BEFORE THE

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

REGULAR MEETING

LOCATION: SHERATON GATEWAY SFO
600 AIRPORT BOULEVARD
BURLINGAME, CALIFORNIA

DATE: JUNE 26, 2008
5:30 P.M.

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

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SAN FRANCISCO, CALIFORNIA; THURSDAY, JUNE 26, 2008

5:30 P.M.

CHAIRMAN KLEIN: ALL RIGHT. IF WE CAN CALL THE MEETING TO ORDER. THANK YOU ALL FOR YOUR PATIENCE. SO, MELISSA KING, WOULD YOU PLEASE LEAD US IN THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN KLEIN: MELISSA, IF YOU'D PLEASE LEAD US THROUGH THE ROLL CALL.

MS. KING: DONALD DAFOE FOR RICARDO AZZIZ.

DR. DAFOE: HERE.

MS. KING: ROBERT PRICE FOR ROBERT BIRGENEAU.

DR. PRICE: HERE.

MS. KING: FLOYD BLOOM. DAVID BRENNER. SUSAN BRYANT.

DR. BRYANT: HERE.

MS. KING: MARSHA CHANDLER. MARCY FEIT.

MS. FEIT: HERE.

MS. KING: MICHAEL FRIEDMAN. LEEZA GIBBONS.

MS. GIBBONS: HERE.

MS. KING: MICHAEL GOLDBERG. SAM HAWGOOD.

DR. HAWGOOD: HERE.

MS. KING: BOB KLEIN.
CHAIRMAN KLEIN: HERE.
MS. KING: SHERRY LANSING.
MS. LANSING: HERE.
MS. KING: LEONARD ROME FOR GERALD LEVEY.
DR. ROME: HERE.
MS. KING: TED LOVE.
DR. LOVE: HERE.
MS. KING: TINA NOVA. ED PENHOET. PHIL PIZZO. CLAIRE POMEROY.
DR. POMEROY: HERE.
MS. KING: FRANCISCO PRIETO.
DR. PRIETO: HERE.
MS. KING: JOHN REED. DUANE ROTH.
MR. ROTH: HERE.
MS. KING: JOAN SAMUELSON.
MS. SAMUELSON: HERE.
MS. KING: DAVID SERRANO-SEWELL. JEFF SHEEHY.
MR. SHEEHY: HERE.
MS. KING: JON SHESTACK. OSWALD STEWARD.
DR. STEWARD: HERE.
CHAIRMAN KLEIN: ALL RIGHT. MY UNDERSTANDING IS WE'RE A LITTLE BOARD LIGHT AT THE MOMENT, AND WE WILL CONTINUE WITH ITEMS THAT DON'T

NECESSARILY REQUIRE A QUORUM SO THAT WE CAN MOVE THIS AGENDA FORWARD.

ON THE CHAIRMAN'S REPORT, WE WILL GO THROUGH SOME OF THIS MATERIAL TOMORROW. MY UNDERSTANDING, DR. TROUNSON, IS YOU'RE GOING TO DO YOUR PRESIDENT'S REPORT IN THE FULL SESSION TOMORROW MORNING; IS THAT CORRECT, OR ARE YOU GOING TO GIVE IT TONIGHT?

MS. KING: TOMORROW. AND NANCY WILL BE TOMORROW HERE TO GIVE HER PRESENTATION, AND MARIE WILL GIVE HER PRESENTATION TOMORROW.

CHAIRMAN KLEIN: OKAY. SO IT SOUNDS LIKE WE'RE HAVING -- BEFORE WE DO OUR FINAL VOTES ON THE AWARDS, WHICH WILL BE TOMORROW MORNING, THAT WE'RE HAVING THE FULL RANGE OF SCIENTIFIC PRESENTATIONS IF THAT IS ACCEPTABLE TO THE PRESIDENT, BUT ANY PORTION OF YOUR REPORT THAT YOU'D LIKE TO HIGHLIGHT TONIGHT FOLLOWING MY REPORT PLEASE DO SO. AND WE'LL BE ENRICHED BY REPETITION AND LEARN SOMETHING.

DR. TROUNSON: YOU KNOW, HOWEVER YOU WANT TO RUN IT, CHAIRMAN. YOU KNOW, IF IT SUITS, BECAUSE WE DON'T HAVE A QUORUM, I'M HAPPY TO DO -- YOU KNOW, TO DO SOME WHICH WOULD ACCOMMODATE THE TIME.

CHAIRMAN KLEIN: ALL RIGHT. AND I'D LIKE TO MAKE SURE THAT IN BEGINNING THE SESSION, WE THANK

JENNIFER PRYNE AND MELISSA KING FOR THE EXTRAORDINARY WORK THEY ALWAYS DO IN BRINGING THESE MEETINGS TOGETHER AND VICTORIA WHO'S HELPING THEM.

(APPLAUSE.)

CHAIRMAN KLEIN: I'D LIKE TO START TODAY, IF WE CAN, BY FOCUSING ON THIS BLACKBERRY THAT UC DAVIS HAS LOANED ME FOR THE MOMENT. IT HAS A PICTURE OF A $20 MILLION CHECK ON IT. NOW, THE PERSON WHO GAVE ME THIS BLACKBERRY SAYS SHE'S NEVER HAD A $20 MILLION CHECK. BUT WHAT'S IMPORTANT HERE TO EMPHASIZE IS THAT WE HAVE A TREMENDOUS TEAM THAT'S WORKED TOGETHER TO GET THIS FUNDING OUT. RICK KELLER ISN'T HERE. AMY LEWIS IS HERE. AMY, COULD YOU STAND UP, PLEASE, FOR A SECOND? AMY LEWIS.

(APPLAUSE.)

CHAIRMAN KLEIN: OUR COUNSEL, BOTH OUR BOARD COUNSEL, JAMES HARRISON, AND OUR IN-HOUSE COUNSEL, TAMAR PACHTER, WORKED VERY HARD ON GETTING THESE OUT. WE HAVE -- IS MARGARET HERE? WHY DON'T WE HAVE ALL THE PEOPLE WHO CONTRIBUTED TO THIS EFFORT TO STAND AT ONCE, PLEASE.

(APPLAUSE.)

CHAIRMAN KLEIN: LYNN, NOW, YOU'RE GOING TO HAVE TO STAND ALONE. LYNN HARWELL, YOU KNOW,

WHETHER IT WAS A SUNDAY AT 7 O'CLOCK AT NIGHT OR A MONDAY AT 7 O'CLOCK AT NIGHT, I CAN NEVER TELL THE DAYS OF THE WEEK BY HER CALLS BECAUSE SHE'S ALWAYS WORKING ON MAKING SURE THIS PROGRAM GOT DONE.

BUT IT IS PHENOMENAL AS WELL, AND WE NEED TO PAY SPECIAL ATTENTION TO THE FACT THAT THE CONTROLLER'S OFFICE, JOHN CHIANG AND HIS STAFF, REALLY WERE TEAM MEMBERS IN THIS. THEY WORKED WITH US AND PREAGREED ON THE STEPS WE NEEDED TO GO TO. THEY WORKED WITH MARGARET ON OUR STAFF AND AGREED THAT THE DAY AFTER THEY GOT THE FINAL DOCUMENTS, THE WARRANTS WOULD ACTUALLY BE ISSUED AND IN THE MAIL. THAT'S SHOWING THE GOVERNMENT'S PERFORMANCE AT ITS VERY BEST.

WHEN BEFORE IN YOUR LIFE HISTORY HAS THE GOVERNMENT EVER SAID THE NEXT DAY I WILL PUT THE CHECK IN THE MAIL AND THEY REALLY MEANT IT? SO WE REALLY ARE VERY THANKFUL TO THE CONTROLLER AND HIS STAFF, UNDERSTANDING HOW CRITICAL THESE MEDICAL RESEARCH FACILITIES ARE FOR PARKINSON'S, DIABETES, HEART DISEASE. NAME THE DISEASE AND SOMEONE IS SUFFERING EVERY DAY. THESE RESEARCH FACILITIES WILL HELP MOVE THOSE THERAPIES FORWARD AND HOLD A GREAT PROMISE FOR REDUCING THAT SUFFERING. SO WE'RE VERY THANKFUL TO THE CONTROLLER, AND WE'LL SEND HE AND

HIS STAFF A VERY SPECIAL NOTE OF THANKS IN THE TEAM EFFORT THAT GOT $195 MILLION OF CHECKS OUT, NOT ON TIME, BUT AHEAD OF TIME IN A GREAT EXHIBIT OF HOW GOVERNMENT SHOULD WORK AT ITS BEST AND A GREAT EXHIBIT OF TEAMWORK ON OUR STAFF AND THEIRS.

I'D ALSO THEMATICALLY LIKE TO TOUCH ON THE FACT THAT WE'RE CELEBRATING ANOTHER FIRST FOR THIS AGENCY BECAUSE WITH DR. TROUNSON'S LEADERSHIP, WE'RE ABLE TO ENTER INTO TWO DIFFERENT MEMORANDA OF UNDERSTANDING FIRST WITH THE STATE OF VICTORIA IN AUSTRALIA. STATE OF VICTORIA HAS THE DISTINCTION OF CONTROLLING ABOUT 50 PERCENT OF THE BIOMEDICAL RESEARCH IN AUSTRALIA JUST AS WE CONTROL ABOUT 50 PERCENT OF THE BIOMEDICAL RESEARCH IN THE UNITED STATES. AND WITH THE COUNTRY OF CANADA ON CANCER STEM CELL RESEARCH.

WHAT'S CRITICAL HERE THEMATICALLY, AND WE'VE REPEATED THIS MANY TIMES, BUT WE'RE NOW IMPLEMENTING IT IN A MANIFEST TANGIBLE WAY, IS THAT WE'RE NOT IN COMPETITION AGAINST OTHER STATES AND OTHER NATIONS. WE ARE IN A WAR AGAINST CHRONIC DISEASE AND INJURY. IT IS VITAL THAT WE LEVERAGE INTELLECTUAL ASSETS OF THIS STATE BY EMPOWERING OTHER NATIONS TO COLLABORATE WITH OUR BEST SCIENTISTS AND HAVE THOSE NATIONS PAY THE COST OF

THAT COLLABORATION SO WHEN ONE OF THE RESEARCH TEAMS IN CALIFORNIA WANTS TO REACH OUT TO THE BEST OF OTHER COUNTRIES TO BRING THEM INTO A DISEASE TEAM OR A TRANSLATIONAL GRANT, THAT THOSE FUNDS ARE COVERED. CANADA PUT UP $100 MILLION TO THAT END. AND THEY HAVE FUNDING FROM FOUR DIFFERENT INSTITUTIONS IN CANADA TO MEET THAT OBJECTIVE.

SO CREATING INTELLECTUAL LEVERAGE BY HAVING OUR SCIENTISTS BEING ABLE TO REACH OUT AND KNOW THAT THEIR COLLABORATORS WILL BE FUNDED IN THESE OTHER COUNTRIES IS TREMENDOUS.

DR. TROUNSON WILL SPEAK TO THIS ISSUE IN GREATER DETAIL, BUT IT IS TREMENDOUS THAT WE HAVE BEEN ABLE TO IMPLEMENT MEMORANDA OF UNDERSTANDING. THE BOARD NEEDS TO UNDERSTAND THAT ANY FUNDING THAT WE PARTICIPATE IN WILL GO THROUGH OUR NORMAL PEER REVIEW PROCESS AND WILL COME TO THIS BOARD FOR APPROVAL, AND THE SYSTEM IS DESIGNED NOT TO SLOW THE SYSTEM DOWN, NOT TO CHANGE THE TIMING, BUT MERELY PROVIDE COLLABORATIVE FUNDING.

AFTER IMPORTING THE GREAT INDIVIDUALS LIKE DR. BIRGENEAU FROM BERKELEY, DR. TROUNSON FROM AUSTRALIA, DR. PERA AT USC, IT'S IMPORTANT THAT, IN ADDITION TO THE GREAT INTERNATIONAL RESOURCES AT WORK IN CALIFORNIA, THAT WE REACH OUT AND

COLLABORATE AGGRESSIVELY. AND CERTAINLY DR. TROUNSON IS LEADING THAT TREMENDOUS EFFORT.

I WOULD SAY THAT WE HAVE ANOTHER VERY IMPORTANT RESPONSIBILITY TO HONOR, AND THAT IS A RESPONSIBILITY TO THE SCIENTISTS IN OTHER STATES WHO HAVE SELFLESSLY GIVEN THEIR TIME TO OUR PEER REVIEW SYSTEM. MARIE CSETE IN A RECENT MEMO NOTED THAT THOSE SCIENTISTS, MANY OF THEM, THEY'RE SO DESPERATE FOR FUNDING AT THIS POINT, THEY HAVE TO SPEND SO MUCH OF THEIR TIME ON FUNDING IN THEIR STATES GIVEN THE SCARCITY OF FUNDING, THEY JUST CAN'T GET THE TIME TO BE AVAILABLE TO CONTINUE TO PARTICIPATE IN OUR PEER REVIEW, SO WE ARE RECRUITING NEW PARTICIPANTS FOR OUR PEER REVIEW.

IT IS VITAL THAT WITH THE NEW ADMINISTRATION IN PLACE NEXT YEAR THAT WE PLAY A LEADERSHIP ROLE WITH CONGRESS AND NIH IN TRYING TO RAISE NIH FUNDING GENERALLY AND SPECIFICALLY WITH STEM CELL FUNDING. FROM A PATIENT VIEWPOINT TO HAVE -- FROM A PATIENT ADVOCATE VIEWPOINT, TO HAVE 50 PERCENT OF THE NATION'S CAPACITY WITHOUT ADEQUATE FUNDING IS JUST NOT AN ACCEPTABLE ALTERNATIVE, AND THERE'S TREMENDOUS TALENT IN THESE OTHER STATES THAT CAN ALSO COMPLEMENT THE TALENT IN THIS STATE IN DISEASE TEAMS AND TRANSLATIONAL EFFORTS THAT WE HAVE

THE BEST TEAMS KNITTED TOGETHER FROM ALL OVER THIS COUNTRY DEDICATED TO ADVANCING MEDICAL RESEARCH.

BUT WE HOPE THAT AS OUR REVIEWERS SEE US HONOR OUR COMMITMENT TO FUNDING FOR THE WHOLE COUNTRY, FOR NIH, AND FOR STEM CELL RESEARCH, THEY WILL BE ABLE TO CONTINUE TO SERVE ON PEER REVIEW PANELS, WHICH IS SUCH A CRITICAL COMPONENT OF GETTING TO THE BEST SCIENCE. AND GETTING TO THE BEST SCIENCE WITH ALL OF THOSE MEMBERS BEING FROM OUT-OF-STATE, SO WE GET AN OBJECTIVE, CLEAR READING, AT LEAST TO THE BEST OF OUR ABILITY ON THE QUALITY OF SCIENCE, THE CONTRIBUTIONS TO MEDICAL ADVANCES, AND IT'S IMPORTANCE IN OUR PORTFOLIO.

WITH THOSE COMMENTS TODAY, I'M GOING TO GO FORWARD TO THE NEXT AGENDA ITEM AND ASK IF THE PRESIDENT WANTS TO MAKE ANY COMMENTS TODAY, ALTHOUGH, AGAIN, THEY WILL BE HIGHLIGHTED TOMORROW IN FULL.

DR. TROUNSON: THANK YOU VERY MUCH, MR. CHAIRMAN. DOESN'T SEEM LONG AGO THAT WE ALL WERE ALL TOGETHER, BUT A LOT OF THINGS HAVE HAPPENED IN THAT VERY SHORT TIME. AND I WANT TO THANK YOU PARTICULARLY -- I WANT TO THANK YOU PARTICULARLY, MR. CHAIRMAN, FOR ALL YOUR HELP. ALSO THE VICE CHAIRMAN, WHO REALLY DOES INPUT INTO SOME OF OUR

ACTIVITIES VERY IMPORTANTLY, AND OTHER MEMBERS OF THE BOARD WHO WE INTERACT WITH FROM TIME TO TIME. IT IS WITH THIS INTEGRATED EFFORT, I THINK, THAT WE'RE ABLE TO MAKE THE KIND OF PACE THAT WE'RE CURRENTLY ON.

SO AS USUAL, IF I MAY START WITH SOME SCIENCE ISSUES, THIS IS REALLY ABOUT SCIENCE. AND I THINK THAT'S WHAT YOU SHOULD BE REALLY PROUD OF. THERE ARE SEVEN OF THE WONDERFUL INSTITUTES, MANY OF WHICH THE PLACES THAT I'VE BEEN THERE'S HOLES IN THE GROUND OR HOLES ABOUT TO APPEAR IN THE GROUND AS THE BUILDINGS GET UNDER WAY. AND THESE ARE FABULOUS INSTITUTES, FABULOUS BUILDINGS. THEY LOOK TERRIFIC. I MEAN IF I WAS A YOUNG SCIENTIST, I'D BE IN ONE OF THOSE, THAT'S FOR SURE. MAYBE IN TWO OR THREE. BUT IT'S -- I'D LOVE TO BE IN THOSE PLACES, AND THEY'RE JUST MAGNIFICENT. IN THIS FORM THEY LOOK TERRIFIC, BUT, YOU KNOW, IT'S GOING TO BE BETTER WHEN IT HAPPENS WITHIN THE NEXT TWO YEARS.

SO LOOKING AT BRINGING YOU FOUR PAPERS IN THIS AREA OF NEW DEVELOPMENTS IN STEM CELLS, AND I THINK THEY ARE COMPLEX IN THE NATURE OF THE WORK HERE, BUT I WANT TO TRY AND DESCRIBE THE SORT OF FEELING THAT WE HAVE AS MANY OF US READ INTO THESE JOURNALS. THIS IS A PAPER IN *NATURE*, JUNE, THIS

MONTH, FROM ALEX MEISSNER AND RUDY JAENISCH'S LABS AT THE MIT AND WHITEHEAD AND HARVARD AND M.A. GENERAL HOSPITAL.

AND IT'S QUESTIONING WHAT IS THIS WORD "PLURIPOTENTIALITY"? WHAT DOES IT MEAN? YOU HEAR THIS WORD, AND WHAT DOES IT ACTUALLY MEAN? WHAT IS THE KEY TO IT?

WELL, THEY'VE STARTED TO LOOK IN SOME DETAIL ABOUT WHAT IS PLURIPOTENTIALITY, AND THEY CAN SEE THAT YOU TAKE A CELL, A SKIN CELL, AN ADULT CELL, WHAT YOU'VE GOT TO REALLY DO IS REACTIVATE WHAT WE CALL THE PLURIPOTENTIALITY RELATED TO IT. SO THESE ARE THE GENES THAT ARE CURRENTLY ON WHEN CELLS HAVE THE ABILITY TO MAKE EVERYTHING ELSE IN THE BODY. SO YOU'VE GOT TO TURN THOSE ON; AND TO DO THAT, YOU'VE GOT TO OPEN THE CHROMATIN.

NOW, THE CHROMATIN IS THE MATERIAL THAT HOUSES THE GENES AND THE CHROMOSOMES. THAT'S GOT TO BE UNWOUND AND OPENED BECAUSE THESE FACTORS THAT TURN ON ARE CALLED TRANSCRIPTION FACTORS, AND THEY'RE FACTORS THAT GOVERN THE EXPRESSION OF OTHER PARTICULAR GENES. SO IT IS -- THEY'VE STARTED TO LOOK AT THESE PROCESSES.

THERE'S A SET OF GENE PRODUCTS CALLED POLYCOMB, AND THESE POLYCOMB-MEDIATED GENES ACTUALLY

REPRESS, THEY PUSH DOWN THE GENES THAT ARE TURNING CELLS TO BE SKIN CELLS OR LIVER CELLS OR WHATEVER CELLS. THEY TURN THOSE GENES DOWN AND OPEN THE CHROMATIN, ALLOW THE ABILITY OF THE GENE TO GO BACK TO THE ZERO POINT.

SO IT IS A RARE EVENT. IT'S CERTAINLY NOT A COMMON EVENT FOR THIS TO HAPPEN. BUT WHAT THEY FOUND IS THAT IF YOU UNDERSTAND THIS PROCESS BETTER, AND THEN YOU ACTUALLY USE DNA DEMETHYLATION; THAT IS, THE METHYLATION GROUPS ARE SOME OF THE GROUPS THAT ALSO GOVERN THE EXPRESSION OF GENES, AND YOU USE RNA INHIBITORS, THAT YOU CAN GET A MUCH MORE EFFECTIVE REPROGRAMMING. SO THEY'RE UNDERSTANDING THE MOLECULAR LEVEL.

ONCE YOU START TO UNDERSTAND THE MOLECULAR LEVEL OF WHAT IS PLURIPOTENTIALITY, WE'LL BE ABLE TO DO THIS WITHOUT THE USE OF COMPLEX VIRAL COMPONENTS AND GENES. AND SO THIS IS, IN FACT, A VERY BASIC, VERY IMPORTANT PAPER.

THE NEXT ONE, LIKEWISE, IS ABOUT PLURIPOTENTIALITY. IT WAS PUBLISHED BY CHEN AND COLLEAGUES WHO ARE FROM SINGAPORE IN THE JOURNAL *CELL*. WHAT THEY FOUND IS INTERESTING IS IN A STRUCTURED SENSE THAT THESE TRANSCRIPTION FACTORS THAT REALLY CLEAVE TO THE WHOLE PROCESS ACTUALLY ARE

CLUSTERED IN TWO AREAS. THERE'S A VERY DEFINED CLUSTERING. THE ONE CLUSTER, WHICH CONTAINS THE SORT OF GOLD STANDARD GENES THAT PEOPLE ALL RECOGNIZE, ARE CLUSTERED IN ONE PLACE, AND THEN THERE'S A SMALLER CLUSTER IN ANOTHER PLACE. AND IT MEANS THESE GENES ARE PLAYING GAMES WITH ONE ANOTHER BECAUSE THEY'RE TRANSCRIPTION FACTORS THAT HAVE AN INFLUENCE ON THE SAME KIND OF STATE. AND IT MAKES GOOD SENSE NOW TO SEE THAT THEY'RE ACTUALLY IN THE SAME PLACE.

SO, AGAIN, FOR TRYING TO KEEP THE OTHER GENES THAT YOU MIGHT WANT TO INFLUENCE TO GET A BETTER OUTCOME, YOU CHOOSE THE GENES IN THOSE KIND OF CLUSTERS, YOU'RE LIKELY TO GET A BETTER OUTCOME. SO THIS IS, AGAIN, A VERY IMPORTANT PIECE OF WORK.

AND I WANTED TO ADD IN ADDITION, BECAUSE I'M NOT SURE WE'VE SPOKEN ABOUT THIS, BUT IN ADDITION, DOUG MELTON AT HARVARD GAVE A VERY INTERESTING PAPER AT THE RECENT INTERNATIONAL STEM CELL SOCIETY MEETING. AND HE SHOWED THAT IF YOU TOOK PANCREATIC EXOCRINE CELLS, THESE ARE THE CELLS THAT -- THEY DON'T ACTUALLY PRODUCE INSULIN, BUT THEY PRODUCE THE DIGESTIVE ENZYMES THAT ARE PRESENT IN THE PANCREAS. BUT HE CAN MAKE THEM TURN INTO INSULIN PRODUCING CELLS BY USING ANOTHER SET OF

TRANSCRIPTION FACTORS.

SO HE CHOSE A PANEL OF TRANSCRIPTION FACTORS FROM THE PANELS THAT HE THOUGHT WERE IMPORTANT, AND HE GOT PART OF THEM BACK INTO A TYPE WHICH ACTUALLY COULD LEAD TO PRODUCE INSULIN.

THIS, I THINK, IS PART OF THIS WHOLE PROCESS HERE THAT WE MAY BE ABLE TO TURN CELLS BACK JUST PART THE WAY AND GET AN OUTCOME WHICH IS REALLY IMPORTANT BECAUSE, YOU SEE, PATIENTS OFTEN HAVE EXOCRINE CELLS IN THEIR PANCREAS, BUT THEY HAVE NO INSULIN PRODUCING CELLS. AND IF YOU CAN CREATE THEM FROM THE ENZYMATICALLY PRODUCING CELLS, YOU MAY CREATE, AGAIN, AN EFFECTIVE PANCREAS WHICH IS PRODUCING INSULIN, AND MAYBE YOU CAN GET THE SOLUTION TO DIABETES.

SO, AGAIN, ALL OF THESE PAPERS ARE MOVING INTO THIS REALLY INTERESTING AREA. I THINK THERE'S A GROWING INTEREST IN THESE IDEAS, CELLS, AND HOW YOU CAN PARTIALLY DIRECT SOME OF THE CELLS BACK, BUT ALSO THE FULL RETURN OF THE CELLS INTO WHAT'S CALLED AN EMBRYONIC STATE IN ORDER TO MAKE THE SYSTEMS A LOT BETTER BY USING SMALL MOLECULES IN THE FUTURE. SO THESE ARE REALLY, REALLY IMPORTANT PAPERS.

AND THE LAST ONE, I THINK, THAT I BRING TO YOU, THE THIRD ONE, I THINK THIS IS AN INTERESTING

ONE. I THINK FOR PEOPLE WHO ARE INTERESTED IN REMYELINATING OR DEMYELINATING DISEASES, THIS IS A GROUP, WINDREM, ET AL. PUBLISHED IN *CELL STEM CELL*, AGAIN IN JUNE. ALL THESE PAPERS WERE PUBLISHED THIS MONTH. STEVE GOLDMAN'S LAB AT THE UNIVERSITY OF ROCHESTER, HE SHOWED THAT IF YOU USED A PROGENITOR CELL FROM THE BRAINS OF FETUS, HUMAN FETUSES, THESE PROGENITOR CELLS ARE PROGENITOR FOR GLIAL CELLS. GLIAL CELLS ARE EITHER ASTROCYTES, WHICH ARE VERY POPULOUS IN THE BRAIN, OR OLIGODENDROCYTES. THE OLIGODENDROCYTES ARE THE ONES WHICH REMYELINATE OR MYELINATE NEURONS.

AND MANY USES IN WHAT WE CALL A SHIVERER MOUSE WHERE YOU GET HYPOMYELINATION, THAT IS A LOSS OF MYELIN SHEATHS, AND HE WAS ABLE TO GET -- THAT REPORT WAS ABLE TO GET REMYELINATION AND CORRECTION OF THE SHIVERER CONDITION. NORMALLY THESE MICE DIE VERY EARLY AND PREDICTABLY, AND ALL OF THE ONES THAT WERE GIVEN THESE HUMAN CELLS REMAINED REASONABLY HEALTHY. THEY CAME OUT OF THEIR SHIVERER CONDITION. AND THEN THEY LOOK IN THERE, THERE'S A LOT OF REMYELINATION HAS GONE ON IN THE BRAINS OF THESE MICE.

NOW, THIS HAS A PARTICULAR IMPORTANCE FOR AN X-LINKED GENETIC DISEASE OF HYPO-PMD. UNLESS

YOU'RE GERMAN, YOU HAVE A LOT OF TROUBLE PRONOUNCING THE NAME OF THAT DISEASE. BUT IT'S AN X-LINKED MISEXPRESSION DISEASE WHICH IS PRESENT IN YOUNG CHILDREN, AND IT'S LETHAL. AND THE IDEA THAT YOU COULD ACTUALLY CORRECT THIS DISEASE WITH PROGENITORS OF THE GLIAL LINEAGE IS REALLY IMPORTANT. AND ALSO IS IMPORTANT TO THE POINT OF VIEW THAT WE CAN MAKE THEM FROM EMBRYONIC STEM CELLS.

AND SO RATHER THAN USING FETAL MATERIAL, HOPEFULLY WE'LL BE ABLE TO USE EMBRYONIC CELL-DERIVED MATERIAL. AND SO I THINK IT'S ANOTHER STEP ALONG THE WAY IN SOME OF THESE REALLY DIFFICULT DEMYELINATING, REMYELINATING DISEASES.

THE LAST ONE I WANT TO TALK TO YOU IS BECAUSE I DID SPEND A LITTLE BIT OF TIME WITH THE GOVERNOR. AND I'M ALSO GETTING OLDER, AND IT'S ALSO GETTING MORE DIFFICULT. I SPEND A LOT OF TIME IN THE GYM TO MAKE VERY LITTLE MUSCLE. IN THE OLD DAYS WHEN I WAS PLAYING RUGBY, I HARDLY SPENT ANY TIME IN THE GYM, AND I USED TO MAKE REASONABLE AMOUNTS OF MUSCLE.

WELL, I ALWAYS THOUGHT IT WAS THE STEM CELLS THAT WERE RUNNING OUT IN THE MUSCLE. BUT THIS STUDY IS A REALLY INTERESTING STUDY THAT'S FROM ONE OF OUR FUNDED OR TWO OF OUR FUNDED SCIENTISTS,

CIRM-FUNDED SCIENTISTS, AT BERKELEY. SO THIS IS A GREAT STUDY PUBLISHED IN *NATURE* AND ADVANCED ONLINE THIS MONTH. A GOOD THING FOR JUNE. GREAT WORK.

WHAT THEY SHOWED WAS THE STEM CELLS IN MUSCLE ARE CALLED SATELLITE CELLS. THERE'S MORE NUMBERS OF THESE SATELLITE CELLS PRESENT IN MUSCLE. AND THE VIEW REALLY WAS THAT AS WE GET OLDER, WE RUN OUT OF THOSE SATELLITE CELLS, AND WE CAN'T MAKE MORE MUSCLE. WELL, WHAT THEY'VE SHOWN IS NOT THAT. WHAT ACTUALLY MAKES MORE MUSCLE, WHAT GETS THOSE SATELLITE CELLS TO MAKE MORE MUSCLE IS A GENE CALLED NOTCH.

NOTCH ACTUALLY GETS THE SATELLITE CELLS TO MULTIPLY TO RESULT IN MUSCLE. BUT THERE'S ANOTHER SET. THIS IS LIKE A TIPPING BALANCE IN THE MUSCLE. THERE'S ANOTHER SET OF GENES WHICH ARE CONTROLLED BY TGFBETA AND PARTICULARLY DOWNSTREAM OF TGFBETA ARE A GENE CALLED PSMAD3 WHICH COMPETE FOR THE SAME AS THE NOTCH, THE SAME RECEPTOR. SO IF YOU'VE GOT LOTS OF NOTCH, YOU'RE GOING TO MAKE MUSCLE. IF YOU'VE GOT LOTS OF TGFBETA, YOU'RE NOT BECAUSE IT'S GOT IT TURNED OFF. IT'S AN OFF-AND-ON SWITCH, AND IT'S QUITE A COMPLEX SWITCH, BUT IT'S A ROCKER SWITCH, IF YOU LIKE.

WHAT HAPPENS IS WHEN WE GET OLDER, WE LOSE

NOTCH. WE DON'T MAKE AS MUCH NOTCH, AND WE'RE MAKING MORE TGFBETA. SO IT'S JUST WE CAN'T TURN ON THE ROCKER SWITCH. WE JUST CAN'T TURN IT ON. AND IF THIS IS THE CASE, IF THIS IS REALLY THE CASE, AND WE CAN SHOW THIS OVER AND OVER AGAIN WITH OTHER LABORATORIES, IT MAY BE VERY IMPORTANT FOR US TO BE ABLE TO MAKE MORE MUSCLE IN A WHOLE LOT OF MUSCLE WASTING DISEASES. THESE ARE THE DYSTROPHIC DISEASES, ALZHEIMER'S AND PARKINSON'S DISEASES, CANCER, AND IN MY CASE AGING.

SO IT'S REALLY -- THIS IS REALLY A GOOD PAPER. AND IF I HAD TIME, I WOULD HAVE TALKED TO THE GOVERNOR ABOUT THIS BECAUSE I THINK HE WOULD BE ALSO INTERESTED IN THIS PAPER. BUT, YOU KNOW, I THINK IN REAL ESSENCE IT IS AN IMPORTANT CONTRIBUTION TO THE FIELD FROM THE BERKELEY GROUP THAT DID THAT.

CHAIRMAN KLEIN: ALAN, HOW DOES THAT ACTIVATION OF NOTCH OR LOSS OF YOUR NOTCH VITALITY AFFECT ALZHEIMER'S?

DR. TROUNSON: IN ALZHEIMER'S DISEASE, IT'S A MUSCLE WASTING DISEASE AGAIN, AND PEOPLE DON'T KNOW REALLY WHY IT'S HAPPENING, BUT IT MAY BE THAT NOTCH IS -- THAT ROCKER SWITCH IS INVOLVED IN ALZHEIMER'S AND PARKINSON'S. IT'S OFTEN THOUGHT

BECAUSE YOU HAVE -- YOU REDUCE YOUR ACTIVITY BECAUSE IT'S MORE DIFFICULT TO MOVE AROUND AND EXERCISE, THAT YOU LOSE IT FROM THAT REASON. BUT IT MAY WELL BE THAT THE ROCKER SWITCH IS DEFECTIVE IN THAT CONDITION. IF IT IS, CLEARLY IF WE CAN DRIVE NOTCH UP, WE MAY HAVE -- MAY BE ABLE TO MAKE MUSCLE, AT LEAST MORE MUSCLE IN SOME OF THOSE CONDITIONS, SO IT'S IMPORTANT.

WELL, I'VE HAD A LOT OF PRIORITIES, AND I JUST WANTED TO QUICKLY JUST TELL YOU WHAT THEY WERE. THE NO. 1 PRIORITY THAT I'VE HAD IN THE TIME I'VE BEEN HERE AND I'VE BEEN WORKING REALLY HARD ON IS TO REALLY GET STAFF MORALE RIGHT AT THE TOP LEVEL AND GET THE DEDICATION TO THE SAME MISSION. SO WE'VE BEEN WORKING ON THE STRUCTURE AND GETTING OPEN DISCUSSIONS ABOUT THE WAY WE'RE COMPOSED AND THE KIND OF STAFF STRUCTURE AS WE MOVE FORWARD. AND I THINK THAT'S RESULTED IN INCREDIBLY HIGH MORALE. WE'RE ACTUALLY ALL WORKING TOGETHER. WE'RE ALL POINTED IN THE SAME DIRECTION.

I THINK IT'S JUST A BREAKTHROUGH FOR PEOPLE, BUT IT TAKES QUITE A LOT OF EFFORT TO DO THAT. YOU'VE REALLY GOT TO MAKE SURE THAT PEOPLE, YOU KNOW, WHERE THEY'RE UNSATISFIED, MAKE SURE THAT THOSE KIND OF PROCESSES, THOSE CONDITIONS ARE

ADDRESSED. AND SO I WOULD SAY AT THE MOMENT WE'VE GOT THE HIGHEST MORALE IN ANY ORGANIZATION THAT I'VE EVER BEEN IN. I THINK THAT'S JUST WONDERFUL, AND IT'S REALLY BECAUSE THE STAFF REALLY HAVE ADOPTED THE SAME PRINCIPLE OF GETTING THE PRIMARY MISSION OUT.

