BEFORE THE INTELLECTUAL PROPERTY TASK FORCE OF THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE FOR THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE ORGANIZED PURSUANT TO THE CALIFORNIA STEM CELL RESEARCH AND CURES ACT

REGULAR MEETING

LOCATION: CIRM HEADQUARTERS

210 KING STREET SAN FRANCISCO, CALIFORNIA

DATE: SEPTEMBER 21, 2006

1: 02 P. M.

BETH C. DRAIN, CSR REPORTER:

CSR. NO. 7152

BRS FILE NO.: 76505

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- 1 SAN FRANCISCO, CALIFORNIA; THURSDAY, SEPTEMBER 21, 2006
- 2 01: 02 P. M.

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- 4 CHAIRMAN PENHOET: GOOD AFTERNOON. WELCOME
- 5 TO THE I DON'T KNOW WHICH INCARNATION THIS IS OF THE
- 6 INTELLECTUAL PROPERTY TASK FORCE. PROBABLY OUR SEVENTH
- 7 MEETING OR SOMETHING LIKE THAT. WE ARE HERE TODAY TO
- 8 DO TWO THINGS. ONE IS TO FURTHER INFORM OURSELVES
- 9 ABOUT THE ISSUES SURROUNDING OPEN-ACCESS PUBLICATIONS.
- 10 AND SO WE HAVE SOME REPRESENTATIVES PRIMARILY FROM THE
- 11 UNIVERSITY OF CALIFORNIA TO PRESENT TO US TODAY.
- 12 WE HAVE NOT INCLUDED ANY FURTHER REFINEMENTS
- 13 OF OPEN ACCESS IN OUR ANTICIPATED POLICY. WE WERE
- 14 CHARGED BY THE ICOC TO CONTINUE TO STUDY THIS ISSUE.
- 15 WE HAVE ALLOCATED ABOUT HALF AN HOUR OR SO TO THIS
- 16 DISCUSSION, AND THEN WE WILL MOVE DIRECTLY INTO A
- 17 DISCUSSION OF THE FOR-PROFIT POLICY.
- AS YOU CAN SEE, I'M THE ONLY MEMBER OF THE
- 19 TASK FORCE PRESENT HERE IN SAN FRANCISCO, BUT WE DO
- 20 HAVE SOME OTHER MEMBERS ON THE PHONE. SO IF MELISSA
- 21 WILL READ THE ROLL CALL, WE'LL FIND OUT WHO ELSE IS OUT
- THERE.
- MS. KING: SUE BRYANT.
- DR. BRYANT: HERE.
- 25 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.

- 1 TED LOVE. ED PENHOET.
- 2 CHAIRMAN PENHOET: HERE.
- 3 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.
- 4 JOHN REED. DUANE ROTH.
- 5 MR. ROTH: HERE.
- 6 MS. KING: JEFF SHEEHY. OSWALD STEWARD.
- 7 JANET WRIGHT.
- 8 CHAIRMAN PENHOET: WELL, THIS IS EITHER
- 9 THEY'RE ALL THRILLED WITH THE PROGRESS WE'VE MADE, OR
- 10 THERE'S ANOTHER EXPLANATION FOR THIS, BUT LET'S ASSUME
- 11 IT'S THE FIRST ONE. WE OBVIOUSLY DO NOT HAVE A QUORUM.
- 12 MS. KING: WE DON'T HAVE A QUORUM. WE ARE
- 13 EXPECTING A COUPLE MORE PEOPLE, BUT WE WON'T HAVE A
- 14 QUORUM.
- 15 CHAIRMAN PENHOET: WE DON'T EXPECT TO HAVE A
- 16 QUORUM TODAY; HOWEVER, THE PURPOSE OF THIS IS TO GAIN
- 17 THE BLESSING OF THE MEMBERS WHO ARE ATTENDING TO ALLOW
- 18 US TO PRESENT THIS TO THE ICOC FOR THEIR DISCUSSION AND
- 19 POSSIBLE ACTION AT THE OCTOBER 11TH ICOC BOARD MEETING.
- 20 AND SO THAT'S A DELIVERABLE WE'D LIKE TO ACHIEVE FROM
- 21 THIS MEETING AS WE MOVE FORWARD TO THAT.
- 22 SO I BELIEVE WE HAVE THE PEOPLE HERE WHO WANT
- 23 TO TALK ABOUT OPEN-ACCESS PUBLISHING. AND IT'S THE
- 24 FIRST THING ON OUR AGENDA, SO WHY DON'T WE JUST MOVE
- 25 RIGHT INTO THAT DISCUSSION, PLEASE.

- 1 MR. OBER: THANK YOU. THANK YOU FOR GIVING
- 2 ME THE OPPORTUNITY TO SPEAK. MY NAME IS JOHN OBER FROM
- 3 THE UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT.
- 4 I'M WITH A UNIT OF THE UNIVERSITY OF CALIFORNIA CALLED
- 5 THE OFFICE OF SCHOLARLY COMMUNICATION. AND MY
- 6 COLLEAGUES AND I THANK YOU FOR ALLOWING US A LITTLE BIT
- 7 OF TIME.
- 8 AT THE UNIVERSITY OF CALIFORNIA WE ARE
- 9 LOOKING AT VARIOUS ISSUES RELATED TO SCHOLARLY
- 10 PUBLISHING. WE HAVE BEEN DISCUSSING SCHOLARLY
- 11 PUBLISHING IN OPEN-ACCESS JOURNALS FOR QUITE SOME TIME.
- 12 I HAVE JUST A FEW SLIDES TO GIVE YOU SOME BACKGROUND
- 13 MATERIAL.
- 14 I'LL START OUT WITH SOME EVIDENCE OF THE
- 15 IMPACT OF OPEN ACCESS AND ITS USE AROUND THE COUNTRY
- 16 AND AROUND THE WORLD. AND THEN MY COLLEAGUE, BEN CROW,
- 17 FROM THE SANTA CRUZ CAMPUS, AND LARRY PITTS FROM UC SAN
- 18 FRANCISCO WILL JOIN ME.
- 19 THE LOGIC THAT SUGGESTS THAT OPEN ACCESS
- 20 MAKES SENSE IS FAIRLY INTUITIVE. IF YOU REDUCE THE
- 21 BARRIERS TO THE RESEARCH RESULTS, THE PUBLICATIONS, YOU
- 22 WOULD EXPECT THAT THERE WOULD BE MORE USE OF THEM AND,
- 23 IN FACT, EVIDENCE IS COMING IN NOW THAT OPEN-ACCESS
- 24 POLICIES, OR MINIMAL BARRIER POLICIES MIGHT BE ANOTHER
- 25 WAY TO THINK OF IT, ARE COMING INTO PLAY. AND HERE'S

- 1 AN EXAMPLE OF AN OPEN-ACCESS CITATION IMPACT ADVANTAGE.
- 2 NOT ONLY THAT IT OCCURS, BUT THAT IT'S BEEN GROWING
- 3 OVER TIME AS OPEN ACCESS IS UNDERSTOOD TO BE ANOTHER
- 4 WAY TO GET ACCESS TO RESEARCH RESULTS. THIS IS FROM A
- 5 RECENT STUDY, A VERY LARGE SET OF ARTICLES. THE
- 6 LARGEST OPPONENT --
- 7 DR. HALL: MAY I ASK A QUESTION? OPEN ACCESS
- 8 IN THIS CASE MEANS? IS THAT THE SAME AS OPEN
- 9 ARCHIVING, OR DO YOU MAKE THAT DISTINCTION? JUST SAY
- 10 WHAT YOU MEAN BY OPEN ACCESS.
- 11 MR. OBER: I THINK FOR THE PURPOSES OF THIS
- 12 DISCUSSION, OPEN ACCESS IS DEFINED AS THE ABILITY TO
- 13 MINIMIZE, IF NOT ELIMINATE, THE COST TO A READER TO
- 14 READ RESEARCH RESULTS. THAT'S A KEY PART. AND THE
- 15 SECOND PART IS THE MINIMIZATION OF BARRIERS IN TERMS OF
- 16 PERMISSION FOR READERS. SO OPEN ACCESS IN --
- 17 DR. HALL: OPEN ARCHIVING IS INCLUDED IN THAT
- 18 TERM?
- 19 MR. OBER: OPEN ARCHIVING FOR AN AUTHOR TO
- 20 DEPOSIT IN OPENLY. AVAILABLE WEBSITE RESEARCH
- 21 PUBLICATIONS OR INSTITUTIONS DO THAT FOR AN AUTHOR.
- 22 DR. HALL: IS THERE A TIME DEFINITION IN
- 23 THAT?
- 24 MR. OBER: HANG ON JUST A MINUTE AND YOU WILL
- 25 SEE SOME OF THAT.

- 1 CHAIRMAN PENHOET: BUT SPECIFICALLY IN THIS
- 2 CHART HERE, WHAT DOES OPEN ACCESS MEAN IN THIS CASE?
- 3 MR. OBER: IT MEANS AVAILABILITY OF THE
- 4 RESEARCH PUBLICATIONS EITHER IN THE FINAL PUBLISHED
- 5 FORM OR IN THE ACCEPTED MANUSCRIPT FORM BEFORE FINAL
- 6 EDITING WITHIN SIX MONTHS OF PUBLICATION.
- 7 THIS SAME STUDY, AND THIS WAS A LARGE STUDY,
- 8 AND I MEANT TO SAY THAT THE LARGEST SUBSET IN A
- 9 DISCIPLINARY SENSE OF THIS PARTICULAR STUDY OF 1200
- 10 ARTICLES DONE RECENTLY, THE LARGEST SUBSET OF ARTICLES
- 11 WERE IN THE BIOSCIENCES. THE AUTHOR OF THIS STUDY, AND
- 12 THIS STUDY GOT A FAIR AMOUNT OF PLAY IN THE MEDIA AND
- 13 THE FOLKS WHO TRACK THESE ISSUES, GOES ON TO SAY, FIRST
- 14 OF ALL, THAT THE BENEFIT, THE IMPACT BENEFIT IS
- 15 SIGNIFICANT EVEN WHEN YOU CONTROL FOR OTHER VARIABLES
- 16 LIKE SELF-CITATION, LIKE WHERE THE ARTICLE CAME FROM,
- 17 IN REGRESSION ANALYSIS, AND SAID THAT OPEN-ACCESS
- 18 STATUS REMAINED A SIGNIFICANT VARIABLE FOR THE NUMBER
- 19 OF CITATIONS FOR THE GREATER USE OF THE ARTICLES.
- 20 AND HE WENT ON TO SAY FINDINGS SUPPORT
- 21 POLICIES OF THOSE GRANTING AGENCIES WHICH HAVE MADE
- 22 OPEN-ACCESS PUBLISHING MANDATORY.
- 23 I THINK YOU ALSO HAVE A DOCUMENT DISTRIBUTED
- 24 FROM PUBMED CENTRAL THAT COVERS SOME OF THIS
- 25 INFORMATION. THIS IS JUST TO SUGGEST THAT MORE AND

- 1 MORE FUNDERS ARE ADOPTING POLICIES OF ONE FORM OR
- 2 ANOTHER SUPPORTING OPEN ACCESS TO SOME EXTENT. FIVE OF
- 3 THESE 28 MEDICAL SCIENCE ORIENTED FUNDING AGENCIES
- 4 REQUIRE IT, ANOTHER FOUR ARE CONSIDERING MAKING IT A
- 5 REQUIREMENT, ANOTHER FIVE STRONGLY ENCOURAGE IT, AND
- 6 THIS ENTIRE LIST IS DRAWN FROM THOSE FUNDING AGENCIES
- 7 WHO DO AGREE TO PAY PUBLICATION CHARGES AS PART OF THE
- 8 GRANTING PROCESS FOR THOSE PUBLICATIONS THAT SAY WE'RE
- 9 FINE TO MAKE THIS OPEN ACCESS PROVIDED THERE'S SOME
- 10 HELP IN SUBSIDIZING THE COST OF PUBLICATION TO BEGIN
- 11 WI TH.
- 12 THAT PARTICULAR APPROACH, WHICH IS NOT A
- 13 SINGULAR APPROACH, THERE ARE OTHER APPROACHES, BUT THAT
- 14 APPROACH, SOMETIMES THE PRODUCER PAYS OR THE AUTHOR
- 15 PAYS FOR THE MODEL OF OPEN ACCESS WHERE A SUBSIDY FOR
- 16 THE WIDE OPEN ACCESS TO THE MATERIAL IS PROVIDED TO THE
- 17 PUBLISHER IN SOME DIRECT FASHION.
- 18 A PARTICULARLY INTERESTING FUNDER THAT HAS
- 19 VERY RECENTLY ADOPTED A REQUIREMENT FOR OPEN ACCESS IS
- 20 THE UK MEDICAL RESEARCH COUNCIL. HERE'S A QUOTE FROM
- 21 THEM SAYING THAT OPEN ACCESS IS A GOOD IDEA. THE UK
- 22 MEDICAL RESEARCH COUNCIL IS A PARTICULARLY INTERESTING
- 23 ONE BECAUSE, AS YOU PROBABLY KNOW BETTER THAN I DO,
- 24 THEY HAVE STEM CELL RESEARCH AS A STRATEGIC PRIORITY
- 25 AND ARE BUILDING UP A FUNDING BASE FOR STEM CELL

- 1 RESEARCH.
- THERE HAS BEEN SOME CONFUSION FROM TIME TO
- 3 TIME ABOUT WHETHER OPEN ACCESS IMPLIES A PARTICULAR
- 4 BUSINESS MODEL AND HOW MUCH OF A THREAT IT IS TO
- 5 PUBLISHERS. HERE'S SOME EVIDENCE THAT SUGGESTS
- 6 PUBLISHERS ARE LEARNING TO DEAL WITH, IF NOT ENCOURAGE,
- 7 OPEN ACCESS. THIRTEEN OF 18 JOURNALS WE POLLED, SOME
- 8 STEM CELL RESEARCHERS AT UC, OF THE MOST LIKELY
- 9 JOURNALS YOU WOULD PUBLISH IN, 13 ALLOW SOME SORT OF
- 10 OPEN ACCESS SIMULTANEOUSLY WITH THE INITIAL PUBLICATION
- 11 OF AN ARTICLE. SEVENTEEN OF THOSE 18 JOURNALS ALLOW
- 12 SOME SORT OF OPEN ACCESS WITHIN SIX MONTHS, AND I SAY
- 13 SOME SORT BECAUSE THERE'S A DISTINCTION HERE BETWEEN
- 14 OPEN ACCESS TO THE FINAL JOURNAL PUBLICATION OR TO THE
- 15 ACCEPTED MANUSCRIPT, THE AUTHOR'S VERSION, BEFORE FINAL
- 16 COPY EDITING AND SO FORTH. AND FINALLY, ALL OF THE
- 17 MOST LIKELY JOURNALS ALLOW SOME SORT OF OPEN ACCESS
- 18 WITHIN 12 MONTHS. THERE'S A CONTINGENCY THAT AT LEAST
- 19 12 MONTHS IS A LONGER THAN NECESSARY DELAY GIVEN THE
- 20 PROBABLE BENEFITS TO EARLY AND OPEN ACCESS.
- 21 MORE EVIDENCE. THE MAJORITY OF RESEARCHERS
- 22 ARE READY FOR OPEN ACCESS. THIS IS A STUDY, A VERY
- 23 LARGE STUDY, THAT SHOWS THAT 81 PERCENT OF RESEARCHERS
- 24 SURVEYED, THIS WAS A UC STUDY OF ABOUT 1800
- 25 RESEARCHERS, WOULD COMPLY WILLINGLY IF THEY WERE

- 1 REQUIRED. ANOTHER 13 PERCENT WOULD COMPLY SOMEWHAT
- 2 RELUCTANTLY, AND 5 PERCENT WOULD IN ANY SENSE TRY TO
- 3 RESIST AN OPEN-ACCESS REQUIREMENT ATTACHED TO THEIR
- 4 FUNDING.
- 5 THERE'S PUBLIC SUPPORT.
- 6 CHAIRMAN PENHOET: BARRIER THERE IS PRETTY
- 7 HIGH. YOU LOSE YOUR GRANT SUPPORT IF YOU DON'T DO IT.
- 8 STRANGE PERSON THAT WOULD SAY I REFUSE TO DO IT.
- 9 MR. OBER: PUBLIC SUPPORT IS MOUNTING. THIS
- 10 IS A HARRIS POLL CONDUCTED IN MAY THAT SUGGESTS 83
- 11 PERCENT OF ADULTS IN THE U.S. AGREE THAT IF TAX DOLLARS
- 12 PAY FOR RESEARCH, PEOPLE SHOULD HAVE FREE ACCESS TO
- 13 RESULTS. SIXTY-TWO PERCENT OF THOSE ADULTS HAD THOUGHT
- 14 ABOUT IT ENOUGH WHEN THIS SURVEY WAS TAKEN TO BELIEVE
- 15 THAT THAT'S A WAY TO ACCELERATE RESEARCH.
- 16 WITH THAT, I'LL TURN IT OVER TO MY COLLEAGUE,
- 17 BEN CROW.
- 18 CHAIRMAN PENHOET: WE'LL TAKE QUESTIONS AT
- 19 THE END. QUESTIONS AT THE END IS PROBABLY A GOOD IDEA.
- 20 MS. KING: LET ME JUST DO A QUICK PHONE
- 21 CHECK. WHO JOINED US ON THE PHONE WITHIN THE LAST
- 22 COUPLE OF MINUTES, PLEASE?
- DR. PRI ETO: FRANCI SCO PRI ETO.
- MS. KING: ANYBODY ELSE?
- DR. WRIGHT: JANET WRIGHT.

- 1 MS. KING: THANK YOU, DR. WRIGHT. WE'RE ON
- 2 AGENDA I TEM NO. 3, PRESENTATIONS ON THE OPEN-ACCESS
- 3 TOPIC.
- 4 DR. PRI ETO: THANK YOU.
- 5 MS. KING: ACTUALLY WE'RE IN THAT SLIDE DECK
- 6 AS WELL, ONE OF THE ONES SENT TO YOU. HOPING YOU HAVE
- 7 THOSE SLIDES.
- 8 DR. WRIGHT: YES, THANKS.
- 9 MS. KING: THE ONE THAT HAS BEN CROW ON IT,
- 10 THAT'S WHERE WE ARE.
- DR. CROW: THAT'S ME. SO I WANT TO MAKE JUST
- 12 A COUPLE OF POINTS AND THEN SPEAK A LITTLE BIT ABOUT
- 13 WHERE THE UNIVERSITY OF CALIFORNIA HAS GOT TO. SO THE
- 14 FIRST POINT I WANT TO MAKE IS THAT IT'S DIFFICULT TO
- 15 UNDERESTIMATE THE IMPORTANCE OF THE CHANGES THAT ARE
- 16 GOING ON IN SCHOLARLY COMMUNICATION. I THINK IT'S
- 17 REASONABLE PEOPLE WHO ARE MAKING COMPARISONS. WITH THE
- 18 BEGINNING OF PRINTING OR THE INDUSTRIAL REVOLUTION,
- 19 THEY MIGHT BE WRONG, BUT I DON'T THINK THEY ARE. I
- 20 THINK WE ARE IN THE MIDDLE OF SOMETHING REALLY VERY
- 21 PROFOUND FOR SOCIETY AND FOR HUMAN CREATIVITY.
- 22 IN THAT SITUATION THERE ARE HUGE ADVANTAGES
- 23 TO BEING AMONGST THE FIRST ADOPTERS. THIS IS TRUE OF
- 24 ANY TECHNOLOGY. AND WHEN IT'S A VERY LARGE, FAR
- 25 REACHING SET OF TECHNOLOGIES, I THINK IT'S MOST UNWISE

- 1 TO BE AMONGST THE TAIL ENDERS. AND I THINK THE PROBLEM
- 2 WITH BEING AMONGST THE TAIL ENDERS IS THE SPEED OF
- 3 UPTAKE OF RESULTS, THE BREADTH OF UNDERSTANDING OF
- 4 ONE'S RESULTS, AND THE GENERAL CREATIVITY THAT ARISES
- 5 FROM GETTING LARGE NUMBERS OF PEOPLE THINKING ABOUT THE
- 6 SAME PROBLEMS. ALL OF THOSE POSSIBILITIES ARE
- 7 RESTRICTED IF YOU ARE A TAIL ENDER.
- 8 AND I THINK THE 500-WORD SUMMARY THAT'S SO
- 9 FAR BEING PROPOSED FIRMLY PUTS THE CIRM IN THE TAIL END
- 10 FOR THREE REASONS. IT DOES NOT GAIN THE POTENTIAL
- 11 BENEFITS OF SPEED OF REPORTING AND OPEN AVAILABILITY.
- 12 EVEN MY STUDENTS ARE BENEFITING. I NOW TEACH FROM
- 13 ORIGINAL ARTICLES WHICH ARE FREELY AVAILABLE. IT'S
- 14 UNWISE FOR RESEARCHERS WHO ARE TRYING TO BE AT THE
- 15 FRONT EDGE OF SCIENCE TO BE GIVING LESSER ACCESS TO
- 16 POTENTIAL READERS THAN UNDERGRADUATE STUDENTS GET. SO
- 17 THE SPEED OF REPORTING AND OPEN AVAILABILITY OF RESULTS
- 18 IS VERY IMPORTANT.
- 19 AS JOHN HAS ALREADY SAID, CIRM WOULD BE
- 20 BEHIND THE CURVE OF MANY INTERNATIONAL RESEARCH
- 21 COUNCILS. SO I'M JUST SUMMARIZING JOHN THERE. I THINK
- 22 WERE IT TO BE WIDELY KNOWN THAT CIRM WAS SO FAR BEHIND
- 23 THE CURVE ON THIS 500-WORD SUMMARY, I THINK THERE COULD
- 24 BE SUFFICIENT PUBLIC OBJECTION, AND I THINK THAT WOULD
- 25 BE REASONABLY FOUNDED OBJECTION IN THE CURRENT

- 1 SITUATION.
- 2 SO UNIVERSITY OF CALIFORNIA HAS BEEN THINKING
- 3 ABOUT THIS ISSUE FOR A COUPLE OF YEARS, THREE YEARS,
- 4 MAYBE MORE. AND WHAT WE -- WHAT THE UNIVERSITY IS IN
- 5 THE PROCESS OF DECIDING TO DO, HAS ALMOST DECIDED, IS
- 6 THAT THERE'S AN EXPECTATION THAT FACULTY ROUTINELY
- 7 GRANT A LICENSE TO THE UNIVERSITY TO PUT THEIR
- 8 PUBLISHED PAPERS AND CONFERENCE PAPERS ON OPEN ACCESS.
- 9 WHAT THIS RESTS ON IS THAT COPYRIGHT IS A BUNDLE OF
- 10 RIGHTS AND PRACTICES AND CAN BE DIVIDED UP, AND IT
- 11 SEEMED AS THOUGH IT IS NOT INFEASIBLE FOR ONE OF THOSE
- 12 RIGHTS, THE RIGHT TO PUT MATERIAL IN ITS FINAL FORM ON
- 13 OPEN ACCESS, DOES NOT UNDERMINE COMMERCIAL AND OTHER
- 14 RI GHTS.
- 15 SO WHAT THE UNIVERSITY HAS ASKED IS THAT THE
- 16 LICENSE FOR OPEN ACCESS SHOULD BE RETAINED BY THE
- 17 UNIVERSITY, AND ROUTINELY MATERIALS SHOULD BE POSTED AS
- 18 SOON AS IT IS ACCEPTED ON AN ONLINE OPEN-ACCESS
- 19 DEPOSITORY. THERE ARE POTENTIAL DIFFICULTIES. SOME OF
- 20 WHICH YOU'VE DISCUSSED IN AN EARLIER SESSION.
- 21 MY COLLEAGUE PROFESSOR PITTS IS GOING TO
- 22 ADDRESS THOSE DIFFICULTIES OF THE FEAR THAT THIS WILL
- 23 AFFECT JUNIOR FACULTY, THE FEAR THAT THIS WILL
- 24 UNDERMINE ACADEMIC FREEDOM. PROFESSOR PITTS WILL
- 25 ADDRESS THOSE, BUT THE PRIMARY WAY IN WHICH THOSE

- 1 WORRIES, CONCERNS, CAN BE ADDRESSED IS THAT THERE IS AN
- 2 OPT OUT CLAUSE IF OPEN ACCESS COMPROMISES COMMERCIAL OR
- 3 OTHER OPPORTUNITIES.
- 4 THIS SET OF CHANGES -- THE PROPOSAL TO CHANGE
- 5 COPYRIGHT SO THAT OPEN ACCESS CAN BE THE NORM
- 6 THROUGHOUT UNIVERSITY OF CALIFORNIA HAS BEEN WIDELY
- 7 DISCUSSED OVER THE LAST 12 MONTHS, AND IT'S GOT PRETTY
- 8 MUCH COMPLETE SUPPORT. WE ARE GOING INTO A FINAL ROUND
- 9 OF DISCUSSIONS, AND THE PRESIDENT OF THE UNIVERSITY HAS
- 10 ESTABLISHED A WORKING GROUP, ON WHICH TWO OF US ARE
- 11 MEMBERS, WHICH WILL BE ORGANIZED IN THOSE FINAL
- 12 DISCUSSIONS, BUT I WOULD BE VERY SURPRISED IF THAT WAS
- 13 NOT ADOPTED BY ABOUT SPRING OF NEXT YEAR.
- 14 SO I THINK THE PROPOSAL IS WELL ON THE WAY TO
- 15 BEING ACCEPTED AND WILL HAVE THE CONSEQUENCE THAT THE
- 16 ROUTINE AVAILABILITY OF UC FACULTY MATERIAL WILL BE
- 17 OPEN ACCESS WITHIN A SHORT PERIOD IN A PUBLICATION.
- 18 OKAY.
- 19 DR. PITTS: THANK YOU, MR. CHAIRMAN. I'M
- 20 LARRY PLTTS, PROFESSOR OF NEUROSURGERY AT UC SAN
- 21 FRANCISCO, AND FOR THE PAST SEVERAL YEARS WORKED WITH
- 22 THE UNIVERSITY OF CALIFORNIA ACADEMIC SENATE AND
- 23 SCHOLARLY COMMUNICATION SUBCOMMITTEE.
- 24 I WANT TO ADDRESS FOUR ISSUES THAT HAVE COME
- 25 TO MY COGNIZANCE OVER THE DISCUSSION OF THIS TOPIC, AND

- 1 THEY'RE SORT OF ACADEMIC IN A SENSE THAT THEY ARE
- 2 THINGS THAT FACULTY SHOULD CERTAINLY WORRY ABOUT, AND
- 3 THEIRS WERE CONSIDERED WHEN THE ACADEMIC SENATE TOOK
- 4 THIS OVERALL TOPIC OF SCHOLARLY COMMUNICATION UNDER ITS
- 5 REVIEW AND ISSUES THAT WERE DISCUSSED BY THE FACULTY.
- THE REVIEW PROCESS THAT BEN CROW MENTIONED
- 7 THAT LED THE SENATE TO REQUEST THE PRESIDENT TO
- 8 ESTABLISH THIS POLICY OF GRANTING A LICENSE FOR FACULTY
- 9 PUBLISHED DOCUMENTS, THE REVIEW PROCESS INVOLVED
- 10 PROBABLY FIVE TO 700 FACULTY AND LOOKED AT A SERIES OF
- 11 WHITE PAPERS WRITTEN AND THE PROPOSED POLICY, THE
- 12 POLICY CHANGE IN TODAY'S CURRENT FORM, VERY WISE
- 13 CHANGES. SO IT HAD A LOT OF ACADEMIC REVIEW AND WILL
- 14 COME BACK TO ALL THE UNIVERSITIES WHEN AND IF A POLICY
- 15 IS PROPOSED BY THE OFFICE OF THE PRESIDENT.
- 16 THE FOUR TOPICS: POTENTIAL LOSS OF ACADEMIC
- 17 FREEDOM, THE TERM POTENTIAL HARM TO JUNIOR
- 18 INVESTIGATORS BY THIS OPEN-ACCESS REQUIREMENT, A
- 19 QUESTION ABOUT CREATING AUTHENTICITY OF THE WORK IF
- THERE IS A PUBLISHER'S VERSION AND AN AUTHOR'S VERSION,
- 21 AND POTENTIAL HARM TO SCHOLARLY SOCIETIES AND JOURNALS.
- 22 THIS LOSS OF ACADEMIC FREEDOM, PLEASE DON'T
- 23 TELL ME WHERE TO PUBLISH. WHAT WE ARE NOT REQUESTING
- OR REQUIRING A FACULTY TO PRODUCE WORK IN A PARTICULAR
- 25 LOCATION. IN FACT, ONE OF THE GAMBITS IS THAT WE ARE

- 1 ENCOURAGING THE FACULTY TO RETAIN SOME OF THE COPYRIGHT
- 2 AS OPPOSED TO THE PAST WHERE THEY ASSIGN THE COPYRIGHT
- 3 AWAY TO PUBLISHERS. IMPROVEMENT IN ACADEMIC FREEDOM,
- 4 ABILITY TO USE MATERIAL IN A WAY THAT IN THE PAST MAY
- 5 HAVE BEEN BLOCKED BY PUBLISHERS OR MAY NOT. SO THERE
- 6 WOULD NOT BE A REGULATORY STATEMENT ABOUT LIMITING
- 7 PUBLICATION SITE.
- 8 AS JOHN OBER SAID, 17 OUT OF 18 JOURNALS ON
- 9 THE LIST OF STEM CELL PUBLISHERS ARE CURRENTLY ALLOWING
- 10 OPEN-ACCESS PUBLISHING WITHIN SIX MONTHS OF THE
- 11 PUBLICATION OR ARTICLE.
- 12 THE OPT-OUT CLAUSE ALLOWS THE AUTHOR TO
- 13 REQUEST A WAIVER OF THE REQUIREMENT FOR OPEN-ACCESS
- 14 ARTICLE PLACEMENT. FOR THIS INCREASINGLY SMALL NUMBER
- 15 OF JOURNALS, DIMINISHING WON'T ALLOW SUCH OPEN ACCESS
- 16 OPT OUT FOR THE JUNIOR AUTHOR, BUT THEY CAN CERTAINLY
- 17 SEEK THAT.
- AN INCREASED ACADEMIC FREEDOM TO RETAIN
- 19 COPYRIGHT IMPROVES ACADEMIC FREEDOM RATHER THAN HARMING
- 20 THE JUNIOR INVESTIGATOR. SENIOR STEM CELL GUYS IN THE
- 21 U.S. SAY THAT IF THEY SEND AN ARTICLE TO JOURNAL X AND
- 22 THEY DON'T WANT IT, I HAVE NO PROBLEM SENDING IT TO
- 23 JOURNAL Y AND THEY WILL TAKE IT. QUESTION IS CAN A
- 24 JUNIOR INVESTIGATOR COMMAND SIMILAR ACCESS, AND THE
- 25 ANSWER MAY BE NOT IN EVERY CASE.

