPLE, THE ASSISTANCE FUND. THAT'S TAF. THEY ARE WELL-KNOWN IN THE THIRD-PARTY INDUSTRY IN SUPPORTING PATIENTS THROUGH NOT ONLY CLINICAL, MORE SO COMMERCIAL, THAT IS, TAKING PATIENTS FROM THE CLINICAL TO THE COMMERCIAL SIDE, BUT THEY'RE PUTTING A LOT OF EFFORTS INTO THAT EARLIER STAGE. JUST TO GIVE YOU AN IDEA, THEY PROBABLY RECEIVE AT LEAST $300 MILLION OF DONATED MONEY FROM NOT ONLY INDUSTRY, BUT OTHER THIRD-PARTY PARTIES THAT -- AND IT'S HANDS OFF. RIGHT? THAT'S THE WAY THE REGS ARE. THEY DO HAVE FAIRLY SOPHISTICATED OPERATIONS. IT WOULD BE ONE COMPANY THAT WE WOULD LOOK AT TO SEE IF IT WAS POTENTIALLY A GOOD FIT AND BRING IT BACK TO THE AAWG FOR INPUT.

NOW THE STRENGTHS. THESE TWO PROVIDE CASE

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MANAGEMENT APPROACH. THERE ARE SOME TURNKEY OPERATIONS. THEY ARE COMPLIANT. THEY DO HAVE DISEASE-SPECIFIC FUNDING AND EDUCATION. AND THAT COULD BE A GREAT THING; BUT IF YOU THINK ABOUT OUR PORTFOLIO OF TRIALS, WE ARE ALL OVER THE -- WE HAVE A DIVERSE SET.

CHAIRMAN TORRES: RIGHT. RIGHT.

DR. TURBEVILLE: RIGHT. VERY DIVERSE, RIGHT, FROM CARDIOVASCULAR TO HIV TO DMD, ET CETERA, ALL WITH DIFFERENT NEEDS. SO THAT'S ONE OF THE WEAKNESSES HERE IN THE SENSE THAT MOST OF THEM ARE DISEASE CENTRIC. AND SO IF THIS IS SOMETHING THAT WE DECIDE TO DO, WE WOULD HAVE TO REALLY CONSIDER HOW CAN WE MAKE OUR CONTRIBUTIONS TO SPECIFIC DISEASES THAT MET, AT LEAST FOR THE MOST PART, OUR PORTFOLIO.

CHAIRMAN TORRES: I DON'T SEE ANY HAND UP, SO WE'LL MOVE ALONG, SEAN.

DR. TURBEVILLE: OKAY. GREAT. AND THEN THERE'S ACADEMIC CENTERS OF EXCELLENCE. SO THIS IS THE THIRD MODEL. SO ACADEMIC INSTITUTIONS PROVIDE THESE SERVICES AS WELL. GENERALLY WE PROVIDE OR ANOTHER ORGANIZATION PROVIDES A GRANT, THE CRO PROVIDES A GRANT, OR THE CRO TAKES CARE OF THIS COMPONENT, BUT IT'S BASICALLY THE SAME THING.

RIGHT. IT'S MUCH SCALED DOWN. THE VOLUME IS HIGH. THE SCALE IS -- WELL, LET'S JUST PUT IT THIS WAY. IT'S VERY DIFFICULT FOR MANY ORGANIZATIONS SUCH AS THE UCSF'S OF THE WORLD OR OTHER UC SYSTEMS TO TAKE CARE OF EVERYTHING THAT'S REQUIRED OF THE PATIENTS. AND QUITE FRANKLY, THEY DO CONTRACT OUT WITH THIRD PARTIES, NOT UNCOMMON, RIGHT, TO TAKE CARE OF THESE SERVICES. NONETHELESS, IT IS IMPACTFUL FOR PATIENTS. IT CAN WORK.

THE STRENGTHS ARE THAT THEY KNOW THE PATIENTS. THEY KNOW ABOUT CLINICAL TRIALS. SO THAT SAVES SIGNIFICANT TIME.

