BEFORE THE
SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS
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: JANUARY 16, 2024
9 A.M.

REPORTER: BETH C. DRAIN, CA CSR
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JANUARY 16, 2024; 9 A.M.

DR. LOMAX: GOOD MORNING, EVERYONE. I'M GEOFF LOMAX. I COORDINATE THIS WORKING GROUP ON BEHALF OF CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE. I'D LIKE TO INTRODUCE ONE OF OUR CO-CHAIRS, JEFF KAHN.

CO-CHAIRMAN KAHN: OVER TO ME.

DR. LOMAX: OVER TO YOU IF YOU'D LIKE TO KICK OFF THE MEETING.

CO-CHAIRMAN KAHN: I WILL HAPPILY DO THAT. WELCOME, EVERYBODY. GOOD MORNING, GOOD AFTERNOON, DEPENDING ON WHERE YOU ARE. MY PLEASURE TO OPEN THE CALL TO ORDER, I GUESS, THIS MEETING OF THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF CIRM.

I'M JEFF KAHN. I'M THE DIRECTOR OF BERMAN INSTITUTE OF BIOETHICS AT JOHNS HOPKINS UNIVERSITY. THAT'S MY REGULAR JOB. I'M VERY HAPPY TO BE THE CO-CHAIR OF THE WORKING GROUP. I SHOULD SAY, BY WAY OF HAPPY TO BE IN CALIFORNIA, I GREW UP IN SOUTHERN CALIFORNIA. MY FRIEND J.T. TO MY LEFT DID AS WELL. SO ALWAYS HAPPY TO BE ABLE TO COME BACK TO ROOTS. I GRADUATED FROM UCLA. SO I FEEL STRONG CONNECTION TO THE STATE AND TO THE MISSION OF CIRM.

YOU WANT TO CALL ORDER OF THE WORKING GROUP?

DR. LOMAX: YEAH. I CAN CALL ROLL. I BELIEVE WE WANT TO HAVE AN ACCOUNTING OF FOLKS THAT ARE ON. SO JEFF KAHN.

CO-CHAIRMAN KAHN: PRESENT.

DR. LOMAX: FRED FISHER. AKSHAY SHARMA. HE MAY BE MUTED. I SAW HIM ONLINE.

BENHUR LEE.

DR. LEE: PRESENT.

DR. LOMAX: CHRISTINE MIASKOWSKI.

DR. MIASKOWSKI: PRESENT.

DR. LOMAX: ELENA FLOWERS. JANET ROSSANT. JOHN WAGNER. KAREN ROMMELFANGER.

DR. ROMMELFANGER: PRESENT.

DR. LOMAX: KAROL WATSON.

DR. WATSON: HERE.

DR. LOMAX: KHRIS SAHA.

DR. SAHA: HERE.

DR. LOMAX: LEONDRA CLARK-HARVEY. MELISSA LOPES.

MS. LOPES: PRESENT.

DR. LOMAX: RAYNE ROUCE. VITO IMBASCIANI.

CHAIRMAN IMBASCIANI: HERE.

DR. LOMAX: SHARON TERRY.

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MS. TERRY: HERE.

DR. LOMAX: GREAT. THANKS SO MUCH FOR JOINING THIS MORNING.

CO-CHAIRMAN KAHN: I THINK WE'RE ALSO SUPPOSED TO SAY THIS MEETING IS BEING TRANSCRIBED AND WILL BE AVAILABLE ON YOUTUBE.

DR. LOMAX: CORRECT. YEAH.

CO-CHAIRMAN KAHN: WE HAVE MARIA.

DR. LOMAX: YES. LIKE TO INTRODUCE MARIA BONNEVILLE, CO-CHAIR OF OUR GOVERNING BOARD. MARIA, DID YOU WANT TO MAKE SOME COMMENTS?

VICE CHAIR BONNEVILLE: THANK YOU SO MUCH, GEOFF. HELLO, EVERYONE. MY NAME IS MARIA BONNEVILLE. I'M THE VICE CHAIR OF THE BOARD. I ALSO ACT AS THE CHAIR OF THE ACCESS AND AFFORDABILITY WORKING GROUP OF THE BOARD. AND OUR CONVERSATION HERE TODAY WILL INFORM MANY ASPECTS OF OUR METHODS FOR ENGAGING WITH PATIENTS AND COMMUNITIES AND ALSO THE POLICY AROUND WHAT SERVICES AND ACTIVITIES WE COVER IN OUR PATIENT ASSISTANCE FUND. SO I THANK YOU FOR THE THOUGHTFUL CONVERSATION AND LOOK FORWARD TO YOUR INSIGHTS AND RECOMMENDATIONS TODAY. THANK YOU.

DR. LOMAX: GREAT. THANK YOU, MARIA. MAYBE I'LL JUST JUMP IN.

CO-CHAIRMAN KAHN: I THINK IT'S TIME FOR SESSION I.

DR. LOMAX: WE HAVE, JUST TO BRIEFLY HIGHLIGHT THE ORGANIZATION OF TODAY, WE HAVE TWO SESSIONS. THESE ARE WHAT I WOULD CALL INFORMATIONAL SESSIONS FROM THE STANDPOINT WE'RE HOPING TO HAVE THE CONVERSATION ABOUT TWO EMERGING AREAS OF CIRM PROGRAMMING WHERE WE THOUGHT -- IT'S ACTUALLY BEEN RECOMMENDED FROM OUR BOARD THAT WE ENGAGE THIS WORKING GROUP. WE ARE GOING TO COVER FIRST OUR COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM. I'LL GIVE A BRIEF OVERVIEW OF THAT PROGRAM IN A MOMENT.

AND THEN THE SECOND SET PANEL WILL BE ON OUR PATIENT SUPPORT PROGRAM. IN BOTH THESE PANELS WE'RE TRYING TO REVIEW ISSUES FOR WHICH THERE MAY BE SORT OF ETHICS POLICY OR PRACTICE CONSIDERATIONS WHERE WE SHOULD TAKE THOSE INTO ACCOUNT AS WE DEVELOP AND IMPLEMENT THESE PROGRAMS. AND BOTH PANELS ARE SIMILAR IN THE SENSE THAT WE'LL HAVE A BACKGROUND PRESENTATION, A COMMENTARY FROM PRACTITIONERS IN THAT SPACE, AND THEN WE HAVE A PANEL OF MEMBERS THAT HAVE PERSPECTIVE OF INSTITUTIONAL REVIEW BOARDS SO THAT THEY CAN ALSO PROVIDE FEEDBACK FROM THE STANDPOINT OF THE IRB'S THAT MAY BE ASKED TO REVIEW THESE PROTOCOLS.

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SO WITH THAT AS BACKGROUND, I'M GOING TO GO AND SEE IF I CAN SHARE MY SCREEN.

CO-CHAIRMAN KAHN: I SHOULD SAY TOO WHILE GEOFF IS PULLING THAT UP, IT'S A HYBRID MEETING OBVIOUSLY. SO THERE ARE SOME OF US IN THE ROOM, BUT MOST OF YOU ALL ARE ONLINE. LET'S USE THE RAISE-HAND FUNCTION IN ZOOM, WHICH I'M SURE WE'RE ALL VERY FAMILIAR WITH AT THIS POINT, AS A WAY OF LETTING US KNOW THAT YOU WANT TO ASK A QUESTION OR MAKE A COMMENT. AND THAT WILL ALLOW ME AND GEOFF TO KEEP A QUEUE.

DR. LOMAX: GREAT. THANKS VERY MUCH. SO CIRM'S MISSION IS ACCELERATING WORLD-CLASS SCIENCE TO DELIVER TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND WORLD.

AND WHAT I'M GOING TO START IN THIS PRESENTATION IS TO PROVIDE AN OVERVIEW OF CIRM'S PROPOSED COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM. IT'S PROPOSED INSOFAR AS OUR BOARD IS STILL GOING TO CONSIDER THE OVERALL CONCEPT LATER THIS MONTH. SO ANY RECOMMENDATIONS OR THOUGHT EMERGING FROM THIS MEETING ARE VERY TIMELY IN TERMS OF INFLUENCING THAT PLAN.

I'M GOING TO SPECIFICALLY FOCUS ON THE

PROGRAM'S OUTREACH AND ENGAGEMENT ACTIVITIES AS THIS IS A RELATIVELY NEW AREA OF CIRM PROGRAMMING AND ONE THAT, AGAIN, WE WANTED TO ENGAGE THE WORKING GROUP ON. AND WE'VE DEVELOPED A FEW QUESTIONS FOR PROGRAM IMPLEMENTATION; BUT, AGAIN, TO THE EXTENT -- THESE CONVERSATIONS TEND TO BE RATHER ENGAGING AND FREE-FLOWING. SO IF WE DON'T GET THROUGH ALL THE QUESTIONS, THAT'S QUITE ALL RIGHT.

SO THE COMMUNITY CARE CENTERS ARE INFRASTRUCTURE. INFRASTRUCTURE PROGRAMS AT CIRM ARE FUNDING THE SUPPORT CENTERS TO NOT IMPLEMENT SPECIFIC RESEARCH GRANTS, BUT PROVIDE THAT SUPPORT STRUCTURE THAT ALLOWS OTHER GRANTS TO OPERATE EFFICIENTLY AND EFFECTIVELY. AND SO, FOR EXAMPLE, WE CURRENTLY HAVE AN ALPHA STEM CELL CLINIC NETWORK WHICH SUPPORTS CLINICAL TRIALS. AND THE COMMUNITY CARE CENTERS ARE AN EXTENSION OF THAT INFRASTRUCTURE SPECIFICALLY WITH THE AIM OF ESTABLISHING GEOGRAPHICALLY DIVERSE CENTERS THAT WILL SUPPORT CLINICAL RESEARCH, PARTICULARLY IN THE AREAS OF ENGAGING PATIENTS THAT HAVE HISTORICALLY HAD LESS ACCESS TO CLINICAL RESEARCH OPPORTUNITIES EITHER BECAUSE OF GEOGRAPHY OR OTHER SOCIAL DETERMINANTS.

GIVE YOU A LITTLE BIT OF A SENSE OF HOW THIS PROGRAM HAS BEEN ROLLING OUT. FOR OVER THE

BETTER PART OF A YEAR, STARTING OVER A YEAR AGO, WE CONDUCTED A STATEWIDE NEEDS ASSESSMENT, ENGAGING COMMUNITIES IN PARTS OF CALIFORNIA WHERE WE'VE HAD LESS PRESENCE, PARTICULARLY BECAUSE THEY ARE AWAY FROM OUR ACADEMIC CENTERS. WE ALSO THEN TOOK THE RESULTS OF THOSE INITIAL LISTENING SESSIONS AND HAD A STATEWIDE PUBLIC WORKSHOP. A NUMBER OF YOU ALL PARTICIPATED IN THAT WORKSHOP.

AND FROM THAT WORKSHOP, WE TOOK THE INFORMATION, THE FEEDBACK, THE VARIOUS THOUGHTS COMING FROM PARTICIPANTS AND CRAFTED A DRAFT CONCEPT PLAN. IN CIRM'S PROCESS, THE CONCEPT PLAN IS THE DOCUMENT THAT LEADS UP TO A FULL PROGRAM, FULL APPLICATION PROGRAM.

THAT CONCEPT PLAN HAS BEEN CONSIDERED BY OUR SCIENTIFIC SUBCOMMITTEE AND OUR ACCESS AND AFFORDABILITY WORKING GROUP. AND WE ARE, AGAIN, NOW BRINGING SOME PIECES OF THAT TO YOU ALL BASED ON FEEDBACK FROM THOSE WORKING GROUPS, AGAIN, PARTICULARLY TO CONSIDER SOME OF THE ETHICS POLICY ASPECTS OF THOSE ACTIVITIES, WITH THE AIM OF GETTING APPROVAL FROM OUR BOARD LATER THIS MONTH AND THEN MOVING INTO THE APPLICATION PHASE LATER THIS YEAR.

TO GIVE YOU A LITTLE BIT OF CONTEXT FOR THIS PROGRAM, BECAUSE IT EXISTS WITHIN A MUCH LARGER

CIRM ECOSYSTEM, THE IDEA OF THIS GRAPHIC HERE, THE IDEA IS THAT YOU HAVE SORT OF THE PATIENTS REALLY IN THE CENTER. IT'S A VERY PATIENT-CENTERED APPROACH. THAT'S HOW WE VIEW OUR CLINICAL PROGRAMS. AND WE HAVE FOUR MAJOR PROGRAMMATIC INITIATIVES DESIGNED TO SUPPORT PATIENTS IN THEIR JOURNEY.

SO I'M STARTING WITH THE ALPHA CLINICS NETWORK THAT I'VE ALLUDED TO, BOTH OUR ALPHA CLINICS AND MANUFACTURING NETWORK. THESE ARE EXISTING AWARDS AT THE MAJOR ACADEMIC CENTERS IN THE STATE. THEY ARE SUPPORTING CLINICAL TRIALS. A MAJORITY OF CIRM-FUNDED CLINICAL TRIALS TAKE PLACE WITHIN THIS NETWORK. AND THIS IS FOR THE MOST PART WHERE PATIENTS HAVE BEEN TREATED AND ENROLLED IN CLINICAL RESEARCH TO DATE.

I'M JUST GOING TO GO DOWN TO THE RIGHT-HAND CORNER HERE AND REMIND YOU ALL THAT ANOTHER MAJOR FUNDING STREAM AT CIRM IS OUR CLINICAL TRIALS PROGRAM. WE'VE FUNDED 96 TO DATE. AND, AGAIN, SO WE ARE BOTH SUPPORTING THE INFRASTRUCTURE TO PERFORM THE TRIALS VIS-A-VIS THE NETWORK, AND WE ARE FUNDING THE TRIALS THEMSELVES THROUGH OUR CLINICAL STAGE PROGRAM AWARDS.

NOW, THIS OTHER AXIS HERE REALLY REPRESENTS TWO NEW PROGRAMS THAT ARE EMERGING TO

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FILL GAPS IN THAT CURRENT CLINICAL RESEARCH SYSTEM. THE FIRST ON THE LOWER LEFT HERE IS OUR PATIENT SUPPORT PROGRAM. THIS PROGRAM WAS AUTHORIZED BY PROPOSITION 14, AND IT'S A DEDICATED FUND THAT IS INTENDED TO SUPPORT PATIENTS, PATIENTS THAT WOULD OTHERWISE MIGHT NOT BE ABLE TO PARTICIPATE IN CLINICAL TRIALS BECAUSE OF EITHER FINANCIAL OR LOGISTICAL BARRIERS. IT'S DESIGNED TO PROVIDE SUPPORT SERVICES TO THOSE PATIENTS BOTH FINANCIAL AND LOGISTICAL.

WE ARE ON THE CUSP OF REVIEWING -- WE'VE RECEIVED APPLICATIONS FROM APPLICANTS FOR THAT PROGRAM, AND WE WILL REVIEWING THOSE APPLICATIONS AND PRESUMABLY MAKING A FUNDING ANNOUNCEMENT LATER THIS YEAR. AND SO THE PATIENT SUPPORT PROGRAM WILL BE THE THIRD PIECE IN THIS SYSTEM OF PATIENT SUPPORT.

AND THEN FINALLY, THE LAST PROGRAM TO COME ONLINE, THE ONE WHERE WE WANT TO ENGAGE YOU ALL ON TODAY, IS OUR COMMUNITY CARE CENTERS OF EXCELLENCE, WHICH WILL BE SUPPORT FOR MEDICAL CENTERS OUTSIDE OF THE ACADEMIC CENTERS THAT CAN SUPPORT CLINICAL RESEARCH. IF YOU'VE HAD A CHANCE TO LOOK AT SOME OF THE MATERIALS WE CIRCULATED, WE REALLY ENVISION THIS ON TWO LEVELS, CENTERS OPERATING AT TWO LEVELS, A

SET OF CENTERS THAT ARE REALLY IN A POSITION POTENTIALLY TO BOTH BRING PATIENTS INTO CLINICAL RESEARCH AND ACTUALLY CONDUCT THE CLINICAL TRIALS AND THEN OTHER CENTERS THAT ARE PROBABLY MORE LIKELY TO SUPPORT PATIENTS, NAVIGATE PATIENTS, BUT THEN REFER THEM TO TREATMENT CENTERS, BUT IDEALLY SUPPORT THOSE PATIENTS ON ALL THE OTHER ASPECTS OF THE CLINICAL RESEARCH OTHER THAN THE ACTUAL TREATMENT. THAT PROGRAM, AGAIN, IS WE HAVE A CONCEPT PLAN WE'RE BRINGING TO OUR BOARD LATER THIS MONTH. AND A COPY WAS PROVIDED AS PART OF THE BACKGROUND MATERIALS.

SO BIG PICTURE, THE COMMUNITY CARE CENTERS OF EXCELLENCE ARE INTENDED TO COVER THREE SORT OF LARGE OPERATIONAL AREAS. AS I JUST ALLUDED TO, THERE'S THE CLINICAL SUPPORT, WHICH IS EITHER SUPPORT TO CONDUCT CLINICAL TRIALS, SERVE AS A REFERRAL HUB TO THE ALPHA CLINICS AND THE PATIENT SUPPORT PROGRAM.

THERE'S ALSO A VERY IMPORTANT CAREER DEVELOPMENT PIECE WHERE WE SEE THESE CENTERS AS SITES THAT WILL BE ABLE TO ADAPT A LOT OF TRAINING CURRICULA THAT HAVE BEEN DEVELOPED EITHER IN THE ALPHA CLINICS OR OTHER CIRM EDUCATION PROGRAMS, AND SERVE AS A SITE, WE HOPE, FOR THEN ALLOWING TRAINEES TO GET EXPERIENCE IN CLINICAL RESEARCH IN

COMMUNITIES. AND SPECIFICALLY WHAT EMERGED OUT OF OUR NEEDS ASSESSMENT IS WE THINK THERE ARE PARTICULAR OPPORTUNITIES TO SUPPORT DEVELOPMENT OF COMMUNITY HEALTH WORKERS AND PATIENT NAVIGATORS. I'M HIGHLIGHTING THAT IN PARTICULAR BECAUSE I THINK THESE ARE ROLES THAT WILL COME UP AS WE TALK ABOUT COMMUNITY ENGAGEMENT.

AND FINALLY, THERE'S GOING TO BE A VERY ACTIVE COMMUNITY ENGAGEMENT PIECE IN THESE PROGRAMS WITH THE AIM OF ENGAGING PATIENTS AND COMMUNITIES. AS PART OF THAT COMMUNITY ENGAGEMENT EFFORT, WE WILL BE SUPPORTING COMMUNITY-BASED ORGANIZATIONS TO PARTNER WITH THESE CENTERS TO SUPPORT THESE ENGAGEMENT EFFORTS WITH A PARTICULAR FOCUS IN POPULATIONS THAT HAVE HISTORICALLY BEEN UNDERREPRESENTED IN CLINICAL RESEARCH.

SO THESE ARE -- AGAIN, THE MAJOR FOCUS FOR TODAY IS THIS COMMUNITY ENGAGEMENT PIECE. THERE'S SOME QUESTIONS HERE THAT WE'VE SORT OF SEEDED TO SORT OF SEED YOUR THINKING AS WE GO THROUGH THIS PANEL. THESE ARE QUESTIONS THAT HAVE COME UP EITHER IN THE CONTEXT OF OUR NEEDS ASSESSMENT OR OUR FURTHER ENGAGEMENT WITH CIRM LEADERSHIP AND OUR BOARD. SO KIND OF LEAVE THEM THERE FOR THE MOMENT. ACTUALLY I'M GOING TO TAKE THEM DOWN BECAUSE WE HAVE

A SECOND PRESENTATION.

BUT IN ORDER TO KIND OF, I THINK, INTRODUCE SORT OF COMMUNITY ENGAGEMENT IN THE CONTEXT OF CLINICAL RESEARCH, WE WANTED TO START WITH A PRESENTATION FROM DR. TENEASHA WASHINGTON BECAUSE HER GROUP HAS ACTUALLY PLAYED THIS ROLE IN THE COMMUNITY. SO WE WANTED TO JUST START, BEFORE WE GET INTO THE CONVERSATION, WITH A LITTLE BIT OF A DESCRIPTION OF WHAT DOES COMMUNITY ENGAGEMENT IN TERMS OF RARE DISEASE OR DISEASE POPULATIONS LOOK LIKE IN A COMMUNITY CONTEXT.

AT THIS POINT, I WOULD LIKE TO TURN IT OVER TO DR. WASHINGTON. AND I'M GOING TO STOP SCREEN SHARING.

DR. WASHINGTON: THANKS, GEOFF. OKAY. HOPEFULLY EVERYBODY CAN SEE MY SCREEN. I'M GOING TO START THE PRESENTATION; BUT IF YOU CAN'T SEE IT, LET ME KNOW.

OKAY. I'M TENEASHA WASHINGTON. NICE TO BE HERE TODAY. THANKS, GEOFF, FOR INVITING ME. I SERVE IN A DUAL CAPACITY. SO I SERVE AS AN ASSISTANT PROFESSOR AT THE UNIVERSITY OF ALABAMA AT BIRMINGHAM HERE IN BIRMINGHAM, ALABAMA, IN THE HEALTH BEHAVIOR SCHOOL OF PUBLIC HEALTH DEPARTMENT HERE. AND IN ADDITION TO THAT, I ALSO ASSIST GLOBAL

GENES WITH THIS PARTICULAR PROGRAM THAT WE'LL BE TALKING ABOUT TODAY. IT'S CALLED ALL IN. RARE. I'M GOING TO TRY TO GET THROUGH IT AS QUICK AS POSSIBLE. I KNOW WE HAVE SOME TIME CONSTRAINTS. IF YOU ALL HAVE ANY QUESTIONS, FEEL FREE TO STOP ME ALONG THE WAY, AND I'M HAPPY TO ADDRESS IT.

OKAY. SO OUR GOAL FOR THE ALL IN. RARE PROGRAM REALLY STARTED OUT FROM, YOU CAN SEE OUR LITTLE FRAMEWORK TO THE RIGHT, WHERE WE WERE CENTERING ALL OF OUR EFFORTS ON PATIENTS AND CAREGIVERS -- GEOFF MENTIONED THIS A LITTLE BIT -- THIS IDEA OF A NEEDS ASSESSMENT. SO WE DIDN'T JUST DECIDE IF WE WERE GOING TO DO THIS TYPE OF PROJECT. THIS ACTUALLY STARTED MAYBE TWO YEARS AGO. WE WERE REALLY ON THE CUSP OF THINKING THROUGH DIVERSITY, EQUITY, AND INCLUSION FROM A RARE DISEASE PERSPECTIVE. AND AS A PART OF THAT, WE WANTED TO REACH OUT WITH A LOT OF DIFFERENT STAKEHOLDERS IN THE COMMUNITY AROUND RARE DISEASE. SO THAT WAS CLINICIANS, BIOPHARM REPRESENTATIVES, PATIENTS, CAREGIVERS. ALL OF THOSE INDIVIDUALS, WE ENGAGED THEM IN FOCUS GROUPS, INDIVIDUAL INTERVIEWS, AND WE ALSO HAD A SURVEY AS WELL THAT KIND OF JUST COLLECTED THEIR THOUGHTS ON THE DIFFERENT ISSUES AND CONCERNS THAT THEY SAW IN THE RARE DISEASE SPACE.

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AS A PART OF THAT, A LOT OF INDIVIDUALS WERE SAYING, ESPECIALLY FROM A PATIENT PERSPECTIVE, LIKE, HEY, WE ARE EXCITED TO DO THIS WORK. WE'RE EXCITED THAT YOU ALL ARE INTERESTED. HOWEVER, ONE OF THE THINGS THAT WE WOULD PREFER IS THAT, INSTEAD OF YOU SENDING THE DR. WASHINGTONS AND ALL OF US IN THE ROOM, HOW ABOUT YOU ENGAGE OUR TRUSTED INDIVIDUAL OR INDIVIDUALS THAT WE SEE AS TRUSTED PEOPLE WITHIN OUR FRAMEWORK. SO WE REALLY TOOK THAT AND RAN WITH IT, AND IT WAS REALLY THINKING ABOUT THIS TERM AROUND COMMUNITY HEALTH WORKERS. FROM OUR PERSPECTIVE, YOU WILL HEAR ME SAY COMMUNITY HEALTH AMBASSADORS, BUT YOU'LL PROBABLY BE MORE FAMILIAR WITH THE TERM "COMMUNITY HEALTH WORKERS." SO AS A PART OF THAT, WE WERE LIKE, OKAY, HOW DO WE GET THIS STARTED?

SO AS OF FEBRUARY OF 2023, WE ACTUALLY STARTED RECEIVING SMALL FUNDS FOR THIS. AND ONE OF THE THINGS THAT WE STARTED OUT BY DOING WAS BUILDING THIS TEAM, A TEAM OF INDIVIDUALS THAT WAS NOT JUST OUR ACADEMIC UNIVERSITIES, BUT WITH ALSO COMMUNITY ORGANIZATIONS. SO WE HAVE TWO SITES, ONE IN KANSAS CITY AND ALSO ONE HERE IN BIRMINGHAM, ALABAMA. AND AS A PART OF THAT, WE STARTED REACHING OUT TO SPECIFIC RARE DISEASE ENTITIES HERE IN ALABAMA AS

WELL AS IN KANSAS CITY.

SO WE WANTED REPRESENTATIVES FROM THERE. WE ALSO HAVE A REPRESENTATIVE FROM THE COMMUNITY HEALTH WORKER FRAMEWORK THAT HAS BEEN TRAINING COMMUNITY HEALTH WORKERS FOR ALMOST TWO DECADES TO REALLY HELP US WITH THE TRAINING ASPECT OF TRAINING INDIVIDUALS WITHIN THIS CAPACITY. AND REALLY OUR GOAL WAS TO GET THE EVERYTHING AROUND RARE DISEASE OUT TO COMMUNITY MEMBERS.

WE HEAR OFTENTIMES, WE TALK ABOUT RARE DISEASE, BUT ONE OF THE THINGS THAT WE LEARNED WAS THAT PEOPLE DON'T NECESSARILY RESONATE WITH THE RARE DISEASE TERM. SO YOU CAN SAY RARE DISEASE, BUT WHAT DOES THAT MEAN TO ME? WE HEARD IN OUR COMMUNITIES THAT SICKLE CELL, WE DIDN'T KNOW THAT THAT WAS REALLY SEEN AS A RARE DISEASE. HOW DO WE BECOME A PART AND ENGAGED IN THIS PARTICULAR ASPECT?

