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

VOLUME I

LOCATION: STANFORD UNIVERSITY

ARRILLAGA ALUMNI CENTER

MC GAW HALL, 326 GALVEZ STREET

STANFORD, CALIFORNIA

DATE: AUGUST 12, 2008

4 P.M.

REPORTER: BETH C. DRAIN, CSR

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| INDEX | |
|---|---------|
| I TEM PAG | Ε |
| CALL TO ORDER | 3 |
| ROLL CALL | 111 |
| APPROVAL OF MINUTES-6/26-27/2008 ICOC MEETING | 114 |
| EXECUTI VE PRESENTATI ONS | |
| CHAIRMAN'S REPORT PRESIDENT'S REPORT | 5 11 |
| ACTION ITEMS | |
| CONSIDERATION OF DEFINITION OF PRINCIPAL INVESTIGATOR | 34 |
| CONSIDERATION OF APPOINTMENT OF NEW SCIENTIFIC MEMBERS FOR GRANTS WORKING GROUP. | 61 |
| CONSIDERATION OF APPOINTMENT OF NEW MEMBER TO STANDARDS WORKING GROUP. | 71 |
| CONSIDERATION OF UPDATE FROM STANDARDS WORKING GROUP AND A REGULATORY AMENDMENT AUTHORIZING A PROCEDURE FOR PETITIONING THE ICOC TO DESIGNA STEM CELL LINES DERIVED BEFORE NOVEMBER 2006 AS ACCEPTABLY DERIVED FOR USE IN CIRM-FUNDED RESEA | |
| CONSIDERATION OF DEFINITION FOR "CALIFORNIA SUPPLIER." | 73 |
| CONSIDERATION OF RECOMMENDATIONS FROM GRANTS WORKING GROUP ON NEW FACULTY AWARDS II APPLICATIONS | 123 |

| 1 | STANFORD, CALIFORNIA; TUESDAY, AUGUST 12, 2008 |
|----|--|
| 2 | 4 P.M. |
| 3 | |
| 4 | CHAIRMAN KLEIN: IF I COULD HAVE YOUR |
| 5 | ATTENTION, WE'RE GOING TO CALL THIS MEETING TO |
| 6 | ORDER. WE HAVE A COUPLE MEMBERS IN CARS IN TRANSIT, |
| 7 | BUT WE CAN GO THROUGH THE ADMINISTRATIVE ISSUES AS |
| 8 | WE BRING THIS TO ORDER AND BE PREPARED FOR THE |
| 9 | QUORUM WHEN THEY ARRIVE. |
| 10 | WELCOME, EVERYONE, TO STANFORD. I HAD THE |
| 11 | GOOD FORTUNE AT ONE TIME IN MY LIFE TO SPEND EIGHT |
| 12 | YEARS HERE, AND I SHOULD HAVE SPENT 12. BUT MANY |
| 13 | THANKS TO OUR HOST, DR. PIZZO AND MYRA INGEL AND |
| 14 | KRISTEN GOLDTHORPE FROM DR. PIZZO'S OFFICE, FOR ALL |
| 15 | THEIR HELP IN ARRANGING THIS TREMENDOUS VENUE FOR |
| 16 | US. LIKE TO ALSO THANK JENNA PRYNE AND MELISSA KING |
| 17 | FOR THEIR NORMAL 11 OR 12 O'CLOCK AT NIGHT HEROICS |
| 18 | TO GET THESE MEETINGS TOGETHER. AND THE SUMMER |
| 19 | INTERN WE HAVE SUPPORTING THEM, VICTORIA, I THINK IS |
| 20 | HERE AS WELL FROM WELLESLEY COLLEGE. |
| 21 | WE HAVE A VERY CHALLENGING SCHEDULE OVER |
| 22 | THE NEXT DAY AND A HALF, BUT I'D LIKE TO BEGIN THAT |
| 23 | SCHEDULE BY WELCOMING OUR NEW BOARD MEMBER |
| 24 | CARDIOLOGIST, ROBERT QUINT, WHO IS OUR PATIENT |
| 25 | ADVOCATE FOR HEART DISEASE APPOINTED BY THE |
| | 3 |

| 1 | TREASURER. AND LET ME SEE. RIGHT HERE. THANK YOU |
|----|--|
| 2 | VERY MUCH. |
| 3 | (APPLAUSE.) |
| 4 | CHAIRMAN KLEIN: HOPEFULLY THE TREASURER |
| 5 | DIDN'T SAY THERE WOULD ONLY BE ONE MEETING A |
| 6 | QUARTER. I HAD A GREAT DISCUSSION WITH DR. QUINT, |
| 7 | AND HE HAS A TREMENDOUS COMMITMENT TO THIS |
| 8 | ORGANIZATION AND APPRECIATION FOR THE WORK THAT'S |
| 9 | ALREADY OCCURRED. |
| 10 | BUT I'D LIKE TO ALSO DRAW TO OUR ATTENTION |
| 11 | THAT WE HAVE ONE OF THE GREAT DEANS OF THE |
| 12 | LEGISLATURE, SENATOR JOHN VASCONCELLOS, A CLOSE |
| 13 | FRIEND OF DR. QUINT, WHO IS WITH US. JOHN, COULD |
| 14 | YOU STAND, PLEASE? |
| 15 | (APPLAUSE.) |
| 16 | CHAIRMAN KLEIN: SENATOR VASCONCELLOS IS A |
| 17 | SENIOR ADVISOR TO THE LEGISLATURE. HE WAS ONE OF |
| 18 | THE CO-SPONSORS IN 1976 WHEN I WROTE THE CALIFORNIA |
| 19 | HOUSING FINANCE AGENCY ACT FOR THE LEGISLATURE. BUT |
| 20 | HE HAD GREAT DISTINCTION IN LEADING THE EFFORTS TO |
| 21 | SUPPORT CALIFORNIA EDUCATION AND THE ENVIRONMENT. |
| 22 | HE'S A MAN OF TREMENDOUS SPECTRUM OF GREAT RESPECT, |
| 23 | AND IS NOW A SENIOR ADVISOR TO THE LEADERSHIP OF THE |
| 24 | STATE LEGI SLATURE. |
| 25 | HE'S ALSO BEEN A TREMENDOUS AND STRONG |
| | $\it \Delta$ |

| 1 | CONTINUOUS SUPPORTER OF STEM CELL RESEARCH AND |
|----|--|
| 2 | PROPOSITION 71. SO, JOHN, WE'RE DELIGHTED TO HAVE |
| 3 | YOU HERE. WE'RE DEEPLY APPRECIATIVE OF YOUR |
| 4 | SUPPORT, AND THANK YOU VERY MUCH FOR PRESIDING OVER |
| 5 | 14 SUCCESSFULLY NEGOTIATED STATE BUDGETS, AN ART |
| 6 | FORM CERTAINLY. |
| 7 | MELISSA KING, WOULD YOU PLEASE LEAD US IN |
| 8 | THE PLEDGE OF ALLEGIANCE. |
| 9 | (THE PLEDGE OF ALLEGIANCE.) |
| 10 | CHAIRMAN KLEIN: MELISSA, I'M NOT SURE |
| 11 | THAT WE YET HAVE A QUORUM BECAUSE WE HAVE TWO |
| 12 | MEMBERS IN TRANSIT. WOULD IT BE BETTER TO JUST WAIT |
| 13 | AND DO THE ROLL CALL WHEN THESE MEMBERS GET HERE, OR |
| 14 | WOULD YOU LIKE TO JUST DO THE ROLL CALL AND WE JUST |
| 15 | SUPPLEMENT? |
| 16 | MS. KING: I THINK WE SHOULD WAIT. THANK |
| 17 | YOU. |
| 18 | CHAIRMAN KLEIN: AS SOON AS WE HAVE A |
| 19 | QUORUM PRESENT, WE HAVE AN ADDITIONAL ITEM TO ADD TO |
| 20 | THE AGENDA THAT WE WILL DISCUSS. JAMES HARRISON |
| 21 | WILL LEAD US THROUGH THAT AT THAT TIME. |
| 22 | AT THIS POINT I WOULD LIKE TO LOOK AT OUR |
| 23 | AGENDA ITEMS, AND WE WILL GO IMMEDIATELY AFTER THE |
| 24 | CHAIRMAN'S REPORT AND THE PRESIDENT'S REPORT TO ITEM |
| 25 | NO. 16. SO JUST BEAR THAT IN MIND. |
| | _ |

| 1 | ON BEGINNING THIS MEETING TODAY, I WOULD |
|----|--|
| 2 | LIKE TO CALL TO OUR ATTENTION FOR SPECIAL NOTE THE |
| 3 | HEROIC EFFORTS OF DAVID AMES TO FIGHT WITH ALS, A |
| 4 | DISEASE THAT RECENTLY CLAIMED HIS LIFE. DR. |
| 5 | GENNEVIEVE AMES, A PROFESSOR OF PUBLIC HEALTH AT UC |
| 6 | BERKELEY, AND HER HUSBAND JOHN STOOD BY HIS SIDE |
| 7 | OVER THE LAST FOUR AND A HALF YEARS AS HE FOUGHT |
| 8 | THIS BATTLE WITH A DEADLY AND TRAGIC DISEASE. |
| 9 | HE WAS AN ATTORNEY IN THE BAY AREA WITH A |
| 10 | YOUNG FAMILY, AN ATTORNEY WHO, DESPITE THE DISEASE, |
| 11 | MAINTAINED A PRACTICE CLOSE TO THE END, INCLUDING |
| 12 | TYPING OUT MANUSCRIPTS WITH A PENCIL IN HIS MOUTH. |
| 13 | WE NEED TO REMEMBER THAT HOWEVER DIFFICULT OUR |
| 14 | PERSONAL EFFORTS, THE INDIVIDUALS FOR WHOM WE CHANGE |
| 15 | OUR SCHEDULES AND MAKE ALL THESE PUBLIC MEETINGS AND |
| 16 | DEDICATE OUR LIVES HAVE A MUCH MORE DIFFICULT DAILY |
| 17 | LIFE, A MUCH MORE DIFFICULT STRUGGLE. AND PERHAPS |
| 18 | WE CAN APPRECIATE THE FACT THAT WE HAVE THE TIME TO |
| 19 | CONTRIBUTE WHILE REMEMBERING THOSE WHO LOSE THEIR |
| 20 | LIVES WHILE WE TRY AND GET MEDICAL RESEARCH TO THE |
| 21 | POINT THAT IT CAN MEANINGFULLY ADDRESS THE TRAGIC |
| 22 | CHRONIC DISEASES AND INJURIES THAT THEY MUST FACE |
| 23 | EVERY DAY AND EVERY NIGHT. |
| 24 | WE HAVE IN THAT EFFORT SOME MAJOR |
| 25 | MILESTONES IN RESEARCH GRANTS THAT WE'VE MADE, OVER |
| | |

| 1 | \$270 MILLION. WE HAVE MAJOR MILESTONES IN MAJOR |
|----|--|
| 2 | FACILITIES GROUNDBREAKINGS THAT ARE BEING SCHEDULED |
| 3 | AROUND THIS GREAT STATE. THOSE FACILITIES, |
| 4 | INCLUDING ONE HERE AT STANFORD OF 200,000 SQUARE |
| 5 | FEET, WILL MAKE A REMARKABLE CONTRIBUTION TO THE |
| 6 | ABILITY OF YOUNG SCIENTISTS AND CLINICIANS TO MOVE |
| 7 | FORWARD THE DESPERATELY NEEDED KNOWLEDGE THAT WITH |
| 8 | PAINSTAKING EFFORT AND YEARS OF COMMITMENT WILL |
| 9 | HOPEFULLY YIELD RESULTS ACROSS A SPECTRUM OF CHRONIC |
| 10 | DI SEASE. |
| 11 | WE HAVE CHALLENGES BEFORE US IN LEARNING |
| 12 | HOW TO WORK IN AN INFORMED COLLABORATIVE |
| 13 | PARTICIPATION WITH THE STATE LEGISLATURE. SENATE |
| 14 | BILL 1565 IS A BILL WHERE WE HAVE SOME COOPERATIVE |
| 15 | AMENDMENTS WITH THE SPONSORING SENATOR, BUT SOME |
| 16 | SIGNIFICANT DISAGREEMENTS. |
| 17 | I WOULD LIKE TO NOTE THAT THOSE |
| 18 | DISAGREEMENTS ARE NOT ONE OF OUR OBJECTIVES, AND |
| 19 | THEY'RE NOT ONES OF VALUES. THEY'RE TECHNICAL |
| 20 | DISAGREEMENTS THAT REQUIRE SUBSTANTIAL DISCUSSIONS, |
| 21 | THAT REQUIRE US TO LOOK AT THIS AS A YEAR-LONG |
| 22 | PROCESS, NOT A PROCESS LIMITED TO THE PERIOD OF |
| 23 | LEGI SLATI VE SESSI ONS. |
| 24 | I WOULD HOPE THAT ALL MEMBERS OF THIS |
| 25 | BOARD AND THE PUBLIC WILL MEET WITH THEIR |
| | |

| 1 | ASSEMBLYMEN AND STATE SENATORS TO TRY AND WALK |
|----------|---|
| 2 | THROUGH SOME OF THESE COMPLICATED ISSUES BECAUSE |
| 3 | CERTAINLY THEY ARE VERY MUCH DEDICATED TO THE SAME |
| 4 | OUTCOMES. AND IT WILL BE CRITICAL TO RAISE THE |
| 5 | LEVEL OF INFORMATION SO WE CAN WORK ON A COMMON |
| 6 | PLATFORM WHERE THE ARGUMENTS ARE BASED UPON |
| 7 | SCIENTIFIC DIFFERENCES, FINANCIAL ANALYSIS |
| 8 | DIFFERENCES, AND ARE NOT BROKEN OR OBSTRUCTED BY THE |
| 9 | LACK OF INFORMATION, INFORMATION THAT CANNOT |
| 10 | EFFECTIVELY BE DELIVERED DURING A LEGISLATIVE |
| 11 | SESSION WHEN INDIVIDUAL ASSEMBLYMEN OR STATE |
| 12 | SENATORS MAY BE TRYING TO MOVE FORWARD ON 20 OR 30 |
| 13 | BI LLS. |
| 14 | SO WE HAVE A MAJOR TASK BECAUSE CERTAINLY |
| 15 | THE LEGISLATORS REPRESENT THE LEADING TRANSLATORS IN |
| 16 | THE SOCIETY FOR TURNING GREAT CONCEPTS INTO |
| 17 | POLITICAL REALITY IN THERAPIES. WE WILL NEED TO |
| 18 | WORK OUT A BETTER PARTNERSHIP, A MORE INFORMED |
| 19 | PARTNERSHIP, AND A MORE DYNAMIC PARTNERSHIP WITH |
| 20 | THEM AS WE GO FORWARD. |
| 21 | WE WILL BE TODAY DISCUSSING THE OUTCOMES |
| 22 | OF THE GRANT WORKING GROUPS FOR NEW FACULTY AWARDS |
| 23 | II. AND FOR THOSE OF YOU IN THE PUBLIC THAT HAVE |
| | |
| 24 | NOT BEEN WITH US, AS WE DISCUSS THE BACKGROUND FOR |
| 24 25 | NOT BEEN WITH US, AS WE DISCUSS THE BACKGROUND FOR THIS REVIEW, PLEASE REMEMBER THAT AT THE NIH IN 1985 |

| 1 | 35 PERCENT OF THE GRANTS WERE APPROVED IN THE |
|----|--|
| 2 | BIOMEDICAL AREA. SO THERE WAS A REAL OPPORTUNITY |
| 3 | FOR THE YOUNG, BRILLIANT SCIENTISTS TO MOVE UP IN |
| 4 | THE BIOMEDICAL AREA. |
| 5 | TODAY IT WILL BE FORTUNATE IF 4 PERCENT OF |
| 6 | THE GRANTS ARE APPROVED IN MANY OF THE INSTITUTES AT |
| 7 | THE NIH. THE SCARCITY OF RESOURCES MEANS THAT THE |
| 8 | GRANTS WILL MOST PROBABLY GO TO THE MOST SENIOR, |
| 9 | WELL-ESTABLISHED INVESTIGATORS, WHICH HAS THE |
| 10 | POTENTIAL TO KILL OFF THE SPIRIT AND DEDICATION OF |
| 11 | AN ENTIRE GENERATION OF NEW CLINICIANS AND |
| 12 | SCI ENTI STS. |
| 13 | SO HOPEFULLY THE FACULTY GRANTS WE ARE |
| 14 | LOOKING AT TODAY PROVIDE A BROAD FOUNDATION FOR |
| 15 | ASSURANCE TO THAT GENERATION THAT THEY ARE CRITICAL |
| 16 | MEMBERS OF THE MISSION OF PROPOSITION 71 IN |
| 17 | CALI FORNI A. |
| 18 | DR. PI ZZO. |
| 19 | DR. PIZZO: JUST FOR THE RECORD, I THINK |
| 20 | THE POINT YOU MADE ABOUT THE NEW FACULTY AWARDS IS |
| 21 | VERY, VERY IMPORTANT AND VERY SIGNIFICANT AND WILL |
| 22 | MAKE AN EXTRAORDINARY DIFFERENCE. BUT I DO THINK, |
| 23 | BECAUSE THIS IS A PUBLIC MEETING, THE NIH FUNDING, I |
| 24 | DON'T THINK, IS AS LOW AS 4 PERCENT. FURTHER, THE |
| 25 | NIH HAS TAKEN SPECIAL EXCEPTION TO TRY AND DEVELOP |
| | |

| 1 | PROGRAMS FOR YOUNG INVESTIGATORS SO THAT THEY CAN |
|----|---|
| 2 | ENTER THE PIPELINE. |
| 3 | THAT SAID, IT'S A PRETTY DIRE SITUATION IN |
| 4 | BETHESDA; BUT JUST BECAUSE WE ARE IN A PUBLIC |
| 5 | SETTING, I DON'T WANT TO GIVE THE WRONG SENSE OF |
| 6 | ACTUAL NUMBERS. |
| 7 | CHAIRMAN KLEIN: AND CERTAINLY WE SHOULD |
| 8 | APPLAUD EVERY EFFORT THE NIH MAKES TO, IN FACT, |
| 9 | PROVIDE A LIFT TO YOUNG INVESTIGATORS TO REALLY |
| 10 | ENCOURAGE THEIR ACTIONS AND COMMITMENT TO THIS |
| 11 | FI ELD. |
| 12 | AS WE GO THROUGH THE MEETING TODAY FOR THE |
| 13 | GRANT REVIEWS, THE CIRM STAFF AND BOARD MEMBERS |
| 14 | HAVE, ONCE AGAIN, GONE THROUGH AN EXTENSIVE PROCESS |
| 15 | TO CHECK FOR CONFLICTS OF INTEREST AND TO ENSURE |
| 16 | THAT BOARD MEMBERS WHO HAVE A CONFLICT ON A |
| 17 | PARTICULAR APPLICATION WILL NOT PARTICIPATE IN THAT |
| 18 | APPLICATION. STAFF HAS PROVIDED EACH BOARD MEMBER |
| 19 | WITH A LIST OF INSTITUTIONS THAT HAVE SUBMITTED |
| 20 | APPLICATIONS, AND THE BOARD MEMBERS' CONFLICTS ARE |
| 21 | NOTED. |
| 22 | IN ADDITION, COUNSEL TO THE BOARD WILL |
| 23 | MAKE CERTAIN TO REVIEW BEFORE ANY VOTES AND BEFORE |
| 24 | DISCUSSIONS OF GRANTS WHICH INDIVIDUALS CANNOT |
| 25 | PARTICIPATE IN THAT DISCUSSION IN THOSE VOTES. |
| | 10 |

| 1 | THE STAFF HAS, BESIDES THE CONFLICTS |
|----|--|
| 2 | LISTED, THEY'RE CLEARLY PROVIDED FOR, HAS GONE |
| 3 | THROUGH THE FORM 700, THE PUBLIC DISCLOSURE FORMS, |
| 4 | PROVIDED BY EVERY BOARD MEMBER TO MAKE CERTAIN AS A |
| 5 | DOUBLE CHECK THAT THERE AREN'T ANY ADDITIONAL |
| 6 | CONFLICTS THAT SHOULD BE NOTED. |
| 7 | I'D LIKE AT THIS POINT TO TURN TO DR. |
| 8 | TROUNSON, WHO I THINK HAS A DISTINGUISHED VISITOR TO |
| 9 | INTRODUCE, AMONG OTHER GREAT POINTS THAT HE WILL |
| 10 | COVER. THANK YOU, DR. TROUNSON. |
| 11 | DR. TROUNSON: THANK YOU VERY MUCH, CHAIR. |
| 12 | LET ME BEGIN FIRST WITH AGAIN THANKING YOU FOR YOUR |
| 13 | COLLEGIATE INPUT TO ALL THE THINGS WE DO. BUT OTHER |
| 14 | MEMBERS OF THE BOARD, ED PENHOET, WHO'S ALWAYS THERE |
| 15 | WITH A GUIDING HAND, JOAN SAMUELSON AND JEFF SHEEHY |
| 16 | HELPING US CONTINUOUSLY WITH PROCESSES, AND FLOYD |
| 17 | BLOOM IN SORT OF SENDING ME MATERIAL TO AWAKEN SOME |
| 18 | OTHER ISSUES FOR ME. |
| 19 | SO THESE ARE THINGS WHICH ARE HAPPENING |
| 20 | ALL THE TIME. WE'VE HAD IN-DEPTH DISCUSSION WITH |
| 21 | RICARDO AZZIZ AND PHIL PIZZO. SO THERE'S A VERY |
| 22 | GOOD RAPPORT GOING ON AND DISCUSSION, AND I JUST |
| 23 | WANTED TO ACKNOWLEDGE THAT FORMALLY. AND I REALLY |
| 24 | DO. WE ALL APPRECIATE IT, ALL MEMBERS OF THE STAFF. |
| 25 | WE HAVE WITH US TODAY JOHN ROBSON WHOSE |
| | 11 |

| 1 | APPOINTMENT AS THE DEPUTY PRESIDENT, OPERATIONS, AND |
|----|--|
| 2 | SO WE THOUGHT WE'D INITIATE HIM INTO THE WILD AND |
| 3 | WOOLY CIRCUS OF A BOARD MEETING. USUALLY THERE'S |
| 4 | SOME EXCITEMENT GOING ON IN THE DISCUSSION, SO WE |
| 5 | THOUGHT IT WOULD BE INFORMATIVE TO HAVE HIM WITH US |
| 6 | TODAY. SO, JOHN, IF YOU WOULDN'T MIND STANDING, AND |
| 7 | THANK YOU VERY MUCH FOR JOINING US. |
| 8 | (APPLAUSE.) |
| 9 | DR. TROUNSON: SO YOU CAN EXPECT HIM TO BE |
| 10 | HAVING INPUT IN THE FUTURE. HE'LL BE JOINING, |
| 11 | ACTUALLY FORMALLY JOINING THE AGENCY IN THE MIDDLE |
| 12 | OF SEPTEMBER. AND WE'RE CERTAINLY LOOKING FORWARD |
| 13 | TO HIS INPUT ON MANY, MANY DIFFERENT THINGS, |
| 14 | PARTICULARLY THE PROCESSES WHICH ARE SO DEMANDING |
| 15 | WITHIN THE INSTITUTION. |
| 16 | SO AS USUAL, CHAIR, IF I MAY, WE START OFF |
| 17 | WITH SCIENCE. THAT'S THE BITTER PILL YOU HAVE TO |
| 18 | HAVE WITH THE PRESIDENT. SO IF I MAY, I WANTED TO |
| 19 | DRAW THE ATTENTION TO THIS FIRST PAPER. IT'S ABOUT |
| 20 | THE INDUCED PLURIPOTENTIAL CELLS. YOU WILL REMEMBER |
| 21 | THOSE ARE THE CELLS WHERE THEY INTRODUCE FOUR |
| 22 | TRANSCRIPTION FACTORS. THESE ARE GENES THAT GUIDE |
| 23 | OTHER GENES IN THE GENOME. AND THESE CELLS WHICH |
| 24 | HAVE HAD THESE GENES TRANSDUCED INTO THEM USING A |
| 25 | RETROVIRAL VECTOR CAN PRODUCE CELLS WHICH HAVE ALL |
| | |

| 1 | THE PROPERTIES OR APPEAR TO HAVE ALL THE PROPERTIES |
|----|--|
| 2 | OF EMBRYONIC STEM CELLS, SO THEY ARE RECOGNIZED AS A |
| 3 | PLURIPOTENT STEM CELL LINE. |
| 4 | WELL, IN THESE GENES I THINK IT'S VERY |
| 5 | INTERESTING. IT'S WORK THAT'S COME OUT OF THE |
| 6 | HARVARD STEM CELL CENTER AND KEVIN EGGAN'S LAB. |
| 7 | KEVIN IS ON OUR STANDARDS COMMITTEE. HE'S A GREAT |
| 8 | YOUNG SCIENTIST, AND ONE OF THOSE PEOPLE WHO'S |
| 9 | DEFINITELY GOING TO FLOURISH WORLDWIDE AS A VERY |
| 10 | IMPORTANT SCIENTIFIC LEADER FROM NOW ON. |
| 11 | HIS WORK HAS BEEN MOVING AROUND TRYING TO |
| 12 | WORK OUT HOW TO DRAW PLURIPOTENTIAL CELLS EITHER BY |
| 13 | NUCLEAR TRANSFER OR BY THE VIRAL INDUCTION SYSTEMS. |
| 14 | AND HE'S SHOWN THAT THESE CELLS HE'S TAKEN CELLS |
| 15 | FROM AN 82-YEAR-OLD WOMAN WHO'S BEEN DIAGNOSED WITH |
| 16 | A FAMILIAL FORM OF AMYOTROPHIC LATERAL SCLEROSIS, |
| 17 | ALS. ALS, YOU WILL RECALL, I'M SURE, FROM MANY |
| 18 | REPORTS IS ONE OF THOSE REALLY DIFFICULT DISEASES |
| 19 | WHICH HAS VERY LITTLE HELP IN THERAPEUTICS |
| 20 | AVAI LABLE. |
| 21 | SO THESE CELLS, I THINK, ARE CAPABLE OF |
| 22 | NOT ONLY FORMING IPS CELLS, BUT DIFFERENTIATING INTO |
| 23 | MOTOR NEURONS, WHICH IS THE CELL TYPE THAT'S |
| 24 | DESTROYED IN ALS. |
| 25 | SO WE BELIEVE THAT THESE CELLS WILL |
| | 12 |

| 1 | PROVIDE INSIGHT INTO THE CAUSE OF ALS, WHICH IS |
|----|--|
| 2 | REALLY IMPORTANT. THE BASIC BIOLOGY HERE IS |
| 3 | ESSENTIAL BECAUSE THAT'S THE WAY YOU FIGURE OUT THE |
| 4 | STRATEGY IF YOU'RE ADDRESSING THESE DISEASES. AND |
| 5 | PARTICULARLY CELLULAR AND MOLECULAR MECHANISMS THAT |
| 6 | DERIVE THIS PARTICULAR PHENOTYPE. SO, OF COURSE, |
| 7 | THEY COULD LEAD TO THE DISCOVERY OF NEW SMALL |
| 8 | MOLECULAR DRUGS. THEY THEMSELVES MAY BECOME A |
| 9 | PHARMACEUTICAL IN TREATING THIS DISEASE. SO THIS IS |
| 10 | AN IMPORTANT EXAMPLE OF WHERE THESE CELLS WILL |
| 11 | PROBABLY PLAY AN IMPORTANT PART. |
| 12 | THE NEXT ONE IS FROM AMY WAGER'S LAB AT |
| 13 | HARVARD STEM CELL INSTITUTE. SHE DID HER ORIGINAL |
| 14 | WORK AT STANFORD. SO, PHILIP, SHE'S ONE OF THE |
| 15 | INIMITABLE GREAT YOUNG SCIENTISTS WHO ARE DEVELOPING |
| 16 | NOW WITH AN INCREDIBLY GOOD PEDIGREE. AND I THINK |
| 17 | SHE'S ALSO RECOGNIZED AS ONE OF THESE REALLY |
| 18 | HIGH-FLYING SCIENTISTS IN THE YOUNG DEVELOPING |
| 19 | GROUP. LOVE TO GET HER BACK TO CALIFORNIA SOMETIME, |
| 20 | BUT SHE'S PART OF SHE'S ON OUR GRANTS WORKING |
| 21 | GROUP. |
| 22 | AND HER PAPER THERE WAS PUBLISHED IN CELL, |
| 23 | WHICH IS ONE OF PRIMARY JOURNALS IN OUR DISCIPLINE. |
| 24 | THEY WERE LOOKING AT THE STEM CELL POPULATION IN |
| 25 | MUSCLE. THERE'S BEEN SOME ARGUMENT ABOUT WHETHER |
| | |

| 1 | THERE IS A STEM CELL POPULATION IN MUSCLE. WHAT |
|----|--|
| 2 | SHE'S DONE IS TO LOOK AMONGST THE SATELLITE CELLS. |
| 3 | THE SATELLITE CELLS WERE THOUGHT TO BE AS CLOSE AS |
| 4 | WE COULD GET TO STEM CELLS IN MUSCLE. AND SHE'S |
| 5 | FOUND, BY LOOKING AT MARKERS, THAT YOU CAN ACTUALLY |
| 6 | IDENTIFY A SMALL NUMBER OF THE CELLS IN THAT |
| 7 | SATELLITE CELL GROUP THAT CAN FUNCTION AS MUSCLE |
| 8 | CELLS. THEY ACTUALLY GO ON TO PRODUCE MUSCLE FIBERS |
| 9 | AND ALL THE CELLS OF MUSCLE. SO THEY APPEAR TO BE A |
| 10 | GENUINE STEM CELL. |
| 11 | AND WHEN THEY ENGRAFTED THESE INTO |
| 12 | DYSTROPHIN-DEFICIENT MOUSE, THAT IS, A MOUSE THAT |
| 13 | DOESN'T HAVE THE PROTEIN DYSTROPHIN, TYPICAL OF |
| 14 | MUSCULAR DYSTROPHY, THAT THESE HUMAN CELLS |
| 15 | CONTRIBUTED UP TO 94 PERCENT OF THE MYOFIBERS, |
| 16 | RESTORING DYSTROPHIN EXPRESSION AND REALLY IMPROVING |
| 17 | THE MUSCLE HISTOLOGY AND CONTRACTILE FUNCTION. |
| 18 | SO THIS IS GOOD NEWS FOR MUSCULAR |
| 19 | DYSTROPHY. AND THESE DATA WILL SUPPORT THE USE OF |
| 20 | PROGENITOR MUSCLE CELLS FOR CELL THERAPY IN MUSCULAR |
| 21 | DYSTROPHY. AND IF WE CAN GET PLURIPOTENTIAL CELLS |
| 22 | THROUGH TO THAT POINT, OF COURSE, THEY WILL ALSO BE |
| 23 | LIKELY TO BE SIGNIFICANT IN THIS PARTICULAR DISEASE. |
| 24 | THE NEXT ONE, I WANTED TO BRING IT TO YOUR |
| 25 | ATTENTION BECAUSE THE SCIENTISTS AT THE INSTITUTE |
| | |

| 1 | II DIFFICULI BECAUSE LIVER CELLS AND HEARI CELLS ARE |
|----|--|
| 2 | THE TWO CELL TYPES THAT THEY WANT TO USE FOR |
| 3 | TOXICOLOGY SCREENING, PARTICULARLY LIVER AND HEART |
| 4 | CELLS, BOTH IN DRUG DESIGN AND ENVIRONMENTAL |
| 5 | TOXICOLOGY. AND YOU GET HEART CELLS WHICH HAVE THE |
| 6 | FETAL PHENOTYPE, BUT YOU DON'T GET THE ADULT |
| 7 | PHENOTYPE. |
| 8 | SO WE ARE NOW THINKING THAT WE OUGHT TO |
| 9 | PROGRESS, PERHAPS PUT TO THE COMMUNITY THAT THERE'S |
| 10 | AN ISSUE HERE THAT WE NEED TO GET THESE CELLS |
| 11 | MATURE. THERE MUST BE WAYS TO DO IT. MAYBE A |
| 12 | TARGETED RFA IN THIS AREA MAY BE NECESSARY BECAUSE |
| 13 | IT COULD WELL BE A BLOCK TO GETTING THESE CELLS |
| 14 | FURTHER DOWN THE TRANSLATIONAL PIPELINE. |
| 15 | NEXT SLIDE. INTERESTINGLY, ANOTHER COUPLE |
| 16 | OF PAPERS PUBLISHED BACK TO BACK IN CIRCULATION |
| 17 | WHERE IPS CELLS, ONE PAPER FROM THE GROUP IN HANOVER |
| 18 | IN GERMANY AND THE OTHER FROM THE YAMANAKA LAB IN |
| 19 | KYOTO. SHINYA YAMANAKA WAS THE PERSON WHO |
| 20 | DISCOVERED IPS CELLS. AND THESE BACK-TO-BACK PAPERS |
| 21 | SHOW THAT IPS CELLS WILL FORM BEATING HEART MUSCLE |
| 22 | CELLS WITH VENTRICULAR, ATRIAL, AND PACEMAKER |
| 23 | PHENOTYPES, BUT THEY ARE A FETAL PHENOTYPE RATHER |
| 24 | THAN AN ADULT PHENOTYPE, BUT THEY PRODUCE THOSE |
| 25 | PHENOTYPES THAT ARE TYPICALLY FETAL. AND THAT'S |
| | |

| 1 | COMPARABLE TO EXACTLY THE SAME DIFFERENTIATION |
|----|---|
| 2 | CAPACITY AS EMBRYONIC STEM CELLS. |
| 3 | SO HERE WE ARE GETTING NOW DIVERGENCE OR |
| 4 | EMERGENCE OF TWO FIELDS COMING TOGETHER, THE |
| 5 | EMBRYONIC STEM CELL AREA WHERE THERE ARE |
| 6 | DIFFERENTIATION PROGRAMS TOGETHER WITH THE IPS |
| 7 | CELLS. AND BOTH PROBABLY SHOWING UP PHENOTYPES |
| 8 | WHICH THEMSELVES ARE VERY ENCOURAGING, BUT THERE |
| 9 | NEEDS TO BE A TRANSITION FROM THIS IMMATURE TO THE |
| 10 | MORE MATURE PHENOTYPES. |
| 11 | WELL, I'VE BEEN GIVING YOU MY PRIORITIES |
| 12 | SO THAT YOU UNDERSTAND WHAT I'M PRESSING ON AT THE |
| 13 | PRESENT TIME. AND SO THAT GIVES YOU AN IDEA OF |
| 14 | WHERE WE'RE GOING. WE'RE REDEVELOPING OR DEVELOPING |
| 15 | THE CIRM 2008 STRATEGIC PLAN. WE'RE IN DRAFT FORM |
| 16 | WITH THAT. THERE WILL BE A PROCESS OF DISCUSSIONS |
| 17 | WITH STAKEHOLDERS. WE'RE IN THE EARLY DRAFTS OF |
| 18 | THAT, AND IT'S LOOKING VERY INTERESTING. |
| 19 | WE'VE GOT TO FOCUS ON THE TRANSLATIONAL |
| 20 | DISEASE TEAM RESEARCH, AND THEY'RE MUCH MORE DOWN |
| 21 | THE PIPELINE TOWARDS THE CLINIC. YOU WILL RECOGNIZE |
| 22 | THAT. IT BRINGS IN A NEW GROUP OF SCIENTISTS. IT |
| 23 | ALSO CONNECTS WITH THE BIOTECHNOLOGY AND POSSIBLY |
| 24 | EVEN PHARMACEUTICAL INDUSTRIES, AND THEY BECOMING A |
| 25 | PART OF OUR WHOLE PROGRAM. SO THERE'S A LOT OF |
| | 10 |

| 1 | DISCUSSIONS GOING ON IN THIS AREA TO GET PEOPLE |
|----|--|
| 2 | COMFORTABLE, GET THEM KNOWLEDGEABLE ABOUT WHERE |
| 3 | WE'RE GOING, AND GET THEM INTERSECTING WITH OUR |
| 4 | CURRENT PRIORITIES. |
| 5 | WE'RE HAVING DISCUSSIONS WITH THE |
| 6 | FOR-PROFIT BIOTECH AND PHARMACEUTICAL SECTOR. THERE |
| 7 | WILL BE WORKSHOPS IN THIS AREA, BUT WE'RE ALSO |
| 8 | HAVING A LOT OF DISCUSSIONS WITH INDIVIDUAL |
| 9 | COMPANIES AND SENIOR EXECUTIVES. WE'RE GETTING A |
| 10 | FEEL FOR, YOU KNOW, HOW THE RELATIONSHIP COULD |
| 11 | DEVELOP. |
| 12 | WE'VE BEEN BUSY ON INTERNATIONAL |
| 13 | CONNECTIONS. I'LL MENTION A FEW OF THOSE IN A |
| 14 | MOMENT. THEY'RE PROGRESSING STEADILY UNDER THE |
| 15 | DIRECTION OF NANCY KOCH. WE'RE LOOKING AT, I THINK, |
| 16 | OF SOME INTEREST IN THE DEVELOPMENT OF PRODUCTIVITY |
| 17 | MEASURES. WHAT'S THE DOLLARS THAT ARE COMING IN? |
| 18 | WE NEED TO START TO CREATE MEASURES, I THINK, CREATE |
| 19 | THE MEASURES OR START TO THINK ABOUT HOW TO CREATE |
| 20 | THE MEASURES FOR WHAT FINANCIAL, WHAT ECONOMIC |
| 21 | BENEFITS ARE ARISING FROM THIS. |
| 22 | SO WE STARTED TO HAVE CONVERSATIONS WITH |
| 23 | PEOPLE WHO WORK IN THIS INTERESTING SECTOR THAT LOOK |
| 24 | AT, SAY, THE STIMULATION OF THE COMMERCIAL SECTOR, |
| 25 | THE NUMBER OF NEW COMPANIES, THE INCREMENT IN THE |
| | |

| 1 | EXPANSION OF COMPANIES THAT COULD BE RELATED TO OUR |
|----|--|
| 2 | MONEY COMING IN. WHAT ARE THE MULTIPLIER EFFECTS OF |
| 3 | NEW SCIENTISTS COMING INTO INSTITUTIONS, THE |
| 4 | INCREASING NUMBER OF SCIENTISTS, YOU KNOW, THAT HAVE |
| 5 | ARRIVED BECAUSE OF THE DEVELOPMENT OF NEW |
| 6 | I NSTI TUTI ONS. |
| 7 | IT IS REALLY LOOKING AT PRODUCTIVITY |
| 8 | MEASURES THAT WE CAN THEN PUT INTO MODELS THAT WE |
| 9 | CAN THEN START ADDRESSING THE QUESTIONS THAT ARE |
| 10 | COMING QUITE FREQUENTLY, I THINK, FROM DIFFERENT |
| 11 | SECTORS ABOUT, WELL, WHAT'S HAPPENING? HOW IS |
| 12 | CALIFORNIA STARTING TO BENEFIT FROM THIS? EVEN |
| 13 | THOUGH IT IS VERY EARLY ON IN TIME, I RECOGNIZE THAT |
| 14 | WE WANT TO DEVELOP THOSE PRODUCTIVITY PARAMETERS. |
| 15 | AND WE'RE HAVING A FULL OF RANGE OF |
| 16 | DISCUSSION WITH RESEARCH INSTITUTES AND KEY |
| 17 | SCIENTISTS. MARIE CSETE IS FREQUENTLY OUT THERE |
| 18 | TALKING TO SCIENTISTS AND KEY MEMBERS OF THE |
| 19 | COMMERCIAL SECTOR, THE WHOLE SET OF PARAMETERS HERE, |
| 20 | ALL OF THE PEOPLE THAT ARE LIKELY TO BE INTERACTING |
| 21 | WITH US. I'M SPENDING A LOT OF TIME AT DIFFERENT |
| 22 | INSTITUTIONS GETTING A FEEL FOR WHAT THEY'VE GOT AND |
| 23 | THEN HOW WE CAN CONNECT AND GIVING THEM A HEADS-UP |
| 24 | THAT THERE ARE THINGS HAPPENING THAT THEY MAY WELL |
| 25 | HAVE NOT THOUGHT OF. SO SOME OF THOSE REMINDERS OF |
| | 20 |