- 1 SO THE UC FACULTY REVIEW PROCESS BASICALLY
- 2 DEMANDED THAT THERE BE AN OPT OUT, THAT IF A FACULTY
- 3 MEMBER SENT A PAPER TO A LOCATION THAT WOULD NOT ALLOW
- 4 OPEN ACCESS, THAT FACULTY MEMBER COULD REQUEST FROM THE
- 5 APPROPRIATE BODY A WAIVER FOR THAT PARTICULAR
- 6 REQUIREMENT. AND THE FACULTY THOUGHT THAT WAS AN
- 7 IMPORTANT OUT FOR JUNIOR FACULTY.
- 8 AS WE SAID, THE PUBLICATION IN OPEN ACCESS
- 9 JOURNALS IMPROVES CITATION NUMBERS AND USE AND THE
- 10 EARLINESS OR THE TIMING WITH WHICH A SCHOLAR'S WORK MAY
- 11 BE USED BY OTHER SCHOLARS, IMPROVEMENT TO THE JUNIOR
- 12 SCHOLAR'S PEERS KNOWING ABOUT HIS OR HER WORK. AND
- 13 THEN IT SPEEDS THIS PROCESS TO OTHER INVESTIGATORS FOR
- 14 THEIR OWN WORK AND AVAILABILITY TO ALL INVESTIGATORS,
- 15 INCLUDING THE JUNIOR INVESTIGATORS WHOM WE'RE TRYING TO
- 16 PROTECT.
- 17 AUTHENTICITY OF WORK, WHAT IS THE RIGHT
- 18 ARTICLE? THE PRINTED PDF FILE IS THE GOLD STANDARD,
- 19 WHAT YOU WOULD EXPECT TO TURN TO, AS OPPOSED TO THE
- 20 AUTHOR'S DRAFT AND WHICH DRAFT. THERE CAN BE SEVERAL
- 21 ON THE WEB. WHICH ONE DO YOU BELIEVE?
- 22 DRAFTS CAN BE DATED, FOUND BY ELECTRONIC
- 23 SEARCHES. THERE HAVE BEEN NEW YORK TIMES ARTICLES
- 24 RECENTLY LOOKING AT UNDERGRADUATE PAPERS THAT ARE DONE
- 25 BY SOMEBODY IN MINNEAPOLIS AND MAILED OUT TO SOME

- 1 STUDENT AT UC SANTA CRUZ. THAT SORT OF PLAGERISM IS
- 2 EASY TO FIND. NOW, ONE SERVICE RECEIVES 60,000 PAPERS
- 3 A WEEK, PUT PROFESSORS CAN SEARCH AND MAKE A SEARCH ON
- 4 THE ORIGINAL REAL POSSIBLE TO SEARCH OUT MATERIAL OR
- 5 COPIES. AND BY APPROPRIATELY DATING THAT, THAT SORT OF
- 6 CONCERN IS PROBABLY NOT A PROBLEM.
- 7 AT THIS POINT 75 PERCENT OF JOURNALS ALREADY
- 8 ALLOW OPEN ACCESS. THE PHYSICS ARXIVE HAS BEEN
- 9 EXTREMELY SUCCESSFUL AT PUTTING VERY IMPORTANT PAPERS
- 10 IN PREPUBLICATION. THE JOURNALS RECEIVED COMMENTS FROM
- 11 A NUMBER OF PHYSICISTS WHOSE FINAL WORK ACTUALLY
- 12 INCLUDED ADJUSTING THE PAPER TO RESPOND TO THOSE
- 13 COMMENTS, AND THAT HASN'T HURT PHYSICS ARCHIVE ONE
- 14 I OTA.
- 15 ATTACHMENT ON THE ELECTRONIC SITE WILL ALLOW
- 16 FOR MUCH EXPANDED PRESENTATION OF MATERIAL. WHICH
- 17 ALLOWS FOR A REAL IMPROVED VERSION OF THE PAPER. ONE
- 18 CAN HAVE EXTENDED DATA, COLOR PRESENTATIONS, VIDEOS
- 19 WITH MOVING PARTS AND SO FORTH. SO AN ELECTRONIC SITE
- 20 HAS A POTENTIAL BENEFIT OVER THE PUBLISHED PDF OF THE
- 21 PAPER JOURNALS OR JOURNAL.
- 22 HARM SCHOLARLY JOURNALS AND SOCIETIES. THE
- 23 QUESTION ARISES ABOUT LOSS OF INCOME TO PUBLISHERS OR
- 24 SCHOLARLY SOCIETIES. I WOULD POINT OUT THAT AS FAR AS
- 25 WE'RE AWARE, THERE ARE NO DATA TO SUPPORT THIS CONCERN.

- 1 I CAN UNDERSTAND IT, BUT, IN FACT, A LARGE NUMBER OF
- 2 JOURNALS ALREADY HAVE BUSINESS MODELS THAT ALLOW OPEN
- 3 ACCESS IN THE STEM CELL JOURNALS THAT WE TALKED ABOUT,
- 4 AND SO THERE IS NO CONCERN ABOUT POOR DOCUMENTATION
- 5 THAT WE CAN POINT TO.
- 6 ONE OF THE THINGS THAT UC IS DOING FOR THE
- 7 POLICY OF THE UNIVERSITY IS GATHER SOME DATA IN A
- 8 REASONABLE SCHOLARLY WAY TO ADDRESS THAT CONCERN OF
- 9 SOCIETIES AND PUBLISHERS.
- 10 SO WE THINK THAT OPEN ACCESS HAS ADVANTAGES
- 11 TO CIRM'S GOALS OF EXTREME HIGH QUALITY RESEARCH BEING
- 12 MADE AVAILABLE WORLDWIDE TO RESEARCHERS AND BROUGHT TO
- 13 THE PUBLIC'S BENEFIT AS EARLY AS POSSIBLE. THIS WOULD
- 14 PUT CIRM IN MORE OF A LEADERSHIP POSITION IN THIS REALM
- 15 OF MAKING RESEARCH DATA AVAILABLE TO A VERY BROAD
- 16 POPULATION.
- 17 AND WE WOULD LIKE TO BELIEVE THAT THIS IS
- 18 SOMETHING THAT CIRM COULD DISCUSS, AND WE WOULD BE
- 19 INORDINATELY GRATEFUL IF CIRM FELT, AS WE DO, THAT
- 20 PUBLIC FUNDED RESEARCH SHOULD BE MADE AVAILABLE TO THE
- 21 PUBLIC AND RESEARCHERS WORLDWIDE IN AN OPEN-ACCESS
- 22 FASHION WITHIN SIX MONTHS OF PUBLICATION. AND I'LL
- 23 STOP THERE.
- 24 (A RECESS WAS TAKEN.)
- 25 CHAIRMAN PENHOET: OKAY. LET'S RECONVENE.

- 1 OUR NEXT SPEAKER IS ROBERT TJIAN, PROFESSOR AT UC
- 2 BERKELEY TO SPEAK ON THE OPEN-ACCESS ISSUE.
- 3 DR. TJIAN: I DON'T HAVE ANY SLIDES, SO I'M
- 4 MUCH LESS PREPARED THAN MY COLLEAGUES WHO JUST
- 5 PRESENTED THEIR VIEW. YOU CAN ALL HEAR ME PRETTY WELL
- 6 ON THE PHONE. IN A STRANGE WAY I'M HERE TO REPRESENT A
- 7 GROUP THAT YOU HAVEN'T HEARD FROM, GRADUATE STUDENTS
- 8 AND POST DOCS. AND I DO THIS BECAUSE, IF I LOOK AT
- 9 WHAT I BELIEVE WILL BE THE MOST IMPORTANT -- ONE OF THE
- 10 MOST IMPORTANT FEATURES OF CIRM IS ITS ABILITY TO
- 11 ATTRACT THE VERY BEST PEOPLE TO COME AND ACTUALLY DO
- 12 THE EXPERIMENTS. AFTER ALL, WE WHO SPEAK HERE ARE NOT
- 13 DOING THE EXPERIMENTS.
- 14 SO TO ME THE BIGGEST BARRIER TO MAJOR RAPID
- 15 PROGRESS IN THE RESEARCH, NEVER MIND THE PUBLICATION OF
- 16 RESEARCH, IS THE ATTRACTION OF THE BEST GRADUATE
- 17 STUDENTS AND POST DOCS.
- 18 NOW, GRADUATE STUDENTS AND POST DOCS AND
- 19 MYSELF ARGUE THAT OPEN ACCESS IS A WONDERFUL IDEA. AND
- 20 WE WISH ALL THE JOURNALS WOULD JUST GET ON WITH IT.
- 21 WHAT I'M REALLY POINTING TO IS THE SIX-MONTH GAP
- 22 BETWEEN WHAT SOME OF THE JOURNALS ARE WILLING TO DO AND
- 23 WHAT WE WOULD LIKE THEM TO DO. AND I WANT YOU TO GET
- 24 IN PERSPECTIVE WHAT THE POTENTIAL PROBLEMS ARE FOR THE
- 25 STUDENTS.

- 1 SO I SURVEYED A LOT OF STUDENTS IN BERKELEY,
- 2 NOT JUST FROM MY LAB, BUT I HAVE A FAIRLY LARGE LAB
- 3 WITH A REASONABLY GOOD SPREAD. I WAS SURPRISED TO FIND
- 4 NOT A SINGLE POST-DOC OR GRADUATE STUDENT THOUGHT IT
- 5 WAS A GOOD IDEA TO MANDATE A REQUIREMENT TO LIMIT
- 6 CIRM-FUNDED WORK TO BE PUBLISHED ONLY IN CERTAIN TYPES
- 7 OF JOURNALS.
- 8 NOW, I FULLY UNDERSTAND THAT THERE IS A
- 9 PROPOSED OPT-OUT CLAUSE, BUT THERE IS CONFUSION OVER
- 10 THE APPLICATION. IF EVERYBODY CAN OPT OUT, IF THEY ALL
- 11 OPT OUT, WHY BOTHER WITH THE OPT OUT? LEAVE IT OFF.
- 12 WHY CREATE MORE LAYERS OF BUREAUCRACY TO DO SOMETHING
- 13 THAT SHOULD REALLY BE EASY? SO I GUESS THAT'S REALLY
- 14 MY BIGGEST POINT. I WAS SURPRISED AND SOMEWHAT
- 15 DISMAYED THAT NOT A SINGLE ONE OF MY STUDENTS AND
- 16 POST-DOCS THOUGHT THIS WAS A GOOD IDEA. I HAD A GROUP
- 17 MEETING WITHIN AN HOUR AGO. THEY ASKED ME TO PLEASE
- 18 MAKE IT CLEAR THAT THIS WILL HAVE A VERY BIG DAMPENING
- 19 EFFECT ON THE ENTHUSIASM FOR CERTAIN OF THESE STUDENTS
- 20 TO GET INTO THE FIELD OF STEM CELL BIOLOGY. AND I
- 21 THINK THAT WOULD BE DEVASTATING FOR CIRM. THAT'S ONE
- 22 I SSUE.
- 23 I GUESS THE SECOND ISSUE IS REALLY TIMING. I
- 24 THINK REALISTICALLY THEY WILL ALL GO IN THAT DIRECTION
- 25 ANYWAY. THAT IS TO SAY, I THINK THE JOURNALS NOT IN

- 1 LINE WITH THE SIX-MONTH HOLDING PERIOD WILL GET THERE
- 2 PROBABLY BEFORE CIRM FUNDING IS ACTUALLY IN PLACE, AND
- 3 THE RESEARCH THAT WE'RE DOING WILL ACTUALLY BE
- 4 AFFECTED. SO I GUESS I'M -- BECAUSE I REALLY BELIEVE
- 5 IN THE OPEN ACCESS IDEA, AND I THINK THAT INFORMATION
- 6 THAT WE GENERATE IN OUR RESEARCH SHOULD BE FREELY
- 7 AVAILABLE. FREELY IS KIND OF A DIFFICULT THING.
- 8 OBVIOUSLY SOMEBODY HAS TO PAY FOR IT, BUT THAT'S A
- 9 SEPARATE ISSUE. I REALLY WANT TO FOCUS ON THE
- 10 IMPORTANCE OF WHAT I THINK IS GOING TO BE A NEGATIVE
- 11 FOR CIRM.
- 12 AND THE FINAL POINT I'D LIKE TO MAKE, ASIDE
- 13 FROM THE RECRUITMENT PROBLEM AND THE TIMING ISSUE, I
- 14 DON'T THINK I NEED TO EMPHASIZE THE FACT THAT SCIENCE,
- 15 WE ALL WOULD LIKE BIOLOGY TO GO AS FAST AS WE CAN GET
- 16 INFORMATION OFF THE INTERNET, BUT THE FACT OF THE
- 17 MATTER IS A LOT OF INFORMATION IS GOING TO BE WRONG.
- 18 WE'VE HAD SOME DRAMATIC EXAMPLES OF THAT IN THE LAST
- 19 YEAR OR TWO. I'M NOT SO SURE THAT RAPID ACCESS IS
- 20 NECESSARILY GOING TO BE GOOD. I DON'T THINK WE SHOULD
- 21 PUT ANY BARRIERS TO IT, BUT I ALSO THINK IT'S PERHAPS
- 22 PREMATURE. I GUESS I FEEL A LITTLE LIKE THE TAIL IS
- 23 WAGGING THE DOG HERE, AND THAT OUR FOCUS REALLY OUGHT
- 24 TO BE HOW DO WE DO THE BEST RESEARCH RATHER THAN
- 25 WORRYING ABOUT WHERE WE'RE GOING TO PUBLISH. THAT'S

- 1 REALLY MY POINT.
- 2 CHAIRMAN PENHOET: OKAY. THANK YOU.
- 3 DR. HALL: CAN I ASK A QUESTION?
- 4 CHAIRMAN PENHOET: UNLESS THERE ARE SOME
- 5 OTHER PEOPLE FROM THE UNIVERSITY WHO WANT TO SPEAK PRO
- 6 OR CON, WE'RE UP TO QUESTIONS FROM DR. HALL.
- 7 DR. HALL: I WANTED TO ASK DR. TJIAN, I
- 8 HAVEN'T KEPT UP WITH THIS FOR A WHILE, AND I WAS A
- 9 LITTLE SURPRISED TO SEE THE ELSIVIER JOURNALS ON THE
- 10 LIST. WHAT ARE MAJOR HOLD-UPS FOR DESIRABLE PLACES
- 11 THAT STUDENTS LIKE TO PUBLISH AND CAN'T?
- 12 DR. TJIAN: PART OF THE CONFUSION ACTUALLY
- 13 STARTED WHEN I QUIZZED THE STUDENTS, SO THERE'S A LOT
- 14 OF CONFUSION. BUT I THINK IT'S PRETTY CLEAR THAT THE
- TOP THREE OR FOUR BIG JOURNALS, ALL BUT ONE, SCIENCE,
- 16 NATURE, CELL, AND A FEW OTHERS, ARE THE ONES. AND I
- 17 SHOULD HAVE MADE THIS POINT. WHY DO THESE STUDENTS
- 18 FEEL SO STRONGLY ABOUT IT? I SHOULD HAVE MADE THIS
- 19 VERY CLEAR. IT'S OBVIOUS TO THOSE WHO ARE FACULTY, BUT
- 20 NOT TO OTHERS. THEIR JOBS ARE ABSOLUTELY DEPENDENT ON
- 21 THAT SCIENCE, CELL, NATURE PAPER. I HATE TO SAY THAT.
- 22 IT'S A HORRIBLE THING TO SAY. YOU SHOULD BELIEVE THAT
- 23 THE FACULTY ARE SMART ENOUGH, WELL, WHAT JOURNALS WILL
- 24 LOOK AT THE CONTENT OF THE PAPER. BUT THE FACT OF THE
- 25 MATTER IS, WHEN THE SEARCH COMMITTEE HAS 500

- 1 APPLICATIONS, YOU ARE NOT GOING TO READ ALL THE PAPERS.
- 2 YOU LOOK AT THE PUBLICATION LIST TO SEE HOW MANY HAVE
- 3 SCIENCE, CELL, NATURE PAPERS. YOU LOOK AT THE FINAL
- 4 LIST, AND THEN YOU ARE GOING READ THEIR PAPERS. SO
- 5 THAT'S WHAT CONCERNS THEM THE MOST.
- 6 DR. PLTTS: THE RESPONSE THAT THE STUDENTS
- 7 HAD, I THINK MORE OFTEN THAN NOT, COMES FROM LACK OF
- 8 UNDERSTANDING. I THINK THERE REALLY IS A LOT OF
- 9 CONFUSION IN THE FACULTY WHO IN THE TIME-HONORED PAST
- 10 WRITE AN ARTICLE, SIGN OFF ON THE PAPER, GIVE THE PAPER
- 11 AWAY, STOP THINKING ABOUT IT. THAT'S EASY AND
- 12 HI STORI CALLY GOOD.
- 13 WHEN YOU LOOK AT DATA -- AND THIS IS A
- 14 QUESTION I WOULD POSE TO YOUR STUDENTS -- WHEN YOU LOOK
- 15 AT THE DATA THAT SHOWS HOW MUCH MORE THE MATERIAL IS
- 16 CITED AND USED, EVEN OPEN ACCESS DEFINED AS SIX MONTHS
- 17 WITHIN PUBLICATION, WHEN YOU DEFINE IT THAT WAY AND YOU
- 18 SHOW THE JUNIOR INVESTIGATOR THAT YOUR STUFF GETS OUT
- 19 THERE BETTER THAN IF YOU DON'T HAVE IT IN OPEN ACCESS,
- 20 I WOULD BE CURIOUS TO KNOW WHAT THE RESPONSE TO THAT
- 21 WOULD BE.
- 22 DR. TJIAN: WE DISCUSSED -- THE STATISTICS
- 23 THAT YOU'VE SHOWN IS VERY ENCOURAGING, THAT OPEN ACCESS
- 24 ACTUALLY HAS A TANGIBLE POSITIVE EFFECT, WHICH IS YOU
- 25 DO GET MORE EXPOSURE. BUT THE BOTTOM LINE IS THAT, YOU

- 1 KNOW, I'M NOT GOING TO NAME ANY SPECIFIC JOURNALS, NOT
- 2 PUBLISHING IN THE TOP FOUR OR FIVE JOURNALS, NOBODY IS
- 3 GOING TO ASK YOU TO LOOK AT WHAT THE CITATION INDEX
- 4 SAYS. IT'S VERY CLEAR THAT BOTH IN THE MINDS OF
- 5 FACULTY WHO ARE MAKING THE SELECTIONS AND, MORE
- 6 IMPORTANTLY, IN THE MINDS OF THE STUDENTS AND
- 7 POST-DOCS, THEY KNOW IF THEY DON'T GET THEIR PAPERS
- 8 INTO THE TOP SEVERAL JOURNALS, THEY'RE AT A BIG
- 9 DI SADVANTAGE.
- 10 NOW, YOU CAN SAY WE REALLY OUGHT TO CHANGE,
- 11 THAT THE SELECTION PROCESS IS FLAWED. I AGREE IT IS,
- 12 BUT I HAVE YET TO BE ABLE TO GET A FACULTY SEARCH
- 13 COMMITTEE TO READ ALL THEIR PAPERS.
- DR. PITTS: BUT THE LISTING UP THERE PRETTY
- 15 MUCH HAS IMMEDIATE OPEN ACCESS FOR ALL OF THE JOURNALS
- 16 YOU JUST NAMED --
- 17 DR. TJIAN: NOT REALLY.
- DR. PITTS: -- WITHIN SIX MONTHS. THE ONLY
- 19 ONE ON THAT LIST THAT DOESN'T ALLOW OPEN ACCESS WITHIN
- 20 SIX MONTHS IS STEM CELLS THAT ALLOWS IT IN A YEAR. SO
- 21 JUST AS -- AND I WORRY THAT THE CONCERN OF THE JUNIOR
- 22 INVESTIGATOR WHO IS NOT VERY FAMILIAR WITH THIS IS
- 23 REALLY A LACK OF KNOWLEDGE RATHER THAN DISAGREEMENT
- 24 WITH THE POLICY.
- DR. TJIAN: THESE GUYS ARE REALLY FAST AT THE

- 1 COMPUTER. AS SOON AS I POSE THE QUESTION TO THEM, THEY
- 2 ASK ME WHICH ONES CAN WE DO. I DON'T ACTUALLY
- 3 REMEMBER, YOU'D HAVE TO GO LOOK ON THEIR SITE. SO THEY
- 4 DID. AFTER THEY LOOKED AT IT ON THEIR SITE, THEY CAME
- 5 BACK TO ME AND SAID BAD IDEA. I DON'T KNOW WHAT TO
- 6 TELL YOU. I DO THINK THERE'S CONFUSION. THERE'S
- 7 CONFUSION IN MY OWN MIND.
- 8 DR. HALL: WHAT ARE THE SPECIFIC JOURNALS?
- 9 I'D BE CURIOUS ABOUT THAT.
- 10 DR. TJIAN: I THINK THAT IT'S THE TOP FEW
- 11 JOURNALS PRIMARILY, BUT I ALSO THINK THAT -- AND WE
- 12 DIDN'T GET INTO THIS AS MUCH WITH THE GRADUATE STUDENTS
- 13 AND POST-DOCS -- THIS ISSUE WHICH WE KIND OF WENT OVER
- 14 ABOUT THE FREEDOM TO CHOOSE, I THINK, HAS MORE WEIGHT
- 15 THAN YOU MIGHT BELIEVE FOR THEM.
- 16 CHAIRMAN PENHOET: NONE OF THEM HAVE THE
- 17 PUBLI SHER' S VERSI ON.
- DR. TJIAN: I GUESS THE COUNTER ARGUMENT TO
- 19 THE AUTHOR'S VERSION IS I THINK IT'S BEEN COMMON
- 20 PRACTICE IN BIOLOGY AT LEAST FOREVER. I CAN REMEMBER
- 21 IF ANYBODY ASKED ME FOR A PREPRINT AFTER MY PAPER IS IN
- 22 PRESS, I'D SEND IT. DIDN'T MATTER WHAT IT WAS. I
- 23 THINK THAT'S IN PRACTICE TRUE IRRESPECTIVE OF WHAT THE
- 24 JOURNALS DO OR DON'T. SINCE OUR E-MAIL IS RIGHT UP
- 25 FRONT WITH THE PUBLISHED DATA, I DON'T THINK THAT IS A

- 1 BARRIER. IF ANYBODY IN THIS ROOM WANTED TO ACCESS A
- 2 PAPER OF MINE IN PRESS BEFORE IT ACTUALLY CAME OUT,
- 3 THEY'D GET IT. SO I DON'T THINK THERE'S A PROBLEM.
- 4 CHAIRMAN PENHOET: THEY'D HAVE TO KNOW WHO
- 5 YOU WERE.
- 6 DR. TJIAN: THEY DON'T HAVE TO KNOW ME; KNOW
- 7 MY E-MAIL.
- 8 MR. REED: I'M A HUNDRED PERCENT IN FAVOR OF
- 9 OPEN ACCESS, BUT I HAVE TWO CONCERNS. NO. 1, WHAT
- 10 WOULD BE THE COST TO THE CIRM? OUR MONEY IS JEALOUSLY
- 11 GUARDED. ARE WE EXPECTED TO PAY THE FEES FOR ALL OF
- 12 THIS? AND THAT'S SOMETHING I WANT TO KNOW.
- 13 SECONDLY, THE 500-WORD, PEOPLE MENTIONED THE
- 14 500-WORD SUMMARY. IT WAS NEVER INTENDED TO BE A
- 15 SCIENTIFIC DEVICE. THAT WAS SO THAT THE PUBLIC COULD
- 16 HAVE A GENERAL IDEA OF WHAT'S GOING ON. SO IT'S A GOOD
- 17 THING. IT WAS NOT INTENDED FOR THAT. BUT THE OPEN
- 18 ACCESS WITHIN 12 MONTHS AFTER THE DATE OF THEIR
- 19 PUBLICATION, THAT WOULD -- THAT WOULD MAKE THE
- 20 INFORMATION AVAILABLE TO EVERYBODY AND STILL ALLOW THEM
- 21 TO MAKE THEIR KILL AS AN INTELLECTUAL.
- 22 DR. TJIAN: I'M NOT EVEN SURE THEY WORRY
- 23 ABOUT THE 12 MONTHS. THEY JUST WANT TO HAVE NO BARRIER
- 24 TO BEING ABLE TO PUBLISH ANYWHERE WITHOUT FEELING SOME
- 25 CONSTRAINTS ABOUT THEIR ABILITY TO PRESENT THEIR DATA

- 1 IN THE MOST HIGH IMPACT FORUM THAT THEY CAN FIND, AND
- 2 THAT FORUM CHANGES OVER TIME. JOURNALS COME AND GO.
- 3 BUT THAT'S THE SENSE THAT I GOT.
- 4 CHAIRMAN PENHOET: I GUESS THE QUESTION I
- 5 HAVE FOR THOSE OF YOU WHO ARE ON THE UCOP IS WHEN YOU
- 6 SAY THIS IS GOING TO BE UNIVERSITY POLICY, BUT PEOPLE
- 7 CAN OPT OUT, WHO POLICES THIS? IS THERE GOING TO BE --
- 8 IS THERE ANY SANCTION FOR A PROFESSOR WHO DOES NEITHER
- 9 AND CONTINUES TO DO WHATEVER? WHAT ARE THE TEETH?
- 10 DR. PITTS: THAT'S AN ISSUE TO BE RESOLVED,
- 11 AND I'M NOT SURE THAT THERE WILL BE SPECIFIC TEETH TO
- 12 THIS IN TERMS OF FACULTY. AS FAR AS MISCONDUCT
- 13 HYPOTHETICALLY AND THE KIND OF ROUTE YOU ARE GOING WHEN
- 14 YOU TALK ABOUT BREAKING POLICY AND SOME TEETH, I THINK
- 15 THAT THE OPT OUT AND THE POLICING AND SO FORTH WOULD BE
- 16 MANAGED ON PROBABLY A CAMPUS-BY-CAMPUS BASIS WITH SOME
- 17 SUBSTANTIAL HELP FROM THE DIGITAL LIBRARY PART OF THE
- 18 UC THAT HANDLES THIS. WE THINK THAT A LOT OF THIS CAN
- 19 BE HANDLED LARGELY ELECTRONI CALLY. CONGRATULATIONS FOR
- 20 GETTING YOUR ARTICLE IN WHATEVER OPEN ACCESS IN SIX
- 21 MONTHS KIND OF THING. SO THAT WE TRY TO TAKE -- INTEND
- 22 AS MUCH AS POSSIBLE TO TAKE THE ONUS OFF THE INDIVIDUAL
- 23 I NVESTI GATORS.
- 24 THE POINT ABOUT SOMEBODY MAY WRITE ME FOR A
- 25 PREPRINT, IT'S THE AUTHOR'S VERSION, HOPEFULLY IN THE

- 1 LAST VERSION THAT WAS EDITED TO GO TO THE JOURNAL.
- 2 IT'S AN ADMINISTRATIVE BURDEN ON THE RESEARCHER TO
- 3 ANSWER ALL THE E-MAIL. THERE'S A WIDESPREAD
- 4 POSSIBILITY IN A PLACE WHERE THAT COULD BE DONE MUCH
- 5 MORE BROADLY BY THE RESEARCHERS WHO DON'T KNOW YOUR
- 6 E-MAIL ADDRESS, DON'T GET BACK IN TOUCH WITH YOU.
- 7 THE TEETH ISSUE IS AN INTERESTING ISSUE
- 8 BECAUSE WE'RE TRYING TO DO GOOD WITHOUT DOING HARM. MY
- 9 GUESS IS THIS IS NOT A MAJOR ISSUE FOR FACULTY. THE
- 10 MISCONDUCT TEETH, FOR NOT DOING THIS.
- 11 CHAIRMAN PENHOET: WHAT TROUBLES ME IS THAT
- 12 YOU MAY BE ASKING US TO DO SOMETHING YOU'RE NOT WILLING
- 13 TO DO FOR YOURSELF. IN THE UNIVERSITY OF CALIFORNIA IF
- 14 YOU WANT TO HAVE A STRONGER POLICY THAN THE UNIVERSITY
- 15 IS WILLING --
- DR. PITTS: POLICY IS THE SAME.
- 17 CHAIRMAN PENHOET: YOU ARE RECOMMENDING,
- 18 THEN, THAT WE HAVE A -- WE HAVE POLICIES WHICH ARE LAW,
- 19 OTHER POLICIES WHICH BASICALLY EXHORT PEOPLE TO DO THE
- 20 RIGHT THING.
- DR. PITTS: REGULATIONS AND SORT OF REQUESTS
- 22 BASICALLY. THE REQUEST ROUTE, I THINK, IS NOT THE WAY
- 23 TO GO. THE SPECIFIC ISSUE THAT I WOULD CITE TO SUPPORT
- 24 MY FEELING IS THAT THE NIH WAS GOING TO BE SIX-MONTH
- 25 MANDATORY OPEN ACCESS FOR FUNDED RESEARCH, BACKED AT

- 1 THE BEHEST OF THE PUBLISHERS AND SCHOOL SOCIETIES, TO
- 2 12 MONTHS VOLUNTARY. AND RIGHT NOW THE NIH STILL
- 3 EXHORTS PEOPLE. FOR OPEN ACCESS, A 6-PERCENT TAKE RATE
- 4 ON THE VOLUNTEERISM APPROACH IS NOT A GOOD WAY TO GO IF
- 5 YOU ARE SERIOUS ABOUT GETTING THE MATERIAL INTO OPEN
- 6 ACCESSIBLE PLACES. SO I THINK THAT A REGULATION AND
- 7 CALIFORNIA UC POLICY, CERTAINLY THERE'S NOT A POLICY
- 8 AGAINST DOING THAT NOW AT UC, BUT A POLICY THAT MAKES
- 9 IT MUCH MORE STANDARD AND ROUTINE, I THINK, WILL
- 10 FACILITATE THIS SUBSTANTIALLY, BOTH FOR UC AND, I
- 11 THINK, VERY HELPFUL FOR CIRM AS WELL.
- MR. ROTH: READY FOR COMMENTS?
- 13 CHAIRMAN PENHOET: YEAH, PLEASE.
- 14 MR. ROTH: MY RESPONSE WOULD BE THE
- 15 FOLLOWING, THAT THE PRESENTATIONS LARGELY OUTLINE THAT
- 16 THE MARKETPLACE IS EFFECTIVELY DEALING WITH THIS. 75
- 17 PERCENT OF ALL THE JOURNALS, 17 OF 18 OF THE STEM CELL
- 18 JOURNALS, ARE ALREADY ADOPTING POLICIES, WHICH MEANS
- 19 THAT IT'S GOING TO HAPPEN. AND I'M NOT REALLY SURE WHY
- 20 CIRM, FOLLOWING YOUR COMMENT, SHOULD BE MANDATING
- 21 SOMETHING THAT EVEN THE NIH FOUND REASONS TO BACK OFF
- 22 OF. YOU CAN SAY IT'S BECAUSE OF THE LOBBYING OF
- 23 JOURNALS.
- 24 BUT THE SECOND COMMENT WOULD BE I'M WORRIED
- 25 ABOUT THE BUSINESS MODEL THAT THIS TYPE OF POLICY WILL

- 1 EVENTUALLY LEAD TO. WE KNOW WHAT THE BUSINESS MODEL IS
- 2 ON PUBLICATION, AND THAT'S RESULTED IN A VERY HIGH
- 3 QUALITY GROUP OF JOURNALS THAT THE SCIENTISTS CAN
- 4 DEPEND ON. THEY HAVE BEEN PEER REVIEWED, HANDLED IN A
- 5 VERY UNDERSTANDING WAY.
- 6 SO WE START WITH A POLICY OF 12 MONTHS OR SIX
- 7 MONTHS, BUT I THINK THE SLIPPERY SLOPE IS WHY NOT ONE
- 8 MONTH OR ONE DAY OR DAY OF. AND THEN WHAT IS THE
- 9 BUSINESS MODEL? THE WAY THE NEWSPAPERS AND OTHER
- 10 PUBLICATIONS HAVE DEALT WITH THIS IS THROUGH AN
- 11 ADVERTISING AND PROMOTION MODEL. SO IF YOU EXPECT THAT
- 12 DOWN THE ROAD THE WAY THESE QUALITY REVIEWS WOULD
- 13 TAKE PLACE WILL BE ADVERTISED AND PROMOTION, THEN YOU
- 14 SHOULD MOVE IN THAT DIRECTION. I'M NOT FULLY READY TO
- 15 SAY THAT'S THE RIGHT THING TO DO.
- 16 SO FINALLY, MY RECOMMENDATION TO THE CIRM
- 17 WOULD BE THAT WE TAKE A POSITION OF SUPPORTING OPEN
- 18 ACCESS, BUT NOT TAKE A POLICY ON OPEN ACCESS.
- 19 DR. BRYANT: SO I'M IN THE SAME AREA AS DUANE
- 20 ON THIS ONE MOSTLY BECAUSE I THINK IF WE REQUIRE OPEN
- 21 ACCESS, THAT MEANS THAT PEOPLE WORKING ON STEM CELLS
- 22 WITH CIRM FUNDING CANNOT PUBLISH IN NATURE OR SCIENCE
- OR A COUPLE OF OTHER JOURNALS.
- DR. HALL: POINT OF FACT HERE.
- 25 DR. BRYANT: ACCORDING TO THIS TABLE HERE,

- 1 THE TABLE THAT WAS IN THE HANDOUT FROM THE FIRST TALK,
- 2 SHOWS NEURON AND ALL THE NATURE JOURNALS AND SCIENCE,
- 3 THERE IS NO TIME WHEN YOU CAN HAVE OPEN ACCESS FROM THE
- 4 PUBLISHER'S VERSION, WHICH IS THE ONE THAT PEOPLE WOULD
- 5 WANT ANYWAY. THAT'S THE ONE THAT'S THE AUTHENTIC
- 6 VERSION. SO I AM ACTUALLY CONCERNED THAT IF THAT IS
- 7 THE CASE, THEN I THINK WE NEED TO BACK OFF AND STRONGLY
- 8 RECOMMEND WHENEVER POSSIBLE TO PUBLISH IN OPEN ACCESS
- 9 JOURNALS AND TO MAKE THE ARTICLES AVAILABLE AS SOON AS
- 10 ALLOWED BY THE JOURNAL IN A PUBLIC PLACE. BUT TO
- 11 REQUIRE IT COULD ACTUALLY BE A PROBLEM FOR SOME PEOPLE,
- 12 AND I AGREE WITH THE SPEAKER FROM SAN FRANCISCO. I
- 13 THINK THAT'S WHO IT WAS, BERKELEY. I JUST THINK,
- 14 ESPECIALLY SINCE THESE ARE THE LEADING JOURNALS IN OUR
- 15 FIELD, AND UNFORTUNATELY THEY DO HAVE THAT CACHE OF
- 16 REVIEWERS WHO LOOK DOWN A LIST OF PUBLICATIONS AND SEE
- 17 HOW MANY OF THE TOP IMPACT PAPERS THERE ARE. IT'S THE
- 18 TOP IMPACT JOURNALS THAT HAVE THIS POLICY OF STINGY
- 19 OPEN ACCESS, I'LL CALL IT.
- 20 MR. OBER: CLARIFICATION. JOHN OBER, AGAIN,
- 21 UC. POINT OF CLARIFICATION. TO THE EXTENT THAT THE
- 22 NIH ACTIONS ARE A USEFUL COMPARISON POINT, THE NIH
- 23 VOLUNTARY POLICY GOT POOR UPTAKE. AND WHEN FACULTY
- 24 RESEARCHERS WERE SURVEYED, IT WAS LESS BECAUSE OF ANY
- 25 PRINTED OBJECTION AND MORE BECAUSE, WITHOUT A

