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

REGULAR MEETING

LOCATION: VIA ZOOM

DATE: AUGUST 2, 2022
2 P.M.

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

FILE NO.: 2022-31

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

I N D E X

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

AUGUST 2, 2022; 2 P.M.

CHAIRMAN TORRES: ALL RIGHT. THE WORKING GROUP WILL COME TO ORDER. MARIANNE, WOULD YOU PLEASE CALL THE ROLL.

MS. DEQUINA-VILLABLANCA: YES. CAN WE MAKE SURE THE RECORDING IS PLACED.

DAN BERNAL.

MR. BERNAL: PRESENT.

MS. DEQUINA-VILLABLANCA: ANN BOYNTON.

MS. BOYNTON: HERE.

MS. BONNEVILLE: JAMES DEBENEDETTI.

MR. DEBENEDETTI: HERE.

MS. DEQUINA-VILLABLANCA: DANA DORNSIFE.

MS. DORNSIFE: HERE.

MS. BONNEVILLE: DAVID GOLDMAN. TED GOLDSTEIN .

MR. GOLDSTEIN: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: HARLAN LEVINE.

DR. LEVINE: HERE.

MS. BONNEVILLE: PAT LEVITT.

DR. LEVITT: HERE.

MS. BONNEVILLE: ADRIANA PADILLA. AMMAR

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

QADAN. AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: MAHESWARI SENTHIL. DAVID SERRANO-SEWELL.

MR. SERRANO-SEWELL: PRESENT.

MS. BONNEVILLE: ADRIENNE SHAPIRO.

MS. SHAPIRO: PRESENT.

MS. BONNEVILLE: JONATHAN THOMA .

CHAIRMAN THOMAS: HERE.

MS. DEQUINA-VILLABLANCA: ART TORRES.

CHAIRMAN TORRES: HERE.

MS. DEQUINA-VILLABLANCA: OKAY. WE'VE GOT QUORUM AND WE MAY BEGIN.

CHAIRMAN TORRES: ALL RIGHT. WELL, THANK YOU VERY MUCH. FIRST OF ALL, I WANT DAN TO SEND A MESSAGE TO MY SISTER NANCY. I'M GLAD SHE IS SAFE. WHAT A COURAGEOUS LEADER WE HAVE TO REPRESENT US IN TAIWAN. I'M SO GLAD SHE MADE THE TRIP.

HAVING REPRESENTED CHINATOWN IN LOS ANGELES FOR OVER 20 YEARS, IT IS NOT AN UNCOMMON CHALLENGE OR COURAGE. SO GIVE HER MY LOVE AND OUR BEST, AND MAY SHE RETURN HOME SAFELY, DAN. THANK YOU.

MR. BERNAL: THANKS, ART. I'LL SHARE THAT WITH HER.

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

CHAIRMAN TORRES: WE WANT TO, FIRST OF ALL, OPEN UP OUR MEETING TO THE ISSUE OF JUST WHERE WE CAN GO IN TERMS OF OUR PATIENT ASSISTANCE PROGRAM. SO I WANTED TO BRING ON BOARD VERY QUICKLY TO GIVE US AN OVERVIEW AS TO WHERE WE ARE IN OUR PARAMETERS BY JAMES HARRISON, WHO WAS THE LEAD AUTHOR ALONG WITH BOB KLEIN AND MYSELF OF PROP 14, BUT REALLY HE WAS THE LAWYER THAT HELPED DRAFT A LOT OF THE LANGUAGE. AND MARIA AND SEAN AND JAMES AND I MET EARLIER THIS WEEK TO MAKE SURE THAT WE HAD THE PARAMETERS OF WHAT WE ARE DOING TO MAKE SURE WE'RE MOVING IN THE RIGHT DIRECTION.

I WANTED JAMES TO GIVE US HIS VIEW ON PROP 14 AND ESPECIALLY THE LANGUAGE THAT APPLIES TO US AS A WORKING GROUP. JAMES.

I THOUGHT I SAW HIM.

MR. HARRISON: I APOLOGIZE. I'VE BEEN HAVING SOME INTERNET DIFFICULTIES SO I SWITCHED TO MY PHONE. I'M SORRY I DID. NICE TO BE HERE WITH ALL OF YOU.

CHAIRMAN TORRES: I THINK THEY ALREADY KNOW WHY WE WANTED YOU TO BE ON THE INITIAL PART OF THIS MEETING, AND I KNOW YOU HAVE TO LEAVE, BUT I JUST WANTED TO GIVE US AN OPPORTUNITY TO HAVE YOUR THOUGHTS WITH US.

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

MR. HARRISON: SURE. THANK YOU FOR THE INTRODUCTION, ART.

SO I'D JUST LIKE TO BRIEFLY TALK ABOUT THE INTENT OF PROP 14. AND BY THAT, I DON'T JUST MEAN THE INTENT OF THE DRAFTERS OF WHICH SENATOR TORRES AND I WERE AMONG, BUT ALSO AS SET FORTH IN THE FINDINGS AND THE DECLARATION OF PURPOSE OF THE MEASURE AS WELL AS THE VARIOUS COMPONENTS, ALL OF WHICH HAVE TO BE READ IN CONTEXT IN ORDER TO GIVE MEANING TO THE LAW.

ONE OF THE MAJOR THRUSTS OF PROP 14, AS SENATOR TORRES NOTES, WAS TO EXPAND ACCESS TO AND THE AFFORDABILITY OF CLINICAL TRIALS AND TREATMENTS AND CURES THAT ARISE FROM CIRM-FUNDED RESEARCH. AS EXPRESSLY STATED IN THE DECLARATION OF INTENTION IN THE LAW, THAT INCLUDES PROMOTING THE ACCESSIBILITY AND AFFORDABILITY OF TREATMENTS AND CURES BY ENSURING THAT MORE CALIFORNIANS HAVE ACCESS TO CLINICAL TRIALS AND BY HELPING CALIFORNIA PATIENTS OBTAIN TREATMENTS AND CURES THAT ARISE FROM CIRM-FUNDED RESEARCH REGARDLESS OF THEIR GEOGRAPHIC LOCATION OR ECONOMIC NEEDS.

AND PROP 14 ACCOMPLISHED THIS IN SEVERAL WAYS. FIRST, IT ESTABLISHED A COMMUNITY CARE CENTERS OF EXCELLENCE PROGRAM IN ORDER TO EXTEND THE

REACH OF THE ALPHA STEM CELL CLINICS TO ENHANCE CLINICAL TRIAL ACCESS BEYOND THE CURRENT GEOGRAPHIC LIMITATIONS AND TO ENSURE THAT PATIENTS OF ALL ECONOMIC MEANS HAD THE ABILITY TO PARTICIPATE IN CLINICAL TRIALS.

IT ALSO ESTABLISHED THIS BODY AND CHARGED YOU WITH THE RESPONSIBILITY TO DEVELOP FINANCIAL MODELS TO PROMOTE ACCESSIBILITY AND AFFORDABILITY, TO RECOMMEND POLICIES AND PROGRAMS TO PROMOTE THOSE GOALS, TO ESTABLISH STANDARDS FOR PATIENT REIMBURSEMENT, AND THEN, FINALLY, TO MAKE RECOMMENDATIONS WITH RESPECT TO THE RESEARCH THAT'S NECESSARY TO HELP YOU ACCOMPLISH ALL OF THOSE GOALS.

ANOTHER COMPONENT OF THE LAW WAS TO EXPAND THE PERMITTED PATIENT REIMBURSEMENT STANDARDS TO INCLUDE TRAVEL EXPENSES, BOTH FOR RESEARCH PARTICIPANTS AS WELL AS THEIR CAREGIVERS. AND IN THIS CASE THE MEASURE EXPRESSLY PROVIDES THAT THE INTENT IS TO ENSURE FUNCTIONAL ACCESS TO CLINICAL TRIALS. SO THIS IS NOT JUST ABOUT REIMBURSING EXPENSES, BUT RATHER ENSURING THAT ALL PATIENTS, REGARDLESS OF GEOGRAPHY AND ECONOMIC MEANS, HAVE THE ABILITY TO PARTICIPATE IN CLINICAL TRIALS.

ANOTHER COMPONENT OF EFFECTING THIS CHANGE WAS TO EARMARK THE REVENUES THAT FLOW TO THE STATE

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

OF CALIFORNIA FROM CIRM-FUNDED RESEARCH, WHICH PREVIOUSLY WENT TO THE GENERAL FUND TO BE USED FOR ANY PURPOSE, TO, INSTEAD, PROVIDE THAT THOSE FUNDS SHOULD BE USED TO OFFSET THE COSTS OF PROVIDING TREATMENTS AND CURES ARISING FROM CIRM-FUNDED RESEARCH TO CALIFORNIA PATIENTS WHO HAVE INSUFFICIENT MEANS TO OBTAIN THEM, INCLUDING BY REIMBURSING THE COSTS OF RESEARCH PARTICIPANTS.

THE REFERENCE TO INCLUDING IS IMPORTANT HERE BECAUSE IT MAKES CLEAR THAT THE FUNDS WERE NOT LIMITED TO USE FOR REIMBURSEMENT OF PATIENTS. SO THAT FUND COULD ALSO, FOR EXAMPLE, BE USED TO COVER COSTS THAT ENHANCE THE OPPORTUNITY FOR PATIENTS WITH INSUFFICIENT MEANS TO PARTICIPATE IN CLINICAL TRIALS; FOR EXAMPLE, THROUGH FUNDING PATIENT NAVIGATION, TRANSLATION SUPPORT, AND OTHER COSTS THAT HAVE A DIRECT NEXUS TO EXPANDING ACCESSIBILITY AND AFFORDABILITY FOR PATIENTS WHO WOULD OTHERWISE NOT BE ABLE TO PARTICIPATE IN CIRM-FUNDED CLINICAL TRIALS.

SO I WANTED TO SHARE THOSE THOUGHTS WITH YOU AS YOU EMBARK ON YOUR MISSION OF DEVELOPING THESE PROGRAMS AND POLICIES. AND I'D BE HAPPY TO ANSWER ANY QUESTIONS YOU HAVE.

CHAIRMAN TORRES: ANY QUESTIONS BY MEMBERS

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

OF THE GROUP? ALL RIGHT.

DR. GOLDSTEIN: I ALWAYS HAVE A QUESTION.

CHAIRMAN TORRES: SURE. GO AHEAD, TED.

DR. GOLDSTEIN: THANKS SO MUCH. TED GOLDSTEIN HERE.

