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:	HILTON SFO BAYFRONT HOTEL 600 AIRPORT BOULEVARD BURLINGAME, CALIFORNIA
DATE:	MARCH 19, 2013 8 A.M.
REPORTER:	BETH C. DRAIN, CSR CSR. NO. 7152
BRS FILE NO.:	92751

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BURLINGAME, CALIFORNIA; TUESDAY, MARCH 19, 2013

9 A.M.

CHAIRMAN THOMAS: IF EVERYBODY COULD TAKE THEIR SEATS PLEASE. I'D LIKE TO CALL THE MARCH 19, 2013, MEETING OF THE ICOC TO ORDER. WELCOME EVERYBODY TO SAN FRANCISCO. IT'S GREAT TO SEE EVERYONE HERE. LET'S PROCEED WITHOUT ADO. MARIA, WILL YOU LEAD US IN THE PLEDGE OF ALLEGIANCE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN THOMAS: MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: HERE.

MS. BONNEVILLE: DAVID BRENNER. ANNE-MARIE DULIEGE. MARCY FEIT.

MS. FEIT: HERE.

MS. BONNEVILLE: LEON FINE. MICHAEL GOLDBERG. SAM HAWGOOD. STEPHEN JUELSGAARD.

DR. JUELSGAARD: HERE.

MS. BONNEVILLE: TED KRONTIRIS.

DR. KRONTIRIS: HERE.

MS. BONNEVILLE: SHERRY LANSING. JACOB LEVIN.

DR. LEVIN: HERE.

MS. BONNEVILLE: BERT LUBIN.
DR. LUBIN: HERE.
MS. BONNEVILLE: MICHAEL MARLETTA. ROBERT PRICE.
DR. PRICE: HERE.
MS. BONNEVILLE: FRANCISCO PRIETO. CARMEN PULIAFITO.
DR. PULIAFITO: PRESENT.
MS. BONNEVILLE: ROBERT QUINT. DUANE ROTH.
MR. ROTH: HERE.
MS. BONNEVILLE: JOAN SAMUELSON.
MS. SAMUELSON: HERE.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: HERE.
MS. BONNEVILLE: JONATHAN SHESTACK. OSWALD STEWARD.
DR. STEWARD: HERE.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: HERE.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: HERE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: HERE.
MS. BONNEVILLE: EUGENE WASHINGTON. DIANE

WINOKUR.

MS. WINOKUR: HERE.

CHAIRMAN THOMAS: ALAN, WE'RE GOING TO START A BIT OUT OF ORDER. WHY DON'T WE BEGIN WITH YOUR REPORT, PLEASE, PRESIDENT'S REPORT.

DR. TROUNSON: THANK YOU, CHAIR. AND IT'S NICE TO BE BACK FROM AUSTRALIA FROM THE BEACH. IT'S RATHER DIFFICULT TO GET BACK ON THE AIRPLANE, I CAN TELL YOU.

SO I WANT TO START, AS USUAL, ABOUT DISCUSSING SOME OF THE SCIENCE THAT I THINK IS REALLY STARTING TO CHANGE AGAIN THE EMPHASIS AND THE DIRECTIONS IN THE AREA OF STEM CELLS. AND THE FIRST ONE IS A REPORT FROM NEURON FROM A GROUP IN BRUSSELS ON PYRAMIDAL NEURONS DEVELOPED FROM HUMAN IPS CELLS WHERE THEY'VE SHOWN THAT THEY INTEGRATE EFFICIENTLY INTO THE MOUSE BRAIN CIRCUIT. SO THEY WERE USING HUMAN ES CELLS AND IPS CELLS CULTURED WITH A GROUP OF MORPHOGENS, THINGS THAT MAKE THEM CHANGE AND DIFFERENTIATE, AND GETTING A SEQUENTIAL FORMATION OF FUNCTIONAL NEURONS, THESE ARE PYRAMIDAL NEURONS, IN ALL SIX LAYERS OF IDENTITIES THAT ARE NECESSARY.

IT'S REALLY QUITE COMPLEX IN THE BRAIN CORTEX, AS YOU MAY IMAGINE. AND IF YOU DON'T GET THE RIGHT KIND OF NEURONS FORMED, YOU WOULDN'T

EXPECT THE FUNCTION TO BE NORMALIZED. WHEN THEY'VE TRANSPLANTED IN THE MOUSE NEONATAL BRAIN, THE ES CELL-DERIVED CORTICAL NEURONS INTEGRATED VERY WELL, VERY ROBUSTLY, AND ESTABLISHED AXONAL PROJECTIONS AND DENDRITIC PATTERNS OF NORMAL CORTICAL NEURONS. AND SO THIS IS A CORTEX, A REALLY CRITICAL PART OF THE BRAIN.

AFTER SEVERAL MONTHS, THEY HAD ESTABLISHED FUNCTIONAL SYNAPSES WITH ALL THE MOUSE BRAIN CIRCUITRY. SO THEY LOOK LIKE THEY'RE REALLY CONNECTED IN THERE AND FUNCTIONAL. THIS IS, I THINK, A VERY STRONG INDICATION THAT THE MODELING FOR THE HUMAN CORTEX IS REALLY GOING TO COME FROM THESE TYPES OF CELLS, BOTH EMBRYONIC STEM CELLS AND IPS CELLS. AND IF YOU LOOK AT THESE AXONAL PROJECTIONS, UP IN THE TOP THIS IS WHERE THEY'RE, I THINK, A COUPLE OF WEEKS AND THEN TWO MONTHS. AND AS THEY GET -- AS THE TRANSPLANT IS OLDER AND OLDER, THE AXONS INCREASE AND THE PROJECTIONS START TO COME FROM THEM, AND ABOUT SIX MONTHS THEY'RE REALLY WELL-DEVELOPED NEURONS THAT LOOK EXACTLY LIKE THEY SHOULD AND APPEAR TO BE VERY WELL CONNECTED INTO THE CIRCUITRY.

IF YOU LOOK AT THE GREEN DOT AT THE TOP ON THE LEFT-HAND SIDE, THAT'S WHERE THE TRANSPLANT WAS.

AND THEY LOOK TO SEE WHERE THE AXONS TOOK THESE CELLS. AND IN THE PICTURES BELOW, IT INDICATES THAT THEY WENT TO ALL OF THESE PATHWAYS THAT YOU WOULD HOPE THESE CELLS WOULD GO TO. SO THESE ARE THE HUMAN CELLS IN A MOUSE BRAIN MAKING ALL THE APPROPRIATE CONNECTIONS, GOING TO THE RIGHT PLACES.

SO I THINK THIS IS A VERY NICE PAPER. IF ANYONE IS INTERESTED, IT'S WORTH A READ OF IT BECAUSE THERE'S A LOT OF DETAIL IN IT, BUT IT'S DONE BEAUTIFULLY. AND IT LOOKS LIKE -- I WOULD BE VERY HOPEFUL THAT THIS KIND OF DIFFERENTIATION WOULD BE EFFECTIVE IN TRANSPLANTS IN THE FUTURE IN THE HUMAN.

THERE'S ALSO ANOTHER COMPLEX AREA, AND I THINK IT'S WORTH SAYING SOMETHING ABOUT, NATURAL KILLER CELLS IN THE IMMUNE SYSTEM. NATURAL KILLER CELLS ARE THE CELLS WHICH REALLY CAUSE A COMPLICATION FOR ANY CELL WHICH IS UNDERDEVELOPED. NATURAL KILLER CELLS ARE AFTER THINGS THAT ARE NOT GOING RIGHT. AND AN UNDERDEVELOPED CELL, LIKE A STEM CELL, IS A GREAT TARGET FOR A NATURAL KILLER CELL.

AND SO THIS REALLY MAKES IT COMPLICATED BECAUSE A LOT OF OUR ANIMAL MODELS DON'T INCLUDE NATURAL KILLER CELLS IN THE MODEL. SO WHEN YOU GO TO THE HUMAN, IF YOU HAVEN'T SORT OF THOUGHT ABOUT

THESE NATURAL KILLER CELLS, YOU MIGHT END UP WITH A LOT OF DESTRUCTION OF THE CELLS THAT YOU PUT IN THERE BECAUSE THEY'LL GO AFTER UNDIFFERENTIATED OR POORLY DIFFERENTIATED CELLS.

SO THEY'VE GOT A CYTOTOXIC FUNCTION, AND THAT IS SUPPRESSED IN TUMORS. AND THAT'S THE WAY TUMORS ESCAPE THESE NATURAL KILLER CELLS. THE HUMAN ES CELLS, IPS CELLS, MESENCHYMAL STEM CELLS ARE MUCH MORE SUSCEPTIBLE TO NATURAL KILLER CELL-MEDIATED CYTOTOXICITY THAN THEIR DIFFERENTIATED PRODUCT. SO IT'S THE UNDIFFERENTIATED CELLS WHICH ARE THE ONES WHICH ARE AT RISK.

SO IT TURNS OUT THE PAPER BY THIS GROUP, JEWETT, ET AL. FROM UCLA AND THE *JOURNAL OF CANCER*, I LIKE VERY MUCH BECAUSE THEY STARTED TO DESCRIBE THE NATURE OF THESE NATURAL KILLER CELLS BECAUSE THEY BELIEVED THAT THEY HAVE TWO STAGES OF MATURATION, ONE WHICH THEY CALL TYPE 1, WHICH IS EFFECTIVE FOR LYSIS OF STEM CELLS IN THE POORLY DIFFERENTIATED PRODUCT. SO THAT'S ONE CHARACTERISTIC IN THEIR MATURATION. THE SECOND PART, WHICH IS REALLY HELPFUL TO THE CELLS, IS REALLY A POSITIVE FOR DIFFERENTIATION IN REGENERATION AND RESOLUTION OF INFLAMMATION; THAT IS, THE REGULATORY NK CELL.

SO IN THIS PARTICULAR CELL, IT HAS TWO STAGES, ONE WHICH IS REALLY DANGEROUS FOR THE STEM CELL OR THE POORLY DIFFERENTIATED CELLS PUT IN THERE, AND THE OTHER WHICH IS GOING TO EMBRACE AND ASSIST THE REGENERATIVE PROCESSES.

THIS IS TOO COMPLEX A SLIDE, BUT WHAT THEY'VE DONE IS SAY THESE CELLS WITH LOTS OF THINGS THAT CAN ATTACH TO THEM, THEY'VE GOT A LOT OF RECEPTORS, AND IT DEPENDS ON THE NATURE OF THE RECEPTORS AND WHAT'S OCCUPYING THEM WHICH WILL SEND THEM INTO THESE DIFFERENT STAGES OF MATURATION. SO IT'S A VERY NICE PAPER, AND I THINK IT'S SOMETHING THAT WE DON'T REALLY THINK MUCH ABOUT, PARTICULARLY IN THE ANIMAL MODELS THAT WE USE. AND I GET A LITTLE CONCERNED THAT WE'LL GET SURPRISES IF WE DON'T TAKE SOME OF THIS INTO ACCOUNT AS WE MOVE FORWARD.

SO I DID REPORT A FEW MEETINGS AGO ON FUNCTIONAL MATURATION OF CARDIOMYOCYTES AND TOLD YOU THAT IPS CELLS IN THE PAPER THAT I HAD SOURCED AT THAT TIME WERE VERY POOR COMPARED TO EMBRYONIC CELLS IN MAKING FUNCTIONAL CARDIOMYOCYTES. WELL, THERE'S A GROUP, LUNDY, ET. AL, PUBLISHED IN *STEM CELLS IN DEVELOPMENT* FROM WASHINGTON, AND THEY STUDIED DIFFERENTIATION OF BOTH EMBRYONIC STEM CELLS AND IPS

CELLS IN PROLONGED CULTURES, THAT IS VERY LONG CULTURES COMPARED TO MOST PEOPLE, TO DETERMINE IF THEY WOULD REALLY MATURE THEIR STRUCTURE AND CONTRACTILITY INTO MORE ADULT PHENOTYPES. AND THEY FOUND THAT IN PROLONGED CULTURE, THAT'S 80 TO 120 DAYS, WHICH IS A LONG PERIOD OF TIME TO MAINTAIN CELLS IN THE LABORATORY, THAT THEY WERE QUITE DIFFERENT, THOSE CELLS, TO THE EARLY STAGE CELLS, WHICH WE USUALLY SEE FROM THE RESEARCH LABS, WHICH ARE ROUNDABOUT 20 TO 40 DAYS. SO QUITE DIFFERENT. AND THEY WERE DIFFERENT IN THEIR MORPHOLOGY AND THE MYOFIBRIL DENSITY AND THEIR ALIGNMENT, VISIBLE SARCOMERES THAT ARE PRESENT ON THE CELLS, AND MULTINUCLEATED -- PROPORTION OF MULTINUCLEATED CELLS.

ALSO, THEIR ELECTROPHYSIOLOGICAL PROPERTIES STARTED TO APPROACH ADULT CARDIOMYOCYTES. AND YOU CAN PROBABLY SEE THIS BEST IN THE LOWER LEFT-HAND PANEL WHERE THE MORE MATURE CELLS ARE ON THE BOTTOM. AND YOU CAN SEE NOW A PATTERN WHICH IS QUITE DIFFERENT FROM THE PATTERN ABOVE IT, WHICH IS THE MORE IMMATURE CELLS. IF YOU CULTURE THEM FOR A LONGER TIME IN THE SYSTEM THAT THEY USED, THEY REALLY DID SEEM TO START TO APPROACH ADULT CARDIOMYOCYTES, WHICH I THINK IS A VERY GOOD

INDICATION OF THESE CELLS WILL ACTUALLY DO THAT MATURATION EITHER IN THE LABORATORY OR WHEN THEY'RE TRANSPLANTED.

SO A VERY NICE PIECE OF WORK AND RATHER DIFFERENT TO A REPORT THAT I GAVE TO YOU FOUR OR FIVE MONTHS AGO, I THINK.

THE LAST ONE I WANT TO DRAW YOUR ATTENTION TO IS, I THINK, A VERY IMPORTANT PAPER. IT'S DONE BY A VERY LARGE GROUP OF PEOPLE IN A LARGE-SCALE COLLECTIVE PROGRAM THAT WAS PUBLISHED IN *PNAS* THIS YEAR. AND IT LOOKS AT THE GENOMIC RESPONSES IN MOUSE MODELS, AND THEY SHOW THESE MOUSE MODELS ARE VERY POOR MIMICS OF HUMAN INFLAMMATORY DISEASES. SO THIS IS A REAL AND GENUINE PROBLEM.

SO CURRENTLY MOUSE MODELS ARE THE CORNERSTONE TO ALL OUR CURRENT BIOMEDICAL RESEARCH. THEY REALLY ARE THE CENTRAL USAGE IN ALL OUR EXPERIMENTAL DATA. HOW WELL DO MOUSE MODELS ACTUALLY MIMIC HUMAN INFLAMMATION IS THE QUESTION. AND, IN FACT, REALLY DOES IT MIMIC IN MANY OF THE CONDITIONS THAT WE'RE LOOKING AT?

SO THESE SCIENTISTS AND LARGE GROUP OF PEOPLE IN THIS CONSORTIUM USED ACUTE INFLAMMATORY STRESSES TO RESULT IN HIGHLY SIMILAR GENOMIC RESPONSES IN THE HUMAN SO THEY CAN SHOW THAT THEY

WERE -- THEY COULD GET THESE RESPONSES AND EVEN THEY'RE REPEATABLE, BUT MOUSE MODELS CORRELATE VERY POORLY WITH THE HUMAN CONDITIONS AND WITH ONE ANOTHER. SO THEIR VIEW WAS THAT THESE MOUSE MODELS ARE NOT OPERATING VERY WELL AT ALL.

AND AMONGST THE GENES THAT CHANGED SIGNIFICANTLY IN THE HUMAN, THE MOUSE ORTHOLOGS, THOSE GENES OR SIMILAR GENES IN THE MOUSE, WERE CLOSE TO RANDOM IN MATCHING THE HUMAN. SO THERE WASN'T REALLY ANY CORRELATIVE CHANGE IN THE GENES THAT YOU WOULD EXPECT. IT WAS MUCH MORE RANDOM THAN IN ANY DIRECTION.

SO WE HAVE TO IMPROVE OUR CURRENT ANIMAL MODEL SYSTEMS. THAT'S VERY CLEAR, AND WE'VE KNOWN THAT FOR A WHILE, BUT I THINK THERE NEEDS TO BE A HIGHER PRIORITY FOR TRANSLATION TO BE FOCUSED ON THE COMPLEX HUMAN CONDITIONS RATHER THAN MOUSE MODELS. OTHERWISE, I THINK WE'RE NOT GOING TO GET WHAT WE EXPECT OUT OF THESE SYSTEMS.

SO IF YOU TAKE A LOOK AT THIS CORRELATION MAP, AT THE TOP END ARE HUMAN BURNS VERSUS HUMAN TRAUMA, AND IT'S A VERY HIGH CORRELATION OF .91 THERE. BUT YOU COME DOWN TO THE OTHER END OF THE SCALE WHERE YOU'RE LOOKING AT MOUSE TRAUMA OR MOUSE BURNS, AND THERE'S VERY LITTLE CORRELATION EVEN WITH

ONE ANOTHER -- WITH EACH OTHER IN THE MOUSE SYSTEM AND ALMOST NO CORRELATION TO THE HUMAN, ALMOST NONE.

AND YOU CAN GO ON AND LOOK AT DIFFERENT SETS OF DATA HERE. THEY'RE LOOKING AT SOME SETS OF DATA, AND IN ONE PART THE DOTTED LINES ARE THE MICE AND THE FIRM LINES SHOWN BELOW THE BAR ON THE PICTURE AT THE BOTTOM RIGHT-HAND SIDE ARE THE HUMAN. OBVIOUSLY THE MOUSE IS RESPONDING TOTALLY DIFFERENT IN TERMS OF GENE REGULATION TO THE HUMAN. THE GENES ARE EVEN IN THE WRONG DIRECTION.

SO YOU CAN GO THROUGH THIS AND LOOK AT ALL OF THESE DIFFERENT THINGS. THIS IS ANOTHER CORRELATION OF THE FAULT CHANGES IN GENES WITH THE PERCENTAGE OF GENES THAT CHANGES. AND YOU CAN SEE THE MOUSE DOWN IN ONE END OF THE SCALE, AND THE HUMANS ARE WAY UP THE OTHER END OF THE SCALE. NO CORRELATION WHATSOEVER WITH ONE ANOTHER. WE'RE USING MOUSE MODELS FREQUENTLY AS TEST, A TEST BASIS, AND WE'RE EXPECTING GENE SYSTEMS TO CHANGE, REALLY ARE. AND I THINK THERE'S A REAL PROBLEM HERE WHICH IS EXEMPLIFIED VERY NICELY IN THIS PAPER. AND I THINK WE'VE GOT TO REASSESS OURSELVES THE WAY WE UTILIZE THESE MODEL SYSTEMS.

SO I WANT TO THEN SORT OF NOW GO ON TO WHAT WE'VE BEEN DOING INTERNALLY IN THE

ORGANIZATION. AND I WANTED TO SAY AT THIS POINT I REALLY DID WANT TO THANK ELLEN FEIGAL FOR STANDING WELL INFORMED DESPITE ME BEING ON THE BEACH AND SANDY AND WHATEVER ELSE. SHE KEPT ME VERY WELL INFORMED. I THINK SHE DID A TERRIFIC JOB. THE TEAM WAS REALLY BONDED AROUND WHERE SHE WENT, AND I FELT VERY POSITIVE ABOUT IT. SO I WANTED TO THANK ELLEN PARTICULARLY.

NOW, THE CIRM-SUPPORTED JOURNAL, WE'RE NOW FINISHED SUPPORTING THE JOURNAL. SO IT'S NOW WE'RE LETTING IT GO ON ITS OWN DEVELOPMENTAL PATHWAY. AND THIS IS SOME OF THE DATA, SUMMARY DATA, THAT WE REQUESTED FROM THE JOURNAL JUST TO REPORT TO YOU. SO IT'S GOT A GREAT CIRCULATION. IT'S GOT A LOT OF USERS. IT'S GOT A VERY GOOD VISITOR TO THE WEB. IT'S INDEXED BY THE NATIONAL LIBRARY OF MEDICINE IN LESS THAN A YEAR, WHICH IS VERY UNUSUAL TO GET THAT. SO THE PAPERS ARE IN *PUBMED* ALREADY WITHIN A YEAR. AND THE ACCEPTANCE OF PAPERS, CURRENTLY IT'S 73 PERCENT, WHICH IS VERY HIGH. I THINK THAT'S GOING TO GO DOWN AS THE JOURNAL RECEIVES MORE AND MORE PAPERS.

I THINK THIS HAS BEEN A SUCCESS. I REALLY THINK THIS HAS BEEN A SUCCESS. THERE'S A LOT OF FOCUS ON THAT JOURNAL NOW, AND I THINK IN THE

TRANSLATIONAL AREA WE'RE SEEING THINGS BEING PUBLISHED IN THERE THAT ARE GETTING QUITE A LOT OF ATTENTION EVEN THOUGH IT'S A VERY NEW JOURNAL. SO I THINK THIS HAS BEEN A GREAT SUCCESS.

WE HAVE A NEW APPOINTMENT IN THE AGENCY, SHEILA CHADWICK. SHE'S THE OFFICE MANAGER. AND SHE'S COME FROM THE WESTERN GOVERNORS UNIVERSITY.

MS. LANSING: ALAN, THIS IS SHERRY. CAN YOU SPEAK LOUDER?

DR. TROUNSON: SHE'S OUR OFFICE MANAGER, THE FIRST PERSON YOU MEET IF YOU CAME TO VISIT US.

THE CURRENT RFA PROGRAM, THE IPS INITIATIVE IS AT THIS MEETING, AS YOU KNOW. RESEARCH LEADERSHIP, THE FUNDING DECISION WILL BE HERE IN MAY 2013, SO IN MAY. AND WE HAD A VERY INTERESTING RFA AND GRANTS WORKING GROUP AROUND THAT. SO I THINK THERE ARE SOME ISSUES THAT WE NEED TO TALK TO YOU ABOUT WITH THAT BECAUSE THERE IS PERHAPS A NEED TO THINK ABOUT WHETHER WE SHOULD EXTEND IT OR WHETHER WE SHOULD CLOSE IT DOWN NOW BECAUSE WE'VE PROBABLY GOT EIGHT OR MORE RECOMMENDED MEMBERS, LEADERSHIP AWARDEES. SO I'D LIKE TO TALK TO YOU ABOUT THAT IN MAY.

THE ALPHA CLINICS, WE EXPECT THE CONCEPT TO COME TO YOU IN MAY AS WELL.

THE STRATEGIC PARTNERSHIP II, THE GRANTS REVIEW WILL BE IN APRIL. AND EARLY TRANSLATION, GRANTS WORKING GROUP WILL BE IN JUNE. SO IT'S A VERY BUSY PROGRAM FOR EVERYONE INVOLVED IN THE GRANTS WORKING GROUP AND OBVIOUSLY KEEPING GIL AND HIS TEAM EXTREMELY BUSY AND ALL OF THE PEOPLE IN THE SCIENCE OFFICE WHO SUPPORT ALL OF THESE RFA'S.

THE STRATEGIC PARTNERSHIP III WE'RE POSTING IN JUNE. TOOLS AND TECHNOLOGIES, THE CONCEPT PROPOSAL WILL COME HERE IN JULY. DISEASE TEAM III, WE'RE EXPECTING THAT IN AUGUST. SO RIGHT IN THE MIDDLE OF YOUR HOLIDAYS FOR SOME PEOPLE ANYWAY. BASIC BIOLOGY V WILL BE IN SEPTEMBER. SO THERE'S A BIG PROGRAM IN FRONT OF US THIS YEAR.

SOME UPDATES ON THE BUSINESS DEVELOPMENT GROUP WHO ARE WORKING UNDER ELONA BAUM AND NEIL LITTMAN, WHO ARE REALLY NOW GETTING US TRACTION IN THE AREA WITH COMPANIES. WE HAD 17 COMPANIES EXHIBIT AT CIRM'S GRANTEE MEETING, WHICH WAS VERY SUCCESSFUL. I THINK THEY WERE VERY HAPPY THERE AND VERY WELCOMED. WE HAVE SOME UPCOMING EVENTS WHERE THERE'S AN INVESTOR MEETING OF CALIFORNIA VC'S THAT'S BEING ORGANIZED FOR JUNE AND A ROUNDTABLE MEETING ON TOOLS AND TECHNOLOGIES, WHICH IS ALSO BEING ORGANIZED IN JUNE.

SO LOTS OF ACTIVITIES AROUND THE BUSINESS DEVELOPMENT AREA, WHICH WE'RE NOW REALLY PUTTING A BIG EMPHASIS ON ENGAGING WITH THOSE COMPANIES.

SO WE JUST FINISHED A CIRM GRANTEE MEETING, WHICH WAS HELD ON MARCH 6 TO 8, SO I WAS BACK FOR THAT. THERE WAS SCIENTIFIC SESSIONS AND TWO WORKSHOPS AND A PUBLIC SESSION. THE ORGANIZERS, UTA GRIESHAMMER AND BECKY JORGENSON, GIL SAMBRANO, DON GIBBONS, GEOFF LOMAX WITH THE SUPPORT OF KIM WILLIAMS AND PAUL FRECH. AND IT WAS A GREAT MEETING.

THESE MEETINGS HAVE BEEN SAID TO BE THE BEST STEM CELL MEETINGS OF THE YEAR. AND I THINK IN MANY RESPECTS THIS ONE WAS LIKE THAT. IT WAS VERY WELL ATTENDED. THERE WERE OVER 500 ATTENDEES, GRANTEES, THAT CAME. I THINK ANY OF THE BOARD -- THERE ARE SOME BOARD MEMBERS WHO ATTENDED SOME OF THE SESSIONS. I THINK TERRIFIC SCIENCE. THERE'S A GREAT POSITIVE BONDING FEELING THROUGHOUT CALIFORNIA AND THOSE SCIENTISTS ALL WANTING TO WORK WITH ONE ANOTHER. OFTEN YOU SEE THESE CONFERENCES ARE A MUCH MORE COMPETITIVE ENVIRONMENT. THIS IS A VERY SUPPORTIVE OF ONE ANOTHER ENVIRONMENT. CLICKING TO CAN WE WORK TOGETHER? CAN WE DO THINGS TOGETHER? AND I THINK SOMEHOW CIRM HAS BEEN ABLE TO ENGAGE

THESE PEOPLE IN A MUCH MORE POSITIVE WAY THAN IN SOME OF THE CONFERENCES I GO TO OUTSIDE CALIFORNIA WHERE FUNDING IS REALLY QUITE DIFFICULT AT THE MOMENT. NIH GRANTS ARE EXPECTING TO BE VERY HARD TO GET. AND SO PEOPLE BECOME MUCH MORE COMPETITIVE UNDER THOSE KIND OF CONDITIONS.

SO I THINK WE'RE PARTICULARLY LUCKY TO BE ABLE TO CREATE THIS KIND OF ENVIRONMENT BECAUSE IT LEADS TO -- GALVANIZES THE RESEARCH RATHER THAN RESTRICTS IT. AND SO I THINK IT WAS A GREAT MEETING. THERE WERE SOME AREAS WHERE WE COULD PERFORM A LITTLE BETTER. WE GOT FEEDBACK ON THAT. SO WE CONTINUE TO HAVE THAT. SO IT WILL BE ANOTHER 15 OR 18 MONTHS BEFORE WE HAVE ANOTHER ONE, BUT IT WAS A TERRIFIC MEETING, AND I THINK SOME OF THE BOARD MEMBERS THERE ALSO ENJOYED IT.

UPCOMING MEETINGS, THERE'S A WORKSHOP ON PARKINSON'S DISEASE. SO SORT OF SET THIS UP SOMETIME EARLY LAST YEAR, AND NOW IT'S ABOUT TO HAPPEN ON MARCH 21ST TO THE 22D. IT'S BEEN ORGANIZED BY ROSA CANET-AVILES WORKING WITH THE NIH AND CIRM AND OTHER INVESTIGATORS AROUND THE WORLD. SO WE'VE GATHERED THE BEST PEOPLE IN PARKINSON'S DISEASE TO COME TOGETHER TO WORK TOGETHER TO LOOK TO SEE WHAT WE CAN DO TO ACCELERATE SOME OPPORTUNITIES,

FIND OUT WHAT ARE THE BLOCKAGES IN THE SYSTEM. WHY AREN'T WE GETTING A MOVEMENT OF REALLY HIGH QUALITY WORK INTO THE CLINIC IN THIS AREA? WHY IS IT SORT OF BEING HELD UP? WHAT CAN WE DO ABOUT ENABLING THAT TO HAPPEN? CAN WE WORK TOGETHER ACROSS THE WORLD TO DO THIS? IT SEEMS LIKE A GREAT OPPORTUNITY. WE DO HAVE THE BEST PEOPLE IN THE WORLD COMING TOGETHER. SO I'M EXPECTING A VERY GOOD OUTCOME, AND I HOPE ROSA MIGHT COME AND REALLY GIVE SUMMARY TO THAT. WE WILL BE WRITING IT UP. ACTUALLY WE'LL BE PREPARING IT AS USUAL AS A WRITTEN DOCUMENT THAT WILL BE MADE AVAILABLE TO YOU.

AND WE'RE HAVING A TOOLS AND TECHNOLOGIES R & D ROUNDTABLE ALSO COMING UP.

THERE HAVE BEEN MEETINGS TO PROMOTE COLLABORATIONS WITH INDUSTRY AND REGULATORY AGENCIES. AGAIN, ELONA HAS BEEN TRAVELING QUITE A BIT AND SETTING UP SOME OPPORTUNITIES FOR US, BIOEUROPE OPPORTUNITY WHICH WAS HELD MARCH 11TH TO THE 15TH IN BARCELONA AND A BIOINTERNATIONAL WHICH IS IN APRIL IN CHICAGO WHERE SHE AND HER COLLEAGUES ARE ATTENDING.

AND THERE'S A WEBINAR ON APRIL THE 15TH WHICH IS CIRM/FDA/INDUSTRY/ACADEMIA WEBINAR ON THE TOPIC MOVING STEM CELL-BASED THERAPIES TO THE

CLINIC. SO AN IMPORTANT WEBINAR WITH ALL THE KEY ORGANIZATIONS INVOLVED.

IN TERMS OF OUR GRANTS MANAGEMENT SYSTEM, WE RECENTLY RELEASED SUPPLEMENTARY APPLICATIONS, SCHEDULED NOTIFICATIONS, SCIENTIFIC OUTCOMES CODING, AND REPORTING TOOLS. THEY'RE ALL NOW RECENTLY RELEASED, SO THEY'RE ALL EFFECTIVE IN THE SYSTEM. CURRENTLY UNDER WAY WE'RE DOING NOTICE OF GRANT AWARDS AND REVIEW IMPROVEMENTS TO ENABLE ALL THIS TO HAPPEN ELECTRONICALLY IN A VERY EASY WAY. AND ALSO OUR DOCUMENT MANAGEMENT, WE'RE FINALIZING THE LICENSING OF A NEW SYSTEM THERE.

SO I'D LIKE TO INVITE CHILA NOW TO COME AND PRESENT THE FINANCE REPORT TO YOU. SHE HAS A LITTLE BIT OF PROBLEM WITH HER VOICE, SO FOR THOSE ON THE PHONE, YOU'LL PROBABLY HAVE TO SPEAK CLOSE TO THE PHONE, CHILA.

MS. SILVA-MARTIN: I DO APOLOGIZE FOR MY VOICE. I WILL TRY TO MAKE THIS QUICK. I'D LIKE TO START BY PROVIDING YOU WITH A HIGH LEVEL FINANCIAL REPORT. OUR GRANT DISBURSEMENTS FOR THE FIRST EIGHT MONTHS OF THE YEAR WERE A LITTLE BIT OVER $116 MILLION AS COMPARED TO THE PRIOR PERIOD WHERE WE DISPENSED $151 MILLION.

WE HAVE A VERY HEALTHY CASH BALANCE. OUR

AVAILABLE CASH FOR GRANT AND LOAN PAYMENTS AND OPERATIONAL EXPENSES AS OF FEBRUARY 28TH WAS $72.4 MILLION. AS YOU MAY RECALL, IN JULY OF 2012, WE BEGAN RECEIVING COMMERCIAL PAPER FUNDING. SO WE'RE NOW RECEIVING FUNDING ON A MONTHLY BASIS VERSUS BOND PROCEEDS, WHICH WE RECEIVED EITHER ONCE OR TWICE A YEAR. SO THIS CHANGE IN FUNDING SOURCE REALLY REQUIRES A SIGNIFICANT AMOUNT OF COORDINATION AND REPORTING WITH THE STATE TREASURER'S OFFICE AND THE DEPARTMENT OF FINANCE, BUT IT'S WORKING VERY WELL FOR US.

MOVING ON TO OUR NEXT REPORT, THIS IS A REVIEW OF OUR OPERATIONAL EXPENSES AS OF FEBRUARY 2013. THIS CHART REFLECTS OUR OPERATING EXPENDITURES BY CATEGORY, AND IT DOES A COMPARISON TO THE PRIOR FISCAL YEAR. THESE ARE EXPENDITURES RECORDED THROUGH FEBRUARY. AND THERE ARE SOME LAGS IN OUR OPERATING EXPENDITURES OF ABOUT FOUR TO $600,000.

I JUST WANT TO COVER SOME OF THE VARIANCES FROM ONE FISCAL YEAR TO THE OTHER. IN OUR EMPLOYEE EXPENSES, OUR COSTS HAVE GONE UP BY ABOUT A MILLION DOLLARS, BUT THAT'S BECAUSE AS OF FEBRUARY OF THIS FISCAL YEAR, WE HAD 59 POSITIONS FILLED AS COMPARED TO FEBRUARY OF 2012 WHERE WE HAD 51 POSITIONS

FILLED.

OUR EXTERNAL EXPENSES ARE DOWN. AND WHILE THERE ARE A VARIETY OF FACTORS IMPACTING THAT, THE TWO BIGGEST FACTORS ARE, AS YOU MAY RECALL, WHEN WE BUILT THE 12-13 BUDGET, WE HAD INDICATED THAT WE WOULD TERMINATE OUR I.T. PROGRAM AND CONSULTING COSTS BY FEBRUARY OF 2013. WE ACTUALLY ENDED THE MAJORITY OF OUR I.T. CONTRACTS BY JANUARY OF 2013, AND NOW THAT WORK IS BEING PERFORMED BY TWO STAFF.

ANOTHER CONTRACT IMPACTING THE REDUCTION IN EXPENDITURES IS OUR INTERNATIONAL COLLABORATION SERVICES. WE ACTUALLY CONVERTED THAT TO A POSITION EARLIER THIS FISCAL YEAR.

OUR REVIEW MEETINGS AND WORKSHOPS ARE UP, AND THAT'S BECAUSE OUR SCIENCE STAFF HAS BEEN VERY BUSY HOLDING GRANT WORK GROUP REVIEWS, CDAP MEETINGS, AS WELL AS OTHER WORKSHOPS. SO OVERALL WE'VE HAD ABOUT 15 MEETINGS DURING THE FIRST EIGHT MONTHS OF THIS FISCAL YEAR AS COMPARED TO ABOUT 12 LAST YEAR, AND THE MAJORITY OF THE ONES THAT WE'VE HAD THIS YEAR HAVE BEEN FULL GRANTS WORK GROUP REVIEWS.

AND OUR MEMBERSHIP AND TRAVEL IS ACTUALLY DOWN THIS FISCAL YEAR, AND THAT WAS BECAUSE WE HAD ONETIME COSTS LAST YEAR FOR THE WORLD STEM CELL

SUMMIT.

OUR NEXT CHART REFLECTS EXPENDITURES BY COST CENTER. AND WHAT I CAN SAY ABOUT OUR EXPENDITURES AT THIS TIME IS THAT THEY'RE PRETTY MUCH ON TRACK. WE EXPECT EXPENDITURES TO COME IN AT ABOUT 90 TO 95 PERCENT OF WHAT WAS BUDGETED.

OUR NEXT TWO CHARTS REFLECT OUR 6-PERCENT ADMINISTRATIVE CAP. FROM WHAT I REPORTED LAST TIME, THERE REALLY ISN'T ANY MAJOR CHANGES. I STILL ANTICIPATE THAT WE WILL BE SPENDING ABOUT $14 MILLION FOR GENERAL GRANT EXPENDITURES IN THIS FISCAL YEAR, LEAVING US A LITTLE BIT OVER $104 MILLION TO CARRY US FROM 13-14 AND BEYOND. AND IN THIS NEXT CHART, IT REFLECTS THAT OUR EXPENDITURES, OUR FORECAST, WE SHOULD BE ABLE TO GO THROUGH THE 20-21 FISCAL YEAR.

AND THE LAST THING THAT I WANTED TO COVER IS OUR 13-14 BUDGET DEVELOPMENT. WE DID DISTRIBUTE THE TEMPLATES AND THE CURRENT YEAR FISCAL DATA TO OUR COST CENTER MANAGERS IN JANUARY. WE GAVE THEM A VERY SHORT TURNAROUND TIME, AND THEY TURNED THOSE BACK TO US IN FEBRUARY. AND WE'VE BEEN DEVELOPING THE BUDGET, AND WE'VE HAD SOME INTERNAL MEETINGS WITH THE PRESIDENT AND THE CHAIR. WE WILL FINALIZE THOSE BUDGETS AND BRING THEM TO THE FINANCE

SUBCOMMITTEE IN APRIL. AND ONCE WE GET INPUT FROM THAT MEETING, WE WILL PREPARE THE FINAL DOCUMENTS AND BRING THEM TO YOU FOR YOUR REVIEW AND APPROVAL IN MAY.

THAT CONCLUDES MY PRESENTATION. ARE THERE ANY QUESTIONS? THANK YOU VERY MUCH. I APOLOGIZE FOR MY VOICE.

MS. SAMUELSON: CAN I JUST ASK. DO WE HAVE ALL THESE CHARTS IN OUR MATERIALS OR ACCESS TO THEM?

MS. BONNEVILLE: THEY'RE NOT IN THE BINDERS.

MS. SAMUELSON: THANKS.

DR. TROUNSON: CHAIR, I WONDER IF I CAN INVITE RICK KELLER TO REPORT THE COMPLETION OF OUR MAJOR FACILITIES PROGRAM TO YOU?

DR. KELLER: GOOD MORNING. TODAY WE'RE GOING TO REVIEW THE FINAL OUTCOMES OF THE 2008 MAJOR FACILITIES GRANTS. THAT INCLUDES A REVIEW OF THE OBJECTIVES, OUR PROCESS, AND, OF COURSE, SOME OF THE OUTCOMES.

THAT PROGRAM INVOLVED THE COMMITMENT OF $271 MILLION IN CIRM FUNDING SPLIT BETWEEN CONSTRUCTION AND EQUIPMENT. THE APPLICANTS COMMITTED AN ADDITIONAL $520 MILLION. OVERALL THE

CIRM FUNDING COMMITTED TO THE PROJECT REPRESENTS 9 PERCENT OF THE TOTAL FUNDS AUTHORIZED BY PROP 71.

THE MAJOR FACILITIES OBJECTIVES DEALT WITH THREE: NEW FACILITIES THAT WERE FREE OF FEDERAL RESTRICTIONS THAT WERE OMINOUS AT THE TIME, EXPANSION OF RESEARCH CAPACITY, AND TO IMPROVE EXISTING FACILITIES. AND TO BORROW A TERM FROM DR. TROUNSON'S PRESENTATION, I THINK NEW FACILITIES ARE ALSO A MORPHOGEN AS THEY ENABLE CHANGE IN A BIG WAY IN THE STRATEGIC PLAN.

THE GRANT PROCESS BEGAN WITH A REVIEW BY THE GRANTS WORKING GROUP WHERE APPLICANTS' PROGRAMS WERE EVALUATED ON THREE PROGRAMMATIC LEVELS ON A SCIENTIFIC BASIS: BASIC RESEARCH, TRANSLATIONAL RESEARCH, AND PRECLINICAL RESEARCH. IF AN APPLICANT DEMONSTRATED COMPETENCE IN THREE OF THESE, THEY WERE ELIGIBLE FOR A CIRM INSTITUTE GRANT OF UP TO $50 MILLION; COMPETENCE IN TWO, A CENTER FOR EXCELLENCE OF A $25 MILLION GRANT; AND COMPETENCE IN ONE ELEMENT WAS CLASSIFIED A SPECIAL PROGRAM WITH GRANTS UP TO $10 MILLION.

ONCE THE GRANTS WORKING GROUP COMPLETED THEIR EVALUATION, 12 APPLICATIONS WERE FORWARDED TO THE FACILITIES WORKING GROUP. THE FACILITIES WORKING GROUP DEVELOPED ITS OWN CRITERIA FOR

EVALUATION AND SCORING OF THE APPLICANTS WHICH BECAME THE BASIS FOR ALLOCATION OF FUNDING.

IN TOTAL, THE MATCHING AND LEVERAGE FUNDS PROPOSED BY THE GRANTEES AMOUNTED TO $519 MILLION ALONG WITH THE CIRM FUNDS, GIVING A TOTAL OF $791 MILLION.

IN OUR PROCESS AFTER APPROVAL OF THE GRANTS, WE DEVELOPED NOTICE OF GRANT AWARDS FOR THOSE APPLICATIONS THAT WERE APPROVED. IT'S IMPORTANT TO NOTE THAT MOST OF THESE WERE ISSUED INITIALLY AFTER THE APPROVALS, BUT SOME, BECAUSE OF FINANCING ISSUES, WERE SOMEWHAT DELAYED. WE ALSO RECEIVED QUARTERLY REPORTS FROM ALL OF THE GRANTEES SHOWING PROGRESS IN CONSTRUCTION. IF THERE WERE CHANGES THAT NEEDED TO BE MADE IN THE BUDGET OR FOR CONSTRUCTION OR FOR EQUIPMENT, THESE WERE SUBMITTED TO CIRM FOR APPROVAL. WE ALSO CONDUCTED ON-SITE VISITS TO ALL OF THE GRANTEES TO REVIEW BOTH THEIR PROGRAM AND BUILDING ISSUES. AND PURSUANT TO THE PROP 71 REQUIREMENTS, AN INDEPENDENT AUDIT WAS PREPARED FOR EACH OF THE TWELVE GRANTS.

IN TOTAL, THE APPLICANTS PROPOSED 500,000 ASSIGNABLE SQUARE FEET OF SPACE TO BE BUILT. BASED ON ACTUAL AS-BUILT DRAWINGS, THAT NOW AMOUNTS TO ABOUT 477,000 ASSIGNABLE SQUARE FEET. THAT VARIANCE

IS MAINLY BECAUSE APPLICATIONS RELIED ON ESTIMATES AND WE ACTUALLY HAVE THE ACTUAL ARCHITECTURAL DRAWINGS AND HAVE DONE THE TAKEOFFS. IN ALL CASES THE FULL SCOPE OF WORK THAT WAS ANTICIPATED WAS COMPLETED.

WITH REGARD TO THE TOTAL ACTUAL AMOUNT SPENT, THE 791 MILLION THAT WAS THE BUDGET AT THE TIME APPLICATIONS WERE APPROVED, THE ACTUAL AMOUNT SPENT IS 758, INDICATING THAT THE PROGRAM OVERALL WAS 4.2 PERCENT OR $33 MILLION UNDER BUDGET. IN SOME CASES APPLICANTS REDIRECTED THESE FUNDS TO EITHER ADDITIONAL EQUIPMENT PURCHASES OR AS SAVINGS.

WITH REGARD TO THE COMPLETION OF PROJECTS, SIX OF THE 12 PROJECTS WERE COMPLETED WITHIN THE APPROVED TIMELINE. FOUR PROJECTS WERE DELAYED BECAUSE OF FINANCIAL ISSUES RELATED TO THE MATCHING OR LEVERAGE FUNDS THAT WERE PROVIDED BY THE GRANTEES. THOSE INCLUDED STATE FUNDS WHICH WERE ACTUALLY FROZEN AT THE TIME BECAUSE OF THE STATE'S FISCAL CONDITION. ONE PROJECT WAS DELAYED DUE TO A SITE CHANGE WHICH ACTUALLY IMPROVED THE EFFECTIVENESS OF THAT PROJECT MOVING IT FROM OFF-CAMPUS TO AN ON-CAMPUS LOCATION. FINALLY, ONE PROJECT WAS DELAYED BECAUSE OF LOGISTICAL AND REGULATORY ISSUES SURROUNDING ANIMAL CARE SPACES.

THE OTHER OUTCOMES THAT WERE IDENTIFIED AS PART OF THE OBJECTIVES WERE TO INCLUDE ENERGY EFFICIENCY IN THESE BUILDINGS. ALL OF THE GRANTS ACHIEVED THEIR LEED CERTIFICATION OBJECTIVES. WE ALSO ACHIEVED THE GOAL OF AT LEAST 50 PERCENT OF THE EXPENDITURES RELATED TO CALIFORNIA SUPPLIERS BY A FAR MARGIN, I WOULD SAY. THERE WERE NO EXCEPTIONS NOTED IN THE INDEPENDENT AUDITS, AND AS A FOLLOW-UP, WE WILL BE SEEING STAFF VISITS TO ALL OF THESE FACILITIES.

JUST TO GIVE YOU SOME BRIEF IMAGES, THE SPECIAL PROGRAMS AT MERCED ON THE LEFT, A RENOVATION. SANTA CRUZ WAS ONE FLOOR OF A BUILDING ON THE RIGHT, AND SANTA BARBARA WAS ALSO A RENOVATION. THE TWO CENTER OF EXCELLENCE PROJECTS WERE $40 MILLION OF CIRM FUNDS. THE UC BERKELEY FACILITY WAS TWO FLOORS OF A BUILDING THAT WAS UNDER CONSTRUCTION, AND THE BUCK INSTITUTE WAS A NEW FACILITY.

OF THE INSTITUTE PROJECTS, THE UCLA PROJECT ON THE LEFT WAS THE LIFE SCIENCES BUILDING, AND OUR PROJECT IS ONE FLOOR OF THAT BUILDING. THE UNIVERSITY OF SOUTHERN CALIFORNIA PROJECT IS AN ADDITION, AND THEN UC DAVIS ACTUALLY RENOVATED AN HISTORICAL BUILDING FROM THE OLD STATE FAIR SITE

INTO A LABORATORY BUILDING.

DR. PULIAFITO: USC IS A NEW BUILDING.

DR. KELLER: IT'S AN ADDITION.

DR. PULIAFITO: CONNECTED TO ANOTHER BUILDING, BUT IT'S A NEW BUILDING. I KNOW. I'M THERE.

DR. KELLER: THE LAST FOUR OF THE INSTITUTES, THE STANFORD PROJECT, WHICH WAS ROUGHLY 20 PERCENT OF THE OVERALL PROGRAM OF $200 MILLION, I NOTE THAT THE ARTWORK WAS NOT PART OF THE PROJECT. IT WAS NOT PART OF THE LEVERAGE. IRVINE ON THE RIGHT, THE SAN FRANCISCO PROJECT, AND THE CONSORTIUM PROJECT IN SAN DIEGO.

I THINK THE FACT THAT ALL 12 PROJECTS WERE COMPLETED DESPITE SOME OF THE CHALLENGES I THINK IS A CREDIT TO ALL THE PEOPLE WHO WORKED ON THE PROJECTS. IF YOU HAVE ANY QUESTIONS, I'D BE GLAD TO ANSWER THEM.

DR. TROUNSON: SO, BOARD, JUST BEFORE YOU DO, I WANTED TO THANK PARTICULARLY RICK FOR A HUGE EFFORT TO PUT THIS WHOLE PROGRAM TOGETHER. HE WAS WORKING FULL TIME ON THIS PROJECT UP UNTIL A FEW YEARS AGO AND HAS CONTINUED TO BE PART TIME SEEING US ALL THE WAY THROUGH THIS. HE CAME FROM THE UC SYSTEM. HE'S DONE A PHENOMENAL JOB, AND WE'VE ALL

APPRECIATED THE PROFESSIONAL EXPERTISE THAT HE'S PROVIDED.

CHAIRMAN THOMAS: THANKS VERY MUCH, RICK. ARE THERE QUESTIONS? MR. JUELSGAARD.

DR. JUELSGAARD: DR. KELLER, ON ONE OF THE SLIDES YOU HAD INDICATED THAT THERE WAS A $33 MILLION SAVINGS IN TERMS OF WHAT WAS BUDGETED. AND IN RESPONSE TO THAT, YOU INDICATED THAT PART OF IT WENT TO PURCHASE ADDITIONAL EQUIPMENT, BUT ALSO PART OF IT WAS SAVINGS. SO OUT OF THAT SAVINGS, HOW MUCH OF THE SAVINGS CAME BACK TO CIRM AS OPPOSED TO GOING TO THE INSTITUTION?

DR. KELLER: NONE OF IT CAME BACK TO CIRM SINCE OUR GRANT ADMINISTRATION POLICY HAD SPECIFIED THAT SAVINGS WOULD ACCRUE TO THE GRANTEES. AND THE ISSUE THERE RELATED TO THE ICOC'S REVIEW OF THAT PROGRAM AND SAID THAT THEY WANTED TO INCENTIVIZE PROGRAMS TO SAVE, BUT AT THE SAME TIME DID NOT WANT TO SHORT THEM SINCE NONE OF THE APPLICANTS RECEIVED THE FULL AMOUNT THAT THEY HAD REQUESTED.

DR. JUELSGAARD: THANKS.

CHAIRMAN THOMAS: OTHER QUESTIONS? MR. SHEEHY.

MR. SHEEHY: I JUST WANT TO ECHO ALAN'S COMMENTS, DR. TROUNSON. RICK HAS DONE A PHENOMENAL

JOB FOR US. AND THINK OF 12 SITES AND WE'RE NOT TALKING ABOUT OVERAGES. WE'RE TALKING ABOUT SAVINGS. JUST ALL OF STAFF AND RICK, I THINK WE SHOULD REALLY APPLAUD THE WORK THAT THEY'VE DONE. THIS IS AMAZING. THIS WAS ONE OF OUR KEY GOALS WHEN PROP 71 WAS PASSED, AND WE CREATED AN ENORMOUS AMOUNT OF NEW SCIENTIFIC CAPACITY IN CALIFORNIA WITH THIS.

