BEFORE THE

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

EMERGENCY MEETING

LOCATION: MEETING CONDUCTED VIA ZOOM

DATE: APRIL 10, 2020
11 A.M.

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

FILE NO.: 2020-07

I N D E X

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APRIL 10, 2020; 11 A.M.

CHAIRMAN THOMAS: OKAY. WELL, THANK YOU, EVERYBODY. I'D LIKE TO WELCOME ALL TO THE FIRST OFFICIAL ZOOM MEETING OF THE ICOC AND APPLICATION REVIEW SUBCOMMITTEE. WANT TO THANK EVERYBODY FOR BEING AVAILABLE FOR THIS SECOND EMERGENCY SESSION AND EXTREMELY SHORT NOTICE, AND SHOUT OUT GOES TO MARIA BONNEVILLE FOR PULLING THIS ALTOGETHER IN WORLD RECORD TIME.

MS. BONNEVILLE: IT WAS A BIG GROUP EFFORT. SO THANK YOU TO DOUG AND TRICIA AS WELL.

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

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: HERE.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: PRESENT.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: HERE.

MS. BONNEVILLE: DEBORAH DEAS. ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: HERE.

UNIDENTIFIED SPEAKER: SORRY THE VIDEO IS NOT WORKING, BUT THEY'LL BE ABLE TO HEAR YOU.

MS. BONNEVILLE: LEON FINE.

DR. FINE: YES.

MS. BONNEVILLE: JUDY GASSON. JUDY, I KNOW YOU'RE ON. I THINK YOU'RE ON MUTE. WE'LL COME BACK TO JUDY.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: LINDA MALKAS. LINDA, I THINK YOU ALSO ARE ON. ARE YOU ON MUTE? HOLD ON. LET ME GO BACK TO JUDY. JUDY IS NOT ON MUTE, BUT CANNOT TALK FOR SOME REASON. I DON'T KNOW WHY. AND, LINDA, YOU'RE ALSO NOT ON MUTE. I SEE YOU ON THERE. SO LET ME COME BACK TO YOU GUYS.

DAVE MARTIN. DAVE, YOU'RE ON MUTE. I CAN SEE THAT YOU'RE ON MUTE. NO, YOU'RE STILL ON MUTE.

LAUREN MILLER. ADRIANA PADILLA.

DR. MARTIN: ALL RIGHT. DAVE'S HERE.

MS. BONNEVILLE: ADRIANA, I ALSO SEE YOUR NAME, BUT YOU'RE ON MUTE. NO, YOU'RE NOT ON MUTE, BUT YOU'RE NOT ABLE TO SPEAK.

DR. MARTIN: THERE'S A LITTLE MUTE TAG AT THE VERY UP RIGHT-HAND CORNER ON THE SCREEN. MY PHONE WASN'T MUTED, BUT YOU HAVE TO UNMUTE THAT.

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THAT'S WHAT I JUST DISCOVERED.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: HERE.

MS. BONNEVILLE: AL ROWLETT. SUZANNE SANDMEYER.

DR. SANDMEYER: HERE.

MS. BONNEVILLE: JEFF SHEEHY. OSWALD STEWARD. JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE. I CHOSE MY BACKGROUND FOR MR. BLUMENTHAL.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: HERE.

MS. BONNEVILLE: DIANE WINOKUR. KEITH YAMAMOTO AND DOUG ZIEDONIS.

DR. ZIEDONIS: I'M HERE.

MS. BONNEVILLE: THANK YOU. J.T, CAN YOU HOLD ON FOR A SECOND BECAUSE I KNOW WE'VE GOT SOME PEOPLE THAT JUST ARE NOT ABLE TO DIAL IN. WAS THAT KEITH THAT SAID HE WAS HERE OR WAS THAT DOUG?

DR. ZIEDONIS: DOUG ZIEDONIS.

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MS. BONNEVILLE: OKAY. THANK YOU. HOLD ON FOR ONE SECOND. JUST GIVE US TWO MINUTES. WE'RE UNMUTING EVERYONE ON OUR END TO SEE IF THAT HELPS WITH A FEW OF THE PEOPLE.

DR. MARTIN: WE CAN HEAR YOU NOW.

MS. BONNEVILLE: WE CAN SEE LINDA, BUT I CAN'T HEAR HER.

DR. MALKAS: YOU CAN SEE ME?

MS. BONNEVILLE: OH, I CAN SEE YOU AND I CAN HEAR YOU NOW. AWESOME. THERE YOU ARE.

JUDY GASSON. STILL NOT YET. HOW ABOUT ADRIANA PADILLA?

MR. TORRES: SHE JUST E-MAILED A CHAT REQUESTING TO PHONE IN.

MS. BONNEVILLE: CAN I CHOOSE PHONE CHECK-IN? HOLD ON FOR ONE SECOND. LET ME SEE ABOUT THAT. LET ME GET BACK TO ADRIANA. HOW ABOUT FRANCISCO PRIETO?

DR. GASSON: MARIA, THIS IS JUDY. I'M HERE.

MS. BONNEVILLE: OH, JUDY. THANK YOU. WE CAN HEAR YOU. THANK YOU.

HOW ABOUT AL ROWLETT?

DR. YAMAMOTO: MARIA, THIS IS KEITH YAMAMOTO. I'M HERE.

MS. BONNEVILLE: DOUG, CAN YOU CHECK ON ADRIANA AND FRANCISCO, AL, AND OS? FRANCISCO, CAN YOU HEAR US AND CAN WE HEAR YOU, I HOPE?

DR. PRIETO: YES, I CAN HEAR YOU NOW. YOU CAN HEAR ME?

MS. BONNEVILLE: YES, WE CAN. HOW ABOUT AL ROWLETT? JEFF SHEEHY, ARE YOU ON?

MR. SHEEHY: YES, I AM.

MS. BONNEVILLE: EXCELLENT. THANK YOU. HOW ABOUT OS? HE SAYS HE'S ON THE PHONE, BUT WE CAN'T HEAR OS. AL IS CALLING BACK IN. STAR SIX.

MR. ROWLETT: MARIA, CAN YOU HEAR ME?

MS. BONNEVILLE: YES. IT'S GREAT TO HEAR YOU, AL.

DR. PADILLA: THIS IS ADRIANA. CAN YOU HEAR ME?

MS. BONNEVILLE: WE CAN. THANK YOU, ADRIANA. I THINK THE ONLY ONE WE'RE MISSING NOW IS OS AND DIANE.

DR. STEWARD: I'M HERE.

MS. WINOKUR: I'M HERE.

MS. BONNEVILLE: OH, WE'VE GOT YOU GUYS. THAT'S GREAT.

OKAY. SO WE'VE GOT ROLL TAKEN CARE OF NOW.

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CHAIRMAN THOMAS: MARIA, WOULD YOU LIKE TO SAY A COUPLE WORDS ABOUT PROCEDURE HERE USING ZOOM WITH QUESTIONS THAT PARTICIPANTS FROM THE BOARD AND THE PUBLIC MAY HAVE?

MS. BONNEVILLE: I THINK WE CAN DO WHAT WE DID LAST TIME, WHICH IS IF YOU HAVE A QUESTION AFTER THE PRESENTATION, JUST LET US KNOW. I'LL WRITE IT DOWN IN ORDER, AND THEN WE CAN CALL ON BOARD MEMBERS AS THEY LET ME KNOW.

AND THEN FOR MEMBERS OF THE PUBLIC, IT WOULD BE THE SAME. IT WOULD BE A THREE-MINUTE LIMIT ON COMMENTS, AND WE CAN DO THE SAME. WE CAN GO THROUGH THE LIST AS PEOPLE RAISE THEIR HANDS OR ASK TO BE CALLED ON. WE CAN THEN TAKE THEM THAT WAY AS WELL.

AND I WOULD JUST LIKE TO REMIND MEMBERS OF THE PUBLIC TO LIMIT PUBLIC COMMENT TO THE AGENDA TOPIC AT HAND. AND THEN IF YOU HAVE GENERAL PUBLIC COMMENT, THAT CAN BE TAKEN AT THE END OF THE MEETING.

CHAIRMAN THOMAS: OKAY. THANK YOU VERY MUCH, MARIA. AND, AGAIN, THANK YOU TO ALL MEMBERS OF THE BOARD AND THE PUBLIC FOR PARTICIPATING TODAY. VERY MUCH HOPE EVERYBODY IS SAFE AND HEALTHY IN THESE MOST UNSETTLING TIMES.

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WE'RE GOING TO PROCEED NOW TO THE ACTION ITEMS. NO. 4 AGENDA TOPIC IS CONSIDERATION OF EXISTENCE OF EMERGENCY SITUATION. EMERGENCY SITUATION MEANS ANY OF THE FOLLOWING AS DETERMINED BY A MAJORITY OF THE MEMBERS OF THE ICOC: A) WORK STOPPAGE OR OTHER ACTIVITY THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY OR BOTH; OR, B) CRIPPLING DISASTER THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY OR BOTH.

OPEN IT UP FOR A MOTION TO BEGIN WITH.

DR. BLUMENTHAL: SO MOVED.

DR. BURTIS: SECOND.

MS. BONNEVILLE: WHO MOVED AND SECONDED, PLEASE?

DR. BLUMENTHAL: BLUMENTHAL MOVED.

MS. BONNEVILLE: THANK YOU.

DR. BURTIS: KEN BURTIS SECONDED.

DR. YAMAMOTO: KEITH YAMAMOTO SECOND.

MS. BONNEVILLE: OKAY. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, EVERYBODY. OPEN IT UP FOR DISCUSSION. AND KEEP IN MIND THIS IS NOT A DISCUSSION ON THE SUBSTANCE OF THE VRO ISSUE. THIS IS A DISCUSSION ON WHETHER OR NOT THIS CONSTITUTES AN EMERGENCY SITUATION AS PROVIDED BY PROP 71.

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ARE THERE ANY COMMENTS FROM MEMBERS OF THE BOARD? HEARING NONE, ARE THERE COMMENTS FROM MEMBERS OF THE PUBLIC? HEARING NONE, WE'LL PROCEED STRAIGHT TO A ROLL CALL VOTE. JAMES, WILL YOU CALL THE ROLL -- MARIA.

MS. BONNEVILLE: I SURE WILL.

GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: YES.

MS. BONNEVILLE: LEON FINE.

DR. FINE: YES.

MS. BONNEVILLE: JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: LINDA MALKAS.

