

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

LOCATION: AVIATION MUSEUM AND LIBRARY
SAN FRANCISCO INTERNATIONAL AIRPORT
SAN FRANCISCO, CALIFORNIA

DATE: AUGUST 29, 2006
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REPORTER: BETH C. DRAIN, CSR
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1 SAN FRANCISCO, CALIFORNIA; TUESDAY, AUGUST 29, 2006

2 01:02 P.M.

3

4 CHAIRMAN PENHOET: WE WILL START, MELISSA, BY
5 TAKING ROLL CALL. I DON'T SEE ANY SLIDES, SO I DON'T
6 KNOW IF WE DO THE PLEDGE.

7 MS. KING: CALLING THE ROLL, SUSAN BRYANT.

8 DR. BRYANT: HERE. I CAN BARELY HEAR YOU.

9 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.
10 TED LOVE. ED PENHOET.

11 CHAIRMAN PENHOET: HERE.

12 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.
13 JEANNIE FONTANA.

14 DR. FONTANA: HERE.

15 MS. KING: DUANE ROTH.

16 MR. ROTH: HERE.

17 MS. KING: JEFF SHEEHY.

18 MR. SHEEHY: HERE.

19 MS. KING: OSWALD STEWARD.

20 MS. INGELS: HE JUST STEPPED OUT, BUT HE'S
21 HERE.

22 MS. KING: JANET WRIGHT.

23 CHAIRMAN PENHOET: I HOPE YOU HAVE ALL HAD AN
24 OPPORTUNITY TO GET THE VARIOUS MATERIALS THAT WE SENT
25 OUT.

1 MS. INGELS: MELISSA, WE CAN'T HEAR ANYTHING.

2 CHAIRMAN PENHOET: I DON'T KNOW IF THIS IS A
3 GOOD PLACE TO START TALKING OUT OF BOTH SIDES OF MY
4 MOUTH, BUT I'LL TRY. DR. PIZZO HAS JOINED US. DOES
5 THAT MAKE A QUORUM?

6 MS. KING: NO, NOT QUITE.

7 CHAIRMAN PENHOET: WE'LL CONTINUE THEN.
8 THANK YOU. SO I SHOULD REMEMBER THE FIRST PART OF THIS
9 MEETING IS GOING TO BE DEVOTED TO A DISCUSSION OF THE
10 INTELLECTUAL PROPERTY POLICY FOR NONPROFIT
11 ORGANIZATIONS; HOWEVER, WE DO HAVE AT LEAST ONE ACTION
12 ITEM ASSOCIATED WITH THAT, SO I THINK WE WILL POSTPONE
13 THAT DISCUSSION UNTIL WE HAVE A QUORUM AND THEN RETURN
14 TO THE DISCUSSION.

15 THE PRINCIPAL ITEM THAT WE WILL DISCUSS,
16 HOWEVER, IS THE -- AS YOU REMEMBER AT THE LAST MEETING,
17 WE DECIDED NOT TO PURSUE A BROAD RESEARCH USE
18 EXEMPTION; HOWEVER, WE REALIZE THAT UNDERNEATH THAT
19 THERE WAS SOMETHING THAT WE HAD INTENDED, WHICH WAS THE
20 ABILITY OF A NONPROFIT FOR THEIR OBLIGATION TO USE
21 THEIR OWN INTELLECTUAL PROPERTY AND ALSO USE IT FOR
22 OTHER NONPROFIT ACTIVITIES. WE'VE GOTTEN FEEDBACK FROM
23 THE UNIVERSITIES THAT THEY LIKE WHAT WE HAVE PUT IN AS
24 AN ALTERNATIVE. WE'VE GOTTEN SOME FEEDBACK FROM THE
25 INDUSTRY THAT THEY DON'T LIKE WHAT WE PUT IN AS AN

1 ALTERNATIVE.

2 (INTERRUPTION IN PROCEEDINGS.)

3 CHAIRMAN PENHOET: I'M GOING TO TRY TO DO
4 THIS WITHOUT A MICROPHONE IN THIS ROOM. WE ARE IN A
5 ROOM WHICH HAS, SHALL WE SAY, AWFUL ACOUSTICS. SO I'M
6 GOING TO SPEAK LOUDLY, AND I URGE ALL OF YOU IN THE
7 AUDIENCE TO MOVE UP AND JOIN US HERE TOWARDS THE FRONT.
8 FEEL FREE TO MOVE YOUR CHAIRS RIGHT INTO THE CENTER OF
9 THE ROOM HERE, FOLKS.

10 (PAUSE IN PROCEEDINGS.)

11 CHAIRMAN PENHOET: WE'LL BEGIN AGAIN. I'M
12 SITTING IN MY CHAIR BECAUSE I HAD KNEE SURGERY ON
13 FRIDAY, SO IF YOU SEE MY LEG PROPPED UP OVER HERE, I
14 DON'T THINK I CAN STAND UP THERE FOR TWO HOURS ON THIS
15 KNEE. BUT YOU DON'T NEED TO WRITE THAT DOWN. MY KNEE
16 IS JUST FINE IN CASE ANY OF YOU ARE INTERESTED.

17 SO WE DO HAVE THIS ISSUE ABOUT A MODIFICATION
18 AND MUCH WEAKER RESEARCH USE EXEMPTION WHICH WE HAVE
19 PUT IN IN PLACE OF THE ORIGINAL ONE WE HAD. AND WE DO
20 HAVE COMMENTS ON BOTH SIDES OF THAT ISSUE. SINCE WE
21 DON'T HAVE A QUORUM, WE'RE GOING TO PUT THAT OFF UNTIL
22 WE DO HAVE A QUORUM.

23 WE DID PRESENT THE -- WE PRESENTED THE
24 RESULTS OF THIS GROUP'S WORK TO THE LAST ICOC MEETING.
25 THE ICOC APPROVED OUR DRAFT POLICY, AND IT WAS UPON

1 THAT APPROVAL THAT WE ENTERED IT INTO THE APA PROCESS.

2 MS. KING: WE HAVE A QUORUM.

3 CHAIRMAN PENHOET: DR. LOVE HAS JOINED US.
4 IT'S ALWAYS GOOD TO HAVE A REAL DOCTOR SITTING NEXT TO
5 YOU A FEW DAYS AFTER YOU'VE HAD SURGERY. THANK YOU,
6 TED.

7 WHERE WAS I? SO WE PRESENTED IT TO THE ICOC,
8 THE ICOC APPROVED THE DOCUMENT THAT WE HAD INDICATED WE
9 DID. WE HAVE BEEN THROUGH THE APA PROCESS AND ITS
10 MODIFICATIONS THROUGH THE APA PROCESS. WE HAVE
11 COMPLETED THE 15-DAY REVIEW FOLLOWING THE 45-DAY
12 REVIEW. AND I THINK AT THIS POINT IN TIME, I CAN
13 COMFORTABLY SAY THAT ALMOST ALL OF WHAT'S IN THERE HAS
14 BEEN ACCEPTED BY THE COMMUNITY AT LARGE WITH THE
15 EXCEPTION OF THE RESEARCH USE ISSUES, WHICH WE'RE NOW
16 ABOUT TO DISCUSS.

17 AND, ALSO, BEFORE I FORGET, AT THE ICOC
18 MEETING, THERE WERE TWO PARTS OF WHAT WE HAD CONSIDERED
19 IN THE PAST AS THE ICOC DIRECTED US TO, IN ONE CASE,
20 PUT THE ISSUE OVER TO THE LEGISLATIVE SUBCOMMITTEE AND
21 TO ASK THEM TO COORDINATE WITH THE LEGISLATURE. AND
22 THAT IS THE WHOLE ISSUE AROUND PATENT POOLING FOR
23 STATE-FUNDED INVENTIONS GENERALLY. SO WE'RE NOT
24 DEALING WITH THE PATENTS. HERE THE LEGISLATIVE
25 SUBCOMMITTEE HAS BEEN DELEGATED THAT RESPONSIBILITY BY

1 THE BOARD. AND WE DO KNOW THAT THERE ARE SOME EFFORTS
2 AT THE STATE LEVEL TO CONSIDER SUCH A THING, AND THE
3 LEGISLATIVE SUBCOMMITTEE WILL WORK ON THAT.

4 THE OTHER ISSUE WE HAVE DISCUSSED, I THINK,
5 AT TWO OF OUR MEETINGS IS OPEN ACCESS. WE DID NOT PUT
6 THE STRONGEST POSSIBLE OPEN-ACCESS REQUIREMENT IN OUR
7 POLICY; HOWEVER, THE ICOC ASKED US TO CONTINUE TO STUDY
8 THIS PROBLEM. AND SO WE ARE, AND THAT IS SOMETHING, A
9 RESIDUUM OF OUR WORK HERE, THAT WE WILL CONTINUE TO
10 DIALOGUE WITH THE PEOPLE IN THE OPEN-ACCESS COMMUNITY,
11 ETC., AND WE'LL CONTINUE TO WORK ON THAT IN THIS GROUP.
12 NOT TODAY, HOWEVER, UNLESS WE HAVE SOME MEMBERS OF THE
13 AUDIENCE WHO WOULD LIKE TO ADDRESS OPEN ACCESS.

14 SO SINCE WE DO HAVE A QUORUM, WHY DON'T WE
15 DIVE INTO THE RESEARCH USE EXEMPTION ISSUES. AS I SAID
16 BEFORE, WE HAD A RATHER BROAD RESEARCH USE EXEMPTION IN
17 OUR FIRST DRAFTS. RATHER BROAD IN THE SENSE THAT IT
18 WOULD HAVE REQUIRED -- IT HAD REQUIREMENTS FOR
19 COMPANIES, ANYONE WHO RECEIVED A GRANT FROM ICOC, AND
20 IT WAS, AS I SAID, QUITE BROAD IN ITS NATURE.

21 WE HEARD A LOT OF PUSHBACK PRIMARILY FROM
22 INDUSTRY SOURCES ABOUT THE RESEARCH USE EXEMPTION,
23 PARTICULARLY ONE INTERPRETATION OF THAT, WHICH IS THAT
24 THEY MIGHT BE REQUIRED, THEY, THE TOOLS COMPANIES,
25 MIGHT BE REQUIRED TO PROVIDE FREE GOODS IN THE CONTEXT

1 OF THAT LANGUAGE, THAT WE TOOK IT OUT.

2 SUBSUMED UNDER THAT WAS AN ASSUMPTION THAT
3 OUR GRANTEE -- BY US THAT OUR GRANTEES WOULD RETAIN THE
4 RIGHTS TO USE THEIR OWN INVENTIONS FOR THEIR OWN
5 PURPOSES. WE HAVE GOTTEN FEEDBACK NOW. WE DID PUT, IN
6 THE LAST VERSION OF THE DOCUMENT THAT CURRENTLY
7 CONSTITUTE APA REGULATIONS IN PROGRESS, WE PUT A NEW
8 PHRASE WHICH IS SIGNIFICANTLY NARROWER THAN THE
9 ORIGINAL RESEARCH USE EXEMPTION THAT WE PUT BEFORE YOU.

10 IF I CAN READ THAT, IT SAYS, "IN LICENSING
11 CIRM-FUNDED PATENTED INVENTIONS, LICENSEES AGREE THAT
12 GRANTEE ORGANIZATIONS RETAIN THE RIGHT TO PRACTICE THE
13 USE OF THE CIRM-FUNDED INVENTIONS FOR ANY NONPROFIT
14 PURPOSE, INCLUDING SPONSORED RESEARCH AND
15 COLLABORATION." SO THIS IS A RETENTION BY OUR GRANTEES
16 THEMSELVES, BUT THIS WOULD ALLOW THEM, IN TURN, TO
17 ALLOW OTHERS TO USE THEIR PATENTED INVENTIONS FOR THESE
18 PURPOSES, NOT FOR ANY COMMERCIAL PURPOSES. THEY STILL
19 CAN MAKE A COMMERCIAL LICENSE EXCLUSIVELY, IF THEY HAD
20 TO, TO SEE THAT IT WAS, BUT FOR COMMERCIAL USE,
21 FOR-PROFIT USE, BUT THEY WOULD BE OBLIGATED -- THEY
22 WOULDN'T BE OBLIGATED, BUT THEY COULD IN THIS CASE IF
23 THEY RETAINED THE RIGHTS THEMSELVES AND THEY COULD USE
24 THOSE FOR ANY PURPOSE WHICH WAS NON -- IT SAYS ANY
25 NONPROFIT PURPOSE, INCLUDING SPONSORED RESEARCH.

1 THE INSTITUTIONS THEMSELVES COULD MAKE THE
2 DECISION ABOUT WHETHER THEY WANTED TO ALLOW SOMEBODY
3 ELSE TO USE THEIR TECHNOLOGY FOR THAT PURPOSE AND ONLY
4 THAT PURPOSE, BUT IT WOULD BE UP TO THEM. THEY'RE NOT
5 OBLIGATED. JUST THEY RETAIN THAT RIGHT. OKAY.

6 SO THE MOST EXTREME CASE ON THE ONE SIDE WAS
7 WHAT WE HAD IN THE FIRST DOCUMENT. THIS IS SORT OF THE
8 MIDDLE GROUND. AND WE'VE HEARD NOW -- AND IS KATHERINE
9 KU IN THE AUDIENCE TODAY? NO. WE'VE HEARD FROM
10 STANFORD, WE'VE HEARD FROM THE UC THAT MADY VS. DUKE IS
11 FINALLY SINKING IN ON THE ACADEMIC COMMUNITY, AND
12 THEY'RE VERY WORRIED ABOUT THIS ISSUE, ABOUT THEIR
13 ABILITY TO CONDUCT RESEARCH IN THE UNIVERSITY
14 ENVIRONMENT IN THE FACE OF LAWSUITS POTENTIALLY AGAINST
15 THEM FOR CARRYING OUT BASIC RESEARCH.

16 AND WE HAVE BEEN TOLD BY KATHERINE, AND MAYBE
17 YOU CAN READ THE LANGUAGE THAT STANFORD NOW INTENDS TO
18 PUT IN ALL OF ITS AGREEMENTS, MARY.

19 DR. MAXON: "RETAINED RIGHTS. STANFORD
20 RETAINS THE RIGHT ON BEHALF OF ITSELF AND ALL OTHER
21 NONPROFIT ACADEMIC RESEARCH INSTITUTIONS TO PRACTICE
22 THE LICENSED PATENT AND USE TECHNOLOGY FOR ANY
23 NONPROFIT PURPOSE, INCLUDING SPONSORED RESEARCH AND
24 COLLABORATIONS. LICENSEE AGREES THAT, NOTWITHSTANDING
25 ANY OTHER PROVISION OF THIS AGREEMENT, IT HAS NO RIGHT

1 TO ENFORCE THE LICENSED PATENT AGAINST ANY SUCH
2 INSTITUTION. STANFORD AND ANY SUCH OTHER INSTITUTION
3 HAS THE RIGHT TO PUBLISH ANY INFORMATION INCLUDED IN
4 THE TECHNOLOGY OR A LICENSED PATENT."

5 DR. PIZZO: I SUPPORT THE STANFORD POSITION.

6 CHAIRMAN PENHOET: DR. PIZZO SUPPORTS THE
7 STANFORD POSITION. WE'VE ALSO HEARD FROM UC THAT THEY
8 INTEND TO DO -- APPARENTLY THERE WAS A MEETING OF A
9 NUMBER OF UNIVERSITIES THIS SUMMER, MAYBE PROMPTED BY
10 US, FRANKLY, BECAUSE I THINK WE WERE THE FIRST TO SHINE
11 A LOT OF LIGHT ON THE MADY VS. DUKE ISSUE AND
12 UNINTENDED CONSEQUENCES, PERHAPS, OF THAT LITIGATION.
13 BUT IT WAS, I GUESS, A NATIONAL MEETING OF LICENSING
14 OFFICERS, ETC., FROM UNIVERSITIES HAVE MET, AND THEY
15 HAVE NOW REALIZED THE THREAT TO THE BASIC RESEARCH
16 ENTERPRISE THAT SOME OF THESE THINGS MIGHT REPRESENT.
17 THEREFORE, THEY'VE SORT OF AGREED AS A GROUP THAT THEY
18 WILL ADOPT THIS OR LANGUAGE LIKE THIS.

19 DR. PIZZO: I THINK THIS IS ALSO, ED, DRIVEN
20 TO SOME DEGREE BY WHAT'S BEEN GOING ON IN WISCONSIN AS
21 WELL, WHICH IS SUCH A NEGATIVE ISSUE.

22 CHAIRMAN PENHOET: SO THIS POLICY, TO BE
23 CLEAR, WOULD ALLOW COMMERCIAL LICENSES. THEY COULD BE
24 EXCLUSIVE OR NONEXCLUSIVE, ACCORDING TO THE REST OF OUR
25 POLICY, ETC., BUT IN EACH CASE WE WOULD STRENGTHEN THE

1 UNIVERSITY'S HAND WHEN WE DO NEGOTIATION BY SAYING,
2 YES, WE THINK WHAT YOU'RE DOING IS GOOD AND,
3 FURTHERMORE, WE'LL MAKE IT A REQUIREMENT ON YOU FROM
4 THIS ORGANIZATION.

5 SO THAT'S THE INTENT OF THIS LANGUAGE HERE,
6 AS I SAID, WHICH DOESN'T GO NEARLY AS FAR AS THE FIRST
7 LANGUAGE WE PUT IN, BUT I THINK ADDRESSES WHAT IS MOST
8 LIKELY TO BE BROADLY UNIVERSITY POLICY AS WE KNOW IT
9 TODAY. SO KATHERINE KU FROM STANFORD GAVE US THEIR
10 LANGUAGE. WENDY STREITZ FROM THE UNIVERSITY OF
11 CALIFORNIA, ALSO NOT HERE TODAY, SAID THEY HAVE VERY
12 SIMILAR LANGUAGE NOW. SO THIS IS SORT OF AN
13 INTERMEDIATE POSITION THAT WE HAVE.

14 AT THIS POINT I KNOW THAT WE HAVE SOME
15 MEMBERS OF OUR AUDIENCE WHO BELIEVE MAYBE THIS GOES TOO
16 FAR, SO WE'LL BE HAPPY TO HEAR FROM THEM, BUT FIRST I
17 WOULD LIKE TO HEAR COMMENTS OTHER THAN DR. PIZZO, WHO
18 SUPPORTS THE STANFORD POSITION.

19 DR. PIZZO: AS A MEMBER OF THE INDEPENDENT
20 OVERSIGHT COMMITTEE.

21 CHAIRMAN PENHOET: STANFORD POSITION, NOT
22 UNIQUE TO STANFORD. DUANE ROTH -- BEFORE I FORGET, I'M
23 SORRY. WELCOME DUANE ROTH TO OUR COMMITTEE NOW
24 OFFICIALLY APPOINTED AS A MEMBER.

25 MR. ROTH: I WON'T WASTE ANY TIME GETTING

1 INTO IT. THE FIRST QUESTION I REALLY HAVE IS A PROCESS
2 QUESTION, AND IT'S A QUESTION OF HOW THAT GOT INTO THE
3 DRAFT WHEN IT WASN'T PART OF THE DISCUSSION AT THE LAST
4 MEETING.

5 CHAIRMAN PENHOET: I WILL REPEAT WHAT HE SAID
6 FOR YOU. OTHERWISE, WE'RE GOING TO HAVE PEOPLE WALKING
7 AROUND THE WHOLE TIME. DUANE ASKED A PROCESS QUESTION.
8 HOW DID THIS NEW LANGUAGE GET INTO THE DOCUMENT IN THE
9 FIRST PLACE? THE ANSWER IS THAT IN EARLIER DRAFTS, WE
10 HAD SIMILAR LANGUAGE. IT WAS OBIATED -- THE NECESSITY
11 FOR THIS LANGUAGE WAS OBIATED BY THE BROADER RESEARCH
12 EXEMPTION WHICH WOULD HAVE SUBSUMED US. WHEN THE
13 BROADER ONE WENT AWAY, WE PUT THIS BACK IN, BUT IT WAS
14 STAFF DECISION BASICALLY.

