BEFORE THE

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
AND THE APPLICATION REVIEW SUBCOMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION:	CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE 1999 HARRISON STREET SUITE 1650 OAKLAND, CALIFORNIA
DATE:	JUNE 28, 2018 9 A.M.
REPORTER:	BETH C. DRAIN, CSR CA CSR. NO. 7152
FILE NO.:	2018-11

I N D E X

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DISCUSSION ITEMS

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OAKLAND, CALIFORNIA; THURSDAY, JUNE 28, 2018

9 A.M.

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY, HIGH ATOP 1999 HARRISON STREET IN BEAUTIFUL DOWNTOWN OAKLAND. I'D LIKE TO CALL THE REGULAR MEETING OF THE ICOC AND APPLICATION REVIEW SUBCOMMITTEE MEETING TO ORDER FOR JUNE 2018. WE'LL MOVE ON.

MARIA BONNEVILLE IS ON THE VERY TAIL END OF A WELL-EARNED VACATION, AND SO WE WILL GO TO A PINCH HITTER, MR. TOCHER, TO CONDUCT THE ROLL.

MR. TORRES: THAT'S NOT THE SAME.

MR. TOCHER: I AGREE. WE LOOK FORWARD TO MARIA'S RETURN.

GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MR. TOCHER: LINDA BOXER.

UNIDENTIFIED SPEAKER: THIS IS LISA. SHE'S JUST FINISHING UP A MEETING.

MR. TOCHER: KEN BURTIS.

DR. BURTIS: PRESENT.

MR. TOCHER: DEBORAH DEAS.

DR. DEAS: HERE.

MR. TOCHER: JACK DIXON.

DR. DIXON: HERE.
MR. TOCHER: ANNE-MARIE DULIEGE.
JUDY GASSON.
DR. GASSON: HERE.
MR. TOCHER: DAVID HIGGINS.
DR. HIGGINS: HERE.
MR. TOCHER: STEPHEN JUELSGAARD. SHERRY LANSING. LINDA MALKAS.
DR. MALKAS: HERE.
MR. TOCHER: BERT LUBIN. DAVE MARTIN.
DR. MARTIN: PRESENT.
MR. TOCHER: SHLOMO MELMED. LAUREN MILLER.
MS. MILLER: HERE.
MR. TOCHER: ADRIANA PADILLA. JOE PANETTA. FRANCISCO PRIETO. ROBERT QUINT.
DR. QUINT: PRESENT.
MR. TOCHER: AL ROWLETT.
MR. TOCHER: SUZANNE SANDMEYER.
DR. SANDMEYER: HERE.
MR. TOCHER: JEFF SHEEHY. OSWALD STEWARD.
DR. STEWARD: HERE.
MR. TOCHER: JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MR. TOCHER: ART TORRES.

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MR. TORRES: HERE.
MR. TOCHER: KRISTINA VUORI.
DR. VUORI: HERE.
MR. TOCHER: DIANE WINOKUR.
MS. WINOKUR: HERE.
MR. TOCHER: THANK YOU.
CHAIRMAN THOMAS: THANK YOU, MR. TOCHER. THAT WAS AN ADMIRABLE EFFORT. YOU NEED TO RECALL --
MR. TOCHER: I WILL RECORD LINDA MALKAS AND STEVE JUELSGAARD AS PRESENT.
DR. LUBIN: GOOD MORNING, EVERYBODY.
CHAIRMAN THOMAS: HI, BERT. NICE TO HAVE YOU ON THE LINE.
DR. LUBIN: IT'S WONDERFUL TO HEAR YOUR VOICES. I'M FEELING REALLY TERRIFIC TODAY, SO YOU DON'T HAVE TO GET INTO ANYTHING RELATED TO CONCERNS FOR MY HEALTH. I'M REALLY HAPPY TO BE ON THE CALL.
CHAIRMAN THOMAS: THANK YOU VERY MUCH FOR JOINING.
OKAY. ANYBODY ELSE? SO WE'RE GOING TO PROCEED RIGHT INTO THE -- WILL MR. TOCHER LEAD US IN THE PLEDGE AS WELL?
MR. TOCHER: I WILL.
(THE PLEDGE OF ALLEGIANCE.)
CHAIRMAN THOMAS: OKAY. WE'LL PROCEED

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RIGHT INTO THE CHAIRMAN'S REPORT. THE FIRST THING WE WOULD LIKE TO DO IS YOU MAY HAVE NOTICED A NEW NAME MENTIONED ON THE ROLL CALL AND WOULD LIKE TO INTRODUCE DR. SUZANNE SANDMEYER FROM UC IRVINE AND ASK HER TO SAY A FEW WORDS TO THE BOARD ABOUT HER BACKGROUND. DR. SANDMEYER.

DR. SANDMEYER: SO I'D FIRST LIKE TO SAY THAT I'M REALLY EXCITED TO BE PART OF THE BOARD AND PART OF THIS EXCITING FRONTIER IN SCIENTIFIC RESEARCH. SO I WAS TRICKED INTO MAKING PERSONAL COMMENTS IN THE NEWS REPORT, AND I WON'T GO INTO PERSONAL ASPECTS OF MY PAST, BUT I GOT MY PH.D. IN BIOCHEMISTRY AT THE UNIVERSITY OF WASHINGTON IN SEATTLE, THEN I DID A POST-DOC WITH MAYNARD OLSON AT THE VERY BEGINNING OF GENOMICS AT WASH U. WHEN HE FIRST STARTED THE LAB I JOINED, WE WERE TURNED DOWN BY NSF FOR A GRANT THAT WAS TO RESTRICTION MAP THE YEAST GENOME, WHICH IS THE MOST GENERAL WAY THAT YOU CAN LOOK AT A GENOME. AND THE RESPONSE THAT NSF GAVE WAS THAT NO ONE WOULD CARE AND IT COULDN'T BE DONE ANYWAY.

SO IN THE YEARS SINCE THEN, WE'VE LEARNED A LOT ABOUT THE GENOME, AND OBVIOUSLY THE YEAST GENOME WAS SEQUENCED A LONG TIME AGO AND THEN THE HUMAN GENOME WAS SEQUENCED. ONE OF THE THINGS WE

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LEARNED ABOUT GENOMES WITH ALL THE SEQUENCING WAS THAT THEY'RE FULL OF REPEATED SEQUENCES THAT CAN ACTUALLY MOVE AROUND IN THE GENOME. SO I BECAME INTRIGUED BY THIS. AND A LOT OF THESE SEQUENCES ARE ACTUALLY RELATED TO RETROVIRUSES WHICH WERE THOUGHT TO HAVE INVADED THE HUMAN GENOME, FOR EXAMPLE, MILLIONS OF YEARS AGO. AND SO MY LABORATORY FOR THE LAST 30 YEARS AT IRVINE WHERE I'VE BEEN A PROFESSOR IN THE DEPARTMENT OF BIOLOGICAL CHEMISTRY HAS BEEN CONSUMED WITH TRYING TO UNDERSTAND THE LIFE CYCLE AND THE WAY IN WHICH THESE GENES THAT MOVE AROUND INTERACT WITH WHAT WE CONSIDER HOST GENES, WHICH ARE ACTUALLY A MUCH SMALLER PART OF THE GENOME.

AND SO IN THE COURSE OF THIS, I BECAME DIRECTOR OF OUR GENOMICS FACILITY, WHICH DOES SEQUENCING, TO LOOK AT TRANSCRIPTOMICS OF GENOMES, HOW THEY'RE EXPRESSED AND THE DNA OF GENOMES, LOOKING FOR MUTATIONS IN THE HUMAN GENOME, FOR EXAMPLE, AND HOW THOSE AFFECT GENE EXPRESSION IN CANCER AND STEM CELLS AND OTHER AREAS.

BUT VERY RECENTLY, JUST TO BRING THIS TO A CLOSE, I WAS APPOINTED VICE DEAN FOR RESEARCH IN THE SCHOOL OF MEDICINE. SO NOW I'M BASICALLY DOWNSIZING MY OWN PERSONAL LAB IN ORDER TO HAVE A BROADER FOCUS ON THE RESEARCH ACTIVITIES IN THE SCHOOL OF

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MEDICINE. AND OBVIOUSLY STEM CELLS ARE A VERY IMPORTANT PART OF THAT PORTFOLIO. SO WE HAVE A STEM CELL RESEARCH CENTER AT UC IRVINE THAT'S DOING VERY EXCITING THINGS. TWO WEEKS AGO WE SUBMITTED A P30 GRANT FOR SKIN STEM CELLS THROUGH THE STEM CELL CENTER THERE. WE'RE NOW WORKING WITH A NUMBER OF INVESTIGATORS FOR A PAUL ALLEN AMERICAN HEART FOUNDATION $43 MILLION GRANT OPPORTUNITY, WHICH IS A VERY LONG SHOT, BUT WE'RE VERY EXCITED TO WORK ON THAT PROJECT WITH STEM CELL RESEARCHERS AT UC IRVINE.

SO I HOPE THAT'S ENOUGH OF A BACKGROUND OF MY INTERESTS, BUT...

CHAIRMAN THOMAS: THANK YOU VERY MUCH, DR. SANDMEYER. WE'RE DELIGHTED TO HAVE YOU ABOARD AND TO HAVE YOUR EXPERTISE, AND YOU JOIN AN AUGUST GROUP WHICH HAS BEEN FIRMLY COMMITTED TO ACCELERATING THERAPIES FOR PATIENTS WITH UNMET MEDICAL NEEDS THROUGH STEM CELL WORK. AND WHAT YOU BRING TO THE TABLE WILL BE VERY VALUABLE. THANK YOU VERY MUCH FOR BEING A PART OF THIS.

IN OTHER BOARD MEMBER NEWS, JUST WANTED TO SAY -- I HOPE THIS ISN'T EMBARRASSING DIANE -- BUT DIANE WINOKUR WAS HONORED BY THE FOUNDATION FOR FIGHTING BLINDNESS ON APRIL 17TH IN A DELIGHTFUL

EVENT AT THE CALIFORNIA ACADEMY OF SCIENCES. SHE WAS RECOGNIZED BY THEM FOR HER EXCEPTIONAL ADVOCACY FOR ALS AND THE WORK SHE HAS DONE IN THE FIELD, AND IT WAS A REALLY ENJOYABLE EVENING.

AND, DIANE, CONGRATULATIONS. AN AWARD VERY WELL EARNED, AND IT WAS GREAT TO BE ABLE TO BE THERE TO SEE YOU GET IT.

ON ONE OTHER NOTE, WHICH I SORT OF GET A TWOFER ON THIS ONE, I JUST MENTIONED TO ART LINDA MALKAS. I HEARD ON A CITY OF HOPE AD WHEN I WAS LISTENING TO THE DODGER GAME ON THE RADIO, AND I THOUGHT, GEE, I KNOW HER. AND THAT WAS REALLY ELOQUENT. AND SO I JUST WANTED TO BRING THAT TO EVERYBODY'S ATTENTION, BOTH TO MENTION LINDA AND TO MENTION THE DODGERS, MR. JUELSGAARD.

TRY TO FIND ANY ANGLE. AL MISSED THAT. I'M REALLY SORRY ABOUT THAT. HE'S JUST WALKING IN.

SO I WANTED TO GIVE EVERYBODY AN UPDATE ON THE FUND-RAISING PLAN IN FRONT. AS YOU KNOW, FURTHER TO OUR MEETING IN DECEMBER, WE ARE LOOKING TO SECURE BRIDGE FUNDING TO BASICALLY TIDE US OVER TO BE ABLE TO KEEP OUR PROGRAMS GOING APACE FROM THE END OF 2019, WHICH IS WHEN WE CURRENTLY FORECAST WE'LL BE RUNNING OUT OF OUR 3 BILLION, TO THE NOVEMBER 2020 ELECTION, AT WHICH TIME WE ANTICIPATE

BOB KLEIN WILL LEAD A CITIZEN INITIATIVE TO REUP CIRM GOING FORWARD.

OUR GOALS WERE TO RAISE 55 MILLION BY THE END OF 2018 AND ANOTHER 55 EACH AT THE MIDPOINT OF 2019, THE END OF 2019, AND THE MIDDLE OF 2020.

WE HAVE A FUND-RAISING TEAM THAT MEETS WEEKLY HERE, WHICH IS MYSELF, MARIA MILLAN, MARIA BONNEVILLE, NEIL LITTMAN, AND MR. TOCHER. AND AT THIS POINT WHAT WE HAVE DONE IS WE'VE NARROWED DOWN TO TWO DIFFERENT OPTIONS FOR GIVING. ONE IS A STRAIGHT CHARITABLE GIFT. A SECOND IS, AND MOST OF YOU WON'T BE FAMILIAR WITH THIS, BACK IN THE EARLIEST DAYS OF CIRM WHEN CIRM WAS IN LITIGATION, BOB WAS ANXIOUS TO JUMP-START FUNDING EFFORTS, HE PUT IN PLACE SOMETHING CALLED BOND ANTICIPATION NOTES, WHICH BASICALLY WERE A LOAN THAT WOULD BE REPAID IF AND WHEN THE LITIGATION WAS SUCCESSFUL. AND SO THOSE WHO MADE THOSE LOANS WERE AT CONSIDERABLE RISK BECAUSE AT THAT POINT NOBODY KNEW WHAT WAS GOING TO HAPPEN IF LITIGATION WOULD HAVE NOT BEEN SUCCESSFUL. THE LOANS WOULD HAVE IMMEDIATELY CONVERTED TO GIFTS. AND, OF COURSE, HAD IT NOT BEEN SUCCESSFUL, WE WOULDN'T HAVE CIRM. BUT IT WAS AND WE DO. AND BOB USED THAT ROUGHLY 45 MILLION IN LOANS AND WAS ABLE TO DEPLOY THAT MONEY

TO GET THINGS STARTED IN THE EARLY DAYS.

SO THINKING BACK ON THAT, I ASKED THE QUESTION, AND WE'VE HAD A LOT OF DISCUSSION ON THIS IN-HOUSE, COULD WE DO SOMETHING SIMILAR HERE TO, INSTEAD OF HAVING AS THE PIVOTAL EVENT THE LITIGATION BEING SUCCESSFUL, THE PIVOTAL EVENT WOULD BE THE BOND MEASURE PASSING. SO COULD WE GO OUT AND HAVE LOANS IN ADVANCE OF THE BOND ELECTION? AND IF THE MEASURE WAS SUCCESSFUL, THEN WE WOULD, IF THE LENDERS SO CHOSE, THEY COULD GET REPAID AS WAS THE CASE WITH THE BAN'S. AND IF THE MEASURE WASN'T SUCCESSFUL, ANY LOANS WOULD BE CONVERTED AT THAT POINT TO A GIFT AND THE TAX CONSEQUENCES OF GIFTS WOULD FOLLOW, ETC.

SO WE HAD THIS EXTENSIVE DISCUSSION WITH THE STATE TREASURER'S OFFICE BOND COUNSEL ON THIS QUESTION AND DETERMINED THAT THAT INDEED WAS A VIABLE WAY TO GO, MUCH AS HAD BEEN THE CASE WITH THE BAN'S, AND SPOKE TO BOB ABOUT IT AS BOB WILL BE THE AUTHOR OF THE NEW INITIATIVE, AND HE WAS FULLY ON BOARD. SO THIS HAS NOW GIVEN US A SECOND TYPE OF OPTION TO OFFER TO POTENTIAL GIVERS TO THE AGENCY TOWARDS OUR BRIDGE FUNDING EFFORT. AND WE'RE STARTING TO TROT THAT OUT AS WE SPEAK.

I WANTED TO SAY AND REEMPHASIZE, WHICH

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I'VE SAID SEVERAL TIMES, OUR FIRST PRIORITY HERE IS TO SECURE ADMINISTRATIVE FUNDS BECAUSE WE WANT TO MAKE SURE THAT WE HAVE OUR STELLAR TEAM INTACT THROUGH THE ELECTION AND BEYOND. IN EVALUATING POTENTIAL FOLKS TO TALK TO, WE'VE HAD IN-DEPTH ANALYSES OF ALL SORTS OF DONORS WHO HAVE SHOWN AN INTEREST IN MEDICAL RESEARCH IN GENERAL, SPECIFICALLY WITH RESPECT TO REGENERATIVE MEDICINE, AND WE'VE SORT OF EVALUATED THEM FROM THE STANDPOINT OF INTEREST, ABILITY TO GIVE, BANDWIDTH, MEANING WHAT THEY'VE ALREADY GIVEN TO, TRACK RECORD IN GIVING, ETC., AND HAVE BEEN IN THE PROCESS OF IDENTIFYING A GREAT MANY HIGH NET WORTH INDIVIDUALS WHO SORT OF FIT INTO THE GENERAL DESCRIPTION OF WHAT WE ARE LOOKING FOR. SO IT WOULD BE BOTH IDENTIFYING THEM, IDENTIFYING ADVISORS TO HIGH NET WORTH INDIVIDUALS, SUCH AS HEALTHCARE, INVESTMENT BANKERS, CONCIERGE MEDICINE PROVIDERS, DONOR-ADVISED FUNDS, ETC. WE'VE HAD DISCUSSIONS WITH MEMBERS OF THE BOARD ABOUT IDEAS THEY WOULD HAVE IN TERMS OF FOLKS TO TALK TO. HAD A LOT OF DISCUSSIONS WITH PRIVATE BANKING GROUPS, WHICH ARE WEALTH MANAGERS OF HIGH NET WORTH INDIVIDUALS, TO SEE WHICH OF THEIR CLIENTS ARE POTENTIALLY INTERESTED IN THIS EFFORT, AND HAVE IDENTIFIED A NUMBER OF MAJOR FOUNDATIONS THAT HAVE

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EVIDENCED AN INTEREST IN HEALTHCARE OVER THE YEARS IN VARIOUS WAYS.

ANOTHER GROUP WOULD BE THERE ARE FOUNDATION ADVISORS OUT THERE THAT MAKE A LIVING IN TALKING TO DIFFERENT FOUNDATIONS AND SUGGESTING PLACES THAT THEY PUT THEIR MONEY, SPECIFICALLY WITH RESPECT TO SCIENCE. DISEASE FOUNDATIONS, OF COURSE, AND COMPANIES. THERE ARE A NUMBER OF COMPANIES OUT THERE THAT WE'RE LOOKING AT POTENTIALLY, PARTICULARLY WITH RESPECT TO COMPUTATIONAL ELEMENTS AND BIOINFORMATICS AND OTHER THINGS THAT WE HAVE INVOLVED IN ALL OF OUR PROJECTS THAT COULD BE THE SUBJECT MATTER OF COLLABORATION.

ONCE WE SORT OF HAVE GIVEN A LOT OF THOUGHT TO ALL THESE DIFFERENT CATEGORIES, WE'VE SPENT A LOT OF TIME SORT OF DETERMINING WHAT POTENTIAL INTEREST SPECIFIC GIVERS MIGHT HAVE STARTING WITH SORT OF THE UNRESTRICTED GIFT, WHICH IS WE LOVE YOU, CIRM. HERE'S X DOLLARS. DO WITH IT WHAT YOU WILL. THOSE THAT MIGHT BE INTERESTED ON THE ADMIN SIDE, THOSE THAT MIGHT BE INTERESTED IN GIVING TO SPECIFIC DISEASES, RESEARCH DEALING WITH WHATEVER IT MIGHT BE, CANCER, DIABETES, ETC. THOSE THAT ARE MOST INTERESTED IN BASIC RESEARCH AS OPPOSED TO LATER STAGE, THOSE THAT ARE INTERESTED IN

EDUCATION, WHETHER IT'S OF THE PI'S OR MEMBERS OF THEIR LAB OR OUR BRIDGES OR SPARK PROGRAM.

WE'RE STARTING TO LOOK PRETTY HEAVILY AT THE AREA OF STEM CELL TOURISM BECAUSE WE CONTINUE TO HAVE INCREASING ISSUES WITH THAT IN CALIFORNIA AS WELL AS THE REST OF THE COUNTRY. SO THERE ARE EDUCATIONAL ASPECTS TO THAT. THOSE THAT MIGHT BE INTERESTED IN ADDITIONAL ALPHA CLINICS. AS YOU NOTED IN OUR REPORT IN DECEMBER, THAT WAS ONE OF THE THINGS THAT WE BUDGETED FOR OUT OF THE 220 MILLION.

LAST, BUT NOT LEAST, CLINICAL TRIALS IN GENERAL OR SPECIFIC WITH RESPECT TO PARTICULAR INDICATION.

ALSO THOUGHT ABOUT THERE ARE, AS YOU WILL RECALL, BACK IN THE EARLY DAYS THERE WERE A NUMBER OF HIGH NET WORTH GIVERS WHO ADDED TO THE 3 BILLION THAT CIRM WAS GOING TO PROVIDE BY PHILANTHROPICALLY GIVING TO SPECIFIC INSTITUTIONS. A LOT OF THAT FUNDING IN THE EARLIEST TIME WENT TO THE BUILDINGS THAT YOU NOW SEE THE STEM CELL INSTITUTES SPREAD OUT THROUGHOUT THE STATE. SO WE'RE INVESTIGATING A NUMBER OF POSSIBLE WAYS TO APPEAL TO PEOPLE WITH RESPECT TO PARTICULAR INSTITUTIONS. AND WERE THEY TO GIVE MONEY, THAT WOULD FREE UP FUNDS FOR US TO PUT ELSEWHERE, ETC.

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SO IN EACH CASE WITH ALL OF THESE, WE'RE SITTING DOWN AND DISCUSSING THE ASK AMOUNT, THE STRATEGY OF THE ASK, AND JUST AS IMPORTANT IS IDENTIFYING PEOPLE TO TALK TO. AND WHAT THE STRATEGY IS IS HOW YOU GET TO THE PEOPLE YOU WANT TO TALK TO. SO WE SPENT A LOT OF TIME IDENTIFYING FOLKS WHO COULD HELP INTRODUCE US THAT SORT OF GIVE INSTANT LEGITIMACY TO THE EFFORT. AND SO THAT COULD BE, FOR EXAMPLE, THESE PRIVATE BANKING GROUPS, WHICH HAVE EXTENSIVE NETWORKS, ARE GREAT CANDIDATES FOR THAT. THERE ARE A NUMBER OF HIGH NET INDIVIDUALS THAT I OR OTHER MEMBERS OF THE BOARD KNOW DIRECTLY. WE KNOW THE HEADS OF FOUNDATIONS. WE'RE TALKING TO PEOPLE ABOUT HAVING MEETINGS SET UP WHERE A NUMBER OF HIGH NET WORTH PEOPLE WOULD COME TOGETHER TO HEAR ABOUT CIRM AND WHAT WE'RE DOING. THAT WOULD BE CONVENED BY ANY NUMBER OF THE DIFFERENT TYPES OF PEOPLE I WAS TALKING ABOUT AND TO GENERATE EXCITEMENT AMONGST THOSE GROUPS TO JOIN WITH US IN COLLABORATING AND STANDING ON THE SHOULDERS OF THE $3 BILLION WE'RE ALREADY DEPLOYING IN OUR WORLD-CLASS PORTFOLIO, WHICH WE VIEW AS A GREAT OPPORTUNITY FOR THEM TO JOIN.

SO A LOT OF THOUGHT HAS GONE INTO THIS; A LOT OF DISCUSSIONS ARE TAKING PLACE. I LOOK FORWARD

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AT OUR NEXT IN-PERSON MEETING TO GIVING AN UPDATE AND LETTING YOU KNOW THE RESULTS OF HOW ALL THESE CONVERSATIONS ARE DOING. SO DOES ANYBODY HAVE ANY QUESTIONS ABOUT THAT?

MS. WINOKUR: I HAVE A QUESTION. CAN WE HAVE A NAME THING FOR THE PEOPLE WHO GIVE, BY THE DIANE WINOKUR FUND FOR?

CHAIRMAN THOMAS: VERY GLAD YOU BROUGHT THAT UP, DIANE. AND I WAS REMISS IN MENTIONING THAT, YES, ABSOLUTELY WE CAN. AND WE'VE HAD A NUMBER OF DISCUSSIONS WITH RESPECT TO POTENTIAL GIFTS THAT PEOPLE MIGHT MAKE THAT WOULD INVOLVE NAMING RIGHTS. IT'S AN EXCELLENT IDEA AND A VERY IMPORTANT IDEA FOR MANY PEOPLE WHO WOULD LIKE TO HAVE THEIR NAMES CONNECTED TO THIS WHOLE WONDERFUL EFFORT. SO THANK YOU FOR BRINGING THAT UP.

MS. WINOKUR: THANK YOU.

CHAIRMAN THOMAS: OTHER QUESTIONS?

DR. LUBIN: CAN YOU HEAR ME?

CHAIRMAN THOMAS: SURE CAN.

DR. LUBIN: I THINK THIS IS FANTASTIC. AND TO THE EXTENT I CAN HELP WITH IT, I REALLY AM MOTIVATED TO DO THAT TO GET BACK INTO LIVING MY LIFE AND REALLY CONTRIBUTING TO THIS. I THINK IT'S WONDERFUL. AND I'D BE HAPPY TO SIT DOWN WITH YOU,

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J.T., AND BOB OR WHATEVER OR PARTICIPATE BY PHONE IN SOME OF THOSE MEETINGS. SO I'M VOLUNTEERING. IF I CAN HELP YOU, I'D BE HAPPY TO HELP.

CHAIRMAN THOMAS: THANK YOU, BERT, AND YOU'RE ON.

OKAY. ANY OTHER QUESTIONS?

DR. SANDMEYER: COULD YOU SAY A LITTLE MORE ABOUT HOW YOU SEE THE TOURISM INSPIRING THE HIGH END DONORS?

CHAIRMAN THOMAS: SO THERE'S BEEN SOME INTEREST IN THE EDUCATIONAL ASPECT OF -- LET ME BACK UP A SECOND. SO WE HAD THIS WONDERFUL ALPHA CLINIC SYMPOSIUM. EVERY YEAR WE HAVE AT ONE OF OUR DIFFERENT ALPHA CLINIC SITES A MEETING THAT BRINGS TOGETHER DIFFERENT SCIENTISTS AND SPEAKERS ON VARIOUS TOPICS. AND AT THE LAST ONE AT UCLA, WE HAD AN IMPASSIONED DISCUSSION BY SOMEBODY ON BEHALF OF PATIENTS SAYING BASICALLY WE, THE PATIENTS, ARE AT A DISADVANTAGE HERE FROM A KNOWLEDGE STANDPOINT. THE DOCTORS KNOW EVERYTHING. WE REALLY DON'T. WE HEAR ABOUT ALL THESE SITES OUT THERE. WE DON'T KNOW WHAT'S WHAT, WHAT'S LEGITIMATE, WHAT ISN'T. AND WHAT'S REALLY NEEDED IS THE SORT OF EFFORT TO EDUCATE THE PATIENT BODY AND THEIR DOCTORS AS TO WHAT ARE SORT OF PROPER ALTERNATIVES FOR THEM AND TO

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DISCOURAGE ALL OF THESE SNAKE OIL, STEM CELL TOURISM PLACES THAT ARE CROPPING UP ALL OVER THE PLACE.

SO WE'VE HAD SOME DISCUSSIONS WITH POTENTIAL DONORS WHO ARE INTERESTED IN THAT AND SORT OF A CERTIFICATION PROCESS. AND THERE'S QUITE A BIT THAT GOES INTO THAT WHOLE THING. IT WOULD NOT BE A TRIVIAL UNDERTAKING. AND SO WE'RE EXPLORING THAT POTENTIALLY AS A SOURCE OF GIFT.

DR. SANDMEYER: SO NOW I UNDERSTAND WHAT YOU MEANT BY TOURISM, BUT I WAS TAKING A DIFFERENT DIRECTION AND WONDERING WHETHER, IF YOU HAD A GROUP OF HIGH END DONORS TO TARGET, YOU COULD PRESENT THEM WITH SOME KIND OF A TRIP, IF YOU WILL, A GUIDED TOUR THROUGH SEVERAL OF THE STEM CELL FACILITIES WHERE THEY WOULD BE INTRODUCED TO INVESTIGATORS, THEY WOULD BE ABLE TO REALLY BE IN CONTACT WITH THE STEM CELL PRODUCTION PIPELINE FROM END TO END. AND THAT MIGHT, FOR A VERY SMALL GROUP OF PEOPLE VISITING DIFFERENT SITES, IT MIGHT BE A PRETTY EXCITING WAY TO RECRUIT YOUR HIGH END DONORS. I DON'T KNOW.

CHAIRMAN THOMAS: THAT'S AN EXCELLENT IDEA. I WILL SAY THAT ANYBODY FROM ANYWHERE WHO GOES TO ANY OF THE -- VISITS ANY OF THE STEM CELL OPERATIONS THAT WE HAVE THROUGHOUT THE STATE IS BLOWN AWAY WITHOUT FAIL. THAT WOULD BE A GREAT

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RECRUITING TOOL. SO THANK YOU VERY MUCH FOR THAT SUGGESTION.

OKAY. I WANTED TO JUST MOVE ON BRIEFLY. WE DID NOT MEET IN PERSON IN MARCH. ONE OF THE THINGS I WANTED TO, WHICH I WAS GOING TO MENTION AT THAT POINT, JUST SO YOU -- THE ALLIANCE FOR REGENERATIVE MEDICINE HAS EARLY IN THE YEAR AN ANNUAL MEETING AT WHICH IT TALKS ABOUT THE STATE OF THE UNION, SORT OF THE STATE OF THE INDUSTRY. AND THEY HAVE SOME INTERESTING PANELS EVERY YEAR. BUT FOR ME THE SORT OF MOST INTERESTING PIECE IS RIGHT AT THE BEGINNING WHICH IS WHERE THEY TALK ABOUT WHAT'S HAPPENING IN THE INDUSTRY AND TRENDS AND ALL THAT SORT OF THING. AND AT THIS --

CAN YOU HOLD ON ONE SECOND? FOR SOME REASON MY LAPTOP JUST WENT DOWN AND I WANTED TO SEE IF -- MR. SENATOR, COULD I BORROW YOUR PLUG?

(PAUSE IN PROCEEDINGS.)

CHAIRMAN THOMAS: SO I THINK LAST YEAR WAS VIEWED AS VERY MUCH OF AN INFLECTION POINT, I THINK. WE HAD A COUPLE OF PRODUCTS THAT WERE ACTUALLY APPROVED BY THE FDA. WE HAD A VERY ACTIVE NEW FDA COMMISSIONER WHO WAS VERY INTERESTED IN IMPLEMENTING THE 21ST CENTURY CURES ACT, AND THERE'S A DESIGNATION FOR SPECIFIC PROJECTS THAT ARE YET

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ACCELERATED STATUS IN THEIR CLINICAL TRIALS. THEY HAD DR. MILLAN. THEY HAD 12 INITIALLY AND THREE OF THOSE WERE OURS, IF I REMEMBER CORRECTLY.

DR. MILLAN: FOUR OF THE FIRST 12.

CHAIRMAN THOMAS: OKAY. SO THIS IS AN EXCITING, IT'S CALLED RMAT, AN EXCITING DESIGNATION BECAUSE IT ALLOWS FOR WHATEVER THE PROJECT IS TO GET SORT OF EXPEDITED TREATMENT AND ACCELERATED ATTENTION, ETC. AT THE END OF 2017, THERE WERE, ACCORDING TO ARM, 854 COMPANIES IN THE WORLD DEALING WITH REGENERATIVE MEDICINE OF WHICH 460 WERE IN THE UNITED STATES, EUROPE WITH 234.

I SHOULD PAUSE HERE FOR A MOMENT AND INVOKE SOMETHING THAT MR. JENSEN IN OUR AUDIENCE HERE DID A PIECE ON THE LAST FEW DAYS WHICH WAS A STATEMENT BY A WELL-KNOWN PLAYER IN THE ECOSYSTEM REGENERATIVE MEDICINE FIELD IN EUROPE WHO COMMENTED THAT EUROPE IS FALLING BEHIND PARTICULARLY THE UNITED STATES IN THE FIELD OF REGENERATIVE MEDICINE AND THAT THEY DON'T HAVE THE SORT OF ECOSYSTEM THAT EXISTS IN THE UNITED STATES AND SPECIFICALLY POINTED OUT CIRM AS THE LEADING EXAMPLE AND NOTED THAT WE GIVE OUT $250 MILLION A YEAR AND HAVE THIS ENTIRE ECOSYSTEM AROUND THAT, AND WHAT A GREAT LEG UP THAT GIVES CALIFORNIA AND THE UNITED STATES. I THOUGHT

THE BOARD WOULD FIND THAT VERY INTERESTING SOMEBODY WOULD INVOKE US FROM, I THINK IT WAS IN BRUSSELS, WHEREVER THE INTERVIEW WAS.

OVER THE COURSE OF THE LAST YEAR, THERE WERE, OF COURSE, GREAT ADVANCEMENTS IN T-CELLS, HSC'S, IPS, MSC'S, ADULT PROGENITORS, ETC. LOTS OF EXCITEMENT AROUND IMMUNOTHERAPY FOR SURE.

FOR THOSE WHO DON'T KNOW, WE HAVE IN OUR PORTFOLIO OF A NUMBER OF, YOU WILL RECALL, WE HAVE IMMUNOTHERAPY PROJECTS, BUT I THINK OUR CANCER PROJECTS IN GENERAL ADD UP TO MANY, MANY TENS OF MILLIONS OF DOLLARS, AND WE'RE, OF COURSE, VERY EXCITED ABOUT THAT AS WELL AS EVERYTHING ELSE THAT WE HAVE. THERE'S NEW ADVANCES IN GENE DELIVERY VEHICLES, MEANING VECTORS OF VARIOUS KINDS. LOTS OF ADVANCE IN GENOME EDITING TAKING CRISPR CAS-9 TO SORT OF NEW LEVELS AND TALENS AND ZINC FINGER NUCLEASES, WHICH OUR OWN SANGAMO IS ONE OF THE WORLD LEADERS. SO THERE'S JUST LOTS OF DIFFERENT ACTIVITY.

JUST ONE NOTE ON CLINICAL TRIALS, AGAIN, THIS IS A LITTLE STALE BECAUSE IT WAS THE END OF 2017, BUT IT'S STILL VERY INTERESTING, THERE WERE 946 CLINICAL TRIALS IN PROGRESS IN REGENERATIVE MEDICINE, 314 OF THOSE PHASE 1, 550 IN PHASE 2, AND

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82 IN PHASE 3. SO THERE ARE A LOT OF THEM THAT ARE PRESSING ALONG. AND IT WAS SORT OF SYMPTOMATIC OF THE LEVEL OF ENTHUSIASM THAT YOU HEARD IN THE ROOM AND THE CONFERENCE ABOUT HOW THINGS ARE, AS THEY HAVE BEEN FOR THE LAST FEW YEARS, REALLY PICKING UP STEAM AND A LOT OF STUFF IN THE PIPELINE. BY FAR THE BIGGEST CATEGORY OF THE TRIALS WAS IN ONCOLOGY, FOLLOWED BY CARDIOVASCULAR, CNS, MUSCULOSKELETAL, ENDOCRINE DISORDERS OF ONE SORT OR ANOTHER, AND ON DOWN THE LINE TO A GREAT MANY RARE OR ORPHAN DISEASES.

I WILL CIRCULATE THE LINK TO THIS. THERE'S A LOT OF STATS ON ALL THE DIFFERENT COMPANIES AND EVERYTHING ELSE. I WILL NOTE ON THE FINANCING SIDE THERE WERE $7.5 BILLION RAISED IN 2017 FOR REGENERATIVE MEDICINE COMPANIES AS COMPARED TO 4.2 BILLION IN 2016. SO THAT'S A VERY LARGE INCREASE. THERE WERE $4.5 BILLION IN GENE AND GENE-MODIFIED CELL THERAPY COMPANIES AS OPPOSED TO 1.7 RAISED IN 2016. 450 ROUGHLY MILLION DOLLARS FOR TISSUE ENGINEERING UP FROM THE PREVIOUS YEAR, AND 4 BILLION IN CELL THERAPY ITSELF, UP FROM 1.8 BILLION. BASICALLY YOU GET THE IDEA. THE FIELD IS REALLY RAMPING UP. I BET IF THEY DID A MIDYEAR REPORT THAT IT WOULD BE THAT MUCH GREATER ALREADY THIS YEAR. SO

I ALWAYS LIKE TO TELL THE BOARD WHAT THE STATE OF PLAY IS IN THE INDUSTRY, AND THINK THAT IT'S NOT ONLY INTERESTING, BUT GREAT TO KNOW THAT WE'RE RIGHT IN THE MIDDLE OF EVERYTHING. SO I THINK WE SHOULD CONTINUE TO FEEL EXTREMELY GOOD ABOUT WHAT WE'RE DOING, THE CONTRIBUTION CIRM IS MAKING TO THE GENERAL FIELD, AND REALLY THE TRANSFORMATIVE AND ACCELERATING IMPACT THAT WE ARE HAVING ON BASICALLY RESEARCH FOR INDICATIONS OF ALL KINDS. SO JUST WANTED TO LET YOU KNOW THAT.