SO WHAT I'M GOING TO DO IS SHOW YOU, THIS SHOWS VALUE TO SOME OF THE WORK THAT WE'VE BEEN DOING. SO THIS IS OUR LEADERSHIP TEAM. AND I ALWAYS SHOW THIS BECAUSE IT'S VERY IMPORTANT, I KNOW WORKING IN ACADEMIA, THAT WE ARE ABLE TO SEE THAT IT'S NOT JUST US IN ACADEMIA, BUT IT'S ALSO OUR PANELISTS WHO SERVE ON OUR LEADERSHIP TEAM AS KEY INDIVIDUALS WITHIN OUR COMMUNITY ENGAGEMENT.

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SO WE HAVE REVEREND CARTER WHO IS IN KANSAS CITY. WE ALSO HAVE BISHOP WOODS HERE IN BIRMINGHAM, ALABAMA. WE ALSO HAVE OUR COMMUNITY HEALTH WORKER TEAM THAT IS A PART OF THIS AS WELL IN OUR ALABAMA BASE AND KANSAS CITY BASE PARTNER, RARE DISEASE PARTNER. SO SARA WITH REKC AND SWAPNA KAKANI WITH ALABAMA RARE, AND, OF COURSE, OUR LARGER TEAM.

AND THESE ARE OUR COMMUNITY ADVISORY BOARD MEMBERS. SO WE REALLY TOOK THE TIME TO THINK THROUGH. WE DIDN'T WANT TO MAKE DECISIONS IN A VACUUM. WE WANTED TO MAKE SURE THAT WE WERE INCORPORATING INDIVIDUALS THAT ARE PART OF THE COMMUNITIES THAT WE WANTED TO ENGAGE. THE TWO CONGREGATIONS THAT WE WORK WITH NOW ARE PREDOMINANTLY AFRICAN-AMERICAN. SO WITH THAT BEING SAID, WE ALLOWED OUR PASTORS TO IDENTIFY WHO THEY WANTED TO SERVE AS COMMUNITY HEALTH WORKERS WITH THE UNDERSTANDING THAT WE WANTED THESE INDIVIDUALS TO BE PEOPLE THAT WERE TRUSTED WITHIN EACH OF THESE RESPECTIVE CONGREGATIONS.

SO THEY IDENTIFY THEM. THEY ALSO IDENTIFY ANOTHER INDIVIDUAL THAT WORKED VERY CLOSELY WITH THEM TO SERVE ON THE COMMUNITY ADVISORY BOARD. AND IN ADDITION TO THAT, WE ALSO SOUGHT OUT RARE DISEASE

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INDIVIDUALS. SARITA HAS A SON WITH A RARE DISEASE AND KEVIN HAS SICKLE CELL. WE ALSO HAVE A GENETICS PERSON ON BOARD FOR THIS PARTICULAR PROGRAM AS WELL.

AND THEN LAST, BUT NOT LEAST, IS OUR STEERING COMMITTEE REPRESENTATIVES AND THEN OUR COMMUNITY HEALTH AMBASSADORS. SO THESE ARE THE INDIVIDUALS WHO ARE ACTIVELY PARTICIPATING IN THIS PROJECT. THEY ARE FOCUSED ON EACH OF THE CONGREGATIONS, AND THEY HAVE PARTICIPATED IN A COMMUNITY HEALTH WORKER TRAINING WITH OUR COMMUNITY-BASED PARTNER IN COMMUNITY HEALTH WORK. AND THEY'VE DONE THAT. IN ADDITION TO THAT, WE ALSO TRAIN THEM ON RARE DISEASE-SPECIFIC CONTENT. SO THAT AS THEY ARE ENGAGING WITH INDIVIDUALS WITHIN EACH OF THESE CONGREGATIONS, THEY'RE PROVIDING THEM WITH INFORMATION ABOUT RARE DISEASE AS WELL, AND THEY CAN ALSO ADDRESS THOSE QUESTIONS THAT MAY ARISE WITHIN THAT PARTICULAR NETWORK OF INDIVIDUALS.

SO I WANT TO PUSH FORWARD TO THE TRAINING PROGRAM BECAUSE I THINK THIS IS SOMETHING THAT A LOT OF PEOPLE ARE PRETTY INTERESTED IN IN TERMS OF WHAT WE THOUGHT WAS VERY VALUABLE FOR OUR COMMUNITY HEALTH WORKERS. I ALSO WANT TO SAY THAT THIS IS A BIDIRECTIONAL EDUCATION.

WITH THAT BEING SAID, AND I GIVE THIS

EXAMPLE BECAUSE IT'S VERY FUNNY, BUT IT'S VERY REAL. I COME IN. I'M LIKE, HEY, WE'RE GOING TO HAVE THIS GREAT PROJECT. WE'RE GOING TO DO THIS. WE'RE GOING TO HAVE THIS COMMUNITY FAIR, AND WE'RE GOING TO DO ALL OF THESE GREAT THINGS. AND MY COMMUNITY HEALTH AMBASSADOR HERE IN BIRMINGHAM WAS LIKE, TENEASHA, THAT'S NOT GOING TO WORK. I WAS LIKE WHAT DO YOU MEAN? THIS IS AWESOME. WE'RE GOING TO DO THIS, WE'RE GOING TO DO THAT. SHE'S LIKE, NO, THAT'S NOT GOING TO WORK. WE CAN BARELY GET PEOPLE TO COME OUT TO TALK ABOUT DIABETES OR ANYTHING ELSE. SO WE'RE GOING TO HAVE TO DO SOMETHING THAT'S VERY UNIQUE TO THE POPULATION THAT WE'RE TRYING TO REACH OUT TO.

IN ADDITION TO THAT, IT'S ALSO IMPORTANT THAT WE RECOGNIZE THAT, YES, THESE ARE FAITH-BASED ORGANIZATIONS. BUT WHEN THEY HOST EVENTS, THEY HOST EVENTS FOR THEIR LARGER COMMUNITY. SO IT DOESN'T JUST MEAN THAT INDIVIDUALS FROM THESE CONGREGATIONS ARE ATTENDING. THIS IS THE COMMUNITY THAT ARE ATTENDING THESE EVENTS TO RECEIVE FREE GROCERIES, ALL THOSE DIFFERENT TYPES OF THINGS. SO IT WAS VERY IMPORTANT THAT WE LISTENED AND REALLY THOUGHT THROUGH WHAT SHE WAS STAYING TO BE ABLE TO OFFER WHAT WE NEEDED TO OFFER.

BUT THIS IS WHERE WE STARTED. SO OUR

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COMMUNITY HEALTH WORKERS WERE REALLY TRAINED ON THE CORE COMMUNITY HEALTH WORKER COMPONENT OF THEIR WORK THROUGH OUR COMMUNITY-BASED ORGANIZATION. IN ADDITION TO THAT, FOR SUSTAINABILITY PURPOSES, AND MORE SO FOR ME, ANY TYPE OF PROJECT THAT I WORK ON, I'M ALL ABOUT MAKING SURE THAT WE ARE NOT JUST TAKING FROM THE COMMUNITY, THAT WE ARE ALSO GIVING TO THE COMMUNITY.

SO WITH THAT BEING SAID, WE TRAINED OUR COMMUNITY HEALTH WORKERS ON THE IRB PROCESS. I'M SURE MANY OF YOU ARE FAMILIAR WITH THAT. MAKING SURE THAT THEY RECEIVE TRAINING AROUND IRB SO THAT REALLY YOU DON'T JUST HAVE TO WORK ON THIS PROJECT. YOU CAN WORK ON MULTIPLE PROJECTS. WHETHER YOU CHOOSE TO WORK IN ACADEMIA, YOU CAN USE THIS SKILL SET BEYOND THIS PARTICULAR PROJECT TO CONTINUE TO FURTHER WHO YOU ARE IN YOUR CAREER DEVELOPMENT. SO THEY HAVE PARTICIPATED IN ALL OF THOSE.

WE ARE ALSO IN THE PROCESS OF DEVELOPING NEW CONTENT FOR RARE DISEASE COMPONENT THAT WE CAN, AGAIN, GO OUT AND ENGAGE EACH OF THESE CONGREGATIONS AND THEIR MEMBERS AROUND RARE DISEASE AND WHAT THAT LOOKS LIKE IN THE WORLD THAT WE LIVE IN TODAY.

AND THEN THIS IS HOW WE KIND OF BUILT OUT THIS PROGRAM FOR THE LARGER GLOBAL GENES NETWORK.

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SO WE HAVE ALL IN. RARE, WHICH IS THE PROGRAM THAT I'VE BEEN DISCUSSING, BUT WE USE ALL IN. RARE AS AN EDUCATIONAL PLATFORM ACROSS ALL OF THE DIFFERENT PROGRAMS WITHIN GLOBAL GENES.

SO IF WE HAVE ANOTHER ANSWERS TO GENETIC TESTING, IT'S ABOUT GENETIC COUNSELING, GENETIC TESTING. RARE CONCIERGE, IN FACT FOR ALL IN. RARE, AS PEOPLE IDENTIFY AS WE BUILD THESE RELATIONSHIPS -- I DIDN'T MENTION THAT -- WE DIDN'T COME TO THE COMMUNITY SAYING GIVE US, GIVE US, GIVE US INFORMATION. I ALWAYS TELL MY STUDENTS, IF YOU'RE WALKING ON THE STREET, DO PEOPLE JUST WALK UP TO YOU AND SAY, HEY, GIVE ME YOUR NAME, GIVE ME YOUR PHONE NUMBER, WHAT IS YOUR DEMOGRAPHIC? NO, THEY THINK THAT'S REALLY STRANGE. SO WHY DO WE THINK THAT COMMUNITIES SHOULD PARTICIPATE IN THAT FORMAT AS WELL. SO WE TRIED OUR BEST TO NOT JUST GET INFORMATION, BUT TO ACTUALLY BUILD AUTHENTIC RELATIONSHIPS WITH COMMUNITY MEMBERS SO THAT THEY ARE ENCOURAGED TO GIVE INFORMATION BASED ON THOSE TYPE OF RELATIONSHIPS.

SO WE ALSO SEND THEM. SO IF THEY HAVE QUESTIONS, IF THEY SAY, YOU KNOW WHAT, SOMEONE IN MY FAMILY DOES HAVE A RARE DISEASE, WE CAN REFER THEM TO THE RARE CONCIERGE PROGRAM. WE CAN LINK THEM TO

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THE ACCESS TO ANSWERS PROGRAM AS WELL.

AND THIS IS OUR WEBSITE. THEY ALSO HAVE ACCESS TO A WEBSITE WHERE THEY FIND OUT INFORMATION ABOUT ALL IN. RARE, BUT THEY CAN ALSO BE CONNECTED TO ADDITIONAL RARE DISEASE RESOURCES IN THE LARGER RARE DISEASE NETWORK.

AND THEN I KNOW YOUR FAMILY HISTORY. WE'RE WORKING ON -- THIS WAS ACTUALLY A SOCIAL MEDIA CAMPAIGN. WE'RE WORKING ON PACKAGING IT INTO AN ACTUAL CURRICULUM SO THAT WE CAN ADD THIS FOR OUR TRAINING FOR OUR COMMUNITY HEALTH WORKERS. IN ADDITION, ONE OF MY MAIN GOALS IS GOING TO BE TO SEND THIS TO THE NATIONAL ACCREDITATION BOARD FOR COMMUNITY HEALTH WORKERS SO THAT ALL COMMUNITY HEALTH WORKERS ARE TRAINED ON RARE DISEASE-SPECIFIC INFORMATION VERSUS THE CORE COMPETENCIES THAT THEY'RE TRAINING ON AS OF NOW.

THESE ARE JUST OUR LESSONS LEARNED, THINGS THAT WE'VE LEARNED. OF COURSE, ANYTHING THAT WE DO, WE TRY TO BE AS TRANSPARENT AS POSSIBLE BECAUSE IT'S VERY IMPORTANT. WE'RE WORKING WITH COMMUNITY. I ALREADY EMPHASIZED BIDIRECTIONAL EDUCATION. AND REALLY AUTHENTIC PARTNERSHIPS. AS I MENTIONED, OUR CONGREGATIONS, OUR PASTORS, THEY SIT ON OUR LEADERSHIP TEAM. WE DON'T PUT THEM ON A SEPARATE

COMMITTEE. THEY'RE ON OUR TEAM. THEY MAKE DECISIONS JUST LIKE WE DO.

AND THEN COMMUNITY ENGAGEMENT IS A PROCESS. AND I KNOW FROM AN ACADEMIC PERSPECTIVE, OFTENTIMES WE'RE NOT BUILT IN A SITUATION THAT IS ALWAYS AMENABLE TO DOING EFFECTIVE COMMUNITY ENGAGEMENT, BUT IT'S SOMETHING THAT DOES INVOLVE A LOT OF TIME AND EFFORT.

I MENTIONED PREVIOUSLY OUR NEXT STEPS IS REALLY TO REALLY THINK ABOUT THESE RARE DISEASE-SPECIFIC EDUCATION MODULES FOR OUR COMMUNITY HEALTH WORKERS AND THEN DEVELOPING ADDITIONAL ACCESS TO BROADER RARE DISEASE-SPECIFIC RESOURCES SHOULD PEOPLE NEED THOSE RESOURCES IN THEIR DAILY LIVES.

I HOPE, GEOFF, I TRIED TO GO THROUGH THAT REALLY QUICKLY BECAUSE I KNOW THERE ARE OTHER SPEAKERS, BUT I'M HAPPY TO ANSWER ADDITIONAL QUESTIONS ABOUT THIS PARTICULAR PROGRAM SHOULD YOU ALL HAVE ANY.

DR. LOMAX: THANK YOU SO MUCH. THAT WAS A PERFECT START. ARE THERE QUESTIONS FROM WORKING GROUP MEMBERS?

CO-CHAIRMAN KAHN: WANT TO RAISE THEIR HANDS IN THE ZOOM. THERE WE GO.

SHELDON, I SEE YOUR HAND.

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DR. MORRIS: I WOULD SAY ONE OF THE THINGS ABOUT -- I MEAN YOU'VE GOT A LOT OF PEOPLE INVOLVED. IT'S AWESOME HOW YOU HAD THE DIFFERENT COMMUNITY ADVISORS. DID YOU -- IS THERE ANY WAY THAT YOU WERE LIKE PROVIDING REIMBURSEMENT FOR THEM? HOW DID YOU KEEP THEM ENGAGED OR INVOLVED IN YOUR PROGRAM?

DR. WASHINGTON: YEAH. GREAT QUESTION, SHELDON. SO, YES, WE HAVE SEVERAL -- IN TERMS OF TRANSPARENCY, WE HAVE PROVIDED STIPENDS FOR ALL OF OUR COMMUNITY PARTNERS. SO EACH OF THEM RECEIVE STIPENDS. IN ADDITION TO THAT, OUR COMMUNITY HEALTH WORKERS ACTUALLY RECEIVE A MONTHLY STIPEND FOR THEIR TIME. SO THEY WORK ABOUT TEN HOURS A WEEK DEPENDING ON WHAT'S GOING ON FOR THE MONTH. AND THEY ALSO -- BUT EVERYBODY ON THE PROJECT IS COMPENSATED FOR THEIR TIME AS MUCH AS WE COULD GIVEN OUR SMALL BUDGET.

CO-CHAIRMAN KAHN: KRIS.

DR. SAHA: THANKS, TENEASHA. THAT WAS A REALLY NICE PRESENTATION, IMPRESSIVE WORK.

I WAS WONDERING ABOUT ONE OF YOUR LAST POINTS, HAVING A SEAT AT THE LEADERSHIP TABLE. HOW HAS THAT WORKED OR NOT WORKED? AND CAN YOU SHARE A BIT MORE ABOUT THE CHALLENGES THERE?

DR. WASHINGTON: YEAH. I WOULD SAY THIS

IS PROBABLY ONE OF THOSE PROJECTS THAT IT ACTUALLY WORKS VERY WELL. I DON'T REALLY HAVE ANYTHING IN TERMS OF NEGATIVE THINGS THAT I WOULD SAY THAT HAVE HAPPENED. I WILL SAY THAT IT DEFINITELY GIVES US A DIFFERENT PERSPECTIVE AROUND EVERYTHING THAT WE TRY TO DO. EVEN DOWN TO OUR PROMOTIONAL ITEMS, WE ASKED OUR STEERING COMMITTEE, WE ARE ASKED OUR LEADERSHIP TEAM, WE ALSO ASKED OUR COMMUNITY ADVISORY BOARD.

SO, IF ANYTHING, I WOULD SAY THAT IT DEFINITELY LENGTHENS THE TIME, WHICH IS WHAT I WAS SAYING IN TERMS OF ACADEMIA. OFTENTIMES WE MAY NOT BE SET UP TO SPEND THAT MUCH TIME, BUT IT DEFINITELY TAKES A LOT OF EFFORT AND TIME TO ENGAGE PEOPLE. BUT WE HAVE DEFINITELY DEDICATED OURSELVES TO DOING THAT. BUT THEY ATTEND THE MEETINGS. WE DON'T HAVE ANY ATTENDANCE ISSUES OR THINGS LIKE THAT. WE ALSO PAY THEM FOR THEIR TIME. WE PAY THEM FOR THEIR SPACE. WE DO ALL OF THOSE DIFFERENT THINGS AS WELL.

DR. SAHA: JUST A QUICK FOLLOW-UP. I WAS WONDERING HOW YOU SEE THAT STRUCTURE CONTRASTING WITH WHAT CIRM HAS IN PLACE ALREADY AND MAYBE SOME SUGGESTIONS ON THINGS TO CHANGE OR NOT CHANGE.

DR. WASHINGTON: YEAH. I THINK IT'S A PROCESS. SO I WOULD SAY IT'S NOT SOMETHING THAT YOU CAN JUST SAY, OH, TOMORROW WE'RE GOING TO DO THIS

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GREAT PROJECT. EACH OF THE INDIVIDUALS THAT WE'VE ENGAGED FOR THIS PARTICULAR PROJECT, WE BUILT A RELATIONSHIP WITH THEM FIRST.

WE ALSO HAD MORE OF A, HEY, OUR LEADERSHIP TEAM, THIS IS WHERE WE ALL COME FROM. THIS IS EACH OF OUR EXPERTISE. MAKING SURE THAT EVERYBODY IS ON THE SAME PAGE WHEN IT COMES TO THAT. AND I THINK THAT PLAYED A LOT OF ROLE IN TERMS OF PEOPLE FEELING LIKE THEY WERE AT LEAST ON THE SAME LEVEL IN TERMS OF WHEN WE MAKE DECISIONS, WHICH IS SOMETHING THAT WAS VERY IMPORTANT TO ME.

SO THAT'S KIND HOW WE'VE DONE IT. I WOULD SAY JUST TRUE, AUTHENTIC ENGAGEMENT, AND THEN ALSO PREPPING OTHER PEOPLE WHO ARE NOT USED TO THAT TYPE OF FORMAT ON HOW YOU CAN DO IT AND HOW IT CAN BE EXCITING AND FUN AND PAINTING THAT CASE FOR THEM BECAUSE THAT CAN BE A PROCESS.

DR. SAHA: THANKS A LOT.

DR. WASHINGTON: YOU'RE WELCOME.

CO-CHAIRMAN KAHN: CHRISTINE, YOU'RE NEXT.

DR. MIASKOWSKI: THANKS SO MUCH. THANKS, TENEASHA, FOR THE EXCELLENT PRESENTATION.

I WAS WONDERING IF YOU COULD TALK A LITTLE BIT ABOUT YOUR METRICS FOR SUCCESS AND HOW YOU GO ABOUT EVALUATING THEM. I THINK THAT WOULD REALLY BE

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OF INTEREST TO US AS WE ENGAGE IN THIS ACTIVITY.

DR. WASHINGTON: YES. AWESOME QUESTION. DEFINITELY. OUR METRICS, THAT ALWAYS COMES UP. SO IN THE BEGINNING, OUR METRICS WERE AROUND COMMUNITY ENGAGEMENT. SO THERE ARE WAYS TO MEASURE COMMUNITY ENGAGEMENT IN TERMS OF THINKING ABOUT A SOCIAL NETWORK ANALYSIS. SO, YES, WE'RE ENGAGING THESE FAITH-BASED ENTITIES, BUT HOW ARE WE CONNECTING INDIVIDUALS WITHIN THESE CONGREGATIONS IN ALL OF THOSE DIFFERENT SPACES? SO THAT'S OUR METRICS.

IN ADDITION TO THAT AROUND COMMUNITY ENGAGEMENT PARTICIPATORY RESEARCH, MAKING SURE THAT EACH OF THE METRICS OF THAT PARTICULAR FRAMEWORK ARE ASSESSED. IN ADDITION TO THE PEOPLE METRICS, MAKING SURE, IN TERMS OF TRAINING, OUR COMMUNITY HEALTH WORKERS, MAKING SURE THAT THEY FEEL LIKE THAT THEY ARE COMPETENT IN WHAT THEY'RE DOING, THEIR SELF-EFFICACY. ALSO WITH THE INDIVIDUALS WE MEET IN COMMUNITIES, JUST BASIC DEMOGRAPHIC INFORMATION AROUND WHAT THEY'RE INTERESTED IN, WHAT ADDITIONAL THINGS THAT WE CAN DO. SO IF WE HOST AN EVENT AT A PARTICULAR CONGREGATION, HOW MANY PEOPLE SHOW UP? HOW MANY EDUCATION COMPONENTS DID WE BRING TO THAT SPECIFIC EVENT?

WE ALSO CREATED THIS RARE DISEASE CAHOOT

GAME. SO AS PEOPLE PARTICIPATE IN DIFFERENT ACTIVITIES, THAT'S ONE WAY TO ENGAGE PEOPLE. WE HAVE PROMOTIONAL ITEMS THAT WE CAN GIVE AND REALLY ULTIMATELY TRYING TO IDENTIFY THEIR KNOWLEDGE GAIN IN TERMS OF RARE DISEASE. BECAUSE THAT'S ONE OF OUR ULTIMATE GOALS, TO MAKE SURE THAT THEY UNDERSTAND THAT THERE ARE RESOURCES OUT THERE TO ENGAGE WITH THEM.

SO THERE'S A LOT OF DIFFERENT METRICS, CHRISTINE, DEPENDING ON WHAT PART WE ARE LOOKING AT, EITHER THE HIGHER LEVEL TRAINING OR THE MORE LOWER LEVEL COMMUNITY-BASED KNOWLEDGE GAIN, THINGS OF THAT NATURE.

DR. MIASKOWSKI: IF I COULD ASK ONE MORE QUESTION. IS ANY OF YOUR WORK ABOUT GETTING PEOPLE INTO TREATMENT WITH THESE RARE DISEASES? I CAN TELL -- I'M AN ACADEMIC TOO. SO I CAN TELL YOU ABOUT NUMEROUS METRICS. THE ULTIMATE GOAL OF GETTING PEOPLE CARE THAT THEY NEED, PARTICULARLY WITH THESE RARE DISEASES, I THINK IS REALLY IMPORTANT.

DR. WASHINGTON: YES. GREAT POINT. HERE ACTUALLY IN BIRMINGHAM, UAV HAS ITS OWN UNDIAGNOSED DISEASE PROGRAMS. SO THERE ARE RESOURCES. OUR COMMUNITY HEALTH WORKERS ARE ABLE TO ENGAGE WITH

INDIVIDUALS AND SEND THEM TO THOSE DIFFERENT RESOURCES WITHIN THE COMMUNITY. SO EACH OF OUR COMMUNITY HEALTH AMBASSADORS CREATED RESOURCE GUIDES, AND THAT'S HOW WE KIND OF TRACK. OKAY. SO WHO WAS SENT TO THIS PLACE? SOMEBODY MAY JUST HAVE NEEDED ACCESS TO FOOD. HOW MANY PEOPLE HAVE WE SENT TO THOSE DIFFERENT RESOURCES?

BUT ULTIMATELY, YES, OUR GOAL IS, IF THEY SAY, HEY, I THINK MY CHILD MAY HAVE A RARE DISEASE, HOW DO I GET ENGAGED IN THE RARE DISEASE NETWORK, WE CONNECT THEM TO THOSE DIFFERENT ENTITIES AND PROGRAMS, EVEN CLINICAL TRIALS IF WE FIND SOMETHING THAT'S AMENABLE.

DR. MIASKOWSKI: FANTASTIC. CONGRATULATIONS.

DR. WASHINGTON: THANK YOU.

CO-CHAIRMAN KAHN: SABRINA.

DR. DERRINGTON: HI. AND THANK YOU, DR. WASHINGTON, FOR SUCH AN INCREDIBLE PRESENTATION. I WANTED TO ASK IF YOU HAD DEVELOPED ANY MECHANISMS FOR ASSESSING AND DEALING WITH POTENTIAL CONFLICTS OF INTEREST AS YOU WERE THINKING ABOUT WHO YOU WANTED AS COMMUNITY PARTNERS, BUT ALSO YOU HAVE SOME INDUSTRY PARTNERS LISTED. SO I JUST WANTED TO HEAR A LITTLE BIT MORE ABOUT THAT.

DR. WASHINGTON: YEAH. SO WE DIDN'T NECESSARILY PUT IN SPECIFIC, LIKE, FRAMEWORKS OR ANYTHING. SABRINA, I WILL SAY WHAT WE DID WAS WE MADE SURE THAT IN TERMS OF ACADEMIA, BIOPHARM, THOSE INDIVIDUALS SIT ON OUR STEERING COMMITTEE. THEY ARE NOT -- THEY DON'T SIT ON OUR LEADERSHIP TEAM. THEY ALSO DO NOT SIT ON OUR COMMUNITY ADVISORY BOARD. SO THEY PLAY THIS HIGH LEVEL, HEY, HERE'S WHAT WE ARE DOING ACTIVELY IN THE COMMUNITY TO KIND OF STOP SOME OF THOSE CONFLICTS OF INTEREST SHOULD THEY EXIST.