- 1 REQUIREMENT, THEY JUST DIDN'T TAKE THE TIME. AND IF
- 2 YOU LOOKED AT THAT EVIDENCE THAT SHOWED THAT 81 PERCENT
- 3 OF RESEARCHERS WOULD WILLINGLY COMPLY, THAT SUGGESTS
- 4 WHAT, IN FACT, IS NOW HAPPENING WITH THE NIH POLICY,
- 5 WHICH IS THAT THE BOARD OF TRUSTEES FOR THE NIH
- 6 RECOMMENDED THAT THE POLICY BE CHANGED TO A MANDATORY
- 7 POLICY.
- 8 AND CONGRESS IN THE CURRENT PROPOSITION,
- 9 BILL, HAS LANGUAGE CONNECTED TO THE PROPOSITION FOR THE
- 10 NIH THAT WOULD MAKE THE POLICY A REQUIRED POLICY AS
- 11 WELL. IN FACT, THE NIH POLICY GOT STARTED AS A REQUEST
- 12 FROM CONGRESS. SO THERE IS SOME EVIDENCE THAT THE NIH,
- 13 AT LEAST OTHER AGENCIES LIKE THE UK MEDICAL RESEARCH
- 14 COUNCIL, THAT UNDERSTAND THAT MAKING IT A REQUIREMENT,
- 15 ESPECIALLY GIVEN THE PUBLISHER'S WILLINGNESS TO GO
- 16 ALONG WITH THIS, IS A WAY TO AMALGAMIZE THE CONTENT AND
- 17 TO ENCOURAGE DEPOSIT. AND THAT'S THE POINT OF IT.
- 18 CHAIRMAN PENHOET: JUST A REMINDER. WE ARE
- 19 NOT SEEKING TO MAKE A DECISION ABOUT THIS TODAY. IT'S
- 20 MORE INPUT. ANYBODY ELSE? JOHN SIMPSON.
- 21 MR. SIMPSON: VERY QUICKLY. IN ALL OF THIS
- 22 DISCUSSION, I THINK YOU'RE FORGETTING ONE THING.
- 23 TAKING THE TAXPAYER'S \$6 BILLION GOING INTO THIS, THEY
- 24 WANT TO BE ABLE TO READ THE RESULTS QUICKLY AND
- 25 PROMPTLY. YOU'VE GOT TO COME UP WITH SOME KIND OF OPEN

- 1 ACCESS FOR THAT REASON. I DON'T CARE ABOUT THE
- 2 INTERNAL ACADEMIC DEBATE. THE TAXPAYERS ARE PAYING FOR
- 3 IT, AND THEY OUGHT TO BE ABLE TO SEE IT.
- 4 DR. HALL: I HAVE A LETTER HERE THAT WAS
- 5 RECENTLY CALLED TO MY ATTENTION DATED JUNE 20TH TO DR.
- 6 ARLENE CHIU FROM HENRY LESTER AT CALTECH. IT JUST
- 7 SAYS -- I'LL SUMMARIZE. THERE IS LITTLE ENTHUSIASM FOR
- 8 THE PROPOSAL AMONG THE GENERAL CALTECH FACULTY MOSTLY
- 9 ON THE BASIS OF GRANT FUNDING. I'LL PUT THAT IN THE
- 10 RECORD SINCE WE DID RECEIVE THAT OPINION.
- 11 I ALSO HAVE A QUESTION ABOUT WHETHER THE
- 12 SPECIAL PROGRAMS GRANTING AGENCY THAT RUNS WITHIN THE
- 13 UNIVERSITY OF CALIFORNIA, WHERE DO THEY STAND WITH
- 14 REGARD TO THIS, BREAST CANCER, FOR TOBACCO RESEARCH,
- 15 FOR ALDS? WHAT DO THEY REQUIRE OF THEIR GRANTEES? DO
- 16 THEY HAVE THE EXPERIENCE WITH IT?
- 17 DR. PITTS: I DON'T THINK THAT THERE IS A
- 18 SPECIFIC POLICY IN THAT GROUP, SO I DON'T THINK THAT
- 19 THEY'RE ANY DIFFERENT FROM THE GENERAL UNIVERSITY
- 20 PUBLICATION.
- DR. HALL: WILL THEY THEN FOLLOW THE POLICY?
- 22 DR. PITTS: IF THE UNIVERSITY OF CALIFORNIA
- 23 ADOPTS THE POLICY, THEN THEY WOULD, AT LEAST FOR UC
- 24 FACULTY MEMBERS, AND THEN WOULD HAVE TO CONSIDER THE
- 25 INTERNAL MATTER WHETHER THEY EXTENDED THAT TO NON-UC,

- 1 TO FUNDED RESEARCH THAT THEY DID OUTSIDE THE
- 2 UNI VERSI TY.
- 3 DR. HALL: UC FUNDING, THE UC-RUN GRANTING
- 4 PROGRAM DOES NOT REQUIRE IT AT PRESENT AND MAY NOT; IS
- 5 THAT RIGHT?
- 6 DR. PITTS: THEY MAY NOT. I DON'T THINK IT'S
- 7 BEEN DISCUSSED, SO I THINK THERE'S NO ANSWER TO THAT
- 8 QUESTION.
- 9 DR. PRI ETO: QUESTI ON HERE.
- 10 CHAIRMAN PENHOET: PLEASE GO AHEAD.
- DR. PRIETO: COMMENT, I SUPPOSE, THAT I THINK
- 12 THAT WE NEED TO REMEMBER THAT SHARING OUR BROAD
- 13 DISSEMINATION OF RESEARCH RESULTS AND TRANSPARENCY IS
- 14 THE BEDROCK OF THE PRINCIPLES OF CIRM THAT THE ICOC HAS
- 15 PUT IN PLACE.
- 16 BUT I STILL HAVE A COUPLE OF QUESTIONS FOR
- 17 DR. PLTTS OR OTHER SPEAKERS ABOUT THE GRADUATE STUDENTS
- 18 REGARDING, I THINK, ED, YOU ASKED THIS QUESTION, BUT I
- 19 DIDN'T HEAR AN ANSWER. UNDER THIS MODEL, WHAT BODY
- 20 WOULD DECIDE ABOUT THE OPT OUT? IS THAT SOMETHING THAT
- 21 THE CIRM WOULD DELEGATE TO THE INSTITUTION OR SOMETHING
- 22 THAT WE WOULD HAVE TO HAVE STAFF TO DO?
- THE OTHER SORT OF COMMENT I HAVE IS THAT IT
- 24 SEEMS TO ME OPEN ACCESS IS BECOMING THE STANDARD, AND
- 25 PERHAPS WE SHOULD PUSH THAT A LITTLE BIT. IF WE SAY

- 1 THAT'S OUR EXPECTATION AND OUR REGULATIONS AND JUST BY
- 2 THE FACT OF OUR SIZE OR THE AMOUNT OF MONEY THAT WE'RE
- 3 PUTTING INTO THE FIELD, THAT I THINK WE WILL TEND TO
- 4 MOVE THINGS IN THAT DIRECTION.
- 5 DR. BRYANT: I THINK IF NIH WERE ALSO -- IF
- 6 IT'S TRUE THAT NIH IS ABOUT TO MAKE THIS DECISION, THEN
- 7 I WOULD COMPLETELY AGREE WITH YOU BECAUSE THEN WE'D
- 8 HAVE THE FUNDING SOURCES PRETTY MUCH COVERED. BUT I
- 9 THINK -- I JUST DON'T THINK AT THIS POINT IT WOULD BE
- 10 ATTRACTIVE TO JUNIOR GRADUATE STUDENTS AND POST-DOCS,
- 11 ESPECIALLY THE ONES WHO HAVE HIGH ASPIRATIONS. THEY
- 12 WOULD NOT WANT THIS POLICY AND FEEL, I THINK ALREADY DO
- 13 FEEL, THAT WOULD HARM THEM. AND IT COULD BECAUSE OF
- 14 THE WAY PEOPLE LOOK AT PUBLICATIONS RIGHT NOW.
- DR. PRI ETO: FOLLOW-UP THEN. HOW FOR THOSE
- 16 BODIES. THE NRC IN THE UK AND OTHERS THAT DO HAVE AN
- 17 OPT OUT, HOW IS THIS BEING HANDLED NOW? AND HOW OFTEN
- 18 DOES IT REALLY COME UP? DO PEOPLE OPT OUT FREQUENTLY
- 19 AND IS IT ONEROUS?
- 20 CHAIRMAN PENHOET: WE'LL DO SOME HOMEWORK AND
- 21 FIND OUT. WE WILL CONTINUE THIS DISCUSSION ON SOME OF
- 22 THESE ISSUES. THAT'S A QUESTION WE CAN GET ANSWERS
- 23 FOR. I DON'T THINK WE HAVE THEM TODAY.
- DR. HALL: SUSAN, ONE QUESTION ABOUT YOUR
- 25 COMMENTS. SUSAN, LET ME UNDERSTAND. I'M LOOKING AT

- 1 THIS GRAPH 16 OF 18 JOURNALS ALLOW SOME SORT OF OPEN
- 2 ACCESS WITHIN SIX MONTHS. ON THAT IT SAYS ALL THE HIGH
- 3 PROFILE JOURNALS WILL ALLOW EITHER AN AUTHOR'S VERSION
- 4 OR PUBLISHER'S VERSION. STEM CELL IS THE ONLY ONE THAT
- 5 DOESN' T.
- 6 CHAIRMAN PENHOET: THE HIGH PROFILE ONES ARE
- 7 ALL THE AUTHOR'S VERSION.
- 8 DR. HALL: HIGH PROFILE ONES FOR *NATURE*, SO
- 9 YOUR OBJECTION, THEN, IS REALLY THAT YOU THINK IT'S NOT
- 10 THE RIGHT THING FOR AUTHORS TO PUT A VERSION ON BEFORE
- 11 PUBLICATION THAT'S NOT THE OFFICIAL VERSION; IS THAT
- 12 RIGHT? IS THAT WHAT THE PUBLISHER'S VERSION BOILS DOWN
- 13 TO BECAUSE IF YOU COMPLY BY THE RULES, AS I UNDERSTAND
- 14 THEM, ALL OF THESE WOULD BE AVAILABLE. THE ONLY
- 15 DIFFERENCE WOULD BE THAT SOME OF THEM ARE AUTHOR'S
- 16 VERSION UNTIL THE SIX MONTHS AND NOT THE PUBLISHER'S
- 17 VERSION. SO IT'S THAT DISTINCTION THAT YOU ARE
- 18 OBJECTING TO; ISN'T THAT RIGHT?
- 19 DR. BRYANT: YES. I DON'T THINK THE AUTHOR'S
- 20 VERSION, THOUGH INFORMATIONAL, BUT IT'S NOT
- 21 NECESSARILY -- NOBODY IS GOING TO CHECK THAT IT'S THE
- 22 SAME VERSION.
- DR. HALL: SOMEBODY SAY NOT GOING TO PUBLISH
- 24 IN NATURE THE AUTHOR'S VERSION, PEOPLE WILL REALLY DO
- 25 THAT?

- 1 DR. BRYANT: NO. NO. I WOULDN'T INHIBIT
- 2 PEOPLE FROM --
- 3 DR. HALL: THEN THE RULE WOULD MAKE NO
- 4 DIFFERENCE.
- 5 DR. BRYANT: PEOPLE WOULD BE AFRAID IF THEY
- 6 COULDN' T.
- 7 DR. HALL: THAT'S OKAY. YOU WOULD STILL
- 8 NOT -- I COULDN'T IMAGINE A STUDENT SAYING I'M NOT
- 9 GOING TO PUBLISH IN NATURE. I DON'T WANT MY AUTHOR'S
- 10 VERSION -- I DON'T WANT THE PUBLISHER'S VERSION TO GO
- 11 ONLINE. THIS IS SIMPLE BY THE RULES WE'RE PROPOSING.
- DR. BRYANT: THE AUTHOR'S VERSION. I THOUGHT
- 13 YOU WERE PROPOSING THAT. I'M SORRY THEN. IF IT'S THE
- 14 AUTHOR'S VERSION, IT SHOULD BE ALLOWABLE FOR OPEN
- 15 ACCESS.
- 16 DR. HALL: THAT IS OPEN ACCESS BY THE
- 17 DEFINITION WE'VE BEEN TALKING ABOUT HERE. OPEN ACCESS
- 18 WOULD INCLUDE 17 OF THE 18 TOP JOURNALS AND NOT INCLUDE
- 19 STEM CELL. THERE ARE JOURNALS THAT I KNOW ABOUT AND
- 20 RECOGNIZE. THE JOURNAL OF CELL BIOLOGY, I DON'T KNOW
- 21 WHERE THEY STAND. THEY MAY BE OUTLIERS ON THIS, BUT
- 22 ACTUALLY I'M, NOT HAVING LOOKED AT THIS FOR A WHILE,
- 23 IMPRESSED BY HOW MANY OF THE PUBLISHING HOUSES HAVE
- 24 COME AROUND TO THIS. AND I THINK -- I DON'T -- I CAN
- 25 UNDERSTAND THIS THING ABOUT I THINK I OUGHT TO BE ABLE

- 1 TO PUBLISH WHERE I WANT. AS A PRACTICAL MATTER, IF WE
- 2 HAD THIS POLICY, IT WOULDN'T STOP SOMEBODY IN YOUR LAB
- 3 PUBLISHING IN ANY ONE OF 17 JOURNALS. IT'S A PRETTY
- 4 GOOD LIST.
- 5 DR. BRYANT: YOU'RE RIGHT. I THOUGHT YOU
- 6 WERE TALKING ABOUT JOURNALS WHERE THE PUBLISHERS PUT
- 7 THEIR VERSION ONLINE.
- 8 UNIDENTIFIED SPEAKER: IF THERE'S NO TEETH,
- 9 WE DON'T NEED A RULE ANYWAY BECAUSE IT'S DOABLE NOW.
- 10 WHY PUT A RULE IN SINCE WE --
- DR. HALL: WE DON'T NEED A RULE. IT IS THE
- 12 I SSUE THAT WE HEARD BEFORE, THAT WE HAVE SOME SORT OF
- 13 SENSE OF RESPONSIBILITY TO THE PUBLIC OF ENCOURAGING
- 14 PEOPLE TO DO THIS. SORT OF BEING ON THE SIDE, I THINK
- 15 MOST OF US FEEL THAT ULTIMATELY, AS YOU SAID, IT'S
- 16 GOING TO HAPPEN AND IT'S A GOOD THING. QUESTION IS
- 17 WHETHER WE WOULD PUSH IT ALONG A LITTLE BIT FASTER IF
- 18 CIRM WERE TO TAKE A POSITION. THE PENALTY FOR THAT
- 19 WOULD BE THE TEETH. WE CAN WRITE SOMETHING INTO OUR
- 20 RULES NOW THAT WE'RE EITHER GOING TO IGNORE LATER,
- 21 WHICH DOESN'T SEEM VERY RIGHT, OR JUST WAIT A LITTLE
- 22 WHILE AND LET THINGS SETTLE DOWN. WE'RE REALLY ARGUING
- 23 ABOUT SIX MONTHS DIFFERENCE OR NO DIFFERENCE RIGHT NOW.
- 24 AND JUST I THINK WE HAVE ENOUGH LAYERS OF BUREAUCRACY
- 25 HERE, THAT WE SHOULDN'T BE LOOKING FOR NEW WAYS OF

- 1 ADDING MORE.
- 2 CHAIRMAN PENHOET: OKAY. UNLESS THERE'S ANY
- 3 FINAL URGENT COMMENT.
- 4 DR. PITTS: ONE POINT OF CLARIFICATION.
- 5 THERE'S A QUESTION THAT WAS RAISED THAT MADE ME
- 6 CONCERNED. THE ASKER OVER THE PHONE WAS CONCERNED
- 7 ABOUT PEER REVIEW AND QUALITY OF PUBLICATIONS GOING TO
- 8 A NEWSPAPER MODEL AND SO FORTH. THIS POLICY TALKS
- 9 ABOUT POSTPUBLICATION OPEN-ACCESS PLACEMENT WHEN THE
- 10 PUBLICATIONS ARE IN THE HIGH QUALITY PEER REVIEWED
- 11 JOURNALS. THAT PROCESS HAS NOT CHANGED ONE LOTA.
- 12 THERE HAS BEEN NO RECOMMENDATION THAT IT BE CHANGED.
- 13 IT IS A REQUEST THAT THOSE THEN BE MADE IN OPEN ACCESS
- 14 AFTER PUBLICATION. AND AS THE CHART THAT WE HAVE HERE
- 15 THAT SHOWS THE JOURNALS, A LOT OF THOSE ALREADY DO IT
- 16 OR WILL DO IT WITHIN SIX MONTHS. AND SO WE'RE NOT
- 17 CHANGING PEER REVIEW; WE'RE NOT CHANGING THE QUALITY IN
- 18 ANY WAY. IT'S NOT INTENDED. WE ABSOLUTELY DO NOT
- 19 DESIRE THAT. SO IT'S REALLY JUST PUTTING IT IN A PLACE
- 20 THAT'S ACCESSIBLE FOR THE PUBLIC AND THE RESEARCH
- WORLD.
- 22 MR. ROTH: I UNDERSTAND THAT COMPLETELY. I
- 23 MADE THE POINT THAT EVENTUALLY, IF YOU STICK TO SIX
- 24 MONTHS, YOU WILL BE REQUESTED TO SHORTEN THE TIME
- 25 PERIOD. AND WHEN YOU GET TO THE POINT WHERE PEOPLE ARE

- 1 ASKING FOR SAME DAY ONLINE, AVAILABLE ON THE INTERNET
- 2 PUBLICATIONS, THE BUSINESS MODEL WILL CHANGE
- 3 REMARKABLY. IT HAS IN THE NEWSPAPER AND OTHER
- 4 INDUSTRIES, WHICH WENT TO A MODEL THAT WAS SUPPORTED BY
- 5 ADVERTISING AND PROMOTION. THAT'S AN ACCEPTABLE MODEL,
- 6 AND THAT BUSINESS -- I'M NOT SURE THAT YOU WANT THAT IN
- 7 SCIENTIFIC JOURNALS. THAT WAS THE POINT I WAS GOING TO
- 8 MAKE.
- 9 AND FINALLY, AGAIN, I THINK THIS IS, YOU
- 10 KNOW, A PROBLEM THAT WILL BE SOLVED BY PEOPLE THAT HAVE
- 11 SPENT FAR MORE TIME THAN WE HAVE AND HAVE FAR GREATER
- 12 RESOURCES THAN WE HAVE, INCLUDING NIH AND UNIVERSITY OF
- 13 CALIFORNIA. YOU SAID YOU STUDIED IT FOR A YEAR AND
- 14 STILL DON'T HAVE A POLICY. NIH HAS BEEN STUDYING IT
- 15 FOR A LONG TIME, AND THEY STILL DON'T HAVE A POLICY.
- 16 WHEN NIH MAKES THIS THE POLICY, THIS THING IS OVER.
- 17 EVERYBODY TAKES NIH MONEY, SO IT GETS SOLVED. I DON'T
- 18 THINK WE SHOULD LEAD. WE DON'T HAVE THE TIME TO FLUSH
- 19 OUT ALL THE ASPECTS OF IT. I'M PERFECTLY WILLING TO
- 20 LEAD THE CHARGE ONCE SOMEBODY COMES OUT WITH A POLICY
- 21 LIKE NIH OR EVEN UNIVERSITY OF CALIFORNIA. GET YOUR
- 22 POLICY APPROVED AND THEN COME BACK TO US. RIGHT NOW I
- 23 THINK WE SHOULD STRONGLY SUPPORT OPEN ACCESS.
- 24 CHAIRMAN PENHOET: OKAY. WE'VE HEARD A LOT
- 25 OF DIFFERENT VIEWS. WE WILL CONTINUE TO STUDY THIS. I

- 1 GUESS ONE ISSUE IS WHERE THE REPOSITORY WOULD BE FOR
- 2 AUTHOR'S MANUSCRIPTS. AND I DON'T KNOW HOW MUCH EFFORT
- 3 IS REQUIRED TO TAKE A MANUSCRIPT AND TURN IT INTO
- 4 SOMETHING TO BE PROUD OF HAVING ON THE WEB. AS AN
- 5 AUTHOR, IS THAT A LOT OF -- I HAVEN'T PUBLISHED A PAPER
- 6 FOR A LONG TIME.
- 7 DR. TJIAN: IT'S WORK.
- 8 MR. OBER: THERE ARE A NUMBER OF
- 9 REPOSITORIES, PUBMED CENTRAL IS ONE THAT NIH WILL USE,
- 10 AND UC HAS A REPOSITORY, E-SCHOLARSHIP REPOSITORY, THAT
- 11 IS PART OF THE SERVICE OFFERED TO CONVERT AUTHOR'S
- 12 MANUSCRIPTS. VARIOUS KINDS OF PUBLISHERS HAVE A
- 13 MANUSCRIPT DEFAULT, WHICH IS PDF, WHICH IS A CONSISTENT
- 14 FORMAT WITH DESCRIPTIVE KINDS OF METADATA AND TAGS
- 15 ALONG WITH IT. THOSE SERVICES ALREADY EXIST AND IT
- 16 WOULD NOT BE MUCH OF A BURDEN, IN MY OPINION, FOR THE
- 17 PRAGMATIC LOGISTICS FOR SUCH A POLICY.
- 18 CHAIRMAN PENHOET: OKAY. WITH THAT, I THINK
- 19 WE'LL MOVE ON TO THE MAIN BODY OF OUR WORK TODAY.
- 20 THANK ALL OF YOU WHO CAME AGAIN TO SHARE YOUR VIEWS ON
- 21 THIS SUBJECT WITH US.
- 22 MOVING RIGHT ALONG, MELISSA, TO THAT SLIDE.
- 23 HERE'S WHERE WE ARE. WE'VE HAD A SERIES OF MEETINGS ON
- 24 THE FOR-PROFIT POLICY ALREADY. WHAT HAS OCCURRED IN
- 25 PREPARATION FOR TODAY'S MEETING IS ESSENTIALLY FLESHING

- 1 OUT THE CONCEPTS THAT WE DEVELOPED AT THE LAST MEETING
- 2 INTO LANGUAGE WHICH IS ESSENTIALLY A PRECURSOR TO WHAT
- 3 WILL BE THE FINAL FORM, HOPEFULLY AFTER THE NEXT ICOC
- 4 MEETING, AND LEAD US INTO THE APA PROCESS, WHICH,
- 5 THROUGH OUR WORK ON THE NONPROFIT PART, WE'RE ALL
- 6 FAMILIAR WITH AT THIS POINT IN TIME.
- 7 SO IF WE CAN GO TO THE NEXT SLIDE. THE NEXT
- 8 ONE, HERE'S WHAT WE'VE DONE SO FAR. WE'VE HEARD FROM
- 9 MANY EXPERTS AND STAKEHOLDERS, AND WE HAVE DONE A LOT
- 10 OF RESEARCH. WHEN I SAY WE, I MEAN MARY. WE DEVELOPED
- 11 THE PRINCIPLES. WE'RE IN THE MIDDLE OF DRAFTING, AND I
- 12 URGE YOU ALL TO TAKE IT IN THAT SENSE. THIS IS A DRAFT
- 13 OF WHAT WE HAVE NOW. IT'S NOT A FINAL DOCUMENT IN ANY
- 14 WAY, SHAPE, OR FORM. WE HOPE THAT IT ACCURATELY
- 15 REFLECTS THE MEETINGS THAT WE'VE HAD TO DATE AND OUR
- 16 ATTEMPT TO PUT IT IN MORE, WHAT SHALL I SAY, SUCCINCT
- 17 LANGUAGE THAT CAN BE USED FOR MOVING US FORWARD IN THE
- 18 AP PROCESS.
- 19 WE WILL MAKE A RECOMMENDATION TO THE ICOC ON
- 20 THE 11TH. IF WE CAN GET TO THAT POINT TODAY, IT WILL
- 21 UNDOUBTEDLY BE REFINED BY THE WHOLE BOARD AND
- 22 ULTIMATELY APPROVED AND THEN SUBMITTED TO THE OAL.
- 23 SO JUST TO REMIND YOU ABOUT THE NEXT SLIDE,
- 24 WE'RE ON PAGE 8 FOR THOSE OF YOU WHO HAVE A COMPUTER IN
- 25 FRONT OF YOU. A NUMBER OF REPORTING REQUIREMENTS ARE

- 1 LISTED HERE. THEY ARE ESSENTIALLY THE SAME AS WHAT WE
- 2 HAVE IN THE NONPROFIT POLICY, I BELIEVE. THAT THEY'LL
- 3 KEEP US INFORMED, THEY'LL SUBMIT ANNUAL REPORTS,
- 4 THEY'LL KEEP US INFORMED ABOUT FILING PATENTS, THAT
- 5 THEY'LL NOTIFY US REGARDING THE ISSUANCE OF PATENTS:
- 6 THAT IF THEY EXECUTE ANY LICENSE AGREEMENTS, THEY WOULD
- 7 LET US KNOW THAT; AND IN THE EVENT REVENUE STREAMS ARE
- 8 CREATED AS A FUNCTION OR CONSEQUENCE OF OUR FUNDING,
- 9 THAT THEY'LL KEEP ACCURATE ACCOUNTS ABOUT HOW MUCH
- 10 MONEY --
- 11 MR. SIMPSON: SECTION III, IF I'M FOLLOWING
- 12 THE DOCUMENT, IS THAT WHAT I'M LOOKING AT?
- 13 CHAIRMAN PENHOET: TERMS AND CONDITIONS, A,
- 14 REPORTING REQUIREMENTS. I'M SORRY. ANY QUESTIONS
- 15 ABOUT THAT?
- 16 WE DO HAVE PUBLICATION REQUIREMENTS, SUCH AS
- 17 IT IS. OKAY. IT DOES CALL FOR THE 500-WORD ABSTRACT
- 18 WITHIN 60 DAYS.
- 19 MS. KING: IF I CAN JUST CATCH UP EVERYBODY
- 20 ON THE PHONE. WE'RE IN ED'S SLIDE DECK, AND WE'RE ON
- 21 SLIDE 9. WHAT WE'RE LOOKING AT IS THE POLICY. WE ARE
- 22 ON PAGE -- DON'T LOOK AT THE POLICY. LOOK AT THE SLIDE
- 23 DECK.
- 24 CHAIRMAN PENHOET: PUBLICATION REQUIREMENTS.
- 25 WE DO HAVE THE REQUIREMENT FOR A 500-WORD ABSTRACT. AS

- 1 DON REED CORRECTLY POINTED OUT, ITS INTENT IS TO PUT IN
- 2 LAY LANGUAGE THE ESSENCE OF THE PAPER AND WHAT IT
- 3 MEANS, ETC., AND HAS THE OTHER THINGS. WE TALKED ABOUT
- 4 THE BIOGRAPHICAL SKETCH, ETC.
- 5 A COPY OF EACH PUBLICATION HAS TO BE
- 6 SUBMITTED. THEY HAVE TO ACKNOWLEDGE OUR FUNDING AND
- 7 ETC. WITH RESPECT TO WHAT THEY PUBLISH. SO THAT'S ALSO
- 8 ESSENTIALLY THE SAME AS WHAT WE HAD IN THE NONPROFIT.
- 9 MR. SIMPSON: ARE YOU GOING TO TAKE QUESTIONS
- 10 ON SOME OF THIS?
- 11 CHAIRMAN PENHOET: WE SHOULD DO IT AS WE GO
- 12 THROUGH IT. ANY QUESTIONS ABOUT THE PUBLICATION
- 13 REQUIREMENTS OR COMMENTS FROM OUR TASK FORCE MEMBERS?
- 14 IF NOT, COMMENTS FROM THE AUDIENCE IN SAN FRANCISCO.
- MR. JENSON: DAVID JENSON, CALIFORNIA STEM
- 16 CELL REPORT. MARY INDICATED THAT THERE MAY BE A
- 17 DIFFERENCE BETWEEN THE SLIDES AND THE DOCUMENT. ARE
- 18 THOSE SIGNIFICANT, OR ARE THEY GOING TO BE POINTED OUT?
- 19 DR. MAXON: SO THE DOCUMENT IS A DRAFT. AND
- 20 THANKS TO MR. SIMPSON AND OTHERS WHO SAID, HEY, YOU
- 21 FORGOT TO PUT THIS IN SECTION III, THERE ARE A COUPLE
- 22 OF MINOR CHANGES, AND WE WILL PUT THESE INTO THE DRAFT
- ON THE WEB.
- MR. JENSON: THEY' RE NOT SIGNIFICANT ONES.
- 25 CHAIRMAN PENHOET: SIGNIFICANT IS IN THE EYE

- 1 OF THE BEHOLDER.
- 2 MR. SIMPSON: DO YOU INTEND AT ALL TO DISCUSS
- 3 THE, I GUESS, SECTION 1?
- 4 CHAIRMAN PENHOET: THE PREAMBLE.
- 5 MR. SIMPSON: AND, FOR INSTANCE, THERE'S A
- 6 RATHER LONG DISCUSSION, VERY USEFUL, ABOUT WHAT
- 7 HAPPENED WITH THE CRADA'S, WHICH RELATES TO PRICING AND
- 8 SOME THINGS LIKE THAT. AND THERE'S SOME POINTS THAT I
- 9 MIGHT WANT TO MAKE ABOUT THAT AT THE APPROPRIATE TIME.
- 10 CHAIRMAN PENHOET: WE CAN RETURN TO THAT IF
- 11 WE GET THROUGH THIS PART.
- 12 THE NEXT ISSUE IS PUBLICATION-RELATED
- 13 BIOMEDICAL MATERIALS REQUIREMENTS. THIS ONE IS A
- 14 LITTLE DIFFERENT THAN WHAT WE HAVE FOR THE NONPROFIT.
- 15 UNLESS A SPECIAL CASE CAN BE MADE THAT DOING SO WOULD
- 16 ENDANGER THE COMPETITIVE POSITION OF THE COMPANY, I
- 17 WANT TO STOP THERE. THIS IS ONE OF THOSE THINGS THAT A
- 18 CASE WILL HAVE TO BE MADE. AS I REMEMBER, SOMEONE WILL
- 19 HAVE TO JUDGE THAT IT'S A FUNCTION THAT WE WOULD HAVE
- 20 TO FUND CIRM TO HAVE THIS KIND OF OVERSIGHT.
- 21 HAVING SAID THAT, AN AWARDEE SHALL SHARE
- 22 BIOMEDICAL MATERIALS IN PUBLISHED SCIENTIFIC ARTICLES
- 23 FOR RESEARCH PURPOSES IN CALIFORNIA WITHIN 60 DAYS,
- 24 BLAH, BLAH, BLAH.
- 25 SO UNDER SPECIAL CIRCUMSTANCES, SAME THING,

- 1 EXCEPTIONS ARE POSSIBLE WITH APPROVAL BY CIRM. AND THE
- 2 REST OF THIS IS SIMILAR TO WHAT WE HAD IN THE
- 3 NONPROFITS. IF REQUESTS BECOME BURDENSOME, THE PEOPLE
- 4 CAN MEET THIS REQUIREMENT BY TEACHING OTHERS HOW TO
- 5 CREATE FOR THEMSELVES THE REAGENTS THAT ARE INVOLVED IN
- 6 THIS. I BELIEVE THAT SOME COMPANIES MIGHT SEE THIS AS
- 7 AN UNACCEPTABLE BURDEN, BUT WE HAVE NOT -- WE EXPECT TO
- 8 HEAR COMMENTS GOING FORWARD. I THINK MANY, HOWEVER,
- 9 ARE QUITE WILLING TO SHARE THESE THINGS IF IT DOESN'T
- 10 ENDANGER THEIR COMPETITIVE POSITION.
- 11 ANY COMMENTS FROM BOARD MEMBERS ON THIS
- 12 SECTION?
- 13 MR. ROTH: I THINK THIS WILL BE AN IMPEDIMENT
- 14 TO INDUSTRY TO SEEK CIRM FUNDS. I THINK IT'S VAGUE,
- 15 AND THE REQUIREMENTS ARE THINGS THAT CAN BE INTERPRETED
- 16 TO MEAN YOU HAVE TO MAKE THESE AVAILABLE AT NO COST TO
- 17 ANYBODY THAT ASKS. AND I THINK THAT WOULD BE AN
- 18 UNUSUAL REQUIREMENT FOR HAVING ACCEPTED GRANT MONEY. I
- 19 THINK JUST AS A POTENTIAL ISSUE, I'D LIKE TO HEAR, IF
- THERE ARE INDUSTRY PEOPLE THERE, WHAT THEIR RESPONSE
- 21 IS.
- 22 CHAIRMAN PENHOET: WE HAVE ANYBODY FROM
- 23 INDUSTRY? I THINK THAT THE NO COST ISSUE, THAT THERE
- 24 HAS TO BE A REASONABLENESS SECTION IN THERE. IT SAYS
- 25 THAT THEY CAN SHOW SOMEONE HOW TO DO IT THEMSELVES. IT