BY THE WAY, THIS WHOLE SENSE OF THINGS ARE REALLY GOING ON AND HAPPENING ALSO ECHOED AT EARLIER THIS YEAR AT THE WORLD STEM CELL SUMMIT IN FLORIDA WHERE THERE WAS PRESENTATION AFTER PRESENTATION GETTING TO THAT SAME RESULT. GREAT ENTHUSIASM.

SO OKAY. WE COME NOW TO A SPECIAL PART OF THE CHAIRMAN'S REPORT. WE HAD A MAJOR PUBLICATION EVENT HAPPEN RECENTLY BY OUR LONGEST AND MOST SUPPORTIVE ADVOCATE.

MR. TORRES: LET'S GET ON WITH IT THEN.

CHAIRMAN THOMAS: I WOULD LIKE TO INTRODUCE OUR OWN DON REED WHO HAS PUBLISHED ANOTHER BOOK ON CIRM WHICH IS A WONDERFUL WORK. ALL MEMBERS OF THE BOARD SHOULD HAVE THEIR COPY, AND WE'LL GET THOSE OF YOU ON THE PHONE AND MAKE SURE EVERYBODY

GETS COPIES SENT TO YOU. IT CHRONICLES WHAT CIRM HAS DONE AND ITS IMPACT AS SEEN THROUGH THE EYES OF DON, WHO IS -- NOBODY COULD BE A BIGGER SUPPORTER OF WHAT WE'RE DOING. SO I WANTED TO GIVE DON THE FLOOR HERE SO HE COULD SAY A FEW WORDS ABOUT HIS BOOK.

MR. TORRES: I JUST WANT LET ALL THE BOARD MEMBERS KNOW THAT THEY DON'T HAVE TO REPORT THIS AS A GIFT UNDER THE FAIR POLITICAL PRACTICES.

CHAIRMAN THOMAS: THANK YOU, MR. SENATOR. MR. REED.

MR. REED: FIRST I'D LIKE TO INTRODUCE MY LOVELY WIFE GLORIA WHO HAS MADE MY LIFE HAPPY FOR HALF A CENTURY NEXT YEAR.

(APPLAUSE.)

MR. REED: HONORED MEMBERS OF THE ICOC, MEMBERS OF THE CIRM TEAM, AND PATIENT ADVOCATES WHO FIGHT BESIDE YOU, EVERY MORNING WHEN I WRITE I GET A PICTURE IN MY MIND OF THE CIRM IN ACTION AND WHAT IT MEANS. I THINK ABOUT THIS VERY ROOM SOMETIMES WHERE DECISIONS ARE MADE HOW BEST TO BENEFIT THE SCIENTISTS HELPING THEM TO EASE SUFFERING AND SAVE LIVES, LIVES LIKE LITTLE EVIE VACARRO, 3 FEET TALL, FULL OF ENERGY, RUNNING AROUND, HER LIFE LITERALLY SAVED BY DONALD KOHN AND THEIR THERAPIES CIRM HELPED FUND.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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ON THE WALL IS A PICTURE OF ROSIE BARERRO WHO WAS COMPLETELY BLIND BUT NOW CAN SEE HER TEENAGE CHILDREN FOR THE FIRST TIME THANKS TO HENRY KLASSEN AND CIRM.

AND THERE ARE SIX PEOPLE NEWLY PARALYZED WHO REGAINED THE USE OF THEIR HANDS AND ARMS THANKS TO STEM CELL THERAPIES CARRIED FORWARD BY CIRM, AND WHICH PRIDE COMPELS ME TO MENTION WAS BEGUN BY A SMALL RESEARCH PROGRAM LONG AGO AT THE ROMAN REED SPINAL RESEARCH ACT OF 1999. BUT THERE IS SO MUCH MORE GOING ON, SO MANY CHALLENGES QUIETLY ACCEPTED, GOING THROUGH THE SLOW STEP-BY-STEP WORK THAT MUST BE DONE AS WE STRUGGLE TO MAKE CURES NOT POSSIBLE BUT INEVITABLE.

DO YOU REMEMBER ANNETTE FUNICELLO, RICHARD PRYOR? THESE GREAT ENTERTAINERS WERE STRICKEN BY MULTIPLE SCLEROSIS, A SLOW PARALYSIS. CURE DID NOT COME IN TIME FOR THEM, BUT THE INTERNATIONAL COOPERATION BETWEEN CALIFORNIA'S CRAIG WALLACE AND AUSTRALIA'S CLAUDE BERNARD MAY HELP OTHERS BY REINSULATING MS DAMAGED NERVES.

MY BROTHER DAVID SHATTERED HIS LEG IN A MOTOR VEHICLE ACCIDENT. HE ENDURED MULTIPLE OPERATIONS, HAD STEEL RODS AND PLATES INSERTED INTO HIS LEG. TOMORROW'S ACCIDENT RECOVERIES MAY BE

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EASIER. AT CEDARS-SINAI DRS. DAN GAZIT AND HYUN BAY ARE WORKING TO USE STEM CELLS TO REGROW THE NEEDED BONE.

GLORIA SUFFERS ARTHRITIS IN HER KNEES. HER PAIN IS SO GREAT SHE TRIES TO MAKE ONLY ONE TRIP A DAY UP AND DOWN THE STAIRS OF OUR HOME. THE CUSHION OF CARTILAGE IN HER KNEES IS WORN OUT SO THERE'S BONE ON BONE. WHAT IF THAT LIVING CARTILAGE COULD BE RESTORED? DR. DENIS EVSEENKO OF UCLA IS ATTEMPTING TO DO JUST THAT.

AND WHAT ABOUT THE DEADLY SCOURGE OF CANCER? IRV WEISSMAN, THE FRIENDLY GRIZZLY BEAR GENIUS OF STANFORD, MAY HAVE THE ANSWER TO CANCER. HE RECOGNIZED THERE WERE CANCER STEM CELLS INVOLVED. NOBODY BELIEVED HIM FOR A WHILE, BUT IT IS NOW INCREASINGLY ACCEPTED THAT THESE CANCER STEM CELLS HAVE A CODING OF PROTEIN LIKE A CLOAK WHICH MAKES THEM INVISIBLE TO THE BODY'S DEFENSES. THE WEISSMAN PROCEDURE MAY PEEL OFF THAT CLOAK OF HIDDEN VISIBILITY SO THE IMMUNE SYSTEM CAN FIND AND KILL ALL THE CANCER STEM CELLS AND CURE THEIR OWNER.

WHAT WILL HAPPEN WHEN CIRM'S FUNDING RUNS OUT? IF WE DO NOTHING, THE GREATEST SOURCE OF STEM CELL RESEARCH FUNDING IN THE WORLD WILL BE GONE. WE NEED TO RENEW CIRM. PATIENTS ALL ACROSS THE WORLD

133 HENNA COURT, SANDPOINT, IDAHO 83864
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ARE DEPENDING ON US. THE CALIFORNIA STEM CELL PROGRAM WAS BEGUN AND LED BY ROBERT N. "BOB" KLEIN. HE NOT ONLY LED THE CAMPAIGN, WAS ITS CHIEF WRITER, NO. 1 DONOR, HE WAS ALSO THE FIRST CHAIRMAN OF THE BOARD, SERVING WITHOUT PAY FOR THE FIRST SIX YEARS. IT WAS AN INCREDIBLE BURDEN. HE WORKED BEYOND EXHAUSTION ROUTINELY. WOULD HE BE WILLING TO TRY IT AGAIN, THIS TIME TO RENEW THE FUNDING OF A SUCCESSFUL PROGRAM? WHEN I ASKED HIM RECENTLY, HE SAID, QUOTE, IF CALIFORNIA POLLS SUPPORT THE CONTINUING EFFORTS OF CIRM, THEN I AM FULLY COMMITTED TO A 2020 INITIATIVE TO RENEW THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE.

SHAKESPEARE SAID IT BEST IN HIS FAMOUS "TO BE OR NOT TO BE" SPEECH, ASKING "WHETHER TIS NOBLER IN THE MIND TO ENDURE THE SLINGS AND ARROWS OF OUTRAGEOUS FORTUNE OR TO TAKE ARMS AGAINST A SEA OF TROUBLES -- AND BY OPPOSING, END THEM." SHALL WE PASSIVELY ENDURE CHRONIC DISEASE AND DISABILITY OR FIGHT FOR CURES? CALIFORNIA'S ANSWER IS CIRM, AND CONTINUING CIRM IS WHY I WRITE. THANK YOU.

(APPLAUSE.)

CHAIRMAN THOMAS: THANK YOU AGAIN, DON. THANK YOU FOR YOUR TIRELESS SUPPORT AND EVERYTHING YOU AND YOUR WIFE AND ROMAN HAVE DONE FOR CIRM AND

CONTINUE TO DO GOING FORWARD AS WE HEAD TOWARDS WHAT WE HOPE AND ANTICIPATE WILL BE A SUCCESSFUL REUP MEASURE IN NOVEMBER OF '20 AND WELL BEYOND THAT. SO THANKS SO MUCH FOR ALL YOU DO. REALLY APPRECIATE IT.

OKAY. THAT CONCLUDES THE CHAIRMAN'S REPORT. I'LL NOW TURN IT OVER -- BEFORE I DO, I HAVE SOMETHING I NEED TO READ HERE. WITH RESPECT TO PUBLIC COMMENT, WE MAY HAVE MEMBERS OF THE PUBLIC AT OTHER SITES, INCLUDING HERE. SO MEMBERS OF THE PUBLIC WHO ARE ON THE PHONE AT A NONNOTICED MEETING LOCATION, WHICH MEANS ELSEWHERE BESIDES THAT LISTED ON THE AGENDA, WILL HAVE THE OPPORTUNITY TO MAKE PUBLIC COMMENT OVER THE PHONE WHEN WE CALL FOR PUBLIC COMMENT. ONCE WE HAVE CALLED FOR PUBLIC COMMENT, MEMBERS OF THE PUBLIC WILL BE ABLE TO DO SO BY PRESSING STAR ONE, WHICH WILL PLACE YOU IN LINE TO MAKE YOUR PUBLIC COMMENT. ONCE WE CALL YOUR NAME -- AND, DOUG, I BELIEVE YOU'RE OVERSEEING THAT -- YOU WILL HAVE THREE MINUTES TO MAKE THAT PUBLIC COMMENT.

SO WITH THAT I'D LIKE TO TURN IT OVER TO DR. MILLAN FOR THE PRESIDENT'S REPORT.

DR. MILLAN: THANK YOU. GOOD MORNING, EVERYBODY, MEMBERS OF THE BOARD, MEMBERS OF THE

133 HENNA COURT, SANDPOINT, IDAHO 83864
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PUBLIC, AND COLLEAGUES. SO IT'S MY PLEASURE TO KICK OFF THE PRESIDENT'S REPORT WHICH IS ACTUALLY GOING TO BE A TEAM EFFORT THIS MORNING. AT THE END OF MY PORTION, I WILL BE INTRODUCING MEMBERS OF THE CIRM TEAM WHO WILL BE GIVING UPDATES IN THE VARIOUS AREAS THAT CIRM IS ENGAGED IN TO PUSH FORWARD OUR MISSION.

SO TO START, OUR MISSION STATEMENT, TO ACCELERATE STEM CELL TREATMENTS TO PATIENTS WITH UNMET MEDICAL NEEDS REMAINS OUR MISSION, GUIDES EVERYTHING WE DO. AS YOU WILL RECALL, THIS BOARD APPROVED THE FIVE-YEAR STRATEGIC PLAN WHICH WE LAUNCHED IN 2016. WE'RE NOW HALFWAY THROUGH THAT, AND IN MIDYEAR OF YEAR THREE I'M HAPPY TO REPORT THAT WE CONTINUE TO BE ON TARGET OR A LITTLE BIT AHEAD OF TARGET IN SOME AREAS.

SO I'M JUST GOING TO GO THROUGH THE BIG SIX COMPONENTS OF THE FIVE-YEAR STRATEGIC PLAN AND JUST GIVE A BIG-PICTURE UPDATE. YOU WILL HAVE A MORE FULL UPDATE AT THE END OF THE YEAR. AND LATER ON IN THIS PRESENTATION, MEMBERS OF THE TEAM WILL GIVE YOU A LITTLE BIT MORE DETAIL IN TERMS OF HOW WE'VE ACCOMPLISHED THIS AND WHAT CHALLENGES ARE IN FRONT OF US AND HOW WE ARE APPROACHING THESE CHALLENGES.

SO ONE OF OUR GOALS WAS TO BUILD A

PIPELINE IN DISCOVERING 50 NEW CANDIDATES THROUGH OUR EARLY STAGE RESEARCH PROGRAMS. AND OUR TARGET WAS 50, AND WE'RE UP TO 29 PROGRAMS WHERE THERE ARE NEW CANDIDATES THAT ARE BEING PURSUED FOR WHETHER THEY COULD BE DEVELOPMENT CANDIDATES.

IN TERMS OF ADVANCING THROUGH DEVELOPMENT, AS WE CALL PROGRESSION EVENTS, THAT'S PROJECTS GOING FROM EARLY STAGE TO THE TRANSLATIONAL STAGE TO THE CLINICAL STAGE. WE'VE HAD A TOTAL OF 50 SUCH EVENTS NOW WITH THIS NEW PROCESS AND OPERATING SYSTEM THAT WE HAVE, WHICH WE CALL CIRM 2.0. AND THIS YEAR WE HAVE THREE. AND REFINING THE REGULATORY PARADIGM, YOU WILL HEAR A LITTLE BIT MORE ABOUT THIS FROM DR. ABLA CREASEY LATER ON, BUT WE WERE FORTUNATE TO BE INVOLVED IN CONVERSATIONS AND ACTIONS THAT LED TO THE PASSAGE OF THE 21ST CENTURY CURES ACT AND PROVIDED FOR AN ACCELERATED PATHWAY THAT J.T. HAD MENTIONED, THE REGENERATIVE MEDICINE ADVANCE THERAPY. YOU WILL HEAR ABOUT WHY THIS IS HELPING US WITH OUR MISSION OF ACCELERATING DEVELOPMENT OF THERAPEUTICS.

AND OF THE 12 PROGRAMS IN EARLY YEAR, I THINK THERE ARE A LITTLE BIT MORE NOW, FOUR OF THEM WERE CIRM-FUNDED PROGRAMS, WHICH IS QUITE REMARKABLE. AND IN TERMS OF SHORTENING TIME TO

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CLINICAL TESTING, WE BUILT INTO THE SYSTEM REQUIREMENTS FOR THE STAGE AND READINESS OF THE PROGRAMS THAT COME IN FOR VARIOUS FUNDING PROGRAMS. WE HAVE MILESTONE-BASED MANAGEMENT OF THESE AWARDS. WE HAVE ACTIVE INTERVENTION THROUGH ADVISORY PANELS. AND THROUGH THAT WE'VE BEEN ABLE TO MAKE STRIDES TOWARD SHORTENING THE DEVELOPMENT TIME AND, THEREFORE, SAVING THE MONEY IN DEVELOPING THESE PRODUCTS.

AND JUST AS A MEASURE OF THAT, WE'VE HAD THREE PROGRAMS THAT WERE ABLE TO ACHIEVE AN IND WITHIN 18 MONTHS. WE SET A TARGET FOR 18 MONTHS FOR WHAT WE CALL THE CLIN1 AWARD, AND WE WERE ABLE TO DO THAT FOR THREE PROGRAMS IN THE PAST TWO YEARS. THAT'S PRETTY REMARKABLE IF ANYBODY HAS BEEN INVOLVED IN A DEVELOPMENT PROGRAM.

WE HAD A TARGET, A VERY BOLD TARGET, OF 50 NEW CLINICAL TRIALS TO ADD TO OUR PORTFOLIO WITHIN A SPAN OF FIVE YEARS. AND WE'VE ADDED 34, BRINGING OUR TOTAL NUMBER OF CIRM-FUNDED PROGRAMS IN STEM CELL REGENERATIVE MEDICINE TO 49. SO IT CONTINUES TO BE BEST IN CLASS, MOST ROBUST PORTFOLIO OUT THERE. AND I'M GOING TO TALK ABOUT WHAT THIS MEANS A LITTLE BIT MORE LATER.

AND WE HAVE HAD A PART IN AND HAVE

WITNESSED AN INCREASE IN INDUSTRY PULL. WHEN WE STARTED THE STRATEGIC PLAN, SOME OF THE PROBLEM SETS WE PUT FORWARD IS THAT THERE JUST ISN'T ENOUGH INVESTMENT INTO THE SPACE FROM THE PRIVATE SECTOR. AND CIRM'S ROLE IN TERMS OF DERISKING THESE PROGRAMS, BUILDING BY QUALITY BY DESIGN PROGRAMS THAT ARE MORE ATTRACTIVE TO INVENTORS, WE HAVE HAD SUCCESS IN ATTRACTING EXTERNAL INVESTORS AND TRADITIONAL INVESTORS AND PARTNERS INTO THE PROGRAMS. AND NEIL LITTMAN LATER WILL GIVE AN UPDATE ON THAT.

WE'RE PLEASED TO REPORT THAT THIS YEAR ALONE WE'VE HAD SIX PARTNERSHIP EVENTS. HE'S GOING TO DESCRIBE THAT A LITTLE BIT MORE. AND IN TOTAL SINCE LAUNCHING THE STRATEGIC PLAN 19. SO IN TERMS OF NUMBERS, THERE'S BEEN AN INCREASE IN TERMS OF DOLLAR AMOUNTS RELATED TO THAT. IT IS, I THINK, ALMOST TENFOLD, BUT NEIL WILL GIVE AN UPDATE ON THAT.

SO WHAT DOES THIS MEAN? IF OUR GOAL IS TO GET THESE STEM CELL TREATMENTS TO PATIENTS, THE WAY TO DO THAT IS TO TEST THEM IN THE CLINICS, TO HAVE 49 CLINICAL TRIALS ACROSS A BROAD SPECTRUM OF DISEASE INDICATIONS FOR UNMET MEDICAL NEED WITH THESE NOVEL, TRANSFORMATIVE APPROACHES IS PRETTY

133 HENNA COURT, SANDPOINT, IDAHO 83864
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REMARKABLE. AND THIS IS NOTED BY EXTERNAL VALIDATION. WE WERE INVITED TO PHACILITATE WORLD STEM CELL SUMMIT THAT J.T. MENTIONED IN FEBRUARY. I, ALONG WITH SOME OF MY COLLEAGUES ON THE LEADERSHIP TEAM, WERE FORTUNATE TO BE INVITED TO PRESENT CIRM'S EXPERIENCE AND THE PROGRESS IN THE FIELD.

AND WE PRESENTED, I PRESENTED ON A PANEL IN THE OPENING PLENARY ON THE LANDSCAPE OF THIS FIELD. THE GENERAL MESSAGE FROM THAT PANEL IS YOU HAVE ARRIVED. ONE OF THE LEADERS IN THE BIDEN CANCER FOUNDATION HAS SAID THAT WHEN THE CURES ACT WAS GOING THROUGH, AND IT RECEIVED BIPARTISAN SUPPORT, BUT ONE OF THE KEY ITEMS THAT LED TO ITS PASSAGE IS THAT BOTH PARTIES ACCEPTED THESE PROVISIONS FOR ACCELERATING AND FOR SUPPORTING REGENERATIVE MEDICINE RESEARCH. SO HE SAID, "IF THAT WAS A DEAL MAKER, THAT'S A PRETTY GOOD SIGN FOR THE FIELD." GREG SIMON, I THINK, WAS WHO SAID THAT.

AND THEN WE PRESENTED ON THE STATE FUNDING MODEL, WHICH IS SOMETHING THAT FOLKS LOOK TO AS A MODEL THAT IS, NO. 1, UNIQUE; NO. 2, HAS GIVEN RESULTS; AND, NO. 3, IS ONE TO BE EMULATED IF IT CAN BE. WE PRESENTED THE PARTNERSHIP MODEL, DERISKING. THERE WERE FOLKS THERE, LEADERS IN THE FIELD AND

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

INDUSTRY, AND THEY GAVE US FEEDBACK THAT THIS IS ABSOLUTELY THE APPROACH. WHAT WE'RE DOING DOES INDEED HELP THEM IN TERMS OF DERISKING, IN TERMS OF TRUE PARTNERSHIP SO THAT THEY CAN TAKE IT UP AND BRING THE PRODUCT DEVELOPMENT FORWARD TO COMMERCIALIZATION.

AND ABLA CREASEY, WHO YOU WILL HEAR FROM TODAY, PRESENTED ON THE ACCELERATED REGULATORY PATHWAY.

CIRM IS VIEWED AS A LEADER. WE'VE HAD OTHER STATE ORGANIZATIONS AND OTHER GROUPS COME UP TO US AND SAY, "WE NEED CIRM TO SUCCEED FOR THIS FIELD TO SUCCEED. YOUR SUCCESS IS OUR SUCCESS." SO IT WAS A REALLY, REALLY CLEAR MESSAGE THAT CAME FROM OTHER SMALLER STATE AGENCIES AND OTHERS WHO ARE WISHING TO DO THIS AS WELL.

AND THE ACCELERATION MODEL IS A VERY UNIQUE MODEL, AS WELL AS THE FACT THAT WE ARE IMMERSED AND WERE FORMED BY AND EMBEDDED WITHIN WHAT WE DO IS PATIENT ADVOCACY AND PARTNERSHIP WITH THE PATIENT GROUPS AND PATIENTS.

SO THAT WAS A NATIONAL MEETING WHERE THERE WAS SOME INTERNATIONAL PRESENCE, BUT THEN I WAS INVITED IN APRIL TO SERVE ON A PANEL AT THE UNITE TO CURE CONFERENCE THAT WAS HELD AT THE VATICAN WHERE

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

THE PONTIFICAL COUNCIL FOR CULTURE OF THE VATICAN CO-SPONSORED THIS MEETING OF THE MINDS OF INTERNATIONAL LEADERS ON POLICY, PHILANTHROPY, SCIENCE, MEDICINE, PATIENT ADVOCACY, AND ALSO THE ENTERTAINMENT INDUSTRY. SO IF YOU FOLLOW FACEBOOK, KATIE PERRY WAS THERE, TONY ROBBINS WAS THERE, JACK NICHOLAS WAS THERE, BUT THEN THERE ALSO WAS FRANCES COLLINS WHO WAS AWARDED, THIS WAS AT THE VATICAN, A PONTIFICAL MEDAL FOR ACHIEVEMENTS IN GENOMICS AND THE HUMAN GENOME PROJECT.

SO IF YOU WILL RECALL, THAT WAS A VERY CONTROVERSIAL TOPIC BACK WHEN. AND THEN FRANCES COLLINS WAS BEING HONORED FOR THAT. WE HAD BERNIE SIEGEL, WHO IS A STAUNCH ADVOCATE FOR EMBRYONIC STEM CELL RESEARCH, WAS ALSO INVITED TO SPEAK. SO IT WAS REALLY QUITE REMARKABLE, AND HE NOTED THAT I CAN'T BELIEVE I'M HERE SPEAKING TO YOU RATHER THAN DEBATING YOU, AND IT WAS REALLY A VERY OPEN CONFERENCE WHERE UPDATES ON THE PROGRESS IN THE FIELD OF REGENERATIVE MEDICINE AND STEM CELLS, ACKNOWLEDGEMENT OF THE IMPORTANCE OF GENOMICS WAS SOMETHING THAT WAS THE THEME OF THE CONFERENCE.

I WAS FORTUNATE TO SERVE ON A PANEL WHERE I PRESENTED THE CIRM MODEL FOR PUBLIC/PRIVATE PARTNERSHIP. HAD A LOT OF INTEREST AFTER THAT IN

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

FOLLOW-ON MEETINGS, INTERESTED PARTIES, AND VARIOUS SECTORS IN TERMS OF KIND OF THE FUTURE FOR THE FIELD, AND MORE ON THAT AT UPCOMING MEETINGS.

WE HAD A PRIVATE ADDRESS BY POPE FRANCIS WHO HAD ACKNOWLEDGED AND ALSO APPRECIATED THE STRIDES THAT HAD BEEN MADE IN MEDICAL RESEARCH AND SCIENCE -- AND, OF COURSE, IT WAS TRANSLATED FOR ME BECAUSE I ACTUALLY WAS DEPENDING ON TRANSLATION -- HAD STATED THAT HE IS ENCOURAGED BY THE CURES THAT WE'RE ALREADY SEEING BY THESE ADVANCEMENTS. AND YOU CAN SEE HERE SOME QUOTES FROM THE *VATICAN NEWS*. ADVANCES IN CELLULAR RESEARCH AND IN THE FIELD OF REGENERATIVE MEDICINE HAVE OPENED NEW HORIZONS. I ENCOURAGE YOU -- AT THE END OF THIS, HE ENCOURAGED US BY SAYING, "I ENCOURAGE YOU THEN TO PURSUE WITH BOLDNESS AND DETERMINATION THE IDEALS THAT HAVE BROUGHT YOU TOGETHER FOR THIS UNITE TO CURE CONFERENCE."

SO THAT WAS A VERY SPECIAL VALIDATION OF OUR MISSION AND THAT IT IS GLOBAL, AND IT'S RECOGNIZED THAT THERE WERE MULTIPLE DIFFERENT FAITH LEADERS WHO WERE PRESENT AT THIS MEETING. SO IT GAVE THE MESSAGE THAT ACROSS RELIGIOUS BOUNDARIES, ACROSS POLITICAL BOUNDARIES, ACROSS VARIOUS CULTURAL DIVERSITY THAT THE IDEA OF CURES AND RELIEVING HUMAN

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

SUFFERING IS A NOBLE CAUSE AND IT'S OUR MORAL IMPERATIVE TO DO THAT. SO THAT WAS A REALLY NICE EXPERIENCE FOR MANY WHO PARTICIPATED, AND ACTUALLY THERE'S A LOT OF PUBLICATIONS AND SOCIAL MEDIA THAT HAVE GONE OUT SINCE.

SO WHAT'S A THEME THAT HAS REALLY BEEN JUST IN THE PAST SIX MONTHS HAS REALLY BEEN COMING TO HEAD IS THE POWER OF COLLABORATION. WE'VE HAD THIS LONG-STANDING COLLABORATION WITH PATIENTS, PATIENT ADVOCACY. THEY'VE BEEN EMBEDDED IN WHAT WE DO. THEY EMPOWER US. THEY FUEL US IN TERMS OF MOTIVATING US AS WELL AS PARTNERING WITH US TO MOVE THINGS FORWARD.

WE HAVE HAD MULTIPLE FORUMS WHERE WE CAN INTERACT AND FIGURE OUT WHAT TO DO. THE ALPHA CLINIC SYMPOSIUM IS ONE OF THEM. THEIR PARTICIPATION IN OUR CLINICAL ADVISORY PANELS AND OUR UPCOMING PANELS AS WELL AS THEIR LEADERSHIP IN OTHER INITIATIVES THAT FEED INTO THE BIG MISSION.

THE RESEARCHERS, OF COURSE, WE PARTNER WITH THEM THROUGH FUNDING, BUT WE SOLVE PROBLEMS TOGETHER. WE DO IT THROUGH NETWORKS SUCH AS ALPHA CLINICS NETWORK. JOHN ZAIA IS HERE IS ONE OF THE PROGRAM DIRECTORS, KEY LEADERS IN THIS NETWORK. YOU WILL HEAR A LITTLE BIT MORE ABOUT THAT LATER ON IN

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

THE YEAR IN AN UPDATE. BUT I WANTED TO JUST FEATURE A COUPLE OF THE NEW THINGS.

THE INDUSTRY PARTNERSHIP, WHICH NEIL LITTMAN WILL GIVE MORE DETAIL, IS SOMETHING THAT WE'RE REALLY STARTING TO SEE MUCH MORE DEEP CONVERSATION WITH INDUSTRY PARTNERS EARLY ON.

(CELL PHONE RINGING.)

DR. MILLAN: THAT WAS NOT MEANT TO BE RELATED TO THE INDUSTRY PARTNERSHIPS BY ANY STRETCH. THANK YOU THOUGH. NEEDED A LITTLE BIT OF THAT.

BUT TWO THINGS I WANTED TO TALK ABOUT WAS OUR PARTNERSHIP WITH THE POLICYMAKERS, AND ABLA CREASEY WILL GIVE THE UPDATE ON HOW WE'VE HAD VERY SUPPORTIVE AND OPEN CONVERSATIONS WITH THE FDA THAT HAVE REALLY HELPED OUR PROGRAM LEVEL, BUT JUST BROADLY FOR THE FIELD, AND SHE WILL DESCRIBE SOME OF THOSE, SOME OF THE OUTPUT OF THAT.

I WANTED TO TALK ABOUT ANOTHER PARTNERSHIP AND JUST ANNOUNCE SOMETHING THAT'S IN THE WORKS RIGHT NOW AND BEING SIGNED IS A PARTNERSHIP WITH THE NHLBI AT THE NIH. WHAT YOU SEE THERE, IT WAS ONE OF THEIR FACEBOOK LIVE AND SAYS WILL BE LIVE SHORTLY. I THOUGHT IT WAS APPROPRIATE. IT WAS A SCREENSHOT. BUT NOW WE ARE GOING TO BE LIVE ONCE I SIGN THE MEMORANDUM OF UNDERSTANDING WITH THE NHLBI. GARY

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

GIBBONS IS AT THE NHLBI HAS LAUNCHED THIS CURE SICKLE CELL INITIATIVE THAT'S A FIVE-YEAR INITIATIVE. BOTH FRANCES COLLINS AND GARY GIBBONS ARE HIGHLY COMMITTED TO THIS. IT'S JUST A TARGET THAT REALLY THERE SHOULD ALREADY BE A CURE BASED ON THE SCIENCE THAT WE HAVE, THE ADVANCEMENTS WE HAVE. AND THE IDEA IS IF WE COULD JUST PUT ALL THE PIECES TOGETHER AND PUT THE BEST ACCELERATION MODELS IN PLAY, THAT WE SHOULD BE ABLE TO DO THIS.

SO LAST JUNE, AS YOU RECALL, THE CIRM TEAM HAD VISITED THE NIH AND MET WITH THE VARIOUS NIH INSTITUTE HEADS. THERE WAS A LOT OF FOLLOW-UP MEETINGS SINCE THEN. THERE'S A RECOGNITION OF THE VALUE OF CIRM IN TERMS OF A TRANSLATIONAL MACHINERY, IN TERMS OF THE ACCELERATION POTENTIAL, AND IN TERMS OF THE ROBUST LATE DEVELOPMENT PORTFOLIO. BUT ONE OF THE THINGS THAT THEY REALLY, REALLY RECOGNIZE THAT ENABLED THIS IS THE ENGINE AND THE PROCESSES, THE FUNDING PROCESS, ALL THE INFRASTRUCTURE RELATED TO THE REVIEW OF FUNDING AND MANAGEMENT OF THESE AWARDS. AND BECAUSE OF THIS, NHLBI HAD MADE A DECISION THAT THEY NEEDED TO PARTNER WITH US IN ORDER TO HAVE THE BEST SHOT AT ACCOMPLISHING WHAT THEY WANT TO DO WITH THIS CURE SICKLE CELL INITIATIVE.

SO THE MOU IS PUT IN PLACE TO WORK OUT THE DETAILS AND THE LOGISTICS. AND AS MORE DETAIL COMES OUT OF THIS, WE WILL BE BRINGING INFORMATION TO THE BOARD. IF THERE ARE AMENDMENTS OR SOME NEW CONCEPTS THAT ARISE TO ENABLE THIS TO OCCUR, WE WILL BRING IT TO THE BOARD. BUT THE BOTTOM LINE IS WHAT THEY WANT TO DO IS USE THE PROCESSES THAT WE ALREADY HAVE IN PLACE. IF IT WORKS, THEY REALLY WANT TO LEVERAGE THAT.

THEY WILL LEVERAGE OUR APPLICATION PROCESS. THE APPLICATIONS THEMSELVES HAVE A VERY EXPEDITED REVIEW ON THEIR SIDE WHILE WE'RE REVIEWING IT SO THAT IT DOESN'T HOLD UP THE RECOMMENDATION TO YOU FOR FINAL FUNDING. AND THEY WILL THEN CO-FUND THE PROGRAMS AT LEAST AT A 50-50 TYPE THING, BUT MAYBE MORE DEPENDING ON -- AND WE'LL WORK THROUGH THAT SCHEME UNDER THIS MOU. AND THE REALLY POSITIVE ASPECT OF THIS FOR CIRM, GIVEN WHERE WE ARE, AS J.T. HAD MENTIONED, REALLY TRYING TO, GIVEN THE FACT THAT WE ARE GETTING DOWN TO OUR LAST DOLLARS IN TERMS OF RESEARCH BUDGET, IS STRETCH THAT WHILE WE'RE ACCELERATING AND WHILE WE'RE CONTINUING TO SUPPORT THE FIELD. PROGRESS AND SCIENTIFIC DISCOVERIES ARE NOT GOING TO STAY ON HOLD WHILE WE'RE WAITING FOR DECISIONS IN TERMS OF WHETHER WE'RE GOING TO BE

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REUPPED. SO THIS IS AN OPPORTUNITY TO LEVERAGE THOSE FOR THE SICKLE CELL CURES INITIATIVE. IT'S ALSO AN OPPORTUNITY TO TEST THE MODEL THAT COULD BE MORE BROADLY APPLIED TO DIFFERENT CONSORTIA AND DIFFERENT TYPES OF GOALS AS WELL.

AND THEN CIRM WILL BE RESPONSIBLE FOR CONTRACTING, MANAGING THE AWARDS AND THE MILESTONE-BASED METHODS. AND IT'S QUITE REMARKABLE. WE'RE ALSO SEEING THAT THE NIH IS -- THEY RECOGNIZED, THEY ACTUALLY SAID, WE KNOW THAT WE'RE SLOW. THEY ACTUALLY SAID THAT WE GET IT. WE'RE SLOW AND WE KNOW THAT, AND THAT'S WHY WE'RE PARTNERING WITH YOU. AND IT WAS JUST REALLY REMARKABLE. SO I'M PLEASED TO ANNOUNCE TODAY THAT WE'RE IN THE BEGINNING AND YOU WILL HEAR MORE ABOUT THAT.

AND SO I WILL TAKE SOME QUESTIONS ON THAT, BUT THEN I WILL INTRODUCE, I CALL IT OUR INTEL INSIDE. HOW DID THIS HAPPEN? IT'S BECAUSE OF THE TEAM. SO I HAVE ASKED MEMBERS OF THE TEAM TO COME AND PRESENT VERY SHORT, SUCCINCT UPDATES RELATED TO VARIOUS TOPICS. GABE THOMPSON WILL GIVE YOU AN UPDATE OF OPERATIONAL EXCELLENCE, HOW TO MOTIVATE BEHAVIOR, AND HOW WE MANAGE THINGS SO THAT WE ACCELERATE. ABLA CREASEY YOU'VE HEARD ME MENTION

SEVERAL TIMES. NEIL LITTMAN ON INDUSTRY ALLIANCE. KEVIN WILL TALK ABOUT HOW WE TELL OUR STORY. PAT OLSON WILL INTRODUCE A NEW TRANSLATIONAL ADVISORY PANEL.

SCOTT TOCHER, MAYBE I'LL GO AHEAD AND START WITH YOU BECAUSE YOU DON'T HAVE A PRESENTATION, BUT YOU WILL GIVE -- BECAUSE YOU'RE COUNTING AND TAKING NOTES, WILL GIVE AT LEAST AN UPDATE, AND THEN THE REST OF THEM, CHILA SILVA-MARTIN AND GIL SAMBRANO WILL BE GIVING THEIR PRESENTATIONS LATER AS THEY REQUIRE ACTION.

SO MAYBE -- SO IF THERE ARE ANY QUESTIONS ABOUT THE NIH COLLABORATION OR ANYTHING ELSE YOU'VE HEARD, I'M HAPPY TO TAKE IT AT THIS TIME.

DR. LUBIN: MARIA, THIS IS PHENOMENAL. FIRST OF ALL, THE STATE OF CALIFORNIA IS PROBABLY ONE OF THE LEADERS IN SICKLE CELL DISEASE BOTH IN NORTHERN AND SOUTHERN CALIFORNIA. A LOT OF GENE THERAPY, BUT NEWBORN DIAGNOSIS FOR SICKLE CELL DISEASE STARTED IN CALIFORNIA. NOW IS U.S. WIDE. TREATMENT PROTOCOLS ARE BEING DEVELOPED THAT ARE NATIONALLY ADOPTED. THIS IS A PHENOMENAL OPPORTUNITY.

