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: LUXE HOTEL SUNSET BOULEVARD
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA

DATE: OCTOBER 10, 2006
5 P.M.

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

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I N D E X

LOS ANGELES, CALIFORNIA; TUESDAY, OCTOBER 10, 2006

CHAIRMAN KLEIN: I'D LIKE TO CALL THE MEETING TO ORDER. WE HAVE A NUMBER OF BOARD MEMBERS IN TRANSIT, BUT WE HAVE A BUSY AGENDA, SO WE'D LIKE TO BEGIN. WE NEED TO RECRUIT OUR LEGAL COUNSEL, SCOTT TOCHER, TO JOIN THE AUDIENCE. OKAY. I WOULD LIKE TO START THIS EVENING WITH OUR ROLL CALL. WE HAVE SOME EXTRAORDINARY STRATEGIC PLAN REVIEW THIS EVENING. WE HAVE A NEW BOARD MEMBER, BUT LET US BEGIN FORMALLY WITH MELISSA KING CALLING THE ROLL.

MS. KING: RICARDO AZZIZ.

DR. AZZIZ: PRESENT.

MS. KING: DAVID BALTIMORE. ROBERT PRICE FOR ROBERT BIRGENEAU. SUSAN BRYANT.

DR. BRYANT: HERE.

MS. KING: MARCY FEIT.

MS. FEIT: HERE.

MS. KING: MICHAEL FRIEDMAN.

DR. FRIEDMAN: HERE.

MS. KING: MICHAEL GOLDBERG. BRIAN HENDERSON. ED HOLMES. DAVID KESSLER. BOB KLEIN.

CHAIRMAN KLEIN: HERE.

MS. KING: SHERRY LANSING. GERALD LEVEY. TED LOVE.

DR. LOVE: HERE.

MS. KING: RICH MURPHY. TINA NOVA. ED PENHOET.

DR. PENHOET: HERE.

MS. KING: PHIL PIZZO. CLAIRE POMEROY.

DR. POMEROY: HERE.

MS. KING: FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. KING: JEANNIE FONTANA FOR JOHN REED. DUANE ROTH. JOAN SAMUELSON. DAVID SERRANO-SEWELL. JEFF SHEEHY. JONATHAN SHESTACK. OSWALD STEWARD. LEON THAL.

DR. THAL: HERE.

MS. KING: JANET WRIGHT.

DR. WRIGHT: HERE.

CHAIRMAN KLEIN: THANK YOU VERY MUCH, MELISSA. ARE YOU GOING TO LEAD US IN THE PLEDGE OF ALLEGIANCE?

MS. KING: YES, I WILL. THE FLAG IS BY THE SCREEN. PLEASE STAND IF YOU ARE ABLE.

(THE PLEDGE OF ALLEGIANCE.)

CHAIRMAN KLEIN: IN A MOMENT WE WILL START A VERY EXCITING AND IMPORTANT, CRITICAL MEETING IN OUR EVOLUTION AND GROWTH AS AN AGENCY WHEN WE FOCUS ON THE STRATEGIC PLAN. BUT FIRST I'D LIKE YOU TO KNOW THAT

THE GOVERNOR, WHEN HE DECIDED TO ADVANCE THE $150 MILLION, ACTUALLY GAVE US MORE THAN 150 MILLION. THIS IS A VERY EXCITING MOMENT FOR US BECAUSE HE ALSO GAVE US A NEW BOARD MEMBER. OUR NEW BOARD MEMBER IS TO MY RIGHT, DR. RICARDO AZZIZ. HE'S APPOINTED BY THE GOVERNOR. HE IS THE CHAIRMAN OF THE DEPARTMENT OF OBSTETRICS AND GYNECOLOGY AT CEDARS-SINAI MEDICAL CENTER, ALSO SERVES AS PROFESSOR AT THE DAVID GEFFEN SCHOOL OF MEDICINE AT UCLA AND VICE CHAIR OF THE DEPARTMENT OF OBSTETRICS AND GYNECOLOGY AT UCLA.

DR. AZZIZ RECEIVED HIS B.A. FROM THE UNIVERSITY OF PUERTO RICO AT MAYAGUEZ AND HIS MEDICAL DEGREE FROM PENN STATE UNIVERSITY COLLEGE OF MEDICINE, COMPLETED HIS RESIDENCY AT GEORGETOWN UNIVERSITY HOSPITAL AND A FELLOWSHIP IN REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY AT JOHN HOPKINS HOSPITAL.

IN ADDITION, DR. AZZIZ EARNED A MASTER'S OF PUBLIC HEALTH AND MASTER'S OF BUSINESS ADMINISTRATION FROM THE UNIVERSITY OF ALABAMA AT BIRMINGHAM, ALABAMA.

SO AS AN EXTREMELY DISTINGUISHED MEMBER OF OUR BOARD, WE'D LIKE TO WELCOME DR. AZZIZ.

(APPLAUSE.)

CHAIRMAN KLEIN: WE HAVE FOR THIS EVENING AN EXCELLENT DRAFT OF THE STRATEGIC PLAN BEFORE YOU. I WILL BE CALLING ON DR. HALL TO PRESENT THE DRAFT AND

LEAD US THROUGH THE EVENING. I'D LIKE TO ALSO ACKNOWLEDGE FROM THE BOARD THAT DR. ARLENE CHIU, PATRICIA OLSON, GIL SAMBRANO, DR. MARY MAXON, KATE SHREVE, AMY LEWIS ON THE FINANCIAL PORTION, AND OUR FRIENDS AT PRICE WATERHOUSE, INCLUDING, I THINK, JERRY IS HERE AS WELL IN THE FRONT ROW AS WELL AS TONY POLARI, WHO HAS DONE YEOMAN'S WORK AS A MEMBER OF ZACH'S STRATEGIC PLAN -- AS A MEMBER OF THE STRATEGIC PLAN TEAM. WE OWE A TREMENDOUS DEBT TO THEM AND FOR ZACH'S LEADING US THROUGH THAT EFFORT. SO I'D LIKE TO OPEN THIS WITH A ROUND ARE APPLAUSE FOR THAT TEAM.

(APPLAUSE.)

CHAIRMAN KLEIN: WE HAVE SEVERAL MEMBERS OF THE STRATEGIC PLANNING ADVISORY COUNCIL HERE TONIGHT, INCLUDING ICOC MEMBERS AND INTERVIEWEES. I WOULD THINK THAT DURING THE NIGHT, DR. HALL MIGHT ACKNOWLEDGE SOME OF THOSE MEMBERS AS HE GOES THROUGH THE PLAN, BUT WE CERTAINLY APPRECIATE ALL OF THOSE INDIVIDUAL CONTRIBUTIONS. DR. HALL, THE FLOOR IS YOURS.

DR. HALL: THANK YOU, MR. CHAIRMAN. THIS IS A VERY EXCITING MOMENT FOR US, A BIG MOMENT, WHEN WE PRESENT THE STRATEGIC PLAN. AND IT IS THE CULMINATION OF A YEAR'S WORK. IF YOU REMEMBER, WE STARTED A LITTLE OVER A YEAR AGO. OCTOBER 1ST AND 2D WE HAD OUR MEETING ON STEM CELL RESEARCH IN CALIFORNIA, CHARTING NEW

DIRECTIONS, IN WHICH WE INVITED PEOPLE FROM ALL OVER THE WORLD TO COME IN AND TELL US WHAT THE OPPORTUNITIES AND CHALLENGES WERE AND TO MAKE RECOMMENDATIONS FOR WHAT WE MIGHT DO. AND THAT WAS THE BEGINNING OF A LONG FACT-FINDING PROCESS THAT WE ENGAGED IN.

IN APRIL 2006 I PRESENTED A PLAN FOR A PLAN TO OUTLINE HOW WE WERE GOING TO DO THIS, AND THEN SHORTLY THEREAFTER WE ENGAGED PRICE WATERHOUSE COOPERS AS CONSULTANTS.

SO IN THE PROCESS WE HAVE INTERVIEWED OVER 70 SCIENTISTS, CLINICIANS, ETHICISTS, PATIENT ADVOCATES, PUBLIC INTEREST REPRESENTATIVES, AN INTERNATIONAL GROUP FROM THE UNITED STATES AND ABROAD. WE HELD THREE PUBLIC MEETINGS FOR THE ICOC AND THE PUBLIC. WE HAD TWO FOCUS GROUPS, ONE FOR PATIENT ADVOCATES AND ONE ON DIVERSITY, AND WE HAD TWO ICOC MEETINGS THAT WERE FOCUSED ON OUR MISSION STATEMENT, OUR VALUES, AND OUR STRATEGIC PRINCIPLES. WE ALSO HAD SEVEN STRATEGIC PLAN ADVISORY COMMITTEES. THIS WAS AN EXCELLENT GROUP IN WHICH WE WERE ABLE TO AIR A NUMBER OF ISSUES, AND THE NEXT SLIDE SHOWS THE MEMBERS OF THAT GROUP. AND I WANT TO THANK ACTUALLY ALL THE PARTICIPANTS IN THE PLAN.

THE STRATEGIC PLAN ADVISORY COMMITTEE: DAVID BALTIMORE, PAUL BERG, GEORGE DALY, STEVE FOREMAN, SHERRY LANSING, BOB KLEIN, ED PENHOET, BILL RASTETTER,

PAST CEO OF BIOGEN IDEC, AND JEFF SHEEHY. IN ADDITION TO THESE, I WANT TO THANK MANY OF YOU WHO WERE INTERVIEWED. YOU PARTICIPATED IN THE MEETINGS. YOU ATTENDED THEM. AND WE REALLY APPRECIATE YOUR PARTICIPATION. WE APPRECIATE THE PARTICIPATION OF MEMBERS OF THE PUBLIC, MANY OF WHOM BECAME ALMOST AS EXPERT IN THE DETAILS OF THIS AS WE DID, BUT MADE VALUABLE CONTRIBUTIONS ALL THE WAY THROUGH.

SO WHAT YOU'RE GOING TO HEAR TONIGHT IS THE WORK OF A LARGE NUMBER OF PEOPLE. WE CALCULATE THAT, IN TERMS OF SPEAKERS AND INTERVIEWEES AND PEOPLE THAT WE TALKED TO DIRECTLY, OVER 200 PEOPLE WERE INVOLVED, AND THEN, OF COURSE, MANY OTHERS AS PARTICIPANTS IN THE AUDIENCE AND IN THE PUBLIC. SO THIS IS A TREMENDOUS GROUP EFFORT FOR EVERYBODY CONCERNED.

I WANT TO JUST ECHO WHAT BOB SAID. THE PLAN REALLY IS A RESULT FROM CIRM OF A VERY DEDICATED AND TALENTED GROUP, AND THE LEADERS OF THIS GROUP ARE FANTASTIC, ABSOLUTELY FANTASTIC. PATRICIA OLSON, SITTING ON MY RIGHT, AND TONY POLARI ON MY LEFT, AND WE COULD NOT HAVE DONE IT WITHOUT THEM. THEY DID AN ABSOLUTELY SUPER JOB. THEY WERE BACKED UP BY RAY ANDERSON OF PWC, ARLENE, GIL, MARY, AMY LEWIS, KATE SHREVE, PAT BECKER, CHRISTINE WOO OF PWC, AND THEN WE HAVE JERRY MCGOUGALL, WHO'S HERE WITH US TONIGHT WHO'S

THE HEAD OF HEALTH SCIENCES AT PRICE WATERHOUSE COOPERS, WHO GAVE US VALUABLE ADVICE AND GUIDANCE, AND ALSO BILL DRACOS, WHO'S NOT HERE TONIGHT, BUT ALSO PARTICIPATED. SO THIS IS THE TEAM, AND I WOULD LIKE TO GIVE THEM ANOTHER ROUND OF APPLAUSE.

(APPLAUSE.)

DR. HALL: I THINK IF YOU LOOK AT THIS, YOU WILL RECOGNIZE IT REPRESENTS A TREMENDOUS AMOUNT OF WORK BY THIS GROUP.

SO THE RESULT IS IN FRONT OF YOU. AND WE HAVE AN EXECUTIVE SUMMARY, THE BODY OF THE REPORT, AND THE APPENDICES. AND WE'RE GOING TO FOCUS TONIGHT ON THE BODY OF THE REPORT. EXECUTIVE SUMMARY IS, WE HOPE, A CONCISE AND USEFUL SUMMARY, BUT TO GET THE FULL FLAVOR OF IT, I THINK, IF NOT EVERY WORD, YOU WANT TO READ AROUND IN THE BODY OF THE REPORT. AND FOR THOSE WHO ARE INTERESTED IN PARTICULAR ASPECTS OF IT, THE APPENDICES, PARTICULARLY ONE THAT PAT OLSON DID ON LOOKING AT INDUSTRY STANDARDS FOR DEVELOPMENT OF THERAPEUTICS AND WORK THAT AMY LEWIS DID ON OUR FINANCIAL BUSINESS PLAN, BOTH OF THOSE I WOULD RECOMMEND TO YOU AS YOU LOOK THROUGH IT.

SO OUR INTENT HERE TONIGHT IS TO PRESENT IT TO YOU IN, FIRST, A GENERAL WAY, AND THEN WE CAN TALK ABOUT SPECIFICS AS YOU WISH. BUT WE REALLY WANT TO

HEAR FROM YOU ABOUT YOUR SENSE OF THE OBJECTIVES, THE GENERAL DIRECTION, THE EMPHASIS. IS IT LARGELY RIGHT? AND I THINK THAT IS WHAT WE REALLY NEED TO HEAR, AND THEN WE CAN WORK ON THE DETAILS LATER. ALMOST EVERYTHING THAT'S SPECIFIC WILL COME UP SEPARATELY TO THE ICOC. WE'RE GLAD TO HAVE SUGGESTIONS NOW, AND WE'LL CHANGE THEM NOW, BUT I THINK THE MAIN POINT IS TO MAKE SURE THAT THE THRUST OF THIS IS IN THE RIGHT DIRECTION AND THAT IT COVERS THE GROUND THAT WE WANT IT TO COVER. AND I WOULD ASK FOR YOUR THOUGHTS ON THAT FIRST AND FOREMOST TONIGHT.

WE WILL ALSO RECEIVE INPUT FROM OTHERS, AND THEN WE WILL SPEND OVER THE NEXT TWO MONTHS MODIFYING IT, AND THEN WE WILL BRING IT BACK TO YOU FOR WHAT WE HOPE WILL BE FINAL APPROVAL IN DECEMBER. AND I'LL TALK LATER ABOUT AT LEAST ONE OTHER MAJOR SECTION THAT WE WILL ADD, AND THEN BOB AND I WILL PUT OUR VALEDICTORIES IN THE FRONT OF IT TOWARD THE END WHEN EVERYTHING IS FINISHED AS WELL.

SO LET'S MOVE ON IN THEN, AND WHAT I WOULD LIKE TO DO ACTUALLY IS NOT WALK YOU THROUGH STEP BY STEP BY STEP, BUT SKIP OVER SOME OF THE MATERIAL AT THE BEGINNING PARTIALLY BECAUSE YOU HAVE DEALT WITH IT ALREADY. THIS IS THE MISSION STATEMENT, THE VALUES, THE STRATEGIC PRINCIPLES. WE'VE SPENT PREVIOUS

EVENINGS LIKE THIS DISCUSSING THOSE, AND I DON'T WISH TO GO INTO DETAIL WITH THOSE RIGHT NOW ALTHOUGH WE WOULD BE HAPPY TO DISCUSS THEM LATER AND COULD COME BACK TO THEM LATER. AND I WOULD POINT OUT THAT WE'VE ALSO ADDED A SERIES OF CHALLENGES AND OPPORTUNITIES, WHICH ALSO WE CAN COME BACK AND DISCUSS WITH YOU LATER.

BUT WHAT I WOULD LIKE TO DO IS GO STRAIGHT TO THE HEART OF THE PLAN, WHICH REALLY ARE THE STRATEGIC OBJECTIVES AND GOALS. THAT, FOR US, WAS THE KEY AND THE MOST IMPORTANT PART. ONCE THAT IS SET -- IT'S THE CAPSTONE IN A SENSE. ONCE THAT'S SET, THEN EVERYTHING ELSE CAN BE ATTUNED TO IT, BUILT AROUND IT, DIRECTED TOWARD IT, BUT THAT WAS ONE OF THE MOST DIFFICULT CHALLENGES WE FACED. AND I WANT TO SPEND A LITTLE TIME ON THAT.

SO LET ME MAKE SOME GENERAL COMMENTS FIRST. WE WANTED THE GOALS TO BE VISIONARY, BUT WE ALSO WANTED TO BE SPECIFIC. WE LOOKED AT A NUMBER OF STRATEGIC PLANS FROM A NUMBER OF OTHER ORGANIZATIONS. AND I HAVE TO TELL YOU AN AWFUL LOT OF THEM OUTLINE VERY, VERY GENERAL PRINCIPLES AND SAY WHAT THEY'RE GOING TO DO IN BROAD STROKES, AND THEY DON'T TELL YOU REALLY WHAT THEY'RE GOING TO DO AND HOW THEY'RE GOING TO GO ABOUT IT AND HOW THEY'RE GOING TO ACHIEVE IT. SO WE WANTED TO KEEP THE VISION IN FRONT OF US, BUT WE ALSO WANTED

IT TO BE VERY SPECIFIC.

AND WE THEN CAME UP WITH THIS IDEA, WHICH ACTUALLY I WILL GIVE CREDIT TO PATRICIA OLSON TO, OF ARTICULATING TWO KINDS OF GOALS, ASPIRATIONAL GOALS; THAT IS, WHAT WE DREAM TO ACHIEVE, AND THE COMMITMENT GOALS. NOW, THE ASPIRATIONAL GOALS ARE THE VISIONARY ONES. IT'S WHY WE'RE ALL HERE. WE WANT TO CURE DISEASE, AND WE WANT CALIFORNIA TO BE A WORLDWIDE LEADER IN STEM CELL RESEARCH. AND THOSE ARE EXTREMELY LARGE, AMBITIOUS GOALS, NO LESS PASSION ON OUR PART, BUT WE ALSO WANTED TO HAVE SOME GOALS THAT WE COULD COMMIT TO AS BEING REASONABLE OVER THE TEN-YEAR TIMEFRAME OF THIS PLAN. AND THE POINT OF THAT IS REALLY TO HAVE SOMETHING FOR WHICH WE CAN BE HELD ACCOUNTABLE. AND THIS IS OUR PROMISE, IF YOU WILL, OUR COVENANT WITH THE PEOPLE OF CALIFORNIA, THAT OVER THE NEXT TEN YEARS, THESE ARE THE GOALS THAT WE BELIEVE WE CAN ACHIEVE. WITH A LITTLE BIT OF LUCK, WE THINK WE CAN DO THIS, AND WE CAN MAKE THE PROMISE OF STEM CELL RESEARCH A REALITY, AS WE SAY HERE.

