

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

LOCATION: STANFORD UNIVERSITY
CLARK HALL, ROOM S-360
318 CAMPUS DRIVE
STANFORD, CALIFORNIA

DATE: TUESDAY, NOVEMBER 22, 2005
10:09 A.M.

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

BRS FILE NO. : 74073

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| CALL TO ORDER | | 003 |
| ROLL CALL | | 004 |
| INFORMATIONAL PRESENTATIONS: | | |
| | APA REGULATIONS - JAMES HARRISON | 011 |
| | TAX-EXEMPT AND TAXABLE BONDS: | |
| | JUAN FERNANDEZ | 019 |
| | PERRY ISRAEL | 026 |
| | ALTERNATIVE MODELS - RICK KLAUSNER | 093 |
| | DISCUSSION OF NRC REPORT - BRIAN WRIGHT | 058 |
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| CONSIDERATION OF PROCESS FOR DEVELOPING INTERIM IP POLICY FOR CIRM TRAINING GRANTS | | 105 |
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1 STANFORD, CALI FORNIA; TUESDAY, NOVEMBER 22, 2005

2 10:09 A.M.

3
4 CHAIRMAN PENHOET: WELL, WELCOME TO THE
5 SUBCOMMITTEE TO DEAL WITH INTELLECTUAL PROPERTY, THE
6 SECOND MEETING OF THIS SUBCOMMITTEE ACTUALLY. BEFORE
7 WE BEGIN ANYTHING ELSE, WE HAVE TO VALIDATE THE SITE IN
8 LOS ANGELES. SO IF YOU WILL LISTEN CAREFULLY WHILE I
9 READ THIS STATEMENT. PURSUANT TO GOVERNMENT CODE
10 SECTION 11125.3(A)(2), THE ICOC UPON A TWO-THIRDS VOTE
11 OF THE MEMBERS MAY ADD A PUBLIC TELECONFERENCE SITE
12 THAT WAS NOT INCLUDED ON THE AGENDA IF IT DETERMINES
13 THAT, ONE, THERE EXISTS THE NEED TO TAKE IMMEDIATE
14 ACTION; AND, TWO, THE NEED FOR ACTION CAME TO THE
15 ATTENTION OF THE BOARD SUBSEQUENT TO THE AGENDA BEING
16 POSTED.

17 WHEN ORIGINALLY NOTICING THE NOVEMBER 22,
18 2005, IP TASK FORCE MEETING, ONE MEETING LOCATION WAS
19 INADVERTENTLY LEFT OFF THE NOTICED VERSION OF THE
20 AGENDA. THIS ERROR DID NOT COME TO THE TASK FORCE'S
21 ATTENTION UNTIL AFTER THE AGENDA WAS POSTED. IT IS
22 NECESSARY TO MAKE THIS SITE AVAILABLE SO THAT TASK
23 FORCE MEMBER SHERRY LANSING MAY PARTICIPATE IN THE
24 MEETING. THE LOCATION LEFT OFF THE NOTICED VERSION IS
25 2121 AVENUE OF THE STARS, SUITE 2020, LOS ANGELES,

1 CALIFORNIA 90067.

2 WE WOULD LIKE TO ASK THE TASK FORCE TO VOTE
3 ON THE MATTER OF ADDING THIS LOCATION TO THE MEETING.
4 DO WE -- THAT'S A MOTION. IS THERE A SECON?

5 DR. BRYANT: SECOND.

6 CHAIRMAN PENHOET: ALL IN FAVOR. ANY
7 OPPOSED? OKAY. YOU'RE NOW OFFICIALLY ADDED, LOS
8 ANGELES.

9 WE'LL MOVE FORWARD. EACH OF YOU HAS IN FRONT
10 OF YOU -- FIRST ISSUE IS TO CALL THE ROLL. MELISSA.

11 MS. KING: SUSAN BRYANT.

12 DR. BRYANT: HERE.

13 MS. KING: MICHAEL GOLDBERG.

14 MR. GOLDBERG: HERE.

15 MS. KING: SHERRY LANSING. TED LOVE. ED
16 PENHOET.

17 CHAIRMAN PENHOET: HERE.

18 MS. KING: PHIL PIZZO.

19 DR. PIZZO: HERE.

20 MS. KING: FRANCISCO PRIETO. JEANNIE
21 FONTANA.

22 DR. FONTANA: HERE.

23 MS. KING: JEFF SHEEHY.

24 MR. SHEEHY: HERE.

25 MS. KING: OS STEWARD. AND JANET WRIGHT.

1 DR. WRIGHT: HERE.

2 CHAIRMAN PENHOET: I THINK WE HAVE A QUORUM,
3 DO WE NOT?

4 MS. KING: WE DO.

5 CHAIRMAN PENHOET: THANK YOU. YOU HAVE IN
6 FRONT OF YOU SOME -- WE HAVE FIVE AREAS THAT WE HAVE TO
7 OPINE ON TODAY. YOU HAVE IN FRONT OF YOU SOME BLANK
8 SHEETS. THESE ARE FOR YOUR CONVENIENCE IN MAKING NOTES
9 ON EACH OF THESE ISSUES AS WE CONFRONT THEM GOING
10 THROUGH AND DURING THE DAY. AS YOU CAN SEE BY THE
11 AGENDA, WE ARE GOING TO HAVE A NUMBER OF PRESENTATIONS
12 AND PUBLIC COMMENT, AND THEN WE WILL DEBATE AND
13 CONSIDER AMONG OURSELVES WHAT RECOMMENDATION WE SHOULD
14 MAKE TO THE ICOC FOR ITS DECEMBER 6TH MEETING. SO WE
15 HAVE A POWERPOINT BEHIND US HERE.

16 SO OUR GOAL FOR THIS MEETING IS TO PROVIDE
17 SOME INTERIM GUIDANCE TO THE ICOC SO THAT AT THE
18 DECEMBER 6TH MEETING THE ICOC COULD VOTE ON AN INTERIM
19 POLICY SO THAT IF WE'RE ABLE TO MAKE THE TRAINING
20 GRANTS, THAT THIS INTERIM POLICY WOULD BE APPLICABLE TO
21 THOSE TRAINING GRANTS.

22 OUR OVERALL GOAL IS TO HAVE A FINAL
23 INTELLECTUAL PROPERTY POLICY IN PLACE SOMETIME DURING
24 THE SPRING OF 2006. SO WE HAVE THESE TWO STEPS, AN
25 INTERIM POLICY AND THEN A FINAL POLICY. IT'S MY HOPE,

1 HOWEVER, WE CAN MAKE AS MUCH PROGRESS AS POSSIBLE TODAY
2 TOWARDS A FINAL POLICY, ALTHOUGH WE WON'T HAVE A FINAL
3 POLICY. I THINK WE'VE HEARD A LOT, WE'VE READ A LOT,
4 AND I APOLOGIZE TO ALL OF YOU FOR THE VOLUMINOUS SETS
5 OF MATERIALS WE'VE BEEN SENDING TO READ, BUT I THINK
6 THEY'RE ALL QUITE INFORMATIVE. I MUST SAY PERSONALLY I
7 THINK WE WERE VERY FORTUNATE TO HAVE THE NATIONAL
8 ACADEMIES COME OUT WITH THIS REPORT RIGHT IN FRONT OF
9 OUR MEETING TODAY. IT'S A SUPERB REPORT. I RECOMMEND
10 IT TO ANY OF YOU IN THE AUDIENCE WHO WANT TO READ A
11 TERRIFIC OVERVIEW AND SOME RECOMMENDATIONS. WE WILL
12 HAVE A PRESENTATION BY ONE OF THE AUTHORS OF THIS
13 REPORT, BRIAN WRIGHT, LATER IN OUR MEETING TODAY, BUT
14 IT'S A VERY NICE REPORT.

15 DR. PIZZO: THIS ISN'T ACTUALLY OUT YET
16 THOUGH.

17 CHAIRMAN PENHOET: IT'S ON THEIR WEBSITE, SO
18 WE'RE FREE TO USE IT. SO IT'S PUBLIC INFORMATION, BUT
19 THE BOOKS ARE NOT AVAILABLE GENERALLY TO THE PUBLIC,
20 BUT THEY WERE PROVIDED TO US FOR THIS PURPOSE.

21 MS. KING: WE HAVE HARD COPIES OF THAT IN THE
22 BACK FOR THE MEMBERS OF THE PUBLIC JOINING US TODAY,
23 AND THERE'S ALSO A LINK TO IT ON OUR WEBSITE AND IT'S
24 TO THIS AGENDA.

25 CHAIRMAN PENHOET: WE DON'T HAVE NAME TAGS.

1 ANYBODY IN THE AUDIENCE NOT KNOW THE CHARACTERS UP
2 HERE? TED LOVE.

3 DR. BRYANT: SUSAN BRYANT.

4 DR. PIZZO: PHIL PIZZO.

5 DR. MAXON: MARY MAXON.

6 CHAIRMAN PENHOET: ED PENHOET.

7 MR. GOLDBERG: MICHAEL GOLDBERG.

8 DR. WRIGHT: JANET WRIGHT.

9 MR. SHEEHY: JEFF SHEEHY.

10 CHAIRMAN PENHOET: AND THE NEXT SLIDE JUST
11 SHOWS OUR WORKFLOW FOR THE NEXT FEW WEEKS. WE'RE
12 HAVING THIS MEETING TODAY. WELL, BACKING UP, WE HAD
13 THE FIRST MEETING OCTOBER 25TH. THERE WAS A
14 LEGISLATIVE HEARING IN SAN FRANCISCO ON THE 31ST, WHICH
15 MANY OF US ATTENDED. THE REPORT WAS EXPECTED ON
16 NOVEMBER 17TH FROM THE NRC, AND IT ARRIVED AS EXPECTED.

17 TODAY IS THE SECOND TASK FORCE. WE HOPE TO
18 COME OUT WITH A WORKING DOCUMENT FROM THIS MEETING THAT
19 WE CAN TAKE TO THE STANDARDS WORKING GROUP ON THE 1ST
20 OF DECEMBER, SENDING THEM A VERSION OF THIS ON THE 28TH
21 SO THEY CAN LOOK AT IT, AND PREPARE OURSELVES, HAVING
22 DONE THAT, TO MAKE A RECOMMENDATION TO THE ICOC AT THE
23 DECEMBER 6TH MEETING.

24 SO IT'S AN AMBITIOUS GOAL, BUT I THINK IF WE
25 WORK ASSIDUOUSLY, AS I KNOW WE WILL, WE CAN MAKE A LOT

1 OF PROGRESS ON THIS BETWEEN NOW AND THEN.

2 SO JUST TO REMIND EVERYONE, THAT AT LEAST ONE
3 IMPORTANT PART OF PROP 71 THAT WE'RE DEALING WITH IS
4 SUBSECTION H, PATENT ROYALTIES AND LICENSE REVENUES
5 PAID TO THE STATE OF CALIFORNIA. YOU CAN ALL READ THIS
6 FOR YOURSELF. I WON'T READ IT ALL. WE'LL ALLOW IT TO
7 STAY UP THERE A LONG ENOUGH TIME THAT YOU CAN LOOK AT
8 IT.

9 WE HAVE PROVIDED YOU QUITE A FEW, IF WE MOVE
10 TO THE NEXT SLIDE, SUPPORTING MATERIALS, ALL OF WHICH
11 ARE AVAILABLE IN THE BACK OF THIS ROOM FOR THE PUBLIC
12 AT LARGE. THE BOOKLET THAT WAS GIVEN OUT AT THE
13 OCTOBER 31ST MEETING OF THE LEGISLATIVE GROUP THAT HAD
14 THE HEARING IN SAN FRANCISCO, REBECCA EISENBERG'S
15 TESTIMONY, WHICH WE WILL READ ALOUD LATER IN THIS.
16 REBECCA IS A VERY HIGHLY REGARDED STUDENT OF BAYH-DOLE
17 AND INTELLECTUAL PROPERTY GENERALLY, ETC., IN THE
18 COUNTRY, AND I THINK GAVE A VERY THOUGHTFUL
19 PRESENTATION AT THE MEETING. SO WE WILL READ THAT INTO
20 THE MINUTES OF THIS MEETING.

21 AND THEN FINALLY, THE REPORT WE HAVE BEEN
22 DISCUSSING FROM THE NATIONAL RESEARCH COUNCIL ON
23 "REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC
24 RESEARCH." OUR ORIGINAL TITLE -- THE TITLE OF THE
25 REPORT ACTUALLY CHANGED BETWEEN THE TIME WE WERE TOLD

1 WHAT IT WOULD BE AND WHAT IT CAME OUT TO BE, BUT IT'S
2 THE SAME REPORT WITH A SLIGHTLY DIFFERENT TITLE.

3 WE HAVE OURSELVES WITHIN THE CIRM AND I KNOW
4 AMONG YOU LOOKED AT LOTS OF RELEVANT REPORTS, AND AGAIN
5 WE'RE HAPPY TO MAKE THIS LISTING AVAILABLE TO ANYONE.
6 THE ONES THAT ARE STARRED HERE ARE ONES THAT HAVE BEEN
7 SUBMITTED TO THIS GROUP, EITHER THE LAST MEETING OR AT
8 THIS MEETING OR IN BETWEEN THE MEETINGS, BUT THERE ARE
9 A NUMBER OF OTHER -- THERE'S A LOT LITERATURE, AS YOU
10 CAN SEE, ON THIS SUBJECT WHICH HAS BEEN GENERATED JUST
11 IN THE LAST FEW YEARS INDICATING THE IMPORTANCE OF THE
12 TOPIC.

13 THESE ARE THE QUESTIONS THAT I THINK WE HAVE
14 TO ADDRESS TODAY IN ORDER TO FORMULATE A POLICY GOING
15 FORWARD. THE FIRST AND FOREMOST IS WE HAVE TO DECIDE
16 WHO WILL OWN THE INVENTIONS THAT ARE MADE BY CIRM
17 GRANTEES, WHERE THE OWNERSHIP RESIDES. AND THEN HOW
18 SHALL THE CIRM REQUIRE THE SHARING OF DATA, TOOLS,
19 TECHNOLOGY, AND INTELLECTUAL PROPERTY? I THINK THAT IN
20 THIS REGARD, THIS NEW DOCUMENT FROM NRC PROVIDES SOME
21 VERY IMPORTANT GUIDELINES TO US ABOUT DATA SHARING.

22 THE THIRD IS SHOULD WE CREATE A RESEARCH
23 EXEMPTION FOR THE USE OF INTELLECTUAL PROPERTY FOR
24 BASIC RESEARCH PURPOSES IN AND AMONG OUR GRANTEE
25 INSTITUTIONS AT LEAST AND PERHAPS BEYOND THAT. IT'S AN

1 ISSUE, I THINK, WE HAVE TO CONFRONT, AGAIN ONE THAT'S
2 BROUGHT UP IN A NUMBER OF REPORTS, INCLUDING THE NRC
3 REPORT.

4 WHAT LICENSING REQUIREMENTS SHOULD BE ADOPTED
5 BY CIRM GRANTEES? THAT IS, IF THE CASE IS THAT CIRM
6 ITSELF DOESN'T OWN THE INTELLECTUAL PROPERTY AND PEOPLE
7 DO LICENSE THAT, WHAT WOULD BE THE REQUIREMENTS THAT WE
8 WOULD ASK A LICENSEE TO AGREE TO IN ORDER TO GET A
9 LICENSE TO CIRM TECHNOLOGY?

10 AND THEN FINALLY, THE LAST POINT IS SHOULD
11 CIRM RETAIN MARCH-IN RIGHTS OF SOME KIND TO ADDRESS A
12 NUMBER OF THE ISSUES GOING FORWARD?

13 SO THAT'S OUR JOB FOR TODAY. YOU EACH HAVE A
14 SET OF BLANK SHEETS IN FRONT OF YOU TO ALLOW YOU TO
15 MAKE NOTES BECAUSE WE WILL TRY TO GENERATE, AS YOU WILL
16 SEE IN THE NEXT SLIDE, IS A BLANK SLIDE. MELISSA WILL
17 BE OUR SCRIBE, AND WE WILL ACTUALLY TRY IN REAL TIME IN
18 THE SECOND HALF OF THIS, AFTER WE'VE HAD A CHANCE TO
19 HEAR FROM A NUMBER OF PEOPLE, TRY TO GENERATE SOME OF
20 THE POLICY RECOMMENDATIONS FOR THE ICOC AS THE
21 PRINCIPAL WORK PRODUCT OF OUR DAY TOGETHER HERE.

22 WITH THAT, I THINK WE'LL MOVE RIGHT INTO THE
23 BEGINNING OF THE INFORMAL INFORMATIONAL PRESENTATION,
24 THE FIRST ONE BY JAMES HARRISON, WHO WILL TALK TO US
25 ABOUT THE INTERRELATIONSHIP BETWEEN IP POLICY FOR CIRM

1 AND THE APA REGULATIONS, WHICH ULTIMATELY WE HAVE TO BE
2 IN COMPLIANCE WITH. SO JAMES.

3 MR. HARRISON: WOULD YOU LIKE ME TO --

4 DR. FONTANA: ED, JEANNIE FONTANA FROM LOS
5 ANGELES. I'M SORRY TO INTERRUPT YOU, BUT WHAT'S APA?

6 MR. HARRISON: THE ADMINISTRATIVE PROCEDURE
7 ACT. AND MAYBE THAT'S A GOOD PLACE TO START WITH A
8 BRIEF OVERVIEW OF THE ADMINISTRATIVE PROCEDURE ACT AND
9 THEN A DISCUSSION SPECIFICALLY ABOUT HOW IT RELATES TO
10 WHAT YOU ALL ARE DOING HERE.

11 PROPOSITION 71, AS MANY OF YOU KNOW,
12 AUTHORIZES THE ICOC TO ADOPT INTERIM STANDARDS. THESE
13 STANDARDS ARE AKIN TO EMERGENCY REGULATIONS, BUT UNLIKE
14 EMERGENCY REGULATIONS, WHICH ONLY REMAIN IN EFFECT FOR
15 120 DAYS, PROPOSITION 71 PERMITS A 270-DAY PERIOD FOR
16 INTERIM STANDARDS THAT YOU ADOPT. THE REASON FOR THAT
17 IS TO ALLOW AMPLE TIME FOR PUBLIC DISCUSSION AND INPUT.

18 DURING THIS PERIOD OF TIME, THE ICOC IS
19 EXPECTED TO ADOPT PERMANENT STANDARDS. AND UNDER
20 PROPOSITION 71 AND UNDER STATE LAW, IT'S REQUIRED TO
21 ADOPT THESE STANDARDS IN ACCORDANCE WITH THE
22 ADMINISTRATIVE PROCEDURE ACT.

23 THE ADMINISTRATIVE PROCEDURE ACT GOVERNS
24 STATE REGULATIONS. AND REGULATION IS A VERY BROADLY
25 DEFINED TERM UNDER STATE LAW. IT MEANS EVERY RULE,

1 REGULATION, ORDER, OR STANDARD OF GENERAL APPLICATION
2 OR AMENDMENT, SUPPLEMENT, OR REVISION OF ANY RULE,
3 REGULATION, ORDER, OR STANDARD ADOPTED BY ANY STATE
4 AGENCY TO IMPLEMENT, INTERPRET, OR MAKE SPECIFIC THE
5 LAW ENFORCED OR ADMINISTERED BY OR TO GOVERN ITS
6 PROCEDURE.

7 THE APA, AS A FIRST MATTER, REQUIRES THE CIRM
8 TO PUBLISH ITS PROPOSED REGULATIONS IN THE CALIFORNIA
9 REGULATORY NOTICE REGISTRY. THIS IS THE FIRST
10 OPPORTUNITY FOR THE PUBLIC ORDINARILY TO REVIEW THE
11 REGULATIONS. HERE YOU ALL ARE GOING THROUGH A PUBLIC
12 PROCESS THAT PERMITS PUBLIC INPUT WHILE YOU'RE IN THE
13 PROCESS OF DEVELOPING THE REGULATIONS AND NOT JUST AT
14 THE POINT THAT THEY'RE PUBLISHED. SO THERE'S AN
15 ADDITIONAL BENEFIT TO THE PUBLIC IN THE SENSE THAT THEY
16 GET AN OPPORTUNITY TO SEE THIS PROCESS FROM THE
17 BEGINNING AND THROUGH TO THE END. AND THE PUBLICATION
18 IN THE NOTICE REGISTRY, THEREFORE, IS SORT OF AN
19 INTERIM POINT.

20 THAT BEGINS A CLOCK PURSUANT TO WHICH THE
21 CIRM IS REQUIRED TO PROVIDE THE PUBLIC WITH A 45-DAY
22 OPPORTUNITY TO ISSUE ANY COMMENTS. THE CIRM IS THEN
23 REQUIRED TO RESPOND TO PUBLIC COMMENTS AND, IF
24 NECESSARY, MAKE DRAFT MODIFICATIONS. IF YOU MAKE
25 SUBSTANTIAL BUT RELATED CHANGES, YOU'RE REQUIRED TO

1 ALLOW AN ADDITIONAL 15-DAY PUBLIC REVIEW PERIOD OF
2 THOSE CHANGES. IF YOU MAKE SUBSTANTIAL CHANGES, IT MAY
3 TRIGGER AN ENTIRELY NEW 45-DAY PUBLIC COMMENT PERIOD.
4 SO THE TIMING IS QUITE IMPORTANT.

5 THE REGULATIONS THEN GO TO THE OFFICE OF
6 ADMINISTRATIVE LAW FOR REVIEW.

7 CHAIRMAN PENHOET: LET ME STOP YOU THERE AND
8 ASK A QUESTION, JAMES. GIVEN THE PROJECTED TIMELINE OF
9 OUR WORK HERE, DOES THE INTERIM POLICY FALL WITHIN
10 THESE GUIDELINES IF WE HAVE AN INTERIM POLICY?

11 MR. HARRISON: YES. WHEN YOU ADOPT -- IF YOU
12 WERE TO TODAY OR RATHER IF THE ICOC ON DECEMBER 6TH
13 WERE TO ADOPT AN INTERIM POLICY FOR IP FOR TRAINING
14 GRANTS, THAT WOULD BEGIN THE 270-DAY CLOCK DURING WHICH
15 TIME YOU WOULD BE EXPECTED TO ADOPT PERMANENT STANDARD
16 PURSUANT TO THE ADMINISTRATIVE PROCEDURE ACT. SO IT
17 GIVES YOU MORE TIME THAN YOU WOULD NORMALLY HAVE IF YOU
18 WERE ADOPTING IT AS AN EMERGENCY REGULATION TO ALLOW
19 MORE PUBLIC INPUT.

20 DR. BRYANT: SO IF IT WERE AN INTERIM POLICY,
21 WE COULD MAKE SURE THAT IT ONLY APPLIED TO THE TRAINING
22 GRANTS FOR THAT PERIOD AND THEN GIVE A LITTLE BIT MORE
23 TIME TO --

24 MR. HARRISON: CORRECT. IN OTHER WORDS, IF
25 THE ICOC ON DECEMBER 6TH WERE TO ADOPT AN INTERIM

1 POLICY FOR IP FOR TRAINING GRANTS, DURING THAT PERIOD
2 OF TIME, YOU COULD REVIEW AND MAKE MODIFICATIONS
3 SUBJECT TO PUBLIC INPUT AND COMMENT BEFORE FINAL
4 ADOPTION OF A PERMANENT POLICY. IN OTHER WORDS, YOU'RE
5 NOT BOUND BY WHAT YOU ADOPT ON DECEMBER 6TH.
6 MODIFICATIONS ARE POSSIBLE AND, IN FACT, ENCOURAGED.
7 THAT'S PART OF WHAT THE PUBLIC HEARING PROCESS IS
8 ABOUT.

9 AS I SAID, THE OFFICE OF ADMINISTRATIVE LAW,
10 ONCE IT RECEIVES THE REGULATIONS, HAS 30 WORKING DAYS
11 TO REVIEW THEM. AND WHAT THE OAL LOOKS FOR ARE THE
12 FOLLOWING CRITERIA. FIRST, IT LOOKS TO SEE WHETHER YOU
13 AS A STATE AGENCY HAVE THE STATUTORY AUTHORITY TO ADOPT
14 REGULATIONS. PROPOSITION 71 CLEARLY ENDOWS YOU WITH
15 THAT AUTHORITY AND SPECIFIES THAT YOU HAVE TO ADOPT A
16 STANDARD, AS ED REFERRED TO EARLIER, TO GOVERN IP
17 AGREEMENTS.

18 SECOND REFERENCE, YOU HAVE TO IDENTIFY THE
19 STATUTE THAT THE REGULATION IMPLEMENTS.

20 CONSISTENCY, WHETHER THE REGULATION IS IN
21 HARMONY WITH STATUTES, COURT DECISIONS, AND OTHER LAWS.

22 CLARITY, WHICH IS PERHAPS ONE OF THE MOST
23 IMPORTANT; THAT IS, WHETHER THE REGULATION IS WRITTEN
24 IN A MANNER SO THAT ITS MEANING WILL BE EASILY
25 UNDERSTOOD BY THE FOLKS WHO HAVE TO COMPLY WITH IT.

1 NONDUPLICATION, WHETHER THE REGULATION SERVES
2 THE SAME PURPOSE AS ANOTHER STATUTE OR REGULATION.

3 AND FINALLY, NECESSITY, WHETHER THE RECORD
4 DEMONSTRATES BY SUBSTANTIAL EVIDENCE THE NEED OF THE
5 REGULATION TO EFFECTUATE THE PURPOSE OF THE STATUTE.

6 LET ME TURN BRIEFLY, AND THAT'S THE END OF
7 THE SLIDES, TO DISCUSS HOW THE APA WILL APPLY TO WHAT
8 YOU'RE DOING AND POINT OUT SOME IMPORTANT ISSUES.

9 FIRST, FOR THOSE OF YOU WHO ARE FAMILIAR WITH
10 THE FEDERAL ADMINISTRATIVE PROCEDURE ACT, THE FEDERAL
11 EQUIVALENT, THE CALIFORNIA ADMINISTRATIVE PROCEDURE ACT
12 IS MORE EXPANSIVE. AND THE APA PROHIBITS CIRM FROM
13 ISSUING, UTILIZING, ENFORCING ANY GUIDELINES, CRITERIA,
14 MANUAL, OR OTHER RULE WHICH IS A REGULATION UNLESS IT'S
15 BEEN ADOPTED PURSUANT TO THE APA. AN EXAMPLE IS
16 FREQUENTLY REGULATIONS WILL REFER TO FORMS. THEY'RE TO
17 BE PROVIDED BY THE AGENCY AND THEN MUST BE SUBMITTED
18 BACK TO THE AGENCY AFTER A CERTAIN PERIOD OF TIME. IF
19 THE FORM INCLUDES A REQUIREMENT THAT'S NOT SET FORTH IN
20 THE REGULATION, IT'S CONSIDERED AN UNDERGROUND
21 REGULATION AND IS UNENFORCEABLE. LIKEWISE, AN AGENCY
22 CAN'T USE A BULLETIN OR A MANUAL TO EMBELLISH UPON A
23 REGULATION.

24 SO, FOR EXAMPLE, IF YOU WERE TO ADOPT AN IP
25 POLICY THAT WAS VERY BROAD AND THOUGHT YOU COULD THEN

1 ADOPT A MANUAL THAT PROVIDE MORE DETAILS AND GUIDANCE
2 TO GRANTEES, YOU VERY WELL COULD RISK A CLAIM THAT THAT
3 IS AN UNDERGROUND REGULATION IF THE BULLETIN OR MANUAL
4 IMPOSES ANY ADDITIONAL REQUIREMENTS.

5 THE FLIP SIDE IS THAT REGULATIONS HAVE TO BE
6 SET FORTH IN CLEAR, CONCISE LANGUAGE SO THAT THEY CAN
7 BE READILY UNDERSTOOD BY THE INDIVIDUALS WHO HAVE TO
8 COMPLY WITH THEM. AND WHAT THAT MEANS IS THAT THE USE
9 OF AN UNDEFINED TERM THAT DOES NOT HAVE A MEANING
10 THAT'S GENERALLY FAMILIAR TO THE REGULATED CLASS
11 VIOLATES THE CLARITY STANDARD. SO, FOR EXAMPLE, IF YOU
12 WERE TO ADOPT A REGULATION THAT SAID SOMETHING LIKE
13 GRANTEES SHALL ENSURE OPEN ACCESS TO THE RESULTS OF
14 THEIR RESEARCH, IT WOULD BE VERY DIFFICULT FOR GRANTEES
15 TO UNDERSTAND HOW PRECISELY THEY WERE TO COMPLY WITH
16 THAT REGULATION BECAUSE OPEN ACCESS, WHILE IT MAY BE A
17 TERM THAT'S USED IN COMMON PARLANCE, DOESN'T HAVE A
18 PRECISE DEFINITION.

19 LIKEWISE, STATEMENTS OF INTENT AND
20 ASPIRATIONAL LANGUAGE DON'T QUALIFY AS REGULATIONS. AN
21 EXAMPLE OF THAT WOULD BE CIRM GRANTEES SHOULD STRIVE TO
22 MAKE THE RESULTS OF THEIR RESEARCH AVAILABLE TO OTHER
23 CIRM GRANTEES. THAT DOESN'T IMPOSE ANY REQUIREMENT AT
24 ALL. IT'S JUST A STATEMENT OF ASPIRATION OR INTENT AND
25 HAS NO EFFECT AND IS UNENFORCEABLE.

1 AN EXPLANATION OF THE REASONS AND THE
2 RATIONALE FOR THE REGULATION THAT YOU ULTIMATELY ADOPT
3 WILL BE SET FORTH AND AVAILABLE TO THE PUBLIC IN A
4 DOCUMENT ENTITLED "THE STATEMENT OF REASONS" THAT'S
5 REQUIRED TO BE FILED ALONG WITH THE REGULATION. SO
6 THAT'S ONE PLACE WHERE YOU CAN EXPLAIN THE INTENT
7 BEHIND THE REGULATION AND WHY YOU'VE COME TO THE
8 DECISION THAT YOU'VE REACHED. YOU SIMPLY CAN'T PUT
9 THAT LANGUAGE IN THE REGULATION ITSELF.

10 ONE WAY TO MAINTAIN SOME FLEXIBILITY THROUGH
11 THIS PROCESS IS ADOPT WHAT ARE KNOWN AS PERFORMANCE
12 STANDARDS RATHER THAN PRESCRIPTIVE STANDARDS. A
13 PERFORMANCE STANDARD SETS FORTH AN OBJECTIVE, BUT
14 LEAVES THE QUESTION OF HOW TO COMPLY WITH THAT
15 OBJECTIVE UP TO THE CLASS THAT'S BEING REGULATED. AN
16 EXAMPLE OF A PERFORMANCE STANDARD MIGHT BE SOMETHING
17 LIKE GRANTEES MUST ENSURE THAT 10 PERCENT OF ANY
18 LICENSE FEES EARNED AS A RESULT OF RESEARCH FUNDED BY
19 CIRM ARE USED TO TREAT MEDICAL PATIENTS. THAT WOULD
20 BE A PERFORMANCE STANDARD. IT SPECIFIES WHAT THE
21 OBJECTIVE IS AND THEN LEAVES IT TO THE GRANTEE AS TO
22 HOW TO MEET THAT GOAL.

23 A PRESCRIPTIVE STANDARD ACTUALLY TELLS THE
24 GRANTEES EVERY STEP THAT THEY MUST TAKE IN ORDER TO
25 COMPLY WITH THE STANDARD. AND BY THE WAY, THE OFFICE

1 OF ADMINISTRATIVE LAW, AS A POLICY MATTER, PREFERS
2 PERFORMANCE STANDARDS OVER PRESCRIPTIVE STANDARDS.

3 WHATEVER YOU DEVELOP STAFF WILL TAKE AND
4 CONVERT INTO REGULATORY LANGUAGE TO ENSURE THAT IT
5 MEETS THESE VARIOUS TESTS THAT I'VE DESCRIBED. THE
6 REGULATION THAT YOU ULTIMATELY ADOPT AS A PERMANENT
7 REGULATION IS NOT SET IN STONE. IT CAN BE AMENDED.
8 AND UNDER THE APA, THAT REQUIRES ANOTHER 45-DAY PUBLIC
9 COMMENT PERIOD AND 30 WORKING DAYS FOR THE OFFICE OF
10 ADMINISTRATIVE LAW TO REVIEW.

11 THERE ARE CIRCUMSTANCES, HOWEVER, WHERE
12 EMERGENCY REGULATIONS CAN BE ADOPTED IF IT'S NECESSARY
13 TO PROTECT THE HEALTH, SAFETY, OR GENERAL WELFARE. AND
14 BELIEVE IT OR NOT, THAT STANDARD IS ACTUALLY MORE
15 FLEXIBLE THAN IT MIGHT SEEM. SO WHAT YOU ULTIMATELY
16 END UP DOING CAN BE REVISED OVER TIME AS YOU LEARN MORE
17 OR AS CHANGES DICTATE IT.

18 I'D BE HAPPY TO ANSWER ANY QUESTIONS YOU
19 HAVE.

20 CHAIRMAN PENHOET: THANK YOU.

21 MR. HARRISON: THANK YOU.

22 CHAIRMAN PENHOET: PARTICULARLY USEFUL IS
23 THAT STATEMENTS OF INTENT CAN'T BE ENFORCED. THAT'S AN
24 IMPORTANT CONCEPT, I THINK, FOR US GOING FORWARD.

25 OUR NEXT DISCUSSION CENTERS ON THE BONDS

1 ISSUE. AND LET'S SEE. IS JUAN HERE? MAYBE IF YOU
2 THREE WANT TO COME AND DO THIS TOGETHER, IN WHICH CASE,
3 YOU CAN JUST PULL YOUR CHAIRS UP AROUND THE PHONE AND
4 DISCUSS RIGHT FROM HERE.

5 MR. FERNANDEZ: GOOD MORNING. MY NAME IS
6 JUAN FERNANDEZ. I'M THE DIRECTOR OF PUBLIC FINANCE FOR
7 THE STATE TREASURER'S OFFICE. OUR JOB IS TO BRING
8 THESE BONDS TO MARKET ONCE ALL THE LEGAL HURDLES HAVE
9 BEEN CLEARED. ALSO, PART OF MY RESPONSIBILITY IS TO
10 MAKE SURE THAT WE COMPLY WITH ALL THE IRS RULES AND
11 REQUIREMENTS AS THEY RELATE TO TAX-EXEMPT BONDS AND
12 THAT WE TRACK -- AFTER THE BONDS ARE ISSUED, WE'RE
13 RESPONSIBLE FOR ALL THE REPORTING REQUIREMENTS TO THE
14 IRS.

15 JOINING ME THIS MORNING IS BOB FEYER AND
16 PERRY ISRAEL FROM ORRICK, HERRINGTON & SUTCLIFFE. THEY
17 ARE STATE BOND COUNSEL, AND PERRY SPECIFICALLY IS THE
18 TAX EXPERT WHO HAS BEEN HELPING US SO FAR WITH THIS,
19 NOT ONLY WITH THIS PARTICULAR BOND ACT, BUT ALL THE
20 BOND ACTS THAT WE ADMINISTER.

21 I JUST HAVE A VERY SHORT PRESENTATION ON JUST
22 GENERAL RULES GOVERNING THE TAX-EXEMPT BONDS AND THAT
23 SORT OF THING, AND THEN WE CAN OPEN UP TO ANY QUESTIONS
24 IF THAT'S OKAY WITH YOU.

25 CHAIRMAN PENHOET: THAT WOULD BE GREAT.

1 THANK YOU.

2 MR. FERNANDEZ: LET ME START BY SAYING THAT
3 GENERALLY BONDS THAT ARE ISSUED BY THE STATE OR LOCAL
4 GOVERNMENT ENTITIES ARE TAX-EXEMPT. MEANS THAT THE
5 INVESTOR WHO HOLDS THE BONDS AND GETS THE INTEREST ON
6 THOSE BONDS DO NOT HAVE TO PAY TAXES. THEREFORE, FOR
7 THE PRIVILEGE, WE GET A LOWER INTEREST RATE. SO
8 GENERAL RULE IS THAT THE BONDS ARE TAX-EXEMPT EXCEPT
9 FOR TWO DIFFERENT SITUATIONS. ONE ARE CALLED ARBITRAGE
10 BONDS, AND THE OTHER ARE CALLED PRIVATE ACTIVITY BONDS.

11 ARBITRAGE BONDS, IN ESSENCE, THERE'S A
12 PROHIBITION AGAINST ISSUERS OF TAX-EXEMPT BONDS FROM
13 ARBITRAGE. SO THE IRS RULES REQUIRE THAT AN ISSUER,
14 ONCE THEY ISSUE THE BONDS, TRACK THE BOND PROCEEDS TO
15 MAKE SURE THEY'RE EXPENDED IN A TIMELY FASHION. AND BY
16 DOING THAT, YOU ALSO TO HAVE TO TRACK THE INVESTMENT
17 EARNINGS ON THOSE PROCEEDS. IN ESSENCE, THE IRS
18 REQUIRES THAT ANY EARNINGS ABOVE THE BOND YIELD IS
19 REBATED A 100 PERCENT. SO IT'S A 100-PERCENT TAX TO
20 THE FEDERAL GOVERNMENT.

21 IN THE CASE OF THE PROP 71, WE'RE MAKING THE
22 ASSUMPTION THAT MOST OF THE MONEY THAT WILL BE GIVEN
23 OUT BY THE ICOC WILL BE IN THE FORM OF GRANTS. FOR
24 ARBITRAGE PURPOSES AND FOR DETERMINING WHEN THE BOND
25 PROCEEDS ARE SPENT, WHEN THE ISSUER MAKES A GRANT TO AN

1 UNRELATED ENTITY, THAT MONEY IS CONSIDERED SPENT FOR
2 TAX PURPOSES, SO YOU DON'T HAVE TO TRACK IT ANYMORE,
3 BUT IT HAS TO BE TO AN UNRELATED ENTITY.

4 IF THE GRANT IS MADE TO A RELATED ENTITY OF
5 THE STATE, SUCH AS THE UC SYSTEM, FOR EXAMPLE, IT'S NOT
6 CONSIDERED SPENT FOR TAX PURPOSES. SO THE STATE
7 TREASURER'S OFFICE, TOGETHER WITH THE UC, AND STATE
8 ISSUES BONDS FOR THE UC ALL THE TIME, SO WE HAVE A
9 WORKING RELATIONSHIP WITH THEM, FOR EXAMPLE. SO WE
10 HAVE TO TRACK THE BOND PROCEEDS TO MAKE SURE THEY'RE
11 SPENT IN A TIMELY FASHION AND TRACK THE EARNINGS ON
12 THOSE BOND PROCEEDS.

13 THERE'S SPECIAL RULES ABOUT LOANS.

14 CHAIRMAN PENHOET: MAYBE THAT'S A POINT WORTH
15 EMPHASIZING BECAUSE THE UNIVERSITY OF CALIFORNIA IS
16 CONSIDERED TO BE A STATE AGENCY FOR ALL PURPOSES
17 RELATED TO OUR DISCUSSION TODAY IS MY UNDERSTANDING.
18 SO WHETHER OR NOT THEY COLLECT ROYALTIES OR DON'T
19 COLLECT ROYALTIES, ETC., IT IS A STATE AGENCY.

20 DR. BRYANT: SO I WAS JUST GOING TO ASK IN
21 THIS PARTICULAR CONNECTION, THAT'S THE ONLY DIFFERENCE
22 BETWEEN GRANTS TO OTHER GRANTEES AND GRANTS TO THE UC
23 IS THAT YOUR OFFICE KEEPS TRACK OF IT.

24 MR. FERNANDEZ: CORRECT.

25 DR. BRYANT: ARE THERE ANY CONSEQUENCES? I'M

1 TRYING TO UNDERSTAND WHAT THAT WOULD LEAD TO.

2 MR. FERNANDEZ: LATER ON WE'LL GET TO IT. AT
3 THIS POINT IT'S JUST DETERMINING WHETHER THE BOND
4 PROCEEDS ARE SPENT OR NOT SPENT. IF WE GIVE IT TO
5 STANFORD, IF THERE'S A GRANT TO STANFORD, FOR EXAMPLE,
6 IT'S CONSIDERED SPENT FOR OUR PURPOSES. WE DON'T HAVE
7 TO TRACK IT ANY FURTHER, BUT THE UC WE'LL HAVE TO TRACK
8 EXPENDITURES.

9 MR. FEYER: IF I COULD ANSWER BRIEFLY, WITH
10 RESPECT TO ALL OF THE CONSTRUCTION PROJECTS, THE STATE
11 HAS ISSUED BILLIONS OF DOLLARS OF BONDS FOR
12 CONSTRUCTION OF UC CAMPUSES. GENERALLY SPEAKING, WHAT
13 HAPPENS IS UC FUNDS CONSTRUCTION FROM ITS OWN FUNDS AND
14 THEN PERHAPS QUARTERLY GETS REIMBURSEMENT FROM THE
15 STATE FROM BOND PROCEEDS FOR THE EXPENDITURES THAT
16 THEY'VE ACTUALLY MADE. THEREFORE, SINCE IT'S A
17 REIMBURSEMENT OF EXPENDITURES ALREADY MADE, THERE'S NO
18 PROBLEM WITH TRACKING THESE EXPENDITURES. AND WHETHER
19 THAT PROCESS WOULD BE USED WITH RESEARCH GRANTS, I
20 DON'T KNOW, BUT THAT'S CERTAINLY A MODEL THAT'S
21 SUCCESSFULLY BEEN USED FOR OTHER UC PROJECTS,
22 BOND-FUNDED PROJECTS.

23 MR. FERNANDEZ: NOW, INSTEAD OF ALLOCATING
24 THE MONEY VIA A GRANT, IF IT'S A LOAN, THE LOANS ARE
25 NOT CONSIDERED SPENT FOR TAX PURPOSES WHETHER THEY'RE

1 MADE TO A RELATED ENTITY OR AN UNRELATED ENTITY. SO IN
2 ANY CASE, WE WOULD HAVE TO TRACK THOSE EXPENDITURES.

3 THAT'S THE BASIC RULES THAT GOVERN ARBITRAGE
4 BONDS.

5 THEN I'M GOING TO TALK ABOUT PRIVATE ACTIVITY
6 BONDS. GENERALLY A BOND IS TREATED AS A PRIVATE
7 ACTIVITY BOND IF IT PROVIDES FOR PRIVATE BUSINESS USE
8 OF THE PROCEEDS OR PRIVATE LOANS. A BOND IS TREATED AS
9 A PRIVATE BUSINESS USE IF IT PASSES TWO TESTS. THE
10 FIRST TEST IS THAT MORE THAN 10 PERCENT OF THE BOND
11 PROCEEDS ARE USED BY A PRIVATE PARTY. THE SECOND IS
12 THAT THE PRIVATE PARTY RETURNS A CERTAIN REVENUE STREAM
13 TO THE ISSUER THAT IS MORE THAN 10 PERCENT OF THE NET
14 PRESENT VALUE OF THE DEBT SERVICE OF THE BONDS, WHICH,
15 IN ESSENCE, IS THE PAR VALUE FOR THE BOND ISSUE.

16 SO THAT'S BASICALLY A PRIVATE ACTIVITY BOND
17 AND WOULD BE TAXABLE GENERALLY.

18 MR. FEYER: CAN I JUST ADD A COUPLE OF
19 THOUGHTS HERE? JUAN SAID IF A PRIVATE PARTY USES MORE
20 THAN 10 PERCENT OF THE PROCEEDS OF AN ISSUE, I THINK
21 THERE'S A COUPLE OF THINGS THAT NEED TO BE UNBUNDLED
22 THERE. ONE IS THAT IT'S ONE OR MORE PRIVATE PARTIES.
23 SO IF YOU MAKE GRANTS TO A WHOLE BUNCH OF PEOPLE AND
24 NONE OF THEM GET MORE THAN 10 PERCENT, BUT IN TOTAL
25 THEY GET MORE THAN 10 PERCENT, THEN YOU MEET THE TEST.

1 THE SECOND PART THAT NEEDS TO BE UNBUNDLED IS
2 WHAT IS THE ISSUE OF THE BONDS. NOW, WHILE WE HAVE A
3 SINGLE AUTHORIZATION UNDER PROP 71 FOR A WHOLE LOT OF
4 BONDS, FROM A FEDERAL TAX POINT OF VIEW, AN ISSUE OF
5 BONDS IS A COLLECTION OF BONDS WHICH IS SOLD AT THE
6 SAME TIME, PAYABLE FROM THE SAME SOURCE OF MONEY.

7 THE STATE ABOUT, WHAT, FOUR, FIVE, SIX TIMES
8 A YEAR DOES AN ISSUE OF VARIOUS PURPOSE GENERAL
9 OBLIGATION BONDS. THAT INCLUDES SCHOOL BONDS AND
10 PRISON BONDS, ENVIRONMENTAL BONDS, AND STEM CELL BONDS
11 WILL BE INCLUDED IN THAT AS WELL. THAT IS THE ISSUE
12 THAT NO MORE THAN 10 PERCENT CAN BE USED IN PRIVATE
13 TRADER BUSINESS.

14 THE OTHER PART THAT'S A LIMITATION ON THAT IS
15 THAT IT IS ACTUALLY THE LESSER OF 10 PERCENT OR \$15
16 MILLION FROM A PARTICULAR BOND ISSUE. AND THE STATE'S
17 BOND ISSUES ARE ALL MORE THAN \$150 MILLION. SO \$15
18 MILLION WILL ALWAYS BE THE LIMIT AS TO THE AMOUNT OF
19 PRIVATE BUSINESS USE FROM ANY PARTICULAR SALE OF BONDS.

20 MR. FERNANDEZ: LET ME THEN SAY THAT THIS IS
21 THE FIRST TIME, TO OUR KNOWLEDGE, THAT GOVERNMENT,
22 STATE ARE LOCAL GOVERNMENT, HAS ISSUED BONDS TO FUND
23 MEDICAL RESEARCH. SO IN OUR VIEW, THE ASSET THAT IS
24 BEING DEVELOPED WITH THE BOND PROCEEDS IS THE
25 INTELLECTUAL PROPERTY THAT WILL BE HOPEFULLY DEVELOPED

1 BY THE GRANTEES, THE RESEARCHERS. SO IF THAT
2 INTELLECTUAL PROPERTY THEN IS LICENSED TO A PRIVATE
3 COMPANY, YOU KNOW, FOR THE MARKETING OF THE
4 INTELLECTUAL PROPERTY, THE THERAPY, AND THE STATE OR A
5 RELATED ENTITY OF THE STATE RECEIVES ROYALTIES BASED ON
6 THAT LICENSING AGREEMENT, THAT WOULD CONSTITUTE THE
7 PRIVATE PAYMENT PART OF THE TEST AND WE GENERALLY
8 REQUIRE THESE BONDS TO BE TAXABLE. THAT'S GENERALLY.