SO ONE OF THE THINGS WHICH I FIND IN MY CONVERSATIONS TO THE GENERAL PUBLIC, I OFTEN GIVE INTRODUCTION TO SCIENCE TYPE TALKS, IS REALLY PEOPLE DON'T REALIZE WHAT STEM CELLS ARE OR THAT THERE ARE THERAPEUTIC MODES FOR IT. AND SO IT STRIKES ME THAT ONE OF THE BIG OPPORTUNITIES HERE IS EDUCATION, AND BOTH CURRICULUM AT THE HIGH SCHOOL LEVEL AND PERHAPS YOUNGER, AND JUST GENERAL AWARENESS AND GETTING A SPOKESPERSON TO GO AROUND AND GIVE TALKS ABOUT THIS, ABOUT WHAT WE DO. AND IT STRIKES ME THAT THIS IS NOT SELLING, BUT FAMILIARITY.

YOU SORT OF HAVE TO DO FAMILIARITY BEFORE YOU KNOW THAT, OH, GEE, I'VE GOT A SERIOUS MEDICAL CONDITION. COULD IT BE -- IS THERE A POSSIBILITY TO CONNECT? THERE IS GREAT REMINDERS ON PHYSICIANS, OF COURSE, TO MAKE THESE CONNECTIONS, BUT PHYSICIANS DON'T KNOW. RIGHT? THEY DON'T KNOW EXACTLY WHAT'S GOING ON. THEY CAN BARELY KEEP UP WITH THE MOUNTAIN OF PAPERWORK THAT THEY HAVE IN STAYING CURRENT.

SO IT STRIKES ME THAT IF THESE FUNDS, AS

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

YOU SAY, COULD BE USED FOR OTHER CONNECTIVE PURPOSES, SOME AMOUNT OF MONEY SPENT ON EDUCATION WOULD BE, AND JUST PROMOTING THE GOOD WORD ABOUT US, I THINK IS IN ORDER .

CHAIRMAN TORRES: THAT'S A VERY GOOD POINT. AND WE'VE BEEN DOING IT FOR YEARS, QUITE FRANKLY, WITH THE BRIDGES PROGRAM. AND THEN I HELPED START THE SPARKS PROGRAM TO ACCENTUATE HIGH SCHOOL PARTICIPATION OF YOUNG PEOPLE. J.T., OUR CHAIR, HAS BEEN AND SO HAS MARIA AND JAMES, FRANKLY, BEEN TO MANY BRIDGES AND SPARKS PROGRAMS WHERE THESE YOUNG PEOPLE BECOME THE FUTURE. AND SO WE ENCOURAGE THEIR PARTICIPATION AND REACH OUT.

WE'RE GOING TO DO MUCH MORE OF THAT WITH OUR PATIENT ADVOCACY THAT WAS DONE ALREADY, AND THAT GOES ALONG THOSE LINES AS WELL. SO THOSE ARE EXCELLENT POINTS.

AND, MARIANNE, WE NEED TO SEND TED AND THE REST OF THE MEMBERS AN OVERVIEW OF OUR BRIDGES AND SPARKS PROGRAM SO THAT THEY'RE AWARE OF WHAT WE'VE BEEN DOING IN THIS AREA WHICH IS VERY EXCITING. I CAN'T TELL YOU THE GLEEM IN THE EYES OF THESE STUDENTS WHEN PARTICIPATING FOR A SUMMER. WE GIVE THEM A STIPEND. AND THEN THE TRACK RECORD THAT WE PROVIDE IN TERMS OF WHERE THEY LAND AFTERWARDS IS

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

JUST ASTONISHING.

DAVID HIGGINS.

DR. HIGGINS: YES. I JUST WANTED TO MAKE TWO COMMENTS REALLY. ONE IS TO, IN CASE ANYBODY DOESN'T KNOW JAMES OR ART OR DON'T KNOW THEM WELL, YOU SHOULD BE THRILLED THAT THESE ARE THE TWO PEOPLE THAT WE'RE WORKING WITH ON THIS TOPIC. THESE ARE LEADERS PAR EXCELLENCE AND ARE WAY AHEAD OF US IN THE THINKING AND THE INSTITUTION OF PROGRAMS LIKE ART JUST ENUMERATED. JAMES TOO. JAMES IS ONE OF OUR FORMER CIRM PEOPLE WHO WE ALL THINK OF IN HEROIC TERMS. AND I'M JUST THRILLED TO HAVE THESE TWO IN PARTICULAR HELPING US.

THE SECOND COMMENT I WANTED TO MAKE, WHICH IS AN EXTENSION OF WHAT TED JUST SAID. I AGREE WITH EVERYTHING HE SAID AND ART'S FOLLOW-UP, BUT I ALSO JUST WANT TO UNDERSCORE THAT WHEN I SAY SOMETHING TO SOME MEMBER OF THE PUBLIC OR SOMETHING WITH CIRM AND DESCRIBE CIRM AS HAVING TO DO WITH STEM CELLS, WITHOUT EXCEPTION, CAN'T YOU JUST GO TO MEXICO FOR THAT? CAN'T YOU GET THAT IN TIJUANA? PEOPLE ARE COMPLETELY CONFUSED BY THIS CRAP THAT'S BEING THROWN AT THEM COMMERCIALLY AND WHAT STEM CELLS POTENTIAL REALLY IS.

SO I KNOW THAT WILL BE PART OF OUR

CONCERN, BUT LET'S JUST MAKE SURE WE BUILD THAT IN THERE. WHEN SOME ADULT'S EYES LIGHT UP BECAUSE YOU SAY STEM CELLS, THEY MAY BE THINKING OF THEIR BUM KNEE THAT THEY'RE GOING TO GET INJECTIONS OF AND CURE. SO I JUST WANT TO LAY ON THAT THE TABLE .

CHAIRMAN THOMAS: WE HAVE A LOT OF WORK TO DO IN THAT AREA AS DAVID SERRANO-SEWALL KNOWS BECAUSE HE WAS A MEMBER OF THE MEDICAL QUALITY ASSURANCE BOARD. WE DON'T GET COOPERATION FROM THESE DOCTORS. WHEN WE BROUGHT THE ISSUE OF BAD STEM CELL CLINICS TO THEIR ATTENTION, THEY DO NOTHING ABOUT IT. I'VE HAD THESE CONVERSATIONS WITH SENATOR ADKINS, THE PRESIDENT OF THE SENATE, WHO HAS APPOINTMENTS TO THIS BOARD, AS WELL AS THE CMA AND OTHER DOCTORS THAT SERVE ON THE BOARD. THERE'S A RELUCTANCE TO GO AFTER THEIR PEERS WHEN IN REALITY MOST OF THESE STEM CELL CLINICS, THESE SHAMS, ARE BEING RUN BY PHYSICIANS THAT REALLY DON'T HAVE A SENSE OF VALUE OR A COMMITMENT, IN MY OPINION, THIS IS ONLY BY OPINION, IN RESPECT TO THEIR PATIENTS.

J.T.

CHAIRMAN THOMAS: THANKS, ART. TED, THANKS FOR THE COMMENTS. JUST FOR THE BENEFIT OF THE MEMBERS OF THE WORKING GROUP HERE, OUR EDUCATIONAL PROGRAM, WHICH ART ALLUDED TO, WHICH

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

ALSO HAS ADDITIONAL LEVELS BESIDES HIGH SCHOOL, UNDERGRAD, MASTER'S, RESEARCH SCIENTISTS, ET CETERA, WE'VE PUT OUT AS AN ORGANIZATION, I THINK, I MAY HAVE THIS A LITTLE OFF, BUT 260 MILLION, SOMETHING LIKE THAT, ON EDUCATIONAL PROGRAMS SINCE INCEPTION TO BASICALLY GET THE WORKFORCE OF TOMORROW EDUCATED AND SEEDING THE PIPELINE FOR WORKERS AS THE FIELD CONTINUES TO MATURE.

SO WE JUST HAD A BRIDGES PROGRAM WHICH WAS FOR COMMUNITY COLLEGES AND UNIVERSITIES THAT DON'T HAVE STEM CELL PROGRAMS. WE FUND A NUMBER OF STUDENTS FROM EACH WHO GO TO ENTITIES THAT DO HAVE STEM CELL PROGRAMS, THE STANFORDS, THE UCSD'S, THE UCLA'S OF THE WORLD, AND THEY SPEND A YEAR IN INTENSIVE TRAINING WITH SCIENTISTS IN THOSE STEM CELL PROGRAMS AND, AT THE END OF THE YEAR, COME OUT WITH THIS INCREDIBLE BODY OF WORK WHICH THEY PRESENT IN AN ANNUAL MEETING WHICH HAPPENS TO HAVE BEEN LAST WEEK WHICH I WENT TO WHERE YOU THINK THESE KIDS HAVE BASICALLY BEEN IN THE FIELD FOR MANY, MANY YEARS AND THEY SOUND LIKE PH.D.'S.

BUT THE POINT IS IS THAT WE'RE ACUTELY AWARE THAT THE EDUCATIONAL COMPONENT OF WHAT WE DO IS ONE OF OUR PRINCIPAL PILLARS AND SOMETHING THAT WE'RE VERY PROUD OF.

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

COMMUNICATION IN GENERAL, WE HAVE AN INCREASINGLY ROBUST COMMUNICATIONS EFFORT. TED, YOU'RE RIGHT. THERE'S STILL PLENTY OF PEOPLE OUT THERE THAT DON'T KNOW WHAT THE STORY IS. ONE OF THE BRIDGES STUDENTS LAST WEEK TOLD AN ANECDOTE WHERE HE'S FROM HUMBOLDT STATE. I THINK HE HAD DONE HIS YEAR AT UCSF'S STEM CELL PROGRAM, AND HE TOLD THE STORY WHEN HE WAS TRYING TO TALK TO PEOPLE UP IN HIS AREA WHERE HE GOES TO COLLEGE, THAT THEY WERE DUBIOUS ABOUT STEM CELLS AND GOT ALL THEIR INFO FROM JOE RHOGAN. AND HE SAID THIS IS A REAL ISSUE, AND WE ACKNOWLEDGED THAT AND ARE COMMITTED TO IMPROVING OUR COMMUNICATIONS EFFORT CONTINUOUSLY.