AND SO THESE ARE OUR BENCHMARK AIMS. THIS IS WHAT WE AGREE TO BE MEASURED BY. THIS IS WHAT WE WILL WORK TOWARD. AND IF WE ARE TO WORK IN A SYSTEMATIC AND CAREFUL WAY, WE NEED THESE VERY, VERY SPECIFIC AIMS, AND WE NEED TO SET FOR OURSELVES GOALS THAT ARE

AMBITIOUS, BUT THAT WE BELIEVE ARE ACHIEVABLE. IN THAT WAY WE CAN MEASURE OUR PROGRESS AS WE WORK TOWARD THEM.

SO WE THEN SET OUT, FIRST OF ALL, OUR TEN-YEAR GOALS. THAT IS, I MADE THIS POINT BEFORE, BUT LET ME EMPHASIZE TO EVERYBODY, STEM CELL RESEARCH IS GOING TO GO ON FOR SEVERAL DECADES. AND DURING THAT PERIOD OF TIME, MORE AND MORE AND MORE DISEASES WILL BE TREATED THROUGH STEM CELL THERAPY. THERE WILL BE MORE ADVANCES IN BASIC SCIENCE. WE WILL HAVE STEM CELLS USED FOR THINGS WE DON'T EVEN KNOW ABOUT YET, AND THEY WILL ENLIGHTEN AREAS OF BIOLOGY THAT WE HAVEN'T YET UNDERSTOOD WE EVEN DIDN'T KNOW ABOUT. THAT DIDN'T COME OUT QUITE RIGHT, BUT I THINK YOU KNOW WHAT I MEAN. THERE'S A LOT TO BE DISCOVERED OUT THERE. AND THE TEN-YEAR TIMEFRAME THAT WE PUT ON THIS IS A SORT OF SLICE. THAT IS, THE WORK IS GOING TO CONTINUE, AND WE'RE GOING TO STOP TIME AT ONE MOMENT AND SAY, OKAY. AT THAT MOMENT WHERE DO WE EXPECT TO BE ON ALL THESE NUMBER OF PROJECTS THAT WE WILL BE WORKING ON?

ONE DECISION WE MADE AT THE BEGINNING WAS TO FOCUS LARGELY ON HUMAN EMBRYONIC STEM CELLS. WE WILL BE FUNDING RESEARCH FOR OTHER KINDS OF STEM CELLS, FETAL STEM CELLS, ADULT STEM CELLS, CORD BLOOD CELLS, AND WE WILL BE FUNDING RESEARCH ON STEM CELLS FROM OTHER SPECIES BECAUSE WE'VE GAINED IMPORTANT INSIGHTS

FROM THAT. BUT THE CENTRAL THEME, WHAT PROPOSITION IS ALL ABOUT, IS PLURIPOTENTIAL HUMAN STEM CELLS. AND WE THOUGHT THAT SHOULD BE THE CENTERPIECE OF OUR PLAN.

THEN THE OTHER ISSUE IS THAT WE ALSO HAVE MADE A FOCUS ON CELL REPLACEMENT THERAPY. THAT IS OUR EMPHASIS, ALTHOUGH NOT EXCLUSIVELY. WE BELIEVE THIS WILL BE THE BIGGEST CHALLENGE FACING US. HUMAN EMBRYONIC STEM CELLS, WE BELIEVE, WILL BE IMPORTANT TOOLS FOR DISEASE RESEARCH AND DRUG DISCOVERY, BUT THE PATHWAYS AND CHALLENGES ARE RELATIVELY WELL-KNOWN THERE. SO WHAT WE HAVE FOCUSED ON, NOT EXCLUSIVELY, AS YOU WILL SEE AS WE GO THROUGH THESE, BUT WE'VE GIVEN A STRONG EMPHASIS TO CELL REPLACEMENT THERAPY BECAUSE THIS IS THE CHALLENGE AND THE DREAM.

SO WE THEN SET TEN-YEAR GOALS AND SET FIVE-YEAR GOALS AS MILESTONES AGAINST WHICH TO MEASURE PROGRESS, BUT I WANT TO STOP FOR A MOMENT AND TELL YOU A LITTLE BIT ABOUT THE PROCESS WE WENT THROUGH BECAUSE WHAT WE THOUGHT ABOUT OR THE WAY WE WENT ABOUT THIS IS TO SAY IF WE WANT TO ACHIEVE A GOAL OF HAVING THERAPIES BASED ON STEM CELL RESEARCH AND WIDESPREAD CLINICAL USE, WHAT HAS BEEN THE EXPERIENCE IN DEVELOPING OTHER KINDS OF THERAPEUTICS? THE PHARMACEUTICAL INDUSTRY NOW HAS A LOT OF EXPERIENCE DEVELOPING SMALL MOLECULE THERAPEUTICS AND NOW BIOLOGICALS. AND WE WERE ABLE TO

DRAW ON THAT EXPERIENCE IN THINKING HOW THE COURSE OF DEVELOPING STEM CELLS AS THERAPIES MIGHT GO.

I THINK THE NEXT SLIDE WILL ILLUSTRATE, THEN, A KIND OF ARROW, WHICH IS VERY COMMON IN THE INDUSTRY, AND IT DEFINES FOUR STAGES. AND MOVING FROM LEFT TO RIGHT, THAT IS, IN MOVING FROM BASIC AND DISCOVERY RESEARCH IN WHICH ONE IS CARRYING OUT SORT OF CURIOSITY DRIVEN RESEARCH, TRYING TO UNDERSTAND THE SYSTEM, TRYING TO UNDERSTAND THE PRINCIPLES, THEN MOVING INTO TAKING WHAT ONE LEARNS IN DISCOVERY AND BASIC RESEARCH AND APPLYING IT TO SPECIFIC DISEASES AND TRYING TO THINK ABOUT THERAPEUTIC APPROACHES TO THOSE. AND THEN AT SOME STAGE, AND HERE WE MIGHT IMAGINE IN TERMS OF STEM CELLS, ONE WOULD TRY A NUMBER OF THINGS IN ANIMAL SYSTEMS, AND AT SOME STAGE YOU WOULD SAY WE THINK WE HAVE NOW A THERAPEUTIC CANDIDATE. THIS IS A REAL BENCHMARK IN THE WHOLE PROCESS BECAUSE WHAT THAT MEANS IS YOU'RE NOW PREPARED TO INVEST A LOT OF TIME AND MONEY INTO DOING ALL THE THINGS NECESSARY TO GET FDA APPROVAL TO USE THAT THERAPEUTIC CANDIDATE IN TRIALS IN PATIENTS.

AND SO THAT IS -- I THINK IT'S AN AREA THAT'S NOT VERY WELL APPRECIATED BY MOST ACADEMICS, CERTAINLY MY OWN UNDERSTANDING OF IT WAS DEFICIENT, BUT IT IS EXTREMELY IMPORTANT. AND BASICALLY IT IS TO ESTABLISH

THAT IF YOU HAVE A THERAPEUTIC, YOU HAVE TO CHARACTERIZE IT, YOU HAVE TO UNDERSTAND ITS PURITY, YOU HAVE TO SHOW THAT YOU CAN PRODUCE IT IN LARGE ENOUGH AMOUNTS, AND THAT YOU CAN REPRODUCIBLY DO SO WITH REPRODUCIBLE STANDARDS OF PURITY FROM BATCH TO BATCH, YOU HAVE TO SHOW THAT IT IS EFFICACIOUS AND CELLULAR IN ANIMAL MODEL SYSTEMS, AND VERY IMPORTANTLY, YOU HAVE TO SHOW THAT IT IS SAFE. AND SO ALL OF THESE THINGS WILL BE IMPORTANT, AND YOU PUT A LOT OF MONEY INTO THIS PARTICULAR AREA.

THEN IF YOU GET APPROVAL FOR AN INVESTIGATIONAL NEW DRUG FROM THE FDA, WE CAN THEN GO AHEAD AND DESIGN CLINICAL TRIALS, AND WE'LL COME BACK LATER TO LOOKING AT THE PHASE I, PHASE II, PHASE III CLINICAL TRIALS. IT'S IN THE BOTTOM PART HERE. LET ME JUST REMIND YOU THAT THE PHASE I TRIALS ARE RELATIVELY SMALL, AND THEIR PRIMARY AIM IS TO TEST SAFETY. OFTEN SEVERAL DOSES ARE GIVEN TO SEE IF THERE IS ANY SIDE EFFECTS OR UNTOWARD EFFECTS OF WHATEVER THE THERAPEUTIC IS. THEN WITH A LARGER GROUP OF PATIENTS, YOU THEN CARRY OUT STUDIES IN WHICH YOU'RE STILL INTERESTED IN ISSUES OF SAFETY, ISSUES OF DOSE, REGIMEN, DELIVERY MAYBE TESTED, BUT WHAT YOU ARE REALLY LOOKING FOR IS SOME SIGNAL OF EFFICACY AT THIS POINT. AND IT'S DURING THIS PHASE THAT MANY CANDIDATES FALL OUT. AND THEN

FINALLY, TO GIVE STATISTICAL PROOF OF EFFICACY; THAT IS, TO HAVE A LARGE ENOUGH NUMBER OF PATIENTS SO THAT YOU CAN SAY THAT THE POWER OF YOUR STATISTICS WILL LET YOU SAY WITH 95 PERCENT CERTAINTY THAT YOU HAVE OBSERVED A BENEFICIAL EFFECT OF THE THERAPY AND, COMPARED AGAINST OTHERS, THIS IS THE PURPOSE OF THE PHASE III TRIALS.

NOW, BOTH THE NUMBERS OF PATIENTS AND THE EXPENSE AND THE TIME IN PART GOES UP AS THESE GET MORE AND MORE COMPLEX.

NOW, THE FIGURES THAT WE LEARNED FROM SMALL MOLECULE AND BIOLOGICAL THERAPEUTIC DEVELOPMENT, WHICH ARE QUITE COMMON IN THE PHARMACEUTICAL INDUSTRY. THOSE OF YOU WHO HAVE HAD EXPERIENCE WITH THIS, TED LOVE AND OTHERS, THESE IDEAS WILL BE VERY FAMILIAR. BUT THE POINT IS FROM THE START OF CLINICAL DEVELOPMENT -- NOW, THIS IS FROM THE START OF YOUR FIRST CLINICAL TRIALS, NOT PRECLINICAL DEVELOPMENT, FROM THE START OF CLINICAL DEVELOPMENT, IT'S ON AVERAGE SEVEN TO NINE YEARS TO GET A DRUG APPROVED FOR USE IN THE MARKET. AND THIS WAS VERY IMPORTANT BECAUSE WHAT IT TOLD US WAS THAT IT WAS UNLIKELY THAT THROUGH WORK SPONSORED BY US, STARTING WITH THE BASIC RESEARCH THROUGH PRECLINICAL RESEARCH, PRECLINICAL DEVELOPMENT ON THROUGH CLINICAL RESEARCH, WE WILL BE VERY UNLIKELY, WE MAY BE LUCKY, BUT IT WILL

BE VERY DIFFICULT IN THAT TIME SPAN TO BRING A THERAPY TO MARKET.

NOW, THE OTHER KEY POINT IS THAT THERE IS ATTRITION AT EVERY STAGE OF DEVELOPMENT. SOME COMPOUNDS OR BIOLOGICALS FALL OUT IN PRECLINICAL DEVELOPMENT. BUT IF YOU LOOK AT THE ONES THAT ENTER CLINICAL DEVELOPMENT, IT TAKES EIGHT OR TEN GOING INTO PHASE I TRIALS IN ORDER TO GET ONE THAT IS APPROVED FOR THE MARKET. SO THEY DO NOT SURVIVE, AND THIS IS PART OF THE REASON THAT DEVELOPING THERAPEUTICS IS SUCH HIGH COST. I'M SURE YOU'VE ALL HEARD THE FIGURES, 800 TO A BILLION DOLLARS. AND PART OF THE POINT THERE IS IT INCLUDES A LARGE NUMBER OF FAILURES THAT ARE INEVITABLE AND THAT YOU CAN'T PREDICT. OF COURSE, MUCH OF THIS, AS I HAVE SAID BEFORE, IS TRYING TO DECIDE -- MUCH OF THE INDUSTRY IS TRYING TO DECIDE AT ANY ONE POINT WHICH ARE THE BEST PRODUCTS TO TAKE INTO THE NEXT PHASE. AND EARLY EVIDENCE OF FAILURE IS SOMETHING PEOPLE LOOK FOR VERY MUCH.

SO TO BRING THIS BACK TO OUR OWN SITUATION, THEN, WHAT WE NEED IS A STRONG PIPELINE THAT WILL CONTINUE TO BRING PRODUCTS INTO THE CLINIC PAST THE TEN-YEAR PERIOD OF THE PLAN. AND WE CAN EXPECT THAT WE WILL HAVE TO BRING MANY TO THE CLINIC IN ORDER TO GET A FEW THROUGH AT THE END. AND I THINK THAT'S JUST VERY

IMPORTANT, AND THIS WAS IMPORTANT FOR OUR STRATEGIC THINKING IN THIS.

THE OTHER POINT I WANTED TO MAKE IS THAT WE WERE IMPRESSED THAT HUMAN EMBRYONIC STEM CELL RESEARCH IS A YOUNG FIELD. HUMAN EMBRYONIC STEM CELLS WERE FIRST DESCRIBED EIGHT YEARS AGO, AND THERE'S THIS ASTONISHING FIGURE, THAT BY THE END OF 2004, THERE WERE IN THE WORLD LITERATURE ONLY A 132 PUBLICATIONS ON HUMAN EMBRYONIC STEM CELLS FROM 97 DIFFERENT INSTITUTIONS, HALF OF WHOM WERE IN OTHER COUNTRIES. SO OVER THE WORLD, THAT IS A DROP IN THE BUCKET IN TERMS OF THE SCIENTIFIC LITERATURE. AND SO IT UNDERLINES -- NOW, OBVIOUSLY, THAT FIGURE IS VERY DIFFERENT. WE DON'T HAVE COMPARABLE FIGURES UP TO DATE. MANY, MANY MORE, I'M SURE THAT FIGURE IS DOUBLED AND MORE IN THAT PERIOD OF TIME, BUT THE POINT IS WE STILL HAVE A GREAT DEAL TO LEARN ABOUT HUMAN EMBRYONIC STEM CELLS. WE'RE STILL IN EARLY DAYS, AND ALMOST EVERYBODY WE TALK TO, DIDN'T MATTER, ACADEMIA, INDUSTRY, WHEREVER, EMPHASIZED THAT FACT, THAT THERE'S STILL A GREAT DEAL TO LEARN ABOUT THESE CELLS AND HOW THEY BEHAVE.

AND THE SECOND POINT IS THAT CELL REPLACEMENT THERAPY REPRESENTS IN MANY WAYS A NEW THERAPEUTIC MODALITY. ALTHOUGH THERE ARE CELLULAR THERAPIES, BONE MARROW TRANSPLANT, FETAL TRANSPLANTS, THAT THESE

INVOLVE, IN GENERAL, MINIMAL MANIPULATION. AT THE POINT IN WHICH YOU BEGIN MANIPULATING CELLS, THAT IS, AT WHICH YOU BEGIN DIFFERENTIATING THEM AND DOING OTHER THINGS, THEN THERE IS ALWAYS THE POSSIBILITY OF INTRODUCING VIRUSES OR INTRODUCING MUTATIONS OR WHATEVER. AND SO THE STANDARDS OF SAFETY, I WOULD SAY, AND HOW ONE WILL GO ABOUT THIS, I THINK, ARE SOMETHING THAT WILL HAVE TO BE WORKED OUT WITH THE FDA OVER THE YEARS. I DON'T THINK THEY KNOW, AND I DON'T THINK WE KNOW EXACTLY.

ED PENHOET AND I WERE AT THE INSTITUTE OF MEDICINE YESTERDAY FOR A SYMPOSIUM ON STEM CELLS, AND GEORGE DALY, WHO'S ON OUR SCIENTIFIC ADVISORY COMMITTEE, MADE A PLEA FOR PATIENT-SPECIFIC CELL LINES, WHICH HE THOUGHT WERE GOING TO BE THE THERAPY OF THE FUTURE. AND WE ENGAGED IN A DISCUSSION THAT I THINK WE DON'T KNOW THE ANSWER TO, AND THAT IS WHAT WOULD BE THE RULES FOR PRECLINICAL DEVELOPMENT FOR PATIENT-SPECIFIC CELL LINES? HOW MUCH WOULD YOU BE ABLE TO RELY ON A STANDARD PROCESS IN WHICH YOU COULD TAKE ANYBODY'S CELLS AND PUT IT THROUGH? OR WOULD YOU HAVE TO HAVE APPROVALS FOR EACH OF THOSE CELL LINES? AND I THINK THESE ARE ISSUES THAT WE DON'T YET REALLY KNOW AND WILL NEED TO THINK ABOUT AS WE GO FORWARD.

OKAY. SO WITH THAT BACKGROUND THEN, LET'S

GET TO THE HEART OF THE MATTER. AND IT SEEMED TO US THAT GOAL NO. 1 WAS THE MOST IMPORTANT GOAL OF THE PROJECT. AND THAT IS TO HAVE CLINICAL PROOF OF PRINCIPLE, THAT TRANSPLANTED CELLS DERIVED FROM PLURIPOTENT CELLS CAN BE USED TO RESTORE FUNCTION FOR AT LEAST ONE DISEASE.

NOW, WHAT THAT MEANS IS THAT WE NEED A SIGN OF EFFICACY. WE NEED SOME SENSE THAT IN A CLINICAL TRIAL THAT TRANSPLANTED CELLS DID WORK IN HUMANS TO RESTORE FUNCTION. AND WHAT THAT MEANS IS THAT WE NEED TO COMPLETE A PHASE II CLINICAL TRIAL FOR AT LEAST ONE DISEASE AND ONE THERAPY.