15 DID YOU UNDERSTAND DUANE'S QUESTION? HOW DID
16 IT GET IN? DO YOU HAVE ANY COMMENTS TO ADD TO THAT?

17 MR. ROTH: HAVING SAID THAT, WHAT I CAME TO,
18 AFTER READING THE PUBLIC COMMENTS AND GOING THROUGH THE
19 DOCUMENT MYSELF, IS EXACTLY WHAT WAS JUST SAID. I
20 BELIEVE IT'S COMPLETELY UNNECESSARY BECAUSE EACH
21 INSTITUTION CAN PUT IN THE LANGUAGE THEY WANT. THEY'RE
22 THE ONES GRANTING THE LICENSE FOR THE OPTION. SO I'M
23 WORRIED ABOUT THE UNINTENDED CONSEQUENCES OF HAVING
24 SOMETHING IN THAT HAS ORGANIZATIONS, PLURAL, AS OPPOSED
25 TO ORGANIZATION WHO'S DOING THE LICENSE, THAT THAT

1 SOMEHOW WILL END UP HAVING A NEGATIVE EFFECT WHEN
2 LAWYERS START TO READ THE LANGUAGE BEFORE THEY ENTER
3 INTO A LICENSING AGREEMENT TO COMMERCIALIZE SOMETHING
4 THAT WE ALL WOULD LIKE TO SEE BROADLY AVAILABLE. SO
5 THAT'S MY CONCERN.

6 CHAIRMAN PENHOET: I'LL TRY TO PARAPHRASE
7 WHAT DUANE JUST SAID. I HOPE I'LL BE ACCURATE, DUANE.
8 DUANE SAID THAT BASICALLY, IN ASKING AROUND, IT APPEARS
9 THAT UNIVERSITIES WILL DO THIS WHETHER WE FORCE IT UPON
10 THEM OR NOT. THEY'VE ALREADY DECIDED TO DO IT. AND
11 HIS CONCERN IS ABOUT THE WORD "ORGANIZATION" HERE,
12 WHICH IS PLURAL, AND WOULD ALLOW UNIVERSITIES NOT ONLY
13 TO USE THE TECHNOLOGY FOR THEIR OWN PURPOSES, BUT TO
14 EMPOWER OTHERS IN THE NONPROFIT SPACE TO DO THE SAME
15 THING.

16 SO, DUANE, I BELIEVE YOU BELIEVE THAT IN THE
17 BEST CASE IT'S REDUNDANT AND THAT IT MIGHT HAVE AN
18 UNINTENDED CONSEQUENCE THAT WE CAN'T FORESEE TODAY?

19 MR. ROTH: THAT'S CORRECT. MY BIGGEST
20 CONCERN IS SOMETHING LIKE THIS CAN BE NEGOTIATED.
21 THERE MAY BE TIMES WHEN THAT LANGUAGE IS COMPLETELY
22 INAPPROPRIATE AND MAY CAUSE SOMEBODY NOT TO ENTER INTO
23 AN AGREEMENT BECAUSE IT'S SO ONEROUS THAT THEY WON'T
24 TAKE THE RISK. I DON'T WANT THAT TO HAPPEN.

25 ON THE OTHER HAND, YOU CAN ALWAYS PUT IT IN,

1 AND STANFORD IS NOW DOING IT, UNIVERSITY OF CALIFORNIA
2 IS GOING TO DO IT. LET THEM DO IT. AT LEAST THEY HAVE
3 THE FLEXIBILITY, IF IT DOESN'T MAKE SENSE IN A
4 PARTICULAR NEGOTIATION, TO BACK AWAY FROM IT.

5 DR. PIZZO: I CERTAINLY ACCEPT THE POINT
6 YOU'RE MAKING, DUANE, AND UNDERSTAND ABSOLUTELY THE
7 CONCERNS ABOUT UNINTENDED CONSEQUENCES. THERE'S
8 ANOTHER DIMENSION TO THIS, HOWEVER, THAT I THINK WE AT
9 LEAST HAVE TO BE SURE TO DISCUSS, WHICH IS WE'RE ALSO
10 ATTEMPTING TO SET A MODEL WHICH WOULD BE USED BY WAY OF
11 EXAMPLE NATIONALLY ABOUT HOW WE AS AN ORGANIZATION
12 HANDLE OUR IP POLICIES. AND I THINK IT'S IMPORTANT FOR
13 THE CIRM TO HAVE A POLICY THAT IS FORWARD-LOOKING, THAT
14 THINKS ABOUT ISSUES OF HOW WE'LL SHARE RESEARCH
15 RESOURCES AND REAGENTS THAT CAN BE LOOKED AT ACROSS THE
16 COUNTRY AS A CORRECT WAY OR GOOD WAY TO DO THINGS.

17 MY FEAR IS THAT IF WE PUT SOMETHING IN THAT
18 SIMPLY LEAVES INSTITUTIONS TO DO IT, WE MAY NOT BE
19 SERVING OUR BEST RESPONSIBILITY IN ASSURING THAT WE'VE
20 GOT AN EXAMPLE THAT SERVES TRULY AS AN EXEMPLAR.

21 CHAIRMAN PENHOET: OKAY. TO PARAPHRASE DR.
22 PIZZO'S COMMENTS --

23 DR. PIZZO: YOU CAN DO THAT IN ABOUT TWO
24 WORDS.

25 CHAIRMAN PENHOET: YOU ARE GOING TO, AMONG

1 OTHER THINGS, TEST MY RECALL IN THIS MEETING. DR.
2 PIZZO --

3 DR. STEWARD: CAN I INTERRUPT FOR A SECOND?
4 THIS IS OS STEWARD DOWN IN IRVINE. WE CANNOT HEAR ANY
5 OF THIS.

6 CHAIRMAN PENHOET: CAN YOU HEAR ME?

7 DR. STEWARD: WE CAN HEAR YOU JUST PERFECTLY,
8 BUT NONE OF THE OTHER SPEAKERS.

9 CHAIRMAN PENHOET: WE'RE NOT GOING TO BE ABLE
10 TO CHANGE THAT. YOU WILL HAVE TO ALLOW ME TO
11 PARAPHRASE WHAT EVERY SPEAKER SAYS.

12 DR. HALL: TAKE THIS THING AROUND. IT'S NOT
13 THAT BIG. IT IS VERY DISCONCERTING TO HEAR LONG
14 PERIODS OF GIBBERISH.

15 CHAIRMAN PENHOET: WE'RE GOING TO MOVE THIS
16 AROUND, AND WE'LL ALLOW DR. PIZZO TO REPEAT WHAT HE
17 JUST SAID.

18 DR. PIZZO: THIS IS PHIL PIZZO SPEAKING
19 AGAIN. I'LL TRY AND SAY BASICALLY WHAT I SAID LAST
20 TIME, WHICH IS THAT WHILE CERTAINLY ACKNOWLEDGING THE
21 IMPORTANCE OF DUANE'S COMMENTS ABOUT ALLOWING THERE TO
22 BE VARIATION AMONG DIFFERENT INSTITUTIONS AND AVOIDING
23 UNINTENDED CONSEQUENCES, I ALSO THINK IT'S IMPORTANT
24 THAT WE RECOGNIZE THAT THE CIRM IS BEING LOOKED AT AS A
25 MODEL FOR HOW TO HANDLE SUCH COMPLICATED ISSUES AS IP

1 ACROSS THE COUNTRY. AND I THINK IT'S IMPORTANT FOR US
2 TO TAKE A STAND AND DEVELOP GUIDELINES WHICH OTHERS CAN
3 MODEL AND NOT SIMPLY HAVE THEM ABDICATED TO LOCAL
4 INSTITUTIONS OR MEMBER INSTITUTIONS.

5 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM
6 THE BOARD IN SAN FRANCISCO? DUANE.

7 MR. ROTH: I'M GOING TO JUST RESPOND TO THAT.
8 YOU WEREN'T AT THE LAST MEETING, BUT I MENTIONED THAT
9 THIS ISSUE HAS GONE ON NOW FOR ABOUT A YEAR ON THE
10 FEDERAL LEVEL. AND I DESCRIBE IT AS AN ISSUE IN SEARCH
11 OF A PROBLEM. AND WHAT I WOULD SUGGEST IS BEFORE WE
12 START PLAYING WITH THIS, BECAUSE IT'S EXTREMELY
13 COMPLICATED IN TERMS OF THE UNINTENDED CONSEQUENCES AND
14 HOW SOMETHING LIKE THIS IS INTERPRETED, THAT WE STAY
15 THE COURSE RIGHT NOW. AND AT THE FIRST INKLING THAT
16 THIS BECOMES AN ISSUE, I THINK WE SHOULD ADDRESS IT.
17 BUT I'M ALWAYS RELUCTANT, GIVEN OUR THIN STAFF AND
18 AMOUNT OF REVIEW WE'VE HAD ON THIS, TO BE OUT IN FRONT
19 ON SOMETHING LIKE THIS WHEN WE'VE GOT SOMETHING THAT'S
20 WORKING EXTREMELY WELL FOR TWENTY YEARS. AND WE HAVE
21 THIS ONE EXAMPLE OF EVERYBODY SAYING, OH, MY GOD. THIS
22 COULD CREATE A BIG PROBLEM, BUT, IN FACT, IT HAS NOT.

23 AND I THINK BEFORE WE START TWEAKING WITH
24 THINGS, LET'S MAKE SURE THERE'S A REAL ISSUE. I
25 CERTAINLY WANT THE RESEARCH TO GO AHEAD, BUT I ALSO

1 WANT TO MAKE SURE THERE'S A COMMERCIAL MARKET CREATED
2 FOR PRODUCTS THAT WILL BE STANDARD AND BE AVAILABLE TO
3 MOVE THE FIELD FORWARD.

4 CHAIRMAN PENHOET: JEFF SHEEHY.

5 MR. SHEEHY: I'D LIKE TO ECHO MR. ROTH'S
6 COMMENTS. I MEAN I KNOW IT'S IMPORTANT FOR US TO SERVE
7 AS A MODEL, BUT I DON'T KNOW THAT IN THIS PARTICULAR
8 INSTANCE, GIVEN THE WAY IN WHICH WE RULEMAKE, IF IT'S
9 APPROPRIATE. OUR RULEMAKING PROCESSES ARE FAIRLY
10 RIGID. THE RULES WE ADOPT ARE HARD TO CHANGE ONCE
11 THEY'RE ADOPTED. THIS IS A VERY -- THIS COVERS A LOT
12 OF GROUND, AND IT MAY BE THAT THIS IS SOMETHING THAT IS
13 BETTER NEGOTIATED ON A CASE-BY-CASE BASIS AT
14 INSTITUTIONS.

15 I ALSO -- YOU KNOW, I'VE GOTTEN TWO OTHER
16 PIECES, TWO OTHER DIFFERENT LANGUAGE RECOMMENDATIONS,
17 AND I WONDER IF IT WOULDN'T BE BETTER TO DO THIS IN A
18 MORE COLLABORATIVE PROCESS WHERE WE TAKE VARIOUS
19 RECOMMENDATIONS FROM THE PUBLIC FOR ALTERNATIVE
20 LANGUAGE AND KIND OF PUT THEM OUT AND SEE IF WE CAN GET
21 SOMETHING THAT EVERYBODY AGREES ON. BUT I AM VERY
22 UNCOMFORTABLE WITH PROCEEDING FORWARD WITH ANY LANGUAGE
23 THAT THERE IS SERIOUS CONCERN FROM ANY STAKEHOLDER OR
24 PARTICIPANT IN THIS PROCESS AT THIS TIME IN THIS KIND
25 OF ARENA WHERE WE'RE TRYING TO CREATE SOMETHING BRAND

1 NEW. THIS IS NOT REALLY A PLACE WHERE I FEEL LIKE I
2 WANT TO BREAK NEW GROUND. IP POLICY IS JUST TOO
3 COMPLEX.

4 CHAIRMAN PENHOET: ANY COMMENTS FROM IRVINE,
5 I GUESS? HELLO, IRVINE.

6 MS. INGELS: NO COMMENTS FROM IRVINE.

7 CHAIRMAN PENHOET: FRANCISCO PRIETO.

8 DR. PRIETO: YES, I'M HERE.

9 CHAIRMAN PENHOET: DO YOU HAVE A COMMENT?

10 DR. PRIETO: NO.

11 CHAIRMAN PENHOET: OKAY. DO WE HAVE COMMENTS
12 FROM THE ASSEMBLED AUDIENCE IN SAN FRANCISCO?

13 MR. LAKAVAGE: I'M TONY LAKAVAGE, AND I'M
14 FROM APPLIED BIOSYSTEMS. WE SUBMITTED PROPOSED
15 ALTERNATIVE LANGUAGE, WHICH MAYBE WE'LL BE TALKING
16 ABOUT IN A SECOND. I COULD JUST SAY OUR -- THE WAY WE
17 LOOKED AT THIS AND THE CONCEPT OF THE INVENTOR
18 ORGANIZATION, INVENTOR/GRANTEE ORGANIZATION BEING ABLE
19 TO PRACTICE THE RIGHT OF THEIR INVENTION SEEMS
20 REASONABLE TO US. IT'S THE REST OF THIS THAT SEEMS TO
21 CREATE THIS VERY SIGNIFICANT PATENT CARVE-OUT WHICH
22 WOULD CONCEIVABLY HAVE THE SAME -- ACTUALLY I THINK
23 LIKELY WOULD HAVE THE SAME NEGATIVE DISINCENTIVE IMPACT
24 THAT THE RUE LANGUAGE MIGHT HAVE HAD.

25 I THINK MY RECOLLECTION IS THAT AT THE LAST

1 TASK FORCE MEETING, THERE WAS AGREEMENT THAT THERE
2 ISN'T A PROBLEM TODAY, SO WHY IS IT NECESSARY TO CREATE
3 NEW LANGUAGE TO ADDRESS SOMETHING THAT IS AGREED IS NOT
4 A PROBLEM. IF THE GRANTEE INVENTOR WAS WITHHOLDING
5 THEIR INVENTION FROM ANOTHER GRANTEE, I THINK THE
6 MARCH-IN RIGHTS AND THE OTHER PROVISIONS IN THE POLICY
7 WOULD APPLY. SO IT JUST SEEMS LIKE IT'S AN UNNECESSARY
8 PROVISION THAT GOES MUCH FURTHER THAN THE SIMPLE INTENT
9 OF THE GRANTEE BEING ABLE TO -- INVENTOR BEING ABLE TO
10 PRACTICE HIS OWN INVENTION.

11 SO IF WE WANT TO, WE CAN TALK ABOUT OUR
12 PROPOSED LANGUAGE OR MAYBE WE SHOULD GO FORWARD.

13 CHAIRMAN PENHOET: MAYBE JUST ADD ONE COMMENT
14 TO YOUR STATEMENT. WE HAVE RECEIVED NEW INFORMATION
15 FROM THE UNIVERSITIES THAT THEY BELIEVE THIS IS A
16 PROBLEM. OUR PRIOR VIEW WAS IT WASN'T A PROBLEM;
17 THEREFORE, WE DIDN'T HAVE TO ADDRESS IT. WE HAVE BEEN
18 TOLD NOW, THEY SENT US THEIR LANGUAGE, THEY SAID IT IS
19 A PROBLEM. WE'VE ALL MET. WE THINK IT'S A PROBLEM.

20 BUT I THINK, IF I REMEMBER YOUR PROPOSAL
21 CORRECTLY, YOUR PROPOSAL WOULD BE THAT THE INSTITUTION
22 ITSELF WOULD STILL BE FREE TO PRACTICE ITS OWN ART, BUT
23 WOULDN'T HAVE THE ABILITY TO LICENSE OTHERS; IS THAT
24 CORRECT?

25 MR. LAKAVAGE: THAT'S CORRECT.

1 CHAIRMAN PENHOET: ANY OTHER COMMENTS? JOHN
2 SIMPSON.

3 MR. SIMPSON: JOHN SIMPSON FROM THE
4 FOUNDATION FOR TAXPAYER & CONSUMER RIGHTS. I SHARE THE
5 VIEW THAT THIS IS AN AMBIGUOUS PHRASE, AND I'M NOT SURE
6 THAT IT ACCOMPLISHES WHAT EVERYONE THINKS IT SHOULD BE
7 ACCOMPLISHING, ALTHOUGH I ALSO THINK WE NEED SOME KIND
8 OF A RESEARCH PROBLEM -- RESEARCH USE EXEMPTION. AND I
9 THINK IT HAS BECOME A PROBLEM. I THINK WARF CLEARLY IS
10 A PROBLEM. AND THE WAY THIS IS PHRASED RIGHT NOW, AS I
11 SEE IT, THIS IS -- THIS WOULD NOT PRECLUDE A GRANTEE
12 FROM ACTING LIKE WARF, WHICH I THINK HAS GOT TO BE IN
13 THE POLICY SOMEHOW.

14 CHAIRMAN PENHOET: WE AGREE WITH YOUR
15 INTERPRETATION. THAT'S CORRECT. THIS WOULDN'T FORCE
16 THE UNIVERSITY IF THEY OWNED THE PATENT TO DO ANYTHING
17 WITH IT. I JUST SAID I AGREED WITH HIS INTERPRETATION
18 OF THIS LANGUAGE. IT DOESN'T FORCE. SO YOUR
19 PROPOSAL --

20 MR. SIMPSON: I'M CONCERNED THAT THERE'S
21 NOTHING THAT REALLY PUTS AN OBLIGATION ON A GRANTEE TO
22 SHARE TAXPAYER-FUNDED RESEARCH. NOW, I'M SYMPATHETIC
23 TO THE TOOLS INDUSTRY AND THE NEED TO COMMERCIALIZE.
24 THERE IS SOME LANGUAGE THAT THEY'VE GOT THAT I'VE BEEN
25 WORKING WITH THEM ON SOME. AND IT MAY BE A SOLUTION.

1 BUT I DO THINK THAT IT'S BEEN DEMONSTRATED THAT NOT
2 EVERY UNIVERSITY ACTS IN THE BROADEST, MOST BENEVOLENT
3 PUBLIC INTEREST. WE MIGHT LIKE TO THINK THAT THEY
4 WILL, BUT WISCONSIN CLEARLY IS NOT. I THINK THAT'S
5 SOMETHING THAT NEEDS TO BE ADDRESSED.

6 SO SINCE JANET WAS THE ONE WHO DRAFTED THIS,
7 MAYBE SHE WOULD WANT TO BE SUGGESTING THE LANGUAGE.
8 I'M NOT SURE.

9 MS. LAMBERT: THIS IS JANET LAMBERT FROM
10 INVITROGEN. I'D JUST LIKE TO MAKE THREE POINTS. ONE
11 IS THE PROCESS POINT. WE REALLY HAVE TRIED TO BE
12 FAITHFUL AND CONSTRUCTIVE PARTICIPANTS IN THE PROCESS,
13 AND WE DID FEEL THAT AFTER THE LAST MEETING THE
14 UNANIMOUS DECISION HAD BEEN TO REMOVE THE RUE LANGUAGE,
15 NOT TO MODIFY IT, NOT TO ADAPT IT, NOT TO COME UP WITH
16 SOMETHING SIMILAR BUT NARROWER. AND THEN TO FIND IN
17 THE PUBLISHED COMMENTS THAT THERE IS KIND OF REVISED
18 LANGUAGE AND THAT YOU ALL SEEMINGLY HAVE BEEN IN
19 CONVERSATION WITH UNIVERSITIES AND SOME STAKEHOLDERS,
20 BUT NOT ALL STAKEHOLDERS, NOT US, WHEN WE'VE EXPRESSED
21 QUITE A LOT OF INTEREST IN THIS ISSUE, I THINK, YOU
22 KNOW, IT CAUSES US A LOT OF CONCERN.

23 AND I THINK IT IS COMPLICATED. AND SO TO
24 JEFF'S POINT, WE WOULD BE HAPPY TO THINK ABOUT WHAT WE
25 CAN DO. I DID IN CONVERSATIONS WITH JOHN SIMPSON

1 SKETCH SOMETHING OUT THIS MORNING, AND I'D BE HAPPY TO
2 BE IN A CONVERSATION WITH HIM AND YOU ABOUT IT TO MAKE
3 SURE THAT IP IS BROADLY SHARED ON REASONABLE TERMS. I
4 THINK LICENSEES UNDER THE POLICY, AS YOU HAVE IT NOW
5 WRITTEN, ARE REQUIRED UNDER THE DEFINITION OF PRACTICAL
6 APPLICATION TO BRING IP -- TO MAKE IP WIDELY AVAILABLE
7 ON REASONABLE TERMS.