I SHOULD NOTE, WHICH WE'LL CIRCULATE TO ALL OF YOU, THAT OUR NEW ANNUAL REPORT IS DUE OUT ANY MINUTE, WHICH IS A WONDERFUL MARKETING DOCUMENT, WHICH I THINK YOU'LL BE MOST INTERESTED TO SEE. SO WE WILL MAKE SURE TO FORWARD THAT TO ALL OF YOU. AND ANY THOUGHTS THAT YOU HAVE ON COMMUNICATIONS, PLEASE DO LET US KNOW BECAUSE IT IS, FOR SURE, ONE OF OUR HIGHEST PRIORITIES. THANK YOU, ART.

CHAIRMAN TORRES: THANK YOU, TED, FOR POINTING THIS OUT BECAUSE IT INEVITABLY HAPPENS. WE NEVER DO ENOUGH OF COMMUNICATIONS .

DR. GOLDSTEIN: WELL, IT'S NOT ENOUGH

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

UNTIL IT'S ENOUGH.

CHAIRMAN TORRES: IT'S A CHALLENGE WHETHER YOU'RE IN PUBLIC LIFE AS AN OFFICE HOLDER OR WHETHER YOU'RE A STATE AGENCY. IT'S SO DIFFICULT TO CONTINUE TO REACH OUT TO THE MASSES THAT NEED TO HEAR WHAT'S GOING ON.

MARIANNE, WOULD YOU PLEASE SEND THE LINK TO EVERYONE THAT WANTS TO PARTICIPATE BECAUSE TOMORROW IS OUR SPARKS PROGRAM. IT'S GOING TO BE ONLINE. I'M GOING TO END THE MEETING TOMORROW ABOUT 4:30 P.M. BUT IT'S A GREAT OPPORTUNITY TO SEE OUR HIGH SCHOOL STUDENTS IN ACTION. THIS YEAR WE'RE HOLDING THE SPARKS MEETING IN OAKLAND AT THE MARTIN LUTHER KING CENTER THERE. AND KELLY SHEPARD, WHO IS THE STAFF PERSON THAT'S BEEN OPERATING AND DIRECTING THIS, HAS JUST BEEN TERRIFIC AT PUTTING THIS TOGETHER.

SO IF YOU HAVE SOME TIME, EVEN TEN MINUTES OR FIVE MINUTES, CHECK INTO THE WEBSITE MARIANNE WILL SEND OUT. IT'S WELL WORTH THE EFFORT.

ANY FURTHER QUESTIONS BEFORE WE GO ON?

CHAIRMAN THOMAS: ART, JUST ONE MORE POINT ON THAT JUST TO BACK WHAT YOU JUST SAID. IF YOU WANT TO HEAR SOMETHING THAT BORDERS ON THE UNBELIEVABLE, THESE KIDS, THESE HIGH SCHOOL KIDS

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

THROUGHOUT THE STATE, HAVE SIX- TO EIGHT-WEEK INTENSIVE COURSES. MOST OF THEM ARE AP, BIO HIGH SCHOOL STUDENTS WHO HAD SOME EXPOSURE TO STEM CELLS, NOT MUCH. AT THE END OF THIS EIGHT WEEKS, THEY CONVENE TO TALK ABOUT WHAT THEY'VE DONE.

ONE OF THE FEATURES OF THE DAY IS THEY HAVE -- A NUMBER OF THE KIDS ARE ASKED TO GIVE FIVE-MINUTE PRESENTATIONS ON THEIR RESEARCH. IF YOU WANT TO BE JUST LIKE BLOWN AWAY LIKE NEVER BEFORE, YOU SHOULD JUST LOG IN AND WATCH THESE KIDS PRESENT BECAUSE THEY SOUND LIKE HIGHLY SEASONED VETERANS AND ARE JUST SO IMPRESSIVE AND SOMETHING TO BEHOLD. SO IF YOU DO GET A CHANCE, THERE WILL BE AN AGENDA WITH THE LINK, AND YOU CAN LOG IN. IT WILL BE WELL WORTH IT. THANK YOU, ART.

CHAIRMAN TORRES: THANK YOU VERY MUCH.

ANY FURTHER INPUT BEFORE WE MOVE ON?

JAMES, I WANT TO THANK YOU AGAIN FOR TAKING THE TIME TO BE WITH US BECAUSE IT'S ALWAYS A PLEASURE TO SEE YOU AND OBVIOUSLY TO WORK WITH YOU.

THE WHOLE CONCEPT OF WHAT WE WORKED THROUGH THIS YEAR HAS BEEN VERY, VERY TIME-CONSUMING AND A LOT OF HARD WORK FROM MARIA MILLAN, MARIA BONNEVILLE, SHYAM, KEVIN MARKS, AND OTHERS, WHO HAVE BEEN PARTICIPATING IN MAKING SURE THAT WHATEVER WE

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

BRING FORWARD TO YOU TODAY, WHICH IS GOING TO BE EXHAUSTIVE, AND I THINK EACH OF YOU HAVE RECEIVED THE PROPOSAL WHICH IS THE CONSIDERATION OF THE CONCEPT PLAN FOR PATIENT ASSISTANCE PROGRAM. I'M GOING TO ASK SEAN NOW GO OVER IT. IT'S GOING TO TAKE A LITTLE BIT OF TIME, BUT IT'S WELL WORTH THE ENERGY AND THE EFFORT. AND, OF COURSE, WE'LL OPEN UP TO QUESTIONS.

NOW, KEEP IN MIND THAT I'VE ALWAYS OPEN TO QUESTIONS IN WRITING FROM ANY OF YOU. IF SOMETHING COMES TO MIND AFTER THIS MEETING AND YOU WOULD LIKE FURTHER INPUT, WE CAN DIRECT THAT TO ANY STAFF PERSON THAT YOU MIGHT HAVE A PARTICULAR INTEREST IN OR A QUESTION THAT YOU DIDN'T THINK OF WHILE THE PRESENTATION WAS GOING ON BECAUSE THAT'S VERY, VERY HELPFUL.

I ALSO HAVE TO REPORT THAT THIS AFTERNOON I WAS IN CONTACT WITH THE GOVERNOR'S OFFICE. THEY'RE STILL WORKING ON PUTTING TOGETHER THE PIECES OF THEIR AFFORDABILITY OFFICE, WHICH, AS YOU KNOW, PASSED THE LEGISLATURE AND SIGNED BY THE GOVERNOR LAST MONTH. THEY DON'T TAKE OPERATION TILL JANUARY 1, 2023, BUT THEY'RE WORKING VERY HARD RIGHT NOW. AND I SPOKE TO A NUMBER OF THE STAFF PEOPLE THAT ARE WORKING ON IT NOW. SO THAT IS A WORK IN PROGRESS,

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

AND I WILL REPORT TO YOU AS I FIND OUT MORE INFORMATION ON WHERE THEY ARE AT IN TERMS OF THE OFFICE OPENING AND THE ABILITY TO HAVE PEOPLE THAT COULD BE ADVISORS TO THAT OFFICE.

SEAN, TAKE IT AWAY. THANK YOU.

DR. TURBEVILLE: I'M GOING TO SHARE THE SCREEN. MARIANNE, CAN YOU CONFIRM THAT YOU SEE THESE?

MS. DEQUINA-VILLABLANCA: YES, I SEE IT .

DR. TURBEVILLE: ALL RIGHT. OKAY. WELL, THANK YOU, JAMES, PARTICULARLY TO YOU, TO PROVIDE AN OVERVIEW OF THE REGS AND THE CONCEPT OF THE PATIENT ASSISTANCE PROGRAM AND PARTICULARLY TO THE AAWG.

SO THIS IS A QUICK UPDATE TO GIVE YOU WHERE WE ARE AT CURRENTLY. THIS IS A FOLLOW-UP TO THE JUNE 21ST AAWG MEETING THAT MANY OF YOU ATTENDED. AND TO ME THAT SEEMS LIKE AGES AGO BECAUSE WE'RE MOVING VERY QUICKLY. WE'VE MADE A LOT OF SIGNIFICANT PROGRESS IN THE LAST SIX WEEKS.

SO THE PURPOSE OF THIS PRESENTATION IS TO FOLLOW UP ON THE PATIENT ASSISTANCE PROGRAM PRESENTED AGAIN ON THAT DATE, PROVIDE AN UPDATE ON OUR GAP ANALYSIS, WHICH WE ARE CURRENTLY DOING RIGHT NOW. AND WE'RE GETTING FEEDBACK AS WE SPEAK ON SOME ADDITIONAL ANALYTICS THAT I CAN PROVIDE MAYBE AT A

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

LATER TIME. MORE IMPORTANTLY, INTRODUCTION TO THE DRAFT CONCEPT PLAN. SO MANY OF YOU HAVE SEEN THAT. THAT WAS POSTED TEN DAYS AGO. IT MAY BE A LITTLE BIT HEAVY WITH RESPECT TO CONTEXT. THAT'S KIND OF MY AREA OF EXPERTISE. SO WE CAN GET INTO THOSE GRANULARITIES IF YOU WANT. I THINK IT'S FAIRLY ROBUST IN TERMS OF WHAT WE'RE GOING AFTER, WHAT OUR VISION IS, AND WE'RE VERY CLOSE TO ACTUALLY MOVING TOWARD, UPON YOUR APPROVAL, TO THE RFP PROCESS.

THE OTHER THING I JUST WANT TO REITERATE JUST TO MAKE SURE, THERE'S BEEN A LOT OF PRESENTATIONS THAT I'VE GIVEN. I THINK JAMES NAILED IT. THE POINT OF THIS PROGRAM IS REALLY TO FOCUS ON THE UNDERSERVED, RIGHT, THOSE PATIENTS WHO DID NOT HAVE AN OPPORTUNITY TO PARTICIPATE IN A CLINICAL TRIAL OR COULD NOT FULFILL THE REQUIREMENTS OF A CLINICAL TRIAL SIMPLY BECAUSE THEY DIDN'T HAVE THE FINANCIAL MEANS TO CONTRIBUTE, THEY DIDN'T HAVE THE LOGISTICAL MEANS TO CONTRIBUTE, THEY DIDN'T HAVE THE FAMILY SUPPORT, ET CETERA.

