

BEFORE THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
IP TASK FORCE SUBCOMMITTEE OF THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
REGULAR MEETING

DATE: MONDAY, JANUARY 23, 2006  
1 P.M.

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

BRS FILE NO. : 74432

LOCATIONS: STANFORD UNIVERSITY  
CLARK CENTER, ROOM S362  
318 CAMPUS DRIVE  
STANFORD, CALIFORNIA

UNIVERSITY OF CALIFORNIA, LOS ANGELES  
ROOM 17-187 CHS  
10833 LE CONTE AVENUE  
LOS ANGELES, CALIFORNIA

SUTTER MEDICAL PLAZA  
8170 LAGUNA BOULEVARD  
CLASSROOM 2  
ELK GROVE, CALIFORNIA

THE CARLYLE  
35 EAST 76TH STREET  
NEW YORK, NEW YORK

I N D E X

	PAGE NO.
CALL TO ORDER	3
ROLL CALL	3
CONSIDERATION OF DRAFT IP POLICY	5
ADJOURNMENT	153

1 MONDAY, JANUARY 23, 2006

2

3 CHAIRMAN PENHOET: THE APPOINTED HOUR HAS  
4 ARRIVED, SO WE WILL CALL THE MEETING TO ORDER AND ASK  
5 MELISSA TO CONDUCT A ROLL CALL.

6 MS. KING: SUSAN BRYANT.

7 UNIDENTIFIED SPEAKER: IRVINE IS HERE. DR.  
8 BRYANT WILL BE JOINING.

9 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.

10 MS. LANSING: HERE.

11 MS. KING: TED LOVE. ED PENHOET.

12 CHAIRMAN PENHOET: HERE.

13 MS. KING: PHIL PIZZO. ON HIS WAY, I'M SURE.  
14 FRANCISCO PRIETO. I KNOW THAT DR. PRIETO IS JOINING BY  
15 PHONE PROBABLY REAL SOON. JEANNIE FONTANA FOR JOHN  
16 REED. JEFF SHEEHY.

17 MR. SHEEHY: HERE.

18 MS. KING: OS STEWARD AND JANET WRIGHT.

19 DR. WRIGHT: HERE.

20 CHAIRMAN PENHOET: WELL, AT THE MOMENT WE  
21 DON'T HAVE A QUORUM; HOWEVER, WE WILL AND WE CAN GO  
22 FORWARD WITH THE AGENDA FOR TODAY. COUPLE OF GROUND  
23 RULES. WE ARE HERE TO CONSIDER A DRAFT IP POLICY AS  
24 THIS TASK FORCE HAS BEEN CHARGED WITH DEVELOPING A  
25 DRAFT POLICY TO PRESENT TO THE WHOLE ICOC BOARD. THIS

1 IS THE THIRD MEETING OF OUR TASK FORCE. WE MET IN  
2 OCTOBER; WE MET IN NOVEMBER; AND WE'RE HAVING THIS  
3 MEETING TODAY IN JANUARY.

4 IN CONSIDERATION OF THE CONSIDERABLE WORK  
5 THAT SOME OF YOU IN THE AUDIENCE HAVE DONE ON THIS  
6 ISSUE, WE HAVE DECIDED TO EXPAND THE TIME FOR PUBLIC  
7 COMMENT TO TEN MINUTES FROM THE USUAL THREE MINUTES, SO  
8 WE WOULD BE DELIGHTED TO ALLOW THOSE OF YOU WHO WISH TO  
9 SPEAK FOR UP TO TEN MINUTES ON THE ISSUES THAT WE'RE  
10 DOING TODAY, WE'D BE HAPPY TO HEAR FROM YOU IN AN  
11 EXTENDED PUBLIC COMMENT PERIOD.

12 SINCE WE'VE HAD TWO MEETINGS AND ACTUALLY THE  
13 MATTERS BEFORE US TODAY WERE CONSIDERED AT THE LAST  
14 ICOC BOARD MEETING, I THOUGHT IT WOULD BE USEFUL FOR US  
15 TO REVIEW WHERE WE ARE BEFORE WE START THE MEETING  
16 TODAY. I HOPE ALL OF YOU HAVE A COPY OF THE DRAFT IP  
17 POLICY IN FRONT OF YOU. AND THE MAJOR FOCUS OF TODAY  
18 IS ACTUALLY TWO THINGS. THE MOST IMPORTANT PART IS TO  
19 FOCUS ON SECTION II OF THIS DOCUMENT BECAUSE SECTION II  
20 ON APPROVAL BY THE FULL ICOC BOARD AND ITS MORPHING, IF  
21 YOU WILL, INTO EVENTUAL APA REGULATION WILL BECOME  
22 EFFECTIVELY STATE LAW, SO WE THINK THAT'S THE MOST  
23 IMPORTANT PART OF THIS.

24 MUCH OF THE REST WILL BE POLICY WHICH IS NOT  
25 GOING TO PART OF STATE LAW, BUT WILL ESSENTIALLY SET

1 BACKGROUND FOR PEOPLE WHO WORK IN THIS FIELD SO THAT  
2 THEY UNDERSTAND WHAT THE POLICIES ARE OF ICOC GOING  
3 FORWARD. AND SO IF ANYBODY IN THE AUDIENCE WOULD LIKE  
4 A COPY OF THIS DOCUMENT, IT IS AVAILABLE. IF ANY OF  
5 YOU WOULD LIKE COPY OF THE DOCUMENT PUT TOGETHER BY THE  
6 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS, YOU'RE  
7 WELCOME TO TAKE ONE.

8 MS. KING: WHO JUST JOINED US, PLEASE?

9 UNIDENTIFIED SPEAKER: IT'S LOS ANGELES.  
10 JEANNIE FONTANA IS ON HER WAY DOWN THE HALL RIGHT NOW.

11 MS. KING: THANK YOU.

12 CHAIRMAN PENHOET: IF WE CAN START PERHAPS  
13 WITH A FEW COMMENTS BY SCOTT TOCHER. SCOTT IS AN  
14 ATTORNEY WORKING WITH CIRM. THOSE COMMENTS REALLY  
15 RELATE TO THE APA PROCESS, AND WE'RE LOOKING FORWARD TO  
16 THE DAY WHEN THE ITEMS CONTAINED HERE IN SECTION II  
17 BECOMES --

18 DR. FONTANA: HI, EVERYBODY. I'M HERE.

19 CHAIRMAN PENHOET: THANK YOU. -- STATE LAW.  
20 SCOTT CAN GIVE US A LITTLE BRIEFING ON THAT WHAT MEANS.  
21 SCOTT.

22 MR. TOCHER: AGAIN, MY NAME IS SCOTT TOCHER.  
23 I'M WITH CIRM AND THEIR LEGAL STAFF. AND I KNOW THAT  
24 THE TASK FORCE HAD A PRESENTATION BACK IN NOVEMBER, A  
25 MUCH MORE DETAILED PRESENTATION, AND DISCUSSED THE

1 RULES THAT ARE APPLICABLE BY VIRTUE OF THE  
2 ADMINISTRATIVE PROCEDURES ACT THAT GOVERN THE ADOPTION  
3 BY STATE AGENCIES OF RULES AND REGULATIONS THAT ARE  
4 APPLIED TO THE PUBLIC AND WILL BE A PART OF THE  
5 INTELLECTUAL PROPERTY COMPONENTS OF THE CIRM POLICY.  
6 BUT STAFF THOUGHT IT MIGHT BE GOOD JUST TO SPEND MAYBE  
7 THREE, FOUR MINUTES JUST REITERATING THE BASIC  
8 PRINCIPLES NOW THAT EVERYONE HAS IN FRONT OF THEM THE  
9 CONCEPT OF AN ACTUAL HARD AND CONCRETE PROPOSAL.

10 SO I THOUGHT I WOULD JUST FIRST BEGIN BY  
11 SHOWING YOU THAT TO EMPHASIZE THE POINT THAT EVENTUALLY  
12 A REGULATION THAT'S DULY ADOPTED BY A STATE AGENCY  
13 PURSUANT TO THE ADMINISTRATIVE PROCEDURES ACT HAS THE  
14 SAME FORCE AND EFFECT AS ANY SORT OF LAW THAT MIGHT  
15 OTHERWISE APPLY TO ANY GIVEN CONCEPT. SO ANYTHING  
16 PASSED BY THE LEGISLATURE AND A REGULATION THAT'S DULY  
17 ADOPTED BY A STATE AGENCY HAS THE SAME FORCE AND EFFECT  
18 AS LAW. SO WHEN YOU LOOK AT THE LANGUAGE IN SECTION 11  
19 OF THE TERMS AND CONDITIONS OF THE IP POLICY, YOU HAVE  
20 TO KEEP IN MIND EVENTUALLY THAT THOSE WILL HAVE, IF  
21 THEY'RE DULY ADOPTED, THE SAME FORCE AND EFFECT AS IF  
22 THEY WERE PASSED BY THE LEGISLATURE.

23 I'LL GET TO IN A MOMENT THIS SECTION HERE OF  
24 AN UNDERGROUND REGULATION, SOMETHING WE WANT TO AVOID.

25 IT'S PROBABLY HELPFUL TO KEEP IN MIND THE

1 STANDARD, THEN, BETWEEN WHAT IS A REGULATION AND WHAT  
2 ISN'T. THE LANGUAGE HERE IS FROM THE GOVERNMENT CODE,  
3 BUT ESSENTIALLY IF YOU THINK OF A REGULATION  
4 ESSENTIALLY --

5 MS. KING: WHO JUST JOINED?

6 DR. PRIETO: MELISSA, THIS IS FRANCISCO  
7 PRIETO UP IN SACRAMENTO. I'M HERE WITH JIM WASSERMAN  
8 FROM THE SACRAMENTO BEE.

9 MS. KING: THANK YOU, DR. PRIETO. WE'RE  
10 RIGHT IN THE MIDDLE OF A PRESENTATION BY SCOTT TOCHER,  
11 AN ATTORNEY WORKING WITH THE CIRM ON THE APA PROCESS.

12 DR. PRIETO: OKAY. I HAVE THE MATERIAL THAT  
13 JENNIFER SENT THIS MORNING ABOUT THAT.

14 MR. TOCHER: SO ESSENTIALLY THE ELEMENTS ARE  
15 ESSENTIALLY EVERY RULE THAT IS ADOPTED BY A STATE  
16 AGENCY THAT INTERPRETS OR ENFORCES THE LAW THAT IS  
17 ADMINISTERED BY THE AGENCY. BASICALLY WHAT THAT MEANS  
18 IS IF THERE IS GOING TO BE A REQUIREMENT ON A GRANTEE  
19 THAT IT DO SOMETHING, THE FAILURE TO COMPLY, WHICH  
20 WOULD RESULT IN EITHER NOT RECEIVING THE GRANT OR  
21 HAVING SOME CORRECTIVE ACTION TAKEN BY THE AGENCY, THEN  
22 THAT IS ESSENTIALLY A RULE THAT MUST BE FOLLOWED BY ALL  
23 GRANTEES. THEREFORE, SUCH A RULE MUST BE IN PLACE,  
24 MUST BE EXPLICIT, AND IT MUST BE ADOPTED PURSUANT TO  
25 THE PROCEDURES OF THE APA.

1 THE APA REQUIRES THAT THE AGENCY PUBLISH THE  
2 PROPOSED REGULATION IN ADVANCE AND ALLOW A MINIMUM OF  
3 45 DAYS OF PUBLIC COMMENT BEFORE THE REGULATIONS ARE  
4 ADOPTED. NOW, WE'RE IN A PRELIMINARY PHASE RIGHT NOW.  
5 WE'RE RECEIVING PUBLIC INPUT, LETTING THE IP TASK FORCE  
6 DO ITS WORK ON ASSEMBLING A DRAFT.

7 WHAT WE'LL BE MOVING TOWARDS IS -- WHAT WE'LL  
8 BE MOVING TOWARDS IS A POLICY THAT WILL, ONCE ADOPTED  
9 BY THE ICOC IN FEBRUARY, IF THEY SAY, OKAY, WE'RE GOING  
10 TO GO FORWARD WITH THESE POLICIES THAT HAVE BEEN  
11 RECOMMENDED TO US, THAT WILL START A 270-DAY TIME FRAME  
12 DURING WHICH WE WILL TAKE THOSE SECTION II POLICIES,  
13 PUT THEM IN FORMAL REGULATORY LANGUAGE, AND BEGIN THE  
14 APA PROCESS. SO WE WILL HAVE TO HAVE THAT COMPLETED BY  
15 NOVEMBER 7TH IF THEY ARE ADOPTED FEBRUARY 10TH. AND  
16 THAT IS A SPECIAL PROCEDURE THAT IS SET FORTH IN THE  
17 STEM CELL ACT THAT ALLOWS THE AGENCY TO ADOPT  
18 REGULATIONS ON AN EMERGENCY BASIS FOR 270 DAYS.

19 ONE OF THE THINGS TO UNDERSCORE IN ADOPTING  
20 THE REGULATIONS IS TO MAKE THE DIFFERENCE BETWEEN  
21 SOMETHING THAT IS A GUIDELINE OR A POLICY VERSUS  
22 SOMETHING WHICH IS A HARD AND FAST RULE BECAUSE ONE  
23 WANTS TO MAKE SURE THAT ANY RULES, ANY REQUIREMENTS OF  
24 THE APA GRANT -- EXCUSE ME -- OF THE IP GRANTS POLICY  
25 MUST BE CONTAINED AND EXPLICITLY SO IN THE REGULATION.



1 SO THINGS THAT ARE CONTAINED IN THIS DOCUMENT IN  
2 SECTION I AND SECTION III, WHICH FORM THE BACKGROUND,  
3 WILL PROVIDE CONCEPTS TO THE RULES WHICH ARE SET FORTH  
4 IN SECTION II. THOSE CANNOT SUPPLEMENT, THEY CANNOT  
5 ADD TO OR BE DIFFERENT FROM WHAT THE RULES ARE IN THAT  
6 SECTION II. SO SECTION II REALLY MUST CONTAIN THE  
7 UNIVERSE OF RULES THAT MUST APPLY. OTHERWISE IT  
8 BECOMES WHAT THAT BOX IN THAT OTHER SLIDE SHOWED, WHICH  
9 IS AN UNDERGROUND REGULATION. AND THAT WOULD BE A  
10 POLICY OR RULE THAT AN AGENCY ENDS UP ENFORCING OR  
11 APPLYING, BUT ACTUALLY IS SPELLED OUT IN THOSE FORMAL  
12 REGULATIONS.

13 SO SECTION I AND III WILL PROVIDE SORT OF A  
14 CONTEXT FOR DISCUSSION HERE TODAY, EVEN IN FEBRUARY,  
15 WHEN THE ICOC TAKES UP THE ITEM, BUT EVENTUALLY THAT  
16 WILL BE STRIPPED AWAY AND THE REGULATIONS WILL CONTAIN  
17 ONLY THE RULES THAT ARE IN SECTION II.

18 SO FINALLY, WHAT THAT ALSO MEANS IS, FIRST OF  
19 ALL, YOU WANT TO MAKE SURE THAT YOUR RULES ARE  
20 CONTAINED IN THAT SECTION II BUT, SECONDLY, YOU WANT TO  
21 MAKE SURE THAT YOU'RE DILIGENT ABOUT GETTING IT KIND OF  
22 RIGHT THE FIRST TIME BECAUSE ANY TIME YOU WANT TO  
23 CHANGE ANYTHING, YOU ARE GOING TO HAVE TO GO THROUGH  
24 THE APA PROCESS OF SENDING OUT A NOTICE, 45 DAYS,  
25 RECEIVING PUBLIC INPUT TO CHANGE THE TERMS OR CHANGE

1 ANY SPECIFICS WITHIN THOSE REGULATIONS ONCE THEY'RE  
2 DULY ADOPTED. ANY QUESTIONS?

3 DR. PRIETO: I HAVE A QUESTION. UNDER THESE  
4 INTERIM RULES, THEN, IS IT UNIQUE TO THE CIRM, OR IS  
5 THIS STANDARD OPERATING PROCEDURE IN CALIFORNIA, THAT  
6 INTERIM REGULATIONS GO INTO EFFECT DURING THE PUBLIC  
7 COMMENT PERIOD?

8 MR. TOCHER: IT'S ACTUALLY NOT UNIQUE.  
9 THERE'S A SEPARATE PROCEDURE SET UP IN THE  
10 ADMINISTRATIVE PROCEDURES ACT THAT ALLOWS STATE  
11 AGENCIES TO ADOPT REGULATIONS ON AN EMERGENCY BASIS  
12 WITHOUT THE TYPICAL ADVANCE NOTICE THAT IS REQUIRED.  
13 AS IN THE CIRM OR STEM CELL ACT PROVISIONS, THOSE  
14 EXPIRE AUTOMATICALLY, JUST AS CIRM'S WOULD, HOWEVER,  
15 THEY EXPIRE IN A SHORTER TIME FRAME OF ABOUT 120 DAYS.  
16 AND THAT IS AN ACKNOWLEDGEMENT THAT THERE ARE CERTAIN  
17 CIRCUMSTANCES THAT AGENCIES FACE WHERE RULES NEED TO BE  
18 ADOPTED, THE PUBLIC NEEDS GUIDANCE; AND WHILE IT HAS  
19 THAT EMERGENCY SYSTEM IN PLACE, THE STATE AGENCY GOES  
20 ABOUT COMPLYING WITH THE FORMAL RULES OF ADOPTION IN  
21 ORDER TO PUT SOMETHING PERMANENTLY IN PLACE.

22 DR. PRIETO: A FOLLOW-UP THEN. THIS MAY BE  
23 SEMANTICS, BUT ASSUMING THE ICOC ADOPTS THIS WITH  
24 WHATEVER CHANGES WE RECOMMEND TODAY AT THE FEBRUARY  
25 10TH MEETING, ARE WE CALLING THESE INTERIM REGULATIONS

1 OR EMERGENCY REGULATIONS?

2 MR. TOCHER: WELL, THE ACT USES THE TERM  
3 "INTERIM," SO THAT WOULD BE THE PHRASE THAT WE WOULD  
4 USE, BUT THE EFFECT IS THE SAME. ONCE THEY'RE ADOPTED  
5 BY THE BOARD, THEY ARE IN EFFECT FOR 270 DAYS UNLESS  
6 AND UNTIL THE ICOC ADOPTS SOMETHING PERMANENTLY  
7 PURSUANT TO THE APA.

8 DR. PRIETO: OKAY.

9 CHAIRMAN PENHOET: ANYBODY IN THE AUDIENCE  
10 HAVE A QUESTION? OKAY. WE'LL MOVE ALONG THEN.  
11 MELISSA, IF WE CAN GO TO OUR PRESENTATION.

12 MS. KING: WHILE I'M DOING THAT, IF I COULD  
13 ASK EVERYBODY WHO'S ON THE PHONE, WE ALSO HAVE OUR  
14 TRANSCRIBER, BETH DRAIN, ON THE PHONE, AND IF YOU  
15 COULD, FOR HER PURPOSES, PLEASE STATE YOUR NAME WHEN  
16 YOU'RE ABOUT TO SPEAK, ESPECIALLY A MEMBER OF THE  
17 PUBLIC. THAT WOULD BE GREAT IF YOU COULD IDENTIFY  
18 YOURSELF. THANK YOU.

19 CHAIRMAN PENHOET: WHILE SHE'S DOING THAT,  
20 LET ME THANK ALL OF THE GROUPS WHICH HAVE HELPED US TO  
21 GET TO THIS POINT WHERE WE ARE TODAY, BUT CALIFORNIA  
22 COMMISSION ON SCIENCE AND TECHNOLOGY HAS PRODUCED A  
23 PRELIMINARY REPORT.

24 MS. KING: WE'RE LIVE AND I CAN FLIP THE  
25 SLIDES WHEN READY.

1 CHAIRMAN PENHOET: MARY MAXON HAS DONE A  
2 YEOMAN'S JOB OF PULLING TOGETHER HUNDREDS OF DOCUMENTS  
3 FROM AROUND THE COUNTRY AND AROUND THE STATE AS  
4 BACKGROUND READING FOR THIS MATERIAL. SO ALL OF THE  
5 MEMBERS OF THIS TASK FORCE HAVE READ A LOT OF IT AND  
6 DIGESTED IT AND ARE CONTRIBUTING GREATLY TO WHAT WE'RE  
7 HERE TO DISCUSS TODAY.

8 SO TO BEGIN, I JUST WANT TO RETURN, JUST  
9 REVIEW THE WORK THAT HAS LED US TO WHERE WE ARE TODAY.  
10 THE FIRST IS THAT IN THE FIRST TWO MEETINGS, WE  
11 ARTICULATED WHAT WE THOUGHT WERE THE KEY ISSUES THAT  
12 SHOULD GUIDE THE IP DISCUSSION. AND THOSE ARE THE FIVE  
13 ISSUES THAT ARE INDICATED HERE ON THIS SLIDE.

14 FIRST OF ALL, WHO SHOULD OWN ANY INVENTIONS  
15 THAT MAY ARISE FROM CIRM FUNDING? THE SECOND BEING HOW  
16 SHALL CIRM REQUIRE THE SHARING OF DATA, TOOLS,  
17 TECHNOLOGY, AND INTELLECTUAL PROPERTY? THIRD IS SHOULD  
18 CIRM CREATE A RESEARCH EXEMPTION FOR THE USE OF  
19 INTELLECTUAL PROPERTY FOR BASIC RESEARCH PURPOSES?  
20 FOUR, WHAT LICENSING REQUIREMENTS SHOULD BE ADOPTED BY  
21 CIRM GRANTEES? AND THEN FINALLY, SHOULD CIRM RETAIN  
22 MARCH-IN RIGHTS, WHICH ARE A SET OF RIGHTS THAT ALLOW  
23 THE GOVERNMENT, IN THIS CASE STATE GOVERNMENT, TO  
24 INTERVENE IF THE INTELLECTUAL PROPERTY AND ITS LICENSEE  
25 IS NOT BEING PROPERLY UTILIZED?

1                   SO WE DID DISCUSS AT THE LAST ICOC MEETING  
2       THESE QUESTIONS AND ARRIVED AT A SERIES OF PRELIMINARY  
3       GUIDELINES AT THAT MEETING, WHICH ARE SHOWN IN THE NEXT  
4       SLIDE. SO WITH RESPECT TO OWNERSHIP, WE CONCLUDED, FOR  
5       A NUMBER OF DIFFERENT REASONS, THAT -- AND I WOULD  
6       REMIND YOU TODAY WE ARE HERE DISCUSSING GRANTS TO  
7       NONPROFIT ORGANIZATIONS ONLY. SO THIS DISCUSSION  
8       DOESN'T HAVE ANYTHING TO DO WITH WHAT OUR POLICY WILL  
9       BE FOR A PROFIT-MAKING ORGANIZATION WHO BENEFIT FROM  
10      CIRM FUNDING. FOR NON-PROFITS, WE AGREED THAT THE  
11      PROFIT -- THAT THE GRANTEE ORGANIZATIONS THEMSELVES  
12      SHOULD OWN THE RIGHTS TO INTELLECTUAL PROPERTY CREATED  
13      DURING THE PERIOD SUPPORTED BY A CIRM GRANT.

14                   SECOND ISSUE WITH RESPECT TO SHARING IS THAT  
15      CIRM WILL STRONGLY SUPPORT A BROAD SHARING POLICY, THAT  
16      WE EXPECT GRANTEES TO SHARE DATA AND BIOMEDICAL  
17      MATERIALS WIDELY AND BEYOND CURRENT PRACTICES.

18                   THE THIRD IS THAT CIRM WILL CREATE A RESEARCH  
19      EXEMPTION TO ALLOW THE USE OF PATENTED CIRM-FUNDED  
20      DISCOVERIES FOR RESEARCH PURPOSES BY CIRM GRANTEES.

21                   THE LAST TWO, I WOULD SAY, BOTH GO  
22      SIGNIFICANTLY FURTHER THAN THE FEDERAL GOVERNMENT GOES  
23      TODAY IN THIS AREA OF SHARING EITHER NONPATENTED OR  
24      PATENTED TECHNOLOGIES FOR RESEARCH PURPOSES.

25                   UNDER LICENSING THE BOARD CONCLUDED THAT CIRM

1 SHOULD ENCOURAGE THE COMMERCIALIZATION OF CIRM-FUNDED  
2 DISCOVERIES. AND IN LICENSING ACTIVITIES, THAT CIRM  
3 WOULD REQUIRE THAT, ALL OTHER THINGS BEING EQUAL,  
4 PREFERENCE BE GIVEN TO COMPANIES WITH PLANS FOR ACCESS  
5 TO RESULTANT THERAPIES FOR UNDERSERVED PATIENT  
6 POPULATIONS. IN ADDITION, CIRM WOULD STRONGLY  
7 ENCOURAGE THE PRACTICE OF NONEXCLUSIVE LICENSING WHEN  
8 POSSIBLE.

9 THE SECOND BULLET POINT, CIRM MAY REQUIRE  
10 THAT A PORTION OF THE GRANTEE ORGANIZATION'S SHARE OF  
11 LICENSING FEES AND ROYALTIES BENEFIT THE STATE OF  
12 CALIFORNIA.

13 AND THEN FINALLY, UNDER MARCH-IN RIGHTS, THAT  
14 CIRM WOULD RETAIN MARCH-IN RIGHTS IN THE EVENT OF  
15 FAILURE TO DEVELOP OR FOR PUBLIC HEALTH OR SAFETY  
16 REASONS.

17 SO THESE WERE THE ANSWERS TO THE FIVE  
18 QUESTIONS POSED TO THE FULL ICOC BOARD AT ITS LAST  
19 MEETING IN DECEMBER, AND IT'S ON THE BASIS OF THESE  
20 ANSWERS TO THOSE FIVE THINGS THAT WE HAVE GENERATED THE  
21 POLICY IN SECTION II THAT WE'RE HERE TO DISCUSS TODAY.

22 SO WE NOW HAVE -- THE DOCUMENT THAT YOU HAVE  
23 IN FRONT OF YOU IS ORGANIZED IN THREE SECTIONS.  
24 SECTION I IS GENERAL INFORMATION ABOUT IP POLICY.  
25 SECTION II IS THE SECTION, AS I SAID BEFORE,

1 INTELLECTUAL PROPERTY TERMS AND CONDITIONS. WHATEVER  
2 WE DECIDE HERE WILL BE TURNED INTO EFFECTIVELY STATE  
3 LAW UNDER THE REGULATIONS IN THE PROCESS THAT SCOTT  
4 TOCHER JUST DESCRIBED TO YOU.

5 THE THIRD IS INTELLECTUAL PROPERTY POLICY,  
6 WHICH IS A BROADER DOCUMENT AND MEANT TO SUPPLEMENT  
7 SECTION II, BUT NOT ALL OF WHICH WOULD BE TRANSLATED  
8 INTO STATE LAW. THE POLICIES ARE WORDED IN THINGS LIKE  
9 ENCOURAGE AND THINGS LIKE THAT, BUT SECTION II IS  
10 REALLY THE HEART OF WHAT WE'RE SEEKING TO RESOLVE TODAY  
11 BECAUSE IT IS SOMETHING THAT THE ICOC AS A WHOLE WILL  
12 CONSIDER IN ITS FEBRUARY 10TH MEETING AND WITHIN 270  
13 DAYS WILL BE CODIFIED AS REGULATIONS PURSUANT TO THE  
14 PROCESS SCOTT OUTLINED FOR YOU.

15 SO WE WANT TO BEGIN TODAY'S MEETING BY  
16 FOCUSING DIRECTLY ON SECTION II. WE THINK, OBVIOUSLY,  
17 IT'S THE MOST IMPORTANT PART OF THE MEETING. AND  
18 SECTION II IS REALLY DIVIDED INTO THREE PARTS HERE. AS  
19 YOU SEE IN THE DOCUMENT, THE INVENTION REPORTING  
20 REQUIREMENTS, THE NOTION OF SHARING OF CIRM-FUNDED  
21 INTELLECTUAL PROPERTY, AND MARCH-IN RIGHTS. SECTION  
22 II, FOR THOSE OF YOU WHO HAVE THE DOCUMENT IN FRONT OF  
23 YOU, BEGINS ON PAGE 14 OF YOUR DOCUMENT.

24 I THINK WE'LL DIVE RIGHT INTO THIS AND  
25 DISCUSS THE VARIOUS PIECES AND PARTS OF THIS AS WE GO

1 THROUGH THE DOCUMENT. SO IF WE CAN HAVE THE FIRST  
2 UNDER G, THE REPORTING REQUIREMENTS. GRANTEE  
3 ORGANIZATIONS ARE REQUIRED -- I MIGHT REMIND EVERYBODY  
4 GRANTEE ORGANIZATIONS MEAN ORGANIZATIONS WHICH ARE DULY  
5 ORGANIZED TO CARRY OUT RESEARCH IN CALIFORNIA. SO ALL  
6 OF THESE FUNDS WILL BE DIRECTED TOWARDS CALIFORNIA  
7 ORGANIZATIONS.

8 THEY ARE REQUIRED TO HAVE WRITTEN AGREEMENTS  
9 WITH RESEARCHERS, REQUIRING DISCLOSURE OF INVENTIONS  
10 MADE IN THE PERFORMANCE OF CIRM-FUNDED RESEARCH.

11 SECOND, THAT GRANTEE ORGANIZATIONS MUST  
12 NOTIFY CIRM ANNUALLY OF ALL RELEVANT INVENTION  
13 DISCLOSURES THROUGH THE USE OF THE CIRM INVENTION  
14 DISCLOSURE. THIS WILL BE A COMMON FORM TO ALL OF OUR  
15 GRANTEES, WHICH WILL BE RECEIVED IN CONFIDENCE BY CIRM.  
16 THE INVENTION DISCLOSURE FORM SHALL IDENTIFY THE GRANT  
17 UNDER WHICH THE INVENTION WAS MADE AND THE INVENTORS.  
18 THAT'S THE PERSONS WHO CARRIED OUT THE INVENTIVE ACT.  
19 IT SHALL BE SUFFICIENTLY COMPLETE IN TECHNICAL DETAIL  
20 TO CONVEY A CLEARING UNDERSTANDING, TO THE EXTENT KNOWN  
21 AT THE TIME OF DISCLOSURE, OF THE NATURE, PURPOSE,  
22 OPERATION, AND PHYSICAL, CHEMICAL, OR BIOLOGICAL OR  
23 ELECTRICAL CHARACTERISTICS OF THE INVENTION.  
24 DISCLOSURE SHALL ALSO IDENTIFY WHETHER A MANUSCRIPT  
25 DESCRIBING THE INVENTION HAS BEEN SUBMITTED FOR



1 PUBLICATION; AND IF SO, WHERE IT HAS BEEN ACCEPTED FOR  
2 PUBLICATION AT THE TIME OF DISCLOSURE.

3 SO THIS IS AN ANNUAL REQUIREMENT OF ALL  
4 GRANTEES. AS I SAY, THE REASON FOR CONFIDENTIALITY IN  
5 THIS CASE IS THAT THE WAY THE PATENT SYSTEM WORKS IS  
6 THAT THERE IS A PERIOD WHEN THE PATENTS -- OR THE  
7 INVENTION HAS BEEN MADE BEFORE THE PATENTS MIGHT HAVE  
8 BEEN PERFECTED. AND THERE'S A CORRESPONDING PERIOD FOR  
9 FILING FOR AN APPLICATION FOR PATENTS WHICH REQUIRED  
10 EXCLUSIVITY BECAUSE IF YOU DISCLOSE ALL THE INFORMATION  
11 UP FRONT, YOU WOULD LOSE YOUR ABILITY SOMETIMES TO  
12 PERFECT A PATENT IN SOME JURISDICTIONS. BUT ALL  
13 PATENTS END UP BEING PUBLISHED. IN THE CASE OF THE  
14 UNITED STATES, 18 MONTHS AFTER THE DATE OF FILING,  
15 PATENTS GET PUBLISHED AND ARE AVAILABLE TO THE GENERAL  
16 PUBLIC. SO THERE'S NO ATTEMPT HERE TO ESSENTIALLY MAKE  
17 SOMETHING A PRIVATE COMMUNICATION EXCEPT TO PROTECT THE  
18 ABILITY TO PERFECT THE PATENT.

19 SO THESE ARE THOSE FIRST TWO ITEMS. THE LAST  
20 HERE, THAT THEY MUST NOTIFY US ON AN ANNUAL BASIS  
21 REGARDING THE FILING OF PATENT APPLICATIONS THAT CLAIM  
22 INVENTIONS DEVELOPED BY CIRM-FUNDED RESEARCH, THAT THE  
23 ORGANIZATION MUST NOTIFY CIRM ON AN ANNUAL BASIS  
24 REGARDING EXECUTION OF ANY LICENSING AGREEMENTS OF  
25 INVENTIONS DEVELOPED IN THE PERFORMANCE OF CIRM-FUNDED

1 RESEARCH. AND THEN FINALLY, IF RELEVANT, GRANTEE  
2 ORGANIZATIONS MUST SUBMIT ANNUALLY THE INVENTION  
3 UTILIZATION REPORT THAT LISTS ALL CIRM-FUNDED  
4 INVENTIONS, PATENTS CLAIMING SUCH INVENTION, AND A  
5 STATEMENT OF EFFORTS MADE TO UTILIZE CIRM-FUNDED  
6 INVENTIONS. SUCH REPORTS SHALL INCLUDE INFORMATION  
7 ABOUT THE STATUS OF DEVELOPMENT, THE DATE OF FIRST  
8 COMMERCIAL SALE OR USE, AND THE ANNUAL SUM OF ANY  
9 LICENSING FEES AND/OR GROSS ROYALTIES RECEIVED BY THE  
10 GRANTEE ORGANIZATION UNDER THE LICENSES OF CIRM-FUNDED  
11 PATENTED INVENTIONS.

12 SO THOSE FIVE ITEMS CONSTITUTE THE TOTALITY  
13 OF THE REPORTING REQUIREMENTS UNDER THE INTELLECTUAL  
14 PROPERTY POLICY. BUT I THINK, RATHER THAN GO THROUGH  
15 THE ENTIRE DOCUMENT, WE WILL STOP AT THIS POINT AND  
16 HAVE SOME DISCUSSION ON THIS FIRST ITEM. YOU'VE ALL  
17 BEEN GIVEN COPIES OF THIS IN ADVANCE, SO I'LL ASK JEFF  
18 AND JANET HERE IN THE ROOM WHETHER EITHER OF YOU HAVE  
19 ANY COMMENTS ON THIS SECTION OF THE DOCUMENT.  
20 QUESTIONS?

21 MR. SHEEHY: THIS IS JEFF SHEEHY. THIS LOOKS  
22 GREAT TO ME SO FAR. I COMMEND MARY FOR THE TREMENDOUS  
23 WORK PULLING TOGETHER THE DOCUMENTS. IT DOESN'T -- THE  
24 ONLY THING THAT, ON AN ANNUAL BASIS SEEMS FINE WITH ME,  
25 BUT OTHERS MAY HAVE OPINIONS ON WHETHER THAT'S OFTEN

1 ENOUGH OR NOT. BUT I THINK THERE IS QUESTION ABOUT OUR  
2 ABILITY TO ABSORB INFORMATION AND WHETHER THERE'S ANY  
3 BENEFIT TO BE DERIVED FROM DOING THIS ON A MORE OFTEN  
4 BASIS THAN AN ANNUAL BASIS. BUT ANNUAL BASIS AT THIS  
5 POINT SEEMS FAIRLY REASONABLE TO ME, BUT THAT WOULD BE  
6 MY ONLY COMMENT.

7 CHAIRMAN PENHOET: IN ANSWER TO YOUR COMMENT,  
8 WHICH IS AN AREA THAT WE DID DO A FAIR AMOUNT OF  
9 CONSULTATION AND BACKGROUND WORK WITH, THE NIH REQUIRES  
10 GRANTEES TO GIVE INVENTION REPORTS WITHIN A CERTAIN  
11 PERIOD OF TIME AFTER THE INVENTION IS DISCLOSED,  
12 USUALLY THREE MONTHS, IF I REMEMBER CORRECTLY. THAT  
13 WOULD MAKE IT ON A MORE FREQUENT BASIS. BUT WE'RE TOLD  
14 IN PRACTICE THAT IT'S TURNED OUT TO BE IMPRACTICAL FOR  
15 PEOPLE TO DIGEST THE INFORMATION ON THE RECEIVING END  
16 OF THAT AND THAT AN ANNUAL REPORT REALLY IN THE SENSE,  
17 BECAUSE THE PATENTS DON'T GET PUBLISHED FOR 18 MONTHS  
18 AND HAS TO BE A CONFIDENTIAL REPORT, OTHERWISE YOU  
19 MIGHT IN SOME WAY -- DISCOURAGE IS NOT THE RIGHT WORD,  
20 BUT YOU MIGHT INTERFERE WITH THE PATENTING PROCESS, WE  
21 CAME TO THE CONCLUSION THAT IT WAS PROBABLY A MORE  
22 PRACTICAL APPROACH TO DO 12 MONTHS AND ON AN ANNUAL  
23 BASIS BECAUSE OTHER REPORTS WOULD ALSO BE DUE ON THE  
24 SAME BASIS. SO IT WAS, IN A SENSE, TRYING TO MAKE THE  
25 PROCESS TO SOME DEGREE SIMPLER FOR OUR GRANTEE

1 ORGANIZATIONS AND AT THE SAME TIME NOT COMPROMISE OUR  
2 ABILITY TO KEEP TRACK OF WHAT'S GOING ON IN THAT TIME  
3 PERIOD.

4 DR. PRIETO: JUST A QUESTION. DOES THE NIH  
5 OR ANY OF THE LARGER PUBLIC FOUNDATIONS THAT RETAIN  
6 MARCH-IN RIGHTS REQUIRE ANNUAL OR MORE OR LESS FREQUENT  
7 REPORTING? WHAT IS THE STANDARD HERE?

8 CHAIRMAN PENHOET: AS I SAID, NIH IS ACTUALLY  
9 TWO MONTHS, I'M REMINDED BY MARY. SO THAT'S MORE  
10 FREQUENT THAN WE'RE ASKING FOR HERE. AND OTHERS DO IT  
11 ON AN ANNUAL BASIS. THERE'S A MIX OF THESE THINGS.  
12 BUT WE HAVE LEARNED THAT ALTHOUGH NIH ASKS FOR IT EVERY  
13 TWO MONTHS, THEY TAKE ACTION ONLY SORT OF ON ANNUAL  
14 BASIS WHEN THEY PULL ALL THESE THINGS TOGETHER. SO WE  
15 THOUGHT THERE'S NO NEED TO IMPOSE A MORE FREQUENT  
16 DISCLOSURE, PARTICULARLY SINCE THE DISCLOSURE ITSELF  
17 WOULDN'T BE MADE PUBLIC UNTIL THE TIME WHEN THE PATENTS  
18 HAVE ACTUALLY BEEN FILED AND THE 18 MONTHS HAVE GONE  
19 BY. SO WE THOUGHT THIS WAS A GOOD COMPROMISE, BUT I  
20 DON'T THINK THERE'S ANY STANDARD PRACTICE, UNLESS YOU  
21 SAY WHAT NIH DOES FORMS THE STANDARD.