8 SO THE ISSUE IS REALLY JUST WHETHER GRANTEE
9 ORGANIZATIONS HAVE TO FACE THAT SAME REQUIREMENT. I
10 THINK INDIRECTLY THEY ALREADY ARE REQUIRED TO DO THAT
11 BECAUSE YOU HAVE MARCH-IN RIGHTS EVEN FOR GRANTEE
12 ORGANIZATIONS IF GRANTEE ORGANIZATIONS DON'T BRING
13 SOMETHING TO PRACTICAL APPLICATION; THAT IS, DON'T MAKE
14 IT WIDELY AVAILABLE ON REASONABLE TERMS.

15 SO LET'S THINK ABOUT WARF. SO IF YOU FUNDED
16 WARF AND WARF BEHAVED AS THEY'RE DOING, CAME UP WITH
17 THEIR INVENTION AND BEHAVED AS THEY DO NOW, YOU WOULD
18 JUST MARCH IN. YOU HAVE THIS WHOLE 100310 THAT SAYS
19 YOU COULD TAKE THE LICENSE, YOU COULD OFFER IT TO
20 ANYBODY ON TERMS YOU THOUGHT APPROPRIATE, AND THESE
21 TERMS LIKE REASONABLE ARE UP TO YOU TO DECIDE.

22 SO I THINK, ONE, WE'RE CONCERNED ABOUT THE
23 PROCESS; TWO, WE THINK YOU ALREADY HAVE A LOT OF
24 PROTECTION AGAINST WARF. IT'S COMPLICATED. WE'RE
25 HAPPY TO BE A PART OF THE PROCESS. BUT FOR US TO KIND

1 OF ALL DO THIS KIND OF ON THE FLY IN FIVE MINUTES IS
2 GOING TO BE PRETTY TOUGH TO DO.

3 AND MAYBE JUST ONE FINAL POINT ON THIS KIND
4 OF IS THERE A PROBLEM, IS THERE NOT A PROBLEM. WE KNOW
5 THERE'S A PROBLEM WITH WARF. AS I SAID, I THINK YOU
6 SOLVED THE WARF PROBLEM ALREADY IN THE DOCUMENT WITHOUT
7 THIS LANGUAGE. WHAT WE KEEP REFERRING TO IS A SERIES
8 OF ACADEMIC STUDIES THAT THE NATIONAL ACADEMIES
9 COMMISSIONED AND JOHN WALSH OF CHICAGO DID THAT
10 SURVEYED A BROAD NUMBER OF RESEARCHERS. THAT STUDY WAS
11 FOLLOWED UP BY SOME WORK THAT AAAS DID, WHICH I KNOW
12 YOU'RE FAMILIAR WITH, WHERE THEY SURVEYED A LOT OF
13 THEIR INDUSTRIAL AND ACADEMIC RESEARCHERS AND FOUND
14 THAT THERE REALLY ISN'T, IN THEIR CONCLUSION, BOTH JOHN
15 WALSH'S AND THE AAAS ANALYST'S CONCLUSION, NOT MUCH OF
16 A PROBLEM HERE.

17 I KNOW EVERYBODY IS KIND OF LOOKING, BECAUSE
18 WE FEEL LIKE THERE MAY BE THE INGREDIENTS OF A PROBLEM,
19 BUT WHEN WE KEEP COMING BACK TO THERE'S NOT MUCH OF A
20 PROBLEM, THAT'S WHAT WE'RE BASING IT ON IS REALLY A
21 COUPLE OF BROAD SURVEYS, BOTH THE ACADEMIC AND THE
22 INDUSTRIAL LANDSCAPE, THAT COME TO THAT CONCLUSION.
23 THANK YOU.

24 CHAIRMAN PENHOET: JEFF.

25 MR. SHEEHY: I REALLY -- I DO HAVE TO KIND

1 OF -- I AM A BIT CONCERNED ABOUT THE PROCESS ISSUE
2 BECAUSE WE DID CONSULT SOME STAKEHOLDERS AND WE DIDN'T
3 CONSULT OTHER STAKEHOLDERS. I REMEMBER AT THE LAST IP
4 MEETING, YOU KNOW, ONE OF MY SUGGESTIONS WAS, LIKE, GET
5 ALL THE STAKEHOLDERS TOGETHER AND SEE IF WE CAN WORK
6 SOMETHING OUT. IT SEEMS LIKE WE TALKED TO A FEW, BUT
7 WE DIDN'T TALK TO ALL OF THEM. I'M VERY UNCOMFORTABLE
8 TAKING ANYTHING FORWARD WHEN WE'VE BEEN SO SELECTIVE
9 ABOUT THE STAKEHOLDERS THAT WE'VE CONSULTED IN
10 PROPOSING THIS POTENTIAL FOR THIS LANGUAGE.

11 I WOULD HOPE THAT OUR PROCESSES ARE NOT
12 DISCRIMINATORY AGAINST CERTAIN STAKEHOLDERS AS OPPOSED
13 TO OTHERS. I SEE THEM ALL BEING EQUAL. AND, YOU KNOW,
14 I MEAN I WOULD HOPE THAT IF WE ARE GOING TO COME UP
15 WITH NEW POLICY ON RESEARCH USE EXEMPTION, THAT WE
16 WOULD GET INPUT FROM ALL THE STAKEHOLDERS WHO HAVE
17 EXPRESSED INTEREST IN THIS ISSUE BEFORE WE PUT
18 SOMETHING FORWARD.

19 CHAIRMAN PENHOET: OKAY. ANY COMMENTS FROM
20 IRVINE?

21 MR. GOSWAMI: HI. THIS IS JOYDEEP GOSWAMI
22 FROM INVITROGEN. JUST A QUICK QUESTION. THE LANGUAGE
23 THAT YOU HAVE GOTTEN FROM STANFORD AND POTENTIALLY FROM
24 UC, HOW MANY INSTANCES HAVE THEY ACTUALLY SIGNED A
25 LICENSE WITH THIS NEW LANGUAGE IN IT? I'M CONCERNED

1 BECAUSE EVERY TIME A UNIVERSITY WANTS TO USE THE NEW
2 LANGUAGE INCLUDED INTO THE STANDARD GRANT, THERE'S A
3 BACK AND FORTH WITH THE POTENTIAL LICENSEE. AND I
4 WOULD HATE TO HAVE THAT LANGUAGE GO INTO A CIRM GRANT.
5 THERE ISN'T MUCH MECHANISM TO HAVE THIS DIALOGUE
6 WITHOUT HAVING FIRST BEEN TESTED ON A NUMBER OF -- IN A
7 NUMBER OF CASES. I JUST WONDER IF YOU CAN PROVIDE SOME
8 CLARIFICATION ON HOW MANY LICENSES STANFORD HAS SIGNED
9 WITH THIS NEW LANGUAGE.

10 CHAIRMAN PENHOET: DO WE KNOW THE ANSWER?
11 BUT YOUR POINT IS WELL TAKEN. IRRESPECTIVE OF HOW MANY
12 THEY HAVE SIGNED, EACH ONE IS A SEPARATE NEGOTIATION,
13 AND WE'RE GOING TO TALK A LOT ABOUT THAT LATER. SO
14 THERE ARE LOTS OF THINGS THEY WOULD LIKE TO HAVE THEY
15 DON'T ALWAYS GET IN EVERY AGREEMENT, WHICH IS FOR SURE
16 TRUE.

17 DR. HALL: I JUST WANT TO SPEAK VERY STRONGLY
18 IN FAVOR OF SOMETHING LIKE THIS. WE MAY NOT HAVE THE
19 WORDING QUITE RIGHT, BUT OUR PRINCIPAL OBJECT HERE IS
20 TO MOVE THE RESEARCH ALONG AS FAST AS WE CAN. AND ALL
21 OF US WHO HAVE DONE RESEARCH KNOW THAT THAT BEST TAKES
22 PLACE WHEN THERE'S FREE EXCHANGE OF IDEAS, OF NEW
23 TECHNOLOGIES ON A LOCAL LEVEL.

24 AND WHAT IS BEING PROPOSED IS, IN FACT, WHAT
25 HAS BEEN COMMON PRACTICE FOR A LONG TIME. THAT NOW HAS

1 BEEN CALLED INTO QUESTION BY THE RECENT LAWSUIT, AND I
2 THINK ALL OF US ARE CONCERNED THAT THERE NOT BE THE
3 KIND OF THINGS THAT WE SEE WITH WARF AND THAT THERE ARE
4 OTHER EXAMPLES AS WELL OF CASES IN WHICH THERE ARE
5 REACH-THROUGH RIGHTS OR WHATEVER, SO YOU REALLY CAN'T
6 COMMUNICATE WITH YOUR NEIGHBOR, YOU CAN'T BORROW A
7 TECHNIQUE THAT'S BEING USED NEXT DOOR WITHOUT INVOLVING
8 THE LAWYERS.

9 THIS IS ALL FOR NONPROFIT PURPOSE. THIS IS
10 NOT ABOUT COMMERCIALIZATION. IT'S ABOUT MOVING THE
11 RESEARCH FORWARD. AND SO I WANT TO SPEAK VERY
12 STRONGLY. I THINK ANYTHING THAT JEOPARDIZES THAT WOULD
13 BE A MISTAKE FOR US.

14 LET ME RECALL THAT AT AN EARLIER MEETING OF
15 THIS COMMITTEE AT STANFORD, THERE WAS A VERY STRONG
16 STATEMENT THAT CIRM WISHED TO PUSH THE ENVELOPE IN
17 TERMS OF SHARING DATA AND IN TERMS OF SHARING IDEAS.
18 AND THAT'S WHAT I THINK THIS IS ABOUT. AND I WOULD
19 SIMPLY SAY THAT WE MAY NEED TO TWEAK THAT LANGUAGE, BUT
20 I HOPE THE SPIRIT OF WHAT'S THERE PREVAILS AND THAT WE
21 ARE ABLE TO HAVE A REGULATION THAT EMBODIES THAT
22 RESOLUTION MADE BY THIS COMMITTEE SEVERAL MEETINGS AGO.

23 MR. TAYMOR: I'D JUST LIKE TO COMMENT ON A
24 FEW POINTS THAT WERE RAISED BEFORE. FIRST, ON THE
25 MARCH-IN RIGHTS. I FIND IT QUITE SURPRISING THAT

1 INDUSTRY WOULD BE ENCOURAGING THE USE OF MARCH-IN
2 RIGHTS, WHICH HAVE BEEN STRONGLY OPPOSED FOR VERY GOOD
3 REASON BECAUSE OF BASICALLY THE OPPORTUNITY TO
4 CONFISCATE PROPERTY THAT INDUSTRY HAS INVESTED A GREAT
5 DEAL OF TIME AND EFFORT AND MONEY INTO. SO IT SAYS
6 SOMETHING TO ME THAT MARCH-IN RIGHTS ARE A USEFUL OR
7 LIKELY DESIRABLE ALTERNATIVE.

8 I THINK IF CIRM STARTS EXERCISING MARCH-IN
9 RIGHTS BECAUSE OF ALLEGATIONS THAT INVENTIONS HAVE NOT
10 BEEN REDUCED TO PRACTICAL APPLICATION IN RAPID ENOUGH
11 TIME, WE WOULD SEE A VERY QUICK SHUTDOWN OF
12 COMMERCIALIZATION OF CIRM-SPONSORED INVENTIONS.

13 SECONDLY, AS ZACH JUST STATED, THE LANDSCAPE
14 IN THIS AREA IS SHIFTING. PRIOR TO THE MEETING IN
15 WHICH THE RESEARCH USE EXEMPTION WAS TAKEN OFF THE
16 AGENDA OR TAKEN OFF THE TABLE BY THIS COMMITTEE, THE
17 ICOC, ON THE ENDORSEMENT OF THIS COMMITTEE, ADOPTED A
18 RESEARCH USE EXEMPTION AS ONE OF ITS CORE PRINCIPLES.
19 SO ALTHOUGH THERE'S SOME ARGUMENT NOW THAT THIS IS A
20 SURPRISE, I THINK THAT MEMBERS OF THE PUBLIC ARE MUCH
21 MORE OPEN TO CLAIMING SURPRISE AND HAVE A RIGHT TO
22 CLAIM SURPRISE OF THE ACTIONS OF THE COMMITTEE AT THE
23 LAST MEETING.

24 AS HAS BEEN SAID, MUCH OF WHAT'S BEING DONE
25 HERE IS COMMON PRACTICE. THE REPORTS THAT WERE

1 REFERRED TO, AT LEAST SOME THAT I'VE READ IN
2 CONJUNCTION WITH THE NAS REPORT, INDICATED THAT MUCH OF
3 WHAT IS BEING DONE IN THE ACADEMY TODAY IS JUST TO
4 IGNORE INTELLECTUAL PROPERTY RIGHTS, NOT THAT IT'S
5 BEING PRACTICED IN ACCORDANCE WITH THE RIGHTS. AND
6 WHAT I THINK ZACH AND WHAT THE STAFF PREVIOUSLY HAD
7 PROPOSED PRIOR TO THE CHANGE THAT WAS MADE AT THIS
8 COMMITTEE'S PREVIOUS MEETING WAS TO ELEVATE COMMON
9 PRACTICE ABOVE THE TABLE, MAKE IT TRANSPARENT, MAKE IT
10 A PRINCIPLE, AND MOVE FORWARD WITH IT. AND IT'S
11 BASICALLY TO AVOID A PROBLEM THAT HAS EMERGED. IT'S
12 EMERGED IN THIS INDUSTRY.

13 AND THE QUESTION THAT I WOULD PRESENT TO THIS
14 COMMITTEE IS DO YOU WANT TO FACE THE SITUATION WHERE
15 THIS INSTITUTE HAS USED TAXPAYER DOLLARS TO FUND A
16 PATH-BREAKING INVENTION SUCH AS SOMATIC CELL
17 REPROGRAMMING, AND THEN HAVE THE INVENTOR AND THE
18 INVENTOR INSTITUTION SAY ANYBODY WHO WANTS TO PRACTICE
19 THIS INVENTION, ANYBODY WHO WANTS TO USE -- REPROGRAM
20 SOMATIC CELLS HAS TO PAY US \$10,000 ANNUAL LICENSE FEE.
21 THAT'S PERFECTLY WITHIN THE PARAMETERS OF THE POLICY
22 THAT YOU PUBLISHED, AND THAT'S WHAT I THINK A NUMBER OF
23 THE MEMBERS OF THE PUBLIC, THE TAXPAYERS, OTHER GROUPS
24 ARE ASKING. DON'T LET THAT HAPPEN. DON'T HAVE THAT BE
25 THE PROBLEM THAT BRINGS YOU BACK TO THE TABLE TO SAY WE

1 NOW NEED A RESEARCH USE EXEMPTION.

2 CHAIRMAN PENHOET: JEFF.

3 MR. SHEEHY: AGAIN, I MEAN I THINK THIS IS,
4 YOU KNOW, BEING REDUCED TO A BLACK-AND-WHITE ISSUE,
5 WHETHER WE HAVE IT OR WE DON'T. I DON'T KNOW WHY WE
6 KEEP FINDING OURSELVES AT THIS IMPASSE WHEN EVERYTHING
7 I'VE HEARD FROM INDUSTRY HAS BEEN A WILLINGNESS TO
8 DISCUSS WORKABLE LANGUAGE THAT ACHIEVES OUR AIMS.

9 IF WE HAD HAD LANGUAGE THAT INDUSTRY -- YOU
10 KNOW, THERE'S NOT -- I MEAN I REALLY DO THINK THERE'S A
11 PROCESS HERE. I DO NOT HEAR FROM INDUSTRY THAT THERE'S
12 TOTAL OPPOSITION TO US DOING ANYTHING IN THIS AREA.
13 ALL THEY'RE SAYING IS TRY TO DRAFT LANGUAGE THAT IS
14 NARROW AND LANGUAGE THAT THEY CAN LIVE WITH. AND I
15 HAVEN'T SEEN ANY EVIDENCE THAT THERE ISN'T A
16 POSSIBILITY OF LANGUAGE THAT WILL WORK FOR THEM. AND I
17 DON'T WANT -- DON'T KNOW WHY THIS HAS TO ALWAYS END UP
18 IN THIS ANTAGONISTIC, ADVERSARIAL REALM WHEN I DO THINK
19 THAT THERE IS ROOM FOR COMPROMISE HERE. AND I WOULD
20 LIKE TO EXHAUST THAT BEFORE WE START -- YOU KNOW, I
21 DON'T THINK ANYBODY DISAGREES WITH THE PRINCIPLE, BUT I
22 WOULD LIKE TO NOT EXHAUST THAT.

23 CHAIRMAN PENHOET: WELL, A REMINDER. WE HAVE
24 TO MOVE ON WITH THIS TASK AS WELL. WE HAVE TO MAKE
25 SOME DECISIONS. WE CAN'T LET IT GO ON FOREVER. WE'RE

1 FACING HUNDREDS OF NEW GRANT APPLICATIONS IN OUR NEW
2 RFA. THIS IS AN ISSUE.

3 WE DO HAVE SOME LANGUAGE JUST PRESENTED TO US
4 BY TONY LAKAVAGE FROM APPLIED BIOSYSTEMS WHICH SAYS, IN
5 LICENSING CIRM-FUNDED PATENTED INVENTIONS, GRANTEE
6 ORGANIZATIONS MAY RETAIN THE RIGHT TO PRACTICE THE USE
7 OF THEIR CIRM-FUNDED PATENTED INVENTIONS FOR
8 NONCOMMERCIAL EDUCATIONAL AND BASIC RESEARCH. SO THIS
9 CHANGES THAT WILL TO THEY MAY. THAT'S NOT A
10 REGULATION, BY THE WAY. THAT WOULD JUST BE SOMEWHERE
11 IN THE DRAFT.

12 I DO BELIEVE THERE IS AN INTERMEDIATE
13 POSITION THAT WE MIGHT CONSIDER ALONG THE FOLLOWING
14 LINES. WE COULD SAY THAT THE GRANTEE ORGANIZATIONS
15 THEMSELVES WOULD RETAIN THE RIGHT TO USE THEIR OWN
16 TECHNOLOGY, AND THAT THEY ARE ENCOURAGED TO DO THE REST
17 OF THIS. SO YOU HAVE A SOFTER PART FOR THEIR ABILITY
18 TO LICENSE OTHERS, BUT YOU WOULDN'T HAVE HARD LANGUAGE
19 AROUND THAT. AND THAT WOULD BE A STEP BACK FROM THIS,
20 BUT STILL HAVE PRESERVED -- I GUESS I HAVE TO SPEAK FOR
21 MYSELF HERE. I FIND IT UNIMAGINABLE THAT WE WOULD FUND
22 A UNIVERSITY TO DO SOME WORK AND THEY WOULD, IN TURN,
23 LICENSE THAT EXCLUSIVELY TO SOMEBODY ELSE AND THEY
24 COULDN'T EVEN FOLLOW UP THE PROGRAM WE INVESTED IN WITH
25 THEIR OWN RESEARCH WOULD SEEM ASTOUNDING TO ME. I'M

1 SURE THAT'S SOMETHING THAT'S NORMALLY DEALT WITH IN DUE
2 COURSE.

3 BUT IF YOU WANTED TO FIND AN INTERMEDIATE
4 GROUND, IT WOULD SAY THAT THE ORGANIZATIONS THEMSELVES
5 ARE FREE TO PRACTICE THEIR ART OF THEIR WORK AND THAT
6 THEY MAY, RATHER THAN THEY MUST, LICENSE. THIS DOESN'T
7 SAY THEY MUST. THAT WOULD BE THEIR CHOICE, BY THE WAY.
8 BUT THIS SAYS THEY MAY DO THAT. IT WOULDN'T REQUIRE
9 THEM TO DO IT. IF SOMEBODY IS WORRIED THAT THIS
10 LANGUAGE, AND DUANE DIDN'T SAY THAT EXACTLY, BUT IF
11 YOU'RE WORRIED THAT THIS LANGUAGE FORCES THE GRANTEES
12 TO LICENSE OTHER NONPROFITS, THAT WOULD CLARIFY THAT
13 ISSUE.