THE WEAKNESSES ARE, OF COURSE, WELL, THEY'RE LIMITED IN SCALE. THEY'RE LIMITED IN TIME. AND WHEN YOU START THINKING ABOUT THE METRICS THAT I TALKED ABOUT EARLIER, IT'S KIND OF HARD TO CONCATENATE ALL THAT METRICS SO THAT WE AS AN ORGANIZATION CAN SEE WHERE WE ARE MAKING AN IMPACT. NEVERTHELESS, IT DOES HELP. IT DOES WORK FOR PATIENTS.

ANY QUESTIONS THERE? GOOD. OKAY. WELL, I'VE DESCRIBED THREE METHODOLOGIES. THERE'S ACTUALLY A FOURTH WHICH ISN'T A METHODOLOGY IN ITSELF, BUT IT'S OUTSIDE THE UNITED STATES. SO IF YOU BENCHMARK THIS STUFF TO PROGRAMS OUTSIDE OF EU,

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THERE ARE UNIQUE PROGRAMS OVER THERE AS WELL. MORE THAN HAPPY TO TALK ABOUT THOSE OFF LINE.

NOW, HERE IS A FIVE-YEAR, REMEMBER WE MENTIONED ABOUT THE FIVE-YEAR TIMELINE FOR THE INITIAL 15.6 ALLOCATION.

CHAIRMAN TORRES: JUST KEEP IN MIND THAT NO FUNDS CAN BE SPENT OUTSIDE THE STATE OF CALIFORNIA.

DR. TURBEVILLE: THAT'S RIGHT. THANK YOU, SIR.

SO THIS COULD BE MODIFIED TO SOME EXTENT, BUT THE WAY WE ARE APPROACHING THIS IS ONE YEAR. YEAR ONE WOULD BE DISCOVERY. THAT IS, BASED ON YOUR GUIDANCE, WE WOULD TAKE THAT TO THE ICOC, GET THEIR GREEN LIGHT, WE WOULD DETERMINE THE MODEL, AND THEN EMPLOY THE MODEL, AT THE SAME TIME DO A GAP ANALYSIS. SO THERE'S A LOT OF INFORMATION OUT THERE THAT WE ARE NOT SEEING IN TERMS OF WHAT PATIENTS ARE EXPOSED TO, WHAT THEY'RE NOT. SO DO A GAP ANALYSIS WHERE WE CAN FIND SYNERGIES, WHERE THERE'S OVERLAP, AND WE TAKE CARE OF THAT. WE WOULD IMPLEMENT BASIC SERVICES AND THEN START MONITORING THIS. AND THIS IS SCALABLE DEPENDING ON WHICH MODEL WE CHOOSE.

SO EVERY YEAR WE'D BE ABLE TO COME BACK TO YOU AS WELL AS THE ICOC WITH NEW METRICS ON WHERE WE

SEE TRENDS AND WHERE WE SEE THINGS THAT WE CAN IMPROVE FOR PATIENTS WHO ARE TRYING TO ENROLL IN THESE TRIALS.

CHAIRMAN TORRES: SO ON THAT ISSUE, WHY DO WE HAVE TO CHOOSE ONE APPROACH OR ANOTHER? SHOULDN'T WE JUST DETERMINE THAT WE WILL PUT AN RFP OUT THERE, AND WHOEVER APPLIED, AT THAT POINT WE DETERMINE WHICH IS THE BEST APPROACH?

DR. TURBEVILLE: SO ABSOLUTELY. SO THANK YOU FOR BACKING ME UP. SO, YES, BASED ON YOUR GUIDANCE AND THE ICOC, WE WOULD DETERMINE WHAT THAT RFP WOULD LOOK LIKE. AND THAT RFP WOULD GO OUT THERE, CORRECT.

CHAIRMAN TORRES: SO WE ARE NOT REQUIRED TODAY TO CHOOSE AN APPROACH OR A MODEL. WE ARE ONLY TALKING ABOUT WHAT WE WANT THE BOARD TO MOVE FORWARD ON AS WE MOVE TOWARD AN RFP, CORRECT?

DR. TURBEVILLE: THAT'S CORRECT.