NOW, WE PRESENTED OUR TEN GOALS AT THE STRATEGIC PLAN ADVISORY COMMITTEE SEVERAL WEEKS AGO, AND WE HAD QUITE A LIVELY DISCUSSION ABOUT WAS THIS AMBITIOUS ENOUGH? WAS IT TOO AMBITIOUS? AND THERE WAS A LOT OF DISCUSSION BACK AND FORTH ABOUT THIS, AND IN GENERAL THE SEASONED VETERANS WHO HAD HAD SOMETHING TO DO WITH THIS SAID, WELL, MAYBE. OKAY. AND I THINK THE GENERAL CONSENSUS WAS THAT THIS IS AN AMBITIOUS, BUT ACHIEVABLE GOAL. AND IT IS A VERY, VERY IMPORTANT ONE BECAUSE I THINK IF WE HAVE THAT, THEN IT WILL ATTRACT INTEREST, IT WILL ATTRACT MONEY, IT WILL MAKE A HUGE DIFFERENCE IN THE WAY IN WHICH WE GO ABOUT THIS, AND THAT THE RESOURCES THAT WILL BE AVAILABLE TO PUSH IT

FORWARD INTO FURTHER AREAS, BUT THAT IS OUR KEY.

NO. 2, WE WOULD LIKE, THEN, TO HAVE SEVERAL OTHER DISEASES IN WHICH WE HAVE THERAPIES BASED ON STEM CELL RESEARCH IN PHASE I OR PHASE II CLINICAL TRIALS. AND THAT, AGAIN, IS AN AMBITIOUS GOAL FOR TEN YEARS. AND I MIGHT SAY THAT IT'S POSSIBLE THAT EVENTS WILL WORK OUT IN SUCH A WAY THAT WE WILL ACHIEVE THESE GOALS BEFORE TEN YEARS, AND WE WOULD ALL BE DELIGHTED IF THAT WERE THE CASE. BUT FOR SOME OF THE FACTORS THAT I'VE MENTIONED, THE ATTRITION IN PARTICULAR, THE LONG TIME LINE JUST TO WORK YOUR WAY THROUGH ALL OF THESE STEPS, THESE SEEM TO US TO BE IMPORTANT, AMBITIOUS, BUT ACHIEVABLE, AND ONES THAT WE WERE WILLING TO COMMIT TO, THAT WE THINK WE CAN DO THIS.

ALL RIGHT. GOAL 3 IS REALLY AN OUTCOME. IF WE'RE SUCCESSFUL IN 1 AND 2, THEN WE BELIEVE WE'LL BE ABLE TO ATTRACT PRIVATE CAPITAL FOR PHASE III. IN FACT, ONE OF OUR INTERVIEWEES EARLY ON, VERY DISTINGUISHED AND SHREWD PERSON, SAID THAT IF AT THE END OF TEN YEARS WE HAD RESULTS, IT WOULD CONVINCE BIG PHRMA TO PUT MONEY INTO THIS. HE SAID NOBODY COULD ASK YOU TO DO MORE.

SO I THINK THAT'S ONE WAY OF PUTTING IT, BUT I THINK IT EMPHASIZES THAT THE RESOURCES TO GO ON PAST PHASE II AND INTO PHASE III CLINICAL TRIALS WILL BE

VERY LARGE, AND WE NEED THE EXPERTISE AND THE CAPITAL, I THINK, OF THE PHARMACEUTICAL INDUSTRY TO DO THAT. I'M CONFIDENT IT WILL COME IF WE'RE ABLE TO PRODUCE THESE RESULTS.

NOW, NO. 4 IS A PROBLEM THAT CAME UP AGAIN AND AGAIN. THAT IS, YOU TRANSPLANT CELLS IN; AND UNLESS THERE IS A MATCH, THEN YOU HAVE AN IMMUNE RESPONSE TO THOSE CELLS. AND SO THE ISSUE OF HOW TO DEAL WITH THAT. IT'S A MAJOR PROBLEM IN BONE MARROW TRANSPLANTS. EVEN WITH HISTOCOMPATIBILITY MATCHING AND BANKS AND SO FORTH, STILL THERE ARE SERIOUS SIDE EFFECTS. AND MANY OF THE FAILURES IN EARLY STAGE PATIENTS ARE DUE, IN FACT, TO COMPLICATIONS THAT ARISE FROM THE LACK OF TOLERANCE. WE BELIEVE THAT ACTUALLY STEM CELLS CAN BE USED IN VARIOUS WAYS TO ACHIEVE IMMUNE TOLERANCE. AND SO THAT IS AN IMPORTANT EMPHASIS THAT WE THINK WILL HAVE BROAD IMPLICATIONS ACROSS DISEASES AND FOR THE THERAPY IN GENERAL.

WE WOULD LIKE TO HAVE PROOF OF PRINCIPLE FOR THERAPIES IN PRECLINICAL MODELS. BY THAT WE MEAN ANIMAL MODEL SYSTEMS IN SIX OR EIGHT -- FOR SIX OR EIGHT DISEASES. AND THEN WE ARE VERY INTERESTED IN USING, OF COURSE, THE PLURIPOTENT CELLS TO FORM HUMAN DISEASE-SPECIFIC LINES. AND WE BELIEVE THAT, ALTHOUGH THE TECHNOLOGY FOR THAT IS NOT QUITE AVAILABLE, THAT WE

THINK IT WILL BE SOON. AND THAT BY THE END OF TEN YEARS, WE SHOULD HAVE DISEASE-SPECIFIC LINES FOR 20 OR 30 DISEASES. I THINK THAT'S A VERY EXCITING PROSPECT FOR ALL OF US.

THE NEXT GOAL, NO. 7, ON THE NEXT SLIDE IS NEW PROCEDURES FOR LARGE-SCALE GMP PRODUCTION OF STEM AND PROGENITOR CELLS. THERE IS ALREADY WORK ON THIS WORLDWIDE, BUT IT IS CLEAR THAT WE WILL NEED TO HAVE PROCEDURES FOR PRODUCING LARGE AMOUNTS. THIS MAY INVOLVE AUTOMATION. IT CERTAINLY WILL INVOLVE USING PROBABLY DEFINED MEDIA. IT MAY INVOLVE SOPHISTICATION ABOUT MATRICES. THERE'S A WORLD OF TECHNOLOGY THERE THAT NEEDS TO BE DEVELOPED AND WILL BE IMPORTANT FOR OUR ULTIMATE AIMS.

A THOROUGH UNDERSTANDING OF THE STEPS OF STEM CELL DIFFERENTIATION. IN THE MOUSE HEMATOPOIETIC STEM CELL SYSTEM, THANKS TO THE WORK OF IRV WEISSMAN AND OTHERS, USING SUITABLE MARKERS, ONE CAN DEFINE EVERY STAGE IN THE DEVELOPMENT FROM ADULT STEM CELLS, HEMATOPOETIC STEM CELLS, THROUGH VARIOUS PROGENITORS, MULTISTAGE, ALL THE WAY OUT TO THE MULTIPLE WHITE AND RED AND PLATELET PRODUCTS OF THE BLOOD SYSTEM. AND THOSE HAVE BEEN CHARACTERIZED IN THE MOUSE FOR SURFACE MARKERS AND FOR CHANGES IN GENE EXPRESSION. CONSIDERABLE IS KNOWN ABOUT THE PATHWAYS OF

DIFFERENTIATION. WE WOULD LIKE TO HAVE COMPARABLE INFORMATION FOR HUMAN EMBRYONIC STEM CELLS. AND THAT IS A LARGE-SCALE, MAJOR GOAL. IT WILL MAKE THE WORK INCREDIBLY EASIER IF WE WERE ABLE TO DO THAT.

GOAL 9 IS A THOROUGH UNDERSTANDING OF FACTORS REGULATING SELF-RENEWAL AND ONCOGENIC POTENTIAL OF STEM CELLS. THIS IS THE YEN AND THE YANG. THE POWER OF STEM CELLS IS THEIR ABILITY TO EXPAND ALMOST INDEFINITELY. AND THE FRIGHTENING THING ABOUT THEM IS THAT IF THAT'S OUT OF CONTROL, OF COURSE, THEN YOU HAVE POSSIBILITY OF TUMORS. AND SO THIS IS EXTREMELY IMPORTANT TO UNDERSTAND.

AND THEN FINALLY, WE SEE STEM CELLS AS THE BEGINNING OF A WHOLE NEW TECHNOLOGY. ED AND I HEARD SOME INTERESTING EXAMPLES JUST YESTERDAY AT THE INSTITUTE OF MEDICINE IN TISSUE ENGINEERING WHERE YOU TAKE DIFFERENT KINDS OF STEM CELLS WITH ARTIFICIAL MATRICES AND YOU'RE ABLE TO CREATE IN VITRO TISSUES THAT CAN BE TRANSPLANTED AND USED TO REPLACE HUMAN PARTS. THIS IS A VERY EXCITING FRONTIER. THERE'S CONSIDERABLE PROGRESS THAT'S BEEN MADE ON IT ALREADY, BUT IT FITS IN VERY NICELY WITH THE IDEA OF USING STEM CELLS AS THE SOURCE OF THE VARIOUS KINDS OF CELLS IN THE TISSUES AND THEN PUTTING IT TOGETHER IN A COMPLICATED WAY AND IN A THREE-DIMENSIONAL STRUCTURE

THAT IS APPROPRIATE FOR WHATEVER ORGAN OR TISSUE THAT YOU ARE TRYING TO LOOK AT.

NOW, LET ME SAY THAT WE THEN OUTLINED OUR FIVE-YEAR GOALS, AND I WON'T GO THROUGH EACH OF THESE ONE BY ONE. I THINK THE TEN-YEAR GOALS WERE IMPORTANT, BUT THE FIVE-YEAR GOALS ARE REALLY MEANT TO SAY IF WE'RE GOING TO GET TO TEN-YEAR GOALS, WHAT DO WE HAVE TO DO IN THE NEXT FIVE YEARS? AND SO WE NEED RIGHT AWAY TO GET SOME THERAPIES BASED ON STEM CELL RESEARCH IN PRECLINICAL DEVELOPMENT SO THAT WE CAN MOVE THEM RIGHT ON THROUGH. WE NEED TO FIND OUT HOW TO MAKE STEM CELL LINES. WE NEED TO GET DISEASE-SPECIFIC STEM CELLS AND SO FORTH, AND WE NEED TO ESTABLISH A STEM CELL BANK.

SO WE WON'T GO THROUGH ALL OF THESE, BUT JUST TO SAY THAT THEY ARE MEANT TO DIRECT US TOWARD OUR TEN-YEAR GOALS AND ALSO TO PROVIDE BENCHMARKS AGAINST WHICH WE CAN ASSESS OUR PROGRESS AT FIVE YEARS.

SO LET ME THEN TALK ABOUT THE NEXT ISSUE, AND THAT IS HOW ARE WE GOING TO ACCOMPLISH THESE VARIOUS AIMS? WELL, WE WILL HAVE A SERIES OF INITIATIVES IN PARTICULAR AREAS. WHAT WE DID ACTUALLY WAS TO TAKE MATERIAL FROM ALL OF OUR SOURCES OF INFORMATION, TRY TO COMBINE IT, AND PUT IT TOGETHER IN WHAT SEEMED TO US SENSIBLE WAYS, ORGANIZE IT, THEN, AROUND INITIATIVES,

SOME RATHER NARROW, SOME RATHER BROAD, AS YOU WILL SEE, BUT ALL INTENDED TO GET US TO OUR GOAL.

AND WE FOUND AS WE THOUGHT ABOUT THESE THAT THEY WERE ALMOST TOO COMPLEX TO CHARACTERIZE IN ANY SINGLE WAY. AND SO WE HIT ON THIS IDEA OF HAVING TWO-DIMENSIONAL SPACE IN WHICH WE REPRESENTED THEM ALONG TWO AXES ACCORDING TO TWO SETS OF VALUES, AND YOU SEE THAT IN THE NEXT SLIDE. THE TOP IS REALLY A VERSION OF THE ARROW THAT YOU SAW BEFORE GOING FROM BASIC RESEARCH TO CLINICAL RESEARCH, AND WE MOVED PRECLINICAL RESEARCH AND DEVELOPMENT TOGETHER FOR THIS PURPOSE. SO WE HAVE LAYING THE FOUNDATION, PREPARING FOR THE CLINIC, AND CLINICAL RESEARCH. SO THAT PROVIDES ONE PART OF IT.

AND THE SECOND IS THE KINDS OF RESOURCES THAT WE HAVE AT OUR DISPOSAL. THAT IS, WHAT KINDS OF THINGS DO WE NEED IN ORDER TO GET THIS, CUTTING ACROSS THOSE VARIOUS -- THAT PROGRESSION FROM THE LABORATORY TO THE CLINIC. AND THOSE ARE ON THE LEFT: SCIENTIFIC TRAINING AND DEVELOPMENT, INNOVATION SCIENCE, MISSION-ORIENTED SCIENCE. WE HAVE ALSO SOME SPECIAL CIRM PROGRAMS THAT SHOULD BE NOTED THERE. TOOLS, TECHNOLOGIES, AND INFRASTRUCTURE, FACILITIES, AND THEN COMMUNITIES OF SCIENCE, AND RESPONSIBILITY TO THE PUBLIC.

AND WHAT WE THEN PROCEEDED TO DO WAS TO THINK ABOUT EACH OF THESE. AND THERE'S A MAJOR SECTION IN OUR STRATEGIC PLAN IN WHICH WE ADDRESS EACH ONE OF THESE AREAS; THAT IS, EACH ONE OF THE HORIZONTAL SEGMENTS AND EACH ONE OF THE VERTICAL SEGMENTS, AND TALK ABOUT THE NEEDS, THE OPPORTUNITIES, THE CHALLENGES. WE TRY TO RELATE THEM TO THE STRATEGIC PRINCIPLES AND THE VALUES THAT YOU LAID OUT. AND IT GIVES US -- WE CAN ACTUALLY PLACE AN INITIATIVE WITHIN THIS SPACE AT VARIOUS PLACES, AND IT GIVES US A RICH CONTEXT IN WHICH TO CONSIDER AND A WAY TO ORDER THEM. WE HAVE SOME GRAPHICAL MEANS OF DOING THAT IN THE STRATEGIC PLAN. UNFORTUNATELY THEY DIDN'T TRANSLATE VERY WELL TO POWERPOINT, SO I WILL LET YOU SEE THEM, BUT WE'LL COME TO THEM IN A DIFFERENT FORM IN A MOMENT.

NOW, WHAT ABOUT THE INITIATIVES? WE TOOK ALL THE INFORMATION THAT WE HAD, AND WE TRIED TO PUT THEM TOGETHER. AND THERE ARE SEVERAL POINTS TO BE MADE ABOUT THEM. FOR EACH INITIATIVE WE WROTE A SECTION THAT DESCRIBED OUR GOALS AND WHAT WE HOPED TO GET OUT OF IT AND TO PROVIDE THE BACKGROUND FOR WHY WE WERE INTERESTED IN THAT PARTICULAR INITIATIVE. WE THEN TALKED ABOUT THE ACTIVITIES RELATED TO THAT INITIATIVE. THAT IS, WHETHER WE MIGHT HAVE AN RFA OR A WORKSHOP OR WHATEVER WE MIGHT WANT TO DO. WE THEN MADE A DOLLAR

ESTIMATE BASED ON THAT. HOW MANY GRANTS? HOW LARGE? AND HOW MANY YEARS? AND I'LL COME BACK TO THAT.

AND THEN I WANT TO MAKE A COUPLE POINTS ABOUT THEM. FIRST OF ALL, THE INITIATIVES, THESE ARE NOT FINAL. THEY'RE NOT MEANT TO BE WRITTEN IN STONE. EACH RFA THAT DERIVES FROM AN INITIATIVE WILL COME TO THE ICOC, AND WE'LL DISCUSS THE REASONS FOR IT, THE SCOPE OF IT, AND HOW MANY GRANTS WE WANT TO GIVE, HOW LONG, HOW MUCH MONEY, AND WHAT THE DOLLAR IMPLICATION IS. THAT IS, WE WILL HAVE A BUDGET FIGURE JUST AS WE HAVE DONE FOR THE RFA'S THAT WE'VE PUT OUT SO FAR.

WE HAVE USED THE BUDGET. IT'S IMPORTANT TO HAVE A BUDGET FIGURE, SO WE CAN FIGURE OUT IF WE HAVE ENOUGH MONEY TO DO ALL THE THINGS WE WANT TO DO AND TO THINK ABOUT HOW THE MONEY IS GOING TO BE PLAYED OUT OVER TIME. BUT THESE FIGURES ARE NOT IMMUTABLE. ONE SUGGESTION WAS WHY DIDN'T WE GIVE A RANGE. THAT MAKES THE CALCULATIONS MUCH MORE COMPLICATED, SO JUST IMAGINE THAT EACH OF THESE FIGURES REPRESENTS THE MIDPOINT OF A RANGE, IF YOU WILL. THEY'RE MEANT TO BE APPROXIMATE AND TO HELP US IN THINKING ABOUT IT, NOT TO BE DEFINITIVE.

SECONDLY, MANY TOPICS, AS YOU LOOK THROUGH THESE, WE HAVE 25 DIFFERENT INITIATIVES. AND THERE ARE MANY, MANY TOPICS IN WHICH WE ARE NOT EXPERTS AND WE

SIMPLY DIDN'T HAVE THE TIME TO GO OUT AND BECOME EXPERTS ON THEM. AND SO WHAT WE WILL DO IN THOSE CASES IS TO HOLD WORKSHOPS IN PARTICULAR AREAS. THE EXAMPLE OF AUTOMATION THAT I MENTIONED EARLIER IS A GOOD EXAMPLE. WE DON'T HAVE THE EXPERTISE. MOST OF YOU DON'T. AND I THINK WHAT WE NEED TO DO IS TO GET TOGETHER SOME BIOLOGISTS KNOWLEDGEABLE ABOUT CELL CULTURE, WE NEED TO GET TOGETHER ENGINEERS, WE NEED TO GET NANOTECH PEOPLE AND TALK ABOUT WHAT THE OPPORTUNITIES ARE, AND TO HAVE A SORT OF MINI VERSION OF OUR MEETING LAST YEAR AND TO FIND OUT. OUT OF THAT WILL COME A BETTER SENSE OF WHAT WE SHOULD BE DOING.