(APPLAUSE.)

DR. KELLER: ANY OTHER QUESTIONS?

MS. SAMUELSON: WHAT'S THE PROTOCOL IF WE WANT TO GO SEE ONE OF THEM IN THE AREA OF ONE OF THE BUILDINGS, FACILITIES?

DR. TROUNSON: IF YOU WANT TO SEE THEM, I THINK IT'S ONLY A MATTER OF CONTACTING THE HEAD OF THE STEM CELL CENTER THERE OR WE COULD HELP ARRANGE IT. THEY'RE FANTASTIC BUILDINGS. THEY'RE JUST WONDERFUL PLACES. AND TO SEE ALL THE PEOPLE WORKING TOGETHER CONNECTED, IT'S JUST MAGNIFICENT. AND IT REALLY DOES SAY SOMETHING VERY SPECIAL. LET'S HOPE WE KEEP THEM ALL FUNDED AND REALLY ON PURPOSE FOR THE NEXT COUPLE OF DECADES AT THE VERY LEAST.

CHAIRMAN THOMAS: ANY OTHER COMMENTS ON ANY OF THE PARTS OF DR. TROUNSON AND TEAM'S PRESENTATION? THANK YOU.

I HAVE A NUMBER OF COMMENTS, NUMBER OF THINGS TO SHARE WITH YOU IN THE CHAIR'S REPORT, BUT I'M GOING TO DEFER THAT TO A BIT LATER IN TODAY'S MEETING. I WANT TO PROCEED NOW TO ITEM 6, WHICH IS IN YOUR BINDER, DEALING WITH THE POLICIES TO IMPLEMENT THE CONCEPT PROPOSAL ADOPTED BY THE BOARD IN RESPONSE TO THE IOM REPORT.

JUST RECAPPING, THOUGH IT'S NOT NECESSARY, THE IOM, AFTER LENGTHY REVIEW, PUBLISHED ITS REPORT ON CIRM, PRESENTED THAT REPORT AT OUR DECEMBER BOARD MEETING THROUGH ITS CHAIR DR. HAROLD SHAPIRO. WE, IN TURN, HAD A WORKSHOP ON JANUARY 23D IN WHICH WE DISCUSSED THAT IOM REPORT AND IN PARTICULAR HAD A FOUR-PLUS HOUR DISCUSSION ON A PLAN THAT I PUT TOGETHER WHICH SOUGHT TO COMPREHENSIVELY ADDRESS ALL ASPECTS OF THE IOM PROPOSAL IN ONE FASHION OR ANOTHER.

AS I SAID AT THE TIME, IT WAS A PLAN THAT THERE WAS SOMETHING FOR EVERYBODY, BUT NOBODY WAS FULLY HAPPY WITH, WHICH SOMETIMES IS KIND OF THE BEST RESULT. AND AT THE CONCLUSION OF THAT SESSION, WE HAD A VOTE IN WHICH THE BOARD ADOPTED THE PLAN ON A 23-0 VOTE WITH ONE ABSTENTION.

WE AT THE CONCLUSION OF THAT DIRECTED THE TEAM TO DEVELOP AMENDMENTS TO EXISTING POLICIES,

BYLAWS, AND REGULATIONS THAT WOULD ALLOW US TO IMPLEMENT THE CHANGES, WHICH CHANGES WE'RE GOING TO HAVE FOR A ONE-YEAR TRIAL PERIOD TO SEE HOW EVERYTHING WORKS OUT.

THE TEAM, WHICH CONSISTED OF MEMBERS OF BOTH THE OFFICE OF THE CHAIR AND THE OFFICE OF THE PRESIDENT, WORKED VERY HARD IN DEVELOPING SIX DIFFERENT RECOMMENDATIONS TO IMPLEMENT VARIOUS ASPECTS OF THE PLAN. AND IT IS, I THINK, NOT ONLY DID THEY COME UP WITH VERY GOOD RESULTS AFTER A LOT OF HARD WORK, BUT I CAN REPORT TO THE BOARD IT WAS A VERY PRODUCTIVE EXERCISE IN TEAMWORK BETWEEN THE OFFICES OF THE CHAIR AND THE OFFICES OF THE PRESIDENT, HAVING HEARD FROM ALL MEMBERS OF BOTH GROUPS THAT IT REALLY WAS A VERY NICE AND HIGHLY COLLABORATIVE EXERCISE.

SO THAT'S KIND OF THE PREMISE HERE. WHAT WE'RE GOING TO DO TODAY IS TO HEAR IN TURN THE DESCRIPTION OF THE VARIOUS ASPECTS OF THE PLAN THAT REQUIRE BOARD VOTE. THEY'RE GOING TO BE PRESENTED VARIOUSLY BY DIFFERENT FOLKS AS WE GO THROUGH HERE.

THE FIRST ONE THAT WE'RE GOING TO ADDRESS IS IN RESPONSE TO ONE OF THE CENTRAL CONCERNS OF THE IOM, THAT THERE WERE PERCEIVED CONFLICTS OF INTEREST ON OUR BOARD BY VIRTUE OF THE FACT THAT WE HAVE A

NUMBER OF INSTITUTIONS REPRESENTED BY VOTING BOARD MEMBERS. YOU WILL RECALL HOW WE CHOSE TO DEAL WITH THAT ISSUE, WHICH HAD TO DO WITH THE MEMBERS FROM THE 13 INSTITUTIONS IN QUESTION ABSTAINING ON ALL GRANT VOTES GOING FORWARD. WE'VE ACTUALLY REFINED THAT TO MAKE IT, I THINK, A LITTLE CLEANER AND IMPROVED.

MR. HARRISON WILL GIVE YOU NOW A REVIEW OF THE MATERIAL YOU HAVE ON THAT RECOMMENDATION. AND I SHOULD NOTE AT THE OUTSET EACH OF THESE RECOMMENDATIONS REQUIRES A VOTE OF THE BOARD. WHAT WE'RE GOING TO DO IS WALK THROUGH EVERYTHING AND COME BACK AND DO THE VOTING AT THE TAIL END OF THE DISCUSSION OF ALL SIX. SO, MR. HARRISON, THE FIRST ITEM, PLEASE.

MR. HARRISON: I WILL TRY TO SPEAK DIRECTLY INTO THE MICROPHONE.

MS. LANSING: I'M HEARING YOU MUCH BETTER. I'VE BEEN ON SINCE 9:30.

MR. HARRISON: THANKS VERY MUCH. GOOD MORNING, EVERYONE. AS CHAIR THOMAS SAID, THIS WAS A COLLABORATIVE EFFORT, AND THE TEAM MEMBERS WHO PARTICIPATED IN DEVELOPING A POLICY FOR YOUR CONSIDERATION TODAY TO ADDRESS THE PERCEPTION OF CONFLICTS OF INTEREST INCLUDED MARIA BONNEVILLE,

PAUL STEIN, IAN SWEEDLER, SCOTT TOCHER, AND MYSELF.

AS CHAIR THOMAS SAID, THE GOAL OF THE GROUP WAS TO PROPOSE A POLICY TO IMPLEMENT THE CONCEPT PROPOSAL THAT WAS APPROVED BY THE BOARD AT YOUR LAST MEETING. JUST AS A REMINDER, THE CONCEPT ENTAILED THE FOLLOWING. THE 13 MEMBERS APPOINTED FROM INSTITUTIONS THAT ARE ELIGIBLE FOR CIRM FUNDING SHOULD ABSTAIN FROM VOTING ON ALL APPLICATIONS FOR RESEARCH FUNDING, NOT JUST APPLICATIONS SUBMITTED BY THEIR OWN INSTITUTION.

THE COROLLARY TO THAT WAS THAT UNLESS THEY OTHERWISE HAVE A CONFLICT OF INTEREST, THE 13 MEMBERS SHOULD BE ABLE TO ABLE TO PARTICIPATE IN THE DISCUSSION AND OFFER THEIR EXPERTISE TO THEIR FELLOW BOARD MEMBERS.

TO IMPLEMENT THIS PLAN, WE PROPOSE TO AMEND THE BYLAWS, AND THE ACTUAL AMENDMENTS ARE INCLUDED IN YOUR BINDER BEHIND TAB 6, ATTACHMENT 1.

THE CHALLENGE FOR THE DRAFTING GROUP WAS TO TRY TO FIND A SOLUTION THAT ADDRESSED THE BOARD'S CONCEPT PROPOSAL WHILE RECOGNIZING THE QUORUM CHALLENGES THAT IT POTENTIALLY PRESENTED. AND BY THAT WHAT I MEAN IS THAT QUORUM IS DEFINED TO MEAN THOSE MEMBERS WHO HAVE BEEN APPOINTED, WHO HAVE TAKEN THE OATH OF OFFICE, AND WHO DO NOT HAVE A

CONFLICT OF INTEREST. SO WHEN A MEMBER ABSTAINS FROM PARTICIPATING IN A VOTE, HE OR SHE IS INCLUDED IN THE QUORUM. AND WHAT THAT CAUSES IS A CHALLENGE BECAUSE IN ORDER TO TAKE ACTION, WE NEED TO HAVE THE AFFIRMATIVE VOTE OF A MAJORITY OF A QUORUM. SO EFFECTIVELY AN ABSTENTION UNDER CERTAIN CIRCUMSTANCES REALLY COUNTS AS A NO VOTE. THAT OBVIOUSLY POSED A CHALLENGE FOR US.

SO TO ADDRESS THAT, WE WOULD PROPOSE TO DO THE FOLLOWING. WE WOULD ESTABLISH A STANDING SUBCOMMITTEE OF THE BOARD, WHICH WE WOULD CALL THE APPLICATION REVIEW SUBCOMMITTEE. THAT SUBCOMMITTEE WOULD BE COMPOSED OF 16 MEMBERS OF THE BOARD, THE PATIENT ADVOCATES, THE LIFE SCIENCE MEMBERS, AND THE CHAIR AND THE STATUTORY VICE CHAIR, WITH THE 13 MEMBERS APPOINTED FROM UNIVERSITIES AND NONPROFIT RESEARCH INSTITUTIONS ACTING AS EX OFFICIO MEMBERS. AND OUR BYLAWS DEFINE EX OFFICIO TO MEAN THAT YOU CAN PARTICIPATE PROVIDED YOU DON'T HAVE A CONFLICT, BUT YOU'RE NOT ENTITLED TO VOTE.

THE SUBCOMMITTEE WOULD MEET CONCURRENTLY WITH THE BOARD WHENEVER THE BOARD IS PRESENTED WITH APPLICATIONS FOR RESEARCH FUNDING. AND THE SUBCOMMITTEE'S CHARGE WOULD BE TO CONSIDER THE GRANTS WORKING GROUP'S RECOMMENDATIONS, TO ENGAGE IN

PROGRAMMATIC REVIEW, AND TO MAKE FINAL DECISIONS ON APPLICATIONS FOR RESEARCH FUNDING.

THE ADVANTAGE OF THIS APPROACH IS THAT OUR QUORUM WOULD THEN BE BASED ON 16 MEMBERS RATHER THAN 29. AND WE WOULD ENSURE THAT ALL THE MEMBERS HAVE THE OPPORTUNITY TO PARTICIPATE, BUT ONLY THOSE 16 WOULD BE ELIGIBLE TO VOTE. SO THAT'S THE PROPOSAL TO IMPLEMENT THE BOARD'S CONCEPT PROPOSAL TO ADDRESS THE PERCEPTION OF CONFLICTS OF INTEREST. I'D BE HAPPY TO ANSWER ANY QUESTIONS. DR. PULIAFITO.

DR. PULIAFITO: WHEN ARE WE GOING TO MOVE? ARE WE GOING TO MOVE ON EACH ONE OF THESE INDIVIDUALLY OR WHAT?

CHAIRMAN THOMAS: I THINK WE WERE GOING TO WAIT TILL WE GET THROUGH ALL SIX AND THEN COME BACK AND VOTE.

MR. SHESTACK: I'M SORRY, BUT THE QUESTION WAS ARE WE VOTING ON THEM INDIVIDUALLY?

CHAIRMAN THOMAS: WE WILL BE VOTING ON THEM INDIVIDUALLY, BUT AT THE TAIL END OF EVERYTHING.

MR. SHESTACK: BUT IF YOU HAVE QUESTIONS ABOUT A PARTICULAR ONE, YOU SHOULD ASK THEM NOW.

CHAIRMAN THOMAS: CORRECT.

MR. SHESTACK: SO I WOULD JUST POINT OUT,

I WOULD REMIND EVERYBODY THAT THIS IS A TRIAL THAT WILL LAST PERHAPS A YEAR. I'D ALSO POINT OUT THAT THIS PUTS A RATHER UNDUE STRESS. THE IOM TALKED TO EVERYONE EXHAUSTIVELY, BUT THEY FAILED TO TALK TO ANY MEMBERS OF THE ADVOCATE COMMITTEE ON THE BOARD. THIS PUTS A BIZARRE STRESS ON THE ADVOCATE MEMBERS OF THE BOARD, MANY OF WHOM ACTUALLY CARE FOR SICK PEOPLE OR ARE SICK THEMSELVES. I, FOR INSTANCE, WILL BE AT FOUR MEETINGS FOR CIRM IN THE MONTH OF MARCH. THAT'S ABSURD.

NOW NONE OF US REALLY CAN AFFORD TO EVER MISS A GRANTS REVIEW MEETING, OR THE PEOPLE OF CALIFORNIA WON'T REALLY HAVE ANYBODY REPRESENTING THEM OTHER THAN INDUSTRY WHEN THESE VOTES ARE TAKEN BECAUSE THE DEANS CAN'T VOTE. SO I JUST WANT TO POINT OUT THAT THIS DOES PUT A LARGE STRESS, AND ADVOCATES WILL HAVE TO MAKE A MUCH MORE SIGNIFICANT EFFORT TO ATTEND ALL THE GRANT WORKING REVIEW SESSIONS, WHICH ARE OFTEN ALSO TWO-DAY MEETINGS, AND THERE ARE OCCASIONALLY MORE THAN ONE OF THEM IN A MONTH.

CHAIRMAN THOMAS: THANK YOU, MR. SHESTACK. ANY OTHER COMMENTS ON THIS PARTICULAR ITEM? OKAY. MR. HARRISON, WHY DON'T YOU STAY UP THERE. LET'S GO ON TO THE --

DR. PRICE: CAN I ASK A QUESTION ON THE PARTICIPATION IN DISCUSSION IF YOU DON'T HAVE A CONFLICT? EXPAND ON WHAT IT MEANS NOT TO HAVE A CONFLICT. IF YOU HAVE 30 APPLICATIONS FOR A GRANT AT A MEETING, AND YOU HAVE FROM YOUR INSTITUTION ONE GRANT IN THAT, ONE APPLICATION.

MR. SHESTACK: YOU'RE SAYING IN THAT TIER?

DR. PRICE: YES. DOES THAT MEAN YOU'RE EXCLUDED FROM ANY DISCUSSION?

MR. HARRISON: NO. SO THIS WOULD OPERATE THE SAME WAY IT OPERATES UNDER THE CURRENT SYSTEM. SO, FOR EXAMPLE, IF YOU HAVE APPLICATIONS FOR BASIC BIOLOGY WHERE THE BOARD IS MAKING MULTIPLE AWARDS AND YOUR INSTITUTION HAS SUBMITTED ONE APPLICATION, YOU CAN PARTICIPATE IN THE BOARDS'S DISCUSSION OF ALL OF THE APPLICATIONS WITH THE EXCEPTION OF THE ONE FROM YOUR INSTITUTION.

THE ONE EXCEPTION TO THAT IS A CIRCUMSTANCE IN WHICH THERE IS A SINGLE AWARD. AND IN THOSE CASES, WE CONSIDER ALL OF THE MEMBERS OF THE BOARD WHO HAVE AN INTEREST IN ANY SINGLE APPLICATION TO BE DISQUALIFIED FROM PARTICIPATING IN THE DISCUSSION OF ANY OF THEM. JUST AS WE'VE DONE HISTORICALLY, YOU WILL EACH BE PRESENTED WITH A SHEET THAT IDENTIFIES THOSE APPLICATIONS IN WHICH

YOU HAVE A CONFLICT. AND THOSE ARE THE APPLICATIONS FROM WHICH WE'D ASK YOU TO ABSTAIN FROM EVEN ENGAGING IN THE DISCUSSION.

DR. PRICE: I HAVE ONE OTHER QUESTION ABOUT THE QUORUM. A QUORUM IS A MAJORITY OF THOSE THAT ARE ELIGIBLE?

MR. HARRISON: NO. A QUORUM IS DEFINED AS 65 PERCENT OF ELIGIBLE MEMBERS. ELIGIBLE MEMBERS IS DEFINED TO MEAN THOSE MEMBERS WHO BEEN APPOINTED, WHO'VE TAKEN THE OATH OF OFFICE, AND WHO DO NOT HAVE A CONFLICT OF INTEREST.

DR. PRICE: SO BACK TO JEFF'S POINT. I WANT TO GET BACK TO YOUR POINT. ASIDE FROM THE ADVOCATES, THIS IS GOING TO PUT INCREDIBLE PRESSURE ON ATTENDANCE BECAUSE -- RIGHT?

MR. HARRISON: THERE WILL BE 16 MEMBERS OF THE SUBCOMMITTEE WHO CAN PARTICIPATE IN DECISIONS REGARDING APPLICATIONS FOR FUNDING.

DR. PRICE: JUST OUT OF CURIOSITY, IF YOU WERE TO APPLY THAT AS JUST SORT OF A TEST CASE, TODAY'S GROUPING, WOULD WE HAVE A QUORUM?

MR. HARRISON: WE WOULD. AND THERE ARE TWO DIFFERENT TYPES OF APPLICATIONS COMING TO THE BOARD TODAY FOR THE REPOSITORY AND DERIVATION AWARDS. THERE'S ONLY A SINGLE AWARD. SO ALL OF THE

MEMBERS WHO HAVE AN INTEREST IN ANY SINGLE APPLICATION WOULD BE DEEMED TO BE DISQUALIFIED FROM PARTICIPATING IN THE DISCUSSION OF ANY OF THE APPLICATIONS.

WITH RESPECT TO THE TISSUE COLLECTION, THERE ARE MULTIPLE AWARDS. SO YOU WOULD ONLY BE DISQUALIFIED FROM PARTICIPATING IN AN APPLICATION SUBMITTED BY YOUR OWN INSTITUTION.

DR. PRICE: WE HAVE ENOUGH OF THOSE OTHER SUBCOMMITTEE MEMBERS HERE?

MR. HARRISON: WE DO AT THE MOMENT.

CHAIRMAN THOMAS: YES, DR. LEVIN, THEN SENATOR TORRES.

DR. LEVIN: JAMES, JUST A QUICK QUESTION. ONE OF THE ADDITIONAL STRESSES ON THE PATIENT ADVOCATES IS THAT THEY'RE NOT ABLE TO HAVE ALTERNATES. AS I RECALL, IS THAT BUILT INTO PROP 71? WE CAN'T CHANGE THAT WITH ANY SORT OF ACTION OF THE BOARD?

MR. HARRISON: THAT'S CORRECT. IT'S BUILT INTO THE LAW ITSELF.

MR. TORRES: INTO THE CONSTITUTION ITSELF.

MR. HARRISON: INTO THE STATUTORY PROVISIONS OF PROP 71.

MR. TORRES: WE ALSO HAVE TO REMEMBER THAT

THE IOM WOULD PREFER TO REMOVE ALL THE INSTITUTIONAL MEMBERS OF THIS BOARD, WHICH WE FOUGHT VERY MUCH AGAINST.

NO. 2, THERE WERE SOME EDITORIALS THAT OPINED THAT YOU SHOULD ALSO BE REMOVED FROM THIS BOARD IN ORDER TO CLEARLY STATE TO THE PUBLIC THERE WOULD BE NO PERCEIVED OR REAL CONFLICTS OF INTEREST. THAT'S WHY I FEEL THIS COMPROMISE IS APPROPRIATE. AND, YES, IT DOES PUT PRESSURE, BUT YOU'RE APPOINTED TO SERVE. AND IF YOU CAN'T SERVE, THEN YOU NEED TO RECONSIDER WHAT YOUR FUTURE POSITION SHOULD BE ON THIS BOARD. THAT'S THE MOST IMPORTANT ISSUE, THAT PATIENT ADVOCATES WILL FEEL THE PRESSURE TO ATTEND MORE MEETINGS. QUITE FRANKLY, WE SHOULD.

AND SECONDLY, WE'VE MADE SOME PROVISIONS WITH SB 1064 TO ALLOW MORE REIMBURSEMENT OF EXPENSES AND A SMALL, ALTHOUGH NOT GENEROUS, STIPEND TO THOSE PATIENT ADVOCATES WHO SERVE ON THIS BOARD. THAT WAS NOT A COMPROMISE EASILY ACCEPTED BY THE LEGISLATURE, BUT IT WAS.

THOSE ARE THE FACTORS THAT ARE THERE, BUT CLEARLY I UNDERSTAND THE PRESSURE OF TIME AND THE PRESSURE OF BUSINESS AND PERSONAL BUSINESS THAT NEEDS TO BE ATTENDED TO. BUT AT THE END OF THE DAY, THE BOARD MEMBERS THAT HAVE BEEN APPOINTED TO THIS

BOARD FROM VARIOUS SOURCES, CONSTITUTIONAL OFFICERS AS WELL AS OTHER AREAS, WE JUST NEED TO TAKE OUR ATTENDANCE MUCH MORE SERIOUSLY.

CHAIRMAN THOMAS: MR. SHEEHY.

MR. SHEEHY: WELL, AS SOMEONE WHO TAKES HIS ATTENDANCE VERY SERIOUSLY, I MUST SAY I DON'T THINK ANY OF THE OTHER PATIENT ADVOCATES TAKE THEIR SERVICE LIGHTLY. IT IS ENORMOUSLY DIFFICULT AND EXTREMELY STRESSFUL TO BE ON THIS BOARD. AND, YOU KNOW, TO SOMEHOW SUGGEST THAT WE SHOULD EN MASSE RESIGN BECAUSE WE CAN'T DEVOTE OUR LIVES TO THIS IS KIND OF --

MR. TORRES: I'M NOT ASKING FOR YOUR RESIGNATION. I'M POINTING OUT WHAT THE VARIABLES ARE THAT PEOPLE ARE LOOKING AT.

MR. SHEEHY: YOU RECEIVE A SALARY.

MR. TORRES: YES, I DO RECEIVE A SALARY.

MR. SHEEHY: I DON'T THINK THE COMPARISON YOU ARE MAKING TO THE REST OF US IS APT.

MR. TORRES: SO DO YOU FROM THE UNIVERSITY OF CALIFORNIA. YOU RECEIVE A SALARY. SO WE BOTH RECEIVE SALARIES. I'M NOT ASKING FOR YOUR RESIGNATION OR ANY OTHER PATIENT ADVOCATE'S RESIGNATION. I'M JUST POINTING OUT THAT WE ARE IN A VERY SERIOUS NEXT FEW STEPS. AND AFTER SPENDING A

DAY IN THE LEGISLATURE YESTERDAY, I WANT TO MAKE SURE THAT WE ARE TAKING THESE RECOMMENDATIONS SERIOUSLY. AS I SAID TO THE LIEUTENANT GOVERNOR AND THE PRESIDENT OF THE SENATE, TO THE TREASURER, TO THE CONTROLLER, AND TO MEMBERS OF BOTH PARTIES OF BOTH POLICY COMMITTEES THAT WE DO TAKE THESE RECOMMENDATIONS SERIOUSLY. AND I HOPE THAT WE DO PROCEED AS I INDICATED TO THEM YESTERDAY, THAT THESE RECOMMENDATIONS WOULD BE VOTED UPON TODAY BY THIS BOARD.

MS. LANSING: I THINK THIS IS OBVIOUSLY A VERY DIFFICULT THING, BUT WE DID COMMISSION THE REPORT, AND THE REPORT CAME BACK WITH THESE RECOMMENDATIONS. AND THEN AT THE LAST MEETING WE WENT THROUGH ALL OF THIS. AND THOUGH I FEEL WE ALL HAVE INCREDIBLY MIXED FEELINGS ABOUT THIS --

CHAIRMAN THOMAS: SHERRY, YOU'VE GOT A LITTLE STATIC. IT'S NOT YOU. APPARENTLY IT'S ON OUR END. PLEASE GO AHEAD.

MS. LANSING: I DON'T KNOW WHAT YOU HEARD. I'LL START AGAIN. I KNOW HOW DIFFICULT THIS IS FOR ALL OF US. REPRESENTING PATIENT ADVOCATES OR REPRESENTING THE INSTITUTIONS, THIS IS VERY, VERY DIFFICULT. BUT WE DID COMMISSION THE REPORT. WE DID ASK FOR IT. AND WE DID SPEND THE LAST MEETING,

I THINK THE BETTER PART OF THE MEETING, ALMOST THE WHOLE DAY, ON BASICALLY AGREEING TO THE RECOMMENDATIONS, MAYBE RELUCTANTLY, BUT AGREEING TO THEM FOR A TRIAL PERIOD.

WHEN I READ THEM YESTERDAY, I THOUGHT WE WERE JUST CODIFYING WHAT WE HAD ALREADY AGREED ON. AND I DO THINK THAT IF WE DON'T DO THIS, WE'RE GOING TO FACE REAL DIRE CONSEQUENCES WITH THE LEGISLATURE AND WITH THE PUBLIC. SO MY STRONG FEELINGS, AFTER READING EVERYTHING, AND I APPRECIATE JAMES GOING THROUGH THIS, IS THAT WE MUST TRY THIS FOR A YEAR. MAYBE WE CAN DO AN EVALUATION IN SIX MONTHS AND SAY THIS PART IS WORKING, THAT PART ISN'T WORKING, AND THAN PASS AGAIN. BUT WE DID SPEND, AS I REMEMBER, ALMOST THE ENTIRE MEETING THE LAST TIME SAYING, OKAY, THIS IS WHAT WE'RE GOING TO DO, AND NOW STAFF GO AND CODIFY IT.

SO I DON'T REALLY SEE ANY CHANGES AS PAINFUL AS IT IS FOR ALL OF US TO GO FORWARD WITH THIS. THIS WAS THE RECOMMENDATIONS THAT CAME OUT FROM AN INDEPENDENT COMMITTEE, AND WE DID PROMISE TO ADDRESS IT.

CHAIRMAN THOMAS: THANK YOU, SHERRY. WE ALL HEARD YOU. THE STATIC WAS FROM MIKES IN HERE AND SOMEHOW THAT DROVE STATIC.

MS. LANSING: I'M REALLY SORRY I'M NOT THERE.

CHAIRMAN THOMAS: PLEASE, WE'RE VERY HAPPY YOU'RE ON BY PHONE. YOU ARE CORRECT. THIS IS BASICALLY CODIFYING EVERYTHING THAT WAS DECIDED. AND IS THERE ANY -- DEAN HAWGOOD.

DR. HAWGOOD: JAMES, I WAS JUST WONDERING WHETHER YOUR GROUP CONSIDERED -- WE'VE HAD SOME DISCUSSION IN THE PAST OF WHEN WE ARE IN CONFLICT WITH A PARTICULAR APPLICATION, THAT WE SHOULD ACTUALLY RECUSE OURSELVES FROM THE ROOM IN ADDITION TO NOT PARTICIPATING, WHETHER YOUR GROUP HAD ANY THOUGHTS ABOUT THAT SO THAT WE HAVE CONSISTENCY.

MR. HARRISON: ABSOLUTELY. YES. AS YOU MAY RECALL, THE BOARD ADOPTED A PROPOSAL FROM THE GOVERNANCE SUBCOMMITTEE LAST YEAR TO REQUIRE MEMBERS NOT ONLY TO DISQUALIFY THEMSELVES WHEN THEY HAVE A CONFLICT, BUT UNDER CERTAIN CIRCUMSTANCES TO LEAVE THE ROOM. AND THOSE CIRCUMSTANCES ARE FAIRLY LIMITED. THEY ARISE WHEN AN APPLICANT SELF-IDENTIFIES BY FILING AN EXTRAORDINARY PETITION OR BY MAKING PUBLIC COMMENT AND A BOARD MEMBER THEN ASKS FOR DEBATE OR DISCUSSION REGARDING THAT PARTICULAR APPLICATION. UNDER THOSE CIRCUMSTANCES, A MEMBER HAS TO LEAVE THE ROOM.

WE'VE AMENDED THE BYLAWS TO APPLY THAT SAME RULE TO THE APPLICATION REVIEW SUBCOMMITTEE. SO IF A CIRCUMSTANCE WERE TO ARISE WHERE YOU HAD A CONFLICT OF INTEREST WITH RESPECT TO AN APPLICATION, THE APPLICANT COMES BEFORE THE BOARD, SELF-IDENTIFIES, MAKES PUBLIC COMMENT, AND A MEMBER OF THE BOARD THEN ASKS FOR BOARD DEBATE REGARDING THAT APPLICATION, AT THAT POINT IN TIME, WE'D ASK YOU TO LEAVE THE ROOM.

MS. SAMUELSON: JAMES, I HAD THOUGHT THAT THE TRADE-OFF WE WERE GOING TO GET WAS IN EXCHANGE FOR LOSING THE VOTES OF THE DEANS, IF YOU WILL, WE ARE GAINING THE EXPERTISE IN THE ROOM AS WE MAKE OUR DECISION. BUT I'M HEARING THAT IT'S LESS PARTICIPATION.

MR. SHESTACK: MAINTAINING THEIR DISCUSSION. AS I UNDERSTAND IT, AND IT IS GOOD TO CLARIFY SO WE REALLY DO UNDERSTAND IT, YOU ARE MAINTAINING THE DISCUSSION AS WE HAVE ALWAYS HAD. THEY WILL BE ABLE TO CHIME IN AND INFORM US AND EACH OTHER ON LARGER AND MORE SPECIFIC ISSUES OF SCIENCE AND THE GRANTS AS BEFORE, NO MORE, NO LESS, BUT THEY WILL NOT BE PERMITTED TO VOTE. AND IN THE INSTANCE WHERE THERE IS A SINGLE PROPOSITION UP FOR FUNDING, PERHAPS OCCASIONALLY, THEY WOULD BE NOT ALLOWED EVEN

TO BE IN THAT DISCUSSION.

MS. SAMUELSON: AND SO THERE'S AT LEAST AS MUCH RECUSAL FILING OUT OF THE ROOM AS WE HAVE HAD. THAT'S DISAPPOINTING TO ME, AND I GUESS I JUST DIDN'T UNDERSTAND THAT. BUT I THOUGHT WE WERE GAINING MORE PARTICIPATION BECAUSE THAT'S THE THING THAT HAS ALWAYS BOTHERED ME, THAT WITH ALL THOSE RECUSALS, WE LOSE THE EXPERTISE.

MR. SHESTACK: THERE IS ONE GAIN, I WOULD POINT OUT, ALTHOUGH IT COMES IN ANOTHER ITEM, BUT IT'S IMPORTANT, I THINK, AND IT'S ACTUALLY -- AND HOPEFULLY WILL MAKE UP FOR SOME OF THE WISDOM THAT WE ARE CODIFYING OUT OF OUR DELIBERATION, WHICH IS THAT STAFF IS ACTUALLY REQUESTED TO TAKE A MORE PROACTIVE POSITION IN RECOMMENDING AREAS AND DISCUSSING WHETHER OR NOT IN PORTFOLIO REVIEW, AND I THINK IT'S GOOD TO HAVE.

SO THERE WILL BE OTHER INFORMATION, NEW INFORMATION, COMING IN KIND OF A PROGRAM -- IN A PLANNED WAY AND THAT CAN'T BE BAD. SO I POINT THAT OUT.

CHAIRMAN THOMAS: AS THERE IS GOING TO BE A LOT OF DISCUSSION ON EACH OF THESE ITEMS, I'M GOING TO TAKE CHAIR'S PREROGATIVE AND REVERSE WHAT I SAID EARLIER. I THINK WE SHOULD ACTUALLY HAVE A

VOTE ON EACH OF THESE IN TURN. BY THE TIME --

DR. PULIAFITO: I'D LIKE TO MOVE THAT WE ACCEPT THIS RECOMMENDATION.

CHAIRMAN THOMAS: MOVED BY DEAN PULIAFITO. IS THERE A SECOND?

MR. JUELSGAARD: I'LL SECOND THE MOTION.

CHAIRMAN THOMAS: OKAY. IS THERE FURTHER BOARD DISCUSSION ON THIS? HEARING NONE, MEMBERS OF THE PUBLIC.

MR. REED: AS SOMEONE WHO DISAGREED WITH THE WHOLE THRUST OF THE IOM REPORT THING, THAT THERE WAS A CONFLICT OF INTEREST BY THIS BOARD'S PRETTY MUCH VERY EXISTENCE, I'VE ALWAYS FELT SINCE DAY ONE THIS WAS A CONVERGENCE OF EXPERTISE, NOT A CONFLICT OF INTEREST. STILL, THE PROBLEM OF THE PERCEPTION HAS BEEN ATTACKING US SINCE DAY ONE, AND IT'S THE ONLY ONE THAT ANYBODY SEEMS TO PAY ATTENTION TO AS A SERIOUS OBJECTION.

SO I REGARD WHAT YOU ARE CONSIDERING NOW AS A SACRIFICE ON THE BOARD, A FURTHER SACRIFICE. YOU ARE ALREADY OVERWORKED AND DRASTICALLY UNDERPAID, HARDLY PAID AT ALL FOR WHAT YOU ARE DOING, BUT THIS IS SOMETHING GOOD THAT YOU ARE DOING.

WHEN I FIRST HEARD THE SUGGESTIONS, I WAS

LIKE DUMBFOUNDED BECAUSE THEY MET EVERY RATIONAL OBJECTION THAT COULD BE MADE. SO I THINK THIS IS A SOLID THING. I THINK IT'S WORTH DOING. I THINK IT WILL BE PAINFUL. I THINK IT WILL BE INCONVENIENT, BUT I THINK IT'S REALLY WORTH DOING TOWARDS THE GREATER GOOD, WHICH IS THE CONTINUED EXISTENCE AND FURTHER, FROM MY OPINION, PART 2 OF THE PROPOSITION 71. I THINK THERE MUST BE A SECOND PART OF THIS. I THINK THIS CLEARS THE WAY OF THE ONLY REMAINING RATIONAL OBJECTION TO IT. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, DON. MR. HARRISON, WILL YOU CALL THE ROLL PLEASE. SORRY. MS. -- ANYONE. MARIA, WILL YOU CALL THE ROLL, PLEASE.

MS. BONNEVILLE: IT CAN BE A VOICE VOTE.

MR. SHESTACK: CALL THE ROLL.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: DAVID BRENNER. ANNE-MARIE DULIEGE. MARCY FEIT.

MS. FEIT: YES.

MS. BONNEVILLE: LEON FINE. MICHAEL GOLDBERG. SAM HAWGOOD.

DR. HAWGOOD: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.
MS. BONNEVILLE: TED KRONTIRIS.
DR. KRONTIRIS: YES.
MS. BONNEVILLE: SHERRY LANSING.
MS. LANSING: YES.
MS. BONNEVILLE: JACOB LEVIN.
DR. LEVIN: YES.
MS. BONNEVILLE: BERT LUBIN.
DR. LUBIN: YES.
MS. BONNEVILLE: MICHAEL MARLETTA. ROBERT PRICE.
DR. PRICE: YES.
MS. BONNEVILLE: FRANCISCO PRIETO. CARMEN PULIAFITO.
DR. PULIAFITO: YES.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: DUANE ROTH.
MR. ROTH: YES.
MS. BONNEVILLE: JOAN SAMUELSON.
MS. SAMUELSON: NO.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: NO.
MS. BONNEVILLE: JONATHAN SHESTACK.
MR. SHESTACK: YES.

MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: EUGENE WASHINGTON. DIANE WINOKUR.
MS. WINOKUR: YES.
CHAIRMAN THOMAS: OKAY. THAT MOTION PASSES. THANK YOU.
GO ON TO ITEM NO. 2 NOW, WHICH IS INVOLVING THE GRANT REVIEW PROCESS. THERE ARE JUST A COUPLE OF PRELIMINARY COMMENTS ON THIS.
I'VE TRIED TO PUT IN PLACE A PROTOCOL HERE WHICH HAS A SIGNIFICANT CHANGE FROM PREVIOUS PRACTICE, WHICH IS SHIFTING PROGRAMMATIC REVIEW FROM THE GRANTS WORKING GROUP TO THE BOARD. THIS CHANGE, AS WELL AS ISSUES SURROUNDING THE INVOLVEMENT OF THE PATIENT ADVOCATES, IS DERIVED FROM THE CONTINUED CONCERN IN THE IOM REPORT ON THE GENERAL THEME OF CONFLICTS OF INTEREST.
HERE, ALTHOUGH IT MIGHT AT FIRST BLUSH

APPEAR THAT THIS HAD TO DO WITH COMMENTS THAT THE IOM HAD ABOUT HOW THE PATIENT ADVOCATES HAVE PERSONAL CONFLICTS BECAUSE OF THE DISEASE OR CONDITION THEY REPRESENTED, THAT WHOLE LINE OF ANALYSIS WAS TROUBLING TO ME FOR A WHOLE VARIETY OF REASONS, NOT THE LEAST OF WHICH EVERY ONE OF US HAS FAMILY MEMBERS, FRIENDS, OR WHATEVER THAT HAVE DISEASES OR CONDITIONS. SO WE'RE ALL VERY CONCERNED, AND THAT DID NOT AT ALL SEEM LIKE A FAIR CRITICISM.

AND INTERESTINGLY ENOUGH, DESPITE THE LANGUAGE IN THE REPORT ON THAT SUBJECT, WHEN IT CAME TO THE NOTION OF PATIENT ADVOCATES IN THE GRANTS WORKING GROUP, THE IOM WAS FINE WITH THAT CONCEPT EXCEPT FOR THE FACT THAT THEY RECOMMENDED THAT NO PATIENT ADVOCATE BOARD MEMBERS SHOULD BE IN THE ROOM AND THAT THE PATIENT ADVOCATES THAT SHOULD BE IN ATTENDANCE AT EACH GRANTS WORKING GROUP MEETING WOULD BE AN ENTIRELY NEW SLATE OF PATIENT ADVOCATES WHO COULD PARTICIPATE, VOTE, ETC. SO THAT CRITICISM WENT AWAY WITH RESPECT TO THAT DISTINCTION.

WHAT THEY REALLY WERE CONCERNED ABOUT AS FAR AS THE PATIENT ADVOCATE BOARD MEMBERS WAS THE CONFLICT OF HAVING BOARD MEMBERS IN THE ROOM VOTING ON THINGS AND THEREBY INFLUENCING POTENTIALLY THE

VOTES OF THE SCIENTISTS IN THE PROGRAMMATIC REVIEW ITSELF.

AND SO TAKING ALL THIS INTO ACCOUNT AND FEELING THAT THERE WERE REAL ADVANTAGES TO HAVING PROGRAMMATIC REVIEW BEING DONE AT THE BOARD IN TERMS OF GIVING THE BOARD FULL DISCUSSION IN THAT ARENA, AS WELL AS THE FACT THAT IT WOULD GREATLY INCREASE THE TRANSPARENCY OF THE PROGRAMMATIC REVIEW PROCESS TO THE GENERAL PUBLIC, WE CAME UP WITH THIS SOLUTION OF MOVING PROGRAMMATIC TO THE BOARD, HAVING THE PATIENT ADVOCATES FROM THE BOARD WHO I INSIST BE IN THE ROOM TO GIVE FULL BENEFIT OF INPUT, HAVE THEM IN THE ROOM AS THEY ALWAYS HAVE BEEN, DO NOT ENTERTAIN THE NOTION OF A SECOND SLATE OF UNRELATED PATIENT ADVOCATES IN THE ROOM. AND THE ONE COMPROMISE HERE, MUCH AS ONE WE HAD IN THE PREVIOUS TOPIC, WOULD BE THAT THE PATIENT ADVOCATES WOULD NOT VOTE IN PROGRAMMATIC REVIEW TO ADDRESS THE CENTRAL CONFLICT OF INTEREST ISSUE IDENTIFIED BY THE IOM.

WHAT WOULD HAPPEN THEN WOULD BE, TAKING A LITTLE BIT OF SCOTT'S THUNDER HERE, BUT I JUST WANTED TO GIVE CONTEXT, THE GRANTS WORKING GROUP WOULD PROCEED, DETERMINE THE SCIENTIFIC ORDERING OF THE PROPOSALS THEY WANTED TO RECOMMEND. THE STAFF WHO WOULD BE IN ALL OF THE GRANTS WORKING GROUP

MEETINGS WOULD ANALYZE THAT, AND THE RESULTS OF THE DELIBERATIONS OF THE GRANTS WORKING GROUP AS WELL AS STAFF RECOMMENDATIONS ON THOSE RESULTS WOULD PROCEED TO THE BOARD. MEMBERS OF THE PATIENT ADVOCATE GROUP IN THE GRANTS WORKING GROUP, HAVING SAT THROUGH -- AND VERY IMPORTANTLY, I FORGOT TO MENTION THE PROPOSAL IS THEY CAN'T VOTE, BUT THEY CAN FULLY PARTICIPATE IN THE DISCUSSIONS. THOSE PATIENT ADVOCATES WOULD THEN BE THE BRIDGE TO THE BOARD SO THAT WHEN WE HAD THE PROGRAMMATIC REVIEW AT THE BOARD ITSELF, IT WOULD BE LED BY THE PATIENT ADVOCATES WHO WOULD HAVE BEEN INFORMED HAVING SAT THROUGH ALL THE RELEVANT PROCEEDINGS. AND THEN THE BOARD WOULD CONDUCT FULL PROGRAMMATIC REVIEW AND WOULD CAST A FINAL VOTE ON PROPOSALS TO BE ADOPTED FOR FUNDING.

SO THAT'S KIND OF THE CONTEXT HERE. WITH THAT, LET ME TURN IT OVER TO MR. TOCHER FOR SPECIFIC REVIEW OF THE AMENDMENTS THAT NEED TO BE MADE TO IMPLEMENT THAT NOTION. I KNOW WE'VE GOT SOME STRONG SENTIMENT ON THIS. I ANTICIPATE AND LOOK FORWARD TO SOME VIGOROUS DEBATE. MR. TOCHER.

MR. TOCHER: THANK YOU, CHAIRMAN THOMAS. I SHOULD HAVE JUST GONE THROUGH MY SLIDES WHILE YOU WERE SPEAKING TO HELP OUT THE DISCUSSION. BEFORE I

BEGIN, I JUST WANT TO -- BEFORE I BEGIN, THOUGH, I WANT TO THANK MY COLLEAGUES DRS. GILL SAMBRANO AND PAT OLSON AS WELL AS THE DEPUTY GENERAL COUNSEL PAUL STEIN AND JAMES HARRISON AND MARIA BONNEVILLE FOR HELPING CRAFT THIS DRAFT POLICY, WHICH ALSO BENEFITED GREATLY AS WELL FROM THE INPUT OF MEMBERS JEFF SHEEHY AND OS STEWARD.

AS J.T. INDICATED, THE CONCEPT PROPOSAL APPROVED BY THE BOARD CONTEMPLATES SHIFTING THE PROGRAMMATIC REVIEW THAT CURRENTLY OCCURS DURING THE GRANTS WORKING GROUP MEETING AND MOVING THAT TO THE BOARD. THERE ARE CERTAIN GUIDING LEGAL PRINCIPLES THAT I WANTED TO JUST RUN OVER REAL QUICKLY THAT SORT OF GAVE US THE FOUR CORNERS OF THE AREA THAT WE HAD TO OPERATE IN IN DRAFTING THIS POLICY.

FIRST ARE THE FUNCTIONS THEMSELVES OF THE GRANTS WORKING GROUP, WHICH IS TO RECOMMEND CRITERIA, STANDARDS, AND REQUIREMENTS FOR CONSIDERING FUNDING APPLICATIONS, TO RECOMMEND STANDARDS FOR AWARD, OVERSIGHT TO THE ICOC, STANDARDS FOR EVALUATION OF GRANTEES TO ENSURE COMPLIANCE AND, FINALLY, OF COURSE, TO REVIEW GRANTS AND MAKE RECOMMENDATIONS FOR AWARDS OF THOSE GRANTS.

PROP 71 ALSO DEFINES THE GRANTS WORKING GROUP MEMBERSHIP IN STATUTE. AND THAT IS AS

COMPRISING FIFTEEN SCIENTIST MEMBERS AND SEVEN PATIENT ADVOCATES FROM THE ICOC. THE PROPOSITION ALSO STATES THAT RECOMMENDATIONS MAY ONLY BE MADE BY A VOTE OF A MAJORITY OF A QUORUM, WHICH, AS YOU HEARD JAMES A FEW MOMENTS AGO SAY, IS AT LEAST 65 PERCENT OF THE MEMBERS ELIGIBLE TO VOTE.

IN ADDITION, THE PROPOSITION ALSO PROVIDES FOR MINORITY REPORTS TO ISSUE FROM A GRANTS REVIEW. AND THAT IS IN THE EVENT OF 35 PERCENT OF THOSE MEMBERS JOINING IN A MINORITY POSITION, THEN A MINORITY REPORT MAY BE MADE TO THE ICOC. SO FROM THIS WE CAN CONCLUDE THAT THE ENTIRE MEMBERSHIP MUST BE INCLUDED IN THE FINAL RECOMMENDATIONS TO THE BOARD AND MUST ALSO PARTICIPATE IN ANY VOTE ON ISSUANCE OF A MINORITY REPORT.

SO WITH THAT, THE POLICY CALLS FOR, FIRST, THE BYLAWS TO PRESCRIBE THE FOLLOWING FUNDING TIERS TO BE INCORPORATED INTO THE INITIAL SCORES AND REVIEWS THAT OCCUR BY THE SCIENTIST MEMBERS PRIOR TO THEM COMING TO THE REVIEW.

TIER I WILL COMPRISE SCORES BETWEEN 75 AND ABOVE AND WILL COMPRISE THOSE RECOMMENDED FOR FUNDING. TIER II WILL BE COMPRISED OF SCORES 65 TO 74 AND WILL REPRESENT APPLICATIONS THAT WERE JUDGED TO BE OF MODERATE SCIENTIFIC QUALITY OR APPLICATIONS

WHERE CONSENSUS ON SCIENTIFIC MERIT COULD NOT BE REACHED AND MAY BE SUITABLE FOR PROGRAMMATIC CONSIDERATION. TIER III, THEN, WILL COMPRISE THE REMAINING APPLICATIONS SCORING 64 AND BELOW AND WILL REPRESENT GRANTS THAT ARE NOT RECOMMENDED FOR FUNDING.

THE GRANTS REVIEW OFFICE WILL INFORM THE REVIEWERS OF THE FUNDING LEVELS IN ADVANCE OF THE GRANTS WORKING GROUP MEETING SO THAT THIS GUIDANCE MAY BE INCORPORATED INTO THEIR REVIEWS AND INITIAL SCORES PRIOR TO COMING TO THE MEETING.

MR. SHESTACK: WHAT WAS THAT AGAIN?

MR. TOCHER: THAT THE GRANTS OFFICE WILL CONVEY THIS TIERED SYSTEM TO THE SCIENTIST MEMBERS AS THEY REVIEW THEIR APPLICATIONS PRIOR TO THE MEETING.

THE REVIEW MEETING WILL THEN BEGIN WITH ALL REVIEWERS ADVISED OF THE SCORING SYSTEM. THE SCIENTIFIC REVIEW WILL BE CONDUCTED AS CURRENTLY PRACTICED WITH SCIENTIFIC MEMBERS DISCUSSING THE GRANTS AND THEN SCORING. IN ADDITION, PATIENT ADVOCATES MAY PARTICIPATE IN THE DISCUSSION, BUT WILL NOT SCORE APPLICATIONS.

AFTER CONSIDERATION OF ALL OF THE APPLICATIONS BY THE SCIENTIST MEMBERS, THOSE MEMBERS

WILL HAVE ONE FINAL OPPORTUNITY TO REVIEW THEIR SCORES AND MAKE ANY CHANGES THEY WISH AS TO ANY GRANT IN WHICH THEY'RE ABLE TO PARTICIPATE. AFTER AN APPROPRIATE AMOUNT OF TIME, THE SCIENTISTS WILL THEN ENTER THEIR FINAL SCORES.

MR. SHESTACK: I'M SORRY. JUST TO UNDERSTAND, THAT IS THE PROCESS THAT IS FOLLOWED NOW; IS THAT RIGHT? SO SCORES ARE AFTER DISCUSSION THERE IS A RESTATEMENT, THERE'S A RESTATEMENT OF SCORES?

MR. TOCHER: THAT'S RIGHT.

MR. SHESTACK: BUT NO TABULATION OR REPORTING BACK TO THE GROUP ON WHAT THEIR SCORES WERE?

MR. TOCHER: THAT'S CORRECT. WHAT I MEAN TO DESCRIBE HERE IS THAT EVEN AT THE CONCLUSION AFTER THE ALL THE GRANTS HAVE BEEN SCORED, BEFORE THEY ARE FINALLY SUBMITTED, THE SCIENTIST MEMBERS CAN CHANGE A SCORE ON THEIR SCORE SHEET BEFORE SUBMITTING. THAT WOULD BE BEFORE ANYTHING IS SHOWN ON A LIST.

MR. SHESTACK: OKAY.

MR. TOCHER: STAFF WILL THEN TALLY THE SCORES. AND IF NO APPLICATION IS AVAILABLE OR ELIGIBLE, I SHOULD SAY, FOR A MINORITY REPORT, AS

I'LL DISCUSS IN A MOMENT, THEN THE ENTIRE GRANTS WORKING GROUP, INCLUDING PATIENT ADVOCATES, WILL VOTE ON A MOTION TO SEND THE ENTIRE SLATE AS COMPRISED IN RANK ORDER AND IN THE RESPECTIVE TIERS TO THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD. IF THERE ARE NO MINORITY REPORTS, THIS WILL CONCLUDE THE GRANTS WORKING GROUP MEETING.