WE WORKED ON THE 2008-9 BUDGET. WE'LL PRESENT THAT TO YOU. WE'RE ON TARGET FOR THE REVISION OF THE CIRM STRATEGIC PLAN. IT'S A YEAR AND A HALF OLD. CURRENTLY WE'RE IN THE STAGE OF ASKING DIFFERENT PEOPLE IN THE ORGANIZATION TO DRAFT DIFFERENT SILOS. WE'RE GOING TO BRING IT TOGETHER. WE'RE GOING TO TALK TO STAKEHOLDERS IN EACH OF THE SECTIONS AND THEN BRING IT TO YOU FOR DISCUSSION AND YOUR INPUTS INTO THAT STRATEGIC PLAN.

WE LOOKED AT STAFF POSITION AND DESCRIPTIONS. WE'VE BEEN THROUGH NEARLY EVERY ONE OF OUR STAFF. I THINK WE'VE GOT EVERYBODY IN A REASONABLY HANDY POSITION, THAT THEY'RE DOING THE THINGS THAT THEY'RE REALLY GOOD AT, AND THEY WILL BE APPRAISED ON THEIR CAPACITY TO DO THOSE JOBS. I THINK THEY'RE VERY MUCH IN LINE NOW WITH WHAT THE STAFF DO AND WHAT THEY'RE REALLY GOOD AT.

WE'VE INTRODUCED A PROGRAM FOR COMPLIANCE INTERNALLY, AND WE'VE STARTED TO LOOK AT COMPLIANCE

OUT IN OUR GRANTEE ORGANIZATION. THERE'S TWO OF THE MEMBERS OF THE CIRM TEAM ARE OUT NOW WORKING WITH OTHER ORGANIZATIONS TO SEE THAT ALL OF THE AGREEMENTS AND REGULATIONS THAT WE IMPOSE WE EXPECT ARE ALL BEING DONE. I HAVE TO SAY THAT I UNDERSTAND THE FIRST ONE, OF COURSE, WAS THE WONDERFUL STANFORD. THE UNIVERSITY, AS USUAL, PASSED WITH FLYING COLORS AT EVERY CORNER.

BUT I THINK THIS IS A PROCESS WHERE WE WOULD LIKE TO LEARN. IF THERE ARE DIFFICULTIES IN OUR REGULATIONS OR INTERACTIONS, CAN WE SORT OF COME BACK AND MAKE ADJUSTMENTS TO HELP EVERYBODY, YOU KNOW, GO THE SAME WAY.

WE LOOK AT INTERNATIONAL, NATIONAL LINKAGES, AND I'LL TALK TO YOU ABOUT THAT A LITTLE LATER.

LOOKING AT CIRM GRANTEE PRODUCTIVITY, BOTH PUBLICATIONS AND PRESENTATIONS, THERE WAS A VERY LARGE CONTINGENT OF CALIFORNIA PRESENTATIONS AT THE RECENT INTERNATIONAL SOCIETY OF STEM CELL RESEARCH. DON GIBBONS IS BUILDING A PORTFOLIO OF FANTASTIC PAPERS THAT ARE COMING OUT OF THE INSTITUTIONS, AND WE'RE GETTING SOME RECOGNITION NOW ON PRIMARY PRESENTATIONS BY SOME OF THE PEOPLE WHO ARE PERFORMING REALLY, REALLY WELL. SO I THINK

PRODUCTIVITY IS TERRIFIC IN THE SHORT TIMEFRAME THAT THIS AGENCY HAS BEEN GOING.

WE'RE LOOKING AT EDUCATION AND STEM CELL LEADERSHIP. AGAIN, WE'RE WORKING WITH DON TO MAKE SURE THAT WE GET A WHOLE NEW ROUND OF EDUCATION PROGRAMS, AND THAT WE RECOGNIZE THE LEADERSHIP THAT WE'RE INVOLVED WITH BY APPEARING IN UNITED STATES AND WORLDWIDE.

WE'RE LINKING WITH BIOTECH AND PHRMA INDUSTRIES. THERE HAVE BEEN LOTS OF MEETINGS WITH THOSE PEOPLE. WE SEE THEM AS BEING IMPORTANT PARTNERS IN DELIVERY OF -- THE NECESSARY DELIVERY OF OUR MISSION. AND WE HAD A GREAT MEETING AT BIO. AS BOB SAID, THERE WERE A LOT OF MEETINGS AND OTHER DISCUSSIONS WITH THE BIOTECH INDUSTRY AND PHRMA INDUSTRY THERE. VERY MUCH MOVING ALONGSIDE OF US.

WE'RE RESPONDING TO THE NEEDS EXPRESSED BY STAKEHOLDERS. WE'RE OUT THERE LISTENING. WE'RE AT CONFERENCES. WE'RE GOING TO THE UNIVERSITIES. WE'RE OUT AMONGST THE BIOTECH INDUSTRY. WE'RE LISTENING TO WHAT THEIR CONCERNS ARE, BRINGING THEM BACK IN-HOUSE, AND SEEING WHERE WE CAN ACTUALLY MAKE ADJUSTMENTS TO ACCOMMODATE WHAT THEIR NEEDS ARE. WE'RE IMPLEMENTING GRANTIUM, WHICH IS A GRANTS MANAGEMENT SYSTEM WHICH WILL TAKE A LOT OF LOAD OFF

OUR INDIVIDUAL PEOPLE.

SO THESE ARE SOME OF THE REAL PRIORITIES THAT I'VE BEEN DEALING WITH LATELY THE LAST MONTH OR SO, LAST TWO MONTHS. AND THEY'RE ALL ACTUALLY WORKING REALLY WELL.

I WOULD LIKE TO BRING YOUR ATTENTION TO THE POSSIBILITY THAT WE CAN HAVE A STEM CELL AWARENESS DAY ON SEPTEMBER 14 OR 15. NOW, THIS WAS RAISED BY THE PREMIER OF VICTORIA TOGETHER WITH THE LEADERS OF THE INSTITUTE THAT I WAS INVOLVED WITH THERE. THEY'RE HAVING THIS STEM CELL AWARENESS DAY, AND THE GOVERNOR WAS VERY, VERY SUPPORTIVE OF SOMETHING LIKE THIS. AND I THINK HIS INSTRUCTION TO THE CHAIRMAN WAS TO GET ON WITH IT OR ACTUALLY EXPECTED THINGS TO BE DONE IN THIS AREA.

I THINK IT'S A GREAT IDEA. AND WHETHER WE TWIN WITH VICTORIA AND START TO PICK UP OTHERS AS WE GO YEAR BY YEAR, I THINK IT'S A GREAT IDEA. AND IT'S ONE WAY WE CAN ACTUALLY GET OUR PATIENT ADVOCATES INTO A PRIMARY POSITION, IN MY VIEW, TO PICK UP THE AWARENESS THAT IS MAINLY LACKING IN SOME OF OUR AREAS. SO I'D LIKE TO PROPOSE THAT, AND I HOPE THE ICOC WOULD BE SUPPORTIVE OF THAT. DON GIBBONS, HE'S SUPPORTING IT. OBVIOUSLY THERE'S A LOT OF WORK INVOLVED IN THAT, AND I THINK A LOT OF

WORK IS NECESSARY WITH PATIENT ADVOCATES TO SEE WHAT WE CAN ACTUALLY DO IN THIS.

WE'VE GOT -- I THINK THERE ARE TWO PERSONNEL. I THINK MARGARET FITZGERALD HAS ALSO BEEN INTRODUCED. MARGARET FERGUSON. SORRY. SHE'S OUR FINANCE MANAGER, AND SHE'LL BE PRESENTING THE BUDGET TO YOU, I GUESS, TOMORROW.

AMY ADAMS IS HERE. SHE'S A COMMUNICATION MANAGER JUST APPOINTED FROM STANFORD.

DR. PIZZO: SHE HAS A ONE-YEAR-OLD PRIORITY. SHE HAS A ONE-YEAR-OLD PRIORITY.

CHAIRMAN KLEIN: SHE HAD A CHILD WHO'S ONE YEAR OLD.

DR. TROUNSON: WE'D UNDERSTAND THAT, WOULDN'T WE. SO TAKING ANOTHER GOOD PERSON FROM STANFORD. SHE'S TERRIFIC, AND SO SHE'LL BE ENGAGED WITH YOU BECAUSE SHE'S A COMMUNICATION MANAGER. SHE'S GOING TO BE WRITING SOME OF THE KEY MATERIAL, SO YOU WILL GET TO KNOW HER.

SCIENCE PROGRAM FUNDING COMMITMENT, JUST TO GIVE YOU A HEADS UP ON THIS, IT'S IMPORTANT FOR YOU TO KNOW WHAT WE HAVE IN OUR MIND. WE'VE ALREADY AGREED TO NEW FACULTY II; THAT IS, WE, THE ROYAL WE, THE ICOC; TOOLS AND TECHNOLOGIES OF 20 MILLION; TRAINING II PROGRAM, 48 MILLION; BRIDGES,

INTERNSHIPS FOR THE YOUNG PEOPLE COMING FROM THE STATE UNIVERSITIES OF CALIFORNIA AND LIKE INSTITUTIONS, 18 MILLION; WE'RE GOING TO PRESENT TO YOU A TRANSLATIONAL PROGRAM, SO WE'RE MOVING THE PIPELINE DOWN. YOU REMEMBER THE PIPELINE THAT I TALKED ABOUT. THE PIPELINE WAS CLEARLY TRANSLATION. A CONCEPT WILL BE PRESENTED TO YOU AT THIS MEETING. AND THE DISEASE TEAMS AND OTHERS, THESE ARE THE CORE PROGRAMS, AND I HOPE YOU WILL AGREE THAT DISEASE TEAMS WILL BECOME PRETTY MUCH THE ICOC AND CIRM CORE BECAUSE I JUST THINK IT'S VERY OBVIOUSLY THAT IT IS, AND IT'S GOING TO BE A BIG PROGRAM. AND WE HOPE TO PRESENT THAT TO YOU OVER THE NEXT FEW MONTHS.

SO THERE'S $340 MILLION. SO THAT'S QUITE AN AMOUNT OF MONEY TO BE GETTING OUT INTO THE RESEARCH COMMUNITY IN THIS NEXT 12 MONTHS.

THE GRANT REVIEWS THAT HAVE JUST BEEN COMPLETED, THE CIRM NEW FACULTY AWARDS II HAS BEEN COMPLETED. THEY WILL BE UP FOR ICOC REVIEW AUGUST 12TH AND 13TH.

TOOLS AND TECHNOLOGIES, A VERY INTERESTING PROGRAM WHERE WE ASKED FOR THE COMMUNITY HERE IN CALIFORNIA TO GIVE US A RESPONSE TO THE NEED FOR NEW TOOLS. YOU KNOW, THESE ARE TOOLS THAT WILL ACTUALLY MOVE OUR PROGRAMS ALONG THE TRANSLATIONAL PIPELINE.

THEY ARE THINGS LIKE FILTERS TO GET RID OF THE UNWANTED CELLS. THEY'RE MARKERS TO TELL US WHICH CELLS ARE WHAT, AND PANELS OF MARKERS NEEDED. WE NEED EXPRESSION. WE NEED REPORTER GENES AND PARTICULAR GENES SO THAT WHEN THEY COME ON, THEY LIGHT UP.

WE NEED THOSE KIND OF TECHNOLOGIES. A WHOLE RAFT OF THEM. A 140 LETTERS OF INTENT. SO IT'S A BIG PROGRAM. THERE ARE 90 FROM THE NOT-FOR-PROFIT ORGANIZATIONS, SO THERE WAS NO SLACKING AMONGST OUR ACADEMIC COLLEAGUES, THAT'S FOR SURE. BUT YOU WILL NOTICE THERE ARE 50 FROM THE BIOTECH INDUSTRY. AND SO HERE I THINK IT'S IMPORTANT -- AN IMPORTANT PROGRAM, AND IT'S GOING TO COST US DEARLY WITH OUR REVIEWERS, I'M AFRAID. WE'RE GOING TO HAVE TO HAVE A DOUBLE PROGRAM OF REVIEW, AND IT IS A BIT OF A STRESS POINT BECAUSE IT'S PRETTY LARGE. THE REVIEWERS WILL BE LOOKING IN DETAIL IN 30 OR 40 GRANT APPLICATIONS. THAT'S A HUGE DEMAND ON ANYONE'S TIME AND EFFORT TO DO THAT.

MS. SAMUELSON: CAN YOU EXPLAIN WHAT THAT MEANS?

DR. TROUNSON: SORRY?

MS. SAMUELSON: WHAT THAT MEANS, DOUBLE PROGRAM REVIEW.

DR. TROUNSON: OH, WE'LL HAVE TO TAKE TWICE THE AMOUNT OF TIME THAT WE WOULD DO FOR A SINGLE PROGRAM BECAUSE WE NORMALLY LOOK AT, HOPEFULLY, 60 TO 70 AT ANY ONE TIME. THAT WOULD BE THE KIND OF PROGRAM THAT WOULD TEND TO STRETCH US AT EACH ONE OF OUR REVIEWS.

MS. SAMUELSON: IT'S ABOUT THE QUANTITY.

DR. TROUNSON: YEAH. IT'S ABOUT THE QUANTITY. AND, OF COURSE, THERE WILL BE A VARIANCE THERE, AND IT WILL BE TOUGH GOING FOR OUR REVIEWERS. WE RECOGNIZE THAT, BUT I LOVE DOING IT, BUT IT'S ONE OF THOSE TIMES WHERE WE WOULDN'T WANT TO DO THAT A LOT. IT HURTS TO HAVE TO DO 40 REVIEWS, 40 GRANT APPLICATIONS.

UPCOMING RFA'S, WE'RE GETTING OUT TO THE TRAINING GRANTS II FOR THE CIRM SCHOLARS. THESE RFA'S ARE IN DRAFT OR NEARLY FINISHED. BRIDGES TO STEM CELL RESEARCH, THAT'S THE INTERNSHIP PROGRAM FOR THE STATE UNIVERSITIES AND LIKE INSTITUTIONS. AND THE TRANSLATIONAL RESEARCH, WE'LL BE SEEKING CONCEPT CLEARANCE HERE AT THIS MEETING FOR THAT.

PROPOSED WORKSHOPS, WE'VE GOT A BUSY SET OF PROGRAMS HERE. THERE'S A VERY INTERESTING ONE ON PREDICTIVE TOXICOLOGY ON JULY 7 AND 8, AND I BRING IT TO YOUR ATTENTION. YOU SHOULD TELL US IF YOU

WOULD LIKE TO BE INVOLVED BECAUSE WE MAKE IT REALLY BY INVITATION, BUT SOME PEOPLE MAY BE VERY INTERESTED IN THIS.

THE TOXICOLOGY IS REALLY USING THE CELL LINES, LIKE LIVER CELL AND HEART CELL, FOR ENVIRONMENTAL SCREENING. USUALLY THEY USE VERY LARGE NUMBERS OF RATS AND MICE FOR THESE STUDIES. WE THINK THAT THE CELL LINES, THE HUMAN CELL LINES THAT ARE THERE NOW AND THEY'RE STABLE AND THEY'RE EFFECTIVE AT LEAST APPEAR TO BE FUNCTIONING EFFECTIVE IN CULTURE AND IN TRANSPLANTATION STUDIES, SO COULD BE USED FOR PREDICTING TOXICOLOGY, BUT ALSO IN DRUG SCREENING. AND IF WE CAN DO THAT, WE WOULD ACTUALLY REDUCE THE COST OF DRUG SCREENING QUITE SUBSTANTIALLY. BUT WE'D ALSO REDUCE THE DEMAND ON USING ANIMALS, AND I THINK BOTH OF THOSE THINGS WOULD BE VERY STRONG QUALITIES.

SO WE'VE GOT A LOT OF INPUT IN THAT PROGRAM FROM BIOTECH AND PHRMA, AS YOU'D EXPECT, AND THEN FROM OUR INSTITUTIONS. SO IT'S GOING TO BE A REALLY WOW WORKSHOP.

CANCER STEM CELLS IS A SMALLER WORKSHOP, BUT I THOUGHT IT WAS IMPORTANT TO GET TOGETHER THE THOUGHT LEADERS IN CANCER IN CALIFORNIA BECAUSE THE PROPOSAL TO WORK IN COLLABORATION WITH THE CANADIANS

DESERVES TO HAVE ALL THE THOUGHT LEADERS COME AND HAVE THEIR INPUT BECAUSE I'D LIKE THEIR SUPPORT IN MOVING FORWARD ON INTEGRATING WITH CANADA. AND I THINK IT'S APPROPRIATE TO ACTUALLY HAVE A DISCUSSION WITH THE THOUGHT LEADERS IN CANCER BECAUSE THEY'RE NOT ALL ABSOLUTELY WITH IT IN CANCER STEM CELLS, AND SO I THINK THEY NEED TO BE ABLE TO HAVE THEIR SAY AND BE ABLE TO RESPOND.

MS. LANSING: I JUST WANTED TO SECOND HOW IMPORTANT I THINK THAT IS BECAUSE THEY KNOW VAGUELY ABOUT THE PROPOSAL FOR CANADA. AND, YOU KNOW, THERE NEEDS TO BE FURTHER CLARIFICATION THAT IT'S ACTUALLY NOT TAKING AWAY ANY OF OUR MONEY. AND, YOU KNOW, YOU JUST HERE ABOUT IT. MY INITIAL REACTION WAS I WAS CONFUSED BY IT. SO NOW THAT I UNDERSTAND IT, I'M COMPLETELY SUPPORTIVE OF IT, BUT I THINK GETTING THE CANCER COMMUNITY BEHIND YOU IS VERY IMPORTANT.

DR. TROUNSON: YEAH. I THINK THAT'S TERRIFIC. WE'LL BE MEETING IN LOS ANGELES, SO, AGAIN, IF ANYONE REALLY WANTED TO ATTEND IT, THEY'LL LET US KNOW.

THE OTHERS THAT WE'VE GOT ARE STILL TO BE DETERMINED EXACTLY WHEN THEY ARE. THE IMMUNOLOGY TOOLS, WE VERY STRONGLY BELIEVE THAT IMMUNOLOGY HAS GOT TO BE EMBRACED IN OUR PORTFOLIO. AND WE NEED

DISCUSSIONS IN A WORKSHOP WITH THE WHOLE CALIFORNIA INDUSTRY TO DO THAT.

WE'VE GOT A COUPLE OF SESSIONS ON IP POLICY BECAUSE WE'RE GETTING FEEDBACK FROM OUR BIOTECH FRIENDS THAT THEY DON'T REALLY UNDERSTAND IT TOO WELL, AND THAT'S GOING TO BE RUN BY THE DEPUTY CHAIRMAN AND NANCY KOCH. THERE WILL BE TWO, ONE IN SAN FRANCISCO AND ONE IN SAN DIEGO. I THINK THIS IS AN IMPORTANT SORT OF MEETINGS WITH THE INDUSTRY TO SORT OF GLEAN THEIR RESPONSE AND HAVE SOME OF THESE THINGS SORTED OUT A LITTLE BIT.

I THINK SOMETIMES THE VIEW THAT OUR INTELLECTUAL PROPERTY REQUIREMENTS ARE ONEROUS TENDS TO GO AWAY WHEN IT'S TALKED OUT. AND AGAIN, MR. CHAIRMAN, I HOPE LEGISLATION DOESN'T SORT OF MAKE THIS MORE DIFFICULT FOR US AS WELL. YOU, OF COURSE, HAVE BEEN WORKING ON THIS WITH THE KUEHL BILL. AND I THINK THE MAJOR PROBLEM THERE IS THAT IF IT GETS SET IN CEMENT, IT WILL BE VERY DIFFICULT TO GET OUR BIOTECHNOLOGY AND PHRMA FRIENDS TO REALLY JOIN US. THEY WANT TO BE TALKED TO, YOU KNOW, NEGOTIATED WITH. AND WE WILL DEVELOP, WE WILL DO THINGS THAT ARE IN THE INTEREST OF THE CALIFORNIA POPULATION. I ASSURE YOU WE WILL DO THAT. WE'LL KEEP THE PRICES DOWN TO VERY MINIMUM, BUT WE NEED TO BE ABLE TO TALK

TO OUR COLLEAGUES IN INDUSTRY.

THE CELL PRODUCTION FACILITIES, WE WANT TO MOVE ON THAT. I'VE ASKED MARIE CSETE AND PAT OLSON AND OTHER MEMBERS OF THE SCIENCE GROUP TO SET UP A WORKSHOP ON CELL PRODUCTION FACILITIES. THESE ARE CELL PRODUCTION FOR THERAPEUTIC AND RESEARCH PURPOSES. WE NEED TO TALK TO ALL OUR FRIENDS WHO HAVE GOT GMP FACILITIES OR WHO ARE IN THE INDUSTRY TO SEE EXACTLY WHAT THEY WANT. WHAT IS IT THAT THEY NEED? I THINK I KNOW, BUT I THINK IT WOULD BE VERY HELPFUL TO HAVE THAT WORKSHOP TELL US VERY SPECIFICALLY WHAT'S NEEDED.

AND THEN LASTLY, WE'RE GOING TO HAVE A LOT MORE ONGOING DISCUSSIONS IN WORKSHOP FORM FOR ENHANCING PRODUCTIVITY AS AN ONGOING PROGRAM SO THAT THE REPORTS THAT WE GET EVERY YEAR, OFTEN IN OTHER AGENCIES THEY ARE JUST SORT OF LOOKED AT QUICKLY AND THEN FILED. WE WANT TO ACTUALLY TAKE THE REPORTS, BRING THE SCIENTISTS TOGETHER IN LIKE-MINDED AREAS, BRING THEM TOGETHER, AND SEE IF WE CAN ENHANCE THE PROGRAM IN SOME SPECIAL AREAS BY MAYBE HELPING THEM TO MAKE RELATIONSHIPS OR ACTUALLY SUGGESTING SOME THINGS THAT COULD MAKE IT MORE PRODUCTIVE.

SO THIS INTEGRATING THE OUTCOMES, I THINK, IS A VERY IMPORTANT AND NEW PROCESS THAT WE WANT TO

ENGAGE IN AGAIN WITH OUR GRANTEES.

THE SCIENCE MEETING, JUST TO BRING IT TO YOUR ATTENTION, THE CIRM 2008 GRANTEE CONFERENCE IS ON SEPTEMBER 17TH TO THE 19TH IN SAN FRANCISCO WITH A PRESS BRIEFING ON THE 17TH. AGAIN, IF THERE ARE MEMBERS OF THE ICOC WHO WOULD LIKE TO BE THERE, COULD YOU LET US KNOW? IT WILL BE REALLY INTERESTING. WE HOPE TO GET THREE TO 400 OF OUR GRANTEES AND MEMBERS OF THE LABS TOGETHER. WE'VE GOT A VERY INTERACTIVE AND INNOVATIVE MEETING. IT'S NOT A NORMAL CONFERENCE. IT'S ONE WHERE WE WANT TO TRY AND BUILD TEAM SPIRIT AND LINK THINGS TOGETHER TO GET PEOPLE TO UNDERSTAND WHAT OTHERS ARE DOING, SO WE CAN BE MUCH MORE OF A SINGLE ENTITY IN CALIFORNIA, AT LEAST IN AWARENESS.

MS. SAMUELSON: AND THE ANSWER MAY BE OBVIOUS, BUT WHAT IS THE PURPOSE OF IT?

DR. TROUNSON: THE PURPOSE IS TO BUILD TEAMS. WHAT WE WILL BE DOING WILL BE HAVING SOME MAJOR TALKS BY SOME PEOPLE IN CALIFORNIA, BUT ALSO SOME PEOPLE FROM OUTSIDE THE STATE SCENE, AND THERE WILL BE SORT OF BRIEF TALKS BY SOME OF THE PEOPLE WHO ARE DOING SOME MARVELOUS WORK. THERE WILL BE SOME POSTERS.

BUT WHAT WE'RE DOING IS THINGS LIKE, FOR

EXAMPLE, SCIENCE DATING. YOU KNOW WHAT SCIENCE DATING WAS. IT'S KIND OF --

MS. SAMUELSON: I DIDN'T DATE SCIENTISTS.

DR. TROUNSON: SO I DON'T KNOW ANYTHING ABOUT THIS. I'M TOO OLD. BUT WHAT YOU DO IS YOU GO AROUND A ROOM WHERE THERE ARE DIFFERENT PEOPLE AND YOU INTRODUCE YOURSELF ABOUT WHAT THE WORK THAT YOU'RE DOING. AND SO YOU MIGHT SPEND ONLY THREE OR FOUR MINUTES, FOUR, FIVE MINUTES DOING THAT, THEN YOU MOVE ON. SO WHAT HAPPENS IS THAT YOU GET, INSTEAD OF THE PEOPLE CONGREGATING IN THEIR OWN GROUPS AT CONFERENCES, WHICH IS THE COMMON THEME, WE'RE GOING TO SORT OF SPREAD THEM OUT.

SO WE'VE GOT A WHOLE LOT OF DIFFERENT INTERACTIVE WAYS OF GETTING THEM TO KNOW ONE ANOTHER, BUT ALSO ACTUALLY TRYING -- LOOKING TO A WAY WE CAN BUILD TEAMS ACROSS SOME OF THESE SPACES, BOTH HOPEFULLY BETWEEN INSTITUTIONS AND WITH THE BIOTECH INDUSTRIES PEOPLE THERE.

CHAIRMAN KLEIN: AND YOUR ULTIMATE GOAL IS TO HELP CREATE THE SYNERGIES THAT WILL END UP IN TRANSLATIONAL TEAMS AND DISEASE SPACE TEAMS. WITH ALL OF THE CRITICAL MASS OF SCIENCE IN CALIFORNIA, WE HAVE EXTRAORDINARY ABILITY HERE TO BRING TOGETHER THE BEST SCIENTISTS IN THE STATE AND THE FIELD AND

BUILD AN INTERDEPENDENT NETWORK THAT CAN BE VERY SYNERGISTIC.

DR. TROUNSON: SO IF YOU'D LIKE TO PICK UP TECHNIQUES THAT SOMEONE ELSE IS DOING, THERE'S LOTS OF GOODS THINGS. IF YOU LOOK AT REALLY SOME OF THE PRIMARY PAPERS THAT I'M SHOWING YOU, OFTEN YOU SEE TWO OR THREE, THREE OR FOUR INSTITUTIONS AND THEY'VE PICKED UP DIFFERENT TECHNIQUES AND BROUGHT THEM INTO FOCUS ON THE STUDY. THAT'S WHAT WE WANT THEM TO DO. YOU KNOW, THERE ARE MARVELOUS THINGS AT ONE INSTITUTION OR OTHER, AND TO ENGAGE THAT AS PART OF THEIR SCIENCE.

SO THAT'S IT. YOU KNOW, I GET ALL THE ACCOLADES AND NICE COMMENTS FROM THE CHAIRMAN AND THE GOVERNOR, WHICH IS VERY NICE, BUT THESE ARE THE PEOPLE THAT ACTUALLY DO THE JOB. IT'S A GREAT GROUP OF PEOPLE, AND THERE ARE A COUPLE WHOSE PICTURES ARE NOT THERE, BUT THEY'RE GETTING ON BECAUSE I HAVEN'T SEEN THE PHOTOGRAPH. BUT THEY'RE FANTASTIC. THEY'RE JUST WONDERFUL, AND THEY'RE ALL DOING REALLY, REALLY WELL. THEY'RE ACTUALLY DOING IT FOR ALL OF US, AND I WOULDN'T MIND GIVING THEM A CLAP.

(APPLAUSE.)

DR. TROUNSON: NOW, I COULD STOP THERE, MR. CHAIRMAN; OR IF YOU WANTED ME TO SORT OF TALK

ABOUT THE MOU'S, I'VE GOT FOUR OR FIVE SLIDES ON THAT.

CHAIRMAN KLEIN: PERHAPS NANCY KOCH IS GOING TO BE HERE TOMORROW.

DR. TROUNSON: YES.

CHAIRMAN KLEIN: AND MAYBE WE COULD MOVE THAT PART OF YOUR PRESENTATION WITH NANCY.

DR. TROUNSON: YES.

CHAIRMAN KLEIN: AND WE'LL DO THAT RIGHT AT THE SAME TIME YOU DO THE INTERNATIONAL STEM CELL.

DR. TROUNSON: I'M HAPPY TO DO THAT. THANK YOU VERY MUCH.

CHAIRMAN KLEIN: THANK YOU. THAT'S A TREMENDOUS REPORT AS ALWAYS, DR. TROUNSON. AND IT WILL BE GREAT TO SEE THE FULL REPORT TOMORROW. BUT PLEASE DO COVER SOME OF THE HIGHLIGHTS TOMORROW FOR SOME OF THE BOARD THAT IS JUST NOT ABLE TO BE HERE TODAY.

AND I'D LIKE TO POINT OUT THAT AT BIO, WHICH DR. TROUNSON AND I AND A NUMBER OF MEMBERS OF THE STAFF, DR. CSETE AND DR. OLSON, I THINK PROBABLY ANOTHER THREE OR FOUR MEMBERS OF THE STAFF, FIVE MEMBERS OF THE STAFF, SCIENTIFIC STAFF, ATTENDED ALONG WITH MELISSA KING OF MY STAFF, WERE EXTREMELY GRATIFIED BY THE GOVERNOR COMMITTING A CENTRAL PART

OF HIS SPEECH TO THE 22,000 PEOPLE PRESENT TO PROPOSITION 71 AND THE WORK OF THIS AGENCY FOR WHICH HE IS EXTREMELY PLEASED.

AND THE SURPRISING PART OF IT IS IS THAT AFTER -- IMMEDIATELY AFTER HIS SPEECH TO THE ASSEMBLED GROUP, WHICH INCLUDED THE PRINCIPAL BALLROOM AND TWO SUPPLEMENTAL BALL ROOMS, TO HEAR HIS SPEECH, HE ASSEMBLED THIS AD HOC PRESS CONFERENCE IN WHICH HE GAVE A PRESENTATION ON KEY POINTS IN CALIFORNIA. AND THEN WITHOUT ANY PARTICULAR NOTICE TURNED IT OVER TO ME TO TALK ABOUT WHAT WE WERE DOING AT THIS AGENCY IN STEM CELL RESEARCH. BUT IT'S AN EXTRAORDINARY LEVEL OF SUPPORT FROM THE GOVERNOR'S OFFICE WHICH WE DEEPLY APPRECIATE.

AND IT WAS VERY HIGHLY APPRECIATED AS WELL BY THE CANADIAN MINISTER OF HEALTH WHO ATTENDED TO SIGN THE MOU. SO WE HAD VERY HIGH LEVEL REPRESENTATION FROM CANADA, AND THEY APPRECIATED THE GOVERNOR MEETING WITH THEM AFTERWARDS TO PERSONALLY THANK THEM. HE MADE A DELEGATION VISIT AS WELL TO OTTAWA LAST YEAR ASKING THAT WE PUSH THIS INITIATIVE. A YEAR LATER HE HAD THE INITIAL COLLABORATIVE FRAMEWORK SET UP, AND THE MINISTER OF HEALTH IN CANADA REALLY FELT THAT THIS WAS A MAJOR

ACCOMPLISHMENT FOR HIS ADMINISTRATION.

ADDITIONALLY, THE MINISTER OF HEALTH, MR. INNOVATION FOR AUSTRALIA, HAD DINNER WITH ALAN AND I AND SEPARATELY STATED HIS DESIRE TO MAKE SURE THAT IT WAS THE ENTIRE COUNTRY OF AUSTRALIA THAT WAS COMMITTED TO THIS EFFORT IN ADDITION TO REMARKABLE COMMITMENTS COMING OUT OF THE STATE OF VICTORIA, WHICH WAS VERY GRATIFYING. AND THE PREMIER OF THE STATE OF VICTORIA WAS EXTREMELY THANKFUL TO THE GOVERNOR WHO HAD COME THERE TO AUSTRALIA A YEAR AND A HALF AGO AND TALKED ABOUT CLIMATE CHANGE IN STEM CELL RESEARCH. SO THE PREMIER WANTED TO LET HIM KNOW, THE GOVERNOR KNOW, THAT THEY WERE FOLLOWING THROUGH ON THEIR COMMITMENT TO MOVE THIS FORWARD ON A GLOBAL BASIS.

WITH A QUORUM THAT I THINK IS PRESENT --

MS. KING: YES.

CHAIRMAN KLEIN: -- AT THIS POINT, I'D LIKE TO GO BACK TO ITEMS 4 AND 5, THE CONCEPT CALENDAR WITH THE APPROVAL OF THE MINUTES OF MAY 6TH AND 7TH. MR. HARRISON, IF I COULD HANDLE THAT IN A SEPARATE CONSENT MOTION FROM THE FINAL APPROVAL OF THE MAJOR FACILITIES GRANT ADMINISTRATION POLICY, IS THAT ACCEPTABLE?

MR. HARRISON: YES. YOU CAN TAKE THEM

SEPARATELY.

CHAIRMAN KLEIN: OKAY. FOR THE APPROVAL OF THE MINUTES.

MS. LANSING: SO MOVED.

CHAIRMAN KLEIN: SO MOVED. IS THERE A SECOND?

MR. ROTH: SECOND.

CHAIRMAN KLEIN: IS THERE ANY PUBLIC COMMENT ON THE MINUTES? SEEING NONE, ALL IN FAVOR. MOTION PASSES.

FINAL APPROVAL OF THE MAJOR FACILITIES GRANTS ADMINISTRATION POLICY, IS THERE A MOTION TO APPROVE THIS ITEM?

DR. HAWGOOD: SO MOVE.

CHAIRMAN KLEIN: MOVED BY DR. HAWGOOD. IS THERE A SECOND?

MR. ROTH: SECOND.

CHAIRMAN KLEIN: SECOND BY DUANE ROTH. IS THERE PUBLIC COMMENT ON THIS? SEEING NONE, IS THERE BOARD COMMENT? ALL IN FAVOR. OPPOSED? MOTION PASSES.

WE WILL NOW GO FORWARD TO --

MS. KING: TEN.

CHAIRMAN KLEIN: -- ITEM 10 UNLESS, DR. TROUNSON, IS IT YOUR PREFERENCE OR MARIE -- I HAD

UNDERSTOOD THAT DR. CSETE WAS INTERESTED IN MAKING A PRESENTATION TOMORROW ON ITEM 9, BUT IT IS YOUR DISCRETION AND DR. CSETE'S DISCRETION AS TO THE TIMING.

DR. TROUNSON: IF WE MAY, CHAIR, I THINK IT WOULD BE TERRIFIC TO GET THE NEW CELL LINE AWARDS DONE. I MEAN I THINK YOU WILL ENJOY MARIE'S PRESENTATION, BUT IT WOULD BE GREAT IF WE COULD GET THESE NEW CELL LINE AWARDS DONE.

CHAIRMAN KLEIN: ALL RIGHT.

DR. TROUNSON: IT'S A MEATY SUBJECT AND WOULD BE WORTH GETTING DONE.

CHAIRMAN KLEIN: ALL RIGHT. THANK YOU, DR. TROUNSON. SO WE'RE GOING TO MOVE TO AGENDA ITEM 10 FOR NEW CELL LINES. AND THAT'S ON TAB 10 IN THE MEETING BINDER. YOU'VE ALSO ACCESS TO PUBLIC SUMMARIES. I'D LIKE TO ASK DR. UTA GRIESHAMMER TO INTRODUCE US TO THIS ITEM.