9 HOWEVER, THERE'S -- PERRY, YOU CAN TALK ABOUT
10 THIS -- MANY ASPECTS OF THE PROP 71 PROGRAM THAT ARE
11 UNIQUE. FOR EXAMPLE, WHEN THE BONDS ARE ISSUED,
12 THERE'S NO CERTAINTY THAT WE'RE GOING TO GET ANY MONEY
13 BACK. EVEN THE DEVELOPMENT OF THE INTELLECTUAL
14 PROPERTY IS UNCERTAIN AT THE TIME WE ISSUE THE BONDS.

15 SO WE WOULD BE WORKING CLOSELY WITH
16 YOURSELVES AND OTHER FOLKS AT CIRM TO DEVELOP A PACKAGE
17 WHICH IS, IN ESSENCE, A PRIVATE LETTER RULING. AND
18 WE'RE GOING TO GO TO THE IRS SEEKING THEIR GUIDANCE IN
19 THIS MATTER.

20 I'M NOT SURE IF AT THIS POINT YOU WANT TO
21 HEAR SOME OF THE THOUGHTS THAT WE HAVE ABOUT THAT
22 PRIVATE LETTER RULING.

23 CHAIRMAN PENHOET: IF I MIGHT GET SOME
24 PERSPECTIVE ON THIS, I THINK THAT WE'VE BEEN LED TO
25 BELIEVE IN SOME QUARTERS THAT THERE'S A BRIGHT LINE

1 HERE. THEY' LL EITHER ALL BE TAXABLE OR NONTAXABLE.
2 WHAT I THINK WE'RE HEARING IS THAT THERE'S ACTUALLY A
3 FAIR AMOUNT OF GRAY AREA IN BETWEEN WHERE WE CAN
4 ARRANGE CERTAIN BOND FINANCING, ETC., DEPENDING ON THE
5 PROGRAMS. AND I THINK, PERRY, THAT YOU'RE PREPARED TO
6 DISCUSS THAT ISSUE.

7 MR. ISRAEL: I'D SAY IT'S VERY GRAY, BUT WE
8 CAN START THERE.

9 CHAIRMAN PENHOET: BUT IT'S NOT BLACK AND
10 WHITE IS THE POINT, SO I THINK THERE'S A FAIR AMOUNT OF
11 ROOM FOR NEGOTIATION WITH THE SERVICE, I SUPPOSE, OVER
12 THESE ISSUES.

13 MS. LANSING: THIS IS SHERRY LANSING. FOR
14 THE RECORD, I'VE BEEN HERE -- I GUESS I MISSED THE
15 FIRST TEN MINUTES. I'M CONFUSED. I THOUGHT THAT -- IS
16 SOMEONE GOING TO EXPLAIN TO US ABOUT THE TAXABLE AND
17 NONTAXABLE BONDS BECAUSE I THOUGHT THAT WAS A PROBLEM
18 TOO?

19 CHAIRMAN PENHOET: PERRY IS GOING TO DO THAT
20 RIGHT NOW.

21 MR. ISRAEL: JUST TO REALLY SORT OF REITERATE
22 WHAT JUAN SAID, THAT IF YOU HAVE MORE THAN \$15 MILLION
23 OF A BOND ISSUE WHICH IS PRIVATELY USED AND YOU'RE
24 RECEIVING PAYMENTS BACK TO THE STATE OR A RELATED PARTY
25 IS RECEIVING PAYMENTS BACK FROM THE PRIVATE USERS THAT

1 IS GOING TO BE MORE THAN \$15 MILLION IN PRESENT VALUE,
2 THEN THOSE BONDS WOULD BE PRIVATE ACTIVITY BONDS AND
3 TAXABLE PRIVATE ACTIVITY BONDS. PRIVATE USE OF THE
4 BOND PROCEEDS INCLUDES USE OF THINGS WHICH ARE
5 PURCHASED OR BUILT OR MADE WITH THE BONDS.

6 SO TO TAKE A SIMPLE EXAMPLE, IF YOU USE BOND
7 PROCEEDS TO BUILD A BUILDING AND THEN YOU LEASE THE
8 BUILDING TO A PRIVATE COMPANY, YOU'VE GOT PRIVATE USE
9 OF THE BUILDING, WHICH MEANS PRIVATE USE OF THE BONDS,
10 AND YOU'VE GOT PAYMENTS COMING BACK.

11 THE VERY FIRST PART, THEN, THAT WE HAVE TO
12 DEAL WITH IS TO CONFIRM WITH THE IRS, WE HAVE DONE THIS
13 ORALLY, BUT WANT TO MAKE SURE IT'S ON PAPER, CONFIRM
14 WITH THEM OUR BELIEF THAT, TO THE EXTENT THAT WE CAN
15 PROPERLY ALLOCATE GRANTS THAT ARE BOND FINANCED TO SOME
16 INTELLECTUAL PROPERTY, THAT THAT INTELLECTUAL PROPERTY
17 WILL BE TREATED AS BEING BONDS, AND THE USE OF IT BY
18 PRIVATE PERSONS WOULD BE PRIVATE USE.

19 THEY HAVE TOLD US THEY DON'T SEE HOW THERE'S
20 ANY WAY AROUND IT, AND I'VE SORT OF SUGGESTED SOME
21 POSSIBILITIES, BUT I'VE GOT TO TELL YOU THE TRUTH OF
22 THE MATTER IS I DON'T SEE ANY REAL WAY AROUND THAT
23 EITHER. I THINK THAT TO THE EXTENT YOU CAN ACTUALLY
24 ALLOCATE PARTICULAR GRANTS FUNDED WITH BONDS TO
25 PARTICULAR INTELLECTUAL PROPERTY, YOU ARE GOING TO HAVE

1 BOND-FINANCED PROPERTY.

2 THE NEXT QUESTION WE HAVE TO DEAL WITH IS HOW
3 DO YOU THAT ALLOCATION. AND THIS IS SOMETHING WHERE
4 WE'RE TRYING TO FIGURE THAT OUT. YOU KNOW, WE
5 UNDERSTAND THAT THERE ARE VARIOUS WAYS OF DOING
6 ALLOCATIONS THAT ARE DEALT WITH NORMALLY IN THE
7 RESEARCH WORLD, AND WE NEED TO UNDERSTAND THAT BETTER.
8 SO BASICALLY WE NEED SOME COMMUNICATION WITH YOU
9 BECAUSE I'M SURE THAT'S WHAT THE IRS IS GOING TO BE
10 ASKING US IS HOW DO WE DO THESE ALLOCATIONS.
11 PRESUMABLY WE'RE GOING TO BE DOING A WHOLE SERIES OF
12 GRANTS TO ONE OR MORE ENTITIES, AND SOMEBODY, LET'S
13 SAY, DEVELOPS SOME INTELLECTUAL PROPERTY. IS THAT
14 INTELLECTUAL PROPERTY TIED TO GRANT ONE, TWO, THREE,
15 FOUR, ALL OF THEM, ANY PARTICULAR PART OF THEM, AND
16 HOW?

17 WE NEED TO FIGURE THAT OUT, AND FOR A COUPLE
18 OF REASONS BECAUSE IT'S THE VARIOUS -- EACH BOND ISSUE
19 IS THE BOND ISSUE WE NEED TO LOOK AT TO SEE WHETHER WE
20 MEET THE \$15 MILLION -- WHETHER WE EXCEED THE \$15
21 MILLION LIMIT. AND IN ADDITION TO THAT, THERE'S
22 ANOTHER POSSIBILITY THAT WE'VE GOT. THE SECOND -- THE
23 NEXT POSSIBILITY IS WHEN THE STATE ISSUES A SERIES OF
24 BONDS, IT ISSUES, AS I SAY, A WHOLE BUNCH OF BONDS AT
25 ONCE. CURRENTLY WHAT HAPPENS IS THAT WE GENERALLY SAY,

1 OKAY, EACH MATURITY OF THOSE BONDS CONSISTS ESSENTIALLY
2 OF A PRO RATA AMOUNT OF EACH OF THE DIFFERENT TYPES OF
3 BONDS THAT ARE BEING ISSUED. BUT ONE APPROACH THAT WE
4 MIGHT MAKE IS TO SAY THE EARLIER MATURITIES OF THOSE
5 BONDS, WITHIN THE CONSTRAINTS OF PROP 71, WHICH PUTS,
6 YOU KNOW, A STARTING POINT WHERE MATURITIES CAN START
7 HAPPENING, BUT THE EARLIER MATURITIES OF THOSE BONDS,
8 MAYBE WE COULD ALLOCATE TO BE THE BONDS THAT FINANCE
9 THE GRANTS.

10 THEN IF WE WIND UP GETTING PAYMENTS SOMETIME
11 IN THE FUTURE, PERHAPS THOSE PAYMENTS WILL BE COMING IN
12 AFTER THE BONDS ARE GONE. OR IF THE INTELLECTUAL
13 PROPERTY IS DEVELOPED AT SOME TIME IN THE FUTURE,
14 PERHAPS THAT INTELLECTUAL PROPERTY WOULD BE DEVELOPED
15 AT SOME POINT AFTER THE BONDS ARE GONE, AND WE'VE
16 BROKEN THE TIE BETWEEN HAVING PAYMENTS AND GRANTS
17 FUNDED WITH THE BONDS BECAUSE THE BONDS ARE GONE.

18 THAT'S, AGAIN, AN ISSUE WE NEED TO TALK WITH
19 THE IRS, BUT ONE WAY HERE IS REALLY TWO SORT OF
20 ALLOCATION QUESTIONS. ALLOCATING THE GRANTS TO THE
21 INTELLECTUAL PROPERTY AND ALLOCATING THE PARTICULAR
22 BONDS THAT FINANCE THE GRANTS TO THE EARLIER MATURING
23 SO THAT WE CAN BREAK THE LINK.

24 OTHER POSSIBILITIES THAT WE WANT TO DISCUSS
25 WITH THE SERVICE ARE PAYMENTS THAT WOULD COME IN THAT

1 WOULD GO TO A 501(C)(3) ORGANIZATION THAT IS NOT A
2 CONTROLLED ENTITY, THAT IS NOT CONTROLLED BY THE STATE
3 OR ANY RELATED PERSON. CAN WE MAKE A GRANT AND SAY,
4 LOOK, TO THE EXTENT THAT IN THE FUTURE SOME
5 INTELLECTUAL PROPERTY IS DEVELOPED AND LICENSED AND
6 LICENSE PAYMENTS COME IN, THAT YOU WILL PAY 20 PERCENT
7 OF THOSE LICENSE PAYMENTS OR WHATEVER THE NUMBER IS
8 OVER TO THIS 501(C)(3) WHICH WE SET UP IN ORDER TO DO
9 OTHER THINGS, BUT WHICH WE DON'T CONTROL, THE STATE
10 DOESN'T CONTROL. THAT'S A QUESTION THAT WE NEED TO
11 TALK WITH THE SERVICE ABOUT.

12 REMEMBER THAT THE QUESTION IS THE PRIVATE
13 PAYMENTS HAVE TO COME TO THE ISSUER OR TO A RELATED
14 ENTITY OF THE ISSUER. MAYBE WE CAN SAY, WELL, WE'RE
15 SENDING PAYMENTS TO AN UNRELATED ENTITY. I DON'T KNOW
16 WHAT THE SERVICE'S RESPONSE TO THAT WILL BE, BUT THAT'S
17 ONE OF THE QUESTIONS WE WANT TO TALK ABOUT.

18 ANOTHER QUESTION THAT WE WANT TO TALK WITH
19 THEM ABOUT HAS TO DO WITH THE CONDITIONS THAT ARE MADE
20 TO THE GRANT. ONE CONDITION MADE TO THE GRANT MIGHT BE
21 THIS CONDITION G, MAKE PAYMENT TO THIS 501(C)(3). WHAT
22 OTHER TYPES OF CONDITIONS? WELL, A CONDITION THAT
23 MIGHT BE MADE IS THAT THERE BE OPEN ACCESS. WE THINK
24 THAT MAKING A CONDITION OF OPEN ACCESS DOES NOT CREATE
25 ANY DEEMED PRIVATE PAYMENT, BUT THAT NEEDS TO BE

1 CONFIRMED WITH THE IRS.

2 WHAT ABOUT A COMMITMENT TO DOING LOW COST
3 THERAPIES TO THE EXTENT THAT THERE'S DEVELOPED SOME
4 INTELLECTUAL PROPERTY THAT LEADS TO THERAPIES OR
5 COMMITMENT TO DOING LOW COST THERAPIES? AGAIN, WE
6 THINK THAT WE CAN CUT THE LINK SO THAT THAT'S NOT
7 TREATED AS BEING A PAYMENT TO THE STATE OR ANY RELATED
8 PARTY, BUT WE WANT TO CONFIRM THAT WITH THE IRS.

9 A FIFTH ITEM, I THINK, IS THE TREATMENT OF
10 THE INVENTOR'S SHARE. WE UNDERSTAND THAT IT IS NORMAL
11 IN THE UC SYSTEM AND OTHER SYSTEMS THAT WHAT HAPPENS IS
12 THAT ROYALTIES ARE DEVELOPED THAT DO COME IN ARE SPLIT,
13 AND THAT THE PEOPLE WHO WORKED ON THE INVENTION GET A
14 PORTION OF THOSE ROYALTIES AND THAT THE UC SYSTEM GETS
15 A PORTION OF THOSE ROYALTIES. WE THINK THAT A VERY
16 GOOD CASE CAN BE MADE THAT ANY INVENTOR'S SHARE WOULD
17 NOT TREATED AS BEING PAYMENTS, PAYMENTS FROM A PRIVATE
18 SOURCE TO THE STATE OR ANY RELATED ENTITY OF THE STATE.
19 BUT AGAIN, WE NEED TO CONFIRM THAT.

20 THE LAST ITEM THAT I WANTED TO TALK ABOUT A
21 LITTLE BIT, AGAIN, TO REALLY LET'S MAKE IT TOTALLY GRAY
22 IS THE QUESTION OF WHETHER THERE WILL BE ANY PAYMENTS
23 EVER IN THE FUTURE AND TO WHAT EXTENT THERE WILL BE,
24 AND HOW MUCH THOSE MIGHT BE, THE UNCERTAINTY. THE
25 ACTUAL SPECIFIC TEST IN ORDER TO HAVE PRIVATE ACTIVITY

1 BONDS IS THAT YOU HAVE TO, AND AGAIN WE'RE TRYING TO
2 AVOID THAT BEING PRIVATE ACTIVITY BONDS, BUT THE TEST
3 IS YOU HAVE TO EXPECT THAT MORE THAN 10 PERCENT OF THE
4 PROCEEDS WILL BE USED IN PRIVATE TRADER BUSINESS. AND
5 YOU HAVE TO EXPECT THAT YOU ARE GOING TO BE RECEIVING
6 PAYMENTS THAT HAVE A PRESENT VALUE OF MORE THAN 10
7 PERCENT OR MORE THAN \$15 MILLION.

8 THAT EXPECTATIONS WORD COULD BE A VERY
9 IMPORTANT WORD. WE UNDERSTAND FROM SOME OF THE REPORTS
10 THAT HAVE BEEN PREPARED THAT THERE HAVE BEEN SOME
11 STUDIES THAT HAVE BEEN DONE THAT SHOW THAT THERE'S
12 MAYBE NOT A GREAT DEAL OF EXPECTATION THAT THERE WILL
13 BE MONEY COMING IN. OR THAT IF THERE WILL BE, THAT THE
14 MONEY WILL BE SUBSTANTIALLY OUT IN THE FUTURE, SO FAR
15 OUT IN THE FUTURE, THAT PERHAPS WE CAN IGNORE IT. SO
16 WE WANT TO TALK WITH THE SERVICE ABOUT THAT
17 UNCERTAINTY, AND WE'RE GOING TO NEED YOUR HELP AND THE
18 HELP OF CCST IN HELPING US TO DEVELOP SOME OF THE
19 INFORMATION THAT WILL HELP US TO CONVINCING THE SERVICE
20 THAT THE EXPECTATION ISN'T THERE.

21 THE MOST IMPORTANT PART OF ALL THIS -- THIS
22 IS REALLY SORT OF THE IDEAS THAT WE'VE GOT NOW AS TO
23 WHAT WE WANT TO TALK WITH THE SERVICE ABOUT. BUT THE
24 MOST IMPORTANT PART OF ALL OF THIS IS TO REMEMBER THAT
25 THE IRS DOES NOT GIVE WHAT THEY CALL THEORETICAL

1 RULINGS. THEY WILL ONLY RULE ON SOMETHING WHERE YOU
2 COME IN WITH SPECIFIC IDEAS ABOUT HOW YOU'RE GOING TO
3 DO SOMETHING. THESE ARE THE IDEAS THAT WE'VE GOT SO
4 FAR. WE NEED TO MAKE SURE THAT THESE IDEAS REALLY
5 REFLECT WHAT YOU GUYS ARE THINKING, WHAT ALL OF THE
6 OTHER STAKEHOLDERS ARE THINKING, WHAT EVERYBODY IS
7 THINKING. WE NEED TO MAKE SURE THAT, TO THE EXTENT
8 THERE ARE IDEAS THAT WE DON'T KNOW, THAT WE HEAR ABOUT
9 THEM SO THAT WE CAN MAKE SURE THAT THOSE ARE RAISED
10 WITH THE SERVICE AS WELL.

11 AND BASICALLY WE WANT TO MAKE SURE THAT GOING
12 TO THE SERVICE AND DOING THIS IS GOING TO BE A PROCESS
13 THAT'S PROBABLY, MY GUESS IS IT'S GOING TO BE A 9- TO
14 12-MONTH PROCESS TO GET ALL THIS CLEARED UP WITH THEM.
15 WE WANT TO MAKE SURE THAT WHEN WE'RE DONE, THAT WE HAVE
16 SOMETHING WHICH IS USEFUL. SO WE NEED YOUR INPUT TO
17 HELP US IN MAKING SURE THAT WE'RE ASKING THE RIGHT
18 QUESTIONS OR THAT WE'RE POSING THE RIGHT WAY THAT THIS
19 IS BEING PUT TOGETHER.

20 A PERFECT EXAMPLE OF THAT, AGAIN TO
21 REITERATE, IS HOW IS IT THAT INTELLECTUAL PROPERTY
22 RIGHTS ARE NORMALLY ALLOCATED AMONG GRANTHOLDERS FOR
23 PURPOSES OF NORMAL GRANT-MAKING. THAT'S SOMETHING THAT
24 I HAVE NO IDEA ABOUT, SO WE NEED TO LEARN ABOUT THAT.

25 DR. PIZZO: I THINK YOU MAY HAVE BEGUN TO

1 ADDRESS THE QUESTION I HAD IN YOUR VERY LAST SET OF
2 COMMENTS; AND THAT IS, WHEN YOU GO TO THE IRS, IS IT A
3 ONE-TIME EVENT WHERE YOU HAVE SORT OF ONE DISCOURSE AND
4 OPPORTUNITY TO GATHER THE DATA, OR IS IT ITERATIVE?
5 AND THE REASON I'M ASKING THAT IS BECAUSE SOME OF THE
6 QUESTIONS THAT YOU RAISED, IF ANSWERED BY THE IRS,
7 WOULD HELP TO INFORM SOME OF THE THINGS THAT I THINK WE
8 WOULD BE THINKING ABOUT. BUT IF YOU NEED TO WRAP THEM
9 ALL UP INTO ONE BUNDLE BEFORE YOU GO, THERE'S A LOT OF
10 UNCERTAINTY, I THINK, IN HOW WE'LL BE ABLE TO RESPOND
11 TO SOME OF THE ISSUES OR QUESTIONS.

12 MR. ISRAEL: I THINK THE TRUTH OF THE MATTER
13 IS THAT IT WILL BE AN ITERATIVE PROCESS. THAT WE WILL
14 GO IN -- WHAT WE WANT TO DO IS WE WANT TO GO IN SORT OF
15 WITH A SCATTER SHOT, AND MAYBE THAT'S SCATTER SHOT
16 DOESN'T COVER EVERYTHING, BUT GET THEM THINKING WITH
17 US. AS MUCH AS ANYTHING ELSE, WHAT I WANT TO DO IS I
18 WANT TO GET THEM THINKING ABOUT HOW THEY CAN HELP US
19 RATHER THAN THEM SITTING THERE AND JUDGING WHAT IT IS
20 THAT WE'RE DOING.

21 DR. PIZZO: HAVE THERE BEEN ANY PRELIMINARY
22 DISCUSSIONS ALREADY?

23 MR. ISRAEL: I'VE HAD SOME TELEPHONE
24 CONVERSATIONS WITH THE WOMAN WHO IS THE HEAD OF THE
25 BRANCH IN CHIEF COUNSEL THAT WILL DEAL WITH THIS

1 QUESTION AND ALSO WITH, I GUESS, HER LI EUTENANT WOULD
2 BE THE BEST WAY TO DESCRIBE HIM.

3 DR. LOVE: I WAS GOING TO ASK A QUESTION.
4 FORTUNATELY, I'VE NEVER HAD TO DEAL WITH THE IRS, BUT
5 I'VE DEALT -- NOT IN AN ITERATIVE WAY. BUT I DEALT
6 WITH THE FDA A LOT IN AN ITERATIVE WAY. I'M CURIOUS TO
7 JUST UNDERSTAND, PERRY, HOW BINDING OR HOW HARD ARE
8 AGREEMENTS THAT YOU FORGE WITH THEM?

9 MR. ISRAEL: WHAT WE'LL BE ASKING FOR
10 ULTIMATELY, IN FACT, INITIALLY, BUT THE ULTIMATE
11 PRODUCT WE'LL BE ASKING FOR FROM THEM IS SOMETHING
12 CALLED A PRIVATE LETTER RULING. A PRIVATE LETTER
13 RULING IS BINDING UPON THE SERVICE AS TO THE PARTICULAR
14 BOND ISSUE THAT IT DESCRIBES. NOW, WE DON'T WANT TO
15 HAVE TO GO IN THERE EVERY TWO MONTHS WHEN THE STATE
16 DOES A NEW BOND ISSUE, AND SO WE'RE GOING TO MAKE IT
17 VERY CLEAR THAT THIS IS A PROGRAM. SO WE WANT TO GET A
18 PRIVATE LETTER RULING THAT WILL COVER THE PROGRAM, BUT
19 IT IS BINDING UPON THE SERVICE WITH TWO -- WELL, ONE
20 EXCEPTION AND AN EXCEPTION TO THE EXCEPTION.

21 THE EXCEPTION IS THEY CAN DECIDE LATER ON
22 THAT THEY MADE A MISTAKE. BUT IF THEY DECIDE LATER ON
23 THAT THEY MADE A MISTAKE, THERE ARE RULES THAT
24 BASICALLY SAY THEY CAN ONLY APPLY THE NEW RULES
25 PROSPECTIVELY TO BONDS THAT ARE ISSUED AFTER THAT

1 POINT.

2 DR. PIZZO: CAN I DO A FOLLOW-UP WITH TO
3 TED'S QUESTION, WHICH IS I THINK THE ANALOGY TO THE FDA
4 IS A GOOD ONE IN THAT YOU CAN GO IN AND GET ADVICE THAT
5 WILL HELP YOU TO SHAPE WHAT YOU'RE WORKING ON. IS THAT
6 THE KIND OF RELATIONSHIP YOU HAVE WITH THE IRS, OR IS
7 IT SORT OF MORE A REGULATOR? MEANING THEY KNOW THE
8 ANSWER; YOU HAVE TO ASK THE RIGHT QUESTION, AND THEN
9 THEY MAYBE RESPOND TO THAT.

10 MR. ISRAEL: IT'S A CHANGING RELATIONSHIP I
11 THINK IT'S FAIR TO SAY.

12 DR. PIZZO: THAT MAKES ME NERVOUS.

13 MR. ISRAEL: IT IS A CHANGING RELATIONSHIP.
14 I WOULD HAVE SAID IT WAS A MUCH MORE INFORMAL OPEN
15 PROCESS. IN RECENT YEARS, THE LAST TWO YEARS IN
16 PARTICULAR IT'S BECOME VERY CLEAR THAT WITH RESPECT TO
17 TAX-EXEMPT BONDS, THE IRS IS A HOSTILE REGULATOR, THAT
18 THEY DO NOT LIKE TAX-EXEMPT BONDS. THE CHIEF COUNSEL'S
19 OFFICE IN THEORY IS THE LEGAL DEPARTMENT THAT DECIDES
20 THINGS ON A NEUTRAL BASIS AS OPPOSED TO THE AUDIT
21 GROUP, WHICH IS OUR HOSTILE REGULATOR, BUT THERE'S SOME
22 INFLECTION THAT SORT OF PASSES OVER.

23 DR. PIZZO: INFLECTION OR CONTAMINATION?

24 MR. ISRAEL: SOME OF EACH. AT THIS POINT
25 WHAT WE WILL BE PLANNING ON DOING IS THERE'S A

1 PROCEDURE FOR DOING WHAT'S CALLED A PRESUBMISSION
2 CONFERENCE. AND OUR ARRANGEMENT WOULD BE TO GO AHEAD
3 AND PREPARE A MEMORANDUM THAT KIND OF OUTLINES THESE
4 ISSUES AND WHAT WE WANT TO TALK ABOUT, AND THEN GO IN
5 FOR A PRESUBMISSION CONFERENCE SO THAT WE CAN KIND OF
6 FIGURE OUT WHAT ISSUES CAN WE BE ASKING AND WHAT ISSUES
7 DO THEY THINK ARE IMPORTANT.

8 DR. PIZZO: THAT'S HELPFUL.

9 DR. BRYANT: I JUST HAD A QUESTION ABOUT THE
10 TIMING OF THE SPENDING OF THE MONEY AND SO FORTH. SO
11 IF THE BOND IS ISSUED AND THEN THE GRANTS ARE MADE
12 IMMEDIATELY, IS THE CONNECTION BROKEN IMMEDIATELY?

13 MR. ISRAEL: YES. ALTHOUGH TYPICALLY WHAT
14 HAPPENS IN THE STATE IS THAT, BECAUSE THIS TRACKING OF
15 THE MONEY EVEN IN THE STATE IS, TO USE A TECHNICAL
16 TERM, A REAL PAIN IN THE BUTT; AND WHEN YOU MOVE IT OUT
17 INTO SOMEBODY ELSE'S HANDS, YOU HAVE TO TRACK IT OUT
18 THERE, IT'S EVEN WORSE. WHAT TENDS TO HAPPEN IS THAT
19 THE STATE HAS A PROCEDURE WHERE WE BORROW MONEY OUT OF
20 THE POOLED MONEY INVESTMENT ACCOUNT. WE USE THAT MONEY
21 TO, LET'S SAY, MAKE THE GRANTS.

22 ONCE THE GRANTS HAVE BEEN MADE AND THE MONEY
23 IS SPENT, THEN WE ISSUE THE BONDS TO REPAY THE POOL
24 INVESTMENT ACCOUNT, SO WE DON'T HAVE TO TRACK THE MONEY
25 AT ALL.

1 DR. BRYANT: I WAS JUST GOING TO ASK A
2 FOLLOW-UP TO THAT WOULD BE, THEN, IN TERMS OF NOT
3 DELAYING THIS PERIOD OF TIME WHEN THE BONDS ARE AROUND,
4 SO THE UC SYSTEM WOULD -- I MEAN IT WOULD MAKE SENSE
5 FOR IT TO RECEIVE THE MONEY INTO A 501(C)(3) RATHER
6 THAN DIRECTLY INTO THE UNIVERSITY. SO THEN IT WOULD BE
7 GONE IN THE SAME WAY GIVING IT TO STANFORD.

8 DR. PIZZO: JUST GIVE IT TO STANFORD.

9 MR. ISRAEL: IF IT GOES INTO A 501(C)(3) THAT
10 IS CONTROLLED BY THE UNIVERSITY, THEN IT'S STILL A
11 RELATED ENTITY.

12 MR. FEYER: BROADLY SPEAKING, THE ISSUE OF
13 THE DISBURSEMENT OF THE MONEY IS NOT A PROBLEM. THE
14 STATE HAS BEEN DOING THIS FOR 20 PLUS YEARS.

15 MR. ISRAEL: AND THE UC SYSTEM --

16 MR. FEYER: WE CAN HANDLE THOSE ISSUES
17 WITHOUT REALLY AFFECTING THE GRANTEE'S ABILITY TO CARRY
18 OUT THEIR WORK.

19 MR. ISRAEL: THE TREASURER'S OFFICE AT UC
20 WILL NEED TO BE INVOLVED.

21 DR. BRYANT: I JUST THOUGHT THAT THERE WAS A
22 PROBLEM IN TERMS OF THE AMOUNT OF TIME. IN ONE CASE
23 THE MONEY IS SPENT IMMEDIATELY, SO THE LINKAGE IS
24 BROKEN; WHEREAS, IN THE UC CASE IT DRAGS ON.

25 MR. ISRAEL: YOU JUST HAVE TO KEEP TRACING

1 IT.

2 DR. BRYANT: THEN IT MAKES IT MORE LIKELY --

3 CHAIRMAN PENHOET: THE LINKAGE IS BROKEN FOR
4 ONE PURPOSE, BUT NOT ANOTHER. IF THE GRANTEES -- IF
5 STANFORD GENERATES INTELLECTUAL PROPERTY AND SENDS SOME
6 BACK TO STATE, THAT LINKAGE IS NOT BROKEN.

7 DR. PIZZO: DOES THE TIME GET AFFECTED IF
8 IT'S A MULTIYEAR GRANT? MOST GRANTS ARE GOING TO BE
9 SPREAD OVER YEARS OF TIME. HOW DO YOU HANDLE THAT?

10 MR. ISRAEL: MY GUESS IS THAT YOU WILL NOT
11 FUND -- THE STATE WILL NOT FUND A MULTIYEAR GRANT ALL
12 AT ONCE. WHAT WILL HAPPEN IS THAT YOU WILL SAY HERE'S
13 A PIECE OF THE GRANT. NOW YOU'VE GOT A WHOLE BUNCH OF
14 BOND ISSUES TO FINANCE THAT GRANT.

15 MR. FEYER: THIS RELATES TO THE QUESTION.
16 PERRY SAID WE NEED -- FROM OUR STANDPOINT, WE NEED TO
17 GET YOU SCIENTISTS TO EXPLAIN TO US HOW THE GRANT
18 PROCESS WORKS AND HOW YOU KEEP TRACK OF THESE THINGS
19 AND ALLOCATING ISSUE SO THAT --

20 DR. PIZZO: YOU SHOULDN'T ONLY BE SPEAKING TO
21 WE SCIENTISTS. YOU SHOULD BE SPEAKING TO OUR GRANTS
22 MANAGEMENT PEOPLE. YOU'LL FIND MORE ACCURATE
23 INFORMATION THERE.

24 MR. FEYER: YOU PUT US IN TOUCH. THE
25 POINT -- I KNOW THERE ARE OTHER QUESTIONS, BUT I WANTED

1 TO KIND OF -- THIS BOB FEYER SPEAKING. I WANTED TO
2 STEP BACK FOR ONE SECOND AND KIND OF GIVE A FURTHER
3 PERSPECTIVE. WHAT PERRY HAS DESCRIBED IS THE THINKING
4 THAT WE HAVE BEEN DOING NOW FOR MANY MONTHS AS WE HAVE
5 IMMERSSED OURSELVES INTO THIS PROCESS AND TALKED WITH A
6 LOT OF PEOPLE. AND WHAT THIS MAKES PLAIN IS THAT THERE
7 ARE A NUMBER OF DIFFERENT SORT OF LEGAL STRATEGIES THAT
8 WE THINK MAY BE SUCCESSFUL WITH THE IRS IN BEING ABLE
9 TO DETERMINE THAT THE LARGE PART OF THE BONDS THAT WILL
10 BE ISSUED UNDER THIS PROGRAM ARE TAX-EXEMPT. CERTAINLY
11 IT APPEARS THAT A CERTAIN AMOUNT OF THE BONDS WILL BE
12 TAX-EXEMPT IN ANY CASE BECAUSE THOSE DON'T GIVE RISE TO
13 THESE TYPES OF INTELLECTUAL PROPERTY ISSUES. AND WE' LL
14 OBVIOUSLY GET INTO THAT FURTHER.

15 BUT AT THE END OF THE DAY, WE WANT TO MAKE
16 CLEAR THAT -- I THINK I SPEAK FOR THE TREASURER'S
17 OFFICE AS WELL -- THE MOST IMPORTANT THING FROM OUR
18 PERSPECTIVE IS THAT CIRM AND THE STAKEHOLDERS WHO ARE
19 INTERESTED IN THE ISSUE SORT OF MAKE THEIR BEST
20 DECISION ON WHAT'S IN THE BEST INTEREST OF CIRM AND THE
21 STATE IRRESPECTIVE OF THE BOND ISSUE, BOND PROBLEMS OR
22 ISSUES THAT ARE RELATED TO THAT, AND THEN WE WILL WORK
23 WITH THAT AND TRY TO GET THE BEST RESULT WE CAN WITH
24 THE BOND ISSUE.

25 BUT WE KIND OF ALWAYS HAVE THOUGHT THAT THIS

1 TAX ISSUE IS A TAIL WAGGING THE DOG IN THAT RESPECT.
2 SO WE'RE HERE TO LEARN FROM YOU, PARTICIPATE IN YOUR
3 PROCESS, AS YOU AS THE SUBCOMMITTEE AND THEN THE FULL
4 BOARD ULTIMATELY DEVELOPS IP POLICIES TO THE EXTENT
5 THAT, AS THIS GOES FORWARD, WE GET FEEDBACK FROM THE
6 IRS ON SOMETHING, WE'LL FEED IT BACK TO YOU, AND THEN
7 THE BOARD MAY CHOOSE, IF IT WISHES, TO ADJUST SOME
8 ELEMENT OF ITS IP POLICY BASED UPON BEING ABLE TO DO
9 MORE TAX-EXEMPT BONDS OR FEWER. BUT AT THE END OF THE
10 DAY, THESE ARE ULTIMATELY POLICY DECISIONS THAT HAVE TO
11 BE MADE.

12 THERE ARE FINANCIAL IMPACTS, OF COURSE, TO
13 THE COST OF THE BONDS. THE TREASURER'S OFFICE HAS MADE
14 SOME ESTIMATES OF THAT. BUT TAKEN OVER A LONG PERIOD
15 OF TIME, IT'S NOT A HUGE AMOUNT OF MONEY DIFFERENCE
16 DOING TAXABLE VERSUS TAX-EXEMPT.

17 LET ME JUST ALSO SAY, BECAUSE THERE SEEMS
18 SOME OF THE PRESS AND OTHER DISCUSSIONS SUGGEST THAT
19 THERE'S SOME REAL HARM TO DOING TAXABLE BONDS, THE
20 STATE HAS DONE TAXABLE BONDS BEFORE. THERE'S A LARGE
21 MULTIBILLION-DOLLAR HOUSING BOND THAT WAS PUT BEFORE
22 THE VOTERS, VOTED BY THE VOTERS, WE'RE IN THE PROCESS
23 OF ISSUING, AND WHERE EVERYBODY HAS KNOWN FROM THE
24 OUTSET THAT A LARGE PART OF THOSE BONDS HAVE TO BE
25 ISSUED ON A TAXABLE BASIS BECAUSE THEY DON'T MEET THE

1 FEDERAL TAX REQUIREMENTS. SO THIS IS NOT THE FIRST
2 TIME THIS ISSUE HAS COME UP WITH REGARD TO STATE BONDS.

3 MR. ISRAEL: JUST TO REITERATE. DON'T LET
4 THE TAX TAIL WAG THE POLICY DOG.

5 CHAIRMAN PENHOET: GOOD POINT.

6 MR. SHEEHY: I HAD A NUMBER OF QUESTIONS.
7 JUST FIRST OF ALL, WHAT IS THE ESTIMATE, BECAUSE I
8 DON'T THINK IT'S BEEN PUT INTO THE RECORD, OF WHAT THE
9 COST DIFFERENTIAL BETWEEN TAX-EXEMPT AND TAX-FREE BONDS
10 IS, JUST A BALLPARK?

11 MR. FERNANDEZ: WE THINK --

12 MR. SHEEHY: THIS IS BASED ON A HUNDRED
13 PERCENT TAXABLE, I'M ASSUMING.

14 MR. FERNANDEZ: EVEN HUNDRED PERCENT TAXABLE,
15 WE THINK THERE'S CERTAIN EXPENDITURES THAT WILL NOT BE
16 TAXABLE. TRAINING GRANTS, GRANTS TO BUILD CERTAIN
17 FACILITIES MAY NOT BE TAXABLE. SO LOOKING AT THE BOND
18 ACT, WE THINK ADMINISTRATIVE EXPENSES FOR FIRMS, FOR
19 EXAMPLE, WILL NOT BE TAXABLE. SO WE THINK IT'S CLOSE
20 TO 80 SOME PERCENT, 89, 88 PERCENT OF THE BONDS WILL BE
21 PRIVATE ACTIVITY BONDS. COULD BE, WORST-CASE SCENARIO.

22 THE LAST TIME I LOOKED AT THIS WAS ABOUT
23 THREE WEEKS AGO. WE LOOKED AT THE DIFFERENCE BETWEEN
24 TAXABLE BONDS AND TAX-EXEMPT INTEREST RATES. AND BASED
25 ON WHAT THE STATE'S BORROWING RATE IS, TAX-EXEMPT RATE,

1 WE THINK IF YOU ADD 75 BASIS POINTS TO THAT, SO 0.75
2 PERCENTAGE POINTS, THAT'S THE DIFFERENCE, THE
3 ADDITIONAL COST, INCREMENTAL COST OF ISSUING TAXABLE
4 BONDS.

5 BASED ON THE 80 SOME PERCENTAGE, WORST-CASE
6 SCENARIO, WE THINK IT'S ABOUT, FOR THE LIFE OF THE
7 BONDS, IT'S \$470 MILLION.

8 MR. GOLDBERG: PRESENT VALUE BASIS?

9 CHAIRMAN PENHOET: NO.

10 (SIMULTANEOUS DISCUSSION.)

11 MR. GOLDBERG: SO THAT'S RELEVANT. IT'S
12 PROBABLY 300.

13 CHAIRMAN PENHOET: NO. LESS THAN THAT.

14 MR. FERNANDEZ: PRESENT VALUE.

15 MR. GOLDBERG: THAT'S A PRETTY LOW DISCOUNT
16 RATE ON THESE THINGS.

17 MR. SHEEHY: THEN PERHAPS IF WE CAN WALK
18 THROUGH JUST WHAT, AS BEST I CAN UNDERSTAND, THE REAL
19 CASES OF WHAT WE WOULD BE MAKING GRANTS. SO LET'S SAY,
20 FOR INSTANCE, WE MAKE A DIRECT GRANT TO A FOR-PROFIT
21 ENTITY, THE CORPORATION, AND WE HAVE DECIDED THAT WE
22 WOULD LIKE TO GET A ROYALTY BACK. THAT WOULD BE A
23 TAX-EXEMPT BOND -- I MEAN THAT WOULD BE A TAXABLE BOND.
24 THAT'S CLEAR TAXABLE --

25 MR. ISRAEL: SUBJECT TO THESE ALLOCATION-TYPE

1 QUESTIONS.

2 MR. SHEEHY: THEY MAY NOT MAKE A PRODUCT THAT
3 PRODUCES ANYTHING, BUT --

4 MR. ISRAEL: OR MAYBE A LONG TIME IN THE
5 FUTURE, BUT YEAH.

6 MR. SHEEHY: NOW, LET'S SAY WE MAKE A GRANT,
7 AND WE USE OUR HOST, I HOPE THAT'S OKAY, TO STANFORD
8 UNDER THE PRESENT BAYH-DOLE REGIME WHICH HAS NO
9 ROYALTIES RETURNING TO CIRM OR THE STATE, BUT REQUIRES
10 STANFORD TO REINVEST IN RESEARCH AND EDUCATION FROM THE
11 PROCEEDS THEY MAKE, THAT WOULD BE IN ALL PROBABILITY A
12 TAX-EXEMPT BOND? LET'S SAY --

13 MR. ISRAEL: YES.

14 MR. SHEEHY: LET'S SAY WE MAKE A GRANT TO A
15 UC ENTITY. DOES IT MAKE A DIFFERENCE WHETHER WE DO IT
16 UNDER THE BAYH-DOLE REGIME OR NOT, WHETHER WE GET A
17 RETURN OR NOT, THAT WHATEVER RETURN THEY GET HAS TO GO
18 THROUGH THESE TESTS, COULD BE POTENTIALLY A TAXABLE
19 BOND?

20 MR. ISRAEL: CORRECT. UC IS TREATED AS BEING
21 EFFECTIVELY THE STATE OR PART OF THE STATE. SO
22 PAYMENTS THAT COME TO UC ARE JUST THE SAME AS PAYMENTS
23 THAT WOULD COME BACK TO CIRM OR TO ANY OTHER STATE
24 AGENCY.

25 MR. SHEEHY: JUST TRYING TO GET --

1 MR. FEYER: THIS IS THE ISSUE HERE THAT PERRY
2 MENTIONED BEFORE, THAT IT'S POSSIBLE THAT EVEN THE
3 AMOUNT -- THE ROYALTIES RECEIVED MIGHT END UP BEING
4 DIVIDED INTO DIFFERENT CATEGORIES AND PART OF IT GOING
5 TO THE INVENTORS, TO THE SCIENTISTS THEMSELVES. THAT
6 PART MIGHT NOT CAUSE TAX PROBLEMS. AND IF UC, FOR
7 INSTANCE, FORGAVE THE OTHER PART OF THE ROYALTIES THAT
8 COULD -- THAT'S A POSSIBLE REGIME THAT COULD WORK.
9 THESE ARE ALL ISSUES WE HAVE TO WORK OUT WITH THE IRS.

10 CHAIRMAN PENHOET: OKAY. ANY OTHER
11 QUESTIONS?

12 MR. GOLDBERG: FIRST OF ALL, THANK YOU, JUAN,
13 FOR ALL YOU'RE DOING TO HELP US AND TO THE PRINCIPALS
14 FROM -- PARTNERS FROM ORRICK HERRINGTON ON THIS. IT'S
15 AN EXTREMELY COMPLEX AREA, BUT IT SEEMS TO ME AT ITS
16 CORE, THIS IS THE COST OF THE BONDS UNDER TWO DIFFERENT
17 SCENARIOS, WHICH WE CAN BOUND, AND THE BENEFITS FROM
18 WHATEVER INTELLECTUAL PROPERTY ROYALTY SHARING
19 ARRANGEMENTS WE MIGHT CONTEMPLATE.

20 MR. ISRAEL: PRECISELY. THAT'S EXACTLY
21 RIGHT.

22 MR. GOLDBERG: AND IT SEEMS TO ME THAT
23 PERHAPS OUR ANALYSIS OF THIS COULD BE ASSISTED BY JUST
24 SOME ECONOMIC MODELS THAT WOULD BETTER REFLECT ACTUAL
25 CIRCUMSTANCES WE THINK WE MAY ENCOUNTER. AND YOU, BY

1 VIRTUE OF YOUR QUESTIONS, I THINK, ARE SUGGESTING
2 DIFFERENT ALTERNATIVE ASSUMPTIONS AND SCENARIOS THAT WE
3 MIGHT BE ABLE TO DO. AND I DON'T KNOW WHETHER THAT'S
4 SOMETHING THAT, JUAN, YOUR OFFICE CAN DO WITH
5 ASSISTANCE OR WHETHER WE AT CIRM SHOULD UNDERTAKE IN
6 TERMS OF MODELING.

7 CHAIRMAN PENHOET: WE WOULD HAVE TO DO IT AT
8 CIRM.

9 MR. GOLDBERG: I THINK THAT CAN BRING A
10 TREMENDOUS AMOUNT OF CLARITY TO KIND OF WHAT THE
11 BOUNDARY SITUATIONS ARE AND HELP US BECAUSE I AGREE WE
12 NEED TO MAKE OUR DECISIONS ABOUT INTELLECTUAL PROPERTY
13 POLICY PRINCIPALLY BASED ON WHAT'S THE RIGHT THING TO
14 DO WITH INTELLECTUAL PROPERTY POLICY, BUT THE
15 RAMIFICATIONS OF POTENTIALLY A 5-PERCENT ROYALTY, A
16 10-PERCENT ROYALTY, A 15-PERCENT ROYALTY DROPPED INTO A
17 MODEL COULD HAVE IMPORTANT RAMIFICATIONS THAT WOULD
18 COST US SUFFICIENTLY MORE IN ISSUANCE THAT WOULD
19 PREVENT US FROM RESEARCH SPENDING, WHICH IS WHY WE'RE
20 HERE. SO AT THE MARGIN, I THINK WE ALL WANT TO TRY TO
21 UNDERSTAND AND MAKE THAT BACK. ANYWAY, I'LL DO
22 WHATEVER I CAN TO HELP.

23 MR. FEYER: TO POINT OUT BECAUSE THE INTEREST
24 COST ON THE BONDS IS GOING TO BE BORNE BY THE GENERAL
25 FUND, NOT BY THE INSTITUTE, NOT BY CIRM'S BOND PROCEEDS

1 EXCEPT IN THE FIRST FIVE YEARS.

2 DR. LOVE: JUST A THOUGHT FROM LISTENING TO
3 THIS. I THINK WE ALSO NEED TO BE MINDFUL THAT WE DON'T
4 CREATE A TRACKING SYSTEM AND AN INFRASTRUCTURE THAT
5 COSTS THE STATE AS MUCH AS THE POTENTIAL REVENUES THAT
6 ONE MIGHT GENERATE. THIS DOES SEEM LIKE SOMETHING THAT
7 COULD BE INCREDIBLY COMPLICATED TO TRACK OVER TIME AND
8 ACROSS TYPES, AND THERE ARE ALSO SOME ALLOCATIONS. AND
9 THEN IF THE ALLOCATIONS AREN'T RIGHT, WHAT DO YOU DO?
10 SIMPLICITY, I WOULD ARGUE, WOULD BE A GOOD THING TO
11 STRIVE FOR HERE TO THE EXTENT THAT ONE COULD DO THAT.

12 MR. ISRAEL: AS WE'VE BEEN TALKING AND AS
13 THESE IDEAS BECOME MORE SOLID, THE ONES I WAS TALKING
14 ABOUT, AND AS MORE IDEAS COME FROM YOU, I THINK THAT WE
15 GET CLOSER AND CLOSER TO HAVING THIS MEETING WITH THE
16 IRS TO SORT OF KICK THINGS OFF. IT MAKES SENSE TO ME
17 THAT WE THINK ABOUT DOING THAT RELATIVELY SOON.

18 CHAIRMAN PENHOET: GOOD. OKAY. THANK YOU
19 VERY MUCH. AND MAYBE ESPECIALLY THANK YOU FOR YOUR
20 WILLINGNESS TO ADDRESS THIS ISSUE IN A SOPHISTICATED
21 WAY BECAUSE YOUR LAST ADMONITION TO US, I THINK, IS AN
22 IMPORTANT ONE. WE SHOULD, MY OPINION, WE SHOULD TRY TO
23 DEVELOP A POLICY WHICH IS FISCALLY RESPONSIBLE, BUT
24 NEVERTHELESS NOT LET THE TAIL WAG THE DOG. TRY TO COME
25 UP WITH THE BEST POLICY WE CAN COME UP WITH FOR THE

1 CIRM IN INTELLECTUAL PROPERTY. AND ONCE WE'VE DONE
2 THAT, THEN THEY WILL ACTUALLY HAVE THE FODDER FOR THEIR
3 CONVERSATIONS. UNTIL WE'VE DONE THAT, WE CAN ALWAYS
4 COME BACK AFTER THOSE CONVERSATIONS.