22 BUT WE HAVE BEEN INFORMED THAT IN PRACTICE  
23 THE NIH STANDARD DOESN'T HAVE A LOT OF MEANING BECAUSE  
24 THE NIH DOESN'T HAVE A GROUP OF PEOPLE AT WORK TO  
25 REVIEW THEM THAT FREQUENTLY THEMSELVES.

1 ANY OTHER QUESTIONS ABOUT THIS PART?

2 DR. FONTANA: IT'S JEANNIE FONTANA IN LOS  
3 ANGELES. WE HAVE SOME QUESTIONS TOO ABOUT THE TIME  
4 FRAME OF REPORTING. AND I GUESS REALLY WHAT WE WOULD  
5 LIKE TO SEE HAPPEN IS THAT THERE'S AN OPEN FORM OF  
6 COMMUNICATION BETWEEN SCIENTISTS. AND I JUST DON'T  
7 KNOW IF YOU DON'T REQUIRE IT, THEN HOW WILL IT GET  
8 DONE? THAT'S QUESTION NO. 1.

9 QUESTION NO. 2 IS WHO WILL BE POLICING THESE  
10 REQUIREMENTS?

11 CHAIRMAN PENHOET: CIRM WILL BE POLICING THE  
12 REQUIREMENTS BECAUSE IT'S AN OBLIGATION. IT WILL  
13 BECOME STATE LAW ESSENTIALLY, THAT THEY PROVIDE THESE  
14 ON WHATEVER TIME SCHEDULE WE DECIDE UPON.

15 DR. FONTANA: OKAY.

16 CHAIRMAN PENHOET: BUT, AGAIN, WE'RE TALKING  
17 HERE INVENTIONS ARE PATENTED INVENTIONS. WE WILL GET  
18 AN ANNUAL SUMMARY OF THE WORK CONDUCTED UNDER A GRANT,  
19 AND THE NORMAL MECHANISM THAT PEOPLE HAVE OF GOING TO  
20 MEETINGS, DISCUSSING THEIR WORK, PUBLISHING, ETC., WILL  
21 GO ON AS IT ALWAYS HAS DONE IN THIS COMMUNITY WITH THE  
22 EXCEPTION THAT WE WILL COME IN LATER SECTIONS IN THE  
23 DISCUSSION TODAY TO SOME NOVELTY TO OUR PROGRAM WHICH  
24 PUSH THE SHARING FURTHER THAN IT HAS TRADITIONALLY BEEN  
25 PUSHED IN THE COUNTRY.

1 MS. LANSING: I JUST ALSO WANT TO COMMEND YOU  
2 AND MARY. I THINK THE WHOLE DOCUMENT IS REALLY, REALLY  
3 WELL THOUGHT OUT. AND THIS PARTICULAR SECTION I ALSO  
4 THINK IS EXTREMELY WELL WORKED OUT. I GUESS I'M  
5 COMFORTABLE WITH LEAVING IT ON ANNUAL BASIS, AND WE  
6 CAN -- IF THEY NEED TO HAVE MORE MEETINGS, THEN THEY  
7 CAN ASK FOR THEM. I MEAN THIS IS THE VERY LEAST THAT  
8 THEY CAN DO, RIGHT?

9 CHAIRMAN PENHOET: WELL, YOU KNOW, THE  
10 GRANTEES, IF THEY TAKE NIH MONEY, ARE USED TO DOING IT  
11 EVERY TWO MONTHS, BUT WE WERE TOLD THAT THAT DOESN'T  
12 HAVE MUCH UTILITY, SO WE'RE TRYING TO COME UP WITH A  
13 PRACTICAL SOLUTION THAT DOESN'T MAKE OUR GRANTEES GO  
14 THROUGH A LOT OF PAPERWORK THAT'S NOT GOING TO BE ACTED  
15 UPON. SO THIS IS A COMPROMISE BETWEEN THE SHORTEST  
16 TIME THAT PROBABLY MAKES SENSE, WHICH IS TWO MONTHS, TO  
17 IN OUR VIEW THEY HAVE TO WRITE AN ANNUAL REPORT ANYWAY,  
18 SO THEY COULD INCLUDE ALL OF THIS IN THE ANNUAL REPORT  
19 TO THE CIRM.

20 MS. LANSING: I AGREE WITH YOU. IF IT'S NOT  
21 ENOUGH MEETINGS, THEN I THINK THEY TAKE IT UPON  
22 THEMSELVES TO REPORT EARLIER.

23 CHAIRMAN PENHOET: OKAY. THEN MAYBE WE ARE  
24 READY TO MOVE ALONG TO SECTION H.

25 MR. FEYER: ROBERT FEYER FROM ORRICK,

1 HERRINGTON & SUTCLIFFE. ONE QUESTION REALLY HERE FOR  
2 COUNSEL. YOU MENTIONED THAT THESE REPORTS WOULD BE  
3 RECEIVED IN CONFIDENCE. IS IT CLEARLY PRODUCTION FROM  
4 THE CALIFORNIA PUBLIC RECORDS ACT UNDER EITHER THE PROP  
5 71 OR GENERALLY THAT WOULD ALLOW YOU TO PROMISE A  
6 GRANTEE THAT THESE REPORTS ARE KEPT CONFIDENTIAL?

7 CHAIRMAN PENHOET: IT'S A GOOD POINT. IN  
8 GRANTEES FROM THE STATE OF CALIFORNIA THAT THE PATENT  
9 PORTFOLIO OF OUR GRANTEES BECOMES COMPROMISED, SO --  
10 AND THEY WILL BECOME PUBLIC WHEN THE PATENTS ARE  
11 PUBLISHED, SO IT WILL BECOME PUBLIC INFORMATION. SO  
12 WE'LL HAVE AN ANSWER TO THAT QUESTION.

13 MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
14 CALIFORNIA. I HAVE A COMMENT, BUT FIRST -- WENDY  
15 STREITZ, UNIVERSITY OF CALIFORNIA. IN ANSWER TO THAT,  
16 IN OUR TECH TRANSFER OPERATION, WE ARE ROUTINELY ABLE  
17 TO REDACT PATENT APPLICATIONS AND INVENTION INFORMATION  
18 BEFORE THE PATENT ISSUES WERE PUBLISHED.

19 CAN WE GO BACK TO G(2) FOR A SECOND?

20 CHAIRMAN PENHOET: SURE.

21 MS. STREITZ: THANK YOU. I THINK THE POINT  
22 OF THAT FIRST SENTENCE, WE HAVE TO NOTIFY CIRM ANNUALLY  
23 OF RELEVANT, YOU'RE LOOKING FOR US TO TELL YOU ABOUT  
24 INVENTIONS THEMSELVES, RIGHT? INVENTION DISCLOSURE IS  
25 DEFINED IN THE DEFINITIONS AS A PUBLIC DISCLOSURE. SO

1 WHAT THIS READS LIKE IS THAT YOU WANT US TO TELL YOU  
2 ABOUT EVERY PUBLICATION, EVERY PRESENTATION, EVERY  
3 PUBLIC DISCLOSURE WHEN I THINK WHAT YOU REALLY WANT TO  
4 SAY IS ANNUALLY ALL RELEVANT INVENTIONS MADE THROUGH  
5 THE USE OF CIRM FUNDS OR SOMETHING LIKE THAT. I CAN  
6 SEE INVENTIONS IN THERE, NOT INVENTION DISCLOSURE.

7 CHAIRMAN PENHOET: I THINK WE CAN STRIKE THE  
8 WORD "DISCLOSURES" AND IT WOULD HAVE THE SAME MEANING.

9 DR. PRIETO: IS THIS G(2) THAT WE'RE  
10 DISCUSSING?

11 CHAIRMAN PENHOET: YES.

12 DR. PRIETO: THANK YOU. STRIKE DISCLOSURES?

13 CHAIRMAN PENHOET: ALL RELEVANT INVENTIONS.

14 DR. PRIETO: THANK YOU.

15 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR  
16 TAXPAYER AND CONSUMER RIGHTS. FIRST A QUESTION AND  
17 THEN A COMMENT. YOU SAID THAT UNDER G(2), THAT WOULD  
18 BE FILED IN CONFIDENCE. I UNDERSTAND THAT. WOULD THE  
19 OTHER ONES, THREE, FOUR, AND FIVE, ALSO BE IN  
20 CONFIDENCE, OR ARE THOSE PUBLIC RECORDS? WASN'T CLEAR  
21 TO ME WHAT THE INTENT WAS THERE.

22 CHAIRMAN PENHOET: IF THEY FILE PATENT  
23 APPLICATIONS, I THINK THE FACT THAT THEY HAVE FILED THE  
24 APPLICATION, IT DOES BECOME A PUBLIC RECORD.

25 MR. SIMPSON: SO PRESUMABLY THE REST OF THEM



1 WOULD BE PUBLIC RECORD.

2 THE OTHER THING IS MY COMMENT, AND THAT IS I  
3 GATHER FROM WHAT YOU WERE SAYING, MR. CHAIRMAN, WAS  
4 THAT NIH HAS SOME VERY GOOD RULES THAT THEY DON'T  
5 BOTHER TO FOLLOW, WHICH IS A CONCERN. AND I WOULD  
6 SUGGEST WHAT WE NEED TO DO HERE IS GET IT RIGHT FOR  
7 CALIFORNIA, WHICH I THINK YOU'RE TRYING TO DO, BUT I  
8 GUESS ON THE TIME FRAME, I'M A LITTLE SKEPTICAL ABOUT A  
9 YEAR. A YEAR IS A LONG TIME IN MY LIFE. SO I WOULD  
10 LEAN MORE TOWARDS PERHAPS YOU SHOULD BE LOOKING AT  
11 QUARTERLY OR SEMI ANNUALLY AT LEAST. A LOT CAN HAPPEN  
12 IN A YEAR.

13 CHAIRMAN PENHOET: WELL, FIRST OF ALL, I  
14 DIDN'T MEAN TO IMPLY THAT NIH DOESN'T FOLLOW ITS RULES.  
15 THEY STILL REQUIRE THAT PEOPLE SUBMIT THEM EVERY TWO  
16 MONTHS, BUT THEY REVIEW THEM ON A LESS FREQUENT BASIS  
17 BECAUSE TWO MONTHS IS A STAGGERED TWO MONTHS, SO THEY  
18 HAVE THESE COMING IN EVERY DAY AT THE NIH. SO IT'S  
19 PRETTY HARD FOR THEM TO INVEST THE CAPABILITY TO  
20 ACTUALLY READ THEM. SO WHAT WE'RE TRYING TO AVOID IS  
21 MAKE WORK IF WE DON'T HAVE THE CAPACITY TO ACTUALLY  
22 STAY UP WITH THE FLOW.

23 BUT I THINK THE ISSUE OF THE FREQUENCY OF  
24 REPORTING IS SOMETHING THAT IS OPEN FOR DISCUSSION  
25 HERE. WE TRIED TO COME UP WITH WHAT WE THOUGHT WAS A

1 PRACTICAL ANSWER, AND WE AGREE WITH YOU. WE SHOULD  
2 COME UP WITH WHAT'S BEST FOR CALIFORNIA.

3 MR. ASTIN: DAVE ASTIN, PETERS BERNEY. I  
4 THINK YOU'RE CONFLATING TWO DIFFERENT REQUIREMENTS.  
5 UNDER ITEM 2, YOU ARE TALKING ABOUT WHEN AN INVENTION  
6 DISCLOSURE SHOULD BE REPORTED TO CIRM. YOU DON'T  
7 ACTUALLY GIVE A DATE HERE. BUT MY UNDERSTANDING IS  
8 THAT THE FEDERAL REGULATIONS HAVE A TWO-MONTH DEADLINE.  
9 WHEN YOU REPORT AN INVENTION DISCLOSURE, THERE'S A  
10 REASON FOR THAT BECAUSE PATENT RIGHTS LAW SAYS IF  
11 THERE'S NO ACTION TAKEN WITHIN A YEAR. SO THERE'S A  
12 FAIRLY TIMELY REQUIREMENT THAT THE DISCLOSURE BE  
13 FORWARDED.

14 UTILIZATION REPORTING, WHICH IS EXACTLY THE  
15 TERM USED UNDER FEDERAL FUNDING, IS ONCE A YEAR. AND  
16 THOSE ARE THE RULES. AND IF SO YOU AMENDED POINT 2 TO  
17 REQUIRE A 60-DAY DISCLOSURE OF INVENTIONS, THEN YOU  
18 WOULD BE CONSISTENT WITH FEDERAL.

19 SECOND QUESTION, THE REPORT ON FINANCIAL  
20 INFORMATION OF LICENSES ISN'T CLEAR TO ME WHETHER THAT  
21 SHOULD BE CONFIDENTIAL OR NOT. AND I THINK IT SHOULD  
22 BE IF IT'S IDENTIFIED FOR A PARTICULAR LICENSE. IT'S  
23 NOT CLEAR HERE. IF YOU ACCUMULATE ALL OF THE INCOME  
24 AND GIVE IT HERE UNDER ALL CIRM INVENTIONS, THEN THAT  
25 WOULD BE TRADE SECRET INFORMATION, BUT I THINK

1 COMPANIES MIGHT BE A LITTLE, AND UNIVERSITIES, BE A  
2 LITTLE SENSITIVE TO THAT FINANCIAL INFORMATION BEING  
3 PUBLISHED.

4 CHAIRMAN PENHOET: WELL, IT'S NOT NECESSARILY  
5 PROSPECTIVE. WHAT IT DOES SAY IS INFORMATION ABOUT THE  
6 STATUS OF DEVELOPMENT, THE DATE OF COMMERCIAL SALE OR  
7 USE, AND THE ANNUAL SUM OF ANY LICENSING FEES OR GROSS  
8 ROYALTIES. I THINK THOSE ARE AVAILABLE GENERALLY. IT  
9 DOESN'T SAY SPECIFICALLY ABOUT THE DETAILED TERMS OF  
10 THE AGREEMENT.

11 I'LL TURN TO A UNIVERSITY REPRESENTATIVE. WE  
12 HAVE SEVERAL. WOULD IT BE ONEROUS FOR YOU TO FOLLOW  
13 THE SAME DISCLOSURE RULES AS THE NIH HAS? IT WOULD  
14 NOT.

15 MS. AURITI: THAT'S THE INITIAL DISCLOSURE.

16 CHAIRMAN PENHOET: YES. I THINK ACTUALLY,  
17 THOUGH, GOING BACK TO ITEM 2 AGAIN, THAT'S PROBABLY  
18 WHAT WE INTENDED HERE WAS THE INVENTION DISCLOSURES,  
19 THE WORD WE JUST STRUCK. BUT IF WE'RE TALKING ABOUT  
20 THE DISCLOSURE BY THE INVENTOR TO THE INSTITUTION,  
21 THAT'S THE TWO-MONTH RULE.

22 MS. AURITI: BUT WHEN YOU DEFINE TERMS, IT'S  
23 NOT DEFINED THAT WAY.

24 CHAIRMAN PENHOET: OKAY. THEN WE OUGHT TO  
25 CHANGE THE DEFINED TERM. SO WE HAVE A SUGGESTION THAT

1 THE INVENTION DISCLOSURE BY THE INVENTOR TO THE  
2 INSTITUTION BE CONFORMED TO EXISTING NIH POLICY, AND  
3 WE' LL TRY TO IDENTIFY RESOURCES THAT CAN KEEP UP WITH  
4 THE FLOW AT CIRM.

5 DR. PRIETO: ARE WE SAYING, THEN, THAT WE' LL  
6 EXPECT EVERY TWO-MONTH REPORTING?

7 CHAIRMAN PENHOET: NO. THEY' LL HAVE TO SEND  
8 IT WITHIN 60 DAYS OF A DISCLOSURE, WHENEVER THAT  
9 OCCURS. SO IT OCCURS ALL YEAR LONG. IT DOESN' T  
10 NECESSARILY MEAN EVERY TWO MONTHS.

11 DR. PRIETO: OKAY. BUT WITHIN 60 DAYS FOR  
12 INITIAL INVENTION.

13 CHAIRMAN PENHOET: SO THE WAY IT WORKS IS IF  
14 A SCIENTIST OR CLINICIANS ARE WORKING AWAY ON A PROJECT  
15 AND THEY BELIEVE THEY HAVE INVENTED SOMETHING, THE  
16 FIRST STEP IS THAT THEY DISCLOSE TO THEIR OWN  
17 INSTITUTION THAT THEY HAVE MADE AN INVENTION. THAT  
18 STARTS THE 60-DAY CLOCK RUNNING, AND THE INSTITUTION  
19 HAS TO THEN TAKE THAT INTO ACCOUNT AND WITHIN 60 DAYS  
20 NOTIFY US THAT THEY HAVE BEEN INFORMED BY ONE OF THEIR  
21 INVENTORS THAT THAT PERSON BELIEVES HE OR SHE HAS MADE  
22 AN INVENTION. THAT' S HOW IT WORKS. THEY' LL BE COMING  
23 IN PERHAPS EVERY DAY, WE HOPE.

24 DR. PRIETO: ED, QUESTION. WILL WE RETAIN OR  
25 IS THERE SOME LANGUAGE THAT WE COULD USE -- MAYBE I

1 MISSED IT -- THAT WOULD RETAIN THE RIGHT FOR US TO  
2 REQUEST, IF WE SUSPECTED THAT SOMETHING WAS OR WAS NOT  
3 BEING DONE WITH REGARDS TO AN INVENTION? IN OTHER  
4 WORDS, REPORTING ON DEMAND.

5 CHAIRMAN PENHOET: THEY HAVE A GENERAL  
6 OBLIGATION TO PURSUE PATENTING, AND WE'D HAVE THE  
7 ABILITY TO AT LEAST HAVE A CONVERSATION WITH THEM ABOUT  
8 WHY NOT. WE DON'T HAVE THE CAPABILITY OURSELVES.  
9 WE'LL NOT HAVE THE CAPABILITY IN THE FUTURE TO BE  
10 A PATENT FILING AGENCY AT CIRM. WE DON'T INTEND TO OWN  
11 THE TECHNOLOGY.

12 DR. PRIETO: I'M THINKING MORE WITH REGARDS  
13 TO, YOU KNOW, FULFILLING THEIR TERMS OF THE AGREEMENT,  
14 WHETHER WE CAN ASK FOR REPORTING AHEAD OF THE ANNUAL  
15 DEADLINE.

16 CHAIRMAN PENHOET: YES, WE CAN. WE CAN ASK  
17 FOR IT ON THIS TWO-MONTH SCHEDULE. THEY HAVE 60 DAYS  
18 TO TELL US ABOUT AN INVENTION.

19 UNDER THE DUE DILIGENCE PROVISIONS, THEY  
20 HAVE -- BUT STILL, AT THE END, THE DISCRETION WHETHER  
21 TO FILE A DISCLOSURE OR NOT HAS TO BE LEFT TO THE  
22 INSTITUTION. IF WE SEE SOME EGREGIOUS CASES WHERE NO  
23 PATENTS ARE BEING FILED, THEN WE HAVE AN OPINION, THAT  
24 WOULD BE AN ADMINISTRATIVE MATTER, I THINK, TO  
25 INTERVENE, BUT IT'S HARD TO IMAGINE. WE WON'T HAVE THE

1 CAPABILITY OURSELVES TO ESSENTIALLY GO THROUGH EVERY  
2 INVENTION DISCLOSURE AND DETERMINE WHETHER IT'S AN  
3 APPROPRIATE INVENTION OR NOT OR WHETHER THERE'S BEEN  
4 PRIOR ART. CIRM SIMPLY WON'T HAVE THE FINANCIAL  
5 WHEREWITHAL TO HAVE A PATENT DEPARTMENT THAT'S CAPABLE  
6 OF DOING THOSE THINGS. WE HAVE TO IN THE END LOOK TO  
7 OUR GRANTEEES WHO TODAY HAVE THAT CAPABILITY ALREADY IN  
8 PLACE TO CARRY OUT THAT WORK.

9 AT LEAST IN THIS, BY HAVING THIS PROVISION,  
10 WE'LL BE INFORMED ABOUT THE TOTALITY OF THE INVENTIONS  
11 WHICH HAVE BEEN DISCLOSED OUT THERE, AND WE'LL HAVE THE  
12 ABILITY TO ENTER INTO CONVERSATIONS WITH GRANTEEES ABOUT  
13 THEIR ADHERENCE TO THE GENERAL POLICY OF PURSUING  
14 PATENTS OF INVENTIONS.

15 DR. PRIETO: OKAY.

16 MS. AURITI: ELLEN AURITI FROM THE UNIVERSITY  
17 OF CALIFORNIA. I HAVE MAYBE A TECHNICAL QUESTION  
18 RAISED BY THE LAST POINT ABOUT DEFINITION OF INVENTION  
19 DISCLOSURE. MY QUESTION MAYBE IS FOR SCOTT TOCHER.  
20 WILL THE DEFINITIONS THAT ARE IN SECTION I BE  
21 INCORPORATED INTO THE REGULATIONS IN SECTION II THAT  
22 ARE EVENTUALLY ENACTED THROUGH THE APA?

23 MR. TOCHER: I THINK THAT'S A GOOD QUESTION.  
24 THAT'S SOMETHING THAT WE WILL BE LOOKING AT AS WE START  
25 TO PULL EVERYTHING INTO A FINAL FORM. WHAT TERMS CAN

1 BELONG SORT OF IN A BROADER GAP POLICY THAT SAY WHICH  
2 TERMS NEED TO BE MORE SPECIFICALLY DEFINED IN THE  
3 CONTEXT OF THE IP POLICY. THAT'S SOMETHING THAT WE'RE  
4 SORT OF DUELING THROUGH RIGHT NOW. I THINK THAT TERM  
5 THERE WOULD BE A CANDIDATE FOR A VERY SPECIFIC  
6 DEFINITION WITHIN THE IP POLICY.

7 CHAIRMAN PENHOET: OKAY. JEFF.

8 MR. SHEEHY: I'M JUST WONDERING IN TERMS OF  
9 PROCESS. SHOULD WE HAVE A MOTION AND VOTE TO ACCEPT  
10 THIS CHANGE OR DO YOU WANT TO --

11 CHAIRMAN PENHOET: MAYBE IT WILL BE EASIER  
12 FOR US TO DO IT ONE BATCH AT A TIME RATHER THAN AN  
13 OMNIBUS AT THE END. I THINK IT'S APPROPRIATE IF YOU  
14 WANT TO MAKE THAT MOTION.

15 MR. SHEEHY: SO I DON'T KNOW -- MAYBE WE DO  
16 ANOTHER PUBLIC COMMENT -- HOW YOU WANT TO HANDLE THE  
17 PUBLIC COMMENT?

18 CHAIRMAN PENHOET: WE'VE HAD OPPORTUNITY, BUT  
19 HAPPY TO GIVE ANYBODY ELSE ANOTHER OPPORTUNITY.

20 MR. SHEEHY: MAYBE WE CAN MAKE ONE MOTION AND  
21 KIND OF CAPTURE ALL THE THINGS WE NEED TO DO.

22 MR. JENSEN: DAVID JENSEN, CALIFORNIA STEM  
23 CELL REPORT. MAYBE I MISSED IT IN HERE, BUT WHEN YOU  
24 TALK ABOUT ANNUALLY, WHAT DO YOU MEAN? THERE'S A  
25 CALENDAR YEAR, FISCAL YEAR. ARE THERE SANCTIONS

1 PROVIDED FOR FAILURE TO COMPLY?

2 CHAIRMAN PENHOET: WELL, FAILURE TO COMPLY IN  
3 THIS CASE WOULD BE A VIOLATION OF STATE LAW. SO THE  
4 REGULATIONS ARE -- IN THIS SENSE WHAT WE'RE -- THIS IS  
5 NEW -- NIH REGULATIONS ARE NOT FEDERAL LAW. THEY'RE  
6 POLICY AND THEY'RE GUIDELINES FOR GRANTEES. SO THIS IS  
7 A MUCH HARDER REGULATION. IF THEY DON'T SEND IT IN,  
8 THEY'RE IN VIOLATION OF THE LAW IN CALIFORNIA. SO THAT  
9 PROVIDES NUMEROUS REMEDIES THAT ARE NOT AVAILABLE TO  
10 PEOPLE WHO ARE NOT IN CONFORMANCE WITH FEDERAL  
11 REGULATIONS TODAY.

12 MR. SIMPSON: DOES THAT MEAN THE ATTORNEY  
13 GENERAL GOES -- THIS IS JOHN SIMPSON FROM THE  
14 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. DOES THE  
15 AG GO AFTER THEM AND PROSECUTE THEM? DO YOU TURN THAT  
16 OVER TO THEM?

17 CHAIRMAN PENHOET: YOU'VE ASKED ME A QUESTION  
18 I DON'T KNOW, BUT MAYBE SCOTT KNOWS THE ANSWER.

19 MR. TOCHER: GENERALLY SPEAKING, THE  
20 PROCEDURE WHICH IS OUTLINED IN A POLICY THAT WILL BE  
21 PRESENTED IS CALLED SORT OF THE GENERAL PRINCIPLES THAT  
22 WILL APPLY TO GRANTS THAT WILL BE BEFORE THE ICOC AT  
23 THE FEBRUARY 10TH MEETING HAS A PROVISION THAT WILL  
24 DESCRIBE THE REMEDIES THAT ARE AVAILABLE TO THE STATE  
25 AGENCY, TO CIRM, IN DEALING WITH PEOPLE WHO FAIL TO



1 COMPLY WITH ALL OF THE ASPECTS OF THESE REGULATIONS AND  
2 RULES.

3 WHAT PARTICULAR ATTORNEY GENERAL JURISDICTION  
4 WOULD BE FOR SOMETHING LIKE THAT IS A THING YOU WOULD  
5 HAVE TO DIRECT TO THAT OFFICE.

6 MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
7 CALIFORNIA AGAIN. JUST SOMETHING FOR YOUR  
8 CONSIDERATION. THE ANNUAL REPORTING WOULD BE MUCH  
9 EASIER ON YOUR GRANTEE INSTITUTIONS IF IT WAS ONCE A  
10 YEAR INSTEAD OF -- I CAN PICTURE THE ANNIVERSARY OF AN  
11 AWARD HAPPENING SEVERAL TIMES DURING THE YEAR. WITH  
12 THE FEDERAL GOVERNMENT WE DO IT ONCE A YEAR AND WITH  
13 SOME OF THE FOUNDATIONS THAT REQUIRE ANNUAL REPORTING  
14 WE DO IT ONCE A YEAR. EITHER WE DO IT ON THEIR FISCAL  
15 YEAR OR WHATEVER.

16 CHAIRMAN PENHOET: I SEE. SO IF YOU HAVE A  
17 GRANT WHICH HAS BEEN IN BUSINESS FOR ONE MONTH, YOU  
18 WOULD REPORT ON EVERYTHING THAT'S -- YOU COLLAPSE ALL  
19 THE PRIOR DATES INTO A SINGLE DATE EACH YEAR FOR THE  
20 ANNUAL REPORTING?

21 MS. STREITZ: THAT'S CORRECT.

22 CHAIRMAN PENHOET: IS THAT THE WAY IT'S DONE?

23 MS. STREITZ: THAT'S CORRECT.

24 CHAIRMAN PENHOET: IS THERE AN ARGUMENT --

25 DR. CHIU: SO IT'S JUST LIKE AN ANNUAL

1 REPORTING OF PATENTS. WE SHOULD TALK ABOUT ANNUAL  
2 REPORTING (INAUDIBLE) AS WELL. SO WE SHOULDN'T CONFUSE  
3 THE TWO ISSUES.

4 MS. KING: NEXT TIME YOU HAVE A COMMENT, THAT  
5 MICROPHONE DOES NOT WORK. IT'S GOING TO HAVE TO BE ONE  
6 OF THE TWO FOR THE SPEAKER PHONE. SORRY. TECHNICAL  
7 DIFFICULTIES. I APOLOGIZE TO EVERYBODY, BUT I NEED YOU  
8 TO COME TO THESE TWO LITTLE BABY MICROPHONES WHEN YOU  
9 HAVE SOMETHING TO SAY AND TELL BETH WHO ARE YOU ARE.  
10 THANK YOU VERY MUCH.

11 CHAIRMAN PENHOET: OKAY.

12 MR. SHEEHY: SO I'D LIKE TO MOVE THAT WE  
13 ADOPT SECTION G WITH THE INCLUSION OF LANGUAGE TO BE  
14 DRAFTED BY STAFF TO ALLOW FOR 60-DAY DISCLOSURE OF  
15 INVENTIONS BY THE INSTITUTION TO CIRM, AND THEN WE  
16 WANTED TO DROP THE LANGUAGE IN SECTION II WHERE IT SAYS  
17 DISCLOSURES AND CHANGE THAT WORD TO MAY. AND I THINK  
18 THAT'S IT. WERE THERE ANY OTHER -- IS ANYTHING HANGING  
19 OUT THERE THAT I NEED TO INCLUDE IN THIS MOTION?  
20 THAT'S THE MOTION.

21 CHAIRMAN PENHOET: DO WE HAVE A SECOND TO  
22 JEFF'S MOTION?

23 DR. WRIGHT: SECOND.

24 CHAIRMAN PENHOET: MADE BY JEFF SHEEHY,  
25 SECONDED BY DR. WRIGHT. ANY OTHER FURTHER DISCUSSION?

1 SO WE HAVE A VOTE ON SECTION G. DON'T HAVE A QUORUM.

2 MS. KING: AS OF RIGHT NOW WE DON'T.  
3 UNFORTUNATELY DR. PIZZO IS SICK, SO WE DON'T HAVE A  
4 QUORUM RIGHT NOW. WE DO HAVE A COUPLE OTHER PEOPLE  
5 JOINING US SOON THOUGH, SO WE WILL HAVE A QUORUM SOON.  
6 UNFORTUNATELY WE ARE GOING TO HAVE TO WAIT ON THAT  
7 MOTION.

8 CHAIRMAN PENHOET: I MIGHT SAY IN THE  
9 UNFORTUNATE CIRCUMSTANCE THAT WE DON'T HAVE A QUORUM  
10 TODAY, IT'S NOT NECESSARY FOR US TO TAKE ACTION ON  
11 THESE ITEMS OFFICIALLY IN PREPARATION FOR THE ICOC  
12 MEETING IN FEBRUARY. THE ICOC AS A WHOLE WILL CONSIDER  
13 ALL OF THESE ITEMS WHETHER OR NOT WE VOTE ON THEM  
14 TODAY, BUT WE WERE HOPING TO HAVE AN OFFICIAL  
15 RECOMMENDATION AND HOPEFULLY WE WILL.

16 MS. LANSING: CAN WE TAKE A VOTE WITHOUT A  
17 QUORUM JUST SO WE CAN REPORT BACK TO THE ICOC?

18 CHAIRMAN PENHOET: APPARENTLY NOT. SCOTT IS  
19 SHAKING HIS HEAD.

20 MS. LANSING: OKAY. I JUST HAVE TO REMIND  
21 YOU I HAVE TO LEAVE AT SIX, SO YOU'RE GOING TO LOSE ONE  
22 MORE PERSON. WE'LL DO THE BEST WE CAN.

23 CHAIRMAN PENHOET: THANK YOU FOR BEING WITH  
24 US AS LONG AS YOU CAN.

25 THE NEXT IS SECTION H. SECTION H DEALS WITH

1 SHARING OF CIRM-FUNDED INTELLECTUAL PROPERTY. THE  
2 FIRST PART IS PUBLICATION REQUIREMENTS. SO WHAT IT  
3 SAYS IS WITHIN TWO MONTHS OF PUBLICATION OF A RESEARCH  
4 RESULT IN A JOURNAL, PI'S, THAT'S THE PRINCIPAL  
5 INVESTIGATORS, MUST SUBMIT TO CIRM A 500-WORD ABSTRACT  
6 WRITTEN FOR THE GENERAL PUBLIC THAT HIGHLIGHTS THE  
7 FINDINGS OF THE PUBLISHED BODY OF WORK.

8 THE ABSTRACT WILL BE DEPOSITED INTO THE  
9 PUBLICLY ACCESSIBLE CELR, WHICH IS THE CIRM ELECTRONIC  
10 LIBRARY REPOSITORY, TO BE ACCESSED VIA THE CIRM  
11 WEBSITE.

12 SO I THINK THIS ONE WE DISCUSSED A LOT AND  
13 REALLY HOPE THAT THESE 500-WORD ABSTRACTS WILL HELP  
14 INFORM THE PUBLIC ABOUT THE NATURE OF WHAT'S GOING ON.

15 SECOND ONE, COPY OF EACH PUBLICATION  
16 RESULTING FROM WORK PERFORMED UNDER A CIRM GRANT MUST  
17 ACCOMPANY THE MANDATORY ANNUAL PROGRESS REPORT.

18 THIRD, IN THE FINAL MANUSCRIPT AUTHORS MUST  
19 INCLUDE THE URL OF A WEBSITE WHERE THE CIRM MTA CAN BE  
20 ACCESSED TO FACILITATE REQUESTS FOR PUBLICATION-RELATED  
21 MATERIAL.

22 AND THEN NO. 4, CIRM GRANTEES MUST  
23 ACKNOWLEDGE CIRM'S SUPPORT OF RESEARCH FINDINGS IN  
24 PUBLICATIONS, ANNOUNCEMENTS, PRESENTATIONS, OR PRESS  
25 RELEASES BY THE GRANTEES. AN ACKNOWLEDGEMENT SHOULD BE

1 TO THE EFFECT THAT, AND THEN YOU SEE THE QUOTES IS VERY  
2 COMMON FOR ESSENTIALLY ATTRIBUTION OF THE FUNDING BY  
3 CIRM.

4 SECOND PART OF THIS, PART B, IS  
5 PUBLICATION-RELATED BIOMEDICAL MATERIALS REQUIREMENTS.  
6 GRANTEES SHALL SHARE BIOMEDICAL MATERIALS DESCRIBED IN  
7 PUBLISHED SCIENTIFIC ARTICLES WITHIN 60 DAYS OF RECEIPT  
8 OF A REQUEST FOR RESEARCH PURPOSES AND WITHOUT BIAS AS  
9 TO THE AFFILIATION OF THE REQUESTER. UNDER SPECIAL  
10 CIRCUMSTANCES, EXTENSIONS BEYOND 60 DAYS MAY BE  
11 POSSIBLE WITH THE APPROVAL OF THE SPO. THAT'S THE  
12 SCIENTIFIC PROGRAM OFFICER AT CIRM. ALTERNATIVELY,  
13 AUTHORS MAY PROVIDE REQUESTERS WITH INFORMATION ON HOW  
14 TO RECONSTRUCT OR OBTAIN THE MATERIAL. MATERIALS ARE  
15 TO BE SHARED WITHOUT COST. UNDER SUCH CIRCUMSTANCES  
16 WHERE SIGNIFICANT EXPENSES ARE REQUIRED TO GENERATE THE  
17 MATERIALS, THE GRANTEES MAY RECOVER THOSE EXPENSES AND  
18 ONLY THOSE FROM THE REQUESTER.

19 THE THIRD PART, PATENT APPLICATIONS  
20 REQUIREMENTS. GRANTEE ORGANIZATIONS SHALL BEAR  
21 RESPONSIBILITY FOR COSTS ASSOCIATED WITH PATENTS AND  
22 PATENT APPLICATIONS CLAIMING THEIR CIRM-FUNDED  
23 INVENTIONS.

24 TWO, GRANTEE ORGANIZATIONS SHALL REPORT  
25 FILINGS OF SUCH PATENT APPLICATIONS THAT CLAIM

1 INVENTIONS DEVELOPED IN THE PERFORMANCE OF CIRM-FUNDED  
2 RESEARCH ON, AND HERE AGAIN, THIS IS THE ANNUAL BASIS,  
3 AND I THINK IT'S THE DISCLOSURES THAT WILL BE DONE  
4 WITHIN TWO MONTHS, BUT THE FILINGS THEMSELVES WILL BE  
5 AGGREGATED ON THE ANNUAL BASIS. THAT'S THE INTENT OF  
6 THIS LANGUAGE.

7 SECTION D WILL BE REQUIREMENTS FOR LICENSING  
8 OF CIRM-FUNDED PATENTED INVENTIONS. GRANTEE  
9 ORGANIZATIONS SHALL ASSUME RESPONSIBILITY FOR LICENSING  
10 ACTIVITIES, INCLUDING IDENTIFICATION OF POTENTIAL  
11 LICENSEES, NEGOTIATION OF LICENSING AGREEMENTS, AND  
12 DOCUMENTATION OF DEVELOPMENT PROGRESS FOR LICENSES  
13 RELATED TO CIRM-FUNDED PATENTED INVENTIONS. GRANTEE  
14 ORGANIZATIONS ARE REQUIRED TO SUBMIT A LICENSING  
15 ACTIVITIES REPORT RELEVANT TO THE CIRM-FUNDED PATENT  
16 INVENTIONS ON AN ANNUAL BASIS.

17 TWO, GRANTEE ORGANIZATIONS SHALL NEGOTIATE  
18 NONEXCLUSIVE LICENSES OF CIRM-FUNDED INVENTIONS  
19 WHENEVER POSSIBLE.

20 THREE, NOTWITHSTANDING THE ABOVE, GRANTEE  
21 ORGANIZATIONS MAY NEGOTIATE AND AWARD EXCLUSIVE  
22 LICENSES IF THEY ARE NECESSARY TO PROVIDE ECONOMIC  
23 INCENTIVES REQUIRED TO ENABLE COMMERCIAL DEVELOPMENT  
24 AND AVAILABILITY OF THE INVENTION. IN GRANTING  
25 EXCLUSIVE LICENSES, GRANTEE ORGANIZATIONS SHOULD

1 CONSIDER DEVELOPMENT AND COMMERCIALIZATION CAPABILITIES  
2 OF THE INTENDED LICENSEE.

3 IN EXCLUSIVE LICENSE AGREEMENTS, GRANTEE  
4 ORGANIZATIONS SHALL INCLUDE TERMS FOR COMMERCIAL  
5 DEVELOPMENT PLANS TO BRING THE INVENTION TO PRACTICAL  
6 APPLICATION. SUCH PROVISIONS SHALL INCLUDE COMMERCIAL  
7 DEVELOPMENT MILESTONES AND BENCHMARKS SO THAT  
8 DEVELOPMENT CAN BE ASSESSED AND MONITORED.

9 FIVE, GRANTEE ORGANIZATIONS SHALL GRANT  
10 LICENSES INVOLVING CIRM-FUNDED PATENTED INVENTIONS TO  
11 ORGANIZATIONS WITH PLANS FOR ACCESS TO RESULTANT  
12 THERAPIES FOR MEDICAL AND UNINSURED CALIFORNIA PATIENT  
13 POPULATIONS.