14 YOU KNOW, I THINK I'D LIKE TO GET THE SENSE
15 OF THE GROUP ON THESE ISSUES. I THINK WE HAVE THREE
16 POSITIONS THAT I'D LIKE TO CONSIDER. ONE IS WE RETAIN
17 THE LANGUAGE BEFORE YOU. TWO, THE INTERMEDIATE
18 SOLUTION I JUST SUGGESTED, WHICH IS THAT THE
19 UNIVERSITIES THEMSELVES RETAIN THE RIGHT AND THAT WE
20 ENCOURAGE THEM TO MAKE BROADLY AVAILABLE, BUT WON'T
21 FORCE THEM TO DO SO. AND THE THIRD ALTERNATIVE IS TO
22 DROP THIS ALTOGETHER.

23 SO IF WE COULD GET A SENSE OF THE GROUP ON
24 ONE, TWO, OR THREE. ONE IS THIS, TWO IS THE
25 INTERMEDIATE LANGUAGE, AND THREE IS DROP THEIR RESEARCH

1 USE EXEMPTION ENTIRELY FROM THE DOCUMENT. SO MAYBE IF
2 WE CAN START OVER HERE. PHIL, WHICH OF HAVE THOSE
3 THREE IS ACCEPTABLE TO YOU?

4 DR. PIZZO: I'M IN FAVOR OF NO. 1.

5 CHAIRMAN PENHOET: PHIL IS IN FAVOR OF NO. 1,
6 WHICH IS KEEP THIS LANGUAGE. JEANNIE FONTANA.

7 DR. FONTANA: I'M IN FAVOR OF THE FOURTH
8 SUGGESTION, WHICH IS MODIFYING THE LANGUAGE FURTHER
9 UNTIL WE HAVE A GENERAL CONSENSUS.

10 CHAIRMAN PENHOET: I WILL PARAPHRASE. SHE'S
11 IN FAVOR OF MODIFYING THE LANGUAGE EVEN FURTHER. I
12 BELIEVE WE HAVE TO DO THIS TODAY, FOLKS. WE DON'T HAVE
13 ANOTHER MEETING. THIS IS GOING TO DRAG ON TOO FAR
14 BEYOND. WE HAVE TO COME TO A RESOLUTION ON THIS ISSUE.

15 SO IF SOMEBODY WANTS TO WORK ON MORE LANGUAGE
16 WHILE WE'RE DOING OTHER THINGS, WE CAN RETURN TO THIS
17 ISSUE LATER.

18 MR. ROTH: I WOULD SUGGEST THAT, ED. I'M
19 WILLING TO CONSIDER YOUR COMPROMISE, AND I THINK THAT
20 THAT'S FAIR. I WANT TO BE PERFECTLY CLEAR. I WANT THE
21 RESEARCH TO GO AHEAD, BUT I ALSO WANT TO SEE COMMERCIAL
22 PRODUCTS COME OUT OF THIS EARLY STAGE RESEARCH THAT
23 HELPS EVERYBODY. IF IT ENDS UP THAT EVERY INSTITUTION
24 HAS TO GO INTO MANUFACTURING BUSINESS, WE GOT A MESS.
25 AND THAT'S WHAT COULD HAPPEN. THEY COULD EASILY SAY,

1 PHIL, YOU HAVE AN OBLIGATION TO MAKE THOSE PRODUCTS
2 AVAILABLE TO ME AT YOUR COST UNDER THIS LANGUAGE. AND
3 I DON'T THINK YOU WANT THAT IF IT'S --

4 CHAIRMAN PENHOET: THAT'S WHAT OUR LAST
5 POLICY SAID. THAT'S NOT WHAT THIS ONE SAYS.

6 MR. ROTH: I WOULD LIKE TO SEE YOUR LANGUAGE
7 SPELLED OUT. I THINK THAT'S PROBABLY A COMPROMISE.

8 CHAIRMAN PENHOET: DUANE MADE THE POINT THAT
9 IF WE COULD ACTUALLY SPELL OUT THE LANGUAGE OF THE
10 COMPROMISE POSITION WHICH WOULD NOT FORCE.

11 DR. PIZZO: I COULD MOVE TOWARD THAT.

12 CHAIRMAN PENHOET: PHIL PIZZO CAN MOVE IN
13 THAT DIRECTION.

14 MR. SHEEHY: I'D LIKE TO HEAR. WE'VE GOT TWO
15 MEMBERS OF THE PUBLIC --

16 CHAIRMAN PENHOET: WELL, WE'RE GOING TO
17 DISCUSS IT -- GET TO THE PUBLIC WHEN WE GET THERE.

18 MR. SHEEHY: YOU KNOW, I WANT SOMETHING THAT
19 WORKS FOR EVERYBODY. WE DID NOT CONSULT THESE FOLKS IN
20 THE INTERIM. YOU'RE PUTTING A GUN TO MY HEAD AND
21 TELLING ME TO PICK WHEN I ASKED AT THE LAST MEETING
22 THAT WE TALK TO INDUSTRY AND WE TALK TO OTHER
23 STAKEHOLDERS AND COME UP WITH A COMPROMISE, AND WE
24 SAID, NO, WE'RE TAKING IT OUT AND THAT WAS FINE.

25 NOW WE'VE GOT LANGUAGE AND I'M TOLD I HAVE TO

1 DECIDE, AND I WANT TO HEAR FROM STAKEHOLDERS. I'M
2 SORRY. I AM NOT AN INTELLECTUAL PROPERTY ATTORNEY, AND
3 I AM NOT MATERIALLY AFFECTED AS A COMPANY BY THE IMPACT
4 OF THESE RULES. AND I WANT TO HEAR ALL THE INFORMATION
5 I CAN GET BEFORE I MAKE MY DECISION. I'M SORRY.

6 CHAIRMAN PENHOET: I DIDN'T ASK FOR A
7 DECISION. I ASKED FOR THE SENSE OF THE TASK FORCE.
8 THAT'S ALL I ASKED, YOUR SENSE OF WHERE YOUR --

9 MR. SHEEHY: MY SENSE IS WE HAVE A VERY BAD
10 PROCESS ON THIS ISSUE.

11 CHAIRMAN PENHOET: FINE. THAT'S NOT VERY
12 HELPFUL TO THE CONVERSATION, BUT NEVERTHELESS WE'VE GOT
13 YOUR POINT OF VIEW. JEFF SAID -- IT'S NOT VERY
14 HELPFUL -- JEFF SAID THAT HE DOESN'T LIKE THE PROCESS.

15 DR. LOVE: SO I WOULD VOTE THAT WE REMAIN
16 SILENT OR WE USE THIS MEETING TO TRY TO COME UP WITH
17 SOME LANGUAGE THAT CAN MAKE THE BROADEST GROUP OF
18 PEOPLE HERE HAPPY, INCLUDING INDUSTRY IN THE PEOPLE
19 THAT WE'VE HAD HERE. I THINK WE ALL ARE TRYING TO GET
20 TO THE SAME POINT, BUT I AM CONCERNED ABOUT UNINTENDED
21 CONSEQUENCES DOWN THE ROAD.

22 CHAIRMAN PENHOET: IRVINE.

23 DR. BRYANT: I'M (UNINTELLIGIBLE) LIKELY TO
24 BE PASSED, BUT I'M WILLING TO LISTEN TO PEOPLE WHEN
25 SOMETHING APPROPRIATE COMES ALONG.

1 CHAIRMAN PENHOET: PLEASE REPEAT WHAT YOU
2 JUST SAID, SUE.

3 DR. BRYANT: I LIKE THE LANGUAGE WE HAVE, BUT
4 I'M WILLING TO CONSIDER A MODIFICATION TO IT, BUT I
5 ACTUALLY LIKE THIS BECAUSE IT'S SIMILAR TO WHAT ALREADY
6 EXISTS WITH OTHER TYPES OF FUNDING. SO IT PROTECTS
7 BASIC RESEARCH, AND I THINK WE NEED TO DO THAT.

8 DR. STEWARD: I FAVOR NO. 1. I THINK WE NEED
9 TO AT LEAST PUT OUT A PRELIMINARY DECISION ON THIS.
10 NOTHING IS NECESSARILY WRITTEN IN STONE. WE CAN ALWAYS
11 MODIFY THINGS LATER ON, BUT THIS IS THE ONE THAT I
12 THINK IS MOST LIKELY TO ADVANCE OUR ABILITY TO DO THE
13 RESEARCH THAT WE'RE TRYING TO DO.

14 CHAIRMAN PENHOET: OKAY. IS THERE SOMEONE
15 ELSE THERE? FRANCISCO PRIETO IN SACRAMENTO.

16 DR. PRIETO: YEAH. COUPLE OF COMMENTS. I
17 HAVE SOME CONCERN ABOUT THE LINE ON MARCH-IN RIGHTS AS
18 A REMEDY IF WE FIND A PROBLEM DOWN THE ROAD. AND
19 THERE'S A PUTATIVE CONNOTATION AT LEAST OF THAT, THAT
20 YOU HAVE FAILED TO MEET YOUR OBLIGATIONS AND,
21 THEREFORE, WE'RE STEPPING IN AND TAKING THIS AWAY FROM
22 YOU. SO I'D RATHER SEE OUR INTENTIONS VERY CLEAR IN
23 THE POLICY. AND I THINK THAT I WOULD FAVOR SOME SORT
24 OF A COMPROMISE WITH ACCEPTABLE LANGUAGE.

25 AND JUST TO RESPOND TO WHAT JEFF HAS SAID, I

1 THINK THAT THE PROCESS HAS BEEN PRETTY OPEN. AND THE
2 STAKEHOLDERS HAVE KNOWN ALL ALONG THAT THEY'VE BEEN
3 FREE TO ADD THEIR COMMENTS AND BRING THEIR COMMENTS TO
4 US. I THINK THAT'S WHAT WE'RE DOING TODAY. SO I
5 REALLY DON'T FEEL ANYONE HAS BEEN SHUT OUT.

6 CHAIRMAN PENHOET: OKAY. ANY FURTHER
7 COMMENTS FROM THE BOARD? I THINK THE GENERAL SENTIMENT
8 IS TO TRY TO DO SOMETHING IN THIS AREA, BUT WE'D LIKE
9 TO HEAR NOW FROM THE AUDIENCE UNLESS THERE ARE MORE
10 COMMENTS FROM THE BOARD.

11 MS. LAMBERT: WELL, OUR POINT IS JUST THAT
12 JOHN SIMPSON AND I HAVE -- THIS IS JANET LAMBERT FROM
13 INVITROGEN. I GUESS I JUST WANT TO MAKE THE COMMENT
14 WHEN WE WERE STARTING TO CONSIDER ALTERNATIVES, THAT IF
15 THERE IS A PROCESS WHEREBY WE'RE THROWING ALTERNATIVES
16 INTO THE MIX, WE DO HAVE ANOTHER ONE WE'D LIKE TO THROW
17 INTO THE MIX.

18 CHAIRMAN PENHOET: FINE. GOOD. CAN YOU READ
19 IT?

20 MS. LAMBERT: SO WE WOULD PROPOSE A SLIGHTLY
21 DIFFERENT APPROACH. AS WE'VE SAID MANY TIMES AND I
22 WON'T REPEAT AGAIN, WE HAVE CONCERNS THAT APPROACHING
23 THE ISSUE OF ACCESS, MAKING SURE THAT YOUR RESEARCHERS
24 AND OTHER RESEARCHERS HAVE ACCESS TO YOUR IP BY
25 CREATING PATENT CARVE-OUTS IS A COMPLICATED WAY TO GO.

1 SO WE WOULD PROPOSE MAYBE JUST GOING AT IT IN A
2 STRAIGHTFORWARD FASHION WITH THE FOLLOWING, JUST TO
3 CREATE A WHOLE NEW SECTION, STRIKE THIS LANGUAGE,
4 CREATE A NEW SECTION IN THE PLACE OF THE RUE THAT CAME
5 OUT CALLED ACCESS TO CIRM-FUNDED IP.

6 THAT SECTION WOULD SAY, "GRANTEE
7 ORGANIZATIONS AGREE TO MAKE THEIR CIRM-FUNDED IP
8 READILY ACCESSIBLE ON REASONABLE TERMS DIRECTLY OR
9 THROUGH LICENSEES TO OTHER GRANTEE ORGANIZATIONS FOR
10 NONCOMMERCIAL, EDUCATIONAL, AND BASIC RESEARCH PURPOSES
11 UPON REQUEST FROM A GRANTEE ORGANIZATION."

12 IN THAT WAY, I THINK YOU MAKE SURE THAT
13 NOBODY IS HOARDING THEIR STUFF, THAT THEY'RE NOT
14 CHARGING TOO MUCH FOR IT, BUT YOU PRESERVE THE
15 POSSIBILITY THAT COMMERCIALIZATION MIGHT BE THE BEST
16 WAY TO GET AT THAT AND MIGHT GET YOU SOME ROYALTIES,
17 AND IT DOESN'T GET YOU INTO THIS KIND OF STICKY WICKET
18 OF NATIONAL PATENT POLICY WHICH PEOPLE ARE SO HEAVILY
19 INVESTED IN BECAUSE OF THE PRECEDENT SETTING NATURE OF
20 IT. SO I THINK IT KIND OF DOES WHAT YOU WANT TO DO
21 WITH THE MINIMUM OF KIND OF UNINTENDED CONSEQUENCES.

22 DR. HALL: I THINK THE PROBLEM WITH THAT IS
23 REASONABLE TERMS.

24 CHAIRMAN PENHOET: WHO'S GOING TO DECIDE?

25 DR. HALL: WHO'S GOING TO DECIDE WHAT

1 REASONABLE TERMS ARE? I THINK THAT WON'T DO FOR GOOD
2 REGULATORY LANGUAGE.

3 CHAIRMAN PENHOET: WE'LL THROW IT UP AS A
4 SUGGESTION MADE IN GOOD FAITH.

5 MS. LAMBERT: REASONABLE TERMS IS IN LOTS OF
6 OTHER PARTS OF THE REGULATION ALREADY.

7 CHAIRMAN PENHOET: I'M SORRY?

8 MS. LAMBERT: JUST TO THE COMMENT THAT
9 REASONABLE TERMS IS A POOR REGULATORY TERM, THAT MAY OR
10 MAY NOT BE THE CASE, BUT IT IS A PHRASE THAT'S USED IN
11 OTHER PARTS OF THE REGULATION.

12 CHAIRMAN PENHOET: SHE POINTS OUT WE'VE USED
13 THAT TERM IN OTHER PARTS OF OUR REGULATION, WHICH IS
14 ALSO IN FEDERAL GOVERNMENT GUIDELINES IN VARIOUS
15 PLACES. WHILE WE'RE WORKING ON THAT --

16 DR. LOVE: JANET, ARE YOU CONCERNED -- WOULD
17 YOU BE CONCERNED THAT THAT DEFINITION OF REASONABLE
18 TERMS CREATES AN ISSUE FOR YOU IN TERMS OF LIABILITY
19 EXPOSURE OF WHETHER OR NOT YOU'RE CHARGING A REASONABLE
20 PRICE?

21 MS. LAMBERT: NO, I DON'T LOVE IT. YOU KNOW,
22 I THINK WE'RE TRYING TO, KIND OF IN THE SPIRIT OF
23 GETTING THIS DONE, ACCEPT THINGS THAT WE DON'T LIKE,
24 BUT WE THINK WE'RE ALL KIND OF TRYING TO MOVE IN THE
25 SAME DIRECTION ON. WE IN THE RESEARCH TOOLS BUSINESS,

1 WE MAKE OUR MONEY BY PROVIDING PRODUCTS TO LOTS AND
2 LOTS AND LOTS OF PEOPLE, SO WE FEEL WE'LL BE ABLE TO
3 MAKE A CASE SHOULD THIS ISSUE OF REASONABLE TERMS COME
4 UP. AND I THINK WE APPRECIATE THAT, YOU KNOW, IT'S
5 SORT OF TWO SIDES OF THE SAME COIN. AT LEAST
6 REASONABLE TERMS GIVES YOU SOME FLEXIBILITY TO HAVE A
7 CONVERSATION.

8 WHAT WORRIES US ABOUT SOME OF THE LANGUAGE
9 THAT'S BEEN PROPOSED, THAT IN CASES WHERE THERE NEEDS
10 TO BE A CONVERSATION, THERE CAN'T BE ONE IF YOU FIX IT.

11 CHAIRMAN PENHOET: MAY I ASK YOU ANOTHER
12 QUESTION? DO YOU OBJECT TO THE FIRST PART OF THE
13 MIDDLE GROUND PROPOSAL THAT I MADE, WHICH IS THAT THE
14 UNIVERSITIES RETAIN FOR THEMSELVES THE RIGHT TO
15 PRACTICE THE ART IN THEIR OWN INSTITUTIONS?

16 MS. LAMBERT: NO, I DON'T OBJECT TO THAT.

17 CHAIRMAN PENHOET: YOU DON'T OBJECT TO THAT,
18 SO THERE MIGHT BE A COMPROMISE THAT SAYS THE FIRST PART
19 SAYS THAT, THE SECOND PART SAYS SOMETHING ALONG THE
20 LINES THAT YOU JUST ARTICULATED.

21 UNIDENTIFIED SPEAKER: COULD YOU SPEAK UP?

22 CHAIRMAN PENHOET: WE'RE TRYING TO FIND A
23 HYBRID SOLUTION BETWEEN THE TWO PROPOSALS.

24 MS. LAMBERT: I THINK MR. LAKAVAGE'S
25 LANGUAGE, FOR EXAMPLE, PLUS OURS SORT OF DOES THAT, OR

1 YOU COULD GET -- I THINK TONY'S IS THE SAME AS THE
2 FIRST PART OF WHAT YOU'RE PROPOSING THERE. I WANT TO
3 LOOK AT IT ONE MORE TIME.

4 CHAIRMAN PENHOET: MAYBE WE COULD SEND A
5 LITTLE SIDE FORCE OFF TO WORK OUT SOME LANGUAGE. MARY,
6 IF YOU WOULDN'T MIND DOING THAT WITH JANET AND PERHAPS
7 KEN AND JOHN AND SCOTT SHOULD GO, AND WE NEED TO GET ON
8 WITH THIS MEETING, SO HOPEFULLY YOU GUYS CAN WORK OUT
9 SOMETHING IN THE CONTEXT OF THIS MEETING.

10 JEFF, I'D LIKE TO ASSURE YOU THAT THERE WERE
11 NO CLANDESTINE MEETINGS.

12 MR. SHEEHY: FOR THE RECORD, I TOOK IT UPON
13 MYSELF WHEN I GOT THE PUBLIC COMMENTS TO CALL THE
14 ATTORNEY WHO GOT IN TOUCH WITH JANET, AND I TALKED TO
15 JOHN. I SUGGESTED THAT JANET TALK TO JOHN. YOU KNOW,
16 I MEAN I DON'T REALLY -- I MEAN MAYBE THAT'S MY JOB IS
17 BRINGING THE STAKEHOLDERS TOGETHER, BUT I KIND OF WOULD
18 HAVE LIKED TO HAVE PROCEEDED THROUGH THE CIRM PROCESS.