5 MS. LANSING: I JUST WANTED TO SAY IN L.A.
6 ALL OF US ARE NODDING OUR HEADS IN AGREEMENT. WE AGREE
7 WITH THIS. THAT'S THE WAY TO APPROACH IT.

8 DR. HALL: JUST A POINT OF CLARIFICATION. AS
9 I UNDERSTAND IT, THE ISSUE OF RETURN TO THE STATE IS
10 IRRELEVANT HERE IN THE SENSE THAT ANY RETURN TO UC FROM
11 INTELLECTUAL PROPERTY CONSTITUTES PRIVATE ACTIVITY.

12 CHAIRMAN PENHOET: THAT'S CORRECT. THAT IS
13 CORRECT. THAT'S A STAKE IN THE GROUND. UC IS A STATE
14 AGENCY. ANY FUNDS THAT GO TO UC ARE DEEMED TO BE
15 PRIVATE ACTIVITY.

16 DR. BRYANT: EXCEPT FOR THE INVENTOR'S SHARE.

17 MR. SHEEHY: FACILITIES AND TRAINING GRANTS.

18 CHAIRMAN PENHOET: AS A MATTER OF RECORD,
19 MARY AND I HAVE LOOKED INTO IT, ABOUT ONE IN 200 GRANTS
20 GENERALLY FROM THE NIH EVER RESULT IN ANY INTELLECTUAL
21 PROPERTY, SO THERE IS A GOOD ARGUMENT THAT SAYS THERE'S
22 A PROBABILITY THAT ANY GIVEN GRANT IS GOING TO CREATE
23 INTELLECTUAL PROPERTY IS LOW BY HISTORICAL STANDARDS.

24 DR. PIZZO: THOSE THAT DO DON'T HAVE A VERY
25 HIGH YIELD.

1 CHAIRMAN PENHOET: DO WE HAVE COMMENTS FROM
2 THE PUBLIC AT THIS POINT? BOB KLEIN, A MEMBER OF THE
3 PUBLIC.

4 MR. KLEIN: THIS IS A GREAT PRIVILEGE TO BE A
5 MEMBER OF THE PUBLIC TODAY AND NOT HAVE THE PRESSURE OF
6 SITTING UP THERE.

7 IT'S, I THINK, VERY IMPORTANT, FIRST OF ALL,
8 TO RECOGNIZE, FOR THE RECORD, THAT THE ALL TAX-EXEMPT
9 BORROWING INTEREST PROJECTION DONE WITH PETER SHAPIRO'S
10 HELP, WHO DOES THE BOND SWAP ARRANGEMENTS FOR BILLIONS
11 AND BILLIONS OF DOLLARS TO THE STATE'S DEBT, WAS \$2.3
12 BILLION AS INTEREST COST. THAT IS NOT WHAT WAS IN THE
13 BALLOT PAMPHLET. THE BALLOT PAMPHLET SHOWED A \$3
14 BILLION INTEREST COST. IT WAS -- IN FACT, IT'S 2
15 BILLION 350 MILLION, SO IT'S ABOUT 650 MILLION MORE.

16 IF YOU TAKE THE TREASURER'S ESTIMATE OF AN
17 ALL TAXABLE PROGRAM COSTING 440 MILLION MORE, YOU CAN
18 SEE THAT YOU CAN ACCOMMODATE THE ALL TAXABLE COSTS
19 DIFFERENTIAL AND STILL HAVE A MARGIN OF 50 PERCENT ON
20 THAT ALL TAXABLE INCREMENT.

21 SO THE BALLOT ARGUMENT DISCLOSURE STATEMENT
22 USED AN INTEREST FIGURE, BECAUSE IT'S A TAXABLE AND
23 TAX-EXEMPT PROGRAM, THAT'S HIGH ENOUGH TO ACCOMMODATE
24 THE WORST-CASE SCENARIO AS PROJECTED.

25 BUT WITH THAT SAID, IT'S IMPORTANT, I THINK,

1 TO REFINE OUR UNDERSTANDING OF THESE ISSUES. JEFF
2 ASKED THE QUESTION IF WE GET ROYALTIES BACK, ARE WE, IN
3 FACT, SUBJECT TO BEING TAXABLE BONDS. AND I'D LIKE TO
4 EXPAND ON THAT BECAUSE I THINK THAT THE ANSWER REALLY
5 IS NOT NECESSARILY YES. AND YOU GAVE US SEVERAL
6 REASONS WHY IT'S NOT NECESSARILY YES.

7 A COUPLE OF BIG REASONS, IF I UNDERSTAND
8 CORRECTLY, AND I'D LIKE YOU TO COMMENT ON THEM, ARE,
9 ONE, THAT UNDER THE 10-PERCENT PRIVATE ACTIVITY RULE,
10 LOOKED AT UNDER TWO DIFFERENT ANALYSES, IF YOU USE 10
11 PERCENT OF THE PRESENT VALUE, YOU HAVE A \$300 MILLION
12 PRESENT VALUE SAFE HARBOR. ON A FUTURE VALUE BASIS,
13 THAT'S ABOUT 900 MILLION BECAUSE OUR AVERAGE ROYALTIES,
14 IF COLLECTED, ARE AN AVERAGE OF 24 YEARS OUT. THERE
15 ARE NONE PROJECTED FOR THE FIRST 14 YEARS. SO IT'S A
16 VERY LATE RECEIPT.

17 MR. ISRAEL: I'M SORRY. JUST TO CLARIFY REAL
18 QUICKLY HERE, YOU'RE RIGHT. REMEMBER, THERE'S A \$15
19 MILLION LIMIT WITH RESPECT TO EACH BOND ISSUE. SO
20 IF --

21 MR. KLEIN: A \$100 MILLION BOND ISSUES, AND
22 YOU USE THE AGGREGATION APPROACH THAT YOU HAVE
23 SUGGESTED, YOU MIGHT HAVE A \$450 MILLION PRESENT VALUE.

24 MR. ISRAEL: WHAT I WAS GOING TO SUGGEST IS
25 IF THE WHOLE 3 BILLION GOT TURNED INTO \$15 MILLION

1 CHUNKS, THAT'S 200 BOND ISSUES OVER WHICH THE BONDS --
2 I'M NOT SURE. DID I DO THAT NUMBER RIGHT? IT THINK
3 IT'S 200 BOND ISSUES OVER WHICH THE BONDS GET DONE.
4 THAT'S PROBABLY TOO LONG OF A TIME PERIOD, BUT YOU'RE
5 RIGHT. THERE'S WAYS TO BREAK THAT UP. THE \$15
6 MILLION --

7 MR. KLEIN: IF IT'S BROKEN INTO \$100 MILLION
8 INCREMENTS THAT ARE AGGREGATED WITH OTHER USES, THEN
9 YOU HAVE 30 INCREMENTS OF 15 MILLION, THERE'S A \$450
10 MILLION PRESENT VALUE TEST, WHICH IS A BILLION 350
11 MILLION DOLLAR FUTURE VALUE WITH A 24-YEAR AVERAGE,
12 WHICH EXCEEDS OUR MAXIMUM ROYALTY PROJECTION.

13 SO THE POINT IS THAT THERE ARE A NUMBER OF
14 SAFE HARBORS HERE BURIED IN THE SUGGESTIONS THAT HE'S
15 MADE THAT CAN GIVE US A WIDE LATITUDE. AND THE
16 SUGGESTION, ALL OF THIS IS SUBJECT TO IRS CONFIRMATION,
17 EVERYTHING, AS HE QUITE CLEARLY SAID, BUT THE
18 SUGGESTION THAT BY USING THE SHORT MATURITIES ASSIGNED
19 TO US, THAT ROYALTIES WOULD BE ACHIEVED LATER IN THE
20 TERM, WHICH IS, IN FACT, EVERYONE'S EXPECTATION, WOULD,
21 IN FACT, PROVIDE ANOTHER MAJOR CARVE-OUT OR EXCEPTION
22 TO THESE RULES.

23 SO THERE'S A NUMBER OF ITEMS AND SUGGESTIONS
24 THAT ARE BURIED IN WHAT YOU SUGGESTED THAT, IF YOU WORK
25 THE MATH OUT, PROVIDE BROAD SAFE HARBORS FOR THE LEVELS

1 OF ROYALTIES; OR IF ROYALTIES EXCEED THE EXPECTATION,
2 MY UNDERSTANDING IS THAT YOU CAN THEN USE AN APPROACH
3 WHERE YOU WILL THEN REFINANCE THOSE BONDS POTENTIALLY
4 INTO TAXABLE DEBT AT THAT POINT SO THAT IF YOUR
5 EXPECTATIONS ARE EXCEEDED BECAUSE WE'VE BEEN MORE
6 SUCCESSFUL AND CREATED MORE THERAPIES, THEN WE CAN CURE
7 THAT DOWNSTREAM, BUT HAVE TAXABLE DEBT FOR A VERY LARGE
8 NUMBER OF YEARS --

9 MR. ISRAEL: TAX-EXEMPT DEBT.

10 MR. KLEIN: -- TAX-EXEMPT DEBT UNTIL THOSE --
11 THE WORST CASE FOR US IS THAT WE MAKE TOO MUCH MONEY,
12 AND THEN WE CAN REFINANCE AND CURE THAT. SO THERE ARE
13 LAYERS AND LAYERS OF WAYS TO APPROACH THIS PRUDENTLY
14 WITH IRS CONFIRMATION AND USE A VERY LARGE PORTION OF
15 THIS AS TAX-EXEMPT DEBT. IS THAT A CORRECT
16 UNDERSTANDING?

17 MR. ISRAEL: I THINK THAT THAT'S CORRECT. I
18 THINK THAT WE HAVE A LOT OF OPPORTUNITY IN TALKING WITH
19 THE IRS. THAT'S WHY I WENT THROUGH THOSE EXAMPLES OF
20 THE VARIOUS THINGS THAT WE NEED TO TALK WITH THEM
21 ABOUT. A COUPLE OF THOSE EXAMPLES ARE ESSENTIALLY
22 SILVER BULLETS THAT WOULD MEAN THAT ALL OF OUR BONDS
23 COULD BE DONE ON A TAX-EXEMPT BASIS.

24 MR. KLEIN: IN TERMS OF THE SILVER BULLETS,
25 USING FUNDS FOR PATIENTS FOR ACCESSIBILITY TO NEW

1 THERAPIES IS THAT LOW INCOME PATIENTS, IS THAT A SILVER
2 BULLET KIND OF CATEGORY WHERE YOU, THE STATE, IS
3 EFFECTIVELY BENEFITING IN THE SENSE THAT EVERYONE IN
4 THE STATE IS BENEFITING, BUT THE STATE IS NOT
5 BENEFITING IN THE NONPERMITTED SENSE?

6 MR. ISRAEL: IN DIRECT PAYMENTS. YES, THAT'S
7 CORRECT, AGAIN WITH THE CONFIRMATION OF THE SERVICE.

8 CHAIRMAN PENHOET: I THINK THE PANEL HAS BEEN
9 CONVINCED NOW AT LEAST TWICE THAT THE TAIL SHOULD NOT
10 WAG THE DOG. THANK YOU FOR EMPHASIZING THAT POINT.

11 WE'VE BEEN JOINED BY DR. FRANCISCO PRIETO AT
12 THE END OF THE TABLE AT THIS END. DID YOU HAVE --

13 DR. PRIETO: THAT'S OKAY.

14 CHAIRMAN PENHOET: WE'VE HAD A LONG
15 DISCUSSION ON THIS ISSUE.

16 MS. STREITZ: MY NAME IS WENDY STREITZ. I'M
17 THE DIRECTOR OF THE UC SYSTEMWIDE INTELLECTUAL PROPERTY
18 POLICY UNIT. I JUST WANTED TO MAKE ONE COMMENT MAYBE
19 THAT WE THINK IS IMPORTANT TO GET ON THE RECORD. WE
20 TALKED ABOUT THE REVENUES COMING BACK TO UC BEING AN
21 ISSUE BECAUSE WE'RE RELATED TO THE STATE. SUE OBSERVED
22 EXCEPT FOR MAYBE THE INVENTORS WOULD BE OKAY. THERE IS
23 ONE OTHER PLACE THAT THOSE REVENUES GO THAT WE THINK IS
24 IMPORTANT AND THAT WE'VE TALKED WITH BOND COUNSEL AND
25 MAY BE ABLE TO BE ADDRESSED, WHICH IS THE RECOVERY OF

1 PATENT EXPENSES.

2 AND THE ISSUE THAT WE'RE CONCERNED ABOUT IS
3 THAT IF WE HAVE AN INVENTION THAT MIGHT BE USEFUL AS A
4 DIAGNOSTIC, A TREATMENT, SOMETHING LIKE THAT, JUST
5 PUBLISHING IT ISN'T GOOD ENOUGH. TO INDUCE A COMPANY
6 TO PICK IT UP AND RUN WITH IT, YOU ALMOST NEED TO
7 PATENT IT SO YOU CAN GIVE SOMEBODY EXCLUSIVE ACCESS.
8 BUT FOR A PUBLIC INSTITUTION TO SPEND THE TENS, MAYBE
9 HUNDREDS OF THOUSANDS OF DOLLARS IN GETTING THE KIND OF
10 PROTECTION THAT'S NECESSARY, WE DON'T HAVE THE MEANS TO
11 DO THAT. SO WE WOULD BE LOOKING TO RECOVER THOSE KINDS
12 OF EXPENSES.

13 WE THINK OUR INITIAL READING FROM BOND
14 COUNSEL IS THAT THAT MAY BE SOMETHING THAT IRS WOULD BE
15 OPEN TO.

16 MR. ISRAEL: IF I COULD ADDRESS THAT REAL
17 QUICKLY.

18 CHAIRMAN PENHOET: THAT'S A POINT MAYBE WORTH
19 EMPHASIZING THAT WE ARE NOT AN ISLAND IN CALIFORNIA.
20 AND AS YOU MAY HAVE NOTICED, IF YOU'VE BEEN READING
21 ANYTHING LATELY, LOTS OF ACTIVITY IN STEM CELLS IS
22 GOING ON OVERSEAS, AND THEY ARE PATENTING THEIR
23 INVENTIONS. SO WE WOULD BE AT GREAT DISADVANTAGE IF WE
24 HAD A SYSTEM WHICH DIDN'T FACILITATE PATENTING
25 INVENTIONS IN CALIFORNIA BECAUSE WE MIGHT FIND

1 OURSELVES FROZEN OUT SOMEDAY BY OTHER ENTITIES THAT
2 HAVE BEEN FILING PATENTS.

3 DR. PIZZO: IN THE UC SYSTEM IS THERE A
4 CERTAIN PERCENTAGE OF WHATEVER ROYALTIES THAT COME IN
5 THAT GO TO THE OFFICE OF TECHNOLOGY TRANSFER TO HELP
6 SUPPORT ITS ACTIVITIES? DOES THAT HAPPEN NOW?

7 MS. STREITZ: IT'S A VERY COMPLICATED
8 FRAMEWORK, EXTREMELY COMPLICATED. WHAT I CAN TELL
9 YOU --

10 DR. PIZZO: I'LL HOLD ON.

11 CHAIRMAN PENHOET: ANY OTHER COMMENTS?
12 PERRY, YOU HAD A POINT. I RUDELY INTERRUPTED YOU. I'M
13 SORRY.

14 MR. ISRAEL: I WAS SIMPLY GOING TO SAY THAT
15 THE QUESTION ABOUT PAYMENTS THAT COME BACK ARE ACTUALLY
16 PAYMENTS THAT ARE, EXCLUDING BOND COSTS, ARE TREATED AS
17 BEING NET PAYMENTS. SO TO THE EXTENT THAT YOU HAVE
18 COSTS IN DEVELOPING AND ACTUALLY FOLLOWING THROUGH AND
19 PURSUING THE PATENT, THOSE ARE AMOUNTS WHICH, I THINK,
20 CAN VERY CLEARLY BE RECOVERED WITHOUT CAUSING YOU TO
21 HAVE PRIVATE ACTIVITY.

22 CHAIRMAN PENHOET: OKAY. GOOD. ANY OTHER
23 QUESTIONS FROM ANYONE?

24 MS. LANSING: WE HAVE PUBLIC HERE IN L. A.

25 CHAIRMAN PENHOET: AND YOU HAVE SOMEBODY WHO

1 WISHES TO SPEAK?

2 MS. LANSING: YES, WE DO.

3 MR. STRASSMAN: IS IT COMING THROUGH HERE?

4 CHAIRMAN PENHOET: WE CAN HEAR YOU.

5 MR. STRASSMAN: THIS IS MARC STRASSMAN. I'M
6 A REPORTER WITH EUTOPIA MEDIA'S CALIFORNIA POLITICS
7 TODAY. I'D LIKE TO ASK MR. KLEIN OR ANY OTHER MEMBERS
8 OF THE ICOC WHO WOULD LIKE TO RESPOND, AT THIS POINT IN
9 TIME, CONSIDERING EVERYTHING THAT'S JUST BEEN DISCUSSED
10 HERE, DO YOU THINK THAT THE PICTURE OF RETURN ON
11 INVESTMENT PAINTED FOR VOTERS IN CALIFORNIA PRIOR TO
12 THE PASSAGE OF PROP 71, INCLUDING SPECIFICALLY THE
13 POSSIBILITY OF UP TO \$1.1 BILLION IN DIRECT PAYMENTS TO
14 THE STATE OF CALIFORNIA, WAS REASONABLE, THE
15 PRESENTATION, OR DO YOU THINK IT WAS OVERSOLD?

16 CHAIRMAN PENHOET: I DON'T THINK THAT'S AN
17 APPROPRIATE QUESTION FOR THIS DISCUSSION TODAY.
18 PERHAPS AFTER THIS MEETING MR. KLEIN WOULD BE HAPPY TO
19 SPEAK WITH YOU, BUT IT'S NOT A SUBJECT THAT WE'RE
20 ADDRESSING IN THIS IP POLICY DISCUSSION HERE TODAY.
21 YOU'RE WELCOME TO CALL BOB KLEIN, IF YOU'D LIKE, AFTER
22 THE MEETING, AND HE'D BE HAPPY TO SPEAK WITH YOU ON
23 THIS ISSUE.

24 ANY OTHER PUBLIC COMMENT IN LOS ANGELES?

25 MS. LANSING: NO. THAT'S IT.

1 MR. REED: I JUST HAD A QUESTION. WAS THAT A
2 STATEMENT THAT THERE WAS 1 PERCENT OF THE PROJECTS
3 FUNDED YIELDED INTELLECTUAL PROPERTY ROYALTIES OR 10
4 PERCENT? WHAT WAS THAT FIGURE?

5 CHAIRMAN PENHOET: NO. NO. IT'S ABOUT 1
6 PERCENT. MAYBE HALF A PERCENT, SOMETHING LIKE THAT.
7 VERY SMALL NUMBER.

8 DR. BRYANT: ONE IN 400 ACCORDING TO THE CCST
9 DOCUMENT.

10 DR. MAXON: ONE IN 400 PATENTS OR GRANTS?

11 DR. BRYANT: EVERY \$2.5 MILLION GIVES YOU
12 ONE.

13 CHAIRMAN PENHOET: OKAY. BACK TO OUR AGENDA.
14 THE NEXT ITEM ON OUR AGENDA IS, LET'S SEE, ITEM C, RICK
15 KLAUSNER, FORMER HEAD OF GLOBAL HEALTH PROGRAMS FOR THE
16 GATES FOUNDATION IN SEATTLE, WILL CALL US AT 12
17 O'CLOCK, SO WE'LL HAVE TO SKIP TO THE NEXT ONE AFTER
18 THAT FOR THE DISCUSSION OF THE NRC REPORT BY BRIAN
19 WRIGHT. WELCOME, BRIAN. THANK YOU COMING TO SEE US
20 TODAY.

21 WE CAN TAKE A FIVE-MINUTE BREAK.

22 (A RECESS WAS TAKEN.)

23 CHAIRMAN PENHOET: I'D LIKE TO RECONVENE THE
24 MEETING. PLEASE TAKE YOUR SEATS. OUR NEXT SPEAKER IS
25 BRIAN WRIGHT. BRIAN IS A PROFESSOR IN AGRICULTURAL AND

1 RESOURCE ECONOMICS AT THE UNIVERSITY OF CALIFORNIA
2 BERKELEY. HE WAS A MEMBER OF THE COMMITTEE WHICH
3 PRODUCED THIS BEAUTIFUL REPORT THAT WE'VE REFERRED TO
4 SEVERAL TIMES TODAY ALREADY. WE'RE DELIGHTED TO HAVE
5 YOU HERE TODAY, BRIAN. THANK YOU FOR DRIVING DOWN FROM
6 BERKELEY. HOPE YOU WON'T GLOAT TOO MUCH OVER LAST
7 SATURDAY'S FOOTBALL GAME WHILE YOU'RE HERE.

8 DR. WRIGHT: I WON'T EVEN MENTION THE GREAT
9 VICTORY.

10 MR. GOLDBERG: AND I WON'T MENTION WOMEN'S
11 VOLLEYBALL.

12 CHAIRMAN PENHOET: THANK YOU FOR COMING.
13 PLEASE, BRIAN, IF YOU CAN COME UP HERE. BRIAN HAS A
14 POWERPOINT PRESENTATION. I'M SORRY THAT YOU CAN'T SEE
15 IT IN LOS ANGELES. YOU DO HAVE THE PREPUBLICATION COPY
16 OF THE REPORT THAT BRIAN WILL REFER TO.

17 DR. WRIGHT: I'M GOING TO GO THROUGH THE
18 WHOLE REPORT ACTUALLY ON POWERPOINT, SO IT SHOULD BE
19 EASY FOR YOU TO FOLLOW IN LOS ANGELES. WHAT I'M USING
20 HERE IS THE POWERPOINT WHICH WAS PRODUCED BY THE
21 COMMITTEE AT THE TIME THEY MADE THE INITIAL BRIEFING.
22 AND I'VE REARRANGED IT AND EMPHASIZED DIFFERENT THINGS
23 FOR YOUR PURPOSES, BUT IT'S BASICALLY THE SAME
24 PRESENTATION.

25 BY THE WAY, THIS COMMITTEE HAS HAD SEVERAL

1 NAMES. ALL THE TIME I WAS ON IT, IT WAS CALLED
2 SOMETHING LIKE COMMITTEE ON INTELLECTUAL PROPERTY IN
3 GENOMICS AND PROTEIN-RELATED RESEARCH OR SOMETHING AND
4 INNOVATION, BUT IT'S NOW CALLED SOMETHING DIFFERENT.

5 THESE ARE THE MEMBERS OF THE COMMITTEE, AND
6 THE TWO CHAIRS WERE SHIRLEY TILGHMAN, PRINCETON
7 UNIVERSITY'S PRESIDENT, AND ROD MCKELVIE, WHO WAS ONCE
8 AN INTELLECTUAL PROPERTY JUDGE.

9 NOW, THE CHARGE OF THE COMMITTEE CAME FROM
10 THE NATIONAL INSTITUTES OF HEALTH, AND WE WERE ASKED TO
11 REPORT ON TRENDS IN THE NUMBER AND NATURE OF
12 U. S. -ISSUED PATENTS BEING GRANTED ON TECHNOLOGIES
13 RELATED TO GENOMICS AND PROTEOMICS; REPORT ON THE
14 STANDARDS THE PATENT OFFICE IS APPLYING IN THESE
15 APPLICATIONS AND OTHER PATENT OFFICES ALSO; REPORT ON
16 HOW THE PATENTING OF GENOMIC AND PROTEOMIC INVENTIONS
17 AND LICENSING IS AFFECTING RESEARCH AND INNOVATION; AND
18 BASED ON THE FINDINGS, RECOMMEND STEPS THAT THE NIH AND
19 OTHERS MIGHT TAKE TO ENSURE THE PRODUCTIVITY OF
20 RESEARCH AND INNOVATION CONTINUES.

21 CHAIRMAN PENHOET: IF I MIGHT INTERJECT HERE
22 FOR THE AUDIENCE. WE BELIEVE THIS IS HIGHLY RELEVANT
23 TO STEM CELLS ALTHOUGH STEM CELLS WERE NOT ADDRESSED IN
24 HERE PER SE, THAT THESE PRINCIPLES AND THE WAY THAT THE
25 FIELD OF STEM CELLS IS LIKELY TO PROCEED WILL BE VERY

1 SIMILAR IN OUR VIEW TO WHAT IS HAPPENING IN THE FIELD
2 OF GENES AND PROTEINS. SO THAT'S WHY THIS -- IT
3 DOESN'T SAY STEM CELL ANYWHERE IN THIS REPORT, BUT THE
4 FINDINGS ARE QUITE RELEVANT. I THINK EVERYONE WHO'S
5 LOOKED AT THIS AGREES.

6 DR. WRIGHT: IN FACT, THERE'S A COMMONALITY
7 IN A LOT OF THESE ISSUES, NOT ONLY BETWEEN THOSE TWO
8 AREAS, BUT EVEN ACROSS TO AGRICULTURE, AND THAT'S ONE
9 REASON WHY I WAS ASKED TO BE ON THE COMMITTEE BECAUSE
10 WE STRUCK SOME ISSUES IN AGRICULTURE MAYBE BEFORE YOU
11 STRUCK THEM IN HEALTH.

12 SO WE HAD A NUMBER OF MEETINGS, AS YOU CAN
13 SEE HERE. I DIDN'T GET TO GO TO THE ONE IN BELLAGIO.
14 I'M SURE IT WAS VERY NICE.

15 LET'S HAVE THE NEXT SLIDE. THE FIRST THING I
16 WANT TO TALK ABOUT IS A SURVEY THAT WAS COMMISSIONED BY
17 THE COMMITTEE AND WAS DONE BY WALSH OF UNIVERSITY OF
18 ILLINOIS CHICAGO AND CHO AND COHEN OF DUKE UNIVERSITY.
19 AND THIS WAS A LARGER VERSION OF A SMALLER SURVEY WHICH
20 HAD BEEN DONE FOR ANOTHER NATIONAL RESEARCH COUNCIL
21 COMMITTEE REPORT A FEW YEARS AGO ON PATENTING IN
22 GENERAL.

23 BUT THIS ONE WAS FOCUSED ON THE AREAS THAT WE
24 WERE STUDYING. BUT AGAIN, I THINK IT HAS SOME
25 RESONANCE FOR THE REST OF BIOTECHNOLOGY, AND I KNOW

1 BECAUSE I'VE DONE A SMALL SURVEY MYSELF THAT HAS
2 RESONANCE IN AGRICULTURE. THEY HAD A 1688-MEMBER
3 SAMPLE, AND THERE WAS SPECIAL SAMPLING TO INCREASE THE
4 MEMBERSHIP OF PEOPLE FROM INDUSTRY AND ALSO SPECIAL
5 ATTENTION TO A COUPLE OF IMPORTANT PATHWAYS THAT WE
6 THOUGHT MIGHT BE INTERESTING TO INFORM US.

7 AND THE ISSUES WERE ISSUES RELATED TO
8 INTELLECTUAL PROPERTY ACQUISITION, INDUSTRY FUNDING,
9 EFFECTS ON START-UPS, THE MOTIVATION OF RESEARCHERS TO
10 DO THEIR RESEARCH IN THE PUBLIC AND THE PRIVATE SECTOR,
11 EXPERIENCE WITH OTHER IP AND HOW DIFFICULT OR HARD IT
12 IS TO HANDLE CONFLICTING IP CLAIMS, AND ALSO THE LAST
13 ONE THERE WAS MTA'S, WHICH TURNED OUT TO BE VERY
14 IMPORTANT.

15 SO WHAT DID WE FIND? WHAT THIS SURVEY FOUND,
16 AND IT'S IN THAT REPORT, IT'S CHAPTER 4 OF THE REPORT,
17 THEY FOUND, FIRSTLY, THAT PATENTING VARIES GREATLY
18 AMONG THE VARIOUS CATEGORIES OF BIOTECHNOLOGY. IN SOME
19 AREAS IT'S QUITE PREVALENT AND SOME IT'S NOT; SOME
20 AREAS ARE AT DIFFERENT STAGES OF DEVELOPMENT, SO THAT'S
21 NATURAL; BUT EVEN APART FROM THAT, THERE SEEMS TO BE
22 VERY DIFFERENT PROPENSITIES TO PATENT.

23 THE SECOND FINDING THERE IS RATHER -- IT'S A
24 VERY TENTATIVE FINDING. IT WAS THAT PATENTING IN THESE
25 AREAS HAD TENDED TO LEVEL OFF AFTER ABOUT 2001. THAT'S

1 VERY DIFFICULT TO REALLY CONFIRM BECAUSE THERE'S A
2 PROBLEM OF PATENT PENDENCY. AND IT MAY, IN FACT, BE
3 JUST THERE'S A BACKLOG THERE THAT WILL BECOME EVIDENT
4 OVER TIME. AND THERE'S A PUBLICATION LAG ALSO, WHICH I
5 ORIGINALLY WASN'T AWARE OF, THAT NOT EVERYTHING GETS
6 PUBLISHED AFTER 18 MONTHS.

7 AND ALSO, WE DID FIND, THOUGH, THAT THE
8 UNITED STATES INVENTORS DOMINATE PATENTING IN THIS AREA
9 IN ALMOST ALL THE CATEGORIES. SO IT'S VERY MUCH A
10 UNITED STATES LED AREA OF SCIENCE BY THESE MEASURES.

11 THERE WAS REFERENCE TO SOME STUDIES WHICH HAD
12 BEEN DONE ON THE DIFFERENT APPROACHES OF PATENT OFFICES
13 IN JAPAN, UNITED STATES, AND THE EUROPEAN COMMUNITY.
14 AND THE FIRST OF THESE POINTS RELATES TO THAT. THERE'S
15 A DIFFERENT LEVEL OF BAR WITH RESPECT TO NONOBVIOUSNESS
16 OR INVENTIVE STEP. AND THERE'S A PERCEPTION AMONG THE
17 THREE PATENT OFFICES THAT THE BAR IS LOWEST IN THE
18 UNITED STATES AND HIGHER IN THE OTHER TWO COUNTRIES. I
19 THINK THAT'S FAIRLY WELL-KNOWN.

20 AND THERE'S ALSO SOME DIFFERENCE IN THE USE
21 OF COMPULSORY LICENSING OR THE POTENTIAL USE OF
22 COMPULSORY LICENSING IN THE OTHER COUNTRIES RELATIVE TO
23 THE UNITED STATES. I DON'T KNOW IF WE WANT TO GET INTO
24 THAT HERE.

25 WE ALSO FOUND THAT THE NUMBER OF PROJECTS

1 THAT HAVE BEEN ABANDONED OR DELAYED AS REPORTED BY THE
2 SCIENTISTS WAS NOT GREAT. THESE ARE PROJECTS WHICH MAY
3 HAVE BEEN ABANDONED OR DELAYED BECAUSE OF INTELLECTUAL
4 PROPERTY REASONS; IN OTHER WORDS, CONFLICTING IP CLAIMS
5 OR BLOCKING IP CLAIMS.

6 THERE ARE ALSO A SMALL NUMBER OF CASES IN
7 WHICH SCIENTISTS HAD TO CHANGE THEIR PLANS OR HAD TO
8 PAY HIGH COST FOR ACCESS TO IMPORTANT INTELLECTUAL
9 PROPERTY. THEY WERE NOT IMPORTANT EITHER IN THE BROAD
10 SCHEME OF THINGS IN THIS SAMPLE. I THINK IN SOME OTHER
11 AREAS OF BIOTECHNOLOGY THAT'S MORE IMPORTANT, BUT NOT
12 SO MUCH AT THIS STAGE OF DEVELOPMENT FOR THIS AREA.

13 AND ALSO WE HAVE AN INTERESTING CASE THAT A
14 LARGE NUMBER OF THE SCIENTISTS THAT WERE SURVEYED
15 ACTUALLY DID HAVE EXPERIENCE PATENTING. I THINK THERE
16 WAS AN AVERAGE OF ABOUT HALF A PATENT PER SCIENTIST.
17 AND SOME OF THEM HAD SUBSTANTIAL AMOUNTS OF ROYALTY
18 REVENUE, BUT THERE REALLY ISN'T ANY EVIDENCE AT ALL
19 THAT THIS IS GREATLY AFFECTING THEIR ATTITUDES ON THESE
20 QUESTIONS. DOESN'T SEEM FROM THE DATA WE CAN SEE
21 THERE; AND FROM SOME OTHER DATA I'VE DONE IN
22 AGRICULTURE, IT DOESN'T SEEM AS IF THERE'S A BIAS
23 INTRODUCED BY THE SCIENTIST'S OWN INVOLVEMENT IN THE
24 SYSTEM WITH RESPECT TO ATTITUDES TOWARDS THE SYSTEM OR
25 VIEWS OF PROBLEMS WITH THE SYSTEM, WHICH IS ENCOURAGING

1 IN SOME WAY.

2 WE ALSO FOUND, THOUGH, THAT -- AND I'VE
3 BOLDED SOME THINGS HERE BECAUSE I THINK THESE MAY BE
4 INTERESTING FOR THIS COMMITTEE MORE THAN SOME OTHER
5 CONCLUSIONS. THE PROPORTION OF ACADEMIC RESEARCHERS
6 WHO ACTUALLY CHECK TO SEE IF WHAT THEY'RE DOING IS
7 COVERED BY A PATENT IS SMALL, IS VERY SMALL. THAT'S
8 NOT ONLY TRUE IN THESE AREAS. IT'S TRUE IN
9 AGRICULTURAL BIOTECHNOLOGY TOO, THAT THE GENERAL
10 PRACTICE IS NOT TO CHECK.

11 IF YOU STOP AND THINK ABOUT IT FOR 15
12 SECONDS, THERE ARE MANY REASONS WHY THAT MIGHT BE THE
13 RESULT YOU WOULD EXPECT. IT'S VERY DIFFICULT TO CHECK
14 COMPREHENSIVELY. IT'S VERY EXPENSIVE, AND MOST OF THE
15 TIME YOU DON'T FIND ANYTHING THAT WOULD CONFLICT
16 ANYWAY. MOST OF THE RESEARCH RESULTS ARE NOT GOING TO
17 BE PATENTABLE, SO DOING EX ANTE CHECKS MAY BE A VERY
18 INEFFICIENT WAY TO DO IT ANYWAY. NEVERTHELESS, WE
19 DIDN'T KNOW THAT FACT UNTIL THE SURVEY RESULT CAME OUT,
20 SO IT'S NOT AS IF THE SCIENTISTS ARE SAYING, OH, MY
21 GOD, I'VE CHECKED ALL THE PATENTS, AND NOW I KNOW I
22 CAN'T DO ANYTHING. THEY JUST SAY I DID THIS AND THAT
23 AND THE OTHER THING, AND IT TURNS OUT THAT SOMEBODY
24 ELSE OWNS THE PATENTS. BUT THAT'S THE WAY IT'S DONE.

25 THAT THE HOLDERS OF PATENTS ARE ACTIVE IN

1 ASSERTING THEIR RIGHTS IN SOME AREAS, AND IN SOME AREAS
2 PURSUE VERY RESTRICTIVE LICENSING. THERE WAS A VERY
3 BIG ISSUE HERE WITH RESPECT TO DIAGNOSTICS, AND THE
4 DIAGNOSTICS REALLY ARE A SEPARATE ISSUE FROM THE REST
5 OF THE SUBJECT MATTER AT HAND. AND THERE WERE SOME
6 BITTER STATEMENTS ABOUT THE EFFECTS OF OVERARCHING
7 PATENTS ON THE FREEDOM, ESPECIALLY OF UNIVERSITY-BASED
8 CLINICIANS TO OPERATE, GIVEN THE BLOCKING PATENTS AND
9 THE EXERCISE OF THE EXCLUSIVITY WITH RESPECT TO THOSE
10 PATENTS.

11 I THINK THAT ACCESS TO PATENTS OR INFORMATION
12 INPUTS WITH RESPECT TO BIOMEDICAL RESEARCH RARELY SEEMS
13 TO IMPOSE A SIGNIFICANT BURDEN ON THESE BIOMEDICAL
14 RESEARCHERS. SO THAT WAS KIND OF A GENERAL CONCLUSION
15 AT THIS TIME SLICE WITH RESPECT TO THESE TECHNOLOGIES.
16 BUT WE DO BELIEVE THAT AS THE TECHNOLOGIES DEVELOP, AS
17 THE PATENT LANDSCAPE GETS MORE COMPLICATED, AND I
18 PERSONALLY THINK AS CERTAIN KEY TECHNOLOGIES BECOME THE
19 KEY PROFITABLE TECHNOLOGIES IN THESE DEVELOPING AREAS,
20 YOU WILL PROBABLY FIND MORE SHOULDERS RUBBING AND MORE
21 CONFLICTS OVER PROPERTY RIGHTS.

22 NOW, ONE OF THE REASONS WHY WE WERE A BIT
23 CONCERNED ABOUT THE FUTURE WAS BECAUSE ONE REASON WHY
24 SCIENTISTS ARE NOT MORE CONSTRAINED BY PRIOR
25 INTELLECTUAL PROPERTY CLAIMS ON TOOLS AND OTHER THINGS

1 IS BECAUSE THEY DON'T CHECK. AND SO FROM THE
2 SCIENTIST'S OWN POINT OF VIEW, THE SCIENTISTS WE'RE
3 TALKING TO ARE NOT RESEARCH DESIGNERS OR NECESSARILY
4 THE PEOPLE SETTING THE DIRECTION OF A PROGRAM, THE GUYS
5 AT THE BENCH DOING THEIR LITTLE THING. AND FROM THEIR
6 POINT OF VIEW, INTELLECTUAL PROPERTY HASN'T BEEN A HUGE
7 ISSUE. FROM THE POINT OF VIEW OF SOMEBODY WHO WANTS TO
8 BRING A PROJECT TO COMMERCIALIZATION, IT MIGHT BE A
9 VERY DIFFERENT STORY AND A SAD STORY WHICH MAY ONLY
10 EVOLVE OVER THE 10, 15 YEARS.

11 ALSO, WE WERE VERY ATTENTIVE TO THE FACT THAT
12 MADY VS. DUKE HAD SORT OF CLARIFIED THE LANDSCAPE WITH
13 RESPECT TO THE EXISTENCE OF RESEARCH EXEMPTION, AND WE
14 HAD SOME CONCERN THAT MAYBE AFTER MADY VS. DUKE, THEN
15 UNIVERSITIES AND OTHER INSTITUTIONS WOULD BECOME
16 MORE RESTRICTIVE -- IMPOSE RESTRICTIONS ON THEIR
17 SCIENTISTS. IT DIDN'T SEEM AS IF THOSE ATTEMPTS, IF
18 THEY HAD BEEN MADE, WERE VERY SUCCESSFUL FROM THE
19 SURVEY. SOME PEOPLE HAVE BEEN CONTACTED, BUT THEIR
20 BEHAVIOR DOESN'T SEEM TO HAVE BEEN CHANGED VERY MUCH.

21 CHAIRMAN PENHOET: PERHAPS IF I COULD, BRIAN,
22 MADY VS. DUKE IS A LAWSUIT BETWEEN A MAN NAMED MADY,
23 WHO WAS A FORMER FACULTY MEMBER AT DUKE WHO LEFT SOME
24 OF HIS INTELLECTUAL PROPERTY AND HIS EQUIPMENT BEHIND.
25 DUKE UNIVERSITY USED THAT PROPERTY AFTER HE LEFT. HE

1 SUED THEM FOR INFRINGING HIS PATENTS. THEY CLAIMED A
2 RESEARCH EXEMPTION BECAUSE THEY WERE JUST DOING GOD'S
3 WORK IN RESEARCH AND HAD NO COMMERCIAL INTENT.

4 FINDING WAS THAT DUKE UNIVERSITY IS
5 FUNDAMENTALLY AN ECONOMIC ENTITY AND HAS BASKETBALL
6 TEAMS AND LICENSES TECHNOLOGY AND DOES LOTS OF
7 COMMERCIAL STUFF; THEREFORE, THEY DON'T GET A PASS. SO
8 IT ROPEDED THE UNIVERSITY INTO THE WHOLE PATENT
9 INFRINGEMENT ARENA. SO THERE IS TODAY NO, QUOTE,
10 UNQUOTE, RESEARCH EXEMPTION IN THE UNITED STATES AS A
11 RESULT. SORRY TO INTERRUPT.

12 DR. WRIGHT: THAT'S RIGHT. AND EVEN THOUGH A
13 LOT OF SCIENTISTS WILL ACTUALLY STILL TELL YOU WHEN YOU
14 ASK THEM THAT THERE IS A RESEARCH EXEMPTION, THERE
15 REALLY ISN'T. ON THE OTHER HAND, IT MAY BE POSSIBLE
16 ALSO TO OVERINTERPRET THE MADY VS. DUKE EXAMPLE BECAUSE
17 THIS WAS A CASE WHERE MORE WAS INVOLVED THAN MONEY, I
18 THINK YOU MIGHT SAY, AND MAYBE NOT A TYPICAL KIND OF
19 CASE THAT A UNIVERSITY MIGHT BE INVOLVED IN IN THE
20 NORMAL COURSE OF THINGS. I DON'T WANT TO DWELL TOO
21 MUCH ON THAT.

22 ALSO, WE'RE ALSO CONCERNED ABOUT
23 PROLIFERATING CLAIMS, ESPECIALLY IN AREAS WHERE YOU'RE
24 USING HIGH THROUGHPUT TOOLS AND YOU NEED MANY, MANY
25 DIFFERENT LICENSES TO BASICALLY COMMERCIALIZE THESE

1 TOOLS. THEN THE SHEAR PROLIFERATION OF RIGHTS AND WHAT
2 WE CALL THE ANTICOMMONS INVOLVED IN TRYING TO GATHER
3 THOSE RIGHTS AND GET FREEDOM TO OPERATE MAY BE A
4 PROBLEM, VERY LIKE THE PROBLEM YOU HAVE WHEN YOU TRY
5 BUILD A HIGHWAY THROUGH A CITY THAT'S ALREADY GOT LOTS
6 OF HOUSES ON IT AND YOU HAVE TO NEGOTIATE WITH EVERY
7 HOMEOWNER TO GET FROM ONE END TO THE OTHER. SO THAT IS
8 SOMETHING THAT COULD BECOME MORE OF A PROBLEM OVER
9 TIME. AND BECAUSE OF WHAT WE'VE SEEN IN THE PATENT
10 DATA, THAT RELATED TO OUR CONCERN IN THIS AREA.

11 BY THE WAY, ONE PLUG FOR THE SPONSOR. THE
12 LARGEST HOLDER OF PATENTS IN SOME OF THESE AREAS MORE
13 THAN ANY INDUSTRY OR GOVERNMENT ENTITY IS THE
14 UNIVERSITY OF CALIFORNIA. SOMETHING ELSE THAT WE
15 DIDN'T KNOW BEFORE WE STARTED.

16 ANOTHER IS THAT, AS YOU CAN SEE HERE, SURVEY
17 DATA REVEALED SUBSTANTIAL EVIDENCE OF POTENTIALLY
18 REMEDIABLE BURDEN ON PRIVATE AS WELL AS PRIVATE
19 RESEARCH STEMMING FROM DIFFICULTIES IN ACCESSING
20 PROPRIETARY RESEARCH MATERIALS WHETHER PATENTED OR
21 UNPATENTED. WHAT THIS MEANS IS THE REAL FREEDOM TO
22 OPERATE ISSUE REVEALED OR EXPRESSED BY SCIENTISTS IS
23 NOT DIFFICULTY OF LICENSING PATENTS OR GETTING FREEDOM
24 TO OPERATE WITH PATENTS, IT'S GETTING SOMEBODY ELSE'S
25 RESEARCH MATERIALS. THAT'S THE PROBLEM. MOST OF THOSE

1 RESEARCH MATERIALS DO NOT HAVE ATTACHED FORMAL
2 INTELLECTUAL PROPERTY RIGHTS; BUT WE FOUND THAT IN THE
3 SURVEY, I THINK, 19 PERCENT OF THE SCIENTISTS SAID THAT
4 THEIR MOST REQUEST FOR THESE RESEARCH MATERIALS HAD
5 BEEN DENIED. AND ALMOST NONE OF THOSE, I WOULD SAY,
6 ARE PROBABLY DUE TO PATENT ISSUES. THEY'RE PROBABLY
7 DUE TO COMPETITION ISSUES AND MAYBE A GENERAL -- MANY
8 SCIENTISTS REPORTED GENERAL INCREASING KIND OF
9 POSSESSIVENESS AND UNWILLINGNESS TO COOPERATE.

10 I WOULDN'T OVERINTERPRET THAT EITHER. I'M
11 NOT QUITE SURE WHETHER THAT PERCEPTION IS REALLY
12 REALITY OR NOT. I DON'T THINK THERE'S TOO MUCH
13 EVIDENCE OF IT, BUT IT IS SOMEWHAT CONCERNING, THAT
14 THERE IS THIS LARGE PROBLEM THAT THERE'S A SUBSTANTIAL
15 AMOUNT OF REFUSAL TO SHARE RESEARCH MATERIALS. THAT'S
16 SOMETHING THAT MIGHT BE RELEVANT FOR THIS COMMITTEE.

17 DR. BRYANT: IS IT ACTUAL REFUSAL OR JUST
18 FAILURE TO RESPOND? THAT'S MORE LIKELY WHAT HAPPENS.

19 DR. WRIGHT: YES. THE END RESULT IS THAT
20 THEY DIDN'T GET --

21 DR. BRYANT: IF THEY REFUSE, YOU CAN GET THEM
22 BECAUSE THEY'RE REQUIRED TO PRODUCE IT.

23 DR. WRIGHT: THAT SYSTEM DOESN'T SEEM TO WORK
24 REALLY SMOOTHLY OR IN A TIMELY FASHION. AND SOMETIMES
25 IF YOU'RE HELD UP THREE OR SIX MONTHS, THAT'S A LONG

1 WHILE.

2 SO ONE OF OUR RECOMMENDATIONS WAS TO
3 EMPHASIZE PURSUIT OF BEST PRACTICES. AND IN THIS AREA
4 WE RECOMMENDED THAT THE NIH SHOULD CONTINUE TO
5 ENCOURAGE THE FREE EXCHANGE OF MATERIALS AND DATA.
6 SHOULD MONITOR THE ACTIONS OF GRANTEES AND CONTRACTORS
7 WITH REGARD TO DATA AND MATERIAL SHARING. AND, IF
8 NECESSARY, REQUIRE GRANTEES AND CONTRACTORS TO COMPLY
9 WITH THEIR APPROVED INTELLECTUAL PROPERTY AND DATA
10 SHARING PLANS. IN OTHER WORDS, WE'RE BASICALLY BANGING
11 THE TABLE AND SAYING THIS IS IMPORTANT. IT SHOULD BE
12 ALWAYS OBSERVED. AND I THINK THIS IS SOMETHING THAT IS
13 RELEVANT FOR OTHER COMMITTEES LIKE YOURS TO THINK ABOUT
14 ALSO. WHAT KIND OF FORCE YOU CAN GET FOR THAT. THERE
15 ARE PROBLEMS WITH THE FORCE THAT NIH CAN REALLY EXERT
16 HERE, BUT WE ENCOURAGE THEM TO OBTAIN AS MUCH FORCE AS
17 THEY CAN AND EXERT IT AS MUCH AS THEY CAN.