CHAIRMAN TORRES: OKAY. I JUST WANTED TO MAKE SURE THAT EVERYBODY KNEW JUST WHAT IS ON THE TABLE BECAUSE WE ARE ON SUCH A NEW GROUND HERE, NEW SPACE HERE IN RESPECT TO THESE ISSUES BECAUSE THIS WASN'T PART OF THE INITIAL INITIATIVE IN 2004. IT IS NEW AND UNIQUE TO THIS INITIATIVE AND, QUITE FRANKLY, I THINK UNIQUE AS A STATE IN THE NATION AS

TO HOW WE PROCEED.

DR. TURBEVILLE: ABSOLUTELY. THANK YOU FOR THAT, SENATOR.

CHAIRMAN THOMAS: ART, J.T. HERE.

CHAIRMAN TORRES: MR. CHAIRMAN, YES.

CHAIRMAN THOMAS: SO THANK YOU, SENATOR. I JUST WANT TO MAKE WHAT'S PERHAPS A VERY OBVIOUS POINT AS ALL OF YOU ARE CONSIDERING THESE VARIOUS MODELS, THAT IN CASE YOU'RE NOT ENTIRELY AND FULLY FAMILIAR WITH WHAT CIRM DOES, WE ARE NOT INVOLVED AT ALL IN THE PATIENT RECRUITMENT. WE JUST FUND THE TRIALS, AND OBVIOUSLY IT'S UP TO THE INSTITUTIONS THAT ARE WORKING ON THE PROJECTS AND THE CLINICAL TRIAL SITES THEMSELVES, THE PEOPLE OPERATING THEM, TO RECRUIT THE PATIENTS. WE HAVE NOTHING TO DO WITH THAT. AND, AGAIN, THAT MAY BE VERY OBVIOUS, BUT JUST ON THE OFF CHANCE IT ISN'T, I WANTED TO MAKE THAT POINT. THANK YOU, SENATOR.

CHAIRMAN TORRES: THAT'S A GOOD POINT; HOWEVER, WE DO POINT OUT, AS YOU WELL KNOW, J.T., BECAUSE YOU'VE BEEN VERY SUPPORTIVE OF THIS, OUR DEI IN RESPECT TO POTENTIAL GRANTS AND HOW WE ENCOURAGE GRANTEES TO REACH OUT TO DIVERSE AND UNDERSERVED COMMUNITIES WITHOUT US PICKING THEM, BUT AT LEAST GIVING THEM THE CHARGE THAT THEY NEED TO DO THAT.

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CHAIRMAN THOMAS: YES, THAT'S EXACTLY RIGHT, WHICH IS ALSO A VERY GOOD POINT. THANK YOU.

CHAIRMAN TORRES: SEAN.

DR. TURBEVILLE: YES, SIR. THANK YOU. SO YES, THIS IS JUST --

MS. BONNEVILLE: I'M SORRY. THERE'S ANOTHER HAND RAISED. DR. SENTHILL.

CHAIRMAN TORRES: WHO IS IT?

MS. BONNEVILLE: DR. SENTHILL.

CHAIRMAN TORRES: OH, DR. SENTHILL, PLEASE.

DR. SENTHIL: THANKS, SENATOR TORRES. I HAVE A QUESTION BECAUSE CIRM HAS NOW FUNDED SEVERAL OF CLINICAL TRIALS. AND IN ORDER TO UNDERSTAND THE NEEDS OR THE CHALLENGES THAT CLINICAL TRIALS HAVE FACED IN TERMS OF SERVING THE UNDERSERVED AND THEIR CHALLENGES THAT THEY HAVE HAD IN RECRUITING THESE PATIENTS, CAN WE GET SOME KNOWLEDGE AROUND THAT TO BE ABLE TO INFORM US? WE HAD A LIST OF EXPENSES THAT ARE COVERED, AND WE ARE TRYING TO FIGURE OUT WHAT IS THE BEST MODEL TO IMPROVE AFFORDABILITY AND ACCESSIBILITY. BUT THAT DATA MIGHT ALREADY EXIST IN TERMS OF WHAT ARE THE CURRENT CHALLENGES BASED ON THE CLINICAL TRIALS THAT HAS ALREADY BEEN DONE. IS THERE ANY INFORMATION FROM THE RESEARCHERS OR THE

RESEARCH UNITS THAT WE CAN GATHER TO BE ABLE TO BETTER INFORM ABOUT OUR ACTIONS?