THE OTHER THING I JUST WANT TO CLARIFY, TWO BUCKETS. SO WE HAVE WHAT'S CALLED THE PATIENT SUPPORT PROGRAM, WHICH IS WHAT WILL BE THE ACRONYM AS PSP. THAT IS AN INFRASTRUCTURE. THAT IN ITSELF PROVIDES A SERVICE FOR PATIENTS. SO THAT IS, IF YOU

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

CAN THINK OF IT THIS WAY, NOT ONLY THE INFRASTRUCTURE WHERE THE PATIENT NAVIGATORS WERE VERY WELL SEASONED AND UNDERSTAND THE SPACE AND CAN PROVIDE GUIDANCE TO PATIENTS AND HEALTHCARE PROVIDERS. THE TELEPHONY SYSTEMS BEHIND THE SCENE, THE SOFTWARE, ALL THAT INFRASTRUCTURE DOES PROVIDE A SERVICE TO PATIENTS. THE SPEED AT WHICH WE CAN GET INFORMATION, WE TALKED JUST RECENTLY, JUST NOW BROUGHT UP THE EDUCATION, THIS IS ANOTHER HURDLE THAT WE CAN ACTUALLY IMPLEMENT SOME EDUCATIONAL PROGRAMS WITHIN THE PATIENT NAVIGATORS TO THOSE PATIENTS AS WELL AS HEALTHCARE PROVIDERS. SO THAT'S IMPORTANT.

THE OTHER THING IS THE PATIENT FUND. SO WE'VE GOT THE OPERATIONS AND THE PATIENT FUND THAT WILL BE UTILIZED THROUGH THE OPERATIONS TO GET FUNDS TO THOSE PATIENTS. AND I'LL DESCRIBE THAT IN A LITTLE BIT MORE DETAIL, BUT I DO WANT TO SEPARATE THOSE TWO BECAUSE IT IS IMPORTANT. WITHOUT THE OPERATIONS, WE CAN'T BE COMPLIANT AND GET THE FUNDS TO THE PATIENTS IN A TIMELY MANNER, WHICH IS ABSOLUTELY CRITICAL, AS WELL AS THE EDUCATIONAL COMPONENT.

SO YOU'VE SEEN THIS SLIDE. THIS IS THE RECOMMENDED FIVE-YEAR TIMELINE. WE ARE TRACKING

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

WELL. WE'RE ACTUALLY A LITTLE BIT ABOVE, A LITTLE BIT EARLY, A LITTLE BIT, BUT TO BE HONEST WITH YOU, WE'RE AHEAD OF SCHEDULE. THIS IS A SLIDE FOR THE TIMELINE FOR THE INITIAL 15.6 ALLOCATION OF THE PATIENT ASSISTANCE FUND. WE'RE STILL IN YEAR ONE. I THINK WE'RE ABOUT FOUR MONTHS INTO THIS. WE ARE STILL DETERMINING THE MODEL. ALTHOUGH, TO BE HONEST WITH YOU, IF YOU READ THAT CONCEPT PLAN, I THINK WE HAVE A PRETTY GOOD IDEA OF WHAT WE WANT TO PUT IN PLAY.

SECOND, THERE'S THE GAP ANALYSIS. AND I'LL SPEAK TO THAT IN A FEW MORE MINUTES, BUT THAT IS ONGOING NOW. AND I ANTICIPATE THAT WE'LL PROBABLY HAVE A FINAL RESOLUTION IN TERMS OF WHAT WE WANT TO PUT IN PLAY FROM THE SERVICE PROVIDER STANDPOINT IN TERMS OF THE METRICS, IN TERMS OF WHAT WE WANT TO SUPPORT FROM A FINANCIAL STANDPOINT, AND WHERE THE TRULY UNMET NEED REALLY IS.

SO JUST AGAIN FOR RECAP, WE TALKED ABOUT ACTUALLY FIVE AREAS EARLIER THAT ARE ASSOCIATED WITH BARRIERS TO ENROLLING IN CLINICAL TRIALS. INFORMATIONAL, OUR CONCEPT CAN TAKE CARE OF LOGISTICAL COORDINATION. OUR PROPOSAL CAN TAKE CARE OF THAT FOR THE PATIENTS. IT'S REALLY THE FINANCIAL THAT WE'RE FOCUSING ON TO GET THOSE GRANULARITIES

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

WITH RESPECT TO THE DELTAS, THAT ADDITIONAL HUNDRED DOLLARS THAT WE CAN PROVIDE FOR, LET'S SAY, TRANSPORTATION, THE ADDITIONAL $50 THAT WE CAN PROVIDE FOR GAS, ET CETERA. SO WE ARE GETTING TO THAT LEVEL, AND WE'LL HAVE THAT INFORMATION SOON .

SO THINK OF IT THIS WAY. JUST A GRAPHIC. THERE'S TWO ONGOING PARALLEL DEVELOPMENT TRACKS. ONE, WE GOT THE GAP ANALYSIS THAT'S OCCURRING RIGHT NOW. WE'RE GOING TO EXPAND THAT. I'LL TALK ABOUT THAT IN A FEW MINUTES. BUT THE REALITY IS THE HEAVY LIFT, IN MY EXPERIENCE, IS WHEN YOU OPERATIONALIZE THESE PROGRAMS. 80 PERCENT OF IT IS REALLY AROUND THE OPERATIONS. WHO'S GOING TO PROVIDE THE SERVICES, THE QUALITY OF SERVICES THAT WE'RE GOING TO PROVIDE TO THE PATIENTS. THE COMPLIANCE, THE INFRASTRUCTURE, THE SCALABILITY, THAT'S ABOUT 80 PERCENT OF THE HEAVY LIFT. THE GAP ANALYSIS, AS YOU CAN SEE FROM THIS GRAPHIC, IS REALLY GOING TO GIVE US THAT FINAL LAST 10 PERCENT, IF YOU WILL. WE CAN USE SOME SPORTS ANALOGIES. IF YOU'VE READ THE CONCEPT PLAN, I THINK WE'RE AT THE 20-, MAYBE EVEN THE 15-YARD LINE RIGHT NOW. WHAT WE ARE JUST WAITING FOR IS THAT ADDITIONAL GAP ANALYSIS INFORMATION THAT WE CAN TIE IN TO FINALIZE THE RFP.

SO THOSE ARE TWO WORK STREAMS THAT WE'RE

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

WORKING THROUGH CURRENTLY. A LOT OF WORK HAS BEEN DONE, AND WE'LL TALK ABOUT THE DRAFT CONCEPT IN A FEW MINUTES.

SO WITH RESPECT TO THE GAP ANALYSIS, CIRM WILL CONTINUE THE GAP ANALYSIS UTILIZING EXISTING ADMINISTRATIVE FUNDS. THIS IS NOT COMING OUT OF THE PATIENT ACCESS FUND. WE ARE SUPPORTING THAT INTERNALLY. WE ARE OPENING UP THE GAP ANALYSIS A LITTLE BIT MORE. WE HAVE REACHED OUT TO SOME OF THE COLLEAGUES ON THE CALL TODAY AS WELL AS THE ALPHA CLINICS, AND WE HAVE COLLECTED QUITE A BIT OF INFORMATION, QUALITATIVE INFORMATION. WE'D LIKE TO GET MORE QUANTITATIVE NOW. SO WE'RE GOING TO EXPAND THE GAP ANALYSIS. WE ARE BRINGING IN AN EXPERT CONSULTANT WHO CAN HELP FACILITATE THIS. WE ARE A FAIRLY SMALL SHOP AS OF NOW, AND WE ARE BUILDING THE MEDICAL AFFAIRS GROUP. THIS CONSULTANT WILL HELP GET US TO THE FINISH LINE.

SO THE RESULTS OF THIS GAP ANALYSIS WILL INFORM US ON A COUPLE OF THINGS. ONE, ENSURE REGULATORY COMPLIANCE AND AVOID DUPLICATED COST. I KNOW THAT'S A TERRIBLY SENSITIVE SUBJECT. WE WANT TO MAKE SURE WE ARE NOT DUPLICATING TAXPAYER MONEY WITH RESPECT TO THE COST OF SUPPORTING THESE TRIALS.

TWO, REFINE OR EXPAND THE SCOPE OF PATIENT

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

COSTS COVERED BY THE PATIENT ASSISTANCE FUND. WE WANT TO MAKE SURE WE ENSURE CONSISTENCY IN ALIGNMENT WITH OTHER CIRM PROGRAMS. WE ARE NOT CANNIBALIZING ANY OTHER PROGRAM THAT'S ALREADY IN PLAY. IF ANYTHING, WE'RE SUPPLEMENTING IT. IT'S GOING TO BE SYNERGY. AND PERHAPS FOR NEW PROGRAMS THAT MOVE PROSPECTIVELY, THIS MIGHT BE THE PROCESS FOR WHICH PATIENTS GET REIMBURSED FOR MANY OF THEIR ANCILLARY COSTS.

FINALLY, OPTIMAL COMPATIBILITY WITH CIRM'S INFRASTRUCTURE PROGRAMS. SO THERE ARE A NUMBER OF NEW CONCEPTS CHEWING AT THE BIT TO PRESENT TO THE AAWG WITH RESPECT TO ACCESS AND AFFORDABILITY SPECIFICALLY FOR GENE THERAPIES, CELL THERAPIES, ET CETERA. THIS CONCEPT IS GOING TO TIE INTO THE ALPHA CLINICS. AS YOU KNOW, WE'RE MOVING VERY RAPIDLY WITH OUR FIRST MEETING WITH RESPECT TO THE COMMUNITY CARE CENTERS OF EXCELLENCE. THIS IS ALL GOING TO TIE IN. IT'S BABY STEPS FOR RIGHT NOW, BUT IT IS PART OF THE FIVE-YEAR STRATEGIC PLAN.

SO JUST A REFRESHER. WHAT WE ARE LOOKING AT IS LOW HANGING FRUIT HERE. IT'S THE TRAVEL EXPENSES, IT'S ACCOMMODATION, IT'S THE MEALS, IT'S THE CHILDCARE, OUT-OF-POCKET HEALTHCARE EXPENSES. WE CONTINUE TO HEAR FROM INVESTIGATORS FROM SITES

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

THAT THIS IS, FOR AT LEAST THE THERAPIES THAT WE ARE SUPPORTING AND OTHER THERAPIES THAT ARE OUT THERE IN THE GENE THERAPY SPACE, THEY CONTINUE TO ACCRUE. RIGHT? THESE ARE NOT CHEAP THERAPIES BY ANY MEANS OR AT LEAST TRIALS. AND WE CONTINUE TO SEE INCREASES IN MOST OF THESE EXPENSES.

WHERE WE'RE STARTING TO SEE THE SIGNAL, QUITE FRANKLY, IS IN TRAVEL EXPENSES FOR PATIENTS AND FAMILY MEMBERS. I THINK THE LAST PRESENTATION I TALKED ABOUT CAR-T AND SOME OF THE REQUIREMENTS, NOT ONLY ON THE INDICATION, THE LABEL, BUT MORE IMPORTANTLY, EACH ONE OF THOSE SITES THAT HAS THEIR OWN REQUIREMENTS FOR PATIENTS AND THEIR FAMILY MEMBERS.