- 1 DOESN'T FORCE THEM TO MAKE THE MATERIALS --
- DR. HALL: WITHOUT OR AT COST. DOESN'T SAY
- 3 YOU CAN'T CHARGE WHAT IT COST AS I INTERPRET IT.
- 4 CHAIRMAN PENHOET: AT COST. THIS IS NOT
- 5 SOMETHING WHERE WE WILL WILLINGLY ENGAGE THOUSANDS OF
- 6 USERS TO DO THIS AS A PUBLIC SERVICE EVEN AT COST. I
- 7 THINK THERE MAY BE SOME MORE DISCUSSION ON THIS ISSUE
- 8 AS WE GO FORWARD.
- 9 ANY OTHER COMMENTS FROM THE AUDI ENCE?
- 10 DR. HALL: CAN I JUST MAKE A GENERAL POINT
- 11 HERE? IT SEEMS TO ME THAT THERE'S A POINT OF
- 12 CONFUSION, I HATE TO GO BACK TO THIS, ALSO REMAINING IN
- 13 OUR DISCUSSION ABOUT NONPROFITS. THE QUESTION OF
- 14 SHARING AND SHARING OF KNOWLEDGE IS ONE THING, AND
- 15 SHARING OF REAGENTS, I DON'T THINK ANYBODY INTENDS THAT
- 16 IF YOU DISCOVER SOMETHING, YOU'VE GOT TO PROVIDE OR
- 17 YOU' VE GOT TO BE A SUPPLIER FOR EVERY RESEARCHER IN THE
- 18 WORLD WHO WANTS TO USE IT.
- 19 CHAIRMAN PENHOET: THAT'S A PROBLEM WITH BOTH
- 20 POLICIES.
- DR. HALL: WE NEED SOME WAY TO DEFINE THAT SO
- 22 THAT YOUR -- I THINK THEY ARE EXPECTED TO PROVIDE SMALL
- 23 SAMPLES, IF POSSIBLE, SO THAT PEOPLE CAN REPRODUCE YOUR
- 24 WORK AND THINGS CAN MOVE FORWARD, NOT TO TURN INTO A
- 25 SUPPLIER. HOW IS THAT -- I DON'T QUITE KNOW. THE

- 1 OTHER REFERS TO THE TERM "REASONABLE," BUT I THINK
- 2 THERE'S ALSO A MISUNDERSTANDING AS WELL THAT SOMEHOW
- 3 WE'RE EXPECTING PEOPLE TO, AT LEAST ON THE PART OF
- 4 SOME, A MISUNDERSTANDING ABOUT EXPECTING PEOPLE TO BE A
- 5 MAJOR SUPPLIER. IF YOU'VE GOT AN ANTIBODY, YOU'VE GOT
- 6 TO PROVIDE IT EVEN IF YOU DON'T HAVE ANY LEFT FOR
- 7 YOURSELF.
- 8 CHAIRMAN PENHOET: WHICH IS UNREASONABLE --
- 9 DR. HALL: THAT'S UNREASONABLE.
- 10 CHAIRMAN PENHOET: -- FOR A COMPANY OR
- 11 ACADEMIA.
- DR. HALL: MAYBE A LITTLE INTENSIVE THOUGHT
- AND WORDSMITHING ON THAT FOR BOTH POLICIES BEFORE THE
- 14 I COC MEETING MIGHT BE USEFUL, I DON'T KNOW, BUT
- 15 CERTAINLY TO GO THROUGH IT SO THAT EVERYBODY
- 16 UNDERSTANDS THE INTENT AND THE PURPOSE OF THIS AND THEN
- 17 TRIES TO MEET THAT THROUGH WHATEVER LANGUAGE WE CAN
- 18 CRAFT.
- 19 MR. ROTH: I ALSO WANT TO REITERATE WHAT YOUR
- 20 POSITION WAS, THAT THIS IS GOING TO BE BURDENSOME IF WE
- 21 ADOPT SOMETHING LIKE THIS WHERE WE HAVE TO HAVE STAFF
- 22 REFEREE AND MAKING DECISIONS. I THINK WE HAVE TO THINK
- 23 ABOUT THAT. MAYBE ONE OF OUR BIGGEST CHALLENGES AT
- 24 CIRM WILL BE THE BURDEN STAFF INHERITS GIVEN THE
- 25 RESTRICTION ON FUNDING.

- 1 DR. HALL: I'M NOT SURE ON THAT PARTICULAR
- 2 ONE. I'M VERY CONCERNED IN BOTH POLICIES. A MAJOR
- 3 CONCERN OF MY MINE IS THAT MATERIALS AND IDEAS AND
- 4 TECHNOLOGIES FLOW FREELY ON THE RESEARCH SIDE OF THINGS
- 5 WITHIN THE RESEARCH COMMUNITY. IT'S A DIFFERENT MATTER
- 6 ONCE YOU CROSS THE BARRIER INTO COMMERCIAL DEVELOPMENT.
- 7 AT LEAST FOR RESEARCH, THAT THERE NOT BE THINGS THAT
- 8 ARE SORT OF LOCKED UP AND PUT OUT OF PLACE. I THINK
- 9 IT'S THE IDEA THAT WE EXPECT MATERIALS TO BE SHARED AS
- 10 THE DEFAULT CASE UNLESS THERE'S A COMPETITIVE POSITION,
- 11 I THINK.
- 12 CHAIRMAN PENHOET: WE CAN PUT LANGUAGE IN
- 13 THAT IF COST BECOMES ONEROUS OR SOMETHING LIKE THAT.
- DR. HALL: SOMETHING LIKE THAT, YES. BUT MY
- 15 SENSE IS THAT THIS IS A VERY, VERY IMPORTANT THING.
- 16 WE'RE GOING TO PUT MONEY IN TO DEVELOP REAGENTS OR
- 17 THINGS CERTAINLY LOCKED AWAY FOR RESEARCH, NOT FOR
- 18 COMMERCIAL DEVELOPMENT, BUT FOR RESEARCH, AND I THINK
- 19 WE OUGHT TO DO EVERYTHING WE CAN TO KEEP THOSE LINES OF
- 20 SUPPLY OPEN TO MAKE IT AS PERMEABLE AS POSSIBLE AS
- 21 AMONG DIFFERENT INSTITUTIONS AND LABORATORIES.
- 22 CHAIRMAN PENHOET: MAYBE WE CAN DO SOME
- 23 HOMEWORK ON THE PRACTICALITIES OF THIS. A NUMBER OF
- 24 THE TYPE OF JOURNALS WE'VE BEEN TALKING ABOUT HAVE
- 25 REQUIREMENTS TO ACTUALLY SHARE THE STUFF IN SOME WAY,

- 1 SHAPE, OR FORM.
- OKAY. MOVING ALONG TO D, PAGE 11, NO. 11 IN
- 3 THE SLIDE DECK, PATENT APPLICATIONS. THIS SAYS THAT
- 4 THE PEOPLE WHO GET THE MONEY, IF THEY FILE FOR PATENTS,
- 5 THEY OWN THEM. AND THEY HAVE TO REPORT TO US ABOUT
- 6 THEIR PATENTED FILINGS. AND WE AGREED IN THE LAST
- 7 SENTENCE TO KEEP THIS CONFIDENTIAL IN ORDER TO HAVE
- 8 THESE PATENT FILINGS EXEMPTED FROM THE PUBLIC RECORDS
- 9 ACT. THAT'S A -- I THINK ANYTHING SHORT OF THIS WOULD
- 10 PROBABLY BE A TRULY ONEROUS REQUIREMENT ON INDUSTRY.
- 11 MR. SIMPSON: PATENTS DO BECOME PUBLIC WHEN
- 12 THEY I SSUE.
- 13 CHAIRMAN PENHOET: OF COURSE, YES.
- 14 MR. SIMPSON: ANOTHER COMMENT ON THIS
- 15 SECTION? I THINK IT'S RELEVANT IN THIS SECTION. I'M
- 16 NOT SURE. AND THAT IS THAT IF YOU LOOK AT THE
- 17 BAYH-DOLE MODEL OR YOU LOOK AT NIH, WHILE IT'S THE CASE
- 18 THAT THE GRANTEE OWNS THE IP AND DEVELOPS IT AND
- 19 COMMERCIALIZES IT. THE GOVERNMENT MAINTAINS A RIGHT TO
- 20 PRACTICE THE INVENTION FOR ITS OWN GOVERNMENTAL
- 21 PURPOSES. AND I WOULD SUGGEST THAT THERE SHOULD BE A
- 22 SIMILAR PROVISION HERE, THAT WHILE THE AWARDEE GETS THE
- 23 IP, THAT CALIFORNIA RESERVES THE RIGHT TO PRACTICE THE
- 24 INVENTION FOR ITS GOVERNMENTAL PURPOSES. IT'S
- 25 COMPLETELY ANALOGOUS TO THE BAYH-DOLE AND THE FEDERAL

- 1 FUNDING MODEL.
- 2 CHAIRMAN PENHOET: WELL, I GUESS IN ONE SENSE
- 3 IT IS TRUE, BUT THE GOVERNMENT HAS ITS OWN RESEARCH
- 4 LABORATORIES. I DON'T THINK THE GOVERNMENT HAS EVER
- 5 INTERPRETED THAT THEY COULD GO INTO THE BUSINESS OF
- 6 MAKING AND SELLING SOMETHING.
- 7 MR. SIMPSON: THAT'S NOT WHAT I'M SUGGESTING.
- 8 THEY PRESUMABLY HAVE SOME STATE LAB THAT WOULD WANT TO
- 9 PRACTICE THE INVENTION FOR RESEARCH PURPOSES.
- 10 CHAIRMAN PENHOET: BACK INTO THE RESEARCH USE
- 11 EXEMPTION DISCUSSION.
- MR. MACFERRIN: KURTIS MACFERRIN, APPLIED
- 13 BLOSYSTEMS. SO JUST SPEAKING TO THAT LAST POINT AND
- 14 DR. HALL'S PREVIOUS POINT ABOUT BIOMEDICAL MATERIALS,
- 15 FROM OUR POINT OF VIEW, AS A PROVIDER OF RESEARCH
- 16 TOOLS, WE DEFINITELY WANT TO ASSURE RESEARCH TOOLS TO
- 17 RESEARCHERS. MY CONCERN ABOUT THE LAST PROVISION FOR
- 18 BIOMEDICAL MATERIALS AND THE PROPOSAL BY MR. SIMPSON ON
- 19 MAKING TOOLS AVAILABLE TO THE GOVERNMENT AND RETAINING
- 20 RESEARCH RIGHTS IS YOU DON'T ENSURE SUPPLY OF SOMETHING
- 21 BY KEEPING ANYBODY FROM MAKING MONEY OFF OF PROVIDING
- 22 IT.
- SO, FOR EXAMPLE, CAR MANUFACTURERS, YOU DON'T
- 24 ENSURE THE SUPPLY OF CARS BY SAYING THAT CAR MAKERS
- 25 CAN'T MAKE A PROFIT.

- 1 THE PROBLEM THAT I SEE POTENTIALLY WITH THE
- 2 BIOMEDICAL TOOL SHARING IS NOBODY CAN MAKE MONEY OFF OF
- 3 PROVIDING THOSE BIOMEDICAL MATERIALS. FOR EXAMPLE, YOU
- 4 COME UP WITH A POLYMERASE ENZYME THAT HAS SOME
- 5 PROPERTY, YOU PUBLISH IT, AND YOU COME UP WITH IT USING
- 6 CIRM FUNDING. IF YOU CAN'T MAKE MONEY OFF OF PROVIDING
- 7 IT TO PEOPLE, NO ONE WILL GO INTO THAT BUSINESS.
- 8 THAT'S MY CONCERN.
- 9 DR. HALL: THESE ARE REAL ISSUES, ED. THESE
- 10 REALLY ARE REAL ISSUES, AND I ACTUALLY FIND IT VERY
- 11 TROUBLING. AND I THINK THE VARIOUS EXAMPLES OF WHAT
- 12 COULD HAPPEN AND WHAT MIGHT HAPPEN, ONE POSSIBILITY IS
- 13 THAT A LOT OF THESE THINGS ON THE FOR-PROFIT SIDE FOR
- 14 NEGOTIATING OF THE CONTRACT, WE'VE SAID ALL ALONG THAT
- 15 IT WOULD BE POSSIBLE TO MAKE SOME BROAD OUTLINES, BUT
- 16 WE HAVE TO SIT DOWN. IF THERE'S A CONTRACT OR GRANT OR
- 17 LOAN, WHATEVER IT IS, IT SEEMS TO ME WE ALMOST HAVE TO
- 18 SIT DOWN AND SAY, WELL, ONE EXPECTED OUTCOME OF THIS IS
- 19 SUPPOSE WE WERE TO PUT OUT MONOCLONAL ANTIBODIES AND
- 20 ASK SOMEBODY TO DEVELOP THESE. AND IT SEEMS TO ME THAT
- 21 WE CERTAINLY WOULD NOT EXPECT A COMPANY TO DEVELOP THE
- 22 NEW MONOCLONAL AND PROVIDE IT FREE FOR RESEARCH TO
- 23 EVERYBODY.
- ON THE OTHER HAND, IT SEEMS TO ME WE WOULD
- 25 EXPECT THEM TO PROVIDE AT LEAST THE DETAILS OF THE

- 1 METHODS OF HOW THEY DID IT. SO IF SOMEBODY WANTED TO
- 2 GO AND MAKE THE MONOCLONAL ANTIBODIES, THEY COULD
- 3 PRESUMABLY MAKE MONEY, NOT BECAUSE YOU HAVE A MONOPOLY,
- 4 BUT BECAUSE THEY CAN DO IT MORE CHEAPLY THAN ANYBODY
- 5 ELSE. AND IT'S WORKED TIME AND AGAIN IN THE RESEARCH
- 6 COMMUNITY. SO THERE ARE A NUMBER OF DIFFERENT
- 7 EXAMPLES. I MYSELF FIND IT HARD TO THINK ABOUT ALL THE
- 8 DIFFERENT POSSIBILITIES WITHOUT ACTUALLY SITTING DOWN
- 9 AND GOING THROUGH THEM AND ALMOST SAYING HERE IS A
- 10 SCENARIO. WHAT DO WE WANT TO HAPPEN HERE? WHAT DO WE
- 11 NOT WANT TO HAPPEN? AND HOW DO WE MAKE IT WORK?
- 12 CHAIRMAN PENHOET: SO ON YOUR SIDE OF THE
- 13 ARGUMENT, WE'VE HEARD FROM MOST OF THE OTHER FUNDERS OF
- 14 COMPANIES THAT EVERY GRANT IS UNIQUE AND THEY NEGOTIATE
- 15 EVERY ONE. HAVING SAID THAT, I THINK ONE OF THE THINGS
- 16 WE TALKED ABOUT AT THE FIRST MEETING WAS TO TRY TO HAVE
- 17 AS DISCRETE GUIDELINES AS WE CAN. OTHERWISE WE DON'T
- 18 HAVE ENOUGH STAFF HERE TO MAKE INDIVIDUAL DEALS WITH
- 19 MORE THAN A FEW HANDFUL OF COMPANIES. BECAUSE, YOU
- 20 KNOW, WE HEARD THAT WELLCOME TRUST HAS 15 PEOPLE, 15 OR
- 21 20 PEOPLE THAT MAKE \$25 MILLION IN GRANTS A YEAR, ETC.,
- 22 TO MANAGE THIS, AND THAT IT TAKES SIX MONTHS TO A YEAR
- 23 TO NEGOTIATE EACH CONTRACT BECAUSE THEY'RE EACH DONE AB
- 24 INITIO.
- 25 AND SO THE OTHER PRINCIPLE WE'RE TRYING TO

- 1 GET TO IS TO DEFINE ENOUGH OF THE PARAMETERS SO THAT
- 2 THEY'RE WELL UNDERSTOOD AND WE DON'T HAVE TO NEGOTIATE
- 3 A YEAR WITH EACH COMPANY IN ORDER TO GET SOME FUNDING
- 4 TO THEM. BALANCE IS A HARD ISSUE. BUT I THINK WE CAN
- 5 AGREE THERE IS NO INTENT HERE TO FORCE COMPANIES TO
- 6 PROVIDE THEIR GOODS AND SERVICES FREE TO THE ENTIRE
- 7 RESEARCH COMMUNITY.
- 8 MR. MACFERRIN: TO PROVIDE THEM AT COST, BUT
- 9 NO MORE IS ALSO A PROBLEM.
- 10 CHAIRMAN PENHOET: SURE.
- 11 MR. TAYMOR: FOLLOWING ON THAT, I GUESS THERE
- 12 ARE TWO COMMENTS FOLLOWING ON THAT. FOLLOWING ON WHAT
- 13 JOHN SIMPSON HAD SAID, I'M NOT SURE IF IT'S APPROPRIATE
- 14 HERE OR ELSEWHERE. THIS QUESTION OF RESEARCH USE
- 15 EXEMPTION AND WHETHER OTHER CALIFORNIA INSTITUTIONS OR
- 16 OTHER NONPROFITS SHOULD BE ALLOWED TO USE CIRM-FUNDED
- 17 RESEARCH, WHETHER THAT RESEARCH IS FUNDED IN THE
- 18 FOR-PROFIT COMMUNITY OR THE NONPROFIT COMMUNITY, FOR
- 19 RESEARCH PURPOSES. IT SEEMS THAT SIMILAR PROBLEMS
- 20 ARISE IN THE RESEARCH EXEMPTION IN THE NONPROFIT WORLD
- 21 AS ARISE IN THE FOR-PROFIT WORLD AS WERE EVIDENCED BY
- 22 THE DEBATE THAT TOOK PLACE AROUND THE NONPROFIT
- 23 RESEARCH EXEMPTION.
- 24 SO THERE'S NO MENTION OF THAT HERE, AND I
- 25 WOULD SECOND THE COMMENTS OF MR. SIMPSON, THAT IT IS

- 1 CONSIDERED. SPINNING OFF OF THAT AND ALONG THOSE
- 2 LINES, WE'RE TALKING HERE ABOUT A CERTAIN TYPE OF
- 3 INTELLECTUAL PROPERTY PATENTS, BUT THERE'S A LOT OF
- 4 OTHER TYPES OF INTELLECTUAL PROPERTY THAT MAY EMERGE,
- 5 PARTICULARLY ONCE YOU MOVE INTO THE WORLD OF FUNDING
- 6 FOR-PROFITS, AS WE DESCRIBED AT SOME OF THE MEETINGS
- 7 HELD BY CIRM AND SOME OF THE STRATEGIC PLANNING
- 8 MEETINGS. SO, FOR EXAMPLE, IF COMPANIES NEEDED SOME
- 9 PRE-IND WORK IN ORDER TO DEVELOP, WITH THE FDA OR
- 10 OTHERWISE, PROTOCOLS FOR SUBMISSIONS TO FDA CERTAIN
- 11 TYPES OF CELL THERAPIES, THERE'S A LOT OF INFORMATION
- 12 THAT'S BEEN CREATED BY THAT PROCESS AND IGNORED BY
- 13 THESE POLICIES.
- 14 IT'S NOT TO SAY THE POLICIES -- I UNDERSTAND
- 15 THERE'S A LOT IN THESE POLICIES, BUT ONLY TO SAY THAT
- 16 PERHAPS WE NEED TO HAVE POLICIES THAT EXTEND BEYOND
- 17 THAT. WE COULD VERY WELL BE IN A SITUATION OF PAYING
- 18 MULTIPLE TIMES FOR THE SAME KIND OF RESEARCH BEING
- 19 DONE. AND ALSO THAT THE PROCESS OF GETTING RESEARCH.
- 20 INTO THE DEVELOPMENT STAGE, INTO THE IND STAGE, AND
- 21 INTO THE CLINIC IS SEVERELY SLOWED DOWN. I'M NOT SURE
- 22 IF WE HAVE PLANS TO ADDRESS THOSE OR A RECOMMENDATION
- 23 HAS BEEN MADE JUST NOT TO ADDRESS THEM BECAUSE THEY
- 24 CAN'T BE OR WHAT. THIS IS A MEMBER OF THE PUBLIC
- 25 CURIOUS ON THAT.

- 1 LASTLY, ON DR. HALL'S POINT ABOUT MAYBE ONE
- 2 SIZE FITS ALL DOESN'T WORK, I UNDERSTOOD FROM THE
- 3 STRATEGIC PLAN MEETINGS THAT THERE SEEMS TO BE SHAPE
- 4 TAKING PLACE IN TERMS OF HOW -- WHAT FOCUS CIRM IS
- 5 GOING TO BE HAVING WITH ITS FUNDING, WHERE THEY'RE
- 6 PUTTING THEIR FUNDING EFFORTS. AND WHILE IT MAY BE
- 7 DIFFICULT TO COME UP WITH A POLICY FOR EVERY KIND OF
- 8 GRANT AND EVERY KIND OF CONTRACT, IT MAY BE QUITE
- 9 DOABLE TO HAVE A MATRIX WHERE YOU HAVE POLICIES
- 10 TAILORED TO NINE AREAS OF PARTICULAR FOCUS THAT CIRM
- 11 WILL BE PURSUING FOR ITS STRATEGIC PLANNING PROCESS.
- 12 AND THE STRATEGIC PLANNING GROUP MAY HAVE NARROWED THE
- 13 RANGE OF ALTERNATIVES, AND YOU MAY BE ABLE TO COME UP
- 14 WITH A FAIRLY DOABLE PROCESS FOR COMING UP WITH
- 15 APPROPRIATE TYPES OF GRANTS WHERE THIS SHARING IS
- 16 APPROPRIATE AND THOSE GRANTS WHERE THE SHARING IS NOT
- 17 APPROPRI ATE.
- 18 CHAIRMAN PENHOET: BACK UP ONE SLIDE, THE
- 19 PUBLICATION-RELATED ONES. I THINK AN UNINTENDED
- 20 CONSEQUENCE OF THIS PROPOSAL MIGHT BE TO ACTUALLY
- 21 ENCOURAGE COMPANIES NOT TO PUBLISH. BECAUSE IF THEY
- 22 HAVE A TRADE SECRET, THEN THEY WOULDN'T HAVE THE
- 23 OBLIGATION TO NOTIFY ON THE PUBLICATION-RELATED
- 24 MATERIALS. THAT'S CERTAINLY NOT SOMETHING WE WANT TO
- 25 ENCOURAGE EITHER NECESSARILY. YOUR POINT IS GETTING

- 1 THE INFORMATION.
- 2 MR. TAYMOR: THAT'S MY POINT. TRADE SECRETS,
- 3 COPYRIGHT MATERIALS, THERE'S A WHOLE RANGE OF
- 4 INTELLECTUAL PROPERTY THAT'S GENERATED BY THE TYPE OF
- 5 COMMERCIAL GRANTS THAT CIRM HAS CONTEMPLATED, AND
- 6 THEY'RE NOT ADDRESSED IN THIS POLICY. IT'S NOT TO SAY
- 7 THE POLICY -- THIS POLICY DOESN'T GO FAR ENOUGH IN
- 8 AREAS WHERE I THINK IT'S GOING TO BE VERY, VERY
- 9 CRITICAL WHERE INTELLECTUAL PROPERTY IS BEING PRODUCED.
- 10 AND IT WOULD BE USEFUL TO SEE WHY IT WAS INTENTIONALLY
- 11 OMITTED OR HOW THEY MIGHT BE ADDRESSED.
- 12 CHAIRMAN PENHOET: WELL, YOU KNOW, NOW JUST
- 13 SPEAKING AS AN INDIVIDUAL HERE, I THINK THE PROBLEM
- 14 WHEN YOU GET -- YOU CAN SPECIFY COPYRIGHT. WHEN YOU
- 15 GET INTO TRADE SECRET, THERE'S NO WAY TO DEFINE IT. SO
- 16 YOU ESSENTIALLY ARE ASKING AN ORGANIZATION TO OPEN
- 17 THEMSELVES TOTALLY UP TO ALL THE INFORMATION THAT YOU
- 18 SEEK TO KNOW ABOUT THEM BECAUSE, YOU KNOW, THERE'S
- 19 NO -- NOBODY SAYS PUT IN A -- THESE ARE OUR TRADE
- 20 SECRETS IN THIS DRAWER HERE. THAT DOESN'T HAPPEN. SO
- 21 TRADE SECRETS ARE SORT OF THE ESSENCE OF MANY
- 22 FOR-PROFIT ORGANIZATIONS. SO I DON'T KNOW HOW YOU
- 23 WOULD EVER DEFINE THAT IN A WAY THAT YOU CAN GET YOUR
- 24 ARMS AROUND.
- 25 MR. TAYMOR: ONE WAY, FOR EXAMPLE, IF YOU'RE

- 1 GIVING A GRANT FOR PRE-IND WORK, THAT YOU SPECIFY WHAT
- 2 KIND OF RESULTS ARE GOING TO BE SHARED. OR IF YOU'RE
- 3 GIVING A GRANT THAT'S GOING TO BE CREATING A DATABASE,
- 4 THAT DATABASE MAY BE PUBLISHED, AND A COPYRIGHT OR
- 5 DATABASE MAY BE RETAINED AND TRADE SECRET. ALL YOUR
- 6 TRADE SECRETS ARE UNDER THIS GRANT, CONTRACT, LOAN, OR
- 7 THIS KIND OF INFORMATION WILL BE MADE AVAILABLE IN THIS
- 8 WAY. AND SO YOU CERTAINLY CAN IDENTIFY THOSE TRADE
- 9 SECRETS BY LICENSING.
- 10 QUITE COMMONLY A LICENSE IS ACCOMPANIED BY A
- 11 KNOW-HOW AGREEMENT. THE KNOW-HOW IS A TRADE SECRET
- 12 KEPT CONFIDENTIAL THROUGH A CONFIDENTIALITY AGREEMENT,
- 13 BUT IT'S CRITICAL FOR THE LICENSEE TO RECEIVE THE
- 14 KNOW-HOW IN ORDER FOR THE LICENSEE TO KNOW THAT WHICH
- 15 IS TRADE SECRET IN ORDER TO EXPLOIT THE LICENSED
- 16 INFORMATION. SO IT'S VERY COMMONLY DONE IN THE
- 17 INDUSTRY AND COULD BE TRANSFERRED AND CARRIED OVER
- 18 HERE.
- 19 CHAIRMAN PENHOET: DON REED.
- 20 MR. REED: I WONDER IF A LOT OF THIS IS TAKEN
- 21 CARE OF AT THE PROPOSAL STAGE WHERE A COMPANY MIGHT --
- 22 FOR INSTANCE, OUR MONEY DEPENDS ON OUR NOT BEING ABLE
- 23 TO COMPLY WITH THIS PARTICULAR PORTION; AND, THEREFORE,
- 24 WHEN THE DECISION IS MADE TO FUND OR NOT TO FUND, WE
- 25 MIGHT SAY THIS LOOKS TOO COMPLICATED. LET'S NOT FUND

- 1 IT. IT'S SELF-INCENTIVE FOR THEM TO WORK OUT SOME
- 2 COMPROMISES ON THEIR OWN TIME.
- 3 CHAIRMAN PENHOET: OWN TIME ENDS UP BEING OUR
- 4 TIME TOO.
- 5 MR. REED: BEFORE THE PROPOSAL. THEY WOULD
- 6 DECIDE, WELL, OUR BUSINESS DEPENDS ON OUR BEING ABLE TO
- 7 TAKE THIS PARTICULAR PRODUCT AND SELL IT, AND WE CANNOT
- 8 POSSIBLY AFFORD TO SHARE IT AT COST OR WHATEVER. AND
- 9 THEY KNOW THIS BEFORE AND SAY THIS BEFOREHAND. PEOPLE
- 10 MAKING THE DECISION TO FUND OR NOT TO FUND WOULD KNOW
- 11 BEFOREHAND.
- 12 CHAIRMAN PENHOET: UH-HUH. YOU KNOW,
- 13 INEVITABLY IT'S CONTRACT UNIQUE WITH A DIFFERENT PARTY
- 14 ON THE OTHER SIDE OF THE TABLE. I THINK OUR GOAL HERE
- 15 IS TO FIND SOME REASONABLE BALANCE BETWEEN SOME SORT OF
- 16 BROAD PRINCIPLES THAT WE'RE TRYING TO ESTABLISH HERE
- 17 AND THE IMPLEMENTATION OF THOSE BY CIRM IN A WAY THAT
- 18 TAKES INTO ACCOUNT THE, YOU KNOW, INDIOSYNCRACIES OF
- 19 THE MARKETPLACE OUT THERE. AND DIFFERENT ORGANIZATIONS
- 20 HAVE DIFFERENT POINTS OF VIEW.
- 21 I THINK ALSO WE HAVE TO KEEP IN MIND WHAT
- 22 WE'RE TRYING TO BALANCE IS PUBLIC INTEREST, OUR
- 23 INTEREST, BUT AT THE SAME TIME NOT DISCOURAGE COMPANIES
- 24 FROM TAKING ADVANTAGE OF THESE MONIES TO FURTHER THEIR
- 25 EFFORTS IN THE STEM CELL AREA BECAUSE CALIFORNIA'S

- 1 FUTURE IS HIGHLY DEPENDENT ON A VIBRANT STEM CELL
- 2 INDUSTRY HERE IN THIS FIELD. THE MONEY HAS TO BE SPENT
- 3 IN CALIFORNIA. SO IT'S THAT BALANCE.
- 4 MR. REED: ISN'T IT THE COMPANIES THEMSELVES
- 5 THAT KNOW EXACTLY WHAT THIS IS AND WE CANNOT KNOW
- 6 BEFOREHAND? SO I DON'T THINK WE CAN PRESCRIBE FOR
- 7 INDIVIDUALS WHEN THEY'RE THE ONLY INDIVIDUALS THAT HAVE
- 8 THEIR PARTICULAR INFORMATION. I DON'T THINK WE CAN
- 9 MAKE A ONE SIZE FITS ALL SITUATION HERE.
- 10 CHAIRMAN PENHOET: I AGREE WITH YOU. HAVING
- 11 SAID THAT, I DO THINK BROAD PRINCIPLES GENERALLY
- 12 ACCEPTED IN THE INDUSTRY, KEN IS RIGHT, USUALLY A
- 13 LICENSE, A PATENT TO TELL THEM HOW TO PRACTICE THE ART
- 14 TO LURE THEM TO ACTUALLY DO SOMETHING USEFUL WITH IT.
- 15 HOW WE WOULD BEGIN TO HAVE POLICIES ABOUT WHAT
- 16 KNOW-HOW, A BROAD POLICY TO SAY WHAT KNOW-HOW WOULD
- 17 FORCE COMPANIES TO DIVULGING TO OTHERS NOT OTHERWISE
- 18 PATENTABLE, ETC. IS VERY HARD TO DESCRIBE THAT EXCEPT
- 19 ON A CASE-BY-CASE BASIS.
- 20 MR. ROTH: AGAIN, JUST LISTENING TO THE
- 21 DISCUSSION THAT'S GOING ON AND REALIZING HOW
- 22 COMPLICATED THIS IS, ONE THING WE CAN CONSIDER IS TO
- 23 LAY DOWN A SET OF EXPECTATIONS FOR GRANT RECIPIENTS
- 24 REGARDING PUBLICATION AND REGARDING THEIR MATERIALS
- 25 AVAILABILITY CLAUSE, WHICH CAN BE A SET OF PRINCIPLES