HOWEVER, AT THE GRANTS WORKING GROUP MEETING AND PRIOR TO THE FINAL VOTE ON THE SLATE OF RECOMMENDATIONS, THE REVIEW OFFICE WILL LEAD THE CONSIDERATION OF OBTAINING MINORITY REPORTS. IF ANY APPLICATION HAS AT LEAST 35 PERCENT OF ITS SCORES PLACING IT IN A TIER OTHER THAN THE ONE THAT IT WAS PLACED BY VIRTUE OF ITS AVERAGE SCORE, THAT APPLICATION WILL BE ELIGIBLE FOR A MOTION TO FORWARD A MINORITY REPORT TO THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD. AND AFTER ALL GRANTS THAT ARE ELIGIBLE FOR A MINORITY REPORT HAVE BEEN CONSIDERED, THEN THE FINAL MOTION ON THE ENTIRE SLATE WOULD BE ENTERTAINED.

IN ANTICIPATION OF THE MEETING OF THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD AT WHICH THE PROGRAMMATIC REVIEW WILL BE CONDUCTED, STAFF WILL PROVIDE THE SUBCOMMITTEE WITH THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP. IN

ADDITION, PRIOR TO THE SUBCOMMITTEE MEETING, STAFF WILL REVIEW THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP, DEVELOP A STAFF RECOMMENDATION, PROVIDE A MEMORANDUM TO THE SUBCOMMITTEE WITH THE STAFF RECOMMENDATIONS, AND PRESENT THOSE RECOMMENDATIONS TO THE SUBCOMMITTEE AT ITS MEETING.

THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP WILL BE FORWARDED TO THE APPLICATION REVIEW SUBCOMMITTEE OF THE BOARD WHERE THE VICE CHAIRS OF THE GRANTS WORKING GROUP WILL MODERATE THE DISCUSSION OF PROGRAMMATIC REVIEW. AGAIN, AT THE SUBCOMMITTEE MEETING, THE STAFF WILL PRESENT AN INTRODUCTION TO THE RFA AND REVIEW, MUCH LIKE IT IS DONE NOW, THE SUMMARY GRANTS WORKING GROUP RECOMMENDATIONS, AND ALSO A PORTFOLIO UPDATE WHEN RELEVANT TO THE PROGRAMMATIC DISCUSSION.

THE SUBCOMMITTEE WILL REVIEW THE APPLICATIONS AND RECOMMENDATIONS WITH A FOCUS ON PORTFOLIO BALANCE, RELEVANCE TO UNMET HEALTH NEED, URGENCY OF TIMELINE, ALIGNMENT WITH THE FOCUS OF PROPOSITION 71, ALIGNMENT WITH THE GOALS AND PRIORITIES OF THE RFA, BUDGET ADJUSTMENTS, IF NECESSARY, AND OTHER ANY OTHER STIPULATIONS. AND, FINALLY, OF COURSE, CONSIDERATION OF PUBLIC COMMENT.

ARE THERE ANY QUESTIONS?

DR. PRICE: GO BACK TO STEP SIX.

MR. SHESTACK: ARE YOU DONE?

DR. PRICE: BULLET TWO, SO DOES THIS ADD SOMETHING NEW WHERE THE STAFF CAN MAKE A DIFFERENT RECOMMENDATION THAN THE GRANTS WORKING GROUP? IT SAYS THE STAFF WILL REVIEW THE GRANTS WORKING GROUP, DEVELOP STAFF RECOMMENDATIONS. SO THAT WAS SAYING THAT THE STAFF/GRANTS WORKING GROUP RECOMMENDS A PARTICULAR RANK ORDERING OF PROPOSALS.

MR. SHESTACK: THE STAFF CAN PROVIDE CONTEXT IN A WAY THAT THEY MIGHT NOT HAVE DONE BEFORE. AND IN THIS CASE THEY MIGHT END UP PROVIDING CONTEXT THAT THE SCIENTISTS ARE NO LONGER ALLOWED TO INJECT INTO THEIR REVIEW PROCESS BECAUSE THERE DOESN'T SEEM TO BE A PROGRAMMATIC REVIEW PART FOR THEM.

DR. PRICE: THIS DOESN'T SAY PROGRAMMATIC REVIEW.

MR. TOCHER: THERE MAY BE, FOR INSTANCE, THOSE APPLICATIONS IN TIER II WHICH HAVE A DIFFERENCE OF OPINION ON SCIENTIFIC MERIT WHICH THE STAFF COULD HELP WEIGH IN ON FOR THE BOARD'S CONSIDERATION.

DR. PRICE: WE'VE DONE THAT IN THE PAST WHEN WE'VE ASKED QUESTIONS AND THE MEMBERS OF THE

STAFF REVIEW THIS. THIS SAYS SOMETHING QUITE DIFFERENT. IT SAYS THE STAFF WILL DEVELOP A RECOMMENDATION WITH RESPECT TO WHAT THE GRANTS WORKING GROUP HAS ALREADY RECOMMENDED. ISN'T THAT WHAT THAT SAYS?

MR. TOCHER: YES. I THINK STAFF WOULD ENGAGE IN THE DISCRETION IT DOES NOW IN TERMS OF IDENTIFYING THOSE APPLICATIONS WHICH BEAR SPECIAL MENTION OR WHICH THEY BELIEVE SHOULD BE HIGHLIGHTED BY THE BOARD.

DR. PRICE: I DON'T REMEMBER A SINGLE INSTANCE THAT THE STAFF HAS RECOMMENDED TO THE BOARD SOMETHING DIFFERENT THAN THE GRANTS WORKING GROUP HAS RECOMMENDED.

CHAIRMAN THOMAS: DR. PRICE, IT'S ACTUALLY NOT CORRECT. DR. TROUNSON, FOR EXAMPLE, YOU MIGHT WANT TO ADDRESS THE CAPRICOR SITUATION.

MS. LANSING: I JUST WANT TO -- CAN I JUST ADD THAT I REMEMBER INCIDENCES WHERE THE STAFF WEIGHED IN ON THINGS, AND I THOUGHT THAT WAS VERY HELPFUL. SO I DON'T THINK THIS IS A NEGATIVE AT ALL.

DR. TROUNSON: WELL, I THINK THE DISCUSSIONS HAVE REALLY GONE ALONG THIS LINE FOR SOME TIME, THAT IF THE STAFF FELT THAT THERE WAS

SOME ISSUE OR SOME ASPECT OF THE GRANT THAT WAS WORTHY TO BRING TO NOTICE OF THE BOARD AND THAT MIGHT STRENGTHEN THAT PROPOSAL OR IT MIGHT WEAKEN THAT PROPOSAL, THEN I THINK THAT THE BOARD WANTS TO HEAR FROM STAFF, THROUGH ME, IF THAT IS AN ISSUE. IT MIGHT BE IN THE FORM OF A RECOMMENDATION, BUT MORE LIKELY, I THINK, IN THE FORM OF A CLARIFICATION OVER SOME MATTER THAT MIGHT HAVE AN IMPACT ON THE WAY YOU SEE THAT PARTICULAR GRANT.

SO I UNDERSTAND THAT THAT'S BEEN THE TENOR OF THE DISCUSSIONS AND CERTAINLY WAS BEFORE I LEFT AND IT HAS BEEN AFTERWARDS. SO I CAN'T ACCOUNT FOR THE DISCUSSIONS PERSONALLY WHILE I WASN'T HERE, BUT I UNDERSTAND THAT'S THE FEELING AROUND THIS ISSUE. SO I DON'T THINK THAT WE WANT TO -- WE WOULD REALLY WANT TO BE MOSTLY VERY SUPPORTIVE OF THE REVIEWERS. BUT IF THERE IS AN ISSUE THAT'S REALLY APPEARED OR AN ISSUE WE THINK IS WORTHY OF BRINGING TO THE ATTENTION OF THE BOARD, I THINK THE BOARD WANTS TO KNOW.

CHAIRMAN THOMAS: THANK YOU. WE HAVE MARCY AND DR. STEWARD.

MS. FEIT: I DON'T THINK THAT -- I MEAN EVERYBODY WELCOMES THE STAFF'S INPUT. WE NEED IT, AND IT'S ALWAYS APPROPRIATE. I THINK IT'S IN THE

WORDING OF ITEM 2, AS DR. PRICE IS POINTING OUT. IT READS AS IF THE STAFF IS GOING TO REDO THE RECOMMENDATIONS RATHER THAN SAY, "AND STAFF WILL MAKE ANY ADDITIONAL RECOMMENDATIONS AS NEEDED." THAT SAYS IT DIFFERENTLY. I THINK IT'S MORE THAT THAN ANYTHING ELSE.

MR. TOCHER: TO THE EXTENT THAT THIS IMPLIES THAT THERE WOULD BE A CHANGE IN THE RECOMMENDATIONS BASED FROM STAFF'S PERSPECTIVE OF WHAT IS COMING OUT OF THE GRANTS WORKING GROUP, THAT'S MY MISTAKE. THAT'S NOT WHAT IT SHOULD IMPLY.

MR. SHESTACK: MARCY, I DON'T KNOW HOW -- WE SHOULD DEFINE IT. AS I IMAGINE IT, IT JUST MEANS THAT THERE IS A PART OF TIME IN THE AGENDA WHERE STAFF IS GOING TO CHIME IN WITH ADDITIONAL OPINIONS IF THEY HAVE THEM. PERSONALLY I WELCOME THEM, AND ALSO WE CAN REMIND OURSELVES OF GRANTS WHERE THE STAFF HAS MADE VERY STRONG RECOMMENDATIONS THAT THE BOARD HAS CHOSEN TO NOT DO. I DON'T THINK IT WILL BE UNDUE NECESSARILY, BUT I DO THINK THAT WE SHOULDN'T FEEL LIKE THERE'S A PARALLEL TRACK OF RECOMMENDATIONS. BUT THERE MAY BE AN INSTANCE WHERE STAFF HAS A STRONG OPINION OR ADDITIONAL INFORMATION, PORTFOLIO REVIEW; AND AS LONG AS IT'S PRESENTED AS THAT, I THINK IT'S A GOOD THING.

MS. FEIT: IT'S IN THE WORDING. IT'S NOT IN THE INTENT. WE ALL GET THE INTENT.

CHAIRMAN THOMAS: THANK YOU, DR. PRICE, MARCY, AND JON. DR. STEWARD.

MS. LANSING: CAN I GET MY NAME IN ORDER?

CHAIRMAN THOMAS: YES, SHERRY. WE'LL HAVE DR. STEWARD AND THEN YOU.

DR. STEWARD: SO A COUPLE OF INTRODUCTORY, BRIEF COMMENTS JUST TO POINT OUT, AS WE DIG DOWN INTO THE WEEDS HERE. THE CONCEPT PROPOSAL THAT WE APPROVED AT THE LAST BOARD MEETING WAS THAT PROGRAMMATIC REVIEW WILL OCCUR AT THE BOARD. THAT WAS IT. AND WHAT WE'RE TALKING ABOUT NOW IS A WHOLE LOT OF OTHER THINGS THAT I, AT LEAST, HAVE SOME CONCERNS ABOUT AND I'LL ASK SOME QUESTIONS.

I WOULD LIKE TO MAKE ONE OTHER SORT OF ANCILLARY POINT TO BUILD ON SOMETHING THAT J.T. SAID, AND THIS HAS BEEN BOTHERING ME EVER SINCE THE IOM REPORT CAME OUT.

THE IOM CLAIM THAT PATIENT ADVOCATES ARE SOMEHOW IN CONFLICT BECAUSE THEY REPRESENT OR HAVE A PARTICULAR DISEASE OR DISORDER IS OUTRAGEOUS. IT MEANS THAT ANYONE WHO HAS A PARTICULAR DISEASE OR DISORDER OR ANY FAMILY MEMBER WITH A PARTICULAR DISEASE OR DISORDER WOULD HAVE TO DECLARE A CONFLICT

WHEN MAKING DECISIONS ABOUT GRANTS. THAT WOULD INCLUDE EVERYONE ON THE BOARD AND EVERYONE ON SCIENCE STAFF.

IF YOU JUST GO DOWN THAT LITTLE ROAD, YOU CAN SEE THAT THAT SUGGESTION OF THE IOM VIOLATES EVERY PRIVACY LAW THAT I KNOW. I JUST WANT TO GO ON RECORD AS SAYING THAT'S OUTRAGEOUS.

NOW, ENOUGH OF THAT. SO A COUPLE OF QUESTIONS, SCOTT, IF YOU COULD. I DO WANT TO SAY SOMETHING ABOUT THE DISCUSSION THAT WE HAD AT THE GRANTS WORKING GROUP, ALTHOUGH I CAN SAVE THAT.

ONE QUESTION IS DURING THE GWG DISCUSSION OF SCIENTIFIC MERIT -- AND I'M ASKING THIS OF EVERYBODY. I DON'T MEAN TO PUT YOU ON THE SPOT ON THIS -- I'M A LITTLE UNCLEAR. IN WHAT WAY IS IT ENVISIONED THAT PATIENT ADVOCATES WOULD PARTICIPATE IN THE DISCUSSION? SO I MEAN A LOT OF THE DISCUSSION IS ADEQUACY OF CONTROL GROUPS, STATISTICAL ANALYSES, ADEQUACY OF ANIMAL MODELS. I'M HAVING TROUBLE SEEING THE ROLE THAT THE PATIENT ADVOCATES PLAY.

MR. TOCHER: WELL, THE ROLE WOULD BE UNCHANGED FROM THE ROLE THAT PATIENT ADVOCATES PLAY NOW IN TERMS OF THE SCIENTIFIC SCORING OF THE GRANTS REVIEW. SO IT'S NOT CONTEMPLATED THAT THERE WOULD

BE A CHANGE.

DR. STEWARD: CAN I JUST SAY SOMETHING? THE WAY IT IS NOW, JUST SO EVERYBODY KNOWS, IN THE GRANTS WORKING GROUP, THE PATIENT ADVOCATES ARE LARGELY QUIET DURING THE REALLY MEAT OF THE SCIENTIFIC REVIEW, THE SCIENTIFIC MERIT REVIEW. AND THEIR COMMENTS COME IN THAT LATER PHASE WHEN THE GRANTS ARE RECALIBRATED, IF YOU WANT, AND WHEN THE ORDER IS RECONSIDERED. SO I MEAN IT CHANGES THE DYNAMIC OF THE GRANTS WORKING GROUP MEETING.

AGAIN, I'M JUST ASKING WHAT PEOPLE ARE THINKING HERE HOW THIS WOULD WORK.

MR. TOCHER: WELL, I CAN'T SPEAK FOR ALL OF MY COLLEAGUES, BUT THE PRIMARY INTENT, FIRST OF ALL, IS TO NOT CHANGE THE RULES OF PARTICIPATING OF THE PATIENT ADVOCATES. IF THEY CHOOSE TO PARTICIPATE MORE OR LESS IN THAT DISCUSSION AS A RESULT OF THE POLICY CHANGE, THAT WOULD BE UP TO THE INDIVIDUAL PATIENT ADVOCATE MEMBER.

DR. STEWARD: AND THERE'S JUST TWO TECHNICAL QUESTIONS. SO AT THE END OF THE DAY, THE GRANTS WORKING GROUP IS GOING TO BE PRESENTED WITH A RANK ORDERED LIST.

MR. TOCHER: CORRECT.

DR. STEWARD: WHAT IF AT THE END OF THE

DAY THE MEMBERS DON'T FEEL THAT THAT RANKING AS DEFINED BY THE SCORES IS CORRECT AND THE MAJORITY VOTES NO?

MR. TOCHER: WELL, THERE MIGHT ISSUE A MINORITY REPORT IF IT WAS SIZABLE ENOUGH. OTHERWISE, THERE WOULD NOT BE A FUNDING RECOMMENDATION MADE TO THE BOARD, AND THE BOARD WOULD TAKE THAT INTO CONSIDERATION WHEN -- I SHOULD SAY THE SUBCOMMITTEE WOULD TAKE INTO CONSIDERATION WHEN IT MEETS TO CONSIDER THEM.

DR. STEWARD: JUST ANOTHER TECHNICAL POINT. YOU MENTIONED THAT THERE WOULD BE A MOTION MADE OR UP FOR CONSIDERATION TO PUT FORWARD A MINORITY REPORT IF 35 PERCENT OF THE GRANTS FELL INTO THE WRONG CATEGORY. WHO IS ELIGIBLE TO VOTE ON THAT MOTION?

MR. TOCHER: THOSE WOULD BE ALL MEMBERS INCLUDING PATIENT ADVOCATES.

DR. STEWARD: I DO WANT TO COME BACK LATER ON AND AT SOME POINT JUST TALK ABOUT THE GRANT WORKING GROUP'S OPINION ON THIS BECAUSE WE TALKED ABOUT THAT AT THE LAST MEETING. I'LL JUST SAY THAT THEY -- I'LL SAY IT NOW SINCE I HAVE THE MICROPHONE.

WE ACTUALLY ASKED THEM DIRECTLY WHAT THEY THOUGHT ABOUT THE PRESENT PRACTICE OF LOOKING AT THE

ORDER OF THE GRANTS AT THE END OF THE DAY, AND VARIOUS WORDS WERE USED: REALITY CHECK, SANITY CHECK, RECALIBRATION, OPPORTUNITY FOR REORDERING OF PRIORITIES. AND EVERY PERSON OF THE GRANTS WORKING GROUP, THE SCIENTIFIC MEMBERS, TALKED ABOUT IT IN A VERY POSITIVE WAY. THERE WASN'T A SINGLE DISSENSION. THEY FELT THAT WAS A VERY IMPORTANT PART OF THE PROCESS.

AND I JUST WANT TO SAY THAT THAT IS A PROCESS THAT GOES ON IN OTHER GRANTING AGENCIES AS WELL, INCLUDING THE NATIONAL SCIENCE FOUNDATION, AND SOME OF YOU KNOW OF OTHER PRIVATE FUNDING ORGANIZATIONS.

SO AT THE END OF THE DAY, IT REALLY IS GETTING INTO THE WEEDS HERE AND THE DETAILS REALLY DO MATTER. AND I'M OPPOSED TO THAT CHANGE. I THINK THAT WHATEVER WE DO AS FAR AS THE PATIENT ADVOCATES, I THINK I PERSONALLY FEEL THAT THE PROCESS WORKS REALLY WELL IN TERMS OF LOOKING AT THOSE ORDERS AT THE END OF THE DAY.

CHAIRMAN THOMAS: SHERRY.

MS. LANSING: WELL, I'M A LITTLE CONFUSED NOW. OS, WHAT WOULD YOU SUGGEST? BECAUSE WHAT I WAS GOING TO SAY IS, AND THIS IS DIFFERENT, I JUST WANT IT TO BE CLEAR THAT THE ADDITION OF STAFF'S

INPUT, I THINK, IS WONDERFUL. AND I KNOW THAT THEY'RE NOT GOING TO ABUSE IT. SO THEY'RE NOT GOING TO REEVALUATE. I DIDN'T INTERPRET THE LANGUAGE THAT WAY. BUT NOW, OS, I'M CONFUSED AS TO WHAT YOU WOULD SUGGEST.

DR. STEWARD: I WOULD SUGGEST THAT THE PROCESS THAT WE HAVE BEEN USING IN THE PAST AT THE LEVEL OF THE GRANTS WORKING GROUP CONTINUE AS IT IS. AND THAT MEANS THAT THE GRANTS WOULD BE CONSIDERED IN ORDER BASED ON THEIR SCORES. IT'S FINE TO USE THE TIER SYSTEM. THAT SORT OF PUTS THINGS IN THE PLACE FOR EVERYBODY TO START THINKING ABOUT, BUT THAT THE ENTIRE GRANTS WORKING GROUP THEN DISCUSS WHETHER THE ORDER IS RIGHT AND WHETHER THE LINES ARE RIGHT AND THAT THERE BE MOTIONS TO FUND THINGS THAT MAY BE BELOW THE LINE AND NOT FUND THINGS ABOVE THE LINE. THAT ACTUALLY HAPPENED AT THE LAST GRANTS WORKING GROUP ROUND. THAT WOULD BE MY SUGGESTION.

MS. LANSING: THANK YOU.

CHAIRMAN THOMAS: JOAN AND THEN MR. SHESTACK.

MS. SAMUELSON: I WANT TO MAKE JUST A COUPLE POINTS, AND I'LL PROBABLY MAKE MORE LATER, BUT TWO POINTS TO ECHO WHAT OS SAID.

FIRST, I WAS ASTONISHED, HONESTLY, BY HOW

SUPPORTIVE THE SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP ARE OF THE PROCESS WE HAVE NOW. AND THEY WERE SAYING THINGS SUCH AS TO SEPARATE OUR PROGRAMMATIC DISCUSSION FROM OUR SCORING DESTROYS THE INFORMATION AND THE PROCESS AND THE CONTENT THAT'S BEING PROVIDED TO THE BOARD FOR THEIR USE IN THEIR DELIBERATIONS. IT REALLY MADE ME MUCH MORE CONCERNED ABOUT CHANGING THAT.

I ALSO WANT TO, JUST FOR THE RECORD, AND I'M SURE THIS IS TRUE, AS OS SAID, OF EVERY PERSON IN THIS ROOM, BUT I JUST WANT TO MAKE THE RECORD BRIEFLY ON MY CONNECTION TO DISORDERS AND LIFE-THREATENING DISEASES. I HAVE A PERSONAL CONNECTION WITH FAMILY AND FRIENDS TO HEART -- THESE ARE THE ONES I THOUGHT OF AT THE TIME, A LITTLE WHILE AGO -- HEART DISEASE, DIABETES, HYPERTENSION, CYSTIC FIBROSIS, SCOLIOSIS, PEDIATRIC CANCER, HIV, MS, COLOR BLINDNESS, AUTISM, HUNTINGTON'S DISEASE, MENTAL ILLNESS AND DEPRESSION, ALS, AUTOIMMUNE DISORDERS, INCLUDING PEDIATRIC ONES AND LUPUS, ALZHEIMER'S, RETINITIS PIGMENTOSA, AND MACULAR DEGENERATION. AND I CAN GIVE TO THIS ANYONE IF YOU NEED IT.

IT'S CRAZY TO THINK THAT WE HAVE SOME SORT OF CONFLICT IMPAIRING OUR JUDGMENT IN THIS BODY.

IT'S OFFENSIVE, AND WE DON'T NEED TO ADOPT THE FULL PLATE OF RECOMMENDATIONS BY THE IOM TO SHOW THEM DUE RESPECT, IN MY OPINION.

MS. LANSING: I WANT TO COMMENT WHEN IT'S MY TURN.

CHAIRMAN THOMAS: WE HAVE MR. SHESTACK AND THEN DIANE, AND THEN SHERRY WE'LL BE BACK TO YOU IN A SEC. MR. SHESTACK.

MR. SHESTACK: THANK YOU VERY MUCH. WELL, I'M GLAD, OS, THAT YOU POINTED THAT OUT. THAT WAS STRIKING HOW MUCH THE SCIENTISTS, IT WAS AN INFORMAL POLL, BUT IT WAS SCIENTISTS AT THE LAST SCIENTIFIC WORK GROUP, LIKED THIS OPPORTUNITY TO ACTUALLY DISCUSS, NOT ONLY RELY ON THEIR RAW NUMBERS, BUT THEN HAVE THE OPPORTUNITY TO ADD CONTEXT TO THEIR RECOMMENDATION BECAUSE THE PURE NUMBERS WITHOUT A RECONSIDERATION HAS NO CONTEXT.

AND I KNOW THAT, J.T., YOU HAVE DISCUSSED FINDING A WAY TO GET SOME OF THAT PROCESS BACK IN. I PERSONALLY WOULD LOVE TO SEE THAT AND WOULD LIKE AND CAN'T VOTE FOR IT UNLESS IT'S ACTUALLY IN.

I WOULD ALSO LIKE TO SAY TO ART I REALLY UNDERSTAND THE SERIOUSNESS OF THE IOM RECOMMENDATIONS. I DON'T REALLY -- I THINK THE REPORT WASN'T COMPLETE, DIDN'T TALK TO A LOT OF

PEOPLE, DIDN'T READ THE LEGISLATION CAREFULLY, DECIDED TO GIVE THE ADVOCATES THREE-FIFTHS OF THEIR PREVIOUS VOTING RIGHTS, BUT FORTUNATELY PROPOSITION 71 LOOKS OUT FOR OUR INPUT.

CHANGING THE -- I DON'T KNOW HOW MR. SHEEHY WILL FEEL ABOUT VOTING AND NOT VOTING. I THINK WE HAVE DIFFERENT OPINIONS ABOUT IT, BUT WHAT I REALLY FEEL IS IMPORTANT, AGAIN, IS NOT BLINDLY FOLLOWING THESE RECOMMENDATIONS THAT WERE NOT MADE WITH THE STAKEHOLDERS' INTERESTS IN HEART. THE IOM REPORT IS WRITTEN BY PEOPLE WHO BASICALLY WANT TO RECREATE THE NIH OF 25 YEARS AGO, AND IT'S NOT HELPFUL TO THE STATE OF CALIFORNIA. SO I FIND THAT HAVING A REAL DISCUSSION THAT IS BAKED INTO THE GRANT REVIEW PROCESS WHERE THE SCIENTISTS AT THE END -- AT THE PENULTIMATE MOMENT GET TO LOOK AT WHAT THEY'VE DONE AND SAY IS THAT REALLY WHAT WE WANT TO RECOMMEND TO THE BOARD? NOW THAT THE DEANS WON'T BE THERE TO INTERPRET, WHERE IT'S JUST SORT OF THE ADVOCATES WHO WILL BE THERE TO INTERPRET AND THEN STAFF TOO, FORTUNATELY THAT'S A GOOD ADDITION, TO THEN SAY THEY CAN'T ADD CONTEXT IS A LOSS FOR US AS A GROUP. AND IT ADDS SMALL TIME TO THE MEETING. THE SCIENTISTS SEEM TO BE MORE THAN WILLING TO DO IT. AND SO I WOULD HATE FOR US TO REGULATE IT OUT

OF OUR LIVES BECAUSE IT IS A REAL PLUS.

CHAIRMAN THOMAS: THANK YOU, MR. SHESTACK. DIANE, THEN SHERRY, AND THEN SENATOR TORRES.

MS. WINOKUR: I HAVE NEITHER ALS NOR MS. I AM AN ADVOCATE ON THIS BOARD FOR BOTH DISEASES. I HAVE SPENT THE LAST 20 YEARS IN ALS RESEARCH. I KNOW THE RESEARCHERS. I KNOW THE PROJECTS. I KNOW THE STATUS OF THE RESEARCH. I GO TO SCIENTIFIC MEETINGS. I JUST CAME BACK FROM A THREE-DAY SYMPOSIUM AT JOHNS HOPKINS IN WHICH ALL THE GRANTEES OF THE PACKARD FOUNDATION FOR ALS RESEARCH REPORTED ON THEIR RESEARCH.

I FEEL THAT I BRING TO DISCUSSIONS OF PROPOSALS THAT ADDRESS THESE TWO ILLNESSES AS MUCH EXPERTISE AS MOST OF THE SCIENTISTS IN THE ROOM WOULD BECAUSE MANY OF THE SCIENTISTS ARE NOT AS SPECIALIZED AS I AM.

I ALSO FEEL THAT PROP 71 HAD A PURPOSE IN DESIGNATING DISEASE ADVOCATES. THEY DIDN'T SPECIFY THAT YOU HAVE TO HAVE THE DISEASE, NOR THAT YOU DIDN'T HAVE THE DISEASE. AND WHEN LIEUTENANT GOVERNOR NEWSOM INTERVIEWED ME BEFORE MY APPOINTMENT, HE WAS VERY INTERESTED IN MY RECOGNITION OF THE SCIENCE THAT WAS OUT THERE REGARDING THE DISEASES.

I FEEL THAT THE ADVOCATES HAVE NOW KIND OF A SECONDARY POSITION ON THE BOARD AND ON THESE DECISIONS. AND I WOULD FIRMLY RECOMMEND THAT THE BOARD THINK THAT THROUGH.

CHAIRMAN THOMAS: THANK YOU. SHERRY, THEN SENATOR TORRES.

MS. LANSING: I COME BACK TO THE FACT THAT I KNOW AS A PATIENT ADVOCATE HOW PAINFUL THIS IS, BUT IT'S ALSO IN THE FIRST ISSUE ABOUT CONFLICT OF INTEREST, WHICH I DON'T THINK ANY OF THE INSTITUTIONS EVER HAVE, THAT WE'RE FACING A SITUATION THAT WE COMMISSIONED AND THAT WE HAVE TO DO SOMETHING.

THE THING THAT I'M ENCOURAGED BY IS IT SAYS, UNLESS I'M NOT UNDERSTANDING THIS RIGHT BECAUSE I'M READING THE PAPER, THAT THE PATIENT ADVOCATES WILL PARTICIPATE IN THE REVIEW. THE SCIENTIFIC MEMBERS OF THE GWG WILL SCORE THE APPLICATIONS AND THEN THE PATIENT ADVOCATES WILL GET TO TALK. AND I SAY THAT WE HAVE LOUD VOICES AND WE GET TO TALK AND WE GET TO MAKE OUR OPINIONS HEARD.

SO I, WHO HAVE NOT BEEN ABLE TO VOTE ON A LOT OF THINGS, HAVE NEVER FELT DISENFRANCHISED BECAUSE OF THAT. I FELT THAT I COULD TALK AND THAT THROUGH CONVERSATION COULD USE PERSUASION.

AGAIN, I'M GOING TO SUPPORT HONESTLY ALL OF THESE ISSUES BECAUSE OF THE SITUATION THAT WE'RE IN. AND I LOOK FORWARD TO REEVALUATING THEM IN SIX MONTHS, IN THREE MONTHS, IN FOUR MONTHS AND LOOKING AT IT AND SEE HOW IT IS AND CONSTANTLY MEASURING THIS. THAT'S IT.

MR. TORRES: I THINK ECHOING GEORGE BUSH'S REMARKS IN THE DEBATE WITH RONALD REAGAN FOR THE PRESIDENTIAL NOMINATION, HE CALLED MR. REAGAN'S ECONOMICS VOODOO ECONOMICS. I SAID THE SAME THING TO DR. SHAPIRO REGARDING THIS NOTION OF ANYONE WITH A DISEASE WOULD HAVE A CONFLICT OF INTEREST AND SHOULDN'T BE PARTICIPATING.

I THEN ASKED FOR THE BEHAVIORAL STUDY THAT ELICITED THIS RESPONSE, AND IT FINALLY CAME TO ME. I FOUND IT WANTING. AND I TOLD DR. SHAPIRO DIRECTLY THAT, AT YOUR HOME AS A MATTER OF FACT, MR. THOMAS, THAT I FELT IT WAS TERRIBLY UNFAIR AND, QUITE FRANKLY, UNSUBSTANTIATED TO SUGGEST THAT ANYONE WITH A DISEASE COULD BE IN A SERIOUS CONFLICT OF INTEREST WHILE VOTING ON MANY OF THESE GRANTS.

AS A COLON CANCER SURVIVOR, AS A BROTHER OF A COLON CANCER SURVIVOR, AS A SON OF A LATE BREAST CANCER SURVIVOR AND A STROKE SURVIVOR, I HAVE ALWAYS TAKEN VERY SERIOUSLY MY VOTE ON ANY GRANT

THAT HAS COME BEFORE THIS BOARD. AND I'VE TRIED TO EXERCISE INDEPENDENT JUDGMENT SO MUCH SO THAT IN MANY OF THE INSTANCES I JUST CITED, I HAVE VOTED AGAINST CERTAIN GRANTS IF I DIDN'T FEEL THEY WERE APPROPRIATE.

CURRENTLY WHAT'S PROPOSED TO US IS TO HAVE THE PATIENT ADVOCATES SPEAK AT THE GRANTS REVIEW PROCESS, CORRECT, BUT NOT TO VOTE, AND THEREBY SHIFTING TO A MUCH MORE TRANSPARENT ARENA THE PROGRAMMATIC REVIEW LED BY OUR CO-VICE CHAIRS, WHOM WE ALL KNOW. THAT'S THE CURRENT PROPOSAL. SO I THINK WE JUST HAVE TO VOTE OUR CONSCIENCE WHETHER WE BELIEVE THAT TO BE THE CASE OR TO REJECT THE IOM RECOMMENDATION REGARDING PATIENT ADVOCATES AND THEIR ALLEGED CONFLICT OF INTEREST.

MR. SHESTACK: SO, SENATOR, THERE'S MORE THAN TWO ISSUES IN HERE THOUGH. IT'S NOT SIMPLY -- AND THIS IS WHAT -- WE MAY NOT ALL BE IN AGREEMENT. MAY I?

CHAIRMAN THOMAS: MR. SHESTACK.

MR. SHESTACK: IT'S NOT -- PREVIOUSLY IN THE GRANT WORKING GROUP THE PATIENT ADVOCATES DID NOT SCORE. THEY WOULD PARTICIPATE IN DISCUSSION, PARTICULARLY TOWARDS THE END, AND I BELIEVE THEY COULD VOTE IN TERMS OF REPRIORITIZING. THIS DOESN'T

ALLOW THEM TO VOTE IN THAT PROCESS, BUT, MORE IMPORTANTLY, DOESN'T ALLOW THAT PROCESS.

THERE ARE TWO ISSUES, THERE ARE TWO THINGS THAT I THINK ARE PARTICULARLY -- COULD BE WHERE THERE'S PARTICULAR ROOM FOR IMPROVEMENT IN ITEM 2. ONE IS THAT THERE ACTUALLY BE ENSHRINED A KIND OF PROGRAMMATIC REVIEW SO THAT THE SCIENTIFIC WORK GROUP GETS TO BASICALLY PUT CONTEXT BACK INTO THE NUMBERS, AND WE CAN BENEFIT FROM THAT KNOWLEDGE. AT THE LAST MEETING, THEY TALKED ABOUT RECALIBRATING. THEY HAD A COUPLE WORDS THAT OS USED. AND WHEN PUT THAT WAY, IT MADE A TREMENDOUS AMOUNT OF SENSE.

AND THEN THE SECOND IS WHETHER OR NOT IT IS SORT OF RIDICULOUSLY DISENFRANCHISING ADDRESSING A BUGABOO OF CONFLICT THAT DOESN'T EXIST TO TELL THE ADVOCATES THAT THEY CAN'T VOTE GIVEN THAT THERE AREN'T THAT MANY AT A GRANT REVIEW MEETING TO BEGIN WITH. THEY CAN'T POSSIBLY GO TO ALL OF THEM. THE FULL COMPLEMENT OF ADVOCATES THAT ARE SUPPOSED TO BE AT A GRANT REVIEW MEETING ARE NOT FREQUENTLY THERE.

I DON'T KNOW THAT THESE TWO THINGS SHOULD BE LINKED, BUT I THINK THAT WE SHOULD FIDDLE WITH THIS A LITTLE BIT AND ALSO WITH MARCY'S RECOMMENDATION AND MAKE IT SOMETHING THAT YOU HAVE A CHANCE OF ACTUALLY GETTING, IF NOT UNANIMITY, THEN

CLOSER TO IT. AND MAYBE A SIMPLE THING, WHAT OS SAID, IS IOM OR SOMEBODY WANTED PROGRAMMATIC REVIEW AT THE BOARD MEETING. THAT'S GREAT. DOESN'T MEAN IT CAN'T BE AT THE OTHER MEETING. IT'S JUST A FORM OF EDUCATED AND INFORMED DISCUSSION, AND THAT DOESN'T SEEM TO BE BAD.

CHAIRMAN THOMAS: DR. SAMBRANO.

DR. SAMBRANO: THANK YOU. I DO WANT TO JUST HIGHLIGHT A COUPLE OF THINGS THAT I THINK ARE IMPORTANT IN THIS DISCUSSION.

FIRST, I CERTAINLY DO AGREE THAT THE SCIENTIFIC MEMBERS OF THE GRANTS WORKING GROUP APPRECIATE THE PARTICIPATION OF PATIENT ADVOCATES IN THE REVIEW. I THINK IN THE DISCUSSION WHERE WE INFORMALLY POLLED THEIR OPINION ABOUT THESE PROPOSALS, ONE OF THE ISSUES IS THAT THE SCIENTIFIC MEMBERS DIDN'T REALLY HAVE THE DETAILS OF THE POLICY BEFORE THEM. SO I THINK IT'S IMPORTANT TO KNOW THAT THESE DETAILS WERE NOT NECESSARILY AVAILABLE.

I THINK THEY WERE CERTAINLY EXPRESSING THEIR APPRECIATION FOR THE PROGRAMMATIC REVIEW THE WAY IT CURRENTLY HAPPENS AND A LOT OF THE OUTCOMES FROM IT. ONE OF THEM WAS THE CALIBRATION, AS WE DISCUSSED, AND THE OPPORTUNITY TO MOVE A GRANT APPLICATION WHERE THEY FELT THAT MAYBE DURING THE

COURSE OF THE REVIEW THEY WEREN'T APPROPRIATELY CALIBRATED AND NEEDED TO MOVE IT.

NOW, IT'S IMPORTANT TO POINT OUT THAT THIS CHANGE IN POLICY IN MANY WAYS DOES ADDRESS THAT ISSUE. SO BY HAVING SPECIFIED TIERS WHERE THE SCORES ARE FIXED, THE SCIENTIFIC MEMBERS ARE BASICALLY VOTING OR ASSIGNING EACH APPLICATION INTO A TIER SIMPLY BY THEIR SCORE WHERE THEY DID NOT DO THAT PREVIOUSLY.

MR. SHESTACK: AVERAGES. THEY'RE SCORING ACCORDING TO THEIR OWN METHOD OF SCORING AND THEN IT'S ADDED UP. AND THEY DON'T GET A CHANCE TO SAY I DIDN'T WANT TO SEE IT IN THE BOTTOM TIER.

DR. SAMBRANO: NO, THEY DO. SO THE WAY IT HAPPENS, SO IMAGINE YOU HAVE YOUR 15 SCIENTIFIC MEMBERS. IF MOST OF THEM CHOOSE TO PUT IT IN TIER III, THEN THEY WILL VOTE BELOW 64. THEIR SCORE WILL BASICALLY BE THEIR VOTE. IF THE WORKING GROUP MEMBERS CHOOSE TO PLACE IT IN TIER I, THAT MEANS THAT, FOR THE MOST PART, THE GRANTS WORKING GROUP MEMBERS WILL SCORE IT 75.

NOW, THE OTHER THING THAT'S IMPORTANT IS THE CALIBRATION. I THINK ONE OF THE THINGS THAT HAS BEEN POINTED OUT IS THAT WHEN YOU BEGIN A REVIEW, WHAT YOU KNOW AT THE START OF THE REVIEW MAY NOT BE

WHAT YOU KNOW AT THE VERY END. YOU KIND OF HAVE TO GO THROUGH ALL THE GRANT APPLICATIONS TO GET A GOOD SENSE OF WHAT THAT CALIBRATION SHOULD BE. ONE OF THE IMPORTANT ASPECTS OF THIS POLICY IS THAT WE NEED TO, DURING THE COURSE OF THE REVIEW, BOTH REMIND AND ENCOURAGE REVIEWERS AT PERIODIC TIMES TO CALIBRATE, AFTER EACH LUNCH BREAK, AFTER THE FIRST DAY, AFTER THE SECOND DAY, SO THAT THEY ARE UPDATING THEIR SCORES SO THEIR CALIBRATION IS CORRECT. AND THEN AT THE VERY END, WHEN THEY GO BACK, WHEN THEY LOOK AT ALL THE SCORES THAT THEY'VE ASSIGNED TO ALL THE APPLICATIONS NOW THAT THEY'VE HAD A LOOK AT ALL OF THEM AND DISCUSSED ALL OF THEM, THEY SHOULD BE ASSURED THAT THEY'RE PLACING ALL OF THE ONES THAT THEY WANTED IN TIER I, IN TIER II, AND TIER III. THEY'RE DOING IT INDIVIDUALLY, NOT AS A COLLECTIVE GROUP, BUT THEY'RE STILL DOING SO. AND THAT'S GOING TO BE AN IMPORTANT ASPECT OF IT.

MR. SHESTACK: THERE ISN'T DISCUSSION. THERE ISN'T CONTEXT. GIL, THERE'S NOTHING YOU CAN SAY THAT MAKES ME THINK THIS IS A GOOD IDEA. THIS IS A BAD IDEA. THIS IS AN IDEA THAT MAKES US ACTUALLY WHERE WE ARE SORT OF WILLFULLY DIMINISHING OUR KNOWLEDGE AND EXPERTISE FOR A REASON THAT IS JUST INCOMPREHENSIBLE TO ME. I REALLY JUST DON'T

GET WHY ONE WOULD SORT OF ENSHRINE IN REGULATION THAT PEOPLE SHOULDN'T HAVE A CHANCE TO LOOK AT IT, DISCUSS, AND MAKE FURTHER RECOMMENDATIONS AND DECIDE WHETHER OR NOT THEY WANT TO PULL SOMETHING UP FOR FUNDING TO RECOMMEND FOR FUNDING OR NOT. AND DOING IT INDIVIDUALLY ISN'T THE SAME --

MS. LANSING: DON'T WE HAVE THAT? WE JUST CAN'T VOTE.

MR. SHESTACK: DOING IT INDIVIDUALLY ISN'T THE SAME AS DOING IT COLLECTIVELY OR ACTUALLY SEEING HOW THE NUMBERS -- WHAT THE NUMBERS ARE. THE NUMBERS ARE STUPID BECAUSE THEY DON'T HAVE CONTEXT. AND WE ARE REMOVING CONTEXT WILLFULLY, AND I WILL NOT VOTE FOR IT.

DR. SAMBRANO: I AGREE WITH YOUR STATEMENT. HOWEVER, WHEN WE DO PROGRAMMATIC REVIEW, THE CONTEXT OF THE DISCUSSION WHERE ALL WORKING GROUP MEMBERS AND PATIENT ADVOCATES DISCUSS AN APPLICATION, IS RELATED TO PROGRAMMATIC ISSUES, NOT SCIENTIFIC CONTENT. SO THE MOVEMENT OF THE APPLICATIONS IS BASED ON I HAVE A PROGRAMMATIC REASON FOR RAISING THIS APPLICATION INTO TIER I OR LOWERING IT INTO TIER III. THE SCIENTIFIC DISCUSSION HAS ALREADY TAKEN PLACE WHEN EACH INDIVIDUAL APPLICATION WAS ASSESSED. SO UNLESS WE

WANT TO DO PROGRAMMATIC, AND I'M NOT GIVING YOU AN OPINION ON WHETHER THAT SHOULD OR SHOULDN'T HAPPEN AT THE GRANTS WORKING GROUP, BUT IF IT'S PURELY SCIENTIFIC, I THINK WE ARE COVERING ALL THE BASES, AND THE POLICY DOES ADDRESS THIS.

CHAIRMAN THOMAS: CAN I JUST ASK DR. STEWARD FOR A POINT OF CLARIFICATION? WHEN YOU'RE TALKING ABOUT THIS DISCUSSION AT THE END OF THE SCORING SEQUENCE, IS THAT BASICALLY A DISCUSSION ON SCIENTIFIC MATTERS, OR ARE YOU CONTEMPLATING THAT BEING BEYOND THAT TO ESSENTIALLY THE PROGRAMMATIC DISCUSSION?

DR. STEWARD: NO. I THINK THE MOST IMPORTANT THING IS THAT RECALIBRATION STEP AND THAT IT SHOULD BE ON SCIENTIFIC MATTERS. OBVIOUSLY WHAT SCIENTISTS OR GRANTS WORKING GROUP MEMBERS CONSIDER TO BE OF SCIENTIFIC NOTE MAY VARY. YOU TALK ABOUT THE EXPERTISE OF THE INVESTIGATOR. IS THAT SCIENCE? NO, BUT IT RANKS AS PART OF THE JUDGMENT ON SCIENTIFIC MERIT.

MR. SHESTACK: SPECIFIC CRITERIA.

DR. STEWARD: NO. WHEN WE TALK -- THE WORD "PROGRAMMATIC REVIEW" MEANS WHERE DOES THIS FIT IN THE CONTEXT OF THE PROGRAM, EXACTLY WHAT WE'RE PROPOSING TO DO AT THE BOARD LEVEL AND THE DOCUMENT

THAT YOU HAVE. THIS LAST STEP IN THE SCIENTIFIC REVIEW IS JUST LETTING EVERYBODY LOOK AT THE LIST AND SAY, GEE, THAT DOESN'T MAKE SENSE. OBVIOUSLY THERE WAS SOMEBODY THAT GAVE IT A 15 OVER HERE THAT BROUGHT IT DOWN INTO TIER III. EVERYBODY ELSE WAS VOTING AT LEAST IN TIER II AND MAYBE EVEN HIGHER, AND THAT'S WRONG. AND THEN YOU MOVE IT FORWARD AND YOU BASICALLY OUTVOTE THE OUTLIER. SO ALL OF THAT'S SCIENCE. IT'S NOT PROGRAMMATIC IN THE SENSE OF WHAT WE NORMALLY THINK OF AS THAT WORD.

CHAIRMAN THOMAS: THANK YOU.

DR. SAMBRANO: I JUST WANT TO RESPOND TO THAT. I THINK THIS POLICY IS ADDRESSING THAT TO A LARGE EXTENT BECAUSE WE HAVE THE OPPORTUNITY TO SUBMIT MINORITY REPORTS. SO AT THE VERY END, WE ARE GOING TO HIGHLIGHT THOSE APPLICATIONS WHERE THERE IS BASICALLY A LARGE STANDARD DEVIATION WHERE YOU HAVE POTENTIALLY A GROUP OR A FEW THAT VOTED OUTSIDE OF THE MARGINS AND ALLOW THAT GROUP TO BRING THAT MINORITY REPORT TO THE BOARD.

DR. STEWARD: WELL, HERE'S A TECHNICAL --

MR. SHESTACK: IN THE FORM OF A MINORITY REPORT?

DR. SAMBRANO: YES.

MR. SHESTACK: THAT IS AN UNWIELDY METHOD

NOT SUITED TO THE ADVOCATE MEMBERS ONE BIT. AGAIN, WE'RE TALKING ABOUT -- I'M TALKING ABOUT A SMALL AMOUNT OF DISCUSSION AT THE END OF A BOARD MEETING THAT WE HAVE HAD TRADITIONALLY FOR MANY YEARS WITH GRANT REVIEW WORKING GROUP MEMBERS WHO HAVE BEEN COMING TO OUR MEETINGS FOR MANY YEARS WHO KNOW WHAT THEY'RE TALKING ABOUT NOW. SO WHY WOULD WE WANT TO PUT A CORK IN THEM? IT JUST DOESN'T MAKE ANY SENSE?

DR. STEWARD: TECHNICAL QUESTION. SO SUPPOSE AT THE END OF THE DAY THERE WAS A QUALIFIED MINORITY REPORT. BUT NOW PEOPLE WHO DIDN'T ACTUALLY VOTE IN THE TIER THAT QUALIFIED IT FOR A MINORITY REPORT WANTED TO JOIN SO THAT IT WOULD EFFECTIVELY BECOME A MAJORITY REPORT.

DR. SAMBRANO: RIGHT. IT WOULD BE BY THE MEMBERS THAT ARE PART OF THAT MINORITY.

DR. STEWARD: SO BASICALLY YOU'RE NOT ALLOWED TO JOIN THAT MINORITY RECOMMENDATION UNLESS YOU VOTED IT IN THE FIRST PLACE.

MR. SHESTACK: IF IT'S HIGH, IT'S A NO. SO THAT'S STRICTLY A MINORITY REPORT.

DR. SAMBRANO: NOT FOR THE PATIENT ADVOCATE MEMBERS. BECAUSE THE PATIENT ADVOCATE MEMBERS JOIN IN THAT VOTE, THEY DO -- THEY CERTAINLY MAY AFFECT WHETHER A MINORITY REPORT COMES TO THE

BOARD OR NOT.

CHAIRMAN THOMAS: MR. HARRISON HAS A POINT.

MR. HARRISON: JUST ONE QUICK POINT OF CLARIFICATION. IT ONLY TAKES A VOTE OF 35 PERCENT OF THE MEMBERS OF THE GRANTS WORKING GROUP TO SEND A MINORITY REPORT. SO IN YOUR SITUATION, OS, YOU'D HAVE A MINORITY REPORT THAT WAS ACTUALLY RECOMMENDED AND ENDORSED BY A MAJORITY OF THE MEMBERS AND THAT WOULD BE REPORTED TO THE BOARD.

DR. STEWARD: AGAIN, THE ONLY VOTE IS NO AT THE END OF THE DAY ON THE ENTIRE SLATE THE WAY THINGS ARE SET UP RIGHT NOW. THERE'S NO VOTE ON INDIVIDUAL. SO IT WOULD BE ODD TO THINK ABOUT HOW TO CONSTRUCT A MINORITY REPORT WHERE BASICALLY YOU'RE SAYING, WELL, I DON'T AGREE WITH THE ORDER OR WE DON'T AGREE WITH THE ORDER AND, THEREFORE, WE'RE PROPOSING THIS -- YOU KNOW, IT DEFEATS EXACTLY WHAT IS SUCH A GREAT THING ABOUT THIS THING RIGHT NOW. I'M GOING TO STOP.

CHAIRMAN THOMAS: DR. LEVIN, THEN MR. ROTH.

DR. LEVIN: THANKS, J.T. IT SEEMS TO ME THAT A LOT OF THIS CONFLICT COULD BE AVOIDED BY JUST MINOR MODIFICATIONS TO THE WORDING OF STEP 3,

CALIBRATION. SO IF ALL OF THE GRANTS WORKING GROUP MEMBERS, INCLUDING THE PATIENT ADVOCATES, ARE ALLOWED THIS PERIOD OF DISCUSSION THAT, AS OS MENTIONED, IS PART OF ANY SORT OF GRANT REVIEW AT THE END SO THAT THE GRANTS CAN BE CALIBRATED SO THAT ALL THE ONES THAT -- YOU CAN LOOK AT EVERYTHING AND SEE IS IT REALLY RANKED APPROPRIATELY HIGHER THAN THAT GRANT BASED ON THE SCORES WHEN COMPARED ACROSS ALL OF THE GRANT REVIEW CRITERION, THAT THAT WOULD SOLVE THE WHOLE PROBLEM OF HAVING TO PRODUCE MINORITY REPORTS OR CUTTING OUT, DISENFRANCHISING THE PATIENT ADVOCATES AS LONG AS THERE'S NO EXPLICIT CRITERION OF DOING PROGRAMMATIC REVIEW THERE.