18 WE ALSO ENDORSE THE BERMUDA RULES.

19 CHAIRMAN PENHOET: CAN WE STOP THERE FOR A
20 MOMENT AND BACK UP, AND CAN I ASK JAMES A QUESTION. IF
21 WE SAID THIS IS A FIRM POLICY, IT WOULD NOT BE A
22 REGULATION, AS YOU STATED. COULD IT BE A -- WHAT'S THE
23 SECOND CATEGORY YOU MENTIONED TO US?

24 MR. HARRISON: IF YOU HAVE A PERFORMANCE
25 STANDARD WHERE YOU SET FORTH A GOAL.

1 CHAIRMAN PENHOET: YES. THIS COULD BE A
2 PERFORMANCE STANDARD, BUT NOT A REGULATION AS WRITTEN;
3 IS THAT RIGHT? I'M TRYING TO UNDERSTAND HERE.

4 MR. HARRISON: EVEN AS A PERFORMANCE
5 STANDARD, IT DOESN'T SATISFY OFFICE OF ADMINISTRATIVE
6 LAW RULES BECAUSE IT DOESN'T REQUIRE ANYONE TO DO
7 ANYTHING.

8 DR. WRIGHT: IT'S ASPIRATIONAL.

9 CHAIRMAN PENHOET: SO IT HAS TO BE MORE
10 CONCRETE THAN THIS FOR US TO BE ABLE TO USE ANYTHING
11 LIKE THIS.

12 MR. HARRISON: CORRECT.

13 DR. WRIGHT: THIS IS OUTSIDE OF MY AREA. MY
14 UNDERSTANDING IS THAT THE WORDING HERE IS BECAUSE OF
15 THE CONSTRAINTS ON NIH, THAT THEY ARE NOT ALLOWED TO
16 REQUIRE CERTAIN THINGS. THEY CAN ONLY ENCOURAGE IT.
17 OTHER PEOPLE MAYBE KNOW MUCH MORE ABOUT THIS. YOU
18 SHOULDN'T FEEL CONSTRAINED IF YOU'RE NOT CONSTRAINED TO
19 FOLLOW --

20 DR. LOVE: WE'RE CONSTRAINED TO BE
21 CONSTRAINED.

22 DR. WRIGHT: THE BERMUDA RULES ON DATA
23 SHARING IN CERTAIN AREAS IS SOMETHING WHICH MAY BE A
24 BLUEPRINT FOR OTHER AREAS THAT MAYBE YOU'LL BE
25 INTERESTED IN.

1 AND ALSO I THINK RECOMMENDATION 3 IS PROBABLY
2 NOT AS IMPORTANT HERE IN DETAIL. THERE IS GENERAL
3 SENSE THAT WE SHOULD ENCOURAGE NATIONAL AND
4 INTERNATIONAL STRONG COMMUNICATION AND FAST SHARING OF
5 DATA.

6 COMMITTEE ENDORSES NIH'S PRINCIPLES AND
7 GUIDELINES FOR RECIPIENTS OF NIH RESEARCH GRANTS AND
8 CONTRACTS ON OBTAINING AND DISSEMINATING BIOMEDICAL
9 RESEARCH RESOURCES AND THE BEST PRACTICES FOR THE
10 LICENSING OF GENOMIC INVENTIONS. IF YOU'RE INTERESTED
11 IN THESE, THESE ARE ON THE NIH WEBSITE. MANY OF YOU
12 ARE OBVIOUSLY GOING TO BE FAMILIAR WITH IT.

13 AND THIS IS, I THINK, ANOTHER THAT MAY BE
14 QUITE RELEVANT TO THIS COMMITTEE. UNIVERSITIES SHOULD
15 ADOPT THE EMERGING PRACTICE OF RETAINING IN THEIR
16 LICENSE AGREEMENTS THE AUTHORITY TO DISSEMINATE THEIR
17 RESEARCH MATERIALS TO OTHER RESEARCH INSTITUTIONS AND
18 TO PERMIT THOSE INSTITUTIONS TO USE PATENTED TECHNOLOGY
19 IN THEIR NONPROFIT ACTIVITIES. I'M SURE YOU'RE WELL
20 AWARE OF THIS, AND YOU'VE ALREADY HAD SOME EXCELLENT
21 REPORTS FROM OTHERS WHO ARE INVOLVED WITH THESE
22 CONCERNS, INCLUDING ALAN BENNETT.

23 THE NEXT RECOMMENDATION, BASICALLY
24 ENCOURAGING STANDARDIZATION AND FACILITATION OF
25 EXCHANGE OF RESEARCH MATERIALS USING SOMETHING LIKE A

1 SIMPLE LETTER AGREEMENT. IN MANY CASES WE SUSPECT THAT
2 PEOPLE ARE RELUCTANT TO OPERATE SHARING MATERIALS
3 THROUGH MTA'S WHEN THEY HAVE TO USE MTA'S BECAUSE THEY
4 VIEW THE MTA PROCESS AS BURDENSOME. IF YOU ASKED A
5 SCIENTIST WHAT CAUSED DELAYS, IN MANY CASES IT WASN'T
6 THE OTHER SCIENTISTS. IT WAS THE PEOPLE ACROSS CAMPUS
7 WORRYING ABOUT SOME SPECIAL MODIFICATION TO AN MTA
8 WHICH MAYBE A SCIENTIST THOUGHT WASN'T THAT RELEVANT.

9 I THINK EVERYBODY SHOULD BE WELL AWARE THAT
10 TWO- OR THREE-MONTH DELAYS GETTING THINGS EXACTLY RIGHT
11 IN SOME CASES MAY NOT THE RIGHT WAY TO GO. BETTER TO
12 HAVE A MORE UNIFORM INSTRUMENT THAT BASICALLY APPLIES
13 AND MAYBE MISSES A FEW NUANCES.

14 THESE ARE ADVICE -- ENCOURAGEMENT TO THE U.S.
15 PATENT OFFICE. I DON'T THINK THESE TWO PROBABLY ARE SO
16 IMPORTANT FOR THIS COMMITTEE, SO MAYBE WE COULD SKIP
17 THOSE. YOU CAN READ THEM IN THE DOCUMENT.

18 RECOMMENDATION 9, PRINCIPAL INVESTIGATORS AND
19 THEIR INSTITUTIONS CONTEMPLATING INTELLECTUAL PROPERTY
20 PROTECTION SHOULD BE FAMILIAR WITH THE USPTO UTILITY
21 GUIDELINES AND AVOID SEEKING PATENTS ON HYPOTHETICAL
22 PROTEINS, RANDOM SINGLE NUCLEOTIDES, POLYMORPHISMS, AND
23 HAPLOTYPES AND PROTEINS THAT HAVE ONLY RESEARCH, AS
24 OPPOSED TO THERAPEUTIC, DIAGNOSTIC, OR PREVENTIVE
25 FUNCTION. IN OTHER WORDS, WHAT WE'RE SAYING HERE IN

1 LOTS OF WORDS I S TRY TO AVOID PATENTING UPSTREAM
2 RESEARCH INPUTS AS MUCH AS YOU CAN BECAUSE THEY CAUSE
3 MOST OF THE PROBLEMS FOR SCIENTISTS.

4 THE UPSTREAM VERSUS DOWNSTREAM DISTINCTION,
5 WHEN IT CAN BE MADE, IS ONE THAT SHOULD BE MADE IN
6 TERMS OF YOUR OPERATIONAL PRACTICE IF YOU CAN GET THAT
7 DONE.

8 SKIP THIS SLIDE. RECOMMENDATION 10, CONGRESS
9 SHOULD CONSIDER EXEMPTING RESEARCH ON INVENTIONS FROM
10 PATENT INFRINGEMENT LIABILITY. THE EXEMPTION SHOULD
11 STATE THAT MAKING OR USING A PATENTED INVENTION SHOULD
12 NOT BE CONSIDERED AN INFRINGEMENT IF DONE TO DISCERN OR
13 DISCOVER, A, THE VALIDITY OF THE PATENT AND SCOPE OF
14 AFFORDED PROTECTION; B, THE FEATURES, PROPERTIES, OR
15 INHERENT CHARACTERISTICS OR ADVANTAGES OF THE
16 INVENTION; C, NOVEL METHODS OF MAKING OR USING THE
17 PATENTED INVENTION; OR, D, NOVEL ALTERNATIVES,
18 IMPROVEMENTS, OR SUBSTITUTES.

19 THIS KIND OF LANGUAGE IS SEEN IN SOME OTHER
20 OVERSEAS COUNTRIES, AND I THINK ALMOST EVERYBODY ON THE
21 COMMITTEE THOUGHT THIS WAS VERY REASONABLE AND
22 SOMETHING THAT EVERYBODY SHOULD BE PUSHING FOR. AND I
23 THINK THIS COMMITTEE SHOULD TRY TO ADD ITS VOICE, IF IT
24 SO AGREES, TO OTHERS. IT SEEMS VERY DESIRABLE THAT YOU
25 CAN DO RESEARCH ON PATENTED INVENTIONS AS A PART OF THE

1 ADVANCEMENT OF SCIENCE.

2 NIH, RECOMMENDATION 11, NIH SHOULD UNDERTAKE
3 A STUDY OF POTENTIAL UNIVERSITY, GOVERNMENT, AND
4 INDUSTRY ARRANGEMENTS FOR THE POOLING AND CROSS
5 LICENSING OF GENOMIC AND PROTEOMIC PATENTS AS WELL AS
6 RESEARCH TOOLS.

7 SO THIS IS SOMETHING ELSE, I THINK, THAT, IF
8 YOU SO DESIRED, YOU COULD GENERALIZE AND SUPPORT HERE.
9 I THINK IT'S BEEN MENTIONED IN SOME OF YOUR OTHER
10 MATERIALS ALREADY. IT SEEMS LIKE ALMOST A NO-BRAINER
11 FOR AT LEAST THE UNIVERSITIES TO GET TOGETHER AND DO
12 THIS. I KNOW THAT UNIVERSITIES ARE ALREADY DOING THIS
13 IN THE AREA OF AGRICULTURE-RELATED BIOTECHNOLOGY IN THE
14 FORM OF THE PIPER INITIATIVE, AND IT'S SOMETHING THAT
15 MAYBE SHOULD BE CONSIDERED.

16 THESE TWO ALSO I THINK ARE MORE SPECIFIC TO
17 THE COMMITTEE, AND I DON'T THINK WE NEED TO GO THROUGH
18 THOSE HERE. I ENCOURAGE YOU TO LOOK AT THEM IF YOU
19 WANT. THOSE WERE THE ASPECTS OF THE REPORT I THOUGHT
20 WERE MOST SALIENT FOR THE COMMITTEE. I'D BE HAPPY TO
21 ANSWER ANY QUESTIONS.

22 CHAIRMAN PENHOET: THANK YOU. QUESTIONS FROM
23 THE GROUP? VERY CLEAR. WELL, CONGRATULATIONS TO YOU
24 ON BEING A PARTICIPANT IN SUCH A VERY THOUGHTFUL
25 REPORT.

1 DR. LOVE: ACTUALLY I HAVE ONE QUESTION.

2 CHAIRMAN PENHOET: BACKGROUND MATERIAL WAS
3 WONDERFUL IN THIS REPORT, BY THE WAY.

4 DR. LOVE: THE SURVEY ONLY INCLUDED ACADEMIC
5 RESEARCHERS. IT DID NOT INCLUDE RESEARCHERS IN
6 INDUSTRY.

7 DR. WRIGHT: NO. IT ACTUALLY OVERSAMPLED
8 RESEARCHERS IN INDUSTRY BECAUSE WE COULDN'T FIND AS
9 MANY SCIENTISTS IN INDUSTRY. THE EARLY PART OF THE
10 REPORT IN CHAPTER 4 DEALS ONLY WITH ACADEMICS BECAUSE
11 THERE ARE SOME QUESTIONS YOU REALLY CAN'T ASK INDUSTRY
12 SCIENTISTS BECAUSE THEY WOULD -- IF THEY ANSWERED,
13 THEY'D BE FIRED. SOME PARTS OF THE REPORT DEAL WITH
14 ACADEMICS.

15 CHAIRMAN PENHOET: ANY OTHER QUESTIONS FROM
16 THE PANEL? FROM THE AUDIENCE? DON REED.

17 MR. REED: YOU SAID SOMETHING ABOUT
18 DOWNSTREAM, UPSTREAM. COULD YOU CLARIFY THAT A LITTLE
19 BIT FOR THE LAY PEOPLE?

20 DR. WRIGHT: YEAH. YEAH, SURE. THE BASIC
21 IDEA IS IT'S NOT ALWAYS POSSIBLE TO DO THIS, BUT IN
22 MANY CASES YOU CAN IDENTIFY INVENTIONS WHICH ARE MOSTLY
23 USED BY SCIENTISTS IN THE ORDINARY COURSE OF FURTHER
24 WORK, ADVANCING THE FLOW OF KNOWLEDGE, OTHERS WHICH ARE
25 BASICALLY PRODUCTS AND USED BY CONSUMERS. AND WE VIEW

1 THE FORMER AS UPSTREAM AND THE MORE PRODUCT-RELATED
2 ONES AS DOWNSTREAM. UPSTREAM AND DOWNSTREAM ON THE
3 PATH BETWEEN BASIC RESEARCH AND APPLICATION.

4 AND THE UPSTREAM PATENTS REFER TO THINGS LIKE
5 RESEARCH TOOLS, THINGS THAT RESEARCHERS USE IN THE
6 COURSE OF FURTHER RESEARCH. IF THE PATENTS ON THOSE
7 THINGS PROLIFERATE, AND IF ONE SCIENTIST NEEDS TO USE
8 MANY DIFFERENT TOOLS, THEN PATENTING CAN BE A REAL
9 PROBLEM BECAUSE IT MAY BE VERY HARD TO GET ACCESS TO
10 ALL THE PROPERTY RIGHTS YOU NEED TO FURTHER YOUR OWN
11 SCIENTIFIC ENDEAVOR.

12 CHAIRMAN PENHOET: THANK YOU. ARE THERE
13 PUBLIC COMMENTS OR QUESTIONS FROM LOS ANGELES?

14 MS. LANSING: NOTHING.

15 CHAIRMAN PENHOET: OKAY. THANK YOU.

16 MELISSA, I THINK WE HAVE TIME FOR YOU TO READ REBECCA
17 EISENBERG'S COMMENTS TO THE LEGISLATIVE HEARING, IF YOU
18 WOULD, PLEASE.

19 MS. KING: ABSOLUTELY. SHOULD I COME BY THE
20 PHONE?

21 CHAIRMAN PENHOET: YES. OTHERWISE, THEY
22 WON'T BE ABLE TO HEAR YOU.

23 MS. KING: I'M GOING TO READ --

24 CHAIRMAN PENHOET: THE COMMITTEE HAVE COPIES.

25 MS. KING: THERE ARE SOME COPIES IN THE BACK,

1 I BELIEVE, AS WELL. SO I WILL BE READING THIS EXACTLY
2 AS SHE WROTE IT. SO WHEN I SAY I, I ACTUALLY MEAN
3 REBECCA EISENBERG.

4 "THANK YOU FOR INVITING ME TO PARTICIPATE IN
5 THIS HEARING. I HAVE SPENT MANY YEARS STUDYING THE
6 ROLE OF INTELLECTUAL PROPERTY AT THE PUBLIC/PRIVATE
7 DIVIDE IN BIOMEDICAL RESEARCH, AND I APPRECIATE THE
8 OPPORTUNITY TO SPEAK TO YOU AS YOU FORMULATE THE IP
9 POLICIES THAT WILL GOVERN THE RESEARCH TO BE SPONSORED
10 BY THE CIRM.

11 "LIKE MANY AMERICANS, I'M GRATEFUL TO THE
12 STATE OF CALIFORNIA FOR THE RESOURCES THAT IT IS
13 COMMITTING TO STEM CELL RESEARCH AT A TIME WHEN THE
14 FEDERAL GOVERNMENT IS LAGGING IN ITS SUPPORT OF THIS
15 PROMISING FIELD. THIS IS A SMART MOVE THAT WILL BRING
16 BENEFITS, NOT ONLY TO THE PEOPLE OF CALIFORNIA, BUT TO
17 ALL OF US.

18 "NONETHELESS, IT IS IMPORTANT TO RECOGNIZE
19 THAT STEM CELL RESEARCH IS NOT AN ISOLATED DOMAIN OF
20 RESEARCH, BUT A PART OF A MUCH LARGER BIOMEDICAL
21 RESEARCH ENTERPRISE. STEM CELL RESEARCH BOTH DRAWS
22 UPON AND CONTRIBUTES TO ADVANCES IN OTHER PARTS OF THIS
23 ENTERPRISE. IT IS A CROSS-CUTTING TECHNOLOGY THAT WE
24 CAN EXPECT TO CONNECT UP TO THE SEAMLESS WEB OF
25 BIOMEDICAL RESEARCH AT MANY DIFFERENT POINTS.

1 "CALIFORNIA HAS LONG BEEN A LEADER IN
2 BIOMEDICAL RESEARCH, BUT IT HAS NEVER BEEN AN ISLAND
3 WITHIN THE BIOMEDICAL RESEARCH COMMUNITY, AND IT WOULD
4 BE BAD FOR BOTH CALIFORNIA AND FOR THE REST OF THE
5 NATION IF IT WERE TO BECOME SUCH AN ISLAND.

6 "THESE TWO REALMS OF CONNECTION, FIRST,
7 CONNECTIONS BETWEEN STEM CELL RESEARCH AND OTHER
8 FIELDS, AND SECOND, CONNECTIONS BETWEEN RESEARCH IN
9 CALIFORNIA AND RESEARCH ELSEWHERE, ARE IMPORTANT TO
10 KEEP IN MIND IN THINKING THROUGH AN APPROPRIATE IP
11 STRATEGY FOR THE CIRM.

12 "AS A LONGTIME STUDENT OF THE BAYH-DOLE ACT
13 AND ITS CONSEQUENCES, I SEE THAT LEGISLATIVE
14 INITIATIVE -- I SEE THAT LEGISLATIVE INITIATIVE AS A
15 MIXED SUCCESS.

16 "ON THE BRIGHT SIDE, THE BAYH-DOLE ACT HAS
17 DONE A REASONABLY GOOD JOB OF PROMOTING TECHNOLOGY
18 TRANSFER FROM UNIVERSITIES TO THE PRIVATE SECTOR AND
19 HAS FACILITATED THE DEVELOPMENT OF COMMERCIAL
20 BIOTECHNOLOGY. TECHNOLOGY TRANSFER AND COMMERCIAL
21 DEVELOPMENT WERE ITS PRIMARY GOAL, AND THIS IS AN
22 IMPORTANT SUCCESS. UNIVERSITIES HAVE NOT, WITH A
23 HANDFUL OF EXCEPTIONS, MADE MUCH MONEY FROM THEIR
24 BAYH-DOLE PATENTS, BUT THIS WAS NEVER THE GOAL OF THE
25 BAYH-DOLE ACT AND IT SHOULDN'T BE THE GOAL, IN MY VIEW.

1 "ON THE OTHER HAND, THE BAYH-DOLE ACT HAS HAD
2 A DOWNSIDE FOR ACADEMIC RESEARCH THAT IS HARDER TO
3 MEASURE. IT HAS SOMETIMES LED TO OVERLY AGGRESSIVE
4 PATENTING AND LICENSING STRATEGIES FOR UPSTREAM
5 RESEARCH DISCOVERIES OF THE SORT THAT COULD OTHERWISE
6 BE READILY DISSEMINATED IN THE PUBLIC DOMAIN WITHOUT
7 THE NEED FOR PATENTS.

8 "IN SOME CASES THE PATENTING OF THESE
9 DISCOVERIES HAS LED TO WASTEFUL TRANSACTION COSTS AND
10 OBSTACLES TO RESEARCH, PERHAPS TO THE LONG-TERM
11 DETRIMENT OF PROGRESS IN RESEARCH AND PRODUCT
12 DEVELOPMENT. BECAUSE MOST UNIVERSITY RESEARCH
13 DISCOVERIES ARE OF THIS UPSTREAM CHARACTER, IT IS
14 IMPORTANT TO EXERCISE CAREFUL JUDGMENT IN CHOOSING WHAT
15 TO PATENT AND WHAT TO LEAVE IN THE PUBLIC DOMAIN AS
16 WELL AS IN FIGURING OUT APPROPRIATE LICENSING
17 STRATEGIES FOR INVENTIONS THAT ARE LIKELY TO BE
18 IMPORTANT FOR SUBSEQUENT RESEARCH.

19 "I HAVE MY CRITICISMS OF THE BAYH-DOLE ACT,
20 AND I HAVE FOLLOWED WITH CONSIDERABLE INTEREST THE
21 DEBATES ABOUT WHAT SORT OF IP POLICIES WOULD BE
22 APPROPRIATE FOR THE CIRM. NONETHELESS, IT IS IMPORTANT
23 TO BEAR IN MIND THAT THE STATE OF CALIFORNIA DOES NOT
24 AND CANNOT WRITE ITS IP POLICIES FOR THIS IMPORTANT
25 INITIATIVE ON A CLEAN SLATE. CIRM IS A RELATIVELY

1 SMALL PART OF A LARGE BIOMEDICAL RESEARCH ENTERPRISE
2 THAT HAS BEEN OPERATING FOR 25 YEARS UNDER THE SCHEME
3 PUT IN PLACE BY THE BAYH-DOLE ACT. THIS MATTERS.

4 "UNIVERSITIES INSIDE AND OUTSIDE CALIFORNIA
5 HAVE BEEN ON A LONG LEARNING CURVE UNDER THE BAYH-DOLE
6 ACT. THERE'S A NOTABLE DIFFERENCE IN THE SUCCESS OF
7 THOSE UNIVERSITIES THAT HAVE HAD TECHNOLOGY TRANSFER
8 OFFICES UP AND RUNNING SINCE THE 1980S AND THOSE THAT
9 HAVE JUMPED MORE RECENTLY ONTO THE TECH TRANSFER BAND
10 WAGON. THE OLD-TIMERS ARE TYPICALLY MORE SAVVY, LESS
11 GREEDY, AND MORE RESPONSIBLE ABOUT THE ROLE OF THEIR
12 PATENTS IN THE RESEARCH COMMUNITY THAN THE NEWCOMERS.

13 "A NEW SCHEME THAT DEPARTS MARKEDLY FROM THE
14 BAYH-DOLE STATUS QUO WOULD START CIRM GRANTEES ON A
15 WHOLE NEW LEARNING CURVE, AND IT WOULD TAKE A LONG TIME
16 FOR EVERYONE TO LEARN THE NEW MOVES. MOREOVER,
17 RESEARCH INSTITUTIONS WITHIN CALIFORNIA ARE OPERATING
18 UNDER THE BAYH-DOLE ACT FOR A SUBSTANTIAL PROPORTION OF
19 THEIR BIOMEDICAL RESEARCH PORTFOLIOS, INCLUDING THE
20 STEM CELL RESEARCH THAT THEY DO WITH GOVERNMENT
21 FUNDING. THIS RESEARCH IS YIELDING INVENTIONS THAT BY
22 THE TERMS OF THEIR GRANTS FROM THE FEDERAL GOVERNMENT
23 THESE INSTITUTIONS SEEK TO PATENT. INTRODUCING A NEW
24 SCHEME ALONGSIDE THE BAYH-DOLE THAT GOVERNS INVENTIONS
25 MADE WITH CIRM FUNDING COULD POTENTIALLY CREATE

1 CONFLICTING AND CONFUSING OBLIGATIONS.

2 "IT IS UNLIKELY THAT CIRM FUNDING WILL
3 DISPLACE FEDERAL FUNDING EVEN FOR RESEARCHERS AND
4 INSTITUTIONS WORKING WITH STEM CELLS WITHIN CALIFORNIA.
5 INDEED, ANY SUCH DISPLACEMENT WOULD LIMIT THE BENEFITS
6 OF CIRM FUNDING AND WOULD BE UNDESIRABLE. BUT EVEN IF
7 STEM CELL RESEARCH WITHIN CALIFORNIA COULD BE GOVERNED
8 BY A DIFFERENT IP REGIME, RESEARCHERS WITHIN CALIFORNIA
9 ARE PART OF A LARGER BIOMEDICAL RESEARCH COMMUNITY THAT
10 EXTENDS BEYOND THE BORDERS OF THE STATES.

11 "TO THE EXTENT THAT THE BAYH-DOLE APPROACH
12 REIGNS BEYOND THE STATE, RESEARCHERS AND INSTITUTIONS
13 WITHIN CALIFORNIA MIGHT FIND THEMSELVES AT A
14 DISADVANTAGE IF THEY DON'T HAVE THE SAME SORTS OF
15 RIGHTS AND BARGAINING CHIPS AS OTHER MEMBERS OF THIS
16 COMMUNITY. SO LONG AS OTHER RESEARCHERS AND
17 INSTITUTIONS HOLD PATENTS ON STEM CELL TECHNOLOGY AND
18 ARE PREPARED TO ENFORCE THEM AGAINST RECIPIENTS OF CIRM
19 FUNDING, CIRM-FUNDED RESEARCHERS MIGHT NEED THEIR OWN
20 PATENT PORTFOLIOS TO PROTECT THEIR OWN FREEDOM TO
21 OPERATE.

22 "SO I THINK THE SHARP DEPARTURE FROM THE
23 BAYH-DOLE APPROACH FOR CIRM-FUNDED RESEARCH COULD
24 BACKFIRE. I HAVE A FEW SUGGESTED MODIFICATIONS
25 CONSISTENT WITH THE OVERALL BAYH-DOLE FRAMEWORK THAT

1 MIGHT ALLEVIATE SOME OF THE PROBLEMS THAT HAVE ARISEN
2 UNDER THE BAYH-DOLE ACT AND HELP TO ADVANCE THE GOALS
3 OF THE CIRM.

4 "NO. 1, UNDER THE BAYH-DOLE ACT, THE FEDERAL
5 GOVERNMENT KEEPS A RETAINED LICENSE TO PRACTICE
6 INVENTION FOR GOVERNMENT PURPOSES. THE THEORY IS THAT
7 IF YOU PAY FOR THE RESEARCH, YOU SHOULDN'T HAVE TO PAY
8 PATENT ROYALTIES TO USE THE RESULTS. NIH HAS TAKEN THE
9 CONSERVATIVE POSITION THAT THIS RETAINED LICENSE DOES
10 NOT COVER USE OF PATENTED INVENTIONS BY ITS GRANTEES.
11 OTHER FEDERAL AGENCIES FEEL DIFFERENTLY, AND I WOULD
12 URGE CALIFORNIA TO CLARIFY IN ITS STATUTE THAT ITS
13 RETAINED LICENSE INCLUDES AT A MINIMUM A RIGHT FOR
14 RESEARCHERS WHO ARE SPONSORED BY THE STATE OF
15 CALIFORNIA TO USE THE PATENTED INVENTIONS THAT HAVE
16 ARISEN OUT OF PREVIOUS CIRM-SPONSORED RESEARCH. YOU
17 MIGHT WANT TO AIM FOR A BROADER RETAINED LICENSE FOR
18 ANY RESEARCH USES WITHIN THE STATE OF CALIFORNIA, BUT
19 AT A MINIMUM YOUR GRANTEES SHOULD NOT HAVE TO PAY FOR
20 ACCESS TO TECHNOLOGY THAT YOU PAID TO DEVELOP IN THE
21 FIRST INSTANCE.

22 "NO. 2, A SECOND RESTRICTION ON THE RIGHTS OF
23 GRANTEES UNDER THE BAYH-DOLE ACT THAT COULD BE
24 FORTIFIED IN THIS CONTEXT IS THE ABILITY OF THE SPONSOR
25 TO DEVIATE FROM THE USUAL RULES WHEN A NONPROPRIETARY

1 APPROACH IS MORE LIKELY TO FURTHER THE GOALS OF
2 TECHNOLOGY TRANSFER. UNDER THE BAYH-DOLE ACT SUCH
3 DEPARTURES ARE LIMITED TO EXCEPTIONAL CIRCUMSTANCES,
4 REFLECTING A WORRY THAT GOVERNMENT SPONSORS WOULD BE
5 QUICK TO ASSUME THAT PATENTS WOULD ALWAYS BE
6 INAPPROPRIATE. BUT THE WORLD HAS CHANGED GREATLY SINCE
7 1980, AND TODAY RESEARCH SPONSORS ARE MUCH LESS HOSTILE
8 TO PATENT RIGHTS THAN THEY WERE AT THE TIME OF THE
9 BAYH-DOLE ACT.

10 "THE TERM "EXCEPTIONAL CIRCUMSTANCES"
11 SUGGESTS THAT PATENTING SHOULD BE THE RULE RATHER THAN
12 THE EXCEPTION; BUT, IN FACT, PATENTING HAS ALWAYS BEEN
13 AND REMAINS THE EXCEPTION IN UNIVERSITY RESEARCH. MOST
14 UNIVERSITY-BASED RESEARCH RESULTS ARE PRIMARILY OF
15 INTEREST TO OTHER RESEARCHERS AND ARE NOT WORTH
16 PATENTING.

17 "FOR UPSTREAM RESEARCH AND TECHNOLOGIES THAT
18 ARE FAR REMOVED FROM THE MARKETPLACE, SUCH AS STEM CELL
19 RESEARCH, MUCH OF THE RESEARCH THAT CIRM WANTS TO
20 SPONSOR IS LIKELY TO FALL INTO THE CATEGORY THAT THE
21 BAYH-DOLE ACT PRESUMES WILL BE EXCEPTIONAL. FOR
22 EXAMPLE, CIRM MAY WISH TO SPONSOR RESEARCH PROJECTS TO
23 CATALOG CHANGES IN GENE EXPRESSION AS STEM CELL LINES
24 BECOME MORE DIFFERENTIATED IN DIFFERENT ENVIRONMENTS.
25 SUCH A RESOURCE WOULD BE A RESEARCH FUNDAMENTAL TOOL

1 WITH RELEVANCE TO A GREAT MANY DIFFERENT PROBLEMS AND
2 CAN BE EXPECTED TO BE DISSEMINATED AND UTILIZED MORE
3 PROMPTLY AND EFFICIENTLY IN THE PUBLIC DOMAIN WITHOUT
4 HAVING TO NEGOTIATE LICENSES.

5 "CIRM SHOULD HAVE THE AUTHORITY TO SPECIFY IN
6 ADVANCE THAT PARTICULAR SPONSORED PROJECTS ARE OF THIS
7 CHARACTER UNBURDENED BY ANY STATUTORY PRESUMPTION THAT
8 SUCH DEPARTURES FROM THE ORDINARY PROPRIETARY SCHEME
9 ARE ONLY APPROPRIATE IN EXCEPTIONAL CIRCUMSTANCES.

10 "THIRD, I AM INTRIGUED BY MERRILL GOOZNER'S
11 SUGGESTION THAT THE CIRM MIGHT CREATE A PATENTS POOL
12 FOR STEM CELL PATENTS. A PROBLEM WITH THE BAYH-DOLE
13 SYSTEM IS THAT IT HAS THE EFFECT OF FRAGMENTING OF
14 OWNERSHIP OF PATENT RIGHTS IN THE HANDS OF MULTIPLE
15 OWNERS, MAKING IT NECESSARY FOR FIRMS THAT WANT TO
16 DEVELOP THE TECHNOLOGY TO GATHER UP LICENSES THROUGH
17 MANY SEPARATE NEGOTIATIONS WITH DIFFERENT OWNERS. THIS
18 IS COSTLY, WASTEFUL, AND DISCOURAGING. AND AS THE
19 NUMBER OF OWNERS PROLIFERATES, THE RISK THAT PRODUCT
20 DEVELOPMENT WILL BE STALLED INCREASES.

21 "THERE MAY BE A ROLE FOR A PATENT POOL IN
22 THIS AREA AT SOME POINT; AND IF THE CIRM BECOMES AN
23 IMPORTANT ENOUGH PLAYER IN THIS FIELD, IT MIGHT BE A
24 LOGICAL INSTITUTION TO GET IT GOING, BUT I WOULD NOT
25 MAKE THAT THE ORGANIZING PRINCIPLE OF YOUR IP POLICY AT

1 THIS STAGE. THERE ARE ALREADY LOTS OF OTHER STEM CELL
2 PATENTS OUT THERE THAT ARE BROADER AND MORE FAR
3 REACHING THAN ANY PATENTS THAT CIRM GRANTEES ARE LIKELY
4 TO GET.

5 "IT IS NOT YET CLEAR WHAT COMMERCIAL
6 DEVELOPMENT OPPORTUNITIES WILL ARISE IN THE STEM CELL
7 FIELD, NOR WHAT PATENTS WILL BE RELEVANT TO THOSE
8 OPPORTUNITIES, BUT IT'S LIKELY THAT ALL YOU WILL NEED
9 IS THE CIRM PATENTS. SO I THINK THIS IS SOMETHING TO
10 KEEP AN EYE ON, AND YOU MIGHT WANT TO BE SURE THAT CIRM
11 HAS THE AUTHORITY IT NEEDS TO PUT TOGETHER A PATENT
12 POOL IN THE FUTURE, IF THAT SEEMS TO BE CALLED FOR, BUT
13 I WOULDN'T START OFF REQUIRING THAT ALL GRANTEE PATENTS
14 GO INTO A PATENT POOL WITHOUT KNOWING WHAT THEY ARE
15 ABOUT AND HOW THEY RELATE TO OTHER PATENTS IN THE
16 FIELD.

17 "NO. 4, ONE FINAL SUGGESTION. THINK ABOUT
18 DATA DISSEMINATION. DATA AS SUCH ARE NOT GENERALLY
19 CONSIDERED PATENTABLE AND, THEREFORE, ARE NOT COVERED
20 BY THE BAYH-DOLE ACT, WHICH APPLIES ONLY TO PATENTABLE
21 INVENTIONS. BUT ONE OF THE MOST VALUABLE OUTPUTS FROM
22 CIRM-FUNDED RESEARCH IS LIKELY TO BE DATA. NIH HAS
23 MADE A POINT IN RECENT YEARS OF PROMOTING DATA
24 DISSEMINATION BY GRANTEES; E.G., BY CALLING FOR GRANT
25 APPLICATIONS TO ADDRESS PLANS FOR DATA DISSEMINATION.

1 THIS IS A VERY GOOD THING FOR SCIENCE, AND CIRM WOULD
2 DO WELL TO FOLLOW THE LEAD OF THE NIH BY ENCOURAGING
3 GRANTEES TO MAKE DATA AVAILABLE TO THE SCIENTIFIC
4 COMMUNITY IN A TIMELY FASHION.

5 "THERE ARE A FEW OTHER ITEMS THAT YOU MAY BE
6 CONSIDERING THAT I WOULD CAUTION AGAINST. NO. 1, FIRST
7 IS RECOUPMENT OF ROYALTIES FOR THE STATE FROM PATENTS
8 ON CIRM-FUNDED INVENTIONS. RECOUPMENT PROVISIONS HAVE
9 BEEN REPEATEDLY PROPOSED IN CONGRESS, AND SO FAR THEY
10 HAVE ALWAYS BEEN DEFEATED. THE REASON FOR THIS IS THAT
11 THE POINT OF THE BAYH-DOLE ACT HAS BEEN TO PROMOTE
12 TECHNOLOGY TRANSFER, NOT TO TAX IT. RECOUPMENT IS A
13 TAX ON PRODUCT DEVELOPMENT. YOU WANT TO ENCOURAGE
14 BUSINESSES TO TAKE RISKS IN DEVELOPING THESE
15 TECHNOLOGIES. CONGRESS HAS ALWAYS CONCLUDED THAT THE
16 BEST WAY TO PROFIT FROM THE RESULTS OF
17 GOVERNMENT-SPONSORED RESEARCH IS TO ALLOW THE LICENSEE
18 BUSINESSES TO FLOURISH AND TO COLLECT THEIR USUAL TAXES
19 ON PREFERENCE.

20 "SECOND IS A PREFERENCE FOR CALIFORNIA
21 BUSINESSES IN THE LICENSING OF INVENTIONS. THE
22 BAYH-DOLE ACT DIRECTS GRANTEES TO GIVE A PREFERENCE IN
23 LICENSING TO BUSINESSES THAT WILL MANUFACTURE PRODUCTS
24 IN THE UNITED STATES. A PREFERENCE FOR
25 CALIFORNIA-BASED BUSINESSES WOULD BE SIGNIFICANTLY MORE

1 RESTRICTIVE. OF COURSE, YOU ARE ALL ACCOUNTABLE TO
2 CALIFORNIA CONSTITUENCIES, AND THE TEMPTATION TO
3 INCLUDE A CALIFORNIA PREFERENCE MAY BE IRRESISTIBLE,
4 BUT IT'S PROBABLY UNWISE, AND YOU WANT TO BE SURE THAT
5 YOU DON'T MAKE IT TOO FIRM.

6 "MANDATORY PREFERENCES FOR LOCAL BUSINESSES
7 AND LICENSEES OF INVENTIONS EMERGING FROM STATE-FUNDED
8 RESEARCH THREATEN TO BRING ABOUT THE BALKANIZATION OF
9 INTELLECTUAL PROPERTY RIGHTS IN THE HANDS OF DIFFERENT
10 FIRMS IN DIFFERENT STATES. THIS MAY MAKE IT DIFFICULT
11 FOR FIRMS TO COLLECT THE RIGHTS THEY NEED TO MOVE
12 FORWARD TOWARDS PRODUCT DEVELOPMENT. THIS WORRY IS
13 PARTICULARLY ACUTE FOR BROAD, CROSS-CUTTING
14 TECHNOLOGIES LIKE STEM CELLS THAT MAY HAVE IMPLICATIONS
15 FOR A RANGE OF PROBLEMS. GEOGRAPHY SHOULD NOT BE THE
16 PRIMARY CRITERION FOR PICKING LICENSEES, AND IT MAY
17 PROVE TO BE A SIGNIFICANT CONSTRAINT. AS A PRACTICAL
18 MATTER, FIRMS WILL PROBABLY WANT TO LOCATE NEAR THE
19 STEM CELL SCIENTIST WHOSE WORK IS FUNDED BY THE CIRM.
20 YOU DON'T NEED TO TRY TO MAKE IT THE LAW. LET GRANTEES
21 FIND THE BEST LICENSEES TO GET THE TECHNOLOGY DEVELOPED
22 AND TRUST THAT CALIFORNIA WILL GET ITS SHARE OF THE
23 RESULTING WORK AND THAT CALIFORNIA RESIDENTS WILL
24 BENEFIT ALONG WITH THE REST OF THE COUNTRY IN THE
25 RESULTING THERAPIES."

1 CHAIRMAN PENHOET: THANK YOU, MELISSA,
2 STANDING IN FOR REBECCA EISENBERG, WHO'S CLEARLY VERY
3 ARTICULATE, BENEFITED FROM HER STANFORD UNDERGRADUATE
4 EDUCATION.

5 IT'S A LITTLE HARD FOR US TO ANSWER QUESTIONS
6 THAT WOULD HAVE BEEN ADDRESSED TO REBECCA, BUT I GUESS
7 WE'D BE HAPPY TO ALLOW YOUR COMMENTS.

8 MS. KING: ANY QUESTIONS YOU HAVE ABOUT THAT,
9 RIGHT HERE.

10 CHAIRMAN PENHOET: ANY COMMENTS ON WHAT WE
11 JUST HEARD? IT'S A VERY THOUGHTFUL PIECE. I HOPE THE
12 REST OF YOU AGREE TO THAT. THAT'S WHY WE WANTED IT
13 REPEATED AGAIN HERE TODAY. AND REBECCA IS ONE OF THE
14 COUNTRY'S FOREMOST PATENT PEOPLE.

15 MR. SHEEHY: I JUST ACTUALLY WANTED TO TRY TO
16 GET SOME UNDERSTANDING OF STATE-FUNDED RESEARCH AND
17 BAYH-DOLE AND THE CCST. SO PRESENTLY STATE-FUNDED
18 RESEARCH IS DONE UNDER A BAYH-DOLE FRAMEWORK?

19 DR. BRYANT: NO. AS I UNDERSTAND IT, EACH
20 INDIVIDUAL GRANT THAT COMES THROUGH THE STATE IS
21 INDIVIDUALLY NEGOTIATED PRETTY MUCH. SO THE IMPETUS
22 FOR HAVING CCST STUDY IT WAS TO GET SOME UNIFORM
23 ARRANGEMENT WHEREBY IP IN THE STATE COULD BE HANDLED.
24 RIGHT NOW IT'S A LOT OF MONEY SPENT ON NEGOTIATING WITH
25 THE AGENCY ABOUT HOW IT'S GOING TO HAPPEN.

1 CHAIRMAN PENHOET: IF I COULD, MY
2 UNDERSTANDING IS THERE'S A DIFFERENCE BETWEEN FOLLOWING
3 BAYH-DOLE AND BEING COMPATIBLE WITH BAYH-DOLE. I THINK
4 SEVERAL PEOPLE IN THE LAST MEETING EMPHASIZED THE
5 COMPATIBILITY ISSUE IS IMPORTANT BECAUSE \$1 OF FEDERAL
6 FUNDING IN A PROGRAM DEMANDS THAT YOU DON'T DO ANYTHING
7 WHICH IS COUNTER TO BAYH-DOLE, BUT YOU CAN ADD LOTS OF
8 OTHER THINGS TO A LICENSING PROGRAM WHICH ARE NOT
9 INCLUDED IN BAYH-DOLE AS LONG AS THEY'RE NOT
10 INCOMPATIBLE WITH BAYH-DOLE. THAT'S THE WAY I
11 UNDERSTAND IT. IS THAT WHAT YOU UNDERSTAND AS WELL?

12 MR. SHEEHY: JUST IN TERMS OF -- BUT THE CCST
13 REPORT ACTUALLY WAS AN INITIAL REPORT ON MUCH --
14 ACTUALLY THE CCST IS GOING TO DO A MUCH BROADER REPORT
15 THAT'S GOING TO CLEAN ALL THIS UP FOR THE STATE AS A
16 WHOLE, RIGHT?

17 DR. BRYANT: THE DRAFT OF THAT IS NOW OUT TO
18 THE COMMITTEE MEMBERS, AND IT'S VERY SIMILAR TO THE
19 INITIAL REPORT THAT WAS ISSUED ON THE STEM CELL.

20 MR. SHEEHY: THAT WOULD BE ADOPTED BY THE
21 LEGISLATURE AT SOME FUTURE POINT PRESUMABLY. IF WE
22 WERE TO PUT IN PLACE A WHOLE SEPARATE SET OF RULES, WE
23 COULD END UP WITH BURDENING UNIVERSITIES WITH ACTUALLY
24 THREE SEPARATE: CIRM-FUNDED RESEARCH, STATE-FUNDED
25 RESEARCH, AND FEDERAL-FUNDED RESEARCH. SO THE LOGIC TO

1 US TO SET UP SOMETHING IN ADVANCE OF THE STATE ACTUALLY
2 ADDRESSING THIS IS NOT CLEAR TO ME. AM I ALONE IN
3 NOT --

4 DR. BRYANT: I THINK THE CCST IS VERY
5 SIMILAR -- THE RECOMMENDATIONS ARE VERY COMPATIBLE WITH
6 BAYH-DOLE; SO IF WE'RE JUST TALKING ABOUT MAKING --
7 EITHER ADOPTING WHAT THEY SAY PLUS SOME SLIGHT
8 MODIFICATIONS, I DON'T THINK THAT WOULD BE A MAJOR
9 ISSUE. BUT I THINK IF WE'RE GOING TO REINVENT THE
10 WHEEL, IT WOULD BE.

11 MR. GOLDBERG: IT'S ALSO IMPORTANT TO POINT
12 OUT TWO ISSUES. ONE IS CCST IS JUST AN ADVISORY BODY
13 TO THE GOVERNOR AND THE LEGISLATURE, SO IT'S ENTIRELY
14 UP TO THE LEGISLATURE AND THE GOVERNOR TO DO WHATEVER
15 THEY WISH WITH THOSE RECOMMENDATIONS.

16 SECONDLY, WITH RESPECT TO TIMING, WE HAVE AN
17 OBLIGATION UNDER PROP 71 TO HAVE INTELLECTUAL PROPERTY
18 AGREEMENTS APPENDED TO OUR GRANTS. SO I'M NOT SURE,
19 UNLESS WE WOULD CHOOSE TO HOLD UP THE RESEARCH
20 APPARATUS, TO GET IN LINE WITH WHAT THE LEGISLATURE MAY
21 OR MAY NOT ELECT TO DO WITH THE CCST REPORT IS GOING TO
22 BE PROBLEMATIC.

23 MR. SHEEHY: NO. I WAS ACTUALLY ARGUING MORE
24 FROM A DIFFERENT POINT OF VIEW, THAT WE SHOULD GO WITH
25 SOMETHING THAT WOULD BE AT A MINIMUM COMPATIBLE. BUT

1 RATHER THAN -- WE'VE BEEN KIND OF -- WE'VE GOT THE
2 BULL'S-EYE ON US AS A FORM OF STATE-FUNDED RESEARCH
3 WITHOUT THIS UNDERLYING AWARENESS THAT THE STATE IS
4 GOING TO ADDRESS THIS IN A SYSTEMATIC WAY. I THINK WE
5 WOULD PROBABLY AS A GROUP, THE ICOC, HAVE A WILLINGNESS
6 TO DEFER TO THE STATE ONCE THE LEGISLATURE MAKES ITS
7 LARGER GLOBAL VIEW ON ALL STATE-FUNDED RESEARCH DOWN
8 THE ROAD. BUT FOR US TO PUT IN PLACE AN INTERIM
9 PROCESS WHERE THE DEMANDS ARE BEING PUT ON US TO PUT IN
10 SOMETHING VERY NOVEL AND UNIQUE TO ADDRESS A WHOLE LIST
11 OF CONCERNS THAT LEGISLATORS HAVE. AND I'VE EVEN HEARD
12 TALK THAT MAYBE LEGISLATION SPECIFICALLY INTRODUCED FOR
13 CIRM. IT SEEMS TO ME THE BURDEN SHOULD BE ON THEM TO
14 TAKE THE LARGER ISSUE ON, AND THEN WE CAN FOLD INTO
15 THAT AS OPPOSED TO THE OPPOSITE, STARTING WITH US. AND
16 THAT WAS THE POINT I WAS TRYING TO MAKE.