- 1 THAT WE WOULD RECOMMEND. AND THAT TO ENFORCE IT, WE
- 2 WOULD TAKE THAT INTO CONSIDERATION IN THE BID PACKAGES
- 3 OR FOLLOWING THAT POLICY OR THOSE EXPECTATIONS FOR
- 4 FUTURE GRANTS.
- 5 SO SOMEBODY GETS A MILLION DOLLAR-GRANT AND
- 6 CIRM RECEIVES A NUMBER OF COMPLAINTS ABOUT X, Y, Z
- 7 COMPANY NOT SHARING INFORMATION OR WITHHOLDING
- 8 INFORMATION OR BEING UNCOOPERATIVE. THAT WOULD GO INTO
- 9 CONSIDERATION FOR ANY FUTURE GRANTS. ANY ONE GRANT
- 10 WE'RE GOING TO BE GIVING TO A COMPANY IS NOT GOING TO
- 11 BE EXTRAORDINARY, AND WHAT THEY REALLY WANT IS TO COME
- 12 BACK AGAIN AND AGAIN AS THEY PROGRESS WITH THE
- 13 DEVELOPMENT OF A PRODUCT AND RECEIVE MORE GRANT
- 14 FUNDING.
- ONE THOUGHT IS INSTEAD OF WRITING RULES,
- 16 WRITE EXPECTATIONS, AND YOU REALLY PUSH THOSE
- 17 EXPECTATIONS. THIS IS WHAT WE EXPECT. IF YOU DON'T
- 18 FOLLOW, DON'T COME TO US FOR ANY MORE MONEY.
- 19 CHAIRMAN PENHOET: WELL, WE HAVE AN
- 20 OBLIGATION TO COME UP WITH SOME RULES, BUT NOT
- 21 EVERYTHING WE DO HAS TO BE A RULE. WE HAVE A BALANCE.
- MR. TOCHER: THE ONLY THING I WOULD ADD THERE
- 23 IS JUST SOMETIMES THAT THE LINE BETWEEN AN EXPECTATION
- AND A RULE CAN BE THIN, AND SOMETIMES IT'S HARD TO
- 25 FIND. BUT ANY TIME WE'RE USING A SET OF CRITERIA TO

- 1 BASE A DECISION ON, SOMEONE'S RIGHTS WHETHER TO RECEIVE
- 2 OR NOT RECEIVE A GRANT OR APPLIED CRITERIA IN JUDGING A
- 3 GRANT WHETHER TO FUND THAT SORT OF THING, THAT'S
- 4 ESSENTIALLY A RULE AT THAT POINT, AND THAT REALLY IS A
- 5 REGULATION.
- 6 MR. TAYMOR: THE STATE OF CALIFORNIA,
- 7 ACTUALLY AND THE FEDERAL GOVERNMENT, USES A SIMILAR
- 8 PROPOSAL VERY EFFECTIVELY, AND IT'S WHAT YOU MIGHT
- 9 CHARACTERIZE AS PUBLIC-PRIVATE PARTNERSHIPS IN THE
- 10 ECONOMIC DEVELOPMENT AND HOUSING FIELD. GRANTS ARE
- 11 AWARDED COMPETITIVELY BY THIS INSTITUTE AND THERE ARE
- 12 PARAMETERS FOR THEIR GRANTS, BUT THE MORE PUBLIC
- 13 BENEFIT THAT IS PROVIDED BY THE APPLICANT, THE HIGHER
- 14 THEIR GRANT. WE COULD HAVE AN ELEMENT OF THE GRANT
- 15 APPLICATION TO SAY TO WHAT EXTENT WILL BE YOU SHARING,
- 16 WILL YOU BE PROVIDING DATA AND ADDITIONAL INFORMATION
- 17 USED BY OTHER GRANTEES ELSEWHERE BY THE STATE. THOSE
- 18 ADDRESS, AS WAS SAID, THE ABILITY TO LET THE INDIVIDUAL
- 19 GRANT APPLICANT SAY HERE'S WHAT I CAN LIVE WITH AND
- 20 HERE'S WHAT MAKES IT ATTRACTIVE.
- DR. HALL: ONE OF THE THINGS THAT WE'VE
- 22 TALKED ABOUT OR IMAGINE THAT WE WOULD DO WOULD BE NOT
- 23 ONLY FOR THINGS LIKE PRECLINICAL DEVELOPMENT, BUT THAT
- 24 WE WOULD ALSO FUND OPEN-ENDED SCIENCE IN COMPANIES.
- 25 BUT WE HAVEN'T THOUGHT VERY MUCH OR FACED THE QUESTION

- 1 OF HOW EXACTLY THIS WOULD HAPPEN MECHANICALLY. IF WE
- 2 CALL FOR A CERTAIN KIND OF GRANT, WE WANT TO FIND OUT
- 3 SOME PROBLEM IN STEM CELL BIOLOGY, WHATEVER IT IS, AND
- 4 A COMPANY APPLIES AND SAYS THEY'D LIKE TO APPLY FOR
- 5 THIS. THEN WE HAVE A GROUP WHERE A FOR-PROFIT
- 6 INSTITUTION AND A GROUP FOR A NONPROFIT INSTITUTION MAY
- 7 BE COMPETING FOR SIMILAR GRANTS AND HOW TO HANDLE THAT
- 8 AND HOW TO DEVELOP CRITERIA.
- 9 ONE OF THE QUESTIONS IS DO YOU JUDGE IT ON
- 10 THE SCIENCE AND THEN NEGOTIATE IT LATER, OR DO YOU, AS
- 11 YOU SUGGEST, SORT OF PUT THAT IN THE CRITERIA? I THINK
- 12 YOU HAVE TO SAY IN AN RFA SOME MINIMUM EXPECTATIONS.
- 13 IF YOUR RFA IS FOR A MONOCLONAL, YOU HAVE TO SAY WHAT
- 14 YOU EXPECT FROM THE START, WHAT YOU EXPECT IN TERMS OF
- 15 WHAT WOULD HAPPEN IN THAT INFORMATION OR KNOWLEDGE OR
- 16 THOSE REAGENTS, AND THEN THERE MAY STILL BE FURTHER
- 17 POINTS THAT HAVE TO BE NEGOTIATED PRIVATELY.
- 18 BUT IT IS AN ISSUE, AND I THINK TO PUT IT
- 19 INTO THE COMPETITION WHERE YOU MIGHT HAVE FOR-PROFIT
- 20 AND NONPROFITS COMPETING, PEOPLE FROM THOSE
- 21 INSTITUTIONS WITH DIFFERENT POLICIES COMPETING AGAINST
- 22 EACH OTHER, I DON'T KNOW. I DON'T KNOW IF THAT'S THE
- 23 BEST THING OR NOT, BUT I JUST THINK IT IS A FURTHER
- 24 COMPLICATION AT THIS POINT, WHICH WE HAVE MANY AROUND
- 25 THIS ISSUE. JOHN SIMPSON.

- 1 MR. SIMPSON: ISN'T IT THE CASE THAT SOME OF
- 2 THIS REALLY SHOULD BE ADDRESSED IN A GRANTS
- 3 ADMINISTRATION POLICY AND THAT, IN FACT, WE ALMOST NEED
- 4 A SEPARATE GRANTS ADMINISTRATION POLICY?
- 5 DR. MAXON: THAT IS THE PLAN. ARLENE IS NOT
- 6 HERE. SHE'S TOLD ME THIS.
- 7 MR. SIMPSON: A NUMBER OF THESE THINGS, IT
- 8 SEEMS TO ME, ARE ADDRESSED THERE RATHER THAN IP, A
- 9 NUMBER OF THEM, NOT NECESSARILY ALL OF THEM.
- 10 CHAIRMAN PENHOET: WELL, YEAH. MANY COULD
- 11 BE. GRANTS ADMINISTRATION POLICY DOESN'T HAVE THE
- 12 EFFECT OF LAW, SO IT'S A GUIDELINE.
- DR. HALL: YES, IT DOES. WHAT HAPPENS IS
- 14 ACTUALLY THE GRANTS ADMINISTRATION POLICY EVENTUALLY
- 15 INCLUDES THE IP POLICY. FOR NONPROFIT, IT BECOMES PART
- 16 OF THE GRANTS ADMINISTRATION POLICY. IT IS PART AND
- 17 PARCEL TO THE WHOLE THING. SO IN A SENSE THEY ARE IN
- 18 THE SAME CATEGORY, AND WE WORK VERY HARD TO TRY TO MAKE
- 19 THOSE TWO CONSISTENT. YOU MUST FOLLOW OUR POLICIES
- 20 HERE AS OUTLINED IN THE INSTITUTIONS. AND I PRESUME WE
- 21 WOULD HAVE SOMETHING SIMILAR.
- 22 SO THE DIFFERENCES ARE GENERAL PRINCIPLES
- 23 WHICH WOULD BE HANDLED. FOR ALL PRACTICAL PURPOSES,
- 24 THOSE WILL BE THE SAME; THAT IS, GRANTS ADMINISTRATION
- 25 POLICY WILL NOT PUT IN POLICIES THAT ARE DIFFERENT FROM

- 1 WHAT'S DECIDED HERE. THEN YOU HAVE THE POSSIBILITY OF
- 2 SPECIFYING IN AN RFA OR RFP EXACTLY WHAT THE CONDITIONS
- 3 ARE.
- 4 AND FINALLY, THERE'S THE ALTERNATIVE OF
- 5 NEGOTIATING INDIVIDUALLY WITH THIS EVEN AFTER THE WHOLE
- 6 THING IS DONE TO SAY HERE'S HOW WE SEE IT WORK, HOW WE
- 7 FIND AN ACCEPTABLE SOLUTION IN THE MIDDLE. SO AT LEAST
- 8 I SEE THOSE THREE LEVELS OF BEING ABLE TO WORK THE
- 9 PROBLEMS OUT. IT DOESN'T MAKE THE PROBLEMS ANY
- 10 SIMPLER. I WOULD SAY THAT.
- 11 CHAIRMAN PENHOET: BUT I THINK YOU ARE RIGHT,
- 12 JOHN. OUR WORK HERE, THERE IS AN INDISTINCT BORDER
- 13 BETWEEN WHAT WE'RE DOING HERE TODAY AND THE, FOR
- 14 EXAMPLE, STRATEGIC PLANNING PROCESS. IS THIS ISSUE OF
- 15 LOANS VERSUS GRANTS A PROPER THING FOR OUR COMMITTEE?
- 16 WE'VE DECIDED WE'LL DISCUSS IT HERE AND TACKLE IT HERE.
- 17 IT COULD BE THAT IT ULTIMATELY BELONGS SOMEWHERE ELSE.
- 18 IT IS TO SOME DEGREE A STRATEGIC PLANNING ISSUE. WE
- 19 HAVE DISCUSSED THIS WITH VARIOUS PEOPLE, INCLUDING BOB
- 20 KLEIN, AND WE'VE DECIDED TO TRY TO AT LEAST GET THE
- 21 DISCUSSION OF THESE ISSUES GOING HERE, BUT THEY'RE NOT
- 22 STRICTLY INTELLECTUAL PROPERTY POLICY.
- 23 MR. SIMPSON: HAVE WE LEFT THE QUESTION OF
- 24 WHETHER WE SHOULD BE FOLLOWING THE NIH MODEL OR THE
- 25 FEDERAL MODEL WITH GOVERNMENT, THE POINT I RAISED?

- 1 CHAIRMAN PENHOET: RETAIN THE LICENSE FOR ITS
- 2 OWN USE?
- 3 MR. SIMPSON: YEAH.
- 4 CHAIRMAN PENHOET: WELL, WE'VE WRITTEN IT
- 5 DOWN AS SOMETHING TO DISCUSS. PRESUMABLY ALL OF THESE
- 6 THINGS, THE POINTS WILL BE BROUGHT UP WITH THE ICOC AS
- 7 A WHOLE. WE CAN POLL THE GROUP HERE TODAY ABOUT THAT
- 8 I SSUE.
- THE QUESTION JOHN SIMPSON SEEKS AN ANSWER TO
- 10 IS WHETHER OR NOT THE STATE OF CALIFORNIA WOULD RETAIN
- 11 THE LICENSE FOR ITSELF TO PRACTICE THE ART OF ANY
- 12 INVENTION MADE BY A -- WELL, IT'S NOT IN THE
- 13 NOT-FOR-PROFIT POLICY, EITHER POLICY.
- DR. HALL: FOR RESEARCH PURPOSES.
- MR. SIMPSON: I'M FOLLOWING THE MODEL --
- 16 DR. HALL: FOR RESEARCH PURPOSES. THE
- 17 FEDERAL POLICY, I THINK, IS DEFINITELY FOR RESEARCH
- 18 PURPOSES.
- 19 MR. SIMPSON: THAT'S WHAT -- I'M ESSENTIALLY
- 20 PARALLELING THE FEDERAL MODEL, WHATEVER THAT IS.
- DR. HALL: I DON'T THINK ANYBODY IS INTENDING
- 22 THAT WE OR ANYBODY ELSE SHOULD DO COMMERCIAL
- 23 DEVELOPMENT OF THESE ON OUR OWN. IT WOULD BE STRICTLY
- 24 SPEAKING FOR --
- 25 CHAIRMAN PENHOET: FOR ITS OWN USE MEANS YOU

- 1 COULDN'T LICENSE IT TO A THIRD PARTY. IT MEANS YOU USE
- 2 IT YOURSELF. IS THAT --
- 3 MR. SIMPSON: YEAH, FOR YOUR OWN USE. THAT'S
- 4 WHAT THE FEDERAL GOVERNMENT RETAINS, FOR ITS OWN USE.
- 5 DR. HALL: THESE THINGS ARE DIFFICULT. BE
- 6 SURE WE'RE UNDERSTANDING THE SAME THING.
- 7 CHAIRMAN PENHOET: THE FEDERAL GOVERNMENT
- 8 DOES A LOT OF RESEARCH. STATE OF CALIFORNIA DOESN'T DO
- 9 MUCH AS FAR AS I KNOW.
- 10 DR. MAXON: UNLESS YOU COUNT UC.
- 11 CHAIRMAN PENHOET: UC IS PART OF THE STATE OF
- 12 CALI FORNI A.
- DR. HALL: YES. BUT LET'S --
- 14 CHAIRMAN PENHOET: I THINK WE HAVE TO DO SOME
- 15 MORE HOMEWORK ON THIS ISSUE.
- 16 MR. SIMPSON: I THINK THAT'S AN INTERESTING
- 17 THING TO PURSUE, I HOPE.
- 18 MS. KHOTANI: THE STATE OF CALIFORNIA WILL
- 19 ALWAYS HAVE THE MARCH-IN RIGHTS BECAUSE THAT IS THE
- 20 PROVISION IN HERE, RIGHT?
- 21 CHAIRMAN PENHOET: YES. IF THE INVENTIONS
- 22 ARE NOT PURSUED BY WHOEVER INVENTS THEM.
- 23 MS. KHOTANI: IF THE PUBLIC HEALTH IS AT
- 24 STAKE.
- 25 MR. SIMPSON: YES, THAT'S TRUE.

- 1 CHAIRMAN PENHOET: OKAY. FLIPPING TWO
- 2 FORWARD, REQUIREMENTS OF LICENSING INVENTIONS, PATENTED
- 3 INVENTIONS, TO THIRD PARTIES. THAT'S PAGE 12. THE
- 4 LANGUAGE IS VERY SIMILAR TO WHAT WE HAVE IN THE
- 5 NOT-FOR-PROFIT POLICY. THIS IS IF AWARDEE
- 6 ORGANIZATIONS CHOOSE TO LICENSE THEIR INVENTION TO
- 7 THIRD PARTIES, NOT IF THEY INTEND TO PURSUE THEM ON
- 8 THEIR OWN, WHICH WE DEAL WITH ELSEWHERE IN THIS
- 9 DOCUMENT.
- 10 MS. KING: WE MIGHT HAVE A COMMENT.
- 11 MR. GILLENWATER: I HAVE A COMMENT ON ITEM
- 12 NO. 4, PROBABLY ON THE NEXT SLIDE.
- 13 CHAIRMAN PENHOET: IT IS ON THE NEXT SLIDE.
- 14 WE CAN GO TO THE NEXT SLIDE. FIRST, ANY COMMENTS ON
- 15 THIS SECTION FROM MEMBERS OF THE TASK FORCE? WE HAVE A
- 16 COMMENT FROM THE AUDIENCE IN SAN FRANCISCO.
- 17 NO. 4 IS ON PAGE 13. AWARDEE ORGANIZATIONS
- 18 SHALL GRANT EXCLUSIVE LICENSES ONLY TO ORGANIZATIONS
- 19 WITH PLANS TO PROVIDE ACCESS AT THE TIME OF
- 20 COMMERCIALIZATION.
- 21 MR. GILLENWATER: THIS IS TODD GILLENWATER
- 22 WITH THE CALIFORNIA HEALTHCARE INSTITUTE. AND ACTUALLY
- 23 I HAVE TWO COMMENTS ON THIS ONE, AND ONE IS A KIND OF A
- 24 30,000 FOOT LEVEL QUESTION. THE OTHER ONE IS A LITTLE
- 25 BIT MORE DETAILED.

- 1 THE FIRST REFERS TO SOMETHING I KNOW WE'RE
- 2 GOING TO GET TO IN A COUPLE SLIDES DOWN, WHICH IS THE
- 3 25-PERCENT TRIGGER OR THRESHOLD. AND KNOWING THAT THIS
- 4 ALSO WAS COVERED IN THE IP POLICY, THE REASON I BRING
- 5 IT UP IS WE BELIEVE IT'S RELEVANT. AND IT'S MORE OF A
- 6 QUESTION, AGAIN, LOOKING FORWARD TO THE THRESHOLD, IS
- 7 APPRECIATING THAT THRESHOLD, APPRECIATING THAT TRIGGER,
- 8 WHICH BASICALLY STATES THAT CIRM BELIEVES THAT ONLY
- 9 WHEN CIRM FUNDING IS A SUBSTANTIAL PART OF THAT FINAL
- 10 PRODUCT SHOULD THESE POLICIES BE TRIGGERED.
- AND THE QUESTION WE HAVE HAD AND WE'VE STATED
- 12 IN OUR COMMENTS ON THE NONPROFIT POLICY, AND WE'LL
- 13 CERTAINLY STATE IT IN THE FOR-PROFIT, IS WHY THE
- 14 TRIGGER OR A THRESHOLD WOULDN'T APPLY TO LICENSED
- 15 INVENTIONS AS WELL. IF I COULD JUST GIVE A QUICK
- 16 EXAMPLE. IT WOULD BE IF A COMPANY ACCEPTS \$10 MILLION
- 17 DIRECTLY FROM CIRM FOR A PRODUCT THAT ULTIMATELY COSTS
- 18 \$500 MILLION TO COMMERCIALIZE, 2 PERCENT, THIS
- 19 THRESHOLD WOULD NOT BE TRIGGERED IF THE 25 PERCENT IS
- 20 THE AMOUNT. HOWEVER, IF THAT SAME COMPANY LICENSED A
- 21 TECHNOLOGY FROM THE UNIVERSITY OF CALIFORNIA, THAT
- 22 TECHNOLOGY HAVING BEEN THE RECIPIENT OF \$10 MILLION IN
- 23 CIRM FUNDING, THE COMPANY THEN GOES ON TO DEVELOP A
- 24 PRODUCT THAT STILL COSTS \$500 MILLION, THE CIRM FUNDING
- 25 THAT GOES INTO THAT RESULTANT PRODUCT IS STILL 2

- 1 PERCENT OF THE FINAL COST -- THAT THE FINAL PRODUCT
- 2 COSTS.
- 3 AND, THEREFORE, HAS THE TASK FORCE CONSIDERED
- 4 WHY THERE IS A DIFFERENCE IN THIS TRIGGERING EVEN
- 5 THOUGH THE COST THAT THE COMPANY TAKES UPON ITSELF OR
- 6 THE COST THAT THE CIRM FUNDING AMOUNTS TO AND THE COST
- 7 OF THE FINAL PRODUCT IS 2 PERCENT IN EITHER CASE, AT
- 8 LEAST IN MY THEORETICAL EXAMPLE.
- 9 DR. HALL: THAT REALLY GOES BACK TO THE
- 10 NONPROFIT POLICY: IS THAT CORRECT?
- 11 MR. GILLENWATER: THAT WAS WHAT -- I TRIED TO
- 12 STATE THAT AS WELL. IT'S SOMETHING THAT WE ADDRESSED
- 13 IN OUR COMMENTS ON THE NONPROFIT.
- 14 CHAIRMAN PENHOET: WELL, THERE ARE A COUPLE
- 15 ANSWERS. I GUESS ONE IS THAT IT'S LIKELY THAT -- WELL,
- 16 IT'S TRUE THAT COMPANY AWARDEES WILL BE CALIFORNIA
- 17 COMPANIES DOING BUSINESS AS COMPANIES. IT'S HIGHLY
- 18 PROBABLE THAT MANY OR MOST OF THE LICENSEES WILL BE
- 19 OUTSIDE CALIFORNIA. AND, THEREFORE, CALIFORNIA WON'T
- 20 GET ANY INDIRECT BENEFIT FROM COMPANY ACTIVITIES, ETC.
- 21 THEY HAVE ONLY THE INVESTMENT THEY MADE IN THE
- 22 TECHNOLOGIES. AND SO THAT'S ONE ARGUMENT.
- 23 TO SOME DEGREE, WE ALSO THOUGHT ABOUT THE --
- 24 THESE ARE SPECIFIC INVENTIONS. PRESUMABLY IF IT'S A
- 25 SINGLE INVENTION WHICH IS LICENSED AND IT'S RESPONSIBLE

- 1 FOR THE ENTIRE DEVELOPMENT, IT REALLY EMPOWERS THESE
- 2 COMPANIES FOR THE ENTIRE PROGRAM, EVEN THOUGH THEY MAY
- 3 SPEND MORE MONEY, BUT THESE ARE SCIENTIFIC INVENTIONS
- 4 WE'RE TALKING ABOUT, PATENTABLE INVENTIONS. THEY'RE
- 5 NOT DEVELOPMENT FUNDS, ETC., THINGS LIKE THAT, THAT GO
- 6 BEYOND THAT. SO IN THE INVENTIVE ACT, I'M NOT SURE WE
- 7 ARTICULATED HERE, BUT IF OUR FUNDING OF THE INVENTION
- 8 WAS LESS THAN A HUNDRED PERCENT, AND THE COMPANY PUT IN
- 9 THEN, THERE ARE SOME PROPORTIONAL PARTS, BUT IT STILL
- 10 DOESN'T REFLECT WHAT YOUR CONCERN, WHICH IS IS THERE A
- 11 THRESHOLD HERE.
- 12 SO THIS IS A CASE WHERE, YOU KNOW, IT'S NOT A
- 13 PERFECT WORLD, FOR SURE, BUT THE COMPANIES WILL KNOW
- 14 THIS GOING IN FOR LICENSEES. IF IT TURNS OUT LATER
- 15 THIS IS A BARRIER, NONE OF THIS TECHNOLOGY IS GETTING
- 16 LICENSED FOR THIS REASON, WE CAN ALWAYS REVISIT THE
- 17 I SSUE. BUT WE THOUGHT IT WOULD BE -- YOU COULD GO BACK
- 18 AND REOPEN THE DISCUSSION ABOUT THE NOT-FOR-PROFITS.
- 19 WE DIDN'T THINK WE SHOULD UNIQUELY PENALIZE THE
- 20 NOT-FOR-PROFITS IN THIS REGARD VIS-A-VIS THE FOR-PROFIT
- 21 ENTITIES AND HAVE DIFFERENT RULES FOR BOTH ABOUT
- 22 LICENSING PATENTED TECHNOLOGY.
- 23 I THINK THAT WE DO WANT TO ENCOURAGE
- 24 COMPANIES IN CALIFORNIA TO INVEST IN THE DEVELOPMENT OF
- 25 THEIR OWN TECHNOLOGY, AND THAT'S WHY THE OTHER SECTION

- 1 DEALS WITH IT DIFFERENTLY THAN OUT-LICENSING IT AND
- 2 PRESUMABLY WOULD MAKE A BIGGER CONTRIBUTION TO AN
- 3 INVENTION THAN WE MAKE TO A WHOLE DEVELOPMENT PROGRAM.
- 4 THE LOGIC IS NOT PERFECT.
- 5 MR. GILLENWATER: OKAY.
- 6 CHAIRMAN PENHOET: YOU HAD A SECOND QUESTION?
- 7 MR. GILLENWATER: IT'S MORE OF A COMMENT THAN
- 8 A QUESTION BECAUSE I DON'T HAVE THE ANSWER MYSELF YET.
- 9 THE SECTION THAT DISCUSSES THE REQUIREMENT THAT
- 10 LICENSEES WILL PROVIDE TO PATIENTS THERAPIES AND
- 11 DIAGNOSTICS WILL BE PURCHASED IN CALIFORNIA BY PUBLIC
- 12 FUNDS THE THERAPIES AND DIAGNOSTICS AT A COST NOT TO
- 13 EXCEED THE FEDERAL MEDICALD PRICE. I KNOW WE'VE HAD
- 14 DISCUSSIONS WITH -- AS PART OF OUR NONPROFIT POLICY
- 15 COMMENTS AND DISCUSSIONS OUTSIDE OF THAT IN TWO AREAS
- 16 OF CONCERN.
- 17 ONE, THE DEFINITION OF FEDERAL MEDICALD
- 18 PRICE; AND, TWO, A LITTLE BIT OF CONCERN AS WE'VE
- 19 RECEIVED FROM OUR MEMBERSHIP ON THE DEFINITION OF
- 20 PUBLIC FUNDS. AND IT ACTUALLY GOES BACK TO THIS TASK
- 21 FORCE MEETINGS IN JULY WHEN THERE WAS A MOTION MADE, I
- 22 BELIEVE, BY DR. PRIETO TO EXTEND IT FROM MEDICALD PRICE
- 23 TO VA OR SOME OF THE OTHER ELEMENTS.
- AND THERE WAS A DISCUSSION ON HOW THAT MIGHT
- 25 TRIGGER A RECALCULATION OF BEST PRICE THAT WOULD AFFECT

- 1 49 OTHER STATES. AND THERE WAS A COMMITMENT OR THE
- 2 STATEMENT THAT THE TASK FORCE DIDN'T WISH TO GO THERE.
- 3 BASED ON SOME OF THE COMMENTS WE'VE GOTTEN BACK FROM A
- 4 SUBSTANTIAL NUMBER OF OUR MEMBERS, THERE IS A DESIRE TO
- 5 GET A LITTLE BIT MORE CLARITY IN THIS DEFINITION, THAT
- 6 THIS REQUIREMENT WOULD NOT APPLY TO SOME SORT OF ENTITY
- 7 THAT WOULD THEN TRIGGER A RECALCULATION OF BEST PRICE
- 8 THAT WOULD AFFECT PRICING IN THE 49 OTHER STATES.
- 9 CHAIRMAN PENHOET: SCOTT TOCHER HAS BEEN
- 10 DOING A FAIR AMOUNT OF WORK ON THIS. YOU DO BRING UP
- 11 AN INTERESTING QUESTION. I GUESS MEDICARE IS BY FAR
- 12 THE BIGGEST PAYOR OF ALL THESE THINGS. BY OUR
- 13 DEFINITION, SCOTT, WOULD MEDICARE PAYMENTS BE
- 14 CONSIDERED PUBLIC FUNDS FOR THIS PURPOSE? I DON'T
- 15 THINK THAT'S WHAT WE HAD IN MIND, BUT IT COULD BE --
- 16 MR. GILLENWATER: THERE IS NO DEFINITION OF
- 17 PUBLIC FUNDS. I THINK THAT'S ONE OF THE QUESTIONS
- 18 WE' VE HAD.
- 19 CHAIRMAN PENHOET: SO I THINK THAT'S A GOOD
- 20 POINT YOU MAKE, AND I THINK WE SHOULD CLARIFY THAT.
- 21 MR. SIMPSON: I THINK WE HAD UNDERSTOOD THOSE
- 22 TO BE STATE OR COUNTY OR CITY.
- 23 CHAIRMAN PENHOET: WE DID.
- 24 MR. SIMPSON: AND I THOUGHT THERE MIGHT HAVE
- 25 BEEN DISCUSSION TO THAT POINT SOMEWHERE, AND MAYBE EVEN

- 1 THE REGS, BUT I DON'T RECALL.
- 2 MR. GILLENWATER: I REMEMBER THE DISCUSSION.
- 3 CHAIRMAN PENHOET: I THINK WE ALL UNDERSTOOD
- 4 WHAT WE MEANT, BUT I'M NOT SURE THAT THE LANGUAGE
- 5 COULDN'T BE INTERPRETED DIFFERENTLY. THANK YOU FOR
- 6 POINTING THAT OUT. SO WE WILL GO BACK AND LOOK AT
- 7 THAT.
- 8 ANY FURTHER COMMENTS ON THIS SECTION?
- 9 DR. PRIETO: JUST WITH REGARD TO THAT COMMENT
- 10 I MADE AT THE PREVIOUS MEETING, MY INTENTION WAS JUST
- 11 THAT CALIFORNIA, HAVING PARTICIPATED IN THE INVENTION,
- 12 SHOULD BE ASSURED THE BEST FEDERAL PRICE OR THE BEST
- 13 AVAILABLE PRICE, PERIOD. AND I'M CERTAINLY OPEN TO
- 14 SUGGESTION, AND I HOPE THAT OUR COUNSEL CAN HELP ME
- 15 WITH THIS ON LANGUAGE THAT WOULD ACHIEVE THAT END
- 16 WI THOUT TRIGGERING SOME OF THESE OTHER POTENTIAL
- 17 PROBLEMS.
- 18 CHAIRMAN PENHOET: YES. I THINK WE'RE GOING
- 19 TO SOLVE THIS PROBLEM BY DEFINING PUBLIC FUNDS AND
- 20 DEFINING WHAT WE MEAN BY FEDERAL MEDICAID PRICE IN SUCH
- 21 A WAY THAT THAT WON'T HAPPEN. WE'LL CERTAINLY RUN IT
- 22 BY YOU BEFORE WE FINALIZE IT.
- MR. GILLENWATER: THANK YOU.
- 24 CHAIRMAN PENHOET: OKAY. MOVING ALONG, F ON
- 25 PAGE 14, ACCESS REQUIREMENTS FOR PRODUCTS DEVELOPED BY

- 1 FOR-PROFIT AWARDEES. THIS SAYS IF OUR FUNDING EXCEEDS
- 2 25 PERCENT, THEN THIS WILL TRIP THE REQUIREMENT ON THAT
- 3 COMPANY TO AGREE TO THE LOWER PRICES AND TO HAVE THE
- 4 PLAN IN PLACE FOR PATIENT ACCESS.
- 5 WE'VE HAD A FAIR AMOUNT OF DISCUSSION ON
- 6 THIS. I BELIEVE I CAN QUOTE JOHN SIMPSON AS SAYING THE
- 7 FIRST DOLLAR SHOULD TRIP THIS REQUIREMENT INTO A
- 8 COMPANY. THE OTHER END, I THINK THE COMPANIES VIEW
- 9 THIS -- SOME COMPANIES VIEW THIS AS AN ONEROUS
- 10 REQUIREMENT AT THE 25-PERCENT LEVEL. TO SOME DEGREE
- 11 THIS NUMBER IS AN IRRATIONAL NUMBER. IT'S A NEGOTIATED
- 12 NUMBER. BUT I THINK IT'S AN AREA OF SUFFICIENT CONCERN
- 13 ON BOTH SIDES, THAT WE SHOULD HAVE A LITTLE BIT FURTHER
- 14 DI SCUSSI ON.
- 15 I'D LIKE TO START WITH THE TASK FORCE. YOU
- 16 GUYS HAVE HAD A MONTH NOW TO THINK ABOUT 25 PERCENT.
- 17 ANY OF YOU WANT TO COMMENT FURTHER ON THAT THRESHOLD?
- 18 SAN DI EGO?
- 19 DR. PRIETO: I THINK I PULLED THIS NUMBER OUT
- 20 OF MY HAT AT THE LAST MEETING.
- 21 CHAIRMAN PENHOET: THANK YOU.
- DR. PRIETO: IN THINKING ABOUT IT, I THINK I
- 23 CAN UNDERSTAND THAT FIRST DOLLAR WOULD BE CONSIDERED
- 24 ONEROUS, BUT 25, I THINK, IS -- I CERTAINLY WOULD NOT
- 25 WANT THIS ANY HIGHER, AND I WOULD BE WILLING TO

- 1 CONSIDER LOWER. EVEN A 10-PERCENT INVESTMENT IN A
- 2 SIGNIFICANT INVENTION COULD MEAN A LOT TO CALIFORNIA,
- 3 COULD MEAN A LOT IN THE FORM OF POTENTIAL THERAPIES FOR
- 4 CALIFORNIANS AND FOR EVERYONE. AND THAT, I THINK,
- 5 WOULD BE A SUBSTANTIAL CONTRIBUTION TO THE INVENTION.
- 6 SO I CERTAINLY WOULD NOT WANT TO GO ABOVE THIS LINE.
- 7 DR. WRIGHT: FRANCISCO, THIS IS JANET. IT'S
- 8 SORT OF FRIGHTENING. I HAD JUST WRITTEN DOWN 10
- 9 PERCENT ON MY NOTEPAD HERE AS YOU WERE SPEAKING.
- 10 BECAUSE I ALSO FEEL THAT FIRST DOLLAR MIGHT BE A MORE
- 11 AGGRESSIVE STANCE THAN WE WANT TO TAKE, BUT THIS IS AN
- 12 OBLIGATION TO OUR PATIENTS IN THE STATE AND OUR
- 13 CITIZENS WHO HAVE CONTRIBUTED. SO I'D BE IN FAVOR OF A
- 14 LITTLE LOWER THRESHOLD.
- DR. BRYANT: I THINK 25 PERCENT SOUNDS LIKE A
- 16 BALANCE TO ME BETWEEN, YOU KNOW, DISCOURAGING INDUSTRY
- 17 FROM COMING IN AT ALL AND DISCHARGING OUR OBLIGATION TO
- 18 PATIENTS. SO I DON'T KNOW WHY IT SOUNDS LIKE A
- 19 REASONABLE NUMBER, BUT IT DOES, TO ME ANYWAY. SO I
- 20 WOULD BE HAPPY TO STAY WITH 25 PERCENT.
- 21 MR. ROTH: I AM ALSO COMFORTABLE WITH 25
- 22 PERCENT.
- 23 CHAIRMAN PENHOET: DO WE HAVE COMMENTS IN SAN
- 24 FRANCI SCO? JOHN SIMPSON.
- 25 MR. SIMPSON: I'M NOT GOING TO GO IMMEDIATELY

- 1 TO THE FIRST DOLLAR ARGUMENT SINCE YOU SO CORRECTLY
- 2 QUOTED ME FROM THE LAST MEETING, BUT IT DOES STRIKE ME
- 3 THAT PERHAPS A PERCENT APPROACH IS THE WRONG APPROACH
- 4 BECAUSE WHAT I THINK WE MIGHT BE LOOKING AT IS A
- 5 SITUATION WHERE AT A PARTICULAR POINT IN THE
- 6 DEVELOPMENT OF A PRODUCT, CIRM'S \$1 MILLION WOULD BE
- 7 KEY BECAUSE IT WOULD THEN TAKE IT TO THE NEXT LEVEL,
- 8 WHICH WOULD THEN RESULT IN \$800 MILLION COMING IN FROM
- 9 BIG PHRMA THAT NEVER WOULD HAVE HAPPENED IF THE ONE
- 10 MILLION HADN'T BEEN PUT IN FROM CIRM.
- 11 SO IT MAY BE THAT THERE SHOULD BE SOME KIND
- 12 OF LANGUAGE INSERTED THAT WOULD SAY FOR PROJECTS WHERE
- 13 CIRM FUNDING WAS DECISIVE IN DEVELOPING A PRODUCT OR IT
- 14 DOES NOT -- OR EXCEEDS 25 PERCENT, THAT MIGHT BE A WAY
- 15 TO GO BECAUSE THERE IS THIS THING OF DOLLARS BEING MORE
- 16 VALUABLE AT DIFFERENT TIMES IN THE PROCESS.
- 17 CHAIRMAN PENHOET: A HARD THING TO NEGOTIATE
- 18 IF YOU'VE EVER TRIED TO DO THAT, JOHN, BUT IT'S A POINT
- 19 WELL TAKEN.
- 20 DR. PRIETO: IF I COULD COMMENT AGAIN. I
- 21 THINK IT MIGHT BE REASONABLE TO PUT IN A LOWER
- 22 PERCENTAGE, BUT WITH A TRIGGERING AMOUNT; THAT IS,
- 23 EITHER IN THE FORM OF A TRIGGERING AMOUNT OF CIRM
- 24 CONTRIBUTION OR OF, YOU KNOW, IN THE FORM OF X REVENUES
- TRIGGER THIS GUARANTEE.