SO THE IDEA OF, OH, DO WE HAVE 11 GRANTS ON RETINITIS PIGMENTOSA OR NONE THAT FOCUS ON WOMEN'S ISSUES, THEN WE CAN TAKE THAT UP HERE AT THE BOARD; BUT THE ACTUAL CALIBRATION, THAT DISCUSSION, WHICH IS SO VITAL TO A GOOD, FAIR GRANT REVIEW AND INVOLVING EVERYBODY, COULD JUST BE DONE IN THIS CALIBRATION STAGE AND NOT GO AGAINST THE IOM RECOMMENDATIONS, IT SEEMS TO ME.

MS. LANSING: CAN WE MAKE THAT A FRIENDLY AMENDMENT, AND THEN MAYBE WE CAN GET SOME CONSENSUS ON THIS?

CHAIRMAN THOMAS: WE ACTUALLY DON'T HAVE

ANY MOTION YET, SHERRY, BUT WE CAN IF THAT'S THE WISH OF THE BOARD.

DR. LEVIN: THE CHANGES WOULD BE TO HAVE THIS CALIBRATION STEP INVOLVE DISCUSSION OF ALL THE MEMBERS OF THE GRANTS WORKING GROUP, PATIENT ADVOCATES AND SCIENTIFIC.

MS. LANSING: CAN I MOVE THE MOTION AND MOVE WITH THAT FRIENDLY AMENDMENT?

DR. STEWARD: I'LL SECOND THAT.

CHAIRMAN THOMAS: YES. THANK YOU, SHERRY. YOU MOST CERTAINLY CAN.

DR. STEWARD: SO LET ME SEE IF I'VE GOT WHAT YOU HAVE IN MIND, SHERRY, WHICH IS TO APPROVE MOVING THE DISCUSSION OF PROGRAMMATIC REVIEW TO THE BOARD AS RECOMMENDED, TO APPROVE ALL OF THE DETAILS IN TERMS OF THE SCORING, THE TIERS ARE FINE, BUT TO RETAIN THE END-OF-THE-DAY DISCUSSION ON THE RANKING OF THE GRANTS THAT WOULD BE THE WRAP-UP FOR THE GRANTS WORKING GROUP.

MS. LANSING: YES. THAT'S A FRIENDLY AMENDMENT.

CHAIRMAN THOMAS: WE HAVE CONTINUED DISCUSSION HERE. FIRST MR. ROTH, THEN DR. SAMBRANO.

MR. ROTH: SO I THINK WHAT WE'RE TRYING TO ACCOMPLISH HERE IS TO ALLOW THE DISCUSSION THAT MANY

OF YOU THINK IS IMPORTANT TO HAVE THERE, BUT NOT THE OBLIGATION ON THE -- AND WE CALL IT PROGRAMMATIC. I KEEP COMING BACK TO IT'S PORTFOLIO. AND THE PORTFOLIO RESPONSIBILITY IS GOING TO COME BACK TO THE BOARD IN A CONTEXT OF A MUCH BIGGER, NOT A SINGLE GRANTS WORKING GROUP, BUT IT'S OUR JOB TO MAKE SURE THE PORTFOLIO IS BALANCED. AND SO THAT'S WHAT I THINK WE GET CONFUSED ON. I DON'T CARE IF THERE'S A DISCUSSION AND CONVERSATION AND MULTIPLE CHANGING OF THE SCORES. BUT ONCE IT COMES TO US, THEN WE'LL DEAL WITH THAT.

BUT IN ADDITION, WE'RE GOING TO ASK THAT STAFF BRINGS TO US ON A REGULAR BASIS THE PORTFOLIO BALANCE AND TALKS TO US ABOUT IT, AND WE THEN CAN INFORM GRANTS WORKING GROUP MEMBERS OF PORTFOLIO WEAKNESSES.

CHAIRMAN THOMAS: DR. SAMBRANO.

DR. SAMBRANO: I JUST WANT TO MAKE A CLARIFICATION. IN TERMS OF THE CALIBRATION, THE SUGGESTION, DR. LEVIN, THAT YOU'RE SUGGESTING IS THAT THE SCORES WOULD STILL REMAIN THE SAME, BUT THAT THE DISCUSSION WOULD HAPPEN AFTER SCORES ARE TABULATED?

DR. LEVIN: THE CALIBRATION STAGE IS WHERE PEOPLE ARE ALLOWED TO ADJUST THEIR SCORES. SO THE

DISCUSSION COULD HAPPEN --

DR. SAMBRANO: THERE'S A GREAT DANGER IN DOING THAT BECAUSE THE ISSUE IS YOU HAVE 15 SCIENTIFIC REVIEWERS WHO GIVE THEIR INITIAL ASSESSMENT. AND WHEN THEY DO SO, THEY DO IT INDEPENDENT OF ONE ANOTHER AND THEY DO IT IN A SECRET VOTE. THEY TABULATE THEIR OWN SCORE.

NOW, IF YOU HAVE A DISCUSSION WHERE YOU SEE THE GENERAL MOVEMENT OF THE GROUP TOWARDS ONE END OF THE SPECTRUM, AND IF YOU HAVE OTHER REVIEWERS WHO CAN CHANGE THEIR SCORE TOWARDS THE OTHER END, YOU'RE GOING TO HAVE PEOPLE THAT MIGHT DELIBERATELY CHANGE THEIR SCORE TO OFFSET THE OPINION OF OTHERS. SO THE REASON IT'S IMPORTANT NOT TO HAVE THAT BROAD DISCUSSION AND THEN ALLOW PEOPLE TO CHANGE THEIR SCORES IS THAT THE SCORE IS NO LONGER GOING TO REFLECT THE SPECIFIC DISCUSSION OF THAT APPLICATION.

SO THE WAY WE NORMALLY DO IT NOW IS WE RETAIN THE SCORE BECAUSE THE SCORES ARE DONE AFTER THE INDIVIDUAL APPLICATION IS DISCUSSED, AND THEN INDIVIDUALLY A GRANTS WORKING GROUP MEMBER CAN CHANGE IT. BUT ONCE DISCUSSION BY THE GROUP BEGINS ABOUT MOVING APPLICATIONS, THE SCORES ARE FIXED SO THAT IT'S CLEAR THAT THE SCORE REMAINS THE SAME, BUT THEN THE RECOMMENDATION WAS MADE TO MOVE IT INTO A

DIFFERENT TIER.

MR. SHESTACK: SO I THINK MAYBE THE BETTER VERSION WOULD BE THE GRANT WORKING GROUP GETS TO LOOK AGAIN, MAYBE VOTE OUT AN OUTLIER, FOR INSTANCE, BY SAYING, YES, EVEN THOUGH THIS WAS TECHNICALLY IN TIER III, WE THINK IT SHOULD BE IN TIER II. AND THAT IS PART OF THE RECOMMENDATION GIVEN TO THE BOARD. THAT'S ENOUGH INFORMATION. I DON'T KNOW IF I CARE ABOUT THE SPECIFIC NUMBER. I DON'T KNOW.

DR. LEVIN: I FUNCTIONALLY DON'T SEE ANY DIFFERENCE WITH THAT IN THE CURRENT SYSTEM, WHICH ALLOWS PEOPLE TO GAME THEIR SCORES BEFOREHAND. I'VE SEEN SCORES AS HIGH AS 95 AND AS LOW AS 15, AND THEN JUST MOVE THE LINES DURING THE MEETING OF WHAT'S FUNDED AND WHAT ISN'T. I THINK IT DEPENDS WHEN YOU ARE GOING TO DO THE GAMING; BUT IF SOMEBODY IS COMMITTED TO DOING THAT, THEY CAN DO IT.

DR. SAMBRANO: THE DIFFERENCE IS THEY DON'T KNOW THE OUTCOME UNTIL THE SCORES ARE FIXED IN THE CURRENT SYSTEM. THEY DON'T KNOW WHAT TIER IT'S GOING TO LAND IN.

CHAIRMAN THOMAS: MR. HARRISON HAD A COMMENT.

MS. BONNEVILLE: I WAS JUST GOING TO SAY BETH NEEDS A BREAK, SO IF WE COULD TAKE A FIVE- OR

TEN-MINUTE BREAK, THAT WOULD BE GREAT.

CHAIRMAN THOMAS: THANK YOU. FIVE MINUTES. WE'LL BE BACK IN FIVE.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: EVERYBODY PLEASE TAKE THEIR SEATS. OKAY. SO ALL MEMBERS OF THE BOARD PLEASE TAKE YOUR SEATS. OKAY. DO WE HAVE FURTHER DISCUSSION?

MR. SHEEHY: SO I'M WONDERING IF A WAY TO RESOLVE THIS, BECAUSE I DO AGREE WITH DR. SAMBRANO, THAT ONCE -- THE SCIENTISTS NEED TO ENTER THEIR SCORES AND LOCK THEM IN. MAYBE A WAY TO RESOLVE THIS IS TO HAVE WHAT I MIGHT CALL A RECALIBRATION STEP. AND IT'S IMPORTANT TO ME THAT EVERYBODY GET TO PARTICIPATE IN THIS, BUT THAT WE LIMIT IT TO SCIENTIFIC ISSUES OR WHAT WE SAY IS THAT THESE WILL NOT BE PROGRAMMATIC OR PORTFOLIO ISSUES.

SO THE SCIENTISTS CAN LOOK AT THE RANK ORDER, AND MAYBE WE DO AWAY WITH OUR AUTOMATIC MINORITY REPORT STIPULATION AND LET THE MINORITY REPORT PROCESS TAKE PLACE IN THIS CONTEXT SO WE MAKE IT A LITTLE BIT MORE FLEXIBLE, BUT THAT WE HAVE THAT MOMENT WHERE -- AND I THINK THIS REALLY GETS TO THE HEART OF WHAT THE ISSUE IS AT LEAST IN TERMS OF MOVING PROGRAMMATIC REVIEW UP HERE. AND WHAT THE

SCIENTISTS WERE CONCERNED ABOUT IS THAT THEY CAN -- THEY LOOK AT THESE GRANTS AND THEY'VE ALL DONE THIS BLINDLY, AND THIS GIVES THEM A CHANCE TO LOOK AND SEE WHAT THEIR SOMETIMES TWO DAYS OF REALLY, REALLY HARD WORK HAS PRODUCED AND TO SEE COLLECTIVELY WHAT THEY'VE DONE AND TAKE A GUT CHECK AND MAKE SOME ADJUSTMENTS.

I WILL NOTE IN GENERAL IN PROGRAMMATIC REVIEW OVER THE LAST, I WOULD SAY, PROBABLY FOUR OR FIVE SESSIONS, MOST OF THE THINGS THAT THEY HAVE PROPOSED MOVING, MOSTLY INITIATIVES TO MOVE STUFF HAVE COME FROM THE SCIENTISTS AND THEY'VE BEEN BASED ON, FRANKLY, GENERALLY SCIENTIFIC KIND OF CONCERNS. IT'S MORE OFTEN THAN NOT THE DISCUSSION ENDS UP BEING WE'RE NOT HERE TO RE-REVIEW THE GRANT. YOU NEED TO DECIDE IF THERE'S A GOOD REASON TO MOVE IT.

IF THAT KIND OF SCHEME MIGHT BE SOMETHING THAT PEOPLE WOULD BE COMFORTABLE WITH. AND, AGAIN, MOVING THE PROGRAMMATIC DISCUSSION CLEARLY TO THE BOARD, BUT JUST A STEP TO RECALIBRATE, TO LOOK, TO BE THOUGHTFUL, TO BE A LITTLE MORE DELIBERATE. AND I THINK IF WE LET EVERYBODY PARTICIPATE, WITH THE PATIENT ADVOCATES BEING AWARE THAT THIS IS NOT THE CHANCE TO SAY MY DISEASE DIDN'T GET A FAIR SHAKE, THAT'S FOR THE BOARD, OR A DISEASE THAT I CARE ABOUT

OR A DISEASE THAT WE'RE UNDERREPRESENTED IN, I DON'T THINK ARE GETTING THE OPPORTUNITY THAT THEY NEEDED TO BE HEARD. THAT DISCUSSION CAN TAKE PLACE HERE. DOES THAT SEEM LIKE --

CHAIRMAN THOMAS: MR. SHEEHY, YOU'RE SUGGESTING THAT THE SCORES STAY THE SAME AS DR. SAMBRANO RECOMMENDS?

MR. SHEEHY: IT WOULD BE ONE ADDITIONAL STEP. SO THIS SLIDE STAYS, BUT MAYBE WHAT WE DO IS WE LOOK AT THE -- WE KIND OF DUMP THE MINORITY REPORT THING AND WE PUT IN A FINAL STEP THAT EVERYBODY LOOKS, THEY LOOK WHERE THE LINES ARE DRAWN BECAUSE ONE THING IS THE LINES ARE DRAWN RATHER ARBITRARILY. THEY MAY THINK THAT 75 IS A LITTLE TOO HIGH OR A LITTLE TOO LOW FOR MERIT OR MAYBE TOO HIGH FOR MERIT, AND THEY MAY WANT TO ADJUST THEIR MERIT LINE DOWN A BIT OR THEIR MERIT LINE UP.

MR. SHESTACK: MOVE SOMETHING TO ANOTHER TIER BASICALLY.

MR. SHEEHY: ALL WITHIN THE NOTION THAT THIS IS GOING TO BE REALLY ON SCIENTIFIC REASONS AND NOT ON PORTFOLIO REASONS.

MR. SHESTACK: PORTFOLIO REASONS WILL BE ADDRESSED AT THE FULL BOARD.

MR. SHEEHY: EXACTLY. AND IF SOMEONE

RAISES A PORTFOLIO ISSUE, YOU GUYS HAVEN'T GOT ENOUGH OF THIS OR THAT, WE WILL SAY THAT'S GOING TO BE SOMETHING WE'LL BE HAPPY -- STAFF WILL MAKE A NOTE OF THAT, AND WE'LL BRING THAT UP AT THE BOARD.

DR. STEWARD: I THINK THAT CAPTURES IT PERFECTLY.

MS. WINOKUR: WHERE IS THE PART ABOUT VOTING?

MR. SHEEHY: WE WOULD ALLOW PATIENT ADVOCATES TO PARTICIPATE IS MY UNDERSTANDING.

CHAIRMAN THOMAS: TOTALLY ALLOWED TO PARTICIPATE, BUT WOULD NOT HAVE THE VOTE ON THE SCIENTIFIC SCORING OR THE RECALIBRATION IN THE GRANTS WORKING GROUP.

MR. SHEEHY: WE WOULD HAVE A VOTE AT THE RECALIBRATION STAGE.

CHAIRMAN THOMAS: I'M SORRY?

MR. SHEEHY: WHAT I PROPOSE IS WE WOULD HAVE -- IF THERE ARE MOTIONS MADE IN THIS RECALIBRATION STAGE, WE WOULD HAVE A VOTE.

CHAIRMAN THOMAS: I UNDERSTAND THAT THE ISSUE, THE REASON FOR HAVING NO VOTE WAS THIS NOTION THAT THE CONFLICT THAT I OUTLINED ORIGINALLY WAS THAT THEY DIDN'T WANT THERE TO BE AN APPEARANCE THAT THROUGH VOTING, HAVING BOARD MEMBERS IN THE GRANTS

WORKING GROUP VOTING ON INDIVIDUAL APPLICATIONS, THAT IT WOULD GIVE THE APPEARANCE OF CONFLICT, WHICH IS WHY, SINCE CONFLICT IS THEIR SORT OF PRINCIPAL THEME THROUGHOUT THIS THING, THAT I PROPOSED THAT IT WOULD NOT HAVE THAT AND THAT THAT BE A COMPROMISE POSITION.

MR. SHEEHY: THAT'S NOT SOMETHING I COULD ACCEPT. I MEAN YOU'RE ASSIGNING A SECOND CLASS STATUS IN NOT ALLOWING US TO PARTICIPATE. I DON'T THINK THE SCIENTISTS AT THE WORKING GROUP WOULD SUPPORT THAT. AND I DON'T SEE THE RATIONALE BECAUSE THE CONFLICT THAT WE'RE TALKING ABOUT IS WHERE WE MIGHT MOVE SOMETHING BASED ON OUR OWN DISEASE PRIORITIES WHEN CLEARLY, IF THE MATTER IS UNDER DISCUSSION OR SCIENTIFIC, WE'RE ONLY GOING TO CONCUR OR NOT CONCUR WITH THE SCIENTIFIC ISSUES THAT THE SCIENTISTS ARE MAKING. AND SOMETIMES WHEN WE AGREE WITH THE SCIENTISTS, WE AGREE WITH THE OUTLIER. AND SOMETIMES WE WILL AGREE WITH AN OUTLIER BECAUSE THEY ARE ENCOURAGING US TO TAKE, JUST GIVE AN EXAMPLE, A GREATER DEGREE OF RISK THAN MIGHT NORMALLY TAKE PLACE, FRANKLY, AT NIH.

SO THEY PUT UP -- A SCIENTIST MAY SAY THIS PROJECT -- AND WE'LL LISTEN TO THEM. WE'VE BEEN SITTING THERE FOR TWO DAYS WITH THEM. AND THERE MAY

BE A PROJECT WHERE SOMEBODY SAID THIS WILL NOT WORK AND SOMEBODY ELSE REALLY BELIEVES THAT IT MIGHT NOT WORK, BUT THIS IS A GOOD TEAM, THEY HAVE A GREAT IDEA, AND IF THIS WORKS, THIS WILL BE TRANSFORMATIVE. AND TO TELL US WE COULDN'T WEIGH IN ON THE SIDE OF THAT OUTLIER OR WE MIGHT WEIGH IN ON THE MORE CONSERVATIVE PERSON BECAUSE WE WANT TO CONSERVE OUR MONEY DOESN'T MAKE SENSE TO ME ON A POLICY BASIS, AND YOU'RE MAINTAINING KIND OF A SEGREGATED -- WELL, I DON'T THINK THAT BECAUSE I THINK THAT REFERS TO A SPECIFIC INCIDENT IN HISTORY, BUT YOU'RE MAINTAINING A VERY DIMINISHED STATUS FOR PATIENT ADVOCATES AT THE WORKING GROUP THAT'S INCONSISTENT WITH THE DIRECT LANGUAGE OF PROP 71.

CHAIRMAN THOMAS: DR. TROUNSON.

DR. TROUNSON: SO I HAVEN'T WEIGHED INTO THIS BECAUSE THERE'S SUCH A LOT OF MILEAGE THAT'S ALREADY GONE ON. BUT AS A SORT OF PERSON LOOKING IN AT THIS, IT SEEMS TO ME THAT IT WAS REJECTED THAT THE IOM, AS I READ IT, SAID THAT THE PATIENT ADVOCATES NEEDED TO BE EITHER ON THE BOARD OR IN THE GRANTS WORKING GROUP. SO EITHER ONE OR OTHER, BUT NOT BOTH. NOW, THAT'S REJECTED.

SO MY PROBLEM IS WHEN IT'S REJECTED AND YOU'VE STILL GOT THE PATIENT ADVOCATES IN BOTH

PLACES, LET'S NOT DESTROY THE REST OF IT BY HAVING THAT. ONCE ONE REJECTION, THE ISSUE IS REJECTED, LET'S TRY AND SORT OF MAKE SURE WE DON'T LOSE THE VALUE OF THE PATIENT ADVOCATES WHO ARE IN BOTH PLACES BECAUSE THAT'S WHAT IT IS STILL.

SO I ACTUALLY SUPPORT WHAT JEFF IS SAYING THERE. I THINK BEING PART OF THE DISCUSSION AND TO HELP SORT OF GET THESE INTO -- SCIENTIFICALLY GET THESE INTO THE RIGHT PLACE SEEMS TO MAKE OKAY SENSE TO ME. AND I THINK THAT'S THE -- I THINK THAT'S WHAT I FELT THE GRANT'S WORKING GROUP SCIENTISTS WERE SAYING. I THINK THAT'S WHAT THE PATIENT ADVOCATES ARE SAYING. SO HAVING DONE THE FIRST THING THAT DIDN'T WANT TO DO WHAT IOM OR COULDN'T DO, IT DOESN'T MATTER, BUT I DON'T THINK WE OUGHT TO GO AND SORT OF DESTROY SOMETHING THAT IS REALLY GOOD AND FEELS GOOD AND IS BEING UTILIZED WELL.

SO IF YOU STICK TO THE SCIENCE, YEAH; BUT THERE ARE A LOT OF THINGS AROUND SCIENCE ISSUES WHICH, IN FACT, ARE SOMETIMES PROGRAMMATIC, SO IT WILL SPILL A BIT. BUT I THINK IN THE END YOU'RE KEEPING THE BEST PART OF IT AND NOW THROWING THE BABY OUT WITH THE BATH WATER. SO I WOULD FEEL MYSELF, AND I'M NOT SPEAKING FOR ANYBODY ELSE BECAUSE I'VE NOT CAUCUSED THAT, BUT I FEEL WHAT JEFF

HAS SUGGESTED IS PROBABLY A REASONABLE OUTCOME GIVEN THAT WE DIDN'T WANT TO DO WHAT THE IOM SUGGESTED.

CHAIRMAN THOMAS: THANK YOU, DR. TROUNSON. MR. TOCHER.

MR. TOCHER: THANK YOU, CHAIR THOMAS. JUST SO WE CAN FOLLOW ON THE SLIDES. AND, JEFF, LET ME SEE IF I'VE INCORPORATED YOUR SUGGESTIONS PROPERLY. SO STEP ONE WITH THE BYLAWS PRESCRIBING THE TIERS WOULD CONTINUE.

SECOND, WE WOULD PROCEED AS PROPOSED IN THE STEP TWO SLIDE. SO THE SCIENTIFIC REVIEW AND SCORING WOULD BE CONDUCTED BY THE SCIENTIFIC MEMBERS WITH THE INPUT OF PATIENT ADVOCATES EXCEPT AS TO SCORING.

ALSO IN STEP THREE, THEN AFTER CONSIDERATION OF ALL THE APPLICATIONS, THE SCIENTISTS WOULD STILL BE GIVEN AN OPPORTUNITY TO CHANGE ANY SCORES AS THEY WISH. AND AFTER AN APPROPRIATE AMOUNT OF TIME, THE FINAL SCORES WOULD BE ENTERED AND THEN THEY WOULD BE TABULATED. AT THAT POINT, THE SCORES WOULD BE FIXED AND THEIR RANK ORDER THEN WOULD BE REVEALED, AND THE SCORES COULD NOT BE CHANGED.

SO INSTEAD OF THIS STEP FOUR, THAT WOULD BE REPLACED WITH THEN THERE WOULD PROCEED A

DISCUSSION OF RECALIBRATION, IF YOU WILL, WHICH WOULD BE THE ABILITY FOR ALL MEMBERS OF THE WORKING GROUP, PATIENT ADVOCATES AND SCIENTIST MEMBERS, TO MAKE A MOTION TO MOVE FOR NONPROGRAMMATIC REASONS AN APPLICATION IN OR OUT OF A GIVEN TIER AND INTO ANOTHER.

MR. SHESTACK: THAT'S DIFFERENT THAN WHAT IT SAYS THERE.

MR. TOCHER: THAT'S RIGHT. I'M TRYING TO SEE IF I'VE GOT HIS PROPOSAL. MINORITY REPORTS WOULD BE KEYED OFF THE VOTES ON THOSE MOTIONS JUST AS THEY ARE TODAY. AND THEN YOU WOULD PROCEED UNTIL THERE ARE NO MORE MOTIONS, AND THEN THERE WOULD BE A FINAL MOTION ON THE WHOLE SLATE UP TO THE BOARD.

MR. SHEEHY: YEAH. I THINK THAT SOUNDS VERY GOOD. I WANT TO HEAR FROM DR. TROUNSON AND DR. SAMBRANO AND POSSIBLY FROM DR. OLSON. IF THAT SOUNDS LIKE -- ESPECIALLY I THINK WE NEED TO STIPULATE FAIRLY CLEARLY THAT PROGRAMMATIC REVIEW IS GOING TO TAKE PLACE AT THE BOARD. SO THIS IS REALLY -- I HOPE THAT IT WOULD BE DRIVEN, FRANKLY, BY THE SCIENTISTS TRYING TO FINE-TUNE THEIR WORK. BUT IF PEOPLE ARE COMFORTABLE WITH THAT, I THINK THAT THAT CAPTURES EXACTLY.

DR. KRONTIRIS: AND THE PATIENT ADVOCATES

ARE VOTING AT THIS LAST STEP?

MR. TOCHER: THAT'S CORRECT.

MS. SAMUELSON: BUT THERE'S NO PROGRAMMATIC DISCUSSION; IS THAT RIGHT?

MR. TOCHER: THE PROGRAMMATIC WILL HAPPEN HERE AT THE BOARD. THIS WOULD BE FOR NONPROGRAMMATIC REASONS.

MS. LANSING: SO THEY'RE VOTING NOW, RIGHT? IS THAT THE DIFFERENCE?

MR. TOCHER: YES. THEY WOULD BE VOTING ON MOTIONS TO MOVE AN APPLICATION OUT OF A TIER AND INTO ANOTHER.

MS. LANSING: THAT'S DIFFERENT THAN WHAT OS AND I HAD SAID, SO THIS USURPS IT.

MR. TOCHER: I DON'T BELIEVE OS PROPOSED AN ADDITIONAL VOTING STEP, BUT I'LL LET OS SPEAK.

DR. STEWARD: IT'S REALLY PRETTY MUCH THE SAME THING. EXACTLY HOW IT HAPPENS, THE OPPORTUNITY TO REORDER THE APPLICATIONS. AND I THINK THE IMPORTANT THING IS THAT EVERYONE WOULD PARTICIPATE IN THE VOTE, IN THE FINAL VOTE, WHICH WOULD BE THE RANK ORDER OF APPLICATIONS IN TERMS OF THEIR RECOMMENDATIONS FOR FUNDING, NOT CHANGING THE NUMBERS.

MR. TOCHER: THAT'S RIGHT.

CHAIRMAN THOMAS: DR. SAMBRANO, DID YOU HAVE A COMMENT?

DR. SAMBRANO: I THINK THIS IS A GOOD AND REASONABLE AMENDMENT TO WHAT WE PROPOSED.

MS. LANSING: OKAY. SO CAN I CALL FOR THE VOTE?

CHAIRMAN THOMAS: HOLD ON ONE SEC, SHERRY. WE STILL HAVE A HAND OR TWO HERE IN THE ROOM.

MR. SHESTACK: MARCY, I THINK, HAD SOME LANGUAGE SHE WANTED TO CHANGE EARLIER ON THAT MAYBE COULD BE WORKED INTO ONE SO IT'S ALL ONE PIECE. IS THAT POSSIBLE?

MR. HARRISON: YES.

CHAIRMAN THOMAS: I THINK THAT WAS ALREADY --

MR. SHESTACK: IT'S BEEN DONE. OKAY.

CHAIRMAN THOMAS: -- BEEN DISCUSSED AND DECIDED UPON.

MR. ROTH: JUST A CLARIFICATION. I WOULDN'T SAY FOR PROGRAMMATIC REASONS. I'D SAY FOR SCIENTIFIC REASONS ONLY. SO WE GET THAT WORD PROGRAMMATIC OUT.

MR. TOCHER: I UNDERSTAND.

MR. SHEEHY: WE HAVE TO BE -- LET'S LEAVE A WIGGLE ROOM. SCIENTIFIC REASONS RELATED TO THE

INTENT OF THE RFA. SO YOU MIGHT THINK -- I THINK ALL OF US ARE THINKING OF THIS IN THE CONTEXT OF THE RFA WE JUST HAD, WHICH WAS A RESEARCH LEADERSHIP AWARD. THERE WERE CERTAIN KIND OF SOFT ISSUES AROUND A PERSON'S BACKGROUND, ETC., ETC., THAT WERE BRINGING THEM IN, THAT YOU MIGHT NOT CALL TRUE SCIENTIFIC REASONS. IF YOU'RE TALKING ABOUT SOMEONE'S LEADERSHIP ABILITY, IS THAT A SCIENTIFIC REASON OR IS THAT A PROGRAMMATIC REASON? WITHIN THE CONTEXT OF THAT RFA, THAT'S ONE OF THE CRITERIA. THAT'S A SCIENTIFIC REASON.

MR. SHESTACK: RELATED TO THE CRITERIA OF THE RFA.

MR. SHEEHY: RELATED TO THE SCIENTIFIC REASONS RELATED TO -- DOES THAT SOUND GOOD?

DR. TROUNSON: WELL, I THINK THEY WERE SCIENTIFIC ANYWAY. AS I SAID, I THINK YOU HAVE TO HAVE SOME LITTLE BIT OF LATERAL FLEXIBILITY HERE BECAUSE YOU'RE RIGHT. WHAT WE DON'T WANT TO DO IS GET -- WE WANT TO GET THE PROGRAMMATIC PART BASICALLY HERE. SO WITH THE INTENT, MAYBE WE'LL DO IT, BUT THE SCIENCE DOES SPREAD OUT A FAIR WAY. AND IT'S THEIR ABILITY TO WORK WITH OTHERS AND IS THERE MATERIAL CAPACITY AT THE PLACE. THERE ARE A LOT OF OTHER THINGS THAT WERE NOT JUST STRICTLY THE SCIENCE

PROJECT, WHICH IS FINE.

CHAIRMAN THOMAS: DR. LEVIN.

DR. LEVIN: IF THE INTENT IS TO JUST MOVE THE PROGRAMMATIC REVIEW UP TO THE ICOC, THEN IT SEEMS YOU SHOULD SAY JUST THAT, THAT IT'S FOR NONPROGRAMMATIC REASONS BECAUSE IT COULD BE FINANCIAL REASONS OR IP. DEPENDING ON THE RFA, THERE'S ALL SORTS OF REASONS THAT ARE PART OF THE RFA, AND THOSE SEEM LIKE VALID REASONS TO MOVE GRANTS IN OR OUT OF A FUNDING TIER. IT'S JUST THAT PROGRAMMATIC REVIEW HAS TO BE THE PURVIEW OF THIS BOARD.

MR. HARRISON: IT SEEMS TO ME THAT WHAT WE'RE TRYING TO GET TO IS THE CRITERIA DEFINED BY THE RFA. SO MAYBE WE SHOULD JUST SAY BASED ON THE ASSESSMENT OF THE CRITERIA IN THE RFA, THE REVIEW CRITERIA.

CHAIRMAN THOMAS: SHERRY, WE'RE ALMOST THERE. JOAN.

MS. SAMUELSON: THE PROBLEM I STILL HAVE WITH IT, I'M SORRY TO BE A STINKER ABOUT THIS, BUT IT SEPARATES THE SCIENTISTS WHO HAVE DONE THIS CAREFUL REVIEW FROM A PROGRAMMATIC DISCUSSION WHICH WILL TAKE PLACE HERE, BUT WILL NOT HAVE THE BENEFIT OF THEIR THOUGHTS WHEN THEY STEP BACK AND GET THAT

30,000 FOOT VIEW, WHICH THEY HAVE EXPRESSED IN THE CASE OF THIS ONE SUBSET OF THE GRANTS WORKING GROUP, THE ONES WORKING WITH THIS LAST FRIDAY, IN WHICH THEY WERE QUITE VEHEMENT THAT THEY LOVED PROGRAMMATIC REVIEW, BEING INVOLVED IN IT, AND THAT THEIR SCORING IS LIFELESS -- THAT'S MY INTERPRETATION OF WHAT THEY SAID -- WITHOUT BEING CONNECTED TO A PROGRAMMATIC DISCUSSION.

WE'RE DOING IT TO PLEASE GOD, SOOTH THE ONE AGITATED BLOGGER -- I CAN SAY THAT BECAUSE I'M A PATIENT ADVOCATE AND I CAN BE RASH ONCE IN A WHILE -- AND WHAT ARE WE GOING TO ACCOMPLISH?

ANOTHER THING THAT THE SCIENTISTS RECOMMENDED I THOUGHT WAS BRILLIANT WAS TO SAY WHAT THEY REALLY SHOULD BE DOING IS DOING A PORTFOLIO REVIEW TO SEE WHERE WE ARE SCIENTIFICALLY AS A RESULT OF THE FUNDING THAT WE HAVE SPENT SO FAR. I THINK THAT'S WHAT WE SHOULD BE DOING AND WOULD INFORM ALL OF OUR DECISION-MAKING GOING FORWARD.

AND IF THAT APPEARS BENEFICIAL, THEN WE'RE GOING TO HAVE COMPLEMENTARY DISCUSSIONS IN SOME EDITORIAL SOMEWHERE BECAUSE WE'LL BE DOING SOMETHING THAT WOULD REALLY BENEFIT OUR MISSION. THIS I SEE AS TRYING TO SOLVE PROBLEMS THAT AREN'T MISSION BASED. AND SO I THINK WE SHOULD DO THAT. THAT

WOULD BE RESPONDING TO THE IOM CERTAINLY, AND WE'RE OBVIOUSLY DOING ALL THIS HARD WORK TO TRY TO RESPOND TO THEIR CONCERNS, AND IT WOULD BE DOING SOMETHING THAT IS IMPORTANT TO THE OVERALL MISSION THAT THE IOM MUST SHARE WITH US. AND WE CAN AVOID CONCERN ABOUT VOTING BY THE DEANS. THAT SEEMS LIKE THE ONE THING THAT HAS RESONATED. IF WE CAN KEEP THE EXPERTISE OF THE DEANS IN OUR DECISION-MAKING, I THINK WE CAN DO THAT, BUT I HATE THE IDEA OF LOSING THE EXPERTISE OF THE WORKING GROUP AFTER ALL THESE YEARS OF INVOLVEMENT BY THEM IN OUR PORTFOLIO.

SO I GUESS THAT'S ANOTHER RECOMMENDATION AS WELL AS AN EXPLANATION FOR A NO VOTE.

CHAIRMAN THOMAS: THANK YOU. MR. SHEEHY, I'M COMFORTABLE WITH YOUR APPROACH. SO I WOULD ENDORSE THE AMENDMENT. MR. HARRISON, DO YOU HAVE A COMMENT?

MR. ROTH: CALL THE QUESTION.

CHAIRMAN THOMAS: QUESTION IS CALLED FOR. MR. HARRISON, DO YOU WANT TO TAKE A STAB AT THE --

MR. HARRISON: SO THE MOTION IS, AS I UNDERSTAND IT, IS TO APPROVE MOVING THE DISCUSSION OF PROGRAMMATIC ISSUES TO THE BOARD, BUT RETAIN THE ABILITY OF THE ENTIRE GRANTS WORKING GROUP, INCLUDING THE PATIENT ADVOCATE MEMBERS, TO

RECALIBRATE FUNDING RECOMMENDATIONS BASED ON THE REVIEW CRITERIA, FOLLOWING THE SUBMISSION OF THE SCORES, BY CONSIDERING MOTIONS TO MOVE APPLICATIONS AND MAINTAIN THE EXISTING PROCESS FOR MINORITY REPORTS.

CHAIRMAN THOMAS: WELL SAID.

MR. TOCHER: I WOULD ONLY ADD THAT IT WOULD ALSO INCLUDE THE STEPS IN STEPS SIX AND SEVEN AS WELL.

CHAIRMAN THOMAS: OKAY. THANK YOU. SO WE HAVE A MOTION. IT'S BEEN SECONDED. ANY FURTHER BOARD DISCUSSION? JOAN MADE SOME POINTS. ANY FURTHER DISCUSSION BY MEMBERS OF THE BOARD? HEARING NONE --

MS. SAMUELSON: AND THIS PORTFOLIO REVIEW, I WOULD RECOMMEND, BE DONE BY THE SCIENTISTS IN THE WORKING GROUP WITH ALL THE EXPERTISE THEY'VE GARNERED OVER THE LAST EIGHT YEARS.

CHAIRMAN THOMAS: I THINK THE NOTION OF PORTFOLIO REVIEW, THAT'S NOT SOMETHING REALLY PROCEDURALLY THAT CAN BE DISCUSSED OUTSIDE THE CONTEXT HERE, BUT I UNDERSTAND THE POINT.

ARE THERE ANY COMMENTS BY MEMBERS OF THE PUBLIC? MS. MARIA, PLEASE TAKE ROLL.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.
MS. BONNEVILLE: DAVID BRENNER. ANNE-MARIE DULIEGE. MARCY FEIT.
MS. FEIT: YES.
MS. BONNEVILLE: LEON FINE. MICHAEL GOLDBERG.
MR. GOLDBERG: YES.
MS. BONNEVILLE: SAM HAWGOOD.
DR. HAWGOOD: YES.
MS. BONNEVILLE: STEPHEN JUELSGAARD.
DR. JUELSGAARD: YES.
MS. BONNEVILLE: TED KRONTIRIS.
DR. KRONTIRIS: YES.
MS. BONNEVILLE: SHERRY LANSING.
MS. LANSING: YES.
MS. BONNEVILLE: JACOB LEVIN.
DR. LEVIN: YES.
MS. BONNEVILLE: BERT LUBIN.
DR. LUBIN: YES.
MS. BONNEVILLE: MICHAEL MARLETTA. ROBERT PRICE.
DR. PRICE: YES.
MS. BONNEVILLE: FRANCISCO PRIETO. CARMEN PULIAFITO.
DR. PULIAFITO: YES.

MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: DUANE ROTH.
MR. ROTH: YES.
MS. BONNEVILLE: JOAN SAMUELSON.
MS. SAMUELSON: NO.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: JONATHAN SHESTACK.
MR. SHESTACK: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: EUGENE WASHINGTON. DIANE WINOKUR.
MS. WINOKUR: YES.
CHAIRMAN THOMAS: OKAY. THANK YOU, EVERYBODY. THAT WAS A VERY ROBUST AND HEALTHY DISCUSSION, AIRING ALL THE APPROPRIATE ISSUES. THANK YOU, EVERYBODY, FOR THEIR SUGGESTIONS AND

INPUT.

LET'S GO ON TO ITEM 3, WHICH IS THE EXTRAORDINARY PETITIONS, ADDITIONAL ANALYSIS, AND APPEALS. MR. HARRISON IS GOING TO REPORT ON THIS.

THE UNDERLYING THOUGHT HERE WAS TO HAVE A UNIFORM SYSTEM OF APPEALS THAT GO FIRST TO STAFF TO EVALUATE ON A VARIETY OF CRITERIA AND THEN HAVING SO DONE, IF THEY DETERMINE THAT THE APPEALS RISE TO THE LEVEL OF WARRANTING ADDITIONAL REVIEW BY A SUBSET OF THE GRANTS WORKING GROUP AS PART OF THE WHOLE PROCESS, THEY WOULD SO ADVISE. THAT WOULD BE TAKEN TO THE SUBSET OF THE GRANTS WORKING GROUP, THEY WOULD DO THEIR EVALUATION, AND THE RESULTS OF THAT WOULD BE MADE PART AND PARCEL OF THE SLATE THAT THEY PASSED ON TO THE BOARD FOR APPROVAL IN THE PROGRAMMATIC REVIEW SEGMENT. SO MR. HARRISON.

MR. HARRISON: THANK YOU. SO AS WITH THE OTHER POLICIES, A GROUP OF US WORKED TOGETHER AND ENGAGED IN A LOT OF BACK AND FORTH REGARDING THE PROPOSAL THAT'S IN YOUR BINDERS AS ATTACHMENT 3. THE MEMBERS INCLUDED MARIA BONNEVILLE, PAT OLSON, GIL SAMBRANO, PAUL STEIN, AND MYSELF. WE ALSO HAD SOME VALUABLE INPUT FROM STEVE JUELSGAARD. AND IF YOU LOOK AT ATTACHMENT 3 TO AGENDA ITEM 6, YOU WILL SEE THAT THERE ARE TRACK CHANGES IN THE POLICY.

THOSE ARE MR. JUELSGAARD'S PROPOSED AMENDMENTS, THE BULK OF WHICH I THINK THE GROUP CONCURS WITH. THERE ARE TWO ISSUES THAT ARE HIGHLIGHTED IN YELLOW WHICH WE'D LIKE TO HAVE A DISCUSSION OF WITH THE BOARD AND GET ALL OF YOUR INPUT.

LET ME BRIEFLY TAKE YOU BACK. AS THE CHAIR SAID, THIS IS IN RESPONSE TO THE CONCEPT PROPOSAL APPROVED BY THE BOARD PURSUANT TO WHICH THE BOARD DECIDED TO MERGE THE EXISTING EXTRAORDINARY PETITION POLICY AND ADDITIONAL ANALYSIS POLICY INTO WHAT IS CURRENTLY AN APPEALS PROCESS FOR CONFLICTS OF INTEREST WHICH IS ADMINISTERED BY CIRM'S SCIENTIFIC STAFF.

TO IMPLEMENT THE BOARD'S CONCEPT PROPOSAL, THE PROPOSED POLICY WOULD DO THE FOLLOWING. IT WOULD REPEAL THE EXTRAORDINARY PETITION POLICY AND THE ADDITIONAL ANALYSIS POLICY, AND IT WOULD REPLACE THESE POLICIES WITH A NEW POLICY THAT'S MODELED LARGELY ON THE POLICY GOVERNING APPEALS IN THE GRANTS ADMINISTRATION POLICY WHICH IS CURRENTLY LIMITED TO CONFLICTS OF INTEREST.

UNDER THE PROPOSED POLICY, APPLICANTS WHO WISH TO APPEAL A RECOMMENDATION OF THE GRANTS WORKING GROUP BASED ON A MATERIAL DISPUTE OF FACT WOULD BE REQUIRED TO SUBMIT AN APPEAL TO CIRM

SCIENTIFIC STAFF RATHER THAN COMING DIRECTLY TO THE BOARD AS HAS BEEN THE CASE IN THE PAST. LIKEWISE, WITH RESPECT TO MATERIAL NEW INFORMATION, WE WOULD REQUIRE APPLICANTS WHO WISH TO REQUEST RECONSIDERATION OF THE GRANTS WORKING GROUP'S RECOMMENDATION BASED ON MATERIAL NEW INFORMATION TO SUBMIT THAT REQUEST TO CIRM SCIENTIFIC STAFF.

WITH RESPECT TO REQUESTS FOR RECONSIDERATION, WE WOULD PROPOSE THAT THEY BE LIMITED TO APPLICATIONS THAT ARE SUBMITTED IN RESPONSE TO A TRANSLATIONAL RFA; THAT IS, AN APPLICATION WHERE THE GOAL IS TO ACHIEVE EITHER A DEVELOPMENT CANDIDATE, AN IND FILING, OR TO COMPLETE A CLINICAL TRIAL. AND THE PURPOSE FOR THIS LIMITATION IS THAT SCIENCE IS CONTINUOUSLY MOVING; SCIENTISTS ARE ALWAYS DEVELOPING NEW DATA. AND FOR PROGRAMS SUCH AS BASIC BIOLOGY, THERE ARE REPEATED OPPORTUNITIES TO SUBMIT. SO IF A SCIENTIST HAS NEW DATA FOLLOWING COMPLETION OF AN APPLICATION IN CONNECTION WITH BASIC BIOLOGY, HE OR SHE CAN SUBMIT A NEW APPLICATION.

THIS IS REALLY GEARED TO TRY TO TAKE ADVANTAGE OF INFORMATION THAT PRESENTS ITSELF WHERE THERE'S A GREAT URGENCY THAT WE PUSH FORWARD QUICKLY.

WE WOULD DEFINE MATERIAL DISPUTE OF FACT AS FOLLOWS, AND AN APPLICANT WOULD HAVE TO DEMONSTRATE EACH OF THESE CRITERIA. THE DISPUTE INVOLVES THE ACCURACY OF A STATEMENT IN THE REVIEW SUMMARY, IT PERTAINS TO AN OBJECTIVELY VERIFIABLE FACT RATHER THAN A MATTER OF SCIENTIFIC JUDGMENT OR OPINION, AND THE DISPUTE WAS NOT RESOLVED PRIOR TO OR DURING THE GRANTS WORKING GROUP MEETING. AND AS I INDICATED IN CRITERIA B, MATERIAL DISPUTE OF FACT WOULD NOT INCLUDE DISAGREEMENTS OVER INTERPRETATION OR ANALYSIS OF FACTS BY THE GRANTS WORKING GROUP OR SPECIALIST REVIEWERS OR DIFFERENCES IN SCIENTIFIC OPINION.

MATERIAL NEW INFORMATION, AGAIN, WOULD HAVE TO MEET THREE CRITERIA. FIRST, THE NEW INFORMATION WOULD HAVE TO CONSIST OF ONE OF THE FOLLOWING ELEMENTS: APPROVAL BY A REGULATORY BODY TO INITIATE OR CONTINUE A CLINICAL TRIAL, A DOCUMENTED AGREEMENT OR CONTRACT BETWEEN THE APPLICANT AND COMMERCIAL PARTNER, FINAL COURT DECISION OR ADMINISTRATIVE ACTION, DOCUMENTATION CONFIRMING THE AVAILABILITY OF CRITICAL MATERIALS NECESSARY TO CARRY OUT THE PROPOSED PROJECT, A MANUSCRIPT CONTAINING RELEVANT NEW SCIENTIFIC DATA THAT'S BEEN PEER REVIEWED AND PUBLISHED OR PEER

REVIEWED AND ACCEPTED FOR PUBLICATION. AND TO THIS LIST WE WOULD ADD TWO SUGGESTIONS BY MR. JUELSGAARD. ONE THAT WOULD INCLUDE NEW INFORMATION CONTAINED IN A FILED PATENT APPLICATION AND, TWO, CONFIDENTIAL DATA THAT'S IN THE POSSESSION OF A FOR-PROFIT APPLICANT. BECAUSE FOR-PROFITS TYPICALLY DON'T PUBLISH THEIR DATA, THIS WOULD CREATE SOME EQUITY BY PROVIDING AN AVENUE FOR FOR-PROFITS THAT'S SIMILAR TO THAT OFFERED TO ACADEMICS IN SUBITEM 5; THAT IS, A MANUSCRIPT CONTAINING NEW SCIENTIFIC DATA THAT'S BEEN PUBLISHED OR ACCEPTED FOR PUBLICATION.

THE OTHER CRITERIA FOR MATERIAL NEW INFORMATION WOULD BE THAT THE NEW INFORMATION MUST HAVE BECOME AVAILABLE TO THE APPLICANT AFTER THE GWG REVIEW MEETING AT WHICH THE APPLICATION WAS CONSIDERED. AND THE REASON FOR THIS IS THAT THERE ARE OTHER OPPORTUNITIES, INCLUDING THE SUPPLEMENTAL INFORMATION PROCESS, FOR APPLICANTS TO SUBMIT NEW INFORMATION PRIOR TO THE GRANTS WORKING GROUP MEETING. AND THEN, FINALLY, THE NEW INFORMATION WOULD HAVE TO RESPOND DIRECTLY TO A SPECIFIC CRITICISM OR QUESTION THAT'S ADDRESSED IN THE REVIEW SUMMARY.

THE PROCESS WOULD LOOK LIKE THIS. FIRST, THE APPLICANT WOULD HAVE TO SUBMIT AN APPEAL OR A

REQUEST FOR RECONSIDERATION WITHIN TEN DAYS OF RECEIVING A WRITTEN SUMMARY OF THE GRANTS WORKING GROUP'S RECOMMENDATION. CIRM SCIENTIFIC STAFF WOULD THEN REVIEW THE APPEAL OR REQUEST FOR RECONSIDERATION TO DETERMINE WHETHER OR NOT THE APPLICANT HAS SET FORTH FACTS DEMONSTRATING EITHER THE OCCURRENCE OF A MATERIAL DISPUTE OF FACT OR THE EXISTENCE OF MATERIAL NEW INFORMATION.

IF THE APPLICANT HAS MET THAT THRESHOLD AND SET FORTH CLEAR GROUNDS, THEN THE APPEAL OR REQUEST FOR RECONSIDERATION WOULD GO ON TO THE NEXT STEP. IF, ON THE OTHER HAND, THE APPLICANT HAS FAILED TO SET FORTH SUCH GROUNDS, THEN STAFF WOULD DENY IT, AND THE GRANTS WORKING GROUP'S RECOMMENDATION WOULD BE PRESENTED TO THE APPLICATION REVIEW SUBCOMMITTEE.

WITH RESPECT TO AN APPEAL OR REQUEST FOR RECONSIDERATION WHERE STAFF DETERMINES THAT THE APPLICANT HAS SATISFIED THOSE CRITERIA, THE APPLICATION WOULD BE DEFERRED UNTIL RESOLUTION IS REACHED. THOSE APPEALS OR REQUESTS FOR RECONSIDERATION WOULD THEN INITIATE A STAFF INVESTIGATION TO DETERMINE WHETHER OR NOT THE APPLICANT CAN SUBSTANTIATE THE CLAIMS IN THE APPEAL OR REQUEST FOR RECONSIDERATION, AND THIS WOULD

INCLUDE POSSIBLY CONSULTING WITH THE REVIEW CHAIR, AND ULTIMATELY STAFF WOULD MAKE A RECOMMENDATION TO THE PRESIDENT WHO WOULD BE CHARGED WITH DETERMINING WHETHER OR NOT THE APPEAL OR REQUEST FOR RECONSIDERATION SHOULD BE REFERRED TO A SUBSET OF THE GRANTS WORKING GROUP.

AND THE FACTORS THE PRESIDENT WOULD CONSIDER WOULD INCLUDE, ONE, WHETHER THE CLAIMS HAVE BEEN SUBSTANTIATED AND, TWO, WHETHER THE DISPUTE OF FACT OR NEW INFORMATION COULD HAVE SIGNIFICANTLY AFFECTED THE OUTCOME OF THE RECOMMENDATION ITSELF. IF THE PRESIDENT APPROVES OR GRANTS AN APPEAL OR REQUEST FOR RECONSIDERATION, THAT A SUBSET OF THE GRANTS WORKING GROUP WOULD BE CONVENED TO REVIEW EITHER THE MATERIAL DISPUTE OF FACT OR THE MATERIAL NEW INFORMATION AND DETERMINE WHETHER OR NOT IT CHANGES THE GRANTS WORKING GROUP'S RECOMMENDATION.