THE OTHER THING WE'RE STARTING TO SEE IS THE FDA. THE COMPETENT AUTHORITIES ARE ASKING FOR ADDITIONAL INFORMATION FROM THESE PATIENTS, FROM THE TRIAL. THAT PUTS MORE PRESSURE NOT ONLY ON THE SITES THAT HAVE TO MODIFY THE PROTOCOL AMENDMENTS; BUT, MORE IMPORTANTLY, IT PUTS MORE PRESSURE ON THE PATIENTS TO MEET THOSE DEMANDS. AND THAT MAY MEAN ADDITIONAL VISITS TO THE CLINIC ITSELF.

SO WHAT WE ARE SEEING IS CERTAINLY A SIGNAL IN TRAVEL EXPENSES. ONE OF THE REQUESTS OVER AND OVER IS ABOUT CHILDCARE. THAT SEEMS TO BE AN

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

AREA WHERE A LOT OF PATIENTS NEED SOME SUPPORT AND OTHER ANCILLARY HEALTHCARE EXPENSES. BUT, AGAIN, THROUGH THAT GAP ANALYSIS, WE'LL GET THE QUANTITATIVE INFORMATION THAT WE NEED TO SAY, HEY, LOOK, AAWG, THIS IS WHAT WE RECOMMEND. HERE'S WHAT WE GO AFTER, THESE THREE VARIABLES, AND HERE'S THE AMOUNT OF MONEY THAT WE CAN SUPPORT.

SO THAT'S IT WITH RESPECT TO THE GAP ANALYSIS. AND I'M PRETTY CONFIDENT IN THE NEXT TWO TO THREE WEEKS WE'LL HAVE THOSE METRICS THAT WE NEED.

FOR NOW I'D LIKE TO MOVE FORWARD TO THE CONCEPT PLAN. SO I KNOW THIS CAN BE A LITTLE BIT HEAVY, BUT HOPEFULLY EVERYBODY'S AT LEAST TAKEN A LOOK AT THAT. I THINK THE TAKE-HOME MESSAGE IS, AGAIN, WE'VE THOUGHT THROUGH THIS VERY CAREFULLY IN TERMS OF WHAT WE WANT THE TYPE OF SERVICE, AND IT'S REALLY ABOUT MOVING FORWARD WITH RESPECT TO FINALIZING THE CONCEPT PLAN WITH YOUR INPUT AND MOVING TOWARDS THAT RFP PROCESS.

CHAIRMAN TORRES: SEAN, I JUST WANT TO MAKE SURE THAT WE STOP FOR A LITTLE BIT TO ASK IF THERE'S ANY QUESTIONS AT THIS POINT BEFORE YOU MOVE ON. J.T.

CHAIRMAN THOMAS: THANKS, ART.

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

SEAN, CAN GAP -- YOU'RE GOING TO HAVE THE ANALYSIS COMPLETED IN THE NEXT TWO TO THREE WEEKS. CAN YOU PLAN TO GIVE A REPORT ON THAT TO THE BOARD IN SEPTEMBER?

DR. TURBEVILLE: OH, YES, CERTAINLY. THAT WILL BE PART OF THE PROGRAM, ABSOLUTELY.

CHAIRMAN THOMAS: THANK YOU.

CHAIRMAN TORRES: ANYONE ELSE? ALL RIGHT. GO AHEAD, SEAN. THANKS.

DR. TURBEVILLE: THANK YOU.

SO A QUICK SUMMARY OF THE CONCEPT PLAN. AND WE CAN GET INTO GRANULARITIES IF YOU WANT, BUT I JUST WANTED TO GIVE YOU A HIGH OVERVIEW. SO NOT TO BE REDUNDANT, BUT THE DRAFT CONCEPT PLAN IN TERMS OF THE OBJECTIVES AND RATIONALE: ESTABLISH A PATIENT SUPPORT PROGRAM WITH FINANCIAL AND LOGISTICAL SUPPORT FOR PATIENTS EVALUATED OR ENROLLED IN CIRM-SUPPORTED CLINICAL TRIALS WITH THE AIM OF IMPROVING ACCESS; IDENTIFICATION, ENROLLMENT, AND RETENTION OF PATIENTS WITH EMPHASIS ON THE UNDERSERVED POPULATIONS.

TO ACHIEVE THESE AIMS, CIRM WILL OFFER A CONTRACT THROUGH A COMPETITIVE REQUEST FOR PROPOSALS, RFP. SO THE APPLICANTS FOR THE PSP WILL BE REQUIRED TO PROVIDE AN APPLICATION DESCRIBING A

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

NUMBER OF ITEMS. ONE, TELL ME ABOUT YOUR CALL CENTER OPERATIONS, THE INTERNAL CAPABILITIES, AND YOUR TECHNOLOGY. WITH RESPECT TO TECHNOLOGY, JUST TO GIVE YOU AN IDEA, THERE'S SOMETHING CALLED NATURAL LANGUAGE PROCESSING THAT YOU'RE PROBABLY FAMILIAR WITH ON THE ARTIFICIAL INTELLIGENCE SIDE. THIS HAS BEEN USED BY CALL CENTERS FOR EIGHT YEARS NOW.

TO GIVE YOU AN IDEA OF THE SPEED AT WHICH WE CAN PROVIDE INFORMATION TO PATIENTS AND THEIR HEALTHCARE PROVIDERS, WHEN A PATIENT CALLS, WHEN A HEALTHCARE PROVIDER CALLS, THAT ARTIFICIAL TOOL BEHIND THE SCENES IS ACTUALLY RECORDING WHAT THAT PATIENT IS ASKING AND WILL PULL UP INFORMATION THAT WILL HOPEFULLY RESPOND OR AT LEAST PROVIDE THE INFORMATION THE PATIENT NEEDS IN FRONT OF THE AGENT. THE AGENT DOESN'T EVEN HAVE TO TYPE IN ANYTHING WITH RESPECT TO A QUERY. THAT TECHNOLOGY IS ALMOST STANDARD INDUSTRY WITH MANY OF THESE CALL CENTERS.

SO THAT'S THE TYPE OF LEVEL OF SERVICE THAT I'M THINKING ABOUT FOR THE PATIENTS AND FOR THE HEALTHCARE PROVIDERS IN GENERAL.

THE OTHER THING IS TELL ME ABOUT THE PATIENT NAVIGATION CAPACITIES. THERE'S LOTS OF DIFFERENT SKILL SETS OUT THERE.

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

THE OTHER THING IS THEIR REIMBURSEMENT EXPERIENCE. TELL ME ABOUT YOUR EXPERIENCE WITH CLINICAL RESEARCH TRIAL PARTICIPATIONS. THAT'S DIFFERENT FROM POSTMARKETING ONCE YOU HAVE MARKETING AUTHORIZATION. SO THAT'S SOMEWHAT NICHEY.

THE OTHER THING IS THE REAL-TIME REPORTING CAPABILITIES. TELL ME ABOUT YOUR CAPABILITIES OF WHAT AM I LOOKING AT, IDENTIFY SIGNALS, WHERE CAN WE ACT, WHERE DO WE SEE GAPS, WHERE DO WE SEE WE'RE DOING A GOOD JOB. WE ARE CONSTANTLY EVALUATING THOSE CALL CENTERS WITH RESPECT TO PERFORMANCE .

THE OTHER THING IS SCALABLE PATIENT SERVICES. WE'VE HEARD FROM MANY FOLKS HERE AS WELL AS OUTSIDE, FOR EXAMPLE, BEHAVIORAL HEALTH. WE'VE SEEN FROM THE ONCOLOGY SPACE HOW PRODUCTIVE THAT'S BEEN FOR PATIENTS. RIGHT. AND THERE'S A LOT OF QUESTIONS NOW ABOUT BRINGING OVER THAT LAYER OF SUPPORT TO NOT ONLY SICKLE CELL PATIENTS, BUT ALSO TO HEMOPHILIA AND OTHER THERAPEUTIC AREAS. SO, IN GENERAL, THAT'S WHAT WE'RE GOING TO BE ASKING AND EVALUATING THEM ON.

SO IN TERMS OF WHO CAN APPLY, WE ARE OPENING UP THE GATES FOR FOR-PROFIT AS WELL AS NOT-FOR-PROFIT ORGANIZATIONS. I DO WANT TO SEE A FULL SPATE OF PATIENT SUPPORT SERVICES OR AT LEAST

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

BE ABLE TO SCALE TO THEM. I DON'T WANT TO BUCKET US IN TO ONLY ONE SERVICE. THAT LIMITS OUR ABILITY TO SCALE FOR THE NEXT FIVE YEARS FOR GENE THERAPIES. AND THIS IS SORT OF AN ORGANIC PROCESS TO BE HONEST WITH YOU. WE'RE STILL LEARNING, RIGHT, THE KITES OF THE WORLD, THE CAR-T'S OF THE WORLD ARE STILL LEARNING ABOUT THE TRANSPORTATION, THE LOGISTICS, ET CETERA, WITH RESPECT TO THESE THERAPIES .

SO I AM REQUESTING THAT WE CAN INITIATE SERVICES WITHIN 120 DAYS. THAT'S THREE MONTHS. WE FLIP THE SWITCH; WE'RE OPEN FOR SERVICE. THAT'S AFTER WE SIGN THE CONTRACT AND DO THE TRAINING. OBVIOUSLY, WE'RE LOOKING FOR CALIFORNIA OPERATING LICENSES. THOSE HERE IN THE STATE UNDERSTAND THE STATE'S THRESHOLD AS WELL AS SOME OF THE CHALLENGES AND OPPORTUNITIES FOR PATIENTS IN THE GENE THERAPY SPACE.

ALL OF THIS IS REALLY STANDARD. WE ARE ALSO LOOKING FOR SOPHISTICATED DATA AND TECHNOLOGY SERVICES. AGAIN, THIS IS INDUSTRY STANDARD. CAN'T TELL YOU HOW MANY TIMES WE REALLY BATTLE TEST BACKUP CAPABILITIES. THIS IS GETTING INTO THE WEEDS. I WANT TO SEE THE BACKUP CAPABILITIES IN CASE THE CALL CENTER GOES DOWN. THAT'S MANDATORY.

SO THAT'S SORT OF THE DUE DILIGENCE THAT

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

WILL BE REQUIRED FROM AN ELIGIBILITY STANDPOINT.