DR. MALKAS: YES.

MS. BONNEVILLE: DAVE MARTIN. ADRIANA

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PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO.

DR. PRIETO: AYE.

MS. BONNEVILLE: ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: SUZANNE SANDMEYER.

DR. SANDMEYER: YES.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OSWALD STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: YES.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: KEITH YAMAMOTO.

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DR. YAMAMOTO: YES.

MS. BONNEVILLE: DOUG ZIEDONIS.

DR. MARTIN: AND DAVE MARTIN YES.

MS. BONNEVILLE: DAVE MARTIN. THANK YOU. MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU, MARIA.

SO, AS YOU ALL ARE AWARE, PROP 71, IN ADDITION TO THE PROJECTS THAT WE NORMALLY HAVE FUNDED OVER THE YEARS, HAS ALWAYS ALLOWED FOR CONSIDERATION OF SOMETHING CALLED VITAL RESEARCH OPPORTUNITIES, WHICH ARE PROJECTS THAT ARE NOT IN SCOPE DIRECTLY, BUT ARE DEEMED BY THE BOARD AND THE GWG TO BE OF SUCH IMPORT AND RELATION TO WHAT WE DO THAT WE WOULD CONSIDER THEM FOR FUNDING AS WELL.

THE PROCESS THAT WE'VE UNDERTAKEN IN SIMILAR CIRCUMSTANCES BEFORE, IF WE HAVE VITAL RESEARCH OPPORTUNITIES, WHICH I SHALL REFER TO AS VRO'S FROM HERE ON OUT, PROCESS WAS TYPIFIED BY AN AGENDA ITEM AT OUR NOVEMBER 2018 BOARD MEETING WHERE WE CONSIDERED THE QUESTION OF WOULD GENE THERAPY AS A CATEGORY QUALIFY FROM AN ELIGIBILITY STANDPOINT FOR SOMETHING THAT THE GWG SHOULD EVALUATE IN ITS NORMAL COURSE. WE HAD A DISCUSSION ON THAT TOPIC. THE BOARD AT THAT MEETING DETERMINED THAT GENE THERAPY WOULD QUALIFY AS A VRO. WE THEN HAD

PROJECTS SUBMITTED THAT WENT TO THE GWG FOR CONSIDERATION BOTH ON SCIENTIFIC MERIT AND ON THE QUESTION OF DOES THIS QUALIFY FOR A VRO OR NOT.

PROJECTS THAT PROCEEDED THROUGH THAT PROCEDURE, IF THEY WERE DEEMED TO BE A VRO, THEY THEN WENT TO THE BOARD AND THE APPLICATION REVIEW SUBCOMMITTEE FOR A FUNDING DECISION THAT THOSE PROJECTS THAT AT THE GWG WERE NOT DEEMED TO BE A VRO, THAT WAS THE END OF THE LINE AND THE PROJECTS WERE WITHDRAWN AT THAT POINT AND DID NOT GO TO THE BOARD OR APPLICATION REVIEW SUBCOMMITTEE FOR ANY FURTHER CONSIDERATION.

SO THAT'S THE PROCESS THAT WE HAVE HAD IN THE PAST. IT'S THE PROCESS WE'RE GOING TO FOLLOW HERE. YOU MAY RECALL AT OUR FIRST EMERGENCY SESSION A COUPLE WEEKS AGO IN PUBLIC COMMENT THERE WAS MENTION OF THE TOPIC OF CONVALESCENT PLASMA. WE HAVE HAD A LOT OF DISCUSSION SINCE THAT BOARD MEETING BOTH INTERNALLY AND INDEED NATIONALLY AND INTERNATIONALLY ON THE TOPIC.

AND SO THE QUESTION HAS ARISEN, GIVEN THAT CONVALESCENT PLASMA IS ONE OF THOSE PROJECT TYPES THAT FALLS OUTSIDE THE SCOPE OF WHAT WE NORMALLY FUND, WOULD THIS BE SOMETHING THAT SHOULD BE DEEMED ELIGIBLE FOR REVIEW BY THE GWG AS A GENERAL TOPIC.

AND SO IT IS TO THAT END THAT WE CALLED THIS SECOND EMERGENCY SESSION TO DISCUSS THAT MATTER; AND, HENCE, WE HAVE ITEM 5 ON THE AGENDA, WHICH READS SPECIFICALLY, "CONSIDERATION OF MODIFICATIONS TO COVID-19 PROJECTS PROGRAM ANNOUNCEMENT TO EXPAND ELIGIBILITY AND MAKE OTHER CHANGES."

SO WHAT WE'RE GOING TO DO HERE IS WE'RE GOING TO HAVE A PRESENTATION FROM DR. SAMBRANO ALL AROUND THE QUESTION OF SHOULD CONVALESCENT PLASMA CONSTITUTE A VRO FOR ELIGIBILITY PURPOSES FOR GWG ANALYSIS. THERE ARE A COUPLE OF SUBQUESTIONS THAT ATTEND TO THAT OVERALL QUESTION, WHICH DR. SAMBRANO WILL BRING UP AS WELL IN HIS PRESENTATION.

SO WITHOUT FURTHER ADO HERE, WHY DON'T WE TURN TO DR. SAMBRANO FOR THAT PRESENTATION. AND AFTER THAT TIME, WE WILL HAVE FULL OPPORTUNITY FOR THE BOARD AND MEMBERS OF THE PUBLIC TO DISCUSS. DR. SAMBRANO.

DR. SAMBRANO: GREAT. THANK YOU, DR. THOMAS.

MEMBERS OF THE BOARD, CIRM TEAM, AND THE PUBLIC, REALLY GOOD TO SEE EVEN IF IT'S ONLY ON VIDEO, BUT GOOD MORNING TO ALL OF YOU.

SO AS MENTIONED, TWO WEEKS AGO WE CAME BEFORE YOU TO PRESENT A PROPOSED SOLICITATION FOR

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COVID-19 PROJECTS. AND SO IF YOU COULD GO TO THE NEXT SLIDE PLEASE, DOUG. SO WE PROVIDED A PROPOSAL FOR ISSUING THAT SOLICITATION. SO THAT HAS BEEN DONE. WE'VE ACTUALLY EVEN HAD OUR FIRST APPLICATION DEADLINE. AND SO WE ARE UTILIZING OUR PROGRAMS ACROSS DISCOVERY AND CLINICAL IN ORDER TO FACILITATE THE APPLICATION REVIEW AND FUNDING PROCESS.

ALSO AT THAT TIME THE BOARD APPROVED AN ALLOCATION OF FIVE MILLION TO SUPPORT THIS PROGRAM. NEXT SLIDE PLEASE.

AND AS WAS ALSO MENTIONED, WE WERE ASKED TO CONSIDER CONVALESCENT PLASMA AS AN OPPORTUNITY TO MAKE AN IMMEDIATE IMPACT ON COVID-19 AT THE LAST BOARD MEETING. AND WE HAVE INDEED LOOKED INTO IT A BIT, AND WE DO AGREE THAT THIS IS AN AREA OF INVESTIGATION THAT DESERVES ATTENTION. SO IN LIGHT OF THIS, THERE'S THREE AMENDMENTS THAT WE'D LIKE TO DISCUSS WITH YOU THAT ARE OUTLINED ON THIS SLIDE, WHICH INCLUDE INCREASING THE SCOPE TO INCLUDE INVESTIGATIONAL STUDIES WITH CONVALESCENT PLASMA AND ITS DERIVATIVES AS A POTENTIAL VITAL RESEARCH OPPORTUNITY.

SECONDLY, TO ALLOW THE USE OF FDA SINGLE-PATIENT EMERGENCY IND PATHWAY FOR CLINICAL STUDIES WITH CONVALESCENT PLASMA.

AND, FINALLY, TO ALLOW FUNDED CLINICAL PROJECTS TO START INCURRING ALLOWABLE PROJECT COSTS FROM THE DATE OF THE APPLICATION SUBMISSION DEADLINE. NEXT SLIDE.

SO LET ME FIRST GIVE YOU A LITTLE BACKGROUND ON CONVALESCENT PLASMA AND WHY IT IS THAT IT COULD OFFER A POTENTIAL VITAL RESEARCH OPPORTUNITY.

SO, AS MANY OF YOU MAY KNOW, CONVALESCENT PLASMA IS THE COMPONENT IN BLOOD THAT'S COLLECTED FROM PATIENTS WHO HAVE RECOVERED FROM AN INFECTION, IN THIS CASE FROM COVID-19, THAT CONTAINS ANTIBODIES AGAINST THE VIRUS. SO THE USE OF CONVALESCENT PLASMA IS AND REMAINS AN INVESTIGATIONAL TREATMENT FOR PATIENTS. IT IS GENERALLY CONSIDERED SAFE, AND IT HAS BEEN USED SINCE EVEN THE EMERGENCE OF THE SPANISH FLU BACK IN THE 1918/1920, AND MORE RECENTLY WITH H1N1, THE AVIAN FLU, AND SARS 1.

MOST RECENTLY THERE HAVE BEEN SOME PUBLICATIONS THAT SHOW PROMISE IN THE CLINICAL SETTING FOR COVID-19 PATIENTS. BUT DESPITE ALL THIS, IT'S STILL NOT YET AN APPROVED PRODUCT UNDER THE FDA. HOWEVER, THE FDA HAS ISSUED SOME SPECIAL GUIDANCE RELATED TO THE USE OF CONVALESCENT PLASMA TO TREAT COVID-19 GIVEN THAT THERE ARE NO OTHER

TREATMENTS AVAILABLE AND THAT THERE IS SOME INDICATION OF PROMISE FOR ITS USE. AND SO THE FDA IS PERMITTING EMERGENCY INVESTIGATIONAL USE UNDER THE CRITERIA OF AN EMERGENCY IND IN ADDITION TO USE OF A STANDARD IND PATHWAY.

SO CLEARLY MORE CLINICAL DATA THAT IS COLLECTED FROM WELL-DESIGNED TRIALS AND STUDIES IS NEEDED ULTIMATELY TO DETERMINE IF THIS APPROACH COULD BE USED MORE BROADLY.