14 AND NO. 6, GRANTEE ORGANIZATIONS SHALL  
15 MONITOR THE PERFORMANCE OF LICENSEES OF CIRM-FUNDED  
16 PATENTED INVENTIONS TO ENSURE THAT LICENSED TECHNOLOGY  
17 IS DEVELOPED IN A TIMELY FASHION. REMEDIES FOR FAILURE  
18 TO DEVELOP MAY INCLUDE MODIFICATION OR TERMINATION OF A  
19 LICENSE IN THE EVENT THAT THE LICENSEE IS UNABLE TO  
20 FULLY DEVELOP THE RIGHTS GRANTED.

21 AND THEN LITTLE I, GRANTEE ORGANIZATION SHALL  
22 NEGOTIATE RELEVANT AND SPECIFIC GROUNDS FOR  
23 MODIFICATION OR TERMINATION OF LICENSE. EXAMPLES WOULD  
24 INCLUDE FAILURE TO MEET AGREED-UPON COMMERCIALIZATION  
25 BENCHMARKS, FAILURE TO KEEP THE LICENSED INVENTION

1 REASONABLY ACCESSIBLE TO THE PUBLIC FOR RESEARCH  
2 PURPOSES, AND FAILURE TO REASONABLY MEET THE  
3 AGREED-UPON PLAN FOR ACCESS TO RESULTANT THERAPIES BY  
4 MEDI -CAL AND UNINSURED CALIFORNIA PATIENT POPULATIONS.

5 GRANTEE ORGANIZATIONS SHALL MONITOR THE  
6 COMMERCIAL DEVELOPMENT ACTIVITIES OF A LICENSEE TO  
7 DETERMINE THE COMPLIANCE WITH THE TERMS OF THEIR  
8 LICENSE AGREEMENT AND INCLUDE REPORTS OF MONITORING  
9 ACTIVITIES ANNUALLY.

10 AND THEN III, GRANTEE ORGANIZATIONS SHALL  
11 TAKE ADMINISTRATIVE ACTION TO MODIFY OR TERMINATE  
12 LICENSE RIGHTS WHERE NECESSARY AND REPORT SUCH ACTION  
13 TO SPO.

14 LETTER E, REQUIREMENTS TO ENABLE RESEARCH  
15 EXEMPTION FOR CIRM-FUNDED PATENTED INVENTION. GRANTEE  
16 ORGANIZATIONS SHALL MAKE THEIR CIRM-FUNDED PATENTED  
17 INVENTIONS AVAILABLE AT NO COST FOR FURTHER RESEARCH BY  
18 CALIFORNIA RESEARCH INSTITUTIONS. THIS REQUIREMENT OF  
19 THE GRANTEE INSTITUTION ALSO EXTENDS TO ANY LICENSEES  
20 OF CIRM-FUNDED INVENTIONS.

21 THIS IS AN AREA WHERE ESSENTIALLY WE GO  
22 BEYOND CURRENT PATENT LAW IN THE UNITED STATES OR  
23 PRACTICE OF THE NATIONAL INSTITUTES OF HEALTH.

24 REVENUE SHARING REQUIREMENTS. IN THE EVENT  
25 OF THE CREATION OF REVENUE STREAMS FROM CIRM-FUNDED



1 PATENTED INVENTIONS, ONE, GRANTEE ORGANIZATIONS SHALL  
2 SHARE A FRACTION OF ANY ROYALTY REVENUES WITH THE  
3 INVENTOR IN ACCORDANCE WITH ESTABLISHED PRACTICES.

4 TWO, 25 PERCENT OF GRANTEE ORGANIZATION'S  
5 SHARE OF ANY REVENUES RECEIVED UNDER A LICENSE  
6 AGREEMENT OF CIRM-FUNDED PATENTED INVENTIONS IN EXCESS  
7 OF \$500,000 SHALL BE RETURNED TO THE STATE OF  
8 CALIFORNIA FOR USE IN RESEARCH AND EDUCATION.

9 THREE, IF FUNDING SOURCES IN ADDITION TO CIRM  
10 WERE USED IN THE CREATION OF A CIRM-FUNDED PATENTED  
11 INVENTION, THE RETURN TO THE STATE OF CALIFORNIA OF ANY  
12 RESULTANT REVENUES SHALL BE TO THE SUPPORT PROVIDED BY  
13 CIRM FOR THE DISCOVERY OF THE INVENTION.

14 G, PRESS RELEASE REQUIREMENTS, BASICALLY A  
15 REQUIREMENT THAT GRANTEES NOTIFY CIRM ABOUT ANY  
16 LICENSES. WE CAN ALL READ THE LANGUAGE THERE.

17 SO IT'S A LOT OF MATERIAL IN THIS SECTION H.  
18 I THINK THE BEST WAY TO PROCEED, WITH YOUR AGREEMENT,  
19 WOULD BE SIMPLY TO GO DOWN THROUGH HERE SECTION BY  
20 SECTION AND SEE IF WE HAVE ANY MODIFICATIONS THAT WE  
21 WOULD LIKE TO MAKE.

22 FIRST OF ALL, UNDER PART A, PUBLICATION  
23 REQUIREMENTS, ARE THERE ANY COMMENTS BY ANY OF YOU ON  
24 THE TASK FORCE ABOUT THE PUBLICATION REQUIREMENTS?

25 DR. PRIETO: ED, JUST UNDER A(1), I REALLY

1 LIKE THIS IDEA OF THE ABSTRACT WRITTEN FOR THE GENERAL  
2 PUBLIC. I JUST WONDER IS THIS SOMETHING WE'RE  
3 INVENTING, OR IS THERE A PRECEDENT FOR THAT?

4 CHAIRMAN PENHOET: I DON'T KNOW THE PRECEDENT  
5 FOR IT ACTUALLY.

6 DR. PRIETO: IT'S A GOOD IDEA.

7 CHAIRMAN PENHOET: WE THINK IT'S A GOOD IDEA  
8 ACTUALLY. IT'S AN EFFORT TO BE TRANSPARENT ABOUT  
9 WHAT'S GOING ON IN LANGUAGE THAT THE LAY PUBLIC CAN  
10 UNDERSTAND.

11 DR. PRIETO: OKAY.

12 CHAIRMAN PENHOET: DO I HAVE COMMENTS FROM  
13 THE AUDIENCE?

14 MR. FEYER: ROBERT FEYER FROM ORRICK,  
15 HERRINGTON. IN PARAGRAPH 4 IN THE ACKNOWLEDGEMENT  
16 PARAGRAPH THERE, I'D RECOMMEND RIGHT AT THE LAST  
17 SENTENCE, OFFICIAL VIEWS OF, AFTER CIRM, ADD THE WORDS  
18 "FOR THE STATE OF CALIFORNIA" JUST TO MAKE IT CLEAR.

19 CHAIRMAN PENHOET: WE ARE A STATE AGENCY, SO  
20 WE MUST CONTINUE TO REINFORCE THAT NOTION. OKAY.  
21 THANK YOU.

22 ANY OTHER COMMENTS ABOUT THE PUBLICATION  
23 SECTION?

24 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR  
25 TAXPAYER AND CONSUMER RIGHTS. I JUST WANT TO REITERATE

1 THAT NO. 1 IS AN EXCELLENT IDEA, AND THE TASK FORCE  
2 SHOULD BE COMMENDED FOR INCLUDING IT. THAT'S  
3 WONDERFUL.

4 THE ONLY THING I WOULD ALSO SUGGEST WITH THAT  
5 IS THAT PERHAPS FROM TIME TO TIME SUCH ABSTRACTS TO BE  
6 BROUGHT TOGETHER AND ISSUED AS A PRESS RELEASE BY YOUR  
7 COMMUNICATIONS OFFICE, SOME SORT OF A PUBLICATION OR  
8 SOMETHING TO GET IT OUT IN A PUBLIC VIEW.

9 CHAIRMAN PENHOET: THANK YOU. THANK YOU FOR  
10 YOUR COMMENT.

11 OKAY. LET'S MOVE ALONG TO THE NEXT SECTION,  
12 PUBLICATION-RELATED BIOMEDICAL MATERIALS REQUIREMENTS.  
13 SO THIS IS A REQUIREMENT ABOUT SHARING OF MATERIALS  
14 WITH OTHER GROUPS. I MIGHT EXPLAIN THE REASON ABOUT  
15 SIGNIFICANT EXPENSES AND EMPOWERING OTHERS TO DO THIS.  
16 THERE ARE CERTAIN BIOMEDICAL MATERIALS WHICH ARE VERY  
17 EXPENSIVE TO PRODUCE AND VERY DIFFICULT TO PRODUCE, AND  
18 IT WOULD BE VERY ONEROUS TO MAKE AN ABSOLUTE  
19 REQUIREMENT ON EVERY GRANTEE THAT THEY, NOT ONLY SHARE  
20 THE KNOW-HOW, BUT THEY ACTUALLY HAVE TO DO THE WORK IN  
21 THEIR OWN LABS TO MAKE THIS AVAILABLE. SO THIS  
22 LANGUAGE ATTEMPTS TO PUT SOME OF THAT BURDEN IF THE  
23 MATERIALS ARE REPLICATABLE; THAT IS, SOMEBODY PRACTICED  
24 IN THE ART CAN GO AWAY AND DO IT FOR THEMSELVES, THAT  
25 THEY EMPOWER THEM TO DO IT, BUT NOT REQUIRE THAT THEY,

1 FOR EXAMPLE, MAKING A MONOCLONAL ANTIBODY AS A REAGENT  
2 CAN BE VERY EXPENSIVE AND TIME-CONSUMING. I THINK IT  
3 COULD BE AN ENORMOUS BURDEN ON A LABORATORY TO PRODUCE  
4 ALL THOSE. THAT'S THE REASON FOR THAT LANGUAGE IN  
5 THERE. AND WE WORKED HARD TO FIND A REASONABLE BALANCE  
6 HERE BETWEEN PUSHING THE SHARING, BUT AT THE SAME TIME  
7 NOT FORCING SOME OF OUR GRANTEES TO GO FULL TIME INTO  
8 MANUFACTURE OF REAGENTS FOR EVERYBODY IN THE COMMUNITY.

9 ARE THERE ANY COMMENTS ON PART B FROM THE  
10 MEMBERS OF THE TASK FORCE?

11 DR. FONTANA: HI, ED. IT'S JEANNIE FONTANA  
12 FROM LOS ANGELES. I GUESS I AGREE WITH THE PRINCIPLE  
13 AND THE CONCEPT, BUT THE DEVIL IS ALWAYS IN THE  
14 DETAILS. WHAT IS EXPENSIVE TO YOU MAY BE INEXPENSIVE  
15 TO ME. DID YOU HAVE SOME IDEA HOW YOU WOULD CLARIFY  
16 WHAT IS EXPENSIVE?

17 CHAIRMAN PENHOET: WELL, I THINK THE LANGUAGE  
18 HERE ANTICIPATES THE INVOLVEMENT OF THE SCIENTIFIC  
19 PROGRAM OFFICER FROM THE FOUNDATION IN ANY SUCH  
20 DISCUSSION. SO IT WOULD BE A THIRD PARTY, AND THAT  
21 PERSON TODAY IS ARLENE CHIU. AND HOPEFULLY IT WILL BE  
22 ARLENE FOR THE FULL TEN YEARS OF OUR PROJECT, BUT SOME  
23 INVOLVEMENT IN CIRM IN ADJUDICATING THE FAIRNESS.

24 DR. FONTANA: SO IT'S YET TO BE DETERMINED?

25 CHAIRMAN PENHOET: WELL, THE SPO IS CALLED

1 OUT IN THIS AS THE PERSON THAT DOES THAT.

2 DR. FONTANA: OKAY.

3 CHAIRMAN PENHOET: WE HAVE A COMMENT FROM THE  
4 UNIVERSITY OF CALIFORNIA.

5 MS. STREITZ: ACTUALLY IT CALLED OUT THE  
6 TERMINATION OF EXTENSIONS BEYOND THE 60-DAY PERIOD.  
7 IT'S NOT CALLED OUT FOR THE TERMINATION WE CAN EXPECT  
8 AND THAT'S PROBABLY A GOOD IDEA.

9 CHAIRMAN PENHOET: OKAY. THAT'S A NUANCE I  
10 DIDN'T QUITE PICK UP ON. ANY OTHER COMMENTS? COMMENTS  
11 FROM THE AUDIENCE? KEN TAYMOR.

12 MR. TAYMOR: I JUST HAVE THREE QUESTIONS. IS  
13 THERE A DIFFERENT STANDARD FOR SHARING WITH ENTITIES  
14 INSIDE CALIFORNIA AND OUTSIDE CALIFORNIA? WOULD THERE  
15 BE A DIFFERENT STANDARD FOR SHARING WITH COMMERCIAL  
16 ENTITIES FOR COMMERCIAL PURPOSES AS OPPOSED TO RESEARCH  
17 PURPOSES? AND IF AN ENTITY -- A GRANTEE SHARED  
18 BIOLOGICAL MATERIALS WITH SOME COMMERCIAL SOURCES,  
19 COULD IT STILL ELECT THE ALTERNATIVE TO SAY TO OTHER  
20 ENTITIES, EITHER COMMERCIAL OR NONCOMMERCIAL, THAT  
21 HERE'S HOW YOU CAN GO OUT AND MAKE THESE OR RECONSTRUCT  
22 THESE MATERIALS?

23 AND THEN LAST, IF A GRANTEE HAS SOME  
24 AFFILIATION WITH A COMMERCIAL ENTITY, CAN IT REFER THE  
25 REQUEST TO ITS AFFILIATED COMMERCIAL ENTITY FOR

1 PURCHASE OR ACQUISITION OF THE BIOLOGICAL MATERIALS?

2 CHAIRMAN PENHOET: ALL GOOD QUESTIONS. I  
3 THINK THE WORD "WITHOUT BIAS" MEANS IT WOULD INCLUDE  
4 ALL PARTICIPANTS, INCLUDING COMMERCIAL ORGANIZATIONS  
5 THAT ARE ENGAGED IN RESEARCH. THE REQUIREMENT WHETHER  
6 IT'S -- AS WRITTEN, IT DOES NOT CONFINE THIS TO THE  
7 STATE OF CALIFORNIA. SO IT'S IN A SENSE PUSHING  
8 NATIONAL POLICY IN THIS DIRECTION. THAT'S ONE REASON.  
9 YOU HAVE TO BE CAREFUL ABOUT THE COST BURDENS  
10 ASSOCIATED WITH DOING THIS RATHER THAN EMPOWERING  
11 SOMEBODY TO DO IT THEMSELVES BECAUSE IT SOON BECOMES A  
12 VERY LARGE BURDEN IF YOU ARE SUPPLYING THE ENTIRE WORLD  
13 WITH BIOMEDICAL MATERIAL THAT YOU INVENTED.

14 DO YOU HAVE A SPECIFIC RECOMMENDATION IN MIND  
15 AMONG THOSE FOUR THINGS THAT YOU BROUGHT UP THAT WE  
16 SHOULD ADD? WITHOUT BIAS MEANT THAT. I THINK WE CAN  
17 CLARIFY WHAT WITHOUT BIAS MEANS. TO SOME DEGREE, I  
18 WOULD POINT OUT THAT SOME PEOPLE HAVE POINTED OUT TO US  
19 WE MAY BE SELECTIVELY DISADVANTAGED VIS-A-VIS THE REST  
20 OF THE COUNTRY BY HAVING THIS REQUIREMENT FOR OPEN  
21 SHARING BECAUSE THE REST OF THE COUNTRY IS NOT REQUIRED  
22 TO SHARE WITH US.

23 ON THE OTHER HAND, WE THINK WE HAVE TO SET A  
24 TONE FOR SHARING, AND HOPEFULLY THIS WILL BE SOMETHING  
25 WHICH TURNS OUT NOT TO BE ONEROUS FOR OUR PEOPLE. AND

1 WE HAVE WORKED HARD TO TRY TO PUSH THE ENVELOPE OF  
2 SHARING, BUT AT THE MOMENT THIS, BY DESIGN, DOESN'T SAY  
3 WILL SHARE WITH OTHER CALIFORNIA INSTITUTIONS.

4 DR. PRIETO: ED, DO WE WANT TO INCLUDE, THEN,  
5 OR ADD A RECIPROCITY CONDITION; THAT IS, THAT WE WILL  
6 SHARE ASSUMING THAT THE ENTITIES WILL ALSO SHARE? I  
7 ASKED THAT QUESTION TO ENTITIES OUTSIDE THE STATE OF  
8 CALIFORNIA NOT COVERED BY CIRM CONDITIONS OR CIRM  
9 FUNDED.

10 CHAIRMAN PENHOET: IT WOULD REQUIRE GRANTEES  
11 TO ENTER INTO AGREEMENTS WITH A LOT OF OTHER  
12 INSTITUTIONS TO DO THAT, BUT IT'S CERTAINLY POSSIBLE  
13 THAT WE COULD DO THAT.

14 MS. STREITZ: SPEAKING ON BEHALF OF THE  
15 UNIVERSITY OF CALIFORNIA, I THINK WE WOULD PREFER TO  
16 TAKE THE HIGH ROAD AND SHARE WITH EVERYBODY REGARDLESS.

17 CHAIRMAN PENHOET: OKAY. THANK YOU.

18 MR. SHEEHY: I WAS GOING TO ADD, BECAUSE WE  
19 DISCUSSED AT THE LAST MEETING, AND THERE WAS KIND OF AT  
20 THE END A TONE THAT AT LEAST AT THE OUTSET WE SHOULD  
21 TRY TO SET A HIGH BENCHMARK. THEN IF IT DOESN'T GET  
22 MET, PERHAPS WE CAN READDRESS IT.

23 DR. PRIETO: OKAY.

24 CHAIRMAN PENHOET: OKAY. THANK YOU.

25 THE NEXT ONE IS PATENT APPLICATION

1 REQUIREMENTS, SECTION C.

2 THE GRANTEE ORGANIZATIONS BEAR THE COSTS AND  
3 THE BURDEN, AND THAT THEY SHOULD REPORT THESE. WE'RE  
4 SHORT A SECTION. UNDER ITEM H, ANY COMMENT ON H(C)?

5 MOVING ALONG TO D. D IS QUITE LONG, SO WE'LL  
6 HAVE TO PARSE D. SO D(1), THAT THE GRANTEE INSTITUTION  
7 SHALL ASSUME RESPONSIBILITY FOR LICENSING ACTIVITIES  
8 AND EVERYTHING THAT THAT ENTAILS AND REPORT TO US ON AN  
9 ANNUAL BASIS THE LICENSING ACTIVITIES THEY'VE  
10 UNDERTAKEN. ANY COMMENTS ABOUT THAT? FROM THE  
11 AUDIENCE?

12 GRANTEE ORGANIZATION SHALL NEGOTIATE  
13 NONEXCLUSIVE LICENSES WHEREVER POSSIBLE. ANY COMMENTS?  
14 JOHN SIMPSON.

15 MR. SIMPSON: HOW DO YOU DEFINE WHENEVER  
16 POSSIBLE? I HAVE DIFFICULTY UNDERSTANDING HOW THAT  
17 TRANSLATES INTO A REGULATION THAT YOU CAN HOLD SOMEONE  
18 TO. CAN'T THEY JUST ALWAYS SAY, BUT IT WASN'T  
19 POSSIBLE? IT WASN'T POSSIBLE.

20 CHAIRMAN PENHOET: WELL, PRESUMABLY THEY  
21 WOULD HAVE TO BACK THAT UP WITH SOME GOOD FAITH EFFORT  
22 TO HAVE DONE SO. AND STILL, OF COURSE, TWO AND THREE  
23 ARE LINKED IN THIS CONCEPT. SO WHY DON'T WE GO ON AND  
24 DISCUSS THREE.

25 NOTWITHSTANDING THE ABOVE, GRANTEE



1 ORGANIZATIONS MAY NEGOTIATE AND AWARD EXCLUSIVE  
2 LICENSES IF THEY ARE NECESSARY TO PROVIDE ECONOMIC  
3 INCENTIVES REQUIRED TO ENABLE COMMERCIAL DEVELOPMENT  
4 AND AVAILABILITY OF THE INVENTION. IN GRANTING  
5 EXCLUSIVE LICENSEES, GRANTEE ORGANIZATIONS SHOULD  
6 CONSIDER DEVELOPMENT AND COMMERCIALIZATION CAPABILITIES  
7 OF THE INTENDED LICENSEE. AND THEN FURTHER, IN  
8 GRANTING EXCLUSIVE LICENSES UNDER 4, GRANTEE  
9 ORGANIZATIONS SHALL INCLUDE TERMS FOR COMMERCIAL  
10 DEVELOPMENT PLANS TO BRING THE INVENTION TO PRACTICAL  
11 APPLICATION. SUCH PROVISIONS SHALL INCLUDE MILESTONES  
12 AND BENCHMARKS SO THAT IT CAN BE ASSESSED AND  
13 MONITORED.

14 SO THESE TWO, THREE, AND FOUR WORKING  
15 TOGETHER ESSENTIALLY EMBODY THE SERIES OF CONCEPTS  
16 HERE. I THINK CERTAINLY NO. 2 MAKES IT EXPLICIT THAT  
17 THAT'S THE FIRST ATTEMPT. YOU KNOW, TO SOME DEGREE  
18 THESE ARE NUANCED DISCUSSIONS WITH THE COMMERCIAL WORLD  
19 THAT ARE ENTERED INTO BY, FOR THE MOST PART,  
20 UNIVERSITIES, SO MAYBE FOR THE SAKE OF THE DISCUSSION,  
21 WE'LL USE UNIVERSITIES TO REPRESENT THE BULK OF THE  
22 NONPROFITS THAT WE'RE TALKING ABOUT HERE. WE STRUGGLED  
23 OBVIOUSLY WITH THIS ISSUE. STRUGGLING TO, FIRST OF  
24 ALL, PUT SOME WEIGHT BEHIND THE STATEMENT ABOUT  
25 NONEXCLUSIVE LICENSES BECAUSE I THINK THERE'S A GENERAL

1 FEELING THAT THE BROADEST UTILIZATION OF THIS  
2 TECHNOLOGY WOULD BE VALUABLE.

3 HAVING SAID THAT, I THINK MANY YEARS OF  
4 EXPERIENCE HAS TAUGHT PEOPLE IN THE LICENSING WORLD  
5 THAT OFTENTIMES, UNLESS THEY ARE PREPARED TO MAKE  
6 EXCLUSIVE LICENSEES, ESPECIALLY FOR THERAPIES WHICH  
7 REQUIRE AN ENORMOUS INVESTMENT ON THE PART OF THE  
8 LICENSEE TO BRING IT TO MARKET, THAT THE INVENTIONS  
9 WON'T BE PURSUED. SO WE TRIED HERE TO BALANCE A  
10 PRESSURE TO DO LICENSING BROADLY WITH THE REALITY THAT  
11 THERE ARE CIRCUMSTANCES. IF HISTORY IS A TEACHER IN  
12 THIS REGARD, THERE ARE CIRCUMSTANCES WHEN TECHNOLOGY  
13 WON'T BE DEVELOPED UNLESS YOU PROVIDE A LICENSEE WITH  
14 AN OPPORTUNITY FOR EXCLUSIVITY. SO THAT'S THE BALANCE  
15 WE SOUGHT TO ACHIEVE HERE IN THESE THINGS.

16 I DON'T KNOW WHETHER ANY OF YOU WHO HAVE  
17 DIRECT EXPERIENCE IN THE UNIVERSITY WORLD WOULD WANT TO  
18 COMMENT FURTHER ON THAT. THAT'S THE ESSENCE OF WHAT WE  
19 TRIED TO DO. MAYBE FIRST, JOHN, IF WE COULD HAVE  
20 COMMENTS FROM THE MEMBERS OF THE TASK FORCE ON TWO,  
21 THREE, AND FOUR TOGETHER SINCE THEY ALL ARE SORT OF  
22 COMMINGLED AND INTERACT WITH ONE ANOTHER.

23 NO COMMENTS FROM THE TASK FORCE, THEN FROM  
24 THE AUDIENCE.

25 MR. SIMPSON: IT'S TREMENDOUSLY DIFFICULT. I

1 UNDERSTAND THAT. I JUST RAISE THE ISSUE OF HOW YOU  
2 PULL THAT. THE OTHER THING I WOULD ADD TO THE MIX  
3 THERE IS THAT YOU MAY WANT TO CONSIDER A PROVISION WHEN  
4 YOU'RE TALKING ABOUT LICENSING EXCLUSIVELY, THAT IT  
5 SHOULD BE FOR DISEASE-SPECIFIC EXCLUSIVITY. SO THERE  
6 ARE POTENTIALLY TIMES WHEN SOMEONE WOULD COME IN AND IF  
7 YOU GAVE THEM A LICENSE FOR ALL SPECIFIC THERAPIES FROM  
8 THAT PARTICULAR PATENT, IT PROBABLY WOULD ONLY WORK AT  
9 DEVELOPING ONE OF THEM AT A TIME, AND IT MIGHT SLOW  
10 THEM TO MARKET. SO YOU MIGHT WANT TO HAVE SOME SORT OF  
11 LANGUAGE ABOUT DISEASE-SPECIFIC EXCLUSIVE LICENSING  
12 RATHER THAN BROAD. I'M NOT SURE.

13 CHAIRMAN PENHOET: THAT'S AN INTERESTING  
14 SUGGESTION. I MEAN ONE WAY TO DO THAT WOULD BE IN THE  
15 DILIGENCE REQUIREMENT. SO WE COULD SAY THAT IN THE  
16 DILIGENCE REQUIREMENT UNDER SUCH LICENSEES  
17 CONSIDERATION WOULD BE GIVEN TO MAXIMIZING USE FOR THE  
18 VARIETY OF DISEASES WHICH WERE POSSIBLE. DOES THAT  
19 ADDITION MAKE SENSE TO YOU? WE'LL HAVE TO REFINE THE  
20 LANGUAGE AROUND THAT, BUT THAT COULD CERTAINLY BE PART  
21 OF THE DUE DILIGENCE REQUIREMENTS.

22 ANY COMMENTS ON JOHN SIMPSON'S SUGGESTED  
23 CHANGE FROM THE TASK FORCE? OTHER COMMENTS FROM THE  
24 AUDIENCE?

25 MS. HOWARD: ELIZABETH HOWARD OF ORRICK.

1 SPEAKING TO TWO AS APPLIES TO THREE AND FOUR, THE  
2 COMMENT WE JUST HEARD OF FIVE, I THINK THAT THIS  
3 NEEDS TO BE -- TWO NEEDS TO BE TIED TO THREE. FOR  
4 EXAMPLE, IF IT WERE TO SAY GRANTEE ORGANIZATIONS SHALL  
5 NEGOTIATE NONEXCLUSIVE LICENSES FOR CIRM-FUNDED  
6 INVENTIONS UNLESS THE SHOWING THAT THREE AND FOUR BELOW  
7 ARE MET. OTHERWISE THERE ARE TWO THINGS THAT CAN  
8 HAPPEN. ONE IS THAT WE DON'T GET ENOUGH NONEXCLUSIVE  
9 LICENSES; BUT IN ADDITION, WHENEVER THERE IS AN  
10 EXCLUSIVE LICENSE, THIS IS GOING TO HAVE THE EFFECT OF  
11 LAW, WHENEVER POSSIBLE FOR THE STANDARD THAT THREE AND  
12 FOUR COULD NEVER OCCUR.

13 CHAIRMAN PENHOET: THAT OKAY WITH EVERYBODY?  
14 THANK YOU. LET'S SEE. WE'VE BEEN JOINED BY JESSE  
15 REYNOLDS HIMSELF.

16 MR. REYNOLDS: JESSE REYNOLDS FROM THE CENTER  
17 FOR GENETICS AND SOCIETY. I SUPPOSE I SHARE A LITTLE  
18 BIT OF MR. SIMPSON'S CONCERNS ABOUT BALANCING OUT THE  
19 NONEXCLUSIVE AND THE EXCLUSIVE LICENSES. AND THE  
20 STATEMENT SEEMS TO -- WELL, I MEAN SOMETIMES THE  
21 EXCLUSIVE LICENSES ARE PREFERABLE FOR GETTING PRODUCTS  
22 TO MARKET AND SO FORTH THAN SOMETIMES NONEXCLUSIVE ARE.  
23 THIS STATEMENT SEEMS TO EXPRESS AN APPROPRIATE  
24 PREFERENCE FOR NONEXCLUSIVE LICENSING. I'M JUST  
25 CONCERNED ABOUT A SITUATION WHERE WHAT'S BEST FOR

1 CALIFORNIA AS A WHOLE DOESN'T NECESSARILY COINCIDE WITH  
2 WHAT'S IN THE INTEREST OF THE GRANTEE AND THE LICENSEE.

3 SO IN THAT REGARD, PERHAPS WHAT COULD BE  
4 BENEFICIAL HERE IS TO HAVE SOME PERSON BE RESPONSIBLE  
5 FOR CHECKING THIS STATEMENT OF PREFERENCE, STATEMENT OF  
6 BALANCE, BE IT WITHIN THE CIRM OR WITHIN THE BROADER  
7 STATE GOVERNMENT.

8 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM  
9 THE AUDIENCES? KEN TAYMOR.

10 MR. TAYMOR: FOLLOWING UP ON THE COMMENTS  
11 ABOUT WHENEVER POSSIBLE, FOR CLARIFICATION, IF A  
12 NONEXCLUSIVE -- IF AN EXCLUSIVE LICENSE WERE GRANTED,  
13 AND I WAS ACCOMPANIED -- I WAS A LAWYER REPRESENTING A  
14 COMPANY THAT WANTED TO CHALLENGE THAT LICENSE AS A  
15 VIOLATION OF THIS REGULATION, WOULD A SIMPLE AFFIDAVIT  
16 FROM THAT COMPANY SAYING WE WOULD BE WILLING TO LICENSE  
17 THAT INVENTION ON A NONEXCLUSIVE BASIS THEREBY BE  
18 ACTIONABLE? IT SEEMS TO ME THAT IT WOULD BE HELPFUL  
19 PERHAPS TO HAVE SOMEONE WITHIN CIRM, SOMEONE WITHIN THE  
20 STATE ULTIMATELY TO MAKE THE DETERMINATION. RATHER  
21 THAN BE A NECESSITY DETERMINATION, REALLY JUST SAY IN  
22 THE, YOU KNOW, OPINION OF THE INSTITUTION, THE GRANTEE  
23 INSTITUTION, AFTER A DILIGENT CHECKLIST, AFTER GOING  
24 THROUGH SOME PROCESS THAT REACHED A DETERMINATION,  
25 THEY -- YOU WILL HAVE A TRACK RECORD. YOU'LL BE ABLE

1 TO VIEW THESE PEOPLE IN ACTION. YOU'LL BE ABLE TO, IF  
2 YOU FEEL THAT THEY'RE GIVING TOO MANY EXCLUSIVE  
3 LICENSES, YOU FEEL THAT THIS WILL BE CHALLENGED BY THE  
4 PUBLIC WITH A GREAT DEAL OF TRANSPARENCY, IT MAY BE  
5 BETTER TO TAKE THE RISK THAT ONE OR TWO CASES MAY BE  
6 DONE IMPROPERLY BY A GRANTEE INSTITUTION THAN TO OPEN  
7 THIS UP TO A TREMENDOUS AMOUNT OF LITIGATION AND  
8 UNCERTAINTY ON THE PART OF POTENTIAL LICENSEES.

9 CHAIRMAN PENHOET: GOOD POINT IN DRAFTING  
10 FINAL REGULATIONS, TO BE SURE. ANY FURTHER COMMENT?  
11 OKAY.

12 FIVE, GRANTEE ORGANIZATIONS SHALL GRANT  
13 LICENSES INVOLVING CIRM-FUNDED PATENTED INVENTIONS TO  
14 ORGANIZATIONS WITH PLANS FOR ACCESS TO RESULTANT  
15 THERAPIES FOR MEDICAL AND UNINSURED CALIFORNIA PATIENT  
16 POPULATIONS.

17 DR. WRIGHT: THIS IS JANET WRIGHT. I HAVE A  
18 QUESTION ABOUT THE INTENT, AND I DON'T HAVE LANGUAGE TO  
19 OFFER, BUT I'M QUESTIONING DOES THIS MEAN SHALL GRANT  
20 PREFERENTIALLY, GRANT LICENSES PREFERENTIALLY?  
21 CERTAINLY DOESN'T MEAN SOLELY.

22 CHAIRMAN PENHOET: I THINK IT MEANS THAT ANY  
23 GRANT -- ANY LICENSE WOULD HAVE TO BE ACCOMPANIED BY A  
24 PLAN FOR ACCESSING THESE THERAPIES TO THESE TWO PATIENT  
25 POPULATIONS.

1 DR. WRIGHT: ALL LICENSES.

2 CHAIRMAN PENHOET: ALL LICENSES. ALL  
3 EXCLUSIVE LICENSES. ALL LICENSES JUST GENERALLY. WHY  
4 NOT?

5 DR. WRIGHT: LET'S NOT SEPARATE.

6 CHAIRMAN PENHOET: JUST ALL LICENSES. SO  
7 EVERY GROUP WOULD HAVE TO COME UP WITH A PLAN. IT'S  
8 HARD TO SPECIFY EXACTLY IN ADVANCE WHAT THAT PLAN MIGHT  
9 BE, BUT PUTS PRESSURE ON ORGANIZATIONS TO GET THOSE  
10 PLANS.

11 DR. PRIETO: I READ THAT THIS APPLIES TO ALL  
12 LICENSES, BUT THE QUESTION I HAVE IS WHO OVERSEES OR  
13 EVALUATES THOSE PLANS?

14 CHAIRMAN PENHOET: WELL, THE GRANTEE  
15 INSTITUTIONS THEMSELVES HAVE THE GENERAL OBLIGATION.  
16 WE WILL BE INFORMED AS TO THE CONTENT OF THE  
17 APPLICATIONS IN THE ANNUAL REPORTS -- I MEAN THE  
18 LICENSES IN THE ANNUAL REPORTS. SO CIRM WILL HAVE SOME  
19 OVERSIGHT IN A SENSE, AT LEAST KNOWLEDGE OF WHAT'S  
20 GOING ON, THE ABILITY TO SIT DOWN WITH GRANTEES AND  
21 DISCUSS THIS. BUT THERE'S NO, YOU KNOW, OFFICIAL BOARD  
22 OR SOMETHING THAT WOULD RENEW ALL THE LICENSES.

23 DR. PRIETO: I WONDER WHETHER THIS WILL END  
24 UP COMING BACK AS A KIND OF CONTENTION OR AN ISSUE  
25 BEFORE THE ICOC OR, YOU KNOW, IN THE PUBLIC IN GENERAL,

1 YOU KNOW, WHETHER THE PLANS ARE ADEQUATE OR NOT. I  
2 JUST WOULD LIKE TO SEE SOME WAY OF EVALUATING THESE  
3 ADEQUATELY.

4 CHAIRMAN PENHOET: WHY NOT -- WE'RE TRYING TO  
5 BALANCE, AND I'M TRYING TO THINK -- MAYBE SOME OF THE  
6 OTHER PEOPLE HAVE AN IDEA ON THIS SUBJECT. THE ISSUE  
7 IS THE RELATIVELY MODEST RESOURCES OF THE FIRM ITSELF  
8 AND, YOU KNOW, TO SOME DEGREE FORCE OF LAW, THERE WILL  
9 BE A BODY IN THE REGULATIONS TO ESSENTIALLY DRIVE  
10 ORGANIZATIONS TO BEHAVE IN THIS WAY. I MEAN THERE WAS  
11 IN -- WE DISCUSSED EARLIER IN THE REPORT BROUGHT TO US  
12 TODAY BY THE CONSUMER GROUP, THERE WAS A PROVISION  
13 ABOUT PRICING, THAT COMPANIES WOULD MAKE THEIR PRODUCTS  
14 AND RESULTANT THERAPIES AVAILABLE AT THE LOWEST  
15 AVAILABLE COMMERCIAL PRICE. THAT IS SOMETHING THAT  
16 PERHAPS MR. SIMPSON WILL BRING UP. IT WAS PART OF  
17 THEIR REPORT. THAT IS SOMETHING WE DISCUSSED BEFORE.  
18 THAT'S ONE POSSIBILITY.

19 BUT IT'S THE ISSUE REALLY OF ENFORCEMENT  
20 HERE. ALSO MAYBE KEN TAYMOR'S CONCERN IS THAT IF THERE  
21 IS VAGUENESS HERE, IT COULD BE CHALLENGED IN COURT  
22 LATER AS BEING UNLAWFUL FOR ONE REASON OR ANOTHER BY A  
23 SUITOR WHO WANTED TO HAVE THE TECHNOLOGY AND SAYS I  
24 HAVE A BETTER PLAN THAN YOU.

25 DR. PRIETO: THAT'S A GOOD POINT. I



1 CERTAINLY DON'T WANT TO OPEN ANYTHING UP FOR MORE  
2 LITIGATION, BUT I JUST -- I WANT THE LANGUAGE TO BE  
3 PRECISE ENOUGH FOR PEOPLE TO UNDERSTAND THEIR  
4 EXPECTATIONS AND FOR US TO HAVE SOME REASONABLE  
5 EXPECTATIONS OF PEOPLE. I DON'T WANT TO IMPOSE MORE ON  
6 CIRM STAFF BECAUSE WE DON'T HAVE ENOUGH STAFF TO POLICE  
7 THAT, BUT I JUST WOULD LIKE THE EXPECTATIONS TO BE  
8 CLEAR.

9 CHAIRMAN PENHOET: MAYBE IT'S THE TIME TO ASK  
10 FOR SOME COMMENT BY THE PUBLIC. YOU WANT TO COMMENT,  
11 MR. SIMPSON?

12 MR. SIMPSON: WE DID MAKE THE PROPOSAL THAT  
13 YOU REFERRED TO, SPECIFICALLY A REQUIREMENT THAT THE  
14 GRANTEES WOULD SELL AT THEIR BEST COMMERCIAL PRICE TO  
15 THE STATE, THINGS LIKE MEDI-CAL. WE THINK THAT'S A  
16 GOOD, SOUND PROPOSAL. THERE ARE SOME OTHER MODELS FOR  
17 THAT WITH THE FEDERAL GOVERNMENT WITH THE VETERAN'S  
18 ADMINISTRATION AND MEDICARE, AS I UNDERSTAND IT. WE  
19 THINK THAT'S A GOOD SPECIFIC MODEL. IT GOES, AGAIN, TO  
20 THE POINT OF WHATEVER REGULATIONS YOU END UP WITH, I  
21 THINK THEY NEED TO BE SPECIFIC AND CLEAR. AND PERHAPS  
22 THE POSITIVE SIDE OF THE LITIGATION THAT'S GOING ON NOW  
23 IS THAT THERE IS A LITTLE BIT OF TIME TO GET THESE  
24 REGULATIONS RIGHT.