IN ANY WAY I CAN HELP, AS SOMEBODY WHO'S DEVOTED TO THIS DISEASE, I'D BE HAPPY TO DO, BUT I

WANT TO CONGRATULATE THE WHOLE TEAM AND YOUR EFFORTS. I THINK IT'S PHENOMENAL.

DR. MILLAN: THANK YOU VERY MUCH, AND WE WILL CALL UPON YOU AND YOUR EXPERTISE.

DR. MALKAS: MARIA, I JUST WANT TO COMPLIMENT YOU AND THE TEAM AS WELL. THIS PARTNERSHIP IS EXTRAORDINARY. THIS IS A REALLY RARE EVENT BY THE NIH TO DO SUCH A THING, AND I THINK IT'S JUST A PHENOMENAL EXAMPLE OF THE RECOGNITION THAT CIRM IS GETTING NATIONWIDE. WE KNOW IT'S GREAT, BUT ACTUALLY AT THAT KIND OF LEVEL AND IN A WAY, AS YOU SAID, THIS IS A PILOT, I COULD SEE OTHER INSTITUTES JOINING IN. IT BECOMES VERY DISEASE SPECIFIC AND VERY, VERY -- THIS IS THE POWER. THE INTEL INSIDE TOTALLY. I WANT TO CONGRATULATE YOU ALL. THIS IS JUST PHENOMENAL.

DR. MILLAN: THANK YOU VERY MUCH, LINDA.

DR. DIXON: ABSOLUTELY EXCELLENT. VERY NICE.

DR. SANDMEYER: I AGREE. IT'S AMAZING. YOU'RE TO BE REALLY CONGRATULATED. BUT I'M CURIOUS HOW THIS AFFECTS GRANTEES OUTSIDE OF CALIFORNIA AND OUTSIDE OF CIRM. SO YOU WOULD BE HANDLING GRANTS THAT ARE NOT CIRM BASED? WOULD YOU BE MEDIATING SOME PART OF THEIR ADMINISTRATION?

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DR. MILLAN: I'LL RESPOND TO THAT IN BROAD STROKES BECAUSE WE ARE WORKING OUT THE MOU TERMS. BUT THE IDEA IS WE DO ALREADY ACCEPT NON-CALIFORNIA OR EX-CALIFORNIA GRANTEES FOR OUR CLINICAL PORTFOLIO. SO WE'RE FOCUSING ON THE CLINICAL AT THIS POINT. AND WHAT IT WOULD JUST MEAN IS THAT THERE IS A POTENTIAL FOR THOSE CALIFORNIA GRANTEES, WHO TYPICALLY ONLY HAVE THE CALIFORNIA COST COVERED BY CIRM, THAT THEY WOULD, IN ADDITION TO THE NIH CO-FUNDING THE CALIFORNIA PORTION, THEY COULD POTENTIALLY ACCESS ADDITIONAL FUNDING FOR THEIR EX-CALIFORNIA COSTS.

BUT, AGAIN, WE WILL HAVE MORE DETAIL ONCE WE HAVE SETTLED ON THE TERMS OF THE RELATIONSHIP AND THE STRUCTURE.

DR. LUBIN: I'M SORRY TO INTERRUPT. IT'S REALLY IMPORTANT THAT THIS INFORMATION IS BROUGHT TO BARBARA LEE'S OFFICE. SHE HAS BEEN COMMITTED TO SICKLE CELL RESEARCH, SICKLE CELL PATIENT CARE, AND SHE'LL BE ECSTATIC TO HEAR WHAT WE'RE DOING. AND SO IF IT HASN'T BEEN DONE, I MIGHT BE ABLE TO HELP. I CERTAINLY CAN. SHE SHOULD KNOW THIS ACTIVITY IS HAPPENING WITH CIRM.

DR. MILLAN: WE WILL SHARE ALL THE DETAILS SHORTLY.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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MR. TORRES: THIS IS THE MOST I'VE HEARD BERT TALK AT A BOARD MEETING. SO IT'S CLEAR THAT HE'S DOING WELL. WE ARE BLESSED THAT HE IS.

DR. MILLAN: SO IF THERE ARE NO OTHER QUESTIONS, I'D LIKE TO HAVE SCOTT GIVE THE LEASE UPDATE, AND THEN WE'LL GO AHEAD AND GET GABE SET UP FOR HIS PRESENTATION.

MR. TOCHER: THANK YOU, MARIA. AS YOU MAY RECALL OR MAYBE NOT FOR THOSE OF YOU WHO JOINED CIRM IN OUR LATER YEARS, BUT WHEN CIRM WAS FIRST CREATED BY THE INITIATIVE, MANY CITIES COMPETED TO LOCATE CIRM'S HEADQUARTERS. WITH SAN FRANCISCO'S SUCCESSFUL BID, ONE OF THEIR INDUCEMENTS WAS THAT THEY NEGOTIATED ON CIRM'S BEHALF FREE RENT FOR A PERIOD OF TEN YEARS. SO --

MR. TORRES: WHO'S RESPONSIBLE FOR THAT?

MR. TOCHER: SENATOR, I THINK THAT MIGHT HAVE BEEN YOU.

MR. TORRES: GAVIN NEWSOM.

MR. TOCHER: GAVIN NEWSOM AND BOB KLEIN, I THINK, AS WELL. SO AT ANY RATE, WE WERE BLESSED WITH ABOUT 20,000 SQUARE FEET, WHICH AT THE TIME, 2004-5, WAS A BIT OF A SLEEPY BACKWATER WHICH IN THE ENSUING TEN YEARS GREW UP WITH VALUE OF RENTS SKYROCKETING. SO THE LANDLORD WASN'T ENTIRELY SAD

TO SEE US GO AFTER TEN YEARS.

AS YOU KNOW, SITTING HERE TODAY, WE RELOCATED TO OAKLAND IN A SOMEWHAT MORE MODEST SIZE SPACE BUT STILL VERY COMFORTABLE LOCATION. THE FLOOR SPACE HERE ON THE 16TH FLOOR COMPRISES JUST 14,000 FEET. AT THE TIME, WITH THE SIZE OF THE GROUP THAT WE HAD, WE ALSO AVAILED OURSELVES OF A SMALL PIECE DOWN ON THE 15TH FLOOR OF JUST ABOUT 2600 SQUARE FEET. WE ANTICIPATED AT SOME POINT THAT WE WOULD HOPEFULLY ABSORB FOLKS SO THAT WE WOULD HAVE THE MORE IDEAL SITUATION OF HAVING EVERYONE LOCATED ON THE SAME FLOOR AND HAVING THE TEAM ALL IN ONE PLACE.

ABOUT A YEAR AGO WE WERE LOOKING INTO THAT AND DECIDED WE COULD ACTUALLY MAKE SOME PROGRESS ON THAT. SO WE MOVED FOLKS THAT WERE DOWNSTAIRS UP HERE AND GOT REAL COZY. AND THEN WITH THE TERM REMAINING ON THE 15TH FLOOR, WE DECIDED TO SEE IF THERE WAS ANY WAY THAT WE COULD GET ANY VALUE FOR THAT SPACE IN THE ABOUT 11 MONTHS THAT WAS REMAINING ON THE LEASE OF THAT SPACE. AND WE WERE LUCKY ENOUGH TO FIND A SUBTENANT. SO ARE ABLE TO RECOUP ABOUT 86 PERCENT OF OUR COST ON THE LEASE FOR A SUBLEASE FOR A TERM OF JUST TEN AND A HALF MONTHS. WE WERE ALSO ABLE TO NEGOTIATE GETTING ALL OF THAT

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PAYMENT UP FRONT. SO WE ELIMINATED THE EXPOSURE. THIS SAVED US ABOUT $87,000 OR SO IN OUR LEASE COSTS FOR THAT PERIOD OF SPACE.

SO WE'RE ALL UP HERE. WE SAVED ABOUT $87,000. WE'RE DELIGHTED THAT WE WERE ABLE TO DO SO. ACTUALLY THAT WAS BETTER THAN OUR EXPECTATIONS. SO WE JUST WANTED TO GIVE YOU AN UPDATE ON THE SPACE. THANK YOU, MARIA. ANY QUESTIONS?

CHAIRMAN THOMAS: THANK YOU, MR. TOCHER. I'D LIKE TO POINT OUT THAT THE ORIGINAL SPACE WE HAD, OF COURSE, WAS A FANTASTIC LOCATION OTHER THAN THE FACT THAT IT WAS DIRECTLY ACROSS FROM THE GIANTS BASEBALL STADIUM. AND WE HAD PUT UP WITH THE SERIES OF WORLD CHAMPIONSHIPS. SO I THOUGHT MOVING TO OAKLAND WAS GOING TO BE A GREAT MOVE. AND LO AND BEHOLD, WE'VE NOW HAD TO PUT UP WITH A SERIES OF WARRIOR PARADES. SO YOU CAN'T ESCAPE THIS STUFF.

MR. TORRES: YOU'RE VERY LUCKY YOU'VE TERMED OUT.

DR. LUBIN: WATCH OUT FOR THE A'S. THE A'S ARE STILL IN IT.

CHAIRMAN THOMAS: THANK YOU, BERT. BETH, HOW ARE YOU DOING? YOU NEED A BREAK OR ARE YOU OKAY?

THE REPORTER: SURE. WE'LL TAKE A BREAK.

CHAIRMAN THOMAS: MARIA, IS THAT OKAY? GIVE BETH A LITTLE REST HERE. WE'LL TAKE A TEN-MINUTE BREAK. WE'LL BE BACK WITH THE REST OF THE PRESIDENT'S REPORT. THANK YOU.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: OKAY. WE'RE GOING TO RESUME NOW BACK TO THE PRESIDENT'S REPORT. DR. MILLAN.

DR. MILLAN: I'D LIKE TO INTRODUCE GABE THOMPSON, WHO'S THE HEAD OF OUR OPERATIONS GRANTS MANAGEMENT FOR CIRM.

MR. THOMPSON: HELLO, BOARD, COLLEAGUES, AND MEMBERS OF THE PUBLIC. I'M GOING TO GIVE A QUICK UPDATE ON WHAT WE'RE DOING TO MEASURE ACCELERATION TO DRIVE PERFORMANCE AND EFFICIENCIES BOTH IN OUR PORTFOLIO ON THE RESEARCH SIDE AS WELL AS ON THE ADMINISTRATIVE SIDE OF THE HOUSE.

SO COUPLE QUICK THINGS TO TALK ABOUT FIRST IS YOU'VE HEARD A LITTLE BIT ABOUT OUR OPERATIONAL MILESTONE MODEL OF FUNDING THAT IS SPECIFIC TO OUR CLINICAL AND TRANSLATIONAL STAGE PROGRAMS. WE SEND OUT DISBURSEMENTS BASED ON MILESTONES. AND SO AS A REMINDER, WHEN AN AWARD LAUNCHES AT CIRM, WE PROVIDE ENOUGH FUNDING BASED ON THEIR OWN BUDGET TO GET TO THE FIRST MILESTONE. AND THEN WE WORK WITH THEM TO

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MAKE SURE THEY'RE ON TARGET. AND ONCE THEY ACHIEVE THAT MILESTONE, WE RELEASE THE SECOND TRANCHE AND SO FORTH THROUGHOUT THE AWARD.

AND SO THIS HAS HELPED US DRIVE BEHAVIOR IN A FEW KEY WAYS. SO FIRST OFF, WE ARE ABLE TO PROVIDE REAL-TIME COURSE CORRECTION FOR THE TEAMS BOTH THROUGH OUR ADVISORY PANELS AS WE WERE TALKING ABOUT BEFORE TO REALLY KIND OF BE THERE WITH A TEAM OF EXPERTS, INCLUDING SCIENTIFIC EXPERTS AND PATIENT ADVOCATES AND REPRESENTATIVES, TO HELP THE TEAMS DEAL WITH PROBLEMS AS THEY OCCUR.

IN ADDITION, WE REQUIRE PROJECT MANAGEMENT ON THE AWARDS AS WELL SO THAT THERE IS A SINGLE PERSON WORKING FOR THAT TEAM THAT KNOWS HOW THE WHOLE PROJECT IS GOING AND CAN KIND OF COORDINATE WITH CIRM TO HELP US MANAGE THE AWARD AND HELP EXECUTE ON THE PROJECT.

IN ADDITION, BECAUSE OF THIS MILESTONE MODEL, EVERY ONCE IN A WHILE AN AWARDEE MIGHT NOT HAVE ENOUGH FUNDING, THAT MILLION DOLLARS IN THAT FIRST DISBURSEMENT MIGHT NOT BE ENOUGH TO GET TO THE FIRST MILESTONE EITHER BECAUSE IT'S TAKING LONGER OR BECAUSE IT WAS MORE EXPENSIVE THAN THEY ANTICIPATED. AND SO THE TERMS OF OUR AWARD REQUIRE THAT THE AWARDEE PROVIDE NON-CIRM CONTINGENCY FUNDS TO BRIDGE

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THAT GAP UNTIL THEY REACH THE MILESTONE. AND TO DATE WE HAVE SEEN AWARDEES PUT UP 24 MILLION IN NON-CIRM CONTINGENCY FUNDS TO HELP BRIDGE THOSE GAPS WHEN NEEDED.

IN ADDITION, IF AWARDS ARE REALLY HITTING KIND OF BOTTLENECKS OR KIND OF PROBLEMS WITH THE PROJECT THAT CAN'T BE RESOLVED, CIRM DOES ON OCCASION TERMINATE AN AWARD IF THERE DOESN'T REALLY SEEM LIKE A WAY FORWARD. AND I'VE GIVEN SOME DATA ON OUR TERMINATIONS. SO SINCE WE LAUNCHED THESE 2.0 PROGRAMS IN THE CLIN AND TRAN SPACE, WE'VE MADE 62 AWARDS TO DATE; THAT IS, STARTING JANUARY OF 2015, AND WE HAVE TERMINATED FOUR AWARDS THAT HAVE RESULTED IN ABOUT 34 MILLION BEING RETURNED TO CIRM WHICH THEN CAN GO BACK INTO THE RESEARCH POT TO BE REDEPLOYED FOR NEW AWARDS.

GIVING YOU AN UPDATE HERE ON THE CIRM-FUNDED ENROLLMENT -- CIRM-FUNDED PATIENTS ENROLLED IN CIRM-FUNDED TRIALS THROUGH QUARTER ONE OF 2018. AND SO YOU CAN SEE PATIENT ENROLLMENT IS STILL RAPIDLY ACCELERATING, AND WE'RE NEARLY APPROACHING -- THIS DATE IS ACTUALLY ALWAYS ABOUT A MONTH OR TWO BEHIND ENROLLMENT IN THE TRIALS. WE ASK FOR QUARTERLY UPDATES ON ENROLLMENT. AND SO WE'RE RAPIDLY APPROACHING A THOUSAND CIRM-FUNDED

133 HENNA COURT, SANDPOINT, IDAHO 83864
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PATIENTS ENROLLED IN CIRM-FUNDED TRIALS.

AND FINALLY, WE ALSO LIKE TO MAKE SURE THAT WE AS THE CIRM TEAM IS ALSO MANAGING THE AWARDS EFFICIENTLY AND DOING ALL WE CAN TO ACCELERATE THESE PROCESSES. SO TWO KEY IMPROVEMENTS IN OUR AWARD MANAGEMENT AREA IS WE IMPLEMENTED DOCU-SIGN ELECTRONIC SIGNATURE OF AWARD DOCUMENTS AND HAVE SEEN THE AVERAGE NUMBER OF DAYS TO EXECUTION OF OUR AWARDS DROP FROM 16 DAYS TO 5 DAYS, WHICH WE'VE BEEN PLEASED WITH. OUR AWARDEES HAVE ALSO APPRECIATED US IMPLEMENTING.

AND THEN SECOND IS WE IMPLEMENTED ELECTRONIC FUNDS TRANSFER. WE USED TO ACTUALLY WORK WITH THE STATE AGENCY TO INITIATE A PAYMENT, AND THEN A PAPER CHECK WOULD BE REGULAR MAILED TO THE AWARDEE, AND IT WOULD TAKE SOMETIMES THREE, FOUR WEEKS TO GET TO THE AWARDEE. AND SO EARLIER THIS YEAR WE CONVERTED TO ELECTRONIC FUNDS TRANSFER AND HAVE BROUGHT PAYMENT PROCESSING TIMES DOWN FROM 16 TO 4 DAYS. THAT NOT ONLY SPEEDS UP THE TIME TO GET CIRM PAYMENTS TO THE AWARDEES, BUT ALSO REDUCES MAILING COSTS AND OTHER COSTS AS WELL AS REDUCES PAYMENT ERRORS WHICH WE WERE EXPERIENCING IN THE OLD PAPER PROCESS WAY. SO WE'RE VERY HAPPY TO SEE IMPROVEMENTS IN THAT AREA.

SO THANK YOU AND I WILL PASS IT OFF TO MY COLLEAGUE ABLA CREASEY. OH, ONE QUESTION HERE.

DR. JUELSGAARD: GOING BACK TO THE CLINICAL TRIAL ENROLLMENT SLIDE, HOW MANY PHASE 3 CLINICAL TRIALS ARE WE INVOLVED WITH NOW?

MR. THOMPSON: ACTIVE PHASE 3S ARE ABOUT THREE OR FOUR.

DR. MILLAN: WE'LL CHECK ON THAT.

DR. JUELSGAARD: ALSO JUST WHERE WE'RE AT ALONG THE ENROLLMENT CONTINUUM FOR THOSE TRIALS; IN OTHER WORDS, WHAT PERCENTAGE ENROLLMENT WE HAVE IN EACH OF THOSE PHASE 3 TRIALS.

MR. THOMPSON: I THINK TWO OF THE TRIALS -- ONE OF THE TRIALS IS FULLY ENROLLED, AND TWO OF THEM ARE VERY EARLY STAGES. IN FACT, THE ACCELERATION YOU SEE IN THE RECENT QUARTERS IS DRIVEN BY A PHASE 3 THAT WE RECENTLY FUNDED. AND THEN I THINK THE FOURTH TRIAL IS NEARING FULL ENROLLMENT AS WELL. THERE'S FOUR.

MR. JUELSGAARD: THANKS.

MR. THOMPSON: ANY OTHER QUESTIONS?

CHAIRMAN THOMAS: JUST LIKE TO NOTE, GABE, THAT THE EXCELLENCE OF THE GRANTS MANAGEMENT PROGRAM IS ONE OF THE THINGS THAT LED NIH TO BE SO INTERESTED IN WHAT WE DO. AND YOU'VE CONTINUED TO

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REFINE IT TO MAKE A GREAT THING EVEN BETTER, AND THIS IS SORT OF A CENTRAL ELEMENT OF EVERYTHING WE DO. JUST WANTED, ON BEHALF OF EVERYBODY, CONGRATULATE YOU FOR REALLY GOOD WORK AND IT'S SHOWN. IT'S NOW A NATIONALLY NOTICED OPERATION. SO THANK YOU VERY MUCH FOR WHAT YOU DO.

MR. THOMPSON: APPRECIATE IT. THANK YOU, J.T.

NOW I WILL PASS IT TO MY COLLEAGUE ALBA CREASEY.

DR. CREASEY: THANK YOU. I'M GOING TO BRIEFLY DESCRIBE TO YOU OUR INTERACTIONS WITH THE FDA AS WELL AS WHAT THE RMAT DESIGNATION IS ALL ABOUT AND WHY IT IS IMPORTANT.

SO THE 21ST CENTURY CURES ACT WAS PASSED IN DECEMBER OF 2017 WHEN PRESIDENT OBAMA WAS IN CHARGE. AND THAT 21ST CENTURY CURES ACT PROVIDED THE FDA WITH FUNDS IN THE AREA OF INNOVATION AND INNOVATION ACTIVITIES. UNDER THAT TERM THEY HAVE SUBTITLE D OF THE 21ST CENTURY CURES ACT. IT'S PATIENT ACCESS TO THERAPIES AND INFORMATION. AND UNDER THAT IS SECTION 3033, ACCELERATED APPROVAL OF REGENERATIVE ADVANCED THERAPIES. AND THAT'S WHERE ALL THE DOLLARS COME FOR MOVING THE FDA IN A MORE EXPEDITED MANNER IN THIS AREA OF SCIENCE.

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SO THE 21ST CENTURY CURES ACT DEFINITION OF REGENERATIVE MEDICINE THERAPY INCLUDES CELL THERAPY, THERAPEUTIC TISSUE ENGINEERING PRODUCTS, HUMAN CELL AND TISSUE PRODUCT AND COMBINATION PRODUCT. WHEN YOU SAY HERE COMBINATION PRODUCT, IT'S DEVICE AND CELLS, TISSUE AND CELLS, MOSTLY REALLY DEVICE AND CELLS OF SORT. AND THE DEVICE CAN BE OF ANY KIND OF DEVICE OR IT COULD BE A SCAFFOLD MADE OF BIOMATERIALS.

SO UNDER THE 21ST CENTURY CURES ACT, THEN, THE REGENERATIVE MEDICINE ADVANCED THERAPY, RMAT, DESIGNATION WAS GENERATED. THIS IS REALLY A BIG AND AN IMPORTANT STEP FOR OUR AREA OF SCIENCE, RESEARCH, MAINLY BECAUSE IT PROVIDES THE PEOPLE WHO ARE WORKING WITH THAT DESIGNATION ALONGSIDE THE PROGRAMS TO HAVE A LOT OF PRIVILEGES RELATED TO INTERACTIONS WITH THE FDA.

AND BEFORE I MOVE FORWARD AND DESCRIBE ALL THIS, I HAVE TO TELL YOU THE FDA HAS BEEN EXTREMELY HELPFUL TO US. MARIA AND I, HONESTLY IT'S DUE TO MARIA'S LEADERSHIP, MARIA AND I HAVE MET WITH THE HEAD OF THE CBER, WHICH IS THE CENTER FOR BIOLOGICS EVALUATION RESEARCH, HE MADE TIME TO TALK TO US VERY CASUALLY IN A HOTEL AS PART OF OUR MEETINGS DURING LIKE THE FIRST WEEK IN JANUARY. AND IT WAS VERY

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CORDIAL. HE MADE HIMSELF AVAILABLE. HE ASKED US TO SEND E-MAILS BACK TO HIM DIRECTLY WHENEVER WE HAVE ANY QUESTIONS RELATED TO THIS AREA. AND HE ANSWERS E-MAILS VERY READILY ALSO WHEN WE HAVE QUESTIONS. THAT ALSO SHOWS LEADERSHIP ON THEIR PART AND ALSO RESPECT FOR CIRM AND OUR LEADERSHIP, AND YOU AS THE BOARD.

SO THE REGENERATIVE MEDICINE ADVANCED THERAPY DESIGNATION, THE RMAT, IS REALLY A SPECIAL PROGRAM TO ADVANCE THE FIELD BY PROVIDING AN ACCELERATED PATHWAY FOR APPROVAL. ACCELERATED PATHWAY, BY THE WAY, NOW IS BEING DEBATED. WE ALL HAVE LEARNED HOW TO DEVELOP DRUGS BY SAYING YOU NEED FIRST A PHASE 1 TRIAL, THEN YOU MAY NEED TWO PHASE 2 TRIALS, THEN YOU MAY NEED ONE OR TWO PHASE 3 TRIALS. THEY'RE SAYING EXPEDITED MEANS CUT TO THE CHASE. IF YOU HAVE NO SAFETY ISSUES AND YOU HAVE A HINT OF ACTIVITY, THEN WE'RE YOUR PARTNERS, AND THEN WE'LL HELP YOU SHAPE THE DESIGN OF THE NEXT TRIAL TO ESSENTIALLY CONFIRM THE SIGNAL THAT YOU'RE SEEING, AND ALL THAT DATA MAY BE AVAILABLE, THEN, FOR POTENTIAL APPROVAL OF A GIVEN THERAPY. SO IT'S NO LONGER THE PARADIGM THAT WAS CARRIED WHEN PEOPLE WERE DEVELOPING SMALL MOLECULES OR LARGE MOLECULES, ANTIBODIES.

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SO THE SPECIAL PROGRAM COVERS REGENERATIVE MEDICINE THERAPIES, DRUGS TARGETING SERIOUS DISEASE OR CONDITIONS, AND AREAS OF UNMET MEDICAL NEED.

THE PROCESS FOR RMAT DESIGNATION, IT'S A VERY BRIEF DOCUMENT THAT A GIVEN CANDIDATE WHO IS APPLYING FOR THAT HAS TO FILL OUT. THERE ARE REALLY THREE MAIN AREAS. REGENERATIVE MEDICINE THERAPY HAS TO BE OBVIOUS. SECOND, IS THERE HIGH UNMET MEDICAL NEED, AND YOU HAVE TO JUSTIFY THAT. THREE IS DO YOU HAVE PRELIMINARY CLINICAL DATA TO ALLOW US TO EVALUATE THAT THERE'S NO SAFETY ISSUES AND THERE ARE HINTS OF EFFICACY.

RECENTLY THEY'VE CHANGED A LITTLE BIT. INSTEAD OF SAYING HINTS OF ACTIVITY WITH EITHER BIOMARKERS OR POTENTIAL BENEFIT, ANY KIND OF BENEFIT, WHETHER DEPENDING ON THE THERAPEUTIC AREA. BY THE WAY, THE RMAT DESIGNATION IS OPEN TO ALL THERAPEUTIC AREAS. IT'S NOT RESTRICTED TO CANCER; IT'S NOT RESTRICTED TO HEART DISEASE. SO NOW THEY ARE REQUESTING CONVINCING, INSTEAD OF PRELIMINARY CLINICAL EVIDENCE, CONVINCING EVIDENCE. AND THAT MEANS MAYBE A LARGER DATABASE OF PATIENTS. THAT MEANS THAT THERE'S A DIFFERENCE BETWEEN UNTREATED AND TREATED, ETC.

THEY ARE WILLING TO GIVE FEEDBACK TO THE

APPLICANTS WITHIN 60 DAYS OF SUBMISSION OF THE REQUEST. THE APPLICANT WILL RECEIVE WRITTEN RESPONSE OF APPROVAL. IT'S EITHER APPROVED OR DENIED.

WHAT ARE THE BENEFITS OF RMAT DESIGNATION? THE KEY PART HERE, AND IT'S ALWAYS IMPORTANT TO KNOW, IS REALLY READY ACCESS TO THE MOST SENIOR PEOPLE AT THE FDA WHO CAN MAKE DECISIONS VERY QUICKLY AND HELP YOU. WE'VE WITNESSED THAT WITH ONE OF OUR GRANTEES WHERE, AS SOON AS THEY GOT THE RMAT DESIGNATION, THEIR PHASE 2 CLINICAL TRIAL DESIGN WAS MODIFIED BY THE FDA WITH THEM TO CHANGE THINGS TO HIGHER DOSE, LESS PATIENTS, AND END POINT CHANGES. AND THE FDA CONVINCED OUR GRANTEE AND THEIR TEAM THAT IF THEY WERE ABLE TO MODIFY THIS, THEN THEY WILL STAY THEIR CHAMPIONS AND PARTNERS IN MOVING THAT TRIAL FORWARD.

SO WE THINK IT'S REALLY A GREAT ASSET FOR US FOR REGENERATIVE MEDICINE. THE POTENTIAL IS HERE FOR RMAT GRANTEES TO HAVE A PHASE 2 TRIAL BE APPROVED FOR GETTING THE THERAPY ON THE MARKET; HOWEVER, THERE MAY BE REQUIREMENT FOR FURTHER CLINICAL STUDIES LIKE WHAT WE USED TO CALL IN THE OLD DAYS PHASE 4 STUDIES. HERE POSTAPPROVAL STUDIES MAY BE NEEDED THAT CAN CONTINUE TO SUBMIT CLINICAL

EVIDENCE AND KEEP MONITORING PATIENT OUTCOMES. SO IN MANY WAYS IT'S EARLY ACCESS, ACCELERATED DEVELOPMENT OF THE PRODUCT.

SO FINALLY, I WANTED TO SHOW YOU -- I GUESS THE ARROWS DON'T SHOW. SO THERE WERE 18 RMAT DESIGNATIONS UNTIL MARCH OF THIS YEAR SINCE 2017-2018. WE LINED THEM UP HERE FOR YOU BY THE YEAR THEY WERE AWARDED AND 18 OF THEM. IN 2017 WE HAD THREE OUT OF THE 12 THAT WERE DESCRIBED BY J.T. AND MARIA: ASTERIAS, HUMACYTE, AND JCYTE. AND THEN IN 2018 WE'VE HAD CAPRICOR AND CALADRIUS GAIN THE RMAT DESIGNATION. SO WE HAVE FIVE OF 18 ARE OUR GRANTEES, AND WE'RE VERY PROUD OF THEM. WE'RE PROUD OF THE FACT THAT THEY NOW HAVE ACCESS TO THE SENIOR AUTHORITIES WITHIN THE AGENCY.

I WILL CONCLUDE BY, FIRST OF ALL, THANKING DR. WILSON BRYAN AT THE FDA WHO'S BEEN WORKING WITH US AS WELL AS DR. PETER MARKS FROM THE FDA, AND THANKING THE CIRM GRANTEES FOR A GOOD JOB IN MAINTAINING AND GAINING THE RMAT DESIGNATION. ANY QUESTIONS?

DR. DIXON: SOUNDS TERRIFIC.

MR. LITTMAN: GOOD AFTERNOON, MR. CHAIRMAN, MEMBERS OF THE ICOC, MEMBERS OF THE PUBLIC. MY NAME IS NEIL LITTMAN. I'M THE DIRECTOR

OF BUSINESS DEVELOPMENT. I WILL BE TALKING TO YOU TODAY BRIEFLY ABOUT CIRM'S INDUSTRY ALLIANCES.

I'D LIKE TO START TALKING ABOUT OUR NEW INDUSTRY ALLIANCE PROGRAM. SO THIS IS SOMETHING THAT WE LAUNCHED EARLIER THIS YEAR IN JANUARY AROUND THE JP MORGAN HEALTHCARE CONFERENCE. AS A REMINDER, THE GOAL FOR THE INDUSTRY ALLIANCE PROGRAM OR WHAT WE CALL IAP FOR SHORT IS TO SECURE INDUSTRY PARTNERSHIPS AND ADDITIONAL FUNDING FOR CIRM'S LARGE AND GROWING TRANSLATIONAL AND CLINICAL STAGE PORTFOLIO.

WE ARE HAPPY TO ANNOUNCE THAT WE HAVE THREE PARTNERS TO DATE: BLUE ROCK THERAPEUTICS, VIVO CAPITAL, AND PANACEA VENTURE. BLUE ROCK IS DEVELOPING TREATMENTS FOR NEURODEGENERATIVE AND CARDIOVASCULAR DISEASES WITH A FOCUS ON IPS CELLS. THEY ARE IN ACTIVE DISCUSSIONS WITH SEVERAL OF OUR GRANTEES. VIVO CAPITAL IS A HEALTHCARE FOCUSED BAY AREA VENTURE CAPITAL FIRM WITH ABOUT $1.8 BILLION UNDER MANAGEMENT. THEY HAVE INVESTED IN AND ARE CURRENTLY SUPPORTING TWO CIRM GRANTEES INCLUDING METEOR THERAPEUTICS AND POSEIDA. AND THEN PANACEA VENTURE IS OUR NEWEST PARTNER. THEY ARE A BRAND NEW $300 MILLION HEALTHCARE DEDICATED FUND IN THE U.S. STARTED BY A FEW EX-PARTNERS FROM KLEINER PERKINS.

THAT IS OUR LATEST PARTNER. THEY ARE CURRENTLY GETTING TO KNOW THE CIRM PORTFOLIO.

I'D LIKE TO SPEND JUST A COUPLE MINUTES TALKING ABOUT LEVERAGE FUNDING IN PARTICULAR, WHAT WE CALL OUR PARTNERSHIP EVENTS. WE DEFINE PARTNERSHIP EVENTS AS LICENSE AGREEMENTS, OPTION AGREEMENTS, AND FOLLOW-ON FUNDING FROM INDUSTRY PARTNERS AND INVESTORS. AS YOU CAN SEE IN THIS CHART, 2000 YEAR-TO-DATE LEVERAGED FUNDING UNDER PARTNERSHIP EVENTS TOTALS ABOUT $415 MILLION. THAT OUTPACES THE TOTAL OF LAST YEAR, WHICH WAS ABOUT $389 MILLION, WHICH WAS A RECORD-BREAKING YEAR FOR CIRM. IN TOTAL OVER THE PAST FOUR YEARS, SINCE 2015, THERE'S BEEN ALMOST A BILLION DOLLARS THAT HAVE BEEN LEVERAGED THROUGH PARTNERSHIP EVENTS. AND IF YOU LOOK FROM THE BEGINNING OF THE LAUNCH OF OUR STRATEGIC PLAN IN JANUARY OF 2016, THERE'S BEEN ABOUT $960 MILLION LEVERAGED.

SO EVERYTHING IS SORT OF TRENDING IN THE RIGHT DIRECTION. WE'RE SEEING AN INCREASED INTEREST FROM INDUSTRY AND INVESTORS IN THE PROGRAMS THAT CIRM HAS FUNDED AND WE'RE CONTINUING TO SEE MORE INTEREST, WHICH IS WONDERFUL.

I WANT TO SPEND A COUPLE MINUTES JUST TALKING ABOUT THE 2018 YEAR-TO-DATE PARTNERSHIP

EVENTS. HUMACYTE HAS RAISED $225 MILLION YEAR TO DATE. THEIR MOST RECENT RAISE WAS $150 MILLION FROM A STRATEGIC PARTNER BY THE NAME OF FRESENIUS. THIS IS TO BRING HUMACYTE BLOOD VESSEL IMPLANTS TO DIALYSIS CLINICS. I'D JUST LIKE TO READ A QUOTE FROM ONE OF THE VP'S OF CLINICAL DEVELOPMENT FROM FRESENIUS. HE STATES, "FRESENIUS AIMS TO NOT ONLY HELP HUMACYTE ADVANCE THEIR CLINICAL PROGRAM, BUT DISTRIBUTE A PRODUCT GLOBALLY THAT IT SEES AS HAVING INCREDIBLE POTENTIAL FOR MEDICINE." AS A REMINDER, HUMACYTE IS DEVELOPING AN ACELLULAR VESSEL IN PATIENTS NEEDING RENAL REPLACEMENT THERAPY.

FORTY SEVEN IS, IF YOU RECALL, A SPINOUT COMPANY BASED ON IRV WEISSMAN'S TECHNOLOGY AT STANFORD. ACTUALLY AS OF YESTERDAY, THEY JUST PRICED THEIR IPO. SO FORTY SEVEN SOLD 7 MILLION SHARES AT $16 A SHARE, RAISING A TOTAL OF $112 MILLION. THAT WAS A VERY EXCITING DEVELOPMENT.

AND THEN NOHLA THERAPEUTICS RAISED A $45 MILLION SERIES B ROUND. POSEIDA RAISED ABOUT $31 MILLION SERIES B ROUND.

THEN ORCHARD THERAPEUTICS IS A COMPANY THAT HAS IN-LICENSED TECHNOLOGY FROM DON KOHN'S LAB AT UCLA. THEY ARE FOCUSED ON RARE DISEASES. THEY RECENTLY ACQUIRED THE RARE DISEASE GENE THERAPY

PORTFOLIO FROM GLAXO-SMITH KLINE, AND THEY ARE INVESTING IN BUILDING MANUFACTURING SITES IN CALIFORNIA.

SO A LOT OF EXCITING DEVELOPMENTS THIS YEAR IN REGARDS TO OUR INDUSTRY ALLIANCES LEVERAGED FUNDING. WITH THAT, I WOULD BE HAPPY TO TAKE ANY QUESTIONS.

DR. JUELSGAARD: SO, NEIL, BACK TO THE FIRST SLIDE ON THE INDUSTRY ALLIANCE PROGRAM. WHAT SPECIFICALLY DOES IT MEAN TO BE A PARTNER? WHAT DO THEY DO? WHAT ADVANTAGES DO THEY GET? WHAT DO WE GET?

MR. LITTMAN: VERY GOOD QUESTION. AS YOU KNOW, OVER THE YEARS WE TRY TO CONNECT INDUSTRY AND INVESTORS WITH OUR PORTFOLIO. OUR PORTFOLIO IS OPEN FOR EVERYONE TO COME AND LOOK AT AND CONNECT WITH. WHAT WE TRIED TO DO UNDER THE IAP IS PUT IN A MORE FORMALIZED STRUCTURE TO FACILITATE THESE CONVERSATIONS. SO BLUE ROCK, FOR EXAMPLE, WAS ONE OF OUR FIRST PARTNERS UNDER THE IAP. AND SO WE HELP FACILITATE THE DIALOGUE BETWEEN THEM AND ANY OF OUR GRANTEES THAT THEY'RE INTERESTED IN SPEAKING WITH.