SO HOW IS IT THAT CIRM COULD MAKE AN IMPACT AND HOW ARE WE UNIQUELY POSITIONED TO DO SO? SO THERE'S THREE BASIC THINGS THAT WE THOUGHT WERE IMPORTANT. SO, FIRST, WE WANT TO FUND PROJECTS THAT USE CONVALESCENT PLASMA AS A TREATMENT FOR PATIENTS IN NEED. THERE ARE OTHERS WHO ARE EXPLORING THE USE OF CONVALESCENT PLASMA AS A PROPHYLAXIS THAT WOULD BE IN GENERALLY HEALTHY INDIVIDUALS, FIRST RESPONDERS, AND SO ON; BUT WE ARE LOOKING TO MAKE AN IMPACT ON PATIENTS WHO ARE SICK, WHO HAVE COVID-19, AND WHERE WE COULD HAVE AN IMPACT ON PEOPLE'S LIVES. SO WE WANT TO FOCUS ON THAT.

CIRM WOULD ALSO SUPPORT FORMAL STUDIES THAT COLLECT CLINICAL DATA FOR ANALYSIS AND TO BETTER ASSESS THE SCIENTIFIC AND MEDICAL VALUE OF THE THERAPEUTIC APPROACH. THIS IS IN ORDER TO

REALLY INFORM WHETHER THIS IS AN APPROACH THAT CAN BE USED MORE BROADLY.

WE ALSO BELIEVE THAT CIRM CAN LEVERAGE THE INFRASTRUCTURE IN CALIFORNIA, SUCH AS ESTABLISHED CLINICAL NETWORKS, TO REACH MORE PATIENTS AND FACILITATE THE PLASMA COLLECTION. AND, OF COURSE, IF THIS IS SOMETHING THAT HAS AND SHOWS EVIDENCE OF WORKING, WE'D OBVIOUSLY BE CONTRIBUTING TO MAKING AN IMMEDIATE IMPACT ON THIS DISEASE.

SO THE NEXT SLIDE, PLEASE. SO I'LL GO OVER THE THREE REQUESTS FOR THE BOARD. THE FIRST ONE IS TO DETERMINE IF CONVALESCENT PLASMA AND ITS DERIVATIVES, SUCH AS IMMUNOGLOBULIN CONTAINED WITHIN THE PLASMA, FOR THE TREATMENT OF COVID-19 SHOULD BE ELIGIBLE FOR FUNDING UNDER CIRM. AND SO NORMALLY THIS IS A BIOLOGIC THAT'S NOT ELIGIBLE FOR ENTRY BECAUSE, AS MENTIONED PREVIOUSLY, THIS DOES NOT CONTAIN STEM CELLS, IT IS NOT A STEM-CELL BASED PRODUCT. BUT UNDER PROP 71 WE'RE PERMITTED TO FUND PROJECTS THAT ARE NOT STEM-CELL RELATED IF THEY ARE DEEMED A VITAL RESEARCH OPPORTUNITY BY THE BOARD AND THE GRANTS WORKING GROUP.

AND THE DEFINITION OF VITAL RESEARCH OPPORTUNITY AS FOUND IN PROP 71 IS QUOTED THERE. SO IF THE BOARD DETERMINES THAT CONVALESCENT PLASMA

PROJECTS ARE A POTENTIAL VITAL RESEARCH OPPORTUNITY, THEN WE WOULD AMEND THE COVID-19 PROGRAM ANNOUNCEMENT TO INCLUDE CONVALESCENT PLASMA AND ITS DERIVATIVES AS ELIGIBLE FOR FUNDING. THESE WOULD UNDERGO GWG REVIEW BASED ON THE VITAL RESEARCH OPPORTUNITY PROCESS USED FOR GENE THERAPY APPLICATIONS WHERE THE GWG WOULD VOTE WHETHER OR NOT THEY BELIEVE IT'S A VITAL RESEARCH OPPORTUNITY. AND THEN IF IT IS, WE WOULD BRING THAT TO YOU FOR APPROVAL.

SO THE NEXT ITEM FOR CONSIDERATION IS OR FOR AMENDMENT IS CLINICAL STUDIES OF CONVALESCENT PLASMA. SO THOSE THAT PROPOSE TO USE CONVALESCENT PLASMA MAY PROPOSE USE OF FDA'S SINGLE-PATIENT EMERGENCY IND PATHWAY IN ORDER TO SATISFY THE CLIN2 ELIGIBILITY REQUIREMENTS FOR A TRADITIONAL IND.

SO WHAT THIS WOULD ALLOW IS REACHING MORE PATIENTS. AND GIVEN THAT CONVALESCENT PLASMA IS SOMETHING THAT IS DETERMINED FOR PATIENT TREATMENT ON A REAL-TIME BASIS, WE FELT THAT FOLLOWING ALONG WITH THE FDA'S GUIDANCE AND ADVICE TO INCLUDE THOSE EMERGENCY IND PATHWAYS SHOULD ALSO BE PART OF THE CLINICAL STUDIES THAT WE SUPPORT.

SO, LASTLY, WE SUGGEST THAT ALL FUNDED CLINICAL PROGRAMS, SO THIS WOULD BE THOSE THAT

INCLUDE CONVALESCENT PLASMA, BUT BASICALLY ANYTHING THAT COMES IN THROUGH THE CLIN1 OR CLIN2, THAT THEY MAY START INCURRING ALLOWABLE PROJECT COSTS, OF COURSE, IT WOULD DO SO AT RISK, FROM THE DATE OF THE APPLICATION SUBMISSION DEADLINE. CURRENTLY APPLICANTS OR ULTIMATELY GRANTEES CANNOT INCUR COSTS UNTIL AFTER THE BOARD APPROVAL. BY EXTENDING THIS BACK TO THE DATE OF THE SUBMISSION DEADLINE, IT ALLOWS PROJECTS TO BEGIN FASTER THAN THEY OTHERWISE WOULD. AND CERTAINLY FOR PROMISING PROJECTS, THAT WOULD BE AN ADVANTAGE FOR THEM. OF COURSE, ONCE AGAIN, DOING SO WOULD BE AT THEIR OWN RISK BECAUSE IF WE CANNOT OR DO NOT ULTIMATELY FUND IT, WE CAN'T COVER THOSE COSTS.

SO THOSE ARE THE THREE REQUESTS TO YOU THE BOARD, AND SO THAT IS THE CONCLUSION OF MY PRESENTATION. DR. THOMAS.

CHAIRMAN THOMAS: THANK YOU, DR. SAMBRANO. WE'VE HEARD THE ASK HERE WITH ITS SUBPARTS. DO I HAVE A MOTION TO APPROVE?

DR. PRIETO: SO MOVED.

MS. WINOKUR: SECOND.

CHAIRMAN THOMAS: I THINK DIANE WAS THE SECOND.

MS. WINOKUR: YES.

MS. BONNEVILLE: THANK YOU. QUICKLY, I JUST WANT TO CONFIRM THAT DAVID HIGGINS HAS JOINED THE CALL.

MR. TORRES: I HAVE A QUESTION.

DR. HIGGINS: YES, MARIA, I'M HERE.

CHAIRMAN THOMAS: YES, SENATOR TORRES.

MR. TORRES: A QUESTION OF GILBERT. IN READING OVER THE FDA MATERIAL, WHICH YOU DIDN'T SUPPLY ME, BUT I DID MY OWN RESEARCH, IT SAYS THAT THEY'RE CONSIDERING THREE PATHWAYS FOR CONVALESCENT PLASMA. THE FIRST ONE BEING A CLINICAL TRIAL, THE SECOND, EXPANDED ACCESS, AND THE THIRD BEING A SINGLE-PATIENT EMERGENCY IND. DO WE HAVE ANY INFORMATION OF WHERE THEY ARE ON ANY OF THESE THREE APPROACHES?

MR. JUELSGAARD: I CAN SPEAK TO THAT. I WAS JUST READING ACTUALLY AN FDA PRONOUNCEMENT THAT CAME OUT, I THINK, THIS MORNING. AND YOU'RE ABSOLUTELY RIGHT. BUT IT SAYS THE FDA SAYS THE FOLLOWING PATHWAYS ARE AVAILABLE FOR ADMINISTERING OR STUDYING THE USE OF COVID-19 CONVALESCENT PLASMA. SO CLINICAL TRIALS, EXPANDED ACCESS, AND SINGLE-PATIENT EMERGENCY IND.

MR. TORRES: STEVE, ON YOUR DOCUMENT, DOES IT SHOW IF THEY'VE MOVED FORWARD ON ANY OF THOSE?

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MR. JUELSGAARD: NO. IT JUST GIVES GUIDANCE TO PEOPLE TO FILE AN IND AND GIVES THEM THREE ALTERNATIVES.

MR. TORRES: OKAY. THANK YOU.

CHAIRMAN THOMAS: ARE THERE COMMENTS FROM MEMBERS OF THE BOARD?

DR. DURON: I'M NOT SURE WHEN MY COMMENTS ARE APPROPRIATE, BUT I WOULD LIKE TO SAY, NOT SURE IF IT'S WRITTEN IN THE LEGISLATIVE LANGUAGE, BUT WE HAVE, I THINK, BOTH A MORAL AND ETHICAL DUTY TO ALL THE PEOPLE OF CALIFORNIA TO ENSURE WHATEVER WE FUND AND WHATEVER KNOWLEDGE IS GAINED IS ACCESSED AND PROVIDED TO ALL THE PEOPLE OF CALIFORNIA.

WE ARE SEEING FROM THE DATA THERE'S AN INCREASING AMOUNT OF DATA THAT SHOWS COMMUNITIES OF COLOR AND RACIAL AND ETHNIC GROUPS ARE FACING DISPROPORTIONATE IMPACTS FROM THE PANDEMIC, BOTH INFECTION AS WELL AS MORTALITY. THESE ARE MANY LOW INCOME AND MIDDLE INCOME WORKERS WHO WORK IN SERVICE JOBS, AND THEY LIVE IN DENSE COMMUNITIES AND CROWDED HOMES. AND I THINK IT'S REALLY IMPORTANT THAT WHATEVER WE DO, HOWEVER WE FUND, AND WHATEVER THE RESULTS ARE, THAT WE BE REALLY ENGAGED IN MONITORING AND TRACKING THAT THE RESULTS IMPACT AND SERVE ALL OF OUR COMMUNITIES.

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I DON'T KNOW HOW WE DO THAT, HOW WE GAUGE THAT, BUT I THINK THAT FUNDING CONCEPT AND RESEARCH IS NOT GOOD ENOUGH. WE REALLY NEED TO KNOW THAT ALL OF THE PEOPLE OF CALIFORNIA ARE GOING TO GET SOME SERVICE AS A RESULT OF THE FINDINGS, AND THEY NEED TO KNOW THAT THEY ALL COUNT.

