BEFORE THE

INTELLECTUAL PROPERTY TASK FORCE OF THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: SACRAMENTO CONVENTION CENTER
1400 J STREET, ROOM 103
SACRAMENTO, CALIFORNIA

DATE: TUESDAY, OCTOBER 25, 2005
1:57 P.M.

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I N D E X

SACRAMENTO, CALIFORNIA; TUESDAY, OCTOBER 25, 2005

01:57 P.M.

CHAIRMAN PENHOET: IT'S 2 O'CLOCK, SO WE'LL BEGIN THIS MEETING. THANK YOU ALL FOR COMING. THANKS TO MY COLLEAGUES FROM THE ICOC, ALL MEMBERS OF THE IP TASK FORCE. WE'RE EXPECTING TWO MORE OF US AT THIS TABLE HOPEFULLY SHORTLY. AND WE ARE HERE TODAY TO GATHER INFORMATION. THIS IS NOT A DECISION-MAKING MEETING. THIS IS A MEETING FOR US TO HEAR PRIMARILY THE WORK OF THE CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY AND ALSO TO HEAR FROM FRED DOREY, WHO IS A LONGTIME PARTICIPANT IN THE BIOTECHNOLOGY INDUSTRY IN CALIFORNIA, TO GIVE SOME PERSPECTIVE ON THE BIRTH AND GROWTH OF THAT INDUSTRY IN THE STATE.

AND THEN FOLLOWING THOSE TWO PRESENTATIONS, WE'LL HAVE AN OPPORTUNITY FOR PUBLIC COMMENT. AND WE HAVE PUT A SIGN-UP SHEET NEXT TO MELISSA ON THE TABLE. I THINK, GIVEN THE SIZE OF THIS AUDIENCE, WE PROBABLY HAVE TIME FOR TEN-MINUTE PRESENTATIONS FROM ANY MEMBER OF THE PUBLIC WHO WISHES TO INFORM US ABOUT ISSUES RELATED TO INTELLECTUAL PROPERTY AND THE CIRM.

SO OUR TASK FORCE HAS THE CHARGE OF COMING UP WITH TWO PRODUCTS. ONE, AN INTERIM INTELLECTUAL PROPERTY POLICY, WHICH WE HOPE TO DEVELOP LITERALLY

OVER THE NEXT SIX WEEKS, SO THAT IT COULD BECOME APPLICABLE TO THE FIRST ROUND OF GRANTS, WHICH ARE TRAINING GRANTS. I MIGHT SAY IN THAT REGARD THAT, IN GENERAL, THERE AREN'T HIGH EXPECTATIONS FOR INTELLECTUAL PROPERTY BEING DEVELOPED IN TRAINING GRANTS BECAUSE THE PURPOSE OF TRAINING GRANTS IS NOT TO DEVELOP IP, BUT, IN FACT, TO TRAIN PEOPLE IN THIS FIELD. BUT ON THE OUTSIDE CHANCE THAT SOME TRAINEE STUMBLES ACROSS SOMETHING OF GREAT INTEREST AND CREATES INTELLECTUAL PROPERTY, WE THINK IT'S WISE FOR US TO GENERATE AN INTERIM POLICY.

AND THEN FINALLY, OVER THE NEXT COMING SEVERAL MONTHS AND CERTAINLY BEFORE WE MAKE ANY REGULAR RESEARCH GRANTS, WE WOULD LIKE TO HAVE A FINAL INTELLECTUAL PROPERTY POLICY IN PLACE.

SO JUST TO REMIND EVERYONE WHAT PROP 71 SAYS, AMONG OTHER THINGS, ON THIS ISSUE, YOU CAN READ THE SLIDE FOR YOURSELF, BUT BASICALLY IT SAYS THE ICOC SHALL ESTABLISH STANDARDS RELATED TO INTELLECTUAL PROPERTY. AND MAYBE EMPHASIZE THE LAST PART OF THE SENTENCE, WITH THE NEED TO ASSURE THAT ESSENTIAL MEDICAL RESEARCH IS NOT UNREASONABLY HINDERED BY INTELLECTUAL PROPERTY AGREEMENTS. SO THIS WAS ANTICIPATED CLEARLY WITHIN THE CONTEXT OF THE INITIATIVE ITSELF.

REMIND YOU AGAIN WHAT PROP 71 DOES. IT AUTHORIZES $295 MILLION A YEAR FOR TEN YEARS TO FUND STEM CELL RESEARCH. IT ATTEMPTS TO ASSURE THAT THE RESEARCH IS DONE SAFELY AND ETHICALLY. IT PROHIBITS BY LAW THE USE OF THIS TECHNOLOGY FOR REPRODUCTIVE CLONING OF HUMANS. AND IT ALSO IS INTENDED TO HAVE A BENEFIT TO CALIFORNIA'S ECONOMY AND TO ADVANCE BIOTECH INDUSTRY IN CALIFORNIA TO WORLD LEADERSHIP. MANY OF US BELIEVE CALIFORNIA DOES HAVE WORLD LEADERSHIP TODAY, BUT CERTAINLY HOPEFULLY THESE INVESTMENTS WILL ALLOW US TO CONSOLIDATE THAT POSITION.

A REMINDER THAT, IN GENERAL, PATIENTS DON'T HAVE ACCESS TO THERAPIES UNLESS SOME COMMERCIAL ORGANIZATION MAKES A LARGE INVESTMENT TO MAKE THE TECHNOLOGY PRACTICAL, TO SCALE IT UP. WE IN THE LAST SCIENCE MEETING, FOR EXAMPLE, WE WENT THROUGH A QUICK CALCULATION THAT IF YOU JUST HAD A GOOD THERAPY FOR DIABETES INVOLVING CREATION OF NEW ISLET CELLS AND YOU WANTED TO TREAT A MILLION PEOPLE WITH TEN TO THE NINTH CELLS EACH, THAT'S ABOUT 10 TO THE 15TH CELLS, FEW HUNDRED KILOGRAMS OF HUMAN ISLET CELLS. THIS CLEARLY IS AN INDUSTRIAL SCALE THAT EVENTUALLY WILL COME INTO PLAY.

SO WHAT WE'RE DOING HERE IS EXTREMELY IMPORTANT BECAUSE OUR GRANTEES ARE VERY UNLIKELY TO BE

COMMERCIAL ENTITIES THEMSELVES. WE MAY IN THE FUTURE FUND SOME COMMERCIAL ENTITIES, BUT MOST OF THE FUNDING WILL GO TO UNIVERSITIES WHO, IN TURN, WILL EMPOWER THE INDUSTRY WITH THE TECHNOLOGY TO ACTUALLY DEVELOP THERAPIES FOR PATIENTS.

YOU HAVE SOME SUPPORTING MATERIALS AVAILABLE TO YOU. WE HAVE THEM AT THIS TABLE, BUT THERE ARE BASICALLY THREE DOCUMENTS: A COPY OF THE CCST INTELLECTUAL PROPERTY REPORT, WHICH IS THE PRIMARY PURPOSE OF OUR MEETING TODAY, TO DISCUSS THAT REPORT; EXCERPTS FROM A REPORT BY THE CALIFORNIA HEALTHCARE INSTITUTE ON CALIFORNIA'S BIOMEDICAL INDUSTRY TODAY; AND THEN A MATRIX, WHICH WAS DEVELOPED BY MARY MAXON AND MYSELF, PRIMARILY MARY, IF TRUTH BE KNOWN, THAT SORT OF SUMMARIZES INTELLECTUAL PROPERTY APPROACHES BY A VARIETY OF DIFFERENT ORGANIZATIONS WHICH MAKE GRANTS AND HOW THEY DEAL WITH THOSE. SO I THINK THIS IS AN EXTREMELY IMPORTANT DOCUMENT, SO I HOPE ALL OF YOU WILL HAVE AN OPPORTUNITY TO LOOK AT THIS BECAUSE IT DOES LAY OUT A BROAD ARRAY OF POSSIBILITIES FOR DEALING WITH INTELLECTUAL PROPERTY.

IF YOU LOOK AT WHAT OUR TASK IS IN THIS GROUP, IN THE NEXT SIX WEEKS, AS I SAID, WE ARE HERE TODAY IN THE FIRST IP TASK FORCE MEETING. AND I EMPHASIZE AGAIN NO DECISIONS WILL BE MADE TODAY, NO

RECOMMENDATIONS WILL BE MADE TODAY. THE FOUR OF US WHO ARE HERE NOW, SOON HOPEFULLY TO BE JOINED BY TWO OTHERS ON OUR TASK FORCE, ARE HERE TO HEAR A REPORT, A VERBAL REPORT, ON THE CCST WORK ON IP AND ALSO HAVE THE OPPORTUNITY TO QUESTION THE GROUP FROM THE CCST, TO HEAR FROM FRED DOREY, AND TO HEAR FROM THOSE OF YOU IN THE PUBLIC WHO WOULD LIKE TO INFORM US IN ANY WAY THAT YOU CAN ABOUT THE TASK THAT WE FACE GOING FORWARD. SO THIS IS NOT A DECISION-MAKING MEETING.

NEXT MONDAY IN SAN FRANCISCO THERE IS A LEGISLATIVE HEARING. IT'S SPONSORED BY SEVERAL DIFFERENT GROUPS WITHIN THE LEGISLATURE. THAT HEARING WILL ADDRESS A NUMBER OF DIFFERENT ISSUES AROUND IP AS IT RELATES TO PROP 71. AGAIN, A NUMBER OF US FROM THIS TASK FORCE WILL BE PRESENT IN THAT MEETING, AND WE WILL BE TRYING TO LEARN AS MUCH AS WE CAN FROM THE DIVERSITY OF VIEWS WHICH HAVE BEEN SOLICITED BY THE LEGISLATURE ON WHICH WE EXPECT TO HEAR TESTIMONY NEXT MONDAY.

ON NOVEMBER 17TH THE NATIONAL RESEARCH COUNCIL OF THE NATIONAL ACADEMIES EXPECTS TO ISSUE ITS REPORT ON PATENTING GENES AND PROTEINS. THIS HAS BEEN A MULTIYEAR STUDY UNDERWAY, COMMISSIONED BY THE NATIONAL INSTITUTES OF HEALTH, LED BY SHIRLEY TILLMAN, THE PRESIDENT OF PRINCETON UNIVERSITY, A REALLY MAJOR UNDERTAKING TO ADDRESS WHAT'S BECOME A DIFFICULT AREA,

WHICH IS THE EXTENT TO WHICH PATENTS ON GENES AND PROTEINS, HOW THEY SHOULD BE DEALT WITH IN OUR SOCIETY.

THIS DOES NOT DIRECTLY -- IT WILL NOT ADDRESS STEM CELL IP; HOWEVER, I THINK MANY OF THE CONCEPTS EMBEDDED IN THAT REPORT ARE LIKELY TO HAVE SOME INFLUENCE ON OUR THINKING GOING FORWARD. SO WE LOOK FORWARD TO THAT BEING RELEASED ON THE 17TH. THEY HAVE TOLD ME IT'S THEIR EXPECTATION TO RELEASE ON THE 17TH. YOU NEVER KNOW WITH THE NATIONAL ACADEMIES WHEN IT ACTUALLY IS RELEASED. HOPEFULLY IT WILL OCCUR ON THAT DATE.

WE WILL TRY TO SCHEDULE A SECOND IP TASK FORCE MEETING SOMETIME LATE IN THE MONTH TO ATTEMPT TO MAKE SOME DECISIONS OR RECOMMENDATIONS TO THE ICOC IN ITS DECEMBER 6TH MEETING CONCERNING AN INTERIM POLICY FOR IP THAT WOULD RELATE TO THE TRAINING GRANTS THAT WE WOULD LIKE TO FURTHER AT THAT TIME. BEFORE THAT DATE, WE EXPECT TO TAKE OUR RECOMMENDATIONS IN FRONT OF THE STANDARDS WORKING GROUP TO RECEIVE ANY COMMENTS FROM THEM WITH RESPECT TO THAT. IT'S OUR UNDERSTANDING THAT THE STANDARDS WORKING GROUP DOES NOT HAVE THE PRIMARY RESPONSIBILITY FOR DEVELOPING THE POLICY, BUT ACCORDING TO PROP 71, THEY HAVE THE OPPORTUNITY TO REVIEW AND COMMENT. SO WE WILL TAKE IT TO THE STANDARDS WORKING GROUP BEFORE IT'S BROUGHT TO THE ICOC MEETING IN

DECEMBER. AND THAT'S THE PURPOSE OF THE INTERIM POLICY.

SO THAT'S THE WORK WHICH IS IN FRONT OF US AS WE SPEAK TODAY. THAT'S THE END OF MY PRESENTATION. AT THIS POINT I'D LIKE TO ASK JAMES HARRISON TO GIVE US AN OVERVIEW AND PERSPECTIVE OF WHAT PROP 71 SAYS PERHAPS IN MORE DETAIL THAN WHAT I'VE JUST LAID OUT FOR YOU. SO, JAMES.

MR. HARRISON: I'LL TRY TO DO THAT. PROP 71 REQUIRES THE ICOC TO ADOPT INTELLECTUAL PROPERTY STANDARDS FOR CIRM-FUNDED RESEARCH. AND SPECIFICALLY, AS ED NOTED, IT REQUIRES THE ICOC TO ADOPT STANDARDS TO REQUIRE THAT GRANT AWARDS INCLUDE AN INTELLECTUAL PROPERTY COMPONENT THAT BALANCES THE STATE'S OPPORTUNITY TO BENEFIT IN THE INVESTMENT WITH THE NEED TO ENSURE THAT THE ADVANCEMENT OF MEDICAL SCIENCE IS NOT UNDULY HINDERED.

THESE TWO GOALS, I THINK, BOIL DOWN TO THE DESIRE TO FOSTER AN ENVIRONMENT WHERE BASIC RESEARCH IS TRANSLATED INTO CURES AND THERAPIES AS QUICKLY AS POSSIBLE AND THE GOAL OF ENSURING THAT CALIFORNIA CITIZENS BENEFIT IN SOME WAYS FROM THEIR INVESTMENT IN THIS RESEARCH.

THE DRAFTERS OF PROPOSITION 71 RECOGNIZE THAT THESE TWIN GOALS MAY AT SOMETIMES WORK AT CROSS

PURPOSES, AND THAT FINDING A BALANCE BETWEEN THE TWO OF THEM WOULD BE A DELICATE AND COMPLEX TASK. AND FOR THAT REASON, THEY LEFT THAT TASK LARGELY IN YOUR HANDS WITH THE GUIDANCE TO TRY TO RECONCILE THOSE TWO GOALS.

CHAIRMAN PENHOET: THANK YOU. AT THIS POINT I THINK THE FIRST AND THE BULK OF THIS MEETING IS GOING TO BE CONDUCTED BY THE CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY. WE'RE DELIGHTED TO HAVE THE EXECUTIVE DIRECTOR OF THE CALIFORNIA COUNCIL, DR. SUSAN HACKWOOD, HERE TODAY, WHO HAS BEEN THE EXECUTIVE DIRECTOR OF THE CCST FOR FIVE YEARS NOW?

DR. HACKWOOD: NINE YEARS.

CHAIRMAN PENHOET: TIME GOES BY RAPIDLY. AND SUSAN AND HER COLLEAGUES, I THINK, UNDERTOOK THIS CHARGE TO COME UP WITH A SERIES OF RECOMMENDATIONS FOR US. THEY'RE EMBODIED IN THE REPORT WHICH I'M SURE ALL OF YOU HAVE SEEN AT THIS POINT IN TIME. OUR PURPOSE, AGAIN, TODAY IS TO HAVE AN OPPORTUNITY TO HEAR A VERBAL DESCRIPTION OF THE REPORT, TO ASK QUESTIONS OF THE CCST PANELISTS WHO ARE HERE WITH US TODAY, ALL OF WHOM CONTRIBUTED TO THE REPORT, AND TO GET AS RICH A DIALOGUE AROUND THIS AS WE CAN BETWEEN THOSE OF US ON THE TASK FORCE AND THOSE ON THE OTHER SIDE OF THE ROOM WHO WROTE THE REPORT. DR. HACKWOOD, TURN THE MEETING OVER TO YOU.

DR. HACKWOOD: THANK YOU. FIRST LET ME INTRODUCE WHO'S AT THE TABLE, AND THEN I'LL TELL YOU HOW WE WERE THINKING OF PRESENTING OUR IP REPORT TO YOU. I'M NOW HOTWIRED.

FIRST OF ALL, AT THE TABLE WE HAVE ALAN BENNETT, WHO IS THE ASSOCIATE VICE CHANCELLOR FOR RESEARCH FROM THE UNIVERSITY OF CALIFORNIA OF DAVIS AND HAS A LOT OF EXPERIENCE IN INTELLECTUAL PROPERTY. NEXT TO HIM IS PAM SAMUELSON, WHO IS A PROFESSOR IN THE SCHOOL OF INFORMATION MANAGEMENT AND SYSTEMS FROM THE UNIVERSITY OF CALIFORNIA BERKELEY. AND ON MY RIGHT IS STEVE ROCKWOOD, WHO IS EXECUTIVE VICE PRESIDENT OF THE SCIENCE APPLICATIONS INTERNATIONAL CORPORATION.

AND HOW WE THOUGHT WE WOULD GO THROUGH TODAY'S PRESENTATION IS I'LL GIVE YOU THE PICTURE OF WHY WE DID THIS IN THE FIRST PLACE, AND THEN MY COLLEAGUES WILL TAKE OVER AND REVIEW ASPECTS OF THE REPORT, AND PARTICULARLY ALAN AND STEVE, AND THEN PAM WILL TAKE OVER AND GIVE MORE OF -- A BROADER PICTURE OF UNDERSTANDING OF INTELLECTUAL PROPERTY WHEN IT'S GENERATED IN THIS KIND OF ARENA IN STEM CELL RESEARCH.

SO I'M PLEASED, IF YOU DO HAVE ANY QUESTIONS OR CLARIFICATIONS, GO AHEAD AND ASK. I'M SURE WE'RE WILLING AND ABLE TO BREAK AND TALK ON OTHER THINGS.

FIRST OF ALL, LET ME TELL YOU WHO WE ARE AND

WHY WE DID THIS PROJECT. WE ARE THE CALIFORNIA COUNCIL ON SCIENCE AND TECHNOLOGY, AND WE WERE CREATED AWHILE AGO. WE'VE BEEN AROUND SINCE 1988. WE WERE CREATED BY LEGISLATION FROM THE STATE, AND THE MODEL THAT IS A SIMPLE MODEL TO KEEP IN MIND, AS ED MENTIONED, THE NATIONAL RESEARCH COUNCIL AND THE NATIONAL ACADEMIES DO A LOT OF WORK IN PROVIDING INDEPENDENT ADVISING, PARTICULARLY IN SCIENCE AND TECHNOLOGY, TO THE FEDERAL GOVERNMENT. WE DO THE SAME KIND OF THINGS FOR THE STATE GOVERNMENT. WE LOOK LIKE, ACT LIKE, AND DO WORK VERY SIMILAR TO THE NATIONAL ACADEMIES. SO OUR PURPOSE IS TO PROVIDE EXPERT ADVICE IN SCIENCE AND TECHNOLOGY, PARTICULARLY STATE FOCUSED.

OUR MEMBERSHIP IS PRETTY BROAD. WE HAVE ABOUT A HUNDRED FIFTY OF THE SCIENCE AND TECHNOLOGY LEADERSHIP IN THE STATE. AND THAT IS ACROSS THE BOARD. ALL ASPECTS OF SCIENCE AND TECHNOLOGY ARE COVERED IN ACADEMIA, INDUSTRY, NOT-FOR-PROFIT ORGANIZATIONS, THE NATIONAL LABORATORIES. WE REPRESENT A VERY BROAD GROUP OF PEOPLE IN THIS ORGANIZATION. AND WE WORK ON ALL SORTS OF DIFFERENT ASPECTS OF SCIENCE AND TECHNOLOGY. RIGHT NOW WE'RE WORKING ON ENERGY RESEARCH. WE WORK ON EDUCATION. WE WORK ON GENETICALLY MODIFIED FOODS. WE WORK ON THE SCIENCE AND MATH TEACHER SHORTAGE PROBLEM. SO WE WORK ON ALL DIFFERENT ASPECTS OF SCIENCE AND

TECHNOLOGY, SO THIS CAME TO US AS ANOTHER KIND OF PROJECT WHERE WE COULD FOCUS SOME EMPHASIS AND EXPERTISE IN SCIENCE AND TECHNOLOGY ON TRYING TO ANSWER THESE QUESTIONS OF INTELLECTUAL PROPERTY.

THIS GROUP STARTED ITS WORK BECAUSE BACK IN '04 ACR 252 WAS CHAPTERED, AND THAT WAS LEGISLATION THAT ASSEMBLYMEMBER GENE MULLIN AUTHORED THAT ASKED US TO CONDUCT AN ANALYSIS OF HOW THE STATE SHOULD HANDLE INTELLECTUAL PROPERTY WHEN IT'S BEEN GENERATED THROUGH CONTRACTS, GRANTS, AND OTHER SUPPORT TO AN EXTERNAL ENTITY. AND THE REASON FOR LOOKING AT THAT WAS BECAUSE THERE IS A LOT OF CONCERN ABOUT INEFFICIENCIES OF HANDLING IP AND, THEREFORE, INEFFICIENCIES OF RUNNING CONTRACTS AND GRANTS. THEREFORE, IT IS NOT AN EFFECTIVE PROCESS.

SO WE STARTED THIS BALL ROLLING LOOKING AT INTELLECTUAL PROPERTY. AND TO OUR KNOWLEDGE, IT'S THE FIRST TIME THAT A STATE AS AN ENTITY SEPARATE FROM THE FEDERAL GOVERNMENT HAS TAKEN THIS TO TASK TO DEVELOP A BLUEPRINT FOR HANDLING IP WHEN IT'S CREATED THROUGH STATE FUNDING.

WE THINK IT WILL HAVE A SIGNIFICANT IMPACT ON AREAS NOT JUST ON THE STEM CELL INITIATIVE, BUT ON ALL SORTS OF OTHER THINGS AS WELL. OUR GOAL IS TO HAVE A FINAL REPORT AT THE END OF THIS YEAR. THAT'S BEING

WRITTEN AT THE MOMENT.

IN THE PROCESS OF GETTING THIS TOGETHER, THOUGH, AS YOU KNOW, PROP 71 PASSED. AND SO WE DISCUSSED IN OUR COUNCIL MEETINGS AMONGST OUR GROUP WOULD IT BE HELPFUL TO FOCUS AN INTERIM REPORT THAT WOULD DEAL WITH IP GENERATED UNDER PROP 71 THAT WOULD BE HELPFUL TO SOME AS YOU ARE DEVELOPING GUIDELINES. AND IN TALKING TO ED AND OTHERS, IT WAS CLEAR THAT IT WOULD INDEED BE A HELPFUL DOCUMENT.

SO ASSEMBLYMEMBER MULLIN AUTHORED ANOTHER PIECE OF LEGISLATION, ACR 24, THAT REQUESTS A STUDY GROUP TO RESPOND, IN ADDITION TO RESPONDING TO 252, TO PRODUCE AN INTERIM REPORT WITH IP GUIDELINES FOR CIRM. AND THAT'S THE REPORT THAT YOU HAVE IN FRONT OF YOU.

THIS WAS VERY MUCH ON A FAST TRACK, AND THE STUDY GROUP STARTED ITS WORK IN APRIL. AND THEY'VE MET FIVE TIMES SINCE THEN AND A LOT OF E-MAILS, A LOT OF TELEPHONE CALLS. AND AS THEY WERE WRITING THE FINAL REPORT, THE SENATE CAME WITH SOME AMENDMENTS TO ACR 24 IN MID-JULY THAT RAISED ADDITIONAL ISSUES. AND SEEING AS THE REPORT WAS ALMOST COMPLETED, THE CO-CHAIRS OF THE REPORT ADDED AN ADDENDUM THAT ADDRESSES SOME OF THOSE ISSUES, BUT NOT ALL OF THEM.

SO THAT'S WHERE WE ARE WITH THE RELEASE OF THE REPORT. THIS IS A STUDY GROUP. IT'S QUITE A

STELLAR GROUP OF INDIVIDUALS, 17 OF THEM, AND THEY REPRESENT ALL SORTS OF AREAS OF TECHNOLOGY AND FROM DIFFERENT SOURCES, DIFFERENT AREAS. THERE ARE FOUR FROM BUSINESS AND INDUSTRY, THERE ARE SEVEN FROM UNIVERSITY CAMPUSES, AND THERE ARE TWO PRIVATE SECTOR LAWYERS, THERE'S ONE FROM THE NATIONAL LABORATORIES THAT ARE RUN BY DOE, THERE'S ONE FROM A FEDERAL LABORATORY RUN BY NASA, AND THAT'S AIMS, AND THERE'S A GOVERNMENT AGENCY PERSON AND A PUBLIC INTEREST PERSON.

LET ME POINT OUT THAT THE ONE THING THAT ALL OF THESE PEOPLE HAVE IN COMMON IS THAT THEY HAVE HAD EXPERIENCE IN DEALING WITH INTELLECTUAL PROPERTY AND COMING FROM DIFFERENT SECTORS. COMING FROM ENERGY RESEARCH, COMING FROM WHATEVER, THEY'VE ALL HAD EXPERIENCE IN HANDLING INTELLECTUAL PROPERTY.

CHAIRMAN PENHOET: MAY I ASK, SUSAN, HOW THEY WERE CHOSEN?

DR. HACKWOOD: YES. THE ANSWER IS WE PUT TOGETHER A RANGE OF EXPERTISE THAT WE WOULD LIKE TO HAVE REPRESENTED IN THE GROUP, SO DIVIDED UP AMONGST ACADEMIA AND RESEARCH. THE ACADEMICS, FOR EXAMPLE, ARE THOSE WHO ARE RESEARCHERS WHO HAVE CREATED IP AND ALSO THOSE WHO HAVE HAD THE EXPERIENCE OF RUNNING IP OFFICES AND TECH TRANSFER OFFICES, SO BOTH. INDUSTRY PEOPLE, THERE ARE A COUPLE WHO ARE FROM THE BIOTECH INDUSTRY,

BUT MANY OF THEM, LIKE STEVE, WHO ARE NOT FROM BIOTECH. THE FEDERAL RESEARCH LABS BECAUSE THEY DEAL WITH LARGE SYSTEMS PROJECTS. THE PUBLIC INTEREST PEOPLE BECAUSE THEY WORK IN PUBLIC INTEREST. SO THAT WAS THE IDEA OF HAVING A RANGE OF EXPERTISE TO BE REPRESENTED.

IN ADDITION TO A STUDY GROUP, WE ALSO HAD APPOINTED A WORKING GROUP, WHO WERE THE PEOPLE WITHIN OUR INSTITUTIONS AND RESEARCH INSTITUTIONS WHO ACTUALLY HANDLED TECH TRANSFER OFFICES, AND SO THEY REALLY HAVE THEIR FEET ON THE GROUND IN KNOWING WHAT IT TAKES TO GET RESEARCH OUT THE DOOR AND TO BE ACCEPTED AND TO BE COMMERCIALIZED.

WE ALSO HAD THE INPUT -- THIS REPORT IS A PEER-REVIEWED REPORT IN THE SAME KIND OF WAY THAT THE NATIONAL ACADEMIES REVIEW THEIR REPORTS. WE HAD ABOUT 50 OF THE HIGH TECH LEADERS IN OUR ORGANIZATION AND OUTSIDE WHO HAVE BEEN REVIEWERS ON THIS.

ALTHOUGH MANY PARTS OF THE HANDLING OF IP ARE COVERED, IT IS NOT A COMPREHENSIVE DOCUMENT. GIVEN THE TIME THAT WE HAD, IT WAS NOT INTENDED TO BE SO, BUT IT IS INTENDED TO BE A STARTING POINT FROM WHICH YOU CAN CONSIDER FURTHER WORK THAT YOU NEED TO DO OR TAKE THIS AS A STARTING POINT.

SO WE'VE MET IN PERSON THREE TIMES AND BY PHONE MANY TIMES. WE'VE ALSO HAD GUEST SPEAKERS WHO

HAVE COME AND ADDRESSED US WHO HAVE ADDITIONAL EXPERTISE THAT WE FELT THAT WE NEEDED TO HEAR FROM. AND THE REPORT HAS, AS I SAID, COME THROUGH WITH -- THE STUDY GROUP HAS COME THROUGH WITH AN INTERIM REPORT WHICH IS ON YOUR DESK AT THE MOMENT, AND THE FINAL REPORT WILL BE AT THE END OF THE YEAR.

WE'D LIKE TO NOW GO, UNLESS THERE ARE QUESTIONS FROM ME, I'D LIKE TO PASS IT ON TO ALAN AND STEVE, WHO CAN WALK THROUGH THE REPORT AND THE RECOMMENDATIONS PIECE BY PIECE.

CHAIRMAN PENHOET: WE DID NOT TAKE A ROLL CALL.

MS. KING: I'M HAPPY TO DO THAT RIGHT NOW, IF THAT WORKS.

ED PENHOET.

CHAIRMAN PENHOET: HERE.

MS. KING: SUSAN BRYANT. MICHAEL GOLDBERG. SHERRY LANSING. TED LOVE. PHIL PIZZO. FRANCISCO PRIETO.

DR. PRIETO: HERE.

MS. KING: JEANNIE FONTANA.

DR. FONTANA: HERE.

MS. KING: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. KING: OSWALD STEWARD. AND JANET WRIGHT.

DR. WRIGHT: HERE.

CHAIRMAN PENHOET: THANK YOU.

DR. WRIGHT: I DO HAVE ONE QUESTION. CALIFORNIA IS ALWAYS THE LEADER SO MANY TIMES IN THINGS. ARE THERE OTHER STATES THAT HAVE SIMILAR COUNCILS, SCIENCE COUNCILS?

DR. HACKWOOD: NO. LAST YEAR WE TEAMED FORMALLY WITH THE NATIONAL ACADEMIES BECAUSE THE NATIONAL ACADEMIES ARE TRYING TO DO SIMILAR THINGS IN OTHER STATES. WE'VE BEEN OUT TEN YEARS AHEAD OF THE CURVE IN HAVING THE COUNCIL ORGANIZED, BUT OTHER STATES, NEW YORK, TEXAS, MICHIGAN, ARE TRYING TO DO THE SAME SORTS OF THINGS.

DR. WRIGHT: I COULD EVENTUALLY SEE SORT OF A FEDERATION OF STATE COUNCILS OF LAYERS OF BUREAUCRACY. BUT THERE MUST HAVE BEEN TIMES WHERE YOU WISHED SOMEONE WAS GOING THROUGH A PARALLEL PROCESS AND ADVISING THEIR STATE LEGISLATURE. YOU'RE BASICALLY TRAILBLAZING IN THIS.

DR. HACKWOOD: DEFINITELY. WITH THE EVOLUTION TO THE STATES OF MORE AND MORE SCIENCE AND TECHNOLOGY POLICY ISSUES, DEFINITELY IT'S NEEDED.

DR. WRIGHT: IT'S A SPECIAL EXPERTISE THAT YOU COULDN'T EXPECT ANYONE OUTSIDE THIS GROUP TO UNDERSTAND.

DR. HACKWOOD: ABSOLUTELY. BEING ABLE TO HAVE COLLEAGUES LIKE THIS AT THE TABLE, THE STUDY GROUP ADVISE THE STATE IS A UNIQUE CAPABILITY.

CHAIRMAN PENHOET: ARE THERE ANY -- ALLOW THE AUDIENCE TO ASK A QUESTION OR TWO IF THEY HAVE ONE OF DR. HACKWOOD. OTHERWISE WE'LL MOVE ON. ANYBODY HAVE A QUICK QUESTION?

MR. FLANAGAN: WHO ARE THE PUBLIC INTEREST MEMBERS?

DR. HACKWOOD: PARDON?

MR. FLANAGAN: THE PUBLIC INTEREST MEMBERS?

DR. HACKWOOD: JULIE MIER WRIGHT WAS THE PUBLIC INTEREST MEMBER ON THIS STUDY GROUP.

MR. FLANAGAN: WHAT'S HER NAME?

DR. HACKWOOD: JULIE MIER WRIGHT.

MR. FLANAGAN: IS THERE AN ORGANIZATION AFFILIATION OF ANY KIND?

DR. HACKWOOD: SHE'S WITH THE SAN DIEGO ECONOMIC DEVELOPMENT CORPORATION.

CHAIRMAN PENHOET: SHE WAS FORMERLY SECRETARY OF COMMERCE FOR THE STATE OF CALIFORNIA IN THE WILSON ADMINISTRATION.

MR. FLANAGAN: WAS THERE -- MY CONCERN HERE IS THAT FROM THE PEOPLE THAT APPEAR TO BE REPRESENTED IN THE COMMITTEE ARE ALL FOLKS THAT COME FROM VARIOUS

BACKGROUNDS, BUT ARE ALL IN THE SORT OF BAYH-DOLE INSTITUTIONAL APPROACH TO INTELLECTUAL PROPERTY. WAS THERE AN EFFORT TO BRING IN FOLKS THAT HAVE CRITICIZED BAYH-DOLE AND LOOKED AT OTHER MODELS? FOR INSTANCE, REBECCA EISENBERG, JENNIFER WASHBURN, MERYL GOOZNER, THESE FOLKS THAT HAVE DONE -- RICK EISNER, UNIVERSITY OF MICHIGAN LAW SCHOOL, MIKE ARNO, ELAINE MOSK, THESE FOLKS WHO HAVE LOOKED AT BAYH-DOLE AND HAVE HAD CONCERNS.

DR. HACKWOOD: WELL, I THINK PAM IS GOING TO TALK MORE ON BAYH-DOLE A LITTLE BIT LATER ON. BUT THE PEOPLE WHO ARE REPRESENTED ON THE STUDY GROUP CERTAINLY DIDN'T JUMP UP AND CHEER THAT BAYH-DOLE WAS THE DE FACTO TO START WITH. PEOPLE LIKE DAVID MOWREY ARE BAYH-DOLE SCHOLARS, AND PAM IS VERY KNOWLEDGEABLE ON BAYH-DOLE. I THINK THAT THE DECISION CAME AFTER A LOT OF DEBATE AND DISCUSSION.

MR. FLANAGAN: THAT WAS THE --

MS. SAMUELSON: THE COMMITTEE ALSO READ A NUMBER OF ARTICLES, INCLUDING THE EISENBERG AND RAI PAPER, THAT TALKED ABOUT POSSIBLE REFORM TO THE BAYH-DOLE ACT. AND WE HEARD FROM DAVID MOWREY, WHO HAS DONE EMPIRICAL RESEARCH ABOUT THE EFFECT OF BAYH-DOLE ON RESEARCH. AND WE ALSO, I THINK, TRIED TO LOOK AT A VARIETY OF PERSPECTIVES. BUT WE DIDN'T HAVE --

CHAIRMAN PENHOET: DIDN'T START WITH A PREDETERMINED OUTCOME.

IF YOU WILL EXCUSE ME, I THINK WE'LL GO ON WITH THE MEETING THEN. THANK YOU.

DR. ROCKWOOD: THANKS, EVERYBODY. GOOD AFTERNOON. I'M STEVE ROCKWOOD. IT'S MY PLEASURE TO BE A CO-CHAIR OF THIS COMMITTEE. VERY GOOD GROUP TO WORK WITH, DYNAMIC GROUP. CERTAINLY A DIVERSITY OF OPINION, SO WE DIDN'T START OUT AS A HOMOGENEOUS LOT, IF THAT'S THE FEAR OR CONCERN THAT OTHERS MIGHT HAVE. AND CERTAINLY WE LOOKED FOR OTHER MODELS THAN BAYH-DOLE. THERE AREN'T MANY. SO YOU ARE BREAKING NEW GROUND HERE IN JUST ABOUT ANY DIRECTION YOU GO, WHICH IS NOT UNUSUAL FOR CALIFORNIA.

JUST A FEW THINGS ABOUT INTELLECTUAL PROPERTY FOR THOSE WHO MIGHT HAVE MISSED WHAT IT IS. IT'S BASICALLY THE WAY BY WHICH YOU CAN CAPTURE THE CREATIVITY WORK THAT YOU PUT IN. WHAT IS IT THAT YOU MIGHT DISCOVER, AND HOW DO YOU PROTECT THAT SO THAT YOU ARE MOTIVATED TO CONTINUE TO CREATE? AND IT'S SORT OF A NATURAL FUNCTION WITHIN OUR BUSINESS ENVIRONMENT TO BE ABLE TO STIMULATE PEOPLE TO BE CREATIVE AND BENEFIT FROM THE EFFORTS OF THEIR CREATIVITY. IT'S CAPTURED LEGALLY IN MANY FORMS HIGHLIGHTED THERE FOR YOU. FAMILIAR, I'M SURE.

TRADEMARKS, EVERYBODY KNOWS MICKEY MOUSE. TRADEMARKS ARE THINGS THAT IDENTIFY YOUR PRODUCT OR YOUR BRAND. THE NIKE SWOOSH, AND YOU REALLY DEFEND THOSE BECAUSE THEY IDENTIFY THE QUALITY OF YOUR PRODUCT AND THE IMAGE THAT YOU'RE TRYING TO PRESENT. PATENTS, STRAIGHTFORWARD. IT IS A DEVICE, A THING, A PROCESS, SOMETHING THAT YOU HAVE DISCOVERED AND YOU FEEL IS UNIQUE AND HAS ECONOMIC VALUE AND YOU WISH TO PROTECT IT AND BUILD A BUSINESS AROUND IT AND CREATE JOBS AND PAY TAXES, AND ALL OF THOSE GOOD THINGS. AND COPYRIGHTS, GENERALLY APPLIED TO WRITTEN MATERIAL, MOST RECENTLY SOFTWARE. AND THEN TRADE SECRETS, TO ME THE FAMOUS ONE IS COCA-COLA. WHAT IS IT THAT THEY PROTECT SO DEARLY? WELL, IT'S WHATEVER YOU WOULD LIKE WHEN YOU DRINK THAT. SO THAT'S REALLY WHAT YOU'RE TRYING TO PROTECT, BUT YOU PROTECT IT IN THE SENSE OF TRYING TO STIMULATE PEOPLE TO CREATE AND BUSINESSES TO BE BUILT UPON THAT.

SINCE OUR ROLE HERE THIS AFTERNOON IS TO GIVE YOU A BRIEFING AND THEN TAKE YOUR QUESTIONS AND HELP YOU AS BEST WE CAN IN DOING YOUR JOB, THIS IS SORT OF A VERY QUICK SYNOPSIS OF WHAT OUR COMMITTEE REACHED AS A CONCLUSION.

OBVIOUSLY CALIFORNIA HAS TAKEN A BOLD STEP. THEY ARE THE FIRST IN THE NATION TO LAUNCH OUT TO FUND

RESEARCH IN EMBRYONIC STEM CELL RESEARCH. FOR THOSE IN THE AUDIENCE, YOU MUST KEEP IN MIND THERE IS STEM CELL RESEARCH OTHER THAN EMBRYONIC STEM CELL RESEARCH. SO IT COVERS A VERY BROAD FIELD, AND SOME IS RELEVANT TO EACH OTHER BACK AND FORTH.

WE WERE CONCERNED AS A COMMITTEE, SOME MEMBERS VERY VOCAL, THAT THE EXPECTATIONS OF SHORT-TERM REVENUE WERE EXAGGERATED AND TO AN EXTENT THAT MIGHT BE COUNTERPRODUCTIVE. WE SAW AS A COMMITTEE THAT BY AND LARGE TO THE GREATEST EXTENT THE BENEFIT TO THE STATE OF CALIFORNIA WILL BE TO ITS CITIZENS BY THE CREATION OF NEW CURES AND TREATMENTS FOR CHRONIC DISEASE, SAVINGS IN HEALTHCARE COST, SAVINGS IN PERSONAL QUALITY OF LIFE. AND THAT BY FUNDING THIS RESEARCH, THE MAJOR OBJECTIVE SHOULD BE TO INCENTIVIZE THE ADOPTION OF WHATEVER INVENTIONS COME AND GET THAT INTO THE PUBLIC DOMAIN AS FAST AS POSSIBLE SO THAT THESE DRUGS AND TREATMENTS ARE AVAILABLE TO THE MARKET.

