

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

LOCATION: SACRAMENTO CONVENTION CENTER
1400 J STREET
ROOM 104 AND 105
SACRAMENTO, CALIFORNIA

DATE: FRIDAY, JULY 14, 2006
9 A.M.

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

BRS FILE NO.: 75628

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1 SAN FRANCISCO, CALIFORNIA; FRIDAY JULY 14, 2006

2

3 CHAIRMAN PENHOET: PEOPLE AT SITES IN IRVINE,
4 AT STANFORD, AND AT CHICO. I THINK WE HAVE JANET
5 WRIGHT IN CHICO.

6 DR. WRIGHT: CORRECT.

7 CHAIRMAN PENHOET: WELL, I GUESS MELISSA WILL
8 CALL THE ROLL, SO I'LL LET HER JUST GO AHEAD AND DO
9 THAT. MELISSA.

10 MR. KING: ALL RIGHT. SUE BRYANT.

11 DR. BRYANT: HERE.

12 MR. KING: MICHAEL GOLDBERG.

13 MR. GOLDBERG: HERE.

14 MR. KING: SHERRY LANSING. TED LOVE. ED
15 PENHOET.

16 CHAIRMAN PENHOET: HERE.

17 MR. KING: PHIL PIZZO. FRANCISCO PRIETO.
18 JOHN REED -- EXCUSE ME -- JEANNIE FONTANA FOR JOHN
19 REED.

20 DR. FONTANA: HERE.

21 MS. KING: JEFF SHEEHY.

22 MR. SHEEHY: HERE.

23 MS. KING: OSWALD STEWARD. JANET WRIGHT.

24 DR. WRIGHT: HERE.

25 CHAIRMAN PENHOET: FINE. THANK YOU. I THINK

1 YOU ALL KNOW I'M ED PENHOET. I'M CHAIRMAN OF THIS TASK
2 FORCE AND VICE CHAIR OF THE ICOC. WE ARE HERE TODAY TO
3 REVIEW COMMENTS THAT WERE MADE DURING THE 45-DAY
4 COMMENT PERIOD ON THE INTELLECTUAL PROPERTY POLICY THAT
5 THIS TASK FORCE RECOMMENDED TO THE ICOC AND WHICH THE
6 ICOC ADOPTED. AND SO I'M GOING TO TAKE A FEW MINUTES
7 JUST TO REVIEW FOR YOU THE HISTORY OF OUR DELIBERATIONS
8 AND TIMEFRAME IN WHICH WE'VE WORKED, AND THEN MOVE ON
9 TO THE SUBJECT OF THE DAY.

10 WE HAD THREE MEETINGS WITH PRESENTATIONS BY
11 VARIOUS DIFFERENT PEOPLE, AND YOU CAN SEE WHO THOSE
12 INDIVIDUALS ARE HERE ON THIS CHART. OUR FIRST MEETING,
13 BELIEVE IT OR NOT, WAS ALREADY NINE MONTHS AGO, MAYBE
14 TEN MONTHS AGO, OCTOBER 25TH. WE HEARD FROM THE CCST
15 BECAUSE THEY HAD BEEN CHARGED BY THE STATE OF
16 CALIFORNIA TO DEVELOP AN IP POLICY FOR STATE-FUNDED
17 RESEARCH GENERALLY. WE HEARD FROM A REPRESENTATIVE OF
18 THE BIOTECHNOLOGY INDUSTRY. ON OCTOBER 31ST THERE WAS
19 A LEGISLATIVE HEARING IN SAN FRANCISCO WHERE WE HEARD
20 FROM A WHOLE VARIETY OF PEOPLE INTERESTED IN THIS
21 SUBJECT. ON NOVEMBER 22D THERE WAS AN IP TASK FORCE
22 MEETING WHERE WE HEARD FROM, AGAIN, A VARIETY OF
23 DIFFERENT PEOPLE WITH POINTS OF VIEW ABOUT THIS.

24 WE HAVE AS A GROUP STUDIED A LARGE NUMBER OF
25 DOCUMENTS RELEVANT TO THIS SUBJECT. THIS IS A PARTIAL

1 LIST OF THOSE DOCUMENTS THAT WE HAVE STUDIED AND
2 DISCUSSED, IN MANY CASES, THIS ISSUE WITH THE AUTHORS
3 OF THESE DOCUMENTS.

4 AND HERE YOU SEE THE TIMEFRAME. THE MEETINGS
5 I JUST REFERRED TO OCCURRED NEAR THE END OF LAST YEAR.
6 IN DECEMBER THE ICOC APPROVED A SET OF PRINCIPLES THAT
7 WOULD GUIDE OUR WORK GOING FORWARD. SO THE ONE STEP IN
8 THIS PROCESS OF ACTUALLY BEGINNING TO FRAME THESE WHAT
9 WILL BECOME REGULATIONS WAS THAT SET OF GUIDING
10 PRINCIPLES THAT WERE ESTABLISHED BY ICOC AT ITS
11 DECEMBER MEETING.

12 WE THEN, WE, PRIMARILY MARY MAXON, SPENT
13 SEVERAL MONTHS DRAFTING THE FIRST VERSION OF THE
14 INTELLECTUAL PROPERTY POLICY FOR NONPROFIT
15 ORGANIZATIONS. I DON'T KNOW HOW YOU SAY IT, BUT
16 IPPNPO, BUT MAYBE NOBODY CAN MAKE AN ACRONYM WORD OUT
17 OF THAT. WE HAD ANOTHER MEETING IN JANUARY OF THIS
18 TASK FORCE, AND THEN FINALLY AT THE FEBRUARY MEETING OF
19 THE ICOC, WE PRESENTED OUR WORK AND THE INTELLECTUAL
20 PROPERTY POLICY, THAT HAS BEEN THE SUBJECT OF OUR
21 DISCUSSIONS SINCE THEN, WAS APPROVED BY THE ICOC BOARD
22 AT ITS FEBRUARY MEETING.

23 SINCE THEN WE HAVE -- WHAT HAPPENED AFTER
24 THAT WAS THE PRECIPITATION OF A 45-DAY COMMENT PERIOD,
25 AND WE HAVE RECEIVED LOTS OF COMMENTS. AND WE THANK

1 ALL OF YOU WHO ARE HERE TODAY WHO MADE COMMENTS AND
2 MANY PEOPLE NOT HERE TODAY FOR RESPONDING AND GIVING US
3 FEEDBACK.

4 THE PURPOSE OF TODAY'S MEETING IS, IN FACT,
5 FOR THE TASK FORCE TO ANALYZE THE COMMENTS. WE HAVE
6 ALL RECEIVED COPIES OF ALL THE COMMENTS THAT WERE MADE.
7 IT'S QUITE A THICK BOOK, AS YOU CAN SEE. AND OUR TASK
8 FORCE MEMBERS HAVE ANALYZED THOSE COMMENTS, AND WE'RE
9 HERE TO CONSIDER THOSE COMMENTS AND THEN, AT THE END OF
10 THIS MEETING, ESSENTIALLY ALLOW FOR AN ADDITIONAL
11 15-DAY COMMENT PERIOD, WHICH WOULD FOLLOW THIS MEETING
12 FOR PEOPLE TO MAKE ANY FINAL COMMENTS THEY WISH TO MAKE
13 ON THE RECOMMENDATIONS THAT WE HAVE PUT IN PLACE HERE
14 TODAY. AND AT THE END OF THAT 15-DAY COMMENT PERIOD,
15 IF IT'S NECESSARY, THEN THIS GROUP WILL MAKE A FORMAL
16 RECOMMENDATION TO THE ICOC IN THE OCTOBER MEETING. AND
17 AT THAT TIME, IF THE ICOC APPROVES THE REGULATIONS,
18 THEN THEY WILL PROCEED TO BECOME OFFICIALLY ADOPTED BY
19 THE ICOC.

20 I WANT TO REMIND EVERYONE THAT WE ARE WORKING
21 ONLY TODAY AND HAVE BEEN WORKING ONLY ON THE
22 INTELLECTUAL PROPERTY POLICY FOR NONPROFIT
23 ORGANIZATIONS. AND SO THAT'S VERY IMPORTANT TO KEEP IN
24 MIND. WE HAVE AN EXPECTATION THAT THE CIRM WILL FUND
25 PROFIT-MAKING ORGANIZATIONS, OR IN MANY CASES IN

1 BIOTECH COMPANIES, COMPANIES THAT HOPE TO MAKE A PROFIT
2 SOMEDAY -- THEIR INTENT IS TO MAKE A PROFIT ANYWAY --
3 IN A SEPARATE SERIES OF DELIBERATIONS WHICH WE'VE HAD
4 ONE MEETING, AND WE WILL HAVE ANOTHER MEETING IN AUGUST
5 ON AUGUST 3D TO BEGIN TO FRAME THOSE REGULATIONS.

6 WE ARE JOINED TODAY BY DUANE ROTH, WHO IS AN
7 ICOC BOARD MEMBER RECENTLY APPOINTED, AND DUANE EXPECTS
8 TO JOIN THIS TASK FORCE, IF APPROVED, AT THE NEXT ICOC
9 MEETING ON AUGUST 2D FOR OUR DELIBERATIONS OF THE
10 FOR-PROFIT POLICY. DUANE IS HERE TODAY, NOT AS A
11 MEMBER OF OUR TASK FORCE, BUT AS AN INTERESTED MEMBER
12 OF OUR BOARD.

13 SO WE HAVE A LOT OF WORK TO DO TODAY. IT IS
14 A WORKING MEETING, AS I SAID, OF THE IP TASK FORCE TO
15 DISCUSS THE PUBLIC COMMENT REGARDING THIS POLICY. ITS
16 PURPOSE IS TO DETERMINE WHETHER ANY OF THE EXTANT
17 PROPOSED REGULATIONS SHOULD BE AMENDED OR ABOLISHED AND
18 WHETHER ANY NEW REGULATIONS SHOULD BE CONSIDERED. AND
19 WE HAVE SOME OF EACH. SOME OF YOU IN THIS ROOM HAVE
20 RECOMMENDED WE ADOPT SOME NEW THINGS, AND MANY OF YOU
21 HAVE RECOMMENDED THAT WE ALTER IN SOME WAY.

22 UNLIKE THE PREVIOUS IP TASK FORCE MEETINGS,
23 WHICH HAVE BEEN VERY OPEN-ENDED AND REALLY ENCOURAGED
24 DIALOGUE AND COMMENT, TODAY'S MEETING IS ACTUALLY
25 LEGALLY REQUIRED ONLY TO CONSIDER THE WRITTEN

1 MATERIALS, ALTHOUGH WE DO EXPECT TO MAKE TIME FOR
2 VERBAL COMMUNICATIONS FROM YOU DURING THE DAY, BUT WE
3 HAVE A LOT OF WORK TO DO AND WE MUST GET THIS WORK DONE
4 IN FOUR HOURS. SO I WILL USE THE CHAIR'S PREROGATIVE
5 TO LIMIT DISCUSSION IF IT GOES ON FOR TOO LONG, BUT I
6 HOPE TO BE ABLE TO HEAR FROM ANY OF YOU WHO WANT TO
7 AUGMENT WHAT YOU'VE ALREADY SAID.

8 WE ARE NOT HERE TODAY TO HEAR ANY NEW
9 PROPOSALS OR ANY NEW COMMENTS. BUT IF YOU WISH TO
10 ELABORATE ON THE COMMENTS THAT YOU'VE ALREADY MADE IN
11 WRITING DURING THE 45-DAY PROCESS, WE WOULD BE HAPPY TO
12 HEAR FROM YOU.

13 AND, SCOTT TOCHER, IF YOU DON'T MIND, YOU CAN
14 SIMPLY REMIND THE GROUP WHAT THE LEGAL REQUIREMENTS
15 ARE. SCOTT, AS YOU KNOW, IS THE ATTORNEY WHO'S
16 FUNCTIONING AS GENERAL COUNSEL AT CIRM.

17 MR. TOCHER: THANK YOU, ED. THERE'S REALLY
18 TWO BODIES OF LAW THAT ARE CONVERGING HERE FOR TODAY'S
19 MEETING. AND THE ONE IS THE ADMINISTRATIVE PROCEDURES
20 ACT WHICH GOVERNS THE PROCESS THAT WE'RE ENGAGED IN
21 HERE TO PROMULGATE REGULATIONS THAT HAVE THE FORCE AND
22 EFFECT OF LAW. THAT REQUIRES A DECISION-MAKING BODY TO
23 DO AS ED JUST SHOWED YOU, OPEN UP A SERIES OF PERIODS
24 FOR PUBLIC COMMENT. THE APA REQUIRES THAT AN AGENCY
25 RESPOND TO EACH AND EVERY COMMENT THAT IT RECEIVES

1 DURING AN OFFICIAL COMMENT PERIOD AND EXPLAIN EITHER
2 WHY IT DISAGREES WITH THE COMMENT OR HOW IT HAS AMENDED
3 ITS REGULATIONS IN A MANNER IT BELIEVES ADDRESSES THE
4 COMMENT.

5 THE ICOC HAS ESTABLISHED THE IP TASK FORCE
6 FOR THE PURPOSE OF ADVISING IT THROUGH THE DEVELOPMENT
7 PROCESS. SO THE MEETING HERE TODAY IS TO DIGEST THE
8 COMMENT THAT WAS RECEIVED DURING THAT 45-DAY PERIOD AND
9 THAT THE LAW REQUIRES US TO WEIGH IN ON.

10 BAGLEY-KEENE, WHICH IS ANOTHER AREA OF LAW,
11 HAS TO DO WITH OPEN MEETINGS. AND THAT'S WHAT REQUIRES
12 AN AGENCY TO PROVIDE OPPORTUNITY FOR THE PUBLIC TO
13 COMMENT AT A GIVEN MEETING. AND AGENCIES ARE WITHIN
14 THEIR RIGHTS, IN ORDER TO ACCOMPLISH THE MISSION OF THE
15 MEETING, TO LIMIT PUBLIC COMMENT IN AN APPROPRIATE
16 MANNER.

17 THE COMMENT THAT IS RECEIVED TODAY IS NOT
18 COMMENT THAT THE AGENCY IS REQUIRED TO ADDRESS IN ITS
19 FINAL SUBMISSIONS TO THE OAL, WHICH IS WHY THERE IS
20 THAT 40-DAY PROVISION AND THEN, AS ED SAID, AN ENSUING
21 15-DAY COMMENT PERIOD AS WELL AS THE REGULATIONS GET
22 REFINED.

23 SO I JUST WANTED TO SORT OF CLEAR UP, I HOPE,
24 SOME CONFUSION AS TO HOW THE PUBLIC COMMENT PERIODS ARE
25 ADDRESSED DIFFERENTLY BY THE TWO AREAS OF LAW.

1 CHAIRMAN PENHOET: THANK YOU, SCOTT. AND
2 THEN AS WE GO FORWARD, I JUST WANTED TO REMIND YOU
3 THESE ARE THE PRINCIPLES THAT WERE ESTABLISHED AT THE
4 ICOC BOARD MEETING VERY EARLY ON IN THE PROCESS THAT
5 HAVE GUIDED OUR WORK IN GENERAL. SO FIRST OF ALL, WE
6 DID, ICOC DID DECIDE THAT NONPROFIT GRANTEES WOULD OWN
7 THE INTELLECTUAL PROPERTY THAT RESULTED FROM THEIR
8 WORK. IN FACT, WE GOT A LOT OF ADVICE, I THINK, AS
9 MANY OF YOU REMEMBER, THAT WE SHOULD TRY TO ADOPT A
10 POLICY WHICH IS COMPATIBLE WITH BAYH-DOLE, BUT NOT
11 NECESSARILY IDENTICAL. AND THIS IS PROBABLY THE HEART
12 OF BAYH-DOLE, AND THIS WAS THE FIRST PRINCIPLE WE
13 ESTABLISHED.

14 WE SAID THAT WE WANTED TO PURSUE A STRATEGY
15 OF TRYING TO ENCOURAGE PEOPLE TO SHARE MATERIALS BEYOND
16 CURRENT PRACTICES. NIH HAS SHARING GUIDELINES, ETC.,
17 AND WE HAVE TRIED TO MOVE THOSE EVEN FURTHER ALONG,
18 ENSURING THAT THE WORK OF THE STEM CELL INVESTIGATORS
19 FUNDED IN CALIFORNIA WOULD NOT BE HINDERED BY THEIR
20 LACK OF ACCESS TO DATA OR BIOMEDICAL MATERIALS. WE DID
21 AGREE TO TRY TO ESTABLISH A RESEARCH EXEMPTION ALONG
22 SIMILAR LINES FOR CIRM-FUNDED PATENT INVENTIONS.

23 AND THEN UNDER THE LICENSING PROVISIONS, ONE
24 WAS SOME COMMITMENT TO UNDERSERVED CALIFORNIA PATIENTS
25 AND LEFT UNDEFINED AT THIS POINT IN TIME, AND THAT A

1 PORTION OF THE GRANTEE SHARE OF REVENUES SHOULD BE
2 RETURNED TO THE STATE.

3 AND THEN, FINALLY, THAT THERE SHOULD BE
4 MARCH-IN RIGHTS, BUT MARCH-IN RIGHTS WHICH ARE LIMITED
5 TO FAILURE TO DEVELOP OR A SIGNIFICANT ISSUE IN PUBLIC
6 HEALTH AND SAFETY.

7 SO THOSE ARE THE GUIDELINES THAT GUIDED US IN
8 OUR WORK. AND AN IMPORTANT ONE OF THOSE IS THE SHARING
9 POLICY. HERE WE SOUGHT TO PROTECT ACADEMIC FREEDOM AND
10 PROMOTE PUBLICATION, MINIMIZE IMPEDIMENTS TO STEM CELL
11 RESEARCH, ALLOW GRANTEES TO CONFORM TO BAYH-DOLE
12 OBLIGATIONS WITH RESPECT TO INVENTIONS THAT RESULT FROM
13 RESEARCH FUNDED BY BOTH CIRM AND FEDERAL FUNDS. IT'S
14 VERY LIKELY THERE WILL BE COMMINGLING IN THE
15 LABORATORIES. ENCOURAGE BROAD DISSEMINATION,
16 FACILITATE THE TRANSLATION OF THESE DISCOVERIES TO
17 THERAPIES, AND THEN ENSURE BROAD ACCESS TO RESEARCH
18 INSTITUTIONS IN THE STATE FOR INVENTIONS MADE WITH CIRM
19 FUNDING WHICH COULD BE USED BY OTHERS IN THE STATE
20 THROUGH A RESEARCH EXEMPTION.

21 CERTAINLY WE ARE GOING TO DEAL WITH ALL OF
22 THESE ISSUES GOING FORWARD. WE HAVE TWO CATEGORIES
23 BASICALLY OF THINGS TO CONSIDER TODAY. COMMENTS ON THE
24 POLICIES THAT WE HAVE PROPOSED. THOSE ARE HERE IN
25 BLACK. WE HAVE GOTTEN A LOT OF FEEDBACK ABOUT THE

1 RESEARCH EXEMPTION, AND WE EXPECT TO HAVE SOME DIALOGUE
2 ABOUT THAT IN THIS MEETING TODAY. WE HAVE GOTTEN
3 FEEDBACK ON MARCH-IN RIGHTS, ON REVENUE SHARING, ON
4 EXCLUSIVE LICENSE ACCESS PLANNED, AND THEN WE HAVE TWO
5 NEW PROPOSALS. ONE IS THAT WE ACTUALLY DEMAND AN OPEN
6 ACCESS ARCHIVE DEPOSITION FOR SCIENTIFIC MANUSCRIPTS,
7 AND THE SECOND ONE IS THAT WE CREATE A PATENT POOL. SO
8 THESE ARE NEW IDEAS NOT CURRENTLY IN OUR REGULATIONS.

9 SO THE FIRST FOUR COMMENTS ARE THINGS WHICH
10 ARE IN THE REGULATIONS, THE LAST TWO ARE NEW PROPOSALS
11 THAT ARE PUT IN FRONT OF US.

12 BEFORE WE GET INTO ANY OF THE DETAILS OF
13 THIS, I MIGHT ASK SCOTT TO JUST TELL YOU HOW THE
14 COMMENTS TODAY ARE STRUCTURED. THERE ARE THREE
15 CATEGORIES, AS YOU WILL SEE, AND WE HAVE SEVERAL
16 PROJECTS IN EACH CATEGORY. AND SCOTT WAS THE FINAL
17 AUTHOR OF THIS, SO, SCOTT, PLEASE.

18 MR. TOCHER: ALL RIGHT. I GUESS THE
19 CRITICISM SHOULD BE DIRECTED HERE THEN. GIVEN THE ROLE
20 OF THE TASK FORCE IN ADVISING THE ICOC AND GIVEN THE
21 CONSTRAINTS OF TIME AND RESOURCES THAT WE HAVE, AN
22 EFFORT WAS MADE TO UTILIZE THE TASK FORCE TO ITS BEST
23 TALENTS, WHICH IS TO ADVISE THE ICOC ON MATTERS OF
24 POLICY AND WHETHER THE REGULATIONS ACHIEVE THOSE
25 MATTERS.

1 SO SOME OF YOU MAY NOTICE PERHAPS THAT SOME
2 COMMENTS THAT ARE IN THE RAW COMMENT AREN'T ACTUALLY
3 FOUND SPECIFICALLY DISCUSSED IN DETAIL IN THE DIGEST
4 THAT YOU HAVE. AS I MENTIONED EARLIER, ALL THE
5 COMMENTS WILL BE ADDRESSED IN A REPORT TO THE ICOC, AND
6 THAT WILL BE ADOPTED BY THE ICOC WHEN IT ADOPTS THE
7 FINAL REGULATIONS. BECAUSE SOME OF THE COMMENTS THAT
8 CAME IN WERE OF A CERTAIN TECHNICAL NATURE OR
9 CLARIFYING NATURE THAT DIDN'T IMPLICATE A POLICY
10 DISCUSSION OR DISPUTE, IT SEEMED THAT THOSE COULD BE
11 DEALT WITH, I GUESS, WITHOUT THE NEED FOR HAVING TO GET
12 INPUT ON A POLICY LEVEL FROM THE TASK FORCE.

13 THE COMMENTS, THEN, WERE SORT OF GROUPED FROM
14 A, B, AND C, NOT IN MATTER OF IMPORTANCE, BUT RATHER IN
15 AN ESTIMATE OF MINE AS TO SORT OF WHAT THE POLICY
16 IMPLICATIONS WERE AND SORT OF THE SUBSTANCE OF THAT
17 PARTICULAR END OF THE DISCUSSION. SO THEY ARE DIVIDED
18 SORT OF IN A ROUGH GENERAL GROUPING OF HOW I SORT OF
19 FORESAW THE LEVEL OF SORT OF DISCUSSION THAT WOULD
20 REVOLVE AROUND POLICY CALLS THAT HAVE BEEN MADE OR
21 POLICY CALLS THAT THE TASK FORCE IS BEING ASKED TO
22 COMMENT ON.

23 CHAIRMAN PENHOET: JEFF SHEEHY.

24 MR. SHEEHY: JUST A LITTLE CLARIFICATION
25 ON -- BECAUSE I THINK THERE WERE COMMENTS FROM KEN

1 TAYMOR AND FROM, I THINK, THE UNIVERSITY OF CALIFORNIA
2 THAT WERE PRETTY MUCH CLEANUP. SO WHAT'S -- WHAT,
3 AGAIN, IS THE PROCESS ON THAT?

4 MR. TOCHER: RIGHT. THOSE -- I'M GLAD YOU
5 BROUGHT THOSE UP. THOSE ARE THE ONES SPECIFICALLY I
6 HAD IN MIND. THE PROCESS GOING FORWARD WILL BE TO TAKE
7 THOSE CLARIFYING COMMENTS AND RENOTICE THE REGULATIONS
8 TO INCLUDE THE CLARIFICATIONS TO ACHIEVE THE CLARITY
9 THAT WE SEEK. AND SO THOSE WILL ENDURE. THOSE
10 SPECIFIC REGULATIONS WILL THEN BE RENOTICED WITH
11 WHATEVER REGULATIONS ELSE WE MODIFY FOR AN ADDITIONAL
12 15-DAY PUBLIC COMMENT PERIOD.

13 MR. SHEEHY: WELL, I HAD ANOTHER QUESTION
14 RELATED TO THAT BECAUSE IT SEEMED LIKE, ESPECIALLY ON
15 THE ISSUE OF DEFINITIONS, THAT THERE WAS SOME LEGALESE
16 GOING ON THERE. AND I WONDER -- I REMEMBER THAT WE
17 HAVE PRO BONO DONATION FROM THE MAYOR OF SAN FRANCISCO
18 OF INTELLECTUAL PROPERTY LAW FIRM TIME. AND I WONDER
19 IF PART OF THIS PROCESS OF THIS KIND OF CLEANUP, WHICH
20 IS REALLY WHAT WE'RE TALKING ABOUT, IF THEY COULD DO A
21 REVIEW OF THIS OR HAVE THEY? JUST TO MAKE SURE
22 TECHNICALLY THAT THE LANGUAGE IS CONSISTENT WITH THE
23 LANGUAGE THAT IS COMMONLY -- AND DEFINITIONS ARE THOSE
24 THAT ARE COMMONLY USED BY PEOPLE IN THE INTELLECTUAL
25 PROPERTY FIELD. IT WOULDN'T COST US ANYTHING BECAUSE I

1 THINK THEY DONATED TENS OF HOURS, IF NOT HUNDREDS OF
2 HOURS.

3 I JUST NOTICE, ESPECIALLY ON KEN TAYMOR'S
4 COMMENTS, THAT THERE WAS SOME QUESTION AS TO SOME OF
5 THE LANGUAGE WE USED, IF THAT WAS CONSISTENT WITH WHAT
6 WAS COMMONLY USED WITHIN THE INTELLECTUAL PROPERTY LAW
7 ARENA. SO MIGHT THAT BE POSSIBLE AS PART OF A GENERAL
8 CLEANUP THAT WE CAN PUT IT OUT FOR 15-DAY COMMENT AND
9 BRING BACK?

10 MR. TOCHER: YES. I DON'T SEE ANYTHING THAT
11 WOULD PREVENT THAT. THAT'S A GOOD SUGGESTION.

12 ALSO, LET ME ALSO JUST ADD THAT IF THE
13 COMMENTER IS HERE OR ANYBODY SEES A COMMENT THAT THEY
14 THINK SHOULD BE MORE SPECIFICALLY ADDRESSED, THERE'S
15 NOTHING WHICH PREVENTS TODAY'S DISCUSSION FROM TAKING
16 UP THAT PARTICULAR COMMENT.

17 CHAIRMAN PENHOET: OKAY. THANK YOU. SO
18 WE'RE GOING TO MOVE THROUGH THIS IN THE ORDER THAT'S IN
19 YOUR BOOK, STARTING WITH CATEGORY A. AND THE FIRST
20 ISSUE IN CATEGORY A REGARDS REVENUE SHARING. LET ME
21 STATE AT THE OUTSET THAT THERE'S BEEN A LOT OF
22 CONFUSION IN THE PRESS AND IN A NUMBER OF OBSERVER'S
23 MINDS ABOUT WHAT 25 PERCENT MEANS. THE PRIMARY
24 CONFUSION THAT I'VE SEEN, AT LEAST, IS THAT MANY PEOPLE
25 HAVE CONSTRUED OUR LANGUAGE AND OUR INTENT HERE TO

1 IMPOSE A 25-PERCENT ROYALTY ON SALES OF PRODUCTS.
2 OKAY. THAT IS NOT THE INTENT. NONPROFIT ORGANIZATIONS
3 THEMSELVES DO NOT MANUFACTURE AND SELL PRODUCTS. WHAT
4 THEY DO IS CREATE INTELLECTUAL PROPERTY AND LICENSE
5 THAT INTELLECTUAL PROPERTY TO COMPANIES WHICH
6 THEMSELVES WILL MANUFACTURE AND SELL THE PRODUCTS. IN
7 EXCHANGE FOR A LICENSE, THEY FREQUENTLY GIVE ROYALTY
8 PAYMENTS TO THE NONPROFIT INSTITUTION TO REFLECT THE
9 VALUE OF WHATEVER THAT INVENTION IS THAT THEY HAVE
10 LICENSED TO THE PROFIT-MAKING ORGANIZATIONS.

11 OUR POLICY SAYS THAT THE NONPROFIT
12 ORGANIZATIONS WILL RETURN TO THE STATE 25 PERCENT OF
13 THE ROYALTIES THAT THEY RECEIVE FROM THIRD PARTIES, NOT
14 A 25-PERCENT ROYALTY. SO TYPICALLY, JUST FOR CLARITY
15 SAKE, ROYALTIES PAID BY COMPANIES TO NONPROFITS
16 GENERALLY VARY IN THE 3- TO 10-PERCENT RANGE. SO IF
17 THAT WAS A TYPICAL CASE, THEN THE TRUE FLOWTHROUGH OF A
18 ROYALTY WOULD BE 25 PERCENT OF 3 PERCENT, OR
19 THREE-QUARTERS OF A PERCENT, TO A MAXIMUM OF 2.5
20 PERCENT ON THE EVENTUAL SALE OF THOSE PRODUCTS. SO
21 THAT GIVES YOU A RANGE, SO TO SPEAK, ON WHAT THE
22 ROYALTY BURDEN WOULD BE OF THIS FLOWBACK TO THE STATE.

23 AND BECAUSE THAT'S BEEN MISUNDERSTOOD IN MANY
24 CASES, I WANTED TO MAKE THAT CLARIFICATION BEFORE WE
25 ENTER INTO A DISCUSSION ABOUT WHETHER WE SHOULD ABOLISH

1 THIS, WE SHOULD KEEP IT, OR WE SHOULD MAKE IT HIGHER.
2 AND THAT'S THE SORT OF BID AND THE ASK HERE. AS SOME
3 PEOPLE SAY, THERE SHOULD BE NO SHARING WITH THE STATE
4 AT ALL OF FINANCIAL REVENUES, AND THE HIGH END OF THE
5 RANGE SAYS THAT WE SHOULD INCREASE THIS NUMBER FROM 25
6 TO 50 PERCENT AND LOWER THE THRESHOLD ABOVE WHICH
7 NONPROFITS WOULD HAVE TO PAY FROM \$500,000 TO \$100,000.

8 IN THAT REGARD, LET ME ALSO CLARIFY THAT OUR
9 DEFINITION OF NET REVENUES ARE THOSE REVENUES WHICH ARE
10 MAINTAINED BY THE NONPROFIT ORGANIZATION EXCLUSIVE OF
11 THE INVENTOR SHARE BECAUSE WE DID NOT WANT TO CREATE A
12 DISINCENTIVE FOR THE INVENTORS IN CALIFORNIA TO
13 ACTUALLY TAKE FUNDS FROM SOMEBODY ELSE IF THEIR SHARE
14 WAS GOING TO BE DECREASED AS A RESULT OF THIS FUNDING.

15 SO THE PROPOSAL IN FRONT OF YOU IS THAT
16 NONPROFITS, IF THEY GET MONETARY REMUNERATION FOR
17 INVENTIONS THEY MAKE WITH CIRM-FUNDED PROGRAMS, WILL
18 RETURN TO THE STATE 25 PERCENT OF EVERYTHING THEY GET
19 IN RESPONSE TO THIS ABOVE \$500,000, NET OF ANYTHING
20 THEY WILL HAVE PAID TO THE INVENTORS THEMSELVES. EACH
21 INSTITUTION HAS SOMEWHAT DIFFERENT POLICIES HOW THEY
22 SHARE REVENUES, ETC., WITH INVENTORS, AND SO THAT'S THE
23 BACKGROUND OF THIS POLICY.

24 WE WORKED HARD ON THIS POLICY. THERE IS AN
25 EXPLICIT REQUIREMENT IN PROP 71 THAT THERE IS REVENUE

1 SHARING WITH THE STATE. WE HEARD LOTS OF ARGUMENT PRO
2 AND CON. WE DECIDED ON THE \$500,000 NUMBER AT THE TIME
3 BECAUSE THAT'S THE ESTIMATE THAT WE GOT WAS TYPICAL FOR
4 WHAT IT COSTS UNIVERSITIES TO MAINTAIN THEIR PATENT
5 OFFICES, ETC. THE NET REVENUES, HOWEVER, DO NOT
6 INCLUDE THE ONGOING OVERHEAD OF THE UNIVERSITIES'
7 PATENT AND LICENSING OFFICES, BUT THAT'S WRAPPED INTO
8 THE \$500,000 NUMBER. SO THAT'S HOW WE GOT WHERE WE
9 ARE.

10 THIS IS A CORNERSTONE OF OUR POLICY, AND I
11 THINK IT'S ONE IN WHICH WE WOULD BE AT THIS POINT
12 PLEASED TO HEAR PUBLIC COMMENT, BUT I WOULD ASK YOU TO
13 LIMIT YOUR COMMENTS TO THE WRITTEN COMMENTS THAT
14 YOU -- IF YOU WANT TO REINFORCE A WRITTEN COMMENT THAT
15 YOU'VE ALREADY MADE, PLEASE DO THAT, AND THAT YOU WOULD
16 LIMIT YOUR COMMENTS TO A THREE-MINUTE PERIOD BECAUSE,
17 AS I SAID BEFORE, WE HAVE A LOT OF MATERIAL TO GO
18 THROUGH TODAY. SO AT THIS POINT I'LL OPEN THE FLOOR TO
19 ANY -- WELL, FIRST OF ALL, LET ME ASK IF THERE ARE
20 QUESTIONS ON THE PART OF OUR TASK FORCE ON THIS ISSUE.

21 MR. SHEEHY: JUST TO KIND OF ADD TO BECAUSE I
22 THINK THERE'S A LITTLE BIT MORE IN THE CLARIFYING.
23 EXCUSE ME. ONE OF THE THINGS WE NEED TO RECOGNIZE IS
24 THAT NEITHER CIRM NOR THE STATE OF CALIFORNIA HAS AN
25 OFFICE OF TECHNOLOGY AND LICENSING. SO WHAT WE HAVE TO

1 RECOGNIZE IS THAT WE'RE RELYING ON THE UNIVERSITIES AND
2 THE NONPROFIT ORGANIZATIONS AND THEIR OFFICES OF
3 TECHNOLOGY AND LICENSING TO DO THIS FOR US.

4 CHAIRMAN PENHOET: THAT'S CORRECT.

5 MR. SHEEHY: SO THAT GIVES KIND OF A FLAVOR
6 OF WHAT WE'RE DOING. WE DO NOT HAVE THE CAPACITY AS AN
7 ORGANIZATION WITH MANDATED 50 EMPLOYEES TO SET UP AN
8 OFFICE OF TECHNOLOGY AND LICENSING AND DO THE
9 SCIENTIFIC REVIEW AND THE MONITORING OF SCIENTIFIC
10 GRANTS THAT WE WILL BE DOING. SO THAT IS NOT SOMETHING
11 THAT'S FEASIBLE FOR US.

12 I WOULD NOTE THAT ASSEMBLYMAN GENE MULLIN HAS
13 A BILL CURRENTLY IN THE LEGISLATURE TO SET UP A
14 STATEWIDE OFFICE OF TECHNOLOGY AND LICENSING, AND THAT
15 THE STATE AS A WHOLE DOES NOT MANAGE THE INTELLECTUAL
16 PROPERTY THAT IT CREATES IN ANY KIND OF SYSTEMATIC WAY.
17 SO THAT IS KIND OF A RESPONSIBILITY FOR THE LEGISLATURE
18 TO ADDRESS. IT'S NOT SOMETHING THAT CIRM CAN OR THE
19 ICOC CAN ADDRESS.

20 AND THEN THERE'S ONE MORE POINT. ONE OF THE
21 THINGS THAT I THINK IS IMPORTANT TO ITERATE IS THAT THE
22 OFFICES OF TECHNOLOGY AND LICENSING AT THE UNIVERSITY
23 LEVEL WILL BE BASICALLY RESPONSIBLE FOR MAKING SURE
24 THAT PATENTS ARE TAKEN OUT ON CIRM-FUNDED INVENTIONS
25 AND THAT MOST OF THOSE WILL NOT BE PROFITABLE. THERE

1 WILL BE TREMENDOUS EXPENSE FOR THE UNIVERSITIES IN
2 MAKING SURE PATENTS ARE APPLIED FOR; BUT GOING BACK TO
3 THE TESTIMONY THAT WE GOT FROM STANFORD AND THE UC
4 SYSTEM, MOST OF THE TIME THAT IS A MONEY LOSER FOR
5 THEM. AND THERE'S ONLY A VERY, VERY SMALL PERCENTAGE
6 OF PATENTS THAT THEY HAVE TAKEN OUT AT GREAT EXPENSE
7 AND THAT THEY GO THROUGH GREAT EXPENSE TO DEFEND THAT
8 ACTUALLY PRODUCE A PROFIT.

9 SO THAT'S WHY WE HAVE THIS \$500,000 LEVEL.
10 JUST TO GIVE A LITTLE BIT OF THE SENSE OF THE FLAVOR OF
11 THE DEBATE THAT TOOK PLACE EARLIER ON THIS.

12 CHAIRMAN PENHOET: THANK YOU, JEFF. ANY
13 OTHER COMMENTS FROM TASK FORCE MEMBERS HERE IN
14 SACRAMENTO? IN IRVINE? STANFORD? OR CHICO? OKAY.
15 WITH THAT, I'LL OPEN THE FLOOR TO BRIEF COMMENTS, AS I
16 SAID BEFORE, CONFINED TO THE MATERIALS THAT YOU HAVE
17 PREVIOUSLY SUBMITTED IN WRITING. JOHN SIMPSON.

18 MR. SIMPSON: JOHN SIMPSON FROM THE
19 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. JUST TO
20 REITERATE WHAT WE PUT IN THERE. AS I SAID, IT --

21 DR. BRYANT: LOUDER.

22 CHAIRMAN PENHOET: THAT MIC MAY NOT BE ON.
23 CAN YOU -- WE ALWAYS TURN IT OFF WHEN YOU START TO
24 SPEAK, JOHN.

25 MR. SIMPSON: JOHN SIMPSON FROM THE

1 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. VERY
2 QUICKLY, WE UNDERSTAND THAT ANY ACTUAL COSTS OF
3 PATENTING, PROSECUTING THE PATENT, DEFENDING THE
4 PATENTS WOULD NOT BE INCLUDED IN NET REVENUES AS IT'S
5 CURRENTLY WRITTEN. SO THAT'S THE REASON THAT IT WOULD
6 COME DOWN -- THOSE WOULD BE REIMBURSABLE, AND SO YOU'RE
7 TALKING ABOUT NET REVENUES.

8 A \$100,000 THRESHOLD OUGHT TO BE ENOUGH TO
9 COVER THE ONGOING OPERATIONS OF THE UNIVERSITIES'
10 OFFICE. THAT'S OUR POINT.