- 1 MR. TAYMOR: WHAT ABOUT A PERCENTAGE BASED ON
- 2 THE AMOUNT THAT HAS BEEN SPENT AT THAT TIME, WHICH, IN
- 3 EFFECT, IS IMPLICIT IN THE NONPROFIT POLICY. THE
- 4 NONPROFIT POLICY YOU'RE SAYING WE'RE ASSUMING THAT ZERO
- 5 OR ONLY A SMALL AMOUNT OF FUNDS HAVE BEEN EXPENDED WITH
- 6 RESPECT TO THIS INVENTION AT THIS TIME; THEREFORE,
- 7 WE'RE GOING TO MAKE IT SUBJECT TO THIS RULE. SO IF 10
- 8 OR 20 PERCENT OF THE FUNDING FOR PRE-IND STAGE HAS COME
- 9 FROM CIRM AND THAT'S ALLOWED THE PROJECT TO GET INTO
- 10 THE CLINIC, THEN MAYBE THIS IS APPLICABLE AS OPPOSED TO
- 11 LOOKING AT THE CIRM DOLLARS AND MATCHING THEM DOLLAR
- 12 FOR DOLLAR AGAINST DOLLARS THAT CAME IN AT PHASE III.
- 13 CHAIRMAN PENHOET: SO YOU WOULD ASK FOR AN
- 14 ACCOUNTING OF HOW MUCH MONEY THEY' VE SPENT BEFORE THEY
- 15 GOT CIRM FUNDING?
- 16 MR. TAYMOR: NO. YOU'RE ASKING FOR THIS
- 17 ACCOUNTING -- YOU'RE GOING TO ASK FOR THIS ACCOUNTING
- 18 AT SOME POINT. I THINK WE HAVE THE 25-PERCENT
- 19 THRESHOLD, AND THE QUESTION RAISED IS DO YOU REALLY
- 20 NEED THE REGULATION BECAUSE ARE YOU GOING TO BE PUTTING
- 21 IN A HUNDRED, \$125 MILLION INTO THAT MANY PROJECTS,
- 22 THAT IT'S REALLY GOING TO BE -- IT'S WORTH A REGULATION
- 23 AS OPPOSED TO SAYING WHEN YOU MAKE A GRANT OF THAT
- 24 SIZE, YOU'RE MAYBE GOING TO MAKE SOME SPECIAL KIND OF
- 25 RULES WITH RESPECT TO IT.

- 1 IF YOU'RE TALKING ABOUT RULES THAT ARE
- 2 GENERALLY GOING OVER A BROAD RANGE OF GRANTS, YOU'RE
- 3 NOT GOING TO MAKE -- ONE OF THE POLICIES WAS DISCUSSED
- 4 AT THE STRATEGIC PLANNING GROUP, IT WAS RAISED BY THE
- 5 CEO'S AND THE OTHER BUSINESS REPRESENTATIVES AT THE
- 6 ROUNDTABLE THAT CIRM PUT ON, IS THAT BUSINESS REALLY
- 7 NEEDS PRE-IND MONEY. SO THAT MONEY, WHICH COULD BE
- 8 VERY INFLUENTIAL TO THE SUCCESS OF THE PROJECT, THEY
- 9 QUOTE IT AS BEING IN THE TWO TO \$10 MILLION RANGE: IS
- 10 THAT CORRECT? IT'S OBVIOUSLY GOING TO BE A NEGLIGIBLE
- 11 AMOUNT IN THE OVERALL DEVELOPMENT COST OF ANY
- 12 THERAPEUTIC, YET THESE INDUSTRY CEO'S ARE SAYING THIS
- 13 IS A CRITICAL PIECE OF FUNDING FOR OUR BUSINESS.
- DR. HALL: THEY'RE SAYING IT'S AN ENABLING
- 15 AMOUNT OF MONEY.
- 16 MR. TAYMOR: RIGHT. SO THAT A WAY OF DOING
- 17 IT IS SAYING IF YOU GET DOWN TO THE END AND YOU GET
- 18 A -- WHEN IT'S GETTING READY FOR COMMERCIALIZATION, YOU
- 19 HAVE TO COME UP WITH THIS PLAN. IF IT TURNED OUT AT
- 20 THAT TIME -- YOU WILL HAVE KEPT SOME RECORDS. YOU'LL
- 21 HAVE ACCOUNTANTS. IT'S NOT GOING TO BE ANY MORE
- 22 DIFFICULT FOR THEM TO FIGURE OUT HOW MUCH MONEY THEY
- 23 HAD SPENT AT THE TIME THEY DID THE IND AND THEY GOT THE
- 24 GRANT -- PRE-IND WORK IF THEY GOT THE GRANT FROM CIRM,
- 25 THEN THEY'RE GOING TO TELL YOU AT THE END OF THEIR

- 1 PHASE III, OR THE END OF THEIR PHASE II IF YOU WANT TO
- 2 SAY THAT'S THE COMMERCIALIZATION POINT.
- 3 CHAIRMAN PENHOET: THE COMMERCIALIZATION
- 4 POINT WOULD BE THE END OF PHASE III.
- 5 MR. TAYMOR: THAT'S RIGHT, I WOULD THINK.
- 6 ANY OF THOSE POINTS, I'M SAYING ANY OF THOSE POINTS,
- 7 THEY'RE GOING TO NEED TO COME UP WITH AN ACCOUNTING.
- 8 THEY COULD COME UP WITH IT FOR WHETHER IT WAS AT THE
- 9 PRE-IND STAGE, BUT THEY ALL SAID THAT THAT SMALL AMOUNT
- 10 OF MONEY COULD BE SOME OF THE BEST MONEY THAT CIRM
- 11 COULD SPEND FOR COMMERCIAL PRODUCTS. AND IT SEEMS LIKE
- 12 A GOOD QUID PRO QUO TO SAY WE'LL SPEND IT, WE'LL
- 13 SUPPORT IT, BUT WE WANT YOU TO PROVIDE THIS PUBLIC
- 14 BENEFIT IN EXCHANGE FOR US TAKING THAT RISK.
- DR. HALL: SO WOULD YOU HAVE A PERCENT AT
- 16 THAT POINT?
- 17 MR. TAYMOR: YEAH. EITHER A PERCENT OR YOU
- 18 COULD JUST MAKE IT A BLANKET ENABLING IF YOU WANTED TO
- 19 DO LT THAT APPROACH.
- 20 CHAIRMAN PENHOET: THERE AGAIN, THEN YOU
- 21 INVOLVE THE CIRM IN A LOT OF NEGOTIATION ABOUT WHAT'S
- 22 ENABLING.
- 23 MR. TAYMOR: THAT'S WHAT I WAS SAYING. THAT
- 24 WAY IT BECOMES --
- DR. HALL: SO WHAT PERCENT WOULD YOU IMAGINE

- 1 WOULD QUALIFY AS ENABLING?
- 2 MR. TAYMOR: 10 PERCENT, SAY IT'S 25 PERCENT.
- 3 I THINK YOU ARE MUCH MORE IN THE GAME IF YOU ARE
- 4 TALKING ABOUT 25 PERCENT. YOUR 2 TO 10 MILLION IS
- 5 GOING TO BE A TRIGGER -- IS GOING TO BE GIVEN IN A
- 6 PRE-IND STAGE. THEN SOME OF THOSE THINGS WILL ACTUALLY
- 7 GET CAUGHT BY THIS NET. THEY'RE NOT GOING TO GET
- 8 CAUGHT BY THIS NET EXCEPT IN EXTRAORDINARY
- 9 CIRCUMSTANCES BECAUSE YOU'RE NOT GOING TO PUT IN A
- 10 HUNDRED, \$125 MILLION INTO THERAPEUTIC DEVELOPMENT.
- 11 CHAIRMAN PENHOET: YOU KNOW, THE DATA WE SAW
- 12 ABOUT WHAT IT COST TO DEVELOP THE DRUG ARE BASED ON THE
- 13 FAILURES. THIS IS PER PROJECT, ONLY THIS PROJECT. SO
- 14 I SUSPECT IT'S A RARE SINGLE PROJECT THAT WILL COST
- 15 \$500 MILLION BECAUSE THE EIGHT OR \$900 MILLION FIGURE
- 16 WE SEE INCLUDES 90 PERCENT OF THE PROJECTS THAT NEVER
- 17 MAKE IT, BUT MIGHT BE \$100 MILLION.
- 18 MR. ROTH: JUST A REMINDER THAT IT IS VERY
- 19 DIFFICULT WHEN YOU PUT THESE KINDS OF CALCULATIONS DOWN
- 20 FOR PEOPLE TO IMAGINE WHAT THAT MIGHT BE IN THE LONG
- 21 RUN. I THINK THE BIG DANGER HERE IS THAT CORPORATIONS
- 22 WILL LOOK AT THIS AND FEAR THAT FOR A MILLION DOLLARS
- OR A \$2 MILLION GRANT, THEY'RE TYING THEIR HANDS DOWN
- 24 THE ROAD.
- 25 I RECALL THE TIME WHEN PEOPLE WOULD COME TO

- 1 SMALL COMPANIES THAT HAVE DEVELOPED INNOVATIONS, AND
- 2 THE FIRST QUESTION FROM BIG PHRMA WAS IS THERE ANY NIH
- 3 MONEY IN THIS THING? BECAUSE THE FEAR WAS AT THAT
- 4 POINT IN TIME, UNTIL NIH STARTED TO CHANGE THEIR
- 5 POLICY, WAS IF THERE'S NIH MONEY IN IT, THE THREAT THAT
- 6 YOU WERE GOING TO BE CALLED OUT DOWN THE ROAD FOR
- 7 HAVING USED PUBLIC FUNDS TO ADVANCE A PRODUCT WERE
- 8 GREATER THAN THE RISK THEY WANTED TO TAKE. I REALLY
- 9 ENCOURAGE US NOT TO MAKE THIS TOO COMPLICATED BECAUSE I
- 10 THINK COMPANIES WILL LOOK AT IT AND SAY WE JUST CAN'T
- 11 AFFORD THE RISK HERE.
- 12 CHAIRMAN PENHOET: WHAT DO YOU THINK ABOUT
- 13 PRE-PHASE III AS THE HURDLE? THERE YOU WOULD HAVE A
- 14 PROOF OF PRINCIPLE. YOU WOULD HAVE HELPED SOMEBODY
- 15 ESTABLISH PROOF OF PRINCIPLE, WHICH USUALLY COMES AFTER
- 16 PHASE II, IF THE THING WILL WORK.
- 17 DR. WRIGHT: ED, WOULD YOU REPEAT THAT?
- 18 CHAIRMAN PENHOET: WELL, IF IT'S NOT THE
- 19 TOTAL AMOUNT OF MONEY THAT AN ORGANIZATION SPENDS, THE
- 20 BIG EXPENSE IS IN PHASE III. SO IF YOU SAID -- IF WE
- 21 PUT IN MORE THAN 25 PERCENT OF THE MONEY PRIOR TO
- 22 INITIATION OF PHASE III CLINICAL TRIALS, THAT'S USUALLY
- THE PHASE WHERE THINGS ARE INVENTED, THINGS ARE PROVEN,
- 24 ETC. PHASE III IS JUST VERIFICATION THAT YOUR PHASE II
- 25 WAS ALSO CORRECT, BUT YOU HAVE TO DO IT WITH A LOT OF

- 1 PEOPLE. AND THAT IS WHERE WE'RE BEING ASKED TO PUT THE
- 2 MONEY.
- 3 DR. HALL: RIGHT. WE IMAGINE, ACTUALLY, THAT
- 4 EVEN FOR SOME OF THE PHASE I, PHASE II TRIALS IN OUR
- 5 FINANCIAL MODEL, THAT WE WILL PAY ONLY 50 PERCENT OF
- 6 THE COST, THAT WE'LL HAVE PARTNERS IN THAT, WHOEVER
- 7 THEY MIGHT BE.
- 8 MR. SIMPSON: AREN'T YOU ESSENTIALLY ENABLING
- 9 WHEN YOU MAKE THAT CONTRIBUTION? WHATEVER IT IS YOU
- 10 PUT IN THERE DOES THE DEAL, WHICH SEEMS TO ME GOES TO
- 11 THE ARGUMENT OF TRIGGERING. IF THEY ASK YOU FOR A
- 12 BUCK, YOU'RE IN.
- 13 CHAIRMAN PENHOET: WELL, MOST GOOD COMPANIES
- 14 HAVE ALTERNATIVE SOURCES OF FUNDS. SO IF WE DON'T FUND
- 15 IT, THEY MIGHT BE ABLE TO FIND IT SOMEWHERE ELSE OUT OF
- 16 STATE. THEY CAN FIND IT IN NEW YORK OR MASSACHUSETTS.
- 17 DR. HALL: SOMEBODY SAID WHAT WE DON'T WANT
- 18 IS TO GET ONLY THOSE COMPANIES THAT ARE SO DESPERATE.
- 19 CHAIRMAN PENHOET: THAT WAS BRAD MARGUS'
- 20 POINT, AND IT WAS A POINT WORTH REMEMBERING.
- DR. HALL: YES, IT IS. YES, IT IS. I THINK
- 22 WE DON'T WANT TO MAKE IT SO ONEROUS FOR A COMPANY THAT
- 23 IT'S THEIR LAST CHOICE. THAT IS, IT'S ONLY THE WAY
- 24 THEY CAN MAKE THIS THING HAPPEN. IN THAT SENSE, YOU
- 25 COULD SAY THAT'S WHAT YOU MEAN BY ENABLING.

- 1 DR. PRI ETO: BUT WE ALSO WANT TO GET
- 2 INNOVATIVE COMPANIES THAT SOME OTHER FUNDING SOURCES
- 3 MIGHT NOT BE WILLING TO TAKE A GAMBLE ON.
- 4 DR. HALL: YES.
- 5 CHAIRMAN PENHOET: THAT'S TRUE.
- 6 DR. HALL: I DIDN'T MEAN TO SAY THAT WE'RE
- 7 THE ONLY ONE, WE SHOULD BE SUSPICIOUS.
- 8 CHAIRMAN PENHOET: I'M NOT SURE, THOUGH, THE
- 9 WAY OUR GRANTING THINGS ARE SET UP, WE'RE GOING TO BE
- 10 LESS RISK AVERSE THAN A VENTURE CAPITALIST. WE'RE
- 11 PROBABLY GOING TO BE MORE RISK AVERSE, FRANKLY.
- 12 MR. ROTH: I THINK THE IMPORTANT ASPECT HERE
- 13 IS NOT SO MUCH THE PERCENTAGE OF WHEN IT KICKS IN. I
- 14 THINK THAT IS IMPORTANT, BUT IT'S WHAT AM I SIGNING
- 15 ONTO? THAT'S WHERE THIS -- THE TRIGGER IS ONE THING,
- 16 BUT TRIGGER OF WHAT? WHAT IS IT THAT I WILL HAVE TO DO
- 17 THAT I CAN EASILY UNDERSTAND IN TERMS OF THE PRICING?
- 18 HOW DOES THAT AFFECT MY NATIONAL PRICING, INTERNATIONAL
- 19 PRICING, AND ALL THE RAMIFICATIONS THEREOF?
- 20 IF THERE WERE A NEGOTIATION ABOUT PRICE AS
- 21 THE TRIGGER, THAT MIGHT BE EASIER TO UNDERSTAND. WHEN
- 22 YOU START TYING IT TO SOMETHING THAT WE DON'T KNOW WHAT
- 23 IT'S GOING TO BE IN THE FUTURE, AND AS TODD POINTED OUT
- 24 FROM CHI, THE ONE WE HAVE RIGHT NOW DOESN'T EVEN EXIST.
- 25 SO THAT'S VERY COMPLICATED TO FIGURE OUT WHAT I'M

- 1 TRI GGERI NG.
- DR. PRIETO: BUT WE CAN COME UP WITH LANGUAGE
- 3 THAT WILL TIE IT TO SOMETHING THAT DOES EXIST AND THAT
- 4 IS A BENCHMARK THAT IS RECOGNIZABLE TO ANY PLAYER IN
- 5 THE FIELD.
- 6 DR. WRIGHT: AND PREDICTABLE ON BOTH SIDES,
- 7 RIGHT? HOW DIFFICULT IT WILL BE AND WHAT THE
- 8 ENTANGLEMENTS WILL BE IN TRYING TO FULFILL THE
- 9 OBLIGATION.
- 10 DR. PRIETO: PARTICULARLY FOR PEOPLE IN
- 11 PHRMA, SOMETHING THEY DEAL WITH ALL THE TIME. IT'S
- 12 PART OF THEIR ROUTINE BUSINESS CALCULATIONS.
- MR. ROTH: WELL, I WOULD LOVE TO BELIEVE THAT
- 14 IT'S ROUTINE, BUT MY EXPERIENCE SAYS IT'S ANYTHING BUT
- 15 ROUTINE, AND IT'S CHANGING CONSTANTLY. PRICING TODAY
- 16 IS SO COMPLICATED, GUYS, THAT EVERYBODY HAS TO HAVE A
- 17 TEAM OF LAWYERS WORKING ON THIS. WE DON'T HAVE TEAMS
- 18 OF LAWYERS AT CIRM.
- 19 DR. HALL: CAN I ASK WHAT THE CONCERN IS WITH
- 20 THE STATEMENT AS WRITTEN BECAUSE AT LEAST SOME PEOPLE
- 21 FELT IT WAS OKAY. SO IS THE OBJECTION THAT THIS IS TOO
- 22 HI GH A TRI GGER? WHAT --
- 23 CHAIRMAN PENHOET: WE'VE GOT TWO CONCERNS, I
- 24 THINK, ON BOTH ENDS OF THE SPECTRUM. SOME CONCERNS ARE
- 25 THAT THIS TRIGGER IS TOO HIGH, AND, THEREFORE, WE'LL

- 1 NEVER GET THIS IN PLACE. THE OTHER CONCERN IS THE
- 2 TRIGGER IS TOO LOW, AND IT WILL ACTUALLY NEVER COME
- 3 INTO PLAY BECAUSE THE TOTAL AMOUNT OF EXPENDITURES WILL
- 4 BE LARGER THAN WE'LL EVER PAY 25 PERCENT OF. SO SOME
- 5 PEOPLE ARE ARGUING THIS IS MOOT BECAUSE WE'LL NEVER PAY
- 6 MORE THAN 25 PERCENT ANYWAY AND --
- 7 DR. HALL: NOBODY WANTS IT MORE THAN THIS,
- 8 RIGHT? THIS IS THE --
- 9 CHAIRMAN PENHOET: I HAVEN'T HEARD THAT
- 10 ARGUMENT.
- DR. HALL: THIS IS THE TOP RANGE.
- 12 MR. GILLENWATER: WE'VE RESERVED THAT RIGHT
- 13 TO OBJECT TO THAT STILL. WE'RE DOING A -- THIS IS,
- 14 AGAIN, TODD GILLENWATER FROM CHI. WE'RE DOING A PRETTY
- 15 BROAD SURVEY OF OUR MEMBERSHIP AND LOOKING AT NIH
- 16 FUNDING AND LOOKING AT OTHER EXAMPLES OF WHERE THIS
- 17 NUMBER SHOULD BE BASED ON A SURVEY OF OUR -- OF AN
- 18 INFORMAL SURVEY OF OUR MEMBERSHIP. SO WE HAVEN'T
- 19 DETERMINED IF IT'S WHERE.
- 20 CHAIRMAN PENHOET: ONE SOLUTION TO THIS WOULD
- 21 BE IF YOU PUT MORE THAN HALF OF THE PRE-IND MONEY, MORE
- 22 THAN 25 PERCENT OF THE PRE-PHASE III MONEY, OR MORE
- 23 THAN 10 PERCENT OF THE TOTAL, THAT THIS WOULD TRIGGER.
- 24 THOSE ARE THE SORT OF MILESTONES IN ANY PRODUCT
- 25 DEVELOPMENT. YOU COULD ANTICIPATE THREE DIFFERENT

- 1 TRIGGERS DEPENDING ON WHICH ONE WAS APPLICABLE IF YOU
- 2 DIDN'T MEET ANY OF THOSE. THAT WOULD BE ANOTHER
- 3 APPROACH TO THIS PROBLEM.
- 4 DR. PRIETO: I THINK THAT WOULD BE A PRETTY
- 5 REASONABLE APPROACH.
- 6 DR. WRIGHT: DUANE, HOW DOES THAT SOUND? IS
- 7 IT CLEARER?
- 8 MR. ROTH: CAN YOU RESTATE IT?
- 9 CHAIRMAN PENHOET: I'M JUST THROWING OUT
- 10 NUMBERS HERE, BUT THE THREE SORT OF MILESTONES IN
- 11 PRODUCT DEVELOPMENT ARE IND, END OF PHASE II, AND END
- 12 OF PHASE III. WE HAVE A BLENDED NUMBER HERE FOR THE
- 13 WHOLE THING. SO IF YOU SAID IF WE PUT IN MORE THAN,
- 14 YOU KNOW, X AMOUNT, IT WOULD BE A HIGHER AMOUNT,
- 15 PRE-IND, JUST FOR SAKE OF ARGUMENT, PICK 25, WE PUT IN
- 16 MORE THAN 15 PRE-PHASE III, OR MORE THAN 10 PERCENT OF
- 17 THE TOTAL DEVELOPMENT COST, INCLUDING PHASE III, THAT
- 18 THIS THING WOULD BE TRIGGERED. I'M NOT MARRIED TO
- 19 THOSE NUMBERS. I'M JUST USING WHAT WE STARTED WITH
- 20 HERE AS A BASIS.
- 21 MR. SIMPSON: THAT'S CERTAINLY ONE APPROACH.
- 22 BUT IF YOU WANT CLARITY AND SIMPLIFICATION, THE
- 23 CLEAREST, SIMPLEST ONE IS IF YOU TAKE ANY MONEY AT ALL,
- 24 IT TRIGGERS. THEN YOU DON'T GET INTO ANY KIND OF A
- 25 NEGOTI ATI ON.

- 1 MR. GILLENWATER: NO ONE WILL ACCEPT YOUR
- 2 GRANTS. NO ONE WILL WANT YOUR GRANTS.
- 3 MR. SIMPSON: THE THINGS THAT ARE TRIGGERED
- 4 ARE HARDLY ONEROUS. ANY RESPECTABLE COMPANY HAS SOME
- 5 SORT OF AN ACCESS PLAN FOR THE PUBLIC.
- 6 MR. GILLENWATER: THAT MAKES IT MOOT ANYWAY.
- 7 THE REGULATION SHOULDN'T EXIST IF IT'S STANDARD
- 8 OPERATING PROCEDURE. YOU CAN GET INTO THAT ARGUMENT.
- 9 CHAIRMAN PENHOET: I THINK WE HAVE AGREED IN
- 10 THE NONPROFIT ONE THAT THAT IS SOMETHING WE WANT IN
- 11 HERE. THERE'S VERY STRONG SUPPORT FOR THAT, ABOUT THE
- 12 ACCESS ONE. IT IS TRUE THE PRICING ONE IS ONLY
- 13 CALIFORNIA. WE HAVE HEARD WE HAVE TO BE VERY CAREFUL
- 14 THAT IT DOESN'T POLLUTE PRICING ELSEWHERE BECAUSE THAT
- 15 WOULD DESTROY THE OPPORTUNITY FOR THE COMPANIES. SO I
- 16 THINK THAT'S A SERIOUS ISSUE.
- 17 ANY OTHER DISCUSSION HERE? I THINK WE'RE
- 18 GOING TO HAVE TO LEAVE THE FINAL RESOLUTION TO THIS TO
- 19 THE BOARD DISCUSSION.
- 20 MS. SEARS: DARCI FROM ASSEMBLYMEMBER MULLIN.
- 21 HELLO, EVERYBODY.
- 22 CHAIRMAN PENHOET: HI. THANKS FOR COMING
- 23 DOWN.
- 24 MS. SEARS: I GUESS MY QUESTION IS TO THE
- 25 EXTENT THAT 2911, AB 2911, ACTUALLY ALREADY WENT

- 1 THROUGH, WILL THERE BE ANY -- IS THERE ANY DESIRE TO
- 2 TRY TO MAKE THIS CONSISTENT WITH THAT WITH SOME OF
- 3 THOSE PROVISIONS, SPECIFICALLY WITH HOW YOU ARE GOING
- 4 TO ADDRESS THE UNINSURED? BECAUSE THERE WERE CERTAIN
- 5 THRESHOLDS THAT HAD TO BE MET, AND THERE WERE THREE
- 6 DIFFERENT BENCHMARKS IN TERMS OF PRICING. WILL YOU BE
- 7 LOOKING AT THAT?
- 8 CHAIRMAN PENHOET: I GUESS WE HAVE TO BE IN
- 9 COMPLIANCE WITH CALIFORNIA LAW. WHERE IS THAT? WHAT'S
- 10 THE STATUS?
- 11 MS. SEARS: ON THE GOVERNOR'S DESK.
- 12 CHAIRMAN PENHOET: IT IS ON THE GOVERNOR'S
- 13 DESK.
- 14 MS. SEARS: 2911 MADE IT OUT, SO IT WAS A
- 15 QUESTION OF WHEN THIS IS GOING TO GET SIGNED.
- DR. PRIETO: WHAT ARE THE STIPULATIONS OF
- 17 2911?
- 18 CHAIRMAN PENHOET: I GUESS WE'LL ALL HAVE TO
- 19 GET UP TO SPEED ON 2911.
- 20 MS. SEARS: I MEAN IT'S SPECIFIC TO HOW THE
- 21 COMPANIES ARE GOING TO BE ADDRESSING THE UNINSURED.
- 22 THERE ARE THREE DIFFERENT BENCHMARKS, AND I'LL HAVE
- 23 TODD SORT OF JUMP IN AS HE CAN BECAUSE I KNOW CHI AND A
- 24 NUMBER OF OTHER ENTITIES WERE HEAVILY INVOLVED IN THAT.
- 25 YOU DID HAVE BEST PRICE, BEST AVAILABLE COMMERCIAL

- 1 PRICE, FEDERAL MEDICALD PRICE, AND THERE WAS A THIRD.
- 2 MR. GILLENWATER: THERE WAS SOMETHING IN
- 3 THERE WITH MANUFACTURER'S PRICE.
- 4 MS. SEARS: MANUFACTURER'S PRICE LESS, LIKE,
- 5 10 PERCENT OR SOMETHING LIKE THAT. IF YOU TAKE A LOOK
- 6 AT AB 2911 ON-LINE, YOU CAN FIND OUT WHAT THAT WAS.
- 7 AND IT WAS AT 300 PERCENT OF POVERTY LEVEL.
- 8 MR. GILLENWATER: I'LL JUST ADD ONE FURTHER
- 9 COMPLICATING FACTOR TO THAT. THIS IS MY UNDERSTANDING
- 10 OF THAT LEGISLATION. THAT REFERS TO OUTPATIENT
- 11 PRESCRIPTION DRUGS; WHERE, OF COURSE, WE PROBABLY
- 12 UNDERSTAND THAT MANY OF THE THERAPIES THAT RESULT FROM
- 13 THIS COULD BE BIOLOGICS, INJECTABLES, INPATIENT
- 14 THERAPIES, WHICH AREN'T COVERED UNDER THAT LEGISLATION.
- MS. SEARS: I THINK IT DID.
- 16 CHAIRMAN PENHOET: WE BETTER HAVE A LOOK AT
- 17 IT THEN.
- 18 OKAY. SO WE HAVE TWO PROPOSALS, A FLAT FEE
- 19 IRRESPECTIVE OF WHAT THE AMOUNT IS, FIRST DOLLAR OR
- 20 SOME OTHER NUMBER, 25 PERCENT, FOR THE SAKE OF THE
- 21 ARGUMENT HERE, OR WHETHER WE SHOULD PARSE THIS INTO
- 22 VARIOUS PHASES, AND THE THIRD THING IS WE HAVE TO MAKE
- 23 IT CONSISTENT WITH WHAT WILL BECOME CALIFORNIA LAW IF
- 24 THE GOVERNOR SIGNS THIS BILL.
- 25 MS. KING: WERE THERE ANY OTHER COMMENTS ON

- 1 THE PHONE?
- 2 MR. ROTH: I WAS GOING TO MAKE JUST ONE
- 3 COMMENT, THAT I THINK WE NEED TO BE COGNIZANT THAT
- 4 THERE ARE CONSTANTLY GOING TO BE CHANGING LAWS LIKE THE
- 5 ONE THAT WAS JUST BEING DISCUSSED. AND THAT WHAT WE
- 6 PROBABLY WANT IS SOMETHING THAT WOULD BE COMPLIANT WITH
- 7 THE THEN IN EFFECT CALIFORNIA LAW THAT GOVERNS PRICING.
- 8 I THINK THE PROBLEM YOU GET INTO WITH ALL THESE
- 9 CHANGING CALCULATIONS AND COVERAGES. THAT YOU ARE GOING
- 10 TO PUT SOMETHING DOWN THAT PEOPLE WILL FEAR THAT, WHILE
- 11 IT MAY BE UNDERSTANDABLE TODAY, IT WON'T BE FIVE OR TEN
- 12 YEARS WHEN THESE PRODUCTS FINALLY GET TO THE MARKET,
- 13 TEN YEARS MOST LIKELY. I THINK YOU HAVE TO BE CAREFUL
- 14 ABOUT WRITING PRICING POLICIES THAT ARE PROBABLY GOING
- 15 TO BE MUCH OUTDATED BY THE TIME OUR FIRST PRODUCTS HIT
- 16 THE MARKET.
- 17 CHAIRMAN PENHOET: WELL, THIS WILL HAVE TO BE
- 18 A LIVING DOCUMENT. HOW LONG DOES IT TAKE TO CHANGE ONE
- 19 OF THESE REGULATIONS, SCOTT?
- 20 MR. TOCHER: ON AN EMERGENCY BASIS, IT CAN BE
- 21 DONE RATHER QUICKLY, IN A MATTER OF DAYS. PERMANENTLY,
- 22 HOWEVER, CHANGING THE REGULATIONS IS DONE JUST IN THE
- 23 SAME PROCEDURE AS WE'RE ADOPTING THEM, WHICH IS WITH A
- 24 SERIES OF PUBLIC NOTICE PERIODS AND REVIEW BY THE
- 25 OFFICE OF ADMINISTRATIVE LAW, USUALLY MEASURED IN