DR. GRIESHAMMER: MR. CHAIRMAN, BOARD MEMBERS, I WOULD LIKE TO PRESENT TO YOU THE RECOMMENDATIONS FOR THE NEW CELL LINES AWARDS APPLICATIONS THAT WERE PUT FORTH BY THE GRANTS WORKING GROUP IN APRIL. AND AS MR. KLEIN ALREADY MENTIONED, THIS IS AGENDA ITEM NO. 10 IN YOUR BINDER.

I WILL FIRST BRIEFLY REMIND YOU OF THE OBJECTIVES OF THE NEW CELL LINES RFA BEFORE PRESENTING TO YOU THE RECOMMENDATIONS MADE BY THE GRANTS WORKING GROUP.

SO THE PURPOSE, AS YOU PROBABLY REMEMBER, OF THE NEW CELL LINES AWARDS IS TO SUPPORT THE DERIVATION OF NEW HUMAN PLURIPOTENT STEM CELL LINES THAT WILL HAVE IMPORTANT RESEARCH AND CLINICAL APPLICATIONS. IN ORDER TO ENSURE THAT THE APPLICATIONS IN RESPONSE TO THIS REQUEST FOR APPLICATIONS WOULD COVER A WIDE RANGE OF SOURCE MATERIAL FOR CELL LINE DERIVATION, WE CREATED TWO CATEGORIES OF RESEARCH AND LIMITED THE NUMBER OF APPLICATIONS IN EACH CATEGORY.

FOR CATEGORY 1 WE ASKED THE INVESTIGATORS TO DERIVE NEW HUMAN EMBRYONIC STEM CELL LINES USING EARLY STAGE PREIMPLANTATION HUMAN EMBRYOS GENERATED BY IN VITRO FERTILIZATION. THIS WOULD INCLUDE EXCESS EMBRYOS THAT ARE NO LONGER NEEDED FOR REPRODUCTIVE PURPOSES, AND IT WOULD INCLUDE EMBRYOS IDENTIFIED BY PREIMPLANTATION GENETIC DIAGNOSIS TO CARRY GENETIC ABNORMALITIES.

RESEARCH IN CATEGORY 2 INVOLVES DERIVATION OF HUMAN PLURIPOTENT STEM CELL LINES USING OTHER SOURCES OF CELLS. AND THIS INCLUDES THE

REPROGRAMMING OF SOMATIC CELLS TO AN EMBRYONIC STEM CELL-LIKE STATE; THAT IS, THE GENERATION OF INDUCED PLURIPOTENT STEM CELLS OR IPS CELLS. IT INCLUDES CELL LINES GENERATED BY SOMATIC CELL NUCLEAR TRANSFER, AND IT INCLUDES FETAL OR ADULT CELLS THAT MAY SPONTANEOUSLY REVERT TO PLURIPOTENCY IN CULTURE.

SO RECOGNIZING THE NEED FOR NEW TYPES AND NEW SOURCES OF PLURIPOTENT STEM CELL LINES AND THE NEED FOR OPTIMIZING EXISTING METHODS FOR THE DERIVATION OF THESE LINES, CIRM ASKS THE APPLICANTS TO THIS RFA TO DERIVE NEW HUMAN CELL LINES WITH IMPROVED CLINICAL QUALITY, WHICH IS A CRITICAL GOAL TOWARD THERAPEUTIC APPLICABILITY OF PLURIPOTENT STEM CELLS. WE ALSO ASKED FOR THE DERIVATION OF CELL LINES WITH OPTIMAL DIFFERENTIATION POTENTIAL.

FURTHERMORE, WE WERE INTERESTED IN INCREASING THE NUMBER OF AVAILABLE HUMAN PLURIPOTENT CELL LINES THAT ARE DISEASE SPECIFIC OR OTHERWISE GENETICALLY DIVERSE TO ENABLE NEW WAYS TO STUDY DISEASE MECHANISM OR TO DISCOVER AND EVALUATE NEW DRUG CANDIDATES, AND WE'RE INTERESTED IN SUPPORTING TECHNOLOGY DEVELOPMENT THAT WILL ALLOW THE DERIVATION OF PATIENT-SPECIFIC CELL LINES, WHICH BRINGS ME TO THE LAST POINT LISTED ON THE SLIDE.

OUR GOAL TO FUND PROPOSALS THAT WILL LEAD

TO THE DISCOVERY OR IMPROVEMENT OF TECHNOLOGY FOR PLURIPOTENT STEM CELL DERIVATION SUCH AS IPS TECHNOLOGY OR SOMATIC CELL NUCLEAR TRANSFER.

SO THE REVIEWERS WERE ASKED TO CONSIDER THREE CRITERIA WHEN EVALUATING THE NEW CELL LINES APPLICATIONS. FOR THE FIRST CRITERION, SIGNIFICANCE, WE ASKED THE REVIEWERS TO ASSESS IF THE PROPOSED WORK WAS LIKELY TO ADVANCE THE STEM CELL FIELD EITHER SCIENTIFICALLY OR TOWARDS BIOMEDICAL APPLICATIONS. WE EMPHASIZED TO THE REVIEWERS THAT INNOVATION IS NOT NECESSARILY IMPORTANT FOR MERITORIOUS APPLICATIONS UNDER THIS RFA, ESPECIALLY WHEN THINKING ABOUT DEVELOPING STRATEGIES FOR DERIVING CLINICAL GRADE HUMAN EMBRYONIC STEM CELL LINES. SO WE ASKED THE REVIEWERS TO CONSIDER INNOVATION ONLY WHEN APPLICABLE.

FOR THE SECOND CRITERION, DESIGN AND FEASIBILITY OF THE RESEARCH PLAN, THE REVIEWERS WERE ASKED TO EVALUATE IF THE RESEARCH IS CAREFULLY DESIGNED TO GIVE MEANINGFUL RESULTS AND IF IT IS FEASIBLE BASED MAINLY ON PRELIMINARY DATA AND THE QUALIFICATIONS OF THE PRINCIPAL INVESTIGATOR.

AND FINALLY, WE ASKED THE REVIEWERS TO ASSESS IF THE APPLICATION WAS RESPONSIVE TO THE RFA,

WHETHER IT WAS LIKELY THAT THE PROPOSED RESEARCH WOULD LEAD TO THE GENERATION OF TRULY PLURIPOTENT STEM CELL LINES.

AND FURTHERMORE, RECOGNIZING THAT WIDE AVAILABILITY OF NEWLY GENERATED STEM CELL LINES WOULD ENSURE GREATEST POSSIBLE IMPACT OF THIS INITIATIVE, WE ASKED THE APPLICANTS TO DESCRIBE THEIR PLANS FOR SHARING OR COMMERCIALIZING THE NEW CELL LINES AND ASKED THE REVIEWERS TO ASSESS IF THESE PLANS WERE ADEQUATE FOR MAKING THE CELL LINES WIDELY AVAILABLE TO OTHER RESEARCHERS.

SO AT THE BOARD MEETING IN OCTOBER LAST YEAR, YOU APPROVED THE CONCEPT FOR THE NEW CELL LINES RFA, INCLUDING THE FUNDING TARGETS LISTED ON THIS SLIDE. THE GOAL WAS TO FUND UP TO 16 GRANTS, EIGHT IN EACH OF THE TWO CATEGORIES THAT I JUST DESCRIBED TO YOU. UP TO $25 MILLION WERE ALLOCATED FOR THIS RFA, AND WE WILL ALLOW UP TO $300,000 IN DIRECT COSTS PER YEAR FOR UP TO THREE YEARS.

THIS RFA WAS OPEN TO INVESTIGATORS CONDUCTING THEIR RESEARCH AT NONPROFIT OR FOR-PROFIT INSTITUTIONS WITH RESEARCH SITES LOCATED IN CALIFORNIA.

SO I'M NOW GOING TO SHOW TO YOU THE RECOMMENDATIONS MADE BY THE GRANTS WORKING GROUP.

AS USUAL, THE GRANTS WORKING GROUP PLACED THE APPLICATIONS INTO THREE TIERS. TIER 1, AS YOU ARE USED TO, CONTAINS THE APPLICATIONS RECOMMENDED FOR FUNDING BY THE GRANTS WORKING GROUP. HOWEVER, THE GRANTS WORKING GROUP ADOPTED LANGUAGE DESCRIBING THEIR RECOMMENDATION FOR APPLICATIONS IN TIER 2 THAT DIFFERS FROM TIER 2 RECOMMENDATIONS FROM PREVIOUS RFA REVIEWS.

PREVIOUSLY, APPLICATIONS IN TIER 2 WERE RECOMMENDED FOR FUNDING IF FUNDS AVAILABLE. HOWEVER, AT THE CONCLUSION OF THE PROGRAMMATIC REVIEW, THE MEMBERS OF THE GRANTS WORKING GROUP PASSED A MOTION STATING THAT APPLICATIONS IN TIER 2 ARE NOT RECOMMENDED FOR FUNDING AND THAT, INSTEAD, APPLICATIONS IN TIER 2 ARE RECOMMENDED TO BE AVAILABLE FOR FUNDING ONLY IF THE ICOC MAKES A PROGRAMMATIC DETERMINATION TO DO SO.

AND FINALLY, AGAIN, AS YOU'RE USED TO, APPLICATIONS IN TIER 3 ARE NOT RECOMMENDED FOR FUNDING.

DR. PIZZO: I'M SORRY. CAN YOU CLARIFY THAT POSITION THAT WAS TAKEN AND THE REASONS FOR IT?

DR. GRIESHAMMER: FOR TIER 2?

DR. PIZZO: YES, PLEASE.

DR. GRIESHAMMER: SO AFTER THE -- MY

REWORDING OF THE FEELING IN THE ROOM AT THE CONCLUSION OF THE PROGRAMMATIC DISCUSSION WAS AS I'LL DESCRIBE TO YOU IN A MOMENT WHEN YOU SEE THE ACTUAL NUMBERS OF APPLICATIONS IN THE VARIOUS TIERS WAS THAT THE MEMBERS OF THE GRANTS WORKING GROUP HAD ALREADY CAREFULLY CONSIDERED ALL THE APPLICATIONS THEY FOUND MERITORIOUS FOR FUNDING AND HAD MOVED THEM INTO TIER 1 --

DR. PIZZO: I SEE.

DR. GRIESHAMMER: -- IF THEY HAD BEEN IN TIER 2, AND THEN THEY WANTED TO BE SURE THAT IT WAS MADE CLEAR TO THE ICOC THAT THEY FELT, AFTER THEIR SCIENTIFIC AND PROGRAMMATIC EVALUATIONS DURING THE REVIEW MEETING, NOT TO JUST -- TO BASICALLY STATE THAT THEY WEREN'T RECOMMENDING THEM FOR FUNDING IF FUNDS AVAILABLE, BUT RATHER ONLY IF THE BOARD WAS INTERESTED IN PROGRAMMATIC.

DR. TROUNSON: SO DEAN PIZZO -- SORRY, DEAN PIZZO. I THINK IT WAS VERY CLEAR THAT THEY FELT THAT THE SCIENCE IN TIER 2 WOULD NOT HAVE CARRIED THE DAY, AND IT WAS REALLY ONLY IF IT WAS A PROGRAMMATIC WISH OF THE ICOC, THAT THE SCIENTISTS DID NOT FEEL THAT THE SCIENCE ACTUALLY CARRIED THE DAY TO WARRANT THE RECOMMENDATION OF BEING FUNDED. THEY TOOK THOSE THAT WERE IN TIER 1, SO THEY WERE

THE ONES BELOW TIER 1 SCIENTIFICALLY NOT RECOMMENDED FOR FUNDING, BUT PROVISIONALLY THE GROUP THERE WOULD BE SUBJECT TO THE ICOC'S VIEWS, THE SCIENCE ASIDE.

CHAIRMAN KLEIN: THE VICE CHAIR, PERHAPS WE COULD HAVE JEFF SHEEHY COMMENT.

DR. PIZZO: GREAT. THANKS.

MR. SHEEHY: YEAH. I THINK A NUANCE TO THIS IS KIND OF BEING LOST IS THAT A LOT OF THESE APPLICATIONS ARE CREATING DISEASE-SPECIFIC LINES. AND SO IN SOME SENSES THERE WAS THE SENSE THAT THERE ARE ALREADY ABUNDANT NUMBER OF DISEASE -- OF THESE LINES EXISTING, THAT THE SCIENCE ITSELF WAS NOT THAT INTERESTING, AND THAT RESEARCHERS HAD ACCESS TO AN ADEQUATE NUMBER OF LINES, AND THERE WAS NO NEED TO DO SO, TO CREATE THE LINE JUST TO DO SO.

I WILL NOTE WE DO HAVE A LETTER FROM ONE OF THE ONES IN THIS TIER IN OUR BINDER. I'VE ALSO HEARD FROM SOMEONE FROM AN ADVOCACY GROUP. IT'S NOT ALWAYS TRUE THAT THE RESEARCHERS ARE AWARE OF ALL THE LINES THAT ARE OUT THERE THAT ARE AVAILABLE. SO I DO THINK WE SHOULD BE A LITTLE BIT CAREFUL.

THERE WAS NOT GREAT ENTHUSIASM FOR THESE, AND THAT'S WHY THEY CREATED THE SECOND CATEGORY. AND THIS WAS A NOVEL WAY TO RESOLVE A GENERAL LACK OF ENTHUSIASM ONCE WE GOT THROUGH THE FIRST TIER.

USUALLY THE SECOND TIER IS, YOU KNOW, IF YOU GUYS WANT TO SPEND THE MONEY, THERE'S SOME REALLY GOOD SCIENCE IN HERE THAT YOU MAY WANT TO TAKE A CRACK AT. IN THIS PARTICULAR INSTANCE, THERE WAS JUST NOT A GREAT DEAL OF ENTHUSIASM FOR THE SCIENCE.

BUT I WOULD NOTE THAT IN MOST OF THE INSTANCES WE WERE TALKING ABOUT CREATING DISEASE-SPECIFIC LINES THAT WOULD BE OF INTEREST PROGRAMMATICALLY, THAT, YOU KNOW, THAT WE NEED TO TAKE UP AND HAVE A REAL DISCUSSION ABOUT AND NOT JUST -- THESE ARE NOT NECESSARILY PURE TIER 3. DOES THAT MAKE SENSE?

DR. PIZZO: IT DOES. IT DOES MAKE SENSE. AND JUST IN A GENERIC WAY, PERHAPS YOU OR, YOU KNOW, ANYONE WHO'S THERE COULD JUST COMMENT. YOU KNOW, THE SCORES, JUST SCANNING THE SCORES, I KNOW WE'RE GOING TO GET TO THIS, BUT BEFORE WE GET TO THE SPECIFICS, YOU KNOW, THEY'RE ALL SOMEWHAT MORE DEPRESSED. THEY START OUT AT A LOWER LEVEL THAN THEY DO TRADITIONALLY. AND I'M JUST SORT OF -- YOU I THINK MAYBE ANSWERED THIS ALREADY, THAT THERE'S KIND OF A RELATIVE DEGREE OF LESS EXCITEMENT ABOUT THIS THAN OTHER PROJECTS. IS THAT A SAFE --

MR. SHEEHY: WELL, I THINK PART OF IT IS IS THAT THERE'S A LOT OF THE IPS. SO THERE'S A LOT

OF, YOU KNOW, THIS WAS HOT FLAVOR OF THE MONTH KIND OF ME-TOOISM TO THAT, IF THAT MAKES SENSE. AND THEY WERE REALLY -- THE ONES THAT SCORED WELL, YOU KNOW, PEOPLE WERE MAKING SIGNIFICANT ADVANCES IN IPS OR MODELING IPS. AND I'M KIND OF HAVING TO DO THIS OFF THE BACK OF MY MEMORY, BUT WERE DOING VERY EXPERIMENTS COMPARING EMBRYO-DERIVED LINE WITH AN IPS LINE. SO THE ONES THAT THEY WERE IMPRESSED WITH WERE MAKING -- REALLY TRYING TO MOVE THE FIELD TECHNICALLY IN A SIGNIFICANT WAY.

SO A LOT OF IT WAS LIKE ME TOO, ME TOO. EVERYBODY HAS GOT TO DO IPS.

DR. PIZZO: A QUICK FOLLOW-UP?

CHAIRMAN KLEIN: DR. PIZZO, IF WE COULD JUST FOR FURTHER CONTEXT.

DR. PIZZO: REMAIN QUIET?

CHAIRMAN KLEIN: I'LL CALL ON YOU. IF I COULD MARCY FEIT, WHO'S CENTRALLY INVOLVED IN THE PROGRAMMATIC REVIEW, COMMENT, SO YOU HAVE A FULL TEXTURE.

DR. PIZZO: I GOT THE MESSAGE.

MS. FEIT: THIS SITUATION TOOK A LOT OF DISCUSSION DURING THOSE REVIEWS. AND I HAVE TO SAY I SAT THROUGH ALMOST ALL OF THE REVIEWS EXCEPT FOR THE ONES I WAS EXCUSED FROM. AND, YOU KNOW, TO SIT

WITH ALL THOSE PROMINENT SCIENTISTS, THEY TAKE THEIR REVIEWS VERY SERIOUSLY. THEY ARGUE OVER WHAT THEY THINK IS RIGHT. THE SCIENCE COMES FIRST. AND I THINK BECAUSE OF THAT, THEY LOOKED AT THE SCORES AND, AS SCIENTISTS, THEY REALLY WERE NOT COMFORTABLE SAYING THAT A SCORE OF 50 SHOULD BE FUNDED.

DR. PIZZO: THAT SOUNDS GOOD.

MS. FEIT: THAT A SCORE OF 40 SHOULD BE FUNDED BECAUSE WE HAD THE FUNDING AVAILABLE. SO, YOU KNOW, AND I ADVOCATED FOR THAT. I KEPT BRINGING THEM BACK TO THAT CONSCIENCE OF SCIENCE. IS THIS THE GOOD SCIENCE THAT YOU AS SCIENTISTS WANT TO FUND? SO THAT'S WHY THIS CAME UP.

UNLIKE THE LARGE GRANT REVIEWS THAT WE DID EARLIER LAST YEAR WHERE THERE WAS JUST SO MANY SPECTACULAR GRANTS TO FUND, WE DIDN'T HAVE ENOUGH MONEY, THIS WAS DIFFERENT. THIS WAS CLEARLY DIFFERENT, AND THERE WAS TRULY A CUTOFF THAT THE SCIENTISTS WERE COMFORTABLE IN FUNDING. AND THEY WANTED TO, HOWEVER, LEAVE AN OPPORTUNITY FOR THIS BOARD TO SAY BUT WE'RE MISSING THIS PROGRAM AND WE WOULD REALLY LIKE TO AND, THEREFORE, YOU COULD EVALUATE THE SCORE AND YOU COULD LOOK AT THE SCIENCE YOURSELVES AND SAY WE WANT THIS ONE GRANTED.

SO THEY WANTED TO LEAVE YOU THAT

OPPORTUNITY. BUT CLEARLY THE MESSAGE FROM THEM WAS THAT THE SCIENCE CAME FIRST, AND THEY WERE UNCOMFORTABLE WITH THE SCORES IN THIS GROUP.

CHAIRMAN KLEIN: MARCY, MAYBE IT'S GOOD TO PUT UP THOSE SCORES BECAUSE I THINK --

DR. GRIESHAMMER: MAYBE I COULD FIRST BRIEFLY DISCUSS THE OVERVIEW OF THE --

DR. PIZZO: GREAT.

MS. KING: CAN WE FINISH THIS AND THEN GO TO THIS GROUP?

CHAIRMAN KLEIN: CAN WE DO THIS. CAN WE GO TO THE SCORES AND COME BACK TO THIS SLIDE? CAN WE DO THAT?

MS. KING: SURE.

CHAIRMAN KLEIN: THE REASON THAT I'D LIKE TO DO THIS IS IN FOLLOWING UP ON MARCY'S COMMENT. OH, I SEE. WE HAVE IT ON TWO DIFFERENT COMPUTERS. THE KEY HERE IS THAT, MARCY, I THINK WHEN WE SEE THE SCORES, THAT THAT TIER 2, WHICH WAS MUCH NARROWER THAN NORMAL, THEY HAVE HAD SOME SCORES THAT WERE FAIRLY CLOSER TO THE TOP TIER, BUT THEN IT FELL OFF FAIRLY SIGNIFICANTLY.

WE HAVE SHERRY AND THEN WE'RE GOING TO GO TO DR. PIZZO. SHERRY AND THEN WE'RE GOING TO GO TO JEFF SHEEHY.

MS. LANSING: WE HAVE THE SCORES IN OUR BOOK. WE HAVE THEM RIGHT HERE. WE CAN SEE THEM.

CHAIRMAN KLEIN: I'D JUST LIKE THE PUBLIC TO BE ABLE TO SEE THEM IF WE CAN.

MS. LANSING: SURE. BUT I ACTUALLY THINK THIS IS GOOD. I MEAN WE'VE ASKED THESE SCIENTISTS TO EVALUATE THE SCIENCE. WE HAVE THE RIGHT TO DISAGREE. I MEAN THAT IS THE RESPONSIBILITY OF THIS BOARD, TO MOVE SOMETHING UP NO MATTER WHAT. BUT I'VE ALWAYS FELT THAT OUR RESPONSIBILITY TO THE CITIZENS OF CALIFORNIA WAS TO SPEND THE MONEY WISELY, AND IT DIDN'T HAVE TO BE SPENT ALL THE TIME. WHATEVER WE HAD ALLOCATED DID NOT ALWAYS HAVE TO BE SPENT AT THAT PARTICULAR DAY. WE HAD TO SPEND IT WHEN WE HAD THE RIGHT SCIENCE TO DO IT ON.

SO I ACTUALLY, WHILE I'M NOT QUESTIONING WHETHER THERE SHOULD BE SOMETHING THAT SHOULD BE MOVED UP, THAT'S CERTAINLY ALWAYS OUR OPPORTUNITY, BUT I REALLY RESPECT THE INTEGRITY OF THIS COMMITTEE, THAT THEY DIDN'T JUST SAY, OH, YOU HAVE X AMOUNT OF DOLLARS AND WE'LL SPEND IT. THEY ACTUALLY WANTED TO SPEND IT WISELY AND KNEW THAT THERE'S ANOTHER DAY, SO TO SPEAK. AND IF THEY DIDN'T RESPOND TO THESE, THAT'S FINE. I MEAN THAT'S THEIR JOB.

CHAIRMAN KLEIN: JEFF, IF YOU COULD -- I THINK WE HAVE DR. PIZZO. THEN WE'LL GO BACK TO JEFF.

DR. PIZZO: I THINK SHERRY MADE THE POINT I WAS MAKING. SHERRY MADE THE POINT I WAS GOING TO, SO I APPRECIATE THAT.

CHAIRMAN KLEIN: THANK YOU. JEFF.

MR. SHEEHY: I JUST WANT TO GO BACK TO MY POINT. I THINK WE'RE REALLY ONLY TALKING ABOUT TWO APPLICATIONS, AND THIS REALLY IS A PROGRAMMATIC DECISION. IF YOU WILL NOTICE, THE DIFFERENCE BETWEEN 69 AND 71 OR THE DIFFERENCE BETWEEN -- AND TWO OF THEM, 67 GOT BUMPED UP FOR PROGRAMMATIC REASONS. THESE ARE BOTH -- YOU KNOW, LOTS OF PEOPLE ARE USING IPS TO MAKE DISEASE-SPECIFIC STEM CELL LINES. AND THIS IS A VERY SPECIFIC PROGRAMMATIC DECISION.

I KNOW WE'RE KIND OF -- I SEE. I SEE THE ATTORNEY LOOKING FOR CONFLICTS. BUT, YOU KNOW, YOU NEED TO KIND OF TAKE THESE FROM A PURE PROGRAMMATIC POINT OF VIEW AND ASK YOURSELF ARE THERE ENOUGH DISEASE -- I DON'T THINK I'M CONFLICTED ON THESE. IF I AM, I'M IN TROUBLE. BUT PHILOSOPHICALLY, IF THE DISEASES THAT ARE -- IN THIS CATEGORY IF THERE'S A SENSE THAT THERE'S ENOUGH LINES AVAILABLE FOR

RESEARCH AND BEING CREATED FOR RESEARCH IN THESE, I THINK THAT'S PART OF WHAT YOU HAVE TO LOOK AT.

CHAIRMAN KLEIN: SO --

MR. SHEEHY: BECAUSE THESE ARE CREATING DISEASE MODELS USING IPS, AND THERE JUST WASN'T A LOT OF -- YOU KNOW, THERE ARE A LOT OF IPS THINGS IN THE TOP TIER, SO IT WASN'T LIKE THEY LOOKED AT THESE AND SAID, OH, WE'RE DOING SOMETHING REALLY GROOVY WITH IPS. I WANT TO DO THIS. THE QUESTION IS DO YOU NEED ANOTHER ONE THAT'S KIND OF ME-TOO IPS BUT IS PROVIDING SOMETHING FOR A DISEASE? AND IF WE SEE HUNTINGTON'S DISEASE AS ONE THAT'S MENTIONED, DO WE NEED MORE HUNTINGTON'S DISEASE STEM CELL LINES? AND THAT IS REALLY THE QUESTION THAT THEY'RE ASKING US TO MAKE PROGRAMMATICALLY.

CHAIRMAN KLEIN: SO IN --

MR. SHEEHY: IT'S NOT LIKE THE QUALITY IS REALLY BAD. IT'S JUST NOT THAT GREAT. IT'S NOT THAT COOL. THAT'S THE POINT.

CHAIRMAN KLEIN: IT COULD BE GOOD SCIENCE, BUT NOT INNOVATIVE SCIENCE THAT FURTHERS KNOWLEDGE, BUT IT IS PROVIDING OTHER CELL LINES WHICH MAY HAVE VALUE IN AND OF ITSELF FOR PROGRAMMATIC REASONS.

DUANE. AND LET'S BE VERY CAREFUL IN THIS DISCUSSION THAT WE'RE TALKING GENERALLY ABOUT POLICY

BECAUSE WE WANT TO MAKE SURE THAT WE'RE NOT CREATING INADVERTENT CONFLICT.

MR. ROTH: SO MY QUESTION IS A VERY GENERAL QUESTION TO THE GROUP. AND THAT DEALS WITH WHAT I HEARD DESCRIBED AS THE CRITERIA FOR THE REVIEW PROCESS. YOU KNOW, THAT SCIENCE CERTAINLY WAS THERE, BUT THE POTENTIAL FOR COMMERCIALIZATION OR ADVANCING TOWARDS COMMERCIALIZATION WAS CLEAR.

AND IN THIS DISCUSSION THAT WE'VE BEEN HAVING, IT WAS SORT OF ALL ABOUT THE SCIENTIFIC REVIEW. AND MY QUESTION IS SIMPLY HOW MUCH CONSIDERATION WAS REALLY GIVEN TOWARDS DOES THIS ADVANCE TOWARDS COMMERCIALIZATION?

CHAIRMAN KLEIN: I WOULD SAY THE PEER REVIEW DID NOT HAVE THE REPRESENTATION THAT WOULD HAVE MADE THAT A MORE SIGNIFICANT CONSIDERATION. THE PEER REVIEW HAD GREAT SCIENTIFIC REPRESENTATION, BUT I THINK DR. TROUNSON AND DR. OLSON MAY HAVE DIFFERENT -- MAY HAVE A GREATER LEVEL OF KNOWLEDGE TO COMMENT ON THAT AS TO THE BACKGROUND OF THE DISTRIBUTION OF THE MEMBERS OF THE PEER REVIEW PANEL.

DR. TROUNSON: SO I THINK, MR. CHAIRMAN, A LOT OF THIS IS VERY EARLY STAGE, AND SO IT'S THE PREPARATION, IN FACT, OF THE CELL LINES. THEY MAY

WELL BE COMMERCIALIZED AS REAGENTS, DUANE, MAYBE ADOPTED FAIRLY QUICKLY AS REAGENTS, BUT THE REVIEWERS NOTED THAT, YOU KNOW, COMMON MAYBE TO ALL OF THE LINES THAT THEY'VE GOT A REAGENT VALUE. SOME OF THEM ALSO POINTED AT THE EVENTUAL DEVELOPMENT OF SMALL MOLECULES INVOLVED IN THAT, AGAIN, VERY EARLY STAGE AT THIS POINT. YOU KNOW, IT'S VERY DIFFICULT TO PREDICT THE OUTCOME.

SO THERE WASN'T REALLY A LOT OF -- YOU KNOW, WE WEREN'T IN THE SPACE WHERE YOU COULD MAKE ANY REMARKABLE CONCLUSIONS ON THE COMMERCIAL VALUE. THEY ALL HAVE SOME COMMERCIAL VALUE DEPENDING ON WHAT THEY'RE USED FOR.

CHAIRMAN KLEIN: AND, DR. OLSON, DO YOU WANT TO COMMENT ON THAT IN ADDITION?

MR. ROTH: WHILE SHE'S GOING UP, ALAN, JUST TO FOLLOW UP ON THAT, IT WASN'T SO MUCH COMMERCIALIZATION OF THE CELL LINES, BUT HOW MUCH CONSIDERATION OR HOW MUCH DISCUSSION ACTUALLY HAPPENED THAT WOULD TALK ABOUT DOES THIS ADVANCE US TOWARDS THE CLINIC IN ANY WAY, MEANINGFUL WAY?

DR. TROUNSON: ADVANCE US TOWARDS THE CLINIC, YOU KNOW, WAS VERY CLEARLY THE CASE. I MEAN THE COMMERCIALIZATION IS MORE DIFFICULT, AS I SAID, BUT THE ADVANCE TOWARDS THE CLINIC IS CLEARLY ONE OF

THE CRITERIA THAT WAS UNDER EVALUATION EACH TIME, YEAH.

CHAIRMAN KLEIN: AND I THINK THAT'S, IN FACT, WHY YOU HAVE A PROGRAMMATIC CONSIDERATION HERE BECAUSE OF THE VALUE TO HAVE ADDITIONAL CELL LINES FOR SPECIFIC DISEASES. DR. OLSON.

DR. OLSON: I JUST WANTED TO SAY THAT I THINK DR. TROUNSON HAS DONE A GOOD JOB OF SUMMARIZING.

CHAIRMAN KLEIN: YOU NEED TO TURN THE MIC ON.

DR. OLSON: I JUST WANTED TO SAY THAT DR. TROUNSON, I THINK, HAS DONE A GOOD JOB OF SUMMARIZING I THINK WHERE WE WERE. FOR THOSE APPLICATIONS THAT, YOU KNOW, TALKED ABOUT -- WHAT DO I WANT TO SAY -- COMMERCIAL APPLICATION, EVEN A COMMERCIAL CELL LINE HAS TO HAVE A SCIENTIFIC RATIONALE AND BASIS BEHIND IT AND APPROPRIATE CHARACTERIZATION. SO I THINK THAT THAT WAS ADEQUATELY ADDRESSED.

CHAIRMAN KLEIN: OKAY. SO AT THIS POINT I'D LIKE DR. GRIESHAMMER TO GIVE US THE BALANCE OF THE GENERAL SCIENTIFIC CONTEXT FOR OUR DISCUSSION, AND THEN WE ARE GOING TO ADJOURN TO EXECUTIVE SESSION AND DINNER TO TRY AND STAY ON A REASONABLE

SCHEDULE HERE. WE WILL PERHAPS VOTE WITH A GREATER ENTHUSIASM AFTER EATING. BUT, DR. PIZZO, DID YOU WANT TO MAKE A --

DR. PIZZO: JUST ONE MORE GENERAL QUESTION. I'M SORRY TO DO THIS, BUT I'M JUST THINKING ABOUT THE POINT THAT SHERRY MADE EARLIER. IF THE SCIENTIFIC ADVISOR OF THE COMMITTEE WASN'T GIVEN A SUM OF MONEY TO GIVE OUT, WOULD THEY HAVE GIVEN OUT THIS MUCH? IN OTHER WORDS, YOU KNOW, THERE ARE TWO WAYS OF DOING IT. I MEAN, YOU KNOW, YOU COULD SORT OF FILL THE POT, OR FOLLOWING SHERRY'S POINTS, THEY WERE JUST GOING TO DO THE VERY BEST. AND I HOPE IT'S THE LATTER.

MR. SHEEHY: YEAH. I THINK THEY -- AT LEAST WHAT THEY RECOMMENDED FOR FUNDING, THEY WERE HAPPY TO FUND THAT. BUT THEY -- YOU KNOW, WHERE THE REAL RUB CAME IS THAT ONCE THEY GOT PAST THAT, THEY LOST ENTHUSIASM DRAMATICALLY. SO I THINK THAT'S THE BEST WAY TO DESCRIBE IT. AND SO THEY WERE NOT WILLING TO GO TO OUR TYPICAL CATEGORY 2, WHICH IS FUND IF FUNDS ARE AVAILABLE. AND WHAT THEY HAVE DONE IS BELOW OUR FUNDING LINE, SO THEY WENT AS FAR AS THEY WANTED TO GO AND THEN SAID STOP.

CHAIRMAN KLEIN: OKAY. DR. GRIESHAMMER.

DR. GRIESHAMMER: EXACTLY. TO SUPPORT

WHAT JEFF JUST SAID, SO THE APPLICATIONS THAT YOU SEE HERE IN TIER 1, THERE ARE 14 APPLICATIONS IN TIER 1. AND THEY ARE -- THE TOTAL FUNDS RECOMMENDED FOR THESE APPLICATIONS IS $20 MILLION, AND THAT FALLS, INDEED, SHORT OF WHAT WAS ORIGINALLY ALLOCATED FOR THIS RFA.

I JUST WANT TO POINT OUT THAT WE HAVE A NICE DISTRIBUTION FOR THE TWO CATEGORIES THAT WE ANTICIPATED. WE HAVE SIX APPLICATIONS THAT PROPOSE RESEARCH IN CATEGORY 1, AND IT'S INDICATED HERE WITH A LITTLE H CAPITAL E FOR HUMAN EMBRYO. AND EIGHT OF THOSE APPLICATIONS IN TIER 1 ARE PROPOSED -- ARE PROPOSING CELL LINE DERIVATION USING OTHER SOURCES OF CELLS.

AND THEN, AS HAS ALREADY BEEN DISCUSSED, TIER 2 CONTAINS JUST THESE TWO APPLICATIONS, ONE IN CATEGORY 1 AND THE OTHER ONE THE OTHER CATEGORY. AND THE TOTAL FUNDS REQUESTED FOR TIER 2 ARE CLOSE TO -- A LITTLE BIT ABOVE $3 MILLION.

AND I DO WANT TO POINT OUT ALSO THAT DURING THE PROGRAMMATIC REVIEW, THE GRANTS WORKING GROUP MEMBERS INDIVIDUALLY DISCUSSED EVERY APPLICATION THAT WAS INITIALLY PLACED INTO TIER 2, AND THEY MOVED SOME APPLICATIONS FROM TIER 2 TO TIER 1 AND TO TIER 3. AND THESE TWO APPLICATIONS WERE

THE ONES THAT REMAINED IN TIER 2.