11 MS. KING: MAKE SURE THIS MIC IS WORKING NOW.
12 CAN THE OTHER SITES HEAR ME?

13 CHAIRMAN PENHOET: DID YOU HEAR JOHN
14 SIMPSON'S COMMENTS?

15 DR. BRYANT: WE DID, YES.

16 MR. GOLDBERG: YES.

17 CHAIRMAN PENHOET: AND THEN WENDY STREITZ
18 FROM THE UNIVERSITY OF CALIFORNIA.

19 MS. STREITZ: OKAY. CAN EVERYBODY HEAR ME?
20 GOOD. WENDY STREITZ, UNIVERSITY OF CALIFORNIA. AND
21 JUST TO RESPOND TO WHAT JOHN SAID, WHEN WE'RE TALKING
22 ABOUT THE ONE INVENTION THAT SUCCEEDS AND MAKES MONEY,
23 YES, THAT'S TRUE. BUT FOR EVERY ONE THAT SUCCEEDS AND
24 MAKES MONEY, THERE ARE A NUMBER OF OTHERS THAT WE'VE
25 INVESTED IN PATENT EXPENSES FOR THAT ULTIMATELY DID NOT

1 SUCCEED. AND THE SIZE OF THAT THRESHOLD, MY
2 UNDERSTANDING IS, WAS INTENDED TO HELP DEFRAY THE COST
3 OF THOSE OTHERS TO ENCOURAGE US TO INVEST IN THOSE AS
4 WELL.

5 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM
6 THE PUBLIC? IF I COULD FOR THE TASK FORCE, I'D LIKE TO
7 PARSE THIS DISCUSSION INTO TWO PIECES. ONE IS THE
8 25-PERCENT SHARING. SO THE RULE, AS WE ADOPTED BEFORE,
9 SAYS THAT NONPROFITS WOULD SHARE 25 PERCENT OF THEIR
10 REVENUES WITH THE STATE OF CALIFORNIA. DO WE HAVE
11 ANYONE ON THE TASK FORCE WHO BELIEVES WE OUGHT TO
12 CHANGE THAT NUMBER, EITHER TO ZERO OR TO 50 PERCENT OR
13 ANOTHER NUMBER?

14 DR. BRYANT: I HAVE A COMMENT ON IT.

15 CHAIRMAN PENHOET: YES.

16 DR. BRYANT: OKAY. THIS IS SUE BRYANT. SO I
17 DO BELIEVE THAT WE HAVE TO DO THIS GIVEN THE SECOND
18 SENTENCE OF PROPOSITION 71, BUT I AM ACTUALLY VERY
19 NERVOUS ABOUT IT BECAUSE I THINK THAT THIS COULD END UP
20 WITH A MAJOR LOSS TO UNIVERSITIES IF NIH AND OTHER
21 FEDERAL AGENCIES DECIDE TO FOLLOW SUIT, IN WHICH CASE I
22 DON'T KNOW WHAT'S GOING TO HAPPEN TO OUR RESEARCH
23 ENTERPRISE.

24 CHAIRMAN PENHOET: JEFF SHEEHY.

25 MR. SHEEHY: I JUST -- I GUESS MY COMMENT ON

1 THIS IS I THINK ONE OF THE MAJOR FACTORS SUPPORTING 25
2 PERCENT IS THAT THAT'S WHAT UNIVERSITIES GIVE TO HOWARD
3 HUGHES IF THEY ACCEPT A HOWARD HUGHES RESEARCHER. SO
4 THIS SEEMS TO BE SOMETHING THAT DOESN'T DISINCENTIVIZE
5 UNIVERSITIES FROM WORKING WITH HOWARD HUGHES
6 RESEARCHERS.

7 SO AND WITH ALL RESPECT TO DR. BRYANT, THE
8 IDEA THAT A PRECEDENT MIGHT BE SET THAT INFLUENCED THE
9 FEDERAL GOVERNMENT ISN'T REALLY A GOOD ARGUMENT FOR
10 FAILING TO FULFILL OUR OBLIGATION TO RETURN -- OUR
11 STATUTORY OBLIGATION TO PRODUCE RETURN TO THE STATE.

12 DR. BRYANT: NO. THIS IS SUE BRYANT AGAIN.
13 I COMPLETELY AGREE. I VOTED FOR THIS AND I'LL VOTE FOR
14 IT AGAIN. I'M JUST SAYING THAT I THINK THAT THERE
15 COULD BE SOME UNINTENDED CONSEQUENCES DOWN THE LINE.
16 AND IT'S TRUE THAT UNIVERSITIES ACCEPT MONEY FROM
17 FOUNDATIONS AT A LOWER PERCENTAGE, BUT THAT'S BECAUSE
18 THE BULK OF THE FUNDING THAT THEY RECEIVE IS NOT THAT
19 WAY. AND IF IT ALL CHANGED, I THINK IT WOULD CAUSE A
20 MAJOR UPSET IN THE WAY WE DO BUSINESS.

21 CHAIRMAN PENHOET: THANK YOU FOR YOUR
22 COMMENTS. ANY OTHER COMMENTS FROM THE TASK FORCE? SO
23 WE DON'T NEED A ROLL CALL VOTE. I'LL SIMPLY ASK DOES
24 ANY TASK FORCE MEMBER WISH TO CHANGE THIS FEATURE,
25 REVENUE SHARING? IF NOT, THEN I THINK WE'VE

1 ESTABLISHED A 25 PERCENT.

2 SECOND ISSUE IS WHAT SHOULD THE THRESHOLD BE.
3 WE HAVE HEARD FROM THE UNIVERSITY OF CALIFORNIA AND
4 FROM JOHN SIMPSON TWO OPPOSING VIEWS. ONE, JOHN'S VIEW
5 IS THAT A \$100,000 SHOULD BE ADEQUATE GIVEN THE FACT,
6 IF I COULD PARAPHRASE YOUR COMMENT, THAT WE DID AGREE
7 TO INCLUDE DIRECT PATENT COSTS FOR THIS PATENT -- THESE
8 SPECIFIC PATENTS IN THE DEFINITION OF NET REVENUES.
9 AND MS. STREITZ MADE THE POINT THAT MOST OF THESE ARE
10 LOSERS AND, THEREFORE, THE \$500,000 WAS SORT OF AN
11 AVERAGE NUMBER. THAT WAS THE TWO SIDES OF THAT
12 DISCUSSION.

13 WE HAVE DISCUSSED IT BEFORE, AND AT THIS
14 POINT I'D LIKE TO HEAR COMMENT FROM BOARD MEMBERS ON
15 THE ISSUE OF THE THRESHOLD. WE HAVE PROPOSED \$500,000.
16 WE HAVE AN ALTERNATIVE PROPOSAL OF \$100,000.

17 MR. SHEEHY: I JUST MIGHT HAVE A QUESTION FOR
18 WENDY. WE'RE TALKING ABOUT -- MY SUSPICION, AND I JUST
19 WONDER, NOT TO KIND OF THROW OR DIRECT HER WHERE SHE
20 SHOULD GO, BUT MY SUSPICION, BASED ON EARLIER
21 TESTIMONY, IS THAT WE'RE NOT LOOKING AT A LOT BETWEEN A
22 HUNDRED AND 500,000, YOU KNOW. I MEAN THIS THRESHOLD
23 IT REALLY IS ONCE YOU HIT THAT 500,000, YOU PROBABLY
24 ARE GOING TO BE MAKING SOME MONEY. AND BELOW THAT, YOU
25 KNOW, IT DOESN'T SEEM LIKE THAT THERE'S A LOT THERE

1 THAT WE REALLY SHOULD BE ANTICIPATING CAPTURING, THAT
2 THE \$500,000 LEVEL IS ADEQUATE TO GET THOSE INVENTIONS
3 THAT ARE REALLY GOING TO MAKE REVENUE AS OPPOSED TO
4 THOSE THAT ARE NOT GOING TO MAKE REVENUE. AND I WONDER
5 IF YOU COULD SPEAK TO THAT.

6 CHAIRMAN PENHOET: IF I COULD, WENDY, ONE WAY
7 TO ANSWER THAT QUESTION WOULD BE THE DISTRIBUTION OF
8 RETURNS. WHEN YOU GET A PATENT WHICH IS USEFUL AND
9 GENERATES REVENUES, DO THEY TEND TO BE BINARY? DO THEY
10 EITHER MAKE A LOT OF MONEY OR NO MONEY? OR ARE THERE A
11 LOT OF PATENTS WHICH YOU MIGHT MAKE \$400,000?

12 MS. STREITZ: THE VAST MAJORITY MAKE NO MONEY
13 OR VERY LITTLE MONEY BELOW EVEN THE 100,000.
14 UNFORTUNATELY I DON'T HAVE THE NUMBERS IN FRONT OF ME,
15 SO I CAN'T TELL YOU WHAT THE SPREAD IS, BUT WHAT YOU
16 SAID, JEFF, SEEMS REASONABLE TO ME.

17 MR. SHEEHY: I THINK THAT'S WHAT THE PERSON
18 WHO FULFILLS YOUR ROLE AT STANFORD HAD SUGGESTED QUITE
19 STRONGLY WHEN WE WERE FORMULATING THIS POLICY. SO I
20 DON'T THINK WE'RE TALKING ABOUT, CONCEPTUALLY, IF WE
21 LOWER IT, THAT WE'RE GOING TO BE LEAVING ANY
22 SIGNIFICANT AMOUNT OF MONEY ON THE TABLE, BUT, YOU
23 KNOW, THERE SEEMS TO BE A SENSE THAT THAT'S FAIRLY
24 TRUE.

25 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM

1 THE BOARD MEMBERS?

2 DR. BRYANT: I WOULD RECOMMEND LEAVING IT AT
3 500,000. I THINK THAT WILL CAPTURE MOST OF WHAT WE
4 WANT. AND IF THERE IS SOMETHING IN BETWEEN A HUNDRED
5 AND 500, IT WILL HELP OFFSET THE PATENT COSTS OF ALL
6 THE FAILURES.

7 MR. GOLDBERG: I SUPPORT THAT.

8 DR. WRIGHT: I AGREE. AND THIS IS JANET
9 WRIGHT. I JUST HAVE A QUESTION. I'M STILL CAUGHT WITH
10 SUE'S CONCERN. REMIND ME OF THE PROCESS. IF WE SEE
11 DOWN THE ROAD THAT THIS HAS HAD A NEGATIVE IMPACT, THIS
12 HAS BEEN AN UNINTENDED CONSEQUENCE, WHAT'S THE PROCESS
13 OF CHANGING SOME OF THIS -- SOME OF THESE PARAMETERS IN
14 THE FUTURE DOWN THE ROAD FIVE YEARS FROM NOW?

15 CHAIRMAN PENHOET: I'LL REFER THAT QUESTION
16 TO SCOTT TOCHER.

17 MR. TOCHER: WELL, THE PROCESS WOULD BE THE
18 SAME AS THE PROCESS IN ADOPTING THE RULE IN THE FIRST
19 PLACE. WE WOULD GO TO THE ICOC. YOU WOULD RECOMMEND A
20 CHANGE TO THE REGULATION THAT ADJUSTS THAT PERCENTAGE,
21 THAT THRESHOLD. IT WOULD GO THROUGH ANOTHER COMMENT
22 PERIOD, JUST AS WE'RE DOING HERE, 45 DAYS, BEFORE THE
23 REGULATION WILL GO INTO EFFECT. SO YOU'D PROBABLY BE
24 LOOKING AT ABOUT A FOUR-MONTH PROCESS TO MAKE AN
25 ADJUSTMENT TO THIS OR, IN FACT, ANY OTHER REGULATION.

1 DR. WRIGHT: GREAT. THANK YOU. THAT SAID,
2 I'M COMFORTABLE WITH THE 500,000 AND THE 25 PERCENT.

3 CHAIRMAN PENHOET: WE HAVE A COMMENT FROM
4 FELLOW BOARD MEMBER DUANE ROTH.

5 MR. ROTH: YES. I WOULD, IN LIGHT OF THIS,
6 BECAUSE I THINK THIS IS REALLY IMPORTANT, IT'S VERY
7 DIFFICULT FOR INSTITUTIONS TO FILE ALL THE PATENTS THAT
8 THEY'RE GOING TO SEE. AND THIS IS GOING TO PRODUCE AN
9 AWFUL LOT. THAT YOU THINK AHEAD, THIS IS A 10-YEAR
10 PROGRAM. WHILE 500,000 MAY BE ACCEPTABLE TODAY AND
11 COVER SOME OF THE COST, I WOULD ENCOURAGE YOU TO PUT
12 SOME KIND OF INFLATIONARY KICKER IN HERE BECAUSE TEN
13 YEARS DOWN THE ROAD, UNLESS WE THINK EVERYBODY IS GOING
14 TO WORK FOR EXACTLY THIS SAME AMOUNT OF MONEY TODAY,
15 YOU'RE GOING TO HAVE THIS NUMBER BE INADEQUATE VERY
16 QUICKLY.

17 DR. MAXON: WE DID THAT ACTUALLY.

18 DR. BRYANT: I SUPPORT THAT. I THINK THAT'S
19 A GOOD IDEA.

20 CHAIRMAN PENHOET: ACCORDING TO MARY MAXON,
21 IT IS EMBODIED.

22 MR. TOCHER: SUBDIVISION B OF 100308 PROVIDES
23 FOR INCREASES, PERIODIC INCREASES, TO REFLECT THE COST
24 OF LIVING INCREASE.

25 DR. WRIGHT: WHAT WAS THAT LAST COMMENT?

1 THIS IS --

2 CHAIRMAN PENHOET: THAT'S FROM SCOTT TOCHER.
3 BASICALLY THERE IS A CPI ADJUSTMENT EMBODIED IN THE --

4 MR. ROTH: IS IT AUTOMATIC AND ANNUAL
5 ADJUSTMENT, OR IS IT FROM TIME TO TIME?

6 CHAIRMAN PENHOET: WE HAVE A LOT OF FURROWED
7 BROWS IN THE ROOM IN SACRAMENTO. WE'LL LET YOU KNOW.

8 DR. BRYANT: I THINK IT'S --

9 DR. MAXON: IT'S AUTOMATIC ACTUALLY.

10 CHAIRMAN PENHOET: IT'S AUTOMATIC AND ANNUAL;
11 IS THAT CORRECT? THANK YOU, JOHN SIMPSON, FOR THAT
12 CLARIFICATION. OKAY. ANY -- SCOTT.

13 MR. TOCHER: WELL, I WAS JUST GOING TO SAY
14 THAT IT COULD CERTAINLY BE CLARIFIED. IF IT TAKES US
15 ALL TWO MINUTES TO COME TO THAT CONCLUSION, WE COULD
16 CERTAINLY CLARIFY THAT TO MAKE CERTAIN THAT OUR INTENT
17 IS OBVIOUS THAT IT BE ANNUAL.

18 DR. BRYANT: ACTUALLY THE BIT THAT I'M
19 READING DOESN'T SOUND LIKE -- THIS IS SUE
20 BRYANT -- IT'S NOT ANNUAL. IT'S FIGURED OUT FOR THE
21 MONTH IN WHICH THE GRANT AWARD IS ACCEPTED BY THE
22 GRANTEE. THAT'S SECTION 100308(B), THE LAST SENTENCE.

23 MR. TOCHER: RIGHT.

24 CHAIRMAN PENHOET: OKAY. WELL, IF IT'S THE
25 DESIRE OF THIS GROUP THAT IT BE ANNUAL, WE CAN

1 INCORPORATE THAT INTO THE LANGUAGE.

2 SO THERE ARE TWO QUESTIONS BEFORE US, THEN,
3 TO BE DECIDED. ONE, THE \$500,000 THRESHOLD. IS THERE
4 ANYONE WHO OPPOSES THE \$500,000 THRESHOLD, OR WISHES TO
5 SUGGEST ANOTHER THRESHOLD? OKAY.

6 SECOND QUESTION IS SHOULD THE \$500,000
7 THRESHOLD BE ADJUSTED ON AN ANNUAL BASIS TO ACCOUNT FOR
8 INFLATION? JEFF, YES OR NO, I GUESS.

9 MR. SHEEHY: YOU KNOW, IF THAT MAKES PEOPLE
10 FEEL BETTER. I THINK THE FORMULATION, WHILE COMPLEX
11 AND BAROQUE, CAPTURES THAT. BUT IF WE WANT TO
12 STIPULATE THAT IT'S ON AN ANNUAL BASIS, THAT SOUNDS
13 FINE TO ME.

14 DR. WRIGHT: I AGREE.

15 CHAIRMAN PENHOET: ANYONE OPPOSED TO THAT?
16 OKAY.

17 THEN OUR RECOMMENDATION WILL BE THAT THERE IS
18 A SHARING OF 25 PERCENT OF THE NET REVENUES WITH THE
19 STATE OF CALIFORNIA ABOVE THE \$500,000 THRESHOLD AND
20 ADJUSTED ANNUALLY TO REFLECT THE COST OF LIVING, AND,
21 TO BE CLEAR IN THIS ROOM, THAT IT EXCLUDES PAYMENTS TO
22 INVENTORS.

23 SO UNLESS THERE ARE ANY FURTHER COMMENTS, WE
24 WILL MOVE ON TO THE NEXT ISSUE, WHICH IS SHOULD THE
25 RESEARCH USE EXEMPTION BE ABOLISHED OR MODIFIED? LET

1 ME SEE. I THINK WE RECEIVED MORE COMMENTS ON THIS THAN
2 ANY OTHER SINGLE ISSUE. AND TO SOME DEGREE, SOME OF
3 THOSE COMMENTS WERE DIRECTED AT AN ASPECT OF THIS WHICH
4 WAS UNINTENDED BY US. AND UNFORTUNATELY A READING OF
5 THE LANGUAGE LED PEOPLE TO BELIEVE THAT WE INTENDED
6 SOMETHING THAT WE WERE NOT INTENDING.

7 MR. GOLDBERG: WE'RE HAVING DIFFICULTY
8 HEARING YOU IN PALO ALTO.

9 CHAIRMAN PENHOET: HELLO.

10 MR. GOLDBERG: IT JUST CHANGED. I DON'T KNOW
11 IF THERE'S A --

12 CHAIRMAN PENHOET: THERE'S A MAN OVER HERE IN
13 THE CORNER WHO ADJUSTS THE VOLUME. CAN YOU HEAR ME
14 NOW?

15 MR. GOLDBERG: YES. THANK YOU.

16 CHAIRMAN PENHOET: OKAY. SO WHAT I DID SAY
17 WAS THAT WAS PROBABLY DUE TO AN AMBIGUOUS LANGUAGE ON
18 OUR PART, SO WE ACCEPT THAT RESPONSIBILITY. THERE HAS
19 BEEN AN INTERPRETATION OF WHAT WE INTENDED BY MANY IN
20 THE COMMENTS WHICH INTERPRETED WHAT WE SAID THAT NOT
21 ONLY SHOULD THERE BE A RESEARCH EXEMPTION, THAT IS,
22 THAT PEOPLE SHOULD BE FREE TO DO RESEARCH IN THE STATE
23 OF CALIFORNIA IN A NONPROFIT INSTITUTION UNIMPEDED BY
24 THE FEAR OF A LAWSUIT THAT WOULD ESSENTIALLY STOP THEIR
25 WORK FROM HAPPENING. IN ADDITION TO THAT, MANY PEOPLE

1 READ THE CURRENT DRAFTING OF OUR LANGUAGE TO SAY THAT
2 ANY PROVIDERS OF MATERIALS THAT WERE MANUFACTURED UNDER
3 LICENSE WOULD BE PROVIDED FREE TO CALIFORNIA
4 RESEARCHERS.

5 WE DID NOT INTEND THAT ANYONE WOULD BE
6 OBLIGATED TO PROVIDE FREE GOODS UNDER THIS STATUTE.
7 SO IF YOU LOOK UNDER THE NOTES, WE HAVE A REDRAFT
8 SUGGESTION FROM STAFF TO CLARIFY THE SCOPE AND INTENT.
9 THIS IS ON PAGE 4 OF YOUR DOCUMENT OF THE RESEARCH USE
10 EXEMPTION. IT SAYS GRANTEES' ORGANIZATIONS AGREE THAT
11 CALIFORNIA RESEARCH INSTITUTIONS ARE FREE TO PRACTICE
12 THE ART OF THE GRANTEE'S CIRM-FUNDED PATENT INVENTIONS
13 FOR RESEARCH PURPOSES WITHOUT REQUIREMENT FOR A LICENSE
14 AND AT NO COST. SO IT'S PRACTICING THE ART. IT IS
15 NOT -- SO BY WAY OF EXAMPLE, IF ONE OF OUR GRANTEES
16 DEVELOPS AN ANTIBODY AGAINST A SPECIFIC MARKER AND
17 ANOTHER GRANTEE WISHES TO USE THAT ANTIBODY IN THEIR
18 RESEARCH, IF THEY ARE WILLING TO MAKE THAT ANTIBODY
19 THEMSELVES OR GET IT FROM THE RESEARCHER WHO GOT IT IN
20 THE FIRST PLACE, THEY'RE FREE TO PRACTICE THAT ART,
21 OKAY, WITHOUT FEAR OF BEING SUED BY ANYONE TO STOP
22 THEIR BASIC RESEARCH. THIS IS NOT COMMERCIALIZATION OF
23 A PRODUCT. IT'S JUST BASIC RESEARCH.

24 SO WE HOPE THAT THE REDRAFT SUGGESTION
25 CLARIFIES THIS ISSUE, THAT WE WERE NOT INTENDING TO

1 FORCE COMPANIES TO PROVIDE FREE GOODS TO PEOPLE DOING
2 BASIC RESEARCH IN THE STATE OF CALIFORNIA FUNDED BY
3 CIRM.

4 I THINK THIS ISSUE HAS -- THIS IS ONE OF
5 THOSE ISSUES, DR. BRYANT, THAT IS BEING TAKEN UP AT THE
6 NATIONAL LEVEL AT A NUMBER OF DIFFERENT LEVELS. IT'S
7 JUST TO GIVE ALL OF YOU IN THE ROOM NOT FAMILIAR WITH
8 THIS AREA SOME BACKGROUND. THERE HAS BEEN A COMMON LAW
9 PRESUMPTION IN THE UNITED STATES THAT IF YOU'RE JUST
10 DOING RESEARCH FOR THE -- WHICH DOES NOT HAVE A DIRECT
11 COMMERCIAL PURPOSE, BASIC RESEARCH, WHICH IS
12 ESSENTIALLY DESIGNED TO FURTHER THE DEVELOPMENT OF
13 KNOWLEDGE, THAT YOU WOULDN'T BE SUED FOR CARRYING OUT
14 BASIC RESEARCH. AND MANY PEOPLE ASSUMED THAT THERE WAS
15 AN EXEMPTION IN THE PATENT LAW THAT FREED PEOPLE DOING
16 BASIC RESEARCH FROM THE THREAT OF LITIGATION FOR DOING
17 THAT RESEARCH USING PATENTED INVENTIONS.

18 AN EXAMPLE OF THAT WE'RE ALL FAMILIAR WITH
19 WOULD BE THE WARF PATENTS ON STEM CELLS. IF A RESEARCH
20 EXEMPTION WAS IN PLACE AND THEY HAD RECEIVED CIRM
21 FUNDING, THEN ANYBODY ELSE WOULD BE ABLE TO DO STEM
22 CELLS WITHOUT INFRINGING THE WARF PATENT, FOR EXAMPLE.

23 THERE WAS A CASE, MADY VS. DUKE, THAT WAS
24 DECIDED IN FAVOR OF MR. MADY, WHICH SAID NO --
25 BASICALLY SAID THERE IS NO SUCH THING AS A RESEARCH

1 EXEMPTION, THAT UNIVERSITIES BENEFIT FROM DOING
2 RESEARCH, THAT THEY GET GRANT MONEY, THAT THEY GET
3 MONEY FROM DONORS, ETC.; THEREFORE, EVEN BASIC RESEARCH
4 HAS A SORT OF IMPLIED PURPOSE BEYOND PHILOSOPHY OR
5 WHATEVER. AND THE MADY CASE HAS BEEN UP OR THE SUPREME
6 COURT FAILED TO REVIEW THE MADY CASE. IT IS NOW LAW.

7 THERE IS A LOT OF CONFUSION IN THE UNITED
8 STATES NOW ABOUT THE COMMON PRACTICE WHICH EXISTED
9 BEFORE MADY, WHICH BASICALLY SAYS PEOPLE DON'T SUE EACH
10 OTHER FOR DOING BASIC RESEARCH. AND THE REALITY THAT
11 THIS CASE LAW ESTABLISHED IN MADY VS. DUKE SAYS THAT,
12 NO, THERE IS NO SAFE HARBOR FOR PEOPLE DOING EVEN BASIC
13 RESEARCH. YOU COULD BE SUED IF YOU'RE INFRINGING
14 SOMEBODY ELSE'S PATENT.

15 THE INTENT OF OUR POLICY WAS TO ENSURE THAT
16 THAT WOULDN'T HAPPEN, THAT PEOPLE WHO WERE DOING BASIC
17 RESEARCH COULD BE FREE TO DO THAT RESEARCH UNIMPEDED BY
18 PATENTS.

19 THERE'S A SUBSEQUENT CASE, MERCK VS. INTEGRA,
20 WHICH CARVED OUT AN AREA FOR PEOPLE TO DO RESEARCH FREE
21 OF PATENT INFRINGEMENT CLAIMS; AND, THAT IS, IF THEY'RE
22 WORKING ON A PRODUCT THAT'S DIRECTLY ON A PATH TO
23 APPROVAL BY THE FDA. IT'S ESSENTIALLY AN EXTENSION OF
24 THE HATCH-WAXMAN ACT FOR THOSE OF YOU WHO KNOW THAT
25 AREA.

1 THE CONCERN WE'VE HEARD FROM THE INDUSTRY WHO
2 SUPPLIES RESEARCH TOOLS ABOUT A RESEARCH USE EXEMPTION
3 IS THAT BASICALLY RESEARCH TOOLS ARE EXTREMELY
4 IMPORTANT, INNOVATION IN BIOLOGY OR ANY OTHER FIELD IS
5 HIGHLY DEPENDENT ON THE TOOLS THAT PEOPLE USE IN THEIR
6 RESEARCH, THAT A RESEARCH USE EXEMPTION MIGHT HAVE THE
7 EFFECT OF DECREASING INVESTMENT IN THE TOOL SPACE IF
8 THEY COULDN'T TAKE PATENTED INVENTIONS UNDER LICENSE
9 FROM UNIVERSITIES AND EXPLOIT THOSE PATENTS IN SUCH A
10 WAY AS TO MAKE IT A PROFITABLE BUSINESS FOR THEM TO
11 CREATE REAGENTS OR OTHER THINGS THAT WOULD BE PURCHASED
12 BY THE RESEARCH COMMUNITY.

13 AND THERE'S NO DOUBT THE RESEARCH TOOLS
14 BUSINESS IS A VERY LARGE BUSINESS IN THE UNITED STATES.
15 AND SECOND OF ALL, THAT RESEARCH TOOLS ARE EXTREMELY
16 IMPORTANT IN THE CONDUCT OF RESEARCH.

17 SO THIS IS AN ISSUE WHERE I THINK THAT, YOU
18 KNOW, POWERFUL AND GOOD ARGUMENTS ARE MADE ON BOTH
19 SIDES OF THIS MATTER; AND IN SPITE OF THE FACT THAT WE
20 HEARD A LOT FROM VARIOUS DIFFERENT OPINIONS THAT WERE
21 ESTABLISHED OR AT LEAST ARTICULATED IN THE COMMENTS
22 WE'VE SEEN, OUR OWN WORK ON THIS ISSUE HAS CONVINCED US
23 THAT THERE IS TODAY NO COMMON LAW RESEARCH EXEMPTION IN
24 THE UNITED STATES BECAUSE MADY VS. DUKE HAS NOW BEEN
25 VALIDATED, AND THE CASE LAW SAYS THAT THERE'S NO

1 RESEARCH EXEMPTION. SOME PEOPLE ARGUE OTHERWISE, BUT
2 PEOPLE LIKE REBECCA ISENBERG AND OTHERS WHO ARE, YOU
3 KNOW, DEEPLY INVOLVED IN THESE STUDIES DON'T BELIEVE
4 THAT A RESEARCH EXEMPTION EXISTS ANYMORE.

5 SO THAT'S THE BACKGROUND FROM MY PERSPECTIVE
6 ON WHERE WE ARE ON THIS ISSUE. A NUMBER OF GROUPS HAVE
7 ARGUED AT THE NATIONAL LEVEL THAT THERE SHOULD BE A
8 RESEARCH EXEMPTION. ONE OF THOSE IS A NATIONAL ACADEMY
9 STUDY CHAIRED BY SHIRLEY TILGHMAN, PRESIDENT OF
10 PRINCETON. AND THAT RECOMMENDED THAT IN THE FACE OF
11 MADY VS. DUKE, WE SHOULD BE ABLE TO CARRY OUT BASIC
12 RESEARCH WITHOUT FEAR OF BEING CLOSED DOWN FOR
13 INTELLECTUAL PROPERTY REASONS.

14 AND THE AMERICAN PROPERTY LAW
15 ASSOCIATION -- INTELLECTUAL PROPERTY LAW HAS
16 RECOMMENDED A NARROWER RESEARCH EXEMPTION. AND HERE WE
17 GET INTO A DISTINCTION WHICH WE MIGHT WANT TO TALK
18 ABOUT THIS MORNING BETWEEN RESEARCH ON AN INVENTION AND
19 RESEARCH WITH AN INVENTION. TODAY BOTH EUROPE AND
20 JAPAN HAVE RESEARCH EXEMPTIONS. IN BOTH CASES THEY
21 ALLOW RESEARCH ON AN INVENTION AND NOT RESEARCH WITH AN
22 INVENTION. AND THE DISTINCTION THERE IS IF YOU'RE
23 DOING RESEARCH ON AN INVENTION, SOMEBODY CLAIMS I
24 INVENTED SOMETHING, YOU CAN ACTUALLY TRY TO SEE IF YOU
25 CAN REPEAT THEIR WORK, AND YOU CAN USE IT TO SEE IF YOU

1 CAN MAKE IMPROVEMENTS, ETC., BUT YOU CAN'T USE THEIR
2 INVENTION DIRECTLY. RESEARCH WITH IS JUST WHAT IT
3 SAYS, RESEARCH WITH AN INVENTION.

4 IN THE CASE OF A MONOCLONAL, IF INVESTIGATOR
5 X AT BURNHAM INVENTS A MONOCLONAL AND PATENTS IT,
6 BURNHAM COULD STILL LICENSE IT UNDER OUR POLICY TO A
7 PROFIT-MAKING COMPANY WHO COULD SELL IT TO EVERYONE
8 OUTSIDE THE STATE FOR WHATEVER THEY WANTED AND INSIDE
9 THE STATE FOR WHATEVER THEY WANTED; BUT IF SOMEBODY
10 ELSE IN THE STATE AT UC IRVINE WANTED TO MAKE THAT
11 ANTIBODY THEMSELVES, THEY'D BE FREE TO DO THAT. AND/OR
12 NOBODY COULD BE CLOSED DOWN -- THEIR WORK COULDN'T BE
13 CLOSED DOWN IF THEY CHOSE TO WORK WITH AN ANTIBODY THAT
14 WAS PATENTED, BUT WE DID NOT INTEND THAT SOMEBODY WOULD
15 HAVE TO PROVIDE THAT TO THEM AT NO CHARGE, SIMPLY THE
16 LICENSE TO DO THAT WORK.

17 SO I KNOW THERE ARE A NUMBER OF COMMENTS ON
18 THIS. I'VE TRIED TO GIVE YOU A THUMBNAIL SKETCH OF THE
19 ISSUES BEHIND THAT. AND AT THIS POINT OPEN THE
20 DISCUSSION TO PEOPLE ON OUR TASK FORCE. JEANNIE, LOOKS
21 LIKE YOU HAVE A COMMENT.

22 DR. FONTANA: MY COMMENT IS MORE GENERAL IN
23 NATURE IN THAT I'M CONCERNED. I DON'T THINK THERE IS A
24 CLEAR ANSWER, A CLEAR PATH. AND I WOULD LIKE TO
25 PROPOSE THAT WE INCLUDE SOME PROPOSITION OF MAYBE AN

1 ANNUAL REVIEW WHERE WE COULD EXAMINE THE EFFECTS OF
2 WHATEVER GUIDELINES THAT WE COME UP WITH. I WOULD HATE
3 TO SLOW DOWN ANY PROGRESS OF RESEARCH THROUGH THE
4 ENGINES THAT ARE ALREADY IN PLACE. HOWEVER, WE ARE
5 SETTING A NEW POLICY. WE'RE IN NEW TERRITORY. WE'RE
6 TRYING TO SET NEW GUIDELINES. I JUST WOULD LIKE TO
7 BRING UP THE IDEA THAT WE SHOULD BE ABLE TO REVIEW AND
8 BE ACTIVE IN OUR REVIEW AND NOT BE CRITICIZED, LIKE
9 MANY DO OF STATE AGENCIES AND GOVERNMENT AGENCIES,
10 WHERE WE DON'T -- WE ARE NOT ABLE TO MODIFY CHANGE. IF
11 IT'S NOT WORKING, LET'S BE ABLE TO CHANGE IT. IF IT IS
12 WORKING, LET'S REINFORCE IT. HOW YOU DO THAT --

13 CHAIRMAN PENHOET: I MIGHT ASK SCOTT TO
14 COMMENT ON THIS. SCOTT, WE ARE FREE TO CHANGE
15 REGULATIONS WHENEVER WE WANT, BUT COULD WE EMBODY FOR
16 SOME PART, LET'S TAKE THIS ONE AS AN EXAMPLE, IF WE
17 WANTED TO HAVE A SEMIANNUAL REVIEW OF OUR RUE POLICY,
18 IS THAT PERMISSIBLE UNDER THE STATE REGULATIONS?

19 MR. TOCHER: IT'S CERTAINLY PERMISSIBLE.
20 IT'S NOT TYPICAL FOR A REGULATING BODY TO MAKE ITSELF
21 THE SUBJECT OF ITS OWN REGULATIONS EXCEPT IN INDIRECT
22 MANNER IN EXPLAINING WHAT ITS PROCESSES WILL BE AND
23 EVALUATING, FOR INSTANCE, A GRANT OR EVALUATING A
24 SUBMISSION BY THE REGULATED COMMUNITY. TYPICALLY IN A
25 SITUATION LIKE THIS, THERE WOULD BE A RECOMMENDATION

1 JUST TO THE ICOC THAT ON AN ANNUALIZED BASIS THE TASK
2 FORCE IS DIRECTED BY THE ICOC TO CONDUCT AN ANNUAL
3 MEETING, AT LEAST ONE MEETING OR TWO MEETINGS A YEAR,
4 FOR THE PURPOSE OF SOLICITING FEEDBACK AND EVALUATING
5 THE FEEDBACK ON THE PERFORMANCE OF THE REGULATIONS THAT
6 ARE IN EFFECT.

7 TYPICALLY IT'S JUST NOT -- TYPICALLY IT'S NOT
8 REGULATORY LANGUAGE, HOWEVER. THERE'S NOTHING THAT
9 PREVENTS US FROM DOING SO. IT'S JUST GIVING YOU
10 THIS --

11 DR. WRIGHT: THIS IS JANET WRIGHT. I JUST
12 WANT TO JUMP ON BOARD WITH JEANNIE'S IDEA. I THINK
13 IT'S A GREAT ONE, AND IT GIVES US THE ACCOUNTABILITY
14 THAT WE NEED AS STEWARDS OF THE RESOURCES AND
15 ACKNOWLEDGES THAT THIS IS LIKELY TO CHANGE OVER TIME
16 AND REQUIRES OUR SURVEILLANCE.

17 DR. BRYANT: THIS IS SUE BRYANT. I
18 COMPLETELY SUPPORT THE ANNUAL REVIEW IDEA ALSO.

19 MR. GOLDBERG: THIS IS MICHAEL GOLDBERG. I
20 PROPOSE A BIENNIAL REVIEW.

21 CHAIRMAN PENHOET: YEAH. AN ANNUAL REVIEW
22 WOULD KEEP US AT WORK ON THIS CONTINUOUSLY ALMOST, AND
23 MAYBE BIENNIAL WOULD BE ENOUGH.

24 DR. BRYANT: OKAY. OKAY.

25 MR. SHEEHY: THIS IS JEFF SHEEHY. I'M

1 NOT -- I GUESS I'M GOING A DIFFERENT DIRECTION ON THIS.
2 I REALLY WANT TO BE VERY CONSERVATIVE ON THIS
3 PARTICULAR ISSUE. I'M NOT CONVINCED THAT THIS IS WHERE
4 WE NEED TO EXERT THIS KIND OF LEADERSHIP AND KIND OF
5 DRIVING THE FIELD. AND I WANT US TO MAYBE BE A LITTLE
6 MORE CONSERVATIVE AND THINK ABOUT WHAT ARE OUR NARROW
7 PUBLIC POLICY GOALS AS STEWARDS OF RESOURCES FOR THE
8 STATE OF CALIFORNIA. AND I WAS PARTICULARLY STRUCK BY
9 DATA ON THE ROLE AND THE IMPACT OF THE TOOLS INDUSTRY
10 IN THE CALIFORNIA ECONOMY. AND I DON'T WANT TO DO
11 ANYTHING TO HAMPER THAT ENGINE. THAT'S PART OF THE
12 MANDATE OF PROP 71. AND I WOULDN'T BE COMFORTABLE WITH
13 ANYTHING GOING FORWARD THAT WAS BASICALLY IN CONFLICT
14 WITH INDUSTRY ON THIS ISSUE.

15 WE'RE NOT TALKING ABOUT SOME OF THE ISSUES
16 HERE THAT ARE RELEVANT TO ACCESS TO CARE FOR PATIENTS
17 OR THERAPIES FOR PATIENTS. IN FACT, WE'RE TALKING
18 ABOUT THE DEVELOPMENT OF TOOLS THAT CAN ACCELERATE THE
19 RATE OF DISCOVERY THAT CAN INCREASE THE PRODUCTIVITY OF
20 THE RESEARCHERS.

21 I LOOK AT THIS AND, IN FACT, I WOULD INVITE
22 INDUSTRY TO INTERACT WITH US IN A MORE COLLABORATIVE
23 WAY. THIS SEEMS TO BE A PLACE WHERE WE COULD RATHER
24 RAPIDLY DEVELOP AN IP-FOR-PROFIT REGIME BECAUSE WE
25 DON'T HAVE THE THERAPY ISSUES. WE DON'T HAVE THE

1 ACCESS ISSUES. THIS COULD ACTUALLY PRODUCE A REVENUE
2 STREAM QUICKER TO THE STATE THAN, SAY, A THERAPY --
3 THAN A THERAPY COULD.

4 AND I JUST KNOW, LOOKING AT THE STRATEGIC
5 PLANNING PROCESS, THAT DEVELOPMENT OF NEW TOOLS ARE
6 URGENTLY NEEDED IN ORDER FOR THIS FIELD TO GO FORWARD.
7 AND THAT IF WE COULD, IN FACT, AND STARTING WITH THIS
8 SPECIFIC ISSUE, START A COLLABORATION WITH THE TOOLS
9 INDUSTRY TO DEVELOP A MUTUALLY ADVANTAGEOUS IP POLICY
10 SO THAT IN THE VERY FIRST ROUNDS OF GRANTS WE CAN START
11 GETTING THESE NEW DEVICES AND THESE NEW TOOLS SO THAT
12 WE CAN ACCELERATE THE PACE OF RESEARCH, THAT WE COULD
13 BECOME THE LEADER AS A STATE AND WITH COMPANIES HERE IN
14 DEVELOPING THE NEW TOOLS THAT WE NEED THAT THE WHOLE
15 WORLD WILL USE. THEN I THINK THAT WE WOULD BE MUCH
16 BETTER PLACED.