AND THEN THE FINAL STEP OF THE PROCESS IS THAT THE RECOMMENDATION OF THE SUBSET OF THE GRANTS WORKING GROUP WOULD THEN BE PRESENTED TO THE APPLICATION REVIEW SUBCOMMITTEE.

THE TWO ISSUES THAT WE WANTED TO FRAME FOR YOUR CONSIDERATION INVOLVE THE APPROPRIATE NUMBER OF MEMBERS, SCIENTIFIC MEMBERS, OF THE GRANTS WORKING GROUP WHO WOULD BE INVOLVED IN THE ADDITIONAL

REVIEW. THE PROPOSAL THAT'S IN FRONT OF YOU SUGGESTS THAT IT BE NO LESS THAN FIVE. MR. JUELSGAARD HAS PROPOSED -- EXCUSE ME. NO LESS THAN THREE. MR. JUELSGAARD HAS PROPOSED THAT IT BE NO FEWER THAN FIVE IN ORDER TO HAVE, I THINK, A BROADER SPECTRUM OF PARTICIPATION. AND THEN, FINALLY, MR. JUELSGAARD PROPOSES TO ELIMINATE REVIEWERS WHOSE SCORES ARE MORE THAN A POINT EITHER ABOVE OR BELOW THE STANDARD DEVIATION FROM THE MEAN SCORE.

SO IF THE STANDARD DEVIATION WAS 12 AND A REVIEWER ASSIGNED A SCORE THAT WAS 13 POINTS AWAY FROM THE MEAN, EITHER ABOVE OR BELOW, THEN THAT REVIEWER WOULD NOT BE INCLUDED IN THE RE-REVIEW.

SO THOSE ARE THE ISSUES FOR DISCUSSION, AND I'D TURN THE TABLE OVER TO MR. JUELSGAARD TO EXPLAIN HIS POINT OF VIEW AND THEN TO PAT OLSON AND GIL SAMBRANO TO OFFER THEIRS.

DR. JUELSGAARD: WHEN I FIRST REVIEWED THIS DOCUMENT AS IT WAS SENT OUT, I REFLECTED ON WHAT WE WERE DOING, WHICH IS TO CHANGE A POLICY THAT WE HAD THAT WAS AVAILABLE TO APPLICANTS, THE EXTRAORDINARY PETITION, AND, IN ESSENCE, TO ELIMINATE THAT IN FAVOR OF A NEW PROCESS, WHICH I'M SUPPORTIVE OF. BUT THE THING THAT I ALSO REFLECTED ON WAS WHETHER THIS PROCESS, IN MY VIEW ANYWAY,

WOULD BE ROBUST ENOUGH AND EQUITABLE ENOUGH TO THE APPLICANT WHO'S AT THE INITIAL INSTANCE OF THE GRANTS WORKING GROUP BEEN DENIED, IN ESSENCE, MOVING THAT APPLICATION FORWARD.

SO THE TWO PRINCIPLES THAT I FOCUSED ON ARE, ONE, THE NUMBER OF PEOPLE THAT ARE INVOLVED IN MAKING THAT DETERMINATION. JUST TO ADDRESS THAT BRIEFLY, AT LEAST IN MY EXPERIENCE, THE FEWER PEOPLE THAT ARE INVOLVED IN MAKING A DETERMINATION, THE MORE LIKELY YOU ARE TO STICK WITH THE STATUS QUO. I DO THINK THAT HAVING A BROADER GROUP BRINGS IN MORE OPINIONS AND MORE POSSIBILITY FOR GIVING A CRITICAL ANALYSIS THAN A SMALLER GROUP. SO RATHER THAN THREE, I THOUGHT FIVE WOULD BE APPROPRIATE. IT SHOULD BE AN ODD NUMBER SO YOU CAN HAVE CLEARLY A MAJORITY VOTE SITUATION.

I REALIZE THAT THESE ARE MY PRINCIPLES AND NOT NECESSARILY EVERYBODY ELSE'S. SO I'M JUST EXPRESSING WHAT I THINK.

THE OTHER IS THE PROCESS ITSELF AND WHO WOULD BE INVOLVED IN WHETHER IT'S THREE OR FIVE PEOPLE. AND I WAS CONCERNED ABOUT THE OUTLIER ISSUE. AND THAT IS IS THAT IF SOMEBODY, LET'S JUST ASSUME THE THREE FOR A MOMENT, IF YOU HAD THREE PEOPLE INVOLVED, BUT ONE WAS AN OUTLIER IN THE

INITIAL REVIEW OF THAT APPLICATION AND GAVE IT A SUBSTANTIALLY NEGATIVE OR POSITIVE REVIEW, WHILE PEOPLE ARE WILLING MANY TIMES TO CHANGE THEIR MIND, THERE ARE ALSO INSTANCES WHICH THEY BECOME STUCK WITH WHERE THEY ORIGINALLY PUT THEMSELVES.

AND SO IN ORDER TO TRY AND ELIMINATE THAT KIND OF BIAS THAT CAN OCCUR, AND I'M NOT SAYING IT WOULD OCCUR, BUT IT CAN OCCUR, I THOUGHT IT WOULD BE MORE PRUDENT TO TRY AND ELIMINATE IN SOME FASHION WHAT I CALL THE OUTLIERS, THE PEOPLE WHO EITHER HAD AN EXTREMELY NEGATIVE OR EXTREMELY POSITIVE IMPRESSION OF AN APPLICATION. AND THE BEST THAT I COULD DO IN THINKING ABOUT IT AT THE TIME WAS THIS NOTION OF WHERE YOU STOOD ON THE STANDARD DEVIATION CURVE.

SO THOSE WERE THE TWO PRINCIPAL REASONS WHY I BROUGHT THOSE TO THE FORE. AND I KNOW THAT THERE ARE CONCERNS ON THE PART OF THE STAFF ABOUT BOTH OF THOSE, SO I HAVE REALLY NOTHING MORE TO ADD.

MR. HARRISON: J.T., CAN I JUST BRIEFLY SUMMARIZE THE STAFF CONCERNS, AND GIL OR PAT CAN HELP ME OUT IF I MISS ONE. WITH RESPECT TO THE NUMBER OF REVIEWERS, THE THINKING OF THE GROUP WAS THAT IT WOULD BE NO MORE THAN THREE, WHICH WOULD NOT NECESSARILY MEAN THAT IT WOULD ALWAYS BE THREE.

THERE MAY BE INSTANCES WHERE THERE'S A PARTICULARLY COMPLEX ISSUE FOR WHICH YOU'D WANT A BROADER GROUP.

CHAIRMAN THOMAS: I THINK YOU MEANT NO FEWER THAN THREE.

MR. HARRISON: NO FEWER THAN THREE. BUT IF THERE'S A FAIRLY STRAIGHTFORWARD ISSUE THAT'S SUSCEPTIBLE TO A FAIRLY QUICK RESOLUTION, THEN HAVING TO FIND FIVE REVIEWERS WHO ARE AVAILABLE IN ORDER TO MAKE THAT ASSESSMENT WOULD BE BOTH TIME-CONSUMING AND PERHAPS UNNECESSARILY BURDENSOME.

WITH RESPECT TO THE QUESTION OF ELIMINATING THE OUTLIERS, I THINK THERE ARE TWO THOUGHTS. ONE IS THAT IN CERTAIN CASES AN OUTLIER MAY BE A PRIMARY REVIEWER; THAT IS, THE INDIVIDUAL WHO SPENT THE MOST TIME REVIEWING AND ASSESSING THE APPLICATION. AND YOU MAY VERY WELL WANT HIS OR HER EXPERTISE. LIKEWISE, IT MAY BE AN ISSUE THAT WAS THE BASIS FOR A PARTICULAR REVIEWER'S SCORE. AND IF THE QUESTION IS WOULD THIS NEW INFORMATION OR RESOLUTION OF A DISPUTE OF FACT HAVE CHANGED THE OUTCOME, THEN YOU'D WANT TO BE ABLE TO ASSESS FROM THAT INDIVIDUAL'S POINT OF VIEW WHETHER THIS CHANGE IN INFORMATION WOULD HAVE MADE THEM VIEW THE APPLICATION AND, HENCE, MAKE A DIFFERENT RECOMMENDATION TO THE BOARD.

DR. SAMBRANO: I THINK THE ONLY THING I WOULD ADD IS THAT GENERALLY THE WAY WE MAKE REVIEW ASSIGNMENTS FOR, SAY, A BASIC BIOLOGY REVIEW, WE ASSIGN THREE INDEPENDENT REVIEWERS TO A GIVEN APPLICATION. SO THEY ARE THE ONES THAT REALLY HAVE THE APPROPRIATE EXPERTISE AND THE IN-DEPTH KNOWLEDGE THAT THEY BRING TO THE WORKING GROUP.

SO IN THINKING ABOUT THIS POLICY, IDEALLY WHAT YOU WOULD WANT TO DO IS GET THOSE THREE ASSIGNED REVIEWERS BE THE ONES THAT YOU ASK THE QUESTION WOULD THIS CHANGE YOUR MIND. THEIR OPINION IS WHAT INFLUENCES THE BROADER GROUP.

I THINK WITH RESPECT TO ELIMINATING THE OUTLIERS, IF THAT OUTLIER HAPPENS TO BE THE KEY EXPERT IN THE AREA WHERE THAT QUESTION PERTAINS, I THINK IT WOULD BE VERY IMPORTANT TO HAVE THE OPINION OF THAT EXPERT THERE AND AVAILABLE. AND I WOULD HATE TO HAVE A COMPLICATING FACTOR DUE TO OUR POLICY THAT WOULD ELIMINATE THEIR OPINION AND HAVING THE ABILITY TO BRING THEIR OPINION INTO CONSIDERATION.

CHAIRMAN THOMAS: DR. LUBIN, THEN DR. TROUNSON. ABSOLUTELY, MR. JUELSGAARD.

DR. JUELSGAARD: IT'S JUST A QUICK RESPONSE, AND I'LL HAVE TO BE HONEST, DR. SAMBRANO. IN THINKING ABOUT THIS, I WAS THINKING MORE OF THE

REVIEWS THAT HAVE TAKEN PLACE IN THE CLINICAL DEVELOPMENT AREA. SO SOME OF THOSE WHERE WE HAD EXTRAORDINARY PETITIONS THAT WE APPROVED. AND SO I WAS REALLY MORE FOCUSED ON THAT END OF THE SPECTRUM THAN BASIC BIOLOGY, AND I CAN APPRECIATE YOUR COMMENT ON THE BASIC BIOLOGY ISSUE.

FOR ME REALLY THE IMPORTANT ONES ARE THE ONES WHERE PATIENTS ARE INVOLVED WHERE THERE ARE DISEASE ENTITIES THAT WE ARE EITHER GOING TO PROVIDE FUNDING TO PURSUE OR NOT.

WITH RESPECT TO THE EXPERTISE OF AN INDIVIDUAL, LET ME JUST ASK. SO ASSUME THAT THIS ISSUE RELATED TO THE EXPERTISE OF ONE MEMBER ON THE GRANTS WORKING GROUP WHO HAPPENED TO BE AN OUTLIER. IS IT NOT POSSIBLE TO INVOLVE SOMEBODY ELSE WHO WASN'T ON THAT INITIAL GRANTS WORKING GROUP, BUT SOME OTHER SCIENTIFIC MEMBER OF THE LARGE GRANTS WORKING GROUP WHO WOULD HAVE EXPERTISE ALSO IN THAT AREA?

DR. SAMBRANO: WE COULD, BUT IT MIGHT END UP LIMITING WHO WE CAN GO TO. PART OF IT IS THAT WE'RE KIND OF TRUSTING THE REVIEWER'S OPINION IN THE FIRST PLACE, AND WE REALLY WANT TO KNOW YOU AS AN EXPERT, WHO HAPPENS TO HAVE THE HANDS-ON KNOWLEDGE IN THAT TECHNOLOGY OR WHATEVER IS IN QUESTION, DOES

THIS NEW INFORMATION AFFECT YOUR OPINION? DOES IT CHANGE YOUR MIND? AND I THINK THAT'S THE ESSENCE OF THE QUESTION. AND IT'S HARD TO KNOW WHAT THE OPINION OF A DIFFERENT REVIEWER MIGHT BE.

SO I DON'T KNOW THAT THAT WOULD NECESSARILY HELP US IN TRYING TO MAKE THE ASSESSMENT WE'RE LOOKING FOR.

DR. JUELSGAARD: JUST ONE FINAL THING. I APPRECIATE THAT. AGAIN, THE CONCERN ON MY PART IS THAT ONCE SOMEBODY SORT OF STAKED A POSITION, FOR SOME PEOPLE IT COULD BE DIFFICULT FOR THEM TO UNSTAKE IT AND CHANGE THEIR MINDS, AND THAT WAS THE THING THAT WORRIED ME THE MOST ABOUT BEING AN OUTLIER. NOT ALL PEOPLE WILL BEHAVE THAT WAY. I GRANT THAT THERE ARE GOING TO BE VERY FAIR PEOPLE WHO WILL LOOK AT SOMETHING AND COMPLETELY CHANGE THEIR MIND, BUT I AM CONCERNED ABOUT SOME PEOPLE WHO MIGHT NOT BE THAT GRACIOUS IN TERMS OF THE WAY THEY LOOK AT THINGS.

DR. SAMBRANO: I THINK THAT THAT'S SOMETHING WE ARE VIGILANT OF, AND I THINK WE WOULD CONTINUE TO BE SO. I THINK WHAT WE'RE ASKING FOR IS JUST FLEXIBILITY IN HOW AND WHO WE CAN ASSIGN TO MAKE SURE THAT WE HAVE THE APPROPRIATE PEOPLE TO DO THIS. I THINK HAVING ONE STANDARD DEVIATION, WHICH,

DEPENDING ON THE SCORES, CAN SOMETIMES BE VERY LOW, SOMETIMES IT'S THREE POINTS, MAY JUST BY VIRTUE OF THAT POLICY TAKE AWAY SOME OF OUR KEY REVIEWERS.

DR. LUBIN: SO YOU ADDRESSED, BOTH OF YOU, THE CONCERNS THAT I WOULD HAVE OF ELIMINATING. I KNOW EVERYBODY -- YOU CHOOSE PRIMARY REVIEWERS WHO ARE EXPERTS IN THE AREA THAT THE GRANT IS RELATED TO. SO I COMPLETELY APPRECIATE THAT.

DO PEOPLE WHO SUBMIT GRANTS KNOW WHO THE REVIEWERS ARE, AND CAN THEY EXCLUDE A REVIEWER IF THEY'RE BOTH BATTLING FOR THE SAME ISSUE AND FEEL A REVIEWER WOULDN'T BE FAIR IN THE ANALYSIS? I JUST WANTED THE BOARD TO KNOW. I KNOW YOU DO THAT.

DR. SAMBRANO: SO THAT HAPPENS IN A COUPLE OF WAYS. SOMETIMES WHEN AN APPLICANT SUBMITS AN APPLICATION, THEY WILL LET ME KNOW OF INDIVIDUALS THEY FEEL THEY HAVE A CONFLICT WITH OR PERSONAL DIFFERENCES WITH THAT, AND WE TAKE THAT INTO CONSIDERATION WHEN MAKING OUR ASSIGNMENTS. AND AFTER THE REVIEW, WE PROVIDE THE ROSTER OF THE GRANTS WORKING GROUP REVIEWERS. SO SHOULD THERE BY A CONFLICT OR ANYTHING ELSE THAT THEY IDENTIFY, THEY CAN CERTAINLY LET US KNOW.

CHAIRMAN THOMAS: DR. OLSON, THEN DR. TROUNSON.

DR. OLSON: I JUST WANT TO REITERATE THE ONE POINT THAT GIL MADE, WHICH IS THE NOTION OF THE OUTLIERS. I THINK YOU WANT TO RETAIN THAT CONCEPT, AND I'M NOT SURE I LIKE IT BECAUSE OF THE REASONS THAT GIL HAS ALREADY SUMMARIZED, WHICH HAS TO DO WITH WHERE THE EXPERTISE MAY BE, BUT YOU REALLY WOULD HAVE TO SET A THRESHOLD BECAUSE WHEN THERE'S A STANDARD DEVIATION OF TWO OR THREE, MANY PEOPLE WILL FALL OUTSIDE OF THAT AND YOU'RE LIKELY TO LOSE ALL YOUR REVIEWERS. I DO REALLY THINK THAT THIS WHOLE NOTION OF OUTLIERS PERHAPS NEEDS SOME THOUGHT.

CHAIRMAN THOMAS: I WOULD NOTE, JUST TO BACK UP ONE POINT GIL MADE, THAT I'VE BEEN IN A REVIEW WHERE THE ENTIRE REVIEW TURNED ON AN EXPERT WHO HAD A PARTICULARLY STRONG OPINION, IN THIS PARTICULAR CASE, AGAINST THE PROPOSAL. AND THIS PERSON WAS THE EXPERT ON THE SUBJECT IN THE ROOM, AND HE WAS THE OUTLIER ON THE VOTE. AND THAT IS A POINT OF VIEW, I THINK, THAT'S IMPORTANT TO MAINTAIN GOING FORWARD.

MR. ROTH: SO I JUST HAD A QUESTION ON THE TIMING. I ASSUME NEW INFORMATION CAN BE SUBMITTED AND IT WOULD BE ENCOURAGED UP UNTIL THE GRANTS WORKING GROUP?

MR. HARRISON: THERE'S AN EXISTING PROCESS

CALLED THE SUPPLEMENTAL INFORMATION PROCESS, WHICH GIL CAN DESCRIBE IN GREATER DETAIL, THAT PERMITS APPLICANTS TO SUBMIT NEW INFORMATION.

MR. ROTH: BECAUSE AFTER THE GRANTS WORKING GROUP AND THE SCORES COME OUT, THAT'S WHEN YOU GET CREATIVE IN TERMS OF NEW INFORMATION. SO JUST SO THAT WE DON'T END UP WITH THINGS. MY BIGGEST CONCERN IS TWO DAYS BEFORE WE MEET SUDDENLY SOMETHING APPEARS THAT CAN'T BE REVIEWED.

MR. HARRISON: THE BENEFIT OF THIS PROCESS IS THAT THE CRITERIA ARE QUITE CLEAR. AND ONLY INFORMATION THAT HAS ARISEN SINCE OR BECOME AVAILABLE SINCE THE GRANTS WORKING GROUP MET WOULD QUALIFY. AND IT WOULD GO TO STAFF FIRST FOR A DETERMINATION OF WHETHER IT EVEN MET THAT INITIAL THRESHOLD.

CHAIRMAN THOMAS: I NEGLECTED DR. TROUNSON.

DR. TROUNSON: WELL, I THINK, CHAIR, I THINK A VERY, VERY IMPORTANT PART OF THIS IS TO ENABLE US TO GET THIS JOB DONE. WE'VE INDICATED THAT WE WANT TO USE A MINIMUM OF THREE. AND I THINK YOU HAVE TO ALLOW US THE RESPONSIBILITY OF DOING THIS THE RIGHT WAY. YOU COULD, IF YOU FORMULATED IN THE WAY THAT STEVE WANTS, YOU COULD HAVE ALL OF THE

PEOPLE WHO REALLY KNEW THE LEAST ABOUT THE PROJECT IN THAT STANDARD DEVIATION. AND TO GET FIVE OF THEM TO DO IT AT A PARTICULAR TIME IS JUST MAKING IT INCREDIBLY DIFFICULT.

I THINK YOU OUGHT TO ALLOW FOR A MINIMUM OF THREE. AND IF WE THINK IT'S A COMPLEX ISSUE OR IT CONTAINS A MEMBER WHO IS REALLY CRITICAL TO THE DISCUSSION, THEN WE WOULD EXPAND THE GROUP TO MAKE IT A REASONABLE REPRESENTATION OF THE GRANTS WORKING GROUP. BUT I THINK TO PUT THESE CUES ON THE STAFF JUST MAKES IT JUST TOO DIFFICULT, IT WILL TAKE US A LOT LONGER TO DO, AND IT WILL AGONIZE THE PROCESS. SO I REALLY THINK YOU OUGHT TO LEAVE THE STAFF TO DO THIS JOB. I THINK THEY CAN DO IT. I THINK THEY TAKE NOTE OF WHAT YOU SAID. I'VE HEARD THESE DISCUSSIONS ABOUT US GETTING IT DONE BEFORE. THE LAST TIME WE DID IT WITH A PATIENT ADVOCATE AND TWO OTHER MEMBERS. THERE WERE PEOPLE THERE WHO CHANGED THEIR MIND QUITE DRAMATICALLY. SO THEY DON'T ALL NOT CHANGE THEIR MIND.

SCIENTISTS ARE PERSUADED BY FACT AND GENERALLY KEEPING THAT FACT PATTERN AND WILL ACTUALLY CHANGE WITH RESPECT TO THE FACTS THAT THEY PRODUCE. THAT'S OUR PROFESSIONAL LIFE, AND THAT'S WHAT WE HAVE TO DO. SO I ACTUALLY THINK THAT WE CAN

GET THIS RIGHT. I DON'T THINK WE NEED TO MAKE THE CONTOURS SO NARROW THAT IT MAKES IT VERY DIFFICULT FOR US TO PERFORM THIS TASK.

DR. JUELSGAARD: I JUST WANT TO MAKE ONE CLARIFICATION AROUND SOMETHING THAT DR. OLSON SAID. SO MATHEMATICALLY ONE STANDARD DEVIATION BELOW TO ONE STANDARD DEVIATION ABOVE THE MEDIAN IS MATHEMATICALLY 68.2 PERCENT OF ALL OF THE PARTICIPANTS WHO VOTED. SO, IN ESSENCE, ONE STANDARD DEVIATION BELOW MATHEMATICALLY IS 34.1 PERCENT AND ONE DEVIATION ABOVE IS 34.1. SO JUST AS A FACTUAL CLARIFICATION OF THE GROUP. SO YOU HAVE OVER TWO-THIRDS OF THE GROUP THAT WOULD BE ABLE TO PARTICIPATE.

DR. TROUNSON: STEVE, IT COULD EXCLUDE THE CRITICAL PEOPLE THAT YOU WANT THERE. SO I THINK YOU SHOULD LEAVE US TO SORT OF FIGURE IT OUT. I THINK WE UNDERSTAND EXACTLY THE POINT YOU'RE MAKING, BUT WE WANT TO DO THIS IN THE BEST WAY POSSIBLE. THESE ARE THE PEOPLE IN THE STAFF OFFICE WHO ACTUALLY HAVE BEEN THROUGH THAT REVIEW. THEY KNOW WHO WE CAN GET. THEY KNOW WHO THE PEOPLE WHO ARE LIKELY TO TURN UP IN A REASONABLE TIME AS WELL. SO I JUST THINK YOU OUGHT TO LEAVE IT TO US TO DO THAT. I THINK THERE'S ENOUGH FLEXIBILITY WITHIN THE PARAMETERS TO GET THE

JOB DONE.

DR. STEWARD: YEAH. JUST TO MOVE THIS FORWARD, I THINK YOUR POINTS ARE WELL TAKEN IN THE GENERAL SENSE. ON THE OTHER HAND, I TOTALLY AM SENSITIVE TO THE FACT THAT TOO MANY RULES JUST MAKES IT REALLY COMPLICATED FOR SCIENCE STAFF TO DO WHAT NEEDS TO BE DONE.

I WOULD LIKE TO MOVE APPROVAL WITHOUT YOUR CHANGES, BUT WITH THE SENSE OF THE BOARD THAT THESE ARE THINGS TO CONSIDER AS YOU'RE PUTTING THESE COMMITTEES TOGETHER.

DR. PRICE: SECOND.

CHAIRMAN THOMAS: IT'S BEEN MOVED AND SECONDED. IS THERE DISCUSSION? JOAN AND THEN DR. LEVIN.

MS. SAMUELSON: MY QUESTION IS ISN'T THERE STILL THE CRITERIA FOR INCLUSION IN THE APPEAL PROCESS WILL NOT INCLUDE SOME OF THE EXTRAORDINARY PETITIONS THAT HISTORICALLY HAVE BEEN BROUGHT BECAUSE OF ESSENTIALLY THE PETITIONER DID NOT FEEL THAT OUR PROCESS HAD GOTTEN IT RIGHT, SCIENTIFICALLY, PROGRAMMATICALLY, FOR WHATEVER REASONS, THAT THERE WERE ERRORS, THAT THERE WAS MISUNDERSTANDING ON WHATEVER BASIS? AND SOME OF THOSE, JEFF TELLS US, TURN OUT TO BE HIGHLY

SUCCESSFUL GRANTS. ISN'T THAT THE CASE? AND WHAT DO WE DO ABOUT THOSE? AND MIGHT THEY NOT ANYWAY COME TO THE BOARD THROUGH THE THREE-MINUTE COMMENT PROCESS SUCH THAT WE DON'T REALLY AVOID THE UNDERLYING PROBLEM?

CHAIRMAN THOMAS: ONE OF THE CRITERIA IS MATERIAL DISPUTE OF FACT, SO THAT GETS TO AT LEAST SOME OF WHAT YOU'RE TALKING ABOUT IN YOUR FIRST QUESTION. AND, YES, THERE IS ALWAYS, AS WE ARE A PUBLIC AGENCY, ALWAYS THE OPPORTUNITY FOR PUBLIC COMMENT AT THE END. DR. LEVIN, THEN MR. SHESTACK.

DR. LEVIN: I JUST WANT TO SAY I THINK THESE PROPOSALS ARE GREAT AND A LONG TIME COMING AND VERY CLEAR AS PUT FORWARD BY THE STAFF. AND I, FIRST OF ALL, JUST WANT TO POINT OUT THAT EVEN IN THE CASE OF AN OUTLYING MEMBER OF A THREE-MEMBER BOARD, THEY CAN STILL BE OUTVOTED BY THE OTHER TWO MEMBERS. AND THAT DOESN'T EVEN QUALIFY AS A MINORITY REPORT AT 33 PERCENT. SO EVEN IF SOMEBODY IS BEING STUBBORN AND DOESN'T MOVE THEIR SCORE, THAT IT COULD STILL GO FORWARD. I THINK THAT WE'RE FINE WITH A THREE-MEMBER BOARD SELECTED BASED ON THEIR EXPERTISE.

I JUST WANTED TO CLARIFY TWO VERY SMALL THINGS. ONE, THAT NEW MATERIAL AS PUT FORTH HERE

CAN ONLY BE INTRODUCED AFTER THE GRANT WORKING GROUP MEETING SO THAT IT IS CLEAR THAT IN BETWEEN WHEN GRANTS ARE SUBMITTED AND THE GRANT WORKING GROUP MEETING, EVERYBODY KNOWS THAT THEY CAN PRODUCE, DELIVER THIS ADDITIONAL MATERIAL FOR CONSIDERATION BECAUSE I'M NOT SURE THAT THAT'S WIDELY KNOWN BY THE APPLICANTS.

AND THE SECOND THING IS IS IT TEN DAYS OR TEN WORKING DAYS THAT THEY HAVE TO TURN THEIR PETITION AROUND?

DR. SAMBRANO: I THINK THE POLICY IS TEN DAYS.

SO THE PROCESS THAT WE HAVE FOR SUBMITTING ADDITIONAL INFORMATION IS TWOFOLD, AND IT APPLIES REALLY TO OUR CLINICAL PROGRAMS. AND WHAT HAPPENS IS THE REVIEWERS, IN MAKING THEIR ASSESSMENT, USUALLY COME UP WITH KEY QUESTIONS THAT MAY BE IMPORTANT IN THEIR REVIEW AND THEIR ASSESSMENT. EITHER THEY FIND OR NEED CLARITY FOR OR NEED ADDITIONAL INFORMATION TO MAKE THEIR EVALUATION. SO WE PROVIDE THESE QUESTIONS TO THE APPLICANTS SO THAT THEY CAN PROVIDE AN ANSWER. AND THE ANSWER MAY BE IN THE FORM OF DATA. SO IT'S AN OPPORTUNITY FOR THEM TO SUBMIT NEW INFORMATION THAT ADDRESSES THE CONCERNS OF THE REVIEWERS.

DURING THE MEETING ITSELF, WE ALSO PROVIDE AN OPPORTUNITY TO ACTUALLY HAVE A SCIENTIFIC MEMBER OR THE GROUP AS A WHOLE, BASED ON THE CHAIR'S AGREEMENT, TO POSE A QUESTION TO THE APPLICANT, THAT THEN THE APPLICANT CAN VIA E-MAIL OR PHONE PROVIDE CLARIFICATION ON. SO IT PROVIDES THEN ANOTHER OPPORTUNITY DURING THE COURSE OF THE MEETING.

BUT IT IS IMPORTANT TO DISTINGUISH IT FROM NECESSARILY HAVING BASICALLY A DATA DUMP FROM THE APPLICANT, THAT THEY DETERMINE THEY WANT TO JUST GIVE YOU MORE DATA. IT IS DRIVEN BY THE REVIEWERS IN TERMS OF WHAT THEY THINK IS IMPORTANT AND ESSENTIAL.

DR. LEVIN: SO SOME OF THESE CATEGORIES, PUBLICATION, PRE-IND MEETING WITH THE FDA, TOXICOLOGY REPORT, SOMETHING LIKE THAT WOULD QUALIFY POST GRANT WORKING GROUP IS NOT ACCEPTABLE BETWEEN THE GRANT SUBMISSION AND THE GRANTS WORKING GROUP?

DR. SAMBRANO: IT IS UNDER A DIFFERENT POLICY THAT IS USUALLY UNDER EACH RFA WHERE ANYTHING THAT HAS BEEN ACCEPTED FOR PUBLICATION, A NEW PUBLICATION, A NEW GRANT AWARD, ANY LICENSES, OR ANY REGULATORY UPDATES ARE ALLOWED TO BE SUBMITTED.

CHAIRMAN THOMAS: MR. SHESTACK, DO YOU HAVE A COMMENT?

MR. SHESTACK: I JUST HAD A QUESTION. LAST TIME IN A COUPLE OF THE ONES THAT I WAS INFORMED ABOUT I THOUGHT THE PROCESS OF RE-REVIEW WORKED FANTASTIC. THERE WAS IN SOME CASES DETERMINATION OF NEW INFORMATION, A PANEL WAS IMPANELED, AND A FAIR, INTERESTING, UNCOOKIE CUTTER DECISION WAS MADE, SO I THOUGHT IT WAS GREAT. I HAVE THE ABILITY TO SORT OF KNOW A LITTLE BIT ABOUT WHAT WAS GOING ON ONLY BECAUSE I HAD BEEN AT A BOARD MEETING WHERE IT CAME UP, THAT MAYBE THERE WOULD BE RE-REVIEW.

SO DURING THIS PROCESS, MY QUESTION IS IS THIS ALL GOING ON AT A STAFF LEVEL AND NO REPORT BACK TO BOARD MEMBERS, OR WOULD BOARD MEMBERS BE EVEN AWARE THAT SOMEBODY HAD ASKED FOR RECONSIDERATION BASED ON MATERIAL FACT OR NEW INFORMATION? WOULD WE EVEN KNOW THAT IT WAS GOING ON?

DR. SAMBRANO: SO I THINK GIVEN THAT IN MOST CASES THE BOARD MEETING FOLLOWS A FEW WEEKS, SAY FIVE TO SIX WEEKS, AFTER THE REVIEW, TYPICALLY THAT'S NOT ENOUGH TIME FOR US TO REALLY DO THIS KIND OF REVIEW. SO INEVITABLY WE WILL BE INFORMING YOU OF THOSE APPLICATIONS THAT ARE NOT GOING TO BE CONSIDERED AT THE BOARD MEETING BECAUSE THEY ARE

UNDERGOING AN APPEAL REVIEW.

MR. SHESTACK: ANSWER IS YES.

DR. SAMBRANO: YES, YOU WOULD KNOW.

MR. SHESTACK: YOU KNOW. OKAY. THANK YOU.

DR. JUELSGAARD: DR. SAMBRANO, JUST IN CONCERT WITH THAT, I THINK IT WOULD BE WORTHWHILE IF YOU COULD ALSO ADVISE THE BOARD OF THE DETERMINATIONS THAT WERE MADE BY THE GRANTS WORKING GROUP EITHER YES OR NO. I'M SURE THE YES ONES WILL COME BACK TO US. IT'S THE NO ONES THAT I WOULD LIKE TO ALSO HEAR ABOUT. PERHAPS OTHER BOARD MEMBERS WOULD AS WELL, AS WELL AS MAYBE A LITTLE BIT OF DISCUSSION ABOUT WHY IT WAS A NO INSTEAD OF A YES.

DR. SAMBRANO: ALL OF THEM WOULD COME BACK TO YOU FOR A FINAL VOTE. SO WE WOULD BRING BACK THE NEW RECOMMENDATION FROM THAT SUBCOMMITTEE, AND THEN IT WOULD BE YOUR VOTE THAT FUNDS OR DOESN'T FUND.

CHAIRMAN THOMAS: DR. KRONTIRIS.

DR. KRONTIRIS: I'D LIKE TO CALL THE QUESTION.

CHAIRMAN THOMAS: QUESTION HAS BEEN CALLED. DO WE HAVE COMMENTS FROM MEMBERS OF THE PUBLIC?

MR. REED: I BASICALLY AM IN OPPOSITION TO

THIS. I FEEL THAT THE CURRENT SYSTEM, ALTHOUGH AWKWARD AND UNWIELDY AND TIME-CONSUMING AND OCCASIONALLY IRRITATING, IS VERY EFFECTIVE. I FEEL THAT IT HAS SAVED SEVERAL REALLY IMPORTANT PROJECTS FROM DYING. AND I THINK THAT THIS IS A MISTAKE. I'M GLAD THIS IS A TRIAL PERIOD, BUT I REALLY DON'T LIKE THE IDEA OF THERE BEING NO PUBLIC PRESENTATION FOR AN OBJECTION TO -- THERE SHOULD BE AN AUTOMATIC APPEALS PROCESS WHICH SHOULD INVOLVE THE BOARD AND THE PUBLIC. I THINK THERE'S SEVERAL INSTANCES WHEN THERE'S BEEN JUST A TERRIFIC PROJECT, I THOUGHT, WHICH WAS TURNED DOWN AND THEN ON ARGUMENT IT WAS BROUGHT FORWARD.

THE PUBLIC -- THIS IS A PATIENT ADVOCATE ISSUE. THERE'S NOT JUST PATIENT ADVOCATES ON THE BOARD. THERE'S ALSO PATIENT ADVOCATES IN THE PUBLIC. AND SOMETIMES WE SEE SOMETHING THAT'S SO IMPORTANT. THE ALZHEIMER'S DISEASE SITUATION WAS REALLY CRUCIAL, AND IT'S GOING FORWARD BECAUSE IT WAS FOUGHT FOR. THIS WOULD REMOVE THAT AVENUE OF FIGHTING. SO I'M AGAINST THIS. I THINK I'M GOING TO LOSE, AND I THINK ALSO SOMETIMES THAT HAPPENS. IT'S CALLED DEMOCRACY. AND ALSO WE HAVE TO DECIDE DO WE TRUST OUR SCIENTIFIC STAFF AND I DO. I THINK THAT THIS GIVES THEM A TREMENDOUS VICTORY FOR THEIR

SIDE. IT'S A DIMINUTION OF YOUR AUTHORITY, WHICH I OPPOSE, BUT I THINK THEY CAN BE TRUSTED WITH IT. SO I'LL SURVIVE AND THE SCIENCE WILL GO FORWARD.

CHAIRMAN THOMAS: THANK YOU, DON. MR. HARRISON.

MR. HARRISON: JUST ONE CLARIFICATION ON THE MOTION. THERE WERE A NUMBER OF TRACK CHANGES WHICH WE'D LIKE TO ACCEPT. I ASSUME THE MOTION REFERRED TO EXCLUDING THOSE THAT WERE IN YELLOW HIGHLIGHTING.

DR. STEWARD: YES.

CHAIRMAN THOMAS: MR. HARRISON, COULD YOU RESTATE PLEASE.

MR. HARRISON: THE MOTION IS TO APPROVE THE APPEAL AND REQUEST FOR RECONSIDERATION POLICY WITHOUT THE LANGUAGE IN YELLOW HIGHLIGHTING.

CHAIRMAN THOMAS: VERY WELL PUT FROM A LEGAL PERSPECTIVE.

DR. LUBIN: WE STILL LOVE THIS BOARD MEMBER.

CHAIRMAN THOMAS: MARIA, PLEASE TAKE THE ROLL.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: DAVID BRENNER.

ANNE-MARIE DULIEGE. MARCY FEIT.

MS. FEIT: YES.

MS. BONNEVILLE: LEON FINE. MICHAEL GOLDBERG.

MR. GOLDBERG: YES.

MS. BONNEVILLE: SAM HAWGOOD.

DR. HAWGOOD: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: TED KRONTIRIS.

DR. KRONTIRIS: YES.

MS. BONNEVILLE: SHERRY LANSING.

MS. LANSING: YES. AND I HAVE A QUESTION. CAN I VOTE IN SUPPORT OF THE OTHER ISSUES IN ADVANCE BECAUSE I HAVE TO LEAVE AFTER THIS VOTE?

MR. HARRISON: YOU'LL HAVE TO TRUST US, SHERRY.

MS. LANSING: OKAY. WELL, JUST KNOW THAT I AM IN SUPPORT BECAUSE I FEEL THAT THE STAFF AND EVERYONE WORKED HARD ON IT, AND WE HAVE DISCUSSED IT. BUT I'M OFFICIALLY VOTING YES FOR THIS. THANK YOU.

CHAIRMAN THOMAS: THANK YOU, SHERRY.

MS. BONNEVILLE: JACOB LEVIN.

DR. LEVIN: YES.

MS. BONNEVILLE: BERT LUBIN.
DR. LUBIN: YES.
MS. BONNEVILLE: MICHAEL MARLETTA. ROBERT PRICE.
DR. PRICE: YES.
MS. BONNEVILLE: FRANCISCO PRIETO. CARMEN PULIAFITO.
DR. PULIAFITO: YES.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: DUANE ROTH.
MR. ROTH: YES.
MS. BONNEVILLE: JOAN SAMUELSON.
MS. SAMUELSON: NO.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: JONATHAN SHESTACK.
MR. SHESTACK: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: YES.

MS. BONNEVILLE: EUGENE WASHINGTON. DIANE WINOKUR.

MS. WINOKUR: YES.

CHAIRMAN THOMAS: OKAY. WE'RE GOING TO TAKE ONE MORE OF THESE UP, AND THEN WE'RE GOING TO GO GRAB OUR BOX LUNCH.

MS. BONNEVILLE: IT'S A BUFFET LUNCH. JUST BRING IT BACK IN.

CHAIRMAN THOMAS: THANK YOU. ACCURACY IS IMPORTANT. IT'S VERY TASTY, I'M INFORMED.

THIS IS ITEM 4, WHICH IS ON THE ISSUES OF DIVISION OF RESPONSIBILITY BETWEEN THE CHAIR AND THE PRESIDENT. THE BACKGROUND ON THIS WAS THERE HAD BEEN CONCERNS EXPRESSED, NOT JUST THE IOM, BUT IN PREVIOUS REPORTS ON THE AGENCY, THAT THERE WERE OVERLAPPING RESPONSIBILITIES THAT CREATED CONFUSION AND PEOPLE'S TOES GETTING STEPPED ON, ETC.

AND THE WAY I PROPOSED TO DEAL WITH THIS WAS TO VERY CLEARLY DELINEATE THAT THE EXPERTISE AND RESPONSIBILITIES WOULD LIE WITH THOSE BEST SUITED TO CARRY OUT THE PARTICULAR ELEMENTS IN QUESTION. WITH RESPECT TO ALL SCIENTIFIC MATTERS, WHICH ARE MANY AND VARIED, THAT WOULD PROPERLY FALL WITHIN THE PURVIEW OF THE PRESIDENT. WITH RESPECT TO

NONSCIENTIFIC MATTERS, SUCH AS ISSUES OF SUSTAINABILITY, GOVERNMENT RELATIONS, PUBLIC COMMUNICATIONS WITH THE OUTSIDE WORLD, AND BOND FINANCING -- I CAN'T BELIEVE I FORGOT THAT ONE -- ANYWAY, THAT WOULD LIE WITHIN THE OFFICE OF THE CHAIR.

THE CONCEPT WAS YOU'D HAVE RESPONSIBILITIES THAT WERE COMPLEMENTARY AND THAT WHEN YOU ADDED THEM, THE SUM OF THE WHOLE WOULD GIVE THE AGENCY ALL OF THE VARIOUS COMPONENTS THAT IT NEEDED TO BE SUCCESSFUL AND WOULD ELIMINATE ANY QUESTIONS ABOUT TURF ISSUES OR STEPPING ON TOES OR OVERLAPPING RESPONSIBILITIES.

MR. HARRISON, DO YOU WANT TO PRESENT ON THIS, PLEASE.

MR. HARRISON: THIS WILL BE BRIEF. THE CURRENT INTERNAL GOVERNANCE POLICY ALLOCATES RESPONSIBILITIES BETWEEN THE CHAIR AND THE PRESIDENT ALONG THE LINES THAT THE CHAIR HAS DESCRIBED. WE DO HAVE ONE CHANGE TO PROPOSE, HOWEVER, TO THE BOARD'S BYLAWS TO CLARIFY THAT THOUGH THE GRANTS WORKING GROUP AND THE OTHER WORKING GROUPS MAKE THEIR RECOMMENDATIONS TO THE BOARD, THEY REPORT TO THE PRESIDENT.

SO THAT'S A PROPOSAL THAT'S CAPTURED IN

THE PROPOSED BYLAWS WHICH ARE ATTACHMENT 1 IN ITEM 6.

CHAIRMAN THOMAS: DO WE HEAR -- MR. HARRISON, IS THERE A MOTION NECESSARY WITH RESPECT TO THE BYLAWS? OKAY. DO WE HAVE A MOTION TO PUT ON THE TABLE?

MR. ROTH: I'LL MOVE.

DR. STEWARD: SECOND.

CHAIRMAN THOMAS: MOVED BY MR. ROTH, SECONDED BY DR. STEWARD. DISCUSSION ON THIS TOPIC?

MR. ROTH: NOT A DISCUSSION, BUT A COMMENT, THAT WE DID SIT DOWN, ALAN AND J.T. AND MYSELF, AND HAVE A LONG DISCUSSION ABOUT SOME ITEMS THAT I WOULD DESCRIBE AS JUST CLARITY BETWEEN THE TWO. AND I THINK THAT MEETING WAS VERY HELPFUL FROM THE STANDPOINT OF BOTH SIDES, TALKING ABOUT THINGS THAT HAPPEN IN JUST NORMAL OPERATIONS WHEN YOU HAVE TWO REPORTING STRUCTURES LIKE THIS.

MS. SAMUELSON: QUESTION. I'M NOT SURE SOMETIMES WHERE THIS WHATEVER IT IS THAT WE'RE BEING PRESENTED, THESE NUMERIC SECTIONS, HOW THAT INTERFACES WITH THE BYLAW CHANGES THAT I SEE TOWARD THE BACK. AND SO THAT'S THE GENERAL ONE.

AND THE SPECIFIC QUESTION IS WITHIN WHICH OF THESE IS THE CHANGE IN AUTHORITY OF THE GRANTS

WORKING GROUP VICE CHAIRS WHICH I SEE IN THE BYLAWS REFLECTED?

CHAIRMAN THOMAS: MR. HARRISON.

MR. HARRISON: THE CHANGES ARE BOTH IN -- THE CHANGES WITH RESPECT TO PROGRAMMATIC REVIEW ARE CAPTURED BOTH IN THE GRANTS WORKING GROUP BYLAWS AND IN THE BOARD BYLAWS.

MS. SAMUELSON: THERE'S ONE THAT CHANGES THE LANGUAGE FROM PRESIDE TO MODERATE OVER A DISCUSSION BY THE VICE CHAIRS. JEFF AND ME ARE THE VICE CHAIRS AT THE MOMENT. AND I'M NOT SURE WHERE THAT FITS IN.

MR. HARRISON: THAT'S LANGUAGE FROM THE BOARD'S BYLAWS THAT RELATES TO THE ESTABLISHMENT OF THE APPLICATION REVIEW SUBCOMMITTEE.

MS. SAMUELSON: SO WE ALREADY PASSED THAT SECTION?

MR. HARRISON: CORRECT.

MS. SAMUELSON: SO WE HAVE EFFECTIVELY APPROVED OF CHANGING OUR AUTHORITY?

MR. HARRISON: YOU'VE APPROVED THE LANGUAGE ABOUT MODERATING THE DISCUSSION. I DON'T KNOW THAT IT'S A SUBSTANTIVE CHANGE. THE DISCUSSION OF PROGRAMMATIC REVIEW AT WHAT IS NOW THE APPLICATION REVIEW SUBCOMMITTEE WILL BE LED BY THE

VICE CHAIRS OF THE GRANTS WORKING GROUP.

MS. SAMUELSON: BUT THE LANGUAGE CHANGING FROM PRESIDE TO MODERATE, WHAT DOES THAT MEAN? IS IT RELEVANT RIGHT NOW? WE DON'T HAVE TO DISCUSS IT RIGHT NOW.

MR. HARRISON: I DON'T BELIEVE SO. I DON'T BELIEVE IT'S SUBSTANTIVE.

MS. SAMUELSON: THEN WHY WAS IT CHANGED?

MR. HARRISON: THIS LANGUAGE WAS CREATED ANEW TO ESTABLISH THE NEW SUBCOMMITTEE.

MS. SAMUELSON: I'LL LET IT GO FOR NOW. WHEN I HAVE MORE BLOOD SUGAR IN MY BRAIN, I'LL GET BACK TO YOU.

DR. JUELSGAARD: JUST AS A POINT OF CLARIFICATION, I KNOW THAT WE HAVE A MOTION ON THE TABLE AND A SECOND TO THAT MOTION, BUT I'M NOT EXACTLY SURE WHAT THE MOTION IS.

MR. HARRISON: THE MOTION IS TO APPROVE AN AMENDMENT TO THE BOARD'S BYLAWS TO ARTICLE VII, SECTION 1, WHICH IS PAGE 8 OF ATTACHMENT 1 TO AGENDA ITEM 6, TO CLARIFY THAT THE WORKING GROUPS REPORT TO THE PRESIDENT.

DR. JUELSGAARD: THANK YOU.

MR. ROTH: CALL THE QUESTION.

CHAIRMAN THOMAS: MARIA, WILL YOU TAKE THE

ROLL, PLEASE. SORRY. FORGOT. COMMENTS FROM MEMBERS OF THE PUBLIC? HEARING NONE, MARIA, PLEASE CALL THE ROLL.

MS. BONNEVILLE: KEN BURTIS.

DR. BURTIS: YES.

MS. BONNEVILLE: DAVID BRENNER. ANNE-MARIE DULIEGE. MARCY FEIT.

MS. FEIT: YES.

MS. BONNEVILLE: LEON FINE. MICHAEL GOLDBERG. SAM HAWGOOD.

DR. HAWGOOD: YES.

MS. BONNEVILLE: STEPHEN JUELSGAARD.

DR. JUELSGAARD: YES.

MS. BONNEVILLE: TED KRONTIRIS.

DR. KRONTIRIS: YES.

MS. BONNEVILLE: SHERRY LANSING. JACOB LEVIN.

DR. LEVIN: YES.

MS. BONNEVILLE: BERT LUBIN.

DR. LUBIN: YES.

MS. BONNEVILLE: MICHAEL MARLETTA. ROBERT PRICE.

DR. PRICE: YES.

MS. BONNEVILLE: FRANCISCO PRIETO. CARMEN PULIAFITO.

DR. PULIAFITO: YES.
MS. BONNEVILLE: ROBERT QUINT.
DR. QUINT: YES.
MS. BONNEVILLE: DUANE ROTH.
MR. ROTH: YES.
MS. BONNEVILLE: JOAN SAMUELSON.
MS. SAMUELSON: YES.
MS. BONNEVILLE: JEFF SHEEHY.
MR. SHEEHY: YES.
MS. BONNEVILLE: JONATHAN SHESTACK.
MR. SHESTACK: YES.
MS. BONNEVILLE: OSWALD STEWARD.
DR. STEWARD: YES.
MS. BONNEVILLE: JONATHAN THOMAS.
CHAIRMAN THOMAS: YES.
MS. BONNEVILLE: ART TORRES.
MR. TORRES: AYE.
MS. BONNEVILLE: KRISTINA VUORI.
DR. VUORI: YES.
MS. BONNEVILLE: EUGENE WASHINGTON. DIANE WINOKUR.
MS. WINOKUR: YES.
MR. GOLDBERG: YES.
CHAIRMAN THOMAS: THANK YOU. LET'S NOW GO OVER AND GET OUR BUFFET LUNCH, AND EVERYBODY PLEASE

BRING IT BACK OVER HERE BECAUSE WE HAVE A LOT OF ITEMS TO GET THROUGH STILL. THANK YOU, EVERYBODY, FOR THE MORNING SESSION. VERY PRODUCTIVE.

(A RECESS WAS TAKEN.)

CHAIRMAN THOMAS: I THINK WE WANT TO RESUME HERE BECAUSE WE HAVE A LOT OF STUFF ON THE AGENDA AND WANT TO GET TO IT WITH ALL DELIBERATE SPEED, AS MR. HARRISON WOULD SAY. SO LET'S MOVE ON TO ITEM 5 ON THE RECOMMENDATIONS FROM THE IOM REPORT. THIS IS NOT AN ITEM THAT REQUIRES ANY VOTE, BUT IS A POINT OF INFORMATION ON THE NEWLY TO BE FORMED SCIENTIFIC ADVISORY BOARD. DR. FEIGAL WILL PRESENT ON THIS ITEM.