SO WE WILL BE DOING THOSE QUITE REGULARLY. AND, THEREFORE, OUR PRIORITIES, OUR TOPICS, AND OUR BUDGETS MAY VERY WELL BE ALTERED AS WE GO THROUGH THIS. SO ALL THIS IS MEANT TO LAY IT OUT. THIS IS SOMETHING THAT WE ARE PUTTING OUT THERE TO GUIDE US, BUT IT'S NOT MEANT TO CONFINE US IN ANY WAY. THAT'S REALLY THE POINT.

NOW, THE NEXT SLIDE JUST SHOWS THE 25 INITIATIVES. YOU WILL BE RELIEVED TO KNOW I WILL NOT GO THROUGH ONE BY ONE IN GREAT DETAIL. THEY ARE WRITTEN UP IN YOUR BOOKS, AND WE WOULD BE HAPPY TO TALK ABOUT ANY ONE OF THEM IF YOU PLEASE. WE'VE GONE INTO A GOOD DEAL OF DETAIL, AS I THINK YOU SEE, AS YOU LOOK

THROUGH THEM.

I WANTED TO CALL OUT ONE INITIATIVE THAT WE THINK IS VERY INTERESTING, A CIRM SPECIAL PROGRAMS INITIATIVE. AND THIS REALLY AROSE DIRECTLY OUT OF OUR FACT-FINDING. WE HAD IN OUR FIRST TWO MEETINGS, FOR THOSE OF YOU WHO MAY HAVE ATTENDED, WE HAD SEVERAL SPEAKERS WHO TALKED ABOUT WAYS OF ORGANIZING GRANT ACTIVITY AND ORGANIZING SCIENCE THAT REALLY REPRESENTED AN INNOVATION, THAT REPRESENTED A DIFFERENT WAY OF GOING ABOUT THINGS FROM THE USUAL WAY, WHICH IS FOR MOST OF US NIH. WE ALSO TALKED TO SEVERAL PEOPLE AND HAD SOME PRESENTATIONS THAT WERE VERY INFLUENTIAL IN OUR THINKING ABOUT THIS.

AND SO WE WANTED TO BE INNOVATIVE IN THIS AREA. WE WANTED NOT TO DO JUST THE SAME OLD THINGS. AND SO WE HAVE AN INITIATIVE, THEN, IN WHICH WE COULD REGARD AS A SORT OF EXPERIMENT IN WHICH WE TRY TO ORGANIZE SCIENTISTS AND CLINICIANS IN NEW WAYS AND ENGINEERS TO GET JOBS DONE. AND THE BASIC CONCEPT IS TO HAVE TEAMS, COLLABORATIVE TEAMS, ACROSS INSTITUTIONS TO TRY TO GET THE BEST PEOPLE IN CALIFORNIA FOR A PARTICULAR JOB AND OUTSIDE OF CALIFORNIA IF WE CAN FIND FUNDING THAT WOULD PAY FOR THOSE PEOPLE TO GO ALONG WITH US THAT WE COULD CO-FUND.

WE ARE INTERESTED IN PROJECTS IN WHICH THERE

IS A SPECIFIC GOAL OR A SET OF GOALS WITH A TIMELINE AND MILESTONES. HERE'S WHAT WE'RE GOING TO DO. HERE'S HOW WE'RE GOING TO DO IT, ABCD, NOT OPEN-ENDED RESEARCH, BUT VERY MUCH GOAL-DIRECTED RESEARCH.

AND THE THIRD POINT WAS THAT IT SHOULD BE STRONGLY MANAGED. WE HEARD A NUMBER OF CASES THAT LED US TO BELIEVE THAT THIS COULD BE VERY, VERY PRODUCTIVE FOR US. AND ACTUALLY ARE IDEAS THAT WE WOULD EVEN PROVIDE FUNDS TO GET AN OUTSIDE PROJECT MANAGER, SOMEBODY WITH EXPERIENCE IN PROJECT MANAGEMENT TO A SPECIFIC GOAL, WHETHER IT'S DRUG DEVELOPMENT OR WHATEVER IT MIGHT BE, THAT WOULD ACTUALLY ORGANIZE THE PROJECT.

ONE KIND OF TEAM WOULD BE DISEASE TEAMS. THAT IS, TO GET THE BEST PEOPLE ACROSS THE STATE FOR A PARTICULAR DISEASE AND SAY HERE'S WHAT WE ARE GOING TO DO. WE'RE GOING TO DO SOME BASIC RESEARCH AND FIND OUT -- ANSWER THIS QUESTION. WE'RE GOING TO USE THAT, THEN, TO GO AHEAD AND COME UP WITH A THERAPY FOR THIS DISEASE. WE'RE GOING TO THEN CARRY OUT THE FOLLOWING STEPS TO TRY TO GET THIS INTO PRECLINICAL DEVELOPMENT AND THEN EVENTUALLY TO THE CLINIC. AND WE THINK BY HAVING A GROUP OF PEOPLE COMMITTED OVER A LONG TIME TO A PROJECT, AND UNDERSTANDING THAT THE PROJECT MOVES FROM PHASE TO PHASE TO PHASE, WE THINK WILL BE VERY

VALUABLE. AND THEN, FINALLY, WE HAVE RESEARCH TEAMS.

FOR THOSE OF YOU WHO ARE GETTING HUNGRY, I JUST HAVE A LITTLE BIT MORE TO GO. I'VE JUST GOTTEN A NOTE SAYING FOOD IS READY, SO THAT'S AN IMPETUS TO US ALL. WHAT I'D LIKE TO DO IS ACTUALLY FINISH UP THIS GENERAL OVERVIEW. MAYBE WE CAN GO OUT AND GET FOOD AND THEN WE CAN COME BACK AND HAVE QUESTIONS, AND THEN WE CAN TALK ABOUT SOME OF THE SPECIFIC INITIATIVES.

AT ANY RATE, THIS IS SOMETHING THAT WE THINK IS VERY EXCITING. THE FINAL POINT I FAILED TO MENTION ON THAT IS THAT WE WOULD HAVE INVOLVEMENT OF CIRM IN IT. AND FOR THOSE OF YOU WHO HEARD THE PRESENTATION BY JILL HEEMSKERK OF NINDS OF THEIR DRUG SCREENING EFFORTS, THIS WAS A PROMINENT FEATURE. AND WE HEARD A LOT FROM SEVERAL FUNDING AGENCIES ABOUT SO-CALLED ACTIVE MANAGEMENT. THAT IS, YOU DON'T SIMPLY GIVE PEOPLE MONEY AND GO AWAY AND COME BACK AND SAY, WELL, LET US KNOW IN FOUR YEARS HOW YOU DID, BUT THAT YOU MEET WITH THEM ON A REGULAR BASIS, OFTEN FORMING PART OF A STRATEGIC PLANNING COMMITTEE OR GUIDANCE COMMITTEE THAT THEN MAKES DECISIONS ABOUT HOW IT GOES THROUGH.

NOW, WE DON'T HAVE THE LUXURY OF HAVING ENOUGH STAFF TO DO THIS AS A WAY OF DOING BUSINESS ACROSS THE BOARD, BUT WE THINK IT WOULD BE VERY INTERESTING TO TRY THIS OUT BOTH FOR DISEASE PURPOSES

AND ALSO FOR OTHER GOALS, OTHER PURPOSES THAT MAY BE TECHNOLOGICAL, THAT MAY BE BIOLOGICAL, WHATEVER THEY ARE. AND WE LOOK FORWARD TO TRYING THAT ACTIVITY.

OKAY. BUDGET. HOW DO WE DO THE BUDGET? WE BEGAN BY -- ACTUALLY AMY LEWIS IS RESPONSIBLE FOR MUCH OF THIS WORKING WITH TONY AND PATRICIA. SHE WORKED WITH BOB KLEIN AND HIS OFFICE TO ESTIMATE HOW MUCH MONEY WILL BE COMING IN FROM THE BOND ISSUANCE EACH YEAR. AND THE ASSUMPTIONS BEHIND THAT ARE IN, I THINK IT'S, APPENDIX 3. THEN WE ESTIMATED THE BUDGETS FOR EACH INITIATIVE BASED ON WHATEVER THEY WERE, WORKSHOPS, RFA'S, BASED ON HOW MANY YEARS, HOW MANY GRANTS, HOW MUCH PER GRANT, HOW LONG WE WERE GOING TO CONTINUE THE INITIATIVE, AND WE CAME UP WITH A DOLLAR FIGURE. AND WE DREW UP A DETAILED YEAR-BY-YEAR PLAN, WHICH IS, I THINK, IN APPENDIX D 3, IF I'M NOT MISTAKEN. IT'S PRACTICALLY THE VERY LAST THING IN THE BOOK THAT AMY LEWIS DREW UP THAT BASICALLY SHOWS YEAR BY YEAR HOW MUCH WE WILL BE FUNDING.

THE GOOD NEWS IS THAT WE FOUND THAT WE ARE ABLE TO DO IN A REASONABLE TIMEFRAME ALL OF THE INITIATIVES THAT WE WANTED TO DO AND THAT WE HAVE A SMALL AMOUNT OF MONEY LEFT OVER EACH YEAR WHICH WE MIGHT CONSIDER AS OPPORTUNITY FUNDS. SO THIS IS NICE ACTUALLY BECAUSE IT GIVES US SOME WIGGLE. IT MEANS

WE'RE NOT PLANNED OUT TO THE WALLS. IF SOMETHING NEW COMES UP, AT LEAST FOR FIRST APPROXIMATION, WE HAVE THE POSSIBILITY OF FUNDING IT OR STARTING IT ON A SMALL SCALE TO SEE IF IT WORKS WITHOUT TAKING MONEY NECESSARILY AWAY FROM OTHER THINGS. SO THIS IS MEANT TO LET US HAVE FLEXIBILITY, WHICH WAS ONE OF THE VALUES THAT WERE ADOPTED.

OH, YES. THE NEXT THING I WANTED TO SAY WAS WE THEN TOOK THAT BUDGET, AND WE MADE AN ESTIMATE FOR EACH OF THE INITIATIVES OF HOW MUCH WAS, ACCORDING TO OUR ARROW, ON THE PATHWAY TO THE CLINIC -- I THINK THAT'S IN THE NEXT SLIDE -- LAYING THE FOUNDATION, PREPARING THE CLINIC, AND CLINICAL RESEARCH. SO WE TOOK OUR INITIATIVES, WE COMBINED THEM UNDER THE VARIOUS ELEMENTS THAT WE HAD ON THE VERTICAL AXIS THERE, AND YOU CAN SEE WHAT WE LAID OUT. FOR EXAMPLE, SCIENTIFIC TRAINING AND DEVELOPMENT WILL INVOLVE MONEY IN ALL OF THOSE AREAS. MISSION-DIRECTED SCIENCE, MOST OF THEM ACTUALLY PLAYED OUT ACROSS THE VARIOUS WAYS. WE MADE SOME ASSUMPTIONS IN DOING THAT, BUT IT LET US SEE HOW MUCH WE WERE SPENDING IN THE THREE AREAS, AND IT COMES OUT ROUGHLY THIRDS: 823 MILLION FOR THE FUNDAMENTAL WORK; A LITTLE BIT MORE, 899 FOR PREPARING THE CLINIC; AND A LITTLE BIT LESS, A BIT LESS, 656 MILLION FOR CLINICAL RESEARCH.

I MIGHT COMMENT ON THAT. BECAUSE SO LITTLE IS KNOWN ABOUT THE FUNDAMENTAL BIOLOGY OF THESE CELLS, THERE IS A DISTINCT AMOUNT THAT WE NEED TO DO IN LAYING THE FOUNDATION. THE LARGEST IS PREPARING FOR THE CLINIC, AND I THINK THAT REFLECTS BOTH THE TIME COURSE OF WHAT WE'RE DOING AND ALSO OUR EXPECTATION THAT THINGS WILL BE MOVING TOWARD THE CLINIC.

THE CLINICAL RESEARCH IS RELATIVELY LESS BECAUSE THAT COMES AT THE END OF THE PROCESS, AND WE WILL BE DOING MORE OF IT AS WE GO ALONG, BUT MUCH OF THE MOST IMPORTANT AND MOST EXPENSIVE OF THAT WILL BE DONE PAST THE TEN-YEAR ARBITRARY LINE THAT WE'VE DRAWN. AND THEN, ALSO, WE MADE THE ASSUMPTION THERE THAT WOULD BE CLINICAL TRIALS, THAT WE WOULD FIND PARTNERS THAT WOULD SPLIT 50-50 THE CLINICAL TRIALS WITH US.

SO THAT'S THE GENERAL OUTLINE. IT SORT OF GAVE US A SENSE OF WHERE WE WERE PUTTING OUR MONEY AND A WAY OF ANALYZING IT AND THINKING ABOUT IT AND SEEING IF WE WERE BALANCED IN ALL THE THINGS THAT WE HAVE TO DO. OUR SENSE WAS THAT IT CAME OUT ABOUT RIGHT, AND WE WOULD APPRECIATE ANY COMMENTS YOU HAVE ABOUT THAT.

THE NEXT SLIDE, I THINK, MAKES THE POINT -- THIS IS THE NEXT TO THE LAST ONE HERE -- THAT IN SHERRY LANSING'S IMMORTAL PHRASE, THIS IS A LIVING PLAN. IT WILL CHANGE. WE WILL BE FLEXIBLE. WE WILL MODIFY IT.

AND WE SUGGESTED A FORMAL PROCESS. WE THOUGHT THREE YEARS AND SEVEN YEARS. WE CHOSE THREE BECAUSE THAT WAS A TIME AT WHICH YOU COULD START TO SAY HOW ARE WE DOING ON OUR FIVE-YEAR GOALS. AND AS YOU WILL HEAR LATER, OUR PLAN IS TO LAY OUT A FAIRLY DETAILED THREE-YEAR OPERATIONAL PLAN FOR WHAT WE'RE GOING TO DO. AND BY THEN YOU WILL NEED TO THINK IN MORE SPECIFIC TERMS, WE ALL WILL, ABOUT THE NEXT THREE YEARS. SO THAT WOULD BE A TIME TO DO THAT.

AND THEN AT THE SEVEN-YEAR MARK, AGAIN, YOU'D WANT TO SEE HOW YOU'RE DOING WITH RESPECT TO YOUR TEN-YEAR GOALS, AND THAT WOULD BE, AGAIN, A TIME TO SET UP ANOTHER THREE YEARS OF VERY DETAILED PLANS.

THE IDEA IS THAT IF YOU'RE AHEAD OF YOUR GOALS, THEN YOU SET THE NEXT ONES TO BE MORE AMBITIOUS. IF YOU'RE RUNNING BEHIND, YOU NEED TO KNOW WHY, AND YOU NEED TO KNOW IF YOU NEED TO MAKE ADJUSTMENTS OR WHAT YOU NEED TO DO, OR MAYBE YOU NEED TO HAVE SOME NEW INITIATIVES TO SOLVE SOME PROBLEMS. IT MAY BE THAT CIRM WOULD SPONSOR A CONFERENCE AT THAT TIME, MUCH LIKE THE CONFERENCE BEFORE. OUR IDEA WOULD BE THAT WHATEVER BROAD GOALS, RECOMMENDATIONS ARE MADE BY THE REVIEW COMMITTEE WOULD BE BROUGHT TO THE ICOC, WHICH WOULD THEN APPROVE THE MODIFICATION. AND THEN THE PRESIDENT AND STAFF WILL THEN TRY TO CONVERT THAT INTO AN

OPERATIONAL PLAN MUCH LIKE THIS ONE FOR YOUR APPROVAL.

SO THAT WOULD BE OUR SUGGESTION. AGAIN, THAT CAN BE MODIFIED. THERE'S NOTHING WRITTEN IN STONE ABOUT THIS, BUT THIS SEEMED TO US, AT LEAST, AS A FIRST APPROXIMATION A GOOD WAY TO THINK ABOUT IT AND TO REMIND US THAT WE WILL BE ADJUSTING. THIS PROVIDES A FORMAL WAY OF DOING THAT.

NOW, WHAT ARE THE NEXT STEPS? WE ARE EAGER TO HEAR YOUR REACTIONS TO THESE. WE WILL MAKE MODIFICATIONS IN THE PLAN. NOW, I JUST REFERRED OBLIQUELY TO A SECTION THAT YOU MAY NOTICE IS BLANK, THAT'S WHAT WE CALL THE FIRST THOUSAND DAYS. AND DEPENDING ON YOUR PROCLIVITIES, YOU CAN THINK OF IT AS PEOPLE TALK ABOUT THE FIRST HUNDRED DAYS OF A NEW PRESIDENT. OR FOR THOSE OF YOU WHO LIKE FOOTBALL, YOU GO IN WITH THE FIRST 20 PLAYS SCRIPTED. SO IT'S OUR ATTEMPT, THEN, TO SAY ALL RIGHT. WE CAN HAVE THESE GENERAL THINGS. WHAT ARE WE GOING TO DO AND WHEN ARE WE GOING TO DO IT OVER THE NEXT THREE YEARS? EXACTLY WHAT ARE OUR RFA'S GOING TO BE? WHEN ARE WE GOING TO PUT THEM OUT? AND REALLY TO TRY TO LOOK FORWARD, THEN, AND SCHEDULE THAT RATHER TIGHTLY. DOESN'T MEAN IT CAN'T BE CHANGED, BUT TO LET'S SEE WHAT THE JOB THAT FACES US IS, SEE WHAT RESOURCES WE NEED, SEE HOW WE CAN GO ABOUT IT.

AND WE THOUGHT IT WAS PREMATURE TO DO THAT UNTIL WE GOT SOME SENSE FROM YOU OF WHETHER YOU AGREED WITH THE OVERALL DIRECTION ON INITIATIVES AND ALL THAT. WE WILL TAKE THAT INFORMATION THAT YOU GIVE US HERE AND WE WILL GO BACK AND THEN TRY TO PUT TOGETHER THAT VERY SPECIFIC PLAN, AND THEN WE'LL BRING IT ALL BACK TO THE ICOC FOR CONSIDERATION, MODIFICATION, APPROVAL IN DECEMBER.