SO I'M HOPING THAT WE CAN BUILD THAT INTO, EVEN AS WE ACCEPT THAT, THAT THE RESEARCHERS AND THE INSTITUTIONS KNOW THAT THIS IS ABSOLUTELY SOMETHING THAT WE BELIEVE IN AND WE EXPECT THEM TO ADHERE TO IN TERMS OF ETHICS AND MORAL DECISION-MAKING.

CHAIRMAN THOMAS: THANK YOU, YSABEL. VERY IMPORTANT POINT.

MR. SHEEHY: CAN I ASK A QUESTION, J.T.?

CHAIRMAN THOMAS: YES, JEFF, ALTHOUGH MARIA IS SORT OF COLLECTING IN ORDER WHO'S GOT THEIR HANDS RAISED. MARIA --

MS. BONNEVILLE: I JUST KNOW THAT SOME BOARD MEMBERS ARE USING THE RAISED HAND OPTION AND SOME ARE NOT, WHICH IS FINE. WE CAN MANAGE IT. BUT I KNOW THAT OS RAISED HIS HAND. I DON'T KNOW IF IT'S BECAUSE HE WANTED ME TO REMIND PEOPLE OF THE RAISED HAND OR IF HE HAD A COMMENT. I DON'T KNOW, OS. AND THEN JEFF COMMENTS NEXT. OS, DO YOU HAVE ANYTHING?

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DR. STEWARD: ACTUALLY I DO. THANK YOU.

THIS IS A PROCEDURAL QUESTION, I GUESS, AND IT MIGHT BE JUST -- AND IT IS RELATED TO THE WHOLE PROCESS OF THE VRO, VOTING THIS PARTICULAR APPROACH AS A VRO. THAT'S QUESTION NO. 1.

AND THEN QUESTION NO. 2 IS IS IT THE PREROGATIVE OF CIRM, NOT THE BOARD, BUT CIRM, TO MAKE A JUDGMENT ON OTHER THINGS THAT COME IN THAT WE MAY NOT RECOGNIZE RIGHT NOW AS BEING POTENTIALLY WITHIN THE VRO CONCEPT AND BEING ABLE TO FORWARD THOSE TO THE GRANTS WORKING GROUP IN A SENSE WITHOUT PRIOR BOARD APPROVAL? I'M ASKING PROCESS HERE. THANK YOU.

MR. HARRISON: SO TO YOUR LAST QUESTION, THE BOARD ESTABLISHES ELIGIBILITY CRITERIA THROUGH THE CONCEPT PLANS THAT IT APPROVES. THE CIRM TEAM THEN ADMINISTERS THOSE ELIGIBILITY CRITERIA IN DETERMINING WHETHER OR NOT AN APPLICATION FOR A PARTICULAR PROJECT MEETS THE REQUIREMENTS OF THE CONCEPT PLAN. ON OCCASION THE PRESIDENT HAS EXERCISED HIS OR HER AUTHORITY TO GRANT AN EXCEPTION TO ALLOW A PROJECT TO MOVE FORWARD. BUT IN THIS CASE, WHAT WE ARE DOING IS ASKING THE BOARD TO DETERMINE IN ADVANCE THAT THESE PROJECTS ARE ELIGIBLE UNDER THE CONCEPT PLAN SO THAT THEY CAN BE

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REVIEWED ALONG WITH OTHER APPLICATIONS AND THE GWG CAN CONSIDER WHETHER IN ITS VIEW IT CONSIDERS THE APPLICATIONS TO PRESENT A VITAL RESEARCH OPPORTUNITY. IF IT DOES, THEN THOSE APPLICATIONS THEN PROCEED TO THE BOARD. IF IT DOES NOT, THEN THE APPLICATIONS ARE DEEMED TO BE WITHDRAWN.

DR. STEWARD: THANK YOU.

MS. BONNEVILLE: JEFF HAD A QUESTION AS WELL AND THEN GEORGE BLUMENTHAL AFTER THAT.

MR. SHEEHY: I WANTED TO SPEAK TO MS. DURON'S POINT. IT HAD BEEN MY HOPE WHEN I FIRST HEARD ABOUT THIS THAT, AND MAYBE WE CAN MAKE AN AMENDMENT TO DO THIS, THAT THERE WOULD BE A PRIORITY GIVEN TO APPLICATIONS THAT WOULD SUPPLY THIS TECHNOLOGY TO UNDERSERVED COMMUNITIES OR CLINICS THAT SERVE UNDERSERVED COMMUNITIES.

WHEN YOU LOOK AT THIS TECHNOLOGY, IT FEELS LIKE SOMETHING THAT UCSF OR UCLA MAY WELL ADOPT ON THEIR OWN. BUT FOR OTHER CLINICS THAT ARE NOT ATTACHED TO LARGE ACADEMIC RESEARCH CENTERS REALLY ACCESSING THESE PROCESSES SEEMS LIKE IT WOULD BE DAUNTING. AND IN THE CONTEXT OF, BECAUSE I DID SEE THE INDIVIDUAL IND WHERE A TREATING PHYSICIAN COULD CONTACT THE FDA AND WITHIN A MATTER OF HOURS GET APPROVAL TO USE THESE CELLS OR TO USE THIS PLASMA TO

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ACTUALLY SAVE A PATIENT'S LIFE, IF AN APPLICANT WERE -- IF WE COULD INCENTIVIZE APPLICANTS WHO WANT TO APPLY TO USE THIS TECHNOLOGY IN COVID TO REALLY FOCUS ON THOSE COMMUNITY CLINICS THAT SERVE THOSE IN CALIFORNIA THAT WOULD HAVE EITHER DELAY OR MAY NOT EVEN HAVE ACCESS TO THIS TECHNOLOGY UNTIL MUCH, MUCH LATER. I THINK THAT WOULD BE VERY USEFUL.

AND IF, PER MS. DURON'S POINT OF HOW WE MIGHT DO THIS, I WOULD LIKE TO SUGGEST AN AMENDMENT TO THIS PROPOSAL TO ENSURE THAT THE GRANTS WORKING GROUP GIVES ADDITIONAL VALUE TO THE APPLICATION IF IT SPECIFICALLY INCLUDES EXPANDING ACCESS TO COMMUNITIES THAT MAYBE FHMC'S OR OTHER CLINIC COMMUNITIES, OTHER CLINICAL PROGRAMS THAT REALLY DON'T HAVE THE CONNECTIONS AND WOULD BE LESS LIKELY TO ACCESS THIS TECHNOLOGY.

CHAIRMAN THOMAS: OKAY. SO, JEFF, YOU ARE PROPOSING AN AMENDMENT TO THAT EFFECT?

MR. SHEEHY: YES.

MR. TORRES: I'LL SECOND THAT.

CHAIRMAN THOMAS: THANK YOU.

DR. PRIETO: I WAS THE MAKER OF THE MOTION. DO I NEED TO ACCEPT THAT AS A FRIENDLY AMENDMENT?

MR. HARRISON: CORRECT. BOTH THE MAKER

AND THE SECOND WOULD NEED TO ACCEPT IT AS A FRIENDLY AMENDMENT.

MS. BONNEVILLE: FRANCISCO AND DIANE?

DR. PRIETO: YES.

MS. BONNEVILLE: DIANE. DIANE, WILL YOU ACCEPT THE FRIENDLY AMENDMENT?

MS. WINOKUR: YES.

MS. BONNEVILLE: GREAT. THANK YOU.

CHAIRMAN THOMAS: WHO WAS --

MR. TORRES: TORRES WAS THE SECOND.

CHAIRMAN THOMAS: THANK YOU.

SO LET'S HAVE DISCUSSION ON THE FURTHER BOARD DISCUSSION ON THE AMENDMENT FIRST.

DR. DULIEGE: CAN YOU REPEAT THE AMENDMENT JUST SO THAT WE'RE ALL ON THE SAME PAGE?

CHAIRMAN THOMAS: SO, JAMES, YOU'RE ALWAYS THE MOST SUCCINCT REPEATER OF MOTIONS HERE. HOW DO YOU HAVE THIS RECORDED PER JEFF'S SUGGESTION?

MR. HARRISON: I WILL GIVE IT A SHOT, BUT JEFF CAN CORRECT ME IF I DIDN'T CAPTURE IT IN ITS ENTIRETY. SO THE MOTION WOULD BE TO APPROVE THE CONCEPT PLAN AMENDMENT AS MODIFIED TO GRANT PRIORITY TO APPLICATIONS THAT PROPOSE TO EXPAND ACCESS FOR UNDERSERVED COMMUNITIES.

CHAIRMAN THOMAS: JEFF, DOES THAT SOUND

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RIGHT?

MR. SHEEHY: I THINK SO. I DON'T KNOW. FRANCISCO MIGHT HAVE SOME INSIGHT IN THIS. I JUST WANT TO MAKE SURE THAT WE'RE REALLY CAPTURING -- GIVEN THAT THIS IS SOMETHING THAT WITH THE INDIVIDUAL IND, THIS CAN ACTUALLY BE SOMETHING THAT CAN BE DELIVERED BY INDIVIDUAL CLINICS THAT WOULD NEVER BE ABLE TO RECEIVE THIS. ANYBODY WHO'S A PRACTICING PHYSICIAN, AND ART MIGHT HAVE A SENSE SITTING ON COVER CALIFORNIA, DO WE NEED TO CALL OUT A SPECIFIC LIKE AN FMHC OR SOMETHING THAT ACTUALLY -- TO MAKE THAT WE'RE ACTUALLY -- SPECIFIC CLINICAL PROGRAMS THAT WE WOULD LIKE TO HAVE INCLUDED SO THAT WE REALLY DRIVE THE OUTREACH TO THOSE CLINICAL PROGRAMS? THEY'RE NOT GOING TO COME ON THEIR OWN, RIGHT. BECAUSE THEY'RE PROBABLY UP TO THEIR NECK IN THIS ALREADY. THE DEGREE OF SPECIFICITY. A LOT OF TIMES WE SAY THESE THINGS, AND THEN THEY DON'T REALLY GET OPERATIONALIZED. THERE'S LIKE THESE VAGUE KIND OF STATEMENTS. THE MORE THAT WE COULD MORE PRECISELY DRIVE INVESTIGATORS TO ACTUALLY REACH OUT TO THOSE CLINICS AND MAKE SURE THAT THEY'RE AWARE AND HAVE PROCESSES THAT WILL FACILITATE THEM ACCESSING THIS WOULD BE MY HOPE.