CHAIRMAN TORRES: YES. BEFORE MARIA MILLAN RESPONDS, AS SHE SHOULD, ON THIS ISSUE, IT'S IMPORTANT TO NOTE THAT WHEN WE DO PUT OUT GRANTS IN RESPECT TO CLINICAL TRIALS, WE SPECIFICALLY REVIEW WHAT IS THEIR APPROACH TO DETERMINING THE UNDERSERVED, WHAT IS THEIR APPROACH TO DETERMINING MINORITY PARTICIPANTS SO THAT WE ARE ABLE -- SO THE REVIEWERS ARE ABLE TO REVIEW JUST WHAT THEY'RE PROPOSING TO MAKE SURE THAT WE KNOW THEY'RE MOVING IN THE RIGHT DIRECTION. MARIA.

DR. MILLAN: THANK YOU, SENATOR TORRES. THANK YOU, DR. SENTHIL.

I THINK WHAT I WOULD SAY IS THAT WE HAVE HAD ON THE GROUND EXPERIENCE AND HAVE HAD A CHANCE TO GET INPUT SPECIFICALLY FROM OUR DIRECTORS OF OUR ALPHA CLINICS NETWORK AND SOME PI'S FROM OUR GRANTS. WE GET THAT INPUT BY WAY OF OUR CLINICAL ADVISORY PANELS. WE GET THAT INPUT BY WAY OF DIRECT COMMUNICATION WITH THE SCIENCE OFFICERS ON THE DEVELOPMENT TEAM. WE GET THAT INPUT IN THE ALPHA CLINICS DIRECTOR MEETINGS.

SO GENERALLY SPEAKING, THE TYPES OF CHALLENGES THAT ARE BEING PRESENTED TODAY ARE KIND

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OF PERVASIVE CHALLENGES ACROSS, THAT IT'S REALLY HARD TO PINPOINT AND JUST SOLVE FOR EACH TRIAL.

SO I THINK THE KEY THING IS IDENTIFYING AN APPROACH THAT WILL BE SOMETHING THAT KIND OF LIFTS ALL BOATS AND PROVIDES A PATHWAY TO ACCESS TO THESE CLINICAL TRIALS TO PATIENTS FROM UNDERSERVED COMMUNITIES.

ONE OF THE RECENT KIND OF EXPERIENCES THAT HAVE BEEN SHARED WITH US HAD COME DURING THE COVID, WE ARE STILL OBVIOUSLY IN IT, BUT IN THE HEIGHT OF THE COVID PANDEMIC, CIRM DID FUND A SPECIAL COVID PROGRAM WHICH INCLUDED CLINICAL TRIALS AND INCLUDED MULTI-INSTITUTION ATTEMPTS TO BRING IN UNDERSERVED POPULATIONS, SPECIFICALLY, FOR INSTANCE, FOR AT THAT TIME CONVALESCENT PLASMA FOR PATIENTS IN THE INLAND EMPIRE, COLLABORATION BETWEEN THE CITY OF HOPE AND IRVINE, FOR INSTANCE. SO WE GAINED A LOT OF INPUT THERE BOTH FROM THE COMMUNITY SIDE, FROM THE PATIENT SIDE, AND FROM THE CLINICAL TRIALISTS.

AND SO I THINK WHAT SEAN IS, I THINK, PRESENTING TODAY, SOME OF THE ADVANTAGES THAT ARE INCLUDED IN CREATING OR BEING ABLE TO COME UP WITH A SYSTEM TO PROVIDE SOLUTIONS FOR PATIENTS IS ALSO THAT IT WILL ALSO INFORM US MORE COMPLETELY. WE ONLY HAVE BITS AND PIECES OF INFORMATION, BUT WE

DON'T HAVE THE COMPLETE LANDSCAPE, SIMPLY NOT COLLECTED IN ANY TYPE OF ORGANIZED OR DELIBERATE WAY. SO I THINK HAVING A SYSTEM THAT'S DEPLOYED, NOT ONLY TO ASSIST PATIENTS, BUT GAIN REAL-WORLD EVIDENCE AND INFORMATION AS IT'S BEING DONE, I THINK, WILL BE EXTREMELY VALUABLE TO HELPING US SOLVE SOME OF THESE HURDLES OR ADDRESS SOME OF THESE HURDLES OR COME UP WITH NOVEL SOLUTIONS IN THE FUTURE.