19 CHAIRMAN PENHOET: THANK YOU FOR DOING IT.

20 MR. SHEEHY: AND WE GOT LANGUAGE TOO.

21 MR. TAYMOR: COULD I ASK ONE CLARIFYING
22 QUESTION?

23 CHAIRMAN PENHOET: KEN TAYMOR.

24 MR. TAYMOR: I THINK THAT PART OF THE SOURCE
25 OF THE DISAGREEMENT OR CONCERNS ALSO STEMS FROM

1 UPSTREAM VERSUS DOWNSTREAM INVENTIONS. AND CIRM WILL
2 BE CONTROLLING TO SOME EXTENT WHAT IT'S AIMING TO FUND
3 IN TERMS OF UPSTREAM OR DOWNSTREAM INVENTIONS, AND
4 EARLY ON YOU'RE GOING TO BE LOOKING FOR INNOVATION
5 GRANTS. I DON'T KNOW IF IT'S PRACTICAL, BUT THERE MAY
6 BE SOMETHING THAT COULD BE DONE AT THE STAFF OR GRANT
7 LEVEL WHICH SAID THAT IN SOME CASES, BECAUSE WE FEEL
8 THAT THIS IS GOING TO BE DOING VERY UPSTREAM, EARLY
9 STAGE, FOUNDATIONAL TYPE OF RESEARCH, THAT MIGHT FALL
10 UNDER THE WHATEVER SORT OF BROADER EXEMPTION, RESEARCH
11 USE EXEMPTION RULE, AND THAT OTHER RESEARCH,
12 PARTICULARLY AS THE YEARS PROGRESS AND THERE'S RESEARCH
13 THAT IS MORE OF APPLICATION FURTHER DOWNSTREAM, THAT
14 THAT WOULD BE LESS OPEN TO THIS RESEARCH USE EXEMPTION
15 WHICH SEEMS TO BE OF GREAT CONCERN TO ONE ASPECT OF THE
16 COMMERCIALIZATION INDUSTRY. IT MAY BE AN IMPRACTICAL
17 SOLUTION, BUT SEEMS TO BE PART OF THE PROBLEM.

18 CHAIRMAN PENHOET: I THINK A BIG PART OF THAT
19 PROBLEM, KEN, FROM OUR WORK IS PEOPLE HAVE A VERY HARD
20 TIME DISTINGUISHING UPSTREAM AND DOWNSTREAM BECAUSE
21 SOMETIMES UPSTREAM BECOMES DOWNSTREAM AND VICE VERSA.
22 AS YOU REMEMBER, WE ALSO HAD SOME DISCUSSIONS ABOUT
23 EXEMPTION FOR RESEARCH ON AN INVENTION RATHER THAN
24 RESEARCH WITH AN INVENTION.

25 IN TALKING TO JAPANESE AND EUROPEAN SOURCES,

1 WE FOUND THAT THEY'RE HAVING A HARD TIME DISTINGUISHING
2 WHEN SOMEBODY IS DOING RESEARCH ON AN INVENTION OR WITH
3 AN INVENTION. SO PEOPLE ARE HAVING A HARD TIME MAKING
4 THIS CALL. AND DUANE ROTH.

5 MR. ROTH: ED, I HAVE ONE MORE COMMENT ON
6 THIS SECTION. IF YOU LOOK AT NO. 100306.

7 CHAIRMAN PENHOET: UNDER TAB 8, PAGE 9?

8 MR. ROTH: THE FIRST TWO PARAGRAPHS ARE
9 GENERAL PARAGRAPHS AND INCLUDES THIS LANGUAGE WE'RE
10 TALKING ABOUT, BUT C, D, E ALL USE THE WORD "EXCLUSIVE"
11 BECAUSE WE'VE MOVED NOW FROM NONEXCLUSIVE, AND THEY'RE
12 ALL PROVISIONS OF EXCLUSIVE LICENSES. AND I BELIEVE
13 THAT F, G, AND H SHOULD ALSO HAVE THE WORD "EXCLUSIVE"
14 IN IT BECAUSE THESE ARE ALL -- MANY OF THESE THINGS
15 WOULDN'T MAKE SENSE IF IT'S NONEXCLUSIVE. YOU DON'T
16 HAVE TO WORRY ABOUT THESE THINGS BECAUSE YOU CAN
17 LICENSE IT TO AS MANY PEOPLE AS YOU WANT.

18 WHEN YOU GO TO AN EXCLUSIVE LICENSE ON A
19 TOOL, I THINK ALL THESE PROVISIONS APPLY. I WONDER IF
20 THAT'S NOT AN OVERSIGHT ON LEAVING OUT ON F, G, H THE
21 WORD "EXCLUSIVE."

22 CHAIRMAN PENHOET: I BELIEVE YOU'RE RIGHT
23 FROM READING THE LANGUAGE AGAIN. SO THAT WAS A --
24 WE'LL GET BACK TO YOU.

25 OKAY. HAVE WE GOT A SUBGROUP WHO'S WILLING

1 TO GO WORK OUT SOME LANGUAGE? SCOTT IS GOING TO DRAFT
2 SOMETHING AND CIRCULATE IT.

3 DR. MAXON: HE'S GOT ALL THE FEEDBACK THAT WE
4 JUST ASSEMBLED. HE'S GOT TONY'S, HE'S GOT JANET, AND
5 HE'S GOT THE LANGUAGE ORIGINALLY. HE'S GOING TO TYPE
6 SOMETHING, AND HE'S GOING TO SHOW IT TO ALL PEOPLE
7 INVOLVED.

8 CHAIRMAN PENHOET: BACK THERE IN THE CORNER.
9 MEANTIME WE'LL MOVE ON.

10 DR. PRIETO: A REQUEST FOR OTHER LOCATIONS.
11 WHEN LANGUAGE IS DONE, COULD IT BE SENT TO US AS AN
12 E-MAIL?

13 CHAIRMAN PENHOET: YES, IT CAN.

14 DR. PRIETO: THANK YOU.

15 MR. GILENWATER: THIS IS TODD GILENWATER WITH
16 THE CALIFORNIA HEALTHCARE INSTITUTE. JUST BASICALLY A
17 QUESTION OF PROCEDURE. AS YOU KNOW FROM OUR COMMENTS,
18 WE ALSO SUGGESTED SOME LANGUAGE AS WELL.

19 PROCEDURALLY, IF WE'RE TALKING ABOUT
20 MODIFICATIONS TO THIS LANGUAGE, WHAT IS THE PROCESS
21 LEGALLY MOVING FORWARD ON OPENING UP YET ANOTHER 15-DAY
22 COMMENT PERIOD ON WHATEVER CONSENSUS MODIFICATION
23 LANGUAGE IS DEVELOPED TODAY?

24 CHAIRMAN PENHOET: WE WILL OPEN UP ANOTHER
25 15-DAY COMMENT PERIOD.

1 MR. GILENWATER: THANK YOU.

2 MR. SIMPSON: TO THE POINT THAT DUANE ROTH
3 JUST RAISED ABOUT EXCLUSIVITY, I THINK YOU'RE LACKING A
4 DEFINITION OF EXCLUSIVE, WHICH YOU NEED IN THE
5 REGULATION. OTHERWISE YOU'RE LEFT IN A POSITION WHERE
6 SOMEONE COULD, FOR INSTANCE, LICENSE SOMETHING IN THE
7 UNITED STATES, IN EUROPE, AND THEN SAY, WELL, IT'S NOT
8 AN EXCLUSIVE LICENSE BECAUSE IT'S STILL AVAILABLE IN
9 SOUTH AMERICA. AND PRESUMABLY, THEN, ALL OF YOUR
10 PROVISIONS FOR ACCESS AND SO ON WOULDN'T KICK IN
11 BECAUSE IT'S NOT AN EXCLUSIVE LICENSE. SO I THINK YOU
12 NEED SOME SORT OF DEFINITION OF EXCLUSIVITY, AND I
13 BELIEVE THAT WAS IN THE WRITTEN PUBLIC COMMENTS, SO I
14 ASSUME YOU'D BE CONSIDERING THAT.

15 CHAIRMAN PENHOET: WELL, WE'RE LIKELY TO HAVE
16 A 15-DAY COMMENT PERIOD, SO WE CAN GO BACK. AND I
17 THINK YOU MAKE A GOOD POINT.

18 OKAY. IF WE CAN MOVE ON TO THE MAIN PURPOSE
19 OF TODAY'S MEETING, BUT THANKS, EVERYONE, FOR THEIR
20 PATIENCE HERE.

21 WE HAVE A SLIDE PRESENTATION THAT WE PUT
22 TOGETHER AND SENT TO ALL OF YOU, WHICH MELISSA IS
23 ATTEMPTING TO RESURRECT. THIS DOES FEEL A LITTLE BIT
24 LIKE A CHURCH. I SHOULD HAVE GIVEN MY COMMENTS FROM UP
25 THERE.

1 OKAY. WHO HAS CONTROL OF THE -- IF YOU THINK
2 WHAT WE'VE JUST DONE WAS HARD, WAIT, WAIT FIVE MINUTES.
3 OKAY. TO REMIND YOU, THE TIMELINE WE WOULD LOVE TO TRY
4 TO FOLLOW, WE'RE HERE ON AUGUST 29TH, A LITTLE BIT LATE
5 BECAUSE WE HAD TO CANCEL THE MEETING A COUPLE WEEKS
6 AGO. WE HOPE TO BE ABLE TO PRESENT THE FIRST DRAFT OF
7 OUR WORK TO THE OCTOBER 11TH ICOC BOARD MEETING. IN
8 ORDER TO DO THAT, WE WILL NEED ANOTHER MEETING OF THIS
9 TASK FORCE. AND THE PREFERRED DATE, BY ME ANYWAY, IS
10 SEPTEMBER 21ST, AND I THINK A NUMBER OF YOU HAVE BEEN
11 POLLED ABOUT YOUR AVAILABILITY ON THAT DATE. AND THEN
12 WE WILL PRESENT IN OCTOBER.

13 IF WE'RE NOT READY IN OCTOBER, WE WOULD
14 THEN -- THE NEXT BOARD MEETING IS NOT UNTIL DECEMBER.
15 THE FIRST ROUND OF GRANTS, I BELIEVE, IS INTENDED FOR
16 NOT-FOR-PROFIT ORGANIZATIONS, NOT FOR COMPANIES, SO WE
17 STILL DON'T INTERFERE WITH THE TIMELINE EVEN IF THIS
18 DRAGS ON TO NEXT YEAR. BUT I THINK IT'S INCUMBENT UPON
19 US TO KEEP MOVING FORWARD HERE.

20 SO TODAY, THE AGENDA, YOU KNOW WHAT IT IS.
21 WE DID JUST COMPLETE -- NO, WE HAVEN'T COMPLETED.
22 WE'RE IN THE PROCESS OF COMPLETING ITEM 1, AND THE
23 SECOND PART IS THE PART WE'RE NOW ENGAGED IN, WHICH IS
24 THE FOR-PROFIT. SO THE NEXT. WE'LL SKIP THIS ONE AND
25 THE NEXT ONE.

1 START INTO THE MEETING. HERE IS WHAT WE'VE
2 DONE. LET'S SEE. ONE OF OUR BOARD MEMBERS HAS NOW
3 DECIDED TO ENGAGE IN THE DRAFTING PROCESS. HERE'S
4 WHAT'S HAPPENED SO FAR. WE HAVE HAD MANY PRESENTATIONS
5 BY BOTH EXPERTS AND STAKEHOLDERS. WE'VE DONE A LOT OF
6 RESEARCH ON VARIOUS MODELS THAT OTHER FUNDING
7 ORGANIZATIONS USE WHEN THEY FUND FOR-PROFIT ENTITIES.

8 WE HAVE BEGUN THE DEVELOPMENT OF THE
9 PRINCIPLES OF THE POLICY, AND WE WILL DISCUSS THOSE IN
10 SOME GREAT DEGREE TODAY.

11 THE NEXT STEP WILL BE TO DRAFT THE POLICY,
12 AND THAT'S WHAT WE HOPE TO HAVE A FIRST DRAFT IN FRONT
13 OF YOU ON SEPTEMBER 21ST AND TO BE ABLE TO TAKE TO THE
14 ICOC ON OCTOBER 11TH. AND THEN THE REST OF THIS IS THE
15 USUAL STUFF WE HAVE TO GO THROUGH IN ORDER TO FINISH
16 THE PROCESS.

17 NEXT SLIDE IS JUST SIMPLY A SUMMARY OF WHAT
18 WE HAVE HEARD FROM VARIOUS DIFFERENT CONSTITUENCIES.
19 WE HAD A MARCH 29TH IP TASK FORCE MEETING WHERE WE
20 HEARD FROM REPRESENTATIVES OF THE FEDERAL GOVERNMENT,
21 FROM A PRIVATE FOUNDATION FUNDING BIOMEDICAL RESEARCH,
22 FROM TWO COMPANIES, AND FROM A RESEARCH INSTITUTE, THE
23 FIRST GROUP. WE THEN HAD THE SECOND IP TASK FORCE
24 MEETING IN LOS ANGELES WHERE WE HEARD FROM THE PEOPLE
25 YOU CAN SEE DOWN THERE. AGAIN, A MIXTURE OF COMPANY

1 REPRESENTATIVES, REPRESENTATIVES OF THE PUBLIC, BEING
2 JOHN SIMPSON, AND FROM JULIE MEIER WRIGHT, WHO WAS
3 FORMERLY HEAD OF TRADE AND COMMERCE IN THE STATE OF
4 CALIFORNIA AND IS NOW HEAD OF THE SAN DIEGO REGIONAL
5 ECONOMIC DEVELOPMENT COMMISSION.

6 AND THEN ON JULY 25TH, ALTHOUGH NOT
7 SPECIFICALLY AIMED AT OUR WORK, BUT AIMED PRIMARILY AT
8 THE WORK OF THE STRATEGIC PLANNING GROUP, WE HAD A
9 MEETING IN SAN FRANCISCO WHERE WE HEARD FROM A NUMBER
10 OF REPRESENTATIVES OF THE COMMERCIAL SECTOR. YOU SEE
11 THEIR NAMES HERE. I THINK IT WAS A VERY GOOD MEETING
12 WITH SOME VERY CLEAR MESSAGES, WE THOUGHT, FROM THAT
13 GROUP MOVING FORWARD.

14 YOU KNOW, I MIGHT ADD AT THIS POINT IN TIME I
15 BELIEVE THAT WE HAVE TO BALANCE SEVERAL INTERESTS IN
16 THIS DISCUSSION WE'RE ABOUT TO HAVE ABOUT WHAT OUR
17 POLICY SHOULD BE FOR THE PROFIT-MAKING SECTOR. BUT IN
18 DOING SO, I THINK WE HAVE TO KEEP IN MIND, NO. 1, THAT
19 THE LONG-TERM GOAL HERE IS TO BENEFIT PATIENTS. AND
20 NO. 2, THAT HAVING SAID THAT, WE DO HAVE TO PROVIDE
21 SOME FORM OF REMUNERATION TO THE STATE IN TERMS OF THE
22 DIRECT PAYBACK TO THE STATE FOR THE INVESTMENT WE MAKE
23 IN BOTH THE NOT-FOR-PROFIT AND THE FOR-PROFIT SECTOR.

24 AND THE THIRD ONE IS, YOU KNOW, I BELIEVE
25 IT'S ENTIRELY POSSIBLE THAT, GIVEN THE TIMING OF A

1 LIKELY CHANGE IN FEDERAL POLICY, ETC., THAT THE LONGEST
2 STANDING BENEFIT OF PROP 71 TO THE STATE OF CALIFORNIA
3 MAY BE A VIGOROUS FOR-PROFIT, FOR LACK OF A BETTER
4 TERM, BIOTECH COMMUNITY IN THE STATE. SO IN DEVELOPING
5 THESE REGULATIONS, WE HAVE TO KEEP THE BALANCE OF ALL
6 THOSE THREE THINGS IN MIND GOING FORWARD. ON THE ONE
7 HAND, ADVANCING THE MEDICINE. ON THE OTHER HAND,
8 PROVIDING RETURN TO THE STATE. BUT IN THINKING THROUGH
9 THE RETURN TO THE STATE, HAVE TERMS WHICH ARE FAIR, BUT
10 DON'T SIGNIFICANTLY INHIBIT COMPANIES FROM MOVING TO
11 CALIFORNIA TO TAKE ADVANTAGE OF PROP 71.

12 SO WE'VE REALLY STRUGGLED WITH HOW TO STRIKE
13 THAT BALANCE, AND WE WILL STRUGGLE FURTHER THIS
14 AFTERNOON, I'M SURE.

15 WE SENT YOU THIS MATRIX. AND, AGAIN, WE HAVE
16 TO THANK MARY FOR AN ENORMOUS AMOUNT OF HARD WORK. IT
17 TURNS OUT NOBODY HAS EVER DONE THIS BEFORE, SO LOTS OF
18 PEOPLE ARE INTERESTED IN SEEING THE FRUITS OF MARY'S
19 LABOR HERE TO GET IN A FEW SHEETS WHAT VARIOUS
20 ORGANIZATIONS DO.

21 WE HAVE BROKEN THIS DOWN INTO THREE
22 CATEGORIES: BASIC RESEARCH GRANTS AND PRECLINICAL WORK
23 AND CLINICAL WORK. AND AS YOU CAN SEE HERE, UNDER
24 BASIC RESEARCH GRANTS, THE SIMPLEST PROPOSAL ANYWHERE
25 ON THE PLANET, I BELIEVE, IS THE NEW JERSEY PROPOSAL.

1 ANYBODY THAT COMMERCIALIZES A NEW JERSEY-FUNDED PROGRAM
2 OF ONE SORT OR ANOTHER -- YOU GUYS HAVE THE SLIDES IN
3 FRONT OF YOU, BY THE WAY, IN REMOTE LOCATIONS? PIPE
4 UP, THEN, IF I CONFUSE YOU ANYWHERE ALONG THE WAY.

5 WE'RE ON THE FIRST OF THE MATRIX SLIDES. NEW
6 JERSEY HAS A FLAT 1 PERCENT THEY CHARGE ON EVERYTHING
7 THAT HAPPENS WITH THINGS THAT THEY FUNDED. THE NIH HAS
8 VERY FEW REQUIREMENTS OF GRANTEES FOR BASIC RESEARCH,
9 BUT THEY MUST REPORT THEIR INVENTIONS. THEY HAVE AN
10 OBLIGATION TO MAKE -- TO PATENT THEIR INVENTIONS IF
11 THEY'RE PATENTABLE. AND THEY DO HAVE MARCH-IN RIGHTS
12 IF THE IP IS NOT EXPLOITED. BUT I THINK, AS KEN TAYMOR
13 RIGHTLY POINTED OUT, THEY'VE ALMOST NEVER BEEN USED.
14 BUT THEY'RE LISTED THERE. AND THEY DO HAVE SOME LEVEL
15 OF PARTICIPATION IN THE EXECUTION OF THESE PROGRAMS BY
16 THE COMPANY THAT THEY FUND.

17 MR. SHEEHY: WOULD YOU CLARIFY THIS LAST?
18 IT'S NOT CLEAR TO ME WHAT THAT MEANS.

19 CHAIRMAN PENHOET: PARTICIPATION? LOTS OF
20 DIFFERENT THINGS. THE WELLCOME FOUNDATION GETS ON THE
21 BOARDS OF DIRECTORS OF COMPANIES WHERE THEY FUND
22 PROJECTS. JDRF FORMS A JOINT STEERING COMMITTEE WHERE
23 JDRF REPRESENTATIVES AND COMPANY REPRESENTATIVES
24 ACTUALLY WORK ON THE PROJECT TOGETHER. THE NIH MEETS
25 WITH THEIR GRANTEES REGULARLY TO MAKE SURE THEY'RE

1 MAKING PROGRESS AND ASSESS THE PROGRESS, ETC. SO IT'S
2 A VARIETY OF DIFFERENT WAYS, SO IT'S A CATCHALL TERM,
3 JEFF, AND IT GOES ALL THE WAY FROM STAYING IN TOUCH TO
4 ACTUALLY SERVING ON THE BOARD OF DIRECTORS IN ALMOST
5 EVERY ONE.