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DR. PRIETO: JEFF, IF I COULD COMMENT?

MR. SHEEHY: PLEASE.

DR. PRIETO: WHAT WE ARE TALKING ABOUT IN TERMS OF CLINICAL RESEARCH OPPORTUNITIES IS NOT JUST UNDERSERVED COMMUNITIES, BUT SPECIFICALLY COMMUNITIES THAT ARE OR APPEAR TO BE MORE HEAVILY IMPACTED OR DISPROPORTIONATELY SUFFERING THE MOST SEVERE COMPLICATIONS OF THE DISEASE, OF THE EPIDEMIC. I'M NOT SURE HOW WE WOULD PUT THAT IN THE RESEARCH PROPOSAL OR THE REQUEST FOR PROPOSALS, BUT I THINK WE WOULD WANT TO ENCOURAGE APPLICANTS TO REACH OUT TO THOSE POTENTIAL PATIENTS. I WOULD HOPE THEY WOULD BE DOING THAT ANYWAYS BECAUSE THIS IS NOT ONLY THE FOLKS WHO APPEAR TO BE MOST HEAVILY IMPACTED, BUT ALSO WHERE ANY PROPOSED THERAPY WITH CONVALESCENT PLASMA WOULD POTENTIALLY HAVE THE GREATEST IMPACT. SO WHERE YOU'D BE MOST LIKELY TO SEE A RESULT IF THAT'S POSSIBLE.

DR. ZIEDONIS: I THINK THE HOSPITALS ARE TELLING EACH OTHER WHO HAS THE CASES. SO I THINK ONE COULD LOOK THERE. I KNOW AT UCSD, BECAUSE WE ALSO DO TESTING AND A VARIETY OF THINGS, WE ARE SEEING A LOT OF THE PATIENTS. SO I THINK WE PROBABLY JUST NEED SOMEBODY WHO'S ON THOSE STATEWIDE CALLS. THE UC SYSTEM HAS A STATEWIDE CALL JUST

WITHIN ITS FIVE HEALTHCARE HOSPITAL-BASED PLACES. BUT IF YOU DIDN'T WANT THAT AS A PRIORITY AND YOU WANTED TO HAVE OTHER HOSPITALS AS A PRIORITY, I THINK IT DEPENDS ON WHAT THE GOAL OF THIS BY ITSELF IS.

I'D ALSO WANT TO KNOW THE INFRASTRUCTURE. COULD SOMEBODY HANDLE THIS? IT'S NICE TO GET THEM THIS, BUT MAKING SURE THAT THEY WANT IT AND THAT THEY WOULD BE ABLE TO USE IT, I THINK, WOULD BE IMPORTANT.

MS. BONNEVILLE: DR. BLUMENTHAL HAD HIS HAND RAISED AS DOES OS. JUST WANTED TO CIRCLE BACK TO THAT.

DR. BLUMENTHAL: I'M REALLY SPEAKING TO THE MAIN MOTION RATHER THAN TO THE AMENDMENT, WHICH I STRONGLY DO SUPPORT THE MAIN MOTION. I DO WITH ONE CAVEAT. AND MY CAVEAT HAS TO DO WITH ALLOWING CLINICAL PROGRAMS TO START INCURRING ALLOWABLE PROJECT COSTS PRIOR TO THE APPROVAL OF THE PROGRAM, BUT RATHER STARTING FROM THE APPLICATION SUBMISSION DEADLINE. THAT RAISES SOME CONCERNS WITH ME, CONCERNS ABOUT WHETHER THAT'S ACTUALLY LEGAL TO DO, CONCERNS ABOUT WHETHER OR NOT THERE'S EVER BEEN A PRECEDENT FOR CIRM HAVING DONE THAT BEFORE, AND CONCERNS ABOUT WHAT IS ACTUALLY THE JUSTIFICATION

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FOR DOING THAT GIVEN THE LIMITED BUDGET WE HAVE FOR THESE GRANTS. COULD YOU ADDRESS THOSE QUESTIONS?

CHAIRMAN THOMAS: DR. SAMBRANO OR DR. MILLAN, WOULD YOU LIKE TO ADDRESS THAT QUESTION PLEASE?

DR. SAMBRANO: SURE. I CAN SPEAK TO IT. SO WE HAVE ACTUALLY DONE THIS BEFORE AND HAD THAT AVAILABLE TO ALL OUR CLINICAL PROGRAMS. AND A COUPLE OF YEARS AGO WE CHANGED IT IN ORDER TO -- WE MOVED IT OVER TO AFTER APPROVAL BY THE BOARD. AND THE REASON THAT WE RECONSIDERED IT IN THIS PARTICULAR CASE IS WE WANTED, GIVEN THE URGENCY OF MANY OF THESE PROJECTS THAT WANT TO GET STARTED, IS TO ALLOW THEM TO INCUR COSTS WHICH WE WOULD REIMBURSE LATER. SO A REIMBURSEMENT-BASED PAYMENT IS NOT UNUSUAL. IT'S JUST REALLY UP TO THE FUNDING ORGANIZATION WHETHER THEY'RE WILLING TO DO IT.

NOW, OF COURSE, IF AN APPLICATION COMES IN AND IT DOESN'T GET FUNDED, THE APPLICANT IS INCURRING COSTS AT RISK, MEANING THAT THEY HAVE TO COVER THE COSTS. WE WOULD NOT BE SUBJECT TO PAYING THOSE. IT WOULD ONLY BE FOR THE CASE WHERE YOU HAVE AN APPLICATION THAT GOES THROUGH, IT GETS APPROVED AND FUNDED; AND THEN ONCE THEY GET THE MONEY FROM US, THEY CAN USE THAT TO COVER THOSE COSTS.

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DR. BLUMENTHAL: BUT IS IT YOUR SENSE THAT THERE ARE PROJECTS THAT WOULDN'T EVEN BEGIN IF IT WEREN'T FOR THIS PARTICULAR POINT?

DR. SAMBRANO: WELL, THERE ARE PROJECTS THAT ARE WANTING TO START AS QUICKLY AS POSSIBLE. AND SO MANY OF THEM HAVE MONEY AVAILABLE THAT THEY CAN UTILIZE TO BEGIN. SO THEY CAN CERTAINLY GET STARTED OR AT LEAST START INCURRING THE COST EVEN THOUGH THEY DON'T NECESSARILY HAVE TO PAY IT OUT. BUT ULTIMATELY IT'S GOING TO BE THEIR RESPONSIBILITY IF WE ARE NOT ABLE TO FUND THEM.

MS. BONNEVILLE: I KNOW OS HAD HIS HAND UP AND ART DOES AS WELL.

CHAIRMAN THOMAS: CAN I JUST -- THANK YOU, DR. BLUMENTHAL, FOR THOSE COMMENTS. IF WE COULD FIRST ADDRESS GOING FORWARD WITH THE AMENDMENT SO WE CAN REACH RESOLUTION ON THAT AND THEN GO BACK TO GENERAL COMMENTS ABOUT THE OVERALL MOTION THEREAFTER.

DR. STEWARD: THANK YOU. SO THIS IS REGARDING THE DISCUSSION, I'M NOT SURE HOW TO CAPTURE IT, BUT IT'S JEFF'S AMENDMENT. AND THIS IS REALLY A QUESTION, I GUESS, FOR EVERYBODY. I'M A LITTLE CONCERNED THAT MAKING THAT A REVIEW CRITERION KIND OF TAKES IT OUT OF THE SCIENTIFIC REALM AND

ALSO GREATLY COMPLICATES THE REVIEW PROCESS. IS THIS SOMETHING WE WANT THE GWG TO LOOK AT, OR IS THIS SOMETHING THAT IS REALLY BETTER EVALUATED AT THE BOARD LEVEL AFTER THE GWG HAS MADE ITS SCIENTIFIC JUDGMENT? THANK YOU.

CHAIRMAN THOMAS: MR. SHEEHY, YOU WANT TO COMMENT ON THAT?

MR. SHEEHY: SURE. YOU KNOW, I'M SPECIFICALLY THINKING THERE'S BEEN A FAIRLY SIGNIFICANT OUTBREAK, FOR INSTANCE, IN RIVERSIDE COUNTY, IF YOU GUYS ARE WATCHING THE STATS. AND IT KIND OF GOES ALSO TO THE COMMENT THAT WAS MADE ABOUT WOULD PEOPLE WANT IT, WOULD THEY HAVE THE INFRASTRUCTURE TO BE ABLE TO DO THIS. THE BIG ACADEMIC RESEARCH CENTERS ARE GOING TO BE ABLE TO DO THIS. TO SOME DEGREE THEY'RE GOING TO BE ABLE TO HAVE RESOURCES IN ORDER TO DO THIS IN THE MAJOR CITIES AND EVEN WITHIN MAJOR CITIES, IN CERTAIN PARTS OF MAJOR CITIES. THE ASPECT OF THIS THAT REALLY ALLOWS US TO EXPAND ACCESS IN A WAY THAT IN MANY WAYS WITH CLINICAL RESEARCH PROGRAMS WE CAN'T. IT'S THE INDIVIDUAL IND THAT, IF PHYSICIANS WERE MADE AWARE OF THIS, IF THE APPLICANT HAD BEEN THOUGHTFUL ABOUT MAKING PHYSICIANS AWARE OF THIS AND HOSPITALS AWARE THAT THIS WAS AVAILABLE, IF THE WAY

THEY DESIGNED THEIR PROGRAM WAS TO PLACE THE MOST MINIMUM BURDEN ON THOSE HOSPITALS AND THOSE CLINICAL PROGRAMS IN DELIVERING THIS, THAT WOULD BE SIGNIFICANT.

AND I JUST WORRY ABOUT THAT THIS WILL END UP BEING SOMETHING THAT WILL GO TO A LOT OF VERY WELL-ESTABLISHED ACADEMIC RESEARCH PROGRAMS THAT COULD POTENTIALLY IMPLEMENT THIS WITHOUT NEEDING CIRM RESOURCES. AND THOSE OTHER CLINICAL PROGRAMS THAT WE KNOW STRUGGLE TO GET RESOURCES, DON'T EVEN HAVE THE RESOURCES OR THE INFRASTRUCTURE TO EVEN THINK ABOUT THIS, ARE GOING TO BE LEFT OUT BECAUSE THEY DON'T HAVE THE NAMES ASSOCIATED WITH THEIR PROGRAM, THEY'RE NOT THE ACADEMIC RESEARCH PROGRAMS THAT TYPICALLY INSPIRE REVIEWERS TO AWARD THEIR GRANTS. YOU ONLY HAVE TO LOOK AT HOW FUNDING HAS BEEN DISTRIBUTED. AND THAT MAKES SENSE WHEN WE ARE TALKING ABOUT VERY SOPHISTICATED STEM-CELL TECHNOLOGIES, BUT THIS IS A RELATIVELY SIMPLE TECHNOLOGY. AND FDA HAS GIVEN A REALLY SIMPLE AND CLEAN PATHWAY TO DO THIS.