WE ALSO ARE FACILITATING THE COMPILATION OF DATA ROOMS, FOR EXAMPLE. SO WE HELP STREAMLINE THE DILIGENCE PROCESS BETWEEN OUR PARTNERS AND OUR

GRANTEES. FROM THE GRANTEE PERSPECTIVE, WE VET THESE PARTNERS. THESE PARTNERS HAVE AN INTEREST IN THE CELL AND REGENERATIVE MEDICINE SPACE. THEY'VE MADE INVESTMENTS IN THE SPACE. THEY'RE CONTINUING MAKING INVESTMENTS IN THE SPACE. THEY'RE NOT SIMPLY WINDOW SHOPPING. SO WE THINK THAT'S IMPORTANT TO GET OUR GRANTEES COMFORTABLE WITH HAVING CONVERSATIONS WITH INDUSTRY PARTNERS AND POTENTIAL INVESTORS.

SO I THINK THERE ARE A LOT OF BENEFITS ON BOTH SIDES. THIS IS REALLY THE CULMINATION OF A LOT OF THINGS WE'VE DONE OVER THE YEARS. THIS IS JUST A MORE STRUCTURED FORMAT TO FACILITATE THESE TYPES OF CONVERSATIONS.

DR. JUELSGAARD: JUST ONE FOLLOW-UP QUESTION THEN. ARE YOU OUT ACTIVELY SOLICITING FUNDS TO BE ONE OF THESE ALLIANCE PARTNERS? HOW DO WE GET TO KNOW THEM, AND HOW DO WE VET THEM?

MR. LITTMAN: GOOD QUESTION. WE ARE ACTIVELY TALKING WITH POTENTIAL PARTNERS. WE ARE SOLICITING NEW PARTNERS ON A SELECTIVE BASIS. SO AS I MENTIONED, WE WANT TO MAKE SURE THAT OUR PARTNERS ACTUALLY HAVE CAPITAL TO INVEST, EXPERTISE TO MOVE THE PROGRAMS FORWARD, ARE NOT JUST WINDOW SHOPPING. SO WE ARE ACTIVELY TALKING TO FUNDS, WE ARE TALKING

TO STRATEGIC PARTNERS. WE DON'T EXPECT THIS TO BE A SUPER HIGH VOLUME-TYPE PARTNERSHIP. WE ARE NOT LOOKING FOR A HUNDRED PARTNERS. WE'RE LOOKING FOR A SELECT NUMBER OF HIGH QUALITY PARTNERS.

DR. MILLAN: SO IN ADDITION, WHAT HAPPENS IS OUR GRANTEES GET FEEDBACK FROM THESE POTENTIAL PARTNERS EARLY THAT CAN HELP THEM SHAPE THEIR STRATEGY AND WHAT THEY THINK ABOUT AND DECISION MAKING. THAT'S BEEN EXTREMELY VALUABLE. AND NEIL AND THE TEAM HAVE BEEN ABLE TO INFLUENCE THE NATURE OF THE CONVERSATIONS; WHEREAS, SOMETIMES ARTIFICIALLY TALKS STOP BECAUSE OF ASSUMPTIONS, WHAT HAVE YOU. CIRM BEING IN THE MIDDLE HAS HELPED TO CREATE A MORE KIND OF OPEN DIALOGUE AND HAMMER OUT THINGS THAT REALLY SHOULDN'T GET IN THE WAY OF CONVERSATIONS.

AND ANOTHER THING WE'RE WORKING TOWARD IS STANDARD LICENSING AGREEMENT, AT LEAST TEMPLATES TO START WITH SO IT STREAMLINES UP-FRONT ISSUES, AND THEN THAT CAN KIND OF SAVE TIME AND EFFORT LATER.

DR. JUELSGAARD: THANK YOU.

MR. LITTMAN: THANK YOU VERY MUCH. UP NEXT I'D LIKE TO INTRODUCE KEVIN MCCORMACK, WHO'S GOING TO TALK A LITTLE BIT ABOUT CIRM'S PROCESS FOR GETTING OUR STORY OUT.

MR. MC CORMACK: THANK YOU, NEIL. CHAIRMAN THOMAS, MEMBERS OF THE BOARD, FRIENDS, AND COLLEAGUES, I'M GOING TO GIVE A BRIEF UPDATE ON COMMUNICATIONS. I SAY BRIEF FOR TWO REASONS. ONE, BECAUSE DR. MILLAN TOLD ME TO KEEP IT BRIEF. WE ALWAYS DO WHAT DR. MILLAN WANTS. SECONDLY, BECAUSE IN ABOUT TEN MINUTES ENGLAND ARE GOING TO BE PLAYING BELGIUM IN THE WORLD CUP, AND MY ABILITY TO FOCUS ON ANYTHING WILL BE GOING OUT THE WINDOW.

PICKING UP WHERE NEIL LEFT OFF, TALKING ABOUT ORCHARD THERAPEUTICS, HE ANNOUNCED THAT THEY DID A DEAL EARLIER THIS YEAR TO TAKE OVER GSK'S GENE THERAPY PROGRAM FOR RARE DISEASES. WE ISSUED A NEWS RELEASE TO EXPLORE ANOTHER SIDE OF THAT NEWS, WHICH IS THAT WITHOUT CIRM, WITHOUT THE VOTING AND THE SUPPORT YOU'VE GIVEN TO THIS WORK, IT WOULDN'T HAVE BEEN POSSIBLE BECAUSE THE BOARD HERE VOTED SOME TIME AGO TO SUPPORT DON KOHN'S WORK IN DEVELOPING A TREATMENT FOR SEVERE COMBINED IMMUNODEFICIENCY OR SCID. IT'S THE TREATMENT THAT HELPED CURE LITTLE EVIE THERE WHOSE PICTURE IS ON THE WALL. BECAUSE OF THAT WORK AND THE SUCCESS THAT DON HAS HAD, ORCHARD BECAME INVOLVED. AND THAT'S NOW THEIR LEAD PROGRAM. AND SINCE THEN THEY'VE OPENED UP ONE CORPORATE OFFICE AND TWO MANUFACTURING FACILITIES HERE IN

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CALIFORNIA. SO THAT INVESTMENT IS OBVIOUSLY PAYING OFF.

ALSO, WHEN YOU VOTE ON SOMETHING, WHEN THE CIRM BOARD VOTES TO RECOMMEND SOMETHING AND APPROVE SOMETHING, IT'S LIKE GIVING IT THE GOOD HOUSEKEEPING SEAL OF APPROVAL BECAUSE EVERYONE KNOWS THAT IT GOES THROUGH A REALLY RIGOROUS SCIENTIFIC REVIEW AND ANALYSIS PROCESS. AND SO COMPANIES LIKE GSK WILL LOOK AT PROGRAMS THAT WE FUND AND THINK THAT THIS IS A REALLY GOOD INVESTMENT FOR THEM. SO THIS IS ONE OF THE THINGS THAT HAPPENED IN THIS CASE.

SO WE USE NEWS RELEASES TO GIVE OUR SIDE OF THE STORY, TO EXPLORE THE FACT THAT THESE THINGS, IT'S GREAT THAT THEY DID THIS DEAL, BUT WITHOUT OUR EARLY SUPPORT, THAT WOULDN'T HAVE HAPPENED.

OTHER THINGS WE USE NEWS RELEASES FOR ARE TO TELL OUR STORY ABOUT THE RESEARCH THAT YOU APPROVE HERE. IN THIS CASE THIS WAS DR. TIPPI MACKENZIE AT UCSF WHO DEVELOPED A THERAPY OR A CLINICAL TRIAL FOR ALPHA THALASSEMIA MAJOR, A REALLY RARE, BUT KIND OF FATAL IMMUNE CONDITION THAT AFFECTS CHILDREN IN UTERO. WHEN SHE WAS ABLE TO TREAT THE FIRST PATIENT WITH THAT, THIS COUPLE HERE WERE ABLE TO DELIVER A HEALTHY CHILD. IT WAS OBVIOUSLY BIG NEWS. IT WAS IN BOTH THE *NEW YORK*

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TIMES, THE *SAN JOSE MERCURY NEWS*, AND A NUMBER OF OTHER OUTLETS AS WELL. THAT'S ALWAYS GREAT EXPOSURE, NOT JUST FOR THE WORK THAT TIPPI MACKENZIE IS DOING, BUT ALSO THE FACT THAT WE'VE BEEN SUPPORTING HER WORK FOR SOME TIME. AND SO WE'RE ABLE TO GIVE PEOPLE SUPPORT AT A REALLY EARLY STAGE AND HELP ADVANCE THEM TO THE POINT WHERE WE CAN SHOW THAT IT WORKS.

THIS IS PARTICULARLY TRUE FOR RARE DISEASES BECAUSE PHARMACEUTICAL COMPANIES AND BIG VENTURE CAPITALIST COMPANIES OBVIOUSLY ARE NOT GOING TO GET INVOLVED IN SOMETHING THAT HAS A VERY LIMITED POTENTIAL FOR PAYBACK.

WE'VE BEEN INVOLVED IN A LOT OF OTHER NEWS COVERAGE AS WELL. WE WORKED WITH NBC 7 IN SAN DIEGO TO HELP THEM DO A STORY ABOUT MANY OF THE STEM CELL CLINICS THAT ARE POPPING UP ALL OVER CALIFORNIA AND AROUND THE COUNTRY TO DO OFTEN UNPROVEN THERAPIES. DR. MILLAN HAS DONE A NUMBER OF INTERVIEWS WITH THE VARIOUS NEWS OUTLETS, AND WE'VE HAD STORIES IN THE *SAN DIEGO UNION TRIBUNE*, KQV NEWS, KQED RADIO. SO WE'RE TRYING TO COVER AS MANY DIFFERENT AREAS AS POSSIBLE.

WE DON'T JUST RELY ON TRADITIONAL MEDIA. WE ALSO USE SOCIAL MEDIA. AND RECENTLY WE HELD OUR

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VERY FIRST FACEBOOK LIVE, ASK THE EXPERT EVENT. THIS IS BASICALLY USING FACEBOOK TO HOST A LIVE WEBINAR. IT'S A ONE-HOUR PROGRAM. AND WE FEATURED IN THIS CASE STROKE THERAPY. WE FEATURED DR. GARY STEINBERG. WE WERE VERY FORTUNATE TO HAVE HIM JOIN US FOR THAT. OUR OWN DR. LILA COLLINS AND DR. STEINBERG BROUGHT ALONG A PATIENT. FOR ONE HOUR THEY TALKED ABOUT THE WORK THAT THEY'RE DOING, THE WORK THAT CIRM IS FUNDING, AND SOME OF THE OTHER PROGRAMS OUT THERE THAT AFFECTED PEOPLE WHO HAD STROKE. AND THE RESPONSE WAS REALLY QUITE AMAZING. IT WAS THE FIRST TIME WE'D DONE SOMETHING LIKE THIS, SO WE WERE INTERESTED TO SEE HOW IT WOULD WORK.

EVEN THOUGH AT THE PEAK OF THE BROADCAST WE HAD 91 PEOPLE INVOLVED, BECAUSE AS SOON AS THE BROADCAST ENDS, IT GETS ARCHIVED. PEOPLE CAN WATCH IT ANY TIME THEY WANT, ANYWHERE THEY WANT. AND SO WE'VE SINCE HAD 6700, MORE THAN 6700 PEOPLE VIEWING IT. NOT JUST VIEWING IT. THEY'RE ENGAGED IN THAT THEY'RE SHARING IT WITH FRIENDS. EVEN WHEN IT WASN'T LIVE, THEY WERE MAKING COMMENTS ON IT, WHICH HAS BEEN REALLY INTERESTING TO SEE THE IMPACT IT HAS.

THE TOP VIEWING LOCATIONS, CALIFORNIA, OBVIOUSLY BECAUSE WE'RE CALIFORNIA BASED. IT WAS

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INTERESTING TO SEE THAT TOKYO CAME SECOND, AND I THINK THAT SPEAKS TO THE FACT THAT WE ARE A GLOBAL ORGANIZATION. OUR IMPACT IS GLOBAL, BUT ALSO THE FACT THAT STROKE IS A GLOBAL PHENOMENA. AND WE ARE KIND OF REACHING OUT AND TALKING TO THAT COMMUNITY. WE'RE GOING TO BE DOING SOME MORE FACEBOOK LIVE EVENTS IN THE COMING MONTHS. WE HAVE ONE FOR SICKLE CELL DISEASE AND THEN ALSO ONE FOR ALS. AND THAT'S COMING UP AT THE END OF JULY AND THEN ALSO AT THE END OF AUGUST. SO WE'LL BE SHARING DETAILS WITH YOU ABOUT THOSE AS THEY BECOME AVAILABLE.

BUT, OF COURSE, DOING STUFF ON LINE AND THROUGH THE MEDIA IS IMPORTANT, BUT WE ALSO LIKE TO KIND OF DO THE IN-PERSON EVENTS AS WELL BECAUSE THOSE ARE A REALLY POWERFUL WAY OF TOUCHING PEOPLE OR GETTING THE WORD OUT. EARLIER THIS YEAR DR. DEAS INVITED US TO HOLD AN EVENT AT UC RIVERSIDE, FOR WHICH WE'RE GRATEFUL. DR. MALKAS MADE THE TREK FROM CITY OF HOPE. AND WE TURNED IT INTO A KIND OF ROADSHOW PATIENT ADVOCATE EVENT WHERE WE TALKED TO THE RESEARCHERS ABOUT FUNDING OPPORTUNITIES, BUT ALSO TO PATIENT ADVOCATES AND PATIENTS ABOUT THE KIND OF WORK THAT WE'RE DOING AND THE PROGRESS THAT'S BEING MADE. AND WE HAD A ROOM THAT WE THOUGHT WOULD BE FINE. IT WAS ABOUT 120 PEOPLE, BUT

IT WAS AN OVERFLOW CROWD. WE DIDN'T HAVE ENOUGH ROOM FOR EVERYONE WHO WANTED TO SHOW UP. I THINK THAT SPEAKS TO THE FACT THAT THERE'S A LOT OF PROMISE OUT THERE AND A LOT OF HOPE, AND A LOT OF PEOPLE FIND OUT WHAT'S GOING ON. AND SO WE HOPE TO DO MORE OF THOSE EVENTS IN THE COMING MONTHS, AND WE'LL BE SHARING NEWS ABOUT THOSE AS THEY BECOME AVAILABLE.

WITH THAT, I'LL HAND OVER TO MY COLLEAGUE PAT OLSON.

DR. OLSON: THANK YOU AND GOOD MORNING. I'D LIKE TO FINISH UP WITH JUST TELLING YOU WHAT WE'RE DOING TO FURTHER HELP PROMOTE THE SUCCESS OF OUR GRANTEES IN THE EARLY STAGE OF DEVELOPMENT. SO WHAT WE'VE DONE IS WE'RE INITIATING AND PUTTING IN PLACE WHAT WE'RE CALLING TRANSLATIONAL ADVISORY PANELS. AS MANY OF YOU KNOW, WHEN YOU MOVE FROM THE RESEARCH PHASE INTO EARLY DEVELOPMENT, THIS IS A VERY CHALLENGING TIME BECAUSE HERE YOU HAVE TO TAKE YOUR RESEARCH PROCESS, YOU HAVE TO MAKE IT A REGULATED PROCESS. YOU HAVE TO SHOW THAT YOU CAN PUT IN PLACE A MANUFACTURING PROCESS THAT GIVES YOU -- THAT IS APPROPRIATE SCALE FOR THE CLINICAL TRIAL YOU INTEND TO CONDUCT, THAT ESSENTIALLY CAN GIVE YOU A CONSISTENT PRODUCT CANDIDATE. SO THAT

MEANS ASSAYS, ALL THOSE RESEARCH ASSAYS, ALL THAT WORK YOU'VE DONE IN RESEARCH HAS TO BE TRANSLATED INTO SOMETHING THAT YOU CAN USE TO SHOW THAT YOU HAVE A GOOD PRODUCT IN DEVELOPMENT. SO IT'S A CHALLENGING TIME.

SO WHAT WE'RE TRYING TO DO IS WE'RE TRYING TO ACCELERATE THE TIMELINES. WE'RE TRYING TO INCREASE THE PROBABILITY THAT OUR GRANTEES WILL MEET THEIR MILESTONES IN TIME AND, MOST IMPORTANTLY, INCREASE THE CHANCES OF PROGRESSING TO THE NEXT STAGE OF DEVELOPMENT. YOU MAY RECALL THAT THE GOAL OF OUR TRAN STAGE PROGRAMS IS TO HOLD A PRE-IND MEETING, WHICH IS WHAT YOU DID GENERALLY BEFORE YOU DO YOUR PIVOTAL STUDIES AND FILE YOUR IND.

OUR SOLUTION, THE TAP, IS MODELED ON THE CLINICAL ADVISORY PANELS. AND WHAT WE'RE TRYING TO DO IS INCREASE THE EXPERTISE THAT'S AVAILABLE TO THE PROJECT TEAM TO SOLVE ISSUES.

SO THE MEMBERSHIP, AGAIN SOMEWHAT MIRRORING THAT OF THE CLINICAL ADVISORY PANELS, IS THERE WILL BE THE CIRM PROGRAM OFFICER AND USUALLY ONE OR TWO OTHER CIRM PARTICIPANTS. THERE WILL BE EXTERNAL SCIENTIFIC EXPERTS USUALLY IN THE AREA OF PROCESS SCALE-UP, POSSIBLY IN PRECLINICAL MODELS, OR THE DISEASE TARGET OF INTEREST. AND THEN THERE WILL

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ALSO BE A PATIENT ADVISOR WHO WILL REPRESENT THE SUBJECT POPULATION WHO IS LIKELY TO BE THE SUBJECTS OF THE CLINICAL TRIAL.

FINALLY, THE CURRENT STATUS, THIS IS RELATIVELY NEW. WE HAVE THE ADMINISTRATIVE, LEGAL, AND I.T. INFRASTRUCTURE IN PLACE. WE'VE ACTUALLY GOT THE FIRST TWO MEETINGS ALREADY SCHEDULED FOR JULY. WE'RE HOLDING THE FIRST ONE NEXT MONDAY. WE'VE RECRUITED, OBVIOUSLY, THE SCIENTIFIC AND THE PATIENT ADVISORS FOR THAT PARTICULAR -- FOR THOSE PARTICULAR MEETINGS. AND I JUST WANT TO POINT OUT THAT KENT FITZGERALD, WHO IS THE ASSOCIATE DIRECTOR OF THE DISCOVERY AND TRANSLATIONAL PROGRAM, IS LEADING THIS EFFORT. AND THEN AMY, WHO DOES EVERYTHING, IS ACTING AS -- IS HANDLING PROGRAM LOGISTICS.

SO WITH THAT, I'M HAPPY TO TAKE ANY QUESTIONS. AND THANK YOU FOR YOUR ATTENTION.

CHAIRMAN THOMAS: DR. OLSON, COULD YOU JUST BRIEFLY COMMENT. YOU JUST CAME BACK FROM ISSCR WHICH, AS EVERYBODY KNOWS, IS THE MAJOR GATHERING OF THE WORLD STEM CELL SCIENTISTS THIS YEAR IN MELBOURNE. DR. OLSON AND DR. FITZGERALD WERE THERE. JUST ANY COMMENTS, TAKEAWAYS?

DR. OLSON: I ACTUALLY DO SEE A SHIFT IN

THEY ARE -- I THINK ISSCR HAS BEEN TRYING TO EMPHASIZE THE FACT THAT THEY'RE MOVING INTO A TRANSLATIONAL SPACE, BUT I THINK YOU'RE SEEING THAT MORE NOW. SO A LOT OF THE PEOPLE WHO SPOKE TALKED ABOUT SOME OF THE SUCCESSES THEY'RE STARTING TO HAVE IN THAT SPACE.

OBVIOUSLY ISSCR SPEAKS FOR ALL THE STEM CELL SCIENTISTS IN THE WORLD. AND, YOU KNOW, THE EXCITING BASIC RESEARCH THAT'S GOING ON, THE USE OF ORGANOIDS TO MODEL DISEASES AND TO HELP DETERMINE SORT OF MECHANISMS OF DISEASES, ALSO WAYS TO TEST POTENTIAL THERAPEUTICS, THAT WAS, I THINK, ONE OF THE HIGHLIGHTS AS WELL. ANY OTHER POINTS?

DR. MARTIN: I HAVE A QUICK QUESTION. I'VE KNOWN HER LONG ENOUGH SO I CAN CALL HER PATTY. THE RECIPIENTS OF THE ADVICE, ARE THERE CIRM STAFF OR DOES IT INCLUDE THE AWARDEES?

DR. OLSON: NO. NO. NO. SO A SPECIFIC GRANTEE. SO IF WE HAD A -- TRANSLATION STAGE PROGRAMS ARE EARLY DEVELOPMENT STAGE PROGRAMS. AND IT IS THE GRANTEE THAT WE ARE PUTTING -- WE ARE GETTING CIRM INTERNAL PEOPLE, WE'RE GETTING EXTERNAL EXPERTS TO MEET WITH THEIR TEAM TO DEAL WITH ISSUES THAT THEY MAY HAVE, AND TO HELP FACILITATE THEY'RE SUCCESSFULLY MOVING THEIR PROGRAM FORWARD. SO IT'S

TAILORED TO A SPECIFIC GRANTEE TEAM.

DR. MARTIN: IS THAT A PUSH OR A PULL FOR THE GRANTEE? ARE YOU PUSHING THAT TO THEM, OR ARE THEY PULLING IT?

DR. OLSON: I THINK THERE'S PROBABLY A LITTLE BIT OF BOTH. I THINK WE'RE TRYING TO HELP THEM ADDRESS THINGS BEFORE THEY BECOME ISSUES. AND I THINK THE RESPONSE, AT LEAST FROM THE CLINICAL ADVISORY PANELS, I THINK HAS BEEN PRETTY UNIFORMLY POSITIVE. AND ESPECIALLY A LOT OF TIMES WITH OUR TRAN STAGE PROGRAMS, THEY HAVE GOOD TEAMS. OBVIOUSLY THE GRANTS WORKING GROUP HAS DONE ITS JOB IN SAYING THIS IS A GOOD TEAM. BUT, YOU KNOW, WE'RE WORKING WITH VERY NOVEL THERAPEUTIC STRATEGIES. WE'RE WORKING WITH THINGS WHERE THERE'S NOT A LOT OF EXPERIENCE IN THE FIELD IN, SAY, AN AUTOLOGOUS GENE-EDITED CELL THERAPY. AND SO THE EXPERTISE -- BRINGING IN EXPERTS WHO CAN TALK ABOUT THOSE THINGS AND WHO HAVE BEEN THERE AND WHO MAYBE CAN GIVE THEM SOME HINTS OR GIVE THEIR CMC PERSON, IT'S A FORUM TO ADDRESS ISSUES AND TRY AND RESOLVE THEM BEFORE THEY DELAY THE PROJECT TOO MUCH.

ANY OTHER QUESTIONS THAT I CAN ANSWER?

CHAIRMAN THOMAS: JUST WANTED TO POINT OUT AGAIN THIS WHOLE NOTION OF THE ADVISORY PANEL IS

ONE OF THE UNIQUE FEATURES OF CIRM. THERE'S NO OTHER MAJOR GRANTING AGENCY THAT FOLLOWS UP IN THE FASHION THAT WE DO AND MEETS REGULARLY WITH GRANTEES TO HELP IMPROVE THE PROJECTS AS THEY PROCEED THROUGH THE PERIOD THAT WE ARE GRANTING. AS DR. OLSON SAYS, IT'S BEEN VERY POSITIVELY RECEIVED BY THE CLINICAL TRIAL GRANTEES. I'M SURE IT WILL BE LIKEWISE FOR THIS, BUT IT'S SOMETHING THAT REALLY ADDS TREMENDOUS VALUE AND GIVES THE PROJECTS AT ISSUE A CHANCE TO BETTER SUCCEED. SO THANK YOU ALL OF YOU WHO WORK ON THESE ADVISORY PANEL PROJECTS. THANK YOU.

OKAY. DR. MILLAN, ARE WE NOW UP TO CHILA?

DR. MILLAN: I BELIEVE THAT'S IT FOR THE PRESIDENT'S REPORT. CHILA HAS AN ACTION ITEM ON THE BUDGET PROPOSAL. SO I THINK IT'S LATER ON IN THE AGENDA. THANK YOU VERY MUCH, EVERYBODY, FOR YOUR ATTENTION. AND I'M HAPPY TO TAKE ANY FINAL QUESTIONS ABOUT THIS AGGREGATE PRESENTATION.

CHAIRMAN THOMAS: ANY COMMENTS?

DR. DIXON: NICELY DONE.

CHAIRMAN THOMAS: THANK YOU VERY MUCH. EXCELLENT WORK BY ALL CONCERNED. SO THANK YOU VERY MUCH AGAIN.

OKAY. WE ARE GOING TO JUST BRIEFLY -- WE HAVE THREE ITEMS ON THE CONSENT CALENDAR WHICH YOU

CAN SEE FROM YOUR AGENDA. I DON'T BELIEVE ANY OF THEM REQUIRE MUCH DISCUSSION. IF ANYBODY HAS ANY QUESTIONS OR WOULD LIKE TO TAKE ANY OF THOSE ITEMS OFF CONSENT PLEASE SPEAK NOW. OTHERWISE, DO I HEAR A MOTION TO APPROVE ITEMS ON THE CONSENT CALENDAR?

MR. TORRES: SO MOVED.

DR. BURTIS: SECOND.

CHAIRMAN THOMAS: MOVED BY SENATOR TORRES, SECONDED BY DR. BURTIS. ALL THOSE IN FAVOR PLEASE SAY AYE.

MR. TOCHER: PUBLIC COMMENT.

CHAIRMAN THOMAS: RIGHT. SORRY. THANK YOU. ANY PUBLIC COMMENT ON THE CONSENT CALENDAR? HEARING NONE, TRY THAT AGAIN. ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? MR. TOCHER, DO YOU HAVE TO POLL THOSE ON THE PHONE FOR CONSENT?

MR. TOCHER: INDEED WE DO. LINDA BOXER.

DR. BOXER: YES.

MR. TOCHER: JACK DIXON.

DR. DIXON: YES.

MR. TOCHER: BERT LUBIN.

DR. LUBIN: YES.

MR. TOCHER: LAUREN MILLER.

MS. MILLER: YES.

MR. TOCHER: OS STEWARD.

DR. STEWARD: YES.
MR. TOCHER: KRISTINA VUORI.
DR. VUORI: YES.
MR. TOCHER: DID I MISS ANY MEMBERS ON THE PHONE?
DR. BLUMENTHAL: YES, GEORGE BLUMENTHAL.
MS. WINOKUR: I VOTE YES.
MR. TOCHER: AND CHANCELLOR BLUMENTHAL.
DR. BLUMENTHAL: I VOTE YES AS WELL.
MR. TOCHER: THANK YOU VERY MUCH. AND THE MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU. SO WE'RE NOW GOING TO MOVE ON TO THE ACTION ITEMS, FIRST OF WHICH IS DISCUSSION AND POSSIBLE ACTION REGARDING PROGRAMMATIC TOOLS. WE'RE GOING TO BEGIN WITH A PRESENTATION BY DR. SAMBRANO AND THEN TURN THE DISCUSSION OVER TO SUPERVISOR SHEEHY.
DR. SAMBRANO: THANK YOU, MR. CHAIRMAN. GOOD MORNING, EVERYONE.
SO THE PRESENTATION, THE WAY WE'VE ORGANIZED IT, IS HOPEFULLY TO FACILITATE A DISCUSSION BY YOU ABOUT THE PROGRAMMATIC REVIEW. SO WHAT I'M GOING TO START WITH IS JUST A VERY BRIEF OVERVIEW OF THE REVIEW PROCESS AS IT EXISTS, WHAT THE ELEMENTS ARE JUST TO PROVIDE THE CONTEXT FOR

WHERE PROGRAMMATIC REVIEW FITS IN. AFTER THAT WE'LL GO ON TO A DISCUSSION, MR. SHEEHY WILL LEAD THAT DISCUSSION, ON ELEMENTS PERTAINING TO PROGRAMMATIC REVIEW AND HOW THAT MAY BE CONDUCTED.

AND THEN I HAVE A SET OF SLIDES THAT OFFER SOME POSSIBLE TOOLS THAT WOULD HELP SUPPORT YOU IN YOUR DISCUSSION ABOUT APPLICATIONS AS THEY COME IN, THINGS THAT WE CAN PROVIDE. AND THESE CAN JUST BE EXAMPLES, SO IT'S OPEN TO SUGGESTIONS FROM YOU IN TERMS OF WHAT ELSE WE CAN PROVIDE OR IN WHAT FASHION WE CAN PROVIDE IT.

SO TO BEGIN, THE REVIEW PROCESS OVERALL IS CONDUCTED IN THREE MAJOR PHASES, AND SO THOSE ARE ILLUSTRATED ON THIS SLIDE. WHEN WE RECEIVE AN APPLICATION, IT FIRST GOES THROUGH THE ELIGIBILITY ASSESSMENT. AND WE LOOK THERE BASICALLY FOR COMPLETENESS, MAKE SURE THE APPLICANT HAS ADDRESSED ALL OF THE ELIGIBILITY CRITERIA THAT ARE PRESENTED IN THE SOLICITATION, AND ULTIMATELY JUST ASKING THE QUESTION CAN CIRM ACCEPT THIS APPLICATION IN ORDER TO MOVE IT THROUGH THE REVIEW PROCESS.

ONCE IT COMPLETES ITS ELIGIBILITY ASSESSMENT, IT GOES ON TO UNDERGO A MERIT REVIEW. SO THE MERIT REVIEW IS DONE BY OUR GRANTS WORKING GROUP. SO THIS IS THE PANEL THAT INCLUDES 15

SCIENTISTS, 7 PATIENT ADVOCATE MEMBERS FROM OUR BOARD THAT TOGETHER ASSESS WHETHER THIS PROJECT OR SET OF PROJECTS ARE SCIENTIFICALLY MERITORIOUS. AND I'LL GIVE YOU A LITTLE MORE DETAIL ON WHAT THEY PROVIDE.

AND THEN, FINALLY, THE LAST PHASE IS THE RECOMMENDATIONS FROM THE GWG COME TO THE ICOC, AND MORE SPECIFICALLY THE APPLICATION REVIEW SUBCOMMITTEE, THAT MAKES THE FINAL FUNDING DECISION ON THOSE APPLICATIONS AND LARGELY ASKING THE QUESTION: IS THIS A PROJECT THAT CIRM SHOULD FUND?

SO IN LIGHT OF THOSE THREE DIFFERENT PHASES, WE'LL FOCUS IN JUST ON THE GWG AS A REMINDER OF THE KINDS OF THINGS THAT THEY LOOK AT. SO THEY CONDUCT THIS REVIEW WITH FOUR MAJOR QUESTIONS IN MIND. SO THESE ARE THE GUIDING PRINCIPLES UNDER WHICH THEY ASSESS AND SCORE AN APPLICATION. AND THESE ARE OVERARCHING THEMES THAT APPLY TO MOST OF THE APPLICATIONS THAT ARE RECEIVED, WHETHER THEY'RE DISCOVERY, TRANSLATIONAL, OR CLINICAL.

SO THE FIRST QUESTION IS DOES THE PROJECT HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR IMPACT. SO THIS IS ASKING THE QUESTION OF WHAT VALUE IT IS THAT THE APPLICATION OR THE PROPOSAL IS BRINGING TO THE FIELD, TO PATIENTS, TO THE GOALS OF

THE RFA OR THE PROGRAM ANNOUNCEMENT THAT WE PUT OUT? IS IT ADDRESSING AN UNMET MEDICAL NEED? AND OVERALL WHAT IMPACT IS IT GOING TO HAVE ON THAT UNMET NEED?

THE NEXT QUESTION THEY ADDRESS IS WHETHER THE RATIONALE IS SOUND. SO THIS IS ASKING WHETHER THE APPLICANTS HAVE A GOOD SCIENTIFIC OR CLINICAL BASIS FOR WHAT THEY'RE PROPOSING TO DO, THAT THEY HAVE SUPPORTIVE DATA, A LOT OF TIMES PRELIMINARY EXPERIMENTS, THAT SHOW THAT THIS IS SOMETHING THAT IS REASONABLE AND CAN BE ACCOMPLISHED.

THE THIRD QUESTION IS WHETHER THE PROJECT IS WELL-PLANNED AND DESIGNED. SO WANTING TO KNOW IF THEY'VE LAID OUT A PLAN THAT IS GOING TO LEAD TO MEASURABLE OUTCOMES AND RESULTS THAT ARE TARGETED TOWARDS THE GOAL OR THE INTENDED GOAL OF THE PROJECT.

AND THEN, FINALLY, THE QUESTION OF WHETHER IS THIS A PROJECT THAT'S FEASIBLE. IS IT SOMETHING THAT THEY CAN DO? AND THAT MAY INCLUDE THINGS SUCH AS DO THEY HAVE THE NECESSARY RESOURCES? DO THEY HAVE QUALIFIED INDIVIDUALS ON THEIR TEAM TO ACHIEVE THE GOALS OF THE PROJECT? AND CAN THEY DO IT WITHIN THE TIME THAT IS PROPOSED OR REQUIRED UNDER THE SOLICITATION?

SO THOSE ARE THE MAJOR QUESTIONS THAT THE

GWG ASKS. THAT'S WHAT, WHEN WE HAVE ANY OF THESE MEETINGS, GUIDE THEM AND POINT THEM TO IN ORDER FOR THEM TO PROVIDE A SCORE THAT ULTIMATELY COMES TO YOU.

AND AS YOU ALREADY KNOW, AND THIS IS AGAIN JUST A REMINDER, THAT THE SCORING THAT WE HAVE FOR THESE APPLICATIONS KIND OF COMES IN TWO DIFFERENT FLAVORS. SO WE HAVE FOR THE DISCOVERY AND TRANSLATION APPLICATIONS, WHICH ARE REVIEWED AS A COHORT OF APPLICATIONS, THEY ARE SCORED ON A SCALE OF ONE TO A HUNDRED, AND THERE'S TWO CATEGORIES THAT THEY CAN FALL INTO, THE RECOMMENDED FOR FUNDING IF THEY SCORE ABOVE 85 OR NOT RECOMMENDED FOR FUNDING IF THEY SCORE BELOW THAT.

FOR OUR CLINICAL APPLICATIONS, WE HAVE A BIT OF A UNIQUE SCORING SYSTEM WHERE APPLICATIONS ARE SCORED AS A 1, 2, OR A 3, WITH THE 1 MEANING THAT THEY HAVE EXCEPTIONAL MERIT AND THEY WOULD WARRANT FUNDING. THE SCORE OF 2 IS ONE THAT ALLOWS THE APPLICANT TO RAPIDLY RESPOND TO CONCERNS FROM THE GWG AND RESUBMIT WITHOUT HAVING TO START THE WHOLE APPLICATION PROCESS. IT'S BASICALLY TAKING COMMENTS THAT CAME FROM THE REVIEW, DIRECTLY ADDRESSING THEM, AND THEN THE GWG CAN DETERMINE WHETHER THEIR CONCERNS HAVE BEEN ADEQUATELY

ADDRESSED OR NOT. AND THEN, FINALLY, A SCORE OF 3, WHICH OFTEN MEANS THAT EITHER THE APPLICATION IS FLAWED TO THE EXTENT THAT THEY DON'T FEEL THAT THEY CAN RESOLVE THOSE WITHIN SIX MONTHS. SOMETIMES IT MAY JUST MEAN THEY NEED TO DO SEVERAL EXPERIMENTS, AND THEY FEEL IT'S GOING TO TAKE MORE THAN SIX MONTHS, AND THEY SHOULDN'T COME BACK BEFORE THAT TIME.

SO THOSE ARE THE ELEMENTS THAT THE GWG USES TO ASSESS THE APPLICATIONS AND TO SCORE THEM, AND THEN ULTIMATELY THOSE ARE ELEMENTS THAT COME TO THE ICOC AS PART OF THE RECOMMENDATION. AND SO JUST ON THIS SLIDE VERY BRIEFLY, WHAT IS THEN PROGRAMMATIC REVIEW THAT HAPPENS AT THE ICOC? JUST THE FIRST TWO BULLETS POINT TO WHAT YOU NORMALLY CONSIDER. WE PROVIDE TO YOU A SUMMARY OF THE REVIEW THAT COMES FROM COMMENTS FROM THE GWG. WE PROVIDE YOU WITH A SCORE AND ANY RECOMMENDATION FROM THE CIRM STAFF ITSELF FOR ANY ISSUES THAT WE'VE NOTICED, OUR CONCURRENCE WITH THE GWG RECOMMENDATION. AND THEN THE SUBCOMMITTEE, THE APPLICATION REVIEW SUBCOMMITTEE, MAY CONSIDER MANY DIFFERENT FACTORS. AND SOME OF THESE ARE ACTUALLY PRESENTED IN THE BYLAWS FOR THE ICOC RELATED TO REVIEW.