| 1 | ME GETTING OUT THERE HAVE STIMULATED A WHOLE NEW |
|----|--|
| 2 | LOOK AT SOME OF THE OPPORTUNITIES THAT ARE COMING. |
| 3 | THE UPDATE ON THE INTERNATIONAL AND |
| 4 | NATIONAL LINKAGES. WE'VE GOT MOU'S SIGNED WITH THE |
| 5 | CANADIAN CANCER STEM CELL CONSORTIUM AND THE STATE |
| 6 | OF VICTORIA IN AUSTRALIA. UNDER NEGOTIATION, NEARLY |
| 7 | COMPLETE, IS THE MEDICAL RESEARCH COUNCIL FROM THE |
| 8 | UNITED KINGDOM AND ALSO THE JUVENILE DIABETES |
| 9 | RESEARCH FOUNDATION. PEN HAS NOT GONE ON PAPER, BUT |
| 10 | MOST OF THE NEGOTIATIONS HAVE BEEN COMPLETED. WE |
| 11 | KNOW WHERE THESE HIGH-LEVEL MOU'S SIT. |
| 12 | AND INTERESTING, THE FOUNDATION FOR |
| 13 | FIGHTING BLINDNESS HAVE CONNECTED STRONGLY WITH US, |
| 14 | AND THEY WANT TO BE PART OF WHAT WE'RE DOING GOING |
| 15 | FORWARD. WE'VE INITIATED TALKS WITH THE ALLIANCE OF |
| 16 | GENE THERAPY, GERMANY, JAPAN, AND ISRAEL, AND WE'VE |
| 17 | ALSO REMINDED THE SINGAPOREANS THAT THEY ALSO HAD AN |
| 18 | INTEREST IN LINKING WITH US. SO WE WANT TO MAKE |
| 19 | SURE THAT WE'RE SORT OF OPENING THE POSSIBILITIES, |
| 20 | NOT IN ALTERING OUR PROGRAMS SPECIFICALLY AT ALL AT |
| 21 | THIS STAGE, BUT MAYBE ALLOWING FOR THEM TO BECOME |
| 22 | CONNECTED WITH US SO THAT THEY WOULD PAY FOR THE |
| 23 | OUT-OF-CALIFORNIA COLLABORATIVE COMPONENT AND THAT |
| 24 | WE GET MAYBE A BETTER EFFECT FROM THE DOLLARS THAT |
| 25 | WE PUT IN THROUGH CALIFORNIA BY THE MULTIPLICATION |
| | |

| 1 | OF GETTING OUR COLLEAGUES, SAY, IN CANADA IN THE |
|----|--|
| 2 | CANCER STEM CELL AREA TO JOIN WITH US. |
| 3 | I THINK THESE ARE FANTASTIC NEW |
| 4 | OPPORTUNITIES FOR US. AND IT'S BEING TAKEN VERY |
| 5 | STRONGLY AS AN INDICATION OF LEADERSHIP THAT'S |
| 6 | COMING FROM CALIFORNIA IN THIS AREA. |
| 7 | I WANTED TO REPORT BRIEFLY ON THE |
| 8 | PREDICTIVE TOXICOLOGY WORKSHOP THAT WE HAD. IT WAS |
| 9 | ORGANIZED FOR US BY ASHA, AND SHE'S HERE BEHIND US. |
| 10 | THANKS, ASHA. THIS WAS A VERY INTERESTING WORKSHOP |
| 11 | THAT BROUGHT MEMBERS OF THE PHARMACEUTICAL INDUSTRY, |
| 12 | IT BROUGHT THE PUBLIC AGENCIES INVOLVED IN |
| 13 | ENVIRONMENTAL TOXICOLOGY, AND RESEARCHERS TOGETHER |
| 14 | WITH US. |
| 15 | AND SOME OF THE IMPORTANT THINGS THAT |
| 16 | EVOLVED OUT OF THAT IS THE NEED FOR A CHEMICAL |
| 17 | REFERENCE LIBRARY TO PROVIDE A REFERENCE SET FOR |
| 18 | VALIDATING THE CELL LINES. THAT IS, IF THE |
| 19 | PHARMACEUTICAL INDUSTRY HAS ALL OF THESE DRUGS THAT |
| 20 | HAVE EITHER WORKED OR NOT WORKED, PREDICTING THAT |
| 21 | THEY MIGHT BE USEFUL, THEY'RE THE ONES THAT WE |
| 22 | SHOULD USE FOR VALIDATION WHEN WE COME BACK AND WANT |
| 23 | TO USE THEM ON, SAY, LIVER CELLS OR HEART CELLS. |
| 24 | AND SO THE PHRMA INDUSTRY IS QUITE |
| 25 | INTERESTED IN PROVIDING THAT. I DON'T SEE THAT |
| | 22 |

| 1 | THERE'S ANY DIFFICULTY IN DOING THAT. THEY PROBABLY |
|----|--|
| 2 | WOULDN'T GIVE US THE FULL GAMUT OF EVERYTHING THAT |
| 3 | THEY WORK WITH, BUT THEY WILL CERTAINLY GIVE US A |
| 4 | RANGE OF DRUGS THAT CAN BE USED IN THIS SETTING. |
| 5 | AND THE VALIDATION OF THE USE OF THESE CELL LINES |
| 6 | COMPARED TO AN ANIMAL, A RAT OR A MOUSE, IS A REALLY |
| 7 | IMPORTANT OPPORTUNITY FOR PARTICULARLY THE |
| 8 | PHARMACEUTICAL COMPANIES BECAUSE IT CUTS DOWN ON THE |
| 9 | COST. AND, INDEED, THE PHARMACEUTICAL COMPANIES ARE |
| 10 | ACTUALLY USING MOUSE EMBRYONIC STEM CELLS TO DO THAT |
| 11 | ALREADY. AND I DIDN'T REALLY KNOW THAT THEY HAD |
| 12 | PROGRESSED THAT FAR, BUT THEY HAVE. THEY HAVEN'T |
| 13 | SWITCHED YET TO HUMAN EMBRYONIC STEM CELLS. THERE |
| 14 | ARE ISSUES OF IP AND COMPLEX MATTERS OF THAT |
| 15 | MATERIAL IN THAT AREA, BUT THEY'RE VERY KEEN TO DO |
| 16 | THAT, TO MOVE INTO HUMAN EMBRYONIC STEM CELL DERIVED |
| 17 | CELLS FOR THIS WORK. |
| 18 | WE'RE LOOKING FOR WHAT WE CALL OLYMPIAD |
| 19 | CELL LINES WHICH ARE ROBUST AND THEY CAN BE |
| 20 | REPRODUCIBLY DIFFERENTIATED WITH HIGH EFFICIENCY. |
| 21 | THOSE CELLS THAT GET TO BE PANCREATIC CELLS, GET TO |
| 22 | BE HEART CELLS, GET TO BE THOSE ONES THAT ARE EASILY |
| 23 | DRIVEN INTO THAT LINEAGE. WE HAVE THOSE. THOSE ARE |
| 24 | THE ONES THAT WE NEED TO BE ABLE TO IDENTIFY. IT |
| 25 | WAS PUT TO US IF WE COULD USE OUR SOURCES TO |
| | |

| 1 | IDENTIFY SOME OF THESE SO-CALLED OLYMPIAD LINES THAT |
|----|--|
| 2 | FORM SPECIAL CELL TYPES AND THEY DO IT IN A ROBUST |
| 3 | AND EASILY INSTRUCTED MANNER, THESE WOULD BE VERY, |
| 4 | VERY IMPORTANT. SO WE THOUGHT THAT THAT MIGHT BE |
| 5 | ONE AREA THAT CIRM COULD GET INVOLVED IN. |
| 6 | THE TOXICITY TESTING IS REALLY ON THE |
| 7 | DESIRE IS ON LIVER CELLS, HEART CELLS, AND NEURONS, |
| 8 | PARTICULARLY LIVER CELLS AND HEART CELLS. AND, AS I |
| 9 | SAID, THERE ARE SOME ISSUES THERE ABOUT GETTING |
| 10 | MATURE CELL TYPES. |
| 11 | CURRENT DIFFERENTIATION PROTOCOLS ARE, AS |
| 12 | I SAID, NOT YIELDING THAT FULLY MATURE CELL TYPE. |
| 13 | SO I THINK THERE IS A CHALLENGE HERE FOR US FOR THE |
| 14 | SCIENTISTS TO GET US THROUGH TO THAT POINT BECAUSE |
| 15 | IF WE DO THAT, THEN I THINK WE'VE GOT A WHOLE NEW |
| 16 | SYSTEM FOR THE ENVIRONMENTAL AS WELL AS THE DRUG |
| 17 | INDUSTRY, THE ENVIRONMENTAL TOXICITY TESTING GROUPS. |
| 18 | SO THIS IS JUST ADDITIONAL POINTS. I |
| 19 | THINK I'VE ALREADY MADE THEM. THE ENVIRONMENTAL |
| 20 | TOXICITY TESTING, THEY ALREADY HAVE SOME MAJOR |
| 21 | TOXICOLOGY ASSAYS, AND THEY WOULD LIKE TO WORK WITH |
| 22 | US AND MAKE IT AVAILABLE TO US AND TO UTILIZE THIS. |
| 23 | SO WE'RE NOW GOING TO WORK OUR WAY INTO A |
| 24 | SET OF RECOMMENDATIONS THAT WE'LL COME BACK TO YOU |
| 25 | ON OF HOW WE MIGHT PROGRESS THIS VERY INTERESTING |
| | |

| 1 | AREA, BOTH TO ASSIST THE DRUG SCREENING SYSTEMS. |
|----|--|
| 2 | THAT WOULD BE HELPFUL ALL AROUND AND WOULD CERTAINLY |
| 3 | REDUCE THE COST AND ALSO FOR IDENTIFYING TOXIC |
| 4 | SUBSTANCES IN OUR ENVIRONMENT. AND IF WE COULD |
| 5 | AVOID USING HUNDREDS OF THOUSANDS OF RATS AND MICE |
| 6 | AND ANIMALS, DOGS, AND SO, I THINK THE COMMUNITY |
| 7 | WOULD BE VERY, VERY SUPPORTIVE OF US HAVING AN |
| 8 | IMPACT IN THIS AREA AND WOULD WELCOME THAT. |
| 9 | THE GRANT REVIEWS, WE COMPLETED THE NEW |
| 10 | FACULTY II AWARDS, AND WE'RE BRINGING THEM TO YOU AT |
| 11 | THIS MEETING. UPCOMING GRANT REVIEWS, THERE WILL BE |
| 12 | A DOUBLE REVIEW BECAUSE THERE WERE SO MANY |
| 13 | APPLICATIONS FOR TOOLS AND TECHNOLOGIES. THESE ARE |
| 14 | THE TOOLS THAT ARE NEEDED BY THE INDUSTRY, BOTH |
| 15 | RESEARCHERS, BUT THE TRANSLATIONAL INDUSTRY TO GET |
| 16 | THE PARAMETERS NEEDED FOR REGISTRATION OF WHATEVER |
| 17 | STRATEGY IS BEING USED FOR CELLS OR DRUGS IN |
| 18 | CLINICAL DEVELOPMENT. |
| 19 | THERE'S A TRAINING GRANTS II. WE'VE |
| 20 | RECEIVED 20 LETTERS OF INTEREST FROM THE BASIC |
| 21 | CALIFORNIA STATE UNIVERSITIES AND PRIVATE COLLEGES. |
| 22 | I HAVEN'T LOOKED SPECIFICALLY IN THERE, BUT YOU CAN |
| 23 | CERTAINLY ASK MICHAEL, WHO'S WITH US, IF YOU WANT |
| 24 | SOME INTERESTING DATA ON THAT. |
| 25 | THE BRIDGES TO STEM CELL RESEARCH, THERE |
| | |

| 1 | WERE 23 LOI'S. I'M SORRY. I READ IT ROUND THE |
|----|--|
| 2 | WRONG WAY. SO THE BRIDGES TO STEM CELL RESEARCH, |
| 3 | THERE WERE 23 OF THEM, 17 FROM THE CALIFORNIA STATE |
| 4 | UNIVERSITIES, TWO PRIVATE COLLEGES, AND FOUR |
| 5 | COMMUNITY COLLEGES. |
| 6 | THE TRAINING GRANTS II IS A REDO OF YOUR |
| 7 | ORIGINAL, LONG BEFORE I WAS HERE, ORIGINAL TRAINING |
| 8 | GRANTS TO INSTITUTIONS. SO I THINK MANY OF THE |
| 9 | INSTITUTIONS THAT WERE UP IN THE FIRST PLACE HAVE |
| 10 | COME BACK WITH NEW PROPOSALS. |
| 11 | UP AND COMING RFA'S, THESE ARE THE |
| 12 | TRANSLATIONAL CLINICAL RFA'S. THE TRANSLATIONAL I, |
| 13 | THE RFA WILL BE RELEASED IN AUGUST, AND THE GRANTS |
| 14 | WORKING GROUP REVIEW IS TIMED FOR FEBRUARY IN THE |
| 15 | NEW YEAR. AND THE DISEASE TEAM RESEARCH AWARDS, WE |
| 16 | THINK WE'LL BE IN A POSITION TO RELEASE THOSE AROUND |
| 17 | NOVEMBER THIS YEAR, AND THE REVIEW WILL PROBABLY |
| 18 | HAPPEN IN APRIL OF THE NEW YEAR. |
| 19 | WE HAVE SOME PROPOSED WORKSHOPS WHERE |
| 20 | WE'RE WORKING WITH THE CALIFORNIA RESEARCHERS AND |
| 21 | INSTITUTES AND COMPANIES. THE FIRST ONE THERE IS |
| 22 | THE CANCER STEM CELL MEETING. IT'S IN LOS ANGELES |
| 23 | ON AUGUST 26TH. WE ARE ADDRESSING ISSUES RELATING |
| 24 | TO THE CALIFORNIA-CANADA COLLABORATION IN CANCER |
| 25 | STEM CELLS. AND THE INVITED MEMBERS HAVE COME |
| | |

| 1 | BROADLY FROM MANY PLACES, BUT THEY INCLUDE THOSE |
|----|--|
| 2 | LISTED BELOW THERE. |
| 3 | THERE'S AN INTELLECTUAL PROPERTY |
| 4 | REGULATIONS AND GRANT WRITING PUBLIC SESSION COMING |
| 5 | UP ON SEPTEMBER THE 11TH IN SAN FRANCISCO AND |
| 6 | SEPTEMBER 12TH IN SAN DIEGO. WE ARE HOPING TO HAVE |
| 7 | THE CELL PRODUCTION FACILITIES AROUND NOVEMBER THE |
| 8 | 3D. I THINK THAT'S WHAT WE'RE AIMING FOR, TO HAVE |
| 9 | THAT DISCUSSION ABOUT GMP-RELATED CELL PRODUCTION |
| 10 | FACILITIES PROGRAM, WORKSHOP PROGRAM, TO BE |
| 11 | DI SCUSSED AROUND THERE. |
| 12 | WE UNDERSTAND THAT THE MRC IN THE UNITED |
| 13 | KINGDOM WOULD LIKE A JOINT DISCUSSION OF 12 |
| 14 | SCIENTISTS FROM THE UK, 12 SCIENTISTS FROM |
| 15 | CALIFORNIA TO TALK ABOUT PRIORITIES IN THE |
| 16 | COLLABORATIONS WITH THE UK IN JANUARY. AND A |
| 17 | WORKSHOP ON IMMUNOLOGY TOOLS, I SENSE THAT IS |
| 18 | OVERDUE NOW. WE'RE PROGRAMMING THAT FOR FEBRUARY IN |
| 19 | THE NEW YEAR. SO LOTS OF DISCUSSION WITH ALL OF THE |
| 20 | STAKEHOLDERS IN THESE AREAS FOR US TO LISTEN, FOR US |
| 21 | GET THE FEEDBACK, AND THEN FOR US TO COMPOSE |
| 22 | SOMETHING THAT EVERYONE WILL BE SUPPORTIVE OF. |
| 23 | THERE'S A GREAT CONFERENCE THAT'S BEING |
| 24 | DEVELOPED, CIRM 2008 GRANTEE CONFERENCE TO BE HELD |
| 25 | SEPTEMBER 17TH THROUGH THE 19TH. ASHA AND GIL HAVE |
| | 27 |

| 1 | BEEN BUSY ORGANIZING THIS. IT'S BRINGING ALL OF THE |
|----|---|
| 2 | INVESTIGATORS AND TRAINEES THAT CIRM'S FUNDING TO |
| 3 | HIGHLIGHT THEIR RESEARCH AND PARTICULARLY ENCOURAGE |
| 4 | SCIENTIFIC DISCUSSION AND COLLABORATION. SO WE'VE |
| 5 | SET THE PROGRAM TO BE VERY INTERLINKED AND |
| 6 | INTERACTIVE AND TO GET PEOPLE TO KNOW WHAT WE'RE |
| 7 | DOING AMONGST THE 350 TO 400 PEOPLE THAT ARE GOING |
| 8 | TO BE ATTENDING THIS. WE HOPE THERE WILL BE A LOT |
| 9 | OF NEW COLLABORATIONS DEVELOP. |
| 10 | THE FOUR TOPICS THAT WE'RE FOCUSED ON ARE |
| 11 | CHALLENGES FACED IN ACHIEVING THE FUNCTIONAL |
| 12 | INTEGRATION OF NEW CELLS INTO EXISTING TISSUES. |
| 13 | THESE ARE IMPORTANT THINGS WHICH REALLY WE HAVEN'T |
| 14 | COMPLETELY SOLVED THE RELATIONSHIP BETWEEN STEM |
| 15 | CELLS AND THE IMMUNE SYSTEM IN CANCER. AGAIN, A |
| 16 | CHALLENGING AND INTERESTING AREA THAT WE WANT TO |
| 17 | FOCUS ON. TRANSLATING STEM CELLS RESEARCH INTO |
| 18 | ADVANCES IN HUMAN HEALTH, SORT OF A VERY BROAD |
| 19 | SPECTRUM. AND PLURIPOTENTIALITY AND CELLULAR |
| 20 | DIFFERENTIATION. AGAIN, THE ISSUE THAT I'VE BEEN |
| 21 | TALKING TO YOU BEFORE IN THE EARLIER SLIDES. |
| 22 | IT'S GOING TO BE A BUZZ. AND WE'VE GOT |
| 23 | SOME OF THE REALLY TOP-LINE PEOPLE FROM OUTSIDE |
| 24 | CALIFORNIA WHO ARE GOING TO JOIN US, AND THEY'RE |
| 25 | SOME OF THE PEOPLE PRODUCING SOME OF THE GREAT WORK |
| | 20 |

| 1 | THAT'S GOING ON AROUND. |
|----|--|
| 2 | THESE ARE ALL THE PEOPLE WHO I AND BOB AND |
| 3 | THE REST OF THE EXECUTIVE WORK INCREDIBLY LONG HOURS |
| 4 | AND BE AVAILABLE AT ANY TIME AND ACTUALLY GET THIS |
| 5 | PROGRAM INTO PLACE. THEY'RE A FANTASTIC GROUP OF |
| 6 | PEOPLE. YOU KNOW MANY OF THEM. |
| 7 | AND WE ARE GOING TO HAVE ONE DEPARTURE, |
| 8 | AND I WANTED TO RECOGNIZE THAT IT IS WITH SORROW FOR |
| 9 | ME AND MY COLLEAGUES THAT TAMAR PACHTER IS GOING TO |
| 10 | GO BACK TO THE ATTORNEY GENERAL'S OFFICE, PROBABLY A |
| 11 | MUCH HIGHER STANDING IN LIFE, OVERLOOKING MANY, MANY |
| 12 | IMPORTANT THINGS. SHE WILL BE AVAILABLE TO US. |
| 13 | SHE'S BEEN A VERY TRUSTED COLLEAGUE OF MINE, HAS SAT |
| 14 | ON MY RIGHT-HAND SIDE, HAS KEPT ME OUT OF MANY |
| 15 | DANGEROUS PLACES. I MISS HER LIKE MAD WHEN SHE'S ON |
| 16 | HOLIDAY, AND I'M GOING TO MISS HER LIKE ANYTHING |
| 17 | WHEN SHE LEAVES US. |
| 18 | AND I'D LIKE TO US TO REGISTER THANKS TO |
| 19 | TAMAR IN THE USUAL WAY. |
| 20 | (APPLAUSE.) |
| 21 | DR. TROUNSON: SO I THINK THERE'S ONLY ONE |
| 22 | MORE. IT ALLOWS ME TO INTRODUCE DON GIBBONS TO YOU |
| 23 | TO TALK ABOUT STEM CELL AWARENESS DAY. WE WANT THE |
| 24 | COMMUNITY TO REJOICE WITH US, ALL OF US, AS WE THINK |
| 25 | AS WE GET UP IN THE MORNING ABOUT STEM CELLS AND AS |
| | 20 |

| 1 | WE GO TO BED AT NIGHT. WE WANT THE WHOLE COMMUNITY |
|----|--|
| 2 | IN CALIFORNIA TO THINK THAT WAY. AND DON'S UP TO |
| 3 | IT. DON. |
| 4 | MR. GIBBONS: THANK YOU, ALAN. MR. |
| 5 | CHAIRMAN, MEMBERS OF THE BOARD, AND MEMBERS OF THE |
| 6 | PUBLIC, I'M GLAD SO MANY OF YOU ARE HERE TODAY |
| 7 | BECAUSE I TAKE THAT TO MEAN I CAN ENLIST YOU TO DO |
| 8 | SOMETHING IN YOUR COMMUNITY FOR STEM CELL AWARENESS |
| 9 | DAY AND YOU AS WELL. |
| 10 | FIRST, A LITTLE BIT OF THE HISTORY. THIS |
| 11 | DAY WAS BORN WHEN THE PREMIER OF THE STATE OF |
| 12 | VICTORIA IN AUSTRALIA WAS TALKING WITH GOVERNOR |
| 13 | SCHWARZENEGGER AT BIO IN SAN DIEGO IN JUNE, AND THEY |
| 14 | THOUGHT THIS WOULD BE A GOOD IDEA. AND SO NOW WE'VE |
| 15 | GOT AN OPPORTUNITY TO MAKE IT FUN AND MAKE IT |
| 16 | HAPPEN. AND I WANT TO TELL YOU A LITTLE BIT OF WHAT |
| 17 | WE'VE GOT PLANNED SO FAR. |
| 18 | OUR DAY WILL ACTUALLY BEGIN A HALF-DAY |
| 19 | EARLY BECAUSE OF AUSTRALIA'S TIME ZONE ISSUES. AT |
| 20 | THE END OF THE DAY ON SEPTEMBER 24TH, THEIR |
| 21 | CELEBRATION IN VICTORIA WILL OPEN WITH COMMENTS LIVE |
| 22 | VIA VIDEO FROM CHAIRMAN KLEIN AND PRESIDENT |
| 23 | TROUNSON. THEY HAVE A WHOLE DAY OF EVENTS PLANNED |
| 24 | DOWN THERE. |
| 25 | WE'LL BE DOING THE USUAL PRESS RELEASE, |
| | 30 |
| | i JU |

| 1 | LETTING PEOPLE IN THE STATE BE AWARE OF OUR EVENTS. |
|----|--|
| 2 | THERE WILL BE A PROCLAMATION FROM GOVERNOR |
| 3 | SCHWARZENEGGER. |
| 4 | THE DAY BEFORE JUST HAPPENS TO BE BAYBIO'S |
| 5 | GENE ACRES ANNUAL CONFERENCE, SO WE'LL GET THEM TO |
| 6 | ANNOUNCE IT THERE AND ENCOURAGE PARTICIPATION AT |
| 7 | THAT EVENT. IT'S ALWAYS A SPECIAL EVENT IN THE BAY |
| 8 | AREA. |
| 9 | WE'RE GOING TO DO SOMETHING A LITTLE BIT |
| 10 | DIFFERENT FOR THE SPOTLIGHT ON DISEASE THAT OPENS |
| 11 | THE SECOND MORNING OF THE LCOC MEETINGS. WE'RE |
| 12 | GOING TO CHOOSE A TOPIC THAT WE THINK WILL BE OF |
| 13 | GREAT INTEREST TO A LARGE NUMBER OF PEOPLE. FOLKS |
| 14 | DOWN IN SAN DIEGO IN THAT COMMUNITY ARE WELCOME TO |
| 15 | SUGGEST IDEAS BECAUSE WE'LL BE CHOOSING PEOPLE FROM |
| 16 | YOUR REGION. AND WE'RE GOING TO LIVE WEBCAST IT SO |
| 17 | THAT WE CAN SHARE THOSE RICH MOMENTS WITH MANY MORE |
| 18 | PEOPLE AROUND THE STATE, AND INFORM SOME OF THE |
| 19 | SCHOOL SYSTEMS OF THAT BECAUSE IT'S GENERALLY DURING |
| 20 | THAT FIRST CLASS PERIOD, AND I'M SURE THERE MIGHT BE |
| 21 | SOME SCIENCE TEACHERS AROUND THE STATE THAT WILL BE |
| 22 | WILLING TO LET THE KIDS LOG IN AND SEE IT. |
| 23 | WE HOPE TO REVEAL THAT DAY OUR NEW AND |
| 24 | IMPROVED AND MUCH MORE CONSUMER FRIENDLY WEBSITE. I |
| 25 | DIDN'T SAY GO LIVE. WE HOPE THAT IS THE CASE. IT'S |
| | 21 |
| | · |

| 1 | SCHEDULED TO BE THE CASE, BUT ANY OF YOU WHO HAVE |
|----|--|
| 2 | BEEN INVOLVED IN LAUNCHING A WEBSITE, YOU |
| 3 | INSTITUTIONS KNOW THAT PROMISING THAT WOULD BE A |
| 4 | LITTLE FOOLHARDY, BUT WE WILL REVEAL IT, AND YOU |
| 5 | WILL GET AT LEAST A PREVIEW OF IT IF IT'S NOT LIVE. |
| 6 | AND IT WILL HAVE MAJOR NEW FEATURES IN IT FOR THE |
| 7 | CONSUMERS OUT THERE AND THE PATIENT ADVOCATES. |
| 8 | WE HOPE TO HAVE A LOT OF OUR RESEARCH |
| 9 | SEARCHABLE BY DISEASE, SO YOU CAN GET TO WHAT WE'RE |
| 10 | DOING IN THE AREA THAT YOU CARE ABOUT. |
| 11 | AND TOWARD THE END OF THE DAY FROM THREE |
| 12 | TO FIVE IN THAT AFTER-SCHOOL PERIOD WHEN KIDS ARE IN |
| 13 | AFTER-SCHOOL PROGRAMS, WE WOULD WORK WITH THE |
| 14 | AFTER-SCHOOL PROGRAMS AROUND THE STATE AND HAVE A |
| 15 | LIVE ASK THE SCIENTIST SESSION ON THE WEB, TRYING TO |
| 16 | GET A SCIENTIST THAT WE FUND FROM VARIOUS |
| 17 | INSTITUTIONS. DR. PIZZO, RENE PERA FROM YOUR |
| 18 | INSTITUTION HAS ALREADY VOLUNTEERED TO BE ONE OF THE |
| 19 | LIVE SCIENTISTS ON THE WEB. SHE'S GREAT AT THIS. |
| 20 | SHE LOVES TALKING WITH THE PUBLIC. |
| 21 | AND WE HOPE TO ENLIST MANY OF THE PATIENT |
| 22 | ADVOCATES AROUND THE STATE TO DO THINGS WITHIN THEIR |
| 23 | GROUPS AND IN THEIR COMMUNITIES. AND WE'VE |
| 24 | ENCOURAGED ALL OF YOUR INSTITUTIONS DO THE SAME, AND |
| 25 | A NUMBER HAVE STEPPED UP TO THE PLATE ALREADY. UC |
| | |

| IRVINE IS DOING A PUBLIC TALK THAT DAY. THE BUCK |
|--|
| INSTITUTE HAS GOT A PUBLIC TALK PLANNED FOR THAT |
| DAY. I'M TOLD STANFORD IS CONSIDERING ONE, AND THAT |
| YOUR NEW WEBSITE FOR YOUR STEM CELL CENTER WILL |
| PROBABLY GO LIVE THAT DAY. |
| THE SAN DIEGO CONSORTIUM IS LOOKING FOR A |
| PROJECT IN THE REGION. AND DR. POMEROY, THE UC |
| DAVIS GROUNDBREAKING IS THE FOLLOWING DAY. WE'RE |
| GOING TO BE AN HONORARY EXTENSION OF STEM CELL |
| AWARENESS DAY ON THE 26TH. |
| BE HAPPY TO TAKE ANY QUESTIONS IF ANYBODY |
| HAS ANY. THANK YOU. |
| (APPLAUSE.) |
| CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| IT'S GOING TO BE A FUN DAY TO JOIN WITH THE |
| AUSTRALIANS AND GLOBALLY MOVE STEM CELL RESEARCH |
| FORWARD. AND I WILL REMIND EVERYONE THAT DR. |
| TROUNSON SPEARHEADED THE EFFORT IN AUSTRALIA TO |
| LEGALIZE THE EFFORTS TO USE EMBRYONIC STEM CELL |
| RESEARCH THERE, SETTING A GREAT EXAMPLE FOR CONGRESS |
| OF THE UNITED STATES AND THE PRESIDENT OF THE UNITED |
| STATES TO FOLLOW THE GREAT EXAMPLE OF AUSTRALIA, THE |
| PROGRESSIVE VIEW OF ALLOWING SCIENCE TO GUIDE US |
| RATHER THAN I DEOLOGY. |
| I'D LIKE TO TURN TO AGENDA ITEM 16, AND WE |
| 33 |
| |

| 1 | WILL BE DOING A DISCUSSION OF THIS ITEM. AS |
|----|---|
| 2 | CONTEXT, I WILL TELL YOU THAT AT 8 0'CLOCK THIS |
| 3 | MORNING WE HAD A QUORUM WITH TWO EXTRA INDIVIDUALS. |
| 4 | WE LOST BOTH OF THOSE TO TOTALLY UNFORESEEABLE |
| 5 | CIRCUMSTANCES. AT 2:30 THIS AFTERNOON WE HAD A |
| 6 | QUORUM. RIGHT NOW IT APPEARS THAT WE HAVE A QUORUM, |
| 7 | BUT WE ACTUALLY HAVE A MEMBER AND AN ALTERNATE FROM |
| 8 | THE SAME INSTITUTION, SO WE HAVE 19, BUT WE DON'T |
| 9 | HAVE 19 AS A QUORUM. |
| 10 | SO WE'RE WORKING ON WE HAVE ONE MEMBER |
| 11 | WHO IS SUPPOSED TO BE HERE HALF AN HOUR AGO, WHO |
| 12 | HALF AN HOUR AGO CALLED TO SAY THAT MEMBER COULDN'T |
| 13 | COME, SO WE'RE WORKING ON AN ALTERNATE FOR THAT |
| 14 | MEMBER TO HOPEFULLY JOIN US A LITTLE LATER AS WE |
| 15 | HAVE PROGRESSED WITH OUR DISCUSSIONS OF ALL THESE |
| 16 | I TEMS. |
| 17 | IT IS APPROPRIATE THAT AS THE SCIENCE |
| 18 | MOVES VERY QUICKLY, WE KEEP ON OUR TOES HERE |
| 19 | ORGANIZATIONALLY, BUT WE ARE WORKING ON |
| 20 | RECONSTITUTING IN REAL-TIME THE QUORUM. |
| 21 | WE WILL, THEREFORE, DISCUSS ITEM 16, MOVE |
| 22 | THROUGH THE ITEM. WE WILL TAKE PUBLIC COMMENT, BUT |
| 23 | WE WILL NOT HAVE A FINAL VOTE ON THE ITEM. |
| 24 | AS WE HAVE BEEN WORKING ON THIS ITEM OVER |
| 25 | THE LAST SEVERAL MONTHS, THE BOARD MEMBERS HEADING |
| | |

| 1 | UP THE TASK FORCE HAVE BEEN DR. AZZIZ AND DR. PIZZO, |
|----|--|
| 2 | ALONG WITH STAFF MEMBERS DR. OLSON, THE CHIEF |
| 3 | SCIENTIFIC OFFICER, DR. MARIE CSETE, AND PRESIDENT |
| 4 | ALAN TROUNSON. I'D LIKE TO ASK DR. AZZIZ AND DR. |
| 5 | PIZZO TO WALK US THROUGH THIS ITEM. DR. AZZIZ |
| 6 | SPECIFICALLY FLEW UP TO PRESENT THIS ITEM WITH DR. |
| 7 | PIZZO. I THINK, DR. AZZIZ, YOU HAVE THE FLOOR. |
| 8 | DR. AZZIZ: THANK YOU. SO JUST TO BRING |
| 9 | THE ICOC UP TO SPEED, ABOUT FOUR MONTHS AGO YOU HAD |
| 10 | ASKED US TO CREATE A TASK FORCE. IT WAS A TASK |
| 11 | FORCE WITH DR. PIZZO, MYSELF TO LOOK AT THE ISSUE OF |
| 12 | THE DEFINITIONS OF PRINCIPAL INVESTIGATORS, THE |
| 13 | AMOUNT OF PERCENT THAT WAS BEING REQUIRED ON THE |
| 14 | APPLICATIONS FROM PRINCIPAL INVESTIGATORS, AND THE |
| 15 | POTENTIAL LIMIT ON NUMBERS OF APPLICATIONS. |
| 16 | SO WE HAVE HAD A VERY PRODUCTIVE THREE |
| 17 | MONTHS. WE HAVE HAD THREE PHONE MEETINGS WITH THE |
| 18 | STAFF AS WELL AS DR. PIZZO AND MYSELF. WE'VE HAD |
| 19 | EXTENSIVE DISCUSSION REGARDING THE VARIANCES. JUST |
| 20 | TO BRING YOU TO REMIND YOU, THE INITIAL ISSUE WAS |
| 21 | THAT SOMETIMES THE DEFINITIONS THAT WERE BEING USED |
| 22 | FOR PRINCIPAL INVESTIGATORS IN SOME OF THE RFA'S |
| 23 | WERE LIMITING PARTICULARLY TO SMALLER COMPANIES WHO |
| 24 | WERE OBVIOUSLY IN THE PROCESS OF BRINGING EXPERTS TO |
| 25 | CALIFORNIA TO WORK ON THESE ISSUES. |
| | |

| 1 | THERE WAS ALSO SOME LACK OF CLARITY |
|----|--|
| 2 | REGARDING WHO EXACTLY WAS A PRINCIPAL INVESTIGATOR |
| 3 | AND WHO WOULD QUALIFY. SO THE PROPOSAL THAT YOU |
| 4 | HAVE IN FRONT OF YOU IS THE RESULT OF EXTENSIVE |
| 5 | DISCUSSION. AND I WILL BRIEFLY GO THROUGH IT, AND |
| 6 | THEN SEE IF THERE ARE QUESTIONS. |
| 7 | THE PRINCIPAL INVESTIGATOR ELIGIBILITY |
| 8 | DEFINITION, THE PI MUST HOLD AN M.D. OR PH.D. OR |
| 9 | EQUIVALENT DEGREE, BE AUTHORIZED BY THE APPLICANT |
| 10 | INSTITUTION TO CONDUCT THE PROPOSED RESEARCH IN |
| 11 | CALIFORNIA, AND BY THE APPLICATION DEADLINE BE AN |
| 12 | INDEPENDENT INVESTIGATOR AT A NONPROFIT APPLICANT |
| 13 | INSTITUTION OR HAVE AN EQUIVALENT POSITION AND BE AN |
| 14 | EMPLOYEE OF A FOR-PROFIT APPLICANT INSTITUTION, HAVE |
| 15 | DOCUMENTED AUTHORITY FROM THE APPLICANT INSTITUTION |
| 16 | TO STAFF THE PROPOSED PROJECT, AND HAVE DOCUMENTED |
| 17 | AUTHORITY FROM THE APPLICANT INSTITUTION FOR ACCESS |
| 18 | TO SPACE AND SHARED RESOURCES SUFFICIENT TO CARRY |
| 19 | OUT THE PROPOSED RESEARCH. |
| 20 | THIS DEFINITION WAS CREATED OR EXPANDED |
| 21 | FROM A PREVIOUS DEFINITION IN THAT THE ONUS TO |
| 22 | ENSURE THAT AN INVESTIGATOR HAD SUFFICIENT AUTHORITY |
| 23 | AND SUFFICIENT RESOURCES DID FALL ON THE APPLICANT |
| 24 | INSTITUTION. THERE WAS NO WAY FOR THE CIRM TO |
| 25 | POLICE THIS A PRIORI. SO WE FELT THAT WE SHOULD |
| | |

| 1 | REQUIRE CERTIFICATION FROM THE APPLICANT |
|----|--|
| 2 | INSTITUTIONS CONCERNING THE ABILITY AND AUTHORITY OF |
| 3 | THE PRINCIPAL INVESTIGATOR. |
| 4 | THE ISSUE OF CO-PRINCIPAL INVESTIGATORS |
| 5 | WAS ALSO BROUGHT UP. THIS IS SOMETHING THAT IS |
| 6 | EVOLVING CLEARLY IN TEAM SETTINGS, AND THESE |
| 7 | PROPOSALS THAT REQUIRE A TEAM APPROACH AND AN |
| 8 | INTERDISCIPLINARY APPROACH, THE PROPOSALS SHOULD AND |
| 9 | WE SHOULD ENCOURAGE CO-PRINCIPAL INVESTIGATORS. WE |
| 10 | FELT THAT THIS WAS THE CASE. WHILE CERTAINLY THE |
| 11 | SPECIFICS OF HOW WE ARE TO MONITOR CO-PRINCIPAL |
| 12 | INVESTIGATORS IS DIFFICULT, THE GENERAL CONCEPT THAT |
| 13 | A PRINCIPAL INVESTIGATOR AND CO-PRINCIPAL |
| 14 | INVESTIGATORS WILL BE ALLOWED ON FUTURE SELECTED |
| 15 | RFA'S IS SOMETHING THAT WAS SUPPORTED BY THE STAFF |
| 16 | OF THE CIRM AND THE TASK FORCE. AND WE, AGAIN, |
| 17 | WANTED TO CODIFY OUR INTENT TO MOVE FORWARD IN |
| 18 | REGARDS TO COMING UP WITH SPECIFIC GUIDELINES FOR |
| 19 | CO-PRINCIPAL INVESTIGATORS. |
| 20 | FOURTHLY, WE DISCUSSED THE ISSUES OF LIMIT |
| 21 | ON PERCENT EFFORT. AND AFTER EXTENSIVE DISCUSSION |
| 22 | CERTAINLY RECOGNIZED THAT THE CIRM IS UNDER SOMEWHAT |
| 23 | DIFFERENT PRESSURE THAN THE NATIONAL INSTITUTES OF |
| 24 | HEALTH, WHICH WE HAD ORIGINALLY USED AS OUR |
| 25 | GUI DELINE, BUT ALSO RECOGNIZE THAT SUCCESSFUL |
| | |

| 1 | INVESTIGATORS ALSO WOULD HAVE A LIMITED AMOUNT OF |
|----|--|
| 2 | TIME TO DEDICATE TO ANY ONE PARTICULAR PROJECT. |
| 3 | SO MINDFUL OF THESE ISSUES, THE TASK |
| 4 | FORCE, AS WELL AS THE CIRM MANAGEMENT, SUGGESTED THE |
| 5 | FOLLOWING TEXT, WHICH I WILL READ FOR YOU. |
| 6 | "THEREFORE, CIRM, MINDFUL OF THE URGENCY |
| 7 | OF ITS MISSION, WILL REQUIRE MINIMAL PERCENT EFFORT |
| 8 | OF THE PI AND CO-PI'S, TYPICALLY 10 PERCENT OR |
| 9 | DEEMED SUCH MINIMAL EFFORT IS NECESSARY TO ENSURE |
| 10 | PI, CO-PI OVERSIGHT AND TIMELY ACCOMPLISHMENT OF THE |
| 11 | PROPOSED RESEARCH. EXTRAORDINARY CIRCUMSTANCES MAY |
| 12 | BE APPLIED BY THE CIRM AT THE DISCRETION OF THE |
| 13 | PRESIDENT TO ALLOW SENIOR RESEARCH SCIENTISTS TO |
| 14 | HAVE REDUCED PERCENT EFFORT COMMITMENT IN THE |
| 15 | INTEREST OF OBTAINING THE BEST OUTCOMES FOR A |
| 16 | RESEARCH PROJECT. |
| 17 | "CIRM AND THE TASK FORCE AGREED THAT NO |
| 18 | CHANGES WILL BE MADE TO THE GAP IN ORDER TO MAINTAIN |
| 19 | FLEXI BI LI TY. " |
| 20 | THIS LAST STATEMENT IS SOMETHING WE |
| 21 | ACTUALLY HAVE ALL AGREED TO THROUGHOUT. WE WILL NOT |
| 22 | BE CHANGING THROUGH THIS MOTION THE GAP, THE GRANT |
| 23 | ADMINISTRATION POLICY, BECAUSE WE DO WANT TO GIVE |
| 24 | THE INSTITUTE AS MUCH FLEXIBILITY. HAVING SAID |
| 25 | THAT, WE DO WANT TO PROVIDE THEM WITH GUIDELINES. |
| | 30 |