CHAIRMAN TORRES: AND ALSO I KNOW THAT HARLAN KNOWS VERY WELL THE NATIVE TRIBES AND RESERVATIONS THAT ARE PARTICULARLY ACCESSIBLE TO HIS AREA AND TRIBAL LEADERS THAT I'VE SPOKEN TO OVER THE LAST YEAR DURING COVID, IT'S ASTONISHING HOW MANY, SENIORS ESPECIALLY, NATIVE AMERICANS WE LOST TO COVID ON THE RESERVATION. SO THEY WOULD HAVE BEEN IN THE FUTURE LIKELY PARTICIPANTS IN CLINICAL TRIALS.

DANA, YOU HAD YOUR HAND UP?

DR. DORNSIFE: YES, THANK YOU, SENATOR. JUST I REALIZE THE DOLLARS CAN'T BE SPENT OUTSIDE THE STATE OF CALIFORNIA, BUT CAN THEY BE SPENT ON PATIENTS COMING INTO THE STATE WHO ARE NOT CALIFORNIA RESIDENTS AND PARTICIPATING IN TRIALS HERE IN CALIFORNIA?

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CHAIRMAN TORRES: THAT'S A VERY GOOD QUESTION, AND I DON'T HAVE THE ANSWER TO THAT.

DR. DORNSIFE: BECAUSE THAT WOULD REALLY LIMIT THE POTENTIAL PATIENT PARTICIPANT POOL.

CHAIRMAN TORRES: YES. BUT MY OWN OPINION IS, GIVEN THE EXPERIENCE THAT I'VE HAD HERE, I DON'T THINK WE ARE ANYWHERE NEAR EXHAUSTING THE PATIENT POOL TO THE UNDERSERVED IN CALIFORNIA. AND A LOT OF THAT EFFORT STILL NEEDS TO GO ON, BUT I WILL BE HAPPY TO DO THAT RESEARCH, AND I WILL GET BACK TO YOU, DANA.

HARLAN.

DR. LEVINE: THANK YOU, SENATOR. I WANT TO ADD TO YOUR COMMENT. I THINK THERE'S A HUGE POOL HERE. AND ONE THOUGHT I WOULD HAVE, LIKE IF YOU HAVE SYSTEMIC, AND MARIA MADE THE SAME POINT, EACH TRIAL WILL BE DIFFERENT. BUT I THINK FOR SOME OF THESE CONDITIONS THAT ARE RELATIVELY RARE, YOU HAVE TO BE PART OF THE ECOSYSTEM OF THE PATIENT'S EXPERIENCE. OTHERWISE, IT ADDS ANOTHER HUGE HURDLE TO GET INVOLVED. ONE-THIRD OF CALIFORNIANS ARE IN THE MEDI-CAL PROGRAM. I WOULD SAY A HIGHER REPRESENTATION OF THE UNDERSERVED ARE IN THE MEDI-CAL PROGRAM.

CHAIRMAN TORRES: YES.

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DR. LEVINE: WE HAVE TO FIND A WAY TO MAKE IT PART OF THAT ECOSYSTEM TO IDENTIFY THESE PATIENTS SO THEY CAN EVEN GET REFERRED IN THE FIRST PLACE. AND I THINK, IN GENERAL, THE MEDI-CAL SYSTEM HAS DONE A NICE JOB OF PROPPING UP GENERAL CARE FOR A POPULATION, BUT IT'S NOT IN THE BUSINESS OF IDENTIFYING EXTRAORDINARY INTERVENTIONS FOR HIGHLY COMPLEX DISEASES. AND I THINK WE NEED TO -- IT'S OUTSIDE THE SCOPE TODAY, SENATOR, I UNDERSTAND THAT, BUT I THINK WE'RE GOING TO LOSE A HUGE POOL IF WE DON'T THINK ABOUT HOW DO WE TAILOR RESOURCES TO HELP SUPPORT THE MEDI-CAL MANAGED CARE PROGRAM TO IDENTIFY THESE PATIENTS AND CONNECT THESE PATIENTS INTO THE RESEARCH TRIALS.