AND I THINK WE NEED TO PUSH, OR ELSE WE'LL END UP WITH THE USUAL SUSPECTS GETTING THE MONEY. AND TO THE DEGREE THAT THEY ACTUALLY -- SOME OF THOSE PROGRAM -- A LOT OF THE INSTITUTIONS ADMIRABLY

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DO SERVE UNDERSERVED COMMUNITIES. BUT I FEEL LIKE IF WE'RE GOING TO REALLY GET OUTSIDE OF OUR USUAL FUNDING TARGETS, THAT IT'S INCUMBENT ON US TO MAKE SURE THAT WE MAKE THIS ACCESSIBLE IN THE BROADEST POSSIBLE WAY, WHICH, FRANKLY, IS THE GREATEST NEED RIGHT NOW.

DR. STEWARD: JUST A COUPLE THOUGHTS, IF I COULD. I'M NOT ARGUING THE CONCEPT. I'M JUST ASKING WHERE IT SHOULD BE REVIEWED.

MR. SHEEHY: WELL, IT'S NOT GOING TO GET OUT OF GWG WITH A GOOD SCORE. SO THAT KILLS IT RIGHT THERE.

DR. MARTIN: LET ME JUST REMIND PEOPLE THAT THIS IS NOT A SIMPLE CLINICAL TRIAL BECAUSE THE PLASMA OR SERA CANNOT BE INFECTIOUS, NOT JUST FOR THE CORONA VIRUS, BUT HIV, FOR EXAMPLE. AND I DON'T KNOW WHAT THE REGULATIONS ARE GOING TO BE COMING FROM THE FDA TO QUALIFY ALL THE VARIOUS SERA THAT ARE GOING TO BE USED, BUT IT'S NOT SIMPLE.

MR. SHEEHY: WELL, THE THING IS WE HAVE FUNDED THROUGH OUR ALPHA CLINIC PROGRAM VERY SOPHISTICATED CELL HANDLING. THAT'S PART OF WHAT THEY DO. AND IT'D REALLY BE GREAT IF WE COULD REPURPOSE THAT TO HANDLE THESE PRODUCTS. I THINK THAT THEY COULD EASILY -- THIS IS WHAT THEY DO ALL

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THE TIME -- VALIDATE THESE PRODUCTS IN A WAY THAT MAKE THEM SAFE TO USE. AND ALL I'M TRYING TO ASK IS THAT IF THEY GET ENGAGED WITH THIS AND THEY'RE DOING THIS, THAT THEY REACH OUT TO HOSPITALS AND CLINICS THAT ARE NOT NECESSARILY ALWAYS ASSOCIATED WITH THESE ALPHA CLINICS.

MR. ROWLETT: I'D LIKE TO MAKE A COMMENT PLEASE.

MR. TORRES: I'VE HAD MY HAND UP FOR A WHILE NOW.

MR. ROWLETT: I'M ON THE PHONE. I DIDN'T SEE IT, SENATOR.

MR. TORRES: GO AHEAD, AL. I'LL FOLLOW YOU.

MR. ROWLETT: AS AN ADVOCATE WHO HAS THE OPPORTUNITY TO WORK WITH THE UNSERVED AND UNDERSERVED POPULATION JEFF IS ADVOCATING FOR, I CERTAINLY, WITHOUT TALKING ABOUT THE SCIENTIFIC MOTTLING OF THIS, WOULD BE AN ADVOCATE FOR AS BROAD OF A CONSIDERATION IN ANY APPLICATION OF THOSE COMMUNITIES AS POSSIBLE. IT IS UNFORTUNATE FOR MANY CITIZENS THAT THEY GET RECOGNITION OF THE IMPACT OF THE DISEASE WHEN THEY ARE VERY SYMPTOMATIC, VERY ILL BECAUSE OF SOME OF THE ISSUES THAT JEFF IS IMPLYING IN HIS POINT. AND SO TO THAT, I ENTHUSIASTICALLY

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AGREE. WE NEED APPLICATIONS THAT TAKE THAT INTO CONSIDERATION. HOW THAT GETS CONSTRUCTED OR HOW THAT GETS REVIEWED CERTAINLY IS INCUMBENT UPON THE GWG AND THE APPLICATION. BUT THE INFERENCE THAT JEFF HAS MADE I AGREE WITH COMPLETELY.

CHAIRMAN THOMAS: SENATOR TORRES.

MR. TORRES: I WANT TO REITERATE FOR THE PERSON THAT BROUGHT UP THIS INITIALLY, WHICH WAS YSABEL, BECAUSE SHE'S VERY FAMILIAR WITH THE GROUPS THAT ARE OUT THERE AS IS JEFF. I THINK WHAT NEEDS TO HAPPEN IS THAT THE APPLICANTS NEED TO KNOW THAT THIS IS THE SENSE OF THE BOARD, THAT IF YOU ARE GOING TO RECEIVE A GRANT, AND ALL THESE GRANTS HAVE TO BE BASED UPON SCIENTIFIC MERIT, ONCE THAT DECISION IS MADE, THEN WE HAVE TO HAVE A VERY FRANK DISCUSSION WITH WHOEVER THE APPLICANTS ARE THAT HAVE WON THE FUNDING OR GAINED THE FUNDING THAT ACCESSIBILITY IS VERY IMPORTANT TO US.

LET ME GIVE YOU AN EXAMPLE. I STARTED LOOKING INTO LAST YEAR HOW MANY NATIVE AMERICANS WERE IN OUR CURRENT CLINICAL TRIALS. IT WAS EMBARRASSING. VERY, VERY FEW. AND SO I REACHED OUT TO THE TRIBES AND I REACHED OUT TO THE APPLICANTS THAT HAD ACCESS OR AT LEAST THOSE THAT HAD AT LEAST ONE NATIVE AMERICAN PATIENT IN A CLINICAL TRIAL TO

DO MORE.

JEFF RAISED RIVERSIDE. THAT'S A VERY IMPORTANT GEOGRAPHIC AREA FOR WHERE COVID-19 IS INCREASING BECAUSE IT'S A POOR AREA, WORKING CLASS AREA, AND A LOT OF BROWN AND BLACK FOLK LIVE IN THOSE COMMUNITIES. WE WHAT WE DO AT COVER CALIFORNIA IS TO REACH OUT TO THE THIRD-PARTY PAYERS TO MAKE SURE THAT THEY KNOW WHAT WE ARE ASKING FOR. IN THIS CASE, I THINK ONCE THE APPLICANTS ARE APPROVED, THEN WE NEED TO HAVE A VERY FRANK DISCUSSION IN TERMS OF THAT WE'RE GOING TO EXPECT THE REPORTING REQUIREMENTS TO US AS TO WHERE THEY GO. FOR EXAMPLE, UCSF HAS A WORKING PARTNERSHIP AND PRESENCE IN FRESNO. THAT'S A VERY IMPORTANT ELEMENT, AS FRANCISCO, I KNOW, TRIED TO POINT OUT, AND THAT IS RURAL CALIFORNIA IS ALWAYS THE LAST ONE TO GET BENEFITS OF ANYTHING IN THE STATE. AND I THINK ACCESSIBILITY TO HEALTHCARE HAS ALWAYS BEEN A PROBLEM IN THOSE AREAS.

SO I THINK THAT IF UCSF WERE TO APPLY AND THEY ARE LUCKY TO GET A GRANT, THEN WE NEED TO MAKE SURE THAT THEY PARTICIPATE WITH FRESNO WHERE THEY HAVE A PRESENCE ALREADY, AND I KNOW DIRECTOR PADILLA KNOWS THIS, THAT THEY MOVE FORWARD IN THAT. THE SAME THING IS TRUE WITH RIVERSIDE, TO MAKE SURE OUR

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BOARD MEMBER AND DEAN OF OUR MEDICAL SCHOOL THERE IS AWARE OF A GRANT THAT MAY HAVE BEEN GRANTED FROM AN AREA THAT NEEDS ATTENTION FROM US.

SO THE PRINCIPLES OF PROP 71, WHICH ALWAYS ATTRACTED ME TO THE LANGUAGE, WAS ACCESSIBILITY WAS GOING TO BE, AND CLEARLY EVEN ACCESSIBILITY TO THOSE THAT DID NOT HAVE HEALTH INSURANCE. THIS HAS TO BE THE PRIORITY FOR US. OTHERWISE, WE'RE FAILING THE DIVERSITY OF THE STATE IN TERMS OF ITS ACCESS TO HEALTHCARE AND CLEARLY TO TREATMENTS AND CURES. SO I THINK ONCE THE DECISIONS ARE MADE BY THE WORKING GROUP, WHICH WAS BASED ON SCIENTIFIC MERIT, THAT'S WHEN WE HAVE A VERY COME-TO-JESUS DISCUSSION. AND ON GOOD FRIDAY THAT'S NOT A BAD PHRASE TO USE IN DISCUSSION WHERE THEY NEED TO GO AND HOW TO PROVIDE THAT OUTREACH. AND CERTAINLY YSABEL, MYSELF, JEFF, AND OTHERS ON THE BOARD, AL, FRANCISCO, DIRECTOR PADILLA KNOW EXACTLY WHERE TO DIRECT US. SO THAT'S NOT GOING TO BE A HARD ALTERNATIVE TO IMPLEMENT. SO THAT'S WHY I SUPPORT WHAT YSABEL AND JEFF ARE TRYING TO DO AND CLEARLY AL AND FRANCISCO BECAUSE WE NEED TO MOVE FORWARD ON THIS.

DR. DURON: MAY I COMMENT? I DON'T WANT TO STEP ON ANYBODY.

MS. BONNEVILLE: KRISTINA HAD HER HAND

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RAISED AND THEN WE CAN GO TO YSABEL.