| 1 | FINALLY, THERE WAS THE ISSUE OF LIMITS ON |
|----|--|
| 2 | NUMBER OF APPLICATIONS. AND, AGAIN, AFTER |
| 3 | DISCUSSION, IT WAS FELT THAT THE INSTITUTE CERTAINLY |
| 4 | SHOULD HAVE THE ABILITY TO PLACE LIMITS ON THE |
| 5 | NUMBER OF PROPOSALS IF THERE WAS GOING TO BE LIMITED |
| 6 | PROJECTED CAPACITY LIMITATIONS FOR RESEARCH |
| 7 | MANAGEMENT OR SCIENTIFIC REVIEWS. OTHERWISE, WE |
| 8 | FELT THAT IT WOULD NOT BE IN THE INTEREST OF |
| 9 | PRODUCING THE BEST RESEARCH TO PUT A PRIORI |
| 10 | LIMITATIONS. |
| 11 | SO THE STATEMENT THAT WE CAME UP WITH IS |
| 12 | "THE CIRM AND THE TASK FORCE AGREED THAT CIRM WILL |
| 13 | PLACE LIMITS ON THE NUMBER OF PROPOSALS FROM |
| 14 | NONPROFIT AND FOR-PROFIT INSTITUTIONS WHEN GOVERNED |
| 15 | BY PROJECTED CAPACITY LIMITATIONS OF THE RESEARCH |
| 16 | MANAGEMENT OR SCIENTIFIC REVIEW GROUPS, BUT IF |
| 17 | LIMITS TO THE NUMBER OF APPLICATIONS ARE |
| 18 | ANTICIPATED, CIRM WILL INCLUDE THE LIMITS IN THE |
| 19 | CONCEPT PLAN WHICH WILL BE APPROVED BY THE ICOC." |
| 20 | AND THAT'S MIND SEARCH. AGAIN, WE AGREED |
| 21 | NOT TO CHANGE THE GAP. |
| 22 | SO THAT IS THE CONCLUSION OF THE TASK |
| 23 | FORCE'S DELIBERATIONS. THIS IS OUR RECOMMENDATIONS |
| 24 | BOTH FOR PRINCIPAL INVESTIGATOR ELIGIBILITY, |
| 25 | CO-PRINCIPAL INVESTIGATOR'S LIMIT ON PERCENT EFFORT |
| | 20 |

| 1 | OF INVESTIGATORS, AND LIMIT ON THE NUMBER OF |
|----|--|
| 2 | APPLICATIONS. AND WELCOME QUESTIONS. |
| 3 | CHAIRMAN KLEIN: I THINK IF WE CAN HAVE, |
| 4 | DR. PIZZO, WOULD YOU LIKE TO ADD ANYTHING TO THIS |
| 5 | COMMENTARY? |
| 6 | DR. PIZZO: I THINK RICARDO HAS SUMMARIZED |
| 7 | THINGS EXTREMELY WELL. AND I THINK WE WOULD BOTH |
| 8 | WANT TO ADD THAT WE TRIED TO BE MINDFUL OF THE |
| 9 | VARIOUS INSTITUTIONS THAT CONSTITUTE THE STATE OF |
| 10 | CALIFORNIA AS WE DELIBERATED THESE AND ALSO MINDFUL |
| 11 | OF THE NEEDS AND EFFORTS OF THE CIRM, BUT ALSO |
| 12 | RECOGNIZE THAT WE'RE PRESENTING THIS TO THE ICOC FOR |
| 13 | THEIR DELIBERATION INDEPENDENTLY AND FOR THEIR |
| 14 | REVIEW AS WELL BEFORE THIS BECOMES AN ACCEPTED SET |
| 15 | OF RECOMMENDATIONS. |
| 16 | CHAIRMAN KLEIN: AND, DR. TROUNSON, WOULD |
| 17 | YOU LIKE TO ADD TO THE COMMENTARY? |
| 18 | DR. TROUNSON: THANK YOU, CHAIR. WE'VE |
| 19 | APPRECIATED THE INTERACTIONS WITH BOTH MEMBERS, |
| 20 | PHILIP AND RICARDO. AND THE DISCUSSIONS WERE ROBUST |
| 21 | AT TIMES, AND I THINK REALLY HELPFUL BECAUSE I THINK |
| 22 | WE SORTED OUT SOME THINGS WHERE, YOU KNOW, WE CAME |
| 23 | DOWN ON RECOMMENDATIONS, WHICH, I THINK, ARE BOTH |
| 24 | WORKABLE, USEFUL, AND WILL DO THE JOB. |
| 25 | AND SO I WANT TO CONGRATULATE BOTH OF THEM |
| | 40 |

| 1 | FOR THEIR PATIENCE IN GOING THROUGH DOCUMENTS AND |
|----|---|
| 2 | HAVING THE DEEP DISCUSSIONS BECAUSE WE HAD A NUMBER |
| 3 | OF THEM. AND I FELT IT WAS A VERY GOOD PROCESS, AND |
| 4 | STAFF APPRECIATED VERY MUCH THE SPIRIT IN WHICH IT |
| 5 | WAS DONE. THANK YOU. |
| 6 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. ANY |
| 7 | ADDITIONAL BOARD COMMENTS? DR. POMEROY AND THEN |
| 8 | DR. BRENNER. |
| 9 | DR. POMEROY: I'D LIKE TO ASK DR. AZZIZ |
| 10 | AND DR. PIZZO WHO DEFINES WHAT AN INDEPENDENT |
| 11 | INVESTIGATOR IS? AND WHO DEFINES WHAT AN EQUIVALENT |
| 12 | POSITION IS? |
| 13 | DR. AZZIZ: SO THE APPLICANT INSTITUTION |
| 14 | DOES. AND SO WE NEED TO LET THE APPLICANT |
| 15 | INSTITUTION TELL US WHAT IS AN INDEPENDENT |
| 16 | INVESTIGATOR IN THEIR SETTING AND WHAT IS AN |
| 17 | EQUIVALENT POSITION IN THEIR SETTING BECAUSE, IN |
| 18 | FACT, FROM THE OUTSIDE IT WAS VERY DIFFICULT, SINCE |
| 19 | THE DIFFERENT THERE'S A VARIETY AND A MYRIAD OF |
| 20 | DIFFERENT ORGANIZATIONS WITH DIFFERENT REGULATIONS. |
| 21 | DR. POMEROY: GOOD ANSWER. |
| 22 | DR. PIZZO: WE ACTUALLY SURVEYED THE |
| 23 | VARIOUS INSTITUTIONS, PUBLIC AND PRIVATE, AND FELT |
| 24 | THAT THE NEED FOR INSTITUTIONAL RESPONSIBILITY AND |
| 25 | FLEXIBILITY WAS THE BEST WAY TO PROCEED. |
| | |

| 1 | CHAIRMAN KLEIN: OKAY. AND DR. BRENNER. |
|----|--|
| 2 | DR. BRENNER: ON THE CO-INVESTIGATORS FROM |
| 3 | ANOTHER INSTITUTION, HOW DO YOU BUDGET FOR THE |
| 4 | INDIRECTS BETWEEN THE INVESTIGATOR'S INSTITUTION AND |
| 5 | THE CO-INVESTIGATOR'S INSTITUTION? |
| 6 | DR. PIZZO: WE CAN MAKE THAT |
| 7 | RECOMMENDATION COME FROM DR. TROUNSON. WE DID HAVE |
| 8 | MUCH DISCUSSION ABOUT THAT, OF COURSE. MAYBE PAT |
| 9 | OLSON. |
| 10 | DR. TROUNSON: I THINK IF I COULD GET PAT |
| 11 | OLSON WOULD GIVE US PROBABLY A BETTER DESCRIPTION OF |
| 12 | THAT. |
| 13 | DR. OLSON: WE WILL BE WORKING ON THAT. |
| 14 | THAT IS ONE OF THE CHALLENGES ABOUT THE |
| 15 | CO-INVESTIGATOR. WE RECOGNIZE I THINK IF YOU |
| 16 | LOOKED AT THE BRIEF SUMMARY WE PUT THERE, BECAUSE OF |
| 17 | THE PROCESSES WE'RE GOING TO BE WORKING WITH, WE |
| 18 | WILL PROBABLY PAY A CHECK TO ONE INSTITUTION, BUT WE |
| 19 | RECOGNIZE THERE IS AN ISSUE WITH DIFFERENT |
| 20 | INDIRECTS. SO WE HAVE A TEAM THAT IS WORKING TO |
| 21 | ADDRESS THAT. WE DO NOT HAVE AN ANSWER YET. |
| 22 | DR. PIZZO: DAVID, AS YOU CAN IMAGINE, WE |
| 23 | FELT VERY STRONGLY THAT THE WORK TOWARD |
| 24 | CO-INVESTIGATORS WAS ESSENTIAL TO OUR FUTURE |
| 25 | SUCCESS. |
| | 42 |

| 1 | DR. OLSON: IT'S PART OF THE TEAM CONCEPT. |
|----|---|
| 2 | CHAIRMAN KLEIN: DR. OLSON, YOU MIGHT WANT |
| 3 | TO COMMENT. THERE'S TREMENDOUS EFFORT THAT'S BEEN |
| 4 | PUT IN CONCURRENT WITH THIS PROCESS TO BRING THE |
| 5 | CO-INVESTIGATOR PRINCIPAL OR STRUCTURE INTO THE |
| 6 | GRANTIUM ONLINE PROCESS. |
| 7 | DR. OLSON: YES. AS PERHAPS YOU MAY OR |
| 8 | MAY NOT KNOW, WHAT WE ARE TRYING TO DO IS GO LIVE |
| 9 | WITH GRANTIUM AT THE TIME FOR OUR DISEASE TEAM |
| 10 | RESEARCH AWARDS. SO WE ARE CURRENTLY ACTUALLY |
| 11 | SHADOWING OUR TRANSLATIONAL APPLICATION IN THE |
| 12 | GRANTIUM SYSTEM. SO SINCE WE ALSO WOULD LIKE TO |
| 13 | INCLUDE CO-INVESTIGATORS IN THE DISEASE TEAM |
| 14 | RESEARCH AWARDS, THIS HAS BASICALLY WHAT DO I |
| 15 | WANT TO SAY? ADDED SOME COMPLEXITY TO OUR |
| 16 | GRANTIUM IMPLEMENTATION. |
| 17 | SO THE GRANTIUM TEAM, BOTH THE EXTERNAL |
| 18 | GRANTIUM ORGANIZATION PLUS OUR INTERNAL TEAM, HAS |
| 19 | ACTUALLY BEEN WORKING QUITE HARD TO BE ABLE TO |
| 20 | IMPLEMENT ESSENTIALLY INDEPENDENT BUDGETS FOR |
| 21 | CO-INVESTIGATORS INTO THAT SYSTEM, HOPEFULLY, IN |
| 22 | TIME TO ALLOW IT TO BE USED FOR THE DISEASE TEAM |
| 23 | RESEARCH AWARDS. |
| 24 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 25 | ADDITIONAL QUESTIONS FROM THE BOARD? |
| | 42 |

| 1 | DR. TROUNSON: MR. CHAIR, JUST TO |
|----|--|
| 2 | EMPHASIZE TO DAVID BRENNER AGAIN, THIS CAN BE DONE. |
| 3 | WE CAN WORK OUT THE INDIRECTS. IT'S JUST A MATTER |
| 4 | OF SETTING SOME EXAMPLES TO HELP US WHEN IT COMES |
| 5 | TO BECAUSE COMPANIES MAY BE PARTNERS AS WELL AS |
| 6 | DIFFERENT INSTITUTIONS. AND SO THERE WILL BE |
| 7 | INSTITUTIONS THAT ARE COMING UP WHO WILL HAVE BEEN |
| 8 | CIRM BUILDINGS CLEARLY, AND SO THERE'S A WHOLE LOT |
| 9 | OF ISSUES ATTACHED TO THAT. BUT WE WILL WORK IN |
| 10 | THESE IN A FAIR-MINDED WAY TO BRING SOME SOMETHING |
| 11 | FORWARD. |
| 12 | I THINK THERE MAY BE QUITE A VARIETY OF |
| 13 | NEED FOR A VARIETY OF ARRANGEMENTS DEPENDING WHO'S |
| 14 | THE PARTNERS. |
| 15 | MS. SAMUELSON: QUESTION. ON THE LAST TWO |
| 16 | PROVISIONS ON LIMITS ON PERCENT EFFORT AND LIMITS ON |
| 17 | THE NUMBER OF APPLICATIONS, BUT THEN AT THE END OF |
| 18 | EACH SAYING THAT THE GAP WON'T BE CHANGED. DOES THE |
| 19 | GAP SAY SOMETHING CONTRADICTORY TO THIS? |
| 20 | DR. AZZIZ: THE GAP IS A VERY GENERAL |
| 21 | I'M SORRY GENERAL STATEMENT OF GRANTS |
| 22 | ADMINISTRATION POLICY. THIS IS A LITTLE MORE |
| 23 | DETAILED THAN THE GAP. THE AGREEMENT WAS THAT WE |
| 24 | WOULD NOT CHANGE THE GAP TO THESE SPECIFICS. THESE |
| 25 | ARE GUIDANCES TO THE INSTITUTE. BUT THEY WOULD NOT |
| | |

| 1 | BE WRITTEN TO THE GAP, BUT TO ALLOW MAXIMUM |
|----|---|
| 2 | FLEXIBILITY FOR THE INSTITUTE. |
| 3 | MS. SAMUELSON: I'M JUST WONDERING IF |
| 4 | THERE'S ANYTHING IN READING THE GAP THAT WOULD SEEM |
| 5 | TO BE IN CONTRADICTION TO THESE TWO PARAGRAPHS. |
| 6 | DR. AZZIZ: IT'S A VERY GOOD QUESTION, |
| 7 | JOAN. NOT THAT I RECALL. WE DID DISSECT THE GAP |
| 8 | BECAUSE OUR ORIGINAL PROPOSAL FROM THE TASK FORCE |
| 9 | WAS TO MODIFY THE GAP. AND I DON'T BELIEVE THERE |
| 10 | WAS ACTUALLY MUCH IN THE GAP CURRENTLY THAT DOESN'T |
| 11 | ALLOW THIS TO OPERATE. |
| 12 | CHAIRMAN KLEIN: AND SO ALLOW ME TO ASK |
| 13 | TAMAR. COULD YOU COMMENT ON THAT, PLEASE? |
| 14 | MS. PACHTER: THERE'S NOTHING CURRENTLY IN |
| 15 | THE GAP THAT WOULD CONTRADICT THIS. AND IN THE |
| 16 | REVISIONS TO THE GAP THAT ARE NOTICED THIS WEEK, WE |
| 17 | HAVE MADE EVERY EFFORT TO MAKE THE PROVISIONS THAT |
| 18 | DO EXIST CONSISTENT WITH THESE POLICIES. |
| 19 | CHAIRMAN KLEIN: OKAY. ANY ADDITIONAL |
| 20 | QUESTIONS OR COMMENTS? |
| 21 | DR. PIZZO: I DO WANT TO MAKE ONE |
| 22 | ADDITIONAL COMMENT, AND THAT IS THAT THE GROUP |
| 23 | TOGETHER WITH GROUP AS REALLY A DIAD, TOGETHER |
| 24 | WITH CIRM DID TRY TO RECONCILE SOME OF THE |
| 25 | COMPLEXITIES, NOT ONLY OF THIS, BUT ALSO SOMETHING |
| | |

| 1 | THAT WE'VE TALKED ABOUT AT VARIOUS MEETINGS; THAT |
|----|---|
| 2 | IS, THE NUMBER OF APPLICATIONS PER INSTITUTION. AND |
| 3 | WE RECOGNIZE THE IMPORTANCE OF BEING COGNIZANT OF |
| 4 | CAPACITY ISSUES, BOTH IN TERMS OF STAFF AS WELL AS |
| 5 | THE SCIENTIFIC REVIEW GROUPS, BUT ALSO VARIANCES IN |
| 6 | TERMS OF THE KINDS OF APPLICATIONS THAT MIGHT COME |
| 7 | FORWARD. |
| 8 | SO, FOR EXAMPLE, FOR NEW INVESTIGATORS |
| 9 | FROM INSTITUTIONS, IT MAKES SENSE, IF THERE IS A |
| 10 | CAPACITY LIMIT, FOR THERE TO BE PRESCREENING THAT |
| 11 | MIGHT TAKE PLACE WITHIN AN INDIVIDUAL INSTITUTION. |
| 12 | FOR VERY COMPLICATED COMPREHENSIVE GRANTS FOR WHICH |
| 13 | WE DON'T YET HAVE EXPERIENCE, SUCH AS THE DISEASE |
| 14 | PLANNING GRANTS, WHERE MULTIPLE INSTITUTIONS OR |
| 15 | MULTIPLE INDIVIDUALS MAY BE INVOLVED AND WHERE THEY |
| 16 | HAVE SPENT AN ENORMOUS AMOUNT OF TIME AND EFFORT IN |
| 17 | PUTTING TOGETHER THE PROPOSAL, IT SEEMED, TO US AT |
| 18 | LEAST, PRUDENT TO RECOMMEND THAT THOSE NOT BE |
| 19 | LIMITED BECAUSE OTHERWISE WE WOULD DISCOURAGE PRO |
| 20 | PRIMUM PEOPLE FROM WORKING TOGETHER ON WHAT MAY BE |
| 21 | SOME OF THE MOST IMPORTANT EFFORTS GOING FORWARD. |
| 22 | SO I ONLY PRESENT THAT AS AN EXAMPLE OF |
| 23 | THE ARRAY AND RANGE OF THINGS THAT I'M SURE THIS |
| 24 | BODY WILL NEED TO CONTEMPLATE THAT TRIES TO PROVIDE |
| 25 | BOTH FLEXIBILITY AND OPPORTUNITY AS WELL AS REALITY |

| 1 | IN TERMS OF WHAT CAN BE REVIEWED IN A SUFFICIENT |
|----|--|
| 2 | WAY. |
| 3 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 4 | MR. ROTH: PHIL, JUST IF I COULD FOLLOW |
| 5 | THAT UP WITH A SIMILAR QUESTION ON THIS EXCEPTION TO |
| 6 | THE 10-PERCENT RULE, THE RECOMMENDATION. IS THERE |
| 7 | ANY CHANCE THAT CAN BE WORKED OUT PROSPECTIVELY WITH |
| 8 | THE CIRM RATHER THAN WAIT TILL AFTER THE GRANT COMES |
| 9 | IN? IF SOMEBODY REALLY CAN'T DO 10 PERCENT, |
| 10 | WOULDN'T IT BE IMPORTANT, BEFORE YOU GO THROUGH THE |
| 11 | PROBLEM OF WRITING THE GRANT, TO GET A RULING ON |
| 12 | THAT? |
| 13 | DR. PIZZO: IT'S A GOOD QUESTION. AND I |
| 14 | THINK YOU'RE CORRECT, THAT IT WOULD NEED TO BE |
| 15 | WORKED OUT. WHAT WE TRIED TO TAKE INTO ACCOUNT, |
| 16 | DUANE, IS THE DIFFERENCES BETWEEN THE RULES THAT WE |
| 17 | ARE MORE FAMILIAR WITH FROM THE NIH WHERE THE |
| 18 | INVESTIGATORS MAY COME IN WITH A 5-PERCENT LEVEL AND |
| 19 | THE DIFFERENCE OF CIRM, WHICH IS THAT IT HAS A FIXED |
| 20 | LIFETIME. WE HAVE A HIGHER DEGREE OF |
| 21 | ACCOUNTABILITY. WE BELIEVE THAT THERE NEEDS TO BE |
| 22 | ON THE AVERAGE A GREATER DEGREE OF, THEREFORE, |
| 23 | COMMITMENT, AND YET WANTED TO PROVIDE SOME |
| 24 | FLEXIBILITY TO CIRM IN TERMS OF EXCEPTIONS. |
| 25 | SO I THINK WHAT I WOULD SAY, AND, OF |
| | 47 |

| 1 | COURSE, RICARDO AND OTHERS SHOULD COMMENT, IS THAT |
|----|---|
| 2 | WE LOOKED AT 10 PERCENT AS BEING THE RECOMMENDED |
| 3 | FLOOR OR FLOOR COMMITMENT, AND ANYTHING LESS THAN |
| 4 | THAT BEING AN EXCEPTIONAL REVIEW. AND I THINK |
| 5 | THAT'S GOING TO HAVE TO HAPPEN ON AN AD HOC BASIS. |
| 6 | WE WANTED TO SIGNAL A GREATER DEGREE OF |
| 7 | RESPONSIBILITY AND ACCOUNTABILITY. |
| 8 | MR. ROTH: I SUPPORT THAT COMPLETELY, BUT |
| 9 | THE QUESTION STILL WOULD BE, BEFORE YOU APPLY AND |
| 10 | THEN ARE TURNED DOWN AFTER THE FACT, COULD YOU NOT |
| 11 | GET THAT QUESTION RESOLVED PROSPECTIVELY? |
| 12 | DR. TROUNSON: LET ME SAY THAT I THINK |
| 13 | MOST OF THOSE PEOPLE TALKED TO US, DUANE. AND SO |
| 14 | WHILE IT'S NO YOU DON'T THEY DON'T READ THAT |
| 15 | DEEPLY TO SEE THAT THERE IS A BARRIER REALLY THERE |
| 16 | MOST OF THE TIME. SO THE DISCUSSION THAT WE HAVE |
| 17 | WHEN THEY'RE IN THE APPLICATION PROCESS WITH US |
| 18 | WOULD IDENTIFY THAT. AND I THINK THERE'S SOME VERY |
| 19 | GOOD REASONS WHY YOU WOULD WANT SOME VERY SPECIAL |
| 20 | PEOPLE TO BE PART OF A PARTICULARLY TEAM APPROACH |
| 21 | THAT MIGHT HAVE A SMALL, BUT VERY SIGNIFICANT INPUT |
| 22 | IN SOME SPECIAL THINGS. |
| 23 | SO WE WANTED TO PICK UP ALL OF THE |
| 24 | ADVANTAGES RATHER THAN BEING TOO PRESCRIPTIVE. AND |
| 25 | THAT'S ONE OF THE REASONS WHY MARIE AND MYSELF AND |
| | |

| 1 | THE SCIENTISTS REALLY IN THE INDUSTRY WITH THE |
|----|--|
| 2 | SCIENTISTS AND INSTITUTIONS AND COMPANIES, GIVING |
| 3 | THEM THAT SORT OF VIEW. |
| 4 | MS. PACHTER: DUANE, I THINK I CAN HELP. |
| 5 | THE GAP PROVIDES THAT A PI CAN REDUCE UP TO 25 |
| 6 | PERCENT THEIR COMMITMENT WITHOUT PRIOR APPROVAL. |
| 7 | AND THERE ARE ALSO PROVISIONS FOR PRIOR APPROVAL OF |
| 8 | OTHER CHANGES IN ADVANCE OF ISSUING THE NGA UNDER |
| 9 | THE NEW PROVISIONS OF THE GRANTS ADMINISTRATION |
| 10 | POLICY. SO YOU COULD APPLY AND THEN SEEK |
| 11 | ESSENTIALLY A WAIVER OF THE 10-PERCENT COMMITMENT |
| 12 | BEFORE THE NGA WAS ISSUED. |
| 13 | MR. ROTH: IT'S VERY SIMPLE. WHAT I'M |
| 14 | TRYING TO AVOID IS SOMEBODY HAVING A GRANT TOSSED |
| 15 | OUT BECAUSE THEY PUT SOMEBODY IN AT 5 PERCENT ON THE |
| 16 | HOPE THAT IT WOULD BE APPROVED, AND THEN THEY SAY, |
| 17 | WELL, THIS IMPORTANT PIECE OF WORK IS ONLY 5 PERCENT |
| 18 | AND, THEREFORE, THE WHOLE GRANT IS OUT. |
| 19 | DR. PIZZO: I THINK YOU RAISE, OBVIOUSLY, |
| 20 | A KEY ISSUE. I WOULD JUST FURTHER ADD, AND I THINK |
| 21 | THAT THIS CAN HAPPEN IN PRACTICE, THAT WE WERE |
| 22 | AWARE, AS MANY IN THIS ROOM ARE, OF THE CHANGES THAT |
| 23 | HAVE BEEN TAKING PLACE AT THE NIH AND THE GRANT PEER |
| 24 | REVIEW PROCESS. I WAS ALSO, AS WERE OTHERS, |
| 25 | ACTIVELY INVOLVED IN SOME OF THAT AND HAD A DIRECT |
| | |

| 1 | DISCUSSION WITH ELIAS ZERHOUNI, THE DIRECTOR OF THE |
|----|--|
| 2 | NIH, ABOUT THIS VERY ISSUE, PERCENT EFFORT, BECAUSE |
| 3 | IT WAS A POINT OF CONTENTION ON THE NATIONAL LEVEL |
| 4 | AS WELL WITH SOME RECOMMENDING ACTUALLY A MUCH |
| 5 | HIGHER PERCENT EFFORT. |
| 6 | I THINK THE NIH CONCLUDED, AND ELIAS |
| 7 | SPECIFICALLY, THAT HAVING INSTITUTE FLEXIBILITY WAS |
| 8 | REALLY IMPORTANT. OUR ARGUMENT, MADE BY ALAN AS |
| 9 | WELL, IS THAT WE WANT TO ENCOURAGE INDIVIDUALS, |
| 10 | PARTICULARLY EXPERIENCED INDIVIDUALS, TO BE INVOLVED |
| 11 | IN MULTIPLE ACTIVITIES TO ENRICH THE OVERALL |
| 12 | TRAINING AND RESEARCH ENVIRONMENT. AND, THEREFORE, |
| 13 | THAT FLEXIBILITY, I THINK, CAN BE HANDLED JUST AS |
| 14 | YOU WOULD WITH A PROGRAM DIRECTOR AT THE NIH, THERE |
| 15 | COULD BE ADVANCE DISCUSSION TO CIRM SAYING, YOU |
| 16 | KNOW, ON THIS GRANT I WOULD REQUEST THAT WE COME IN |
| 17 | AT 5 PERCENT RATHER THAN TEN. WHAT ARE THE |
| 18 | REALITIES THAT THAT MIGHT BE REVIEWED? I THINK THAT |
| 19 | THAT CAN BE DONE. |
| 20 | CHAIRMAN KLEIN: DR. AZZIZ. |
| 21 | DR. AZZIZ: I JUST WANTED TO THIS IS |
| 22 | DUANE, THAT WAS A VERY GOOD QUESTION. AND, AGAIN, |
| 23 | YOU'VE GOTTEN A LOT OF GOOD DISCUSSION. FROM THE |
| 24 | TASK FORCE'S POINT OF VIEW, WE DID NOT WANT TO |
| 25 | MICROMANAGE THE OPERATIONS OF THE INSTITUTES SO THAT |
| | |

| 1 | THIS IS A GENERAL PRINCIPLE. BUT I AGREE. |
|----|--|
| 2 | CERTAINLY THAT WOULD BE BETTER TO BE ASKED A PRIORI; |
| 3 | BUT SINCE WE'RE GOING TO BE REQUIRING SOME SORT OF |
| 4 | MINIMAL FLOOR, THEN INVESTIGATORS AND APPLICANTS |
| 5 | SHOULD DO THAT AHEAD OF TIME. WE DIDN'T, AS YOU |
| 6 | NOTICE, SPECIFY MECHANISM HERE BECAUSE THAT'S AN |
| 7 | INTERNAL WORKINGS OF THE INSTITUTE. |
| 8 | CHAIRMAN KLEIN: ALL RIGHT. THANK YOU. |
| 9 | ANY ADDITIONAL BOARD QUESTIONS OR COMMENTS? ANY |
| 10 | PUBLIC COMMENTS? |
| 11 | MR. REED: DON REED, MEMBER OF THE PUBLIC. |
| 12 | I HAVE A POINT AND A QUESTION. MY QUESTION IS WOULD |
| 13 | THE NATIONALITY OF THE PI AFFECT THE CHANCES OF THE |
| 14 | GRANT? ONE OF THE STAKEHOLDERS MENTIONED THAT THEY |
| 15 | FELT THAT THE FACT THAT THEIR PI'S WORKS HAD BEEN |
| 16 | WRITTEN UP IN RUSSIAN PUBLICATIONS RATHER THAN |
| 17 | ENGLISH HAD ACTUALLY HAD A NEGATIVE EFFECT OF THEIR |
| 18 | CHANCE OF BEING CHOSEN. |
| 19 | NOW, I HAVE NO IDEA IF THAT IS A |
| 20 | LEGITIMATE QUESTION OR NOT, BUT I THOUGHT I WOULD |
| 21 | RAISE IT. |
| 22 | SECOND THING, AS A MEMBER OF THE PUBLIC, I |
| 23 | FEEL I WOULD BE REMISS IN NOT MENTIONING SOMETHING |
| 24 | ABOUT TAMAR PACHTER. THAT'S THAT ON THE THERE |
| 25 | WAS A MOMENT WHEN I FEEL SHE STEPPED INTO CIRM |
| | |

| 1 | HISTORY BOOKS, AND THAT WAS DURING THE TRIAL AND THE |
|----|--|
| 2 | LAWSUITS. AND I WENT TO ALL FOUR DAYS, AND THE |
| 3 | OPPOSITION WAS THROWING HOURS WORTH OF ONE ASSERTION |
| 4 | AND CHARGES AFTER ANOTHER, JUST ALL THIS STUFF. AND |
| 5 | THEN SHE STOOD UP. AND I THOUGHT THIS PERSON LOOKS |
| 6 | SO YOUNG TO BE DEFENDING US, TO HAVE SO MUCH RIDING |
| 7 | ON HER SHOULDERS. AND USING THE LAW WITH PRECISION |
| 8 | AND ACCURACY, LIKE A SCALPEL, SHE JUST GUTTED THE |
| 9 | OPPOSITION, AND I CEASED TO WORRY. |
| 10 | AND HER LEAVING US IS A TREMENDOUS LOSS. |
| 11 | AND AS A PATIENT ADVOCATE, I JUST HAVE TO SAY THANK |
| 12 | YOU SO MUCH. |
| 13 | (APPLAUSE.) |
| 14 | DR. TROUNSON: LET ME JUST PREFACE IT BY |
| 15 | SAYING THAT, YOU KNOW, THAT I'M STILL AUSTRALIAN. I |
| 16 | HAVEN'T SO WE'RE DEFINITELY NOT THERE'S NO BOX |
| 17 | TO TICK ON WHERE YOU COME FROM. IT'S MORE ABOUT, IF |
| 18 | WE GO BACK TO WHAT PHILIP AND RICARDO SAID, IT'S |
| 19 | ABOUT WHETHER THE INSTITUTION RECOGNIZES YOU AS A |
| 20 | MEMBER OF THEIR INSTITUTION OR THEIR COMPANY. AND |
| 21 | IT'S REALLY NOTHING TO DO WITH, YOU KNOW, WHERE YOU |
| 22 | COME FROM. AND HOPEFULLY THAT WILL STAY THAT WAY |
| 23 | FOR A WHILE. |
| 24 | DR. CSETE: THERE ARE COMMENTS THAT |
| 25 | REVIEWERS MAKE, JUSTIFIABLY, ABOUT THE QUALITY OF |

| 1 | THE JOURNALS IN WHICH APPLICANTS HAVE PUBLISHED. |
|----|---|
| 2 | AND WE MAKE THOSE JUDGMENTS FOR ENGLISH-SPEAKING |
| 3 | JOURNALS, AND IT BECOMES A DIFFICULT PROCESS TO |
| 4 | EVALUATE PUBLICATIONS IN OTHER LANGUAGES. AND |
| 5 | THAT'S WHERE YOU MAY HAVE SEEN THIS ISSUE IN |
| 6 | REVIEWS, BUT IT'S NOT NATIONALITY ITSELF. IT'S OUR |
| 7 | ABILITY TO JUDGE THE QUALITY OF THE JOURNALS. |
| 8 | MR. SIMPSON: JOHN SIMPSON WITH CONSUMER |
| 9 | WATCHDOG. TWO POINTS. UNDER THE LIMITS ON PERCENT |
| 10 | OF EFFORT, I, AS A MEMBER OF THE PUBLIC, AND SEEING |
| 11 | \$3 BILLION BEING HANDED OUT, WOULD LIKE TO FEEL THAT |
| 12 | YOUR CEILING WAS A LITTLE BIT HIGHER THAN 10 PERCENT |
| 13 | AS A CEILING. I MEAN THERE MAY BE SOME CASES AND |
| 14 | SOME GRANTS WHERE YOU WOULD SUGGEST 10 PERCENT |
| 15 | EFFORT WOULD BE RIGHT. |
| 16 | CHAIRMAN KLEIN: JOHN, YOU'RE SAYING THE |
| 17 | FLOOR. |
| 18 | MR. SIMPSON: THE FLOOR. IN OTHER WORDS, |
| 19 | I THINK TYPICALLY YOU MIGHT BE REQUIRING AT LEAST 20 |
| 20 | PERCENT AS THE NORM. I HAVE A QUESTIONS ABOUT THE |
| 21 | WAY THE RESEARCH FUNDS TEND TO BE HANDED OUT OVER |
| 22 | AND OVER AGAIN TO TOO MANY OF THE SAME SENIOR, |
| 23 | WELL-NETWORKED INVESTIGATORS WHO THEN ONLY PUT IN A |
| 24 | 10-PERCENT EFFORT, AND I THINK THAT'S A PROBLEM. SO |
| 25 | I THINK THAT YOUR PERCENTAGE MINIMUM PERCENT EFFORT |
| | |

| 1 | SHOULD BE AT LEAST 20 PERCENT. |
|----|--|
| 2 | THE SECOND POINT THAT I WOULD MAKE HAS TO |
| 3 | DO WITH THE TIMES WHEN YOU NEED TO PUT CAPS ON |
| 4 | THINGS. AS I RECALL, THE LAST TIME THIS CAME UP, |
| 5 | ONE OF THE ISSUES WAS THAT THE CAPS ON THE |
| 6 | APPLICATIONS FOR FOR-PROFIT INSTITUTIONS WERE LESS |
| 7 | THAN THE CAPS ON NONPROFITS. AND THEN BY |
| 8 | RESOLUTION BY MOTION THAT WAS AMENDED AT THE |
| 9 | BOARD MEETING SO THAT THE CAPS WERE THE SAME ACROSS |
| 10 | THE BOARD. I THINK, AS I RECALL, IT WAS FOUR |
| 11 | APPLICATIONS FROM EACH ENTITY. |
| 12 | SO I WOULD SUGGEST THAT IF YOU ADD |
| 13 | LANGUAGE HERE THAT ESSENTIALLY SAYS THAT WHEN YOU |
| 14 | HAVE AN RFA THAT'S OPEN TO BOTH NONPROFITS AND |
| 15 | FOR-PROFITS AND THERE ARE CAPS, THAT THEY BE OFFERED |
| 16 | AT THE SAME LEVEL TO BOTH NONPROFITS AND |
| 17 | FOR-PROFITS. I THINK THAT'S AN IMPORTANT POINT TO |
| 18 | MAKE. I DON'T THINK YOU SHOULD BE DRAWING |
| 19 | DISTINCTIONS BETWEEN THE TWO IF EVERYONE IS OPEN UP |
| 20 | FOR THE RFA. THANK YOU. |
| 21 | CHAIRMAN KLEIN: DR. AZZIZ. |
| 22 | DR. AZZIZ: JOHN, THOSE ARE TWO GOOD |
| 23 | POINTS. THE TASK FORCE ACTUALLY EXTENSIVELY |
| 24 | DISCUSSED THOSE. SO LET ME ACTUALLY TRY TO ADDRESS |
| 25 | THEM. |
| | |

| 1 | THE FIRST ONE HAS TO DO WITH PERCENT |
|----|--|
| 2 | EFFORT. WHILE 10 PERCENT IS, AGAIN, THE MINIMUM |
| 3 | REQUIRED, IT IS ALSO TO BE RECOGNIZED THAT YOU DON'T |
| 4 | ACTUALLY JUST DO SCIENCE BASED ON ONE PROJECT, |
| 5 | WHETHER IT IS CIRM WHO FUNDS IT OR NIH OR WHATEVER. |
| 6 | IN FACT, WHILE IT MAY SEEM THAT THE SAME |
| 7 | INVESTIGATORS GET THE KIND OF REPEATED, REMEMBER |
| 8 | THAT WE WANTED TO DO AS A TASK FORCE WAS ACTUALLY TO |
| 9 | REWARD THE BEST SCIENCE FOR THE BEST OUTCOME. AND, |
| 10 | AGAIN, THE BEST SCIENCE OFTEN COMES FROM |
| 11 | INVESTIGATORS WHO ARE BUSY AND WHO HAVE ACTUALLY A |
| 12 | LARGER TEAM PUT TOGETHER SO THAT REAL SCIENCE IN |
| 13 | STEM CELL RESEARCH AND OTHER INTERDISCIPLINARY TYPE |
| 14 | OF RESEARCH, IF YOU MANDATE A VERY HIGH EFFORT FOR A |
| 15 | PARTICULAR SINGLE PROJECT, YOU BASICALLY ARE THEN |
| 16 | DISSUADING A LARGE NUMBER OF PEOPLE WHO COULD |
| 17 | CONTRIBUTE TO GREATER DEGREES BY LIMITING THE AMOUNT |
| 18 | OF EFFORT THAT THEY COULD PUT INTO HERE. |
| 19 | IT SOUNDS PARADOXICAL BY SIMPLY SAYING |
| 20 | THAT IF WE PUT A HIGHER LIMIT, WE'RE GOING TO GET |
| 21 | BETTER RESPONSE. WE'RE ACTUALLY GOING TO GET A |
| 22 | WORSE RESPONSE BECAUSE THEN THE PEOPLE WHO ACTUALLY |
| 23 | ARE BUSY, HAVE LARGE TEAMS, AND ARE ABLE TO PRODUCE |
| 24 | SIGNIFICANT AMOUNT OF WORK ARE SIMPLY NOT GOING TO |
| 25 | BE ABLE TO QUALIFY. SO THAT'S ACTUALLY WHY THAT |
| | |

| 1 | PARADOXICAL RELATIONSHIP THAT YOU ACTUALLY BROUGHT |
|----|--|
| 2 | UP, WHICH I THINK IS SOMETHING THAT IS ON OUR MIND, |
| 3 | IS WHAT WE TRIED TO ADDRESS BY THE TASK FORCE. |
| 4 | THE SECOND ISSUE HAS TO DO WITH THE PROFIT |
| 5 | AND NOT-FOR-PROFIT AND CAPS, AND WE ABSOLUTELY |
| 6 | AGREE. THIS IS WHY IN THIS LANGUAGE AS A GUIDANCE |
| 7 | WE ACTUALLY DIDN'T PUT A STATEMENT TO WHO WOULD BE |
| 8 | FAVORED OR NOT. AND SINCE THESE CAPS HAVE TO COME |
| 9 | TO THE ICOC FOR APPROVAL AS A CONCEPT PLAN, THEN WE |
| 10 | WOULD LET IT, AT THAT TIME IF THERE WAS SUCH A CAP, |
| 11 | LET THE DISCUSSION OF THE BOARD OCCUR IN THE VOTING. |
| 12 | SO WE DIDN'T WANT TO MICROMANAGE IT, BUT YOU ARE |
| 13 | ABSOLUTELY CORRECT. WE DIDN'T, IN FACT, WANT TO |
| 14 | BUILD THAT INTO THE STATEMENT. VERY GOOD POINTS. |
| 15 | DR. PIZZO: JUST, AGAIN, A SORT OF FACTUAL |
| 16 | COMMENT BACK TO YOU, JOHN. THIS IS AN IMPORTANT |
| 17 | ISSUE, AND IT WAS A BIG TOPIC ON A NATIONAL LEVEL AS |
| 18 | WELL. AND IT WAS STUDIED IN TERMS OF HOW OFTEN DOES |
| 19 | IT HAPPEN THAT THERE ARE INVESTIGATORS WHO HAVE |
| 20 | MULTIPLE GRANTS, LET'S SAY THREE OR MORE. AND IT |
| 21 | TURNS OUT TO BE A VERY SMALL PERCENTAGE OF THE |
| 22 | OVERALL POOL OF INVESTIGATORS, SOMEWHERE BETWEEN 2 |
| 23 | TO 4 PERCENT. |
| 24 | AND IT ALSO TURNS OUT THAT MANY OF THOSE, |
| 25 | AS DR. AZZIZ SAID, HAPPEN TO BE AMONG THE MOST |
| | |