17 CHAIRMAN PENHOET: I GUESS THE POINT IS
18 UNFORTUNATELY TIMING. WE DON'T KNOW IF OR WHEN THE
19 STATE WILL GET AROUND TO ACTUALLY TURNING THE
20 RECOMMENDATIONS FROM CCST INTO SOME SORT OF LAWS THAT
21 PROBABLY WOULD BE AMENDED. AND IT'S REALLY HARD TO
22 KNOW WHEN THAT MIGHT OCCUR. AND WE HAVE TO START
23 GIVING GRANTS OUT HOPEFULLY EARLY NEXT YEAR.

24 DR. PRIETO: I WANT TO MAKE THE POINT I THINK
25 THE OTHER WAY TO LOOK AT THAT CONCERNING THIS, AS

1 MICHAEL SAID, THAT WE DO NEED TO HAVE INTELLECTUAL
2 PROPERTY POLICIES IN PLACE, IS THAT WE CAN CREATE A
3 MODEL FOR THE STATE. IF WE DO A GOOD JOB WITH THIS, I
4 THINK, THEN, WE WILL HAVE DONE THAT.

5 MR. KLAUSNER: ED, THIS IS RICK KLAUSNER.

6 CHAIRMAN PENHOET: THANK YOU, RICK. RICK
7 KLAUSNER HAS JOINED US. MAYBE WE'LL DEFER FURTHER
8 CONVERSATION ON THIS ISSUE TO ALLOW RICK TO MAKE A FEW
9 COMMENTS TO US. THANK YOU FOR JOINING US, RICK. RICK
10 KLAUSNER IS THE FORMER HEAD OF THE GLOBAL HEALTH
11 PROGRAMS AT THE GATES FOUNDATION IN SEATTLE. PRIOR TO
12 THAT, HE WAS THE DIRECTOR OF THE NATIONAL CANCER
13 INSTITUTES AT THE NIH. IN SEVERAL CONVERSATIONS IN THE
14 LAST SIX MONTHS OR SO, THERE HAS BEEN REFERENCE IN
15 CALIFORNIA TO THE IP POLICIES OF THE GATES FOUNDATION
16 AS THEY REFLECT ON LICENSEES OR GRANTEEES OF THE GATES
17 FOUNDATION FOR USE OF TECHNOLOGY IN THE THIRD WORLD,
18 BUT ALSO HOW THAT RELATES TO USE OF THOSE SAME
19 TECHNOLOGIES IN THE U. S. , WESTERN EUROPE, AND DEVELOPED
20 COUNTRIES. RICK HAS KINDLY AGREED TO GIVE US SOME
21 PERSPECTIVE ON HOW GATES VIEWS ITS THIRD WORLD
22 GRANTING -- THIRD WORLD IP POLICIES VERSUS ITS U. S.
23 POLICIES TO SIMPLIFY THE ISSUE. SO THANKS, RICK, FOR
24 GIVING US A LITTLE OF YOUR PERSPECTIVE ON THIS.

25 MR. KLAUSNER: SURE. SO I'M SITTING IN A

1 ROOM IN A HOTEL, AND I SEE THERE'S A LOT OF ACTION
2 HERE. I DID GET TO HEAR THE END OF BECKY'S, WHICH
3 WASN'T BECKY, I KNOW, BUT SOUNDED LIKE HER, AT LEAST
4 THE CONTENT, AND I THINK, AS ALWAYS WITH HER, THOSE
5 WERE REALLY USEFUL, I THOUGHT, RECOMMENDATIONS.

6 I JUST WOULD FROM DEALING A LOT, PARTICULARLY
7 AT THE CANCER INSTITUTE, WITH BAYH-DOLE, IT IS REALLY
8 IMPORTANT TO DISTINGUISH, AND THEN I'LL GET TO THE
9 GATES FOUNDATION, WHAT BAYH-DOLE CONSTRAINS YOU TO
10 VERSUS HOW IT'S PRACTICED. I THINK IT'S COME TO BE
11 PRACTICED IN, I'LL JUST SAY, IN A STRANGE WAY THAT I
12 THINK IN MANY WAYS DOES GET IN THE WAY OF BOTH THE BEST
13 USE OF PATENT LAW AND THE VALUE OF PATENTING AND ALSO
14 LARGER INSTITUTIONAL/SOCIETAL GOALS THAT I DON'T THINK
15 BAYH-DOLE WAS EVER MEANT TO GET IN THE WAY OF.

16 SO I THINK BECKY'S POINTS ABOUT THE DEC, THE
17 DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES, ETC., ETC.,
18 YOU KNOW, YOU CAN BE COMPATIBLE WITH BAYH-DOLE, BUT
19 CREATE A SET OF POLICIES ABOUT HOW PATENTS AND LICENSES
20 AND RIGHTS ARE ASSIGNED AND USED THAT DON'T VIOLATE
21 BAYH-DOLE, DON'T NEED YOU TO REVISIT BAYH-DOLE, BUT CAN
22 REFLECT A WHOLE VARIETY OF VALUES THAT THE FUNDING
23 PROGRAM OR IN THIS CASE THE STATE OF CALIFORNIA HAS.
24 AND THAT'S VERY CONSISTENT WITH THE SITUATION THAT I
25 FOUND WHEN I CAME TO GATES FOUNDATION. WE HAD NO IP

1 POLICY AT ALL WHEN I GOT HERE, AND WE DEVELOPED -- AND
2 AGAIN, WHEN YOU DON'T, AND THAT'S THE POINT, NOT HAVING
3 AN IP POLICY IS A RECIPE FOR DISASTER BECAUSE YOU WILL
4 CREATE OR ALLOW TO BE CREATED SUCH A THICKET OF
5 POSITIONS THAT ARISE ON INTELLECTUAL PROPERTY CREATED
6 FROM GRANT FUNDING AND ALSO WITH NO ONE AT FAULT. NO
7 BAD INTENTION. IT'S JUST ENDLESS INTERPRETATIONS,
8 APPROACHES, AND OFTEN LACK OF KNOWLEDGE ABOUT THE
9 IMPLICATIONS OF PATENTS OR LICENSING AGREEMENTS
10 PARTICULARLY ON BEHALF OF GRANTEES AND UNIVERSITIES.

11 SO WE DEVELOPED SOMETHING THAT WE CALLED A
12 GLOBAL ACCESS PLAN. AND AGAIN, IT WAS MEANT TO
13 ARTICULATE, FIRST AND FOREMOST, WHAT OUR CHARITABLE
14 PURPOSE WAS ABOUT -- IS ABOUT IS AT THE GATES
15 FOUNDATION. AND THE CHARITABLE PURPOSE OF THE DOLLARS
16 IN THE GATES FOUNDATION HAD NO POSITION ONE WAY OR
17 ANOTHER ON PATENTS. IS IT GOOD? IS IT BAD? DO YOU
18 WANT IT? DO YOU NOT WANT IT? BUT VERY MUCH HAD A
19 POSITION THAT HOWEVER INTELLECTUAL PROPERTY WOULD BE
20 USED, YOU WANTED TO ASK THE GRANTEES TO ADDRESS HOW
21 THEY WOULD USE ALL OF THE TOOLS OF INTELLECTUAL
22 PROPERTY IN ORDER TO DO TWO THINGS. ONE, NOT TO
23 PROHIBIT ACHIEVING YOUR CHARITABLE PURPOSE, IN THIS
24 CASE THE GATES FOUNDATION FUNDING THE CREATION OF
25 KNOWLEDGE, TOOLS, TECHNOLOGIES THAT WOULD BENEFIT THE

1 DEVELOPING WORLD.

2 AND SO WE DEVELOPED A SET OF GUIDELINES AND
3 POLICIES AND ASKED GRANTEES, BEFORE THEY WOULD GET
4 THEIR FUNDING, AND IT WOULD SLOW THINGS DOWN, BUT IT'S
5 BEEN INCREDIBLY USEFUL, TO THINK ABOUT THE IMPLICATIONS
6 OF ANY IP ACTION, PATENT ACTION, ETC., THAT THEY WOULD
7 TAKE. AND THE FIRST THING WAS A SORT OF PHYSICIANS DO
8 NO HARM, AND THAT IS THINK ABOUT, BEFORE YOU DO
9 SOMETHING THAT WOULD DRAMATICALLY CONSTRAIN ACCESS,
10 USE, OR LICENSE OF INTELLECTUAL PROPERTY, THAT YOU
11 DIDN'T WANT -- YOU WANTED TO BE SURE THAT THE RESULTS
12 OF THOSE DECISIONS WOULD NOT PROHIBIT WHAT WOULD BE
13 REQUIRED FOR THE FRUITS OF THE RESEARCH TO REACH THE
14 DEVELOPING WORLD.

15 AND SO, FOR EXAMPLE, JUST TO BE VERY CLEAR,
16 YOU WOULD REALLY NOT BE HAPPY WITH GIVING A GRANT TO
17 SOMEONE WHO WAS WILLING TO GIVE AN EXCLUSIVE LICENSE
18 WITHOUT THAT LICENSE SAYING THAT IF THE LICENSEE CHOSE
19 NOT TO PURSUE MARKETS IN THE DEVELOPING WORLD, THEN
20 THAT'S NOT A GLOBAL ACCESS PLAN. AND SO YOU WOULD WANT
21 TO MAKE SURE THAT THERE WERE -- THERE EITHER WAS A
22 NONEXCLUSIVE LICENSE, THERE WOULD BE RESIDUAL RIGHTS
23 COMING BACK TO THE FOUNDATION, OR SOME GUARANTEE THAT
24 NO DEALING WITH INTELLECTUAL PROPERTY PROHIBITED
25 ULTIMATE ACCESS TO THE DEVELOPING WORLD. AND THE

1 ACCESS WOULD BE, YOU KNOW, AT THE LEVEL OF HOW AND
2 WHERE IT WOULD BE MANUFACTURED, THE PRICE, ETC., AND
3 THE APPROPRIATENESS OF THE PRODUCT FOR THE PATIENTS WHO
4 WE CARED ABOUT.

5 THEN THERE WERE POSITIVE ISSUES. THAT WAS
6 THE NEGATIVE. DO NO HARM. AGAIN, I'M SAYING THIS
7 WITHOUT GIVING YOU THE DETAILS ABOUT HOW WE REALLY GAVE
8 GUIDANCE. AND I'M HAPPY -- I'M NOT AT THE FOUNDATION
9 ANYMORE, ALTHOUGH I STILL ADVISE THEM. I KNOW FOR A
10 FACT THE FOUNDATION WOULD BE EXTREMELY HAPPY TO PROVIDE
11 ALL OF THIS DOCUMENTATION TO YOU.

12 THEN THERE WERE THE POSITIVES. WE ASKED FOR
13 A POSITIVE GLOBAL ACCESS PLAN, AND THAT WOULD BE WHAT
14 THE GRANTEE WAS PROPOSING TO DO SO THAT THEY ACTUALLY
15 THOUGHT THROUGH WHAT TO PUT IN PLACE TO MAKE IT MOST
16 LIKELY THAT THE FRUITS OF THEIR WORK WOULD BE
17 ACCESSIBLE TO THE DEVELOPING WORLD. AND THAT TOTALLY
18 DEPENDS UPON THE STAGE OF THE RESEARCH. IS IT
19 KNOWLEDGE GENERATION? IS IT A SPECIFIC PRODUCT? AND
20 IT VARIES TREMENDOUSLY. FOR KNOWLEDGE GENERATION, WE
21 DEMAND THAT THE, LIKE NIH, THAT THE INFORMATION BE
22 WIDELY ACCESSIBLE. AND, IN FACT, WE REALLY ENCOURAGED
23 IN MANY OF THE PROGRAMS THAT THE INFORMATION BE
24 ACCESSIBLE TO PEOPLE IN THE DEVELOPING WORLD, WHICH
25 REQUIRED SOMETHING LIKE BEING IN OPEN-ACCESS JOURNALS

1 THAT INDIVIDUALS NOT HAVE TO PAY FOR.

2 AND IF IT WAS A PRODUCT, LIKE A VACCINE OR
3 POTENTIAL DRUG OR POTENTIAL VACCINE OR POTENTIAL
4 DIAGNOSTIC, WE WOULD ASK WHAT ARE YOU DOING? WHAT WILL
5 YOU BE DOING TO ASSURE SUPPLY AND PRICE AND ACCESS TO
6 THE DEVELOPING WORLD? AND NOW WE HAVE LOTS OF EXAMPLES
7 OF, QUOTE, GLOBAL ACCESS PLANS THAT HAVE EMERGED IN
8 RESPONSE TO THIS.

9 WE ALWAYS DID SAY THAT THERE WOULD BE
10 RESIDUAL RIGHTS; THAT IF THERE WAS NO ATTEMPT TO
11 ASSURE, AND IT'S VERY MUCH LIKE THE MARCH-IN RIGHTS OF
12 THE GOVERNMENT, IF THERE WAS NOTHING DONE TO ALLOW OR
13 ENSURE ACCESS TO THE TARGET OF OUR CHARITABLE PURPOSE,
14 THEN THERE WOULD BE A REMEDIATION FOR THAT, SUCH AS THE
15 RIGHTS WOULD RETURN TO FOR THE GOVERNMENT, THE
16 GOVERNMENT; FOR THE GATES FOUNDATION, THE GATES
17 FOUNDATION.

18 THE REAL ISSUE HERE TO ME IS HOW IMPORTANT IT
19 IS TO BE CLEAR ABOUT THE GOALS THAT THE FUNDING ENTITY,
20 THE STEM CELL INITIATIVE HAS FOR THE USE OF IP TO, I
21 THINK PERSONALLY, NOT GET INTO -- AND WE DIDN'T IN THE
22 GATES FOUNDATION -- ANY IDEA THAT IP WAS BAD, THAT YOU
23 DIDN'T WANT IT. IN FACT, JUST THE OPPOSITE. IT'S
24 REALLY HOW IT'S USED. HAVING GUIDELINES ABOUT WHETHER
25 AND WHAT TO PATENT AND NOT TO PATENT, BUT MUCH MORE

1 IMPORTANT THAN WHETHER TO PATENT, HOW YOU CONSTRUCT THE
2 PATENT IN ORDER, AGAIN, NOT TO INTERFERE WITH THE
3 ULTIMATE CHARITABLE PURPOSE, WHICH THE STEM CELL
4 INITIATIVE OUGHT TO BE ABLE TO DETERMINE.

5 THERE' S ISSUES ABOUT WHAT CONTROLS OR
6 CRITERIA YOU PUT ON PATENTS AND LICENSES. THERE' S THE
7 ISSUE OF RESIDUAL RIGHTS, AND THERE' S LOTS OF OTHER,
8 QUOTE, IP ISSUES, LIKE THINGS THAT YOU ACTUALLY FEEL
9 SHOULD NOT BE PATENTED OR JUST WOULD NOT BE PATENTED,
10 BUT YOU WANT TO MAKE SURE ARE AVAIL ABLE TO THE
11 COMMUNI TY, SUCH AS PUBLI CATION RULES, DATA SHARI NG
12 RULES, AND POTENTIALLY EVEN RULES OF THINGS THAT YOU
13 DON' T WANT GENE SEQUENCES PATENTED. I THINK IT' S
14 PERFECTLY -- WE FELT IT WAS PERFECTLY REASONABLE TO
15 HAVE VIEWPOINTS ON THAT.

16 WE LOOKED AT THE QUESTION OF WHETHER THERE
17 SHOULD BE RECOUPING FUNDS AND ROYALTIES COMING BACK TO
18 THE FOUNDATION AND DECIDED THAT THAT WAS NOT A GOOD
19 IDEA. AND THERE ARE A LOT OF OTHER ISSUES THAT WE
20 DEALT WITH THAT VERY INTERESTINGLY OVERLAP WHAT BECKY
21 EISENBERG' S PAPER SAID.

22 LET ME JUST STOP THERE AND SAY THAT, AGAIN, A
23 LOT OF THIS IS NOT THE FANTASY THAT THERE' S SOME
24 INCREDI BLE SECRET GOLD TO BE GOTTEN BY DOING DRAMATIC
25 THINGS WITH INTELLECTUAL PROPERTY, BUT REALIZI NG THAT

1 WITHIN, I THINK, EVEN CURRENT FRAMEWORKS OF BAYH-DOLE,
2 ETC., THAT AN ENORMOUS AMOUNT IS ACHIEVED BY POLICY,
3 GUIDANCE, CLARITY OFTEN TO A COMMUNITY THAT DOESN'T
4 THINK ABOUT THIS MUCH. DOESN'T THINK ABOUT IT.
5 DOESN'T THINK ABOUT THE IMPLICATIONS. AND AGAIN, TO BE
6 HONEST, OFTEN -- I FELT WHEN I WAS DIRECTOR OF NCI, THE
7 MOST PROBLEMATIC ASPECT OF DEALING WITH IP WAS NOT
8 INDUSTRY, BUT WAS THE ACADEMIC COMMUNITY THAT MADE
9 ACCESS, PARTICULARLY TO RESEARCH TOOLS, OFTEN VERY,
10 VERY DIFFICULT.

11 THE ONE LAST THING I WOULD SAY IS THAT THING
12 ABOUT RESEARCH TOOLS OR RESEARCH EXEMPTIONS, WHICH
13 DON'T REALLY EXIST, AS FAR AS I KNOW, IN TERMS OF
14 CURRENT LEGAL STANDING, I'M SURE OTHERS CAN CORRECT ME,
15 BUT THAT DOESN'T MEAN THE FUNDER, THE STEM CELL
16 INITIATIVE, COULDN'T HAVE A VIEWPOINT AND A POLICY
17 AROUND WHAT'S EFFECTIVELY A RESEARCH EXEMPTION. AND
18 THAT IS THAT, ESPECIALLY FOR PLATFORM AND ENABLING
19 TECHNOLOGIES, THERE OUGHT TO BE CONDITIONS OR ONE MIGHT
20 POSIT THAT THERE OUGHT TO BE CONDITIONS UNDER WHICH
21 RESEARCHERS ARE NOT PROHIBITED FROM ACCESS FOR
22 FURTHERING THEIR RESEARCH AS OPPOSED TO ACCESS TO A
23 THING THAT YOU CAN EASILY PATENT AND CONTROL.

24 SO I DON'T KNOW IF THAT'S HELPFUL, BUT I
25 THINK THERE'S A LOT OF EMERGING DISCUSSION, A LOT OF

1 WHICH WE'VE BEEN DEALING WITH IN GLOBAL HEALTH ABOUT
2 HOW TO CREATE GUIDELINES TO ACHIEVE SOCIETAL GOALS,
3 WHICH CLEARLY ARE MOTIVATING THE STEM CELL INITIATIVE,
4 THAT ACTUALLY CAN BE ACHIEVED WITHOUT VERY DRAMATIC OR
5 LITIGIOUS OR ANTICOMPETITIVE OR IN SOME SENSE
6 SELF-DEFEATING RADICAL APPROACHES TO EITHER BAYH-DOLE
7 OR PATENT LAW OR THE ABILITY TO PATENT.

8 CHAIRMAN PENHOET: GREAT. THANK YOU VERY
9 MUCH, RICK. WE HAVE A PANEL HERE. I'M SURE SOME OF
10 THEM MIGHT HAVE SOME QUESTIONS FOR YOU. TED, YOU HAVE
11 A QUESTION?

12 DR. LOVE: JUST MAYBE ONE THING TO ASK YOU TO
13 ELABORATE ON, RICK, WAS OBVIOUSLY THE ASSUMPTION HERE
14 IS THAT THE GATES FOUNDATION HAS A LOT OF MONEY FROM A
15 SINGLE PERSON, BUT ALSO IT'S DOING SOMETHING, SO
16 REPLENISHING THAT SOURCE OF MONEY, AT LEAST
17 CONCEPTUALLY, IS NOT A TERRIBLE THING. I JUST WANT TO
18 ASK GIVEN THAT BACKGROUND, WHY WAS THE DECISION MADE TO
19 NOT THINK ABOUT APPLYING ROYALTIES THAT WOULD COME BACK
20 AND FURTHER REPLENISH THE FOUNDATION?

21 MR. KLAUSNER: I THINK THERE WERE TWO ASPECTS
22 TO IT. ONE WAS JUST THE PERCEPTION AND THE PUBLIC
23 PERCEPTION. HERE YOU HAVE THE LARGEST FOUNDATION IN
24 THE WORLD, AND I THINK THERE'S THE PUBLIC PERCEPTION
25 THAT WE WERE MAYBE IN THIS FOR, QUOTE, MAKING MONEY,

1 EVEN THOUGH IT WOULD GO RIGHT BACK TO THE CHARITABLE
2 PURPOSE, WAS PROBLEMATIC GIVEN A LIVING DONOR,
3 BENEFACTOR, ETC. I THINK THERE WAS THAT.

4 IN FACT, WE ALSO LOOKED AT IT FROM THE
5 VIEWPOINT OF WAS IT WORTH IT AND CAME TO THE CONCLUSION
6 THAT MANAGING THESE SORTS OF ROYALTIES BACK TO THE
7 FOUNDATION WOULD GET US INVOLVED IN A LEVEL OF
8 NEGOTIATION THAT WOULD JUST BE ONE MORE DIFFICULT
9 BARRIER TO GETTING WORK DONE. AND WE BASICALLY JUST
10 DECIDED THAT THE PROPOSITION WASN'T WORTH IT FOR
11 GETTING THE WORK DONE AND FOR WHAT WE PREDICTED THE
12 FINANCIAL RETURN WOULD BE.

13 CHAIRMAN PENHOET: ANY OTHER QUESTIONS?
14 THANK YOU. THANKS A LOT FOR TAKING TIME OUT OF YOUR
15 BUSY SCHEDULE. ARE THERE ANY QUESTIONS FOR RICK FROM
16 THE GROUP IN LOS ANGELES?

17 DR. FONTANA: THANK YOU FOR PRESENTING SUCH A
18 WONDERFUL PERSPECTIVE.

19 MR. KLAUSNER: AGAIN, AS I TOLD YOU, WE'RE
20 HAPPY -- THE GATES FOUNDATION, I'M SURE, IS HAPPY TO
21 PROVIDE ANY FURTHER INFORMATION OF REAL DOCUMENTATION
22 ABOUT HOW THIS IS WORKING.

23 CHAIRMAN PENHOET: OKAY. THEN FINALLY, RICK,
24 WHEN YOU DID MAKE GRANTS TO DEVELOP POTENTIAL PRODUCTS
25 THAT HAD USES IN THE THIRD WORLD, WHICH IS YOUR PRIMARY

1 OBJECTIVE IN THE GATES FOUNDATION, BUT THEY ALSO WOULD
2 HAVE USE IN THE DEVELOPED WORLD, WHAT WAS YOUR POLICY
3 ON PRICING, ETC., IN THE DEVELOPED WORLD?

4 MR. KLAUSNER: RIGHT. SO WE HAD NO POLICY ON
5 IT. BASICALLY THAT WOULD BE DRIVEN BY THE MARKET. AND
6 WE WERE VERY, VERY SUPPORTIVE OF TIERED PRICING, AND
7 THAT COULD BE LOW PRICE, PRICE OF COST. WE'VE DONE A
8 LOT OF INDIVIDUAL NEGOTIATIONS WITH COMPANIES NOW ABOUT
9 THAT, ABOUT THE NATURE OF TIER PRICING. BUT BASICALLY
10 FROM THE GATES FOUNDATION PERSPECTIVE, WE DIDN'T TAKE A
11 POSITION ON THE PRICING LEVEL FOR WHAT AT THE GATES
12 FOUNDATION WE CALLED THE RICH WORLD AND THOUGHT THAT
13 THAT -- IF THAT DEFRAIDED THE ABILITY OF COMPANIES TO
14 THEN PROVIDE EITHER IN COST OR SOMETIMES EVEN FOR FREE
15 A TIERED PRICING FOR THE DEVELOPING WORLD, THAT WE WERE
16 HAPPY WITH THAT.

17 I WILL SAY THAT THERE'S PRECEDENT FOR THAT IN
18 BOTH THE PHARMACEUTICAL INDUSTRY AND, I THINK -- I
19 NEGOTIATED, JUST AS I WAS LEAVING THE NCI, FOR A
20 MICROBICIDE, A POTENTIAL MICROBICIDE, WHICH WAS THE
21 U.S. GOVERNMENT, AND THAT IS DEALING WITH WHAT WAS SORT
22 OF AN ACCESS POLICY FOR PRICING THAT WAS NOT AT THE
23 DEVELOPING WORLD, BUT WAS DOING AT IT INDIVIDUALS WHO
24 WERE IN POVERTY OR INDIVIDUALS WHO COULDN'T AFFORD IT.
25 SO I THINK YOU CAN ACTUALLY IMAGINE THAT IN A DOMESTIC

1 MARKET. I CAN'T IMAGINE DOING IT BY GEOGRAPHY. I
2 CAN'T IMAGINE YOU SEPARATING OUT CALIFORNIA FROM THE
3 REST OF THE UNITED STATES FOR ALL SORTS OF REASONS,
4 SUCH AS THE FEDERAL PROCUREMENT AND LOTS OF THINGS. I
5 DON'T THINK IT WOULD REALLY HELP, BUT WE DEALT A LOT
6 WITH PRICE TIERING.

7 CHAIRMAN PENHOET: OKAY. THANK YOU VERY
8 MUCH.

9 MR. KLAUSNER: OKAY. THANK YOU. SORRY I WAS
10 ONLY ABLE TO PARTICIPATE FOR A FEW MINUTES.

11 CHAIRMAN PENHOET: IT WAS VERY HELPFUL.
12 THANK YOU.

13 MR. KLAUSNER: BYE-BYE.

14 CHAIRMAN PENHOET: THAT IS THE END OF OUR
15 PRESENTATIONS. BEFORE WE GET INTO THE PROCESS OF
16 ACTUALLY TRYING TO DEVELOP SOME PRINCIPLES AT LEAST
17 UPON OUR POLICIES WILL BE BASED, LET ME ASK IF THERE
18 ARE ANY COMMENTS FROM THE PUBLIC AT THIS POINT IN
19 STANFORD, CALIFORNIA? NONE. HOW ABOUT FROM LOS
20 ANGELES?

21 DR. FONTANA: NO.

22 CHAIRMAN PENHOET: THEN WE'LL MOVE ALONG TO
23 TRY TO PROVIDE ANSWERS TO SOME OF THE QUESTIONS THAT WE
24 POSED HERE TO DEVELOP THESE PRINCIPLES.

25 WE DO HAVE SOME BOXED LUNCHES AVAILABLE FOR

1 THE PANELISTS AND FOR SPEAKERS. WE NEED A BIO BREAK,
2 SO WHY DON'T WE RECONVENE IN TEN MINUTES.

3 (A RECESS WAS TAKEN.)

4 CHAIRMAN PENHOET: WELL, THE FIVE QUESTIONS
5 ARE IN FRONT OF YOU PRINTED OUT. AND I PRINTED THEM
6 OUT WITH BLANK SPACES SO YOU COULD EACH TAKE NOTES AND
7 THINK THROUGH THIS AS WE GO FORWARD. YOU KNOW, THE
8 FIRST QUESTION SEEMS SO OBVIOUS TO ME, THAT PROBABLY I
9 SHOULDN'T LEAD THE DISCUSSION, BUT DOES ANYBODY HAVE A
10 POINT OF VIEW DIFFERENT THAN THE GRANTEES SHOULD OWN
11 THE INTELLECTUAL PROPERTY?

12 AMONG OTHER THINGS, THE CIRM COULD OWN IT,
13 BUT WE DON'T HAVE THE FINANCIAL RESOURCES TO MANAGE IT
14 EVEN IF WE OWNED IT. IT WOULD REQUIRE A HUGE
15 ORGANIZATION.

16 DR. LOVE: AND DUPLICATION OF AN ADMIN
17 STRUCTURE.

18 CHAIRMAN PENHOET: IT WOULDN'T BE COMPATIBLE
19 WITH BAYH-DOLE. IT WOULD FORCE THE SEPARATION OF THE
20 SCIENTISTS FROM ONE ANOTHER WHO ARE WORKING ON CIRM
21 STUFF FROM OTHER SCIENTISTS. SO IT LOOKS TO ME LIKE,
22 BESIDES THE FACT THERE WERE A FEW ARGUMENTS MADE BY
23 PEOPLE AT VARIOUS TIMES IN THE LAST SIX MONTHS THAT WE
24 OUGHT TO LOOK AT OWNING THE TECHNOLOGY OR THE STATE
25 SHOULD OWN, ETC., I HAVEN'T SEEN A CREDIBLE ARGUMENT, A

1 WORKABLE ARGUMENT, I'LL PUT IT THAT WAY, NOT CREDIBLE,
2 BUT NOT WORKABLE. SO ARE WE ALL IN AGREEMENT THAT
3 GRANTEE INSTITUTIONS SHOULD OWN THE INTELLECTUAL
4 PROPERTY?

5 DR. PRIETO: WHAT ABOUT -- WE TALKED A LITTLE
6 BIT ABOUT THIS. WHAT IF IT'S NOT AN INSTITUTION? I
7 THINK THE ANSWER IS THE SAME, BUT WE'RE GOING TO FUND
8 SOME PRIVATE ENTITIES. AND DOES IT RAISE ANY OTHER
9 QUESTIONS?

10 CHAIRMAN PENHOET: PROBABLY NOT. THE NIH
11 TODAY GIVES GRANTS TO COMPANIES, FOR EXAMPLE, UNDER
12 SEVERAL SBIR PROGRAMS, ETC., AND IT FOLLOWS BASICALLY
13 THE SAME METHODOLOGY. WE WILL HAVE TO NEGOTIATE,
14 HOWEVER, OURSELVES WHEN WE MAKE A GRANT TO A PRIVATE
15 INSTITUTION, THEN CIRM ACTUALLY WILL HAVE TO ENGAGE
16 THAT PRIVATE INSTITUTION IN THE LICENSING ACTIVITIES
17 ITSELF. SO IT WOULD BE DIFFERENT IN THAT SENSE,
18 FRANCISCO; BUT I THINK WITH RESPECT TO THIS SPECIFIC
19 QUESTION, THAT THAT WOULD BE THE CASE.

20 ARE YOU AROUND IN LOS ANGELES?

21 DR. FONTANA: WE ARE.

22 CHAIRMAN PENHOET: THEN I GUESS WE SHOULD
23 TAKE A VOTE ON HOW DO WE -- HOW DO WE DO THIS?

24 MR. HARRISON: YOU NEED TO DO IT AS A ROLL
25 CALL VOTE, SO YOU HAVE A TELEPHONE.

1 CHAIRMAN PENHOET: WHAT WE ARE MAKING TODAY
2 IS NOT POLICY. IT IS SIMPLY FORMULATING A
3 RECOMMENDATION TO THE ICOC. AND I THINK IT'S EASIER IF
4 WE PARSE THIS OUT INTO PIECES RATHER THAN TRYING TO DO
5 IT GLOBALLY. AT THE MOMENT --

6 MR. SHEEHY: RATHER THAN GOING ON EACH
7 INDIVIDUAL PIECE, UNLESS -- I THINK WE'RE IN GENERAL
8 AGREEMENT, BUT IF THERE'S -- DEPENDING ON WHAT WE DO
9 WITH MARCH-IN RIGHTS AND ANY KIND OF RETAINED LICENSING
10 RIGHTS, YOU KNOW, COULD AFFECT WHETHER OR NOT WE OWN
11 INVENTIONS. I WOULD BE FINE TO GIVE UP OWNING THE
12 INVENTIONS DEPENDENT ON WHAT WE DECIDE ON SOME OF THE
13 OTHER ISSUES. BUT DOES THAT MAKE SENSE? IN GENERAL, I
14 GET THE PRINCIPLE. IN GENERAL I'M IN AGREEMENT
15 PERSONALLY.

16 CHAIRMAN PENHOET: WELL, WE DON'T HAVE TO
17 TAKE A VOTE. WE CAN GO ALONG.

18 DR. PIZZO: SO YOU'D LIKE TO GO THROUGH THEM
19 AND THEN COME BACK AND VOTE THEM TOGETHER?

20 MR. SHEEHY: IT SEEMED LIKE THESE ALL EXIST
21 IN RELATIONSHIP TO EACH OTHER.

22 DR. PIZZO: MAYBE I THINK YOUR SUGGESTION,
23 JEFF, IS A GOOD ONE BECAUSE WE MIGHT FIND OURSELVES
24 GETTING BOUND BY ONE THING AND THEN HAVING TO GO BACK.
25 MAYBE WHAT WE COULD DO AS AN ALTERNATIVE, IF THIS IS

1 PERMISSIBLE, IS TO TAKE A STRAW VOTE. COULD WE AT
2 LEAST GET A SENSE OF THE GROUP AS TO WHETHER WE AGREE
3 AND THEN JUST ROLL ON THAT WAY?

4 CHAIRMAN PENHOET: IS IT THE SENSE OF THE
5 GROUP, THAT GIVEN ALL WE'VE HEARD AND READ, THAT IT
6 MAKES SENSE TO HAVE THE GRANTEE INSTITUTIONS OWN THEIR
7 OWN IP? THAT'S THE SENSE OF THE GROUP.

8 AND TO SOME DEGREE, THE FIRST -- MANY OF THE
9 DISCUSSIONS OF THE OTHER THINGS WILL BE DEPENDENT ON
10 THAT THING, AS YOU CORRECTLY POINT OUT.

11 SO THE SECOND ISSUE IS HOW SHALL CIRM REQUIRE
12 THE SHARING OF DATA, BIOMEDICAL MATERIALS, AND
13 TECHNOLOGY? I THINK THIS THEME HAS BEEN REPEATED IN
14 SEVERAL OF THE PRESENTATIONS WE HAVE HEARD. NRC REPORT
15 URGES THE SCIENTIFIC COMMUNITY TO MOVE IN THIS
16 DIRECTION OF MORE SHARING, ETC. THE COMMENTS THAT
17 BECKY EISENBERG, HER PRINCIPAL CONCERN ABOUT THE
18 APPLICATION OF BAYH-DOLE WAS ITS EFFECT ON BASIC
19 RESEARCH.

20 SO I PERSONALLY HAVE HEARD A LOT OF
21 THOUGHTFUL COMMENT THAT SAYS THAT WE SHOULD PUSH THIS
22 IN THE DIRECTION OF REQUIRING A PRETTY HIGH DEGREE OF
23 SHARING AND TRANSPARENCY. THE QUESTION IS AMONG WHOM?
24 AMONG OUR GRANTEES, FORCING THEM TO SHARE WITH PEOPLE
25 WHO AREN'T OUR GRANTEES, ETC. HOW WOULD WE ARTICULATE

1 THAT?

2 MAYBE SOME OF OUR COLLEAGUES FROM THE
3 UNIVERSITY WORLD COULD START.

4 DR. BRYANT: I THINK A MINIMUM SHOULD BE --
5 CIRM GRANTEES WOULD BE THE MINIMUM, BUT --

6 CHAIRMAN PENHOET: SHARING AMONG THEMSELVES.

7 DR. BRYANT: RIGHT.

8 DR. PIZZO: WHAT ABOUT WITHIN THEIR GROUPS,
9 WITHIN THEIR UNIVERSITIES?

10 DR. BRYANT: YEAH. I MEAN ACTUALLY IF WE
11 REALLY WANT STEM CELL RESEARCH TO MOVE AHEAD, I THINK
12 WE SHOULD MAKE IT MORE OPEN TO RESEARCH IN GENERAL.

13 DR. PIZZO: RIGHT. BECAUSE THE DANGER WOULD
14 BE IF YOU JUST SAID THE GRANTEES, THEN YOU RUN THE RISK
15 OF HAVING WHAT WE'VE ALL SEEN HAPPEN BEFORE, WHICH IS
16 THE GRANTEE LIVES IN A MICROCOSM, AND THEN THEY FEEL
17 THAT THEY CAN'T SHARE WITH THEIR NEIGHBORS WHO MAY
18 ACTUALLY HAVE SOMETHING TO CONTRIBUTE OR BENEFIT FROM.
19 SO IF YOU START TO EXTRAPOLATE THAT, THEN WE'RE
20 EMBRACING OUR SORT OF UNIVERSITIES AND ALL THE FUNDED
21 COMPONENTS WITHIN CALIFORNIA. THAT'S THE LOGICAL
22 EXTENSION OF THAT. AND I DON'T KNOW WHETHER THAT'S THE
23 RIGHT BOUNDARY TO MOVE TO.

24 MR. GOLDBERG: I WOULD THINK THE QUESTION IS
25 WHAT DO WE DO ABOUT INDUSTRY BECAUSE ACADEMIA, I THINK,

1 IS A RELATIVELY EASY ONE.

2 DR. PIZZO: RIGHT. YOU TURNED TO US ABOUT
3 THAT, SO NOW DO YOU WANT TO DO THE --

4 DR. BRYANT: BEFORE WE FINISH THAT, THOUGH,
5 ARE WE GOING TO MAKE THE CALIFORNIA BORDER TO BORDER,
6 OR ARE WE GO TO SAY NATIONALLY?

7 DR. PIZZO: EXACTLY. I'M PUSHING THIS TO BE
8 A LITTLE BIT RHETORICAL BECAUSE I WAS GOING TO GO
9 THERE. AND THEN SO FOR IT BEING IN ACADEMIA AND WE'RE
10 BEING ENCOURAGED TO BE OPEN-MINDED, DO WE DRAW THE
11 LINES AROUND HERE AND, WHAT'S THE NEXT CLOSEST PLACE,
12 OREGON, AND KOREA? THAT'S RIGHT. KOREA WILL BE THE
13 NEXT CLOSEST BORDER.

14 CHAIRMAN PENHOET: I THINK THIS IS ONE OF THE
15 FEW AREAS WHERE WE HAVE A REAL OPPORTUNITY TO SORT OF
16 GET IN FRONT OF NATIONAL POLICY.

17 MR. SHEEHY: DOES IT ENHANCE OUR BARGAINING
18 POSITION WITH OTHER -- LIKE WARF AND OTHER FOLKS, WHO
19 SEEM TO BE ACCUMULATING MASSES OF PATENTS, TO HAVE SOME
20 SORT OF WALL AROUND OUR PATENTS?

21 MR. GOLDBERG: THIS IS PRE THAT. I THINK
22 WE'RE UPSTREAM IN THIS CONVERSATION. IN THIS
23 CONVERSATION I THINK WE'RE UPSTREAM FROM THAT. YOUR
24 POINT IS WELL TAKEN, JEFF.

25 DR. BRYANT: SO WHAT WOULD BE THE ARGUMENT

1 AGAINST OPENING IT UP TO RESEARCH ANYWHERE?

2 MR. GOLDBERG: WELL, LET ME SUGGEST THIS AS
3 ONE WAY TO DEAL WITH IT. WE COULD MAKE IT AN
4 AFFIRMATIVE OBLIGATION TO SHARE WITHIN CALIFORNIA AND A
5 DISCRETIONARY ISSUE WHETHER -- IT'S UP TO THE
6 INVESTIGATORS.

7 DR. PRIETO: AT THE DISCRETION OF
8 INVESTIGATORS?

9 MR. GOLDBERG: YEAH. OUTSIDE CALIFORNIA.

10 DR. PIZZO: IS THAT A MODEL THAT WE WANT TO
11 BE EXTRAPOLATED TO OTHER PLACES? LET'S TAKE ANOTHER
12 PLACE WHERE WE MIGHT HAVE DIFFERENCES OF OPINION LIKE
13 WISCONSIN WHERE THEY'VE GOT SOME FIRM OPINIONS ABOUT
14 HOW THEY'RE GOING TO HANDLE IP. DO WE WANT EVERY STATE
15 TO HAVE ITS DISCRETION ABOUT WITH WHOM IT COMMUNICATES?
16 THEN WE CAN HAVE A LOT OF COMPARTMENTALIZATION ACROSS
17 THE COUNTRY. WHATEVER WE SET UP, I THINK ONE OF THE
18 THINGS THAT I'M HEARING IS THAT WHATEVER WE SET UP IS
19 GOING TO HAVE IMPLICATIONS FOR OTHER PROGRAMS. SO IF
20 WE'RE TOO BROAD ABOUT IT, JUST TO SAY ALL ACADEMIC
21 PROGRAMS, THEN DO WE RESTRICT OURSELVES TO THE UNITED
22 STATES? THAT'S EASY. WE CAN CERTAINLY DO THAT. THAT
23 WOULD EXCLUDE KOREA, BUT YOU HAVE TO THINK ABOUT THE
24 CONSEQUENCES OF THAT. AND SO THAT'S ONE EXTREME.

25 MR. GOLDBERG: THE WAY I WAS TRYING TO POSIT

1 IT CONCEPTUALLY WAS THERE WILL BE SOME INSTANCES WHERE
2 WE SHOULD HAVE AN AFFIRMATIVE, POSITIVE OBLIGATION.
3 THE OTHER ONE WE CAN DEAL WITH. WE DON'T NEED TO
4 NECESSARILY HAVE A PROHIBITION. IT JUST IS UP TO THE
5 DISCRETION OF THE INVESTIGATORS.

6 DR. PIZZO: RIGHT. I UNDERSTAND THAT PART,
7 MICHAEL, BUT I'M JUST SAYING IF OTHER STATES BEGIN
8 LOOKING AT WHAT WE'RE DOING --

9 MR. GOLDBERG: YOUR QUESTION IS WHETHER WE
10 SHOULD APPLY THE POSITIVE CASE.

11 DR. PIZZO: RIGHT. LET'S SAY NEW JERSEY NOW
12 HAS A BOND AND THEY'VE GOT STEM CELL RESEARCH. SHOULD
13 THEY DECIDE THAT THEY WANT TO HAVE DISCRETION ABOUT
14 COMMUNICATING WITH NEW YORK?

15 MR. GOLDBERG: SO I'M TRYING TO THINK ABOUT
16 IT JUST PERSONALLY AS A TAXPAYER IN CALIFORNIA. SO WHY
17 SHOULD I BE COMFORTABLE WITH THAT? I SHOULD BE
18 COMFORTABLE WITH THAT BECAUSE THROUGH THIS KIND OF
19 JUMP-STARTING OF THE REGENERATIVE MEDICINE ENTERPRISE
20 IN CALIFORNIA, WE'RE GOING TO STIMULATE WORK THAT'S
21 GOING TO POTENTIALLY BENEFIT CALIFORNIANS, AND WE DON'T
22 CARE IF IT BENEFITS OTHER PEOPLE.

23 DR. BRYANT: BY THE SAME TOKEN, YOU COULD GO
24 ABROAD. A LOT OF PEOPLE IN THIS COUNTRY WILL END UP
25 COLLABORATING OUTSIDE THE COUNTRY.

1 MR. GOLDBERG: DO YOUR INVESTIGATORS
2 PRESENTLY HAVE AFFIRMATIVE OBLIGATION EITHER THROUGH
3 THE UNIVERSITY OR THROUGH THEIR FEDERAL GRANTS TO
4 SERVICE MATERIAL TRANSFER REQUESTS?

5 DR. PIZZO: BY THE WAY, THE WORLD'S EXPERT
6 HAPPENS TO BE SITTING HERE. KATHY COO RUNS THE OTL FOR
7 STANFORD. AND YOU WANT TO COMMENT? YOU SHOULD COMMENT
8 ON EVERYTHING AS WE'RE GOING THROUGH.

9 CHAIRMAN PENHOET: KATHY COO IS APPROACHING
10 US NEAR THE PHONE.

11 MS. COO: MATERIAL TRANSFERS AND HOW THEY'RE
12 HANDLED ARE INITIATED BY OUR FACULTY GOING OUT, THEY'RE
13 INITIATED BY FACULTY WHO WANT MATERIALS THAT ARE COMING
14 IN. EVERYBODY KNOWS ABOUT THE NIH GUIDELINES. SOME
15 PUBLICATIONS REQUIRE THAT MATERIALS THAT ARE PUBLISHED
16 BE MADE AVAILABLE, AND THEY'RE AWARE OF THOSE. WE
17 DON'T SEE VERY MANY REQUESTS THAT ARE DENIED, BUT IT
18 MIGHT NOT COME TO OUR OFFICE WHEN THERE'S A DENIAL.

19 DR. PIZZO: I THINK THAT'S RIGHT, THAT IT
20 PROBABLY DOESN'T COME TO YOUR OFFICE. AS WE HEARD
21 EARLIER, THESE JUST LEAD TO THE GREAT OFFENSES THAT
22 EXIST BETWEEN INVESTIGATORS.

23 DR. BRYANT: WHAT ABOUT INTERNATIONAL
24 TRANSFERS?

25 MS. COO: INTERNATIONAL TRANSFERS, THE ONLY

1 THING THAT WE CARE ABOUT AS A CENTRAL OFFICE IS THAT
2 THEY MEET SORT OF EXPORT REGULATION ISSUES.

3 DR. PIZZO: SO JUST A REACTION TO THE
4 DISCUSSION THAT WE'VE BEEN HAVING, IF MICHAEL'S
5 PROPOSAL WAS THAT WE WOULD HAVE COMPLETE SHARING IN
6 CALIFORNIA AND DISCRETIONARY SHARING WITH OTHER STATES
7 VERSUS OPEN SHARING WITH ALL ACADEMIC PROGRAMS, LET'S
8 LIMIT IT RIGHT NOW TO THE UNITED STATES, DOES THAT
9 INFLUENCE THE WAY YOU WOULD BE THINKING? HOW WOULD AN
10 INSTITUTION -- WE'RE NOT A STATE INSTITUTION OBVIOUSLY,
11 SO WE'RE A PRIVATE INSTITUTION -- HOW WOULD THE PRIVATE
12 INSTITUTION BE AFFECTED BY THAT, IF AT ALL?

13 MS. COO: WE WOULDN'T BE AFFECTED
14 PROCEDURALLY. IT SEEMS TO ME YOU WOULD BE SENDING A
15 MESSAGE, AS DEAN PIZZO SAYS, THAT IF YOU SAY SOMETHING
16 IS REQUIRED AND OTHERS IS DISCRETIONARY, IT SEEMS TO ME
17 I WOULD RATHER SEE IT SOMETHING IS REQUIRED, PERIOD,
18 EVEN IF IT'S NOT THE WHOLE UNIVERSE.

19 DR. PIZZO: SO A COMFORTABLE ZONE WOULD BE
20 THE UNITED STATES TO START WITH. I JUST WORRY ABOUT
21 THE RESTRICTIONS OF THE MESSAGE WE'RE SENDING BECAUSE
22 PART OF THE MESSAGE WE WANT TO SEND, IF WE ARE LUCKY
23 ENOUGH TO ACTUALLY HAVE THE BONDS APPROVED AND
24 FINANCING, WE'RE GOING TO BE THE LEAD GUARD FOR THE
25 COUNTRY, MAYBE THE WORLD, AND WE WANT TO BE ABLE TO SAY

1 WE' RE GOING TO SHARE OUR KNOWLEDGE WITH YOU EVEN THOUGH
2 WE MIGHT BE ABLE TO -- WE STILL HAVE AN OBLIGATION TO
3 KEEP OUR REVENUE, IF YOU WILL, OR EARNINGS IN
4 CALIFORNIA. THAT' S WHERE THE GRANTS ARE GOING TO BE.