SO THAT CONCLUDES, THEN, MY OPENING COMMENTS ABOUT THIS. I SUGGEST WE ADJOURN FOR DINNER AND THEN WE COME BACK, AND WE'D BE HAPPY TO ANSWER QUESTIONS. WE CAN DISCUSS SPECIFIC ITEMS THAT YOU MAY WISH TO DISCUSS, OR IT'S AN OPEN FLOOR THEN, AND WE WILL BE LISTENING VERY MUCH TO YOUR COMMENTS AND SUGGESTIONS. THANK YOU.

(APPLAUSE.)

CHAIRMAN KLEIN: THE DINNER, AS I UNDERSTAND IT, WILL BE SERVED IN THE COURTYARD ALONG THE WALKWAY THAT YOU CAME IN RIGHT AFTER THE MAIN LOBBY. ALL OF THE AUDIENCE IS INVITED TO EAT IN THE MAIN DINING ROOM, BUT FOR THE MEMBERS OF THE BOARD, THERE IS FOOD IN THAT SPECIFIC COURTYARD. IN ORDER TO EXPEDITE IT, I THINK THAT THE THOUGHT WAS, AND, DR. HALL, PLEASE GUIDE US HERE, THAT WE MIGHT SPEND MAYBE 45 MINUTES AT DINNER AND COME BACK RATHER THAN SPENDING A FULL HOUR BECAUSE

LEAVING MOST TIME FOR THE AGENDA. IS THAT REASONABLE FOR THE BOARD? OKAY. SO 45 MINUTES.

(A RECESS WAS TAKEN.)

CHAIRMAN KLEIN: IF WE COULD PLEASE RECONVENE. IF WE COULD PLEASE RECONVENE, WE HAVE A STRATEGIC PLAN IN FRONT OF US THAT WILL TAKE SOME TIME. WE MUST GET STARTED WITH IT NOW. THE BOARD NEEDS TO SET AN EXAMPLE OF HOW TIMELY WE CAN ACCOMPLISH THESE TIMELINES IN THE STRATEGIC PLAN. DR. HALL, YOU HAVE THE FLOOR.

DR. HALL: WELL, I WOULD TURN IT BACK TO THE COMMITTEE. I DON'T HAVE FURTHER SPECIFIC PREPARED STATEMENTS TO MAKE. WE'RE HERE TO LISTEN TO YOU, GET THE REACTIONS AND RESPONSES OF THE ICOC TO THE PLAN, ANY SUGGESTIONS, MODIFICATIONS. SO WE LOOK FORWARD TO HEARING YOUR COMMENTS. WE ARE PREPARED. WE HAVE ON THE SCREEN HERE, THE COMPUTER, DIFFERENT PIECES OF IT, SO IF YOU WANT TO TALK ABOUT ONE THING, WE CAN PUT IT UP ON THE SCREEN. SO WHATEVER WE -- I WOULD SAY LET'S OPEN IT UP FOR QUESTIONS, DISCUSSIONS. WE WANT VERY MUCH TO HEAR FROM YOU AT THIS STAGE.

CHAIRMAN KLEIN: I WOULD START WITH SOME GOOD NEWS. AND THAT GOOD NEWS IS THAT ON PAGE 103, IT NOTES THAT IN THE FIRST BULLET POINT, THE MAXIMUM AMOUNT OF NEW BONDS THAT CAN BE ISSUED IS CAPPED AT 350 MILLION

PER CALENDAR YEAR. THE GOOD NEWS IS IT'S NOT ACTUALLY CAPPED AT 350 MILLION UNLESS ALL PRIOR YEARS HAVE BEEN AT 350 MILLION. SO THIS IS A DRAFT.

IT'S AN EXCELLENT PIECE, BUT FROM APPENDIX D 2, YOU WILL SEE THAT THERE IS POINT 15 WHERE IT SAYS ASSUMING NO MORE THAN 350 MILLION IN GO BONDS IS ISSUED IN ANY ONE CALENDAR YEAR. I WANT TO ASSURE YOU THAT THAT'S JUST AN ASSUMPTION BECAUSE CERTAINLY IF YOU WORK THROUGH THE NUMBERS, YOU WOULD FIGURE OUT THAT THE 2007, IF WE WERE CAPPED AT 350 MILLION A YEAR, THE NUMBERS WOULDN'T WORK BECAUSE WE HAVE $150 MILLION TO REFINANCE THE GOVERNOR'S LOAN, PLUS 45 MILLION IN BAN'S PLUS CAPITALIZED INTEREST, THAT'S 200 MILLION; AND IF WE WERE TO DO 150 MILLION IN FACILITIES, THAT'S 350 MILLION. THERE WOULD BE NO MONEY FOR RESEARCH. THAT IS NOT THE OUTCOME.

SO THIS IS AN INTERPRETATION, WHICH, IN FACT, IS CONSERVATIVE AND, IN FACT, BECAUSE WE HAVEN'T ISSUED 350 MILLION IN 2005 AND 2006, WE HAVE A ROLL-FORWARD CAPACITY WHICH WILL NOT CONSTRAIN US IN 2007.

WITH THAT FLEXIBILITY ON THE TABLE, ARE THERE BOARD COMMENTS? DR. FRIEDMAN.

DR. FRIEDMAN: JUST A COUPLE OF COMMENTS. I THINK THE DOCUMENT IS ASTONISHINGLY WELL WRITTEN.

DR. HALL: PARTICULARLY NOW THAT I HEARD IT,

COULD YOU SAY THAT A LITTLE LOUDER, PLEASE?

DR. FRIEDMAN: I SAID THERE'S NOT ENOUGH MONEY BEING SPENT ON THE HARD OF HEARING, AND I DEMAND THAT WE DON'T. I THINK THAT IT IS REALLY VERY CLEARLY AND VERY PROFESSIONALLY WRITTEN. THERE ARE A NUMBER OF THINGS THAT I REALLY LIKE ABOUT IT. I DO LIKE THE FORMALITY AND THE CLEAR SET OF EXPECTATIONS AND THE FORMAL INCORPORATION OF POINTS IN TIME WHEN WE WILL REVIEW AND BE SELF-CRITICAL. AND I THINK THAT THAT RIGOR AND THAT DISCIPLINE IS ABSOLUTELY ESSENTIAL, AND I CONGRATULATE THE GROUP FOR PUTTING THAT TOGETHER.

I'M NOT SURE THAT TONIGHT IS THE TIME FOR A LOT OF LITTLE POINTS OF DISCUSSION, ALTHOUGH OTHERS ON THE COMMITTEE MAY DISAGREE WITH ME. AND I THINK MY SUGGESTION IS TO LOOK AT THE BIG ISSUES AND SEE IS THERE ANYTHING THAT WE'VE FORGOTTEN. MY OWN VIEW IS THAT THE SORT OF PROPORTIONS THAT ARE LISTED HERE FOR THE VARIOUS INITIATIVES SEEM PRETTY MUCH OKAY TO ME. YOU COULD ARGUE THAT SOME COULD BE A LITTLE MORE, SOME COULD BE LESS, BUT I'M NOT SURE THAT AT THIS POINT, SINCE YOU'VE SET THESE OUT AS GENERAL GUIDELINES THAT WILL BE REVIEWED AS NEW OPPORTUNITIES OR NEW PROBLEMS ARISE, I'M NOT SURE THAT IT MAKES A WHOLE LOT OF SENSE. I THINK IT'S VERY IMPORTANT FOR US TO MAKE SURE THAT WE HAVEN'T LEFT THINGS OUT. AND IF WE HAVE, TO FIGURE OUT

HOW TO RECONFIGURE THE BUDGETS THAT ARE LEFT.

THERE ARE ONLY A COUPLE OF THINGS THAT I'D LIKE TO MENTION, NOT FOR DETAILED DISCUSSION TONIGHT BECAUSE I'M NOT SURE THAT'S THE APPROPRIATE WAY TO DO IT. I'M REALLY LOOKING AT THE CLINICAL EVALUATION, AND THAT'S THE 660 OR SO MILLION DOLLARS, A VERY IMPORTANT PART OF IT. AND I THINK IT BE WOULD VERY GOOD FOR THE INSTITUTE TO DECIDE WHETHER IT'S WORTHWHILE TO SET UP SOME SORT OF INFRASTRUCTURE FOR DATA MONITORING AND QUALITY APART FROM THE INDIVIDUAL GRANTEES.

NOW, YOU COULD SUBCONTRACT THIS OUT TO ONE OF THE INSTITUTIONS OR TO ANOTHER ORGANIZATION, BUT IT SEEMS TO ME THAT WHAT MAKES THIS WHOLE PROGRAM POSSIBLE IS CREDIBILITY. AND ESPECIALLY SINCE YOU MENTIONED EARLIER ABOUT SOME OF THE REGULATORY CHALLENGES THAT PEOPLE FACE, AND I'M NOT SUGGESTING FOR A MOMENT THAT ANY OF THE INDIVIDUAL INSTITUTIONS WILL HAVE DATA OF THE HIGHEST QUALITY, I'M ASSUMING THEY WILL, BUT EVERY REGULATORY BODY REQUIRES SOME AUDITING AND MONITORING THAT'S USUALLY NOT BUILT INTO A PLAN, AND LATER WE FIND THAT WE WISHED WE HAD. AND I RECOMMEND THAT WE CONSIDER THIS BETWEEN NOW AND DECEMBER AS TO WHETHER YOU WANT TO DO SOMETHING WITH THAT.

A SECOND POINT IS THAT OFTEN IT'S THE END OF GRANTS THAT GET SHORTCHANGED AND NOT THE BEGINNING. SO

WHEN ONE IS TALKING ABOUT THE PHASE I GRANTS OR EVEN THE PHASE II CLINICAL TRIAL GRANTS, I THINK WE SHOULD HAVE SOME EXPECTATION OF REALLY LONG-TERM FOLLOW-UP FOR THOSE INDIVIDUALS. WE TALK ABOUT A MILLION AND A HALF A YEAR FOR TWO YEARS OR THREE YEARS, AND THAT'S GREAT, EXCEPT THAT I THINK WHAT WE HAVE IS AN OBLIGATION TO FOLLOW THOSE PATIENTS FOR A MUCH LONGER PERIOD OF TIME. AND WE SHOULD BUILD THAT INTO THE PROPOSALS AS WE GO FORWARD. IF I MISSED IT, IF IT'S THERE, I APOLOGIZE.

DR. HALL: WE DID NOT WRITE THAT AND OUR EXPECTATION IS THAT WE MIGHT VERY WELL REQUIRE THAT IN RFA'S, PARTICULAR RFA'S, AS PART OF THE -- I MEAN ALL OF THESE THINGS WILL HAVE TO GO BACK AND BE FILLED OUT IN GREAT DETAIL, THINK ABOUT EXACTLY WHAT WE WANT.

I THINK THE ISSUE OF LONG-TERM FOLLOW-UP IS A VERY IMPORTANT ONE. WE'LL TALK A LITTLE BIT IN THE MORNING ABOUT OUR EGG CONFERENCE: ASSESSMENT OF MEDICAL RISK FOR EGG DONORS. CERTAINLY THAT WAS AN ISSUE THERE, THAT THERE'S AN OPPORTUNITY THERE TO REALLY LEARN MORE ABOUT THAT. AND I THINK WE WANT TO HAVE LONG-TERM AIMS FOR THESE THINGS. I THINK YOU'RE QUITE RIGHT.

DR. FRIEDMAN: THE COST OF FOLLOW-UP FOR LONG-TERM TOXICITIES, AND THAT'S WHAT YOU NEED TO DO EVEN FOR THE PHASE I STUDIES, CAN REALLY BE

SUBSTANTIAL. AND YOU'VE SORT OF LIMITED. YOU SAY THESE WILL BE THREE-YEAR GRANTS AND FOUR-YEAR GRANTS. IN A SENSE YOU DON'T MEAN THAT, OR YOU NEED TO JUST SAY THAT THEY WILL BE THREE YEARS OF INTERVENTION AND THEN AN INDETERMINATE AMOUNT OF TIME OF FOLLOW-UP. AGAIN, I DON'T WANT TO TRY AND SOLVE IT TONIGHT EXCEPT TO SAY THAT I THINK IT'S WORTH DOING THAT BECAUSE I THINK THE SIDE EFFECTS AND THE TOXICITIES WILL BE AS IMPORTANT AS THE EFFICACY FOR SOME OF THE ONCOLOGIC REASONS AND THE OTHER THINGS THAT YOU POINTED OUT EARLIER.

THE LAST POINT IS I THINK IT'S REALLY IMPORTANT BECAUSE OF THE FACT THAT YOU STATED RIGHT UP FRONT THAT THERE ARE GOING TO BE A LOT OF FAILED EXPERIMENTS. THERE HAVE TO BE. THAT'S THE NATURE OF THIS. AND WE'VE SCALED THE PROGRAM TO TRY AND HAVE THE OUTPUT BE SUFFICIENT, RECOGNIZING THERE'S GOING TO BE A BIG ATTRITION ALONG THE WAY. I WONDER IF IT WOULDN'T BE WORTHWHILE TO HAVE -- AGAIN, MAYBE YOU'LL BUILD IT IN AS AN EXPECTATION, OR YOU WILL HAVE A SEPARATE KIND OF GRANT MECHANISM THAT HELPS US TO UNDERSTAND OUR FAILURES. I MEAN IN THAT A RATHER FORMAL WAY. SO THAT WHEN YOU HAVE A FAILED PHASE I EXPERIMENT OR YOU HAVE A FAILED IN VITRO EXPERIMENT OR ANYTHING IS THAT THERE ACTUALLY IS SHARED LEARNING.

ONE OF THE THINGS WE'RE TRYING TO BUILD HERE,

WHETHER IT'S IN SAN DIEGO WHERE THEY'RE COLLABORATING IN UNIQUE WAYS OR OTHER PARTS OF THE STATE, YOU HAVE A SENSE OF COLLEGIALITY AND COLLABORATION THAT'S A LITTLE BIT UNUSUAL, AND THAT WE COULD ACTUALLY FOSTER SOMETHING IMPORTANT, WHICH IS TO SHARE THE LEARNINGS OF WHY AN EXPERIMENT GOES WRONG. DID IT NOT HOME RIGHT, BLAH, BLAH? YOU UNDERSTAND WHAT I'M SAYING.

AND I THINK THAT MIGHT BE WORTH BUILDING IN, AGAIN, AS A SORT OF FORMAL EXPECTATION. THE ONLY REASON I MENTION IT IS USUALLY THERE'S NOT MONEY FOR THAT SORT OF THING. YOU SPEND THE MONEY AND IT'S GONE, AND YOU SAY, GEE, I'D LIKE TO DO THAT, BUT IT'S JUST NOT PART OF IT.

DR. HALL: MAKE A COMMENT ON THAT. ROB NEGREN MADE THE COMMENT AT OUR -- FROM STANFORD, HE'S A HEMATOLOGY ONCOLOGY PERSON VERY EXPERIENCED IN BONE MARROW TRANSPLANT THAT LEADS A TEAM DOWN THERE. HE MADE THE POINT THAT WE NEED TO LEARN FROM OUR FAILURES ABOUT CLINICAL TRIALS, AND HE SAID THAT IN THE CONTEXT OF EMPHASIZING THE IMPORTANCE OF HAVING CLINICAL TRIALS CARRIED OUT IN ACADEMIC MEDICAL CENTERS AND BEING ABLE TO DO THAT.

AND IT'S INTERESTING. WE HAD THE INTERESTING EXPERIENCE AS WE WENT THROUGH THIS OF TALKING TO SOMEBODY FROM INDUSTRY, WHO SAID I'VE GOT A BIG

POWERFUL MACHINE SET UP HERE FOR DOING CLINICAL TRIALS AND FOR GETTING INFORMATION, AND IT IS ABSOLUTELY TERRIFIC; HOWEVER, IT IS AN INCREDIBLY EXPENSIVE MACHINE TO RUN. AND THIS PERSON MADE THE -- SAID, YOU KNOW, WITH ALL GOODWILL IN THE WORLD, ACADEMICS COME TO US AND THEY SAY WE REALLY WANT TO KNOW THIS QUESTION OR REALLY WANT TO KNOW THAT. CAN WE INCORPORATE IT IN OR CAN WE DO THIS?

AND SHE EMPHASIZED -- DIDN'T MEAN TO REVEAL THE GENDER HERE, BUT AT ANY RATE, THIS PERSON EMPHASIZED THAT ONE HAS TO MAKE JUDGMENTS, THEN, OF WHETHER YOU ACTUALLY SPEND THE MONEY TO FIND OUT THE INFORMATION. AND I THINK IT WAS AN INTERESTING PERSPECTIVE, AND I THINK THIS WILL BE A REAL CHALLENGE GOING DOWN THE LINE. THESE ARE VERY, VERY EXPENSIVE THINGS TO DO. AND SO YOU HAVE TO SORT IT OUT. WE WANT TO GET THE MOST INFORMATION, WE WANT TO MOVE IT FORWARD AS QUICKLY AS POSSIBLE. ON THE OTHER HAND, WE WILL ONLY HAVE A LIMITED AMOUNT OF MONEY AND WE WILL HAVE TO SPEND IT WISELY.

I DON'T KNOW THE ANSWER TO IT. I THINK YOUR UNDERLINING THE POINT IS USEFUL.

DR. FRIEDMAN: JUST FOR FURTHER DISCUSSION. I THINK IT'S VERY --

DR. HALL: WE WILL ALL LEARN MORE ABOUT AS WE

GET FURTHER DOWN THE LINE.

DR. FRIEDMAN: AND THERE WILL BE PLENTY OF OPPORTUNITIES. I THINK IT'S REALLY SOMETHING THAT THE CITIZENS OF THE STATE WILL LOOK AT IT AND SAY THAT THEY THINK WE'RE MOVING IN A THOUGHTFUL AND PROFESSIONAL DIRECTION. SO THANKS TO EVERYBODY WHO WORKED ON IT.

DR. HENDERSON: I'D LIKE TO ALSO STATE IT'S A VERY WELL-DONE, VERY PROFESSIONAL DOCUMENT, SOMETHING THAT YOU AND YOUR STAFF SHOULD BE VERY PROUD OF, ALL THE PEOPLE THAT CONTRIBUTED. IT'S AN ENORMOUS HELP, I THINK, TO THOSE OF US ON THE BOARD. GIVES US A LOT OF CONFIDENCE, ME, THAT WE HAVE A SENSE OF WHERE WE'RE GOING THAT I CERTAINLY DIDN'T HAVE BEFORE THIS SORT OF DOCUMENT TURNED UP. SO I CONGRATULATE YOU AND THANK YOU FOR THAT.