SO THEY ARE THINGS SUCH AS THE MISSION OF

CIRM, THE PORTFOLIO AND HOW THE APPLICATION MAY FIT WITHIN THE PORTFOLIO, THE OBJECTIVES OF THE PROGRAM ANNOUNCEMENT OR THE RFA, UNMET MEDICAL NEED, OR THE OVERALL BUDGET. A LOT OF TIMES THE BUDGET MAY DETERMINE. FOR EXAMPLE, IF WE HAVE SET A SPECIFIC ALLOCATION, WE CAN FIT ONLY A CERTAIN NUMBER OF -- OR FUND ONLY A CERTAIN NUMBER OF APPLICATIONS WITH THAT BUDGET. SO SOMETIMES DISCUSSIONS GO IN THAT MANNER.

SO HERE I WILL TURN IT OVER TO MR. SHEEHY JUST TO LEAD A DISCUSSION ON WHAT PROGRAMMATIC REVIEW MAY BE ABOUT.

SUPERVISOR SHEEHY: THANK YOU, DR. SAMBRANO. SO ONE OF THE REASONS WE'RE DOING THIS IS WE'RE GETTING TOWARDS THE END OF OUR FUNDING. FOR THOSE WHO HAVE BEEN AROUND FOR A WHILE, DR. PRIETO, COUPLE OTHERS, WE USED TO HAVE QUITE VIGOROUS PROGRAMMATIC REVIEW IN THE EARLY DAYS AND IT ACTUALLY HAD A DIFFERENT BIAS. THE BIAS WAS USING A LOT OF THESE FACTORS, AND WE WERE BRINGING PEOPLE WHO WERE ON THE CUSP OF BEING FUNDED, WE'RE BRINGING THEM UP AND FUNDING THEM. AND PART OF THAT -- A BIG MOTIVATION FOR THAT WAS WE WERE REALLY DEVELOPING NEW TECHNOLOGY, AND WE REALLY WANTED TO STIMULATE THE FIELD. AND IT REALLY DID GIVE A BOOST TO

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EVERYBODY IN CALIFORNIA. AND SOME OF THOSE ONES THAT WE PULLED UP ACTUALLY TURNED OUT TO BE SUCCESSFUL.

SO IT WAS NOT AN IRRATIONAL EXERCISE TO REALLY LOOK AT SOME OF THESE FACTORS AND TO SAY, HEY, THIS ONE WAS CLOSE. IT DIDN'T QUITE MAKE IT. OUR SCORING WAS A LITTLE BIT DIFFERENT TOO. WE DIDN'T HAVE THE 1, 2, 3. SO YOU'D HAVE ONES WHO HAD SOME MINOR FLAWS THAT DIDN'T QUITE MAKE IT. AND SO THAT WAS THE PROCESS WE USED EARLIER. FOR THE LAST FEW YEARS IT'S ALL BEEN FAIRLY LINEAR. WE'VE BEEN LARGELY GUIDED BY ALMOST EXCLUSIVELY THE SCORES OF THE WORKING GROUP, WHICH IS GREAT AND REASONABLE. STEVE AND I TALKED ABOUT THIS A LITTLE BIT OVER THE LAST COUPLE OF YEARS.

AS WE START TO GET TO THE FINAL AMOUNT OF MONEY, IT FEELS TO ME, AT LEAST MY VIEW IS, AND I HAVE NOT BEEN VOTING FOR EVERY APPLICATION THE LAST TWO COUPLE OF REVIEWS, AND THERE ARE QUESTIONS ABOUT WHETHER, EVEN THOUGH SOMETHING IS SCIENTIFICALLY MERITORIOUS, DO WE REALLY NEED TO BE THE AGENCY THAT FUNDS IT? AND I THINK I PERSONALLY HAVE BEEN FEELING, AS WE GET TO THE END OF OUR FUNDING, THAT I'M USING A DIFFERENT SET OF CRITERIA, THAT I'M FEELING A SENSE OF PROGRAMMATIC REVIEW, WHICH IS THE

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DUTY OF THE APPLICATION REVIEW SUBCOMMITTEE, IS TO IMPOSE ADDITIONAL CRITERIA TO MAKE SURE THAT WHATEVER WE'RE FUNDING MEETS CIRM'S MISSION. AND FOR ME I KIND OF FEEL LIKE I PERSONALLY WANT TO PRESERVE THAT FUNDING FOR THINGS THAT ARE MORE ALIGNED WITH OUR MISSION. BUT I THINK WE'RE HEADING TO A PLACE WHERE THE DISCUSSIONS ARE GOING TO BE MORE ROBUST, AND WE MAY END UP NOT DECIDING TO FUND SOME APPLICATIONS THAT HAVE BEEN SCORED FUNDABLE BY THE GRANTS WORKING GROUP.

AND SO IN ORDER TO BE ABSOLUTELY TRANSPARENT WITH OUR GRANTEES, IT SEEMS REASONABLE TO HAVE A DISCUSSION ABOUT THIS SO THAT SOME SENSE OF THE CRITERIA THAT WE MAY BE USING COLLECTIVELY TO MAKE THESE DECISIONS CAN BE PROVIDED, MAYBE PROVIDE SOME STRUCTURE TO HOW WE MAKE THOSE DECISIONS.

I KNOW DR. MARTIN IN THE LAST ONE WAS REALLY QUESTIONING WHETHER AN APPLICATION WAS REALLY IN SCOPE. WAS IT "STEMMY" ENOUGH FOR US? AND ESPECIALLY AS WE FUND SOME OF OUR LATE STAGE, LIKE PHASE 3 TRIALS, WHERE IF IT'S NOT A REAL -- IN FACT, RANDY, WHEN HE WAS REVIEWING, COINED THE TERM "CIRMY." IF NOT FOR CIRM, WHO WOULD FUND THIS? AND SO I REALLY THOUGHT AND I THINK, AGAIN TALKING TO STEVE AND OS, THAT WE SHOULD HAVE A DISCUSSION ABOUT

THIS AND REALLY KIND OF TEST THE QUESTION BECAUSE WE ARE, AS WE KNOW, GETTING TO THE LAST OF OUR MONEY. AND I THINK IF WE COULD JUST OPEN UP A DISCUSSION AND ASK OURSELVES DO WE WANT TO REALLY HAVE A VIGOROUS PROGRAMMATIC REVIEW IN THE APPLICATION REVIEW SUBCOMMITTEE TO REALLY ASK OURSELVES IS THIS, WITH THE REMAINING DOLLARS WE HAVE, AND HOPEFULLY 2020 WE GET REUPPED, AND THE REMAINING DOLLARS WE HAVE, DO WE REALLY WANT TO FOCUS MORE BASED ON CERTAIN CRITERIA ON PROJECTS THAT TO US FEEL MORE APPROPRIATE FOR THE MISSION OF THIS AGENCY THAN MAYBE SOME OTHERS.

AND I KNOW PART OF THE REASON WE'VE BEEN VERY AGGRESSIVE IN TRYING TO REACH 50 CLINICAL TRIALS. WE'RE AT 49. RIGHT? BUT I THINK THIS IS A QUESTION WE NEED TO ASK. AND I'D BE HAPPY TO OPEN UP THE DISCUSSION IF OTHER FOLKS HAVE THOUGHTS ABOUT IT.

DR. HIGGINS: IT SEEMS LIKE IF WE'RE GOING TO THINK ABOUT THESE THINGS IN ADVANCE, THAT WE OWE IT TO APPLICANTS TO SOMEHOW REPRESENT THOSE IN THE RFA SO THEY DON'T SUBMIT GRANTS THAT NEVER HAD A CHANCE OF ACTUALLY MAKING IT ALL THE WAY THROUGH. IS THERE SOME WAY TO DO THAT, OR DOES THAT SORT OF SHORT-CIRCUIT THE VERY FLEXIBILITY YOU'RE TRYING TO

KEEP?

SUPERVISOR SHEEHY: I'M JUST ASKING THE QUESTION. I'M HAPPY TO TAKE ANY IDEAS, BUT I DO THINK -- I JUST KNOW THAT, FOR INSTANCE, IF I SEE A SMALL MOLECULE PRODUCT FOR ALMOST ANYTHING, I'M NOT GOING TO VOTE FOR IT. THAT'S JUST WHERE MY HEAD IS RIGHT NOW. I FEEL LIKE IF I SEE SOMETHING THAT INVOLVES EITHER IPS, AND I'M JUST TALKING PERSONALLY JUST TO GIVE YOU WHERE MY HEAD IS, OR EMBRYONIC STEM CELLS, I'M ALMOST CERTAIN TO VOTE FOR IT IF IT MAKES IT THROUGH THE WORKING GROUP. JUST BECAUSE WHO ELSE IS REALLY FUNDING THAT IN THAT SPACE? AND THEN THERE'S A WHOLE LOT OF PRODUCTS THAT FALL IN BETWEEN. I WANT TO BE CANDID ABOUT THAT'S WHERE MY HEAD IS. AND, AGAIN, MAYBE THAT'S SOMETHING THAT GOES INTO THE RFA.

DR. DEAS: I CERTAINLY AGREE WITH WHAT DAVID SAID. A LOT OF WORK GOES INTO PREPARING AN APPLICATION. AND IF THE APPLICANTS KNOW ON THE FRONT END THAT THEIR SPECIFIC THINGS THAT WILL BE FUNDED AND WILL NOT, I THINK IT'S A GOOD SERVICE TO THE APPLICANT, THAT THEY NOT PUT THAT TIME AND EFFORT BECAUSE THEY'RE TAKING AWAY FROM SOMETHING ELSE.

THE OTHER POINT THAT I WANTED TO MAKE IS

THAT I REALLY FEEL STRONGLY, AND I KNOW CIRM DOES AS WELL, THAT WE SHOULD LOOK AT THE SCIENCE AND THE IMPACT THAT THESE PROPOSALS WILL MAKE. I ALSO THINK THAT WHILE WE ARE AT THIS STAGE WHERE WE HAVE FEWER RESOURCES TO USE FOR FUNDING, WE SHOULD ALSO LOOK AT THE SOCIETAL IMPACT EVEN BEYOND THE SCIENCE. AND I THINK ABOUT APPLICATIONS THAT ARE RECRUITING FROM POPULATIONS WHO ARE DIVERSELY REPRESENTED. AND I KNOW IN THE DISCUSSION EARLIER TODAY THERE WAS A REPORT ABOUT CIRM'S VISIT TO THE RIVERSIDE INLAND EMPIRE, AND THAT IS A POPULATION THAT IS VERY DIVERSE. AND I WONDER HOW MANY -- WHAT IS THE DEMOGRAPHICS OF THE APPLICATIONS THAT WE HAVE ALREADY FUNDED AND THE PARTICIPANTS IN THOSE PROJECTS SO THAT IN THE END WE HAVE DATA THAT IS REALLY GENERALIZABLE TO THE POPULATION AS A WHOLE.

SO I WONDER HOW WE MIGHT INTRODUCE THOSE DIVERSITY FACTORS IN MAKING SOME DECISIONS NOW THAT WE'RE AT THE FINAL LINE.

SUPERVISOR SHEEHY: DR. PRIETO.

DR. PRIETO: I'D LIKE TO ENDORSE WHAT DR. DEAS SAID BUT ALSO REMIND EVERYONE THAT THIS NOT ONLY ALIGNS WITH OUR MISSION, A MORE ROBUST PROGRAMMATIC REVIEW ALIGNS WITH OUR MISSION, BUT ALSO WITH THE LANGUAGE OF THE PROPOSITION, WHICH

SAID THAT WE WOULD PREFERENTIALLY TRY TO FUND WORK THAT WOULD HAVE DIFFICULTY BEING FUNDED. AND THIS WAS PARTICULARLY IMPORTANT WHEN THIS WAS A NEW FIELD, BUT WE'VE NOW BROUGHT THE FIELD FORWARD TO A POINT THAT OTHER FUNDERS HAVE COME INTO THIS SPACE, SOMETIMES IN A BIG WAY, AND THERE ARE APPLICATIONS LIKE SOME OF THE SMALL MOLECULES THAT YOU MENTIONED THAT MAY BE FUNDABLE, MAY HAVE SCIENTIFIC MERIT UNDER OUR CRITERIA, BUT ARE ALSO FUNDABLE FROM OTHER SOURCES. AND WE NEED TO LOOK AT WHERE WE NEED TO PUT OUR LIMITED RESOURCE.

CHAIRMAN THOMAS: SO THE ISSUE SUPERVISOR SHEEHY RAISES IS NOT JUST SORT OF IN SOME SENSES THEORETICAL OR PHILOSOPHICAL, BUT WE'RE GOING TO BE SHORTLY FACED WITH DECISIONS THAT NEED TO BE MADE WHERE WE HAVE GWG RECOMMENDATIONS FOR FUNDING ON A PARTICULAR ROUND OF GRANTS THAT EXCEED THE BUDGET FOR THAT PARTICULAR TYPE OF GRANT. AND AS YOU RECALL, WE HAVE SET FORTH VERY SPECIFIC NUMBERS WITH RESPECT TO EACH OF THE HOW MANY CLINICAL TRIALS, HOW MANY CLIN1S FOR THE PRECLINICAL, IND-ENABLING, ETC., AND ALL THE WAY DOWN TO THE QUEST AND INCEPTION AWARDS.

SO WE ARE IN A VERY REAL SENSE VERY SHORTLY GOING TO BE HAVING TO DEAL WITH THIS, AND WE

NEED TO FIGURE OUT IF YOU HAVE MORE PROJECTS THAT ARE RECOMMENDED FOR FUNDING THAN WE HAVE BUDGETED, WHAT ARE THE FACTORS THAT GO INTO DETERMINING HOW YOU MAKE THAT DECISION BECAUSE IT WILL BE A REAL-LIFE DECISION AS SOON AS JULY.

SUPERVISOR SHEEHY: DR. MARTIN.

DR. MARTIN: AS MENTIONED, THERE HAS BEEN EVOLUTION IN THE LAST TEN YEARS IN TERMS OF HOW MANY ENTITIES ARE THERE OUT THERE THAT WILL FUND NOW THINGS THAT SAY STEM CELL. FORGET WHETHER IT'S EMBRYONIC OR NOT. BUT THERE'S ALSO AN EVOLUTION IN TERMS OF THE FIELD OF WHAT ARE THE RISKS OF SUCCESS. AND I THINK THAT HAS CHANGED ENORMOUSLY. AND I THINK THE WHOLE PROCESS IS VERY DYNAMIC WITH CHANGING FACTORS THAT GO INTO THE SUCCESS OF ANYTHING THAT'S STEM CELL RELATED, RECOGNITION OF OTHER VALID STEM CELL OPPORTUNITIES OR STEM CELL COMPONENTS OR COMPONENTS OF MEDICINE THAT INVOLVE STEM CELLS THAT WE DIDN'T KNOW EXISTED TEN YEARS AGO.

SO I THINK THAT -- I THINK IT'S VERY IMPORTANT TO DO, BUT WE ALMOST NEED A MAP OF WHAT HAS EVOLVED OVER THE LAST TEN YEARS AND HOW SHOULD THAT INFLUENCE OUR THINKING ABOUT THE CURRENT MISSION OF CIRM AND GOING FORWARD FOR THE NEXT

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HOPEFULLY FUNDING ROUTE. IT'S AN EVOLUTIONARY PROCESS, AND IT'S PROBABLY NEVER BEEN AND MAY NEVER BE AGAIN MORE DYNAMIC THAN IT'S BEEN IN THE LAST 15 YEARS.

DR. MALKAS: I WANT TO AGREE WITH THAT. I THINK THAT'S A VERY IMPORTANT POINT BECAUSE WE'RE THINKING THAT, BECAUSE THE FUNDS ARE RUNNING LOW, THAT WE HAVE TO MAKE DECISIONS. BUT THE DECISIONS YOU MAKE NOW ARE THE REALLY IMPORTANT ONES FOR THE NEXT WHEN THE NEW INITIATIVE COMES FORWARD, WHEN THE SPIGOT PRESUMABLY WILL OPEN UP AGAIN.

SO THE QUESTIONS THAT YOU'RE ASKING NOW ARE WHERE YOU WANT TO FOCUS NOW, AND I AGREE WITH THE IDEA OF A MAP ALMOST, OF WHERE ARE THE TRENDS, WHERE IS THE FUTURE, AND WHERE COULD WE PLAY AN IMPORTANT ROLE IN GOOSING IT. LIKE YOU SAY, THERE'S A LOT OF OTHER FUNDING AGENCIES. MARIA HAS BEEN TALKING WITH THE NIH. THEY MAY EVEN GIVE HER SOME INSIGHT WHERE THEY SEE AS THE FUTURE. SO THE DECISIONS THAT ARE MADE NOW REALLY SHOULD BE REFLECTING WHAT WE'RE PLANNING FOR THE NEXT INITIATIVE AS WELL. THAT'S GOING TO BE WHAT WE'RE GOING TO MESSAGE TO PEOPLE.

SUPERVISOR SHEEHY: OTHER THOUGHTS? DR. BURTIS.

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DR. BURTIS: I GUESS I JUST WANT TO SAY I THINK THIS AGENCY HAS ALWAYS DONE ITS BEST TO CHOOSE THE FUNDING OPPORTUNITIES THAT BEST ALIGN WITH ITS MISSION AS STATED AT THE TIME. I THINK THE MISSION HAS BEEN RESTATED OVER THE YEARS AND HAS BEEN SHARPENED PERHAPS AND FOCUSED IN DIFFERENT WAYS. I DON'T KNOW, SOMETHING MAKES ME A LITTLE BIT THINKING THAT WE WOULD SOMEHOW TREAT THIS LAST MONEY DIFFERENTLY THAN THE FIRST MONEY. ALL THE MONEY WAS A PRECIOUS RESOURCE GIVEN TO US BY THE STATE, AND I THINK WE'VE DONE THE BEST JOB POSSIBLE IN SPENDING ALL THAT MONEY. THAT SAID, I ENDORSE EVERYTHING THAT'S BEEN SAID. I THINK AT THIS POINT TO THE EXTENT THAT THINGS BEST FULFILL THE MISSION AS STATED NOW AT ALL POINTS OF REVIEW, WE SHOULD ALL HAVE THAT FOREMOST IN OUR MIND. AND I THINK THE GROUP HAS DONE A GOOD JOB OVER THE YEARS DOING THAT, AND SO I ENDORSE YOUR EFFORTS TO CONTINUE TO DO THAT.

MR. ROWLETT: I AGREE WITH THE SENTIMENT THAT'S BEEN SHARED. ADDITIONALLY, AND PERHAPS THIS IS A BIT OF A ROVING THOUGHT, IT WOULD BE HELPFUL FOR ME IN TERMS OF MAKING MY DECISION FOR STAFF TO APPRECIATE WHAT THE SHIFTING THINKING IS AS ARTICULATED BY JEFF. GIVEN THE CURRENT CIRCUMSTANCE

OF THE ORGANIZATION, CERTAINLY THE OPTIMISM THAT IS ALWAYS ARTICULATED RELATED TO CONTINUATION OF THE ORGANIZATION, BUT THERE'S ALSO THE OTHER REALITY. AND SO NOT THAT STAFF WOULD TRY TO INFLUENCE VOTING, BUT INFLUENCING -- PROVIDING US WITH INFORMATION GIVEN WHAT JEFF SAID ABOUT THE PORTFOLIO AND WHERE GWG PROPOSALS FIT WITH THE EXISTING PORTFOLIO IS HELPFUL, ESPECIALLY GIVEN THE AMOUNT OF RESOURCES AVAILABLE TODAY. AND IF STAFF COULD, NOT THAT I'M TRYING TO ESTABLISH AN ADDITIONAL CRITERIA, BUT IF STAFF COULD SPEAK TO THAT, THAT WOULD BE HELPFUL.

CHAIRMAN THOMAS: ONE SUGGESTION, MR. SUPERVISOR, THAT I WOULD MAKE WITH RESPECT TO THE COMMENTS ABOUT WHO ELSE IS FUNDING WHAT, ETC., IS THAT WE DON'T WANT TO BE DUPLICATIVE. WE DON'T HAVE OR I DON'T BELIEVE TRADITIONALLY HAVE HAD ANY SORT OF REQUIREMENT FOR A COMPREHENSIVE, COMPETITIVE LANDSCAPE ANALYSIS BY APPLICANTS. AND I THINK THAT DOING THAT WOULD BE SOMETHING THAT WOULD HELP US BECAUSE WHEN YOU GET INTO GWG, OCCASIONALLY SOMEBODY WILL SAY, WELL, I KNOW SOMEBODY IS DOING THIS OR THAT, BUT THERE'S NO WAY THAT WE HAVE A GREAT FEEL FOR IT. AND SOMEBODY WHO'S APPLYING FOR A GRANT IS GOING TO KNOW WHO'S DOING WHAT AND WHO'S FUNDING WHAT.

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SO I THINK THAT ADDING THAT AS A REQUIREMENT FOR GRANTS WOULD BE HELPFUL IN GUIDING US TO ADDRESS THAT VERY ISSUE.

SUPERVISOR SHEEHY: AND JUST ONE QUESTION I'D LIKE TO PUT OUT THERE. YOU KNOW, OUR SCOPE HAS INCREASED DRAMATICALLY IN THE LAST TWO OR THREE YEARS. I THINK PART OF IT IS THE EVOLUTION OF THE FIELD, BUT IS THAT SOMETHING WE WANT TO REEXAMINE? IN THE WORKING GROUP WE ROUTINELY, I WOULD SAY ALMOST AT LEAST EVERY OTHER REVIEW, THERE'S A QUESTION LIKE IS THIS REALLY IN SCOPE. AND THAT MAY BE SOMETHING WE WANT TO REEXAMINE AS WELL AS LOOKING AT -- BECAUSE IT WAS TIGHTER AND NOW IT IS MUCH LOOSER, AND PART OF THAT WAS OUR DESIRE TO GET INTO CLINICAL TRIALS, BUT ALSO A BIG PIECE OF IT WAS THE EVOLUTION OF THE FIELD. IT WAS RATHER NARROWLY DEFINED WHEN WE STARTED. WE DIDN'T HAVE IPS CELLS, FOR INSTANCE, WHEN WE STARTED. SO THE IDEA OF DISEASE MODELING WITH IPS CELLS WAS A TESTING PRICE ON THAT.

SO HOW WOULD YOU LIKE TO PROCEED? IT SEEMS LIKE WE KIND OF ACKNOWLEDGED THIS IS A DISCUSSION WE WANT TO HAVE. DO WE WANT TO THEN ACTUALLY TALK ABOUT SPECIFIC CRITERIA THAT WE MIGHT EXAMINE? THIS ISN'T SOMETHING WE HAVE TO DO

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COMPLETELY TODAY, BUT I PERSONALLY FEEL LIKE THAT THIS IS SOMETHING THAT, AND I KIND OF GET THERE'S SOME AGREEMENT, THAT WE REALLY NEED TO LOOK AT WHERE WE ARE JUST TO BE MOST EFFECTIVE WITH THE REMAINING DOLLARS. I THINK THAT'S -- I THINK THAT WE ALL WANT TO DO THAT. AND WE DID HAVE A COUPLE OF DISPARITIES, ADDRESSING DISPARITIES IS AN ISSUE WE HAVEN'T REALLY PUT ON THE TABLE, AND I THINK IT'S MORE CRITICAL NOW THAN EVER, ADDING THAT TO THE MIX. BUT IF WE WANT TO TAKE THE DISCUSSION A STEP FURTHER AND START TALKING ABOUT SPECIFIC CRITERIA, WE MAY WANT TO SAY THAT WE MAY CONSIDER WHEN MAKING THESE DECISIONS. I JUST HAVE A FEELING THESE DEBATES ARE GOING TO COME UP. WHETHER WE WANT TO OR NOT, WE'RE GOING TO END UP, WE'LL BE AT THE END OF THE YEAR WE'VE GOT $30 MILLION LEFT, SAY, IN THE CLIN PORTFOLIO, WE'VE FOUR MERITORIOUS PROGRAMS, AND IT COMES TO 50 MILLION, AND HOW ARE WE GOING TO PICK WHICH ONE?

DR. DEAS: PERHAPS YOU CAN TAKE THIS -- YOU'VE HEARD FROM THE BOARD MEMBERS AND PERHAPS YOU COULD TAKE THIS INFORMATION BACK INTERNALLY AND DISCUSS AND DEVELOP SOME OF THE CRITERIA THAT YOU GLEANED FROM THESE DISCUSSIONS AND THEN SEND IT OUT TO THE BOARD TO SEE IF THOSE ARE THINGS THAT WE

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WOULD AGREE WITH.

DR. HIGGINS: TO THAT SUGGESTION, WOULD THAT JUST BE PULLING STUFF OUT THAT ALREADY EXISTS AS GUIDANCE, OR WOULD IT BE CREATING NEW GUIDANCE?

DR. DEAS: COULD BE BOTH.

SUPERVISOR SHEEHY: I'VE THOUGHT ABOUT THIS. SO THE CRITERIA, AND I'LL JUST GIVE YOU AS AN EXAMPLE, WHEN I THINK ABOUT THIS, I THINK ABOUT DISEASE TARGET. I'M NOT REALLY INTERESTED IN KNEE REPLACEMENT EVEN THOUGH I NEED -- I KNOW, ART. I'M SORRY. BUT WHEN YOU COMPARE THAT WITH DISEASES THAT ARE DEADLY OR CONDITIONS THAT ARE REALLY SEVERE, I HAVE A LOT OF TROUBLE GETTING AROUND KNEE REPLACEMENT JUST PERSONALLY.

SOMETHING THAT I DON'T KNOW A LOT OF PEOPLE THINK ABOUT I THINK INFRASTRUCTURE. SO IF WE HAVE IN CALIFORNIA A CERTAIN REALLY WELL-DEVELOPED EXPERTISE IN ENTITIES LIKE WE BUILT FACILITIES THERE. I SEE CITY OF HOPE. SO THEY HAVE THIS AMAZING COMPETENCY IN GENE THERAPY AND MANUFACTURING, IN WORKING WITH IMMUNE CELLS TO GENE-MODIFY THEM TO IMPACT DISEASE. SO I REALLY FIND THAT VERY INTERESTING TO CONTINUE TO SUPPORT THAT INFRASTRUCTURE THAT WE'VE CREATED IF GOOD PROJECTS ARE COMING OUT BECAUSE THAT'S A LEGACY OF

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CIRM. SOME OF THOSE PROGRAMS NOW, THEY WERE WORLD CLASS, BUT THEY'RE LIKE SUPER WORLD CLASS.

OTHER CRITERIA THAT I LOOK AT -- THOSE ARE SOME OF THE KEY ONES. I COULD GO ON AND ON, BUT THAT'S KIND OF WHAT I TEND TO LOOK AT. AND I DID MENTION THE "CIRM-INESS" OF THE PROJECTS. BUT I DON'T KNOW IF WE WANT TO DISCUSS WHAT SOME OF THOSE ARE. I KNOW GIL ON HIS SET OF SLIDES HAS BROUGHT UP SOME OF THAT. I KNOW KEN HAS RAISED HIS HAND OR NOT. OR STEVE.

DR. JUELSGAARD: SO I THINK WE JUST OUGHT TO BE A LITTLE MORE DEFINITIVE INSTEAD OF SORT OF THIS GRANDER APPROACH. AND WHAT I THINK WE OUGHT TO DO BECAUSE WHAT'S GOING TO HAVE TO HAPPEN IF WE DECIDE TO PROCEED IS THAT CIRM STAFF ARE GOING TO NEED TO DEVELOP TOOLS TO GIVE THE INFORMATION TO US THAT WE WANT. THAT'S NOT GOING TO HAPPEN OVERNIGHT. THAT'S GOING TO TAKE A LITTLE BIT OF EFFORT.

SO LET ME POINT TO A SPECIFIC EXAMPLE BECAUSE FOR ME IT'S ONE OF THE MORE INTERESTING ONES. WE FUND A LITTLE SUBSET OF TRIALS IN A GRAND UNIVERSE OF TRIALS THAT ARE GOING ON. AND BY GRAND UNIVERSE I MEAN NOT JUST THE STEM CELL MECHANISM OF ACTION, BUT ALL SORTS OF MECHANISMS OF ACTION. AND FOR ME THE REAL QUESTION IS ARE WE REALLY ADDRESSING

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AN UNMET MEDICAL NEED. I'LL JUST USE CANCER AS AN EXAMPLE, AND IN THIS CASE WE'RE GOING TO TALK ABOUT GLIOBLASTOMA A LITTLE BIT LATER. SO WE REALLY DON'T KNOW WHEN WE VOTE ON THE TRIAL THAT IS ASKED TO BE FUNDED WHAT'S HAPPENING IN THE GLIOBLASTOMA AREA. I DO KNOW THAT AS A GENERAL MATTER CANCER IS PROBABLY ONE OF THE MOST HEAVILY INVESTED DISEASE ENTITIES AT THIS POINT CERTAINLY IN THE CORPORATE WORLD.

AND SO THERE'S A LOT THAT'S GOING ON. AND THE REAL QUESTION, THEN, FOR ME IS, AND THIS IS WHAT HAPPENS INSIDE A COMPANY, IS YOU REALLY LOOK AT SOMETHING YOU'RE ABOUT TO SPEND A LOT OF MONEY ON AND SAY WHAT DOES THE LANDSCAPE LOOK LIKE OUT THERE? YOU HAVE GATHERED AS MUCH INTELLIGENCE AS YOU CAN, AND THEN YOU MAKE A DECISION ABOUT WHETHER YOU'RE GOING TO PROCEED AND INVEST THAT MONEY OR YOU'RE GOING TO STOP AND PUT THE MONEY ELSEWHERE. BECAUSE ONCE THAT MONEY IS SPENT, IT CAN'T BE SPENT ON SOMETHING ELSE, AND SO YOU ALWAYS WANT TO TRY AND OPTIMIZE YOUR SPENDING.

SO THAT FOR ME MAKES A LOT OF SENSE, BUT OTHER PEOPLE MAY DISAGREE AND THAT'S FINE. IT'S THAT KIND OF THING. IT'S REALLY DEFINING WHAT IS IT THAT YOU REALLY WANT TO KNOW BEFORE YOU VOTE. WILL IT MAKE A DIFFERENCE IN THE DECISION? AS I SAID, IF

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THAT WERE TO BE ONE OF THEM, THAT WILL TAKE A LITTLE BIT OF TIME TO PUT TOGETHER A COMPREHENSIVE ANALYSIS OF THE DIFFERENT MODALITIES OF THERAPIES THAT ARE BEING PURSUED FOR THE TREATMENT OF A SPECIFIC CONDITION.

I WILL JUST TELL YOU THIS, FOR EXAMPLE, IN WHAT WE'RE GOING TO LOOK AT TODAY, GLIOBLASTOMA VERSUS ALS, ONE HECK OF A LOT MORE MONEY IS BEING SPENT ON GLIOBLASTOMA CLINICAL TRIALS THAN WAS BEING SPENT ON ALS. NOW, SHOULD THAT MAKE A DIFFERENCE OR NOT? WE CAN ALL HAVE OUR OPINIONS, BUT IT MAY INFORM HOW WE WOULD VOTE ON SOMETHING.

DR. BURTIS: SO I HAVE TWO THINGS. ONE, I JUST WANTED TO DISTINGUISH IN YOUR COMMENTS BETWEEN SCOPE AND PRIORITIZATION. SO YOU COULD DEFINE OUR SCOPE AS NO LODGER INCLUDING KNEES, AND LIST SCOPE, BUT I DON'T THINK THAT'S REALLY IT. WHAT YOU'RE ASKING FOR IS THE ABILITY TO PRIORITIZE WITHOUT SAYING, SO OUR SCOPE IS LISTED IN OUR MISSION STATEMENT, MEANING UNMET MEDICAL NEEDS, WHICH COULD INCLUDE KNEES, WHICH COULD INCLUDE GLIOBLASTOMAS. WHAT YOU'RE REALLY ASKING FOR IS SORT OF A BLESSING TO BE ABLE TO PRIORITIZE IN A TIME OF NOT UNLIMITED FUNDING IN MAKING DECISIONS BETWEEN EQUALLY MERITORIOUS, EQUALLY WITHIN SCOPE, BUT FOR WHATEVER

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REASON THE DIFFERENTIALLY PRIORITIZED OPTIONS. SO I THINK THAT'S AN IMPORTANT DISTINCTION.

THE SECOND THING I'D LIKE TO ADD, NOT TO MAKE IT MORE COMPLICATED, BUT IF WE'RE MOVING INTO A PERIOD OF TIME IF CHAIRMAN THOMAS IS SUCCESSFUL IN HIS PHILANTHROPIC EFFORTS TO ACQUIRE NEW FUNDING DURING THIS BRIDGE BETWEEN NOW AND WHATEVER THE NEW LEGISLATION SETS AS PRIORITIES AND SCOPE, ALL OF US WHO HAVE WORKED WITH PHILANTHROPY KNOW THAT IT OFTEN COMES WITH STRINGS. AND SO THE GROUPS THAT ADJUDICATE THESE THINGS ARE GOING TO PROBABLY HAVE TO DEAL WITH SOME NEW ISSUES THEY HAVEN'T HAD TO DEAL WITH BEFORE OF MONEY THAT COMES INTO CIRM, BUT WITH SOME BOUNDARIES ATTACHED POSSIBLY BASED ON THE WISHES OF THE DONOR. MAYBE THEY'LL ALL COME IN, HERE'S YOUR MONEY. DO WHAT YOU LIKE WITH IT. MY EXPERIENCE IS THAT THAT PROBABLY WON'T BE THE CASE.

SO I THINK THIS IS VERY TIMELY. I THINK IN PREPARING FOR WHAT WE DO WITH THE LAST OF THE FIRST GROUP OF STATE DOLLARS, YOU ALSO MAY BE PREPARING FOR HOW YOU'RE GOING TO DEAL WITH MONEY THAT COMES IN WITH STRINGS ATTACHED FROM PHILANTHROPY.

MR. TORRES: YES, I DO HAVE A KNEE REPLACEMENT AND I DON'T WANT ANOTHER ONE. BUT I

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NEED TO HELP YOU UNDERSTAND HOW I MAKE MY DECISIONS. COMING FROM THE LEGISLATIVE PROCESS, MAKING DECISIONS HAS TO BE WHAT'S GOOD FOR THE LARGEST PORTION OF THE POPULATION. WHAT'S GOING TO BE GOOD FOR THE LARGEST PORTION MAY NOT MEET THE NEEDS OR DECISION MAKING OF THIS BODY. WHEN I LOOK AT KNEE REPLACEMENTS, I LOOK AT THE AGING POPULATION OF CALIFORNIA. AND IT'S INCREASING TREMENDOUSLY AND HAS AN IMPACT. WHEN I LOOK AT DIABETES, AND WE SPEND 40 BILLION IN THIS STATE ALONE, IF WE CAN FIND A CURE, WE'LL MAKE A MAJOR IMPACT AND FULFILL THE MISSION THAT THE VOTERS GRANTED US IN 2004.

IF I LOOK AT HEART DISEASE, DR. QUINT, AS YOU WELL KNOW, IS ONE OF THE LEADING CAUSES OF DEATH IN CALIFORNIA, AND YET WE'VE DONE SOME GOOD WORK IN THAT AREA AS WELL. SO WHEN I APPROACH THESE DECISIONS, WHETHER IT'S IN THE WORKING GROUP THAT I SERVE ON OR WHETHER IT'S HERE AS A BOARD, I TRY TO FIGURE OUT WHAT'S GOING TO HAVE THE MOST IMPACT IN TERMS OF THE POPULATION OF CALIFORNIA WITHOUT SACRIFICING THE NEED TO LOOK AT OTHER AREAS. FOR EXAMPLE, FOR ME HIV IS VERY IMPORTANT. CANCER IS VERY IMPORTANT AS A COLON CANCER SURVIVOR. SO I LOOK AT BOTH THESE THINGS, AND YOU CANNOT REMOVE YOUR PERSONAL EXPERIENCES FROM THESE DECISIONS, BUT

YOU ALSO HAVE TO LOOK BEYOND THAT. AND THAT'S WHY I DO THINK THAT KNEE REPLACEMENT, EVEN THOUGH WE HAVEN'T FUNDED IT THAT MUCH, CAN HAVE AN IMPACT BECAUSE IT CAN ALSO MOVE TOWARD ELBOWS, ARMS, ETC., IN TERMS OF REGENERATION OF CARTILAGE. AND THAT AFFECTS PEOPLE THAT ARE AGING IN CALIFORNIA, AND THE ECONOMIC IMPACT THAT WE CAN HAVE IN REDUCING THE NEED FOR $60,000 KNEE REPLACEMENT SURGERIES PLUS ALL THE ATTENDANT THERAPY IS ALSO AN ECONOMIC FACTOR THAT I TAKE INTO ACCOUNT.