SO HOW WILL WE MONITOR THE PROGRAMS? SO THERE THIS GETS A LITTLE GEEKY, BUT WE DO GET QUITE IN THE WEEDS WITH RESPECT TO MONITORING. THIS HAS TO DO WITH NOT ONLY THE FINANCIAL ASSISTANCE SERVICES THAT WE'RE PROVIDING, WHO ARE WE PROVIDING IT TO, BASIC EPIDEMIOLOGY, RIGHT, PERSON, PLACE, AND TIME. WHAT'S THE UTILIZATION? WE'RE GOING TO GET FEEDBACK, RIGHT, TO EXPAND THIS PROGRAM AND PROVIDE A REGULAR LEVEL OF SPECIFICITY BASED ON THE INFORMATION THAT WE'RE GETTING FROM THE CONTACT CENTER. WHAT ARE THE NONCOVERED COSTS OF SERVICES? WHAT ARE THE LOGISTICS WITH RESPECT TO TRAVEL?

WE ALSO WANT TO MAKE SURE THAT WE ARE TYING THIS INTO THE ALPHA CLINICS AND THE FUTURE COMMUNITY CARE CENTERS WITH REFERRALS AND SATISFACTION. SO THERE'S A WAY FOR US TO ACTUALLY REFER PATIENTS TO THESE SITES. SO IN ADDITION TO WHAT THEY'RE DOING, THIS IS ANOTHER LEVEL THAT MIGHT BE ABLE TO IDENTIFY PATIENTS THAT COULD BE GOOD CANDIDATES FOR THE TRIALS.

I WON'T GET INTO THE PROGRAM DASHBOARDS. I THINK YOU'VE SEEN THOSE IN PREVIOUS DISCUSSIONS AND PRESENTATIONS. WE DO LOOK AT EVALUATION MEASURES OF CASE MANAGERS. BELIEVE IT OR NOT, EVERY

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

CALL IS RECORDED. WE LISTEN TO THE CALL. WE THINK ABOUT HOW WE MIGHT BE ABLE TO IMPROVE THE CUSTOMER SATISFACTION AND THE LEVEL OF SERVICE THAT WE ARE PROVIDING TO THE PATIENTS.

AND IN CLINICAL TRIAL RECRUITMENT AND RETENTION SCORES, AND THEN THERE'S ALSO SOME INSTRUMENTS THAT WE CAN USE FOR PATIENT SATISFACTION SURVEYS TO MAKE SURE WE'RE GETTING GOOD FEEDBACK FROM THE PATIENTS, AND ARE WE HITTING THE MARK, ARE THERE THINGS THAT WE CAN IMPROVE UPON.

IN TERMS OF THE BUDGET ALLOCATION, I THINK YOU HAVE ALL SEEN THIS BEFORE. CIRM HAS ALLOCATED 15.6 MILLION OVER FIVE YEARS FOR DIRECT PATIENT SUPPORT. WE HAVE ALREADY 600,000 ALLOCATED FOR THIS YEAR, REMAINING OF THE YEAR, WHICH CAN CARRY OVER TO NEXT YEAR, TWO MILLION IN THE 2023-24 COHORT, THREE MILLION AND THEN FIVE MILLION IN 2024-25.

I NEED TO MAKE THIS CLEAR. THE ENTIRE 15.6 MILLION WILL BE ALLOCATED TO PATIENT SUPPORT SERVICES. THE ADMINISTRATION AND OPERATIONAL COSTS OF SERVICE WILL BE ALLOCATED FROM CIRM'S ADMINISTRATION BUDGET. AND WE ASSUME, THERE ARE SOME MODELING, BUT WE ASSUME THAT IT WILL BE LESS THAN 500,000 FOR THE FOUR- TO FIVE-YEAR PERIOD FOR THE ADMINISTRATION COSTS, ALL THE OPERATIONS. AND

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

THERE ARE QUITE A FEW ORGANIZATIONS THAT ARE JUST CHEWING AT THE BIT TO GET ACCESS TO THIS PROGRAM TO BE COMPETITIVE. AND I SUSPECT THEY'RE GOING TO BE HIGHLY COMPETITIVE BECAUSE IT IS SOMETHING UNIQUE, QUITE FRANKLY. THIS IS AN INDUSTRY, RIGHT. THIS IS A DIRECT PATIENT SUPPORT PROGRAM FOR THE PATIENTS OF CALIFORNIA.

AND THEN, FINALLY, SO SUMMARY AND NEXT STEPS BEFORE WE GET INTO THE GRANULARITIES AND I OPEN IT UP TO QUESTIONS. SO THE WAY WE'RE LOOKING AT THIS, WE ARE GOING TO CONTINUE WITH THE SYSTEMWIDE GAP ANALYSIS AND FINALIZATION OF THE CONCEPT PLAN. IF THE AAWG IS IN AGREEMENT WITH THE CONCEPT PLAN THAT WE POSTED TODAY WITH INPUT, WE WILL SHARE THIS WITH THE ICOC IN SEPTEMBER AND LAUNCH THE RFP PROCESS. AFTER THAT, THE RFP WILL BE POSTED AND APPLICATIONS WILL BE EVALUATED BY CIRM. WE HAVE A STANDARDIZED INSTRUMENT THAT I HAVEN'T PRESENTED, BUT THERE IS A METHODOLOGY FOR HOW WE ASSESS CONTACT CENTERS AND PATIENT SUPPORT SERVICES. THE CIRM TEAM WILL THEN MAKE A RECOMMENDATION FOR THE TOP CHOICES AFTER WE DO THAT DUE DILIGENCE INTERNALLY. AND THEN THE FINAL CONTRACT WILL BE BROUGHT TO THE ICOC FOR FINAL APPROVAL.

SO WITH THAT, I'M CERTAINLY CONSCIENTIOUS

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

OF TIME. WE'RE AT 2:40. I WANT TO PAUSE THERE AND SAY THANK YOU. AND, ART, LIKE TO OPEN IT UP FOR ANY COMMENTS .

CHAIRMAN TORRES: THANK YOU VERY MUCH, SEAN. I KNOW HOW HARD YOU AND MARIA MILLAN AND OTHERS, KEVIN MARKS ESPECIALLY AS WELL, HAVE WORKED ON THIS PROJECT. LET ME TELL YOU ONE THING WHICH IS VERY IMPORTANT TO ME. AND I KNOW BECAUSE I'VE HAD THESE PERSONAL DISCUSSIONS WITH THE GOVERNOR AND MEMBERS OF THE LEGISLATURE. THE FACT THAT WE MONITOR OR INTEND TO MONITOR THE EXPENDITURE OF THESE FUNDS IS EXTREMELY IMPORTANT. BECAUSE A LOT OF THE MEMBERS THAT I HAVE SPOKEN TO OVER THE YEARS DIDN'T REALIZE THAT WE MONITOR THE GRANTS. IF THE GRANTS AREN'T MEETING THEIR GOALS, WE REMOVE THE MONEY AND WE HAVE DONE SO. WE ARE VERY FISCALLY STRICT IN TERMS OF THE TAXPAYERS' MONEY IN RESPECT TO THE EXPENDITURE OF FUNDS RELATED TO STEM CELL RESEARCH AND THE PROGRAMS THAT WE PROVIDE.

SO CIRM WILL FUND SOME OF THESE PROGRAMS FOUR TO FIVE YEARS, USUALLY FIVE YEARS; BUT EVERY YEAR WE ARE INSTITUTING AN AUDIT TO ASSESS THE OVERALL IMPACT OF THE PROGRAM. IN OTHER WORDS, WE'RE GOING TO DO PERIODIC REVIEWS. AND IF THEY'RE NOT HOLDING THEIR COMMITMENT TO WHAT THEY PROMISED

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

TO DO FOR THE MONEY, THAT MONEY MAY NOT BE FORTHCOMING. AND WE'LL LOOK FOR OTHER APPLICANTS. SO I THINK PEOPLE ARE AWARE OF THAT, AND NOW THE TAXPAYERS NEED TO BE MORE AWARE OF THE FACT THAT WE ARE VERY STRICT FISCAL STEWARDS OF THE MONEY THAT THE PUBLIC HAS PROVIDED US.

AND LASTLY, BEFORE WE MOVE TO ANY QUESTIONS, THIS IS NOT THE END OF THE REVENUE STREAM. THERE WILL BE OTHER PATENTS THAT WILL COME AND ROYALTIES THAT WILL COME TO US IN THE VERY NEAR FUTURE. I DON'T KNOW HOW FAR ALONG THAT MAY BE, BUT THERE IS NO LIMIT TO WHAT MONEY CAN BE RECEIVED FROM THE ROYALTIES THAT WILL BE INCURRED FROM OTHER TREATMENTS THAT ARE DISCOVERED AND COME BACK INTO THIS PATIENT ASSISTANCE FUND. SO 16 MILLION IS NOT THE END-ALL OF THIS PROGRAM. OBVIOUSLY THOSE FUTURE INCOME SUPPORTS WILL BE COMING THROUGH THE LEGISLATURE PROCESS AS WE PROVIDE THEM WITH THIS INITIATIVE TO THE BEGIN WITH.

MARIA MILLAN, I WANTED TO TURN TO YOU IF YOU HAD ANY INPUT OR IMPACT BEFORE WE MOVE TO OTHER MEMBERS OF THE BOARD .

DR. MILLAN: NOT AT ALL. THIS IS EXCELLENT. WE REALLY LOOK FORWARD TO THE AAWG DISCUSSION SO WE CAN BRING THIS TO THE BOARD IN

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

SEPTEMBER.

CHAIRMAN TORRES: OKAY. TED.

DR. GOLDSTEIN: JUST VERY QUICKLY. AND, ART, I THINK IT'S GREAT THAT YOU TALK ABOUT IT. IN THE INSURANCE BUSINESS WE HAVE A WHOLE SEPARATE FUNCTION CALLED FRAUD, WASTE, AND ABUSE. AND IT'S KIND OF A WATCHDOG FUNCTION ON DOING REIMBURSEMENT AND ESPECIALLY WHERE ANY TIME THERE'S A POT OF MONEY, RIGHT, WE BECOME A TARGET OF FRAUDSTERS, AND WE NEED TO, OF COURSE, MANAGE THAT. AND IT'S GREAT THAT WE MADE THIS A PRIORITY.