| 1 | SUCCESSFUL SCIENTISTS. I THINK THAT WHAT WE'RE |
|----|---|
| 2 | TRYING TO DO IS SEND A SIGNAL, BUT ALSO SEND SOME |
| 3 | FLEXIBILITY SO THAT, IN ESSENCE, AT THE END OF THE |
| 4 | DAY, CIRM CAN MAKE A JUDGMENT WHICH WILL ALLOW BOTH |
| 5 | THE BEST SCIENCE AND THE MOST QUALIFIED PEOPLE TO |
| 6 | COME FORWARD AND NOT DISCOURAGE THAT FROM HAPPENING |
| 7 | EI THER. |
| 8 | CHAIRMAN KLEIN: I THINK IT'S ALSO |
| 9 | SOMETHING TO FOCUS ON. REMEMBER, WE'RE GOING TO |
| 10 | HAVE CO-PRINCIPALS HERE ON MANY OF THESE VERY LARGE |
| 11 | GRANTS. AND SO YOU'VE GOT TO LOOK AT THE AGGREGATE |
| 12 | INVESTED TIME OF THE CO-PRINCIPALS IN UNDERSTANDING |
| 13 | HOW THIS PIE GETS CUT UP WHERE YOU'RE GETTING THE |
| 14 | BEST EXPERTISE FROM SEVERAL PEOPLE TO HELP LEAD A |
| 15 | VERY LARGE TEAM. |
| 16 | DO WE HAVE JOAN. |
| 17 | MS. SAMUELSON: I'VE JUST GOT A QUESTION |
| 18 | AND A COMMENT ABOUT THIS. MAYBE WE NEED TO LET THIS |
| 19 | OPERATE FOR A WHILE AND THEN REVISIT IT. I DON'T |
| 20 | CHAIRMAN KLEIN: I THINK WE'RE GOING TO |
| 21 | LEARN |
| 22 | MS. SAMUELSON: CLAIM TO HAVE THE |
| 23 | EXPERTISE THAT THE TASK FORCE MEMBERS HAVE. BUT IF |
| 24 | WE'RE TRYING TO BE BOLD AND HAVE AN IMPACT ON OUR |
| 25 | MISSION, AND IF THAT EQUATES TO VERY ENGAGED |
| | |

| 1 | INVOLVEMENT OF THE BEST AND THE BRIGHTEST, INCLUDING |
|--|--|
| 2 | THOSE WHO HAVE EARNED THAT FROM THEIR EXPERIENCE IN |
| 3 | THE LAB, AND SINCE WE'RE THE BIG KID ON THE BLOCK |
| 4 | FINANCIALLY, MIGHT WE NOT TO BE ABLE TO CHANGE THE |
| 5 | CULTURE AT LEAST INSOFAR AS OUR MONEY IS CONCERNED |
| 6 | AND MAYBE DRIVE URGENCY A BIT BY REQUIRING A HIGHER |
| 7 | COMMITMENT? PEOPLE ARE GOING TO WANT TO GET IN ON |
| 8 | OUR MONEY, SO THAT MIGHT BE ONE THING THEY HAVE TO |
| 9 | DO. AND THEN MAYBE WE WOULD HAVE SOMEWHAT MORE |
| 10 | GRANTS THAT HAVE WORK PRODUCT THAT ISN'T SO MUCH |
| 11 | JUST THE PRODUCT OF BUSINESS AS USUAL, BUT ACTUALLY |
| 12 | MAKES A DIFFERENCE AND ADVANCES THE FIELD MORE |
| 13 | QUI CKLY. |
| | |
| 14 | DR. PIZZO: ON THE AVERAGE, JOAN, I THINK |
| 14 15 | DR. PIZZO: ON THE AVERAGE, JOAN, I THINK THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH |
| | |
| 15 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH |
| 15 16 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR |
| 15 16 17 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR EFFORT OF PARTICULARLY NEWER AND YOUNGER |
| 15 16 17 18 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR EFFORT OF PARTICULARLY NEWER AND YOUNGER INVESTIGATORS. WHAT WE WANTED TO AVOID WHERE |
| 15 16 17 18 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR EFFORT OF PARTICULARLY NEWER AND YOUNGER INVESTIGATORS. WHAT WE WANTED TO AVOID WHERE POSSIBLE WAS PRECLUDING EXPERIENCED INVESTIGATORS |
| 15 16 17 18 19 20 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR EFFORT OF PARTICULARLY NEWER AND YOUNGER INVESTIGATORS. WHAT WE WANTED TO AVOID WHERE POSSIBLE WAS PRECLUDING EXPERIENCED INVESTIGATORS FROM SERVING ON GRANTS THAT WERE COLLABORATIVE. AND |
| 15 16 17 18 19 20 21 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR EFFORT OF PARTICULARLY NEWER AND YOUNGER INVESTIGATORS. WHAT WE WANTED TO AVOID WHERE POSSIBLE WAS PRECLUDING EXPERIENCED INVESTIGATORS FROM SERVING ON GRANTS THAT WERE COLLABORATIVE. AND THAT'S WHERE THE PERCENT EFFORT BECOMES POTENTIALLY |
| 15 16 17 18 19 20 21 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR EFFORT OF PARTICULARLY NEWER AND YOUNGER INVESTIGATORS. WHAT WE WANTED TO AVOID WHERE POSSIBLE WAS PRECLUDING EXPERIENCED INVESTIGATORS FROM SERVING ON GRANTS THAT WERE COLLABORATIVE. AND THAT'S WHERE THE PERCENT EFFORT BECOMES POTENTIALLY A RESTRICTIVE MODE. AND THAT'S WHY WE CHOSE THE |
| 15 16 17 18 19 20 21 22 23 | THERE WILL BE CERTAIN GRANTS WHICH WILL BE VERY HIGH PERCENTAGE ALLOCATIONS BECAUSE THEY'LL BE A SINGULAR EFFORT OF PARTICULARLY NEWER AND YOUNGER INVESTIGATORS. WHAT WE WANTED TO AVOID WHERE POSSIBLE WAS PRECLUDING EXPERIENCED INVESTIGATORS FROM SERVING ON GRANTS THAT WERE COLLABORATIVE. AND THAT'S WHERE THE PERCENT EFFORT BECOMES POTENTIALLY A RESTRICTIVE MODE. AND THAT'S WHY WE CHOSE THE DIRECTION OR RECOMMENDED THE DIRECTION WE DID. |

| 1 | TALKED ABOUT, WHICH IS THAT THIS IS AN EXPERIENTIAL |
|----|---|
| 2 | SET OF EVENTS. WE'LL SEE HOW THIS WORKS AND WE CAN |
| 3 | REVISIT THIS. THIS IS NOT THAT'S WHY IT'S NOT |
| 4 | BEING CAST IN, IF YOU WILL, GAP LANGUAGE. IT'S |
| 5 | BEING CAST IN RECOMMENDATION. |
| 6 | CHAIRMAN KLEIN: THANK YOU. PUBLIC |
| 7 | COMMENT? |
| 8 | MR. ADAMS: I'M WILLIAM ADAMS. I'M A |
| 9 | CO-FOUNDER OF INTERNATIONAL STEM CELL. AND MY FIRST |
| 10 | QUESTION TO THE PANEL, ESPECIALLY TO DR. AZZIZ AND |
| 11 | THE OTHER PANEL MEMBERS THAT I KNOW, IS DO YOU |
| 12 | REALLY WANT THE BEST? DO YOU WANT THE BEST |
| 13 | APPLICATIONS? DO YOU WANT THE BEST RFA'S THAT CAN |
| 14 | BE PUT FORWARD? AND GIVEN THE RESTRICTIONS THAT |
| 15 | WERE PUT ON US AS A FOR-PROFIT COMPANY AND HAVING TO |
| 16 | PICK A PI THAT CAME OUT OF OUR PH.D., M.D. STAFF, |
| 17 | WHICH, BY THE WAY, WE'RE THE GUILTY ONES. WE'RE THE |
| 18 | ONES THAT WERE TOLD THAT WE PUBLISHED IN OBSCURE |
| 19 | JOURNALS, AND WE ARE RUSSIANS, ALTHOUGH I DON'T |
| 20 | SPEAK THE LANGUAGE. |
| 21 | AND THAT WAS ONE OF THE REASONS THAT I |
| 22 | THINK WE HAD A PROBLEM, ALTHOUGH WE HAVE WE HAVE |
| 23 | PUBLISHED IN <i>CLONING</i> AND <i>STEM CELL</i> BOTH THIS YEAR |
| 24 | AND LAST YEAR, AND WE ARE THE COMPANY THAT HAS |
| 25 | DEVELOPED PARTHENOGENIC CELL LINES AND HOMOZYGOUS |
| | |

| 1 | LINES FROM UNFERTILIZED EGGS, WHICH IS PART OF THE |
|----|--|
| 2 | REASON THAT WE ARE EXTREMELY CONCERNED ABOUT NOT |
| 3 | BEING CONSIDERED FOR RFA 0705 FOR NEW STEM CELL |
| 4 | LI NES. |
| 5 | BUT GIVEN THAT, I THINK AS THE RULES ARE |
| 6 | CURRENTLY WRITTEN, AND DR. AZZIZ IS ON THE COMMITTEE |
| 7 | THERE, US NOT HAVING THE ABILITY TO HAVE A CO-PI, |
| 8 | AND WE HAD SEVERAL THAT WANTED TO WORK WITH US FROM |
| 9 | MAJOR INSTITUTIONS HERE IN CALIFORNIA, I THINK OUR |
| 10 | APPLICATION WAS DEFICIENT; AND, THEREFORE, WE |
| 11 | RECEIVED A SCORE THAT WE DID RECEIVE. HAD WE BEEN |
| 12 | ABLE TO BRING IN THE TOP PEOPLE THAT WANTED TO WORK |
| 13 | WITH US, WHO, BY THE WAY, WERE IDENTIFIED IN OUR |
| 14 | APPLICATION, I THINK WE WOULD HAVE DONE A LOT |
| 15 | BETTER. |
| 16 | I'VE GOT COMMENTS ON OTHER AREAS THAT ARE |
| 17 | GOING TO COME UP HERE IN THE NEXT DAY OR TWO, BUT I |
| 18 | THINK THE PI AREA IS ONE THAT SHOULD BE A |
| 19 | NO-BRAINER. YOU SHOULD BE LOOKING FOR THE BEST OF |
| 20 | THE BEST OF THE BEST ON ALL OF THESE APPLICATIONS |
| 21 | BECAUSE YOU WANT TO SEE THE BEST SCIENCE, AND WE |
| 22 | WANT TO GET TO THE CLINIC, AND BOB AND I WANT TO |
| 23 | CURE DI ABETES. THANK YOU. |
| 24 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 25 | ADDITIONAL PUBLIC COMMENT? IF THERE'S NO ADDITIONAL |
| | |

| 1 | COMMENTS AT THIS TIME, WHAT I'D LIKE TO DO IS MOVE |
|----|--|
| 2 | TO THE NEXT AGENDA ITEM. AND WE'LL JUST KEEP THE |
| 3 | MOMENTUM GOING SO THAT WE'VE GONE THROUGH THE |
| 4 | SUBSTANCE HERE. AS SOON AS WE HAVE A QUORUM, WE CAN |
| 5 | THEN TAKE ACTION ON ALL THOSE ITEMS. |
| 6 | SO I'D LIKE TO MOVE AT THIS POINT TO THE |
| 7 | NEXT AGENDA ITEM, THE ONE THAT WOULD HAVE FALLEN IN |
| 8 | THE NORMAL ORDER, WHICH IS AGENDA ITEM NO. 7. AND, |
| 9 | DR. GIL SAMBRANO, WOULD YOU LIKE TO WALK US THROUGH |
| 10 | RECOMMENDATIONS FOR APPOINTMENT OF NEW SCIENTIFIC |
| 11 | MEMBERS FOR THE GRANTS WORKING GROUP? |
| 12 | DR. SAMBRANO: THANK YOU VERY MUCH. MR. |
| 13 | CHAIRMAN AND MEMBERS OF THE BOARD AND THE PUBLIC, |
| 14 | TODAY WE'RE BRINGING FOR YOUR CONSIDERATION NOMINEES |
| 15 | FOR ALTERNATE GRANTS WORKING GROUP MEMBERS WHO ARE |
| 16 | GOING TO EXPAND OUR OVERALL EXPERTISE IN AREAS SUCH |
| 17 | AS BIOENGINEERING, IMAGING, CHEMICAL SCREENING, AND |
| 18 | NANOTECHNOLOGI ES. |
| 19 | AMONG THE GROUP ARE SEVERAL INDIVIDUALS |
| 20 | WITH EXPERIENCE IN BIOTECH AND PHARMACEUTICAL |
| 21 | COMPANIES THAT WILL BRING AN IMPORTANT AND NEEDED |
| 22 | PERSPECTIVE TO THE WORKING GROUP. I THINK THE LIST |
| 23 | OF MEMBERS IS IN YOUR NOTEBOOKS WITH THEIR BRIEF |
| 24 | BI OS. |
| 25 | I WILL JUST REMIND YOU AGAIN THAT AS |
| | 61 |

| 1 | ALTERNATE GRANTS WORKING GROUP MEMBERS, THESE |
|----|--|
| 2 | INDIVIDUALS MAY BE CALLED UPON TO PARTICIPATE IN A |
| 3 | GRANTS WORKING GROUP MEETING AS AD HOC REVIEWERS OR |
| 4 | ASKED TO BECOME A REGULAR MEMBER OF THE WORKING |
| 5 | GROUP TO REPLACE CURRENT MEMBERS AS NECESSARY. |
| 6 | ALTERNATE GRANTS WORKING GROUP MEMBERS ARE |
| 7 | SUBJECT TO AND MUST AGREE TO ABIDE BY THE SAME |
| 8 | CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE POLICY |
| 9 | AS REGULAR WORKING GROUP MEMBERS. AND SO I'LL JUST |
| 10 | GO OVER THE NAMES AND AFFILIATION OF THESE NOMINEES. |
| 11 | WE HAVE TEN OF THEM. |
| 12 | WE BEGIN WITH DR. SANGEETA BHATIA FROM |
| 13 | MIT; DR. PAULA MARIE BOKESCH FROM HOSPIRA, INC.; |
| 14 | DR. MARK FURTH FROM WAKE FOREST BAPTIST MEDICAL |
| 15 | CENTER; DR. MARCIE GLICKSMAN FROM BRIGHAM AND |
| 16 | WOMEN'S HOSPITAL AT HARVARD; DR. KURT GUNTER FROM |
| 17 | HOSPIRA, INC.; DR. PAUL KULESA FROM THE STOWERS |
| 18 | INSTITUTE FOR MEDICAL RESEARCH; DR. HAI-QUAN MAO |
| 19 | FROM JOHNS HOPKINS UNIVERSITY; DR. TODD MCDEVITT |
| 20 | FROM GEORGIA INSTITUTE OF TECHNOLOGY; DR. ALAN |
| 21 | RUSSELL FROM THE UNIVERSITY OF PITTSBURGH; AND |
| 22 | DR. SHUICHI TAKAYAMA FROM UNIVERSITY OF MICHIGAN. |
| 23 | SO THE CIRM REQUESTS YOUR APPROVAL AND |
| 24 | APPOINTMENT OF THESE NOMINEES AS ALTERNATE MEMBERS |
| 25 | OF THE WORKING GROUP. |
| | |

| 1 | CHAIRMAN KLEIN: OKAY. AT THIS POINT ARE |
|----|--|
| 2 | THERE ANY QUESTIONS FROM THE MEMBERS AS TO ANY OF |
| 3 | THESE ALTERNATES? |
| 4 | MS. SAMUELSON: I'D APPRECIATE IT IF, GIL, |
| 5 | YOU COULD ELABORATE A LITTLE BIT ON WHAT THIS |
| 6 | PACKAGE OF CANDIDATES BRINGS THAT THE WORKING GROUP |
| 7 | DID NOT HAVE HAS NOT HAD ENOUGH OF. |
| 8 | DR. SAMBRANO: SO WHAT WE'RE TRYING TO DO |
| 9 | IS FILL IN A FEW GAPS IN THE WORKING GROUP AS WE |
| 10 | MOVE ALONG. I THINK THIS GROUP CERTAINLY BRINGS A |
| 11 | LOT OF EXPERIENCE IN THE BIOENGINEERING AREA. I |
| 12 | THINK THAT'S AN AREA WHERE WE HAVE BEGUN TO GET MORE |
| 13 | APPLICATIONS, PARTICULARLY AS WE LOOK AT THE TOOLS |
| 14 | AND TECHNOLOGIES RFA. THAT IS AN AREA WHERE |
| 15 | BIOENGINEERING, NANOTECHNOLOGIES, CHEMICAL SCREENING |
| 16 | ARE GOING TO PLAY A BIG ROLE. |
| 17 | I THINK THE OTHER, AS WE ALSO MOVE ON TO |
| 18 | ACCEPTING APPLICATIONS FROM FOR-PROFIT COMPANIES, I |
| 19 | THINK WE NEED EXPERIENCE FROM INDIVIDUALS WHO HAVE |
| 20 | COMPANY EXPERIENCE TO SOME EXTENT. SO THIS IS |
| 21 | BEGINNING TO DELVE INTO THOSE AREAS OF EXPERTISE, |
| 22 | BUT I THINK WE NEED TO CONTINUE TO BROADEN IT EVEN |
| 23 | MORE THAN THAT. |
| 24 | MR. ROTH: MR. CHAIRMAN, GIL, I WANT TO |
| 25 | FOLLOW UP ON THAT QUESTION BECAUSE I WAS LOOKING AT |
| | 63 |

| 1 | THESE APPLICANTS, AND THERE'S SOME REALLY TALENTED |
|----|---|
| 2 | PEOPLE HERE, BUT I WOULDN'T CONSIDER ANY OF THEM TO |
| 3 | BE REALLY EFFICIENT AT EVALUATING THE TRANSLATIONAL |
| 4 | GRANTS OR LOANS. THEIR EXPERIENCE IS QUITE LIMITED. |
| 5 | THEY' RE NOT INDUSTRY PEOPLE. |
| 6 | AND, ALAN, THIS REALLY I WOULD DIRECT IT |
| 7 | AT YOU. MY VIEW IS, WHEN WE GET TO THOSE PRODUCT |
| 8 | TRANSLATIONAL GRANTS OR LOANS, THAT WE STRONGLY |
| 9 | CONSIDER A COMPLETELY DIFFERENT GROUP, 15 DIFFERENT |
| 10 | PEOPLE ALL FROM INDUSTRY WITH INDUSTRY EXPERIENCE, |
| 11 | WHETHER M.D.'S IN CLINICAL RESEARCH OR WHETHER |
| 12 | THEY'RE REGULATORY AFFAIRS OR FINANCE OR OTHERS. |
| 13 | OTHERWISE I VIEW A MIXTURE OF SORT OF RESEARCH |
| 14 | SCIENTISTS TRY TO WORK OUT WITH A HANDFUL OF QUASI |
| 15 | INDUSTRY SAVVY PEOPLE. AND I THINK IT WOULD BE FAR |
| 16 | BETTER IF WE HAD A COMPLETELY DIFFERENT SLATE. |
| 17 | DR. TROUNSON: I UNDERSTAND THE POINT |
| 18 | YOU'RE MAKING, AND I ACTUALLY AGREE WITH THAT. SO |
| 19 | WE ARE SEEKING TO GET REFEREES WHO HAVE |
| 20 | TRANSLATIONAL EXPERIENCE. I WOULDN'T NECESSARILY |
| 21 | WRITE OFF PEOPLE LIKE MYSELF. I ACTUALLY STARTED UP |
| 22 | SEVEN COMPANIES. FIVE OF THEM MANAGED TO STAY |
| 23 | AFLOAT AND SO ON. SO THERE ARE BASIC SCIENTISTS WHO |
| 24 | ARE ACTUALLY IN THAT SPACE WHO ACTUALLY DO TAKE THE |
| 25 | DISCOVERIES FORWARD WHO CAN BE PARTICULARLY USEFUL |
| | |

| | B/MMSTERS REFORTING SERVICE |
|----|--|
| 1 | IN THE PROCESS. |
| 2 | SO WHILE I RECOGNIZE THE IMPORTANCE OF |
| 3 | HAVING BOTH A CLINICAL EXPERTISE AND THE GENUINE |
| 4 | TRANSLATIONAL EXPERTISE FROM A COMPANY PERSPECTIVE, |
| 5 | I WOULDN'T NECESSARILY BURN OUT THE SMART SCIENTIST |
| 6 | WHO ALWAYS LOOKS THAT DIRECTION. I'D LIKE TO SEE |
| 7 | MORE OF THOSE PEOPLE AROUND. SOME OF THE PHYSICIAN |
| 8 | PH. D. 'S COULD BE REALLY HELPFUL IN THAT. |
| 9 | SO WHAT WE WILL DO IS SEE IF WE CAN |
| 10 | COMPOSE IT IN THE BEST WAY, MOST FITTING WAY. SOME |
| 11 | OF THE WE'VE HAD TO ADDRESS SOME OF THE PROBLEMS |
| 12 | OF POTENTIAL CONFLICT BECAUSE IN THE SENSE OF |
| 13 | COMPANIES, THEY OFTEN HAVE LOTS OF CONNECTIONS |
| 14 | WITHIN THE COMPANIES. AND THAT CAN SORT OF TAKE |
| 15 | GO ALL OVER THE PLACE. AND THERE'S ALSO, YOU KNOW, |
| 16 | WHILE THEY MIGHT BE SITED OUTSIDE CALIFORNIA, THEIR |
| 17 | COMPANY MAY WELL BE IN CALIFORNIA. SO IT'S NOT |
| 18 | QUITE AS EASY AN EASY TASK AS ONE MIGHT IMAGINE |
| 19 | TO GET A FULL LOAD OF THEM, BUT WE'RE OUT THERE |
| 20 | PHYSICALLY DOING THOSE THINGS. |
| 21 | AND MARIE IS SPENDING A LOT OF TIME. HER |
| 22 | EXPERTISE IN THE CLINICAL AREA IS VERY HELPFUL, BUT |
| 23 | WE'RE ALSO MAKING CONNECTIONS WITH COLLEAGUES, YOUR |
| 24 | COLLEAGUES. PEOPLE LIKE YOURSELE. TRYING TO GET SOME |

SUGGESTED NOMINEES THAT WE CAN SEE IF WE CAN GET

25

| 1 | THEM TO FIT IN GIVEN THAT THE CONFLICTS PROBABLY |
|----|--|
| 2 | COULD BE QUITE COMPLEX. |
| 3 | MR. ROTH: I SUPPORT THAT COMPLETELY ON |
| 4 | THE CONFLICT QUESTION, BUT I WOULD ARGUE THAT THE |
| 5 | SAME IS TRUE OF RESEARCH INVESTIGATORS. THEY HAVE |
| 6 | THEIR CONNECTIONS ALL OVER THE COUNTRY. AND EVEN |
| 7 | THOUGH THEY'RE OUTSIDE THE STATE, THEY KNOW THESE |
| 8 | PEOPLE QUITE WELL. BUT I WOULD STRIVE I THINK IT |
| 9 | WOULD BE IMPORTANT FOR US TO TAKE OUT A CLEAN SHEET |
| 10 | OF PAPER ON THIS AND MAKE SURE WE HAVE THE RIGHT |
| 11 | PEOPLE, EVEN INCLUDING SOME SCIENTISTS LIKE YOU |
| 12 | SUGGEST THAT ARE REALLY CLINICALLY YOU KNOW, |
| 13 | THERE'S SOME VERY BRIGHT PEOPLE IN RESEARCH |
| 14 | INSTITUTES DOING THAT, BUT THEY HAVE TO BE THE RIGHT |
| 15 | PEOPLE. |
| 16 | DR. TROUNSON: WE'RE TAKING YOUR POINT. |
| 17 | DR. CSETE: DUANE, I ALSO WANTED TO |
| 18 | ADDRESS THAT BECAUSE THIS LIST REALLY REFLECTED OUR |
| 19 | ACUTE NEED FOR PARTICULAR AREAS ON TOOLS AND |
| 20 | TECHNOLOGIES, WHICH IS BEING REVIEWED IN SEPTEMBER. |
| 21 | TAKES A LOT OF TIME TO CONTACT THESE PEOPLE, WORK |
| 22 | WITH THEM, GET THEM ON THE GROUP, PUT THE |
| 23 | BIOGRAPHIES TOGETHER. GIL AND I HAVE ESTABLISHED A |
| 24 | LIST OF PEOPLE WITH MUCH MORE LONG-TERM EXPERIENCE |
| 25 | IN INDUSTRY. THOSE WILL BE ON NEXT MONTH'S AGENDA. |
| | |

| 1 | MS. SAMUELSON: I GUESS WHAT I'D |
|----|--|
| 2 | APPRECIATE, MARIE, IS A LITTLE BIT MORE ABOUT WHERE |
| 3 | YOU SEE MAYBE YOURSELF AND STAFF IN THE PROCESS OF |
| 4 | DEVELOPING THE FULL TEAM THAT YOU WOULD FIND TO BE |
| 5 | EQUIPPED TO REALLY ADDRESS ALL THE STUFF THAT'S |
| 6 | BROUGHT TO US IN THE WORKING GROUP SCIENTIFICALLY. |
| 7 | DR. CSETE: I FELT REALLY STRONGLY THAT WE |
| 8 | NEED A MUCH LARGER POOL OF ALTERNATE GRANTS WORKING |
| 9 | GROUP PEOPLE BECAUSE THE BREADTH OF THE KINDS OF |
| 10 | RFA'S THAT WE'RE PUTTING OUT IS ENORMOUS. AND |
| 11 | PEOPLE ARE ALSO THE PEOPLE THAT WE'RE GETTING ARE |
| 12 | EXTREMELY BUSY BECAUSE THEY'RE VERY SOUGHT AFTER AS |
| 13 | REVIEWERS, AND THEY'RE BUSY IN THEIR OWN |
| 14 | LABORATORIES AND IN THEIR OWN INDUSTRY. |
| 15 | SO AT FIRST WE REALLY HAD TO SCRAMBLE TO |
| 16 | PUT TOGETHER MOSTLY BIOENGINEERING EXPERIENCE FOR |
| 17 | TOOLS AND TECHNOLOGIES JUST TO GET THE ADEQUATE |
| 18 | PEOPLE THAT WE NEEDED FOR THE SEPTEMBER REVIEW. WE |
| 19 | ARE ALSO WORKING IN THE LONG TERM TO BEEF UP, NOT |
| 20 | ONLY OUR INDUSTRY EXPERIENCE PEOPLE, BUT PEOPLE WITH |
| 21 | REGULATORY EXPERIENCE, PHYSICIAN/SCIENTISTS WHO HAVE |
| 22 | CARRIED OUT CLINICAL TRIALS, ETC. AND ALL THOSE |
| 23 | PEOPLE ARE PEOPLE I'VE BEEN ON THE PHONE WITH, GIL |
| 24 | HAS BEEN ON THE PHONE WITH, WE'RE WORKING TO GET |
| 25 | THEM ON PANELS. IT DOESN'T HAPPEN IN AN INSTANT. |
| | |

| YOU'VE BEEN WORKING, AS STAFF DOES. DR. CSETE: WE LOVE RECOMMENDATIONS FROM |
|--|
| DR. CSETE: WE LOVE RECOMMENDATIONS FROM |
| |
| YOU, AND I'VE HARASSED SOME OF YOU. IF YOU CAN GIVE |
| ME NAMES THAT HAVEN'T COME TO MY ATTENTION, I'D BE |
| HAPPY TO LOOK INTO THAT. |
| MS. SAMUELSON: MR. CHAIRMAN, I DON'T KNOW |
| IF THIS RISES TO THE LEVEL OF A TASK FORCE OR NOT, |
| AND MR. PRESIDENT, BUT I WOULD LOVE US TO GET THE |
| FULL BENEFIT OF DUANE'S THOUGHTS ABOUT THIS AND |
| ANYONE ELSE ON THE BOARD WHO BRINGS SUCH GREAT |
| EXPERTISE TO THIS QUESTION AND CONTEXT. PEOPLE WHO |
| THEY COULD REALLY PUT THE HAND ON AND SELL ON BEING |
| INVOLVED IN OUR PROCESS BECAUSE IT'S NOT AN EASY |
| SELL BECAUSE IT IS SO HARD, AS WE ALL KNOW. |
| SO I'D LIKE TO FORMALIZE THAT TO THE |
| EXTENT WE NEED TO TO BE SURE THAT WE'RE GOING TO |
| FOLLOW UP ON IT. |
| CHAIRMAN KLEIN: BETWEEN NOW AND THE |
| SEPTEMBER MEETING, KNOWING WE'RE GOING TO NEED TO |
| RECRUIT A LOT OF NEW PEOPLE, I'D ASK THE BOARD |
| GENERALLY TO SUBMIT SOME NAMES AND RECOMMENDATIONS |
| TO MARIE SO THAT WE CAN REALLY POOL THESE RESOURCES. |
| AND THEN BASED UPON THAT, WE CAN ANALYZE WHAT |
| ADDITIONAL STEPS WE NEED. SO WE CAN CREATE |
| |
| |

| 1 | MAYBE, JOAN, YOU CAN CREATE A DIALOGUE WITH MARIE |
|----|--|
| 2 | BETWEEN NOW AND THEN AND SEE WHAT THE RESPONSE IS |
| 3 | BECAUSE WE'RE GOING TO NEED VERY LARGE POOLS, AS |
| 4 | WE'VE JUST TALKED ABOUT, BRINGING IN NEW PEOPLE. |
| 5 | I WOULD ALSO, THOUGH, SAY, DUANE, THAT |
| 6 | JUST AS NEW PRIVATE COMPANIES WILL GO IN AND RECRUIT |
| 7 | SOMEONE FROM AN ACADEMIC SETTING THAT HAS A CRITICAL |
| 8 | LINK OF KNOWLEDGE, IN THESE DISEASE TEAMS THERE MAY |
| 9 | BE SOME VERY WONDERFUL ACADEMIC RESEARCHERS WHO ARE |
| 10 | ON THE VERGE OF CREATING THEIR OWN COMPANY OR HAVE A |
| 11 | CRITICAL LINK OF KNOWLEDGE THAT WOULD BE VERY GOOD, |
| 12 | EVEN THOUGH THEY DON'T HAVE A HISTORY IN THE PRIVATE |
| 13 | SECTOR, TO HAVE ON THOSE TEAMS. AND THE CULTURE IS |
| 14 | SUCH THAT THAT KNOWLEDGE IS INTEGRATED WELL, AS |
| 15 | WE'VE SEEN PREVIOUSLY WHERE WE HAVE DIFFERENT |
| 16 | DISPARATE BACKGROUNDS BRINGING TOGETHER AN EFFECTIVE |
| 17 | CULTURE THAT MOBILIZES ALL THE KNOWLEDGE OF THE |
| 18 | WHOLE GROUP. |
| 19 | MR. ROTH: SO MY SUGGESTION WOULD BE TO |
| 20 | WRITE A REALLY GOOD JOB DESCRIPTION HERE AND GET IT |
| 21 | TO CHI, BIOCOM, BAYBIO, EVEN BIO AND PHARMA AND ASK |
| 22 | FOR THEIR HELP TO IDENTIFY PEOPLE THAT WOULD BE GOOD |
| 23 | REVIEWERS FOR EXACTLY THE KINDS OF PEOPLE YOU'RE |
| 24 | TALKING ABOUT. AND I THINK YOU WILL GET A VERY |
| 25 | LARGE LIST. |
| | |

| 1 | CHAIRMAN KLEIN: ALL RIGHT. MARIE WOULD |
|----|--|
| 2 | LOVE TO RECRUIT THE WORLD. SO THANK YOU FOR THOSE |
| 3 | SUGGESTIONS. ANY ADDITIONAL QUESTIONS OR COMMENTS |
| 4 | ON THIS PANEL OF SUGGESTED ALTERNATES? |
| 5 | DR. TROUNSON: MR. CHAIR, JUST TO REMIND |
| 6 | THE BOARD THAT WE DO ALSO HAVE SPECIALISTS WHO DON'T |
| 7 | VOTE, BUT WHO ARE PREPARED TO GIVE US THEIR TIME |
| 8 | BECAUSE THEY'VE GOT A PARTICULAR EXPERTISE IN |
| 9 | SOMETHING THAT IS NOT READILY AVAILABLE ANYWHERE. |
| 10 | AND SO WE'VE REACHED WE'VE OFTEN REACHED OUT TO |
| 11 | GET SPECIALISTS WHO REALLY INFORM THE REVIEW PROCESS |
| 12 | WITHOUT MAKING ANY VOTES. |
| 13 | CHAIRMAN KLEIN: AND WHOSE TIME |
| 14 | REQUIREMENTS ARE MORE NARROWLY FOCUSED. SO, AGAIN, |
| 15 | FROM THE BOARD, I THINK WE'D ASK THAT IF YOU HAVE |
| 16 | ADVICE ON SPECIALISTS THAT COULD BE VERY HELPFUL IN |
| 17 | PROVIDING CRITICAL INFORMATION FOR THE TRANSLATIONAL |
| 18 | OR DISEASE TEAM ROUNDS, IN PARTICULAR, BETWEEN NOW |
| 19 | AND THE NEXT BOARD MEETING, IN FACT, LET'S TRY AND |
| 20 | SAY TEN DAYS BEFORE THAT BOARD MEETING SO WE CAN |
| 21 | AGGREGATE THE INFORMATION, PLEASE SUBMIT THOSE LISTS |
| 22 | TO THE SCIENTIFIC STAFF. |
| 23 | ARE THERE PUBLIC COMMENTS ON THIS PANEL OF |
| 24 | NOMI NEES? |
| 25 | MS. SAMUELSON: I'VE GOT ONE MORE QUICK |
| | 70 |
| | , o |

| 1 | FOLLOW-UP FOR GIL. AS OF TODAY, DO WE HAVE ANY |
|----|---|
| 2 | VACANCIES ON THE ACTUAL WORKING GROUP MEMBERSHIP |
| 3 | ITSELF? |
| 4 | DR. SAMBRANO: WE HAVE ACTUALLY ONE |
| 5 | VACANCY IN THE GRANTS WORKING GROUP, NOT THE |
| 6 | ALTERNATE MEMBERS, AND THEY'RE NOT WE OFTEN CALL |
| 7 | THEM PERMANENT MEMBERS, BUT THEY ACTUALLY HAVE A |
| 8 | SIX-YEAR APPOINTMENT. THERE ARE THE 15 REGULAR |
| 9 | MEMBERS. SO I THINK WE'D LIKE TO BRING TO YOU A |
| 10 | NOMINATION. I THINK IF YOU HAVE THE ROSTER OF THE |
| 11 | GRANTS WORKING GROUP MEMBERS, I THINK WE NEED TO GO |
| 12 | OVER THAT CAREFULLY AND DECIDE HOW WE WANT TO AND |
| 13 | WHO WE WANT TO BRING INTO THAT REGULAR MEMBERSHIP |
| 14 | FOR THAT VACANCY. |
| 15 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 16 | WITH THAT, WE'LL CONTINUE OUR MOMENTUM AND MOVE TO |
| 17 | ITEM NO. 8. AND DR. GEOFF LOMAX IS GOING TO PRESENT |
| 18 | A NEW MEMBER PROPOSAL FOR THE STANDARDS WORKING |
| 19 | GROUP. |
| 20 | DR. LOMAX: THANK YOU, MR. CHAIRMAN. ONE |
| 21 | OF THE ETHICIST MEMBERS OF THE STANDARDS WORKING |
| 22 | GROUP, PATRICIA KING OF GEORGETOWN UNIVERSITY, |
| 23 | ANNOUNCED HER NEED TO STEP DOWN FROM THE WORKING |
| 24 | GROUP EARLIER THIS SUMMER. SHE WAS FINDING IT |
| 25 | DIFFICULT TO ATTEND THE DELIBERATIONS. I THINK |
| | 71 |

| 1 | PARTICULARLY THE LONG TRAVEL WAS A BIT OF A PROBLEM. |
|----|--|
| 2 | SHE FILLED A ROLE ON THE WORKING GROUP |
| 3 | THAT WAS FOCUSED. SHE HAD EXPERTISE PARTICULARLY ON |
| 4 | HEALTH ISSUES, HEALTH ISSUES RELATING TO UNDERSERVED |
| 5 | COMMUNITIES. SO WE THEN SOUGHT TO IDENTIFY A |
| 6 | REPLACEMENT MEMBER THAT COULD BRING THOSE |
| 7 | QUALIFICATIONS TO THE WORKING GROUP. |
| 8 | AT THIS TIME THE RESULT OF THAT SEARCH IS |
| 9 | THE RECOMMENDATION OF DOROTHY ROBERTS, PROFESSOR OF |
| 10 | LAW AT NORTHWESTERN UNIVERSITY SCHOOL OF LAW IN |
| 11 | CHICAGO. IT'S OUR RECOMMENDATION TO THE BOARD. |
| 12 | CHAIRMAN KLEIN: ALL RIGHT. ANYONE HAVE |
| 13 | ANY DISCUSSION OR POINTS OF INFORMATION? |
| 14 | MS. LANSING: HI. I JUST WANT TO SAY THAT |
| 15 | OBVIOUSLY HER RESUME SPEAKS VERY MUCH FOR ITSELF. |
| 16 | SHE'S FROM OUT-OF-STATE, WHICH IS TERRIFIC. HER |
| 17 | QUALIFICATIONS ARE EXTRAORDINARY. MY CO-CHAIR, |
| 18 | BERNIE LO, HAS SPOKEN TO HER. SHE'S ANXIOUS TO |
| 19 | SERVE, AND I THINK SHE'LL BE A WONDERFUL, WONDERFUL |
| 20 | ADDI TI ON. |
| 21 | CHAIRMAN KLEIN: ALL RIGHT. ANY |
| 22 | ADDITIONAL COMMENTS ON THIS MEMBER? |
| 23 | MR. SHEEHY: I WOULD JUST LIKE TO SECOND |
| 24 | WHAT SHERRY SAID. PAT KING LEAVES A VERY DEFINITE |
| 25 | GAP. SHE WAS VERY INFLUENTIAL, VERY KNOWLEDGEABLE |
| | 70 |

| 1 | ABOUT WOMEN'S ISSUES AND THE ISSUES OF DIVERSE |
|----|--|
| 2 | COMMUNITIES WITHIN THE STATE AND COUNTRY. AND I |
| 3 | THINK DOROTHY ROBERTS WILL REALLY FILL THAT NICHE, |
| 4 | THAT GAP. I DO AGREE WITH WHAT SHERRY SAID AS WELL, |
| 5 | AND I HOPE WE MOVE HER FORWARD. |
| 6 | CHAIRMAN KLEIN: OKAY. THANK YOU. PUBLIC |
| 7 | COMMENT? SEEING NO PUBLIC COMMENT ON THIS ITEM, |
| 8 | I'VE BEEN TOLD THAT THERE'S A NUMBER OF INDIVIDUALS |
| 9 | IN THE AUDIENCE THAT HAVE PUBLIC CONTRIBUTIONS TO |
| 10 | MAKE ON ITEM NO. 10. SO FOR THE MOMENT I'M GOING TO |
| 11 | GO TO ITEM NO. 10, CALIFORNIA SUPPLIER. AND DUANE |
| 12 | ROTH AND TED LOVE WERE THE TWO-PERSON TASK FORCE |
| 13 | FROM THE BOARD THAT HAVE LED THIS EFFORT VERY |
| 14 | SUCCESSFULLY IN COLLABORATION WITH ASSEMBLYMAN |
| 15 | MULLIN'S OFFICE TO BRING TOGETHER, I THINK, |
| 16 | CONSENSUS ON THIS. SO, DUANE, WOULD YOU LIKE TO |
| 17 | LEAD THE DISCUSSION ON THIS ITEM? |
| 18 | MR. ROTH: I WOULD BE HAPPY TO. LET ME |
| 19 | START WITH JUST RECOGNIZING THAT I PROBABLY MADE THE |
| 20 | UNDERSTATEMENT OF THE YEAR IN SACRAMENTO WHEN THIS |
| 21 | ISSUE CAME UP, AND I SUGGESTED THAT WE COULD GET |
| 22 | TOGETHER FOR AN HOUR AND WORK IT OUT. THAT WAS A |
| 23 | TREMENDOUS UNDERSTATEMENT. |
| 24 | SO YOU'VE MENTIONED THAT TED LOVE AND I |
| 25 | WORKED TOGETHER, AND I THANK TED FOR ALL HIS WORK |
| | |