5 CHAIRMAN PENHOET: WE HAD A COMMENT FROM LOS
6 ANGELES.

7 DR. FONTANA: YES. IT' S JEANNIE FONTANA.
8 AND I WANT TO JUST USE WHAT' S BEEN LEARNED THROUGH THE
9 DISEASE ADVOCACY GROUPS WHICH ARE FOCUSED AT FINDING
10 CURES. SOME OF THE GROUPS HAVE USED THE CONCEPT OF
11 SHARING BOTH POSITIVE AND NEGATIVE OUTCOME DATA WHERE
12 YOU WANT TO ESTABLISH AN ENVIRONMENT OF COLLABORATION
13 WHILE MAINTAINING A HEALTHY OUTCOME FROM COMPETITION.
14 AND PERHAPS ONE WAY WE COULD DO THIS WITH CIRM IS TO
15 REQUIRE THE PARTICIPATION IN AN ANNUAL MEETING WHERE
16 ONE REPORTS BOTH POSITIVE AND NEGATIVE OUTCOMES AND
17 THAT IT WOULD BE OPEN TO THE PUBLIC.

18 CHAIRMAN PENHOET: WE MAY HAVE HUNDREDS OF
19 GRANTEES BEFORE WE FINISHED, I THINK. SO THERE' S A
20 LOGISTICS ISSUE ASSOCIATED WITH THAT.

21 DR. FONTANA: WE HAVE LARGE SCIENTIFIC
22 MEETINGS WHERE DATA IS PRESENTED.

23 DR. BRYANT: POSTERS.

24 DR. FONTANA: AND IT COULD BE GROUPED BY
25 DISEASES. I MEAN THERE' S A NUMBER OF DIFFERENT

1 APPROACHES. IT'S JUST A THOUGHT.

2 MS. STREITZ: THIS IS WENDY STREITZ,
3 UNIVERSITY OF CALIFORNIA. I WAS WONDERING IF I COULD
4 MAKE A SUGGESTION THAT IS SORT OF A MULTI PRONGED
5 APPROACH THAT MIGHT WORK. ONCE YOU FIGURE OUT WHAT
6 AREA YOU WANT TO REQUIRE SHARING OF RESEARCH RESOURCES
7 AND DATA AND WHATEVER, YOU CAN STRONGLY ENCOURAGE THE
8 WHOLE REST OF THE WORLD, AND THEN MAYBE ASK THEM TO
9 EXPLAIN IN AN IP MANAGEMENT PLAN HOW THEY PLAN ON
10 HANDLING THEIR RESEARCH RESULTS TO GET SOME CLARITY ON
11 IT. AND THEN IN REVIEWING GRANTS, THAT COULD BE ONE OF
12 THE CRITERIA.

13 DR. BRYANT: GOOD POINT.

14 DR. LOVE: I'M JUST CURIOUS TO GO TO MAYBE
15 THE OTHER EXTREME. WHY WOULDN'T WE JUST REQUIRE THE
16 SHARING ON A WORLDWIDE BASIS BECAUSE IF THE INTENT
17 REALLY IS TO FACILITATE THE RESEARCH, WE DON'T WANT
18 KOREA NECESSARILY TO NOT SHARE WITH US THINGS THAT
19 COULD ADVANCE THE THERAPIES HERE.

20 DR. PIZZO: THAT'S RIGHT. PARTLY THE REASON
21 I SAID IT WAS JUST AROUND TRYING TO STAY CONSONANT WITH
22 EXISTING PRINCIPLES OF BAYH-DOLE AND THE LIKE. SO I,
23 FOR ONE, AM OPEN TO MUCH MORE GLOBAL SHARING, BUT I
24 THINK WE JUST WANT TO BE SURE THAT WE'RE SORT OF
25 STAYING WITHIN THE ZONE OF HOW OTHERS MIGHT REACT.

1 DR. LOVE: SO WE'RE TALKING ABOUT RESEARCH
2 DATA AND MATERIALS. WE'RE NOT TALKING ABOUT PATENTS
3 AND, IN FACT --

4 CHAIRMAN PENHOET: NOT IN THIS DISCUSSION.
5 WE'LL COME TO THAT NEXT.

6 DR. LOVE: SO MY THINKING IS THAT THE PATENTS
7 REALLY BEING IN PLACE FACILITATE, IN FACT, SHARING OF
8 THE INFORMATION IN THE BROADEST POSSIBLE SCALE.

9 MR. SHEEHY: MY QUESTION IS -- I'M A VERY
10 CYNICAL PERSON -- IS SOME SORT OF RECIPROCITY BUILT IN?
11 SO MAYBE THE DISCRETION COMES IF YOU DON'T HAVE AN
12 OBLIGATION TO SHARE WITH SOMEONE WHO'S NOT SHARING
13 BACK. YOU KNOW, I WOULD BE FINE WITH SHARING WITH THE
14 WHOLE WORLD, BUT THE INVESTIGATOR HAS THE OPTION NOT TO
15 SHARE WITH AN INVESTIGATOR WHO REFUSES TO SHARE THEIR
16 STEM CELL LINE OR THEIR ADVANCE SO THAT THERE'S SOME
17 STUFF THAT WE SET UP WITH SOME VERY AFFIRMATIVE WAY
18 THAT WE BELIEVE IN SHARING, AND WE WILL SHARE WITH
19 ANYONE WHO SHARES WITH US; BUT IF YOU DON'T SHARE WITH
20 US, OUR INVESTIGATORS ARE NOT BURDENED WITH THE
21 REQUIREMENT TO SHARE WITH YOU.

22 DR. PRIETO: I THINK THAT'S A GOOD POINT. I
23 HADN'T THOUGHT OF THAT, BUT I THINK WE SHOULD KEEP IN
24 MIND THE PRINCIPLE THAT OUR ULTIMATE GOAL IS THE
25 FASTEST POSSIBLE DEVELOPMENT OF THE RESEARCH AND

1 PROGRESSING TO THERAPIES, AND I THINK THE WIDEST
2 POSSIBLE SHARING. I WOULD HAVE NO PROBLEM WITH PUTTING
3 THIS KIND OF CONDITION ON IT BECAUSE I THINK THAT WOULD
4 ENCOURAGE SHARING ON THE PART OF --

5 DR. PIZZO: I ACTUALLY LIKE THAT, JUST SORT
6 OF THINKING ABOUT IT. I THINK IT OPENS UP THE DIALOGUE
7 AND IN A SENSE MORE PROACTIVELY SAYS WE'VE TAKEN THE
8 STEP. WE'D LIKE YOU TO TAKE AN EQUAL STEP. IF YOU
9 CHOOSE NOT TO, THAT'S OKAY, BUT THEN YOU'RE NOT GOING
10 TO GET ANY MORE FROM US.

11 CHAIRMAN PENHOET: MELISSA, AS THE SCRIBE,
12 MAYBE YOU CAN JUST TYPE IN HERE SOME THESE CONCEPTS,
13 QUID PRO QUO, MAXIMUM SHARING. WHENEVER YOU HEAR
14 KEYWORDS, PUT THEM DOWN AND WE'LL TRY TO CRAFT THIS
15 INTO SOME LANGUAGE BEFORE WE GET OUT OF HERE.

16 MR. REED: I WOULD BE WARY OF ANY QUID PRO
17 QUO WHEN IT COMES TO INFORMATION BECAUSE THEN WE HAVE
18 TO WEIGH THE VALUE OF EACH CONTRIBUTION. I THINK
19 SCIENTISTS DO BEST WHEN THEY HAVE ACCESS TO ALL
20 KNOWLEDGE. AND THE GREATER KNOWLEDGE SHARING THAT WE
21 HAVE, THE MORE BENEFIT FOR EVERYONE.

22 DR. PIZZO: THE ONLY -- I AGREE WITH THAT.
23 IN THE WORLD WE'D LIKE TO LIVE IN, THERE'D BE FREE FLOW
24 OF INFORMATION AND EXCHANGE AND NO CONSTRAINTS ABOUT
25 IT. I THINK THAT IF THE FREE FLOW TURNS OUT TO BE

1 UNIDIRECTIONAL, I THINK THAT'S WHAT JEFF IS RAISING,
2 THAT THERE'S ONE GROUP OR PERSON OR TEAM OR LAB THAT'S
3 GETTING THE INFORMATION AND UNWILLING TO SHARE IN TURN
4 WHATEVER THEY'RE DISCOVERING IN THEIR LAB, THAT'S NOT A
5 GOOD PRINCIPLE.

6 SO I THINK THE WAY I WOULD FRAME THIS OR
7 FRAME YOUR SUGGESTION IS YOU'D ALMOST HAVE AN
8 ANTECEDENT STATEMENT WHICH WOULD SAY OUR GOAL IS TO
9 CREATE A FREE EXCHANGE OF INFORMATION THAT IS
10 BILATERAL. AND THAT MEANS THAT WE'RE WILLING TO
11 PROACTIVELY SHARE INFORMATION WITH THE UNDERSTANDING
12 THAT OTHER LABS OR GROUPS WILL EQUALLY SHARE
13 INFORMATION WITH US AND WITH OTHERS INVOLVED IN THE
14 COMMUNITY OF RESEARCH ON STEM CELLS. SO WE'D SET A
15 VERY HIGH LEVEL PRINCIPLE.

16 DR. HALL: I THINK THIS REQUIRES SOME THOUGHT
17 BECAUSE I THINK WHAT IT MEANS FOR EACH OF THOSE THINGS,
18 WHICH ARE A LITTLE BIT DIFFERENT, I THINK ONE HAS TO
19 SAY WHAT DOES IT MEAN TO SHARE DATA? AND WHAT SHALL WE
20 REQUIRE? AND HOW WILL WE POLICE IT? AND I THINK DOES
21 THAT MEAN UNPUBLISHED DATA? DOES THAT MEAN, AS RICK
22 SAID, TO ENCOURAGE OR MAYBE EVEN REQUIRE OPEN ARCHIVING
23 PUBLISHING OR OPEN-ACCESS PUBLISHING? ONE OF THE
24 PROBLEMS RIGHT NOW IS WE KNOW IS THERE ARE NOT THAT
25 LARGE A NUMBER OF HIGH QUALITY OPEN-ACCESS JOURNALS.

1 IF YOU REQUIRE THAT, THAT PUTS A BURDEN ON PEOPLE.

2 DR. PIZZO: VERY IMPORTANT CAVEAT.

3 DR. HALL: AND THEN I THINK --

4 DR. FONTANA: CAN I ASK HIM TO SPEAK INTO THE
5 SPEAKER? WE CAN'T HEAR HERE.

6 DR. HALL: SO JUST TO MAKE THE POINT THAT
7 EACH OF THESE, ALL OF US WANT THE WIDEST POSSIBLE
8 SHARING OF DATA, BIOMEDICAL MATERIALS, AND TECHNOLOGY,
9 BUT WHAT WE MEAN BY THAT IS WE HAVE TO BE VERY CAREFUL.
10 I THINK EACH OF THOSE NEEDS TO BE TREATED DIFFERENTLY,
11 AND I THINK WE HAVE TO BE VERY THOUGHTFUL ABOUT WHAT IT
12 IS WE REQUIRE FROM OUR GRANTEEES SO AS, NO. 1, NOT TO
13 IMPOSE AN UNREASONABLE BURDEN ON THEM; AND, NO. 2,
14 SOMETHING THAT I THINK THAT WE CAN ADEQUATELY, IF NOT
15 POLICE, AT LEAST RESPOND TO IN CASES OF VIOLATION --
16 RESPOND TO APPROPRIATELY IN CASES OF VIOLATION.

17 SO WHAT DOES IT MEAN TO SAY YOU SHARE DATA?

18 CHAIRMAN PENHOET: IT COULD MEAN PROMPT
19 PUBLICATION.

20 DR. HALL: THERE ARE TWO THINGS.

21 DR. PIZZO: WE HAVE TO DEFINE THAT THOUGH.

22 DR. HALL: WHAT DOES PROMPT PUBLICATION MEAN?
23 WHO DECIDES WHEN SOMETHING IS READY TO BE PUBLISHED? I
24 THINK FOR US TO STEP IN AND TRY TO DEAL WITH THAT IS
25 DIFFICULT. BUT I THINK ONE ISSUE IS ONCE IT'S

1 PUBLISHED, WHO IS IT AVAILABLE TO. AND THERE THE OPEN
2 ARCHIVE AND OPEN-ACCESS PUBLISHING ADDRESS THESE
3 ISSUES.

4 FOR UNPUBLISHED DATA, I THINK WE HAVE TO BE
5 VERY CAREFUL ABOUT WHAT WE REQUIRE PEOPLE TO SHARE. WE
6 CAN SET UP MECHANISMS THAT ENCOURAGE PEOPLE TO SHARE
7 WITH OTHER RESEARCHERS UNPUBLISHED DATA THROUGH
8 MEETINGS AND THINGS LIKE THAT, BUT I THINK IT'S VERY
9 DIFFICULT TO REQUIRE IT. AND I UNDERSTAND JEANNIE
10 FONTANA'S POINT ABOUT NEGATIVE RESULTS. BY THE WAY,
11 PLOS, FOR THOSE OF YOU WHO DON'T KNOW, HAS JUST STARTED
12 A JOURNAL CALLED PLOS CLINICAL TRIALS THAT AIMS TO
13 PUBLISH BOTH POSITIVE AND NEGATIVE RESULTS FROM
14 CLINICAL TRIALS. I THINK THAT'S ACTUALLY WHAT JEANNIE
15 MEANS. LET ME NOT SPEAK FOR HER.

16 IF YOU TELL A BASIC SCIENTISTS TO PUBLISH
17 NEGATIVE RESULTS OR TO SHARE THEM, THIS BECOMES A HUGE
18 BURDEN.

19 CHAIRMAN PENHOET: ON THE WHOLE COMMUNITY.

20 DR. HALL: HOW MANY TIMES DO YOU TRY AN
21 EXPERIMENT AND IT DOESN'T WORK; BUT IN ORDER TO MAKE IT
22 A DEFINITIVE NEGATIVE, YOU HAVE TO PUT A LOT OF TIME
23 INTO IT THAT YOU MAY NOT WANT TO DO. SO I THINK JUST
24 HOW WE STATE THIS BECOMES VERY IMPORTANT.

25 I THINK ALSO FOR BIOMEDICAL MATERIALS, AND WE

1 HAVE TALKED ABOUT THIS A LITTLE BIT IN THE STANDARDS
2 WORKING GROUP, AND I THINK DAVID BALTIMORE MADE A POINT
3 ABOUT THIS IN ONE OF OUR ICOC MEETINGS, IF YOU SAY THAT
4 ANY TIME ANYBODY MAKES A NEW CELL LINE OR THAT THEY
5 ALTER IT BY TRANSECTING IN MATERIALS OR WHATEVER, THAT
6 THEY TO SHARE IT, THIS BECOMES A BURDEN. AND
7 PARTICULARLY FOR HUMAN STEM CELLS, THE GROWING AND
8 SHARING OF THESE CELLS IS VERY EXPENSIVE.

9 DOUG MELTON'S LAB, WHICH IS APPARENTLY VERY
10 GENEROUS ABOUT SHARING THE LINES THAT THEY GENERATE,
11 HAVE TWO FULL-TIME TECHNICIANS WHO DO NOTHING BUT
12 RESPOND TO REQUESTS FOR CELLS. MOST PEOPLE CANNOT
13 AFFORD THAT. HE IS A VERY WELL-FUNDED HHMI
14 INVESTIGATOR.

15 SO THERE OUR POLICY ON THAT, I THINK, SHOULD
16 BE TIED TO WHAT WE DO ABOUT A STEM CELL BANK, AND THAT
17 BECOMES IMPORTANT AS WELL. SO WHAT WE -- AT WHAT POINT
18 WE SAY PEOPLE SHOULD SHARE AND HOW THEY SHOULD SHARE IS
19 SOMETHING, I THINK, WE HAVE TO BE VERY THOUGHTFUL
20 ABOUT.

21 AS FAR AS TECHNOLOGY IS CONCERNED, I ASSUME
22 THAT MEANS YOU HAVE A NEW TECHNIQUE WHICH MAY OR MAY
23 NOT BE PUBLISHED, WHICH MAY OR MAY NOT BE PATENTED,
24 AND, AGAIN, WE WANT THAT TO BE AS WIDELY USED AS
25 POSSIBLE, BUT ALSO, I THINK AGAIN, NEED TO BE VERY,

1 VERY THOUGHTFUL ABOUT WHAT AND HOW, HOW IT'S TO BE
2 IMPLEMENTED AND HOW WE ARE TO, AS I SAY, ENSURE
3 COMPLIANCE. IT'S A BIG JOB.

4 DR. PIZZO: ZACH, WHILE YOU'RE THERE, CAN I
5 ASK YOU A QUESTION? I THINK WHAT YOU ARE DOING IS, I
6 THINK, REALLY IMPORTANT, GETTING INTO SOME OF THE
7 DETAILS THAT WOULD NEED TO BE SORTED OUT. MY
8 UNDERSTANDING IS THAT THOSE CAVEATS, IMPORTANT CAVEATS,
9 ARE GOING TO BE SORT OF THE NEXT STEP.

10 WHAT I THOUGHT WE WERE DOING AS A START WAS A
11 VERY BIG BROAD, GENERAL PRINCIPLE WHICH WOULD BE
12 GOVERNED BY THE DETAILS. AND IN TERMS OF --

13 DR. HALL: I APOLOGIZE. I WAS OUT FOR THE
14 PREAMBLE FOR THIS, AND I MAY HAVE MISSED AN IMPORTANT
15 POINT, BUT MY UNDERSTANDING WAS YOU'RE PUTTING IN PLACE
16 A POLICY THAT IS TO GO OUT WITH THE GRANTS
17 ADMINISTRATION POLICY FOR TRAINING GRANTS. SO ONCE
18 THAT GOES OUT, THEN IT IS SOMETHING THAT THE SCIENTIFIC
19 COMMUNITY WILL LOOK AT AND SAY WHAT DOES THIS MEAN?
20 HOW AM I GOING TO HAVE TO ACT? SO I'M JUST CAUTIONING
21 AGAINST --

22 DR. PIZZO: NO. I ACTUALLY MEANT SOMETHING A
23 LITTLE BIT DIFFERENT. THAT IS THAT I MEANT THAT WE
24 WERE DOING -- WE ARE AT THE HIGH LEVEL AT THIS POINT OF
25 THE DISCUSSION, AND THAT WE WERE GOING TO AMEND THAT.

1 I THINK YOUR AMENDMENTS OR YOUR QUALIFICATIONS ARE
2 REALLY IMPORTANT.

3 DR. HALL: JUST CAUTIONS.

4 DR. PIZZO: THEY'RE VERY IMPORTANT.

5 CHAIRMAN PENHOET: IT'S A DIFFICULT AREA.

6 DR. LOVE: ACTUALLY ON A RELATED POINT, THE
7 ISSUE OF NOT SHARING, HOW DO WE DEFINE THAT THEY'RE NOT
8 SHARING? WHAT IF SOMEBODY AT STANFORD SAYS THE GUYS AT
9 HARVARD AREN'T SHARING? ARE WE GOING TO POLICE THAT?
10 IT'S VERY COMMON. I KNOW THAT. I DID IT ALL THE TIME.
11 HOW DO WE REALLY MEASURE THAT?

12 CHAIRMAN PENHOET: THESE ARE VERY IMPORTANT
13 INTERRELATED POINTS THAT BOTH ZACH MADE AND YOU JUST
14 MADE. HOW DO YOU POLICE? ON THE OTHER HAND, I THINK
15 THAT WE WOULDN'T DO DOING OUR JOB IF WE DIDN'T TRY TO
16 PUSH THE BALL A LITTLE BIT FURTHER TOWARDS MUCH GREATER
17 DEGREE OF TRANSPARENCY THAN CURRENTLY EXISTS IN THE
18 ENVIRONMENT.

19 DR. PIZZO: AS A PRINCIPLE.

20 CHAIRMAN PENHOET: I THINK I SEE PRETTY MUCH
21 AGREEMENT AROUND THE TABLE, THAT WE DO HAVE THE
22 OPPORTUNITY TO PUSH THIS ENVELOPE FURTHER.

23 MR. NAUGHTON: HAVING WORKED IN A STEM CELL
24 COMPANY AND HAVING SCIENTISTS TRY TO SHARE DATA, WE
25 SOMETIMES DIDN'T HAVE BENCH SCIENTISTS SITTING ACROSS

1 FROM EACH OTHER SHARING IT. IT ALWAYS CAME DOWN TO
2 WHAT WAS THE MOTIVATION OF THE PERSON AND BUILDING THE
3 TRUST BETWEEN THEM. SO I WOULD JUST ENCOURAGE YOU TO
4 KEEP AN OPEN, TRUSTING, SORT OF FREE MARKET APPROACH.

5 THERE IS ALSO THE ISSUE OF YOU NEED
6 ADDITIONAL CAPITAL DOWN THE ROAD, AND WHATEVER YOU
7 DECIDE COULD IMPACT OTHER PEOPLE WHO COME IN LATER.
8 YOU ALSO HAVE TO KEEP THAT IN MIND, AND THEY'RE GOING
9 TO BE FREE MARKET THINKERS GENERALLY.

10 DR. LOVE: JUST ONE MAYBE SLIGHTLY CONTRARIAN
11 POINT TO THE ISSUE ABOUT RECIPROCITY AND SHARING. I'M
12 NOT A LAWYER, SO I'M GOING WAY OUT HERE, BUT I'LL BE
13 RESCUED, I'M SURE. THE UNITED STATES HAS POLICIES IN
14 PLACE THAT REGULATE COMPANIES AROUND DOING THINGS LIKE
15 BRIBING FOREIGN OFFICIALS, BRIBING GOVERNMENT, AND WE
16 HAVE NO REQUIREMENT THAT SAYS BOEING CAN GET AWAY WITH
17 BRIBING PEOPLE IF THE COMPANIES IN THAT NATION
18 PARTICIPATE IN BRIBING PEOPLE. AND MANY PEOPLE IN THE
19 BUSINESS WORLD, QUITE FRANKLY, FEEL THAT THAT'S UNFAIR.

20 BUT HAVING SAID THAT, I'M NOT SURE -- I KNOW
21 THIS IS A SLIGHTLY DIFFERENT ISSUE, BUT THERE IS A
22 CONSISTENCY OF DO WE WANT TO MODEL THE BEHAVIOR THAT WE
23 WANT AROUND THE WORLD, OR DO WE WANT TO FOCUS MORE ON
24 RECIPROCITY?

25 AND I THINK TO THE POINTS THAT HAVE BEEN

1 MADE, I GUESS AT THE END OF THE DAY, WE WANT TO TRY TO
2 GET THE BEST OUTCOME. SO MAYBE THE MODELING IS NOT THE
3 PERFECT WAY TO GET THE BEST OUTCOME.

4 DR. PIZZO: I THINK WE WERE EARLIER TALKING
5 ABOUT THE MODELING, AND I THINK THAT'S WHERE WE WERE IN
6 THE EARLY PHASE OF THE DISCUSSION. I THINK WE ALSO
7 NEED TO FRAME IT. IT THINK THIS IS WHAT YOU WERE
8 RELATING TO. JUST GET DOWN TO THE INVESTIGATOR LEVEL
9 FOR A MOMENT, AND I THINK THIS IS WHAT ZACH IS TALKING
10 ABOUT. IF I'M AN INVESTIGATOR AND I HAVE A NEW
11 DISCOVERY, IS THERE AN EXPECTATION NOW IMPOSED ON ME?
12 IF WE SAY SHARING IS SOMETHING WE WANT TO FOSTER, DOES
13 THAT REQUIRE ME TO ACTUALLY COMMUNICATE RESULTS? I
14 THINK THAT'S NOT -- I CERTAINLY WASN'T AT THAT LEVEL.
15 I THINK I PRETTY MUCH LEAPT AHEAD TO WHERE ED WAS WHEN
16 YOU WERE TALKING ABOUT DATA THAT WAS ABOUT READY OR
17 BEING PROPOSED. I MEAN I WOULD USE PLOS AS SORT OF THE
18 EXAMPLE OF WHERE YOU'D BE SHARING INFORMATION AT THAT
19 LEVEL. OTHERWISE, YOU COULD WIPE INDUSTRY OUT OF THE
20 EQUATION. THEY'RE NOT GOING TO BE INTERESTED IN THAT.
21 YOU COULD WIPE MOST OF OUR INVESTIGATORS OUT. THEY
22 WOULD BE FURIOUS IF THEY THOUGHT THAT THEIR IDEAS WERE
23 GOING TO HAVE TO BE PUBLICLY SHARED AND THEN STOLEN.

24 DR. HALL: LET ME SAY THAT THE ISSUE OF
25 SHARING AND TRANSPARENCY IS ONE OF INTERNATIONAL

1 CONCERN. AND THAT HAVING BEEN INVOLVED IN SEVERAL
2 FIELDS OVER THE COURSE OF A FAIRLY LONG CAREER, I CAN
3 SAY THAT THE SPIRIT IN THE STEM CELL WORLD, I THINK,
4 RIGHT NOW IS EXEMPLARY IN THIS REGARD. THAT IS, THAT
5 MANY OF THE LEADING PEOPLE ARE VERY INTERESTED IN
6 HAVING TRANSPARENCY. SO THROUGH GROUPS LIKE THE
7 INTERNATIONAL STEM CELL FORUM, I THINK THERE WILL BE A
8 REAL EFFORT TO HAVE BANKS FROM WHICH -- INTERNATIONALLY
9 FROM WHICH PEOPLE CAN DRAW CELL LINES AND TO HAVE THE
10 WHOLE EFFORT TO CREATE STANDARDS TO CHARACTERIZE THEM,
11 TO BE SURE THAT WHAT YOU GET IS WHAT YOU THINK YOU ARE
12 GOING TO GET. THESE CELLS ARE DIFFICULT TO GROW.

13 AND I AM REMINDED OF THE COMMENT MADE EARLIER
14 THAT THE MAJOR DIFFICULTY, ACTUALLY BY RICK AND ALSO BY
15 THE OTHER SPEAKER, THAT THE SCIENTISTS' RELUCTANCE TO
16 SHARE THEIR MATERIALS FOR COMPETITIVE REASONS, ACADEMIC
17 SCIENTISTS, IS AS BIG A PROBLEM AS ELSEWHERE. AND IT'S
18 NOT UNCOMMON TO GET A HUMAN CELL LINE FROM SOMEBODY AND
19 YOU CAN'T GROW IT UP. YOU DON'T KNOW WHY. AND SO THE
20 WHOLE IDEA OF TRYING TO MAKE REAGENTS WIDELY AVAILBLE
21 IS, I THINK, SOMETHING THAT THERE IS ACTIVE MOVEMENT IN
22 THIS AREA. WE WANT TO PARTICIPATE FULLY, AND I THINK
23 WE WANT TO SUPPORT THOSE EFFORTS, AND WE WANT THERE TO
24 BE INTERNATIONAL TRANSPARENCY. TO HAVE A QUID PRO QUO,
25 I THINK, ANNOUNCES A SUSPICION AT THE BEGINNING THAT'S

1 MAYBE NOT WHAT WE ULTIMATELY INTEND.

2 DR. WRIGHT: I THINK ALSO WE'VE LEARNED THIS
3 FROM THE TRADE AREA AND OTHER AREAS IN ECONOMICS, THAT
4 IF YOU START WITH RECIPROCAL RELATIONS, WHICH ARE
5 GEOGRAPHICALLY LIMITED, IT'S VERY HARD TO GO FROM THAT
6 TO AN OPEN INTERNATIONALWIDE SHARING RELATION. I THINK
7 IF YOU ARE IN DOUBT ABOUT HOW TO MAKE THESE POLICIES,
8 MAKE THEM IN FAVOR OF OPENNESS, AND THEN SEE WHERE YOU
9 HAVE TO CLOSE UP. IF YOUR START OUT CLOSED, PROPERTY
10 RIGHTS WILL BE ESTABLISHED, YOU WILL NEVER GET IT BACK
11 TO BEING OPEN.

12 DR. PIZZO: HOW DO YOU WANT TO GET DOWN TO
13 THE --

14 CHAIRMAN PENHOET: LET'S GO THROUGH THESE AND
15 THEN GO BACK. SO THE NEXT ONE MAY BE EASIER THAN THIS
16 ONE. NEXT ONE IS --

17 DR. PIZZO: DID WE REACH -- DO WE WANT TO
18 TAKE A SORT OF STRAW, OR DO WE FEEL LIKE WE'RE ALL ON
19 THE SAME PAGE ON THIS BECAUSE THE PAGE HAS BEEN TURNED
20 A FEW TIMES.

21 CHAIRMAN PENHOET: LET'S ASK THE -- MAYBE WE
22 CAN ADDRESS THE SPECIFIC QUESTION. SHOULD WE TRY TO
23 CREATE A SITUATION IN WHICH WE'D LIKE TO BE A MODEL FOR
24 OPEN SHARING WITHOUT BORDERS, OR SHOULD WE TRY TO BE
25 MORE RESTRICTIVE AND MORE LOCAL IN OUR EFFORTS?

1 DR. HALL: FOR RESEARCH PURPOSES.

2 DR. PIZZO: AND THE DETAILS OF WHAT WE SHARE
3 IS GOING TO COME IN A SUBSEQUENT PART OF THE
4 DISCUSSION.

5 CHAIRMAN PENHOET: JUST SHOW OF HANDS BECAUSE
6 THIS IS A STRAW VOTE. HOW MANY WANT TO GO FOR THE OPEN
7 MODEL? JEANNIE?

8 DR. FONTANA: YES.

9 CHAIRMAN PENHOET: OKAY. GOOD. THAT'S A
10 PRINCIPLE, I THINK, WE'VE ESTABLISHED.

11 THE NEXT ONE IS SHOULD CIRM CREATE A RESEARCH
12 EXTENSION FOR THE USE OF INTELLECTUAL PROPERTY FOR
13 BASIC RESEARCH PURPOSES? THIS IS EASIER TO DEAL WITH
14 BECAUSE IT'S VERY A SPECIFIC THING. IT'S ALREADY IN
15 THE PUBLIC DOMAIN IF SOMEBODY HAS FILED A PATENT, ETC.,
16 SO IN A SENSE WHAT WOULD THE BORDERS OF THIS BE. THERE
17 IS NO SUCH THING IN LAW, BUT WE CAN -- BUT WE CAN
18 IMPOSE IT BY POLICY. IF YOU ACCEPT OUR MONEY, YOU WILL
19 AGREE THAT IF YOU HAVE A PATENTED INVENTION, YOU WILL
20 MAKE IT FREELY AVAILABLE FOR RESEARCH PURPOSES ONLY.

21 SO I THINK WE'RE ON CLEARER LEGAL GROUNDS
22 HERE. WE HAVE THE RIGHT TO DO THIS. I THINK IT'S ONE
23 OF THE FIVE RECOMMENDATIONS OF THE REPORT FROM THE NRC.

24 DR. WRIGHT: I THINK IT'S CONSISTENT WITH THE
25 DESIRES OF MOST COMPANIES. THEY'RE NOT REALLY

1 INTERESTED IN RESTRICTING SCIENTISTS FROM ADOPTING
2 THEIR TECHNOLOGY. IN FACT, THEY'D LIKE THAT TO HAPPEN
3 SO THAT THEN CAN GET --

4 CHAIRMAN PENHOET: I THINK IT ADDRESSES ONE
5 OF BECKY EISENBERG'S PRINCIPAL POINTS ABOUT SHARING.
6 BUT KATHY COO HAS A POINT OF VIEW.

7 MS. COO: I JUST WANTED TO MAKE SURE YOU ARE
8 NOT JUST AIMING AT UNIVERSITIES BECAUSE WE LICENSE
9 PHARMACEUTICAL COMPANIES A LOT OF TIMES BIOLOGICAL
10 MATERIALS FOR A PRICE, EVEN THOUGH THEY CAN USE IT
11 FREELY FOR INTERNAL RESEARCH PURPOSES.

12 MANY OF US UNIVERSITIES ALSO LICENSE RESEARCH
13 MATERIALS FOR COMPANIES' INTERNAL RESEARCH PURPOSES.
14 AND SO IF THEY HAD THE RESOURCE EXEMPTION, THEN WE
15 WOULDN'T, WHICH IS, AGAIN, FINE WITH US. I JUST WANT
16 TO MAKE SURE YOU UNDERSTAND THAT.

17 CHAIRMAN PENHOET: IS THAT A BIG PART OF
18 YOUR, QUOTE, UNQUOTE, BUSINESS?

19 MS. COO: IT CAN BE. I MEAN BIG IS RELATIVE.
20 WE PROBABLY MAKE, I DON'T KNOW, 100,000 OR SOMETHING.

21 CHAIRMAN PENHOET: A YEAR?

22 MS. COO: A YEAR. WE LICENSE A LOT OF
23 PATENTS FOR INTERNAL RESEARCH PURPOSES. WE LICENSE
24 MICE FOR INTERNAL RESEARCH PURPOSES, YEARLY FEE,
25 SOFTWARE, LOTS OF STUFF FOR INTERNAL RESEARCH PURPOSES.

1 CHAIRMAN PENHOET: SO THAT'S A DOWNSIDE FOR
2 UNIVERSITY GRANTEES.

3 MS. COO: BUT IT'S OKAY WITH US IF THAT'S
4 YOUR PROBLEM.

5 MS. STREITZ: JUST TO SORT OF EXPAND ON THAT
6 A LITTLE BIT, SOMETIMES THE INTERNAL RESEARCH PURPOSE
7 IN A COMPANY IS THE COMMERCIAL USE. SOMETIMES,
8 DEPENDING ON THE NATURE OF THE INVENTION, THE COMPANY'S
9 INTERNAL RESEARCH PURPOSES IS THE COMMERCIAL USE OF THE
10 INVENTION; SAY, FOR EXAMPLE, A HIGH THROUGHPUT ASSAY OF
11 SOME SORT. AND WHILE UNIVERSITIES MAY BE ABLE TO WORK
12 WITH THAT, ONE OF THE SECTORS THAT IT MIGHT
13 DISADVANTAGE WOULD BE BIOTECH COMPANIES WHO RECEIVE
14 CIRM FUNDING, AND THEN THEIR PRODUCT IS A RESEARCH TOOL
15 AND IT'S HOW THEY STAY IN BUSINESS.

16 CHAIRMAN PENHOET: THEY COULD CHOOSE TO TAKE
17 OUR FUNDING OR NOT BASED ON THAT.

18 DR. LOVE: IF THEY DEVELOP IT USING OUR
19 MONEY.

20 CHAIRMAN PENHOET: SO WITH THE APPROPRIATE
21 LANGUAGE AROUND THIS, THE STRAW POLL SAYS WE'D LIKE TO
22 MOVE IN THIS DIRECTION?

23 NOW, WE CAN -- NOW WE HAVE THE HARD ONE
24 COMING. WHAT LICENSING REQUIREMENTS SHOULD BE ADOPTED
25 BY CIRM GRANTEES? AGAIN, BAYH-DOLE, IF WE WANT TO BE

1 COMPATIBLE WITH BAYH-DOLE, WE CAN BE COMPATIBLE. SO
2 FAR I THINK WE'VE DONE NOTHING IN THIS CONVERSATION,
3 AND LICENSING REQUIREMENTS GIVE YOU A LOT OF LATITUDE
4 ABOUT HOW WE PROCEED WITH IT. WE HAVE HEARD A VARIETY
5 OF DIFFERENT PROPOSALS OVER THE LAST SIX MONTHS THAT
6 WE'VE BEEN DEALING WITH THESE ISSUES.

7 IT'S HERE WHERE I THINK CONCERNS ABOUT ACCESS
8 FOR THE UNDERSERVED IN OUR STATE BECOME EVIDENT AND
9 WHERE I THINK WE HAVE TO HAVE SOME ATTENTION PAID TO
10 THAT.

11 SECOND ISSUE IS AN ISSUE THAT HAS BEEN
12 DISCUSSED MANY TIMES ABOUT WHETHER IF OUR GRANTEES OWN
13 THE TECHNOLOGY AND RECEIVE REMUNERATION FOR LICENSING
14 THE TECHNOLOGY TO A THIRD PARTY, DO THEY SHARE ANY OF
15 THAT BACK WITH THE STATE WITH A PRIVATE 501(C)(3) SET
16 UP TO HELP PAY FOR THERAPIES THAT EMERGE FROM THESE
17 RESEARCH PROGRAMS, BUT IN SOME WAY SHARE THAT WITH SOME
18 ENTITY WHICH WILL USE THE FUNDING FOR NOBLE PURPOSE OF
19 SOME KIND.

20 AND THE CCST REPORT RECOMMENDS THAT WE DON'T
21 HAVE THAT SHARING BACK. REBECCA EISENBERG MADE THE
22 SAME POINT IN HER DISCUSSION. ON THE OTHER HAND, I
23 THINK THERE IS AN EXPECTATION EVIDENT IN PROP 71 THAT
24 THERE WOULD BE SHARING BACK, AND WE CAN'T IGNORE THAT
25 TOTALLY. AND SO I THINK THE SIMPLEST SHARING MODEL IS

1 A SIMPLE TAX ON THE ROYALTIES, A FIXED PERCENTAGE.

2 DR. PIZZO: OFF THE TOP.

3 CHAIRMAN PENHOET: OFF THE TOP SO THAT CIRM
4 WOULD NOT ITSELF ENGAGE IN WHAT THE ABSOLUTE AMOUNT OF
5 THE ROYALTY IS.

6 DR. BRYANT: AND ABOVE A CERTAIN AMOUNT.

7 DR. PIZZO: SO HOW WOULD THIS BE DIFFERENT?
8 I'D ASK KATHY. YOU HAVE TO COME FORWARD. BUT HOW
9 WOULD THIS BE DIFFERENT FROM WHAT HAPPENED, SAY, AT A
10 PRIVATE UNIVERSITY LIKE STANFORD WHERE THERE'S A TAX
11 OFF THE TOP THAT SUPPORTS OTL, AND THEN THERE'S
12 PROPORTIONATE AMOUNTS THAT GO TO THE INVESTIGATOR? WE
13 HAVE A DIFFERENT MODEL IN A PRIVATE UNIVERSITY WHICH
14 MEANS A THIRD GOES TO THE -- THE REMAINDER GOES TO THE
15 INVENTOR DEPARTMENT AND THEN THE SCHOOL AT LARGE, BUT
16 THERE'S AN OFF-THE-TOP PORTION THAT GOES TO SUPPORT THE
17 TECHNOLOGY TRANSFER OFFICE.

18 SO YOU'D HAVE -- THE MODEL MIGHT BE THAT YOU
19 JUST HAVE A SIMILAR SORT OF OFF-THE-TOP PROPORTION THAT
20 GOES TO THE STATE, AND THEN YOU CAN FROM THAT
21 REAPPORTION EVERYTHING -- APPORTION EVERYTHING ELSE
22 ACCORDINGLY. SO IT'S NET OF THAT THAT COMES TO THE
23 SCHOOL, AND THEN THEY USE THEIR OWN POLICIES BECAUSE I
24 THINK THEY'RE DIFFERENT AT UC FROM WHAT I CAN GATHER AS
25 COMPARED TO PRIVATE UNIVERSITIES.

1 DR. BRYANT: MY FEELING IS THAT WE'D HAVE TO
2 DO IT AT A DIFFERENT LEVEL RATHER THAN OFF THE TOP. IT
3 WOULD BECOME PART OF THE DOWNSTREAM BECAUSE THE
4 POLICIES ALREADY SAY HOW MUCH THE INVESTIGATOR IS GOING
5 TO GET OR THE INVENTOR IN THE UC SYSTEM.

6 MS. COO: SO WE WOULD BE WILLING TO SHARE.
7 WE SHARE WITH HHMI, FOR EXAMPLE. WHAT WE DO IS WHAT WE
8 WOULD RECOMMEND IS KEEP THE INVENTOR'S SHARE WHOLE, OUR
9 15 PERCENT OFF THE TOP, BLAH, BLAH, BLAH, AND THEN
10 WHAT'S LEFT OVER IS SORT OF INSTITUTIONAL BETWEEN
11 DEPARTMENT AND SCHOOL. AND WHAT WE DO IS SPLIT THAT
12 WITH HHMI, AND ALSO DO THAT WITH THE VA NOW. SO IT'S
13 DOABLE.

14 MR. SHEEHY: CAN I ASK BECAUSE THIS IS A
15 POINT WHERE WE GET BOGGED DOWN AND WE GET ASSAULTED IN
16 THE MEDIA AND BY POLITICIANS. CAN WE MAKE A STRICT
17 SEPARATION BETWEEN THE ARRANGEMENTS WE'RE MAKING WITH
18 ACADEMIC INSTITUTIONS AND WHAT WE MIGHT MAKE WITH THE
19 FOR-PROFIT INSTITUTIONS AND STIPULATE THAT WE'RE
20 TALKING EXCLUSIVELY ABOUT ACADEMIC INSTITUTIONS?

21 CHAIRMAN PENHOET: NONPROFIT INSTITUTIONS.

22 DR. PIZZO: TO THAT REGARD, WE'RE
23 COMPARTMENTALIZING IT A LITTLE BIT BECAUSE WE'RE
24 TALKING ABOUT PRIVATE AND STATE ACADEMIC INSTITUTIONS
25 WHERE THERE MAY BE SOME DIFFERENT GUIDEPPOSTS, AT LEAST

1 AS I'M HEARING THEM. IT CAN WORK OUT. IT'S JUST A
2 MATTER WHERE IN THE STREAM.

3 DR. WRIGHT: THERE'S ONE ISSUE HERE. IF YOU
4 ARE GOING TO CONSIDER THIS IN THE LIGHT OF YOUR PATENT
5 POOLING CONSIDERATIONS, DEALING WITH THIS IN INDIVIDUAL
6 INVESTIGATORS HAVING A STAKE MIGHT COMPLICATE THE
7 POOLING ISSUES. THAT'S INEVITABLE, BUT YOU HAVE TO
8 THINK ABOUT IT.

9 CHAIRMAN PENHOET: WHETHER WE TAX IT OR NOT,
10 WE STILL HAVE THAT ISSUE, BUT IT'S A GOOD POINT.

11 DR. BRYANT: I WOULD -- I THINK THE
12 RECOMMENDATION IN THE CCST REPORT IS ONLY TO DO THAT
13 KIND OF SHARING WHEN YOU REACH A CERTAIN MINIMUM, WHICH
14 IS REFERRED TO, I THINK, 500,000 A YEAR IN REVENUES.

15 CHAIRMAN PENHOET: THAT'S ONE APPROACH.
16 WE'VE HEARD THIS FROM ALL THE UNIVERSITIES WE'VE TALKED
17 TO IS AT LEAST NOT UNTIL THEY'VE COVERED THE COST OF
18 THEIR PATENT. SO IT'S A PORTION OF THE, QUOTE,
19 UNQUOTE, PROFITS THEY WOULD MAKE, NOT FROM THE FIRST
20 DOLLAR, WHETHER IT'S A FLAT AMOUNT OR --

21 MS. COO: AND THE QUESTION WOULD BE WHETHER
22 THE STATE WOULD SHARE IN THE RISK. SO EVEN THOUGH WE
23 SHARE WITH THE VA OR THE HHMI, THEY ALSO PAY FOR PATENT
24 EXPENSES THAT WE HAVE NOT BEEN SUCCESSFUL IN LICENSING,
25 SO THEY SHARE IN THE RISK. AND I DON'T KNOW WHETHER

1 THE STATE CAN AFFORD TO DO THAT.

2 DR. PIZZO: ISN'T IT ALSO TRUE, WHEN YOU TALK
3 ABOUT SOME THRESHOLD NUMBER, LET'S JUST USE THE NUMBER
4 OF \$500,000, THAT'S A REAL MINORITY OF THE OVERALL
5 INVENTIONS THAT COME IN. FOR US IT'S LIKE LESS THAN
6 TEN.

7 MS. COO: TWO OR THREE.

8 DR. PIZZO: SO IT GETS TO BE VERY SMALL.
9 MOST OF THEM ARE WAY BELOW \$100,000.

10 MS. STREITZ: THE THRESHOLD, PICK A NUMBER,
11 BUT THERE'S A VALID REASON FOR A THRESHOLD. YOU TALKED
12 ABOUT THE LOSERS. HHMI DOES SHARE IN COST OF THE
13 INVENTIONS AND THEY SHARE IN THE LOSERS AS WELL AS THE
14 WINNERS. ONE OF THE THINGS THAT WE DO OFTEN WITH
15 NONPROFIT INSTITUTIONS THAT INSIST UPON SHARING
16 REVENUES, BUT REFUSE TO HELP WITH THE EXPENSES, TO HELP
17 WITH THE RISK, IS WE SET THE THRESHOLD, ESPECIALLY WITH
18 THE LARGE FOUNDATIONS, AND WHAT THIS DOES IS SAY THAT
19 WE'RE GOING TO PROBABLY HAVE A NUMBER OF INVENTIONS
20 UNDER YOUR FUNDING. SOME OF THEM WON'T WORK, SOME OF
21 THEM WILL, AND THE ONES THAT DO, WE'RE GOING TO
22 WITHHOLD A CERTAIN AMOUNT THAT'S GOING TO HELP US AT
23 LEAST COVER THE ONES THAT DIDN'T AND KEEP US
24 INCENTIVIZED TO PURSUE THOSE BECAUSE YOU DON'T KNOW IN
25 ADVANCE WHICH ONES ARE GOING TO BE SUCCESSFUL.

1 MS. COO: ANOTHER THING THAT WE'VE NEGOTIATED
2 WITH A NONPROFIT FOUNDATION WAS THAT THE ROYALTY SHARE
3 THAT THEY WOULD LIKE TO HAVE WOULD BE SPENT AT
4 STANFORD. SO EVEN THOUGH THEY HAVEN'T ALLOCATED
5 ROYALTY SHARE, IT'S ACTUALLY USED TO SUPPORT RESEARCH,
6 FURTHER RESEARCH AT STANFORD IN THEIR FIELD. SO IN
7 SOME WAYS, IT STAYS IN RESEARCH.

8 DR. BRYANT: SO IT'S LIKE GIVING IT TO
9 STANFORD.

10 MS. COO: BUT IT'S FOR A PROGRAM. FOR A GOOD
11 PURPOSE.

12 CHAIRMAN PENHOET: I THINK ANOTHER ISSUE IS
13 RELATED TO THE WHOLE ISSUE OF LICENSING TO RESPONSIBLE
14 ENTITIES, AND THE CONCERN ABOUT AFFORDABILITY, ETC., OF
15 THESE THERAPIES WHEN THEY EMERGE. I THINK A NUMBER OF
16 DIFFERENT MECHANISMS HAVE BEEN DISCUSSED TO DEAL WITH
17 IT. ONE IS TO USE THE ROYALTY STREAM, IF THERE IS ONE,
18 TO HELP PAY FOR THESE THINGS.