DR. MARTIN: I WOULD CERTAINLY AGREE THAT'S A VERY IMPORTANT CRITERION. BUT IN ADDITION, THERE'S AN ENTIRE ISSUE OF INNOVATION. AND I THINK THAT ONE OF THE THINGS THAT CIRM HAS DONE, AND MOST OF MY EXPOSURE HAS BEEN FROM THE OUTSIDE, IS REALLY INNOVATE IN THE FIELD OF STEM CELL BIOLOGY AT A TIME WHEN ALMOST EVERYTHING THAT WAS BEING DONE WAS INNOVATIVE. AND, AGAIN, THAT'S EVOLVED. AND SO YOU HAVE INNOVATION, YOU HAVE PUBLIC IMPACT, SOCIETAL IMPACT, AND THEN YOU ALSO HAVE RISK. AND FUNDING RISKY PROJECTS THAT ARE INNOVATIVE AND HAVE THE POTENTIAL FOR A MAJOR SOCIETAL IMPACT BEGINS TO PUT TOGETHER SOME PIERS ON WHICH TO BUILD.

BUT I THINK THAT IT REALLY REQUIRES MORE THAN ANY ONE OF THOSE. AND THE ENVIRONMENT HAS

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CHANGED, HAS EVOLVED. AND SO IN THE CONTEXT OF THE CURRENT ENVIRONMENT AND WHAT WE ANTICIPATE ITS BECOMING OR EVOLVING INTO OVER THE NEXT DECADE AS WE GO FORWARD, I THINK, IS REALLY IMPORTANT. SO IF WE COULD GET A LITTLE BIT OF A STRUCTURE IN THERE WITH NOT 15 CRITERIA, BUT MAYBE THREE, FOUR, FIVE CRITERIA, NOT NECESSARILY WEIGHT THEM ALL, BUT CONSIDER THEM ALL.

MR. TORRES: EXCELLENT.

SUPERVISOR SHEEHY: THANK YOU. AND THEN I'M JUST GOING TO ADD ONE MORE THING BECAUSE IT JUST OCCURRED TO ME AND IT'S GOING TO MAKE THE TEAM'S HEAD EXPLODE. FOR PEOPLE WHO HAVE BEEN HERE FOR A WHILE, WHEN WE WERE ACTUALLY DOING MORE ACTIVE REVIEW, WE ALSO HAD A LITTLE BIT DIFFERENT ACCESS TO THE APPLICATIONS. REMEMBER WHEN WE USED TO GO INTO CLOSED SESSION? ALSO, THAT'S SOMETHING, IF WE'RE GOING TO DO THIS, I THINK FOR THOSE OF US WHO ARE ABLE TO SIT IN THE REVIEWS, WE COME WITH A LOT MORE INFORMATION, BUT I THINK FOR OTHER INDIVIDUALS WHO ARE ON THE APPLICATION REVIEW SUBCOMMITTEE, BUT ALSO MAYBE OTHER MEMBERS, IT'S REALLY HARD. YOU SEE A SUMMARY AND YOU'RE TRYING TO FIGURE IT OUT AND YOU HAVEN'T HAD THE BENEFIT OF THE DISCUSSION, AND THERE'S ALL SORTS OF, AS SCOTT WELL KNOWS, PUBLIC

RECORD, BROWN ACT TYPES OF THING THAT WE HAVE TO NEGOTIATE. BUT MAYBE, ALSO, THAT'S SOMETHING WE MIGHT LOOK AT GIVEN THAT WE DO HAVE PEOPLE WHO ARE PARTICIPATING WHO HAVEN'T HAD A CHANCE. THE INEQUITY IN KNOWLEDGE BASE THAT EXISTS AMONG MEMBERS OF THE APPLICATION REVIEW SUBCOMMITTEE DOESN'T FEEL URGENT IN THE SENSE WE'RE MOSTLY RATIFYING DECISIONS OF THE PEER REVIEW GROUP. BUT IF WE'RE ACTUALLY GOING TO BE MORE ACTIVELY MAKING DECISIONS ABOUT THIS, THEN I THINK WE ALSO MIGHT CONSIDER ASKING THE TEAM TO COME UP -- TO CONSIDER SOME WAYS IN WHICH WE CAN PROVIDE MORE INFORMATION TO INDIVIDUALS IN SOME SORT OF CLOSED SESSION FASHION LIKE WE USED TO DO IN THE PAST.

MR. TORRES: THAT MIGHT BE EASIER GIVEN WHAT WE TALKED ABOUT IN TERMS OF CRITERIA AND OVERLAY OF WHAT YOU'RE JUST SAYING, WHICH I SUPPORT WHAT YOU ARE SAYING.

SUPERVISOR SHEEHY: SO THAT'S ONE THING I THING WE MIGHT WANT TO LOOK AT.

DR. PRIETO: I'M NOT SURE HOW MUCH OF THIS NEEDS TO BE IN CLOSED SESSION. SOME OF IT CERTAINLY DOES. WE HAD A LOT OF THAT DISCUSSION BECAUSE OF PROPRIETARY INFORMATION THAT WAS BEING DISCUSSED OR PRESENTED BY THE APPLICANT. STAFF HAS DONE A VERY

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GOOD JOB OF GIVING US INFORMATION ON THE DISTRIBUTION OF OUR PORTFOLIO BY DISEASE STATE. WE HAVEN'T HAD AS MUCH INFORMATION, AND I THINK STEVE IS TOUCHING ON THIS, ON WHAT OTHER ACTIVITY THERE IS IN A PARTICULAR SPACE, OTHER FUNDERS IN PARTICULAR TYPES OF THERAPY OR PARTICULAR DISEASE STATES, OTHER WORK BEING DONE ON DISEASES OR CONDITIONS THAT AFFECT SPECIFIC POPULATIONS. THAT'S PART OF UNMET MEDICAL NEED. THERE ARE LARGE POPULATIONS THAT SUFFER DISPROPORTIONATELY FROM CONDITIONS THAT WE HAVEN'T ADDRESSED IN A MAJOR WAY. I THINK WE'RE ASKING STAFF TO BRING FORWARD MORE INFORMATION.

SUPERVISOR SHEEHY: CHAIRMAN THOMAS.

CHAIRMAN THOMAS: I WOULD ALSO BE INTERESTED, WHEN CIRM FIRST GOT GOING, ONE OF THE PHRASES THAT WAS USED IN TERMS OF OUR ROLE WAS TO FUND RESEARCH IN THE VALLEY OF DEATH. AND IN THE EARLIER DAYS, THE VALLEY OF DEATH, WHICH WAS DEFINED AS THINGS THAT NOBODY ELSE WOULD FUND BECAUSE IT'S TOO EARLY IN THE R&D PROCESS, AND FOR QUITE A WHILE YOU DIDN'T SEE PHARMA OR VC'S OR WHATEVER LOOK TO GET INTO THE GAME UNTIL PROOF OF CONCEPT HAD BEEN ESTABLISHED, SAY, AT THE END OF PHASE 2 OR WHATEVER. I THINK YOU'RE STARTING TO SEE THAT VALLEY OF DEATH SHRINKING BECAUSE PLAYERS ARE GETTING INTO THE SPACE

EARLIER, NOT IN ANY SORT OF STAMPEDE WAY, BUT THERE ARE A NUMBER THAT ARE BEGINNING TO REALIZE THAT THE TRAIN AT SOME POINT IS GOING TO LEAVE THE STATION, AND THEY'VE GOT TO GET IN EARLIER THAN THEY USED TO IN THE PAST.

SO I THINK WE SORT OF NEED A BIT OF A REDEFINITION OF WHAT THE VALLEY OF DEATH IS AS REGARDS WHAT WE'RE FUNDING. SO PERHAPS THE TEAM COULD GIVE A LITTLE THOUGHT TO THAT. MIGHT THROW THAT ONE ON NEIL, FOR EXAMPLE, BECAUSE THAT HAS TO DO WITH WHAT'S HAPPENING IN THE CORPORATE SPHERE AND WHAT THE WILLINGNESS IS TO GET INTO THE GAME EARLIER BECAUSE IF THERE IS A WILLINGNESS EARLIER, THEN THAT'S SOMETHING WE NEEDN'T WORRY ABOUT AS MUCH FUNDING. SO I WOULD THROW THAT OUT AS A CONSIDERATION AS WELL.

DR. JUELSGAARD: I JUST WANT TO FOLLOW UP ON SOME COMMENTS I MADE EARLIER. AND I'M FOCUSED ON THIS GLIOBLASTOMA TRIAL BECAUSE I JUST THINK FOR ME IT'S A REAL LIVE ISSUE, AND IT'S NOT SAYING HOW I WOULD VOTE ON IT, BUT THE IDEA IN THIS TRIAL IS TO TAKE AN EXISTING AGENT THAT'S BEING SOLD ALREADY AS CHEMOTHERAPY BEING USED TO TREAT GLIOBLASTOMA AND TRY TO MAKE IT MORE EFFECTIVE. SO IF IT'S ALREADY BEING SOLD, IT MEANS, THEN, THERE ARE MANUFACTURERS,

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THERE ARE PHARMACEUTICAL COMPANIES OUT THERE THAT ARE SELLING IT.

ONE OF THEM IS MERCK, WHICH IS A RATHER LARGE INTERNATIONAL PHARMACEUTICAL COMPANY. AND ONE OF THE QUESTIONS I WOULD ASK IF SOMEBODY CAME TO ME AND WANTED FUNDING IS HAVE YOU KNOCKED AT THE DOOR OF THOSE COMMERCIAL ENTERPRISES THAT MAKE THIS PRODUCT? IF YOU'RE SUCCESSFUL IN THIS CLINICAL TRIAL, AND THERE'S A PUBLIC LETTER ASSOCIATED WITH IT FROM THE CITY OF HOPE, SO IT'S THE CITY OF HOPE THAT'S ASKING FOR THE FUNDING. SO HAS THE CITY OF HOPE APPROACHED ANY OF THE MANUFACTURERS TO SEE IF THEY WOULD BE WILLING TO SUPPORT THIS TRIAL BECAUSE IF THIS TRIAL WERE SUCCESSFUL, THEY WOULD BE GREAT BENEFICIARIES ECONOMICALLY OF IT.

SO PART OF THIS IS WHAT OTHER DOORS HAVE YOU KNOCKED ON TO GET FUNDING, OR ARE WE JUST AN EASY DOOR BECAUSE IF IT'S GOT GREAT SCIENTIFIC MERIT, WE'LL APPROVE IT. THAT'S, I THINK, KIND OF WHAT WE'VE BEEN DOING OVER TIME.

SUPERVISOR SHEEHY: SO OTHER THOUGHTS? I THINK I KIND OF -- WHAT I'M HEARING IS THAT THERE'S SUPPORT FOR CONSIDERING THIS. THIS IS NOT THE FINAL DISCUSSION, RIGHT, AND I DID, AND I HOPE THE TEAM HAS BEEN TAKING NOTES, BUT JUST THE COMPETITIVE

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

LANDSCAPE, DISPARITIES, GETTING A MAP OF THE EVOLUTION OF THE RESEARCH, COMPETITIVE LANDSCAPE, SOME OF THESE THINGS ARE NECESSARY WORK THAT WE CAN MAYBE -- AND THEN, OF COURSE, WE MENTIONED OTHER CRITERIA. SO WE'RE TALKING SCOPE AND PRIORITIZATION.

WHEN I WAS THINKING OF KNEES, I ACTUALLY WAS THINKING OF BOTH. I HAD IN MIND SPECIFICALLY ADIPOSE STEM CELL-DERIVED KNEE PRODUCT, AND I WAS LIKE WHAT IS THAT DOING HERE. I THINK PEOPLE ARE DOING THAT ALL OVER THE PLACE, OFTEN IN POPUP, NOT QUITE LEGIT CLINICS.

WE CAN GO ON ALL DAY ON THIS, BUT MAYBE THAT'S A FRAMEWORK THAT WE CAN ASK THE TEAM TO COME BACK AT ANOTHER MEETING IN THE FUTURE AND WE CAN HAVE A FURTHER DISCUSSION. I DO THINK THAT -- BEFORE YOU GET UP, GIL, I'LL LET PUBLIC COMMENT BECAUSE I KNOW DON HAS BEEN WAITING VERY PATIENTLY, BUT COME BACK AND HAVE A FOLLOW-UP DISCUSSION AND MAYBE SEE IF WE CAN GET SOMETHING THAT'S A LITTLE FIRMER JUST TO GUIDE US. MORE IMPORTANTLY, AS WAS BROUGHT UP, TO GUIDE APPLICANTS SO THAT THEY'RE NOT JUST SHOCKED WHEN THEY COME IN WITH A ONE AND THEY'RE LIKE, I'M SORRY, WE'RE NOT GOING TO FUND YOU. THEY'LL HAVE SOME SENSE OF WHAT'S GOING ON,

WHICH MAY, IN FACT, INFLUENCE THE TYPES OF PROJECTS THEY SUBMIT TO US. THEY MAY BE MORE AGGRESSIVE, KIND OF ALLUDING TO WHAT STEVE JUST SAID, IN SEEKING OTHER SOURCES OF FUNDING BEFORE THEY ACTUALLY COME TO US BECAUSE THEY HAVE THAT CAPABILITY.

DON, YOU WANTED TO SPEAK. ALWAYS LOVE TO HEAR WHAT YOU HAVE TO SAY.

MR. REED: THANK YOU. TWO THINGS. FIRST OF ALL, I THINK THIS IS A HUGELY IMPORTANT ISSUE. I THINK IT'S GREAT TO AGENDIZE IT AND HAVE EVERYBODY HAVE THEIR THOUGHTS READY WHEN IT COMES. TIME IS IMPORTANT.

SECONDLY, YOU MENTIONED THIS A LITTLE BIT, JEFF, I'M REMINDED OF THE EARLIER LANGUAGE, WHICH WAS THAT CIRM WOULD TRY TO FUND THINGS UNLIKELY TO BE FUNDED IN OTHER AREAS. I THINK CONSIDERING THE CURRENT CLIMATE IN WASHINGTON, I THINK THAT'S SOMETHING WE OUGHT TO TAKE STRONGLY. IF WE'RE EVER GOING TO DO EMBRYONIC STEM CELL RESEARCH, IT'S GOING TO BE US. I DON'T THINK IT'S GOING TO BE WASHINGTON. SO I REALLY HOPE THAT WE CONSIDER OUR PREVIOUS COMMITMENT, THAT CIRM WOULD FUND THAT WHICH IS -- WOULD GIVE PREFERENCE TO THAT WHICH IS UNLIKELY TO BE FUNDED ELSEWHERE. THANK YOU.

DR. CHIU: YOU HAVE A DIFFICULT PROBLEM

AHEAD OF YOU. AND YOU'RE PARTLY A VICTIM OF YOUR OWN SUCCESS IN THE LAST SEVERAL YEARS BECAUSE WHEN YOU TALK ABOUT SOMETHING THAT'S "CIRMY," IT COVERS A WIDE RANGE OF THINGS. AND THE SUCCESS IN BRINGING SUCH A REMARKABLE NUMBER OF CLINICAL TRIALS, CLEARLY DOING MUCH BETTER THAN THE NIH, AND NOT BEING DONE BY THE NIH, HAS ALSO EXACTED A TOLL. AND THE TOLL IS THAT YOU ARE NOT POSSIBLY AT THE SAME TIME FUNDING BASIC RESEARCH THAT WOULD BE LEADING UP TO NEW THINGS IN EMBRYONIC AND IPSC'S. AND THOSE GUYS ARE SO NEW THAT IT WILL TAKE AWHILE BEFORE ANYTHING REALLY PRODUCTIVE AND AS SOPHISTICATED COME UP FOR CLINICAL TRIALS.

SO HOW DO YOU COMPARE THAT? BECAUSE AS MANY OF YOU ON THE BOARD HAVE SAID, ALL THE THINGS THAT YOU FUND HAVE GREAT IMPACT. ALL THE THINGS THAT YOU FUND CAN BE USED BY INDUSTRY. OTHERWISE INDUSTRY WOULDN'T BE STREAMING IN. WHY HASN'T INDUSTRY BEEN STREAMING IN BEFORE AND FUNDING THESE THINGS? BECAUSE THEY DIDN'T KNOW THAT IT WOULD BE SO PRODUCTIVE, THAT THEY DIDN'T KNOW THAT THESE DISEASES COULD BE LOOKED AT AND TREATED. SO YOU'RE SORT OF STUCK BETWEEN A ROCK AND A HARD PLACE OF YOUR OWN SUCCESS, AND I DON'T ENVY YOU.

I WOULD JUST LIKE TO ASK YOU TO SERIOUSLY

CONSIDER BEFORE YOU PRIORITIZE ONE OVER THE OTHER THAT YOU'VE MADE A BIG IMPACT. IT IS HARD TO CHOOSE HOW TO SPEND YOUR LAST DOLLARS, BUT DON'T BE PARTICULARLY SWAYED COMPLETELY BY YOUR PORTFOLIO OR THE LACK OF YOUR PORTFOLIO BECAUSE SOMETIMES THINGS THAT ARE NOT READY, IF YOU DON'T FEED THEM, WILL NEVER BE READY. AND WHEN YOU DON'T GIVE OPPORTUNITY FOR EARLY INNOVATION, DISCOVERY THINGS, THEY WON'T GROW UP. BUT ON THE OTHER HAND, THERE ARE PRODUCTS THAT COULD VERY EASILY BE MOVING INTO INDUSTRY, AND YOU WOULD REAP THE SUCCESS OF THESE THINGS.

SO I'M JUST GOING TO SAY YOU HAVE A HARD PROBLEM, BUT PLEASE DON'T JUST JUMP INTO PRIORITIES OR BE IN A RUSH TO FIX THIS PROBLEM. THANK YOU.

SUPERVISOR SHEEHY: THANK YOU. IS THERE ADDITIONAL PUBLIC COMMENT?

SO SHOULD WE CONSIDER THIS -- DR. SAMBRANO HAS SOME MORE SLIDES THAT REALLY GET MORE SPECIFICITY, BUT I'M WONDERING IF WE WANT TO SAVE THOSE AND DO THAT IN THE CONTEXT. IT'S YOUR CALL. I DON'T KNOW HOW MUCH TIME YOU WANT TO SPEND ON THIS. WE'VE KIND OF DECIDED THIS IS A DISCUSSION WE WANT TO HAVE. WE NEED TO GO THROUGH SOME MORE SPECIFICS. OR WE CAN ALLOW THE TEAM TO PULL TOGETHER SOME OF THE OTHER FACTORS THAT YOU BROUGHT

UP TODAY AND HAVE THIS DISCUSSION LATER. EITHER WAY.

DR. MALKAS: I THINK THE TEAM NEEDS TO PREPARE. THEY CAN PREPARE A SERIES OF INFORMATION THAT WOULD BE MORE USEFUL TO THIS DISCUSSION. THAT'S JUST MY OPINION.

DR. DIXON: GOOD THOUGHT.

SUPERVISOR SHEEHY: WE CONCUR ON THAT? OKAY. THANK YOU, DR. SAMBRANO. AND THANK YOU. I THINK THIS IS AN INTERESTING START BECAUSE WE ARE GETTING TO THE END, AT LEAST THIS FIRST TRANCHE.

CHAIRMAN THOMAS: OKAY. THANK YOU, MR. SUPERVISOR. THANK YOU, EVERYBODY, FOR ALL YOUR COMMENTS.

SO WHAT I WOULD LIKE TO DO NOW IS WE HAVE A COUPLE MORE ACTION ITEMS. I'D LIKE TO DO ONE MORE AND THEN BREAK FOR LUNCH. AND SO --

MR. TOCHER: I'M SORRY I DIDN'T MEAN TO INTERRUPT YOU. GO AHEAD AND FINISH. I HAVE A SUGGESTION FOR THE PRIORITIZATION.

CHAIRMAN THOMAS: PLEASE.

MR. TOCHER: WE'RE COMING CLOSE TO OUR QUORUM. I WOULD RECOMMEND THAT WE TAKE UP THE BUDGET FOR THE UPCOMING YEAR, FISCAL YEAR BUDGET, AND THEN PROCEED WITH THE CLINICAL APPLICATION

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REVIEW.

CHAIRMAN THOMAS: GREAT MINDS THINK ALIKE, MR. TOCHER. THAT IS THE NEXT ITEM ON THE AGENDA, SO WE WERE GOING TO GO TO CHILA AND BUDGET FORTHWITH HERE. OR ARE YOU SUGGESTING THAT WE PUSH THAT OFF FOR A MINUTE? SO, CHILA, YOU'RE ON. THANK YOU.

MS. SILVA-MARTIN: GOOD MORNING, EVERYONE, OR IT MAY BE AFTERNOON, I GUESS. THANK YOU FOR THE OPPORTUNITY TO PRESENT THE '18/'19 PROPOSED BUDGET. FOR THOSE OF YOU ON THE PHONE, I WILL TRY TO CALL OUT THE SLIDES THAT WE'RE ON SO YOU CAN FOLLOW WITH US.

SO ON SLIDE 3 IS THE AGENDA FOR THE PRESENTATION. I'D JUST LIKE TO REVIEW THAT BRIEFLY WITH YOU. WE'LL FIRST LOOK AT THE CURRENT YEAR OPERATING BUDGET. WE'LL REVIEW THE BUDGET THAT WAS APPROVED BY THE ICOC BOARD AS WELL AS WHERE WE EXPECT TO END THE FISCAL YEAR AS OF TOMORROW. AND THEN I'LL BRIEFLY DISCUSS SOME OF THE MAJOR DRIVERS THAT ARE IMPACTING THOSE FINAL RESULTS.

NEXT WE'LL LOOK AT THE '18/'19 PROPOSED BUDGET. WE'LL REVIEW THE BUDGET REQUEST AGAINST WHERE WE EXPECT TO END THE FISCAL YEAR FOR '17/'18 AND TALK ABOUT SOME OF THE DRIVERS THAT ARE

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IMPACTING THE REQUEST AND THEN IDENTIFY A FEW RISKS THAT MAY IMPACT THE FINAL RESULTS. AND, LAST, I'D LIKE TO JUST REVIEW THE BUDGET REQUEST AGAINST THE NUMBERS THAT WE PROVIDED AT THE NOVEMBER 2017 TRANSITION PLAN MEETING.

SO MOVING ON TO SLIDE 5, THIS CHART HERE REPRESENTS THE CURRENT YEAR BUDGET AND THE EXPECTED RESULTS AT THE CATEGORICAL LEVEL. SO THE EXPENDITURES ARE IDENTIFIED BY CATEGORIES AND THEY'RE REPRESENTED IN THE FIRST COLUMN. THE SECOND COLUMN REPRESENTS THE BUDGET THIS BOARD APPROVED FOR THE '17/'18 FISCAL YEAR. SO AS YOU CAN SEE IN THE TOTAL ROW, IT WAS JUST UNDER $18.6 MILLION. THE THIRD COLUMN REPRESENTS WHERE WE EXPECT TO END THE YEAR WHICH IS JUST A LITTLE BIT LESS THAN $16 MILLION, 15.7 MILLION. AND THEN, FINALLY, THE LAST COLUMN IS THE VARIANCE, SO THE SAVINGS, THE UNDERRUNS OR OVERRUNS IN THE EXPECTED RESULTS. SO RIGHT NOW WE ANTICIPATE THAT OUR VARIANCE IS GOING TO BE ABOUT $2.7 MILLION IN SAVINGS.

SO NEXT I'D LIKE TO JUST BRIEFLY TALK ABOUT SOME OF THE HIGHER VARIANCES AND WHY THEY OCCURRED. SO THERE'S THREE AREAS WHERE WE HAD SOME FAIRLY SIGNIFICANT VARIANCES AND MAKE UP A MAJORITY OF THE $2.7 MILLION THAT IS GOING UNSPENT. THE

LARGEST IS IN OUR EMPLOYEE EXPENSES, WHICH IS ABOUT $1.5 MILLION IN SAVINGS. AND THEN IN OUR REVIEWS, MEETINGS, AND WORKSHOPS, WE'RE ANTICIPATING OVER HALF A MILLION DOLLARS IN SAVINGS. AND THEN FOR EXTERNAL SERVICES ABOUT $400,000. I DIDN'T CALL OUT THE SLIDE. SO THAT WAS SLIDE NO. 6. SO WE'RE NOW MOVING ON TO SLIDE NO. 7.

SO WHY DID THESE THINGS OCCUR?

SO OVERALL WE'RE SEEING LOWER EMPLOYEE EXPENSES. AS YOU MAY RECALL, THE '17/'18 BUDGET SUPPORTED A TOTAL OF 52 POSITIONS. THIS WAS THE NUMBER OF POSITIONS THAT WE FELT WERE NECESSARY FOR US TO ENSURE THAT WE COULD DELIVER ON OUR STRATEGIC PLAN AND MEET ALL OF OUR MILESTONES.

AT THE BEGINNING OF THE FISCAL YEAR, FIVE OF THOSE 52 POSITIONS WERE VACANT, BUT YOU MAY ALSO RECALL THAT WE HAD SOME FAIRLY MAJOR CHANGES IN OUR LEADERSHIP. DR. MILLAN WAS APPOINTED TO LEAD THE ORGANIZATION WHEN DR. MILLS STEPPED DOWN. SO AS A RESULT, WE ALSO EXPERIENCED SOME OTHER LEADERSHIP CHANGES IN THE ORGANIZATION. DR. CREASEY AND NEIL LITTMAN, FOR EXAMPLE, IN OUR THERAPEUTIC AND STRATEGIC INFRASTRUCTURE PROGRAMS.

SO THE POSITIONS THAT WERE UNFILLED AT THE BEGINNING OF THE FISCAL YEAR, WE DECIDED TO HOLD

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THEM VACANT UNTIL EACH OF THE LEADERSHIP TEAM MEMBERS COULD WORK WITH THEIR INDIVIDUAL TEAMS TO ENSURE THAT THEY COULD IMPLEMENT AND MAINTAIN OPERATIONAL EFFICIENCIES TO PROVIDE AS MANY SHOTS ON GOAL AS POSSIBLE. SO THE TEAM WAS NOT ONLY ABLE TO MEET, BUT IN MANY CASES THEY WERE ABLE TO EXCEED OUR STRATEGIC PLAN GOALS WITHOUT FILLING THE POSITIONS. AND THEY REMAINED VACANT THROUGHOUT THE YEAR AND HAVE BEEN ELIMINATED GOING FORWARD.

IN ADDITION TO THE VACANCIES, AS GABE THOMPSON REPORTED EARLIER, WE DID SOME OPERATIONAL CHANGES THAT HELPED TO REDUCE SOME OF OUR POSITIONS. SO, FOR EXAMPLE, HE TALKED ABOUT ELECTRONIC FUNDS TRANSFER. SO OUR GRANT INFORMATION TECHNOLOGY AND FINANCE TEAMS WORKED REALLY CLOSELY WITH THE STATE CONTROLLER'S OFFICE TO IMPLEMENT EFT. AND AS A RESULT OF THAT, EFFICIENCIES INCREASED IN THE FINANCE OFFICE AND WE WERE ABLE TO ELIMINATE A POSITION. SO OVERALL OUR EMPLOYEE EXPENSES WAS UNDERRUN BY ABOUT $1.5 MILLION.

SO MOVING ON TO SLIDE 8, ANOTHER AREA WHERE WE HAD SAVINGS IS IN EXTERNAL SERVICES. THAT'S REALLY AS A RESULT OF TWO FACTORS. FIRST OF ALL, THE EXPENSES CAME IN LOWER THAN WAS BUDGETED. I TALKED ABOUT THE ORGANIZATION GOING THROUGH A LOT

OF CHANGE LAST YEAR. WELL, WE EVEN HAD MORE CHANGE. AS YOU MAY RECALL, WE PREVIOUSLY CONTRACTED FOR OUR GENERAL COUNSEL POSITION. AND DURING THE '17/'18 FISCAL YEAR, WE BROUGHT THAT TASK IN HOUSE. AS A RESULT OF THE CHANGE, WE HAD ANTICIPATED THAT WE WOULD NEED SOME OUTSIDE COUNSEL. AND SO BASED ON HISTORICAL DATA, WE BUDGETED FOR OUTSIDE COUNSEL. HOWEVER, THE EXPENSES DID NOT MATERIALIZE ANYWHERE NEAR WHAT WE HAD BUDGETED. SO WE SAW SAVINGS THERE OF ABOUT $170,000. SO OUR REALLY SMALL, BUT EFFICIENT TEAM UNDER SCOTT TOCHER'S LEADERSHIP WAS ABLE TO ACCOMPLISH ALL THE WORK WITH MINIMAL OUTSIDE SUPPORT.

THE PERFORMANCE AUDIT IS ANOTHER AREA WHERE SOME OF THE COSTS CAME IN LOWER THAN WE HAD ANTICIPATED, AND WE SAW SAVINGS THERE OF ABOUT $78,000.

AND THEN THE LAST FACTOR IMPACTING IT IS THAT WE BUDGETED FOR SOME EXTERNAL SERVICES, AND THEY JUST SIMPLY DID NOT OCCUR. FOR EXAMPLE, WE DID BUDGET FOR SOME BUSINESS DEVELOPMENT CONSULTING, AND WE FOUND THAT NEIL LITTMAN DID NOT REQUIRE THOSE SERVICES. SO OVERALL IN THAT CATEGORY WE SAW ABOUT $412,000 IN SAVINGS.

MOVING ON TO SLIDE NO. 9, THE LAST AREA

133 HENNA COURT, SANDPOINT, IDAHO 83864
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THAT I WANT TO COVER AS PART OF THE MAJOR DRIVERS ARE REVIEWS, MEETINGS, AND WORKSHOPS. DURING THE '16/'17 FISCAL YEAR, WE IMPLEMENTED SOME OPERATIONAL EFFICIENCIES BY BRINGING IN SOME OF OUR MEETINGS IN-HOUSE. AS YOU CAN RECALL, WE BROUGHT THE ICOC MEETINGS IN-HOUSE DURING THAT FISCAL YEAR. SO DURING THE '17/'18 FISCAL YEAR, WE DECIDED TO BRING ALL OF THE ICOC MEETINGS IN-HOUSE AS WELL AS ALL OF OUR OTHER MEETINGS, SUCH AS REVIEWS AND OUR CAPS. AND AS A RESULT, WE ARE SEEING OVERALL DECREASES IN THIS CATEGORY.

SO MARIA BONNEVILLE REALLY LED THE EFFORT IN THAT AREA WITH HER TEAM, AND THEN SHORTLY THEREAFTER GIL SAMBRANO AND DR. CREASEY FOLLOWED AND IMPLEMENTED OUR REVIEWS AND MEETINGS IN-HOUSE, AND WE'RE SEEING SAVINGS OVERALL. SO ALL OF THESE DRIVERS ARE REALLY BRINGING THE OVERALL COST DOWN.

AND SO THAT COVERS THE '17/'18 BUDGET, AND NOW I'D LIKE TO MOVE ON TO THE '18/'19 PROPOSED BUDGET. SO THEN WE'RE LOOKING NOW AT SLIDE NO. 11. SO THIS CHART PROVIDES YOU THE '18/'19 BUDGET REQUEST, AND IT REALLY COMPARES IT AGAINST WHERE WE THINK WE'RE GOING TO END THE FISCAL YEAR FOR '17/'18. SO, AGAIN, THE FIRST COLUMN REPRESENTS THE CATEGORICAL AREAS OF EXPENDITURE. THE SECOND COLUMN

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

REPRESENTS WHAT THIS BOARD ALLOCATED FOR '17/'18, $18.6 MILLION. AND THE THIRD COLUMN WE'RE SEEING WHERE WE THINK WE'RE GOING TO END THE FISCAL YEAR, WHICH IS ABOUT $15.7 MILLION. AND THE BUDGET REQUEST IS REFLECTED IN THE LAST COLUMN. AS YOU CAN SEE, THE BUDGET REQUEST IS JUST OVER $16.8 MILLION.

SO HOW DOES THIS COMPARE YEAR OVER YEAR? SLIDE NO. 12 PROVIDES THAT INFORMATION. SO IN '17/'18 WE HAD AUTHORITY OF $18.6 AND WE BROUGHT THE OVERALL EXPENDITURES IN AT ABOUT 15.7.

THE '18/'19 BUDGET REQUEST IS $16.8 MILLION, AND THAT'S ABOUT $1.9 MILLION LESS THAN WHAT WAS BUDGETED IN '17/'18 AND JUST OVER $1 MILLION MORE THAN THE '17/'18 YEAR FORECAST.

SO WHAT'S DRIVING THAT $1 MILLION DIFFERENCE? NOW WE'RE ON SLIDE 13. SO THE CATEGORY THAT'S DRIVING THE LARGEST INCREASE YEAR OVER YEAR IS EMPLOYEE EXPENSES, WHICH IS OUR LARGEST RESOURCE. WE'RE A STATE AGENCY. AS A STATE AGENCY, WE'RE REQUIRED TO PROVIDE OUR EMPLOYEES BENEFITS SUCH AS RETIREMENT AND HEALTH. WE ARE NOT ABLE TO NEGOTIATE THOSE BENEFIT RATES. THEY ARE ACTUALLY DONE BY SEVERAL STATE CONTROL AGENCIES, SUCH AS THE CALIFORNIA PUBLIC EMPLOYEE RELATION SYSTEM AND THE CALIFORNIA DEPARTMENT OF HUMAN RESOURCES. THEY HAVE

133 HENNA COURT, SANDPOINT, IDAHO 83864
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PROVIDED US WITH THEIR LATEST DATA; AND BASED ON THAT INFORMATION, WE BELIEVE THAT OVERALL WE'RE GOING TO SEE ABOUT A 6-PERCENT INCREASE IN THAT AREA. SO THAT HAS BEEN BUILT INTO THE '18/'19 BUDGET. AND THEN EMPLOYEE EXPENSES ALSO INCLUDES AN ANNUAL SALARY ADJUSTMENT FOR THE CIRM TEAM. WE ARE OVERALL SEEING OTHER AREAS THAT ARE INCREASING, OTHER CATEGORICAL AREAS. SOME OF IT IS DUE TO NEW ACTIVITIES, SUCH AS DR. OLSON MENTIONED, IMPLEMENTATION OF OUR ADVISORY PANELS IN OUR TRANSLATIONAL PROGRAM. AND THEN WE DO ANTICIPATE INCREASED ACTIVITY IN OUR CLINICAL PORTFOLIO. AND THEN JUST OVERALL WE'RE SEEING SOME ACROSS-THE-BOARD COST OF LIVING INCREASES IN THE OTHER CATEGORIES OF OPERATING EXPENSES.

SO MOVING ON TO SLIDE 14, AS YOU CAN SEE FROM THE REQUEST, I BELIEVE THAT OUR TEAM IS WORKING HARD AND ACTIVELY TO MANAGE OUR EXPENSES. THE BUDGET REFLECTS THIS EFFORT. IT ALLOWS US TO BRING QUALITY REVIEWS AND HIGH PERFORMING AWARDS, BUT THERE ARE SOME FACTORS THAT WE DON'T CONTROL OR HAVE LITTLE OR HAVE LITTLE CONTROL OVER, AND THEY COULD IMPACT THE FINAL RESULTS NEXT YEAR. ONE OF THOSE IS THE MANDATED EMPLOYEE COST. WHILE WE'VE BEEN PROVIDED WITH THE LATEST RATE CHANGES, OFTEN THESE

CONTROL AGENCIES GO IN AND MAKE ADDITIONAL CHANGES. IF THOSE INCREASE, WE CAN SEE OUR EMPLOYEE COSTS INCREASING.

ANOTHER AREA WHERE WE CAN'T PREDICT IS OUR TURNOVER. SO IF WE HAVE A HIGH TURNOVER, IT'S POSSIBLE THAT OUR EMPLOYEE EXPENSES COULD GO DOWN. AND THEN, FINALLY, THE ONE AREA WHERE WE DON'T REALLY HAVE CONTROL OVER IS OUR PORTFOLIO ACTIVITY. SO OUR BUDGET IS BASED ON HISTORICAL DATA, BUT THE FINAL NUMBERS MAY BE DIFFERENT. WE MIGHT SEE A SURGE IN APPLICATION ACTIVITY. AND IF THAT HAPPENS, IT WOULD DRIVE OUR COST UP. CONVERSELY, IF THE PORTFOLIO ACTIVITY REDUCES, OUR COSTS COULD GO DOWN.