17 WE'RE KIND OF DOING SOMETHING FOR THE BENEFIT
18 OF THE LARGER RESEARCH ENTERPRISE, LARGER, YOU KNOW,
19 ACADEMIC RESEARCH OR WHAT HAVE YOU, AND I DON'T SEE
20 THAT AS OUR WRIT. I SEE OUR WRIT TO, FIRST OF ALL, NOT
21 DISADVANTAGE OURSELVES BY HAVING TO PAY FOR SOMETHING
22 TWICE. AND THAT SEEMS TO ME THE MOST NARROW WRIT.

23 THEN I SEE OUR OTHER BURDEN ACTUALLY TO BE
24 THE OPPOSITE OF THIS, TO ENCOURAGE THE
25 COMMERCIALIZATION AND DEVELOPMENT OF PRODUCTS AND THE

1 SPEEDY DEVELOPMENT OF THIS INDUSTRY.

2 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

3 DR. FONTANA: JEFF, JEANNIE FONTANA. IT'S
4 NOT THAT I DISAGREE WITH WHAT YOU'RE SAYING. IF YOU
5 SET UP A POLICY THAT YOU FEEL IS RIGHT AND IS
6 SUPPORTING THOSE GOALS, YET IF YOU DON'T REVIEW IT TO
7 SEE THAT YOUR POLICY IN PLACE IS LEADING TOWARDS THOSE
8 RESULTS, THEN WHERE DO YOU STAND?

9 MR. SHEEHY: I'M COMFORTABLE ON REVIEW, BUT I
10 MEAN THAT ASSUMES THAT WE STAY WITH THE EXISTING
11 POLICY. AND I GUESS MY THING HERE IS WHATEVER WE PUT
12 IN PLACE, I'M NOT CONVINCED WE NEED TO BE BREAKING NEW
13 GROUND, WHICH IS WHAT WE'RE DOING. IN SOME AREAS WE
14 ARE BREAKING NEW GROUND. AND, FOR INSTANCE, THE
15 REVENUE SHARING, WE HAVE A STATUTORY OBLIGATION TO DO
16 THAT. WHAT WE'RE DOING HERE IS SOMETHING THAT THE
17 RESEARCH COMMUNITY IS GRAPPLING WITH, AND WE'RE TAKING
18 THE FIRST STAB AT INNOVATION HERE. AND IT SEEMS LIKE
19 THAT THE BURDEN OF INNOVATION, IF WE DON'T DESIGN OUR
20 POLICY CORRECTLY, IS GOING TO BE THE RESEARCH TOOLS
21 INDUSTRY, WHICH HAS A LARGE PRESENCE IN THE STATE OF
22 CALIFORNIA, WHO HOPEFULLY WE CAN CREATE -- AND AGAIN, I
23 REITERATE MY POINT. I THINK MAYBE WE SHOULD SEPARATE
24 THE TOOLS PORTION OF THE IP POLICY FOR FOR-PROFITS FROM
25 THE THERAPY DEVELOPMENT, WHICH IS MUCH MORE COMPLEX.

1 AND THIS SEEMS VERY SIMPLE BECAUSE WE'RE NOT
2 TALKING ABOUT ACCESS PLANS FOR THE UNINSURED. WE'RE
3 NOT TALKING ABOUT PRICING FOR GOVERNMENT PURCHASERS,
4 SOME OF THE THORNY ISSUES WE HAD TO DEAL WITH IN THIS
5 INSTANCE THAT WE'LL HAVE TO DEAL WITH AGAIN, THAT WE'RE
6 JUST TALKING REALLY ABOUT REVENUE SHARING AND FIGURING
7 OUT THE WAY IN WHICH TO FIGURE OUT HOW TO DO THAT.

8 AND THIS IS SOMETHING THAT REALLY SHOULD GO
9 OUT, THE FUNDING OF NEW TOOLS, BASED ON SOME OF THE
10 STUFF I'VE SEEN IN THE STRATEGIC PLANNING PROCESS.
11 THERE ARE DESPERATELY NEEDED NEW TOOLS IN THE STEM CELL
12 FIELD THAT WE SHOULD BE FINANCING. AND THAT THEY COULD
13 BECOME -- THEY COULD BE WORLD BEATERS, AND THIS COULD
14 ACTUALLY PRODUCE REVENUE BACK TO THE STATE, AND WE
15 COULD FULFILL PART OF OUR MANDATE TO THE VOTERS.

16 SO ALL I'M SAYING IS RATHER THAN TRYING TO BE
17 THE INNOVATORS ON THIS PARTICULAR PIECE OF POLICY,
18 LET'S REALLY GET DOWN IN THE TRENCHES WITH INDUSTRY AND
19 FIGURE OUT IF WE'RE GOING TO CHANGE CURRENT PRACTICE,
20 THAT THE CHANGES THAT WE MAKE DO NO HARM.

21 DR. WRIGHT: RIGHT, JEFF. THIS IS JANET. IT
22 MAY BE THE DISTANCE FROM SAN FRANCISCO TO CHICO, BUT
23 I'M NOT HEARING YOU DISAGREE WITH REVISITING THIS
24 POLICY PERIODICALLY TO JUDGE ITS IMPACT AND ADJUST IT.

25 MR. SHEEHY: NO. I'M JUST TALKING ABOUT -- I

1 MEAN IT DEPENDS HOW YOU'RE VISUALIZING. YOU'RE
2 VISUALIZING IN TERMS OF THE STATUS QUO WITH THE POLICY
3 THAT WE'VE ALREADY DEVELOPED. IT DOESN'T MATTER
4 WHETHER WE REVIEW IT OR NOT. I DON'T THINK WE SHOULD
5 GO FORWARD WITH THIS POLICY WITH THE STRONG OBJECTIONS
6 FROM INDUSTRY.

7 IF IN THE CONTEXT OF WHATEVER WE EVENTUALLY
8 COME OUT WITH AND DOING A REVIEW, I THINK THAT MAKES A
9 LOT OF SENSE BECAUSE I DO THINK, AS ED ALLUDED TO, THIS
10 IS A FIELD IN MOTION. AND CERTAINLY WE DON'T WANT TO
11 BE STUCK IN A PRIOR -- UNDER A PRIOR REGIME WHEN
12 EVERYBODY ELSE IN THE WORLD OR AT LEAST WITHIN THE
13 UNITED STATES HAS MOVED TO A DIFFERENT REGIME. SO A
14 REVIEW THAT WOULD ALLOW US TO CATCH UP WITH EVERYBODY
15 ELSE OR AT LEAST KEEP PACE SEEMS PERFECTLY REASONABLE,
16 BUT NOT IN THE CONTEXT OF PRESENT POLICY THAT HAS
17 RECEIVED SO MUCH -- YOU KNOW, IT MAY BE A LITTLE FEAR
18 MONGERING, BUT I THINK WE HAVE TO TAKE IT SERIOUSLY.
19 WE DO NOT WANT TO HURT THIS INDUSTRY.

20 DR. FONTANA: SO, JEFF, ARE YOU SUGGESTING WE
21 ABOLISH THE RESEARCH SHARING?

22 MR. SHEEHY: I DON'T KNOW. I MEAN WE HAVE
23 COMPROMISE LANGUAGE THAT'S BEEN PROPOSED IN FRONT OF
24 US. WE ALSO HAVE SOME COMPROMISE LANGUAGE FROM SHAWN
25 O'CONNOR IN SEATTLE FROM THE CENTER FOR ADVANCED STUDY

1 IN RESEARCH ON INTELLECTUAL PROPERTY. I DON'T KNOW IF
2 ANY OF THOSE ARE FEASIBLE. I DON'T KNOW IF WE TAKE A
3 STEP BACK AND, YOU KNOW, MAYBE PUT THIS ON HOLD.
4 TAKE -- THERE'S A POTENTIAL PLAN. THERE'S ONE 15-DAY
5 PERIOD. AS I NOTED FROM OUR THING, WE HAVE TILL
6 OCTOBER. IF WE NEED TO SIT DOWN WITH INDUSTRY AND
7 CRAFT SOMETHING THAT WORKS FOR EVERYBODY AND NOT FIX
8 THIS TODAY, THAT'S FINE WITH ME, BUT I DON'T WANT TO
9 GET IT WRONG.

10 DR. PRIETO: JEFF, I HAVE A QUESTION. AND
11 I'M SORRY THAT I CAME IN LATE. BUT ARE YOU TALKING
12 ABOUT ELIMINATING THE RESEARCH EXEMPTION ONLY FOR
13 RESEARCH TOOLS, AND HOW WOULD YOU DEFINE THOSE?

14 MR. SHEEHY: I'M NOT TALKING SPECIFIC -- I
15 DON'T HAVE THE SPECIFIC POLICY. I KNOW WE HAVE A
16 POLICY THAT INDUSTRY HAS TOLD US WILL NOT WORK FOR THEM
17 THAT WILL RETARD THEIR ABILITY TO DEVELOP NEW TOOLS
18 THAT WILL DISINTEREST THEM INTO ACCEPTING INVESTMENTS
19 FROM US. AND I'M SAYING THAT THOSE ARE PRECISELY NOT
20 OUR PUBLIC POLICY GOALS. OUR PUBLIC POLICY GOALS ARE
21 TO ENCOURAGE THEM TO DEVELOP TOOLS, TO ENCOURAGE THEM
22 TO TAKE INVESTMENT FROM US. WE WILL NEED TO INVEST IN
23 THE TOOLS INDUSTRY, I THINK, WITHIN -- WHENEVER WE GET
24 OUR MONEY. I THINK WITHIN THAT FIRST YEAR IT BEHOOVES
25 US TO MAKE SUBSTANTIAL INVESTMENTS IN NEW TOOLS TO

1 INCREASE THE PRODUCTIVITY OF THE SCIENTISTS DOING
2 RESEARCH FOR US. AND IT WOULD BEHOVE US TO BE WORLD
3 LEADERS AS CALIFORNIANS IN THE DEVELOPMENT OF THESE
4 TOOLS, SO WE CAN SELL THEM TO EVERYBODY ELSE.

5 DR. FONTANA: I AGREE WITH YOU TOO, JEFF.
6 AND I'M CURIOUS TO ADDRESS ED'S ISSUE, THAT THE LAW
7 ISN'T IN EXISTENCE, AND THAT WAS IN PART WHAT YOU WERE
8 TRYING TO ADDRESS IN THIS STATEMENT.

9 CHAIRMAN PENHOET: I THINK THERE ARE A NUMBER
10 OF POSSIBILITIES FOR GOING FORWARD. ONE IS ADOPTING
11 THIS POLICY AS CLARIFIED BY THE NEW LANGUAGE. THE
12 SECOND ONE WOULD BE TO DEVELOP A POLICY WHICH PROVIDES
13 AN EXEMPTION FOR RESEARCH ON AN INVENTION, BUT NOT
14 RESEARCH WITH AN INVENTION. THAT'S AN INTERMEDIATE
15 GROUND, BUT GOES MOST OF THE WAY TOWARDS ACTUALLY NOT
16 HAVING A RESEARCH EXEMPTION. AND THE THIRD POSSIBILITY
17 IS TO DELETE THIS CATEGORY IN ITS ENTIRETY AND ALLOW
18 THE WORLD TO GO ON AS IT CURRENTLY IS GOING ON AND FACE
19 A RISK THAT SOME OF OUR RESEARCHERS MAY, IN FACT, BE
20 SHUT DOWN BY LITIGATION ASSOCIATED WITH THIS.

21 BUT WE CAN REVIEW IT ANNUALLY OR BIANNUALLY
22 IN EITHER DIRECTION. IF WE HAVE NO POLICY IN THIS
23 AREA, WE COULD SAY, WELL, IF IT BECOMES A BURDEN TO
24 RESEARCHERS IN CALIFORNIA BECAUSE THEY'RE GETTING SUED
25 FOR DOING BASIC RESEARCH, WE WOULD REVISIT THIS ISSUE

1 AND LOOK AT THE WEIGHT OF THE COST ESSENTIALLY OF NOT
2 HAVING IT VERSUS HAVING IT. SO WE CAN REVIEW IT
3 REGULARLY IN EITHER DIRECTION.

4 MR. SHEEHY: WHO'S THE LITIGANT? WHO ARE YOU
5 ANTICIPATING TO BE THE LITIGANT?

6 CHAIRMAN PENHOET: DOESN'T HAVE TO BE
7 LITIGATED. WE CAN DECIDE AS A BOARD --

8 MR. SHEEHY: NO. NO. BUT YOU'RE
9 ANTICIPATING LITIGATION AGAINST CALIFORNIA RESEARCHERS
10 USING TOOLS THAT WE PAID TO DEVELOP, RIGHT? THIS
11 RESEARCH USE EXEMPTION IS FOR TOOLS THAT WE PAID TO
12 DEVELOP. AND SO YOU'RE TALKING ABOUT OTHER CALIFORNIA
13 RESEARCHERS GETTING SUED. YOU KNOW, SO THAT SEEMS TO
14 BE OUR PUBLIC POLICY GOAL, AND SO THAT -- YOU KNOW, AND
15 THE LITIGANT IS PRESUMABLY SOMEBODY THAT WE FUNDED
16 WHO'S THEN GONE ON AND LICENSED THIS TOOL. SO I
17 DON'T -- IT'S ALMOST LIKE WE'RE GOING TO BE SUING
18 OURSELVES IN SOME FASHION.

19 CHAIRMAN PENHOET: THAT'S WHAT WE'RE TRYING
20 TO AVOID.

21 MR. SHEEHY: EXACTLY.

22 CHAIRMAN PENHOET: THAT'S EXACTLY WHAT WE'RE
23 TRYING TO AVOID. THAT'S WHY WE HAVE THE RESEARCH
24 EXEMPTION.

25 MR. SHEEHY: SO THIS IS WHY I THINK THAT --

1 AND MAYBE IF WE COULD OPEN THIS UP TO INDUSTRY A BIT, I
2 THINK THAT THERE'S A WAY OUT OF THIS MORASS. I DON'T
3 THINK I KNOW, BUT, YOU KNOW, LIKE I SAID, IF WE CAN
4 FOCUS ON THE NARROWEST PUBLIC POLICY GOAL. THIS SEEMS
5 TO BE OCCUPYING A LOT OF REALLY SMART PEOPLE IN
6 WASHINGTON AND OTHER PLACES, AND THEY HAVEN'T GOT THE
7 ANSWER YET. AND I DON'T THINK WE -- THERE ARE PLACES
8 WE CAN EXERT LEADERSHIP AND OUGHT TO. IT WAS BOLD OF
9 US TO TRY IN THIS FIELD, BUT I'M NOT CONVINCED, IF
10 THERE'S AN ECONOMIC COST TO THE STATE OF CALIFORNIA,
11 THAT I CAN IN GOOD CONSCIENCE GO FORWARD WITH THAT.

12 CHAIRMAN PENHOET: WELL, ONE QUESTION,
13 PERHAPS A DIRECTED QUESTION TO THE INDUSTRY. WHAT
14 FRACTION -- WELL, LET'S ASK INVITROGEN DIRECTLY. WHAT
15 FRACTION OF YOUR REVENUES TODAY ARE DERIVED FROM
16 LICENSED PRODUCTS THAT YOU HAVE LICENSED FROM
17 CALIFORNIA UNIVERSITIES AND PAID ROYALTIES TO THEM ON?
18 WHAT FRACTION ARE YOUR TOTAL REVENUES?

19 MR. GOSWAMI: I DON'T KNOW ABOUT CALIFORNIA
20 UNIVERSITIES.

21 CHAIRMAN PENHOET: WELL, UNIVERSITIES IN
22 GENERAL.

23 MR. SHEEHY: CAN I CONTEXTUALIZE THAT?
24 BECAUSE WHAT WE DO HERE IS ALSO GOING TO BE APPLICABLE
25 IN WHAT, I HOPE, WILL BE A RELATIVELY RAPID ROUND OF

1 FINANCING FOR DEVELOPMENT OF NEW TOOLS DIRECTLY TO A
2 COMPANY LIKE INVITROGEN.

3 CHAIRMAN PENHOET: WE ARE NOT TALKING ABOUT
4 THE FOR-PROFIT POLICY HERE TODAY, JEFF.

5 MR. SHEEHY: BUT WHY? IT'S THE SAME THING.
6 WE'RE GOING TO BE PAYING TO DEVELOP TOOLS.

7 CHAIRMAN PENHOET: IT'S VERY DIFFERENT.

8 MR. SHEEHY: HOW?

9 CHAIRMAN PENHOET: WE'RE GOING TO FIND OUT
10 WHEN WE DO THE FOR-PROFIT POLICY. THIS IS FOR
11 NONPROFITS WHO INVENT TECHNOLOGIES --

12 MR. SHEEHY: BUT AREN'T WE GOING TO WANT THE
13 SAME RESEARCH EXEMPTIONS? WHEREVER WE PAY FOR IT AT,
14 ARE WE NOT GOING TO WANT THE SAME SORT OF EXEMPTIONS?

15 CHAIRMAN PENHOET: WHICH SIDE ARE YOU NOW
16 ARGUING? I'M CONFUSED.

17 MR. SHEEHY: I'M ARGUING --

18 CHAIRMAN PENHOET: MAYBE WE CAN HEAR FROM
19 INDUSTRY, AND IT MIGHT CLARIFY SOME OF THESE ISSUES.
20 DR. PRIETO HAS JOINED US. DO YOU HAVE A COMMENT?

21 DR. PRIETO: YEAH, A COUPLE. ONE IS THAT I
22 THINK THAT WE'D ESTABLISHED EARLY ON THAT SHARING OF,
23 YOU KNOW, BASIC RESEARCH MATERIALS IS ONE OF THE
24 FUNDAMENTAL PRINCIPLES WE WANTED TO PROMOTE, AND WE
25 THOUGHT THAT THIS WOULD ADVANCE THE SCIENCE. AND I

1 THINK IT IS AN IMPORTANT DISTINCTION THAT WE'RE TALKING
2 ABOUT THE NONPROFITS, THE THINGS THAT ARE GOING TO BE
3 DEVELOPED, INCLUDING RESEARCH TOOLS AT NONPROFIT
4 INSTITUTIONS, THAT WILL LATER BE LICENSED TO, WILL BE
5 USED BY FOR-PROFIT COMPANIES. WE PRESUME AND HOPE.
6 BUT THAT I DON'T WANT TO SEE, AND I SHARE ED'S CONCERN,
7 ONE OF OUR GRANTEES SUING ANOTHER FOR USING A BASIC
8 RESEARCH TOOL IN THE COURSE OF ADVANCING THEIR
9 RESEARCH. A BASIC RESEARCH TOOL THAT WE PAID TO -- YOU
10 KNOW, THAT WE FUNDED THE INVENTION OF. AND I THINK
11 THAT'S A REAL CONCERN.

12 MR. SHEEHY: THAT'S WHAT I SEE AS OUR MAIN
13 CONCERN.

14 DR. PRIETO: THAT SORT OF LAWSUIT.

15 MR. SHEEHY: YEAH.

16 CHAIRMAN PENHOET: PLEASE IDENTIFY YOURSELF.

17 MS. LAMBERT: I'M JANET LAMBERT. I'M FROM
18 INVITROGEN. I JUST WANTED TO MAKE A COUPLE COMMENTS IN
19 RESPONSE TO THINGS THAT YOU'VE SAID ABOUT, AS WE SEE
20 IT, THE WORLD THAT EXISTS. IF WE TOOK OUT THIS
21 RESEARCH USE PROVISION, WHAT WOULD YOU HAVE? YOU'D
22 HAVE WHAT YOU HAVE TODAY, WHICH IS A SITUATION IN WHICH
23 COMPANIES LIKE MINE LICENSE TECHNOLOGIES FROM
24 UNIVERSITIES, MAKE SUBSTANTIAL INVESTMENTS IN THEM IN
25 ORDER TO ENHANCE THEM, QUALITY ASSURE THEM, MANUFACTURE

1 THEM, PUT THEM IN A BOX, PUT INSTRUCTIONS TOGETHER,
2 SHIP THEM OUT, PUT THEM ON A WEBSITE, PROVIDE TECHNICAL
3 SUPPORT, AND SO ON. AND WE THINK IN THAT WAY WE HAVE A
4 NICE PARTNERSHIP WITH NONPROFITS, WHICH ARE THE SUBJECT
5 OF THIS POLICY, THAT WE'D LIKE TO CONTINUE AND WE THINK
6 CAN HELP ADVANCE STEM CELL RESEARCH AND THERAPIES. SO
7 THAT'S PART OF THE WORLD AS IT EXISTS TODAY.

8 I THINK THE OTHER PART OF THE WORLD AS IT
9 EXISTS TODAY IS THAT THERE IS A FEAR, AS DR. PENHOET
10 SAID, OF FOLKS BEING SUED IN THE WAKE OF THESE COURT
11 CASES; BUT THERE'S, IN FACT, NOT ANY EVIDENCE THAT
12 THAT'S HAPPENING. AND, IN FACT, THE EVIDENCE THAT DOES
13 EXIST SUGGESTS THAT IT ISN'T HAPPENING. SO THERE'S NOT
14 REALLY A PROBLEM ON THE GROUND THAT NEEDS ADDRESSING IN
15 A VERY DRAMATIC WAY.

16 I THINK ALSO -- AND THAT'S WHY THERE HAS BEEN
17 A LOT OF DIFFICULTY IN TRYING TO COME UP WITH A SORT OF
18 RESPONSE TO THE RESEARCH USE EXCEPTION MATTER, AND THAT
19 THOSE THAT HAVE BEEN PUT FORWARD BY AIPLA AND THE
20 NATIONAL ACADEMIES AND OTHERS ARE VERY, VERY, VERY MUCH
21 MORE TARGETED THAN WHAT YOU'VE PROPOSED HERE.

22 I THINK THE OTHER IMPORTANT THING IS EVEN
23 WITHOUT YOUR RESEARCH USE PROVISION, YOU'VE ACTUALLY
24 PUT A LOT OF BELT AND SUSPENDERS ON THIS ISSUE INTO THE
25 POLICY. SO THE POLICY ALREADY SAYS THAT IF YOU LICENSE

1 A TECHNOLOGY, YOU HAVE TO MAKE IT BROADLY AVAILABLE TO
2 THE PUBLIC ON REASONABLE TERMS. SO IT SEEMS TO ME THAT
3 OTHER PROVISIONS OF YOUR PROPOSED POLICY ACTUALLY
4 BETTER ADDRESS YOUR CORE GOAL, WHICH IS, IF YOU'RE
5 GOING TO INVENT AN IMPORTANT TECHNOLOGY, YOU WANT TO
6 MAKE SURE THAT EITHER THE INVENTOR OR THE LICENSOR
7 DON'T MAKE IT UNAVAILABLE TO OTHERS. AND I KNOW YOU'VE
8 GOT AN EXAMPLE WHERE THERE'S A PROBLEM.

9 SO I THINK YOU ALREADY EFFECTIVELY ADDRESSED
10 THAT IN OTHER SECTIONS OF THE POLICY IN A WAY THAT
11 DOESN'T CREATE THE PROBLEM THAT WE FEEL THAT THE
12 RESEARCH USE PROVISION CREATES, WHICH IS THAT IT JUST
13 MAKES YOUR TECHNOLOGY -- RESEARCH TOOLS FUNDED BY CIRM
14 UNATTRACTIVE TO COMPANIES AS A POTENTIAL TECHNOLOGY
15 WE'D WANT TO LICENSE.

16 CHAIRMAN PENHOET: COULD I ASK A QUESTION?
17 WHAT FRACTION OF YOUR BUSINESS IS CALIFORNIA VERSUS THE
18 REST OF THE WORLD? AND WHAT FRACTION IN CALIFORNIA IS
19 LIKELY TO BE CIRM FUNDED? WE ONLY HAVE JURISDICTION
20 OVER PEOPLE WHO ARE TAKE OUR FUNDS.

21 MS. LAMBERT: RIGHT. I DON'T KNOW THE ANSWER
22 TO YOUR QUESTION, ALTHOUGH I'D BE HAPPY TO TRY TO FIND
23 OUT FOR YOU. BUT HERE'S WHY I'M NOT SURE IT'S THE
24 RIGHT QUESTION, RIGHT? ESSENTIALLY WHAT THE RESEARCH
25 USE EXCEPTION PROVISION SAYS IS I CAN'T ENFORCE A

1 PATENT ON A CIRM-FUNDED RESEARCH TOOL IN THE STATE OF
2 CALIFORNIA. AND SO WHAT YOU'D BE ASKING ME AS A
3 COMPANY PERSON TO DO IS TO LICENSE A TECHNOLOGY THAT
4 HAS -- FOR WHICH I CAN PROSECUTE MY PATENT WHICH I
5 REALLY HAVE PATENT PROTECTION IN 49 STATES. AND THAT
6 TO ME IS A VERY COMPLICATED THING TO DO, WHICH I
7 PROBABLY DON'T HAVE ANY INTEREST IN DOING. AND I WOULD
8 SAY THAT AT LEAST FOR THE TIME BEING, I THINK WE ALL
9 HOPE THIS IS NOT TRUE IN THE LONG TERM, BUT FOR THE
10 TIME BEING, TO THE EXTENT WE'RE TALKING ABOUT RESEARCH
11 TOOLS THAT HAVE TO DO WITH EMBRYONIC STEM CELL
12 RESEARCH, THE GAME IS IN CALIFORNIA.

13 SO WHERE I HAVE, EVEN THOUGH, YEAH, THERE MAY
14 BE AN OPPORTUNITY FOR ME TO LICENSE A CIRM-FUNDED
15 TECHNOLOGY AND SELL IT TO SOMEBODY AT HARVARD, THE GAME
16 FOR THE TIME BEING IS IN CALIFORNIA. SO TO SORT OF
17 SAY, WELL, YOUR PATENT IS NOT APPLICABLE IN CALIFORNIA
18 IS, A, JUST COMPLEX FROM THE POINT OF VIEW OF MANAGING
19 A PORTFOLIO. IT COULD CERTAINLY SEND US LOOKING FOR
20 SOMEBODY ELSE'S TECHNOLOGY. AND, TWO, I THINK YOUR
21 MARKET, WHILE IT MAY NOT ALWAYS BE, IS, IN FACT, A
22 PRETTY DOMINANT PART OF THE EMBRYONIC STEM CELL
23 RESEARCH MARKET, ASSUMING YOU GET UP AND GOING.

24 MR. SHEEHY: YOU KNOW, WITH RESPECT TO ED, I
25 DON'T THINK IT'S A GOOD QUESTION HOW MUCH BECAUSE WE'RE

1 GOING TO BE FUNDING CALIFORNIA. I MEAN I'VE GOT SIX
2 FRONT AND BACK PAGES FROM THE LAST STRATEGIC PLANNING
3 COMMITTEE MEETING OF TECHNOLOGIES WE NEED TO START
4 FUNDING RESEARCHERS AND UNIVERSITIES AND INDUSTRY TO
5 DEVELOP IN ORDER TO MOVE THIS FIELD FORWARD. I MEAN
6 THIS CAME UP LAST FALL AT THE SCIENTIFIC MEETING, THAT
7 THERE ARE TOOLS THAT NEED TO BE DEVELOPED IN ORDER TO
8 ADVANCE THIS FIELD. SO I THINK HISTORY IS NOT A GUIDE
9 HERE AT ALL.

10 BUT MY SECOND POINT IS IS THAT IS THERE A WAY
11 THAT SOME OF OUR CONCERNS ABOUT NOT BEING LITIGATED,
12 ABOUT NOT NECESSARILY HAVING TO PAY FOR THIS TWICE CAN
13 BE ADDRESSED? IS THERE SOME WAY TO COMPROMISE HERE AND
14 GET TO SOME OF OUR CONCERNS? AND THE MORE SPECIFIC THE
15 LANGUAGE AND WHERE TO PLACE IT WOULD BE MOST HELPFUL, I
16 THINK.

17 MS. LAMBERT: I CAN SPEAK FOR INVITROGEN, AND
18 THERE ARE OTHERS HERE WHO MAY WANT TO SPEAK FOR THEIR
19 COMPANIES. I THINK WE WOULD BE DELIGHTED TO ENGAGE IN
20 THE DIALOGUE THAT YOU PROPOSED IN YOUR EARLIER REMARKS
21 ABOUT HOW DO WE DO THIS. AGAIN, THOUGH, I WOULD JUST
22 REITERATE, I THINK YOU'VE DONE A PRETTY GOOD JOB
23 ALREADY. YOU HAVE SAID IF YOU LICENSE THIS TECHNOLOGY,
24 YOU HAVE TO MAKE IT BROADLY AVAILABLE FOR RESEARCH
25 PURPOSES ON REASONABLE TERMS. THAT'S PRETTY GOOD. I

1 THINK THAT'S WHAT YOU WANT, RIGHT. YOU WANT TO --

2 MR. SHEEHY: I DO WANT TO AVOID THE SITUATION
3 WHERE WE INVENT A CRITICAL TOOL AND EVERYBODY WE FUND
4 USES THAT TOOL. AND I MEAN ARE WE GOING TO PAY FOR IT
5 TWICE? ARE WE GOING TO -- WHAT'S OUR PRICE GOING TO
6 BE? IS THAT A REAL CONCERN? GO AHEAD.

7 MR. GOSWAMI: I JUST WANT TO MAKE ONE COMMENT
8 ON THAT, RIGHT. THAT IS NOT -- THAT IS A CONCERN
9 WHETHER YOU'RE IN THERAPEUTICS OR RESEARCH TOOLS. SO
10 WHY ISOLATE RESEARCH TOOLS FOR THAT PAYING. THEN LET'S
11 HAVE THE SAME POLICY FOR THERAPEUTICS AS WELL. RIGHT?
12 YOU PAID FOR IT. WHY SHOULD ANYONE HAVE TO PAY FOR IT
13 AGAIN? AND I THINK JANET'S POINT IS TOOLS DON'T JUST
14 HAPPEN, RIGHT? THE BASIC CONCEPT IS THERE. WE SPEND
15 YEARS OF DEVELOPING.

16 I CAN GIVE YOU ONE OF THE HOTTEST
17 TECHNOLOGIES. I THINK ABI HAS ONE. QUANTUM DOTS TOOK
18 ABOUT 20 YEARS BEFORE IT BECAME A REALITY. SO I DON'T
19 UNDERSTAND THE POINT WHY RESEARCH TOOLS IS BEING
20 SEPARATED OUT AS BEING SO DIFFERENT FROM THERAPEUTICS
21 WHEN THE INVESTMENT, THE TIME, AND EVERYTHING THAT IS
22 REQUIRED IS THE SAME.

23 NOW, AGAIN, THE NUMBERS MIGHT BE DIFFERENT IN
24 TERMS OF HOW MUCH INVESTMENT, BUT CLEARLY THE OPERATING
25 MARGINS OF COMPANIES AND EVERYTHING IS DIFFERENT. SO

1 THE CONCEPTS, I THINK, ARE NOT DIFFERENT, WHETHER
2 YOU'RE TALKING RESEARCH TOOLS OR THERAPEUTICS. PAYING
3 TWICE, YOU'RE PAYING FOR SOMETHING WHICH IS FURTHER
4 DEVELOPMENT ON A BASIC CONCEPT.

5 THIS IS JOYDEEP GOSWAMI, INVITROGEN.

6 CHAIRMAN PENHOET: WHILE YOU ARE THERE, MAY I
7 ASK YOU A QUESTION? TALKING ABOUT THE PRACTICE
8 ASPECTS, IS IT PRACTICAL UNDER OUR POLICY IN ORDER FOR
9 SOMEONE -- IF A UNIVERSITY HAD INVENTED QUANTUM DOTS,
10 THEY WOULD HAVE -- IN ORDER FOR THEM -- IS IT LIKELY
11 ANOTHER UNIVERSITY IS GOING TO MANUFACTURE QUANTUM DOT
12 ASSAYS GOING FORWARD? VERY UNLIKELY. SO I'M NOT SURE
13 THAT, IN FACT, YOUR ARGUMENT ABOUT PRACTICALITY MAKES
14 ANY SENSE EITHER BECAUSE THE REALITY IS UNIVERSITIES
15 ARE NOT IN THE BUSINESS OF SCALING UP AND DOING ALL
16 THIS WORK. THERE'S NOTHING IN OUR POLICY --

17 MR. GOSWAMI: THAT'S TRUE.

18 CHAIRMAN PENHOET: THIS JUST SAYS OUR OWN
19 NONPROFIT GRANTEES WILL CARVE OUT A LICENSE FOR ALL OF
20 OUR OTHER GRANTEES. IT DOESN'T IN ANY WAY INHIBIT
21 QUANTUM DOT DEVELOPMENT.

22 MR. GOSWAMI: YOU KNOW, IT'S A FAIR POINT,
23 ED. I THINK THE ISSUE AT POINT IS WHETHER YOU OR WE,
24 AS A BUSINESS, WHEN WE LOOK AT TEN DIFFERENT
25 TECHNOLOGIES, WILL GO IN AND SPEND OUR MONEY AND EFFORT

1 ON SOMETHING WHICH HAS NO INTELLECTUAL PROPERTY
2 PROTECTION IN OUR MIND. RIGHT? AND THAT'S WHAT WE ARE
3 TRYING TO COMMUNICATE TO YOU, THAT RUE ACTUALLY WEAKENS
4 THAT PROTECTION IN OUR MINDS FOR INTELLECTUAL PROPERTY.
5 THAT'S ONE ASPECT. RIGHT?

6 THE SECOND ASPECT WHICH I THINK IS IMPORTANT,
7 AND I WANT TO MAKE THE COMMENTS ON THIS LATER, I WILL
8 RESERVE THEM, BUT I THINK YOU CAN LOOK AT IT FROM THE
9 POINT OF VIEW OF FINANCES FOR OUR INDUSTRY, BUT I THINK
10 YOU ALSO NEED TO LOOK AT IT AS IF WE DO NOT INVEST, AND
11 I'LL TAKE THE QUANTUM DOTS EXAMPLE. IF WE DO NOT
12 INVEST, WE PASS UP ON THAT TECHNOLOGY, THAT IS NOT
13 GOING TO BE AVAILABLE TO RESEARCHERS ULTIMATELY, RIGHT?
14 AND THAT'S THE BIGGER LOSS AND THE ADD-ON EFFECTS TO
15 NOT GETTING THE RESEARCH DONE AND CURES ULTIMATELY TO
16 PEOPLE WHO NEED THEM. THAT'S WHAT CONCERNS ME MORE,
17 AND I THINK AGAIN AND AGAIN YOU WILL SEE THIS, AND I
18 CAN PULL OUT AS MANY EXAMPLES AS YOU WANT ON THIS.

19 MR. GILBERT: I'M DENNIS GILBERT. I'M CHIEF
20 SCIENTIFIC OFFICER FOR APPLIED BIOSYSTEMS AND HEAD OF
21 R&D IN A CALIFORNIA-BASED COMPANY FOUNDED IN
22 CALIFORNIA. AND THERE'S REALLY TWO WAYS TO LOOK AT IT.

23 FROM A RESEARCH TOOL PERSPECTIVE IN THE
24 INDUSTRY, IT'S A -- THIS MAY BE A DIFFERENT VIEW,
25 RIGHT. OUR SINGLE MOST IMPORTANT THING IS TO GET THE

1 TOOLS IN THE SCIENTIST'S HANDS. SO WHEN IT COMES BACK
2 ABOUT GOING AFTER ONE OF OUR CUSTOMERS, IT'S JUST NOT A
3 LOGICAL THING WE THINK ABOUT, RIGHT? SO OUR WHOLE GOAL
4 IS TO GET THEM TO DO SCIENCE. AND I KNOW THAT THERE
5 ARE SOME REALLY SIMPLE EXAMPLES LIKE A NEW RECIPE OR AN
6 ANTIBODY OR SEQUENCE OF A GENE, SOMETHING THAT ANYBODY
7 IN THE ART CAN READ THE PATENT AND MAKE, RIGHT? THAT'S
8 REALLY SIMPLE, RIGHT? THAT'S NOT THE WE'RE PAYING
9 TWICE THING.

10 BUT I GO TO ONE OF THE -- I THINK THE BEST
11 EXAMPLES FOR CALIFORNIA IS DNA SEQUENCING DESCRIBED IN
12 PATENTS BY LEE HOOD IN 1981. HOW DO YOU DO SEQUENCING
13 AUTOMATEDLY? WE COULD HAVE ALL BUILT THAT LITTLE THING
14 IN OUR GARAGE, BUT IT TOOK US 12 YEARS BEFORE THE
15 SYSTEM WAS DEVELOPED ENOUGH. SO AT THAT POINT THE
16 CUSTOMER WASN'T SAYING I'M PAYING TWICE. IT WAS A
17 FULLY DEVELOPED, MATURE SYSTEM, AND THE DIFFERENCE
18 BETWEEN INVENTION, WHICH IS THE IDEA, AND INNOVATION,
19 WHICH IS THE COMMERCIAL EMBODIMENT.

20 AGAIN, SOME OF US WHO ARE SCIENTISTS, YOU
21 DECIDE DO I MAKE THIS BUFFER MYSELF OR DO I BUY IT FROM
22 SOMEBODY ELSE AND YOU MAKE THAT ECONOMIC DECISION.

23 AND THE OTHER POINT I'D LIKE TO MAKE IS ON
24 THE BACK END, RIGHT? ON HOW DOES CALIFORNIA RETURN
25 REVENUE QUICKLY? IF YOU LOOK AT ANY LARGE FEDERALLY

1 FUNDED OR STATE-FUNDED INSTITUTES, THE REVENUE BACK TO
2 THE STATE HAS BEEN THROUGH THE RESEARCH TOOLS FIRST
3 BECAUSE THE WINDOW IS NARROWER IN TIME.

4 AND BACK TO YOUR INITIAL QUESTION, I DON'T
5 KNOW THE NUMBER OF CUSTOMERS TO BREAK THAT DOWN, BUT I
6 WOULD SAY CONSERVATIVELY WE'RE ABOUT A \$2 BILLION
7 COMPANY, ABOUT TWO-THIRDS MAYBE OF OUR PRODUCTS THAT WE
8 SELL, WE WRITE ROYALTY CHECKS TO CALIFORNIA RESEARCH
9 INSTITUTES. CALTECH IS ONE OF THE BIG ONES WHERE WE
10 LICENSE DNA SEQUENCING, AND THAT PROVIDED A LOT, NOT
11 ONLY APPLIED BIOSYSTEMS REVENUE, BUT PUT THAT INTO THE
12 RESEARCHERS BACK AT THE UNIVERSITIES.

13 MR. SHEEHY: WHAT'S 25 PERCENT OF 3 PERCENT
14 OF THAT? THAT'S NOT A BAD START.

15 MR. GOLDBERG: JEFF, IT DIDN'T HAVE A CAP.

16 MR. GILBERT: AGAIN, FROM OUR PERSPECTIVE,
17 IT'S ALWAYS BEEN A COLLABORATION WITH THE SCIENTISTS
18 AND ALIENATING THEM, BUT GETTING THE TOOLS OUT THERE
19 HAS BEEN THE PRIMARY OBJECTIVE. WE KNOW IT'S NOT A
20 PERFECT SYSTEM.