CHAIRMAN TORRES: YOU'RE ABSOLUTELY RIGHT. AND I WANTED TO CALL ON JAMES DEBENEDETTI. DID YOU HAVE ANYTHING TO ADD ON THIS BECAUSE I KNOW IN COVERED CALIFORNIA, WHEN I SERVED ON THE BOARD, THAT WE HAD A TREMENDOUS OUTREACH WORKING WITH MEDI-CAL AND ALSO THE FACT THAT OUR CHAIR OF COVERED CALIFORNIA IS THE SECRETARY FOR HEALTH AND HUMAN SERVICES. JAMES.

MR. BENEDETTI: I DON'T HAVE ANYTHING TO ADD. MEDI-CAL IS VERY IMPORTANT, AND WE ARE WORKING WITH THEM AS CLOSELY AS WE CAN.

CHAIRMAN TORRES: OKAY. GREAT. I JUST WANTED TO MAKE SURE PEOPLE KNEW THAT.

SOMEBODY ELSE'S HAND WAS JUST UP, I THINK. NO. I THINK WE ARE FINE. OKAY. SEAN, YOU WANT TO CONTINUE.

DR. TURBEVILLE: I THINK ADRIENNE HAD HER HAND UP.

CHAIRMAN TORRES: OH, ADRIENNE. I'M SORRY.

MS. SHAPIRO: YES, I DID. THANK YOU. SO I THINK THAT -- I HAVE TO BRING THIS UP. WHEN WE'RE TALKING ABOUT POPULATIONS LIKE MINE, WHICH IS AFRICAN-AMERICAN, AND MY DAUGHTER IS PART OF THE AFRO-LATINO POPULATION AND WAS DISABLED, WE REALLY HAVE TO LOOK AT -- HOW CAN I PUT THIS? AGAIN, THAT POPULATION THAT'S COVERED BY MEDI-CAL, IN MY BOOTS ON THE GROUND WORK, WE FIND THAT PATIENTS WHO ARE UNDER THE MANAGED CARE AND WHO ARE ON THOSE PROGRAMS FAIR FAR WORSE THAN OUR PATIENTS WHO ARE UNDER OTHER PROGRAMS, AND THEY ARE REALLY STRETCHED. THERE ISN'T A REAL MEANS FOR OUTREACH AS FAR AS FOLLOWING AND LOOKING AFTER PATIENTS.

AND ALSO BECAUSE, AS WE'RE GOING INTO THESE CARE PLANS, WE ARE FINDING FEWER AND FEWER PLACES THAT ACTUALLY HAVE THE EXPERTISE THAT WE NEED

OR THE HOSPITALS ARE BECOMING LIMITED WHERE PATIENTS CAN GO FOR CARE. SO I JUST NEED FOR US TO KEEP THAT IN MIND.

AND THE OTHER THING IS REALLY WHEN WE LOOK AT CULTURALLY WHAT SOME OF THE BARRIERS ARE OR CAVEATS ARE, IT IS NOT THAT WE DON'T TRUST SCIENCE. IT'S THAT WHEN WE GO FOR MEDICAL CARE, WE ARE GENERALLY TREATED UNFAIRLY. I'M GOING TO SAY THAT. I MEAN IT'S ALL DOCUMENTED AND EVERYTHING. AND SO EARNING TRUST AND DOING SOMETHING NEW AND UNFOUNDED, I GUESS, IN CLINICAL TRIALS AND BEING TOLD THAT YOU ARE GOING TO HAVE TO DEPEND ON THESE MEDICAL INSTITUTIONS WHICH HAVE NOT BEEN COMPLETELY, I'M GOING TO SAY, FAIR OR EQUITABLE FOR YOU IS A HUGE, A HUGE LEAP, RIGHT, IN REALITY. AND SO I GET A LITTLE BIT NERVOUS WHEN I HEAR SOME OF THIS.