25 CHAIRMAN PENHOET: WE CERTAINLY HAVE 270 DAYS

1 TO REFINE ALL THESE CONCEPTS. THAT'S FOR SURE. I  
2 THINK THAT IS A PROPOSAL FROM THAT GROUP. LOWEST  
3 AVAILABLE U.S. COMMERCIAL PRICE WOULD BE A SPECIFIC  
4 BENCHMARK. SO JUST AS A PRACTICAL MATTER, IN THE WAY  
5 PRICING WORKS, IT WOULD BE HARD TO SAY THAT IT WILL BE  
6 A PRICE LESS THAN THE LOWEST AVAILABLE COMMERCIAL PRICE  
7 BECAUSE MANY OF THE OTHER GROUPS LIKE THE VETERANS  
8 ADMINISTRATION HAVE A MOST FAVORED NATION CLAUSE IN  
9 THEIR PURCHASING, SO PRETTY SOON THE PRICE WOULD GO TO  
10 ZERO IF YOU FOLLOWED IT DOWN QUICKLY ENOUGH. BUT  
11 MATCHING THE LOWEST AVAILABLE COMMERCIAL PRICE FOR  
12 THESE TWO POPULATIONS WOULD BE REALISTIC.

13 DR. PRIETO: I DON'T KNOW IF THE PRICE GOES  
14 TO ZERO, BUT PRETTY SOON EVERYBODY GETS THAT SAME  
15 LOWEST PRICE, BUT THERE ARE OTHER WAYS OF PROVIDING --  
16 MAKING TREATMENTS AVAILABLE WITHOUT SPECIFICALLY  
17 DISCUSSING PRICING. I KNOW BOB HAS BROUGHT UP THE  
18 ISSUE OF PILOT PROJECTS, AND THERE ARE VARIOUS WAYS  
19 THIS COULD BE DONE. I JUST WOULD LIKE TO SEE SOMETHING  
20 IN THE LANGUAGE, AND MAYBE IT DOESN'T HAVE TO BE IN THE  
21 INITIAL VERSION, TALKING ABOUT HOW THESE PLANS ARE  
22 LOOKED AT JUST SO THAT THEY DO GET SOME EVALUATION.

23 CHAIRMAN PENHOET: I'M TRYING TO THINK HARD  
24 ABOUT WHO WOULD DO THAT.

25 DR. PRIETO: I REALIZE IT'S A PROBLEM.

1 CHAIRMAN PENHOET: I MUST SAY PERSONALLY I  
2 DON'T HAVE AN AVERSION TO THE LOWEST AVAILABLE U. S.  
3 COMMERCIAL PRICE AS SOMETHING -- FOR THESE TWO  
4 POPULATIONS. THIS IS NOT FOR ALL CALIFORNIANS. IT'S  
5 FOR UNINSURED CALIFORNIANS AND MEDI-CAL RECIPIENTS. I  
6 DON'T KNOW WHETHER THAT WOULD BE A FEATURE THAT WOULD  
7 PRECLUDE -- WHAT YOU WORRY ABOUT WHEN YOU LOAD TOO MANY  
8 OF THESE THINGS ON IS THAT WE WON'T FIND BUYERS FOR OUR  
9 TECHNOLOGY AND, THEREFORE, THE TECHNOLOGY WON'T BE  
10 DEVELOPED. THAT'S THE CONCERN ON THE OTHER SIDE.

11 DR. PRIETO: RIGHT.

12 CHAIRMAN PENHOET: WE HAVE WENDY FROM THE UC.

13 MS. STREITZ: THIS IS ONE OF OUR BIG CONCERNS  
14 WITH THIS KIND OF CLAUSE IN GENERAL IS THAT IT WILL  
15 SCARE COMPANIES AWAY AND WE WON'T BE ABLE TO GET  
16 ANYTHING TURNED INTO A TREATMENT AND OUT TO THE PUBLIC.

17 ONE OF THE BEAUTIES ABOUT THIS THING WITH  
18 REQUIRING THE COMPANIES THEMSELVES TO COME UP WITH A  
19 PLAN IS THEY CAN BE VERY CREATIVE AND VERY FLEXIBLE.  
20 THEY KNOW THEIR MARKET AND WHAT THEY CAN AND CAN'T DO,  
21 AND THIS WOULD ENCOURAGE THEM TO BE VERY FLEXIBLE. NOT  
22 HAVING TO TELL THEM IN ADVANCE HOW TO DO IT WITHOUT  
23 TELLING THEM IN ADVANCE HOW TO DO IT, SO THAT'S A PLUS  
24 HERE.

25 ONE CONCERN ABOUT -- I HAVE A NUMBER OF

1 POINTS. I'M TRYING TO THINK WHICH ONES I WANT TO MAKE  
2 RIGHT NOW. CONTRARY TO POPULAR BELIEF, WE DON'T HAVE  
3 COMPANIES LINED UP OUTSIDE OUR DOOR WAITING TO LICENSE  
4 OUR INVENTIONS. WE'RE LUCKY TO HAVE ONE COMPANY.  
5 THAT'S A HIT. IF WE HAVE SOMEBODY THAT WANTS TO  
6 LICENSE AN INVENTION, THAT'S A GOOD THING. SO WE DON'T  
7 ALWAYS HAVE MULTIPLE BIDDERS. IN FACT, WE RARELY HAVE  
8 MULTIPLE BIDDERS.

9 ONE OF MY CONCERNS WITH THIS IS IF YOU  
10 REQUIRE THAT EVERY LICENSEE HAVE A PLAN, IF THE ONLY  
11 COMPANY THAT'S WILLING TO STEP UP TO THE PLATE AND  
12 INVEST THE MONEY TO DEVELOP THE INVENTION SAYS WE'RE  
13 NOT DOING A PLAN, THEN WHAT DO WE DO? DO WE SHELF THE  
14 TECHNOLOGY AND NOBODY GETS IT? SO YOU MAY WANT -- WHAT  
15 I WAS THINKING HERE THAT MAY WORK IS SOMETHING ALONG  
16 THE LINES OF WHAT BAYH-DOLE DOES FOR SMALL BUSINESSES.  
17 THEY SAY THAT WE HAVE TO BASICALLY GIVE THEM AN  
18 ADVANTAGE AND WE HAVE TO SEEK THEM PREFERENTIALLY. WE  
19 HAVE TO PREFERENTIALLY LICENSE TO SMALL BUSINESSES.  
20 AND THAT MIGHT BE A GREAT WAY TO GO HERE IS TO SAY THAT  
21 WE HAVE TO PREFERENTIALLY LICENSE TO THOSE WITH A PLAN  
22 FOR ACCESS TO THESE POPULATIONS. YOU CAN SAY WITH THE  
23 BEST PLAN FOR ACCESS, ASSUMING THAT WE'RE FORTUNATE TO  
24 GET TWO COMPANIES THAT EACH HAVE PLANS FOR ACCESS.

25 MR. TOCHER: WOULD YOU SAY, THEN, THAT THE

1       LOWEST AVAILABLE U. S. COMMERCIAL PRICE, THEN, INFRI NGES  
2       TOO MUCH ON THE FLEXIB ILITY THAT YOU WERE SAYING THE  
3       CURRENT DRAFT EMBODIES?

4               MS. STREITZ:   I THINK THERE ARE COMPANIES OUT  
5       THERE WHO MIGHT COME UP WITH CREATIVE APPROACHES WE  
6       HAVEN' T THOUGHT OF THAT DON' T INVOLVE THE LOWEST  
7       COMMERCIAL PRICE.   YEAH.

8               CHAIRMAN PENHOET:   WELL, COULD THERE BE SOME  
9       LANGUAGE INSTEAD.   PLANS WHICH MAY INCLUDE AVAILABIL ITY  
10       AT THE LOWEST AVAILABLE COMMERCIAL PRICE TO AT LEAST  
11       PUT SOME BENCHMARK IN THERE?

12              MR. TOCHER:   YOU CAN ALWAYS PROVIDE GUIDANCE  
13       AS A PERMISSIBLE SORT OF EXAMPLE, THAT SORT OF THING,  
14       WHICH CAN BE HELPFUL.   IT DEPENDS ON HOW YOU PHRASE IT,  
15       OR YOU CAN MAKE IT EXCLUSIVE, THIS OR SOMETHING ELSE.  
16       HOWEVER, THE OR SOMETHING ELSE IS ALREADY ITSELF SO  
17       BROAD, WHATEVER YOU WANT (INAUDI BLE).

18              CHAIRMAN PENHOET:   WE COULD HAVE LANGUAGE  
19       THAT SAID ACCEPTABLE PLAN OR A COMMITMENT TO MAKE  
20       THERAPIES AVAILABLE AT THE LOWEST AVAILABLE COMMERCIAL  
21       PRICE.

22              MR. TOCHER:   RIGHT.

23              MR. REED:   I' M A PATIENT ADVOCATE.   I' M  
24       CONCERNED ABOUT ANYTHING THAT MAY OFFER NEW GROUNDS FOR  
25       LAWSUITS THAT SLOW US DOWN.   I WONDER IF THERE' S A WAY

1 THAT WE CAN PUT SOMETHING IN THERE THAT GRANTEE  
2 ORGANIZATIONS SHALL GIVE PREFERENCES TO PROPOSALS WITH  
3 PLANS FOR ACCESS OR IN SOME WAY PREFERENTIALLY TO  
4 ENCOURAGE THEM TO COME UP WITH CREATIVE WAYS, BUT  
5 NOTHING THAT BINDS US IN WORDS OF IRON, WHICH WILL  
6 IMMEDIATELY BE GROUNDS FOR A LAWSUIT.

7 CHAIRMAN PENHOET: UNFORTUNATELY SOMETIMES  
8 WORDS OF IRON ARE THE BEST WAY TO AVOID A LAWSUIT, BUT  
9 THAT'S A GOOD POINT, DON.

10 MR. SHEEHY: I JUST HAVE A CONCERN ABOUT THE  
11 FIXATION ON BEST COMMERCIAL PRICE. IF YOU ARE TALKING  
12 ABOUT UNINSURED PATIENTS, THAT ISN'T NECESSARILY A  
13 RELEVANT CONCEPT. IN FACT, MANY COMPANIES DO VERY WELL  
14 WITH EXPANDED ACCESS PROGRAMS FOR UNINSURED. AND I  
15 WONDER IF WE DRAFT THIS LANGUAGE USING BEST COMMERCIAL  
16 PRICE, THE WAY IN WHICH LANGUAGE HAS BEEN TALKED ABOUT  
17 WAS FOR MEDI-CAL AND UNINSURED PATIENT POPULATIONS.  
18 JUST BEING ABLE TO GET IT CHEAPER ISN'T GOING TO MAKE  
19 IT NECESSARILY MORE ACCESSIBLE.

20 AND WHILE THE IDEA OF THE BEST PLAN SEEMS  
21 REALLY -- HAVING MORE GENERIC LANGUAGE SEEMS KIND OF  
22 MUDDY. SOME COMPANIES DO DO VERY WELL ON MAKING THEIR  
23 THERAPIES ACCESSIBLE TO PEOPLE WHO REALLY NEED THEM FOR  
24 FREE. AND WE CAN'T -- I'M CONCERNED ABOUT WRITING THIS  
25 IN A WAY THAT FORECLOSES GOOD CITIZENS FROM CONTINUING

1 TO BEHAVE AS GOOD CITIZENS, AND WITH THE GOAL OF  
2 FOCUSING EXCLUSIVELY ON PRICE. SO THAT IS MY CONCERN  
3 ABOUT REALLY ZEROING IN ON THE BEST COMMERCIAL PRICE.

4 MS. LANSING: YOU DON'T WANT TO TAKE THE  
5 PRICE THING OUT BECAUSE JUST THAT GOES HAND IN HAND  
6 WITH ACCESSIBILITY AS WELL.

7 MR. SHEEHY: PARDON ME?

8 MS. LANSING: YOU WANT TO ADD TO IT. YOU  
9 DON'T WANT TO TAKE THE PRICING OUT, THAT THEY DO IT FOR  
10 THE MEDI-CAL AND UNINSURED. YOU WANT TO ADD TO IT. AM  
11 I MISUNDERSTANDING YOU?

12 MR. SHEEHY: YOU KNOW, TO BE HONEST, I KIND  
13 OF LIKE THE LANGUAGE -- YOU KNOW, IN GENERAL I LIKE THE  
14 IDEA OF PUTTING THE BURDEN ON THE COMPANY TO BE  
15 CREATIVE BECAUSE, FIRST OF ALL, WE DON'T KNOW WHAT THE  
16 THERAPIES ARE GOING TO BE. SO THE LANGUAGE AS IT IS  
17 WITH SOME TUNING ALMOST MAKES MORE SENSE TO ME THAN TO  
18 BE TALKING ABOUT PRICING IN THIS PARTICULAR. I GET  
19 UNCOMFORTABLE WHEN WE START TALKING SPECIFICALLY ABOUT  
20 PRICING.

21 MS. LANSING: YOU'RE TALKING ABOUT LEAVING IT  
22 AS IT IS WITH SOME FINE-TUNING.

23 MR. SHEEHY: WELL, A LITTLE BIT OF TUNING. I  
24 DO THINK THAT FRANCISCO HAS RAISED SOME VALID POINTS  
25 ABOUT HOW ARE WE GOING TO KNOW THAT WE'RE GETTING THE

1 BEST PLANS, THAT THERE'S SOME DILIGENCE TO MAKE SURE  
2 THAT -- THAT THERE'S BEEN AN EFFORT TO FIND A  
3 COMPETITOR WITH A PLAN. THERE MAY BE COMPANY A THAT  
4 MAY BE THE RESEARCHER'S OWN COMPANY THAT SAYS I WANT TO  
5 DEVELOP THIS AND I DON'T WANT TO COME UP WITH A PLAN.  
6 YOU MIGHT BE ABLE TO OFFER IT TO OTHER FOLKS WHO, BIG  
7 PHARMA, FOR INSTANCE, MIGHT BE WILLING TO COME UP WITH  
8 A PLAN. I'M NOT -- I THINK THIS IS A TOUGH POINT, BUT  
9 I THINK THAT THERE'S A DEGREE OF GENERALIZATION THAT IS  
10 GOOD HERE.

11 MS. LANSING: I'M VERY COMFORTABLE WITH THE  
12 LANGUAGE. I DON'T MIND ADDING TO THE LANGUAGE, BUT I  
13 ACTUALLY THOUGHT THE LANGUAGE AS IS WAS VERY GOOD. I  
14 UNDERSTAND WHAT FRANCISCO IS SAYING. I JUST THINK --  
15 I'M VERY COMFORTABLE WITH WHAT IS HERE. IF YOU WANT TO  
16 ADD SOMETHING, BUT I WOULDN'T WANT TO ANY WAY --

17 DR. PRIETO: IF I CAN ADD SOMETHING. I THINK  
18 I TEND TO AGREE WITH JEFF. I'M A LITTLE WARY OF USING  
19 WORDS LIKE PRICING OR AFFORDABILITY. IN A SENSE IT  
20 MIGHT EVEN GIVE SOME LICENSEES TOO EASY AN OUT. THEY  
21 CAN JUST INSERT A CLAUSE, OKAY, WE WILL GRANT THE  
22 LOWEST COMMERCIAL PRICE TO MEDI-CAL AND UNINSURED  
23 POPULATIONS. AND THERE ARE SOME MORE IMAGINATIVE AND  
24 BETTER PLANS OUT THERE, AND THEY'VE EXISTED FOR A  
25 NUMBER OF THERAPIES, AND WE DON'T WANT TO DISCOURAGE



1 THAT KIND OF CREATIVITY. MY ONLY POINT REALLY WAS THAT  
2 I THOUGHT SOMEBODY SHOULD LOOK CRITICALLY. I DON'T  
3 KNOW IT NECESSARILY NEEDS TO BE THE CIRM, BUT THAT  
4 THERE NEEDS TO BE SOME OVERSIGHT OF THE PLANS JUST TO  
5 SAY, OKAY, THIS IS GOOD OR THIS REALLY ISN'T VERY GOOD.

6 MS. LANSING: I UNDERSTAND. I UNDERSTAND.

7 CHAIRMAN PENHOET: MAYBE I COULD MAKE A  
8 SUGGESTION, THAT I THINK MEDI-CAL AND UNINSURED, AND  
9 THEY'RE TWO DIFFERENT PATIENT POPULATIONS.

10 MS. LANSING: SAY THAT AGAIN. I DIDN'T HEAR  
11 YOU.

12 CHAIRMAN PENHOET: WE HAVE LOTS OF MEDI-CAL  
13 AND UNINSURED IN THE SAME SENTENCE HERE, AND THEY'RE  
14 ACTUALLY TWO DIFFERENT PATIENT POPULATIONS. ONE  
15 POSSIBILITY WOULD BE TO INCLUDE THE LOWEST AVAILABLE  
16 COMMERCIAL PRICE LANGUAGE WHEN IT REFERS TO MEDI-CAL  
17 RECIPIENTS BECAUSE MEDI-CAL DOES PAY FOR THERAPIES.  
18 AND PLANS FOR ACCESS TO UNINSURED, WHICH ARE MORE  
19 OPEN-ENDED, BECAUSE JEFF IS RIGHT. MANY COMPANIES,  
20 BIOTECH AND PHARMA, TODAY PROVIDE FREE GOODS TO  
21 UNINSURED PATIENTS.

22 MS. LANSING: THAT COVERS THE BASES.

23 CHAIRMAN PENHOET: SO IF WE SPLIT MEDI-CAL  
24 AND UNINSURED AND PUT SOME LANGUAGE ABOUT ESSENTIALLY  
25 LOWEST AVAILABLE U.S. COMMERCIAL PRICE INTO THE

1 MEDI -CAL PIECE AND LEFT OPEN TO THE CREATIVITY OF THE  
2 WORLD TO ADDRESS THE OTHER ISSUE. I ALSO THINK WITH  
3 RESPECT TO THE LAST ITEM IF WE SAID THAT THAT APPLIES  
4 TO UNINSURED POPULATIONS IN CALIFORNIA, WE COULD HAVE  
5 AN ANNUAL REPORT TO THE ICOC ON WHAT THOSE ARE. AND IF  
6 THEY TURN OUT AFTER A FEW YEARS NOT TO BE ADEQUATE, WE  
7 CAN ALWAYS READDRESS IT AGAIN. BUT WE DON'T IMPOSE A  
8 HEAVY HAND ON THAT RIGHT UP FRONT, BUT NEVERTHELESS  
9 MONITOR IT OVER TIME. WE CERTAINLY CAN HAVE THAT  
10 REPORT AVAILABLE IN A PUBLIC MEETING.

11 DR. PRIETO: I LIKE THAT IDEA.

12 CHAIRMAN PENHOET: DO YOU LIKE THE IDEA OF  
13 SPLITTING IT THEN TOO, ABOUT PRICING WITH MEDI -CAL AND  
14 PLANS FOR UNINSURED?

15 DR. PRIETO: YES. I THINK THAT'S REASONABLE.

16 CHAIRMAN PENHOET: WE' LL TRY TO DO THAT.

17 MS. LANSING: I ALSO LIKE THE IDEA OF THE  
18 REPORT. I HAVE TO SAY I THINK IT'S REALLY GOOD, ED,  
19 WHAT YOU CAME UP WITH. IT COVERS BOTH BASES. I ALSO  
20 LIKE THE IDEA OF THE REPORTS BECAUSE IT MAKES PEOPLE  
21 ACCOUNTABLE.

22 CHAIRMAN PENHOET: OKAY.

23 DR. FONTANA: WHAT ABOUT THE COMPANIES THAT  
24 ARE IN THE EARLY STAGES OF TECHNOLOGY WHERE THERE MAY  
25 NOT BE DIRECT APPLICATIONS TO DRUG DEVELOPMENT? ARE

1 YOU GOING TO REQUIRE THEM TO MAKE A PLAN?

2 CHAIRMAN PENHOET: I THINK THESE ARE FOR  
3 THERAPIES AND DIAGNOSTICS, AND MAYBE WE SHOULD MAKE  
4 THAT CLEAR, NOT FOR RESEARCH TOOLS AND OTHER.

5 DR. FONTANA: MAKE SOME EXEMPTION.

6 DR. PRIETO: I THINK --

7 CHAIRMAN PENHOET: WE'LL CLARIFY THAT  
8 LANGUAGE.

9 DR. FONTANA: AND THEN WE HAVE ONE MORE  
10 QUESTION.

11 MS. DELAURENTIS: HI, ED. THIS IS SUSAN  
12 DELAURENTIS FROM THE ALLIANCE FOR STEM CELL RESEARCH.  
13 I JUST WANTED CLARIFICATION ON SOMETHING. WITH THE  
14 POSSIBILITY THAT THERE'S ONE COMPANY IN THE WORLD OR IN  
15 THE COUNTRY OR IN CALIFORNIA, WHEREVER IT IS, THAT CAN  
16 BE LICENSED FOR A PARTICULAR THERAPY AND THEY REFUSE TO  
17 PROVIDE ACCESSIBILITY, IS THAT SOMETHING THAT WE WILL  
18 DENY THEM THEN?

19 CHAIRMAN PENHOET: WELL, YOU KNOW, WE'VE LEFT  
20 THEM A LOT OF LATITUDE TO WHAT CONSTITUTES A PLAN AT  
21 THE MOMENT. IF WE GET THAT KIND OF INFORMATION, WE'LL  
22 SAY THAT. A PLAN DOESN'T HAVE TO BE AN EBULLIENT PLAN.  
23 IT CAN BE A MODEST PLAN. HOPEFULLY IT WOULD BE AN  
24 AGGRESSIVE PLAN, BUT WE'LL HAVE TO MONITOR THAT WITH  
25 TIME. WE'RE NOT PROSCRIBING TODAY WHAT THE PLAN WOULD

1 HAVE IN IT.

2 MS. LANSING: BUT IT IS OUR INTENT. THIS IS  
3 A BIG THING, YOU KNOW, IS TO PROVIDE ACCESSIBILITY OF  
4 WHAT COMES OUT OF THIS TO PEOPLE WHO ARE UNINSURED OR  
5 MEDI-CAL PATIENTS.

6 DR. PRIETO: YOU KNOW, WE DO HAVE THE  
7 LEVERAGE, IF YOU WILL, ALTHOUGH THESE ARE GOING TO BE  
8 COMPANIES DOWNSTREAM OF THE ORIGINAL RESEARCH, OF GOING  
9 TO THEM AND SAYING, LISTEN, THIS TECHNOLOGY YOU  
10 PROPOSED TO COMMERCIALIZE ONLY EXISTS BECAUSE OF THE  
11 INVESTMENT ON THE PART OF THE CITIZENS OF CALIFORNIA,  
12 AND THIS IS A REQUIREMENT WE PUT IN PLACE. I THINK  
13 THAT ANY REASONABLE COMPANY WILL MAKE AN EFFORT. ANY  
14 REASONABLE COMPANY WE WOULD WANT TO DO BUSINESS WITH  
15 WILL MAKE AN EFFORT TO COME UP WITH SOME SORT OF A GOOD  
16 FAITH PLAN.

17 MS. LANSING: I AGREE.

18 MR. SHEEHY: COULD I MAKE JUST ONE MORE  
19 POINT? IF WE'RE GOING TO DO A PRICING THING AND  
20 SPECIFY MEDI-CAL, WE SHOULD MAYBE DO A LITTLE RESEARCH  
21 AND INCLUDE OTHER. I THINK HEALTHY FAMILIES ALSO IS A  
22 PURCHASER OF THERAPIES. AND NOT TO BE PAROCHIAL, BUT  
23 WE DO HAVE THE AIDS DRUG ASSISTANCE PLAN, WHICH IS A  
24 PURCHASER OF THERAPIES. AND THERE MAY BE OTHERS.  
25 THOSE ARE THE TWO THAT I KNOW OF OFF THE TOP OF MY

1 HEAD.

2 CHAIRMAN PENHOET: GOOD. MR. REYNOLDS.

3 MR. REYNOLDS: THANK YOU. A LOT OF THE  
4 THINGS I WAS GOING TO BRING UP WERE RECENTLY BROUGHT UP  
5 BY THE MEMBERS OF THE BOARD. WHAT WE'RE BALANCING HERE  
6 IS WE'RE BALANCING ON THE ONE HAND, TRYING TO ACHIEVE  
7 ACCESSIBLE PRICE STRUCTURES AND ACCOUNTABILITY TO THAT  
8 STANDARD WITH THE FLEXIBILITY ON THE PART OF THE  
9 LICENSEES. AND WHAT I'VE HEARD IS THAT SOME COMPANIES  
10 WANT TO BE CREATIVE AND BE FLEXIBLE AND PROPOSE NEW  
11 IDEAS AND OTHERS MIGHT NOT WANT THAT. SO ONE  
12 POSSIBILITY WOULD BE TO HAVE SOMETHING OF A DEFAULT IN  
13 BOTH CASES, MEDI-CAL AND UNINSURED POPULATION. PERHAPS  
14 HAVE THE LOWEST AVAILABLE PRICE AS THE DEFAULT AND THEN  
15 HAVE THE OPTION OF SUBMITTING A CREATIVE PLAN FOR THOSE  
16 LICENSEES THAT WISH TO DO THAT.

17 SECOND, I WOULD SUGGEST THAT THOSE PLANS BE  
18 APPROVED BY SOMEBODY OUTSIDE OF THE GRANTEE  
19 INSTITUTION, WHETHER THAT BE SOMEONE AT CIRM OR THE  
20 BROADER STATE GOVERNMENT.

21 AND THIRD, I WAS GOING TO BRING UP WHAT I  
22 THINK DR. PENHOET -- I DON'T THINK IT WAS YOU  
23 ORIGINALLY -- BROUGHT UP THE IDEA OF AN ANNUAL REPORT,  
24 SOME SORT OF PUBLIC DOCUMENT PARTICULARLY ABOUT THE  
25 EXCEPTIONS TO THE CREATIVE PLANS, EXCEPTIONS TO MOST

1 AFFORDABLE PRICE, SO THAT THERE CAN BE SOME SORT OF  
2 PUBLIC ACCOUNTABILITY AND SEE WHETHER THAT'S FOLLOWED  
3 THROUGH OR NOT.

4 CHAIRMAN PENHOET: THANK YOU. ANY OTHER  
5 COMMENTS?

6 MR. TAYMOR: FIRST, JUST A TECHNICAL  
7 QUESTION. IF IT'S YOUR INTENTION THAT EACH LICENSE OF  
8 A CIRM-FUNDED IP, THE SUBJECT OF THIS RULE, THEN IT  
9 SHOULD BE SOMETHING ALONG THE LINES THAT EACH LICENSE  
10 GRANTED BY THE GRANTEE ORGANIZATION SHALL INVOLVE  
11 BECAUSE AS THIS IS DRAFTED THE GRANTEE ORGANIZATION  
12 COULD COMPLY. SINCE THEY HAVE A PORTFOLIO OF 10 OR 15  
13 PIECES OF IP, IT WOULD QUALIFY BY ONLY GRANTING ONE OR  
14 TWO.

15 SOMETHING I THINK IS PERHAPS MORE  
16 SUBSTANTIVE. MANY THERAPIES HAVE MULTIPLE COMPONENTS  
17 OF IP AND ALSO MULTIPLE COMPONENTS IN TERMS OF ACTUAL  
18 RECEIPT BY THE PATIENT. IF YOU HAVE A PARTICULAR  
19 THERAPEUTIC THAT HAS BOTH OF THE COMPONENTS OF THE  
20 CIRM-FUNDED IP, NON-CIRM-FUNDED IP, DOES THE CIRM  
21 LICENSE HAVE TO HAVE TERMS IN IT, AS I BELIEVE THIS  
22 WOULD SAY IT DOES, THAT IT TRUMPS ALL OTHER LICENSES.  
23 SO THAT IF YOU HAVE ANY PIECE OF CIRM IP IN YOUR  
24 RESULTING THERAPEUTIC, WHATEVER LANGUAGE YOU COME UP  
25 WITH TODAY ABOUT MOST FAVORED PRICING AND SO FORTH

1 WOULD HAVE TO APPLY TO THAT PARTICULAR PIECE OF IP.

2 SECONDLY, I THINK IT WOULD BE WORTH EXPLORING  
3 THERAPIES WHERE THE ACTUAL COST OF THE MATERIAL AND SO  
4 FORTH IS ONLY A SMALL PORTION OF THE OVERALL COST OF  
5 GETTING THE THERAPY TO THE TARGET PATIENT POPULATION.  
6 I BELIEVE THAT AT LEAST IN STEM CELL THERAPIES THAT WE  
7 HAVE IN THE MARKETPLACE TODAY, THE ACTUAL OVERALL COST  
8 TO A PATIENT OF RECEIVING THAT PARTICULAR THERAPEUTIC  
9 AGENT IS SMALL. AND THIS MAY NOT HAVE THE DESIRED  
10 EFFECT OF GETTING THIS TYPE OF THERAPIES AVAILABLE TO A  
11 BROAD RANGE OF LOWER INCOME PATIENTS IN CALIFORNIA IF  
12 THAT ELEMENT'S NOT ADDRESSED.

13 SO I GUESS THE TWO QUESTIONS ARE, ONE, THE  
14 SORT OF MULTIPLE IP INVOLVEMENT IN THE THERAPEUTIC,  
15 AND, SECOND, A THERAPEUTIC THAT'S ONLY A SMALL PORTION  
16 OF THE OVERALL DELIVERY COST.

17 CHAIRMAN PENHOET: ANY OTHER COMMENTS? I  
18 GUESS THE SENSE OF THE GROUP IS PROBABLY THAT OUR RULES  
19 WOULD TRUMP. AND WITH RESPECT TO COSTS, IF YOU WANT TO  
20 SCARE AWAY GRANTEES, I THINK IT'S A VERY HARD TO ISSUE  
21 TO GET INTO. YOU CAN DEAL WITH PRICING IN A SENSE MORE  
22 STRAIGHTFORWARDLY THAN COST. COSTS ARE HARD TO  
23 DETERMINE OFTENTIMES.

24 DOES ANYBODY WANT TO RESPOND TO THAT?

25 MR. SHEEHY: I DON'T THINK PROP 71'S PURPOSE

1 IS TO RETAIN HEALTHCARE COSTS. ALL WE CAN DO IS TRY TO  
2 IMPACT THE PRICE OF THE GOODS THAT ARE DEVELOPED. YOU  
3 ARE TALKING ABOUT REACHING AN ADVOCATE COMPANY. I CAN  
4 IMAGINE THAT SOME OF THESE THERAPIES MAY BE SURGICAL.  
5 SO YOU'RE GOING TO REACH IN AND TELL THE COMPANY THAT  
6 THEY'RE GOING TO TELL THE SURGEON WHAT PRICE HE'S GOING  
7 TO CHARGE TO DO THE SURGERY. WE CAN'T SOLVE -- I THINK  
8 IF WE ARE ADDRESSING SOME ACCESS AND SOME PRICE ISSUES,  
9 I THINK WE'RE TAKING A STEP FORWARD.

10 I DON'T KNOW -- I WAS JUST LOOKING AT MY PROP  
11 71 COPY BEFORE I CAME OVER HERE. THE IRONY THAT PROP  
12 72, WHICH DIDN'T PASS, IS INCLUDED IN THAT, WHICH WOULD  
13 HAVE MANDATED EMPLOYER HEALTH CARE FOR EVERYBODY --  
14 EVERY EMPLOYEE IN CALIFORNIA. THE IRONY IS NOT LOST ON  
15 ME. SO I DO THINK THAT THE VOTERS DID HAVE THAT  
16 OPTION, AND THAT PROP 71, AS MUCH AS I WOULD LIKE IT TO  
17 SOLVE THE HEALTH EQUITY PROBLEMS OF CALIFORNIA, THAT'S  
18 NOT -- IT'S TO FUND RESEARCH.

19 CHAIRMAN PENHOET: OKAY. SHERRY, MINDFUL --  
20 IS SHERRY LANSING THE LAST PERSON, IF WE LOSE SHERRY,  
21 WE NO LONGER HAVE A QUORUM?

22 MS. LANSING: I'M HERE.

23 MS. KING: WE ACTUALLY DON'T HAVE ONE RIGHT  
24 NOW. WE WILL SOON.

25 MS. LANSING: I HAVE TO LEAVE IN 15 MINUTES



1 UNFORTUNATELY.

2 CHAIRMAN PENHOET: LET'S GO TO ITEM 6 ABOUT  
3 MONITORING. ANY COMMENTS ABOUT -- PUTS THE ONUS ON  
4 GRANTEE ORGANIZATIONS TO MONITOR THESE LICENSEES AND TO  
5 TAKE ADMINISTRATIVE ACTIONS TO MODIFY OR TERMINATE THE  
6 LICENSE WHERE NECESSARY IN ORDER TO ENSURE ESSENTIALLY  
7 DUE DILIGENCE ASSOCIATED WITH THIS. ANY COMMENTS FROM  
8 THE TASK FORCE MEMBERS?

9 MR. SHEEHY: I WOULD HOPE THE LANGUAGE IN  
10 5 -- IT'S KIND OF OBVIOUS, JUST AS STATED, THAT  
11 LANGUAGE IN 1 AND LANGUAGE IN 5 SHOULD BE SIMILAR.

12 CHAIRMAN PENHOET: OKAY. AUDIENCE COMMENTS  
13 ON THIS PARTICULAR. WE'RE NOW ON 6, YES, SIR.

14 MR. SIMPSON: AS I UNDERSTAND THIS, YOU'RE  
15 ASKING GRANTEE ORGANIZATIONS TO MONITOR PERFORMANCE OF  
16 THEIR LICENSE?

17 CHAIRMAN PENHOET: THAT'S CORRECT.

18 MR. SIMPSON: OBVIOUSLY THEY SHOULD BE DOING  
19 THAT, BUT IT WOULD SEEM TO ME THERE SHOULD BE SOME  
20 ADDITIONAL OVERSIGHT BEYOND THAT EITHER AT THE CIRM OR  
21 ELSEWHERE IN THE STATE GOVERNMENT TO SEE THAT LICENSEES  
22 WERE BEING APPROPRIATELY ADMINISTERED BY THE GRANTEE  
23 ORGANIZATIONS.

24 CHAIRMAN PENHOET: WE DO HAVE THEIR ANNUAL  
25 REPORTS ON THEIR LICENSES, ETC. WE CAN ALSO ASK THEM

1 TO REPORT ANNUALLY ON THE PERFORMANCE OF THEIR  
2 LICENSEES UNDER THE AGREEMENTS. WE CAN ADD THAT  
3 LANGUAGE.

4 MR. SIMPSON: AGAIN, I WOULD SAY THAT MIGHT  
5 BE A TIME WHEN YOU MIGHT WANT A QUARTERLY RATHER THAN  
6 ANNUALLY. A YEAR IS A LONG TIME FOR THINGS.

7 CHAIRMAN PENHOET: NOT IN DRUG DEVELOPMENT,  
8 UNFORTUNATELY, OR CELL THERAPY. WE DON'T WANT TO  
9 BURDEN THEM -- YOU KNOW, WE'RE STARTING TO ADD A LOT OF  
10 THINGS TO THE BURDEN, BUT IT'S A GOOD POINT.

11 DR. PRIETO: UNDER ROMAN NUMERAL II OF 6, IT  
12 DOES SAY THE GRANTEE ORGANIZATIONS SHALL MONITOR THE  
13 COMMERCIAL AND DEVELOPMENT ACTIVITIES OF THE LICENSEES  
14 AND INCLUDE REPORTS OF MONITORING ACTIVITIES ANNUALLY.

15 CHAIRMAN PENHOET: THAT'S RIGHT. IT IS  
16 ANTICIPATED HERE.

17 OKAY. ANY OTHER COMMENTS? ITEM E, NO. 1,  
18 GRANTEE ORGANIZATION SHALL MAKE THEIR FUNDED PATENTED  
19 INVENTIONS AVAILABLE AT NO COST FOR FURTHER RESEARCH BY  
20 CALIFORNIA RESEARCH INSTITUTIONS. THIS REQUIREMENT  
21 EXTENDS TO ANY LICENSEES OF CIRM-FUNDED INVENTIONS. SO  
22 THIS IS A BROAD SCALE RESEARCH EXEMPTION. WE ARE IN  
23 NEW TERRITORY HERE.

24 THE ARGUMENT I HAVE HEARD AGAINST THIS HAS  
25 BEEN THAT IT MIGHT DISCOURAGE PATENTING AND

1 COMMERCIALIZATION OF TOOLS AND REAGENTS FOR THIS FIELD.  
2 SO A NUMBER OF US HAVE DISCUSSED THIS BACK AND FORTH.  
3 THIS IS A RECOMMENDATION THAT THE STAFF HAS IN SPITE OF  
4 THAT CONCERN, BUT THAT'S A CONCERN I'VE HEARD BEFORE  
5 ABOUT THIS PROVISION.

6 MR. HALJIN: DOES THIS MEAN THAT FOR  
7 CALIFORNIA RESEARCH INSTITUTIONS, THEY WOULD NOT PAY A  
8 ROYALTY FOR RESEARCH TOOLS, BUT INSTITUTIONS IN OTHER  
9 STATES, HARVARD, MIT, WOULD PAY FOR OTHER INSTITUTIONS  
10 AND COMPANIES TO PAY FOR RESEARCH TOOLS?

11 CHAIRMAN PENHOET: THIS WAS NOT, AGAIN,  
12 GEOGRAPHICALLY RESTRICTIVE ALONG THE LINES OF WHAT WE  
13 DISCUSSED EARLIER FOR SHARING BIOMEDICAL MATERIALS, BUT  
14 IT'S A QUESTION THAT WE SHOULD ADDRESS HERE. THIS SAYS  
15 WE WOULD REQUIRE -- THERE'S A RESEARCH EXEMPTION FOR  
16 ALL CIRM-FUNDED RESEARCH THAT SAYS THAT IT WOULD BE  
17 AVAILABLE BROADLY FOR RESEARCH, THAT THEY WOULD BE  
18 AVAILABLE FOR RESEARCH PURPOSES WITHOUT --

19 DR. PRIETO: IT DOES SAY CALIFORNIA.

20 CHAIRMAN PENHOET: EXCUSE ME.

21 MR. HALJIN: THAT WAS MY QUESTION.  
22 CALIFORNIANS ARE EXEMPT. THOSE OUTSIDE OF CALIFORNIA  
23 ARE GOING TO HAVE TO PAY.

24 CHAIRMAN PENHOET: IN THIS CASE IT MEANS JUST  
25 WHAT IT SAYS, FOR CALIFORNIA. WE HOPE THAT THIS WILL

1 SPUR A NATIONAL MOVEMENT TO CREATE A NATIONAL RESEARCH  
2 EXEMPTION, BUT RIGHT NOW THIS IS -- AND THIS WAS A  
3 ISSUE OF RECIPROCI TY ON PATENTED INVENTIONS.

4 MR. TAYMOR: COULD I SUGGEST THAT THE  
5 COMMITTEE COME UP WITH A DEFINITION OF RESEARCH  
6 INSTITUTION, WHETHER THAT'S MEANT TO BE ACCREDITED  
7 UNIVERSITIES, NONPROFITS, WHETHER IT WOULD INCLUDE ANY  
8 INSTITUTION THAT WAS SET UP BY A COMMERCIAL ENTITY.  
9 THIS ENTITY IS SET UP TO DO RESEARCH, BUT THE ENTITY IS  
10 CAPTIVE BY A COMMERCIAL ENTITY AND THEREBY GETS A  
11 RESEARCH EXEMPTION, BUT LICENSING TO DO WHATEVER IT  
12 WANTS. I GATHER WHAT YOU WANTED IT TO BE FOR  
13 RESEARCH -- INSTITUTIONS WHO WE COMMONLY THINK OF AS  
14 RESEARCH INSTITUTIONS, ABOUT, AGAIN, LOOKING AT THIS AS  
15 A LAWYER, I COULD COME UP WITH -- RESEARCH INSTITUTION  
16 IS PROBABLY NOT WHAT YOU HAD IN MIND.