21 CHAIRMAN PENHOET: THANK YOU. MICHAEL
22 GOLDBERG, DO YOU HAVE A COMMENT?

23 MR. GOLDBERG: YEAH. I THINK ONE OF THE
24 THINGS THAT'S CONFUSING ABOUT THE CONVERSATION IS I
25 THINK THERE'S A MEANINGFUL DIFFERENCE BETWEEN RESEARCH

1 REAGENT WHICH MAY BECOME COMMERCIAL RESEARCH REAGENTS
2 AND RESEARCH INSTRUMENTATION, WHICH MAY BECOME
3 COMMERCIAL INSTRUMENTATION. AND THERE'S SUBSTANTIAL
4 AMOUNT OF ADDITIONAL -- WELL, ANYWAY, THAT'S, I THINK,
5 A MAJOR DISTINCTION BETWEEN THE LAST TWO COMMERCIAL
6 SPEAKERS REPRESENTING THE TWO FIRMS.

7 I APPRECIATE THE COMMENTS. AS A COMMERCIAL
8 PERSON, I'M REALLY NOT THAT TROUBLED. I WILL JUST SAY
9 FOR MY COUNTERPARTS WHO MAY NOT BE AS FAMILIAR WITH
10 SOME OF THIS AS SOME OF MY COLLEAGUES IN INDUSTRY,
11 BECAUSE WE FREQUENTLY LICENSE THINGS FOR SPECIFIC
12 FIELDS, WE FREQUENTLY LICENSE THINGS FOR SPECIFIC
13 USAGES, AND WE'RE SKILLED AT BEING ABLE TO DETERMINE
14 ECONOMIC VALUES FOR PARTS OF MARKETS, ALL OF MARKETS,
15 AND DIFFERENT TYPES OF MARKETS. SO ALL OF THIS IS --
16 NONE OF IT IS FATAL, AND I JUST WANT TO POINT THAT OUT.

17 WE CAN WORK WITH OR INDUSTRY CAN WORK, IN MY
18 VIEW, WITH HOWEVER THIS SORTS ITSELF OUT, AND I DON'T
19 THINK IT'S GOING TO CREATE LARGE DISINCENTIVES.

20 AS A RESEARCHER, AS YOU POINTED OUT EARLIER,
21 ED, RESEARCH WILL HAVE A CHOICE, IF THERE'S A
22 COMMERCIALLY AVAILABLE REAGENT, WHETHER THEY CAN BUY A
23 HIGHLY QUALITY CONTROLLED RELIABLE ONE OR WHETHER THEY
24 WANT TO TRY TO MAKE ONE. I THINK WHAT WE WANT TO
25 PREVENT IS HAVING OUR OWN RESEARCHERS BLOCKED FROM

1 BEING ABLE TO MAKE ONE, PARTICULARLY IF THEY'RE
2 REAGENTS THAT HAVEN'T BEEN SELECTED FOR
3 COMMERCIALIZATION OR WON'T BE SELECTED FOR
4 COMMERCIALIZATION.

5 CHAIRMAN PENHOET: ANOTHER COMMENT FROM THE
6 AUDIENCE?

7 MR. MACFERRIN: THANK YOU FOR THE OPPORTUNITY
8 TO COMMENT. AND IF I COULD JUST RESPOND TO THAT --

9 CHAIRMAN PENHOET: CAN YOU COME A LITTLE
10 CLOSER TO THE MIC AND IDENTIFY YOURSELF?

11 MR. MACFERRIN: HI. YEAH. I'M CURTIS
12 MACFERRIN. I'M THE LITIGATION DIRECTOR WITH APPLIED
13 BIOSYSTEMS. AND I THINK THAT'S A VERY GOOD CONCERN. I
14 THINK, TO RESPOND TO THE OTHER COMMENT ABOUT NOT BEING
15 INNOVATIVE, THE OTHER PROVISIONS, ASIDE FROM THE
16 RESEARCH USE EXEMPTION THAT ARE IN HERE THAT PROVIDE
17 FOR WIDE AVAILABILITY, ARE INNOVATIVE. IT IS ADVANCING
18 THE STATE OF THE ART THERE. AND THOSE PROVISIONS
19 ADDRESS THAT CONCERN. SO THOSE PROVISIONS DO REQUIRE,
20 AS WAS MENTIONED, WIDE COMMERCIAL AVAILABILITY.

21 ALSO, ONE THING THAT HASN'T BEEN MENTIONED IS
22 THERE ARE MARCH-IN RIGHTS IN HERE. SO IF THERE EVER IS
23 A MARKET FAILURE WHERE THE INVENTION IS NOT BEING
24 COMMERCIALIZED, THERE IS THE ABILITY TO STEP IN AND
25 GRANT THOSE RIGHTS TO PEOPLE WHO NEED THOSE.

1 JUST ONE OTHER QUICK COMMENT ABOUT THE RULE
2 ITSELF. I'VE HEARD SOME SUGGESTIONS DISTINGUISHING
3 BETWEEN TYPES OF RESEARCH, NONCOMMERCIAL VERSUS
4 COMMERCIAL AND BASIC VERSUS APPLIED. THERE'S NO SUCH
5 DISTINCTION IN THE RULE. IT WOULD COVER EVERYTHING.
6 IN THAT SENSE IT'S VERY EXTREME, AND THERE'S NO
7 PRECEDENT FOR IT IN EUROPE OR JAPAN. THEIR RULES ARE
8 NOT SO BROAD.

9 AND ALSO, THE PERCEIVED COMMON LAW RESEARCH
10 EXEMPTION THAT EXISTED BEFORE MADY V. DUKE WAS ALSO NOT
11 NEARLY SO BROAD. THANK YOU.

12 MR. SHEEHY: MAYBE COULD WE GET AN OPINION ON
13 SOME -- I MEAN THERE'S A COUPLE OF -- YOU'VE OFFERED A
14 COUPLE OF DIFFERENT ALTERNATIVES. COULD WE GET A
15 FEELING ON HOW -- WHAT YOUR PERSPECTIVE IS ON THOSE,
16 LIKE THE ONE ON THE REDRAFT SUGGESTION?

17 CHAIRMAN PENHOET: IF WE CAN GO THROUGH.
18 WE'VE HEARD, JEFF, THE CONCERNS NOW FROM THE INDUSTRY
19 ABOUT AS DRAFTED.

20 MR. TAYMOR: STANFORD HAS A QUESTION FROM THE
21 PUBLIC. IT'S APPROPRIATE NOW?

22 CHAIRMAN PENHOET: YES, FINE. GO AHEAD.

23 MR. TAYMOR: OKAY.

24 MR. GOLDBERG: PLEASE ANNOUNCE YOURSELF.

25 MR. TAYMOR: THIS IS KEN TAYMOR.

1 DR. BRYANT: HELLO. WE LOST YOU. WE'RE NOT
2 HEARING ANYTHING HERE IN IRVINE.

3 CHAIRMAN PENHOET: NOR ARE WE IN SACRAMENTO.
4 WELL, WHILE SOMEBODY TRIES TO FIX THAT PROBLEM, WE HAVE
5 FOUR ALTERNATIVES. RESEARCH ON IS WHAT THEY HAVE IN
6 JAPAN AND EUROPE. IT IS A FAIRLY NARROW EXEMPTION AS
7 OPPOSED TO RESEARCH WITH. AND, YOU KNOW, AS ONE OF THE
8 ALTERNATIVES, WOULD ANY OF YOU CARE TO COMMENT ON IF WE
9 HAD A POLICY OF RESEARCH ON AND AGREED TO REVIEW THIS
10 ON AN ANNUAL BASIS TO WEIGH THE BENEFITS AND
11 DISADVANTAGES OF A BROADER POLICY? WOULD THAT BE SEEN
12 AS ONEROUS BY THE INDUSTRY?

13 MR. MACFERRIN: YES. I'D BE HAPPY TO REACT
14 TO THAT. AGAIN, CURTIS MACFERRIN. AND THIS ISSUE WITH
15 RESEARCH ON VERSUS RESEARCH WITH IS THAT THERE'S ALWAYS
16 A WAY TO DESCRIBE OR TO CHANGE THE RESEARCH WITH SO
17 THAT IT LOOKS LIKE IT'S RESEARCH ON. SO IT'S NOT MUCH
18 OF A BARRIER. SO THERE I THINK IT'S HARD TO REALLY SEE
19 THE DISTINCTION IN PRACTICE.

20 ALSO, THERE ARE OTHER PROVISIONS IN HERE.
21 WHEN YOU THINK OF AN ALTERNATIVE, THERE ARE ALREADY
22 ALTERNATIVES THAT ARE IN HERE. THEY'RE THE SUSPENDERS
23 TO THE BELT.

24 MR. TAYMOR: THIS IS STANFORD AGAIN.

25 CHAIRMAN PENHOET: OKAY. THANK YOU. GO

1 AHEAD. WE LOST YOU.

2 MR. TAYMOR: WE WANT TO MAKE AN OBSERVATION
3 THAT AMONG BOB KLEIN'S MANY, MANY TALENTS IS NOT
4 MANIPULATING THE POLYCOM.

5 WHAT I WAS STARTING TO SAY IS THAT THERE'S
6 BEEN A LOT OF DISCUSSION FROM THE COMMITTEE THAT THE
7 RESEARCH USE EXEMPTION IS LIMITED TO BASIC RESEARCH OR
8 THAT IT JUST COVERS THE RIGHT OF A NONPROFIT GRANTEE TO
9 USE INVENTIONS OF OTHER NONPROFIT GRANTEES. BUT THAT'S
10 NOT WHAT'S DRAFTED, AND I THINK THAT'S THE CONCERN THAT
11 A WIDE RANGE OF PEOPLE HAVE.

12 FOR EXAMPLE, IF A CIRM GRANTEE DEVELOPS A
13 LINE OF HEPATIC CELLS THAT COULD BE USED TO TEST
14 TOXICITY, THERE'S NO LIMITATION ON ANY ENTITY THAT
15 COULD SHOEHORN ITSELF INTO BEING A CALIFORNIA RESEARCH
16 INSTITUTION, WHICH COULD BE A VERY BROAD RANGE OF
17 ENTITIES, INCLUDING AN ENTITY THAT WAS JUST SET UP BY A
18 BIOTECH COMPANY TO DO RESEARCH TO SUPPORT THE
19 COMMERCIAL GOALS OF THE BIOTECH COMPANY. THERE'S NO
20 LIMITATION ON THAT BIOTECH COMPANY FROM USING ANY
21 DEVELOPMENTS OUT OF THAT LINE -- OUT OF THAT HEPATIC
22 CELL LINE TO TEST TOXICITY OF ITS POTENTIAL SMALL
23 MOLECULE PRODUCTS.

24 AND I THINK THAT WOULD RAISE A QUESTION,
25 PERHAPS, OF WHETHER MICHAEL WOULD INVEST OR MICHAEL'S

1 COMPANY OR OTHER PEOPLE WOULD INVEST IN THAT INVENTION,
2 WHICH COULD BE A VERY, VERY VALUABLE INVENTION. AND I
3 THINK THAT EXAMPLE COULD BE REPLICATED WITH NEURAL
4 CELLS. IT COULD BE USED TO TEST SMALL MOLECULES FOR
5 STIMULATING DOPAMINE PRODUCTION. IT COULD GO ON AND
6 ON. THAT'S AN AREA THAT'S ONE OF, YOU KNOW, FROM THE
7 SCIENTIFIC CONFERENCES, ONE OF THE KEY POTENTIAL
8 BENEFITS AND NEAR-TERM BENEFITS THAT CIRM COULD
9 ACHIEVE.

10 SO I THINK THAT'S PART OF WHY THERE'S A BIT
11 OF TALKING PAST ONE ANOTHER. TO THE EXTENT THAT YOU'RE
12 LOOKING AT THIS AS JUST BASIC RESEARCH, JUST AS TRYING
13 TO CAPTURE A SMALL PART OF WHAT DUKE VS. MADY TOOK AWAY
14 OR DEFINED WAS NEVER THERE, THAT'S ONE THING. BUT
15 THAT'S NOT WHAT YOU'VE WRITTEN.

16 CHAIRMAN PENHOET: OKAY. THANK YOU FOR YOUR
17 COMMENT. MAYBE ONE MORE COMMENT FROM JANET LAMBERT.

18 MS. LAMBERT: FIRST, I WOULD JUST SECOND THE
19 COMMENT THAT WAS JUST MADE. I THINK IN SOME RESPECTS
20 THE PROVISIONS AS YOU'VE WRITTEN IT, WHICH MAY BE NOT
21 EXACTLY WHAT YOU MEANT, IS SORT OF AN UNNECESSARY
22 SUBSIDY TO COMMERCIAL FIRMS, FRANKLY, WHO ARE IN A
23 POSITION TO PAY FOR CIRM-FUNDED IP IN THE CONDUCT OF
24 THEIR COMMERCIAL RESEARCH AND DON'T REALLY NEED TO BE
25 GIVEN IT FOR FREE.

1 AND SECOND, ON THE ISSUE OF ON VERSUS WITH AS
2 AN ALTERNATIVE, I THINK, AGAIN, AS A BLANKET MATTER, WE
3 WOULD LOVE TO SIT DOWN AND TALK TO YOU AND TRY TO WORK
4 THIS OUT. IT'S COMPLICATED. I THINK THE GOAL THAT
5 WE'RE TRYING TO GET TO IS SIMPLE, BUT THE COMING UP
6 WITH THE RIGHT LANGUAGE IS HARD. I WOULD JUST SAY THAT
7 IN EUROPE IT'S TRUE THAT THE EUROPEAN COMMISSION HAS AN
8 ON VERSUS WITH DISTINCTION, BUT THAT'S BEEN INTERPRETED
9 IN THE DIFFERENT MEMBER STATES VERY, VERY DIFFERENTLY,
10 WHICH I THINK JUST DEMONSTRATES THAT, EVEN THOUGH IT
11 SOUNDS SIMPLE TO SAY, THAT, AGAIN, IN PRACTICE IT'S
12 DIFFICULT TO IMPLEMENT, AND IT DOESN'T MEAN THE SAME
13 THING TO EVERYBODY.

14 SO I GUESS I WOULD SAY WE PROBABLY CAN'T JUST
15 TAKE THAT TODAY WITHOUT SOME FURTHER DISCUSSION ABOUT
16 WHAT EXACTLY ARE WE TRYING TO DO AND WHAT ARE WE
17 EXACTLY DOING WITH THE LANGUAGE.

18 CHAIRMAN PENHOET: DUANE ROTH IN SACRAMENTO.

19 MR. ROTH: YEAH. I THINK IN LISTENING TO
20 THIS CONVERSATION, THERE'S THREE THINGS THAT STRUCK ME.
21 NO. 1, IT IS REALLY IMPORTANT THAT THESE TOOLS GET OUT
22 THERE IN A STANDARD, HIGH QUALITY FASHION FOR THIS
23 RESEARCH TO GO FORWARD. AND NO. 2, I THINK JEFF SUMMED
24 IT UP BEST. I THINK IT'S TOO EARLY FOR MUCH OF A
25 POLICY HERE. AND I THINK THAT WE SHOULD FIND OUT IF

1 THERE'S A REAL PROBLEM BEFORE WE JUST EXPECT THAT THERE
2 WILL BE A PROBLEM. AND THAT'S WHERE I'D PICK UP AND GO
3 BACK TO A REVIEW. BUT ANYTHING YOU DO ON A REVIEW, BE
4 VERY CAREFUL THAT THAT DOESN'T SEND A SIGNAL TO
5 POSSIBLE INVESTORS, COMPANIES OR OTHERWISE, THAT YOU'RE
6 GOING TO RETROSPECTIVELY MARCH IN AND CHANGE THINGS
7 BECAUSE THAT WILL CONCERN THEM ABOUT THE INVESTMENT.
8 THEY WANT TO KNOW THERE'S SOME CERTAINTY TO WHAT
9 THEY'RE LICENSING FROM ANY ACADEMIC CENTER.

10 SO I THINK IT NEEDS TO BE PROSPECTIVE, AND I
11 WOULD SUGGEST EVEN THAT YOU NOT MAKE IT ANNUAL,
12 SEMIANNUAL, BUT DEAL WITH IT IF IT BECOMES A PROBLEM.
13 IF WE HAVE A PROBLEM, AND I THINK JEFF ALSO SAID THERE
14 ARE MANY SMART PEOPLE LOOKING AT THIS AND TRYING TO
15 FIGURE IT OUT, WE DON'T HAVE THE RESOURCES THEY DO TO
16 WADE THROUGH ALL THIS, SO I THINK THE TIME IS EARLY FOR
17 US.

18 CHAIRMAN PENHOET: ANY FURTHER COMMENTS FROM
19 BOARD MEMBERS? DR. PRIETO.

20 DR. PRIETO: I HAVE JUST A COUPLE OF COMMENTS
21 OR QUESTIONS. ONE IS WHETHER, IN SPITE OF THE PROBLEMS
22 WITH THE LANGUAGE, AND I THINK YOU ALWAYS HAVE PROBLEMS
23 WITH LANGUAGE, ISN'T INDUSTRY LIVING WITH A NARROWER
24 EXEMPTION, THE RESEARCH ON VERSUS RESEARCH WITH
25 EXEMPTION IN EUROPE AND JAPAN AND MANAGING TO GO

1 FORWARD?

2 AND THEN THE QUESTION IF WE DO NOT -- IF WE
3 DELETED THIS AND USED THE OTHER LANGUAGE WE HAVE ABOUT
4 MAKING TOOLS WIDELY AVAILABLE AS THE REMEDY, HOW DO WE
5 DEFINE WIDELY AVAILABLE AND HOW DO WE ENFORCE THAT?

6 ONE OF THE ENFORCEMENT PROVISIONS THAT WAS
7 MENTIONED WAS MARCH-IN RIGHTS. WELL, WE KNOW FROM THE
8 HISTORY OF MARCH-IN RIGHTS THAT THEY HAVE VIRTUALLY
9 NEVER BEEN EXERCISED. DO WE -- IS IT PROPOSED OR WOULD
10 INDUSTRY SUGGEST THAT WE STRENGTHEN THE MARCH-IN RIGHTS
11 AND EXPLICITLY GO FORWARD SAYING THAT WE INTEND TO USE
12 THEM AT A MUCH LOWER THRESHOLD?

13 DR. WRIGHT: OR DOES THAT SEND THAT SAME
14 SIGNAL TO INDUSTRY THAT DUANE MENTIONED, THAT INJECTS A
15 LACK OF CERTAINTY?

16 DR. PRIETO: YEAH. THAT'S A CONCERN, I
17 THINK.

18 MR. SHEEHY: BUT WE DO PROVIDE FOR A CURE
19 PERIOD. AND I THINK IT WOULD BE TRIGGERED BY A
20 SPECIFIC INCIDENT WHICH WOULD OPEN UP THE POTENTIAL FOR
21 NEGOTIATION. IN OTHER WORDS, WE'D HAVE A RESEARCHER
22 THAT WOULD SAY TO US, THAT WE'RE FUNDING, THAT I CAN'T
23 GET X FROM INVITROGEN. AND THEN WE WOULD GO TO
24 INVITROGEN AND SAY, HEY, WE'RE GOING TO MARCH IN. AND
25 THEN WE'D SIT DOWN AND LOOK AT THE FACTS. I DON'T

1 THINK -- I DON'T THINK -- I THINK THAT'S EXACTLY THE
2 PLACE WE'D WANT TO BE IN THIS PARTICULAR ENVIRONMENT.
3 AND I DON'T THINK THAT THE WORLD WOULD COME TO AN END
4 AND THE RESEARCH WOULD STOP. I THINK WE'D MAKE A DEAL
5 FAIRLY QUICKLY. THAT'S MY GUESS.

6 MR. GOSWAMI: SO TWO COMMENTS, RIGHT. I
7 THINK ONE IS JUST, YOU KNOW, JUST BECAUSE --

8 CHAIRMAN PENHOET: IDENTIFY YOURSELF AGAIN.

9 MR. GOSWAMI: JOYDEEP GOSWAMI FROM
10 INVITROGEN. SO I THINK TWO COMMENTS. ONE IS JUST
11 BECAUSE THERE HASN'T BEEN MARCH IN, YOU KNOW, DOESN'T
12 MEAN IT'S A BAD THING, RIGHT? MAYBE THE TOOLS AND
13 REAGENTS ARE ALREADY AVAILABLE, SO THERE HASN'T BEEN A
14 NEED FOR MARCH IN. THE PROVISION EXISTS IN, I THINK,
15 NIH-FUNDED TOOLS THAT WE LICENSE IN FROM ANY
16 UNIVERSITY.

17 I THINK THE SECOND THING IS, YOU KNOW,
18 DESPITE THE FACT THAT THERE HAS BEEN NO EXEMPTION IN
19 THE UNITED STATES, THIS COUNTRY IS BY FAR THE LEADER IN
20 INTRODUCING THESE TOOLS AND, OF COURSE, EXPORTING THEM
21 TO THE REST OF THE WORLD, RIGHT? SO I DON'T SEE ANY
22 LACK OF AVAILABILITY THAT IS EVIDENCED IN THIS
23 INDUSTRY.

24 AND I DO WANT TO COME BACK TO THE WARF ISSUE
25 FOR A SECOND BECAUSE I THINK THAT IS AN EXTREME ISSUE.

1 THE THIRD THING, I THINK JANET MENTIONED THAT
2 THE LITIGATION ENVIRONMENT IN JAPAN AND IN EUROPE ARE
3 QUITE DIFFERENT FROM THE U.S. SO I DON'T THINK I CAN
4 DRAW THOSE PARALLELS IMMEDIATELY.

5 I THINK FOURTH POINT, SOMEBODY ON THE PHONE
6 MENTIONED, YOU KNOW, THERE'S BASIC RESEARCH AND
7 NOT-FOR-PROFIT ACADEMIC RESEARCH, ETC. IT IS QUITE
8 HARD TO DRAW THE LINE BETWEEN, YOU KNOW, BASIC AND
9 APPLIED. AND SECONDLY, ONE HAS TO REMEMBER THAT THE
10 AREA WHERE STEM CELLS IS TODAY, A MAJORITY OF THE
11 RESEARCH IS NOT GETTING CARRIED OUT IN INDUSTRY, BUT IN
12 ACADEMIC RESEARCH. RIGHT. SO TO SAY THAT IT'S OKAY
13 FOR ACADEMICS AND NOT-FOR-PROFITS TO USE THIS WITHOUT
14 REQUIRING A PATENT OR A LICENSE, I THINK, HAS THE SAME
15 EFFECT ON OUR INDUSTRY. SO I THINK THAT ISN'T GOING TO
16 BE THE CASE.

17 AND THE LAST POINT I WANTED TO MAKE IS WARF,
18 RIGHT. THIS IS A VERY, VERY SPECIFIC CASE. THIS IS
19 ACTUALLY NOT A COMPANY, RIGHT. THIS IS A UNIVERSITY
20 WHICH, AGAIN, IT HAS -- THERE ARE OTHER THINGS WHICH WE
21 BROUGHT UP AT THE FOR-PROFIT. IT'S A VERY PECULIAR
22 PATENT WHICH ONE UNIVERSITY HAS CORNERED. IF THERE
23 WERE MARCH-IN RIGHTS, IF THERE WERE THE ABILITY FOR
24 EITHER THE GOVERNMENT OR WHOEVER TO STEP IN AND SAY
25 YOU'VE GOT TO MAKE THIS AVAILABLE TO PEOPLE AT A

1 REASONABLE PRICE, YOU WOULDN'T BE SEEING THIS. THIS IS
2 NOT A COMPANY THAT IS DICTATING THIS. THIS IS NOT ANY
3 INDUSTRY.

4 AND AGAIN, TO GO BACK TO THIS POINT, JEFF, IS
5 IT IS NOT IN OUR INTEREST TO NOT MAKE TOOLS AVAILABLE?
6 THAT HARMS OUR REVENUE, RIGHT? WE LOOK AT THE TOP AND
7 BOTTOM LINE, SO WHY WOULD WE PAY A HUGE AMOUNT UP FRONT
8 TO A UNIVERSITY AND THEN DECIDE, HEY, WE'LL JUST SIT ON
9 IT? RIGHT? AND IF WE DO, WE HAVE THE RIGHTS TO COME
10 IN AND SAY YOU'RE NOT DOING A GOOD ENOUGH JOB, EITHER
11 GIVE UP THIS THING OR WE'LL LICENSE IT TO OTHER
12 COMPANIES, AS THE PROVISION ALREADY EXISTS, RIGHT? IF
13 YOU DO EXCLUSIVE LICENSING, IF WE DON'T PRODUCE IT OR
14 DON'T PRODUCE ENOUGH OF IT, YOU CAN COME AND TURN IT
15 INTO A NONEXCLUSIVE. SO, AGAIN, I REALLY DON'T SEE THE
16 NEED FOR A RULE IN THIS CONTEXT, AND I WANT TO MAKE
17 SURE IT'S THIS CONTEXT OF NO EVIDENCE FOR ANY LACK OF
18 AVAILABILITY, THE EXISTENCE OF OTHER CLAUSES IN THE
19 EXISTING DOCUMENT.

20 CHAIRMAN PENHOET: ANY FINAL QUICK COMMENTS?
21 I GUESS WE'RE GOING TO HAVE TO ADDRESS THIS ISSUE.
22 I'LL SPEAK FOR MYSELF. I'VE BEEN PERSUADED BY THE
23 ARGUMENTS OF JEFF SHEEHY AND DUANE ROTH AND OTHERS
24 THAT, ALTHOUGH THIS IS A POTENTIAL PROBLEM, I ACTUALLY
25 THINK IT'S NOT A PROBLEM THAT EXISTS IN ANY MEANINGFUL

1 WAY TODAY IN THE RESEARCH COMMUNITY. AND I THINK WE
2 HAVE ENOUGH OF A BURDEN TO SOLVE PROBLEMS THAT ARE
3 PROBLEMS FOR US WITHOUT TACKLING THIS ISSUE, WHICH
4 MIGHT BE A PROBLEM. SO I WILL PROBABLY COME DOWN ON
5 THE SIDE OF ELIMINATING THIS PROPOSAL NOW, BUT I WOULD
6 HOPE WE WOULD REVISIT IT WITHIN TWO YEARS OR AT ANY
7 TIME WHEN IT BECOMES A PROBLEM BECAUSE I DO THINK --
8 I'VE BEEN PERSUADED BY ESPECIALLY DUANE'S ARGUMENT.
9 THE ACADEMIC RESEARCH COMMUNITY IN THE MAIN CARRIES OUT
10 ITS WORK TODAY WITHOUT BEING SUED FOR DOING SO. AND I
11 THINK WE'RE ADDING AN EXTRA LAYER OF COMPLEXITY HERE.

12 I WOULD LIKE TO -- I'M SPEAKING FOR MYSELF
13 NOW. I WOULD LIKE TO SEE IT MONITORED ON A REGULAR
14 BASIS, AND I DO BELIEVE THAT WE DO HAVE SOME OTHER
15 PROVISIONS IN OUR POLICY WHICH WILL ALLOW US TO
16 ACTUALLY PUT SOME TEETH INTO THINGS IF THINGS ARE NOT
17 AVAILABLE. SO I'VE CHANGED MY VIEW ON THIS SUBJECT
18 FROM ORIGINALLY. THAT'S MY POINT.

19 ANYBODY ELSE WANT TO MAKE A STATEMENT?

20 DR. BRYANT: THIS IS SUE BRYANT. SO I WOULD
21 AGREE WITH YOU COMPLETELY. I THINK WE NEED TO DO NO
22 HARM TO THE TOOLS INDUSTRY; AND I THINK THAT SINCE
23 THERE ISN'T NOW A PROBLEM, I COMPLETELY AGREE WE SHOULD
24 ELIMINATE THIS.

25 CHAIRMAN PENHOET: YOU ARE IN A UNIVERSITY.

1 SO HAVE YOU -- HAS THIS -- THIS HAS NOT BEEN A PROBLEM
2 FOR UC IRVINE?

3 DR. BRYANT: NO, NOT THAT I KNOW ABOUT.

4 CHAIRMAN PENHOET: YOU WANT TO MAKE ANY
5 FURTHER COMMENTS, JEFF?

6 MR. SHEEHY: IT SEEMS LIKE -- ELIMINATING
7 THIS SOUNDS FINE. I DO THINK IT WOULD BE INTERESTING
8 TO GET INTO A DIALOGUE WITH THE TOOLS INDUSTRY. THERE
9 SEEMS TO BE SOME WILLINGNESS. I DO THINK, AND MAYBE
10 THIS IS FURTHER DOWN THE ROAD AS WE START TO GO MORE
11 INTO THE FOR-PROFIT RULEMAKING, BUT LET'S SEE IF WE CAN
12 MAYBE GET THROUGH -- YOU KNOW, SET UP SOME SORT OF
13 PROCESS SO THAT WE COULD FAIRLY EXPEDITIOUSLY GET SOME
14 RULES IN PLACE FOR FOR-PROFIT IP GRANTING IN THE TOOLS
15 AREA SO THAT WE CAN MAKE THOSE GRANTS FAIRLY SOON.

16 I MEAN I THINK WHERE THERAPIES ARE CONCERNED,
17 I THINK WE'VE GOT A LOT OF REALLY TOUGH ISSUES, BUT WE
18 MAY BE ABLE TO GET THROUGH THIS AND REALLY GET SOME --
19 START TO FUND SOME OF THESE INVENTIONS AND GET A
20 RETURN. AS I THINK SOMEONE NOTED, THIS WILL PRODUCE A
21 MUCH -- A RETURN MUCH SOONER TO THE STATE OF CALIFORNIA
22 SO THE TAXPAYERS CAN ACTUALLY SEE SOME REVENUE STREAM
23 COMING IN FROM THEIR INVESTMENT. SO I THINK TAKING IT
24 OUT IS GREAT, BUT LET'S TAKE ADVANTAGE OF THEIR
25 WILLINGNESS TO SIT DOWN WITH US AND MAYBE JUMP START

1 THE FOR-PROFIT DISCUSSIONS AND MAYBE EVEN SEGMENT OUT
2 THIS PIECE OF IT.

3 CHAIRMAN PENHOET: THEY WILL BE MORE THAN
4 WELCOME TO JOIN US ON AUGUST 3D FOR THE SECOND IN THE
5 FOR-PROFIT MEETINGS. THE THIRD FOR-PROFIT MEETING. WE
6 ARE GOING TO HAVE A MEETING AUGUST 3D UNLESS WE CHANGE
7 IT.

8 ANY MORE COMMENTS BEFORE WE TAKE A VOTE OF
9 THE GROUP FROM TASK FORCE MEMBERS?

10 DR. WRIGHT: ED, THIS IS JANET. I WOULD JUST
11 SAY PROBABLY -- I FULLY AGREE WITH YOUR COMMENTS, AND
12 INHERENT IN THEM IS THE HOPE THAT WE LEARN FROM OTHERS
13 WHO ARE ALSO STRUGGLING WITH THIS ISSUE ACROSS THE
14 COUNTRY. IT SOUNDS PREMATURE TO PUT A POLICY IN PLACE,
15 BUT I'D HOPE WE CAN LEARN FROM OTHER PEOPLE TOO.

16 CHAIRMAN PENHOET: WELL, AMONG OTHERS THE
17 AAAS HAS A RESEARCH EXEMPTION WORKING GROUP AT WORK ON
18 THIS VERY PROBLEM. IT IS BEING DEALT WITH AT MANY
19 OTHER -- IN MANY OTHER ORGANIZATIONS. AND SO THE
20 RESULT OF THAT MAY HAVE FEDERAL CONSEQUENCES THAT WE
21 WILL ALL LIVE BY ONE WAY OR THE OTHER.

22 I GUESS WE NEED -- ON THIS ISSUE WE HAVE
23 VARIOUS VIEWS EXPRESSED. WHAT WE NEED IS A ROLL CALL
24 VOTE, IF WE COULD. WELL, WE REMEMBER WHO'S THERE. IN
25 IRVINE, THERE'S A MOTION TO DROP THE RUE OR TO RETAIN

1 IT AS IT IS. IN IRVINE.

2 DR. BRYANT: I'M IN FAVOR OF DROPPING IT.

3 CHAIRMAN PENHOET: IN STANFORD. ARE YOU

4 THERE AT STANFORD?

5 MR. GOLDBERG: YEAH, WE'RE HERE.

6 CHAIRMAN PENHOET: MICHAEL.

7 MR. KLEIN: THE QUESTION IS WHETHER THERE'S A

8 FORMAL MOTION OR WHETHER THERE WAS A SECOND.

9 DR. FONTANA: MOTION.

10 CHAIRMAN PENHOET: WE NEED A MOTION AND

11 SECOND. I'M TRYING TO GET US INTO THE GROUP.

12 DR. BRYANT: SECOND.

13 CHAIRMAN PENHOET: ANYWAY, GO AHEAD.

14 DR. FONTANA: MOTION TO ABOLISH THE RESEARCH

15 USE EXEMPTION AS WRITTEN IN THIS DOCUMENT.

16 CHAIRMAN PENHOET: OKAY.

17 MR. SHEEHY: SECOND.

18 CHAIRMAN PENHOET: OKAY. WE'LL HAVE A ROLL

19 CALL VOTE BY MELISSA. SO THE MOTION IS TO ABOLISH RUE

20 SECTION.

21 MS. KING: SUE BRYANT.

22 DR. BRYANT: YES.

23 MS. KING: MICHAEL GOLDBERG.

24 MR. GOLDBERG: YES.

25 MS. KING: ED PENHOET.

1 CHAIRMAN PENHOET: YES.

2 MS. KING: JEANNIE FONTANA.

3 DR. FONTANA: YES.

4 MS. KING: JEFF SHEEHY.

5 MR. SHEEHY: YES.

6 MS. KING: FRANCISCO PRIETO.

7 DR. PRIETO: YES.

8 MS. KING: JANET WRIGHT.

9 DR. WRIGHT: YES.

10 CHAIRMAN PENHOET: OKAY. THANK YOU. WE'LL

11 MOVE ON NOW TO MARCH-IN RIGHTS. AND HERE, AGAIN, WE

12 HAVE A SPECTRUM OF VIEWS. WE HAVE A PROPOSED

13 REGULATION WHICH PROVIDES MARCH-IN RIGHTS IN TWO

14 CIRCUMSTANCES. ONE OF THOSE BEING -- THE FIRST BEING

15 THE FAILURE TO DEVELOP. AND THE SECOND BEING -- WHAT'S

16 THE EXACT LANGUAGE?

17 MR. TOCHER: 00310.

18 CHAIRMAN PENHOET: IT'S HERE IN YOUR BOOK.

19 MR. TOCHER: IT'S PAGE 18 OF THE REG PACKET.

20 CHAIRMAN PENHOET: THERE ARE FOUR CONDITIONS.

21 RESPONSIBLE EFFORTS TO ACHIEVE PRACTICAL APPLICATION,

22 FAIL TO ADHERE TO AGREED-UPON PLAN FOR ACCESS TO

23 RESULTANT THERAPIES AS DESCRIBED LATER, TO MEET THE

24 REQUIREMENTS FOR PUBLIC USE, AND THE REQUIREMENTS

25 HAVEN'T BEEN SATISFIED, AND TO ALLEVIATE PUBLIC HEALTH

1 AND SAFETY NEEDS WHICH ARE NOT REASONABLY SATISFIED BY
2 THE ORGANIZATION. SO THOSE ARE THE FOUR COMPONENTS OF
3 MARCH-IN RIGHTS AS CURRENTLY ARTICULATED.

4 WE'VE HEARD TODAY SOME COMMENTS SAYING THE
5 MARCH-IN RIGHTS PROVIDE A LEVEL OF PROTECTION ABOUT
6 FAILURE TO DEVELOP, ETC., IN THE LAST CONVERSATION WE
7 JUST HAD. WE HAVE COMMENTS ON BOTH ENDS OF THE
8 SPECTRUM HERE. AT ONE END TO ABOLISH THIS FEATURE
9 ALTOGETHER AND AT THE OTHER END TO ACTUALLY SUPPORT
10 MARCH IN -- EXPANDED MARCH IN TO INCLUDE REASONABLE
11 PRICING AS ONE OF THE CONSIDERATIONS.

12 SO WITH THAT, OPEN THE DISCUSSION TO FELLOW
13 TASK FORCE MEMBERS. ANYBODY HERE IN SACRAMENTO WANT TO
14 SPEAK TO THE ISSUE OF MARCH-IN RIGHTS?

15 DR. PRIETO: FRANCISCO PRIETO. I THINK,
16 HAVING JUST HEARD FROM INDUSTRY THAT THIS WOULD BE ONE
17 OF THE REMEDIES WE COULD USE IF WE ABOLISH THE RESEARCH
18 USE EXEMPTION, I THINK IT'S IMPORTANT TO KEEP THIS. I
19 THINK THAT PRICING, EVEN AT THE BASIC RESEARCH LEVEL,
20 MAY BE AN ISSUE IF A COMMERCIAL COMPANY LIKE INVITROGEN
21 IS DEVELOPING A TOOL, FOR EXAMPLE, AND ANOTHER GRANTEE
22 OF OURS COMES BACK TO US AND SAYS, YES, THEY'RE MAKING
23 THIS AVAILABLE, BUT AT A PRICE THAT IS PROHIBITIVE,
24 THAT IS GOING TO EAT UP SOME HUGE PORTION OF THE GRANT
25 THAT I NEED TO PURSUE THIS IDEA, THAT'S GOING TO BE A

1 PROBLEM FOR US. SO IN THAT SENSE I THINK PRICING
2 SHOULD BE ONE OF THE CRITERIA WE USE.

3 MR. SHEEHY: YEAH. I WOULD LIKE TO SAY THAT
4 I HAVE HUGE TROUBLES. AND I WOULD NOTE THAT THE
5 COMMENT DIDN'T REFER TO PRICING FOR TOOLS, WHICH WE
6 JUST HEARD FROM INDUSTRY. IT'S A SELF-DEFEATING
7 PROPOSITION TO OVERPRICE, BUT IT -- ACTUALLY THE
8 RECOMMENDATIONS TO MAKE THE RESULTING THERAPIES
9 AVAILABLE AT A REASONABLE PRICE. MY INITIAL PROBLEM
10 WITH THAT IS THAT REASONABLE PRICE IS AN UNDEFINABLE
11 TERM, SO THAT SHOULD BE ENOUGH ON THE FACE OF IT. BUT
12 AS SOMEONE WHO HAS THE POLICY GOAL OF SEEING THESE
13 THERAPIES GET TO AS MANY PEOPLE AS POSSIBLE, THE
14 QUESTION IS NOT ONE OF PRICE. IT'S OF ACCESS. SO IT'S
15 THE WRONG PLACE TO BE FOCUSING OUR ENERGY.