THE ONE WORD THAT I THINK, AND THE SLIDE WAS GREAT AND I WOULD ONLY ADD ONE WORD, AND THAT IS EMOTIONAL SUPPORT. SO ALL THE PATIENTS ARE UNDERGOING SOME LIFE TRAUMA. AND THERE'S PATIENT SUPPORT JUST TO MAKE THE CONNECTION AND FACILITATE THE TRAVEL ARRANGEMENTS AND SO ON, BUT THERE'S ALSO AN EMOTIONAL SUPPORT. AND GETTING THE VENDORS TO BE ABLE TO SPEAK TO THAT AND DEMONSTRATE THAT, I THINK, WOULD BE USEFUL. IT'S SOMETHING WE ENGINEERED IN A CANCER CONCIERGE PROGRAM THAT I HELPED ORGANIZE, AND IT PROVES TO BE ESSENTIAL

CHAIRMAN TORRES: RIGHT. YOU'RE ABSOLUTELY RIGHT, WHICH IS WHY WE ADDED TWO MENTAL HEALTH PHYSICIANS TO THE BOARD WHEN WE WERE WRITING

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

PROP 14 BECAUSE BOTH BOB KLEIN, WHO SUFFERED A LOT WITH IS MOTHER WITH ALZHEIMER'S AND SON WITH DIABETES AND PASSED AWAY AT THE AGE OF 25, WAS WELL AWARE OF THAT EMOTIONAL SUPPORT AND HOW IMPORTANT THAT IT IS IN ADDITION TO THE PATIENT, BUT ALSO TO THE CAREGIVERS, THE FAMILY THAT ARE PART OF THAT WHOLE SCENARIO. AND HAVING BEEN A CAREGIVER FOR MY MOTHER AND FATHER IN YEARS PAST, I'M ACUTELY AWARE OF THE PRESSURES THAT A LOT OF PEOPLE CANNOT AFFORD TO PROVIDE FOR THEIR FAMILIES DURING THIS DISTRESSFUL PERIOD.

MR. ROWLETT, YOU HAD A COMMENT.

MR. ROWLETT: THANKS, SENATOR.

CHAIRMAN TORRES: AND ANN WILL FOLLOW.

MR. ROWLETT: AS YOU KNOW, WE'VE BEEN DOING A LOT OF WORK TO MORE EFFECTIVELY INCULCATE DEI IN OUR GWG RFP'S. AND SO I WANT TO MAKE SURE THAT THAT GETS CALLED OUT, AND THAT ANY APPLICANT WOULD HAVE TO DEMONSTRATE, NOT ONLY AN UNDERSTANDING AND APPRECIATION OF THE IMPORTANCE OF DEI, BUT REALLY HAVE IT REFLECTED IN THE RESPONSE. AND, THEREFORE, YOU NEED TO INCLUDE IT IN THE RFP SO THAT THE POPULATION THAT I ADVOCATE FOR ALL THE TIME, THE MEDI-CAL POPULATION, WHICH OFTEN IS UNDERSERVED, IS GIVEN, AGAIN, AN AMPLE OPPORTUNITY TO PARTICIPATE IN

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

THE TRIALS THAT ARE SO IMPORTANT .

CHAIRMAN TORRES: WOULD YOU PLEASE EXPLAIN WHAT DEI STANDS FOR SO THAT EVERYONE KNOWS?

MR. ROWLETT: DIVERSITY, EQUITY, AND INCLUSION. AGAIN, IT IS IN RESPECT TO THE UNSERVED AND UNDERSERVED IN OUR STATE THAT OFTENTIMES THAT THE CENTER ADVOCATES FOR VERY EFFECTIVELY RESIDE IN REGIONS OF OUR STATE WHERE SOME OF OUR TRIALS DON'T REACH OUT TO. AND SO WE WANT TO MAKE SURE THAT WE INCLUDE IT IN THE RFP .

CHAIRMAN TORRES: I ALSO WANT TO THANK PAT LEVITT AND ALSO HARLAN FOR BRINGING THE ATTENTION TO ME ON THE MEDI-CAL PATIENT POPULATION. I KNOW I HAVEN'T GOTTEN BACK TO YOU, BUT I HAVE BEEN WORKING ON IT WITH THE DIRECTOR OF MEDI-CAL AND ALSO WITH OUR SECRETARY.

ANN BOYNTON AND THEN HARLAN .

MS. BOYNTON: THANK YOU. I'M QUITE FAMILIAR WITH CALL CENTER OPERATIONS, LESS SO WITH THE PATIENT ASSISTANCE STRUCTURE. AND I KNOW WE INTENSELY MONITOR THE CALL CENTERS THEMSELVES. I WONDER IF THERE ARE EQUALLY ROBUST MEASURES AT THE BACK END FOR REIMBURSEMENT STRUCTURES, FOLLOWING ON WITH AL'S COMMENT AS WELL, THE DISTRIBUTION OF THE MONEY, THE EFFECTIVENESS OF THE SPEED OF THAT, OUR

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

ABILITY TO ENSURE THE PAYMENTS ARE BEING RECEIVED BY THE PEOPLE WHO NEED THEM. IS THAT SOMETHING THAT IS ROUTINE IN THESE KINDS OF SERVICES, SEAN? HAVE WE GOT A VERY ROBUST WAY TO RATE APPLICANTS ON THAT?

CHAIRMAN TORRES: PLEASE RESPOND, SEAN.

DR. TURBEVILLE: CERTAINLY. GREAT QUESTION. I DIDN'T GET IN THAT GRANULARITY, BUT WE DO MONITOR THAT. THAT'S A FISCAL RESPONSIBILITY. AND WHEN I GET BACK TO -- WHEN I MENTION SPEED, SPEED AT WHICH YOU GET THAT INFORMATION TO PATIENTS, SPEED AT WHICH YOU CAN GET THOSE FUNDS REIMBURSED, ABSOLUTELY. THOSE WILL BE IN WHAT WE CALL THE BUSINESS RULES WHEN WE START LAUNCHING THE PROGRAM, AND THAT IS -- ALL OF IT IS HIGHLY MONITORED. SO THE ANSWER IS YES TO BOTH OF THOSE .

CHAIRMAN TORRES: HARLAN.

DR. LEVIN: I WANT TO PICK UP ON TWO OF THE COMMENTS AND MAYBE MAKE THREE COMMENTS BECAUSE OF THAT. ONE IS ON THE MENTAL HEALTH OR THE BEHAVIORAL HEALTH ISSUES. I THINK IT'S REALLY IMPORTANT FOR THAT AND FOR OTHER SERVICES THAT THERE'S A COMMITMENT TO INTEGRATE WITH WHAT THE CENTERS ARE DELIVERING ALSO. WE DON'T WANT PATIENTS TO GET DOUBLE PHONE CALLS OR NOT REALLY KNOW WHAT THEY NEED TO DO OR GOT CAUGHT IN A LACK OF

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

COORDINATED CARE. SO I JUST WANT TO BE SENSITIVE TO THAT.

AND THEN THE SECOND POINT, AND I THINK IT WAS INHERENT IN WHAT AL'S COMMENT WAS, BUT I JUST WANT TO ADD TO HIS COMMENT, IS IT'S NOT JUST ENOUGH TO, LIKE, REACH INTO UNDERSERVED AREAS OR MINORITY AREAS. IT'S HAVING THE CULTURAL COMPETENCE. THESE PEOPLE ARE HIGHLY VULNERABLE. THESE PEOPLE MEANING PEOPLE WHO NEED GENE THERAPY. AND IF YOU'RE NOT PROVIDING CARE AT A LEVEL THAT INSTILLS TRUST AND ALSO SENSITIVITY TO THEIR LIFE SITUATION, IT'S JUST NOT AS USEFUL. SO I WOULD REALLY LOOK FOR A SPECIFIC CALL-OUT ABOUT NOT JUST NUMBERS, BUT ACTUAL COMPETENCY IN THESE AREAS.

CHAIRMAN TORRES: I JUST WANT TO SAY THAT HARLAN WALKS HIS TALK BECAUSE I KNOW THE CITY OF HOPE, THROUGH HIS LEADERSHIP, HAS BEEN EXTRAORDINARY IN THAT REGARD. SO THANK YOU AGAIN, HARLAN.

DANA.

MS. DORNSIFE: I WAS JUST WONDERING, SEAN, IF THIS IS BUILT AS A TRUE REIMBURSEMENT PROGRAM WHERE YOU'RE REQUIRING THAT PATIENTS SUBMIT RECEIPTS FOR REIMBURSEMENT BECAUSE OTHERWISE YOU RUN INTO A 1099 AND ADDITIONAL INCOME ISSUE THAT BUMPS POTENTIAL MEDICARE -- MEDICAID PATIENTS UP INTO A

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

HIGHER INCOME LEVEL.

DR. TURBEVILLE: SO WE'RE GOING TO MAP THAT OUT WITH THE PROCESS FLOW, TO BE HONEST WITH YOU. THERE'S A NUMBER OF DIFFERENT METHODOLOGIES THAT YOU COULD USE. I SHOULDN'T SAY NUMBER. THERE'S A COUPLE. FEDERAL POVERTY LEVEL IS SOMETHING THAT'S STANDARDIZED OUT THERE. WE WILL PROBABLY REQUIRE SOME INFORMATION FROM THE PATIENT WITH RESPECT TO INCOME AND WHERE THEY SIT WITH THE SES. THAT'S PROBABLY IMPERATIVE IF WE'RE STARTING TO GO AFTER CERTAINLY THE UNDERSERVED PATIENT POPULATIONS.

TO ANSWER THAT QUESTION, I WOULD STAY AWAY FROM RECEIPTS QUITE FRANKLY. WE CERTAINLY NEED TO VALIDATE THAT THEY'RE USING THE INFORMATION. THERE'S ALSO TRIAL CARDS THAT YOU'RE PROBABLY FAMILIAR WITH THAT ARE QUITE OFTEN USED IN THE INDUSTRY WITH RESPECT TO PATIENT SUPPORT AND THE CLINICAL TRIAL SUPPORT. SO I THINK --

DR. DORNSIFE: YOU CAN STILL -- IT'S STILL CONSIDERED ADDITIONAL INCOME THOUGH. WE CAN HAVE A CONVERSATION OFFLINE IF YOU'D LIKE TO. WE HAVE 16 YEARS OF DOING THIS, AND WE'VE BUILT A REALLY ROBUST REIMBURSEMENT SYSTEM .