DR. FEIGAL: THANKS VERY MUCH. SO, YES, YOU DON'T HAVE TO VOTE ON THIS. IT'S JUST AN INFORMATION ITEM.

SO THE IOM RECOMMENDED THAT CIRM SHOULD ESTABLISH A SCIENTIFIC ADVISORY BOARD THAT COMPRISED INDIVIDUALS WITH EXPERTISE IN SCIENTIFIC, CLINICAL, ETHICAL, INDUSTRY, AND REGULATORY ASPECTS OF STEM CELL BIOLOGY AND CELL-BASED THERAPIES. A SINGLE SCIENTIFIC ADVISORY BOARD, AS OPPOSED TO MULTIPLE ADVISORY BOARDS THAT WERE PROPOSED IN OUR 2012 STRATEGIC PLAN, WOULD PROVIDE COHESIVE LONGITUDINAL AND INTEGRATED ADVICE TO THE PRESIDENT REGARDING

STRATEGIC PRIORITIES, WHICH IS LACKING IN THE CURRENT CIRM ORGANIZATIONAL STRUCTURE.

THE IOM RECOMMENDED THAT THE MAJORITY OF THE MEMBERS OF THE SCIENTIFIC ADVISORY BOARD BE EXTERNAL TO CALIFORNIA, APPOINTED BY AND REPORTING TO THE PRESIDENT, THAT SUCH A BOARD COULD BE INVALUABLE IN VETTING IDEAS FOR NEW RFA'S, SUGGESTING RFA'S THAT OTHERWISE WOULD NOT HAVE BEEN CONSIDERED, HELPING CIRM MAINTAIN AN APPROPRIATE BALANCE IN ITS RESEARCH PORTFOLIO, AND THAT, WITH INPUT FROM THIS BOARD, HELP CIRM MAKE SOME FUNDAMENTAL DECISIONS ABOUT DEALING WITH CHALLENGES THAT CUT ACROSS PARTICULAR DISEASES, AND ALSO DETERMINE HOW BEST TO ENGAGE INDUSTRY PARTNERS IN DEVELOPING THERAPIES. THE SCIENTIFIC ADVISORY BOARD'S REPORTS AND THE PRESIDENT'S RESPONSE TO THOSE REPORTS WOULD BE PRESENTED BACK TO THE ICOC AND DISCUSSED IN OPEN SESSION.

THE LEGAL ASSESSMENT OF THIS WAS THAT THE PRESIDENT IS ALREADY EMPOWERED TO ESTABLISH A SCIENTIFIC ADVISORY BOARD THAT CAN PROVIDE COUNSEL ON THESE TYPES OF ISSUES AND IN OTHER MATTERS THAT ARE IDENTIFIED BY SENIOR MANAGEMENT, AND NO BOARD ACTION IS REALLY REQUIRED TO IMPLEMENT THIS RECOMMENDATION.

SO OUR RESPONSE IS THAT WE WILL ESTABLISH SUCH A SCIENTIFIC ADVISORY BOARD TO PROVIDE COUNSEL ON SUCH ISSUES AND THAT THIS ADVISORY BOARD WOULD BE SEPARATE AND COMPLEMENTARY TO OTHER AD HOC PANELS AND COUNCILS THE OFFICE OF THE PRESIDENT HAS THE DISCRETION TO CALL UPON AND CREATE.

SO LET ME JUST GO THROUGH WHAT WE'RE THINKING OF IN TERMS OF THE SCOPE AND ALSO THE COMPOSITION, THE FREQUENCY OF MEETINGS, AND THE REPORTING RELATIONSHIP JUST VERY BRIEFLY.

A BOARD WILL ENGAGE WITH THE PRESIDENT AND OTHER KEY STAFF ON CRITICAL AND MAJOR STRATEGIC ISSUES THAT WILL ACCELERATE THE IMPACT AND THE DELIVERY OF THE CIRM MISSION, THAT THE AREAS OF REVIEW AND RECOMMENDATION WILL INCLUDE THE FOCUS OF CIRM SCIENCE AND TRANSLATIONAL PROGRAMS, TO ENSURE LEADERSHIP AND DELIVERY WITHIN THE CURRENT FUNDING TIMELINES. THERE WOULD BE ADVICE IN THE DEVELOPMENT ON CIRM PARTNERSHIPS THAT WILL ALIGN WITH THE FUTURE DELIVERY OF CLINICAL OUTCOMES. THERE WOULD BE IDENTIFICATION OF NEW OPPORTUNITIES FOR CIRM IN THE FIELD AS WELL AS IDENTIFICATION OF KEY AREAS THAT MIGHT NEED FURTHER FUNDING AND FOCUS. IT COULD ALSO PROVIDE ADVICE ON CIRM'S INTERNATIONAL CONNECTIONS FOR AMPLIFYING CIRM'S SCIENTIFIC AND TRANSLATIONAL

PROGRESS, AND ALSO PROVIDE AN ASSESSMENT OF CIRM'S FUNDING MODEL AND HOW IT MIGHT BE FORTIFIED IN THE FUTURE.

SO THESE TOPICS FOR DISCUSSION WILL BE MUTUALLY DEVELOPED BY THE OFFICE OF THE PRESIDENT AND THE SCIENTIFIC ADVISORY BOARD.

FOR THE COMPOSITION, THE PRESIDENT WILL APPOINT THE MEMBERSHIP OF THE SCIENTIFIC ADVISORY BOARD AND BE RESPONSIBLE FOR THEIR MEETINGS AND REPORTS. IT WILL BE COMPOSED OF SIX TO EIGHT MEMBERS WITH APPROXIMATELY 50 PERCENT OR MORE OF THE MEMBERS EXTERNAL TO CALIFORNIA. THESE MEMBERS WOULD CUMULATIVELY REPRESENT EXPERTISE IN SCIENTIFIC, CLINICAL, ETHICAL, INDUSTRY, AND REGULATORY ASPECTS OF STEM CELL BIOLOGY AND CELL-BASED THERAPIES. WE WILL EXCLUDE FROM CONSIDERATION INDIVIDUALS FROM INSTITUTIONS OR COMPANIES THAT ARE CIRM GRANTEES OR LOAN RECIPIENTS, AND MEMBERS OF THE SAB WILL ALSO ABIDE BY CIRM CONFLICT OF INTEREST AND CONFIDENTIALITY POLICIES.

WE ESTABLISHED A TERM OF MEMBERSHIP OF TWO YEARS, BUT THERE WILL BE AN OPPORTUNITY FOR CIRM TO REAPPOINT THE MEMBERS FOR ANOTHER TWO-YEAR TERM IF THERE'S MUTUAL INTEREST IN DOING SO. THE PRESIDENT WILL ALSO RETAIN THE ABILITY TO APPOINT NEW MEMBERS

IN RELEVANT EXPERTISE DEEMED APPROPRIATE TO THE SCIENTIFIC MISSION OF CIRM AND TO REPLACE MEMBERS WHO LEAVE THE SAB.

IN TERMS OF FREQUENCY, WE THOUGHT AT LEAST TWO TO FOUR TIMES PER YEAR WITH AT LEAST ONE OF THOSE MEETINGS TO BE A FACE-TO-FACE, IN-PERSON MEETING. AND IN TERMS OF REPORTING, THE BOARD WILL -- THE SAB WILL REPORT TO THE PRESIDENT WITH RECOMMENDATIONS BY THE SCIENTIFIC ADVISORY BOARD TO BE SUBJECT TO KEY SENIOR MANAGEMENT REVIEW AND COMMENTARY BEFORE BEING PRESENTED TO THE ICOC.

SO WHAT I WAS JUST SAYING IS BASICALLY THE IOM MADE A RECOMMENDATION THAT WE ACTUALLY STRONGLY ENDORSE AND IT'S ALREADY WITHIN OUR POWER TO IMPLEMENT IT AND PUT IT TOGETHER. AND THIS IS JUST A CONCISE SUMMARY OF WHAT WE PLAN TO DO MOVING FORWARD.

CHAIRMAN THOMAS: THANK YOU, DR. FEIGAL. DR. STEWARD.

DR. STEWARD: JUST ONE QUESTION. WILL THE MEETINGS OF THE BOARD BE OPEN TO THE PUBLIC OR CLOSED?

DR. FEIGAL: NO. THESE ARE CLOSED MEETINGS. THESE ARE CLOSED MEETINGS, BUT WE WILL BRING REPORTS OR WE WILL BRING COMMENTARY ON THOSE

REPORTS TO THIS BOARD MEETING.

DR. LUBIN: I JUST WANT TO CLARIFY THERE ARE NO FIDUCIARY RESPONSIBILITIES THAT THIS ADVISORY BOARD --

DR. FEIGAL: THEY MAKE NO DECISIONS. THIS IS PURELY ADVICE. ALL THE FUNDING DECISIONS ARE MADE BY THIS OVERSIGHT BOARD.

MS. SAMUELSON: CAN YOU EXPLAIN THE COMBINATION OF BOTH IN-STATE AND OUT-OF-STATE MEMBERS ON THIS ADVISORY BOARD?

DR. FEIGAL: THE COMBINATION? BECAUSE WE THINK THERE ACTUALLY IS RELEVANT EXPERTISE AND PEOPLE THAT WE MIGHT WANT TO DRAW UPON WITHIN THE STATE. AND WE THOUGHT, THOUGH, AT A MINIMUM WE WOULD HAVE 50 PERCENT EXTERNAL TO CALIFORNIA.

MS. SAMUELSON: AND WHEN YOU SAID THERE WOULD BE SOMETIMES ADDITIONS, DID THAT MEAN AN INCREASE IN THE NET SIZE OF THE GROUP OR JUST PEOPLE SWAP IN AND OUT?

DR. FEIGAL: WE'D KEEP THE SIZE OF THE MEMBERSHIP TO SIX TO EIGHT MEMBERS, BUT THERE MAY BE THE REQUIREMENT, MAYBE THERE'S A PARTICULAR TOPIC OR ISSUE WE NEED TO HAVE DISCUSSED WHERE WE MIGHT WANT TO BRING IN SOMEBODY WITH THAT RELEVANT EXPERTISE. SO I THINK WE'D WANT TO MAINTAIN THAT FLEXIBILITY TO

DO SO.

DR. LEVIN: I WAS JUST CURIOUS IF THERE'S SOME SORT OF COMPENSATION THAT IS ANTICIPATED GOING ALONG WITH BEING ON THIS BOARD.

DR. FEIGAL: RIGHT NOW WE'RE ACTUALLY THINKING OF REIMBURSEMENT FOR EXPENSES AT THIS POINT IN TIME, BUT WE'RE STILL IN DISCUSSIONS ABOUT THAT. OBVIOUSLY IT WOULD BE IN KEEPING WITH OUR POLICIES.

DR. KRONTIRIS: AD HOC MEMBERS, WOULD THERE BE AD HOC MEMBERS?

DR. FEIGAL: WOULD THERE BE AD HOC MEMBERSHIP? I THINK THE MAIN PURPOSE IS TO HAVE A LONGITUDINAL GROUP OF ADVISORS THAT WE CAN WORK WITH, BUT I WOULDN'T RULE OUT FOR PARTICULAR INSTANCES WE MAY WANT TO ADD AN AD HOC MEMBER.

CHAIRMAN THOMAS: DR. STEWARD.

DR. STEWARD: MOVE APPROVAL.

CHAIRMAN THOMAS: THERE'S NO ACTION REQUIRED.

DR. FEIGAL: THIS IS REALLY JUST IF YOU HAVE QUESTIONS, THIS IS A GOOD TIME JUST TO ASK QUESTIONS. WE THINK THIS IS PARTICULARLY IMPORTANT AS WE'RE MOVING FORWARD INTO THE PRIORITIZATION AND FOCUS PHASE OF THE INSTITUTE, AND WE THINK THIS WILL BE A VERY USEFUL TOOL FOR US TO HAVE.

CHAIRMAN THOMAS: I ABSOLUTELY AGREE. I THINK IT WILL BE VERY, VERY VALUABLE INPUT FROM A WIDE RANGE OF FOLKS WHO CAN REALLY HELP US FURTHER ADVANCE THE CAUSE.

MS. SAMUELSON: ON A FUTURE AGENDA I'D LIKE TO SEE DISCUSSION OF A PORTFOLIO REVIEW BY THE BOARD, ASSISTED BY SOME SET OF SCIENTIFIC ADVISORS. AND MY RECOMMENDATION WOULD BE THAT THEY BE DRAWN FROM THE GRANTS WORKING GROUP WHERE THEY HAVE SUBSTANTIAL EXPERTISE OVER EIGHT PLUS YEARS OF REVIEWING OUR GRANTS FUNDING DECISIONS.

CHAIRMAN THOMAS: DR. FEIGAL.

DR. FEIGAL: WELL, FIRST OF ALL, LATER TODAY, AND I HOPE WE DO HAVE TIME FOR IT, WE ARE GOING TO GIVE YOU A TRANSLATIONAL UPDATE ON OUR PORTFOLIO TO THIS BOARD. AND AS I SAID BEFORE, WE HAVE THE DISCRETION. WE CAN TAKE YOUR INPUTS AS TO THOUGHTS ABOUT PEOPLE ON THE BOARD, BUT THE PRESIDENT WILL APPOINT THE MEMBERS.

MS. SAMUELSON: MY CONCERN IS THAT I HAVE A FIDUCIARY OBLIGATION TO OBEY A STATUTE IN THE CONSTITUTION THAT TELLS ME THAT WE HAVE TO MOVE FORWARD TOWARD EFFECTIVE THERAPEUTIC INTERVENTION SOON. WE'RE RUNNING OUT OF TIME. AND I'M LOOKING AT URGENT STRATEGIES TO PERFORM MY FIDUCIARY

OBLIGATION. AND THIS DOESN'T SOUND URGENT ENOUGH, NOR DOES IT MAKE SENSE TO ME, AFTER THE DISCUSSION WE HAD IN THE WORKING GROUP ON FRIDAY, WHERE THE SCIENTISTS THERE EXPRESSED SUCH A GREAT COMBINATION OF EXPERTISE AND CONCERN FOR OUR SHARED VIEW OF THE MISSION, AND DOESN'T INVITE ANOTHER CONFLICT OF INTEREST MERRY-GO-ROUND BECAUSE IT'S ENTIRELY OUT-OF-STATE.

DR. FEIGAL: JUST TO BE CLEAR, WE ARE GOING TO CONTINUE WITH VERY ROBUST SCIENTIFIC DISCUSSIONS AT GRANT REVIEW GROUP OF RESEARCH APPLICATIONS THAT COME IN. THIS SCIENTIFIC ADVISORY BOARD WILL HAVE NO INPUT ON THAT. WE'RE ASKING THEM MORE HIGH LEVEL STRATEGIC ISSUES. WE DO THINK THAT IT'S URGENT. WE PLAN TO PUT THIS IN PLACE VERY QUICKLY.

MS. SAMUELSON: I CAN'T IMAGINE ANYTHING MORE HIGH LEVEL THAN HAVING THE RIGHT FUNDING PORTFOLIO THAT'S GOING TO MOVE US THE MOST SPEEDILY.

DR. FEIGAL: I THINK WE AGREE ON THAT.

CHAIRMAN THOMAS: THAT'S DEFINITELY A HIGH PRIORITY CONCERN DR. FEIGAL HAS FRONT AND CENTER. OKAY. LET'S MOVE ON TO ITEM 6.

MS. SAMUELSON: TWO TO FOUR TIMES A YEAR ISN'T GOING TO CUT IT BY SIX TO EIGHT PEOPLE. THEY

CAN'T POSSIBLY DO THE JOB I HAVE IN MIND. MY APOLOGIES FOR INTERRUPTING.

DR. FEIGAL: LET ME JUST SAY THIS IS HOW WE PROPOSE MOVING FORWARD. IF WE FEEL THAT WE NEED -- THIS DOESN'T LIMIT US. IF WE THINK WE NEED MORE FREQUENT MEETINGS, WE HAVE THE ABILITY TO DO THIS. THIS IS NOT IN STONE. THIS IS JUST GIVING YOU THE FRAMEWORK OF WHAT WE'RE PROPOSING TO MOVE TOWARD WITH.

CHAIRMAN THOMAS: THE OTHER POINT I'D MAKE, JOAN, IS THAT STAFF, ALL OF THESE TOPICS ARE DISCUSSED VIRTUALLY DAILY AND REEVALUATED. IT'S NOT AS THOUGH IT GOES ONLY TWO TO FOUR TIMES A YEAR TO BE HEARD. THEY'RE VERY MUCH TRYING TO CONSTANTLY PRIORITIZE AND MAKE SURE WE ADVANCE THE BALL.

MS. SAMUELSON: I CAN NEVER GET AN ANSWER TO THE QUESTION WHERE ARE WE WITH OUR STRATEGIC AGENDA.

DR. FEIGAL: YOU ARE GOING TO HEAR AN UPDATE OF OUR TRANSLATIONAL PORTFOLIO TODAY IF WE GET TO THAT TOPIC.

CHAIRMAN THOMAS: OKAY. THANK YOU FOR YOUR COMMENTS. SO ITEM 6 DR. FEIGAL IS ALSO GOING TO BE SPEAKING ON, WHICH HAS TO DO WITH SUGGESTIONS BY THE IOM REGARDING INITIATIVES IN THE REGULATORY

AND ETHICS SPACE. DR. FEIGAL.

DR. FEIGAL: ONCE AGAIN, THIS IS AN INFORMATION ITEM. THERE'S NO ACTION NEEDED ON YOUR PART FOR THIS. IT'S JUST IF YOU HAVE QUESTIONS. AND CERTAINLY IF YOU WANT TO HAVE CONTINUED INPUTS, WE'RE VERY RECEPTIVE TO THAT.

SO THE IOM RECOMMENDATION WAS THAT CIRM FUND RESEARCH AND TRAINING ON ETHICAL AND REGULATORY ISSUES. THEY RECOMMENDED THAT CIRM SHOULD SPONSOR TRAINING PROGRAMS AND WORKSHOPS AND OFFER NEW GRANT OPPORTUNITIES AIMED SPECIFICALLY AT IDENTIFYING AND ADDRESSING ETHICAL AND REGULATORY ISSUES SURROUNDING STEM CELL-BASED CLINICAL TRIALS RESEARCH, THAT CIRM SHOULD USE THE INFORMATION RESULTING FROM THESE INITIATIVES TOGETHER WITH CURRENT KNOWLEDGE TO STRENGTHEN ITS ETHICAL STANDARDS FOR CIRM-FUNDED HUMAN SUBJECTS RESEARCH BASED ON SOUND EMPIRICAL AS WELL AS THEORETICAL GROUNDS.

OUR LEGAL ASSESSMENT OF THIS WAS THAT THE PROPOSAL FOR FUNDING, WHETHER WE SUPPLEMENT EXISTING INITIATIVES OR LEVERAGE THEM OR DO A NEW RFA, IS SOMETHING THAT WOULD BE TREATED AS ANY OTHER FUNDING INITIATIVE REQUESTING ADDITIONAL FUNDS, AND THAT WE CAN PUT TOGETHER WORKSHOPS AT ANY TIME. THAT'S WITHIN OUR DOMAIN. THAT CAN OCCUR WITHOUT BOARD

APPROVAL IF WE STAY WITHIN OUR BUDGET.

SO JUST LETTING YOU KNOW, IF IT IS A NEW INITIATIVE, YOU WILL SEE IT. AND IF IT'S A WORKSHOP, YOU WILL CERTAINLY HEAR ABOUT IT. AND IF IT REQUIRES ADDITIONAL BUDGET, YOU'LL DEFINITELY HEAR ABOUT IT BECAUSE WE'LL NEED TO ASK YOU FOR MONEY.

SO OUR RESPONSE TO THE RECOMMENDATIONS ARE THAT WE WOULD ESTABLISH INITIATIVES ON ETHICAL AND REGULATORY ISSUES THAT RELATE TO HUMAN SUBJECTS RESEARCH. SO WHAT WE DID WITH THIS RECOMMENDATION IS WE STARTED OUT, AND I SHOULD SAY THAT GEOFF LOMAX PLAYED A PARTICULARLY STRONG ROLE IN HELPING TO MOVE THESE THOUGHTS FORWARD AND TO GAIN PERSPECTIVES WITH HIS CO-RUNNING OF THE STANDARDS WORKING GROUP ALREADY. SO WE WENT OUT AND SOUGHT INPUT AND PERSPECTIVES FROM THE STANDARDS WORKING GROUP MEMBERS, FROM CIRM-FUNDED RESEARCHERS, AND ALSO OTHER EXPERTS. AND WE ARTICULATED, WE COMMUNICATED WHAT THE IOM RECOMMENDATIONS WERE CONCERNING ETHICS AND PUBLIC POLICY PROGRAMS AND CONSIDERED THEIR INPUT IN PROPOSING THE FOLLOWING ITEMS.

ONE, REGARDING BASIC RESEARCH AND IPS RESEARCH AND BIOLOGICAL REPOSITORIES, I THINK IT'S PARTICULARLY PERTINENT BECAUSE THAT'S GOING TO BE ON

YOUR AGENDA TOPICS THAT YOU'RE HEARING ABOUT, THE BANK REPOSITORIES BECAUSE THESE CONTAIN SPECIMENS FROM PEOPLE. AND SO THERE ARE A LOT OF ISSUES REGARDING WHO DONATES TO THAT, HOW DOES IT GET USED.

SO WE THOUGHT AN AREA, A SCOPE FOR SOME OF THESE ISSUES WOULD BE THE LEGAL AND ETHICAL RIGHTS OF SOMATIC CELL DONORS AND MATERIALS SHARING IN IPS RESEARCH. WE FELT AND THE PEOPLE PROVIDING INPUT TO US FELT THIS IS A PRESSING TOPIC AS PATIENT DONORS HAVE GREAT EXPECTATIONS IN THE RESEARCH ENTERPRISE. FOR EXAMPLE, PATIENTS WANT TO BE INFORMED OF DISCOVERIES MADE WITH THEIR RESEARCH CELL LINES AND THAT PATIENTS AND PATIENT GROUPS WANT TO ENSURE THAT THE DISCOVERIES CAN BENEFIT THE COMMUNITY, AND THAT ACCESS BARRIERS SUCH AS THEY WANTED US TO CONSIDER PATENTS, LICENSES ARE NOT FURTHER ERECTED TO BAR THE ACCESS. FURTHER, THE ADVOCACY GROUPS HAVE INTEREST IN BENEFIT SHARING THAT CAN SUPPORT PATIENTS.

SO WE THOUGHT AS A START WE'D PROBABLY HAVE A WORKSHOP, AND WE COULD CONSIDER THE DISCUSSION OF WHETHER OR NOT WE WANT TO PUT INITIATIVES IN PLACE THAT COULD DEFINE THE NEEDS AND EXPECTATIONS OF DIFFERENT DONOR POPULATIONS, WHETHER OR NOT WE WANT TO HAVE A POLICY ANALYSIS TO CONSIDER EXISTING CONSTRAINTS THAT ARE FACED BY RESEARCHERS

AND RESEARCH INSTITUTIONS, WHETHER THERE MIGHT BE SOME MODEL EXAMPLES OR BEST PRACTICES THAT WE COULD USE FOR DONOR INVOLVEMENT THAT ARE CONSISTENT WITH THE ESTABLISHED REGULATORY FRAMEWORK FOR DONOR PROTECTION AND PRIVACY, FOR EXAMPLE, WITH THE COMMON RULE AND WITH HIPAA, TO IDENTIFY POLICY NEEDS OR APPROACHES TO ENABLE A MORE ROBUST DONOR INVOLVEMENT, AND IDENTIFYING TOOLS THAT MIGHT ALLOW FOR GREAT FLEXIBILITY OF BEING INVOLVED IN THIS TYPE OF RESEARCH, AND ALSO TO BE TAKEN IN THE CONTEXT OF CELL REPOSITORIES AND GENOMICS RESEARCH TO REDUCE THE LIKELIHOOD OF DONOR IDENTIFICATION.

THERE WERE ALSO SOME ADDITIONAL AREAS THAT CAME TO OUR ATTENTION IN TERMS OF THOUGHTS ABOUT EMBRYO DONATION AND STEM CELL RESEARCH AND PERHAPS THE NEED FOR A BANK OF HUMAN EMBRYONIC STEM CELLS, ALTHOUGH THAT CAN BE ACCOMMODATED BY THE IPS REPOSITORY WE'RE PUTTING FORWARD, FOR COMPATIBLE TRANSPLANTS. ALSO, THE SECONDARY, IN ADDITION TO BASIC, WAS FOR THE TRANSLATIONAL RESEARCH FOR THE ETHICAL CONDUCT OF HUMAN CLINICAL TRIALS AND IDENTIFY SOME STRATEGIC FOCUS AREAS.

AS YOU KNOW, WE HAVE A VARIETY OF DISEASE TEAMS AND STRATEGIC PARTNERSHIPS AND OTHER ENTITIES THAT ARE WORKING ON THE TRANSLATIONAL AND

DEVELOPMENT PATHWAY, AND THAT WE MIGHT PUT TOGETHER A WORKSHOP TO HELP INFORM THE DEVELOPMENT OF AN RFA THAT ADDRESSES THIS PART OF OUR DEVELOPMENT PROGRAMS. FOR EXAMPLE, WE COULD TALK TO THEM ABOUT WHAT THE PATIENT EXPECTATIONS ARE WITH REGARD TO THERAPIES. CAN WE DEVELOP SYSTEMS THAT PROVIDE ALTERNATIVES TO THE ROGUE CLINICS THAT WE ALL HEAR ABOUT THAT ARE POPULATING NOT JUST THIS STATE BUT ACROSS THE UNITED STATES, ACROSS THE WORLD?

TALK ABOUT WHAT THE BEST MODE OF COMMUNICATION MIGHT BE ESPECIALLY IN CASES WHERE WE HAVE THE OPPORTUNITY TO HAVE A DISCUSSION WITH THE PATIENT OR POTENTIAL PARTICIPANTS IN CLINICAL RESEARCH AND HELP THEM IN TERMS OF NAVIGATING THAT PATHWAY. HELP PATIENT ADVOCATES AND PROVIDER NETWORKS WHO MIGHT BE ABLE TO INTERACT TO MEET PATIENT NEEDS. AND WHAT WOULD BE SOME OF THE EFFECTIVE MODELS FOR BILATERAL COMMUNICATION AND STAKEHOLDER ENGAGEMENT?

IN ADDITION, MAYBE TALK ABOUT HOW ADVISORY BOARDS, WITH REPRESENTATION FROM THE COMMUNITY, COULD HELP SUPPORT CLINICAL RESEARCH IN PATIENTS. AND THAT SOME OF OUR FUNDING MIGHT BE CONSIDERED TO SUPPORT THE IDENTIFICATION OF THESE MODEL SYSTEMS THAT HAVE A PROVEN TRACK RECORD IN ADDRESSING THESE

ISSUES AND QUESTIONS.

OTHER AREAS THAT WERE ALSO BROUGHT TO OUR ATTENTION IS THE USE OF CERTAIN TYPES OF STEM CELL TREATMENTS AND THE ETHICAL ISSUES INVOLVED IN UTILIZING THEM. MAYBE THE ROLE OF CALIFORNIA PHYSICIANS IN STEM CELL TOURISM. TALK ABOUT THE PATIENT ADVOCACY ROLE IN REGULATORY APPROVAL, FOR EXAMPLE. I KNOW THAT DUANE PARTICIPATED IN A MEETING THAT WAS HELD LATE LAST YEAR WITH THE HASTINGS CENTER ABOUT MAYBE FIGURING WAYS TO ENHANCE THE ROLE OF THE PATIENT ADVOCATE EARLIER IN THE PROCESS OF PRODUCT DEVELOPMENT.

SO THERE'S A VARIETY OF SUGGESTIONS YOU SEE HERE WHICH COULD BE THE TOPIC OF A WORKSHOP OR PERHAPS OF A LEVERAGED INITIATIVE. ALSO IN YOUR ATTACHMENT THERE'S JUST A GRAPHIC IN TERMS OF THE TYPES OF INTERACTIONS WE COULD TAKE WITH BASIC RESEARCH THAT INVOLVES THE CONTRIBUTION OF SPECIMENS FROM PEOPLE OR WITH THE CLINICALLY RELEVANT RESEARCH.

THESE ARE THE AREAS THAT WE'RE THINKING ABOUT ENGAGING, AND WE JUST WANTED TO SHARE THIS AS AN INFORMATION ITEM AT THIS POINT.

CHAIRMAN THOMAS: THANK YOU. VERY THOUGHTFUL, VERY THOROUGH. THANK YOU TO YOU. THANK

YOU, DR. LOMAX, AS WELL FOR YOUR INPUT. ARE THERE ANY COMMENTS?

DR. LUBIN: I KNOW YOU KNOW THIS, BUT THE STATE OF CALIFORNIA ALSO IN THE PUBLIC HEALTH DEPARTMENT HAS A STEM CELL PROGRAM. AND I THINK WE SHOULD ALIGN WITH THEM AND NOT DUPLICATE THINGS. IT'S NOT VERY ACTIVE RIGHT NOW, BUT IT'S GONE THROUGH A LOT OF THESE THINGS INITIALLY, AND WE SHOULD BENEFIT FROM THAT AND NOT DUPLICATE.

DR. FEIGAL: THANK YOU.

CHAIRMAN THOMAS: OTHER COMMENTS? THANK YOU, DR. FEIGAL.

WE'RE NOW GOING TO GO -- THERE WERE ELEMENTS IN THE IOM REPORT DEALING WITH INTELLECTUAL PROPERTY ISSUES. THE IP AND INDUSTRY SUBCOMMITTEE MET TO DISCUSS THOSE AND TO DETERMINE WHAT COURSE OF ACTION SHOULD BE TAKEN. SCOTT, YOU'RE JUST STANDING BY FOR QUESTIONS, OR ARE WE GOING TO GO TO MR. JUELSGAARD DIRECTLY?

MR. TOCHER: YES. I'LL BE PREPARED TO PRESENT. SO LAST MONTH THE IP AND INDUSTRY SUBCOMMITTEE MET AT THE DIRECTION OF THE BOARD TO CONSIDER THE RECOMMENDATIONS OF THE IOM REGARDING CIRM'S IP POLICIES. THE REPORT REVIEWED THE DEVELOPMENT OF CIRM'S IP POLICIES AND ITS COMPONENTS

AND CONCLUDED AT THE BEGINNING THAT THEY REFLECT A REASONABLE EFFORT TO BALANCE CONFLICTING INTERESTS. NEVERTHELESS, THE IOM MADE TWO RECOMMENDATIONS.

THE FIRST RECOMMENDATION IS IN THE EVENT THAT CIRM WINDS DOWN, THE AGENCY SHOULD INCORPORATE FUTURE ENFORCEMENT OF IP POLICIES IN A SUSTAINABILITY PLATFORM. AND THE SECOND IS TO CONSIDER HARMONIZING THE IP POLICIES WITH BAYH-DOLE.

SO AS DID IOM, LET ME BEGIN WITH JUST A FEW PRELIMINARY POINTS ABOUT CIRM'S IP POLICIES. FIRST IS THAT THE POLICIES ARE ANCHORED IN THREE PRIMARY POINTS. FIRST IS PROPOSITION 71 ITSELF, WHICH REQUIRES CIRM TO BALANCE COMPETING BENEFITS TO CALIFORNIA FROM PATENTS, ROYALTIES, AND LICENSES WHILE ASSURING THAT ESSENTIAL RESEARCH IS NOT UNREASONABLY HINDERED BY IP AGREEMENTS. SECOND, SENATE BILL 1064 RECENTLY CODIFIED CIRM REGULATIONS REGARDING REVENUE SHARING AND ACCESS PLANS. AND FINALLY, THE THIRD COMPONENT ARE CIRM'S REGULATIONS THEMSELVES.

AND I JUST WANT TO DESCRIBE FOR A MOMENT A COUPLE BACKGROUND POINTS ABOUT THIS POLICY DEVELOPMENT THAT HAS OCCURRED OVER THE LAST SEVEN YEARS. FIRST, AS MANY OF YOU KNOW, CIRM DEVELOPED ITS NONPROFIT GRANTEE POLICY IN 2005 AND 2006.

THESE COMPONENTS WERE THEN IMPORTED INTO A SUBSEQUENT POLICY OVER THE NEXT TWO YEARS THAT APPLIED TO FOR-PROFIT GRANTEES. FINALLY, THESE POLICIES WERE FURTHER REFINED IN THE CONSOLIDATED POLICY TO APPLY TO BOTH FOR-PROFIT AND NONPROFIT GRANTEES IN 2008 AND 2009. AND IN ADDITION TO THESE PROCESSES REGARDING THESE SPECIFIC POLICIES, THERE WERE NUMEROUS OTHER RULEMAKINGS THAT THE BOARD HAS ENGAGED IN TO FURTHER CLARIFY THE SCOPE AND MEANING OF CIRM'S IP POLICIES. AND ALL OF THIS HAS BEEN DONE SUBJECT TO THE ADMINISTRATIVE PROCEDURE ACT, WHICH REQUIRES THE AGENCY TO CONSULT THE STAKEHOLDERS TO RECEIVE INPUT AND TO INCORPORATE THAT INPUT, WHERE APPROPRIATE, INTO THE POLICIES SO THAT EVERYONE IS AT THE TABLE DURING THEIR DEVELOPMENT.

BUT I ALSO WANT TO NOTE THAT CIRM HAS GONE BEYOND JUST THE LEGAL REQUIREMENTS OF THE APA SUCH THAT IN ADDITION TO THE RULEMAKING PROCEDURES, CIRM ENGAGES IN NUMEROUS EFFORTS TO GAUGE THE IMPACT OF THESE POLICIES. FOR INSTANCE, CIRM CONDUCTS ANNUAL MEETINGS WITH GRANTEES, MEETS WITH THE MEMBERS OF THE TECH TRANSFER OFFICES OF OUR GRANTEE INSTITUTIONS, AND ENGAGES IN VARIOUS OTHER MEETINGS AND CONSULTATIONS WITH POTENTIAL INDUSTRY PARTNERS

AND OTHER MEMBERS OF THE BIOTECH COMMUNITY.

SO IN SUMMARY, CIRM HAS A VERY ROBUST PRACTICE OF GAUGING THE TEMPERATURE OF OUR STAKEHOLDERS AND OUR IP POLICIES. SO WITH THAT BACKGROUND, I'LL TURN TO THE COMPONENTS THAT THE REPORT FOCUSED ON.

AND THOSE WERE FOUR FEATURES OF THE IP POLICIES. THE FIRST AND PERHAPS MOST OBVIOUS DIFFERENCE BETWEEN THE CIRM POLICY AND THE FEDERAL POLICY OF BAYH-DOLE IS REVENUE SHARING. ALTHOUGH THE REPORT NOTES IN THE DISCUSSION OF CIRM'S REVENUE SHARING THAT THERE USED TO BE A FEDERAL COMPONENT AS WELL WHICH WAS ABANDONED WITH BAYH-DOLE. HOWEVER, THE REPORT ITSELF NOTES THAT INDUSTRY AND ACADEMIC CRITICISM HAS BEEN, QUOTE, MUTED, DO NOT APPEAR TO RANK HIGH AMONG THE CONCERNS OF POTENTIAL GRANTEES AND LICENSEES.

THE SECOND COMPONENT THAT WAS DISCUSSED IS CIRM'S ACCESS PLANS, WHICH PROVIDE THAT THE DRUGS SHOULD BE -- A PLAN OF ACCESS SHOULD BE AFFORDED TO CALIFORNIANS WITH NO OTHER MEANS TO PURCHASE A DRUG. AND THIS PARTICULAR COMPONENT OF CIRM'S IP POLICIES IMPLICATED BOTH RECOMMENDATIONS, THE FUTURE ENFORCEMENT AND ALSO THE COHESION WITH BAYH-DOLE. HERE THE REPORT DOES NOTE THAT THERE ACTUALLY WAS A

SIMILAR PROGRAM HISTORICALLY IN THE FEDERAL SCHEME, BUT WHICH WAS ABANDONED UNDER OPPOSITION FROM INDUSTRY. HOWEVER, THE REPORT GOES ON TO NOTE THAT CIRM'S ACCESS PLANS ARE FAR NARROWER THAN THE FEDERAL SCHEME WAS, AND IT ONLY APPLIES TO A MUCH SMALLER GROUP SUBSET OF CALIFORNIANS.

THE THIRD COMPONENT IS CIRM'S MARCH-IN RIGHTS. THE IOM DISCUSSES A GENERAL WARNING ABOUT THE CONCEPT OF MARCH-IN WHICH, ALTHOUGH THE FEDERAL SCHEME HAS, THE FEDS HAVE NEVER ACTUALLY EXERCISED IT. AND IT IS THIS LACK OF EXERCISE OF MARCH-IN RIGHTS BY THE FEDERAL GOVERNMENT THAT HAS BROUGHT SOME LEVEL OF COMFORT WITH RESEARCHERS AND COMPANIES REGARDING ITS EXECUTION. HOWEVER, BECAUSE CIRM IS YOUNG AND BECAUSE THERE MAY BE UNCERTAINTY ABOUT WHO MIGHT EXERCISE THIS POWER IN THE FUTURE AFTER CIRM, THE REPORT WARNS THAT MAY BE A HINDRANCE TO PARTICIPATION DOWN THE ROAD.

FINALLY, THE REPORT ADDRESSED THE BIOMEDICAL MATERIALS SHARING COMPONENT OF CIRM'S IP POLICIES. HERE THE REPORT ACKNOWLEDGES, HOWEVER, THAT THERE ARE SIMILAR REQUIREMENTS IN OTHER JURISDICTIONS, CALLING OUT CONNECTICUT, TEXAS, MARYLAND, AND NEW YORK. AND IN FACT, THE FEDERAL GOVERNMENT ITSELF ALSO REQUIRES A PLAN FOR SHARING

IN GRANTS GREATER THAN $500,000.

SO THE SUBCOMMITTEE REVIEWED THE RECOMMENDATIONS AND THE HISTORY OF CIRM'S DEVELOPMENT OF ITS IP POLICIES. AND BASED ON THE CURRENT LEGAL REQUIREMENTS THAT SHAPE CIRM'S IP POLICIES AND ITS CURRENT PRACTICE OF SOLICITATION AND ENGAGEMENT FOR FEEDBACK FROM STAKEHOLDERS, THE RECOMMENDATION TO THE BOARD IS THAT CIRM MAINTAIN THIS CURRENT APPROACH AND CONTINUE ITS EFFORTS TO FINE-TUNE THESE POLICIES AS NECESSARY.

WITH RESPECT TO THE FUTURE ENFORCEMENT, CIRM HISTORICALLY, CIRM STAFF HISTORICALLY HAS ENGAGED OTHER STATE AGENCIES, SPECIFICALLY THE CONTROLLER'S OFFICE AND THE STATE TREASURER'S OFFICE, ON ITEMS RELATED TO CIRM'S IP REVENUE SHARING; FOR INSTANCE, THE CONTROLLER'S OFFICE, WHICH MIGHT ENFORCE THE REVENUE REQUIREMENTS IN THE FUTURE, AND THE TREASURER'S OFFICE, WHO WOULD BE CHARGED WITH ACTUALLY RECEIVING AND DEPOSITING THE REVENUES.

AGAIN, THOSE WERE CONVERSATIONS THAT WERE BACK IN SOME OF THE EARLIER DAYS OF THE AGENCY. AND THE RECOMMENDATION FROM THE IP SUBCOMMITTEE TO THE BOARD IS THAT STAFF BE DIRECTED TO REENGAGE THE APPROPRIATE STATE ACTORS TO, NOW THAT WE HAVE SORT

OF A BETTER LAY OF THE LAND, TO DETERMINE WHAT THE APPROPRIATE NEXT STEPS WOULD BE AND TO BRING THOSE RECOMMENDATIONS BACK TO THE IP SUBCOMMITTEE FOR FURTHER RECOMMENDATION TO THE BOARD.

CHAIRMAN THOMAS: WOULD LIKE TO NOTE -- ACTUALLY, MR. JUELSGAARD, DO YOU HAVE A COMMENT YOU'D LIKE TO MAKE? AND THEN I'LL PASS ON AN ADDITIONAL COMMENT.

DR. JUELSGAARD: NO. WE HAD THE MEETING OF THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE AND WENT THROUGH THIS MUCH AS SCOTT HAS OUTLINED AND DECIDED THAT THE RECOMMENDATIONS THAT SCOTT'S OUTLINED ARE THE ONES THAT SEEM MOST APPROPRIATE. I'LL JUST REPEAT, IN ESSENCE, WHAT HE SAID.

I UNDERSTAND THE NOTION OF REGULATORY CLARITY DOWN THE ROAD OF WHO'S GOING TO BE RESPONSIBLE WHEN CIRM ISN'T AROUND ANYMORE. I THINK THE SOONER THAT WE GET SOME CLARITY ON THAT, THE BETTER FOR EVERYBODY, INCLUDING THIS ORGANIZATION.

BUT THE OTHER ISSUES ARE REALLY IN THE SHORT TIME THAT I'VE BEEN HERE, A YEAR AND A HALF, I REALLY HAVEN'T SEEN MUCH IN THE WAY OF PUSH-BACK ON ANY OF THESE ISSUES. AND AS SCOTT'S INDICATED, THEY'RE EITHER EMBEDDED IN PROP 71 OR IN STATUES

THAT HAVE BEEN ENACTED ON CONCERN WITH PROP 71. SO IT WOULD BE VERY DIFFICULT, I THINK, TO BACKTRACK ON SOME OF THAT STUFF AT THIS POINT.

AND THIS SCHEME IS VERY DIFFERENT THAN THE NIH SCHEME IN MY MIND. SO IT'S MUCH MORE NARROWLY FOCUSED, AND I THINK PEOPLE APPRECIATE THE OPPORTUNITY TO GET THIS KIND OF FUNDING. AND SO I THINK WE'RE RIGHT WHERE WE SHOULD BE.

CHAIRMAN THOMAS: DR. PRICE.

DR. PRICE: IF MY RECOLLECTION SERVES ME, THESE IP POLICIES WERE NEGOTIATED PAINSTAKINGLY BY DUANE, BY ED PENHOET, AND THEY REPRESENT, YOU MIGHT SAY, A GRAND BARGAIN BETWEEN INDUSTRY ON ONE HAND, THE STATE LEGISLATURE ON THE OTHER, AND CIRM IN THE MIDDLE. AND I JUST THINK THE IDEA OF GOING BACK AND REDOING ALL THIS IS A RECIPE FOR I DON'T KNOW WHAT. DUANE, HOW MUCH TIME DO YOU HAVE FOR THE NEXT COUPLE OF YEARS?

MR. ROTH: I DON'T.

CHAIRMAN THOMAS: OTHER COMMENTS?

MR. SHESTACK: I JUST WANTED TO SAY I THINK THIS RESPONSE IS MEASURED, THAT THE PRACTICES THAT WERE EXHAUSTIVELY WORKED OUT BY ED PENHOET AND A GROUP OF PEOPLE REALLY ARE BEST PRACTICES IN IP AND CERTAINLY BEST PRACTICES FOR CALIFORNIA. AND TO

TAKE MOST OF THE IOM RECOMMENDATIONS THAT SERIOUSLY WOULD BE TO BE GOING BACK IN TIME, AND IT WASN'T ANY BETTER THEN.

MS. BAUM: THANK YOU. I WANTED TO JUST EMPHASIZE THAT THERE IS AN ACTION ITEM ON OUR AGENDA ADDRESSING SOME PROPOSED AMENDMENTS TO REVENUE SHARING AND OTHER ASPECTS OF OUR IP REGULATIONS, AND THEY ARE A DIRECT RESULT OF OUR INTERFACING WITH THE REGULATED COMMUNITY, ACADEMIA AND INDUSTRY. SO WE ARE IN TOUCH, AND WE ARE RESPONSIVE. AND I THINK THAT'S A GOOD EXEMPLAR.

DR. STEWARD: MOVE TO APPROVE THE RECOMMENDATIONS, IF THAT'S APPROPRIATE.

CHAIRMAN THOMAS: MOVED AND SECONDED. ANY OTHER COMMENTS?

THE REPORTER: I'M SORRY, MR. CHAIRMAN. I DIDN'T HEAR THE SECOND.

CHAIRMAN THOMAS: SECOND WAS MR. SHESTACK.

I WILL JUST NOTE FOR THE RECORD THIS IS LITERALLY HOT OFF THE PRESS. COURTESY OF MR. GIBBONS, HE GAVE ME AN ARTICLE FROM THE *NEW YORK TIMES* TODAY WHICH IS ENTITLED "SEEKING A PROFIT SHARE FOR TAXPAYERS AS FEDERAL SCIENCE SPENDING SHRINKS." AND IT IS AN ARTICLE ABOUT HOW NOW THEY ARE RECONSIDERING RETURNS ON NIH INVESTMENT AND

ISSUES OF AFFORDABILITY, AND IT CONCLUDES WITH THE FOLLOWING QUOTE FROM CONGRESSMAN WAXMAN, WHICH IS, "AMERICAN TAXPAYERS ARE ENTITLED TO REALIZE A RETURN ON THEIR INVESTMENT IN NIH RESEARCH RESULTING IN THIS OR ANY OTHER BIOTECHNOLOGY DRUG." THIS IS IN CONNECTION WITH A PARTICULAR DRUG. "'SURELY PRICE GOUGING ISN'T WHAT THEY EXPECT OR DESERVE,' SAID REPRESENTATIVE HENRY WAXMAN."

SO THIS WHOLE NOTION OF SHARING REVENUE AND AFFORDABILITY, WHICH HAS BEEN A HALLMARK OF CIRM FROM THE GET-GO AS REFINED BY THE DEVELOPMENT OF VERY CONSIDERED IP REGS, IS CUTTING-EDGE AND NOW BEING ABOUT TO BE EMULATED PERHAPS BY THE FEDERAL GOVERNMENT. SO CIRM, ONCE AGAIN, ON THE FRONTIER OF SUCH NOTIONS.

IS THERE ANY PUBLIC COMMENT ON THIS ISSUE? MR. REED.

MR. REED: JUST THAT I REMEMBER ABOUT SIX LAWS THAT WERE ATTEMPTS, TO MY VIEW, TO MICROMANAGE CIRM, AND IN EVERY ONE OF THEM THEY BROUGHT UP IP. AND IN EVERY CASE THE ICOC CAREFULLY CONSIDERED EVERYTHING THEY OFFERED AND FOUND WAYS TO PICK AND CHOOSE THE BEST ONES THERE. THIS IS AN AGONIZINGLY ARRIVED AT SET OF REGULATIONS WHICH TOOK UP MUCH, MUCH, MUCH TIME OF EVERYBODY. AND I THINK WE ARE

THE LEADER TO EMULATE. WE SHOULD NOT THINK IN TERMS OF GOING BACK AND STARTING OVER.

CHAIRMAN THOMAS: THANK YOU, MR. REED. MOTION ON THE TABLE. ANY FURTHER DISCUSSION? CAN WE DO THIS ON A VOICE VOTE? VOICE VOTE. DO WE NEED A RESTATEMENT, MR. HARRISON?

MR. HARRISON: THE MOTION IS TO APPROVE THE RECOMMENDATIONS OF THE IP AND INDUSTRY SUBCOMMITTEE WITH RESPECT TO THE IOM RECOMMENDATIONS.

CHAIRMAN THOMAS: ALL THOSE IN FAVOR PLEASE SAY AYE. OPPOSED? ON THE PHONE?

MR. GOLDBERG: AYE.

CHAIRMAN THOMAS: THANK YOU. ANY ABSTENTIONS? MOTION CARRIES. THAT WAS, FOR THOSE KEEPING SCORE, ITEM 7.

CHAIRMAN THOMAS: DR. VUORI.

DR. VUORI: YES. I VOTE AYE.

CHAIRMAN THOMAS: THANK YOU. MOTION PASSES. THAT WAS ITEM 7 ON THE AGENDA.

WE'RE NOW GOING TO MOVE ON TO ITEM NO. 8, CONSIDERATION OF THE APPLICATIONS FOR RFA'S 1202, 03, 04 REGARDING CIRM HUMAN PLURIPOTENT STEM CELL INITIATIVE. DR. GRIESHAMMER IS GOING TO BE PRESENTING ON BEHALF OF STAFF.

DR. GRIESHAMMER: THANK YOU. CHAIR, BOARD MEMBERS, I'M GOING TO PRESENT THE GRANTS WORKING GROUP RECOMMENDATIONS FOR THE HUMAN INDUCED PLURIPOTENT STEM CELL INITIATIVE FOR YOUR CONSIDERATION, AGENDA ITEM NO. 8.

JUST TO REMIND YOU, THE GOAL OF THIS INITIATIVE IS TO FUND THE GENERATION OF A COMPREHENSIVE INDUCED PLURIPOTENT STEM CELL RESOURCE OR IPS CELL RESOURCE. THE CREATION OF THIS RESOURCE INVOLVES THREE ACTIVITIES AS SHOWN HERE: THE TISSUE COLLECTION FROM PATIENTS, THE GENERATION OF IPS CELL LINES FROM THE COLLECTED SAMPLES, AND THEN THE BANKING AND DISTRIBUTION OF THE IPS CELL LINES.

THESE RESOURCES, ONCE GENERATED, CAN THEN BE USED BY RESEARCHERS WORLDWIDE FOR DISEASE MODELING AND FOR THE DISCOVERY OF NEW DRUG TARGETS, AS WELL AS BY DRUG DEVELOPERS TO DISCOVER AND DEVELOP NEW DRUGS.

EACH OF THESE THREE STEPS LEADING TO THIS RESOURCE WILL BE FUNDED BY ITS OWN RFA. SOME OF THE SPECIFICS OF EACH OF THESE RFA'S IS LISTED HERE, AND I'M GOING TO BRIEFLY GO OVER THEM. UNDER RFA 12-02, SEVERAL GRANTS WILL FUND THE PROCUREMENT OF TISSUES FROM PATIENTS WITH VARIOUS PREVALENT GENETICALLY COMPLEX DISEASES AND ALSO THE COLLECTION OF MEDICAL

INFORMATION THAT WILL BE ASSOCIATED WITH EACH CELL LINE TO INFORM FUTURE STUDIES.