DR. VUORI: THANKS, MARIA. SO JUST QUICKLY, I ABSOLUTELY AGREE WITH WHAT EVERYBODY HAS SAID. I SPECIFICALLY AGREE WITH WHAT DAVE MARTIN SAID JUST A LITTLE WHILE EARLIER. THIS IS NOT A TRIVIAL TREATMENT THAT IS READY FOR PRIME TIME. IT WILL INVOLVE RESEARCH AND TRIAL AND ERROR MOST LIKELY. SO WHAT MY RECOMMENDATION WOULD BE IS THAT THE GRANTS WORKING GROUP FOCUSES ON THE SCIENTIFIC MERIT, BUT AT THE SAME TIME, WE WILL ASK EVERY APPLICANT TO OUTLINE HOW THEY WILL SPECIFICALLY ADDRESS THE NEEDS OF THE UNDERSERVED POPULATION IN CALIFORNIA. AND THAT THEN THERE BE A CONVERSATION THAT THE ICOC TAKES AND ESSENTIALLY PROGRAMMATICALLY PRIORITIZE THESE APPLICATIONS HOW THEY WISH.

DR. DURON: AM I UP?

CHAIRMAN THOMAS: THANK YOU, KRISTINA.

DR. DURON: THANK YOU VERY MUCH. I HAVE NEVER BEEN AGAINST SCIENTIFIC MERIT. BUT I'M ALSO OPEN TO EVERYBODY UNDERSTANDING WHAT'S AT STAKE AND WHEN IT IS APPROPRIATE FOR THEM TO START CONSIDERING THIS. SO I THINK THAT IT'S ALMOST TOO LATE FOR ANYBODY TO COME BACK OUT OF THE ICOC AND START SAYING, WELL, YOU'VE GOT TO MAKE THIS A BETTER PROPOSAL AND IT'S GOT TO BE INCLUSIVE. I THINK THAT

GOING INTO THE APPLICATION PROCESS, THEY SHOULD ALREADY KNOW HOW IT IS THEY NEED TO CONSIDER MAKING SURE THAT THERE'S PARITY AND INCLUSION OF THESE UNDERSERVED POPULATIONS WITHIN THAT APPLICATION. OTHERWISE, THERE'S A LOT OF ASSUMPTION ON OUR PART AND ON MANY GROUPS' PARTS THEY'LL DO THE RIGHT THING OR THAT WE CAN PUSH THEM INTO DOING THE RIGHT THING.

THERE IS THE REASON FOR PATIENT ADVOCACY BECAUSE WE HAVE ASKED TIME AFTER TIME AFTER TIME FOR CHANGE AND INCLUSION AND PARITY; BUT WITHOUT THE PROPER POINTS MADE IN THE APPLICATION PROCESS, TO COME AFTERWARDS AND SAY COULD YOU CHANGE THIS OR WOULD YOU IMPROVE THIS IS THE TIME WHEN THERE'S A LOT OF, I THINK, UNNECESSARY DICKERING, IF YOU WILL, BACK AND FORTH BETWEEN WHAT IS AN ACCEPTABLE NUMBER OR WHAT DOES THAT MEAN, WHAT IS DIVERSITY. I JUST THINK THAT WE NEED TO INCLUDE IT FROM THE VERY BEGINNING IN THE APPLICATION, STATEMENTS MADE, EXPECTATIONS MADE, DEMOGRAPHICS OF THE POPULATIONS YOU WILL RESEARCH, HOW YOU WILL MAKE SURE IT'S PROPORTIONAL AND INCLUSIVE.

BUT BEYOND THAT, I THINK THAT -- I KNOW THAT YOU'VE HAD IT SET UP FOR THE REVIEW TO BE FOR SCIENTIFIC MERIT. I SAT ON THE CALIFORNIA RESEARCH PROGRAM FOR BREAST CANCER, AND WE WERE -- AS PART OF

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THE BOARD WE REVIEWED AS PATIENT ADVOCATES AT THE SAME TIME BECAUSE SOMETIMES SCIENTIFIC MERIT IS NOT JUST THE ONLY THING ONE SHOULD BE LOOKING AT.

SO I WOULD SUGGEST THAT AT THAT POINT IN TIME YOU ALSO NEED TO HAVE SOME PATIENT ADVOCATES BE LOOKING AT THOSE GRANTS AS WELL TO HAVE SOME THINGS TO SAY. BUT I REALLY DO THINK THAT THE INSTITUTIONS AND RESEARCH APPLICANTS GOING IN SHOULD ALREADY KNOW THAT THERE'S AN EXPECTATION OF INCLUSIVITY AND PARITY THAT THEY'RE SUPPOSED TO BE AIMING FOR. AND LATER YOU CAN DISCUSS WHAT THEIR PLANS ARE TO DISSEMINATE AND SHARE, ET CETERA, ET CETERA.

BUT I THINK THEY NEED TO KNOW AND THAT THE REVIEW BOARD IS ACTUALLY ALSO INCLUDING IN THEIR POINT STRUCTURE, HOWEVER THEY ASSESS IT, THAT THEY LOOK SPECIFICALLY FOR HOW THEY HAVE RESPONDED IN THEIR APPLICATION TO THAT KIND OF THING. THAT IS AS IMPORTANT TO ME AS SCIENTIFIC MERIT. THANK YOU.

MR. TORRES: I AGREE WITH THAT, AND I THINK THAT DR. SAMBRANO CAN CERTAINLY INCLUDE THAT IN ANY APPLICATION THAT GOES OUT AND THAT THE REVIEW BOARD LOOKS AT IT VERY CAREFULLY AS WELL AND THEN WE FOLLOW UP.

MS. BONNEVILLE: DAVID HIGGINS HAD HIS HAND RAISED.

DR. HIGGINS: THANKS. JUST A QUICK COMMENT TO ADD. I THINK MOST PEOPLE KNOW THAT DOWN HERE IN SAN DIEGO I FOCUS ON A VARIETY OF MEDICAL CARE, MEDICAL SERVICES TO THE UNDERMET POPULATIONS IN THE SOUTH BAY. SO I VERY MUCH APPRECIATE THE VALUE OF FOCUSING ON THAT.

WHAT I WANTED TO SAY WAS JUST THAT I AGREE WITH OS AND JEFF, THAT THIS NEEDS TO BE PART OF THE EVALUATION. WHAT I JUST WANTED TO PUT MY TWO CENTS WORTH ON IS I DON'T THINK IT SHOULD BE PART OF THE GWG ANALYSIS. I THINK IT SHOULD EITHER BE BEFORE THAT IN AN AD HOC COMMITTEE OR, AS ART WAS SUGGESTING, AFTER THAT IN THE ICOC REVIEW. BUT THERE SHOULD BE SPECIFIC CRITERIA GIVEN TO THE GRANT APPLICANTS EARLY, BUT I WOULD NOT HAVE THE GWG DO THE EVALUATION FOR THIS PARTICULAR ASPECT. THAT'S ALL. THANKS.

MR. SHEEHY: COULD I RESPOND UNLESS I'M JUMPING IN FRONT OF PEOPLE? I JUST WANT TO NOTE WE HAVE PRECEDENT FOR THIS. WHEN WE DO OUR TRAINING PROGRAMS, WE SPECIFICALLY REQUIRE THE APPLICANTS AND SCORE THE APPLICANTS BASED ON INCLUSION. AND I THINK THAT THE GWG IS EQUIPPED TO BE ABLE TO DEAL WITH THAT. THIS IS NOT THE FIRST TIME WE'VE ASKED PEOPLE TO DO THAT.

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MR. TORRES: CORRECT. CALL FOR THE QUESTION.

CHAIRMAN THOMAS: ALL RIGHT. QUESTION HAS BEEN CALLED FOR. WE WILL SEE NOW DO WE HAVE ANY COMMENTS FROM MEMBERS OF THE PUBLIC?

MS. BONNEVILLE: HOLD FOR ONE SECOND. LET ME CHECK IN WITH DOUG. IF MEMBERS OF THE PUBLIC THAT HAVE DIALED IN WOULD LIKE TO MAKE COMMENT, PLEASE DIAL STAR NINE.

MR. GUILLEN: WE HAVE TWO SO FAR.

MS. BONNEVILLE: TWO. WE HAVE TWO HANDS THAT HAVE BEEN RAISED BY MEMBERS OF THE PUBLIC. SO WE'RE GOING TO START WITH THOSE. PLEASE REMEMBER THE THREE-MINUTE TIME ALIGNMENT. THANK YOU.

DR. ZAIA: THIS IS JOHN ZAIA FROM CITY OF HOPE. THANK YOU FOR THIS OPPORTUNITY. TO BE TRANSPARENT, I HAVE MORE OR LESS PUSHED FOR THIS IDEA THAT CIRM DO SOMETHING IMMEDIATELY. AND THE USE OF CONVALESCENT PLASMA FROM COVID CONVALESCENT PATIENTS IS ONE SUCH WAY TO DO IT. THE QUESTIONS THAT HAVE BEEN RAISED ARE REALLY GOOD ONES. HOW TO OPERATIONALIZE IT, BECAUSE THE REAL COMPLEXITY IS THAT YOU CAN FIND THE DONOR AND YOU CAN FIND THE PATIENT, BUT BEING ABLE TO DETERMINE IF THE PATIENT IS NOT INFECTIOUS AND HAS THE RIGHT ANTIBODY LEVELS

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THAT THE FDA HAS RECOMMENDED IS THE DIFFICULTY.

THE COLLECTION CENTERS DON'T HAVE THE ABILITY TO HAVE A QUANTITATIVE ANTIBODY TEST, NOR DO THEY HAVE THE SWABS AND THE MOLECULAR DIAGNOSTIC TESTS THAT ARE AVAILABLE USING A PUBLIC HEALTH ARENA OR SOME MAJOR HOSPITAL. SO IT IS POSSIBLE TO CREATE A CIRM-FUNDED TESTING CENTER THAT WOULD BE ABLE TO PROVIDE ITS SERVICES, NOT ONLY TO THE MAJOR CENTERS LIKE THE UC'S, AND I HAVE TALKED TO THE UC'S AND THERE IS, I THINK, SOME DEGREE OF INTEREST IN HAVING A TESTING SERVICE THAT WOULD BE AVAILABLE FOR EVERYBODY.