CHAIRMAN KLEIN: ALL RIGHT. DR. TROUNSON, WOULD YOU ALSO LIKE TO MAKE ANY GENERAL COMMENT BECAUSE OF THE ABSENCE OF SOMATIC CELL NUCLEAR TRANSFER AND THE ISSUES THAT AROSE BECAUSE OF -- PURSUANT TO OUR CURRENT REGULATIONS, THE LIMITATIONS ON ACCESS TO OOCYTES?

DR. TROUNSON: THANKS, MR. CHAIRMAN. THERE WAS NO -- THERE WERE NO RECOMMENDED APPLICATION IN THE AREA OF NUCLEAR TRANSFER. AND, YOU KNOW, PARTLY THAT IS -- PARTLY THAT IS A PROBLEM OF VERY STRONGLY PERCEIVED PROBLEM OF ACCESSIBILITY OF HUMAN OOCYTES.

AND I DO THINK THIS IS AN ISSUE THIS IS IN FRONT OF THE STANDARDS WORKING GROUP AND WILL BE RESOLVED ONE WAY, EITHER AS IT IS OR IN SOME OTHER WAY. I THINK THE -- I THINK THERE IS -- I THINK THERE'S INTEREST IN THIS SUBJECT, NUCLEAR TRANSFER, BUT I'D HAVE TO SAY THAT I THINK IF WE'RE GOING TO TACKLE THIS SUBJECT, THAT IT WOULD BE REALLY ENHANCE -- THE OPPORTUNITY WOULD REALLY BE ENHANCED BY GETTING THE GROUPS TO WORK TOGETHER AS TEAMS. IT'S REALLY BECAUSE THE ACCESS OF HUMAN OOCYTE MATERIAL WILL BE VERY LIMITED.

I THINK THERE'S SOME VERY SPECIAL

EXPERTISE AVAILABLE IN CALIFORNIA AND BY THESE GROUPS, BUT YOU'VE GOT TO TURN IT INTO, YOU KNOW, A GENUINE OPPORTUNITY RATHER THAN ONE WHICH IS JUST SIMPLY HOPEFUL.

NOW, I THINK IF YOU -- I THINK WHAT WE WOULD LIKE TO DO WOULD BE TO GO THROUGH THE STAGES WITH THE STANDARDS WORKING GROUP, SEE WHERE WE COME OUT WITH WITH A SENSE OF ACCESS OF HUMAN OOCYTES. IF THAT IS -- IF IT IS POSSIBLE FOR US TO, I THINK THROUGHOUT CALIFORNIA WITH PEOPLE WORKING TOGETHER, ACCESS THE KIND OF NUMBERS THAT WE NEED, THEN I THINK WE NEED, THEN, TO FOCUS ON A VERY SPECIALIZED RFA TO DO THAT AND ASK THE TEAMS TO WORK TOGETHER. I THINK IF WE DO THAT, THEY MAY NOT WANT TO WORK TOGETHER, IF THEY DO WORK TOGETHER, I THINK THEN WE WILL HAVE A MUCH BETTER CHANCE OF GETTING AN OUTCOME. AND I THINK, AGAIN, WE WOULD TAKE SOME VERY PRIME LEADERSHIP IN THIS AREA.

I KNOW FROM MY COLLEAGUES OR OUR COLLEAGUES IN THE UK, THEY'RE HAVING A TERRIBLE TIME AT THIS. OUR COLLEAGUES ON THE EAST COAST ARE HAVING A TERRIBLE TIME OF THIS. IT'S ALL BECAUSE THERE'S NO PARTNERSHIPPING ARRANGEMENTS OR BECAUSE THEY'RE USING VERY FEW OOCYTE MATERIAL. THEY'RE NOW TRYING TO USE CATTLE EGGS, OTHER SPECIES. THEY'RE

FLOUNDERING. SO I DON'T THINK THAT'S IN OUR INTEREST TO BE LIKE THAT. I THINK WE NEED -- WHEN WE'RE READY TO GO, WE NEED TO GO WITH THE BEST POSSIBLE CHANCE OF AN OUTCOME. AND I WOULD LIKE TO SEE THAT HAPPEN AFTER OUR STANDARDS WORKING GROUP LOOKS AT WHAT WE CAN GENUINELY ACCESS IN TERMS OF HUMAN MATERIAL.

AND THEN IF WE CAN SEE IF WE CAN ENCOURAGE OUR COLLEAGUES HERE IN CALIFORNIA TO WORK TOGETHER, I THINK THAT WOULD BE A MUCH BETTER OUTCOME AND MORE LIKELY TO SUCCEED.

CHAIRMAN KLEIN: ALL RIGHT. JEFF SHEEHY.

MR. SHEEHY: I JUST WANT TO BE CLEAR THAT I THINK WE HAVE -- WE'RE TALKING ABOUT ALTERING A CONSENSUS. THAT'S A CONSENSUS ON OBTAINING OOCYTES, AND I THINK WE SHOULD BE VERY CAREFUL. AND I ALSO AM NOT COMPLETELY CERTAIN THAT THERE'S UNIVERSAL ENTHUSIASM FOR THE TECHNIQUE AMONG THE SCIENTIFIC COMMUNITY, AND THAT MAY HAVE BEEN A REASON WHY THOSE APPLICATIONS DID NOT SCORE AS WELL WHEN WE HAVE IPS TECHNIQUES THAT WORK, THAT CAN GIVE YOU THE SAME SORT OF DISEASE-SPECIFIC CELL LINES.

SO I JUST -- YOU KNOW, I THINK THE ETHICAL CONCERNS THAT HAVE BEEN EXPRESSED AND ENSHRINED IN PROP 71 AND SB 1260 ARE REAL. I THINK WE'VE HAD A

VERY GOOD PROCESS UP TO DATE. AT THE STANDARDS WORKING GROUP WE'VE BEEN VERY DELIBERATIVE. BUT JUST BECAUSE SOME SCIENTISTS WANT TO DO SOMETHING DOESN'T MEAN THAT WE SHOULD. SO I WOULD -- THAT'S ALL -- AND SCNT MAY NOT BE THE MAGIC BULLET THAT PEOPLE THINK IT IS. AND WE CAN'T DO IT AND WE CAN DO IPS.

CHAIRMAN KLEIN: JEFF, CURRENTLY OUR STANDARDS ARE MORE RESTRICTIVE THAN PROP 71, AND CERTAINLY WE CAN'T CHANGE WHAT'S IN PROP 71, BUT WHATEVER WE DO THERE --

MR. SHEEHY: THAT'S YOUR INTERPRETATION.

CHAIRMAN KLEIN: THAT'S ABSOLUTELY TRUE. BUT CLEARLY --

MR. SHEEHY: PROP 71 GIVES THE STANDARDS -- CONSIDERING THAT THE STANDARDS WORKING GROUP HAS OPERATED CONSISTENT WITH PROP 71, I THINK THAT WHAT IS -- STANDARDS WORKING GROUP HAS DONE AN AMAZING JOB. I'M JUST NOT WILLING TO START PULLING THE CLOTH APART.

CHAIRMAN KLEIN: OKAY.

MR. SHEEHY: JUST BECAUSE, YOU KNOW, I NEED A LITTLE BIT MORE JUSTIFICATION.

CHAIRMAN KLEIN: ABSOLUTELY. BUT I DON'T WANT TO PREJUDGE A DEBATE THAT HAS TO BE THOUGHTFUL,

THOROUGH, AND INVOLVE A BROAD GROUP OF PEOPLE. SO WHATEVER WE DO --

MR. SHEEHY: STANDARDS WORKING GROUP IS MEETING AT THE END OF JULY, AND I THINK WE SHOULD LET THAT PROCESS GO FORWARD. I THINK --

MS. LANSING: AS CO-CHAIR I WOULD ACTUALLY LIKE TO SECOND THAT.

CHAIRMAN KLEIN: I COMPLETELY AGREE. I COMPLETELY AGREE.

SO THERE ARE TWO INDIVIDUALS HERE THAT IT'S MY UNDERSTANDING WANT TO MAKE COMMENTS RELATED TO THIS ROUND OF APPLICATIONS FROM THE PUBLIC. AND THEY HAVE TIME CONSTRAINTS THAT ARE FAIRLY SIGNIFICANT. THEY EACH HAVE THREE MINUTES. LET ME ASK THE QUESTION WHETHER THOSE INDIVIDUALS WANTING TO MAKE A COMMENT NOW, OR WHETHER THEY WANT TO MAKE A COMMENT LATER AT THE TIME ANY PARTICULAR GRANT THAT THEY'RE CONCERNED WITH COMES UP. SO THE QUESTION IS --

MR. REED: TWO COMMENTS. FIRST, IT SEEMS TO ME WE MIGHT WANT TO HAVE SOMETHING LIKE WE DID FOR THE COMPUTER INDUSTRY, WHICH WAS AN INCUBATOR PROGRAM TO HELP THE NEW GROUPS GET STARTED, MELLENCOMP INDUSTRIES OF TOMORROW. PERHAPS A ONE-DAY WORKSHOP ON HOW TO DO A GRANT TO FIT THE

REQUIREMENTS MIGHT BE USEFUL.

SECONDLY, AND I APOLOGIZE, THIS IS NOT WHAT YOU'RE ON, BUT I HAVE TO -- I'M BEING DRAGGED KICKING AND SCREAMING TO DISNEYLAND, AND I HAVE TO LEAVE. I APOLOGIZE. BUT SENATE BILL 1565, THE LAST HEARING IS COMING UP SOON. IT WILL PROBABLY BE THE 9TH, BUT WE DON'T KNOW THAT FOR SURE.

I'VE BEEN TO VISIT EACH MEMBER OF THE NEXT COMMITTEE GROUP, AND THE LEVEL OF UNDERSTANDING, AT LEAST AMONG THE STAFF, VARIES WILDLY. ONE STAFFER TOLD ME TO HIS KNOWLEDGE, STEM CELL RESEARCH WAS ILLEGAL IN CALIFORNIA. OKAY. BEAR IN MIND THAT THE -- ONE OF THE PROCESSES THAT THEY'RE BEGINNING, WHICH IS UNNECESSARY BECAUSE IT CAN BE DONE WITHOUT A LAW, IS THE LITTLE HOOVER COMMISSION, BUT IT IS NOT JUST AN EXAMINATION. IT IS ALSO TO RECOMMEND AND DESCRIBE AND BEGIN TO ENACT LEGISLATION TO MAKE THE CHANGES, AMONG WHICH THEY SPECIFICALLY MENTION THE CONFLICTS OF INTEREST OF THIS BOARD.

TO MY MIND, WHAT WE HAVE HERE IS A CONVERGENCE OF EXPERTISE, AND I WOULD BE TERRIBLY UPSET IF THIS WAS TO BE REMOVED AND REPLACED BY POLITICAL APPOINTEES. THIS MUST BE FOUGHT. I KNOW THAT YOU'RE GOING TO TALK ABOUT THIS TOMORROW, BUT, FOLKS, EVERY PERSON IN THIS ROOM, IF I COULD HAVE MY

WAY, WOULD BE UP THERE TALKING TO THIS NEXT PERSON. SENATOR LENO OR ASSEMBLYMAN LENO IS A REASONABLE MAN, BUT THEY MUST UNDERSTAND WHAT IS AT STAKE HERE.

RIGHT NOW EVERY COMMITTEE HEARING HAS BEEN LOST TO OUR SIDE. THERE HAS NOT BEEN ONE VOTE THAT'S BEEN CAST ON OUR SIDE SO FAR. THEY DO NOT UNDERSTAND. THANK YOU.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. THE ADDITIONAL COMMENT, AND LET'S TRY AND KEEP IT VERY SHORT, JOHN SIMPSON.

MR. SIMPSON: JOHN SIMPSON FROM CONSUMER WATCHDOG. A QUICK QUESTION. THIS WAS, I THINK, THE FIRST RFA THAT ALLOWED COMPANIES TO APPLY. MY QUESTION IS ARE ANY OF THE TIER 1 GRANTS BEING RECOMMENDED TO COMPANIES?

CHAIRMAN KLEIN: WITHOUT -- WE'RE GOING TO JUDGE THESE ALL ON A SCIENTIFIC BASIS. AND WITHOUT PREJUDICING THE REVIEW, I THINK THAT THE INTENT WAS NOT TO GO THROUGH THAT DISCLOSURE AT THIS TIME. WE WANT TO HAVE AN UNBIASED AWARD. IS THAT A CORRECT STATEMENT, DR. OLSON?

DR. OLSON: THAT IS A CORRECT STATEMENT. THOSE RESULTS WILL BE MADE AVAILABLE WHEN THE BOARD HAS MADE ITS DECISIONS.

CHAIRMAN KLEIN: OKAY. BUT WE'RE EXCITED

TO HAVE COMPANIES IN THE COMPETITION.

IS THERE SOMEONE ELSE WHO NEEDS TO MAKE A COMMENT ON CELL LINES AT THIS TIME AS VERSUS AT A LATER TIME ON CELL LINES?

MR. WOLCOTT: MR. CHAIRMAN, THANK YOU FOR TAKING MY COMMENTS. I WILL ASK YOU THIS. I'M NOT SURE WHAT YOUR AGENDA IS IN TERMS OF RETURNING FROM DINNER, BUT IF -- I MIGHT BE ABLE TO STAY.

CHAIRMAN KLEIN: WE'RE GOING TO RETURN IN ABOUT AN HOUR.

MR. WOLCOTT: I'M SORRY?

CHAIRMAN KLEIN: IT'S ABOUT AN HOUR FOR DINNER, AND WE'LL BE IN EXECUTIVE SESSION DURING THAT TIME.

MR. WOLCOTT: OKAY. THEN I BETTER SPEAK NOW. I STAND IN A PRECARIOUS PLACE BECAUSE I'M BETWEEN YOU AND DINNER. OKAY. GOOD. YES, I WILL. LET ME INTRODUCE MYSELF, AND MY GOAL IS TO TELL YOU A LITTLE BIT ABOUT OUR EXPERIENCE WITH EXACTLY THIS SUBJECT MATTER. AND IN PARTICULAR, I'VE BEEN A LITTLE BIT MORE EDUCATED NOW ABOUT SCNT. BEFORE I CAME TO THIS MEETING, I DIDN'T QUITE UNDERSTAND THAT ISSUE AS WELL AS I DO NOW.

AND ALSO I'D LIKE TO ALSO MAKE SOME SUGGESTIONS ABOUT THE CELL LINE PROCESS AS AN

EXAMPLE.

SO, FIRST OF ALL, MY NAME IS KEN WOLCOTT, AND I AM THE CHIEF BUSINESS OFFICER OF CASCADE LIFE SCIENCES, A STEM CELL COMPANY IN SAN DIEGO. AS BACKGROUND, I AM NOT A SCIENTIST. I'M A LAWYER. AND I DEFER TO THE SCIENTISTS IN MUCH OF THIS AREA, BUT I DO KNOW THAT THERE'S A PARTICULAR LAWYER HERE AT THE TABLE THAT MADE A BIG DIFFERENCE IN SCIENCE, SO I FEEL FAIRLY COMFORTABLE TALKING ABOUT STEM CELLS.

I SPENT 20 YEARS IN THE BIOTECH INDUSTRY. I'M WITH A FOR-PROFIT ORGANIZATION. I AM VERY GRATEFUL THAT CIRM IS CONSIDERING GRANTING -- GIVING GRANTS TO FOR-PROFIT ORGANIZATIONS. AND I WANTED TO, YOU KNOW, SAY THAT IF I READ THE WEBSITE CORRECTLY, AND I READ PROP 71 AND I'VE READ THE MATERIALS, A FOR-PROFIT ENTERPRISE AND CIRM ARE VERY COMPATIBLE. WE ALL NEED AT THE END OF THE DAY PRODUCTS THAT WILL HELP PEOPLE.

AND WITH THAT IN MIND, WHEN WE RECEIVED THE RFA TO -- FOR THE CELL LINE DEVELOPMENT RFA, IT WAS OUR FIRST REAL OPPORTUNITY AS A FOR-PROFIT TO PARTICIPATE WITH CIRM. WE WERE VERY PLEASED TO SEE THAT IN PARTICULAR SCNT WAS A STATED GOAL OF CELL LINE DEVELOPMENT. WE LICENSE THIS TECHNOLOGY

EXCLUSIVELY FROM UNIVERSITY OF OREGON. AND IN NOVEMBER OF 2007, IT WAS PUBLISHED IN *NATURE* AS THE FIRST SUCCESSFUL CLONING OF PRIMATES WITH SCNT.

AND FROM A BUSINESS STANDPOINT, NOT FROM A SCIENTIFIC STANDPOINT, THE NATURAL QUESTION WHEN WE WERE OUT THERE TRYING TO RAISE MONEY WAS THERE'S NOT A LOT OF MONEY IN TREATING PRIMATES. YOU NEED TO BE AT THE HUMAN LEVEL. AND SO OUR NEXT LOGICAL GOAL FROM A BUSINESS STANDPOINT WAS TO TRANSLATE THE PRIMATE RESEARCH TO HUMAN RESEARCH.

WHEN WE GOT THE RFA, IT SEEMED VERY CLEAR THAT THAT WAS A GOAL THAT WAS SHARED BY THIS COMMITTEE. OUR EXPERIENCE WITH THAT WAS A LITTLE BIT DIFFERENT UNFORTUNATELY. WE SUBMITTED AN APPLICATION, AND ONE OF THE COMMENTS, THERE WERE MANY COMMENTS, BUT I'LL TRY TO BE BRIEF. ONE OF THE COMMENTS WAS WE CAN'T FUND THIS BECAUSE IT LACKS ANY NOVELTY TO GO FROM PRIMATES TO HUMANS.

AND THAT REALLY CONCERNS ME AS A PROCESS BECAUSE IN MY READING OF YOUR OWN PAPERS AND ACTUALLY UTA -- HI -- ACTUALLY WHEN I WAS LISTENING TO HER PRESENTATION, ONE OF THE THINGS THAT YOU SAID WAS THAT NOVELTY WAS NOT NECESSARILY THE HIGHEST CRITERIA. SO I HAVE A CONFLICT IN THAT I'M READING YOUR RFA AND I'M HEARING YOUR PRESENTATION; BUT WHEN

WE GOT OUR SCORE BACK AND WE GOT OUR COMMENTS BACK, ONE OF THE THINGS THAT STRUCK ME AS A LAWYER, NOT AS A SCIENTIST, WAS THERE'S NO NOVELTY TO GO FROM PRIMATES TO HUMAN.

AND SO AS A CONSEQUENCE, WE WEREN'T FUNDED. AND I'M NOT HERE TO ARGUE EACH INDIVIDUAL POINT OF THAT, BUT WHAT I'D LIKE TO SUGGEST IS ONE OF THE THINGS THAT IS TROUBLING IS WE BELIEVE THAT THE REVIEWERS IN THIS CASE SIMPLY DIDN'T READ OUR APPLICATION VERY CAREFULLY, IF AT ALL IN SOME SENSES, APPLIED A VERY HIGH STANDARD SCIENTIFICALLY TO OUR WORK, WHICH IS APPROPRIATE; BUT TO SUGGEST THAT GOING FROM PRIMATE TO HUMAN WHERE WE CAN GET PLENTY OF FUNDING FOR PRIMATE WORK, BUT THE CIRM'S MISSION AND ITS GOAL IS TO FUND HUMAN WORK. AND IT SEEMED LIKE A LOGICAL TRANSITION TO US.

HAVING SAID THAT, I KNOW THIS DOESN'T PROVIDE FOR PROCEDURE FOR THIS; BUT, YOU KNOW, WHEN WE APPLY AT NIH OR SBIR OR STTR GRANTS, THERE'S A PROCESS BY WHICH YOU GET YOUR COMMENTS. IF THERE'S A MISUNDERSTANDING OR A MISCOMMUNICATION, YOU CAN RESPOND BACK. AND SO I'M SUGGESTING THE COMMITTEE MIGHT CONSIDER A LITTLE BIT OF A DIALOGUE BETWEEN THE APPLICANTS AND THE REVIEWERS.

SECONDLY, WHEN I LOOKED AT THE VERY

DISTINGUISHED LIST OF YOUR REVIEWERS, AND IT WAS ON YOUR WEBSITE, IT JUST SIMPLY SHOWED THEIR AFFILIATIONS, SO I'M OPERATING A LITTLE BIT IN THE DARK. I DIDN'T SEE ANYONE THAT HAD ANY COMMERCIAL AFFILIATION. NOW, THEY MAY HAVE COMMERCIAL BACKGROUND FROM OTHER ACTIVITIES.

CHAIRMAN KLEIN: I APPRECIATE YOUR COMMENTS. WE NEED TO APPROPRIATELY LIMIT EVERYONE'S COMMENTS. SO --

MR. WOLCOTT: SO I GUESS MY POINT IS, LET ME CLOSE BY SAYING, OUR EXPERIENCE WAS VERY DIFFERENT THAN OUR EXPECTATION BASED ON THE THINGS THAT WERE PRESENTED TO US FROM YOUR COMMITTEE OR FROM YOUR STAFF. AND NOW I'VE HEARD A DIFFERENT REASON WHY SCNT MAY NOT BE FAVORABLE, BUT THAT WASN'T WHAT WAS PRESENTED TO US AS A REVIEW COMMENT. AND SO WE'RE JUST A LITTLE DISMAYED ABOUT THE PROCESS, AND WE HOPE PERHAPS THERE'S ANOTHER OPPORTUNITY WHEN YOU ADDRESS THE ISSUES YOU SUGGESTED JUST A FEW MINUTES AGO, THAT THERE WOULD BE ANOTHER OPPORTUNITY TO DO A GRANT IN SCNT, BUT IT WASN'T CLEAR TO US THAT THAT'S -- THAT WAS THE PROGRAM THAT WE WERE APPLYING FOR.

CHAIRMAN KLEIN: I THINK IT'S VERY IMPORTANT THAT WE HAVE AND OUR REVIEWERS HAVE TO

REMAIN ABSOLUTELY TRUE TO THE STANDARDS WE HAVE IN PLACE AT THE TIME. AND WE HAVE TO BE VERY CAREFUL, AS JEFF SHEEHY INDICATED, IN OBSERVING THE CONSENSUS BECAUSE IT'S VERY THOUGHTFULLY PUT TOGETHER. AND SO I THINK GENERALLY, AS DR. TROUNSON INDICATED, EFFECTIVE SCNT APPLICATIONS, WE HAVE TO MOVE THOUGHTFULLY AND WITH FULL CONSENSUS. BUT THERE ARE -- WE DON'T REALLY WANT TO GET INTO THE FULL REVIEW AT THIS TIME.

MR. WOLCOTT: I UNDERSTAND. I UNDERSTAND. JUST PROCESSWISE, WE WOULD LIKE TO HAVE A BETTER UNDERSTANDING GOING IN AND PERHAPS A DIALOGUE WITH THE REVIEWERS.

CHAIRMAN KLEIN: RIGHT.

MR. WOLCOTT: I THANK YOU.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. ALL RIGHT. SO, DR. GRIESHAMMER, WERE YOU ABLE TO COMPLETE THE ITEMS THAT YOU WANTED TO PRESENT TO US?

DR. GRIESHAMMER: WE WERE.

CHAIRMAN KLEIN: YOU WERE. ALL RIGHT. SO AT THIS POINT I'D LIKE TO ADJOURN INTO EXECUTIVE SESSION IF, MR. HARRISON, YOU WANT TO CITE THE PROVISIONS UNDER WHICH WE WILL ADJOURN FOR EXECUTIVE SESSION.

MR. HARRISON: YES. WE'LL BE GOING INTO

CLOSED SESSION FOR DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT AND PREPUBLICATION CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA UNDER HEALTH AND SAFETY CODE SECTION 125290.30(D), PARAGRAPHS (3)(B) AND (C).

CHAIRMAN KLEIN: THANK YOU VERY MUCH.

DR. POMEROY: BOB, CAN I ASK YOU A QUESTION?

CHAIRMAN KLEIN: DR. POMEROY.

DR. POMEROY: CAN JAMES CLARIFY FOR US THE CONFLICT OF INTEREST SITUATION AND WHO CAN COMMENT PUBLICLY AND WHAT WE CAN DO IN THE CLOSED SESSION?

MR. HARRISON: SURE. YOU ALL HAVE A LIST IN FRONT OF YOU OF THE APPLICATIONS IN WHICH YOU HAVE AN INTEREST; AND YOU MUST, THEREFORE, ABSTAIN FROM PARTICIPATING IN ANY DISCUSSION OF THOSE APPLICATIONS. SO TO THE EXTENT IN CLOSED SESSION A PARTICULAR APPLICATION IS BEING REVIEWED IN WHICH YOU HAVE AN INTEREST, YOU CAN'T PARTICIPATE IN THAT.

ONCE WE GET BACK INTO OPEN SESSION, AT THE OUTSET OF THE DISCUSSION WITH RESPECT TO ANY APPLICATION, WE WILL ANNOUNCE THE NAMES OF THOSE MEMBERS WHO CAN'T PARTICIPATE, AS A REMINDER, AND WE'LL FOLLOW THE SAME PROCESSES WE'VE USED IN THE PAST.

DR. POMEROY: SO WE CAN REVIEW THE OTHERS?
THE REPORTER: I'M SORRY.
MR. HARRISON: CORRECT.
CHAIRMAN KLEIN: WE CAN REVIEW THE ONES THAT ARE NOT IN SESSION. AND WITHIN EXECUTIVE SESSION, FOR THE BENEFIT OF THE PUBLIC, WE HAVE A MONITORING SYSTEM TO ENSURE THAT NO ONE IS SITTING INTO A CLOSED EXECUTIVE REVIEW OF ANY APPLICATION IN WHICH THEY HAVE A CONFLICT. THEY ARE FIRST CLEARED TO GO INTO THAT DISCUSSION WITH THE STAFF MEMBER, AND THEN THE STAFF MEMBER MONITORS THE FACT THAT ONLY THOSE PEOPLE WITHIN THAT REVIEW WHO HAVE NO CONFLICTS CAN EVEN SIT AND LISTEN TO THE REVIEW. AND OBVIOUSLY NO ONE CAN COME IN AND COMMENT IF THEY HAVE A CONFLICT. SO IT IS A MONITORED PROCESS.
SO, MR. HARRISON, ARE WE APPROPRIATELY READY TO ADJOURN TO EXECUTIVE SESSION?
MR. HARRISON: YES, WE ARE.
(A RECESS WAS TAKEN.)
CHAIRMAN KLEIN: DR. TROUNSON, ARE THERE ANY MORE GENERAL COMMENTS THAT YOU WOULD LIKE THE SCIENTIFIC STAFF TO MAKE BEFORE WE GO THROUGH THE SPECIFIC REVIEW?
DR. TROUNSON: NO. I THINK THE -- I THINK WHAT I PRESENTED TO YOU EARLIER, THAT THE AREA OF

THE IPS CELLS IS EXTREMELY INTERESTING, AND I THINK IS REFLECTED IN THE INTERESTS IN THE GENERAL SCIENTIFIC COMMUNITY. AND WE WOULD EXPECT TO BE INCREASING, I GUESS, MORE WORK IN THAT AREA, SO I THINK THAT'S REFLECTIVE. I THINK THE ISSUES OF NUCLEAR TRANSFER STILL REMAINS A LITTLE PROBLEMATIC, BUT IT'S STILL INTERESTING, I FEEL, AT THIS STAGE, BUT A LITTLE BIT PROBLEMATIC. AND WE MIGHT NEED TO FIND WAYS TO SOLVE THAT.

I THINK, YOU KNOW, THE GENETICALLY AFFECTED EMBRYOS ARE VERY INTERESTING. THERE ARE, I THINK, A NUMBER OF CELL LINES IN DIFFERENT TYPES OF DISEASES, SO SOME PROBABLY NEED TO BE INCREASED. OTHERS ARE PROBABLY SUFFICIENT. BUT, YOU KNOW, THERE'S A FAIR VARIANCE OF ALL OF THESE THINGS.

WE ARE TRYING TO SEE IF WE CAN NEGOTIATE GOOD ACCESS TO SOME OF THE GENETICALLY ABNORMAL ES CELL LINES TO ENABLE OUR COLLEAGUES, SCIENTIFIC COLLEAGUES, TO ACCESS AT REASONABLE, VERY REASONABLE RATES IN LARGE NUMBERS. SO, YOU KNOW, WE'RE KIND OF MOVING TO TRY AND HELP THE GENERAL SCIENTIFIC COMMUNITY HERE TO MOVE ON IN THIS AREA.

CHAIRMAN KLEIN: OKAY. THANK YOU VERY MUCH, DR. TROUNSON.

SO AS WE GO INTO THE CONSIDERATION OF THE

CELL LINES, JEFF, HOW WOULD YOU LIKE TO PROCEED? WOULD YOU LIKE THE CHART UP ON THE SCREEN?

MR. SHEEHY: YES. I THINK THAT'S A GOOD START. MAYBE -- YOU KNOW, TYPICALLY WE START OFF WITH THE HISTOGRAM AND TRY TO CHOP A FEW OFF THE TOP AND OFF THE BOTTOM, BUT I THINK WE'VE LOST THE HISTOGRAM.

DR. OLSON: WE DO NOT HAVE THE SLIDE OF THE HISTOGRAM. WE WILL TRY AND MAKE A POINT OF -- DO WE HAVE IT AT ALL FOR TOMORROW? WE CAN TRY AND GET IT FOR --

MR. SHEEHY: I MEAN WE ALREADY HAVE -- YOU KNOW, USUALLY WE USE THAT TO KIND OF GET THE TOP -- SOME OF THE TOP TIER OUT OF THE WAY AND SOME OF THE BOTTOM TIER OUT OF THE WAY, I THINK. ISN'T THAT HOW WE USUALLY --

DR. OLSON: WE CERTAINLY DO IT IN THE REVIEW MEETING THAT WAY.

MR. SHEEHY: I CAN'T REMEMBER.

DR. OLSON: WE DON'T INTEND TO DO IT AT THIS MEETING.

MR. SHEEHY: SHOULD WE JUST GO ONE BY ONE?

CHAIRMAN KLEIN: IN ORDER TO AVOID THE CONFLICT --

MR. SHEEHY: YOU WANT TO JUST GO ONE BY

ONE AND JUST MAYBE PUT UP THE CHART, AND WE'LL JUST TAKE MOTIONS ONE BY ONE, WHICH IS FINE.

CHAIRMAN KLEIN: YEAH. WE COULD TAKE -- MR. HARRISON, WE COULD TAKE A MOTION WITH THOSE MEMBERS VOTING ON THOSE THAT THEY'RE NOT IN CONFLICT WITH.

MR. HARRISON: RIGHT. I WAS JUST GOING TO REMIND YOU THAT IN THE PAST WHAT WE'VE DONE IS TO START WITH THE APPLICATIONS IN TIER 3 AND ASK THE BOARD WHETHER ANY MEMBER WOULD LIKE TO MAKE A MOTION TO MOVE AN APPLICATION IN TIER 3 UP TO TIER 1. ONCE THOSE MOTIONS HAVE BEEN EXHAUSTED, WE MOVE TO TIER 2 AND FIND OUT WHETHER ANY MEMBERS WOULD LIKE TO MAKE A MOTION TO MOVE AN APPLICATION FROM TIER 2 INTO TIER 1.

THEN ONCE THE APPLICATIONS ARE ASSEMBLED IN THE VARIOUS TIERS, WE TAKE A MOTION TO FUND THOSE APPLICATIONS IN TIER 1 OBVIOUSLY WITH MEMBERS ABSTAINING FROM ANY APPLICATIONS IN WHICH THEY HAVE AN INTEREST. AND OBVIOUSLY, IF THERE ARE APPLICATIONS IN TIER 1 THAT MEMBERS WOULD LIKE TO MAKE A MOTION TO MOVE OUT OF TIER 1, THAT'S PERMISSIBLE AS WELL.

CHAIRMAN KLEIN: ALL RIGHT. SO, JEFF, WOULD YOU LIKE TO START WITH TIER 3 AS WE HAVE IN

THE PAST AND ASK IF ANY MEMBER WOULD LIKE TO MOVE ANY ONE FROM TIER 3 UP?

MR. SHEEHY: SURE. IS THERE ANY INTEREST --

DR. PIZZO: COULD YOU JUST REPEAT?

MR. SHEEHY: THAT'S OKAY. AFTER A WHILE THIS ALL KIND OF RUNS TOGETHER. YEAH. WELL, IS THERE A MOTION TO MOVE ANYTHING FROM TIER 3 INTO TIER -- ACTUALLY I THINK THE MOTION WOULD BE TO TIER 1 BECAUSE I DON'T THINK THERE'S ANY POINT TO BEING IN TIER 2. AND IF NOT --

CHAIRMAN KLEIN: IF THERE'S NOT, MAYBE WE COULD ASK IF THERE'S PUBLIC COMMENT ON ANY ITEM IN TIER 3. IS THERE ANY PUBLIC COMMENT ON ANY ITEM IN TIER 3?

MR. SHEEHY: AND THEN I THINK THE NEXT QUESTION WOULD BE DO WE WANT TO MOVE ANYTHING IN TIER 1 INTO TIER 3? SO DO WE WANT TO MOVE ANYTHING THAT'S CURRENTLY FUNDED, CURRENTLY GREEN, INTO THE UNFUNDED CATEGORY?

AND THEN IF THERE'S NOT, THEN I THINK THE FINAL QUESTION IS THERE ANYTHING IN THE GRAY AREA WE WOULD LIKE TO MOVE EITHER WAY, EITHER INTO THE FUNDED -- WE WILL, THEY'RE ALREADY IN THE NON -- JAMES, YOU MIGHT CLARIFY. THAT'S A NOT

FUNDED CATEGORY AT THIS POINT?

MR. HARRISON: THAT'S RIGHT. THAT CATEGORY IS PROVISIONALLY NOT RECOMMENDED FOR FUNDING.

MR. SHEEHY: OKAY. THEN WE NEED -- DO WE WANT TO MOVE EITHER OF THOSE APPLICATIONS INTO TIER 1, I THINK, IS THE MOTION WE WOULD NEED.

CHAIRMAN KLEIN: LEEZA.

MR. ROTH: I WOULD MAKE A MOTION WE MOVE THEM BOTH INTO TIER 1.

CHAIRMAN KLEIN: IS THERE --

MR. HARRISON: FOR THE PURPOSES OF ASSISTING US IN HANDLING CONFLICTS, IF WE COULD HANDLE THOSE ONE AT A TIME, IT MIGHT BE EASIER.

MR. ROTH: THAT'S FINE. SO I'LL DO THE HUNTINGTON'S. WHAT NUMBER IS IT?

MS. GIBBONS: 678.

MR. ROTH: 678. SO I MOVE THAT INTO TIER 1.

MS. GIBBONS: SECOND.

CHAIRMAN KLEIN: AND LEEZA SECONDED.

MS. KING: CHAIRMAN KLEIN, THE CONFLICTS FOR THAT ONE ARE BRYANT, LANSING, AND STEWARD.

MR. SHEEHY: OKAY. WOULD YOU LIKE A LITTLE DISCUSSION?