16 AND WE HAVE ADDRESSED THE ACCESS ISSUES BY
17 REQUIRING THAT THE BEST AVAILABLE PRICE, WHICH IS THE
18 FEDERAL PRICE, IS MADE AVAILABLE TO GOVERNMENT ENTITIES
19 THAT PURCHASE THESE THERAPIES, AND THEN WE'VE ASKED
20 COMPANIES TO PROVIDE ACCESS PLANS FOR UNINSURED
21 CALIFORNIANS. SO IN THAT PROVISION OF, YOU KNOW, IN
22 THE -- WHICH IS REALLY -- IT'S IN HERE. I FORGET WHERE
23 IT IS. BUT THOSE TWO THINGS REALLY CAPTURE WHAT PEOPLE
24 MEAN WHEN THEY SAY, I THINK, WHEN THEY START TALKING
25 ABOUT A REASONABLE PRICE FOR THERAPIES. BECAUSE THE

1 REALITY IS ALMOST NOBODY PAYS FOR THEIR OWN DRUGS,
2 RIGHT, UNLESS YOU'RE UNINSURED. AND WE PROVIDED A
3 PROVISION FOR ACCESS FOR THE UNINSURED.

4 SO WHAT WE'RE TALKING ABOUT IS IN SOME WAY
5 SETTING OURSELVES UP AS A PRICE CONTROL BOARD FOR THE
6 INSURANCE INDUSTRY, WHICH IS THE ONLY PEOPLE I THINK
7 THAT WOULD BE MATERIALLY BENEFITED BY THIS PROVISION.
8 AND I DON'T REALLY FEEL LIKE GOING TO WORK FOR HEALTH
9 NET. I DON'T THINK THAT'S OUR MANDATE. OUR MANDATE IS
10 TO MAKE THESE THERAPIES ACCESSIBLE TO CALIFORNIANS, NOT
11 TO SET OURSELVES UP AS A WAGE AND PRICE BOARD.

12 DR. PRIETO: IF I CAN RESPOND TO THAT. I
13 REALLY WASN'T TALKING -- I AGREE WITH YOU ABOUT PRICING
14 FOR THERAPEUTICS. I THINK THAT WE'VE ADDRESSED THAT IN
15 A REASONABLE WAY WITHOUT USING THIS KIND OF LANGUAGE.
16 I WAS THINKING MORE AT THE EARLIER STAGE THAT WE'RE AT
17 NOW AND THIS KIND OF PRICING OF MATERIALS FOR
18 RESEARCHERS.

19 MR. SHEEHY: BUT THE PUBLIC COMMENT WAS FOR
20 THERAPIES. THE PUBLIC COMMENT IS FAILURE TO MAKE THE
21 RESULTANT THERAPIES AVAILABLE TO THE PUBLIC AT A
22 REASONABLE PRICE.

23 DR. PRIETO: THEN I WOULD SHARE YOUR
24 CONCERNS. I MEAN I DON'T -- MY PROBLEM WITH THAT
25 LANGUAGE IS JUST THAT IT IS SO UNDEFINED.

1 CHAIRMAN PENHOET: I SUPPOSE WE'D HAVE SOME
2 LATITUDE UNDER THE WIDELY AVAILABLE IF SOMETHING WAS SO
3 OUTRAGEOUSLY PRICED THAT NOBODY COULD AFFORD TO BUY IT.
4 OKAY. COMMENTS FROM IRVINE? ANYBODY STILL THERE?

5 DR. BRYANT: OH, YES. I'M SORRY. I HAD THE
6 MUTE BUTTON ON.

7 CHAIRMAN PENHOET: THAT'S --

8 DR. BRYANT: NO. I DON'T HAVE ANY COMMENTS
9 ON THIS ONE.

10 CHAIRMAN PENHOET: OKAY. FROM STANFORD?
11 HELLO, STANFORD. HAS BOB BEEN PLAYING WITH THE PHONE
12 AGAIN?

13 MR. GOLDBERG: HE'S HERE.

14 CHAIRMAN PENHOET: ANY COMMENTS FROM
15 STANFORD?

16 MR. GOLDBERG: NOPE.

17 CHAIRMAN PENHOET: FROM CHICO?

18 DR. WRIGHT: NOPE.

19 CHAIRMAN PENHOET: DO WE HAVE COMMENTS FROM
20 THE AUDIENCE IN SACRAMENTO? YES.

21 MR. GILENWATER: MY NAME IS TODD GILENWATER.
22 I'M WITH THE CALIFORNIA HEALTHCARE INSTITUTE. AS WE
23 ADDRESSED IN OUR COMMENTS, OUR KEY CONCERNS WITH THE
24 MARCH-IN PROVISIONS, ESPECIALLY AS THEY REFER TO
25 REASONABLE PRICING, IS THE IMPACT IT COULD HAVE ON THE

1 DESIRE OF POTENTIAL LICENSEES TO ACTUALLY LICENSE
2 TECHNOLOGY THAT SOMEDAY DOWN THE ROAD, 10, 15 YEARS
3 DOWN THE ROAD, COULD ACTUALLY BECOME A THERAPY, AND
4 THAT MARCH-IN RIGHTS, BASED ON PRICING, COULD BE A
5 SIGNIFICANT DISINCENTIVE TO POTENTIAL LICENSEES.

6 OUR SECOND CONCERN WITH MARCH-IN RIGHTS DEALS
7 WITH REALLY THE PROCEDURES REGARDING MARCH IN. AND THE
8 INSURANCE THAT GRANTEES, LICENSEES, AND OTHER
9 STAKEHOLDERS ACTUALLY HAVE THE OPPORTUNITY TO BE
10 INVOLVED IN A PROCESS TO DEFEND AGAINST ANY CLAIM OF
11 UNREASONABLE PRICING, THAT THEY ACTUALLY HAVE THE
12 OPPORTUNITY TO APPEAL ANY DECISION, AND THAT THE
13 DECISION BE HELD IN ABEYANCE DURING THAT APPEAL BEFORE
14 ANY FINAL MARCH-IN ACTION IS ACTUALLY TAKEN. THANK
15 YOU.

16 CHAIRMAN PENHOET: THANK YOU. JOHN SIMPSON.

17 MR. SIMPSON: JOHN SIMPSON FROM THE
18 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. LET ME
19 GIVE YOU AN EXAMPLE OF UNREASONABLE PRICING AND THE
20 SORT OF THING THAT WE'RE TRYING TO GET IN HERE. AND I
21 THINK THAT IF THE INDUSTRY IS, IN FACT, COMMITTED TO
22 FAIRNESS, THEY SHOULD WORK WITH PEOPLE WHO ARE
23 CONCERNED ABOUT THIS TO COME UP WITH LANGUAGE THAT
24 MEETS THE KINDS OF GOAL THAT WE'RE TRYING TO ACHIEVE
25 THAT WOULD PRECLUDE THIS SORT OF EGREGIOUS MISUSE OF

1 PRICING.

2 GENENTECH HAS A DRUG CALLED AVASTIN. IT IS
3 POTENTIALLY VERY GOOD IN DIFFERENT TYPES OF CANCER.
4 WITH THE LATEST DOSAGES THAT ARE BEING REPRESENTED, IT
5 COSTS A \$100,000 A YEAR ESSENTIALLY BECAUSE THAT'S WHAT
6 THEY THINK THE MARKET WILL BEAR. THAT'S WHAT THEY
7 SAID. THEY ALSO DON'T BOTHER TO TELL PEOPLE THAT THEY
8 RECEIVE \$44.6 MILLION OF FEDERAL MONEY AT A MINIMUM.

9 NOW, I KNOW THAT'S WHAT THE NCI GAVE THEM,
10 THE NATIONAL CANCER INSTITUTE, FOR CLINICAL TRIALS,
11 MOUSE MODELS, AND DEVELOPING SOME ANTIBODIES IN HUMANS.
12 THAT, TO ME, IS UNREASONABLE PRICING. IT OUGHT TO NOT
13 BE SOMETHING THAT THE PEOPLE OF CALIFORNIA STAND FOR
14 WHEN THEY'RE PUTTING PUBLIC MONEY INTO PRODUCTS.

15 NOW, I UNDERSTAND THAT THERE IS SOME NEED FOR
16 CERTAINTY IN THE FUTURE, ALL OF THOSE KINDS OF THINGS.
17 WE DON'T WANT DISINCENTIVES, BUT IT DOES SEEM TO ME
18 THAT IT IS CLEAR THAT WHEN YOU ACCEPT PUBLIC MONEY,
19 THERE SHOULD BE AN OBLIGATION OF PUBLIC BENEFIT. AND I
20 DON'T THINK THAT ALLOWING THAT SORT OF -- THE
21 POSSIBILITY OF THAT KIND OF PRICING TO GO THROUGH IS
22 APPROPRIATE.

23 NOW, THERE ARE OTHER PEOPLE IN THE PACKET WHO
24 SAY THE SAME THING. I'M SPEAKING SPECIFICALLY ABOUT
25 PROFESSOR MURGIS, I THINK, IN THE BOLT HALL PACKAGE.

1 HE TALKED ABOUT EGREGIOUS OVERPRICING OVER A LONG
2 PERIOD OF TIME. I MEAN I THINK THIS IS -- I DON'T
3 CLAIM TO HAVE ALL OF THE ANSWERS ALL OF THE TIME, AND
4 I'M ALSO VERY GRATEFUL FOR THE WAY THAT THIS BOARD HAS
5 INTERACTED AND LISTENED TO ALL OF THE STAKEHOLDERS AND
6 TAKES IT VERY SERIOUSLY. AND I TOO WOULD BE DELIGHTED
7 TO SIT DOWN AND TRY TO CRAFT LANGUAGE WITH THE INDUSTRY
8 ON THIS KIND OF THING THAT SHOWS THE GOOD FAITH,
9 GOODWILL COMMITMENT ON THEIR PART TO SERVE THE PUBLIC
10 AS THEY SHOULD DO. THANK YOU.

11 CHAIRMAN PENHOET: ANY OTHER COMMENTS? DUANE
12 ROTH.

13 MR. ROTH: YES. YOU KNOW, AGAIN, I THINK THE
14 WAY THIS IS WRITTEN, AND I WOULD REMIND THE
15 INSTITUTIONS THAT THEY BEAR THE RESPONSIBILITY HERE IF
16 THEY GET GRANTS AND DON'T COMMERCIALIZE OR MAKE WIDELY
17 AVAILABLE, THE MARCH-INS APPLY TO THEM. AND I THINK
18 THAT'S PROBABLY OKAY BECAUSE IF IT'S NOT BEING MADE
19 WIDELY AVAILABLE BECAUSE SOMEBODY IN THE LICENSING
20 OFFICE OF THE INSTITUTION IS ASKING FOR UNREASONABLE
21 TERMS AND IT'S NOT COMING FORWARD, THEN YOU HAVE A WAY
22 TO FORCE THEIR HAND TO GET IT OUT THERE. SO I THINK
23 THAT'S GOOD.

24 I AGREE WITH WHAT TODD GILENWATER JUST SAID,
25 HOWEVER, ON THIS ACCESS TO REASONABLE PRICE THERAPIES

1 TIED TO THESE INSTITUTIONAL PATENTS. AND I THINK THAT
2 SHOULD BE STRUCK FROM THIS PARTICULAR PART OF IT. I
3 THINK IT CAN BE DEALT WITH IN OTHER PLACES, BUT MARCH
4 IN SHOULD BE TO GET TECHNOLOGY INTO EVERYBODY'S HANDS
5 THAT NEEDS IT WHEN SOMEBODY IS TRYING TO DELIBERATELY
6 STALL OR HOLD PEOPLE UP FOR A HIGHER MARKET VALUE.

7 MR. SHEEHY: DOES A PRICING PROVISION EXIST
8 IN THE MARCH-IN RIGHTS?

9 UNIDENTIFIED SPEAKER: NO.

10 CHAIRMAN PENHOET: JOHN HAS PROPOSED THAT WE
11 ADD A PRICING PROVISION.

12 MR. SHEEHY: AND YOU GUYS ARE RESPONDING TO
13 THAT PROPOSAL?

14 CHAIRMAN PENHOET: YES.

15 MR. SHEEHY: BECAUSE YOU SEEM TO HAVE --

16 MR. GILENWATER: TODD GILENWATER AGAIN WITH
17 THE CALIFORNIA HEALTHCARE INSTITUTE. AND WE WILL
18 ADDRESS IT WHEN WE GET ACTUALLY TO THE PRICING, THE
19 BEST PRICE, AND THE ACCESS PLANS, WHICH WE ALSO OPPOSE.
20 SO WE ACTUALLY OPPOSE MARCH IN BEING APPLIED ON ANY
21 PRICING, REASONABLE PRICING.

22 MR. SHEEHY: WELL, THE MARCH IN THAT IS
23 DESCRIBED HERE IS FOR THE ACCESS PLAN, WHICH IS
24 COGENERATED.

25 MR. GILENWATER: CORRECT. BUT --

1 MR. SHEEHY: SO IT'S THEIR FAILURE TO KEEP A
2 PROMISE THAT WE'RE MARCHING IN ON.

3 MR. GILENWATER: BUT ON OUR READ, THAT THAT
4 PLAN HAS TO BE PART OF THE LICENSING AGREEMENT, IS HOW
5 WE'VE READ IT.

6 MR. SHEEHY: YEAH.

7 MR. GILENWATER: ON A PRODUCT THAT ISN'T EVEN
8 GOING TO EXIST FOR TEN TO FIFTEEN YEARS. SO WE BELIEVE
9 THAT IT ADDS A PRETTY SIGNIFICANT BURDEN ON LICENSEES
10 WHO ARE GOING TO LICENSE A PRODUCT TO HAVE TO PUT
11 TOGETHER A PLAN FOR ACCESS TO A PRODUCT THAT DOESN'T
12 EVEN EXIST. BUT WE CAN ADDRESS --

13 CHAIRMAN PENHOET: I THINK PROCEDURALLY, I
14 THINK IF WE VOTE TO RECOMMEND THIS PROVISION AS
15 ARTICULATED HERE, IT WOULD BE SUBJECT TO THE FACT THAT
16 WE LATER IN THIS MEETING TODAY APPROVED THIS PART.
17 OTHERWISE WE'LL HAVE TO COME BACK AND AMEND THIS PART.
18 HE'S TALKING ABOUT THE ACCESS PLANS. IT'S REFERRED TO
19 HERE. YOU CAN MARCH IN IF SOMEBODY --

20 MR. SHEEHY: NO. THAT'S EXACTLY WHAT I'M
21 TALKING ABOUT.

22 CHAIRMAN PENHOET: BUT WE HAVEN'T YET VOTED
23 FOR THE ACCESS RULE. SO WE WOULD HAVE TO DO THIS IN AN
24 ITERATIVE PROCESS. IF WE VOTE FOR THIS AS IT EXISTS
25 AND LATER TODAY WE TALK ABOUT ACCESS --

1 MR. SHEEHY: AND WE VOTE OUT THE ACCESS.

2 CHAIRMAN PENHOET: -- AND WE VOTE OUT ACCESS,
3 WE WOULD COME BACK AND MODIFY THIS ACCORDINGLY. THESE
4 TWO ARE TOUGH.

5 MR. SHEEHY: I KNOW. I KNOW. SO WHY NOT
6 SKIN THIS CAT RIGHT NOW? YOU KNOW, I MEAN THIS SEEMS
7 LIKE -- AND I JUST HAVE TO SAY WE'VE GOT A CURE PERIOD.
8 AND I WOULD NOTE, AND I KEEP TELLING FOLKS THIS ON AN
9 ACTIVIST WEBSERVE FOR AIDS DRUGS FOR AIDS ACTIVISTS.
10 AND SOMEONE SENT AROUND THE EXPANDED ACCESS PROGRAMS
11 FOR THE UNINSURED AND THE COLUMNS AND COLUMNS OF DRUGS.
12 IT'S NOT JUST THE ARV'S. IT'S ALSO ANTIBIOTICS. SO
13 COMPANIES ARE DOING THIS.

14 AND ALL WE'RE ASKING IS THAT THEY MAKE THIS
15 COMMITMENT TO DO THAT, THAT THEY COME UP WITH A
16 REASONABLE PLAN THAT WORKS FOR THEM, AND THAT THEY
17 IMPLEMENT IT AS PROMISED. I DON'T THINK ANYBODY IS
18 IMAGINING THAT THIS IS GOING TO BE A SIMPLE PROCESS.
19 WE DON'T KNOW HOW THESE THINGS ARE GOING TO BE
20 DELIVERED. I DON'T THINK THIS IS AN ANTAGONISTIC
21 THING. ALL IT'S SAYING IS MAKE THE COMMITMENT AND KEEP
22 THIS COMMITMENT. AND IF THE LANGUAGE NEEDS TO BE
23 TIGHTENED TO REFLECT THAT, BUT THIS IS ALSO WHAT
24 INDUSTRY IS DOING ALREADY. AND WE JUST WANT TO MAKE
25 SURE THAT WHAT IS PRETTY MUCH INDUSTRY STANDARD IS NOT

1 SOMETHING THAT IS NOT PART OF CIRM-FUNDED RESEARCH.

2 MR. GILENWATER: TODD GILENWATER AGAIN WITH
3 THE CALIFORNIA HEALTHCARE INSTITUTE. I WOULD JUST -- I
4 WOULD SUGGEST THAT, AND I DON'T HAVE ALL THE EVIDENCE
5 IN FRONT OF ME, THAT MOST OF THOSE COMPANIES DEVELOP
6 THOSE ACCESS PLANS WHEN THEY ACTUALLY HAVE THE PRODUCT,
7 NOT WHEN THEY ACTUALLY -- NOT WHEN THEY HAVE A VERY
8 EARLY STAGE INGREDIENT TO THAT PRODUCT.

9 AND IF -- JUST JUMPING AHEAD TO THE ACCESS
10 PLAN, IF I MAY, THE NIH UP UNTIL JUST OVER A DECADE AGO
11 ALSO HAD AS PART OF THEIR CRADA AGREEMENTS, THEIR
12 COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS, HAD A
13 FAIR PRICING REQUIREMENT INCLUDED IN THOSE. AND AS THE
14 EVIDENCE -- THAT WAS REMOVED IN 1995. AND AS THE
15 EVIDENCE HAS SHOWN, WHEN THOSE FAIR PRICING
16 REQUIREMENTS WERE PART OF THOSE, INDUSTRY DID NOT
17 PARTICIPATE.

18 MR. SHEEHY: YOU KEEP TALKING ABOUT PRICE.

19 CHAIRMAN PENHOET: THE FAIR PRICING, TO BE
20 FAIR, THE FAIR PRICING PROVISION AT THE NIH WAS BROADLY
21 REFERRED TO AS A PRICING PROVISION. IT WASN'T SPECIFIC
22 TO AN ACCESS PLAN FOR AN UNINSURED, NOR WAS IT SPECIFIC
23 TO A MEDICARE POPULATION. IT WAS PRICING, PERIOD. SO
24 IT WAS MUCH BROADER THAN WE'RE TALKING ABOUT HERE.

25 MR. SHEEHY: AND UNIVERSAL HEALTHCARE MAY

1 SOLVE THIS, BY THE WAY, BY THE TIME THE THERAPIES ARE
2 DEVELOPED.

3 CHAIRMAN PENHOET: JOHN.

4 MR. SIMPSON: MAY I HAVE ONE MORE THREE
5 MINUTES?

6 CHAIRMAN PENHOET: YES, YOU MAY.

7 MR. SIMPSON: AGAIN, I'M PERFECTLY -- WELL,
8 I'M NOT PERFECTLY WILLING TO AGREE THAT THE REGULATION
9 MAY NOT BE THE PLACE FOR THE PRICING, BUT ONE OF THE
10 THINGS THAT INTRIGUES ME IS THAT THE IP POLICY AS
11 CRAFTED HAS THREE CHAPTERS. THE SECOND CHAPTER IS
12 ESSENTIALLY WHAT IS BECOMING THE REGS. THE THIRD
13 CHAPTER, AS I UNDERSTAND IT, IS WHERE YOU EXPRESS
14 VARIOUS KINDS OF NOTIONAL ASPIRATIONS. IT'S WHERE YOU
15 HAVE A COMMITMENT TO TRY TO GET PEOPLE TO, FOR
16 INSTANCE, GO WITH OPEN-SOURCE PUBLISHING. I WOULD
17 SUBMIT TO YOU THAT IF YOU DON'T SEE THE WAY TO GET SOME
18 SORT OF REASONABLE PRICING PROVISION WORKED OUT IN
19 CONCERT WITH INDUSTRY, I DON'T UNDERSTAND WHY THEY
20 CAN'T IN GOOD FAITH STEP UP AND SIT DOWN AND SAY, LOOK,
21 LET'S WORK THIS OUT TOGETHER RATHER THAN PUSHING AND
22 BLUSTERING AND SAYING WE'RE GOING TO GO AWAY AND PICK
23 UP OUR PETRIE DISHES AND GO HOME. I DON'T GET IT.

24 I MEAN LET'S SIT DOWN AND WORK OUT THE
25 LANGUAGE; BUT IF WE CAN'T DO THAT IN THE REGS, A

1 PERFECTLY APPROPRIATE PLACE TO SORT OF SAY THAT IT IS
2 CIRM'S BELIEF THAT IF YOU TAKE PUBLIC MONEY, THERE
3 COMES WITH IT A RESPONSIBILITY FOR PUBLIC GOOD AND
4 AFFORDABILITY. THAT COULD BENEFICIALLY FIND ITS WAY
5 INTO YOUR THIRD CHAPTER.

6 MR. SHEEHY: I THINK -- I HAVE TO TAKE STRONG
7 OBJECTION TO THIS PRICING. YOU KNOW, WE SAW THIS IN
8 AIDS. AND I REFER TO A SPECIFIC DRUG THAT WAS
9 DEVELOPED THAT WAS PROBABLY UNDERPRICED, AND THAT WAS
10 T20 FUZEON. THEY ANTICIPATED A MARKET THAT WAS TOO
11 BIG. IT WAS THE FIRST INJECTION DRUG WHICH CARRIED
12 WITH IT A PRICE MULTIPLIER BECAUSE YOU HAVE TO DELIVER
13 THE INJECTORS WITH THE DRUG. IT'S NOT A PILL. AND THE
14 MARKET FOR IT WAS NEVER GOING TO BE VERY BIG. AND
15 WE -- THE ACTIVISTS BEAT THEM DOWN TO A PRICE THAT I
16 DON'T THINK REALLY SUSTAINS THE DEVELOPMENT OF NEW
17 PRODUCTS IN MY MIND. AND THEY WERE LOOKING AT 25,
18 \$30,000 A YEAR.

19 AND IF YOU LOOK AT HIV DRUGS, EVEN YOUR
20 EXAMPLE OF \$100,000 A YEAR, IT'S STILL WITHIN THE RANGE
21 OF WHAT MANY HEALTHCARE ECONOMISTS THINK IS REASONABLE
22 TO SPEND TO KEEP A PERSON ALIVE. I HEAR A MARKET OF
23 \$250,000 BEING A CUTOFF MARKET, AT LEAST THAT'S WHAT
24 THE DIRECTOR OF PUBLIC HEALTH IN SAN FRANCISCO SAYS IS
25 HIS CUTOFF FOR AN INTERVENTION. SO \$100,000 A YEAR IS

1 NOT NECESSARILY EGREGIOUS PRICING WHEN YOU'RE LOOKING
2 ON A D-A-L-Y BASIS.

3 SO, YOU KNOW, LET'S BRING IN SOME ECONOMISTS
4 IF WE'RE GOING TO TALK ABOUT PRICING. LET'S BE MORE
5 SOPHISTICATED, BUT, FIRST, LET'S HAVE A THERAPY THAT
6 WE'RE TALKING ABOUT, WHICH WE DON'T, WHICH ARE SEVERAL
7 YEARS DOWN THE ROAD. UNREASONABLE PRICING IS
8 IRRELEVANT IN MY MIND. PRICING IS IRRELEVANT FROM A
9 PATIENT'S POINT OF VIEW. THE ONLY THING THAT'S
10 RELEVANT IS ACCESS. AM I GOING TO GET IT TO SAVE MY
11 LIFE? AND THAT'S WHERE OUR OBLIGATION IS.

12 UNIDENTIFIED SPEAKER: (INAUDIBLE).

13 MR. SHEEHY: NO, IT IS NOT. IT IS NOT. MOST
14 PEOPLE DO NOT PAY FOR THEIR DRUGS.

15 CHAIRMAN PENHOET: OKAY. IF I MIGHT --

16 DR. PRIETO: MR. CHAIRMAN --

17 CHAIRMAN PENHOET: -- TAKE THE CHAIR'S
18 PREROGATIVE TO INTERVENE HERE. I WOULD LIKE TO GO BACK
19 TO THE MARCH-IN RIGHTS, AND WE WILL DEAL WITH THE
20 PRICING CONSIDERATIONS IN CATEGORY B, NO. 5. SO WITH
21 THE PROVISIO THAT IF WE CHANGED ANY OF THOSE, WE WOULD
22 HAVE TO COME BACK AND CHANGE THE MARCH-IN RIGHTS. SO
23 DO WE HAVE ANY FURTHER COMMENT ABOUT THE MARCH-IN
24 RIGHTS AS WRITTEN FROM THE MEMBERS OF THE TASK FORCE?
25 JEANNIE FONTANA.

1 DR. FONTANA: I'M GOING TO SUGGEST THAT WE
2 DELETE A LINE HERE, THE LAST SENTENCE OF THE PARAGRAPH
3 THAT STARTS OFF WITH "CIRM MARCH-IN RIGHTS MAY BE
4 EXERCISED IN THE EVENT OF, BUT NOT LIMITED TO FAILURE
5 TO LICENSE FUNDED PATENTABLE INVENTIONS," AND THEN
6 LET'S DELETE FAILURE TO MEET PLAN OUTLINED IN LICENSING
7 AGREEMENT.

8 DR. PRIETO: MAY I RESPOND?

9 CHAIRMAN PENHOET: YES.

10 DR. PRIETO: YEAH. I WOULD DISAGREE WITH
11 THAT. I THINK THIS IS WHAT WE'RE HEARING FROM CHI, BUT
12 I THINK WE'RE HEARING MORE THAN THAT. THEY WANT NO
13 PRICING AGREEMENTS, WHICH THERE ARE NO PRICING
14 AGREEMENTS IN THIS AS CURRENTLY WORDED. NO ACCESS
15 PLAN, EVEN THE NO ACCESS PLAN WOULD BE DRAFTED BY
16 INDUSTRY, NO RESEARCH USE EXEMPTION, WHICH WE'VE
17 GRANTED, AND ESSENTIALLY NO MARCH-IN RIGHTS OR NO TERMS
18 UNDER WHICH WE COULD MARCH IN, AND I THINK WHAT WE'RE
19 HEARING IS GIVE US THE MONEY WITH NO STRINGS AND TRUST
20 US TO DO THE RIGHT THING. AND I'M SORRY. I JUST DON'T
21 THINK THAT'S APPROPRIATE. I THINK AS WORDED, WITHOUT
22 ANY LANGUAGE ADDRESSING PRICING, THAT THIS IS A GOOD
23 POLICY, AND I THINK WE NEED TO HAVE SOME TEETH, SOME
24 TERMS UNDER WHICH WE COULD MARCH IN IF WE NEED TO. AND
25 I THINK THIS IS ONE OF THOSE.

1 THE ACCESS PLAN WOULD BE DRAFTED BY THE
2 GRANTEE. AND IF THEY CAN'T LIVE BY THEIR AGREEMENTS,
3 THEY SHOULDN'T MAKE THOSE AGREEMENTS IN THE FIRST PLACE
4 OR THEY SHOULDN'T ACCEPT OUR MONEY.

5 CHAIRMAN PENHOET: ANY COMMENTS FROM IRVINE?
6 FROM STANFORD?

7 MR. GOLDBERG: WELL SAID, DR. PRIETO.

8 DR. BRYANT: I'M SORRY. I HAD MY MUTE BUTTON
9 ON AGAIN. SO I AGREE WITH JEANNIE'S SUGGESTION TO
10 DELETE THAT SECTION, AND I ALSO HAVE A GREAT DEAL OF
11 RESPECT TO CHI CALLING ATTENTION TO AREAS THAT ARE
12 GOING TO CAUSE US PROBLEMS IN TERMS OF GETTING THE
13 THINGS OUT. SO THAT WAS WHAT I WANTED TO SAY.

14 CHAIRMAN PENHOET: WE'VE GOT SOME CONFUSION
15 ON EXACTLY WHICH ONE YOU WOULD --

16 MR. SHEEHY: AND I'M ON PAGE 18, WHICH IS THE
17 ACTUAL REGS.

18 DR. PRIETO: WE'RE WORKING OFF DIFFERENT
19 DOCUMENTS.

20 DR. FONTANA: I'M ON PAGE 5.

21 MR. TOCHER: SHE'S WORKING OFF THE SUMMARY
22 VERSUS THE REGULATIONS.

23 MR. SHEEHY: LET'S WORK OFF PAGE 18 IF WE
24 CAN.

25 MR. TOCHER: OF THE REGULATIONS. THAT'S YOUR

1 SECOND ATTACHMENT.

2 DR. FONTANA: NOW I GOT TO FIND IT.

3 MR. SHEEHY: BECAUSE I WOULD HAVE TO SAY I
4 COULD NOT SUPPORT GOING FORWARD WITH THAT (INAUDIBLE).
5 I THINK COMPANIES WOULD KEEP THEIR WORD MYSELF.

6 CHAIRMAN PENHOET: THEN THERE'S NO SENSE
7 HAVING AN ACCESS PLAN IF YOU CAN'T ENFORCE IT. I THINK
8 YOUR OPPORTUNITY TO GET TO THIS ISSUE WILL COME LATER.
9 IF YOU WANT TO ABOLISH THE ACCESS PLAN REQUIREMENT,
10 THAT'S A DISCUSSION IN B(5). THIS JUST SAYS IF THERE
11 IS SUCH A PLAN, THAT THIS IS THE WAY TO ENFORCE IT.

12 MR. GOLDBERG: WE'RE HAVING DIFFICULTY
13 HEARING AT STANFORD.

14 DR. BRYANT: AND AT IRVINE.

15 DR. WRIGHT: AND CHICO.

16 DR. FONTANA: AND SACRAMENTO.

17 CHAIRMAN PENHOET: ON LINE 11, ITEM 2, ON
18 PAGE 18 IS A WAY TO ENFORCE THE ACCESS PLANS. IT'S IN
19 THE MARCH-IN RIGHTS AS AN ENFORCEMENT PROVISION. IF
20 THERE'S NO ENFORCEMENT OF THE PROVISION, THEN YOU MIGHT
21 AS WELL NOT HAVE THE PROVISION. SO WE ARE GOING TO
22 DISCUSS IN A FEW MINUTES THE PROVISION ITSELF, AND WE
23 HAVE ALREADY SAID THAT IF WE DROP THE PROVISION, WE'LL
24 COME BACK AND MODIFY THE MARCH-IN RIGHTS. SO, FRANKLY,
25 I THINK THE SIMPLEST WAY WOULD BE TO SLICE THIS BABY

1 AND DEAL WITH THE MARCH-IN RIGHTS AS WRITTEN YES OR NO
2 AND THEN DEAL WITH THE ACCESS PLAN ISSUE. AND IF WE
3 DECIDE NOT TO HAVE AN ACCESS PLAN REQUIREMENT, THEN
4 THERE'S NO REASON TO HAVE A MARCH IN TO ENFORCE
5 SOMETHING WE DON'T HAVE. SO IF THAT WOULD BE
6 ACCEPTABLE TO YOU, JEANNIE, IT SEEMS TO ME --

7 DR. FONTANA: SORT OF WHICH COMES FIRST. YOU
8 TALK ABOUT THE ISSUES AND THEN INCLUDE THEM IN THE
9 MARCH-IN RIGHTS. YOU KNOW, WHATEVER FORMAT -- YOU'RE
10 SUGGESTING A FORMAT, BUT I'M SUGGESTING, WELL,
11 SHOULDN'T WE BE TALKING ABOUT THESE ISSUES AND THEN
12 ADDRESS THEM IN THE MARCH-IN RIGHTS.

13 CHAIRMAN PENHOET: WELL, WE CAN -- THE
14 PLEASURE OF THE GROUP. IF PEOPLE WANT TO SKIP NOW
15 FORWARD AND LEAVE ASIDE THE ISSUE OF MARCH-IN RIGHTS,
16 THEN YOU WANT TO DISCUSS THE ACCESS PLANS.

17 DR. BRYANT: YES.

18 CHAIRMAN PENHOET: OKAY. WELL, THEN -- IT'S
19 OKAY BY ME. LET'S DO THAT. SO WE'RE GOING TO TABLE
20 ANY VOTE ON THE MARCH-IN RIGHTS AND MOVE NOW TO
21 CATEGORY B.

22 MS. KING: BETWEEN THE TWO DOCUMENTS, JUST
23 FOR THE PEOPLE ON THE PHONE, YOU WANT TO MAKE SURE THEY
24 UNDERSTAND THAT WHEN YOU SAY WHAT YOU'RE TALKING ABOUT
25 RIGHT NOW. CATEGORY B, YOU'RE IN THE SUMMARY DOCUMENT,

1 FIRST DOCUMENT, AS OPPOSED TO THE REGULATIONS.

2 CHAIRMAN PENHOET: WE'RE IN THE SUMMARY
3 DOCUMENT. PAGE 6, CATEGORY B, ISSUE NO. 4, DEFINE THE
4 CRITERIA TO REMOVE OR TERMINATE LICENSES DUE TO FAILURE
5 TO KEEP THE LICENSED INVENTION AVAILABLE TO THE PUBLIC
6 FOR RESEARCH PURPOSES. OKAY.

7 YOU WANT TO GO DIRECTLY TO 5? OKAY. NO. 5,
8 REMOVE THE REQUIREMENT FOR EXCLUSIVE LICENSEES TO HAVE
9 A PLAN FOR ACCESS. THAT'S THE ISSUE. AS WRITTEN, IT
10 SAYS GRANTEE ORGANIZATIONS, ETC. YOU CAN READ IT
11 THERE. WE SPENT A LOT OF TIME ON THIS. WE'VE HEARD A
12 STRONG ARGUMENT FROM JEFF SHEEHY. THIS WAS A
13 COMPROMISE POSITION. WE ARE NOT SPECIFYING WHAT THAT
14 PLAN HAS TO BE. WE DECIDED ORIGINALLY THAT WE DID NOT
15 WANT TO HAVE A DIRECT PRICING POLICY BECAUSE WE HEARD
16 FROM INDUSTRY THAT PRICING CONSTRAINTS PER SE WERE
17 TRULY ONEROUS FROM MANY COMPANIES. SO WE STAYED AWAY
18 FROM PRICING PER SE; BUT AS A WAY OF ADDRESSING THE
19 CONCERNS OF THE ACCESSIBILITY TO THE PUBLIC, ETC., WE
20 HAVE TWO COMPONENTS.

21 ONE IS THIS ONE, THAT WE WOULD REQUIRE
22 LICENSEES TO HAVE A PLAN FOR ACCESS FOR UNINSURED
23 WITHOUT SPECIFYING WHAT THAT PLAN WOULD BE. AND THE
24 SECOND PIECE OF THAT WOULD BE THAT PRODUCTS WOULD BE
25 MADE AVAILABLE TO PUBLICLY FUNDED AGENCIES AT THE PRICE

1 SPECIFIED BY MEDICARE AND THE FEDERAL GOVERNMENT.
2 THOSE ARE THE TWO PIECES THAT RELATE IN A DIRECT OR
3 INDIRECT WAY TO PRICING.

4 SO THE ONE WE'RE NOW DISCUSSING IS THE PLAN
5 FOR ACCESS. AND SO, JEANNIE, YOUR PROPOSAL IS WE
6 DELETE THE REQUIREMENT THAT LICENSEES OF OUR NONPROFITS
7 HAVE ANY PLAN FOR ACCESS; IS THAT RIGHT?

8 DR. FONTANA: I'M RESPONDING TO HIS COMMENT,
9 TODD, IN CHI. AND I'D LIKE TO HEAR HIS OPINION MORE
10 ELABORATED.

11 CHAIRMAN PENHOET: OKAY.

12 MR. GILENWATER: AGAIN, OUR CONCERN IS TO,
13 ONE, TO AGREE THAT MANY COMPANIES DO HAVE ACCESS PLANS
14 FOR PRODUCTS THAT ARE FDA APPROVED AND BEING PLACED
15 ONTO THE MARKET. AND OFTENTIMES THOSE ACCESS PLANS ARE
16 DEVELOPED NEAR THE END STAGE OF THE FDA APPROVAL. OUR
17 CONCERN IS WITH REGARDS TO LICENSING REQUIREMENTS, THAT
18 ANY LICENSEE BE REQUIRED TO ESTABLISH AN ACCESS PLAN
19 FOR A PRODUCT THAT DOES NOT YET EXIST AND MAY NOT EVER
20 EXIST. AND IF IT DOES EXIST, MAY NOT EXIST FOR 15 TO
21 20 YEARS IS A SIGNIFICANT DISINCENTIVE TO ANY POTENTIAL
22 LICENSEE TO LICENSE THAT PRODUCT.

23 MR. SHEEHY: CAN I COMMENT ON THAT?

24 CHAIRMAN PENHOET: SURE. GO AHEAD.

25 MR. SHEEHY: YOU KNOW, AIDS DRUGS ARE A

1 BILLIONS OF DOLLAR MARKET. AND I THINK ANYBODY WHO
2 DEVELOPS AN AIDS DRUG HAS THE EXPECTATION THAT THEY'RE
3 GOING TO HAVE AN ACCESS PLAN BECAUSE WE INSIST ON IT.
4 SO HISTORY DOESN'T SUPPORT YOUR ASSERTION. AND AS A
5 PATIENT ADVOCATE, I WOULD FEEL THAT I HAD FAILED IN MY
6 DUTY, BOTH TO THE STATE OF CALIFORNIA AND TO PATIENTS,
7 IF WE DID NOT INCLUDE THIS PROVISION. IT'S JUST NOT
8 TRUE. IF YOU WERE A DEVELOPER OF AN HIV DRUG AND YOU
9 HAD YOUR ATTITUDE, YOU WOULDN'T GO INTO THAT MARKET.
10 YET PEOPLE ARE GOING INTO IT AND THEY'RE MAKING
11 BILLIONS OF DOLLARS. THEY KNOW THAT ACTIVISTS, NOT
12 ONLY THAT, THEY KNOW THE ACTIVISTS ARE GOING TO REQUIRE
13 THEM TO PROVIDE THOSE DRUGS AT LOWER COST TO THE
14 DEVELOPING WORLD. AND WE HAVEN'T EVEN -- YOU KNOW, SO
15 I DON'T -- I DON'T SEE THE ONEROUSNESS OF THIS BURDEN.
16 I REALLY DON'T.

17 I THINK YOU'RE TALKING IN A VERY SPECULATIVE
18 SENSE, AND I HAVE A VERY REAL-WORLD EXAMPLE WHERE
19 PEOPLE ARE WILLING TO GO INTO THE FIELD TO DEVELOP
20 DRUGS KNOWING, THEY KNOW THAT THEY'RE GOING TO HAVE TO
21 HAVE SOME PROVISION FOR ACCESS.

22 MR. GILENATER: AND OUR CONCERN HAS
23 ADDRESSED THESE POTENTIALLY LICENSED TECHNOLOGIES WHERE
24 MANY OF THE GRANTEES OR THE LICENSEES DON'T YET KNOW
25 THE SPECIFIC APPLICATION. AND AT ITS EARLY STAGE --

1 MR. SHEEHY: SO WE'RE JUST SILENT ON IT?

2 MR. GILENWATER: AS FAR AS I KNOW, AT THE
3 FEDERAL LEVEL, THERE IS NO -- AS BAYH-DOLE, THERE IS NO
4 LICENSING REQUIREMENT FOR GRANTEES AT THAT EARLY STAGE
5 TO HAVE AN ACCESS PLAN.