SO WE REALLY LOOKED AT MANY WAYS TO BENEFIT THE STATE OF CALIFORNIA. I THINK IF YOU FOCUS ENTIRELY ON HOW MANY NICKELS AND DIMES GO BACK TO THE STATE TREASURY, YOU WILL MISS THE POINT. THAT'S NOT THE MAIN POINT OF THIS RESEARCH. THIS RESEARCH IS TO CREATE CURES FOR DISEASES, WE HOPE. WE HOPE THOSE DISCOVERIES WILL COME FROM THAT.

YOU, CIRM, IN YOUR POLICY SHOULD LOOK TO PATHWAYS THAT ARE MOST EXPEDITIOUS TO GETTING THE RESULTS OF INVENTIONS OUT INTO THE PUBLIC DOMAIN THROUGH THE FDA AND WHATEVER OTHER REGULATORY COMMISSIONS ARE INVOLVED AS FAST AS POSSIBLE.

THESE ARE WHAT WE WOULD RECOMMEND AS THE GENERAL POLICY OBJECTIVES. HOW YOU TURN THESE INTO SPECIFICS IS YOUR JOB. FIRST OF ALL, WE RECOMMEND PROCEED CAUTIOUSLY. DON'T BECOME OVERLY RESTRICTIVE OR PRESCRIPTIVE EARLY ON BECAUSE YOU ARE THE FIRST ONES TO HAVE DONE THIS. OUR GUIDING PRINCIPLE WAS DO WHAT YOU CAN TO ACCELERATE THE TRANSPORT OF THIS DISCOVERY INTO THE PUBLIC DOMAIN.

AS YOU WELL KNOW, WHAT YOU'RE FUNDING AT THIS POINT IN TIME IS BASIC RESEARCH. YOU ARE MAKING FUNDAMENTAL DISCOVERIES. TO THE GREATEST EXTENT POSSIBLE, THAT KNOWLEDGE SHOULD BE DISTRIBUTED WIDELY, NOT HELD CLOSELY. THE MORE BRAINS YOU HAVE THINKING ABOUT A PARTICULAR DISCOVERY, THE MORE LIKELY YOU ARE FOR SOMEONE TO COME UP WITH A BENEFICIAL USE. SO KNOWLEDGE BEGETS MORE KNOWLEDGE. YOU WANT TO GET IT OUT.

RESEARCH TOOLS SHOULD BE MADE BROADLY AVAILABLE AS MUCH AS YOU CAN. AND THIS IS LIKELY WHAT YOU WILL DISCOVER. AND HERE YOU WILL ALSO NOTICE AN

ENTANGLEMENT. RESEARCH TOOLS THAT ARE APPLICABLE TO ADULT STEM CELLS MAY BE EQUALLY APPLICABLE TO EMBRYONIC STEM CELLS. I'M GOING TO COME TO A POINT LATER ON, BUT WE NEED TO MAKE SURE THAT WHAT POLICIES THE STATE OF CALIFORNIA HAS ARE AS COMPATIBLE AS POSSIBLE WITH FEDERAL POLICY BECAUSE YOU DO NOT WANT TO DENY YOURSELF ACCESS TO THAT BIG POT OF MONEY THAT THE FEDERAL GOVERNMENT HANDS OUT. SO YOU DON'T HAVE TO COMPLY BY BEING IDENTICAL, BUT YOU SHOULDN'T DELIBERATELY BECOME NONCOMPLIANT. THAT REALLY JUST DOESN'T HELP.

CHAIRMAN PENHOET: ON THOSE FIRST TWO POINTS, I ASSUME WHEN YOU MEAN BROADLY, IT MEANS GLOBALLY, NOT KEEPING THESE THINGS WITHIN CALIFORNIA? DID YOU EXAMINE THE ISSUE OF WHETHER THE RESEARCH REAGENT, FOR EXAMPLE, AND TOOLS SHOULD BE SHARED ONLY AMONG GRANTEES, OR SHOULD THEY BE SHARED MORE BROADLY?

DR. ROCKWOOD: I'M A SCIENTIST BY TRAINING, SO TO SPEAK OF SCIENCE, TO ME, THAT MEANS BROADLY IN THE SENSE OF GLOBALLY. I'M ALSO A CITIZEN OF THIS STATE AND I PAY TAXES, SO WE DID THINK ABOUT HOW DO WE GIVE SOME BENEFIT TO STARTING YOUR BUSINESS IN CALIFORNIA OR HOW TO RETAIN THESE INVENTIONS WITHIN CALIFORNIA TO STIMULATE THE GROWTH OF NEW TAX BASE AND THINGS LIKE THAT. I DON'T THINK WE CAME UP WITH A WONDERFUL, GREAT IDEA, BUT WE WOULD LIKE TO SEE THE

MAJORITY OF THIS WORK END UP BEING JOBS BY CITIZENS IN THE STATE OF CALIFORNIA.

IS THERE A QUESTION? IF NOT, I'LL GO TO THE NEXT SLIDE. I'M NOT GOING TO READ EACH ONE OF THESE TO YOU. YOU KNOW HOW TO READ.

COLLABORATION BETWEEN COMMERCIAL ENTITIES AND NONPROFIT INSTITUTIONS IS ESSENTIAL. YOUR DISCOVERIES WILL BE BASIC DISCOVERIES. IN THE DEVELOPMENT OF DRUGS, THE DISCOVERY IS OFTEN LESS THAN 10 PERCENT OF THE TOTAL COST OF GETTING THE DRUG TO MARKET. I DON'T KNOW IF THE PUBLIC REALLY RECOGNIZES WHAT A PROLONGED AND EXPENSIVE PROCESS DRUG DEVELOPMENT IS, BUT IT'S TYPICALLY ON THE ORDER OF 10 TO 15 YEARS BEFORE A NEW DRUG IS APPROVED FOR PUBLIC USE. AND TODAY IT'S RUNNING VERY CLOSE TO A BILLION DOLLARS. SO THE STATE, THROUGH ITS RESEARCH, MAY HAVE FUNDED THE FIRST 20, 30, 40 MILLION, I DON'T KNOW HOW MUCH, BUT YOU NEED TO ATTRACT OTHER PEOPLE'S MONEY FOR THE NEXT 90 PERCENT, OR NOBODY GETS A DRUG. AND THAT IS THE NATURE OF THE WORK.

SO FOR THOSE THAT WOULD SAY THE ONLY PEOPLE THAT BENEFIT ARE THE EXECUTIVES OF DRUG COMPANIES, I WOULD SAY NO. THAT'S BEING CYNICAL. BUT IT IS TRUE THAT THE PRIVATE CONCERN WILL PUT IN 90 PERCENT PLUS OF THE MONEY THAT IT TOOK TO GET THAT DRUG TO MARKET, AND

THERE MUST BE SOME RETURN THERE. AND THAT'S POINT 8. YOU MUST HAVE POLICIES WHICH ENCOURAGE OTHER INVESTMENT. THE STATE OF CALIFORNIA WILL NOT GET THERE ALONE, AT LEAST I DON'T SEE IT DOING THAT AT THIS PRESENT TIME. THAT'S NOT WHAT PROP 71 DOES.

ALWAYS MINIMIZE COST OF ADMINISTRATION. DON'T HAVE THREE OR FOUR PLACES AND AGENCIES, EACH TRYING TO ADMINISTER INTELLECTUAL PROPERTY. NOW I WOULD SPEAK AS A BUSINESSMAN OR YOU COULD SPEAK AS A HOMEOWNER. IF YOU GO TO GET A BUILDING PERMIT, YOU WANT TO GO TO ONE PLACE AND DEAL WITH ONE PERSON WHO HAS THE AUTHORITY TO GIVE YOU THE PERMIT AND YOU'RE DONE. IF I WANT TO LICENSE INTELLECTUAL PROPERTY, I'D LIKE ONE-STOP SHOPPING. I DON'T THINK YOU CAN QUITE GET THERE. EVEN BAYH-DOLE LEAVES THE IP WITH ALL THE VARIOUS INSTITUTIONS, BUT THEY HAVE STREAMLINED THEIR POLICIES. IT'S THE BEST, I THINK, WE'VE GOT AT THE MOMENT.

AND LASTLY, POINT 10 IS JUST WHAT I SAID. THE BIOTECH WORLD IS UNIQUE, QUITE UNIQUE. THE COMPUTER INDUSTRY IS VERY FAST. YOU INVENT SOMETHING TODAY AND SIX MONTHS FROM NOW IT MAY BE IN THE MARKET. THAT IS NOT TRUE OF A REGULATED DRUG. SO WE REALLY HAVE A LONG TIME SCALE THERE. IP IS VERY IMPORTANT OR YOU WILL NOT SUSTAIN THAT INVESTMENT FOR THE LONG TERM.

I THINK THIS IS ALAN. I'M GOING TO HAND THE BATON TO ALAN UNLESS THERE'S A QUESTION TO ME.

CHAIRMAN PENHOET: ANY QUESTIONS FROM MY COLLEAGUES THERE? JEFF.

MR. SHEEHY: SOME OF THIS JUST I DIDN'T QUITE GET. LIKE WHEN YOU SAID WE'RE THE FIRST ONES TO DO THIS, I DON'T REALLY KNOW WHAT THAT MEANS. WE'RE NOT THE FIRST ENTITY TO FUND RESEARCH. SO --

DR. ROCKWOOD: I WAS REFERRING TO STEM CELL RESEARCH.

MR. SHEEHY: THAT SHOULDN'T BE -- IT SHOULD BE NO DIFFERENT THAN ANY OTHER KIND OF FUNDING MECHANISM. IT SHOULDN'T TAILOR OUR IP NECESSARILY JUST BECAUSE WE'RE THE FIRST ONES TO FUND IT.

THEN THE SECOND, THIS WHOLE ISSUE OF NONCOMPLIANCE WITH FEDERAL, WHICH I DON'T GET EITHER. I MEAN IF WE HAVE A PARTICULAR IP ARRANGEMENT IN THE FEDERAL GOVERNMENT WHICH IS DOING THEIR THING, WHAT WOULD BE THE CONTEXT OF THAT? IT SEEMED TO IMPLY A CONFLICT THAT I DON'T KNOW THAT WHATEVER WE PUT IN PLACE WOULD NECESSARILY CONFLICT ANY MORE THAN LIKE THE UNIVERSITIES HAVE THEIR OWN IP POLICIES. SO WHY, IF WE HAD OUR OWN IP POLICY, WOULD THAT NECESSARILY AUTOMATICALLY PUT US IN CONFLICT -- WE'D BE NONCOMPLIANT?

MS. SAMUELSON: COULD I SUGGEST THAT'S A WONDERFUL QUESTION. I THINK THAT IT WILL BE EASIER TO ANSWER IT, AND PART OF THE ANSWER MAY BE MORE APPARENT TO YOU IF WE CONTINUE. I THINK ALAN IS GOING TO TALK A LITTLE BIT ABOUT BAYH-DOLE, AND I ALSO HAVE A LITTLE BIT MORE PRESENTATION ABOUT IT. BECAUSE THERE ARE SOME REQUIREMENTS THERE THAT IF YOU ARE GOING TO HAVE BOTH FEDERAL MONEY AND CIRM MONEY WORKING ON THE SAME PROJECT, THERE ARE REQUIREMENTS THAT AT LEAST NEED TO BE THOUGHT ABOUT.

MR. SHEEHY: THAT'S FINE. I'M JUST TRYING TO UNDERSTAND.

DR. ROCKWOOD: TWO QUESTIONS THERE. THE FIRST ONE, MAYBE I WAS TOO QUICK AND DIDN'T ELABORATE ENOUGH. BUT WHAT I WAS REALLY TALKING ABOUT IS THE FIRST STATE TO MY KNOWLEDGE TO MAKE A SERIOUS INVESTMENT IN FUNDING BIOTECH-TYPE RESEARCH WHICH HAS THIS UNIQUE TIMELINE AND VERY LARGE INVESTMENT. IT IS A DIFFERENT KIND OF ECONOMIC DEVELOPMENT THAN INVESTMENTS IN OTHER THINGS. JUST THE 10 TO 15 YEARS THE INDUSTRY HAS TO STEP IN OR SOMEBODY HAS TO STEP IN AND SUPPLEMENT YOUR RESEARCH FUNDING.

MR. SHEEHY: JUST TO GET A CONTEXT.

DR. ROCKWOOD: THAT'S WHAT I MEANT. PAM IS CORRECT. SHE CAN GIVE YOU MORE PARTICULARS ON WHERE

THE CONFLICTS WOULD OCCUR FOR INSTITUTIONS THAT ARE TAKING BOTH FEDERAL AND STATE MONEY.

DR. HACKWOOD: IT IS ALSO THE SINGLE LARGEST STATE INVESTMENT IN RESEARCH OTHER THAN UNIVERSITY OF CALIFORNIA, OF COURSE, WHICH IS A BUDGET LINE ITEM. BUT THE NEXT ONE DOWN IN THIS STATE IS THE PUBLIC INTEREST ENERGY RESEARCH PROGRAM AND THE NATIONAL GAS PROGRAM, WHICH IS ABOUT $75 MILLION A YEAR. SO IT REALLY IS AN OUTLIER IN NUMBER. THAT'S IMPORTANT.

DR. BENNETT: I DIDN'T CATCH YOUR NAME.

MR. SHEEHY: JEFF SHEEHY.

DR. BENNETT: SOME OF MY COMMENTS WILL BEGIN TO ADDRESS.

MR. SHEEHY: I FIGURED. I DIDN'T KNOW. I FIGURED THAT IT MIGHT COME OUT.

DR. BENNETT: I THINK IT'S HELPFUL TO MAKE THAT POINT, AND WE CAN TRY TO ELABORATE.

DR. WRIGHT: JEFF IS ALWAYS OUT IN FRONT OF THE REST OF US.

DR. BENNETT: I'LL PROVIDE A FEW INTRODUCTORY REMARKS, AND THEN I'LL WALK THROUGH WHAT THE SPECIFIC RECOMMENDATIONS ARE THAT ADDRESS SOME OF THESE OBJECTIVES. FIRST OF ALL, MY NAME IS ALAN BENNETT, AND I HAVE A ROLE AT UC DAVIS, AND BEFORE THAT IN THE UC SYSTEM. BUT I'M ALSO DIRECTOR OF A ROCKEFELLER

FOUNDATION-SPONSORED PROGRAM CALLED THE PUBLIC INTELLECTUAL PROPERTY RESOURCE FOR AGRICULTURE. AND THIS IS A PROGRAM THAT'S DEDICATED TO SOCIALLY RESPONSIBLE MANAGEMENT OF IP IN AGRICULTURE. AND THE REASON I MENTION THIS ORGANIZATION IS THAT IT'S AN EXAMPLE OF STRATEGIES TO MANAGE IP IN WAYS THAT ARE CONSISTENT WITH BAYH-DOLE, AND I'LL TALK ABOUT THAT A BIT, BUT THAT ALSO ADD ON OR OVERLAY SOCIAL OBJECTIVES TO THE STANDARD FRAMEWORK OF IP POLICY, FEDERAL IP POLICY.

I THINK THIS IS REALLY SIMILAR TO THE APPROACH THAT CCST WAS TAKING IN ITS RECOMMENDATIONS, TO TRY TO FIND STRATEGIES THAT WERE CONSISTENT WITH FEDERAL POLICY THAT OFTEN DOMINATE THE LANDSCAPE WE LIVE IN, BUT ALSO LOOK AT FEATURES THAT ADDRESS SOME OF THESE SOCIAL OBJECTIVES THAT PROP 71 IS ALSO LOOKING AT.

SO LET ME JUST TAKE A MINUTE TO INTRODUCE THE BAYH-DOLE FRAMEWORK SINCE THIS KEEPS COMING UP. AND WHAT I'M GOING TO INTRODUCE IS JUST THE FRAMEWORK, AND PAM LATER, I THINK, WILL TALK A LITTLE BIT IN MORE DETAIL ABOUT BAYH-DOLE ALSO.

SO BAYH-DOLE STARTS A LITTLE BIT AFTER WORLD WAR II WHEN THE CIVILIAN RESEARCH FUNDING BY THE FEDERAL GOVERNMENT WAS REALLY RAMPING UP. AND, OF

COURSE, THIS RAMPED UP DURING THE '50S AND AFTER SPUTNIK, PARTICULARLY IN THE '60S. FUNDING FROM THE FEDERAL GOVERNMENT WAS LARGELY GOING TO UNIVERSITIES, NONPROFIT INSTITUTIONS, BUT ALSO PRIVATE CONTRACTORS. AND AS THIS SPONSORED RESEARCH RAMPED UP, THE QUESTION EMERGED WHO'S GOING TO OWN THE INVENTIONS, WHO'S GOING TO OWN THE INTELLECTUAL PROPERTY THAT COMES OUT OF THIS RESEARCH? CLEARLY THAT WAS IN THE '60S. BAYH-DOLE CAME ALONG SOMETIME LATER. SO THERE WAS A PERIOD OF UNCERTAINTY, CONFUSION, AND REALLY A LACK OF CLARITY ABOUT WHO WAS GOING TO MANAGE THESE INVENTIONS.

TYPICALLY THE FEDERAL AGENCIES OWNED THE INTELLECTUAL PROPERTY, BUT THEY HAD NO CAPACITY TO MANAGE THE INTELLECTUAL PROPERTY. WHEN THEY DID MANAGE IT, IT WAS LICENSED ON A NONEXCLUSIVE BASIS TO ANYONE WHO WISHED TO PRACTICE THE INVENTION. AND AS A RESULT, NOT MUCH HAPPENED.

SO BY 1980 THERE WERE ABOUT 28,000 PATENTS THERE WERE OWNED BY THE FEDERAL GOVERNMENT WITH A VERY SMALL PERCENTAGE LICENSED TO INDUSTRY OR BEING DEVELOPED INTO COMMERCIAL PRODUCTS. SO THE ISSUE APPEARED, THEN, THAT EITHER WITHOUT HAVING STRONG IP PROTECTION, WITH HAVING SOME UNCERTAINTY AROUND OWNERSHIP, OR THE ABILITY TO OBTAIN EXCLUSIVE LICENSES, COMPANIES JUST HAD LITTLE INCENTIVE TO TAKE THOSE EARLY

STAGE INVESTMENTS AND TO INVEST THE DOLLARS THAT STEVE REFERRED TO THAT ARE REALLY NECESSARY TO MOVE THAT INTO MARKETABLE PRODUCTS.

AT THE SAME TIME A BUREAUCRACY HAD DEVELOPED IN FEDERAL AGENCIES, EVERYONE NEGOTIATING THEIR OWN CONTRACTS. AND IT WAS PRETTY MUCH AN INCOHERENT SYSTEM. IN 1980 THE BAYH-DOLE ACT WAS PASSED, AND THIS IS REALLY INTENDED TO STREAMLINE THE PROCESSES FOR MANAGING FEDERALLY FUNDED INTELLECTUAL PROPERTY AND, IMPORTANTLY, TO PROVIDE A SYSTEMATIC PROCESS.

THESE ARE JUST A FEW BULLET POINTS OF WHAT BAYH-DOLE DID, BUT THERE ARE IMPORTANT ONES TO THINK ABOUT AS WE LOOK AT THE POLICIES FOR CALIFORNIA. I THOUGHT IT WAS FAIRLY BRILLIANT LEGISLATION. IT DIDN'T COST THE GOVERNMENT ANYTHING, AND IT DID A SIMPLE THING. IT ALLOWED UNIVERSITIES TO ELECT TITLE TO INVENTIONS THAT WERE DEVELOPED THROUGH FEDERAL FUNDING, BUT THEN ALSO LEVERAGED A NUMBER OF REQUIREMENTS ON THOSE UNIVERSITIES WHO ELECTED TO OWN FEDERALLY SPONSORED INVENTIONS.

AND THE FIRST WAS THAT UNIVERSITIES MUST FILE PATENTS ON INVENTIONS THEY ELECT AT THEIR EXPENSE. UNIVERSITIES MUST HAVE WRITTEN AGREEMENTS WITH FACULTY AND STAFF REQUIRING DISCLOSURE AND ASSIGNMENT OF INVENTIONS. THE UNIVERSITY MUST SHARE A PORTION OF

REVENUE WITH INVENTORS, AND ANY EXCESS REVENUE MUST BE USED SOLELY SO SUPPORT RESEARCH AND EDUCATION. SO REALLY NOT ALLOWED TO BUY YACHTS OR CARS FOR THE PRESIDENT. MAYBE COMES FROM ANOTHER SOURCE. THE GOVERNMENT RETAINS NONEXCLUSIVE LICENSE TO THE INVENTION, AND THIS IS IMPORTANT AS WELL, THAT THE GOVERNMENT CAN PRACTICE THE INVENTION ON A ROYALTY-FREE BASIS.

THE GOVERNMENT RETAINS MARCH-IN RIGHTS. IF THE UNIVERSITY'S ENTITY IS NOT DILIGENTLY DEVELOPING THE INVENTIONS, THE GOVERNMENT CAN COME BACK AND TAKE OVER THAT INVENTION. AND THEN THERE'S A REQUIREMENT FOR SUBSTANTIAL U.S. MANUFACTURE. AGAIN, TRYING TO TARGET THE BENEFITS OF THESE INVENTIONS TO THE DOMESTIC U.S. ECONOMY. SO THERE ARE MANY THINGS THAT WE'LL DISCUSS IN OUR RECOMMENDATIONS THAT PARALLEL SOME OF THE POINTS HERE.

THESE REQUIREMENTS ARE OFTEN REFERRED TO AS BAYH-DOLE OBLIGATIONS BY UNIVERSITIES THAT HAVE THESE OBLIGATIONS. AND THEY TRULY ARE. THEY'RE LEGAL OBLIGATIONS. THIS IS FEDERAL LAW THAT REALLY GOVERNS HOW WE MANAGE INTELLECTUAL PROPERTY. SO WE TAKE THESE OBLIGATIONS SERIOUSLY, PARTICULARLY BECAUSE THE VAST MAJORITY OF RESEARCH FUNDING AT ALL THE UNIVERSITIES IN CALIFORNIA ARE FROM FEDERAL AGENCIES AND SO, THEREFORE,

FALL UNDER THESE REQUIREMENTS.

THEY ALSO APPLY IF THE FEDERAL GOVERNMENT ONLY SUPPLIED A PORTION OF THE RESEARCH FUNDS. AND THIS IS SORT OF THE $1 RULE. IF A FEDERAL DOLLAR TOUCHES THE RESEARCH, THEN THESE OBLIGATIONS APPLY. IT REALLY GETS AT THE ISSUE OF IF THERE ARE MULTIPLE FUNDING SOURCES, WHY DO WE HAVE TO WORRY ABOUT THIS? WE DO HAVE TO WORRY ABOUT IT BECAUSE TYPICALLY FEDERAL LAW TRUMPS WHATEVER OTHER POLICIES WE MIGHT EMPLOY.

AS A CONSEQUENCE, MOST OF THE UNIVERSITIES HAVE INTELLECTUAL PROPERTY POLICIES THAT MIRROR THESE FEDERALLY MANDATED OBLIGATIONS. THESE INSTITUTIONAL POLICIES ALSO HAVE THE FORCE OF LAW. AND SO WE DO HAVE POLICIES, FOR EXAMPLE, THAT GOVERN HOW WE SHARE REVENUES WITH INVENTORS. TO THE EXTENT THAT WE DON'T FOLLOW THOSE POLICIES, WE'RE SUBJECT TO CIVIL ACTION BY OUR OWN INVENTORS, AND THE UNIVERSITY OF CALIFORNIA HAS BEEN THE SUBJECT OF THOSE ACTIONS MANY TIMES AND LOST. SO WE DO HAVE OBLIGATIONS BASED ON OUR POLICIES AS WELL THAT MIRROR THESE.

ONE THING THAT YOU NOTICE ABOUT THIS FRAMEWORK IS THAT IT'S NOT PRESCRIPTIVE IN MANY RESPECTS AND ALLOWS A GREAT DEAL OF FLEXIBILITY. FOR EXAMPLE, IT DOESN'T REQUIRE EXCLUSIVE LICENSING, ALTHOUGH YOU MIGHT INFER THAT FROM SOME OF THE THINGS

WRITTEN ABOUT BAYH-DOLE. IT DOESN'T REQUIRE SPECIFIC ROYALTY RATES, AND IT DOESN'T REQUIRE PROVISIONS FOR LOW COST ACCESS TO PRODUCTS, BUT IT DOES RECOGNIZE THAT A WIDE RANGE OF APPROACHES MAY BE NECESSARY TO INDUCE THE PRIVATE SECTOR INVESTMENT THAT'S NEEDED TO ADVANCE THE INVENTION TO A COMMERCIAL PRODUCT. IT'S THIS FLEXIBILITY THAT IN MANY WAYS IS BOTH THE GREAT STRENGTH AND IN SOME CASES THE WEAKNESS OF BAYH-DOLE AS WELL BECAUSE IT DOES ALLOW FOR BAD ACTORS AS WELL IN THIS SENSE.

SO THIS REALLY STARTED THE CURRENT PERIOD OF CONSISTENT INTELLECTUAL PROPERTY POLICIES THAT PERMIT GRANTEES TO PATENT INVENTIONS. THEY CAN LICENSE THOSE INVENTIONS TO OTHER ENTITIES, INCLUDING PRIVATE FIRMS, THAT ARE WILLING TO MAKE THE ADDITIONAL INVESTMENT FOR COMMERCIALIZATION. SO AS A RESULT, MANY UNIVERSITIES AND LABS BEGAN TO ENCOURAGE FACULTY TO REPORT THEIR INVENTIONS AND TO PROTECT THOSE INVENTIONS. BUT IT IS ALSO IMPORTANT TO NOTE THAT BECAUSE IT REQUIRED THESE MANY ADMINISTRATIVE ACTIONS ON BEHALF OF THE UNIVERSITY, THAT MOST UNIVERSITIES ESTABLISHED TECHNOLOGY TRANSFER OFFICES TO MANAGE INVENTION REPORTING, PATENT PROCESSING AND LICENSING. AND THIS IS NOW AN INSTITUTIONAL CAPABILITY THAT IS ROUTINE FOR ANY RESEARCH UNIVERSITY. AND AS I'LL MENTION AGAIN AND

POINT OUT AGAIN, ONE THAT WOULD BE VERY COSTLY TO TRY TO DUPLICATE OR REPLICATE.

SO GENERALLY BAYH-DOLE IS CREDITED WITH HAVING LED TO SOME OF THE TECHNOLOGIES BEING DEVELOPED OUT OF UNIVERSITIES THAT WOULDN'T HAVE BEEN DEVELOPED IN ITS ABSENCE. IT'S ALSO BEEN A TOPIC OF CRITICISM FOR SOME OF THE CLOSE RELATIONSHIPS THAT UNIVERSITIES DEVELOP WITH INDUSTRY. SO IT'S A LIGHTNING ROD FOR REALLY BOTH VERY POSITIVE AND SOME NEGATIVE ATTRIBUTIONS.

SO THIS JUST HAS FEW MORE POINTS ABOUT BAYH-DOLE. IT IS DIFFICULT TO MEASURE THE DIRECT EFFECT OF BAYH-DOLE ON TECH TRANSFER, BUT THERE IS A LARGE LITERATURE ON THIS. AND IT'S GENERALLY CONSIDERED TO HAVE CONTRIBUTED POSITIVELY TO THE DEVELOPMENT OF TECHNOLOGIES AND TO ECONOMIC DEVELOPMENT. THERE ARE SOME, INCLUDING DAVID MOWRY, WHO TALKED TO OUR COMMITTEE, WHO BELIEVE THAT BAYH-DOLE WAS COINCIDENTAL WITH OTHER THINGS LIKE SUPREME COURT DECISIONS THAT ALLOWED PATENTING OF LIFE FORMS LIKE THE HUGE RAMP-UP IN NIH FUNDING, WHICH WERE AT LEAST EQUALLY IMPORTANT IN THE KIND OF ECONOMIC DEVELOPMENT WE'VE SEEN COMING OUT OF UNIVERSITY INVENTIONS.

BUT IN MANY WAYS CALIFORNIA TODAY RESEMBLES THE SITUATION PRIOR TO THE PASSAGE OF BAYH-DOLE. WE

NEGOTIATE WITH MANY AGENCIES ON AN AGENCY-BY-AGENCY BASIS TO DEVELOP INTELLECTUAL PROPERTY TERMS AND AGREEMENTS. THIS IS VIEWED AS A VERY INEFFICIENT AND INEFFECTIVE PROCESS AND IS ONE OF THE REASONS THAT THIS COMMITTEE WAS ORIGINALLY CHARGED TO LOOK AT STATE IP POLICY IN GENERAL.

AND THE LAST POINT IS FEDERAL POLICY TAKES PRECEDENCE OVER STATE POLICY, AND SO WE DO NEED TO BE CONCERNED ABOUT BAYH-DOLE AND THE POSSIBILITY THAT FEDERAL FUNDING, FEDERAL DOLLARS MAY COEXIST IN A SINGLE LABORATORY, MAY COEXIST IN A SINGLE INVENTION IN SPITE OF THE FACT THAT THE TYPE OF RESEARCH THAT CIRM IS SET UP TO FUND IS CURRENTLY ISOLATED FROM FEDERAL RESEARCH AT THIS TIME.

SO THOSE WERE MANY OF THE ISSUES, BUT THIS IS THE REALITY SORT OF FRONT AND CENTER THAT WE STARTED WITH. AND SO WE DEVELOPED SEVERAL PRINCIPLES TO GUIDE THE KIND OF SPECIFIC RECOMMENDATIONS THAT WE WOULD MAKE. AND THE RECOMMENDATIONS TO CIRM ARE IN LINE WITH THESE PRINCIPLES.

THE FIRST SHOULD BE CONSISTENCY WITH BAYH-DOLE. DOESN'T MEAN IDENTICAL WITH BAYH-DOLE. IT DOESN'T MEAN EXACTLY BAYH-DOLE, BUT IT SHOULD BE COMPLIANT. AND TO THE EXTENT THAT WE'RE COMPLIANT WITH BAYH-DOLE, THERE ARE STILL MANY WAYS TO OVERLAY SOCIAL

OBJECTIVES OR ECONOMIC OBJECTIVES ON THIS POLICY.

SHOULD CREATE INCENTIVES FOR COMMERCE IN CALIFORNIA FROM STATE-FUNDED RESEARCH TO THE GREATEST EXTENT POSSIBLE. CLEARLY, ONE OF THE OBJECTIVES OF PROP 71 IS TO STIMULATE ECONOMIC DEVELOPMENT. NATURALLY WE WOULD LIKE THAT ECONOMIC DEVELOPMENT TO RESIDE IN CALIFORNIA RATHER THAN MASSACHUSETTS. HAVING SAID THAT, IF OUR OBJECTIVE IS TO GET A LOW COST TREATMENT TO CALIFORNIANS, WE MAY ACTUALLY NEED TO LICENSE TECHNOLOGY TO GENERIC MANUFACTURERS IN INDIA. SO THERE ARE A LOT OF WAYS THAT THIS MAY PLAY OUT, AND IT MAY NOT BE POSSIBLE TO ARRIVE AT A SIMPLE POLICY RECOMMENDATION.

WE ALSO, AS A GENERAL PRINCIPLE, WANT TO ENCOURAGE TIMELY PUBLICATION OF RESULTS, SHARING OF INFORMATION AND TOOLS, AND FINALLY, TO ENCOURAGE DILIGENT DEVELOPMENT OF INTELLECTUAL PROPERTY INTO PRODUCTS THAT BENEFIT THE PUBLIC. SO THESE ARE THE GENERAL PRINCIPLES THAT ALL OF THE RECOMMENDATIONS ARE MEANT TO ADDRESS.

SO LET'S JUST WALK THROUGH THESE QUICKLY. RECOMMENDATION ONE IS TO PERMIT GRANTEES TO OWN INTELLECTUAL PROPERTY FROM CIRM-FUNDED RESEARCH. SO THIS IS A RECOMMENDATION THAT IS CONSISTENT WITH BAYH-DOLE. THERE'S WHY IT'S IMPORTANT. FROM THE

GRANTEES' PERSPECTIVE, IT ALLOWS THEM TO LEVERAGE OTHER FUNDING AS APPROPRIATE AND AVOIDS THE ADMINISTRATIVE BURDEN TO ISOLATE CIRM-FUNDED RESEARCH FROM OTHER RESEARCH ONGOING IN THE SAME LABORATORY. ALSO, AND I THINK MORE IMPORTANTLY, IT ACKNOWLEDGES BOTH THE INSTITUTIONS' AND THEIR RESEARCHERS' EXPERIENCE AND SPECIFIC KNOWLEDGE IN THE INVENTIONS TO IDENTIFY THE BEST STRATEGY FOR MOVING THESE INVENTIONS FROM BASIC RESEARCH TOWARDS THE COMMERCIAL REALM.

IN OUR OWN EXPERIENCE AT UC DAVIS AND THE UC SYSTEM OVERALL, IT'S THIS DIRECT LINKAGE TO RESEARCHERS WHO NOT ONLY UNDERSTAND THE INVENTIONS, BUT THE CONTEXT IN WHICH THE INVENTION WAS MADE AND THE WHOLE FIELD AROUND IT. SO BEING CLOSE TO THE RESEARCHER AND CLOSE TO THE RESEARCH IS AN IMPORTANT ISSUE. IT'S ONE THAT THE CALIFORNIA TECHNOLOGY TRADE AND COMMERCE AGENCY POINTED OUT IN A REPORT LAST YEAR, THAT THIS IS REALLY A KEY ISSUE, HAVING IP MANAGED CLOSE TO THE INVENTORS. THEY'RE IN A GOOD POSITION TO KNOW HOW TO LEVERAGE THAT TECHNOLOGY.

THERE'S ALSO THE COROLLARY, THAT THE COST OF RECREATING TECHNOLOGY TRANSFER CAPABILITIES OUTSIDE OF THESE INDIVIDUAL INSTITUTIONS WOULD BE VERY HIGH. AND EACH OF THE INSTITUTIONS WITHIN CALIFORNIA WHO ARE LIKELY TO BE CARRYING OUT CIRM-FUNDED RESEARCH HAS THAT

CAPABILITY NOW.

RECOMMENDATION TWO, REQUIRE THAT GRANTEES, INDIVIDUALS, INSTITUTIONS, OR BOTH PROVIDE A PLAN DESCRIBING HOW IP WILL BE MANAGED FOR THE ADVANCEMENT OF SCIENCE AND FOR THE CALIFORNIA PUBLIC BENEFIT. AND CLEARLY THERE IS A LOT OF PUBLIC SCRUTINY, A LOT OF PUBLIC INTEREST IN HOW CIRM-FUNDED RESEARCH IS GOING TO BENEFIT THE CALIFORNIA ECONOMY. THIS IS SOMETHING THAT WE, AS A COMMITTEE, SPENT A LOT OF TIME THINKING ABOUT. DO WE REQUIRE LICENSING TO A CALIFORNIA COMPANY? WHAT EXACTLY DO YOU REQUIRE? AND WHAT WE CAME UP WITH IS THAT EVERY SITUATION IS LIKELY TO HAVE DIFFERENT PERMUTATIONS. AS I MENTIONED, THE EXAMPLE WHERE YOU REALLY WANT GENERICS MANUFACTURING COMPANY OVERSEAS TO DO YOUR MANUFACTURING MAY BE THE BEST WAY TO HELP CALIFORNIA.

SO THE WAY WE LEFT IT, AND I THINK THIS IS AN AREA THAT DOES NEED MORE WORK, IS TO ALLOW THE GRANTEES THEMSELVES TO PROVIDE A PLAN, AND THAT THIS PLAN MAY BE PART OF THE REVIEW PROCESS TO UNDERSTAND HOW THE RESEARCH AND THE RESULTING TECHNOLOGY CAN BE EMPLOYED TO BENEFIT CALIFORNIA.

CHAIRMAN PENHOET: MAY I ASK A QUESTION AT THIS POINT? DO I UNDERSTAND, THEN, THIS IS NOT A UNIFORM PLAN THAT WOULD BE AGREED TO BY ALL GRANTEES,

BUT EACH GRANT WOULD CONTAIN A SECTION THAT ADDRESSED THIS ISSUE? IF WE GOT THIS GRANT, THERE'S HOW WE WOULD DEAL WITH THE IP THAT RESULTS FROM IT. IS THAT THE THOUGHT?

DR. BENNETT: THAT'S THE THOUGHT, THAT THIS WOULD BE ON AN INDIVIDUAL BASIS AND LET THE GRANTEE MAKE THAT KIND OF RECOMMENDATION.

DR. PRIETO: YOU MENTIONED THE PROBLEM OF RESEARCHERS HAVING TO SEGREGATE OUT RESEARCH OR AVOIDING THE PROBLEM OF HAVING TO SEGREGATE OUT RESEARCH FUNDED WITH CIRM DOLLARS FROM RESEARCH FUNDED THROUGH OTHER MEANS. BUT DON'T THEY ALREADY HAVE TO DO THAT? PARTICULARLY WITH REGARDS TO THE NIH, THERE'S A VERY STRICT LINE. A FACILITY CAN'T BE SHARED. THERE'S ALREADY THAT LINE IN PLACE.

DR. BENNETT: IN TERMS OF OUR INTELLECTUAL PROPERTY POLICIES, WE HAVE INTELLECTUAL PROPERTY POLICIES IN THE UC, AND IT'S TRUE IN EVERY UNIVERSITY, THAT ARE VERY CONSISTENT WITH BAYH-DOLE, AND THEY APPLY TO FUNDING FROM ALMOST EVERY SOURCE. THERE ARE RARE OCCASIONS WHERE WE DO -- WHERE WE HAVE TO MAKE AN EXCEPTION TO THOSE POLICIES AND THEN ENSURE THAT WITHIN THE LABORATORY THERE IS CLEAR SEGREGATION. BUT IN GENERAL, THE KINDS OF POLICIES THAT WE EMPLOY TO ACCEPT RESEARCH DOLLARS FROM A WIDE RANGE OF SOURCES,

INCLUDING PRIVATE SOURCES, ARE CONSISTENT WITH THE BAYH-DOLE FRAMEWORK. AND SO WE REALLY STRIVE TO DO THAT BECAUSE THERE IS MINGLING. AND EVEN IN AREAS WHERE RESEARCHERS ARE DILIGENT IN TRYING TO SEGREGATE DOLLARS, THAT MINGLING CAN HAPPEN.

SO, IN GENERAL, WE WORK TOWARDS A SOLUTION WHERE THERE'S A COMMON POLICY FRAMEWORK IN ALL OF OUR RESEARCH RELATIONSHIPS. AGAIN, THERE ARE THE RARE CASES.

DR. PRIETO: THIS IS ONE AREA SPECIFICALLY WHERE, BECAUSE OF CURRENT FEDERAL POLICY, IT HAS TO BE AN ABSOLUTE DIVISION.

DR. BENNETT: TO THE EXTENT THAT ALL THE RESEARCH IS ON EMBRYONIC STEM CELLS THAT ARE NOT PART OF THE FEDERAL CELL LINES, THAT'S CORRECT. YOU MIGHT ANTICIPATE THAT THERE WILL BE RESEARCH FUNDED BY CIRM THAT DOES FALL OUTSIDE OF THAT NARROW AREA AND MAY WELL OVERLAP WITH NIH-FUNDED RESEARCH. WE MAY ANTICIPATE IN THE FUTURE THAT FEDERAL POLICY MAY CHANGE IN THIS ARENA AS WELL. YEAH. YOU'RE ABSOLUTELY RIGHT FOR THAT NARROW SECTOR OF RESEARCH, THAT THIS ANTICIPATES SOME BROADER SPILLOVER.