| 1 | WITH SCOTT TOCHER. AND I THINK WE NOW HAVE IN FRONT |
|----|--|
| 2 | OF YOU SOMETHING THAT WE WOULD RECOMMEND AS THE |
| 3 | DEFINITION FOR A CALIFORNIA SUPPLIER. |
| 4 | YOU MENTIONED ASSEMBLYMEMBER MULLIN AND |
| 5 | PARTICULARLY DARCY SEARS, WHO PLAYED AN IMPORTANT |
| 6 | ROLE, AND A NUMBER OF THE COMPANIES, INVITROGEN, |
| 7 | BECKMAN DICKINSON, ROCHE, J & J, AND OTHERS, IN |
| 8 | COMING UP WITH THE LANGUAGE. |
| 9 | SO IF YOU'D TURN TO THE DEFINITION, THE |
| 10 | PROPOSED ADOPTION FOR THIS MEETING, THERE ARE REALLY |
| 11 | THREE BROAD HEADINGS TO QUALIFY AS A CALIFORNIA |
| 12 | SUPPLIER. AND THE FIRST ONE IS THAT YOU'RE |
| 13 | HEADQUARTERED IN THE STATE OF CALIFORNIA. THAT'S |
| 14 | YOUR PRINCIPAL PLACE OF BUSINESS AND WHERE IT'S |
| 15 | DIRECTED FROM. |
| 16 | THE SECOND WAY TO QUALIFY IS IF YOU HAVE A |
| 17 | SOLE PROPRIETORSHIP, A PARTNERSHIP, OR JOINT |
| 18 | VENTURE, OR OTHER CORPORATION IN THE STATE THAT |
| 19 | EMPLOYS AT LEAST ONE-THIRD OF ALL YOUR EMPLOYEES, |
| 20 | EVEN THOUGH YOU'RE NOT HEADQUARTERED HERE, YOU |
| 21 | EMPLOY ONE-THIRD OF YOUR TOTAL EMPLOYMENT HERE. SO |
| 22 | THAT WOULD GET SMALL COMPANIES WHO ARE HEADQUARTERED |
| 23 | IN ANOTHER STATE, BUT HAVE A REAL PRESENCE HERE, |
| 24 | QUALIFIED AS A CALIFORNIA SUPPLIER. |
| 25 | AND THEN ANY BUSINESS UNIT, DIVISION, OR |
| | 7.4 |

| 1 | SUBSIDIARY THAT'S, AGAIN, NOT LOCATED WHERE THE |
|----|--|
| 2 | HEADQUARTERS IS LOCATED, BUT A DIVISION IS LOCATED |
| 3 | HERE THAT PRODUCES PRODUCTS THAT ARE USED BY LIFE |
| 4 | SCIENCE RESEARCH INSTITUTES. |
| 5 | AND THEN THERE'S A FURTHER QUALIFICATION, |
| 6 | NO. C, AND THAT DEALS WITH THE PRODUCTS THAT ARE |
| 7 | ACTUALLY MANUFACTURED IN THE STATE OF CALIFORNIA AND |
| 8 | THE CORPORATION IS OUTSIDE THE STATE. SO THOSE |
| 9 | PRODUCTS WOULD QUALIFY AS, QUOTE, CALIFORNIA |
| 10 | PRODUCTS OR FROM A CALIFORNIA SUPPLIER. SO THAT'S |
| 11 | THE SECOND WAY. BROAD CATEGORY. YOU'RE NOT |
| 12 | HEADQUARTERED HERE, BUT YOU HAVE SIGNIFICANT |
| 13 | BUSINESS UNITS FOR OPERATIONS HERE. |
| 14 | AND THE THIRD ONE IS ANY MAJOR CALIFORNIA |
| 15 | SUPPLIER, AND WE HAVE TWO CATEGORIES HERE. AND A |
| 16 | MAJOR CALIFORNIA PRESENCE. I SHOULDN'T SAY |
| 17 | SUPPLIER. A MAJOR CALIFORNIA PRESENCE. AND SO ANY |
| 18 | COMPANY THAT HAS 800 CALIFORNIA RESIDENTS EMPLOYED |
| 19 | IN THE LIFE SCIENCE RESEARCH FIELD QUALIFIES |
| 20 | EVERYTHING. AND FINALLY, IF YOU DON'T HAVE LIFE |
| 21 | SCIENCE CATEGORIES THAT MEET THE 800, BUT YOU EMPLOY |
| 22 | 5,000 CALIFORNIANS, THEN YOU'RE CONSIDERED A |
| 23 | CALIFORNIA SUPPLIER. |
| 24 | SO THERE'S REALLY THREE MAJOR HEADINGS. |
| 25 | THE ONLY OTHER IMPORTANT ASPECT I'D CALL YOUR |
| | |

| 1 | ATTENTION TO IS THAT THE COMPANIES THEMSELVES, SO |
|----|--|
| 2 | THAT CIRM DOESN'T HAVE THE STAFF AND RESOURCES TO |
| 3 | CERTIFY, THE COMPANIES WILL SELF-CERTIFY. WE'LL |
| 4 | PROBABLY PLACE THOSE ON A WEBSITE SO IT WILL BE KEPT |
| 5 | UP TO DATE BY THEM. THAT'S STILL TO BE WORKED OUT, |
| 6 | BUT THE GENERAL COUNSEL OF THE CORPORATION OR THE |
| 7 | CEO OR A PARTNER OR A DIRECTOR WILL HAVE TO SIGN |
| 8 | THAT CERTIFICATION SO THAT WE KEEP EVERYBODY HONEST. |
| 9 | HAVING BEEN A FORMER SALES REPRESENTATIVE |
| 10 | EARLY IN MY LIFE, I'M QUITE SURE IT WILL BE POLICED |
| 11 | BY THE COMPETITORS. SO I THINK WE'LL HAVE A PROGRAM |
| 12 | THAT WORKS HERE. I THANK EVERYBODY THAT WORKED ON |
| 13 | THIS. ED PENHOET AND BOB, YOU GUYS GAVE US SOME |
| 14 | GOOD INPUT INTO IT. WE GOT SOME GREAT COMMENTS BACK |
| 15 | FROM, NOT ONLY THE COMPANIES, BUT THE APPLICANTS, |
| 16 | THE RESEARCH INSTITUTES THAT THIS IS WORKABLE. |
| 17 | THANK YOU. |
| 18 | CHAIRMAN KLEIN: SO, DUANE, JUST TO DRAW |
| 19 | OUT YOUR POINT ABOUT POLICING, SINCE THIS WILL BE A |
| 20 | PUBLIC SITE, THAT IF SOMEONE HASN'T CERTIFIED |
| 21 | PROPERLY, YOU HAVE NO DOUBT THAT THE COMPETITORS |
| 22 | WILL DRAW IT TO OUR ATTENTION AND THEREFORE |
| 23 | MR. ROTH: I'M QUITE SURE THAT WILL |
| 24 | HAPPEN. |
| 25 | CHAIRMAN KLEIN: THERE WILL BE A GREAT |
| | 76 |
| | 10 |

| 1 | DEAL OF PUBLIC ACCOUNTABILITY AND OVERSIGHT BUILT |
|----|--|
| 2 | INTO THIS SYSTEM. |
| 3 | MR. ROTH: CORRECT. |
| 4 | CHAIRMAN KLEIN: ALL RIGHT. AND ARE THERE |
| 5 | INDIVIDUALS, DUANE, HERE THAT WOULD LIKE TO OFFER |
| 6 | PUBLIC COMMENT? OR LET ME ASK FIRST ARE THERE BOARD |
| 7 | COMMENTS BEFORE THE PUBLIC COMMENTS? |
| 8 | DR. LOVE: MAYBE I'LL JUST ADD A COUPLE OF |
| 9 | POINTS. ONE IS THAT I ALSO MADE THE ROTH MISTAKE IN |
| 10 | SACRAMENTO. I JOINED IN THIS EFFORT THINKING THAT, |
| 11 | BOY, THIS WILL BE QUICK AND THIS WILL BE SIMPLE, AND |
| 12 | I'LL BE ABLE TO GET CREDIT FOR HAVING DONE SOMETHING |
| 13 | WITHOUT DOING MUCH WORK. IN FACT, IT'S TURNED OUT |
| 14 | TO BE EXTRAORDINARILY COMPLEX, INVOLVED A LOT OF |
| 15 | PEOPLE CONTRIBUTING. I JUST WANT TO ACKNOWLEDGE |
| 16 | THAT I THINK DUANE, AS CHAIR OF THIS EFFORT, DID AN |
| 17 | EXTRAORDINARY JOB. AND MY CONTRIBUTION RELATIVE TO |
| 18 | DUANE'S WAS REALLY MINUSCULE. AND SCOTT ALSO DID A |
| 19 | TREMENDOUS JOB. AND I ALSO WANT TO THANK ALL THE |
| 20 | COMPANIES AND ALL THE INDIVIDUALS FROM OUTSIDE WHO |
| 21 | REALLY GOT INVOLVED. |
| 22 | AND, IN FACT, I THINK IT WAS AN EXEMPLARY |
| 23 | PROCESS IN THE END IN THAT ALL THE STAKEHOLDERS THAT |
| 24 | HAD A STAKE IN THIS CAME TO THE TABLE, CONTRIBUTED |
| 25 | VIGOROUSLY TO THE PROCESS. I THINK WE ENDED UP WITH |
| | |

| 1 | WHAT WE'RE SUPPOSED TO END UP WITH, WHICH IS A |
|----|--|
| 2 | PROCESS WHICH REALLY DOES FOCUS ON TRYING TO DIRECT |
| 3 | THE RESOURCES TOWARD COMPANIES THAT ARE FOCUSED ON |
| 4 | HELPING CALIFORNIA IN BENEFITING OUR CITIZENS. |
| 5 | CHAIRMAN KLEIN: THANK YOU VERY MUCH, DR. |
| 6 | LOVE. PUBLIC COMMENT ON THIS ITEM? |
| 7 | MR. HAWKINS: MR. CHAIRMAN, I'M MICHAEL |
| 8 | HAWKINS. I'M HERE ON BEHALF OF THE CALIFORNIA |
| 9 | HEALTHCARE INSTITUTE, AND THEY'RE IN SUPPORT OF |
| 10 | THESE REGULATIONS AND ENCOURAGE YOU TO PASS THEM. |
| 11 | AND WANT TO THANK MR. ROTH AND MR. LOVE FOR ALL |
| 12 | THEIR WORK ON THIS. THANK YOU. |
| 13 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. IS |
| 14 | THERE ADDITIONAL PUBLIC COMMENT? |
| 15 | MR. LAKAVAGE: GOOD EVENING. I'M TONY |
| 16 | LAKAVAGE, AND I'M HERE FROM BD, BECKMAN DICKINSON. |
| 17 | AND I WANT TO THANK YOU ALL FOR YOUR PATIENCE ON |
| 18 | THIS ISSUE. WE'VE BEEN TALKING ABOUT IT FOR MONTHS. |
| 19 | AND THANK YOU, DUANE AND TED, FOR YOUR LEADERSHIP |
| 20 | AND, SCOTT, FOR YOUR SUPPORT IN BRINGING US TOGETHER |
| 21 | ON THIS. |
| 22 | I THINK IT WAS A LONG PROCESS, BUT WE HAVE |
| 23 | A DEFINITION NOW THAT I THINK INCLUDES CALIFORNIA |
| 24 | COMPANIES OF ALL SIZES AND SHAPES THAT MAKE A |
| 25 | CONTRIBUTION. AND JUST ON BEHALF BD, WE'RE LOOKING |
| | 70 |

| 1 | FORWARD TO WORKING TOGETHER ON THIS INITIATIVE AND |
|----|--|
| 2 | WITH THE BIOMEDICAL RESEARCH COMMUNITY TO REALIZE |
| 3 | THE GOALS OF THE INITIATIVE. THANKS VERY MUCH. |
| 4 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 5 | ADDITIONAL PUBLIC COMMENT? |
| 6 | MS. SNIDER: JENNIFER SNIDER ON BEHALF OF |
| 7 | ROCHE. JUST ALSO WANTED TO EXPRESS OUR SUPPORT FOR |
| 8 | THIS LANGUAGE. AND I'M APPRECIATIVE OF THE WORK OF |
| 9 | DUANE AND THE FOLKS THAT WORKED ON THIS TOGETHER. |
| 10 | SO THANK YOU. |
| 11 | CHAIRMAN KLEIN: THANK YOU. FURTHER |
| 12 | PUBLIC COMMENT? |
| 13 | MS. LAMBERT: WELL, I'M JANET LAMBERT FROM |
| 14 | INVITROGEN. I GUESS I WAS ONE OF THE PEOPLE WHO GOT |
| 15 | THIS STARTED, FOR WHICH I APOLOGIZE, MAYBE, OR I |
| 16 | DON'T KNOW WHAT THE RIGHT TERM IS. BUT I ALSO JUST |
| 17 | WANT TO SAY WE'RE PLEASED WITH THE WAY IT CAME OUT. |
| 18 | WE WERE A VIGOROUS CONTRIBUTOR THROUGHOUT. AND I DO |
| 19 | THANK DUANE AND TED FOR THEIR PATIENCE. AND I THINK |
| 20 | WE CAME OUT WITH AN OUTCOME WHICH BOTH PRESERVES THE |
| 21 | FLEXIBILITY THAT GRANTEES NEED, RECOGNIZES THAT |
| 22 | COMPANIES COME IN A LOT OF DIFFERENT SHAPES AND |
| 23 | FLAVORS, BUT WHICH ALSO KIND OF HOLDS TRUE TO THE |
| 24 | WHOLE POINT OF THE PREFERENCE, WHICH WAS TO TRY TO |
| 25 | CREATE AS MUCH POSITIVE ECONOMIC RIPPLE EFFECT IN |
| | 7.0 |

| 1 | CALIFORNIA FROM WHAT IS THE MOST IMPORTANT JOB HERE, |
|----|--|
| 2 | WHICH TO DO GREAT RESEARCH AND MOVE US CLOSER TO |
| 3 | CURES. I THINK THIS IS A JOB WELL DONE, AND WE |
| 4 | WOULD ENCOURAGE YOU TO SUPPORT IT. |
| 5 | CHAIRMAN KLEIN: JANET, I THINK WE SHOULD |
| 6 | ACTUALLY THANK YOU. IT'S A VIGOROUS PUBLIC PROCESS, |
| 7 | BUT IT WAS WORKED OUT IN THE BEST INTERESTS OF |
| 8 | EVERYONE WITH A NUMBER OF PUBLIC HEARINGS, DRAWING |
| 9 | EVERYONE'S ATTENTION TO THE ISSUE SO THAT THERE |
| 10 | COULD BE BROADER PARTICIPATION. AND CERTAINLY WE |
| 11 | HAD A FULL RANGE OF CALIFORNIA COMPANIES THAT ENDED |
| 12 | UP PARTICIPATING. |
| 13 | MS. LAMBERT: THAT WE DID. |
| 14 | CHAIRMAN KLEIN: THANK YOU. ANY |
| 15 | ADDITIONAL PUBLIC COMMENT? |
| 16 | MR. SIMPSON: JOHN SIMPSON FROM CONSUMER |
| 17 | WATCHDOG. BELIEVE IT OR NOT, I WAS PARTY TO SOME OF |
| 18 | THOSE CONVERSATIONS AND DISCUSSIONS THAT INVOLVED |
| 19 | THE COMPANIES. AND IT DID SEEM TO MOVE IN THE RIGHT |
| 20 | DI RECTI ON. |
| 21 | MY QUESTION WOULD BE, THOUGH, WHAT NOW IS |
| 22 | THE STATUS OF ASSEMBLYMAN MULLIN'S BILL, WHICH |
| 23 | ESSENTIALLY IS THIS LANGUAGE VERBATIM? DOES ANYONE |
| 24 | KNOW WHETHER THAT INTENDS TO GO FORWARD OR WHAT |
| 25 | HAPPENS? IT DOES SEEM TO ME, FOR THE RECORD, IT |
| | |

| 1 | SHOULD BE MADE CLEAR THAT PART OF THE THING DRIVING |
|----|---|
| 2 | THE WHOLE EFFORT WAS ASSEMBLYMAN MULLIN'S BILL, |
| 3 | WHICH I THINK IS AN EXAMPLE SOMETIMES OF HOW THE |
| 4 | LEGISLATURE CAN HAVE A POSITIVE IMPACT ON WHAT'S |
| 5 | DONE HERE AT CIRM BECAUSE THIS DID COME ABOUT IN |
| 6 | WHAT IS SOMETHING THAT FITS THE BILL AND IS GOOD. |
| 7 | SO WHATEVER ASSEMBLYMAN MULLIN DECIDES TO |
| 8 | DO WITH HIS BILL, I ENCOURAGE YOU TO PASS THIS FOR |
| 9 | YOUR OWN REGULATIONS. THANK YOU. |
| 10 | CHAIRMAN KLEIN: THANK YOU VERY MUCH, MR. |
| 11 | SIMPSON. AND IT'S AN INTERESTING ISSUE WE HAVE TO |
| 12 | SEPARATELY ADDRESS BECAUSE, IRONICALLY, FOR US TO |
| 13 | PASS OUR REGULATION, WE THEN HAVE A COMMENT PERIOD |
| 14 | BECAUSE, AS GREAT AS THE PARTICIPATION HAS BEEN, |
| 15 | IT'S A BIG STATE. AND SO WE'RE IN AN INTERESTING |
| 16 | POSITION WHERE WE DON'T WANT TO CUT OFF THE PUBLIC |
| 17 | COMMENT, WHICH IS BUILT INTO THE ADMINISTRATIVE |
| 18 | PROCEDURES ACT, SO WE'LL HAVE TO HAVE ADDITIONAL |
| 19 | CONVERSATIONS WITH MR. MULLIN ON THIS AND HOW WE |
| 20 | RECONCILE THESE ISSUES. |
| 21 | MR. ROTH: MR. CHAIRMAN, I THOUGHT I |
| 22 | UNDERSTOOD AT ONE TIME WE COULD ADOPT THESE ON AN |
| 23 | EMERGENCY BASIS. |
| 24 | CHAIRMAN KLEIN: WE CAN EXACTLY. WE HAVE |
| 25 | LANGUAGE THAT'S SITTING OUT THERE. SO LET ME ASK |
| | |

| 1 | MR. HARRISON. MY UNDERSTANDING IS THAT THERE IS |
|----|--|
| 2 | PLACEHOLDER LANGUAGE THAT WAS WAITING FOR THIS TO |
| 3 | MATURE THAT IS, IN FACT, SITTING THERE. IS THAT A |
| 4 | CORRECT STATEMENT? |
| 5 | MR. HARRISON: THERE IS PLACEHOLDER |
| 6 | LANGUAGE IN THE PROPOSED AMENDMENTS TO THE GRANTS |
| 7 | ADMINISTRATION POLICY, WHICH HAS BEEN APPROVED |
| 8 | SOLELY FOR THE PURPOSES OF OBTAINING PUBLIC COMMENT. |
| 9 | WHAT WE'D PROPOSE TO DO WITH THE CALIFORNIA SUPPLIER |
| 10 | REGULATION IS TO ADOPT IT AS AN INTERIM REGULATION, |
| 11 | WHICH WOULD THEN GIVE US A 270-DAY PERIOD IN WHICH |
| 12 | TO COMMENCE AND HOPEFULLY COMPLETE THE FORMAL |
| 13 | ADMINISTRATIVE PROCEDURE ACT PROCESS. |
| 14 | CHAIRMAN KLEIN: THAT IS THE EMERGENCY |
| 15 | REGS THAT YOU ARE REFERRING TO, DUANE, WHICH MAKES |
| 16 | IT IMMEDIATELY EFFECTIVE. OKAY. |
| 17 | SO WITH THAT TESTIMONY, I WOULD LIKE TO BE |
| 18 | ABLE TO MOVE TO ITEM 9, WHICH WE PASSED OVER TO GET |
| 19 | A NUMBER OF THE COMMENTS THAT CAME FROM THE PUBLIC |
| 20 | BECAUSE SOME OF THE PUBLIC MEMBERS THAT WERE HERE |
| 21 | FOR THIS ITEM HAD DEFINITIVE TIMETABLES THAT THEY |
| 22 | HAD TO MEET IN TERMS OF MAKING PLANES OR |
| 23 | TRANSPORTATION ARRANGEMENTS. |
| 24 | SO ON ITEM NO. 9, DR. LOMAX, WOULD YOU |
| 25 | PRESENT THE ITEM? |
| | 82 |

| 1 | DR. LOMAX: THANK YOU, MR. CHAIRMAN. WHAT |
|----|--|
| 2 | I'D LIKE TO DO IS REPORT BACK ON TWO ITEMS THAT |
| 3 | EMERGED FROM THE MOST RECENT STANDARDS WORKING GROUP |
| 4 | MEETING. FIRST, I'D LIKE TO DESCRIBE THE CONCEPT OF |
| 5 | A GRANDFATHERING PROVISION. CURRENTLY CIRM HAS |
| 6 | DETAILED REGULATIONS FOR THE USE OF WHAT ARE DEFINED |
| 7 | AS ACCEPTABLY DERIVED HUMAN EMBRYONIC STEM CELL |
| 8 | LINES. AND ONE ELEMENT OF THE REGULATIONS IS THAT |
| 9 | THEY APPLY RETROACTIVELY TO LINES DERIVED PRIOR TO |
| 10 | NOVEMBER 2006, WHICH IS THE DATE THE ICOC EXCUSE |
| 11 | ME THE DATE THE REGULATIONS TOOK EFFECT. |
| 12 | AS A CONSEQUENCE, STEM CELL LINES CREATED |
| 13 | PRIOR TO THIS DATE MAY NOT BE ELIGIBLE FOR USE BY |
| 14 | CIRM GRANTEES. IT WAS THE SENSE OF THE STANDARDS |
| 15 | WORKING GROUP MEMBERS THAT CIRM SHOULD ADOPT A |
| 16 | PROCESS FOR EVALUATING SUCH LINES. SO WHAT I'D LIKE |
| 17 | TO DO IS DESCRIBE IN THE NEXT SET OF SLIDES THE |
| 18 | CONTOURS OF THIS PROCESS. |
| 19 | FIRST OF ALL, AN APPLICANT, IN THIS CASE |
| 20 | THE INSTITUTION, THAT, SAY, DEVELOPS A STEM CELL |
| 21 | LINE, WOULD PETITION FOR THE LINE TO BECOME ELIGIBLE |
| 22 | FOR USE. AS PART OF THAT PETITION, INFORMATION |
| 23 | WOULD BE PROVIDED REGARDING INFORMED CONSENTS THAT |
| 24 | WENT INTO THE INFORMED CONSENTS FOR THE MATERIALS |
| 25 | THAT WERE USED TO CREATE THAT STEM CELL LINE, THE |
| | |

| 1 | STATUS OF IRB APPROVAL OF THE STEM CELL LINE |
|----|--|
| 2 | DERIVATION, ANY VALUABLE CONSIDERATION OR |
| 3 | COMPENSATION THAT MAY HAVE BEEN PROVIDED TO DONORS |
| 4 | OF MATERIALS THAT WERE USED TO CREATE THE EMBRYO |
| 5 | FROM WHICH THE LINE WAS DERIVED, THE PREVAILING |
| 6 | STANDARDS UNDER WHICH THE LINE WAS DERIVED, AND A |
| 7 | STATEMENT OF THE SCIENTIFIC SIGNIFICANCE OF THE |
| 8 | LINE. |
| 9 | THIS PETITION WOULD THEN BE REVIEWED BY |
| 10 | THE CO-CHAIRS OF THE STANDARDS WORKING GROUP AND |
| 11 | CIRM STAFF TO DEVELOP A RECOMMENDATION REGARDING THE |
| 12 | USE OF THE STEM CELL LINE. THAT RECOMMENDATION |
| 13 | WOULD THEN BE BROUGHT TO THE ICOC FOR YOUR |
| 14 | SUBSEQUENT APPROVAL. |
| 15 | SO WHAT WE'RE DOING IN THIS PROCESS IS |
| 16 | TRYING TO COLLECT THE MAXIMUM AMOUNT OF INFORMATION |
| 17 | NECESSARY TO DETERMINE WHETHER A LINE SHOULD BE |
| 18 | BROUGHT IN FOR SCIENTIFIC USE; AND, OF COURSE, BY |
| 19 | BRINGING IT TO THE ICOC, WE PROVIDE MAXIMUM |
| 20 | TRANSPARENCY IN THE PROCESS, SO ALL THE INFORMATION |
| 21 | COLLECTED AS PART OF THIS PROCESS WOULD BE AVAILABLE |
| 22 | TO THE PUBLIC. |
| 23 | WE HAVE DEVELOPED LANGUAGE FOR AN INTERIM |
| 24 | REGULATION, AGAIN, A REGULATION THAT WOULD BE IN |
| 25 | EFFECT FOR 270 DAYS, AND THAT RECOMMENDATION TO |
| | |

| 1 | APPROVE THAT NOT RECOMMENDATION BUT YOUR |
|----|--|
| 2 | OPPORTUNITY TO APPROVE THAT LANGUAGE WILL, I ASSUME, |
| 3 | UNDER A QUORUM, THAT'S WHAT WOULD BE REQUIRED TO |
| 4 | HAVE THE REGULATION BECOME EFFECTIVE. |
| 5 | SO ARE THERE ANY QUESTIONS ON THIS |
| 6 | SPECIFIC REGULATION? |
| 7 | DR. PRICE: AT WHAT POINT DO YOU SEE AN |
| 8 | APPLICANT MAKING THIS PETITION? I DON'T QUITE |
| 9 | UNDERSTAND THIS. |
| 10 | DR. LOMAX: IT COULD BE AT ANY POINT. |
| 11 | THERE ARE LINES THAT WE HAVE IDENTIFIED OF |
| 12 | SCIENTIFIC SIGNIFICANCE THAT ARE CURRENTLY |
| 13 | INELIGIBLE FOR USE BY OUR GRANTEES. SO ONE OF THE |
| 14 | DRIVERS BEHIND THIS DISCUSSION WAS THE RECOGNITION |
| 15 | THAT THERE ARE LINES THAT ARE CURRENTLY IN |
| 16 | SCIENTIFIC USE THAT DO NOT CONFORM TO THE EXACT |
| 17 | DETAILS OF OUR CURRENT STANDARDS, AND THE |
| 18 | RETROSPECTIVE NATURE OF OUR STANDARDS MAKES THEM |
| 19 | INELIGIBLE FOR USE. |
| 20 | DR. PRICE: LET'S SAY WE PUT OUT AN RFA, |
| 21 | AND ONE OF THE APPLICANTS FOR THIS RFA WANTS TO USE |
| 22 | ONE OF THESE LINES. YOU SET UP A PROCESS WHICH IS |
| 23 | SO LENGTHY, THAT BY THE TIME THEY GOT APPROVAL, THE |
| 24 | DEADLINE FOR APPLICATION FOR THE GRANT WOULD HAVE |
| 25 | PASSED. |
| | OE |

| 1 | DR. LOMAX: WELL, DURING THE COURSE OF THE |
|----|--|
| 2 | DELIBERATIONS, WHAT WAS ANTICIPATED WAS IT WOULD NOT |
| 3 | BE THE GRANTEE ACTUALLY FILING THE PETITION. |
| 4 | RATHER, IT WOULD BE THE ENTITY THAT HAS THE LINE IN |
| 5 | THEIR POSSESSION WHO HAS CONTROL OF THE LINE COMING |
| 6 | TO CIRM AND ASKING THAT IT BE MADE ELIGIBLE FOR ANY |
| 7 | FUTURE APPLICATION. |
| 8 | MS. LANSING: IS IT NOT TRUE THAT WE KNOW |
| 9 | OF CERTAIN LINES THAT OTHER STATES ARE ABLE TO USE |
| 10 | AND WE'RE NOT ABLE TO USE THEM? |
| 11 | DR. LOMAX: THAT'S CORRECT. |
| 12 | MS. LANSING: WE DON'T WANT TO BE |
| 13 | PENALI ZED. |
| 14 | DR. PRICE: I UNDERSTAND, BUT COULDN'T WE |
| 15 | PROACTIVELY SEEK THAT RATHER THAN WAIT FOR |
| 16 | SOMEBODY SOME APPLICANT TO PETITION US? |
| 17 | MS. LANSING: THEY'RE NOT OURS. YOU WANT |
| 18 | TO ANSWER THAT, JEFF? YOU HAVE MORE KNOWLEDGE. |
| 19 | MR. SHEEHY: I'M JUST VERY NERVOUS ABOUT |
| 20 | GRANDFATHERING IN A WHOLE SET OF LINES THAT DON'T |
| 21 | MEET THE ETHICAL STANDARDS OF THE NATIONAL ACADEMIES |
| 22 | OF SCIENCE OR OUR ETHICAL STANDARDS. AND SO I THINK |
| 23 | DOING THIS ON A CASE-BY-CASE BASIS, I MEAN ONE OF |
| 24 | THE MAJOR LIMITATIONS, AND I DON'T KNOW IF YOU SAW |
| 25 | DR. MORENO'S ARTICLE WITH RICK WEISS IN THE |
| | 86 |

| 1 | CHRONICLE. THERE ARE LINES THAT HAVE BEEN MADE |
|----|--|
| 2 | WITHOUT APPROPRIATE INFORMED CONSENT FROM ONE OF THE |
| 3 | GAMETE DONORS, AND THOSE ARE BOTH SOMEWHAT SUSPECT |
| 4 | BECAUSE THERE ARE WE ARE TAKING AWAY A CERTAIN |
| 5 | RIGHT FROM THOSE INDIVIDUALS TO DECIDE WHETHER THEIR |
| 6 | GENETIC MATERIAL IS USED FOR RESEARCH THAT THEY |
| 7 | FUNDAMENTALLY DON'T SUPPORT FROM A VERY DEEP MORAL |
| 8 | AND ETHICAL PLACE. |
| 9 | AND THE OTHER POINT IS THAT NOT HAVING THE |
| 10 | IDENTITY AND THE CONSENT OF THOSE GAMETE DONORS |
| 11 | MEANS THAT WE WILL NOT IN MANY INSTANCES, IT MAY |
| 12 | NOT BE THE BEST LINES TO PROCEED FORWARD WITH |
| 13 | CLINICALLY BECAUSE OF FDA CONSIDERATIONS. |
| 14 | FOR THOSE TWO REASONS, IT SEEMS LIKE IF |
| 15 | SOMEONE CAN COME UP WITH A COMPELLING SCIENTIFIC |
| 16 | RATIONALE, AND THIS IS IN THIS GRAY PERIOD BEFORE |
| 17 | EITHER OUR STANDARDS OR THE NATIONAL ACADEMY |
| 18 | STANDARDS WERE IN PLACE, AND THEY WANT TO ASK US TO |
| 19 | USE THOSE LINES, I THINK THAT WE SHOULD GIVE THEM |
| 20 | CONSIDERATION. THERE COULD BE, YOU KNOW, VERY |
| 21 | COMPELLING REASONS TO LET THOSE LINES BE USED. |
| 22 | BUT I DON'T THINK WE SHOULD START DOING A |
| 23 | BLANKET, YOU KNOW, ACCEPTANCE OF THESE LINES THAT |
| 24 | WEREN'T DERIVED WITH APPROPRIATE ETHICAL UNDER |
| | |
| 25 | APPROPRIATE ETHICAL GUIDELINES OR SCIENTIFIC |

| 1 | GUIDELINES, BY THE WAY, BECAUSE THERE IS A FAIRLY |
|----|--|
| 2 | SCIENTIFIC RATIONALE TO HAVE THE CONSENT AND THE |
| 3 | ABILITY TO DO GENETIC TESTING ON THE DONORS OF |
| 4 | THESE EACH GAMETE DONOR. |
| 5 | DR. PIZZO: MAY I JUST FOLLOW UP ON JEFF'S |
| 6 | COMMENT BECAUSE THERE ARE YOU REFERRED TO THE |
| 7 | WEISS ARTICLE. AND THERE ARE TWO CELL LINES, I |
| 8 | BELIEVE, IN THE ORIGINAL APPROVED GROUP IN AUGUST OF |
| 9 | 2001 THAT FAIL OR SEEM TO FAIL MEETING THOSE |
| 10 | CRITERIA. AND THAT HAS LED A NUMBER OF INSTITUTIONS |
| 11 | TO PUT IN PLACE EXAMINATIONS AS TO WHETHER THOSE |
| 12 | CELL LINES WILL BE USED AT THOSE INSTITUTIONS. |
| 13 | I THINK THIS IS AN ISSUE THAT HAS NOW |
| 14 | TAKEN ON A BROADER DISCUSSION, IN FACT, OUTSIDE OF |
| 15 | CALIFORNIA AS WELL. |
| 16 | MS. LANSING: THIS WAS AN ENTIRE DAY'S |
| 17 | DEBATE. AND THE POINTS THAT JEFF AND PHIL ARE |
| 18 | BRINGING UP AND THAT CAME FROM THE PUBLIC AS WELL, |
| 19 | OUR COMMITTEE MADE A DECISION TO MOVE SLOWLY, BUT WE |
| 20 | ARE A COMMITTEE THAT'S MEETING AGAIN IN THE NEXT |
| 21 | COUPLE OF WEEKS, WE HOPE. WE'RE TRYING TO GET AN |
| 22 | ACCEPTABLE TIME. BECAUSE THERE'S ANOTHER WHOLE |
| 23 | ISSUE THAT YOU'RE GOING TO BRING UP ALSO THAT'S PART |
| 24 | OF THIS. AND WE'RE TAKING BABY STEPS. I'M NOT |
| 25 | GOING TO TELL YOU THAT WE'RE NOT, BUT WE'RE VERY |
| | 0.0 |

| 1 | CONCERNED ABOUT GETTING THE BEST LINES POSSIBLE. |
|--|--|
| 2 | AND SO WE DECIDED TO DO IT ON A CASE-BY-CASE BASIS. |
| 3 | NOW, I THINK WE CAN MOVE AGGRESSIVELY WHEN |
| 4 | WE HAVE AN EXCEPTION THAT WE WANT TO MAKE. |
| 5 | DR. PRICE: I UNDERSTAND ALL THAT. THAT'S |
| 6 | WHY YOU SET UP THIS PROCEDURE. WHAT I DON'T |
| 7 | UNDERSTAND IS HOW YOU ENVISION AN APPLICANT COMING |
| 8 | FORWARD, AND WHEN THEY DO COME FORWARD, WHETHER THIS |
| 9 | TIMELINE THAT YOU'VE SET UP HERE IS NOT SO LONG THAT |
| 10 | IT WILL DISCOURAGE ANYBODY FROM DOING IT BECAUSE |
| 11 | THEY CAN'T DO THE SCIENCE. IT COULD TAKE MONTHS, |
| 12 | COULD TAKE A YEAR BEFORE THAT PROCESS WORKS ITS WAY |
| 13 | OUT. |
| | DD DENIIOET I THINK THE LIKELY OACE IC |
| 14 | DR. PENHOET: I THINK THE LIKELY CASE IS |
| 14 15 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD |
| | |
| 15 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD |
| 15 16 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE |
| 15 16 17 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE OF THESE LINES TO BECOME A PETITIONER. THEY'RE NOT |
| 15 16 17 18 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE OF THESE LINES TO BECOME A PETITIONER. THEY'RE NOT INTENDED TO DO IT ON THEIR OWN. THAT WOULD START |
| 15 16 17 18 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE OF THESE LINES TO BECOME A PETITIONER. THEY'RE NOT INTENDED TO DO IT ON THEIR OWN. THAT WOULD START THE PROCESS, AND IT WOULD TAKE SOME TIME. |
| 15 16 17 18 19 20 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE OF THESE LINES TO BECOME A PETITIONER. THEY'RE NOT INTENDED TO DO IT ON THEIR OWN. THAT WOULD START THE PROCESS, AND IT WOULD TAKE SOME TIME. MS. LANSING: I THINK THERE'S ACTUALLY |
| 15 16 17 18 19 20 21 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE OF THESE LINES TO BECOME A PETITIONER. THEY'RE NOT INTENDED TO DO IT ON THEIR OWN. THAT WOULD START THE PROCESS, AND IT WOULD TAKE SOME TIME. MS. LANSING: I THINK THERE'S ACTUALLY SOMETHING IN PROCESS. |
| 15 16 17 18 19 20 21 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE OF THESE LINES TO BECOME A PETITIONER. THEY'RE NOT INTENDED TO DO IT ON THEIR OWN. THAT WOULD START THE PROCESS, AND IT WOULD TAKE SOME TIME. MS. LANSING: I THINK THERE'S ACTUALLY SOMETHING IN PROCESS. DR. LOMAX: THERE IS JUST ONE OTHER |
| 15 16 17 18 19 20 21 22 23 | THAT A CIRM INVESTIGATOR IN CALIFORNIA WOULD INITIATE THIS PROCESS BY ASKING SOMEONE WHO HAS ONE OF THESE LINES TO BECOME A PETITIONER. THEY'RE NOT INTENDED TO DO IT ON THEIR OWN. THAT WOULD START THE PROCESS, AND IT WOULD TAKE SOME TIME. MS. LANSING: I THINK THERE'S ACTUALLY SOMETHING IN PROCESS. DR. LOMAX: THERE IS JUST ONE OTHER COMMENT TO MAKE ALONG THOSE LINES. |

| 1 | IS SUCH A COMPLICATED ISSUE, AND WE WERE ABLE TO GET |
|----|--|
| 2 | CONSENSUS AMONG OUR GROUP AND ACTUALLY, AT LEAST |
| 3 | FROM THE PUBLIC THAT WAS THERE, WE WERE ALSO ABLE TO |
| 4 | GET CONSENSUS WITH THE IDEA THAT THIS WAS NOT DONE. |
| 5 | SIMPLY IT WAS THE IDEA THAT WE WERE COMING BACK SOON |
| 6 | BECAUSE WE HAVE A WHOLE BUNCH OF OTHER ISSUES THAT |
| 7 | ARE ALSO INVOLVING THIS. AND THERE'S A SECOND POINT |
| 8 | TO THIS AS WELL. |
| 9 | DR. LOMAX: ONE OTHER BIT OF INFORMATION |
| 10 | THAT THE STANDARDS WORKING GROUP, AS A RESULT OF A |
| 11 | CHARGE FROM THE STANDARDS WORKING GROUP, WAS TO |
| 12 | EVALUATE THE LEVEL OF CURRENT INFORMATION THAT'S |
| 13 | AVAILABLE TO EVALUATE EXISTING HUMAN EMBRYONIC STEM |
| 14 | CELL LINES. AND THE RESULT OF THAT EVALUATION WAS |
| 15 | AT THE MOMENT WE CURRENTLY LACK SUFFICIENT DETAIL ON |
| 16 | CELL LINES TO PERFORM A LEVEL OF DUE DILIGENCE TO |
| 17 | MAKE A DETERMINATION. |
| 18 | NOW, THAT MAY CHANGE OVER TIME THROUGH THE |
| 19 | DEVELOPMENT OF STEM CELL REGISTRIES, WHICH ARE BEING |
| 20 | DEVELOPED AS WE SPEAK; BUT AT THE MOMENT, THE |
| 21 | ABSENCE OF THE TYPE OF INFORMATION THAT WE WOULD |
| 22 | REQUIRE TO MAKE A COMPLIANCE DETERMINATION LED US TO |
| 23 | A PROCESS LIKE THIS WHERE WE WOULD ACTIVELY SEEK THE |
| 24 | INFORMATION. |
| 25 | CHAIRMAN KLEIN: DR. AZZIZ. AND THEN I'D |
| | 00 |

| 1 | LIKE TO HAVE DR. TROUNSON ALSO HAVE AN OPPORTUNITY |
|----|--|
| 2 | TO COMMENT. |
| 3 | DR. AZZIZ: JUST A QUICK QUESTION TO |
| 4 | ADDRESS BOB'S CONCERN ABOUT HOW FAST THIS IS. WE'RE |
| 5 | ASSUMING THAT THIS PROCESS ACTUALLY WILL BE A |
| 6 | PROCESS THAT IS CONSTANTLY IN PLACE AND NOT REALLY |
| 7 | JUST SET UP FOR ONE RFA. PEOPLE ARE NOT SUPPOSED TO |
| 8 | BE SCRAMBLING AT THE LAST MINUTE TRYING TO GET THESE |
| 9 | THINGS APPROVED; IS THAT RIGHT? IT SOUNDS LIKE WE |
| 10 | SHOULD SO WHILE I APPRECIATE THE CONCERN ABOUT |
| 11 | TIME, I MEAN PEOPLE WHO ARE DOING SERIOUS STEM CELL |
| 12 | RESEARCH SHOULD SIMPLY BE PLANNING THIS TYPE OF |
| 13 | EXPERIMENTS YEARS IN ADVANCE. I'M NOT QUITE SURE |
| 14 | THAT WE'LL DISSUADE PEOPLE FROM ACTUALLY USING THESE |
| 15 | WHEN THERE'S THIS PROCESS IN PLACE. I DO AGREE THAT |
| 16 | WE HAVE TO BE SOMEWHAT CAREFUL IN USING THESE LINES. |
| 17 | DR. LOMAX: THE FACT THAT THE PROPOSED |
| 18 | PROCESS INVOLVES THE WORKING GROUP CO-CHAIRS AND |
| 19 | THEN THE ICOC REFLECTS THE CONCERN THAT IT BE |
| 20 | EXPEDITIOUS AND THINGS MOVE QUICKLY. SO THAT WAS |
| 21 | CONTEMPLATED IN THIS RECOMMENDATION, AND I THINK |
| 22 | IT'S REFLECTED IN THE LANGUAGE WHICH WE BRING |
| 23 | FORWARD TO YOU. |
| 24 | CHAIRMAN KLEIN: DR. TROUNSON. |
| 25 | DR. TROUNSON: I THINK THERE'S TWO LEVELS. |
| | 0.1 |