6 JDRF, WE TALKED ABOUT SEVERAL TIMES, HAS
7 REMUNERATIONS THAT COMES IN THE FORM OF ROYALTIES.
8 OFTENTIMES IN THEIR CASE THOSE ROYALTIES ARE CAPPED AT
9 A CERTAIN MULTIPLE OF THE INVESTMENT THEY MADE IN THE
10 TECHNOLOGY. THREE TO 5 X WOULD BE A TYPICAL THING. I
11 MUST SAY, IN HEARING FROM THE BUSINESS COMMUNITY, THE
12 MOST CONSISTENT MESSAGE HAS BEEN WE'RE WILLING TO
13 CONSIDER REMUNERATION. WE BELIEVE IT'S PART OF THE
14 DEAL THAT WE PAY BACK, BUT THEY WOULD LIKE TO HAVE
15 THEIR OBLIGATIONS DESCRIBED -- NOT BE OPEN-ENDED, BUT
16 BE CAPPED IN SOME WAY, SHAPE, OR FORM. THAT'S ONE OF
17 THE THINGS WE'VE HEARD.

18 THE WELLCOME TRUST IN SOME WAYS IS THE MOST
19 AMBITIOUS. THEY GET REVENUE AND EQUITY SHARING. THEY
20 HAVE TO GIVE THEIR CONSENT TO AN ORGANIZATION TO
21 EXPLOIT THE IP. AND THEY SERVE, AS I SAID, ON THE
22 BOARD OF DIRECTORS. THEY ARE VERY DEEPLY INVOLVED IN
23 THIS. WE HAVE HEARD THAT SOME COMPANIES IN THE UK
24 WON'T TAKE THEIR MONEY AS A RESULT. THEY SEE THEM AS
25 TOO INTRUSIVE. SO THAT'S PROBABLY THE MOST INTRUSIVE

1 MODEL THAT WE FOUND.

2 CYSTIC FIBROSIS FOUNDATION IS SOMEWHERE IN
3 THE MIDDLE. AS YOU CAN SEE, ALMOST ALL OF THESE HAVE
4 MARCH-IN RIGHTS IF THE IP IS NOT ENFORCED. THAT'S A
5 COMMON FEATURE OF EVERY ONE.

6 NEXT SLIDE. THERE'S THE PRECLINICAL OR
7 TRANSLATIONAL RESEARCH GRANTS. I DON'T WANT TO READ
8 THE WHOLE TABLE TO YOU, BUT SIMPLY TO INDICATE THAT
9 THERE IS NO UNIFORM POLICY ABOUT THIS. ALMOST ALL
10 THESE ORGANIZATIONS DO IT DIFFERENTLY. EXCEPT FOR THE
11 FEDERAL GOVERNMENT, VIRTUALLY ALL OF THEM EXPECT SOME
12 FORM OF REMUNERATION.

13 AND IN THE CLINICAL TRIALS CASE, AGAIN, WITH
14 THE THREE ORGANIZATIONS WHO HAVE THE MOST EXPERIENCE,
15 JDRF, WELLCOME TRUST, AND CYSTIC FIBROSIS, THERE IS A
16 ROYALTY. AND THESE THINGS ARE NEGOTIATED ON A
17 CASE-BY-CASE BASIS.

18 SO, YOU KNOW, I THINK IT'S BEEN A USEFUL
19 EXERCISE, PROBABLY GUIDES US IN SOME WAYS, BUT THE
20 SPECTRUM OF REMUNERATION, SPECTRUM OF ENGAGEMENT, AND
21 THE SPECTRUM OF WHAT GETS FUNDED IS SO BROAD.
22 BASICALLY HANDS OFF PRETTY MUCH FROM THE FEDERAL
23 GOVERNMENT TO VERY DEEP PARTICIPATION BY THE WELLCOME
24 AND UK, THAT I THINK THIS IS VALUABLE TO GIVE US SOME
25 PERSPECTIVE ON WHAT'S ACCEPTABLE AT LEAST TO SOME

1 COMPANIES.

2 MELISSA REMINDS ME THAT THIS TABLE IS FOR OUR
3 PURPOSES ONLY. LOTS OF PEOPLE ARE INTERESTED IN THIS
4 TABLE. WE WANT TO MAKE SURE IT'S A HUNDRED PERCENT
5 ACCURATE, SO, PLEASE, IF YOU HAVE THIS, DON'T
6 DISTRIBUTE IT TO ANYONE ELSE. IT'S FOR YOUR WORK IN
7 THIS COMMITTEE MEETING ONLY. IT'S NOT TO BE
8 DISTRIBUTED ELSEWHERE.

9 DR. FONTANA: ARE YOU TAKING QUESTIONS NOW?

10 CHAIRMAN PENHOET: I'M TRYING TO GO THROUGH A
11 FAIR AMOUNT OF THIS PRESENTATION SO WE CAN SORT OF GET
12 A GENERAL VIEW OF THE SUBJECT AND THEN OPEN IT UP FOR
13 DISCUSSION, IF YOU DON'T MIND, JEANNIE. WE'LL COME
14 BACK TO ALL THESE POINTS.

15 HERE ARE THE THEMES WE'VE HEARD. THERAPY
16 DEVELOPMENT IS RISKY, LENGTHY, AND EXPENSIVE. THE
17 TUFTS STUDY NOW SAYS EIGHT OR \$900 MILLION FOR EVERY
18 SUCCESSFUL DRUG. A BIG CHALLENGE FOR US IS THAT A
19 ONE-SIZE-FITS-ALL APPROACH TO THIS IS NOT LIKELY TO BE
20 WORKABLE FOR US AND THAT CIRM WILL HAVE TO BUILD A
21 SMALL STAFF TO ENGAGE EACH AND EVERY COMPANY THAT GETS
22 A GRANT OR A CONTRACT FROM US AND FORMALIZE THAT. TO A
23 GREAT DEGREE, WE'LL BE DOING A GREAT SERVICE TO THE
24 CIRM GOING FORWARD IF WE CAN MAKE AS MANY OF THESE
25 THINGS SIMPLIFIED AND CODIFIED AS POSSIBLE.

1 HAVING SAID THAT, WE HAVE BEEN TOLD BY EVERY
2 ORGANIZATION THAT EVERY DEAL THEY MAKE WITH A COMPANY
3 IS ACCOMPANIED BY A NEGOTIATION AND LEGAL AGREEMENT,
4 AND EACH ONE IS DIFFERENT THAN THE OTHER.

5 TO GIVE YOU SOME PERSPECTIVE OF THE
6 CHALLENGE, WELLCOME IS PUTTING ABOUT 25 TO \$30 MILLION
7 A YEAR INTO PROGRAMS FOR COMPANIES. THEY HAVE 15
8 PEOPLE ON THEIR STAFF TO MANAGE THAT PROGRAM FOR THEM.
9 SO, YOU KNOW, WITH CIRM'S LIMITATIONS, BOTH FINANCIAL
10 AND PERSONNEL, WE HAVE TO -- I THINK IT'S GOING TO BE
11 VERY DIFFICULT FOR US TO ESSENTIALLY MANAGE A PORTFOLIO
12 OF GRANTS WITH COMPANIES UNLESS WE HAVE SOME PRETTY IN
13 THE END CONSTRAINING GUIDELINES, BUT WE CAN SEND OUR
14 PEOPLE OUT EVERY TIME AND START EVERY NEGOTIATION FROM
15 SCRATCH. WE SIMPLY WON'T HAVE THE RESOURCES AVAILABLE
16 TO US TO DO THAT.

17 INDUSTRY USES FUNDS FROM MANY SOURCES TO
18 DEVELOP PRODUCTS. AND THIS WILL COME UP LATER. COMES
19 UP ESPECIALLY IN THE NONMONETARY RETURNS THAT WE WILL
20 DISCUSS. AND THE ISSUE WILL BE AT WHAT POINT, IN TERMS
21 OF OUR TOTAL FUNDING OF SOMETHING, DO WE HAVE THE
22 RIGHT, IF YOU WILL, TO ASK FOR THE NONMONETARY
23 CONSIDERATIONS THAT WE HAVE IN OUR NOT-FOR-PROFIT
24 POLICY, THE ACCESS PROGRAMS AND THE PRICING FOR
25 STATE-FUNDED AGENCIES.

1 AT THE EXTREME, I GUESS ANY FAIR-MINDED
2 PERSON WOULD SAY IF YOU FUNDED A HUNDRED PERCENT OF THE
3 WORK, THOSE ARE PERFECTLY REASONABLE THINGS TO ASK FOR.
4 THE OTHER EXTREME, IF YOU PUT IN 1 PERCENT, DOES IT
5 MAKE SENSE FOR YOU TO ASK FOR THOSE THINGS? IT MAY
6 BECAUSE THAT WOULD BE A CHOICE PEOPLE WOULD MAKE, BUT
7 THAT'S SOMETHING WE'LL HAVE TO DISCUSS.

8 AS I SAID BEFORE, CERTAINTY IN PAYBACK TERMS
9 IS HIGHLY DESIRED BY THE INDUSTRY, A VERY COMMON THEME
10 AMONG INDUSTRY REPRESENTATIVES.

11 AND THEN FINALLY, MARCH-IN RIGHTS FOR FAILURE
12 TO DEVELOP ARE GENERALLY ACCEPTABLE TO THE PEOPLE WE
13 HEARD FROM IN THE INDUSTRY GOING FORWARD.

14 SO THIS SLIDE SIMPLY SUMMARIZES THE WHOLE --
15 THIS IS A SLIDE FROM GERON'S ANNUAL REPORT. WE COULD
16 POTENTIALLY FUND PROJECTS IN COMPANIES LIKE GERON AT
17 ANY STAGE IN THIS DEVELOPMENT CYCLE, AND THE ISSUES
18 THAT WE WOULD FACE WOULD BE QUITE DIFFERENT. IF WE
19 FUND EARLY STAGE RESEARCH AND IT RESULTS IN PATENTS,
20 THEN THE PATENT POLICY, THEY WOULD BE -- YOU KNOW, BILL
21 RASTETTER, I THINK, WAS THE MOST FORTHRIGHT IN SAYING
22 THAT COMPANIES SHOULD BE ABLE TO ESSENTIALLY APPLY FOR
23 BASIC RESEARCH GRANTS LIKE UNIVERSITIES. WHY WOULD YOU
24 HAVE A BIAS AGAINST COMPANY RESEARCH? THERE WAS SOME
25 DISCUSSIONS IN SOME QUARTERS THAT COMPANIES DON'T DO

1 BASIC RESEARCH; BUT AS WE ALL KNOW, MANY COMPANIES DO
2 BASIC RESEARCH. IN FACT, GERON FUNDED DERIVATION OF
3 EMBRYONIC STEM CELLS AS AN EXAMPLE. SO WE HAVE TO
4 THINK ABOUT THE WHOLE ARRAY OF THINGS THAT WE COULD
5 CONCEIVABLY FUND GOING FORWARD.

6 THE NEXT SLIDE, WE THINK THERE ARE PROBABLY
7 THREE MECHANISMS THAT WE ARE LIKELY TO USE TO FUND
8 RESEARCH IN COMPANIES. ONE ARE GRANTS. SECOND WOULD
9 BE LOANS. AND THIS IS A MODEL WHICH IS BEING USED WITH
10 INCREASING FREQUENCY OUT THERE. AND THE THIRD IS
11 CONTRACTS.

12 YOU WILL NOTICE THAT EQUITY PURCHASES ARE NOT
13 ON THIS SLIDE. NO. 1, THE CONSTITUTION OF CALIFORNIA
14 FORBIDS ANY STATE AGENCY TO OWN ANY EQUITY. WE COULD,
15 HOWEVER, HAVE EQUITY SURROGATES, WHICH SOME FUNDERS ARE
16 DOING; THAT IS, YOU GET A STOCK APPRECIATION RIGHT,
17 WHICH IS NOT A STOCK, BUT IT'S A CERTAIN AMOUNT OF
18 MONEY THAT'S LIKE A -- WELL, EXACTLY WHAT IT SAYS. A
19 STOCK APPRECIATION RIGHT IS A SURROGATE FOR A STOCK,
20 AND GET PAID IN CASH RATHER THAN OWNING A STOCK. IF WE
21 WANT REMUNERATION THAT PARTICIPATED IN THE INCREASED
22 VALUE OF A COMPANY, AT LEAST IN PART DUE TO CIRM
23 FUNDING, YOU COULD THINK ABOUT A STOCK APPRECIATION
24 RIGHT.

25 DR. LOVE: IS THAT DONE LIKE A WARRANT?

1 CHAIRMAN PENHOET: IT'S ALMOST LIKE A WARRANT
2 OR AN OPTION.

3 NEXT SLIDE, SOME OF THIS, INTERESTINGLY
4 ENOUGH, IT'S NOT CLEAR THAT IT'S INTELLECTUAL PROPERTY,
5 BUT WE DON'T KNOW WHERE ELSE TO PUT IT. WE'VE BEEN
6 HAVING SOME CONVERSATIONS WITH PATRICIA AND OTHERS
7 ABOUT OVERLAPPING THIS PART BETWEEN THE STRATEGIC
8 PLANNING EFFORT AND THE INTELLECTUAL PROPERTY EFFORT.
9 YOU COULD IMAGINE, FOR EXAMPLE, IN THIS CASE WE THINK
10 IN GRANTS THAT PUBLICATIONS AND PATENTS ARE LIKELY
11 OUTCOMES. IF WE MAKE LOANS TO PEOPLE TO DO THE SAME
12 THING, THE OUTCOMES MIGHT BE THE SAME. IF YOU GIVE
13 THEM CONTRACTS, IT'S MORE LIKELY TO BE A SERVICE. THE
14 STATE, ALL OF OUR GRANTEES NEED, I DON'T KNOW, ANTIBODY
15 Z OR MEDIA Y, OR WHATEVER IT IS, WE WOULD JUST SIMPLY
16 HAVE A CONTRACT. THAT PROBABLY HAS NO IP POLICY AROUND
17 IT. IT WOULD BE A SIMPLE PURCHASE OF A GOOD OR SERVICE
18 FROM AN INDUSTRY REPRESENTATIVE.

19 NEXT, THE RETURN OPTIONS FOR FUNDING
20 MECHANISMS. GRANTS WOULD BE PAID BACK IF SUCCESSFUL,
21 NOT PAID BACK IF THEY WEREN'T SUCCESSFUL. AT LEAST
22 THAT'S ONE MODEL THAT'S BEING USED BY A NUMBER OF
23 ORGANIZATIONS. BUT IF YOU DON'T WANT TO HAVE ANY
24 OBLIGATION HERE, THE COMPANY WOULD PROBABLY HAVE TO
25 THINK ABOUT A HIGHER RETURN IF THEY ONLY HAVE TO PAY

1 BACK IF IT'S SUCCESSFUL.

2 LOANS WILL BE PAID BACK IRRESPECTIVE OF
3 WHETHER THE PROJECT FUNDED BY CIRM WAS SUCCESSFUL. WE
4 WEREN'T RESPONSIBLE FOR THE CHOICE, BUT THE LOAN WOULD
5 BE OBVIOUSLY AT A MUCH LOWER RATE BECAUSE THE PAYBACK
6 RETURN WOULD BE LOWER BECAUSE THE PAYBACK WOULDN'T HAVE
7 CERTAINTY ASSOCIATED WITH IT.

8 GIVEN ALL THAT BACKGROUND AND CONVERSATIONS
9 WITH LOTS OF PEOPLE, THESE ARE AT LEAST PRINCIPLES WE
10 THINK WE NEED TO DEAL WITH TODAY. AS IN THE
11 NOT-FOR-PROFIT POLICY, WE THINK THE GRANTEES SHOULD OWN
12 THE INTELLECTUAL PROPERTY GENERATED AS A RESULT OF OUR
13 FUNDING, THAT IF THEY TAKE CIRM MONEY, THEY SHOULD
14 RESPECT OBLIGATION. I THINK WE ALL FEEL WE WANT TO
15 MAKE SURE THAT THE RESULTS OF THE WORK ARE IN THE
16 LITERATURE, AND THAT PEOPLE CAN ESSENTIALLY TRY AND
17 REPEAT THOSE STUDIES AND BUILD UPON THOSE STUDIES, THAT
18 BIOMEDICAL MATERIALS SHOULD BE SHARED AS IN THE
19 NOT-FOR-PROFIT POLICY.

20 AND THE ONE PROPOSAL, ONLY ONE, WOULD BE THAT
21 WHEN COMPANIES ACTUALLY APPLY FOR A GRANT OR A LOAN --
22 NO. THEY APPLY FOR SUPPORT FOR A PROGRAM, THAT ONCE
23 IT'S APPROVED, THEY CAN EITHER CHOOSE TO TAKE A LOAN OR
24 A GRANT DEPENDING ON -- THAT WOULD GIVE THEM SOME
25 FLEXIBILITY.

1 NOW, HERE THIS PART GETS A LITTLE BIT
2 STICKIER. WHAT WE HEARD FROM BILL RASTETTER AND OTHERS
3 IS THAT COMPANIES WOULD LIKE TO APPLY FOR RESEARCH
4 GRANTS IN THE SAME POOL AS THAT. WE THINK THAT'S A
5 GOOD IDEA. WE THINK THAT IF THEY'RE IN THE SAME POOL,
6 THEY OUGHT TO BE TREATED THE SAME WAY. SO THIS NEXT
7 ONE SAYS THAT IF A COMMERCIAL ENTITY CHOOSES TO LICENSE
8 CIRM-FUNDED PATENTED INVENTIONS TO THIRD PARTIES, THE
9 REQUIREMENTS FOR LICENSING ARE THE SAME AS IN OUR
10 INTELLECTUAL PROPERTY POLICY FOR NON-FOR-PROFITS EXCEPT
11 THAT THEY PAY BACK 17 PERCENT OF THEIR REVENUES AFTER
12 \$500,000 RATHER THAN 25 PERCENT.

13 WHY THE DIFFERENCE? THE DIFFERENCE IS
14 UNIVERSITIES ARE PAYING THE INVENTORS TYPICALLY ABOUT A
15 THIRD OF THEIR REVENUES. AND WE GET 25 PERCENT OF THE
16 AMOUNT LEFT OVER AFTER THEY'VE PAID THEIR INVENTORS.
17 IN THE CASE OF A COMPANY, THE INVENTORS WORK FOR THE
18 COMPANY. AND OUR LOGIC IN THINKING ABOUT THIS WAS
19 THAT, THEREFORE, THE COMPANY OUGHT TO GET THE BENEFIT
20 OF THE INVENTOR'S SHARE BECAUSE THE INVENTOR IS
21 EMPLOYED BY THE COMPANY, PAID A SALARY BY THE COMPANY,
22 ETC. THIS IS SOMETHING CLEARLY THAT WE'LL ALL WANT TO
23 DISCUSS.

24 FOR GRANTS, IF A COMMERCIAL ENTITY CHOOSES TO
25 DEVELOP THE PRODUCT THEMSELVES, THE PAYBACK WOULD BE

1 CONDITIONED UPON SUCCESS WITH A MULTIPLE OF CIRM
2 FUNDING TO BE PAID BY THE GENERAL FUND. AND THIS COULD
3 BE IN THE FORM A ROYALTY THAT WOULD BUILD UP TO A
4 CERTAIN DOLLAR AMOUNT OR MILESTONES. WE THINK THERE
5 COULD BE A BLOCKBUSTER PHRASE IN THIS, THAT IF --
6 SEVERAL PEOPLE IN THE INDUSTRY HAVE TOLD US THAT THAT
7 WOULD BE ACCEPTABLE -- IF THE PRODUCT SALES EXCEED \$250
8 MILLION OR SOMETHING, THAT THERE WOULD BE A ONE-TIME
9 PAYMENT ASSOCIATED WITH SUCH A MILESTONE; THAT IS, IF
10 IT WAS A BIG SUCCESS.

11 FOR LOANS, IF THE COMMERCIAL ENTITY CHOOSES
12 TO DEVELOP IT THEMSELVES, THE PAYBACK WOULD BE AT SOME
13 MARKET RATE PLUS A SMALL FACTOR OR A LARGE FACTOR,
14 DEPENDING ON YOUR POINT OF VIEW, IN A CERTAIN PERIOD OF
15 TIME.