RFA 12-03 WILL FUND THE DERIVATION OF ALL IPS CELL LINES FROM THOSE TISSUES. A KEY FEATURE OF THE DERIVATION EFFORT IS THAT THIS WILL BE ACCOMPLISHED BY A SINGLE DERIVER USING A SINGLE DERIVATION METHOD, THEREBY MINIMIZING THE EXPERIMENTAL VARIATION BETWEEN IPS CELL LINES.

FINALLY, RFA 12-04 WILL FUND THE ESTABLISHMENT OF A SINGLE REPOSITORY FOR THESE IPS CELL LINES AND FOR ADDITIONAL PLURIPOTENT STEM CELL LINES, WHICH MAY INCLUDE, AS DR. FEIGAL MENTIONED JUST A MOMENT AGO, HUMAN EMBRYONIC STEM CELL LINES GENERATED BY CALIFORNIA INVESTIGATORS. THE REPOSITORY WILL BANK AND DISTRIBUTE THESE HUMAN PLURIPOTENT STEM CELL LINES AND ALSO MAKE AVAILABLE THE DEIDENTIFIED MEDICAL INFORMATION.

YOU APPROVED $4 MILLION FOR THE FUNDING OF RFA 12-02, THE TISSUE COLLECTION; $60 MILLION FOR IPS CELL DERIVATION; AND $10 MILLION FOR THE REPOSITORY. ALL THREE RFA'S WERE OPEN TO NONPROFIT AND FOR-PROFIT INSTITUTIONS. AND OUR INTENT IS TO INCLUDE ABOUT 3,000 TISSUE DONORS IN THIS INITIATIVE.

TO PROVIDE SOME CONTEXT NOW AS TO HOW

THESE THREE RFA'S WERE REVIEWED, THE REVIEW HAPPENED IN A SINGLE REVIEW, TWO-AND-A-HALF-DAY REVIEW MEETING. AND I'M GOING TO BRIEFLY GO OVER THE REVIEW CRITERIA FOR EACH RFA, WHICH, OF COURSE, ARE GOING TO BE VERY DIFFERENT FROM EACH OTHER SINCE THEY'RE VERY DIFFERENT ACTIVITIES.

FOR RFA 12-02 FOR TISSUE COLLECTION, THE REVIEWERS WERE ASKED TO EVALUATE THE SIGNIFICANCE OF THE PROPOSED PROJECT. DOES THE TARGETED DISEASE REPRESENT AN UNMET MEDICAL NEED? REGARDING THE RATIONALE, REVIEWERS WERE ASKED TO ASSESS IF IT WILL LIKELY BE POSSIBLE TO USE IPS CELLS TO MODEL THE DISEASE.

IN CONSIDERING THE QUALITY OF THE PROTOCOLS, THE REVIEWERS WERE EVALUATING WHETHER THE TISSUE DONOR CONSENT IS ADEQUATE TO SUPPORT THE GOALS OF THIS RFA WHILE PROTECTING THE RIGHTS OF THE TISSUE DONORS. IS THE PRIVATE TISSUE DONOR INFORMATION MANAGED IN ACCORDANCE WITH ALL APPLICABLE LAWS AND REGULATIONS? AND IS THE MANAGEMENT OF THE TISSUE INVENTORIES AND THE ASSOCIATED MEDICAL INFORMATION WELL THOUGHT OUT? IS THE PROJECT FEASIBLE? DOES THE APPLICANT HAVE ACCESS, FOR INSTANCE, TO THE APPROPRIATE PATIENT POPULATIONS? IS THE BUDGET APPROPRIATE? AND DOES

THE TEAM HAVE THE EXPERIENCE WITH TISSUE DONOR RECRUITMENT, CONSENTING, AND COLLECTING THE MEDICAL INFORMATION?

FOR RFA 12-03, THE IPS DERIVATION AWARD, REVIEWERS LOOKED AT WHETHER THE PROPOSED PROTOCOLS FOR IPS CELL DERIVATION AND CHARACTERIZATION WOULD LEAD TO THE PRODUCTION OF HIGH QUALITY IPS CELL LINES. IN ASSESSING THE DOCUMENTATION AND QUALITY CONTROL, REVIEWERS WERE ASKED TO LOOK AT THE ACTIVITIES PERFORMED, TO LOOK AT WHETHER THE ACTIVITIES PERFORMED BY THE DERIVER OCCUR UNDER ESTABLISHED STANDARD OPERATING PROCEDURES. IS THERE A QUALITY PROGRAM IN PLACE TO DETECT AND RESOLVE EMERGING QUALITY PROBLEMS? IS IT FEASIBLE TO PRODUCE THE LARGE NUMBER OF HIGH QUALITY IPS CELL LINES IN THREE YEARS? DOES THE APPLICANT HAVE THE PATENTS AND/OR LICENSES REGARDING IPS CELL DERIVATION TECHNOLOGY ENABLING THE USE OF THE IPS CELL LINES BY BOTH NONPROFIT AND FOR-PROFIT END USERS?

I WILL JUST MENTION HERE, SINCE THIS REPRESENTS CONFIDENTIAL INFORMATION, ANY DISCUSSION OF THIS MATTER WOULD HAVE TO TAKE PLACE IN CONFIDENTIAL SESSION.

AND THEN, FINALLY, DOES THE PROGRAM

DIRECTOR AND TEAM HAVE THE QUALIFICATIONS TO DERIVE THE IPS CELL LINES? AND AGAIN, IS THE BUDGET APPROPRIATE?

FINALLY, RFA 12-04, THE REVIEWERS EVALUATED THE QUALITY OF THE REPOSITORY FACILITY AND ITS EQUIPMENT SUITABLE FOR THE TASK. ARE THE CELL HANDLING PROCEDURES APPROPRIATE TO ENSURE THE DISTRIBUTION OF A HIGH QUALITY RESOURCE? SIMILAR TO THE PREVIOUS RFA, REVIEWERS LOOKED AT QUALITY CONTROL. THEY ALSO LOOKED AT THE CELL LINE AND DATA MANAGEMENT SYSTEMS. WERE THEY SUITABLE FOR TRACKING THE IPS CELL LINES AND THE ASSOCIATED MEDICAL DATA AND MAKING THAT INFORMATION AND THE CELLS AVAILABLE TO POTENTIAL IPS CELL USERS? IS THE MANAGEMENT OF THE REPOSITORY WELL THOUGHT OUT? IS THERE A REASONABLE PLAN IN PLACE TO BECOME SUSTAINABLE AFTER CIRM FUNDING ENDS?

AND FINALLY, AS PART OF THE QUALITY OF THE REPOSITORY, IS THERE A GOOD PLAN FOR BANKING ADDITIONAL HUMAN PLURIPOTENT STEM CELL LINES GENERATED BY CALIFORNIA INVESTIGATORS?

CONSIDERING FEASIBILITY, REVIEWERS LOOKED AT WHETHER THE PROPOSED REPOSITORY CAN BE ESTABLISHED OR EXPANDED AND OPERATED WITHIN FOUR YEARS? AND AGAIN, DOES THE PROGRAM DIRECTOR AND

TEAM HAVE THE QUALIFICATIONS TO EXECUTE ALL THESE ACTIVITIES? AND IS THE BUDGET REASONABLE?

SO I'M JUST BRIEFLY GOING TO DESCRIBE TO YOU THE ACTUAL PROCEEDINGS AT THE REVIEW MEETING. CIRM RECEIVED 16 APPLICATIONS FOR TISSUE COLLECTION, 6 APPLICATIONS FOR IPS CELL DERIVATION, AND 4 APPLICATIONS FOR THE REPOSITORY AWARD. DURING GRANTS WORKING GROUP REVIEW, APPLICATIONS TO EACH OF THESE RFA'S WERE INDIVIDUALLY REVIEWED AND SCORED. AND THOSE ARE THE SCORES THAT YOU WILL BE LOOKING AT IN A MOMENT.

SINCE THE EXECUTION OF THIS INITIATIVE WILL REQUIRE A FAIR AMOUNT OF COORDINATION BETWEEN THE DIFFERENT COMPONENTS, WE STATED IN THE RFA'S THAT IT WAS POSSIBLE FOR APPLICANTS TO COORDINATE THE DERIVATION AND BANKING EFFORTS BY REFERRING TO EACH OTHER'S EFFORTS IN THE APPLICATIONS. WE ALSO STATED THAT THE GRANTS WORKING GROUP WOULD BE ASKED TO CONSIDER WHETHER CERTAIN APPLICATIONS, SUCH AS THOSE FROM A DERIVER AND A REPOSITORY, ARE ABLE TO HARMONIZE AND ALIGN IN ORDER TO ACHIEVE THE GOALS OF THIS INITIATIVE.

AND SO THIS REVIEW WAS THEN ACCOMPLISHED AT THE GRANTS WORKING GROUP REVIEW MEETING BY A DISCUSSION OF POSSIBLE DERIVER REPOSITORY PAIRS.

AND ALL OF THIS WAS THEN FOLLOWED BY A PROGRAMMATIC REVIEW AND VOTING ON RFA 12-02, THE TISSUE COLLECTION AWARDS, AND ON THE DERIVER REPOSITORY PAIRS.

THE NEXT TWO SLIDES I WILL DESCRIBE THE RECOMMENDATIONS BROUGHT FORTH BY THE GRANTS WORKING GROUP ON THESE TWO ITEMS THEY VOTED ON. FOR RFA 12-02, TISSUE COLLECTION, SEVEN APPLICATIONS ARE RECOMMENDED FOR FUNDING. THEY REPRESENT ELEVEN DISEASES. THE TOTAL NUMBER OF PROPOSED TISSUE DONORS IN THESE RECOMMENDED APPLICATIONS IS ABOUT 3,600. ABOUT 2,580 OF THOSE WOULD BE FROM DISEASED INDIVIDUALS AND A LITTLE MORE THAN A THOUSAND FROM UNAFFECTED CONTROLS. AND THE TOTAL FUNDS REQUESTED BY THESE SEVEN APPLICATIONS AMOUNT TO ABOUT $6.3 MILLION.

REVIEWERS ARGUE THAT, IN THE CONTEXT OF GENETICALLY COMPLEX DISEASES, IT WOULD BE APPROPRIATE TO INCLUDE A WELL-CHOSEN GROUP OF TISSUE DONORS TO SERVE AS SHARED CONTROLS. THIS WOULD ALSO MAXIMIZE THE EFFECTIVE USE OF THE FUNDS AS FEWER TOTAL CONTROL TISSUE DONORS THAN PROPOSED MAY BE INCLUDED. AND SO THE GRANTS WORKING GROUP, THEREFORE, RECOMMENDED THAT CIRM NEGOTIATE NEW COHORTS OF SHARED CONTROLS WITH THE AWARDEES. THEIR

BUDGETS, THEN, WOULD BE APPROPRIATELY ADJUSTED, AND ONE OF THE GOALS OF THESE NEGOTIATIONS THEN WOULD BE TO ARRIVE AT ABOUT THE 3,000 TISSUE DONORS CONTEMPLATED FOR THIS INITIATIVE.

SO THOSE ARE THE RECOMMENDATIONS FOR RFA 12-02.

MR. SHESTACK: WAS THERE ALSO A SENSE THAT SINCE A LOT OF THE RECRUITMENT FOR THIS TISSUE DERIVATION HAS ACTUALLY ALREADY BEEN DONE IN MANY OF THESE CASES, THAT STAFF MIGHT BE ABLE TO FIND SOME ADDITIONAL SAVINGS IN HERE THAT MIGHT HELP US JUSTIFY GOING UP IN TERMS OF THE TOTAL AMOUNT OF PEOPLE WE ARE CONSIDERING?

DR. GRIESHAMMER: YOU MEAN THOSE APPLICANTS WHO HAVE ALREADY PATIENT COHORTS CONSENTED, LET'S SAY, FOR OTHER ACTIVITIES OR MAYBE EVEN FOR IPS CELL --

MR. SHESTACK: THEY'RE THE EXACT SAME PATIENTS, BUT FOR OTHER ACTIVITIES, AND THEY MAY BE CHARGING US. SO WE COULD SAVE SOME MONEY.

DR. GRIESHAMMER: SO THE APPLICANTS WERE ASKED TO PROVIDE A BUDGET BASED ON THE ACTIVITIES THEY WOULD HAVE TO PERFORM TO RECRUIT THEIR PATIENTS. AND IN THE APPLICATIONS THEY TALKED A LOT ALSO ABOUT THE ACTUAL PATIENT COHORTS, THAT THEY ARE

ALREADY -- THE DOCTORS IF THEY'RE SEEING THEM AND HOW THEY HAVE BEEN INTERACTING WITH THEM. SO THE BUDGETS FOR EACH OF THESE APPLICATIONS SHOULD REFLECT THE ACTUAL COSTS FOR RECRUITMENT.

MR. SHESTACK: THERE MIGHT BE ROOM FOR SAVINGS.

DR. GRIESHAMMER: SO WE CAN LOOK AT THAT. THAT'S A GOOD IDEA.

THE RECOMMENDATIONS OF THE GRANTS WORKING GROUP FOR THE DERIVATION AND REPOSITORY AWARDS, I WANT TO REMIND YOU THAT IN THIS CASE ONLY ONE APPLICATION WILL BE AWARDED FOR EACH OF THESE RFA'S. THE REVIEWERS RECOMMENDED THE TOP SCORING DERIVER APPLICATION AND THE STOP SCORING REPOSITORY APPLICATION FOR FUNDING. THIS IS THE FIRST CHOICE PAIR INDICATED ON THE SLIDE. IN ADDITION, REVIEWERS PROVIDED CIRM WITH A SECOND AND THIRD CHOICE PAIR COMBINATION.

IN CONSIDERING THESE APPLICATIONS, REVIEWERS ASKED CIRM TO COMPARE AND CLARIFY LICENSING FEES AND ROYALTIES ASSOCIATED WITH IPS CELL DERIVATION TECHNOLOGIES DESCRIBED IN THE DERIVATION APPLICATIONS AND OTHER BUSINESS CONSIDERATIONS. CIRM DID INVESTIGATE THESE ISSUES. AS THIS INFORMATION IS CONFIDENTIAL, WE WOULD BE

PREPARED TO TALK ABOUT CIRM'S FINDINGS IN THIS REGARD IN CLOSED SESSION.

MY FINAL SLIDE SUMMARIZES THE GRANTS WORKING GROUP RECOMMENDATIONS. AS I JUST MENTIONED, THE COMBINED BUDGETS FOR THE SEVEN RECOMMENDED TISSUE COLLECTION PROPOSALS AMOUNTS TO $6.3 MILLION. THIS DOES EXCEED THE APPROVED BUDGET OF $4 MILLION. AND AS I HAD MENTIONED, THIS MAY BE REDUCED THROUGH IMPLEMENTATION OF SHARED CONTROLS AND SOME OTHER CREATIVE ACTIVITIES. BUT I WOULD LIKE TO ASK IF YOU APPROVE THOSE SEVEN APPLICATIONS FOR FUNDING, YOU APPROVE THE CURRENTLY REQUESTED $6.3 MILLION AS WE DO NOT YET KNOW EXACTLY HOW THE BUDGETS WILL CHANGE.

AND THEN AS PART OF THE FIRST CHOICE PAIR, THE RECOMMENDATION FOR DERIVER AND ONE REPOSITORY ARE RECOMMENDED FOR FUNDING AT THE ORIGINALLY APPROVED BUDGETS OF 16 AND $10 MILLION RESPECTIVELY.

AND I WILL END BY JUST MENTIONING THAT WE DID RECEIVE FOUR EXTRAORDINARY PETITIONS. WE RECEIVED A LETTER OF RESPONSE TO THIS REVIEW AS WELL AS VARIOUS OTHER PIECES OF INFORMATION, SOME OF WHICH ARE CONFIDENTIAL INFORMATION.

CHAIRMAN THOMAS: UTA, ON THE EXTRAORDINARY PETITIONS, WHICH OF THE RFA'S DID THOSE PERTAIN SPECIFICALLY?

DR. GRIESHAMMER: ALL THREE. TWO FOR DERIVER, AND THEN THE LETTER OF RESPONSE IS FOR ANOTHER DERIVER APPLICATION, ONE FOR A REPOSITORY AND ONE FOR TISSUE CULTURE.

CHAIRMAN THOMAS: OKAY.

MR. SHESTACK: ARE THEY IN THE BINDER?

DR. GRIESHAMMER: YES. IF YOU LOOK AT THE NUMBERS ASSOCIATED WITH THE APPLICATION, IF IT'S AN I.T., A NUMBER THAT STARTS WITH I.T., IT'S FOR TISSUE COLLECTION. IF IT'S I.D., IT'S FOR DERIVATION. IF IT'S I.R., IT'S FOR REPOSITORY.

CHAIRMAN THOMAS: OKAY. I THINK THAT WE'RE GOING TO BE NEEDING TO HAVE A CLOSED SESSION. BUT IN ORDER TO BEST INFORM THAT, UTA, WOULD YOU LIKE TO ORCHESTRATE PUBLIC COMMENT BY THE EXTRAORDINARY PETITIONERS IN ADVANCE?

DR. GRIESHAMMER: I THINK THE OTHER THING WE CAN ALSO GO FORTH WITH, IF I UNDERSTAND CORRECTLY, IS TO ACTUALLY LOOK AT, AS WE NORMALLY DO AT THIS POINT, AND THIS TIME IT'S GOING TO BE A LITTLE BIT MORE COMPLICATED SINCE WE CONSIDERED THREE RFA'S, BUT GIL WOULD PRESENT THE ACTUAL RANKED RECOMMENDATIONS.

CHAIRMAN THOMAS: YES, THANK YOU. AND THEN WE GO ON TO THE PUBLIC COMMENT.

MR. SHESTACK: UTA, CAN YOU ADDRESS THE TIMING? THE RECOMMENDED REPOSITORY IS NOT FROM CALIFORNIA. AND THE RECOMMENDED DERIVER IS OR IS NOT?

DR. GRIESHAMMER: IS NOT.

MR. SHESTACK: NEITHER ARE. AND MAYBE NOT EVEN ON THE SECOND TIER AS WELL, BUT YET A LOT OF THE TISSUE COLLECTIONS MIGHT BE READY QUICKLY. WILL IT TAKE EXCESSIVE TIME FOR THESE PEOPLE TO BUILD FACILITIES IN CALIFORNIA? AND CAN YOU ADDRESS THEIR ACTUAL COMMITMENT TO LONG-TERM INVESTMENT IN CALIFORNIA?

DR. GRIESHAMMER: SO THIS WAS LOOKED AT BY THE REVIEWERS. AND I CAN SAY THAT THE TOP DERIVER AND REPOSITORY, ALTHOUGH FROM OUTSIDE OF CALIFORNIA, WERE ACTUALLY LAUDED FOR HAVING ALREADY IDENTIFIED AND LEASED THE APPROPRIATE SPACE AND DO SEEM TO BE ABLE TO BE READY PRETTY QUICKLY IN SETTING UP THE FACILITIES. BUT, YES, THIS WAS A CONCERN THAT THE GRANTS WORKING GROUP DID CONSIDER.

DR. TROUNSON: SO, JON, I THINK THAT WOULD BE FAIR TO SAY FOR ALL OF THEM, THAT THEY GAVE A COMMITMENT TO GET THESE ESTABLISHED IN RATHER QUICK ORDER. AND THERE ARE LETTERS THERE TO YOU SUPPORTING THAT. SO I THINK ALL OF THEM TOOK A

COMMITMENT TO GET THIS DONE IN A VERY RAPID FASHION.

DR. GRIESHAMMER: IF I CAN MAKE ONE OTHER COMMENT IN THIS REGARD. REALIZING THAT THERE WOULD BE A LOT OF COORDINATION THAT ACTUALLY DOES HAVE TO HAPPEN BETWEEN ALL THE MOVING PARTS HERE, CIRM WILL ORGANIZE WITHIN THE NEXT FEW MONTHS A MEETING OF ALL THE AWARDEES TO GET STARTED ON COORDINATING VARIOUS ACTIVITIES. AND THEN CIRM WILL BE INVOLVED IN MAKING SURE ALL THE PIECES ARE MOVING AT THE PROPER SPEED.

MR. SHESTACK: AND YOU PLAN TO HAVE A DEDICATED STAFF MEMBER TO JOCKEY ALL THIS TOO; IS THAT CORRECT?

DR. TROUNSON: AT THE MOMENT WE HAVEN'T APPOINTED SOMEONE, BUT WE'RE IN THE PROCESS, WE'RE BEING OUT THERE IN THE PROCESS --

MR. SHESTACK: THAT'S A GREAT IDEA.

DR. TROUNSON: -- TRYING TO FIND SOMEBODY, NOT ONLY, I THINK, IMPORTANTLY TO HELP WITH THE INTEGRATION OF THE PROGRAMS HERE, BUT ALSO THE UTILIZATION OF THOSE CELLS IN THE BANK BECAUSE WE DON'T WANT THEM SET DOWN AND NOT UTILIZED AT THE HIGHEST POSSIBLE RATE. YEAH. WE WILL HAVE THAT PERSON AS SOON AS POSSIBLE, BUT WE HAVEN'T ACTUALLY APPOINTED ANYONE.

MR. SHESTACK: YOU COULD MAKE A LOT OF USE OUT OF THAT PERSON. THAT PERSON COULD MAKE SURE THAT THIS MATERIAL IS USED. IT'S A GREAT IDEA.

CHAIRMAN THOMAS: DR. STEWARD.

DR. STEWARD: JUST A POINT OF ORDER. FROM WHAT YOU'VE SAID, I THOUGHT MAYBE YOU WERE IMPLYING THAT THERE WOULD BE PUBLIC COMMENT FOR ALL OF THE EXTRAORDINARY PETITIONS. AND MAYBE I'M MISREMEMBERING WHAT OUR TRADITIONAL POLICY HAS BEEN, BUT I THOUGHT IT WAS THE CASE THAT ONLY THOSE EXTRAORDINARY PETITIONS THAT WERE BROUGHT UP BY A MEMBER OF THE BOARD WERE ACTUALLY PRESENTED IN A PUBLIC SESSION. AM I WRONG ON THAT?

CHAIRMAN THOMAS: NO. THAT IS CORRECT. THAT'S THE NORMAL PROCEDURE, BUT THE QUESTION WAS, WE ARE GOING INTO CLOSED SESSION, WOULD IT BE BENEFICIAL FOR THE BOARD'S SAKE TO HEAR SOME PUBLIC COMMENT IN ADVANCE TO INFORM THAT CLOSED SESSION, WHICH WOULD BE DEFINITELY DEVIATION FROM THE NORM, BUT THAT WAS HOW WE AROSE AT THAT CONCLUSION.

DR. TROUNSON: I THINK THAT'S A VERY GOOD IDEA. I THINK THIS IS A COMPLEX ISSUE. IT'S A RATHER COMPETITIVE MATTER AND IT'S A LITTLE DIFFERENT THAN WHAT WE'VE DONE IN THE PAST. SO I THINK IT MIGHT BE HELPFUL TO HEAR THOSE PEOPLE

BEFORE WE GO TO CLOSED SESSION, AND IT WILL GIVE YOU A BETTER CHANCE TO, I THINK, INTERROGATE THE PROCESSES AND THE RECOMMENDATIONS.

DR. STEWARD: MAYBE IT'S A MOOT POINT BECAUSE THIS WILL BE, I GUESS, THE LAST TIME WE'RE DOING IT IN THIS WAY WITH AN EXTRAORDINARY PETITION PROCESS. BUT JUST I WOULD LIKE TO GO ON RECORD AS THIS BEING AN EXCEPTION TO OUR NORMAL PROCEDURE.

CHAIRMAN THOMAS: SO NOTED. THANK YOU.

MS. SAMUELSON: AND I WOULD LIKE TO HEAR FROM ONE OF THE PETITIONS.

CHAIRMAN THOMAS: WE'RE NOT QUITE READY YET FOR THAT. ANY QUESTIONS FOR UTA? DR. SAMBRANO.

DR. SAMBRANO: SO WHAT I'M SHOWING YOU HERE IS SOMETHING YOU ALREADY HAVE IN YOUR BOOKS, WHICH IS THE LISTING IN RANK ORDER OF THE TISSUE COLLECTION APPLICATIONS. AND I ALSO HAVE ANOTHER SPREADSHEET HERE FOR THE DERIVATION AND REPOSITORY APPLICATIONS INDICATING -- IT IS IN THE BOOK TOO BECAUSE I KNOW IT'S ALMOST IMPOSSIBLE TO READ AT THIS LEVEL. BUT IT MAY BE WORTHWHILE TO GO OR TO CONSIDER AT LEAST ONE BEFORE YOU GO TO THE NEXT ONE. SO THE TISSUE COLLECTION ONE IS THE ONE I'M PUTTING UP FIRST IF YOU WANT TO TAKE THAT INTO CONSIDERATION.

MR. HARRISON: WHILE THE MEMBERS ARE REVIEWING THE TISSUE COLLECTION SCORES IN THEIR BOOKS, LET ME JUST POINT OUT THAT THE APPLICATION REVIEW SUBCOMMITTEE IS NOW MEETING TO CONSIDER THESE APPLICATIONS.

(THE ICOC WAS THEN RECESSED AND RECONVENED AS THE APPLICATION REVIEW SUBCOMMITTEE, THE TRANSCRIPT OF WHICH IS BOUND UNDER SEPARATE COVER.)

(THE ICOC WAS THEN RECONVENED AND HEARD AS FOLLOWS:)

CHAIRMAN THOMAS: MARIA, CAN WE DO 12?

MS. BONNEVILLE: WE DO NOT HAVE A QUORUM.

CHAIRMAN THOMAS: HOW ARE WE ON GETTING JOAN BACK IN THE ROOM?

MS. BONNEVILLE: WITHOUT DR. PULIAFITO, UNFORTUNATELY WE DON'T HAVE A QUORUM.

CHAIRMAN THOMAS: OKAY. SO WE APPEAR TO -- I'M WAITING FOR MARIA TO FINISH HER DISCUSSION. WOULD THE BOARD LIKE AN UPDATE ON THE TRANSLATIONAL PORTFOLIO?

DR. TROUNSON: I THINK WE SHOULD DO IT IF YOU'VE GOT THE TIME. I THINK IT'S IMPORTANT.

CHAIRMAN THOMAS: HOW ABOUT THIS? HOW ABOUT IF YOU COULD DO IT FOR THE BOARD HERE, AND

THEN YOU COULD SEND HER THE PRESENTATION AND WALK HER THROUGH IT OVER THE PHONE AT A SUBSEQUENT DATE? LET'S DO THAT. IT'S THE BOARD'S PLEASURE TO HEAR THIS. I THINK THIS WOULD BE VERY INTERESTING FOR EVERYBODY. DR. FEIGAL, PLEASE PROCEED.

DR. FEIGAL: WE ARE DELIGHTED, DR. OLSON AND I, TO BRING YOU AN UPDATE ON THE PROGRESS ON THE TRANSLATIONAL PORTFOLIO. WHAT WE PLAN TO DO IS GIVE YOU AN UPDATE ON WHERE WE ARE WITH THE DIFFERENT DISEASE TEAMS. I'LL GIVE YOU SOME ILLUSTRATIVE EXAMPLES FROM EYE, NEURODEGENERATIVE DISEASE, AND CARDIOVASCULAR PORTFOLIO, AND THEN JUST RAISE SOME QUESTIONS FOR CONSIDERATION ABOUT OUR PORTFOLIO IN TERMS OF THERAPEUTIC AREAS, THE TYPE OF CELL PLATFORM WE'RE USING, THE BALANCE, NOT TO GET ANSWERS TODAY, BUT JUST TO GO THROUGH SOME OF THE ISSUES THAT WE NEED TO FACE AS WE GET INTO OUR FOCUS AND DELIVER PHASE OF THIS AGENCY.

SO FIRST OF ALL, I WANT TO ACKNOWLEDGE DR. RAHUL THAKAR WHO PUT TOGETHER A TREMENDOUS AMOUNT OF WORK TO GATHER THE DATA FOR US AND ALSO, OF COURSE, TO OUR SCIENCE OFFICERS VERY ABLY LED BY DR. BETTINA STEPHEN FOR THE DEVELOPMENT TEAM, DR. PAT OLSON FOR THE EARLY TRANSLATION TEAM. SO THIS REPRESENTS A TREMENDOUS AMOUNT OF WORK FROM MANY PEOPLE.

REMINDING YOU ABOUT WHERE WE'RE TRYING TO GO, WE'RE TRYING TO ADVANCE THE SCIENCE TO DEVELOP TREATMENTS FOR PATIENTS. THESE ARE CURES, TREATMENTS. WE'RE TRYING TO TRANSFORM MEDICINE. THE FIRST FIVE YEARS OF CIRM, CULTIVATING THE FIELD, INTELLECTUAL CAPITAL. YOU HEARD FROM RICK KELLER EARLIER TODAY ABOUT THE PHYSICAL INFRASTRUCTURE WE PUT INTO PLACE. AND THE SEED FUNDING THAT WAS PUT INTO PLACE AS WELL.

WE'RE NOW IN WHAT WE CALL THE FOCUS PHASE WHERE WE'RE TRYING TO PRIORITIZE OUR PROJECTS, OUR INVESTMENTS TO DRIVE THE SCIENCE INTO CLINICAL TRIALS FOR PATIENTS SO THAT WE CAN DETERMINE WHETHER OR NOT WE'RE GETTING THAT PRELIMINARY EVIDENCE OF THERAPEUTIC BENEFIT. FRANKLY, YOU'RE GIVING A SUPPLEMENT NOW TO ONE OF OUR FRONT RUNNING DISEASE TEAMS THAT IS GOING TO ENABLE US TO ACCELERATE OUR ABILITY TO GET THERE.

THIS IS ALSO AN IMPORTANT TIME ABOUT DEVELOPING PARTNERSHIPS WITH DIFFERENT DISCIPLINES, WITH PATIENTS, WITH INDUSTRY SO THAT WE CAN ACTUALLY MOVE FORWARD IN 2016 TO FACILITATE THE COMMERCIALIZATION OF THERAPIES, TO ADVANCE THOSE THERAPIES TO PATIENTS, AND TO ENABLE A BUSINESS MODEL FOR STEM CELL-BASED THERAPIES.

TO DATE WE HAVE OVER 560 RESEARCH AND FACILITY AWARDS TO OVER 60 INSTITUTES AND COMPANIES, 12 NEW INSTITUTES AND CENTERS OF REGENERATIVE MEDICINE, OVER 1200 MAJOR SCIENTIFIC PAPERS, WE BROUGHT OVER 130 NEW MAJOR STEM CELL RESEARCHERS IN CALIFORNIA, AND I THINK YOU HEARD TODAY WE'RE BRINGING MORE. WE'RE BRINGING COMPANIES TO CALIFORNIA AND JOBS.

OF THOSE 560 AWARDS, 77 OF THEM ARE TRANSLATIONAL DEVELOPMENT PROGRAMS THAT ARE WORKING ON MOVING THE SCIENCE TOWARDS PATIENTS. OF THOSE 77, 50 ARE EARLY TRANSLATION. THAT'S TO SAY DEVELOPING THAT PRECLINICAL PROOF OF CONCEPT AND IDENTIFYING THAT DEVELOPMENT CANDIDATE. TWENTY-FIVE OF THEM ARE DISEASE TEAMS, THESE ARE TEAMS THAT ARE WORKING TO FILE THAT IND AND ACTUALLY TO CONDUCT A CLINICAL TRIAL, AND TWO STRATEGIC PARTNERSHIPS WHICH ARE REALLY GEARED TOWARDS BRINGING INDUSTRY INTO THE EQUATION. OF THE 1.7 BILLION THAT'S ALREADY BEEN AWARDED, 632 MILLION ARE TOWARDS THESE TRANSLATIONAL PROGRAMS.

IN OUR FOCUS AND DELIVER PHASE, SOME OF THE NEW THINGS THAT WE'RE PUTTING TOGETHER THAT I WANTED TO TELL YOU ABOUT, AND YOU HEARD A FEW OF THEM EARLIER TODAY, WE'RE CREATING A SCIENTIFIC

ADVISORY BOARD TO PROVIDE ADVICE ON CRITICAL AND MAJOR STRATEGIC ISSUES TO ACCELERATE THE IMPACT AND DELIVERY OF CIRM'S MISSION. WE ARE REALLY THINKING OF THIS IN AN URGENT WAY. WHETHER IT'S TWO MEETINGS, FOUR MEETINGS, OR EIGHT MEETINGS, WE'RE GOING TO HAVE THESE ADVISORS COME TO HELP US IN TERMS OF THE FOCUS ON OTHER STRATEGIES, WHETHER OR NOT WE'VE GOT THE RIGHT PARTNERSHIPS ALIGNED WITH THE FUTURE DELIVERY OF THE CLINICAL OUTCOMES, AND IDENTIFY NEW OPPORTUNITIES, NEW FUNDING AREAS, AND MAKING SURE THAT WE HAVE THE RIGHT INTERNATIONAL CONNECTIONS TO AMPLIFY CIRM'S PROGRESS HERE IN CALIFORNIA.

WE THINK THAT COMMUNICATION IS VITALLY IMPORTANT. WE'RE PUTTING TOGETHER NEW PUBLIC ABSTRACTS FROM THE ANNUAL PROGRESS REPORTS TO BETTER INFORM THE PUBLIC ABOUT CIRM'S RESEARCH. WE PLAN TO DO THIS IN EASY OR EASIER TO UNDERSTAND LANGUAGE WITHOUT SO MUCH TECHNICAL JARGON ABOUT THE ACCOMPLISHMENTS THAT ARE BEING MADE ON THESE PROJECTS, HOW THE ACCOMPLISHMENTS RELATE TO THE GOALS OF THE PROJECT, CONCISE AND CLEAR SUMMARY OF HOW THE RESEARCH CONTRIBUTES TO ADVANCING STEM CELL RESEARCH, AND WHY THIS IS IMPORTANT.

IN ADDITION, WE'RE GOING TO EMPHASIZE

OUTCOMES REPORTING. THIS WILL BE BRINGING BACK TO YOU NEW RESEARCH AREAS OF FOCUS, NEW COLLABORATIONS, NEW FUNDING, NEW COMPANIES THAT HAVE BEEN FORMED OR ALLIANCES FORGED, REGULATORY FILINGS, CLINICAL TRIALS, INVENTION DISCLOSURES, PATENT APPLICATIONS, LICENSING ACTIVITIES, AND HOW AND TO WHAT USE ARE THE BIOLOGIC REAGENTS, TECHNIQUES, TOOLS AND TECHNOLOGIES THAT WE'RE FUNDING ARE GETTING USED, AND ALSO TELL YOU ABOUT JOB CREATION. WE'VE GOT A LOT OF TRAINING PROGRAMS WITH CIRM SCHOLARS WITH A VARIETY OF OUR DIFFERENT PROGRAMS. WE'RE GOING TO LET YOU KNOW WHAT HAPPENS TO THESE INDIVIDUALS.

THIS IS A CUMULATIVE LOOK AT OUR FUNDING BETWEEN 2009 AND 2012. YOU ALREADY KNOW ABOUT WHERE THE FUNDING WENT IN THE FIRST FEW YEARS OF CIRM. IT WAS THE INTELLECTUAL CAPITAL, IT WAS THE PHYSICAL INFRASTRUCTURE, IT WAS THE BASIC SCIENCE, IT WAS THE SEED FUNDING. IT WASN'T UNTIL 2009, REALLY JUST ABOUT FOUR YEARS AGO, THAT WE EVEN STARTED FUNDING THE EARLY TRANSLATIONAL PROGRAMS. IT WASN'T UNTIL 2010 THAT THE DISEASE TEAMS EVEN GOT STARTED, AND IT WASN'T TILL 2012 UNTIL WE HAD OUR SECOND COHORT OF DISEASE TEAMS.

SO WE CURRENTLY HAVE 77 PROGRAMS FUNDED TO THE TUNE OF 632 MILLION. OF THOSE 77 PROGRAMS RIGHT

NOW, SOME OF THEM HAVE CLOSED, SOME OF THEM HAVE NOT YET STARTED. SO ACTUALLY WE HAVE 70 ACTIVE CIRM TRANSLATIONAL PROJECTS. OF THOSE, THE DOLLARS THAT HAVE BEEN SPENT ON -- THAT ARE BEING SPENT ON THIS PART OF THE PORTFOLIO IS 552 MILLION.

FOR THE EARLY TRANSLATION PART OF THE PORTFOLIO, WE HAVE A TOTAL OF 52 EARLY TRANSLATION AWARDS, WHICH INCLUDE TWO CONVERSIONS FROM THE DISEASE TEAM. ONE OF THE THINGS THAT YOU GAVE US AS AN OPTION WAS THAT IF THE DISEASE TEAMS, THEY'RE MAKING PROGRESS, BUT THEY'RE NOT REALLY GOING TO BE ON TRACK FOR THEIR IND, WE HAVE THE OPPORTUNITY TO MOVE THEM TO AN EARLIER PHASE OF THE RESEARCH PROJECT, AND WE HAVE DONE THAT IN TWO INSTANCES.

WE'VE ALSO HAD CLOSURE OF SOME OF THE EARLY DISEASE TEAMS SO THAT RIGHT NOW WE HAVE A TOTAL OF 47 EARLY TRANSLATIONAL PROJECTS. TWO OF THOSE EARLY TRANSLATIONAL PROJECTS THAT ARE WORKING ON DEVELOPMENT CANDIDATES HAVE ADVANCED IN THE PIPELINE TO DISEASE TEAMS. SO IT GOES BOTH WAYS. SOME OF THE DISEASE TEAMS, THEY NEED TO GO BACK EARLIER. SOME OF THE EARLY ARE TO ADVANCE TO DISEASE TEAM.

THIS IS A BIG PICTURE UPDATE OF THE DISEASE TEAM I STATUS. REMEMBER, THESE ARE THE 14

TEAMS THAT WERE FUNDED IN 2010. OF ALL THOSE 14 DISEASE TEAMS, TWO ARE ACTUALLY NOW READY TO GO INTO A CLINICAL TRIAL. THE FIRST IS BY DR. MARBAN. AN IND WAS APPROVED IN JUNE OF LAST YEAR. HIS TRIAL HAS ALREADY STARTED WITH SOME FUNDING BY NIH. HE SUCCESSFULLY COMPETED THROUGH THE COMPANY CAPRICOR FOR THE CLINICAL TRIAL THROUGH A DISEASE TEAM II.

THE SECOND CLINICAL TRIAL THAT'S STARTING IS FROM THE COMPANY CALIMMUNE. WHAT WE DID WITH THAT AWARD IS REALLY GET A TWOFER. THE CHEN COMPONENT IS CONTINUING TO WORK ON EARLY COMPONENTS OF SOME OF THE TOOLS THAT ARE NEEDED TO TRANSLATE THE INTERESTING SCIENCE INTO WHAT CAN BE USED FOR HIV DISEASE. THE OTHER COMPONENT OF THE DISEASE TEAM, WHICH WAS CO-PI'D BY CALIMMUNE, ACTUALLY WERE ABLE TO FILE THEIR IND, GET IT APPROVED, AND ARE MOVING FORWARD WITH A CLINICAL TRIAL IN HIV DISEASE.

THE OTHER ONES, AS YOU CAN SEE, ONE WAS TERMINATED.

CHAIRMAN THOMAS: DR. FEIGAL, WHEN IS, JUST FOR THE BOARD'S SAKE, THAT TRIAL SET TO BEGIN?

DR. FEIGAL: I'M GOING TO SHOW YOU A SUMMARY SLIDE, BUT ALL THE CLINICAL TRIALS I'M GOING TO TELL ABOUT ARE GOING TO START IN 2013. THERE WILL BE THREE CLINICAL TRIALS STARTING IN 2013.

CHAIRMAN THOMAS: THANK YOU.

DR. FEIGAL: THE BERGER TEAM, AS YOU ALREADY KNOW, WAS TERMINATED DUE TO INABILITY TO MEET -- THEY HAD NO-GO MILESTONES. THEY WEREN'T ABLE TO GET THE DATA. THEY DID THE RESEARCH, THE DATA DIDN'T COOPERATE; AND SO AS WE ARE ABLE, WE TERMINATED THAT AWARD BECAUSE THEY DIDN'T MEET THAT NO-GO MILESTONE.

IN ADDITION, THERE'S ANOTHER AWARD FROM GOLDSTEIN ON ALS WHERE THEY'RE MAKING PROGRESS, THEY'RE DOING GOOD RESEARCH, BUT THEY'RE REALLY AT AN EARLIER STAGE OF DISEASE. SO WE REFINED THE SCOPE AND THE BUDGET OF THAT PROJECT AND CONVERTED THEM TO AN EARLY TRANSLATION AWARD.

LET ME TELL YOU ABOUT THE OUTCOMES OF THE CONTINUING DISEASE TEAMS THEN. MARBAN, AS I SAID, NOW HAS A FILED, APPROVED IND THROUGH THE COMPANY CAPRICOR. THEY ATTRACTED OUTSIDE DOLLARS TO CONDUCT THE PHASE I OF THE PHASE I-II CLINICAL TRIAL OF ALLOGENEIC CARDIOSPHERE CELL THERAPY. THEY'RE CURRENTLY ENROLLING PATIENTS ON THE PHASE I THIS YEAR. THEY SECURED CIRM FUNDING THROUGH A DISEASE TEAM II AWARD. THE PI ON THAT AWARD IS DR. SMITH. THEY'RE LEVERAGING THEIR FUNDING WITH US TO CONDUCT THE PHASE II COMPONENT IN PATIENTS WITH RECENT HEART

ATTACK WHO HAVE HEART FAILURE. WE'RE EVEN UP ON CLINICAL.GOV. THAT'S THE CLINICALTRIALS.GOV IDENTIFIER FOR THE TRIAL.

THE NEXT ONE IS DR. SYMMONDS. HE WAS THE CO-PI ON THE CHEN AWARD. WE GAVE HIM, THE REMAINING FUNDS FROM THAT DISEASE TEAM I AWARD, SO IT DIDN'T REQUIRE ADDITIONAL DOLLARS, A DISEASE TEAM WITH THEIR OWN NUMBER NOW WHERE WE HAD THE CLINICAL DEVELOPMENT ADVISORY PANEL REVIEW THEIR PROTOCOL AND THE BACKGROUND DATA TO LEVERAGE DISEASE TEAM I FUNDING OF THE COMPANY CALIMMUNE TO ENTER A FIRST-IN-HUMAN CLINICAL TRIAL WITH THEIR AUTOLOGOUS CELL THERAPY THAT ATTACKS HIV ENTRY. IT'S THROUGH THE CCR5 AND THROUGH A C 46 FUSION. THEY ARE ALREADY WORKING ON THEIR IRB APPROVALS, THEIR SITE INITIATIONS ARE IN PROGRESS IN CALIFORNIA, AND THEY PLAN TO ENROLL PATIENTS AT CALIFORNIA SITES THIS YEAR. THEY HAVE ALSO SHARED THE TRIAL DESIGN AND WILL SHARE DATA WHEN IT BECOMES AVAILABLE FROM A SECOND PLANNED, FUTURE EX-U.S. TRIAL WITH THE SAME PRODUCT IN A DIFFERENT SUBGROUP OF HIV PATIENTS. WE THINK THIS WILL BE EXTREMELY HELPFUL US AND COMPLEMENT THE TYPE OF WORK THAT WE'RE DOING HERE IN THE STATES BY THEIR ABILITY AND WILLINGNESS TO SHARE THAT DATA THAT THEY'LL DO WITH AN EX-U.S. TRIAL.

ONCE AGAIN, THIS IS UP ON WWW.CLINICALTRIALS.GOV, AND THIS IS THE CLINICALTRIALS.GOV IDENTIFIER FOR THAT FIRST-IN-HUMAN CLINICAL TRIAL.

DR. ZAIA CONTINUES WITH HIS LEAD CANDIDATE AT CITY OF HOPE WITH AN AUTOLOGOUS STEM CELL THERAPY. HE'S ACHIEVED PRECLINICAL PROOF OF CONCEPT. HE'S LOOKING AT A NEW APPLICATION OF A TECHNOLOGY TO ENHANCE TRANSDUCTION AND SAFETY OF THAT PRODUCT TO ATTACK HIV ENTRY. HE'S USING A DIFFERENT MECHANISTIC APPROACH THAN THE SYMMONDS TEAM, AND HE'S PLANNING FOR FIRST-IN-HUMAN TRIALS FOR HIV PATIENTS.

DR. SLAMON, WORKING AT UCLA, AND HIS TEAM, THEY ALSO HAVE A CANADIAN PARTNER, HAVE COMPLETED THE IND-ENABLING STUDIES FOR THEIR FIRST CANDIDATE MOLECULE. THEY HAVE IDENTIFIED THE LEAD CANDIDATE IN A SECOND PROGRAM AND ARE CONDUCTING THE IND-ENABLING STUDIES. THEY'RE PLANNING A FIRST-IN-HUMAN FOR PATIENTS WITH SOLID CANCERS.

DR. ABOODY IS AT CITY OF HOPE. SHE'S WORKING ON NEURAL STEM CELL-BASED TREATMENTS THAT ACTUALLY WILL HOME TO A VERY HARD TO TREAT TUMOR, BRAIN CANCER, AND IT'S DELIVERING AN ENZYME THAT WILL HOPEFULLY ENHANCE CHEMOTHERAPY DELIVERY TO THE

SPECIFIC AREA OF THE CANCER IN THE BRAIN. THEY'VE ALSO BEEN AWARDED NIH/NINDS FUNDS TO DO THEIR WORK. THEY'VE ALSO ACHIEVED PRECLINICAL PROOF OF PRINCIPLE. THEY'VE HELD THEIR PRE-IND MEETING WITH THE FDA. THEY'VE DEVELOPED AN IN VIVO IRON-BASED CELL LABELING PROTOCOL, AND THREE PATIENTS HAVE ALREADY RECEIVED IT. IT'S VERY IMPORTANT. THEY'RE ACTUALLY TRYING TO ADVANCE THE FIELD BY IDENTIFYING HOW TO TRACK THESE CELLS ONCE YOU INJECT THEM INTO THE BRAIN. SO THIS IS VERY IMPORTANT TECHNOLOGY.

IN ADDITION, SHE'S FOUNDED A COMPANY, THERABIOLOGICS. SHE'S IN THE MIDST OF PLANNING HER CLINICAL TRIAL FOR PATIENTS WITH BRAIN CANCER.

CHAIRMAN THOMAS: DR. FEIGAL, I BELIEVE I HEARD, I THINK THE BOARD WOULD BE INTERESTED, THAT ONE OF THE PARTIES INVOLVED IN DEVELOPING THE TRACKING TECHNOLOGY IS A BRIDGES STUDENT, IF I'M NOT MISTAKEN. HAD YOU HEARD THAT? I THINK -- VERY PROUD OF THAT. THAT'S ADDITIONAL VINDICATION OF OUR OBVIOUSLY OUTSTANDING BRIDGES PROGRAM.

DR. FEIGAL: THANK YOU FOR BRINGING THAT UP.

DR. WEISSMAN AT STANFORD IS WORKING ON A NOVEL THERAPEUTIC CANDIDATE WHICH IS AN INHIBITOR TO A MARKER CALLED CD 47, WHICH IS WHAT HE

CHARACTERIZES AS A DON'T EAT ME SIGNAL. SO BASICALLY HE'S GETTING AN INHIBITOR TO THIS MARKER SO THAT THE CELLS CAN BE EATEN BY THE HOST IMMUNE RESPONSE. HE'S ACHIEVED PRECLINICAL PROOF OF PRINCIPLE. HE'S DONE HIS PILOT TOXICOLOGY AND PHARMACOLOGY. HE'S SUBMITTED ONE PATENT FILING. HE'S HELD HIS -- HE HAS A PRE-IND MEETING WITH THE FDA THAT'S SCHEDULED. HE HAS COLLABORATIVE FUNDING PARTNER DOLLARS FUNDING WITH THE UK, AND HE IS PLANNING HIS FIRST-IN-HUMAN CLINICAL TRIALS FOR PATIENTS WITH LEUKEMIA AND OTHER CANCERS.

CHAIRMAN THOMAS: MY UNDERSTANDING, AGAIN FOR THE BOARD'S KNOWLEDGE, I BELIEVE THAT THE CD 47 HAS BEEN IDENTIFIED ON AT LEAST SEVEN DIFFERENT TYPES OF CANCER STEM CELLS AND THAT THE APPLICATION OF THIS, WERE IT TO PAN OUT, WOULD BE VERY PROFOUND ACROSS A WIDE RANGE OF SOLID TUMOR CANCERS AND INDEED SOME BLOOD CANCERS AS WELL; IS THAT CORRECT?

DR. FEIGAL: YES. SO WHAT I MENTIONED IN THE LAST SENTENCE OF THE SLIDE IS THAT HE IS PLANNING NOT JUST FOR LEUKEMIA, BUT FOR OTHER CANCERS AS WELL.

DR. CARSON HAS ALSO IDENTIFIED A LEAD CANDIDATE, AN INHIBITOR TO ROR 1 ON CANCER STEM CELL. HE TOO HAS ACHIEVED PRECLINICAL PROOF OF

PRINCIPLE. HE'S PERFORMING PILOT PHARMACOLOGY AND TOXICOLOGY STUDIES. THEY'VE ALREADY SELECTED THEIR MANUFACTURER FOR THE PRODUCT. HE TOO HAS LEVERAGED FUNDING WITH CANADA, AND HE IS PLANNING HIS FIRST-IN-HUMAN CLINICAL TRIALS FOR PATIENTS WITH LEUKEMIA.

DR. KOHN IS WORKING ON AN AUTOLOGOUS CELL THERAPY APPROACH TO REENGINEER THE PRODUCTION OF NORMAL RED BLOOD CELLS FOR PATIENTS WHO HAVE SICKLE CELL DISEASE. HE'S ACHIEVED PRECLINICAL PROOF OF PRINCIPLE. HE'S COMPLETED HIS PRE-IND MEETING WITH THE FDA. HE'S HAD A PROTOCOL THAT'S BEEN CLEARED FROM THE RECOMBINANT ADVISORY COMMITTEE. HE'S ALREADY ESTABLISHED -- HE HAS ESTABLISHED CLINICAL SCALE MANUFACTURING PROCESS. HE'S IN THE PROCESS OF DOING HIS TOXICOLOGY STUDIES, AND HE'S FILED AN INVENTION DISCLOSURE.