MR. SHEEHY: I'M STILL NOT GETTING THIS ONE. BECAUSE IF THERE'S A SEPARATE FUNDING SOURCE THAT'S NOT NIH, LET'S SAY PHARMA CONTRACTS WITH THE UC

INSTITUTION, SO WHAT YOU'RE SAYING IS THAT UC WILL NOT ENTER INTO AN AGREEMENT WITH AN OUTSIDE ENTITY IN GENERAL UNLESS THEY CAN MAINTAIN SOME UNDERLYING IP RIGHT?

DR. BENNETT: THAT'S CORRECT.

MR. SHEEHY: SO THAT IS WHAT YOU MEAN BY THE CONSISTENCY WITH BAYH-DOLE IS THAT YOU WANT THE SAME -- THE UC'S ALL WANT TO RETAIN THE SAME UNDERLYING IP RIGHT WITH ANY FUNDING SOURCE THAT THEY RECEIVE FUNDING FROM BASED ON THE FEDERAL MODEL.

DR. PRIETO: HOW DO YOU DIVIDE THAT? LET'S SAY THE EXAMPLE THAT JEFF GAVE. IF YOU ENTER INTO A CONTRACT TO DEVELOP A NEW THERAPY WITH A COMMERCIAL ENTITY, A PHARMACEUTICAL COMPANY, YOU RETAIN -- UC RETAINS IP RIGHTS. AND HOW DO YOU HANDLE THAT ROYALTY DIVISION? OBVIOUSLY THE PHARMACEUTICAL COMPANY IS LOOKING FOR A RETURN ON INVESTMENT, YET YOUR INVENTOR, YOUR RESEARCHER'S RETAINING RIGHTS TO THAT.

DR. BENNETT: LET ME EXPLAIN. WE COULD SPEND DAYS ON THIS ISSUE.

DR. PRIETO: I'M SURE WE WILL.

DR. BENNETT: WE'VE ALREADY SPENT DAYS. YES. IN THE CASE OF PHARMA-FUNDED RESEARCH AT THE UNIVERSITY OF CALIFORNIA, WE MAINTAIN OWNERSHIP RIGHTS IN THE INTELLECTUAL PROPERTY. WHAT WE WILL OFFER THE SPONSOR

IS A RIGHT TO NEGOTIATE A LICENSE, AND DEPENDING ON THE PARTICULAR ARRANGEMENT, EVEN AN EXCLUSIVE LICENSE TO THAT INTELLECTUAL PROPERTY. AT THE TIME THAT THE INVENTION IS MADE, WE UNDERSTAND THE VALUE, THEN WE'LL NEGOTIATE THE TERMS OF THAT LICENSE AT A FAIR MARKET VALUE. AS A PUBLIC INSTITUTION, IT'S IMPORTANT THAT WE ARE LICENSING ON A FAIR MARKET VALUE, NOT GIVING AN UNDUE ADVANTAGE TO ONE COMPANY AT THE EXPENSE OF ANOTHER. SO WE DO RETAIN OWNERSHIP RIGHTS. WE DO PROVIDE A COMMITMENT TO NEGOTIATE A LICENSE WITH THAT COMPANY.

DR. PRIETO: AS A PUBLIC INSTITUTION, THROUGH THOSE LICENSING FEES, YOU GET A RETURN.

DR. BENNETT: CORRECT.

MS. SAMUELSON: ONE OF THE THINGS ACTUALLY THAT BAYH-DOLE REQUIRES IS THAT FOR NONPROFITS LIKE UNIVERSITIES, IS THAT THEY DON'T ASSIGN THE RIGHTS TO OTHER ENTITIES. RETAINED OWNERSHIP IS ACTUALLY A REQUIREMENT OF BAYH-DOLE IF YOU TAKE BAYH-DOLE -- OR IF YOU TAKE FEDERAL FUNDING.

MR. SHEEHY: IT DOES SEEM LIKE THAT WE'RE LETTING THE RIGHTS -- WE'RE TRANSFERRING OUR RIGHTS FROM ONE PART OF THE STATE TO ANOTHER PART OF THE STATE. AND THE REVENUE STREAM THEN STAYS IN THE UNIVERSITY INSTEAD OF AT CIRM OR ANY OTHER.

DR. BENNETT: WELL, IN THE PARTICULAR CASE OF OUR DISCUSSION, IF I WAS STANFORD, THAT WOULDN'T BE THE CASE, OF COURSE, BUT IT WOULD BE TRANSFERRED TO THE GRANTEE. THE ENTITY DOING THE RESEARCH HAS THE RESPONSIBILITY TO --

DR. PRIETO: ONE REALITY ON THE GROUND THERE IS THAT WE HAVE A LARGE COMPLEX OF MAJOR RESEARCH UNIVERSITIES THAT ARE PUBLIC ENTITIES, AND WHAT IS THAT RELATIONSHIP BETWEEN THE CIRM AND THE UNIVERSITIES OF CALIFORNIA GOING TO BE AND WHO RETAINS THOSE LICENSING RIGHTS, YOU KNOW, THE INTELLECTUAL PROPERTY RIGHTS?

DR. BENNETT: WELL, I THINK ANOTHER ISSUE THAT YOU WILL GRAPPLING WITH AS WELL IS DO YOU HAVE A CONSISTENT FRAMEWORK WITH PUBLIC RESEARCH INSTITUTIONS AS WELL AS PRIVATE BECAUSE CIRM WILL CERTAINLY BE FUNDING RESEARCH IN BOTH UNIVERSES.

DR. FONTANA: I'D LIKE JUST TO TAKE A STEP BACK AND ASK A LITTLE MORE BASIC QUESTION ABOUT THE PARADIGM THAT WE'RE FOLLOWING HERE. I BELIEVE IT STARTED WHEN NIXON LAUNCHED HIS WAR AGAINST CANCER, AND THERE WAS GREAT DISCUSSION ABOUT SHOULD THERE BE A GOVERNMENT-FUNDED MANHATTAN PROJECT WHERE THE GOVERNMENT OWNED SOME OF THOSE RIGHTS AND BROUGHT PEOPLE TOGETHER VERSUS LET'S JUST FUND THE INDIVIDUAL RESEARCHER AND LET THE SCIENTISTS TAKE THE SCIENCE

WHEREVER THEY CHOOSE.

AT THE TIME I BELIEVE THERE WAS SOME GREAT DEBATE OVER WHICH APPROACH WAS THE ONE TO TAKE. AND THE INDIVIDUAL WON OUT, AND THEN NOW WE'RE TALKING ABOUT THAT SYSTEM AGAIN, AND WE'RE TALKING JUST ABOUT FOLLOWING IT. I'M WONDERING WITH YOUR KNOWLEDGE AND YOUR DISCUSSIONS, WAS IT EVER BROUGHT UP PERHAPS CIRM COULD MAYBE COME UP WITH A NEW MODEL WHERE WE COULD TAKE ADVANTAGE OF MORE COLLABORATIVE EFFORTS, I KNOW IT'S IDEALISTIC, IN HOW TO DEAL WITH ALL THE PROPERTY ISSUES, BUT REALLY WHERE WE INCENTIVIZE COLLABORATIONS IS MORE HEADS TOGETHER ARE BETTER. HOW DO WE GET AROUND THOSE FINANCIAL INCENTIVES AND DISINCENTIVES TO DO THAT? AND IS THAT A REASONABLE APPROACH? IS THAT SOMETHING THAT WE SHOULD BE EXAMINING?

DR. BENNETT: I'LL ANSWER AND I'LL INVITE MY COLLEAGUES TO ANSWER AS WELL. I THINK WHAT WE'RE SEEING ON THE NATIONAL LANDSCAPE, FEDERAL FUNDING FROM ALL AGENCIES, INCLUDING THE NIH, IS A MOVE TOWARDS MUCH BIGGER SCIENCE, COLLABORATIVE EFFORTS, GENOME SCALE PROJECTS, FOR EXAMPLE, THAT DO REQUIRE MULTIPLE INSTITUTIONS TO WORK TOGETHER, AND ULTIMATELY TO COLLABORATIVELY MANAGE THE RESULTS OF THAT RESEARCH. SO IT'S OCCURRING MUCH MORE FREQUENTLY TODAY THAN CERTAINLY TEN YEARS AGO AND EVEN TWO OR THREE YEARS

AGO.

AT THAT LEVEL MULTIPLE INSTITUTIONS, WHETHER THEY'RE WITHIN THE UC SYSTEM OR ACROSS THE WHOLE COUNTRY, GET TOGETHER AND TYPICALLY IDENTIFY A LEAD INSTITUTION THAT'S GOING TO MANAGE SOME OF THESE RESULTS TO THE EXTENT THAT THEY'RE COINVENTED IN THAT FRAMEWORK BECAUSE TYPICALLY ALL THOSE DOLLARS ARE STILL FEDERAL DOLLARS AND GOVERNED BY BAYH-DOLE. THESE INTERINSTITUTIONAL RELATIONSHIPS ARE DRIVEN BY THESE SAME KIND OF POLICY CONSIDERATIONS. SO I THINK IT'S AN IMPORTANT POINT.

IT'S ONE THAT WILL REALLY PLAY OUT IN THE WAY THAT CIRM DECIDES TO FUND RESEARCH. I THINK THE DISCUSSION THAT YOU'RE TALKING TO AS WELL ENDED UP BEING A BIT OF THE BABY WAS DIVIDED TO SOME EXTENT. THE NIH DOES HAVE A HUGE CAMPUS AND A HUGE INTERNAL MANHATTAN PROJECT FORCE, BUT IT'S ALSO COMPLEMENTED BY THESE WIDE RANGE OF INDIVIDUAL INVESTIGATORS THROUGHOUT THE COUNTRY. MOST LIKELY THAT KIND OF BALANCE IS AN APPROPRIATE ONE. YOU STIMULATE CREATIVITY AMONG A LARGE NUMBER OF INDIVIDUALS AND STILL MAINTAIN A CORE OF COLLABORATIVE RESEARCHERS THAT ARE ABLE TO DO VERY MUCH MORE TARGETED RESEARCH.

MS. SAMUELSON: CERTAINLY INTELLECTUAL PROPERTY LAW AS A KIND OF DEFAULT RULE WILL SAY THAT IF

THERE ARE INVENTORS FROM DIFFERENT INSTITUTIONS THAT THERE ARE COINVENTORS AND THERE WILL BE A KIND OF A CO-OWNERSHIP OF THE INTELLECTUAL PROPERTY RIGHTS. I THINK ENCOURAGING COLLABORATION, ESPECIALLY IN THIS KIND OF FIELD, IS EXCEPTIONALLY IMPORTANT. BUT I THINK THAT THE ISSUE ABOUT HOW INTELLECTUAL PROPERTY RIGHTS IS MANAGED IS SOMEWHAT ORTHOGONAL TO THAT.

DR. FONTANA: IT APPEARS TO ME, I MEAN I CAN TALK ABOUT SPECIFIC EXAMPLES WHERE I HAVE A CLINICAL APPLICATION, SOMETHING IS HAPPENING WITH BASIC RESEARCH AT DIFFERENT INSTITUTIONS, AND I SEE IT AS INCREDIBLY PROMISING, EXCITING, YET IT'S NOT HAPPENING BECAUSE OF THE INTELLECTUAL PROPERTY BATTLES THAT ARE HAPPENING BETWEEN THE TWO INSTITUTIONS. NOW, I SIT THERE AS A PATIENT ADVOCATE GOING HOW DO WE GET AROUND THIS, BUT I ALSO UNDERSTAND THE FINANCIAL.

MS. SAMUELSON: IT'S ONE OF THE THINGS THAT WE ARE TRYING TO ENCOURAGE HERE IS FOR CIRM TO ACTUALLY FACILITATE LICENSING ON THAT KIND OF OPEN AND BROAD BASIS AND TO FOLLOW THE EXAMPLE OF NIH IN ENCOURAGING, FOR EXAMPLE, WIDE AVAILABILITY OF RESEARCH TOOLS AND OPEN ACCESS POLICIES TO DATABASES AND THE LIKE. SO I THINK THERE ARE WAYS IN WHICH CIRM CAN MITIGATE THOSE BATTLES. I DON'T THINK THAT THEY -- I THINK THAT ENOUGH OF THE SCIENTISTS WHO ARE GOING TO BE ENGAGED IN

DOING THIS WORK WANT TO MAKE SURE THAT THE SCIENCE HAPPENS SO THAT PEOPLE WILL HAVE INCENTIVES TO MAKE THOSE THINGS AVAILABLE.

I THINK IF YOU CREATE A VIRTUAL CYCLE, I'LL MAKE MY RESEARCH TOOLS AVAILABLE ON THIS OPEN BASIS; AND THEN IF YOU DO THE SAME, THEN WE CREATE A VIRTUAL CYCLE FOR THE RESEARCH COMMUNITY. AND THAT SEEMS TO ME TO BE A WAY TO DEAL WITH THAT, NOT JUST SAY, WELL, DON'T PAY ANY ATTENTION TO THIS.

DR. ROCKWOOD: THIS MAY BE OVERLY SIMPLISTIC, AND I'M TRYING TO THINK OF AN EXAMPLE TO CAPTURE YOUR POINT. THROUGH ITEM 2 THERE, WE ARE SUGGESTING YOU ASK THE GRANTEES TO DESCRIBE HOW THEY WILL MANAGE THE IP AS PART OF THEIR APPLICATION FOR THE GRANT. THAT GIVES YOU A HOOK, IF YOU WILL, TO DEMAND THAT THEY COME UP WITH A SHARED PLAN ON THE IP BEFORE THEY GET ONE DOLLAR FROM YOU. AND THAT GIVES YOU SOME ABILITY TO ENFORCE COLLABORATIONS AND SHARING IF IT'S NOT HAPPENING NATURALLY. WE ALSO DIDN'T PRECLUDE THAT SOME FRACTION OF THE ROYALTIES MIGHT COME TO YOU OR BE REINVESTED IN OTHER RESEARCH. WE JUST DIDN'T WANT TO MANDATE THAT IT'S ALWAYS X PERCENT OFF THE TOP.

DR. PRIETO: IT WOULD HAPPEN UNDER THIS PROVISION? IF THAT THERE WERE TO HAPPEN, YOU'RE SAYING IT WOULD HAPPEN UNDER THIS PROVISION.

DR. ROCKWOOD: WHAT IS THE IT, THE COLLABORATION?

DR. PRIETO: THE RETURN.

DR. ROCKWOOD: I DON'T KNOW IF ALAN GOT TO POINT 3 THERE. WE'RE NOT PRECLUDING THAT THE IP PLAN COULDN'T SAY WE'LL PUT THIS MUCH BACK INTO CIRM FOR FURTHER RESEARCH. IT CAN SAY THAT. WE JUST DIDN'T WANT TO MANDATE THAT YOU HAVE TO PUT X PERCENT BACK IN.

DR. PRIETO: I HAVE A QUESTION. UNDER BAYH-DOLE AND THE RETAINED NONEXCLUSIVE LICENSE, HAS THE -- I WONDERED IF THE GOVERNMENT HAS EVER USED, AS A MAJOR PURCHASER OF HEALTHCARE, THAT LICENSE TO ATTEMPT TO DO ANYTHING WITH PRICING OR ACCESS OF DOWNSTREAM INVENTIONS OR THERAPIES THAT THEY THEN HAD TO PURCHASE THAT THEY HAD PARTICIPATED IN THE DEVELOPMENT OF.

MR. SHEEHY: ACTUALLY, NOT TO STEP ON FRANCISCO, BUT THIS RELATES -- I WAS GOING TO ASK AT SOME POINT FOR A LITTLE BIT FURTHER DISCUSSION ABOUT MARCH-IN RIGHTS BECAUSE I THINK THIS IS REALLY RELEVANT TO THIS.

MS. SAMUELSON: I WAS GOING TO COVER THAT, BUT WE'RE GETTING VERY DISTRACTED.

DR. BENNETT: WHY DON'T WE RUN THROUGH ALL THIS.

DR. HACKWOOD: IF WE CAN GET THE

RECOMMENDATIONS ON THE TABLE AND THEN GO BACK BECAUSE PAM HAS SUBSTANTIVE STUFF TO TALK ABOUT ON BAYH-DOLE THAT MAY ANSWER SOME OF YOUR QUESTIONS, AND THEN RAISE THE ISSUES THAT YOU ARE TALKING ABOUT FURTHER.

DR. BENNETT: BEFORE LEAVING THIS, WHEN WE DID HAVE THIS DISCUSSION, WHICH WE DID MANY TIMES, ABOUT THIS ANTI-COMMONIST EFFECT OF WOULDN'T IT BE BETTER TO HAVE ALL THE IP IN ONE PLACE SO YOU JUST HAVE IT ALL TOGETHER, THE ISSUE THAT CAME UP MOST FREQUENTLY IS THAT YOU CAN BRING TOGETHER THE WHOLE CIRM PIECE OF THE PIE BY YOUR POLICY, IF YOU SEEK TO DO THAT, BUT IT'S GOING TO BE VERY INCOMPLETE BECAUSE IT WON'T CONTAIN THE RELATED IP THAT CAME OUT OF NIH FUNDING OR THE RELATED IP THAT'S OUTSIDE OF CALIFORNIA.

SO THE VIEW WAS THAT WITHIN WHAT CIRM CAN DO WITH ITS POLICY, IT'S NOT GOING TO CAPTURE VERY MUCH, AND SO IT'S PROBABLY NOT A WORTHWHILE PURSUIT. I THINK IT IS A WORTHWHILE PURSUIT OUTSIDE OF THE CIRM CONTEXT. COULD YOU REALLY DEVELOP A FRAMEWORK THAT WOULD GET BROAD COLLABORATION AND MANAGEMENT OF IP? AND THERE ARE GROUPS THAT WORK AROUND THAT ISSUE, BUT I THINK IT'S OUTSIDE THE PURVIEW OF THIS COMMITTEE AND OF CIRM ACTUALLY.

I'LL QUICKLY GO THROUGH THESE RECOMMENDATIONS. RECOMMENDATION THREE IS GRANTING

RESEARCH FUNDS WITHOUT REQUIRING THE GRANTEES TO COMMIT TO PROVIDE A REVENUE STREAM TO THE STATE. THIS WAS A VERY INTERESTING CONVERSATION. AND, FRANKLY, A LOT OF THIS CONVERSATION REALLY HINGED ON THE VIEW OF THE COMMITTEE, THE WIDELY HELD VIEW, THAT OF THE MANY BENEFITS TO THE STATE FROM CIRM-SPONSORED RESEARCH, ROYALTY INCOME IS LIKELY TO BE THE SMALLEST. AND TO DO ANYTHING THAT MAY IMPEDE THE RAPID DEVELOPMENT OF THERAPIES WOULD HAVE UNINTENDED CONSEQUENCES OF ACTUALLY REDUCING THE REAL BENEFITS.

THIS ISSUE IS ALSO COMPLICATED BY THE USE OF TAX-EXEMPT BONDS TO FUND THE RESEARCH. WE HAVE BEEN ADVISED BY TAX COUNSEL, WHO I UNDERSTAND WILL BE AT THIS MEETING NEXT MONDAY AS WELL, THAT THIS CREATED -- WAS GOING TO CREATE ANOTHER LAYER OF ISSUES. AND SO THE COMMITTEE JUST FELT OVERALL, SINCE THIS IS PROBABLY THE LEAST SIGNIFICANT BENEFIT AND THE REQUIREMENT TO SHARE REVENUE COULD ACTUALLY IMPEDE THE TRANSFER PROCESS, AND IT WAS GOING TO GET HOOKED UP IN TAX-EXEMPT BONDS, THE SIMPLEST AND BEST RECOMMENDATION IS NOT TO REQUIRE SHARING OF REVENUE.

CHAIRMAN PENHOET: MAY I ASK. THE BELIEF THAT A REVENUE SHARING MODEL WOULD INHIBIT TRANSFER IS THAT THE UNIVERSITY WOULD ASK FOR A HIGHER ROYALTY IN ORDER TO BE ABLE TO GET THE SAME BENEFIT TO THEMSELVES

AND PROVIDE SOME FUNDING TO THE STATE? IS THAT THE LOGIC?

DR. BENNETT: THAT WAS PART OF THE LOGIC, YEAH. OR THAT IT MAY DISINCENTIVIZE UNIVERSITIES TO AGGRESSIVELY MANAGE AND LICENSE THE IP AT ALL IF THE POTENTIAL RETURN WAS GREATLY DIMINISHED.

DR. ROCKWOOD: THERE WERE EVEN SOME ON THE COMMITTEE WHO FEARED IF THE RESEARCHER OF AN INSTITUTION HAD THE CHOICE OF TAKING NIH MONEY THAT GAVE THEM FULL RIGHTS AND STATE MONEY, WHICH HAD CERTAIN BURDENS ATTACHED, THEY WOULD OPT TO GO WITH THE FEDERAL MONEY. THERE WAS ALSO CONCERN THAT IT WOULD LIMIT THE NUMBER OF APPLICANTS FOR YOUR GRANTING PROCESS. THERE WERE MANY REASONS, NOT ONE CLEAN, SIMPLE REASON.

AND TO ECHO WHAT ALAN SAID, SINCE ROYALTIES, IN GENERAL, ARE A RATHER SMALL AMOUNT OF BENEFIT MONETARILY COMPARED TO OTHERS, WHY CREATE A HUGE ISSUE OVER THE SMALLEST AMOUNT OF MONEY ON THE TABLE.

MR. SHEEHY: I JUST HAVE A QUESTION. I JUST KNOW AN EXAMPLE WHERE IT HAS BEEN A HUGE AMOUNT OF MONEY.

DR. ROCKWOOD: THERE'S ALWAYS AN EXCEPTION. I AGREE WITH YOU.

MR. SHEEHY: EMORY JUST GOT WELL OVER $500

MILLION FOR AN HIV DRUG.

DR. ROCKWOOD: STATISTICALLY YOU WILL FIND THAT MOST ROYALTIES RETURN A FEW MILLION DOLLARS. THERE'S ALWAYS THE HOME RUN.

MR. SHEEHY: THAT'S NOT EVEN REALLY A HOME-RUN DRUG. IT'S A B-PLUS DRUG.

DR. BENNETT: WELL, FOR A UNIVERSITY THAT WOULD BE A HOME RUN. THE OTHER ISSUE IS THE VAST MAJORITY ARE THE LICENSES THAT WE HAVE THAT RETURN MAYBE A $100,000 IN ROYALTY REVENUES, BUT YOU KNOW THAT THESE -- THAT THE PRODUCTS ARE SAVING THOUSANDS OF LIVES. WE REALLY THINK THAT'S WHERE THE FOCUS SHOULD BE ON IS GETTING THOSE THERAPIES OUT, PROVIDING HEALTH BENEFITS, SAVING LIVES, AND STIMULATING ECONOMIC DEVELOPMENT. SO THAT'S WHERE IT CAME OUT.

FOURTH RECOMMENDATION IS TO MAKE CIRM-DEVELOPED RESEARCH TOOLS WIDELY AVAILABLE TO OTHER RESEARCHERS.

DR. ROCKWOOD: COULD I ADD A POINT TO THE GENTLEMAN'S QUESTION? I WILL GRANT YOU THERE ARE ALWAYS EXCEPTIONS AND THERE'S ALWAYS THAT MIRACLE. BUT I DON'T THINK POLICY SHOULD BE GEARED FOR THE MIRACLE. IT SHOULD BE GEARED FOR THE NORM. IT SHOULD BE GEARED FOR WHAT'S THE NOMINAL EXPECTATIONS, NOT THE GREAT HEROIC EXPECTATION. THAT'S MY PERSONAL OPINION.

MR. SHEEHY: I DON'T HAVE A BIAS EITHER WAY. MY UNDERSTANDING IS THAT UNIVERSITIES, ESPECIALLY UC, IS GETTING MUCH BETTER; BUT IF WE HAD A GRAPH ON THEIR RETURN FROM ROYALTIES AND TRACK IT OVER TIME, WE'D SEE IT GOING UP. I THINK THAT UNIVERSITIES HAVE GOTTEN MUCH BETTER AT NEGOTIATING THESE AGREEMENTS. SO THAT'S WHAT I'VE HEARD, THAT THEY'RE DOING BETTER AT THIS THAN THEY HAVE IN THE PAST.

DR. BENNETT: IT'S ALL ANECDOTAL. MY VIEW IS IT'S LEVELING OFF IN MOST AREAS. BIOTECH HOME RUNS HAVE COME AND ARE NOW LEAVING.

MR. SHEEHY: I JUST THINK WE'RE GOING TO BE TALKING ABOUT -- WE'RE GOING TO BE TALKING ABOUT MONEY. THERE HAS TO BE SOME RECOGNITION THAT IN SOME INSTANCES THERE'S SOME REAL MONEY INVOLVED. I'M NOT SAYING THAT I NECESSARILY AGREE THAT --

DR. BENNETT: FRANKLY, ALTHOUGH THE COMMITTEE FELT THAT THIS WAS -- THAT THE BEST WAY TO GO IS NOT TO REQUIRE THIS REVENUE STREAM. HAVING SAID THAT, I DON'T THINK THERE WAS ONE INSTITUTION AROUND THE TABLE WHO'S LIKELY TO BE A GRANTEE THAT WAS PHILOSOPHICALLY OPPOSED WITH SHARING REVENUE WITH THE STATE OR ANYONE ELSE. IT DID GO ON TO STATE THAT IF THERE IS SOME SORT OF REVENUE SHARING THAT CIRM LOOKS AT, THAT THE BEST WAY TO SHARE THAT REVENUE WOULD BE TO REINVEST IT IN

RESEARCH AND EDUCATION BECAUSE THIS HAS THIS BAYH-DOLE CONSISTENCY. AND THERE MAY, IN FACT, BE STRATEGIES OR MECHANISMS.

DR. PRIETO: WHY NOT IN THERAPIES?

DR. BENNETT: WELL, THE BAYH-DOLE STIPULATES THAT EXCESS REVENUE IN EXCESS OF EXPENSES BE REINVESTED IN RESEARCH AND EDUCATION. ONE COULD LOOK AT OTHER POSSIBLE USES. WHILE I KNOW THERE HAVE BEEN DISCUSSIONS AROUND IT, I THINK THERE'S ROOM FOR CREATIVITY. BUT THAT WAS OUR RECOMMENDATION.

DR. ROCKWOOD: ALAN, JUST SO THE COMMITTEE HERE IS CLEAR ON WHAT I THINK OUR COMMITTEE'S POINT OF VIEW WAS, IT WAS MOSTLY WE DID NOT THINK IT WAS WISE TO HAVE A HARD, FIXED PERCENTAGE. WE WOULDN'T PRECLUDE REVENUE BACK TO YOU OR TO THE STATE, PARTICULARLY IN THE CASE OF A HOME RUN. WE WOULDN'T WANT TO START OUT THIS POLICY BY DICTATING YOU WILL DO THIS AND IN THE PROCESS SCARE AWAY POTENTIALLY INTERESTING RESEARCH.

CHAIRMAN PENHOET: BY A HARD NUMBER YOU MEANT FOR THE ABSOLUTE AMOUNT OF THE ROYALTY OR THE FRACTION WHICH IS SHARED BY THE UNIVERSITIES WITH A THIRD PARTY, IN WHICH MEANING?

DR. ROCKWOOD: I'M NOT SURE I SEE THE DIFFERENCE.

CHAIRMAN PENHOET: WELL, WE COULD SAY YOU

MUST GIVE A 6-PERCENT ROYALTY FOR ALL TECHNOLOGY DEVELOPED WITH CIRM FUNDING, OR WE COULD SAY DO YOUR BEST TO GET A FAIR MARKET VALUE FOR THIS TECHNOLOGY AND SEND A FRACTION BACK TO THE STATE OR TO THE THERAPY FUND OR --

DR. ROCKWOOD: IT WOULD BE THE FORMER.

CHAIRMAN PENHOET: THE FORMER, THAT YOU WOULD RECOMMEND AGAINST.

DR. PRIETO: YOU WOULD RECOMMEND AGAINST A FIXED AMOUNT, BUT NOT NECESSARILY AGAINST SOME FRACTIONAL RETURN?

DR. ROCKWOOD: I THINK OUR COMMITTEE WAS SORT OF OPEN-MINDED ON SOME FRACTIONAL RETURN. WHAT WE REALLY BELIEVED IS EACH BUSINESS OPPORTUNITY IS SOMETHING UNIQUE. EACH INVENTION WILL LEAD TO CERTAIN DEALS, AND WHAT'S RIGHT FOR ONE DEAL IS NOT NECESSARILY RIGHT FOR THE OTHER. SO YOU NEED THE ABILITY TO BE FLEXIBLE AND CREATE THE RIGHT DEAL FOR THAT BUSINESS TO MOVE OUT.

DR. BENNETT: A LOT OF THIS DISCUSSION FOCUSED JUST SIMPLY ON THE IDEA THAT IT'S LIKELY TO BE A VERY SMALL REVENUE STREAM. TO THE EXTENT THIS POLICY AND CIRM FOCUSES ON THIS, THERE'S LIABLE TO BE DISAPPOINTMENT FIVE YEARS FROM NOW BECAUSE IT WON'T COME SOON AND IT WON'T BE LARGE.

DR. HACKWOOD: THE LATEST AUTM DATA FOR THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, IS ONE IN 400 INVENTIONS OVER ITS LIFETIME WILL GENERATE A MILLION DOLLARS OR MORE.

DR. PRIETO: I THINK ANY OF US WHO HAVE ANY FAMILIARITY WITH RESEARCH KNOW HOW RARE IT IS TO HAVE A HOME RUN, BUT I THINK THERE WOULD ALSO BE DISAPPOINTMENT IF AT THE FRONT SOME HOME-RUN DRUG OR TREATMENT OR CURE WAS DEVELOPED THAT, YOU KNOW, MEANT HUGE SUMS OF MONEY FOR SOMEONE AND THE STATE SAW NOTHING OF THAT, WE WOULD HEAR ABOUT IT.

DR. FONTANA: I CAN'T HELP BUT VOICE MY OPINION. THIS ALL COMES DOWN TO A KIND OF ACCOUNTABILITY. WHAT YOU WOULD HATE TO SEE HAPPEN IS THAT TAXPAYERS HAVE PUT IN ALL THIS MONEY, AND WE HAVE NOTHING TO SHOW FOR IT IN FIVE, TEN YEARS EXCEPT MAYBE ONE PHARMACEUTICAL COMPANY THAT HAS ONE THERAPY FOR A HAIR TRANSPLANT, AND THEY'RE MAKING MILLIONS AND MILLIONS AND MILLIONS OF DOLLARS. I DON'T THINK WE WANT TO SEE SOMETHING LIKE THAT.

I DON'T THINK OF PHARMA AS A BIG BAD WOLF; BUT ON THE OTHER HAND, OUR FOCUS REALLY IS TO FUND RESEARCH THAT LEADS TO CURES, THERAPIES, NOT JUST CURES. I THINK THAT'S FARFETCHED. THE BENEFIT ON OUR ECONOMY BASED UPON THAT IN AND OF ITSELF IS DRAMATIC.

SO THESE ROYALTY ISSUES, WHILE I HAVE SOME SYMPATHY TO THE EMOTION BEHIND IT, I THINK IS SO SMALL IN COMPARISON TO THE IMPACT THAT THIS RESEARCH COULD POSSIBLY HAVE. AND LET'S GO FOR IT.

DR. ROCKWOOD: WE'RE IN AGREEMENT HERE.

DR. BENNETT: THAT'S EXACTLY WHERE THIS COMMITTEE WAS COMING FROM.

CHAIRMAN PENHOET: WE HAVE LOTS OF TIME COMPARED TO YOU.

DR. HACKWOOD: WE WANT TO JUST GET THE INFORMATION OUT FIRST AND HOPE THAT WILL GENERATE MORE DISCUSSION.

DR. BENNETT: MAKING RESEARCH TOOLS AVAILABLE. CLEARLY I THINK CIRM POLICIES SHOULD ENSURE THE RESEARCH TOOLS ARE NOT LOCKED UP, ARE WIDELY AVAILABLE TO ADVANCE THE ENTIRE FIELD. AND THE IP POLICY SHOULD SPEAK TO THAT SO THAT GRANTEES, WHEN THEY DO LICENSE IP, RESERVE RIGHTS FOR USE AT LEAST IN NONCOMMERCIAL OR OTHER CIRM RESEARCH INSTITUTIONS.

FIVE, REQUIRE DILIGENT EFFORTS TO DEVELOP CIRM-FUNDED IP AND THERAPEUTICS AND DIAGNOSTICS. WHERE THERE ARE EXCLUSIVE LICENSES, TO HAVE DILIGENCE PROVISIONS SO THAT THE GRANTEES CAN TERMINATE THOSE LICENSES IF THERE REALLY ISN'T DILIGENT DEVELOPMENT AND THE KIND OF INVESTMENT FROM THE PRIVATE SECTOR THAT

WE'RE REALLY SEEKING TO STIMULATE.

DR. PRIETO: SO WE COULD YANK THE LICENSE.

DR. BENNETT: RIGHT.

DR. ROCKWOOD: ABSOLUTELY.

DR. BENNETT: AND BECAUSE BAYH-DOLE REQUIRES THAT WE WORK TOWARDS THE PUBLIC BENEFIT, ANY EXCLUSIVE LICENSE THAT UC EXECUTES NOW HAS ROUTINELY VERY STRONG DILIGENCE TERMS, AND WE DO TERMINATE LICENSES. IT SHOULD BE AN IMPORTANT PART OF WHAT CIRM REQUIRES AS WELL.

RETAIN WITHIN CIRM BAYH-DOLE LIKE RIGHTS TO STEP IN IF THE OWNER IS NOT ENSURING THIS DILIGENCE.

DEVELOPMENT, NO. 6 AND NO. 9, I THINK, DO HAVE ADMINISTRATIVE IMPLEMENTATIONS FOR CIRM, BUT THIS IS A RECOMMENDATION THAT CIRM HAVE SOME CAPABILITY TO MONITOR WHAT'S GOING ON WITH THE INTELLECTUAL PROPERTY DEVELOPED FROM CIRM FUNDING. MONITOR AND BE PREPARED TO TAKE SOME PROACTIVE STEPS.

SEVEN GETS BACK TO WHAT STEVE MENTIONED A FEW TIMES. LEAVE LICENSE PARTICULARS TO THE OWNER WHO IS IN THE BEST POSITION TO JUDGE HOW BEST TO ENSURE THAT THESE DISCOVERIES GET OUT THERE. SO NOT REQUIRE 6-PERCENT ROYALTY ACROSS THE BOARD OR YOU NAME IT X, Y, Z.

EIGHT, RESERVE THE RIGHT TO USE IP BY OR ON

BEHALF OF CIRM. CIRM ESSENTIALLY RETAINS SOMETHING EQUIVALENT TO THE GOVERNMENT RIGHT UNDER BAYH-DOLE.

AND LASTLY, TO ESTABLISH AND MAINTAIN A CIRM DATABASE TO TRACK IP TO ENSURE THAT IT IS BEING DEVELOPED DILIGENTLY, AND ALSO TO BEGIN TO ESTABLISH A COMMON DATABASE WHERE YOU DO AT LEAST HAVE A PLACE TO GO AND UNDERSTAND WHAT THE UNIVERSE OF TECHNOLOGIES ARE AND INVENTIONS ARE.

I BELIEVE THAT'S THE END OF THAT.

DR. HACKWOOD: STEVE IS JUST GOING TO WRAP UP WITH THE --

DR. ROCKWOOD: WE DID NOT FINISH IN THE TIME WE HAD ON THE COMMITTEE. I'LL LET YOU READ THESE. THE RETURN TO THE STATE, CLEARLY THAT'S COMPLEX. THERE'S MANY WAYS OF RETURNING BENEFIT TO THE STATE. AND HOW YOU DEFINE THE BENEFIT CHANGES YOUR OUTCOME CONSIDERABLY. WE'VE TOLD YOU OUR DECISION AS TO WHAT THE MAJOR BENEFIT WOULD BE. THAT IS IN THE TREATMENT OF CHRONIC DISEASE AND IMPROVEMENT OF QUALITY OF LIFE, SO WE PUT THAT AS THE MAJOR RETURN.

WE DIDN'T HAVE TIME TO GET INTO A DETAILED ECONOMIC ANALYSIS. ALSO, FOR YOUR INFORMATION, I GUESS WE CAN SAY THE STATE OF NEW JERSEY HAS RECENTLY PUT OUT A STUDY AS WELL ON WHAT RETURNS TO THE STATE MIGHT BE FOR SIMILARLY FUNDED STEM CELL RESEARCH. THEY

DECIDED --

DR. PRIETO: THEY DON'T HAVE A POLICY YET.

DR. ROCKWOOD: NO, THEY DO NOT.

ORPHAN DISEASES, WE TALKED ABOUT THAT. IT WAS A CONCERN. WE WOULD LIKE TO SEE WAYS TO INCENTIVIZE TREATMENTS AND THERAPY, BUT WE HAD NO FURTHER BRILLIANT IDEAS IN THE TIME AVAILABLE TO US ON THAT ONE.

SHARING RESEARCH TOOLS HAS BEEN ADDRESSED. IT IS IMPORTANT.

PUBLICATIONS AS WELL. AND THEN I DON'T KNOW IF THIS IS YOUR PROBLEM OR THE UNIVERSITY'S PROBLEM, IN ALL HONESTY, BUT THAT LAST POINT THERE, IF FIREWALLS ARE NEEDED BETWEEN NIH- AND CIRM-FUNDED STEM CELL RESEARCH, WHAT ARE THEY AND WHAT DOES IT TAKE TO MAKE THEM LEGALLY BINDING -- BINDING IS THE WRONG WORD -- BUT IF CHALLENGED, THEY WOULD WITHSTAND A LEGAL CHALLENGE. THAT MAY BE MORE UP TO THE RESEARCH INSTITUTION.

DR. PRIETO: I WOULD THINK THAT WOULD BE MORE THE RESPONSIBILITY OF THE GRANTEE SINCE IT'S REALLY THE NIH PUTTING THE RESTRICTIONS IN PLACE AND NOT US.

DR. ROCKWOOD: I AGREE WITH YOU. IT IS A POINT WE RAISED AS A POSSIBLE COMPLICATION AND JUST DIDN'T HAVE TIME TO GO INTO IT.

DR. FONTANA: I HAVE A QUESTION JUST BEFORE YOU LEAVE. SOME OF THE DISCUSSION THAT YOU HAD ON HOW YOU WOULD SHARE A DATABASE, WHICH I THINK IS GREAT, HOW DO YOU GET AROUND SOME OF THOSE IP ISSUES THAT, LET'S SAY, IT'S A CELL LINE. SOMEBODY MAY NOT WANT TO SHARE THE CELL LINE UNTIL IT'S PATENTED. DO YOU WAIT TILL IT'S PATENTED? DID YOU DISCUSS THAT?

DR. ROCKWOOD: YOU CAN SEE WHAT WE DID IS I WON'T SAY PUNT, BUT WE LEFT THE PARTICULARS TO THAT PARTICULAR SITUATION. WE HAVE GIVEN OR ADVISED THAT YOU RETAIN RIGHTS. YOU HAVE USE OF THAT CELL LINE FOR ANY CIRM-FUNDED ACTIVITY. THAT WAS ONE OF THE POINTS THAT WE GAVE YOU. YOU ALSO RETAIN MARCH-IN RIGHTS IF THEY'RE NOT DOING WHAT YOU THINK THEY SHOULD WITH IT. SO IF IT'S JUST LYING FALLOW, YOU SHOULD COME IN AND SAY YOU'RE NOT WORKING ON THIS. WE'RE GOING TO PUT IT UP FOR AUCTION AND LICENSE IT TO SOMEBODY ELSE.

DR. FONTANA: OR WE COULD PERHAPS FOLLOW SOUTH KOREA'S MODEL WHERE THE GOVERNMENT FUNDS THE PRODUCTION OF STEM CELL LINES AND NOW THEY'RE SELLING IT TO THE REST OF THE WORLD.