19 A SECOND IS THERE IS A CONCEPT OF LOWEST
20 AVAILABLE PUBLIC SECTOR PRICE, THAT GRANTEES WOULD
21 AGREE TO PLACE A CONSTRAINT ON THEIR LICENSEES WHICH
22 SAYS THAT THEY WOULD MAKE THERAPIES AVAILABLE TO
23 CALIFORNIANS, TO UNDERSERVED CALIFORNIANS, HOWEVER WE
24 WANT TO DEFINE THAT, AT THE LOWEST AVAILABLE PUBLIC
25 SECTOR PRICE. THAT USUALLY IS EFFECTIVELY WHAT THE

1 FEDERAL GOVERNMENT IS PAYING FOR THESE THINGS.

2 WE HAVE DISCUSSED INTERNALLY THE ISSUE OF IF
3 YOU WANTED MORE FAVORABLE PRICING THAN THAT, WOULD IT
4 BE POSSIBLE? WOULD YOU GET ANY GRANTEEES TO TAKE A
5 LICENSE? UNFORTUNATELY THE FEDERAL GOVERNMENT AND
6 OTHER PURCHASERS HAVE WHAT ARE CALLED MOST FAVORED
7 NATION CLAUSES. SO IMMEDIATELY IF A COMPANY MADE A
8 LICENSED THERAPY AVAILABLE TO CALIFORNIANS AT A LOWER
9 PRICE THAN THE GOING RATE, THAT WOULD BECOME THE RATE
10 THROUGHOUT THE U.S. IT'S JUST THE WAY THINGS UNFOLD
11 EXCEPT IN THE PRIVATE MARKET. THE FEDERAL GOVERNMENT
12 WOULD THEN GET THAT PRICE AS WELL. SO I THINK THIS IS
13 A HARD ISSUE OF HOW YOU FRAME THIS LANGUAGE.

14 WE'VE TALKED TO SEVERAL PEOPLE IN THE
15 LEGISLATURE, AND THE OTHER THING IS YOU COULD GIVE
16 PREFERENCES TO COMPANIES WHICH ACTUALLY HAVE PROGRAMS
17 AVAILABLE FOR PROVIDING THEIR PRODUCTS TO PEOPLE WHO
18 COULDN'T OTHERWISE AFFORD THEM. GENENTECH, FOR
19 EXAMPLE, HAS A PROGRAM FOR SMALL -- FOR PEOPLE WHO --
20 DWARFS WHO COULD BENEFIT FROM GROWTH HORMONE THERAPY.
21 THEY CAN'T AFFORD TO BUY TO IT, THEY WILL PROVIDE SOME.
22 YOU COULD GIVE SOME KIND OF PREFERENCE TO COMPANIES
23 THAT HAVE PROGRAMS LIKE THAT. SO THERE ARE A VARIETY
24 OF THINGS THAT CAN BE DONE.

25 DR. PRIETO: IN THIS VEIN, I REALLY LIKE THE

1 GATES FOUNDATION MODEL OF REQUIRING THE GRANTEES TO
2 DEFINE HOW THEY' LL PROVIDE PUBLIC BENEFIT AND
3 PUTTING --

4 CHAIRMAN PENHOET: IN THE LICENSE.

5 DR. PRIETO: AND PUTTING SOME OF THE ONUS ON
6 THEM TO COME UP WITH THE BEST IDEAS FOR DOING THIS.

7 AND THE OTHER THING I WONDER ABOUT REGARDING
8 THIS SPECIFIC ISSUE IS WHETHER THERE' S A WAY AROUND THE
9 WHOLE NONTAXABLE VERSUS TAXABLE BONDS IF A CERTAIN
10 PROPORTION OR PERCENTAGE OF THERAPIES ARE GIVEN AWAY,
11 NOT SOLD, SO NOT VIOLATING THE LOWEST PRICE
12 STIPULATION, BUT ZERO PRICE.

13 CHAIRMAN PENHOET: THAT' S WHAT WE WERE
14 REFERRING TO VOLUNTARILY DO THAT TODAY.

15 DR. PRIETO: ONE THING JUST IN THE
16 PHARMACEUTICAL WORLD, MOST COMPANIES HAVE SOMETHING
17 LIKE THIS. FROM A PRACTICAL POINT OF VIEW OF TREATING
18 PATIENTS, SOME DO IT MUCH BETTER THAN OTHERS, MORE
19 GENEROUSLY THAN OTHERS. SOME REQUIRE SO MANY HOOPS TO
20 BE JUMPED THROUGH SO FREQUENTLY, THAT AS A PRACTICAL
21 MATTER, THEY' RE REALLY NOT PROVIDING MUCH BENEFIT.

22 DR. LOVE: I LIKE WHAT YOU JUST SAID. I MEAN
23 I THINK IF WE COULD SOMEHOW MAKE THIS PART OF THE
24 APPLICATION, WE MIGHT FIND OURSELVES IN A POSITION
25 WHERE WE GET MORE CREATIVE IDEAS THAN WE COULD HAVE

1 GENERATED ON OUR OWN, AND WE ALSO DON'T PUT OURSELVES
2 AT RISK OF COMING UP WITH SOMETHING THAT ULTIMATELY
3 BLOCKS INSTITUTIONS FROM ACTUALLY WANTING TO DO THIS
4 BECAUSE PRESUMABLY THEY'RE ONLY GOING TO PROPOSE WHAT
5 THEY'RE WILLING TO DO.

6 CHAIRMAN PENHOET: BUT THAT TIME WOULD OCCUR
7 WHEN YOU'RE ACTUALLY ENGAGED WITH THE LICENSEE, NOT
8 WITH THE GRANTEE. I THINK IT WOULD BE HARD FOR
9 UNIVERSITIES TO ANTICIPATE IN ADVANCE HOW THAT WOULD
10 WORK.

11 DR. PIZZO: I RESPECT THE GOAL, BUT I HAVE A
12 SIGNIFICANT WORRY ABOUT IT, WHICH IS THAT WE'RE LIVING
13 IN A VERY PUBLIC ENVIRONMENT. I REALIZE THAT THE GATES
14 FOUNDATION IS AS WELL, BUT IT'S DIFFERENT BECAUSE
15 THEY'RE FOCUSED ON DEVELOPING NATIONS AND THAT'S THEIR
16 GOAL. I THINK IF WE WERE TO HAVE HIGH DEGREES OF
17 VARIANCE COMING OUT WITH DIFFERENT INDIVIDUALS AND
18 DIFFERENT CENTERS COMING FORWARD WITH RECOMMENDATIONS,
19 WE MAY WIND UP POLITICIZING THIS IN VERY SIGNIFICANT
20 WAYS, SOME THAT WE'RE NOT ANTICIPATING NOW. I THINK
21 THAT, ALTHOUGH IT MAY BE MORE BURDENSOME, I THINK IT
22 WOULD BE BETTER FOR US TO COME UP, AT LEAST FOR THE
23 FIRST PASS, WITH SOME PRINCIPLES THAT WE COULD LIVE
24 WITH. AND WE CAN ALWAYS WELCOME CREATIVE SUGGESTIONS,
25 BUT I WOULD TRY TO CODIFY THEM AS COMPARED TO MAKING

1 THEM ONE OFF FROM EACH OTHER.

2 DR. LOVE: JUST TO CLARIFY, I WAS ACTUALLY
3 ONLY TALKING ABOUT PRIVATE INSTITUTIONS, COMPANIES,
4 APPLYING, AND NOT SOMETHING THAT WOULD PASS BACK TO THE
5 GRANTEE. SO IF A GENENTECH WERE APPLYING, THIS IS HOW
6 WE EXPECT.

7 CHAIRMAN PENHOET: BUT FOR THIS DISCUSSION
8 TODAY, WE'RE TALKING ABOUT NONPROFIT INSTITUTIONS.

9 MR. GOLDBERG: I HAD A COUPLE. THE FIRST
10 CONCERN I'VE GOT, AND I THINK IT'S A GOOD IDEA, BUT AS
11 A PRACTICAL MATTER, I DON'T KNOW WHO HERE, WHETHER IT'S
12 STAFF, IT'S CERTAINLY NOT GOING TO BE OUR EXTERNAL PEER
13 REVIEWERS, IN CONNECTION WITH A SCIENTIFIC GRANT
14 APPLICATION TRYING TO FIGURE OUT WHAT THE SOCIAL POLICY
15 IMPLICATIONS ARE OF VARIOUS PROPOSALS. SO I'M TROUBLED
16 BY THAT BURDEN THAT WE WOULD UNDERTAKE IN AN EFFORT TO
17 TRY TO DO GOOD.

18 BUT I AM REMINDED OF THE COMMENT THAT, I
19 GUESS, PERRY MADE WHEN HE WAS HERE ABOUT THE
20 POSSIBILITY OF ESTABLISHING A 501(C)(3) BECAUSE THIS IS
21 WHAT MANY COMPANIES DO TO ACTUALLY ADMINISTER AND
22 MANAGE THEIR INDIGENT PATIENT PROGRAMS SO THAT THEY
23 DON'T ACTUALLY GET INVOLVED IN THE ADMINISTRATION OF
24 THE PROGRAM, AND THEY DON'T GET -- THEY JUST BASICALLY
25 GIVE A PORTION OF EITHER GRANT PROCEEDS OR A PORTION

1 OF, QUOTE, UNQUOTE, FREE GOODS, AND THEN THEY KIND OF
2 GET OUT OF THE WAY AND THEY ENGAGE WITH PATIENT
3 ADVOCACY -- THE ONES THAT DO IT WELL IS MY
4 OBSERVATION -- ENGAGE WITH PATIENT ADVOCACY
5 ORGANIZATIONS THAT, IN ESSENCE, GUIDE THE DISBURSEMENT
6 OF THOSE BENEFITS.

7 AND I GUESS THE QUESTION I'VE GOT, NOT TO BE
8 RESOLVED HERE, BUT PERHAPS MIGHT PROVIDE A DOUBLE-EDGED
9 SOLUTION FOR US IS TO GET US OUT OF THIS PROCESS, TO
10 TAKE A PORTION OF THE ROYALTIES THAT WOULD OTHERWISE
11 FLOW BACK TO CIRM, LET THEM GO INTO THIS 501(C)(3)
12 THAT'S NOT CONTROLLED BY CIRM, AND COME UP WITH SOME
13 METHOD BY WHICH THAT 501(C)(3) WOULD APPROPRIATELY
14 DISBURSE FUNDS FOR THE PURPOSE OF ADDRESSING INDIGENT
15 PATIENT GROUPS.

16 DR. BRYANT: SO THE DOWNSIDE OF THAT IS THAT
17 THEY MIGHT DO SOMETHING WE WOULDN'T LIKE, BUT WE'D HAVE
18 NO CONTROL OVER IT.

19 DR. WRIGHT: BUT YOU'RE SAYING WE'D SET THE
20 POLICY FOR THAT 501(C)(3).

21 MR. GOLDBERG: WE CAN'T CONTROL IT.

22 CHAIRMAN PENHOET: I THINK WE CAN CONTROL IT
23 IF IT'S A STATE AGENCY. THERE ARE WAYS THAT ITS
24 CHARTER CAN CERTAINLY BE ESTABLISHED.

25 MR. SHEEHY: HOW CAN WE ALLOCATE GENERAL FUND

1 DOLLARS? WE DON'T HAVE THE POWER. I DON'T SEE PROP 71
2 GIVING US THE ABILITY TO TAKE RETURN THAT'S BEEN
3 PROMISED IN PROP 71 TO THE STATE AND THEN REALLOCATING
4 IT TO ANOTHER ENTITY. THAT SEEMS VERY PRESUMPTUOUS.

5 DR. BRYANT: THAT WAS THE WAY THAT WAS
6 SUGGESTED IT BE RETURNED TO THE STATE.

7 MR. SHEEHY: WE SET UP -- WE'RE GOING TO
8 COLLECT ROYALTIES WITH STATE BONDS AND SET UP A
9 SEPARATE ENTITY. BUT WHAT I WAS WONDERING ACTUALLY --

10 MR. GOLDBERG: NO. WE COULD SAY FOR A
11 HYPOTHETICAL, YOU DON'T EVEN HAVE TO SET UP A
12 501(C)(3), WE COULD SAY IN THE GRANT AGREEMENT THE
13 INTELLECTUAL PROPERTY ROYALTIES, AND THEY GO THE
14 AMERICAN CANCER SOCIETY, JUST TO PICK ONE, OR THE
15 AMERICAN CARDIOLOGY SOCIETY.

16 DR. PIZZO: STANFORD UNIVERSITY.

17 MR. GOLDBERG: THAT WAS A FAILURE OF MY
18 UNDERGRADUATE EDUCATION.

19 MR. SHEEHY: I HAVE TROUBLE WITH US ASSIGNING
20 SOMETHING OF VALUE TO THE STATE OF CALIFORNIA,
21 ESPECIALLY DOLLARS AND CENTS TO SOME OTHER ENTITY. I
22 THINK THAT'S A LEGISLATIVE FUNCTION MYSELF.

23 THE QUESTION I HAD IS WHAT WOULD KEEP US FROM
24 USING -- FROM PUTTING IN A MARCH-IN RIGHT ASKING FOR
25 THE LOWEST AVAILABLE PUBLIC SECTOR PRICE FOR CALIFORNIA

1 STATE BULK PURCHASERS?

2 CHAIRMAN PENHOET: WE CAN DO THAT.

3 MR. SHEEHY: THAT MIGHT BE THE WAY TO GET
4 THERE AS A MARCH-IN RIGHT. AND THEN IT'S A -- THAT WAY
5 WE WOULD GUARANTEE THAT THE STATE FOR INVENTIONS THAT
6 ARE PRODUCED FROM SUBSTANTIAL AMOUNTS OF CALIFORNIA --
7 CIRM-FUNDED INTELLECTUAL PROPERTY MIGHT BE A BETTER WAY
8 TO GET TO THE PRICING ISSUE. I'M LEERY OF THESE -- OF
9 TRYING TO SET UP SOMETHING -- AND I COME AT THIS FROM
10 THE HIV POINT OF VIEW. WE HAVE ADAP, WHICH IS THE AIDS
11 DRUG ASSISTANCE PROGRAM, THAT WE SET UP SOMETHING WITH
12 THE GOVERNMENT AND STATES TO COME IN AND BUY DRUGS, AND
13 IT'S A VERY IMPERFECT SITUATION. AND IT'S AN ATTEMPT
14 TO SOLVE THE PROBLEM THAT'S A MUCH LARGER PROBLEM. AND
15 WE'RE GOING TO END UP WHERE THERE'S A WAITING LIST FOR
16 SOMEBODY SOMEWHERE. AND THERE ARE WAITING LISTS FOR
17 ADAP IN PARTS OF THIS COUNTRY, AND IT'S A HUGE
18 POLITICAL ISSUE, THAT I COULD GET DRUGS THAT PEOPLE IN
19 SOUTH CAROLINA CAN'T GET.

20 AND I THINK THAT THERE'S NOT GOING TO BE A
21 REAL SIMPLE SOLUTION THAT WE CAN PUT INTO
22 ADMINISTRATIVE LAW CODE.

23 DR. LOVE: I THINK IF YOU HAVE THE PRICING,
24 FAVORED PRICING FOR CALIFORNIANS, I AS A CEO OF A
25 COMPANY WOULDN'T TOUCH THE MONEY. I WOULDN'T TOUCH THE

1 MONEY BECAUSE I THINK IT WILL CREATE UNIMAGINABLE
2 CHALLENGES AROUND FINANCING THE REST OF YOUR COMPANY.
3 SO I DON'T KNOW.

4 CHAIRMAN PENHOET: WELL, CAN WE DISTINGUI SH,
5 TED, BETWEEN TWO ISSUES? ONE IS MORE FAVORABLE PRICING
6 IN CALIFORNIA THAN ELSEWHERE. THE SECOND IS LOWEST
7 AVAIL ABLE PUBLIC SECTOR PRICING. THAT IS, YOU WOULD
8 ALLOW CALIFORNI ANS TO BUY AT THE SAME PRICE AS THE
9 FEDERAL GOVERNMENT.

10 DR. LOVE: IT'S 20 PERCENT OF THE MARKET.

11 MR. SHEEHY: ALLOW PUBLIC SECTOR PURCHASERS.

12 CHAIRMAN PENHOET: IT'S THE PUBLIC SECTOR
13 THAT WE'RE TALKING ABOUT, UNDERSERVED AND MEDI -CAL
14 PATIENTS.

15 DR. PRIETO: I THINK WHAT THAT DOES IS
16 BASICALLY IT JUST IMPACTS THE OVERALL PRICING. IT
17 DOESN'T REALLY NECESSARILY GUARANTEE A LEVEL OF
18 AFFORDABIL ITY THAT'S REASONABLE. AND MAYBE THERE ARE
19 SOME OTHER WAYS TO DO IT. IT WAS BROUGHT UP EARLIER
20 THE NOTION OF A STATE TAXING ROYALTIES, TAXING
21 DOWNSTREAM, AND MAYBE THIS WOULD JUST BE A
22 RECOMMENDATION THAT WE COULD PUT FORWARD FOR ALL
23 STATE-FUNDED RESEARCH, NOT JUST CIRM-FUNDED RESEARCH,
24 THAT THE LEGISLATURE WOULD ENACT THAT STATE-FUNDED
25 RESEARCH SHALL RETURN X PERCENT, I DON'T KNOW, 2

1 PERCENT, 27 PERCENT OF ROYALTY NET PROCEEDS BACK INTO
2 THE GENERAL FUND, AND COMPLETELY TAKE IT OUT OF OUR
3 HANDS, BUT GUARANTEE A RETURN IF THERE IS ONE.

4 DR. FONTANA: HOW ABOUT INSTEAD OF THE
5 GENERAL FUND, PUT IT INTO MEDI-CAL?

6 DR. PRIETO: FINE. WE WILL NOT DEFINE THAT.
7 WE COULD ENCOURAGE IT AND SAY WE COULD LIVE WITH THAT,
8 WE WOULD HAVE NO PROBLEM WITH IT, BUT IT WOULD BE A
9 GENERAL POLICY FOR ALL STATE-FUNDED RESEARCH.

10 CHAIRMAN PENHOET: I THINK THERE ARE TWO WAYS
11 OF COMING AT THE SAME ISSUE OF AFFORDABILITY. ONE IS
12 DIRECTING A TAX ON ROYALTIES TO A SPECIFIC PURPOSE,
13 WHICH IS TO HELP PAY FOR THESE THERAPIES. AND THE
14 SECOND APPROACH IS TO ADDRESS THE PRICING ISSUE MORE
15 SQUARELY. I THINK TED LOVE, AS AN INDUSTRY
16 REPRESENTATIVE, IS WORRIED ABOUT THAT APPROACH. AND
17 YOU KNOW, THE LAST THING -- IT WOULD BE UNWISE, I
18 THINK, TO DISCOURAGE PRIVATE SECTOR INVESTMENT IN THIS
19 TECHNOLOGY GOING FORWARD BECAUSE WE ALL KNOW THAT IN
20 ORDER TO REACH PATIENTS, PRIVATE SECTOR SOONER OR LATER
21 HAS TO GET ENGAGED.

22 MR. GOLDBERG: THERE'S MORE THAN JUST THE
23 PRICING ISSUE THAT TED POINTS OUT. THERE'S ALSO THE
24 POINT, MAYBE IT WAS BECKY EISENBERG'S REMARKS, THAT
25 INDICATED THERE'S A DRUG DIVERSION ISSUE THAT WE HAVE

1 IN CANADA. BECAUSE OF THE PRICING DISCREPANCY IN
2 CANADA BETWEEN THE UNITED STATES, WE HAVE DRUG
3 DIVERSION ISSUES WITH CANADA, AND WE COULD HAVE DRUG
4 DIVERSION ISSUES WITHIN CALIFORNIA AS A RESULT OF THIS
5 KIND OF PRICING POLICY, WHICH I DON'T THINK IS A
6 PARTICULARLY GOOD THING TO INTRODUCE, AT LEAST
7 UNKNOWINGLY.

8 DR. LOVE: AT ONE POINT WE WERE TALKING ABOUT
9 THE UNCERTAINTIES IS WHERE PEOPLE GET REALLY NERVOUS.
10 AND I THINK HAVING THINGS OUT THERE WHICH ARE HARD TO
11 DEFINE, BUT THE IMPLICATIONS ARE REALLY GOING TO BE
12 DOWN THE ROAD, WILL DISCOURAGE A LOT OF PEOPLE FROM
13 PUTTING THEIR MONEY AT RISK THAT WILL ULTIMATELY FUEL
14 THIS.

15 CHAIRMAN PENHOET: MAYBE THIS IS A GOOD TIME
16 FOR PUBLIC COMMENT. DON REED HAS HIS HAND UP, SO YOU
17 CAN START.

18 MR. REED: ALL THESE ARE WONDERFUL
19 SUGGESTIONS, BUT I THINK WE HAVE TO GO BACK TO WHAT DR.
20 PRIETO SAID EARLIER. BECAUSE THERE ARE THESE --
21 EVERYTHING IS SO VARIED AND SO UNCERTAIN, IF THE
22 INDIVIDUAL GRANT PERSON IS RESPONSIBLE FOR SAYING HOW
23 THE PUBLIC WILL BENEFIT, THAT LEAVES US OPEN FOR ALL
24 KINDS OF POSSIBILITIES, ALL KINDS OF SOLUTIONS. AND
25 ALSO I'M THINKING ABOUT THOSE WHO WOULD LIKE TO IMPOSE

1 NEGATIVE LEGAL RESTRICTIONS ON US LIKE AN SCA 13. ONE
2 OF THE THINGS THAT THE MOST RECENT VERSION OF IT SAID
3 THAT THE BEST FAITH EFFORT MUST BE MADE TO BRING THE
4 PUBLIC BENEFIT AND AFFORDABLE COST. IF THIS WAS THE
5 INDIVIDUAL SUGGESTING THIS AS PART OF HIS OR HER
6 RESEARCH PROPOSAL, THEN ONLY THAT GRANT WOULD BE AT
7 RISK, NOT THE ENTIRE PROGRAM. ONLY THAT GRANT COULD BE
8 SUED, NOT THE ENTIRE PROGRAM. SO I'D LIKE TO SEE THE
9 INDIVIDUAL HAVE RESPONSIBILITY FOR HOW HIS OR HER
10 PROJECT WOULD AFFECT THE STATE.

11 CHAIRMAN PENHOET: I'LL SPEAK AS A FORMER
12 LABORATORY SCIENTIST. WHEN I WAS IN THAT ROLE, I
13 DIDN'T HAVE A CLUE. THAT'S THE PROBLEM. SO 99 PERCENT
14 OF OUR GRANTEES WOULDN'T -- THEY SPEND THEIR LIVES
15 FOCUSING AT A VERY NARROW SET OF ISSUES.

16 MR. REED: BUT FOR MONEY AND SURVIVAL, THEY
17 COULD LEARN.

18 CHAIRMAN PENHOET: THERE'S AN ISSUE OF
19 DISTRACTING THEM FROM THEIR IMPORTANT WORK. WHERE IT
20 WOULD COME DOWN IS THAT THE KATHY COOS OF THE WORLD WHO
21 RUN TECHNOLOGY TRANSFER OFFICES SPECIFICALLY TO
22 ASSEMBLE THIS BURDEN FOR AN INSTITUTION LIKE STANFORD
23 IN ONE PLACE WHERE THEY'RE EXPERT AT THIS, SO I THINK
24 THAT THE PRESSURE POINT WOULD END UP BEING THE
25 LICENSING OFFICE, NOT THE INDIVIDUAL GRANTEES.

1 DR. HALL: LET ME JUST SAY I THINK IT WOULD
2 BE A TERRIBLE MISTAKE TO ASK INDIVIDUAL INVESTIGATORS
3 TO DO THIS. I THINK WHAT ED SAYS IS CORRECT. WHAT
4 WOULD HAPPEN IS PEOPLE WOULD FIGURE OUT SOME WAY NOT TO
5 BE DISTRACTED BY IT. YOU CAN'T ASK EVERYBODY TO GO OUT
6 AND PICK UP SOME NEW SCHEME. FOR MANY OF THEM, THERE'S
7 NO PRACTICAL END. THEY'RE NOT -- IT'S NOT SOMETHING --
8 IF RESEARCH IS NOT SOMETHING THEY ENGAGE IN, THEIR
9 PROJECT WOULD BE AN IMMEDIATE END.

10 YOU COULD ASK INSTITUTIONS TO DO IT. BUT I
11 SEE THE PROBLEM THAT WAS BROUGHT UP BEFORE. HOW ARE
12 WE -- IF THIS IS DONE BEFORE THE GRANTS ARE JUDGED, HOW
13 IS THIS TO BE FIT IN? WHO'S TO MAKE THE JUDGMENT? AND
14 IT SEEMS TO ME THAT OPENS US UP TO ALL KINDS OF
15 PROBLEMS. ONE INSTITUTION IS GOING TO BE FAVORED OVER
16 ANOTHER BECAUSE THEY HAVE A PARTICULAR PLAN.

17 I WOULD SUGGEST IF WE WANT TO GET ALL THESE
18 INDIVIDUAL IDEAS, THAT WHAT WE WOULD DO WOULD BE TO
19 HAVE A WORKSHOP WITH REPRESENTATIVES FROM VARIOUS
20 INSTITUTIONS TO SAY LET'S HEAR FROM YOU WHAT YOUR IDEAS
21 MIGHT BE ABOUT HOW TO SOLVE THIS PROBLEM. AND THEN
22 DRAW ON REPRESENTATIVES FROM ALL THESE PEOPLE TO COME
23 UP. AND PEOPLE LIKE KATHY AND WENDY, THERE'S AN
24 ENORMOUS AMOUNT OF TALENT IN THE CALIFORNIA NONPROFIT
25 RESEARCH INSTITUTION COMMUNITY OF PEOPLE WHO'VE THOUGHT

1 A LOT ABOUT THIS, WHO ARE VERY SAVVY ABOUT IT, AND WHO
2 MAY VERY WELL HAVE CREATIVE IDEAS.

3 I WOULD SUGGEST WE DON'T NEED THAT FOR OUR
4 INTERIM POLICY, BUT IT MIGHT BE SOMETHING TO THINK
5 ABOUT AS WE MOVE FROM AN INTERIM TO A FINAL REGULATION.

6 MR. REYNOLDS: GOOD AFTERNOON. JESSE
7 REYNOLDS. JUST A COUPLE OF THOUGHTS TO COMPLICATE
8 THINGS. I'M ENCOURAGED BY THE TONE OF THE CONVERSATION
9 ABOUT HOW TO REALLY ADDRESS AFFORDABILITY AND
10 ACCESSIBILITY HEAD ON. ONE THING TO CONSIDER, THOUGH,
11 IS THAT IF STEM CELL RESEARCH HEADS DOWN THE ROAD OF
12 THESE CUSTOMIZABLE CELL LINES AND CELL-BASED THERAPIES,
13 AND IF THOSE THERAPIES ARE REALLY EXPENSIVE, YOU MIGHT
14 END UP WITH A SITUATION WHERE, ONE, IF THOSE THERAPIES
15 ARE NOT COVERED BY, LET'S SAY, MEDI-CAL, THAT EVEN IF
16 THEY ARE MADE AVAILABLE AT THE LOWEST PUBLIC SECTOR
17 AVAILABLE PRICE, THEN THAT STILL MIGHT BE OUT OF REACH.
18 AND THEN SECOND, THERE'S ALSO A DEMOGRAPHIC THAT IS
19 ABOVE THE MEDI-CAL THRESHOLD, BUT STILL RELATIVELY LOW
20 INCOME, LIKE A LOWER MIDDLE CLASS, AND THIS IS
21 PARTICULARLY THE CASE AS THESE PROGRAMS ARE CUT BACK
22 WHERE THAT WOULD CONTINUE TO BE -- WHERE THIS IS A
23 CONSIDERATION WHERE THIS MIGHT BE A SEGMENT OF THE
24 POPULATION THAT CAN BE OVERLOOKED IF YOU PEG IT SOLELY
25 TO MEDI-CAL OR OTHER STATE PROGRAMS. THANKS.

1 DR. PIZZO: I WANT TO RESPOND TO THAT IN
2 MAYBE A LITTLE BIT TANGENTIAL WAY. I THINK THE POINTS
3 YOU'RE RAISING ARE REALLY IMPORTANT, BUT I THINK THEY
4 GO BEYOND STEM CELLS AND THEY SPEAK TO THE FACT THAT WE
5 DON'T HAVE A HEALTHCARE SYSTEM EITHER IN THIS STATE OR
6 IN THIS NATION. AND WE NEED TO ADDRESS THOSE
7 FUNDAMENTAL PROBLEMS BECAUSE THEY ARE MUCH BROADER THAN
8 STEM CELLS.

9 DR. PRIETO: ALONG THE SAME LINES, IN REGARDS
10 TO JESSE'S FIRST POINT, THIS WOULD BE LOWEST AVAILABLE
11 PUBLIC SECTOR PRICING FOR THE CALIFORNIA PUBLIC SECTOR,
12 WHICH IS MEDI-CAL, SO THAT BY DEFINITION WOULD BE --
13 MEDI-CAL WOULD BE INVOLVED. BUT THE OTHER IS THAT, AS
14 PHIL POINTED OUT, THE PROBLEMS WITH OUR HEALTHCARE
15 SYSTEM ARE MUCH, MUCH BIGGER THAN ANYTHING THAT CIRM
16 COULD EVER HOPE TO ADDRESS. IT IS DYSFUNCTIONAL.

17 DR. PIZZO: THIS WOULD BE A GREAT PLACE FOR
18 US TO BE A MODEL.

19 DR. PRIETO: WE CAN'T SOLVE IT.

20 CHAIRMAN PENHOET: WE UNDERSTAND THAT AT
21 LEAST UNDER SOME CIRCUMSTANCES UNINSURED HAVE BEEN
22 INCLUDED IN PROGRAMS LIKE THIS, SO YOU EXPAND IT BEYOND
23 MEDI-CAL TO OTHER UNINSURED IN CALIFORNIA. THERE
24 PROBABLY IS A WAY FOR US TO INCLUDE AT LEAST SOME
25 FRACTION OF THE POPULATION. THAT DOES EXPAND THE

1 PRICING BASE TO SOME DEGREE, BUT NEVERTHELESS, MAYBE TO
2 A BASE THAT WOULDN'T BE ABLE TO AFFORD THESE THERAPIES.
3 BOB.

4 MR. KLEIN: JUST RELATING TO JESSE'S COMMENT
5 ON THE LIMITED NATURE OF THESE AND POTENTIALLY CREATING
6 THE LOWEST PUBLIC PRICE FOR MEDI-CAL MAY NOT WORK
7 BECAUSE IT'D BE TOO HIGH A PRICE FOR MEDI-CAL TO COVER
8 IT IN CALIFORNIA ON A BROAD SCALE, THAT IF WHATEVER
9 SHARE OF ROYALTIES OR LICENSING REVENUES ARE SET ASIDE
10 ARE SET ASIDE TO ESTABLISH MODEL ACCESS PROGRAMS FOR
11 NEW THERAPIES FOR THE MEDI-CAL LEVEL PATIENT, THEN THE
12 STATE HAS THE BENEFIT OF FOCUSING ITS FUNDS TO GET REAL
13 ACCESSIBILITY, EFFECTIVE ACCESSIBILITY, AT LEAST FOR
14 THE MODEL GROUP AND HOPEFULLY BY FUNDING EARLY
15 INTERVENTION OF STEM CELL THERAPIES.

16 IN THE SPINAL CORD INJURY FIELD, FOR EXAMPLE,
17 YOU COULD SHOW THAT TREMENDOUS DOWNSTREAM COSTS WERE
18 AVOIDED, AND YOU'D HAVE EVIDENTIARY MATERIAL TO
19 CONVINCING THE STATE LATER TO APPROPRIATE AT A LEVEL THAT
20 WE COULD AFFORD TO HAVE STATE COVERAGE. OR WITH
21 DIABETES YOU COULD SHOW BY EARLY INTERVENTION YOU AVOID
22 BLINDNESS, YOU AVOID KIDNEY LOSS, YOU AVOID
23 AMPUTATIONS, HUGE DOWNSTREAM COSTS. AND ON A COST
24 BASIS CONVINCING THE STATE THAT THE STATE SHOULD PAY FOR
25 COVERAGE OF THESE NEW THERAPIES.

1 SO A MODEL ACCESS PROGRAM THAT FOCUSES
2 LIMITED AMOUNTS OF ROYALTIES MIGHT VERY EFFECTIVELY BE
3 THE BASE FROM WHICH YOU PROVE THE POINT THAT IT IS
4 IMPORTANT AND EQUITABLE TO HAVE THESE THERAPIES
5 AVAILABLE TO EVERYONE AND IT IS ON A COST-BENEFIT BASIS
6 EFFECTIVE FOR THE STATE.

7 DR. PIZZO: I JUST WANT TO OFFER THE CONCERN,
8 THIS IS JUST A CONCERN FOR THE RECORD, IS WE TALK ABOUT
9 TRYING TO USE ROYALTIES FOR COVERING UNINSURED OR
10 UNDERSERVED IN VERY APPROPRIATE AND IMPORTANT WAYS. MY
11 FEAR IS THAT WE ARE SETTING AN EXPECTATION THAT'S NOT
12 GOING TO BE FULFILLABLE BECAUSE I DON'T REALLY IN MY
13 HEART BELIEVE THAT THERE'S GOING TO BE THAT MUCH
14 REVENUE THAT'S GOING TO BE GENERATED TO ALLOW THAT TO
15 HAPPEN. I THINK IT'S SORT OF A JUST -- I DON'T WANT TO
16 OVERSTATE IT BASED UPON ANY ONE INSTITUTION'S
17 EXPERIENCE, BUT STANFORD HAS HAD, JUST AS THE UC'S, A
18 VERY STRONG RECORD IN TECHNOLOGY TRANSFER. AND THERE'S
19 NOT -- FOR ALL THE PATENTS THAT COME FORWARD, THERE ARE
20 VERY FEW THAT YIELD LARGE AMOUNTS OF MONEY. AND EVEN
21 THOSE THAT YIELD -- LET'S TAKE THE LARGEST ONE THAT WAS
22 SHARED BETWEEN UC AND STANFORD, THE COHEN BOYER. SO
23 THAT'S NOT GOING TO COVER A LOT OF PEOPLE WHEN WE GET
24 RIGHT DOWN TO IT. EVEN IF WE SPENT EVERY PENNY ON IT,
25 IT'S NOT GOING TO SOLVE THE PROBLEM.

1 SO I THINK WE NEED TO BE IN OUR DISCOURSE
2 WITH THE STATE AND WITH THE COMMUNITY AND WITH OTHERS,
3 WE NEED TO BE VERY HONEST ABOUT WHAT'S LIKELY TO COME
4 OUT OF ROYALTIES. I DON'T THINK IT'S GOING TO BE THE
5 VEHICLE FOR PROVIDING FOR CARE. I THINK IT MAY HELP A
6 BIT, BUT I DON'T THINK THAT'S GOING TO BE THE SOLUTION.

7 DR. PRIETO: I THINK IN TERMS OF DOLLARS
8 SPENT OR DOLLARS RECOVERED, YOU'RE RIGHT. BUT I THINK
9 THE POINT THAT BOB MADE IS STILL THAT YOU CAN
10 DEMONSTRATE SOMETHING IN A MODEL PROGRAM THAT HAS A
11 GREAT VALUE DOWN THE ROAD.

12 DR. PIZZO: DIFFERENT ISSUE.

13 DR. PRIETO: RIGHT, IT IS A DIFFERENT ISSUE.
14 I WANT TO COME BACK TO THE POINT I MADE ABOUT
15 SUGGESTING SOMETHING TO THE LEGISLATURE AND PASSING
16 THIS OFF, THAT IT'S NOT JUST AN ISSUE FOR CIRM. IT'S
17 AN ISSUE FOR ALL STATE-FUNDED RESEARCH. AND THE STATE
18 WOULD ALSO BENEFIT FROM HAVING A MORE UNIFIED,
19 CONSISTENT APPROACH TO THAT. IT'S NOT OUR ISSUE.

20 DR. PIZZO: LET ME JUST -- IF I CAN BE THE
21 DEVIL'S ADVOCATE FOR A MOMENT. IN WHAT WAYS WOULD OUR
22 ROYALTY EARNINGS BETTER HELP OR BEST HELP THE COMMUNITY
23 OF CALIFORNIA CITIZENS IN NEED OF DISCOVERIES? THE
24 ARGUMENT THAT WE'RE PROCEEDING ALONG IS THAT WE WOULD
25 UTILIZE WHATEVER PROCEEDS WERE AVAILABLE TO ACTUALLY

1 PAY FOR CARE. SO THAT'S -- OR PAY FOR THE STEM CELL
2 THERAPIES. THAT'S THE THING THAT WE ARE CURRENTLY
3 POSITING.

4 THE ALTERNATIVE ARGUMENT WHICH I WOULD OFFER
5 IS THAT WE WOULD BE BETTER SERVED IF WE REINVESTED THAT
6 IN RESEARCH THAT GENERATED MORE DISCOVERIES THAT
7 FURTHER LOWER THE COST OF CARE BECAUSE OF THEIR IMPACT
8 UPON A MUCH BROADER COMMUNITY. I THINK THAT IS WHERE
9 THERE'S A BIGGER RETURN ON THE INVESTMENT, BUT THAT'S A
10 DIFFERENT DIALOGUE.

11 DR. PRIETO: HOW ABOUT MUTUALLY EXCLUSIVE?

12 DR. PIZZO: THEY'RE NOT MUTUALLY EXCLUSIVE
13 EXCEPT BY WAY OF EXPECTATION. WHAT I'M SPEAKING TO NOW
14 IS THAT WE'RE SETTING AN EXPECTATION, AT LEAST AS I
15 READ THE DISCOURSE THAT'S GOING ON IN THE PUBLIC ARENA,
16 IT IS THAT IF ROYALTIES ARE EARNED, A PORTION OF THE
17 ROYALTIES ARE GOING TO GO TO PROVIDE FOR THOSE WHO
18 DON'T HAVE ACCESS TO THERAPY, A MERITORIOUS GOAL, BUT
19 THE POINT I'M MAKING IS I DON'T BELIEVE THAT THERE'S
20 GOING TO BE ENOUGH MONEY IN THAT POOL TO REALLY SERVE
21 THAT. IF I HAD TO CHOOSE WHERE TO PUT THAT MONEY, I
22 WOULD INVEST IT IN ADDITIONAL RESEARCH THAT WOULD
23 PROMOTE BETTER LONG-TERM CURES THAT WOULD HAVE A
24 LOWERING OF THE COST FOR CARE IN CALIFORNIA.

25 DR. PRIETO: I'D ARGUE THAT A MODEL PROGRAM

1 LIKE THAT, JUST BECAUSE OF THE VISIBILITY OF IT AND
2 DEMONSTRATING THE EFFECTIVENESS, IF YOU TAKE A PERSON
3 WHO WOULD OTHERWISE BE DISABLED, SPINAL CORD INJURY IS
4 A GREAT EXAMPLE OR DIABETES, AND YOU TURN THOSE PEOPLE
5 INTO OR ALLOW THEM TO REMAIN PRODUCTIVE CITIZENS, THE
6 DOWNSTREAM BENEFIT, NOT JUST THE AVOIDANCE OF COST, BUT
7 THE BENEFIT OF MAKING THOSE PEOPLE TAXPAYERS AGAIN IS
8 TREMENDOUS. THAT WOULD PERHAPS DRAW MONEY INTO THE
9 FIELD BECAUSE IT WOULD CONCRETELY DEMONSTRATE PROMISE.

10 DR. PIZZO: I'M NOT SURE WE'RE SAYING THINGS
11 THAT ARE VERY DIFFERENT. TO ME IT'S REALLY JUST THE
12 SOURCE OF THE MONEY. I THINK WHAT I HEARD BOB TALKING
13 ABOUT AS A MODEL PROGRAM IS THAT YOU WOULD BE ABLE TO
14 ENTER PATIENTS OR ENTER INDIVIDUALS INTO A PROGRAM TO
15 ALLOW THE BENEFITS TO BE DEMONSTRATED, AND THEN
16 HOPEFULLY REPLICATE IT ON A LARGER SCALE REGARDLESS OF
17 THE SOURCE OF THE MONEY. WHAT I'M SPEAKING ABOUT IS IF
18 YOU WERE DEPENDENT UPON THE SOURCE FOR THAT COMING OUT
19 OF ROYALTY, I DON'T THINK IT'S GOING TO HAVE THE
20 EFFECT. I THINK WE NEED TO BE MORE BROAD-MINDED ABOUT
21 THAT.

22 I DO THINK THAT THAT IS WHERE WE NEED TO HAVE
23 THE DISCOURSE WITH OUR PUBLIC BETTER ALIGNED SO THAT
24 THEIR EXPECTATIONS ARE THAT THIS ISN'T GOING TO BE THE
25 PANACEA FOR HOW WE'RE GOING TO BE ABLE TO COVER THESE

1 COSTS FOR CARE.

2 MR. SHEEHY: I ACTUALLY WANT TALK TO DR.
3 PIZZO ABOUT HIS RESEARCH POINT. I THINK THAT'S KIND OF
4 MISSED BECAUSE THAT IS ONE OF THE POINTS TO BAYH-DOLE
5 IS THE REINVESTMENT. WE KIND OF JUST GLIDE OVER THAT
6 AS IF THAT IS OF NO SUBSTANCE.

7 DR. BRYANT: AND IT WILL SLOW DOWN THE
8 RESEARCH PROGRAMS.

9 MR. SHEEHY: MY ONLY QUESTION IS IS MAYBE TO
10 BE MORE ATTENTIVE. PERHAPS IS IT POSSIBLE TO BE MORE
11 DIRECTED WITH HOW THAT REINVESTMENT HAPPENS? IN OTHER
12 WORDS, RATHER THAN -- BAYH-DOLE HAS THIS VERY BROAD
13 RESEARCH AND EDUCATION, WHICH I THINK GIVES A LOT OF
14 LATITUDE, BUT IT'S MAYBE A BIT AWAY FROM THE PURPOSE OF
15 PROP 71. PERHAPS PROP 71, OUR FUNDS CAN BE
16 SPECIFICALLY DIRECTED BACK INTO BIOMEDICAL RESEARCH AT
17 INSTITUTIONS THAT RECEIVE OUR GRANTS. THAT SEEMS TO ME
18 THAT THAT WOULD CREATE THIS KIND OF VIRTUOUS CIRCLE OF
19 SELF-SUSTAINING BIOMEDICAL RESEARCH THAT DOES
20 ACCOMPLISH ONE OF THE PRIMARY GOALS OF PROP 71, WHICH
21 IS TO ADVANCE THE STATE OF SCIENCE IN THE STATE OF
22 CALIFORNIA.

23 DR. PIZZO: I AGREE.

24 DR. WRIGHT: I THINK THE POINT ABOUT NOT
25 RAISING EXPECTATIONS UNDULY HIGH IS VERY WELL MADE. IN

1 THE CONFERENCE ON BIODIVERSITY, THERE ARE DETAILED
2 REGULATIONS WHICH HAVE BEEN ADOPTED BY A LOT OF
3 COUNTRIES ON HOW YOU GIVE ACCESS TO BIOPROSPECTORS AND
4 HOW YOU PAY THE MONEY BACK AND THE ROYALTIES. THAT'S
5 LED MOSTLY TO NO ACCESS AND TREMENDOUS DISAPPOINTMENT
6 AND LOTS OF ARGUMENTS OF BAD FAITH AND IMPUGNMENT OF
7 EVERYBODY'S MOTIVES. I THINK THAT THAT COULD HAPPEN
8 HERE IF YOU RAISE EXPECTATIONS TOO HIGH.

9 CHAIRMAN PENHOET: AND IT'S BLOCKING
10 RESEARCH.

11 DR. WRIGHT: IT'S BLOCKING RESEARCH AND
12 ACCESS AND BENEFIT SHARING. IT'S ALL SHUT DOWN.

13 DR. BRYANT: I WOULD ARGUE FOR KEEPING IT
14 CONSISTENT WITH BAYH-DOLE BY SAYING THAT ANY REVENUE
15 SHOULD GO BACK INTO RESEARCH AND EDUCATION. I THINK
16 EDUCATION IS IMPORTANT FOR THE PROGRESS OF RESEARCH
17 TOO. AND THAT IF WE WANTED TO BE MORE RESTRICTIVE THAN
18 THAT, I WOULD SAY WITH A PREFERENCE TO RESEARCH THAT
19 RELATES TO STEM CELL RESEARCH.

20 DR. PIZZO: YES, I AGREE.

21 DR. BRYANT: RATHER THAN A MORE GENERAL.

22 CHAIRMAN PENHOET: OKAY. I'M NOT SURE WE
23 HAVE THE LEGAL BASIS FOR DEMANDING THAT, BUT WE CAN
24 CERTAINLY RECOMMEND IT TO THE LEGISLATURE.

25 DR. HALL: ED, LET ME JUST ASK A QUESTION.

1 YOU'RE NOW TALKING, LET'S ASSUME THAT WE HAVE A
2 BAYH-DOLE-TYPE MODEL.

3 DR. BRYANT: RIGHT. I'M ASSUMING THAT WE
4 DON'T HAVE A SET ASIDE.

5 DR. HALL: IT HELPS TO REFER TO IT WITHOUT
6 USING THOSE TERMS. SO THE GRANTEE INSTITUTION THEN
7 PATENTS ITS INTELLECTUAL PROPERTY, IT LICENSES OR MAKES
8 AN ARRANGEMENT WITH THE COMPANY. THERE IS A ROYALTY
9 STREAM, AND NOW THAT ROYALTY STREAM WE'VE SAID,
10 ACCORDING TO THE PARTICULAR INSTITUTION, SOME AMOUNT
11 GOES TO THE INVESTOR. THAT'S FINE. SOME AMOUNT
12 ACCOUNT FOR THE ORIGINAL COSTS. THAT'S FINE. AND THEN
13 WHAT'S LEFT OVER RIGHT NOW BELONGS TO THE INSTITUTION.

14 WE COULD SPECIFY THAT THE INSTITUTION USE
15 THAT. I'M NOT SURE THAT'S WHAT YOU MEAN.

16 DR. BRYANT: THAT'S WHAT I MEAN.

17 DR. HALL: IN ADDITION, THE QUESTION IS
18 WHETHER A PIECE OF THAT SHOULD NOW COME BACK TO THE
19 STATE, CIRM, A 501(C)(3), WHATEVER IT IS. I THINK
20 THOSE ARE -- AND THEN IT'S THE SECOND QUESTION OF WHAT
21 IS THAT MONEY TO BE USED FOR. AND BUT I THINK IT IS
22 WITHIN OUR REALM, IS IT NOT, TO BE ABLE TO SAY WHAT
23 HAPPENS TO THE FIRST PART OF THAT?