DR. LANE IS WORKING ON A VERY RARE GENETIC DISORDER THAT REALLY ATTACKS THE EPITHELIUM, THE LAYER OF THE SKIN. IT'S A HIGHLY MORBID DISEASE, CAUSES A LOT OF PAIN AND SUFFERING, PARTICULARLY IN CHILDREN AND ADOLESCENTS, AND CAN BE CAUSE OF DEATH. HE'S ACTUALLY ACHIEVED PRECLINICAL PROOF OF PRINCIPLE. HE'S USING AN ADVANCED TECHNOLOGY, AND HIS TEAM HAS GENERATED PATIENT-DERIVED GENE

CORRECTED LINES. THE DEFECT IN THIS DISEASE IS THAT THERE'S A DEFICIT IN COLLAGEN FACTOR 7, AND HE'S LOOKING TO REPLACE THAT DEFICIENT PROTEIN IN THESE PATIENTS.

HE IS USING AN IPS INDUCED PLURIPOTENT STEM CELL TECHNOLOGY. THIS IS THE ONLY IPS CELL THERAPY WE HAVE IN OUR DEVELOPMENT PORTFOLIO. SO HE'S REALLY A PIONEER IN TRYING TO MOVE AN IPS TECHNOLOGY THROUGH THE REGULATORY PATHWAY. SO WE'RE GOING TO LEARN A LOT FROM THIS PROJECT THAT CAN HOPEFULLY BE THOUGHT ABOUT AS WE TRY AND MOVE SOME OF THESE OTHER TYPES OF PLATFORMS FORWARD.

DR. HUMAYUN YOU JUST HEARD BRIEFLY ABOUT. HE'S ACHIEVED PRECLINICAL PROOF OF PRINCIPLE. HE'S SUBMITTED SEVEN PATENT FILINGS. HE'S COMPLETED HIS PRE-IND MEETING. HE'S CREATED A COMPANY CALLED REGENERATIVE PATCH TECHNOLOGIES FOR DEVELOPMENT OF THIS PRODUCT IN PATIENTS WITH AGE-RELATED MACULAR DEGENERATION. HE HAS COLLABORATIVE FUNDING PARTNER FUNDING WITH THE UNITED KINGDOM.

DR. ROBINS IS WORKING ON A VERY MAJOR ILLNESS IN THIS COUNTRY, DIABETES. HE'S ACHIEVED PRECLINICAL PROOF OF PRINCIPLE. HE'S FILED TWO INVENTION DISCLOSURES. HE'S DONE PROCESS SCALE-UP AND MANUFACTURING FOR THE CELLS, THE DEVICES, AND

THE COMBINATION PRODUCT. THIS PRODUCT IS ACTUALLY A PROGENITOR TO PRODUCING INSULIN. IT'S IN AN IMMUNE ISOLATION DEVICE SO THAT THE INSULIN CAN GET OUT, BUT THE CELLS DON'T. THE HOST IMMUNE RESPONSE WILL NOT BE ABLE TO ATTACK IT. SO THAT'S MOVING FORWARD. AND HE'S COMPLETED HIS PRE-IND MEETING. HE'S INITIATED HIS IND-ENABLING SAFETY AND TOXICOLOGY STUDIES, AND HE HAS COLLABORATIVE FUNDING PARTNER DOLLARS WITH THE JUVENILE DIABETES RESEARCH FOUNDATION.

DR. STEINBERG AT STANFORD HAS ACHIEVED PRECLINICAL PROOF OF PRINCIPLE. HE HAS ALREADY STARTED A COLLABORATIVE PARTNERSHIP WITH A GERMAN TEAM. HE'S HELD HIS PRE-IND MEETING WITH THE FDA, AND HE'S WORKING ON A CELL-BASED THERAPY FOR PATIENTS WITH STROKE.

SO OF ALL THESE 11 PROJECTS, THE POINT IS THEY ARE MAKING SIGNIFICANT PROGRESS IN A RATHER SHORT AMOUNT OF TIME. SO IT'S VERY AMBITIOUS GOALS, BUT THEY ALL HAVE MILESTONES THAT THEY'RE ON TRACK WITH. WE'RE MEETING WITH THEM. THEY HAVE EXTERNAL ADVISORS. THEY HAVE GOT LEVERAGED FUNDING, AND MANY OF THEM ARE WORKING WITH COLLABORATIVE FUNDING PARTNERS.

A BRIEF VIGNETTE ABOUT DISEASE TEAM II AND

STRATEGIC PARTNERSHIP I. THIS ICOC ACTUALLY AWARDED 12 AWARDS BACK IN JULY AND SEPTEMBER OF THIS YEAR TO 12 TEAMS. LET ME TELL YOU THE STATUS. WE'VE GOT ABOUT 13 DIFFERENT DISEASE AREAS FOR THESE 12 DISEASE TEAM II'S AND TWO STRATEGIC PARTNERSHIPS.

FOR THE DISEASE TEAM II, SIX OF THESE ARE ALREADY STARTING. THEY'VE ALREADY EXECUTED THEIR AWARD AGREEMENTS AND THEY'RE MOVING FORWARD WITH THEIR RESEARCH. THREE OF THESE ARE STILL WORKING THROUGH THE FINAL DISCUSSIONS ABOUT THEIR MILESTONES AND THEIR BUDGET. THEY'RE IN WHAT WE CALL PREFUNDING ADMINISTRATIVE REVIEW. ONE OF THEM WORKING ON ALZHEIMER'S DISEASE IS STILL PENDING AND IS IN CONFIDENTIAL DISCUSSION REGARDING THE CONDITION IN TERMS OF A LOAN AWARD.

ONE OF THE DISEASE TEAM II'S WAS ACTUALLY RECOMMENDED AT THE TIME OF THE ICOC TO BE CONVERTED TO AN EARLY TRANSLATION AWARD. SO THAT HAS BEEN DONE. ONE OF THE AWARDS, ACTUALLY THE APPLICANT ELECTED NOT TO BORROW THESE FUNDS FROM CIRM. SO THAT WILL NOT BE ON OUR LIST OF CONTINUED PROGRAMS WITHIN CIRM.

FOR THE TWO STRATEGIC PARTNERS, WE HAVE ONE THAT'S IN THEIR PREFUNDING ADMINISTRATIVE REVIEW WORKING ON BETA THALASSEMIA. AND THIS IS GOING TO

START CLINICAL TRIALS ALSO SOMETIME LATER THIS YEAR. AND ON THE SLIDE YOU SEE THE CLINICALTRIALS.GOV IDENTIFIER.

AND THEN THE LAST STRATEGIC PARTNER I, WE'RE STILL IN DISCUSSIONS WITH THEM. THEY'RE STILL IN SEVERAL DISCUSSIONS WITH POTENTIAL PARTNERS.

SO THE KEY HIGHLIGHTS OF THE DISEASE TEAMS AND THE STRATEGIC PARTNERSHIPS ARE THAT OVER HALF OF THE FIRST COHORT OF DISEASE TEAMS HAVE SUCCESSFULLY ADVANCED THROUGH THEIR PRE-IND MEETING WITH THE FDA TOWARDS AN APPROVABLE IND. WE HAVE THREE CIRM-FUNDED CLINICAL TRIALS THIS YEAR. TWO AROSE FROM DT I'S, ONE FROM STRATEGIC PARTNERSHIP AWARD. THE THREE TRIALS ARE IN PATIENTS WITH RECENT HEART ATTACK AND EVIDENCE OF SOME CONGESTIVE HEART FAILURE. A SECOND TRIAL IS IN HIV DISEASE, AND A THIRD TRIAL IS IN BETA THALASSEMIA, A BLOOD DISORDER.

WE ANTICIPATE FIVE CLINICAL TRIALS BY THE END OF NEXT YEAR. FIVE OF THE DT I'S HAVE COLLABORATIVE FUNDING PARTNERS. ONE HAS A COLLABORATION WITH A DISEASE FOUNDATION. TWO HAVE COMPANIES AS THE PI OR THE CO-PI, AND TWO HAVE FOUNDED COMPANIES. TWO OF THE DISEASE TEAMS II'S HAVE COLLABORATIVE FUNDING PARTNERS WITH NIH AND

WITH ANDALUCIA. TWO HAVE COMPANIES AS THE PI, EIGHT ARE AIMING FOR COMPLETION OF A CLINICAL TRIAL, AND TWO ARE AIMING FOR FILING OF AN APPROVABLE IND.

ALSO IN OUR STRATEGIC PLAN WE HAVE AN UPCOMING DISEASE TEAM III WHERE WE'RE GOING THROUGH RECENT LETTERS OF INTENT, AND THAT WILL BE REVIEWED LATER THIS YEAR, AND WE'LL BE COMING BACK TO YOU WITH RECOMMENDATIONS FROM THAT REVIEW. AND THEN WE HAVE A REVIEW THAT'S GOING TO TAKE PLACE NEXT MONTH FOR STRATEGIC PARTNERSHIP II.

SO ONCE AGAIN, WE'RE GOING TO HAVE THE ABILITY TO TRANSITION THOSE TEAMS THAT ARE MAKING PROGRESS INTO THE NEXT PHASE OF CIRM FUNDING, IN ADDITION TO BEING ABLE TO BRING IN EXOGENOUS RESEARCH INTO OUR PIPELINE.

I JUST WANT TO GIVE YOU THREE QUICK EXAMPLES AS SORT OF AN EXAMPLE OF THE SPECTRUM OF THE DEPTH AND SCOPE OF WHAT WE DO HERE AT CIRM. AND THEN AFTER THESE EXAMPLES, I'M GOING TO HAVE DR. OLSON TALK ABOUT SOME OF THE BIG PORTFOLIO ISSUES AND SOME OF THE QUESTIONS WE'RE GRAPPLING WITH.

THIS IS IN THE AREA OF EYE DISORDERS. IF YOU REMEMBER, I SAID WE HAVE 542 MILLION FOR THE 70 ACTIVE PROGRAMS. WE HAVE FOUR ACTIVE AWARDS IN DISEASES OF THE EYE TO THE TUNE OF $40.8 MILLION.

THE DISEASES THAT WE'RE WORKING ON ARE AGE-RELATED MACULAR DEGENERATION, CORNEAL INJURY, AND RETINITIS PIGMENTOSA. SO ALL OF THESE OBVIOUSLY CAUSE SEVERE VISION LOSS. AND THIS IS SHOWING YOU THE DIFFERENT AMOUNTS OF MONEY THAT WE'RE SPENDING ON THESE DIFFERENT AREAS.

WHAT THIS SLIDE IS TRYING TO SHOW YOU IS THE SLICE OF THE PIE THAT WE'RE WORKING ON FOR EYE DISEASE. AND THEN WHAT WE'RE SHOWING YOU IS WHERE IT FITS ON THE SPECTRUM OF WHAT CIRM FUNDS. SO YOU CAN SEE THE SPECTRUM OF WHAT WE'RE FUNDING IN AGE-RELATED MACULAR DEGENERATION, IN CORNEAL INJURY, AND IN RETINITIS PIGMENTOSA. AND THE SORT OF FADED AWAY RECTANGLE IS SHOWING THE ADVANCEMENT OF THAT PARTICULAR PROJECT INTO A DISEASE TEAM AWARD.

THIS IS SHOWING YOU SOME OF THE DETAILS ABOUT THE PI, THE INSTITUTION WHERE THEY'RE WORKING, THE GOAL OF THAT PROJECT, THE DISEASE OR INJURY THAT THEY'RE WORKING ON, AND THE APPROACH. SO YOU CAN SEE THAT WE'RE WORKING ON ALLOGENEIC APPROACHES, ON AUTOLOGOUS APPROACHES, AND THEN ON SOME EX VIVO EXPANSION OF SOME CORNEAL EPITHELIAL PROGENITOR CELLS.

THE OTHER EXAMPLE I WANTED TO POINT OUT TO YOU IS CARDIOVASCULAR DISORDERS. HERE WE HAVE EIGHT

ACTIVE AWARDS TO THE TUNE OF 61.7 MILLION. THIS IS SHOWING YOU, WE TRIED TO DO IT WITH A CREATIVE COLOR SCHEME, OF ALL THE SHADES OF BLUE ARE THE DIFFERENT TYPES OF CELL THERAPY THAT WE'RE WORKING ON. THE PURPLISH PINK ARE THOSE CELL THERAPIES THAT ARE ON A SCAFFOLD. THE GREEN ARE THOSE CELL THERAPIES THAT ARE GENETICALLY MODIFIED. THE PURPLE ARE THOSE THERAPIES WHERE WE'RE WORKING ON SMALL MOLECULE DISCOVERY USING DISEASE IN A DISH. THAT'S WHAT THE D.I.D. STANDS FOR, DISEASE IN A DISH. AND THEN THE RUST COLORED SLICE IS FOR GENE TRANSFER FOR DIRECT REPROGRAMMING OF CELLS.

ONCE AGAIN, THIS IS SHOWING THE SLICE OF THE PIE. IT'S SHOWING YOU WHERE IT FITS ON THE SPECTRUM OF WHAT WE FUND. IN CARDIOVASCULAR AND A RARE GENETIC DISORDER CALLED DANON'S DISEASE, WHICH AFFECTS THE HEART MUSCLE AS WELL AS SKELETAL MUSCLE, WHERE WE ARE WITH END STAGE HEART FAILURE, AND ALSO HEART DYSFUNCTION AFTER A HEART ATTACK FOR THOSE WHO HAVE RESIDUAL HEART FAILURE. SO I DON'T THINK WE HAVE TIME TO GO OVER ALL OF THESE, BUT THIS IS JUST TO GIVE YOU EXAMPLES OF THE DEPTH OF WHAT WE'RE WORKING ON AND WHERE IT FITS ON THE MATURATION OF THE DIFFERENT PROJECTS.

AND THIS IS JUST GIVING YOU MORE DETAIL

ABOUT THE PROJECTS THAT YOU CAN GO OVER AT YOUR LEISURE. YOU HAVE ALL OF THESE SLIDES.

NEURODEGENERATION IS THE LAST EXAMPLE AND IS REALLY OUR BIGGEST SLICE OF THE PIE, AND THAT'S NEURODEGENERATION. HERE WE'RE SPENDING ABOUT 93 MILLION OF THE 540 MILLION THAT'S BEEN ALLOTTED TO TRANSLATIONAL PROGRAMS. AND ONCE AGAIN, THIS IS JUST SHOWING YOU THE PROPORTION THAT ARE IN CELL THERAPY, IN GENETICALLY MODIFIED CELL THERAPY, AND THOSE THAT ARE WORKING ON EITHER THE ENDOGENOUS STEM CELL OR WITH DISEASE IN A DISH TECHNOLOGY TO TRY AND DISCOVER SMALL MOLECULES THAT MIGHT BE ABLE TO TREAT DIFFERENT DISEASES.

THIS, ONCE AGAIN, IS SHOWING YOU THE SLICE OF THE PIE. IT'S A LITTLE BIT BIGGER SLICE THAN THE OTHER TWO, SHOWING YOU WHERE IT FITS ALONG THE TRAJECTORY OF MOVING FROM BASIC TO CLINICAL TRIALS IN ALS, IN ALZHEIMER'S DISEASE, IN MULTIPLE SCLEROSIS, IN HUNTINGTON'S DISEASE, AND IN PARKINSON'S.

SO WHAT WE CAN DO AT THIS POINT MAYBE IN THE RECOGNITION OF TIME IS TO LET PAT OLSON GO AHEAD AND DESCRIBE SOME OF THE PORTFOLIO ISSUES IF YOU'D LIKE.

CHAIRMAN THOMAS: I JUST HAVE ONE POINT

THAT'S INTERESTING ABOUT ONE OF OUR PI'S THAT I DIDN'T KNOW, I'M SURE ALL SCIENCE STAFF DID, MARK HUMAYUN. I WAS READING AN ARTICLE IN *NEW YORK TIMES* LAST MONTH ON THE FDA APPROVAL OF THE BIONIC EYE, WHICH INVOLVES AN ARTIFICIAL RETINA. AND LO AND BEHOLD, ONE OF THE PARTIES INVOLVED IN THAT WAS OUR OWN DR. HUMAYUN, WHICH IS PRETTY IMPRESSIVE.

DR. FEIGAL: WELL, HE'S A WORLD RECOGNIZED EXPERT IN THIS AREA. SO I THINK IT'S QUITE OPTIMAL AND NO SURPRISE THAT HE MIGHT BE PART OF THESE INNOVATIVE PROJECTS.

IF THERE AREN'T ANY QUESTIONS FOR ME, WHAT I'D LIKE TO DO IS GO AHEAD AND LET DR. OLSON TALK ABOUT THE PORTFOLIO AND SOME OF THE QUESTIONS THAT WE'D JUST LIKE TO RAISE FOR CONSIDERATION.

CHAIRMAN THOMAS: THANK YOU, DR. FEIGAL. THIS IS EXTREMELY INTERESTING AND INFORMATIVE AND GREAT TO HEAR IN GENERAL AND OBVIOUSLY TO HELP US UNDERSTAND HOW FAR THINGS HAVE COME AND ARE GOING. IT'S FANTASTIC. DR. OLSON.

DR. OLSON: THANK YOU. I WOULD JUST LIKE TO POINT OUT THAT I THINK PROBABLY ONE OF THE DOCUMENTS THAT MARIA ALSO PROVIDED TO YOU WAS THE FULL LIST OF THE PORTFOLIO BY DISEASE AREA, AND IT TALKS ABOUT THE APPROACH TOO. SO THE THIRD SLIDE IN

EACH OF THOSE EXAMPLES THAT ELLEN GAVE YOU, YOU CAN TAKE A LOOK AND YOU CAN GET A SENSE FOR DIFFERENT DISEASES OF THE DIFFERENT APPROACHES WE'RE TAKING, WHAT THE END GAMES ARE IN EACH CASE. SO SOME OF THE INFORMATION. SO I THINK IT'S HELPFUL TO TAKE A LOOK AT THAT.

WHAT I'D LIKE TO DO IS, FIRST, JUST REMIND YOU, I THINK IT'S BEEN CLEAR TO YOU, BUT I WANT TO MAKE SURE YOU RECOGNIZE THAT WHEN WE TALK ABOUT THE TRANSLATIONAL PORTFOLIO, WE TALK ABOUT THOSE PROJECTS THAT ARE FUNDED UNDER EARLY TRANSLATIONAL AWARDS, UNDER DISEASE TEAM AWARDS, AND UNDER STRATEGIC PARTNERSHIP AWARDS, OR, AS ELLEN INDICATED, IN SOME CASES CONVERSIONS FROM THE ONE TO THE OTHER. SO I JUST WANT TO MAKE SURE THAT EVERYBODY UNDERSTANDS THAT IS WHAT WE WERE REFERRING TO.

YOU KNOW, I WANT TO POINT OUT THAT WE TALKED ABOUT 70 PROJECTS WHERE THIS BOARD HAS AUTHORIZED ABOUT $550 MILLION WORTH OF FUNDING. IF YOU JUST THINK ABOUT THE AVERAGE TERM OF THESE PROJECTS AS ROUGHLY FIVE YEARS OR THREE YEARS OR SO, SOMEWHERE BETWEEN THREE AND FOUR, WE'RE TALKING ABOUT A RUN RATE OF SPENDING ON THIS TRANSLATIONAL PORTFOLIO OF ABOUT 150 TO $180 MILLION. WE LOOK

LIKE A BIOTECH COMPANY. WE LOOK LIKE A FAIRLY REASONABLE SIZE BIOTECHNOLOGY COMPANY. SO I WANT YOU TO REALIZE THAT THAT IS, IN ESSENCE, WHAT WE HAVE AT THIS POINT. WE HAVE A PORTFOLIO OF 70 TRANSLATIONAL PROJECTS. AND SO I'D LIKE PEOPLE TO JUST RECOGNIZE A COUPLE OF THINGS ABOUT THAT.

IF YOU LOOK AT THIS DIAGRAM RIGHT HERE, IT HIGHLIGHTS THE END GOAL OF EACH OF THESE PROJECTS YOU FUNDED. AND I DO WANT TO POINT OUT THAT 23 OF THESE PROJECTS ARE WHAT I'LL CALL DEVELOPMENT. THEY'RE EITHER IN IND-ENABLING DEVELOPMENT OR THEY'RE IN CLINICAL DEVELOPMENT, BUT THEY COMPRISE 70 PERCENT OF THE COST. THIS IS NO SURPRISE TO ANY OF US. I THINK THAT WE ALL KNOW THAT WHEN YOU MOVE INTO DEVELOPMENT AND WHEN YOU MOVE INTO THE CLINIC, COSTS GO UP, I WON'T SAY EXPONENTIALLY, BUT THEY GO UP SUBSTANTIALLY. AND CIRM IS TRYING TO LEVERAGE THAT IN SOME CASES. WE'VE ASKED FOR CO-FUNDING. WE TRY AND PARTNER PROJECTS. BUT THIS IS SOMETHING THAT WE ALL HAVE TO RECOGNIZE.

SO OF THE PROJECTS THAT ARE IN EARLY TRANSLATION, SO PARTICULARLY THE DC'S, WE HAVE 26 DC'S. THIS IS GREAT. THIS GIVES US IN SOME CASES SOME PROJECTS THAT MAY MOVE FORWARD, IT GIVES US A PIPELINE TO SAY, GEE, WE CAN SELECT FROM THESE. IT

ALSO ALLOWS US, AS ELLEN NOTED, WE GET PROJECTS FROM OUTSIDE. WHEN IT COMES RIGHT DOWN TO IT, HOW MANY -- WE'RE GOING TO HAVE TO ABLE TO PICK THE BEST, THE MOST COMPETITIVE, AND THAT'S SOMETHING WE NEED TO THINK ABOUT. WE WILL NOT BE ABLE TO MOVE EVERYTHING FORWARD. WE WILL NOT EVEN BE ABLE TO MOVE EVERYTHING FORWARD THROUGH CLINICAL DEVELOPMENT POTENTIALLY. BECAUSE IF YOU CONSIDER IND ENABLING ANYWHERE FROM 10 TO 20 MILLION, IF YOU CONSIDER CLINICAL TRIALS ANYWHERE FROM 10 TO 30 MILLION TO GET TO THE END OF STAGE II, SO I THINK THAT'S AN IMPORTANT CONSIDERATION.

DISEASE AREAS, ON THE LEFT YOU SEE WHAT'S IN THE EARLY TRANSLATIONAL PORTFOLIO AND ON THE RIGHT YOU SEE WHAT'S IN THE DEVELOPMENT PORTFOLIO. WE HAVE 16 DISEASE AREAS, SORT OF BROAD DISEASE AREAS, THAT ARE IN THE COMBINED ET AND DEVELOPMENT PORTFOLIO. WE HAVE ROUGHLY, I BELIEVE, TEN IN THE -- SORRY -- 11 ARE ACTUALLY IN THE DEVELOPMENT PORTFOLIO. THIS A LARGE NUMBER OF DISEASE AREAS. AND SO WHEN WE THINK ABOUT THIS, A QUESTION THAT WE ASK IS, AGAIN, THINKING ABOUT THIS VALLEY OF DEATH, THE FACT THAT HOW EASY IS IT GOING TO BE FOR US TO CARRY THEM ON OURSELVES BECAUSE WE MAY NEED TO DO THAT IN SOME CASES OR READY THEM FOR PARTNERING OR

FIND A PARTNER, ONE OF THE THINGS THAT HELPS IN DOING THAT, ONE OF THE THINGS THAT HELPS IN EITHER GIVING US CONFIDENCE THAT WE MIGHT HAVE SOMETHING THAT CAN MOVE FORWARD AND BRING BENEFIT TO PATIENTS, A THING THAT HELPS US THINK ABOUT, WELL, WE SHOULD BE ABLE TO PARTNER THIS MORE EFFECTIVELY, FIND FOLLOW-ON FINANCING, A LOT OF WHAT ELONA IS DOING, IS WHAT DISEASES CAN GIVE US AN ACTIVITY EFFICACY SIGNAL EARLY WITHOUT TESTING IN 500 PATIENTS OR 300 PATIENTS? SO THOSE ARE JUST CONSIDERATIONS. OBVIOUSLY THEY HAVE TO BE WEIGHED INTO ALL THE OTHER CONSIDERATIONS, BUT IT IS A CONSIDERATION.

OUR CELL THERAPY IS A MAJOR THERAPEUTIC APPROACH OF OUR PORTFOLIO. SO IF YOU LOOK AT THIS HERE, YOU CAN SEE OF THAT 552 MILLION IN ACTIVE PROJECTS OR SOON TO BE ACTIVE PROJECTS, SO THE 70 PROJECTS WE'RE TALKING ABOUT, ROUGHLY 75 PERCENT OF IT IS IN CELL THERAPIES. AND IF YOU LOOK AT THE KINDS OF CELL THERAPIES, WE DON'T HAVE JUST SIMPLE CELL THERAPIES. WE HAVE GENETICALLY MODIFIED CELL THERAPIES AND WE HAVE COMBINATIONS PRODUCTS. SO CIRM REALLY IS ON THE EDGE OF INNOVATIVE APPROACHES. THIS IS PERHAPS -- YOU KNOW, YOU THINK ABOUT IT. PROP 71 WAS ALL ABOUT BRINGING STEM CELL THERAPIES FORWARD TO THE BENEFIT OF PATIENTS, STEM CELL

THERAPIES, BECAUSE THIS IS ONE OF THE WAYS WHERE YOU FULLY REALIZE THE BENEFITS OF STEM CELLS. BUT WE DO NEED TO REALIZE THAT THIS IS A HIGHLY INNOVATIVE PORTFOLIO.

IF YOU LOOK AT THE KINDS OF -- IF YOU LOOK AT WITHIN THAT CELL THERAPY CATEGORY, WHAT ARE WE TALKING ABOUT WHEN WE TALK ABOUT AUTOLOGOUS VERSUS ALLOGENEIC? BASICALLY A LOT OF OUR -- THERE ARE ROUGHLY EQUAL NUMBERS OF PROJECTS IN DEVELOPMENT, AT LEAST, THAT ARE PURSUING AUTOLOGOUS STRATEGIES. SO AUTOLOGOUS, REMEMBER, MEANS YOUR OWN CELLS. WE DO SOMETHING TO YOUR OWN CELLS, WHETHER IT'S AN IPS CELL OR WHETHER IT'S A TISSUE OR ADULT STEM CELL, IT'S YOUR CELLS THAT ARE GOING BACK INTO YOU. THAT HAS BENEFITS IN SOME SENSES. THERE'S PRESUMABLY FEWER ISSUES OF IMMUNOGENICITY.

THERE ARE, HOWEVER, QUESTIONS, I THINK, PARTICULARLY WITH RESPECT TO CELL MANUFACTURING. EVERYBODY IS A LOT OF ONE, N EQUAL ONE. SO THE PRODUCTION, THE RELEASE CRITERIA, ALL OF THAT BECOMES AN N EQUALS ONE. THIS MAY BE OKAY IN SOME SITUATIONS, BUT I KNOW THAT THERE ARE ISSUES ASSOCIATED WITH THAT. SO IT'S JUST ONE OF MANY CONSIDERATIONS WHEN YOU THINK ABOUT THAT.

ALLOGENEIC ARGUABLY HAS COMMERCIALIZATION

POTENTIAL, SO-CALLED OFF THE SHELF; THAT IS, YOU NEED THIS THERAPY, YOU CAN GO BUY IT. BUT AGAIN, THE ISSUES THERE ARE THE ISSUES OF IMMUNOGENICITY. SO YOU HAVE TO START ASKING QUESTIONS ABOUT THE DURATION OF THE CELL. HOW LONG IS THIS CELL GOING TO LAST? IS THAT GOING TO BE AN ISSUE IN TERMS FOR IT TO DO ITS ACTION? YOU HAVE TO TALK ABOUT SITE. IS IT GOING TO WORK AT SO-CALLED IMMUNE PRIVILEGED SITES? IS IT ENCAPSULATED? IS IT DOING SOMETHING TO EVADE THE IMMUNE SYSTEM? SO IT'S, AGAIN, ANOTHER POINT TO THINK ABOUT WHEN YOU LOOK AT HOW OUR PORTFOLIO HAS DEVELOPED.

THE KINDS OF CELLS THAT WE'RE WORKING WITH, WHAT ARE THE CELL TYPES? THERE ARE REALLY ROUGHLY EQUAL NUMBERS OF WHAT I'LL CALL PLURIPOTENT STEM CELL-DERIVED CELL THERAPIES AS THERE ARE TISSUE ADULT STEM CELL THERAPIES. AND SO I THINK WE WERE ORIGINALLY FOUNDED ON THE NOTION OF HUMAN EMBRYONIC. I THINK WE'VE EMBRACED THE NOTION OF IPS DERIVED IN THAT SORT OF PLURIPOTENT. BOTH OF THOSE CARRY THE SAME SORT OF SO-CALLED REGULATORY CONSIDERATIONS. IF YOU HAVE A TISSUE THAT IS INFINITELY PROLIFERATIVE AND CAN DIFFERENTIATE TO ANY CELL TYPE, THE REGULATORS NOW ARE STARTING TO HAVE EXPERIENCE WITH IT. I THINK WE ALL KNOW THAT BOTH

ACT AND GERON WERE SUCCESSFUL IN GETTING IND'S APPROVED AND CLINICAL TRIALS INITIATED FOR PSC-DERIVED CELL THERAPIES. SO THERE IS BECOMING EXPERIENCE, BUT IT IS A BIT MORE OF A REGULATORY CONCERN.

I WILL POINT OUT THAT THOSE ARE NOT TOTALLY GONE WITH THE NOTION OF TISSUE OR ADULT STEM CELLS, DEPENDING ON HOW PROLIFERATIVE THE POPULATION IS, DEPENDING ON WHAT IT CAN DO. IN THAT CASE I THINK ABOUT 177 MILLION OF THAT 221 IS SPLIT BETWEEN MSC-DERIVED THERAPIES, HSC-DERIVED THERAPIES, AND MSC-DERIVED THERAPIES. THESE ARE CELL TYPES THAT, AGAIN, I THINK THE REGULATORS ARE BECOMING A LITTLE BIT MORE COMFORTABLE WITH MSC'S, AT LEAST WHEN THEY'RE THERE JUST FOR SORT OF PROVIDING FACTORS. THEY'RE THERE TO PROVIDE FACTORS THAT ARE A TEMPORARY THING. SO THAT'S JUST ONE THING TO CONSIDER IN THE TALK OF THE PORTFOLIO.

IF YOU LOOK AT OUR PORTFOLIO, SO THE OTHER 20 PERCENT OF IT IS GOING TO APPROACHES THAT ARE OUTSIDE OF CELL THERAPY. THIS IS THE REVERSE OF WHAT IT WOULD BE IN ANY KIND OF BIG PHARMA OR ANY MAJOR BIOTECH NOW. AS A MATTER OF FACT, YOU'D PROBABLY FIND VERY LITTLE CELL THERAPY IN MOST CASES. MOST OF THE BIOTECH WOULD BE FOCUSED ON

SMALL MOLECULE APPROACHES, ON BIOLOGIC. AND BY BIOLOGICS, TYPICALLY I MEAN MONOCLONAL ANTIBODIES OR THERAPEUTIC PROTEINS. MR. JUELSGAARD CAN SPEAK. GENENTECH IS A FINE EXAMPLE OF A COMPANY WHO'S BEEN VERY SUCCESSFUL IN ESSENTIALLY WORKING IN THIS SPACE AND ACTUALLY ONE OF THE LEADERS IN INTRODUCING BIOLOGICS AS THERAPEUTIC PROTEINS.

THESE ARE WHAT I'LL CALL AT THIS POINT STRATEGIES OR APPROACHES THAT ARE WELL UNDERSTOOD IN TERMS OF PRODUCTION, IN TERMS OF GOING THROUGH THE REGULATORY PATHWAY, AND I WON'T SAY ARE LOW RISK, BUT ARE LOWER RISK. AND SO IN THINKING ABOUT WHAT CIRM IS TRYING TO DO, HOW FAR SHOULD WE CARRY FUND DEVELOPMENT OF SMALL MOLECULES OR BIOLOGICS? I ALSO HAVE TO POINT OUT THAT IN MANY CASES, EXCEPT WHERE ENDOGENOUS STEM CELLS ARE TARGETED, THE SMALL MOLECULE, EXCEPT WHERE CANCER STEM CELLS ARE CONVINCINGLY TARGETED, THE SMALL MOLECULE OR BIOLOGIC, ACTUALLY THE WORK IS DONE USUALLY BACK IN EARLY TRANSLATION, AND HOW MUCH MORE WORK CAN BE DONE IN DEVELOPMENT THAT IS ACTUALLY STEM CELL RELATED? SO THIS IS AN IMPORTANT CONSIDERATION. THIS IS BIG PHARMA'S AND BIG BIOTECH'S BAILIWICK. SO THAT'S ANOTHER CONSIDERATION.

THIS JUST AGAIN SHOWS YOU THE STEM CELL

CLASS BY EITHER EARLY TRANSLATION OR DEVELOPMENT. AND, AGAIN, NOT SURPRISINGLY, WHAT ARE THOSE THINGS THAT WERE, IF YOU LIKE, MORE READY FOR DEVELOPMENT? AND IT'S THE TISSUE-DERIVED STEM CELLS. IT'S SOME PLURIPOTENT. I THINK ELLEN HIGHLIGHTED THAT ONE OF OUR DISEASE TEAM I PROGRAMS IS AN IPS ONE DERIVED, SO A PSC-DERIVED PRODUCT. IT'S ALSO GOT SOME THINGS THAT ARE TARGETING ENDOGENOUS STEM CELLS. THAT'S THE MONOCLONAL ANTIBODY. THE CD 47 WOULD BE AN EXAMPLE OF THAT, THE CFC. THE PROJECT FROM CARSON AND FROM SLAMON BOTH ARE TARGETING CSC'S. SO THOSE ARE THE KINDS OF THINGS THAT YOU SEE IN THE DEVELOPMENT PORTFOLIO.

IF YOU LOOK AT THE EARLY TRANSLATION PORTFOLIO, YOU SEE A FOCUS ON SOME VERY MUCH MORE, WHAT DO I WANT TO SAY, NEW CUTTING-EDGE STRATEGIES, THINGS LIKE REPROGRAMMING TECHNOLOGY, MORE OF THE DISEASE-IN-THE-DISH-TYPE THINGS WHERE ACTUALLY THE OUTCOME IS IN MANY CASES A SMALL MOLECULE. WHAT THEY ARE TRYING TO DO IS THEY ARE TRYING TO DEVELOP -- THEY'RE USING HUMAN-DERIVED DISEASE -- OUR IPSC INITIATIVE IN ORDER TO GET BETTER, POTENTIALLY BETTER, IN VITRO MODELS THAT MIGHT ALLOW THE DISCOVERY OF DRUGS THAT ARE MORE RELEVANT. SO THAT'S WHAT WE'RE DOING THERE.

I JUST HIGHLIGHTED HERE JUST BECAUSE WE WERE TALKING ABOUT IPSC INITIATIVE ACTUALLY WITHIN OUR TRANSLATIONAL PORTFOLIO, THAT WE DO HAVE 16 PROJECTS THAT ARE EITHER DOING DISEASE IN A DISH OR ACTUALLY USING IPSC, IN SOME CASES DISEASE LINES THAT ARE CORRECTED, AS THERAPEUTIC STRATEGIES. THE DISEASE IN A DISH, THIS IS A SMALL PART OF ABOUT THE 40 OR 50 WE'RE DOING. I'LL LEAVE YOU TO LOOK THROUGH IT AT YOUR LEISURE.

WHAT I DO WANT TO MAKE THE POINT NOW IS THAT CIRM NOW HAS A TRANSLATIONAL PORTFOLIO THAT IS BROAD AND IS OFTEN DEEP IN MANY THERAPEUTIC AREAS. WE ARE ADVANCING PROJECTS THROUGH THE PIPELINE. AND SOME OF THE QUESTIONS THAT I THINK WE SHOULD ASK AS WE MOVE FORWARD IS WHERE TO FOCUS AND PRIORITIZE TO MEET OUR STRATEGIC GOALS. WHAT IS THE BALANCE OF PROJECTS AT THE DIFFERENT STAGES OF PROJECT DEVELOPMENT? ARE THERE SPECIFIC DISEASE AREAS WE WANT TO EMPHASIZE? WHAT IS THE RIGHT BALANCE OF NOVEL THERAPEUTIC APPROACHES, I.E., CELL THERAPY, RELATIVE TO THE WELL-ESTABLISHED APPROACHES. AND WITHIN CELL THERAPY, WHAT IS THE BALANCE BETWEEN THE AUTOLOGOUS VERSUS THE ALLOGENEIC AND THE PLURIPOTENT RELATIVE TO THE TISSUE OR ADULT STEM CELLS?

WITH THAT, I WANT TO THANK YOU FOR YOUR

ATTENTION. AND THINK ABOUT IT WHEN YOU DREAM TONIGHT. AS WE MOVE FORWARD, I THINK AS WE MOVE FORWARD ON OUR AWARDS, WE'LL BE BRINGING YOU ELEMENTS OF THIS.

MR. TORRES: (INAUDIBLE.)

DR. FEIGAL: I THINK THANK YOU BECAUSE IT'S BEEN YOU AND THE PATIENTS THAT HAVE ACTUALLY HELPED MAKE THE DECISIONS THAT WE CAN MOVE FORWARD. SO THANK YOU.

MR. SHEEHY: AGAIN, TREMENDOUS. DOING A PHENOMENAL JOB. PAT, DR. OLSON, I LOVE YOUR QUESTIONS.

I JUST WONDER, I KNOW WE'RE KIND OF DIGESTING THE IOM REPORT, BUT IF THERE'S SOME POINT IN THE FUTURE WHERE WE MIGHT HAVE A BOARD WORKSHOP, MAYBE GET HERE A DAY EARLY, AND REALLY TALK ABOUT THESE QUESTIONS. I THINK THEY'RE VERY FUNDAMENTAL. I DON'T WANT TO PUT MORE WORK BECAUSE I KNOW HOW MUCH PRODUCTIVITY STAFF -- I MEAN STAFF IS JUST CRAZY BUSY. I DON'T KNOW HOW YOU GUYS ARE MAKING IT THROUGH THIS MARCH. IF THERE'S A MOMENT WHEN PEOPLE GET A BREATH TO REALLY TAKE A BIT OF TIME AND REALLY LOOK AT THOSE QUESTIONS. I THOUGHT YOU FRAMED IT BEAUTIFULLY. I APPRECIATE THE AMOUNT OF WORK YOU TOOK TO COME UP WITH THOSE, TO REALLY DISTILL SOME

OF THE KEY QUESTIONS WE NEED TO ASK INTO REALLY A FAIRLY SMALL SET OF QUESTIONS. BUT I THINK IT WOULD BE WORTHWHILE IF THAT COULD -- IF THAT WAS WORTHWHILE OBVIOUSLY FROM STAFF'S POINT OF VIEW, BUT IT WOULD BE VERY INTERESTING TO TRY TO WORK THROUGH SOME OF THAT BECAUSE WE DO HAVE SOME TOUGH QUESTIONS AHEAD OF US.

DR. FEIGAL: I THINK PART OF IS JUST THAT YOU SEE THINGS AT A SNAPSHOT. YOU GET INITIATIVES BROUGHT TO YOU AT CERTAIN POINTS IN TIME. IT'S PRETTY RICH AT THIS POINT. AND WE WANT YOU TO BE AWARE THAT NOT JUST ALL THE NEW STUFF, BUT ALL THE STUFF WE'VE ALREADY INVESTED IN, WHAT'S HAPPENING TO THAT. AND SO WE THINK THIS IS JUST AN IMPORTANT PART OF WORKING WITH YOU. AND IF A HALF-DAY SESSION TO ACTUALLY GO OVER IT IS SOMETHING PEOPLE ARE INTERESTED IN, I'M SURE WE CAN WORK SOMETHING OUT.

CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY. I TOTALLY ECHO THAT. I THINK IT WOULD BE A VERY WORTHWHILE THING TO DO IF STAFF THOUGHT THAT WOULD BE PRODUCTIVE TO HAVE BOARD INVOLVEMENT IN THAT DISCOURSE.

DR. OLSON: I THINK ONE OF THE THINGS WE DID COMMENT ON IN SORT OF THE PROPOSAL FOR THE PROGRAMMATIC REVIEW IS THAT PART OF WHAT STAFF WOULD

LIKE TO BRING THE BOARD WHEN WE COME TO FUNDING DECISIONS IS A RELEVANT PORTFOLIO DISCUSSION TO THAT PARTICULAR THING.

CHAIRMAN THOMAS: VERY HELPFUL. SO THANK YOU VERY MUCH. THAT WAS OUTSTANDING.

I WILL WRAP UP HERE. WE HAVE A COUPLE OF ITEMS THAT HAVE TO BE HELD OVER FOR THE NEXT MEETING, BUT I DO WANT TO WRAP UP WITH A VERY BRIEF CHAIRMAN'S REPORT.

FIRST AND FOREMOST, SINCE THE LAST MEETING, OBVIOUSLY WE SPENT A HUGE AMOUNT OF TIME ON THE IOM-RELATED ISSUES. I DO WANT TO THANK ALL PARTIES WHO WERE INVOLVED IN DEVELOPING THE IMPLEMENTATION STEPS THAT WE VOTED ON TODAY. AS OF EARLIER THIS AFTERNOON, THE BOARD HAS NOW COMPLETED ITS WORK IN CONNECTION WITH THE IOM REPORT. WE'RE NOW SET FOR A ONE-YEAR TRIAL PERIOD. I JUST WANT TO CONGRATULATE EVERYBODY ON STEPPING UP AND DOING WHAT WE NEEDED TO DO TO GET ALL THIS IN PLACE IN RESPONSE TO THAT REPORT.

AND AS I SAID BACK IN JANUARY, GIVEN THAT WE'RE A GOVERNMENT AGENCY AND WE'RE FACED WITH SOME EXTREMELY MAJOR RECOMMENDATIONS, WE'VE MOVED AT WARP SPEED TO COME UP WITH SOMETHING THAT'S VERY RESPONSIVE AND I BELIEVE TIME WILL SHOW WILL BE A

VERY SOLID GROUP OF IMPLEMENTATION STEPS TO RESPOND TO THAT REPORT. SO CONGRATULATIONS TO ALL OF US FOR THAT.

SINCE THE LAST MEETING, THERE ARE A COUPLE THINGS I'D LIKE TO HIGHLIGHT. THERE'S A BUNCH OF OTHER STUFF. THE TWO MAIN THINGS ARE WE HAD THE CFAOC MEETING WHERE THE CONTROLLER AND HIS PANEL CONDUCTED THEIR ANNUAL REVIEW OF OUR ECONOMIC SITUATION IN THEIR OVERSIGHT CAPACITY. WE HAD A NUMBER OF FOLKS WHO PRESENTED TO THEM, DR. FEIGAL, CHILA, ALEX, JAMES, AND MYSELF. MARIA WAS THERE AS WELL. THAT MEETING, I THINK, DEMONSTRATED THAT BEING EXTREMELY PREPARED PAYS GREAT DIVIDENDS. WE WERE ABLE TO DEAL WITH ALL ISSUES CONNECTED TO OUR FINANCIAL SITUATION, CONNECTED TO THE MOSS-ADAMS AUDIT, AND THEY HAD A FEW QUESTIONS ON THE IOM. I THINK BY THE TIME WE GOT TO THAT, IT WAS SO LATE IN THE DAY, THEY DIDN'T HAVE A LOT OF QUESTIONS.

BUT THE CONTROLLER CAME UP AFTERWARDS AND SAID THAT HE FELT IT WAS AN OUTSTANDING MEETING, THAT WE WERE HIGHLY RESPONSIVE TO THEIR CONCERNS. AND THAT WAS ECHOED BY A COUPLE OF THE OTHER BOARD MEMBERS. SO I JUST WANT TO REPORT TO EVERYBODY THAT THAT MEETING WENT VERY WELL, AND I THINK THE STATUS OF OUR RELATIONSHIP WITH THE CONTROLLER'S OFFICE AS

WELL AS THAT WITH ALL OF THE CONSTITUTIONAL OFFICERS IS AS GOOD AS IT HAS EVER BEEN.

THE OTHER THING I WANTED TO REPORT ON, WHICH A NUMBER OF YOU MAY RECALL, THANKS TO DON REED, WHO ISN'T HERE ANY LONGER AT THE MEETING, HE NOMINATED US TO RESEARCH AMERICA FOR ONE OF THEIR MAJOR ADVOCACY AWARDS. AND VERY HAPPILY WE WERE PICKED FOR THE PAUL ROGERS AWARDS. PAUL ROGERS IS THE LATE CONGRESSMAN WHO EX OF HOGAN AND HARTSON IN WASHINGTON, D.C., WHO AFTER HIS CONGRESSIONAL CAREER, BOTH DURING AND AFTER, FOUGHT TIRELESSLY ON A NUMBER OF HEALTH-RELATED MATTERS.

WE HAD THE ANNUAL DINNER AT RESEARCH AMERICA THAT TOOK PLACE LAST WEEK. ABOUT 500 PEOPLE IN ATTENDANCE. VERY INTERESTING CROWD. IT INCLUDED HHS SECRETARY SEBELIUS, FRANCIS COLLINS FROM NIH, PEGGY HAMBURG FROM FDA, AND MANY MEMBERS OF CONGRESS. THIS WAS A VERY HIGH LEVEL ATTENDED DINNER.

THERE WERE A NUMBER OF ADVOCACY AWARDS. WE RECEIVED ONE FOR CIRM AS AN ORGANIZATION. I HAD THE PRIVILEGE OF GOING BACK AND ACCEPTING THAT AWARD ON BEHALF OF ALL OF US. DEAN POMEROY WENT AS WELL AS DID BOB. HE CAME BACK. BOB, YOU MAY RECALL, WAS A RECIPIENT INDIVIDUALLY OF A RESEARCH AMERICA AWARD

ABOUT THREE YEARS AGO. THERE WAS A GREAT DEAL OF DISCUSSION IN THE RECEPTIONS PRECEDING AND POST ABOUT WHAT WE WERE DOING AND A GREAT DEAL OF INTEREST ABOUT WHAT'S HAPPENING OUT ON THE WESTERN FRONTIER IN WHAT EVERYBODY VIEWED AS THE NATION'S PREMIERE STEM CELL PROGRAM.

SO CONGRATULATIONS TO EVERYBODY FROM RESEARCH AMERICA. IT WAS SOMETHING, I THINK, THAT WAS REALLY A NICE EVENT AND APPRECIATED GREATLY.

YOU KNOW WE'VE ALSO SPENT, ONE OTHER THING HERE, QUITE A BIT OF TIME WITH EDITORIAL BOARDS SINCE THE IOM MEETING WE HAD IN JANUARY. AND YOU'VE ALL GOTTEN COPIES OF WHAT HAS COME OF THAT SO FAR. I THINK WE WENT FROM ZERO POSITIVE PRESS AT THE TIME THE IOM REPORT CAME OUT IN DECEMBER. I'D SAY WE'RE NOW UP TO ABOUT 70 PERCENT. I WANT TO THANK KEVIN AND DON AND AMY AND TODD FOR THEIR GREAT WORK ON COMMUNICATIONS SETTING UP THESE MEETINGS. I'VE GONE VARIOUSLY WITH OUR SCIENTISTS AND PATIENT ADVOCATES THAT WERE ASKED TO JOIN, DEPENDING ON THE PARTICULAR PAPER, AND WE'VE HAD SOME VERY GOOD SESSIONS AND I THINK GOTTEN SOME VERY NICE EDITORIALS. AND I'M HOPEFUL THAT WHAT WE'VE SUCCEEDED IN DOING IS STARTING TO TURN THE DIALOGUE AWAY FROM PROCEDURAL ISSUES, INTERNAL ISSUES, ETC. AND GET THINGS FOCUSED

ON THE MARVELOUS AND GROUNDBREAKING SCIENTIFIC WORK THAT WE'RE DOING THAT WE JUST HEARD ABOUT IN SPADES FROM DRS. FEIGAL AND OLSON.

SO WE'RE GOING TO PICK UP THE PACE ON THE COMMUNICATIONS FRONT GOING FORWARD AND CONTINUE TO GET THE MESSAGE OUT ABOUT WHAT GREAT WORK WE'RE DOING.

SO WITH THAT, VARIOUS OTHER THINGS THAT HAPPENED. ONLY LAST THING I WOULD LIKE TO MENTION THAT WAS REFERRED TO. I WANTED TO BE ABLE TO MAKE THE ANNOUNCEMENT FIRST, BUT SINCE THIS IS LAST, LEEZA HAS DECIDED TO STEP DOWN FROM THE BOARD, WHICH IS, OF COURSE, A BIG LOSS TO US. SHE WAS A WONDERFUL BOARD MEMBER WITH GREAT EMPATHY FOR PATIENTS AND THEIR FAMILIES AND BROUGHT TO THE BOARD A GREAT DEAL OF HIGH LEVEL ENTHUSIASM AND VISIBILITY. WE WILL PROPERLY HONOR HER AT A FUTURE BOARD MEETING.

SO WITH THAT, I WANT TO THANK EVERYBODY FOR A LONG DAY. I THINK IT'S BEEN EXTREMELY PRODUCTIVE. THANK YOU TO STAFF FOR ALL YOUR INCREDIBLE HARD WORK. I HOPE THAT EVERYBODY IS HAPPY WITH THE RESULTS OF THE DAY. AND WE WILL SEE EVERYBODY IN MAY. THIS MEETING STANDS ADJOURNED.

(THE MEETING WAS THEN CONCLUDED AT 04:42 P.M.)

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

HILTON SFO BAYFRONT HOTEL
600 AIRPORT BOULEVARD
BURLINGAME, CALIFORNIA
ON
MARCH 19, 2013

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

BETH C. DRAIN, CSR 7152
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