| ı | UNE IS THAT THERE ARE SUME ISSUES THAT HAVE BEEN |
|----|--|
| 2 | BROUGHT TO OUR ATTENTION ABOUT WHETHER A CELL LINE, |
| 3 | WHICH HAS BEEN DEVELOPED TO A VERY HIGH DEGREE AND |
| 4 | HAS GOT A LOT OF RELIABILITY, IS GMP APPROPRIATE AND |
| 5 | SO FORTH. SO THAT THERE'S BEEN A LOT OF WORK DONE, |
| 6 | AND BECAUSE OF ONE ELEMENT, IT DOESN'T MEET OUR |
| 7 | REQUIREMENTS UNDER THE STANDARDS. SO HAVING A |
| 8 | PROCESS, HAVING A PROCESS WOULD ENABLE US TO MAKE A |
| 9 | DECISION ON THEM. |
| 10 | WITHOUT THE PROCESS, YOU CAN'T GET A |
| 11 | DECISION BECAUSE, YOU KNOW, THERE WAS NO WAY INTO |
| 12 | IT. SO CREATE THE PROCESS AND THEN ENABLE THE |
| 13 | DECISION TO TAKE PLACE BECAUSE IN THIS ONE |
| 14 | PARTICULAR EXAMPLE, IT WILL BE A VERY SIGNIFICANT |
| 15 | DECISION BECAUSE THESE MATTERS WERE STARTED BEFORE |
| 16 | OUR REGULATIONS CAME INTO PLACE. |
| 17 | SECONDLY, A LOT OF MATERIAL WHICH IS IN |
| 18 | EMBRYONIC FORM WHICH IS FROZEN DOWN IN THE FREEZERS |
| 19 | CAME ABOUT HAVE BEEN THERE FOR A LONG TIME. AND |
| 20 | I THINK I'D ASK DR. AZZIZ MAYBE TO COMMENT ON THAT |
| 21 | BECAUSE HE'S A PROFESSOR OF OBSTETRICS AND |
| 22 | GYNECOLOGY AND CHAIR. BUT IT'S BEEN BROUGHT TO OUR |
| 23 | ATTENTION THAT PRIOR TO THE PROCEDURE KNOWN AS ICSI, |
| 24 | WHERE YOU DID SPERM INJECTION OF VERY WEAK SPERM |
| 25 | FROM HUSBANDS INTO EGGS, YOU GENERALLY USE DONOR |
| | |

| 1 | SPERM TO ENABLE FERTILIZATION TO OCCUR. |
|----|--|
| 2 | AND SPERM DONATION VERY RARELY, IN MY |
| 3 | KNOWLEDGE AT LEAST OUTSIDE THIS COUNTRY, WAS |
| 4 | ACCOMPANIED BY ANY BOX ABOUT RESEARCH. SO IT'S |
| 5 | BECAUSE SPERM DONATION HAS BEEN GOING ON FOR MANY, |
| 6 | MANY YEARS. SO PERHAPS RICARDO CAN GIVE US A SENSE |
| 7 | OF WHAT HAPPENS IN THIS COUNTRY, BUT THERE ARE A LOT |
| 8 | OF THOSE KIND OF EMBRYOS THAT DON'T HAVE THAT |
| 9 | PARTICULAR INFORMED CONSENT IN THE FREEZER. SO |
| 10 | THERE'S TWO KINDS OF SITUATIONS. |
| 11 | CHAIRMAN KLEIN: YOU KNOW, MY |
| 12 | UNDERSTANDING IS THAT'S NOT THE CASE WE'RE |
| 13 | ADDRESSING TONIGHT. THAT CASE THE STANDARDS WORKING |
| 14 | GROUP MAY LOOK AT IN THE FUTURE. THIS CASE WE'RE |
| 15 | DISCUSSING TONIGHT IS WHERE THERE'S CONSENT ON BOTH |
| 16 | THE OOCYTE AND THE SPERM. |
| 17 | MS. LANSING: CORRECT. THIS PROBLEM WE |
| 18 | ARE GOING TO ADDRESS. WE DON'T HAVE THE ANSWER. |
| 19 | AND WE'RE REALLY TRYING TO DETERMINE A LOT OF |
| 20 | THINGS. ONE IS HOW DOES OTHER RESEARCH DEAL WITH |
| 21 | THAT, DO YOU KNOW? WE'RE TRYING TO GET A LOT OF |
| 22 | DATA SO WE CAN MAKE AN INFORMED DECISION. |
| 23 | CHAIRMAN KLEIN: OKAY. DR. AZZIZ, DR. |
| 24 | TROUNSON WAS ASKING FOR SOME PERSPECTIVE FOR FUTURE |
| 25 | CONSIDERATION ON THIS SPECIFIC ISSUE. |
| | |

| 1 | DR. AZZIZ: SO AS I UNDERSTOOD IT, ALAN, |
|----|--|
| 2 | JUST TO MAKE SURE THAT I ADDRESS WHAT YOU SAID, I |
| 3 | WAS TYPING, BUT THERE'S THE ISSUE OF USING SPERM |
| 4 | DONATION, NOT JUST WITH ICSI, BECAUSE YOU MENTIONED |
| 5 | ICSI, BUT ICSI IS A RECENT DEVELOPMENT, BUT ACTUALLY |
| 6 | IT'S BEEN USED FOR IN VITRO FERTILIZATION FOR A |
| 7 | NUMBER OF YEARS. ACTUALLY YOU'RE RIGHT, ALAN, I DO |
| 8 | ACTUALLY IN VITRO FERTILIZATION AS WELL AS |
| 9 | GYNECOLOGY. |
| 10 | THE ISSUE OF SPERM OF MALE SPERM |
| 11 | DONATION HAS ACTUALLY BEEN IN PLACE HISTORICALLY FOR |
| 12 | OVER A HUNDRED YEARS. THE TURKEY BASTER KIND OF |
| 13 | APPROACH THAT YOU MAY BE FAMILIAR WITH IS ACTUALLY |
| 14 | TRUE. SO IT'S BEEN AROUND FOR A LONG, LONG TIME. |
| 15 | MALE SPERM DONORS ARE GENERALLY DISCONNECTED BOTH |
| 16 | CULTURALLY AS WELL AS SYSTEMATICALLY FROM THE |
| 17 | PROGENY. THEY'VE BEEN PROTECTED VERY WELL. THEY'VE |
| 18 | BEEN DISCONNECTED FROM THAT PROCESS. IT IS AN |
| 19 | ANONYMOUS PROCESS. AND SO, HENCE, THERE HAS NEVER |
| 20 | BEEN ANY MAJOR INTENT IN GETTING THESE DONORS TO |
| 21 | SIGN UP FOR ANY RESEARCH OR CONSENT BECAUSE, IN |
| 22 | FACT, AS YOU JUST SAID, THERE HAS NOT BEEN ANY |
| 23 | PROCESS FOR GETTING IT. SO THEY DONATE SPERM, IT |
| 24 | GETS PUT INTO EITHER A BANK OR A CLINIC, AND IT'S |
| 25 | GONE, AND THEY ARE COMPLETELY DISCONNECTED FROM |
| | O/I |

| 1 | THI S. |
|----|--|
| 2 | NOW, WE CAN SIT HERE AND ARGUE ABOUT THIS, |
| 3 | BUT THE REALITY IS THAT ALL RESEARCH USING THAT TYPE |
| 4 | OF SPERM DOESN'T REALLY REQUIRE A PRIORI CONSENT |
| 5 | FROM THE DONOR BECAUSE, IN FACT, THE DONOR WANTS TO |
| 6 | HAVE AS MUCH DISCONNECT FROM WHAT HAPPENS IN THE |
| 7 | FUTURE. SO, IN FACT, IF THE PROBLEM IS THAT YOU'RE |
| 8 | FACING, WHICH I'M NOT SURE, I'M NOT ON THE STANDARDS |
| 9 | COMMITTEE |
| 10 | MS. LANSING: DO WE HAVE CONSENT FROM THEM |
| 11 | AND DO WE NEED CONSENT. |
| 12 | DR. AZZIZ: CORRECT. DO YOU HAVE ASSENT? |
| 13 | AND SO THE QUESTION IS DO YOU HAVE ASSENT, NOT |
| 14 | CONSENT BECAUSE CONSENT WOULD REQUIRE SOMEBODY TO |
| 15 | SPECIFICALLY SAY IT, DO YOU HAVE ASSENT FROM THE |
| 16 | MALE DONORS TO UTILIZE WHATEVER THE PRODUCTS ARE IN |
| 17 | WAYS THAT ARE SEEN FIT BY AN ETHICS COMMITTEE? AND |
| 18 | THE ANSWER IS YES. WE HAVE ALWAYS TAKEN THAT |
| 19 | APPROACH BECAUSE, AGAIN, DONORS WANT THE MINIMUM |
| 20 | AMOUNT OF MALE DONORS WANT THE MINIMUM AMOUNT OF |
| 21 | INTERACTION POSSIBLE WITH AND, IN FACT, THE LAWS |
| 22 | HAVE BEEN SUCH WRITTEN THAT THEY HAVE VERY LITTLE |
| 23 | CONTACT WITH WHATEVER PRODUCT OCCURS. |
| 24 | SO THAT IS THE QUESTION. I MAY HAVE |
| 25 | MISSED, ALAN, YOUR QUESTION. IF THAT'S THE |
| | |

| 1 | QUESTION, THEN THAT IS THE CURRENT STANDING IN BOTH |
|----|---|
| 2 | IN VITRO FERTILIZATION, OF COURSE, AND REPRODUCTIVE |
| 3 | MEDICINE. |
| 4 | MS. LANSING: SO THAT'S EXTREMELY HELPFUL, |
| 5 | AND I PROBABLY WILL INVITE YOU TO SPEAK TO OUR |
| 6 | COMMITTEE. BUT OUR COMMITTEE IS GOING TO GO BACK |
| 7 | AND TACKLE THAT PROBLEM. I THINK IT WOULD BE UNFAIR |
| 8 | TO OUR COMMITTEE TO DECIDE, AT LEAST I WOULD NOT |
| 9 | CHAIRMAN KLEIN: IT'S NOT OUR INTENT TO |
| 10 | DEAL WITH THAT ISSUE. |
| 11 | MR. LANSING: BUT OUR COMMITTEE, I CAN |
| 12 | SAY, JEFF, CORRECT ME IF I'M WRONG, BUT I THINK OUR |
| 13 | COMMITTEE, THE FEELING OF OUR COMMITTEE WAS THAT WE |
| 14 | DIDN'T WANT TO HOLD STEM CELL RESEARCH TO A |
| 15 | DIFFERENT STANDARD THAN ALL OTHER RESEARCH. AND SO |
| 16 | THAT'S EXACTLY WHAT WE WERE TRYING TO GET THE |
| 17 | INFORMATION ON. AND THAT'S VERY, VERY HELPFUL TO |
| 18 | US, BUT THAT IS NOT ON THE AGENDA FOR TODAY. |
| 19 | BUT, GEOFF, OUR GROUP NEEDS TO MEET SOON, |
| 20 | DO YOU KNOW. AND I KNOW YOU'RE COORDINATING THAT. |
| 21 | CHAIRMAN KLEIN: AND SO IN TERMS OF WHAT |
| 22 | WE'RE DISCUSSING TONIGHT, YOU'RE ADDRESSING TWO |
| 23 | SEPARATE ISSUES TONIGHT? |
| 24 | DR. LOMAX: THAT'S CORRECT. AND I |
| 25 | PRESENTED THE FIRST ISSUE FOR WHICH YOU ALL HAVE |
| | |

| 1 | RECOMMENDED LANGUAGE FOR AN INTERIM REGULATION, |
|----|--|
| 2 | WHICH YOU WILL CONSIDER, PRESUMABLY, TOMORROW. |
| 3 | CHAIRMAN KLEIN: RIGHT. |
| 4 | MS. LANSING: NOW WE SHOULD DO THE SECOND |
| 5 | ONE. |
| 6 | CHAIRMAN KLEIN: GO AHEAD AND PRESENT THE |
| 7 | SECOND ITEM. |
| 8 | DR. LOMAX: MR. CHAIRMAN, WOULD YOU LIKE |
| 9 | TO TAKE PUBLIC COMMENT ON THIS ITEM? |
| 10 | CHAIRMAN KLEIN: WE COULD DO IT ON BOTH OF |
| 11 | THEM. WE'RE GOING TO TAKE IT AGAIN WHEN WE ALSO |
| 12 | HAVE A VOTE. WE'RE GOING TO TAKE IT NOW AFTER |
| 13 | GIVING THE PUBLIC THE FULL VIEW OF THIS, AND THEN |
| 14 | WE'RE GOING TO TAKE IT AGAIN AT THE TIME OF THE |
| 15 | VOTE, SO THE PUBLIC IS GOING TO HAVE TWO DIFFERENT |
| 16 | BITES AT THIS APPLE. |
| 17 | MS. LANSING: AND THEY ARE ACTUALLY |
| 18 | RELATED TO EACH OTHER. |
| 19 | DR. LOMAX: SO BY WAY OF BACKGROUND, THE |
| 20 | EXISTING STOCK OF IVF-EMBRYOS INCLUDE EMBRYOS FOR |
| 21 | WHICH THE SPERM OR OOCYTE DONOR WAS COMPENSATED. |
| 22 | I'VE UNDERLINE IVF-EMBRYO THERE TO EMPHASIZE THE |
| 23 | POINT THAT THESE WERE EMBRYOS THAT WERE CREATED |
| 24 | SPECIFICALLY FOR REPRODUCTIVE PURPOSES. THE |
| 25 | INTENTION WAS REPRODUCTION. THEY ARE NO LONGER |
| | 97 |

| 1 | DEEMED NECESSARY FOR THAT PURPOSE, AND THEY |
|----|---|
| 2 | TYPICALLY RESIDE IN FREEZERS WAITING FINAL |
| 3 | DI SPOSI TI ON. |
| 4 | THE CIRM REGULATIONS CONTAIN A BROAD |
| 5 | RESTRICTION ON PAYMENTS. AND AS A RESULT, CELL |
| 6 | LINES DERIVED FROM SUCH EMBRYOS CANNOT BE USED. AND |
| 7 | IN ADDITION, THE EMBRYOS THEMSELVES CANNOT BE USED |
| 8 | TO DERIVE LINES. IN THIS RESPECT THE CIRM |
| 9 | REGULATIONS ARE INCONSISTENT WITH OTHER STATES AND |
| 10 | THE RECOMMENDATIONS OF THE NATIONAL ACADEMIES OF |
| 11 | SCIENCE. NONE OF THE MAJOR STATES AND NATIONAL |
| 12 | ACADEMIES HAVE SUCH A RESTRICTION. |
| 13 | IT WAS THE SENSE OF THE STANDARD WORKING |
| 14 | GROUP MEMBERS THAT IVF-EMBRYOS AND/OR CELL LINES |
| 15 | DERIVED FROM SUCH EMBRYOS BEFORE TODAY SHOULD BE |
| 16 | AVAILABLE FOR RESEARCH. AND SO THE SENSE OF THE |
| 17 | STANDARD WORKING GROUP MEMBERS IS TO EXEMPT |
| 18 | IVF-EMBRYOS CREATED ON OR BEFORE 8/12/08 FROM |
| 19 | PAYMENT RESTRICTIONS. |
| 20 | THE AMENDMENT WOULD AUTHORIZE THE USE OF |
| 21 | STEM CELL LINES DERIVED FROM IVF-EMBRYOS, AND IT |
| 22 | WOULD AUTHORIZE RESEARCHERS TO UTILIZE SUCH EMBRYOS |
| 23 | IN RESEARCH, FOR EXAMPLE, RESEARCH TO DERIVE A STEM |
| 24 | CELL LINE. |
| 25 | MS. LANSING: THESE WERE THE ISSUES THAT |
| | 98 |
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| 1 | WE DEBATED. AND ACTUALLY WE GOT UNANIMOUS CONSENT, |
|----------------------|--|
| 2 | AND ACTUALLY THE PUBLIC WAS EXTRAORDINARILY HELPFUL |
| 3 | TO US. AND, AGAIN, WE'RE GRANDFATHERING IN FROM |
| 4 | TODAY BEHIND. WE DO NOT WANT TO HAVE ANY |
| 5 | CONCLUSIONS REACHED FROM TODAY ON. AND THE |
| 6 | REASON AND WE KNOW THAT NOBODY CAN BE PAID |
| 7 | ACCORDING TO OUR PROPOSITION, BUT THERE WAS NOBODY |
| 8 | WHO ENTERED INTO IN VITRO FERTILIZATION THAT DID IT |
| 9 | WITH THE INTENT OF DONATING IT TO STEM CELL RESEARCH |
| 10 | AND, THEREFORE, GETTING PAID FOR IT. |
| 11 | SO THAT WAS HOW WE CAME TO THE EXCLUSION. |
| 12 | AND, JEFF, YOU WERE SUCH A HUGE PART OF THIS. DID |
| 13 | YOU WANT TO ADD IN ANY WAY? |
| 14 | MR. SHEEHY: THAT'S BASICALLY THE GIST OF |
| 15 | IT. IT'S MAKING THAT VERY BRIGHT LINE BETWEEN |
| 16 | EMBRYOS THAT WERE CREATED SOLELY FOR REPRODUCTIVE |
| 17 | PURPOSES, AND THIS IS TO BE CONSISTENT WITH |
| 18 | PROPOSITION 71, WHICH DOES NOT ALLOW PAYMENT FOR |
| 19 | OOCYTES USED FOR RESEARCH. BY SETTING A DATE, WE |
| 20 | |
| | KNOW THAT EVERYBODY BEFORE THE ADOPTION OF THIS |
| 21 | KNOW THAT EVERYBODY BEFORE THE ADOPTION OF THIS REGULATION WHO WAS CONSIDERING IVF HAD ABSOLUTELY |
| | |
| 22 | REGULATION WHO WAS CONSIDERING IVF HAD ABSOLUTELY |
| 21 22 23 24 | REGULATION WHO WAS CONSIDERING IVF HAD ABSOLUTELY DONATING OOCYTES FOR IVF HAD ABSOLUTELY NO IDEA THAT |
| 22 23 | REGULATION WHO WAS CONSIDERING IVF HAD ABSOLUTELY DONATING OOCYTES FOR IVF HAD ABSOLUTELY NO IDEA THAT THOSE OOCYTES WOULD EVENTUALLY END UP BEING PART OF |

| 1 | THAT WAS IN THE MIND OF THE DONOR. AND SO IN THAT |
|----|--|
| 2 | WAY, WE HAVE INOCULATED OURSELVES AGAINST ANY SENSE |
| 3 | THAT THE REPRODUCTIVE ASPECT OF THIS WHAT WE'VE |
| 4 | DONE IS SEPARATE THE REPRODUCTIVE ASPECT FROM THE |
| 5 | RESEARCH ASPECT, AND WHAT WE'RE REALLY TRYING TO |
| 6 | ADDRESS IS THAT IN MANY WAYS THOSE EMBRYOS MAY BE |
| 7 | ONES THAT PEOPLE HAVE LESS INTEREST IN HOLDING ONTO. |
| 8 | THE GAMETES ARE DONATED. THEY'VE FINISHED THEIR |
| 9 | FAMILIES. THEY'RE PAYING TO STORE THESE, AND IT |
| 10 | WOULD BE VERY VALUABLE FOR THEM TO BE ABLE TO GIVE |
| 11 | THESE TO RESEARCH. |
| 12 | ONE INSTITUTION SAID HALF OF THEIR WALK-IN |
| 13 | DONORS ARE FROM PEOPLE IN THIS SITUATION WHO HAVE A |
| 14 | PAID DONOR AND THEY'VE BEEN TOLD THEY CAN'T DONATE. |
| 15 | BUT IT WAS VERY IMPORTANT FOR US TO NOT TO HAVE ANY |
| 16 | INFLUENCE ON THE REPRODUCTIVE PROCESS, AND THIS VERY |
| 17 | CLEARLY DOES NOT. |
| 18 | MS. LANSING: THERE WAS ALSO RAISED THE |
| 19 | CONCERN THE PUBLIC WAS VERY HELPFUL TO US IN |
| 20 | THIS. I REALLY WANT TO THANK ALL OF THEM. THEY |
| 21 | WERE JUST VERY, VERY INSIGHTFUL, AND IT WAS GREAT |
| 22 | THAT WE WERE ABLE TO REACH UNANIMOUS CONSENT IN THIS |
| 23 | GROUP FOR THE PAST. |
| 24 | AND THE CONCERN WAS THAT IT WAS POSSIBLE |
| 25 | THAT SOMEONE WHO WAS DOING IN VITRO FERTILIZATION, A |
| | |

| 1 | CORRECTION. I ALSO WANT TO THANK BERNIE LO WHO |
|----|--|
| 2 | WOULD NOT HAVE MADE THOSE FALSE STATEMENTS THAT I |
| 3 | DI D. |
| 4 | CHAIRMAN KLEIN: ALL RIGHT. I THINK IT IS |
| 5 | APPROPRIATE AT THIS POINT TO ASK FOR PUBLIC COMMENT. |
| 6 | MR. REYNOLDS: HELLO. GOOD EVENING. |
| 7 | THANKS FOR THE OPPORTUNITY TO SPEAK. I'M JESSE |
| 8 | REYNOLDS OF THE CENTER FOR GENETICS AND SOCIETY. |
| 9 | REGARDING THE FIRST PROPOSAL, ATTACHMENT |
| 10 | 1, I THINK THAT THIS MAKES AN AWFUL LOT OF SENSE. |
| 11 | YOU CAN'T REALLY EXPECT ANYBODY TO FOLLOW RULES THAT |
| 12 | DIDN'T EXIST AT THE TIME THAT THOSE ACTIONS WERE |
| 13 | TAKEN. GIVEN THE NATURE OF STEM CELL DERIVATION, |
| 14 | WHERE THE LINES EXIST FOR LENGTHS OF TIME |
| 15 | AFTERWARDS, I THINK IT MAKES SENSE. |
| 16 | THE PUBLIC PROCESS, I THINK, IS KEY TO |
| 17 | THIS. THIS WILL BE UNDERTAKEN AT A PUBLIC ICOC |
| 18 | MEETING WHERE THE NATURE OF THE DEVIATION FROM THE |
| 19 | STANDARDS CAN BE WEIGHED. THERE'S DIFFERENT TYPES |
| 20 | OF THERE'S DIFFERENT DEGREES OF CONSENT, THERE'S |
| 21 | DIFFERENT DEGREES OF PAYMENTS, AND THESE THINGS MUST |
| 22 | BE TAKEN IN CONTEXT. AND THE DATE IS, OF COURSE, |
| 23 | APPROPRIATE BEING THE DATE OF THE ADOPTION OF THE |
| 24 | RESEARCH STANDARDS. |
| 25 | THE SECOND PROPOSAL I'M SOMEWHAT MORE |
| | 102 |

| AMBIVALENT ABOUT BECAUSE FOR A COUPLE OF REASONS, |
|---|
| AND PERHAPS I CAN PROPOSE THESE AS QUESTIONS TO BE |
| ADDRESSED BY THE BOARD. |
| FIRST, IT CREATES A BLANKET POLICY SO THAT |
| INSTEAD OF BEING ADDRESSED ON A CASE-BY-CASE BASIS |
| BY THE ICOC OR BY THE STANDARDS WORKING GROUP IN A |
| PUBLIC SESSION, THIS IS A BLANKET POLICY AND A |
| CHANGE IN EXISTING POLICY. SO MY FIRST QUESTION |
| WOULD BE IS THIS SOMETHING THAT WOULD BE BETTER |
| ADDRESSED AS A PUBLIC ISSUE? |
| SECOND IS THE PARTICULAR DATE ON THE |
| POLICY ON THE PROPOSAL. AS OPPOSED TO NOVEMBER |
| OF '06, IT USES TODAY. AND IT JUST STRIKES ME AS |
| SOMEWHAT INCONSISTENT BECAUSE CERTAINLY BY NOVEMBER |
| OF '06, THE RULES WERE ESTABLISHED AND KNOWN. |
| SO I SUPPOSE THE SECOND QUESTION WOULD BE |
| WOULD THIS PROPOSAL BE BETTER WITH THE DATE BEING |
| NOVEMBER OF '06? |
| I SUPPOSE IF YOU PUT THOSE TWO THINGS |
| TOGETHER, IT DOVETAILS THE TWO POLICIES INTO ONE IN |
| A WAY. SO ARE WE TALKING ABOUT TWO ITEMS, OR ARE WE |
| TALKING ABOUT ONE? THANKS. |
| CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| ADDITIONAL PUBLIC COMMENT? |
| JEFF, WOULD YOU LIKE TO RESPOND BEFORE |
| 103 |
| |

| 1 | THIS PUBLIC COMMENT? |
|----|--|
| 2 | MR. SHEEHY: IT'S EASIER BECAUSE I THINK |
| 3 | YOU'RE KIND OF MISSING THIS, JESSE. IT'S KIND OF |
| 4 | SURPRISING BECAUSE MARCY WAS THERE. THESE ARE |
| 5 | REALLY TWO SEPARATE ISSUES. AND ONE IS IT INVOLVES |
| 6 | INFORMED CONSENT PRIMARILY, AND THIS ONE INVOLVES |
| 7 | PAYMENT FOR AN OOCYTE DONATION THAT IS COMPLETELY |
| 8 | UNRELATED TO RESEARCH. WE PICKED THIS AUGUST DATE |
| 9 | BECAUSE THERE'S NO CONCEIVABLE WAY BEFORE THIS DATE |
| 10 | THAT ANYBODY WAS PAID FOR AN OOCYTE DONATION TO |
| 11 | CREATE AN EMBRYO WITH THE IDEA THAT THAT EMBRYO |
| 12 | WOULD BE USED IN RESEARCH BECAUSE THAT SIMPLY WAS |
| 13 | NOT POSSIBLE UNDER CIRM RULES. |
| 14 | SO, YOU KNOW, THE IDEA HERE IS TO NOT HAVE |
| 15 | THOSE EMBRYOS THAT WERE CREATED, THAT PARENTS ARE |
| 16 | PAYING TO STORE, THAT THEY WISH TO DONATE TO BE |
| 17 | DENIED THEIR RIGHT TO MAKE THAT DONATION, ASSUMING |
| 18 | THAT THEY AND THE DONOR OF THE OOCYTE ALL AGREE THAT |
| 19 | THIS DONATION IS APPROPRIATE. AND THE VALUE THAT |
| 20 | WE'RE TRYING TO PRESERVE IN THAT PARTICULAR INSTANCE |
| 21 | IS THE VALUE OF THE REPRODUCTIVE PROCESS. AND WE |
| 22 | FEEL VERY, VERY CERTAIN THAT THE VALUE OF THE |
| 23 | REPRODUCTIVE PROCESS IS THERE. THE INFORMED |
| 24 | CONSENTS ARE ALL THERE. THESE ALL COMPLY THESE |
| 25 | EMBRYOS WOULD ALL COMPLY WITH ALL OF OUR STANDARDS |
| | |

| 1 | AND THE NATIONAL ACADEMY STANDARDS. |
|----|--|
| 2 | THE ONLY SUSPECT ISSUE IS THE OOCYTE |
| 3 | DONATION AND WHETHER THAT OOCYTE DONATION MIGHT IN |
| 4 | EVEN THE MOST CONCEIVABLE WAY HAVE BEEN PAID FOR IN |
| 5 | A WAY THAT THEY THOUGHT THAT THIS OOCYTE DONATION |
| 6 | AND THE RESULTING EMBRYO WOULD HAVE ENDED UP IN |
| 7 | RESEARCH. THAT'S JUST SIMPLY NOT POSSIBLE BECAUSE |
| 8 | IT WASN'T POSSIBLE WHEN THE DONATION WAS MADE. |
| 9 | CHAIRMAN KLEIN: THANK YOU, JEFF. PUBLIC |
| 10 | COMMENT? |
| 11 | MS. STAYN: SUSAN STAYN FROM STANFORD |
| 12 | UNIVERSITY. I HAVE A COMMENT ON THE SECOND |
| 13 | PROPOSAL. I WOULD RESPECTFULLY ENCOURAGE THIS BOARD |
| 14 | TO MAKE A DECISION BASED ON THE PRINCIPLE WITHOUT |
| 15 | TYING THE PAYMENT ISSUE TO A PARTICULAR AUGUST DATE. |
| 16 | IF A PERSON IS PAID TO PROVIDE GAMETES TO |
| 17 | AN INFERTILE COUPLE SO THAT THEY HELP THEM BUILD |
| 18 | THEIR FAMILY, THAT PAYMENT IS FOR A REPRODUCTIVE |
| 19 | PURPOSE. AND AS MR. SHEEHY NOTED, THAT'S COMPLETELY |
| 20 | SEPARATE FROM ANY DECISION TO DONATE THE EXCESS |
| 21 | EMBRYO LATER TO RESEARCH. |
| 22 | THE RESEARCHERS ARE NOT MAKING ANY PAYMENT |
| 23 | HERE TO ANY DONOR. THE PAYMENT IS BETWEEN THE EGG |
| 24 | OR SPERM DONOR, THE COUPLE, AND THE FERTILITY |
| 25 | AGENCY. THOSE PARTIES ARE COMPLETELY SEPARATE FROM |
| | 105 |

| THE RESEARCH INSTITUTION AND THE RESEARCH ENTITY |
|--|
| THAT MAY RECEIVE THE DONATION LATER. |
| AS DR. LOMAX NOTED, CIRM'S CURRENT |
| REQUIREMENT IS INCONSISTENT WITH SEVERAL OTHER |
| STATES AS WELL AS THE NAS AND ISSCR GUIDELINES. SO, |
| AGAIN, I WOULD RESPECTFULLY ENCOURAGE THIS BOARD TO |
| CONSIDER MAKING A DECISION BASED ON PRINCIPLE, THAT |
| THE PAYMENT WAS FOR REPRODUCTIVE PURPOSES, NOT FOR |
| THE DONATION, AND TO PLEASE ATTEND THAT THE PAYMENT |
| EARLIER ON IN THE CHAIN DOESN'T TAINT THE LATER |
| DECISION TO DONATE TO RESEARCH. THANK YOU. |
| CHAIRMAN KLEIN: I THINK YOU MAY FIND THE |
| CHAIR OF THE STANDARDS WORKING GROUP INVITING YOU TO |
| THE NEXT STANDARDS WORKING GROUP BECAUSE IT'S VERY |
| IMPORTANT TESTIMONY, BUT RIGHT TODAY WHAT WE HAVE |
| BEFORE US IS AT LEAST BRING IT A CURRENT DATE SO |
| THAT RESEARCHERS CAN ADEQUATELY ACCESS THOSE EMBRYOS |
| THAT ARE AVAILABLE FOR ACCESS AVAILABLE FOR |
| CONTRIBUTION. AND DEAL WITH THE ISSUE THAT WE HAVE |
| SOME VERY FRUSTRATED INDIVIDUALS WHO WANT TO |
| CONTRIBUTE THOSE GAMETES WHO DEEPLY FEEL THAT THE |
| RESEARCH IS IMPORTANT, BUT CANNOT AT THIS POINT. SO |
| WE'RE TRYING TO INCREMENTALLY ADDRESS THIS SUBJECT, |
| BUT YOU MIGHT HAVE AN INVITATION THAT WE HOPE YOU |
| WILL BE OPEN TO. |
| 106 |
| |

| 1 | MS. LANSING: YOU DEFINITELY DO. |
|----|--|
| 2 | MS. STAYN: THANK YOU. |
| 3 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 4 | JEFF SHEEHY. |
| 5 | MR. SHEEHY: JUST TO BE CLEAR, WE DID IN |
| 6 | SOME WAYS START TO TALK ABOUT THE LARGER PRINCIPLE. |
| 7 | BUT ONE OF THE THINGS I THINK TO BEAR IN MIND IS |
| 8 | THAT AN EMBRYO CREATED AFTER THIS DATE COULD NOT |
| 9 | CONCEIVABLY BE AVAILABLE FOR A RESEARCH DONATION FOR |
| 10 | AT LEAST A YEAR, AND I THINK THAT THAT WOULD BE |
| 11 | INCREDIBLY OPTIMISTIC BECAUSE THOSE EMBRYOS THAT ARE |
| 12 | CREATED WOULD HAVE TO BE IMPLANTED, YOU'D HAVE TO |
| 13 | HAVE A SUCCESSFUL PREGNANCY, THE FAMILY WOULD THEN |
| 14 | HAVE TO MAKE SOME SORT OF DECISION ABOUT THEIR |
| 15 | REPRODUCTIVE FUTURE, WHETHER THEY WANTED TO END IT, |
| 16 | WHATEVER THEY WANTED TO DO. |
| 17 | WE HAVE SAID THAT WE WOULD GET TO THE |
| 18 | LARGER PRINCIPLE AT SOME LATER DATE, BUT THIS IS, |
| 19 | FRANKLY, TO USE THE LEGAL TERM, RIPE FOR THOSE |
| 20 | EMBRYOS THAT ARE CREATED AFTER THAT DATE BECAUSE ANY |
| 21 | EMBRYO CREATED AFTER AUGUST 12TH THAT IS AVAILABLE |
| 22 | FOR RESEARCH BEFORE AT LEAST A YEAR, I WOULD HAVE |
| 23 | TROUBLE BELIEVING IT WAS ETHICALLY DERIVED. |
| 24 | MS. STAYN: RESPECTFULLY, THE EMBRYOS THAT |
| 25 | ARE CREATED TOMORROW, GENERALLY IF THERE'S A GAMETE |
| | 107 |

| 1 | DONOR, THEY OFTEN ARE OF HIGHER QUALITY, BUT THERE |
|----|--|
| 2 | ARE A CERTAIN PERCENTAGE THAT SOMETIMES MAY BE |
| 3 | ABNORMAL. AND IF THEY'RE ABNORMAL AND UNSUITABLE |
| 4 | FOR TRANSFER TO A PATIENT, THEN THOSE COULD BE |
| 5 | DONATED TO RESEARCH AFTER TOMORROW. AGAIN, BECAUSE |
| 6 | THEY ARE SEEMED ABNORMAL IN A PROCESS THAT'S |
| 7 | COMPLETELY SEPARATE FROM THE TREATMENT DECISION. |
| 8 | MS. LANSING: BUT WE'RE NOT DEALING WITH |
| 9 | THOSE TODAY. WE'RE DEALING WITH EVERYTHING FROM THE |
| 10 | PAST. |
| 11 | CHAIRMAN KLEIN: THANK YOU FOR YOUR |
| 12 | I NSI GHT. |
| 13 | MR. SIMPSON: JOHN SIMPSON FROM CONSUMER |
| 14 | WATCHDOG. I WAS AT THE MEETING AND PART OF THE |
| 15 | DISCUSSION AND THOUGHT IT WAS EXACTLY THE WAY THESE |
| 16 | SORTS OF THINGS SHOULD BE TALKED OUT. I THINK IT'S |
| 17 | IMPORTANT TO NOTE, TO THE POINT THE LAST SPEAKER WAS |
| 18 | MAKING, THAT I UNDERSTOOD THAT THERE'S A COMMITMENT |
| 19 | TO DEAL WITH THE ISSUE OF GOING FORWARD IN THE |
| 20 | FUTURE AT ANOTHER MEETING. THAT'S AN IMPORTANT |
| 21 | THI NG. |
| 22 | THE OTHER THING THAT I WOULD JUST LIKE TO |
| 23 | ADD AS A PROCESS NOTE, THE WORKING GROUP |
| 24 | UNFORTUNATELY DID NOT HAVE A QUORUM. IT HAD A |
| 25 | MAJORITY PRESENT, BUT BECAUSE YOU HAVE A SUPER |
| | 108 |
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108

| 1 | MAJORITY REQUIREMENT, THIS WAS JUST THE SENSE OF THE |
|----|--|
| 2 | GROUP. AND I KEEP SUGGESTING THAT YOU WOULD SERVE |
| 3 | YOURSELVES BETTER IF YOUR WORKING GROUP BYLAWS |
| 4 | ALLOWED FOR A QUORUM TO BE SIMPLY A MAJORITY. AND |
| 5 | THAT WOULD HAVE GIVEN THIS THE FULL VOTED QUORUM |
| 6 | FORCE RATHER THAN SENSE OF THE GROUP. |
| 7 | MS. LANSING: AS I REMEMBER IT, AND MAYBE |
| 8 | I'M WE WENT SORT OF AROUND THE ROOM AND ASKED |
| 9 | EVERYBODY, AND IT WAS KIND OF UNANIMOUS. |
| 10 | MR. SIMPSON: IT WAS UNANIMOUS OF ALL |
| 11 | PRESENT, AND I BELIEVE ALL THE PUBLIC THERE |
| 12 | SPEAKING. IT'S JUST A PROCESS ISSUE THAT THE |
| 13 | WORKING GROUPS COULD PERHAPS STREAMLINE THINGS WITH |
| 14 | A SIMPLE MAJORITY. |
| 15 | CHAIRMAN KLEIN: SO, SHERRY, THAT'S |
| 16 | SOMETHING YOU COULD DISCUSS WITH JAMES HARRISON AND |
| 17 | SOME OF THE LEADERSHIP OF THE WORKING GROUP. AND |
| 18 | IT'S A VERY INTERESTING |
| 19 | MS. LANSING: IT'S A GOVERNANCE ISSUE. |
| 20 | CHAIRMAN KLEIN: VERY INTERESTING |
| 21 | SUGGESTION. THANK YOU VERY MUCH. AT THIS POINT I |
| 22 | THINK WE HAVE HAD THE DISCUSSION THAT WE CAN HAVE. |
| 23 | WE NEED TO BREAK FOR DINNER AT THIS POINT. |
| 24 | NOW, MY QUESTION TO COUNSEL IS, TO BE |
| 25 | EFFICIENT ON BREAKING FOR DINNER, COULD WE |
| | 100 |

| 1 | APPROPRIATELY HAVE THE EXECUTIVE SESSION FOR THE NEW |
|----|--|
| 2 | FACULTY DURING DINNER? |
| 3 | MR. HARRISON: YES, WE COULD. |
| 4 | CHAIRMAN KLEIN: SO WOULD YOU LIKE TO |
| 5 | RECITE THE STATUTORY BASIS ON WHICH THAT EXECUTIVE |
| 6 | SESSION WOULD OCCUR. |
| 7 | MR. HARRISON: YES. WE'LL BE GOING INTO |
| 8 | CLOSED SESSION FOR A DISCUSSION OF CONFIDENTIAL |
| 9 | INTELLECTUAL PROPERTY OR WORK PRODUCT AND |
| 10 | PREPUBLICATION CONFIDENTIAL SCIENTIFIC RESEARCH OR |
| 11 | DATA RELATING TO THE NEW FACULTY II APPLICATIONS |
| 12 | PURSUANT TO HEALTH AND SAFETY CODE SECTION |
| 13 | 125290.30(D)(3)(B) AND (C). |
| 14 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 15 | AND, MELISSA, IF YOU CAN INSTRUCT US AS TO WHERE THE |
| 16 | BOARD MEMBERS WILL GO. |
| 17 | MS. KING: WE'RE GOING OUT THE DOOR AND |
| 18 | KEEP WALKING STRAIGHT DOWN THE HALL, AND IT WILL BE |
| 19 | IN A ROOM, THE LAST DOOR ON THE LEFT. |
| 20 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 21 | GIVEN THIS IS AN EXECUTIVE SESSION AND DINNER, THIS |
| 22 | MAY BE AN HOUR, HOUR-AND-TEN-MINUTE BREAK. |
| 23 | (A RECESS WAS TAKEN.) |
| 24 | CHAIRMAN KLEIN: WE'RE GOING TO RECONVENE |
| 25 | HERE. OKAY. THANK YOU. WE'RE GOING TO RECONVENE. |
| | 110 |