IN TERMS OF WHEN I WAS TALKING ABOUT OUR NEEDS ASSESSMENT, SO OUR NEEDS ASSESSMENT HAPPENED ABOUT TWO YEARS AGO. SO THAT'S WHEN WE HEAVILY ENGAGED BIOPHARM AND CLINICIANS AND INDIVIDUALS OF THAT NATURE, BUT THEY DON'T PLAY THAT SAME ROLE IN THE DAY-TO-DAY ACTIVITIES FOR THIS PARTICULAR PROGRAM.

DR. DERRINGTON: THANK YOU.

DR. WASHINGTON: YOU'RE WELCOME.

CO-CHAIRMAN KAHN: I INSERTED MYSELF IN THE QUEUE. SO MAYBE I'LL TAKE THIS OPPORTUNITY. I SEE MARIA, BUT LET ME GO FIRST IF THAT'S OKAY.

SO, TENEASHA, THANKS SO MUCH BOTH FOR BEING HERE AND FOR YOUR PRESENTATION. I WONDER IF WE CAN ASK YOU TO HELP GENERALIZE SOME OF THE

LESSONS YOU'VE LEARNED FROM THIS GOOD WORK AND SHARE WITH US WHAT YOU THINK THE BARRIERS, THE BIGGEST BARRIERS HAVE BEEN AND WHAT YOU HAVE DONE TO OVERCOME THEM. SO YOU TALKED A LOT ABOUT EDUCATION AND COMMUNICATION, I GUESS, TOO IN TERMS OF MEETING PEOPLE WHERE THEY ARE. AND OBVIOUSLY YOU SPENT A LOT OF TIME WORKING ON THAT.

ONE OF THE THINGS THAT, I THINK, WE HEAR ABOUT, AND MAYBE YOU CAN TELL US IT'S NOT AS REAL AS THE DISCUSSION WOULD MAKE IT SEEM, IS THAT THERE'S A LACK OF TRUST, A REAL CHALLENGE WITH TRUST ON THE PART OF CERTAIN COMMUNITIES. MAYBE THE EXPERIENCE WITH RARE DISEASE IS A LITTLE DIFFERENT THAN OTHER, BUT MAYBE YOU CAN SAY A LITTLE BIT ABOUT WHETHER THAT IS SOMETHING THAT YOU HAVE NEEDED TO CONFRONT. AND IF SO, REALLY IMPORTANT, I THINK, FOR THIS CONVERSATION, HOW YOU DID THAT SUCCESSFULLY.

DR. WASHINGTON: YEAH. SO I THINK IN TERMS OF TRUST, I JUST THINK THAT'S SOMETHING THAT'S UNDERLYING JUST BASED OFF OF, AS WE ALL KNOW, THE HISTORY AROUND RESEARCH. ONE OF THE THINGS THAT WE'VE DONE, I WOULDN'T SAY NECESSARILY TO GET AROUND IT, IS REALLY BE TRANSPARENT ABOUT THINGS THAT HAVE HAPPENED IN TERMS OF CLINICAL RESEARCH AND THE HISTORY BEHIND WHAT THAT LOOKS LIKE AND HOW RECENT

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THAT WAS. WHEN YOU THINK ABOUT IT, OUR INSTITUTIONAL REVIEW BOARDS WEREN'T SET UP BUT FOR SO LONG. SO JUST BEING VERY TRANSPARENT ABOUT THAT.

ALSO ONE OF THE THINGS THAT I THINK GOES A VERY LONG WAY, SOMETHING THAT WE HAVEN'T NECESSARILY DONE ON THIS PARTICULAR PROGRAM, BUT THINGS THAT HAVE WORKED FOR ME IN OTHER PROGRAMS IS REALLY EDUCATING PEOPLE ON THE CLINICAL TRIAL PROCESS. SO A LOT OF THAT MISTRUST, FROM MY PERSPECTIVE, IS A MISUNDERSTANDING OF THE CLINICAL TRIAL PROCESS BECAUSE IT IS SO DIFFICULT SOMETIMES TO UNDERSTAND.

SO ONE OF THE TIMES -- SO, FOR EXAMPLE, SOMEBODY WAS PARTICIPATING IN A CLINICAL TRIAL ONE TIME. THEY DIDN'T KNOW IT, BUT I KNOW IT BECAUSE I'VE BEEN TRAINED, IN TERMS OF BLINDING. SO SHE WENT TO GO ASK ONE OF THE COORDINATORS SOME INFORMATION ABOUT WHAT SHE WAS DOING. AND THE LADY WAS, LIKE I CAN'T TELL YOU THAT INFORMATION. SO FOR HER, AS A BLACK WOMAN, SHE WAS, LIKE, OH, ABSOLUTELY NOT. I'M GOING TO REMOVE MYSELF FROM THIS CLINICAL TRIAL. AND I TOLD HER, NO, WHAT WAS HAPPENING WAS, BECAUSE THE TRIAL WAS BLINDED, THERE IS CERTAIN INFORMATION THAT SHE CANNOT GIVE YOU IN TERMS OF WHICH PART OF THE TRIAL YOU WERE IN.

SO I THINK A LOT OF THAT IS SHEER

EDUCATION AROUND WHAT IS A CLINICAL TRIAL PROCESS. WHAT DOES IT LOOK LIKE IN TERMS OF EDUCATION? IN ADDITION TO THAT, THE UNDERSTANDING FOR PEOPLE TO KNOW THAT, IN ORDER FOR SOMETHING TO ACTUALLY REACH THE CLINICAL TRIAL PROCESS, THERE HAS BEEN A LONG SET OF YEARS THAT HAVE GONE INTO MAKING SURE THAT THE PROTOCOL IS SET UP IN A WAY THAT IT IS TRYING TO BE SET UP WHERE IT'S GOING TO BE AMENABLE TO EVERYBODY THAT PARTICIPATES.

SO I THINK IN TERMS OF THAT SPECIFICALLY, JEFFREY, THAT IS LITERALLY AROUND EDUCATION AND PEOPLE UNDERSTANDING THAT PROCESS.

WE ALSO BUILT RELATIONSHIPS. I THINK THAT WE ARE NOT USED TO GOING ABOUT BUILDING RELATIONSHIPS IN THE WORK THAT WE DO. AUTHENTIC RELATIONSHIPS, THAT ALSO GOES A LONG WAY.

AND THE LAST THING I'LL SAY ABOUT THAT IS I USED TO THINK OFTENTIMES THAT IT WAS A TRUST ISSUE AS WELL. BUT I WAS -- I HEARD FROM SOMEONE ELSE, AND I THOUGHT THAT THIS WAS KEY. MOST PEOPLE THAT SAY THEY DON'T PARTICIPATE IN CLINICAL TRIALS, SPECIFICALLY PEOPLE OF COLOR, SAY THAT THEY DON'T PARTICIPATE BECAUSE THEY WEREN'T ASKED. SO I THINK THAT'S A HUGE GAP. IT'S NOT NECESSARILY THAT THEY DON'T TRUST. IT'S THAT THEY'RE NOT ASKED FROM THE

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FOREFRONT TO PARTICIPATE IN A CLINICAL TRIAL BECAUSE THEY'RE ALREADY DEEMED AS SOMEBODY THAT'S GOING TO NOT SHOW UP. THEY AREN'T GOING TO HAVE THE RESOURCES TO PARTICIPATE. SO THAT TYPE OF INFRASTRUCTURE VERSUS THE TRUST ISSUE, I THINK, IS MOST IMPORTANT.

CO-CHAIRMAN KAHN: SUPER HELPFUL. ONE LAST THING WHILE I HAVE YOU HERE IS YOU MENTIONED A CONCIERGE SERVICE. IT CONNECTS TO LAST THE POINT YOU JUST MADE. CAN YOU SAY TWO MORE WORDS ABOUT WHAT THAT IS AND HOW IT WORKS?

DR. WASHINGTON: SO BASICALLY GLOBAL GENES HAS A PROGRAM WHERE YOU CAN THINK, LET'S SAY IF PEOPLE HAVE A QUESTION ABOUT THEIR DIAGNOSIS, THEY CAN ACTIVITY ENGAGE WITH SOMEONE FROM GLOBAL GENES AROUND THAT PARTICULAR TOPIC. THEY HAVE ACCESS. THEY CAN CHAT WITH INDIVIDUALS. THEY CAN PARTICIPATE AND FIND DIFFERENT RESOURCES TO ENGAGE IN THE PART OF THEM WITHIN THEIR DIAGNOSIS TRAJECTORY. SO THERE'S JUST A RESOURCE OF PEOPLE THAT CAN HELP THEM IN THAT PROCESS OF BEING DIAGNOSED ALL THE WAY DOWN TO WHAT DO YOU NEED TO DO AFTER YOU'RE DIAGNOSED.

CO-CHAIRMAN KAHN: GOT YOU. THANK YOU. MARIA.

VICE CHAIR BONNEVILLE: THANK YOU. THANK YOU, DR. WASHINGTON, FOR YOUR PRESENTATION. IT WAS WONDERFUL.

AS WE PUT TOGETHER OUR CONCEPT PLAN AND BUDGETS AROUND IT, I ALSO AGREE THAT THE PEOPLE WHO ARE DOING THE WORK ON THE GROUND NEED TO BE COMPENSATED. AND WE'VE STRUGGLED WITH UNDERSTANDING WHAT A COMPARABLE IS AND HOW TO PUT THAT TOGETHER SO THAT EVERYONE FEELS VALUED AND GOOD ABOUT THE WORK THAT THEY'RE DOING AND THAT IT'S AS SERIOUS AS ANYTHING ELSE THAT WE'RE DOING. SO IF YOU COULD SPEAK TO THAT A LITTLE, THAT WOULD BE GREAT.

DR. WASHINGTON: IN TERMS OF WHAT -- OFTENTIMES WE WERE GIVING PEOPLE STIPENDS FOR THEIR SPECIFIC ROLE. SO THE INDIVIDUALS THAT HAD ENGAGED WITH US FOR A VERY LONG TIME, WE WERE GIVING THEM STIPENDS FOR THAT PARTICIPATION BECAUSE OF THE TIME THAT THEY WERE PUTTING INTO THE WORK OVER THE LAST TWO OR THREE YEARS. IT WAS A VERY MODEST STIPEND. SO I MEAN I THINK IT WAS MAYBE 25, $3,000 FOR THEIR TIME SO FAR ON THE PROJECT.

NOW, FOR OUR STEERING COMMITTEE MEMBERS, OUR STEERING COMMITTEE MEMBERS, TO SABRINA'S POINT EARLIER ABOUT CONFLICTS OF INTEREST, THEY DO NOT RECEIVE STIPENDS BECAUSE THEY ARE OFTENTIMES

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208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

REPRESENTING BIOPHARM COMPANIES, THINGS OF THAT NATURE.

NOW, OUR COMMUNITY INDIVIDUALS THAT ARE REPRESENTED, OUR STEERING COMMITTEE MEMBERS, THEY ALSO RECEIVE ABOUT A $1500 STIPEND. SO WE'VE SET IT UP -- I SAID ALL THAT TO SAY, MARIA, WE SET IT UP IN A WAY THAT ANY TIME, OFTENTIMES WHEN WE HAVE STEERING COMMITTEES, WE PAY PEOPLE THAT ARE PART OF THOSE COMMITTEES. SO IT WASN'T SOMETHING THAT WE REALLY HAD, SO WE SAY, HEY, HOW MUCH DO WE USUALLY PAY OUR STEERING COMMITTEE MEMBERS OR OUR COMMUNITY ADVISORY BOARD MEMBERS TO PARTICIPATE.

NOW, IN TERMS OF EVENT-BASED THINGS IN EACH OF THE CONGREGATIONS, WE HAD A BUDGET PUT ASIDE FOR THEM TO HOST THE EVENT THAT WERE SPECIFIC TO OUR PROGRAM. SO JUST LIKE WE WOULD PAY FOR AN OFFSITE SITE TO LAUNCH AN EVENT, WE WOULD PAY THE EXACT SAME THING TO OUR CONGREGATION MEMBERS. I HAVE DEFINITELY HAD PUSHBACK FROM THEM, SAYING, OH, NO. WE HAVE PRINTERS. WE DON'T NEED ANY FUNDS. AND I ALWAYS SAY, IF UAV GETS A GRANT, GUESS WHAT. THEY'RE GOING TO PULL MONEY, 50 SOMETHING PERCENT ACTUALLY, THAT GOES TOWARDS ALL OF THOSE INDIRECT COSTS. SO MAKING SURE THAT WE THINK ABOUT THAT IN TERMS OF OUR COMMUNITY MEMBERS AS WELL. BUT THEY

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WILL GIVE PUSHBACK BECAUSE THEY'RE NOT USED TO IT.

VICE CHAIR BONNEVILLE: THANK YOU.

DR. LOMAX: GREAT. I JUST WANT TO AT THIS POINT -- THANK YOU SO MUCH. BY THE WAY, I'VE GOT A LONG LIST OF VERY CONCRETE RECOMMENDATIONS HERE. I'M HAPPY REITERATE AT THE END IF THAT'S HELPFUL AS A SUMMARY. THANK YOU SO MUCH. THIS IS ALL, AGAIN, INFORMATION THAT WILL INFORM OUR PROCESS.

I WANTED TO INVITE MARSHA TREADWELL AND LIZA JOHNSON IN NOW INTO THE CONVERSATION. WE INVITED THEM IN -- AGAIN, THEY ALSO, I THINK HAVE SOME FAMILIARITY DOING SOME RELATED WORK, PARTICULARLY IN THE SICKLE CELL SPACE, WHICH I THINK IS AN AREA IN TERMS OF OUR CLINICAL PORTFOLIO NOW AND MOVING FORWARD. SO I'D KIND OF LIKE TO INVITE THEM BOTH TO COME IN, MAYBE JUST MAKE SOME INITIAL REMARKS IN TERMS OF SPECIFICALLY SORT OF THEIR EXPERIENCE IN APPLYING SOME OF THESE PRINCIPLES OR SOME OF THIS FRAMEWORK IN THEIR WORK. AND PARTICULARLY TO THE EXTENT, MARSHA, THERE'S THINGS MAYBE UNIQUE IN CALIFORNIA WE NEED TO THINK ABOUT, WE REALLY INVITE YOUR PERSPECTIVE AND WELCOME IT. THANK YOU.

DR. TREADWELL: THANK YOU SO MUCH AND THANK YOU FOR THE PRESENTATION AND CONVERSATION THAT

JUST OCCURRED.

SO I'M MARSHA TREADWELL. I'M THE CO-DIRECTOR OF THE UCSF SICKLE CELL CENTER OF EXCELLENCE, AND I'M ALSO THE CO-CHAIR FOR THE BENIOFF CHILDREN'S HOSPITAL'S DIVERSITY, EQUITY, AND INCLUSION AND ANTIRACISM COUNCIL.

SO AS THIS CONVERSATION WAS OCCURRING, I MADE A FEW NOTES ABOUT AREAS TO REINFORCE OR EXPAND ON AS YOU'RE THINKING ABOUT THESE COMMUNITY ENGAGEMENT PROGRAMS.

FIRST, I REALLY WANTED TO HIGHLIGHT THE IMPORTANCE OF SORT OF THE ACADEMIC RESEARCHER/ CLINICIAN SIDE OF THINGS. SO WHEN YOU'RE LOOKING AT EVALUATING PROGRAMS OR OVERSEEING PROGRAMS, TENEASHA NICELY POINTED OUT AUTHENTIC RELATIONSHIPS, TRANSPARENCY. AND IT WILL BE IMPORTANT TO REALLY LOOK AT HOW IS THAT OPERATIONALIZED.

SO AN EXAMPLE FOR US WAS THAT WE HAVE A REGIONAL COLLABORATIVE. HRSA ASKED US TO ALIGN WITH COMMUNITY-BASED ORGANIZATIONS. AND WE HAVE A NUMBER OF CLINICS AND CLINICIANS. AND SO THE CBO'S, SOME OF THEM, HAVE VERY DIFFERENT CAPACITIES TO ACTUALLY ENGAGE AND PARTNER. AND SOME OF THE CLINICIANS DIDN'T HAVE AS MUCH EXPERIENCE WITH PARTNERING.

SO WE HAVE REGULAR MEETINGS BETWEEN THE

TWO ENTITIES WITH THE LEADERSHIP AND WHERE WE COACH CLINICIANS ON THAT ENGAGEMENT, THOSE CONVERSATIONS WITH THE COMMUNITY, THE CONCRETE STEPS TO EDUCATE, TO BUILD TRUST, AND SO ON.

AND THE OTHER THING IS THAT PART OF OUR EVALUATION IS WE ASK THEM HOW MUCH HAVE YOU TWO MET OVER THE COURSE OF THE FUNDING CYCLE. AND SO WE WANT THEM, AGAIN, TO OPERATIONALIZE THE COMMUNICATION THAT THEY HAVE BETWEEN THEM AND THEN -- SO THE PROCESS PART, AND THEN AS TENEASHA POINTED OUT, THEN WE MOVE INTO THE EVALUATION, THE OUTCOMES, WHAT WE ARE REALLY LOOKING FOR.

SECOND THING THAT I WANTED TO EXPAND ON A LITTLE BIT IS TRUST. AND THE HISTORY OF INEQUITY AND EXPLOITATION AND NEGLECT IS NOT IN THE PAST. SO IT'S NOT A HISTORY. SO WHEN YOU'RE LOOKING AT APPLICATIONS OR PUTTING OUT AN OUTLINE AROUND COMMUNITY ENGAGEMENT PROGRAMS, LOOK AT ENVIRONMENTAL INJUSTICE. YOU WILL SEE THAT COMMUNITY, BI-POP COMMUNITIES, ARE EXPOSED TO WASTE, HIGH INCIDENCE OF ASTHMA, ARE EXPOSED TO FACTORY EMISSIONS. AND SO COMMUNITIES KNOW THIS. AND IF WE GO TO COMMUNITIES AND TALK ABOUT A HISTORY, IT'S ALSO IMPORTANT FOR US TO TALK ABOUT WHAT IS CURRENTLY HAPPENING IN TERMS OF HEALTH DISPARITIES, HEALTH INEQUITIES, AND

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ENVIRONMENTAL INJUSTICE THAT LENDS TO THOSE INEQUITIES.

SO, AGAIN, I'M JUST EMPHASIZING THAT IT'S NOT DISTANT. PEOPLE EVEN, SAY, YEARS AGO OR TUSKEGEE; BUT, NO, IT'S NOT DISTANCE. IT'S NOW.

AND THEN A THIRD THING IS THIS ACCESS TO COMPREHENSIVE CARE THAT CHRISTINE BROUGHT UP. AND FOR SICKLE CELL DISEASE, IT'S NOT JUST ABOUT THE EXPENSIVE TECHNOLOGIES AND THE RESEARCH. IT'S ABOUT THE LACK OF COMPREHENSIVE CARE, PARTICULARLY FOR ADULTS WITH SICKLE CELL DISEASE. SO ANY CLINICAL PROGRAM THAT WOULD BE APPLYING FOR FUNDING NEEDS TO REALLY TALK ABOUT HOW ARE THEY PROVIDING COMPREHENSIVE CARE NOW. HOW WILL THEY PROVIDE LONG-TERM FOLLOW-UP FOR PEOPLE WHO DO PARTICIPATE IN THE CELL AND GENE THERAPIES? AND HOW DO THEY REALLY LOOK AT RECTIFYING A HISTORY OF NEGLECT?

AND THEN THE LAST THING I'LL SAY IS ABOUT AN ANTIRACISM FRAMEWORK. AND THERE ARE A LOT OF ISMS THAT IMPACT HEALTH. SO SEXISM, ABLEISM. BUT STARTING WITH RACISM, GIVEN ITS FUNDAMENTAL ASPECT IN THIS COUNTRY, CAN BE REALLY HELPFUL. AND IT DOESN'T MEAN THAT THERE ISN'T ATTENTION TO OTHER FACTORS. IT JUST MEANS THAT IT IS A ROOT OF INEQUITY AND HEALTH INEQUITY IN THIS COUNTRY AND IN

133 HENNA COURT, SANDPOINT, IDAHO 83864
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THE STATE OF CALIFORNIA.

SO AN ANTIRACISM FRAMEWORK, THERE IS A SCIENCE AND A PRACTICE TO IT. AND SO, AGAIN, IN SORT OF ASSESSING HOW WELL MIGHT A PROGRAM GO TOWARDS ADDRESSING INEQUITIES, EXERCISING THE ANTIRACISM PRACTICE AND FRAMEWORKS CAN BE REALLY HELPFUL AND REALLY LOOKING AT INTERPERSONAL, PERSONAL, INSTITUTIONAL, AND STRUCTURAL AND ADDRESSING ALL OF THOSE LEVELS.

AND I'LL JUST WRAP UP WHAT I'M SAYING RIGHT NOW BY BRINGING IT BACK TO THAT ANTIBIAS TRAINING FOR PROVIDERS, TRAINING FOR THEM TO APPRECIATE, AND RESEARCHERS, TO APPRECIATE THE -- I INTERRUPTED MY OWN TRAIN OF THOUGHT -- ANTIBIAS TRAINING AND THEN TRAINING FOR -- APPRECIATION OF DIVERSITY AND HEALTH DISPARITIES AND HISTORIC ISSUES CAN BE REALLY HELPFUL. SO THAT NEEDS TO BE A PART OF WHAT HAPPENS, AND THERE NEEDS TO BE ACTUAL TRAINING AND DRAWING ON PEOPLE WHO ACTUALLY HAVE EXPERTISE IN THESE AREAS.

AGAIN, THERE IS A SCIENCE AND PRACTICE TO ANTIRACISM, AND THAT NEEDS TO REALLY BE LOOKED AT, NOT JUST PUTTING THE WORD OUT THAT WE'RE DEALING WITH HEALTH INEQUITIES, BUT HOW ARE YOU DOING IT GIVEN THE SCIENCE AND PRACTICE THAT IS OUT THERE

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THAT CAN BE GUIDING.

SO I'LL STOP THERE AND SEE IF YOU HAVE QUESTIONS OR HOWEVER THIS FLOW WILL BE.

DR. LOMAX: LIZA, WOULD YOU LIKE TO ADD TO THIS AND, AGAIN, WE'LL COME BACK FOR ROUND. I DON'T SEE ANY HANDS UP.

DR. JOHNSON: YEAH. THAT'S GREAT. GOOD MORNING, EVERYONE. MY NAME IS LIZA JOHNSON. I'M A PHYSICIAN AT THE ST. JUDE CHILDREN'S RESEARCH HOSPITAL. AND I STUDY INFORMED CONSENT, AND I WORK WITH DR. AKSHAY SHARMA, WHO MANY OF YOU KNOW FROM BEING ON THE GROUP ALTHOUGH HE'S NOT HERE TODAY. AND MY WORK HAS LED ME TO TAKING SORT OF A COMMUNITY-BASED PARTICIPATORY RESEARCH APPROACH WITH PARENTS OF CHILDREN WITH SICKLE CELL DISEASE OR PATIENTS WITH SICKLE CELL DISEASE REGARDING HIGH RISK, HIGH REWARD INTERVENTIONS AND JUST BONE MARROW TRANSPLANT OR GENE THERAPY.

AND SO WE'VE HAD A PATIENT ADVISORY COUNCIL THAT WE WORKED WITH FOR TWO YEARS. AND WE HAD A STEERING COMMITTEE ABOUT THAT. SO I ALSO KIND OF TOOK SOME NOTES DURING THE FIRST TWO PRESENTATIONS. I THINK SOME THINGS TO REMEMBER IS THAT THERE ARE DEFINITELY IMPLICIT AND EXPLICIT BIASES THAT RESULT IN CERTAIN POPULATIONS NOT BEING

OFFERED CLINICAL TRIALS BECAUSE THEY'RE NOT A GOOD PARTICIPANT FOR WHATEVER SORT OF REASON THE INVESTIGATOR OR CLINICIAN THINKS THAT THEY WOULDN'T WANT TO PARTICIPATE OR THEY WOULDN'T COME TO ALL THE REQUIRED STUDY VISITS.

BUT WE DO HAVE SOME EMPIRIC RESEARCH AT OUR INSTITUTION WHICH SHOWED THAT BLACK RACE WAS THE SINGLE PREDICTOR OF NOT ENROLLING IN A GENOMIC SEQUENCING STUDY, ACTUALLY TWO DIFFERENT GENOMIC SEQUENCING STUDIES. IT WAS SORT OF WE WERE LOOKING BACK AT WHO DECLINED, AND WE SAW SIGNIFICANT DIFFERENCE THERE; BUT BECAUSE OF SORT OF THE APPROACH, WE DON'T KNOW WHY THE INDIVIDUALS SAID NO TO THOSE STUDIES. AND WE'RE TRYING TO UNDERSTAND A LITTLE BIT MORE ABOUT THAT IN SOME ONGOING RESEARCH.

I THINK WE HAVE LEARNED FROM THE ADVISORY COMMITTEE THAT IT'S IMPORTANT TO HAVE PATIENT STAKEHOLDERS INVOLVED EARLY ON FROM THE BEGINNING OF SOME PROCESS. SO I THINK ANY GROUPS APPLYING FOR COMMUNITY ENGAGEMENT, THEY SIT ON THEIR STEERING COMMITTEE OR HAVE SOME PATIENTS INVOLVED IN THE PROCESS. AND THEN WHEN IT RELATES TO CLINICAL TRIALS, ALSO HAVING A PATIENT STAKEHOLDER.

I THINK IN EVALUATING PROGRAMS, SORT OF THE SUCCESS WE HAD WAS THAT OUR FACILITATOR WAS SEEN

133 HENNA COURT, SANDPOINT, IDAHO 83864
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AS AN ALLY AMONG THE PATIENT ADVISORY GROUP. IT WAS SOMEONE WHO HAD A LONG SORT OF HISTORY OF WORKING WITH PATIENTS WITH SICKLE CELL DISEASE. I THINK THAT FACILITATORS, IT'S HELPFUL IF THEY HAVE FACILITATION EXPERIENCE OR EXPERIENCE SORT OF WITH QUALITATIVE INTERVIEWING SO THEY CAN SORT OF HELP GUIDE WORK WITH COMMUNITY MEMBERS. I THINK IT'S IMPORTANT TO HAVE A STRUCTURE, BUT NOT SORT OF BE TOO RIGID WITH THE GOALS OF AN APPLICATION. SO IT'S SORT OF AN ITERATIVE PDSA TYPE APPROACH.