16 AND THEN FINALLY, FOR GRANTS AND LOANS -- I
17 JUST TALKED ABOUT THE BLOCKBUSTER FEATURE -- FOR LOANS
18 AND GRANTS WHERE CIRM FUNDING REPRESENT MORE THAN A
19 CERTAIN PERCENT OF THE INVENTION OR THE PROJECT, THE
20 COMPANY WILL PROVIDE PLANS FOR ACCESS TO ENSURE AND
21 WILL PROVIDE THEIR GOODS TO PUBLICLY FUNDED AGENCIES IN
22 CALIFORNIA THE MEDICAID PRICE. THIS IS THIS ISSUE,
23 THOUGH, OF PROPORTIONAL PARTS OF FUNDING. WHAT WOULD
24 BE A FAIR THING IN THIS REGARD GOING FORWARD?

25 THESE ARE ALL DIFFICULT ISSUES THAT WE HAVE

1 TO GRAPPLE WITH HERE TODAY. SO I THINK THAT'S IT.
2 LEAVE THAT ONE UP, PLEASE.

3 DR. MAXON: COULD WE TAKE A BREAK?

4 CHAIRMAN PENHOET: WE HAVE A REQUEST FROM
5 MARY MAXON TO TAKE A BREAK. WE ARE HALFWAY THROUGH THE
6 MEETING, ALMOST HALFWAY. THESE ARE THE SLIDES. NOT IN
7 THE BOOK.

8 DR. MAXON: THESE ARE SLIDES THAT WENT TO
9 REMOTE SITES BECAUSE YOU'RE SEEING THE SLIDES HERE.

10 MR. SHEEHY: SO THIS IS THE FIRST TIME WE'VE
11 SEEN THESE?

12 DR. MAXON: THAT'S RIGHT.

13 MR. SHEEHY: AND WE DON'T HAVE A PAPER COPY?

14 DR. MAXON: WE CAN GET PAPER COPIES, I GUESS.

15 CHAIRMAN PENHOET: OKAY. IS IT OKAY WITH THE
16 TASK FORCE IF WE TAKE A BREAK? WHAT, TEN MINUTES, SO
17 WE'LL RECONVENE AT 2:40.

18 (A RECESS WAS TAKEN.)

19 CHAIRMAN PENHOET: WE'RE GOING TO START. SO
20 IF WE FOLLOW THE SAME PROCEDURE THAT WE HAVE USED IN
21 THE PAST, WHAT WE HOPE TO DO NOW IS GET SOME AGREEMENT
22 AROUND THESE PRINCIPLES TODAY. THAT'S THE GOAL FOR
23 TODAY. WE WILL TRY TO AS BEST WE CAN DEFINE THOSE
24 PRINCIPLES. AND THEN FROM THOSE PRINCIPLES, MARY,
25 SCOTT, AND OTHERS WILL GO BACK AND DEVELOP A DRAFT OF A

1 POLICY WHICH WE WILL REVIEW AT OUR NEXT MEETING
2 HOPEFULLY ON SEPTEMBER 21ST.

3 SO, FIRST OF ALL, THESE ARE PROPOSED
4 PRINCIPLES BY US, AND I'D LIKE TO SIMPLY GO DOWN
5 THROUGH THESE IN THE ORDER THAT THEY'RE UP HERE, AND
6 THEN IN ADDITION TO THAT BE HAPPY -- WE MAY HAVE
7 OVERLOOKED SOME PRINCIPLES THAT SOME OF YOU THOUGHT
8 SHOULD BE EMBODIED IN THIS DOCUMENT. SO WE'D BE HAPPY
9 TO TAKE SUGGESTIONS FOR OTHER PRINCIPLES AS WE GO
10 FORWARD.

11 SO MAYBE IF WE CAN -- IS THAT ACCEPTABLE TO
12 EVERYONE?

13 FIRST OF ALL, THE GRANTEES OWN THE
14 INTELLECTUAL PROPERTY. THIS IS THE CORNERSTONE OF OUR
15 NONPROFIT/FOR-PROFIT POLICY. I BELIEVE THAT WE
16 PROBABLY HAVE GENERAL AGREEMENT THAT THAT SHOULD BE THE
17 CASE HERE BECAUSE WE DON'T HAVE THE ABILITY TO MANAGE
18 INTELLECTUAL PROPERTY INTERNALLY AT CIRM.

19 SO IS THERE ANY OBJECTION TO THAT AS ONE OF
20 THE PRINCIPLES? ALL RIGHT.

21 SECOND ONE IS THAT WE HAVE THE SAME
22 PUBLICATION REQUIREMENT AS IN IPPNPO, IN THE
23 NOT-FOR-PROFIT. AND PUBLICATION REQUIREMENTS, TO
24 REFRESH YOUR MEMORY, THERE IS AN AFFIRMATIVE
25 REQUIREMENT FOR PUBLICATION, BUT A CARVE-OUT PERIOD FOR

1 FILING PATENTS AND OTHER FORMS OF INTELLECTUAL
2 PROPERTY. SO DO I HAVE ANY DISCUSSION ABOUT THIS
3 PRINCIPLE FROM ANYONE? SOME THROATS ARE BEING CLEARED
4 IN IRVINE.

5 UNIDENTIFIED SPEAKER: WHEN YOU SAY
6 PUBLICATION REQUIREMENTS, ALL PATENTS PUBLISHED. ARE
7 YOU SAYING THEY NEED TO PUBLISH BEFORE THE 18TH MONTH
8 DEADLINE FOR THE APPLICATION?

9 CHAIRMAN PENHOET: WELL, IF THE PATENTS ARE
10 ALL PUBLISHED. I THINK WE HAVE A GENERAL REQUIREMENT
11 WHETHER IT'S THE SUBJECT OF THE PATENT OR NOT, THAT
12 PEOPLE SHOULD, IN GENERAL, BE PUBLISHING THE RESULTS OF
13 THEIR WORK.

14 DR. MAXON: AND WHEN THEY DO, THEY NEED TO
15 ALSO PRODUCE A 500-WORD ABSTRACT WRITTEN FOR THE LAY
16 PUBLIC WITHIN 60 DAYS AFTER THE PUBLICATION OF THE
17 SCIENTIFIC SCHOLARLY ARTICLE.

18 CHAIRMAN PENHOET: THERE'S AN ADMONITION TO
19 MAKE SURE IT'S TIMELY PUBLICATION, BUT IT CAN BE
20 MODIFIED BY THE PRACTICAL REQUIREMENTS OF THE
21 INSTITUTION.

22 ANY OTHER QUESTIONS FROM THE TASK FORCE? WE
23 HAVE A QUESTION IN THE AUDIENCE IN SAN FRANCISCO.

24 MR. OLMERT: JUST A QUESTION. POINT OF
25 CLARIFICATION. THIS IS JOHN OLMERT FROM THE UNIVERSITY

1 OF CALIFORNIA. TO THE EXTENT THAT OPEN ACCESS
2 DISCUSSION IS STILL OPEN, IF THAT CHANGES FOR THE
3 NONPROFIT POLICY, IT WOULD PRESUMABLY APPLY HERE AS
4 WELL.

5 CHAIRMAN PENHOET: LIKELY. OKAY. DO WE
6 HAVE -- ARLENE CHIU.

7 DR. CHIU: I HAVE HEARD THAT PUBLICATION OF
8 PATENTS TAKES PLACE IN EUROPE. IS THAT A REQUIREMENT
9 IN THE UNITED STATES OR ONLY AFTER THEY'RE APPROVED OR
10 THEY FILED? ARE THEY PUBLISHED?

11 CHAIRMAN PENHOET: THE RULES ARE DIFFERENT.
12 THERE HAS BEEN A LOT OF WORK PUT INTO HARMONIZATION OF
13 EUROPEAN AND U.S., BUT IN GENERAL IT'S NOT A
14 REQUIREMENT THAT U.S. PATENTS ARE PUBLISHED UNTIL
15 THEY'RE ISSUED. THEY ARE PUBLISHED IN EUROPE WITHIN 18
16 MONTHS AFTER THEY'RE FILED.

17 DR. PRIETO: WHETHER GRANTED OR NOT?

18 CHAIRMAN PENHOET: WHETHER GRANTED OR NOT,
19 THE APPLICATIONS ARE PUBLISHED; THAT'S CORRECT.

20 UNIDENTIFIED SPEAKER: I HAVE A
21 CLARIFICATION. ALL PATENTS IN THE UNITED STATES ARE
22 PUBLISHED AT 18 MONTHS UNLESS THE PERSON OPTS OUT.
23 THAT'S ONLY IF THEY DON'T FILE IN (UNINTELLIGIBLE) OF
24 FOREIGN COUNTRY. IF THEY FILE IN A FOREIGN COUNTRY,
25 THEY HAVE TO BE PUBLISHED AT 18 MONTHS AFTER THE

1 APPLICATION AND ALSO TO PUBLISH WHEN THEY'RE ISSUED.

2 DR. LOVE: I WAS JUST GOING TO MAKE A POINT
3 THAT THIS IS REALLY REFERRING TO PUBLICATION OF
4 SCIENTIFIC RESULTS, NOT FOCUSED ON PUBLICATION OF
5 PATENTS. SO I'M NOT SURE IF WE NEED TO SPEND TOO MUCH
6 TIME ON THE SPECIFIC PATENT PUBLICATIONS.

7 CHAIRMAN PENHOET: MAYBE FOR US THIS QUESTION
8 MIGHT BE IS THE PUBLICATION OF A PATENT CONSIDERED
9 PUBLICATION FOR THIS PURPOSE?

10 DR. LOVE: I UNDERSTAND, BUT I THINK WHAT WE
11 HAD PUT INTO THE IPPNPO WAS AN EXPECTATION THAT YOUR
12 RESEARCH ACTIVITIES COULD BE UNCOVERED BY PATENTS
13 PUBLISHING IN EUROPE, YOUR APPLICATIONS PUBLISHING IN
14 EUROPE, AND YOU'RE PROTECTED AGAINST THAT ALREADY. I
15 JUST WANTED TO MAKE PEOPLE KNOW THAT'S BEEN THOUGHT
16 THROUGH AND DEALT WITH. SO, IN FACT, IT ISN'T A NEW
17 ISSUE FOR THIS DEBATE, I THINK.

18 CHAIRMAN PENHOET: OKAY. AND THEN BIOMEDICAL
19 MATERIALS SHARING IS A FEATURE OF THE NONPROFIT POLICY.
20 IN THIS CASE I BELIEVE IF THERE ARE SIGNIFICANT
21 BIOMEDICAL MATERIALS, YOU STILL HAVE TO DEPOSIT THEM
22 WHEN YOU FILE A PATENT. THE SHARING RULES MIGHT BE
23 SLIGHTLY DIFFERENT FOR A COMPANY. WE DO HAVE LANGUAGE
24 IN THE NOT-FOR-PROFIT ABOUT, YOU KNOW, IF THE DEMANDS
25 ARE ONEROUS, ETC., THAT THEY SIMPLY CAN EMPOWER

1 SOMEBODY ELSE TO SHARE THIS MATERIAL. SO IT'S NOT AN
2 OPEN-ENDED OBLIGATION ON THE INSTITUTION, BUT IT IS AN
3 OBLIGATION NEVERTHELESS THAT SOMEHOW THEY SEE THAT THE
4 MATERIALS EITHER ARE SHARED OR THAT YOU TEACH SOMEBODY
5 ELSE HOW TO MAKE THEIR OWN.

6 ANY COMMENTS ON THAT PART OF OUR POLICY?

7 MR. SNODGRASS: I HAVE A QUESTION. RALPH
8 SNODGRASS FROM VISTAGEN. IF THE BIOMEDICAL MATERIAL IS
9 ACTUALLY PART OF THE COMMERCIAL PRODUCT, SUCH AS A DRUG
10 SCREENING ASSAY, A TOXICITY ASSAY, WHAT'S THE
11 IMPLICATIONS OF THAT? IF THE BIOMEDICAL MATERIAL IS
12 ACTUALLY PART OF THE COMMERCIALIZATION PROCESS OR
13 PRODUCT, SUCH AS A PHARMACEUTICAL SCREENING ASSAY, A
14 TOXICITY SCREENING ASSAY, HOW WOULD THE SHARING RIGHTS,
15 SHARING OBLIGATIONS IMPACT THAT COMMERCIAL PRODUCT?

16 CHAIRMAN PENHOET: YOU KNOW, I DO THINK THAT
17 THAT'S A SPECIAL CASE THAT WE'LL HAVE TO THINK ABOUT
18 BECAUSE IT'S ENTIRELY POSSIBLE THAT YOU DEVELOP A
19 UNIQUE CELL LINE OR AN ASSAY WHICH IS PROPRIETARY TO
20 YOU, AND YOU NEED TO USE THAT TO YOUR PROPRIETARY
21 ADVANTAGE IN SCREENING COMPOUNDS OR WHATEVER IS GOING
22 TO BE DONE. I DON'T THINK IT WAS OUR INTENT TO
23 VIOLATE.

24 MR. SNODGRASS: CLEARLY THAT IS OUR BUSINESS
25 MODEL, TO DO THAT, PROVIDE THESE TYPES OF BIOMEDICAL

1 ASSAYS AND TOOLS.

2 CHAIRMAN PENHOET: HE SAID IT'S THEIR
3 BUSINESS MODEL TO PROVIDE THOSE KIND OF MATERIALS.

4 DR. HALL: I THINK TWO THINGS TO BE BALANCED
5 IN THIS ARE PROPRIETARY INTERESTS OF A COMPANY, WHICH
6 ARE LEGITIMATE, AND THE ABILITY OF OTHERS TO REPRODUCE
7 THE WORK. AND I THINK WE WOULD HAVE TO NEGOTIATE IN
8 SPECIFIC INSTANCES, DEPENDING ON WHAT WAS BEING DONE,
9 HOW THAT WOULD BE HANDLED. AS I SAY, I THINK WE HAVE
10 TO THINK IT THROUGH.

11 CHAIRMAN PENHOET: I GUESS THE CIRCUMSTANCE
12 MIGHT BE THAT YOU INVENT AN IMPORTANT COMPONENT OF AN
13 ASSAY THAT SOMEBODY NEEDS TO EXPLOIT FOR THEIR OWN
14 PURPOSES. ZACH'S POINT WOULD BE THAT YOU WOULD STILL
15 BE SUBJECT TO THE PUBLICATION REQUIREMENTS, BUT IN THAT
16 CASE MIGHT NOT BE SUBJECT TO THE OBLIGATION TO
17 DISTRIBUTE THAT TO YOUR COMPETITORS. WE'LL HAVE TO
18 DEAL WITH THAT, I THINK, ON A CASE-BY-CASE BASIS, BUT
19 THAT'S A NUANCE IN HERE THAT'S SOMEWHAT DIFFERENT THAN
20 IN OUR NOT-FOR-PROFIT.

21 MR. ROTH: THIS IS COMPLICATED. I THINK WHAT
22 WE'RE GOING THROUGH RIGHT NOW ARE GENERAL GUIDELINES;
23 BUT WHEN IT GETS DOWN TO WHAT YOU ACTUALLY WRITE UP, WE
24 NEED TO OFFER, I THINK, GREAT FLEXIBILITY TO DEAL WITH
25 THINGS THAT WE CAN'T POSSIBLY ANTICIPATE TODAY THAT ARE

1 GOING TO HAPPEN OVER THE NEXT 10, 12 YEARS HERE. AND
2 GIVING THE INSTITUTIONS THE CAPABILITY OF NEGOTIATING
3 THOSE THINGS IS PROBABLY MUCH BETTER THAN A LOT OF
4 RULES AND REGULATIONS FROM CIRM GOVERNING THIS. I
5 THINK WE SHOULD GIVE THE GENERAL INTENT WHENEVER
6 POSSIBLE. THOSE KIND OF LANGUAGE CRITERIA, I THINK,
7 ARE GOOD, BUT LEAVE OPEN THE FLEXIBILITY SO THAT WE
8 DON'T END UP SEVEN OR EIGHT YEARS WITH SOMEBODY COMING
9 BACK AND WANTING TO AMEND THE POLICY SO THEY CAN ENTER
10 INTO AN AGREEMENT THAT WILL GIVE THEM AUTHORITY TO
11 COMMERCIALIZE.

12 AND EXAMPLES ARE ALREADY BEING SUGGESTED OF
13 WHERE THAT COULD BE A PROBLEM, AND WE'VE GOT TO THINK
14 THROUGH THAT VERY CAREFULLY.

15 MR. SNODGRASS: IN OUR SPECIFIC CASE, WE
16 WOULD BE POTENTIALLY APPROACHING CIRM DIRECTLY TO
17 GENERATE GRANT SUPPORT FOR A COMMERCIAL IDEA CONCEPT
18 THAT WE HAVE OF TAKING HUMAN EMBRYONIC STEM CELLS AND
19 DEVELOP VERY SPECIFIC PHARMACEUTICAL DISCOVERY AND
20 SCREENING ASSAYS. SO IN THAT SENSE, IF WE GET GRANT
21 MONEY TO SUPPORT THAT TYPE OF COMMERCIAL DEVELOPMENT,
22 WE'D BE DEALING DIRECTLY, I ASSUME, WITH CIRM.

23 CHAIRMAN PENHOET: YES. I THINK YOUR POINT,
24 DUANE, THE REALLY DIFFICULT ISSUE WE'RE TRYING TO
25 BALANCE IS THE MORE AMBIGUITY WE LEAVE IN THIS THING,

1 THE MORE DIFFICULT THE JOB OF THE -- THE MORE DIFFICULT
2 THE JOB OF THE PEOPLE AT CIRM WHO NEGOTIATE EACH OF
3 THESE AGREEMENTS IF THEY HAVE A LOT OF LATITUDE ONE WAY
4 OR THE OTHER. SO WE'RE GOING TO HAVE TO FIND SOME
5 REASONABLE BALANCE. I THINK THIS IS REALLY IMPORTANT.

6 MR. GILENWATER: WITH REGARD TO BIOMEDICAL
7 MATERIALS, THIS IS SOMETHING THAT WE ACTUALLY COMMENTED
8 ON IN OUR COMMENTS, AND THAT IS IN THE DEFINITIONS OF
9 BIOMEDICAL MATERIALS. AND IF THIS IS DEVELOPED FOR THE
10 FOR-PROFIT DEFINITIONS, WE WOULD REQUEST THAT THAT BE
11 CLARIFIED THAT THOSE ARE ENTITIES OF BIOMEDICAL
12 REFERENCE FIRST PRODUCED AS A CONSEQUENCE OF
13 CIRM-FUNDED SCIENTIFIC RESEARCH TO NARROW AND CLARIFY
14 THAT DEFINITION. THAT WOULD BE INCLUDED IN THE CHI
15 COMMENTS IN A REVIEW OF THE IPPNPO COMMENTS THAT WERE
16 ON THE WEB PAGE THIS MORNING. I BELIEVE THAT WAS ALSO
17 INCLUDED IN THE UC COMMENTS AS WELL.

18 CHAIRMAN PENHOET: THANK YOU. SUBJECT TO
19 THOSE KIND OF FUZZY EDGES TO THIS CONCEPT, WHICH WE'LL
20 HAVE TO WORK OUT, BUT THE GENERAL CONCEPT IS ACCEPTABLE
21 TO YOU GUYS? OKAY. WE'LL MOVE ON.

22 THIRD ONE IS THAT THE COMMERCIAL ENTITY CAN
23 CHOOSE AT THE TIME OF THE APPLICATION WHETHER IT WOULD
24 LIKE A GRANT OR A LOAN FOR THE BUDGETED AMOUNT. THIS
25 PRESUMES WE'LL HAVE A LOAN PROGRAM, BUT WE WOULD LEAVE

1 THE CHOICE -- WE WOULDN'T SPECIFY THESE KINDS OF THINGS
2 ARE ONLY LOANS. ALTHOUGH WE COULD LOAN COMPANIES TO
3 BUILD FACILITIES NEEDED TO MAKE REAGENTS FOR A LARGE
4 NUMBER OF GROUPS. LOANS COULD COVER A LOT OF DIFFERENT
5 KINDS OF ACTIVITY. SOME OF THEM, FRANKLY, HAVE NOTHING
6 TO DO WITH INTELLECTUAL PROPERTY. THERE IS A QUESTION
7 WHETHER IT IS THE PROPER PURVIEW OF THIS TASK FORCE OR
8 WHETHER THEY SHOULD BE SOMEWHERE ELSE INSIDE CIRM. AND
9 WE HAVE DISCUSSED INTERACTION NOW BETWEEN THE STRATEGIC
10 PLAN, WHICH IS UNDER WAY, AND OUR ACTIVITIES ON THIS
11 TASK FORCE.