DR. ROCKWOOD: THAT'S POSSIBLE. BEAR IN MIND A LOT OF OUR POLICIES ARE TAILORED TO THE FACT THAT THIS IS BASIC RESEARCH. IF THE STATE OF CALIFORNIA CHOSE TO GO FROM RESEARCH TO TRANSLATIONAL RESEARCH TO

ANIMAL TRIALS TO POSSIBLY HUMAN TRIALS, THE MORE YOU WANT TO FUND DOWN THAT LINE, THE MORE THE STATE SHOULD OWN EVERYTHING BECAUSE YOU PUT IN THE MONEY. IF ALL YOU PUT IN IS THE RESEARCH AND SOMEBODY ELSE HAS COME IN AND PUT IN ALL THE REST OF THE MONEY, YOU HAVE TO CONSIDER WHAT RIGHTS THEY HAVE.

DR. FONTANA: HOW DO YOU GET THE DATA OUT THERE EARLY ENOUGH SO THAT OTHER PEOPLE CAN TAKE ADVANTAGE OF IT WITHOUT DEALING WITH DISINCENTIVIZING PEOPLE AND INCENTIVIZING PEOPLE?

MR. SHEEHY: WE DID KIND OF TALK ABOUT THAT IN THE STANDARDS WORKING GROUP. SO ACTUALLY THE STANDARDS WORKING GROUP IS --

DR. FONTANA: BUT IT REALLY COMES DOWN TO THE MONEY. WHO OWNS THE PROPERTY?

MR. SHEEHY: IT'S ACTUALLY THE RECOMMENDATION THAT A BANK BE ESTABLISHED EVENTUALLY AND THAT ALL LINES BE BANKED. AND THAT -- I CAN'T REMEMBER THE EXACT LANGUAGE, BUT I THINK THAT ALL LINES BE BANKED EVENTUALLY WAS THE RECOMMENDATION, AND THAT THE LINES WOULD BE MADE AVAILABLE EITHER UPON PUBLICATION OR WITHIN 12 MONTHS AFTER A PATENT APPLICATION WAS FILED. SO THAT THERE WOULD BE A REQUIREMENT THAT CELL LINES DERIVED THROUGH CIRM-FUNDED RESEARCH SHALL BE SHARED WITH OTHER INVESTIGATORS EITHER THROUGH THEIR

INSTITUTION -- WELL, THROUGH A CIRM-DESIGNATED BANK, SO THERE'S STILL SOME -- BECAUSE THERE'S GOING TO BE SOME GAP PROBABLY BETWEEN. AND THEN THAT FULLY ENABLING INFORMATION TO FUNCTIONALLY REPLICATE THE CELL LINES AND THE MEDIA TO MAINTAIN THEM WILL BE MADE AVAILABLE AND TO REQUIRE THE DEPOSIT OF THE CELL LINES IN THE BANK WITHIN 12 MONTHS OF FILING THE FULL PATENT OR PUBLICATION DATE, WHICHEVER IS EARLIER.

AT LEAST FOR THE LINES ISSUE, THERE'S SOME MOVEMENT FROM THE ETHICISTS.

CHAIRMAN PENHOET: POINT WORTH NOTING, THE FEDERAL PATENT LAW WAS ACTUALLY ENACTED IN ITS HISTORY, IN THE BEGINNING, TO ALLOW THE DISSEMINATION OF RESEARCH RESULTS. IF THE ALTERNATIVE IS ONLY THAT YOU KEEP THE INFORMATION TO YOURSELF IN THE FORM OF TRADE SECRETS, THEN YOU DON'T DISBURSE IT. SO ONE OF THE GOALS OF THE PATENT LAW TO BEGIN WITH WAS THE FACT THAT ONCE YOU FILED THE PATENT, THEN YOU'RE FREE TO DISSEMINATE THE INFORMATION BECAUSE YOU HAVE ESTABLISHED THE VALUE IN FILING A PATENT APPLICATION.

DR. LOVE: AND IT'S WORKED BEAUTIFULLY. LET'S FACE IT. IT'S WORKED WONDERFULLY.

DR. FONTANA: SO WE CAN STREAMLINE THAT PROCESS.

DR. HACKWOOD: SO YOU GET THE PICTURE SO FAR

WHERE THE REPORT IS GOING, AND WE HAD A LOT OF QUESTIONS ABOUT BAYH-DOLE. WE THOUGHT IT WOULD BE WORTHWHILE PUTTING A LOT MORE TIME IN GOING INTO THE DETAILS OF BAYH-DOLE AND THE IMPLICATIONS AND ALSO ON THE DATA SHARING. AND PAM IS AN EXPERT ON THIS, SO PAM WILL TAKE OVER AND GIVE US SOME IDEA OF WHY AND HOW.

MS. SAMUELSON: SO, LIKE ALAN, I'LL SAY JUST A BIT MORE ABOUT MYSELF BEFORE WE GET STARTED WITH THIS. AS SUSAN MENTIONED, I TEACH AT THE SCHOOL OF INFORMATION MANAGEMENT AND SYSTEMS. I ALSO TEACH AT THE LAW SCHOOL, AND I'M A DIRECTOR OF THE CENTER FOR LAW AND TECHNOLOGY AT BOALT HALL SCHOOL OF LAW, ALSO AN ADVISOR OF THE HIGH TECHNOLOGY AND LAW AND PUBLIC POLICY CLINIC AT UC BERKELEY'S LAW SCHOOL, WHICH PROVIDES ACTUALLY REPRESENTATION OF PUBLIC INTEREST PERSPECTIVES IN CASES INVOLVING LITIGATION OR MATTERS PENDING BEFORE STATE LEGISLATURES OR BEFORE THE FEDERAL COMMUNICATIONS COMMISSION AND OTHERWISE. AND SO EVEN THOUGH I WASN'T CHOSEN, I THINK, TO BE A PUBLIC INTEREST REPRESENTATIVE ON THE COMMITTEE, I CONSIDER THAT MY ROLE AT UC BERKELEY IS TO PROMOTE THE PUBLIC INTEREST. AND SO I COME TO THIS PARTICULAR ENDEAVOR WITH VERY MUCH A PUBLIC INTEREST PERSPECTIVE IN MIND.

WE PROBABLY DIDN'T COORDINATE AS WELL AS WE SHOULD HAVE HERE AND MAYBE IT WOULD HAVE BEEN BETTER TO

START WITH THIS, BUT WHAT THE HECK, WE'LL DO WHAT WE CAN HERE. ONE WAY I ACTUALLY THINK THAT IT'S WORTH OUR THINKING ABOUT THE INTELLECTUAL PROPERTY POLICY IS REALLY TO RECOGNIZE THAT THERE ARE LOTS OF DIFFERENT KINDS OF RESEARCH OUTPUTS THAT MIGHT BE POTENTIALLY PROTECTABLE BY INTELLECTUAL PROPERTY LAWS. AND ONE REASON, FOR EXAMPLE, THAT JUST SAYING SUCH-AND-SUCH PERCENTAGE HAS TO FLOW IS THAT WE MAY WANT TO SORT OF THINK ABOUT THAT IN TERMS MORE OF THE THERAPEUTICS THAN OF SOME OTHER PARTS OF THE TOOL.

SO, FOR EXAMPLE, FUNCTIONAL DESIGNS OF SOFTWARE, BIOINFORMATICS SOFTWARE THAT MIGHT BE DEVELOPED WITH CIRM MONEY MIGHT ACTUALLY BE PATENTABLE SUBJECT MATTER, BUT MAYBE THIS IS ACTUALLY AN EXAMPLE WHERE YOU DON'T WANT TO ACTUALLY PATENT IT. YOU WANT -- IF THE RESEARCHER THINKS THAT IT'S FASTER TO GET THE TECHNOLOGY TRANSFERRED TO OTHER RESEARCHERS BY CREATING AN OPEN SOURCE SOFTWARE PROGRAM, THEN ELECTING NOT TO PATENT, BUT EXPLAINING THE REASON FOR NOT PATENTING THESE FUNCTIONAL DESIGNS, THAT'S NOT WHERE THE BIG VALUE IS. THAT'S NOT GOING TO CURE THE DISEASES, BUT THINGS THAT WILL MOVE RESEARCH ALONG, I THINK, WE CAN COUNT ON OUR UNIVERSITY RESEARCHERS TO REALLY TRY TO THINK ABOUT SORT OF WHAT NEEDS TO GET OUT THERE QUICKLY, WHAT NEEDS TIME TO DEVELOP, WHAT NEEDS

MORE RESOURCES TO DEVELOP, AND THINGS LIKE BIOINFORMATICS TOOLS MIGHT ACTUALLY BE SOMETHING WHICH CAN BE TRANSFERRED ON AN OPEN SOURCE BASIS EVEN THOUGH THERE MAY BE SOME POTENTIALLY PATENTABLE INVENTION IN IT.

BUT, AGAIN, A REASON NOT TO JUST HAVE A COOKIE CUTTER OF SO MANY PERCENT OF ANYTHING HAS TO FLOW IS BECAUSE THERE ARE DIFFERENT KINDS OF INTELLECTUAL PROPERTY THAT MAY BE -- DIFFERENT KINDS OF RESEARCH OUTPUTS THAT MAY BE SUBJECT TO INTELLECTUAL PROPERTY RIGHTS, AND SOME OF THE ROYALTY BEARING MAY BE MORE APPROPRIATE FOR SOME RATHER THAN OTHERS. SO I THINK IT'S IMPORTANT TO THINK ABOUT THAT. ALSO, WHILE THE ATTENTION IS MOSTLY PATENTABLE INVENTIONS, IT'S IMPORTANT, ESPECIALLY GIVEN THAT SO MUCH OF WHAT CIRM IS GOING TO BE DOING IS FUNDING BASIC RESEARCH, IS TO HAVE A COPYRIGHT POLICY, NOT JUST A PATENT POLICY, AND THAT POLICY WOULD COVER THINGS LIKE SOFTWARE, DATABASES OF RESEARCH DATA, AND RESEARCH REPORTS AND ARTICLES. AND SO THAT'S ACTUALLY NOT SOMETHING THAT BAYH-DOLE DEALS WITH. I'LL TALK ABOUT THAT IN A LITTLE BIT GREATER DETAIL AS WE GO.

I THINK IT'S HELPFUL TO SORT OF JUST SAY WHAT KIND OF THINGS ARE OUT THERE, AND THEN LET'S THINK ABOUT THE INTELLECTUAL PROPERTY POLICY THAT YOU FOLKS

ARE GOING TO BE TRYING TO RECOMMEND BY NOT JUST SAYING, OH, IT'S JUST ABOUT THERAPEUTICS. IN FACT, IT'S ABOUT A NUMBER OF DIFFERENT KINDS OF THINGS.

WE'VE TALKED ABOUT PATENTS AND MAYBE EVERYBODY KNOWS THIS, BUT IT'S PROBABLY, FOR THOSE OF YOU WHO ARE NOT PATENT MAVENS, JUST TO REALIZE THAT PATENTS ARE AVAILABLE FOR NEW, USEFUL, AND NONOBVIOUS, AND NONOBVIOUS IS KIND OF A TERM OF ART, IT'S A WAY OF TRYING TO MEASURE WHAT'S ACTUALLY AN INVENTION. IF SOMETHING WOULD BE OBVIOUS TO SOMEONE WHO IS SKILLED IN THE ART, THEN IT'S NOT PATENTABLE BECAUSE IT DOESN'T HAVE AN INVENTIVE STEP. BUT IF IT WOULD BE NONOBVIOUS TO SOMEONE SKILLED IN THE ART, THEN THAT'S ENOUGH INVENTION TO QUALIFY FOR A PATENT. AND THERE ARE FOUR CATEGORIES OF SUBJECT MATTER THAT CAN BE PATENTED: MACHINES, MANUFACTURERS, COMPOSITION OF MATTER, AND PROCESSES.

AGAIN, THINKING ABOUT THIS FROM THE STANDPOINT OF THOSE DIFFERENT KINDS OF RESEARCH OUTPUTS, I THINK YOU CAN SAY THE COMPOSITIONS OF MATTER ARE PROBABLY THE CHIEF KIND OF THING THAT WE'RE LOOKING FOR IN TERMS OF THERAPEUTIC AND DIAGNOSTICS, BUT MACHINES, MANUFACTURERS, AND PROCESSES MAY ALSO BE APPROPRIATE GIVEN, FOR EXAMPLE, THAT SOFTWARE IS A VIRTUAL MACHINE. PROCESSES CAN BE VERY IMPORTANT, AND

SO THESE ARE ALL THE DIFFERENT TYPES OF THINGS THAT QUALIFY FOR PATENT PROTECTION.

YOU DON'T GET PATENT PROTECTION AUTOMATICALLY. YOU HAVE TO APPLY TO THE PATENT OFFICE, AND YOU HAVE TO DISCLOSE THE INVENTION. THE DISCLOSURE WAS MENTIONED BEFORE. IT'S ACTUALLY PART OF WHAT THE PUBLIC IS SUPPOSED TO GET IMMEDIATELY FROM THE ISSUANCE OF A PATENT IS THE INFORMATION ABOUT HOW TO MAKE THE INVENTION, HOW IT'S DIFFERENT FROM THE STATE OF THE ART, AND WHY SOMEBODY THINKS IT ACTUALLY IS IMPORTANT. AND YOU HAVE TO CLAIM SPECIFIC ELEMENTS OF THE INVENTION. YOU CAN'T JUST SAY, OH, WELL, THERE'S THIS MOLECULE OUT THERE. YOU ACTUALLY HAVE TO SAY SOMETHING MUCH MORE SPECIFIC ABOUT WHAT THE SCOPE OF YOUR CLAIM IS AND WHAT YOU REALLY INVENTED.

EXAMINERS ARE CHARGED WITH REVIEWING THE PATENT APPLICATIONS, SEARCHING FOR THE PRIOR ART. THEY OFTEN INSIST ON CHANGES TO CLAIM LANGUAGE, USUALLY NARROW IT. THEN THEY MAKE A DECISION WHETHER TO ISSUE A PATENT OR NOT. THE PATENT WILL GIVE THE INVENTOR EXCLUSIVE RIGHTS TO MAKE, USE, OR SELL THE INVENTION FOR UP TO 20 YEARS FROM THE DATE OF APPLICATION, BUT IT'S VERY COSTLY TO APPLY FOR A PATENT. ESTIMATES USUALLY RUN FROM TEN TO $25,000 TO DO THAT, AND THERE ARE RENEWAL FEES. SO TO KEEP A PATENT ALIVE FOR THE

FULL TERM THAT IT'S AVAILABLE IS SOMETHING THAT ALSO IS COSTLY. AND THAT'S ONE OF THE FACTORS THAT I THINK IS IMPORTANT TO KEEP INTO -- TAKE INTO ACCOUNT HERE IS THAT IT'S NOT JUST A TRIVIAL PROCESS TO GET A PATENT. AND SO PATENTS REALLY OUGHT NOT TO BE FOR EVERY TOM, DICK, AND HARRY OF A THING THAT MIGHT QUALIFY, BUT YOU SHOULD FOCUS ON WHAT REALLY ARE THE IMPORTANT THINGS AND APPLY FOR THAT.

WITH COPYRIGHT, THE PROCESS IS REALLY QUITE DIFFERENT. SO IS THE SUBJECT MATTER. ORIGINAL WORKS OF AUTHORSHIP THAT QUALIFY FOR COPYRIGHT PROTECTION FROM THE FIRST TIME THEY'RE FIXED IN A TANGIBLE FORM, THE PROTECTION LASTS, TODAY, THE LIFE OF THE AUTHOR PLUS 70 YEARS. THE COPYRIGHT PROTECTS THE AUTHOR'S EXPRESSION, NOT IDEAS, NOT FACTS, NOT THEORIES IN THE WORK, NOT METHODS OR PROCESSES THAT ARE EMBODIED. AND THESE DAYS SOFTWARE IS CONSIDERED AN ORIGINAL WORK OF AUTHORSHIP IF THERE'S SOME SPARK OF CREATIVE EFFORT IN THE DEVELOPMENT OF THE PROGRAM, BUT THE METHODS AND PROCESSES IN THE PROGRAM ARE NOT COVERED.

YOU DON'T NEED TO REALLY REGISTER YOUR CLAIM OF COPYRIGHT EXCEPT IF YOU WANT TO FILE AN INFRINGEMENT SUIT, AND SO IT'S VERY DIFFERENT IN TERMS OF THE DEMANDS THAT IT PLACES ON PEOPLE TO CLAIM THE RIGHTS.

DEFAULT OWNERSHIP RULES OF PATENT AND

COPYRIGHT ARE SOMEWHAT DIFFERENT. ONLY THE INVENTOR MAY APPLY FOR A PATENT, BUT CONTRACTS OFTEN ALLOCATE OWNERSHIP RIGHTS SO THAT EMPLOYERS, FOR EXAMPLE, WILL OFTEN ASK EMPLOYEES TO SIGN AGREEMENTS TO TRANSFER PATENT RIGHTS OR WILL AGREE TO SOME SORT OF ROYALTY SHARING IF THE EMPLOYEE IS A CREATIVE INVENTOR ON THE JOB. BAYH-DOLE REGULATES CLAIMS OF PATENT RIGHTS FOR U.S.-FUNDED RESEARCH. AUTHORS OWN COPYRIGHTS IN HER WORK. THERE IS A WORK MADE PRIOR RULE THAT TREATS EMPLOYERS AS AUTHORS FOR WORK CREATED WITHIN THE SCOPE OF EMPLOYMENT. THERE'S A QUITE WELL RECOGNIZED TEACHER EXCEPTION TO THAT, AND MANY UNIVERSITY POLICIES ALLOW PROFESSORS AND RESEARCHERS TO CLAIM COPYRIGHT EXCEPT IN THINGS THAT ARE SPECIFICALLY DONE FOR THE UNIVERSITY AS OPPOSED TO JUST DOING THE PERSON'S RESEARCH. AND, AGAIN, CONTRACTS REGULATE OWNERSHIP IN MANY INSTANCES.

I'M GOING TO GO BACK OVER VERY BRIEFLY SOME GROUND THAT ALAN COVERED. AS HE MENTIONED, U.S. GOVERNMENT USED TO CLAIM PATENTS IN LOTS OF GOVERNMENT-FUNDED RESEARCH, BUT THE GOVERNMENT WAS NOT IN A VERY GOOD POSITION TO MAKE DECISIONS ABOUT WHAT KINDS OF TECHNOLOGY TO TRANSFER. IT WAS DOING IT ON A NONEXCLUSIVE BASIS. AND WHERE THERE NEEDS TO BE COSTLY INVESTMENT TO TAKE RESEARCH DISCOVERY AND MAKE IT INTO A COMMERCIAL PRODUCT, PEOPLE CAN'T RECOUP R & D COSTS.

THAT WAS A PROBLEM BOTH IN TERMS OF THE NONEXCLUSIVE LICENSING PRACTICES OF THE U.S. GOVERNMENT; AND ALSO IF THE PATENTS WEREN'T FILED, THE INVENTION GOES INTO THE PUBLIC DOMAIN IF IT'S BEEN DISCLOSED. AND, AGAIN, IF AN INVENTION'S IN THE PUBLIC DOMAIN AND IT'S COSTLY TO TAKE IT FROM HERE TO THERE, THEN PRIVATE INVESTMENT FIRMS MAY BE RELUCTANT TO ENGAGE IN THAT INVESTMENT.

ALTHOUGH SOME GOVERNMENT CONTRACTORS WERE ABLE TO NEGOTIATE TO RETAIN PATENTS, THE GOVERNMENT TYPICALLY RETAINED UNLIMITED RIGHTS TO USE THE INVENTIONS FOR THEMSELVES AND ALSO TO LICENSE OTHERS, AND THAT ALSO UNDERMINED INCENTIVES FOR PRIVATE FIRMS. AND THERE WERE ALSO A LOT OF HIGH COSTS ASSOCIATED WITH NONSTANDARD CONTRACTS.

BAYH-DOLE ACTUALLY IN SECTION 202 OR 200 ACTUALLY GIVES AN EXAMPLE OF WHAT ITS GOALS ARE. BUT I THINK IF YOU LOOK AT THE GOALS, IN THE STATUTE THEY ARE ACTUALLY VERY FOCUSED ON BENEFITING THE PUBLIC. THEY'RE TRYING TO PROMOTE DEVELOPMENT AND DISSEMINATION OF PRODUCTS THAT EMBODY USEFUL ADVANCES TO THE PUBLIC TO INDUCE PRIVATE FIRMS TO SEEK PARTNERSHIPS WITH UNIVERSITY RESEARCHERS BECAUSE LICENSED PATENT RIGHTS WILL ENABLE THE FIRMS TO RECOUP THEIR INVESTMENTS. IT DELEGATES TO THE GRANTEES DECISIONS ABOUT APPROPRIATE LICENSING STRATEGIES AND PROVIDES OPPORTUNITIES FOR

FURTHER RESEARCH FUNDING BY ENSURING THAT SOME PORTION OF THE ROYALTY COMES BACK TO -- GETS REINVESTED IN RESEARCH.

READING BAYH-DOLE, I SEE A LOT OF THE CHECKS AND BALANCES REALLY BUILT INTO IT. I PROVIDED THE FULL --

CHAIRMAN PENHOET: WHAT IS THAT TYPICAL FRACTION IN CALIFORNIA UNIVERSITIES TODAY THAT DOES GET REINVESTED IN RESEARCH?

MS. SAMUELSON: I THINK LIKE ABOUT -- IT VARIES BY UNIVERSITY.

CHAIRMAN PENHOET: JUST AVERAGE WHAT WOULD YOU GUESS? I KNOW YOU DON'T HAVE THE FIGURES.

DR. BENNETT: THE SORT OF AVERAGE ACROSS THE COUNTRY IS 30 PERCENT, A THIRD, A THIRD, A THIRD.

MS. SAMUELSON: AGAIN, I'M NOT GOING TO GO OVER SOME OF THESE BECAUSE WE MISCOMMUNICATED. I THOUGHT I WAS SUPPOSED TO DO THIS AND HE THOUGHT HE WAS SUPPOSED TO DO THIS. I THINK WE PROBABLY COVERED MOST OF THESE POINTS.

DR. HACKWOOD: ALAN TALKED ABOUT UNIVERSITIES MOST OF THE TIME. MAYBE YOU COULD MENTION BUSINESS BECAUSE SMALL BUSINESSES WERE A TARGET OF BAYH-DOLE AS WELL.

MS. SAMUELSON: SO ACTUALLY THERE ARE SOME

DIFFERENCES IN BAYH-DOLE IN THE REGULATION OF UNIVERSITIES AND SMALL BUSINESSES. IN SOME RESPECTS UNIVERSITIES ARE MORE REGULATED. UNIVERSITIES, FOR EXAMPLE, CAN'T ASSIGN PATENTS THAT ARE OBTAINED WITH FEDERALLY FUNDED RESEARCH; WHEREAS, SMALL BUSINESSES ARE GRANTED THE RIGHT TO ASSIGN THE PATENTS. AND ALL GRANTEES HAVE THE DUTY TO REPORT INVENTIONS TO THE GRANTING AGENCY. THE AGENCY HAS THE RIGHT TO APPLY FOR THE GRANT. AND SO ALL THESE DUTIES THAT ACTUALLY BAYH-DOLE IMPOSES ARE ONES THAT AREN'T JUST ON UNIVERSITIES, BUT THEY'RE ALSO ON OTHER GRANTEES.

THE MARCH-IN RIGHTS CAME UP SOMEWHAT EARLIER, SO IT'S PROBABLY WORTH SPENDING A MINUTE ON THAT. THE PROVISION OF BAYH-DOLE THAT TALKS ABOUT MARCH-IN RIGHTS ISN'T VERY LONG. BUT SECTION 203 SAYS THAT A FEDERAL AGENCY UNDER WHOSE FUNDING AGREEMENT THE SUBJECT INVENTION WAS MADE SHALL HAVE THE RIGHT, IN ACCORDANCE WITH SUCH PROCEDURES THAT ARE PROMULGATED, BLAH, BLAH, BLAH, TO REQUIRE A CONTRACT OR EXCLUSIVE LICENSEE OF A SUBJECT MATTER INVENTION TO GRANT A NONEXCLUSIVE, PARTIALLY EXCLUSIVE, OR EXCLUSIVE LICENSE IN ANY FIELD TO A RESPONSIBLE APPLICANT ON TERMS THAT ARE REASONABLE UNDER THE CIRCUMSTANCES.

SO THERE ARE A LOT OF SORT OF JUDGMENTS THAT HAVE TO BE MADE THERE, AND THERE ARE FOUR CONDITIONS

THAT ARE SET FORTH IN THE STATUTE THAT IDENTIFY CIRCUMSTANCES UNDER WHICH MARCH-IN CAN TAKE PLACE. THE FIRST IS WHERE THE ACTION IS NECESSARY BECAUSE THE CONTRACTOR HAS NOT UNDERTAKEN OR IS NOT EXPECTED TO UNDERTAKE WITHIN A REASONABLE TIME EFFECTIVE STEPS TO ACHIEVE PRACTICAL APPLICATION OF THE SUBJECT INVENTION IN THE FIELD OF USE THAT'S APPLIED.

SECOND IS THAT THE ACTION IS NECESSARY TO ALLEVIATE HEALTH OR SAFETY NEEDS WHICH ARE NOT REASONABLY SATISFIED BY THE CONTRACT OR OTHER LICENSEES. AND THERE ARE A COUPLE OF VARIANTS ON THAT, BUT THOSE ARE THE TWO CRITICAL BASES ON WHICH MARCH-IN RIGHTS CAN BE EXERCISED. AND ONE OF THE REASONS NOT TO ALLOW THE NONPROFITS TO ASSIGN AWAY THE RIGHTS IS TO ENSURE THAT THE GOVERNMENT RETAINS THE MARCH-IN RIGHTS SO THAT THERE IS DILIGENT PURSUANCE AND MAKING AVAILABLE ON A REASONABLE BASIS THE PRODUCTS THAT MIGHT RESULT.

MR. SHEEHY: CAN I GET A LITTLE MORE DETAIL ON THAT? IT SEEMS TO ME THAT THE LANGUAGE IN THERE IS REALLY BROAD, AND SO CASE LAW SEEMS TO HAVE LIMITED IN A WAY THAT DOESN'T -- I MEAN WE TALK ABOUT HEALTH AND SAFETY. YOU COULD TALK ABOUT PRICING, YOU COULD TALK ABOUT ACCESS, YOU COULD TALK ABOUT ALL SORTS OF ISSUES, BUT IT SEEMS THAT WITHIN THE CONTEXT OF THE WAY THE LAW

HAS BEEN PROSECUTED BY NIH, SO TO SPEAK, THAT IT'S BEEN A VERY NARROW INTERPRETATION. I JUST WONDER HOW OFTEN MARCH-IN RIGHTS HAVE BEEN INVOKED.

MS. SAMUELSON: I THINK THE MAIN REASON TO HAVE MARCH-IN RIGHTS IS SO THAT GRANTEES KNOW THAT THIS SORT OF DAMOCLES IS OVER THEIR HEAD. I THINK IT HELPS SELF-POLICE THE ACTIVITY OF THE ENTITIES. SO FAR AS I KNOW, THERE'S NEVER BEEN A FORMAL EXERCISE OF THE MARCH-IN RIGHTS, BUT THERE HAVE BEEN NUMEROUS SITUATIONS IN WHICH NIH, FOR EXAMPLE, HAS PUT PRESSURE. SO THE EISENBERG AND RAI AND THE ARTICLE THAT THEY WROTE ABOUT BAYH-DOLE TALK ABOUT NIH SAYING THAT IT WOULD BOYCOTT DUPONT UNLESS DUPONT MADE CERTAIN TECHNOLOGY AVAILABLE ON A BROADER LICENSE BASIS. AND WHERE DOES THE AUTHORITY TO PUT SOME PRESSURE COME FROM? IT COMES FROM THE ABILITY TO DO MARCH-IN RIGHTS IN THE FIRST PLACE.

MR. SHEEHY: WHAT WOULD BE OUR ABILITY TO ENFORCE THOSE RIGHTS? WE DON'T HAVE A GOOD FEDERAL MODEL. IN OTHER WORDS, YOU'RE ALMOST SAYING THAT NIH JAWBONES INDUSTRY TO GET THEM TO RELEASE THE PRODUCTS. AND I'M JUST WONDERING IF WE DON'T HAVE A GOOD FEDERAL KIND OF STANDARD, WE'RE NOT NIH, PEOPLE CAN JUST REFUSE TO DO IT. YOU'VE OFFERED A MODEL IN BAYH-DOLE THAT DOESN'T HAVE A GOOD LITIGATION HISTORY, IT SOUNDS LIKE.

SHORT OF LITIGATING --

MS. SAMUELSON: I ACTUALLY DON'T CONSIDER A LAW TO BE UNSUCCESSFUL IF IT DOESN'T LEAD TO LITIGATION. ACTUALLY GOOD LAWS MAKE LITIGATION UNNECESSARY, AND IT SEEMS TO ME THAT THE POWER THAT NIH AND OTHER FEDERAL AGENCIES HAVE TO DO MARCH-IN ACTUALLY PUTS A VERY SUBSTANTIAL AMOUNT OF PRESSURE ON THE GRANTEES. AND REMEMBER THAT MOST OF THE GRANTEES THAT WE'RE TALKING ABOUT HERE ARE GRANTEES WHO ARE GOING TO BE DOING BASIC RESEARCH. THEY'RE GRANTEES THAT ARE UNIVERSITY PEOPLE WHO HAVE ALSO A COMMITMENT TO TRANSFORMING THESE STEM CELL RESEARCH IDEAS INTO THERAPIES. AND SO I THINK THAT THERE'S MORE HARMONY HERE THAN -- MARCH-IN RIGHTS ARE THERE IF YOU NEED THEM, BUT I DON'T THINK HAVING TO MARCH IN IS A GOOD THING.

MR. SHEEHY: I'M JUST SAYING -- BECAUSE YOU'VE TALKED ABOUT THE FEDERAL GOVERNMENT. YOU'RE TALKING ABOUT A LEVEL OF POWER THAT DOESN'T EXIST FOR US. THE EFFICACY OF BAYH-DOLE AND MARCH-IN RIGHTS AT THE FEDERAL LEVEL IS -- I THINK THIS IS ONE OF THE KEY PIECES FOR US, AND THIS COMES UP AGAIN AND AGAIN, THAT WE NEED SOME SORT OF MECHANISM TO MAKE SURE THAT WHATEVER WE DEVELOP, ESPECIALLY IF WE'RE GOING TO MAKE THESE THERAPIES OR WHATEVER WE HAVE, IF OUR GOAL IS

REALLY TO ACCELERATE RESEARCH, WE HAVE TO HAVE SOME WAY TO MAKE SURE PEOPLE DON'T SIT ON THEIR STUFF, RIGHT.

YOU KEEP TALKING ABOUT BAYH-DOLE WHERE THE FEDERAL GOVERNMENT SAYS, LOOK, IT'S US. IF YOU DON'T DO IT, WE'LL NEVER GIVE YOU ANOTHER -- WE HAVE A VERY LIMITED FUNDING SOURCE THAT WILL RUN OUT IN TEN YEARS. PEOPLE CAN SIT -- THIS WAS RAISED YESTERDAY WHERE PEOPLE WERE NOT GETTING ACCESS. A RESEARCHER TRIED TO GET ACCESS TO A LINE THAT WAS DEVELOPED BY ANOTHER RESEARCHER THAT WAS UNIQUE, AND THE RESEARCHER SAID NO. LET'S IMAGINE THAT SCENARIO FOR US. WE HAVE SOME SORT OF MARCH-IN RIGHT AND THERE'S SOMETHING THAT'S BEEN DEVELOPED AND THEY SAY NO TO ANOTHER RESEARCHER. WHAT'S OUR RECOURSE?

AND, YOU KNOW, IS SIMPLY DUPLICATING THE LANGUAGE IN BAYH-DOLE GOING TO GET US THERE, ESPECIALLY WITH SUCH A DIRECT REFERENCE TO BAYH-DOLE, WHEN THERE'S NOT -- I JUST DON'T -- IT'S JUST NOT CLEAR TO ME. I'M TRYING TO UNDERSTAND HOW THESE MECHANISMS ARE GOING TO WORK.

CHAIRMAN PENHOET: IF I COULD, JEFF, I BELIEVE WHAT WE WOULD DO IN THE END IS ENTER INTO A CONTRACT WITH EACH GRANTEE. AND IF BY CONTRACT WITH WHOEVER, STANFORD UNIVERSITY, AS THEIR REQUIREMENT FOR TAKING OUR FUNDS, THEY WOULD SIGN THIS CONTRACT THAT

SAYS IF THEY TAKE OUR FUNDS, THEY WILL AGREE TO THE FOLLOWING THINGS, INCLUDING THE FACT THAT WE COULD MARCH IN. SO WE WOULD HAVE AN INDEPENDENT RIGHT TO MARCH IN THAT WAS INDEPENDENT OF WHATEVER THE FEDERAL GOVERNMENT HAS DONE. WE'RE NOT EMPOWERING THE FEDERAL GOVERNMENT TO DO IT FOR US. THEY WOULD HAVE TO REWRITE THE CONTRACT.

OUR RECOURSE, ON THE OTHER HAND, IF THEY DON'T -- MARCHING IN IF THEY SOMEHOW BLOCK US OR LOCK THEIR LABS OR WHATEVER WOULD BE LITIGATION, BUT I SUSPECT IT WOULD BE --

DR. ROCKWOOD: ED'S EXACTLY RIGHT ON. THAT WAS OUR THOUGHT. WE'RE SAYING DON'T -- YOU DON'T TAKE BAYH-DOLE VERBATIM, BUT YOU DON'T CREATE POLICY THAT'S COUNTER TO IT. YOU'VE GOT A CONTRACT AND THEY'RE IN BREACH OF CONTRACT, AND YOU ENFORCE IT THROUGH CONTRACT LITIGATION.

MR. SHEEHY: I DO THINK THAT THERE'S A PRICING ISSUE BECAUSE WE HAVE SEEN IN THE CONTEXT -- I HAVE A VERY DIRECT EXAMPLE FROM HIV. THIS IS, YOU KNOW, WHERE ABBOTT HAS A PATENTED INGREDIENT THAT'S A KEY BOOSTER FOR PROTEASE INHIBITORS THAT THEY HAVE JUST DECIDED TO QUADRUPLE THE PRICE FOR. AND THERE IS SOME FEDERAL ASPECT TO THIS. AND ACTIVISTS TRIED TO GET SOME MARCH-IN BECAUSE WHAT IT'S DONE IS MAKE THE ABBOTT

PRODUCT -- IT HAS GIVEN THEM A COMPETITIVE ADVANTAGE AND HAS ASSIGNED ALL OF THESE ADDITIONAL COSTS TO VARIOUS TYPES OF HEALTHCARE SYSTEMS, WHETHER IT'S MEDI-CAL OR WHAT HAVE YOU, AND THIS IS A DRUG THAT'S BEEN OUT IN THE ENVIRONMENT FOR A LONG TIME THAT THEY'VE ALREADY MADE A TON OF MONEY IN. YET WE'RE TOLD ON THAT PARTICULAR ASPECT, WHERE THERE'S A PRICING ISSUE, THAT MARCH-IN RIGHTS DON'T APPLY.

BUT IT DOESN'T SEEM LIKE THEY'VE MADE THEIR TECHNOLOGY AVAILABLE ON A REASONABLE BASIS. IT SEEMS -- DO YOU SEE? THE FEDERAL GOVERNMENT HAS NOT BEEN VERY GOOD ON USING MARCH-IN RIGHTS ON SOME OF THESE MORE ACCESS-RELATED PRICING ISSUES, IT SEEMS TO ME.

DR. BENNETT: LET ME JUST MAKE A QUICK COMMENT. IT'S A REAL BALANCE. NIH HAS TAKEN A CERTAIN APPROACH. AND THE BALANCE IS IF YOU'RE FRIVOLOUSLY EXERCISING MARCH-IN RIGHTS, THEN WHAT DOES THE LICENSEE ACTUALLY HAVE? DO THEY REALLY HAVE A LICENSE? I THINK NIH AND THE FEDERAL GOVERNMENT HAS TAKEN A VIEW THAT THEY'VE USED THESE RIGHTS VERY CAUTIOUSLY, HAVEN'T EXERCISED THEM, AND THIS GIVES LICENSEES A SIGNIFICANT AMOUNT OF COMFORT THAT THEY ACTUALLY HAVE A LICENSE.

AS CIRM OR ANYONE, I THINK THAT'S A KEY POINT. WE HAVE TO DECIDE WHAT IS THE BALANCE. BUT IF

YOU GO TOO FAR IN EXERCISING MARCH-IN RIGHTS, THEN EFFECTIVELY NO COMPANY HAS A REAL LICENSE, AND YOU'RE RIGHT BACK WHERE YOU STARTED WHERE NOBODY HAS THE TECHNOLOGY.

MR. FLANAGAN: THE POINT THAT WAS MADE AT THE TABLE, WHAT HAPPENS IF A GRANT RECIPIENT 15 YEARS FROM NOW, SO FIVE YEARS AFTER THE CIRM NO LONGER HAS ANY MONEY TO DISTRIBUTE, SAYS YOU KNOW WHAT, WE'RE NOT GOING TO ABIDE BY WHATEVER CONTRACT WAS SET. THERE'S NO MORE MARCH-IN AUTHORITY, I WOULD ASSUME, BY THE CIRM BECAUSE IT NO LONGER EXISTS. HOW CAN THEN THE BAYH-DOLE MODEL PROVIDE FORWARD-GOING CONTROL OVER THAT PATENT? SPECIFICALLY I THINK A KEY QUESTION BECAUSE, AS PEOPLE IN THE CIRM HAVE SAID AND THE CCST HAVE SAID, THE RESEARCH PRODUCTS FOR THE STEM CELL RESEARCH MONEY MAY NOT BE 30 YEARS DOWN THE ROAD. THE CIRM WILL BE 20 YEARS NO LONGER WITH US UNFORTUNATELY OR AS IT MAY BE.

SO HOW DO WE BUILD IN CONSTRAINTS NOW THAT PROVIDE ONGOING PUBLIC CONTROL OVER THAT RESEARCH, ONE? AND THEN TWO, THE QUESTION OF BALANCE HAS BEEN MADE. IN OUR VIEW, FROM A PUBLIC INTEREST PERSPECTIVE, I'D BE CURIOUS TO HEAR THE PROFESSOR'S POSITION ON THIS, THAT THE NIH HAS NOT BEEN BALANCED AT ALL. THEY'VE LET ALL OF THE IDEA -- ALL OF THE DRUG COMPANIES REALLY RUN THE SHOW NOT USING MARCH-IN, NOT INTERPRETING MARCH-IN AS

DEALING WITH AFFORDABILITY. IT'S NOT AS IF WE'VE HAD A FLOOD OF LITIGATION. I AGREE. WE'D RATHER HAVE A MODEL THAT DOESN'T CREATE THE NEED FOR LITIGATION, BUT WE NEED A MODEL THAT HAS A REAL HAMMER TO MAKE SURE THAT THE PUBLIC INTEREST IS BEING IMPLEMENTED, WHICH FOR A LOT OF SENIORS WHO CAN'T AFFORD THEIR MEDICATIONS THAT HAVE BEEN DEVELOPED BY TAXPAYER MONEY, THERE CERTAINLY DOES APPEAR TO BE AN IMBALANCE IN HOW PUBLIC FUNDS ARE BEING USED.

HOW DO WE TAKE THAT CRITICISM OF BAYH-DOLE NATIONALLY AND PROVIDE SOME REAL CONNECTIONS HERE WITH CONTROLS OVER AFFORDABILITY, WHICH FOR MOST CALIFORNIANS WILL BE THE KEY TO WHETHER THEY CAN HAVE ACCESS TO NEW STEM CELL RESEARCH.