ONE EXAMPLE IS ONE OF OUR FACILITATORS SHOWED A SHORT VIDEO ABOUT GENE THERAPY THAT WAS PRODUCED BY SORT OF A MAJOR ACADEMIC CENTER IN CALIFORNIA ACTUALLY. AND THEN SHE JUST ASKED FOR FEEDBACK. AND SO THE GROUP ALREADY HAD TRUST WITH EACH OTHER BECAUSE THEY'D OFTEN DONE SORT OF ICEBREAKERS AT THE BEGINNING OF THE FOCUS GROUP SESSIONS. THE PATIENTS -- OR THE PARTICIPANTS FELT VERY SORT OF OPEN AND HONEST, AND THEY WERE SORT OF LIKE THAT MAN IS TOO ATTRACTIVE TO BE LIKE A SICKLE CELL DISEASE PATIENT UNDERGOING GENE THERAPY. LIKE WHY DOES HE HAVE HAIR AT THE BEGINNING AND NOT HAIR AT THE END?

AND SO I THINK THAT REALLY SORT OF HAVING A GROUP THAT FOSTERS OPENNESS, YOU REALLY SORT OF

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GET KIND OF LIKE HONEST ANSWERS. I WOULD HAVE THOUGHT AS A MEDICAL PROVIDER WHO TREATS PATIENTS WITH SICKLE CELL DISEASE THAT THE VIDEO WAS SORT OF GREAT. BUT YOUR COMMUNITY MEMBERS SORT OF HAVE A DIFFERENT APPROACH. SO WE WEREN'T SORT OF TOO RIGID. WE WERE JUST REALLY TRYING TO FEEDBACK.

TO BACK UP, I SHOULD SAY THE AIM OF THIS WORK IS TO DEVELOP EDUCATION ABOUT GENE THERAPY FOR PATIENTS WITH SICKLE CELL DISEASE.

AND THEN I THINK A LESSON THAT I LEARNED AS SORT OF FACILITATING THIS GROUP IS SORT OF POTENTIAL PITFALLS OR BLIND SPOTS OR CHALLENGES THAT INDIVIDUALS OF LOW SOCIOECONOMIC STATUS MAY HAVE. SO OUR GROUP WAS REGIONALLY DIVERSE. AND WE ALL MET IN CHICAGO BECAUSE IT WAS A DIRECT FLIGHT FROM THE SORT OF DIFFERENT AREAS OF THE UNITED STATES. AND WE HAD PAID FOR THE HOTEL ROOMS; BUT WHEN OUR PARTICIPANTS HAD TO CHECK IN, THEY HAD TO PUT A CREDIT CARD ON FILE FOR THE DEPOSIT FOR THE WEEKEND STAY FOR INCIDENTALS. AND MANY OF THEM DIDN'T HAVE A CREDIT CARD AND THEY HAD A DEBIT CARD. SORT OF THE HOLD FROM THE HOTEL WAS ALL THE MONEY THAT THEY HAD TO SPEND FOR THE WEEKEND IN CHICAGO.

SO I THINK THAT WHEN WORKING WITH SORT OF DISADVANTAGED GROUPS, THAT WAS SOMETHING I DIDN'T

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ANTICIPATE A PROBLEM COMING UP. SO I THINK ALSO, IF I WERE TO DO IT OVER AGAIN, I WOULD HAVE MAYBE INVOLVED ONE OF THE PATIENTS MORE HEAVILY SORT OF IN THE PLANNING OR JUST SORT OF RECOGNIZING THAT IF YOU'RE EVALUATING PROJECTS THAT HAVE PEOPLE OF LOWER SOCIOECONOMIC STATUS, HOW IS IT GOING TO BE POSSIBLE SORT OF PARTICIPANTS IN THE COMMUNITY TO SORT OF REACH KIND OF INTERVENTIONS OR THE DIFFERENT SESSIONS THAT ARE HAPPENING. I THINK THAT THOSE ARE ALL MY POINTS.

CO-CHAIRMAN KAHN: GREAT. ANY QUESTIONS OR COMMENTS?

DR. LOMAX: I'VE GOT ONE. APPARENTLY I'M NOT JUMPING THE QUEUE. SO, AGAIN, THANK YOU ALL.

SO YOU ALLUDED TO A NUMBER OF OCCASIONS WHERE YOU WERE WORKING WITH SORT OF WITHIN PROGRAM GRANTS, TYPE OF THINGS THAT CIRM MIGHT FUND. AND ONE OF THE POINTS OUR BOARD MEMBERS RAISED IS SORT OF MAKING SURE THAT WE PLAY AN APPROPRIATE ROLE IN TERMS OF HELPING SUPPORT, GUIDE, FACILITATE, WHAT DOES THAT LOOK LIKE IS REALLY MY QUESTION.

FROM YOUR PERSPECTIVE, I KNOW YOU'VE WORKED IN THESE TYPES OF RELATIONSHIPS AND THESE PROGRAMS, DO YOU THINK THE FUNDING PARTNER CAN BE PARTICULARLY USEFUL, SOMEWHAT USEFUL, OR POTENTIALLY

NOT THAT HELPFUL, SO WE KIND OF UNDERSTAND WITHIN THAT LANDSCAPE HOW WE THEN MIGHT APPLY OUR CIRM RESOURCES IN TERMS OF A SORT OF APPROACH TO MANAGING THIS AWARD?

DR. JOHNSON: I CAN GO FIRST SINCE OUR PROJECT WAS FUNDED WITH A TWO-YEAR AWARD. WE HAD A LIAISON WHO WAS SORT OF ASSIGNED. AND SO SHE WAS THE PERSON WE MET WITH, I THINK, QUARTERLY, MAYBE EVERY OTHER MONTH. OR WE MET WITH HER, I THINK, QUARTERLY AND WOULD SEND PROGRESS REPORTS ON THE OTHER MONTHS. AND THEN SHE WOULD REPORT BACK HOW THE COMMUNITY GROUP WAS WORKING TO SORT OF THE BOARD OR STEERING COMMITTEE. AND THEN SORT OF IF THEY HAD ANY QUESTIONS OR CONCERNS RELAY THEM.

AND SHE HAD SOME EXPERIENCE IN THE RESEARCH METHODS WE WERE USING. SO IT WAS SORT OF HELPFUL TO JUST GET HER PERSONAL PERSPECTIVES AND HELP GUIDE OUR DISCUSSIONS. SO I THINK WE HAD SUPPORT, BUT IT WASN'T LIKE THE HAND ON US WASN'T TOO DIRECTIVE TO BE SORT OF INTERFERING. IT WAS DEFINITELY HELPFUL. AND I'LL LET THE OTHERS CHIME IN.

DR. TREADWELL: WE'VE CERTAINLY HAD A NUMBER OF AGREEMENTS WHERE THE FUNDER IS VERY CLOSELY WORKING WITH US IN REGULAR MEETINGS. SO I

WORKED WITH DIFFERENT MODELS. AND I WOULD THINK ONE OF THE -- THE IMPORTANT THING TO DO IS MAKE SURE YOU HAVE IN PLACE ADEQUATE TECHNICAL ASSISTANCE. SO WHEREVER THAT COMES FROM, IF IT HAS TO BE FUNDED SEPARATELY OR IF THERE'S A COORDINATING CENTER THAT IS GOING TO PROVIDE THAT TECHNICAL ASSISTANCE, OR IF IT COMES FROM THE FUNDER PER SE, WHEREVER IT COMES FROM, THAT IS WHAT YOU NEED TO HAVE REALLY IS, AGAIN, JUST ACCESS FOR THE PROGRAMS ON THE GROUND TO HAVE MENTORING, COACHING, WHATEVER YOU WANT TO CALL IT, BUT, AGAIN, ACCESS TO TECHNICAL ASSISTANCE.

SO I WORKED IN DIFFERENT MODELS, AS YOU MENTIONED, WHERE THERE'S MORE OF A CLOSE RELATIONSHIP WITH THE FUNDER OR NOT. AND I THINK THAT'S REALLY MORE THE KEY THOUGH IS THAT SOMEONE IS THERE TO PROVIDE ALL OF US WITH TECHNICAL ASSISTANCE IF IN FACT THE FUNDER DOESN'T HAVE AS MUCH EXPERIENCE IN THE AREA.

CAN I COMMENT ON THE -- I DON'T THINK WE REALLY ADDRESSED THE SPECIFIC CALIFORNIA ISSUES THAT MIGHT COME UP. AND WE FOCUSED ON THE BLACK AND AFRICAN-AMERICAN POPULATION ON THE PANEL. BUT CALIFORNIA IS THE MOST DIVERSE STATE IN THE COUNTRY. AND SO I THINK THAT, JUST AS BLACKS AND AFRICAN-AMERICANS ARE NOT A MONOLITHIC GROUP,

DIFFERENT GROUPS, DESPITE FACING NEGATIVE SOCIAL DRIVERS OF HEALTH, ARE GOING TO FACE IT IN DIFFERENT WAYS.

AND SO SPECIFICALLY IN SICKLE CELL, FOR EXAMPLE, WHEN WE LOOK AT THE LATINX, LATIN-A POPULATION, ENGAGEMENT IN OUR COMPREHENSIVE SICKLE CELL CENTERS, IT REALLY TAKES WORK AND PARTNERSHIP BECAUSE THE DISEASE HAS BEEN SO MUCH ALIGNED WITH THE BLACK AND AFRICAN-AMERICAN EXPERIENCE. AND THEN IN THALASSEMIA WHERE IN CALIFORNIA WE HAVE SUCH A LARGE SOUTHEAST ASIAN POPULATION, AGAIN, THERE ARE DIFFERENT DRIVERS OF HEALTH THAT REALLY HAVE TO BE EVALUATED AND REALLY ADDRESSED VERY SPECIFICALLY, WHETHER IT'S LANGUAGE, TRANSPORTATION, JUST THE RANGE.

SO I THINK IN CALIFORNIA WE DO HAVE UNIQUE CHALLENGES IN REALLY ENSURING THAT THESE ENGAGEMENT PROGRAMS LOOK AT THE HISTORY OF EACH POPULATION, BUT ALSO INDIVIDUALIZE AND REALLY LOOK AT THE STRUCTURES THAT ARE IN PLACE THAT MAY BE POSING BARRIERS TO PARTICIPATION OR TO COMPREHENSIVE CARE.

CO-CHAIRMAN KAHN: HELPFUL. CHRISTINE, I SEE YOUR HAND.

DR. MIASKOWSKI: THANKS VERY MUCH, JEFF. I WAS CURIOUS AND I'D APPRECIATE ANY OF THE SPEAKERS

133 HENNA COURT, SANDPOINT, IDAHO 83864
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SHARING. HAVE YOU AT ALL IN YOUR PROGRAMS ENGAGED THE MEDIA, SO NEWSPAPERS, RADIO, TWITTER, WHATEVER IT IS, TO INCREASE YOUR COMMUNITY ENGAGEMENT? I SIT ON THE COMMUNICATIONS COMMITTEE FOR CIRM TOO. SO I WAS WONDERING ABOUT THOSE ACTIVITIES.

AND, MARSHA, IT'S NICE TO SEE YOU AGAIN. IT'S BEEN A LONG TIME.

DR. TREADWELL: GREAT TO SEE YOU. SO I'LL START.

WE DEFINITELY HAVE ENGAGED THE MEDIA AND ARE WORKING WITH ALSO PEOPLE WITH SICKLE CELL DISEASE AS WELL AS GENERATIONS WHO ARE MOST COMFORTABLE OR MOST KNOWLEDGEABLE ABOUT THE SOCIAL MEDIA WAYS TO APPROACH THINGS.

SO WE'VE HAD INTERVIEWS WITH BLACK AFRICAN-AMERICAN OUTLETS. AND, IN FACT, I WAS INTERVIEWED BY A PAPER IN SACRAMENTO. AND MY COUSIN IN ST. LOUIS SHOWED ME THAT THE ARTICLE MADE IT THERE. SO YEAH. WE'RE ENGAGING DEFINITELY. BUT I THINK THE SOCIAL MEDIA AND REALLY BEING ON TOP OF INSTAGRAM NOW, TIKTOK, AND IT'S NOT FACEBOOK FOR SURE. SO THESE THINGS WE'RE DEFINITELY ENGAGED WITH.

CO-CHAIRMAN KAHN: OTHERS OF YOU HAVE EXPERIENCE THAT WAY?

DR. JOHNSON: WE HAVEN'T DIRECTLY ENGAGED WITH THE MEDIA. OUR FUNDER DID A STORY ABOUT OUR PROJECT. THEY PUBLISHED IN THEIR NEWSLETTER, AND IT'S BEEN OUT THERE. WE'RE DEVELOPING SOME CONTENT. AND PROBABLY ONCE THE CONTENT IS READY FOR PRIME TIME, WE WILL SORT OF PUT IT OUT THERE A LITTLE BIT MORE.

I'VE SUBMITTED A WORKSHOP PROPOSAL TO A CONFERENCE, AND WE INVITED ONE OF THE FOCUS GROUP -- ONE OF THE PARTICIPANTS IS INVITED TO BE ON THE PANEL AS A PATIENT REPRESENTATIVE. SO I THINK WE'RE TRYING TO GET IT OUT THAT WAY IF THAT MAKES SENSE.

CO-CHAIRMAN KAHN: I SEE JOHN'S HAND.

DR. TUPIN: SO DAVIS HAS MOVED TO DIRECT CONTACT WITH INDIVIDUALS WITHIN OUR CATCHMENT AREA. AND SO THE PROBLEM THAT WE ENCOUNTERED IS THAT LARGELY MEDIA IS NOT VERY EFFECTIVE, NEWSPAPERS, TV, RADIO. SO WE HAVE CREATED A TEXTING PROGRAM.

AND SO WHAT WE'VE DONE IS WE'VE CREATED A LEGAL FRAMEWORK BY WHICH WE CAN REACH OUT TO KNOWN INDIVIDUALS THAT WE'VE ENGAGED THROUGH COMMUNITY ENGAGEMENT, ET CETERA. AND THEN ONCE WE HAVE A LITTLE BIT OF INFORMATION ABOUT THEM, EITHER THEY'VE ALREADY BEEN SEEN AT ONE OF OUR CLINICS OR THEY'VE COME TO ONE OF OUR OUTREACH. COVID WAS ACTUALLY

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VERY HELPFUL FOR OUTREACH BECAUSE WE WENT INTO THE COMMUNITIES AND DID TESTING AND DID VACCINES, ET CETERA. BUT THE TEXTING IS -- 95 PERCENT OF THE ADULT POPULATION HAVE PHONES. AND SO IF THEY KNOW WHO YOU ARE AND IF YOU ANNOUNCE WHO YOU ARE IN THE TEXT, HEY, THIS IS DAVIS AND WE'VE GOT THIS THING THAT WE THINK YOU'D BE INTERESTED IN, AND THEN CREATE A LANDING PAGE FOR THEM IN THEIR NATIVE LANGUAGE.

SO YOU'RE CREATING YOUR OWN MEDIA. AND THAT IS SOMETHING THAT WE'VE BEEN WORKING REALLY HARD TO MOVE FORWARD AND HAVE PARTNERED WITH STUDYPAGES, WHICH IS A PLATFORM THAT WE USE FOR ADVERTISING OUR CLINICAL TRIALS. SO WE CAN BRING PEOPLE TO US. AND IT'S A BIT MORE OF A FOCUSED SHOT. AND THE RESPONSE RATE IS REALLY MUCH HIGHER THAN YOU WILL GET WITH EMAIL AND NEWSPAPER AND ET CETERA. SO I'LL KEEP YOU ALL POSTED AS THAT PROGRAM CONTINUES TO EVOLVE, BUT HIGHLY RECOMMEND LOOKING AT ALTERNATIVES AND DIRECT MARKETING.

CO-CHAIRMAN KAHN: TENEASHA, I SEE YOU MUTED THERE BEFORE.

DR. WASHINGTON: I LOVE THAT, BY THE WAY. THAT'S PHENOMENAL. I'LL LOOK THAT UP A LITTLE BIT. I WILL SAY TO THAT POINT AND I'LL SAY IT BRIEFLY, WE

HAVE FOUND THERE ARE DEFINITELY GENERATIONAL DIVIDES. SO THE SAME THING THAT HAS WORKED IN TERMS OF INSTAGRAM AND TIKTOK AND ALL OF THOSE THINGS, SOMETIMES IN SOME OF THE CONGREGATIONS, WE HAVE HAD TO DO VERY PAPER-BASED, NO QR CODE BECAUSE THEY LIKE HANDWRITTEN THINGS. SO I THINK JUST BEING VERY UNIQUE, TO JOHN'S POINT, BEING VERY SPECIFIC TO THE POPULATION THAT YOU'RE REACHING OUT TO.

CO-CHAIRMAN KAHN: THAT'S HELPFUL.

DR. LOMAX: I THINK MAYBE WE CAN JUST -- WE'RE AHEAD OF SCHEDULE, WHICH IS A GREAT PROBLEM TO HAVE. THIS HAS BEEN TERRIFIC. CERTAINLY CAPTURED A LOT OF DETAIL HERE. SO WE CAN TAKE OUR BREAK EARLY AND THEN I THINK MAYBE JUST GO INTO THE NEXT SESSION.

CO-CHAIRMAN KAHN: YOU WANT TO DO A RECAP OF THE TAKEAWAYS, OR DO YOU WANT TO HAVE MORE TIME TO DIGEST BEFORE YOU DO THAT? I DON'T MEAN TO PUT YOU ON THE SPOT.

DR. LOMAX: LET ME SEE IF MY NOTETAKING SKILLS ARE ANY GOOD.

SO THERE WERE A NUMBER OF THINGS WHICH -- AGAIN, THIS WAS REALLY HELPFUL IN ADDING SOME RESOLUTION TO THINGS WE HAD HEARD, BUT THIS GAVE US A MUCH BETTER PERSPECTIVE OR MORE INFORMED

PERSPECTIVE. THE TERMINOLOGY WAS DIFFERENT. SO ONE OF THE ONES THAT I KIND OF IN TERMS OF MOVING UP THE LIST WAS GETTING PEOPLE ON THE SAME LEVEL. I THINK IT SORT OF SPEAKS TO THE NOTION OF RESPECT FOR PERSONS IN TERMS OF ETHICAL FRAMEWORKS.

I CERTAINLY THINK THE WAY WE'VE STRUCTURED THE CONCEPT PLAN IN TERMS OF PUTTING RESOURCES INTO THOSE TYPES OF SPACES WHERE THE RESPECT CAN SORT OF EMANATE FROM THE RELATIONSHIPS THAT CAN EMERGE THERE IS IMPORTANT. AND THEN SOME OF THE MORE OPERATIONAL ASPECTS OF THAT, VIS-A-VIS STEERING COMMITTEES, ADVISORY GROUPS, AGAIN, OUR INTENT WAS TO REALLY SUPPORT THOSE OPERATIONS EFFECTIVELY. SO HOPEFULLY WE GET THERE.

IN ADDITION, I THINK IT WAS LOUD AND CLEAR THAT THE RESOURCING SHOULD INCLUDE FUNDING SUPPORT, ALL THE THINGS THAT OTHER PARTNERS WOULD GET FOR DOING WORK. AGAIN, THOSE RESOURCES ARE THERE, AND WE'VE TRIED TO STRUCTURE THE BUDGET IN A WAY TO MAKE THOSE RESOURCES PREDICTABLE AND AVAILABLE TO THE SUCCESSFUL APPLICANTS AND THEIR PARTNERS.

A LOT OF REALLY GOOD POINTS AND POINTERS, AND WE'LL COME BACK TO YOU IN TERMS OF YOUR BEST ADVICE IN TERMS OF TOOLS, IS MEASUREMENT, PARTICULARLY SOCIAL NETWORK ANALYSIS, SOME OF THE

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METRICS USED IN TERMS OF COMMUNITY-BASED PARTICIPATORY RESEARCH, SOME OF THE METRICS THAT CAN HELP UNDERSTAND IMPACT OF BOTH COMMUNITY HEALTH WORKERS AND THE EDUCATION COMPONENT.

ONE THAT I THINK WE'VE HEARD BEFORE, BUT SORT OF TRIPLED DOWN ON WAS SOME OF MAYBE THESE EDUCATION EFFORTS. MAYBE A GOOD STARTING POINT WOULD BE REALLY MAKE SURE THAT WE'VE GOT THE CLINICAL TRIAL PROCESS DESCRIBED IN A VERY ROBUST WAY. SO IT PROBABLY MEANS MULTIPLE WAYS OF DESCRIBING THAT. WE'VE GOT A VIDEO TOO. I DON'T KNOW IF IT WAS THE ONE THAT WAS REFERRED TO OR NOT. BUT THERE'S PROBABLY LIKE MULTIPLE TOOLS THAT NEED TO HAPPEN THERE BASED ON THE HETEROGENEITY OF THE AUDIENCE.

AND THAT SORT OF LEADS INTO THE SEGMENTATION PIECE, WHICH, AGAIN, I THINK WAS A THEME THAT RAN THROUGH BOTH DR. WASHINGTON'S PRESENTATION AND THEN WAS REITERATED, I THINK, A NUMBER OF TIMES IS REALLY I THINK WE WOULD ASK THE APPLICANTS, FOR EXAMPLE, WHAT ARE THEIR STRATEGIES FOR REALLY SEGMENTING THEIR ENGAGEMENT EFFORTS IN WAYS THAT WILL SERVE THE PURPOSE OF THE PROGRAM. AND SO THEY NEED TO BE CREATIVE THERE.

AND I THINK, AGAIN, SORT OF LOOKING AT

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SOME OF THESE ANTIRACISM TOOLS AND SOME OF THOSE CURRICULA, THOSE TRAININGS, AGAIN, TO THE EXTENT THERE ARE TRAININGS, THERE ARE EDUCATION TOOLS, THERE ARE THINGS THAT WE CAN SORT OF ATTACH, I THINK THAT SERVES THE CAREER DEVELOPMENT ASPECTS AND THE TRAINING ASPECTS OF THIS PROGRAM. AND I THINK THAT WILL BE VALUABLE.

AND I THINK I'LL STOP THERE. THOSE WERE THE ONES THAT -- OH, THERE WAS ONE OTHER ONE THAT DR. TREADWELL REALLY EMPHASIZED. CONGRATULATIONS. YOU'RE COACHING PHYSICIANS. THAT'S A HERCULEAN TASK, AND IT SOUNDS LIKE THEY'RE VERY RECEPTIVE, AND WE PROBABLY NEED TO LEARN A BIT MORE ABOUT THAT AS WELL. SO THANK YOU.

CO-CHAIRMAN KAHN: PERFECT. GREAT. THANK YOU FOR DOING THAT. ALL RIGHT. SHOULD WE TAKE A BREAK?

DR. LOMAX: FIFTEEN-MINUTE BREAK.

CO-CHAIRMAN KAHN: DOES THAT WORK FOR EVERYBODY? WE'LL SEE YOU IN FIFTEEN. SO IT 13 MINUTES PAST ACCORDING TO MY COMPUTER.

DR. LOMAX: SO HALF PAST THE HOUR?

CO-CHAIRMAN KAHN: HALF PAST THE HOUR.

(A RECESS WAS TAKEN.)

DR. LOMAX: WE ARE BACK LIVE. OKAY. YOU

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CAN HEAR US; IS THAT CORRECT? THANK YOU.

CO-CHAIRMAN KAHN: SO WE'RE GOING TO SHIFT GEARS A LITTLE BIT NOW AND TALK ABOUT PATIENT SUPPORT FOR CLINICAL TRIALS. WE'RE GOING TO DO IT IN THE FOLLOWING WAY. WE'LL HAVE A PRESENTATION AGAIN FROM GEOFF TALKING ABOUT CIRM'S PATIENT SUPPORT PROGRAM. WE'LL HEAR MORE ABOUT WHAT IT DOES, BUT IT AIMS TO PROVIDE FINANCIAL AND LOGISTICAL SUPPORT FOR PATIENTS ENROLLED IN CIRM-FUNDED CLINICAL TRIALS. THEN WE'LL HAVE A PRESENTATION FROM CHRISTINE GRADY, WHO I'LL INTRODUCE BEFORE SHE SPEAKS. WE WILL TALK ABOUT ETHICAL PRINCIPLES OF GOVERNING OR APPLYING TO REIMBURSEMENT AND PAYMENT OF PATIENTS PARTICIPATING IN TRIALS. AND THEN HAVE WE'LL HAVE A PANEL MADE UP OF MEMBERS OF IRB'S FROM ACROSS THREE INSTITUTIONS HERE IN CALIFORNIA. I'LL INTRODUCE THOSE FOLKS BEFORE THAT PANEL.

THAT SUFFICIENT TEEING UP?

DR. LOMAX: FANTASTIC. THANKS VERY MUCH. THANK YOU.

OKAY. SO MOVING ON, AGAIN, TO CIRM'S PATIENT SUPPORT PROGRAM. AGAIN, AS A REMINDER, WE'RE IN THE PROCESS OF EVALUATING APPLICATIONS TO THIS PROGRAM WITH THE PROGRAM ANTICIPATED TO BE

INITIATED THIS YEAR. SO, AGAIN, THIS DISCUSSION IS IMPORTANT FROM THE STANDPOINT OF JUST ENSURING THAT WE'RE IMPLEMENTING THESE PROGRAMS APPROPRIATELY. SO I'LL GIVE A BRIEF PRESENTATION INTENDED IN THIS CASE TO DESCRIBE THE PROGRAM'S OPERATIONAL REQUIREMENTS. SO IT WILL BE A BIT MORE DETAILED THAN THE COMMUNITY CARE PRESENTATION INSOFAR AS THAT THIS IS NOW THE SPECIFIC ACTIVITIES WE'VE ASKED THE APPLICANT TO PERFORM.