CHAIRMAN TORRES: RIGHT. SEAN, IF YOU CAN

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

CONNECT WITH DANA OFFLINE, I THINK THAT WOULD BE GREAT BECAUSE IT'S AN IMPORTANT POINT THAT PEOPLE ALWAYS ARE SUFFERING FROM BECAUSE THEIR INCOME INCREASES, NOT TO A DETRIMENT OF THEIR OWN, YET IT BECOMES ONE.

DR. TURBEVILLE: ABSOLUTELY. DANA, CERTAINLY OFFLINE I'D LIKE TO GET YOUR INPUT ON THAT.

CHAIRMAN TORRES: DR. PADILLA FROM THE GREAT AREA OF FRESNO.

DR. PADILLA: THANK YOU. I HAVE A QUESTION JUST ON THE LOGISTICS OF THE PROPOSAL. BECAUSE ALL THE RESEARCH AWARDEES ARE ALSO GIVEN FUNDING TO REACH OUT TO PATIENTS AND TO SUPPORT PATIENT RECRUITMENT AND SERVICES AND OTHER EXPENSES, HOW DO YOU MOLD THE TWO FUNDING STREAMS SO THAT THEY'RE NOT ON TOP OF EACH OTHER, BUT COHESIVE IN A WAY AND SMOOTH IN TRANSITION?

AND THEN I HAVE ONE MORE. THE SECOND QUESTION IS FOR THE INFRASTRUCTURE. IS THIS GOING TO BE BASED AT THE CIRM HEADQUARTERS? IS THERE ANOTHER WORKING GROUP, MONITORING GROUP, THAT'S GOING TO BE MANAGING THE RFP AND EVERYTHING THAT'S ASSOCIATED WITH THAT?

CHAIRMAN TORRES: SEAN .

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

DR. TURBEVILLE: CERTAINLY. GOOD QUESTION. SO WE ARE DOING THE ADVANCED IN-DEPTH GAP ANALYSIS NOW TO COME UP WITH A SOLUTION FOR HOW WE'RE NOT DUPLICATING COST WITH THE MONEY THAT'S ALREADY OUT THERE, RIGHT. SO THAT'S KIND OF THE RETROSPECTIVE OF WHAT WE'VE ALREADY FUNDED. WE'RE NOT GOING TO INTERVENE WITH THAT. WE'RE GOING TO LOOK AT AREAS WHERE WE MIGHT BE ABLE TO SUPPLEMENT THAT, WHERE WE MIGHT HAVE SOME ADDITIONAL RESOURCES. WHERE WE'RE COMPLIANT, WE MIGHT SAY, AS I MENTIONED EARLIER, WE HAVE SOME ADDITIONAL RESOURCES FOR TRAVEL THAT'S COMPLIANT WITHIN PHARMA GUIDELINES, IF YOU WILL. THERE'S ADDITIONAL RESOURCES FOR, LET'S SAY, AIRFARE OR HOTELS THAT WE MIGHT BE ABLE TO SUPPLEMENT FOR THOSE PROGRAMS.

MOVING FORWARD, HOWEVER, I THINK PROSPECTIVELY WE HAVE SORT OF A CLEAN SLATE. THAT'S SOMETHING WE NEED TO THINK ABOUT INTERNALLY. WHETHER WE CONTINUE THAT RETROSPECTIVE PROGRAM OR, IN FACT, WE DO A CLEAN SLATE, AND ALL OF THE PATIENT SUPPORT FUNDING ACTUALLY GOES TO THIS PROGRAM .

CHAIRMAN TORRES: AND THE OVERSIGHT WILL BE DONE THROUGH CIRM .

DR. TURBEVILLE: THAT'S CORRECT. SO CERTAINLY HAVE THE SKILL SET TO DO THOSE AUDITS. WE

WILL BE CONTRACTING OUT WITH A THIRD-PARTY PROVIDER THAT PROVIDES THESE SERVICES. SO THE ACTUAL CALL CENTER WILL NOT BE IN-HOUSE AT CIRM. IT WILL BE CONTRACTED OUT. I THINK THAT'S PRETTY CLEAR. WE HAVE THE RIGHT TO OBVIOUSLY GO IN ON MONTHLY BASIS. WE WILL BE LOOKING AT THOSE METRICS. SO THAT GIVES US FEEDBACK; BUT IN TERMS OF OFFICIAL AUDITS OF THOSE PROGRAMS, THAT WILL BE DONE BY CIRM.

CHAIRMAN THOMAS: ALL RIGHT. BEFORE WE MOVE TO PUBLIC COMMENT, ANY OTHER COMMENTS FROM MEMBERS OF THE WORKING GROUP? IS THERE ANY PUBLIC COMMENT? MARIANNE, IS THERE ANY PUBLIC COMMENT?

I'M SORRY I DIDN'T SEE YOU. PAOLA.

MS. ANDREA: THANK YOU SO MUCH. MY NAME IS PAOLA ANDREA. I AM THE MOTHER OF JAKOB GUZIAK. WE LIVE IN CANADA. FIRST OF ALL, I WANTED TO SAY THANK YOU ALL OF YOU FOR ALL YOUR RESEARCH, YOUR EFFORTS, AND SACRIFICES HERE. I HAVE BEEN KEEPING UP WITH THE MEETINGS, AND I KNOW THAT THE BUDGET IS REALLY TIGHT.

I WANTED TO SAY PLEASE DON'T GIVE UP ON OUR ADA-SCID CHILDREN. I BELIEVE THAT SAVING THESE CHILDREN WILL SHOW THE WORLD HOW NECESSARY GENE THERAPIES ARE AND HOW WE CAN IMPACT THE LIVES OF MANY PATIENTS WITH GENETIC DISEASES. I FEEL THAT

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

SOMETIMES PUTTING A FACE TO THE STORY WILL BRING NEW POSSIBILITIES FOR OTHERS TO FINALLY UNDERSTAND THAT WE CAN ACHIEVE LESS RISK IN TRANSPLANTS, LESS HOSPITAL VISITS, AND STILL MAKE OTHER THERAPIES EQUAL OR MORE PROFITABLE.

I JUST WANTED TO SAY THANK YOU TO ALL OF YOU BECAUSE OF ALL OF YOU, YOU CAN TALK ABOUT HOPE. AND LET'S SHOW THE WORLD THAT HOPE REALLY EXISTS. THANK YOU.

CHAIRMAN TORRES: THANK YOU BECAUSE WE KNOW THE SACRIFICES YOU ARE MAKING AS A PARENT AND CLEARLY IN OUR ADVOCACY. WE WANT YOU TO KNOW IT DOES NOT GO UNNOTICED.

OUR NEXT STEP AND OUR FINAL STEP, QUITE FRANKLY, IS TO ASK FOR A VOTE FROM THIS WORKING GROUP SO THAT I CAN REPORT TO THE FULL BOARD THAT THE WORKING GROUP HAS APPROVED THIS CONCEPT. OBVIOUSLY IT'S GOING TO BE CHANGING REGULARLY AS WE MOVE FORWARD, BUT IN TERMS OF THE ENTIRE CONCEPT WHICH SEAN HAS PRESENTED, I WOULD LIKE TO HAVE A VOTE OF THE WORKING GROUP SO WE CAN SAY -- WE DON'T NEED AN APPROVAL BY THE BOARD, BUT I DO WANT AN APPROVAL BY THE WORKING GROUP THAT WE CAN MOVE FORWARD TO THE NEXT STEPS THAT WE HAVE TO MAKE. IS THERE A MOTION?

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

DR. HIGGINS: SO MOVED .

CHAIRMAN TORRES: MOVED BY DR. HIGGINS, SECONDED BY --

MR. ROWLETT: AL ROWLETT SECOND .

CHAIRMAN TORRES: -- AL ROWLETT. ANY FURTHER DISCUSSION? MARIANNE, PLEASE CALL THE ROLL.

MS. DEQUINA-VILLABLANCA: DAN BERNAL.

MR. BERNAL: AYE.

MS. DEQUINA-VILLABLANCA: ANN BOYNTON.

MS. BOYNTON: AYE.

MS. BONNEVILLE: JAMES DEBENEDETTI.

MR. DEBENEDETTI: AYE.

MS. DEQUINA-VILLABLANCA: DANA DORNSIFE.

MS. DORNSIFE: AYE.

MS. BONNEVILLE: TED GOLDSTEIN .

MR. GOLDSTEIN: AYE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: AYE, YES.

MS. BONNEVILLE: HARLAN LEVINE.

DR. LEVINE: AYE.

MS. BONNEVILLE: PAT LEVITT.

DR. LEVITT: AYE.

MS. BONNEVILLE: ADRIANA PADILLA.

DR. PADILLA: YES.

MS. DEQUINA-VILLABLANCA: AL ROWLETT.

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

MR. ROWLETT: AYE.

MS. BONNEVILLE: DAVID SERRANO-SEWELL.

MR. SERRANO-SEWELL: AYE.

MS. BONNEVILLE: ADRIENNE SHAPIRO.

JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. DEQUINA-VILLABLANCA: ART TORRES.

CHAIRMAN TORRES: AYE. CAN WE CALL ADRIENNE AGAIN? IS SHE STILL ON?

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

MS. DEQUINA-VILLABLANCA: SHE MAY HAVE DROPPED OFF .

CHAIRMAN TORRES: ALL RIGHT. THE MOTION CARRIES.

MS. DEQUINA-VILLABLANCA: THE MOTION CARRIES.

CHAIRMAN TORRES: THE MOTION CARRIES UNANIMOUSLY. AND I JUST WANT TO POINT OUT TO EACH MEMBER OF THE WORKING GROUP, THIS WAS A VERY HISTORIC VOTE, A VERY HISTORIC VOTE IN TERMS OF WHAT WE JUST DID. AND IT'S GOING TO BE LOOKED AT IN THE FUTURE AS TO HOW WE'VE ENCOMPASSED OUR EMBRACE OF PATIENTS AND PATIENT ADVOCACY TO MAKE SURE THAT PEOPLE HAVE ACCESS TO THE TREATMENTS THAT THE TAXPAYERS HAVE HELPED US PROVIDE. SO THANK YOU AGAIN FOR EACH AND EVERY ONE OF YOUR SERVICES TODAY AND ALSO FOR THE FUTURE. PAT YOURSELF ON THE BACK BECAUSE YOU DESERVE IT.

ALL RIGHT. ANY FURTHER QUESTIONS? IF NOT, THE MEETING IS ADJOURNED. THANK YOU SO MUCH.

(THE MEETING WAS THEN CONCLUDED AT 2:57 P.M.)

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

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON AUGUST 2, 2022, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
133 HENNA COURT
SANDPOINT, IDAHO
(208) 920-3543