CHAIRMAN PENHOET: LET ME CLARIFY ONE QUESTION AT A TIME. JAMES, AFTER CIRM IS COMPLETED, I ASSUME THE RESIDUALS OF CIRM ARE OWNED BY THE STATE OF CALIFORNIA; IS THAT CORRECT?

MR. HARRISON: YEAH. THAT --

CHAIRMAN PENHOET: AND THEY WILL HAVE THE LEGAL RIGHT TO EXERCISE THE AUTHORITY THAT THEY HAVE AS A RESULT OF THIS 10-YEAR FUNDING CYCLE.

MR. HARRISON: THAT'S CORRECT. THE TERMS AND CONDITIONS OF THE CONTRACTS WITH THE GRANTEES WILL PROVIDE A CONTINUING ENFORCEMENT MECHANISM OVER THE

CONTRACT ITSELF.

MR. FLANAGAN: THE SECOND QUESTION, SO THAT'S GOOD NEWS, BUT THEN THE KEY THING IS THAT THERE IS ACTUALLY SOME ENFORCEABLE STANDARDS. I HAVE SOME CONCERNS WITH DOWNSTREAMING THOSE STANDARDS TO THE CONTRACTS BECAUSE THEN YOU HAVE TO FIGHT THE BATTLE ONE CONTRACT AT A TIME. WHY NOT HAVE A CIRM-WIDE PRINCIPLE, A STANDARD, A BEGINNING POINT THAT CAN BE THEN MODIFIED IN CONTRACT, BUT WHY DOWNSTREAM ALL OF THAT TO THE INDIVIDUAL CONTRACTS RATHER THAN HAVE SOME KIND OF A PRINCIPLE POSITION AT THE CIRM?

CHAIRMAN PENHOET: THEN YOU ASKED A SPECIFIC QUESTION.

MS. SAMUELSON: SO THERE CERTAINLY HAVE BEEN OTHER INITIATIVES THAT HAVE TRIED TO THINK ABOUT BUILDING AFFORDABILITY REQUIREMENTS INTO THE GRANT-MAKING PROCESS, AND WE ACTUALLY SPENT A LOT OF TIME ON THE COMMITTEE READING ABOUT SOME OF THOSE PRIOR SUGGESTIONS AND GRAPPLING WITH THEM, I THINK, WITH SOME PAIN. THAT IS TO SAY, THAT WE'RE VERY SYMPATHETIC WITH THE AFFORDABILITY CONCERNS. YOUR EXAMPLE OF WHAT SEEMS TO BE EXCESSIVE PRICING FOR PUBLICLY FUNDED RESEARCH PRODUCT OUTRAGES ME TOO.

BUT I THINK THAT AS WE CONTINUE TO TALK THROUGH AND WEIGH THE PROS AND CONS OF DIFFERENT WAYS

OF THINKING ABOUT THIS, THAT WE SAID THAT IF YOU PUT REQUIREMENTS INTO THESE CONTRACTS AND SAY TO WHOEVER IS THE LICENSEE OF THE GRANTEE YOU MUST MAKE THESE THINGS AFFORDABLE, ANYBODY WHO MIGHT WANT TO MAKE THAT EXTRA $100 MILLION INVESTMENT COULD TAKE THE THING FROM A PROMISING RESEARCH DISCOVERY TO A MARKETABLE PRODUCT IS GOING TO SAY I DON'T KNOW WHAT THIS MEANS. I CAN'T PREDICT WHAT MY RETURN MIGHT BE. IF I START MAKING THAT INVESTMENT AND I WANT TO RECOUP THAT INVESTMENT AND I NOT ONLY HAVE TO WORRY ABOUT RECOUPING MY INVESTMENT ON THIS PARTICULAR THING WHERE I'M WILLING TO COMMIT THIS MUCH MONEY TO SUPPORT THE SORT OF CLINICAL TRIALS AND ALL THE OTHER RESEARCH THAT'S REQUIRED, BUT I'M ALSO GOING TO HAVE TO SORT OF ESSENTIALLY BALANCE ALSO THE RISKS ON SOME OF THE OTHER THINGS THAT I ALSO CONTRACTED FOR PROMISING THINGS THAT TURNED OUT NOT TO PAN OUT. IF I HAVE TO SAY, WELL, I DON'T KNOW WHAT MY RETURN. I CAN'T KNOW WHAT MY PRICING IS. I CAN'T KNOW WHETHER THERE'S GOING TO BE LITIGATION AT THE END OF THE DAY.

OUR CONCERN REALLY WAS THAT THAT WAS ACTUALLY GOING TO DETER THE INVESTMENT IN THAT TRANSFORMATION FROM THE PROMISING RESEARCH DISCOVERY TO THE THERAPEUTIC. AND I WOULD LIKE TO THINK THAT THE GRANTEES UNDER THE STEM CELL INITIATIVE IN CALIFORNIA,

INSTITUTIONS WILL BE LOOKING VERY CAREFULLY TO TRY TO FIND APPROPRIATE INSTITUTIONS TO BE THEIR LICENSEES FOR WHATEVER THE THERAPEUTICS MIGHT BE. AND SO MAYBE THEY DON'T GO WITH ABBOTT BECAUSE ABBOTT HAS A BAD TRACK RECORD, AND MAYBE ONE OF THE THINGS THAT BOTH PUBLIC INTEREST ORGANIZATIONS IN CALIFORNIA CAN DO AND MAYBE CIRM TOO IS REALLY TRY TO SORT OF POINT TO SOME GOOD CITIZENS.

AND JUST I THINK THAT EITHER BUILDING AFFORDABILITY REQUIREMENTS, WHICH NOBODY CAN PREDICT WHAT THEY ARE. FRANKLY, THE VENTURE CAPITALISTS THAT WE TALKED TO, WE HAD ONE MEMBER ON OUR COMMITTEE WHO SAID I'D MUCH RATHER DEAL WITH A PERCENT BECAUSE A PERCENT, I KNOW WHAT A PERCENT IS. AFFORDABLE, I DON'T KNOW WHAT THAT MEANS. AND BEFORE I'M WILLING TO SAY TO THE PEOPLE WHOSE MONEY I'M INVESTING IN SORT OF TAKING THAT PROMISING RESEARCH RESULT TO MARKET, I'M GOING TO HAVE TO -- I'M GOING TO HAVE TO KIND OF KNOW MORE THAN THIS WOULD ALLOW. SO THAT'S A REASON WHY WE HAVE SOME CONCERN ABOUT WHY WE --

DR. ROCKWOOD: I'D LIKE TO ADD TO THIS. I MEAN THE AFFORDABLE PRICING IS VERY EMOTIONAL. WE ALL HAVE SYMPATHY WITH SENIORS AND LOW INCOME PEOPLE, AND WE'D LOVE TO MAKE DRUGS AVAILABLE TO EVERYBODY. PLEASE BE CAREFUL WITH THIS ISSUE. THE COMMENT LIKE THERE ARE

SENIORS WHO CAN'T AFFORD DRUGS THAT WE WERE DEVELOPED AT TAXPAYERS' EXPENSE, I DON'T KNOW EXACTLY WHAT DRUGS YOU'RE REFERRING TO. NIH DOES NOT PUT A DRUG ON THE MARKET. THEY ONLY FUND RESEARCH UP TO ABOUT PHASE I CLINICAL TRIALS. THAT DOESN'T GET A DRUG ON THE MARKET.

SO I DON'T KNOW THE FACTS THERE. LET'S BE CAREFUL WITH THEM. AFFORDABILITY HAS TO WORK BOTH WAYS. IT HAS TO BE AFFORDABLE TO THE CONSUMER, HAS TO BE AFFORDABLE TO THE PRODUCER. WE CAN'T FORCE A PRODUCER TO PRODUCE SOMETHING AT A LOSS. THEN YOU HAVE NO PRODUCT, AND THE PUBLIC IS NEVER SERVED. SO THIS IS NOT EASY. THIS IS A VERY COMPLICATED ISSUE. WE'VE GOT TO LEAVE SOME BALANCE THERE.

DR. PRIETO: I WOULD AGREE THAT AFFORDABILITY IS A VERY NEBULOUS CONCEPT AND TERM, BUT WHAT ABOUT PREFERENTIAL PRICING, WITH OR WITHOUT A SPECIFIC PERCENTAGE? I'D CERTAINLY BE HAPPY IF THAT MAKES THINGS MORE CERTAIN FOR PEOPLE AND ENSURES THAT THIS GETS TO THE POINT OF THERAPIES, WHICH IS WHAT WE'RE ALL ABOUT. BUT I'M CONCERNED THAT DOWN THE ROAD THAT AT LEAST THE STATE OF CALIFORNIA IS NOT DISADVANTAGED IN TERMS OF PURCHASING THESE FOR ITS PROGRAMS TO SERVE LOW INCOME PEOPLE, PURCHASING THESE TREATMENTS, THESE THERAPIES, WHATEVER COMES OUT OF OUR RESEARCH. WHY NOT

GUARANTEE THAT THE STATE OF CALIFORNIA IS THE FAVORED CUSTOMER, WITH X PERCENTAGE BELOW WHATEVER THE MARKET RATE? CONCERNING THAT IF THERE IS A MARKETABLE PRODUCT, WE'RE GOING TO HAVE A RELATIVELY SMALL FRACTION OF WHAT THE TOTAL MARKET. THERE WILL BE A GLOBAL MARKET, BUT CALIFORNIA GETS X PERCENT DISCOUNT BECAUSE WE PARTICIPATED FROM THE BEGINNING.

MS. SAMUELSON: ONE OF THE REASONS THAT WE MADE THE RECOMMENDATION ABOUT ASKING GRANTEES TO PUT FORTH A PLAN ABOUT BENEFITING CALIFORNIA WAS TO PROVIDE SOME OPPORTUNITY FOR THAT KIND OF FEATURE TO BE PART OF THE MIX. SO I THINK, AGAIN, THE CONVERSATION UNDERSTANDABLY FOCUSES ON ONE CLASS OF THINGS THAT MIGHT COME OUT OF THIS STEM CELL FUNDED RESEARCH. AND THAT'S THE THERAPEUTICS. BUT REMEMBER THERE ARE THESE OTHER KINDS OF OUTPUTS, AND SO I THINK THAT WE THOUGHT THAT THAT WOULD BE A WAY OF TRYING TO ACCOMMODATE THAT CONSIDERATION. AND IT MAY BE THAT CIRM WOULD WANT TO IDENTIFY CERTAIN THINGS TO LOOK FOR IN THAT PORTION.

DR. PRIETO: UNDER THE TERMS OF THAT.

MR. SHEEHY: I MEAN IT SOUNDS VERY CLOSE TO WHAT THE GATES MODEL IS. IF THAT PIECE HAD BEEN PUT IN THERE ALONG -- GATES FOUNDATION, WHEN THEY ISSUE GRANTS, BASICALLY SAY, HEY, ROYALTIES, WE'RE NOT GOING TO WORRY ABOUT. WE'RE GOING TO DEMAND PREFERENTIAL

PRICING FOR UNDEVELOPED COUNTRIES. YOU'RE GOING TO COME FORWARD AND PROVIDE US WITH A PLAN ON HOW YOU'RE GOING TO, OR LESS DEVELOPED COUNTRIES, ON HOW YOU ARE GOING TO DO THAT BEFORE WE ISSUE YOUR GRANT, WHICH SOUNDS LIKE WHAT YOU JUST SAID HERE, WHICH IS NOT AN UNREASONABLE WAY TO GO.

MS. SAMUELSON: I DON'T THINK IT'S THE SAME. ONE REASON I DON'T THINK IT'S THE SAME IS BECAUSE I THINK THE GATES FOUNDATION VERY APPROPRIATELY IS FOCUSED ON DRUGS FOR THE DEVELOPING WORLD, BUT THE DRUGS THAT WILL BE DEVELOPED UNDER THE GRANTS THAT WE'RE TALKING ABOUT ARE THINGS THAT ARE ACTUALLY GOING TO HAVE TO GO THROUGH THE CLINICAL TRIALS AND OTHER REGULATORY PROCESSES THAT ACTUALLY ADD A SET OF COSTS TO DEVELOPMENT OF THERAPEUTICS AND ACTUALLY DIFFERENTIATES IT FROM SORT OF PLAN THAT THE GATES FOUNDATION --

DR. PRIETO: I THINK THE CONCEPT IS THE SAME THOUGH, JUST THE CONCEPT THAT YOU COME WITH A PLAN OF HOW YOU ARE GOING TO DO THIS IS SORT OF WHAT YOU PRESENTED HERE.

MS. SAMUELSON: THAT WAS A WAY WE THOUGHT OF TRYING TO ACCOMMODATE THAT.

DR. ROCKWOOD: FIRST OF ALL, I THINK THE COMMITTEE WOULD AGREE. SOMEBODY WALKS IN TO YOU WITH A

PROPOSAL AND SAYS I GUARANTEE THE STATE OF CALIFORNIA X PERCENT BELOW THE MARKET PRICE. YOU ARE THE FUNDING AGENCY. I LOVE YOUR PROPOSAL. YOU GOT THE MONEY. YOU HAVE THAT OPPORTUNITY.

MR. SHEEHY: THIS IS WHAT WE'RE MISSING. WE'RE MISSING IN THIS WHOLE SCHEME SOMETHING THAT REALLY TALKS TO SOMEONE WHO'S A PATIENT IN CALIFORNIA AND SAYS THAT THEY'RE GOING TO BENEFIT FOR FOREGOING $3 BILLION THAT COULD GO INTO MEDI-CAL TOMORROW, THEY COULD GO INTO HEALTHY FAMILIES TOMORROW, AND THAT'S WHAT WE'RE MISSING IN THIS EQUATION. I UNDERSTAND FOREGOING THE ROYALTIES, BUT THAT'S -- UNLESS WE CAN PROVIDE SOMETHING LIKE THAT, I THINK -- IS IT A PERCENT? IS IT SOME PREFERENTIAL PRICING BUILT INTO THE CONTRACTS? I DON'T KNOW.

DR. PRIETO: I THINK THAT THIS COULD HAPPEN IN SEVERAL DIFFERENT WAYS. LET'S START TO LOOK AT THIS BECAUSE I ANTICIPATE THAT WE'RE GOING TO PARTICIPATE NOT JUST IN BASIC RESEARCH AT THE BEGINNING, BUT FIVE AND EIGHT YEARS DOWN THE ROAD, THAT WE'RE GOING TO BE PARTICIPATING IN OTHER SORTS OF RESEARCH THAT MAY BE MUCH CLOSER TO THERAPIES. AND THEN ALL OF THIS WILL NOT BE PHARMACEUTICALS, I CAN ALMOST GUARANTEE, BUT WE'LL BE LOOKING AT OTHER THINGS AND FUNDING OTHER KINDS OF RESEARCH.

DR. BENNETT: JUST A SHORT COMMENT. I THINK WE DID OBVIOUSLY SPEND A LOT OF TIME TALKING ABOUT THIS. SOME OF THE ISSUES THAT CAME UP, ONE ABOUT THE GATES MODEL IS THAT BASICALLY IT GUARANTEES THAT THERAPIES, TREATMENTS, WHATEVER IS DEVELOPED WILL BE PROVIDED TO A NONCOMMERCIAL MARKET. IT'S NOT A BIG LEAP. CALIFORNIA IS OBVIOUSLY A HUGE COMMERCIAL MARKET, AND IS THIS GOING TO BE A DISINCENTIVE TO CARRY THESE VERY EARLY STAGE TECHNOLOGIES FORWARD. I THINK THAT'S THE BIG QUESTION.

THE OTHER THING IS THAT IT'S VERY LIKELY, AND I THINK YOU HIT ON IT EARLIER, WE'RE NOT REALLY TALKING ABOUT ONE INVENTION, ONE THERAPY HERE. IT'S MOST LIKELY THAT THERAPIES WILL BE COMPRISED OF INVENTIONS FROM A NUMBER OF PLACES, SOME OF WHICH MAY COME FROM CIRM, SOME OF WHICH MAY COME FROM THE LICENSEE ITSELF, SOME OF WHICH MAY COME FROM UNIVERSITY OF ARKANSAS OR YOU NAME IT. SO WHAT TRIGGERS THIS REQUIREMENT? IT'S REALLY WHY WE STRUGGLED WITH IT. WE COULDN'T THINK OF ONE SORT OF STRUCTURE THAT'S GOING TO ACCOMMODATE WHAT WE IMAGINE WILL BE A HUGE DIVERSITY OF OUTCOMES. AND IT'S WHY WE TURNED TO THIS NET CALIFORNIA BENEFIT, THAT WE NEED TO LOOK CREATIVELY. AND MANY SITUATIONS MAY HAVE DIFFERENT WAYS THAT YOU ADDRESS THIS NET CALIFORNIA BENEFIT, BUT WE COULDN'T COME UP WITH --

MR. GOSWAMI: JUST A COMMENT I THINK ON A COUPLE OF THINGS, RIGHT. SETTING PRICES IS PROBABLY THE QUICKEST WAY TO KILL A MARKET. I'LL PICK ON THE EXAMPLE OF ABBOTT. WHEN THEY RAISED THE PRICE FOUR TIMES, DID THEY EFFECTIVELY -- DID PEOPLE EFFECTIVELY STOP TAKING THE DRUG? IT PROBABLY ISN'T. YOU SEE THIS REPEATEDLY WITH GENERICS AND DRUGS IN THIS MARKET. WHEN DRUGS LIKE THE DEPRESSION DRUG THAT WENT OFF FROM LILLY, WENT OFF MARKET, ITS PRICE PLUMMETED BY 90 PERCENT IN A MATTER OF, I THINK, SIX DAYS, BUT THAT DIDN'T KILL THE OTHER DRUGS THAT WERE ON THE MARKET THAT WERE VERY SIMILAR TO LILLY.

THERE'S THE THING, RIGHT. IF WE WANT TO GET CALIFORNIANS A BENEFIT FOR THIS, I THINK A REVENUE MODEL WHERE SOMEBODY -- LET THE MARKET SET THE PRICES AND LET US BENEFIT FROM THE MONEY THAT COMES IN FROM SALES OF THOSE THERAPIES WHEREVER IN THE WORLD THAT MIGHT OCCUR. ONE OF THE THINGS, I THINK, WE'RE TRYING TO DO HERE IS DO RESEARCH THAT DEVELOPS THERAPIES THAT BENEFITS THE ENTIRE WORLD, NOT JUST CALIFORNIA. SO WHY SHOULDN'T WE HAVE PART OF THAT BENEFIT FLOW BACK TO THE STATE RATHER THAN JUST ASKING FOR A DISCOUNT ON CERTAIN X MILLION POPULATION THAT LIVES HERE AND JUST ASKING FOR A DISCOUNT ON THOSE.

MR. SHEEHY: FIRST, THIS REPORT DID NOT

RECOMMEND THAT WE DO THAT. AND THEN THE SECOND IS THAT THAT MAY AFFECT OUR ABILITY TO ISSUE TAX-EXEMPT BONDS. IF OUR BONDS ARE NOT TAX-EXEMPT, WE'VE JUST ADDED -- I'VE SEEN DIFFERENT ESTIMATIONS. SO I'M NOT GOING TO THROW OUT HOW MUCH MORE THIS WILL ADD TO THE COST OF ISSUING BONDS, BUT THAT'S REAL MONEY THAT GETS ADDED TO THE TAB.

MR. GOSWAMI: SO ROYALTIES OF ANY KIND?

DR. PRIETO: ROYALTIES MAY RULE OUT -- IF WE PARTICIPATE IN ROYALTIES WITH FOR-PROFIT INSTITUTIONS SOMEWHERE DOWN THE STREAM HERE, THAT MAY, MAY, MAKE IT IMPOSSIBLE FOR US TO ISSUE TAX-EXEMPT BONDS. AND THAT WOULD INCREASE THE COST OF FINANCING SIGNIFICANTLY.

CHAIRMAN PENHOET: I THINK NEXT MONDAY, PETER, IF I'M CORRECT, WE'RE GOING TO HAVE A DISCUSSION OF THIS ISSUE ON THE 31ST.

DR. LOVE: I JUST WANTED TO MAKE A COUPLE OF POINTS. FIRST, I WANTED TO THANK YOU ALL FOR WHAT I THOUGHT WAS A VERY THOUGHTFUL REPORT. AND I THINK WHAT YOU'RE HEARING IS A LOT OF ISSUES THAT PERSONALLY, AS A PHYSICIAN, I'M VERY SYMPATHETIC TO. I'M SYMPATHETIC TO THE FACT THAT HEALTHCARE, AS IT'S PRACTICED IN THIS COUNTRY, IS UNEQUAL IN A LOT OF WAYS. IT'S UNEQUAL AROUND RACE, IT'S UNEQUAL AROUND GEOGRAPHY, IT'S UNEQUAL AROUND PEOPLE'S WEALTH. BUT MY CONCERN, QUITE

FRANKLY, IS THAT OUR MISSION IS MUCH NARROWER THAN THAT. I DON'T WANT TO SEE US FAIL ON OUR MISSION BY TRYING TO SOLVE THINGS, QUITE FRANKLY, WHICH GO WAY BEYOND THE SCOPE OF WHAT WE CAN POSSIBLY SOLVE.

WE'RE WILLING TO SPEND AN ENORMOUS AMOUNT OF HEALTHCARE ON PEOPLE IN THE VERY LAST DAY OF THEIR LIVES. AND WE HAVE DIFFICULTY SOMETIMES PROVIDING CARE TO PEOPLE JUST WITH SIMPLE THINGS LIKE IMMUNIZATION AND LUNCH PROGRAMS. SO, AGAIN, I THINK MY POINT REALLY IS THAT THERE ARE A LOT OF ISSUES HERE. I THINK MANY OF THE ISSUES GO FAR BEYOND THE SCOPE OF WHAT CIRM SHOULD BE BURDENING ITSELF WITH, AND I WOULD JUST ASK US TO AT LEAST MAKE SURE THAT WE DON'T FIND OURSELVES IN A POSITION WHERE WE'RE TRYING TO SOLVE SO MANY PROBLEMS, THAT WE END UP THROWING THE BABY OUT WITH THE BATH WATER.

DR. ROCKWOOD: I'M SORRY. I APOLOGIZE TO THE COMMITTEE. I THOUGHT OUR PART ENDED AT FOUR. I SCHEDULED A FLIGHT. MY COMMITTEE MEMBERS, I DON'T KNOW THEIR SCHEDULE, BUT THEY'RE FULLY ABLE AND BETTER THAN I TO CONTINUE. BUT IF THERE WAS A LAST-MINUTE QUESTION FOR ME, I'M LAYING MYSELF OPEN.

CHAIRMAN PENHOET: THANK YOU VERY MUCH FOR YOUR PARTICIPATION. I THINK WE DID TELL YOU WE THOUGHT WE WOULD END AT FOUR.

DR. HACKWOOD: PAM HAS TWO MORE SLIDES TO FINISH OFF.

MS. SAMUELSON: WE ALWAYS GET EXCITED WHEN WE TALK ABOUT MARCH-IN RIGHTS. ONE OF THE THINGS THAT I WANTED TO POINT OUT IS THAT THERE ARE A LOT OF THE THINGS THAT I THINK CIRM HAS TO CONCERN ITSELF WITH THAT ARE NOT IN BAYH-DOLE. AND SO THIS SLIDE MENTIONED THAT THERE'S NO -- BAYH-DOLE DOESN'T SAY ANYTHING ABOUT COPYRIGHT. EVEN THOUGH GOVERNMENT-FUNDED WORK, PARTICULARLY WHEN IT'S SOFTWARE, ACTUALLY CAN BE VERY COMMERCIALLY IMPORTANT TOO. SOFTWARE, DATABASES, AND RESEARCH REPORTS AND ARTICLES ARE THINGS THAT, IF I WERE YOU, I WOULD WANT TO HAVE A POLICY ABOUT. THERE'S NO SPECIFIC POLICY ABOUT RESEARCH TOOLS.

IN OUR REPORT WE APPENDED AS APPENDIX D EXCERPTS FROM THE NIH GUIDELINES ABOUT RESEARCH TOOLS. AND I THINK THE COMMITTEE WAS VERY SYMPATHETIC WITH THE APPROACH THAT NIH HAD TAKEN TO THAT. SIMILARLY, WHILE WE THOUGHT IT WAS NOT APPROPRIATE TO BE HIGHLY PRESCRIPTIVE ABOUT EXCLUSIVE VERSUS NONEXCLUSIVE LICENSING, WE WERE CONCERNED THAT, IN GENERAL THAT RESEARCH TOOLS BE NONEXCLUSIVELY LICENSED SO THAT THEY COULD BE MADE AS WIDELY AVAILABLE TO THE RESEARCH COMMUNITY. AND THAT IT WOULD BE A TRULY EXCEPTIONAL CASE WHEN AN EXCLUSIVE LICENSE COULD BE JUSTIFIED IN AT

LEAST THE RESEARCH TOOL AREAS, BUT THERE MAY BE IN THE THERAPEUTICS AREA THE NEED FOR EXCLUSIVE LICENSING IN ORDER TO ENSURE THAT THE INVESTMENTS GET MADE.

THERE'S NO POLICY IN BAYH-DOLE EITHER ABOUT MATERIAL TRANSFER AGREEMENTS. AGAIN, NIH HAS A POLICY WHICH TRIES TO ENCOURAGE THE USE OF AGREEMENTS THAT ARE NO MORE RESTRICTIVE IN MATERIAL TRANSFER AGREEMENTS THAN THE UNIFORM AGREEMENT THAT IS AVAILABLE. AND THERE ISN'T, AS SUCH, A POLICY ABOUT DISCLOSURE OF DATA OR KNOW-HOW, AND I THINK ALL OF THESE THINGS ARE ESPECIALLY IMPORTANT FOR GETTING THE RESEARCH RESULTS OUT VERY QUICKLY AND GETTING THEM TO AS WIDE AN AUDIENCE AS POSSIBLE.

CHAIRMAN PENHOET: MY COMMENT, I BELIEVE THE NRC REPORT I REFERRED TO EARLIER WILL, IN FACT, HAVE SOME RECOMMENDATIONS ON A NUMBER OF THESE POINTS THAT YOU HAVE ON THIS SLIDE. HOPEFULLY THAT WILL COME OUT ON NOVEMBER 17TH.

MS. SAMUELSON: WE DISCUSSED IN OUR COMMITTEE ESPECIALLY THE SORT OF ISSUES ABOUT OPEN SOURCES AND OPTION FOR -- AN OPEN SOURCE OPTION FOR SOFTWARE, BIOINFORMATICS TOOLS, AND THE LIKE THAT MIGHT BE DEVELOPED WITH CIRM FUNDS, CREATIVE COMMONS LICENSES FOR RESEARCH REPORTS AND ARTICLES. CREATIVE COMMONS IS ESSENTIALLY FOR OTHER KINDS OF CONTENT TRYING TO BE FOR

IT WHAT OPEN SOURCE LICENSES HAVE BEEN FOR SOFTWARE.

WE SUGGESTED THAT CIRM MIGHT WANT TO LOOK INTO EITHER DEVELOPING PREPRINT SERVERS FOR STEM CELL RESEARCH, OR OTHER KINDS OF OPEN ACCESS SITES, MAYBE DIGITAL LIBRARIES, SUCH AS CALIFORNIA DIGITAL LIBRARY. AS MUCH, WE THINK, SHOULD GO INTO THE PUBLIC DOMAIN AS QUICKLY AS POSSIBLE AS LONG AS THAT'S, IN FACT, GOING TO LEAD TO FASTER RESEARCH AND DISSEMINATION.

SO WE WERE CONCERNED. AS I'M SURE ALL OF YOU KNOW, A NUMBER OF COMMERCIAL PUBLISHERS THAT HAVE SPECIALIZED SCIENTIFIC JOURNALS AND DATABASES CHARGE VERY HIGH FEES AND RESTRICT ACCESS BOTH TO THE JOURNALS AND THE DATABASES. THEY'RE MAKING 40, 50 PERCENT PROFITS ON THOSE, AND THE RESEARCH COMMUNITIES ARE SUFFERING AS A RESULT OF THAT AND SO ARE UNIVERSITIES THAT ARE HAVING TO PAY EVER HIGHER PRICES. SO THIS MAY BE A PLACE WHERE, BECAUSE CIRM IS GOING TO BE FUNDING SOME CUTTING EDGE RESEARCH, THAT YOU CAN START ANOTHER VIRTUAL CYCLE HERE WITH THE RESEARCH ARTICLES, REPORTS, AND DATABASES TO REALLY ENCOURAGE THAT TO BE MADE AS WIDELY AVAILABLE BECAUSE I THINK AS WIDELY AS THAT CAN BE MADE AVAILABLE, THE FASTER YOU ARE GOING TO END UP WITH THE DEVELOPMENT OF THERAPEUTICS.

MR. SHEEHY: THIS SOUNDS GREAT, BUT HOW WOULD WE DO THIS IN PRACTICE? YOU SAY ENCOURAGE. WOULD WE

STIPULATE THAT, FOR INSTANCE, PEOPLE MUST PUBLISH IN PLOS? WOULD WE STIPULATE THAT -- CREATIVE COMMONS IS A NEW CONCEPT TO OPEN SOURCE. WHAT WOULD BE THE ACTUAL MECHANICS OF PUTTING AT LEAST THIS PIECE IN PLACE, WHICH SEEMS --

MS. SAMUELSON: I'M NOT A SCIENTIST IN THIS PARTICULAR FIELD, SO IT'S A LITTLE HARD FOR ME TO GIVE PRECISE GUIDANCE. BUT I ASSUME THAT ACTUALLY THERE'S A COMMUNITY OF STEM CELL RESEARCH SCIENTISTS WHO MIGHT SAY, OH, WELL, I HAVE A DIGITAL LIBRARY. WHY DON'T WE MAKE AN AGREEMENT THAT EVERYBODY PUBLISH IN THIS. THEY MAY PUBLISH WITH SOME JOURNAL, BUT LET'S MAKE SURE THAT THEY'RE ALSO MAKING THEIR WORKS AVAILABLE IN THIS REPOSITORY, DIGITAL LIBRARY OR OTHER REPOSITORY, WHERE PEOPLE WILL BE ABLE TO -- PEOPLE WHO ARE IN THAT RESEARCH COMMUNITY WILL BE ABLE TO HAVE ACCESS TO IT ON EITHER A COMPLETELY OPEN BASIS OR ON A BASIS WITH A MODEST SUBSCRIPTION FEE.

I THINK THAT IT'S THIS KIND OF INITIATIVE THAT REALLY CAN SET A GOOD EXAMPLE AND CAN, YOU KNOW, OFFER LICENSING AGREEMENTS. ONE OF THE THINGS ACTUALLY I WILL SAY TO YOU IS THAT THIS HIGH TECHNOLOGY CLINIC THAT I TALKED ABOUT SOMEWHAT EARLIER, WE'RE LOOKING TO DO THINGS THAT PROMOTE THE PUBLIC INTEREST. SO ONE OF THE THINGS THAT CIRM COULD BE A CLIENT AND COULD COME

AND SAY DRAFT US SOME LICENSES OR SUGGEST HOW WE MIGHT TRY TO DO A LICENSING STRATEGY FOR THIS KIND OF THING OR THAT. SO I THINK THERE ARE SOME EXISTING EXAMPLES IN THE SCIENTIFIC COMMUNITY WHERE PEOPLE HAVE ESTABLISHED PREPRINT SERVERS OR DIGITAL LIBRARIES. I DON'T REALLY KNOW, BECAUSE I'M NOT IN THE FIELD, WHAT EXISTING MECHANISMS THERE ARE TO BUILD ON. I JUST WOULD HATE FOR, ESPECIALLY THE RESEARCH PRODUCTS NOT TO BE MADE WIDELY AVAILABLE, AND FOR REED ELSEVIER TO BENEFIT MORE FROM THE CIRM RESEARCH ARTICLES THAN THE RESEARCH COMMUNITY. THAT JUST SEEMS WRONG TO ME.

CHAIRMAN PENHOET: DR. HALL HAS THOUGHT A LOT ABOUT THESE ISSUES. DO YOU WANT TO COMMENT AT THIS POINT, ZACH?

DR. HALL: NO. ONLY TO SAY THAT, NOT IN ANY DETAIL, ONLY TO SAY THAT WE HAVE HAD CONVERSATIONS WITH PLOS ABOUT THE POSSIBILITY OF START A STEM CELL JOURNAL THAT WOULD BE OPEN ACCESS, WEB BASED, AND HAVE ALSO APPROACHED THE INTERNATIONAL SOCIETY FOR STEM CELL RESEARCH ABOUT THE POSSIBILITY ALSO TO PARTICIPATE WITH US. WE'RE VERY INTERESTED IN THAT. AND WE HAVE RECEIVED ALSO A PETITION FROM UNIVERSITY OF CALIFORNIA ACADEMIC SENATE SUGGESTING THAT WE INSTITUTE THE RULES, THE ORIGINAL ZERHOUNI GUIDELINES FOR PUBLICATION, THAT WITHIN SIX MONTHS EVERYTHING GOES INTO A PUBLIC

DATABASE. BUT WE HAVE NOT -- SOMEHOW WE'VE BEEN OCCUPIED WITH OTHER THINGS SO AS NOT TO PURSUE THOSE AS AGGRESSIVELY AS WE WANT, BUT THEY'RE VERY MUCH ON OUR RADAR SCREEN. I'M ACTUALLY PLEASED TO HEAR ABOUT YOUR CLINIC, AND PERHAPS WE CAN HAVE A CONVERSATION SOMETIME.

MS. SAMUELSON: ONE OTHER THING THAT I'LL MENTION IS THAT THE CENTER FOR LAW AND TECHNOLOGY AT UC BERKELEY IS ORGANIZING ITS MAJOR CONFERENCE THIS YEAR ON THE LEGAL AND POLICY CHALLENGES OF THE STEM CELL RESEARCH INITIATIVE HERE IN CALIFORNIA. AND SO WE'RE GOING TO HAVE SESSIONS ON ALL THE ISSUES THAT WE'VE ACTUALLY TALKED ABOUT TODAY. AND SO WE WILL BE PUTTING UP -- THERE'S A LITTLE PLACEHOLDER RIGHT NOW ON OUR WEBSITE, BUT WE'LL BE PUTTING UP A SCHEDULE. WE HAVE COMMISSIONED SOME RESEARCH REPORTS THAT WILL ACTUALLY BE PUBLISHED IN THE BERKELEY TECHNOLOGY LAW JOURNAL, AND WE HOPE THAT SOME OF YOU CAN EITHER BE THERE WITH US OR GET THE WORD OUT ABOUT THE CONFERENCE BECAUSE WE WANT IT TO BE AN OPPORTUNITY FOR PEOPLE WITH LOTS OF DIFFERENT POINTS OF VIEW TO CONTRIBUTE TO THE THINKING.

AND REBECCA EISENBERG IS ACTUALLY ONE OF THE PEOPLE WHO WILL BE GIVING A PAPER ON SHARING DATA. SHE AND ARTIE RAI WILL BE DOING A PAPER, AND THERE WILL BE A NUMBER OF PAPERS THAT I THINK WILL BE OF INTEREST TO

THIS GROUP.

CHAIRMAN PENHOET: YOU DO OR DON'T HAVE A PRECISE DATE FOR THE MEETING YET?

MS. SAMUELSON: IT'S MARCH 3D AND 4TH, 2006, A DAY AND A HALF CONFERENCE.

DR. PRIETO: WE'RE ALL INVITED?

CHAIRMAN PENHOET: DR. HACKWOOD, ARE YOU FINISHED WITH YOUR PRESENTATION?

DR. HACKWOOD: YES. I WILL MENTION THAT THIS REPORT HAS BEEN WRITTEN AS A CONSENSUS REPORT FROM 17 PEOPLE FROM VERY DIFFERENT BACKGROUNDS AND REPRESENTING VERY DIFFERENT FIELDS. WHAT YOU HAVE IS A CONSENSUS, THAT THESE ARE THE BEST SUGGESTIONS THAT THIS GROUP HAS TO OFFER.

ONE THING THAT HAS NOT BEEN MENTIONED IS THAT EVERY ONE OF THE GROUP MEMBERS WOULD POINT OUT THAT THE IMPORTANCE OF GETTING PRODUCT TO MARKET BEING THE MOST IMPORTANT THING BECAUSE IF THE GOAL IS TO HELP PEOPLE, YOU NEED TO GET PRODUCT TO MARKET. AND EVERYONE, IN TURN, MENTIONED THAT THE CREATION OF NEW COMPANIES AND NEW JOBS AND NEW INDUSTRIES THAT SERVE THAT PURPOSE IS EXTREMELY IMPORTANT.

SEVERAL OF THE UNIVERSITIES SAID INTELLECTUAL PROPERTY OWNERSHIP IS LESS IMPORTANT THAN ALL OF THESE THINGS. AND I HAVE A SLIDE FROM STANFORD, OF COURSE,

THAT PROVES THAT OVER THE LAST 15 YEARS, A HUNDRED FIFTY OF THE LARGEST PUBLICLY TRADED COMPANIES IN SILICON VALLEY HAVE COME OUT OF STANFORD ALUMNI AND STUDENTS. THEY'RE THE OWNERS OF THE REAL KNOWLEDGE. HEWLETT PACKARD, SUN, YAHOO, YOU NAME IT, EBAY THAT CAME OUT --

CHAIRMAN PENHOET: GOOGLE.

DR. HACKWOOD: GOOGLE, RIGHT. IT'S THE STIMULATION. IT'S THAT LITTLE SEED OF STIMULATION THAT CAUSES THIS BIG EVENT TO HAPPEN. AND ALL WHO ARE IN RESEARCH ECHO THAT, AND SO TO MAKE IT AS EASY AS POSSIBLE FOR THAT TO HAPPEN IS CERTAINLY A GOAL THAT WE HAD IN WRITING THE REPORT.

CHAIRMAN PENHOET: THANK YOU. ANY FURTHER QUESTIONS FROM THE AUDIENCE FOR THIS PANEL? IF NOT, WE ALL ARE IN YOUR DEBT.

MR. HALLUIN: UNDER BAYH-DOLE YOU SAID THAT THE INVENTORS ARE GOING TO BE SHARING SOME OF THE ROYALTIES, AND THAT WORKS WELL WITH THE UNIVERSITIES AND INSTITUTIONS BECAUSE THEY HAVE POLICIES WHERE THE INVENTORS WILL SHARE THE ROYALTIES. I'M NOT SURE IT WORKS WITH PRIVATE INDUSTRY. I UNDERSTAND THAT CIRM WILL BE MAKING GRANTS TO PRIVATE INDUSTRY. AND HAVE YOU CONSIDERED HOW TO DEAL WITH THAT, AND ALSO THE HYBRID SITUATION WHERE MAYBE THAT CERTAIN RESEARCH

GRANTS FOR A CERTAIN AREA WILL BE GOING TO A UNIVERSITY OR INSTITUTION AND ALSO TO A COMPANY THAT'S WORKING WITH THEM?

DR. BENNETT: I DON'T THINK OUR REPORT REALLY SPOKE TO THAT. I THINK OUR GOAL WAS THAT IF THE INSTITUTION, THE GRANTEE HAD OWNERSHIP AND WAS MANAGING INTELLECTUAL PROPERTY, IT WOULD BE ABLE TO DO SO UNDER ITS POLICY FRAMEWORK.

MS. SAMUELSON: ACTUALLY THE BAYH-DOLE, THE REQUIREMENT OF SHARING WITH THE INVENTOR IS A REQUIREMENT FOR NONPROFITS. SO AS I SAID, THERE ARE -- IT APPLIES TO BOTH PROFIT-MAKING AND NONPROFIT FIRMS GENERALLY, BUT THESE -- THAT PARTICULAR REQUIREMENT IS ONE THAT'S IMPOSED ON NONPROFITS, NOT ON THE PROFIT-MAKING FIRMS.