IT'S INTERESTING IN EVALUATION, ONGOING EVALUATION, YOU HAVE A COUPLE OF SENTENCES THAT ALREADY HAVE BEEN REFERRED TO ABOUT THAT PROCESS. I'VE OVER THE COURSE OF MY CAREER WRITTEN I DON'T KNOW HOW MANY PROGRESS REPORTS ON MY GRANTS ON AN ANNUAL BASIS, AND I DOUBT THAT ANYBODY EVER READ ANY OF THEM OR THAT THEY EVER WERE USED FOR ANY CONSTRUCTIVE PURPOSE OTHER THAN TO MAKE SURE I GOT THE CONTINUING BUDGET AWARD. AND IT WILL BE INTERESTING TO SEE IF YOU CAN FIND A WAY TO ACTUALLY TAKE ADVANTAGE OF PROGRESS REPORTS IN A

DYNAMIC FASHION INSTEAD OF THE MORE PASSIVE FASHION THAT WE'RE ACCUSTOMED TO AT THE NIH.

IT'S SORT OF IMPLIED YOU ARE GOING TO DO SOMETHING LIKE THAT, BUT I THINK A LITTLE MORE THOUGHT HOW TO DO THAT. I THINK IT'S BEYOND THE CAPABILITIES OF YOUR STAFF PROBABLY TO BE RUNNING THIS COMPLEX GRANT PROGRAM THAT'S GOING TO NEED SO MUCH ONGOING DAY-TO-DAY EFFORT. PERHAPS SOMEONE ELSE OR SOME OTHER GROUP NEEDS TO TAKE ON THE TASK OF HOW DO YOU MAKE PROGRESS REPORTS REALLY MEANINGFUL COMMUNICATION VEHICLES THAT NOT ONLY COMMUNICATE BETWEEN SCIENTISTS, BUT, MORE IMPORTANTLY, GIVE YOU FEEDBACK ON THE PLAN THAT YOU HAVE SO YOU HAVE SOME SORT OF ONGOING FEEDBACK. I DON'T KNOW HOW TO DO THAT. IT JUST SEEMS IT'S WORTHY OF SERIOUS DISCUSSION.

CHAIRMAN KLEIN: DR. THAL AND THEN DR. BRYANT.

DR. THAL: ZACH, WHEN I READ THE DOCUMENT, I WAS ACTUALLY ENORMOUSLY IMPRESSED WITH IT BECAUSE MOST STRATEGIC PLANS, AS YOU SAY, ARE EXTREMELY WORDY, HAVE LOFTY GOALS, AND NO SPECIFIC AIMS. YOUR TWO-LAYER APPROACH, ONE TO HAVING LOFTY GOALS, BUT ALSO HAVING SPECIFIC AIMS IS VERY WELCOME. I THINK IT'S GREAT. I THINK IT'S VERY NICE TO HAVE VERY CONCRETE SPECIFIC GOALS THAT PEOPLE CAN LOOK AT AND SAY THEY MAY BE ACHIEVABLE, THEY MAY NOT BE ACHIEVABLE.

I THINK SOME PEOPLE MAY HAVE LOOKED AT IT AND SAID THE GOALS ARE TOO MODEST. I WOULD ACTUALLY DISAGREE. I WOULD SAY THE GOALS ARE ACTUALLY REALISTIC; AND IF YOU CAN ACTUALLY GET AS FAR IN ACCOMPLISHING THE SPECIFIC GOALS THAT YOU'VE SET UP, GIVEN THE COSTS OF DEVELOPMENT OF REAGENTS FOR CLINICAL USE, I THINK CIRM WILL HAVE DONE EXTREMELY WELL.

THERE ARE ONLY TWO SORT OF SMALL SUGGESTIONS THAT I WOULD MAKE, AND I'M NOT QUITE SURE HOW TO BUILD THESE IN. ONE IS THAT YOU TALK ABOUT A COMMUNITY OF SCIENCE AND THAT'S GOING TO DEVELOP. I THINK THE QUESTION IS HOW TO HARNESS IT TO MAKE SURE THAT THE INFORMATION THAT IS GATHERED IS DISTRIBUTED AND UTILIZED. ONE WAY THAT SOME ORGANIZATIONS, FOUNDATIONS OFTEN USE ARE TO BRING PEOPLE TOGETHER ON A REGULAR BASIS. OBVIOUSLY IT'S GOING TO DEPEND ON THE NUMBER OF INVESTIGATORS THAT YOU HAVE. IF THERE ARE THOUSANDS IN THE STATE, IT'S NOT GOING TO WORK. IF THERE ARE DOZENS OR KEY INVESTIGATORS, IT WILL WORK. SO THAT PEOPLE CAN ACTUALLY HEAR WHAT OTHER PEOPLE ARE DOING ON A REGULAR BASIS BECAUSE PEOPLE AREN'T GOING TO READ OTHER PEOPLE'S PROGRESS REPORTS EVEN IF YOU POST THEM ON THE WEBSITE. BUT IF KEY ISSUES ARE DISCUSSED AT MEETINGS AND CONFERENCES, KEY PROBLEMS ARE POSED, OTHER SCIENTISTS WILL HEAR ABOUT IT AND WILL COME UP WITH

IDEAS. AND YOU WILL BE ABLE TO LEVERAGE THE WORK OF CIRM TO A MUCH GREATER EXTENT. SO THAT'S ONE. I THINK THAT'S GOING TO BE AN IMPORTANT ISSUE, TO MAKE SURE THAT THERE ARE FUNDS PLACED TO BRING PEOPLE TOGETHER.

I GUESS THE SECOND ONE, AND I'M NOT SURE HOW TO STATE IT IS, BECAUSE YOU HAVE PUT SPECIFIC NUMBERS IN HERE, TO SOMEHOW OR OTHER COUCH IT AND SAY AT THE BEGINNING THAT THESE NUMBERS ARE TO GIVE YOU A VERY GOOD IDEA OF HOW WE THINK WE WILL PROCEED. OBVIOUSLY WHEN SCIENTIFIC OPPORTUNITIES ARISE, WE WILL GRAB THOSE OPPORTUNITIES AND GO AFTER THEM. SO IT MAY BE THAT NOTHING COMES TO CLINICAL TRIALS BECAUSE THE BASIC SCIENCE MOVES TOO SLOWLY, AND SOMETHING EMERGES VERY EARLY ON IN THE COURSE OF LABORATORY INVESTIGATIONS AND IT LOOKS LIKE THAT CAN MOVE FORWARD VERY QUICKLY INTO THE CLINICAL ARENA. SO I JUST WANT TO MAKE SURE THAT YOU DON'T LOSE THE FLEXIBILITY AND THE EXCITEMENT AND THE ABILITY TO RAPIDLY TRANSITION RESOURCES AND TO MAKE THOSE DECISIONS AS WE PROCEED.

THOSE ARE THE ONLY TWO SUGGESTIONS.

DR. HALL: THANK YOU FOR YOUR COMMENTS. BOTH VERY, VERY GOOD ONES. I PERSONALLY AM A GREAT BELIEVER IN MEETINGS, AND I THINK THAT PART OF THE CREATIVITY OF BEING A SCIENTIFIC STAFF MEMBER IN A GRANTING INSTITUTION AND I THINK WHAT MAKES IT INTERESTING TO

PEOPLE IS THE OPPORTUNITY TO BRING PEOPLE TOGETHER IN UNEXPECTED COMBINATIONS WHERE YOU SEE THE COMMONALITY OF INTEREST, PERHAPS GET THEM TO TALK TO EACH OTHER, AND THEN OUT OF IT SOMETHING HAPPENS.

I PARTICIPATED IN SUCH MEETINGS, AND I'M A FIRM BELIEVER IN THEM. IT WILL BE A CHALLENGE, HOWEVER. I DON'T THINK WE NEED TO WORRY ABOUT IT TONIGHT, BUT WE WILL NEED TO WORRY ABOUT IT AS THERE ARE A LOT OF FUNCTIONS HERE WITH WORKSHOPS AND MEETINGS FOR WHICH THE SOURCE OF SUPPORT IS UNCLEAR. AND I THINK WE WILL NEED TO SPEND SOME TIME WITH LAWYERS AND OTHERS JUST SORTING OUT HOW WE CAN SUPPORT THAT. I SEE IT AS A VITAL ACTIVITY BOTH IN TERMS OF PLANNING OUR OWN PROGRAM AND THEN IN TERMS OF MAKING NEW THINGS HAPPEN, PUTTING PEOPLE TOGETHER SORT OF IN NEW WAYS THROUGHOUT THE STATE AND BEYOND.

AND SO, ANYHOW, WE VERY MUCH ASPIRE TO DO THAT AND WANT TO DO THAT. I APPRECIATE YOUR COMMENTS ON IT.

AND THE OTHER POINT IS, YES, WE DO WANT TO REMAIN FLEXIBLE. AND THAT'S WHY HAVING THE LITTLE EXTRA MONEY IS USEFUL. IT MEANS YOU CAN DO SOMETHING WITHOUT HAVING TO STOP ANOTHER PROGRAM ON THE DIME, OR YOU HAVE THAT MONEY AND THERE ARE OPPORTUNITIES THAT DO ARISE. AND I THINK WE WANT TO BE ABLE TO DO THAT. WE

WILL HAVE TO SEE, I THINK, WHETHER WHAT WE'VE ALLOCATED IS ENOUGH OR TOO MUCH. ALL THESE NUMBERS WILL CERTAINLY BE SHIFTED AND ADJUSTED AS WE GO FORWARD.

FORTUNATELY, PROPOSITION 71 HAS THE VERY WISE PROVISION THAT WE CAN KEEP MONEY OVER, SO THAT MAKES A BIG DIFFERENCE. IT'S A HUGE ADVANTAGE FOR US. AND SO I NOD TO THE AUTHOR ON THAT. THAT'S VERY MUCH APPRECIATED. THAT'S A KEY ELEMENT.

DR. BRYANT: I JUST WANTED TO SAY THAT I'VE JUST FOUND THIS EXPERIENCE OF GOING THROUGH THIS ONE OF THE MOST UNUSUAL EXPERIENCES IN MY LIFE IN TERMS OF READING A DOCUMENT OF THIS KIND BECAUSE, FOR ME, I FEEL LIKE YOU'VE MANAGED TO DRAW A CIRCLE AROUND THE PROBLEM. YOU'VE ENCAPSULATED IT WELL. YOU'VE ACTUALLY PUT IN A LOT OF DETAIL ABOUT HOW WE'LL DO THIS BIT OR THAT BIT, BUT IT'S ALSO FLUID. AND IT FEELS FLUID TO ME, SO IT FEELS FLUID IN A WAY THAT I'M NOT -- I DON'T FEEL LIKE I HAVE TO, EVEN THOUGH QUESTIONS ARISE, I FEEL LIKE WHY BOTHER ASKING BECAUSE I CAN SEE THAT THIS IS A DOCUMENT THAT IS DESIGNED TO BE MODIFIED AS WE GO ALONG. AND I JUST WOULD LIKE TO CONGRATULATE YOU. I'VE NEVER SEEN ANYTHING QUITE LIKE IT. IT'S VERY UNUSUAL, AND I LOVE IT.

DR. POMEROY: I THINK THE CLEAR-CUT CONSENSUS AT DINNER WAS THAT THIS IS AN OUTSTANDING DOCUMENT.

AND I TOO CONGRATULATE THE TEAM. I DID HAVE TWO QUESTIONS WHICH MAYBE I'M SURE WERE DISCUSSED DURING THIS PROCESS THAT YOU COULD CLARIFY FOR US.

THE FIRST IS -- THESE ARE BOTH QUESTIONS THAT HAVE COME UP BEFORE. THE FIRST IS WHAT WILL THE BALANCE BE BETWEEN EMBRYONIC, CORD, AND ADULT STEM CELLS, HOW IS THAT ADDRESSED IN THIS STRATEGY? AND THE SECOND IS WHAT WILL THE BALANCE BE BETWEEN STUDIES OF NONHUMAN VERSUS HUMAN STEM CELLS? THESE ARE BOTH THINGS THAT THE ICOC HAS BEEN ASKED ON A NUMBER OF OCCASIONS. AND I WONDER -- I'M SURE IT'S ADDRESSED IN HERE, BUT MAYBE YOU CAN SUMMARIZE.

DR. HALL: IT'S NOT EXPLICITLY, AND THAT'S VERY PURPOSEFUL. AND THAT IS, OUR SENSE IS THAT WHAT WE NEED TO DO IS TO FUND THE BEST SCIENCE AND IN SOME SENSE LET THAT EMERGE FROM THE PROJECTS THAT ARE PROPOSED. THAT IS, A NUMBER OF THE MECHANISMS, THE BIOLOGY OF STEM CELLS, THE INNOVATION INITIATIVE, EVEN SOME OF THE SPECIFIC ONES, IMMUNE TOLERANCE, FOR EXAMPLE, WILL HAVE TO BE DONE IN MICE AND MAYBE PRIMATES BEFORE IT'S DONE IN HUMANS. SO THERE WILL BE OPPORTUNITIES FOR A LOT OF WORK. BUT RATHER THAN SAY WE'RE GOING TO HAVE A SET ASIDE FOR THIS MUCH, WE WANT TO SEE WHAT THE SCIENCE IS LIKE AND TO LET IT EMERGE FROM THAT.

SO WE WILL HAVE MANY RATHER OPEN COMPETITIONS AND SEE WHAT'S READY AND SEE WHAT LOOKS GOOD AND WHAT IS WORTH. WE WANT TO FUND -- ONE OF THE VALUES ENDORSED BY THE ICOC, I THINK, IS EXCELLENCE, AND WE WANT TO STRIVE FOR THAT AND GET THE MOST FOR OUR MONEY IN THESE THINGS. I THINK THAT'S IN THE END THE BEST WAY TO GO.

NOW, WITH THAT SAID, WE JUST LOOKED UP TODAY, WHICH IS VERY INTERESTING, THE FUNDING FROM NIH FOR STEM CELLS FOR '05. AND THE TOTAL FUNDING FOR STEM CELLS IS $607 MILLION SPENT ON RESEARCH. HUMAN EMBRYONIC STEM CELLS IS 39. NONHUMAN EMBRYONIC IS 95, HUMAN NONEMBRYONIC, THAT IS, FETAL AND ADULT, IS 200; AND NONHUMAN NONEMBRYONIC IS 273. SO OF THAT 600, WHAT, 470 OF IT, OVER TWO-THIRDS, IS ON ADULT NONHUMAN STEM CELLS. SO THAT WORK -- YOU UNDERSTAND MY POINT. SO THE FIRST-RATE WORK THAT COMES OUT THAT THAT RISES TO THE SURFACE AND THAT FOR WHATEVER REASONS IS NOT FUNDED BY NIH, WE CERTAINLY WILL FUND. BUT I THINK WE FEEL OUR FIRST OBLIGATION IS TO, PARTICULARLY AT THIS MOMENT IN HISTORY, IS TO FUND HUMAN EMBRYONIC STEM CELL RESEARCH.

DR. POMEROY: I WONDER, SINCE THIS QUESTION HAS BEEN BROUGHT UP SO OFTEN BY SO MANY PEOPLE, IF A PARAGRAPH THAT EXPLICITLY SORT OF JUST SUMMARIZES THAT

THINKING WOULD BE USEFUL BECAUSE WE'RE GOING TO GET ASKED IT.

DR. HALL: WELL, WE ARE AND WE TRY TO WALK THE LINE ACTUALLY. WE PUT EXPLICITLY IN THE RECENT RFA THAT THE FACT THAT WE WERE CALLING FOR HUMAN EMBRYONIC STEM CELL GRANTS DID NOT MEAN THAT IN THE FUTURE WE WOULD NOT BE FUNDING OTHER GRANTS. AND THERE MAY BE SPECIAL SITUATIONS WHERE WE WILL BE. IN FACT, FOR SOME OF THESE QUESTIONS, WHAT WE KNOW ABOUT THE STEM CELL'S RELATIONSHIP TO THEIR NICHE COMES LARGELY FROM WORK IN INVERTEBRATES ACTUALLY, AND IT TURNS OUT TO BE VERY RELEVANT TO WORK IN OUR HIGHER SYSTEMS. AND I THINK THAT WILL BE TRUE AGAIN AND AGAIN, BUT IT NEEDS TO BE TIED TO SPECIFIC QUESTIONS AND QUALITY OF WORK RATHER THAN AS A SORT OF SET ASIDE.

SO OUR POINT IS, AND THIS WAS ORIGINALLY, AGAIN, PROPOSITION 71 EXPRESSED IT VERY CLEARLY, THAT WE GIVE PREFERENTIAL TREATMENT TO THIS AREA THAT HAS BEEN NEGLECTED BY FEDERAL FUNDS, BUT WE'RE ALSO OPEN TO OTHER OPPORTUNITIES. SO HOW TO PUT IT, WE WANT TO KEEP OUR EMPHASIS, BUT WE WANT TO KEEP THE DOOR OPEN, SO WE DON'T HAVE A SIMPLE MESSAGE TO GET OUT. IT'S A LITTLE BIT COMPLEX IN THAT WAY, BUT WE WILL TRY TO ENCOURAGE PEOPLE.

AND AS THEY COME OUT, WE WILL SEE THAT. I

MEAN IF WE HAVE A BIOLOGY OF STEM CELLS RFA, FOR EXAMPLE, THAT IT WILL BE VERY CLEAR THAT THAT CAN BE ANYWHERE, AND SAME WILL BE TRUE FOR SOME OF THE OTHER THINGS, BUT WE'VE STARTED OUT, AS YOU KNOW, WITH TRYING TO PUSH THE HUMAN EMBRYONIC BECAUSE THAT IS, AS YOU CAN SEE FROM THESE BUDGET FIGURES, THAT'S SO NEGLECTED.