HOW WOULD YOU GET IT TO THE SITES THAT ARE NOT IN THE UC SYSTEM AND ARE UNDERSERVED AREAS? YOU COULD PROPOSE THAT A WEB-BASED SYSTEM WOULD ALLOW A PERSON TO LOG ON, REGISTER THEMSELVES, THEY CAN GET INFORMATION ABOUT HOW TO DO THE E-IND, AND HOW TO SEND THE SPECIMENS ON THEIR DONOR -- THEY HAVE TO IDENTIFY THEIR OWN DONOR -- TO YOU, TO THIS TESTING CENTER, RECEIVE THE RESULTS, AND THEN BRING THAT TO THE COLLECTION CENTER NEARBY.

WE HAVE TALKED TO SEVERAL COLLECTION CENTERS WHO SAY THE PROBLEM THEY HAVE IS EXACTLY THAT, HOW TO QUALIFY THE DONORS. SO THERE ARE WAYS TO DO THIS. AND I ENCOURAGE THE BOARD TO APPROVE A

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PROGRAM SUCH AS THAT DESCRIBED EARLIER. THANK YOU VERY MUCH.

CHAIRMAN THOMAS: THANK YOU, DR. ZAIA. WHO'S OUR SECOND PUBLIC COMMENT?

MR. BEHN: THIS IS BILL BEHN JUST WITH A COMMENT. THERE MIGHT BE AN OPPORTUNITY FOR THE FDA TO LEND THEIR SPECIFICATIONS ABOUT WHAT SHOULD BE INCLUDED IN PATIENT AVAILABILITY. EARLIER THERE WAS A REFERENCE TO THE LETTER THAT CAME OUT FROM THE FDA ON APRIL 8TH. IT HAS A SHORT DISCUSSION ABOUT PATIENT ELIGIBILITY WHICH DOES NOT MENTION ANYTHING RELATIVE TO INCLUSIVENESS. AND AS WITH MOST FDA DOCUMENTS, IT HAS A MUCH MORE DETAILED GUIDANCE THAT'S REFERENCED IN THAT. SO THERE MAY BE A WAY JUST TO HAVE A CONVERSATION WITH THE FDA ABOUT THIS SPECIFICALLY AND HOW THAT COULD BE USED AS A WAY TO ENCOURAGE INCLUSION IN THE ACTUAL RESEARCH THAT'S FUNDED. THAT'S ALL I HAVE.

CHAIRMAN THOMAS: THANK YOU. ARE THERE OTHER COMMENTS FROM MEMBERS OF THE PUBLIC?

MS. BONNEVILLE: NO, THERE ARE NOT.

CHAIRMAN THOMAS: THANK YOU, MARIA. HEARING NONE, WE'RE GOING TO BE FIRST VOTING ON THE AMENDMENT. WE'VE HAD A VERY GOOD --

MR. TORRES: A POINT OF ORDER. THE

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AMENDMENT WAS MADE WITH THE CONSENT OF THE MAKER WITH THE ORIGINAL MOTION AND THE SECOND, SO WE SHOULD BE VOTING ON THE MAIN MOTION AS AMENDED.

MR. HARRISON: I BELIEVE THAT'S CORRECT.

CHAIRMAN THOMAS: THANK YOU. SO THE DISCUSSION HAS BEEN VERY GOOD. THERE'S STILL SOME OPEN ISSUES THAT HAVE BEEN IDENTIFIED IN THE COURSE OF THE DISCUSSION THAT ARE GOING TO HAVE TO BE WORKED OUT WITH RESPECT TO WHAT'S GOING TO BE CONSIDERED BY THE GWG, WHAT THE DIRECTIONS ARE GOING TO BE TO THE GWG, ALL OF THAT SORT OF THING, WHICH, IF THIS MOTION PASSES, WILL REQUIRE FURTHER DISCUSSION. SO IN ANY EVENT, MARIA, WILL YOU PLEASE CALL THE ROLL ON THE MOTION AS AMENDED.

MS. BONNEVILLE: I SURE WILL.

GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: YES.

MS. BONNEVILLE: LEON FINE.
DR. FINE: YES.
MS. BONNEVILLE: JUDY GASSON.
DR. GASSON: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
MR. JUELSGAARD: YES.
MS. BONNEVILLE: LINDA MALKAS.
DR. MALKAS: YES.
MS. BONNEVILLE: DAVE MARTIN. ADRIANA PADILLA.
DR. PADILLA: YES.
MS. BONNEVILLE: JOE PANETTA.
MR. PANETTA: YES.
MS. BONNEVILLE: FRANCISCO PRIETO.
DR. PRIETO: AYE.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: AL ROWLETT.
MR. ROWLETT: YES.
MS. BONNEVILLE: SUZANNE SANDMEYER.
DR. SANDMEYER: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.

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MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: DIANE WINOKUR.
MS. WINOKUR: YES.
MS. BONNEVILLE: KEITH YAMAMOTO.
DR. YAMAMOTO: YES.
MS. BONNEVILLE: DOUG ZIEDONIS.
DR. ZIEDONIS: YES.
MS. BONNEVILLE: THE MOTION CARRIES.
CHAIRMAN THOMAS: THANK YOU, EVERYBODY, FOR THAT. I THINK THAT LATTER DISCUSSION WAS EXCEPTIONALLY IMPORTANT AND REALLY GETS TO THE CORE OF WHAT CIRM IS ALL ABOUT AND PROP 71 IS ALL ABOUT. SO I THINK WE SHOULD FEEL VERY GOOD ABOUT THIS GOING FORWARD. WE JUST NEED TO MAKE SURE WE IMPLEMENT IT IN THE BEST POSSIBLE WAY.
WE ARE NOW AT THE PUBLIC COMMENT FOR ANY ITEMS --
MS. BONNEVILLE: WE HAVE ONE MORE ITEM. IT'S THE ADDITIONS --
CHAIRMAN THOMAS: YES, THANK YOU, MARIA.

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ITEM 6, APPOINTMENT AND REAPPOINTMENT OF SCIENTIFIC MEMBERS TO THE GWG. DR. SAMBRANO.

DR. SAMBRANO: THANK YOU, DR. THOMAS. SO AS BEFORE, WE ARE CONTINUING OUR QUEST FOR EXPERTS IN THE AREA OF COVID-19 AND RELATED AREAS. SO WE ARE BRINGING TWO NOMINATIONS AS WELL AS SOME REAPPOINTMENTS OF GWG MEMBERS. AND SO THOSE BIOS WERE PROVIDED TO YOU. THE NEW MEMBERS ARE DR. CHANNAPPANAVAR, WHO IS A VIRAL IMMUNOLOGIST AT UT SOUTHWESTERN IN TEXAS, AND DR. GORDON RUBENFELD, WHO IS IN TORONTO WITH EXPERTISE IN TRAUMA, EMERGENCY, AND CRITICAL CARE WITH EXPERIENCE WITH ACUTE RESPIRATORY DISTRESS SYNDROME AND ACUTE LUNG INJURY.

THE PROPOSED REAPPOINTMENTS ARE FOR DR. ADRIAN GEE, DR. JAMES GUEST, AND DR. MICHELLE WILLIAMS. SO WE REQUEST APPOINTMENT AND REAPPOINTMENT OF THESE INDIVIDUALS.

CHAIRMAN THOMAS: IS THERE A MOTION TO THAT EFFECT?

DR. GASSON: SO MOVED.

CHAIRMAN THOMAS: SECOND?

DR. HIGGINS: I'LL SECOND IT.

MS. BONNEVILLE: THANK YOU.

CHAIRMAN THOMAS: DISCUSSION BY MEMBERS OF THE BOARD? HEARING NONE, DISCUSSION BY MEMBERS OF

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THE PUBLIC? OKAY. AS WITH OUR CALL TWO WEEKS AGO, THIS IS NORMALLY A VOICE VOTE; BUT SINCE WE'RE ALL REMOTE, WE NEED TO DO THIS IN A ROLL CALL VOTE. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: GEORGE BLUMENTHAL.

DR. BLUMENTHAL: YES.

MS. BONNEVILLE: LINDA BOXER.

DR. BOXER: YES.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: YES.

MS. BONNEVILLE: LEON FINE.

DR. FINE: YES.

MS. BONNEVILLE: JUDY GASSON.

DR. GASSON: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: LINDA MALKAS.

DR. MALKAS: YES.

MS. BONNEVILLE: DAVE MARTIN. ADRIANA

PADILLA.

DR. PADILLA: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

DR. QUINT: YES.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: YES.

MS. BONNEVILLE: SUZANNE SANDMEYER.

DR. SANDMEYER: YES.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: YES.

MS. BONNEVILLE: OSWALD STEWARD.

DR. STEWARD: YES.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: AYE.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: YES.

MS. BONNEVILLE: DIANE WINOKUR.

MS. WINOKUR: YES.

MS. BONNEVILLE: KEITH YAMAMOTO. DOUG ZIEDONIS.

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DR. ZIEDONIS: YES.

MS. BONNEVILLE: THANK YOU, EVERYONE. THE MOTION CARRIES.

CHAIRMAN THOMAS: THANK YOU, MARIA. NOW WE ARE AT PUBLIC COMMENT. ANY COMMENTS BY MEMBERS OF THE PUBLIC ON ANY TOPIC THEY WISH TO DISCUSS AT THIS POINT?

MS. BONNEVILLE: NONE.

CHAIRMAN THOMAS: THANK YOU. HEARING NONE, I JUST WANT TO SAY TO EVERYBODY STAY SAFE AND HEALTHY. I WOULD LIKE TO ADJOURN TODAY'S MEETING IN THE MEMORY OF GLORIA REED, DON'S WIFE, WHO VERY SADLY PASSED AWAY EARLIER THIS WEEK. GLORIA, AS YOU KNOW, WAS A WONDERFUL FRIEND TO CIRM AND A MAJOR SUPPORTER SINCE THE INCEPTION OF THE AGENCY. WANT TO PASS ON BEHALF OF CIRM TO DON, I'M SURE YOU'RE LISTENING, THAT OUR DEEPEST CONDOLENCES TO YOU AND THE FAMILY AT THIS TIME. AND WE ARE, AS ALWAYS, HERE FOR YOU GOING FORWARD.

SO WITH THAT, PLEASE, EVERYBODY, AGAIN STAY SAFE AND HEALTHY UNTIL WE TALK AGAIN. WE STAND ADJOURNED.

MS. BONNEVILLE: THANK YOU, EVERYONE, FOR GETTING THIS TOGETHER. SO THANK YOU.

(THE MEETING WAS THEN CONCLUDED AT 12:20 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 ZOOM MEETING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS EMERGENCY MEETING HELD ON APRIL 10, 2020, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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