MR. HALLUIN: THANK YOU. I HAVE ONE OTHER QUESTION. DID YOU CONSIDER THE SITUATION OF WHERE CIRM IS MAKING GRANTS AND THERE ARE OVERLAPPING PATENTS THAT CAN SAY THEY GIVE A GRANT TO A GRANTEE AND THE GRANTEE IS MAYBE VIOLATING AN EXISTING PATENT, AND WHO WILL HAVE THE RESPONSIBILITY FOR DEALING WITH THOSE THIRD-PARTY PATENTS, THE GRANTEE OR CIRM?

MS. SAMUELSON: I WOULD BE SURPRISED IF ANYBODY BUT THE ENTITY THAT WAS POTENTIALLY VIOLATING THE PATENT WOULD HAVE ANY RESPONSIBILITIES. I DON'T

SEE WHAT ROLE THAT CIRM.

DR. LOVE: I THINK ONE OBSERVATION TO MAKE IS THAT PATENTS IN AND OF THEMSELVES DON'T HAVE MUCH VALUE. YOU COULD ARGUE THEY HAVE NO VALUE. BUT PATENTS, THE VALUE OF PATENTS DERIVED THROUGH PRODUCTS, SO AT THE END OF THE DAY, IF THERE'S A PRODUCT THAT COMES OUT THAT HAS OVERLAPPING PATENTS, AND WHAT ENDS UP HAPPENING GENERALLY IS STACKING OF ROYALTIES, AND ALL THAT STUFF JUST GETS NEGOTIATED AROUND THE CONCEPT OF ACTUALLY PRODUCING A COMMERCIAL PRODUCT. SO IT GETS RESOLVED, IN OTHER WORDS.

IF THERE'S A PRODUCT THERE, PEOPLE WILL RESOLVE IT. IF THERE'S NO PRODUCT THERE, THERE'S NO REASON TO RESOLVE IT.

CHAIRMAN PENHOET: WELL, THANK YOU, ALL OF YOU, FOR --

MR. REED: ARE WE AT ITEM 6 OR ARE WE PUBLIC COMMENT YET?

CHAIRMAN PENHOET: WE'RE ENGAGING IN DIALOGUE WITH THIS PANEL AT THE MOMENT. WE ARE GOING TO HAVE A WHOLE SECTION ON PUBLIC COMMENT.

CHAIRMAN PENHOET: WE'RE STILL ON ITEM 3, WHICH IS THE DIALOGUE WITH THIS PANEL. SO IF WE HAVE NO MORE QUESTIONS FOR THE PANEL, WE'LL THANK THEM.

(APPLAUSE.)

OUR NEXT SPEAKER IS FRED DOREY. DO WE WANT TO TAKE A BREAK? LET'S TAKE A TEN-MINUTE BREAK BEFORE FRED. FRED WILL HAVE A MUCH SHORTER PRESENTATION, INTRODUCED WELL BY SUSAN HACKWOOD BECAUSE ONE OF THE EXPLICIT GOALS OF PROP 71 IS TO ENHANCE CALIFORNIA'S BIOTECHNOLOGY INDUSTRY, SO WE'VE ASKED FRED DOREY, WHO HAS BEEN A PARTICIPANT FROM ALMOST THE BEGINNING, TO GIVE US AN OVERVIEW OF BIOTECH INDUSTRY IN CALIFORNIA, WHICH HE WILL DO IN TEN MINUTES.

(A RECESS WAS TAKEN.)

CHAIRMAN PENHOET: READY TO BEGIN AGAIN. OUR TEN MINUTES HAS EXPIRED. AS I STATED IN THE PREFACE TO THIS MEETING, AND AS SUSAN HACKWOOD EMPHASIZED, THE COOPERATION OF INDUSTRY IS IMPORTANT FOR BRINGING THERAPIES TO PATIENTS. AND ALSO, SINCE ONE OF THE EXPLICIT GOALS OF PROP 71 WAS TO ENHANCE CALIFORNIA'S BIOTECH INDUSTRY, I THOUGHT IT WAS USEFUL TO HAVE SOMEONE DEEPLY FAMILIAR WITH CALIFORNIA'S BIOTECH INDUSTRY PRESENT AN OVERVIEW OF BIOTECH AS IT EXISTS TODAY. SO WE'RE PLEASED TO HAVE FRED DOREY SPEAK WITH US THIS AFTERNOON.

FRED IS AN ATTORNEY WHO IS SPECIAL COUNSEL IN THE LIFE SCIENCES GROUP AT COOLEY GODWARD, ONE OF THE MAJOR LAW FIRMS IN THE BAY AREA. FRED HAS LONG BEEN ASSOCIATED WITH THE BIOTECHNOLOGY MOVEMENT, I WOULD

SAY, BECAUSE IT HAS BEEN PARTIALLY IN COMPANIES AND PARTIALLY IN NONPROFITS. HE WAS THE FIRST PRESIDENT OF THE BAY AREA BIOSCIENCE CENTER, WHICH HAS UNIVERSITY MEMBERS, BUSINESS MEMBERS, SUPPORT GROUP MEMBERS, LOTS OF DIFFERENT TYPE OF MEMBERSHIP. AND IN ADDITION TO THAT, FRED NOW SERVES AS ADVISOR TO A NUMBER OF BIOTECH COMPANIES. IN ADDITION TO THAT, HE'S A DIRECTOR OF A NUMBER OF NONPROFITS, INCLUDING A VERY ACTIVE DIRECTOR OF THE AMERICAN LIVER FOUNDATION.

I MIGHT ADD PARENTHETICALLY HIS WIFE IS ONE OF AMERICA'S GREAT GASTROENTEROLOGIST SPECIALIZING IN LIVER DISEASE. HE'S ALSO A DIRECTOR OF THE WORLD AFFAIRS COUNCIL OF NORTHERN CALIFORNIA, BAY BIO, SANFRANCISCO BOYS CHORUS. ANYWAY, WELCOME, FRED. WE LOOK FORWARD TO AN OVERVIEW OF CALIFORNIA'S BIOTECHNOLOGY INDUSTRY.

DR. DOREY: THANK YOU, ED. IN HELPING FOUND THE BAY BIO AND BEING ITS PRESIDENT FOR SEVEN YEARS, I HAD A CHANCE TO SORT OF TALK ABOUT BIOTECHNOLOGY, THE INDUSTRY, THE GROWTH OF THIS INDUSTRY, AND HOW IT GOT TO BE WHERE IT IS IN NORTHERN CALIFORNIA A GREAT DEAL. IN WORKING NOW IN THE BIOTECH INDUSTRY, I REPRESENT BOTH BIOTECH COMPANIES AND SOME UNIVERSITIES, NONPROFITS, AND NGO'S, SO I'VE KIND OF WORKED BOTH SIDES OF THE STREET. AND IT'S GIVEN ME KIND OF A

SPECIAL PERSPECTIVE ON THINGS.

AND THERE IS ONE STATEMENT I CAN MAKE ABOUT CALIFORNIA'S -- STATE OF CALIFORNIA'S BIOTECH INDUSTRY WITHOUT EQUIVOCATION, AND THAT IS OUR SUCCESS IN BIOTECHNOLOGY IS THE ENVY OF THE WORLD. WE NEED TO STEP BACK AND KIND OF APPRECIATE AND UNDERSTAND WHAT HAS HAPPENED HERE UNIQUELY IN THE ENTIRE WORLD. NO OTHER STATE OR NATION HAS ACHIEVED ANYTHING LIKE WHAT WE HAVE DONE, EVEN THOUGH EVERYBODY HAS BEEN TRYING NOW FOR 20, 25 YEARS. IT IS BORN MORE THAN ANYTHING ELSE OF THAT UNIQUE RELATIONSHIP BETWEEN OUR ACADEMIC RESEARCH INSTITUTIONS AND THE UNIQUE PRIVATE SECTOR, THE PEOPLE WHO HAVE MOVED COMPANIES FORWARD IN CALIFORNIA. THAT UNION AND THAT COOPERATION, THAT COLLABORATION IS WHAT HAS CREATED THIS BIOTECH INDUSTRY AND THIS BIOTECH COMMUNITY IN ALL OF CALIFORNIA.

I WAS PRIVILEGED IN WORKING IN NORTHERN CALIFORNIA TO ENTERTAIN HUNDREDS OF DELEGATES FROM AROUND THE WORLD WHO CAME REGULARLY TO STUDY OUR BIOTECH INDUSTRY. HOW DID YOU DO IT? CAME IS THE WRONG WORD. THEY CAME ON A PILGRIMAGE. THE WOULD COME IN AWE. HOW DID THIS HAPPEN? WHAT DID YOU DO? HOW DID YOU MAKE IT HAPPEN? WE'VE PUT A CITY OUT THERE AND WE'VE MOVED A CITY, WE'VE MOVED SCIENTISTS OUT THERE, WE GAVE IT A LOT OF MONEY, AND IT HASN'T HAPPENED.

WHAT DO YOU DO?

AND WHAT WE HAVE DONE, I THINK, YOU HAVE TO APPRECIATE THE IMPACT THIS HAS ON THE REST OF THE WORLD. STARTING FROM ZERO IN 1975, WE HAVE THE FIRST, SECOND, THIRD, AND FIFTH LARGEST AND MOST SUCCESSFUL BIOTECHNOLOGY COMPANIES IN THE WORLD. AND NO. 4 IS LARGELY A CALIFORNIA COMPANY, HALF BOSTON, HALF CALIFORNIA. SO WE REALLY OWN THIS AREA.

WE HAVE ABOUT 1600 BIOTECHNOLOGY COMPANIES IF YOU USE THE TERM "BIOTECH" IN ONE FORM. IF WE EXPAND THE DEFINITION OF BIOTECH AS, FOR EXAMPLE, CALIFORNIA HEALTHCARE INSTITUTE DOES, AND WE SAY THE FULL BIOMEDICAL INDUSTRY, WHICH INCLUDES ACADEMIC RESEARCH INSTITUTIONS, MEANING THE DEPARTMENTS AND THE SECTIONS AND THE DIVISIONS OF THOSE RESEARCH INSTITUTIONS IN THE UC SYSTEM OR STANFORD OR UCSD OR SCRIPPS OR SOMETHING, THE BIOPHARMACEUTICAL COMPANIES, AND ALSO THE MEDICAL DEVICE COMPANIES, DIAGNOSTIC COMPANIES, AND LABORATORY SERVICE COMPANIES, IF YOU TAKE THAT AS AN INDUSTRY GROUP, WHICH IS A LOGICAL AND CONSISTENT WAY TO GROUP IT, A LOT OF THAT, I CAN SAY MOST OF THAT HAS DEVELOPED IN CALIFORNIA SINCE THE 1970S.

AND AS THE CALIFORNIA HEALTHCARE INSTITUTE HAS PUBLISHED, AND THESE NUMBERS ARE FROM THEM, WE HAVE ABOUT 2600 OF THOSE COMPANIES, 230,000 PEOPLE TOTAL

EMPLOYMENT, $14 BILLION IN WAGES AND SALARIES, ALMOST $3 BILLION IN NIH GRANTS LAST YEAR, 2004, AND A SIGNIFICANTLY LARGER CHUNK OF THAT IN PRIVATE RESEARCH MONEY THAT THESE COMPANIES AND ORGANIZATIONS ARE PUTTING INTO THEIR OWN RESEARCH THAT IS NOT NIH DRIVEN. SO IS THERE --

CHAIRMAN PENHOET: THAT'S A NUMBER I HADN'T SEEN BEFORE. SO YOU'RE SAYING THAT BETWEEN THE NIH GRANTS TO THE STATE AND THE PRIVATE COMPANIES, THE STATE TODAY IS INVESTING ALMOST $19 BILLION A YEAR?

DR. DOREY: NOT THE STATE. PRIVATE COMPANIES.

CHAIRMAN PENHOET: WITHIN THE STATE OF CALIFORNIA SOMEBODY IS INVESTING.

DR. DOREY: I'M QUOTING THE CALIFORNIA HEALTHCARE INSTITUTE, BUT I DID A BACK OF THE ENVELOPE, AND IT MAKES SENSE TO ME. THERE'S ALWAYS DEFINITIONAL ISSUES AND KIND OF WHAT MEANS HERE AND WHAT GOES THERE, AND IS THIS -- HOW MUCH RESEARCH DID A FOREIGN COMPANY DO THAT'S IN ITS RESEARCH CENTER IN CALIFORNIA? WHAT'S THAT DOLLAR VALUE? BUT I THINK THAT'S -- I'M COMFORTABLE WITH THAT AS A BACK-OF-THE-ENVELOPE NUMBER.

BUT BEFORE I GET TOO FAR INTO JUST THE PLAIN JOBS, EMPLOYMENT, TAXES, AND THAT SORT OF THING, WE'VE GOT TO REMEMBER THAT THIS IS NOT VIDEO GAMES. THIS IS

NOT THE LATEST FASHION MODE. THESE ARE ACTUAL THERAPEUTIC BENEFITS TO PEOPLE THAT WE ALL DURING OUR LIVES WILL BENEFIT FROM, AND MANY OF US ARE HERE TODAY BECAUSE OF THEM OR OUR LOVED ARE OR WE BENEFITED FROM THE ALONG THE WAY. A SAFER BLOOD SUPPLY, SCREENING FOR HIV AND HEPATITIS, LONGER LIFE FOR CANCER PATIENTS. IS THERE ANYBODY IN THIS ROOM WHO DOESN'T APPRECIATE WHAT GENENTECH HAS DONE IN THE LAST FOUR OR FIVE YEARS, IN THE LAST SEVERAL YEARS? IT'S A TRULY REMARKABLE SET OF ACHIEVEMENTS IN CANCER AND EXTENDING THE LIFE OF CANCER PATIENTS.

ANEMIA, AMGEN HAS DONE REMARKABLE THINGS THERE. IF ANYBODY HAS SEEN SOMEONE GO THROUGH CHEMOTHERAPY, YOU KNOW HOW IMPORTANT AMGEN'S PRODUCTS ARE. HEPATITIS B VACCINE, AVIAN FLU TREATMENT. YOU MAY KNOW THAT ROCHE IS THE COMPANY THAT'S GETTING A LOT OF THE FOCUS FOR THE PRODUCTION OF TAMIFLU, BUT THAT IS A PRODUCT OF GILEAD, ONE OF NORTHERN CALIFORNIA'S PREMIERE BIOTECH COMPANIES. SLOWING THE PROGRESS OF HIV INFECTION, MULTIPLE SCLEROSIS, HEPATITIS B, AND DIABETES ARE JUST SOME OF THE AREAS THAT THE ACTUAL PRODUCTS OF THIS INDUSTRY HAVE BROUGHT FORWARD TO HELP PEOPLE.

THE INDUSTRY IS LARGELY OR HAS BEEN DRIVEN TO A LARGE DEGREE IN THIS BY COLLABORATIONS BETWEEN

UNIVERSITIES AND THE PRIVATE SECTOR. THESE ARE JUST A SAMPLE OF THEM. WE PUT STEM CELLS IN THERE JUST TO POINT OUT THE FACT THAT UNIVERSITY OF WISCONSIN AND GERON HAVE AN IMPORTANT ROLE IN THAT. BUT HUMAN INSULIN, UCSF, CITY OF HOPE, GENENTECH, AND CHIRON. HUMAN GROWTH HORMONE, TISSUE PLASMINOGEN ACTIVATOR, TPA, HEPATITIS B VACCINE. WE CAN HAVE LONG LISTS LIKE THIS. IT ALWAYS GETS A LITTLE SORT OF DEFINITIONAL AS YOU GET DOWN TO WHO DID WHAT AND WHERE IT IS, BUT THE FACT IS THAT THE ENERGY OF THIS REMARKABLE INDUSTRY HAS COME THROUGH THOSE UNIVERSITIES AND OUT INTO THE PRIVATE SECTOR IN CALIFORNIA.

NOW, HOW DID THIS INDUSTRY HAPPEN IN CALIFORNIA? THAT'S WHAT THESE VISITORS WANT TO KNOW. THEY ALWAYS SAY WHAT DID YOU DO? TELL US WHAT YOU THINK THE FACTORS ARE. AND THEY'RE REALLY PRETTY BASIC. SOME OF THEM ARE OBVIOUS, SOME OF THEM AREN'T SO OBVIOUS. THE FIRST ONE, AND I THINK WE ALL HAVE TO ACKNOWLEDGE, NIH GRANTS. THE GROWING FEDERAL SUPPORT FOR BASIC SCIENTIFIC RESEARCH BASICALLY POSTWAR, BUT PARTICULARLY FROM THE 1970S, SPUTNIK AND THE LIKE, BASIC RESEARCH, THAT PART OF THE PIPELINE THAT THE PRIVATE SECTOR WAS LESS LIKELY TO PUT MONEY INTO. A SIGNIFICANT AMOUNT OF MONEY INCREASING OVER TIME, OVER THE YEARS HAS BEEN GOING UP. AND A VERY, VERY

IMPORTANT ASPECT OF THAT MONEY FOR CALIFORNIA IS THIS THIRD BULLET, AWARDED BY PEER REVIEW.

IT MEANS THAT A GROUP OF ESTEEMED SCIENTISTS WILL TAKE A LOOK AT THE GRANTS AND GIVE THE BEST GRANTS THE MOST MONEY. THE BEST IDEAS GET THE MOST MONEY. AND THAT IS IN DIRECT CONTRAST TO THE SYSTEM IN A LOT OF OTHER COUNTRIES. JAPAN, OLD EUROPE, AND THE LIKE, THE OLDEST, MOST ESTABLISHED SENIOR PROFESSORS GET THE MOST AMOUNT OF MONEY, AND THEN THE NEXT TIER DOWN, AND THE NEXT TIER DOWN. BY THE TIME THE MONEY GETS TO THE YOUNG LIONS, THE PEOPLE THAT ARE REALLY DOING THE WORK, OFTENTIMES THE MONEY ISN'T THERE, AND THEY HAVE TO WAIT 25 YEARS TILL THEY GET TO THE POINT THEY DO THAT. OUR SYSTEM IS SKEWED TOWARDS QUALITY. WHY IS THAT IMPORTANT FOR CALIFORNIA? BECAUSE GUESS WHAT, WE'VE GOT WORLD LEADING RESEARCH CENTERS.

I WOULDN'T SAY THIS OUTSIDE TOO MUCH, BUT IT'S THOSE WHO GOT GET. WE HAVE SOME OF THE BEST RESEARCHERS THAT PUT SOME OF THE BEST IDEAS ON THE TABLE, AND THEY GOT SOME OF THE BEST AMOUNTS OF MONEY. SO UCSF, STANFORD, BERKELEY, SAN DIEGO, SCRIPPS, UCLA, ALL THOSE ENGINES OF RESEARCH AND INNOVATION ARE PUTTING THOSE GRANTS OUT, THEY'RE GETTING THE LARGE SHARE OF PEER-AWARDED NIH GRANTS. AND YOU KNOW, YOU GET THE GOOD GRANTS, YOU GET THE GOOD REPUTATION, YOU

PUBLISH THE MOST PAPERS, STUDENTS WANT TO COME. IT BECOMES A CYCLE THAT HAS BEEN EXTREMELY BENEFICIAL TO CALIFORNIA. IT'S HELPED GROW THESE INSTITUTIONS IN CONTRAST TO THE REST OF THE UNITED STATES, AND IT'S HELPED US BECAUSE WE HAVE BEEN ABLE TO ATTRACT MORE STUDENTS.

ONE OF THE CONSTANT BATTLES AND ONE OF THE THINGS THAT, FORTUNATELY, WE HAVE A GEOGRAPHIC FOCUS IN THE CIRM, ONE OF THE BATTLES OF NIH GRANTS HAS BEEN THAT BATTLE BETWEEN AWARDING EXCELLENCE THROUGH PEER REVIEW AND THE KIND OF GEOGRAPHIC AND POLITICAL CARVING UP OF RESEARCH MONEY THAT CONGRESS AND BUREAUCRACIES ALWAYS WANT TO DO. EVERYBODY WANTS A GRANT FOR THEIR HOME STATE, THEIR REGION, THEIR UNIVERSITY, OR THIS PARTICULAR DISEASE, THAT PARTICULAR THING; WHEREAS, AN AWFUL LOT OF THIS MONEY -- THIS HAS BEEN SO SUCCESSFUL BECAUSE IT WENT TO THE BEST IDEAS BASED ON PEER REVIEW AND PEOPLE TRYING TO ASSESS WHAT'S GOING ON.

NOW, WE HAVE THE MONEY COMING INTO CALIFORNIA'S INSTITUTIONS. CALIFORNIA'S INSTITUTIONS ARE CHURNING OUT RESEARCH, AND WHAT DID THAT FIT INTO? WE WERE EXTRAORDINARILY LUCKY AT THE TIME OF THE BIOTECH REVOLUTION IN THE 1970S BECAUSE WE HAD DEVELOPED AN INFRASTRUCTURE TO COMMERCIALIZE SCIENCE. IT DEVELOPED POST WORLD WAR, STARTING WITH HP AND THE

LIKE, AROUND ELECTRONICS, TRANSISTORS, COMPUTERS, DEFENSE TECHNOLOGIES. THE PEOPLE WHO UNDERSTOOD COMMERCIALIZING SCIENCE, THEY UNDERSTOOD TAKING THINGS ALONG, TAKING RISKS, HAVING TECHNOLOGY FAIL, BUT MOVING IT FORWARD. A VENTURE CAPITAL COMMUNITY DEVELOPED AROUND THAT ELECTRONICS AND THAT INFORMATION TECHNOLOGY, WHICH IS WILLING TO TAKE RISKS, THAT UNDERSTOOD WHERE YOU WE WERE GOING, THAT YOU HAD TO THINK FORWARD IN TERMS OF INNOVATION AND WHAT THE MARKET WOULD BE 4, 5, 6, 10 YEARS FROM NOW TO GET THE RETURN NECESSARY TO INVEST MONEY AT T ZERO.

BUT IT'S NOT JUST VENTURE CAPITAL. IT'S LAW FIRMS, ACCOUNTING FIRMS, COMMUNICATIONS, REAL ESTATE, EMPLOYMENT SPECIALISTS. IT'S A WHOLE COMMUNITY OF PEOPLE WHO UNDERSTAND WHAT IT IS TO TAKE THESE COMPANIES THAT CAN BE VERY RISKY, AND THEY DON'T LOOK RIGHT TO MUCH OF THE REST OF THE WORLD. IF THEY RECOGNIZE THEM, THEN THINGS CAN GO FORWARD. TWO GUYS FROM GOOGLE WALKING INTO A VENTURE CAPITALIST WOULDN'T LOOK GOOD TO MOST OF THE REST OF THE WORLD, BUT IT LOOKED PRETTY GOOD TO SOME PEOPLE ON SANDHILL ROAD, AND THE REST IS HISTORY.

SO RISK TAKING WAS ENCOURAGED. BOB SWANSON GOING UP TO UCSF AND SITTING DOWN WITH HERB BOYER AND SAYING WE CAN MAKE THIS INTO A COMPANY. THIS IS AN

IDEA TO ACTUALLY MANUFACTURE PHARMACEUTICAL PRODUCTS. WE CAN MAKE THIS GO. THAT RISK TAKING IS ENCOURAGED, BUT THE CRITICAL ELEMENT ON TOP OF THOSE THREE IS THE U.S. INTELLECTUAL PROPERTY SYSTEM.

I DON'T KNOW WHETHER YOU'VE HEARD ABOUT THE BAYH-DOLE ACT. I'VE GOT A COUPLE OF SLIDES THERE TO GO THROUGH THE PIECES OF IT IF YOU'RE NOT FAMILIAR WITH IT. BUT THERE REALLY IS. ONE OF THE POINTS MADE EARLIER WAS THERE IS A CONFLUENCE BETWEEN NIH FUNDING BETWEEN THE BAYH-DOLE ACT AND THE EVOLUTION OF THE U.S. PATENT SYSTEM. IF YOU ASK ME TO SUMMARIZE THE BAYH-DOLE ACT IN THREE BULLET POINTS, IT'S THOSE THREE POINTS.

IT LOCALIZED THE OWNERSHIP OF THE INVENTIONS. THESE INVENTIONS OR THIS MONEY THAT WENT OUT AROUND THE UNITED STATES, AND PARTICULARLY IN CALIFORNIA, IT DIDN'T HAVE TO GO BACK TO WASHINGTON FOR THE DEAD HAND OF THE BUREAUCRACY TO KIND OF WORK THROUGH A MASSIVE SYSTEM TO DO IT. IT WAS DONE RIGHT THERE. YOU COULD GO DOWN THE HALL, YOU COULD GO DOWN THE STREET. SOMETIMES YOU HAD TO GO TO OAKLAND IF YOU WE WERE FROM BERKELEY OR SOMETHING OR FROM SAN FRANCISCO, BUT THE POINT IS IT WAS CLOSE, AND IT LOCALIZED THE INVENTION.

IT LOCALIZED THE LICENSING DECISIONS. IT LOCALIZED THE PEOPLE WHO WE WERE DEALING WITH THE

LICENSES. WHAT KIND OF ROYALTY ARE WE REALLY TALKING ABOUT HERE? WHAT'S THE PROCESS FOR AN EXCLUSIVE VERSUS A NONEXCLUSIVE LICENSE? WHO'S GOING TO USE THIS? IF YOU ARE LICENSING THE COHEN BOYER PATENT FROM STANFORD, YOU ARE GOING TO THINK AM I GOING TO DO THIS EXCLUSIVELY, OR AM I GOING TO DO THIS NONEXCLUSIVELY? WHAT'S THE MODEL FOR THIS SORT OF THING? THAT WAS ONE MODEL FOR NONEXCLUSIVE LICENSE BROADLY LICENSED. OTHERS ARE EXCLUSIVE BECAUSE YOU UNDERSTAND THAT THAT MARKET WILL ONLY ACCEPT OR THAT PARTICULAR MOLECULE OR THAT PARTICULAR THERAPY WILL WORK ONLY IN AN EXCLUSIVE CONTEXT. AND THAT'S MUCH BETTER DONE LOCALLY.

AND IT LOCALIZES THE REWARDS FROM THAT LICENSING. THAT TECHNOLOGY LICENSING OFFICER WAS THINKING A THIRD, A THIRD, A THIRD, MY INVENTOR, MY DEPARTMENT -- WELL, FIRST, THE COST FOR MY TECHNOLOGY LICENSING OFFICE, THEN THE INVENTOR, THE DEPARTMENT, AND THE UNIVERSITY, A THIRD, A THIRD, A THIRD. MAYBE IT'S A 40/20/20 OR MAYBE IT'S 40/40/20. MAYBE IT'S SOME OTHER SPLIT, BUT THE POINT IS THAT THEY'RE THINKING SPLITTING IT HERE AND NOT HAVING A GREAT CHUNK OF IT GOING BACK TO WASHINGTON, D.C., OR HAVING TO GET IT ALL APPROVED BY THE BUREAUCRATS IN WASHINGTON, D.C. OR SOMEBODY IN THE NIH. THEY CAN DO IT HERE.

THE OTHER THING IT DID, THE OTHER KEY, I

THINK, WAS THE EVOLUTION OF THE U.S. PATENT SYSTEM. NOW, YOU'RE GOING TO HEAR A LOT ABOUT PATENTS, AND I'M NOT GOING TO GO INTO GREAT DETAIL. AT THAT TIME WE GOT A VERY FORTUITOUS -- I'M NOT GOING TO SAY IT WAS INSIGHTFUL, BUT FORTUITOUS EVOLUTION IN THE U.S. PATENT SYSTEM TO PROTECT NEW GENETIC ORGANISMS AND NEW LIFE FORMS, AND I'LL GET TO THAT IN JUST A SECOND.

BUT THE FIFTH THING, THE FIFTH REASON WE HAVE TO BE CONSCIOUS OF IS WHY THIS HAS DEVELOPED HERE, WHY THE BIOTECH INDUSTRY HAS DEVELOPED HERE, IS BECAUSE PEOPLE WANT TO BE HERE. CALIFORNIA IS A PLACE THEY WANT TO LIVE AND WORK. IF YOU'RE A SCIENTIST OR AN ENTREPRENEUR AND YOU WANT TO FIGURE OUT HOW TO DO YOUR COMPANY HERE, BOTTOM LINE IS WHEN GREAT SCIENTISTS GRADUATE FROM STANFORD OR UCSD OR UCSF, THEY DON'T GET ON THE FIRST PLANE OUT OF TOWN. THEY WANT TO STAY HERE STAY HERE. THEY WANT TO STAY HERE BECAUSE THEY LIKE CALIFORNIA AS A PLACE TO LIVE, BECAUSE IT'S GOT A CULTURE OF INNOVATION AND ACHIEVEMENT, BECAUSE THIS IS WHERE THE ACTION IS. THIS IS WHERE THE CHIRONS AND THE FIVE PRIMES AND THE GENENTECHS AND THE OTHER COMPANIES ALONG THE WHOLE PIPELINE ARE BEING DEVELOPED. IT'S WHERE THE GOOGLES COME FROM. THIS IS WHERE THE ACTION IS.

AND AS A FUNCTION OF OUR SUCCESS, OUR

WORKFORCE IS IMPORTANT. EVERY OTHER REGION, ALMOST EVERY OTHER REGION HAS TO FIGURE OUT WHERE TO GET THE WORKERS FOR THE COMPANIES IF THEY GROW. WE'VE GOT A LARGE AND PRETTY WELL-TRAINED BIOMEDICAL WORKFORCE. COMPANIES CAN HIRE FROM WITHIN THIS REGION. IT'S GOOD BECAUSE WE ALL KNOW IT'S EXPENSIVE HERE. YOU'RE NOT GOING TO GET PEOPLE TO BRING WHOLE TEAMS OF SCIENTISTS FROM SOMEWHERE AROUND THE WORLD, BUT A LOT OF TIMES YOU CAN FIND THE PEOPLE TO WORK HERE. AND MANY TIMES THE VALUE OF THOSE PEOPLE IS THEY'VE WORKED AT THREE OTHER BIOTECH COMPANIES, THEY'VE WORKED IN THREE OTHER CONTEXTS. THEY UNDERSTAND WHERE THE MISTAKES ARE. THEY'RE NOT KIND OF DOING THIS AFRESH OR JUST HAVING SPENT 25 YEARS IN NEW JERSEY AT A PHARMACEUTICAL COMPANY. THEY KNOW IT NEEDS TO MOVE QUICKLY AND SHIFT GEARS AND BE RESPONSIVE.

SO THOSE ARE THE FIVE THINGS, THOSE FIVE KIND OF REASONS THAT THE BIOTECH INDUSTRY HAS REALLY DEVELOPED HERE. I THINK FOR MY MONEY, THAT'S THE FIVE KEY POINTS.

I WANT TO GO BACK TO IP SINCE THIS IS AN IP COMMITTEE AND YOU'RE FOCUSING ON THIS PARTICULAR ISSUE. IF THERE WAS A DATE, IT WAS DIAMOND V. CHAKRABARTY, JUNE 1980 IN THE U.S. SUPREME COURT THAT APPROVED PATENTING A NOVEL LIFE FORM. THAT SAID, BIOTECH'S

PRODUCTS, THE KINDS OF THINGS WHICH ARE UNLIKE ANYTHING ANYBODY HAD BEEN DOING IN THE PATENT SYSTEM UP TO THAT TIME COULD BE PROTECTED. PATENTS COULD NOW PROTECT A PRODUCT AND PROVIDE MARKET EXCLUSIVITY, THE RIGHT TO EXCLUDE OTHERS FROM PRACTICING THAT INVENTION.

AS TED SAID, WHEN THERE'S A PRODUCT, WHEN THERE'S SOMETHING WORTH -- A PRIZE WORTH ACHIEVING, THEN I CAN EXCLUDE OTHERS FROM DOING THAT AND PROTECT MY INVESTMENT OVER TIME. IT IS NO COINCIDENCE THAT THE GENENTECH IPO WAS FOUR MONTHS LATER. GENENTECH WAS A HOT PRODUCT; BUT UNTIL THE INVESTORS UNDERSTOOD THAT THOSE PRODUCTS, THOSE PARTICULARLY NEW LITTLE BACTERIA THAT WE'RE GOING TO USE TO PRODUCE TO GROW UP THESE PRODUCTS CAN BE PROTECTED, THERE WAS NOT THE INVESTOR CONFIDENCE TO INVEST IN. THAT OPENED THE DOOR. IN THE 1980S AND 1990S WE SAW A DRAMATIC INCREASE IN COMPANIES, IN THE TOTAL AMOUNT OF UNIVERSITY LICENSING, BOTH WITHIN CALIFORNIA AND AROUND THE NATION, INDEED AROUND THE WORLD, AND PRODUCTS.

THE LIST OF PRODUCTS IN THE PIPELINE, BIOTECH PRODUCTS IN THE PIPELINE, THAT HAVE COME FROM THIS PARTICULAR INTERACTION WITH THE UNIVERSITY RESEARCH AND COMPANIES COMMERCIALIZING IS GROWING AND GROWING AND GROWING.

NOW, ONE OF THE REASONS THAT WE NEED

THAT MARKET EXCLUSIVITY AND PATENT PROTECTION IS, AS YOU HAVE ALL HEARD AND YOU WILL HEAR MORE, DRUG DEVELOPMENT TAKES AN INCREDIBLE AMOUNT OF TIME, MONEY, AND HAS AN INCREDIBLY HIGH FAILURE RATE. NOW, THAT IS IN CONTRAST TO THE INTERNET, THE SOFTWARE SYSTEMS, THE DISK DRIVES, AND THE OTHER HIGH TECHNOLOGY TOOLS WHICH I'M WORKING ON IT IN OCTOBER 2005 AND OCTOBER 2006 THAT WILL BE ON THE MARKET, AND WE'LL KNOW WHETHER IT'S A GO OR NOT IN A YEAR OR TWO.

DRUG DEVELOPMENT REQUIRES THE PATENT PROTECTION BECAUSE IT IS INCREDIBLY EXPENSIVE AND TIME-CONSUMING TO DEVELOP THESE PRODUCTS. THE NUMBERS ALWAYS FALL WITHIN A WIDE RANGE, BUT GENERALLY SPEAKING, OVER $900 MILLION TO GET TO -- THE TOTAL COST TO GET A MOLECULE ALL THE WAY THROUGH TO THAT APPROVED STAGE WHERE IT'S ACTUALLY GOING INTO PATIENTS IN HOSPITALS WIDELY ACROSS THE COUNTRY. AT LEAST TEN YEARS, TEN YEARS IN CHEMISTRY TO APPROVED PRODUCT. SOMETIMES A LITTLE SHORTER, OFTEN A LOT LONGER. SO THERE'S A DRAMATIC DIFFERENCE FROM ANY OF THESE HIGH TECHNOLOGY OR SOFTWARE SYSTEMS OR INTERNET SCHEMES WHICH WILL TELL YOU IN A MATTER OF A FEW YEARS WHETHER THAT PAYS OFF; AND IF NOT, WE MOVE ON TO THE NEXT THING. YOU'VE GOT TO WORK THROUGH THIS, AND THERE'S A DRAMATIC ATTRITION RATE.

IT LOOKS LIKE THE EIFFEL TOWER LYING ON ITS SIDE. YOU START OUT WITH 10,000 COMPOUNDS, AND IT NARROWS DOWN AND NARROWS DOWN AND GETS DOWN TO A COUPLE HUNDRED, GETS DOWN TO A FEW DOZEN, GETS DOWN TO A FEW TO GET ONE THAT ACTUALLY GETS PAST THE FDA AND IS OUT IN THE MARKET MAKING A RETURN.

AND ANOTHER IMPORTANT THING THAT IS VERY IMPORTANT TO OUR COMMUNITY, OUR AREA, TO CALIFORNIA, IS THAT PATENT LICENSES MAY BE A START-UP COMPANY'S ONLY ASSET. WELL, LET ME PUT IT THIS WAY. PATENT LICENSES AND THE TALENT AND SKILL AND ENERGY OF ITS SKELETAL STAFF, SMALL STAFF, MAY BE THE ONLY ASSETS THESE SMALL COMPANIES HAVE. THAT IS WHAT INVESTORS ARE BANKING ON. AND IF YOU LOOK AT THE MODEL OF THE PHARMACEUTICAL INDUSTRY, EVERYTHING YOU READ ABOUT THE PHARMACEUTICAL INDUSTRY NOW IS THEY'RE LOOKING TO THE BIOTECH INDUSTRY, LOOKING TO THE SMALL, EFFICIENT, FAST QUICK-ON-THEIR FEET COMPANIES STARTING OUT LIKE THIS TO PROVIDE THE PIPELINE, TO PROVIDE THE PRODUCTS. THE MODEL OF BIG PHARMA WITH ITS RUSSIAN ARMY KIND OF APPROACH TO JUST PRODUCT DEVELOPMENT IS BROKE. AND THEY'RE LOOKING TO THE LIKES OF CALIFORNIA AND THE BIOTECH INDUSTRY TO COME UP WITH THE IDEAS THAT THEY'RE GOING TO HAVE TO MOVE THROUGH THEIR SIZABLE AND SIGNIFICANT PRODUCTION AND DEVELOPMENT PIPELINE TO

PRODUCE THOSE PRODUCTS FOR FUTURE USE.

I WANT TO GO BACK AND KIND OF GO OVER A LITTLE BIT OF THIS TECH TRANSFER AND SOME OF THE TOPICS YOU'VE DISCUSSED THERE IN THE FEW MINUTES I HAVE LEFT. I WILL TRY TO NOT REPEAT WHAT WE'VE SAID BEFORE IN THE PREVIOUS SESSION, BUT ALL THROUGH FEDERAL LAW THERE ARE MANDATES AND REQUIREMENTS AND IMPERATIVES TO MOVE USEFUL TECHNOLOGY FROM GOVERNMENT LABS TO PRIVATE SECTOR. THAT'S WHAT YOU READ IN EVERY PREAMBLE IN LEGISLATION THESE DAYS.

GOALS, YOU'RE COMPETITIVE, AND THERE'S JOB CREATION, ECONOMIC BENEFIT. THOSE ARE HOLY GRAILS. THEY WANT THIS TO HAPPEN. IT IS BUILT AROUND THE PATENT PROTECTION AND TECHNOLOGY LICENSED TO THE PRIVATE SECTOR. WE MOVE IT OUT. THE NIH AND THE FDA, GOD LOVE THEM, DO NOT PRODUCE PRODUCT, THEY DO NOT PRODUCE DRUGS. IT IS AT THIS POINT THE PRIVATE SECTOR ALMOST EXCLUSIVELY IN THE UNITED STATES THAT ACTUALLY PRODUCES THE DRUGS THAT THE WORLD IS USING.

AND THE FEDS, THEY RESERVE FEDERAL USE. THERE'S AN APPROPRIATE RESERVATION FOR RESEARCH AND FEDERAL USE IN FEDERALLY FUNDED RESEARCH LIKE THAT. CALIFORNIA, NOW, IF WE TAKE KIND OF A VERSION OF THAT IN CALIFORNIA, SAME THING. YOU WILL SEE LOTS OF PREAMBLES AND RECITATIONS OF PUBLIC POLICY IN

CALIFORNIA ENCOURAGING ECONOMIC DEVELOPMENT, ENCOURAGING DEVELOPMENT OF PRODUCTS TO BENEFIT THE PUBLIC AND THE LIKE, BUT IT'S EASY TO FORGET THAT THIS BIOTECH INDUSTRY AND THIS GROWTH OF WEALTH AND PRODUCTS AND RESEARCH EXCELLENCE HAS BENEFITED THE UNIVERSITIES IN A LOT OF WAYS.