17 CHAIRMAN PENHOET: ACTUALLY WE DID NOT INTEND  
18 TO EXCLUDE COMMERCIAL ENTITIES OPERATING IN CALIFORNIA  
19 FROM THIS DEFINITION IN PART BECAUSE IF WE MAKE GRANTS  
20 TO THEM, THEN WE'LL EXPECT THEM TO DO THE SAME THING.  
21 SO WE DIDN'T SEE ANY REASON TO EXCLUDE FOR-PROFIT  
22 ORGANIZATIONS FROM THIS DEFINITION IF THEY'RE CARRYING  
23 OUT BASIC RESEARCH.

24 MR. TAYMOR: THEN I THINK YOU SHOULD FOLLOW  
25 UP ON WHAT HAL SAID. SAY WHAT DOES IT MEAN TO BE A

1 CALIFORNIA RESEARCH INSTITUTION THEN. IF HARVARD WERE  
2 TO OPEN UP A MAILBOX AND SAY PLEASE --

3 CHAIRMAN PENHOET: WELL, THERE IS A  
4 DEFINITION IN PROP 71 OF WHAT CONSTITUTES A CALIFORNIA  
5 INSTITUTION. AND SO IT WOULD HAVE TO BE -- WE'LL MAKE  
6 IT COMPATIBLE WITH THAT, AND YOU CAN'T DO THAT BY  
7 OPENING A MAILBOX.

8 MR. SIMPSON: THIS, I THINK, MAY BE THE POINT  
9 WHERE THIS SHOULD BE CONSIDERED. JOHN SIMPSON,  
10 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. THIS  
11 SEEMS TO ME TO BE A REALLY GOOD IDEA. I ALSO WONDER  
12 WHETHER YOU SHOULDN'T HAVE LANGUAGE WHICH WOULD ALLOW  
13 FIRM IN SOME INSTANCES TO SAY THIS PARTICULAR KIND OF  
14 RESEARCH IS SOMETHING FOR WHICH NO PATENT IS AVAILABLE.  
15 IT SHOULD JUST RIGHT UP FRONT BE KNOWN AS BASIC  
16 RESEARCH, AND YOU SHOULD RESERVE THE RIGHT TO BE ABLE  
17 TO DO THAT. IF SOMEONE COMES IN AND SAYS WE WANT TO  
18 EXPLORE THIS PARTICULAR KIND OF ENDEAVOR, YOU SAY FINE.  
19 HERE'S THE MONEY, BUT WE DON'T EXPECT THERE TO BE ANY  
20 PATENT ON THIS. YOU SHOULD BE ABLE TO WITHHOLD THAT  
21 RIGHT.

22 MIGHT ALSO BE A TIME TO RAISE THE QUESTION AS  
23 TO WHETHER YOU SHOULD NOT BE REQUIRING A PATENT POOL,  
24 AT LEAST SOME.

25 CHAIRMAN PENHOET: ANYBODY WANT TO RESPOND TO

1 THAT? ONE THING -- I'LL TELL YOU WHAT'S HARD ABOUT  
2 INVENTIONS. IN ORDER TO GET A PATENT, YOU HAVE TO  
3 PROVE THAT IT HAS NOVELTY. SO IT MEANS BY DEFINITION  
4 IT'S IMPOSSIBLE TO PREDICT IT IN ADVANCE. SO I THINK  
5 THERE MIGHT BE A PRACTICAL PROBLEM WITH THAT. AND, YOU  
6 KNOW, I DO -- THE VAST MAJORITY OF INVENTIONS ARE NOT  
7 PATENTED IN OUR FIELD. I THINK, AGAIN, IT WOULD  
8 REQUIRE US TO REVIEW ALL THESE THINGS GOING FORWARD.

9 WITH RESPECT TO PATENT POOLING, IT WAS  
10 DISCUSSED IN EXTENSO AT THE MEETING THAT DEBORAH ORTIZ  
11 HAD. WE'VE DISCUSSED, AS HAVE YOU, WITH MANY GROUPS.  
12 I THINK MOST PEOPLE I'VE SPOKEN WITH, I'LL SPEAK FOR  
13 MYSELF, HAVE FELT THAT IT'S PREMATURE BECAUSE WE DON'T  
14 HAVE ANY PATENTS TO POOL, BUT IT'S SOMETHING WE SHOULD  
15 KEEP IN THE BACK OF OUR MINDS, THAT IT MAY BE USEFUL  
16 FOR THIS EFFORT SOMEDAY IN THE FUTURE. SO THAT'S SORT  
17 OF HOW I VIEW THAT.

18 MR. SHEEHY: I ALSO THINK THAT WITH THE STATE  
19 COMING UP PURPORTEDLY WITH INTELLECTUAL PROPERTY RULES  
20 FOR ALL STATE-FUNDED RESEARCH, THAT IF THEY WERE TO DO  
21 THAT, THAT PATENT POOLING SEEMS LIKE AN IDEA, LIKE UC  
22 DAVIS IS ALREADY DOING THAT ON SOME AGRICULTURAL  
23 PATENTS, THAT THE STATE COULD IMPOSE THAT FRAMEWORK FOR  
24 ALL STATE-FUNDED RESEARCH SO THAT WE COULD FLOW INTO  
25 THAT. OUR ABILITY WITH OUR SET ASIDE FOR

1 ADMINISTRATIVE COSTS WOULD NOT ALLOW US TO ADMINISTER  
2 PATENT LAW. IF THE STATE WERE SET UP PATENT POOLS FOR  
3 ALL STATE-FUNDED RESEARCH AND THEN PROVIDE THE FUNDS TO  
4 ADMINISTER THAT, WE COULD EASILY GLOM ONTO THAT EFFORT.  
5 THAT'S WHAT THE CCST REPORT WAS ORIGINALLY FOR WAS FOR  
6 ALL STATE-FUNDED RESEARCH. WE JUST KIND OF CAME IN AT  
7 THE TAIL END.

8 SO IF THE STATE COULD TAKE LEADERSHIP IN  
9 DOING THAT, THAT WOULD BE A MODEL THAT WE COULD EASILY,  
10 I THINK, FIT INTO AND WOULD BE WILLING TO, BUT WE CAN'T  
11 ADMINISTER THAT FINANCIALLY WITH OUR 6 PERCENT.

12 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

13 MS. HOWARD: I JUST THINK THAT THE LANGUAGE  
14 PERHAPS IS A LITTLE BIT AMBIGUOUS. WHEN YOU SAY  
15 GRANTEE ORGANIZATIONS SHALL MAKE THEIR CIRM-FUNDED  
16 PATENTED INVENTIONS AVAILABLE AT NO COST, THAT SOUNDS  
17 LIKE THE BIOMEDICAL MATERIALS (INAUDIBLE). I THINK IF  
18 IT WERE TO SAY THAT GRANTEE ORGANIZATIONS PROVIDE A  
19 NONEXCLUSIVE RESEARCH EXEMPTION OF THEIR CIRM-FUNDED  
20 PATENTED INVENTIONS AT NO COST, THAT IT WOULD BE LESS  
21 AMBIGUOUS.

22 CHAIRMAN PENHOET: OKAY. SOMEONE JOIN US?

23 MS. STREITZ: IN THE UNIVERSITY OF  
24 CALIFORNIA, WE DON'T A TREMENDOUS BUDGET FOR MANAGING  
25 INVENTIONS. AND TO MANAGE ONES THAT AREN'T --

1 IMPLEMENT LICENSES AND MANAGE THAT PROCESS FOR  
2 INVENTIONS THAT WE'RE NOT GOING TO SPEND MONEY FOR  
3 WOULD MAKE NO SENSE. WE DO ROUTINELY SHARE OUR  
4 INVENTIONS WITH OTHER NONPROFIT RESEARCH INSTITUTIONS,  
5 BUT WE DON'T DO IT BY MEANS OF A LICENSE. IF YOU CAN  
6 IMAGINE UNDER COHEN BOYER PUTTING LICENSES IN PLACE FOR  
7 EVERY RESEARCH INSTITUTION THAT WANTED TO USE THAT,  
8 WE'D HAVE BEEN DOING NOTHING BUT THAT. SO WHAT WE  
9 USUALLY DO IS WE JUST DON'T ASSERT.

10 AND IN OUR EXCLUSIVE LICENSES, AND THIS IS  
11 TRUE FOR MOST UNIVERSITIES, IN OUR EXCLUSIVE LICENSES  
12 WE RESERVE THE RIGHT TO USE THE TECHNOLOGY OURSELVES  
13 AND TO ALLOW OTHER NONPROFIT RESEARCH INSTITUTIONS TO  
14 USE IT AS WELL, BUT WE DON'T USUALLY FOLLOW THROUGH AND  
15 ISSUE LICENSES BECAUSE IT'S TOO MUCH OF AN  
16 ADMINISTRATIVE BURDEN. WE WOULD WITH THE FOR-PROFIT  
17 COMMUNITY.

18 MS. HOWARD: MY ONLY CONCERN IS THAT THIS  
19 COULD BE TAKEN -- READ SO IT SHOWS A BURDEN TO PROVIDE  
20 MATERIAL. SO IF IT WERE WRITTEN IN A WAY THAT THAT WAS  
21 CLEAR.

22 CHAIRMAN PENHOET: OKAY. THANK YOU. ANY  
23 OTHER COMMENTS? OKAY. REVENUE SHARING REQUIREMENTS.  
24 I'M MINDFUL OF THE FACT THAT WE'RE GOING TO LOSE SHERRY  
25 IN FOUR MINUTES, SO CAN YOU DO A QUICK ROLL CALL AND



1 SEE WHETHER WE DO OR DO NOT HAVE A QUORUM AT THIS POINT  
2 IN TIME?

3 MS. KING: SUSAN BRYANT.

4 MS. INGELS: SHE' LL BE HERE IN ABOUT 15  
5 MI NUTES.

6 MS. KING: MI CHAEL GOLDBERG. SHERRY LANSING.  
7 TED LOVE. ED PENHOET.

8 CHAIRMAN PENHOET: YES.

9 MS. KING: PHI L PIZZO. FRANCI SCO PRI ETO.

10 DR. PRI ETO: YES.

11 MS. KING: JEANNIE FONTANA.

12 DR. FONTANA: YES.

13 MS. KING: JEFF SHEEHY.

14 MR. SHEEHY: YES.

15 MS. KING: OS STEWARD. JANET WRIGHT.

16 DR. WRIGHT: YES.

17 CHAIRMAN PENHOET: WE DON' T HAVE A QUORUM.  
18 OKAY. WE' LL CONTINUE OUR WORK AND MAKE AN UNOFFICIAL  
19 RECOMMENDATION TO THE ICOC HOPEFULLY AT THE MEETING ON  
20 FEBRUARY 10TH.

21 NEXT, REVENUE SHARING REQUIREMENTS. IN THE  
22 EVENT OF CREATION OF REVENUE STREAMS, THE GRANTEE  
23 ORGANIZATION SHALL SHARE A FRACTION OF ANY ROYALTY  
24 REVENUES WITH THE INVENTORS IN ACCORDANCE WITH THEIR  
25 ESTABLISHED POLICY. SO THIS IS CLEAR. WE DON' T WANT

1 ORGANIZATIONS TO START NEW POLICIES JUST FOR  
2 CIRM-INVENTED TECHNOLOGIES.

3 TWENTY-FIVE PERCENT OF THE GRANTEE  
4 ORGANIZATION'S SHARE OF ANY REVENUES RECEIVED UNDER A  
5 LICENSE AGREEMENT OF CIRM-FUNDED PATENTED INVENTIONS IN  
6 EXCESS OF \$500,000 SHALL BE RETURNED TO THE STATE OF  
7 CALIFORNIA FOR USE IN RESEARCH AND EDUCATION.

8 FINALLY, THE LAST NO. 3 IS A PROPORTIONAL  
9 PARTS PROPOSAL IF IT WAS FUNDED BY OTHERS AS WELL.  
10 THIS HAS BEEN A TOPIC OF A GREAT DEAL OF CONVERSATION  
11 AND DISCUSSION IN THE LAST FEW MONTHS, TO BE SURE. AND  
12 THIS IS OUR PROPOSAL AFTER A LOT OF CONSIDERATION OF  
13 VARIOUS DIFFERENT POINTS OF VIEW ON THIS SUBJECT.

14 THE NUMBER OF 25 PERCENT WAS ARRIVED AT  
15 BASICALLY TRYING TO COME UP WITH A MEANINGFUL NUMBER  
16 WHICH WOULD ADDRESS THE INTENT TO HAVE A RETURN TO THE  
17 STATE WHILE AT THE SAME TIME PROVIDING SOME INCENTIVE  
18 AND, FRANKLY, PROVIDING THE OPPORTUNITY FOR THE GRANTEE  
19 ORGANIZATIONS TO RECOUP SOME OF THEIR CONSIDERABLE  
20 EXPENSES THAT THEY WILL INCUR IN ACTUALLY COMPLYING  
21 WITH THE GENERAL OBLIGATION TO FILE PATENTS AND LOOK  
22 FOR GRANTEES AND CONDUCT LICENSES, ETC.

23 THE \$500,000 NUMBER COMES FROM A SURVEY OF,  
24 FIRST OF ALL, THE EXPENSES INCURRED IN GENERAL BY  
25 GRANTEE ORGANIZATIONS IN PURSUING THIS AND LOOKING AT

1 THE POLICIES OF A NUMBER OF OTHER INVENTORS OTHER THAN  
2 THE FEDERAL GOVERNMENT WHO, IN FACT, FROM TIME TO TIME  
3 DO GET RETURNS ON THEIR INVENTIONS. AND SO THIS NUMBER  
4 SEEMS TO BE VALIDATED BY A NUMBER OF THIRD PARTIES AS  
5 ESSENTIALLY THE AVERAGE COST OF KEEPING A PATENT  
6 PORTFOLIO IN BUSINESS AND GOING THROUGH ALL THE  
7 LICENSING AND PATENTING, ETC. SO THAT'S HOW THE  
8 \$500,000 NUMBER WAS CHOSEN. IT'S A NUMBER USED BY THE  
9 AMERICAN HEART ASSOCIATION, BY THE AMERICAN CANCER  
10 SOCIETY, AND I THINK BY OTHERS. PROBABLY THEY GOT THE  
11 NUMBER FROM WORKING WITH SIMILAR GRANTEE ORGANIZATIONS  
12 IN THE PAST. SO THAT'S THE PROPOSAL FOR THAT. FIRST  
13 OF ALL, FROM THE TASK FORCE.

14 MR. SHEEHY: I HAD TWO QUESTIONS. ONE IS  
15 THAT IF WE WERE MODELING BAYH-DOLE LANGUAGE, THE  
16 RESEARCH AND EDUCATION PIECE IS ACTUALLY FOR THE 75  
17 PERCENT THAT REMAINS AT THE INSTITUTION, AND THAT WE  
18 SHOULD BE RETURNING THE FUNDS TO THE GENERAL FUND FOR  
19 THE LEGISLATURE TO APPROPRIATE, BUT THAT WE SHOULD  
20 MAINTAIN THE BAYH-DOLE LANGUAGE THAT REQUIRES THE  
21 GRANTEE TO REINVEST IN RESEARCH AND EDUCATION SO IT'S  
22 NOT JUST FREE MONEY. DOESN'T BAYH-DOLE REQUIRE THE  
23 PROFITS -- THAT RETURN ON THE ROYALTIES BE REINVESTED  
24 IN RESEARCH AND EDUCATION OF THE RECIPIENT  
25 INSTITUTIONS?

1 I THINK WE SHOULD MAINTAIN THAT LANGUAGE, BUT  
2 I DO THINK WE SHOULDN'T ASSERT -- APPROPRIATE A RULE  
3 FOR OURSELVES. WE SHOULD RETURN IT TO THE GENERAL  
4 FUND. I WOULD HOPE THAT THE LEGISLATURE WOULD USE IT  
5 TO FUND THERAPIES OR FURTHER RESEARCH OR WHATEVER, BUT  
6 PREVENTION MIGHT BE THE BEST USE, TO BE PERFECTLY  
7 HONEST. THAT WOULD BE HOW I MIGHT CHANGE THAT.

8 CHAIRMAN PENHOET: LET ME REMIND EVERYONE  
9 THAT THE PRINCIPLE THAT WE'VE USED HERE IS TO TRY TO  
10 FIND A SYSTEM OF IP WHICH IS COMPATIBLE WITH BAYH-DOLE,  
11 BUT NOT NECESSARILY IDENTICAL TO BAYH-DOLE, SO THERE  
12 ARE A NUMBER OF DIFFERENCES, BUT NOT INCOMPATIBLE.  
13 WE'RE NOT A HUNDRED PERCENT SURE WHETHER THERE'S A  
14 REACH-THROUGH PROVISION IN THE BAYH-DOLE THAT SAYS THAT  
15 25 PERCENT SHOULD BE USED FOR THIS PURPOSE.

16 THERE WAS SOME THOUGHT THAT SINCE THE GENERAL  
17 FUND IS EXPENDED ON RESEARCH AND EDUCATION IN LARGE  
18 MEASURE, THAT THE FUNDS COULD BE SET ASIDE FOR THAT.  
19 MONEY IS FUNGIBLE. THEY CAN USE OTHER PARTS, BUT I  
20 THINK YOUR PROPOSAL IS ONE THAT MANY PEOPLE HAVE  
21 DISCUSSED.

22 MS. STREITZ: UNIVERSITY OF CALIFORNIA.  
23 WE'VE EXPLORED THIS WITH OUR GENERAL COUNSEL BECAUSE WE  
24 REALLY WANT TO MAKE SURE THAT THERE'S SOMETHING LIKE  
25 THIS IN THERE, THAT WITHOUT THE RESEARCH AND EDUCATION,

1 THAT WE WOULD BE ABLE TO ACCEPT THE FUNDS. AND THEY  
2 BASICALLY SAID THAT THE BAYH-DOLE REQUIREMENT, IF THERE  
3 WERE FEDERAL FUNDS INVOLVED ALSO, OF COURSE, IF THERE  
4 AREN'T FEDERAL FUNDS INVOLVED, THEN THIS DOESN'T MATTER  
5 AT ALL, IF THERE WERE FEDERAL FUNDS INVOLVED ALSO, WHAT  
6 IT SAYS IS WE CAN RECOVER OUR EXPENSES, WE PAY OUR  
7 INVENTORS, EVERYTHING ELSE HAS TO GO TO RESEARCH AND  
8 EDUCATION. THAT WOULD INCLUDE THIS 25 PERCENT.

9 THE BOTTOM LINE QUESTION WE POSED TO OUR  
10 GENERAL COUNSEL WAS THAT IF WE KNEW THERE WERE FEDERAL  
11 FUNDS INVOLVED IN THE RESEARCH, WOULD WE ABLE TO ACCEPT  
12 CIRM FUNDS IF WE KNEW THAT THIS 25 PERCENT WASN'T GOING  
13 NECESSARILY TO RESEARCH AND EDUCATION, AND HE SAID NO.

14 MR. SHEEHY: MY POINT IS WE'D LET YOU OFF THE  
15 HOOK FOR THE 75 PERCENT FOR RESEARCH.

16 MS. STREITZ: BUT THE FEDERAL GOVERNMENT  
17 DOESN'T LET US OFF THE HOOK FOR THIS FUNDING.

18 MR. SHEEHY: YEAH, BUT WE'RE NOT -- THE  
19 FEDERAL GOVERNMENT'S NOT FINANCING THIS RESEARCH. SO  
20 IN THIS INITIAL PERIOD, YOU WOULD BE OFF THE HOOK AND  
21 YOU COULD USE THAT 75 PERCENT FOR WHATEVER YOU WANTED.

22 MS. STREITZ: IF THE INVENTIONS HAVE ANY  
23 FEDERAL DOLLARS FUNDING IT, THE FEDERAL GOVERNMENT --

24 MR. SHEEHY: YEAH, BUT IN THE ABSENCE OF --  
25 UNLESS -- I WOULD NOT BE COMFORTABLE, AS MUCH AS I LOVE

1 UC, GIVING UC 75 PERCENT OF THE RETURN ON AN INVENTION  
2 WITHOUT HAVING EARMARKED IT FOR RESEARCH AND EDUCATION.  
3 THEY CAN USE IT FOR SALARIES. THEY CAN USE IT FOR -- I  
4 THINK THAT THAT 75 PERCENT SHOULD HAVE THE SAME  
5 BAYH-DOLE REQUIREMENT, THAT IT GET REINVESTED IN  
6 RESEARCH AND EDUCATION. IT SHOULDN'T BE FREE MONEY.

7 MS. STREITZ: I MISUNDERSTOOD YOU.

8 MR. SHEEHY: AS FOR THE 25 PERCENT, I DO NOT  
9 SEE OUR ROLE, AND MAYBE THE LEGISLATURE WILL HAVE TO  
10 ADDRESS THIS AS BEING INAPPROPRIATE, I DON'T SEE HOW WE  
11 CAN TAKE WHAT WE RECEIVE BACK AND DIRECT THE USE OF IT  
12 AT THE STATE LEVEL. THAT'S WHY I DIDN'T SUPPORT --  
13 EVEN IF IT'S NOT COMPATIBLE WITH BAYH-DOLE, I KNOW  
14 THAT'S PROBLEMATIC, BUT I THINK THE ATTORNEYS CAN GIVE  
15 US A RULING THAT SAYS IT HAS TO BE THAT WAY. I'D BE  
16 HAPPY TELLING THE STATE OF CALIFORNIA TO USE IT FOR  
17 RESEARCH AND EDUCATION, BUT I'M NOT SURE WE CAN.

18 CHAIRMAN PENHOET: MAYBE ONE FIX TO THIS  
19 WOULD BE, WE'VE GOT ONE STATEMENT OF WHAT THE UC  
20 GENERAL COUNSEL HAS TOLD THEM, WHICH IS THERE'S A  
21 LOOK-THROUGH TO THE FINAL USE OF THE DOLLARS IS WHAT  
22 THEY SAID, WHICH WOULD OBLIGATE THE STATE TO USE IT,  
23 COULD NOT BE IN VIOLATION OF BAYH-DOLE. I SUPPOSE A  
24 FIX TODAY FOR THAT COULD BE 25 PERCENT RETURNED TO THE  
25 GENERAL FUND UNLESS SUCH USE WAS IN VIOLATION OF A

1 FEDERAL LAW, WHATEVER IT IS. THE REALITY IS THAT MANY  
2 OF OUR GRANTEES WILL HAVE COMMINGLED FUNDS WITH FEDERAL  
3 DOLLARS, WE HOPE INCREASINGLY OVER TIME.

4 MR. SHEEHY: WE'LL PUT THE SENTENCE THAT THEY  
5 HAVE TO TAKE THEIR RETURN AND INVEST IT IN RESEARCH AND  
6 EDUCATION. WE'RE GOING TO PUT THAT PART IN.

7 CHAIRMAN PENHOET: WELL, SOMETHING GOES TO  
8 THE INVENTOR, BUT THE REMAINDER --

9 MS. O'NEIL: SALLY O'NEIL FROM STANFORD  
10 UNIVERSITY. I DID HAVE A QUESTION IN THE FIRST LINE,  
11 THE 25 PERCENT SHARE OF ANY REVENUES. AND I'M  
12 INTERESTED TO KNOW WHAT THE DEFINITION OF ANY REVENUES  
13 IS. WOULD A UNIVERSITY OR OTHER NONPROFIT GRANTEE BE  
14 ABLE TO DEDUCT COSTS OR ANY OTHER COST?

15 CHAIRMAN PENHOET: THAT'S THE \$500,000  
16 EXEMPTION THAT WE'VE GIVEN YOU. ON TOP OF THE  
17 \$500,000, I BELIEVE OUR INTENT WAS ALL OTHER MONIES  
18 RECOVERED, LICENSING PAYMENTS, ROYALTIES, OR OTHER  
19 PAYMENTS ASSOCIATED WITH THE LICENSES IN EXCESS OF  
20 \$500,000.

21 DR. STEWARD: THIS IS OS STEWARD. I JUST  
22 JOINED YOU. JUST WANTED TO LET YOU KNOW.

23 CHAIRMAN PENHOET: THANK YOU, OS. GREAT.

24 MR. REED: COULD WE PUT SOMETHING IN THERE TO  
25 THE EFFECT THAT UNLESS THERE IS A CONFLICT WITH FEDERAL

1 LAW IN THE LANGUAGE?

2 CHAIRMAN PENHOET: YES. YES.

3 MS. KING: WE'RE ON PAGE 17 OF THE DOCUMENT,  
4 SECTION F, AS IN FRANK, REVENUE SHARING REQUIREMENTS,  
5 DR. STEWARD.

6 DR. STEWARD: THANK YOU.

7 CHAIRMAN PENHOET: WE DID HAVE A LONG  
8 DISCUSSION WITH BOND COUNSEL ON THIS ISSUE OF THE 25  
9 PERCENT. WE WERE INFORMED THAT THERE ARE A NUMBER OF  
10 WAYS TO FUND THIS PROGRAM WITH THIS PROVISION IN PLACE  
11 THAT DO NOT REQUIRE THE SALE OF TAXABLE BONDS IN ITS  
12 ENTIRETY. SOME OF THE BONDS IN SOME TIME PERIODS MAY  
13 HAVE TO BE TAXABLE, BUT STATE TREASURER'S OFFICE HAS  
14 GIVEN US REASONABLE ASSURANCE THAT THEY BELIEVE THERE  
15 ARE WAYS IN WHICH THIS FUNDING COULD OCCUR WITHOUT  
16 HAVING IT ALL HAVE TO BE TAXABLE BONDS. SUBSTANTIAL  
17 FRACTION COULD BE NONTAXABLE BONDS EVEN WITH THE 25  
18 PERCENT. ESPECIALLY SINCE IN ALL CIRCUMSTANCES THE  
19 UNIVERSITY OF CALIFORNIA IS A STATE AGENCY, WHICH HAS  
20 SAID MAY BE OF THE TOTAL FUNDING. THAT'S BEEN  
21 CLARIFIED WITH CERTAINTY NOW, THAT THE UNIVERSITY OF  
22 CALIFORNIA IS A STATE AGENCY.

23 MS. HOWARD: ELIZABETH HOWARD, ORRICK. JUST  
24 TO CLARIFY WITH RESPECT TO THE 500,000, THAT REFERRED  
25 TO REVENUES RECEIVED BY THE INSTITUTE UNDER A GIVEN



1 LICENSE AGREEMENT.

2 CHAIRMAN PENHOET: PER LICENSE AGREEMENT.

3 MS. HOWARD: AND MULTIPLE INVENTIONS, PER  
4 INVENTION.

5 CHAIRMAN PENHOET: PER INVENTION.

6 MS. HOWARD: IT COULD BE THREE DIFFERENT  
7 THINGS.

8 CHAIRMAN PENHOET: WE COULD HAVE AN OMNIBUS  
9 LICENSE FOR MORE THAN ONE INVENTION. I THINK IT'S  
10 PROBABLY PER LICENSE, ISN'T IT?

11 MR. FEYER: ROBERT FEYER. I THINK, ALSO  
12 AGAIN FOR CLARITY, YOU MIGHT WANT TO SAY IN EXCESS OF  
13 \$500,000 IN THE AGGREGATE, SO THERE'S NO IMPLICATION.

14 THE OTHER COMMENT I HAVE IN RELATION TO THE  
15 COMMENT SHE MADE, IT'S A TECHNICALITY, BUT ASSUME  
16 THERE'S NO -- EVEN IN AN INVENTION THAT HAS NO FEDERAL  
17 FUNDS, THEY'RE JUST STRAIGHT CIRM POLICY THAT WAS  
18 INVOLVED HERE, I WOULD THINK THAT IF, IN FACT, IT  
19 REQUIRES THE INSTITUTION TO SPEND MORE THAN \$500,000 TO  
20 OBTAIN A PATENT TO DO THE DEVELOPMENT, THAT ALTHOUGH  
21 THEY WOULD HAVE TO START THE 25 PERCENT SHARING WITH  
22 THE STATE OVER THE \$500,000 THRESHOLD, THEY MIGHT BE  
23 ALLOWED TO COLLECT THE BALANCE, RECOUP THE BALANCE OF  
24 THEIR ACTUAL DEVELOPMENT COSTS RATHER THAN HAVING TO  
25 APPLY THE REST TO RESEARCH AND EDUCATION, AS I BELIEVE

1 BAYH-DOLE WOULD ALLOW. ANYWAY, THIS IS A TECHNICALITY  
2 FOR THE SCIENTISTS.

3 CHAIRMAN PENHOET: INTERESTING NUANCE I  
4 HADN'T THOUGHT ABOUT. ANY OTHER COMMENTS THIS SECTION?

5 MR. TAYMOR: JUST WHETHER -- YOU MAY WANT TO  
6 CONSIDER WHETHER YOU WANT TO MAKE SOME PRESENT DOLLAR  
7 VALUE FOR THE 500,000, WHETHER IT'S 2006 DOLLARS.  
8 THESE LICENSES -- LAWS WILL APPLY TO LICENSES 20 YEARS  
9 FROM NOW.

10 CHAIRMAN PENHOET: THAT'S TRUE.

11 MR. TAYMOR: LEGAL FEES AREN'T LIKELY TO GO  
12 DOWN.

13 CHAIRMAN PENHOET: THE ONLY THING WE CAN  
14 COUNT ON. OKAY.

15 PRESS RELEASE REQUIREMENTS. ANY COMMENTS  
16 ABOUT PRESS RELEASE REQUIREMENTS?

17 THEN I BELIEVE WE HAVE FINISHED OUR  
18 DISCUSSION OF SECTION H. SO LET'S GO BACK HERE AND SEE  
19 IF WE CAN SUMMARIZE THE REQUESTED CHANGES.

20 DR. MAXON: I'M KEEPING TRACK OF THEM, BUT  
21 THEY'RE MOSTLY IN MY HEAD.

22 GREGG: WITH DR. STEWARD'S JOINING US, DOES  
23 THAT MEAN WITH DR. BRYANT'S ARRIVAL WE'LL HAVE A  
24 QUORUM?

25 MS. KING: THAT IS ABSOLUTELY CORRECT, AND WE

1 WOULD LOVE HER TO BE HERE AS SOON AS SHE CAN.

2 CHAIRMAN PENHOET: IF WE HAVE A  
3 REQUIREMENT -- NO. H(A)(4), OFFICIAL VIEWS OF CIRM OR  
4 STATE OF CALIFORNIA.

5 PUBLICATION-RELATED BIOMEDICAL MATERIALS. WE  
6 SAID THAT THEY'D SHARE THEM PROMPTLY, AND THE APPROVAL  
7 OF THE SPO IS REQUIRED FOR THE WHOLE SET OF THINGS  
8 UNDER THAT.

9 (INTERRUPTION IN PROCEEDINGS.)

10 DR. WRIGHT: IN THAT FIRST SECTION, H(A),  
11 THERE WAS THAT SUGGESTION ABOUT COLLECTING THE  
12 ABSTRACTS INTO SORT OF A COMPENDIUM.

13 CHAIRMAN PENHOET: ANNUAL REPORT. THANK YOU.  
14 PATENT APPLICATION REQUIREMENTS. GRANTEE  
15 ORGANIZATIONS BEAR THE COST. THEY REPORT FILINGS ON AN  
16 ANNUAL BASIS.

17 IN D, REPORTS ON AN ANNUAL BASIS. GRANTEE  
18 ORGANIZATIONS SHALL -- NOW, WE HAVE DECIDED TO COMBINE  
19 TWO AND THREE INTO A SINGLE PARAGRAPH, AND WE HAVE  
20 AGREED IT'S NO LONGER WHENEVER POSSIBLE. IT'S GOING TO  
21 ADD SOME LANGUAGE THAT LINKS THE NONEXCLUSIVE LICENSEES  
22 DIRECTLY TO THE NOTWITHSTANDING LANGUAGE IN THREE. IS  
23 THAT WHAT WE AGREED?

24 MS. KING: THAT WAS SECTION H(D) FOR THOSE OF  
25 YOU ON THE PHONE.

1 CHAIRMAN PENHOET: H(D) (2) AND (3) ARE NOW  
2 GOING TO BE COMBINED.

3 NO. 4, I BELIEVE, WAS AS STATED.

4 NO. 5, MY UNDERSTANDING, AT LEAST OF THE  
5 PROPOSAL THAT WE HAVE HEARD, IS TO SPLIT THIS INTO ONE  
6 FOR MEDI-CAL AND OTHER PROVIDERS, STATE-FUNDED  
7 PROVIDERS OF -- PURCHASERS. FOR THAT ONE WE WOULD  
8 INCLUDE THE LANGUAGE PROPOSED BY MR. SIMPSON AND HIS  
9 GROUP ABOUT LOWEST AVAILABLE COMMERCIAL PRICE, U. S.  
10 COMMERCIAL PRICE. AND FOR UNINSURED PATIENT  
11 POPULATIONS, WE WOULD ASK FOR PLANS FROM ANY LICENSEE,  
12 AND THAT WE WOULD REVIEW THOSE PLANS ANNUALLY AT ICOC.

13 DR. WRIGHT: WHERE IT SAYS THERAPIES AND  
14 DIAGNOSTICS.

15 CHAIRMAN PENHOET: THERAPIES AND DIAGNOSTICS,  
16 NOT ALL LICENSES.

17 AND THEN UNDER SIX.

18 MR. TOCHER: MULTILICENSE SITUATIONS, CIRM  
19 LICENSES AS WELL.

20 CHAIRMAN PENHOET: I THINK EXISTING LANGUAGE  
21 IMPLIES THAT. I'M NOT SURE WE WANT TO BE SO BALD-FACED  
22 ABOUT TRUMPING OTHER PEOPLE.

23 THEN MONITOR PERFORMANCE.

24 6(I), WE'LL AMEND THE LANGUAGE TO MATCH WHAT  
25 WE TALKED ABOUT IN 5. ANY OTHER CHANGES TO 6?

1 MR. SHEEHY: WHERE DID WE HAVE THE LANGUAGE  
2 ABOUT WHEN -- IT WAS KEN TAYMOR'S COMMENT ABOUT THERAPY  
3 MAY HAVE APPLICATIONS TO MANY DISEASES.

4 CHAIRMAN PENHOET: OH, YES.

5 MR. SHEEHY: WHAT'S YOUR FORMULATION FOR  
6 THAT? MY HANDWRITING --

7 CHAIRMAN PENHOET: IN THE DUE DILIGENCE  
8 PROVISION, THERE WOULD BE A REQUIREMENT THAT THEY  
9 DILIGENTLY PURSUE ALL DISEASES FOR WHICH A TECHNOLOGY  
10 IS APPLICABLE. I THINK THAT WAS THE ESSENCE OF YOUR  
11 PROPOSAL.

12 MR. SIMPSON: I GOT AT IT ANOTHER WAY, AND  
13 THEN YOU CAME BACK WITH THAT. I WAS SAYING IF IT WAS  
14 AN EXCLUSIVE LICENSE, IT WOULD BE SPECIFIC, BUT YOU  
15 SAID THE DUE DILIGENCE.

16 CHAIRMAN PENHOET: THE REMEDY WOULD BE THEY  
17 INCLUDE THE LICENSE FOR THOSE DISEASES.

18 AND THEN (E) WE HAD A --

19 DR. FONTANA: WHAT ABOUT THE ANNUAL REPORT,  
20 ED? DIDN'T YOU HAVE THAT IN 6?

21 DR. MAXON: WE GOT IT.

22 CHAIRMAN PENHOET: IT'S 6 TWO LITTLE I'S IS  
23 THE ANNUAL REPORT.

24 AND THE RESEARCH EXEMPTION IS WELL CLARIFIED,  
25 THAT IT'S FOR HOWEVER WE DEFINE RESEARCH INSTITUTIONS

1 BROADLY IN PROP 71, AND WE MADE THE POINT THAT BURDEN  
2 OF PROVIDING LICENSES TO EVERY ORGANIZATION TO THEIR  
3 PATENTING TECHNOLOGY WOULD BE OVERWHELMING. AND THAT'S  
4 PROBABLY TRUE. SO JUST MAKE IT AVAILABLE. I'M TRYING  
5 TO REMEMBER WHAT SPECIFIC LANGUAGE.

6 DR. MAXON: ELIZABETH HOWARD SAID THAT WE  
7 NEED TO CLARIFY THAT THIS DOESN'T REFER TO BIOMEDICAL  
8 MATERIAL.

9 CHAIRMAN PENHOET: OKAY. DEFINITELY DOES  
10 NOT. ALL RIGHT.

11 AND THEN THE REVENUE SHARING REQUIREMENTS, IT  
12 WOULD BE FOR USE IN THE GENERAL FUND UNLESS SUCH USE IS  
13 PRECLUDED BY FEDERAL LAW. THAT WHAT WE SAID? I THINK  
14 SO.

15 MR. SHEEHY: WE HAD THE MATCH TO THE GRANTEE  
16 ORGANIZATION, 75 PERCENT TO MATCH BAYH-DOLE.

17 CHAIRMAN PENHOET: THEIR 75 PERCENT.

18 MR. TOCHER: AFTER FULL RECOUPMENT OF COSTS.

19 DR. MAXON: I MAY BE WRONG, BUT I THINK THEY  
20 ALREADY HAVE THAT OBLIGATION. AM I RIGHT?

21 MR. SHEEHY: ONLY IF THEY'RE FEDERAL FUNDS.

22 DR. MAXON: JEFF IS RECOMMENDING THAT WE  
23 PRESCRIBE USE OF THE 75 PERCENT FOR RESEARCH AND  
24 EDUCATION PURPOSES. MY UNDERSTANDING IS YOU ALREADY  
25 HAVE THAT AS A CONDITION OF BAYH-DOLE.

1 MS. STREITZ: MOST INSTITUTIONS THAT  
2 RECEIVE -- WE HAVE ONE FORMULA FOR DISTRIBUTING  
3 LICENSING INCOME, AND IT CONFORMS TO BAYH-DOLE, AND WE  
4 APPLY IT WHETHER THEY'RE FEDERAL FUNDS OR NOT.