110

| 1 | AND HAS THE COMMITTEE MADE A PLACE CARD FOR OUR |
|----|--|
| 2 | YES. DR. JACOB LEVIN HAS BEEN SWORN IN IN THE |
| 3 | INTERREGNUM. WE HAVE THE BENEFIT THAT DR. LEVIN WAS |
| 4 | IN THE AUDIENCE, SO HE HAS LISTENED TO THE ENTIRE |
| 5 | DIALOGUE. WE WEREN'T ABLE UNTIL THE BREAK TO GET IN |
| 6 | CONTACT WITH THE MEMBER AT HIS INSTITUTION TO GET |
| 7 | HIM DESIGNATED AS AN ALTERNATE AND GET HIM SWORN IN, |
| 8 | BUT HE DID PARTICIPATE IN THE AUDIENCE AND LISTENED |
| 9 | TO THE DI ALOGUE. |
| 10 | AS WE GO THROUGH THESE ITEMS, DR. LEVIN, |
| 11 | PLEASE FEEL FREE TO RAISE ANY SPECIFIC QUESTIONS |
| 12 | THAT YOU FEEL WERE UNANSWERED. BUT WHAT WE'D LIKE |
| 13 | TO DO IS CALL THE ROLL AND THEN QUICKLY RUN THROUGH |
| 14 | THE ITEMS THAT HAVE BEEN OTHERWISE DISCUSSED BY THE |
| 15 | BOARD. AND, AGAIN, DR. LEVIN WILL ASK IF THERE'S |
| 16 | ANY SPECIFIC QUESTIONS BEFORE WE MOVE TO A VOICE |
| 17 | VOTE OR A ROLL CALL ON ANY ITEM. WE'D LIKE TO CALL |
| 18 | THE ROLL. |
| 19 | MS. KING: DONALD DAFOE. |
| 20 | DR. DAFOE: HERE. |
| 21 | MS. KING: ROBERT PRICE. |
| 22 | DR. PRI CE: HERE. |
| 23 | MS. KING: FLOYD BLOOM. |
| 24 | DR. BLOOM: HERE. |
| 25 | MS. KING: DAVID BRENNER. |
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| | DARRISTERS REPORTING SERVICE | |
|----|--|--|
| 1 | DR. BRENNER: HERE. | |
| 2 | MS. KING: JACOB LEVIN. | |
| 3 | DR. LEVIN: HERE. | |
| 4 | MS. KING: MARSHA CHANDLER. MARCY FEIT. | |
| 5 | MICHAEL FRIEDMAN. | |
| 6 | DR. FRIEDMAN: HERE. | |
| 7 | MS. KING: LEEZA GIBBONS. MICHAEL | |
| 8 | GOLDBERG. | |
| 9 | MR. GOLDBERG: HERE. | |
| 10 | MS. KING: SAM HAWGOOD. BOB KLEIN. | |
| 11 | CHAIRMAN KLEIN: HERE. | |
| 12 | MS. KING: SHERRY LANSING. | |
| 13 | MS. LANSING: HERE. | |
| 14 | MS. KING: GERALD LEVEY. TED LOVE. | |
| 15 | DR. LOVE: HERE. | |
| 16 | MS. KING: TINA NOVA. ED PENHOET. | |
| 17 | DR. PENHOET: HERE. | |
| 18 | MS. KING: PHIL PIZZO. | |
| 19 | DR. PI ZZO: HERE. | |
| 20 | MS. KING: CLAIRE POMEROY. | |
| 21 | DR. POMEROY: HERE. | |
| 22 | MS. KING: FRANCISCO PRIETO. ROBERT | |
| 23 | QUI NT. | |
| 24 | DR. QUINT: HERE. | |
| 25 | MS. KING: JOHN REED. DUANE ROTH. | |
| | 112 | |

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| 1 | MR. ROTH: HERE. |
|----|--|
| 2 | MS. KING: JOAN SAMUELSON. |
| 3 | MS. SAMUELSON: HERE. |
| 4 | MS. KING: DAVID SERRANO-SEWELL. |
| 5 | MR. SERRANO-SEWELL: HERE. |
| 6 | MS. KING: JEFF SHEEHY. |
| 7 | MR. SHEEHY: HERE. |
| 8 | MS. KING: JON SHESTACK. OSWALD STEWARD. |
| 9 | DR. STEWARD: HERE. |
| 10 | MS. KING: AND WE DO HAVE A QUORUM. |
| 11 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. |
| 12 | NEVER BEEN QUITE AS EXCITED TO HAVE A QUORUM. |
| 13 | WE WILL RETURN TO THE ORDER WE WERE IN |
| 14 | BEFORE WITH THE EXCEPTION THAT I WOULD ASK FOR AN |
| 15 | APPROVAL OF THE CONSENT ITEMS, SPECIFICALLY THE |
| 16 | MINUTES; IS THAT CORRECT, MELISSA KING? |
| 17 | MS. KING: YES. IT'S JUST MINUTES ON THE |
| 18 | CONSENT CALENDAR. BUT BEFORE WE DO THAT, I BELIEVE |
| 19 | WE SHOULD CONSIDER THE ADDITIONAL AGENDA ITEM AND |
| 20 | EXPANSION OF ITEM NO. 9. |
| 21 | CHAIRMAN KLEIN: I DON'T THINK THAT'S |
| 22 | SENSITIVE TO THAT ORDER. I THINK WE CAN DO THE |
| 23 | CONSENT ITEMS FIRST. IS THERE A MOTION TO APPROVE |
| 24 | THE MINUTES AS A CONSENT ITEM? |
| 25 | MS. LANSING: SO MOVED. |
| | 113 |

| 1 | DR. BRENNER: SECOND. |
|----|--|
| 2 | CHAIRMAN KLEIN: THERE'S A MOVE AND A |
| 3 | SECOND. CAN WE IDENTIFY WHO MADE THE MOTION? |
| 4 | SHERRY LANSING. WHO'S THE SECOND? DR. BRENNER. |
| 5 | THANK YOU. ANY PUBLIC DISCUSSION ON THE MINUTES? |
| 6 | SEEING NONE, MOVE THE QUESTION. ALL IN FAVOR. |
| 7 | APPROVED. |
| 8 | LET'S GO TO ITEM 16. AND I'D LIKE, MR. |
| 9 | HARRISON, DO WE HAVE AN EXTRAORDINARY MOTION WE NEED |
| 10 | TO PUT WHICH ITEM ON THE AGENDA? |
| 11 | MS. KING: NOT THAT ONE. WE COULD |
| 12 | CONSIDER 16 BEFORE. |
| 13 | CHAIRMAN KLEIN: THAT'S FINE. I'M GOING |
| 14 | TO MOVE THROUGH ITEM 16, CONSIDERATION OF THE |
| 15 | RECOMMENDATIONS ON THE RFA APPLICANT POLICY. WE'VE |
| 16 | HEARD THE PRESENTATION BY DR. AZZIZ AND DR. PIZZO. |
| 17 | ANY ADDITIONAL BOARD COMMENTS? SEEING NONE, |
| 18 | ADDITIONAL PUBLIC COMMENTS? SEEING NONE, CALL THE |
| 19 | QUESTION. ALL IN FAVOR. APPROVED. WE MOVE |
| 20 | FORWARD. |
| 21 | MR. ROTH: YOU DON'T HAVE A MOTION. |
| 22 | CHAIRMAN KLEIN: THAT'S GOOD. WE SHOULD |
| 23 | HAVE A MOTION. WHO WOULD LIKE TO MAKE THE MOTION? |
| 24 | DR. PENHOET: SO MOVED. |
| 25 | CHAIRMAN KLEIN: DR. PENHOET. SECOND? |
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114

| | BARRISTERS' REPORTING SERVICE |
|----|---|
| 1 | DR. FRIEDMAN: SECOND. |
| 2 | CHAIRMAN KLEIN: AGAIN, ANY PUBLIC COMMENT |
| 3 | ON THIS? NO. ALL IN FAVOR. OPPOSE? AYES HAVE IT. |
| 4 | THANK YOU. |
| 5 | MS. KING: JUST TO CLARIFY THAT WAS ITEM |
| 6 | NO. 16, CHAIRMAN KLEIN? |
| 7 | CHAIRMAN KLEIN: THAT WAS ITEM NO. 16. |
| 8 | MS. KING: EXCELLENT. THANK YOU. AND |
| 9 | THAT MOTION CARRIED. |
| 10 | CHAIRMAN KLEIN: THAT'S CORRECT. WE DON'T |
| 11 | NEED AN EXTRAORDINARY MOTION FOR ITEM 7, SO WE WILL |
| 12 | GO TO ITEM 7, APPOINTMENT OF THE NEW SCIENTIFIC |
| 13 | MEMBERS FOR THE GRANTS WORKING GROUP. ITEM WAS |
| 14 | DISCUSSED AND PRESENTED BY DR. GIL SAMBRANO. WE'VE |
| 15 | HAD DISCUSSION OF MEMBERS. THERE'S A SLATE, AND |
| 16 | THERE ARE TEN MEMBERS; IS THAT CORRECT? |
| 17 | DR. SAMBRANO: YES. |
| 18 | CHAIRMAN KLEIN: TEN MEMBERS. ANY |
| 19 | DISCUSSION BY THE BOARD ON THOSE MEMBERS? |
| 20 | MR. ROTH: MOTION TO APPROVE. |
| 21 | CHAIRMAN KLEIN: MOTION TO APPROVE BY |
| 22 | DUANE ROTH. IS THERE A SECOND? |
| 23 | DR. LEVIN: SECOND. |
| 24 | CHAIRMAN KLEIN: SECOND JACOB LEVIN. |
| 25 | PUBLIC COMMENT? SEEING NONE, CALL THE QUESTION. |
| | 115 |

115

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| 1 | ALL IN FAVOR. OPPOSED? THE AYES HAVE IT. ITEM 7 |
| 2 | PASSES. |
| 3 | ITEM 8, STANDARDS WORKING GROUP ITEM HAS |
| 4 | BEEN PRESENTED BY DR. GEOFFREY LOMAX. IT'S |
| 5 | APPOINTMENT OF A NEW MEMBER FOR THE STANDARDS |
| 6 | WORKING GROUP. COMMENT? |
| 7 | MS. LANSING: I'D LIKE TO MOVE. |
| 8 | CHAIRMAN KLEIN: SHERRY LANSING IS MOVING |
| 9 | THE ITEM. IS THERE A SECOND? |
| 10 | DR. FRIEDMAN: SECOND. |
| 11 | CHAIRMAN KLEIN: SECOND BY DR. FRIEDMAN. |
| 12 | BOARD COMMENT? PUBLIC COMMENT? SEEING NONE, ALL IN |
| 13 | FAVOR. OPPOSED? ITEM CARRIES. |
| 14 | ITEM 9, CONSIDERATION OF THE UPDATE FROM |
| 15 | THE STANDARDS WORKING GROUP. DR. GEOFFREY LOMAX |
| 16 | PRESENTED THIS ITEM. |
| 17 | MS. KING: AND FOR THIS ITEM, CHAIRMAN |
| 18 | KLEIN, WE ACTUALLY DO NEED TO APPROVE THE ADDITIONAL |
| 19 | AGENDA ITEM, AN EXPANSION OF ITEM NO. 9 IN ORDER TO |
| 20 | COVER BOTH PARTS. |
| 21 | CHAIRMAN KLEIN: I THINK THAT'S THE SECOND |
| 22 | PART OF ITEM 9; IS THAT CORRECT? |
| 23 | MS. KING: BUT IT'S PART OF AGENDA ITEM 9. |
| 24 | CHAIRMAN KLEIN: ALL RIGHT. WE'LL DO IT |
| 25 | AT THE BEGINNING OF THE ITEM. JAMES HARRISON, WOULD |
| | |
| | 116 |

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| 1 | YOU LIKE TO EXPLAIN TO THE BOARD THE PROCEDURE IN |
|----|--|
| 2 | THIS CASE? |
| 3 | MR. HARRISON: YES. ITEM NO. 9 WAS |
| 4 | INITIALLY LIMITED TO THE FIRST REGULATION THAT DR. |
| 5 | LOMAX PRESENTED RELATED TO GRANDFATHERING. AFTER |
| 6 | THE AGENDA WAS ISSUED, WE AMENDED IT IN ORDER TO |
| 7 | EXPAND THE SCOPE OF ITEM 9 TO INCLUDE CONSIDERATION |
| 8 | OF A PROPOSED INTERIM REGULATION RELATING TO USE OF |
| 9 | EMBRYOS DERIVED FROM PAID GAMETE DONORS |
| 10 | CHAIRMAN KLEIN: BEFORE |
| 11 | MR. HARRISON: FOR REPRODUCTIVE |
| 12 | PURPOSES ONLY. |
| 13 | CHAIRMAN KLEIN: BEFORE THE DATE OF? |
| 14 | MR. HARRISON: BEFORE THE DATE OF THIS |
| 15 | MEETI NG. |
| 16 | CHAIRMAN KLEIN: AUGUST 12TH, 2008. |
| 17 | MR. HARRISON: CORRECT. BECAUSE WE |
| 18 | EXPANDED THE SCOPE OF THE AGENDA LITEM AFTER THE |
| 19 | AGENDA WAS ISSUED, WE NEED TO HAVE AN DETERMINATION |
| 20 | BY THE BOARD AND UNANIMOUS APPROVAL OF ACTION TO |
| 21 | CONSIDER THIS ITEM. THE GROUNDS ARE THAT THERE IS A |
| 22 | NEED TO TAKE IMMEDIATE ACTION, AND THAT THE NEED FOR |
| 23 | THE ACTION CAME TO THE ATTENTION OF THE BOARD AFTER |
| 24 | THE AGENDA WAS ISSUED. |
| 25 | CHAIRMAN KLEIN: THANK YOU VERY MUCH. IS |
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| 1 | THERE A MOTION TO |
|----|---|
| 2 | DR. LOVE: SO MOVED. |
| 3 | CHAIRMAN KLEIN: SO MOVED BY DR. LOVE. IS |
| 4 | THERE A SECOND? |
| 5 | DR. PI ZZO: SECOND. |
| 6 | CHAIRMAN KLEIN: SECOND BY DR. PIZZO. |
| 7 | DISCUSSION BY THE BOARD? DISCUSSION BY THE PUBLIC? |
| 8 | ALL IN FAVOR? OPPOSED? SEEING NONE OPPOSED, IT IS |
| 9 | UNANIMOUS APPROVAL. THE ITEM IS ATTACHED TO ITEM 9. |
| 10 | ITEM 9, WE HAVE LANGUAGE. COULD WE SEE |
| 11 | THE LANGUAGE ON THE BOARD, PLEASE, ON THE |
| 12 | PRESENTATION SCREEN. |
| 13 | ALL RIGHT. THE LANGUAGE HAS BEEN |
| 14 | REDISPLAYED ON THE SCREEN. IT HAS BEEN PRESENTED BY |
| 15 | DR. GEOFFREY LOMAX. IT'S BEEN DISCUSSED BY THIS |
| 16 | BOARD. MR. HARRISON, WOULD YOU LIKE TO SUMMARIZE |
| 17 | THIS FOR A MOTION? |
| 18 | MR. HARRISON: YES. THE MOTION WE WOULD |
| 19 | REQUEST WOULD BE TO ADOPT THE PROPOSED |
| 20 | GRANDFATHERING PROVISION AS AN INTERIM REGULATION |
| 21 | WHICH WOULD BE IN EXISTENCE FOR 270 DAYS AND PERMIT |
| 22 | US TO UNDERGO THE FORMAL ADMINISTRATIVE PROCEDURE |
| 23 | ACT PROCESS. |
| 24 | CHAIRMAN KLEIN: WITH PUBLIC COMMENT. |
| 25 | MR. HARRISON: WITH PUBLIC COMMENT. |
| | 110 |

118

| 1 | CHAIRMAN KLEIN: ALL RIGHT. AND SO IT HAS |
|----|--|
| 2 | BEEN DISPLAYED TO THE PUBLIC AND TO THE BOARD |
| 3 | MEMBERS, AND THE LANGUAGE WILL BE CAPTURED IN THE |
| 4 | FORMAL REGULATORY FORM; IS THAT CORRECT, SCOTT |
| 5 | TOCHER? |
| 6 | MR. TOCHER: THAT'S RIGHT. |
| 7 | CHAIRMAN KLEIN: THAT'S CORRECT. OKAY. |
| 8 | IS THERE A MOTION TO APPROVE? |
| 9 | DR. LOVE: SO MOVED. |
| 10 | CHAIRMAN KLEIN: MOVED BY DR. LOVE. |
| 11 | SECOND? |
| 12 | DR. PRICE: SECOND. |
| 13 | CHAIRMAN KLEIN: DR. PRICE. COMMENT FROM |
| 14 | THE PUBLIC? LET IT BE KNOWN DR. PENHOET. |
| 15 | DR. PENHOET: I BELIEVE THE ALGORITHM |
| 16 | WE'RE GOING TO APPROVE IS NOT ON THIS SLIDE. THIS |
| 17 | IS THE BACKGROUND. |
| 18 | MR. HARRISON: THAT'S CORRECT. WE |
| 19 | ACTUALLY DO HAVE LANGUAGE WHICH IS IN YOUR BINDERS |
| 20 | AND WAS POSTED ON THE WEBSITE. |
| 21 | CHAIRMAN KLEIN: THAT'S MY REFERENCE TO |
| 22 | THE FACT THE REGULATORY LANGUAGE CAPTURES THIS |
| 23 | INFORMATION. |
| 24 | DR. PIZZO: BUT DOESN'T PAY THE EMBRYOS. |
| 25 | MR. HARRISON: THE ACTUAL LANGUAGE OF THE |
| | 119 |
| | |

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| 1 | PROPOSED INTERIM REGULATION IS IN YOUR BINDER BEHIND |
|----|--|
| 2 | TAB 9. |
| 3 | CHAIRMAN KLEIN: SO I WANT TO SEE THE |
| 4 | OTHER SLIDE. IT DOESN'T REALLY MATTER WHICH ORDER |
| 5 | WE ADOPT THESE TWO PROVISIONS. BUT IN CASE, FOR THE |
| 6 | RECORD, ONE OF THESE IS TO GRANDFATHER ACCEPTABLY |
| 7 | DERIVED HUMAN CELL LINES, AND THE OTHER DEALS WITH |
| 8 | EMBRYOS. WE'RE GOING TO DEAL WITH THE FIRST |
| 9 | MOTION IS DEALING WITH HUMAN EMBRYONIC STEM CELL |
| 10 | LINES BEING GRANDFATHERED. ALL RIGHT. SO IS THERE |
| 11 | A MOTION ON THE TABLE? |
| 12 | MR. TOCHER: THERE IS. |
| 13 | CHAIRMAN KLEIN: THERE IS A MOTION ON THE |
| 14 | TABLE. FINE. PUBLIC COMMENT? ALL IN FAVOR? |
| 15 | OPPOSED? IT PASSES UNANIMOUSLY. |
| 16 | LET US GO TO THE SECOND SLIDE, PLEASE. SO |
| 17 | THE SECOND SLIDE IS A GRANDFATHERING DEALING WITH |
| 18 | IVF-DERIVED EMBRYOS. AND REMIND EVERYONE THE DATE |
| 19 | OF AUGUST 12, 2008, WAS CHOSEN SO THERE COULD BE NO |
| 20 | IMPLICATIONS THAT THE ACTIONS OF THIS BOARD INDUCED |
| 21 | ANYONE TO GO INTO IVF FOR RESEARCH PURPOSES. |
| 22 | IS THERE A MOTION TO SUPPORT THE LANGUAGE |
| 23 | HERE THAT HAS BEEN INCORPORATED IN THE REGULATORY |
| 24 | LANGUAGE THAT IS IN YOUR BINDER? |
| 25 | DR. PRICE: SO MOVED. |
| | 120 |
| | 120 |

| 1 | CHAIRMAN KLEIN: DR. PRICE MOVES. IS |
|----|---|
| 2 | THERE A SECOND? |
| 3 | DR. QUINT: SECOND. |
| 4 | CHAIRMAN KLEIN: DR. QUINT. IS THERE |
| 5 | DISCUSSION FROM THE BOARD? IS THERE DISCUSSION FROM |
| 6 | THE PUBLIC? SEEING NONE, CALL THE QUESTION. ALL IN |
| 7 | FAVOR. OPPOSED? OKAY. |
| 8 | ON CALIFORNIA SUPPLIERS, MR. HARRISON, |
| 9 | COULD YOU SUMMARIZE ON CALIFORNIA SUPPLIERS THE |
| 10 | STATUTORY BASIS FOR BEGINNING WITH AN INTERIM |
| 11 | REGULATION AND ADOPTING THE LANGUAGE PRESENTED HERE |
| 12 | TODAY? |
| 13 | MR. HARRISON: YES. PROPOSITION 71 |
| 14 | AUTHORIZES THE BOARD TO ADOPT INTERIM REGULATIONS |
| 15 | THAT WILL BE IN EFFECT FOR 270 DAYS TO ALLOW PUBLIC |
| 16 | COMMENT AND APPROVAL THROUGH THE FORMAL |
| 17 | ADMINISTRATIVE PROCEDURE ACT PROCESS. SO WE WOULD |
| 18 | PROPOSE THAT THE BOARD CONSIDER ADOPTING THE |
| 19 | DEFINITION OF CALIFORNIA SUPPLIER THAT IS IN TAB 10 |
| 20 | OF YOUR BINDERS AS AN INTERIM REGULATION. |
| 21 | CHAIRMAN KLEIN: AND THIS IS THE SPECIFIC |
| 22 | LANGUAGE WHICH WAS PRESENTED EARLIER BY DUANE ROTH |
| 23 | AND COMMENTED ON BY THE PUBLIC. |
| 24 | MR. HARRISON: CORRECT. AND THIS |
| 25 | REGULATION AS AN INTERIM REGULATION WOULD TAKE |
| | 101 |

| 1 | EFFECT UPON YOUR APPROVAL. |
|----|---|
| 2 | CHAIRMAN KLEIN: THANK YOU. IS THERE A |
| 3 | MOTION? |
| 4 | MR. ROTH: I'LL RECOMMEND THAT WE APPROVE |
| 5 | THE DEFINITION UNDER TAB 10 IN ITS ENTIRETY AS AN |
| 6 | INTERIM REGULATION ON CALIFORNIA SUPPLIER. |
| 7 | CHAIRMAN KLEIN: THANK YOU. IS THERE A |
| 8 | SECOND? |
| 9 | DR. PI ZZO: SECOND. |
| 10 | CHAIRMAN KLEIN: SECOND DR. PIZZO. |
| 11 | MR. HARRISON: MR. CHAIR, COULD I JUST |
| 12 | REQUEST ONE CLARIFICATION. IF WE COULD INCLUDE |
| 13 | WITHIN THE SCOPE OF THAT MOTION APPROVAL FOR THE |
| 14 | STAFF TO INITIATE THE ADMINISTRATIVE PROCEDURE ACT |
| 15 | PROCESS, THEN WE CAN GET THAT UNDERWAY AS WELL. |
| 16 | CHAIRMAN KLEIN: AS A FRIENDLY AMENDMENT? |
| 17 | MR. ROTH: YES, I ACCEPT THE FRIENDLY. |
| 18 | CHAIRMAN KLEIN: IT'S BEEN ACCEPTED. BY |
| 19 | THE SECOND? |
| 20 | DR. PI ZZO: YES. |
| 21 | CHAIRMAN KLEIN: IT'S ACCEPTED BY THE |
| 22 | SECOND. WITH THAT UNDERSTANDING, ANY COMMENT BY THE |
| 23 | BOARD? ANY COMMENT BY THE PUBLIC? MOVE THE |
| 24 | QUESTION. ALL IN FAVOR. OPPOSED? PASSES |
| 25 | UNANI MOUSLY. THANK YOU VERY MUCH. |
| | 100 |

122

| 1 | (APPLAUSE.) |
|----|--|
| 2 | CHAIRMAN KLEIN: AND DO WE HAVE ANY ITEM |
| 3 | THAT WE HAVE NOT COVERED? |
| 4 | MS. KING: WE DO ACTUALLY. THE ADDITIONAL |
| 5 | AGENDA ITEM THAT THE BOARD HAS NOW AGREED TO |
| 6 | CONSIDER, WHICH WILL IMPACT THE TRANSLATIONAL I RFA |
| 7 | THAT THE BOARD CONSIDERED AT THE LAST MEETING AND |
| 8 | ASKED STAFF TO BRING BACK PART OF WITH REGARD TO |
| 9 | ELIGIBILITY REQUIREMENTS, IF WE COULD DO THAT NOW, |
| 10 | THAT WOULD BE GREAT. |
| 11 | CHAIRMAN KLEIN: WE COULD DO THAT |
| 12 | TOMORROW. WE COULD DO THAT ITEM TOMORROW. WE DON'T |
| 13 | HAVE A TIME PRESSURE ON THAT ITEM. |
| 14 | MS. KING: BUT WE MIGHT HAVE A TIME |
| 15 | PRESSURE ON OUR QUORUM TOMORROW. I KNOW THIS HAS TO |
| 16 | HAPPEN. |
| 17 | CHAIRMAN KLEIN: WE HAVE TO HAVE A QUORUM |
| 18 | TOMORROW. SO I TAKE IT YOU COLLECTED ALL THE |
| 19 | PASSPORTS? THANK YOU. |
| 20 | SO WHAT I'D LIKE TO DO, IF THERE'S NO |
| 21 | UNFINISHED BUSINESS FROM THIS MORNING FROM THIS |
| 22 | AFTERNOON AND EVENING, IS TO BEGIN THE CONSIDERATION |
| 23 | OF THE GRANTS WORKING GROUP ON NEW FACULTY II |
| 24 | APPLICATIONS. AND I'D LIKE TO ASK DR. MIKE YAFFE TO |
| 25 | TAKE US THROUGH THIS ITEM. DR. YAFFE. |
| | 122 |

| THE DOADD INDINKE TO DESCRIT TO YOU FOR YOUR |
|--|
| THE BOARD, I'D LIKE TO PRESENT TO YOU FOR YOUR |
| CONSIDERATION THE RECOMMENDATIONS OF THE GRANTS |
| WORKING GROUP ON THE NEW FACULTY II APPLICATIONS. |
| THIS IS AGENDA ITEM NO. 11. |
| JUST TO REMIND YOU THAT THE GOALS OF THIS |
| INITIATIVE ARE TO SUPPORT INNOVATIVE RESEARCH |
| PROGRAMS FROM NEWLY INDEPENDENT SCIENTISTS AND |
| PHYSICIAN SCIENTISTS AT A CRUCIAL EARLY STAGE IN |
| THEIR CAREERS AND, FURTHER, TO RECRUIT THE TOP YOUNG |
| SCIENTISTS AND PHYSICIAN/SCIENTISTS TO STEM CELL |
| RESEARCH. |
| FEATURES OF THIS PROGRAM INCLUDE THE |
| SUPPORT FOR INNOVATIVE RESEARCH USING A FULL |
| SPECTRUM OF STEM CELL TYPES AND EXPERIMENTAL |
| APPROACHES, INCLUDING MODEL SYSTEMS. THESE AWARDS |
| WILL FUND FOR UP TO FIVE YEARS DIRECT PROJECT COSTS |
| OF UP TO \$300,000 PER YEAR FOR SCIENTIST AWARDS AND |
| \$400,000 PER YEAR FOR PHYSICIAN/SCIENTIST AWARDS. |
| THIS HIGHER LEVEL FOR THE PHYSICIAN/SCIENTISTS IS |
| MEANT IN PART TO COMPENSATE FOR LOSS OF CLINICAL |
| INCOME FOR PHYSICIAN/SCIENTISTS WHO WILL BE SPENDING |
| AN INCREASED AMOUNT OF TIME IN THE LABORATORY ON |
| THEIR RESEARCH PROGRAMS. |
| WITH REGARD TO THE ITEM THAT YOU DISCUSSED |
| 124 |
| |

| 1 | EARLIER TODAY, THERE'S A REQUIREMENT THAT AWARDEES |
|----|---|
| 2 | DEVOTE AT LEAST 33 PERCENT OF THEIR TIME TO THE |
| 3 | RESEARCH UNDER THESE AWARDS. |
| 4 | YOU ORIGINALLY APPROVED IN JANUARY FUNDING |
| 5 | FOR 14 AWARDS WITH A TOTAL BUDGET OF UP TO \$41 |
| 6 | MILLION. THE CRITERIA BY WHICH THESE APPLICATIONS |
| 7 | WERE JUDGED BY THE GRANTS WORKING GROUP FOCUSED ON |
| 8 | THREE MAIN AREAS. THE FIRST WAS RESEARCH PLAN. THE |
| 9 | GRANTS WORKING GROUP REVIEWERS CONSIDERED THE |
| 10 | SIGNIFICANCE AND INNOVATION OF THE PROJECTS AND |
| 11 | THEIR DESIGN AND FEASIBILITY. |
| 12 | THE SECOND AREA WAS THE PRINCIPAL |
| 13 | INVESTIGATOR. HERE REVIEWERS CONSIDERED THE |
| 14 | QUALIFICATIONS AND PARTICULARLY THE POTENTIAL FOR |
| 15 | LEADERSHIP IN STEM CELL RESEARCH AND, IN ADDITION, |
| 16 | CAREER DEVELOPMENT AND MENTORING PLANS OF THE |
| 17 | APPLI CANTS. |
| 18 | AND THE THIRD AREA WAS THE APPLICANT |
| 19 | INSTITUTION. HERE REVIEWERS WERE CONCERNED WITH THE |
| 20 | COMMITMENT TO THE INSTITUTION TO THE INVESTIGATOR, |
| 21 | THE TRACK RECORD OF THE INSTITUTION IN PROMOTION OF |
| 22 | YOUNG FACULTY AND SUPPORT OF THEIR ACTIVITIES, AND |
| 23 | THE FUTURE PLANS FOR THE INSTITUTION FOR ADDITIONAL |
| 24 | GROWTH IN STEM CELL RESEARCH AND REGENERATIVE |
| 25 | MEDICINE. |
| | 125 |

| 1 | THE GRANTS WORKING GROUP MET IN JUNE AND |
|----|--|
| 2 | CONSIDERED 54 APPLICATIONS. THEY RANKED THOSE |
| 3 | APPLICATIONS FROM ZERO TO 100, 100 BEING THE TOP |
| 4 | POSSIBLE SCORE. I'LL SHOW YOU NOW THE DISTRIBUTION |
| 5 | OF THOSE SCORES OF THE 54 APPLICATIONS. |
| 6 | HERE'S THE HISTOGRAM. IN GOLD ARE |
| 7 | APPLICATIONS FOR SCIENTIST AWARD. IN BLUE I |
| 8 | APOLOGIZE TO OUR STANFORD HOST HERE FOR THE GOLD AND |
| 9 | BLUE COLORS. IN BLUE ARE THE APPLICATIONS FOR |
| 10 | PHYSICIAN/SCIENTIST AWARD. |
| 11 | DR. PIZZO: WE'RE WINNING UNDER ANY |
| 12 | CI RCUMSTANCE. |
| 13 | MS. SAMUELSON: LOOK AT THE COLOR OF THE |
| 14 | FABRI C. |
| 15 | DR. YAFFE: AND THE GRANTS WORKING GROUP |
| 16 | DREW THE RED AND BLUE LINES TO INDICATE THE TIERS. |
| 17 | TIER 1, RECOMMENDED FOR FUNDING. TIER 2, |
| 18 | RECOMMENDED IF FUNDS ARE AVAILABLE. TIER 3, NOT |
| 19 | RECOMMENDED FOR FUNDING. |
| 20 | CHAIRMAN KLEIN: AND, MIKE, IF YOU COULD |
| 21 | POINT OUT THE DIFFERENCE IN THE TIER 2 CATEGORY IN |
| 22 | THIS GRANT FROM THE PREVIOUS ONE. |
| 23 | DR. YAFFE: YES. IN THE PREVIOUS ROUND, |
| 24 | THE EXACT LANGUAGE ESCAPES ME, BUT IT WAS NOT |
| 25 | RECOMMENDED FOR FUNDING UNLESS THERE WERE |
| | 126 |

| 1 | PROGRAMMATIC REASONS TO ADVANCE THEM INTO THE |
|----|--|
| 2 | RECOMMENDED. |
| 3 | IN THIS CASE THE GRANTS REVIEW GROUP |
| 4 | REVERTED TO THE OLDER DEFINITION FOR TIER 2, WHICH |
| 5 | IS RECOMMENDED IF FUNDS ARE AVAILABLE. |
| 6 | IN TIER 1 THERE ARE 20 APPLICATIONS; IN |
| 7 | TIER 2, 12; AND TIER 3, NOT RECOMMENDED, 22 |
| 8 | APPLICATIONS. FUNDS REQUIRED TO FUND AND SUPPORT |
| 9 | ALL OF THE APPLICATIONS IN TIER 1 WOULD BE AND IS |
| 10 | RECOMMENDED BY THE GRANTS WORKING GROUP AT \$51.7 |
| 11 | MILLION. I'LL REMIND YOU 41 MILLION WAS THE |
| 12 | ORIGINAL AMOUNT BUDGETED FOR THIS PROGRAM. |
| 13 | IF THE 12 APPLICATIONS IN TIER 2 WERE |
| 14 | FUNDED IN ADDITION, IT WOULD REQUIRE AN ADDITIONAL |
| 15 | \$30 MILLION. |
| 16 | IF WE LOOK AT THE 20 RECOMMENDED FOR |
| 17 | FUNDING IN TIER 1, TEN OF THESE ARE |
| 18 | PHYSICIAN/SCIENTISTS AWARDS. TEN ARE FOR SCIENTIST |
| 19 | AWARD. FOR YOUR REFERENCE, FROM AN EARLIER RFA, NEW |
| 20 | FACULTY I, THE YIELD WAS SIX PHYSICIAN/SCIENTIST |
| 21 | AWARDS AND 16 SCIENTIST AWARDS. |
| 22 | TURN IT BACK TO YOU, MR. CHAIRMAN. I'M |
| 23 | AVAILABLE FOR QUESTIONS. |
| 24 | CHAIRMAN KLEIN: ALL RIGHT. I'D LIKE TO |
| 25 | TURN THIS OVER TO JOAN SAMUELSON AND JEFF SHEEHY FOR |
| | 407 |

| 1 | COMMENTS. AND, JEFF, WHEN THESE COMMENTS ARE |
|----|--|
| 2 | CONCLUDED, JUST AS OPENING COMMENTS COMING FROM THE |
| 3 | PEER REVIEW SIDE, IF YOU COULD LEAD US THROUGH THE |
| 4 | MOTIONS ON THIS HISTOGRAM, PLEASE. |
| 5 | MS. SAMUELSON: I DEFER TO JEFF. JEFF HAS |
| 6 | BEEN LEADING US VERY ABLY IN THE PROGRAMMATIC REVIEW |
| 7 | ASPECTS OF THE WORKING GROUP. IT'S ALL HIS. |
| 8 | MR. SHEEHY: WELL, I DON'T REALLY HAVE |
| 9 | THAT MANY INTRODUCTORY COMMENTS EXCEPT MAYBE I THINK |
| 10 | FOLKS SHOULD REALLY FOCUS ON THE INTENT OF THE RFA, |
| 11 | WHICH DID HAVE THREE DIFFERENT COMPONENTS. A LOT OF |
| 12 | TIMES WE TEND TO REALLY FOCUS ON THE SCIENCE. AND I |
| 13 | THINK STAFF DID AN ADMIRABLE JOB IN THIS PROCESS OF |
| 14 | REALLY GETTING THE WORKING GROUP TO LOOK AT ALL |
| 15 | THREE ELEMENTS, WHICH WAS NOT ONLY THE SCIENCE, BUT |
| 16 | ALSO SUPPORT OF THE INSTITUTION AND ACTUALLY THE |
| 17 | QUALITY OF THE INDIVIDUAL AND WHAT THEIR FUTURE IS. |
| 18 | AND PERHAPS FINALLY AN EDITORIAL COMMENT |
| 19 | IS TO LOOK AT WHAT NIH IS DOING IN TERMS OF FUNDING |
| 20 | SCIENTISTS AT THE BEGINNING OF THEIR CAREERS. I |
| 21 | THINK WHATEVER WE END UP DOING HERE TONIGHT, WE ARE |
| 22 | FILLING A GAP IS THAT INCREASINGLY BEING LEFT AT THE |
| 23 | NIH. I THINK THE MEDIAN AGE OF AN RO1 NOW IS |
| 24 | ABOUT |
| 25 | DR. PI ZZO: 41. |
| | 128 |
| | 120 |

| 1 | MR. SHEEHY: IS 41, EXACTLY. I THINK |
|----|--|
| 2 | IF WE CAN GO STRAIGHT TO THE HISTOGRAM. I'M NOT |
| 3 | SURE YOU KNOW, THERE WERE SOME PROGRAMMATIC |
| 4 | CONSIDERATION, SO I DON'T KNOW IF YOU WANT TO REDRAW |
| 5 | THE LINE OR GO DIRECTLY TO THE CATEGORIES AS THEY |
| 6 | ARE. SINCE THE HISTOGRAM MAY NOT BE APPROPRIATE |
| 7 | WITH THE WE HAVE ONES THAT SCOREWISE WOULD HAVE |
| 8 | BEEN IN TIER 1 THAT ARE IN TIER 2, AND SCOREWISE |
| 9 | IN OTHER WORDS, THE SCORES AREN'T LINEAR IN THE |
| 10 | HISTOGRAM FASHION. SO UNLESS SOMEONE WANTS TO DRAW |
| 11 | LINES JUST LOOKING AT THE HISTOGRAM, THEN MAYBE |
| 12 | DR. YAFFE: WE PROBABLY SHOULD GO THEN TO |
| 13 | THE LIST OF APPLICATIONS. |
| 14 | MR. SHEEHY: LIST OF APPLICATIONS. I |
| 15 | THINK THE FIRST MOTIONS WILL BE TO TAKE ANY ITEM OUT |
| 16 | OF TIER 1 AND MOVE IT INTO TIER 2 OR TIER 3, AND |
| 17 | THEN TO TAKE MOTIONS TO MOVE APPLICATIONS OUT OF |
| 18 | TIER 3, MOVE THEM TO TIER 2 OR TIER 1, AND THEN TAKE |
| 19 | THE LAST CATEGORY OF TIER 2 AND MOVE THOSE INTO TIER |
| 20 | 1 OR LEAVE THEM THERE TO FALL INTO TIER 3. |
| 21 | CHAIRMAN KLEIN: AND LET ME ASK THIS |
| 22 | QUESTION. COUNSEL, SINCE AT THIS POINT WE ARE NOT |
| 23 | DISCUSSING ANY INDIVIDUAL APPLICATION, CAN I SOLICIT |
| 24 | A GENERAL POSITION FROM THOSE ON THE BOARD WHO CAN |
| | |
| 25 | ADDRESS THE CRITICAL NATURE OF PHYSICIAN/SCIENTIST |

| 1 | AND THE SHORTAGE OF PHYSICIAN/SCIENTISTS IN TERMS OF |
|----|--|
| 2 | DELIVERING ON OUR MISSION. BECAUSE WE'RE NOT |
| 3 | DISCUSSING ANY INDIVIDUAL APPLICATION, AS A MATTER |
| 4 | OF GENERAL POLICY, AS PROGRAM POLICY, I DON'T SEE A |
| 5 | CONFLICT IN THAT GENERAL DISCUSSION; IS THAT |
| 6 | CORRECT? |
| 7 | MR. HARRISON: THAT'S CORRECT. AS YOU |
| 8 | RECALL, A PART OF THIS RFA WAS INTENDED TO MEET THE |
| 9 | NEED TO BRING MORE PHYSICIAN/SCIENTISTS INTO THE |
| 10 | AREA OF STEM CELL RESEARCH. |
| 11 | CHAIRMAN KLEIN: FOR THE PUBLIC RECORD, IF |
| 12 | WE CAN GET SOME COMMENTS SO THE PUBLIC UNDERSTANDS |
| 13 | HOW CRITICAL THE SHORTAGE IS OF PHYSICIAN/SCIENTISTS |
| 14 | AND HOW VITAL THEY ARE TO REALLY BEING ABLE TO |
| 15 | DELIVER ON THIS ROLE, I THINK IT MIGHT BE HELPFUL. |
| 16 | DR. PIZZO: THERE ARE MANY AT THIS TABLE |
| 17 | QUALIFIED TO SPEAK ON THIS TOPIC. AND I WOULD JUST |
| 18 | SAY THAT, FIRST OF ALL, IT'S IMPORTANT TO DEFINE |
| 19 | WHAT A PHYSICIAN/SCIENTIST IS. AND THAT IS SOMEONE |
| 20 | WHO HAS AT LEAST COMPLETED AN M.D. DEGREE, BUT WHO |
| 21 | ALSO MAY HAVE DONE AN ADVANCED DEGREE, PH.D. OR |
| 22 | MASTER'S DEGREE, WHO SPENDS A SIGNIFICANT PROPORTION |
| 23 | OF HER OR HIS TIME IN RESEARCH AS WELL AS IN PATIENT |
| 24 | CARE. |
| 25 | NOW, MANY WOULD IDENTIFY, AND THE NIH DOES |
| | 130 |
| | |