IT'S NOT JUST GOING OUT TO THE COMPANIES. IT'S NOT JUST A ONE-WAY STREET. UNIVERSITIES GET SPONSORED RESEARCH. THE COMPANIES WILL COME AROUND AND FUND MILLIONS OF DOLLARS, PROBABLY BILLIONS OF DOLLARS OF RESEARCH AT THE UNIVERSITIES, AT OUR CALIFORNIA UNIVERSITIES, BECAUSE OF THE SKILL OF THOSE SCIENTISTS. THEY KNOW ABOUT THE IP PROBLEMS. THEY KNOW THAT THE UNIVERSITY WILL OWN THAT TECHNOLOGY. THEY'LL HAVE TO LICENSE IT BACK FROM THE UNIVERSITY. MAYBE THEY HAVE A COMPOSITION OF MATTER PATENT, BUT THE UNIVERSITY WILL OWN THAT. THEY KNOW THAT, BUT THEY NEED TO GET TO THOSE GOOD SCIENTISTS. THEY NEED TO GET TO THOSE PEOPLE. THEY NEED TO GET TO THOSE FACILITIES. THEY UNDERSTAND THAT, BUT THEY STILL GO TO IT BECAUSE THEY NEED THAT SKILL, AND THAT'S A VERY IMPORTANT PART OF OUR UNIVERSITIES' FUNDING, THE RESEARCH FUNDING.

SALES OF PRODUCT, THE ROYALTIES BY BOTH DEVELOPMENT AND SALES OF PRODUCT. GIFTS AND ENDOWMENTS, MONEY COMES BACK INTO THE UNIVERSITIES

THROUGH GIFTS AND ENDOWMENTS. EXCHANGE PROGRAMS, INTERNSHIP, AND THE LIKE. AND INDUSTRIAL PARKS, YOU ONLY NEED TO WORK DOWN IN PALO ALTO TO UNDERSTAND WHAT THE IMPACT OF AN INDUSTRIAL PARK LIKE STANFORD'S INDUSTRIAL PARK CAN BE. THAT IS THE WORLD'S DEFINITION OF WHAT YOU ARE TRYING TO DO WHEN YOU CREATE INDUSTRIAL PARKS, WHICH EVERYBODY AROUND THE WORLD IS TRYING TO DO ADJACENT TO THEIR UNIVERSITIES IN THE WAY STANFORD HAS DONE IT AND SEVERAL OTHER UNIVERSITIES HAVE DONE IT. THOSE BUSINESSES, THEY LIKE THE GLOW. THEY LIKE TO BE IN THE GLOW OF THOSE UNIVERSITIES, SO IT'S A VERY, VERY COMPATIBLE SITUATION.

NOW, IT'S IMPORTANT, AND I DON'T WANT TO END ON A DOWN NOTE, BUT IT'S IMPORTANT FOR THE COMMITTEE HERE TO UNDERSTAND. PATENTS DO NOT GUARANTEE COMMERCIALIZATION. THERE AIN'T NOTHING ABOUT GETTING A PATENT THAT SAYS THIS IS GOING TO BE A PRODUCT. THE PATENT PROTECTION CAN BE EXPENSIVE, IT'S TIME-CONSUMING. IT TAKES A LOT OF EFFORT TO WORK THROUGH THESE PATENTS, TO GET YOUR SCIENTISTS TO FOCUS ON IT, TO GET THE LAWYERS TO WORK IT THROUGH, TO FIND OUT WHAT THE PRIOR ART IS, TO GO THROUGH ALL THAT. IT'S A PROCESS.

COUNTRIES AND LANGUAGES, OKAY, ARE WE GOING TO PROTECT THIS AROUND THE WORLD? WE GOT TO THINK

PROTECTING THIS FOR THE COMMERCIAL MARKET THAT SOMEBODY WILL SEE IN THAT. DO WE NEED TO PROTECT THIS IN EUROPE, IN JAPAN, SINGAPORE, IN AUSTRALIA, CANADA? WHAT DO WE DO? HOW MUCH DOES THAT COST? WHAT OTHER PATENTS ARE THERE THAT ARE COMPETING WITH THIS?

WE'VE GOT SOME UNIVERSITY PEOPLE HERE, BUT IT'S A VERY INTERESTING DYNAMIC. THE UNIVERSITIES DON'T WANT TO PAY FOR PATENTS. THEY LIKE TO TAKE DISCLOSURES, BUT THEY WOULD PREFER AND THEY LOATHE PAYING HARD MONEY FOR PATENTS. THEY WANT A COMPANY TO PITCH UP, TO STAND UP AND TAKE THAT PATENT. SO WHEN YOU TALK ABOUT, WELL, THE UNIVERSITY IS GOING TO OWN ALL THIS IP AND THAT SORT OF THE THING, THE FACT IS UNIVERSITIES WON'T OWN VERY MUCH OF IT IF THEY CAN'T FIND COMPANIES TO COME IN AND WRITE THE CHECK TO PAY FOR THOSE PATENTS.

AND ONE OF THE GREAT CHALLENGES, IF YOU WORK IN A UNIVERSITY LICENSING OFFICE IN CALIFORNIA OR ANYWHERE ELSE, IS TRYING TO FIND THE COMPANIES THAT ARE GOING TO LICENSE THESE PRODUCTS. AND YOU'RE PUTTING IT ON THE INTERNET, YOU'RE GOING TO CONFERENCES, YOU'RE OUT THERE PUSHING ALL THESE INVENTIONS, AND THERE'S A LOT OF THEM. AND YOUR SCIENTISTS ARE POURING THESE OUT, AND YOU'RE TRYING TO MAKE SURE THERE'S SOME COMPANY OUT THERE THAT YOU CAN GET THIS IN FRONT OF WHO

WILL SAY, YEAH, HOW MUCH IS THAT PATENT GOING TO COST ME, AND WHAT'S THAT LICENSE GOING TO COST ME, AND WRITE THE CHECK FOR IT. BECAUSE IF YOU DON'T, THE PATENT IS GOING TO FAIL, AND THE CHANCES OF THAT TECHNOLOGY EVER SEEING ANY COMMERCIALIZATION ARE ALMOST ZERO.

ONE OF THE THINGS COMPANIES UNDERSTAND IS THEY ARE ALWAYS GOING TO HAVE TO PAY THE FULL PATENT COST. UNIVERSITIES DON'T PAY FOR THOSE PATENT PORTFOLIOS GOING FORWARD. IF YOU LICENSE IT, A YEAR INTO THE PATENT PROCESS BECAUSE THE UNIVERSITY HAS BEEN WILLING TO PUT MONEY INTO IT, YOU PAY THEM BACK FOR THOSE COSTS, AND YOU PAY EVERY PENNY OF THE PATENT EXPENSES GOING FORWARD. YOU WILL PAY FOR ENFORCING THAT PATENT, YOU'LL PAY FOR PROTECTING THAT PATENT, YOU'LL PAY FOR OTHER COUNTRIES AND OTHER JURISDICTIONS TO FILE THAT PATENT.

MANAGING A PATENT PORTFOLIO FOR A COMPANY IS A COMPLEX TASK. YOU'VE GOT HALF A DOZEN PATENTS. DO I KEEP THEM ALL IN EACH COUNTRY? WHERE DO I GO? WHAT'S THE ROYALTY? WHAT'S MY YEARLY MAINTENANCE FEE BACK TO THE STANFORD TECHNOLOGY LICENSING OFFICE ON EACH OF THESE PATENTS? IT'S A PROCESS. IT'S A LITTLE COTTAGE INDUSTRY WITHIN THESE COMPANIES JUST TO MANAGE THEIR PATENT PORTFOLIO, BUT IT IS ABSOLUTELY NECESSARY. WITHOUT IT, YOU DON'T HAVE THE PROTECTABLE IP. YOU

DON'T HAVE THE PROTECTABLE COMMERCIAL VALUE.

AND MANY PATENTS DO NOT REPAY THEIR EXPENSE. THERE ARE A LOT OF PATENTS THAT HAVE PAID THOUSANDS, TENS OF THOUSANDS, EVEN HUNDREDS OF THOUSANDS OF DOLLARS TO PROTECT AN ENTIRE PATENT PORTFOLIO. AND GUESS WHAT. THAT PRODUCT DIDN'T MAKE IT. WE DIDN'T MAKE IT TO THE FINISH LINE. WE GOT IT OUT THERE. IT WASN'T A COMMERCIAL SUCCESS. AFTER WE GOT IT OUT THERE, SOMEBODY CAME ALONG THAT WAS BETTER, AND THE DOCS ALL WENT IN THAT DIRECTION. WE'RE OUT ALL THE COST OF THAT PATENT.

SO THERE'S NO GUARANTEE OF SUCCESS FROM THIS PATENT PROCESS; BUT WITHOUT IT, WE WOULDN'T HAVE A BIOTECH INDUSTRY. WE WOULDN'T HAVE THAT SUCCESS, THOSE JOBS, THOSE PRODUCTS, AND THE ALMOST MYTHIC REPUTATION WE HAVE AROUND THE WORLD IN CALIFORNIA.

I CANNOT -- I WANT TO CLOSE ON THAT PARTICULAR THING. YOU CANNOT APPRECIATE THE REPUTATION THAT WE HAVE AROUND THE WORLD WITH THIS BIOTECH SUCCESS WE'VE HAD IN CALIFORNIA. AND AS I WILL TELL PEOPLE WHEN THEY ASK, RESEARCH GRANTS, THE IP OWNERSHIP, AND GETTING THESE INVENTIONS OUT TO THE PRIVATE SECTOR IN CALIFORNIA HAS PRODUCED REMARKABLE MEDICAL PRODUCTS, A THRIVING BIOTECH INDUSTRY, AND BUSINESS ACHIEVEMENT UNMATCHED ANYWHERE ELSE IN THE WORLD. AND THAT IS

SOMETHING THAT I THINK CIRM AND THIS COMMITTEE HAS TO KEEP IN MIND WHEN YOU ARE LOOKING AT THIS PICTURE OF HOW DO WE USE THIS IP AND PROTECT THE IP AND MOVE THIS THING FORWARD TO PRODUCTS. I'M AVAILABLE FOR QUESTIONS.

CHAIRMAN PENHOET: THANK YOU, FRED.

(APPLAUSE.)

CHAIRMAN PENHOET: DO WE HAVE SOME QUESTIONS FOR FRED?

MR. REED: IT'S NOT A QUESTION. I'VE JUST BEEN WANTING A LONG TIME FOR SOMEONE LIKE YOU TO COME AND CLEARLY STATE THE ENERGY AND THE POWER OF CALIFORNIA'S BIOTECH INDUSTRY. SO THANK YOU VERY MUCH.

DR. DOREY: HAPPY TO DO IT.

DR. FONTANA: I REALLY APPRECIATED YOUR PRESENTATION. AND I'M CURIOUS WHAT YOUR RECOMMENDATIONS WOULD BE FOR US, COMBINING WITH THE FIRST PRESENTATION, SOME OF THE ISSUES THAT WERE RAISED. WHAT ARE SOME OF YOUR THOUGHTS?

DR. DOREY: I WAS THINKING THROUGH A LOT OF THAT GOING ALONG THERE, AND I DON'T WANT TO JUMP INTO THE DEBATE, AND I'D BE HAPPY -- THE PROPER LEGAL RESPONSE IS I'LL BE HAPPY TO PROVIDE YOU THAT INFORMATION.

I THINK YOU HAVE TO RESPECT -- LET ME PUT IT

IN MORE CONTEXT. ONE OF THE CONCERNS I HAVE AND ONE OF THE THINGS I'VE SEEN TOO OFTEN IS VERY GOOD TECHNOLOGIES, VERY GOOD PRODUCT, VERY GOOD IDEAS THAT NEVER MAKE IT TO THE FINISH LINE. THEY NEVER GET TO THE CLINIC BECAUSE THEY JUST GET BOGGED DOWN IN COMPLEXITY AND TOO MANY COMPETING, JUST EXPENSIVE PROCESSES AND PARTIES AND ACTIONS.

SO I THINK THE IMPORTANT THING IS TO UNDERSTAND THAT IF THERE IS A SYSTEM OUT THERE THAT'S WORKING, BAYH-DOLE MAY NOT BE PERFECT, AND THERE'S WAYS TO IMPROVE ON IT, BUT TO TRY AND TURN THE CORNER AND CREATE AN ENTIRELY DIFFERENT SYSTEM IN A VERY NEW, EARLY STAGE TECHNOLOGY IS ONLY GOING TO ADD TRAUMATIC AND DRAMATIC COMPLEXITY AND INEFFICIENCY AND COST TO THIS PROCESS, AND YOU COULD VERY EASILY WIND UP WITH THIS JUST KIND OF DRIBBLING AWAY TO SORT OF NOTHING BECAUSE THERE'S SO MUCH JUST COMPLEXITY.

DR. PRIETO: HOW MUCH OF A PROBLEM DO YOU THINK IT COULD BE TO PATENT INTERNATIONALLY THINGS LIKE CELL LINES AND SCIENTIFIC PROCESSES THAT MAY COME OUT OF CIRM RESEARCH? AND, FOR EXAMPLE, THE WI-CELL PATENTS, I UNDERSTAND THEIR CELL LINES ARE NOT RECOGNIZED IN EUROPE.

DR. DOREY: I'M GLAD YOU ASKED THAT BECAUSE WE HAVE A REAL PATENT LAWYER IN THE AUDIENCE. AL

HALLUIN HAS HAD AS MUCH EXPERIENCE IN THE BIOTECH PATENT AS ANYBODY WALKING TODAY.

IN TERMS OF THE ACTUAL PATENTABILITY AND THE ABILITY TO -- WHETHER FOREIGN COUNTRIES OR FOREIGN PATENT SYSTEMS ARE GOING TO RECOGNIZE THE SAME KINDS OF PATENTS OR THE SAME PATENT SCHEMES THAT WE DO, I DON'T KNOW THE ANSWER TO THAT. THERE'S A PRETTY GOOD INTERNATIONAL SYSTEM NOW, AND IT WORKS PRETTY WELL. IT DOES KEEP A NUMBER OF BRETHREN EMPLOYED IN SOME LITIGATION FROM TIME TO TIME, BUT IT DOES WORK PRETTY WELL, I THINK, WITHIN THE DEVELOPED COUNTRIES WHERE THERE ARE THE BIGGEST MARKETS. AND I THINK, AGAIN, WE NEED TO SORT OF WORK ON THE MARGINS TO IMPROVE ASPECTS OF IT, BUT NOT TRY AND REINVENT THE WHEEL.

MR. HALLUIN: THERE ARE DIFFERENT AREAS OF PATENTS AND DIFFERENT WAYS THAT YOU CAN CLAIM INVENTIONS, LIKE, SAY, THE WI-CELLS, THAT PER SE MAY NOT BE PATENTABLE IN EUROPE AND OTHER COUNTRIES. BUT YOU CAN -- THERE'S WAYS OF CLAIMING TO SAVE THAT INVENTION COMING AT IT A DIFFERENT WAY. FOR EXAMPLE, IN THE AREA OF MEDICAL USE, THE EUROPEANS DON'T LIKE YOU TO HAVE A CLAIM THAT TREATING -- A METHOD OF TREATING FOR SOME MEDICAL USE OR THERAPY. AND SO THERE ARE WAYS OF CLAIMING AROUND THAT BECAUSE YOU CLAIM THE COMPOSITION FOR USE IN THIS MEDICAL THERAPY, AND YOU'RE

COVERING THAT MEDICAL USE IN KIND OF AN INDIRECT WAY.

SO IN TIME THESE THINGS EVOLVE, AND I THINK THAT RIGHT NOW THERE IS A LOT OF DEBATE IN EUROPE ABOUT THINGS THAT YOU CAN PATENT AND CAN'T PATENT.

SO CLEVER PATENT ATTORNEYS WORK THEIR WAY AROUND THAT ISSUE. IT'S GOING TO VARY FROM COUNTRY TO COUNTRY, AND EACH OF THE COUNTRIES HAVE THEIR OWN CULTURE AND THEIR LAWS THAT IF YOU FIT IN WITH THE WAY THEY'RE THINKING, AND SOMETIMES IT IS BLOCKED. MANY YEARS AGO THERE WE WERE CERTAIN PHARMACEUTICAL TYPE OF PATENTS YOU COULDN'T GET IN ITALY. AND THEN THE SMART COMPANIES FILED THEIR PATENTS IN ITALY ANYWAY, AND THEY WE WERE JUST SITTING THERE, AND THEN THEY CHANGED THE LAW, AND THEN THEY LIT UP SOME PATENTS.

DR. LOVE: FIRST I WANT TO APOLOGIZE. WE NEVER MET BEFORE, AND I ANSWERED YOUR QUESTIONS NOT KNOWING WHO YOU WERE. I TRULY APOLOGIZE.

BUT I WANTED TO ASK FRED. ONE OF THE THINGS THAT I THINK WE HAVE TO BE CAREFUL ABOUT IS THAT TO SOME EXTENT WE'RE SELLING A DREAM ALSO, A DREAM THAT I THINK WILL COME TRUE. BUT YOU HAVE A LOT OF EXPERIENCE IN THIS BUSINESS, AND YOU'VE SEEN ALL THE CHARTS ABOUT ALL THE MONEY THAT'S BEEN INVESTED IN BIOTECHNOLOGY, MY BUSINESS, AND HOW MUCH MONEY HAS BEEN INVESTED AND HOW MUCH VALUE HAS BEEN CREATED. IN FACT, IT'S NOT A VERY

GOOD RETURN. EVEN THOUGH WE PRODUCE SOME WONDERFUL PRODUCTS, SOME PRODUCTS THAT I'VE WORKED ON PERSONALLY LIKE RITUXIN AND HERCEPTIN FROM GENENTECH, FOR EXAMPLE; BUT AS A BUSINESS MODEL, IT HAS NOT BEEN THE PAYOFF THAT PEOPLE THINK.

I THINK THAT'S ANOTHER THING FOR US TO KEEP IN MIND AS WE ARE REALLY TRYING TO BUILD SOMETHING THERE THAT PEOPLE WILL INVEST IN, WILL PUT THE BILLIONS OF DOLLARS INTO. WE JUST NEED TO BE COGNIZANT OF THE FACT THAT TO SOME EXTENT WE ARE TRYING TO BUILD EXCITEMENT AND BUILD ENTHUSIASM FOR A LOT OF MONEY AND A LOT OF INTEREST TO COME IN AN AREA WHICH, QUITE FRANKLY, HAS A TREMENDOUS AMOUNT OF RISK ASSOCIATED WITH IT.

DR. DOREY: AND CERTAINLY THE INVESTORS IN BIOTECH ARE NOT UNMINDFUL OF THAT 10- AND 15-YEAR TIME FRAME AND THE PRICING ISSUES, THE COMPETITIVENESS ISSUES, INDEED PERSONALIZED MEDICINE. IT'S NOT GETTING ANY CHEAPER TO DO A CLINICAL TRIAL, BUT YOU MAY HAVE A MUCH SMALLER COHORT OF PATIENTS YOU CAN APPLY THAT PRODUCT TO NOW. SO THE ECONOMICS OF THE WHOLE PHARMACEUTICAL DEVELOPMENT PROCESS KEEP PUSHING IN THE WRONG DIRECTION TO ATTRACT MONEY THE WAY THE NEXT GOOGLE WILL. SO THERE IS A LOT OF BALANCING THAT YOU'RE GOING HAVE TO DO IN THIS PROCESS.

MR. FLANAGAN: THE FACT THAT THE BIOTECH INDUSTRY EMBRACES BAYH-DOLE IS NOT SURPRISING TO ME AS A MODEL IN TERMS OF OWNERSHIP OF THE INTELLECTUAL PROPERTY AND ROYALTIES RETENTION. I WOULD ASSUME THAT TO THE EXTENT THAT BIOTECH RECEIVES MONEY UNDER NIH AND HAVE LOOKED AT HUGE FEDERAL GRANTS TO PHARMACEUTICAL COMPANIES THAT HAVE DONE VERY WELL UNDER BAYH-DOLE, I UNDERSTAND FROM THAT FINANCIAL PERSPECTIVE WHY THOSE POLICIES WOULD BE BENEFICIAL TO THE INDUSTRY TO BE BROUGHT INTO CALIFORNIA.

DR. DOREY: I'M NOT SURE I FOLLOWED EACH OF THE PIECES YOU PUT TOGETHER, BUT GO AHEAD.

MR. FLANAGAN: THE ISSUE, THOUGH, IS THAT TO MAKE THE ARGUMENT THAT IN ORDER TO ENCOURAGE BIOTECH INVOLVEMENT IN THIS PROJECT, THAT SOMEHOW ALL OF THE INTELLECTUAL PROPERTY RIGHTS HAVE TO BE OWNED IN TOTAL BY THE INDUSTRY OR THAT ALL THE ROYALTIES HAVE TO GO TO BIOTECH TO ME IS A FLAW IN REASONING. THAT BECAUSE WE HAVE TO INCENTIVIZE THEM IN THE BEGINNING, WE HAVE TO GIVE THEM EVERYTHING.

DR. DOREY: I WOULD ASK YOU JUST TO BE PRECISE WITH YOUR LANGUAGE HERE BECAUSE IT IS VERY IMPORTANT. THE BIOTECH INDUSTRY DOESN'T OWN ANYTHING THEY LICENSE FROM THE UNIVERSITIES. THEY OWN NOTHING. THE UNIVERSITIES OWN IT ALL.

MR. FLANAGAN: WELL, BUT THE UNIVERSITIES UNDER BAYH-DOLE HAVE THE RIGHTS TO PROVIDE EXCLUSIVE CONTRACTS.

DR. DOREY: TRUE. EXCLUSIVE LICENSES.

MR. FLANAGAN: AND THAT IN A SENSE PROVIDES THE EXCLUSIVE RIGHTS TO THAT PRODUCT TO THE BIOTECH INDUSTRY.

DR. DOREY: WHICH IS WHAT'S REQUIRED TO GET THE INVESTMENT, BUT THERE IS THE DILIGENCE REQUIREMENTS. THEY HAVE TO MOVE THOSE ALONG OR THEY LOSE THE LICENSE.

MR. FLANAGAN: MY CONCERN IS MORE ON THE AFFORDABILITY ISSUES, THAT THE FINANCIAL VALUE THAT'S PUT ON THE GRANTING OF THOSE EXCLUSIVE LICENSURES HAS NOT BEEN ADEQUATE UNDER THE FEDERAL BAYH-DOLE ACT TO PROTECT PUBLIC INTEREST. A LOT OF THESE TECHNOLOGIES DEVELOPED WITH PUBLIC FUNDS HAVE BEEN LICENSED EXCLUSIVELY TO PRIVATE INDUSTRY FOR FAR TOO LITTLE MONEY. MY FAVORITE EXAMPLE IS THE CHERYL STOLEBERG NEW YORK TIMES EXAMPLE IN 2000 LOOKED AT XALATAN, A GLAUCOMA DRUG, THAT WAS DEVELOPED AT COLUMBIA FOR $4 MILLION IN TAXPAYER DOLLARS. COLUMBIA THEN SOLD THE RIGHTS TO XALATAN. THEY SOLD THE RIGHTS TO THAT PRODUCT FOR $150,000.

DR. DOREY: DID THEY SELL THE RIGHTS OR DID

THEY LICENSE THE RIGHTS?

MR. FLANAGAN: THEY GRANTED AN EXCLUSIVE CONTRACT TO PHARMACIA CORPORATION.

DR. DOREY: LET'S GET THIS RIGHT. THEY GRANTED AN EXCLUSIVE LICENSE, AND THE LICENSE FEE WAS $150,000.

MR. FLANAGAN: LET ME FINISH THE POINT. IN THE FIRST YEAR ALONE, PHARMACIA MADE $100 MILLION ON XALATAN, FOR 50 BUCKS A BOTTLE FOR INGREDIENTS THAT COST PENNIES TO PRODUCE.

DR. DOREY: AND WHAT WAS THE ROYALTY RATE THAT COLUMBIA RECEIVED FOR ITS LICENSE?

MR. FLANAGAN: THAT INFORMATION IS NOT PUBLICLY AVAILABLE SINCE 1995. NIH HAS NOT DONE A GOOD JOB OF REPORTING. BUT THE LAST TIME WE HAD DATA FROM NIH IN TERMS OF THE ROYALTIES RECEIVED, IT'S A FRACTION OF THE DOLLAR. MY POINT --

DR. DOREY: THAT'S AN IMPORTANT POINT. COLUMBIA WILL TELL -- WILL ANNOUNCE HOW MUCH IT RECEIVES IN TOTO IN ROYALTIES EACH YEAR. AND COLUMBIA DOES VERY WELL IN ROYALTIES. COLUMBIA IS A BIG TICKET WINNER IN THIS PROCESS. MAYBE THE DELTA THERE IS BIGGER THAN IT IS IN SOME OTHER PRODUCTS. AND MAYBE PHIZER -- MAYBE PHARMACIA DID A BETTER JOB OF NEGOTIATING THAN THEY DID IN OTHER SITUATIONS THAN

OTHER COMPANIES HAVE DONE, BUT I HAVE NEGOTIATED WITH COLUMBIA. THEY DON'T GIVE STUFF AWAY.

MR. FLANAGAN: MY CONCERN IS LESS WITH THE ROYALTIES, ALTHOUGH THAT IS IMPORTANT.

DR. DOREY: THAT'S WHAT YOU'RE LOOKING AT FOR A $500 MILLION SALE.

MR. FLANAGAN: HOWEVER, THE KEY THING IS THOSE ARE PUBLIC FUNDS GIVEN TO PRODUCE THE GLAUCOMA MAKE DRUG, BUT THERE WAS NO CONTROL TO MAKE SURE THAT THE END PRODUCT WAS AFFORDABLE OR THE PRICE WAS -- THE MARCH-IN RIGHT LANGUAGE IS AVAILABLE TO THE PUBLIC ON REASONABLE TERMS. MY CONCERN IS CONTINUALLY WITH UTILIZING BAYH-DOLE IS TO MAKE SURE THAT AFFORDABILITY OF THAT END PRODUCT IS BUILT INTO THE INTELLECTUAL PROPERTY MODEL.

DR. PRIETO: I HAVE A LOT OF THESE SAME CONCERNS, BUT I -- ALSO IF YOU -- AFFORDABILITY IS A VERY NEBULOUS CONCEPT. HOW DO YOU -- YOU HAVE TO PUT A NUMBER ON IT. OTHERWISE IF YOU JUST SAY WE ARE GOING TO IN SOME WAY RESTRICT THIS, WHAT'S TO MAKE PHARMACIA TAKE THAT MOLECULE AND MAKE IT INTO A DRUG AND MAKE IT COMMERCIALLY AVAILABLE RATHER THAN THE NEXT MOLECULE THAT DOESN'T HAVE THOSE CONSTRAINTS BECAUSE IT WAS DEVELOPED PRIVATELY? THEN IT DOESN'T GET ANYWHERE AND IT DOES NOBODY ANY GOOD.

MR. FLANAGAN: THIS GOES TO THE COMPLEXITY ISSUE AND MY CONCERN OVER THE TIMELINE WHICH THESE POLICIES ARE BEING DEVELOPED. BUT THE FIRST RULE WOULD BE NOT TO LEAVE IT UP TO PHARMACIA TO DEVELOP -- UNDERSTAND WHAT AFFORDABILITY MEANS, BUT EITHER A PUBLIC -- SOME OTHER ENTITY, EITHER A POOLING OF PATENTS. IT'S COMPLICATED, BUT THE DEFAULT SHOULD NOT BE, WELL, LET'S JUST DO WHAT THE BAYH-DOLE ACT IS DOING. CALIFORNIA HAS THE OPPORTUNITY HERE WITH STEM CELL RESEARCH TO REDEFINE HOW PUBLICLY FUNDED RESEARCH IS TREATED.

THIS IS THE CORE OF PROP 71, THAT CALIFORNIA WOULD BE ABLE TO BENEFIT FROM THE RESEARCH. IF THE RESEARCH IS NOT AFFORDABLE, I CAN'T AFFORD THE PRESCRIPTION THAT MY TAXPAYERS DEVELOPED, THEN THE BENEFIT IS UNDERMINED. THIS COMMITTEE HAS TO REALLY GRAPPLE WITH THOSE ISSUES AND DEAL DIRECTLY WITH OTHER MODELS.

DR. PRIETO: I'D ABSOLUTELY GRANT YOU THAT, BUT I WOULD ALSO SAY THAT IF YOU NEVER GET A THERAPY, THEN THAT'S A GREATER FAILURE.

MR. FLANAGAN: RIGHT. BUT SIMPLY SAYING THAT WITHOUT DIGGING IN AND DEVELOPING THE POLICIES --

DR. PRIETO: THAT'S WHAT WE'RE DOING HERE.

MR. FLANAGAN: BUT MY CONCERN WITH THE CCST

REPORT IS THAT ALTHOUGH THEY CLAIM INTERNAL CONFLICT, THE REPORT IS JUST TAKE BAYH-DOLE WITHOUT A DISCUSSION OF VARIOUS OTHER MODELS THAT HAVE BEEN TALKED ABOUT IN TERMS OF CORRECTING BAYH-DOLE FOR THE LAST 20 YEARS. THIS COMMITTEE SHOULD DEAL DIRECTLY WITH THOSE INDIVIDUALS AND THE BODY OF RESEARCH THAT HAS LOOKED AT OTHER MODELS DIRECTLY DEALING WITH BAYH-DOLE. AND, AGAIN, IT'S COMPLICATED. IT'S A TASK THAT NEEDS TIME.

DR. PRIETO: THAT'S WHY WE'RE HERE, AND WE ARE LOOKING AT OTHER MODELS. AND I THINK THE OTHER THING WE HAVE TO LOOK AT OR REMEMBER IS THE FACT THAT WE ARE NOT JUST TALKING, IN FACT, WE ARE MAYBE MOSTLY NOT TALKING ABOUT PHARMACEUTICALS HERE. SO WE ARE TALKING A DREAM.

CHAIRMAN PENHOET: WE HAVE MADE THE POINT PREVIOUSLY THAT THE CCST REPORT IS AN IMPORTANT PIECE OF INFORMATION FOR US TO UNDERSTAND AND DIGEST IN OUR DELIBERATIONS TO THE FORM AN IP POLICY, BUT IT'S NOT PROSCRIPTIVE FOR US. WE HAVE THE CHARGE. IT'S OUR RESPONSIBILITY TO DEVELOP CIRM POLICY. THAT'S AN IMPORTANT PIECE OF INFORMATION FOR US TO TAKE INTO ACCOUNT. A THOUGHTFUL GROUP OF PEOPLE DID A LOT OF WORK, BUT WE ARE HEARING OTHER POINTS OF VIEW. ESPECIALLY NEXT MONDAY WE'LL HEAR SEVERAL DIFFERENT MODELS. WE ARE NOT CLOSE-MINDED ON THIS AT THIS POINT

IN TIME. WE ARE HERE LISTENING AND HAVING THESE DISCUSSIONS, TO HEAR YOU, AMONG OTHER PEOPLE, AND ADDRESS --

MR. FLANAGAN: I WOULD JUST SAY IN THE FUTURE, SINCE THIS IS A PUBLIC MEETING, THAT YOU MOVE THE PUBLIC SPEAKING PART UP BEFORE THE BIOTECH INDUSTRY'S PROMOTIONAL TALK ABOUT THE STATE OF CALIFORNIA. IT'S REALLY IMPORTANT, THESE MEETINGS. ONE, TO REALLY EMPHASIZE THE PUBLIC ROLE; AND, TWO, IDEALLY TO HOLD SOME OF THESE -- AT LEAST ONE MORE PUBLIC MEETING ON THE IP ISSUE IN THE EVENING OR ON THE WEEKENDS SO THE MEMBERS OF THE PUBLIC WHO ARE CONCERNED CAN ACTUALLY ATTEND. WE WORK A LOT WITH THE PUBLIC. IT WOULD BE GREAT IF YOU COULD DO SOMETHING AT LEAST ONE MORE MEETING IN THE EVENING OR ON A WEEKEND SO PUBLIC MEMBERS COULD ATTEND DIRECTLY.

CHAIRMAN PENHOET: THAT'S A GOOD SUGGESTION. SO WE DECIDED THAT WE WOULD ALLOW TIME, WE DO HAVE ANOTHER 40 MINUTES, FOR PEOPLE WHO WISH TO ADDRESS THIS GROUP. AND WE DID HAVE A SIGN-UP SHEET. I'M NOT SURE HOW MANY OF YOU SIGNED UP. HOW MANY WOULD LIKE TO SPEAK AT THIS POINT? WE AGREED EARLIER IF WE HAD TIME, WE WOULD GIVE YOU EACH TEN MINUTES. HOPEFULLY WE'VE HAD AN OPPORTUNITY TO HEAR FROM ALL THREE OF YOU BEFORE THIS TIME. I DON'T KNOW WHO WOULD LIKE TO GO FIST.

DON REED, YOU'RE A VERY STRONG PATIENT ADVOCATE.

MR. REED: MY NAME IS DON REED. MY SON, ROMAN REED, IS PARALYZED. WE PASSED A LAW NAMED AFTER HIM CALLED THE ROMAN REED SPINAL CORD INJURY RESEARCH ACT. THESE ISSUES ARE EXTREMELY IMPORTANT TO ME.

I'VE STUDIED THE EXCELLENT DOCUMENT WHICH WAS PUT TOGETHER BY CCST. AS THE AUTHOR OF FIVE BOOKS AND A TEACHER OF WRITING, IT'S COMPLICATED INFORMATION IN A VERY CLEAR, CONCISE MANNER. EXCELLENT JOB.

MY MAIN CONCERN IS I DON'T WANT US TO MAKE IT SO DIFFICULT TO DEVELOP ELECTRICITY, THAT WE LOSE THE LIGHTBULBS. WHAT WE'RE UP AGAINST IS GIGANTIC. JUST ONE TINY EXAMPLE. I WALKED INTO THE REST ROOM A MINUTE AGO, AND THERE'S A VERY SMALL URINAL VERY CLOSE TO THE FLOOR. AND MOST PEOPLE THINK THAT'S FOR SHORT PEOPLE, CHILDREN. IT'S NOT. THAT IS FOR WHEELCHAIR PEOPLE WHO CANNOT MAKE IT TO THE BIG STALL SO THEY CAN HAVE A WAY TO CATHETERIZE THEMSELVES. THIS IS A SMALL, HIDDEN EXPENSE, AND THERE'S TONS OF THEM.

AN EXPERT ON ALZHEIMER'S ONCE ESTIMATED IT COSTS $50,000 TO TAKE CARE OF ONE ALZHEIMER'S PATIENT FOR ONE YEAR. THERE'S AN ESTIMATED FIVE MILLION ALZHEIMER'S PATIENTS, FIVE MILLION TIMES 50,000, 250 BILLION. THAT'S ONE-EIGHTH OF THE TOTAL INCOME TAXES, FEDERAL INCOMES TAXES, BOTH PERSONAL AND CORPORATE, IN

AMERICA, AND THAT'S JUST ONE CONDITION.

WE MUST NOT LET ANYTHING GET IN THE WAY OF FUNDING OUR SCIENTISTS. BAYH-DOLE IS A FACT OF LIFE. WE CANNOT JUST SAY, WELL, WE DON'T LIKE IT. IF WE DO THAT, I'LL TELL YOU EXACTLY WHAT'S GOING TO HAPPEN. THE ROMAN REED ACT HAS PROVIDED ROUGHLY $4.8 MILLION OF CALIFORNIA TAX MONEY, $4.8 MILLION OVER FIVE YEARS. WE HAVE ROUGHLY $1 MILLION A YEAR OF CALIFORNIA FUNDING, BUT WE ATTRACTED 25 MILLION IN FEDERAL GRANTS.

NOW, IF WE HAD BEEN IN VIOLATION OF BAYH-DOLE, WE COULD NOT -- WE WOULD HAVE LOST 25 MILLION BUCKS. INSTEAD CALIFORNIA MADE A PROFIT. NOW, RIGHT NOW WE FACE A WASHINGTON WHICH IS NOT REALLY SUPPORTIVE OF MANY OF OUR GOALS, BUT THEY WILL NOT BE THERE FOREVER. THREE YEARS FROM NOW, I DON'T KNOW HOW MANY DAYS IT IS, THERE WILL BE NEW PEOPLE THERE. AND WE DON'T WANT TO BE TIED DOWN TO SOME RESTRICTIONS THAT BLOCK US FROM GETTING FEDERAL GRANTS. I WANT US TO GET MATCHING GRANTS FIVE TO ONE LIKE WE GET FROM THE ROMAN REED ACT.

I WANT -- CALIFORNIA'S LAW IS SEED MONEY, AND WE MUST PROTECT IT. WE MUST NOT LET SHORT-TERM ATTEMPTS TO MAKE A COUPLE NICKELS THERE BLOCK US FROM THE BILLIONS THAT LIE AHEAD. WHEN YOU LOOK AT -- THERE'S A WONDERFUL DOCUMENT WHICH IS REFERRED TO IN

THE IP DOCUMENT HERE WHICH IS THE 2000 REPORT OF THE JOINT ECONOMIC COMMITTEE OF THE SENATE OF THE UNITED STATES. AND THEY ADDED UP THE TOTAL COSTS OF DIRECT AND INDIRECT MEDICAL EXPENDITURES. 1.3 TRILLION OUT OF POCKET, 1.7 TRILLION INDIRECT, LIKE TIME LOST FROM WORK, 3 TRILLION BUCKS. ALL INCOME TAXES TIED TOGETHER, FEDERAL, INDIVIDUAL, AND CORPORATE COMBINED, $2 TRILLION. VERIFY THAT, GO TO IRSATAGLANCE.ORG, $2 TRILLION LAST YEAR. THE 3 TRILLION FIGURE COMES FROM 1992, SO IT HASN'T GONE DOWN. 50 PERCENT MORE THAN ALL INCOME TAXES TOGETHER, THIS IS THE SECRET MEDICAL TAX WE'RE ALL PAYING. THERE'S NO WAY WE CAN CONTINUE TO PAY THESE OUTRAGEOUS COSTS. THE ONLY WAY IS CURE.

IF WE DO FOR OTHER DISEASES WHAT WE DID FOR POLIO, WE SAVE MONEY. POLIO HAS BEEN ESTIMATED TO SAVE BETWEEN 28 AND $30 BILLION EVERY SINGLE YEAR. THAT'S WHAT OUR SCIENTISTS CAN DO. THAT'S WHAT WE HAVE TO KEEP THEM FREE TO DO. WE CANNOT ALLOW SHORT-TERM GAINS, SMALL GAINS TO BLOCK US FROM THE GIANT GOALS AND THE ENDING OF GIGANTIC SUFFERING WHICH IS ON US NOW. THANK YOU.

CHAIRMAN PENHOET: THANK YOU.

MR. FLANAGAN: JERRY FLANAGAN, HEALTHCARE POLICY DIRECTOR FOR THE FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. WE'RE THE STATE'S LEADING

NONPARTISAN, NONPROFIT CONSUMER ADVOCACY GROUP. WE AGREE WITH -- OUR ORGANIZATION SUPPORTS THE VOTERS' INTENT TO EXPAND STEM CELL RESEARCH IN CALIFORNIA. OUR CONCERN HAS BEEN IN THE IMPLEMENTATION, FIRST ON CONFLICTS AND EXEMPTIONS OF THE CIRM FROM STATE OVERSIGHT, INCLUDING PUBLIC RECORDS ACT, OPEN MEETINGS, POLITICAL REFORM ACT. BUT THE FOCUS TODAY OBVIOUSLY IS INTELLECTUAL PROPERTY. AND WE BELIEVE IT IS PROBABLY THE MOST IMPORTANT ISSUE IN TERMS OF ACHIEVING THE STATED INTENT OF PROP 71, THE PLAIN LANGUAGE MEANING OF PROP 71 AS IT WAS PROMOTED TO TAXPAYERS AND VOTERS, WHICH WAS THAT CALIFORNIANS WOULD BENEFIT IN SOME MEANS FROM STEM CELL RESEARCH HERE IN CALIFORNIA.

AND THEN, TWO, I THINK AN IMPORTANT TWO, IS THAT CALIFORNIA WOULD ALSO BENEFIT AS A STATE FROM SOME ROYALTIES. AND THERE WAS A REPORT THAT WAS PROMOTED BY THE PROPONENTS OF PROP 71 THAT WE LEARNED LATER WAS ACTUALLY FUNDED BY THE PROPONENTS OF PROP 71 THAT SAID ROYALTIES WILL BE IN THE RANGE OF 500 MILLION TO $1.1 BILLION RESULTING FROM PROP 71 GRANTS AND PUBLIC FUNDS.