6 MR. SHEEHY: HOW CAN WE -- THE THING IS THAT
7 WE HAVE A RESPONSIBILITY TO MAKE SURE THESE THERAPIES
8 IN SOME WAY GET DELIVERED TO THE PEOPLE OF CALIFORNIA.
9 I'M WILLING TO ACCEPT THE SUGGESTION OF ALTERNATIVE
10 LANGUAGE, BUT I THINK ASKING THAT AN ACCESS PLAN, WHICH
11 IS ALMOST ROUTINE BY MOST PHARMA, FOR UNINSURED THAT
12 THEY DEVELOP THEMSELVES IS NOT AN UNREASONABLE BURDEN
13 TO ASK. I MEAN THEY'RE GOING TO DO IT ANYWAY. WE JUST
14 WANT TO MAKE SURE THAT WHAT WE FUND IS NOT THE ODD
15 COMPANY THAT DECIDED THEY'RE NOT GOING TO DO IT. I
16 JUST DON'T SEE THIS BEING A BURDEN.

17 CHAIRMAN PENHOET: IS THERE AN ACCEPTABLE
18 MIDDLE GROUND HERE WHICH WOULD SAY THAT A LICENSEE
19 WOULD AGREE TO HAVE AN ACCESS PLAN IN PLACE BEFORE THE
20 PRODUCTS WERE COMMERCIALIZED? BECAUSE MARCH-IN RIGHTS
21 COULD ONLY OCCUR AT THE TIME -- YOU WOULD KNOW WHETHER
22 THEY'RE ADHERING TO IT OR NOT.

23 MR. GILENWATER: OUR CONCERN IN CHI, AGAIN --
24 I'M SORRY. OUR CONCERN IS NOT THAT LICENSEES AND THE
25 EVENTUAL PRODUCTS THERE SHOULD NOT BE AN ACCESS PLAN.

1 OUR CONCERN IS THAT THIS COULD BE A DISINCENTIVE TO BE
2 REQUIRED TO HAVE AN ACCESS PLAN FOR A PRODUCT THAT NO
3 ONE KNOWS WHAT THE PRODUCT IS GOING TO BE 20 YEARS DOWN
4 THE ROAD.

5 MR. SHEEHY: DOES ED'S FIX -- I MEAN ED'S FIX
6 SOUNDS REASONABLE. FRANCISCO, WHAT DO YOU THINK?

7 DR. PRIETO: I JUST WOULD LIKE TO STRONGLY
8 AGREE WITH WHAT YOU SAID, JEFF. THIS IS REALLY THE
9 ROUTINE AND I THINK IS AN EXPECTATION. THIS IS MERELY
10 A STATEMENT THAT IT IS OUR EXPECTATION FOR DOWNSTREAM
11 THERAPIES. WE'RE NOT GOING TO MARCH IN ON SOMEONE WHO
12 IS NOWHERE NEAR THE POINT OF HAVING A THERAPY. AND AT
13 EARLY STAGE GRANTS, I EXPECT THAT IF THERE IS ANY SUCH
14 PLAN IN THE GRANT PROPOSAL, IT'S GOING TO BE EXTREMELY
15 GENERAL. BUT WHEN WE GET FIVE OR TEN OR EIGHTEEN YEARS
16 FROM NOW AND WE HAVE A THERAPY, WE'RE GOING TO EXPECT
17 THAT.

18 AND ALL THIS STATES IS WE'RE GOING TO EXPECT
19 THAT IF YOU -- WE'RE GOING TO LOOK AT THAT. IF YOU
20 DON'T HAVE THAT, YOU KNOW, YOU SHOULD NOT EXPECT TO
21 TAKE CIRM MONEY OR IF YOU'VE MADE A COMMITMENT, BECAUSE
22 I THINK THIS WAS AN INNOVATIVE PROPOSAL THAT CAME OUT
23 OF OUR PREVIOUS DISCUSSIONS ON THIS SAME POINT, YOU'RE
24 GOING TO COME UP WITH THE PROPOSAL. IF YOU FAIL TO
25 MEET YOUR WORD, THAT'S GROUNDS FOR US TO MARCH IN. AND

1 THAT'S ALL THAT THIS SAYS. THE CURRENT LANGUAGE SAYS
2 IF YOU FAIL TO MEET YOUR WORD, WE CAN MARCH IN. DON'T
3 SAY WHAT YOU DON'T MEAN.

4 CHAIRMAN PENHOET: I DO THINK THE PRACTICAL
5 REALITY IS YOU WOULDN'T KNOW WHETHER THEY'RE MEETING IT
6 OR NOT UNTIL THEY COMMERCIALIZED BECAUSE THAT'S THE
7 TIME WHEN IT HAPPENS.

8 DR. PRIETO: OF COURSE.

9 CHAIRMAN PENHOET: SO WE COULD CHANGE THIS
10 LANGUAGE TO SAY BEFORE A PRODUCT IS COMMERCIALIZED THAT
11 RESULTS FROM SUCH A LICENSE THAT THE ACCESS PLAN WOULD
12 BE IN PLACE.

13 DR. PRIETO: IT DOES SAY FOR RESULTANT
14 THERAPIES.

15 CHAIRMAN PENHOET: YES.

16 DR. PRIETO: THE CURRENT LANGUAGE SAYS
17 RESULTANT THERAPIES. SO WE'RE NOT TALKING ABOUT
18 ANYTHING BEFORE THERAPIES.

19 MR. SHEEHY: DOES THAT CLARIFICATION HELP?

20 MR. GILENWATER: YES.

21 MR. SHEEHY: OKAY.

22 DR. FONTANA: I JUST WANT TO COMMENT. I WANT
23 TO BE THE VOICE FOR THOSE ORPHAN DISEASES. YOU KNOW,
24 YOU ARE ALL EXPECTING THESE GREAT THERAPIES THAT ARE
25 GOING TO MAKE LOTS OF DOLLARS FOR THE DRUG COMPANIES,

1 YOU KNOW, HIV IS A GREAT EXAMPLE, BUT, YOU KNOW, WHAT
2 ABOUT FOR MY ILLNESS THAT I REPRESENT, WHICH IS ALS,
3 WHERE IT'S VERY DIFFICULT TO GET ANY COMPANIES TO EVEN
4 FURTHER A PRODUCT, LET ALONE BECAUSE THE BASIC SCIENCE
5 ISN'T THERE. AND PART OF THE ROLE THAT CIRM IS PLAYING
6 IS PROVIDING FUNDING FOR THOSE RESEARCH PROJECTS THAT
7 WOULD NOT OTHERWISE BE FUNDED BY INDUSTRY. AND SO I
8 DON'T WANT TO LOSE SIGHT OF US LITTLE GUYS OVER HERE
9 THAT DON'T HAVE A HUGE MARKET CAP FOR DRUG DEVELOPMENT.
10 AND THE REASON WHY WE DON'T HAVE A THERAPY, NOT ONE, IS
11 BECAUSE THE BIOTECH INDUSTRY DOESN'T VIEW IT AS A LARGE
12 MARKET CAP. SO WE'RE ALSO THE VOICE FOR THOSE
13 UNDERDOGS, FOR THOSE DISEASES THAT DON'T RECEIVE A LOT
14 OF THE FUNDING.

15 MR. SHEEHY: I DON'T THINK IT'S FAIR TO PIT
16 DISEASE AGAINST DISEASE. I MEAN I HAVE -- I THINK
17 WE'RE ALL HERE. I USE THAT AS AN EXAMPLE AND I
18 REALLY -- I'M NOT COMFORTABLE WITH THAT, STARTING TO
19 PIT DISEASE AGAINST DISEASE KIND --

20 DR. FONTANA: I DON'T INTEND TO PIT DISEASES,
21 BUT JUST USE IT AS AN EXAMPLE WHERE THE PHARMA IS
22 INVOLVED WITH THOSE DISEASES WHERE THERE'S A LARGE
23 MARKET CAP. FACT OF LIFE.

24 DR. PRIETO: COULD I RESPOND TO THAT POINT?
25 I THINK THAT AS WE LOOKED AT PROPOSALS, WE WOULD EXPECT

1 THE PLAN FOR ACCESS OF AN ALS TREATMENT WOULD BE
2 DIFFERENT THAN THE PLAN FOR ACCESS OF AN HIV TREATMENT
3 OR A DIABETES TREATMENT WHERE THERE ARE MILLIONS OF
4 PEOPLE INVOLVED.

5 MR. SHEEHY: THAT'S WHERE WE DIDN'T --

6 DR. PRIETO: AND THAT'S WHY WE DID NOT -- I
7 THINK WE SPECIFICALLY MADE THE DECISION NOT TO DEFINE
8 THESE AND TO PUT THIS BACK IN THE COURT OF THE GRANTEE
9 AND LET THE GRANTEE COME UP WITH THE PLAN. AND IF YOU
10 COME UP WITH SOMETHING GOOD AND INNOVATIVE, WE'RE GOING
11 TO LOOK AT THAT FAVORABLY.

12 MR. SHEEHY: YEAH.

13 CHAIRMAN PENHOET: SO AT LEAST IN SACRAMENTO
14 I THINK THAT, IF I'M READING MY COLLEAGUES HERE
15 CORRECTLY, AND THE INDUSTRY REPRESENTATIVE, THAT WE
16 COULD LIVE WITH A COMPROMISE WHICH SAYS A PLAN WOULD BE
17 IN PLACE BEFORE A PRODUCT WAS COMMERCIALIZED.

18 DR. WRIGHT: I'M SORRY, ED. I LOST YOU AT
19 THE LAST. WOULD YOU REPEAT THAT REVISION?

20 CHAIRMAN PENHOET: THAT A PLAN WOULD BE IN
21 PLACE BEFORE A PRODUCT WAS COMMERCIALIZED.

22 DR. WRIGHT: GOTCHA.

23 CHAIRMAN PENHOET: SO IT POSTPONES THE PLAN
24 UNTIL THE TIME THAT THEY ARE ACTUALLY ABOUT TO SELL A
25 PRODUCT. YES. ONE MORE COMMENT FROM THE PUBLIC.

1 MR. JACKSON: JIMMY JACKSON REPRESENTING
2 BIOCOM. WE REPRESENT 500 BIOTECHNOLOGY COMPANIES IN
3 THE SAN DIEGO AND SOUTHERN CALIFORNIA AREA. I THINK
4 THAT DR. PENHOET'S COMPROMISE LANGUAGE IS VERY GOOD.
5 IT STRIKES -- I'M NOT AWARE OF ANY OF OUR COMPANIES
6 THAT HAVEN'T PRODUCED AN ACCESS PLAN WHEN THEY GO TO
7 COMMERCIALIZATION STAGE.

8 MR. SHEEHY: THAT'S MY POINT.

9 CHAIRMAN PENHOET: IF WE COULD --

10 MR. GILENWATER: TODD GILENWATER OF CHI.
11 WE'RE COMFORTABLE WITH THAT CLARIFICATION.

12 MR. SHEEHY: WE'RE NOT TRYING TO CREATE A
13 BURDEN.

14 MR. SIMPSON: I THINK THAT YOU DON'T NEED THE
15 COMPROMISE. I THINK IT'S IMPLICIT IN THE LANGUAGE
16 THAT'S THERE. AS IT'S BEEN SAID, YOU WOULDN'T BE ABLE
17 TO MARCH IN OR ANYTHING UNTIL THERE'S A POINT OF
18 COMMERCIALIZATION. THIS IS WHY -- THIS IS WHAT IT'S
19 GOING TO BE. BUT -- SO I GUESS -- I MEAN, AS A
20 MINIMALIST, IF YOU'VE GOT LANGUAGE THAT WORKS, I DON'T
21 KNOW WHY YOU FIDDLED AROUND WITH IT.

22 CHAIRMAN PENHOET: I THINK WE'RE JUST TRYING
23 TO MAKE IT ABUNDANTLY CLEAR.

24 DR. PRIETO: DO WE HAVE SOME PROPOSED
25 LANGUAGE?

1 CHAIRMAN PENHOET: I MADE A MOTION TO PROPOSE
2 THAT WE AMEND 5 TO SAY THAT THE REQUIREMENT FOR AN
3 ACCESS PLAN WOULD BE THAT THAT REQUIREMENT IS IN PLACE
4 BEFORE A PRODUCT IS COMMERCIALIZED.

5 DR. PRIETO: DO WE NEED LANGUAGE THAT WOULD
6 BE INSERTED --

7 DR. BRYANT: SECOND.

8 DR. PRIETO: -- INTO THE REGS THOUGH?

9 CHAIRMAN PENHOET: YES. SCOTT IS WORKING ON
10 THAT FOR US.

11 DR. PRIETO: IS THAT WHAT HE'S DOING NEXT TO
12 ME?

13 MR. SIMPSON: THERE IS OTHER LANGUAGE IN
14 THERE THAT MIGHT ALSO BE RELEVANT TO THE SAME SORT OF A
15 THING. AND THAT IS NOW YOU'VE GOT THE PROVISION OF
16 THE -- NOT TO EXCEED THE MEDICAID PRICE IS ANOTHER.
17 THAT'S IN THERE. IT'S IN THAT SENTENCE. I MEAN
18 WOULDN'T IT PERHAPS BE SERVING EVERYONE'S GOOD, MORE TO
19 THE POINT, IF IT SAID NOT TO EXCEED THE LOWEST
20 NEGOTIATED PRICE?

21 MR. SHEEHY: NO.

22 MR. SIMPSON: WHICH WOULD PERHAPS THEN LET IT
23 BE THE VETERANS ADMINISTRATION WHICH OFTEN NEGOTIATES.

24 CHAIRMAN PENHOET: WE TRIED THAT FIRST, AND
25 WE GOT FEEDBACK FROM THE LEGISLATURE THAT THEY DIDN'T

1 LIKE THAT LANGUAGE.

2 MR. SIMPSON: THE LANGUAGE THEY DIDN'T LIKE
3 WAS BEST COMMERCIAL PRICE, WHICH IS DIFFERENT. WHAT
4 WE'RE TALKING ABOUT IS OPENING IT UP TO THE ABILITY,
5 FOR INSTANCE, TO MAKE IT -- YOU CAN MAKE IT THE BEST
6 FEDERALLY NEGOTIATED PRICE.

7 MR. SHEEHY: I THOUGHT THAT'S THE LANGUAGE WE
8 HAD.

9 MR. SIMPSON: BEST MEDICAID AND IN A NUMBER
10 OF PLACES SOME OTHER AGENCIES GET BETTER DEALS.

11 DR. PRIETO: FRANCISCO PRIETO. IF WE'RE
12 MOVING ON TO THAT POINT, I DO THINK THAT THAT'S A VALID
13 CONCERN, THAT THE LOWEST MEDICAID PRICE IS USUALLY, BUT
14 MAY NOT NECESSARILY BE THE LOWEST PUBLICLY CONTRACTED
15 PRICE OR FEDERALLY CONTRACTED PRICE. THE EXAMPLE HE
16 GAVE OF THE VA SYSTEM IS A LARGE SYSTEM THAT PURCHASES
17 VERY MANY THERAPEUTICS AND SOMETIMES DOES HAVE THE
18 LOWEST CONTRACTED PRICE. I THINK THE PRINCIPLE HERE IS
19 THAT IF CALIFORNIA PAYS FOR THE DEVELOPMENT OF AN
20 INVENTION, THAT WE SHOULD NOT THEN HAVE TO GO BACK TO
21 THE PEOPLE OF CALIFORNIA AND SAY, YES, YOU PAID TO
22 DEVELOP THIS, BUT WE'RE GOING TO LET THE DEVELOPER
23 CHARGE YOU A HIGHER PRICE THAN THEY'RE CHARGING ANOTHER
24 PUBLIC AGENCY THAT DID NOT PARTICIPATE IN THE
25 INVENTION.

1 I THINK ALL WE'RE SAYING HERE OR ALL I WOULD
2 LIKE US TO SAY IS THAT CALIFORNIA, HAVING PARTICIPATED
3 IN THE DEVELOPMENT OF THIS, GETS THE BEST CONTRACTED
4 PRICE. WE SAY NOTHING ABOUT ANYONE ELSE'S PRICE, ABOUT
5 THE COMMERCIAL PRICE, BUT CALIFORNIA PUBLIC AGENCIES
6 GET THE BEST CONTRACTED PRICE.

7 DR. WRIGHT: I AGREE.

8 CHAIRMAN PENHOET: THE BEST FEDERALLY --

9 DR. PRIETO: THE BEST FEDERALLY
10 CONTRACTED -- AGAIN, SCOTT, CAN BE HARD AT WORK HERE
11 GIVING US LANGUAGE.

12 CHAIRMAN PENHOET: I THINK WE HAVE A MOTION
13 TO AMEND THIS PROVISION FROM DR. PRIETO, WHICH SAYS --
14 YOU'RE PROPOSING THAT WE ADOPT THE PROVISION AS WRITTEN
15 WITH THE INCLUSION, WELL WITH TWO MODIFICATIONS NOW,
16 ONE MODIFICATION MADE SUGGESTED BY ME, WHICH IS BEFORE
17 COMMERCIALIZATION, AND THE SECOND MODIFICATION
18 SUGGESTED BY YOU, THE LOWEST AVAILABLE FEDERALLY
19 NEGOTIATED PRICE.

20 DR. PRIETO: YES.

21 CHAIRMAN PENHOET: OKAY. SO THOSE ARE THE
22 TWO MODIFICATIONS THAT HAVE BEEN PROPOSED.

23 DR. PRIETO: YES. I'LL MAKE SUCH A MOTION.
24 SO MOVED.

25 CHAIRMAN PENHOET: ALL RIGHT.

1 DR. FONTANA: SECOND.

2 CHAIRMAN PENHOET: SO WE HAVE TWO COMMENTS.
3 EXCUSE ME JUST A MOMENT, PLEASE. ANY COMMENTS FROM
4 IRVINE ON THAT?

5 DR. BRYANT: NO. I THINK THAT WAS A GOOD
6 SUGGESTION.

7 CHAIRMAN PENHOET: STANFORD?

8 MR. GOLDBERG: NO COMMENT.

9 CHAIRMAN PENHOET: CHICO?

10 DR. WRIGHT: NOPE.

11 CHAIRMAN PENHOET: OKAY. WE THEN HAVE A
12 PERSON IN SACRAMENTO WISHING TO MAKE A COMMENT.

13 MR. VALENCIA: THANK YOU, MR. CHAIRMAN. MY
14 NAME IS JOHN VALENCIA WITH THE SACRAMENTO LAW FIRM OF
15 WILKE, FLEURY, HOFFELT, GOULD & BIRNEY. I REPRESENT A
16 VARIETY OF PHARMACEUTICAL MANUFACTURERS THAT ENGAGE
17 REGULARLY IN CONTRACTS WITH THE STATE MEDICAL PROGRAM.

18 THE AREA THAT YOU'RE TROLLING AROUND NOW IS
19 IN THE AREA KNOWN AS BEST PRICE. I SUSPECT THE REASON
20 THAT COUNSEL MAY HAVE SUGGESTED THAT YOU PEG YOUR
21 REGULATIONS TO FEDERAL MEDICAID PRICE IS THAT ANY PRICE
22 BEYOND THAT, LOWER THAN THAT THAT IS MADE AVAILABLE FOR
23 COMPULSION IN THIS CASE BY A MANUFACTURER TO ANY
24 CUSTOMER BECOMES A NATIONAL BEST PRICE. AND THE
25 CONSEQUENCE, THEN, IS THAT YOU WILL IMPEDE THE

1 AVAILABILITY OF THE PRODUCTS IF YOU COMPEL THAT PRICE.

2 WHAT THAT PRODUCER OF THE PRODUCT WILL NOT
3 HAVE IS ANY KIND OF AN EXEMPT STATUS SUCH AS A STATE
4 PHARMACEUTICAL ASSISTANCE PROGRAM, MEDICAID ITSELF.
5 YOU MAY NOT ABLE BY REGULATIONS TO PEG THE RESULTANT
6 CONSEQUENCES THAT THAT MANUFACTURER WILL THEN OWE THAT
7 PRICE TO 50 STATES WORTH OF MEDICAID PROGRAMS, WHETHER
8 OR NOT THOSE STATE PROGRAMS HAVE NEGOTIATED THAT PRICE
9 AND MYRIAD OTHER GOVERNMENTAL CUSTOMERS.

10 THIS PROGRAM, CIRM AND THE RESULTANT
11 THERAPIES, IS MERELY VIEWED AS ANOTHER CLASS OF TRADE.
12 AND THE MANUFACTURER OF THE EVENTUAL PRODUCT PROBABLY
13 WON'T BE IN A POSITION FINANCIALLY TO COMPLY WITH THIS
14 COMPULSION. I WOULD SUBMIT TO YOU THAT IT'S WORTH
15 TABLING THIS PARTICULAR ISSUE TEMPORARILY UNTIL YOU
16 HAVE A CHANCE TO STUDY THE IMPLICATIONS OF TRYING TO
17 DRIVE PRICE TO A DIFFERENT PEGGED LEVEL LEST YOU MAKE
18 IT A PRICE THAT NO ONE CAN AFFORD. IT'S PRINCIPALLY
19 THE MANUFACTURER, SUPPLIER, DISTRIBUTOR CHAIN OF THE
20 PRODUCT.

21 CHAIRMAN PENHOET: WELL, PERHAPS YOU COULD
22 HELP. I BELIEVE WE DID NOT INTEND TO TRIP A CASCADE OF
23 ESSENTIALLY MOST FAVORED NATION PRICING. THAT WAS NOT
24 OUR INTENTION HERE. SO --

25 MR. VALENCIA: BASED ON WHAT I HEARD,

1 HOWEVER, THAT IS WHAT WILL RESULT.

2 CHAIRMAN PENHOET: THAT'S WHAT I'M TRYING TO
3 ASK YOU. SO IF THE PROPOSAL WAS THAT IT WAS PAID TO
4 THE --

5 MR. KLEIN: GO BACK TO THE MEDICARE PRICE.

6 CHAIRMAN PENHOET: -- WOULD THAT TRIP IN YOUR
7 VIEW?

8 MR. VALENCIA: NO. PEGGED TO FEDERAL
9 MEDICAID PRICE, OVERARCHING FEDERAL LAW OBRA 90 AND
10 OBRA 93 AT TITLE 42, UNITED STATES CODE, SECTION 1396,
11 LITTLE R-8[A] GUARANTEES TO THE FEDERAL GOVERNMENT ANY
12 PRICE THAT EXCEEDS THE PRICE THAT THE FEDERAL
13 GOVERNMENT SETS FOR MEDICAID. SO THAT IF IN THIS
14 ACTION YOU COMPEL A MANUFACTURER TO GO LOWER TO THAT --

15 CHAIRMAN PENHOET: LOWER THAN MEDICAID.

16 MR. VALENCIA: LOWER THAN MEDICAID, IF YOU
17 PEG IT TO THE PUBLIC HEALTH SYSTEM, IF YOU PEG IT TO
18 THE VA, IF YOU PEG IT TO THE DEPARTMENT OF DEFENSE, ANY
19 OTHER FEDERAL STANDARD, THE FEDERAL GOVERNMENT MEDICAID
20 PROGRAM FOR 50 STATES WORTH OF MEDICAID PROGRAMS NOW
21 CAN COMPEL THAT PARTICULAR PRICE FOR NEW PRODUCT X BE
22 ACCORDED TO IT.

23 THE FIRST THING THAT A PHARMACEUTICAL
24 MANUFACTURER DOES WHEN IT GETS A PRODUCT APPROVED BY
25 THE FDA, THEIR FIRST STOP IS CMS, THE CENTERS FOR

1 MEDICARE AND MEDICAID SERVICES. THEY SIGN A CONTRACT
2 THAT CONFORMS WITH THIS ASPECT OF FEDERAL LAW THAT
3 BINDS THEM SHOULD THEY PROVIDE A PRICE TO ANY OTHER
4 CUSTOMER AT A PRICE LOWER THAN WHAT THEY'VE GUARANTEED
5 TO THE FEDERAL MEDICAID PROGRAM UNLESS UNDER FEDERAL
6 LAW, SCOTT, THAT OTHER CUSTOMER ENJOYS A SPECIFIC
7 EXEMPTION AND THEY ARE SPECIFIED IN THAT STATUTE.
8 EXAMPLES OF THOSE EXEMPTIONS ARE STATE PHARMACEUTICAL
9 ASSISTANCE PROGRAMS, AIDS DRUG ASSISTANCE PROGRAM IN
10 CALIFORNIA, FOR EXAMPLE. THAT PROGRAM IS ELIGIBLE TO
11 NEGOTIATE A, FOR LACK OF A BETTER DESCRIPTION, A BETTER
12 THAN BEST PRICE OR A BETTER THAN MEDICAID PRICE LEVEL.
13 AND IT DOES NOT TRIP OBRA 90 AND OBRA 93.

14 DR. PRIETO: I HAVE A QUESTION.

15 CHAIRMAN PENHOET: I DON'T THINK THAT WAS OUR
16 INTENTION.

17 MR. VALENCIA: WHERE I HEARD THE DIRECTION
18 GOING AND THE LANGUAGE THAT WAS SUGGESTED WOULD TAKE
19 YOU EXACTLY THERE.

20 DR. PRIETO: BUT DOES FEDERAL -- WOULD THAT
21 ALLOW THE VA SYSTEM, FOR EXAMPLE, OR OTHER FEDERAL
22 AGENCIES WHO ARE ABLE TO NEGOTIATE A BETTER THAN
23 MEDICAID PRICE CURRENTLY?

24 MR. VALENCIA: THEY ARE FOR THEIR PARTICULAR
25 PATIENT BASE.

1 DR. PRIETO: THAT DOES NOT TRIGGER THE
2 MEDICAID REQUIREMENT?

3 MR. VALENCIA: NO. BECAUSE THEY ARE
4 CONTEMPLATE -- THAT ASPECT OF FEDERAL LAW SAYS THAT
5 AGENCY AND ITS CONSTITUENCY MAY ENJOY A DIFFERENT LEVEL
6 OF PRICE. WHAT YOU'RE TALKING ABOUT IS PEGGING UNKNOWN
7 MANUFACTURER X AND THE RESULTANT THERAPIES TO THAT
8 OTHER LOW PRICE. UNDER FEDERAL LAW AND BY CONTRACT, IT
9 WILL OWE THAT VA PRICE OR DOD PRICE OR PHS PRICE BACK
10 TO MEDICAID.

11 DR. PRIETO: WHAT'S TO STOP A MANUFACTURER,
12 MAYBE A HYPOTHETICAL, BUT FROM THEN CALCULATING INTO
13 THEIR PRICING NEGOTIATIONS WITH THE FEDERAL MEDICAID
14 SYSTEM THE KNOWLEDGE THAT, OKAY, THIS IS GOING TO BE
15 THE FLOOR. THIS IS THE NEW FLOOR BECAUSE WE WILL NOT
16 BE ABLE TO GO -- YOU KNOW, THIS WILL BE THE VA PRICE,
17 THIS WILL BE THE MEDICAID PRICE, THIS WILL BE THE FLOOR
18 PRICE FOR NONCOMMERCIAL PUBLIC ENTITIES.

19 MR. VALENCIA: LET ME CORRECT ONE BASIC
20 MISUNDERSTANDING. THERE IS NO NEGOTIATION WITH THE
21 FEDERAL GOVERNMENT. THE PRICE THAT A MANUFACTURER OWES
22 TO THE FEDERAL GOVERNMENT IS SET IN STATUTE, THE ONE I
23 JUST CITED TO YOU AND COUNSEL, AND IF THAT PARTICULAR
24 PRICE IS EXCEEDED BY PRICE INCREASES BEYOND CONSUMER
25 PRICE INDEX AND A PARTICULAR INDEX WITHIN THAT INDEX,

1 THAT IS A PENALTY THAT'S OWED TO THE FEDERAL
2 GOVERNMENT. IF YOU DRIVE A PRICE EVEN LOWER THAN THAT,
3 THAT WILL BE OWED TO THE FEDERAL GOVERNMENT, BUT THERE
4 IS NO NEGOTIATION. IT'S JUST A STATUTORILY
5 PRESCRIBED --

6 DR. PRIETO: WELL, HOW CAN THE PRICE SET FOR
7 A NEW PRODUCT THAT DOES NOT YET EXIST BE SET IN
8 STATUTE? WHEN YOU DEVELOP A NEW PRODUCT AND COME
9 FORWARD WITH A PRICE FOR THAT PRODUCT, HOW IS THAT
10 PRICE DETERMINED AT MEDICAID?

11 MR. VALENCIA: OKAY. THAT'S A VERY GOOD
12 QUESTION.

13 MR. KLEIN: IT'S A GIVEN RETURN.

14 MR. VALENCIA: WHEN A PRICE IS SET BY A
15 MANUFACTURER OF A PHARMACEUTICAL PRODUCT, IT'S AKIN TO
16 THE SUGGESTED RETAIL PRICE FOR A VEHICLE. MSRP IS
17 EQUIVALENT TO WHAT'S CALLED AVERAGE WHOLESAL PRICE.
18 THE JARGON IS AIN'T WHAT NOBODY PAYS. AVERAGE
19 WHOLESAL PRICE IS A RECOMMENDED EVENTUAL RETAIL PRICE.
20 THE FEDERAL STATUTE THAT I'VE CITED TO YOU SETS A LEVEL
21 BELOW THAT REGARDLESS OF THE EXISTENCE OF THE PRODUCT.
22 WHENEVER THE PRODUCT COMES INTO EXISTENCE, REGARDLESS
23 OF ITS RECOMMENDED PRICE, IT WILL BE STATUTORILY
24 PRESCRIBED TO BE AT THE SECOND LEVEL PRICE.

25 DR. PRIETO: WHICH SECOND LEVEL?

1 MR. VALENCIA: THE MEDICAID BEST PRICE.

2 DR. PRIETO: NO. BUT HOW IS THAT LEVEL
3 DETERMINED? HOW IS THAT NUMBER ARRIVED AT?

4 MR. VALENCIA: IT'S STATUTORILY SET AT 15.1
5 PERCENT OF YET ANOTHER TERM, AVERAGE MANUFACTURER'S
6 PRICE. THERE IS NO NEGOTIATION WITH THE FEDERAL
7 GOVERNMENT. THERE IS AN EXTRA PROVISION IN THAT
8 STATUTE THAT SAYS THAT 15.1 PERCENT IS WHATEVER
9 MANUFACTURER OF EVERY PRODUCT REIMBURSED BY MEDICAID
10 MUST PAY IN REBATE TO THE FEDERAL GOVERNMENT. THAT
11 LEVEL --

12 DR. PRIETO: SO IT'S NOT --

13 MR. VALENCIA: LET ME FINISH, IF I MAY. THAT
14 LEVEL IS THEN AUGMENTED IF THE MANUFACTURER RECOMMENDED
15 PRICE INCREASES EXCEED A CERTAIN INDEX WITHIN THE CPI,
16 THE BROADER CPI INDEX. THAT ALSO AS A PENALTY IS OWED
17 TO THE FEDERAL GOVERNMENT. IF BY THIS REGULATION YOU
18 SAY TO THAT MANUFACTURER THERE'S A THIRD AND
19 ARTIFICIALLY SET LEVEL THAT YOU HAVE TO MAKE YOUR
20 PRODUCTS AVAILABLE TO THE PURCHASING PUBLIC BECAUSE IT
21 FLOWS FROM THIS SOURCE OF FUNDING, THAT ALSO WILL BE
22 OWED TO THE FEDERAL GOVERNMENT WITHOUT NEGOTIATION AND
23 WITHOUT ARGUMENT.

24 DR. PRIETO: 15 PERCENT DISCOUNT FROM THE --

25 MR. VALENCIA: SUGGESTED PRICE.

1 DR. PRIETO: FROM THE SUGGESTED PRICE.

2 MR. VALENCIA: PLUS THE CPI PENALTY IF IT
3 EXISTS. THAT'S WHY I SUGGESTED --

4 CHAIRMAN PENHOET: WELL, I THINK AS A MATTER
5 OF LAW, I DO THINK WE DISCUSSED QUITE A LOT NOT PUTTING
6 IN PLACE A --

7 MR. GOLDBERG: WE CAN'T HEAR YOU, ED.

8 CHAIRMAN PENHOET: -- TRIP WIRE WHICH WOULD,
9 IN FACT, AFFECT THE OTHER 49 STATES. SO I THINK ONE
10 SOLUTION TO THIS DILEMMA MAY BE TO ADOPT THIS PROPOSAL
11 AS WRITTEN AND GO BACK AND STUDY THE LAW BETWEEN THAT.
12 THE UNINTENDED CONSEQUENCE OF WHAT WE WOULD DO BY
13 CHANGING IT TO ANOTHER PRICING CONSIDERATION COULD BE
14 THAT WE WOULD TRIP A MOST FAVORED NATION CLAUSE AND
15 CAUSE ENORMOUS IMPACT BEYOND THE CALIFORNIA --

16 DR. PRIETO: CAN I CHANGE MY MOTION, THEN, TO
17 REMOVE THAT?

18 MS. KING: BEFORE YOU DO THAT, DR. PRIETO, I
19 JUST WANT TO MAKE SURE. IS IRVINE ON THE LINE?
20 IRVINE.

21 DR. BRYANT: YES, I'M HERE.

22 MS. KING: IS STANFORD ON THE LINE?

23 MR. GOLDBERG: YES.

24 MS. KING: CHICO?

25 DR. WRIGHT: YES.

1 MS. KING: OKAY.

2 MR. GOLDBERG: I SUPPORT THAT RECOMMENDATION,
3 ED.

4 CHAIRMAN PENHOET: OKAY. FRANCISCO.

5 DR. PRIETO: I'LL ACCEPT THAT.

6 CHAIRMAN PENHOET: OKAY. ALL RIGHT. SO I
7 THINK WHAT'S BEFORE US NOW IS TO ACCEPT THE PLAN FOR
8 ACCESS AND THE PRICING PROVISIONS AS CURRENTLY DRAFTED,
9 WHICH IS THE MEDICAID PRICE. AND SO IF WE COULD --
10 YES. WENDY STREITZ, UNIVERSITY OF CALIFORNIA.

11 MS. STREITZ: YES. JUST FOR POINT OF
12 CLARITY, I THOUGHT WE HAD DECIDED THAT THE ACCESS PLAN
13 SHOULD BE AVAILABLE AT THE TIME OF COMMERCIALIZATION.
14 AND DESPITE WHAT JOHN SAID, I DON'T THINK THAT'S WHAT
15 IT SAYS RIGHT NOW. WHAT THE LANGUAGE SAYS NOW IS THAT
16 THE PLAN HAS TO BE IN PLACE AT THE TIME OF LICENSE.

17 CHAIRMAN PENHOET: WE UNDERSTAND THAT. AND I
18 THINK THAT'S A MODIFICATION WE -- THE MOTION IS TO
19 MODIFY THE ACCESS PLAN SO THAT IT'S IN PLACE BEFORE A
20 PRODUCT IS COMMERCIALIZED, AND THEN WITH RESPECT --

21 MR. TOCHER: AND THAT'S IT. NO FURTHER
22 CHANGES.

23 CHAIRMAN PENHOET: THAT'S RIGHT. OKAY. AT
24 THE MOMENT PEGGED TO MEDICAID WITH A PROVISIO WE'LL GO
25 BACK AND STUDY THE LAW TO MAKE SURE THAT THE

1 INTERPRETATION WE'VE JUST HEARD IS CORRECT. I'M NOT A
2 LAWYER, AND SCOTT'S PROBABLY NOT WELL VERSED IN 101 B,
3 SECTION 4372 LITTLE A, LITTLE I 2. SO SOMEBODY HAS TO
4 GO READ ALL THIS. BUT FOR THE MOMENT AT LEAST, WE'LL
5 LEAVE THAT PART AS IT IS. SO THAT'S THE MOTION ON THE
6 TABLE.

7 IRVINE?

8 DR. BRYANT: COULD YOU REPEAT IT, PLEASE? WE
9 MISSED PART OF WHAT YOU SAID.

10 CHAIRMAN PENHOET: CATEGORY B, ITEM 5, PLAN
11 FOR ACCESS AND THE MEDICAID PRICE, THE PLAN FOR ACCESS
12 NOW HAS TO BE IN PLACE BEFORE A PRODUCT IS
13 COMMERCIALIZED, AND WE LEAVE THE MEDICAID PEG PRICING
14 AS IT IS.

15 MR. SHEEHY: WE NEED TO HAVE A SECOND FOR THE
16 PROCESS.

17 DR. BRYANT: I APPROVE.

18 CHAIRMAN PENHOET: WE NEED A SECOND. JEFF
19 SECONDED THE MOTION. OKAY. IRVINE.

20 DR. BRYANT: I APPROVE.

21 CHAIRMAN PENHOET: STANFORD?

22 MR. GOLDBERG: YES.

23 CHAIRMAN PENHOET: CHICO?

24 DR. WRIGHT: YES.

25 CHAIRMAN PENHOET: HERE IN THE ROOM?

1 MS. FONTANA? PRIETO YES.

2 MR. SHEEHY: YES.

3 CHAIRMAN PENHOET: JEFF AND I MADE THE

4 MOTION. SECONDED. OKAY. SO NO. 5 IS NOW COMPLETE.

5 I THINK WE CAN RETURN TO MARCH-IN RIGHTS NOW.

6 WITH THE CLARIFICATION THAT WE HAVE JUST ARTICULATED

7 WHICH LEAVES ACCESS PLAN IN PLACE, BUT CHANGES THE

8 TIMING OF ITS CREATION. ARE WE READY TO APPROVE THE

9 MARCH-IN RIGHTS AS WRITTEN? DO WE HAVE A MOTION?

10 MR. GOLDBERG: YES.

11 CHAIRMAN PENHOET: MICHAEL GOLDBERG HAS

12 MOVED.

13 DR. WRIGHT: SECOND. JANET.

14 CHAIRMAN PENHOET: JANET WRIGHT. IRVINE?

15 DR. BRYANT: YES.

16 CHAIRMAN PENHOET: STANFORD?

17 MR. GOLDBERG: YES.

18 CHAIRMAN PENHOET: CHICO?

19 DR. WRIGHT: YES.

20 CHAIRMAN PENHOET: HERE IN SACRAMENTO?

21 SHEEHY?

22 MR. SHEEHY: YES.

23 CHAIRMAN PENHOET: PENHOET. YES.

24 DR. FONTANA: YES.

25 CHAIRMAN PENHOET: FONTANA YES.

1 DR. PRIETO: YES.

2 CHAIRMAN PENHOET: PRIETO YES. GOOD. THANK
3 YOU.

4 NOW, CATEGORY B, ISSUE 4. SINCE WE HAVE
5 DROPPED THE RESEARCH USE EXEMPTION, DOES 4 HAVE ANY
6 MEANING ANYMORE, MR. TOCHER? CATEGORY B, PAGE 6, ITEM
7 4, DEFINE THE CRITERIA TO REMOVE OR TERMINATE A LICENSE
8 DUE TO FAILURE TO KEEP A LICENSED INVENTION AVAILABLE
9 TO THE PUBLIC. OH, NO. THAT STILL HAS FORCE, DOES IT
10 NOT? YES, IT DOES. THAT'S PART OF THE SUSPENDERS.
11 THAT'S EXACTLY RIGHT.