MR. ROTH: YES. ON THIS ONE I WOULD LIKE WHOEVER REVIEWED THE PROGRAM TO TELL US AS MUCH AS YOU CAN ABOUT THE REVIEW THAT'S NOT CONTAINED NECESSARILY IN THE BOOK, BUT WHAT THE DISCUSSION WAS BETWEEN THE REVIEWERS AND THE REASON THAT IT'S IN THIS CATEGORY, RECOMMENDING PROGRAMMATIC REVIEW.

DR. OLSON: THAT WILL BE -- DR. ASHA NIGH WILL HAVE THAT DISCUSSION.

DR. NIGH: SO THIS IS AN APPLICATION TO DERIVE CELL LINES FROM PREIMPLANTATION GENETIC DIAGNOSIS CAN USE THE IPS TECHNOLOGY FOR HUNTINGTON'S DISEASE. AND THE CELLS WILL BE DIFFERENTIATED INTO NEURONS, AND A DISEASE MODEL WILL BE DEVELOPED. AND THE NEURONS WILL THEN BE DIFFERENTIATED IN ORDER TO PROVIDE CELLS THAT MIGHT BE USED FOR TRANSPLANTATION FOR A CELL THERAPY.

AND YOU WANTED ME TO GO STRAIGHT INTO THE CRITICISMS; IS THAT CORRECT?

MR. ROTH: YEAH. AND ESPECIALLY IT'S AIM NO. 3 THAT SEEMED TO BE -- AIM 1 AND 2 THERE SEEMED LIKE A GREAT AGREEMENT, AND THEN THREE IS WHERE THIS GOT OFF TRACK.

DR. NIGH: THAT'S CORRECT. THE REVIEWERS HAD TECHNICAL ISSUES WITH THE AIM, INCLUDING DOUBTING THE ABILITY OF A COLLABORATING COMPANY TO

MAKE A VERY LARGE SHRNA CONSTRUCT WHICH HAD NEVER BEEN DONE BEFORE BY THIS COMPANY. THEY HAVE MADE SIMILAR SHRNA'S, BUT SMALLER. AND CONCERNS THAT THE APPLICANT MIGHT NOT BE ABLE TO PRODUCE A POPULATION OF THE PURE NEURONS REQUIRED.

THERE WERE MINOR CONCERNS ABOUT THE SHRNA TECHNOLOGY IN GENERAL, BUT THOSE WERE THE TWO MAIN CRITICISMS.

CHAIRMAN KLEIN: OKAY.

DR. NIGH: DID YOU WANT TO GO OVER THE STRENGTHS?

MS. GIBBONS: I WOULD JUST LIKE FOR US TO STRONGLY CONSIDER THIS ONE. IT SEEMS LIKE THE REVIEWERS FOUND GREAT CONFIDENCE IN THIS TEAM AND THE CREDIBILITY OF THE TEAM, THE EXPERIENCE OF THE TEAM, AND THAT IF WE'RE REALLY GOING TO TAKE A CHANCE ON SOMETHING AS OBLIQUE AS HUNTINGTON'S WITH APPLICATIONS FOR OTHER NEUROLOGICAL -- NEURODEGENERATIVE DISEASES, THAT THIS TEAM WOULD SEEM TO HAVE AN AWFUL LOT OF STRENGTH GIVEN THE HOPELESSNESS OF THIS PARTICULAR PROGRAMMATIC AREA. THAT'S WHY IT WAS INTERESTING TO ME.

MR. SHEEHY: ANY OTHER COMMENTS?

CHAIRMAN KLEIN: I WOULD LIKE -- THERE'S A MEMBER OF THE PUBLIC THAT SPECIFICALLY CAME HERE FOR

THIS ITEM, AND I'D LIKE TO SEE IF STAFF CAN LOCATE.

MR. SHEEHY: SHE'S GONE.

CHAIRMAN KLEIN: SHE WAS --

MS. KING: SHE'S NOT HERE RIGHT NOW. WE CAN TRY AND FIND HER.

CHAIRMAN KLEIN: IF WE TRY AND FIND HER, PLEASE. I BELIEVE SHE HEADS THE HUNTINGTON FOUNDATION IN THE SACRAMENTO AREA.

AND IN TERMS OF MOVING THE DISCUSSION FORWARD, THOUGH, THERE IS -- LET ME ASK THIS QUESTION. DID THEY BELIEVE THAT THERE WAS A FEASIBILITY TO ACHIEVING PART OF THIS -- THE AIMS OF THIS PROPOSAL?

DR. NIGH: THERE -- YES. SO THE -- THE QUESTION OF FEASIBILITY WAS REGARDED IN DIFFERENTIATION. REVIEWERS COMMENTED THAT THIS HAS NOT BEEN ACHIEVED YET AND WAS NOT -- WAS NOT FULLY DESCRIBED IN THE APPLICATION IN A WAY THAT CONVINCED THEM --

CHAIRMAN KLEIN: BUT THERE WAS ANOTHER COMMENT AS TO A PORTION OF IT. THEY DID BELIEVE THAT THERE WAS FEASIBILITY WITH THIS TEAM.

DR. NIGH: OH, ABSOLUTELY. THERE WAS DEFINITELY -- THERE WAS A FEELING THAT GENERATING THE LINES WOULD NOT BE AN ISSUE FROM EITHER

PREIMPLANTATION GENETIC DIAGNOSIS OR FROM USING IPS.

CHAIRMAN KLEIN: OKAY.

DR. NIGH: AND THAT THERE WAS VALUE TO THAT, AND THAT WAS THE DISCUSSION OF VALUE TO THE SPECIFIC AIMS 1 AND 2 WAS GENERATING --

MS. GIBBONS: MAY WE ASK AS WELL ABOUT THE EXISTENCE OF THE -- OR THE NUMBER OF THE EXISTING CELL LINES ALREADY AND HOW RELEVANT IT MAY OR MAY NOT BE THAT THEY ARE IN CALIFORNIA?

DR. NIGH: REVIEWERS COMMENTED THAT THERE WERE ALREADY SEVERAL LINES IN EXISTENCE, UP TO NINE THAT THE REVIEWERS COULD THINK OF, AND THAT THEY WERE FREELY AVAILABLE.

CHAIRMAN KLEIN: ARE THEY -- ARE THOSE LINES THAT ARE AVAILABLE IN CALIFORNIA TO THE REVIEWERS IN CALIFORNIA?

DR. NIGH: THEY DID NOT DISCUSS WHETHER THEY WERE IN CALIFORNIA OR AVAILABLE TO CALIFORNIA RESEARCHERS, BUT THEY MENTIONED THAT THEY WERE AVAILABLE.

CHAIRMAN KLEIN: OKAY.

MR. SHEEHY: FOR WHAT IT'S WORTH, I DID HAVE A VERY BRIEF CONVERSATION WITH THE INDIVIDUAL THAT WE'RE WAITING FOR. AND IN THE EVENT THAT SHE CAN'T BE LOCATED, HER EXPERIENCE WAS THAT LINES WERE

NOT AVAILABLE, AT LEAST IN CALIFORNIA, FOR THE RESEARCH THAT WAS GOING ON AND THAT SHE SPECIFICALLY THOUGHT THAT THAT CRITIQUE -- OH, SHE'S HERE. GOOD. SHE CAN ADDRESS IT.

CHAIRMAN KLEIN: SO, ASHA, IF YOU WILL REMAIN AVAILABLE, BUT I'D VERY MUCH LIKE TO GET THIS WOMAN'S SPECIFIC INPUT. WHY DON'T YOU TAKE THE STAGE AND GIVE US -- THE SPECIFIC GRANT ON HUNTINGTON'S THAT YOU'RE CONCERNED WITH IS UP, AND YOU HAVE THREE MINUTES TO PRESENT YOUR POSITION. WE WERE TRYING TO, AS A SENSE OF EQUITY AND FAIRNESS, TO PRESENT A COUPLE OF YOUR POINTS, BUT ONLY YOU CAN REALLY APPROPRIATELY ADDRESS THEM.

MS. ROBERSON: THANK YOU. I'M SORRY I HELD YOU GUYS UP. I JUST WANTED TO SAY HELLO, AND I'M A PATIENT ADVOCATE FOR HUNTINGTON'S DISEASE. I'M JUDY ROBERSON. I LIVE IN SACRAMENTO, AND I REPRESENT 15,000 PEOPLE IN CALIFORNIA WHO HAVE HD OR ARE AT RISK FOR HUNTINGTON'S. AND I SERVE AS PRESIDENT OF THE NORTHERN CALIFORNIA CHAPTER FOR HUNTINGTON'S DISEASE. AND ALTHOUGH I'M A NURSE, I'VE CHOSEN TO WORK FULL TIME AS A VOLUNTEER FOR HD.

SEVENTEEN YEARS AGO MY FAMILY INITIATED THE HUNTINGTON'S CLINIC AT UC DAVIS MEDICAL CENTER. AND TO DATE IT'S ONE OF THE LARGEST HD CLINICS IN

THE U.S.

THIS YEAR MARKS A MILESTONE FOR OUR FAMILY. WE'VE GIVEN HALF MILLION DOLLARS TO UC DAVIS FOR THAT CLINIC. SO WE REALLY CARE. WHY I CARE IS MY FAMILY HAS LOST FOUR MEMBERS TO HUNTINGTON'S DISEASE, INCLUDING MY SWEET HUSBAND WHO DIED FOUR YEARS AGO. HE WAS ONLY 51, AND WE HAVE FOUR ADORABLE CHILDREN WHO ARE AT RISK. WE HAVE ONE ILL FAMILY MEMBER RIGHT NOW, AND 17 MEMBERS ARE AT RISK.

I JUST HAVE A FEW POINTS TO MAKE. THERE WAS -- THERE'S A CELL LINE PROJECT FOR HUNTINGTON'S DISEASE WHICH SCORED A 69. IT'S RL 100678-1. AND I JUST HAVE A FEW POINTS TO MAKE.

THE REVIEW STATED THAT THERE ARE CURRENTLY EIGHT CELL LINES FOR HUNTINGTON'S DISEASE, INCLUDING ICP LINE, BUT THE RESEARCHERS THAT I'VE JUST SPOKEN TO HAVE BEEN SEARCHING, AND THEY CAN ONLY FIND FIVE LINES. AND THERE ARE NO -- I GUESS I'M CALLING IT WRONG -- IPS LINES. THOSE ARE THE FIBROBLASTS. AND THERE ARE THREE MAIN REASONS WHY WE NEED MORE CELL LINES.

WE WANT TO LEARN WHY IN ONE FAMILY THE SAME CAG REPEAT CAN PRODUCE DIFFERENT AGES OF ONSET, DIFFERING SYMPTOMS, AND WHY THE COGNITIVE AND CHOREA

SYSTEMS VARIES. FOR INSTANCE, IN MY FAMILY MY HUSBAND'S CAG REPEAT WAS 46. HE HAD ONSET IN HIS 30S. HE WAS VERY RIGID AND HE HAD TERRIBLE PSYCH PROBLEMS. HIS BROTHER, JOE, DIED AT 52. HE HAD TERRIBLE CHOREA WITH A LITTLE BIT MORE SOCIAL THAN MY HUSBAND. THEIR SISTER, SUE, SHE'S 52 YEARS OLD, SO SHE'S OUTLIVED SOME OF THE OTHER FAMILY MEMBERS. SHE'S ALIVE AND WALKS AND IS DOING PRETTY GOOD, AND WE DON'T KNOW WHY.

SO HAVING MANY CELL LINES COULD HELP ENSURE ALSO THAT MANY -- THAT ANY SMALL MOLECULE THERAPIES THAT WORK, WE WANT THEM TO WORK FOR MOST HD PATIENTS RATHER THAN JUST BEING OVERLY SPECIFIC FOR ONE CELL LINE. IF WE HAD ENOUGH CELL LINES, WE MIGHT BE ABLE TO FIND NEW DRUG TARGETS THAT ARE SPECIFIC FOR COGNITIVE AND MOTOR SYMPTOMS, WHICH ARE BIG PROBLEMS.

HD IS DIFFERENT THAN OTHER GENETIC DISEASES BECAUSE THE MUTATION CAN BE DIFFERENT IN EVERY PATIENT. IN JUVENILE HUNTINGTON'S, 10 PERCENT OF OUR CASES ARE JUVENILE. THEY GET THIS DISEASE BEFORE AGE 18. THEIR CAG REPEATS RESULT IN A LONGER AND EARLIER ONSET, AND THEY HAVE REALLY LONG REPEATS, AS HIGH AS -- DOCUMENTED AS HIGH AS 250. COMPARE THAT TO MY HUSBAND AT 46.

SO THERE'S A QUESTION. ARE THESE TWO DIFFERENT DISEASES, THE ADULT VERSION AND THE JUVENILE HUNTINGTON'S? OR ARE NEW MECHANISMS INVOLVED? OR IS IT JUST A MORE AGGRESSIVE FORM OF THE ADULT DISEASE?

BUT IF WE HAD A PANEL OF CELL LINES WITH DIFFERENT CAG REPEATS, WE COULD DEVELOP BETTER ASSAYS TO CORRELATE THE LENGTH OF THE CAG EXPANSION AND THE SYMPTOMS. AND SUCH ASSAYS WOULD ADD SIGNIFICANT POWER TO OUR SCREENS TO FIND THERAPIES.

SO I AM ASKING FOR YOU TO CONSIDER RESCORING THE 69. WE HAVE NO TREATMENT FOR HUNTINGTON'S. WE DON'T HAVE L-DOPA, WE DON'T HAVE DBS, AND STEM CELLS ARE OUR BIG HOPE. THANK YOU.

CHAIRMAN KLEIN: CAN I ASK YOU, AS I UNDERSTAND YOUR POINT, EVEN BEYOND THE POINT OF DIFFERENTIATION BETWEEN JUVENILE AND ADULT, YOU'RE SAYING THAT BETWEEN YOUR HUSBAND, HIS BROTHER, AND HIS SISTER, THE MANIFESTATIONS OF THE DISEASE ARE SO DIFFERENT --

MS. ROBERSON: YES.

CHAIRMAN KLEIN: -- THAT YOUR POINT IS IF YOU HAVE MORE CELL LINES AND YOU COULD CROSS COMPARE THEM, THERE MAY BE GENETIC DIFFERENCES THAT GIVE YOU THE CLUES TO UNDERSTAND WHAT FINE POINTS IN THE

GENETIC -- IN THE GENETIC MUTATIONS ARE LEADING TO THESE REMARKABLE DIFFERENCES IN THE MANIFESTATION OF THE DISEASE AND THE SEVERITY. IS THAT YOUR POINT?

MS. ROBERSON: YES. AND ALSO THAT THEY HAVE YET TO, BUT THEY WOULD LIKE TO LOOK AT WHAT OTHER GENE MODIFIERS ARE OUT THERE THAT MIGHT BE AFFECTING. WE HAVE SOMEBODY IN OUR SUPPORT GROUP WHO IS ONLY 48 YEARS OLD WITH A VERY LOW REPEAT, 39. SHE MAYBE SHOULDN'T HAVE GOTTEN THIS MAYBE TILL SHE WAS 70. SHE'S VERY SICK. SHE USES A CANE. SHE HAS TERRIBLE COGNITIVE PROBLEMS.

WE HAVE SOMEBODY ELSE IN OUR SUPPORT GROUP, A MAN, WHO'S 81, WITH A REPEAT OF 40. HE'S DOING PRETTY GOOD. SO HERE WE ARE JUST WHEN WE THINK WE'VE KIND OF GOT THIS THING FIGURED OUT WHERE WE'VE GOT AGE OF ONSET AND SEVERITY OF SYMPTOMS LINKED WITH THE REPEAT LENGTHS, THESE VARIABLES ARE POPPING UP ALL THE TIME. SO WE'D LOVE TO UNDERSTAND IT BETTER, AND I HAVE A FEELING WE CAN DO IT IS WITH MORE CELL LINES.

CHAIRMAN KLEIN: OKAY.

MS. ROBERSON: OH, CAN I MAKE JUST ONE MORE COMMENT? THERE WAS A MAN EARLIER WHO SPOKE ABOUT WISHING THAT THERE WOULD BE SOME KIND OF REBUTTAL PROCESS AFTER THEY GOT THE RESULTS BACK

FROM THIS. AND I THOUGHT ABOUT THAT. I KIND OF LIKE THAT IDEA BECAUSE FOR US OUR RESEARCHERS HAD NO WAY TO GIVE YOU FEEDBACK THAT, HEY, WE'VE SEARCHED. YOU GUYS SAY WE HAVE EIGHT CELL LINES, BUT WE CAN'T FIND THEM. WE CAN ONLY FIND FIVE. AND YOU SAY WE HAVE FIBROBLAST STEM CELLS. WE DON'T HAVE ANY.

SO, ANYWAY, MAYBE THAT'S SOMETHING YOU GUYS CAN TAKE UNDER CONSIDERATION. THANK YOU SO MUCH.

CHAIRMAN KLEIN: THANK YOU VERY MUCH.

MR. ROBERSON: ONE LAST THING. NEXT TIME I PAY MY STATE TAXES, I WON'T COMPLAIN SO MUCH BECAUSE I THINK OUR MONEY IS DOING GOOD WORK HERE. THANK YOU.

CHAIRMAN KLEIN: THANK YOU. ALL RIGHT. ADDITIONAL COMMENTS BY THE BOARD? DR. PIZZO.

DR. PIZZO: I JUST WANT TO SEE IF I CAN JUST CLARIFY AT LEAST FOR MYSELF ONE FACTOR. AND THAT IS THE CONCERN THAT WAS RAISED, AS I HEARD IT EXPRESSED, WAS WITH REGARD TO THE FEASIBILITY FOR AIM 3, WHICH IS REALLY A PRETTY BOLD, AMBITIOUS AIM THAT MIGHT BE A WHOLE SERIES OF COMPLICATED EXPERIMENTS DONE BY EITHER THIS LAB OR OTHERS. WHEREAS, WHAT WE'RE REALLY TALKING ABOUT IN THE PROPOSAL IS GENERATING CELL LINES THAT COULD BE

STUDIED.

SO I THINK THAT IN A SENSE THERE ARE TWO STANDARDS BEING APPLIED, AND THAT'S MY CONCERN AS I'M NOW HEARING THE DISCUSSION MORE ELUCIDATED, WHICH IS, ON THE ONE HAND, GENERATING CELL LINES, WHETHER IT'S FIVE, EIGHT, 20, I MEAN THERE MAY BE A NEED FOR MULTIPLE CELL LINES AS STUDIES WERE TO EVOLVE SEPARATE FROM ACTUALLY DOING SOMETHING THAT WOULD BE QUITE DRAMATIC. AND THAT IS, QUOTE, CURING THE GENETIC DEFECT. THAT I VIEW AS A WHOLE DIFFERENT KIND OF STUDY. I MEAN THAT'S NOT GENERATING CELL LINES. THAT'S, YOU KNOW, A DISEASE-BASED SPECIFIC SET OF APPROACHES.

SO I THINK THAT RAISES A QUESTION IN MY MIND ABOUT WHETHER THE METRIC WE'RE USING IS BEING APPLIED IN THE RIGHT MANNER IN THIS REGARD.

CHAIRMAN KLEIN: THANK YOU, DR. PIZZO. ADDITIONAL COMMENTS? SEEING NO ADDITIONAL COMMENTS --

DR. LORREY: JUST TO HIGHLIGHT, THESE ONE OR TWO WERE CONSIDERED FEASIBLE.

CHAIRMAN KLEIN: THEY WERE CONSIDERED FEASIBLE. OKAY.

DR. PIZZO: CAN I JUST TO CLARIFY THAT, THERE ARE -- THE QUESTION ABOUT THE CELL LINES THAT

ARE AVAILABLE, AND I DON'T KNOW WHAT THE RIGHT NUMBER IS BECAUSE I COULD ENVISION, YOU KNOW, THAT YOU MIGHT HIT A HOME RUN WITH ONE CELL LINE OR YOU MAY NEED 20 OR 30 OF THEM. WHAT IS THE STORY WITH REGARD TO THE AVAILABILITY OF THE LINES? THERE ARE FIVE CELL LINES, QUOTE, NOW AVAILABLE. THAT, I THINK, WE HAVE CLARIFIED.

CHAIRMAN KLEIN: WELL, THAT'S THE POINT BEING MADE BY THE SPEAKER.

DR. PIZZO: EIGHT KNOWN, FIVE AVAILABLE.

CHAIRMAN KLEIN: IF WE CAN TAKE ADDITIONAL COMMENT, DR. LORREY.

DR. LORREY: I'M SORRY TO INTERRUPT, BUT I JUST LOOKED UP ON PUBMED. I'M JEAN LORREY. I WORK ON HUMAN EMBRYONIC STEM CELLS. AND I USED TO -- I HAVE WORKED ON HUNTINGTON'S DISEASE IN THE PAST AND CHAIRED A STUDY SECTION AT NIH THAT REVIEWED GRANTS. AND I KNOW THAT THREE OF THESE LINES COME FROM ONE GROUP IN CHICAGO, VALINSKY. THOSE LINES ARE NOT AVAILABLE.

DR. PIZZO: I SEE.

DR. LORREY: AND I HAVEN'T FOUND -- I SEE ONE MORE THAT WAS -- IS AVAILABLE. IT WAS MADE IN BELGIUM. I DON'T KNOW THESE PEOPLE. AND I, FRANKLY, DON'T THINK THERE ARE CELL LINES AVAILABLE.

DR. PIZZO: OKAY.

DR. LORREY: I COULD ONLY FIND FOUR, AND I WOULDN'T CHOOSE THREE OF THEM.

DR. PIZZO: OKAY. I MEAN IN PRINCIPLE GENERATION OF DISEASE-SPECIFIC CELL LINES IS, TO ME AT LEAST, STILL AN IMPORTANT OBJECTIVE.

CHAIRMAN KLEIN: OKAY. THANK YOU VERY MUCH. DR. OLSON.

DR. OLSON: CHAIRMAN KLEIN, I JUST WANTED TO SAY ONE THING. I DID ATTEND A WORKSHOP, I BELIEVE LAST YEAR, THAT WAS SPECIFICALLY FOCUSED ON HUNTINGTON'S DISEASE. AND AT THAT -- YOU KNOW, AGAIN, IT WAS MADE -- THE POINT WAS MADE THAT THERE ARE DISEASE-SPECIFIC CELL LINES WITH A RANGE OF CAG REPEATS IN THEM. I DO NOT -- YOU KNOW, I'M NOT GOING TO COMMENT ON WHETHER, YOU KNOW, THE NUMBER OF LININGS IS THAT ADEQUATE TO ADDRESS ALL THE CONCERNS THAT, YOU KNOW, OBVIOUSLY EVERYBODY'S GENETIC MAKEUP CAN INFLUENCE. SO THAT'S A SEPARATE COMMENT ENTIRELY. BUT IT IS TRUE THAT I THINK THERE ARE LINES AVAILABLE, AND I BELIEVE THERE ARE MORE THAN FIVE BASED ON, AT LEAST, MY ATTENDANCE AT THAT WORKSHOP AND DISCUSSIONS ABOUT LINES.

PEOPLE WERE PARTICULARLY CONCERNED ABOUT THE NUMBER OF LINES THAT WERE AVAILABLE AND ABOUT

THE, YOU KNOW, THE VARIATION IN REPEATS AND USING THEM TO GENERATE ESSENTIALLY THE SPINY MOTOR, THE MOTOR NEURONS. SO...

DR. PIZZO: I'M SORRY TO PROLONG THIS, BUT I THINK THAT BECOMES AN IMPORTANT ISSUE. I MEAN SO THERE'S A DISCORDANCE IN WHAT WE'RE HEARING, AND I DON'T KNOW HOW TO SOLVE THAT RIGHT NOW IN TERMS OF ARE THERE OR AREN'T THERE. I'M AT THE POINT WHERE I'M CONSIDERING THIS FROM THE PERSPECTIVE OF THE NEED TO GENERATE THE LINES AND FOR THOSE LINES TO BE AVAILABLE, NOT -- I'M NOT FOCUSING, AT LEAST I'M NOT FOCUSING, ON AIM 3, WHICH I THINK IS A DIFFERENT KIND OF SET OF EXPERIMENTS. TO ME THAT'S A SEPARATE SET OF APPLICATIONS ALMOST.

BUT NOW I'M CONFUSED AS TO WHETHER THERE ARE OR AREN'T AN ADEQUATE NUMBER OF LINES.

CHAIRMAN KLEIN: THERE'S -- THERE'S TWO DIFFERENT POINTS, I THINK, BEING MADE HERE. ONE IS LINES CAN BE AVAILABLE, BUT NOT ACCESSIBLE. OKAY. AND WE HAVE HEARD SOME TESTIMONY THAT THEY'RE AVAILABLE, BUT NOT ACCESSIBLE.

THE SECOND POINT IS WE'VE HEARD JUST INDIVIDUAL TESTIMONY THAT EVEN WITHIN A FAMILY GROUP, THERE'S RADICAL DIFFERENCES IN THE MANIFESTATION.

DR. PIZZO: I UNDERSTAND BOTH OF THOSE, BOB, BUT I'M REACTING TO DR. OLSON'S COMMENT, THAT THERE WERE -- AT A SPECIFIC MEETING THAT THERE WERE LOTS OF CELL LINES AVAILABLE. AND I THINK WE SHOULD JUST KNOW -- I MEAN IF A STATEMENT LIKE THAT IS MADE, IT WOULD BE HELPFUL TO KNOW THE VERACITY OF IT.

CHAIRMAN KLEIN: WELL, WHAT WE DO KNOW IS THAT THE REVIEWERS BELIEVE, WHETHER IT'S EIGHT OR NINE LINES WERE AVAILABLE, AND IT APPEARS THAT OF THE EIGHT OR NINE LINES AVAILABLE, DR. LORREY IS AWARE THAT THERE ARE FOUR, WHICH THERE APPEAR TO BE ACCESS QUESTIONS OR QUALITY, WHICH WOULD TEND TO INDICATE THAT BETWEEN THE REVIEWERS AND THE INFORMATION THAT CAN BE VERIFIED, THAT THERE MAY BE FIVE LINES AVAILABLE. WE DO NOT KNOW WHETHER THEY ARE JUVENILE OR ADULT, WHICH IS THERE'S SIGNIFICANT DIFFERENCES.

AND ON A STATISTICAL BASIS, THERE MAY BE ADVANTAGE IN HAVING MORE LINES TO BE ABLE TO COMPARE THE GENETIC DIFFERENCES IN THESE LINES. CAN SOMEONE ADDRESS THAT SCIENTIFICALLY?

DR. PIZZO: IF SOMEONE COULD ADDRESS THAT SCIENTIFICALLY, I WOULD BE ASTOUNDED. I THINK THAT TO KNOW WHAT THE N IS, WHAT THE ADEQUATE NUMBER OF

LINES IS, TO ANSWER THAT, ASSUMES A BODY OF KNOWLEDGE --

CHAIRMAN KLEIN: I SUSPEND MY QUESTION. I WOULD ASSUME THAT HAVING SOME MORE LINES MIGHT INCREASE THE PROBABILITY OF SUCCESS.

DR. PIZZO: BUT WE DON'T KNOW WHAT THE ACTUAL NUMBER IS. IT MAY BE -- YOU KNOW, IT COULD BE IF YOU HAD TWO LINES, YOU'D FIGURE IT ALL OUT, OR IT MAY MEAN THAT YOU NEED HUNDREDS OF LINES. I DON'T KNOW WHAT THE RIGHT NUMBER IS PRO PRIMUM.

DR. HAWGOOD: COULD I JUST ASK A QUESTION WHETHER ANY OF THE KNOWN LINES ACTUALLY HAVE A CELL PHENOTYPE? BECAUSE IF THEY DON'T, THEN GENERATING ADDITIONAL ONES...

DR. OLSON: I WILL JUST SAY THAT I THINK -- YOU KNOW, THE THOUGHT IS THAT THE CELL LINE OR THAT THE CELL THAT IS THE DISEASE CELL HERE IS THE SPINY MOTOR NEURON. THERE'S SOME PEOPLE WHO AREN'T EVEN SURE THAT -- OR EVEN CONVINCED THAT'S THE RIGHT CELL. NO ONE HAS BEEN SUCCESSFUL IN GENERATING THAT PARTICULAR CELL TYPE. SO THAT REALLY IS THE ISSUE.

AND I THINK YOU HEARD THAT FROM THE REVIEWERS TOO, THAT THEY WERE -- THAT THE TECHNICAL CHALLENGE OR THE TECHNICAL ISSUE WITH RESPECT TO

THIS APPLICATION, WHICH DOESN'T MEAN THAT PEOPLE SHOULDN'T TRY, IS THE ABILITY TO GENERATE THAT SPECIFIC PHENOTYPE. SO -- I'M SORRY -- TO GENERATE THAT CLASS OF NEURONS.

CHAIRMAN KLEIN: THAT'S THE THIRD AIM.

DR. PIZZO: NO, THAT'S NOT THE THIRD AIM. THE THIRD AIM IS TO CORRECT THE GENETIC LESION.

MR. SHEEHY: THAT'S THE SECOND AIM, WHICH WAS FEASIBLE, BY THE WAY.

MS. GIBBONS: I THINK THAT WE CERTAINLY --

DR. HAWGOOD: I THINK THE POINT I WAS TRYING TO MAKE, UNTIL THAT DIFFERENTIATION STEP IS SOLVED, THEN HAVING 50 LINES THAT SIMPLY DIFFERENTIATE INTO EARLY NEURONS IS NOT PARTICULARLY USEFUL.

MS. GIBBONS: IT DEPENDS ON WHAT THEY WERE. THERE WERE OTHER EXPERIMENTS PROPOSED FOR THE USE OF THE LINES SUCH AS BIOMARKERS OR DEVELOPING DRUGS WHICH CAN BE DONE ON PROGENITORS WAS THE IDEA.

CHAIRMAN KLEIN: OKAY. DR. PRIETO.

DR. PRIETO: JUST A QUESTION, THAT IF THAT DIFFERENTIATION IS A CRUCIAL STEP AND WE DON'T FUND THE RESEARCH THAT MIGHT ACHIEVE THAT, WHO'S GOING TO DO IT?

MS. GIBBONS: I THINK THAT THE --

CHAIRMAN KLEIN: WHAT WAS THE CONCLUSION AS TO THE QUALITY OF THE TEAM AND PRINCIPALS?

DR. NIGH: THE QUALITY OF THE TEAM WAS CONSIDERED OUTSTANDING.

CHAIRMAN KLEIN: OKAY.

DR. DAFOE: IF I COULD COMMENT. THE ISSUE OF THE APPEAL PROCESS, SLIGHTLY DIFFERENT ISSUE, BUT RELATED BECAUSE IF THERE IS AN APPEAL PROCESS, AND I UNDERSTAND THERE IS, THERE IS NO OPPORTUNITY TO REBUT BECAUSE HERE IT WOULD BE HELPFUL BECAUSE THE INVESTIGATORS COULD COME BACK WITH THEIR INFORMATION ABOUT AVAILABILITY. SO I THINK THAT IS AN INTERESTING POINT, THAT I KNOW THAT SUBSEQUENT GRANTS WILL HAVE AN APPEAL PROCESS BECAUSE THAT'S REALLY WHAT IN MY MIND WE NEED RIGHT NOW IS SOME CONFIRMATION ABOUT ACCESSIBILITY.

MS. GIBBONS: IT SEEMS TO ME THAT, YOU KNOW, WE CERTAINLY APPRECIATE THAT THE REVIEW TEAM DID AN AMAZING JOB AT REVIEWING EXACTLY WHAT WAS SUBMITTED HERE, AND I BELIEVE THE DISCUSSION NOW IS THAT, AT LEAST FOR ME, WE'RE LOOKING AT AIMS 1 AND 2 AND WHETHER WE THINK THIS WOULD BE SOMETHING MEANINGFUL TO FUND BASED ON THOSE AIMS. AND I UNDERSTAND WHERE THE SCORE CAME FROM WITH AIM 3.

BUT GIVEN -- I WOULD LIKE TO SEE US GO FORWARD GIVEN THE STRENGTH OF THIS TEAM AND GIVEN THE OPPORTUNITY, THE ACCESS THAT THEY HAVE, AND IT SEEMS LIKE WE'RE AT LEAST ARGUING ENOUGH FAVORABLY THAT WE CERTAINLY HAVE SOME QUESTIONS ABOUT IT BEING IN TIER 2.

CHAIRMAN KLEIN: ALL RIGHT. JEFF SHEEHY.

MR. SHEEHY: I STILL WANT TO GO BACK TO THE ISSUE ON TIER -- ON AIM 2. AIM 2 IS FEASIBLE, RIGHT? AND AIM 2 IS THE POINT THAT DR. OLSON ADDRESSED, THAT YOU NEED -- THAT YOU NEED TO DERIVE THE SPECIFIC TYPE OF NEURONAL MOTOR -- NO? AS I SEE AIM 2 IS TO -- SPECIFICALLY INTO NEURONAL SUBTYPES INVOLVED IN HD IS WHAT AIM 2 IS, AND AIM 1 AND 2 WERE BOTH CONSIDERED FEASIBLE.

DR. NIGH: AIM 1 WAS TO DERIVE HESC FROM HUNTINGTON DISEASE BLASTOCYSTS. AIM 2 IS TO DERIVE IPS CELLS FROM PATIENTS DIAGNOSED WITH A CAG REPEAT. AND AIM 3 IS TO GENETICALLY MANIPULATE IPS CELLS --

MR. SHEEHY: I'M READING FROM THE REVIEW I HAVE IN FRONT OF ME. CELLS WILL BE DIFFERENTIATED INTO NEURONS, SPECIFICALLY TO NEURONAL SUBTYPES INVOLVED IN HD. THEN IT SAYS IN AIM 3, SO THIS IS UNDER AIM 1 OR 2, WHICH WERE CONSIDERED FEASIBLE. AND THAT WAS THE POINT THAT IT SEEMS TO BE MISSING.

SO IT SEEMS TO ME THAT THIS IS SOMETHING WE SHOULD FUND.

WE JUST HAD A STATEMENT THAT THAT WAS A PROBLEM WITH THE LINES THAT EXIST. THAT GOES TO DR. HAWGOOD'S POINT, AND THIS IS PART OF AIM 1 AND 2, WHICH WERE FEASIBLE AS DETERMINED BY THE REVIEWERS. SO I THINK WE SHOULD GO AHEAD AND VOTE ON THIS AND APPROVE IT.

MR. ROTH: MR. CHAIRMAN, CAN I CALL THE QUESTION?

CHAIRMAN KLEIN: YES. CALL THE QUESTION. WE WILL NEED A ROLL CALL VOTE. AND PLEASE WOULD YOU RESTATE THOSE IN CONFLICT?

MS. KING: CONFLICTS ARE BRYANT, LANSING, AND STEWARD.

CHAIRMAN KLEIN: THANK YOU.

MS. KING: DONALD DAFOE.

DR. DAFOE: YES.

MS. KING: ROBERT PRICE.

DR. PRICE: YES.

MS. KING: DAVID BRENNER.

DR. BRENNER: YES.

MS. KING: MARCY FEIT.

MS. FEIT: YES.

MS. KING: LEEZA GIBBONS.