- 1 MONTHS.
- 2 CHAIRMAN PENHOET: OKAY. MOVING TO SECTION
- 3 G, PAGE 15, REVENUE SHARING. WE DISCUSSED THIS LAST
- 4 TIME. BASICALLY IT'S VERY SIMILAR TO WHAT WE HAD FOR
- 5 UNIVERSITIES EXCEPT THAT WE HAVE A 17-PERCENT NUMBER
- 6 HERE INSTEAD OF A 25-PERCENT NUMBER. ON PAGE 16. PAGE
- 7 15, I THINK, IS IDENTICAL TO THE NOT-FOR-PROFIT.
- 8 17, THE LOGIC FOR 17 RATHER THAN 25 IS THAT
- 9 THE NET REVENUE DESCRIPTION FOR UNIVERSITIES CARVED OUT
- 10 THE PAYMENTS TO INVENTORS. IN THE CASE OF COMPANIES,
- 11 THE INVENTORS WORK FOR THE COMPANIES AND GENERALLY
- 12 DON'T GET PAID SEPARATELY. SO THIS IS TO REWARD THE
- 13 COMPANY FOR THE INVENTOR'S SHARE. THAT'S WHY IT'S 17
- 14 AND NOT 25. THAT'S THE LOGIC OF THIS.
- AND THEN IF FUNDING SOURCES IN ADDITION WERE
- 16 USED, INCLUDING INTERNAL FUNDING, THEN THE RESULTANT
- 17 REVENUE SHALL BE PROPORTIONATED ON THE BASIS OF THE
- 18 INVESTMENT, AND THEY HAVE TO FOLLOW UP.
- 19 ANY COMMENTS SO FAR?
- 20 OKAY. ON PAGE 17, REVENUE SHARING
- 21 REQUIREMENTS. IN THE EVENT THAT THEY CREATE A REVENUE
- 22 STREAM FROM SELF-COMMERCIALIZED PRODUCTS, AND MY OWN
- 23 BIAS IS WE SHOULD BE INCENTING COMPANIES TO FORWARD,
- 24 INTEGRATE, AND COMMERCIALIZE THEIR OWN PRODUCTS IN
- 25 CALIFORNIA. THAT'S WHAT CREATES THE MOST JOBS, THE

- 1 MOST INCOME TAX, ALL THE OTHER BENEFITS FROM INCREASED
- 2 ACTIVITIES. IT SAYS THAT THE AWARDEE ORGANIZATIONS
- 3 SHALL SHARE REVENUES WITH THE STATE OF CALIFORNIA IN
- 4 THE FORM OF ROYALTIES CAPPED AT THREE TIMES THE TOTAL
- 5 AWARDED MONEY.
- 6 WE HAVE SOME ISSUES AROUND THE RATE AT WHICH
- 7 THIS SHOULD HAPPEN; AND THAT IS, WE WOULDN'T WANT TO
- 8 KEEP ALL OF THE PROFITS FROM THIS FOR THE FIRST YEAR OR
- 9 TWO WHEN THE COMPANY IS JUST FINALLY MAKING IT TO
- 10 MARKET. THE QUESTION, WE DON'T HAVE IT ARTICULATED
- 11 HERE, OVER WHAT PERIOD OF TIME THAT SHOULD EXIST OR NOT
- 12 GREATER THAN A CERTAIN PERCENTAGE OF THE TOTAL PROFITS
- 13 OR SOMETHING LIKE THAT. I THINK WE STILL HAVE TO
- 14 ADDRESS THAT ISSUE. IT'S NOT LISTED HERE.
- 15 BUT THERE ARE TWO ISSUES. THE FORM IS A
- 16 ROYALTY, AND THE CAP IS THREE TIMES THE AWARDED AMOUNT
- 17 OF MONEY. WE DID HEAR CONSISTENTLY FROM INDUSTRY WE'RE
- 18 WILLING TO PAY BACK, BUT WE'D LIKE A CAP SO WE KNOW
- 19 WHAT THE TOTAL EXPOSURE IS.
- 20 DR. BRYANT: I JUST WONDERED WHY YOU PICKED
- 21 THREE.
- 22 CHAIRMAN PENHOET: WELL, WE SURVEYED A NUMBER
- OF OTHER ORGANIZATIONS WHICH ARE FUNDING COMPANIES, AND
- 24 THAT'S A VERY COMMON NUMBER THESE DAYS. I THINK JDRF
- 25 IS ASKING FOR A THREEFOLD RETURN. I BELIEVE THAT

- 1 CYSTIC FIBROSIS IS SOMETHING SIMILAR. WELLCOME TRUST
- 2 HAS MANY DIFFERENT WAYS. BUT IF YOU AVERAGE OUT ALL
- 3 THEIR WAYS OF PARTICIPATING, IT'S SORT OF IN THAT
- 4 RANGE.
- 5 DR. BRYANT: OKAY.
- 6 CHAIRMAN PENHOET: IT'S LOWER THAN MOST
- 7 VENTURE CAPITALISTS HOPE TO GET, BUT IN A SENSE WE'RE
- 8 TAKING MORE RISK THAN VENTURE CAPITALISTS. SO I THINK
- 9 IT'S NOT AN OUTRAGEOUS NUMBER, BUT IT'S FAIRLY TYPICAL
- 10 OF WHAT'S GOING ON.
- 11 MS. SEARS: IS THIS GOING STRAIGHT INTO THE
- 12 GENERAL FUND OR IS --
- 13 CHAIRMAN PENHOET: DARCI ASKED WHETHER THIS
- 14 MONEY WOULD GO TO THE GENERAL FUND. YES, IT WOULD GO
- 15 TO THE GENERAL FUND IN THIS CASE. IF WE MAKE LOANS,
- 16 THOUGH, APPARENTLY ACCORDING TO PROP 71, THAT THE
- 17 MONIES ARE RETURNED TO CIRM TO BE REINVESTED IN THE
- 18 FIELD. SO WE HAVE --
- 19 MS. SEARS: THERE'S NO ACCOUNT WITHIN THE
- 20 GENERAL FUND THAT YOU'RE GOING TO HAVE IT DEPOSITED
- 21 INTO? AND IF SO, WOULD THAT FUND BE CONTINUOUSLY
- 22 APPROPRIATED AND FOR WHAT PURPOSE?
- CHAIRMAN PENHOET: WE WERE WARNED OFF OF
- 24 THAT. BAYH-DOLE REQUIRES THAT THE MONEY IS USED FOR
- 25 RESEARCH AND EDUCATION. WE DECIDED THAT THE STATE

- 1 CAN -- AND WE WANT TO BE COMPATIBLE WITH BAYH-DOLE, BUT
- 2 WE BELIEVE THAT THE TOTAL BUDGET FOR RESEARCH AND
- 3 EDUCATION IN CALIFORNIA IS LARGE ENOUGH, THAT WHEN THE
- 4 TIME COMES THAT MONEY IS COMING IN, SOMEBODY IN THE
- 5 CONTROLLER'S OFFICE CAN FIGURE OUT WHERE TO PUT IT IN
- 6 ORDER TO MEET THAT REQUIREMENT. YOU DON'T BELIEVE
- 7 THAT'S THE CASE?
- 8 MS. SEARS: NO. MY RECOMMENDATION WOULD BE
- 9 THAT YOU ACTUALLY HAVE THAT ACCOUNT ALREADY SET UP WITH
- 10 THE SPECIFIC INTENT TO MEET FEDERAL REQUIREMENTS, THAT
- 11 IT GO BACK TO RESEARCH AND EDUCATION, HOWEVER THAT
- 12 NEEDS TO BE WORDED, BUT THAT IT ALSO BE CONTINUOUSLY
- 13 APPROPRIATED, NOT THAT WE DON'T LOVE THE FACT THAT THE
- 14 BUDGET PROCESS HAS BEEN SMOOTHLY LATELY, NOT IN ALL
- 15 YEARS HAS IT; THEREFORE, IT COULD DELAY WHATEVER THOSE
- 16 FUNDS MAY END UP BEING ALLOCATED FOR.
- 17 CHAIRMAN PENHOET: MANY OF YOUR COLLEAGUES IN
- 18 SACRAMENTO FOUGHT US VERY HARD ON THIS ISSUE.
- 19 MS. SEARS: I KNOW. THAT'S MY PERSONAL
- 20 OPINION.
- 21 CHAIRMAN PENHOET: DO ANY OF YOU IN THE
- 22 AUDIENCE HAVE AN OPINION ABOUT THIS ISSUE OF EARMARKING
- 23 THESE FUNDS?
- 24 MR. SIMPSON: I ACTUALLY THINK IT WOULD NOT
- 25 BE BAD IF IT CAME BACK TO CIRM, BUT I DON'T KNOW IF

- 1 THAT'S ALLOWED.
- 2 CHAIRMAN PENHOET: I THINK NOT.
- 3 MS. SEARS: THAT DOESN'T MEET THE STANDARD OF
- 4 PUTTING IT BACK TO RESEARCH IF IT GOES STRAIGHT BACK
- 5 INTO --
- 6 CHAIRMAN PENHOET: THE STATE COULD REALLOCATE
- 7 IT BACK TO CIRM IF IT WANTED TO DO THAT. WE'VE SPENT
- 8 MANY HOURS IN THE HALLS OF SACRAMENTO ON THIS ISSUE.
- 9 KIRK, YOU MIGHT WANT TO --
- 10 MR. KLEINSCHMIDT: IT WOULD ALSO REQUIRE
- 11 LEGISLATION TO SET UP THIS KIND OF FUND, SO IT WOULD BE
- 12 BEYOND THE SCOPE OF THIS GROUP.
- MS. KING: DID THE PEOPLE ON THE PHONE HEAR
- 14 KIRK'S COMMENT?
- DR. WRIGHT: NO.
- 16 CHAIRMAN PENHOET: IT WOULD REQUIRE SPECIAL
- 17 LEGISLATION TO SET SOMETHING LIKE THAT UP. IN THIS
- 18 CASE WE HAVE LOTS OF TIME TO THINK ABOUT THIS ISSUE.
- 19 MR. ROTH: HAS THE ROYALTY RATE BEEN SET
- 20 UNDER SLIDE 17?
- 21 CHAIRMAN PENHOET: IT HAS NOT. THE CAP HAS
- 22 BEEN SET WITH THE GENERAL PRINCIPLE THAT THE ROYALTY
- 23 RATE SHOULDN'T BE SO HIGH AS IT WOULD FORCE THE COMPANY
- NOT TO BE PROFITABLE RIGHT UP FRONT TO PAY THE MONEY
- 25 BACK IMMEDIATELY. SO THE CAP IS SET. AND I THINK WE

- 1 HAVE TO FIGURE OUT EXACTLY HOW TO SAY WHAT RATE IT
- 2 SHOULD BE TO GET TO THE CAP.
- 3 MR. ROTH: OKAY. BECAUSE I THINK THAT'S
- 4 REALLY KEY.
- 5 AND THE SECOND WOULD BE IN THE EVENT OF
- 6 STACKING ROYALTIES, THERE BE A SEPARATE PROVISION. I
- 7 MEAN THERE CAN BE MULTIPLE PATENTS ON A PRODUCT, AS YOU
- 8 KNOW. AND ONE PATENT MIGHT BE CIRM FUNDED AND
- 9 GENERATED THROUGH CIRM FUNDING, BUT THE COMPANY MAY
- 10 HAVE TO LICENSE THREE OR FOUR ADDITIONAL PATENTS. SO
- 11 THERE HAS TO BE -- IN ALMOST ALL NEGOTIATIONS NOW,
- 12 THERE'S A CLAUSE ABOUT STACKING ROYALTIES.
- 13 CHAIRMAN PENHOET: YES. AGAIN, WE THINK THE
- 14 OPERATIVE THAT EXPOSURE FOR THE COMPANIES IS REALLY THE
- 15 CAP.
- MR. ROTH: THAT'S CORRECT.
- 17 CHAIRMAN PENHOET: SO --
- 18 MR. ROTH: IF THEY THINK THAT THEY MIGHT HAVE
- 19 TO PAY IT, LET'S SAY THAT WE WERE TO ASK FOR A
- 20 2-PERCENT ROYALTY, BUT THEY HAVE TO PAY 6 PERCENT TO --
- 21 2 PERCENT TO THREE OTHER PARTIES, WE MAY IN THOSE CASES
- 22 WANT TO SET A CAP ON THE TOTAL ROYALTY THAT'S PAID OUT
- 23 ON THE PRODUCT. IN THAT CASE THE REPAYMENT WOULD BE
- 24 SLOWER.
- 25 CHAIRMAN PENHOET: THAT'S RIGHT. I THINK WE

- 1 HAVEN'T -- WE'LL HAVE TO SIT DOWN. THERE WILL BE
- 2 DIFFERENT CASE BY CASE, SO I THINK THE RATE AT WHICH
- 3 IT'S REPAID IS SOMETHING WE MAY HAVE TO LEAVE TO THE
- 4 CIRM NEGOTIATORS.
- 5 MR. SIMPSON: BUT YOU'RE PROBABLY THINKING OF
- 6 SINGLE DIGITS FOR A ROYALTY RATE, 3 TO 8 PERCENT, OR
- 7 SOMETHING LIKE THAT, I WOULD IMAGINE, RIGHT?
- 8 CHAIRMAN PENHOET: YEAH. PROBABLY NOT HIGHER
- 9 BECAUSE WE DON'T WANT TO DEPRIVE THESE COMPANIES OF
- 10 SOME EARLY RETURN ON THEIR OWN INVESTMENTS IN THIS
- 11 AREA.
- 12 AND THEN THERE'S SOME LANGUAGE HERE ABOUT
- 13 THEY HAVE TO LET US KNOW HOW THEY' RE CALCULATING THESE
- 14 THI NGS.
- 15 LOANS, WE'RE IN A LITTLE BIT OF UNCHARTERED
- 16 TERRITORY HERE. THERE'S BEEN A LOT OF QUESTION WHETHER
- 17 THIS WHOLE LOAN PROVISION IS -- WHETHER THE NOTION OF
- 18 LOANS VERSUS GRANTS SHOULD BE A DISCUSSION FOR US, OR
- 19 IT'S REALLY A STRATEGIC PLANNING ISSUE, ETC. BUT WE'VE
- 20 AGREED THAT WE WOULD AT LEAST PUT IT IN HERE AND
- 21 DI SCUSS IT.
- WE CAN MAKE LOANS. THE DIFFERENCES ARE THAT
- 23 LOANS WOULD HAVE TO BE REPAID WHETHER THE PROJECT WAS
- 24 SUCCESSFUL OR NOT. THE NOTION HERE IS THAT LOANS WOULD
- 25 BE AT A FAIRLY LOW RATE. SO IT MIGHT BE A FAIR AMOUNT

- 1 LESS MONEY FOR A COMPANY THAN THE THREE TIMES THING.
- 2 AND WE'VE SORT OF THOUGHT THAT THE COMPANIES MAYBE
- 3 COULD DECIDE WHETHER THEY WANTED A LOAN OR A GRANT TO
- 4 FUND A CERTAIN PROJECT. SO PRIME PLUS TWO IS A NUMBER
- 5 THAT WE JUST SORT OF PICKED OUT. COULD BE ANY NUMBER.
- 6 COULD BE PRIME RATE. COULD BE ANOTHER NUMBER.
- 7 AND, YOU KNOW, IN THINKING THROUGH WHETHER
- 8 YOU'D WANT A LOAN UNDER THESE TERMS OR WHETHER YOU'D
- 9 WANT A GRANT, I GUESS YOU WOULD TAKE A LOAN IF YOU
- 10 THOUGHT THE PROGRAM WAS VERY DERISKED AND HAD A HIGH
- 11 PROBABILITY OF WORKING. IF YOU THINK IT'S A SUPER
- 12 RISKY PROGRAM, THEN YOU'D PROBABLY TAKE THE GRANT.
- 13 WE HAVE SOME UNCERTAINTY ABOUT WHETHER OUR
- 14 RFA SHOULD BE LOANS AND FOR GRANTS, OR SAY WE HAVE AN
- 15 RFA FOR PEOPLE WHO WANT TO DO X, Y, OR Z, AN RFP FOR
- 16 PEOPLE WHO WANT TO DO THIS. AND IF YOU'RE A COMPANY
- 17 THAT WANTS TO DO THIS, YOU CAN ELECT WHETHER YOU WANT
- 18 TO GO DOWN THE LOAN PATH OR THE GRANT PATH. THAT WOULD
- 19 BE THE TWO WAYS YOU COULD DO THIS.
- 20 MR. TAYMOR: WELL, I'M GLAD TO HEAR THAT THIS
- 21 IS NOT THE DEFINITIVE WORD ON LOANS BECAUSE IT SEEMS TO
- 22 ME THAT THERE ARE A LOT OF OTHER PARAMETERS FOR A LOAN
- 23 THAT ARE IMPORTANT, AT LEAST TO GIVE THE PUBLIC THE
- 24 OPPORTUNITY TO HAVE SOME COMMENT ON IN TERMS OF
- 25 REPAYMENT TERMS, SECURITY, A RANGE OF THINGS. AT THE

- 1 LAST MEETING YOU SAID THE LOANS WOULD BE AT MARKET
- 2 RATE, I THOUGHT. AT LEAST I THOUGHT I HAD HEARD THAT
- 3 THEY WERE TO BE AT MARKET RATE. AND THESE LOANS IN
- 4 MANY CASES WOULD BE WELL BELOW MARKET AT PRIME PLUS
- 5 TWO.
- 6 I'M WONDERING IF YOU HAD EXPLORED THE
- 7 POSSIBILITY OF HAVING, SINCE YOU DO HAVE OTHER
- 8 PARTICIPATIONS IN A SENSE IN A GRANT, OF HAVING A LOAN
- 9 THAT'S A PARTICIPATING LOAN, ONE THAT THE PARTICIPATION
- 10 MAY, AGAIN, REFLECT THE SUCCESS RATE. PARTICULARLY
- 11 BECAUSE A NUMBER OF THESE LOANS BASICALLY, UNLESS --
- 12 EVEN IF THEY WERE SECURE, LOANS TO EARLY STAGE
- 13 COMPANIES, THE LIKELIHOOD OF THEIR BEING REPAID IF THE
- 14 COMPANY IS UNSUCCESSFUL OR THE PROJECT IS UNSUCCESSFUL
- 15 IS FAIRLY LOW, SO THE LOAN ALMOST BECOMES A GRANT. IT
- 16 SEEMS THAT, AGAIN, FOR LOANS TO EARLY STAGE COMPANIES
- 17 WHERE THERE IS NO COLLATERAL, AN IMPROBABLE LIKELIHOOD
- 18 OF REPAYMENT, THAT THERE SHOULD BE SOME PARTICIPATION
- 19 AS IN THE GRANTS CIRCUMSTANCES. BUT I WOULD ENCOURAGE
- 20 YOU NOT TO REALLY ADDRESS LOANS IN THIS DOCUMENT, TO
- 21 ADDRESS IT IN A FORUM IN WHICH THE FULL PARAMETERS OF A
- 22 LOAN PROGRAM AND LOAN TERMS COULD BE AT LEAST DISCUSSED
- WITH THE PUBLIC.
- 24 CHAIRMAN PENHOET: YEAH. AS YOU CORRECTLY
- 25 POINT OUT, LOANS IS A VERY BROAD CATEGORY. IT CAN

- 1 COVER ALL KINDS OF DIFFERENT AND THE CONDITIONS
- 2 ASSOCIATED WITH A LOAN. JUST FOR YOUR INFORMATION,
- 3 THOUGH, TO A START-UP COMPANY, NO, A START-UP COMPANY
- 4 CAN'T GET ANY LOANS. BUT A COMPANY THAT'S A LITTLE
- 5 WAYS ALONG, TYPICALLY VENTURE DEBT THESE DAYS, IF YOU
- 6 ADD IN ALL THE COST, IS ABOUT 20 PERCENT INTEREST RATE,
- 7 IF YOU ADD IN COST OF THE WARRANTS AND --
- 8 MR. TAYMOR: THAT'S MY POINT IS THAT THIS IS
- 9 WAY BELOW MARKET. IT WOULD BE LIKE AN EQUIPMENT
- 10 FINANCING.
- 11 CHAIRMAN PENHOET: BUT THE VIEW IS WE'RE HERE
- 12 TO HELP COMPANIES, NOT TO GET IN THE VENTURE -- COMPETE
- 13 WITH THE VENTURE CAPITAL COMMUNITY OR THE VENTURE DEBT
- 14 COMMUNITY. SO YOU ARE RIGHT. THESE ARE UNDER MARKET
- 15 FOR AN ORGANIZATION WITH THAT RISK PROFILE. NO DOUBT
- 16 ABOUT THAT.
- 17 MR. TAYMOR: WE CAN BALANCE IT, THOUGH. WE
- 18 CAN HELP THEM OUT AND SAY AT SOME POINT, IF YOU HAVE A
- 19 SUCCESSFUL -- AS YOU ARE WITH GRANTS, THE GRANTS ARE
- 20 DESIGNED TO HELP COMPANIES, BUT YOU STILL HAVE A
- 21 PARTICIPATION, YOU STILL TAKE A SUBSTANTIAL ROYALTY, 3
- 22 X, MAYBE THE LOAN WOULD BE PAID BACK UP TO 50 PERCENT
- 23 HALF X OR 1 X.
- 24 CHAIRMAN PENHOET: WELL, YOU KNOW, I'VE HAD
- 25 MIXED FEELING MYSELF ABOUT WHETHER WE SHOULD BE

- 1 DISCUSSING LOANS IN THIS CONTEXT ANYWAY. I DON'T KNOW
- 2 WHAT THE FEELING OF THE TASK FORCE IS. TO MAKE THIS
- 3 SYMMETRICAL TO THE NOT-FOR-PROFIT, WE CAN TAKE THE
- 4 LOANS -- WE'RE NOT MAKING ANY LOANS TO NOT-FOR-PROFITS.
- 5 THEY DON'T WANT TO BORROW MONEY FROM US. THEY PROBABLY
- 6 CAN'T ANYWAY EVEN IF THEY WANTED TO, SO THAT'S NOT A
- 7 POSSI BI LI TY.
- 8 ONE THING IS WE CAN JUST DEFER THE WHOLE LOAN
- 9 DISCUSSION TO ANOTHER GROUP. TO THE STRATEGIC PLANNING
- 10 GROUP. IF WE'RE GOING TO MAKE LOANS, SOMEBODY HAS TO
- 11 DEFINE THE POLICY UNDER WHICH THE LOANS ARE MADE.
- 12 MR. ROTH: I'VE THOUGHT AND THOUGHT ABOUT WHY
- 13 ANYBODY WOULD TAKE A LOAN VERSUS A GRANT, AND I REALLY
- 14 HAVE TROUBLE COMING UP WITH A REAL GOOD REASON FOR THAT
- 15 UNLESS THERE'S A DIFFERENT HURDLE FOR GETTING THE
- 16 MONEY.
- 17 AND SECOND, I THINK IT'S EXTREMELY
- 18 COMPLICATED FOR THE STAFF AND EVERYBODY TO HAVE TO SET
- 19 UP THIS LOAN PROGRAM. AND THEN THE DILIGENCE REQUIRED
- 20 TO MAKE SURE THAT THIS DEBT IS SECURED OR UNSECURED OR
- 21 WHATEVER IT'S GOING TO BE, IT'S EXTREMELY COMPLICATED.
- 22 AND I WONDER IF THERE AREN'T SOME STATE RAMIFICATIONS
- 23 OF THAT OUTSTANDING DEBT THAT MIGHT ENTER IN AS WELL.
- I REALLY WOULD ENCOURAGE US NOT TO TRY TO
- 25 DEAL WITH THIS UNLESS THERE IS A DEMAND FOR IT.

- 1 CHAIRMAN PENHOET: ANY OTHER VIEWS ON THIS?
- 2 SUSAN, ARE YOU STILL THERE?
- 3 DR. BRYANT: I'M HERE. I TEND TO AGREE. I
- 4 THINK IF WE DEFER IT, WE'LL HEAR FROM PEOPLE IF THERE'S
- 5 A NEED FOR A LOAN PROGRAM. OTHERWISE WE COULD JUST LET
- 6 IT LAY UNTIL IT BECOMES AN ISSUE.
- 7 CHAIRMAN PENHOET: JANET.
- 8 DR. WRIGHT: I'M OKAY WITH THAT.
- 9 CHAIRMAN PENHOET: FRANCISCO.
- 10 DR. PRIETO: I'M OKAY WITH THAT TOO. I'M
- 11 SURE THIS WILL COME UP AT LEAST AS A TOPIC IN THE
- 12 STRATEGIC PLANNING PROCESS.
- 13 CHAIRMAN PENHOET: ANY COMMENT FROM THE
- 14 AUDI ENCE ANYWHERE? I THINK THAT WE SHOULD PROBABLY
- 15 TAKE IT -- I AGREE WITH YOU GUYS. I THINK WE SHOULD
- 16 JUST IGNORE IT FOR NOW AND COME BACK LATER WITH A LOAN
- 17 POLICY. THE LOAN POLICY LATER COULD BE IN LIEU OF
- 18 GRANTS, AND THEN YOU JUST SLIP IT INTO THE SAME POLICY.
- 19 I THINK IT REQUIRES A LOT FURTHER WORK THAN WE CAN PUT
- 20 IN AT THIS POINT IN TIME. SO WE'RE GOING TO DELETE THE
- 21 LOAN PROVISIONS.
- 22 WE DID DISCUSS LAST TIME A BLOCKBUSTER
- 23 PAYMENT THAT --
- DR. MAXON: THIS IS THE PART THAT'S DIFFERENT
- 25 FROM WHAT'S IN THE POLICY.

- 1 CHAIRMAN PENHOET: OKAY. THIS IS DIFFERENT
- 2 THAN IN THE DRAFT THAT YOU SUBMITTED BEFORE. AGAIN,
- 3 THIS IS JUST A PROPOSAL. IT SAYS FOR -- THIS IS PAGE
- 4 19. FOR BOTH GRANTS AND LOANS, WE'LL TAKE OUT THE
- 5 LOANS, THAT LEAD TO SUCCESSFUL COMMERCIAL PRODUCTS, A
- 6 BLOCKBUSTER PAYMENT EQUAL TO THREE TIMES THE ORIGINAL
- 7 AWARD AND PAID BACK OVER FIVE YEARS IS DUE AFTER
- 8 REVENUES EXCEED \$250 MILLION PER YEAR. THIS WOULD BE
- 9 IN ADDITION TO WHAT OTHER PAYMENTS YOU OWED.
- 10 SO IF YOU GOT A GRANT AND YOU HAD TO PAY BACK
- 11 THREE TIMES ON THE GRANT, YOU HAVE TO PAY THREE TIMES
- 12 AGAIN, ACCORDING TO THIS, IF YOU HAVE A BLOCKBUSTER,
- 13 WHOSE SALES -- BLOCKBUSTER HERE IS DEFINED AS \$250
- 14 MILLION A YEAR. SO IT'S ESSENTIALLY A FEE ASSOCIATED
- 15 WITH A BIG SUCCESS.
- 16 WE ARE GOING TO HAVE LOTS OF PROJECTS THAT
- 17 DON'T WORK. MOST OF THEM WON'T WORK. I THINK WE HEARD
- 18 THAT THE BLOCKBUSTER CONCEPT, AT LEAST, WAS ACCEPTABLE
- 19 TO INDUSTRY. QUESTION IS IS \$250 MILLION THE RIGHT
- 20 NUMBER? WE PUT THAT UP FOR DISCUSSION.
- 21 ANY COMMENT BY THE TASK FORCE MEMBERS?
- 22 DR. PRIETO: DO WE HAVE ANY DATA ON WHAT THE
- 23 NUMBER OR THE PROPORTION OF PRODUCTS OUT THERE NOW ARE
- 24 CURRENTLY AT THIS LEVEL?
- 25 CHAIRMAN PENHOET: YOU KNOW, IT'S HARD TO

- 1 SAY. IN THE CELL THERAPY BUSINESS, I'M SURE THERE ARE
- 2 NONE.
- 3 UNIDENTIFIED SPEAKER: IS THAT ANNUALLY OR
- 4 TOTAL?
- 5 CHAIRMAN PENHOET: NO, ANNUALLY. BLOCKBUSTER
- 6 IS THE SALES REACH \$250 MILLION A YEAR. BECAUSE YOU
- 7 COULD HAVE A LOUSY PRODUCT WHICH SELLS \$25 MILLION A
- 8 YEAR AND YOU NEVER MAKE ANY MONEY ON IT; BUT AFTER 10
- 9 YEARS, IF IT WAS A CUMULATIVE TOTAL, YOU'D GET TO THIS
- 10 NUMBER. SO THIS IS AN ANNUAL REVENUES OF \$250 MILLION
- 11 OR GREATER. IT WOULD BE A NICE SUCCESS.
- DR. PRIETO: I WOULD PRESUME THE ONLY MODELS
- 13 NOW WOULD BE PHARMACEUTICALS. I JUST WONDER -- I KNOW
- 14 THERE ARE SEVERAL. I JUST DON'T KNOW --
- 15 CHAIRMAN PENHOET: IN EXCESS OF 250, THERE
- 16 ARE PROBABLY 500 OF THEM.
- 17 DR. PRI ETO: OKAY.
- 18 MR. ROTH: THERE WOULD BE A CONSIDERABLE
- 19 NUMBER OVER 250 MILLION WORLDWIDE SALES. I DON'T THINK
- 20 THIS IS A PARTICULARLY ONEROUS CLAUSE TO PUT IN. I
- 21 DON'T THINK ANYBODY IS GOING TO OBJECT IT. IT'S
- 22 CAPPED. YOU KNOW WHAT IT IS GOING IN. AT THE POINT IN
- 23 TIME YOU'RE TAKING THE MONEY, YOU HOPE THAT YOU CAN PAY
- 24 THAT SOMEDAY.
- 25 CHAIRMAN PENHOET: INDEED. OKAY. THEN WE

- 1 HAVE --
- 2 DR. PRIETO: AND INTO THAT UPPER INCOME TAX
- 3 BRACKET, RIGHT. HOPE YOU GET THERE.
- 4 CHAIRMAN PENHOET: INDEED. WE HAVE SOME
- 5 PRESS RELEASE REQUIREMENTS, PROBABLY NONCONTROVERSIAL.
- DR. MAXON: SAME AS THE LAST POLICY.
- 7 CHAIRMAN PENHOET: SAME AS THE LAST POLICY.
- 8 MARCH-IN RIGHTS, THE WORDING IS SOMEWHAT
- 9 DIFFERENT, BUT THE INTENT IS THE SAME. BASICALLY MOST
- 10 OF THIS TALKS ABOUT FAILURE TO COMMERCIALIZE, FAILURE
- 11 TO LIVE UP TO ANY OF THE AGREED UPON CRITERIA, AND TO
- 12 ALLEVIATE PUBLIC HEALTH AND SAFETY NEEDS. I THINK THIS
- 13 IS IDENTICAL LANGUAGE TO WHAT WE HAD BEFORE OR
- 14 VIRTUALLY IDENTICAL.
- DR. MAXON: THERE ARE TWO CHANGES. THE WORD
- 16 "AWARDEE" APPEARS WHERE IT USED TO BE GRANTEE. AND IN
- 17 NO. 3, THE TERM "AWARDEE" WAS INCLUDED WHERE BEFORE IT
- 18 WAS NOT IN THE DRAFT POLICY. SO THAT IT NOW SAYS,
- 19 "BECAUSE THE AWARDEE OR LICENSEE HAS FAILED TO ADHERE
- 20 TO THE AGREED UPON PLAN FOR ACCESS TO RESULTANT
- 21 THERAPI ES. "
- 22 CHAIRMAN PENHOET: ANY COMMENTS ON THAT?
- MR. GILLENWATER: AGAIN, TODD GILLENWATER
- 24 FROM THE CALIFORNIA HEALTHCARE INSTITUTE. THIS IS JUST
- 25 REITERATING SOME COMMENTS WE MADE IN THE NONPROFIT

- 1 COMMENTS ON MARCH-IN IS LOOKING AT THE FEDERAL CODE AND
- 2 THE FEDERAL REGULATIONS WITH REGARDS TO MARCH-IN, AT
- 3 THE NIH ESPECIALLY, COVER A COUPLE OF PAGES WITH
- 4 REGARDS TO THE ABILITY FOR THOSE WHO ARE ABOUT TO BE
- 5 MARCHED IN ON TO DEFEND THEMSELVES AGAINST THAT. AND
- 6 WE'VE ASKED -- WE WILL ASK AGAIN THAT, IN CONSIDERATION
- 7 FOR THE FOR-PROFIT, THAT YOU TAKE A LOOK AGAIN AT THE
- 8 FEDERAL MARCH-IN PROCESS AND LOOK TO INCORPORATE THOSE
- 9 TO ENSURE THAT FOLKS HAVE A CHANCE TO DEFEND THEMSELVES
- 10 AGAINST MARCH-IN PROCEEDINGS IN THE VERY FEW INSTANCES
- 11 WE HOPE THAT WOULD EVER HAPPEN.
- 12 CHAIRMAN PENHOET: I BELIEVE WE DISCUSSED
- 13 BEFORE A REASONABLE CURE PERIOD WOULD BE SOMETHING WE
- 14 SHOULD PUT IN. I THINK WE FORGOT TO PUT THAT IN. I'M
- 15 SORRY. WE WILL CATCH THAT THIS TIME.
- 16 MR. SIMPSON: JOHN SIMPSON FROM THE
- 17 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. IN THE
- 18 MARCH-IN IN NO. 3, TO MEET REQUIREMENTS FOR PUBLIC USE,
- 19 I WOULD SUGGEST LANGUAGE THAT CLARIFIES WHAT PUBLIC USE
- 20 IS. AND I WOULD SUGGEST THAT THE LANGUAGE THAT YOU
- 21 INSERT THERE WOULD BE SO IT WOULD READ, TO MEET THE
- 22 REQUIREMENTS FOR PUBLIC USE, MEANING REASONABLY
- 23 AVAILABLE AT A FAIR PRICE TO ALL CALIFORNIANS, COMMA.
- MR. GILLENWATER: OBJECTION.
- 25 MR. SIMPSON: THAT WOULD BE ONE THING. THE

- 1 OTHER THING I WOULD SUGGEST, IF WE WERE UNCOMFORTABLE
- 2 WITH THE NOTION OF FAIR PRICE, THAT YOU SIMPLY MAKE IT
- 3 TO MEET THE REQUIREMENTS -- YOU MAKE IT TO MEET THE
- 4 REQUIREMENT OF PUBLIC USE, MEANING REASONABLY AVAILABLE
- 5 TO ALL CALIFORNIANS.
- 6 CHAIRMAN PENHOET: DR. MAXON.
- 7 DR. MAXON: WE CONSULTED THE FEDERAL
- 8 GOVERNMENT FOR THEIR TERM "PUBLIC USE." THAT TERM
- 9 COMES FROM THE FEDERAL GOVERNMENT'S MARCH-IN RIGHTS.
- 10 AND THEY TOLD ME THAT THAT IS THE DEFINITION. IT IS
- 11 NOT FURTHER DEFINED THAN PUBLIC USE.
- MR. GILLENWATER: THAT IS CORRECT.
- DR. PRIETO: WHAT IS THE DEFINITION, MARY?
- DR. MAXON: THAT IS THE DEFINITION. THAT'S
- 15 WHAT THEY HAVE.
- 16 CHAIRMAN PENHOET: BROADLY DEFINED,
- 17 AMBI GUOUSLY DEFINED.
- 18 MR. SIMPSON: I'M TRYING TO IMPROVE UPON
- 19 IMPRECISE LANGUAGE AND OFFER CLARITY.
- DR. PRIETO: PUBLIC USE, MEANING IS DEFINED
- 21 AS REASONABLE AVAILABILITY?
- 22 CHAIRMAN PENHOET: NO. IT'S NOT DEFINED ANY
- 23 FURTHER. IT'S WHATEVER YOU THINK IT IS. PUBLIC USE.
- DR. PRIETO: I CERTAINLY WOULDN'T HAVE ANY
- 25 OBJECTION TO ADDING DEFINED AS REASONABLE AVAILABILITY.