12 DR. MAXON: STRIKE A PHRASE.

13 CHAIRMAN PENHOET: WHICH IS?

14 MR. TOCHER: ON LINE 10 ON PAGE 13 OF THE
15 REGULATIONS, LINE 10, PAGE 13, IN THE MIDDLE OF THAT
16 SENTENCE, SUBDIVISION F, THERE'S THE FAILURE TO KEEP
17 THE LICENSED INVENTION REASONABLY ACCESSIBLE TO THE
18 PUBLIC FOR RESEARCH PURPOSES. SINCE THAT WAS REDUNDANT
19 WITH SORT OF THE RESEARCH USE EXEMPTION, IT WAS THOUGHT
20 TO BE UNNECESSARY. AND, OF COURSE, WITH THE
21 ELIMINATION OF THE RUE, FOR CONSISTENCY SAKE, THAT
22 SENTENCE SHOULD -- THAT CLAUSE SHOULD BE REMOVED.

23 CHAIRMAN PENHOET: EXCEPT IT WAS PART OF THE
24 BELT AND SUSPENDERS. REASONABLY ACCESSIBLE FOR
25 RESEARCH PURPOSES. OKAY. AND I BELIEVE WE CAN LEAVE

1 IT IN.

2 MR. TOCHER: ALL RIGHT.

3 CHAIRMAN PENHOET: ALL RIGHT. SO DO WE HAVE

4 A MOTION TO APPROVE CATEGORY B, NO. 4 AS WRITTEN?

5 DR. FONTANA: I MOTION TO APPROVE.

6 CHAIRMAN PENHOET: MOVED BY JEANNIE FONTANA.

7 DR. PRIETO: SECOND.

8 CHAIRMAN PENHOET: SECOND BY DR. PRIETO. ANY

9 DISCUSSION? IRVINE?

10 DR. BRYANT: YES.

11 CHAIRMAN PENHOET: STANFORD?

12 MR. GOLDBERG: YES.

13 CHAIRMAN PENHOET: CHICO?

14 DR. WRIGHT: YES.

15 CHAIRMAN PENHOET: IN SACRAMENTO?

16 DR. FONTANA: YES.

17 MR. SHEEHY: YES.

18 DR. PRIETO: YES.

19 CHAIRMAN PENHOET: YES. YES, WE'RE ALL IN

20 AGREEMENT. OKAY.

21 OPEN ACCESS. MARY, WOULD YOU LEAD THIS

22 DISCUSSION, PLEASE. YOU'RE WORLD AUTHORITY ON THIS

23 ISSUE NOW.

24 DR. MAXON: WOW, I'VE JUST BEEN PROMOTED.

25 CHAIRMAN PENHOET: DEMOTED PROBABLY.

1 DR. MAXON: OKAY. WE HAVE -- WE DON'T HAVE A
2 REGULATION IN OUR -- THAT STEMS FROM OUR POLICY
3 REGARDING OPEN ACCESS. WHAT WE HAVE IS AN
4 ENCOURAGEMENT FOR GRANTEES TO PUBLISH IN OPEN-ACCESS
5 JOURNALS. SO THIS WOULD BE WHAT WAS FORMERLY MENTIONED
6 AS SECTION III OF OUR POLICY, ASPIRATIONAL OR
7 RECOMMENDATIONS THAT WE'VE MADE TO GRANTEES. SO NO
8 REGULATION EXISTS WITH RESPECT TO ASKING GRANTEES OR
9 MANDATING THAT GRANTEES PUT THEIR PUBLICATIONS AND
10 THEIR MANUSCRIPTS ANYWHERE.

11 THAT SAID, WE ALSO HAVE AN INCENTIVE TO ABIDE
12 BY OUR RECOMMENDATION IN THAT WE HAVE OFFERED A
13 SUPPLEMENT TO PAY FOR ANY COSTS ASSOCIATED WITH
14 PUBLICATION IN OPEN-ACCESS JOURNALS. SO NOT ONLY DO WE
15 RECOMMEND IT, WE ALSO PROVIDE FUNDS AFTER THE FACT TO
16 SUPPLEMENT THE COST OF ACTUALLY TAKING OUR
17 RECOMMENDATION.

18 SO TODAY WE HAVE NO MANDATE FOR ANY OPEN
19 ACCESS OF A SCIENTIFIC MANUSCRIPT. THE NEW PROPOSAL
20 THAT WE HAVE, YOU CAN SEE THE SCREEN HERE, INDICATES
21 THAT THERE'S A REQUEST FOR A MANDATE OF OPEN-ACCESS
22 ARCHIVE DEPOSITION FOR SCIENTIFIC MANUSCRIPTS. THIS
23 COMES FROM THE UC ACADEMIC COUNCIL, IF I'M NOT
24 MISTAKEN. AND IT ASKS -- SINCE I'M NOT EXACTLY A WORLD
25 AUTHORITY ON THIS, IT ASKS THAT, IF I UNDERSTAND IT

1 CORRECTLY, IT ASKS THAT MANUSCRIPTS BE DEPOSITED IN
2 NONCOMMERCIAL AND PUBLICLY ACCESSIBLE DATABASE, AND
3 THAT IN ORDER TO DO THAT, THE GRANTEES WOULD BE
4 REQUIRED TO MAKE SURE THAT THEY KEEP COPYRIGHT OF THEIR
5 MANUSCRIPTS.

6 SO TODAY WE DON'T HAVE ANYTHING THAT ASKS OUR
7 GRANTEES, WHEN THEY PUBLISH THEIR MANUSCRIPTS OR
8 ATTEMPT TO PUBLISH THEIR MANUSCRIPTS, TO REQUEST A
9 COPYRIGHT PERMISSION. AND THE PROPOSAL TODAY IS THAT
10 WE CONSIDER THIS.

11 SO, SCOTT, COULD YOU GIVE US A HANDLE ON WHAT
12 WE DO FOR A RECOMMENDATION FOR A POLICY -- A REGULATION
13 THAT DOESN'T YET EXIST?

14 MR. TOCHER: IN LIGHT OF THE FACT THAT, IN MY
15 OPINION, IT'S BEYOND THE SCOPE OF OUR INITIAL NOTICE
16 THAT WAS PUBLISHED WITH OAL. SO A PROVISION LIKE THIS,
17 IF PART OF THE EXISTING REGULATORY PROCESS FOR THE REGS
18 THAT WE HAVE BEFORE US NOW, WOULD PROBABLY, TO BE SAFE,
19 OPEN US UP TO A 45-DAY COMMENT PERIOD AS OPPOSED TO THE
20 SMALLER 15.

21 SO IT WOULD BE MY RECOMMENDATION THAT YOU
22 HAVE TWO CHOICES. YOU CAN MAKE IT PART OF THE EXISTING
23 REGULATORY PROCESS, WHICH WOULD SUBJECT EVERYTHING TO
24 ONGOING 45-DAY PUBLIC COMMENT PERIOD, A NEW ONE; OR IF
25 THERE'S A DESIRE FOR THIS POLICY, AT LEAST TO MOVE

1 FORWARD WITH IT, IT COULD BECOME ITS OWN STANDALONE
2 REGULATION, THUS IT'S OWN REGULATION PROJECT, AND WE
3 COULD INITIATE A NEW OAL PROCESS FOR THIS ONE AREA OR
4 SUGGESTION BY ITSELF.

5 SO MOVING FORWARD, WE WOULD MAKE A
6 RECOMMENDATION TO THE ICOC AS TO WHETHER OR NOT TO
7 PURSUE IT; AND IF SO, PRESUMABLY TO PURSUE IT ON ITS
8 OWN TRACK.

9 CHAIRMAN PENHOET: THIS IS NOT WITHOUT
10 CONTROVERSY IN THE ACADEMIC COMMUNITY. THE COUNCIL OF
11 THE UC HAS PUT FORWARD THIS, BUT MANY UC FACULTY DON'T
12 AGREE WITH THIS POSITION. JUST FOR CONTEXT, THE WORLD
13 GENERALLY OF PUBLICATION IS MOVING MORE AND MORE
14 TOWARDS OPEN ACCESS DRIVEN BY THINGS LIKE THE PUBLIC
15 LIBRARY OF SCIENCE AND OTHER ONLINE JOURNALS THAT HAVE
16 BEEN FORMED. I THINK WE HAVE PRETTY GOOD EXHORTATION
17 IN OUR CURRENT POLICY TO ENCOURAGE PEOPLE FOR OPEN
18 ACCESS. WE DO REQUIRE THEM TO WRITE A 500-WORD SUMMARY
19 OF THE PAPER TO BE DEPOSITED IN THE CIRM AND AVAILABLE
20 AT THE CIRM WEBSITE WHICH IS WRITTEN IN LAY LANGUAGE SO
21 THE PUBLIC CAN UNDERSTAND THE THRUST OF THE SCIENCE
22 THAT'S GOING FORWARD.

23 SO FOR ME TO SOME DEGREE THIS IS ANOTHER AREA
24 WHERE THE WORLD IS MOVING STRONGLY IN THIS DIRECTION
25 NOW ANYWAY, AND IT'S ONE OF THOSE PROBLEMS WE DON'T

1 HAVE TO FIX OURSELVES. OTHER PEOPLE, LOTS OF OTHER
2 PEOPLE ARE WORKING ON OPEN-ACCESS JOURNALS. AND I
3 THINK TO UNNECESSARILY DELAY OUR PROCESS BY AN EXTRA 30
4 DAYS FOR A PROBLEM WHICH IS BEING ADDRESSED IN MANY
5 OTHER QUARTERS AND, FRANKLY, WILL INFLUENCE A VERY
6 SMALL FRACTION OF THE WORLD'S SCIENTIFIC LITERATURE,
7 HAVING SAID ALL THIS, I HAVE TO GIVE YOU A DISCLAIMER
8 AS PRESIDENT OF THE MOORE FOUNDATION, WE ARE THE
9 PRIMARY FUNDER OF THE PUBLIC LIBRARY OF SCIENCE. SO
10 I'M NOT SURE I SHOULD EVEN VOTE ON THIS ISSUE, BUT I
11 HAVE A STRONG PERSONAL VIEW ABOUT SHARING SCIENTIFIC
12 INFORMATION, BUT I DON'T THINK THIS IS SOMETHING THAT
13 WE HAVE TO TACKLE IN A WAY THAT GOES BEYOND WHAT WE'VE
14 ALREADY DONE.

15 MR. GOLDBERG: ED, INDEPENDENT OF WHETHER YOU
16 ABSTAIN OR NOT, WHAT WOULD THE -- WOULD YOU PROPOSE A
17 MOTION FOR US?

18 CHAIRMAN PENHOET: THE MOTION, THAT WE DO NOT
19 EXPAND THE SCOPE OF OUR REGULATIONS TO INCLUDE AN
20 OPEN-ACCESS REQUIREMENT. THAT'S THE MOTION, BUT WE'LL
21 HAVE PLENTY OF COMMENT. JEFF SHEEHY.

22 MR. SHEEHY: I ACTUALLY PERSONALLY BELIEVE
23 THAT THIS IS THE PLACE WHERE WE SHOULD MAKE NEW GROUND,
24 AND I WOULD SEPARATE IT OUT AND GO FOR THE 45-DAY
25 PERIOD. I MEAN IT IS SO DIFFICULT TO GET YOUR HANDS,

1 AS A LAYPERSON TRYING TO KEEP UP WITH WHAT'S GOING ON
2 IN RESEARCH, IF YOU DON'T HAVE A SUBSCRIPTION TO *JAMA*
3 OR THE *NEW ENGLAND JOURNAL* OR *LANCET*, AND YOU CAN'T SEE
4 THIS. AND WE'RE PAYING FOR IT.

5 AND I THINK ABOUT -- NOT TO GO BACK TO HIV,
6 BUT, YOU KNOW, THERE WAS A STUDY THAT CAME OUT SHOWING
7 THE ABILITY TO HAVE T-CELLS COME OUT OF A -- DERIVED
8 FROM EMBRYONIC CELLS. AND I HAD A PRESS RELEASE WHICH
9 IS THE EQUIVALENT OF A LAY ABSTRACT, AND I SENT IT TO A
10 REPORTER BECAUSE THAT'S HOW I TRY TO FIND OUT. I SENT
11 IT TO THE REPORTER, AND THEN THE REPORTER WRITES A
12 STORY; AND IF THEY GET THE PAPER, SOMETIMES I GET THE
13 PAPER FROM THE REPORTER BECAUSE THEY'LL GIVE IT TO THE
14 REPORTER. AND IT WAS AT MY INSTITUTION, SO I COULDN'T,
15 YOU KNOW, GET IT FROM THE RESEARCHER.

16 AND THE REPORTER SAID, "OH, IT'S IN RATS.
17 NOT GOING TO DO IT." SO I HAVE NO IDEA WHAT WAS IN
18 THAT RESEARCH PAPER AND I CAN'T GET IT. AND IF WE'RE
19 PAYING FOR THIS, I THINK IT'S A REAL BARRIER TO THE
20 PUBLIC.

21 I JUST COME BACK TO WHAT STEVE SHERWIN SAID
22 YESTERDAY, WHO IS FROM CELL GENESIS. I FORGET THE NAME
23 OF HIS COMPANY. CELL GENESIS. AND ONE OF THE THINGS
24 HE ENCOURAGES US TO DO WAS TO ACTIVELY ENGAGE THE
25 ADVOCACY COMMUNITY IN PARTNERSHIP WITH INDUSTRY AS IT

1 COMES TIME TO DEVELOP THESE THERAPIES.

2 WELL, THE ADVOCACY COMMUNITY CANNOT BE
3 ENGAGED IN THE SCIENCE IF THEY DON'T HAVE ACCESS TO THE
4 SCIENCE. AND IF WE DON'T HAVE ACCESS TO THE SCIENCE TO
5 AT LEAST FACILITATE THE ACCESS FOR THE ADVOCACY
6 COMMUNITY, HOW IS THAT GOING TO HAPPEN? I WOULDN'T
7 PARTICIPATE IN A RESEARCH PROJECT BASED ON A LAY
8 ABSTRACT. AND PEOPLE CAN EDUCATE. WE'RE ALL -- YOU
9 KNOW, I KNOW A LOT MORE ABOUT STEM CELL RESEARCH THAN I
10 DID A YEAR AGO. WE HAVE TO MOVE OURSELVES UP THIS
11 LEARNING CURVING. WE CAN'T DO IT.

12 AND IT SEEMS LIKE THE PRIMARY -- THE ONLY
13 REALLY STRONG OBJECTION I'VE HEARD IS FOR JUNIOR
14 RESEARCHERS WHO NEED PRESTIGE JUST PUBLISH IN ORDER TO
15 ADVANCE THEIR CAREER. BUT WE HAVE A WAIVER IN THIS
16 THAT MIGHT SEEM TO ADDRESS THAT ISSUE. BUT PERSONALLY
17 I THINK THIS IS A PLACE THAT WE CAN REALLY PUSH THINGS
18 FORWARD.

19 CHAIRMAN PENHOET: OKAY. OTHER COMMENTS IN
20 SACRAMENTO? DR. PRIETO.

21 DR. PRIETO: I'LL TRY TO BE BRIEF. BUT I
22 WOULD AGREE THAT, A, WE SHOULD CARVE THIS OUT. IF
23 WE'RE GOING TO ADDRESS IT, IT SHOULD BE A SEPARATE
24 ISSUE SO THAT WE CAN MOVE FORWARD WITH THE OTHER REGS.
25 AND ALSO THAT AS, ED, YOUR IMPRESSION IS, THIS IS ALSO

1 MY IMPRESSION OF WHAT'S HAPPENING IN SCIENTIFIC
2 PUBLICATION IN GENERAL IS THAT THINGS ARE BECOMING MORE
3 AVAILABLE RATHER THAN LESS. BUT IF THERE IS AN ISSUE
4 HERE, I WOULD WANT US TO ERR ON THE SIDE OF AND TO PUSH
5 IN THE DIRECTION OF MORE WIDE AVAILABILITY OF THIS
6 KNOWLEDGE.

7 CHAIRMAN PENHOET: JEANNIE FONTANA.

8 DR. FONTANA: I AGREE WITH THAT. AND I'M
9 HARKING BACK TO SOME OF THE NONPROFITS THAT I KNOW THAT
10 WORK IN THESE ORPHAN DISEASES, AND SOME OF THE POLICIES
11 THAT THEY SET UP IS MANDATING THE DISCUSSION AMONG
12 SCIENTISTS SO THAT THERE'S SHARING OF INFORMATION. AND
13 YOU HEAR RESEARCH FROM THE HIV WORLD THAT MAY BE
14 APPLICABLE IN THE DIABETES WORLD THAT MAY BE APPLICABLE
15 IN THE NEURODEGENERATIVE WORLD. I SEE THE INFORMATION
16 SIMILARLY AS A RESEARCH TOOL. INFORMATION IS
17 KNOWLEDGE. KNOWLEDGE IS POWER. AND IT SHOULD BE
18 VIEWED THAT WAY. AND I PERSONALLY AM IN FAVOR OF OPEN
19 ACCESS, IN FACT, EVEN BEFORE PUBLICATION BECAUSE
20 EVERYBODY GETS EVERYTHING ONLINE SO QUICKLY. IT SHOULD
21 BE ON THE WEB. AND I SUPPORT THE PUBLICATION OF BOTH
22 POSITIVE AND NEGATIVE RESULTS.

23 DR. BRYANT: THIS IS SUSAN BRYANT. SO I'M IN
24 FAVOR OF DEFERRING THIS DISCUSSION BECAUSE IT IS A LOT
25 MORE COMPLICATED THAN WE HAVE TIME FOR AT THIS POINT.

1 I'M COMPLETELY IN FAVOR OF ENCOURAGING OPEN ACCESS, BUT
2 THERE ARE ISSUES TO DO WITH SOME OF THE PROFESSIONAL
3 SOCIETIES THAT SUPPORT CONFERENCES AND SO FORTH, AND
4 DIFFERENT DISCIPLINES ARE SUPPORTED BY INCOME FROM
5 JOURNALS. AND IT WILL TAKE THEM SOME TIME TO MAKE SOME
6 TRANSITION AWAY FROM THAT, GET WEANED OFF THAT. SO BY
7 REQUIRING IT, BY MAKING IT A STRICT REQUIREMENT TO BE
8 PUBLIC ACCESS, THAT COULD CAUSE DAMAGE. AND I DON'T
9 WANT TO DO THAT, BUT I DO WANT TO ENCOURAGE PEOPLE TO
10 USE OPEN ACCESS WHEREVER POSSIBLE. BUT I THINK WE
11 SHOULD HEAR FROM BOTH SIDES IN THE FUTURE.

12 CHAIRMAN KLEIN: STANFORD, ANY COMMENTS?

13 MR. GOLDBERG: I THINK IT'S BEYOND THE SCOPE
14 OF TODAY'S DISCUSSION. HAPPY TO TABLE IT FOR ANOTHER
15 MEETING.

16 DR. WRIGHT: CHICO AGREES.

17 CHAIRMAN PENHOET: OKAY. SCOTT, IF I COULD.
18 HOW DO WE DEAL WITH THIS? WE WOULD REMOVE THIS --
19 WELL, WE HAVE TWO -- I'M TRYING TO FIGURE OUT, FIRST,
20 WHAT WE WOULD DO IF THEY DO SOMETHING. IF WE WANT -- I
21 GUESS THE ICOC AT ANY TIME COULD SET UP A SEPARATE
22 REGULATION TO DEAL WITH OPEN ACCESS. IS THAT THE IDEA?

23 MR. TOCHER: THAT'S RIGHT.

24 CHAIRMAN PENHOET: SO IF WE PASSED -- IF WE
25 MAINTAIN THE CURRENT POLICY, WHICH HAS AN EXHORTATION

1 ABOUT OPEN ACCESS, BUT NOT A REGULATION, THAT WOULDN'T
2 BE INCONSISTENT WITH US DEVELOPING LATER A SEPARATE
3 POLICY, OR SHOULD WE REMOVE EVEN THE EXHORTATION FROM
4 THIS DOCUMENT?

5 MR. TOCHER: NO. NO. THE EXHORTATION WHICH
6 IS NOT REGULATORY --

7 CHAIRMAN PENHOET: IT'S NOT REGULATORY.

8 MR. TOCHER: -- IS FINE AS A POLICY.

9 CHAIRMAN PENHOET: FINE. OKAY.

10 MR. TOCHER: THE RECOMMENDATION, THOUGH, THE
11 PROCESS WOULD BE LIKELY RECOMMENDING TO THE ICOC AT ITS
12 NEXT MEETING OR WHATEVER THAT THE ISSUE HAS BEEN
13 RAISED, AND WOULD THE ICOC AS A POLICYMAKER LIKE THE
14 TASK FORCE TO PURSUE INVESTIGATING A REGULATION THAT
15 WOULD REQUIRE OPEN ACCESS, AND THAT WOULD BE A SEPARATE
16 PROCEDURE.

17 CHAIRMAN PENHOET: SO THE MOTION ON THE
18 TABLE IS THAT WE MAKE SUCH A REQUEST OF THE ICOC
19 SEPARATELY FROM THE APA REGULATIONS THAT WE'RE DEALING
20 WITH TODAY.

21 MR. TOCHER: CORRECT.

22 CHAIRMAN PENHOET: AND I THINK -- NO, IT
23 WASN'T MINE. I BELIEVE IT WAS JEANNIE FONTANA,
24 SECONDED BY DR. PRIETO, IF I UNDERSTOOD CORRECTLY. SO
25 THAT'S THE MOTION, THAT WE DO NOT INTRODUCE THIS

1 CONCEPT INTO THE CURRENT APA REGULATION PROCESS, BUT
2 THAT WE DEAL WITH IT SEPARATELY AT THE ICOC. IS THAT
3 CORRECT?

4 MR. TOCHER: YES.

5 CHAIRMAN PENHOET: OKAY. IRVINE?

6 DR. BRYANT: APPROVED.

7 CHAIRMAN PENHOET: STANFORD?

8 MR. GOLDBERG: YES.

9 CHAIRMAN PENHOET: OH, WAIT A MINUTE. WE
10 DIDN'T HAVE TIME FOR PUBLIC COMMENT. I'M SORRY. DOES
11 ANYBODY HERE WISH TO MAKE A PUBLIC COMMENT?

12 MR. PITTS: THANK YOU, MR. CHAIRMAN. I'D
13 LIKE TO RISE IN OPPOSITION TO THE MOTION ON THE FLOOR
14 WHICH YOU WILL BE CONSIDERING SHORTLY. I'M LARRY
15 PITTS, PROFESSOR OF NEUROSURGERY AT UCSF, RECENT CHAIR
16 OF THE UNIVERSITY OF THE CALIFORNIA ACADEMIC SENATE,
17 AND CURRENTLY THE CHAIR OF THE ACADEMIC COUNCIL'S
18 SPECIAL COMMITTEE ON SCHOLARLY COMMUNICATION.

19 IT'S A TOPIC THAT THE UC SENATE HAS BEEN
20 INVESTIGATING FOR THE PAST SEVERAL YEARS, GREW OUT OF
21 ISSUES WITH THE VERY HIGH-COST JOURNALS, PARTICULARLY
22 SCIENTIFIC JOURNALS, AND A VERY ADVERSE EFFECT ON A
23 WIDE SPECTRUM OF PUBLICATIONS THAT THE UNIVERSITY OF
24 CALIFORNIA PURCHASES. AND SO WE'VE BEEN LOOKING AT
25 THIS FOR A WHILE.

1 AND I THINK THAT THERE ARE SOME
2 MISCONCEPTIONS, FIRST OFF, IN REVIEWING THE MATERIAL ON
3 THE WEB FOR THIS MEETING. THERE WERE NO ACADEMIC
4 STATEMENTS AGAINST OPEN ACCESS. THERE MAY BE
5 DISCUSSIONS THAT ARE NOT PART OF THE PUBLIC RECORD AND
6 WHICH I HAVE NO EASY WAY TO ADDRESS. THERE CERTAINLY
7 ARE DIVISIONS OF OPINION IN GENERAL.

8 THE OPINION STRONGEST FOR NOT REQUIRING OPEN
9 ACCESS COMES FROM THOSE ENTITIES THAT HAVE A SPECIFIC
10 COMMERCIAL REASON FOR THAT PURPOSE. IN POINT OF FACT,
11 THERE ARE NO DATA TO SUPPORT LOSS OF REVENUE BY OPEN
12 ACCESS TO DATE. AND, IN FACT, IN BOOK PUBLISHING, SOME
13 SALES ARE STIMULATED BY OPEN ACCESS OF THE MATERIAL IN
14 THE ELECTRONIC FORM THAT STIMULATES SOMEONE TO WANT A
15 HARD COPY AND BUY IT. SO THERE ARE VALID -- THERE IS A
16 REAL QUESTION AS TO THE IMPORTANCE OF THE ECONOMIC
17 FEELINGS BY PUBLISHERS AND SOME SCHOLARLY SOCIETIES.

18 THERE'S SOME SCHOLARLY SOCIETIES THAT HAVE
19 TAKEN A STANCE AGAINST OPEN ACCESS FOR EXACTLY THE
20 CONCERN THAT YOU RAISE. IN POINT OF FACT, A NUMBER OF
21 THEIR MEMBERS WITHIN THE SCHOLARLY SOCIETY HAVE
22 DISAGREED WITH THEIR MANAGEMENT, SO TO SPEAK, AND SO
23 THAT'S A QUESTION THAT'S VERY MUCH UP IN THE AIR.

24 I WOULD MAKE THE POINT THAT WHEN FACULTY, AND
25 THESE ARE SOME POINTS THAT WERE MADE IN OUR SUBMISSION,

1 YOUR REFERENCE NO. 5, THAT WHEN SWAN AND BROWN IN 2005
2 FOUND THAT 81 PERCENT OF RESEARCHERS WOULD WILLINGLY
3 COMPLY WITH A MANDATE FROM THEIR EMPLOYER OR RESEARCH
4 FUNDER TO PROVIDE COPIES OF ARTICLES IN OPEN ACCESS, 82
5 PERCENT OF THE PUBLIC BELIEVES THAT IF TAX DOLLARS PAY
6 FOR SCIENTIFIC RESEARCH, PEOPLE SHOULD HAVE FREE ACCESS
7 TO THE RESULTS OF THE WORK ON THE INTERNET.

8 THERE ARE MOVES AFOOT, AS YOU RIGHTLY POINT
9 OUT, PARTICULARLY AT THE NIH LEVEL, THERE'S A PROPOSED
10 LEGISLATION BY SENATORS CORNYN AND LIEBERMAN FOR THE
11 FEDERAL RESEARCH PUBLIC ACCESS ACT, REQUIRING OPEN
12 ACCESS FOR WORK PUBLISHED BY AGENCIES WITH MORE THAN
13 \$100 MILLION IN FUNDING. AND THE HOUSE APPROPRIATIONS
14 BILL HAS DIRECTED THE NIH TO INSTITUTE MANDATORY
15 SIX-MONTH PUBLIC ACCESS TO THEIR FUNDED RESEARCH.
16 THAT'S NIH RESEARCH.

17 SO FAR THE NIH HAS A VOLUNTARY POLICY WHICH
18 IS BASICALLY WHAT CIRM IS ASKING FOR AT THIS STAGE.
19 THEIR TAKE RATE ON VOLUNTARY OPEN ACCESS IS
20 EXTRAORDINARILY LOW. IT'S ABOUT 4 PERCENT. AND PAYING
21 TO HAVE IT PUT IN OPEN ACCESS IS NOT LIKELY WHILE
22 THAT'S -- DR. MAXON PRESENTED THAT AS AN INDUCEMENT.
23 IN POINT OF FACT, IT'S A DEFRAYMENT OF THE COST. IT IS
24 NOT ACTUALLY AN INDUCEMENT TO DO IT. IT'S JUST SAYING
25 YOU CAN DO IT AND WE'LL PICK UP THE TAB IF YOU DO THAT.

1 THAT IS NOT LIKELY, IN OUR JUDGMENT, TO VERY MUCH
2 INCREASE THE PLACEMENT OF OPEN ACCESS.

3 THREE OF THE UNIVERSITY -- I'M SORRY -- THREE
4 OF THE UNITED KINGDOM RESEARCH COUNCILS HAVE RECENTLY
5 ENACTED A REQUIREMENT FOR OPEN-ACCESS PUBLICATION, A
6 FOURTH STRONGLY RECOMMENDS IT. THE MEDICAL RESEARCH
7 COUNCIL OF THE UNITED KINGDOM HAS ADOPTED AN
8 OPEN-ACCESS SIX-MONTH POLICY, AND THEY HAVE IN IT VERY
9 MUCH ALMOST NEARLY THE SAME WORDING AS UNIVERSITY OF
10 CALIFORNIA, A RECENT ACADEMIC SENATE RESOLUTION
11 ALLOWING AN OPT-OUT. SO THE ARGUMENT THAT YOU CAN'T
12 GET YOUR ARTICLES A JUNIOR INVESTIGATOR WANTS TO
13 PUBLISH IN A PARTICULAR JOURNAL THAT WON'T ALLOW OPEN
14 ACCESS, THERE'S AN OPT-OUT CLAUSE IN THE LANGUAGE THAT
15 WE'VE RECOMMENDED.

16 SO WE BELIEVE THAT THERE ARE WAYS TO DEAL
17 WITH THE PERCEIVED PROBLEMS, AND WE HONESTLY BELIEVE
18 MOST OF THE PERCEIVED PROBLEMS ARE NOT REAL. AT LEAST
19 THERE ARE NO DATA TO SUGGEST THAT THE PERCEIVED
20 PROBLEMS ARE REAL. WE THINK THAT THE PROPOSAL THAT WE
21 HAVE SUBMITTED TO YOU IN ITS MOST CURRENT FORM IS
22 APPROPRIATE, AND I WOULD BE SORRY TO SEE IT BE PUT INTO
23 A PLACE THAT WOULD MAKE IT LONGER TO COME INTO REALITY,
24 WHICH IS WHAT THE MOTION ON THE FLOOR PROPOSES.

25 THERE IS A RECENT ARTICLE -- AND SO WHAT I'M

1 SAYING NOW IS BASICALLY AN UPDATE IN PART TO OUR
2 SUBMISSION THAT'S IN YOUR PACKAGE.

3 CHAIRMAN PENHOET: COULD WE HAVE THE
4 THREE-MINUTE TIME LIMIT HERE.

5 MR. PITTS: OKAY.

6 CHAIRMAN PENHOET: IF WE GO FORWARD ON THE
7 PATH WE'RE ON, WE'RE HAPPY TO ENGAGE YOU FURTHER IN HOW
8 WE WOULD IMPLEMENT THIS. IN ANY CASE, WE -- FIRST OF
9 ALL, WE THINK WE HAVE MORE WORK TO DO BEFORE ADOPTING
10 ANY SPECIFIC WAY OF HANDLING THIS, BUT WE DO APPRECIATE
11 YOUR COMMENT.

12 DR. PRIETO: IF I COULD JUST RESPOND TO THAT.
13 I THINK THE MOTION ON THE FLOOR DOES NOT SAY THAT WE
14 ARE OPPOSED TO OPEN ACCESS, BUT POSTPONES THIS DECISION
15 AND ASKS FOR SOME GUIDANCE FROM THE ICOC. AND I, FOR
16 ONE, WOULD BE WELCOME TO HAVE YOU COME TO THE ICOC AND
17 MAKE THESE SAME POINTS. I THINK OUR BIAS IN GENERAL
18 WOULD BE IN FAVOR OF OPEN ACCESS, BUT WE HAVE SEVERAL
19 STEPS TO TAKE IN A PUBLIC COMMENT PERIOD IF WE'RE GOING
20 TO PUT THAT IN THE FORM OF REGULATIONS.

21 MR. SHEEHY: I THINK THAT'S YOUR PROBLEM. WE
22 HAVE A PROCEDURAL ISSUE THAT STAFF AND COUNSEL HAS SAID
23 THAT IF WE DO THIS, IF WE INCLUDE IT AS PART OF WHAT WE
24 DO TODAY, THE ENTIRE DOCUMENT GOES IN FOR A 45-DAY
25 REVIEW PER ADMINISTRATIVE PROCEDURES ACT. OR WE CAN

1 SEPARATE IT OUT, BUT TO SEPARATE IT OUT REQUIRES A
2 MOTION THAT WE HAVE ON THE FLOOR TO SEND IT BACK TO THE
3 ICOC TO INITIATE THE PROCESS OF MAKING A NEW RULE,
4 WHICH I THINK THE SENSE -- I THINK IT SEEMS LIKE A LOT
5 OF US HERE ARE WITH YOU ON THIS. IT'S JUST THAT THE
6 PROCESS HAS TO BEGIN AT THE ICOC.

7 DR. FONTANA: SO LET'S FOLLOW UP WITH THAT,
8 SO WE WANT TO EXPEDITE IT. LET'S HAVE THE INTENTION
9 THAT WE MAKE -- GO WITH THE MOTION. WE PULL IT OUT,
10 BUT THAT WE SET A DATE ON THE CALENDAR IN THE VERY NEAR
11 FUTURE. THIS IS NOT SOMETHING TO BE PUT OFF FOR MONTHS
12 AND MONTHS AND MONTHS, BUT THAT WE DO IT PERHAPS A WEEK
13 AFTER THE NEXT ICOC MEETING AND ADDRESS IT.

14 DR. PRIETO: WOULDN'T THIS BE REPORTED IN THE
15 REPORT OF THIS MEETING TO THE ICOC AT OUR NEXT MEETING?

16 DR. FONTANA: AND THEN WE SET AN APPOINTMENT
17 THEREAFTER WHERE WE CAN DISCUSS THIS IN DETAIL.

18 MR. ROTH: WHILE SYMPATHETIC TO THE ARGUMENT
19 THAT WAS JUST MADE, IN REALITY THERE WON'T EVEN BE
20 FUNDING FOR ANOTHER YEAR. SO TO GET AHEAD OF WHAT IS A
21 TREND, I THINK I WOULD NOT RUSH THIS BECAUSE I HAVE
22 SOME IP ISSUES THAT I WOULD WORRY ABOUT IN TERMS OF
23 DISCLOSURE AND OTHER THINGS THAT SHOULD BE CONSIDERED
24 AS WELL.

25 CHAIRMAN PENHOET: WE WON'T HAVE ANY

1 CIRM-FUNDED PUBLICATION FOR SOME TIME. OKAY. WE HAVE
2 A MOTION -- OH. ANY OTHER COMMENT? MR. SIMPSON.

3 MR. SIMPSON: JOHN SIMPSON FROM THE
4 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I MEAN I
5 THINK IT'S ABSOLUTELY CRITICAL THAT IT GET -- THAT YOU
6 HAVE OPEN ACCESS. THE PUBLIC'S PAYING FOR IT. AND IF
7 THE PROCEDURAL THING, I REALLY THINK YOU GOT TO MAKE
8 CRYSTAL CLEAR THAT IT'S A DATE CERTAIN THAT IT WILL BE
9 TAKEN UP SO THAT THE MOTION OUGHT TO READ THAT IT WILL
10 BE TAKEN UP AT THE PROBABLY -- WHAT IS IT? -- AUGUST 3D
11 IP MEETING, AND PERHAPS YOU COULD HAVE LANGUAGE IN
12 THERE TO DISCUSS AT THAT MEETING.

13 MR. SHEEHY: I THINK IT NEEDS -- AS I
14 UNDERSTAND THE PROCESS, IT NEEDS TO BE BROUGHT UP AT
15 THE ICOC FIRST.

16 DR. WRIGHT: WHICH IS ON THE 2D, JEFF.

17 DR. FONTANA: AND IT HAPPENS TO BE IN UCSF.

18 CHAIRMAN PENHOET: I THINK THAT'S THE SENSE
19 OF THE GROUP. THAT'S EMBODIED IN THIS. SO WITH THAT,
20 WE HAVE A MOTION.

21 DR. PRIETO: CALL THE QUESTION.

22 CHAIRMAN PENHOET: AND A SECOND. CALL FOR A
23 VOTE. IRVINE?

24 DR. BRYANT: YES.

25 CHAIRMAN PENHOET: STANFORD?

1 MR. GOLDBERG: YES.

2 CHAIRMAN PENHOET: CHICO?

3 DR. WRIGHT: YES.

4 CHAIRMAN PENHOET: SACRAMENTO?

5 DR. FONTANA: YES.

6 DR. PRIETO: YES.

7 MR. SHEEHY: YES.

8 CHAIRMAN PENHOET: OKAY. AND WE'LL MOVE

9 ALONG TO THE NEXT ITEM, OKAY, WHICH IS TO MANDATE

10 CONTRIBUTION OF PATENTED INVENTIONS TO A PATENT POOL.

11 THIS IS THE SECOND NEW ITEM THAT HAS BEEN BROUGHT

12 BEFORE US. WE HAD DISCUSSED PATENT POOLS BEFORE AND

13 REJECTED THE NOTION OF CREATING PATENT POOLS, BUT WE DO

14 HAVE A PATENT POOL MANDATE THAT'S BEEN SUGGESTED TO US.

15 SO ANY COMMENT BY THE BOARD? ANY COMMENT FROM THE --

16 MR. SHEEHY: WELL, I THINK WE SHOULD

17 REITERATE WHY -- YOU KNOW, I MEAN I'LL TRY TO

18 RECAPITULATE EARLIER THINKING SUCCINCTLY. BUT THE

19 REASON WE CAN'T DO IT IS, I THINK, ALLUDED TO EARLIER.

20 THERE'S NO OFFICE OF TECHNOLOGY AND LICENSING AT CIRM.

21 THERE DOES NOT EXIST ONE PRESENTLY AT THE STATE LEVEL.

22 SO THIS IS PHYSICALLY IMPOSSIBLE. WE DON'T HAVE THE

23 MECHANISMS BY WHICH TO IMPLEMENT A PATENT POOL. I

24 THINK IT'S A GREAT IDEA. I'D LOVE TO SEE IT. I'D LOVE

25 TO SEE GENE MULLIN'S LEGISLATION GO FORWARD AND THAT A

1 AN OFFICE OF TECHNOLOGY AND LICENSING WOULD BE SET UP
2 BY THE STATE, BUT AT PRESENT IT'S JUST NOT SIMPLY
3 WITHIN THE REALM OF SOMETHING WE CAN ACHIEVE.

4 CHAIRMAN PENHOET: OKAY. ANY COMMENTS FROM
5 THE PUBLIC? JOHN SIMPSON.

6 MR. SIMPSON: THAT WAS MY PROPOSAL, I THINK,
7 SO THAT'S WHY I THOUGHT I BETTER -- I MEAN, AGAIN,
8 THERE HAS BEEN A NUMBER OF DISCUSSIONS IN WHICH PEOPLE
9 HAVE SAID, I THINK, IN ESSENCE, THAT THIS IS A VERY
10 GOOD IDEA, THE TIME IS NOT READY YET, AND THAT SORT OF
11 THING. MY POINT IS THAT THE TIME NEVER COMES UNLESS
12 YOU MAKE IT COME. AND I MEAN REBECCA ISENBERG WAS ONE
13 OF THOSE WHO SAID THAT THERE COULD BE A ROLE FOR THIS.
14 IT COULD BE THAT MULLIN'S EFFORT WOULD BENEFIT FROM
15 SOME SORT OF APPROPRIATE RESOLUTIONS THAT THIS SHOULD
16 BE STUDIED AND SERIOUSLY STUDIED. AND WE APPRECIATE
17 THAT KIND OF APPROACH.