I KNOW WE'RE GOING TO DO IN THIS PERIOD OF TIME, BUT IN THIS PERIOD WHERE WE ARE ACTUALLY OUR DISCOVERY, I REALLY HOPE THAT WE DO A DEEP DIVE INTO OUTCOMES THAT PEOPLE ARE HAVING NOW AND THINKING ABOUT HOW THAT WILL TRANSLATE INTO WHAT COULD BE IN THE FUTURE.

CHAIRMAN TORRES: THANK YOU, ADRIENNE.

ANY OTHER HANDS UP THAT I CAN'T SEE? ALL RIGHT. SEAN, YOU WANT TO WRAP IT UP?

DR. TURBEVILLE: YEAH, CERTAINLY. THERE'S THE SLIDE.

CHAIRMAN TORRES: GOOD TIMING.

DR. TURBEVILLE: THANK YOU FOR THE OPPORTUNITY TO PRESENT AND VERY STIMULATING IDEAS. I AM GOING TO OPINE A LITTLE BIT HERE. ONE, I THINK WE ARE IN A POSITION AT CIRM AND EVERYBODY ON THE BOARD HAS THE OPPORTUNITY TO REALLY CONSIDER A FIRST IN CLASS, IF YOU WILL, BEST IN CLASS PATIENT SUPPORT SERVICES FOR CIRM AND EVEN A BENCHMARK FOR PERHAPS DOWN THE ROAD FOR ALL CALIFORNIA RESIDENTS REGARDLESS OF THE THERAPY. SO IT'S A UNIQUE OPPORTUNITY, AND I WANT TO THANK YOU FOR ALL THE INPUT AND THE ABILITY TO PRESENT TODAY. THANK YOU.

CHAIRMAN TORRES: THANK YOU.

MARIA, I WANTED TO ASK YOU FIRST, MILLAN, GIVEN WHAT YOU HEARD TODAY, I STILL THINK THAT WE NEED TO MOVE FORWARD TO HAVE THE BOARD APPROVE OUR ABILITY TO ISSUE AN RFP AND SEE WHAT'S OUT THERE. WHAT MAY COME BACK MAY BE A COMBINATION OF ALL THESE THREE ALTERNATIVES. I DON'T KNOW. SO I JUST WANTED TO GET YOUR INPUT.

DR. MILLAN: I THINK THAT WHEN SEAN STARTED THE MEETING, HE ARTICULATED THAT WHAT WE HOPE TO GET OUT OF TODAY'S MEETING IS AN INDICATION

FROM THE AAWG IN TERMS OF THE FOCUS, SCOPE, GENERALLY SPEAKING, THAT WE CAN BUILD AN RFP AROUND AND CERTAIN KIND OF JUST IDEAS, NOT IN DETAIL, BUT IDEAS OF WHAT CAPABILITIES AND ATTRIBUTES THAT THE AAWG FEEL WOULD BE IMPORTANT TO INCLUDE IN AN RFP THAT WOULD BRING IN ORGANIZATIONS, AND WE DON'T MEAN TO LIMIT IT TO ANY SPECIFIC TYPE OF ORGANIZATION, BUT MERELY LIMIT TO -- I MEAN MERELY PUT IT OUT THERE SO WE CAN ATTRACT THE BEST PROPOSALS ACCORDING TO THE SCOPE, WHICH WE'LL DEVELOP FURTHER, AND THE PRIORITIES THAT WE HOPE THAT AFTER TODAY'S PRESENTATION, THERE WERE SOME LISTS THERE IN TERMS OF WHAT TYPES OF ASSISTANCE, ET CETERA, AND WHAT TYPE OF CAPABILITIES. SO I DON'T KNOW IF THERE'S GOING TO BE TIME. I THINK WE HAVE THREE MINUTES; IS THAT RIGHT, OR WE HAVE A HALF HOUR.