SO THE PROGRAM IS BASED ON THE RECOGNITION THAT CELL AND GENE THERAPY TRIALS ARE BECOMING OR HAVE BECOME VERY DEMANDING ON PATIENTS AND REQUIRE CONSIDERABLE SUPPORT. WE WERE LOOKING AT ONE OF THE PUBLISHED PROTOCOLS FOR ONE OF THE SICKLE CELL TREATMENTS. AND I BELIEVE OVER A 24-MONTH PERIOD, THERE WERE NO LESS THAN 30 CLINICAL INTERACTIONS REQUIRED AT SOME LEVEL BETWEEN THE PATIENT RECEIVING THE TREATMENT AND THE CLINICAL TRIAL TEAM. SO WE'RE DEALING WITH A LEVEL OF INTENSITY THAT IS QUITE UNIQUE TO OUR FIELD.

AND SO WHAT WE'VE DONE IS LAUNCH A PATIENT SUPPORT PROGRAM TO, AGAIN, PROVIDE LOGISTICAL AND FINANCIAL SUPPORT TO PATIENTS SEEKING TO ENROLL IN CLINICAL TRIALS WITH THE AIM OF IMPROVING ACCESS, RETENTION, AND DIVERSITY IN THESE PROGRAMS.

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

SO THIS, AGAIN, IS WE PUT OUT AN APPLICATION, WE RECEIVED RESPONSES. THE APPLICANTS WERE SPECIFICALLY ASKED TO ADDRESS OR PROVIDE PLANS FOR FOUR MAJOR PROGRAM ACTIVITIES. FIRST BEING PATIENT INTAKE AND NAVIGATION STARTING WITH A CALL CENTER THAT WOULD BE CAPABLE OF ADDRESSING INQUIRIES AND THEN REFERRING PATIENTS TO CLINICAL SITES IF THERE IS A TRIAL AVAILABLE OR RELEVANT TO THEIR CONDITION. IF THE PATIENT SUBSEQUENTLY, AFTER INTERACTING WITH A CLINICAL SITE, WOULD LIKE TO ENROLL IN A TRIAL, THEN THE CENTER WOULD BE RESPONSIBLE FOR DETERMINING FINANCIAL ELIGIBILITY. SO THERE WILL BE A FINANCIAL ELIGIBILITY REQUIREMENT TO RECEIVE CERTAIN SUPPORT FROM THIS CENTER.

AND THEN ONCE THAT DETERMINATION IS MADE, A MAJOR ROLE WILL BE SUPPORTING ACCESS, AT LEAST INITIALLY, VERY MUCH THE FOCUS WILL BE ON TRAVEL, CHILDCARE, MEALS, AND OTHER TRIAL-ASSOCIATED EXPENSES THAT WOULD OTHERWISE COME FROM OUT OF THE PATIENT'S POCKET. WE'RE TRYING TO AVOID THOSE COSTS ALTOGETHER. AND THEN ALSO MAINTAIN A SYSTEM, AN ACCOUNTING SYSTEM BECAUSE WE HAVE TO MAINTAIN STRICT ACCOUNTING OF THESE FUNDS FOR A VARIETY OF REASONS RELATED TO COMPLIANCE WITH A HOST OF FEDERAL AND STATE REGULATIONS.

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I JUST WANT TO GO BACK AND SAY ONE MORE THING HERE BECAUSE POINT THREE. SO THE INITIAL -- WE VIEW THIS AS REALLY A TWO-STEP ROLLOUT. INITIALLY THE PROGRAM IS FOCUSING ON OUT-OF-POCKET EXPENSES; BUT AS PART OF THE EXPERIENCE IN THIS PROGRAM, WE ALSO WANT THE APPLICANT OR THE PATIENT SUPPORT PROGRAM TO BE PERFORMING EVALUATION OF THE PATIENT EXPERIENCE IN A WAY WHERE THEY MIGHT INFORM ARE THERE OTHER BARRIERS OR OTHER NEEDS FOR SUPPORT OR RESOURCES IN A SORT OF SUBSEQUENT STAGE, WHICH WE'RE CALLING PHASE 2, WHICH I KNOW CAN BE CONFUSING BECAUSE CLINICAL TRIALS ARE DESCRIBED BY PHASES, BUT A SECOND PHASE OF THE PROGRAM WHERE WE WOULD EXPAND THE RESOURCES TO OTHER AREAS. AND THAT'S A LITTLE BIT TO BE DETERMINED. WE WERE LOOKING FOR THE EVIDENCE TO SUPPORT SUCH AN EXPANSION.

BUT FOR THE PURPOSES OF THIS DISCUSSION, WE WANT TO SORT OF REMAIN FLEXIBLE. AND WE WOULD TALK ABOUT OUT-OF-POCKET COSTS, BUT ARE THERE THINGS WE NEED TO BE THINKING ABOUT. AND I KNOW PEOPLE RAISE ISSUES LIKE LOST WAGES OR ACTUALLY PAYING PATIENTS. THAT THEN STARTS TO RAISE SORT OF ETHICAL CONSIDERATIONS, BUT MAYBE TO THINK ABOUT SOME OF THOSE ISSUES AS WE MOVE THROUGH THE CONVERSATION TODAY.

SO, AGAIN, WE ARE TALKING ABOUT THE FINANCIAL SUPPORT PIECE HERE, COVERAGE OF OUT-OF-POCKET COSTS, LOGISTICAL SUPPORT, AGAIN, WITH THE POTENTIAL TO EXPAND THESE SERVICES BASED ON PROGRAM EVALUATION.

WE HAVE A SET OF QUESTIONS HERE THAT MAYBE FOLKS COULD BE THINKING ABOUT OR MAY BE ADDRESSED IN THE FOLLOW-UP PRESENTATION. SO I'M GOING TO PAUSE THERE. I'VE GIVEN YOU THE CONTOURS OF WHAT WE ARE IN THE PROCESS OF DEVELOPING, AND WE WANTED TO GET SOME COMMENTARY IN TERMS OF THE STANDARD OF PRACTICE. SO I'LL TURN IT OVER TO YOU, JEFF.

CO-CHAIRMAN KAHN: DO YOU WANT TO TALK ABOUT THIS NOW, OR DO YOU WANT TO HAVE CHRISTINE?

DR. LOMAX: I THINK WE SHOULD HAVE CHRISTINE OPEN TO KIND OF SET THE POLICY FRAMEWORK.

CO-CHAIRMAN KAHN: PERFECT. SO, CHRISTINE, YOU CAN GET READY TO SHARE YOUR SLIDES. LET ME DO JUST A BRIEF INTRODUCTION. WELCOME. GOOD TO SEE YOU.

CHRISTINE GRADY IS THE DIRECTOR OF THE BIOETHICS DEPARTMENT IN AN NIH CLINICAL CENTER. SHE'S A LONGTIME SCHOLAR AND EXPERT IN BIOETHICS AND IN PARTICULAR HAS WORKED A LOT ON THIS TOPIC, ON COMPENSATION FOR PARTICIPATION IN CLINICAL TRIALS.

SO WELCOME, CHRISTINE. GOOD TO SEE YOU. THANK YOU FOR BEING WILLING TO DO THIS AND TURN IT OVER TO YOU.

DR. GRADY: THANK YOU, JEFF. CAN YOU SEE MY SLIDES? YES?

DR. LOMAX: PERFECT.

DR. GRADY: OKAY. GOOD. I'M GOING TO PUT THEM ON SLIDE SHOW AND THEN MIGHT HAVE TO DO THE REVERSE. THERE YOU GO.

SO FIRST OF ALL, THANK YOU FOR INVITING ME TO BE PART OF THIS DISCUSSION. AND I WAS VERY PRIVILEGED TO BE THE PART OF THE PREVIOUS DISCUSSION BECAUSE I FOUND IT WAS QUITE INTERESTING. AND I'M GO TO SPEND JUST A FEW MINUTES TALKING ABOUT ISSUES RELATED TO FINANCIAL SUPPORT FOR RESEARCH PARTICIPATION.

AS JEFF MENTIONED, I WORK FOR THE FEDERAL GOVERNMENT, BUT THESE ARE MY VIEWS, NOT THE FEDERAL GOVERNMENT'S, AND I HAVE NO OTHER CONFLICTS OF INTEREST.

I UNDERSTAND THAT THE OBJECTIVE OF THE PATIENT SUPPORT PROGRAM IS TO PROVIDE LOGISTICAL AND FINANCIAL SUPPORT TO PATIENTS SEEKING TO ENROLL IN CIRM STUDIES. AND SO WHAT I THOUGHT I'D DO IS EXPLORE A LITTLE BIT WITH YOU BOTH WHY AND HOW WE

OFFER FINANCIAL SUPPORT TO PATIENTS IN RESEARCH AND WHAT ARE THE ETHICAL CONCERNS.

SO STARTING WITH THE WHY AND HOW, YOU MAY BE VERY WELL AWARE THAT OFFERING PAYMENT TO RESEARCH PARTICIPANTS IS A LONG-STANDING PRACTICE. IT'S WIDESPREAD, IT'S COMMON, AND IT'S LONG-STANDING. WE DID A STUDY 20 YEARS AGO WHICH FOUND MORE THAN -- ABOUT 80 PERCENT OF THE INSTITUTIONS THAT WE SURVEYED OFFERED PAYMENT IN AT LEAST SOME OF THEIR STUDIES TO THE PEOPLE THAT ENROLLED IN THEIR STUDY.

AND YOU MAY BE FAMILIAR WITH WALTER REED'S EXPERIMENTS IN 1900 WHERE HE ACTUALLY OFFERED PARTICIPANTS A HUNDRED DOLLARS IN GOLD AND A HUNDRED DOLLARS MORE IF THEY GOT INFECTED WITH YELLOW FEVER. PAYABLE TO THEIR FAMILIES IF THEY DIED, BY THE WAY.

AND WE KNOW THAT OFFERING PAYMENT IS ALLOWED BY REGULATIONS. IT'S ALSO ETHICALLY ACCEPTABLE, BUT IT IS INTERESTINGLY PERENNIALLY FRAUGHT. JEFF MENTIONED I'VE BEEN WORKING ON THIS FOR A LONG TIME. I GOT INTERESTED IN IT MORE THAN 20 YEARS AGO BECAUSE IT WAS SO FRAUGHT. PEOPLE RANGE FROM YOU CAN'T DO IT TO YOU HAVE TO DO IT AND EVERYTHING IN BETWEEN. IT'S STILL THERE.

SO WHAT ABOUT THE REGULATIONS? BOTH THE FDA AND THE OHRP GUIDANCE, IT'S NOT IN THE

REGULATIONS, BUT THEY BOTH HAVE GUIDANCE ABOUT PAYMENT, AND THEY BOTH SAY PAYING PARTICIPANTS IS COMMON AND ACCEPTABLE. IT NEEDS TO BE JUST AND FAIR. AND THEN MUCH OF THEIR GUIDANCE IS ABOUT WHAT THE IRB SHOULD LOOK AT WHEN THEY'RE DECIDING WHETHER THE OFFER OF PAYMENT IS ACCEPTABLE. SO IT'S NOT ONLY AMOUNT AND METHOD AND TIMING, BUT ALSO WHAT THE PAYMENT IS FOR AND BEING SENSITIVE, OF COURSE, TO THIS CONCERN OF UNDUE INFLUENCE, WHICH I'LL COME BACK TO.

SO WHY DO WE OFFER PAYMENT TO RESEARCH PARTICIPANTS? I THINK THE MAIN REASON THAT MOST PEOPLE WILL SAY IS BECAUSE IT'S TO HELP RECRUITMENT AND ENROLLMENT FOR STUDIES. SO IT'S AN INCENTIVE TO INCENTIVIZE ENROLLMENT. AND THIS IS IMPORTANT BECAUSE WE ALL KNOW WE NEED, IN ORDER TO COMPLETE STUDIES AND IN ORDER FOR THEM TO BE SOCIALLY AND SCIENTIFICALLY VALUABLE, THEY NEED TO HAVE THE RIGHT NUMBER AND THE TIMELY ENROLLMENT OF PARTICIPANTS IN ORDER TO SUCCEED. AND MANY STUDIES DO NOT ACHIEVE THAT. SO THERE'S ALWAYS THE IDEA THAT IF YOU THE OFFER PAYMENT TO PEOPLE, IT WILL INCREASE ENROLLMENT.

I THINK IT'S INTERESTING TO ASK THE QUESTION OF HOW WELL DOES IT WORK. SO IF YOU LOOK

AT THE DATA THAT EXISTS, FOR EXAMPLE, FOR SURVEYS, THE DATA IS UNEQUIVOCAL. EVEN SMALL AMOUNTS OF MONEY, $5, SOMETIMES $2, WILL INCREASE THE RESPONSE RATES FOR SURVEYS.

IN STUDIES WITH HEALTHY VOLUNTEERS, IT SEEMS ALMOST YOU CAN'T DO A STUDY UNLESS YOU OFFER SOME PAYMENT. AND WHEN YOU THINK ABOUT THAT, IT MAKES SOME SENSE BECAUSE A HEALTHY VOLUNTEER HAS NO OTHER, OTHER THAN PERHAPS CURIOSITY OR ALTRUISM, THEY HAVE NO OTHER REASON TO WANT TO SPEND TIME DOING A STUDY.

THE DATA ON CLINICAL TRIALS IS A LITTLE MORE MIXED AND NOT AS CLEAR IN TERMS OF ENROLLMENT OF PARTICIPANTS. THIS IS ONE STUDY THAT WAS PUBLISHED IN 2021. SCOTT HALPERN AND HIS COLLEAGUES HAVE DONE A NUMBER OF REALLY INTERESTING STUDIES. THIS ONE WAS A COMPARISON OF TWO DIFFERENT TRIALS. WITHIN TWO DIFFERENT CLINICAL TRIALS, THEY EMBEDDED A RANDOMIZED ASSIGNMENT TO DIFFERENT LEVELS OF REIMBURSEMENT OR INCENTIVE, I GUESS IS THE WAY I WOULD DO IT.

SO IN THIS SMOKING TRIAL, THEY OFFERED PEOPLE -- THEY WERE RANDOMIZED TO ZERO, $200, OR $500, AND THE OTHER ONE A LITTLE BIT OF A SHORTER SPREAD, BUT BASICALLY SAME IDEA.

AND INTERESTINGLY, WHAT THEY FOUND IS IN THIS STUDY THE AMOUNT OF MONEY INCREASED ENROLLMENT BY -- IT DOUBLED IT BASICALLY. SO FROM ZERO TO THOSE WHO RECEIVED $500. WHEREAS, IN THE OTHER STUDY, IT DIDN'T HAVE AN EFFECT AT ALL. AND SO IT RAISES THE QUESTION OF WHAT ARE THE OTHER REASONS THAT PEOPLE ARE ENROLLING IN THESE STUDIES AND WHAT ARE THE OTHER FACTORS THAT INFLUENCE THEIR DECISIONS? AND THERE'S SOME OTHER INTERESTING THINGS ABOUT THIS DATA WE COULD TALK ABOUT IF WE HAVE TIME.

SO I THINK THAT THE INTERESTING QUESTION TO FOCUS ON IS WHAT ARE THE KNOWN MOTIVATIONS FOR PARTICIPATION IN CLINICAL TRIALS AND WHAT ARE THE KNOWN BARRIERS? AND THAT THAT MIGHT HELP US DECIDE WHAT THE ROLE OF MONEY MIGHT BE, IF AT ALL.

SO CERTAINLY THIS IS NOT NEWS TO ANYBODY IN THIS AUDIENCE. THERE ARE A NUMBER OF REASONS THAT HAVE BEEN DOCUMENTED BY SOME STUDIES, THERE COULD BE MORE DATA, BUT THAT PEOPLE PARTICIPATE IN CLINICAL TRIALS. THE MOST COMMON ONE BEING A HOPE FOR PERSONAL BENEFIT, THERAPEUTIC BENEFIT, BUT OFTEN ALSO BECAUSE THEY TRUST THEIR PHYSICIANS, SOMETIMES THEY WANT KNOWLEDGE ABOUT THEIR CONDITION, THEY WANT TO CONTRIBUTE TO KNOWLEDGE, THEY ARE ALTRUISTIC, AND

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THEY WANT ACCESS TO CARE. ALL OF THOSE ARE KNOWN MOTIVATIONS FOR PARTICIPATING IN CLINICAL TRIALS.

THIS WAS AN INTERESTING STUDY THAT WAS DONE WITH 12,000 PEOPLE AROUND THE WORLD ACTUALLY ASKING THEM WHAT WERE THE IMPORTANT THINGS THAT INFLUENCED THEIR DECISIONS TO ENROLL IN CLINICAL RESEARCH. THESE ARE ALL PEOPLE WHO HAVE BEEN IN RESEARCH. YOU CAN SEE IT'S RISKS AND BENEFITS AND THE PURPOSE, AND THE TYPE OF THINGS THEY'RE BEING ASKED TO ENDURE ARE THE MOST INFLUENTIAL. BUT THEN THERE'S A WHOLE HOST OF THE THINGS, INCLUDING COSTS AND REIMBURSEMENTS, THAT HAVE AN INFLUENCE ON A LITTLE MORE THAN 50 PERCENT OF THE PEOPLE IN THIS PARTICULAR SURVEY.

SO THIS IS A SYSTEMATIC REVIEW THAT JOSEPH UNGER AND COLLEAGUES PUBLISHED A COUPLE YEARS AGO JUST LOOKING AT PEOPLE WHO ENROLLED IN CANCER CLINICAL TRIALS. AND THEY FOUND THROUGH THIS SYSTEMATIC META-ANALYSIS THAT THEY DID PATIENTS ACTUALLY GET INFORMATION ABOUT CLINICAL TRIALS FROM THEIR DOCTORS, NOT SURPRISING. AND THAT ELIGIBLE PATIENTS SAY YES MORE THAN 50 PERCENT OF THE TIME WHEN THEY ARE ACTUALLY OFFERED TRIAL PARTICIPATION.

DR. WASHINGTON SAID SOMETHING ABOUT THIS IN THE LAST PANEL, THAT SOMETIMES THE REASON THAT

PEOPLE DON'T PARTICIPATE IS THAT THEY'RE NOT OFFERED. THEY'RE NOT MADE AWARE OF THE TRIAL. AND THE REASONS THAT UNGER AND COLLEAGUES FOUND THAT PEOPLE DECLINED PARTICIPATION INCLUDE SOMETIMES A DESIRE TO DETERMINE THEIR OWN TREATMENT OR LOSS OF CONTROL OR FEAR OF SIDE EFFECTS, BUT OFTEN CONCERNS ABOUT COSTS AND LOGISTICAL BARRIERS LIKE TRANSPORTATION.

THERE HAVE BEEN OTHER STUDIES THAT HAVE LOOKED AT THE INFLUENCE OF COST ON WILLINGNESS TO PARTICIPATE IN TRIALS. AND I THINK EVERYBODY KNOWS THAT PARTICIPATING IN A TRIAL CAN POSE COSTS. SOME OF THEM ARE HEALTH-RELATED COSTS, THINGS THAT THE TRIAL DOESN'T COVER OR THE INSURANCE DOESN'T COVER, BUT A LOT OF THEM ARE THE COSTS RELATED TO TRAVEL, LOST WAGES, LODGING, MEALS, ET CETERA, THAT COME WITH THE FREQUENT VISITS TO THE CLINIC. AND DATA HAVE SHOWN THAT POPULATIONS AT HIGHEST RISK FOR THIS KIND OF FINANCIAL TOXICITY ARE EXACTLY THOSE THAT ARE THE LEAST LIKELY TO PARTICIPATE IN CLINICAL TRIALS, WHICH CAN, OF COURSE, SKEW THE PARTICIPATION AND LIMIT VALIDITY.

THIS WAS A BLOG ACTUALLY THAT HAD SOME REALLY INTERESTING DATA POINTING TO THE FACT THAT RESEARCH HAS LEFT PATIENTS BEHIND WHO COME FROM

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

UNDERREPRESENTED AND UNDERRESOURCED COMMUNITIES. AND THOSE COMMUNITIES OR PEOPLE IN COMMUNITIES THOSE ALREADY MORE LIKELY TO EXPERIENCE POVERTY AND POOR HEALTH OUTCOMES. BUT FOR RESEARCH, THEY'RE LESS LIKELY TO PARTICIPATE. AND THEY OFTEN IDENTIFY TIME AND RESOURCE CONSTRAINTS ASSOCIATED WITH PARTICIPATION AS A BARRIER TO PARTICIPATING. AND, OF COURSE, THEY GO ON TO SAY THIS CAN LEAD TO A SYSTEM WHERE THE MAJORITY OF BENEFICIARIES WHO ENROLL IN TRIALS ARE THOSE WHO HAVE ENOUGH ACCESS TO TRANSPORTATION AND CHILDCARE AND SICK LEAVE OR THE ABILITY TO MISS A PAYCHECK.

SO IN ADDITION TO INCREASING ENROLLMENT OR RECRUITMENT, I THINK ONE OF THE THINGS THAT I'VE WORKED ON FOR MANY YEARS IS THAT THERE ARE MANY OTHER REASONS TO OFFER MONEY TO PEOPLE WHEN THEY'RE PARTICIPATING IN RESEARCH. ONE IS JUST TO ENABLE PARTICIPATION SO THAT THEY CAN GET TO THE CLINIC OR THEY CAN PAY FOR THE CHILDCARE. ANOTHER UNRELATED ONE IS TO MAKING PARTICIPATION MORE OR LESS REVENUE NEUTRAL SO THAT THEY DON'T END UP WORSE OFF FINANCIALLY BY PARTICIPATING IN THE STUDY.

ANOTHER IS COMPENSATING PEOPLE FOR THEIR TIME, THEIR CONTRIBUTION, AND THEIR WILLINGNESS TO ASSUME RISK. AND THIS IS SOMETHING THAT WE HEARD

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

FROM THE LAST PANEL AND IS IMPORTANT FOR COMMUNITY ADVISORY BOARD PARTICIPANTS AND OTHER COMMUNITY HEALTH WORKERS THAT IS CERTAINLY IMPORTANT IN MANY CASES FOR RESEARCH PARTICIPANTS AS WELL.

IT ALSO MINIMIZES THE POSSIBILITY OF EXPLOITATION BECAUSE THEY END UP BENEFITING MORE THAN THEY WOULD IF IT WAS COSTING THEM MONEY AND DEMONSTRATES RESPECT AND GRATITUDE. AND INTERESTINGLY, PAYMENT FOR ANY OF THESE OTHER REASONS COULD ALSO FACILITATE RECRUITMENT.

YEARS AGO WE PROPOSED SEVERAL MODELS OF PAYMENT WHICH DO A COUPLE OF DIFFERENT THINGS. ONE IS THEY GIVE THE REASONS OR THE REASONS THAT YOU MIGHT OFFER MONEY TO RESEARCH PARTICIPANTS. AND THEY ALSO HELP TO DETERMINE HOW MUCH MONEY YOU MIGHT OFFER IN A GIVEN CIRCUMSTANCE. SO A REIMBURSEMENT MODEL BASICALLY IS, OF COURSE, REIMBURSING EXPENSES, AND, THEREFORE, IT'S DETERMINED BY HOW MUCH THE EXPENSES ARE.

THE WAGE PAYMENT MODEL WAS A MODEL THAT WE PROPOSED AS A WAY TO COMPENSATE PEOPLE FOR THEIR TIME AND THEIR INCONVENIENCE. AND AT THE TIME WE SUGGESTED THAT COULD BE A SORT OF HOURLY WAGE OR WAGE ACCORDING TO TIME THAT WAS BASED ON THE SORT OF LOCAL UNSKILLED LABOR WAGE IN THE JURISDICTION WHERE

133 HENNA COURT, SANDPOINT, IDAHO 83864
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THE STUDIES WERE TAKING PLACE.

THOSE ARE BOTH CONTRASTED WITH THE MARKET MODEL, WHICH WAS YOU PROVIDE AMOUNTS OF MONEY AS INCENTIVES TO OVERCOME INERTIA AND OVERCOME OTHER KINDS OF REASONS THAT PEOPLE WOULDN'T PARTICIPATE THAT GO BEYOND REIMBURSING THEM OR COMPENSATING THEM FOR THEIR TIME AND INCONVENIENCE.

SOME PEOPLE HAVE ADDED AN APPRECIATION MODEL WHICH IS BASICALLY A WAY TO SHOW APPRECIATION FOR THE PARTICIPATION OF A PERSON. I THINK IT'S LESS HELPFUL IN DETERMINING AMOUNTS BECAUSE YOU CAN APPRECIATE PEOPLE WITH A SMALL AMOUNT OF MONEY THAT ISN'T BASED ON SOME OF THESE OTHER THINGS.

WHAT ARE THE COMMON ETHICAL CONCERNS? I'M SURE YOU'RE ALL FAMILIAR WITH THEM. COERCION IS ONE THAT PEOPLE TALK ABOUT ALL THE TIME, UNDUE INFLUENCE OR INDUCEMENT, AND DECEPTION IS ANOTHER ONE THAT I THINK WE SHOULD TALK ABOUT. AND A LOT OF PEOPLE HAVE WRITTEN ABOUT THESE CONCERNS.

I'M GOING TO SAY COERCION IS SOMETHING THAT WE SHOULD GET OFF THE LEXICON FOR OFFERING PAYMENT. BY DEFINITION, IT INVOLVES A THREAT. IT'S A THREAT TO MAKE SOMEBODY WORSE OFF BY VIOLATING THEIR RIGHTS OR DEPRIVING THEM OF SOMETHING TO WHICH THEY ARE OTHERWISE ENTITLED. SO THEY FEEL LIKE THEY

133 HENNA COURT, SANDPOINT, IDAHO 83864
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DON'T REALLY HAVE A CHOICE BUT TO COMPLY. THE CLASSIC EXAMPLE, OF COURSE, IS YOUR MONEY OR YOUR LIFE. AND SEVERAL PEOPLE HAVE WRITTEN THAT THE OFFERED PAYMENT ACTUALLY CAN MAKE SOMEONE BETTER OFF, NOT WORSE OFF; AND, THEREFORE, OFFERING PAYMENT IS NOT A COERCIVE PROCESS.

UNDUE INFLUENCE OR UNDUE INDUCEMENT IS SOMETHING THAT'S LESS WELL DEFINED AND STILL REARS ITS HEAD QUITE FREQUENTLY IN THE CONTEXT OF DISCUSSING PAYMENT FOR RESEARCH PARTICIPANTS.