OUR CONCERN HERE IS THAT THE FEDERAL BAYH-DOLE ACT HAS BEEN A COMPLETE FAILURE IN PROVIDING THE FIRST GOAL OF -- WHAT WOULD BE THE FIRST GOAL OF THE PROP 71 INITIATIVE, WHICH IS THE PUBLIC ACCESS TO PRESCRIPTION DRUGS. AGAIN, THE KEY THING IS THAT

PRESCRIPTION DRUGS NATIONALLY HAVE BEEN LARGELY FUNDED BY TAXPAYER DOLLARS. THE NIH STUDY IN 1995, THE LAST TIME THEY PRODUCED THESE FIGURES, SAW THAT MEDICAL RESEARCH IN THE UNITED STATES, 44 PERCENT OF THAT IS DEVELOPED BY TAXPAYER DOLLARS. DESPITE THAT, THE FEDERAL BAYH-DOLE ACT AND REGULATORS HAVE NEVER USED ONCE THE MARCH-IN RIGHTS TO MAKE SURE THAT THE PRODUCTS OF PUBLICLY FUNDED RESEARCH WERE AVAILABLE TO THE PUBLIC AT REASONABLE TERMS.

THERE'S BEEN A DEBATE WHETHER THAT ACTUALLY MEANT TO INCLUDE AFFORDABILITY OR NOT. WHETHER IT DID OR NOT, CALIFORNIA MUST INCLUDE AFFORDABILITY IN THE PROVISIONS OF THE IP POLICY BECAUSE FOR MANY, MANY CALIFORNIANS, AFFORDABILITY WILL BE THE KEY TO WHETHER THEY CAN ACTUALLY ACCESS THE PRESCRIPTION DRUGS OR WHATEVER THE BENEFIT -- WHATEVER THE PRODUCTS ARE OF RESEARCH EITHER NEXT YEAR OR 30 YEARS FROM NOW.

OBVIOUSLY WE'VE HEARD STORIES OF PEOPLE NOT AFFORDING PRESCRIPTION DRUGS. MANY OF THESE ARE DEVELOPED AT TAXPAYER EXPENSE. AIDS AND CANCER DRUGS, ANOTHER GAO REPORT FOUND THAT UP TO 50 PERCENT OF AIDS AND CANCER DRUGS HAVE BEEN DEVELOPED AT TAXPAYER EXPENSE, BUT AGAIN NO AFFORDABILITY STANDARDS ONCE THOSE PRODUCTS ARE COMPLETED.

IN CALIFORNIA IF YOU CAN'T AFFORD YOUR

PRESCRIPTION DRUG AND YOU GO THROUGH A LONG PROCESS OF DEALING WITH AFFORDABLE MEDICATIONS, A LOT OF PEOPLE GO BANKRUPT OR OPENLY GO ON PUBLIC PROGRAMS. PUBLIC PROGRAMS WILL THEN PROVIDE FOR THOSE DRUGS AT THE FULL PRICE. ULTIMATELY CALIFORNIANS LOSE WHEN DRUG COMPANIES ARE NOT HELD ACCOUNTABLE FOR MAKING THEIR PRODUCTS AFFORDABLE, PARTICULARLY THOSE PRODUCTS THAT ARE DEVELOPED AS A RESULT OF PUBLICLY FUNDED RESEARCH.

THAT'S A DIFFICULT TASK FOR THIS COMMITTEE, BUT IT'S THE KEY TASK IS THE QUESTION OF AFFORDABILITY, HOW WE RETAIN THE ABILITY TO MAKE SURE THAT PEOPLE GET ACCESS TO THOSE PRESCRIPTION DRUGS DOWN THE ROAD. THE GREATEST BREAKTHROUGH IN MEDICAL RESEARCH WON'T BE SOMETHING THAT CALIFORNIA VOTERS CAN BENEFIT FROM IF THEY CAN'T AFFORD THE PRICE THAT THE PRIVATE COMPANY WHO'S BEEN GRANTED AN EXCLUSIVE CONTRACT DECIDES TO CHARGE FOR THAT MEDICATION OR THAT PRESCRIPTION.

I KNOW THAT A LOT OF THESE GRANTS WILL PROVIDE FUNDING FOR INTERIM PIECES THAT WILL BE ASSEMBLED TO CREATE SOME END RESULT PRODUCT THAT DOWN -- THAT WILL COMBINE WITH OTHER PATENTS. THAT MAY BE TRUE, AND I THINK THAT'S THE MODEL WE'VE SEEN NATIONALLY, BUT THAT DOES NOT MEAN THAT WE CANNOT DEVELOP AN INTELLECTUAL PROPERTY MODEL, A POLICY, THAT RETAINS PUBLIC CONTROL OF SOME PIECE OF THAT END

PRODUCT. SIMPLY TO SAY THAT THERE'S GOING TO BE MANY PIECES GOING TOGETHER, THEREFORE, WE'RE GOING TO WALK AWAY FROM THE WHOLE THING IS, I THINK, AN ERROR IN LOGIC. WE HAVE TO DEAL WITH THE FACT THAT -- DEAL WITH THE POLICY THAT CAN TRACK THAT PUBLIC INVESTMENT AND MAKE SURE THE END PRICE IS REFLECTIVE OF THAT PUBLIC INVESTMENT.

AND WE ALSO SUPPORT, AS THE GENTLEMAN SAID BEFORE, BRINGING DOWN FEDERAL DOLLARS. I THINK IF WE HAD A MEMO IN TERMS OF WHAT ARE THE THREE THINGS WE NEED TO DO IN ORDER TO NOT PREEMPT FEDERAL DOLLARS, IT WOULD BE A VERY SHORT LIST OF ITEMS THAT CALIFORNIA HAS TO BE CAREFUL OF IN ORDER NOT TO RESTRICT FEDERAL DOLLARS. THE FEDERAL STANDARDS FOR PUBLICLY FUNDED RESEARCH ARE BASICALLY ABSENT AS FAR AS A LOT OF THE PATIENT ADVOCACY MOVEMENT IS CONCERNED. SO THERE'S NOT A LOT OF THINGS WE HAVE TO WORRY ABOUT.

THERE'S A COUPLE PROVISIONS, BUT THE BOOGIE MONSTER OF SOMEHOW STEPPING ON FEDERAL FUNDING, IF WE DON'T ADOPT THE FEDERAL POLICY IN TOTAL, I THINK, AGAIN, IS ANOTHER ERROR IN LOGIC, ERROR IN REASONING.

CERTAINLY THE GOAL OF GETTING PRODUCTS TO MARKET VERY QUICKLY SHOULD BE THE ABSOLUTE GOAL. AGAIN, PRODUCTS ON THE MARKET QUICKLY THAT AREN'T AFFORDABLE, THE BENEFIT OF THAT IS UNCLEAR, AND I THINK

WOULD PROBABLY BE A VIOLATION OF THE PROP 71 PLAIN LANGUAGE. THE IP POLICY BEING THE CRITICAL CONNECTOR BETWEEN HOW OUR MONEY IS SPENT AND WHETHER WE BENEFIT.

IF YOU ACT IN DECEMBER, WHICH I CAN'T IMAGINE YOU ADOPTING AN INTERIM POLICY FOR PURPOSES OF INTELLECTUAL PROPERTY FOR THE RESEARCH GRANTS, BUT IF YOU DO MOVE THAT QUICKLY, MAKE SURE THAT YOU PUT IN THE CONTRACTS THAT ARE PROVIDED THAT IF AND WHEN FUTURE INTELLECTUAL PROPERTY STANDARDS ARE PUT IN PLACE FOR THE PURPOSES OF RESEARCH GRANTS, THEY MUST ABIDE BY THOSE NEW STANDARDS. DON'T LOCK THOSE CONTRACTS IN TO SOME INTERIM STANDARD THAT, YOU KNOW, BECAUSE AT THE TIME WAS NOT FULLY DEVELOPED, BUT WE WANTED TO MOVE QUICKLY. LET THEM KNOW HERE'S THE RULES OF THE GAME RIGHT NOW. WE'RE GOING TO GIVE YOU A GRANT; BUT WHEN WE CREATE SOME NEW RESEARCH INTELLECTUAL PROPERTY STANDARDS, YOU'RE GOING TO HAVE TO ABIDE BY THOSE. YOU CAN PUT SOME LANGUAGE IN THE THING OF HERE'S THE REALM OF ISSUES THAT WE'RE MOVING TOWARD, AND WE HAVEN'T WORKED OUT ALL THE POLICY IMPLICATIONS YET, AND LAY THOSE GOALS OUT SO COMPANIES KNOW WHAT THEY'RE GETTING INTO.

JUST GOING BACK TO THE BEGINNING OF THE ARGUMENT THAT SOMEHOW WE HAVE TO ENCOURAGE THE PRIVATE MARKET TO GET INVOLVED AND, THEREFORE, WE HAVE TO GIVE

THEM EVERYTHING, IN TERMS OF ROYALTIES AND OWNERSHIP OF INTELLECTUAL PROPERTY, I FIND JUST TO BE AT ITS FACE MOVING MUCH -- VIOLATING THE PUBLIC TRUST, GIVING THAT OWNERSHIP AND NOT ENGAGING IN A WAY TO FIND EVERY OPPORTUNITY TO MAKE THAT PUBLIC OWNERSHIP AND PUBLIC BENEFIT REALITY WILL BE, I THINK, ONE, A VIOLATION OF THE PLAIN LANGUAGE OF PROP 71 AND A LEGAL PROBLEM, BUT ALSO SORT OF THE MORAL, ETHICAL REQUIREMENTS OF THIS COMMITTEE TO DEAL WITH THOSE COMPLEXITIES AND DEAL WITH IT SIMPLY.

I THINK WE HAD THE OPPORTUNITY IN 1980 WHEN BAYH-DOLE WAS PASSED. THERE WAS SOME LIP SERVICE GIVEN TO MARCH-IN RIGHTS AND THE REASONABLE TERMS AVAILABLE TO THE PUBLIC AT REASONABLE TERMS, BUT BECAUSE THE WAY THAT LAW WAS WRITTEN, THAT ENFORCEMENT WAS DELEGATED TO THE INDIVIDUAL DEPARTMENTS. AND BECAUSE IT DIDN'T HAVE A LOT OF SPECIFICITY, IT HASN'T BEEN USED. THAT LACK OF SPECIFICITY, I WOULD ARGUE, WAS NOT BY MISTAKE. IT WAS THE DRUG COMPANIES, THE BIOTECH COMPANIES THAT WERE LOBBYING CONGRESS, MUCH LIKE THEY DID WITH MEDICARE, SAYING WRITE IT THIS WAY. AND THEY GOT -- THEY PUT SOME LANGUAGE IN ABOUT AFFORDABILITY GENERALLY IN ORDER TO APPEASE THE PUBLIC CONCERN ABOUT HAVING FOLKS INVEST IN SOMETHING, BUT HAVE NO GUARANTEE FOR A RETURN. BUT UNFORTUNATELY IT DIDN'T HAVE THE TEETH IN IT TO

ACTUALLY PROVIDE THAT MECHANISM.

CALIFORNIA HAS THE OPPORTUNITY NOT ONLY TO ADOPT AN IP POLICY THAT PROTECTS THE INTENT OF PROP 71, BUT ALSO BECOME A MODEL FOR NATIONAL INTELLECTUAL PROPERTY RESEARCH AND DIVISION OF ROYALTIES AND IP OWNERSHIP. THAT'S THE KIND OF THING WE HEARD FROM CALIFORNIA IS HAS THE GLOW OF BIOTECH SUCCESS AND THE ENVY OF THE WORLD. WELL, THAT'S TRUE FOR THE DRUG COMPANIES AND THE BIOTECH PERSPECTIVE IF YOU WERE MAKING A LOT OF MONEY OUT HERE -- AND MAKING A LOT OF MONEY. HOWEVER, FROM THE PATIENT ADVOCACY PERSPECTIVE, THE WAY THAT CALIFORNIA WOULD THEN MOVE TO THE PINNACLE, IN THE TAXPAYERS' PERSPECTIVE, MOVE THE PINNACLE OF IP STANDARD WOULD BE TO DEVISE A POLICY THAT NOT ONLY GETS THOSE PEOPLE TO PLAY, BUT ALSO IN SOME REAL WAY PROVIDES PUBLIC BENEFIT AND A MECHANISM FOR PUBLIC CONTROL.

I'M HAVING A DIFFICULT TIME OF IMAGINING A WAY OF DOING THAT WITHOUT ALLOWING SOME JOINT PUBLIC OWNERSHIP OF THOSE PATENTS. ONCE YOU LET THE IP POLICY TO BE OWNED BY THE UNIVERSITIES AND THE UNIVERSITIES TO GRANT EXCLUSIVE CONTRACTS, YOU'VE REALLY DELEGATED ALL THAT RESPONSIBILITY DOWN LINE TO UNIVERSITIES TO DETERMINE WHETHER WHAT'S A GOOD RETURN ON THE DOLLAR AND YOU'VE GIVEN THAT AWAY.

ALSO, THE QUESTION OF WHAT IF THE RECIPIENT VIOLATES SOME TERM OF THE CONTRACT LATER ON, YOU ARE GOING TO HAVE TO LITIGATE THAT AT EACH CONTRACT. EVEN THE BIOTECH AND PHARMACEUTICAL COMPANIES WANT TO DO THE RIGHT THING. THEY ALSO HAVE A FIDUCIARY RESPONSIBILITY TO THEIR SHAREHOLDERS TO MAKE AS MUCH MONEY AS POSSIBLE. THEY'RE A CORPORATION AND AS A PUBLICLY TRADED ENTITY, AS SHAREHOLDERS, THAT'S THEIR NO. 1 JOB. IF THEY DON'T DO THAT AS THE NO. 1 JOB, THEY GET IN TROUBLE WITH THEIR SHAREHOLDERS. SO YOU NEED TO GIVE THEM THE PROTECTION, SO TO SPEAK, OF SAYING, LOOK, WE'D LIKE TO TAKE ALL THAT $3 BILLION AND POCKET IT, BUT CALIFORNIA HAS LAID SOME REALLY TOUGH RULES. YOU KNOW, WE WANTED EVERYTHING, BUT IT'S $3 BILLION IN RESEARCH THEY'RE HANDING US, AND WE GET TO OWN SOME OF THE IP, AND WE'LL BE IN THE GAME WHEN THE PRODUCTS ARE BROUGHT MARKET, AND WE'RE GOING TO GET SOME BOON ON THAT, THEY'RE GOING TO STAY IN.

SO I WOULD BE VERY, VERY CAREFUL OF LOOKING AT THE COMPLEXITY OF JUST LETTING THOSE ISSUES GO UNTIL WE WORK OUT THE CONTRACTS BECAUSE THE MORE THAT ISSUE IS DELEGATED DOWNSTREAM TO BE WORKED OUT AT EACH CONTRACT LEVEL, YOU'LL HAVE TO HAVE A DISCUSSION AT EACH OF THOSE CONTRACT LEVELS, CONTRACTS ARE GOING TO BE COMING IN, THERE'S GOING TO BE LESS TIME, YOU'RE

GOING TO BE MOVING VERY QUICKLY. STANDARDS NEED TO BE PUT IN PLACE NOW. I WOULD ARGUE VERY STRONGLY THAT THOSE STANDARDS HAVE TO INCLUDE ULTIMATE AFFORDABILITY. THE ROYALTY ISSUE IS ALSO SOMETHING WE SHOULD LOOK AT SINCE THAT WAS SOMETHING THAT WAS PROMOTED AS PART OF PROP 71.

I THINK THERE WAS SOMETHING IN THE PAPER TODAY ABOUT POTENTIALLY BLENDED BONDS, BOTH HAVING TAX EXEMPT AND NONTAX-EXEMPT, SO THAT THERE COULD BE A PIECE OF ROYALTIES FROM THOSE NONTAX-EXEMPT. NOW, I THINK IT'S VERY IMPORTANT TO HAVE A LINE-BY-LINE ANALYSIS OF WHETHER DOING THAT IS THE BEST RETURN ON THE DOLLAR. WE CERTAINLY DON'T WANT TO GET A ROYALTY BACK IF IT'S GOING TO COST US MORE IN FINANCING. THAT'S THE LAST THING THAT CALIFORNIA TAXPAYERS NEED, BUT THERE APPEARS TO BE OTHER WAYS THAT NEED TO BE INVESTIGATED TO DEAL WITH THAT ROYALTY ISSUE.

I THINK THAT'S STILL A SECONDARY ISSUE TO THE OWNERSHIP OF THE IP AND THAT CONTROL OF THE IP. SOME OF THE MODELS HAVE BEEN DISCUSSED, AND I THINK WE'LL HEAR ABOUT ON MONDAY AT THE ORTIZ HEARING ARE THINGS LIKE A POOLING MECHANISM FOR CONTROL OF THE INTELLECTUAL PROPERTY. THE PATENTS ARE PART OF A POOL. COMPANIES THAT PROVIDE PATENTS TO THAT POOL HAVE A CONTROL OVER EACH OF THOSE PATENTS. THERE'S SOME KIND

OF A PUBLIC ENTITY -- PUBLIC CHECK ON THAT THAT HAS AN IMMEDIATE ENFORCEMENT OF THE PUBLIC GETTING SOME BENEFIT. I THINK THESE ARE THINGS THAT REALLY NEED TO BE SERIOUSLY LOOKED AT.

AGAIN, I'M VERY CONCERNED ABOUT THAT DECEMBER 2D TIMELINE, I ASSUME YOU FOLKS ARE TOO, BECAUSE THAT'S A LOT OF WORK THAT NEEDS TO GET DONE BY DECEMBER. IF YOU DO DO SOMETHING ON INTERIM IP POLICIES FOR RESEARCH GRANTS THAT HAVE BEEN AWARDED, BUT NOT FUNDED, MAKE CLEAR IN THOSE CONTRACTS THAT WHEN WE ADOPT FUTURE IP POLICIES, YOU'RE GOING TO HAVE TO PLAY BY THOSE RULES SO THAT IN CASE WE'RE MISSING SOMETHING HERE IN THAT QUICK TIMELINE, THAT WE DON'T UNFORTUNATELY MISS THE OPPORTUNITY TO LIVE UP TO THE INTENT OF PROP 71.

I RECOMMEND THAT, GIVEN THE STATUS, AS I UNDERSTAND IT, IN TERMS OF GETTING SOME BRIDGE FUNDING FOR THOSE TRAINING GRANTS, THAT, WELL, WHAT'S THE RUSH? WE DON'T WANT TO PUSH TOO FAST ON GETTING THOSE IP POLICIES IN PLACE. I THINK THE BEST TIMING WOULD BE AS SOON AS THOSE GRANTS BECOME AVAILABLE, THEN YOU WANT TO HAVE AN INTERIM POLICY, BUT WHY GET OUT AHEAD OF IT BY WHAT COULD BE MONTHS. FRANKLY, FROM MY UNDERSTANDING, I ONLY KNOW WHAT I READ IN THE PAPER, THE ATTRACTION TO THESE BRIDGE FUNDS HAVE BEEN MET WITH SOME -- WELL, FROM THE PUBLIC, PRIVATE MARKET I DON'T THINK THERE'S

BEEN MUCH INTEREST. I UNDERSTAND THERE'S SOME PUBLIC FINANCE THAT'S GOING TO PROVIDE SOME OF THAT MONEY, BUT IT'S UNCLEAR TO ME WHAT THE RUSH IS GIVEN THE FACT YOU DON'T HAVE ANY MONEY TO HAND OUT RIGHT NOW.

I THANK YOU VERY MUCH.

CHAIRMAN PENHOET: THANK YOU FOR YOUR COMMENT. THEY ARE TRAINING GRANTS AND NOT RESEARCH GRANTS.

MR. GOSWAMI: JOYDEEP GOSWAMI, INVITROGEN. I HEAD UP THE STEM CELL BUSINESS AT INVITROGEN. YOU KNOW, BEFORE TAKING MY CURRENT JOB, I WAS ACTUALLY HEAD OF LICENSING TECHNOLOGY, SO I'LL JUST GIVE YOU MY PERSPECTIVE OF LICENSING AND WHAT I'VE SEEN AT LICENSING OR TRYING TO LICENSE, I SHOULD SAY, FROM DIFFERENT UNIVERSITIES AND THE NIH. IN 90 PERCENT OF THE DISCUSSIONS, PRICE IS AN ISSUE, BUT IS NOT THE MAIN ISSUE. THE THING THAT PROLONGS AND FRUSTRATES PEOPLE THE MOST IS WHEN THERE ARE TERMS THERE WHICH ARE AMBIGUOUS AND, YOU KNOW, THINGS THAT ARE LEGAL TERMS WHICH NO ONE IS REALLY SURE ABOUT. THINGS SUCH AS AFFORDABILITY, AND THAT'S NEVER COME UP IN ISSUES FOR ME, BUT THERE ARE SIMILAR THINGS THAT COME UP.

I THINK A LOT OF PEOPLE HAVE MADE THE COMMENT THAT SIMPLICITY IS THE BEST THING YOU CAN DO TO GET THESE PRODUCTS TO MARKET. TO ME, AT LEAST FROM A

PUBLIC POINT OF VIEW, I THINK THE BEST PART OF PROP 71 IS TO ENABLE THERAPIES, TREATMENTS, REAGENTS, ETC., WHATEVER, TO COME TO MARKET FAST. THAT'S THE WAY IT BENEFITS THE COMMUNITY. TO NICKEL AND DIME THINGS OR TO PUT IN THERE THINGS THAT ARE AMBIGUOUS AND, FRANKLY, WE HAVE NO CONTROL OVER IS GOING TO INVARIABLY SLOW DOWN THE PROCESS.

ONE OTHER THING, I THINK THE ISSUE OF WRF WAS BROUGHT UP EARLIER. AGAIN, THE ISSUE OF NEGOTIATIONS WITH WRF ON WHATEVER FRONTS, AGAIN, IS NOT ABOUT MONEY. AND THEIR IP ISSUES, THEY HAVE OTHER ISSUES IN FILING. THEY ACTUALLY SCREWED UP THEIR FILING IN FOREIGN COUNTRIES. IT'S NOT THAT THIS IS AN ISSUE OF PEOPLE ARE BALKING ON THE AMOUNT OF MONEY AGAIN.

SO AGAIN, MAKE IT SIMPLE, MAKE IT CONSISTENT, AND I THINK PEOPLE WILL TAKE YOUR INVENTIONS AND WHAT COME OUT OF YOUR MONEY AND MAKE GOOD USE OF IT.

I THINK THE ISSUE OF DRUG PRICING, I WANT TO TOUCH ON IT BECAUSE I HAD DONE QUITE AN EXTENSIVE WORK AT LOOKING AT WHAT ARE THE ACTUAL COSTS IN DEVELOPING A DRUG. AND IT'S VERY EASY TO FOLLOW ONE DRUG AND SAY, OH, MY GOD, YOU GAVE THAT THING AWAY. THE PROBLEM IS RISK. YOU NEVER -- YOU CAN'T FACTOR IN THAT ONLY 10 PERCENT OF DRUGS EVER REACH THE MARKET. I'M NOT SAYING THAT ISN'T A CONCERN ABOUT -- NOT EVEN THAT ACTUALLY.

NOT EVEN THAT. DEPENDS ON WHEN YOU START THE CLOCK. IF YOU ADD UP AND IF YOU PUT IN THE DENOMINATOR RISK OF EVERY PHASE IN THE DRUG, I WILL TELL YOU THE 800 MILLION THAT PEOPLE ARE TALKING ABOUT IS A GROSS UNDERESTIMATE.

MR. FLANAGAN: BUT CIRM IS GOING TO GIVE AWAY $3 BILLION IN RESEARCH. WHERE IS THE RISK IN THAT?

MR. REED: THIS IS HIS TURN.

MR. GOSWAMI: LET ME ANSWER THAT QUESTION. IT IS. AND THERE IS -- WITH ANY PUBLIC FUNDING, THERE IS AN ISSUE OF SOMEONE HAS TO BEAR THE RISK TO LAY FOUNDATIONS. AND THAT'S WHAT PUBLIC RESEARCH SUCH AS NIH IS DOING. REMEMBER NIH FUNDING IN LABORATORY RESEARCH DOESN'T CREATE DRUGS, DOESN'T CREATE REAGENTS. IT LAYS THE FOUNDATION FOR SOMEBODY TO THEN TAKE THAT AND THEN CONVERT IT INTO A DRUG. 90 PERCENT OF THE INVESTMENT IN ANY DRUG IS THROUGH CLINICAL TRIALS, THROUGH ACTUALLY GETTING THESE TESTED ON WHAT USED TO BE AN EARLIER NUMBER OF A HUNDRED, 500 IN PHASE II, AND 3,000. THOSE NUMBERS ARE GOING UP NOW, AND THEY'RE GOING TO GO UP EVEN MORE BECAUSE OF VIOXX AND OTHER ISSUES.

THIS DRUG PRICING ISSUE IS AN ECONOMIC ISSUE. IF CIRM WANTS TO WRESTLE WITH IT, I THINK GREAT, BUT I AGREE WITH YOU. I THINK THIS IS A VERY COMPLICATED

ISSUE, AND IT WILL ONLY SET US BACK IN TRYING TO DETERMINE WHAT THE RIGHT PRICE OF A DRUG IS.

LET ME TURN THIS THING ON ITS HEAD. GIVE ME AN EXAMPLE OF THERAPIES THAT HAVE COME OUT. HOW MANY OF THEM HAVE BEEN DONE OUTSIDE THE UNITED STATES WHERE THERE'S A MUCH MORE OPEN POLICY AND MUCH MORE SOCIALISTIC POLICY VERSUS THE U.S. THAT'S NO. 1. NO. 2 IS HOW MANY TREATMENTS HAVE ACTUALLY NOT REACHED THE U.S. PUBLIC BECAUSE OF, OH, MY GOD, THE PRICES ARE HIGH? I DON'T THINK YOU CAN GIVE ME TOO MANY EXAMPLES. YOU CAN TAKE WHATEVER DRUG. THE U.S. PUBLIC GETS ACCESS TO THE BEST DRUGS FASTEST ANYWHERE IN THE WORLD. AND IT'S NOT BECAUSE WE'RE A RICH COUNTRY. THERE ARE MANY OTHER RICH COUNTRIES. BUT IF YOU WANT TO APPROACH THE AFFORDABILITY ISSUE, ANSWER THAT QUESTION FIRST OF HOW MANY DRUGS HAVE ACTUALLY FAILED TO REACH.

THE ISSUE OF PRICING, I AGREE, NEEDS TO BE TACKLED, BUT IT'S A MUCH MORE COMPLEX ISSUE THAN LET ME SET THE PRICE ON A DRUG. YOU GOT TO DO THAT. EVERY DRUG IF DIFFERENT. YOU CANNOT WRITE THAT INTO THE RULES HERE.

ONE OTHER POINT I WANTED TO MAKE, AND IT'S TOWARDS THE BENEFITING AND PROVIDING ACCESS. I'M GOING TO TAKE THE REAGENTS POINT OF VIEW. AGAIN, MY ISSUE IS WHATEVER IP COMES OUT OF THESE THINGS, YOU SHOULD MAKE

IT AVAILABLE AT A PRICE, I'M NOT SAYING FOR FREE, TO PEOPLE, TO INDUSTRY, TO COMPETITION, AND THEN LET COMPETITION TO PLAY OUT ITS COURSE AS TO WHO WILL MAKE THE MOST OUT OF THAT BASIC TECHNOLOGY AND TAKING IT TO MARKET.

SOMEBODY POINTED OUT THE ISSUE OF IT'S NOT A PARTICULAR INVENTION THAT IS MADE THAT BECOMES THE PRODUCT. AND IT'S GOING TO BE INCREASINGLY THE CASE. WE'VE SEEN THIS AT INVITROGEN, THAT YOU TAKE A TECHNOLOGY AND THEN YOU ADD ON OTHER TECHNOLOGIES TO IT TO MAKE IT SOMETHING USEFUL. I'LL TAKE THE EXAMPLE OF CELLS. YES, THERE ARE CERTAIN INVENTIONS FROM THE BASIC STEM CELL. THAT IS A USEFUL INVENTION. THE PATENTING ISSUES ARE DIFFERENT BECAUSE EUROPE AND OTHER PARTS OF THE WORLD HAVE DIFFERENT IDEAS OF WHAT CAN BE PATENTED OR NOT. BUT TO MAKE THAT CELL AN EVEN MORE USEFUL CELL, YOU COULD ADD TECHNOLOGIES THAT CAN PUT IN PARTICULAR GENES OR PATHWAYS THAT CAN LIGHT UP WHEN A CELL GOES DOWN A PARTICULAR PATHWAY.

IF YOU TELL ME THAT YOU KNOW THE VALUE OF THAT CELL, GREAT. I'LL SAY GIVE ME THAT THEORY AND I'LL PRICE IT THAT WAY, BUT THERE ARE 15 DIFFERENT THINGS AROUND THAT.

I THINK YOU SHOULD LET OTHERS HAVE THE FREEDOM TO ADD ON THESE TECHNOLOGIES AND GET PRODUCTS

TO MARKET, AND THEN LET THE MARKET FIGURE OUT WHAT PRICE IT WANTS TO CHARGE FOR IT. IF I PRICE SOMETHING TOO HIGH AT INVITROGEN, I KNOW IT'S NOT GOING TO BE TAKEN UP BY THE MARKET. PEOPLE ARE GOING TO GO ELSEWHERE. WE'VE SEEN THIS BEFORE. WE'VE TRIED TO GET CERTAIN TECHNOLOGIES OUT IN THE MARKET AND CHARGE A HUGE SITE LICENSE, AND IT DIDN'T WORK, AND WE JUST BACKED AWAY FROM IT.

LASTLY, I WILL SAY THIS. I THINK THE GENTLEMAN WHO WAS GIVING THE TALK POINTED THIS OUT. PROBABLY THE FASTEST WAY TO GET THINGS TO THE MARKET IS COLLABORATION, ESPECIALLY IN A TECHNOLOGY LIKE STEM CELLS. IT'S COLLABORATION BETWEEN THE INDUSTRY AND ACADEMICS. AND I WOULD JUST REQUEST THAT YOU DON'T DO SOMETHING WHICH INHIBITS THAT. AGAIN, THE ISSUE HERE IS NOT MONEY. WE'LL FIGURE OUT A WAY TO MAKE THE ECONOMICS WORK, AND INDUSTRY HAS DONE THAT. THIS IS A CAPITALISTIC COUNTRY. THAT'S WHAT INDUSTRY DOES. BUT JUST MAKE IT EASIER, MAKE IT SIMPLE FOR PEOPLE TO TAKE TECHNOLOGIES THAT COME OUT AND RUN WITH IT. THAT'S IT.

CHAIRMAN PENHOET: THANK YOU. WE HAVE ANY OTHER COMMENTS?

MR. REYNOLDS: CAN I SPEAK BRIEFLY?

CHAIRMAN PENHOET: I'M RELIEVED TO KNOW THAT WE DIDN'T GET THROUGH A MEETING WITHOUT YOU.

MR. REYNOLDS: I'LL BE BRIEF BECAUSE SO MUCH HAS BEEN SAID ALREADY. AND I'VE BEEN THINKING A LOT ABOUT THE INTELLECTUAL PROPERTY ISSUE, AND I TEND TO AGREE THAT IT'S THE MOST IMPORTANT ISSUE ON YOUR PLATE RIGHT NOW. THE LANGUAGE OF PROPOSITION 71 AND MUCH OF THE FOCUS TODAY HAS BEEN ABOUT BALANCING GETTING PRODUCTS TO MARKET AND BALANCING THE OPPORTUNITY FOR THE STATE TO HAVE A RETURN ON INVESTMENT, BUT THERE'S THREE OTHER KEYS AREAS THAT THE IP IS GOING TO HAVE AN IMPACT ON. ONE THAT'S BEEN BROUGHT UP A LITTLE BIT IS THE ACCESSIBILITY OF PRICING. I THINK IT'S A LITTLE BIT MISLEADING TO SAY BECAUSE A PRODUCT IS ON THE MARKET, THAT IT'S ACCESSIBLE. IF IT'S OUT OF THE REACH OF A LARGE PORTION OF AMERICANS, THEN IT'S NOT TRULY ACCESSIBLE.

ANOTHER AREA TOUCHED ON A LITTLE BIT IS PREVENTING EXCESSIVE PATENTING FROM INTERFERING WITH RESEARCH SOMETIME CALLED AN ANTI-COMMONS EFFECT. I'M SURPRISED THAT THAT WASN'T BROUGHT UP THAT MUCH TODAY, BUT THIS IS INTEGRAL WITH THIS. YOU COULD END UP WITH REPLICATING A SITUATION LIKE THE WISCONSIN SITUATION WHERE VERY EARLY RESEARCH TOOLS ARE PATENTED.

AND THEN FINALLY, THIS IS A LITTLE FUZZIER, BUT THE IP POLICIES ARE LIKELY TO HAVE A BIG IMPACT UPON THE PUBLIC'S PERCEPTION OF THE CALIFORNIA

INSTITUTE OF REGENERATIVE MEDICINE. I'VE LOOKED AT THE ADS THAT CONVINCED THE VOTERS TO VOTE. THEY DIDN'T LIKELY READ THE WHOLE TEXT OF THE LAW. IT TOOK ME AWHILE TO GET THROUGH IT MYSELF, BUT THEY SAY WE'LL DO BEST TO GET CURES AND CURES TO YOU. THEY ALSO TALK FAIRLY FREQUENTLY ABOUT THE OPPORTUNITY OF RETURNS TO THE STATE. SO THESE ARE TWO AREAS WHERE IT MIGHT NOT BE MANDATED BY LAW, BUT IT IS PART OF THE PROMISE GIVEN IN THE ADVERTISING.

SO I COME AWAY FROM THIS WITH TWO RECOMMENDATIONS. ONE IS TO REALLY DO YOUR BEST TO BRING FORTH AND TRULY LISTEN TO A DIVERSITY OF VOICES. I THINK THAT THE SCHEDULED SPEAKERS TODAY WERE LARGELY FROM PRIVATE INDUSTRY AND FROM UNIVERSITIES, PARTICULARLY THE TECHNOLOGY TRANSFER OFFICES. THESE ARE THE OFFICES AND INSTITUTIONS THAT ARE BENEFITING FROM BAYH-DOLE, SO THEY WILL TEND TO BE HAPPIER WITH BUSINESS AS USUAL. THERE'S A LOT OF IDEAS OUT THERE, LOOKING AT DATA, FOR EXAMPLE, THAT BAYH-DOLE MIGHT GET SOMETHING TO MARKET FAST; BUT IF IT KEEPS THE PRICE TOO HIGH, WELL, WAS THAT REALLY A SUCCESS. AND THEN, FINALLY, THE CARROT IS AN EASIER -- IT'S EASIER TO USE THAN THE STICK, SO TO SPEAK. YOU HAVE THE CARROT RIGHT NOW. SO IF YOU BUILD THESE CONCERNS IN EARLY ON BEFORE THE GRANTS GO OUT THE DOOR, THEN YOU CAN SAVE YOURSELF

THE POSSIBILITY OF LITIGATION OR THREATENING TO MARCH IN OR SO FORTH MUCH LATER. IT WOULD BE MUCH EASIER TO ADDRESS THESE THINGS NOW. THANK YOU.

CHAIRMAN PENHOET: THANK YOU. OKAY. WELL, WE'RE -- ANY OTHER COMMENTS FROM THE AUDIENCE? OKAY. THANK YOU.

WE HAVE ONE MORE ITEM WHICH IS REALLY BACK TO ITEM 5, WHICH IS THE PROCESS FOR GOING FORWARD WITH THIS TASK. LET ME ASSURE YOU THAT WE ARE NOT GOING TO RUSH TO JUDGMENT ON THIS ISSUE. WE'RE GOING TO HEAR LOTS OF POINTS OF VIEW. WE APPRECIATE THE NUMEROUS POINTS OF VIEW WE HEARD TODAY ACTUALLY. AND THAT OUR GOAL FOR THE DECEMBER 6TH MEETING IS REALLY JUST TO DEFINE A POLICY WHICH WILL BE APPLICABLE TO THE TRAINING GRANTS WHERE THE EXPECTATION FOR IP IS VERY MODEST.

MR. FLANAGAN: I WOULD STILL SAY -- AGAIN, IF YOU DO DO THAT, MAKE IT CLEAR IN THOSE CONTRACTS THAT WHEN A NEW TRAINING GRANT IP POLICY IS ADOPTED, THEY HAVE TO PLAY BY THOSE RULES.

CHAIRMAN PENHOET: WE HEARD YOU, YOUR RECOMMENDATIONS, SO WE'LL CERTAINLY TAKE THAT INTO ACCOUNT. WE DO BELIEVE THERE'S A REASONABLE PROSPECT FOR GETTING THE TRAINING GOING. THERE IS A SENSE OF URGENCY, I THINK, BECAUSE, AS YOU ALL READ IN THE

NEWSPAPERS, WE ARE NOT THE ONLY PEOPLE IN THE WORLD DOING STEM CELL RESEARCH. WHATEVER WE DO, THE REST OF THEM ARE ALL FILING PATENTS.

SO AMONG OTHER REASONS, WE THINK WE HAVE TO MOVE ON WITH THIS. AND CERTAINLY TRAINING A TRAINED WORKFORCE IS AN IMPORTANT ELEMENT IN ALL THIS. WE DO HAVE A SCHEDULE LAID OUT IN FRONT OF US. WE ARE TRYING TO SCHEDULE ANOTHER MEETING OF THIS TASK FORCE IN THE LAST HALF OF NOVEMBER. WE DON'T HAVE A FINAL DATE YET. I DON'T KNOW IF WE CAN BE RESPONSIVE TO YOUR ISSUE OF NIGHTS OR WEEKENDS, BUT WE'LL LOOK INTO IT AND TRY TO SCHEDULE THAT MEETING.

AND I THINK THAT'S -- OUR CHARGE NOW IS TO TRY TO HEAR WHAT A BROADER AUDIENCE HAS TO SAY NEXT MONDAY. OF COURSE, PEOPLE ARE WELCOME TO WRITE TO US AND LET US KNOW THEIR VIEWS ANYTIME AT CIRM. MARY MAXON IS MY DEPUTY AND RESPONSIBLE FOR TAKING CARE OF THOSE ISSUES FOR US.

WE'LL TRY TO HAVE A SENSIBLE GROUNDWORK IP POLICY DONE BY THE 6TH OF DECEMBER, SO WE CAN MAKE THAT RECOMMENDATION, BUT WE DON'T KNOW WHETHER THAT WILL BE POSSIBLE OR NOT. WE'LL TRY OUR BEST. NEVERTHELESS, I WANT TO ASSURE EVERYONE IN THE ROOM THAT THAT IS A STEPPING STONE ON THE WAY TO A FINAL POLICY, AND FINAL POLICY COULD BE VERY DIFFERENT FROM THE INTERIM POLICY

AND WON'T IMPLY THAT ELEMENTS EITHER ARE OR ARE NOT.

WITH THAT, ANY OF YOU HAVE ANY FINAL COMMENTS TO OUR AUDIENCE? I THINK WE HAD A GOOD, VIGOROUS DISCUSSION FROM THE AUDIENCE TODAY. I APPRECIATE YOUR INPUT. I'M SURE MY FELLOW MEMBERS OF THE TASK FORCE WOULD AGREE.

DR. WRIGHT: LEARNED A LOT.

CHAIRMAN PENHOET: THANKS VERY MUCH.

(THE MEETING WAS THEN ADJOURNED AT 05:54 P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INTELLECTUAL PROPERTY TASK FORCE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

SACRAMENTO CONVENTION CENTER
1400 J STREET, ROOM 103
SACRAMENTO, CALIFORNIA
ON
TUESDAY, OCTOBER 25, 2005

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

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