CHAIRMAN KLEIN: ZACH, AS YOU KNOW, IN THE BRIEFING THAT I HAD MONDAY WITH YOU ON THIS, I RAISED THE SAME ISSUE THAT CLAIRE HAS RAISED. WHILE THIS IS AN EXCELLENT REPORT AND THE GOALS ARE VERY SOLID, IT WOULD BE HELPFUL POTENTIALLY, AND MAYBE THIS IS WHAT CLAIRE WAS SAYING, TO AT LEAST HAVE A SHORT STRATEGIC DISCUSSION OF THE RELATIONSHIP OF OTHER VITAL RESEARCH OPPORTUNITIES IDENTIFIED, OF COURSE, IN THE INITIATIVE AS A SECONDARY PRIORITY AND REQUIRING A TWO-THIRDS VOTE OF THE WORKING GROUP TO ADVANCE THOSE RESEARCH INITIATIVES TO MAKE CERTAIN THAT THERE WAS A REAL NEED TO ADVANCE THEM.

BUT WE HAVE SOME POTENTIAL OPPORTUNITIES IN THE INTERFACE BETWEEN ADULT AND EMBRYONIC STEM CELL RESEARCH. WE HEARD ABOUT THE UCLA TRIAL WITH ADULT STEM CELLS THAT HAD GENE MODIFICATIONS, AND THOSE CLINICAL TRIALS ARE IN PROGRESS; BUT TO EXPAND THOSE TO BE EFFECTIVE, THEY MAY NEED TO HAVE AN INTERFACE WITH EMBRYONIC STEM CELLS SO THAT THEY'RE NOT CUSTOMIZING TO

DEAL WITH ISSUES OF IMMUNE TOLERANCE. THOSE STRATEGIC INTERFACES BETWEEN ADULT AND FETAL AND CORD BLOOD AND EMBRYONIC AS WELL AS THE OPPORTUNITIES THAT MAY OCCUR BECAUSE OF SHORT FUNDING OF THE NIH, MY UNDERSTANDING IS THERE MAY BE AN ANNOUNCEMENT SOON OF FURTHER REDUCTIONS TO THAT FUNDING, WHERE THERE ARE ADVANCED OPPORTUNITIES THAT MIGHT BE BROUGHT TO CLINICAL APPLICATIONS WHERE, WITHOUT THIS FUNDING, WE'RE MISSING CRITICAL LINK IN JUST GETTING TO THAT CLINICAL TRIAL STAGE.

I MEAN A STRATEGIC STATEMENT JUST ON THE RELATIONSHIPS OF THESE OPPORTUNITIES TO THE PRIORITY FOR EMBRYONIC STEM CELL RESEARCH IS, I THOUGHT, CLAIRE, WHERE YOU WERE GOING.

DR. POMEROY: RIGHT. EXACTLY. I WOULD NOT CHANGE ANY OF THE NUMBERS, FOR EXAMPLE, OR THE CATEGORIES, BUT JUST PERHAPS A PARAGRAPH DISCUSSING THE FACT THAT COMPARATIVE STUDIES MAY BE IMPORTANT, ETC., MIGHT BE USEFUL.

DR. LOVE: BOB, I WANTED TO EMPHASIZE TO ZACH THAT I THINK THIS WAS AN EXTRAORDINARY DOCUMENT. AND WHEN I BEGAN TO READ IT, QUITE FRANKLY, I HAD NO IDEA HOW MUCH WORK HAD BEEN DONE, HOW MUCH THOUGHTFUL THINKING HAD BEEN DONE. AND ACTUALLY JUST READING THE DOCUMENT WAS EXTRAORDINARY BECAUSE IT READ LIKE A

DOCUMENT THAT WAS WRITTEN BY A SINGLE INDIVIDUAL EVEN THOUGH WE ALL KNOW THAT NO INDIVIDUAL COULD REPRESENT ALL THE KNOWLEDGE CONTAINED IN THE DOCUMENT. SO IT WAS ABSOLUTELY EXTRAORDINARY. AND MY GREATEST CONGRATULATIONS TO YOU.

YOU ASKED US FOR HIGH LEVEL FEEDBACK. I DO THINK YOU WERE RIGHT ON THE MARK ON ALMOST EVERYTHING CONTAINED IN THE DOCUMENT. I DO WANT TO EMPHASIZE ONE THING, THOUGH, THAT MICHAEL MENTIONED. AND THAT IS THAT I DO THINK THAT, AS WE GO FORWARD, WE'VE GOT TO MAKE SURE THAT SAFETY TAKES AN EXTRAORDINARILY UNUSUAL PRIORITY BECAUSE I THINK WE ALL KNOW THAT NOTHING KILLS RESEARCH, NOTHING CREATES CRISIS IN AN AREA OF RESEARCH LIKE SAFETY. AND SO I THINK AS WE EXPOSE PATIENTS, AS WE ENJOY THE PATIENTS COMING FORWARD, ALLOWING THEMSELVES TO BE SUBJECTS FOR THIS THERAPY, WE'VE REALLY GOT TO MAKE SURE THAT WE'RE VERY THOUGHTFUL ABOUT THE FOLLOW-UP OF THOSE PATIENTS AND MAKE SURE THAT WE HAVE THE RIGHT KIND OF SYSTEMS IN PLACE TO TRY TO PICK UP PATTERNS AND PICK UP PROBLEMS AS QUICKLY AS POSSIBLE.

AND I THINK YOU ALL KNOW THAT THE FDA AND OTHERS ARE REALLY VERY MUCH FOCUSED ON THE RIGHT KINDS OF SYSTEMS AND TECHNOLOGIES TO FOLLOW SAFETY, AND I THINK WE SHOULD REALLY MAKE SURE THAT WE LEVERAGE ALL

OF THAT THINKING AND BRING IT TO BEAR IN THIS PROGRAM.

DR. WRIGHT: ZACH, YOU REFERRED TO FOOTBALL EARLIER. I THINK WE'RE GOING TO GET PENALIZED FOR PILING ON. THAT'S A PENALTY FLAG, RIGHT? PILING ON IN A POSITIVE WAY. I WOULD JUST AGAIN COMMEND THE ENTIRE TEAM WHO PRODUCED THIS DOCUMENT. IT WAS ACTUALLY FUN READING. I AGREE WITH SUSAN. WHOEVER THOUGHT READING A STRATEGIC PLAN WOULD BE FUN? SUSAN TALKED ABOUT GETTING THIS WHOLE CIRCLE, AND I WAS THINKING ON THE PLANE, NOT THAT I JUST READ IT ON THE PLANE, ABOUT A SKELETON. YOU GUYS HAVE GIVEN US A NICE STURDY SKELETON ON WHICH TO ADD ALL THE IMPORTANT BODY PARTS THAT WILL FOLLOW.

AND I JUST WANT TO ESPECIALLY COMMENT ON THE INCLUSION OF OUR OBLIGATION TO THE PUBLIC AND CITIZENS, BOTH IN TERMS OF EDUCATING THEM ABOUT THE SCIENCE AND, I GUESS USED COUPLE OF TIMES, MANAGING EXPECTATIONS AND HOW CRITICAL THAT IS TO BALANCE THE HOPE AND HYPE COMPONENTS. IT WAS MENTIONED SEVERAL TIMES DURING THE WHOLE DOCUMENT OR WITHIN THE DOCUMENT, KIND OF WOVEN THROUGHOUT, SO I LIKE THE FACT THAT IT WAS INTEGRATED IN EVERY PART. AS YOU ADDRESS THE SCIENCE, YOU ALSO ADDRESSED THE PUBLIC EDUCATION COMPONENT. SO MANY CONGRATULATIONS.

MS. FEIT: I WANT TO CONGRATULATE THE STAFF

AND EVERYBODY. THE STRATEGIC PLANNING ADVISORY COMMITTEE IS OUTSTANDING. I READ THROUGH THE DOCUMENT PARTLY YESTERDAY AND TODAY, AND IT REALLY PULLED TOGETHER THE WORK THAT THE INSTITUTE HAS BEEN DOING IN THE LAST TWO YEARS IN SUCH A FLUID WAY. I PARTICULARLY WAS IMPRESSED WITH HOW THE FUNDING WAS LAID OUT, AND I THINK GOING FORWARD, THAT'S GOING TO BE IMPORTANT TO HAVE THAT IN THE DOCUMENT. SO CONGRATULATIONS TO ALL OF YOU.

I HAVE A COUPLE QUESTIONS. ONE WOULD BE ON IF THERE'S GOING TO BE A LITTLE MORE FORMAL WORK DONE AROUND THE IMPLEMENTATION PHASE OF THE STRATEGIC PLAN AS WE GO FORWARD. WE'VE TALKED BITS AND PIECES ABOUT DOING CERTAIN THINGS UNDER CERTAIN CATEGORIES, BUT IF THAT IS GOING TO BE FORMALIZED.

AND THEN THE SECOND QUESTION WOULD BE AROUND COMMUNICATION OF THE STRATEGIC PLAN TO THE PUBLIC. IT'S ONE OF THE BEST DOCUMENTS I'VE READ, AND IT WAS -- I WOULD ECHO DR. WRIGHT'S COMMENTS. IT WAS ENJOYABLE TO READ. SO CONGRATULATIONS.

DR. HALL: THANK YOU VERY MUCH, MARCY. WE WOULD WELCOME SUGGESTIONS ABOUT COMMUNICATION TO THE PUBLIC. IT'S NOT A SMALL DOCUMENT. AND THE EXECUTIVE SUMMARY, WHILE USEFUL, AT LEAST TO MY READING, IS DRY. AND I FIND IT MUCH LESS INTERESTING THAN THE BODY OF

IT. AND SO IF ANYBODY HAS THOUGHTS ABOUT THAT, WE WOULD WELCOME THAT. I DON'T KNOW HOW WE CAN BEST DO IT. WE WILL BE FACING THAT AS ALL OF US GO OUT AND TALK. WE WILL NEED A WAY TO PRESENT IT TO SORT OF TRY TO CAPTURE SOME OF WHAT WE'VE DONE IN A CONCISE WAY, AN ENGAGING WAY.

AS FOR THE IMPLEMENTATION, I THINK THAT'S PRECISELY WHAT WE MEAN BY FIRST THOUSAND DAYS. AND SO WE WILL BACK AND SAY, NOW, OKAY, IN GREAT DETAIL HERE'S WHAT WE'RE GOING TO BE DOING NEXT YEAR WITH THESE AND HERE IN THE NEXT YEAR, AGAIN NOT FINAL. WE WILL BRING EACH RFA TO THE ICOC FOR DISCUSSION AND APPROVAL, BUT WE HAVE TO HAVE SOME SORT OF COORDINATED PLAN, OTHERWISE WE CAN'T HAVE -- 25 INITIATIVES IS A LOT, SOME WITH SEVERAL RFA'S, AND WE CAN'T HAVE THESE JUST COMING OUT HELTER-SKELTER.

I DID NOT MENTION ABOUT PRIORITIES. THERE IS A PAGE -- I THINK WE DECIDED IT WAS TOO CUMBERSOME TO PUT IN, BUT IF YOU LOOK AT PAGE 18, YES, PAGE 18 IN THE EXECUTIVE SUMMARY, IT'S ALSO REPRODUCED ELSEWHERE, BUT THE POINT IS THAT WE DON'T NEED TO GO THROUGH THIS IN DETAIL, BUT JUST AS YOU GLANCE, WHAT YOU SEE IS THAT IN DIFFERENT PHASES OF THE TEN-YEAR PLAN PROJECTS RISE AND FALL IN RELATIVE IMPORTANCE. AND I THINK WE WILL ALL AGREE THAT THAT'S APPROPRIATE. WHETHER THE EXACT

CHOICE HERE IS THE CORRECT ONE, WE CAN DISCUSS. BUT IN CASE, WE WILL TRY TO ORDER THESE IN SOME WAY AND THEN BRING THEM TO YOU. AND THE DECEMBER PART, THAT FIRST THOUSAND DAYS, WILL BE A VERY DETAILED IMPLEMENTATION PLAN OVER THE NEXT THREE YEARS. AGAIN, YOU KNOW, FOR THE NEXT SIX MONTHS, WE BETTER BE PRETTY CLOSE TO RIGHT, AND THREE YEARS FROM NOW, OF COURSE, WE MAY CHANGE IT, BUT WE WILL TRY TO DO THAT.

MS. SAMUELSON: I HAD ONE THOUGHT ON THE COMMUNICATIONS ROUTE BEFORE I PILE ON FOR A SECOND MYSELF, WHICH IS I THINK THAT WE WILL NEED AN INNOVATIVE COMMUNICATIONS ENTERPRISE THAT'S AS INNOVATIVE AS THIS WHOLE EFFORT FROM THE DRAFTING OF THE INITIATIVE HAS BEEN AND AS INVOLVING OF THE PEOPLE OF THE STATE OF CALIFORNIA AND BEYOND. BECAUSE I THINK THIS WILL SUCCEED IF AND ONLY IF THEY'RE WITH US AND UNDERSTAND WHAT WE'RE DOING AND WHAT THE RISKS ARE AND WHAT'S APPROPRIATE RISK AND WHAT ISN'T AND CAN BACK US WHEN WE TRIP AND FALL, WHICH WE WILL HAVE TO DO IF WE'RE GOING TO BE MOVING AGGRESSIVELY ENOUGH AND SO ON, WHICH WILL TAKE DESCRIBING SCIENCE CLEARLY ENOUGH AND SO ON.

I WOULD ASSUME THAT NONE OF US KNOW HOW TO DO THAT BECAUSE THAT'S NOT WHAT WE ALL WERE TRAINED TO DO, AND WE'LL NEED TO BRING IN SOME VERY CLEVER

PROFESSIONALS.

BUT WHAT I REALLY WANTED TO SAY IS I'VE GOT VARIOUS THOUGHTS AND COMMENTS. IT'S THOUGHT PROVOKING, WHICH IS ONE OF THE WONDERFUL THINGS ABOUT IT, AND SEVERAL OF THEM HAVE ALREADY BEEN MENTIONED. BUT I DON'T REALLY WANT TO GET INTO THAT BECAUSE I JUST THINK IT'S SUCH AN EXTRAORDINARY DOCUMENT AND SUCH A PRODIGIOUS WORK PRODUCT BY SO MANY PEOPLE, AND IT EVIDENCES SO MUCH HARD WORK, THAT I'D JUST RATHER KIND OF LEAVE IT AT THAT RIGHT NOW. I DON'T WANT THAT TO GET LOST IN THE SHUFFLE OF LOTS OF WHAT WE'LL DO NEXT, WHICH THE EXCITING THING ABOUT IT IS THAT IT DOES PROVOKE ALL OF THAT. THANK YOU SO MUCH FOR ALL YOUR HARD WORK.

WHEN YOU CONSIDER THAT WE DIDN'T HAVE ANYTHING IN NOVEMBER OF '04, AND THAT WASN'T THAT LONG AGO, THAT'S A WONDERFUL THING. SO THANK YOU.

DR. HALL: I APPRECIATE THAT. I THINK ALL OF US DO. WE APPRECIATE THAT VERY MUCH.

THE COMMUNICATION THINGS IS INTERESTING AND IMPORTANT, AND I THINK IT'S A PROBLEM WE STRUGGLE WITH NATIONWIDE IN THE WHOLE HOW TO BALANCE THESE THINGS. I KNOW THERE IS A LOT OF DISCUSSION ABOUT IT IN VARIOUS PLACES. BUT AS FAR AS CIRM IS CONCERNED, I THINK MY VIEW HAS BEEN THAT IN THINKING ABOUT ALL OF OUR

ACTIVITIES, THAT THE FIRST ORDER OF BUSINESS IS TO GET OUR SCIENTIFIC STRATEGIC PLAN IN PLACE. THAT IS, TO UNDERSTAND WHAT IT IS WE'RE ABOUT IN OUR CENTRAL MISSION, AND THEN WE CAN ADD THESE OTHER PIECES AROUND THAT TO ADVANCE THAT MISSION. COMMUNICATIONS, FOR EXAMPLE, BEING ONE VERY IMPORTANT PART OF THEM, THE COMMUNITIES OF SCIENCE THAT LEON MENTIONED, AND I THINK THERE MAY BE OTHER THINGS THAT ACTUALLY WE DON'T TOUCH ON IN THE REPORT. BUT THERE WILL NEED TO BE OTHER PIECES OF OUR ACTIVITY THAT NOW GET FILLED IN AND I HOPE DEFINED AND ORIENTED BY WHAT'S IN THE PLAN.

MS. SAMUELSON: THAT MAKES SENSE TO ME, DOING IT IN THAT ORDER. GREAT.

CHAIRMAN KLEIN: ZACH, DOES ONE OF THOSE ADDITIONAL PIECES DEAL WITH INTERNATIONAL COLLABORATION? FOR EXAMPLE, THE AUSTRALIAN GOVERNMENT OF VICTORIA STATE HAS ANNOUNCED A HUNDRED MILLION DOLLAR JOINT VENTURE WITH UNIVERSITY OF CALIFORNIA SAN DIEGO. IS THERE ANOTHER PIECE THAT WOULD ADDRESS INTERNATIONAL COLLABORATION AND COMPARATIVE ADVANTAGE WHERE WE LOOK AT THE COMPARATIVE ADVANTAGE OF CERTAIN COUNTRIES AND CERTAIN SPECIALIZED AREAS OF RESEARCH, COMPARE THAT TO THE RESEARCH INITIATIVE IN CALIFORNIA, MAKE CERTAIN THAT WE'RE REALLY WORKING OFF THE BENEFIT OF THEIR KNOWLEDGE AND EXPERTISE RATHER THAN PURELY

DUPLICATING IT?

THE ISSUE IS HOW SHOULD WE THINK ABOUT THE COLLABORATION? WE'RE PART OF THE INTERNATIONAL STEM CELL FORUM, WHICH IS A GREAT PRIVILEGE. AND FOR THE PUBLIC'S BENEFIT AND OUR BENEFIT, I THINK LOOKING AT THE ISSUES OF RESOURCE ALLOCATION, COMPARATIVE ADVANTAGE, AND INTERNATIONAL COLLABORATION AS A WAY TO LEVERAGE AND EFFICIENTLY ALLOCATE OUR RESOURCES IS A SEPARATE PIECE MAYBE, BUT AN IMPORTANT AREA TO EXPLORE.