SO THE LAST ITEM I JUST BRIEFLY WANTED TO COVER WAS THE BUDGET REQUEST AGAINST THE TRANSITION PLAN THAT WE PRESENTED IN NOVEMBER OF 2017. MOVING ON TO SLIDE 15, AS YOU MAY RECALL, AT THIS NOVEMBER TRANSITION MEETING, WE FORECASTED THAT WE ANTICIPATED THE '18/'19 BUDGET REQUEST WOULD BE APPROXIMATELY $17.1 MILLION. THE REQUEST BEFORE YOU IS ACTUALLY LOWER, $16.8 MILLION. SO THAT'S ABOUT $300,000 LESS, BUT PRETTY MUCH IN LINE WITH WHAT WE'VE PRESENTED AND NO MAJOR CHANGES.

THIS DOES CONCLUDE THE BUDGET PRESENTATION. I UNDERSTAND THAT YOU WERE PROVIDED

WITH AN APPENDIX THAT PROVIDES YOU WITH DETAILED BUDGET REPORTS FOR EACH OF OUR COST CENTERS. WE REQUEST YOUR APPROVAL OF THE '18/'19 BUDGET, AND I'M HAPPY TO ANSWER ANY QUESTIONS YOU MAY HAVE.

DR. PRIETO: I'LL MOVE TO APPROVE.

DR. DIXON: SECOND.

MR. JUELSGAARD: SECOND.

CHAIRMAN THOMAS: MOVED BY MR. JUELSGAARD, SECONDED BY SENATOR TORRES. ANY DISCUSSION BY MEMBERS OF THE BOARD EITHER IN THE ROOM OR ON THE PHONE? IS THERE ANY PUBLIC COMMENT IN THE ROOM OR ON THE PHONE.

BEFORE WE VOTE, JUST LIKE TO SAY, CHILA, THANK YOU FOR YOUR TIRELESS EFFORTS. THIS IS A LOT OF WORK. AND IT IS, AS MR. JUELSGAARD FREQUENTLY POINTS OUT, IN A FORMAT THAT IS EXTREMELY READABLE AND UNDERSTANDABLE AND LOGICAL. AND SO WE THANK YOU FOR ALL THAT YOU DO --

MS. SILVA-MARTIN: THANK YOU.

CHAIRMAN THOMAS: -- ON AN ONGOING BASIS.

IS THIS A ROLL CALL VOTE, MR. TOCHER?

MR. TOCHER: NO, IT'S NOT. IT CAN BE BY VOICE WITH A ROLL CALL FOR THE MEMBERS ON THE PHONE.

CHAIRMAN THOMAS: ALL THOSE IN FAVOR OF THE BUDGET PLEASE SAY AYE. OPPOSED? ABSTENTIONS?

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

MR. TOCHER, PLEASE CALL THE ROLL OF THOSE ON THE PHONE.

MR. TOCHER: JACK DIXON.

DR. DIXON: AYE.

MR. TOCHER: BERT LUBIN.

DR. LUBIN: YES.

MR. TOCHER: LAUREN MILLER.

MS. MILLER: YES.

MR. TOCHER: OS STEWARD. KRISTINA VUORI.

DR. VUORI. YES.

MR. TOCHER: DIANE WINOKUR.

MS. WINOKUR: YES.

MR. TOCHER: GREAT. THANK YOU. MOTION CARRIES.

CHAIRMAN THOMAS: OKAY. THANK YOU ALL. AGAIN, THANK YOU VERY MUCH, CHILA AND EVERYBODY WHO WORKS WITH CHILA FOR OUTSTANDING WORK.

MR. TOCHER, YOU HAD A LOGISTICAL QUESTION.

MR. TOCHER: WE ARE NEARING THE EDGE OF OUR QUORUM AT THE MOMENT. THE PLAN WAS TO TAKE ABOUT A 25, 30-MINUTE BREAK TO ALLOW MEMBERS HERE TO GET THEIR LUNCH AND THEN RETURN TO CONTINUE NEXT WITH THE CONSIDERATION OF THE CLINICAL APPLICATIONS. BUT BEFORE BREAKING, I JUST WANTED TO GET ASSURANCE FROM THOSE MEMBERS REMAINING ON THE PHONE THAT THEY

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

WILL BE ABLE TO REMAIN WITH US THROUGH THAT BRIEF BREAK AND THEN FOR CONSIDERATION OF THE CLINICAL APPLICATIONS.

SO, DR. DIXON, WILL YOU BE AVAILABLE FOR THE FORESEEABLE NEXT HOUR AND A HALF OR SO?

DR. DIXON: I'LL BE AROUND.

MR. TOCHER: THANK YOU. DR. LUBIN.

DR. LUBIN: I WILL NOT BE. I HAVE TO SIGN OFF.

MR. TOCHER: FOR HOW MUCH LONGER WILL YOU BE AVAILABLE?

DR. LUBIN: I WAS PLANNING NOT TO PARTICIPATE AFTER 12 MOON.

MR. TOCHER: LAUREN MILLER.

MS. MILLER: YES, I'M AROUND.

MR. TOCHER: GREAT. THANK YOU. KRISTINA VUORI.

DR. VUORI: YES, I WILL STAY ON.

MR. TOCHER: THANK YOU. AND DIANE WINOKUR.

MS. WINOKUR: I WILL STAY ON.

MR. TOCHER: OKAY. AND, OS, ARE YOU GOING TO BE AVAILABLE? HE'S DIALING BACK IN. OKAY. WE'LL BE IN GOOD SHAPE.

CHAIRMAN THOMAS: I THINK THE IDEA WAS

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

JUST TO GIVE FOLKS A CHANCE TO HAVE A BIT OF A BREAK AND GRAB THEIR LUNCH. SO WE WILL NOW RECESS FOR -- WE'LL RECONVENE AT 12:45. FOR THOSE OF YOU WHO ARE ON THE PHONE, I HOPE YOU ARE STILL THERE. THERE SEEMS TO BE A CLAMORING TO DO A WORKING LUNCH. SO LET'S TAKE A TEN-MINUTE BREAK TO LET EVERYBODY GET THEIR LUNCH AND RECONVENE, AND WE'LL GO STRAIGHT INTO THE REMAINING ACTION ITEM.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: ALL RIGHT, EVERYBODY. IF YOU COULD PLEASE TAKE YOUR SEATS, WE'RE GOING TO CONTINUE WITH THE AGENDA. OKAY. BACK IN SESSION NOW. GOING TO GO ON TO ACTION ITEM NO. 10, CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO THE CLINICAL TRIAL AWARDS. WE'LL START WITH A PRESENTATION BY DR. SAMBRANO AND MOVE TO PROGRAMMATIC DISCUSSION LED BY SUPERVISOR SHEEHY.

DR. SAMBRANO: THANK YOU, MR. CHAIRMAN. SO WE'RE BRINGING FOR YOUR CONSIDERATION TWO APPLICATIONS IN RESPONSE TO OUR CLINICAL STAGE PROGRAM ANNOUNCEMENTS. BOTH OF THESE APPLICATIONS ARE CLIN1S, MEANING THESE ARE LATE STAGE PRECLINICAL PROJECTS, SO NOT YET CLINICAL TRIALS. THE GOAL OF THE LATE STAGE PRECLINICAL PROJECT PROGRAM IS TO GET PROGRAMS TO FILE AN IND AND TO DO SO IN ABOUT 18

MONTHS. SO THOSE ARE THE TYPES OF PROJECTS WE'RE GOING TO CONSIDER TODAY.

A REMINDER OF THE SCORING SYSTEM FOR OUR CLINICAL APPLICATIONS. I MENTIONED BEFORE THAT WE HAVE THE SCORE OF 1, 2, AND 3, AND SO THAT WAS UTILIZED IN THIS PROGRAM.

SO THE FIRST APPLICATION TO BE CONSIDERED IS CLIN1-10967. THIS IS LATE STAGE PRECLINICAL STUDIES FOR A THERAPY FOR GLIOBLASTOMA. SO THE THERAPY OR THE PRODUCT IS A GENETICALLY MODIFIED BLOOD STEM CELL. SO THOSE STEM CELLS ARE THEN TRANSPLANTED IN ORDER TO ALLOW PATIENTS WITH GLIOBLASTOMA TO UNDERGO GREATER LEVELS AND CYCLES OF THE STANDARD OF CARE, TEMOZOLOMIDE THERAPY.

SO OBVIOUSLY THE INDICATION IS FOR PATIENTS WITH NEWLY DIAGNOSED GLIOBLASTOMA OR GRADE IV GLIOMA. THE GOALS OF THE PROJECT ARE TO OPTIMIZE THEIR MANUFACTURING OF THE VECTOR, GENERATION OF THE CELL PRODUCT, TO CONDUCT PRECLINICAL SAFETY AND EFFICACY STUDIES THAT WILL ALLOW THEM TO PREPARE AND FILE AN IND. THE FUNDS REQUESTED ARE 3.7 MILLION APPROXIMATELY FOR THIS PROJECT.

THE GWG REVIEWED THIS PROPOSAL AND GAVE IT A SCORE OF 1. THE SCORE OF 1 WAS ACHIEVED WITH TEN VOTES FROM THE GWG MEMBERS THAT GAVE IT A ONE, THERE

WERE TWO MEMBERS THAT SCORED IT A 2, AND TWO MEMBERS THAT SCORED IT A 3. THE CIRM TEAM ALSO, AS MENTIONED, LOOKS AT THE APPLICATION PARTICULARLY IN TERMS OF THE OVERALL PROCESS OF THE REVIEW, IF THERE WERE ANY IRREGULARITIES OR ISSUES THAT WE WOULD WANT TO CALL TO YOUR ATTENTION. THERE WERE NONE. AND SO WE CONCUR WITH THE RECOMMENDATION OF THE GWG TO FUND THIS APPLICATION IN THE AWARD AMOUNT OF 3.7 MILLION. MR. SHEEHY.

SUPERVISOR SHEEHY: SO DO WE HAVE A MOTION TO EITHER ACCEPT THE GRANTS WORKING GROUP RECOMMENDATION OR TO NOT ACCEPT IT?

MR. TORRES: MOVE TO ACCEPT.

SUPERVISOR SHEEHY: DO I HAVE A SECOND?

CHAIRMAN THOMAS: SECOND.

SUPERVISOR SHEEHY: SO DISCUSSION?

DR. JUELSGAARD: SO I HAD A QUESTION EARLIER WHEN WE WERE TALKING ABOUT PROGRAMMATIC REVIEW. AND I KNOW THAT WE HAVE AT LEAST ONE REPRESENTATIVE FROM OR WE HAD ONE REPRESENTATIVE FROM THE CITY OF HOPE HERE AND WE STILL DO.

SO THE QUESTION IS, GIVEN THAT THIS IS DESIGNED TO ENHANCE THE ACTIVITY OF AN EXISTING THERAPEUTIC AGENT WHICH IS BEING MARKETED BY, I THINK IT'S PROBABLY ALSO GONE GENERIC, BY AT LEAST

ONE MAJOR DRUG COMPANY, MERCK. WHAT EFFORTS WERE MADE TO GO OUT TO INDUSTRY TO SEEK FUNDING FOR THIS PARTICULAR APPROACH? I CAN UNDERSTAND INNOVATIVE THERAPIES THAT ARE REALLY JUST STARTED AND NOT BOOTSTRAPPING ONTO WHAT ALREADY EXISTS BECAUSE IT DOESN'T EXIST, BUT HERE SOMETHING DOES EXIST IN THE FORM OF ENHANCING A CHEMOTHERAPEUTIC. SO IF SOMEBODY FROM CITY OF HOPE COULD SPEAK TO THAT, THAT WOULD BE GREAT.

DR. ZAIA: THANK YOU. MY NAME IS JOHN ZAIA. I'M THE PI FOR THE PROJECT. I BASICALLY HAVE TWO COMMENTS TOWARDS THAT END. ONE IS THAT THE PROJECT IS NOT JUST TO BE ABLE TO USE MORE OF THIS DRUG CALLED TEMODAR, BUT TO ALSO PROTECT THE STEM CELLS AS ULTIMATELY AN ATTACK ON THE STEM CELLS, WHICH IS MORE EFFICIENT DURING THE TREATMENT OF GLIOBLASTOMA THAN ARE THE DRUGS ON TREATMENT OF THE ACTUAL TUMOR. SO WE HAVE A METHOD BY WHICH WE CAN PROTECT THE STEM CELLS AND INCREASE AT THE SAME TIME THE SENSITIVITY OF THE TUMOR TO THE TEMODAR. AND THAT'S WHAT THIS OTHER DRUG O-6 PG. SO THERE'S NO COMPANY THAT MAKES THAT DRUG AT CITY OF HOPE OR NIH. IN THIS CASE IT'S MADE IN CITY OF HOPE. BUT IT IS POSSIBLE THAT, IF IT WERE SUCCESSFUL, WE WILL USE LESS TEMODAR THAN IS CURRENTLY THE STANDARD OF CARE.

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

SO WHEN WE CALCULATED THE DOSING FOR THE POSSIBLE FUTURE CLINICAL TRIAL, THAT WAS THE CASE, THAT WE WOULD ACTUALLY BE USING LESS TEMODAR. FOR THAT REASON WE HAVE NOT APPROACHED MERCK FOR SUPPORT FOR THIS. WE DON'T THINK MERCK WOULD BE INTERESTED IN A STUDY THAT WOULD USE LESS DRUG THAN THEY CURRENTLY HAVE.

THE OTHER THING IS IS THIS A "CIRM-ISH" STUDY? AND I WANT TO ARGUE THAT IT IS BECAUSE, AS I SAID BEFORE, THE PROBLEM OF TREATING GLIOBLASTOMA RIGHT NOW IS THE INABILITY OF OUR TREATMENT TO PROTECT THE STEM CELLS. SO PATIENTS ARE HAVING SIDE EFFECTS REALLY BECAUSE THEIR WHITE COUNT GOES LOW AND THEIR PLATELETS GO LOW AND THEY END UP IN THE HOSPITAL WITH INFECTIONS. AND THE QUALITY OF LIFE IS AFFECTED BY THAT. SO THE PILOT STUDIES THAT HAVE BEEN DONE, AND ONE WAS DONE AT THE FRED HUTCH, ONE WAS DONE AT CASE WESTERN, FOUND THAT YOU COULD -- YOU DO SEE A BETTER EFFECT ON THE TUMOR, BUT YOU HAD LESS HOSPITALIZATIONS AND BETTER QUALITY OF LIFE.

SO WE THINK THAT THIS IS AN OPPORTUNITY TO REALLY SHOW ONCE AND FOR ALL THAT WE HAVE A METHOD TO IMPROVE THE OUTCOME OF GLIOBLASTOMA. SO WITH THAT, I WILL END UNLESS THERE'S OTHER QUESTIONS.

SUPERVISOR SHEEHY: ADDITIONAL QUESTIONS?

MR. TORRES: I WANT TO THANK YOU FOR ALL THE INCREDIBLE HARD WORK YOU'VE BEEN DOING OVER THE YEARS, JOHN. BUT MORE IMPORTANTLY, AS A STRONG SUPPORTER OF OUR HIGH SCHOOL PROGRAM, THE SPARK PROGRAM, THE FACT THAT YOU TOOK THE TIME TO TALK TO THESE HIGH SCHOOL STUDENTS AT THE CITY OF HOPE WAS VERY MOVING TO THEM AND THEIR FAMILIES. SO I JUST WANT TO SAY THANK YOU AGAIN FOR DOING THAT. IT'S NOT OFTEN WE GET PI'S ACTUALLY CONNECTING WITH HIGH SCHOOL STUDENTS AND TAKING THE TIME TO DO THAT. I JUST WANT TO SAY THANK YOU.

DR. DIXON: HERE. HERE.

SUPERVISOR SHEEHY: OTHER QUESTIONS OR COMMENTS? ANY PUBLIC COMMENTS? ARE YOU CALLING THE ROLL TODAY, SCOTT?

MR. TOCHER: I SURE AM.

DR. CHIU: I SUGGESTED TO DR. ZAIA TO MENTION THE FACT THAT THIS PROCESS, IF IT WORKS, WILL NOT BE ONLY FOR TREATMENT OF GLIOBLASTOMA, BUT FOR OTHER AGGRESSIVE CANCERS FOR WHICH YOU WANT TO PROTECT THE PATIENT'S OWN BLOOD STEM CELLS. THANK YOU.

SUPERVISOR SHEEHY: THANK YOU.

MR. TOCHER: SO THE MOTION IS TO FUND APPLICATION 10967.

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

HIGGINS.
DR. HIGGINS: YES.
MR. TOCHER: JUELSGAARD.
MR. JUELSGAARD: YES.
MR. TOCHER: MARTIN.
DR. MARTIN: YES.
MR. TOCHER: LAUREN MILLER.
MS. MILLER: YES.
MR. TORRES: WE'RE GETTING FEEDBACK. THAT'S WHY SHE'S NOT PICKING IT UP.
MR. TOCHER: DR. PRIETO.
DR. PRIETO: AYE.
MR. TOCHER: QUINT.
DR. QUINT: YES.
MR. TOCHER: ROWLETT.
MR. ROWLETT: YES.
MR. TOCHER: SHEEHY.
SUPERVISOR SHEEHY: YES.
MR. TOCHER: STEWARD. OS, ARE YOU WITH US?
DR. STEWARD: YES, I AM. YES IS THE VOTE.
MR. TOCHER: J.T.
CHAIRMAN THOMAS: YES.
MR. TOCHER: TORRES.
MR. TORRES: AYE.

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

MR. TOCHER: AND WINOKUR.

MS. WINOKUR: YES.

MR. TOCHER: THE MOTION CARRIES.

SUPERVISOR SHEEHY: THANK YOU. BEFORE WE GO TO THE NEXT APPLICATION, MAYBE THIS, AT LEAST FOR THESE CLINICAL APPLICATIONS, MAYBE THIS IS A FEATURE WE WANT TO DO IS INVITE THE PI'S BECAUSE I THOUGHT THAT THAT WAS VERY INTERESTING. AND THAT ACTUALLY COULD BE A WAY WE COULD -- THE AMOUNT OF MONEY THAT'S UNDER DISCUSSION, I THINK, WARRANTS A PLANE FLIGHT. SO PLEASE, DR. SAMBRANO.

DR. SAMBRANO: SO THE NEXT APPLICATION IS CLIN1-11059. THIS IS A LATE STAGE PRECLINICAL STUDY OF A THERAPY FOR PARKINSON'S DISEASE. SO THIS IS A PRODUCT WHICH IS NEURAL PROGENITOR CELLS THAT ARE GENETICALLY MODIFIED WITH GDNF, WHICH IS A COMPOUND THAT PROTECTS OTHER NEURAL CELLS. SO THE IDEA BEHIND THIS IS THAT THESE CELLS WOULD PROVIDE PROTECTION FOR DOPAMINERGIC NEURONS IN THE PUTAMEN REGION OF THE BRAIN. THAT IS THE REGION THAT IS AFFECTED BY PARKINSON'S DISEASE.

THE INDICATION IS FOR MIDSTAGE PARKINSON'S DISEASE. THE GOALS OF THE PROJECT ARE TO MANUFACTURE THE CELLS AND DEVELOP THEIR PROCESS, CONDUCT LONG-TERM SAFETY STUDIES, DEMONSTRATE SAFETY

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

AND TOLERABILITY ALSO IN A LARGE ANIMAL MODEL. THE FUNDS REQUESTED ARE 5.8 MILLION FROM THIS APPLICANT.

THE GWG REVIEW GAVE IT A SCORE OVERALL OF 1. THERE WERE NINE MEMBERS SCORING IT A 1, THERE WERE SIX MEMBERS THAT SCORED IT A 2, AND NO MEMBERS GIVING IT A SCORE OF 3. THE CIRM TEAM RECOMMENDATION IS ALSO TO FUND FOR THE AWARD AMOUNT OF 5.8 MILLION. MR. SHEEHY.

SUPERVISOR SHEEHY: THANK YOU. DO I HAVE A MOTION TO EITHER ACCEPT THE RECOMMENDATION OR REJECT THE RECOMMENDATION?

DR. HIGGINS: SO MOVED TO ACCEPT.

SUPERVISOR SHEEHY: WE GOT A SECOND?

MR. TORRES: SECOND.

SUPERVISOR SHEEHY: ANY DISCUSSION?

DR. SANDMEYER: IS IT APPROPRIATE TO ASK WHAT THE VIEW OF THE SIX VOTERS IN THE MINORITY WAS?

SUPERVISOR SHEEHY: YES.

DR. SAMBRANO: YES, ABSOLUTELY. SO LET ME JUST TRY TO SUMMARIZE. OVERALL THE CONCERNS THAT WERE BROUGHT UP BY THE GROUP WERE RELATIVELY MINOR, BUT THEY RELATED TO THE ANIMAL STUDY PROPOSED. THEY HAD A LONG TIMELINE OF UP TO NINE MONTHS TO LOOK AT SAFETY AND TUMOROGENICITY. THEY WERE SUGGESTING A REVISION AND ADDING A SIX-MONTH TIME POINT BECAUSE

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

THEY DIDN'T HAVE ONE BETWEEN THREE AND NINE MONTHS AND THEY FELT THAT WAS IMPORTANT.

THERE WERE QUESTIONS ABOUT THE DELIVERY METHOD. SO THEY USE A CANNULA SYSTEM THAT HAS BEEN USED PREVIOUSLY. AND, IF ANYTHING, IT WAS REALLY CLARIFICATIONS ON HOW IT WOULD BE USED AND TESTED IN ORDER TO ENSURE THAT THE CELLS SURVIVE THROUGH THE USE OF THE CANNULA SYSTEM, WHICH IS PROBABLY SOMETHING THAT THEY WILL BE DOING IN THEIR IN VIVO STUDIES UNDER THIS GRANT AWARD IF THEY RECEIVE IT.

AND THEN A QUESTION ABOUT THEIR IMAGING CONTRAST AGENT THAT THEY PROPOSE TO USE AS PART OF INTRODUCING THE CELLS, WHETHER THAT ACTUALLY HAS VALUE TO INCLUDE IT OR NOT. SO THOSE WERE THE CONCERNS THAT WERE BROUGHT UP.

DR. SANDMEYER: THANK YOU.

SUPERVISOR SHEEHY: OTHER QUESTIONS? THOUGHTS? OKAY. IS THERE PUBLIC COMMENT ON THIS? SCOTT, COULD WE CALL THE ROLL PLEASE?

MR. TOCHER: SURE. THE MOTION IS TO FUND APPLICATION 11059.

HIGGINS.

DR. HIGGINS: YES.

MR. TOCHER: JUELSGAARD.

MR. JUELSGAARD: YES.

MR. TOCHER: MARTIN.
DR. MARTIN: YES.
MR. TOCHER: MILLER.
MS. MILLER: YES.
MR. TOCHER: PRIETO.
DR. PRIETO: AYE.
MR. TOCHER: QUINT.
DR. QUINT: YES.
MR. TOCHER: ROWLETT.
MR. ROWLETT: YES.
MR. TOCHER: SHEEHY.
SUPERVISOR SHEEHY: YES.
MR. TOCHER: STEWARD.
DR. STEWARD: YES.
MR. TOCHER: THOMAS.
CHAIRMAN THOMAS: YES.
MR. TOCHER: TORRES.
MR. TORRES: AYE.
MR. TOCHER: WINOKUR.
MS. WINOKUR: YES.
MR. TOCHER: THANK YOU. THE MOTION CARRIES.
SUPERVISOR SHEEHY: THANK YOU. ARE WE GOING INTO THE NEXT ONE -- SO THAT FINISHES CLIN. WE HAVE QUEST NEXT.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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DR. SAMBRANO: NO. THAT'S JULY.

SUPERVISOR SHEEHY: SO ARE WE DONE? THANK YOU.

CHAIRMAN THOMAS: THANK YOU VERY MUCH, MR. SUPERVISOR. THAT CONCLUDES THE ACTION ITEM PORTION OF THE AGENDA. WE'LL PROCEED NOW TO DISCUSSION ITEM NO. 12, FINANCIAL AUDIT RESULTS FROM THE MACIAS FIRM. WE HAVE CRAIG HARNER HERE TO PRESENT. MR. HARNER.

MR. HARNER: AFTERNOON, MR. CHAIRMAN AND MEMBERS OF THE ICOC. I'M CRAIG HARNER. I'M A SENIOR MANAGER WITH MGO. WE'RE THE INDEPENDENT AUDITOR FOR CIRM.

AND SO THIS AFTERNOON I'M GOING TO PRESENT THE RESULTS OF NOT ONE, BUT TWO OF OUR AUDITS THAT WE DID FOR THE FISCAL YEARS ENDING 2016 AND 2017. AND SO WE WERE ENGAGED BY CIRM TO AUDIT THE FINANCIAL STATEMENTS OF THEIR GOVERNMENTAL ACTIVITIES AND ALSO THE STEM CELL FUND AND THE RELATED NOTE DISCLOSURES TO THOSE FINANCIAL STATEMENTS, AS I MENTIONED, FOR FISCAL YEARS '15-'16 AND '16/'17. AND THE REASON WE'RE PRESENTING TWO YEARS TODAY IS THAT FOR FISCAL YEAR '16, DUE TO THE STATE IMPLEMENTING A NEW FINANCIAL MANAGEMENT FINANCIAL INFORMATIONAL SYSTEM, THERE WERE DELAYS IN

GETTING THE BOOKS CLOSED AND FOR US TO BE ABLE TO START OUR AUDIT. SO THAT DIDN'T HAPPEN UNTIL ABOUT DECEMBER OR JANUARY 2017. SO WE WERE A LITTLE DELAYED IN ISSUING OUR AUDIT FOR THAT YEAR, SO WE WILL PRESENT BOTH TODAY.

AND THEN WHEREVER THERE IS -- WITH BOTH YEARS OF OUR AUDIT, WHEREVER THE INFORMATION IS EXACTLY THE SAME, I'LL JUST KIND OF MENTION THAT. AND THEN WHEREVER IT'S DIFFERENT, I'LL JUST SPEAK TO EACH INDIVIDUALLY.

SO I'LL START WITH 2016. AS I MENTIONED, WE ISSUED OUR AUDIT REPORT IN APRIL OF 2017, AND WE ISSUED WHAT'S CALLED AN UNMODIFIED OPINION ON THOSE FINANCIAL STATEMENTS. NOW, AN UNMODIFIED OPINION IS THE HIGHEST LEVEL OF ASSURANCE THAT AN INDEPENDENT AUDITOR CAN GIVE AN ENTITY REGARDING THE FAIR PRESENTATION OF THOSE FINANCIAL STATEMENTS. SO IT'S VERY GOOD THERE.

AND THEN SAME IN 2017. WE ISSUED OUR FINANCIAL STATEMENT REPORT ON OCTOBER 16, 2017, SO BACK ON OUR NORMAL, USUAL CYCLE. AGAIN, IN 2017 WE ISSUED AN UNMODIFIED OPINION THERE AS WELL.

AND THEN ASIDE FROM OUR INDEPENDENT AUDITORS REPORTS, WHAT YOU'LL FIND IN YOUR PACKETS ARE WHAT'S CALLED A REQUIRED COMMUNICATIONS OR

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REPORTS ADDRESSED TO THE ICOC. THESE ARE JUST REQUIRED BY PROFESSIONAL AUDITING STANDARDS. AT THE END OF OUR ENGAGEMENTS, WE REPORT TO THE BOARD OR WHAT'S CALLED THOSE CHARGED WITH GOVERNANCE ANY WHAT WE CALL SIGNIFICANT AUDIT FINDINGS. AND NOT THAT WE HAVE ANY FINDINGS. IT'S REALLY JUST THE NAME WE HAVE TO USE. BUT IT'S KIND OF JUST A SUMMARY OF SOME KEY IMPORTANT ITEMS THAT OCCURRED DURING THE AUDIT.

THE FIRST ITEM THERE, AND THIS WILL BE THE SAME FOR BOTH YEARS BECAUSE BOTH YEARS OF THIS INFORMATION WAS EXACTLY THE SAME, SO THIS WILL COVER '16 AND '17. THE FIRST ITEM UNDER THERE IS CALLED QUALITATIVE ASPECTS OF ACCOUNTING PRACTICE, AND WE JUST WANT TO HIGHLIGHT THIS, THAT ASIDE FROM QUANTITATIVE NUMBERS, THERE'S ALSO SOME QUALITATIVE THINGS THAT GO INTO THOSE FINANCIAL STATEMENTS, MORE SUBJECTIVE TYPES OF INFORMATION. THE FIRST IS THAT MANAGEMENT IS RESPONSIBLE. SO MANAGEMENT OF CIRM IS RESPONSIBLE FOR SELECTING APPROPRIATE ACCOUNTING POLICIES, AND THOSE ARE DISCLOSED IN NOTE 2 TO THEIR FINANCIAL STATEMENTS. AND THERE WERE NO CHANGES IN ANY OF THE ACCOUNTING POLICIES THAT WERE ADOPTED DURING EITHER 2016 OR 17. AND WE NOTED NO TRANSACTIONS THAT LACKED AUTHORITATIVE GUIDANCE THAT

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ENTERED INTO THE FINANCIAL STATEMENTS. AND THEN ALSO ALL THE SIGNIFICANT TRANSACTIONS WERE RECOGNIZED IN THEIR PROPER PERIODS. SO NO ISSUES THERE.

THE SECOND ITEM HERE HAS TO DO WITH ESTIMATES. ESTIMATES ARE AN INTEGRAL PART OF THOSE FINANCIAL STATEMENTS BECAUSE SOME OF THOSE BALANCES REQUIRE MANAGEMENT TO MAKE AN ESTIMATE TO RECORD THE AMOUNT PROPERLY. AND THERE'S SOME THAT ARE PARTICULARLY SENSITIVE JUST BECAUSE OF THEIR NATURE. AN ESTIMATE, THE ACTUAL FUTURE EXPERIENCE COULD BE VERY DIFFERENT FROM WHAT YOU THINK MIGHT HAPPEN AT THE DAY YOU ARE REQUIRED TO RECORD IT.

JUST TO HIGHLIGHT, IN CIRM'S FINANCIAL STATEMENTS THERE'S ACTUALLY NO ESTIMATES THAT WE CONSIDERED PARTICULARLY SENSITIVE OR SIGNIFICANT. SO HIGHLIGHT THAT.

AND THEN THE LAST COUPLE ITEMS HERE, WE ARE REQUIRED TO REPORT ANY DIFFICULTIES THAT WE ENCOUNTERED IN PERFORMING OUR AUDITS OR ANY DISAGREEMENTS WE HAD WITH MANAGEMENT. AND WE'RE VERY HAPPY TO REPORT WE HAD NEITHER OF SUCH INSTANCES DURING EITHER 2016 OR 2017.

AND THEN THE VERY LAST THING I'LL GO OVER IS THAT, AS PART OF THE PROP 71 THAT REQUIRES CIRM

TO HAVE A FINANCIAL STATEMENT AUDITED ALSO REQUIRED THE CALIFORNIA STATE CONTROLLER'S OFFICE TO INSPECT ALL OF OUR AUDIT WORKPAPERS AFTER THE CONCLUSION OF OUR AUDIT. SO EVERY YEAR A COUPLE MONTHS AFTER WE ISSUE OUR AUDIT REPORT, THE STATE CONTROLLER SENDS IN A TEAM OF AUDITORS TO LOOK THROUGH IN VERY METICULOUS DETAIL ALL OF OUR WORKPAPERS, AND THEN THEY ISSUE A REPORT AFTERWARDS. AND SO THIS IS CALLED THEIR QUALITY CONTROL REVIEW REPORT. AND FOR THE 2016 FINANCIAL STATEMENT AUDIT THAT WAS ISSUED ON SEPTEMBER 8, 2017, AND THEY HAD NO FINDINGS AND FOUND THAT ALL OF OUR WORK WAS PERFORMED IN ACCORDANCE WITH THE PROFESSIONAL STANDARDS FOR AUDITING AND ALSO WITH THE CALIFORNIA BUSINESS AND PROFESSIONAL CODE. AND THEN FOR 2017 THEY ISSUED THE REPORT IN FEBRUARY 23D OF THIS YEAR, 2018. AGAIN, THEY HAD NO FINDINGS ON OUR WORK.

AT THIS POINT I WILL CONCLUDE AND ASK IF THERE'S ANY QUESTIONS?

MR. TORRES: SO HOW MANY AUDITS DO WE HAVE TO UNDERGO?

MR. HARNER: ONE EACH YEAR FOR THE FINANCIAL STATEMENTS.

MR. TORRES: AND THEN THERE IS ALSO AN AUDIT BY THE CONTROLLERS ON THOSE FINANCIAL

133 HENNA COURT, SANDPOINT, IDAHO 83864
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STATEMENTS.

MR. HARNER: CORRECT.

MR. TORRES: SO THAT'S TWO.

MR. HARNER: THAT IS REALLY TWO AUDITS. I SHOULD HAVE MENTIONED THAT.

MR. TORRES: I WANT THE PUBLIC TO KNOW THAT WE ARE THE MOST AUDITED AGENCY IN STATE GOVERNMENT. AND THE OTHER AUDIT THAT WE HAVE TO GO THROUGH, WHICH I HAD TO NEGOTIATE WITH SENATOR DURING THE PERIOD OF TIME IN '09, IS A MANAGEMENT AUDIT. SO WE HAVE THREE AUDITS THAT WE UNDERGO. NO OTHER STATE AGENCY IS SUBJECT TO THAT KIND OF FINANCIAL AND SUBSTANTIVE REVIEW, AND THEY SHOULD BE, QUITE FRANKLY, WHEN YOU LOOK AT THE OPERATIONS.

MS. SILVA-MARTIN: I WOULD LIKE TO ADD THAT EVERY ONE OF OUR INVOICES AND EVERY PAYMENT THAT WE PROCESS THROUGH THE CONTROLLER'S OFFICE IS AUDITED. SO WE UNDERGO A HUNDRED PERCENT AUDIT BY THE STATE CONTROLLER'S OFFICE EVERY DAY FOR EVERYTHING WE PAY. I DON'T KNOW OF ANY OTHER STATE AGENCY THAT DOES THAT.

MR. TORRES: NO. AND YOU KNOW MY EXPENSE ACCOUNT IS VERY SMALL. MR. JENSEN, VERY SMALL. I DON'T GO TO CONFERENCES. I DON'T GO -- I ONLY DRIVE TO FRESNO AND SACRAMENTO, NO. 1.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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NO. 2, I GOT AUDITED BY THE CONTROLLER'S OFFICE BECAUSE THERE WAS $16 DISCREPANCY IN THE GAS RECEIPT THAT I SUBMITTED ON THE RENTAL CAR THAT I USED, AND I WAS FINALLY FOUND IN THE RIGHT BECAUSE ENTERPRISE HAD THE PROBLEM.

MR. HARNER: I CAN'T SPEAK TO THE CONTROLLER'S OFFICE. ANY OTHER QUESTIONS OR ANYTHING ELSE I CAN ANSWER?

CHAIRMAN THOMAS: I JUST WANT TO REITERATE THAT, IN ADDITION TO BEING VERY HAPPY WITH WHAT YOU'VE REPORTED, THAT, ONCE AGAIN, DEMONSTRATES THE GREAT WORK THAT CHILA AND HER TEAM IS DOING ON AN ONGOING BASIS THAT LEADS TO THESE SPARKLING RESULTS. SO THANK YOU, MR. HARNER. AND, AGAIN, THANK YOU, CHILA AND YOUR TEAM.

MR. HARNER: ALL RIGHT. THANK YOU.

CHAIRMAN THOMAS: OKAY. SO WE NOW HAVE KEVIN WHO WANTS TO DO AN INTRODUCTION OF THE SPECIAL GUEST.

MR. MC CORMACK: LADIES AND GENTLEMEN, BELGIUM 1, ENGLAND NIL. REALLY, THAT'S GOOD NEWS BECAUSE ENGLAND GET THE SOFTER GROUP IN THE NEXT ROUND. SO IT'S ALL CALCULATION.

CHAIRMAN THOMAS: ARE YOU SAYING THEY'RE THROWING THE GAME?

133 HENNA COURT, SANDPOINT, IDAHO 83864
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MR. MC CORMACK: NO. IT SLIPPED OUT OF THEIR GRASP. IT'S ALL STRATEGY.