- 1 I DON'T THINK I WANT TO GET ANY MORE SPECIFIC THAN
- 2 THAT, AND I DIFFER WITH MY FRIEND JOHN HERE IN NOT
- 3 WANTING TO INSERT THE TERM "FAIR PRICING" BECAUSE I
- 4 KNOW THAT GIVES EVERYBODY IN BUSINESS THE
- 5 HEEBI E-JEEBI ES.
- 6 MR. GILLENWATER: WITH REGARDS TO REASONABLE
- 7 ACCESS, REASONABLE PRICING, TO JUST MAKE CLEAR, EVEN
- 8 THOUGH IT'S NOT DEFINED IN THE FEDERAL CODE BEYOND
- 9 PUBLIC USE, THE NIH HAS NUMEROUS TIMES, WHEN MARCH-INS
- 10 HAVE BEEN PETITIONED, THEY HAVE REFUSED TO APPLY THAT
- 11 BASED ON ANY TYPE OF PRICING GROUNDS.
- 12 CHAIRMAN PENHOET: WELL, YOU CAN MAKE IT
- 13 EXPLICIT BECAUSE SOMEBODY COULD INTERPRET REASONABLY
- 14 AVAILABLE AS PRICE WOULD BE A FACTOR IN DETERMINING
- 15 WHAT IS REASONABLY AVAILABLE.
- 16 MR. TAYMOR: I WOULD JUST SAY THAT IF IT IS
- 17 DECISION, AND I THINK THE EVIDENCE THAT'S BEEN PRODUCED
- 18 IS THAT FAIR PRICING WOULD BE VERY DAMAGING, THEN I
- 19 THINK YOU SHOULD MAKE IT EXPLICIT. AND IF MEMBERS OF
- 20 THE PUBLIC HAVE A PROBLEM WITH THAT, THEN THEY SHOULD
- 21 BE ALLOWED TO VOICE IT, BUT THERE IS IN THE REPORT AT
- 22 THE POLICY'S BEGINNING AND OTHER EVIDENCE THAT FAIR
- 23 PRICING IS PROBLEMATIC. AND I THINK YOU CAN BE SURE
- 24 THAT SOMEONE WILL TRY TO BRING A FAIR PRICING CASE IF
- 25 WE SHOULD BE SO FORTUNATE TO HAVE THERAPIES ON THE

- 1 MARKET.
- 2 SO I THINK CIRM SHOULD TAKE A POSITION ON
- 3 THAT NOW AND SHOULD ENDORSE IT ONE WAY OR THE OTHER.
- 4 CHAIRMAN PENHOET: SOME LANGUAGE --
- 5 MR. TAYMOR: PUBLIC USE DOES NOT MEAN FAIR
- 6 PRICING OR THIS IS NOT --
- 7 CHAIRMAN PENHOET: THERE IS A PROPOSAL.
- 8 PUBLIC USE WOULD MEAN REASONABLY ACCESSIBLE FOR REASONS
- 9 OTHER THAN PRICE, OR SOMETHING LIKE THAT.
- 10 MR. GILLENWATER: THAT'S PROBABLY COVERED IN
- 11 THE PLANS FOR ACCESS AND THE STILL TO BE DEFINED
- 12 MEDICALD PRICE.
- 13 CHAIRMAN PENHOET: WELL, THAT'S FOR PUBLICLY
- 14 FUNDED. OTHER PEOPLE IN CALIFORNIA --
- MR. GILLENWATER: THAT'S WHY WE'VE ALSO
- 16 SUGGESTED THAT, INSTEAD OF ACCESS PLANS FOR UNINSURED,
- 17 WE'VE POINTED OUT THAT MOST COMPANIES' ACCESS PLANS
- 18 AREN' T FOR THE UNINSURED, THEREFORE, FINANCIALLY NEEDY,
- 19 AND HAVE SUGGESTED, INSTEAD OF HAVING THE DEFINITION
- 20 FOR ACCESS PLANS BE DEFINED TO THE UNINSURED, THAT THEY
- 21 BE CONSISTENT WITH INDUSTRIES' PLANS, WHICH ARE USUALLY
- 22 BASED ON FINANCIAL NEED.
- 23 CHAIRMAN PENHOET: AND I GUESS THAT'S WHAT'S
- 24 ALSO IN YOUR BILL; IS THAT RIGHT?
- 25 MS. SEARS: IT'S IN THE PERADA-NUNEZ-KELLER

- 1 BILL, YEAH.
- 2 CHAIRMAN PENHOET: WE'LL GO BACK AND LOOK AT
- 3 THAT. THERE IS A LONG LIST OF THINGS TO GO BACK AND
- 4 LOOK AT.
- 5 OKAY. ANY OTHER COMMENTS? I'LL ATTEMPT TO
- 6 SUMMARIZE THIS MEETING IF THERE ARE NO OTHER COMMENTS
- 7 AT THIS POINT.
- 8 FOCUSING ON THE THINGS WHERE WE NEED FURTHER
- 9 CLARIFICATION --
- 10 MR. SIMPSON: ONE FINAL COMMENT. THIS GOES
- 11 TO IN THE EARLY PART OF THE REPORT WHERE WE'RE TALKING
- 12 ABOUT CRADA'S AND THE UNFORTUNATE PROBLEMS THEY HAD
- 13 WITH PRICING. AND I WANTED TO MAKE IT CLEAR THAT
- 14 CRADA'S ARE NOT EXACTLY ANALOGOUS TO WHAT WE'RE DOING
- 15 HERE. CRADA'S ARE ESSENTIALLY ABOUT TECHNOLOGY
- 16 TRANSFER FROM FEDERAL LABORATORIES TO COMMERCIAL
- 17 ENTITIES. AND UNDER A CRADA NO FEDERAL DOLLARS GO TO
- 18 THE CRADA PORTION.
- 19 IT'S NOT A FUNDING THING. IT'S ESSENTIALLY
- 20 AN IDEA THAT YOU CAN USE IP THAT HAS BEEN DEVELOPED IN
- 21 A FEDERAL LAB IN A WAY TO BRING THAT INTO
- 22 COMMERCI ALI ZATI ON.
- 23 SO TO SUGGEST THAT THE EXPERIENCE WITH
- 24 CRADA'S WHERE PEOPLE WERE UNWILLING TO PARTNER IS
- 25 SOMETHING THAT'S NOT ANALOGOUS TO TAKING PUBLIC MONEY,

- 1 WHICH COMES WITH IT AN OBLIGATION TO THE PUBLIC. WE'RE
- 2 TALKING HERE ABOUT DIRECT FUNDING OF COMMERCIAL
- 3 ENTITIES WITH TAXPAYER DOLLARS. AND A CRADA IS A
- 4 DIFFERENT SORT OF THING. THAT'S ASKING TO GO IN AS A
- 5 PARTNER. AND WE'RE NOT TALKING ABOUT PARTNERSHIPS.
- 6 WE'RE TALKING ABOUT GIVING TAXPAYER DOLLARS TO PRIVATE
- 7 ENTERPRISE.
- 8 SO I THINK IT'S DEFINITELY APPROPRIATE TO DO
- 9 SOMETHING. AND I CONTINUE TO SAY THAT THERE OUGHT TO
- 10 BE A WAY THAT INDUSTRY WOULD BE WILLING TO WORK WITH
- 11 US. IN FACT, THE TOOLS INDUSTRY, I THINK, DID ADDRESS
- 12 SOME OF THESE KINDS OF ISSUES AT THE LAST MEETING.
- 13 WHAT YOU WANT TO PREVENT IS EGREGIOUS PROFITEERING WITH
- 14 THE FRUITS OF TAXPAYER-FUNDED RESEARCH. AND I THINK
- 15 THERE IS LANGUAGE THAT CAN DO THAT AND SHOULD BE
- 16 INSERTED IN HERE. THANK YOU.
- 17 CHAIRMAN PENHOET: WELL, YOUR POINT ABOUT
- 18 CRADA'S, IF YOU THINK IT'S NOT RELEVANT, ARE YOU ASKING
- 19 THAT WE REMOVE IT FROM THIS DIALOGUE, THE INTRODUCTORY
- 20 SECTION? I DON'T THINK IT MAKES MUCH DIFFERENCE TO THE
- 21 CONTENT ONE WAY OR THE OTHER. WE'RE PERFECTLY HAPPY TO
- 22 DO THAT. WHAT DO OTHER PEOPLE THINK?
- 23 MR. REED: I THINK IT BELONGS IN THERE.
- 24 CHAIRMAN PENHOET: I MEAN A CRADA, EVEN IF
- 25 THEY TRANSFERRED TECHNOLOGY, IT'S STILL TRANSFERRING

- 1 VALUE TO A COMPANY, FOR SURE.
- 2 MR. SIMPSON: I THINK THERE'S AN IMPORTANT
- 3 POINT TO BE MADE, THAT IT NEEDS TO BE CLEAR THAT
- 4 THEY' RE NOT GETTING CASH. AND JUST PHILOSOPHICALLY, IF
- 5 WE'RE TALKING ABOUT WHETHER THAT'S AN ISSUE THAT'S
- 6 APPROPRIATE TO BE DEALT WITH --
- 7 CHAIRMAN PENHOET: WE DON'T WANT OUR
- 8 DISCUSSION OF IT TO BE MISLEADING TO ANYONE, SO WE
- 9 SHOULD BE CLEAR ABOUT WHAT THE GOVERNMENT WAS PUTTING
- 10 IN THE CASE OF CRADA.
- 11 MR. REED: I THINK THE CRADA DOES BELONG
- 12 THERE BECAUSE THIS IS AN EXAMPLE OF WHAT HAPPENS IF WE
- 13 TRY TO IMPOSE TOO MANY CONDITIONS BEFORE. WE DON'T
- 14 WANT TO STRANGLE THE BABY BEFORE IT'S GROWN.
- 15 CHAIRMAN PENHOET: WELL, WE WILL MAKE IT
- 16 CLEAR WHAT A CRADA IS AND WHAT IT ISN'T, SO PEOPLE CAN
- 17 PUT THAT IN PERSPECTIVE AND USE THE EXAMPLE AS THEY
- 18 WISH, BUT AT LEAST WITH AN ACCURATE DESCRIPTION OF WHAT
- 19 A CRADA IS. SO WE'LL BE HAPPY TO DO THAT.
- 20 OKAY. SO WE'LL CONTINUE TO WORK ON OPEN
- 21 ACCESS. WE HEARD DIFFERENT VIEWS TODAY, AGAIN. I
- 22 GUESS AS A FORMER UC FACULTY MEMBER, I FIND IT
- 23 ASTOUNDING THEY COME HERE AND ASK US TO DO SOMETHING
- 24 THEY'RE NOT WILLING TO DO THEMSELVES.
- 25 DR. BRYANT: WHY WOULD YOU BE ASTOUNDED AT

- 1 THAT?
- 2 CHAIRMAN PENHOET: THEY SAY PLEASE FORCE OUR
- 3 GUYS TO DO IT, WOULD YOU, BECAUSE WE CAN'T.
- 4 I THINK WE DID HEAR STRONG SENTIMENT FOR OPEN
- 5 ACCESS EVEN FROM THE PEOPLE WHO HAVE CONCERNS ABOUT THE
- 6 WAY IT'S DONE, ETC., THAT WE SHOULD TRY TO MAKE
- 7 INFORMATION AVAILABLE AS QUICKLY AS POSSIBLE AND TRY TO
- 8 WORK THIS FURTHER AND EVENTUALLY COME UP WITH A POLICY
- 9 ABOUT THIS ISSUE.
- 10 WE DID GO THROUGH THE PRINCIPLES. JUST TO
- 11 REVIEW, I THINK WE ALL AGREE THAT THE GRANTEES WILL OWN
- 12 THE IP, THAT THE PUBLICATION REQUIREMENTS ARE THE SAME
- 13 AS IN THE NONPROFIT, THAT WE HAVE SOME ISSUES AROUND
- 14 BIOMEDICAL MATERIALS SHARING TO CLARIFY THE SCOPE OF
- 15 WHAT SHARING WOULD BE. IS THAT A REASONABLE WAY TO
- 16 DESCRIBE WHERE WE ARE WITH THAT ISSUE? OKAY. WHAT'S
- 17 THE SCOPE OF THE SHARING?
- 18 WE'RE GOING TO PUNT ON LOANS. SO THIS ISSUE
- 19 OF A COMMERCIAL ENTITY CAN CHOOSE -- I'M ON PAGE 7 NOW.
- 20 A COMMERCIAL ENTITY CAN CHOOSE AT THE TIME OF
- 21 APPLICATION WHETHER THEY'D LIKE A GRANT OR A LOAN. WE
- 22 WILL JUST SIMPLY DELETE THAT FOR NOW, AND SOMEONE WILL
- 23 COME BACK TO THAT ISSUE SOMEDAY.
- 24 MR. ROTH: COULD I JUST SUGGEST THAT WE COULD
- 25 LEAVE OPEN ANY APPLICANT THAT WISHES TO PURSUE A LOAN

- 1 CAN ASK FOR US TO DEVELOP A POLICY?
- 2 CHAIRMAN PENHOET: OKAY.
- 3 MR. ROTH: I THINK THAT WILL LEAVE IT OPEN,
- 4 SO THEY WON'T TAKE IT OUT. IF I REMEMBER RIGHT, IT WAS
- 5 IN THE LEGISLATION.
- 6 CHAIRMAN PENHOET: WE CAN MAKE LOANS, THOUGH
- 7 NOT REQUIRED TO MAKE LOANS IN THE LEGISLATION. SO WE
- 8 COULD SAY IF A COMMERCIAL ENTITY WISHES TO PURSUE A
- 9 LOAN RATHER THAN A GRANT, THEY CAN APPROACH --
- 10 MR. ROTH: THEY SHOULD SUGGEST A POLICY OR
- 11 THEY SHOULD SUGGEST A METHOD FOR SUCH LOANS, AND WE'LL
- 12 CONSIDER IT.
- DR. MAXON: AND THIS WOULD BE IN RESPONSE TO
- 14 AN RFA?
- 15 CHAIRMAN PENHOET: NO. IT WOULD HAVE TO BE
- 16 DONE MUCH BEFORE THAT.
- 17 MR. ROTH: I THINK WE SHOULD INVITE PEOPLE
- 18 THAT THINK THE LOAN IDEA IS A GOOD IDEA TO PROPOSE
- 19 SOMETHING AND LET US REACT TO IT BECAUSE I THINK WE'RE
- 20 HAVING TROUBLE FIGURING OUT WHY THAT SHOULD BE PART OF
- 21 THI S.
- 22 CHAIRMAN PENHOET: PROBABLY WOULDN'T BE IN
- 23 THIS POLICY. WE'LL STATE IT SEPARATELY SOMEWHERE ELSE.
- WE'VE GOT THE 17 PERCENT RATHER THAN THE 25.
- WE ARE STILL GETTING SOME PUSHBACK ON THE

- 1 WHOLE CONCEPT OF LICENSEES BEING FORCED TO DO SOMETHING
- 2 THAT FULLY INTEGRATED COMPANIES ARE NOT FORCED TO DO
- 3 WITH RESPECT TO THE NO TRIGGER OTHER THAN TAKING A
- 4 LICENSE. WE WENT THROUGH SOME LOGIC FOR THAT. I THINK
- 5 THAT, AS ALL THINGS IN LIFE, THERE'S PROBABLY NO
- 6 PERFECT ANSWER TO THIS. BUT IF YOU GUYS ARE
- 7 COMFORTABLE WITH CONTINUING ON THIS PATH WE'RE ON,
- 8 THAT'S WHAT I WOULD PROPOSE WE DO.
- THE 3 X MULTIPLE, WE DIDN'T HAVE ANY FURTHER
- 10 DISCUSSION OF THAT. IS EVERYBODY COMFORTABLE? GIVEN
- 11 THE FACT THAT THIS 3 X MULTIPLE WILL BE COUPLED WITH
- 12 SOME REASONABLE RATE OF PAYBACK SO AS NOT TO UNDULY
- 13 HARM THE COMPANY'S NEAR-TERM PROSPECTS OR SOMETHING
- 14 LIKE THAT. THAT OKAY WITH EVERYBODY?
- DR. PRI ETO: THAT' S REASONABLE.
- DR. BRYANT: OKAY WITH ME.
- DR. WRIGHT: YEP.
- 18 CHAIRMAN PENHOET: THEN WE DELETE THE LOANS
- 19 PART. WE AGREED ON THE BLOCKBUSTER PAYMENT. AND WE'RE
- 20 GOING TO TAKE SEVERAL DIFFERENT VARIATIONS OF THE
- 21 THRESHOLD ISSUE TO THE BOARD FOR A DISCUSSION WITH THE
- 22 WHOLE BOARD: IS THAT RIGHT?
- DR. WRIGHT: THAT'S WHAT I HEARD.
- 24 CHAIRMAN PENHOET: WE CAN CIRCULATE TO YOU
- 25 GUYS BEFORE THE BOARD MEETING WHAT VARIOUS DIFFERENT

- 1 ALTERNATIVES MIGHT LOOK LIKE.
- 2 DR. PRI ETO: THAT WOULD BE HELPFUL.
- 3 MR. SIMPSON: WHAT ABOUT RETAINING IP,
- 4 LICENSE TO PRACTICE FOR THE STATE?
- 5 CHAIRMAN PENHOET: A LICENSE TO PRACTICE FOR
- 6 THE STATE. THANK YOU. ANOTHER ISSUE, WHAT THAT
- 7 ACTUALLY WOULD MEAN FOR THE STATE.
- 8 I THINK WE DECIDED IT DOESN'T MEAN THE STATE
- 9 WOULD BE FREE TO LICENSE SOMEONE ELSE TO GO INTO
- 10 BUSINESS AND COMPETE. IT'S FOR THE STATE'S OWN USE.
- 11 MR. SIMPSON: IT'S FOR THE STATE'S OWN USE.
- MR. TAYMOR: BASICALLY THE RESEARCH USE
- 13 EXEMPTION THAT YOU HAVE IN THE NONPROFITS WOULD SAY
- 14 THAT IT WOULD BE IMPORTANT TO THE STATE AS OPPOSED TO
- 15 ANY CALIFORNIA NONPROFIT.
- 16 CHAIRMAN PENHOET: THERE'S A QUESTION ABOUT
- 17 WHETHER, FOR THIS PURPOSE, UC IS CONSIDERED TO BE PART
- 18 OF THE STATE.
- 19 AND THEN THE BLOMEDICAL MATERIALS WE'VE
- 20 TALKED ABOUT ALREADY. WE NEED A REASONABLENESS
- 21 STANDARD THERE.
- 22 I GUESS THAT'S PRETTY MUCH WHAT I REMEMBER OF
- 23 THIS MEETING. ANYBODY ELSE HAVE SOMETHING ELSE?
- 24 MR. SIMPSON: WHERE DID YOU COME DOWN ON THE
- 25 PUBLIC USE, DEFINITION OF PUBLIC USE AND WHETHER THAT

- 1 NEEDS TO BE DEFINED STILL IN THE MARCH-IN?
- 2 CHAIRMAN PENHOET: I THINK WE HAD A CONCEPT
- 3 OF MAKING SURE IT'S BROADLY AVAILABLE TO CALIFORNIANS
- 4 EXCEPT FOR REASONS OF PRICE. I THINK SOMETHING LIKE
- 5 THAT.
- 6 MR. TAYMOR: THE QUESTION OF OTHER FORMS OF
- 7 INTELLECTUAL PROPERTY.
- 8 CHAIRMAN PENHOET: THERE'S A QUESTION. I'LL
- 9 EXPRESS MY OWN PERSONAL BLAS. YOU ARE CORRECT. THERE
- 10 ARE MANY FORMS OF INTELLECTUAL PROPERTY. MY OWN VIEW
- 11 IS THAT TO WADE INTO NONPUBLISHED FORMS, AT LEAST, OF
- 12 INTELLECTUAL PROPERTY IS ALMOST IMPOSSIBLE TO DO
- 13 BECAUSE THERE'S NO END TO IT. AND SO IT'S -- YOU'RE
- 14 ESSENTIALLY, I BELIEVE, ASKING A COMPANY TO OPEN ITS
- 15 ENTIRE RECORDS, ETC., TO YOU TO PERUSE.
- 16 IF YOU HAVE SOME SUGGESTIONS ABOUT -- I MEAN
- 17 WE INCLUDE COPYRIGHTS.
- 18 MR. TAYMOR: I WAS SUGGESTING, FOR EXAMPLE,
- 19 SPECIFIC DATABASES THAT ARE GENERATED. I'M FOCUSING
- 20 MOSTLY, FOR EXAMPLE, ON THE PRE-IND WORK THAT SEEMS TO
- 21 HAVE BEEN THE FOCUS IN THE LAST STRATEGIC PLAN MEETING
- 22 AND NOT HAVING A SITUATION WHERE CIRM HAS TO FUND
- 23 MULTIPLE COMPANIES IN THEIR PRE-IND APPLICATIONS TO
- 24 FIGURE OUT WHAT THE FDA IS GOING TO WANT, WHAT TYPE OF
- 25 PROTOCOLS, WHAT TYPE OF ACTIVITY, AS THAT INFORMATION

- 1 IS BEING GENERATED, THAT IT'S BEING SHARED AND THAT
- 2 THERE'S ACCESS TO THAT INFORMATION. AND THEN ALSO
- 3 ACCESS TO INFORMATION AND DATABASES AND SIMILAR TYPES
- 4 OF INFORMATION THAT MAY BE CREATED ON THE SAME LEVEL AS
- 5 THERE'S ACCESS TO OTHER PUBLISHED INFORMATION.
- 6 CHAIRMAN PENHOET: SCOTT, CAN WE PUT SOME OF
- 7 THAT IN ASPIRATIONAL LANGUAGE RATHER THAN IN LEGAL
- 8 LANGUAGE?
- 9 MR. TOCHER: AGAIN, SO LONG AS IT'S
- 10 ASPIRATIONAL. AND IN A POLICY, THAT'S FINE. IT
- 11 WOULDN'T BELONG IN THE ACTUAL REGULATIONS THAT WOULD BE
- 12 ADOPTED.
- 13 CHAIRMAN PENHOET: I THINK IN ASPIRATIONAL
- 14 LANGUAGE, I THINK WE COULD. AREAS LIKE REQUIREMENTS
- 15 FOR IND SUBMISSION, ETC. IF WE CAN GET PEOPLE TO SHARE
- 16 THOSE, IT WOULD BE A GOOD THING.
- 17 MR. TOCHER: BUT YOU WANT TO BE CLEAR THAT IT
- 18 IS ASPIRATIONAL AND NOT A REQUIREMENT.
- 19 CHAIRMAN PENHOET: WELL, UNLESS IT'S VERY
- 20 WELL DEFINED. SEE, I'M REALLY WORRIED THAT
- 21 COMPANIES -- THIS WOULD BE, IF I WAS RUNNING ONE OF
- THESE COMPANIES, MORE SCARY TO ME THAN ANYTHING ELSE
- 23 WE'RE TALKING ABOUT HERE SO FAR. I CAN TELL YOU WHY
- 24 THERE ARE NO BIOTECH COMPANIES IN BERKELEY, FOR
- 25 EXAMPLE. BECAUSE BERKELEY HAD A LAW ON ITS BOOKS SAID

- 1 YOU HAD TO ALLOW THE CITY OF BERKELEY TO GO IN AND
- 2 EXAMINE YOUR BOOKS AND STUFF. AS A RESULT, THERE WERE
- 3 NEVER ANY BIOTECH COMPANIES IN BERKELEY. THERE ARE NOW
- 4 30 YEARS LATER, BUT THEY ALL LEFT.
- 5 MR. ROTH: I THINK THE IDEA ON MANY OF THESE
- 6 THINGS WE TALKED ABOUT TODAY IS TO TRY TO CAPTURE THOSE
- 7 IN THE PREAMBLE TO THIS POLICY, WHICH ARE ASPIRATIONAL,
- 8 AND AVOID TRYING TO MAKE THESE HARD RULES THAT I THINK
- 9 MAY COME BACK TO HAUNT US DOWN THE ROAD, THAT WE DIDN'T
- 10 MAKE THAT INTENTION. WE'VE ALREADY UNCOVERED A NUMBER
- 11 OF THINGS THAT, WELL, THAT'S NOT REALLY WHAT WE MEANT
- 12 BY WHAT WE SAID IN THE POLICY, AND I THINK WE WANT TO
- 13 AVOID THAT WHEREVER POSSIBLE. SO THINGS LIKE OPEN
- 14 SOURCE OR OPEN ACCESS, THOSE KIND OF THINGS, I THINK,
- 15 CAN BEST BE ADDRESSED IN THE PREAMBLE.
- 16 CHAIRMAN PENHOET: OKAY. SO DO I HAVE YOUR
- 17 PERMISSION TO PRESENT THIS TO THE LCOC ON OCTOBER 11TH
- 18 ALONG THE LINES WE DESCRIBED, PRESUMABLY HAVING SENT
- 19 YOU BEFOREHAND SOME OF THESE CLARIFICATIONS AND OTHER
- 20 ALTERNATIVES THAT WE'RE GOING TO PRESENT?
- 21 MR. ROTH: YES IN SAN DIEGO.
- DR. BRYANT: YES, DEFINITELY.
- DR. WRIGHT: SO MOVED.
- DR. PRIETO: YES. I DON'T THINK WE CAN MOVE
- 25 BECAUSE WE DON'T HAVE A QUORUM.

- 1 CHAIRMAN PENHOET: WE'RE NOT MOVING ANYTHING.
- 2 WHAT DO WE GET, THE SENSE OF THE GROUP, A CONSENSUS OF
- 3 THE GROUP.
- 4 DR. PRI ETO: YES, ABSOLUTELY.
- 5 CHAIRMAN PENHOET: THANK YOU. ANY OTHER
- 6 ISSUES THAT ANY OF YOU ON THE PHONE WANT TO BRING UP AT
- 7 THIS POINT?
- 8 DR. PRIETO: I WOULD LIKE TO THANK YOU FOR
- 9 ALL YOUR WORK, AND THANK MARY FOR ALL HER WORK. I VERY
- 10 MUCH APPRECIATED THE HISTORICAL BACKGROUND IN THE
- 11 DRAFT.
- 12 CHAIRMAN PENHOET: INDEED.
- 13 (APPLAUSE.)
- 14 CHAIRMAN PENHOET: MARY IS IN THE UNFORTUNATE
- 15 POSITION TODAY OF BEING THE WORLD'S AUTHORITY ON
- 16 INTELLECTUAL PROPERTY POLICIES FOR -- IT'S TRUE. NO
- 17 ONE ELSE IN THE WORLD KNOWS AS MUCH AS MARY DOES AT THE
- 18 MOMENT BECAUSE NO ONE ELSE HAS EVER TAKEN A SYSTEMATIC
- 19 STUDY OF WHAT EVERYBODY ELSE IS DOING. SO SHE CAN GET
- 20 A PUBLICATION OUT OF THIS ANYWAY.
- DR. WRIGHT: KEEP HER SAFE. DON'T LET
- 22 ANYTHING HAPPEN TO HER.
- 23 CHAIRMAN PENHOET: YOU KNOW, SHE'S ROWDY.
- 24 THAT'S A HARD JOB. OKAY. THANKS TO ALL OF YOU TASK
- 25 FORCE MEMBERS, AND THANKS FOR THE MEMBERS OF THE PUBLIC

FOR VERY IMPORTANT INPUT. WE APPRECIATE IT. SCOTT, MAYBE, AS A FINAL WORD, YOU CAN GIVE US A STATUS REPORT ON THE NOT-FOR-PROFIT. MR. TOCHER: WE'VE JUST COMPLETED THE LATEST ROUND OF PUBLIC COMMENT ON THE LATEST REVISIONS, AND WE'RE LOOKING AT PERHAPS FINE-TUNING ONE REG AND MAYBE TWO ON JUST MINOR POINTS TO GET EVERYTHING IN PLACE FOR THE OCTOBER ICOC MEETING FOR ADOPTION. CHAIRMAN PENHOET: OKAY. MR. TOCHER: IF ALL GOES AS PLANNED. MR. GILLENWATER: AND THAT INCLUDES --CHAIRMAN PENHOET: TWO NEW DEFINITIONS. MR. TOCHER: INCLUDING THE FEDERAL MEDICALD PRICE, VERIFICATION. THANK YOU. CHAIRMAN PENHOET: OKAY. (THE MEETING WAS THEN ADJOURNED AT 04:01 P.M.)

1	REPORTER'S CERTIFICATE
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3	
4	
5	I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY
6	CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INTELLECTUAL PROPERTY TASK FORCE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW
7	
8	
9	
10	CIRM HEADQUARTERS
11	210 KING STREET SAN FRANCISCO, CALIFORNIA
12	ON SEPTEMBER 21, 2006
13	·
14	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.
15	
16	
17	
18	
19	Beth C. Drain
20	BETH C. DRAIN, CSR 7152 BARRISTER'S REPORTING SERVICE 1072 S.E. BRISTOL STREET SUITE 100 SANTA ANA HEIGHTS, CALIFORNIA (714) 444-4100
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