24 DR. BRYANT: I THINK SO. IF IT'S GOING BACK
25 INTO STEM CELL RESEARCH AND EDUCATION, THEN MAYBE WE

1 DON' T NEED THE SECOND PART, WHICH IS THE SET ASIDE.

2 CHAIRMAN PENHOET: IT COMPLIES WITH PROP 71,
3 SO I MIGHT INTERRUPT NOW TO ASK JAMES. I BELIEVE THAT
4 PROP 71 ANTICIPATES A RETURN TO THE STATE AND THAT THE
5 FUNDS WOULD GO INTO THE GENERAL FUND, IF I REMEMBER
6 CORRECTLY.

7 MR. GOLDBERG: A POSSIBLE SOLUTION --

8 MR. HARRISON: I LIKE SOLUTIONS BEFORE I GET
9 TO ANSWER THE QUESTION.

10 MR. GOLDBERG: TO THE EXTENT THAT WE HAVE
11 NONACADEMIC INSTITUTIONAL GRANTEES WHOSE ROYALTY
12 RETURNS WOULD FLOW BACK INTO THE STATE GENERAL FUND,
13 DOES THAT SUFFICIENTLY CHECK THE BOX?

14 DR. WRIGHT: EVEN IF IT'S COMING FROM A
15 NONACADEMIC.

16 CHAIRMAN PENHOET: IF 10 PERCENT OF THE MONEY
17 WENT TO COMPANIES AND YOU GOT A RETURN TO THE STATE
18 WITH THOSE GRANTS, COULD YOU GET BY WITH 90 PERCENT NOT
19 HAVING A, QUOTE, UNQUOTE, RETURN TO THE STATE?

20 DR. PRIETO: HAVING AN INDIRECT RETURN TO THE
21 STATE.

22 MR. HARRISON: YOU HAVE A FAIR AMOUNT OF
23 DISCRETION HERE IN DETERMINING WHAT YOU DO. HAVING
24 SAID THAT, THE LAW DOES SPECIFY THAT YOU ARE TO ASSURE
25 THAT YOU BALANCE THE RIGHT OF THE STATE TO BENEFIT WITH

1 THE NEED TO MOVE THE RESEARCH FORWARD. I THINK YOU
2 COULD MAKE THE CASE THAT THAT WOULD SATISFY THE
3 REQUIREMENT IMPOSED UPON YOU. HAVING SAID THAT, I'M
4 SURE YOU COULD FIND OTHERS WHO ARE WILLING TO TAKE A
5 CONTRARY POSITION.

6 IN RESPONSE TO YOUR INITIAL QUESTION, IT'S A
7 MATTER THAT'S BEEN SUBJECT TO SOME DISPUTE. THE
8 LANGUAGE IS FAIRLY VAGUE. IT SAYS BENEFIT TO THE STATE
9 OF CALIFORNIA. SOME HAVE INTERPRETED THAT TO MEAN TO
10 THE GENERAL FUND OF THE STATE OF CALIFORNIA. SOME HAVE
11 INTERPRETED IT TO MEAN THAT THE CIRM HAS, AND YOU AS
12 BOARD MEMBERS, HAVE DISCRETION TO DETERMINE HOW THE
13 FUNDS SHOULD BE USED. THAT'S STILL AN OPEN QUESTION,
14 BUT ONE THAT OBVIOUSLY WE NEED TO COME TO GRIPS WITH,
15 DEPENDING UPON WHICH WAY YOU DECIDE TO GO.

16 DR. BRYANT: IS IT NOT OPEN -- LET ME PHRASE
17 IT DIFFERENTLY. CAN BENEFIT TO THE STATE ONLY MEAN
18 FINANCIAL BENEFIT?

19 MR. HARRISON: I WOULD TAKE THE POSITION THAT
20 BENEFIT TO THE STATE HAS A MUCH BROADER MEANING THAN
21 FINANCIAL BENEFIT, BUT THEN THE STATUTE DOES REFER
22 SPECIFICALLY TO ROYALTIES AND LICENSE FEES, WHICH
23 SUGGESTS THAT THERE IS SOME MONETARY COMPONENT TO IT.

24 DR. BRYANT: RIGHT. IF THOSE LICENSE FEES
25 ARE USED TO DO SOMETHING LIKE EXTRA RESEARCH OR

1 WHATEVER, THEN MAYBE -- I DON'T KNOW.

2 MR. HARRISON: THAT'S ABSOLUTELY CORRECT.
3 YOU CAN CERTAINLY MAKE THAT CASE.

4 CHAIRMAN PENHOET: COULD WE QUICKLY
5 ADDRESS -- OH, BOB, YOU'VE GOT A QUICK POINT.

6 MR. KLEIN: SINCE I WROTE THAT PROVISION. DO
7 I HAVE TO COME UP?

8 CHAIRMAN PENHOET: IT WOULD BE BETTER IF YOU
9 WOULD.

10 MR. KLEIN: I WOULD JUST SAY THAT IT'S
11 IMPORTANT TO RECOGNIZE THAT A BENEFIT TO THE STATE WAS
12 NOT CONSIDERED IN THE NARROWEST SENSE OF A DOLLAR TO
13 THE GENERAL FUND. THE BENEFIT TO THE STATE IS BROADLY
14 REVIEWED IN THE OTHER ECONOMIC BENEFITS, INCLUDING
15 DIRECT AND INDIRECT BENEFITS, INCLUDING ATTRACTING
16 COMPANIES TO THE STATE. SO IT WAS NOT INTENDED IN THE
17 NARROWEST SENSE, BUT WHETHER IT'S MODEL ACCESS PROGRAMS
18 THAT DEMONSTRATE THERE'S A BENEFIT TO THE PATIENTS AND
19 THE STATE HAS FUTURE SAVINGS, OR WHETHER IT GOES TO
20 RESEARCH THAT BENEFITS THE STATE OR WHETHER IT GOES
21 DIRECTLY TO OFFSET, THOSE ARE ALL BENEFITS TO THE STATE
22 IN THE CONTEXT.

23 AND THE WEIGHING FUNCTION WAS MEANT TO BE A
24 VERY IMPORTANT FUNCTION SO AS NOT TO UNDULY BURDEN THE
25 ADVANCEMENT OF THE MEDICINE, WHICH IS THE GUIDING

1 PRINCIPLE OF THE PROPOSITION AND THE MISSION OF THE
2 PROPOSITION.

3 CHAIRMAN PENHOET: OKAY. WE ARE BEYOND OUR
4 APPOINTED HOUR; HOWEVER, WE STILL HAVE TO COME OUT OF
5 THIS WITH SOME WORK PRODUCT. OUR INTENT WAS TO HAVE
6 SOME PRINCIPLES IN PLACE TO GUIDE THE TRAINING GRANT
7 RECIPIENTS. WOULD IT BE WITHIN THE LAW IF WE SIMPLY
8 SAID THAT TRAINING GRANT RECIPIENTS WOULD HAVE TO
9 COMPLY WITH THE FINAL GUIDELINES THAT WE PRODUCE OVER
10 THE NEXT FOUR MONTHS? AND IF A UNIVERSITY ACCEPTED THE
11 MONEY, THEY WOULD TAKE THE RISK, BUT THEY WOULD BE ABLE
12 TO LIVE WITH WHATEVER CAME OUT OF IT.

13 MR. HARRISON: I THINK THAT'S CORRECT BECAUSE
14 THEY, OF COURSE, WOULD HAVE THE OPPORTUNITY NOT TO
15 ACCEPT THE MONEY IF THEY DIDN'T WANT TO TAKE IT BASED
16 ON THAT CONDITION.

17 CHAIRMAN PENHOET: MARCH-IN RIGHTS COULD BE
18 EITHER SIMPLE OR ONEROUS TO GO THROUGH. I THINK THE
19 SIMPLE VERSION SAYS FAILURE TO DEVELOP WOULD BE A CAUSE
20 FOR MARCHING IN. THAT'S THE MOST OBVIOUS GENERALLY.
21 THAT WHETHER WE DEALT WITH SOME KIND OF MOST FAVORED
22 NATION LICENSING COULD EITHER --

23 MR. SHEEHY: I'D BE WILLING TO LET THAT GO.
24 I'D BE WILLING TO GO WITH STRAIGHT BAYH-DOLE MARCH-IN
25 MYSELF. ACTUALLY LISTENING TO THIS --

1 CHAIRMAN PENHOET: PUBLIC HEALTH.

2 MR. SHEEHY: -- I ALMOST GET THE SENSE THAT
3 WE SHOULD DO STRAIGHT BAYH-DOLE, TAKE A LITTLE
4 PERCENTAGE FROM THE UNIVERSITIES, NEGOTIATE A BIGGER
5 PERCENTAGE FROM CORPORATE ENTITIES WHEN WE DO IT. AND
6 MAYBE AS THAT'S DOWNSTREAM, WE HAVE TIME BETWEEN NOW
7 AND THEN TO THINK ABOUT MAYBE ASKING THEM PROACTIVELY
8 TO PROVIDE SOME ACCESS AS PART OF THE GRANT
9 APPLICATIONS. BUT WE'VE GOT AT LEAST A YEAR BEFORE
10 WE'D BE GIVING THEM MONEY, BUT IT SEEMS --

11 CHAIRMAN PENHOET: I THINK WE AS A GROUP
12 THOUGH BELIEVE THAT WE WANT TO PUSH THE ENVELOPE OF
13 DATA SHARING AND TRANSPARENCY FURTHER THAN THE CURRENT
14 PRACTICE OF BAYH-DOLE HAS DONE. WE'RE STILL ALL IN
15 AGREEMENT WITH THAT.

16 AND SO IF WE COULD JUST TAKE A FEW MINUTES
17 THEN TO TRY TO RECOMMEND SORT OF THE KEYSTONES OF AN
18 INTERIM POLICY THAT WE COULD SHARE, THE PRINCIPLES THAT
19 WE COULD SHARE WITH THE BOARD AND WITH THE STANDARDS
20 WORKING GROUP THAT CAME OUT OF THIS MEETING TODAY
21 WITHOUT BEING PROSCRIPTIVE, BUT IN THE SENSE OF THE
22 LAW, BUT GIVING GUIDANCE ABOUT IF YOU ACCEPT THE MONEY,
23 HERE ARE THE THINGS YOU'RE LIKELY TO HAVE TO TAKE ON.
24 THIS IS RISKS BEYOND YOUR -- AS A TRAINEE.

25 MANY PEOPLE ARGUE TRAINEESHIP'S GENERALLY ARE

1 NOT REGARDED AS LEADING TO MUCH INTELLECTUAL PROPERTY
2 BECAUSE THE TRAINING PEOPLE ARE NOT FUNDING RESEARCH.
3 NEVERTHELESS, A TRAINEE COULD INVENT SOMETHING OF
4 VALUE, SO WE'VE GOT SOMETHING IN PLACE.

5 I THINK WE HAVE A STRAW VOTE THAT SAYS WE
6 HAVE AGREEMENT ON ESSENTIALLY THE GRANTEES OWNING THE
7 TECHNOLOGY. THESE ARE NONPROFIT GRANTEES; IS THAT
8 RIGHT?

9 MR. CARDALL: MY NAME IS CHAS CARDALL. I'M
10 ACTUALLY A PERSON AT ORRICK, HERRINGTON & SUTCLIFFE
11 ALSO. JUST ONE COMMENT. WHEN PERRY WAS HERE BEFORE,
12 HE WAS TALKING ABOUT APPROACHING THE IRS. AND THE MORE
13 DEFINED OF A POLICY YOU CAN HAVE, THE EASIER IT WILL BE
14 FOR US TO ACTUALLY GO TO THE IRS. SO JUST -- THERE'S A
15 SIGNIFICANT TIMING LAG THERE, SO I DON'T KNOW WHAT THE
16 TIMING OF THE REST OF THIS IS, BUT THERE'S REAL VALUE
17 TO GETTING A LITTLE MORE CERTAINTY AT THE FRONT END SO
18 THAT WE HAVE MORE CERTAINTY TO GO AND TRY TO ANSWER
19 THOSE QUESTIONS.

20 CHAIRMAN PENHOET: WE WILL ENDEAVOR TO MOVE
21 THIS ALONG QUICKLY, BUT I'M AFRAID WE WON'T GET IT DONE
22 TODAY. SOME OF OUR MEMBERS HAVE ALREADY HAD TO LEAVE.

23 I WOULD LIKE TO -- LET'S HAVE A SIMPLIFIED
24 VERSION OF WHAT WE TALKED ABOUT TODAY IN TERMS OF
25 PRINCIPLES THAT WE WILL BRING TO THE ICOC.

1 SO THE FIRST PRINCIPLE IS THAT GRANTEES OWN
2 THE TECHNOLOGY. THE SECOND PRINCIPLE UNDER THE DATA
3 SHARING, HOW SHALL WE REQUIRE THE SHARING OF THE DATA
4 AND BIOMEDICAL MATERIALS? I THINK ALL WE CAN SAY AT
5 THIS POINT IS WE WANT TO PUSH THE ENVELOPE OF CURRENT
6 PRACTICE IN THE DIRECTION OF MUCH GREATER DEGREE OF
7 TRANSPARENCY, OPENNESS OF DATA, AND MATERIALS SHARING
8 THAN IS CURRENTLY WIDESPREAD PRACTICE.

9 DR. HALL: I WAS JUST GOING TO SUGGEST A
10 WORDING THAT SAYS THAT YOU STRONGLY SUPPORT THE WIDEST
11 POSSIBLE SHARING, SO ON AND SO ON AND SO AND SO. WE
12 CAN COME IN LATER AND FILL ALL THAT IN.

13 CHAIRMAN PENHOET: OKAY. AND THEN WE BELIEVE
14 THAT, TO THE DEGREE WE CAN DO IT LEGALLY, WE WILL
15 CREATE A RESEARCH EXEMPTION FOR OUR GRANTEES FOR
16 INTELLECTUAL PROPERTY FOR BASIC RESEARCH PURPOSES, NOT
17 CONFINED TO NONPROFITS.

18 I THINK IF WE EXPECT COMPANIES LIKE GERON TO
19 SHARE THEIRS TO ALLOW US TO DO RESEARCH WITH THEIR
20 BASIC MATERIALS, WE HAVE TO DO SOMETHING IN THAT. IS
21 THAT WHAT WE AGREED THERE?

22 AND THEN THE MORE STICKY ONE OF LICENSING
23 REQUIREMENTS ADOPTED BY CIRM GRANTEES, A PREFERENCE FOR
24 ORGANIZATIONS THAT HAVE A DEMONSTRATED TRACK RECORD
25 OF -- HOW WOULD YOU CALL IT, WHATEVER IT IS FOR --

1 DR. LOVE: DRUG ACCESS.

2 DR. PRIETO: THE RESPONSIBLE --

3 DR. LOVE: THESE ARE PROBABLY NOT LIKELY TO
4 BE DRUGS. PATIENT THERAPY ACCESS.

5 MR. FEYER: IN DOING THIS POLICY, I'D
6 STRONGLY SUGGEST YOU KEEP IN MIND THE TWO TIER ON THIS
7 POINT, THE RULES FOR NON-PROFITS AND RULES FOR
8 FOR-PROFITS.

9 CHAIRMAN PENHOET: WE'RE ONLY TALKING ABOUT
10 NON-PROFITS. THESE ARE RECOMMENDATIONS WE HAVE TO MAKE
11 FOR PEOPLE WHO ARE GOING TO GET TRAINING GRANTS.

12 DR. PRIETO: WE RECOMMEND TO THEM FOR
13 DOWNSTREAM LICENSING.

14 DR. BRYANT: WE DIDN'T DISCUSS LICENSING IN
15 CALIFORNIA.

16 DR. LOVE: DO WE NEED THAT? DO WE NEED THE
17 ACCESS?

18 CHAIRMAN PENHOET: WE WILL HAVE A THRESHOLD.
19 I GUESS WE HAVE NOT FINALLY DECIDED ON THIS ISSUE OF,
20 QUOTE, UNQUOTE, TAX. I THINK WE CAN ANTICIPATE THERE
21 MAY BE A TAX ON ROYALTIES PAYABLE TO FURTHER -- WHAT'S
22 THE RIGHT WORD, BOB?

23 MR. KLEIN: MODEL ACCESS.

24 CHAIRMAN PENHOET: -- INTEREST OF THE
25 CITIZENS OF CALIFORNIA IS STILL AN OPEN ITEM. PEOPLE

1 WHO ARE GOING TO TAKE THIS MONEY SHOULD RECOGNIZE THERE
2 MAY BE.

3 MR. SHEEHY: WHAT IF WE RECOMMEND A TAX FOR
4 THE TRAINING GRANTS SO THAT WE GET THAT OUT THERE, AND
5 THEN WE CAN DISCUSS WHETHER WE CAN -- THEN WE CAN GET
6 LEGAL OPINIONS ON WHETHER WE CAN LEAVE IT AS DIRECTED
7 RESEARCH.

8 CHAIRMAN PENHOET: THAT'S NOT A BAD IDEA.

9 DR. PIZZO: IT'S A PRETTY SAFE THING. IT'S
10 UNLIKELY THAT THERE'S GOING TO BE ANYTHING --

11 CHAIRMAN PENHOET: SO --

12 MR. SHEEHY: THEN WE'RE NOT CREATING --

13 CHAIRMAN PENHOET: GOOD SUGGESTION.

14 DR. BRYANT: BUT THEN THAT CREATES AN
15 EXPECTATION THAT THE OTHER GRANTS --

16 CHAIRMAN PENHOET: IT WILL HAVE A BOARD
17 DISCUSSION NOW OVER THE NEXT FEW MONTHS.

18 DR. BRYANT: I WOULD ARGUE AGAINST IT BECAUSE
19 I THINK IT CREATES AN EXPECTATION THAT THAT'S THE WAY
20 WE WILL GO EVENTUALLY, AND WE MIGHT NOT.

21 MR. SHEEHY: WE MAY HAVE TO IS MY ONLY
22 PROBLEM.

23 DR. BRYANT: IT DEPENDS. IF YOU CAN CRAFT IT
24 SO THAT RESEARCH -- MORE STEM CELL RESEARCH GETS DONE.

25 MR. SHEEHY: THAT WOULD BE MY BIAS.

1 DR. BRYANT: THEN YOU DON'T HAVE TO HAVE A
2 SET ASIDE.

3 MR. SHEEHY: I THINK YOU MIGHT GET A MAJORITY
4 OF THE ICOC TO ACCEPT THAT BIAS. THAT'S WHY WE'RE ALL
5 SITTING HERE. THE QUESTION IS WHETHER WE CAN LEGALLY
6 DO IT WITHIN THE CONFINES OF PROP 71. I DON'T THINK WE
7 WANT TO INVITE ADDITIONAL LITIGATION. THAT'S A REASON
8 WHY I THINK IT MIGHT BE HELPFUL --

9 CHAIRMAN PENHOET: I THINK WE CAN ANTICIPATE
10 THAT THERE MIGHT BE A TAX ON ROYALTIES.

11 DR. PIZZO: IT WOULD BE STILL REDIRECTED TO
12 STEM CELL RESEARCH.

13 CHAIRMAN PENHOET: WITHOUT SPECIFYING TODAY
14 WHERE IT WOULD GO.

15 DR. PIZZO: JUST OFFER THE CAVEAT.

16 CHAIRMAN PENHOET: AND THEN FINALLY AT LEAST
17 FOR THE MOMENT MARCH-IN RIGHTS WOULD BE VIRTUALLY NOW
18 THE SAME AS BAYH-DOLE. SO THIS IS NOT EXACTLY
19 BAYH-DOLE, BUT IT'S SIMILAR, COMPATIBLE.

20 MS. COO: WENDY WANTED ME TO MENTION THAT
21 WHEN YOU -- WENDY WANTED ME TO MENTION THAT WHEN THERE
22 WERE MARCH-IN RIGHTS IN BAYH-DOLE, MANY COMPANIES WERE
23 AFRAID TO TOUCH FEDERAL MONEY. SO SHE WAS WORRIED THAT
24 COMPANIES -- I DON'T KNOW HOW YOU WOULD FEEL -- WOULD
25 NOT WANT TO TOUCH THIS MONEY.

1 DR. PRIETO: I THOUGHT BAYH-DOLE HAD MARCH-IN
2 RIGHTS FROM THE BEGINNING.

3 DR. BRYANT: BAYH-DOLE HAS MARCH-IN RIGHTS.

4 MS. COO: IT DID. COMPANIES DIDN'T WANT TO
5 TAKE LICENSES.

6 DR. PRIETO: BUT AS IT EVOLVED, COMPANIES --

7 MS. COO: SO COMPANIES THAT ARE FILING FOR
8 FEDERAL, WE'RE JUST WONDERING WHETHER THEY'LL CARE --

9 MR. SHEEHY: THIS IS NOT APPLICABLE FOR
10 COMPANIES. I MEAN FOR COMPANIES, WE COULD PROBABLY
11 GIVE UP THE MARCH-IN RIGHT AND TAKE A STRAIGHT ROYALTY
12 RETURN AND NEGOTIATE A COMMERCIAL AGREEMENT TO GET
13 CASH.

14 CHAIRMAN PENHOET: NO. WE'RE TALKING ABOUT
15 WHAT OUR GRANTEES IN THE PUBLIC SECTOR DO WITH RESPECT
16 TO AN ULTIMATE LICENSEE.

17 MS. COO: THE FEDERAL GOVERNMENT CAN MARCH IN
18 ON THE LICENSEE. THEY'RE NOT GOING TO MARCH IN ON US.
19 THEY'LL MARCH IN ON THE LICENSEE BECAUSE THEY HAVEN'T
20 DEVELOPED THE TECHNOLOGY.

21 MR. GOLDBERG: AS A PRACTICAL MATTER, AS AN
22 INDUSTRY PERSON --

23 CHAIRMAN PENHOET: THE PRACTICE HAS BEEN
24 BENIGN.

25 (OVERLAP IN DISCUSSION.)

1 DR. PRIETO: IF THE PRACTICE DEVIATED TOO
2 RADICALLY, THE BACKLASH WOULD BE IMMEDIATE, SO IT WILL
3 SORT OF BE A NATURAL CHECK AND BALANCE ON THAT.

4 DR. HALL: THIS WAS ONE OF REBECCA
5 EISENBERG'S POINTS ACTUALLY, THAT SHE URGED THAT WE
6 EXPAND MARCH-IN RIGHTS, AND SHE SAID, AS I UNDERSTAND,
7 KATHY, AND CORRECT ME IF I'M WRONG, BUT IN THE EARLY
8 DAYS, THEY HAD A VERY STRICT POLICY AGAINST IT BECAUSE
9 THEY WERE VERY MUCH AFRAID OF WHAT YOU JUST SAID; THAT
10 IS, THE COMPANIES WOULD BE AFRAID THAT GOVERNMENT WAS
11 GOING TO COME IN ON THEM. SO THEY PURPOSELY ADOPTED A
12 VERY, VERY CONSERVATIVE POLICY.

13 AS I UNDERSTOOD WHAT SHE SAID, IT WAS THAT
14 TIMES ARE DIFFERENT NOW, AND THAT ONE MIGHT EXERCISE
15 THOSE RIGHTS MORE ACTIVELY. I CAN ASSURE YOU THAT IF
16 THAT BECOMES AN ISSUE, THERE WILL BE THOSE URGING US TO
17 EXERCISE THEM VERY ACTIVELY ON A NUMBER OF ISSUES. AND
18 I THINK THE KINDS OF CONCERNS THAT ARE EXPRESSED MAY
19 BECOME RELEVANT. SO THE QUESTION IS HOW TO BALANCE. I
20 THINK WE CAN GO BACK TO WHAT RICK SAID ABOUT THE GATES
21 FOUNDATION, HOW TO BALANCE WHAT WE NEED FOR OUR AIMS.
22 AND THAT IS, TO HAVE THE RESEARCH THAT'S DONE BE
23 DEVELOPED AND TO REACH THE PATIENTS, HOW TO INTERPRET
24 MARCH-IN RIGHTS BEST WITHIN THAT CONTEXT. BUT WHETHER
25 ACCESSIBILITY BECOMES A REASON FOR MARCH-IN, THAT'S

1 WHERE I THINK YOU MIGHT VERY WELL GET IN TROUBLE WITH
2 COMPANIES NOT WANTING TO RISK THAT DANGER.

3 MS. COO: WELL, I'M THINKING PREFERENCE FOR
4 COMPANIES WITH PATIENT THERAPY ACCESS. HISTORY MEANS
5 NO START-UP COMPANY.

6 MR. GOLDBERG: THAT'S NOT TENABLE.

7 MR. SHEEHY: I THINK THAT'S PROBLEMATIC
8 MYSELF.

9 DR. PRIETO: YOU MIGHT WANT A MODEL OR
10 EXAMPLE RATHER THAN SOMETHING SPECIFIC LIKE THAT.

11 CHAIRMAN PENHOET: IT COULD BE PREFERENCE
12 WITH A PLAN.

13 MR. GOLDBERG: RIGHT, EXACTLY. COMMITMENT TO
14 ESTABLISH.

15 DR. LOVE: SHOULD WE TAKE MODEL ACCESS OFF
16 THAT? IS THAT RIGHT?

17 MR. SHEEHY: I THINK WE NEED TO COME TO SOME
18 PHILOSOPHICAL POINT ON THE ACCESS QUESTION AND JUST BE
19 STRAIGHT FORTH. EITHER WE'RE GOING TO TRY TO DO IT OR
20 NOT. THAT'S HOW I FEEL.

21 DR. LOVE: I'LL TAKE A STAB AT IT. I'LL
22 RECOMMEND WE DON'T DO IT. AND THE REASON WHY I
23 THINK -- PHIL KIND OF TOUCHED ON IT. THE HEALTHCARE
24 SYSTEM IS BROKEN. WE NEED TO SOLVE THE HEALTHCARE
25 SYSTEM. IT'S NOT A BURDEN THAT WE REALLY NEED TO BE

1 TAKING ON.

2 I CAN IMAGINE A SITUATION WHERE THE BEST
3 THERAPY FOR A PERSON IS SUBSIDIZED TO THIS KIND OF
4 THINGS, BUT IN THE WHOLE WORLD, IT REALLY ISN'T THE
5 BEST THERAPY. I CAN IMAGINE THAT GENENTECH IS
6 PRODUCING A PRODUCT THAT'S VERY SIMILAR TO A COMPANY
7 THAT GOT SOME CIRM FUNDING, AND GENENTECH PRODUCT IS
8 SLIGHTLY BETTER, BUT YET EVERYBODY IS GIVEN THIS
9 PRODUCT TO CALIFORNIANS WHO ARE INDIGENT FOR THAT
10 REASON.

11 I'M JUST NOT SURE IF WE WANT TO SET UP THE
12 INCENTIVES FOR A HEALTHCARE SYSTEM TO DO ANYTHING OTHER
13 THAN THE BEST THING FOR THE PATIENT IN FRONT OF HIM OR
14 HER.

15 DR. PIZZO: AND WE SHOULD GO NOW WORK ON
16 MAKING A HEALTHCARE SYSTEM THAT WORKS FOR THE UNITED
17 STATES.

18 CHAIRMAN PENHOET: NOW THAT WE'VE GOT THIS
19 EASY JOB.

20 DR. PRIETO: COULD I JUST RESPOND TO THAT. I
21 AGREE THAT ABSOLUTELY WE CANNOT SOLVE THE HEALTHCARE
22 SYSTEM, THE PROBLEMS OF THE HEALTHCARE SYSTEM, BUT I'D
23 ARGUE FROM A PUSHING THE RESEARCH FORWARD POINT OF
24 VIEW, THAT AGAIN MODELING BEHAVIOR, MODELING THERAPIES,
25 AND GETTING THEM OUT THERE THROUGH MODEL PROGRAMMING

1 MAY, IN FACT, PUSH THE RESEARCH MORE AGGRESSIVELY THAN
2 ANYTHING THAT SOMEONE IS DOING PRIVATELY IN A LAB,
3 WHICH MIGHT BE VERY EXCITING FOR PEOPLE IN THIS ROOM,
4 PARTICULARLY PEOPLE IN SCIENCE, BUT NOT SOMETHING THAT
5 THE WORLD AT LARGE IS AWARE OF.

6 MR. GOLDBERG: I THINK THAT'S RIGHT. I THINK
7 THAT'S A DISTINCTION BECAUSE WHEN I HEARD JEFF SAY
8 ACCESS, I'M THINKING ALL OF A SUDDEN WE'RE GOING TO
9 HAVE TO FIGURE OUT HOW TO BRING THESE THINGS OUT. THAT
10 CONSTITUTES A POSITION ON ACCESS.

11 MR. SHEEHY: I HAVE TROUBLE -- AND I GUESS
12 I'M THE ONLY ONE THAT'S TAKEN ADVANTAGE -- THAT'S HAD
13 TO RELY ON A PUBLIC SECTOR IN ORDER TO SAVE MY LIFE,
14 HAVING BEEN DIAGNOSED WITH A FATAL DISEASE AND NOT
15 HAVING INSURANCE OR THE MEANS TO BUY THE DRUGS. I
16 THINK IT BECOMES AN ALLOCATION ISSUE. I DON'T WANT TO
17 BE THE ONE SITTING HERE DECIDING WHO LIVES AND WHO
18 DIES, WHO WALKS AND WHO DOESN'T. I THINK THAT IS
19 BEYOND US, AND I THINK WE SHOULD BE STRAIGHTFORWARD
20 WITH THE PUBLIC ABOUT WHAT WE CAN AND CANNOT DO.

21 AND IN THE AIDS FIELD, WE HAVE A WHOLE
22 PLETHORA OF RELATIONSHIPS IN ORDER TO GET DRUGS TO
23 PEOPLE IN ALL SORTS OF ECONOMIC CONDITIONS AND
24 INSURANCE CONDITIONS ALL ACROSS THE GLOBE AND CASE BY
25 CASE. THERE'S NO MODEL THAT WE CAN CREATE THAT WILL DO

1 MORE THAN POP A PIMPLE. AND LET'S BE HONEST ABOUT THAT
2 AND STOP MISLEADING THE PUBLIC ABOUT IT.

3 DR. WRIGHT: IF YOU CREATE SOME INTERESTING
4 THERAPIES, AND EVEN IF PEOPLE PAY FOR THEM, YOU WILL
5 GET DATA ABOUT WHAT THE EFFECTIVENESS OF THAT THERAPY
6 IS AND HOW MUCH LATER TREATMENT YOU WILL SAVE, ETC.
7 AND THEN WE COULD THEN MODEL THAT JUST WITH THAT
8 INFORMATION TO TELL YOU HOW MUCH IT MIGHT SAVE, SAY,
9 THE MEDI-CAL. AND SO YOU CAN DO THAT. WHATEVER
10 HAPPENS, IF THESE THINGS GET ADOPTED BY ANYBODY, WE'LL
11 GET A LOT OF INFORMATION WHICH WILL ENABLE YOU TO MODEL
12 THE SAVINGS FOR INDIGENT PEOPLE. I THINK YOU SHOULD
13 SEPARATE THAT MODELING ISSUE AND THAT COST ISSUE FROM
14 THE ACTUAL ALLOCATION OF THE RESOURCES. I THINK
15 THEY'RE TWO DIFFERENT ISSUES.

16 DR. PIZZO: I JUST SORT OF WANT TO STAY ON
17 THAT. I THINK THAT IS WHERE WE SHOULD BE BECAUSE I'M
18 WITH JEFF ON THIS. I THINK THAT IF WE WERE TO GO DOWN
19 THE PATH, EVEN WITH OUR IDEAL HOPES THAT WE'RE GOING TO
20 HAVE THINGS THAT ARE GOING TO, QUOTE, IMPACT ON PEOPLE,
21 THE PROBABILITY THAT WE'LL BE ABLE TO MOVE THAT DIAL
22 VERY FAR IS SMALL. AND I THINK WHAT WE KNOW WE CAN DO
23 IS GENERATE, CONTINUE TO GENERATE KNOWLEDGE, CONTINUE
24 TO GENERATE RESEARCH FINDINGS, AND OUR HOPE HAS TO BE
25 THAT THE RESEARCH FINDINGS WILL IMPROVE HEALTH AND THAT

1 WILL IMPROVE THE ECONOMICS. SO IF WE STAY IN THAT
2 DOMAIN, I THINK WE'RE SAFE.

3 AND WHAT I'M MOST WORRIED ABOUT IS THE PUBLIC
4 EXPECTATIONS. WE HAVE TWO PROBLEMS WITH PUBLIC
5 EXPECTATION RIGHT NOW. ONE OF THEM IS THAT THEY HAVE A
6 HIGH DEGREE OF EXPECTATION OF CURES COMING FROM STEM
7 CELL RESEARCH WAY AHEAD OF THE TIMELINE THAT THEY'RE
8 LIKELY TO BE GENERATED. SO THIS IS GOING TO BE A
9 PUBLIC CHALLENGE THAT WE'RE GOING TO FACE. I MEAN WE
10 ALL HOPE THAT SOMETHING HAPPENS MIRACULOUSLY, BUT
11 EVERYONE WHO'S BEEN IN RESEARCH KNOWS THAT IT TAKES A
12 WHILE FOR THAT TO TAKE PLACE. IF YOU ADD TO THAT THE
13 EXPECTATION THAT WHEN THERE'S A TREATMENT, THAT THE
14 COST FOR IT, THE STATE LEGISLATORS ARE GOING TO LOOK
15 TOWARD US AS THE VEHICLE FOR PAYING FOR IT, I THINK
16 THAT SETS UP TWO PARTS OF A PERFECT STORM.

17 MR. REED: WHEN MY SON WENT DOWN, THE MOST
18 ADVANCED MEDICATION WE COULD GET WAS SOMETHING CALLED
19 SYGEN, WHICH WAS A GANGLI OCIDE OF DRIED-UP COW BRAINS,
20 AND IT WAS THOUGHT TO BE WORTH TRYING, AND WE DID IT.
21 WE GOT HIS TRICEPS BACK. OKAY. BEFORE THAT, I HAD TO
22 LIFT HIM OUT OF THE BED AND PUT HIM IN THE WHEELCHAIR.
23 WITH THE RETURN OF HIS TRICEPS, HE IS NOW RELATIVELY
24 INDEPENDENT, SAVING HUGE COSTS OF MONEY, HUGE. INSTEAD
25 OF A 24-HOUR ATTENDANT, HUGE COSTS. OKAY. IF WE HAD A

1 MODEL -- IF THAT'S UP THERE, ROYALTIES TAX, I DON'T
2 WANT THAT MONEY TO GO BACK IN THE GENERAL FUND. I WANT
3 THAT TO GO INTO SOMETHING WHICH DIRECTLY AFFECTS US.

4 I LIKE THE IDEA OF A MODEL PROGRAM, EVEN IF
5 IT'S JUST TO FOLLOW A SCIENTIST THROUGH WHAT THEY'RE
6 DOING SO THE PUBLIC CAN SEE WHAT WE'RE DOING. IF IT
7 WAS AN INDIVIDUAL, WHY NOT? IF IT WAS AN INDIVIDUAL --

8 MR. SHEEHY: WHO DECIDES?

9 MR. REED: A LOTTERY, JUST FLIP IT AND JUST
10 MAKE IT PURE CHANCE SO THERE'S NO POSSIBILITY. HAVE
11 YOU STAND THERE AND PUT YOUR HAND INSIDE THERE AND HOLD
12 UP A TICKET, WHATEVER.

13 MR. SHEEHY: I GET TO HOLD UP THAT TICKET
14 KNOWING THAT THERE WERE OTHER PEOPLE WHO COULDN'T GET A
15 TICKET?

16 MR. REED: AS OPPOSED TO NOT LETTING THE
17 PEOPLE KNOW WHAT'S GOING ON, AS OPPOSED TO HAVING THE
18 MONEY GO INTO THE BOTTOMLESS POOL. CARE IS ZILLIONS.

19 MR. SHEEHY: IT'S A DIVISIVE WAY TO GO ABOUT
20 IT. IT'S BETTER THAT WE ALL WORK TOGETHER AND GET THE
21 LEGISLATURE TO ALLOCATE THE FUNDS TO BUY THE
22 TREATMENTS.

23 MR. REED: AN EXAMPLE IS THE BEST WAY. AN
24 EXAMPLE IS THE BEST WAY TO BRING EVERYBODY TOGETHER.
25 WE'RE ALL FIGHTING FOR THE SAME THING. BUT IF WE CAN

1 GET PEOPLE TO SEE A FACE, THEN IT'S NOT JUST FACELESS
2 BUREAUCRACY. IT'S NOT JUST MONEY GONE INTO THE GENERAL
3 FUND.

4 AND ALSO, WE HAD ORIGINALLY UP THERE AS A
5 MODEL AS A PROPOSAL. I THINK THAT BELONGS UP THERE.

6 MR. KLEIN: I'D LIKE TO FOCUS, I THINK, ON
7 WHAT DEAN PIZZO SAID AND WHAT SOME OF THE OTHER
8 COMMENTS ARE. I THINK WE NEED TO BE VERY CLEAR, AS I
9 TRIED TO IN MY COMMENTS STATE, THAT HAVING THE LOWEST
10 PUBLIC PRICE MAY MEAN NO ONE GETS SERVED BECAUSE THAT
11 PRICE IS TOO HIGH. IF WE HAVE A MODEL WHERE THE
12 PURPOSE IS TO PRODUCE THE DATA TO DEMONSTRATE
13 SPECIFICALLY IN REAL NUMBERS WHAT THE DOWNSTREAM
14 SAVINGS CAN BE, YOU CREATE THE INFORMATION ON WHICH
15 INTELLIGENT DECISIONS CAN BE MADE FROM THE LEGISLATURE
16 ON WHETHER TO, IN FACT, AFFORD THAT COST FOR THE BROAD
17 SPECTRUM OF THE PUBLIC.

18 IN FACT, THAT IS HOW MANY OF THE PROGRAMS AT
19 THE FEDERAL LEVEL HAVE BEEN PROVEN IN ORDER TO GET
20 BROAD SUPPORT IN CONGRESS FOR EXPANDING COVERAGE. SO A
21 MODEL PROGRAM, IF WE'RE CLEAR WITH THE PUBLIC, WE DON'T
22 HAVE THE MONEY FOR BROAD-SCALE TREATMENT. WE ONLY HAVE
23 THE MONEY TO LOOK AT MODEL TREATMENTS AND SEE WHAT THE
24 DOWNSTREAM OF WHAT ITS COSTS ARE.

25 DR. PIZZO: SO IF I CAN OFFER JUST A CAVEAT,

1 AND FOLLOWING JEFF'S EXPERIENCE, I'M GOING TO
2 PERSONALIZE THIS. WHEN I WAS IN THE VERY EARLY PHASES
3 OF DEVELOPING THERAPIES FOR CHILDREN WITH AIDS, THERE
4 WERE NO THERAPIES AVAILABLE AT THAT TIME. AND THE ONLY
5 WAY THAT WE MOVED THE BALL FORWARD WAS TO DEMONSTRATE
6 THAT THERE WAS ACTIVITY IN CLINICAL TRIALS. SO IF I
7 WERE TO USE THE TERM "CLINICAL TRIAL" AS COMPARED TO
8 "MODEL PROGRAM," TO ME THAT'S WHERE YOU GET THE
9 DETERMINATION. IT COMES FROM THE DEMONSTRATION THAT
10 YOU ACTUALLY HAVE SOMETHING THAT COULD WORK. AND THEN
11 IT BECOMES DEPENDENT UPON, QUOTE, THE SYSTEM, WHICH IS
12 THE COLLABORATION BETWEEN GOVERNMENT, PHARMACEUTICAL
13 INDUSTRY, AND OTHERS TO FIGURE OUT HOW TO GET IT TO
14 BROADER COMMUNITIES.

15 WHAT I'M TRYING TO DO IS TAKE OUT OF THAT
16 SORT OF THE TRANSLATION EFFECT, THE EXPECTATION THAT
17 THERE'S GOING TO BE A POOL OF MONEY SITTING IN
18 ROYALTIES THAT'S GOING TO MAKE THAT HAPPEN. THAT'S MY
19 BIGGEST WORRY. I THINK SUPPORTING THE RESEARCH,
20 GETTING THE CLINICAL TRIALS DONE THAT DEMONSTRATE THE
21 ACTIVITY, AND THEN HAVING THAT, IN ESSENCE, FORCE
22 WHATEVER SYSTEM WE HAVE TO FIGURE OUT HOW TO MAKE IT
23 MORE BROADLY AVAILABLE IS, I THINK, THE WAY THAT I
24 WOULD RECOMMEND THAT WE PROCEED AT THIS JUNCTURE.

25 MR. SHEEHY: COST-EFFECTIVENESS STUDIES ARE

1 NOT THAT EXPENSIVE.

2 DR. BRYANT: I WOULD SECOND THAT. I ALSO
3 THINK THAT'S WHAT I WAS THINKING OF WHEN YOU WERE
4 DESCRIBING WHAT YOU WERE DESCRIBING WAS THAT THIS IS A
5 CLINICAL TRIAL. THIS IS WHAT IT WOULD LOOK LIKE. IF
6 WE HAD A CALL FOR PROPOSALS, IT WOULD BE A CALL FOR
7 PROPOSALS OF CLINICAL TRIALS OF MODEL SYSTEMS OR
8 SOMETHING.

9 DR. PRIETO: I THINK THIS WOULD BE A CLINICAL
10 TRIAL WITH A DISTINCTION PERHAPS THAT WOULD BE HIGHLY
11 PUBLIC CLINICAL TRIAL.

12 DR. PIZZO: I THINK WE HAVE TO BE VERY
13 CAREFUL ABOUT THAT AS WELL.

14 DR. PRIETO: WE WANT TO PUT OUT POSITIVE AND
15 NEGATIVE RESULTS.

16 DR. PIZZO: I KNOW THAT, BUT WE WANT TO
17 PUT -- WE WANT TO START -- WHEN WE GET TO THE POINT OF
18 STARTING OUR CLINICAL TRIALS, WE WANT THEM TO BE
19 COMPLETELY UNBIASED. WE WANT THEM TO BE HOPEFULLY
20 REASONABLY HYPOTHESIS DRIVEN, AND THE RESULTS ARE GOING
21 TO BE THE RESULTS. WE HOPE THEY'LL BE POSITIVE, BUT WE
22 HAVE NO WAY OF KNOWING HOW THAT'S GOING TO BE.

23 DR. HALL: SMALL POINT JUST TO SHIFT, THE
24 MARCH-IN RIGHTS, COULD I ASK THAT YOU SAY MAINTAIN
25 MARCH-IN RIGHTS FOR FAILURE TO --

1 (OVERLAPPING DISCUSSION.)

2 MS. KING: CAN YOU TELL ME THAT WAS? I HEARD
3 FIVE DIFFERENT VOICES.

4 CHAIRMAN PENHOET: FAILURE TO DEVELOP AND FOR
5 PUBLIC HEALTH AND SAFETY.

6 I GUESS WHAT I NEED FROM THIS GROUP NOW IS A
7 MOTION TO EMPOWER MARY AND ME TO GO TO THE STANDARDS
8 WORKING GROUP AND DISCUSS WITH THEM THESE PRINCIPLES
9 WHICH WE'VE OUTLINED HERE.

10 MR. GOLDBERG: SO MOVED.

11 DR. LOVE: SECOND.

12 CHAIRMAN PENHOET: AND IF THEY AGREE, THEN WE
13 WILL PRESENT THE SAME PRINCIPLES TO THE ICOC WITH THE
14 CAVEAT THAT THESE ARE NOT REGULATIONS. THEY ARE
15 PRINCIPLES IN ANTICIPATION OF FINAL REGULATIONS. AND
16 IF ANYONE ACCEPTS MONEY FROM US FOR TRAINING GRANTS,
17 THEY WOULD HAVE TO BUY A PIG IN THE POKE, BUT THE
18 PEOPLE WILL LIKE THIS.

19 ARE THERE ANY COMMENTS FROM LOS ANGELES?

20 DR. FONTANA: CAN WE JUST HAVE A QUICK REVIEW
21 OF WHAT WE JUST WENT OVER?

22 CHAIRMAN PENHOET: MELISSA, MAYBE YOU CAN
23 READ -- I'LL READ IT. THE PRINCIPLES WE'VE AGREED
24 UPON: GRANTEES OWN THE TECHNOLOGY. WITH RESPECT TO
25 DATA SHARING, WE WANT TO PUSH THE ENVELOPE OF CURRENT

1 PRACTICE WITH MUCH MORE OPEN, ETC. WE STRONGLY SUPPORT
2 THE WIDEST POSSIBLE SHARING. WE WANT TO CREATE A
3 RESEARCH EXEMPTION. THAT WITH RESPECT TO LICENSING, WE
4 HAVE NOT MADE A FINAL DECISION, BUT WE ANTICIPATE THAT
5 THERE MIGHT BE A TAX ON ROYALTIES PAYABLE TO SOME
6 ENTITY TO FURTHER THE INTERESTS OF THE STATE. AND WE
7 HAVE EXPRESSED A PREFERENCE FOR COMPANIES WITH A PLAN
8 FOR PATIENT THERAPY ACCESS. AND THEN WITH RESPECT TO
9 MARCH-IN RIGHTS, CIRM WOULD BE MAINTAIN MARCH-IN RIGHTS
10 TO ADDRESS FAILURE TO DEVELOP OR FOR PUBLIC HEALTH AND
11 SAFETY REASONS.

12 SO THOSE ARE THE PRINCIPLES ARTICULATED ON
13 THIS SLIDE. WE'LL CLEAN IT UP A LITTLE BIT, OF COURSE,
14 BEFORE -- BETWEEN NOW AND THEN. DID WE LOSE FRANCISCO?
15 I DON'T KNOW IF WE STILL HAVE A QUORUM. SO WE'D LIKE A
16 ROLL CALL VOTE. CALL THE ROLL, PLEASE.

17 MS. KING: SUSAN BRYANT.

18 DR. BRYANT: YES.

19 MS. KING: MICHAEL GOLDBERG.

20 MR. GOLDBERG: YES.

21 MS. KING: SHERRY LANSING.

22 DR. FONTANA: SHE'S ABSENT.

23 MS. KING: TED LOVE.

24 DR. LOVE: YES.

25 MS. KING: ED PENHOET.

1 CHAIRMAN PENHOET: YES.
2 MS. KING: PHIL PIZZO.
3 DR. PIZZO: YES.
4 MS. KING: FRANCISCO PRIETO.
5 DR. PRIETO: YES.
6 MS. KING: JEANNIE FONTANA.
7 DR. FONTANA: YES.
8 MS. KING: JEFF SHEEHY.
9 MR. SHEEHY: YES.
10 MS. KING: OSWALD STEWARD IS ABSENT. AND
11 JANET WRIGHT.
12 CHAIRMAN PENHOET: OKAY. THANK YOU. WE'LL
13 LOOK FORWARD TO A DIALOGUE FOR SEVERAL MORE MONTHS, BUT
14 I THINK AT LEAST WE HAVE SOME PRINCIPLES TO WORK WITH.
15 (THE MEETING WAS THEN CONCLUDED AT 02:38
16 P. M.)
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REPORTER'S CERTIFICATE

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

STANFORD UNIVERSITY
CLARK CENTER, S-360
318 CAMPUS DRIVE
STANFORD, CALIFORNIA
ON
TUESDAY, NOVEMBER 22, 2005

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

BETH C. DRAIN, CSR 7152
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