5 CHAIRMAN PENHOET: IT'S A SUSPENDERS AND  
6 BELTS APPROACH.

7 MR. SHEEHY: THAT'S UC. WE'RE GOING TO BE  
8 FUNDING A LOT OF DIFFERENT ORGANIZATIONS.

9 MR. TOCHER: IN THE AGGREGATE TO THE 500,000.

10 DR. MAXON: CLARIFICATION FOR 2006 DOLLARS.

11 DR. FONTANA: COULD YOU EXPLAIN WHAT THE 2006  
12 DOLLARS IS?

13 CHAIRMAN PENHOET: WELL, IF INFLATION HAPPENS  
14 AND THE DOLLAR IS WORTH 20 CENTS --

15 DR. FONTANA: GOT IT.

16 CHAIRMAN PENHOET: -- IN 2015, THEN IT WOULD  
17 BE GROSSED UP BY THAT AMOUNT.

18 DR. FONTANA: IT WOULDN'T BE FAIR JUST TO SAY  
19 DEDUCTING ALL COSTS FOR PATENT FILING OR LICENSING  
20 FILING?

21 CHAIRMAN PENHOET: IT WOULD BE FAIR, BUT IT'S  
22 MUCH MORE CUMBERSOME. AND THIS NUMBER SEEMS TO BE ONE  
23 THAT'S BEEN VETTED BY A NUMBER OF DIFFERENT  
24 ORGANIZATIONS. I THINK THEIR CONCERN IS IT'S AN  
25 AVERAGE NUMBER TO SOME DEGREE. OBVIOUSLY, UNIVERSITIES

1 DO SPEND A LOT OF MONEY SOMETIMES PURSUING PATENTS  
2 WHICH NOBODY EVER TAKES A LICENSE TO. AND SO IF YOU  
3 USE THE ACTUAL COSTS ASSOCIATED WITH EACH LICENSE, IT  
4 MIGHT DISADVANTAGE THEM OR ADVANTAGE THEM. IT DEPENDS.  
5 IT'S HARD TO KNOW THE CIRCUMSTANCES.

6 AND MARY DID A LOT OF THE CALLING AROUND AND  
7 HOMEWORK, AND YOU HAVE SOME OF IT IN FRONT OF YOU ON  
8 THESE CHARTS, WHAT OTHER GROUPS DO.

9 DR. FONTANA: OKAY.

10 CHAIRMAN PENHOET: OKAY. FOR THOSE OF YOU  
11 WHO HAVE JUST JOINED US, WE TRIED TO PARSE THIS SECTION  
12 II INTO THREE PIECES. G, AND WE DISCUSSED G AND  
13 APPROVED G, I THINK. WE DID NOT HAVE A QUORUM.

14 MS. KING: WE ACTUALLY HAVE A QUORUM NOW, I  
15 BELIEVE. DR. BRYANT, HAVE YOU JOINED US?

16 MS. INGELS: SUE BRYANT IS HERE NOW.

17 MS. KING: EXCELLENT. DR. BRYANT HAS JOINED  
18 US. I COULD TAKE A ROLL CALL; AND IF WE HAVE A QUORUM,  
19 WE MIGHT WANT TO GO BACK THROUGH AND --

20 CHAIRMAN PENHOET: SO THEN WE SHOULD GO BACK  
21 TO G. REPORTING REQUIREMENTS ARE IN G.

22 MS. KING: WE'RE LOOKING AT PAGE 14 OF THE  
23 POLICY DRAFT, SECTION G, INVENTION REPORTING  
24 REQUIREMENTS.

25 CHAIRMAN PENHOET: THE PRINCIPAL MODIFICATION



1 WE MADE TO THIS IS THAT DISCLOSURES OF INVENTIONS BY  
2 INVENTORS TO THE INSTITUTION SHOULD BE REPORTED TO THE  
3 CIRM WITHIN 60 DAYS OF THE TIME OF SUCH DISCLOSURE. SO  
4 THAT WAS ADDED TO THIS SECTION. I BELIEVE THAT WAS THE  
5 ONLY SUBSTANTIAL CHANGE WE MADE TO G.

6 SO DO WE HAVE A MOTION TO APPROVE G WITH A  
7 QUORUM PRESENT?

8 DR. WRIGHT: SO MOVED.

9 MR. SHEEHY: SECOND.

10 CHAIRMAN PENHOET: MOVED BY JANET WRIGHT,  
11 SECOND BY JEFF SHEEHY. WE NEED A ROLL CALL.

12 MS. KING: SUSAN BRYANT.

13 DR. BRYANT: YES.

14 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.  
15 TED LOVE. ED PENHOET.

16 CHAIRMAN PENHOET: YES.

17 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.

18 DR. PRIETO: YES.

19 MS. KING: JEANNIE FONTANA.

20 DR. FONTANA: YES.

21 MS. KING: JEFF SHEEHY.

22 MR. SHEEHY: YES.

23 MS. KING: OS STEWARD.

24 DR. STEWARD: YES.

25 MS. KING: JANET WRIGHT.

1 DR. WRIGHT: YES.

2 MS. KING: MOTION CARRIES.

3 CHAIRMAN PENHOET: SECTION H, MUCH MORE  
4 EXTENSIVE CHANGES. WE JUST WENT THROUGH THEM.  
5 OBVIOUSLY BEFORE THE ICOC MEETING, WE WILL GET ALL THE  
6 LANGUAGE HOPEFULLY RIGHT. BUT FOR THE PURPOSES OF THIS  
7 MEETING, I THINK WE HAVE A CLEAR STATEMENT OF INTENT OF  
8 WHAT THE LANGUAGE IS SUPPOSED TO SAY. SO A MOTION  
9 WOULD BE IN ORDER TO APPROVE SECTION H AS AMENDED WITH  
10 THE NUMEROUS AMENDMENTS THAT WE HAVE MADE HERE TODAY.

11 MR. SHEEHY: SO MOVED.

12 DR. WRIGHT: SECOND.

13 CHAIRMAN PENHOET: MOVED BY SHEEHY, SECOND BY  
14 WRIGHT. CALL THE ROLL, MELISSA. I'M SORRY. STILL  
15 NEED TO ASK FOR COMMENT. WE'VE HAD LOTS OF COMMENTS AS  
16 WE'VE GONE ALONG HERE TODAY.

17 MS. KING: COMMENTS OR QUESTIONS FROM ANYONE  
18 ON THE PHONE?

19 DR. FONTANA: NONE HERE.

20 MS. KING: SO I WILL TAKE THE ROLL CALL.  
21 SUSAN BRYANT.

22 DR. BRYANT: YES.

23 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.  
24 TED LOVE. ED PENHOET.

25 CHAIRMAN PENHOET: YES.

1 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.  
2 DR. PRIETO: YES.  
3 MS. KING: JEANNIE FONTANA.  
4 DR. FONTANA: YES.  
5 MS. KING: JEFF SHEEHY.  
6 MR. SHEEHY: YES.  
7 MS. KING: OSWALD STEWARD.  
8 DR. STEWARD: YES.  
9 MS. KING: JANET WRIGHT.  
10 DR. WRIGHT: YES.  
11 CHAIRMAN PENHOET: OKAY. NOW WE MOVE TO I,  
12 MARCH-IN REQUIREMENTS.  
13 MS. KING: WHICH THOSE OF YOU ON THE PHONE,  
14 WE HAVE NOT YET DISCUSSED IN ANY DEPTH.  
15 CHAIRMAN PENHOET: WE HAVEN'T DISCUSSED AT  
16 ALL EVEN, WHICH INCLUDES ANY DEPTH. OKAY. CAN YOU  
17 MOVE THE SLIDE TO THE NEXT ONE, MARCH-IN RIGHTS. WITH  
18 REGARD TO CIRM-FUNDED PATENTED INVENTIONS, CIRM SHALL  
19 HAVE THE RIGHT TO REQUIRE THE GRANTEE ORGANIZATION OR  
20 EXCLUSIVE LICENSEE OF A CIRM-FUNDED INVENTION TO GRANT  
21 A NONEXCLUSIVE, PARTIALLY EXCLUSIVE, OR EXCLUSIVE  
22 LICENSE IN ANY FIELD OF USE TO A RESPONSIBLE APPLICANT  
23 OR APPLICANTS, UPON TERMS THAT ARE REASONABLE UNDER THE  
24 CIRCUMSTANCES; AND IF THE GRANTEE ORGANIZATION,  
25 NONEXCLUSIVE LICENSEE, OR EXCLUSIVE LICENSEE REFUSES

1 SUCH REQUEST TO GRANT SUCH A LICENSE ITSELF, IF THE  
2 CIRM DETERMINES THAT SUCH AN ACTION IS REQUIRED: ONE,  
3 BECAUSE THE GRANTEE ORGANIZATION OR THE LICENSEE HAS  
4 NOT MADE RESPONSIBLE EFFORTS IN A REASONABLE TIME TO  
5 ACHIEVE PRACTICAL APPLICATION OF A CIRM-FUNDED  
6 INVENTION.

7 TWO, TO MEET REQUIREMENTS FOR PUBLIC USE AND  
8 THE REQUIREMENTS HAVE NOT BEEN SATISFIED BY THE GRANTEE  
9 ORGANIZATION OR ITS LICENSEES.

10 THREE, TO ALLEVIATE HEALTH AND SAFETY NEEDS  
11 WHICH ARE NOT REASONABLY SATISFIED BY THE GRANTEE  
12 ORGANIZATION OR ITS LICENSEE.

13 THOSE ARE THE THREE CONDITIONS UPON WHICH  
14 CIRM, STATE OF CALIFORNIA, COULD MARCH IN. ARE THERE  
15 ANY COMMENTS FROM THE BOARD MEMBERS? JEFF SHEEHY.

16 MR. SHEEHY: I'M WONDERING IF WE WANT TO  
17 PERHAPS INCLUDE -- WE HAVE A LOT OF STUFF IN HERE ABOUT  
18 SHARING, IF YOU TO WANT PUT SOMETHING IN AT THIS POINT  
19 BECAUSE THIS IS OUR MAIN ENFORCEMENT MECHANISM, AS I  
20 UNDERSTAND IT. SO IF THEY'RE NOT SHARING. I'M JUST  
21 PUTTING THIS OUT THERE. LANGUAGE THAT WOULD COVER NOT  
22 SHARING ACCORDING TO THIS DOCUMENT.

23 AND THEN I THINK IF THEY COME UP -- IF THE  
24 LICENSEE DOESN'T FULFILL THE PLAN FOR ACCESS AND FOR  
25 AFFORDABILITY, I WONDER IF THAT MIGHT BE A MARCH-IN

1 POINT AS WELL. GIVEN THAT THEY'VE PRESENTED US WITH A  
2 PLAN AND THEN THEY DON'T FULFILL THEIR PLAN, IT SEEMS  
3 REASONABLE TO SAY TO THEM, WELL, WE'RE GOING TO LICENSE  
4 THIS TO SOMEONE WHO WILL FULFILL AT A MINIMUM THE PLAN  
5 THAT YOU PUT FORTH. DOES THAT SOUND REASONABLE?

6 CHAIRMAN PENHOET: THESE ARE THE TEETH LOTS  
7 OF OTHER PEOPLE HAVE BEEN ASKING FOR. SO, JEFF, YOU  
8 MADE TWO SUGGESTIONS. NO. 1 IS THAT WE ADD THAT THEY  
9 COMPLY WITH THE SHARING OBLIGATIONS INDICATED ELSEWHERE  
10 UNDER G, I BELIEVE IT IS. IT'S SECTION H -- I'M  
11 SORRY -- H, NO. 1. AND NO. 2, THAT WE ADD ONE THAT  
12 THEIR FAILURE TO COMPLY WITH THE AGREED-UPON PLAN FOR  
13 ACCESS.

14 ANY OTHER COMMENTS FROM THE BOARD? FROM THE  
15 AUDIENCE? LET'S SEE. JOHN SIMPSON.

16 MR. SIMPSON: FROM THE FOUNDATION FOR  
17 TAXPAYER AND CONSUMER RIGHTS. I JUST WANTED TO  
18 UNDERSCORE THE NEED TO HAVE WHAT JEFF JUST SAID ADDED.  
19 I THINK IT'S VERY IMPORTANT THAT YOU MARCH IN ON THOSE  
20 THINGS.

21 I WOULD ALSO -- IN OUR REPORT WE RAISE WHAT  
22 WE THINK AS THE APPROPRIATENESS OF HAVING --  
23 ACKNOWLEDGING THAT CIRM DOES NOT HAVE THE STAFF TO DO  
24 THE MARCH-IN. WOULD IT BE SPECIFICALLY THE ATTORNEY  
25 GENERAL WHO WOULD DO THAT, COULD DETERMINE IF THE

1 OBLIGATIONS WERE NOT BEING MET.

2 THE OTHER PROPOSAL WOULD BE SUGGESTING THAT  
3 ALSO SOME SORT OF MARCH-IN RIGHT THAT WOULD GO ALONG  
4 WITH EXCESSIVE PRICING IF THAT WERE FOUND TO BE THE  
5 CASE OF A PARTICULAR THERAPY. IF IT WAS SHOWN THAT IT  
6 WAS PRICED IN AN UNREASONABLE WAY, IF IT COULD BE  
7 DETERMINED AND THEN BE A MARCH-IN RIGHT.

8 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

9 MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
10 CALIFORNIA. THERE WERE A COUPLE THINGS IN  
11 CONSIDERATION. ONE WAS THE SUGGESTION OF MARCH-IN IF  
12 NOT SHARING. IF THE GRANTEE RESERVES THE RIGHT TO  
13 SHARING, THEN LICENSEE DOESN'T HAVE TO SHARE, RIGHT?  
14 YOU DON'T NECESSARILY NEED TO MARCH IN ON THE LICENSEE  
15 IF THE GRANTEE HAS RESERVED THE RIGHT TO DO THE SHARING  
16 WITH PEOPLE. AND THE ONUS IS ON THE GRANTEE IN THESE  
17 TERMS AND CONDITIONS TO MAKE SURE THAT THE SHARING  
18 HAPPENS, SO I'M NOT SURE THAT MARCH-IN IS THE RIGHT  
19 SOLUTION THERE.

20 WE ALSO TALKED ABOUT NOT FULFILLING THE PLANS  
21 FOR ACCESS. THAT IS -- WE TALKED ABOUT EARLIER, THAT  
22 IS A MEANS FOR THE -- THE GRANTEE HAS TO BUILD INTO  
23 THEIR LICENSE, AS WE DISCUSSED EARLIER, THAT THEY CAN  
24 MODIFY OR REVOKE THE LICENSE IF THE GRANTEE IS NOT  
25 MEETING THEIR ACCESS PLANS ALREADY. SO THAT'S ALREADY

1 IN THERE AND IS GOING TO BE A REQUIREMENT OF LAW. SO  
2 I'M NOT SURE. MY MAIN CONCERN WITH THE MARCH-IN IS  
3 WHETHER WE'RE GOING TO BE ABLE TO GET COMPANIES TO  
4 TOUCH THE TECHNOLOGY BECAUSE OF THE UNCERTAINTY. AND  
5 THESE ARE CONCEPTS, THESE THREE ARE CONCEPTS THAT  
6 COMPANIES ARE FAMILIAR WITH THROUGH BAYH-DOLE ALREADY.  
7 THEY WON'T KNOW HOW CIRM IS GOING TO IMPLEMENT THEM, SO  
8 THERE'S A LITTLE BIT OF UNCERTAINTY THERE. BUT THESE  
9 OTHERS WE'VE DEALT WITH ELSEWHERE, AND MAYBE WE CAN  
10 LEAVE THEM DEALT WITH ELSEWHERE SO WE'RE NOT INCREASING  
11 THE (INAUDIBLE) --

12 AND THAT WOULD BE MY COMMENT WITH THE  
13 EXCESSIVE PRICING TOO. WHAT IS -- WHO DETERMINES --  
14 DOES IT TELL YOU UP FRONT WHAT'S GOING TO BE THE  
15 CRITERIA FOR DETERMINING EXCESSIVE PRICING SO THEY KNOW  
16 GOING IN WHAT THEY'RE GETTING INTO?

17 DR. WRIGHT: I WOULD JUST SAY THAT MULTIPLE  
18 TIMES DURING THIS DISCUSSION THIS AFTERNOON, WE'VE  
19 TALKED ABOUT AUDIT FUNCTIONS OF THE CIRM OR POLICING  
20 FUNCTIONS. I THOUGHT EARLIER THAT'S HOW MARY GOT HER  
21 TITLE AS DEPUTY CHAIR. BUT SERIOUSLY, IT IS A BALANCE  
22 TO PROVIDE ENCOURAGEMENT/ENFORCEMENT OF THESE  
23 REGULATIONS, BUT ALSO PROVIDE ENOUGH FREEDOM TO  
24 ENCOURAGE THE RESEARCH. AND ALTHOUGH I AGREE, JEFF,  
25 WITH THE THINGS THAT YOU SUGGESTED, IT SOUNDS LIKE YOUR

1 COMMENT TELLS US THAT WE HAVE POLICE IN THE FIELD. WE  
2 HAVE POLICE THROUGH THE GRANTEE ORGANIZATIONS WHEREIN  
3 THIS RESPONSIBILITY ACTUALLY LIES. SO MAYBE THAT'S  
4 MORE APPROPRIATE FOR THE TWO ITEMS THAT YOU HAD.

5 MR. SHEEHY: I WOULD CONCEDE SHARING BECAUSE  
6 IT DOES SEEM LIKE A GRANTING RESPONSIBILITY.  
7 CONSIDERING WHAT WE'RE DOING WITH NONPROFIT ACADEMIC  
8 INSTITUTIONS, WHICH I THINK DO HAVE A BIAS ANYWAY, I  
9 HOPE NOT ALWAYS, BUT I DO FEEL LIKE IF WE'RE GOING TO  
10 GO TO COMPANIES AND THEY'RE GOING TO GIVE US A PLAN  
11 THEY'VE PUT TOGETHER, WE OUGHT -- WE'LL HEAR ABOUT IT.  
12 WE DON'T NECESSARILY HAVE TO HAVE POLICE IN THE FIELD;  
13 BUT IF WE HEAR THAT A COMPANY IS NOT FULFILLING THEIR  
14 PLAN, I'D RATHER JUST GO OVER THE HEADS OF OUR GRANTEES  
15 AND SAY, LOOK, THE LICENSE IS TAKEN BACK AND WE'RE  
16 GIVING IT TO SOMEBODY WHO'S GOING TO DO IT.

17 IF WE'RE GOING TO GO THAT STEP AND LET THEM  
18 PROVIDE A PLAN, I THINK WE HAVE TO HAVE -- REALLY  
19 INDICATE THAT WE EXPECT THEM TO FULFILL THAT PLAN.

20 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM  
21 THE BOARD MEMBERS?

22 DR. BRYANT: YES. I THINK THAT WHAT WENDY  
23 SAID IS A SERIOUS CONCERN. I THINK WE NEED TO KNOW  
24 WHETHER THAT WOULD, IN FACT, INHIBIT COMPANIES FROM  
25 COMING IN. BECAUSE I THINK THE ULTIMATE GOAL HERE IS



1 TO GET COMPANIES TO COME AND TO DEVELOP THEM INTO  
2 PRODUCTS. IF WE'RE PUTTING ROADBLOCKS IN THE WAY, AS  
3 LONG AS THERE IS A PROTECTION IN THERE ELSEWHERE IN THE  
4 LANGUAGE AGAINST THAT, SO I JUST I WOULD BE CONCERNED.

5 CHAIRMAN PENHOET: MY VIEW, FOR WHAT IT'S  
6 WORTH, IS THAT IF A COMPANY HAS -- IT'S A  
7 SELF-GENERATED PLAN BY THE COMPANY, SO ALL WE'RE ASKING  
8 THEM TO DO IS LIVE UP TO THEIR OWN PLAN. I DON'T THINK  
9 THAT SHOULD PRESENT A BARRIER. IT'S A KNOWN QUANTITY  
10 TO THEM UP FRONT. IT'S NOT -- WHAT THEY FEAR MOST, IN  
11 MY EXPERIENCE, IS THE UNKNOWN. THEY CAN COME IN HERE  
12 FOR SOME REASON THEY MAKE UP AND TAKE MY LICENSE AWAY.  
13 BUT IF THEY PUT THE PLAN FORWARD AND AGREE TO THE PLAN  
14 UP FRONT, I THINK -- DON.

15 MR. REED: CAN WE PUT IN SOMETHING SO THEY  
16 CAN BE WARNED BEFORE MARCH-IN? YOU WILL HAVE SIX  
17 MONTHS TO FULFILL IF THEY'RE IN VIOLATION. SO IF THEY  
18 UNKNOWINGLY GO INTO VIOLATION, THAT THEY COULD HAVE  
19 TIME TO FIX IT.

20 CHAIRMAN PENHOET: SURE. YOU CAN SAY AFTER A  
21 REASONABLE CURE PERIOD, NOT TO EXCEED ONE YEAR, OR  
22 SOMETHING LIKE THAT. YOU CAN ALWAYS --

23 MR. SHEEHY: I DO THINK WE NEED TO HAVE THAT  
24 IN THERE THOUGH.

25 CHAIRMAN PENHOET: THAT COULD BE A GENERAL

1 STATEMENT ABOUT ALL THREE OF THESE, FRANKLY. MAYBE IT  
2 SHOULD BE.

3 DR. BRYANT: I THINK THAT'S A GREAT IDEA.

4 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

5 DR. FONTANA: I THINK YOU'VE DONE A GREAT  
6 JOB. THANK YOU.

7 CHAIRMAN PENHOET: SO THEN WE HAVE A PROPOSAL  
8 TO ADOPT THIS WITH TWO AMENDMENTS. ONE IS THAT WE  
9 EMBODY A CURE PERIOD IN THE LANGUAGE OF NOT MORE THAN  
10 ONE YEAR. IS THAT A REASONABLE NUMBER FOR YOU PEOPLE?

11 DR. WRIGHT: NOT MORE THAN ONE YEAR.

12 CHAIRMAN PENHOET: GET A YEAR TO CURE, BUT  
13 NOT MORE, AND THAT WE USE A BELT AND SUSPENDERS  
14 APPROACH AGAIN TO THIS ISSUE OF LIVING UP TO THEIR  
15 PLAN. THAT'S THE SHEEHY AMENDMENT.

16 MR. SHEEHY: I MIGHT HAVE A SHORTER CURE  
17 PERIOD FOR THAT ONE. I WOULD SAY SIX MONTHS SIMPLY  
18 BECAUSE IF YOU JUST IMAGINE WHAT THE CIRCUMSTANCES  
19 WOULD BE WHEREBY WE MIGHT DECIDE WE WANT TO MARCH IN.  
20 I DON'T KNOW. THAT MEANS THAT SOMEBODY NEEDS THIS  
21 THERAPY, THEY'RE NOT GETTING IT, THE INSTITUTION IS  
22 UNABLE. I THINK WE NEED TO SHOW THAT WE ARE SERIOUS  
23 ABOUT COMPANIES FULFILLING THEIR PLANS TOO SO THAT THEY  
24 TAKE IT SERIOUSLY AS AN OBLIGATION AT THE OUTSET.  
25 WE'RE NOT TELLING THEM WHAT THEY HAVE TO BE, BUT WE'RE

1 ASKING THEM TO COME FORWARD WITH THAT. I THINK A YEAR  
2 IS A LONG TIME.

3 CHAIRMAN PENHOET: YOU WANT SIX MONTHS ACROSS  
4 THE BOARD?

5 MR. SHEEHY: JUST ON ONE. THE OTHERS I'M  
6 FINE IF YOU WANT TO DO A YEAR, BUT AT LEAST FOR THAT  
7 ONE.

8 CHAIRMAN PENHOET: OKAY. WE CAN DRAFT THAT.  
9 ANY COMMENTS BY THE PUBLIC?

10 MR. TAYMOR: YOU HAVE A ONE-YEAR CURE FOR ANY  
11 MARCH-IN FOR ANY HEALTH AND SAFETY NEEDS. SO EVEN IF  
12 THERE'S A PUBLIC EMERGENCY. IT'S UNLIKELY THEY'LL SELL  
13 YOU THE THERAPY UNDER THE BAYH-DOLE CONTEXT, BUT WE'D  
14 BE LOOKING AT THAT TYPE OF EMERGENCY. BUT IF CELLULAR  
15 THERAPIES OF THE TYPE PROGRESSED TO THE POINT WHERE, IN  
16 FACT, THEY ARE ESSENTIAL, YOU'RE STILL SAYING TO A  
17 COMPANY THERE WILL BE A ONE-YEAR DELAY BEFORE MARCH IN  
18 BECAUSE OF PUBLIC HEALTH AND SAFETY.

19 CHAIRMAN PENHOET: THAT'S THE PROPOSAL ON THE  
20 TABLE. IT'S HARD TO COVER EVERY EVENTUALITY.

21 MR. SHEEHY: I'M NOT THAT COMFORTABLE WITH  
22 THE CURE PROVISION ACTUALLY. I REALLY FEEL LIKE THAT  
23 THIS IS GOING TO BE BUMPED UP TO US. IT'S GOING TO BE  
24 CIRM AND ICOC. WHEN THIS HAPPENS, THIS IS NOT GOING TO  
25 BE ROUTINE. I FEEL LIKE IT'S GOING TO BE LIKE WHEN

1 SOMETHING HAS GONE WRONG. I JUST DON'T THINK WE'RE  
2 GOING TO BE SITTING ON TOP OF PEOPLE LIKE THIS. THE  
3 FEDERAL GOVERNMENT HAS NEVER ACTUALLY INVOKED MARCH-IN  
4 RIGHTS. FOR US TO ACTUALLY STEP UP AND DO THAT, IT'S  
5 GOING TO BE IN THE CONTEXT OF SOME PERCEIVED GROSS  
6 FAILURE OR GROSS NEED. AND I JUST DON'T SEE THAT IT  
7 NEEDS A CURE PERIOD.

8 CHAIRMAN PENHOET: COUNTERARGUMENT TO THAT,  
9 JEFF, WOULD BE NO ONE KNOWS TODAY WHO THE ICOC WILL BE  
10 IN THE FUTURE AND WHAT THEY MIGHT DO AND ON WHAT  
11 GROUNDS THEY WOULD DO IT. SO THIS IS A GUIDING  
12 DOCUMENT TO THE FUTURE.

13 AND SECOND OF ALL, I DO THINK MOST LICENSE  
14 AGREEMENTS THAT I'M FAMILIAR WITH DO HAVE A CURE PERIOD  
15 IF YOU'RE ON TRACK BECAUSE SOMETIMES PEOPLE GET OFF  
16 TRACK FOR LOTS OF DIFFERENT REASONS. AND SO IF THERE'S  
17 A HEALTH EMERGENCY AT RISK, THEN MAYBE SOMETHING COULD  
18 BE DONE. I THINK TO THE DEGREE TO WHICH YOU EXPOSE  
19 ORGANIZATIONS TO TOTALLY UNKNOWN SET OF CIRCUMSTANCES  
20 WITH NO OPPORTUNITY TO CURE, MEANING SOMEBODY CAN DRIVE  
21 IN THERE ANY DAY AND SAY, OH, YOU'RE DONE, IT MAKES IT  
22 MUCH HARDER. I THINK I'M SPEAKING FOR ALL YOU GUYS.  
23 TRYING TO FIND SOME REASONABLE BALANCE IN HERE, AND I  
24 THINK A CURE PERIOD IS A WAY TO STRIKE. AT LEAST  
25 COMPANIES HAVE A CHANCE TO RESPOND.

1           MR. REED:   AND AGAIN, ON THE LAWSUITS, I  
2   THINK THERE ARE PEOPLE WHO REALLY WANT TO SHUT US DOWN  
3   BY ANY MEANS NECESSARY.   IF THEY CAN FIND SOME  
4   TECHNICALITY AND SUE, BOOM.   I THINK WE HAVE TO HAVE  
5   SOME MODICUM OF TIME TO ALLOW THEM TO ADJUST IN CASE  
6   SOMETHING COMES UP THEY DIDN' T FORESEE.

7           MS. HOWARD:   ELIZABETH HOWARD, ORRICK.   THAT  
8   TAKES US BACK TO THE LANGUAGE ACTUALLY WHERE, FOR  
9   EXAMPLE, YOU WERE SPEAKING OF GROSS NEGLIGENCE OR  
10   SOMETHING LIKE THIS.   WE'VE GOT REASONABLE -- FAILURE  
11   TO MAKE THESE EFFORTS IN A REASONABLE TIME.   IT'S NOT  
12   GROSS NEGLIGENCE.   IF THEY FAIL TO MEET THAT STANDARD,  
13   IF THAT'S THE STANDARD TO BE ENFORCED, THEN WE NEED TO  
14   HAVE SORT OF TIME TO REMEDY.   IF THAT'S NOT THE  
15   STANDARD THAT WE WANT, THEN MAYBE WE NEED TO RETHINK IN  
16   ORDER TO NOT HAVE TOO MUCH OF A CHILLING EFFECT.

17           MR. SHEEHY:   I CONCEDE ON THE CURE POINT.   I  
18   WOULD GO FOR THE SHORTEST WINDOW THAT PEOPLE FEEL IS  
19   REASONABLE.

20           DR. WRIGHT:   LET ME HEAR WHAT ARE THE  
21   CHANNELS AND THE CONDUITS FOR INFORMATION BACK TO US  
22   AND AT WHAT INTERVALS?   WE'RE GOING TO BE GETTING  
23   ANNUAL REPORTS WITH A LOT OF CONTENT, AND WE'VE ADDED  
24   TO THAT CONTENT TODAY, APPROPRIATELY SO, BUT WHAT OTHER  
25   MEANS DO WE HAVE TO ASSESS THESE THINGS THAT WE ARE

1 MEASURING? HOW WILL WE GATHER THAT INFORMATION BECAUSE  
2 IT SEEMS TO ME OUR PERIOD OF RESPONSE AND OUR CURE  
3 PERIOD OUGHT TO BE IN SYNC WITH THOSE.

4 CHAIRMAN PENHOET: THE CONDUIT WILL BE THE  
5 ANNUAL REPORT, AND LICENSEES HAVE TO REPORT,  
6 PRESUMABLY, PRIMARILY ON AN ANNUAL BASIS ON GRANTEE  
7 ORGANIZATIONS.

8 DR. WRIGHT: SO IT LEADS US TO, LIKE YOU  
9 SAID, NOT MORE THAN A YEAR. WE'RE BACK TO THAT LONG  
10 PERIOD, BUT SHOULD WE HAVE SOME LANGUAGE ABOUT AN  
11 EMERGENCY SITUATION THAT WOULDN'T PERMIT SUCH A LONG  
12 INTERVAL FOR CURE?

13 CHAIRMAN PENHOET: SURE. WE CAN EASILY  
14 DEFINE THE TERM "EMERGENCY SITUATION." IT'S POSSIBLE  
15 TO DO THAT.

16 MR. TOCHER: TO THE EXTENT THAT THERE'S A  
17 TENSION BETWEEN ADDRESSING A CRISIS, BUT ALSO ALLOWING  
18 A CURE FOR A SITUATION THAT THE GRANTEE OR LICENSEE MAY  
19 NOT HAVE BEEN AWARE OF AND MAY BE FULLY CAPABLE OF  
20 ADDRESSING, THEN YOU CAN CERTAINLY BUILD THAT IN AS AN  
21 OPTION, SUCH AS ALLOWING WHAT YOUR PERIOD OF CURE IS IN  
22 THE CIRCUMSTANCES, EXCEPT WHEN THE ICOC DETERMINES AN  
23 EMERGENCY OR CRISIS EXISTS, IN WHICH CASE...

24 CHAIRMAN PENHOET: THAT'S GOOD.

25 DR. WRIGHT: YOU DO THIS FOR A LIVING.

1 CHAIRMAN PENHOET: ANY OTHER COMMENTS BY  
2 BOARD MEMBERS? COMMENTS BY THE AUDIENCE?

3 MS. STREITZ: YOU MIGHT WANT TO ADD TO THAT.  
4 IF YOU HAVE YOUR CURE PERIOD, WHATEVER YOU DETERMINE,  
5 YOU MIGHT JUST WANT TO SAY EXTENDED UPON MUTUAL  
6 AGREEMENT OF CIRM AND WHATEVER.

7 THE REPORTER: I COULDN'T HEAR THAT.

8 MS. STREITZ: I WAS JUST SAYING THAT IN  
9 ADDITION TO WHAT WAS JUST SAID, YOU COULD MAYBE ADD  
10 THAT CURE PERIOD COULD BE EXTENDED BY MUTUAL AGREEMENT  
11 OF CIRM AND THE COMPANY IF THE CIRCUMSTANCES WARRANT.  
12 IT WOULD GIVE THEM A LITTLE BIT MORE MEASURE.

13 CHAIRMAN PENHOET: OKAY. LET ME SEE IF I CAN  
14 FIGURE OUT WHERE WE ARE. WE HAVE A PROPOSAL TO ADD A  
15 FOURTH ITEM, WHICH IS FAILURE TO FOLLOW THE PLANS FOR  
16 ACCESS. WE HAVE A DESIRE FOR ONE YEAR ACROSS THE  
17 BOARD. OKAY. SUBJECT, HOWEVER, TO --

18 MR. TOCHER: ICOC DETERMINATION.

19 MR. SHEEHY: BUT IT'S WENDY'S LANGUAGE  
20 ALLOWING -- FOR A NEGOTIATED LONGER PERIOD.

21 CHAIRMAN PENHOET: BY MUTUAL AGREEMENT.

22 MR. REYNOLDS: JESSE REYNOLDS. JUST BRIEFLY,  
23 I THINK IT MIGHT BE BENEFICIAL TO CLARIFY WHO WOULD  
24 NECESSARILY BE RESPONSIBLE FOR DETERMINING AND THEN  
25 FOLLOWING THROUGH WITH THE POTENTIAL MARCH-IN. I'M NOT

1 SURE WHETHER THIS NEEDS TO BE SPELLED OUT IN THE  
2 REGULATION OR JUST CLARIFY IT AS A MATTER OF PRACTICE.

3 I THINK IT IS KEY TO HAVE THE ATTORNEY  
4 GENERAL HAVE A ROLE IN THIS BECAUSE I THINK IT MIGHT BE  
5 A STRANGE POSITION TO PUT THE ICOC IN A POSITION OF  
6 DETERMINING, FOR EXAMPLE, WHETHER A PUBLIC HEALTH  
7 CRISIS EXISTS OR NOT. I THINK THAT THAT, AS WELL AS  
8 PURSUING THE PUBLIC INTEREST, MAY BE A MORE NATURAL  
9 ROLE FOR THE ATTORNEY GENERAL'S OFFICE, FOR EXAMPLE.

10 CHAIRMAN PENHOET: OKAY. I'M NOT SURE WE  
11 HAVE THE EXPERTISE, NOR DO WE HAVE THE AGREEMENT OF THE  
12 ATTORNEY GENERAL TO DO ANY OF THIS STUFF FOR US.

13 MR. REYNOLDS: IT COULD BE A REQUEST.

14 CHAIRMAN PENHOET: SO WE'LL TAKE THAT UNDER  
15 ADVISEMENT BETWEEN NOW AND THE 10TH OF FEBRUARY WHEN WE  
16 HAVE THE ICOC MEETING AND GET SOME CLARIFICATION OF WHO  
17 THE ENFORCEMENT OFFICE WILL BE FOR THE STATE.

18 MR. REYNOLDS: THANK YOU.

19 MR. SIMPSON: I GUESS WE'D WANT TO UNDERSCORE  
20 THAT'S -- JOHN SIMPSON, FOUNDATION FOR TAXPAYER AND  
21 CONSUMER RIGHTS. THAT ESSENTIALLY WAS OUR PROPOSAL IN  
22 THE REPORT WE SENT YOU LAST WEEK, THAT IT SHOULD BE AN  
23 ELECTED OFFICIAL, AND WE SUGGESTED THE ATTORNEY  
24 GENERAL.

25 CHAIRMAN PENHOET: KEN TAYMOR.



1 MR. TAYMOR: IN EXPLORING WHETHER OR NOT THE  
2 ATTORNEY GENERAL IS THE APPROPRIATE OFFICIAL, I'D JUST  
3 ASK THAT CIRM LOOK AT THE PAST ATTORNEY GENERALS THAT  
4 CALIFORNIA HAS HAD AND THINK AS TO WHETHER EACH AND  
5 EVERY ONE OF THEM WOULD BE AN OFFICIAL WITH WHOM WE  
6 FELT THAT CIRM HAD A SHARED GOAL.

7 CHAIRMAN PENHOET: WE WILL SEEK LOTS OF  
8 ADVICE ON THIS ISSUE IN THE NEXT THREE WEEKS. OKAY.  
9 SO WITH -- ALL RIGHT. WE NEED A MOTION, THEN, I GUESS,  
10 TO APPROVE SECTION I AS STATED AND AMENDED BY JEFF  
11 SHEEHY TO INCLUDE A FOURTH ITEM, WHICH IS FAILURE TO  
12 ADHERE TO THE PLANS FOR ACCESS DEVELOPED BY THE  
13 LICENSEE AND THE LANGUAGE TO DEAL WITH THE CRISIS,  
14 WHOEVER WE END UP DEFINING IT OR PURSUING IT, WE HAVE  
15 TO ADD THAT, AND A CURE PERIOD OF ONE YEAR.

16 DR. WRIGHT: MORE THAN ONE YEAR.

17 CHAIRMAN PENHOET: NOT MORE THAN ONE YEAR  
18 EXCEPT BY AGREEMENT OF THE PARTIES.

19 DR. WRIGHT: SO MOVED.

20 CHAIRMAN PENHOET: MOVED BY WRIGHT.

21 DR. FONTANA: SECOND.

22 CHAIRMAN PENHOET: SECONDED BY JEANNIE  
23 FONTANA. CALL THE ROLL. ANY OTHER COMMENTS?

24 SUSAN BRYANT.

25 DR. BRYANT: YES.

1 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.  
2 TED LOVE. ED PENHOET.  
3 CHAIRMAN PENHOET: YES.  
4 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.  
5 DR. PRIETO: YES.  
6 MS. KING: JEANNIE FONTANA.  
7 DR. FONTANA: YES.  
8 MS. KING: JEFF SHEEHY.  
9 MR. SHEEHY: YES.  
10 MS. KING: OSWALD STEWARD.  
11 DR. STEWARD: YES.  
12 MS. KING: JANET WRIGHT.  
13 DR. WRIGHT: YES.  
14 MS. KING: THAT MOTION CARRIES.  
15 CHAIRMAN PENHOET: OKAY. THAT CONCLUDES WHAT  
16 I THINK IS THE MOST IMPORTANT PART OF TODAY'S WORK  
17 BECAUSE PART OF THIS WILL EVENTUALLY BECOME APA  
18 REGULATIONS AND, THEREFORE, LAW IN THE STATE OF  
19 CALIFORNIA. WE DO HAVE TWO OTHER PARTS TO THIS  
20 DOCUMENT, THE GENERAL INFORMATION SECTION AND THE  
21 POLICIES. OBVIOUSLY THE POLICY PARTS WE'LL HAVE TO  
22 CONFORM WITH WHAT WE NOW CHANGED IN SECTION II.  
23 MARY HAS WHISPERED TO ME THAT MANY PEOPLE IN  
24 THIS ROOM MAY LIKE A FIVE-MINUTE BREAK. WHY DON'T WE  
25 TAKE A FIVE-MINUTE BREAK AND COME BACK REALISTICALLY IN

1 TEN MINUTES.

2 DR. FONTANA: ED, CAN YOU GIVE ME A FORECAST  
3 OF WHAT'S TO COME?

4 CHAIRMAN PENHOET: A DISCUSSION OF -- WELL,  
5 BASICALLY SECTION I IS INFORMATION. SO JUST TO GET  
6 YOUR COMMENTS ON HOW WE MIGHT IMPROVE THIS GENERAL  
7 INFORMATION SECTION BEFORE WE PRESENT IT TO THE WHOLE  
8 ICOC. AND THEN SECTION III IS INTELLECTUAL PROPERTY  
9 POLICY. A PROPOSED SECTION II WHICH WILL BECOME APA  
10 REGULATIONS. SECTION III IS A SORT OF MORE FULSOME  
11 DISCUSSION OF THESE ITEMS AND CONTAIN SOME NONLEGAL  
12 LANGUAGE ABOUT ADMONITION AND COURAGE AND THINGS LIKE  
13 THAT THAT WILL NOT BECOME PART OF THE LAW, BUT WILL  
14 BECOME PART OF THE POLICIES OF CIRM. SO IMPORTANT  
15 DISTINCTION.