DR. HALL: WE THOUGHT -- WE CERTAINLY WANT TO HAVE COLLABORATIONS WITH, NOT ONLY INTERNATIONAL COLLABORATIONS, WE WANT TO HAVE COLLABORATIONS WITH DISEASE GROUPS, INJURY GROUPS, WE WANT TO HAVE COLLABORATIONS, AS I'VE SAID, WITH OTHER STATES, AND, WHO KNOWS, MAYBE ONE DAY EVEN WITH OUR OWN COUNTRY.

CHAIRMAN KLEIN: OPTIMISM.

DR. HALL: AND WE THOUGHT ABOUT WHETHER WE SHOULD SET UP SOME SORT OF SPECIAL MECHANISM FOR THAT. AND I THINK THAT WHERE WE CAME DOWN WAS THAT WE SHOULD KEEP THE PRIORITIES RELATED TO SCIENTIFIC AIMS AND BE OPEN AT ANY POINT TO FITTING IN THESE COLLABORATIONS. THAT IS, IT'S VERY IMPORTANT THAT THEY MAKE SCIENTIFIC SENSE, AND THAT WE DON'T DO IT JUST BECAUSE IT'S A COLLABORATION.

WE WERE IN A DISCUSSION ACTUALLY WITH A

CANADIAN GROUP IN VANCOUVER NOT TOO LONG AGO, AND THEY HAD AN IDEA FOR A COLLABORATION FOR CANCER STEM CELLS. BUT IN MY VIEW, THE PROBLEM IS IT'S NOT OUR JOB TO PUT THAT IN PLACE. THE CANCER STEM CELL SCIENTISTS IN CALIFORNIA HAVE TO BE ENTHUSIASTIC ABOUT IT, AND WE HAVE TO BE CONVINCED THAT WE GET MORE OUT OF IT BY HAVING BOTH TOGETHER. THEN IT REALLY IS SYNERGISTIC. WE CAN DO THAT. I THINK THERE WILL BE OPPORTUNITIES, AND THE REAL POINT IS THERE'S A LOT OF STEM CELL RESEARCH THAT DOES NOT GO ON IN CALIFORNIA. AND THERE ARE WHOLE AREAS THAT ARE NOT PARTICULARLY WELL REPRESENTED HERE, AND WE WILL NEED TO MAKE PARTNERSHIPS WITH THOSE. AND HOW TO GUIDE AND FOSTER THOSE PARTNERSHIPS WITHOUT DIRECTING THEM FROM THE TOP DOWN, WHICH IS ALWAYS, I THINK, A MISTAKE, WILL BE THE NARROW LINE THAT ONE HAS TO WALK.

SO WE'RE OPEN, WE'RE INTERESTED, WE WANT TO MAKE OUR MECHANISMS AVAILABLE. AND IF THERE CAN BE SOMETHING PUT TOGETHER THAT FITS INTO ONE OF OUR INITIATIVES, AND OUR INTENT IS THAT IT WOULD BE, THEN WE WOULD WELCOME THAT. THAT WOULD BE TERRIFIC.

CHAIRMAN KLEIN: IF IT'S APPROPRIATE, ZACH, COULD WE TAKE QUESTIONS FROM THE AUDIENCE?

DR. HALL: ABSOLUTELY.

CHAIRMAN KLEIN: ARE THERE MEMBERS OF THE

AUDIENCE THAT WOULD LIKE TO MAKE COMMENTS OR HAVE QUESTIONS? IF YOU WILL TRY AND KEEP IT TO THREE MINUTES SO THAT IF THERE'S MULTIPLE SPEAKERS, YOU'LL ALL BE HEARD.

MR. REED: THIS IS WHAT HAD TO HAPPEN FOR EVERYBODY'S DREAMS TO GO FORWARD. AND THANK YOU, EVERYBODY, FOR MAKING THIS MAGNIFICENT THING A REALITY. IT'S TREMENDOUS.

THE ONLY SUGGESTION THAT I WOULD HAVE IS I WOULD LIKE THE ASPIRATION PART HIT HARDER. I'M NOT HERE TO FIND A NEW DEGREE OF A SCIENTIFIC PROBLEM SOLVED. I'M HERE SO THAT MY SON WILL WALK AGAIN. AND I KNOW YOU FEEL EXACTLY THAT SAME WAY. EVERYBODY HERE SHARES THAT. WE KNOW THAT. I THINK THAT HAS TO COME OUT STRONGER IN THE ASPIRATIONAL PART, EVEN IF IT'S A SERIES OF QUESTIONS. WILL IT BE POSSIBLE FOR US TO REBUILD THE HUMAN EYE FROM WITHIN AND GIVE SIGHT TO THE BLIND? WILL WE SEE OUR CHILDREN WALK AGAIN? WILL WE SEE LIVES SAVED IN THIS GENERATION? FOR THESE GREAT THINGS TO HAPPEN, HERE ARE THE CONCRETE STEPS WE MUST DO FIRST.

I THINK THAT THE HARD PART IS DONE, BUT I DO THINK WE NEED A LITTLE BIT MORE ON WHAT BROUGHT EVERYBODY HERE IN THE FIRST PLACE. SO THANK YOU FOR A MAGNIFICENT JOB, AND THOSE ARE MY THOUGHTS. ALSO, I

HAVE TO SAY, WELL, MY SON IS GOING TO SAY IT BETTER. I AM TOO MOVED. MY SON, MY SON, PLEASE.

CHAIRMAN KLEIN: ROMAN REED.

MR. ROMAN REED: THANK YOU, LADIES AND GENTLEMEN. HOW KISMET IT IS TODAY TO BE HERE ON A DAY WHEN AT UC BERKELEY AND AT UC IRVINE, CHRISTOPHER REEVE IS BEING HONORED FOR ALL THAT HE DID. WHEN YOU THINK OF CHRISTOPHER REEVE, YOU THINK OF A GREAT MAN WHO LAID FORTH A PATH FOR ALL THE CURES TO BE ABLE TO FIND THE WAY TO THE PEOPLE WHO SUFFER. CHRISTOPHER REEVE BLAZED A PATH.

AND WHEN I LOOK AT THIS DOCUMENT, I STILL FEEL AKIN TO HAVING A ROAD MAP TO CURES. I WOULD LIKE TO THANK YOU SO MUCH FOR ALL OF YOU THAT HAVE DONE SO MUCH TIRELESS AMOUNTS OF WORK AND EFFORT. AND I THANK YOU FROM THE BOTTOM OF MY HEART BECAUSE I BELIEVE ONE DAY THAT YOU ARE GOING MAKE MY PROMISE TO MY SON COME TRUE. AND I PROMISED MY SON THAT ONE DAY I WOULD BE ABLE TO WALK, STAND NEXT TO HIM, AND GO HOLD MY WIFE'S HAND. AND SEEING THIS ROAD MAP TO CURES, I KNOW THAT THIS WILL COME TRUE.

FROM THE BOTTOM OF MY HEART, I THANK EACH AND EVERY ONE OF YOU. THANK YOU.

(APPLAUSE.)

DR. HALL: I THINK WE WANT TO THANK THE REEDS

FOR BEING A CONSONANT AND CONTINUAL SOURCE OF INSPIRATION TO US. THEY'VE BEEN WONDERFUL, MAGNIFICENT.

CHAIRMAN KLEIN: ARE THERE ADDITIONAL QUESTIONS OR COMMENTS FROM THE PUBLIC?

MR. SIMPSON: JOHN SIMPSON FROM THE FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I THINK IT'S VERY IMPORTANT TO HAVE THE ASPIRATIONAL GOALS THAT THE REEDS JUST REFERRED TO. BUT I ALSO THINK THAT IT IS TREMENDOUSLY IMPORTANT FOR ALL CALIFORNIANS THAT THERE BE A REALISTIC ASSESSMENT OF WHAT CAN BE EXPECTED OVER THE NEXT DECADE. I THINK THIS DOCUMENT DOES THIS VERY WELL. ALL TOO OFTEN THERE HAS BEEN HYPE ASSOCIATED WITH STEM CELL RESEARCH. WE KNOW THAT IT WILL GIVE US THE CURES SOMETIME, BUT I THINK THAT THIS IS A VERY REALISTIC DOCUMENT THAT HAS BENCHMARKS THAT ARE ACHIEVABLE WITH SOME VERY HARD WORK, AND IT'S AN IMPORTANT RECOGNITION OF THAT. SO IT'S A VERY, VERY GOOD DOCUMENT.

I WAS PARTICULARLY PLEASED WITH THE OUTREACH AND THE PUBLIC WAY IN WHICH IT WAS PULLED TOGETHER. THAT WAS A PROCESS THAT DID NOT LOOK LIKE IT WAS GOING TO START OUT THAT WAY, BUT EVOLVED. ONCE THE PLAN FOR THE PLAN CAME OUT, IT WAS CLEAR THAT IT WAS AN EXCELLENT THING. YOU EVEN TALKED TO ME. AND I THINK I

MIGHT HAVE EVEN HAD A FEW GOOD IDEAS THAT WENT INTO IT.

THE OTHER THING I WOULD SAY IS THIS, AND THAT IS THAT NO MATTER HOW GOOD A SCIENTIFIC STRATEGIC PLAN IS, TO A CERTAIN EXTENT, IT'S MEANINGLESS IF YOU DON'T HAVE OTHER POLICIES IN PLACE THAT PROVIDE FOR ACCESS AND AFFORDABILITY FOR ALL OF THE FRUITS OF THE RESEARCH THAT COME OUT. I WOULD THINK THAT THE IP POLICIES ARE WHERE THAT'S GOING TO HAVE TO HAPPEN, AND I'LL PROBABLY RAISE A FEW POINTS ABOUT THAT TOMORROW BECAUSE I DON'T THINK THEY'RE THERE YET.

FINALLY, I WOULD ASK A QUESTION. AS SOME OF MAY WELL KNOW, WE DON'T LOOK TOO FAVORABLY ON THE PATENTS HELD BY THE WISCONSIN ALUMNI RESEARCH FOUNDATION. WE HAVE CHALLENGED THEM. THEY HAVE GRANTED -- THE USPTO HAS GRANTED THAT REEXAMINATION. AND THEY SAY THAT IN 70 PERCENT OF SUCH CASES THE CLAIMS ARE AT LEAST NARROWED. BUT MY QUESTION IS TO THE VERY IMPORTANT WORK OF THE STEM CELL BANK, HOW WOULD THAT BE POSSIBLE IF THOSE PATENTS ARE UNFORTUNATELY UPHELD? I'M ASSUMING WE WOULD HAVE TO HAVE FULL, FAIR, FRANK EXCHANGES OF VIEWS IN A MUTUALLY PRODUCTIVE ATMOSPHERE WITH COLLEAGUES IN WISCONSIN AND WOULD HAVE TO GET LICENSES, WHICH THEY MIGHT NOT AT ALL BE INCLINED TO OFFER, FOR A STEM CELL BANK HERE.

SO MY QUESTION IS HAS THERE BEEN THOUGHT

GIVEN IN A SERIOUS WAY TO THE LICENSING ASPECTS OF NOT JUST THE STEM CELL BANK, BUT SOME OF THE OTHER ASPECTS OF THE PLAN? THANK YOU.

DR. HALL: THE SIMPLE ANSWER IS WE HAVE NOT REALLY LOOKED AT THAT IN DETAIL. WE WILL, I THINK, BE HAVING DISCUSSIONS TOMORROW AND LATER ABOUT THIS, BUT THIS IS NOT SOMETHING WE TRIED TO ADDRESS. I THINK THERE'S CLEARLY SCIENTIFIC NEED FOR THE STEM CELL BANK. HOW THAT WOULD WORK IN TERMS OF THE LICENSES IN TERMS OF WARF, I THINK WE WOULD HAVE TO SORT OUT.

MS. GLORIA REED: MY NAME IS GLORIA REED, AND I JUST WANTED TO THANK EVERYONE FOR CHOOSING MY SON'S SLOGAN AND PUTTING HIS NAME ON THE BROCHURE. THANK YOU.

MS. SAMUELSON: IT'S EASY. IT'S SO GOOD.

CHAIRMAN KLEIN: ANY ADDITIONAL COMMENTS?

DR. FRIEDMAN: I DON'T WANT TO PROLONG THIS. JUST A COUPLE OF OTHER THOUGHTS OCCURRED TO ME. ONE IS THAT WE HAD A CONSIDERABLE DISCUSSION AT AN EARLIER POINT ABOUT THE INVOLVEMENT OF ORGANIZATIONS TO HELP DRAFT THE PLAN AND TO SPEND SOME MONEY TO DO THAT. AND I SUGGEST THAT, SINCE ONE OF THE THINGS WE DO IS SHOW THE CITIZENS OF THE STATE THAT WE'RE GOOD STEWARDS WITH THEIR MONEY, I THINK AS MUCH CONGRATULATIONS AS I OFFER TO THE INTERNAL STAFF, I FEEL REASONABLY CONFIDENT THAT

WE WOULDN'T HAVE HAD SUCH A FINE AND POLISHED DOCUMENT WITHOUT ASSISTANCE OF THE PROFESSIONAL CONSULTATION. AND THAT I THINK YOU ALL ARE TO BE RECOGNIZED FOR HAVING MANAGED THAT PART OF IT SO WELL. EACH TIME WE DO THIS, WE LEARN SOMETHING, AND WE WANT TO BE VERY CAREFUL WITH EACH DOLLAR WE SPEND, BUT I THINK THIS IS A REAL GOOD INVESTMENT AND THAT IT WAS PROPERLY DONE AND I THINK CONFIRMS THE WISDOM OF DOING IT THAT WAY.

THE SECOND IS TO JUST STATE THE OBVIOUS. ALL OF US HAVE BEEN INVOLVED WITH STRATEGIC PLANS. AND WHEN WE START OFF WITH ARTICULATING THEM, IT SEEMS LIKE THAT'S THE HARDEST THING IN THE WORLD. WHEN WE LOOK BACK, OF COURSE, THAT'S THE EASIEST THING IN THE WORLD, AND THE HARD WORK REALLY STARTS ONCE YOU APPROVE THE PLAN. EVERYTHING DEPENDS ON EXECUTION, EVERYTHING DEPENDS ON DISCIPLINES AND RIGOR, AND THE HARD WORK GETS MUCH, MUCH MORE INTENSE AS WE MOVE ON. THAT SHOULDN'T DETRACT FROM THE FEELING THIS EVENING OF WHAT A FINE START THIS IS.

DR. HALL: THANK YOU. LET ME JUST ECHO YOUR COMMENTS ABOUT THE PRICE WATERHOUSE TEAM. THEY HAVE BEEN ABSOLUTELY TERRIFIC. THE NICEST PART IS HOW WELL WE HAVE WORKED TOGETHER WITH THEM. AND I WOULD SAY THAT I CAN TELL YOU WE GOT A LOT FOR -- WE GOT OUR MONEY'S WORTH. THESE GUYS WORKED VERY, VERY HARD, THEY

REALLY DID, SO WE ARE GRATEFUL.

(APPLAUSE.)

CHAIRMAN KLEIN: I THINK, MR. PRESIDENT, IF YOU HAVE NO OTHER COMMENTS, THAT WE SHOULD ADJOURN. WE ACTUALLY --

DR. HALL: MR. CHAIR, I HAVE ONE COMMENT JUST TO MAKE. WE RECEIVED A LETTER FROM THE GREENLINING INSTITUTE ABOUT OUR POLICIES WITH RESPECT TO CONTRACTORS AND FACILITIES. I THINK THAT LETTER IS AVAILABLE.

MS. KING: IT WILL BE TOMORROW.

DR. HALL: IT WILL BE AVAILABLE TOMORROW. AND I JUST WANTED TO SAY MY SENSE WAS THAT IT CAME TO US BECAUSE -- THROUGH THE STRATEGIC PLAN, BUT I MAY BE WRONG.

MS. KING: ACTUALLY IT ADDRESSES AN AGENDA ITEM ON THE AGENDA TOMORROW. IT'S ACTUALLY AGENDA ITEM NO. 7. IT'S TO DO WITH THE FACILITIES WORKING GROUP.

DR. HALL: YES. IT REALLY IS AN ITEM THAT WILL BE APPROPRIATE FOR A FACILITIES RFA. I THINK THAT'S WHERE IT PROBABLY SHOULD BE TAKEN CARE OF OR PERHAPS OUR GRANTS ADMINISTRATION POLICY FOR FACILITIES. BUT JUST TO SAY WE RECEIVED THE LETTER. WE APPRECIATED IT. WE ARE NOT IGNORING IT. ITS TIME HAS NOT COME YET IS MY VIEW.

CHAIRMAN KLEIN: I THINK WE STAND ADJOURNED. EXCUSE ME. WE HAVE ONE MORE COMMENT.

DR. PHAM: HI. I AM RANDALL PHAM. I'M HERE OFFICIALLY REPRESENTING THE NETWORK OF ETHNIC PHYSICIAN ORGANIZATION. UNOFFICIALLY I'M REPRESENTING THE CMA. AND I HAVE TO COMMENT ALL OF YOU FOR COMING UP WITH THIS IMPORTANT DOCUMENT. IT'S A GIANT STEP FOR CALIFORNIA. AND I CAN CERTAINLY ASSURE YOU, WITH ALL THE ABILITY I COULD BRING THIS DOCUMENT BACK TO THE CMA AND GIVE IT AS MUCH SUPPORT THAT I CAN. THANK YOU.

CHAIRMAN KLEIN: THANK YOU VERY MUCH. DR. PHAM IS LIAISON FOR OUR BOARD WITH THE CALIFORNIA MEDICAL ASSOCIATION. I'M REMINDED THAT HE'S BEEN WITH US FOR QUITE A WHILE BECAUSE HE WAS WITH US AT OUR FIRST DIVERSITY COUNCIL MEETING IN FRESNO. AND THANK YOU VERY MUCH FOR TRAVELING THE STATE WITH US AND BEING A GATEWAY OF INFORMATION BACK TO THE CALIFORNIA MEDICAL ASSOCIATION, WHO HAS BEEN A STRONG ENDORSER AND SUPPORTER FROM THE VERY BEGINNING. SO THANK YOU.

ADDITIONAL COMMENTS? WE STAND ADJOURNED. THANK YOU.

(THE MEETING WAS THEN ADJOURNED.)

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

LUXE HOTEL
11461 SUNSET BOULEVARD
LOS ANGELES, CALIFORNIA
ON
OCTOBER 10, 2006

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

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