MS. GIBBONS: YES.
MS. KING: SAM HAWGOOD.
DR. HAWGOOD: YES.
MS. KING: BOB KLEIN.
CHAIRMAN KLEIN: YES.
MS. KING: LEONARD ROME.
DR. ROME: YES.
MS. KING: TED LOVE. PHIL PIZZO.
DR. PIZZO: YES.
MS. KING: CLAIRE POMEROY.
DR. POMEROY: YES.
MS. KING: FRANCISCO PRIETO.
DR. PRIETO: YES.
MS. KING: DUANE ROTH.
MR. ROTH: YES.
MS. KING: DAVID SERRANO-SEWELL.
MR. SERRANO-SEWELL: YES.
MS. KING: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. KING: MR. CHAIRMAN, THAT MOTION CARRIES.
CHAIRMAN KLEIN: ALL RIGHT. JEFF SHEEHY, YOU WOULD LIKE TO MOVE TO --
MR. SHEEHY: YEAH. SO WE HAVE ONE MORE, AND I THINK MR. ROTH WOULD LIKE TO MAKE A MOTION TO

MOVE THIS.

MR. ROTH: SO I WOULD ALSO MOVE THAT WE FUND 649.

MR. SHEEHY: DO I HAVE A SECOND?

MR. SERRANO-SEWELL: SECOND.

MR. SHEEHY: SECOND FROM DAVID SERRANO-SEWELL. CAN WE GET SOME INFORMATION AND BACKGROUND ON THIS FROM --

MS. KING: JUST BEFORE THAT, I JUST WANTED TO ANNOUNCE THAT THE CONFLICT WITH THIS IS DR. BRYANT.

CHAIRMAN KLEIN: OKAY.

DR. NIGH: THIS IS A PROPOSAL TO IMPROVE SOMATIC CELL REPROGRAMMING IN ORDER TO GENERATE INDUCED PLURIPOTENT STEM CELLS FOR USE IN A CELL-BASED DISEASE MODEL. AND IN AIMS 1, THE APPLICANT PROPOSES TO TEST THE INDUCIBLE VECTORS AND SYSTEMS THAT WILL ALLOW EXCISION OF GENES. SO HE IS IMPROVING ON THE IPS PROCEDURES.

CHAIRMAN KLEIN: DR. NIGH, IF YOU COULD SPEAK A LITTLE CLOSER TO THE MIC.

DR. NIGH: OH, I'M SORRY.

CHAIRMAN KLEIN: MAYBE YOU CAN BEND IT UP A LITTLE.

DR. NIGH: OKAY. SO AIM 1 IS ACTUALLY

WORKING ON THE PROCEDURES FOR GENERATING IPS CELLS AND IMPROVING THOSE.

IN AIM 2 THE APPLICANT PROPOSES TO GENERATE IPS CELLS FROM PATIENTS WITH RETT SYNDROME AND ALS. AND IN AIM 3 HE WILL -- HE OR SHE WILL MAKE IPS CELLS FROM HEMATOPOETIC OR HEPATIC LINEAGES IN ORDER TO EXPLORE CELL THERAPY OPTIONS FOR BLOOD AND LIVER DISEASES.

AND, AGAIN, THE STRENGTH OF THIS PROPOSAL WAS THE HIGHLY ACCOMPLISHED INVESTIGATOR AND HIS COLLABORATOR.

AND THE CRITICISMS WERE REALLY THAT THIS WAS A VERY AMBITIOUS PROPOSAL TO GENERATE SEVERAL DIFFERENT TYPES OF DISEASE-BASED LINES. AND SPECIFICALLY IN AIM 3 THERE WAS CRITICISM THAT THE APPLICANT MOVES AWAY FROM THEIR AREA OF CONCENTRATION TO MOVE INTO BLOOD DISORDERS AND HEMOPHILIA AND AN AREA THAT THE APPLICANTS DO NOT HAVE MUCH EXPERTISE IN.

DURING PROGRAMMATIC REVIEW, THE REVIEWERS ACTUALLY DISCUSSED THIS APPLICATION AT LENGTH BECAUSE OF THE STRENGTH OF THE TEAM AND BECAUSE THEY FELT THAT DISEASE MODEL FOR RETT SYNDROME WOULD BE OF VALUE. HOWEVER, OVERALL, THEY REMAINED CONCERNED WITH THE LACK OF FOCUS AND DID NOT MOVE TO MOVE IT

UP INTO TIER 1.

SO AGAIN, THE OVERALL ASSESSMENT WAS THAT THIS PROPOSAL WAS OVERLY AMBITIOUS.

MR. SHEEHY: IF YOU WOULD PLEASE, THERE'S A LETTER IN YOUR -- THAT YOU MAY OR MAY NOT HAVE READ, SO I'M GOING TO READ IT INTO THE RECORD BECAUSE IT DOES REBUT SOME OF THIS. I'D LIKE TO READ THE LETTER.

DR. STEWARD: JEFF, EXCUSE ME. BEFORE YOU DO, I'M JUST A LITTLE CONCERNED ABOUT THAT PRACTICE BECAUSE IT SEEMS TO ME -- AND I'M NOT SPEAKING AGAINST THE APPLICATION ONE WAY OR ANOTHER. I'M JUST TALKING ABOUT THIS LETTER WHICH IS, IN FACT, A REBUTTAL. AND WE'VE ALREADY HEARD TONIGHT THAT SOME OF THE APPLICANTS DID NOT KNOW THAT THERE WAS AN OPPORTUNITY FOR REBUTTAL OR FOR SENDING IN A LETTER. PEOPLE KNOW THAT THEY HAVE AN OPPORTUNITY TO COME IN AND SPEAK PUBLICLY FOR THREE MINUTES.

I THINK IN THE INTEREST OF MAINTAINING A LEVEL PLAYING FIELD, WE SHOULD CONSIDER WHETHER OR NOT WE SHOULD HEAR THIS LETTER IN PRINCIPLE.

CHAIRMAN KLEIN: DOCTOR, WE HAVE PREVIOUSLY RECEIVED LETTERS WHICH WE HAVE, IN FACT, READ INTO THE RECORD. AND WHEN PEOPLE CANNOT BE PRESENT, THEY HAVE THE ABILITY TO SEND LETTERS IN.

SO IT IS NOT INCONSISTENT WITH OUR HISTORY TO RECEIVE LETTERS INTO EVIDENCE FOR THE MEMBERS AND FOR THE PUBLIC'S BENEFIT.

DR. STEWARD: SO IF THAT IS THE CASE, THEN I THINK IT'S VERY IMPORTANT THAT CIRM MAKE THAT CLEAR AS AN AVAILABLE PROCEDURE TO APPLICANTS BECAUSE WE HAVE ALREADY HEARD THAT THERE IS A GENERAL FEELING THAT THAT IS NOT AN OPTION FOR THEM.

CHAIRMAN KLEIN: IT IS NOT A RECOMMENDED OPTION. IT IS LEGALLY AVAILABLE TO THE APPLICANTS. IT IS -- I THINK WE SHOULD TAKE A MOMENT HERE AND MAYBE HAVE DR. TROUNSON ADDRESS THE --

MR. SHEEHY: I MEAN I THINK -- I MEAN I WANT TO BE PERFECTLY CLEAR. WE'RE AN OPEN GOVERNMENT RULED AGENCY. THIS IS IN ALL OF OUR PACKETS. THIS SHOULD BE READ INTO THE RECORD. AND I WAS IN THE PROCESS OF READING IT WHEN I WAS STOPPED, AND I THINK I SHOULD BE ABLE TO CONTINUE TO READ IT.

MR. SERRANO-SEWELL: JUST LET ME ADD TO THAT --

MR. SHEEHY: AND ANYBODY CAN COME BEFORE A PUBLIC AGENCY AND AVAIL THEMSELVES OF PUBLIC COMMENT. AND BECAUSE ALL OF US HAVE IT, YOU KNOW, THOSE OF US WHO HAVE READ THIS, YOU KNOW, WE SHOULD

CONSIDER THIS.

CHAIRMAN KLEIN: JEFF, WHY DON'T YOU READ IT INTO THE RECORD, AND THEN I'M GOING TO ASK FOR DR. TROUNSON BECAUSE WHAT I DO WANT FOR THE PUBLIC TO UNDERSTAND AND THE BOARD TO UNDERSTAND, THAT THERE IS A DISCUSSION THAT GOES ON, I THINK, AFTER THE REVIEW WITH SUBMISSION OF COMMENTS FROM THE REVIEW BACK TO THE APPLICANT. AND I WANT TO MAKE SURE THAT THAT PROCESS IS UNDERSTOOD.

MR. SHEEHY: AND THE OTHER PART IS TOO WE DID HAVE A LENGTHY DISCUSSION AROUND, YOU KNOW, WE DID MAKE IT VERY CLEAR AROUND THE FACILITIES THAT PEOPLE COULD COME AND DO A THREE-MINUTE PRESENTATION. AND WE HAVE RECEIVED LETTERS IN THE PAST ON VARIOUS ISSUES THAT HAVE BEEN DIRECTED TO US. THEY BECOME PART OF THE PUBLIC RECORD. I THINK BECAUSE WE'RE HAVING THIS DISCUSSION ABOUT THIS APPLICATION, WE'RE PUTTING INTO THE RECORD THE CRITICISMS OF THE APPLICATION. THE FACT THAT WE HAVE IN FRONT OF US THE ANSWER TO THOSE CRITICISMS AND WE DON'T PUT THAT INTO THE RECORD, EVEN THOUGH I'VE READ THIS AND THIS MATERIAL INFLUENCED MY DECISION, DOESN'T SEEM LIKE QUITE THE APPROPRIATE PROCESS.

CAN I JUST GO AHEAD?

CHAIRMAN KLEIN: GO AHEAD.

MR. SHEEHY: IT'S FROM FRED GAGE, THE VI AND JOHN ADLER PROFESSOR OF AGE-RELATED AND NEURODEGENERATIVE DISEASES AT THE SALK INSTITUTE FOR BIOLOGICAL STUDIES. I'M NOT GOING TO START WITH THE INTRODUCTION. I'LL STAY WITH THE MAIN POINTS.

THE REVIEW PANEL FELT THAT THESE STUDIES WERE UNFOCUSED. WE CHOSE SPECIFICALLY TO FOCUS ON THE DERIVATION OF CELL LINES AS REQUESTED IN THE RFA RATHER THAN A RESEARCH PROGRAM BASED ON A SPECIFIC DISEASE. THE REAL HEART OF THIS EFFORT IS TO VALIDATE FIBROBLAST IPS DERIVATION TECHNIQUES FOR USE IN A WIDE RANGE OF HUMAN DISEASES.

TWO, NONE OF THE OTHER PROJECTS SELECTED FOR FUNDING UNDER THIS RFA ADDRESS ALS, RETT SYNDROME, OR HEMOPHILIA. WE HAVE A SHORT TIMEFRAME IN SUPPORT OF THIS APPLICATION IN ORDER TO GENERATE UNIQUE MODEL HUMAN STEM CELL LINES FOR THESE DISEASES THAT ARE NOT OTHERWISE AVAILABLE.

IMPORTANTLY, THE REVIEWERS STATE THAT THE CONTRIBUTION OF THE ALS WORK IS NOT CLEAR AND THAT MOUSE MODELS FOR THIS DISEASE ARE ALREADY AVAILABLE. WE WOULD LIKE TO ARGUE THAT THE VAST MAJORITY OF DRUGS THAT HAVE DEMONSTRATED SIGNIFICANT EFFICACY IN ALS MURINE MODELS FAIL IN HUMAN CLINICAL TRIALS.

THE ONLY FDA APPROVED DRUG FOR ALS EXTENDS PATIENT'S LIVES FOR NO MORE THAN TWO MONTHS. THEREFORE, THERE IS AN URGENT NEED FOR NEW ALS HUMAN SPECIFIC MODELS THAT HAVE THE POTENTIAL TO BE TRANSLATED INTO CLINICAL TRIALS.

THREE, AS THE REVIEWERS HAVE NOTED, DR. VERMA, MYSELF, AND THE RESEARCH TEAM WORKING ON THIS PROJECT ARE LEADERS IN THE FIELD. TOGETHER WE HOPE TO CREATE ONE OF THE STRONGEST STEM CELL RESEARCH TEAMS IN THE STATE. WE WILL NOT BE ABLE TO PERFORM THESE UNIQUE IPS CELL STUDIES WITHOUT SOME SUPPORT.

FOUR, THE CRITICISMS OF AIM 3 REGARDING OUR EXPERTISE IN BLOOD DISORDERS AND CHOICE OF CELL TYPES ARE NOT WARRANTED. DR. VERMA DEVELOPED THE FIRST MOUSE MODEL OF HEMOPHILIA, AND *PNAS* IS THE PUBLICATION WHERE IT WAS PUBLISHED, AND HAS PIONEERED GENE THERAPY IN CURING BOTH MICE AND DOGS OF THE DISEASE. THIS, AGAIN, PUBLISHED IN *PNAS* IN 1999, 2000, AND 2003. GENE THERAPY TRIALS FOR HEMOPHILIA USING THE SAME VECTORS ARE CURRENTLY UNDER WAY IN HUMANS. THE VERMA LABORATORY HAS ALSO DEVELOPED A MOUSE STRAIN THAT IS PERMISSIVE TO HUMAN HEPATOCYTE TRANSPLANTATION, *PNAS* 2007. THIS ALLOWS IN VIVO TESTING OF HEPATOCYTES DERIVED FROM IPS FOR

SECRETION AND FUNCTION OF F 8 AND F 9 IN CONTRAST TO THE REVIEWERS CONCERNS WHETHER ENDOTHELIAL CELLS OR HEPATOCYTES IN VIVO SECRETE THESE FACTORS IS CONTROVERSIAL; HOWEVER, IT IS CLEAR THAT HEPATOCYTES CAN DO THE JOB ONCE DIRECTED TO DO SO.

CHAIRMAN KLEIN: OKAY.

MR. SHEEHY: AND I WOULD STATE THAT DR. GAGE IS WELL KNOWN AS BEING ONE OF THE LEADERS IN THE FIELD.

CHAIRMAN KLEIN: OKAY. THANK YOU.

MR. SERRANO-SEWELL: JEFF, I WANTED TO QUICKLY SAY SOMETHING BECAUSE I DON'T WANT TO GET ON A SIDE TRACK HERE, BUT I THOUGHT OS' COMMENT WAS VERY IMPORTANT ABOUT THE PROCESS. OKAY. AND JEFF GAVE, I THINK, A VERY GOOD EXAMPLE OR BOB.

WE SPECIFICALLY BUILT IN THE FACILITIES PROCESS AN OPPORTUNITY FOR THE APPLICANTS TO GIVE US FEEDBACK. IT WAS SPECIFICALLY MENTIONED IN THE COMPETITIVE BID DOCUMENT. OKAY. WE HAVEN'T DONE THAT WITH THESE OTHER GRANTS. I'LL LEAVE NOT FOR DISCUSSION NOW OR AT ANY TIME, BECAUSE THERE'S LOTS OF DIFFERENT COMPETING INTERESTS, WHETHER WE SHOULD DO THAT WITH OUR -- INTEREST, IDEAS, OPINIONS, WHETHER WE SHOULD DO THAT WITH THESE SCIENTIFIC APPLICATIONS. THERE'S PROBABLY PROS AND CONS ON

EACH SIDE.

OUR RFA'S ARE SILENT ON THAT ISSUE. SO REALLY IT'S UP TO EACH APPLICANT ON THEIR OWN INITIATIVE TO WRITE A LETTER, WHICH I THINK THEY'RE ENTITLED TO DO, BUT -- SO I'LL JUST SAY THAT.

AND THEN SECONDLY, MORE BROADLY SPEAKING, I THINK EACH MEMBER HAS A RIGHT TO STATE WHATEVER THEY PLEASE IN THE RECORD. IF I WANTED TO READ MY WIFE'S CHOCOLATE CHIP RECIPE, I CAN.

DR. PRICE: THE LAWYERS MAY SAY SOMETHING ABOUT IT.

MR. SERRANO-SEWELL: NO. NO. NO. THE LAWYERS -- I'LL SAY IT ANYWAYS. I HAVE A RIGHT TO DO THAT. I JUST WANT TO SAY THAT THERE IS THAT INHERENT RIGHT WITH COMMISSIONERS TO STATE WHAT THEY FEEL IS APPROPRIATE ON THE RECORD, AND I THINK THAT IS AN IMPORTANT RIGHT, AND ONE THAT I FEEL STRONGLY ABOUT.

DR. STEWARD: I JUST WANT TO TAKE -- I WON'T TALK FOR MORE THAN 30 SECONDS, BUT IT IS THE PROCESS AND IT IS THE FAIRNESS OF THE PROCESS THAT I'M TALKING ABOUT HERE. JUST TO MAKE AN OBSERVATION, WE HAVE APPROXIMATELY 50. I DON'T KNOW HOW LONG IT TOOK JEFF, BUT ROUGHLY FIVE MINUTES. IF WE HAVE 50 LETTERS THAT TAKE FIVE MINUTES TO READ,

THAT'S GOING TO TAKE A VERY LARGE PROPORTION OF OUR DAY. IF WE'RE GOING TO ALLOW THEM, WE NEED TO MAKE IT CLEAR TO THE APPLICANTS THAT IT IS AN OPTION. THAT'S ALL I'M SAYING.

CHAIRMAN KLEIN: I THINK THE FAIRNESS OF THE PROCESS IS VERY IMPORTANT, WHICH IS WHY I WANT TO TURN TO DR. TROUNSON. BUT LET US REALIZE THAT WE'RE MOST LIKELY, IN A PRACTICAL SENSE, TO GET LETTERS AT THE MARGIN WHEN THE POINTS ARE VERY CLOSE BECAUSE IT'S -- IF IT'S NOT CLOSE IN TERMS OF THE SCORE, THEN IT'S GOING TO BE VERY DIFFICULT IN A SHORT LETTER TO ADDRESS THE SUBJECT. BUT MAKING SURE AND ALWAYS DOUBLE-CHECKING OURSELVES AND SELF-CRITIQUING THE PROCESS IS A HEALTHY PROCESS.

COULD WE GET DR. TROUNSON TO JUST DESCRIBE THE PROCESS THAT GOES ON AFTER REVIEW SO THAT WE'RE ALL WORKING WITH THE SAME INFORMATION?

MS. FEIT: MR. KLEIN, I HAVE A COMMENT.

CHAIRMAN KLEIN: YES. MARCY.

MS. FEIT: AFTER DR. TROUNSON.

DR. TROUNSON: WELL, I THINK YOU NEED TO BE VERY CAREFUL WHAT YOU'RE DOING HERE. THE GOOD PART IS THAT YOU NEED TO RECOGNIZE THAT EVERY ONE OF THE SCIENTISTS HAVE PUT UP THEIR PROJECTS AS AN APPLICATION WILL INCREDIBLY BELIEVE IN IT. AND THE

MORE SENIOR AND MORE ARTICULATE YOU ARE, THEN YOU WILL ENTER THE DEBATE ABOUT WHETHER THE OTHERS ARE RIGHT OR WRONG.

THERE IS A REVIEW PROCESS WHICH WE SEEK TO ASK 15 OF THE BEST SCIENTISTS OUTSIDE CALIFORNIA TO RANK THESE ACCORDING TO THE INFORMATION THAT THEY HAVE. AND THERE MAY BE AT TIMES INCORRECT INFORMATION. THAT'S POSSIBLE. EVEN AMONGST THOSE 15 SCIENTISTS, THAT'S POSSIBLE.

I THINK, YOU KNOW, I THINK WE DON'T REALLY HAVE GROUNDS FOR REVERSING OR CHANGING DECISIONS ON AN ARGUED BASIS SCIENTIFICALLY. IT'S MORE ABOUT PROGRAMMATIC INTEREST OR PROGRAMMATIC WILL THAT'S CHANGEABLE BECAUSE OTHERWISE, QUITE RIGHTLY, AS DR. STEWARD HAS POINTED OUT, EVERY ONE OF THOSE SCIENTISTS SHOULD BE HERE AND ARGUE THEIR CASE MORE OR LESS ARTICULATELY FOR THREE MINUTES OR MORE.

NOW, YOU KNOW, I THINK YOU'VE GOT TO ACCEPT THAT THE SCIENTISTS THAT DO INDEED HAVE ACCEPTED INTO THAT REVIEW PANEL HAVE DONE A REASONABLE JOB ON THE WHOLE. BUT THERE WILL BE AT TIMES A DISAGREEMENT, AND PARTICULARLY IF YOU ARE GRANT ISN'T AWARDED. I MEAN I KNOW BECAUSE I'VE HAD GRANTS THAT ARE NOT AWARDED, SO I'VE DISAGREED, FELT AGGRIEVED AND DISAPPOINTED BECAUSE THAT'S THE WAY

SCIENCE IS.

AND SO YOU NEED TO SORT OF MAKE SURE THAT THE PERSPECTIVE OF THE SYSTEM YOU'VE CREATED IS NOT ACTUALLY DECAYED BY WHAT WE'RE TRYING TO DO. I'M NOT SPEAKING IN FAVOR OR NOT ABOUT THE STUDIES. I THINK IT IS ALSO VERY IMPORTANT, IF YOU CREATE A CELL LINE, THAT YOU KNOW WHAT THE HECK YOU ARE GOING TO ACTUALLY MEASURE. YOU CAN SET UP ANY NUMBER OF CELL LINES YOU LIKE; AND IF YOU'VE GOT NO WAY OF DETERMINING WHAT YOU ARE GOING TO MEASURE, YOU MIGHT SPEND THE NEXT 15 YEARS IN THAT PHASE. SO THE SCIENTISTS WILL LOOK, WILL LOOK DOWNSTREAM, THEY WILL LOOK TO SEE WHETHER IT HAS AN OBJECTIVE FOR OUR MISSION. YOU KNOW, THAT'S WHAT IT'S ABOUT.

AND SO WHAT I'M SAYING, I THINK, TO YOU IS DON'T DECAY THE REVIEW PROCESS TO THE POINT WHERE THAT IT'S NOT PARTICULARLY USEFUL BECAUSE IF YOU DO, WE WON'T HAVE ANY REVIEWERS. AND I THINK YOU'VE DEFEATED WHAT -- A BEAUTIFUL SYSTEM THAT YOU'VE SET UP. BUT I DO BELIEVE THAT AT TIMES WE WILL INDIVIDUALLY AND COLLECTIVELY DISAGREE WITH THE REVIEWERS, AND THERE MAY BE INFORMATION THAT HAPPENS PER CHANCE BETWEEN THE REVIEW AND WHEN WE GET HERE AS WELL.

SO THERE ARE ALL OF THOSE TYPES OF

SITUATIONS. SO I THINK CARE IS NEEDED TO NURTURE THIS VERY DELICATE PROCESS, AND I WOULD SEEK YOUR, YOU KNOW, YOUR THOUGHTFULNESS IN PRESERVING IT.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. IN TERMS OF -- I'M GOING TO GO TO SOME GENERAL COMMENTS. I WOULD LIKE TO SAY THAT, WELCOMING THE SPIRIT OF WHAT YOU'VE SAID, YOUR LAST COMMENTS ARE VERY IMPORTANT CONSTITUTIONALLY AND STATUTORILY BECAUSE CERTAINLY WE ARE CHARGED WITH LOOKING AT ALL OF THE JUDGMENTS THAT COME FROM PEER REVIEW, ALTHOUGH WITH GREAT RESPECT FOR THE SCIENTIFIC INPUT. IF, AS YOU SAY, THERE'S NEW INFORMATION THAT COMES FORTH OR, IN FACT, THERE'S INFORMATION ON THIS BOARD OR IN THE AUDIENCE, IN THE PUBLIC PROCESS IN OUR FINAL DECISIONS, WE HAVE TO TAKE ALL THAT INTO ACCOUNT, WHETHER IT'S THE SCIENTIFIC OR THE PROGRAMMATIC PART OF THE REVIEW WHILE TRYING TO RESPECT THE ESSENCE OF YOUR COMMENTS.

DR. PIZZO. MARCY, ABSOLUTELY, AND THEN TO DR. PIZZO.

MS. FEIT: THANK YOU, DR. TROUNSON, BECAUSE YOU'RE REALLY SPEAKING ON WHAT I WAS ABOUT TO SAY. I SAT THROUGH THOSE REVIEWS, AND I'VE BEEN SITTING HERE WITH A HOLE IN MY GUT THROUGH THIS DISCUSSION TONIGHT BECAUSE GREAT SCIENTIFIC MINDS

FROM ALL OVER THE COUNTRY CAME TOGETHER, AND IN THEIR SPECIFIC FIELDS REVIEWED ALL OF THESE RFA'S. AND I SAT THROUGH THEM. THEY WERE MINDFUL. THEY WERE RESPECTFUL. THEY WERE PROFESSIONAL. AND I WOULD HATE TO SEE US START TO REDO THOSE REVIEWS HERE BECAUSE THEY WERE GREAT.

THEY DID NOT WANT TO FUND THESE TWO RFA'S. THEY'VE STATED THAT TO US, AND THEY SAID IF WE FELT IT WAS A PROGRAM ISSUE, THAT WE SHOULD MAKE THE DECISION BASED ON THAT.

AND I REALLY WOULD BE AGAINST ANY EXTENSIVE REBUTTAL PROCESS BECAUSE I THINK IT WOULD UNDERMINE THOSE GREAT SCIENTISTS WHO TAKE THE TIME OUT FOR SEVERAL DAYS TO COME HERE AND DO THE WORK OF CIRM. AND I THINK THAT WOULD BE A MISTAKE. SO I WOULD SAY WE WOULD LOOK AT THESE TWO PROGRAMS AND MAKE A PROGRAM DECISION AND NOT TRY TO REDO THE SCIENCE REVIEW.

CHAIRMAN KLEIN: ALL RIGHT. I THINK DR. PIZZO AND THEN DR. PRICE.

DR. PIZZO: I THINK THANK YOU, MARCY, FOR THOSE COMMENTS. I WOULD JUST ADD ONE OTHER PART, AND THAT IS I THINK THAT THIS REVIEW, TO ME AT LEAST, IS A LITTLE -- IS DIFFERENT THAN SOME OF THE OTHERS THAT WE'VE DONE BECAUSE -- AND I THINK THERE

PERHAPS MAY HAVE BEEN, I'M TRYING TO PUT MYSELF, NOT HAVING BEEN, AS JEFF AND MARCY WAS, AT THAT MEETING, IN HOW THE SCIENTIFIC ADVISORY GROUP MIGHT HAVE BEEN LOOKING AT THESE GRANTS BECAUSE WHAT WE'RE REALLY TALKING ABOUT HERE IS METHODOLOGICAL -- TECHNICAL STUDIES GENERATING CELL LINES.

AND I THINK THERE'S A STANDARD BEING APPLIED TO THEM ACTUALLY THAT GOES SORT OF ABOVE AND BEYOND THAT. AND I THINK THAT, FROM MY POINT OF VIEW, AT THIS STAGE, AND WE MAY FEEL DIFFERENTLY ABOUT THIS A YEAR OR TWO FROM NOW AS WE LEARN MORE ABOUT THIS, BUT AT THIS STAGE, IF THERE'S A HIGH QUALITY TEAM ABLE TO GENERATE NEW CELL LINES IN NEW DISEASE AREAS, I THINK THAT'S AN ADVANTAGE. I MEAN I DON'T KNOW WHERE THE PAYOFF IS GOING TO COME, BUT I THINK, YOU KNOW, I'D LIKE -- IT'S A LITTLE BIT LIKE THE TRAINING, YOU KNOW, THE TRAINING PIPELINE. I MEAN WE NEED A PIPELINE OF CELL LINES, AND MAYBE, YOU KNOW, ONE OF THESE GROUPS WILL HIT IT.

I FEEL FURTHER COMPELLED BECAUSE, LIKE I THINK MOST OF US IN THIS ROOM, WE KNOW BOTH OF THESE INVESTIGATORS, AND THEY ARE, YOU KNOW, FIRST CLASS INVESTIGATORS, SO I THINK THAT RAISES THE LIKELIHOOD THAT NEW CELL LINES IN A NEW AREA BY OUTSTANDING INVESTIGATORS WILL PROVIDE A REAGENT THAT EITHER

THEY OR SOMEONE ELSE CAN EMPLOY.

CHAIRMAN KLEIN: THANK YOU. AND THEN WE'RE GOING TO GO TO DR. PRICE, THEN TO LEEZA GIBBONS.

DR. PRICE: I WANT TO SPEAK IN FAVOR OF MOVING THIS PROPOSAL UP INTO THE FUNDING CATEGORY. AND I DO IT ACTUALLY IN SUPPORT OF THIS RECOMMEN- -- OF THIS REVIEW, NOT AS A CRITIC OR AS REBUTTAL OF IT. AND I WANT TO MAKE THIS POINT IN TWO WAYS.

FIRST, I WANT TO LOOK AT THE SCORES. THIS HAD A SCORE OF 69, I BELIEVE. YES. AND THE LAST OF THE, I THINK, OF THE FUNDING CATEGORY, THAT'S A 71. THE 71 -- WELL, 67. BUT LET'S LOOK AT THE 71. THE DIFFERENCE BETWEEN 69 AND 71, I'M SORRY, IS NOT REALLY A DIFFERENCE IN SCORE IN ANY REASONABLE WAY. PROBLEM WITH THESE KINDS OF NUMERICAL SCORES IS THEY GIVE A FALSE SENSE OF CONCRETENESS. AND I WOULD -- IT WOULD BE A NICE EXPERIMENT TO GIVE THESE SAME THINGS TO ANOTHER GROUP OF PEOPLE AND SEE WHAT THEIR SCORES ARE.

AND WHILE I SUSPECT THINGS WILL GROUP SIMILARLY, I THINK IT'S VERY UNLIKELY THAT YOU'RE GOING TO GET EXACTLY THE SAME SCORES. AND AS GOOD A CHANCE AS ANY IS THIS WOULD BE THE 71 AND THE OTHER ONE WOULD BE 69. SO I LOOK AT THE DIFFERENCE IN

THOSE SCORES AS TO SAY THERE'S REALLY NO DIFFERENCE, AT LEAST IN THE NUMERICAL RANK, NO REAL DIFFERENCE IN THE NUMERICAL RANKING. OKAY. THAT'S THE FIRST POINT.

MORE IMPORTANTLY, I'D LIKE TO READ TO YOU THE REVIEWERS' COMMENTS OR AT LEAST A SUMMARY OF THE COMMENTS IN OUR BOOKLET. A MAJOR STRENGTH OF THIS PROPOSAL IS THAT THE TWO GROUPS INVOLVED IN THE EXPERIMENTS ARE RECOGNIZED AS LEADERS IN THE FIELD AND HAVE THE EXPERIENCE AND THE TECHNICAL KNOW-HOW TO CARRY OUT THE WORK DESCRIBED. THE PROPOSED METHOD FOR GENERATING IPS CELLS IS NOVEL AND WOULD BE A SIGNIFICANT ADVANCE IN IPS CELL TECHNOLOGY. THE CELL LINE THAT'S TO BE GENERATED THROUGH NEW REPROGRAMMING WOULD BE APPROPRIATELY TESTED FOR THEIR PLURIPOTENCY. EACH PART OF SPECIFIC AIM 1, IF ACCOMPLISHED, WOULD ADVANCE THE FIELD.

AS FAR AS I'M CONCERNED, THAT IN ITSELF IS ENOUGH REASON TO FUND THIS IRRESPECTIVE OF WHAT THEY SAY ABOUT AIMS 2 AND 3. IT SEEMS TO ME THAT IS A RECOMMENDATION FOR FUNDING AND A RECOMMENDATION ABOUT THE QUALITY OF THE SCIENCE. IT DOESN'T SAY THE SCIENCE IS BAD AND UNWORTHY.

CHAIRMAN KLEIN: OKAY. LEEZA.

MS. GIBBONS: YOU KNOW, I APOLOGIZE

BECAUSE THIS COMES FROM THE TOPIC OF JEFF READING THE LETTER FROM THE SALK INSTITUTE, AND I PROMISE NOT TO BE ON IT BUT A SECOND, BUT I THINK IT IS IMPORTANT AT LEAST FOR ME TO UNDERSTAND WHAT'S ADMISSIBLE. THIS LETTER WAS ADDRESSED TO EACH OF THE ICOC MEMBERS. AND WHILE I UNDERSTAND THAT THERE IS A PROCESS BY WHICH LETTER WRITING CAN HAPPEN, ISN'T THERE A MORE APPROPRIATE VENUE THAT EACH INDIVIDUAL MEMBER BEING SOLICITED WITH REBUTTAL INFORMATION, AND ARE WE, IN FACT, REQUIRED NOT TO ADDRESS THESE LETTERS? ARE WE -- ARE WE --

CHAIRMAN KLEIN: NO.

MS. GIBBONS: WHAT'S OUR INSTRUCTION? ARE WE INSTRUCTED NOT TO READ THEM?

CHAIRMAN KLEIN: NO. NO. ANY MEMBER OF THE PUBLIC AS WELL AS ANY APPLICANT CAN WRITE TO ANY MEMBER OF THIS BOARD. AND THE INFORMATION THAT IS PRESENTED TO THEM CAN BE CONSIDERED IN A PUBLIC HEARING.

MS. GIBBONS: THAT'S IT.

CHAIRMAN KLEIN: OKAY. THANK YOU. WE WANT TO GET TO SHERRY WHO HAS NOT SPOKEN AND THEN JEFF SHEEHY.

MS. LANSING: I JUST WANT TO WITH ALL DUE RESPECT TO BOB, JUST TO SAY THAT I DON'T KNOW WHAT

THE YELLOW ONES ARE. MAYBE THAT'S 69 ALSO. I DON'T KNOW. I MEAN, YOU KNOW, SO I AGREE WITH YOU, THAT AN EMPIRICAL SCORE WITHIN A RANGE, YOU KNOW, IS SOMETHING THAT CAN SHIFT AND THAT THE TWO POINTS DOESN'T MEAN ANYTHING. THE THING THAT'S INTERESTING TO ME IS I DON'T KNOW WHAT ALL THE YELLOW ONES ARE. THEY COULD BE -- THEY COULD BE ONE POINT, THEY COULD BE THE SAME POINT. SO I GUESS WHAT I WOULD SAY IS I URGE US TO REALLY EVALUATE IT BASED ON THE SCIENCE, BASED ON WHETHER IT'S UNIQUE, BASED ON, YOU KNOW, WHETHER WE BELIEVE THAT IT IS SO GOOD THAT WE'RE GOING TO OVERRULE THE TEAM THAT DIDN'T FEEL THAT WAY ABOUT IT. OR IN ALL FAIRNESS, DIDN'T FEEL THAT UNLESS WE FELT PROGRAMMATICALLY IT WAS NECESSARY.

DR. PRIETO: MR. CHAIRMAN.

CHAIRMAN KLEIN: DR. PRIETO AND THEN ASHA.

DR. PRIETO: YEAH. JUST A BRIEF COMMENT.

CHAIRMAN KLEIN: DO WE HAVE A -- EXCUSE ME. MY MISTAKE. JEFF SHEEHY.