16 WHAT'S IN SECTION II WILL BECOME LAW. WHAT'S  
17 IN SECTION III ARE MORE INFORMAL POLICIES OF THE CIRM.  
18 SO WE'LL RECONVENE IN TEN MINUTES. DO WE NEED A VOTE  
19 ON ANY OF THE REST OF THIS?

20 MS. KING: I WAS JUST ABOUT TO ASK. OUR  
21 QUORUM IS SO THIN THAT IF THERE IS ANYTHING ELSE ON  
22 WHICH WE WANT TO TAKE ACTION, WE MIGHT WANT TO MAKE  
23 SURE EVERYBODY IS COMING BACK.

24 CHAIRMAN PENHOET: BEFORE WE TAKE A BREAK, WE  
25 CAN ASK. YOU'VE ALL HAD A CHANCE TO REVIEW THIS. ARE

1       THERE ANY ITEMS HERE THAT, ASIDE FROM MAKING THINGS TO  
2       CONFORM TO WHAT WE JUST TALKED ABOUT IN ITEM 2, THAT WE  
3       FEEL UNCOMFORTABLE NOW PRESENTING TO THE FULL ICOC WITH  
4       OUR APPROVAL?

5                MS. KING:   PARTICULARLY FOR DR. BRYANT AND  
6       DR. STEWARD, SINCE YOU JOINED LATER IN THE DAY, THANK  
7       YOU VERY MUCH, IF YOU HAD ANY QUESTIONS ABOUT THAT  
8       AND/OR -- MAYBE THE BREAK WOULD BE BENEFICIAL.  I  
9       WANTED TO SUGGEST THAT TOO FOR PEOPLE TO TAKE A CHANCE  
10      TO READ SECTION III IF THERE'S ANYTHING TO VOTE ON.

11             DR. STEWARD:  I JUST WANTED TO ASK WHETHER WE  
12      WILL NEED A FORMAL VOTE ON MAKING THAT LANGUAGE  
13      CONSISTENT.

14             CHAIRMAN PENHOET:  BETWEEN THE TWO SECTIONS?  
15      I THINK WE WILL DO THAT, BUT WE CERTAINLY COULD TAKE A  
16      FORMAL VOTE ON THAT, TO ASK STAFF TO GO BACK AND  
17      CONFORM SECTION III TO THE CHANGES WE MADE IN SECTION  
18      II.

19             DR. STEWARD:  WHATEVER.  I'M NOT ASKING FOR  
20      IT.  I'M ASKING IF IT'S SOMETHING THAT WE NEED TO VOTE  
21      ON REALLY.

22             CHAIRMAN PENHOET:  PROBABLY BE USEFUL TO DO  
23      THAT.

24             MS. KING:  WE CAN DO THAT NOW.  WE JUST NEED  
25      A MOTION.

1 CHAIRMAN PENHOET: THE MOTION BY OS STEWARD,  
2 SECOND BY ED PENHOET.  
3 MS. KING: SUSAN BRYANT.  
4 DR. BRYANT: YES.  
5 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.  
6 TED LOVE. ED PENHOET.  
7 CHAIRMAN PENHOET: YES.  
8 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.  
9 DR. PRIETO: JUST A POINT OF CLARIFICATION.  
10 WHAT ARE WE VOTING ON?  
11 CHAIRMAN PENHOET: TO CONFORM SECTION III TO  
12 WHAT WE AGREED TO IN SECTION II.  
13 DR. PRIETO: OKAY. YES.  
14 MS. KING: JEANNIE FONTANA.  
15 DR. FONTANA: YES.  
16 MS. KING: JEFF SHEEHY.  
17 MR. SHEEHY: YES.  
18 MS. KING: OSWALD STEWARD.  
19 DR. STEWARD: YES.  
20 MS. KING: JANET WRIGHT.  
21 DR. WRIGHT: YES.  
22 CHAIRMAN PENHOET: OKAY. WE'LL NOW TAKE A  
23 TEN-MINUTE BREAK AND RECONVENE TO DISCUSS SPECIFICALLY  
24 WHAT'S IN III EXCEPT THOSE PARTS WHICH ARE OUT OF  
25 CONFORMANCE TO II, WHICH WE AGREED TO CHANGE.

1 (A RECESS WAS TAKEN.)

2 CHAIRMAN PENHOET: WE'RE READY. OKAY. WE  
3 ARE RECONVENED. WELCOMING YOU BACK TO THE CLARK CENTER  
4 AT STANFORD, CALIFORNIA. WE'RE READY TO CONTINUE THE  
5 DISCUSSION. I'VE BEEN ASKED BY SEVERAL PEOPLE WHAT OUR  
6 PLANS ARE. I'M NOT SURE WE'LL NEED ANY FURTHER VOTES  
7 TODAY BECAUSE SECTION II IS THE CORE OF WHAT WE MUST  
8 GET DONE IN ORDER TO START THE CLOCK RUNNING ON THE  
9 270-DAY FOR APA REGULATIONS, ETC. BUT BETWEEN NOW AND  
10 5 O'CLOCK, WHICH IS THE TIME WE SET ASIDE FOR THIS  
11 MEETING, WE WOULD LIKE TO DISCUSS WITH YOU AS MUCH AS  
12 POSSIBLE THE ITEMS ESPECIALLY IN SECTION III,  
13 INTELLECTUAL PROPERTY POLICY.

14 AND YOU'RE ALL TIRED OF HEARING ME SPEAK, I'M  
15 SURE, SO I DON'T INTEND TO READ ALL THESE PAGES AS I  
16 DID FOR THE OTHER ONES. SO IF WE COULD JUST GO PAGE BY  
17 PAGE THROUGH THE DOCUMENT, KEEPING IN MIND THAT WE HAVE  
18 ALREADY VOTED TO CONFORM THE POLICY TO THE CHANGES WE  
19 MADE IN WHAT WILL BECOME THE REGULATION. PLEASE  
20 PROVIDE ANY INPUT YOU HAVE FOR US IN REDRAFTING THIS  
21 STATEMENT FOR PRESENTATION TO THE ICOC BOARD ON  
22 FEBRUARY 10TH.

23 SO THIS ITEM 3, SECTION III IN THE DOCUMENT  
24 BEGINS ON PAGE 19 AND IS A DISCUSSION OF THE TYPES OF  
25 INTELLECTUAL PROPERTY. SO DOES ANYONE HAVE ANY

1 COMMENTS ON THE MATERIAL CONTAINED ON PAGE 19? IT'S  
2 PRIMARILY BACKGROUND MATERIAL FOR THIS DOCUMENT.

3 SO ON PAGE 20, THE LAST PARAGRAPH OF SECTION  
4 J DOES SPEAK TO CIRM POLICIES AND MANDATES. SO IF YOU  
5 LOOK CLOSELY AT THAT PARAGRAPH FOR A MOMENT, IT'S SORT  
6 OF A GENERAL STATEMENT OF CIRM POLICY AND ITS  
7 APPLICATION TO THE FIELD BROADLY. ANY OF YOU HAVE ANY  
8 COMMENTS ON THAT? ANY COMMENTS FROM THE BOARD MEMBERS?  
9 ANY COMMENTS FROM THE AUDIENCE? OKAY.

10 THEN SECTION K, CORE PRINCIPLES OF THE POLICY  
11 FOR NONPROFIT ORGANIZATION. THESE ARE THE PRINCIPLES  
12 WE AGREED UPON BEFORE. WE HAVE CLEARLY MADE SOME -- A  
13 RESTATEMENT OF THOSE CORE PRINCIPLES, BUT WE HAVE  
14 CLEARLY EXPANDED THIS AND MODIFIED IT AS A RESULT OF  
15 OUR WORK TODAY. AND SO I THINK FOR CLARITY SAKE GOING  
16 FORWARD, ALTHOUGH THESE ARE THE CORE PRINCIPLES THAT  
17 WERE APPROVED AT THE LAST MEETING, THEY WERE APPROVED  
18 IN ANTICIPATION OF OUR FURTHER WORK, WE WOULD PROBABLY  
19 NOT WANT TO RESTATE THEM THE SAME WAY THEY'RE STATED  
20 HERE, BUT THIS IS ONE SECTION WHERE WE CAN CONFORM THIS  
21 TO WHAT WE NOW DID IN WORKING ON SECTION II. UNLESS  
22 YOU HAVE ANY SPECIFIC COMMENTS ABOUT THAT, WE WILL  
23 CARRY OUT THAT CONFORMING WORK ON SECTION K, WHICH WILL  
24 MAKE IT CONFORM TO WHAT WE JUST DISCUSSED. ANY  
25 COMMENTS ABOUT THAT?

1                   SECTION L, RIGHTS IN OWNERSHIP ON PAGE 21.  
2           BASICALLY AN EXPANDED SECTION OF WHAT WE DISCUSSED  
3           ABOUT MANY OF THESE ISSUES, PUBLICATION, REPORTS,  
4           ACKNOWLEDGEMENTS, ETC., AND PRESS RELEASES AGAIN. FAIR  
5           AMOUNT OF REDUNDANCY TO WHAT'S IN II, BUT WITH  
6           DIFFERENT LANGUAGE.

7                   AGAIN, IN SECTION L, PAGE 22, UNDER A, CIRM  
8           SUPPORTS, WE ANTICIPATE -- WE ARE, IN ADDITION TO  
9           TRYING TO PUSH THE ENVELOPE WITH RESPECT TO SHARING OF  
10          INTELLECTUAL PROPERTY AND SHARING OF RESEARCH REAGENTS,  
11          WE WANT TO SHARE THE RESEARCH RESULTS AS QUICKLY AND AS  
12          BROADLY AS POSSIBLE. SO SECTION A(1) SAYS TO ENCOURAGE  
13          THE USE OF OPEN ACCESS MEDIA BY CIRM-FUNDED  
14          RESEARCHERS, CIRM WILL SUPPORT PUBLICATION COSTS  
15          ASSOCIATED WITH PUBLICATION OF SCIENTIFIC ARTICLES IN  
16          OPEN ACCESS JOURNALS. THIS IS A POLICY OF CIRM. IT'S  
17          CONSISTENT WITH WHAT HHMI DOES TODAY IN THIS REGARD.

18                   NIH DOES NOT SPECIFICALLY CALL THAT OUT, BUT  
19          ALLOWS GRANTEES TO USE GRANT FUNDS FOR THAT PURPOSE,  
20          BUT IT'S, AGAIN, AN AREA WHERE WE'RE TO SOME DEGREE  
21          BREAKING NEW GROUND. DO WE HAVE ANY COMMENTS ABOUT US  
22          DOING THAT?

23                   DR. WRIGHT: I HAVE A QUESTION MARK DRAWN  
24          NEXT TO THAT WHEN I READ IT THE FIRST TIME. THE  
25          SUPPORT WOULD COME THROUGH THE GRANT PROCESS THEN. THE



1 GRANT IS WHERE THOSE FUNDS COME FROM. GRANTS TO --

2 DR. CHIU: WE CAN GIVE A SUPPLEMENT TO THE  
3 GRANT.

4 DR. BRYANT: IT WOULD AN ALLOWABLE EXPENSE ON  
5 THE GRANT MAYBE.

6 CHAIRMAN PENHOET: THERE ARE TWO CONCEPTS AT  
7 WORK. WE CAN EITHER -- HHMI ACTUALLY ALLOWS  
8 INVESTIGATORS TO PAY FOR THIS WITH MONEY ABOVE AND  
9 BEYOND THE GRANT ALLOCATION. SO WE CAN EITHER  
10 ENCOURAGE IT BY ACTUALLY FUNDING THESE PUBLICATIONS OR  
11 WE CAN HAVE IT BE AN ALLOWABLE EXPENSE. THOSE ARE THE  
12 TWO ALTERNATIVES, BUT THEY'D HAVE TO BE CONSISTENT  
13 PROBABLY ACROSS THE BOARD. HOWARD HUGHES ACTUALLY  
14 SEPARATELY PAYS FOR THOSE PUBLICATIONS. THAT'S THE  
15 STRONGEST WAY TO ENCOURAGE IT. OR A LESS STRONG WAY  
16 WOULD BE ALLOW IT TO BE ALLOWED AS AN ALLOWABLE EXPENSE  
17 IN A GRANT, BUT IT WOULD HAVE TO COMPLY WITH THE GRANT.

18 I THINK WE HAVE GOTTEN AN OPINION THAT THIS  
19 IS AN ALLOWABLE EXPENSE FOR CIRM THAT COULD COME OUT OF  
20 THE GRANT POT OF MONEY, NOT OUT OF THE ADMINISTRATIVE  
21 POT OF MONEY. IF IT WERE TO COME OUT OF  
22 ADMINISTRATIVE, I THINK IT WOULD BE A FINANCIAL BURDEN  
23 ON CIRM, BUT COMING OUT OF THE GRANT. AGAIN, MANY  
24 PEOPLE BELIEVE THAT WE SHOULD GO FURTHER THAN SIMPLY  
25 ALLOWING IT, THAT WE SHOULD ENCOURAGE IT. SO TO

1 ENCOURAGE IT, WE WOULD PAY FOR IT SEPARATELY FROM THE  
2 GRANT, BUT ONLY TO OUR GRANTEES, NOT TO --

3 DR. BRYANT: I THINK THAT WOULD BE TERRIFIC  
4 AS LONG AS IT DOESN'T CREATE A WHOLE LOT OF EXTRA  
5 PAPERWORK FOR EVERYBODY, FOR YOU PARTICULARLY, FOR  
6 CIRM.

7 CHAIRMAN PENHOET: ARLENE IS SHAKING HER HEAD  
8 NO, THAT IT WOULDN'T CREATE A LOT OF PAPERWORK.

9 DR. BRYANT: GOOD. I'M FOR IT.

10 CHAIRMAN PENHOET: DO WE HAVE ANY OTHER  
11 COMMENTS ABOUT THAT?

12 DR. STEWARD: I THINK IT'S VERY IMPORTANT TO  
13 ACTUALLY PAY FOR IT OVER THE TOP IF YOU WANT BECAUSE  
14 REALLY ALLOWABLE EXPENSES WOULD THEN DETRACT FROM FUNDS  
15 THAT ONE COULD USE FOR RESEARCH, SO THERE'S REALLY NO  
16 INCENTIVE THERE.

17 CHAIRMAN PENHOET: YES. OKAY. SO THAT'S A  
18 POLICY ISSUE. THERE IS SOME SUBSTANCE IN HERE AFTER  
19 ALL. OKAY.

20 THEN WE PROPOSE ANOTHER POLICY ISSUE, TO  
21 CREATE THE ELECTRONIC LIBRARY REPOSITORY ACCESSIBLE  
22 THROUGH THE WEBSITE. IT WILL BE THE REPOSITORY OF  
23 THOSE SUMMARIES WE TALKED ABOUT EARLIER, WHICH ARE NOW  
24 GOING TO BE MANDATED. BUT THIS WILL BE AN EXPENSE OF  
25 CIRM ITSELF. SHOULDN'T BE A HIGH EXPENSE. IT'S

1 BASICALLY A WEBSITE, BUT IT IS SOMETHING WE'LL HAVE TO  
2 DO GOING FORWARD.

3 MR. REED: IF I COULD ASK THAT THE SCIENTISTS  
4 THEMSELVES HAVE TO CONTRIBUTE BIOGRAPHIES AS A PART OF  
5 THAT.

6 CHAIRMAN PENHOET: DON ASKED THAT SCIENTISTS  
7 SUBMIT BIOGRAPHIES TO THIS AS WELL. IF THEY'RE PI'S ON  
8 OUR GRANTS, THAT THEIR BIOGRAPHIES BE AVAILABLE ON THE  
9 WEBSITE, THE RELEVANT PARTS OF THEIR BIOGRAPHIES.  
10 OKAY.

11 THEN THREE LITTLE I'S IS COPIES OF FINAL  
12 MANUSCRIPTS SUPPORTED IN WHOLE OR IN PART MAY BE  
13 DEPOSITED TO PUBMED CENTRAL AND MADE FREELY AVAILABLE  
14 WITHIN X NUMBER OF MONTHS AFTER THE JOURNAL PUBLISHER'S  
15 OFFICIAL DATE OF FINAL PUBLICATION. THE BALANCE HERE  
16 IS WE WANT TO MAKE SURE THESE THINGS ARE BROADLY  
17 AVAILABLE, BUT WE DO NOT WANT TO PRECLUDE OUR  
18 INVESTIGATORS FROM PUBLISHING IN CERTAIN HIGH QUALITY  
19 JOURNALS WHICH ARE VERY IMPORTANT TO THEM, SOME OF  
20 WHICH HAVE A SOMEWHAT LONGER PERIOD OF TIME TO -- WHERE  
21 THEY'RE KEPT. YOU HAVE TO GET ACCESS TO THE JOURNAL IN  
22 ORDER TO READ THE ARTICLES.

23 WE COULD PUT SOME LANGUAGE IN, NOT LATER THAN  
24 THE EXPIRATION OF THE COPYRIGHT OF THE JOURNALS. MARY  
25 HAS DONE A FAIR AMOUNT OF HOMEWORK ON THIS ISSUE.

1 DR. MAXON: THERE ARE SOME JOURNALS THAT ARE  
2 NEVER FREE. SO IT'S A TOUCHY ISSUE.

3 DR. BRYANT: WHICH ONES ARE THEY?

4 DR. MAXON: I DON'T KNOW THEM ALL, BUT I DO  
5 KNOW THAT -- I READ SEVERAL REPORTS THAT DESCRIBE  
6 DIFFERENT CLASSES OF JOURNALS, SOME OF WHICH HAVE OPEN  
7 ACCESS POLICIES IMMEDIATELY, SOME OF WHICH HAVE OPEN  
8 ACCESS POLICIES AFTER A PERIOD OF TIME, SIX MONTHS, A  
9 YEAR, IT DEPENDS. AND THERE ARE SEVERAL JOURNALS IN  
10 EACH ONE OF THESE CATEGORIES, AND THEN ANOTHER CATEGORY  
11 WHERE THEY NEVER HAVE OPEN ACCESS.

12 SO HERE'S THE SITUATION. IF WE WERE TO  
13 MANDATE THIS IN SOME WAY, WE WOULD PREVENT OUR GRANTEEES  
14 FROM PUBLISHING IN SOME OF THEIR FAVORITE JOURNALS.

15 DR. BRYANT: YEAH.

16 CHAIRMAN PENHOET: AS A PLACEHOLDER, COULD WE  
17 PUT DOWN 12 MONTHS AND THEN DO SOME MORE HOMEWORK ABOUT  
18 WHICH THOSE JOURNALS MIGHT BE?

19 DR. BRYANT: YEAH.

20 CHAIRMAN PENHOET: WE ARE PUSHING FOR MORE  
21 ACCESS GENERALLY. IF IT'S JUST A FEW JOURNALS THAT ARE  
22 BEYOND 12 MONTHS, THAT WOULD BE A PRICE.

23 DR. STEWARD: IT WOULD BE WORTH ACTUALLY  
24 PUSHING THESE JOURNALS JUST A LITTLE BIT. IT IS  
25 POSSIBLE FOR A JOURNAL TO SELECTIVELY PUT AN ARTICLE

1 OUTSIDE THE FIREWALL, SO TO SPEAK. AND MAYBE WE COULD  
2 GET SOME OF THESE TO ACTUALLY AGREE TO DO THIS IN THE  
3 CASE OF CIRM-FUNDED RESEARCH IF THAT WERE THE POLICY OF  
4 CIRM. I DON'T KNOW THAT FOR SURE, BUT IT WOULD BE  
5 WORTH EXPLORING.

6 MR. SHEEHY: ON THIS ISSUE, GIVEN THE FUNDING  
7 SOURCE, I THINK IT'S IMPORTANT THAT THE RESULTS OF OUR  
8 RESEARCH ARE AVAILABLE AT SOME POINT. I CAN'T IMAGINE  
9 SAYING, WELL, THE ONLY WAY YOU CAN ACTUALLY READ THE  
10 RESULTS OF A CIRM-FUNDED PROJECT IS TO BUY THE JOURNAL.  
11 I THINK OS MAKES AN IMPORTANT POINT. IF WE CAN GIVE  
12 REASONABLE MEANS, SIX MONTHS OR A YEAR, WE CAN PUSH  
13 THEM TO DO BETTER, WHICH SHOULD BE IN THEIR INTEREST AT  
14 SOME POINT. THEY'LL RECOGNIZE THAT, EVEN IF THEY  
15 HAVEN'T ALREADY. BUT I ALMOST THINK WE NEED TO  
16 STIPULATE THAT EVEN IF IT CLOSES SOME JOURNALS OUT. DO  
17 YOU KNOW THE NAME OF ANY OF THE JOURNALS?

18 DR. MAXON: I DO, BUT I'D RATHER NOT SAY THEM  
19 IN A PUBLIC MEETING.

20 CHAIRMAN PENHOET: WE HAVE TO BRING THIS IN  
21 THE PUBLIC AT SOME POINT. IF WE CAN PUT 12 MONTHS AS A  
22 PLACEHOLDER, AND THEN WE'LL GO BACK AND GET A LIST SO  
23 WE CAN DISCUSS IT. THEIR POLICIES ARE PUBLIC  
24 INFORMATION, BY THE WAY, YOU CAN READ THEM IN THEIR  
25 JOURNAL.

1 MS. AURITI: CAN I JUST CLARIFY WHETHER YOU  
2 MEAN 12 MONTHS WITHIN THE DATE OF THE EXPIRATION OF THE  
3 COPYRIGHT. I JUST WANTED TO MENTION THAT IN INTERNAL  
4 DISCUSSIONS THAT WE'VE HAD, SOME OF THE CONSIDERATIONS  
5 THAT WE'VE TALKED ABOUT ARE THE PARTICULAR IMPACTS ON  
6 MAYBE YOUNGER OR NEWER INVESTIGATORS ON MAYBE BECOMING  
7 A GREATER CAREER NAME TO PUBLISH IN SOME OF THESE  
8 PARTICULARLY PRESTIGIOUS PEER REVIEW JOURNALS. WE  
9 UNDERSTAND BOTH VIEWS, BUT IT'S IMPORTANT TO TAKE THAT  
10 INTO CONSIDERATION WHEN DEVELOPING THE POLICY.

11 AND RELATED TO THAT, I WANTED TO FLIP BACK TO  
12 SECTION L ON RIGHTS IN OWNERSHIP, THE THIRD PARAGRAPH.  
13 I THOUGHT IT REQUIRED CIRM TO -- REQUIRED THE GRANTEE  
14 ORGANIZATION TO ALLOW CIRM WITHOUT CHARGE OF ANY FEES  
15 TO REPRODUCE, PUBLISH, OR OTHERWISE USE THE COPYRIGHTED  
16 MATERIAL FOR PUBLIC BENEFIT. THE GRANTEE ORGANIZATION  
17 IS THE INSTITUTION. WE'RE NOT NORMALLY NEGOTIATING THE  
18 COPYRIGHT WITH THE PUBLISHERS. THAT'S SOMETHING THAT  
19 THE PI DOES, AND IT WILL REQUIRE THEM TO HAVE TO  
20 NEGOTIATE AND TO HAVE THE KNOWLEDGE TO GO AHEAD AND  
21 RESERVE THOSE RIGHTS. AND IT'S SOMETHING THAT YOU  
22 MIGHT WANT TO LOOK AT IN A LITTLE BIT MORE DETAIL TO  
23 SEE IF THAT'S GOING TO BE FEASIBLE.

24 CHAIRMAN PENHOET: OKAY. THANK YOU. WE'RE  
25 GOING TO PUT 12 MONTHS AS A PLACEHOLDER TO GET A LIST

1 OF JOURNALS WHICH HAVE A LONGER PERIOD THAN THAT SO WE  
2 CAN EVALUATE WHAT JOURNALS.

3 MR. SHEEHY: AND I WOULD JUST MAKE THIS  
4 POINT. I UNDERSTAND THE BURDENS ON OTHER PEOPLE'S  
5 CAREERS, BUT THAT'S NOT -- WE'RE DOING A SCALE HERE.  
6 IT'S A BALANCE. NOT MAKING PUBLICLY FUNDED RESEARCH  
7 AVAILABLE, TO ME IT'S MORE MAKING IT AVAILABLE.

8 CHAIRMAN PENHOET: IF WE LEAVE IT AT 12  
9 MONTHS --

10 MR. SHEEHY: I'M FINE WITH THAT.

11 CHAIRMAN PENHOET: YOU WANT TO PUSH IT  
12 FURTHER.

13 MR. SHEEHY: YEAH. I JUST -- I DON'T KNOW IF  
14 WE NEED TO TAKE A VOTE ON IT OR WHAT, BUT I THINK IT'S  
15 IMPORTANT.

16 CHAIRMAN PENHOET: LET'S VOTE ON THIS WHOLE  
17 SECTION WHEN WE -- A COPY IN THE ANNUAL REPORT, NO  
18 PROBLEM. ALL PUBLICATION. ALL RIGHT. SO WE'VE HAD  
19 SEVERAL PROPOSALS TO MODIFY SECTION LITTLE A. ALL  
20 RIGHT. FIRST IS PAY FOR IT OVER AND ABOVE THE GRANT  
21 AMOUNT ITSELF. PAY FOR OPEN ACCESS PUBLICATIONS.  
22 PRESUMABLY THEY CAN BUY FULL PAGE ADS IN THE NEW YORK  
23 TIMES FOR YOUR PAPERS.

24 THEN DON REED'S PROPOSAL TO INCLUDE  
25 BIOGRAPHIES OF OUR PRINCIPAL INVESTIGATORS TO BE

1 INCORPORATED INTO TWO LITTLE I ' S.  
2 THREE LITTLE I ' S, PUTTING A 12-MONTH  
3 PLACEHOLDER, AND WE ' LL GET MORE INFORMATION ABOUT WHICH  
4 JOURNALS WILL BE INCLUDED IN THAT SO WE LAY THE BALANCE  
5 ON FEBRUARY 10TH.  
6 I GUESS THE REST OF THIS IS RELATIVELY  
7 SIMPLE. SO LET ' S SEE HOW MANY PEOPLE WE STILL HAVE  
8 LEFT HERE. THOSE ARE THE SUGGESTED. DO I HAVE A  
9 MOTION TO APPROVE A WITH THOSE CHANGES?  
10 MR. SHEEHY: SO MOVED.  
11 DR. WRIGHT: SECOND.  
12 CHAIRMAN PENHOET: MOVED AND SECONDED.  
13 MS. KING: SUSAN BRYANT.  
14 DR. BRYANT: YES.  
15 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.  
16 TED LOVE. ED PENHOET.  
17 CHAIRMAN PENHOET: YES.  
18 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.  
19 WE HAVE LOST OUR QUORUM.  
20 CHAIRMAN PENHOET: OKAY.  
21 MS. KING: JEANNIE FONTANA. JEFF SHEEHY.  
22 MR. SHEEHY: YES.  
23 MS. KING: OSWALD STEWARD.  
24 DR. STEWARD: YES.  
25 MS. KING: JANET WRIGHT.



1 DR. WRIGHT: YES.

2 CHAIRMAN PENHOET: WE'LL RECORD THE SENTIMENT  
3 OF THE GROUP. HOW'S THAT?

4 PRESS RELEASES. INVENTION REPORTING. TO  
5 SOME DEGREE I THINK THIS DOES ANSWER SOME OF THE  
6 QUESTIONS THAT CAME UP EARLIER ABOUT WHO WILL KEEP  
7 TRACK OF THIS STUFF. I SEE WENDY STREITZ IN THE BACK  
8 ROW.

9 MS. STREITZ: THIS IS WENDY STREITZ,  
10 UNIVERSITY OF CALIFORNIA. I WAS WONDERING IF I COULD  
11 ASK A COUPLE QUESTIONS ABOUT THIS ONE. ONE IS IT SEEMS  
12 TO IMPLY IN THE FIRST LINE THE DATABASE WOULD TRACK  
13 INVENTIONS, PATENTS, AND LICENSE AGREEMENTS. AND THE  
14 QUESTION THAT RAISES FOR US IS WHETHER CIRM EXPECTS THE  
15 GRANTEE INSTITUTIONS TO PROVIDE COPIES OF THE LICENSE  
16 AGREEMENTS, WHICH WE DON'T EVEN DO FOR THE FEDERAL  
17 GOVERNMENT RIGHT NOW. AND THE ISSUE IS COMPANIES  
18 CONSIDER THOSE VERY PROPRIETARY. IF YOU THINK THERE'S  
19 A NEED FOR SOME INFORMATION, MAYBE WE CAN EXTRACT  
20 CERTAIN INFORMATION OUT OF THE LICENSES THAT'S  
21 IMPORTANT AS A BETTER WAY TO DO THAT. SO SOMETHING TO  
22 THINK ABOUT.

23 IN THE FOURTH LINE IT TALKS ABOUT EXECUTING  
24 WRITTEN AGREEMENTS WITH INVENTORS AND LICENSEES, AND  
25 I'M WONDERING WHAT THAT'S MEANT TO GET AT. WHAT

1 AGREEMENTS DO WE NEED WITH OUR LICENSEES AND INVENTORS  
2 HERE?

3 CHAIRMAN PENHOET: YOU HAVE A POLICY OF  
4 SHARING WITH INVENTORS. PRESUMABLY THAT'S A WRITTEN  
5 POLICY.

6 MS. STREITZ: IT SAYS IN ORDER TO MAINTAIN  
7 THIS DATABASE, WE NEED TO EXECUTE THESE AGREEMENTS.

8 DR. WRIGHT: SOUNDS LIKE THE AGREEMENT --  
9 (SIMULTANEOUS DISCUSSION.)

10 CHAIRMAN PENHOET: YOU HAVE WRITTEN  
11 AGREEMENTS WITH YOUR INVENTOR, SO WE WOULD LIKE A COPY  
12 OF THIS, WHATEVER YOUR AGREEMENT IS. UNIVERSITY OF  
13 CALIFORNIA HAS A SHARING AGREEMENT.

14 MS. STREITZ: OKAY. SO LET'S TAKE THAT AS AN  
15 EXAMPLE. WE HAVE A POLICY AND WE HAVE A STANDARD THING  
16 THAT EVERYBODY SIGNS.

17 CHAIRMAN PENHOET: YEAH. THAT'S AN  
18 AGREEMENT.

19 MS. STREITZ: WE CAN'T NECESSARILY GO DIG UP  
20 THE ONE THAT EACH INVENTOR SIGNED.

21 CHAIRMAN PENHOET: WE JUST NEED THE POLICY  
22 BECAUSE EVERY INVENTOR IS SUBJECT TO THAT POLICY.

23 MS. STREITZ: SO MY NEXT QUESTION IS WHY DO  
24 YOU NEED THAT IN ORDER TO SET UP THE DATABASE? WE'RE  
25 OKAY WITH PROVIDING IT. I'M JUST NOT SURE WHY IT'S

1 NECESSARY. I'M NOT SURE YOU NEED THE AGREEMENT THAT  
2 WOULD HAVE ANYTHING IN PARTICULAR IN A AGREEMENT WITH  
3 THE LICENSEE EITHER AS LONG AS WE'RE ABLE TO PROVIDE  
4 YOU THE INFORMATION YOU NEED FOR THE DATABASE.

5 DR. WRIGHT: ARE WE SEEKING TO RECORD THE  
6 LICENSE, THE FACT THAT THERE IS A LICENSE BETWEEN A  
7 GRANTING ORGANIZATION AND A LICENSEE? WE DON'T REALLY  
8 WANT TO KNOW THE AGREEMENT, OR WE WANT TO KNOW THAT  
9 YOUR ORGANIZATION HAS LICENSES OUT TO --

10 CHAIRMAN PENHOET: I THINK WE'VE ALREADY  
11 ESTABLISHED WE WANT TO KNOW WHAT THE ACCESSIBILITY  
12 PROVISION IS. WE WON'T HAVE ANY WAY OF MONITORING IT  
13 OTHERWISE.

14 DR. WRIGHT: THAT COMES IN THE ANNUAL REPORT,  
15 OR ARE WE BUILDING A DATABASE OF --

16 CHAIRMAN PENHOET: YEAH.

17 DR. MAXON: THE SECTION C HERE, IT'S THE MINI  
18 VERSION BEHIND WHAT YOU SAW IN SECTION II. IT  
19 BASICALLY IN SHORT FORM SAYS CIRM IS GOING TO HAVE A  
20 DATABASE, AND IT'S GOING TO TAKE ALL THE INFORMATION  
21 THAT IT'S ASKED OF THE GRANTEES AND PUT IT IN THE  
22 DATABASE. AND WHAT IT ASKS FOR ARE INVENTION  
23 DISCLOSURE, PATENT FILING, WHETHER THERE'S A LICENSE  
24 AGREEMENT OR NOT, AND WE'VE ALREADY DISCUSSED PUTTING A  
25 PLAN IN THERE TOO AS OF TODAY, WHAT THE PLAN IS, AND

1 THEN THE UTILIZATION REPORT. WE'LL WANT TO KNOW WHAT  
2 ACTIVITIES THE GRANTEE ORGANIZATIONS DID TO TRY TO  
3 LICENSE THE THING OVER THAT GIVEN YEAR. SO THIS IS  
4 MEANT TO JUST CAPTURE THOSE IDEAS JUST IN A VERY SMALL  
5 SECTION.

6 DR. WRIGHT: THE CONTENTS OF THE ANNUAL  
7 REPORT --

8 DR. MAXON: ONE CAN IMAGINE THAT THERE'S AN  
9 ANNUAL PROGRESS REPORT THAT HAS FINANCIAL AND THE  
10 SCIENTIFIC PROGRESS DOCUMENTS, AND THEN ON THAT ANNUAL  
11 REPORT, YOU COULD SEE A CHECK BOX THAT SAYS DID YOU  
12 HAVE ANY INVENTIONS THIS YEAR. YOU CHECK IT OR YOU  
13 DON'T. IF YOU CHECK IT, THEN HAVE YOU FILED ANY  
14 APPLICATIONS FOR THOSE INVENTIONS FOR PATENTS? YES OR  
15 NO? DO YOU HAVE ANY LICENSES, AND THEN IT WOULD TAKE  
16 YOU TO ANOTHER WHOLE FORM. SO THAT'S THE INTENT HERE.

17 THE INTENTION TO EXPLAIN WHY WE WANT ALL THAT  
18 INFORMATION. BECAUSE WE WANT TO PUT IT INTO A DATABASE  
19 AND TRACK IT. IT WASN'T INTENDED TO BE ANYTHING MORE  
20 THAN THAT ACTUALLY. SO IF IT DIDN'T MAKE THAT POINT --

21 CHAIRMAN PENHOET: IT NOW HAS TO CONFORM TO  
22 WHAT WE ALREADY DID.

23 DR. MAXON: EXACTLY.

24 CHAIRMAN PENHOET: THIS IS THE IMPLEMENTATION  
25 OF REGS THAT ARE IN II. THEN WE WILL HAVE TO MODIFY.

1 CORE PRINCIPLES UNDER BACKGROUND INFORMATION.  
2 ANYBODY DISAGREE WITH ANY OF THOSE CORE PRINCIPLES?  
3 GO TO THE LANGUAGE ON PAGE 24.  
4 DR. WRIGHT: GOING BACK TO ONE OF THE CORE  
5 PRINCIPLES. I HAVE A QUESTION MARK NEXT TO THE WORD  
6 "PUBLIC GOOD." ONE OF OUR CORE PRINCIPLES IS -- I'M  
7 NOT SURE NOW WHERE I GOT THAT. ISN'T THAT ONE OF OUR  
8 CORE PRINCIPLES, ASSURING THE PUBLIC GOOD WITH THE  
9 RESULTS OF THE RESEARCH?  
10 DR. MAXON: THIS IS THE CORE PRINCIPLES OF  
11 THE SHARING POLICY. THERE ARE ALSO OTHER CORE  
12 PRINCIPLES.  
13 DR. WRIGHT: THAT MUST BE WHERE I GOT THAT.  
14 CHAIRMAN PENHOET: FOR ALL YOUR INFORMATION,  
15 I AM A MEMBER OF THE SCIENCE, TECHNOLOGY, AND ECONOMIC  
16 POLICY BOARD OF THE NATIONAL ACADEMY, WHICH IS THE  
17 SPONSOR OF REAPING THE BENEFITS OF GENOMIC AND  
18 PROTEOMIC RESEARCH; HOWEVER, I HAD NOTHING TO DO WITH  
19 THE REPORT ITSELF. I WASN'T INVOLVED IN THAT REPORT  
20 OTHER THAN TO VOTE.  
21 MR. HALUIN: HAL HALUIN. I HAVE A QUESTION  
22 AT THE TOP OF PAGE 25, SHARING THE DATA WITH FELLOW  
23 CIRM-FUNDED SCIENTISTS. AND I THINK MAYBE FOR  
24 CLARIFICATION THAT SHOULD BE CONSISTENT WITH THE  
25 OPEN --

1 CHAIRMAN PENHOET: THEY JUST COULDN'T HEAR  
2 YOU. MAYBE IF YOU COULD SPEAK MORE DIRECTLY INTO THE  
3 MICROPHONE.

4 MR. HALUIN: MY POINT WAS THAT THERE'S  
5 COMPLETE OPEN SHARING. IF YOU READ THIS LITERATURE,  
6 THEN THE SCIENTISTS WOULD BE SHARING AMONGST  
7 THEMSELVES, AND THAT COULD BLOCK AT LEAST SOME  
8 INTERNATIONAL FOREIGN PATENT RIGHTS, SO I THINK IT  
9 SHOULD BE CLARIFIED THAT IT WOULD BE DONE IN SUCH A WAY  
10 THAT IT DOES NOT PRECLUDE PATENTING IN FOREIGN  
11 COUNTRIES.

12 CHAIRMAN PENHOET: GOOD POINT. PROTECTING  
13 ACADEMIC FREEDOM AND PROMOTING PUBLICATION, PAGE 25.  
14 SOUNDS LIKE A GOOD THING TO DO. MINIMIZE IMPEDIMENTS  
15 TO STEM CELL RESEARCH. STREAMLINE THE PROCESS OF  
16 RESEARCH, TRANSFERRING RESEARCH TOOLS.