THE SECRETARY'S ADVISORY COMMITTEE ON HUMAN RESEARCH PROTECTIONS IN 2019 PUT TOGETHER SOME GUIDANCE AND RECOMMENDATIONS ON PAYING RESEARCH PARTICIPANTS. AND THEY DEFINED UNDUE INFLUENCE AS OCCURRING WHEN THERE'S AN EXCESSIVE OFFER OF SOMETHING VALUABLE OR DESIRABLE THAT LEADS TO POOR JUDGMENT OR COMPROMISED DECISION-MAKING AND, IN TURN, LEADS TO DECISIONS THAT ALLOW A PERSON TO ENGAGE IN A HARMFUL ACTIVITY THAT CONTRAVENES THEIR INTERESTS.

AND ONE OF THE THINGS THAT SACHRP POINTED OUT IS, IN THE CONTEXT OF RESEARCH WHERE WE'RE OFFERING RESEARCH TO PARTICIPANTS, BECAUSE RESEARCH IS REVIEWED BY AN IRB BEFORE IT BEGINS AND BECAUSE OF ONE GOALS OF THE IRB IS TO MAKE SURE THAT THE

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

RISKS ARE REASONABLE IN RELATION TO THE PURPOSE OF THE STUDY OR THE BENEFITS AND/OR THE BENEFITS TO THE PARTICIPANTS, AT THE POSSIBILITY OF SOMEBODY ENGAGING IN A HARMFUL ACTIVITY THAT CONTRAVENES THEIR INTEREST OR OBLIGATIONS IS MUCH LESS IN RESEARCH THAN IT MIGHT BE IN SOME OTHER CONTEXT. THAT DOESN'T NECESSARILY, HOWEVER, REMOVE THE POSSIBILITY THAT AN INDIVIDUAL, BECAUSE OF THEIR CIRCUMSTANCES OR IDIOSYNCRASIES, MIGHT BE SUBJECT TO UNDUE INDUCEMENT.

SO BASICALLY UNDUE INDUCEMENT OR INFLUENCE ALSO OCCURS WHEN IT INHIBITS OR APPEARS LIKELY TO INHIBIT PARTICIPANTS ADEQUATE CONSIDERATION OF REFLECTION ABOUT IMPORTANT STUDY FEATURES, LIKE RISKS OR BURDENS OR DISCOMFORTS, AND IMPAIRS THEIR UNDERSTANDING. THE SORT OF IDEA THAT THEY'RE BLINDED BY THE MONEY. AND THERE HAVE BEEN A NUMBER OF STUDIES THAT HAVE TRIED TO LOOK AT THIS AND FIGURE OUT WHETHER OR NOT THIS IS WHAT'S HAPPENING WHEN PEOPLE ARE OFFERED MONEY IN RESEARCH. MOST OF THEM HAVE CONCLUDED THAT IT IS NOT.

SO THERE'S SEVERAL STUDIES THAT HAVE SHOWED THAT HIGH PARTICIPATION PAYMENTS, OR OFFERING PEOPLE LOTS OF MONEY, INCREASES THEIR PERCEPTION OF RISK AND ALSO INCREASES THE AMOUNT OF TIME THAT THEY

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

SPEND REVIEWING AND CONSIDERING THE RISKS OF A PARTICULAR STUDY.

OTHER STUDIES HAVE SHOWN THAT MONEY IN HYPOTHETICAL STUDIES INCREASES RESPONDENTS' WILLINGNESS TO PARTICIPATE IN RESEARCH REGARDLESS OF THE RISK, BUT THAT THAT WILLINGNESS DECREASES AS THE RISK INCREASES. AND THAT IS NOT ATTENUATED BY THE AMOUNT OF MONEY THAT'S BEING OFFERED.

IN HEALTHY VOLUNTEER STUDIES, THERE HAVE BEEN A COUPLE OF INTERESTING FINDINGS THAT, EVEN THOUGH HEALTHY VOLUNTEERS VARY CLEARLY SAY THAT THEY ARE MOTIVATED BY MONEY TO PARTICIPATE, IN ONE STUDY THAT WE DID SOME YEARS AGO WHERE WE HAD A COMPREHENSION SCORE ABOUT WHAT THEY UNDERSTOOD ABOUT THE STUDY, THOSE WHO SAID THEY HAD BEEN MOTIVATED PRIMARILY BY MONEY HAD HIGHER COMPREHENSION SCORES THAN THOSE WHO HAD PARTICIPATED FOR OTHER REASONS.

AND IN A VERY LARGE STUDY OF HEALTHY VOLUNTEERS, THE HEALTHY VOLUNTEERS SAID MONEY WAS IMPORTANT TO EVERY DECISION THAT THEY MADE, BUT RISK WAS MORE IMPORTANT TO THEIR ENROLLMENT DECISION THAN THE MONEY.

SO WHAT ABOUT DECEPTION? THIS IS ANOTHER THING THAT PEOPLE WORRY ABOUT. AND THIS WAS, I THINK, POINTED TO INITIALLY BY, WELL, A NUMBER OF

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

DIFFERENT STUDIES, BUT THERE WAS ONE IN 2013 THAT ERIC DEVINE AND COLLEAGUES PUBLISHED WHERE THEY FOUND THAT OUT OF A HUNDRED PARTICIPANTS IN A COUPLE OF TRIALS, ALMOST A THIRD HAD CONCEALED HEALTH PROBLEMS OR MEDICATIONS OR PRETENDED TO HAVE A CONDITION THAT THEY DIDN'T HAVE, AND THAT THIS WAS ASSOCIATED WITH GREATER INTEREST IN MONETARY REWARDS.

NEAL DICKERT, WHO'S WRITTEN A LOT ABOUT INCENTIVE PAYMENTS, SAID THIS COULD BE A RESULT OF THE PAYMENTS.

I THOUGHT A REALLY INTERESTING PAPER THAT CAME JUST ABOUT A MONTH AGO IN THE DMJ WHICH TALKS ABOUT MISREPRESENTATION, COERCION, AND UNDUE INFLUENCE ALL IN THE SAME SENTENCE, SO THIS IS WHAT IS HAPPENING IN THE STUDY. AND THIS IS DEFINITELY MISREPRESENTATION. THIS WAS A STUDY DONE IN ZIMBABWE WHERE PREVIOUS WORK HAD SHOWED THAT THE MINERS THAT WORKED IN THIS SPECIFIC MINE HAD HIGH LEVELS OF MERCURY IN THEIR URINE. AND SO THEY WANTED TO REPEAT THE STUDY, AND THEY DIDN'T FIND IT. THEY DIDN'T FIND IT IN THE REPEAT STUDY. AT FIRST THEY COULDN'T FIGURE OUT WHY. AND THEN THEY REALIZED THAT THEY DONE THE STUDY IN THE TOWN INSTEAD OF IN THE MINE, AND THEY WERE OFFERING

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

PARTICIPANTS $5. THAT'S NOT A LOT OF MONEY. BUT WHAT IT DID WAS IT ATTRACTED A LOT OF PEOPLE WHO WERE NOT MINERS WHO WERE PEOPLE WHO WORKED IN THE DOWNTOWN OFFICES AND WHO HAD MISREPRESENTED THEMSELVES AS MINERS IN ORDER TO GET THE $5.

NOW, THE REASON I SAY THIS IS CONFUSING IS BECAUSE IT IS CLEARLY MISREPRESENTATION. IT IS NOT COERCION. THERE'S NO THREAT HERE. AND I DON'T THINK IT'S UNDUE INFLUENCE EITHER. THESE ARE RATIONAL DECISIONS. $5 TO GIVE A URINE SAMPLE. THAT'S PRETTY -- THERE'S NO RISK THERE, AND THERE'S NO HARMFUL ACTIVITY THERE.

THE OTHER THING THAT WE DON'T KNOW IS WHETHER MISREPRESENTATION OCCURS JUST AS OFTEN IN STUDIES THAT OFFER NO PAYMENT. REBECCA DRESSER WROTE A PAPER A FEW YEARS AGO CALLED "SUBVERSIVE SUBJECTS" AND TALKED ABOUT MISREPRESENTATION. SHE SAID, ALTHOUGH I DIDN'T SEE A LOT OF DATA IN THERE, THE POTENTIAL MEDICAL BENEFIT OFFERED BY LATER PHASE TRIALS THAT CREATES AN INCENTIVE FOR PATIENT SUBJECTS TO LIE. AND PEOPLE COPING WITH DEBILITATING OR LIFE THREATENING ILLNESSES ENTER TRIALS WITH THE GOAL OF IMPROVING THEIR HEALTH. IF THOSE REQUIREMENTS OF THE TRIAL INTERFERE WITH THAT GOAL, THEY MAY MISREPRESENT THEMSELVES IN ORDER TO

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

BE PART OF THE STUDY.

SO I THINK ONE WAY THAT I'VE SEEN THE WORLD OF DISCUSSION ABOUT OFFERING PAYMENT TO RESEARCH PARTICIPANTS CHANGE OVER THE YEARS IS BECAUSE OF THE SOME OF THE DATA AND SOME OF THE GUIDANCE THAT HAS COME OUT AND SOME OF THE COMMENTARIES THAT HAVE COME OUT. AND BASICALLY WHAT THE SORT OF DEFAULT SEEMS TO BE NOW IS THAT RESEARCH -- THIS IS A QUOTE FROM CIOMS, THE CIOMS INTERNATIONAL GUIDELINES. PARTICIPANTS SHOULD BE REASONABLY REIMBURSED FOR COSTS THAT THEY DIRECTLY INCUR, AND THEY SHOULD BE COMPENSATED FOR THEIR INCONVENIENCE AND TIME SPENT, AND THAT COULD BE MONETARY OR NONMONETARY.

A FRAMEWORK THAT L. GELINAS AND OTHERS PUBLISHED IN THE *NEW ENGLAND JOURNAL* A COUPLE OF YEARS AGO RECOMMENDED A FEW ADDITIONAL THINGS, THAT THERE SHOULD BE CLARITY ABOUT THE RATIONALE FOR OFFERING MONEY AND JUSTIFICATION FOR THE AMOUNTS. SO WHETHER IT'S REIMBURSEMENT OR COMPENSATION OR INCENTIVE AND HOW MUCH IS IMPORTANT. AND THE IRB SHOULD REVIEW ALL THAT. THEY WENT ON, HOWEVER, TO SAY REIMBURSE UNLESS THERE ARE REASONS NOT TO AND CONSIDER COMPENSATION BEFORE ASSESSING ANY NEED FOR ADDITIONAL INCENTIVES. AND THEY ALSO TALKED ABOUT

133 HENNA COURT, SANDPOINT, IDAHO 83864
208-255-5453 208-920-3543 DRAIBE@HOTMAIL.COM

THE NEED TO INCREASE SAFEGUARDS AS THE AMOUNT OF MONEY INCREASED, INCLUDING MAXIMIZING UNDERSTANDING OR TAKING STEPS TO MAXIMIZE UNDERSTANDING AND MINIMIZE PERCEPTION.

SO I WAS THINKING AS I WAS THINKING ABOUT THIS AND DECIDING WHAT FINANCIAL SUPPORT SHOULD BE OFFERED AND TO WHOM AS PART OF THE PATIENT SUPPORT PROGRAM AND HOW TO STRUCTURE IT IN ORDER TO BE FAIR AND JUST. IT WOULD BE VERY HELPFUL TO UNDERSTAND, AND IT SOUNDS LIKE SOME OF THIS WORK IS BEING DONE, WHAT THE CURRENT MOTIVATIONS, FACILITATORS, AND BARRIERS ARE TO PARTICIPATION IN CIRM STUDIES? ALSO WHAT THE INSTITUTIONAL, BUT ALSO LOCAL SOCIETAL, LEGAL, AND CULTURAL NORMS ARE. AND I WAS STRUCK BY SOMEONE'S COMMENT IN THE LAST SESSION ABOUT THE DIVERSITY OF POPULATIONS WITHIN THE STATE OF CALIFORNIA, AND THESE CULTURAL NORMS MIGHT BE DIFFERENT IN DIFFERENT POPULATIONS.

AND THEN, IMPORTANTLY, UNDERSTANDING WHAT PATIENTS WHO ARE ENROLLEES IN SOME OF THESE TRIALS PERCEIVE ABOUT THE PROS AND CONS OF OFFERING FINANCIAL SUPPORT IN DIFFERENT WAYS. AND SO I THINK THAT WOULD BE A REALLY IMPORTANT THING TO TRY TO COLLECT DATA ON IF YOU HAVEN'T ALREADY.

AND THAT IS ALL I WANT TO SAY. THANK YOU

VERY MUCH. AND I WAS GOING TO ALSO THINK ABOUT SOME OF THE QUESTIONS THAT GEOFF LOMAX POINTED OUT.

CO-CHAIRMAN KAHN: THANK YOU. DO YOU WANT TO DO THE PANEL OR --

DR. LOMAX: PARTICULARLY INITIAL SORT OF CLARIFICATION-TYPE QUESTIONS.

CO-CHAIRMAN KAHN: DOES ANYBODY HAVE ANY -- I DO, BUT ANYBODY HAVE ANY QUESTIONS OR COMMENTS THEY WANT TO START WITH? I'LL START AND MAYBE OTHERS CAN RAISE HANDS.

SO THANKS FOR THAT, CHRISTINE. REALLY HELPFUL AND VERY CLEAR. ONE THING I DIDN'T HEAR YOU TALK ABOUT WAS EXPLOITATION, WHICH I THINK (UNINTELLIGIBLE) GIVEN THE KIND OF PARTICIPATION WE ARE TALKING ABOUT AND SORT OF HOW THAT SORT OF FITS INTO THE FRAMEWORK THAT YOU SHARED WITH US. I PRESUME YOU'LL SAY SOMETHING LIKE UNDUE INFLUENCE LEADS TO EXPLOITATION OR COULD. AND WHAT, IF ANYTHING, DOES USING THAT TERM AND WHAT IT MEANS DO TO CHANGE WHAT YOU WOULD SAY IN TERMS OF RECOMMENDATIONS?

DR. GRADY: THANKS FOR THAT QUESTION, JEFF. I ACTUALLY HAD A COUPLE SLIDES ON EXPLOITATION, THEN TOOK THEM OUT BECAUSE I THOUGHT I HAD TOO MUCH TO SAY. BUT INTERESTINGLY, ONE OF THE

THINGS THAT I'VE TRIED TO DO OVER THE COURSE OF MY WORK IS TRY TO SEPARATE THESE CONCEPTS BECAUSE I THINK IT'S REALLY IMPORTANT TO KEEP THEM STRAIGHT.

AND SO I THINK EXPLOITATION IS DIFFERENT THAN UNDUE INFLUENCE. A LOT OF PEOPLE THINK OF EXPLOITATION AS WHEN A PERSON WHO IS -- A PERSON IS EXPLOITED WHEN THEY'RE BEING TAKEN ADVANTAGE OF OR UNFAIR ADVANTAGE OF IN A WAY THAT THEY DON'T BENEFIT PROPORTIONAL TO THE AMOUNT OF RISK OR BURDEN THAT THEY'RE ASSUMING OR THE BENEFITS THAT OTHER PEOPLE ARE GETTING FROM THEIR PARTICIPATION. AND SO A LOT OF THE PEOPLE WHO HAVE WRITTEN ABOUT EXPLOITATION IN THE CONTEXT OF PAYING RESEARCH PARTICIPANTS HAVE SUGGESTED THAT THE WAY TO AVOID EXPLOITATION IS TO PAY THEM MORE, INCREASE THE AMOUNTS, MAKE SURE THAT THEY'RE GETTING SOME BENEFIT FROM THEIR PARTICIPATION THAT COMES IN THE FORM OF MONEY.

CO-CHAIRMAN KAHN: THAT'S WHAT I HAD WRITTEN TO MYSELF ACTUALLY IN A NOTE, THAT THE WAY TO ADDRESS EXPLOITATION IS NOT TO PAY PEOPLE LESS, BUT TO PAY THEM MORE. AND SO ONE THING FOR US TO TALK ABOUT AS A GROUP IS IT'S NOT JUST MONEY THAT IS POTENTIALLY EXPLOITIVE OF PEOPLE. TALKING ABOUT ACCESS TO NOVEL THERAPIES IN THE CONTEXT OF RESEARCH. SO HOW THE CONCEPT OF EXPLOITATION KIND

OF GETS CASHED OUT, NO PUN INTENDED, NOT JUST AROUND COMPENSATION, BUT ACCESS TO PARTICIPATION. MAYBE NOT -- IF YOU HAVE OPINION, PLEASE GO AHEAD. BUT I GUESS I'M JUST TRYING TO FRAME THIS FOR OUR FURTHER DISCUSSION.

DR. GRADY: I THINK IT'S A REALLY GOOD POINT. AND I GUESS THE QUESTION IS IS THE CURRENT STATUS COMPETITION FOR ACCESS OR TRYING TO GET MORE PEOPLE ENROLLED OR BOTH. MAYBE IN DIFFERENT PLACES IT OPERATES DIFFERENTLY. SO I GUESS I WOULD RESPOND TO THOSE TWO SLIGHTLY DIFFERENT.

CO-CHAIRMAN KAHN: I SEE SOME OTHER HANDS, WHICH IS GREAT. CHRISTINE.

DR. MIASKOWSKI: THANK YOU, DR. GRADY, FOR YOUR PRESENTATION. I WAS REALLY, REALLY INTRIGUED WITH YOUR MODELS FOR PAYING RESEARCH SUBJECTS. I THOUGHT THEY WERE QUITE COMPREHENSIVE. AND THE QUESTION I HAVE RELATES TO, FOR LACK OF A BETTER TERM, EXPERIENCE WITH SLIDING SCALE FOR REIMBURSEMENT DEPENDING ON THE LEVEL OF FINANCIAL TOXICITY A PARTICIPANT MAY EXPERIENCE FOR BEING IN A CLINICAL TRIAL. I'VE DONE A LOT OF STUDIES AND I OFTEN TRY TO RECRUIT PEOPLE FROM UNDERSERVED POPULATIONS. AND THEY SAY TO ME, CHRIS, WE'D LOVE TO PARTICIPATE; BUT IF I DON'T GO TO WORK, MY

CHILDREN CAN'T EAT OR I CAN'T BUY THE MEDICATION THEY NEED. SO I'D BE CURIOUS ABOUT YOUR THINKING ABOUT THAT AND HOW AN IRB WOULD REACT TO THAT BECAUSE I THINK IT IS GOING TO BE A CHALLENGE FOR US AS WE MOVE FORWARD.

DR. GRADY: MY THINKING IS THE FOLLOWING. I THINK THAT ONCE WE ARE CLEAR ABOUT WHY WE ARE OFFERING FINANCIAL SUPPORT TO PEOPLE, THEN WE CAN MAKE OTHER KINDS OF DECISIONS. SO, FOR EXAMPLE, IF THE REASON TO OFFER SUPPORT IS TO REDUCE FINANCIAL TOXICITY SO THAT NOBODY ENDS UP BEING WORSE OFF FINANCIALLY BECAUSE OF PARTICIPATION, THAT'S A FIRST STEP IN BEING CLEAR ABOUT THAT. THEN THE DECISION CAN BE MADE, OKAY, WHAT DOES THAT INCLUDE. DOES THAT INCLUDE MORE THAN JUST REIMBURSEMENT FOR EXPENSES? MAYBE IT INCLUDES SOME EXTRA MONEY FOR LOST WAGES OR SOMETHING LIKE THAT. I THINK THAT'S A LEGITIMATE KIND OF THINKING.

AND THEN THE QUESTION IS IS IT OKAY FOR SOME PEOPLE TO GET THAT AND NOT EVERYBODY TO GET THAT? AND I THINK THERE HAS TO, AGAIN, BE A JUSTIFICATION, BUT I THINK THERE IS -- THERE ARE PEOPLE WHO CAN AFFORD A DAY OFF FROM WORK MUCH MORE THAN OTHER PEOPLE CAN. SO HAVING SOME CRITERIA FOR SORT OF SAYING IF THAT'S WHAT WE ARE DOING, THIS HOW

WE DECIDE WHO GETS WHAT IN TERMS OF AMOUNTS. THAT'S THE WAY I WOULD DO IT.

NOW, YOU ASKED ALSO, DR. MIASKOWSKI, WHAT AN IRB WOULD SAY. AND THE ANSWER IS I DON'T KNOW. I AM A MEMBER OF AN IRB. I CAN TELL YOU WHAT MY IRB WOULD SAY, BUT I THINK EACH IRB IS SLIGHTLY DIFFERENT.

DR. LOMAX: RAYNE.

DR. ROUCE: I THOUGHT MAYBE I HEARD RAIN. GREAT PRESENTATION THIS MORNING. I JUST WANTED TO KIND OF UNDERSCORE, I THINK, THAT -- SO I'M A PEDIATRIC PHYSICIAN/SCIENTIST. AND BY DEFINITION, ALL THE PATIENTS I TREAT ARE RARE DISEASES, AND I DO CAR-T CELL THERAPY. AND OUR CLINICAL TRIALS ARE EXTREMELY TIME INTENSIVE AND OFTEN REQUIRE PEOPLE TO UPROOT AND REMAIN WITHIN OUR AREA FOR FOUR TO SIX WEEKS, AND OFTEN ARE THE ONLY SITE AVAILABLE IN THE ENTIRE UNITED STATES. SO THESE PATIENTS AND CHILDREN WHO ARE SEVEN DON'T TYPICALLY TRAVEL UNACCOMPANIED TO STAY AT A HOTEL BY THEMSELVES FOR FOUR TO SIX WEEKS. SO IT'S EXTREMELY DISRUPTIVE TO THE ENTIRE FAMILY.

AND SO IN THESE SITUATIONS I THINK YOUR ADVICE IS GREAT, DR. GRADY, WHERE WE'RE SAYING THERE ARE CLEAR ASPECTS OF THIS TRIAL THAT LODGING,

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TRANSPORTATION, LOST WAGES, THE ABILITY TO NOT BE THERE THAT WE CAN CLEARLY DEFINE AND OUTLINE AND MAKE A VERY STRONG CASE FOR WHY WE WOULD PROVIDE SOME PATIENT SUPPORT. AND IN MOST OF THE CIRM APPLICATIONS THAT I REVIEW, THERE ARE CLEAR ASPECTS WHERE YOU CAN SEE THAT. AND I DON'T VIEW THAT AS COERCION, AND I CERTAINLY DON'T VIEW THAT AS BEING THE PRIMARY INCENTIVE TO WHY SOMEONE WOULD WANT TO POTENTIALLY PARTICIPATE IN THIS TRIAL WHEN BY DEFINITION MANY OF THESE PATIENTS DO NOT HAVE OTHER VIABLE CLINICAL OPTIONS.

AND SO I'M AN IRB MEMBER AS WELL. AND JUST LIKE CHRISTINE SAID, I CAN TELL EXACTLY WHAT MY IRB WOULD SAY. I THINK WE ALL KIND OF GET THE GIST OF OUR DIFFERENT IRB'S. BUT I WOULD ENCOURAGE US THAT BEING ABLE TO ITEMIZE AND IDENTIFY THESE ASPECTS THAT ARE IN A LOT OF WAYS OUT OF THE NORM, IN A LOT OF WAYS VERY DIFFERENT THAN STANDARD OF CARE, AND SOMETIMES A STANDARD OF CARE IS NOT APPROPRIATE FOR THESE PATIENTS. AND I THINK THAT -- I LOVE THAT WE'RE MOVING IN THIS DIRECTION BECAUSE I THINK IT'S VERY, VERY IMPORTANT.

THE OTHER THING I WOULD SAY IS THAT, AS SOMEONE WHO WEARS HEALTH EQUITY AND ACCESS AND DIVERSITY, EQUITY, AND INCLUSION HATS

INSTITUTIONALLY AND ON A NATIONAL LEVEL IN A NUMBER OF DIFFERENT ORGANIZATIONS, WE OFTEN FIND -- THE SPEAKER EARLIER THIS DISCUSSED THIS -- THAT OUR HYPERVIGILANCE ABOUT ENSURING THAT WE ARE NOT -- THAT THIS ASPECT OF THE PROSPECT OF EXPERIMENTATION OR EXPLOITATION, ESPECIALLY OF UNDERREPRESENTED POPULATIONS, WE OFTEN FIND, AND EVIDENCE SHOWS, THAT OFTEN IT LEADS TO INVESTIGATORS NOT OFFERING CERTAIN CLINICAL TRIALS DUE TO THEIR HYPERVIGILANCE ABOUT ENSURING THEY DON'T WANT TO APPEAR AS IF THEY'RE EXPLOITING, BUT ALSO ABOUT ASSUMPTIONS ABOUT WILLINGNESS TO PARTICIPATE BASED ON SOCIOECONOMIC STATUS AND LOGISTICAL ABILITY TO BE ABLE TO PARTICIPATE IN THE STUDY AS DESIGNED.

AND BUT OVERWHELMINGLY PATIENTS AND FAMILIES SAY THAT WHEN GIVEN, LIKE YOU SAID, OVER 50 PERCENT OF PEOPLE THAT ARE OFFERED A CLINICAL TRIAL WILL ACTUALLY PARTICIPATE. SO I JUST CAUTION ALL OF US THAT WE CONSTANTLY HAVE TO DO THIS AND ENSURE THAT WHAT WE KNOW ABOUT THE SOCIOECONOMIC SITUATION AND WHAT WE KNOW ABOUT PERHAPS CULTURAL AND HISTORICAL EVENTS THAT HAVE HAPPENED DOESN'T MAKE US NOT INVITE PEOPLE TO PARTICIPATE IN RESEARCH. INSTEAD, MAKES US DISCUSS THESE SAFEGUARDS THAT ARE IN PLACE AND KIND OF DEMYSTIFY AND ADDRESS UP FRONT

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SOME OF THESE ISSUES.

BUT ALSO WHEN WE ARE CONCEIVING THE TRIAL AND LOOKING AT OUR BUDGETS, THINK ABOUT HOW WE'RE GOING TO OFFSET FOR SOME OF THESE COSTS. I CONGRATULATE CIRM FOR HAVING THESE IMPORTANT DISCUSSIONS AND REALLY APPRECIATED BOTH OF THE DISCUSSIONS THAT WE'VE HAD TODAY.

CO-CHAIRMAN KAHN: SHELDON NEXT.