MR. SHEEHY: I JUST -- FIRST OF ALL, I WANT TO ADDRESS THE POINT OF THE LETTER. I WAS MOTIVATED TO READ THAT LETTER. JUST BECAUSE WE GET 50 LETTERS DOESN'T MEAN 50 ARE GOING TO BE READ INTO THE RECORD. I READ IT INTO THE RECORD SPECIFICALLY IN TERMS OF THE GOAL OF THE RFA AND THE PROGRAMMATIC

REASON WHY THIS WAS MADE AVAILABLE TO US AT THE WORKING GROUP -- FROM THE WORKING GROUP, WHICH IS STATED IN THE REVIEW. THE MAJOR ADVANCE WILL BE THE DEVELOPMENT OF AN IN VITRO SYSTEM OF THE COMPLEX DISORDER RETT SYNDROME. THAT IS THE POINT OF THIS RFA. THAT'S A PROGRAMMATIC CONSIDERATION FOR US.

DO WE WANT TO CREATE A STEM CELL LINE FOR RETT SYNDROME? THAT'S PROGRAMMATIC. THAT'S -- I DO. THAT'S WHY I READ THE LETTER. THAT'S WHY I'M FIGHTING FOR THIS. I DON'T HAVE RETT SYNDROME, BUT SOMEBODY DOES AND WOULD LIKE TO HAVE A DISEASE MODEL. AND I THINK THAT'S WHY WE'RE HERE, AND I DON'T THINK THAT'S OVERRULING THE WORKING GROUP. THAT'S WHY THEY PUT IT IN FOR PROGRAMMATIC CONSIDERATION. YOU MAY FEEL DIFFERENT. YOU MAY NOT FEEL LIKE WE NEED A DISEASE -- THAT WE NEED A STEM CELL LINE FOR THAT CONDITION. THAT TO ME IS WHAT IT ALL BOILS DOWN TO.

THESE PEOPLE ARE PERFECTLY CAPABLE AND WILL DEVELOP A STEM CELL LINE BASED ON THIS CRITIQUE BY THE REVIEWERS FOR RETT SYNDROME. I THINK THOSE FOLKS DESERVE TO HAVE A LINE TO STUDY.

CHAIRMAN KLEIN: THANK YOU VERY MUCH, JEFF. I BELIEVE DR. PRIETO AND THEN ASHA.

DR. PRIETO: I JUST WANT TO REITERATE MY

THOUGHTS ARE ALONG THE LINES OF JEFF'S, THAT I THINK I DON'T FEEL QUALIFIED TO OVERRULE THE SCIENTIFIC REVIEW, BUT I DON'T THINK WE'RE DOING THAT. AND I THINK, AS BOB PRICE PUT IT, THESE NUMERICAL SCORES REALLY DO GIVE US A FALSE NOTION THAT THERE'S SOME RIGID NUMERICAL HIERARCHY THAT I REALLY JUST DON'T THINK EXISTS. OUR DECISION IS PROGRAMMATIC. DO WE THINK THAT THIS SHOULD BE PART OF OUR PROGRAM? AND IF SO, WE SHOULD VOTE FOR IT.

CHAIRMAN KLEIN: OKAY. ASHA.

DR. NIGH: ALL THE COMMENTS I HAD WERE SPECIFICALLY RELATED TO THE SCIENTIFIC REVIEW, BUT GIVEN THAT THE DISCUSSION HAS MOVED TOWARDS THE PROGRAMMATIC REASONS, I DON'T FEEL NECESSARY TO COMMENT.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. YES, DR. POMEROY.

DR. POMEROY: I JUST HOPE THAT EVERYBODY UNDERSTANDS THAT A VOTE NOT TO FUND THIS DOESN'T MEAN WE DON'T CARE ABOUT THE DISEASES THAT ARE COVERED IN THIS PROPOSAL. THERE ARE MANY OF THE UNFUNDED ONES THAT ARE ABOUT DISEASES THAT WE CARE DEEPLY ABOUT. AND I THINK I CAN SPEAK FOR EVERY MEMBER ON THIS PANEL THAT I'VE TALKED TO IS WE WOULD LOVE TO HAVE AN ANSWER TO RETT SYNDROME. I THINK

THAT WOULD BE A FANTASTIC THING.

THAT, I DO BELIEVE, IS A VERY DIFFERENT QUESTION THAN WHETHER THIS IS AN APPROPRIATE USE OF $1.7 MILLION.

CHAIRMAN KLEIN: OKAY.

DR. DAFOE: I JUST WANT TO COMMENT IN ANTICIPATION OF THE VOTE. AND IT'S SIMPLY THAT MY CONCERN IS THAT, DESPITE THE EXPERTISE OF THE INVESTIGATORS, OF THE SCIENTISTS, OUR WORKING GROUP OF SCIENTISTS SUGGESTED IT NOT BE FUNDED. SO I THINK THAT SUGGESTS TO ME THERE IS A BIG FLAW HERE. AND ONE THAT RESONATES WITH ME IS THE DIFFUSENESS OF IT AND THE UNFOCUS BECAUSE I REALIZE THE ISSUE IS A GENERIC TECHNIQUE, BUT THE FACT THAT WE'RE TALKING ABOUT ALS AND RETT SYNDROME AND THEN HEMATOPOETIC CELLS AND THEN HEPATIC CELLS TO ME JUST BEGINS TO SOUND JUST AS THEY SAY TOO UNFOCUSED AND DIFFUSE. SO THAT'S JUST MY COMMENT.

CHAIRMAN KLEIN: ALL RIGHT. THANK YOU VERY MUCH. SHERRY, DID YOU HAVE A COMMENT?

MS. LANSING: NO.

CHAIRMAN KLEIN: YES. SO WHAT I'D LIKE TO DO AT THIS POINT, PUBLIC COMMENT PLEASE IF THERE'S PUBLIC COMMENT. THANK YOU, DR. NIGH.

MR. SIMPSON: JOHN SIMPSON FROM CONSUMER

WATCHDOG. THIS GOES TO THE PROCESS. I'D LIKE TO THANK MEMBER SHEEHY FOR READING THAT LETTER INTO THE RECORD, BUT I AM SHOCKED THAT THERE WOULD BE A LETTER DISTRIBUTED TO ALL OF YOU THAT YOU ALL HAVE IN YOUR PACKET THAT WAS NOT MADE AVAILABLE TO THE PUBLIC. AND IT WAS NOT AND SHOULD HAVE BEEN.

CHAIRMAN KLEIN: THE INTENTION WOULD HAVE BEEN TO MAKE IT AVAILABLE. SO WE WILL -- GIVEN -- WELL, THE STAFF WILL SPECIFICALLY FOCUS ON A CHECKLIST TO MAKE SURE THAT IT IS.

MR. SIMPSON: AND THIS SORT OF THING CAME UP BEFORE, AND THERE WAS A SUGGESTION THAT WHEN YOU RECEIVE COMMUNICATIONS, THEY SHOULD ALL BE POSTED IN A PLACE IN ADVANCE OF THE MEETING FOR THE PUBLIC TO READ. I WOULD SUGGEST THAT LETTERS LIKE THIS SHOULD GO INTO THAT KIND OF A FILE SO THAT EVERYBODY CAN READ THEM.

CHAIRMAN KLEIN: AND CERTAINLY THAT IS THE INTENT. THE STAFF HAS BEEN WORKING TILL EIGHT OR NINE AT NIGHT. WE JUST HAVE A LACK OF SOME STAFF CAPACITY, BUT WE WILL MAKE SURE IT'S A VITAL ITEM ON THE CHECKLIST. STAFF WORKED VERY HARD IN TRYING TO ACHIEVE THAT GOAL, AND WE'LL JUST WORK HARDER AT IT. THANK YOU.

OKAY. I'D LIKE TO CALL THE QUESTION, IF

WE COULD PLEASE, WITH A ROLL CALL.

MS. KING: JUST TO REMIND EVERYBODY THAT DR. BRYANT IS IN CONFLICT WITH THIS APPLICATION.

DONALD DAFOE.

DR. DAFOE: NO.

MS. KING: ROBERT PRICE.

DR. PRICE: YES.

MS. KING: DAVID BRENNER.

DR. BRENNER: YES.

MS. KING: MARCY FEIT.

MS. FEIT: NO.

MS. KING: LEEZA GIBBONS.

MS. GIBBONS: YES.

MS. KING: SAM HAWGOOD.

DR. HAWGOOD: NO.

MS. KING: BOB KLEIN.

CHAIRMAN KLEIN: IF YOU COULD PASS AND COME BACK TO ME.

MS. KING: SHERRY LANSING.

MS. LANSING: I'D LIKE TO DO THE SAME, BUT I WON'T, SO I'LL SAY NO.

MS. KING: LEONARD ROME.

DR. ROME: NO.

MS. KING: TED LOVE.

DR. LOVE: NO.

MS. KING: PHIL PIZZO.
DR. PIZZO: YES.
MS. KING: CLAIRE POMEROY.
DR. POMEROY: NO.
MS. KING: FRANCISCO PRIETO.
DR. PRIETO: YES.
MS. KING: DUANE ROTH.
MR. ROTH: YES.
MS. KING: DAVID SERRANO-SEWELL.
MR. SERRANO-SEWELL: YES.
MS. KING: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. KING: OSWALD STEWARD.
DR. STEWARD: ABSTAIN.
MS. KING: BOB KLEIN.
CHAIRMAN KLEIN: YES.
MS. KING: COUNSEL, I'M GOING TO DEFER TO YOU.
MR. HARRISON: THE MOTION FAILS.
MR. SERRANO-SEWELL: WHAT WAS THE VOTE?
MR. HARRISON: THE VOTE WAS EIGHT YES, SIX NO. A QUORUM IS 17, SO YOU NEED A MAJORITY OF THE QUORUM BECAUSE THERE'S AN ABSTENTION AS WELL AND A CONFLICT.
MR. SERRANO-SEWELL: SO HOW MANY VOTES DO

YOU NEED FOR A PASSAGE?

MR. HARRISON: YOU NEED NINE VOTES FOR PASSAGE.

MR. SERRANO-SEWELL: WE HAD ONE ABSTENTION.

MR. HARRISON: CORRECT.

CHAIRMAN KLEIN: SO THE QUESTION -- I'LL JUST PUT THE QUESTION TO THE PERSON ABSTAINING.

DR. STEWARD: YOU KNOW, IF HE HADN'T WRITTEN A LETTER, I WOULD HAVE VOTED YES. I HAVE TO SAY THAT I WAS IN FAVOR OF SUPPORTING THIS.

CHAIRMAN KLEIN: DR. POMEROY HAS ASKED, JAMES, DO WE HAVE THE ABILITY TO HAVE A RECONSIDERATION OF THIS MOTION?

MR. SERRANO-SEWELL: PEOPLE CAN CHANGE THEIR VOTE.

MR. HARRISON: SURE. YES.

CHAIRMAN KLEIN: OKAY.

(SIMULTANEOUS DISCUSSION.)

MS. LANSING: WE'RE GOING TO REVOTE AGAIN?

CHAIRMAN KLEIN: WELL, WE'RE GOING TO SEE IF A REVOTE WOULD BE WORTHWHILE OR NOT.

MS. LANSING: THEN I'M GOING TO ABSTAIN.

DR. PIZZO: WE JUST HEARD THAT IT DIDN'T CARRY AND NOW WE WANT TO REVOTE? SO IS THAT -- THAT

MAKES IT SOUND LIKE, YOU KNOW, YOU'VE GOT SOMETHING THAT YOU WANT TO SEE THE OUTCOME.

CHAIRMAN KLEIN: NO. HERE IS THE ISSUE IS THAT WE HAVE SOMETHING THAT --

DR. PIZZO: I MEAN I VOTED YES FOR THIS, BUT THE FACT IS, YOU KNOW, WE DID IT, AND WE'RE ASKING TO DO IT AGAIN.

CHAIRMAN KLEIN: THE ISSUE HERE, DR. PIZZO, IS THAT WE HAVE A MAJORITY IN FAVOR OF A MOTION; BUT ON AN ISSUE OF A TECHNICAL QUORUM, WE HAVE AN ISSUE THAT IT HASN'T PASSED BECAUSE WE HAVE AN ABSTENTION, RIGHT? SO IT IS NOT A SITUATION WHERE THERE WAS A MINORITY THAT VOTED YES. SO IN THIS FACT PATTERN, I'M TRYING TO ASCERTAIN THIS IS NOT A FACT PATTERN THAT PRESENTS ITSELF FREQUENTLY.

DR. PIZZO: THANK GOD.

CHAIRMAN KLEIN: YEAH. OKAY. SO THE -- SO CAN I ASK TO MAKE SURE --

MR. HARRISON: YOU WOULD NEED A MOTION TO RECONSIDER.

CHAIRMAN KLEIN: I'M JUST ASKING WHETHER IT'S WORTHWHILE HAVING A VOTE TO RECONSIDER.

MR. HARRISON: COULD YOU JUST GIVE US ONE SECOND WHILE WE LOOK CLOSELY AT THE VOTES TO MAKE SURE THAT THE THREE NOTE TAKERS' NOTES ARE ALL

ALIGNED?

DR. PIZZO: DO YOU HAVE ANY CHADS THERE, BY THE WAY?

CHAIRMAN KLEIN: THIS WOULD BE A GOOD TIME TO -- WHY DON'T WE HAVE A FIVE-MINUTE RECESS.

(A RECESS WAS TAKEN.)

CHAIRMAN KLEIN: OKAY. IF WE COULD RECONVENE HERE, I THINK OUR PROBLEM HAS BEEN SOLVED FOR US. AND I'D LIKE TO, FOR THE BENEFIT OF THE TRANSCRIBER, INDICATE THAT THE TRANSCRIBER WOULD APPRECIATE IT IF EVERYONE AFTER THEY SPEAK WOULD TURN THEIR MICS OFF BECAUSE IF WE HAD TOO MANY MICS ON, THEN THE NEXT PERSON'S MIC WILL NOT GO ON AND SHE CAN'T HERE IT. AND ALSO DON'T MOVE YOUR MIC RIGHT UP AGAINST YOU BECAUSE THAT ALSO DISTORTS THE SOUND FOR THE PEOPLE IN THE AUDIENCE, INCLUDING THE TRANSCRIBER. I GOT IT RIGHT? THANK YOU.

SO LET US GET A CLARIFICATION. I WANT TO BE VERY CAREFUL WITH THIS BECAUSE IN LISTENING TO THE VOTE, I WAS CONCERNED WITH THE VOTE. BUT THE TIME THEY'VE HAD TO GO BACK THROUGH IT, I'D LIKE TO GET A CORRECTED VOTE, AND I'D LIKE TO CONFIRM -- I'D LIKE THEM TO READ OFF EACH OF THE VOTES SO THAT WE CAN CONFIRM THAT WE HAVE THE VOTES CORRECTLY. OKAY. GO AHEAD.

MR. HARRISON: SO FIRST OF ALL, LET ME APOLOGIZE BECAUSE WE DID HAVE A COMPUTATIONAL ERROR, WHICH IS WHY WE ASKED FOR THE BRIEF DELAY SO WE COULD CROSS VERIFY AND MAKE SURE THAT WE HAD DONE IT CORRECTLY. SO THE ULTIMATE OUTCOME WAS NINE YES VOTES, SIX NO VOTES, AND ONE ABSTENTION. SO BECAUSE THE MOTION HAD A MAJORITY OF A QUORUM VOTE YES, IT PASSED.

FOR THE RECORD, THE VOTES WERE AS FOLLOWS: DAFOE, NO; PRICE, YES; BRENNER, YES; FEIT, NO; GIBBONS, YES; HAWGOOD, NO; KLEIN, YES; LANSING, NO; ROME, NO; LOVE, NO; PIZZO, YES; POMEROY, NO; PRIETO, YES; ROTH, YES; SERRANO-SEWELL, YES; SHEEHY, YES; STEWARD, ABSTAIN.

CHAIRMAN KLEIN: OKAY. NOW, LET ME ASK A MORE BASIC QUESTION. NINE AND SIX IS 15.

MR. HARRISON: I'M SORRY. THERE WAS ONE CONFLICT.

CHAIRMAN KLEIN: OKAY. ALL RIGHT. THANK YOU. I JUST WANTED TO MAKE SURE WE'RE TECHNICALLY CORRECT.

MR. HARRISON: I'M SORRY. THERE ARE SEVEN NOES.

CHAIRMAN KLEIN: OKAY. THAT'S -- SO IF THE -- SOMEONE MIGHT HAVE NOTICED THAT I WAS TRYING

TO KEEP TRACK WHEN I PASSED, AND I WOULD NOT HAVE VOTED IF IT WOULDN'T HAVE MADE A DIFFERENCE. AND SO WHEN I VOTED, I THOUGHT THAT IT DID MAKE A DIFFERENCE. BUT IN ANY CASE, WHAT IS IMPORTANT HERE IS THAT WE DO HAVE THREE DIFFERENT PEOPLE KEEPING THESE RECORDS. AND IMMEDIATELY AFTER A VOTE, WE CROSS VALIDATE THEM TO MAKE CERTAIN THAT IF WE'VE MADE AN ERROR, WE HAVE A WAY TO CORRECT IT. SO THE SYSTEM INCURRED AN ERROR AND CORRECTED ITSELF.

DR. PIZZO: IT ONLY CORRECTED ITSELF BECAUSE WE HAD AN ABSTENTION. OTHERWISE WE MIGHT NOT HAVE KNOWN.

CHAIRMAN KLEIN: WELL, THE --

DR. PIZZO: YOU DON'T HAVE TO COMMENT FURTHER, BOB. JUST FOR THE RECORD.

CHAIRMAN KLEIN: ALL RIGHT. AT THIS POINT I'D ALSO LIKE TO MAKE A POINT THAT -- DR. TROUNSON, MY UNDERSTANDING THAT THERE WAS ONE GRANT IN THE NOT RECOMMENDED CATEGORY THAT, IN FACT, THERE WAS A PROBLEM WITH IT THAT IT TECHNICALLY HAS TO BE REREVIEWED; IS THAT CORRECT?

DR. TROUNSON: THANKS, CHAIR. THERE IS -- THERE'S ONE GRANT THAT I RECOMMENDED, FOLLOWING DISCUSSIONS WITH THE CHAIR OF THE WORKING GROUP, THAT WE TAKE BACK FOR REEXAMINATION.

CHAIRMAN KLEIN: THAT'S NOT ON THIS LIST.
DR. TROUNSON: NO.
CHAIRMAN KLEIN: SO IT WILL COME TO US LATER?
DR. TROUNSON: YEP.
CHAIRMAN KLEIN: OKAY. THANK YOU. AND OF THE GRANTS THAT ARE BEFORE US TODAY, I THINK THAT -- MELISSA KING, HOW MANY MEMBERS DO WE HAVE TOMORROW PRESENT?
MS. KING: TWENTY-TWO.
CHAIRMAN KLEIN: TWENTY-TWO. SO WE ADD --
MS. KING: EXCUSE ME. TWENTY-ONE.
CHAIRMAN KLEIN: TWENTY-ONE. SO I THINK THAT THE GENERAL INTENT WAS TO TRY AND HAVE THE LAST VOTE ON THIS GROUP OF GRANTS TOMORROW MORNING WHEN WE HAVE THE ADDITIONAL MEMBERS. IS THAT A CORRECT STATEMENT?
MS. KING: WELL --
MS. LANSING: WHY DON'T WE DO IT NOW? LET'S DO IT NOW. LET'S HAVE A VOTE.
CHAIRMAN KLEIN: THAT'S FINE. WE STILL HAVE OUR QUORUM. OKAY. WE STILL HAVE OUR QUORUM BEFORE US. ALL RIGHT. SO, JEFF, YOU WANT TO PROCEED?

MR. SHEEHY: SO I BELIEVE, JAMES, WHAT'S THE APPROPRIATE MOTION AT THIS POINT?

MR. HARRISON: THE APPROPRIATE MOTION IS FOR SOMEONE WHO DOESN'T HAVE AN INTEREST IN ANY OF THE APPLICATIONS THAT ARE WITHIN TIER 1 TO MAKE A MOTION TO FUND ALL OF THE APPLICATIONS IN TIER 1.

MR. SHEEHY: THE NONCONFLICTED MEMBERS ARE DUANE ROTH, DAVID SERRANO-SEWELL.

MS. KING: TED LOVE, LEEZA GIBBONS.

CHAIRMAN KLEIN: SO WOULD ONE OF THE MEMBERS WHO DOES NOT HAVE A CONFLICT WITH ANY APPLICATIONS LIKE TO MAKE MOTION? DR. LOVE.

DR. LOVE: I SO MOVE.

CHAIRMAN KLEIN: OKAY. SECOND?

DR. PRICE: SECOND.

CHAIRMAN KLEIN: YOU CAN'T SECOND.

MS. GIBBONS: I SECOND.

CHAIRMAN KLEIN: LEEZA IS THE EASIER SECOND. OKAY. NOW, I THINK JEFF WAS CONFUSED THAT ONE OF THEM MIGHT HAVE BEEN FROM BERKELEY, BUT IT'S NOT. OKAY. SO THE MOTION HAS BEEN MADE AND SECONDED. IS THERE PUBLIC DISCUSSION? IS THERE DISCUSSION FROM THE PUBLIC? SEEING NO PUBLIC COMMENT, IS THERE MEMBER DISCUSSION?

I CAN HAVE A ROLL CALL, AND I WILL REMIND

YOU IF YOU VOTE, VOTE FOR THOSE WITH WHICH YOU DO NOT HAVE A CONFLICT. JAMES, WOULD YOU LIKE ADDITIONAL INSTRUCTION?

MR. HARRISON: NO. THAT'S FINE. THAT WAS THE REMINDER I WANTED TO MAKE.

MS. KING: DONALD DAFOE.

CHAIRMAN KLEIN: YOU WOULD VOTE -- IF YOU ARE IN FAVOR, YOU WOULD VOTE YES FOR ALL OF THOSE FOR WHICH I DO NOT HAVE A CONFLICT.

DR. DAFOE: YES.

MS. KING: YES, EXCEPT FOR THOSE WITH WHICH YOU HAVE A CONFLICT.

DR. DAFOE: YES.

MS. KING: ROBERT PRICE.

DR. PRICE: YES, AND I HAVE NO CONFLICT, SO I VOTE FOR ALL OF THEM.

MS. KING: DAVID BRENNER.

DR. BRENNER: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: SUSAN BRYANT.

DR. BRYANT: YES, EXCEPT FOR THOSE THAT I HAVE A CONFLICT.

MS. KING: MARCY FEIT.

MS. FEIT: YES, EXCEPT FOR THOSE IN WHICH I HAVE A CONFLICT.

MS. KING: LEEZA GIBBONS.
MS. GIBBONS: YES.
MS. KING: SAM HAWGOOD.
DR. HAWGOOD: YES, EXCEPT FOR THOSE THAT I HAVE A CONFLICT.
MS. KING: BOB KLEIN.
CHAIRMAN KLEIN: YES.
MS. KING: SHERRY LANSING.
MS. LANSING: YES, EXCEPT FOR THOSE WITH WHICH I AM CONFLICTED.
MS. KING: LEONARD ROME.
DR. ROME: YES, EXCEPT FOR THOSE FOR WHICH I AM CONFLICTED.
MS. KING: TED LOVE.
DR. LOVE: YES.
MS. KING: PHIL PIZZO.
DR. PIZZO: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.
MS. KING: CLAIRE POMEROY.
DR. POMEROY: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.
MS. KING: FRANCISCO PRIETO.
DR. PRIETO: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.
MS. KING: DUANE ROTH.

MR. ROTH: YES.
MS. KING: DAVID SERRANO-SEWELL.
MR. SERRANO-SEWELL: YES.
MS. KING: JEFF SHEEHY.
MR. SHEEHY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MS. KING: AND OSWALD STEWARD.
DR. STEWARD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.
MS. KING: THAT MOTION CARRIES.
CHAIRMAN KLEIN: OKAY. THANK YOU VERY MUCH. AND I'D LIKE TO THANK THE SCIENTIFIC TEAM FOR THE TREMENDOUS AMOUNT OF WORK IN THIS.
(APPLAUSE.)
CHAIRMAN KLEIN: WHAT I'D LIKE TO DO --
MS. PACHTER: MR. CHAIR, THERE NEEDS TO BE AN ADDITIONAL MOTION NOT TO FUND THE APPLICATIONS IN TIER 2.
CHAIRMAN KLEIN: IN TIER 3.
MS. PACHTER: WHAT REMAINS IN TIER 3.
CHAIRMAN KLEIN: ALL RIGHT. OKAY. SO WHO WOULD LIKE TO MAKE THE MOTION NOT TO FUND THOSE IN TIER 3?
DR. LOVE: I'LL DO IT. SO MOVED.
CHAIRMAN KLEIN: DR. LOVE AND DR. PRIETO.

DR. POMEROY: YOU CAN'T.

DR. PRIETO: OH, I CAN'T. I'M SORRY.

MR. ROTH: SECOND.

CHAIRMAN KLEIN: SECOND IS DUANE ROTH. OKAY. DR. LOVE MADE THE MOTION; DUANE ROTH SECONDED THE MOTION. ADDITIONAL DEBATE? MEMBERS OF THE PUBLIC? SEEING NONE, ROLL CALL.

MS. KING: DONALD DAFOE.

DR. DAFOE: NO, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MR. HARRISON: LET ME JUST RESTATE THE MOTION FOR THE BENEFIT OF THE MEMBERS. THE MOTION IS NOT TO FUND THE REMAINING APPLICATIONS, THOSE IN TIER 3, SO A YES VOTE WOULD MEAN THEY WOULD NOT BE FUNDED.

DR. POMEROY: SO DO IT AGAIN.

DR. DAFOE: YES, EXCEPT FOR THOSE ON WHICH I HAVE -- FOR WHICH I HAVE -- ON WHICH I AM CONFLICTED.

CHAIRMAN KLEIN: I THINK WE HAVE A CLEAR ENOUGH RECORD OF THAT VOTE.

MS. KING: ROBERT PRICE.

DR. PRICE: YES.

MS. KING: DAVID BRENNER.

DR. BRENNER: YES, EXCEPT THOSE I'M IN

CONFLICT.

MS. KING: SUSAN BRYANT.

DR. BRYANT: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: MARCY FEIT.

MS. FEIT: YES, EXCEPT FOR MY CONFLICTS.

MS. KING: LEEZA GIBBONS.

MS. GIBBONS: YES.

MS. KING: SAM HAWGOOD.

DR. HAWGOOD: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.

MS. KING: BOB KLEIN.

CHAIRMAN KLEIN: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.

MS. KING: SHERRY LANSING.

MS. LANSING: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: LEONARD ROME.

DR. ROME: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.

MS. KING: TED LOVE.

DR. LOVE: YES.

MS. KING: PHIL PIZZO.

DR. PIZZO: YES.

MS. KING: CLAIRE POMEROY.

DR. POMEROY: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.

MS. KING: FRANCISCO PRIETO.

DR. PRIETO: YES, EXCEPT FOR THOSE FOR WHICH I HAVE A CONFLICT.

MS. KING: DUANE ROTH.

MR. ROTH: YES.

MS. KING: DAVID SERRANO-SEWELL.

MR. SERRANO-SEWELL: YES.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: AND OSWALD STEWARD.

DR. STEWARD: YES, EXCEPT FOR THOSE WITH WHICH I HAVE A CONFLICT.

MS. KING: ALL RIGHT. AND THAT MOTION CARRIES.

CHAIRMAN KLEIN: ALL RIGHT. BOTH COUNSEL, ARE WE PREPARED TO MOVE TO THE NEXT ITEM? OKAY. WHAT I WOULD LIKE TO DO IS NOT BREAK UP THE DISEASE TEAM DISCUSSION, SO WHAT I'D LIKE TO DO, IF POSSIBLE, IS HAVE -- COVER A COUPLE OF ITEMS THAT WE CAN DO QUICKLY IF THAT'S ACCEPTABLE, DR. TROUNSON?

DR. TROUNSON: YEAH, SURE.

CHAIRMAN KLEIN: SO THE CONSIDERATION OF

THE CONCEPT PLAN FOR TRANSLATION -- THE TRANSLATIONAL RFA. WOULD THAT BE SOMETHING THAT WE COULD DO AT THIS MOMENT?

DR. TROUNSON: I'M SURE OUR STAFF WILL BE READY IN A MOMENT. ROSA.

DR. PIZZO: VOTES ON ANY OF THE OTHER ITEMS?

CHAIRMAN KLEIN: YES. CONCEPT RFA IS.

DR. POMEROY: I THINK THE QUESTION IS HOW ARE THEY --

DR. PIZZO: ACTUALLY I DO HAVE SOMETHING I NEED TO GET TO.

CHAIRMAN KLEIN: OKAY. WOULD TEN MINUTES BE ALL RIGHT? NO.

DR. PRICE: PIZZO HAS A LATE DATE.

CHAIRMAN KLEIN: NO. COULD WE -- HOW ABOUT IF WE CONSIDERED THIS ITEM AND THEN ADJOURNED? ALL RIGHT.

DR. CANET-AVILES: I'M GOING TO SPEAK FAST.

CHAIRMAN KLEIN: THIS IS THE CONSIDERATION OF THE CONCEPT PLAN FOR TRANSLATIONAL RFA.

DR. CANET-AVILES: CHAIRMAN KLEIN AND BOARD MEMBERS, STAFF, AND MEMBERS OF THE AUDIENCE, TODAY I WOULD LIKE TO PRESENT A CONCEPT PROPOSAL FOR

THE EARLY TRANSLATIONAL RFA AND REQUEST APPROVAL FOR CONCEPT CLEARANCE FOR THE TRANSLATIONAL I GRANT. THIS IS AGENDA ITEM NO. 15 IN YOUR BINDERS.

EARLY TODAY BOARD MEMBERS -- WELL, NO. THAT'S GOING TO BE TOMORROW ACTUALLY. SO TOMORROW BOARD MEMBERS ARE GOING TO CONSIDER THE RECOMMENDATIONS FROM THE GRANTS WORKING GROUP ON EXISTING PLANNING APPLICATIONS.

MR. ROTH: MR. CHAIRMAN.

DR. CANET-AVILES: TRANSLATIONAL I IS PART OF THE CIRM PROGRAM THAT BEGAN WITH THE DISEASE TEAM INITIATIVE TO FUND PROGRAMS THAT WILL HELP BRING THE STEM CELL-BASED THERAPIES TO THE CLINIC.

THIS DIAGRAM THAT YOU'VE ALL SEEN MANY TIMES REPRESENTS THE PATH THAT THE TYPICAL THERAPY WOULD TAKE FROM DISCOVERY TOWARD CLINICAL TESTING WITH THE SCOPE OF THE EARLY TRANSLATIONAL, WHAT WE CALL ALSO TRANSLATIONAL I RESEARCH. HERE I WOULD LIKE TO DRAW THE ATTENTION OF THE BOARD TO THE FACT THAT THE KEY OBJECTIVE OF THE TRANSLATIONAL I RESEARCH AWARDS WILL BE THE IDENTIFICATION OF A DEVELOPMENT CANDIDATE THAT HAS THE NECESSARY SUPPORTIVE DATA, INCLUDING ACTIVITY IN RELEVANT IN VITRO AND IN VIVO MODELS OF DISEASE, TO BE CONSIDERED FOR FURTHER FUNDING UNDER A SEPARATE RFA,

TRANSLATIONAL II, FOR ACTIVITIES TO ENABLE A REGULATORY FILING FOR CLINICAL TESTING.

ACTIVITIES GOING FROM A DEVELOPMENT CANDIDATE LEADING TO THE APPROVAL OF AN IND OR INVESTIGATIONAL NEW DRUG, WILL BE ALSO COVERED BY THE DISEASE TEAM AWARDS, THE SCOPE OF WHICH WILL BE FULLY ADDRESSED BY DR. STEFFEN, AND IT HAS ALREADY BEEN ADDRESSED.

THE GOAL FOR THIS RFA IS TO PROVIDE FUNDING TO ENSURE THAT PROMISING DISCOVERIES IN STEM CELL RESEARCH CAN BE TRANSLATED INTO POTENTIAL STEM CELL BASED-CURES, THERAPIES, AND DIAGNOSTICS FOR THE BENEFIT OF PATIENTS.

IN TERMS OF THE SCOPE FOR THIS RFA, THIS AWARD WILL SUPPORT TWO TYPES OF EARLY TRANSLATIONAL RESEARCH, INCLUDING RESEARCH THAT RESULTS IN A DEVELOPMENT CANDIDATE THAT MEETS A MEDICAL NEED. THIS RESEARCH WILL BE THEN ELIGIBLE FOR FURTHER FUNDING UNDER A SEPARATE RFA, TRANSLATIONAL II, FOR ACTIVITIES TO ENABLE A REGULATORY FILING FOR CLINICAL TESTING.

A SECOND KEY OBJECTIVE OF THIS RFA WILL BE TO FIND SOLUTIONS TO BOTTLENECKS FOR EFFECTIVE TRANSLATIONAL THAT, IF OVERCOME, COULD ALLOW THE MORE RAPID ADVANCEMENT OF DISCOVERIES IN STEM CELL

BIOLOGY TO THE IDENTIFICATION OF BETTER DEVELOPMENT CANDIDATES FOR CLINICAL TESTING.

IN TERMS OF PRINCIPAL INVESTIGATOR ELIGIBILITY, THE CIRM TRANSLATIONAL I RESEARCH AWARDS PROGRAM WILL BE OPEN TO PRINCIPAL INVESTIGATORS WITH A PH.D., AN M.D., OR AN EQUIVALENT DEGREE WHO ARE AUTHORIZED BY THE APPLICANT INSTITUTION TO CONDUCT THE RESEARCH, WHICH MEANS THAT THEY HAVE DOCUMENTED AUTHORITY FROM THE APPLICANT INSTITUTION TO STAFF THE PROPOSED PROJECT AND ACCESS TO SPACE AND SHARED RESOURCES SUFFICIENT TO CARRY OUT THE PROPOSED RESEARCH.

GIVEN THE CRITICAL IMPORTANCE AND MAGNITUDE OF THESE AWARDS, CIRM WILL WANT A 10-PERCENT MINIMUM EFFORT COMMITMENT BY THE PRINCIPAL INVESTIGATOR IN THIS RFA.

TRANSLATIONAL RESEARCH IS OFTEN MOST EFFECTIVELY CONDUCTED BY A MULTIDISCIPLINARY TEAM, AND CIRM ENCOURAGES PI'S, PRINCIPAL INVESTIGATORS, TO FORM SUCH COLLABORATIVE ENDEAVORS, INCLUDING COLLABORATION BETWEEN NONPROFIT AND FOR-PROFIT INSTITUTIONS.

IN TERMS OF INSTITUTIONAL ELIGIBILITY, NONPROFIT AND FOR-PROFIT INSTITUTIONS WILL BE ELIGIBLE TO APPLY FOR THESE AWARDS. NONPROFIT

APPLICANT INSTITUTIONS WITH ACCREDITED MEDICAL SCHOOLS WILL BE ELIGIBLE TO SUBMIT UP TO THREE APPLICATIONS. OTHER NONPROFIT INSTITUTIONS AND FOR-PROFIT INSTITUTIONS WITH OVER 500 EMPLOYEES WILL BE ELIGIBLE TO SUBMIT UP TO TWO APPLICATIONS. NONPROFIT AND FOR-PROFIT APPLICANT INSTITUTIONS WITH FEWER THAN 500 EMPLOYEES MAY SUBMIT ONE APPLICATION.