CHAIRMAN TORRES: NO, WE HAVE A HALF HOUR LEFT. I JUST DIDN'T WANT --

DR. MILLAN: THAT WOULD BE GREAT IF THE AAWG FEELS THAT THEY HAVE ENOUGH INFORMATION TODAY OR HAVE ENOUGH OF A BASE TO GIVE THE CIRM TEAM SOME RECOMMENDATIONS OF WHAT WE SHOULD PRIORITIZE. SEAN AND THE GROUP WILL THEN TAKE ALL THAT AND CREATE A DRAFT FOR THE AAWG TO TAKE A LOOK AT. AND WHEN IT'S AT A POINT THAT IS SUITABLE TO BRING TO THE ICOC,

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THEN THAT WOULD BE THE CONCEPT PROPOSAL THAT WOULD SET THE PARAMETERS AND THE SCOPE AROUND THE RFP THAT WOULD BE BROUGHT TO OUR BOARD FOR APPROVAL. AND THEN THE TEAM CAN GO TO WORK IN TERMS OF IMPLEMENTATION.

CHAIRMAN TORRES: ALL RIGHT. MARIA, WHEN IS OUR NEXT BOARD MEETING?

MS. BONNEVILLE: OUR NEXT BOARD MEETING IS AT THE END OF JUNE. WE MEET AS A FULL BOARD.

CHAIRMAN TORRES: WHAT I'D LIKE TO PROCEED UPON IS NOT TO TAKE ANY ACTIONS TODAY, BUT RATHER TO LEAVE THE DOOR OPEN FOR ALL OF OUR MEMBERS, OF WHICH THERE ARE 17, TO COME FORWARD WITH ANY SUGGESTIONS YOU HAVE IN THE NEXT TWO WEEKS THAT YOU WOULD WANT TO SEE ADDED TO THESE PROPOSALS. AND THEN HAVE THE TEAM COME BACK TO US AS A WORKING GROUP IN A VERY SHORT MEETING JUST TO LOOK AT THE PROPOSALS THAT THEY'RE LOOKING AT SO WE CAN APPROVE IT BECAUSE I DO NOT WANT TO SEE ANYTHING GO TO THE FULL BOARD WITHOUT THIS WORKING GROUP'S APPROVAL AND INPUT BECAUSE THAT'S THE WHOLE PURPOSE OF WHY YOU EXIST. AND SO --

MS. BONNEVILLE: ART.

CHAIRMAN TORRES: YES.

MS. BONNEVILLE: WE HAVE ANOTHER AAWG

MEETING IN JUNE PRIOR TO THE BOARD MEETING. SO THAT COULD BE AN OPPORTUNITY FOR YOU ALL TO MEET AGAIN.

CHAIRMAN TORRES: RIGHT. PERFECT. BUT AS LONG AS WE HAVE SOME SUGGESTIONS, I THINK THE TWO-WEEK PERIOD IS LONG ENOUGH FOR YOU ALL TO DIGEST WHAT YOU HEARD TODAY AND THEN COME UP WITH ANY IDEAS THAT YOU WANT TO SEND TO US THAT YOU THINK OUGHT TO BE INCLUDED OR EXPANDED, AND THEN THAT WILL BE TAKEN AND BROUGHT TO THE JUNE MEETING OF OUR GROUP BY THE TEAM. AND THEN AT THAT POINT WE'LL VOTE ON WHAT TO RECOMMEND TO THE FULL BOARD FOR APPROVAL. DOES THAT SOUND OKAY TO EVERYONE? I TAKE SILENCE AS CONSENT.

(MULTIPLE YES RESPONSES.)

CHAIRMAN TORRES: ALL RIGHT. ARE THERE ANY PUBLIC COMMENTS THAT WE HAVE NOT TAKEN INTO ACCOUNT? ARE THERE ANY MEMBERS OF THE PUBLIC OUT THERE?

MS. BONNEVILLE: THERE ARE NO HANDS RAISED.

CHAIRMAN TORRES: ALL RIGHT. WELL, I THINK WE ARE DONE UNLESS SOMEBODY ELSE HAS SOMETHING TO ADD. ALL RIGHT.

AS CHAIR I'LL EXERCISE THE OPTION TO ADJOURN THIS MEETING. THANK YOU ALL FOR BEING HERE AND FOR YOUR TIME ESPECIALLY.

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MS. BONNEVILLE: THANK YOU, EVERYONE.

CHAIRMAN TORRES: THANK YOU, SEAN. THANK YOU, MARIA.

(THE MEETING WAS THEN CONCLUDED.)

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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 VIRTUAL PROCEEDINGS BEFORE THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MAY 17, 2022, 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, CSR 7152
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