DR. LOMAX: SHELDON, CAN I JUST -- BY THE WAY, THE VARIOUS INTUITIONAL SPEAKERS, CAN YOU JUST INTRODUCE YOURSELF BECAUSE I KNOW WE DIDN'T GET A CHANCE AT THE FRONT END. SO I JUST WANTED, FOR THE BENEFIT OF THE AUDIENCE, TO KNOW WHO'S REPRESENTED HERE PLEASE.

DR. MORRIS: OH, SURE. I'M SHELDON MORRIS. I'M A PROFESSOR AT UCSD, AND I'M DIRECTOR OF SANFORD CLINICAL CENTER WHICH ALSO HOUSES THE ALPHA CLINIC FOR UC SAN DIEGO. AND I'VE BEEN AN IRB MEMBER FOR 15 YEARS IN UCSD AND TEACH ETHICS OF CLINICAL TRIALS HERE.

I MEAN MY QUESTION GOES TO THIS IDEA THAT THE DIFFERENCES BETWEEN IRB'S TOO CAN BE PROBLEMATIC BECAUSE I KNOW THAT THE IDEA OF TRYING TO GIVE COMPENSATION TO PEOPLE WHO NEED IT MORE IS A PROBLEM. MY IRB WILL SAY YOU HAVE TO OFFER THAT TO

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EVERYBODY. SO EVEN IF THE PERSON DOESN'T NEED IT, YOU'RE SUPPOSED TO SOMEHOW OFFER THAT TO THEM. I GUESS THAT'S WHAT YOU HAVE TO DO IF YOU JUST WANT TO HELP EVERYBODY. BUT IT'S HARDER TO HAVE THIS IDEA OF HELPING THE PEOPLE THAT REALLY NEED IT AND PROVIDING MORE RESOURCES TO WHERE THE NEED IS AGAINST THIS IDEA THAT IT NEEDS TO BE ACROSS -- EVERYBODY NEEDS TO BE OFFERED THE SAME THING.

AND THEN THE SAME ARGUMENT THAT I GET SOMETIMES IS, WELL, IF PEOPLE ARE, SAY, LOWER SOCIOECONOMIC, THEN THEY DON'T NEED AS MUCH INCENTIVE BECAUSE THEY NEED LESS MONEY. THAT, I THINK, CARRIES LESS WEIGHT THESE DAYS. BUT I USED TO HEAR THAT TOO, WHICH I REALLY THOUGHT WAS RIDICULOUS HONESTLY BECAUSE YOU WANT TO GIVE MORE COMPENSATION TO PEOPLE THAT NEED IT MORE.

IS THERE ANY WAY TO GET IRB'S ALL ON THE SAME SORT OF LEVEL ABOUT HOW THEY ACCEPT THESE KINDS OF SYSTEMS OF COMPENSATION FOR STUDIES SO THAT THOSE THAT DO NEED IT CAN GET IT?

DR. GRADY: I WOULD JUST SAY ONE THING ABOUT THAT. I THINK THERE'S BEEN A LOT OF PROGRESS IN THE LAST 20 YEARS IN TERMS OF HOW IRB'S THINK ABOUT THIS, HOW PEOPLE THINK ABOUT IT IN GENERAL, PEOPLE INVOLVED IN RESEARCH. BUT ONE OF THE THINGS

THAT AT LEAST I'VE NOTICED FROM MY EXPERIENCE ON AN IRB IS THAT OFTENTIMES ANY DETAIL ABOUT WHY MONEY IS BEING OFFERED OR HOW IT'S BEING THOUGHT THROUGH OR HOW THEY DECIDED TO COME UP WITH AN AMOUNT IS NOT PROVIDED. AND SO IRB'S MIGHT BENEFIT FROM GETTING MORE DETAIL ABOUT HERE'S THE JUSTIFICATION, HERE'S WHY WE WANT TO PAY FOR LODGING, HERE'S WHY WE WANT TO COVER -- HERE'S WHY I WANT TO GIVE A STIPEND TO CERTAIN PEOPLE BECAUSE THEY CAN'T PARTICIPATE IF THEY HAVE TO TAKE A DAY OFF FROM WORK.

I DON'T KNOW THAT ALL IRB'S WILL BUY THAT, BUT I THINK THEY'RE NOT GETTING JUSTIFICATIONS FOR THE REASONS THAT PEOPLE ARE CHOOSING DIFFERENT LEVELS OF MONEY.

CO-CHAIRMAN KAHN: I'M JUST WHISPERING HERE TO GEOFF ON MY RIGHT. I THINK THAT -- IN ANSWER TO YOUR QUESTION, SHELDON, THAT THAT'S PART OF WHAT THE WORK OF THIS GROUP CAN BE, TO HELP CREATE BEST PRACTICES AND EXPECTATIONS FOR AT LEAST CIRM-FUNDED TRIALS. I'VE SAID THIS A NUMBER OF TIMES IN A DIFFERENT CONTEXT. CALIFORNIA IS A BIG STATE, AND CIRM IS A VERY POWERFUL ENTITY. AND SO BEST PRACTICES FROM CIRM, I THINK, CAN ALSO HAVE IMPACT MUCH MORE WIDELY THAN JUST CIRM TRIALS AND JUST CALIFORNIA. SO I THINK THERE'S IMPORTANT WORK

TO DO.

DR. GRADY: CAN I SAY ONE MORE THING ABOUT THAT? ONE OF THE THINGS THAT I THOUGHT ABOUT AND IT WAS REINFORCED BY SOMETHING THAT SOMEBODY SAID THIS MORNING IS OTHER THING IS TO ASK PATIENTS. AND THEY MAY VERY CLEARLY SUPPORT DIFFERENTIAL PAYMENT FOR PEOPLE WHO NEED IT MORE BASED ON HELPING PEOPLE BEING ABLE TO PARTICIPATE WITHOUT FINANCIAL TOXICITY.

CO-CHAIRMAN KAHN: YEAH. OR A DIFFERENT SLIDING SCALE FOR SOME THINGS, BUT NOT FOR OTHERS IS A WAY TO DO THIS, I THINK. MAYBE WE SHOULD -- SORRY. I DIDN'T SEE YOUR HAND, SABRINA. GO AHEAD.

DR. DERRINGTON: THAT'S OKAY. I WAS REALLY GOING TO SAY SOMETHING ALONG THE SAME LINES OF WHAT DR. GRADY JUST EMPHASIZED, WHICH IS THAT I THINK THERE IS A ROLE FOR THE FUNDING ORGANIZATION TO CREATE SOME STANDARDS AND GUIDELINES WHICH WILL HOPEFULLY HAVE DOWNSTREAM EFFECTS ON THE WAYS THAT IRB'S AND DIFFERENT INVESTIGATORY TEAMS ARE STRUCTURING THESE PROGRAMS. BUT THERE'S GOING TO BE SO MUCH LOCAL VARIATION, AND SO IT ACTUALLY ALIGNS REALLY NICELY WITH THE COMMUNITY ENGAGEMENT PROCESSES THAT WE WERE TALKING ABOUT EARLIER THIS MORNING.

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CO-CHAIRMAN KAHN: GOOD. SO WE HAVE WITH US THREE PEOPLE WHO CAN BRING ADDITIONAL IRB PERSPECTIVE. SO I WANT TO TURN NOW TO THE THREE PANELISTS THAT WE'VE INVITED. JOHN TUPIN FROM UC DAVIS, SABRINA, YOURSELF, FROM CHILDREN'S HOSPITAL IN L.A., AND NICOLE WALTERS FROM UC DAVIS.

I KNOW WE DIDN'T ASK YOU TO PREPARE PRESENTATIONS. IT'S NOT WHAT WE'RE ASKING. WE REALLY WANT KIND OF COMMENTARY AND REACTION FROM YOUR INDIVIDUAL PERSPECTIVES. WHOMEVER WANTS TO GO FIRST.

DR. TUPIN: I HAVE SO MANY THOUGHTS HEARING THIS CONVERSATION, EVERYTHING FROM WE COVER SUCH A HUGE GEOGRAPHICAL AREA BEING IN SACRAMENTO DOWN TO FRESNO AND UP PAST REDDING. AND SO TRAVEL EXPENSES IS REALLY, REALLY A BIG DEAL AS IS HOTELLING AND MEALS, ET CETERA.

COUPLE OF THINGS THAT I DIDN'T HEAR THAT I THINK THAT CIRM REALLY NEEDS TO BE VERY COGNIZANT OF IS MANY OF THESE PEOPLE DON'T HAVE THE ABILITY TO RECEIVE PAYMENT IN A TRADITIONAL WAY. THEY DON'T HAVE A SOCIAL SECURITY NUMBER. SO IF YOU'RE PAYING OVER $600, THAT'S SUPPOSED TO BE REPORTED. SO YOU NEED TO FIND A WAY OF COMPENSATING AND COMPLYING WITH THE LAW. IF THAT'S HELPING THEM GET A TIN OR

SOME OTHER MEANS OF COMPENSATION, THAT'S A BIG DEAL.

THE OTHER ISSUE THAT WE RUN INTO A LOT WITH PEDIATRIC STUDIES IS MOM OR DAD, AND THIS IS REALLY MORE ON THE EMERGENCY SETTING, DON'T HAVE THE ABILITY TO LEAVE WORK OR GET TRANSPORTATION FROM WORK IN A TIMELY MANNER TO SIGN AN INFORMED CONSENT. SO HOW DO YOU -- HOW DO YOU COLLECT THE DATA THAT YOU'RE LOOKING TO COLLECT IN AN OBSERVATIONAL STUDY OR A STANDARD OF CARE VERSUS STANDARD OF CARE TYPE OF STUDY. SO DO YOU WAIVE IT, AND DO YOU HOPE TO GET IT ON THE BACK END, OR DO YOU HAVE A TIERED INFORMED CONSENT REQUIREMENT?

AND THEN A LOT OF THE FOLKS THAT ARE GOING TO BE INTERESTED IN WHAT CIRM IS DOING ARE GOING TO HAVE A THERAPEUTIC MISCONCEPTION COMING IN. AND THAT REALLY BOTHERS ME. AND HOW DO YOU GIVE THEM THE INFORMATION THAT THEY REALLY NEED TO KNOW, THAT THIS IS AN EXPERIMENT? WE ARE HOPING FOR THE BEST. BUT A LOT OF PEOPLE COME IN THINKING I'M GETTING THE SECRET SAUCE. AND IT'S KIND OF A BACK-END COERCION, OR UNDUE INFLUENCE ACTUALLY IS THE PROPER TERM. SO THERE'S ALL THESE DIFFERENT PROBLEMS AROUND INCENTIVIZING. BUT I THINK AT THE VERY MINIMUM, IT'S COMPENSATING FOR LOSSES AND THEN FACILITATING ACCESS.

CO-CHAIRMAN KAHN: SO ONE QUICK MAYBE JUST COMMENT AND A QUESTION BACK TO YOU, JOHN. WE DON'T PAY PEOPLE WHEN THEY COME TO THE DOCTOR TO RECEIVE HEALTHCARE. SO DOES PAYMENT HELP SIGNAL TO PEOPLE THAT THIS IS DIFFERENT THAN GOING TO RECEIVE CARE? AND DIFFERENT (INAUDIBLE) AND RESEARCH IS DIFFERENT FOR ALL THE REASONS THAT WE DON'T HAVE TO REHEARSE FOR EACH OTHER. BUT MAYBE PAYMENT HELPS MAKE THAT CLEAR. AND MAYBE BLUNT SOME OF THE CONCERNS ABOUT SOME OF THE CONCERNS ABOUT THEIR PRECONCEIVED PERCEPTION. WHAT DO YOU THINK ABOUT THAT?

DR. TUPIN: I THINK THAT FROM PERSONAL PERSPECTIVE, AND LOOK AT ME, WHAT PERSPECTIVE DO I REALLY HAVE, THE PAYMENT WOULDN'T NECESSARILY TIP ME OFF THAT IT IS SOMETHING DIFFERENT. I WOULD ALMOST TAKE THOSE AS SEPARATE ISSUES. I THINK THAT THE THERAPEUTIC MISCONCEPTION REALLY IS THE ONE THAT I THINK IS THE MOST DAUNTING. AND IT'S BASED ON THINGS THAT PEOPLE ARE SEEING IN THEIR ENTERTAINMENT, EVERYTHING FROM VIDEOGAMES TO MOVIES TO TV, THIS PERSON HAS BEEN ENHANCED. AND SO LOOK AT WHAT SCIENCE CAN DO FOR ME. AND WHERE THE MONEY IS IS KIND OF A -- I THINK PEOPLE GET WHAT THE MONEY IS ABOUT, BUT GETTING THAT RIGHT IS REALLY A BIG DEAL. I'M INTERESTED IN THE HOW WOULD YOU

DIFFERENTIATE SOMEONE WHO NEEDS THE MONEY VERSUS SOMEONE WHO DOESN'T. AND THEN WHERE DO YOU DRAW THAT LINE, AND IS IT YOUR JOB TO DRAW THAT LINE? I CAN GET INTO DEEP PHILOSOPHICAL CONVERSATIONS ABOUT THAT.

CO-CHAIRMAN KAHN: I SEE YOUR HAND RAYNE. I WANT TO MAKE SURE WE GET SABRINA. I DON'T THINK NICOLE IS ON.

DR. TUPIN: SHE COULDN'T. UNFORTUNATELY THERE IS A UCOP MEETING THAT SHE'S COVERING RIGHT NOW.

CO-CHAIRMAN KAHN: THANK YOU. SO I WANT TO LET SABRINA MAKE COMMENTS IF SHE'D LIKE AND THEN I'LL COME TO YOU, RAYNE.

DR. DERRINGTON: THANK YOU. SABRINA DERRINGTON. I'M THE DIRECTOR OF THE CENTER FOR BIOETHICS AT CHILDREN'S HOSPITAL LOS ANGELES WHERE I ALSO DIRECT THE RESPONSIBLE AND ETHICAL CONDUCT OF RESEARCH COURSE, AND I SIT ON THE ADVISORY BOARD FOR OUR ALPHA CLINIC AT CHLA AND USC.

SO I HAVE REALLY APPRECIATED THE PRESENTATIONS AND ALL OF THE COMMENTARY TODAY. I THINK THE THING THAT JUST REALLY STANDS OUT TO ME IS THE IMPORTANCE OF APPROACHING EACH COMMUNITY THAT WE HOPE TO ENGAGE WITH HUMILITY. AND SO ONE OF THE

THINGS THAT I DIDN'T HEAR SPECIFICALLY ADDRESSED WAS THE IMPORTANCE OF THE INITIAL EVALUATION ASSESSMENT AND SORT OF DEVELOPING RELATIONSHIPS.

AND WE HEARD A LITTLE BIT ABOUT THAT FROM DR. WASHINGTON THIS MORNING. SHE ALLUDED TO THE REALLY MULTIPLE YEARS OF WORK THAT THEY DID IN DEVELOPING THE NETWORK IN THEIR COMMUNITY. AND SO I WANT TO MAKE SURE THAT THAT IS A PART OF HOW WE ARE THINKING ABOUT FUNDING THIS WORK, THAT IT WOULD ALSO INCLUDE THAT SORT OF PRELIMINARY PHASE. AND THAT AS A PART OF THAT I THINK A LOT OF THESE QUESTIONS CAN BE ENGAGED WITH AND ANSWERED AROUND APPROPRIATE SUPPORT STRUCTURES.

ONE OF THE QUESTIONS THAT GEOFF HAD ASKED US TO THINK ABOUT WAS WHETHER SUPPORT SHOULD BE EQUAL TO ALL PATIENTS OR BASED ON ECONOMIC NEED OR SOME OTHER FACTOR. AND TO ME THAT REALLY MIRRORS THE QUESTION OF, NOT SO MUCH A QUESTION, BUT MOVING FROM EQUALITY TO EQUITY AND REALLY THINKING ABOUT IT IN TERMS OF THE JUSTICE FRAMEWORK, WHICH I THINK ALSO LINKS TO HOW WE -- JUST WANTING TO MAKE SURE THAT WE ARE BEING REALLY RESPONSIBLE AND THOUGHTFUL STEWARDS OF THESE RESOURCES AND THAT THE MONEY IS GOING IN A WAY THAT INCREASES JUSTICE AND EQUITABLE ACCESS FOR PATIENTS WHO MIGHT NOT OTHERWISE BE ABLE

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TO PARTICIPATE.

AND THEN LAST COMMENT, I JUST AM -- I THINK THAT THE TIMING ISSUE WAS ANOTHER QUESTION OF WHEN SHOULD THESE SUPPORT PROGRAMS BE INTRODUCED? AND I'M SURE THERE ARE A LOTS OF DIFFERENT PERSPECTIVES ON THIS, BUT I THINK THAT ONE OF THE THINGS WE WANT TO ENSURE IS THAT POTENTIAL RESEARCH PARTICIPANTS ARE ABLE TO MAKE A REALLY AUTHENTIC DECISION, WHICH WOULD NEED TO INCLUDE RELEVANT INFORMATION TO THAT INDIVIDUAL. AND SO A PART OF THAT EARLY DISCUSSION ABOUT POTENTIAL ENROLLMENT WOULD THEN NEED TO AT LEAST INDICATE THAT IF THERE ARE BARRIERS TO PARTICIPATION, THAT THOSE -- THAT THERE ARE MECHANISMS FOR THOSE BARRIERS TO BE REDUCED OR SUPPORTED IN SOME WAY. AND THAT MAYBE DOESN'T HAVE TO GO INTO A LOT OF DETAIL IN TERMS OF HOW MUCH OR IN WHAT WAYS, BUT AT LEAST THAT THERE'S SOME ASSESSMENT OF WHAT THOSE BARRIERS MIGHT BE.

CO-CHAIRMAN KAHN: THANK YOU FOR THAT. RAYNE, I SEE YOUR HAND.

DR. ROUCE: IT'S ACTUALLY VERY RELATED TO THE PRIOR COMMENT. IN CLINICAL SETTINGS, IT IS NOT ATYPICAL TO DO A PSYCHOSOCIAL AND A FINANCIAL ASSESSMENT. AND SO THERE IS LOTS OF PRECEDENCE FOR IDENTIFYING PATIENTS WHO NEED FINANCIAL ASSISTANCE

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EVEN FOR THEIR STANDARD OF CARE. IN THE SAME WAY, PUBLIC INSURANCE LIKE MEDICAID OFFERS MEALS AND LODGING AND TRANSPORTATION THAT SOME OTHER PRIVATE INSURANCES DON'T. AND THAT IS A NEEDS-BASED ASSESSMENT BASED ON YOUR INCOME AND YOUR LEVEL OF SOCIOECONOMIC STATUS.

SO I DO THINK THAT PROBABLY A BEST PRACTICE TO DO IN ROLLING THIS OUT IS TO REQUIRE, ESPECIALLY SINCE ALL OF THESE ALPHA CLINICS, ALL OF THESE INFRASTRUCTURES HAVE SOME ABILITY TO DO SOCIAL WORK AND FINANCIAL ASSESSMENT, IS THAT YOU ALLOW THE CLINIC, THE INSTITUTION, TO DO THAT. AND THEN FOR THOSE PATIENTS THAT MEET THAT CRITERIA, THOSE WILL BE ONES THAT WOULD BE ELIGIBLE FOR THIS ADDITIONAL ASSISTANCE.

THAT IS A WAY TO, IN SOME WAYS, REMOVE IT FROM -- BECAUSE I AM DEFINITELY ON AN IRB WHERE IF YOU'RE NOT DOING IT FOR EVERYONE, IT WILL BE FROWNED UPON. BUT THAT'S ALSO NOT REALLY EQUITABLE. WHEN WE'RE TALKING ABOUT EQUITY, IF YOU HAVE SOMEONE WHO IS VERY WEALTHY AND HAS A PRIVATE JET AND HAS THE ABILITY TO FLY AROUND THE WORLD TO SEEK HEALTHCARE, THAT'S NOT THE SAME AS SOMEONE ELSE. AND SO WHEN YOU THINK ABOUT RESPONSIBLE USE OF FUNDS, I THINK ALLOWING THESE INFRASTRUCTURES THAT DO ASSESSMENTS

OF NEED BASED -- NEEDS ANYWAY, WHICH IT HAPPENS IN EVERY LARGE MEDICAL CENTER AND EVEN IN COMMUNITY MEDICAL CENTERS, THE ABILITY TO HAVE THAT INFORMATION TO ALLOW IT TO CREATE THIS SORT OF SLIDING SCALE, IF YOU WILL, BECAUSE THOSE THINGS REALLY ARE TRULY BARRIERS FOR SOME PEOPLE WHERE THEY ARE NOT ABLE TO NOT BE AT WORK TO BE A CAREGIVER FOR SOMEONE WHO'S PARTICIPATING IN A TRIAL, BUT THAT'S NOT NECESSARILY THE SAME SITUATION AS SOMEONE ELSE.

SO THAT'S JUST A THOUGHT THAT I MIGHT RECOMMEND AND VERY CLOSELY RELATED TO WHAT THE PRIOR SPEAKER SAID. I ALSO JUST WANT TO JUST UNDERSCORE THAT ALL -- EVERYONE IN A CIRM COMMUNITY IS NOT CREATED EQUAL. SO THE ABILITY -- WE NEED -- I LEAD COE AT OUR INSTITUTION FOR OUR COMPREHENSIVE CANCER CENTER, AND WE DO LOTS OF OUTREACH WITH DIFFERENT CHURCHES AND COMMUNITY CENTERS AND DO HAVE COMMUNITY HEALTH WORKERS AND PEOPLE THAT ARE AMBASSADORS, BUT THEY DON'T NECESSARILY SPEAK FOR THE ENTIRE CONGREGATION OR FOR THE ENTIRE COMMUNITY.

SO IT JUST ALSO UNDERSCORES THE ABILITY TO DO THESE INDIVIDUALIZED ASSESSMENTS THAT WE DO FROM A MEDICAL CENTER PERSPECTIVE ANYWAY AND ALLOW THAT TO REMOVE THAT KIND OF BURDEN IN SOME WAYS OF CIRM DECIDING WHO NEEDS THE ADDITIONAL FUNDS AND WHO

DOESN'T JUST AS AN IDEA.

CO-CHAIRMAN KAHN: THANKS. I HAVE SOME THOUGHTS, BUT I SEE STEPHANIE'S HAND. SO LET'S GO TO STEPHANIE AND THEN MAYBE WE CAN COME BACK. GO AHEAD.

DR. FARRELL: HI THERE. I WAS THINKING FROM AN IRB PERSPECTIVE. I WORK AT A COMMUNITY HOSPITAL AND CANCER CENTER AND SIT ON THE IRB AND DO CANCER CLINICAL TRIALS AND OTHERS. AND ONE OF THE THINGS WE CAN DO IS REFRAME THE CONVERSATION FROM PAYMENT FOR PARTICIPATION TO REIMBURSING PATIENTS FOR EXPENSES BECAUSE THEN YOU'RE NOT PAYING ONE PERSON ONE THING AND ANOTHER PERSON ANOTHER. I'VE HAD CHALLENGES BOTH WITH GETTING THESE THINGS THROUGH THE IRB AND ACTUALLY NEGOTIATING WITH THE SPONSORS OF CLINICAL TRIALS.

IF YOU PUT IN $500 FOR PAYMENT BECAUSE YOU WANT TO TRY TO COVER CHILDCARE AND THE HOTEL FOR THEM TO STAY OVERNIGHT AND THEIR MILEAGE, ONE PERSON MAY HAVE DIFFERENT THINGS. SO THAT'S -- WE FOUND THAT TO BE SUCCESSFUL IN SOME SITUATIONS WHERE INSTEAD OF JUST GETTING A REALLY HIGH PAYMENT, YES, THERE IS A PAYMENT FOR PARTICIPATION, BUT THERE'S ALSO LANGUAGE IN THE CONSENT AND IN THE CLINICAL TRIAL AGREEMENT TO REIMBURSE FOR FAIR AND REASONABLE

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EXPENSES FOR THEM TO STAY IN COMPLIANCE WITH THAT CLINICAL TRIAL PROTOCOL.

CO-CHAIRMAN KAHN: CAN I ASK BOTH YOU, STEPHANIE AND RAYNE WHAT YOU JUST SAID, ARE YOU SUGGESTING LIMITING TO REIMBURSEMENT FOR COSTS, WHATEVER THEY MAY BE, AND NO INCENTIVE TO PARTICIPATE AS A MATTER OF COMPENSATION, OR AM I MISUNDERSTANDING YOUR THOUGHTS?

DR. FARRELL: I THINK IT'S OKAY TO PAY PATIENTS TO PARTICIPATE IN A CLINICAL TRIAL BECAUSE THERE IS TIME AND EFFORT AND THEY'RE TAKING A RISK; BUT I THINK, WHEN THOSE DOLLAR AMOUNTS GET TOO HIGH, THE IRB CAN GET A LITTLE NERVOUS AND WORRY THAT YOU ARE COERCING. SO I THINK YOU COULD DO A REASONABLE PAYMENT, BUT THEN ALSO PROVIDE REIMBURSEMENT AND LET THE PATIENT KNOW. HEY, LOOK. IF YOU HAVE TO TRAVEL 180 MILES BECAUSE WE SEE PATIENTS FROM WAY OUT IN BLYTHE. AND IF YOU HAVE TO TRAVEL ALL THE WAY IN, WE'RE GOING TO REIMBURSE YOU FOR YOUR GAS, OR IF YOU NEED TO STAY OVERNIGHT, WE'LL COVER THE HOTEL SO YOU CAN GET YOUR DAILY RADIATION OR THINGS LIKE THAT. LITTLE BIT OF BOTH.

DR. ROUCE: I FEEL A LITTLE BIT DIFFERENTLY BECAUSE I STRUGGLE WITH WHAT IS AN APPROPRIATE AMOUNT TO PAY SOMEONE TO HAVE THEIR ONLY

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CHILD, WHO HAS A LIFE-THREATENING ILLNESS, PARTICIPATE IN A CLINICAL TRIAL. AND WHEN WE THINK ABOUT THE POTENTIAL FOR RISK, BUT ALSO THE POTENTIAL FOR BENEFIT, I THINK IT'S VERY CHALLENGING TO COME UP WITH A REASONABLE AMOUNT TO PAY. SO I ERR MORE ON THE SIDE OF REIMBURSING FOR EXPENSES. AND IN THE PAYMENT ASPECT, IF YOU HAVE THE ABILITY TO REIMBURSE FOR LOST WAGES, I THINK THAT THAT'S -- IT'S SOMETHING THAT I SEE SO INFREQUENTLY IN LOTS OF CLINICAL TRIALS, BUT IT'S SOMETHING THAT REALLY CAN MAKE A DIFFERENCE.