17 MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
18 CALIFORNIA. HERE AND IN SEVERAL OTHER PLACES IN  
19 REFERENCE TO A CIRM MTA, WHICH IS A FINE AND A USEFUL  
20 TOOL, MY QUESTION IS WHETHER CIRM WOULD ALLOW AN  
21 INSTITUTION TO USE ITS OWN MTA IF IT'S GENERALLY  
22 SIMILARLY NONRESTRICTIVE.

23 CHAIRMAN PENHOET: I BELIEVE THE ANSWER IS  
24 YES. DOES ANYBODY HAVE A DIFFERENT VIEW ABOUT THAT?

25 CIRM MTA OR SIMILAR DOCUMENT GENERATED BY A

1 GRANTEE INSTITUTION.

2 ALLOWING TO CONFORM TO BAYH-DOLE OBLIGATIONS.  
3 ONE OF THE CORE PRINCIPLES, REALIZING, FOR THOSE OF YOU  
4 WHO ARE NOT FAMILIAR WITH IT, \$1 OF FEDERAL FUNDS IN  
5 ANY RESEARCH PROGRAM REQUIRES YOU TO FOLLOW THIS  
6 FEDERAL LAW. SO WE THINK THAT WE DON'T WANT TO  
7 DISCOURAGE COMMINGLING OF OUR FUNDS WITH THE FEDERAL  
8 MONEY. THAT'S THE IDEA BEHIND CONFORMING TO BAYH-DOLE.  
9 COMPATIBLE WITH BAYH-DOLE IS THE RIGHT LANGUAGE.

10 BROAD DISSEMINATION. THERE MAY BE SOME  
11 ISSUES UNDER THIS. WE'RE ON PAGE 26 NOW. ANY COMMENTS  
12 FROM BOARD MEMBERS ON PAGE 26? PART OF IT IS SOMEWHAT  
13 REDUNDANT WITH WHAT'S IN SECTION II.

14 DR. PRIETO: I WAS NOTICING THAT MATERIALS  
15 DESCRIBED IN A PUBLICATION MUST BE SHARED -- ACTUALLY  
16 THIS IS TALKING ABOUT BIOLOGICAL MATERIALS RATHER THAN  
17 THE ISSUE THAT CAME UP EARLIER ABOUT THEY DON'T WANT TO  
18 SHARE THEIR PUBLICATION.

19 CHAIRMAN PENHOET: YES, THAT'S RIGHT. IT'S  
20 THE MATERIALS. OKAY.

21 PAGE 27. AGAIN, BOTTOM OF THE PAGE, IT SAYS  
22 THEY SHOULD MAKE USE OF THE CIRM MTA. SO CIRM MTA OR A  
23 SIMILAR DOCUMENT. WHAT WE'RE TRYING TO GET AT HERE IS  
24 A LOT OF TIMES THE SLOWING DOWN OF THIS PROCESS IS  
25 CREATING A UNIQUE MTA FOR EVERYTHING ON THAT. WE'RE

1 FOREVER GOING TO BE THINKING ABOUT THAT. WE WANT TO  
2 MAKE SURE THEY'RE SOMETHING FAIRLY STANDARD. THERE ARE  
3 A WHOLE BUNCH OF THINGS THAT SHOULD BE INCLUDED IN AN  
4 MTA. YOU GUYS AT THE UNIVERSITY LEVEL HAVE A RESPONSE  
5 TO THE LAUNDRY LIST ON PAGE 28?

6 MR. TAYMOR: I'M NOT AT THE UNIVERSITY LEVEL.  
7 I HAVE A QUESTION. AT THE BOTTOM CIRM DOES NOT SUPPORT  
8 THE FOLLOWING TERMS. IS THAT CIRM DISCOURAGES? IF ANY  
9 OF THE FOLLOWING TERMS ARE INCLUDED, IT'S OKAY, CIRM IS  
10 NOT GOING TO DO ANYTHING ABOUT IT, OR YOU JUST DON'T  
11 WANT TO SEE IT.

12 CHAIRMAN PENHOET: ENCOURAGE IS THE BETTER  
13 WORD.

14 MR. TAYMOR: THEY'RE PERMITTED, BUT  
15 DISCOURAGED.

16 CHAIRMAN PENHOET: YEAH. PAGE 29. ARE WE  
17 MISSING A WORD IN THE TITLE THERE, MARY?

18 DR. MAXON: I THINK WE ARE.

19 CHAIRMAN PENHOET: SHOULD IT BE DISCLOSING  
20 AND PATENTING OF INVENTIONS? MARY AND I HAVE READ THIS  
21 SO MANY TIMES BY NOW.

22 DR. MAXON: EYE YEI YEI.

23 CHAIRMAN PENHOET: DISCLOSURE AND PATENTING  
24 OF INVENTIONS. ANY COMMENTS FROM ANYONE? 29. KEN  
25 TAYMOR.



1 MR. TAYMOR: WELL, THAT WOULD BE CONFORMED  
2 TO. IT'S MORE RESTRICTIVE, I THINK, THAN THE LANGUAGE  
3 OF THE REGULATION. THIS IS SCIENTIFIC RESEARCH  
4 INSTITUTIONS IN THE STATE OF CALIFORNIA, BUT IS THAT --

5 CHAIRMAN PENHOET: WE HAVE TO COME UP WITH A  
6 DEFINITION OF RESEARCH INSTITUTIONS, WHICH WE'RE GOING  
7 TO --

8 DR. WRIGHT: WE DIDN'T CALL IT SCIENTIFIC.

9 CHAIRMAN PENHOET: YEAH. I BELIEVE YOU'RE  
10 RIGHT.

11 PAGE 30, TECHNOLOGY TRANSFER. THIS WHOLE  
12 SECTION HAS TO BE CONFORMED TO WHAT WE TALKED ABOUT IN  
13 SECTION II. IT'S MOSTLY BACKGROUND MATERIAL HERE ON  
14 PAGE 30.

15 SIMILARLY ON PAGE 31. MORE SPECIFICS ABOUT  
16 THE CONTENTS OF LICENSES.

17 MR. TAYMOR: JUST TO FOLLOW UP ON A COMMENT  
18 THAT WAS MADE BY THE UNIVERSITY OF CALIFORNIA, AND JUST  
19 FOR CLARIFICATION. IS IT THE EXPECTATION THAT LICENSES  
20 WILL NOT BE GIVEN, FOR EXAMPLE, WITH FINANCIAL TERMS  
21 REDACTED? IT WILL NOT BE AVAILABLE TO THE PUBLIC, THAT  
22 CIRM WILL NOT REQUIRE AND DOES NOT EXPECT THAT LICENSES  
23 BETWEEN GRANTEES AND THEIR LICENSEES WILL BE AVAILABLE  
24 TO THE PUBLIC?

25 CHAIRMAN PENHOET: WITH THE EXCEPTION THAT

1 THE PROVISION -- I THINK WE TALKED ABOUT EARLIER THAT  
2 THE PROVISION FOR ACCESS WOULD BE MADE AVAILABLE TO  
3 CIRM AND TO THE PUBLIC, BUT THAT THE OTHER PROVISIONS  
4 WOULD NOT.

5 MR. TAYMOR: DOES A REMEDY FOR THE BREACH OF  
6 ACCESS, IS THAT A PROVISION FOR THE ACCESS? IT SEEMS  
7 TO ME, FOR UNDERSTANDING THE ACCESS PROVISION, YOU NEED  
8 TO KNOW THE REMEDY PROVISION FOR IT THAT WAS CONTAINED  
9 WITHIN THE LICENSE.

10 CHAIRMAN PENHOET: I THINK ALL -- THE WAY I  
11 UNDERSTOOD THE CONVERSATION WE HAD IS THE LICENSEE  
12 WOULD PUT FORTH A PROPOSAL FOR ADDRESSING UNINSURED  
13 POPULATIONS IN CALIFORNIA THROUGH A PLAN. THEY'RE  
14 EITHER IN CONFORMANCE WITH THE PLAN OR NOT. I THINK  
15 THE PLAN WOULD NECESSARILY IN THE ORDINARY COURSE  
16 SPECIFY THE REMEDY TO GET THEMSELVES BACK IN COMPLIANCE  
17 WITH THE PLAN.

18 MR. TAYMOR: THAT'S THE PLAN, BUT MY QUESTION  
19 GOES TO THE ACTUAL LICENSE, THE ACTUAL DOCUMENT BECAUSE  
20 A PLAN COULD BE PROVIDED AS PART OF A LETTER OF INTENT  
21 OR A BUSINESS OUTLINE OF THE ARRANGEMENT.

22 (INTERRUPTION IN PROCEEDINGS.)

23 DR. PRIETO: ARE WE STILL CONNECTED?

24 DR. BRYANT: APPEAR TO BE. THE MUSIC  
25 STOPPED.

1 DR. PRIETO: ED, ARE YOU STILL THERE? SUSAN?  
2 DR. BRYANT: YES, IT'S ME.  
3 DR. PRIETO: HI, THIS IS FRANCISCO PRIETO.  
4 IT SOUNDS LIKE THE TWO OF US ARE CONNECTED, BUT I DON'T  
5 KNOW THAT WE'RE STILL CONNECTED TO THE MEETING.  
6 DR. BRYANT: MAYBE WE NEED TO DIAL BACK IN  
7 THEN.  
8 THE REPORTER: THIS IS BETH. MAYBE WE'RE  
9 JUST WAITING FOR THEM TO COME BACK ON.  
10 CHAIRMAN PENHOET: WE'RE BACK.  
11 MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
12 CALIFORNIA. MAYBE I CAN SPEAK TO THAT.  
13 CHAIRMAN PENHOET: THE QUESTION WE'RE  
14 DISCUSSING IS WHETHER THE COMPLETE LICENSES THAT ARE  
15 GRANTED TO LICENSEES BY GRANTEE INSTITUTIONS SHOULD BE  
16 MADE AVAILABLE TO THE PUBLIC. AND THE ANSWER WE'VE  
17 GIVEN IS THAT SO FAR WE HAVE NOT CONTEMPLATED THE  
18 COMPLETE LICENSING AVAILABLE TO THE PUBLIC. WE HAVE  
19 CONTEMPLATED THAT THE PROVISIONS OF THE LICENSE THAT  
20 REFER TO PLANS FOR ACCESS FOR UNINSURED WOULD BE MADE  
21 AVAILABLE TO CIRM AND TO THE ICOC FOR ITS REVIEW. NOW,  
22 WHETHER THAT MEANS PUBLIC, WELL, THEY MIGHT BE  
23 DISCUSSED IN A PUBLIC MEETING OF ICOC. EVENTUALLY THEY  
24 COULD BE MADE PUBLIC, THAT PART OF LICENSE. WENDY  
25 STREITZ WAS RESPONDING TO THAT.

1 MS. STREITZ: THAT WAS GOING WHERE I WAS  
2 GOING WITH THAT IS MAKING THE PUBLIC ACCESS PLAN  
3 AVAILABLE TO THE PUBLIC. PREMATURELY MAY BE A  
4 DISINCENTIVE ALSO. I'M KIND OF THINKING OUT LOUD HERE.  
5 MAYBE A COMPROMISE WOULD BE TO BE WILLING TO KEEP THE  
6 PUBLIC ACCESS CONFIDENTIAL, OF COURSE, CIRM AND ICOC  
7 WOULD NEED TO KNOW, UNTIL THERE'S A PRODUCT AVAILABLE  
8 BECAUSE UNTIL THERE'S A PRODUCT AVAILABLE...

9 DR. PRIETO: I SEE A POTENTIAL PROBLEM WITH  
10 THAT IN THAT IF IT'S MADE AVAILABLE TO CIRM OR  
11 CERTAINLY IF IT'S MADE AVAILABLE TO THE ICOC, I THINK  
12 IT WOULD AUTOMATICALLY BECOME A PUBLIC DOCUMENT. AND I  
13 DON'T KNOW WHETHER THAT'S A PROBLEM OR NOT. IF THAT'S  
14 A DISINCENTIVE, THEN WE NEED TO LOOK AT IT. THE  
15 LICENSE ITSELF, I WOULD EXPECT THAT WE'RE LOOKING TO  
16 THE GRANTEES TO DETERMINE COMPLIANCE WITH THE LICENSE  
17 AGREEMENT, AND IT'S CERTAINLY IN THEIR INTEREST TO DO  
18 THAT SO THAT -- I DON'T KNOW THAT IT'S THAT IMPORTANT  
19 THAT THE WHOLE LICENSE AGREEMENT BE PUBLIC.

20 CHAIRMAN PENHOET: THAT WOULD CERTAINLY BE A  
21 DISINCENTIVE FOR LICENSING. NEVERTHELESS THEY HAVE THE  
22 POWER TO DO IT.

23 DR. PRIETO: IF IT WERE PUBLIC, YOU MEAN?

24 CHAIRMAN PENHOET: YEAH, THE WHOLE LICENSE.

25 HAL HALUIN.

1                   MR. HALUIN: I HAVE A QUESTION. MAYBE I'M  
2 NOT SEEING IT HERE, BUT A SITUATION WHERE YOU HAVE A  
3 COLLABORATION BETWEEN PRIVATE INDUSTRY AND A RESTRICTED  
4 INSTITUTION, OFTEN THE CASE, AND WE SPEAK TO THAT  
5 PARTNERSHIP HERE BETWEEN PRIVATE INDUSTRY AND CIRM  
6 FUNDED. SO WHERE THE PRIVATE INDUSTRY IS NOT FUNDED  
7 AND WHERE THE INSTITUTION IS FUNDED, AND I CAN SEE  
8 SITUATIONS WHERE THIS HAPPENS QUITE OFTEN, WE HAVE  
9 CO-INVENTORSHIP, CO-OWNERSHIP OF THOSE RIGHTS. AND  
10 WHERE PRIVATE INDUSTRY MAY NOT NEED TO BE BOUND BY SOME  
11 RESTRICTIONS HERE AND WHETHER WE SHOULD BE ADDRESSING  
12 THAT BECAUSE THAT'S A QUESTION THAT WILL COME UP QUITE  
13 FREQUENTLY.

14                   CHAIRMAN PENHOET: WELL, WE DID ANTICIPATE  
15 PART OF YOUR QUESTION EARLIER IN THE DISCUSSION ABOUT  
16 PROPORTIONAL PARTS. THAT IS, THAT THE VALUE WOULD  
17 BE -- THERE ARE MULTIPLE FUNDERS. AND THIS IS  
18 COLLABORATION AND THE OTHER PARTY IS A FUNDER, THAT A  
19 REQUIREMENT OF OUR LICENSE WOULD BE A FRACTION BASED ON  
20 THE INVESTMENT BY THE TWO PARTIES. THAT DOESN'T FULLY  
21 COVER YOUR CONCERN, I KNOW.

22                   MR. HALUIN: I THINK IT HAS TO DO WITH  
23 OWNERSHIP. AND ACTUALLY MY QUESTION REALLY DEALT WITH  
24 THE DISCLOSURE ISSUES, AND THE DESIRE FOR THE PRIVATE  
25 COMPANY WOULD BE TO KEEP THEIR THINGS CONFIDENTIAL AND

1 NOT HAVE THE KIND OF MANDATED DISCLOSURES THAT ARE  
2 REQUIRED BY CIRM, FOR INSTANCE.

3 CHAIRMAN PENHOET: THE WHOLE CONSTRUCT WE'VE  
4 JUST MADE PROBABLY INHIBITS TO SOME DEGREE THOSE KINDS  
5 OF COLLABORATIONS. THAT MAY BE AN UNINTENDED  
6 CONSEQUENCE OF WHAT WE'RE DOING. I'M NOT SURE WE CAN  
7 FIX THAT. COMMENTS ON THIS ISSUE? OKAY.

8 WHERE ARE WE ON THIS ISSUE OF REPORTING?  
9 WE'RE GOING BACK NOW TO THE REPORTING REQUIREMENTS FOR  
10 THE PUBLIC ACCESS PORTION. I THINK THAT UNIVERSITY OF  
11 CALIFORNIA HAS A POINT. WE HAVE TO BEGIN TO LOOK AT  
12 THE TOTAL WEIGHT OF THE REQUIREMENTS THAT WE'RE PUTTING  
13 IN PLACE HERE ON THE BALANCE THAT YOU TALKED ABOUT.

14 PUTTING MY BUSINESSMAN HAT ON, I GUESS THAT  
15 PART OF THE AGREEMENT WOULD NOT BE SOMETHING I'D BE  
16 OVERLY CONCERNED ABOUT PUBLICIZING IF I WERE A  
17 LICENSEE. THERE ARE OTHER COMMERCIAL FIRMS THAT ARE  
18 OFTEN MUCH MORE SENSITIVE THAN THAT WOULD BE. DOES  
19 STANFORD HAVE A POINT OF VIEW ON THIS?

20 MS. O'NEIL: PARTLY I THINK THAT WE'RE  
21 TALKING ABOUT SOMETHING IMPORTANT THAT WE'RE NOT GOING  
22 TO BE DEALING WITH INITIALLY.

23 CHAIRMAN PENHOET: YES. THAT'S TRUE, NOT FOR  
24 A LONG TIME.

25 MS. O'NEIL: TO SOME DEGREE I WONDER IF IT'S

1 SOMETHING WE SHOULD TABLE AND THINK ABOUT WITH RESPECT  
2 TO COMPANIES.

3 CHAIRMAN PENHOET: WELL, ONE SUGGESTION,  
4 WENDY'S SUGGESTION WAS THAT WE AT THE TIME OF FIRST  
5 COMMERCIAL SALE, THAT THESE THINGS BECOME PUBLICLY  
6 AVAILABLE SO WE CAN DETERMINE WHETHER THEY'RE IN  
7 COMPLIANCE OR NOT. I GUESS YOU DON'T REALLY NEED TO  
8 KNOW UNTIL THEN IN A WAY.

9 MR. SHEEHY: IT DOESN'T SEEM UNREASONABLE  
10 THAT THE ACCESS PLAN NOT BE MADE AVAILABLE UNTIL  
11 THERE'S ACTUALLY A THERAPY OUT THE DOOR. BUT IF PEOPLE  
12 HAVE OTHER THOUGHTS. IT DOESN'T SEEM LIKE AN  
13 UNREASONABLE BECAUSE THE PLAN DOESN'T EXIST IN REALITY  
14 UNTIL THERE IS A THERAPY. MR. SIMPSON MAY HAVE SOME  
15 COMMENTS. I REALLY HAD NOT THOUGHT ABOUT IT. I DON'T  
16 SEE WHY A COMPANY WOULDN'T WANT TO ADVERTISE THAT THEY  
17 WERE MAKING SOME PROVISION. BUT IN -- BUT I CAN'T --  
18 ON THE OTHER HAND, I CAN'T SEE HOW IT WOULD MAKE ANY  
19 DIFFERENCE THAT THAT NOT BE PUBLICIZED UNTIL THE  
20 THERAPY IS OUT THE DOOR.

21 DR. PRIETO: I WOULD AGREE WITH JEFF, THAT  
22 UNTIL THERE IS SOMETHING IN HAND, IT'S NOT A BIG ISSUE.  
23 AND SO I WOULD CERTAINLY BE WILLING TO ADD THAT LINE.  
24 AND IF IT WOULD MAKE A DIFFERENCE IN SOMEONE'S DECISION  
25 TO PURSUE A LICENSE OR NOT PURSUE A LICENSE, I'D

1 CERTAINLY RATHER THAT THEY PURSUE A LICENSE.

2 MR. SHEEHY: I JUST HAD ONE MORE CAVEAT. IT  
3 SEEMS TO ME THAT SOME ACCESS PLANS DO COME INTO PLAY IN  
4 PHASE III. AND I DON'T -- YOU KNOW, I SEE PEOPLE WITH  
5 HIV GETTING ACCESS TO THE NEWEST, LATEST A LOT IN  
6 REALLY PROMISING PHASE III STUDIES. THEIR ACCESS PLAN  
7 MAY ACTUALLY INCLUDE SOME ACCESS IN PHASE III FOR  
8 PEOPLE WHO ARE TERMINAL. I JUST PUT THAT OUT THERE.

9 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR  
10 TAXPAYER AND CONSUMER RIGHTS. I COME FROM THE POINT OF  
11 VIEW THAT ALL SHOULD BE PUBLIC AS SOON AS POSSIBLE, BUT  
12 IT WOULD SEEM TO ME THAT EVERY COMPANY WOULD WANT TO --  
13 IT WOULD BE TO THE COMPANY'S ADVANTAGE TO SORT OF SAY  
14 THIS IS OUR GREAT IDEA, SO THEY WOULD WANT TO HAVE IT  
15 OUT. THAT WOULD BE THE KIND OF THING THAT COMPANIES  
16 WOULD PUT PRESS RELEASES OUT ABOUT.

17 MORE THAN THAT THOUGH, IF YOU ARE TRYING TO  
18 CREATE CREATIVE IDEAS AND SOLUTIONS, THEN YOU WANT THEM  
19 OUT THERE SO THAT ANOTHER COMPANY CAN COME ALONG AND  
20 SAY, OH, THAT'S A REAL GOOD IDEA. WE'RE GOING TO ADOPT  
21 THAT ONE TOO. I THINK IT SHOULD BE DISCLOSED RIGHT UP  
22 FRONT.

23 MR. SHEEHY: WHAT DO YOU SUGGEST? I NEVER  
24 PUT THAT HAT ON, LIKE MAKING THOSE KINDS OF DECISIONS.  
25 DO YOU THINK THAT WOULD BE INHIBITING?



1 CHAIRMAN PENHOET: I'M NOT WORRIED ABOUT IT  
2 IN ISOLATION. I'M A LITTLE BIT WORRIED ABOUT THE TOTAL  
3 WEIGHT OF THE THING. I'M TRYING TO THINK THAT THROUGH.  
4 BUT AS A LICENSEE, IT WOULDN'T HAVE BOTHERED ME AS A  
5 BUSINESS GUY TO MAKE THAT PART OF THE AGREEMENT PUBLIC.  
6 BUT I MIGHT NOT. I DON'T SPEAK FOR THE INDUSTRY IN  
7 THIS SETTING, THAT'S FOR SURE, AND I HAVEN'T DONE IT  
8 FOR EIGHT YEARS.

9 MS. O'NEIL: ONE OTHER THING TO KEEP IN MIND  
10 IS THAT WHAT WE WOULD BE LICENSING OUT OF THIS RESEARCH  
11 WOULD BE EARLY, EARLY STAGE STUFF, REQUIRING LONG  
12 LICENSES. AND IN OUR EXPERIENCE, WE AMEND LICENSES, WE  
13 CHANGE PLANS AS THE TECHNOLOGY DEVELOPS. SO I WORRY  
14 THAT IT WOULD BE A DISINCENTIVE TO COMPANIES TO SAY,  
15 DEPENDING ON HOW MUCH INFORMATION WE'RE ASKING THEM TO  
16 PUT OUT, IT'S INCENTIVE TO SAY PUBLICIZE YOUR ACCESS  
17 PLAN TODAY BECAUSE I THINK CHANCES ARE VERY GOOD OR THE  
18 LICENSE, THINGS COULD CHANGE, I HOPE, DRAMATICALLY.

19 MR. SHEEHY: WHAT IF WE SAID THAT THE  
20 PUBLICATION -- WE COULD GET ACCESS TO IT WHEN ANY  
21 PRODUCT GOES INTO PHASE III? THEN YOU KNOW A LOT OF  
22 WHAT'S GOING ON.

23 CHAIRMAN PENHOET: EVEN WITH THE LANGUAGE  
24 THAT SAYS YOU WOULD ENCOURAGE THE PUBLICATION OF THE  
25 PUBLIC ACCESS POLICY AT ANY TIME AFTER A LICENSE IS

1 CONSUMMATED, BUT NOT LATER THAN THE INITIATION OF PHASE  
2 III CLINICAL TRIALS. DOES THAT MAKE SENSE?

3 DR. MAXON: SAY THAT AGAIN.

4 CHAIRMAN PENHOET: OKAY. THE REST OF YOU  
5 HAVE A SENSE ABOUT THAT? DOES THAT MAKE SENSE TO YOU?

6 DR. PRIETO: I LIKE THAT.

7 CHAIRMAN PENHOET: OKAY. THANK YOU.

8 MOVING RIGHT ALONG. I THINK WE'RE ON PAGE  
9 31. 31 IS PRIMARILY INFORMATIONAL AGAIN. 32, AGAIN,  
10 MUCH OF THIS CONFORMS TO WHAT WE TALKED ABOUT,  
11 INCLUDING THE REVENUE SHARING ON 33.

12 MR. TAYMOR: IN THE SECOND SENTENCE OF  
13 LICENSING POLICY ELEMENT TO ENCOURAGE PATENT PROTECTION  
14 FOR CELL LINES. IN LOOKING AT THIS IN THE CURRENT  
15 COMPETITIVE LANDSCAPE, THAT IS AN AREA WHERE PATENT  
16 PROTECTION IS BEING SOUGHT OUT. AND I GUESS YOU'RE  
17 SAYING THAT IF A CIRM-FUNDED RESEARCHER DECIDES TO  
18 PATENT A CELL LINE, THEY CAN DO THAT.

19 CHAIRMAN PENHOET: YES.

20 MR. TAYMOR: BUT I THINK THERE OUGHT TO BE  
21 SOME EXPLANATION AS TO WHY IF THAT'S BEING DONE IN  
22 WISCONSIN, IF IT'S LIKELY TO BE DONE IN MASSACHUSETTS,  
23 IN MARYLAND, WHY IT SHOULDN'T BE DONE IN CALIFORNIA.  
24 IT MAY BE A BAD IDEA BECAUSE IT WOULD BE GREAT IF IT  
25 WASN'T DONE ANYPLACE IN THE COUNTRY, BUT GIVEN THAT

1 OTHER RESEARCHERS ELSEWHERE IN THE COUNTRY ARE DOING  
2 IT, WHY SHOULD SOMEONE BE YOU' RE SORT OF OUTSIDE OF OUR  
3 POLICY, AND THEN THAT MEANS MAYBE THE NEXT TIME YOU  
4 APPLY FOR A GRANT, PRESUMABLY YOU' RE GOING TO BE  
5 DISFAVORED BECAUSE YOU' RE NOT FOLLOWING OUR POLICIES  
6 EVEN THOUGH YOU' RE NOT IN VIOLATION OF THE LAW.

7 DR. PRIETO: HOW ABOUT ELSEWHERE IN THE  
8 WORLD? IT' S NOT BEING DONE IN THE UK, IS IT?

9 MR. TAYMOR: I HAVEN' T LOOKED AT THOSE  
10 PATENTS. I KNOW THE WARF PATENTS VERY CLEARLY MAKE A  
11 CLAIM ON CELL LINES.

12 UNIDENTIFIED SPEAKER: ALL EMBRYONIC STEM  
13 CELLS.

14 MR. TAYMOR: THEY DO IT ON A NUMBER OF  
15 THINGS. ONE CLAIM IS SPECIFICALLY FOR ALL LINES WITH  
16 THOSE CHARACTERISTICS. BUT OTHER RECENT APPLICATIONS  
17 ARE FOR LINES, FOR EXAMPLE, IN PARTICULAR AT A  
18 PARTICULAR CELL TYPE LIKE NEURO OR CARDIAC.

19 CHAIRMAN PENHOET: I THINK THERE IS A CLEAR  
20 DISTINCTION BETWEEN TWO DIFFERENT TYPES OF CELL LINES.  
21 SO IT' S THE INTENT TO USE THEM. SOME CELL LINES ARE  
22 PRODUCED FOR RESEARCH PURPOSES ONLY, AND OTHER KINDS OF  
23 CELL LINES MIGHT ACTUALLY BE THERAPEUTIC. IN THAT CASE  
24 I DON' T THINK WE' D WANT TO DISCOURAGE PRIMARILY -- THIS  
25 PART WAS PRIMARILY INTENDED TO DEAL WITH MAKING

1 RESEARCH REAGENTS AVAIL ABLE. SO PERHAPS WE CAN CRAFT  
2 SOME LANGUAGE, MARY, THAT DISTINGUI SHES A CELL LINE' S  
3 PRIMARY PURPOSE FOR USE AS REAGENTS FOR BASI C RESEARCH  
4 AS OPPOSED TO CELL LINES THAT ARE -- BECAUSE WE WOULD  
5 BE AT A COMPETITIVE DISADVANTAGE IN THIS FIE LD, I  
6 THINK, IF WE -- THIS IS SOFT LANGUAGE, BUT I THINK THE  
7 INTENT WAS MORE ON THE RESEARCH TOOL SIDE AND NOT  
8 NECESSARIL Y ON THE STEM CELLS THAT COULD BECOME  
9 THERAPEUTI C.

10 THAT MAKE SENSE TO EVERYBODY TO TRY TO  
11 DISTINGUI SH THOSE? THERE' S NO HARD BORDER THERE  
12 BETWEEN THOSE. THIS LANGUAGE IS ADVI SORY LANGUAGE  
13 NOT --

14 MR. TAYMOR: ONE QUESTION ON THAT. WOULD IT  
15 BE THE CASE -- AND MAYBE THIS IS MORE FOR DR. CHIU --  
16 THAT IF SOMEONE WAS REPEATEDLY SEEING -- A GRANTEE WAS  
17 REPEATEDLY SEEN AS VI OLATING POLI CY, WHETHER THAT MIGHT  
18 NOT BE I NCLUDED I N YOUR REPORT I N EVALUATING FUTURE  
19 GRANTS BY THAT APPLICANT -- BY THAT GRANTEE AND  
20 CONSIDER WHETHER OR NOT THAT GRANTEE OUGHT TO BE  
21 AWARDED A GRANT, I N WHICH CASE THE SOFT LANGUAGE MAY  
22 HAVE --

23 DR. CHIU: I THINK WE WOULD EVALUATE THAT ON  
24 A CASE-BY-CASE BASI S. SO WE HAVE I N OUR GRANT  
25 ADMI NI STRATI VE POLI CY A SECTI ON ON FAI LURE OF

1 COMPLIANCE. THERE WILL BE STAGES THAT WE MIGHT  
2 REGULATE. THE MAIN TOOL WE HAVE IS DURING THE COURSE  
3 OF THE GRANT WITHHOLD SOMETHING UNTIL WE SEE SOME  
4 BETTER BEHAVIOR. ONCE A GRANT IS OVER, IT BECOMES  
5 HARDER TO ASK FOR RETURN OF FUNDS. AND WE'VE HAD A  
6 DISCUSSION ABOUT THAT.

7 NOW, THE NEXT LEVEL WOULD BE DURING REVIEW  
8 PROCESS, IF SUCH BEHAVIOR IS GOING TO BE LOOKED AT ON  
9 THE SECOND LEVEL OF REVIEW AS SOMETHING (INAUDIBLE).  
10 IN TERMS OF CRIMINAL CONDUCT, THEN IT MIGHT BE  
11 SOMETHING ELSE THAT IS BEYOND THE SCOPE OF CIRM, SO WE  
12 MIGHT HAVE TO TURN IT OVER EARLIER.

13 MR. TAYMOR: DOES THAT MEAN -- AGAIN, THIS IS  
14 A POLICY. SO IF DURING THE -- IF THERE WAS A  
15 DISCLOSURE MADE BY A GRANTEE SAYING I HAVE OR ACTUALLY  
16 THE GRANTEE INSTITUTION SAYS ONE OF OUR PI'S GIVES A  
17 DISCLOSURE, DO WE FILE A PATENT APPLICATION ON A CELL  
18 LINE, THAT THERE WOULD BE A RISK THAT THAT GRANT WOULD  
19 BE WITHHELD UNLESS THERE'S A VIOLATION OF A POLICY  
20 UNLESS THE APPLICATION WAS WITHDRAWN? WHAT I'M TRYING  
21 TO DO IS UNDERSTAND WHAT IT MEANS TO --

22 CHAIRMAN PENHOET: IT DOESN'T ENVISION ANY  
23 SANCTION NECESSARILY UNLESS YOU SEE REPETITIVE AND  
24 WIDESPREAD DISREGARD FOR THE ADVISORY PIECES OF THIS  
25 SPECIFICALLY. SPECIFICALLY IT DOES SAY DOESN'T ALLOW.

1 IT SAYS IT DOESN'T ENCOURAGE.

2 REVENUE SHARING WE TALKED ABOUT BEFORE.

3 RESEARCH EXEMPTION WE TALKED ABOUT BEFORE.

4 MARCH-IN RIGHTS. SO WE HAVE TO MAKE THAT  
5 CONFORM. OKAY.

6 WE CAN GO BACK TO THE BEGINNING. ANY  
7 COMMENTS ON THE GENERAL INFORMATION CONTAINED IN  
8 SECTION I, CIRM IS A STATE AGENCY?

9 MS. STREITZ: WENDY STREITZ, UNIVERSITY OF  
10 CALIFORNIA. ON THE LAST PARAGRAPH OF PAGE 2, THERE'S A  
11 REFERENCE TO THE UPDATING OF POLICIES PERIODICALLY BY  
12 CIRM. AND IT WOULD BE HELPFUL TO HAVE A CLARIFICATION  
13 THAT POLICIES AS THEY'RE REVISED WON'T APPLY  
14 RETROACTIVELY TO AGREEMENTS THAT HAVE ALREADY BEEN  
15 SIGNED.

16 DR. CHIU: WE ARE TRYING TO CHANGE LANGUAGE  
17 IN OUR DRAFT OF THE INTERIM GRANT ADMINISTRATION  
18 POLICY. AS WE HAVE DISCUSSED, WE FEEL THAT IF THERE'S  
19 A CHANGE OF POLICY IN THIS STREAM IN THE MIDDLE OF THE  
20 GRANT, AS YOU KNOW, AS EACH GRANT COMES TO ITS  
21 ANNIVERSARY DATE, IT GETS REVIEWED. WE WILL SEND OUT A  
22 NEW NOTICE OF GRANT AWARD, AND IF ANY INSTITUTION FINDS  
23 THAT THE NEW TERMS ARE ONEROUS, THEY DO NOT HAVE TO  
24 SIGN ON. AND THAT WOULD BE THE END OF FUNDING OF THAT  
25 GRANT, JUST FOR THE PREVIOUS PERIOD, BUT NO FURTHER

1 FUNDS WILL BE AWARDED UNLESS THEY DEGREE TO THE NEW  
2 POLI CY.

3 CHAIRMAN PENHOET: BY DEFINITION IT'S NOT  
4 RETROACTIVE.

5 ANY OTHER COMMENTS ON THE GENERAL INFORMATION  
6 SECTION?

7 MR. SIMPSON: I JUST WANT TO SAY I FOUND IT  
8 VERY INFORMATIVE, VERY USEFUL, AND VERY  
9 WELL-CONSTRUCTED.

10 CHAIRMAN PENHOET: THANK YOU. YOU HAVE MARY  
11 MAXON TO THANK. I HAVE TO SAY, GETTING NEAR THE END,  
12 MARY HAS DONE A YEOMAN'S WORK HERE. IT'S A HUGE EFFORT  
13 TO PUT THIS THING TOGETHER. THERE'S A MOUNTAIN OF  
14 PAPERS ABOUT THIS HIGH THAT SHE'S GONE THROUGH AND MANY  
15 DIFFERENT PEOPLE SHE'S DISCUSSED WITH.

16 OKAY. ANY OTHER COMMENTS? IF NOT --

17 MS. AURITI: FOR THE GLOSSARY -- ELLEN AURITI  
18 AT THE UNIVERSITY OF CALIFORNIA. FOR THE DEFINITION OF  
19 AUTHORIZED ORGANIZATIONAL OFFICIAL, THERE IS AN  
20 IMPLICATION IN THERE THAT THE INDIVIDUAL SIGNING  
21 ACTUALLY ASSUMES THE OBLIGATIONS IMPOSED BY THE LAWS,  
22 REGULATIONS. OBVIOUSLY OUR INDIVIDUALS DON'T --

23 DR. MAXON: DULY NOTED. WILL BE CORRECTED.

24 CHAIRMAN PENHOET: OKAY. WELL, I THINK WE  
25 ARE IN A POSITION TO WRITE A FINAL RECOMMENDATION FOR

1 THE BOARD MEETING. IT WILL BE AN OFFICIAL DOCUMENT --  
2 IT WILL BE AN OFFICIAL POSITION OF THIS TASK FORCE WITH  
3 RESPECT TO SECTION II. AND WITH RESPECT TO THE  
4 CONFORMING SECTION III TO II THAT WE VOTED ON, IT WILL  
5 NOT BE AN OFFICIAL RECOMMENDATION WITH RESPECT TO THE  
6 CHANGES WE JUST DISCUSSED IN ITEM 3 OTHER THAN THOSE OR  
7 IN ITEM 1, BUT WE'LL PRESENT THE WHOLE DOCUMENT TO THE  
8 BOARD WITH THOSE CAVEATS.

9 WITH THAT, I THINK ANY CLOSING REMARKS BY  
10 ANYONE IN THE ROOM? ANY BOARD MEMBERS WISH TO MAKE A  
11 CLOSING REMARK?

12 MR. SHEEHY: I JUST WANT TO THANK ED.

13 DR. WRIGHT: ME TOO.

14 (APPLAUSE.)

15 CHAIRMAN PENHOET: REMARKS FROM THE AUDIENCE?

16 MR. SIMPSON: ONE QUICK QUESTION. WHEN DO  
17 YOU EXPECT THAT THE DOCUMENT THAT YOU WILL BE  
18 PRESENTING TO THE ICOC WILL BE AVAILABLE TO THE PUBLIC?

19 DR. MAXON: FEBRUARY 5TH, FIVE DAYS BEFORE  
20 THE MEETING.

21 MS. KING: ONLINE.

22 MR. REED: I WOULD JUST LIKE TO SAY I WAS  
23 LOOKING AT THE BACK ISSUES OF THE ICOC MEETINGS, AND  
24 THIS STRUGGLE BEGAN OVER A YEAR AGO. WHAT'S BEEN MADE  
25 A SOLID AND REAL, I FEEL EVERY REASONABLE OBJECTION HAS



1 BEEN MET. THIS IS SOMETHING EXCELLENT AND CAUSE FOR  
2 PRIDE.

3 (APPLAUSE.)

4 CHAIRMAN PENHOET: THANK YOU, DON. WITH  
5 THAT, WE' LL ADJOURN.

6 (THE MEETING WAS THEN CONCLUDED AT 04:58  
7 P. M. )

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REPORTER'S CERTIFICATE

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

STANFORD UNIVERSITY  
CLARK CENTER, ROOM S362  
318 CAMPUS DRIVE  
STANFORD, CALIFORNIA

UNIVERSITY OF CALIFORNIA, LOS ANGELES  
ROOM 17-187 CHS  
10833 LE CONTE AVENUE  
LOS ANGELES, CALIFORNIA

SUTTER MEDICAL PLAZA  
8170 LAGUNA BOULEVARD  
CLASSROOM 2  
ELK GROVE, CALIFORNIA

THE CARLYLE  
35 EAST 76TH STREET  
NEW YORK, NEW YORK

ON JANUARY 23, 2006, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152  
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1072 S.E. BRISTOL STREET  
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