ANYWAY, ONE OF THE THINGS I LOVE ABOUT MY JOB, OTHER THAN UPDATING YOU ON WORLD CUP SCORES, IS THAT I REGULARLY GET TO MEET PATIENTS AND PATIENT ADVOCATES. AND THEY'RE SOME OF THE MOST EXTRAORDINARY AND INSPIRING PEOPLE THAT YOU CAN MEET. THE STORY, THEIR COURAGE, THE DETERMINATION IS A REMINDER WHY WE DO THIS WORK.

EARLIER THIS YEAR I WENT TO THE CIRM ALPHA CLINIC SYMPOSIUM AT UCLA. IT WAS A GREAT MEETING, LOTS OF REALLY INTERESTING SPEECHES, BUT THE PRESENTATION, I THOUGHT, THAT STOOD OUT ABOVE ALL OF THOSE WAS THE ONE YOU'RE GOING TO HEAR NEXT. AND IT'S FROM A PATIENT ADVOCATE. AND WHILE I WAS LISTENING TO IT, I THOUGHT I'LL TAKE SOME NOTES HERE FOR A BLOG. AND THEN I THOUGHT YOU CAN'T TAKE THIS DOWN. YOU HAVE TO HEAR IT. SO IT'S MY GREAT PLEASURE TO INTRODUCE GIANNA MCMILLAN.

(APPLAUSE.)

MS. MC MILLAN: THANK YOU FOR INVITING ME TO JOIN YOU TODAY. THESE ARE THE COMMENTS THAT I GAVE IN APRIL. I'M HAPPY TO SHARE THEM AGAIN. AND I APOLOGIZE IF THIS IS A REPEAT PERFORMANCE FOR SOME OF YOU.

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

STEM CELL RESEARCH AND REGENERATIVE MEDICINE ARE APPEALING BECAUSE PATIENTS, FAMILIES, AND SOCIETY ARE WEARY OF INELEGANT INTERJECTIONS THAT INFLICT IN SOME CASES AS MUCH HARM AS BENEFIT. WE ARE TIRED, PATIENTS AND FAMILY AND SOCIETY, WE'RE TIRED OF PUTTING POISON IN OUR LOVED ONES TO KILL THEIR CANCER OR FEELING HELPLESS AS OTHER DISEASES ATTACK OUR OWN BODILY FUNCTIONS.

CALIFORNIA IS FULL OF DREAMERS AND GO-GETTERS. SO, OF COURSE, WE EMBRACE THIS NEW IDEA, STEM CELL THERAPEUTICS REGENERATIVE MEDICINE, TO FORGE BRAVELY AND ENTHUSIASTICALLY AHEAD.

IT'S IMPORTANT TO REMEMBER THAT ALL BIOMEDICAL RESEARCH, EVEN A NEW FIELD AS EXCITING AND INSPIRING AS STEM CELL THERAPEUTICS, MUST ADHERE TO BASIC PREMISES. IT MUST BE VALID SCIENCE, AND IT MUST BE BASED ON AN ETHICAL PARTNERSHIP WITH PATIENTS AND RESEARCH SUBJECTS.

IN THE WORLD OF RESEARCH ETHICS, I WEAR A LOT OF HATS. I'VE BEEN A SUBJECT, A CAREGIVER, AN INSTITUTIONAL REVIEW BOARD MEMBER, IRB MEMBER, SOMEONE WHO ACTUALLY REVIEWS AND APPROVES RESEARCH STUDIES BEFORE THEY'RE ALLOWED TO PROCEED, AND I WORKED WITH THE GOVERNMENT ON REGULATORY COMMITTEES. THESE DAYS I'M FINISHING MY DOCTORAL STUDIES IN

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

BIOETHICS. AND WHILE I LOVE THE INTERPLAY OF PHILOSOPHY AND ETHICAL PRINCIPLES, I MOST TRULY IDENTIFY AS IN-THE-TRENCHES PATIENT SUBJECT ADVOCATE. I AM COMPELLED TO CHAMPION PATIENTS WHO STRUGGLE WITH NEW AND DEVASTATING DIAGNOSES, HOPING DESPERATELY FOR A CURE, WHO MIGHT BE FACED WITH DECISIONS ABOUT PARTICIPATING IN RESEARCH FOR THEIR OWN BENEFIT AND FOR THE GREATER GOOD OF SCIENCE.

IN THE OLD DAYS DOCTORS MADE DECISIONS ON BEHALF OF THEIR PATIENTS, WHO, MEEKLY GRATEFUL FOR THE GUIDANCE, DID WHATEVER THEY WERE TOLD. IT'S A LITTLE DIFFERENT NOW. PATIENTS ARE BETTER INFORMED. THEY OFTEN DO THEIR OWN HOMEWORK, AND THEY PRETTY MUCH DEMAND TO BE AN INTEGRAL PART OF THEIR TREATMENT PLAN.

THE WORLD OF RESEARCH HAS UNDERGONE SIMILAR CHANGES. INSTEAD OF INVESTIGATORS DOING THINGS TO RESEARCH SUBJECTS, NEW BEST PRACTICES INVOLVE PATIENTS IN THE DESIGN OF CLINICAL TRIALS. PATIENTS AND EXPERIENCED SUBJECTS HELP DECIDE WHAT SPECIFIC QUESTIONS SHOULD BE THE FOCUS OF THE RESEARCH. THEY IDENTIFY ENDPOINTS IN THE RESEARCH THAT IS MEANINGFUL TO THE PATIENT POPULATION BEING STUDIED. THEY IDENTIFY TOOLS AND STRATEGIES TO INCLUDE PATIENT AND SUBJECT-REPORTED OUTCOMES AND

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THE DELIVERY OF STUDY RESULTS. THE INVESTIGATOR AND THE RESEARCH SUBJECT HAVE COME TO BE SEEN AS PARTNERS. AND WHILE THE EVOLUTION OF THIS IMPORTANT RELATIONSHIP IS HEALTHY AND WONDERFUL, IT SHOULD NOT BE ASSUMED THAT IT IS AN EQUAL PARTNERSHIP.

WHY? BECAUSE SUBJECTS ARE ALWAYS AT A DISADVANTAGE. NOW, I REALIZE THAT THIS MIGHT BE AN UNCOMFORTABLE CONCEPT. PHYSICIAN INVESTIGATORS IN CHARGE OF THE STUDY MIGHT BE UNCOMFORTABLE SAYING THIS OUT LOUD, AND THEY WOULD WANT TO QUALIFY IT BY ADDING, BUT WE DO OUR BEST TO ACCOMMODATE THEIR NEEDS. AND SUBJECTS PROBABLY DON'T WANT TO ADMIT THIS EITHER BECAUSE IT'S HARD TO MAKE A DECISION WITH COMPETENCE WHILE ACKNOWLEDGING, WOW, I'M REALLY AT A DISADVANTAGE HERE.

I HAVE LEARNED THE HARD WAY THAT AN HONEST PARTNERSHIP REQUIRES ADDRESSING SOME UNCOMFORTABLE REALITIES. SO LET ME TELL YOU A PERSONAL STORY. WHEN MY OLDEST SON WAS FIVE, HE WAS DIAGNOSED WITH MALIGNANT BRAIN CANCER. MY HUSBAND AND I ARE WELL EDUCATED, AND HUBBY IS A BRILLIANT LAWYER. WE WERE SCHEDULED TO MEET WITH OUR SON'S TREATMENT TEAM FOR THE FIRST TIME, AND WE HAD IT ALL PLANNED OUT. MY HUSBAND, ARTICULATE AND CONCISE, WOULD TAKE THE LEAD. HE HAD A LEGAL PAD WITH A LIST OF QUESTIONS.

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AND EACH QUESTION AND ANSWER WOULD TAKE US DOWN THE PAGE UNTIL AT LAST WE WOULD USE ALL THAT INFORMATION TO MAKE A DECISION, A LIFE OR DEATH DECISION, ON BEHALF OF OUR YOUNG CHILD.

SO THE DAY OF THE MEETING CAME. AND FOR SOME REASON WE WERE IN A PROCEDURE ROOM, AND WE WERE ALL SITTING ON LITTLE ROUND STOOLS WITH WHEELS. THE NEUROSURGEON EXPLAINED A FEW THINGS, AND THE RADIOLOGIST SAID HIS PIECE, AND THE ONCOLOGIST OFFERED AN OPINION. AND THEN EVERYONE LOOKED EXPECTANTLY AT MY HUSBAND BECAUSE IT WAS HIS TURN. AND THIS LOVELY MAN OPENED HIS MOUTH AND HE CLOSED HIS MOUTH AND HE OPENED IT AGAIN AND THEN HE BURST INTO TEARS. AND HE PUSHED HIMSELF ON HIS WHEELY STOOL INTO THE FAR CORNER OF THE ROOM, AND HE HELD THE LEGAL PAD OVER HIS CHEST AND HE SOBBED. HE COULD NOT SPEAK.

THERE WERE A FEW SECONDS OF HORRIFIED SILENCE, AND THEN I ROLLED MY STOOL TO THE CENTER OF THE ROOM AND I STAMMERED OUT WHAT FEW QUESTIONS I COULD REMEMBER. AND, FRANKLY, I HAVE NO IDEA HOW THEY WERE ANSWERED. THE DOCTORS' MOUTHS MOVED, AND I LEANED IN AND I NODDED AND I MADE EYE CONTACT, BUT ALL I HEARD WAS A LOUD WHITE NOISE THAT FILLED MY SKULL AND MY HUSBAND'S RASPY BREATHING AND MY OWN

133 HENNA COURT, SANDPOINT, IDAHO 83864
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VOICE CRYING OUT IN THE BACK OF MY HEAD. OH, MY GOD. MY CHILD. MY CHILD.

THE POINT OF THIS STORY IS TO ILLUSTRATE THAT GOOD PEOPLE, EDUCATED AND PREPARED, READY TO BRING THEIR VERY BEST SELVES TO MAKE THE MOST IMPORTANT DECISION THEY WILL EVER MAKE, ONE THAT WOULD AFFECT THE LIFE OF THEIR BELOVED CHILD, THESE PEOPLE COULD NOT FUNCTION. AND THESE NONFUNCTIONING PEOPLE, MY HUSBAND AND I, IN A VERY SHORT TIME WERE INTRODUCED TO THE IDEA OF A RESEARCH STUDY, ONE THAT MIGHT CURE OUR CHILD WHILE LIMITING THE DAMAGE TO HIS GROWING BRAIN. MIGHT. NO ONE KNEW FOR SURE. THAT'S WHY IT WAS A RESEARCH STUDY. NO MATTER HOW WELL INTENTIONED THE RESEARCH TEAM WAS, NO MATTER HOW DESIROUS THEY WERE OF A PARTNERSHIP WITH US, WE WERE AT SUCH A DISTINCT DISADVANTAGE THAT THE RELATIONSHIP WE HAD WITH THESE INVESTIGATORS COULD NOT BE CATEGORIZED AS ONE AMONG EQUALS.

DOESN'T THAT JUST RUB YOU THE WRONG WAY? EVEN NOW, MORE THAN 20 YEARS LATER, IT'S PAINFUL FOR ME TO REFLECT ON THIS. BUT I HAVE WORKED WITH HUNDREDS OF FAMILIES WHOSE CHILDREN WENT INTO CLINICAL TRIALS. AND WHAT WE'VE LEARNED IS THAT IF WE CAN BE HONEST ABOUT THE SITUATION, WE MIGHT TAKE SOME ACTIONS TO IMPROVE IT.

133 HENNA COURT, SANDPOINT, IDAHO 83864
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SO LET ME BE SPECIFIC ABOUT THE WAYS THAT RESEARCH SUBJECTS ARE AT A DISADVANTAGE. ONE, THEY OFTEN DON'T SPEAK THE LANGUAGE OF THE DISEASE. THEY ARE UNFAMILIAR WITH THE PROCESS OF RESEARCH. THEY ARE WRESTLING WITH EMOTIONS, DESPAIR, DENIAL, ANGER, HOPE. THEIR LIFE HAS BEEN DISRUPTED, AND THERE ARE CONSEQUENCES. COMPARE THIS TO THE RESEARCH TEAM WHO KNOWS THE LINGO, DESIGNED THE RESEARCH PLAN, IS NOT PERSONALLY AFFECTED BY THE SCENARIO, AND, WELL, THIS IS BUSINESS AS USUAL, ENROLL A SUBJECT, LET'S GET GOING. NOW, THAT'S A GROSS GENERALIZATION TO MAKE A POINT.

HOW IS THE NOTION OF PARTNERSHIP AFFECTED BY SUCH UNEQUAL CIRCUMSTANCES? IS A MEANINGFUL PARTNERSHIP EVEN POSSIBLE? WELL, YES. AND THIS NOTION OF PARTNERSHIP IS ESPECIALLY IMPORTANT AS NEW TECHNOLOGIES COME TO INVADE THE INTIMATE QUALITIES OF SELF AND THE BUILDING BLOCKS OF WHAT MAKES EACH OF US HUMAN. BUT WE NEED TO BE REALISTIC ABOUT WHAT THIS PARTNERSHIP LOOKS LIKE, AND IT IS NOT EQUAL. AND, FRANKLY, I'M GOING TO TAKE A STAND HERE AND SAY THAT THE PARTNER WHO HAS THE ADVANTAGE, IN THIS CASE THE RESEARCHER AND SCIENTIST, IS MORALLY OBLIGATED TO MEANINGFULLY ADDRESS THE DISADVANTAGE OF THE OTHER PARTY. I'M GOING TO SAY THAT AGAIN. THE

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PARTNER WHO HAS THE ADVANTAGE IS MORALLY OBLIGATED TO MEANINGFULLY ADDRESS THE DISADVANTAGE OF THE OTHER PARTY.

WE NEED TO BE REASONABLE ABOUT HOW THIS MIGHT HAPPEN. WE NEED TO BE REASONABLE ABOUT HOW A RESEARCH TEAM MIGHT ADDRESS THESE DISADVANTAGES. THERE'S PROBABLY NOT MUCH A DOCTOR OR A PHYSICIAN INVESTIGATOR CAN DO ABOUT THE EMOTIONAL STATE OR LIFE CIRCUMSTANCES OF THE SUBJECT. BUT HERE'S WHAT I'VE HEARD OVER AND OVER FROM SUBJECTS AND SUBJECT FAMILIES. TELL ME WHAT I NEED TO KNOW. TELL ME IN A WAY THAT I CAN HEAR IT. TELL ME AGAIN AND AGAIN.

LET ME EXPAND ON THIS. FIRST, IF I'M NEW TO A DIAGNOSIS, A TREATMENT, OR A RESEARCH, I PROBABLY DO NOT KNOW WHAT I DO NOT KNOW. HELP ME LEARN THE VOCABULARY, THE PROCEDURES, THE HOSPITAL SYSTEMS. TELL ME ABOUT THE ELEMENTS OF INFORMED CONSENT SO THAT I RECOGNIZE THEM WHEN I SEE THEM IN THE DOCUMENTS THAT YOU WANT ME TO SIGN. EXPLAIN THE DIFFERENCE BETWEEN STANDARD OF CARE AND EXPERIMENTAL TREATMENT. HELP ME UNDERSTAND THE RESEARCH QUESTION IN THE CONTEXT OF THE DISEASE IN GENERAL AND IN MY OWN AILMENT IN PARTICULAR. GIVE ME THE WORDS TO ASK THE QUESTIONS THAT I SHOULD BE ASKING.

SECONDLY, THERE ARE MANY DIFFERENT WAYS OF

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SHARING THIS INFORMATION: PRINT, VIDEO, WEBSITES, PEER MENTORS, NURSE EDUCATORS, RESEARCH TEAM MEMBERS. HIT THE TOPIC FROM ALL SIDES IN MULTIPLE FORMATS.

THIRDLY, PLEASE REALIZE THAT THERE IS A LEARNING CURVE FOR ME, AND IT IS CLOSELY TIED TO MY EMOTIONAL JOURNEY WITH MY PREDICAMENT. I MAY NOT BE ABLE TO ABSORB CERTAIN FACTS IN THE VERY BEGINNING; BUT A FEW WEEKS LATER, I MIGHT BE MENTALLY AND COGNITIVELY IN A DIFFERENT PLACE. OBVIOUSLY I MIGHT BE AN INEXPERIENCED RESEARCH SUBJECT WHEN I SIGN THE CONSENT FORM; BUT A FEW MONTHS LATER, I WILL BE A VASTLY MORE SOPHISTICATED PARTICIPANT. AND AT THAT TIME I NEED THE OPPORTUNITY TO ASK MY MORE CONSIDERED AND CONTEXT SAVVY QUESTIONS.

HERE'S WHAT I WANT TO POINT OUT. RESEARCHERS HAVE ACCESS TO A DEEP WELL OF WISDOM, A RESOURCE THAT CAN ADVISE AND SUPPORT ETHICAL ACTIONS THAT WILL HELP THEIR DISADVANTAGED PARTNERS. RESEARCHERS CAN ASK THEIR EXPERIENCED SUBJECTS FOR ADVICE. THOSE HUNDREDS OF FAMILIES I WORKED WITH WHOSE CHILDREN ULTIMATELY ENROLLED IN CLINICAL TRIALS, THESE EXPERIENCED PARENTS SAY, LET ME TELL YOU WHAT I NEEDED TO KNOW. LET ME TELL YOU HOW I NEEDED TO HEAR IT.

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

GETTING INPUT FROM THESE EXPERIENCED SUBJECTS AND CAREGIVERS DOES TWO THINGS. THE RESEARCH TEAM WILL BE LEVERAGING THE INVESTMENT THEY'VE ALREADY MADE INTO THESE PARTICIPANTS IN THEIR STUDIES. AND, SECONDLY, AND I THINK VERY IMPORTANTLY, THEY ARE EMPOWERING THE PREVIOUSLY DISADVANTAGED PARTNER. EXPERIENCED SUBJECTS CAN SHARE WHAT THEY HAVE LEARNED, THEY CAN GIVE SUGGESTIONS TO THE RESEARCH TEAM WHO MIGHT EVEN BUILD A STABLE OF PEER MENTORS WHO COULD HELP NEWBIES LEARN THE PROCESS.

EVERYTHING THAT I'VE SAID APPLIES TO ALL AVENUES OF CLINICAL RESEARCH, BUT THESE ARE ESPECIALLY IMPORTANT CONSIDERATIONS IN THE FACE OF NEW AND EXCITING SCIENCE. IT TOOK A LONG TIME FOR MORE TRADITIONAL RESEARCH PRACTICES TO EVOLVE INTO AN INVESTIGATOR/SUBJECT PARTNERSHIP MODEL. STEM CELL RESEARCH AND REGENERATIVE MEDICINE HAS THE OPPORTUNITY TO DO THIS FROM THE VERY START AND BENEFIT FROM THE LESSONS PREVIOUSLY LEARNED.

WHEN I WAS PREPARING THESE REMARKS, SOMEONE CASUALLY MENTIONED THAT I MIGHT TALK ABOUT THE IMPORTANCE OF BALANCING TRUTH TELLING IN THE INFORMED CONSENT PROCESS WITH THE RESPECT FOR THE HOPE OF THE FAMILY. I WOULD LIKE TO UNEQUIVOCALLY

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STATE THAT THE VERY NATURE OF AN INFORMED CONSENT PROCESS REQUIRES 100 PERCENT TRUTH. AND THAT IS HOW YOU SHOW THE UTMOST RESPECT FOR THE FAMILY, 100 PERCENT TRUTH. AND THIS DOES NOT UNDERMINE OUR CAPACITY FOR HOPE. WE PLACE OUR HOPE IN THIS EXCITING AND NEW SCIENCE AND IN THE DOCTORS AND RESEARCHERS WHO ARE THE PIONEERS. WE UNDERSTAND THAT THERE ARE MANY UNKNOWNS IN THIS NEW FIELD. PLEASE BE HONEST WITH US SO THAT WE MIGHT SORT OUT OUR THOUGHTS AND OUR HOPES FOR OURSELVES IN OUR OWN CONTEXT.

SO WHAT MESSAGE -- WHAT'S THE TAKEAWAY MESSAGE? WELL, I WOULD WANT YOU TO HEAR. I PUT ON MY PATIENT RESEARCH SUBJECT ADVOCATE HAT AND MY PATIENT SUBJECT ADVOCATE VOICE AND I WOULD SAY, "TELL ME WHAT I NEED TO KNOW." THANK YOU FOR LISTENING.

(APPLAUSE.)

MS. MC MILLAN: YOU HAVE ANY COMMENTS OR QUESTIONS?

CHAIRMAN THOMAS: MY ONE COMMENT IS IT WAS AN EXTREMELY POWERFUL SPEECH AS DELIVERED AT UCLA, AND IT HASN'T LOST ONE OUNCE OF POWER IN HEARING IT A SECOND TIME. SO THANK YOU. AND IT'S A PERSPECTIVE THAT IS CRITICAL FOR US AND ANYBODY IN

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

THE FIELD TO HEAR. SO THANK YOU VERY MUCH.

MS. MC MILLAN: THANKS VERY MUCH, AND THANK YOU FOR THE GOOD WORK THAT ALL OF YOU DO.

SUPERVISOR SHEEHY: SO HAS YOUR PERSPECTIVE INFORMED OUR ALPHA CLINICS? BECAUSE THIS IS VERY MUCH ALIGNED GOING BACK TO WHEN WE FIRST STARTED DISCUSSING THE CONCEPT AND VERY MUCH ALIGNED WITH SOME OF THE WAYS IN WHICH WE WERE ENVISIONING THESE TO FUNCTION BECAUSE THEY ARE ABOUT REGENERATIVE MEDICINE. AND IT'S NOT CLEAR TO ME THAT WE ACTUALLY HAVE BEEN ABLE TO OPERATIONALIZE IT IN THE WAY THAT YOU ARE TALKING ABOUT IT AND WE SHOULD. AND THE CLARITY AND THE THOUGHTFULNESS WITH WHICH YOU DEVELOPED YOUR ANALYSIS OF THIS WHOLE PROCESS I WOULD HOPE, GIVEN THAT WE HAVE, WHAT, FOUR OF THESE NOW, FIVE ALPHA CLINICS, I MEAN THIS SHOULD BE STRUCTURED AND ORGANIZED AND IMPLEMENTED AS PART OF OUR ALPHA CLINIC PROGRAM AS PART OF THE INNOVATION WE'RE DOING.

SO I DON'T KNOW IF THE TEAM HAS PICKED UP ON THAT, HOW WELL THIS ALIGNS. WE DO HAVE ONE ALPHA CLINIC DIRECTOR HERE PRESENTLY, I THINK, BUT IT WOULD BE INTERESTING TO REALLY, IF IT'S POSSIBLE, AND I KNOW YOU HAVE YOUR OWN DEMANDS ON YOUR TIME, BUT TO ACTUALLY -- ONE OF THE THINGS THAT HAS BEEN

GREAT ABOUT THIS AGENCY IS THAT WHEN WE HAVE MET INNOVATION, WE'VE ACTUALLY BEEN ABLE TO OPERATIONALIZE IT.

AND A THIRD OF OUR BOARD IS PATIENT ADVOCATES, AND THAT'S PARTIALLY OPERATIONALIZING PATIENT VOICES. BUT GIVEN THAT WE HAVE THIS INNOVATIVE PROGRAM, WE COULD GO FROM -- I THOUGHT IT WAS JUST BRILLIANT THE WAY IN WHICH YOU'VE REALLY BEEN ABLE TO ANALYZE THIS PIECE, THIS IMPORTANT RELATIONSHIP PIECE OF THE RESEARCH PROCESS, TO SEE IT OPERATIONALIZED IN PROGRAMS WHICH WE DIRECTLY FUND.

MS. MC MILLAN: I WOULD BE HAPPY TO WORK WITH YOU ON THAT KIND OF THING IF YOU ARE INTERESTED. IT'S BECAUSE I HAVE 20 YEARS IN THE FIELD IN A VARIETY, LIKE WITH SIGNIFICANT IRB EXPERIENCE AND I'VE WORKED WITH THE FDA AND I'VE WORKED ON REGULATORY COMMITTEES. SO I HAVE A CONTEXT THAT HELPS ME KIND OF FOCUS IN ON THE KEY ELEMENTS, ESPECIALLY FROM MY POINT OF VIEW AS AN ADVOCATE. SO I THINK YOUR IDEA OF OPERATIONALIZING IS REALLY IMPORTANT FOR WHAT YOU'RE DOING.

SUPERVISOR SHEEHY: WE ACTUALLY HAVE AN ALPHA CLINIC DIRECTOR HERE, JOHN ZAIA. WE COULD PUT THE CHARGE TO HIM RIGHT NOW. I REALLY -- THAT WAS

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AMAZING.

DR. ZAIA: WE REALLY BENEFITED FROM HEARING THIS TALK IN UCLA. AND CIRM ACTUALLY SET UP THE ALPHA CLINICS WITH THIS IN MIND. SO OUR PATIENT CARE COORDINATORS ARE THE EDUCATORS THAT MEET WITH THE PATIENTS AND PROVIDE A GOOD DEAL OF EDUCATION. BUT THEY HAVE TO HEAR IT MULTIPLE TIMES, ALMOST EVERY VISIT WHEN YOU COME BACK. AND THERE'S TWO KINDS OF PROBLEMS. THERE'S THE ACUTE CATASTROPHIC PROBLEM THAT YOU DESCRIBE WHERE EVERYBODY IS EMOTIONALLY UPSET, EVEN THE PHYSICIAN WHEN HE HAS A CHILD WITH THIS PROBLEM, AND THEN THERE'S THE CHRONIC DISEASE. LET'S SAY THE ALS PATIENTS AND THE PARKINSON'S. THEY'VE BEEN SICK FOR A WHILE. I THINK THEY CAN GRAPPLE WITH THIS EASIER.

UCLA HAS TACKLED THIS IN THE FOLLOWING WAY. THEY ARE DEVELOPING AN IPAD THAT WILL HAVE INFORMATION ABOUT THE PROTOCOL AND THE BACKGROUND INFORMATION, AND THEY JUST GIVE THE IPAD TO -- FOR A FEW HUNDRED BUCKS, YOU CAN GIVE THE IPAD TO THE PATIENT TO TAKE HOME, LOOK AT IT, READ ALL THE INFORMATION, AND COME BACK. THAT'S DIFFICULT BECAUSE FOR EACH PROTOCOL YOU HAVE TO PROGRAM THINGS. AND IF YOU WANT TO BUILD IT INTO THE CONSENT, YOU HAVE TO BE ABLE TO DOCUMENT THAT THE

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PATIENT AND THE FAMILY UNDERSTOOD EACH ITEM. AND IF THEY HAVE A QUESTION, THEY CAN MAKE A NOTE IN THE TEXT, AND THEN YOU CAN THEN INDICATE THAT YOU ANSWERED THAT QUESTION.

SO THAT REQUIRES A LITTLE MORE TECHNOLOGY THAT WE HAVEN'T MASTERED. I THINK WE'RE GETTING THERE SLOWLY, BUT SURELY. BUT YOUR SITUATION IS THE WORST OF ALL WHEN YOU HAVE THAT ACUTE CRISIS WHEN A NEWLY DIAGNOSED PATIENT ARRIVES. AND THEN YOU'VE GOT A FEW TRIALS, AND MANY TIMES YOU HAVE THREE OR FOUR, AND THAT BALANCE WHICH ONE IS THE ONE THEY WANT. THANK YOU.

SUPERVISOR SHEEHY: JUST CURIOUS. YOU RECOGNIZE THE MORAL AND ETHICAL OBLIGATION TO ADDRESS THE KNOWLEDGE AND POWER IMBALANCE. THAT'S JUST LIKE IS THAT A PRINCIPLE? I MEAN THAT -- AND THAT REALLY GOES TO THE HEART OF IT. I HEAR YOU SAYING GIVE INFORMATION. I DO THINK THAT PART OF WHEN WE WERE TALKING ABOUT INFORMED CONSENT, GEOFF WILL REMEMBER, WE DID WANT TO DO A LITERACY -- LITERACY IS NOT THE RIGHT WORD, BUT WHERE THE PEOPLE UNDERSTOOD WHAT THEY WERE DOING AND PUT IN MEASURES TO MAKE THAT FIRMER. BUT REALLY THIS WHOLE KNOWLEDGE IMBALANCE AND RECOGNIZING THAT AS A MORAL AND ETHICAL OBLIGATION, I FEEL LIKE THAT SHOULD BE A

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PRINCIPLE THAT WE ENSHRINE.

MS. MC MILLAN: I'M GOING TO SAY IF YOU LOOK AT THE HISTORY OF THE PHYSICIAN/PATIENT RELATIONSHIP, THAT'S ALMOST -- IT'S LIKE A SACRED RELATIONSHIP WHERE THE WELL-BEING OF THE PATIENT IS THE MOST IMPORTANT THING. THE RELATIONSHIP BETWEEN A SUBJECT AND AN INVESTIGATOR, THE PURPOSE OF THAT RELATIONSHIP IS TO GENERATE INFORMATION AND IT IS NOT TO BENEFIT THE SUBJECT. SO THERE'S A PATIENT, AND THAT WHOLE WORD "PATIENT" IMPLIES SOMETHING, AND A RESEARCH SUBJECT IS NOT A PATIENT. IT'S A RESEARCH SUBJECT WHO'S PARTICIPATING IN ORDER TO GENERATE NEW INFORMATION.

WHAT'S THE GOAL? WHERE IS THE GOAL GENERATED? IT'S GENERATED FROM WHAT THE INVESTIGATOR IS TRYING TO LEARN. HERE IT'S FROM THE PATIENT -- THIS IS WHAT THE PATIENT NEEDS. HERE'S WHAT THE INVESTIGATOR NEEDS. AND FOR THAT REASON, IN THE SUBJECT/INVESTIGATOR RELATIONSHIP, THERE IS AN INHERENT IMBALANCE. BUT THAT'S OKAY AS LONG AS WE ACKNOWLEDGE IT AND AS LONG AS WE DEAL WITH IT AND PUT IT IN A CONTEXT WHERE AS MUCH JUSTICE AND FAIRNESS CAN HAPPEN.

BY THE WAY, WHEN I GIVE THESE KINDS OF TALKS, NOT JUST TO SCIENTISTS AND PHYSICIANS, BUT

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ALSO TO PATIENT GROUPS, BECAUSE THEY HAVE A RESPONSIBILITY ALSO TO STAND UP FOR THEMSELVES, TO EDUCATE THEMSELVES, AND INTERACT IN AN APPROPRIATE AND RATIONAL WAY WITH PHYSICIANS AND SCIENTISTS. SO THERE ARE TWO PARTIES HERE, AND THEY BOTH HAVE WORK TO DO. BUT YOU CAN'T GET AWAY FROM THE FACT THAT IN THIS INSTANCE THERE IS AN IMBALANCE, BUT OKAY SO THEN WE ACKNOWLEDGE IT AND WE DO SOMETHING ABOUT IT. THAT'S WHAT I THINK IS THE ETHICAL IMPERATIVE THERE.

ANYWAY, THANK YOU VERY MUCH FOR YOUR ATTENTION.

SUPERVISOR SHEEHY: THANK YOU.

MR. ROWLETT: JUST ONE PERSPECTIVE OF A PATIENT ADVOCATE, THE TRIAD THAT YOU DESCRIBE, HAVING A PERSON WITH LIVED EXPERIENCE WITH THE INVESTIGATOR WITH THE SUBJECT. IDEALLY IT SPEAKS TO, I THINK, WHAT PHILOSOPHICALLY JEFF IS TALKING ABOUT. AND THEN EMPHASIZING TO THE SUBJECT AS A PERSON WITH LIVED EXPERIENCE THE IMPORTANCE OF THEM DOING SOME OF THEIR OWN RESEARCH AND BECOMING INFORMED TO BE ABLE TO NOT JUST QUALITATIVELY, BUT QUANTITATIVELY RESPOND TO WHAT'S BEING PRESENTED TO THEM. AND, AGAIN, I WOULD SAY THAT WITHOUT DETRACTING FROM WHAT YOU SAID, IN MY OWN LIFE JOURNEY, I'VE UNDERSTOOD THE IMPORTANCE OF HAVING A

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PATIENT ADVOCATE BECAUSE WHEN YOU HEAR THAT, WHAT YOU HEARD, IT BECOMES IMMOBILIZING. SO YOU SIT THERE WONDERING, WELL, I'M AN ARTICULATE PERSON, BUT RIGHT NOW I JUST GOT TOLD I HAVE CANCER AND I DON'T KNOW WHAT TO DO WITH THAT. SO HAVING A PERSON WITH LIVED EXPERIENCE HELP YOU NORMALIZE THAT AND THEN WALK THROUGH THAT TO ANSWER QUESTIONS, ESPECIALLY IN THE INITIAL PHASE AFTER YOU'VE GIVEN THE INFORMED CONSENT, IS WHAT YOU JUST DESCRIBED. A CRITICAL AND IMPORTANT MODEL FOR THE FUTURE. THANK YOU.

DR. MALKAS: ACTUALLY I JUST WANTED TO ADD IT WAS WONDERFUL, AND I LOVED THE IDEA OF THE MENTORSHIP FOR THESE. I GUESS THE THING IS FOR CIRM TO CONSIDER, AND NOT JUST CIRM, BUT ALPHA CLINICS, BUT TO ACTUALLY BUILD A PIPELINE OF THESE TYPE OF PEOPLE. SO IT'S A NEW SKILL SET ALMOST THAT HAS TO BE CONSTRUCTED.

MS. MC MILLAN: IT IS ABSOLUTELY A NEW SKILL SET. IN MY PREVIOUS WORK, WE ACTUALLY DESIGNED WHAT WE CALLED A VETERAN PARENT PROGRAM, WHICH WOULD BE PARENTS WHO ARE EXPERIENCED WITH THEIR CHILDREN HAVING BRAIN TUMORS WHO WERE AT A CERTAIN PLACE IN THEIR JOURNEY. WE TRAINED THEM TO BE PEER MENTORS WHO THEN HELPED THE NEWLY DIAGNOSED.

ONE THING ABOUT THIS THAT WORKED IN MY

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ORGANIZATION WAS THAT THEY COME NEEDING HELP, THEY'RE AT THE MOST VULNERABLE, AND THEY GET A PEER MENTOR. LATER ON DOWN THE PATH, THEY ARE TRAINED TO HELP SOMEBODY ELSE WHICH BECOMES THE LAST PART OF THEIR HEALING CYCLE. SO THAT THEY ARE -- THEY START OFF AS SORT OF VICTIMIZED AND AT A DISADVANTAGE, AND IN THE END THEY HAVE SOME KIND OF POWER AND AGENCY OVER THEIR OWN EXPERIENCE AND THEY CAN HELP SOMEBODY ELSE. IT'S BEAUTIFUL. IT'S TAKES VERY SPECIFIC TRAINING, AND NOT EVERYONE HAS THE TEMPERAMENT TO BE AN EFFECTIVE PEER MENTOR. THERE'S A LARGE BODY OF WORK AND RESEARCH ON THAT AND MANY PROGRAMS THAT DO THIS KIND OF THING THAT COULD BE GENERALIZED TO WHAT YOU DO HERE.

SUPERVISOR SHEEHY: ALSO COULD SUPPORT ADVOCATES. ANYBODY WHO'S DONE ADVOCACY GENERALLY RECOGNIZES IT DOESN'T PAY.

CHAIRMAN THOMAS: THANK YOU VERY MUCH. AND, KEVIN, THANK YOU FOR INVITING OUR SPEAKER. THAT WAS WONDERFUL AND VERY IMPORTANT TO HEAR.

WE'RE DOWN TO GENERAL PUBLIC COMMENT. DOES ANYBODY HAVE ANYTHING THEY WOULD LIKE TO COMMENT ABOUT EITHER HERE OR ON THE PHONE? OKAY. HEARING NONE, BEFORE WE ADJOURN, JUST AS ALWAYS, LIKE TO THANK OUR VERY HARDWORKING TEAM WHO PUT THIS

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TOGETHER, AMY, DOUG, TRICIA, EVERYBODY WHO HAD A ROLE IN STAGING THIS, IT WAS ANOTHER WONDERFUL MEETING HERE AT HEADQUARTERS. THANK YOU VERY MUCH FOR ALL YOUR HARD WORK.

WITH THAT, LET YOU KNOW THAT OUR NEXT MEETING OF THE ICOC AND APPLICATION REVIEW SUBCOMMITTEE IS JULY 19TH. THAT'S TELEPHONIC. AND OUR NEXT IN-PERSON MEETING IS OCTOBER 18TH ALSO HERE AT HEADQUARTERS. WITH THAT, THANK YOU VERY MUCH, EVERYBODY. WE STAND ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 1:23 P.M.)

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REPORTER'S CERTIFICATE

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

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SUITE 1650
OAKLAND, CALIFORNIA
ON
JUNE 28, 2018

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.

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