I DON'T THINK IT'S ETHICALLY WRONG TO PAY FOR PARTICIPATION. I THINK IT'S VERY EASY TO IDENTIFY WHAT A REASONABLE AMOUNT WOULD BE A SURVEY THAT TAKES 30 MINUTES OR AN INTERVIEW, BUT IT'S VERY CHALLENGING FOR ME TO THINK, TO GRASP WHAT SORT OF PAYMENT YOU WOULD DO FOR A FIRST-IN-HUMAN GENE MODIFIED CELL THERAPY TRIAL. IT'S JUST CHALLENGING FOR ME TO THINK ABOUT, BUT I DON'T THINK IT'S WRONG.

CO-CHAIRMAN KAHN: THERE'S A CONCEPTUAL QUESTION HERE, THOUGH, ABOUT WHETHER PAYING SOMEONE TO PARTICIPATE IN A THERAPEUTIC TRIAL. I THINK IT'S WHAT WE'RE MEANING HERE. IT'S QUITE DIFFERENT THAN BAYING SOMEONE TO FILL OUT A SURVEY, AS YOU PUT IT.

DR. ROUCE: EXACTLY.

CO-CHAIRMAN KAHN: WHICH IS TYPICALLY WHERE COMPENSATION COMES IN, INCENTIVES TO PARTICIPATE. SO THERE'S A KIND OF REALLY FUNDAMENTAL QUESTION HERE, I THINK, WHICH I WOULD LOVE FOR US TO TALK THROUGH ABOUT WHETHER PAYING PEOPLE TO PARTICIPATE IN CLINICAL TRIALS IN THE WAY THAT WE ARE IMAGINING IS REALLY EVER APPROPRIATE. I SEE SHELDON, CHRISTINE, AND THEN JOHN.

DR. MORRIS: I GUESS I WAS JUST THINKING THAT GOING BEYOND JUST COMPENSATING PEOPLE, WE'RE THINKING OF PEOPLE THAT HAVE SPECIFIC RARE DISEASES, THEY HAVE OTHER CHALLENGES THAT AREN'T JUST TRAVEL OR COMPENSATION RELATED. THEY HAVE CHILDCARE, THEY HAVE CARE FOR OTHER LOVED ONES, THEY HAVE OTHER RESPONSIBILITIES. PEOPLE HAVE WORK THAT YOU JUST CANNOT TAKE TIME OFF EVEN IF YOU WANTED TO AND BE REIMBURSED FOR IT. THE WORK SAYS IF YOU LEAVE, YOU'RE FIRED.

SO THOSE ISSUES ARE NOT REALLY BEING ADDRESSED BY JUST A COMPENSATION MODEL TOO. I DON'T KNOW WHAT THE ANSWER IS, BUT IT HAS TO BE OTHER TYPES OF AMENITIES TO HELP THOSE PEOPLE TO PARTICIPATE.

CO-CHAIRMAN KAHN: THAT SOUNDS LIKE REIMBURSEMENT TO ME, BUT IT'S REIMBURSEMENT FOR JUST

A WIDER RANGE OF THINGS. SO WE'RE ARE BEING MORE EXPANSIVE ON HOW WE UNDERSTAND WHAT PEOPLE'S NEEDS ARE. SO I REALLY WANT TO DRILL DOWN AND SEE IF WE CAN COME TO SOME CONSENSUS ABOUT THIS.

CHRISTINE.

DR. GRADY: I DON'T KNOW IF I CAN COME TO CONSENSUS, BUT I WAS GOING TO ACTUALLY SAY SOMETHING THAT WAS SIMILAR TO WHAT SHELDON JUST SAID. I THINK THAT THE PROBLEM WITH SIMPLY REIMBURSING EXPENSES FOR WHICH YOU CAN PROVIDE A RECEIPT IS THAT IT'S OFTEN NOT ENOUGH AND THAT PEOPLE CAN'T -- IT DOESN'T MAKE PARTICIPATION REVENUE NEUTRAL. IT STILL COSTS PEOPLE MONEY.

I ALSO THINK IT'S REALLY HARD TO ARGUE WITH THE IDEA THAT DR. ROUCE SAID BEFORE. PEOPLE WHO HAVE A VERY SERIOUS ILLNESS OR PEOPLE WHOSE CHILDREN HAVE A VERY SERIOUS ILLNESS, THEY'RE NOT -- THEY MIGHT BE PAYING TO THE ATTENTION TO THE AMOUNT OF MONEY THAT THEY CAN GET IN ORDER TO MAKE IT POSSIBLE, BUT THAT'S NOT THE REASON THEY'RE THERE. THEY'RE THERE BECAUSE THEY NEED SOME KIND OF TREATMENT AND THEY'RE HOPING THEY CAN GET IT. AND THAT THEY HOPE, EVEN IF THEY ARE NOT -- DON'T HAVE A THERAPEUTIC MISCONCEPTION, THEY HOPE THAT THEY'RE GOING TO BENEFIT FROM WHAT THEY'RE GETTING IN THIS

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STUDY.

BUT THERE IS A REALLY INTERESTING WAY TO THINK ABOUT WHAT THEY NEED IN ORDER TO MAKE PARTICIPATION REVENUE NEUTRAL BECAUSE, AS SOMEBODY POINTED OUT, ESPECIALLY FOR CELL THERAPIES, THERE ARE A LOT OF TIMES PEOPLE STAY FOR MONTHS IN A PLACE AWAY FROM HOME. AND SO IT'S NOT JUST PAYING FOR THE LODGING, BUT SOME KIND OF PER DIEM OR SOME KIND OF HOW DO I TAKE CARE OF THE REST OF MY FAMILY KIND OF STUFF. THINKING ABOUT THOSE THINGS. I THINK THAT'S MORE THAN WHAT WE USUALLY THINK OF AS REIMBURSEMENT, BUT IT'S ALSO PERHAPS DETERMINED IN A WAY THAT'S DIFFERENT THAN WHAT I HAVE SORT OF TRADITIONALLY CALLED COMPENSATION, WHICH IS MORE COMPENSATION FOR THE ACTUAL THINGS YOU'RE ASKING THEM TO DO.

CO-CHAIRMAN KAHN: JOHN AND THEN VITO HERE IN THE ROOM.

DR. TUPIN: COMING FROM A DIFFERENT DIRECTION, I THINK REIMBURSEMENT IS KIND OF YOUR BASELINE. AND THAT'S REIMBURSEMENT OF GETTING THERE AND EATING AND SPENDING THE NIGHT, HOWEVER MANY NIGHTS THAT IS. AND THEN CHRISTINE WAS SAYING HOW DO I TAKE CARE OF OTHER FOLKS AND ET CETERA. WHAT DO YOU DO WITH YOUR DOWNTIME? SO YOU CAN GET VERY EXPANSIVE VERY QUICKLY ABOUT WHAT YOU'RE GIVING

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THESE FOLKS, LIKE AN ENTERTAINMENT PER DIEM AND THINGS LIKE THAT.

SO I GUESS THAT -- COMING AT IT FROM AN IRB, IF A PHYSICIAN CAME TO US AND SAID, I WANT TO COMPENSATE FOR X, IT REALLY IS A CASE-BY-CASE BASIS. BUT WHAT I HEAR MOST OFTEN THAN NOT ASKED BY THE MEMBERS ARE WHAT IT IS GOING TO COST THIS INDIVIDUAL TO PARTICIPATE? AND THE OTHER THING THAT THEY OFTEN ASK ABOUT IS THERE'S A LOT OF STANDARD OF CARE THAT'S WOVEN INTO THE PROTOCOL. AND SO IS THE STANDARD OF CARE GOING TO BE BILLED THEIR INSURANCE? WHAT IF THE INSURANCE DOESN'T COVER IT? ON AND ON AND ON. WHAT IF -- SO YOU'VE GOT THESE OTHER WEIRD EXPENSES THAT DO CROP UP.

SO I GUESS THAT MY RECOMMENDATION WOULD BE SET AN ABSOLUTE BASELINE TO COVER THE EXPENSE OF GETTING THERE AND HAVING A PLACE TO BE AND FOOD. AND THEN I WOULD SAY THAT MAYBE THERE'S SOME MODIFIERS THERE BASED ON INCOME, BASED ON TIME AWAY FROM YOUR COMMUNITY, DOWNTIME, ALL THESE WEIRD LITTLE THINGS THAT YOU GUYS ARE MAKING ME THINK ABOUT NOW. AND IF SOMEBODY CAME TO ME AND ASKED FOR IT, WOULD A NINTENDO BE REASONABLE FOR THIS KID TO PLAY WITH FOR THE EIGHT WEEKS HE'S SITTING IN A HOTEL?

DR. IMBASCIANI: THANK YOU. THIS IS A FASCINATING CONVERSATION, AND THANKS FOR LETTING ME BE PART OF IT. I'M NOT ON AN IRB, NEVER HAVE BEEN, AND I DON'T TEACH ETHICS, BUT I'VE BEEN IN THE GOVERNOR'S CABINET FOR THE LAST EIGHT YEARS BEFORE I CAME TO CIRM WHERE DEI AND HOW WE APPLY IT EQUITABLY TO ALL CALIFORNIANS IS VERY IMPORTANT. IF YOU WILL ALLOW ME TO MAYBE TRY TO APPLY THAT TO THIS CONCEPT OF REIMBURSEMENT, I'M THINKING IN MY MIND, I HOPE I CAN DESCRIBE IT TO YOU, A THREE-PANEL CARTOON.

IT'S THREE INDIVIDUALS WHO ARE TRYING TO WATCH A BASEBALL GAME FROM BEHIND A FENCE, BUT THE FENCE IS TOO TALL. I'M SURE MANY OF YOU HAVE SEEN THIS. EQUALITY SAYS THAT THEY ALL GET A BOX TO STAND ON. WELL, THAT HAPPENS AND TWO OF THEM CAN NOW SEE THE GAME, BUT THE CHILD, WHO'S SHORTER, CANNOT.

EQUITY WOULD SAY GIVE THAT CHILD A LARGER BOX TO STAND ON, AND NOW ALL THREE PEOPLE CAN. SO I'D LIKE TO APPLY THAT. I THINK IT WAS CHRISTINE, I'M NOT SURE. I'VE LISTENED TO SO MANY OF THE NICE THINGS YOU HAD TO SAY. I LIKE THE CONCEPT OF GIVING EVERYONE -- THIS IS THE EQUALITY PART -- GIVING EVERYONE A PER DIEM, A BASIC STIPEND, IF YOU WILL, SO THAT WE CAN CHECK OFF ETHICALLY ALL OF THOSE

BOXES THAT THE IRB'S REQUIRE. BUT THEN MAYBE THROUGH THE PROCESS OF REIMBURSEMENT FOR RECEIPTS, THAT WOULD BE THE EQUALITY FACTOR THAT WOULD GET EVERYBODY TO WHAT I WOULD SEE AS A LEVEL PLAYING FIELD. THANKS.

CO-CHAIRMAN KAHN: THE SECOND PART. SURE. THANK YOU FOR SAYING THAT. I THINK WHAT WE ARE ALL SAYING IS SOME VERSION OF MORE EXPANSIVE OR COMPREHENSIVE UNDERSTANDING OF COSTS AND SAYING IT SHOULD BE COST NEUTRAL TO PARTICIPATE. THOSE SEEM LIKE THE TWO THINGS THAT ARE THE TAKEAWAYS HERE. THAT'S EASY TO SAY, HARD TO DO, I GUESS, IS WHAT I WOULD ALSO SAY AS PART OF THE TAKEAWAY. HOPEFULLY THAT'S HELPFUL.

I DON'T THINK ANYBODY SO FAR HAS SAID ANYTHING THAT'S BEEN DISAGREEING WITH WHAT I JUST SAID AS THE TWO MAIN TAKEAWAYS.

ANYBODY WANT TO GO FURTHER OR SAY SOMETHING DIFFERENT?

DR. MORRIS: I GUESS I WAS THINKING OF THE STRUCTURE OF THAT AND HOW THAT WORKS. DOES IT HAPPEN AT THE INSTITUTIONAL LEVEL, OR DOES IT HAPPEN IN A DIFFERENT LEVEL? I THINK THAT THE -- I WOULD THINK THAT -- SOMEONE MENTIONED THAT WE HAVE SOCIAL WORKERS IN THE HOSPITALS, BUT THEY ACTUALLY DON'T

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WORK ON OUR CLINICAL TRIALS GROUPS. AND WE DON'T HAVE BUDGET FOR SOCIAL WORKERS. DO WE KNOW THAT ASSESSMENT ISN'T REALLY GOING TO HAPPEN? I THINK AT MOST OF THE ALPHA CLINIC LEVEL. HOW THAT'S ALL GOING TO HAPPEN IS TOUGHER. AND IF EACH THING IS DIFFERENT AND EACH CASE IS DIFFERENT, THEN YOU'D HAVE TO COME UP WITH. YES, YOU CAN PUSH IT INTO A BUDGET OR LINE ITEM ISSUE, THAT EVERYBODY SHOULD BUDGET, BUT THAT'S ALSO A PROBLEM. IF IT'S AN AFTERTHOUGHT, IT DIDN'T OCCUR ON THE ORIGINAL STUDY BUDGET AND, THEREFORE, IT'S LIKELY NOT GOING TO HAPPEN.

SO THERE HAS TO BE A MECHANISM THAT THIS EQUITY PIECE CAN HAPPEN, WHETHER IT'S CENTRALIZED OR HAPPENING AT AN INSTITUTIONAL LEVEL, THERE, OF COURSE, NEEDS TO BE THEN THE INSTITUTIONAL RESOURCES TO DO THAT AND A PAYLINE TO THAT.

DR. ROUCE: I THINK THAT'S SUCH AN IMPORTANT AND EXCELLENT POINT. AND I THINK WHEN WE ARE THINKING ABOUT INVESTMENT AND THINGS THAT WOULD BE REALLY IMPORTANT, HAVING A SORT OF NAVIGATOR FROM THE CIRM STANDPOINT THAT WOULD BE ABLE TO DO A FINANCIAL ASSESSMENT OFTEN IN CONCERT WITH THE ASSESSMENT THAT A SOCIAL WORKER AT AN INSTITUTIONAL LEVEL HAS ALREADY DONE ARE SEPARATE TO SEE WHAT

RESOURCES THEY'RE ALREADY RECEIVING BECAUSE MANY PATIENTS WHO ARE AT A SOCIOECONOMIC LEVEL WHERE THEY WOULD NEED ADDITIONAL ASSISTANCE WILL ALSO GET ASSISTANCE IN MEALS AND TRAVEL FROM MEDICAID, FOR EXAMPLE.

AND SO THE ABILITY, WHEN FINANCIAL COUNSELORS AND SOCIAL WORKERS AT MY INSTITUTION SCREEN PATIENTS WHO ARE COMING FROM ELSEWHERE AND LINKED TOGETHER, THEY OFTEN SAY THEY ALREADY HAVE THIS, THIS, AND THIS. AND EVEN AS WE'RE KIND OF JOKINGLY TALKING ABOUT THIS NINTENDO, WHICH I THINK THE KIDS WOULD SAY THEY DON'T USE THAT ANYMORE, BUT THE PLAY STATION OR WHATEVER THE NEW THING THAT THEY USE -- WE'RE AGING OURSELVES -- BUT FOR THOSE, THERE ARE FOUNDATIONS THAT OFTEN WILL PROVIDE THOSE.

SO I DO THINK CIRM'S ABILITY TO HAVE SOMEONE WHO CAN DO AN ASSESSMENT OF WHAT FUNDS FROM CIRM WOULD ACTUALLY COVER SO THAT YOU'RE NOT TAKING AWAY THAT PERSON'S ABILITY TO GET THE FULL BENEFITS FROM THEIR INSURANCE PLAN, FOR EXAMPLE, BUT IT'S AUGMENTING AND ROUNDING OUT IN A WAY THAT WOULD BE MOST BENEFICIAL FOR THAT PATIENT. AND I DO THINK THAT DOING IT ON THE INDIVIDUAL LEVEL WITH THE PARTICIPANT IS HELPFUL BECAUSE IT'S NOT GOING TO BE ONE SIZE FITS ALL, AND WE CAN'T -- I THINK WE HAVE A

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CLEAR UNDERSTANDING OF KIND OF THE BASELINE, WHICH I REALLY HAVE APPRECIATED THIS IS THE BASELINE OF WHAT WE WOULD LIKE TO COVER, BUT THEN ABOVE AND BEYOND THAT, I THINK GETTING THAT INDIVIDUAL LEVEL INFORMATION WOULD BE HELPFUL, AND AN INVESTMENT IN SOMEONE WHO CAN FACILITATE DOING THAT WOULD BE HELPFUL.

CO-CHAIRMAN KAHN: CHRISTINE.

DR. GRADY: JUST ONE OTHER THOUGHT. I DON'T KNOW THE PORTFOLIO THE WAY YOU DO. BUT IT MAY ALSO BE HELPFUL TO THINK DIFFERENT STUDIES REQUIRE DIFFERENT KINDS OF COMMITMENTS AND, THEREFORE, HAVE DIFFERENT BARRIERS. SO STUDY BY STUDY OR CATEGORY BY CATEGORY OR SOMETHING LIKE THAT TO THINK ABOUT WHAT THE NEEDS MIGHT BE.

CO-CHAIRMAN KAHN: I'M ALSO SAYING ABOUT THAT SHELDON'S POINT THAT THERE WILL BE SOME PATIENTS WHO ARE ALREADY VERY CONNECTED TO THE SYSTEM IN A WAY THAT SOCIAL SERVICES ASPECT WILL BE WELL UNDERSTOOD AND OTHERS PROBABLY NOT SO MUCH. SO IT'S GOING TO BE INDIVIDUAL OR AT LEAST, AS YOU SAY, MAYBE TRIAL BY TRIAL. OKAY.

DR. LOMAX: MAYBE I'LL JUST TAKE A QUICK PAUSE HERE. JUST CHECKING. BY CHANCE, IS THERE ANY PUBLIC LISTENING, ANY PUBLIC COMMENT? WE WANT TO

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MAKE SURE.

CO-CHAIRMAN KAHN: DO WE ARE HAVE PUBLIC MEMBERS JOINING?

DR. LOMAX: NOT SEEING ANY.

CO-CHAIRMAN KAHN: NO RAISED HANDS.

DR. LOMAX: I THINK -- THE ONE SORT OF QUICK -- AGAIN, THIS IS VERY RICH. I THINK THIS IS A CONVERSATION WE'LL END UP SHARING WITH WHOEVER ENDS UP ULTIMATELY GETTING THE CONTRACT TO IMPLEMENT THE PATIENT SUPPORT PROGRAM. BUT I THINK TO ONE POINT, I THINK WE VERY INTENTIONALLY WANT TO MAKE SURE -- IT'S NICE TO HEAR ABOUT THERE'S -- COMING OUT OF THIS CONVERSATION I THINK THERE'S SOMEONE DESCRIBED, I THINK, JOHN, YOU DESCRIBED THERE'S SORT OF A BASELINE FOR WHICH THINGS THAT SOMEONE SHOULD NOT HAVE COSTS FOR PARTICIPATION. WE'VE GOT THAT COVERED. BUT IT'S REALLY THIS AS WE GAIN TO -- AND JUST GETTING THAT SYSTEM UP AND RUNNING IS GOING TO -- IS A TASK. BUT I THINK AS WE GO THROUGH THAT EXPERIENCE, THEN SORT OF BEGINNING TO THINK ABOUT SOME OF THESE ADDITIONAL QUESTIONS, WHICH IS EXACTLY THE PLAN WE HAVE TO WORK WITH BOTH THE PROVIDER AND OUR ACCESS AND AFFORDABILITY WORKING GROUP.

SO THIS HAS BEEN VERY HELPFUL FROM THE STANDPOINT OF SORT OF GIVING US A SENSE OF THE

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LANDSCAPE, THE THINKING, THE CONSTRAINTS. I THINK WE DEFINITELY WILL WANT TO RE-ENGAGE WITH THE ALPHA CLINICS NETWORK A BIT AROUND SORT OF SOME OF THESE ISSUES AROUND SORT OF HOW YOU PRESENT THESE SERVICES IN A WAY THAT IS ACCEPTABLE TO IRB'S, BUT ACHIEVES THE GOALS OF REALLY TRYING TO MAKE SURE PEOPLE CAN PARTICIPATE, THAT EQUITY PIECE.

SO ALL VERY HELPFUL. AND JUST WANTED TO, FROM THE CIRM SIDE, THANK THE PANELISTS FOR ALL THESE INPUTS. THAT'S, I THINK, HOW WE SEE WE'LL TAKE THIS CONVERSATION MOVING FORWARD TOWARDS THE PROGRAM DEVELOPMENT.

CO-CHAIRMAN KAHN: GREAT. ANYTHING ELSE YOU HAVE ON YOUR AGENDA FOR US?

DR. LOMAX: I THINK WE'VE ASKED FOR PUBLIC COMMENT. WE'RE AHEAD OF TIME, WHICH IS GREAT BECAUSE I KNOW SOME PEOPLE COULDN'T STAY PAST THE HOUR ANYWAY. I DON'T KNOW IF THERE'S ANY ADDITIONAL LAST MINUTE COMMENTS, ANYTHING FROM ANY OF THE CIRM MEMBERS. STEPHANIE.

DR. FARRELL: I WAS THINKING THOSE OF US WHO EITHER WORK IN CANCER CENTERS OR ARE PARTNERED WITH CANCER CENTERS AT OUR INSTITUTIONS, ONCOLOGY HAS KIND OF ALREADY DONE A LOT OF THIS EVEN IN LIKE A SMALLER COMMUNITY SETTING LIKE MINE, THAT'S JUST A

SMALL NON-PROFIT, NONACADEMIC. WE HAVE FINANCIAL NAVIGATORS, WE HAVE SOCIAL WORKERS, WE HAVE PATIENT NAVIGATORS THAT ARE HELPING ALL OF OUR PATIENTS ACCESS TREATMENT WHETHER IT'S THOSE GETTING STANDARD OF CARE OR THOSE PARTICIPATING IN CLINICAL TRIALS WHERE THERE'S THAT ASSESSMENT.

SO I THINK THERE'S SOME -- WE CAN LEVERAGE A LOT OF THAT INFRASTRUCTURE THAT'S THERE EVEN IN COMMUNITY CANCER CENTERS AND MODEL THAT FOR WHAT WE ARE DOING WITH THE CIRM CLINICS. ESPECIALLY I'M THINKING THE COMMUNITY CENTER CLINICS. A LOT OF IT IS THERE, AND WE ALREADY HAVE PARTNERSHIPS WITH COMMUNITY CHARITIES THAT OFFER PATIENTS FINANCIAL ASSISTANCE TO HELP PAY FOR THEIR CANCER CARE. WE HAVE SOME OF THOSE THINGS HERE, BUT IT IS LIMITED TO CANCER CARE AND NOT EVERYTHING ELSE. BUT CERTAINLY THERE ARE THINGS IN PLACE ALREADY THAT WE COULD -- WE DON'T HAVE TO REINVENT THE WHEEL, I DON'T THINK.

I DON'T KNOW. ARE OTHER PEOPLE THAT WORK IN CANCER CENTERS? DO YOU HAVE THOSE KIND OF PSYCHOSOCIAL SUPPORT PROGRAMS THAT ARE READILY AVAILABLE, FINANCIAL NAVIGATORS, SOCIAL WORKERS, WHO ARE DOING ASSESSMENTS, NURSE NAVIGATORS, CLINICAL TRIAL COORDINATORS, ALL THAT GOOD STUFF?

CO-CHAIRMAN KAHN: VERY GOOD SUGGESTION.

MARIA.

CO-CHAIR BONNEVILLE: THANK YOU. I JUST WANTED TO THANK EVERYONE WHO PARTICIPATED TODAY. THIS WAS REALLY VALUABLE AND HELPS THE WORKING GROUP WHEN THIS PROGRAM COMES TO US FOR REVIEW AND IN CHOOSING A PARTNER. IT REALLY HELPS US FRAME THE CONVERSATION AROUND WHAT WE NEED TO BE COGNIZANT OF. SO I REALLY APPRECIATE ALL THE HARD WORK YOU ALL PUT IN TODAY. SO THANK YOU SO MUCH.

DR. LOMAX: THANK YOU.

CO-CHAIRMAN KAHN: ANYONE ELSE?

DR. LOMAX: OKAY.

CO-CHAIRMAN KAHN: WE'LL GIVE SOME TIME BACK.

DR. LOMAX: WE'RE PLEASED TO FINISH A LITTLE BIT EARLY. THANK YOU. AND WE WILL BE REACHING OUT TO MEMBERS OF THE WORKING GROUP. WE ACTUALLY DO HAVE ANOTHER MEETING. WE'RE LOOKING TOWARDS FEBRUARY FOR YOUR PARTICIPATION. AND WE ACTUALLY HAVE SOME FOLLOW-ON TO THAT AS WELL. SO I THINK WE'LL BE QUITE ACTIVE IN THE FIRST HALF OF THE YEAR HERE. SO MORE TO COME. WE'LL REACH OUT TO YOU OVER EMAIL.

AND I JUST WANT TO GIVE A SPECIAL THANKS TO MARIVEL FOR ALL THE LOGISTICAL SUPPORT. THESE

MEETINGS DON'T HAPPEN BY ACCIDENT. THEY TAKE A TON OF WORK. AND, DOUG GUILLEN, THANKS FOR BACKING US UP. COULDN'T DO IT WITHOUT YOU. EMILY. IF YOU WERE IN THE ROOM, YOU'D BE ENJOYING COFFEE AND PASTRIES. SHE SAVED US BY TENDING TO OUR CORE NEEDS. THANKS, EVERYONE.

(THE MEETING WAS THEN CONCLUDED AT 11:51 A.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS 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 JANUARY 16, 2024, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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