CIRM PROPOSES TO FUND UP TO TEN THREE-YEAR AWARDS WITH JUSTIFIABLE PROJECT COST OF UP TO $1.2 MILLION PER YEAR FOR A TOTAL PROGRAM COST OF UP TO $60 MILLION.

CIRM HAS ESTABLISHED THE FOLLOWING PROVISIONAL TIMETABLE FOR THIS RFA WHICH COULD BE RELEASED IN AUGUST OF 2008, AND YOU CAN SEE THE TIMETABLE.

CHAIRMAN KLEIN: AND CAN I ASK WHAT DATE? AND THE REASON I'M ASKING IT, WHAT DATE IS OUR AUGUST MEETING?

DR. CANET-AVILES: 12 AND 13.

CHAIRMAN KLEIN: 12 AND 13TH. AND WHAT I'D LIKE TO CALL ATTENTION TO IS THAT IT'S A MINIMUM EFFORT, AND A COUPLE OF THESE OTHER CRITERIA THERE IS A TASK FORCE WORKING. IT'S MADE GREAT PROGRESS. IT SHOULD BE CONCLUDING ITS WORK BY THIS TIME, AND SO, FOR EXAMPLE, THE MINIMUM EFFORTS COULD BECOME A

RECOMMENDED MINIMUM EFFORT WITH THE PRESIDENT HAVING THE ABILITY TO MAKE EXCEPTIONS. AND IT'S MY UNDERSTANDING, DR. TROUNSON, THAT THE RESULTS OF THAT TASK FORCE WORK, AS THEY'RE BROUGHT BACK TO THIS BOARD, WOULD BE INCORPORATED IN THE ACTUAL ISSUANCE OF THE RFA. IS THAT A CORRECT STATEMENT?

DR. TROUNSON: YOU KNOW, I THINK THAT'S RIGHT. SORRY. I DIDN'T PICK UP THE FIRST PART OF YOUR --

CHAIRMAN KLEIN: THIS IS GOING TO BE, IT APPEARS, TO BE ISSUED RIGHT AFTER THE NEXT BOARD MEETING. AND AT THE NEXT BOARD MEETING, IT'S OUR INTENT TO HAVE FULFILLED THE TASK FORCE THAT'S ADDRESSING THE ISSUE OF MINIMUM EFFORT, FOR EXAMPLE.

DR. TROUNSON: OH, I SEE. YES.

CHAIRMAN KLEIN: WE MAY HAVE A RECOMMENDED MINIMUM EFFORT.

DR. TROUNSON: YES.

CHAIRMAN KLEIN: AND THE PRESIDENT HAVE BUILT TO MAKE EXCEPTIONS SO THAT THOSE REFINEMENTS WOULD BE INCLUDED IN THIS RFA.

DR. TROUNSON: WE AGREED WITH THE SUBCOMMITTEE TO DISCUSS THAT AT THE NEXT MEETING, AND SO I THINK YOU'RE RIGHT ABOUT THE TIMING, YES.

CHAIRMAN KLEIN: OKAY. THANK YOU. I'M

SORRY. THANK YOU.

DR. CANET-AVILES: SO, THEREFORE, CIRM REQUESTS TO THE BOARD MEMBERS APPROVAL OF THE CONCEPT PLAN FOR THE CIRM TRANSLATIONAL I RFA.

CHAIRMAN KLEIN: THANK YOU. DISCUSSION? DR. STEWARD.

DR. STEWARD: I DON'T KNOW WHETHER THIS IS MORE APPROPRIATE WHEN THE FULL PROPOSAL COMES FORWARD, BUT MAYBE IT IS BECAUSE I THINK THERE ARE SOME THINGS TO THINK ABOUT, AND CERTAINLY TIME EFFORT IS ONE.

THE OTHER ONE THAT I'M A LITTLE CONCERNED ABOUT, THIS SEEMS TO IMPLY THAT THIS WOULD BE A SINGLE PROPOSAL FROM AN INSTITUTION. BY THAT I MEAN THERE WOULD NOT BE AN OPPORTUNITY FOR TWO OR SOMETIMES MORE INSTITUTIONS TO COME TOGETHER COLLABORATIVELY WITH MULTIPLE PI'S. AND I WOULD JUST SAY THAT FOR SOME SMALL FOCI OF DISORDER, IT MIGHT BE HIGHLY ADVANTAGEOUS TO HAVE A MULTICAMPUS REPRESENTATION.

CHAIRMAN KLEIN: DR. TROUNSON.

DR. TROUNSON: DR. STEWARD, THAT'S PART OF THE DISCUSSIONS WE'RE HAVING WITH THE SUBCOMMITTEE. THAT WILL BE RESOLVED. WE WOULD CONTINUE TO ANTICIPATE THE BUILDING OF TEAMS IN POSSIBLY ALL OUR

GRANTS UNLESS THERE'S SOME REASON WHY THEY'D BE SPECIFICALLY INSTITUTE ORIENTED; FOR EXAMPLE, TRAINEE GRANTS. SO WE HOPE TO COME BACK WITH A SET OF RECOMMENDATIONS, AS I SAID, AT THE NEXT BOARD MEETING, AND THAT WILL BE BASED ON THE DISCUSSIONS WE'RE HAVING WITH THE SUBCOMMITTEE.

CHAIRMAN KLEIN: OKAY. THANK YOU. DR. OLSON.

DR. OLSON: BUT I WOULD JUST MAKE THE POINT THAT I DON'T THINK THAT IT WOULD BE -- THERE CERTAINLY IS NOTHING INTENDED IN THIS CONCEPT THAT WOULD PRECLUDE, YOU KNOW, INSTITUTIONS TO COLLABORATE WITH EACH OTHER IN ORDER TO, YOU KNOW, PUT FORTH A RESEARCH PROPOSAL. HOWEVER, THERE WILL BE A PRINCIPAL INVESTIGATOR.

CHAIRMAN KLEIN: JEFF SHEEHY AND THEN DUANE ROTH.

MR. SHEEHY: WELL, SHOULD WE PERHAPS MAYBE LEAVE SOME FLEXIBILITY IN THE NUMBERS BECAUSE THAT COULD BE A DETRIMENT IF IT COUNTS AGAINST YOUR THREE OR YOUR TWO OR YOUR ONE. AND I ABSOLUTELY AGREE WITH THE NEED TO LIMIT BECAUSE, AS WE CAN SEE, PERHAPS WE GAVE ACADEMIC INSTITUTIONS TOO MANY TOOL AND TECHNOLOGY APPLICATIONS BECAUSE THEY SURE CAME BACK WITH A LOT. AND INDUSTRY WAS NOT THE BIG

BREAKOUT, IN FACT, THAT WAS ANTICIPATED. IT WAS ACTUALLY THE ACADEMIC RESEARCH INSTITUTIONS THAT SUBMITTED THE OVERAGE.

BUT IT WOULD BE HELPFUL TO GET THE RATIONALE FOR THE THREE, TWO, ONE AT SOME POINT. I DON'T WANT TO KEEP DR. PIZZO, BUT, YOU KNOW, I WOULD LIKE TO UNDERSTAND HOW WE DERIVED THAT FORMULA.

CHAIRMAN KLEIN: SO, JEFF, I THINK THAT THE GOAL IS THAT AT THE BOARD MEETING ON THE 12TH, THERE WILL BE A DISCUSSION OF THIS, OF THESE ITEMS, AND THIS APPROVAL WILL BE RECONCILED TO THE FINALIZATION OF THOSE ITEMS. THAT'S MY UNDERSTANDING. DR. OLSON.

DR. OLSON: WELL, I THINK IT'S THE GENERAL CONCEPT OF, YOU KNOW, ARE WE -- UNDER WHAT CIRCUMSTANCES DO WE SET LIMITS THAT THE TASK FORCE IS ADDRESSING, UNDER WHAT CIRCUMSTANCE -- WHAT KIND OF PERCENT EFFORT REQUIREMENT SO THAT THE TASK FORCE, I BELIEVE, AND DR. PIZZO IS, OF COURSE, WELCOME TO CORRECT ME, IS ADDRESSING THE GENERAL PRINCIPLES AS OPPOSED TO THE SPECIFICS.

DR. PIZZO: THAT'S RIGHT. IT IS THE GENERAL PRINCIPLES, JEFF, NOT THE SPECIFICS THAT WE'VE DONE. I THINK THOSE SHOULD BE TOPICS FOR DISCUSSION; HOWEVER, OBVIOUSLY AT THE ENTIRE BOARD.

CHAIRMAN KLEIN: BUT, FOR EXAMPLE, IF THE QUESTION IS APPROPRIATELY BROUGHT UP HERE IS HOW EVERYONE, AS A GENERAL PRINCIPLES, RECOGNIZES THE NEED TO LIMIT THE NUMBER OF APPLICATIONS TO BE APPROPRIATELY DEALT WITH. THE QUESTION THAT WAS BROUGHT UP THAT PROBABLY NEEDS TO BE REFINED IS HOW ARE WE GOING TO COUNT JOINT APPLICATIONS BETWEEN INSTITUTIONS AGAINST THE ALLOCATION GIVEN TO INSTITUTIONS? THAT COULD BE ADDRESSED IN THE AUGUST MEETING IS THE INTENT SO THAT EVERYONE HAS A CLEAR UNDERSTANDING.

DR. OLSON: WELL, AND AGAIN, I WOULD JUST MAKE THE POINT THAT THE SPECIFIC ALLOCATION MAY DEPEND ON THE TYPE OF RFA. AND SO I THINK IT'S, AGAIN, THE GENERAL PRINCIPLE. AND, YOU KNOW, TYPICALLY THIS IS THE PLACE WHERE WE ADDRESS THAT KIND OF QUESTION, AT THE CONCEPT APPROVAL.

CHAIRMAN KLEIN: OKAY. OS STEWARD. DR. STEWARD.

DR. STEWARD: YEAH. JUST YOUR LAST COMMENT WENT SORT OF QUICKLY, AND I JUST WOULD ENCOURAGE SOME MAYBE THOUGHT ABOUT THAT, THAT BEING THAT THERE IS ONLY ONE PI. IF WE'RE GOING TO HAVE REAL COLLABORATIVE VENTURES BETWEEN MULTIPLE INSTITUTIONS, I THINK THAT THERE MIGHT BE A NEED TO

CONSIDER CO-PI'S ON THESE KINDS OF THINGS.

DR. OLSON: SORRY. I DID NOT MEAN TO SUGGEST THAT WE WERE AGAINST THE NOTION OF CO-PI'S. WE ARE FULLY SUPPORTIVE OF IT. WE DO NOT -- WE ARE TRYING TO PUT IN PLACE THE INFRASTRUCTURE THAT WILL ALLOW US TO DO THAT. OUR SYSTEM, AS YOU -- I THINK, AS DR. TROUNSON HIGHLIGHTED TO YOU, WE ARE IMPLEMENTING OUR GRANTS MANAGEMENT SYSTEM, AND THAT SYSTEM ALLOWS FOR A SINGLE PRINCIPAL INVESTIGATOR, BUT WE CAN ACKNOWLEDGE CO-PI'S AS FAR AS FROM AN INSTITUTIONAL BASIS THAT THEY RECEIVE CREDIT AS BEING, YOU KNOW, HAVING THE SCIENTIFIC AND THE LEADERSHIP INPUT INTO THE PROJECT, THAT FROM A BRINGING MONEY INTO AN INSTITUTION, ALTHOUGH, AGAIN, OUR SYSTEM MAY PRECLUDE US, IT LOOKS LIKE IT WILL PRECLUDE US FROM PAYING -- WE WILL ONLY BE ABLE TO PAY ONE. WE ARE TRYING TO PUT IN PLACE WAYS THAT WILL ENSURE THAT A CO-PI GETS CREDIT FOR BRINGING MONEY TO AN INSTITUTION AS WELL.

SO THOSE ARE THE THINGS THAT WE NEED TO ADDRESS SPECIFICALLY, BUT RECOGNIZING THAT WE ARE SUPPORTIVE OF THE CONCEPT OF CO-INVESTIGATORS. IT'S THE NOTION OF A LEADER AMONG EQUALS, I THINK, IN A LOT OF THESE CASES.

CHAIRMAN KLEIN: THE ISSUE, TO MAKE IT

CLEAR, IS OUR GRANTS MANAGEMENT SYSTEM, FOR FINANCIAL ACCOUNTABILITY, IS SET UP RIGHT NOW TO HAVE A LEAD PI FOR FINANCIAL ACCOUNTABILITY SO THAT THERE IS INPUT AND RECONCILIATION TO ONE INSTITUTION ON EACH GRANT. HOW THEY REDISTRIBUTE THOSE FUNDS ACCORDING TO THE MANAGEMENT PROGRAM OF A TEAM IS BETWEEN INSTITUTIONS, BUT THEY ARE GOING TO TRY AND MODIFY THAT SYSTEM LATER. THIS IS WHAT WE CAN WORK WITH AT THE MOMENT.

DR. BRYANT.

DR. BRYANT: I WAS JUST WONDERING, SINCE THAT WILL CAUSE SOME PROBLEMS, I THINK, AMONGST PEOPLE, I MEAN IT'S BETTER IF IT'S NOT THAT WAY. NOT ACKNOWLEDGING CO-PI'S HAS BEEN, NOT THIS INSTITUTION, BUT IN GENERAL WHEN SYSTEMS DON'T DO THAT, IT'S JUST NOT SATISFACTORY. AND IT'S NOT APPROPRIATE REALLY.

BUT SO I WAS GOING TO SAY I UNDERSTAND YOU'RE WORKING ON IT, BUT IN THE MEANTIME, IF YOU'RE HAVING MULTI-INSTITUTIONAL AWARDS, WHY DON'T YOU REVIEW THE PROPOSAL AS ONE LUMP AND THEN GIVE EACH INSTITUTION A SUBAWARD SEPARATELY SO THAT THE PI AT EACH -- THE CO-PI AT EACH INSTITUTION THEN WOULD BE -- WOULD HAVE THAT. I MEAN IT'S A PAPER WAY OF DOING IT, BUT I THINK IT WOULD HELP.

CHAIRMAN KLEIN: LET'S --

DR. PIZZO: CAN I JUST --

CHAIRMAN KLEIN: LET'S DO THIS. FOR THE PURPOSES -- THERE'S A LOT OF GOOD POINTS BEING RAISED AND PUT ON THE TABLE HERE. DR. PIZZO HAS A SPECIFIC TIME CONSTRAINT HERE. WE ARE GOING TO BRING BACK THIS FOR FULL DISCUSSIONS IN THE AUGUST BOARD MEETING, INCLUDING INTERIM TASK FORCE DISCUSSIONS ON IT. DR. PIZZO.

DR. PIZZO: I THINK THE COMMITTEE IS HAPPY THAT I HAVE A TIME CONSTRAINT, BUT I WOULD SAY THAT WE ARE MOVING INTO A DISCUSSION WHICH IS BEYOND THIS SPECIFIC PROPOSAL, BUT BEGS A REALLY IMPORTANT SET OF ISSUES WITH REGARD TO EFFORT, CO-PI'S, ETC., FOR WHICH THERE HAS BEEN AT THE SUBCOMMITTEE LEVEL A LOT OF DISCUSSION AND WHICH WE SHOULD CONTINUE AT THE NEXT MEETING BECAUSE THESE ARE VERY IMPORTANT POINTS.

AND I WILL JUST UNDERSCORE THAT THE SUBCOMMITTEE FAVORS CO-PI'S, AND I THINK THAT THERE WILL BE DISCUSSION ABOUT THAT. AND WE CAN'T LET THE SYSTEM GET IN THE WAY OF ACHIEVING SOMETHING THAT WE ALL WANT TO ACCOMPLISH.

CHAIRMAN KLEIN: ALL RIGHT. AND TO BE LEGALLY ACUTE, THIS IS A TASK FORCE AS VERSUS A

COMMITTEE. I USED THE WRONG TERM. IT IS A TASK FORCE.

DR. PIZZO: I USED THE WRONG TERM BECAUSE YOU DID IT.

CHAIRMAN KLEIN: I KNOW. I TAKE RESPONSIBILITY FOR THAT MISCREANT ACTIVITY.

MR. ROTH: CHAIRMAN KLEIN, I KNOW THE HOUR IS GETTING LATE, AND I REALLY -- THERE'S SOME QUESTIONS IN THE EARLIER SLIDES THAT GET TO WHO'S ELIGIBLE AND HOW YOU SET THAT CRITERIA THAT LOOK PRETTY SPECIFIC TO ME. AND WHEN I VOTE ON THIS, IF WE VOTED TONIGHT, I WOULD CERTAINLY WANT TO MAKE SURE THAT AT THE AUGUST MEETING THINGS CAN CHANGE AND IT DOESN'T COME, HERE IT IS. WE ARE READY TO GO WITH THE RFA.

CHAIRMAN KLEIN: THAT'S WHY I CONFIRMED WITH DR. TROUNSON THAT THE WORK OF THE TASK FORCE WOULD, IN FACT, COME TO THIS BOARD AUGUST 12TH, AND THIS WOULD BE RECONCILED TO THAT OUTCOME TO THE EXTENT THAT THE PRINCIPLES THAT WERE ADOPTED WERE INCONSISTENT WITH THIS.

MR. ROTH: WELL, IT'S JUST THE CRITERIA. THIS IS TOO IMPORTANT OF AN AWARD, TRANSLATIONAL. WE'RE STARTING AT $60 MILLION, AND TO NOT HAVE EVERYBODY HAVE A CHANCE TO FIGURE OUT IF THEY CAN

GET INCLUDED HERE OR NOT, YOU KNOW, I SAW MEDICAL SCHOOLS, AFFILIATIONS, AND THINGS LIKE THAT.

CHAIRMAN KLEIN: I WOULD HOPE, TO MOVE THIS ALONG -- I WOULD HOPE TO MOVE THIS ALONG, THAT WE CAN VOTE TO APPROVE THIS FOR THE CONTENT SCIENTIFICALLY AND MEDICAL CONTENT HERE AND THE DIRECTION AND AS TO THE -- AS TO THE NUMBER AND HOW THEY'RE RECONCILED TO THESE CRITERIA TO ALLOW THE STAFF AND THE TASK FORCE TO CONTINUE TO REFINE THEIR PRINCIPLES. AND AT THE AUGUST MEETING RECONCILE THESE VERY SPECIFIC ITEMS ON THE CONTROL AND THE NUMBERS TO THE EXTENT WE HAVE SOMETHING THAT'S DISPARATE FROM THE PRINCIPLE THAT'S FINALLY ARRIVED AT. DOES THAT MAKE SENSE, DR. TROUNSON? OR WOULD YOU LIKE TO TAKE A DIFFERENT APPROACH?

DR. TROUNSON: NO. I THINK THE PRINCIPLE HERE IS THAT THERE WILL BE SOME GENERAL PRINCIPLES THAT UNDERLINE WHAT WE'RE TALKING ABOUT. NO. 1, WE NEED TO DERIVE THOSE, AND SO THAT HAS BEEN AN ONGOING DISCUSSION, AND WE'LL CONTINUE AND WE WILL HOPEFULLY HAVE A CONSENSUS VIEW WHEN WE COME TO THE NEXT BOARD.

YOU KNOW, THERE'S NO DOUBT ABOUT IT, THAT WE'VE GOT TO HAVE SOME LIMITATIONS BUILT IN HERE. SOME OF -- THE REASONS FOR SOME OF THESE NUMBERS ARE

THAT, YOU KNOW, IF YOU HAVE A SMALL COMPANY OR IF YOU HAVE A SMALL RECENTLY SET-UP INSTITUTION, IT'S NOT THE SAME AS IF YOU'VE GOT A MAJOR COMPANY OR A MAJOR INSTITUTION. AND SO WE'RE TRYING TO REFLECT SOME DIFFERENCES. WE'RE TRYING TO SORT OF MAKE SOME GRADIENT IN HERE BECAUSE, YOU KNOW, THERE NEEDS TO BE SOME LIMITS.

BUT WHEN YOU COME TO CO-PI'S, HOW THEY GET COUNTED IS CLEARLY IMPORTANT. AT THIS STAGE WE HAVE A ONE-MILLION-DOLLAR GRANTIUM SYSTEM. I'M NOT ABOUT TO PULL OUT THE GRANTIUM -- $1 MILLION OF GRANTIUM SYSTEM TO COPE WITH CO-PI'S. WE WILL RECONSTRUCT IT AS WE MOVE, BUT IT WILL TAKE US SOME TIME BECAUSE THE SOFTWARE DOESN'T ALLOW US TO HAVE MULTIPLE INSTITUTIONS THERE. SO WE'RE ACTUALLY GOING TO GET THIS SYSTEM IN FUNCTIONING, AND THEN WE'RE GOING TO WORK TOWARDS GETTING WHAT WE NEED OUT OF IT.

SO I THINK YOU HAVE TO ALLOW US IN MANAGEMENT TO DO WHAT WE CAN AND WORK WITHIN THE GENERAL PRINCIPLES.

AND THE OTHER THING, OF COURSE, IS THESE WILL BE REALLY IMPORTANT GRANTS, VERY MUCH IN THE TRANSLATIONAL PIPELINE. WE'LL BE LOOKING FOR REALLY KEY ENTITIES TO COME IN THERE. THEY WILL NOT BE REQUIRED TO HAVE AN IND IN FOUR TO FIVE YEARS AS

DISEASE TEAMS ARE, BUT THEY WILL BE BUILDING ON THE HOPES OF ALL OF US TO MOVE US TOWARDS THE OPPORTUNITY TO GET INTO THAT DISEASE TEAM FRAMEWORK.

AND SO WHAT WE WANT TO DO IS BE ABLE TO PICK UP THOSE EARLY ELEMENTS THAT CANNOT GET INTO IND IN THAT SHORT TIMEFRAME. AND WE'LL BE LOOKING FOR THE VERY BEST APPLICATIONS THAT ARE CONCEIVABLE THAT DO NOT, YOU KNOW, MEET THOSE CRITERIA. AND SO WE'LL BE TOUGH. WE'LL BE HOPEFUL, AND WE'LL LOGICALLY WANT PARTNERSHIPS IN THIS AREA.

SO I THINK UNDER THE TERMS OF THE ICOC'S NEEDS HERE, WE'LL CERTAINLY TAKE ON BOARD WHAT THE GENERAL PRINCIPLES ARE AND HOPEFULLY APPLY IT IN AN APPROPRIATE WAY IN ORDER TO GET THE KIND OF OUTCOMES THAT WE'RE LOOKING FOR.

CHAIRMAN KLEIN: OKAY.

DR. OLSON: I WOULD JUST MAKE ONE -- CHAIRMAN KLEIN.

CHAIRMAN KLEIN: DR. OLSON.

DR. OLSON: IF I COULD MAKE ONE ADDITIONAL COMMENT. THE NUMBERS WERE ALSO -- THEY WERE ESSENTIALLY MODELED AMONG THE KIND OF -- THE INSTITUTIONS WHO HAVE APPLIED TO US SO FAR. AND, YOU KNOW, THINKING THAT IF WE'RE TALKING TRANSLATIONAL, THAT IF YOU HAVE A MEDICAL SCHOOL,

THEN YOU MAY HAVE MORE, YOU KNOW, MORE PEOPLE WHO MIGHT HAVE CERTAIN APPLICANTS. AGAIN, I THINK YOU'VE ALREADY HEARD THE DISCUSSION ABOUT THE COMPANY SIZE, AND WE RECOGNIZE THAT THERE'S SOME VERY GOOD IDEAS IN SMALL COMPANIES, BUT WE'RE TALKING ABOUT A $2-MILLION-A-YEAR AWARD, AND WE'D LIKE YOU TO THINK ABOUT IT.

ALSO, THESE ARE LIKELY TO BE COMPLEX APPLICATIONS, MORE SO THAN SOME OF OUR OTHER ONES. SO, AGAIN, WE ARE TRYING TO THINK ABOUT THE REVIEWERS AND THEIR WORKLOAD. WE WOULD RATHER NOT GET IN A SITUATION AS WE ARE WITH THE TOOLS AND TECHNOLOGIES WHERE SUDDENLY ONE REVIEW BECOMES TWO. SO THOSE ARE JUST THINGS, AND THAT'S THE POINT THAT I MADE WHEN, YOU KNOW, I REFERRED TO THE PRINCIPLES THAT THE TASK FORCE IS ADDRESSING IS THAT, IN GENERAL, YOU KNOW, THE NOTION OF WHAT -- I MEAN THESE ARE NOT THE KIND OF LIMITATIONS I MIGHT -- WE MIGHT RECOMMEND TO THE BOARD FOR A DIFFERENT TYPE OF RFA. YOU KNOW, THEY MAY VARY WITH THE NATURE OF THE RFA.

I THINK, YOU KNOW, THE TASK FORCE AND MANAGEMENT, YOU KNOW, IS TAKING IN GENERAL THE OPINION THAT WE MAY HAVE TO HAVE SOME LIMITS IN SOME CASES, BUT THE NATURE OF THE LIMITS, I FORESEE, IS

MORE RFA SPECIFIC THAN NOT. SO THOSE ARE THE THOUGHTS I WOULD LEAVE THE BOARD WITH.

CHAIRMAN KLEIN: AND, DR. OLSON, JUST AS A POINT FOR CONSIDERATION, UNDER THE FIRST CATEGORY, UNDERSTANDING THE CRITERIA, YOU MIGHT CONSIDER THAT A QUESTION WOULD ARISE AT THE AUGUST MEETING: WHAT DO YOU DO IF YOU HAVE A NONPROFIT INSTITUTION THAT APPLIES WITH A RESEARCH HOSPITAL?

DR. OLSON: NO. AND AGAIN, THOSE ARE -- I THINK THOSE ARE DETAILS WE HAVE TO CONSIDER. AND IF THEY HAVE A CO-PI OR A COLLABORATING INSTITUTION, IN THE PAST OUR APPROACH HAS BEEN THEY'RE NOT PRECLUDED FROM HAVING A PI APPLYING AS PI.

CHAIRMAN KLEIN: RIGHT. OKAY. THANK YOU. SO IT'S BEEN A GOOD DISCUSSION. IS THERE A MOTION ON THE TABLE FOR APPROVAL?

MS. LANSING: SO MOVED.

CHAIRMAN KLEIN: SHERRY LANSING MOVES. IS THERE A SECOND?

DR. HAWGOOD: SECOND.

CHAIRMAN KLEIN: SECOND, DR. HAWGOOD. IS THERE PUBLIC COMMENT? SEEING NONE, IS THERE ANY ADDITIONAL BOARD COMMENT?

MR. ROTH: I'M GOING TO MAKE ONE VERY QUICKLY JUST SO I UNDERSTAND THE MOTION. THE MOTION

IS CONCEPT ONLY.

MS. LANSING: YES.

MR. ROTH: IT'S NOT APPROVING THIS SET OF SLIDES?

CHAIRMAN KLEIN: IT IS WITH AN UNDERSTANDING THAT THIS SET OF SLIDES WILL BE RECONCILED TO THE PRINCIPLES THAT ARE ADOPTED AT THE AUGUST MEETING BASED UPON THE TASK FORCE INPUT AND THE DEBATE IN THE AUGUST MEETING OF THIS BOARD.

MR. ROTH: OKAY. I JUST WANT TO MAKE SURE THAT WE'RE NOT VOTING ON WHAT'S ON THOSE SLIDES.

CHAIRMAN KLEIN: WE ARE VOTING ON WHAT'S ON THESE SLIDES, BUT, IN FACT, WE WILL HAVE A VOTE IN THE AUGUST MEETING ON OUR PRINCIPLES --

MR. SERRANO-SEWELL: THEY CAN'T ISSUE THE RFA, RIGHT?

CHAIRMAN KLEIN: THE RFA WILL BE RECONCILED TO THE AUGUST MEETING'S PRINCIPLES BEFORE IT IS ISSUED.

DR. POMEROY: BOB.

MR. SERRANO-SEWELL: IT'S NOT ISSUED UNTIL AFTER AUGUST.

CHAIRMAN KLEIN: THAT'S MY UNDERSTANDING.

DR. POMEROY: IT'S NOT ISSUED UNTIL AFTER AUGUST, BUT WE WON'T SEE IT AGAIN. THAT WAS A

QUESTION.

CHAIRMAN KLEIN: WE CAN -- LET ME ASK A QUESTION TO HELP HOPEFULLY PROMOTE THIS. DR. TROUNSON, AT THE AUGUST TASK FORCE MEETING, IN ORDER TO PROVIDE A TANGIBLE UNDERSTANDING OF THE PRINCIPLES, IT WOULD BE MY EXPECTATIONS THAT THIS BOARD WOULD LIKE TO BE ABLE TO DISCUSS HOW THOSE PRINCIPLES MIGHT APPLY TO THIS RFA. SO WOULD IT BE APPROPRIATE AT THE AUGUST MEETING TO HAVE THE RECONCILIATION OF THE PRINCIPLES ADDRESSED?

DR. TROUNSON: YEAH. I THINK I'D PROBABLY PREFER TO USE THE TASK FORCE TO ENSURE THAT IT'S WITHIN THE PRINCIPLES, BUT I DON'T NECESSARILY WANT TO COME BACK HERE AND DEBATE THE WHOLE THING AGAIN. IF IN CONCEPT IT'S APPROVED, THEN I THINK THE DETAILS OF IT NEED TO BE WITHIN THE FRAMEWORK OF THE GENERAL AGREEMENT. SO I'M NOT SURE THAT -- YOU KNOW, I'M NOT SURE WE WANT TO BRING IT BACK, THE WHOLE CONCEPT DISCUSSION AGAIN.

CHAIRMAN KLEIN: I'M FEELING THE SENSE OF COMMITTEE IS THAT THE ISSUE ON THE APPLICATION -- HOW THE APPLICATION NUMBERS ARE APPLIED AND ISSUES LIKE MINIMUM EFFORT, THE ISSUES THAT ARE UNDER CONSIDERATION OF THE TASK FORCE, THOSE ITEMS SPECIFICALLY WOULD BE DISCUSSED IN THE CONTEXT OF

THE TASK FORCE REPORT.

DR. PIZZO: RIGHT. CAN I JUST AFFIRM THIS. I THINK DUANE SAID IT THE WAY I WOULD HAVE SAID IT, WHICH IS WE'RE ASKING FOR A CONCEPTUAL APPROVAL FOR THE TRANSLATIONAL AWARDS WITH AN APPROXIMATE NUMBER BEING TEN THREE-YEAR AWARDS AT THE X, $1.2 MILLION PER YEAR UP TO $2 MILLION A YEAR. AND THEN THE DETAILS OF HOW THEY'RE GOING TO BE ALLOCATED TO SPECIFIC INVESTIGATORS OR INSTITUTIONS IS GOING TO BE DELINEATED AS A CONSEQUENCE OF THE DISCUSSION AND THE RECOMMENDATIONS THAT COME FROM THE TASK FORCE.

CHAIRMAN KLEIN: OKAY. IS THAT -- THAT IS MY UNDERSTANDING. IS THAT THE MOTION, MAKER OF THE MOTION?

MS. LANSING: THAT WAS MY UNDERSTANDING AND THAT WAS THE MOTION.

CHAIRMAN KLEIN: AND IS THAT THE UNDERSTANDING OF THE SECOND?

DR. HAWGOOD: YES, SIR.

DR. POMEROY: WITH THE UNDERSTAND -- THIS IS A QUESTION ABOUT THE MOTION. WITH THE UNDERSTANDING THAT IT WILL NOT BE COMING BACK TO THIS BOARD AGAIN, THAT THAT WILL BE DELEGATED TO STAFF ON THE BASIS OF THE TASK FORCE RECOMMENDATION?

CHAIRMAN KLEIN: BUT RECONCILED TO THOSE --

DR. PIZZO: THE TASK FORCE RECOMMENDATIONS ARE GOING TO COME TO THE ICOC.

CHAIRMAN KLEIN: YES.

DR. POMEROY: RIGHT. BUT THIS RFA WILL NOT COME BACK HERE?

DR. PIZZO: RIGHT.

MS. LANSING: IT WILL ADHERE TO THE TASK FORCE RECOMMENDATIONS AND THE TASK FORCE --

DR. PIZZO: IT WILL ADHERE TO THE ICOC DECISIONS ON THE TASK FORCE RECOMMENDATIONS.

CHAIRMAN KLEIN: ON THOSE PRINCIPLES. OKAY.

DR. PIZZO: PRINCIPLES, RIGHT.

CHAIRMAN KLEIN: SO WE HAVE A DISTINGUISHED MEMBER OF THE PUBLIC?

MR. SIMPSON: I CAN'T HELP BUT ASK THE QUESTION. EVERY OTHER TASK FORCE THAT YOU'VE HAD HAS DONE EVERYTHING IN PUBLIC. I KNOW OF NO TASK FORCE MEETINGS THAT HAVE BEEN DONE PUBLICLY OR DISCUSSIONS OF THE TASK FORCE. DO YOU HAVE -- THIS IS THE FIRST WE'VE HEARD OF THE TASK FORCE, I THINK.

CHAIRMAN KLEIN: NO. THIS IS A TASK FORCE THAT WAS DESIGNATED AT THE MARCH BOARD MEETING. IT

IS A TWO-PERSON TASK FORCE.

MR. SIMPSON: I WOULD HAVE EXPECTED THAT THEY WOULD HAVE FOLLOWED THE USUAL PROCEDURES AS THE LOAN TASK FORCE DID.

CHAIRMAN KLEIN: THERE'S A VERY LIMITED SCOPE, AND THE INTENT WAS TO BRING IT BACK FOR A FULL PUBLIC HEARING AS A PART OF THE BOARD MEETING AND A FULL PUBLIC DEBATE ON THEIR REPORT BECAUSE WE DON'T HAVE A LARGE MEMBERSHIP. THIS IS JUST A TWO-PERSON. SO THE WHOLE BOARD NEEDS TO PARTICIPATE WITH THE PUBLIC IN RECEIVING THE REPORT AND DEBATING THE REPORT.

MR. SIMPSON: THANK YOU.

CHAIRMAN KLEIN: YEAH. MORE PROPERLY, IT MAY BE CALLED A STUDY GROUP. OKAY.

DR. PIZZO: A DUET.

CHAIRMAN KLEIN: THANK YOU. WE HAVE A MOTION ON THE FLOOR. WE HAVE CALLED THE QUESTION. ALL IN FAVOR. OPPOSED? MOTION PASSES.

WE ARE ADJOURNED UNTIL WHAT TIME IN THE MORNING?

MS. KING: 8:30.

CHAIRMAN KLEIN: 8:30 IN THE MORNING.

(THE MEETING WAS THEN ADJOURNED AT 10:40 P.M. TO RECONVENE AT 8:30 A.M. ON JUNE 27, 2008.)

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 OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

SHERATON GATEWAY SFO
600 AIRPORT BOULEVARD
BURLINGAME, CALIFORNIA
ON
JUNE 26, 2008

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE STENOGRAPHICALLY TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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