18 CHAIRMAN PENHOET: ALL RIGHT. DO WE HAVE A
19 MOTION TO APPROVE THIS AS WRITTEN -- NO -- TO REJECT
20 THE ADDITION. THAT WOULD BE THE MOTION.

21 MR. SHEEHY: SO MOVED.

22 CHAIRMAN PENHOET: MOVED BY SHEEHY.

23 DR. FONTANA: SECOND.

24 CHAIRMAN PENHOET: SECOND BY FONTANA.

25 IRVINE?

1 DR. BRYANT: YES.

2 CHAIRMAN PENHOET: STANFORD?

3 MR. GOLDBERG: YES.

4 CHAIRMAN PENHOET: CHICO?

5 DR. WRIGHT: YES.

6 CHAIRMAN PENHOET: SACRAMENTO?

7 DR. FONTANA: YES.

8 DR. PRIETO: YES.

9 CHAIRMAN PENHOET: YES. ALL IN AGREEMENT.

10 MR. SHEEHY: MAYBE WE SHOULD FOLLOW UP ON --

11 CHAIRMAN PENHOET: THERE WAS A SUGGESTION

12 THAT WE STUDY THIS FURTHER, WHICH WE'LL BE HAPPY TO DO.

13 MR. SHEEHY: WELL, WHAT MIGHT BE GOOD IS TO

14 ASK THE LEGISLATIVE SUBCOMMITTEE OF THE ICOC TO TAKE

15 THIS UP AND ENGAGE IN SOME SORT OF DIALOGUE WITH

16 ASSEMBLYMAN MULLIN JUST TO TRY TO -- BECAUSE IF HE'S

17 GOING TO SET UP AN OFFICE OF TECHNOLOGY AND LICENSING,

18 THEN THAT PROVIDES AT LEAST A MECHANISM BY WHICH WE CAN

19 START TO THINK ABOUT THIS POSSIBILITY. SO MAYBE THE

20 MOTION IS TO SUGGEST THAT THE LEGISLATIVE SUBCOMMITTEE

21 OF THE ICOC TAKE THIS UP.

22 CHAIRMAN PENHOET: IS THAT -- I MEAN WE CAN

23 MAKE THAT SUGGESTION AS INDIVIDUALS. DO WE NEED TO

24 MAKE IT AS A TASK FORCE? IS THAT -- I DON'T KNOW.

25 MR. TOCHER: IT COULD BE EITHER.

1 DR. PRIETO: JUST CARRY MORE WEIGHT IF WE SAY
2 IT'S A SENSE OF OUR TASK FORCE THAT THIS IS AN ISSUE WE
3 HAVE LOOKED AT. WE DON'T THINK IT'S QUITE READY YET,
4 BUT WE WOULD LIKE YOU TO ENGAGE THE LEGISLATURE IN
5 DISCUSSIONS.

6 CHAIRMAN PENHOET: OKAY. SO THERE'S A MOTION
7 THAT WE MAKE A REQUEST OF THE LEGISLATIVE SUBCOMMITTEE
8 TO DO THIS --

9 DR. PRIETO: I'LL SECOND IT.

10 CHAIRMAN PENHOET: -- TO LOOK AT THIS
11 PROBLEM.

12 MR. SHEEHY: TO LOOK AT LEGISLATIVE --
13 LEGISLATION IN THE LEGISLATURE REFERENCING THIS TO
14 SEE --

15 CHAIRMAN PENHOET: REFERENCING THE USE OF
16 PATENT POOLS.

17 MR. SHEEHY: WELL, REFERENCING THE
18 ESTABLISHMENT OF THE STATE OFFICE OF TECHNOLOGY AND
19 LICENSING. I MEAN THIS IS NOT EVEN AN ISSUE WE CAN
20 CONSIDER BECAUSE IT'S SIMPLY PHYSICALLY IMPOSSIBLE. WE
21 DON'T HAVE THE PERSONNEL, THE STATE DOESN'T HAVE THE
22 MECHANISM TO IMPLEMENT THIS.

23 CHAIRMAN PENHOET: WE'RE JUST LOOKING FOR A
24 LIAISON.

25 MR. SHEEHY: WE'RE PUTTING IT ON THE AGENDA

1 FOR THE LEGISLATIVE SUBCOMMITTEE.

2 MR. TOCHER: I THINK THE POINT IS THAT THERE
3 ISN'T A RECOMMENDATION SPECIFIC AS TO WHICH WAY TO GO,
4 BUT JUST THAT THE CONTEXT FOR THE DISCUSSION WOULD BEST
5 OCCUR IN THE LEGISLATIVE REALM RIGHT NOW AS OPPOSED TO
6 WITHIN OUR REGULATIONS.

7 CHAIRMAN PENHOET: OKAY. WELL STATED.
8 IRVINE?

9 DR. BRYANT: YES.

10 CHAIRMAN PENHOET: STANFORD?

11 MR. GOLDBERG: YES.

12 CHAIRMAN PENHOET: CHICO?

13 DR. WRIGHT: YES.

14 CHAIRMAN PENHOET: IN SACRAMENTO?

15 DR. FONTANA: YES.

16 DR. PRIETO: YES.

17 MR. SHEEHY: YES.

18 CHAIRMAN PENHOET: OKAY. WE'LL REFER IT TO
19 THE LEGISLATIVE SUBCOMMITTEE.

20 WE NOW END UP -- WE'RE IN CATEGORY C, WE HAVE
21 ALMOST AN HOUR TO GO. THE FIRST -- THESE ARE PRIMARILY
22 CLARIFICATION, ETC., AS YOU SEE HERE. WE'LL START WITH
23 ISSUE 8, THAT WE SHOULD ADD A STATEMENT REGARDING THE
24 ATTORNEY GENERAL'S MARCH-IN RIGHTS. WE HAVE DISCUSSED
25 THIS BEFORE. AS YOU WILL NOTE, THE STAFF RECOMMENDS

1 AGAINST IT BECAUSE THE ATTORNEY GENERAL'S LAW
2 ENFORCEMENT JURISDICTION IS NOT A MATTER FOR US TO
3 REGULATE. AND THE ATTORNEY GENERAL HAS THIS RIGHT WITH
4 OR WITHOUT THE LANGUAGE. AND SO OUR VIEW IS, THE STAFF
5 VIEW IS, THAT THIS IS AN UNNECESSARY ADDITION AND
6 OVERSTEPS OUR BOUNDS.

7 MR. SHEEHY: I NOTE THE ATTORNEY GENERAL IS
8 OUR ATTORNEY -- I MEAN IT WAS AN AG THAT SAT NEXT TO ME
9 WHEN I WAS DEPOSED. SO I HAVEN'T FOUND ANY
10 UNWILLINGNESS OF THEM TO PROVIDE SERVICE TO THE ICOC
11 AND CIRM. THERE HAS BEEN VERY CAPABLE REPRESENTATION.

12 DR. PRIETO: I DON'T KNOW THAT WE EVEN NEED A
13 MOTION.

14 CHAIRMAN PENHOET: NO, WE DON'T.

15 DR. PRIETO: IF THE REGULATIONS OR STATUTE,
16 THE ATTORNEY GENERAL ENFORCES STATUTES, THEN IT'S
17 UNNECESSARY.

18 CHAIRMAN PENHOET: WELL, UNLESS SOMEBODY
19 WANTS TO MAKE A MOTION TO PUT IT IN.

20 DR. FONTANA: DON'T WE MAKE A MOTION TO TAKE
21 IT OUT?

22 CHAIRMAN PENHOET: NO, IT'S NOT IN NOW.

23 DR. PRIETO: IT'S NOT IN.

24 DR. FONTANA: MOTION IS TO ADD.

25 CHAIRMAN PENHOET: SO IF SOMEBODY WANTS TO

1 PUT IT IN, THEY CAN MAKE SUCH A MOTION. IF NOT, WE'LL
2 MOVE ON TO THE NEXT ITEM.

3 DR. FONTANA: MOVE ON.

4 CHAIRMAN PENHOET: OKAY. DEFINE A RESEARCH
5 INSTITUTION. A CLARIFICATION OF WHETHER THE
6 INSTITUTION MUST BE AN EXCLUSIVE, PRIMARILY, OR
7 MINIMALLY INVOLVED IN RESEARCH, ETC. TO SOME DEGREE,
8 YOU KNOW, RESEARCH INSTITUTION WILL BE DEFINED BY AN
9 INSTITUTION WHICH DOES RESEARCH IN CALIFORNIA. THERE'S
10 SOME CONCERN HERE IT'S SELF-DEFINITION. THERE'S SOME
11 CONCERN ABOUT A DROP BOX AND THEN USING THE FUNDS. THE
12 PROP 71 CLEARLY STATES THAT THE FUNDS MUST BE SPENT IN
13 THE STATE OF CALIFORNIA. SO IT'S NOT WHERE THE PARENT
14 COMPANY IS. IT'S NOT WHERE THE DROP BOX IS. IT'S
15 WHERE THE ACTIVITIES OCCUR. SO I THINK THIS IS AN
16 UNNECESSARY ADDITION MYSELF, BUT IF ANYBODY HAS -- BUT
17 PERHAPS WE COULD DEFINE IT SOMEWHAT MORE CAREFULLY.
18 SCOTT.

19 MR. TOCHER: MARY AND I HAVE MADE A
20 SUGGESTION IN ITALICS IN THE NOTES BOX OF ISSUE NO. 9
21 THAT MIGHT SORT OF CLARIFY WHAT YOU JUST SAID, ED. TO
22 CLARIFY THAT IT IS FOR RESEARCH IN CALIFORNIA WHICH
23 WOULD EXPLICITLY SORT OF REMEDY, I THINK, THE DROP BOX
24 SCENARIO.

25 MR. SHEEHY: THAT'S WHAT I WAS GOING TO SAY.

1 CHAIRMAN PENHOET: THIS IS MIXED UP HERE.
2 THIS IS BACK TO THE RESEARCH EXEMPTION, SCOTT.

3 MR. TOCHER: I'M SORRY.

4 MR. SHEEHY: DO WE ADDRESS THIS IN THE
5 CLEANUP ON DEFINITIONS? I NOTICE THERE'S A LOT OF
6 CLEANUP.

7 DR. MAXON: RIGHT. RIGHT.

8 MR. SHEEHY: SO THIS ISSUE REALLY IS MOOT.

9 CHAIRMAN PENHOET: IT WILL BE. AND WITHOUT A
10 RESEARCH EXEMPTION, IT'S UNNECESSARY AT THIS POINT IN
11 TIME.

12 MR. GOLDBERG: YOU NEED TO TALK LOUDER.

13 CHAIRMAN PENHOET: WE TOOK CARE OF THAT
14 EARLIER. OKAY.

15 ITEM 10, REQUIRE -- WE ARE NOT DEALING WITH
16 NO. 9. IT'S NOW MOOT BECAUSE IT WAS PRIMARILY IN THE
17 CONTEXT OF RESEARCH EXEMPTION THAT WE HAD TO DEFINE A
18 RESEARCH INSTITUTION.

19 DR. FONTANA: JUST FOR CLARIFICATION, IT'S
20 NO. 9 IN OUR BOOKLETS, YET IT'S NUMBER SOMETHING ELSE
21 IN THE E-MAIL FAX.

22 DR. MAXON: SO THIS IS THE FINAL COPY OF THE
23 SUMMARY IN THE BINDER.

24 CHAIRMAN PENHOET: IN YOUR BOOK.

25 MS. KING: BUT IT'S IN THE BINDER, AND THE

1 PEOPLE ON THE PHONE SHOULD HAVE RECEIVED THAT LAST
2 NIGHT.

3 CHAIRMAN PENHOET: ITEM 10, REQUIRE
4 RECIPROCAL SHARING OF PUBLICATION-RELATED BIOMEDICAL
5 MATERIALS. THIS HAS TO DO WITH THE RECIPROCITY OUTSIDE
6 THE STATE, MANDATING THAT OUR GRANTEES AGREE THAT IF
7 SOMEBODY OUTSIDE THE STATE AGREES TO SHARE IT WITH
8 THEM, THEY'LL AGREE TO SHARE IT WITH THE PEOPLE
9 OUT-OF-STATE. MY OWN VIEW IS IT'S A LITTLE BIT
10 OVERSTEPPING OUR BOUNDS. I MEAN THIS IS WHAT
11 UNIVERSITIES DO EVERY DAY. THAT'S PART OF THEIR
12 BUSINESS. I'M NOT SURE HOW YOU WOULD ENFORCE THIS,
13 FRANKLY.

14 DR. PRIETO: MY -- YEAH, IN LOOKING OVER THIS
15 YESTERDAY AND THE DAY BEFORE, IT OCCURRED TO ME THERE
16 WAS A COMMENT OR THE NOTES SAYING THAT THIS WOULD
17 CREATE PROBLEMS AND REQUIRE REPORTING. I'M NOT
18 SURE -- I THINK THIS WOULD BE POLICED BY THE GRANTEES
19 THEMSELVES, AND THEY WOULD REPORT TO US IF THERE WAS A
20 PROBLEM.

21 CHAIRMAN PENHOET: YOU KNOW, WHAT DOES
22 HAPPEN, THOUGH, FRANCISCO, IN THE RESEARCH COMMUNITY,
23 THIS IS NOT DONE BY THE INSTITUTIONS. THIS IS ALMOST
24 ALWAYS DONE BY INDIVIDUAL INVESTIGATORS, AND THEY WORK
25 THIS OUT WITH THEIR COLLEAGUES AROUND THE COUNTRY. I

1 THINK IT'S -- IT WOULD BE HARD -- IT WOULD BE VERY
2 DIFFICULT TO IMAGINE THAT UCSF AND HARVARD COULD
3 NEGOTIATE A MUTUAL RECIPROCAL SHARING OF STUFF FOR ALL
4 THEIR FACULTY, ETC. IT'S ALMOST ALWAYS DONE BY
5 INDIVIDUAL INVESTIGATORS AT THAT LEVEL.

6 DR. PRIETO: ARE YOU SAYING, THEN, THAT YOU
7 THINK THE SHARING WOULD TAKE PLACE ANYWAYS? THAT WE
8 DON'T --

9 CHAIRMAN PENHOET: IT MAY OR MAY NOT, BUT WE
10 WOULD -- IT'S PART OF THE NORMAL BUSINESS OF UNIVERSITY
11 LIFE TO MAKE THESE ARRANGEMENTS WITH OTHER RESEARCHERS
12 AROUND THE COUNTRY.

13 DR. WRIGHT: IT STRIKES ME THAT THIS IS MORE
14 OF A PHILOSOPHICAL STATEMENT THAT WE WANT TO MAKE
15 RATHER THAN A REGULATION.

16 CHAIRMAN PENHOET: MAYBE, SUE BRYANT, COULD
17 YOU COMMENT ON THIS?

18 DR. BRYANT: SORRY. I WAS JUST DISTRACTED
19 FOR A MINUTE. WHAT WAS IT?

20 CHAIRMAN PENHOET: WE'RE TALKING ABOUT THE
21 REQUIREMENT OF OUR GRANTEE INSTITUTIONS TO ENGAGE IN
22 RECIPROCAL SHARING WITH OTHER INSTITUTIONS AROUND THE
23 COUNTRY. IF WE SHARE WITH THEM, THEY HAVE TO SHARE
24 WITH US AND VICE VERSA.

25 DR. BRYANT: I DON'T THINK WE NEED TO

1 REGULATE THAT. THAT IS THE PRACTICE AND IT IS DONE
2 PERSON TO PERSON, NOT INSTITUTION TO INSTITUTION. SO I
3 ACTUALLY DON'T SEE -- I MEAN THIS DOESN'T ADD ANYTHING
4 TO WHAT ALREADY HAPPENS.

5 CHAIRMAN PENHOET: OKAY. ANY COMMENTS FROM
6 THE PUBLIC ON THIS ISSUE?

7 DR. PRIETO: WELL, JUST MY ONLY CONCERN WOULD
8 BE THAT AT SOME POINT IN THE FUTURE WE MIGHT HAVE A
9 GRANTEE WHO, FOR WHATEVER REASONS, DECIDED TO KEEP
10 MATERIALS VERY CLOSE TO THE VEST AND NOT SHARE, AND
11 THAT WE'D WANT TO DISCOURAGE SUCH BEHAVIOR.

12 CHAIRMAN PENHOET: WELL, WE DO HAVE A SHARING
13 REQUIREMENT IN OUR POLICY FOR CIRM-FUNDED RESEARCHERS
14 TO SHARE WITH OTHER CIRM-FUNDED, SO WITHIN THE PURVIEW
15 OF OUR OWN -- BORDERS OF OUR OWN AUTHORITY, WE DO HAVE
16 THAT TODAY.

17 DR. PRIETO: THIS WOULD BE BROADER BECAUSE IT
18 WOULD EXTEND BEYOND CIRM-FUNDED RESEARCHERS.

19 CHAIRMAN PENHOET: YES, THAT'S RIGHT. IT
20 WOULD.

21 DR. PRIETO: WHICH I THINK WOULD BE A GOOD
22 THING.

23 CHAIRMAN PENHOET: WE COULD PUT SOME LANGUAGE
24 IN OUR POLICY, NOT IN THE REGULATIONS, BECAUSE WE
25 COULDN'T ENFORCE THIS, BUT WE CAN CERTAINLY EXHORT

1 PEOPLE TO BE GOOD CITIZENS IN OUR POLICY ALONG THESE
2 LINES.

3 MR. SIMPSON: I GUESS, AGAIN, I WAS THE ONE
4 WHO WAS SUGGESTING THIS. AND I MEAN IT SEEMED THAT IT
5 WAS TRYING TO GET TO THE NOTION THAT THERE WAS GOING TO
6 BE VALUABLE WORK THAT SHOULD BE SHARED GOING ON OUTSIDE
7 OF CALIFORNIA AND THAT THERE ARE PERHAPS SOME
8 INSTITUTIONS WHO ARE NOT COOPERATIVE. SUCH AS WICELL
9 AND WARF AND THOSE PATENTS. AND THAT THIS WOULD FOSTER
10 COOPERATION AMONGST OTHERS WHO WERE WILLING TO
11 COOPERATE AND PERHAPS COUNTERACT THOSE VERY SIGNIFICANT
12 PATENTS THAT ARE IMPEDING RESEARCH ACROSS THE COUNTRY.
13 SO I WOULD THINK THAT SOMETHING IN HERE WOULD BE VERY
14 GOOD. I WOULD LIKE TO SEE IT AS A REGULATION. AGAIN,
15 A FALLBACK POSITION, I THINK, THAT IS VALUABLE IS YOUR
16 PHILOSOPHICAL STATEMENTS.

17 CHAIRMAN PENHOET: SO WE CAN -- COULD WE
18 EXPAND THAT STATEMENT WITHOUT TRIPPING THE 45-DAY
19 REQUIREMENT, MR. TOCHER, IN THE POLICY PART? YES, IT'S
20 NOT A REGULATION.

21 DR. WRIGHT: RIGHT.

22 CHAIRMAN PENHOET: THANK YOU. I ANSWERED MY
23 OWN QUESTION. I'M GETTING GOOD AT TALKING TO MYSELF
24 HERE. OKAY. SO THE SENSE OF THE GROUP, THIS IS NOT AN
25 APA REGULATION. OKAY. WE HAVE TO VOTE. SHOULD WE

1 INCLUDE THIS AS AN APA REGULATION? OKAY.

2 DR. WRIGHT: I MOVE WE DO NOT.

3 CHAIRMAN PENHOET: OKAY.

4 DR. FONTANA: NO.

5 CHAIRMAN PENHOET: SECONDED BY FONTANA.

6 IRVINE?

7 DR. BRYANT: I THINK WE SHOULD NOT INCLUDE

8 IT, BUT MAKE IT AN EXHORTATION SOMEWHERE ELSE IN

9 POLICY, IN WHATEVER DESCRIPTIONS WE HAVE OF OUR

10 PROGRAM.

11 CHAIRMAN PENHOET: LET'S INCLUDE THAT IN A

12 SINGLE MOTION WHICH I THINK WILL PASS, WHICH IS WE

13 DON'T INTEND TO MAKE THIS AN APA REGULATION, BUT WE DO

14 INTEND TO BEEF UP THE LANGUAGE OF OUR POLICY TO INCLUDE

15 A STRONGER EXHORTATION TO SHARING BROADLY. OKAY. SO

16 THAT'S THE MOTION. YOU AGREE TO DO THAT?

17 DR. BRYANT: YES.

18 CHAIRMAN PENHOET: STANFORD?

19 MR. GOLDBERG: YES.

20 CHAIRMAN PENHOET: CHICO?

21 DR. WRIGHT: YES.

22 CHAIRMAN PENHOET: SACRAMENTO?

23 DR. FONTANA: YES.

24 DR. PRIETO: YES.

25 CHAIRMAN PENHOET: YES. OKAY. FINE. WE'RE

1 AT NO. 11, THE LAST ONE ON THE LIST. BUTTRESSING,
2 EXCLUSIVE LICENSING PROVISIONS. SO THERE ARE THREE
3 COMMENTS. ONE IS A DISCRETION NOT TO PATENT. I THINK
4 THE GENERAL LANGUAGE HAS A REQUIREMENT THAT GRANTEES
5 PATENT INVENTIONS, BUT LEAVES UP TO THOSE GRANTEES THE
6 DISCRETION TO DETERMINE WHETHER A GIVEN INVENTION IS
7 WORTHY OF THE EXPENSE AND TROUBLE OF GOING THROUGH A
8 PATENT. SO I BELIEVE SUCH DISCRETION EXISTS TODAY.
9 AND WENDY STREITZ' INTERPRETATION IS THE SAME, I GUESS,
10 IF I SEE HER NODDING CORRECTLY, FROM THE UNIVERSITY OF
11 CALIFORNIA.

12 I'M NOT SURE WE NEED EXTRA LANGUAGE HERE TO
13 SAY THAT. THERE IS A GENERAL SORT OF OVERRIDING
14 REQUIREMENT THAT UNIVERSITIES TAKE THIS SERIOUSLY AND
15 PATENT WHERE IT'S WARRANTED, BUT THEY HAVE TO HAVE
16 DISCRETION ABOUT WHETHER SOMETHING IS WORTH THE
17 INVESTMENT OR NOT PATENTING. I'M NOT SURE THIS PIECE
18 IS NECESSARY.

19 CREATE AN EXPLICIT PRESUMPTION FOR
20 NONEXCLUSIVE LICENSES. SAYS MAKE THESE LICENSES
21 NONEXCLUSIVE WHENEVER POSSIBLE SHOULD BE STRENGTHENED
22 TO REQUIRE GRANTEES TO JUSTIFY DEVIATION FROM AN
23 EXPLICIT PRESUMPTION IN FAVOR OF THEM. SCOTT'S
24 RESPONSE DOWN THERE WOULD BE IT WOULD LIKELY REQUIRE A
25 NEW REGULATION DEFINING CRITERIA AND PROCEDURE FOR CIRM

1 EVALUATION OF GRANTEE DEPARTURE. AGAIN, WE'VE
2 OUTSOURCED TO SOME DEGREE AND TRUSTED OUR GRANTEES TO
3 ACT ON OUR BEHALF IN THEIR LICENSING PROCEDURES. I
4 THINK THAT THEY'RE ALL ORGANIZATIONS WHO GENERALLY WORK
5 IN GOOD FAITH.

6 IS THERE ANY COMMENT FROM A FELLOW BOARD
7 MEMBER ON THIS ISSUE?

8 DR. BRYANT: YES. I WOULD LEAVE IT AS IS. I
9 THINK WHENEVER POSSIBLE IS A MESSAGE TO REALLY THINK
10 CAREFULLY BEFORE YOU DEAL WITH AN EXCLUSIVE LICENSE.
11 AND I THINK SETTING UP A SEPARATE PROCEDURE FOR
12 EVALUATION IS GOING TO SLOW EVERYTHING DOWN, SO I WOULD
13 JUST SAY LEAVE IT.

14 CHAIRMAN PENHOET: OKAY.

15 DR. WRIGHT: THIS IS JANET. I'D BE CONCERNED
16 ABOUT THE LEVEL OF OVERSIGHT THAT THAT WOULD CREATE FOR
17 CIRM.

18 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM
19 THE BOARD? COMMENTS FROM THE PUBLIC IN SACRAMENTO?
20 ANYWHERE ELSE? OKAY.

21 THE THIRD ONE WAS CIRM REVOCATION OF
22 LICENSES. SUBDIVISION H DIRECTS GRANTEES TO TAKE
23 ACTION TO MODIFY OR REVOKE LICENSE. CIRM SHOULD
24 EXPRESSLY RESERVE THE RIGHT TO ESSENTIALLY DO SO
25 ITSELF. AGAIN, IT'S ALONG THE SAME LINES. WE DON'T

1 ENVISION HAVING A STAFF DEVOTED TO THIS EXERCISE AND TO
2 MONITOR ALL THESE THINGS CAREFULLY. WE'VE PUT THIS IN
3 THE HANDS OF OUR GRANTEES. AND IT WOULD BE A SERIOUS
4 BURDEN TO DO THIS. THAT'S THE REASON WHY WE DON'T
5 RECOMMEND DOING THIS.

6 DR. PRIETO: QUESTION. DON'T OUR MARCH-IN
7 RIGHTS ESSENTIALLY GRANT US THIS AUTHORITY ANYWAYS?

8 CHAIRMAN PENHOET: YES. WHEN IT REACHES A
9 LEVEL OF MATERIALITY, THAT IS, IT BECOMES ESSENTIALLY
10 VISIBLE, THEN WE HAVE THAT RIGHT. THAT'S CORRECT.

11 ANYONE WANT TO IN THE BOARD SPEAK TO THIS
12 PARTICULAR PROVISION? OKAY. THEN WE HAVE A MOTION,
13 THEN, TO DISREGARD THE ADVICE IN 11 TO BUTTRESS
14 EXCLUSIVE LICENSING PROVISIONS AND LEAVE IT THE WAY IT
15 IS.

16 DR. FONTANA: I MOTION.

17 CHAIRMAN PENHOET: MOVED BY FONTANA.

18 DR. WRIGHT: SECOND.

19 MR. GOLDBERG: SECOND.

20 DR. BRYANT: SECOND.

21 CHAIRMAN PENHOET: SECOND BY SOMEONE OUT
22 THERE. MICHAEL GOLDBERG. IRVINE. SUE, YOU DON'T
23 SOUND LIKE MICHAEL, BUT HE WAS RIGHT IN THERE AT THE
24 SAME TIME.

25 DR. BRYANT: FINE. WHATEVER.

1 CHAIRMAN PENHOET: WE'RE VOTING TO KEEP IT AS
2 IT IS. IRVINE?
3 DR. BRYANT: YES.
4 CHAIRMAN PENHOET: STANFORD?
5 MR. GOLDBERG: YES.
6 CHAIRMAN PENHOET: CHICO?
7 DR. WRIGHT: YES.
8 CHAIRMAN PENHOET: SACRAMENTO?
9 DR. FONTANA: YES.
10 DR. PRIETO: YES.
11 CHAIRMAN PENHOET: OKAY. SO WE'RE ALL IN
12 AGREEMENT.
13 THAT BRINGS US TO THE END OF THE WORK WE WERE
14 CHARGED TO DO FOR TODAY. WE'RE HAPPY AT THIS POINT TO
15 TAKE PUBLIC COMMENT OR BOARD COMMENT ON ANY OF THESE
16 ISSUES. THANK EVERYONE FOR A LOT OF HARD WORK THIS
17 MORNING. WE HAVE A COMMENT FROM DON REED IN
18 SACRAMENTO.
19 DR. REED: THIS IS A POINT OF INFORMATION.
20 EVERYONE IS AWARE THAT HUGELY SIGNIFICANT LEGISLATION
21 WILL BE DECIDED ON TUESDAY. THE STEM CELL RESEARCH
22 ENHANCEMENT ACT CONTAINS THE POTENTIAL TO VASTLY
23 MULTIPLY CIRM'S FUNDING. REMEMBER, AS IT WOULD BE, THE
24 NEW STEM CELL LINES WHICH WILL BE DEVELOPED WOULD BE
25 ELIGIBLE FOR MATCHING GRANTS FROM THE NIH IF SCREA

1 WOULD PASS -- STEM CELL RESEARCH ADVANCEMENT ACT WOULD
2 BE PASSED. WE'VE ONLY GOT A FEW LITTLE TIME LEFT TO
3 INFLUENCE IT. AND RIGHT NOW THE LATEST THAT I KNOW OF
4 IS WE'VE GOT ABOUT 60 VOTES, WHICH IS EXACTLY WHAT WE
5 NEED. WE HAVE NO CUSHION, NO MARGIN. SO IF ONE PERSON
6 TURNING AWAY WOULD CAUSE A LOSS, AN EXTRA PERSON MIGHT
7 GIVE US A CUSHION, AND IT'S STILL POSSIBLE THAT THE
8 PRESIDENT MIGHT SURPRISE EVERYONE AND VOTE FOR IT.

9 REMEMBER, HE HAS BEEN PREDICTED TO VOTE
10 AGAINST OTHER THINGS LIKE THE FAIR CAMPAIGN PRACTICES
11 ACT, WHICH HE DID THEN SIGN. SO IF ANYBODY HAS ANY
12 CONTACTS, PARTICULARLY OUTSIDE THE STATE, CONTACT THE
13 SENATORS, THIS IS A GREAT TIME FOR US TO ACT AS
14 INDIVIDUALS. AND PARTICULARLY OUR FRIENDS IN THE
15 BIOTECH INDUSTRY, THIS CONCERNS YOU ALSO. SO ANYBODY
16 THAT CAN HELP, PLEASE DO. THANK YOU.

17 CHAIRMAN PENHOET: JOHN REED. WE'VE GOT JOHN
18 REED SITTING OVER HERE. JOHN SIMPSON.

19 MR. SIMPSON: JOHN SIMPSON FROM THE
20 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I WOULD
21 REQUEST THAT THE IP COMMITTEE PUT ON ITS AGENDA AT AN
22 APPROPRIATE TIME IN THE FUTURE AN INVESTIGATION OF THE
23 IMPACT OF THE THREE PATENTS THAT ARE CURRENTLY HELD BY
24 THE WISCONSIN ALUMNI RESEARCH FOUNDATION AND THEIR
25 IMPACT ON CALIFORNIA AND STEM CELL RESEARCH ELSEWHERE

1 AND OFFER SOME SORT OF REPORT JUST ON THE STATUS OF
2 THAT.

3 CHAIRMAN PENHOET: WE CAN DO SOME STAFF WORK
4 ON THAT TO BE SURE, AND MAYBE DISCUSS IT AT ONE OF OUR
5 UPCOMING MEETINGS IF THAT'S THE PLEASURE OF THE GROUP.

6 DR. PRIETO: I'D BE VERY INTERESTED IN THAT.
7 CERTAINLY SEVERAL CONCERNS WERE RAISED BY INDUSTRY AT
8 THE SAN DIEGO MEETING ABOUT THOSE PATENTS. AND I THINK
9 IT COULD CONCEIVABLY BE A MAJOR ISSUE FOR CIRM AS WE GO
10 FORWARD. SO I'D LIKE TO EXPLORE THAT.

11 CHAIRMAN PENHOET: OKAY. ANY OTHER COMMENTS?
12 WELL, YOU KNOW, WE MAY OR MAY NOT BE AT THE END OF THIS
13 PROCESS. WE'LL SEE WHAT THE ICOC DECIDES ON AUGUST 2D
14 AND WHAT THE 15 DAYS ADDITIONAL COMMENT PERIOD BRINGS.
15 BUT, YOU KNOW, I THINK THIS HAS BEEN A VERY REWARDING
16 AND VERY COLLABORATIVE PROCESS BETWEEN BOARD MEMBERS,
17 MEMBERS OF THE COMMUNITY, YOU KNOW, ESPOUSING QUITE
18 DIFFERENT VIEWS, BUT I THINK ALL WORKING IN GOOD SPIRIT
19 AND GOOD FAITH TO TRY TO COME UP WITH A POLICY WHICH
20 MAKES SENSE.

21 AND SO ON BEHALF OF ALL MY COLLEAGUES ON THIS
22 TASK FORCE, I WANT TO THANK ALL OF YOU IN THE PUBLIC
23 FOR YOUR IMPORTANT CONTRIBUTIONS TO THIS POLICY AT THIS
24 STAGE.

25 DR. WRIGHT: THANK YOU VERY MUCH.

1 CHAIRMAN PENHOET: JOHN SIMPSON ASKS IF WE
2 COULD RECAP QUICKLY WHAT WE HAVE DECIDED TODAY. I'D BE
3 HAPPY TO DO THAT IF YOU GUYS WANT TO BEAR WITH ME FOR A
4 LITTLE BIT LONGER. BUT I THINK THERE'S NO MORE
5 BUSINESS OF THIS COMMITTEE, SO IF WE WANT TO MOTION TO
6 ADJOURN THE TASK FORCE MEETING, WE COULD ENTERTAIN THAT
7 MOTION, AND PEOPLE COULD GO OFF AND DO OTHER THINGS
8 FROM THE TASK FORCE IF THEY WISH TO.

9 DR. BRYANT: SO MOVED.

10 DR. WRIGHT: SO MOVED.

11 DR. FONTANA: SO MOVED, BUT I JUST WANT TO
12 GIVE THANKS AND APPRECIATION TO BOTH SCOTT AND MARY AND
13 YOU, ED, FOR A JOB EXTREMELY WELL DONE.

14 (APPLAUSE.)

15 CHAIRMAN PENHOET: ESPECIALLY THOSE TWO.
16 OKAY. SO THE MEETING IS ADJOURNED, BUT I WILL NOW JUST
17 REVIEW FOR EVERYONE WHO WISHES TO STAY WHAT I THINK WE
18 DECIDED TODAY.

19 NO. 1, WITH RESPECT TO REVENUE SHARING, WE
20 HAVE LEFT THE POLICY AS IS.

21 WITH RESPECT TO THE RESEARCH USE EXEMPTION,
22 WE HAVE REMOVED THE RESEARCH USE EXEMPTION FROM THE APA
23 REGULATIONS.

24 WITH RESPECT TO MARCH-IN RIGHTS, WE HAVE LEFT
25 THE MARCH-IN RIGHTS INTACT AS THEY WERE DRAFTED.

1 WITH RESPECT TO DEFINING THE CRITERIA FOR
2 FAILURE TO KEEP LICENSED INVENTION AVAILABLE TO THE
3 PUBLIC FOR RESEARCH PURPOSES, IT WAS PART OF THE BELT
4 AND SUSPENDERS, WE HAVE MAINTAINED IT AS WRITTEN.

5 ITEM 5, THE PLAN FOR ACCESS HAS BEEN MODIFIED
6 IN ONE WAY. THE PLAN FOR ACCESS, INCLUDING THE PRICING
7 PROVISIONS, WERE MODIFIED, THAT A LICENSEE WILL HAVE A
8 PLAN IN PLACE BEFORE THE PRODUCT IS COMMERCIALIZED. SO
9 THE TIME IS NOW -- THERE IS A DISTINCT TERMINUS OF THAT
10 TIME, WHICH IS COMMERCIALIZATION DATE, WHATEVER THAT
11 IS, THAT HAS TO BE BEFORE THAT.

12 AND THAT WE HAVE KEPT THE LANGUAGE AS IS WITH
13 RESPECT TO MEDICAID PRICING, BUT WE DID AGREE TO DO
14 SOME FURTHER ANALYSIS OF THE MOST FAVORED NATION
15 PROVISIONS AND TO SEE WHETHER THE UNINTENDED
16 CONSEQUENCE OF WHAT WE MIGHT DO DIFFERENTLY WITH
17 RESPECT TO THIS WOULD BE TO TRIP A NATIONWIDE PROBLEM.

18 WITH RESPECT TO OPEN ACCESS, WE HAVE DECIDED
19 NOT TO INCLUDE IT IN THESE APA REGULATIONS, BUT TO
20 BRING IT TO THE ICOC BOARD FOR A DISCUSSION AND,
21 THEREFORE, HAVE A SPECIAL GROUP TO LOOK INTO THE ISSUE
22 OF OPEN ACCESS WITH THE POSSIBILITY THAT IT COULD BE
23 MADE A REGULATION AT A LATER DATE. IT COULD BE A
24 STANDALONE REGULATION UNDER THOSE CIRCUMSTANCES.

25 WITH RESPECT TO PATENT POOL, WE HAVE DECIDED

1 TO REFER OR DEFER, IN A WAY, TO THE LEGISLATIVE
2 SUBCOMMITTEE OF THE ICOC THIS ISSUE TO WORK WITH THE
3 LEGISLATURE TO CONTINUE TO DEVELOP THE STATE
4 REGULATIONS, ETC., IN THIS REGARD.

5 WITH RESPECT TO THE ATTORNEY GENERAL, WE
6 BELIEVE THAT WE ARE NOT IN A POSITION WHERE WE SHOULD
7 DICTATE TO THE ATTORNEY GENERAL WHAT THEY DO AND DON'T
8 DO, BUT THEY HAVE THE RIGHT UNDER THE LAW TO ENFORCE
9 APA REGULATIONS. SO IT WOULD BE REDUNDANT ON OUR PART
10 TO MAKE SUCH A REQUIREMENT.

11 THE DEFINITION OF A RESEARCH INSTITUTION IS
12 NOW LESS IMPORTANT, BUT WILL BE SOMEWHAT MORE CLARIFIED
13 BECAUSE A LOT OF THIS DEALT WITH THE RESEARCH USE
14 EXEMPTION, WHICH IS NO LONGER IN EXISTENCE.

15 THE RECIPROCAL SHARING IS SOMETHING THAT WE
16 WILL STRENGTHEN IN OUR EXHORTATION IN THE POLICY, THAT
17 PEOPLE BE GOOD CITIZENS.

18 AND WE HAVE REJECTED THE THREE PROPOSALS FOR
19 BUTTRESSING THE EXCLUSIVE LICENSING PROVISIONS.

20 SO THAT'S YOUR CHAIRMAN'S PERSPECTIVE ON WHAT
21 WE DID TODAY. IF I MISSED ANYTHING, PLEASE LET ME
22 KNOW.

23 (APPLAUSE.)

24 DR. WRIGHT: NICELY DONE. THANK YOU SO MUCH.

25 CHAIRMAN PENHOET: OKAY. JOHN SIMPSON HAS

1 RECOMMENDED THAT WE PUT SOME --

2 (RECORDING THEN ENDED AND THE MEETING WAS CONCLUDED.)

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REPORTER'S CERTIFICATE

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

SACRAMENTO CONVENTION CENTER
1400 J STREET
ROOM 104 AND 105
SACRAMENTO, CALIFORNIA
ON
JULY 14, 2006

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE TRANSCRIBED BY ME TO THE BEST OF MY ABILITY TO HEAR AND UNDERSTAND THE RECORDING. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
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