| 1 | IDENTIFY PHYSICIAN/SCIENTIST AS SOMEONE WHO WILL |
|----|--|
| 2 | HAVE CONTACT WITH PATIENTS, NOT SIMPLY BE WORKING ON |
| 3 | PATIENT-RELATED SAMPLES. AND IT'S A TOUGH ROLE FOR |
| 4 | THOSE INDIVIDUALS BECAUSE THEY'RE DRAWN BETWEEN MANY |
| 5 | DIFFERENT DEMANDS. AND, OF COURSE, THERE ARE TWO |
| 6 | MAJOR PRESSURES THAT ARE IMPACTING THE FUTURE |
| 7 | DEVELOPMENT OF PHYSICIAN/SCIENTISTS. ONE ALLUDED TO |
| 8 | BY MANY ALREADY TODAY IS THE DECREASED AMOUNT OF |
| 9 | FUNDING FROM THE NIH, WHICH PUTS AN ENORMOUS |
| 10 | PRESSURE ON SUCCESS AND EVEN CREATES AN IMPEDIMENT |
| 11 | TO MOVING DOWN THIS PATHWAY AS A CAREER OPTION. |
| 12 | AND THE SECOND, OF COURSE, IS THE |
| 13 | MARKETPLACE OF CURRENT MEDICINE, WHICH MEANS THE |
| 14 | INCREASED DEMANDS ON THESE INDIVIDUALS TO BE |
| 15 | CLINICALLY PRODUCTIVE AND TO FULFILL THE DEMANDS OF |
| 16 | CLINICAL PRACTICE IN ORDER TO ACHIEVE COMPENSATION. |
| 17 | SO PROGRAMS THAT, AS WAS ALLUDED TO IN THE |
| 18 | PRESENTATION, THAT, IN ESSENCE, BUYS TIME SO THAT |
| 19 | THESE INDIVIDUALS WHO DO THE CROSSTALK BETWEEN THE |
| 20 | LABORATORY, WHETHER WET OR DAY, AND THE CLINIC WHERE |
| 21 | PATIENTS ARE AND ALLOWS THEM TO HAVE INCREASED TIME |
| 22 | FOR RESEARCH ARE OF ESSENTIAL IMPORTANCE. |
| 23 | THE STARK REALITY IS THAT NOT JUST OVER |
| 24 | THE LAST FIVE YEARS, TEN YEARS, BUT FOR THE LAST 15 |
| 25 | TO 20 YEARS, THERE HAS BEEN A DEARTH OF |
| | |

| 1 | PHYSICIAN/SCIENTISTS. AND THE PROBLEM IS ONLY |
|----|--|
| 2 | ACCELERATING AT THIS JUNCTURE IN TIME, AND MANY |
| 3 | ORGANIZATIONS ARE SPENDING A LOT OF EFFORT IN TRYING |
| 4 | TO THINK ABOUT HOW TO TRAIN AND GENERATE MORE |
| 5 | INDIVIDUALS WHO ARE CONVERSANT IN BOTH SCIENCE AND |
| 6 | MEDICINE. |
| 7 | I WOULD AGREE THAT AWARDS LIKE THIS NEW |
| 8 | FACULTY AWARDS THAT HAVE AN ENHANCER FOR THOSE WHO |
| 9 | ARE PHYSICIAN/SCIENTISTS WILL FIT A VERY IMPORTANT |
| 10 | NICHE IN THEIR DEVELOPMENT. AND I WOULD FURTHER |
| 11 | SAY, AS I'VE STATED IN OTHER MEETINGS, AND I CAN SAY |
| 12 | IT PARTICULARLY BEING HERE IN THE CARDINAL RED |
| 13 | ENVIRONMENT OF STANFORD, THAT WE, LIKE OTHER |
| 14 | RESEARCH INTENSIVE SCHOOLS OF MEDICINE, ARE FEELING |
| 15 | THE PAIN OF RESEARCH FUNDING FROM THE NIH. AND I |
| 16 | WOULD ADD THAT WERE IT NOT FOR CIRM FUNDING, WE |
| 17 | WOULD BE SUFFERING CONSIDERABLY MORE AS BROAD |
| 18 | BIOMEDICAL INSTITUTIONS ON THE BROADEST LANDSCAPE, |
| 19 | AND MORE SPECIFICALLY IN DEVELOPING AND GENERATING |
| 20 | THE NEXT GENERATION OF LEADERS IN SCIENCE WHO MIGHT |
| 21 | START OUT IN STEM CELL RESEARCH AND THEN, IF YOU |
| 22 | WILL, DIFFERENTIATE TO OTHER AREAS, BUT AT LEAST |
| 23 | THEY'RE GET THEIR GROUNDING AND THEIR BEGINNING IN |
| 24 | THIS AREA. |
| 25 | CHAIRMAN KLEIN: THANK YOU VERY MUCH, DR. |
| | 132 |
| | 104 |

| 1 | PIZZO. ANY OTHER BOARD MEMBER WOULD LIKE TO ADDRESS |
|----|---|
| 2 | THIS ISSUE? I THINK YOU DID AN ELOQUENT JOB IN |
| 3 | PRESENTING THE ITEM. WITH THAT, SEEING NO OTHER |
| 4 | COMMENTS DR. TROUNSON. |
| 5 | DR. TROUNSON: WELL, I AGREE VERY MUCH |
| 6 | WITH DR. PIZZO. I THINK WE ALSO NEED THERE IS |
| 7 | ALSO A NEED TO SUPPORT THE BASIC SCIENCE AS WELL |
| 8 | BECAUSE THE PH.D. ONLY IS SUFFERING AT THE HANDS OF |
| 9 | DIFFICULT GRANTSMANSHIP. SO HAVING A MIXTURE, I |
| 10 | THINK, IS IN OUR BEST INTEREST. AND THAT SHOULDN'T |
| 11 | OBSCURE THE NEED TO HAVE REALLY GOOD SCIENCE, GOOD |
| 12 | INSTITUTIONS, AND SO FORTHWITH IT. WHILE AGREEING |
| 13 | ABSOLUTELY, I JUST WANTED TO MAKE SURE THAT IT |
| 14 | WASN'T TOO PRIMARY. |
| 15 | DR. PIZZO: AND I CERTAINLY DIDN'T MEAN TO |
| 16 | NOT FOCUS ON THAT. I WAS SPECIFICALLY ASKED TO |
| 17 | SPEAK SPECIFICALLY ON PHYSICIAN/SCIENTISTS, BUT I |
| 18 | WOULD ADD THAT MANY INSTITUTIONS, INCLUDING OURS, |
| 19 | ARE FOCUSING ON PH.D. SCIENTISTS WHO ARE LEARNING |
| 20 | FROM TRANSLATIONAL MEDICINE AS WELL. |
| 21 | CHAIRMAN KLEIN: THANK YOU. IN FACT, IN |
| 22 | YOUR NEW BUILDING YOU HAVE CLINICAL BENCHES IN THE |
| 23 | BASIC SCIENCES LAB SUITE TO GET AN INTEGRATION AND |
| 24 | CONTRIBUTION FROM BOTH THE BASIC AND CLINICAL SIDE. |
| 25 | SO WITH THAT, TO GIVE JEFF SHEEHY A SENSE |
| | |

| 1 | OF THE TIME TO WORK WITH, IS IT THE SENSE OF THE |
|----|--|
| 2 | BOARD THAT YOU WANT TO QUIT NOW AND GO TOMORROW |
| 3 | MORNING, OR DO YOU WANT TO GET THROUGH TIER 1, WHICH |
| 4 | HOPEFULLY, I THINK, WE CAN DO PRETTY QUICKLY? WHAT |
| 5 | IS YOUR SENSE ON TIMING? SHALL WE TRY 15 MINUTES OR |
| 6 | SO TO GET THROUGH TIER 1? FLOYD IS NODDING HIS |
| 7 | HEAD. I CAN'T SEE THE OTHER SIDE. |
| 8 | GIVEN WHAT WE'VE BEEN THROUGH THUS FAR |
| 9 | TODAY ABOUT QUORUMS AND MAKING SURE WE'RE INSULATED, |
| 10 | HOW ABOUT GIVING JEFF JUST 15 MINUTES TO SEE IF WE |
| 11 | CAN GET THROUGH TIER 1? IS THAT ALL RIGHT? |
| 12 | MR. SHEEHY: AND SO IF WE CAN THROW UP |
| 13 | TIER 1, AND I THINK, REALLY, WE JUST WANT TO ASK ONE |
| 14 | QUESTION. IS THERE ANY ITEM IN TIER 1, IS THERE A |
| 15 | MOTION TO MOVE ANY OF THOSE OUT OF TIER 1, EITHER |
| 16 | INTO TIER 2 OR TIER 3? |
| 17 | CHAIRMAN KLEIN: AND THESE ARE PROVISIONAL |
| 18 | VOTES THAT WILL BE REVISITED WE WILL HAVE THE |
| 19 | OPPORTUNITY TO VISIT TOMORROW; IS THAT CORRECT, |
| 20 | JEFF? |
| 21 | MR. SHEEHY: RIGHT. RIGHT. |
| 22 | CHAIRMAN KLEIN: THIS IS A PROVISIONAL |
| 23 | APPROVAL, WHICH IF WE DON'T CHANGE IT TOMORROW, |
| 24 | WOULD STAND AS AN APPROVAL. |
| 25 | MS. SAMUELSON: COULD YOU REMIND US OF THE |
| | 134 |
| | I 34 |

| 1 | ORIGINALLY APPROVED AMOUNT AND NUMBER OF GRANTS AND |
|----|--|
| 2 | THE AMOUNT AND NUMBER OF GRANTS WE'VE GOT IN TIER 1? |
| 3 | CHAIRMAN KLEIN: I'M GOING TO GO TO JEFF |
| 4 | AS SOON AS WE ANSWER THIS QUESTION, IF WE COULD THEN |
| 5 | GO TO JAMES HARRISON. IT'S 41 MILLION ORIGINALLY |
| 6 | BUDGETED, AND THERE'S 40 MILLION ORIGINALLY |
| 7 | BUDGETED, 51 MILLION IN TIER 1 AS IT SITS RIGHT NOW. |
| 8 | MR. SHEEHY: EVENLY DIVIDED, TEN |
| 9 | PHYSICIAN/SCIENTISTS AND TEN BASIC SCIENTISTS. |
| 10 | MR. HARRISON: AS LONG AS WE HAVE A QUORUM |
| 11 | THIS EVENING, THE BOARD CAN TAKE ACTION ON MOTIONS |
| 12 | TO MOVE APPLICATIONS FROM TIER 1 TO TIER 3. THE |
| 13 | FINAL VOTE TO APPROVE ALL OF THE APPLICATIONS IN |
| 14 | TIER 1 AND TO NOT FUND THOSE IN TIER 3 GENERALLY |
| 15 | HAPPENS AFTER WE'VE GOTTEN THROUGH ALL OF THE |
| 16 | MOTIONS TO MOVE APPLICATIONS. |
| 17 | CHAIRMAN KLEIN: I UNDERSTAND THAT, BUT |
| 18 | CAN WE DO A CONDITIONAL PROVISIONAL VOTE ON TIER 1 |
| 19 | THAT WOULD STAND IF WE LOSE OUR QUORUM TOMORROW? I |
| 20 | KNOW I'VE NEVER ASKED YOU THE QUESTION BEFORE. |
| 21 | MR. HARRISON: WELL, I SUPPOSE IF THE |
| 22 | MOTION IS FRAMED THAT WAY, YES. |
| 23 | CHAIRMAN KLEIN: OKAY. THAT'S WHAT I HAD |
| 24 | EXPECTED AND THANK YOU. IF THAT'S THE DESIRE OF THE |
| 25 | BOARD, AS INSURANCE WE HAVE THE OPTION TO DO THAT. |
| | 125 |

| 1 | THANK YOU. |
|----|--|
| 2 | MR. SHEEHY: I KNOW YOU HAVE IT IN YOUR |
| 3 | BOOKLETS, AND MAYBE IF WE COULD THROW UP THE |
| 4 | EXISTING TIER 1. AND IF THE MEMBER MY COLLEAGUES |
| 5 | WOULD LIKE TO JUST LOOK AT THOSE IN TIER 1, WHICH |
| 6 | WILL BE WHITE IN YOUR BOOK, ARE THERE ANY OF |
| 7 | THESE IS THERE ANY MOTION TO MOVE ANY OF THESE IN |
| 8 | TIER 1 TO TIER 3 BECAUSE WE'RE ALREADY OVER BUDGET? |
| 9 | SO WHATEVER WE DON'T LEAVE IN TIER 1 IS NOT GOING TO |
| 10 | GET FUNDED. |
| 11 | IF THERE IS NO MOTION DO SO, WE'VE |
| 12 | DISPENSED WITH TIER 1. |
| 13 | CHAIRMAN KLEIN: SO WE CAN DO A |
| 14 | CONDITIONAL APPROVAL IN A MOTION, WHICH WE COULD |
| 15 | HAVE THE ABILITY TO CHANGE TOMORROW IF WE HAVE A |
| 16 | QUORUM. |
| 17 | MR. SHEEHY: IS THERE A MOTION TO APPROVE? |
| 18 | IF YOU'RE OKAY WITH IT, JAMES. I SEE THAT LOOK. |
| 19 | MR. HARRISON: WE NEED TO BE A LITTLE BIT |
| 20 | CAREFUL HERE BECAUSE BOARD MEMBERS WHO HAVE AN |
| 21 | INTEREST IN APPLICATIONS IN TIER 1 CANNOT |
| 22 | PARTICIPATE EITHER IN THE MOTION OR THE DISCUSSION |
| 23 | OF IT. |
| 24 | CHAIRMAN KLEIN: THAT'S RIGHT. |
| 25 | MR. HARRISON: WHICH IS WHY WE TYPICALLY |
| | 136 |
| | 130 |

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| 1 | VOTE INDIVIDUALLY ON MOTIONS TO MOVE APPLICATIONS |
|----|--|
| 2 | AROUND AND THEN VOTE ON THE ENTIRE CATEGORY. |
| 3 | UNDERSTANDING THAT WE'RE GOING TO HAVE TO |
| 4 | CHAIRMAN KLEIN: INNOVATE. SO THE POINT |
| 5 | IS THAT, AS SOMEONE WITHOUT A CONFLICT, I, FOR |
| 6 | EXAMPLE, COULD MAKE A CONDITIONAL MOTION. SOMEONE |
| 7 | ELSE WITHOUT A CONFLICT COULD DO SO. AND THE |
| 8 | MEMBERS COULD THEN VOTE TO APPROVE EXCEPT FOR THOSE |
| 9 | WITH WHICH THEY HAVE A CONFLICT. |
| 10 | MR. HARRISON: CORRECT. I THINK WE WOULD |
| 11 | JUST NEED TO MAKE CLEAR THAT THE MOTION WILL BE |
| 12 | EFFECTIVE UNLESS THE BOARD TAKES A VOTE TO MODIFY IT |
| 13 | TOMORROW. |
| 14 | CHAIRMAN KLEIN: EXACTLY. SO IN THAT |
| 15 | SPIRIT, I WOULD MAKE A MOTION TO PROVISIONALLY AND |
| 16 | CONDITIONALLY APPROVE THIS UNLESS THE BOARD TAKES AN |
| 17 | ACTION TOMORROW TO MODIFY THE APPROVAL TONIGHT. AND |
| 18 | SO IN THAT SENSE, IT'S PROVISIONAL, BUT IT WILL |
| 19 | STAND IF WE DO NOT MODIFY IT TOMORROW. |
| 20 | MR. HARRISON: AGAIN, JUST TO REMIND THE |
| 21 | MEMBERS, ONLY THOSE WHO DON'T HAVE AN INTEREST IN |
| 22 | ANY APPLICATION IN TIER 1 CAN SECOND THE MOTION. |
| 23 | DR. LOVE: I'LL SECOND. |
| 24 | MR. SHEEHY: I BELIEVE ONLY THOSE WITHOUT |
| 25 | AN INTEREST IN TIER 1 CAN ENGAGE IN DISCUSSION. SO |
| | 137 |

| 1 | IS THERE ANYONE UNCONFLICTED? |
|----|--|
| 2 | CHAIRMAN KLEIN: SO, JAMES AND SCOTT, |
| 3 | WOULD YOU READ THE NAMES OF THE MEMBERS WHO ARE NOT |
| 4 | CONFLICTED, WHO HAVE NO CONFLICTS. |
| 5 | MR. HARRISON: IT'S GOING TO TAKE US A |
| 6 | MINUTE BECAUSE WE HAVE THE LIST OF THOSE WHO DO HAVE |
| 7 | CONFLICTS, SO WE HAVE TO EXTRAPOLATE. |
| 8 | CHAIRMAN KLEIN: IF YOU READ THE LIST OF |
| 9 | THOSE WHO DO HAVE CONFLICTS, BY EXCEPTION WE WILL |
| 10 | MR. HARRISON: WE'RE HAPPY TO DO THAT. |
| 11 | AND I APOLOGIZE. THERE WILL BE SOME REPETITION |
| 12 | BECAUSE WE'LL JUST BE READING THE LIST OF ALL THE |
| 13 | APPLICATIONS IN TIER 1. |
| 14 | DR. PIZZO: WHY NOT JUST GO AROUND THE |
| 15 | TABLE AND ASK BECAUSE THEY'LL KNOW WHETHER THEY HAVE |
| 16 | CONFLI CTS. |
| 17 | CHAIRMAN KLEIN: I THINK THE MORE |
| 18 | CONSERVATIVE VIEWPOINT, DR. PIZZO, WOULD BE TO LIST |
| 19 | THOSE WHO HAVE CONFLICTS. |
| 20 | MR. HARRISON: I'LL READ THE LIST. BEAR |
| 21 | WITH ME. FEIT. THESE ARE THE LIST OF ALL OF THOSE |
| 22 | MEMBERS WHO HAVE AN INTEREST IN APPLICATIONS IN TIER |
| 23 | 1. AND I WILL TRY TO SKIP OVER NAMES WHERE I CAN. |
| 24 | FEIT, HAWGOOD, LANSING, SHEEHY, BRYANT, STEWARD, |
| 25 | PENHOET, PRICE, POMEROY, BLOOM, BRENNER, REED, |
| | 138 |

| _ | 2.505 0012250 2150 |
|----|--|
| 1 | DAFOE, GOLDBERG, PI ZZO. |
| 2 | CHAIRMAN KLEIN: WHILE HE'S LOOKING FOR |
| 3 | ANY OTHER CONFLICTS, AGAIN, THIS MOTION IS WITHOUT |
| 4 | PREJUDICE TO THE ABILITY TO BRING UP AN ITEM IN TIER |
| 5 | 1 TOMORROW AND DEBATE IT FULLY. |
| 6 | MR. HARRISON: THAT ENCOMPASSES THE NAMES |
| 7 | OF ALL THE MEMBERS WHO HAVE AN INTEREST IN AN |
| 8 | APPLICATION IN TIER 1 AND WHO ARE PRESENT HERE |
| 9 | TONI GHT. |
| 10 | MEMBER JACOB LEVIN AS WELL. |
| 11 | CHAIRMAN KLEIN: SO IS THERE ANY |
| 12 | MR. SHEEHY: IS THERE ANY DISCUSSION FROM |
| 13 | AN UNCONFLICTED MEMBER? IS THERE ANY PUBLIC |
| 14 | COMMENT? |
| 15 | DR. LOVE: COULD WE SEE THE ALLOCATION OF |
| 16 | DOLLARS ON THE HISTOGRAM SO THAT WE CAN KIND OF SEE |
| 17 | WHERE MONEY IS BEING EXPENDED, WHERE WE, LET'S SAY, |
| 18 | FOR EXAMPLE, \$40 MILLION. |
| 19 | DR. YAFFE: I DON'T BELIEVE YOU CAN SEE |
| 20 | THAT ON THE HISTOGRAM. I CAN TELL YOU THAT |
| 21 | INFORMATION. ACTUALLY IF WE GO BACK TO THE LIST OF |
| 22 | GRANTS, I CAN TELL YOU. |
| 23 | WHILE THEY'RE GETTING THIS UP, LET ME |
| 24 | CLARIFY THAT THE HISTOGRAM WAS THE STARTING POINT |
| 25 | FOR THE WORKING GROUP, AND THEN GRANTS WERE MOVED UP |
| | |
| | 139 |

| 1 | AND DOWN ON THAT HISTOGRAM. SO IT NO LONGER |
|----|---|
| 2 | REPRESENTS ACTUALLY THE RECOMMENDATION. IT |
| 3 | REPRESENTS THE STARTING POINT. |
| 4 | \$40.6 MILLION WOULD INCLUDE 910 AND ABOVE, |
| 5 | APPLICATION 910 AND ABOVE. THE TITLE STARTS OUT |
| 6 | "DERIVATION AND CHARACTERIZATION." RIGHT THERE |
| 7 | WHERE THE POINTER IS. |
| 8 | TO INCLUDE THE NEXT TWO GRANTS WOULD TAKE |
| 9 | US TO \$46.8 MILLION. TO INCLUDE THE NEXT TWO |
| 10 | GRANTS, WHICH BRINGS US TO THE BOTTOM OF THE |
| 11 | RECOMMENDED CATEGORY, TAKES US TO 51.7. |
| 12 | CHAIRMAN KLEIN: MR. SHEEHY, COULD I MAKE |
| 13 | A COMMENT HERE? I POINT OUT THAT FOUR OF THE |
| 14 | GRANTS FOUR OF THE FIVE GRANTS BELOW THAT \$40 |
| 15 | MILLION CUTOFF ARE PHYSICIAN/SCIENTISTS. AND |
| 16 | PHYSICIAN/SCIENTISTS ARE COMPETING IN AN AREA WHERE |
| 17 | WE DESPERATELY NEED A REASONABLE DISTRIBUTION OF |
| 18 | PHYSICIAN/SCIENTISTS, PARTICULARLY BECAUSE, IF YOU |
| 19 | LOOK AT THE BALANCE ON THE TOTAL SHOWN EARLIER IN |
| 20 | THE FIRST ROUND, THERE WERE MANY FEWER |
| 21 | PHYSICIAN/SCIENTISTS. THERE WERE 16 BASIC |
| 22 | SCIENTISTS AND SIX PHYSICIAN/SCIENTISTS. |
| 23 | SO WE'RE WORKING ON AN OVERALL PORTFOLIO, |
| 24 | WE'RE WORKING AT A DEFICIT HERE, AND IT IS VERY |
| 25 | IMPORTANT PROGRAMMATICALLY TO NOTICE THAT FOUR OUT |
| | 1.10 |

| 1 | OF THOSE LAST FIVE ARE PHYSICIAN/SCIENTISTS. |
|----|---|
| 2 | MS. SAMUELSON: WEREN'T THEY ALSO WHERE |
| 3 | THE GRANTS WENT WHEN THE WORKING GROUP DECIDED TO |
| 4 | MOVE GRANTS UP INTO THE FUNDABLE RANGE DURING THE |
| 5 | PROGRAMMATIC REVIEW? SO THOSE WERE THE ONES THAT |
| 6 | THEY PARTICULARLY SAW. MAY NOT MEAN THEY LIKED THEM |
| 7 | MORE, BUT THEY CERTAINLY DIDN'T LIKE THEM LESS. |
| 8 | CHAIRMAN KLEIN: I THINK JOAN IS MAKING |
| 9 | THE POINT THAT THE BOTTOM TWO OUT OF THAT FIVE ARE |
| 10 | ONES THAT WERE CLEARLY MOVED UP BY THE PEER REVIEW |
| 11 | GROUP. |
| 12 | MR. SHEEHY: DO WE HAVE PUBLIC COMMENT? |
| 13 | MR. SIMPSON: THIS IS JOHN SIMPSON FROM |
| 14 | CONSUMER WATCHDOG. MORE BY WAY OF A QUESTION, CAN |
| 15 | YOU GO OVER YOUR BUDGET? CAN YOU DO YOU HAVE THE |
| 16 | EXTRA ELEVEN? |
| 17 | CHAIRMAN KLEIN: YES. |
| 18 | MR. SIMPSON: DO YOU HAVE THE EXTRA 30 |
| 19 | BECAUSE I WOULD MAKE THE CASE THAT YOU MIGHT |
| 20 | SERIOUSLY BE CONSIDERING MOVING ALL OF TIER 2 UP |
| 21 | BECAUSE NEW FACULTY ARE CRITICAL. EVERYONE AGREES |
| 22 | THAT THEY'RE NOT GETTING FUNDED. THIS OUGHT TO BE A |
| 23 | PRI ORI TY. |
| 24 | MR. SHEEHY: SURE. PLEASE ANSWER. I'M |
| 25 | REALLY RELUCTANT TO SAY ANYTHING FROM MY CHAIR |
| | 141 |
| | |

| 1 | BECAUSE OF THE CONFLICTS ISSUE OTHER THAN TO JUST |
|----|---|
| 2 | ADMINISTER. |
| 3 | CHAIRMAN KLEIN: THE WAY THE INITIATIVE IS |
| 4 | WRITTEN IS FUNDS NOT USED IN ANY YEAR ACCRUE, SO |
| 5 | THEY'RE PULLED FORWARD. SO WE HAVE, BECAUSE OF THE |
| 6 | TWO YEARS WE LOST IN LITIGATION, WE HAVE A VERY |
| 7 | LARGE ACCRUED RESERVE THAT CAN BE APPLIED WHERE, |
| 8 | THROUGH PROPER STEWARDSHIP, WE'RE ADDRESSING REAL |
| 9 | PRIORITIES FOR SCIENCE AND FOR MEDICINE AND OUR |
| 10 | MISSION OBJECTIVES. |
| 11 | MR. REED: I WONDER IF WE COULD GO BACK TO |
| 12 | ONE SLIDE WHICH SHOWED THE TURTLE. THERE'S A |
| 13 | PICTURE OF A TURTLE UNDER THERE. |
| 14 | CHAIRMAN KLEIN: DON, WE CAN VISUALIZE IT. |
| 15 | MR. REED: OKAY. I AM THE ONLY PERSON IN |
| 16 | THIS ROOM THAT HAS EXPERTISE IN THIS AREA. THAT'S |
| 17 | THE SEA TURTLE. THAT'S KNOWN AS THE RIDLEY SEA |
| 18 | TURTLE. IT WAS CONSIDERED TO BE A |
| 19 | ONE-GENERATION-ONLY ANIMAL. IT WAS LIKE THE STERILE |
| 20 | CROSS BREEDING OF A HORSE AND MULE, WHATEVER, IT |
| 21 | BECOMES A DONKEY AND IT GETS STERILE. WELL, THIS IS |
| 22 | CONSIDERED TO BE THE GREEN AND LOGGERHEAD IS A |
| 23 | STERILE SPECIES. INSTEAD, IT BECAME ONE OF THE MOST |
| 24 | BEAUTIFUL AND SUCCESSFUL REPTILES OF ALL TIME AND |
| 25 | IT'S STILL AROUND TODAY. |
| | 1/12 |

| 1 | AND I JUST WOULD SUGGEST THAT WHAT YOU ARE |
|----|--|
| 2 | DOING HERE IS NOT JUST FOR THE ONE TIME, BUT IT WILL |
| 3 | ESTABLISH A PATTERN FOR MANY, MANY OTHER PROGRAMS TO |
| 4 | COME. THANK YOU. |
| 5 | MR. SHEEHY: IS THERE ADDITIONAL PUBLIC |
| 6 | COMMENT? ANY OTHER COMMENTS FROM THE BOARD? I |
| 7 | THINK WE GO TO A VOTE IF PERHAPS I THINK WE NEED |
| 8 | DAVID SERRANO-SEWELL FOR A QUORUM. |
| 9 | MS. KING: HE'S ON HIS WAY. HE'S PROBABLY |
| 10 | GOING TO BE ABOUT 30 SECONDS. TALK AMONGST |
| 11 | YOURSELVES. |
| 12 | MR. HARRISON: WHILE DAVID IS COMING BACK, |
| 13 | I WOULD JUST REMIND MEMBERS WHEN THEY VOTE ON THIS |
| 14 | ITEM TO MAKE SURE TO VOTE TO APPROVE OR DISAPPROVE |
| 15 | EXCEPT AS TO THOSE APPLICATIONS IN WHICH YOU HAVE A |
| 16 | CONFLICT OF INTEREST. |
| 17 | MR. SHEEHY: AND, JAMES, YOU WANT TO GO |
| 18 | AHEAD, AND DO YOU REMIND RESTATING THE MOTION WHILE |
| 19 | WE'RE WAITING FOR DAVID? |
| 20 | MR. HARRISON: YES. THE MOTION IS TO |
| 21 | APPROVE THE APPLICATIONS IN TIER 1 CONDITIONALLY. |
| 22 | THE MOTION WILL BE EFFECTIVE UNLESS THE ICOC TAKES |
| 23 | ADDITIONAL ACTION WITH RESPECT TO THE APPLICATIONS |
| 24 | IN TIER 1 TOMORROW. |
| 25 | MR. ROTH: MR. CHAIRMAN, WHILE WE'RE |
| | 143 |

| 1 | WAITING, CAN I ASK A QUESTION ABOUT ANY PRECEDENT |
|----|--|
| 2 | FOR PARTIAL FUNDING OF GRANTS? |
| 3 | CHAIRMAN KLEIN: CERTAINLY. SO, MR. |
| 4 | HARRISON, WHAT IS OUR ABILITY, WHETHER TONIGHT OR |
| 5 | TOMORROW, TO DECIDE THAT WE'RE GOING TO FUND SOME OF |
| 6 | THE GRANTS OR ALL OF THEM AT A LOWER LEVEL THAN THE |
| 7 | REQUESTED AMOUNT, BUT STILL FUND THE GRANTS? |
| 8 | MR. HARRISON: THE BOARD, OF COURSE, HAS |
| 9 | THE ULTIMATE AUTHORITY TO MAKE SUCH A DECISION. I |
| 10 | WOULD DEFER TO SCIENTIFIC STAFF FOR COMMENT ABOUT |
| 11 | THE WISDOM OF SUCH A MOVE, BUT LEGALLY YOU'RE |
| 12 | ENTITLED TO. |
| 13 | CHAIRMAN KLEIN: JUST AS A VARIATION, SO |
| 14 | WE CAN GET THE PRESIDENT'S FULL COMMENT, |
| 15 | THEORETICALLY IN CATEGORY 2, IF WE COULD APPROVE IT |
| 16 | FOR THREE YEARS INSTEAD OF FIVE YEARS, INSTEAD OF |
| 17 | CUTTING A PERCENTAGE OFF EACH YEAR. |
| 18 | MR. HARRISON: THAT'S CORRECT. |
| 19 | DR. TROUNSON: SO, MR. CHAIR, I'D STRONGLY |
| 20 | ADVISE AGAINST EITHER OF THOSE MOVES. ONE IN WHICH |
| 21 | THE APPLICANTS HAVE BEEN ASKED TO PROVIDE A BUDGET |
| 22 | THAT WOULD COVER THE PROGRAM, THAT WE HAVE STARTED |
| 23 | TO INTERROGATE TO ENSURE THAT THE AMOUNTS THAT THEY |
| 24 | REQUESTED ARE SUITABLE FOR DOING THE JOB. |
| 25 | I THINK THE WORST SITUATION FOR |
| | 144 |
| | I TT |

| 1 | RESEARCHERS AT ANY TIME IS TO GET AN INSUFFICIENT |
|----|--|
| 2 | AMOUNT TO DO THE WORK THAT YOU'RE ASKING THEM TO DO. |
| 3 | SO I WOULDN'T BE IN FAVOR OF REDUCING THE AMOUNT, AT |
| 4 | LEAST NOT WITHOUT NEGOTIATING DIRECTLY WITH THE |
| 5 | APPLICANTS. AND I THINK THAT WOULD BE THAT WOULD |
| 6 | BE A DIFFICULT NEGOTIATION. |
| 7 | SECONDLY, I THINK THE UNDERSTANDING |
| 8 | AMONGST THE APPLICANTS IS THAT THE APPOINTMENT IS |
| 9 | FOR THE LENGTH OF THE FIVE YEARS. AND SO CREATING A |
| 10 | DIFFERENT SET WILL CERTAINLY CREATE SOME CONCERNS |
| 11 | ABOUT THE APPLICANTS OF THE INFORMATION THAT WE'RE |
| 12 | PROVIDING THEM. AND THE INSTITUTIONS, I DARE SAY, |
| 13 | WOULD HAVE A VERY STRONG VIEW ABOUT THIS, I'D |
| 14 | I MAGI NE. |
| 15 | CHAIRMAN KLEIN: DR. TROUNSON, AS A |
| 16 | VARIATION ON THAT, IF IN THE MIDDLE CATEGORY THERE'S |
| 17 | A CONCERN ABOUT WHETHER THE RESULTS ARE ACHIEVABLE, |
| 18 | IF THAT IS THE CASE, AND YOU HAVE TO LOOK AT EACH |
| 19 | GRANT, CAN YOU CONDITIONALLY SAY WE'LL APPROVE THREE |
| 20 | YEARS; AND IF YOU HAVE MADE SUFFICIENT PROGRESS, YOU |
| 21 | GET THE OTHER TWO? BUT ESSENTIALLY CREATE A |
| 22 | MILESTONE WITHOUT CHANGING THE AMOUNTS. |
| 23 | |
| 23 | DR. TROUNSON: WELL, AGAIN, CHAIR, WE |
| 24 | DR. TROUNSON: WELL, AGAIN, CHAIR, WE DIDN'T ASK THE REVIEWERS FOR THAT ASSESSMENT. SO WE |
| | |

| 1 | UNLESS STAFF ARE CHARGED WITH THAT ISSUE. AND I |
|----|--|
| 2 | DON'T THINK THAT'S I DON'T THINK THAT'S THE |
| 3 | INTENTION OF THE ICOC TO DO THAT. |
| 4 | SO, AGAIN, THAT WOULD CREATE A MUCH LONGER |
| 5 | PHASE. I THINK YOU SHOULD, IN MY OWN VIEW, MAKE |
| 6 | IF YOU ARE CONSTRAINED BY THE BUDGET, AS WE SHOULD |
| 7 | BE IN THESE TIMES, PERHAPS THEN GO FOR THE BEST |
| 8 | QUALITY, THE BEST OUTCOME, YOU KNOW, BASED ON THE |
| 9 | CRITERIA AND BASED ON THE GRANT WORKING GROUP'S |
| 10 | RECOMMENDATION AND WHAT YOU HEARD IN CLOSED SESSION. |
| 11 | I'D STRONGLY RECOMMEND YOU TRAVEL ON THAT ROAD, YOU |
| 12 | KNOW, FOR THE WHOLE OF THE ICOC AND FOR THE SAKE OF |
| 13 | THE ABILITY OF THE MANAGEMENT TO DEAL WITH THE |
| 14 | ISSUES AS THEY MAY COME UP. |
| 15 | CHAIRMAN KLEIN: JEFF SHEEHY, I THINK |
| 16 | WE'RE GOING TO LOSE DAVID UNLESS WE HAVE A MOTION. |
| 17 | MR. SHEEHY: I THINK WE'RE READY TO CALL |
| 18 | THE ROLL. DO WE NEED TO REPEAT THE MOTION FOR YOU, |
| 19 | DAVI D? |
| 20 | MS. KING: DONALD DAFOE. |
| 21 | DR. DAFOE: APPROVE EXCEPT FOR THOSE WITH |
| 22 | WHICH I HAVE A CONFLICT. |
| 23 | MS. KING: ROBERT PRICE. |
| 24 | DR. PRICE: APPROVE EXCEPT FOR THOSE WITH |
| 25 | WHICH I HAVE A CONFLICT. |
| | 144 |

| | DARRISTERS REPORTING SERVICE |
|----|--|
| 1 | MS. KING: FLOYD BLOOM. |
| 2 | DR. BLOOM: APPROVE EXCEPT FOR THOSE WITH |
| 3 | WHICH I HAVE A CONFLICT. |
| 4 | MS. KING: DAVID BRENNER. |
| 5 | DR. BRENNER: APPROVE EXCEPT FOR THOSE |
| 6 | WITH WHICH I HAVE A CONFLICT. |
| 7 | MS. KING: JACOB LEVIN. |
| 8 | DR. LEVIN: APPROVE EXCEPT FOR THOSE WITH |
| 9 | WHICH I HAVE A CONFLICT. |
| 10 | MS. KING: MICHAEL FRIEDMAN. |
| 11 | DR. FRIEDMAN: APPROVE EXCEPT FOR THOSE |
| 12 | WITH WHICH I HAVE A CONFLICT. |
| 13 | MS. KING: MICHAEL GOLDBERG. |
| 14 | MR. GOLDBERG: APPROVE EXCEPT FOR THOSE |
| 15 | WITH WHICH I HAVE A CONFLICT. |
| 16 | MS. KING: BOB KLEIN. |
| 17 | CHAIRMAN KLEIN: APPROVE. |
| 18 | MS. KING: SHERRY LANSING. |
| 19 | MS. LANSING: APPROVE EXCEPT FOR THOSE |
| 20 | WITH WHICH I'M CONFLICTED. |
| 21 | MS. KING: TED LOVE. |
| 22 | DR. LOVE: APPROVED. |
| 23 | MS. KING: ED PENHOET. |
| 24 | DR. PENHOET: APPROVE EXCEPT FOR THOSE |
| 25 | WITH WHICH I HAVE A CONFLICT. |
| | 1.47 |
| | 147 |

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| | BARRISTERS' REPORTING SERVICE |
|----|---|
| 1 | MS. KING: PHIL PIZZO. |
| 2 | DR. PIZZO: APPROVE EXCEPT FOR THOSE WITH |
| 3 | WHICH I HAVE A CONFLICT. |
| 4 | MS. KING: CLAIRE POMEROY. |
| 5 | DR. POMEROY: APPROVE EXCEPT FOR THOSE |
| 6 | WITH WHICH I HAVE A CONFLICT. |
| 7 | MS. KING: ROBERT QUINT. |
| 8 | DR. QUINT: APPROVE. |
| 9 | MS. KING: DUANE ROTH. |
| 10 | MR. ROTH: APPROVED. |
| 11 | MS. KING: JOAN SAMUELSON. |
| 12 | MS. SAMUELSON: APPROVED. |
| 13 | MS. KING: DAVID SERRANO-SEWELL. |
| 14 | MR. SERRANO-SEWELL: APPROVED. |
| 15 | MS. KING: JEFF SHEEHY. |
| 16 | MR. SHEEHY: APPROVE EXCEPT FOR THOSE WITH |
| 17 | WHICH I HAVE A CONFLICT. |
| 18 | MS. KING: OSWALD STEWARD. |
| 19 | DR. STEWARD: APPROVE EXCEPT FOR THOSE |
| 20 | WITH WHICH I HAVE A CONFLICT. |
| 21 | MS. KING: MOTION CARRIES. |
| 22 | MR. SHEEHY: THANK YOU. TURN IT BACK TO |
| 23 | BOB. |
| 24 | CHAIRMAN KLEIN: THANK YOU ALL. IT'S BEEN |
| 25 | AN INNOVATIVE, WONDERFUL EVENING. WE DEEPLY |
| | 148 |
| | |

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1
     APPRECIATE EVERYONE'S COMMITMENT, AND WE DEEPLY
 2
     APPRECIATE THE SCIENTISTS AND THE FACULTY AND THE
     STAFF OF THIS AGENCY FOR THEIR TREMENDOUS
 3
 4
     COMMITMENT. THANK YOU. GOOD NIGHT.
 5
                      (THE MEETING WAS THEN CONCLUDED AT
     09: 30 P.M.)
 6
 7
 8
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11
12
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14
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16
17
18
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20
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24
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                                149
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REPORTER'S CERTIFICATE

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

STANFORD UNIVERSITY
ARRILLAGA ALUMNI CENTER, MC GAW HALL
326 GALVEZ STREET
STANFORD, CALIFORNIA
ON
AUGUST 12, 2008

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. Whave
BETH C. DRAIN, CSR 7152
BARRISTER'S REPORTING SERVICE
1072 BRISTOL STREET
SUITE 100
COSTA MESA, CALIFORNIA
(714) 444-4100