12 BOB KLEIN, THE CHAIRMAN, HAS ASKED US TO
13 CONTEMPLATE THESE ISSUES HERE EVEN IF THEY DON'T END UP
14 SPECIFICALLY INSIDE THE IP POLICY BECAUSE THIS GROUP IS
15 NOW COLLECTIVELY THE MOST EXPERIENCED DEALING WITH
16 THESE ISSUES. DR. PIZZO.

17 DR. PIZZO: THIS IS REALLY JUST FOR
18 CLARIFICATION. IT'S A MATTER OF PERSONAL IGNORANCE.
19 I'M NOT FAMILIAR WITH NONPROFIT ORGANIZATIONS,
20 SCIENTIFIC ORGANIZATIONS RENDERING LOANS AS PART OF
21 THEIR SCIENTIFIC ENTERPRISE. AND I'M INTERESTED IN
22 KNOWING WHAT THE EXPERIENCE IS WITH THAT. WHEN THAT'S
23 DONE, ARE THESE NONINTEREST LOANS? ARE THEY INTEREST
24 BEARING LOANS? WHAT DOES IT REALLY MEAN AS PART OF THE
25 OVERALL PORTFOLIO?

1 CHAIRMAN PENHOET: FIRST OF ALL, SOME OF THE
2 FOUNDATIONS DO PROVIDE LOANS, AND IT WILL BE UP TO US
3 TO DECIDE WHAT THE RETURN SHOULD BE ON THE LOAN. THE
4 LOAN COULD BE PRIME RATE. THE LOAN COULD BE PRIME PLUS
5 SOME RISK FACTOR, ETC. THE LOAN, I THINK IN THIS
6 CONTEXT AT LEAST, WOULD BE TO SOME DEGREE A SURROGATE
7 FOR A GRANT, BUT WITH DIFFERENT PAYBACK TERMS AND
8 CONDITIONS. SO THERE ARE -- YOU KNOW, COMPANIES HAVE
9 TOLD US THEY HAVE A WHOLE VARIETY OF WAYS THEY FUND
10 PROJECTS, VENTURE CAPITAL, LOANS, VENTURE DEBT, GRANTS
11 FROM DIFFERENT ORGANIZATIONS, A CONTRACT. THERE'S A
12 WHOLE PANOPLY OF THINGS THEY DRAW ON.

13 I THINK THE PRIVATE SECTOR WOULD, YOU KNOW,
14 PROBABLY WELCOME A LOAN PROGRAM; BUT IN THIS CASE I
15 THINK THE ORGANIZATIONS THAT HAVE DONE THE MOST LOANING
16 THE MONEY PROBABLY IS THE WELLCOME FOUNDATION.

17 DR. PIZZO: JUST TO FOLLOW THAT FOR A MOMENT,
18 IS THE POLICY FOR LOANS RESTRICTED TO COMMERCIAL
19 ENTITIES? OR WOULD THEY ALSO APPLY TO ACADEMIC
20 INSTITUTIONS AS A CASE IN POINT? AND WHAT'S THE
21 GUIDANCE REGARDING THAT? THAT'S A VERY DIFFERENT
22 MECHANISM AT LEAST THAT I'M FAMILIAR WITH USING TODAY.
23 I'M OPEN IT TO, BUT IT'S JUST DIFFERENT.

24 DR. HALL: I JUST WANT TO SAY I THINK ONE CAN
25 THINK ABOUT CONTEMPLATING TWO KINDS OF LOANS IN A WAY.

1 ONE IS A LOAN IN THE SENSE OF AN INVESTMENT TO HELP A
2 COMPANY GET STARTED OR TO HELP A UNIVERSITY DO
3 SOMETHING. THAT'S THE QUESTION YOU'RE ASKING OR A
4 NONPROFIT. I THINK THE OTHER IS A BIT DIFFERENT, AND
5 IT IS A WAY OF PROVIDING A RETURN TO THE STATE. THAT
6 IS, I THINK ONE OF THE PROBLEMS IS, AS YOU LOOK
7 DOWNSTREAM, YOU INVEST IN SOMETHING THAT MAY GO ON AND
8 YOU DON'T KNOW WHAT IT WILL GENERATE IN THE END. I
9 THINK COMPANIES WANT CERTAINTY ABOUT HOW THIS WILL BE
10 PAID BACK. I THINK ONE WAY TO STRUCTURE IT IS SIMPLY
11 TO SAY THAT IF THIS RESULTS IN A PRODUCT OVER
12 SUCH-AND-SUCH AMOUNT, THEN THE COMPANY WOULD GIVE THREE
13 TIMES THE LOAN TO THE STATE THE GENERAL FUND, SORT OF
14 LIKE THE BLOCKBUSTER PAYMENT, AND THIS THEN BECOMES A
15 MECHANISM, AS I UNDERSTAND IT, OF SIMPLY STRUCTURING
16 YOUR PAYBACK. AND IT SHOULD BE ATTRACTIVE TO COMPANIES
17 IN A CERTAIN WAY BECAUSE IT'S LIMITED. IT'S NOT
18 INDEFINITE INTO THE FUTURE. AND THAT WOULD BE ONLY
19 APPLICABLE PRESUMABLY TO COMPANIES.

20 DR. PIZZO: I DON'T WANT TO BELABOR THIS TOO
21 MUCH, BUT JUST AS A CASE IN POINT TO UNDERSTAND IT. SO
22 LET'S SURMISE THAT AT SOME POINT IN TIME CIRM WILL BE
23 ABLE TO ADMINISTER \$300 MILLION OR APPROXIMATELY THAT
24 PER ANNUM. IT'S GOING TO BE IMPORTANT, AT LEAST FOR
25 ME, TO UNDERSTAND WHAT PROPORTION OF THAT OR PERCENTAGE

1 OF THAT TOTAL IS ACTUALLY GOING TO BE LOANS VERSUS
2 GRANTS OR CONTRACTS BECAUSE THAT COULD FUNDAMENTALLY
3 CHANGE THE WAY WE DO OUR BUSINESS, HOW WE SUPPORT OUR
4 ACTIVITIES. AND FROM THE POINT OF VIEW OF A
5 UNIVERSITY, IT WOULD HAVE HUGE IMPLICATIONS. IF THE
6 PORTFOLIO SHIFTED AND THERE WERE LOTS OF LOANS, LET'S
7 SUPPOSE THAT WAS THE WAY PEOPLE THOUGHT IT SHOULD BE,
8 THAT'S GOING TO RENDER ALL KINDS OF QUESTIONS AS TO
9 WHO'S GOING TO SERVICE THE DEBT ON THOSE LOANS, WHERE
10 THE FUNDS FOR THAT COME FROM, AND THAT'S GOING TO BE
11 HANDLED VERY DIFFERENTLY AMONG COMMERCIAL VERSUS
12 NONCOMMERCIAL ENTITIES.

13 SO AS WE OPEN THIS DOOR, I'M REALLY JUST
14 RAISING QUESTIONS ABOUT WHAT WE MIGHT FIND ON THE OTHER
15 SIDE.

16 DR. HALL: I THINK IT'S NOT INVESTMENT AND
17 THIS IS CONTEMPLATED AT CIRM. IS IT? WE'RE NOT
18 INVESTORS IN COMPANIES IN THAT SENSE.

19 CHAIRMAN PENHOET: NO. WE'RE LOANING THEM
20 MONEY FOR A SPECIFIC PURPOSE. THEY WILL APPLY FOR A
21 LOAN TO ACCOMPLISH A SPECIFIC OBJECTIVE. WE'RE NOT
22 TRYING TO PRESAGE TODAY WHAT THAT OBJECTIVE WOULD BE,
23 BUT THAT'S A CONCEPT. I THINK THE MIX OF CONTRACT,
24 LOANS, AND GRANTS IS A STRATEGIC PLANNING ISSUE THAT
25 THE BOARD WILL HAVE TO CONTEMPLATE IN THE CONTEXT OF

1 THE STRATEGIC PLAN. IF LOANS EMERGE, HOWEVER, AND
2 THOSE LOANS ARE USED TO DO RESEARCH AND GENERATE
3 INTELLECTUAL PROPERTY, WELL, THEN IT PROBABLY DOES
4 FALL, AT LEAST PARTLY, IN OUR CAMP.

5 MR. SHEEHY: I THINK THERE'S KIND OF A
6 CONTRADICTION HERE BECAUSE IF YOU'RE LEAVING IT TO A
7 COMMERCIAL ENTITY AND WE OPEN ALL RFA'S, PRESUMABLY IF
8 THIS WAS IN PLACE, THIS FIRST ROUND OF SEED GRANTS AND
9 COMPREHENSIVE RESEARCH GRANTS WOULD BE OPEN TO
10 COMMERCIAL ENTITIES. ACCORDING TO THIS PRINCIPLE, THEY
11 HAVE THE CHOICE. IT'S NOT A PREDETERMINED POLICY THAT
12 WE MAKE THAT 10 PERCENT OF THIS IS GOING TO BE LOANS.
13 WE'RE SAYING HERE THAT THE ENTITY, WHEN THEY GET
14 APPROVED FOR THE GRANT OR GET THEIR APPLICATION
15 APPROVED, CAN THEN DECIDE TO RECEIVE THE MONEY EITHER
16 IN THE FORM OF A GRANT OR A LOAN. SO I'M NOT CLEAR.
17 THIS SAYS SOMETHING DIFFERENT FROM WHAT YOU JUST SAID
18 BECAUSE YOU'RE KIND OF INDICATING THAT WE'RE GOING TO
19 HAVE A BROADER POLICY ON LOANS. THIS SAYS THAT THIS IS
20 REALLY AN INDIVIDUAL ENTITY ISSUE AFTER THEY HAVE BEEN
21 APPROVED FOR A -- THEIR PROPOSAL HAS BEEN APPROVED BY
22 ICOC, THAT THEY CAN CHOOSE TO TAKE THEIR MONEY AS A
23 LOAN INSTEAD OF A GRANT.

24 CHAIRMAN PENHOET: WHAT I THINK I SAID IS
25 THAT'S A BROADER ISSUE, AND WE'RE DEALING WITH THE

1 NARROWER ISSUE HERE, WHICH IS IF THEY'RE IN A POOL WITH
2 OTHER APPLICANTS, UNIVERSITIES IN GENERAL ARE NOT IN
3 THE HABIT, I DON'T THINK, OF BORROWING MONEY, AND THEY
4 DON'T HAVE ANY PAYBACK REQUIREMENTS TO US.

5 UNIDENTIFIED SPEAKER: THERE'S A LOT OF
6 STATIC ON THIS END. IS SOMEONE MESSING WITH THE PHONE?

7 CHAIRMAN PENHOET: WE'LL TRY TO DO THE BEST
8 WE CAN. WE'LL TRY NOT TO EVER USE THIS ROOM AGAIN, FOR
9 STARTERS, BUT WE'RE HERE TODAY, SO WE'RE DOING THE BEST
10 WE CAN.

11 SO I THINK WE'RE NOT HERE TODAY TO DECIDE
12 WHETHER LOANS ARE A GOOD VEHICLE OR NOT, ETC. FIRST OF
13 ALL, LOANS ARE ANTICIPATED IN PROP 71, AND THEY COULD
14 BE USED TO FUND LOTS OF DIFFERENT THINGS. COMPANIES
15 TODAY FUND RESEARCH WITH A WHOLE BUNCH OF MONEY FROM
16 DIFFERENT SOURCES, EQUITY, LOANS. AS I SAID BEFORE,
17 THERE'S A PANOPLY OF THINGS THEY USE.

18 THERE ARE SOME COMPANIES WHO WORRY ABOUT
19 HAVING DEBT ON THEIR BALANCE SHEET. I THINK IF YOU'RE
20 GOING TO HAVE A LOAN PROGRAM AND A GRANT PROGRAM,
21 THOUGH, THAT THE PAYBACK TERMS OF THE GRANT PROGRAM IN
22 A SENSE, BECAUSE IT DOES REQUIRE REPAYMENT, IT DOESN'T
23 END UP ON YOUR BALANCE SHEET, WOULD HAVE TO BE MORE
24 AGGRESSIVE ON THE GRANT SIDE BECAUSE YOU'RE NOT TAKING
25 THE SAME LEVEL OF RISK AS A COMPANY AS YOU WOULD IF YOU

1 GOT A LOAN. SO CIRM PROBABLY WOULD ARGUE THAT OUR
2 PAYBACK ON THE GRANTS WOULD BE HIGHER THAN OUR PAYBACK
3 ON LOANS BECAUSE LOANS WOULD BE REPAID UNLESS THE
4 COMPANY WENT BANKRUPT OR COULDN'T PAY FOR ONE REASON OR
5 ANOTHER. LOTS OF DETAILS ABOUT HOW THESE LOANS WILL BE
6 STRUCTURED AND WHETHER THE COMPANY WOULD HAVE TO
7 DEMONSTRATE CREDITWORTHINESS IN ORDER TO BE FUNDED.
8 ALL THOSE THINGS ARE DETAILS WE'LL HAVE TO WORK OUT.

9 SO WE'RE JUST HERE PROVIDING ALTERNATIVES
10 THAT WE DON'T YET QUITE UNDERSTAND THE DETAIL OF HOW
11 THEY'LL PLAY OUT. THAT'S WORK THAT'S STILL IN FRONT OF
12 US.

13 MR. SHEEHY: THE PRINCIPLE IS ONE OF CHOICE.

14 CHAIRMAN PENHOET: THE PRINCIPLE HERE IS THAT
15 COMPANIES CAN CHOOSE WHETHER TO TAKE A LOAN OR A GRANT.
16 WE WILL DEFINE WHAT THE CONSEQUENCES OF THAT WILL BE
17 FOR THEM IF THEY MAKE THAT CHOICE, AND WE HAVEN'T YET
18 COME TO THAT, SO WE'LL NEED TO CIRCLE BACK TO IT.

19 DR. HALL: YOU SUGGEST THAT TO ENDORSE THAT
20 SPECIFIC POLICY AT THIS STAGE MIGHT BE PREMATURE. I
21 THINK THE WHOLE BUSINESS OF TRYING TO CONSIDER WHAT THE
22 CONSEQUENCES ARE OF GRANTS, LOANS, HOW THEY MIGHT BE
23 STRUCTURED, WHETHER IT WILL COME BACK TO CIRM. AND IF,
24 IN FACT, IT IS UP TO THE COMMERCIAL ENTITY TO MAKE A
25 CHOICE, THEN THE POINT THAT PHIL RAISED ABOUT EVEN

1 DETERMINING HOW MUCH OF OUR BUDGET WOULD BE ONE WAY OR
2 THE OTHER IS OUT OF OUR HANDS. I WOULD SUGGEST IT'S A
3 LITTLE EARLY TO ENDORSE THAT. I THINK THAT MIGHT BE
4 PUT ON THE TABLE TO THINK ABOUT A POSSIBILITY, BUT I
5 WOULD SUGGEST WE NEED A LOT MORE WORK TO DO ON THAT
6 BEFORE WE COME TO A FINAL CONCLUSION OR YOU MAKE A
7 RECOMMENDATION IN THESE POLICIES.

8 CHAIRMAN PENHOET: I THINK THERE ARE TWO WAYS
9 TO HANDLE THIS. ONE IS IF WE MAKE LOANS, THESE ARE THE
10 TERMS, RATHER THAN SAYING FOR SURE WE WILL MAKE LOANS,
11 WHICH I BELIEVE IS A BROADER ISSUE THAN WE'RE DEALING
12 WITH HERE. PROP 71 ANTICIPATES MAKING LOANS; AND WE
13 THINK THAT IN DEVELOPING THE POLICY, WE AT LEAST HAVE
14 TO SAY IF THERE ARE LOANS, THAT THEY WOULD HAVE, FROM
15 THIS POINT OF VIEW, SOME --

16 DR. PRIETO: COUPLE COMMENTS AND SORT OF A
17 QUESTION, WELL, ONE QUESTION. ONE IS I THINK WE CAN
18 DEFINE SORT OF WHAT THE INTELLECTUAL PROPERTY
19 IMPLICATIONS ARE OF GRANTS VERSUS LOANS, BUT THE
20 QUESTION OF WHETHER CIRM MAKES LOANS PART OF OUR
21 PORTFOLIO OF LOANS, THAT SEEMS TO BE SORT OUT OF OUR
22 PURVIEW AND MAYBE FITS INTO THE STRATEGIC PLAN AND
23 BOARD LEVEL DECISION-MAKING RATHER THAN ANYTHING THAT
24 WE'RE GOING TO SETTLE.

25 THE OTHER QUESTION I HAVE IS REGARDING THE

1 REMUNERATION MECHANISM. ARE THERE SOME BOND LAW
2 IMPLICATIONS THAT WE SHOULD BE CONSIDERING?

3 CHAIRMAN PENHOET: I DON'T KNOW THE ANSWER,
4 BUT WE WILL FIND OUT. ARE THERE SOME RESTRICTIONS ON
5 THE USE OF GENERAL OBLIGATION BONDS THAT WE SHOULD KNOW
6 ABOUT IN THIS REGARD? UNLESS SOMEBODY ELSE IN THE ROOM
7 KNOWS THE ANSWER TO THAT QUESTION, I GUESS I DON'T.
8 I'VE ASSUMED THAT THEY'RE ANY LEGITIMATE PURPOSE OF
9 CIRM, BUT I'M NOT SURE THAT'S THE ANSWER, SO WE'LL GO
10 FIND OUT.

11 DR. PRIETO: THAT CAME UP LAST YEAR REGARDING
12 WHAT SORT OF BONDS WE COULD USE. I DON'T KNOW THE
13 QUESTION WAS EVER REALLY SETTLED, SO I GUESS IT WOULD
14 BE MY QUESTION TO THE ATTORNEY.

15 CHAIRMAN PENHOET: OKAY. WE WILL PROVIDE AN
16 ANSWER BEFORE OUR NEXT MEETING.

17 DR. PRIETO: THANK YOU.

18 CHAIRMAN PENHOET: SO WE'RE NOT ENDORSING A
19 LOAN PROGRAM, BUT WE AT LEAST MIGHT ANTICIPATE IF LOANS
20 ARE USED, THIS IS HOW WE WOULD HANDLE THAT POLICY. I
21 THINK THAT'S A GENERALLY ACCEPTED VIEW.

22 THE NEXT ONE IS IF A COMMERCIAL ENTITY
23 CHOOSES TO LICENSE CIRM-FUNDED PATENTED INVENTIONS TO
24 THIRD PARTIES, THE REQUIREMENTS WOULD BE THE SAME AS IN
25 THE NONPROFIT POLICY EXCEPT THAT THEIR OBLIGATION WOULD

1 BE REDUCED TO 17 PERCENT RATHER THAN 25 PERCENT TO GIVE
2 THEM ESSENTIALLY CREDIT FOR THE INVENTOR'S SHARE. SO
3 THAT'S THE PROPOSAL.

4 MR. SHEEHY: AGAIN, JUST A QUESTION. ARE WE
5 NOT DISINCENTIVIZING LICENSING IN THAT WE HAVE UNCAPPED
6 REVENUE RETURN ON ONCE YOU LICENSE, BUT IF YOU DEVELOP
7 IT YOURSELF, YOU'RE CAPPED. THERE'S NO CAP ON THE 17
8 PERCENT; BUT IF YOU DEVELOP THE PRODUCT YOURSELF, IT'S
9 A NEW CAP.

10 CHAIRMAN PENHOET: WELL, I THINK TWO THINGS.
11 FIRST OF ALL, IT IMPLIES YOU MADE A MUCH BIGGER
12 INVESTMENT YOURSELF IF YOU DEVELOP IT YOURSELF. IF YOU
13 LICENSE IT TO A THIRD PARTY, IN GENERAL THEY MAKE THE
14 DOWNSTREAM, NOT YOU. AND WE'RE NOT DICTATING THE TERMS
15 OF THOSE LICENSES. SO A COMPANY CAN CHOOSE THEMSELVES.
16 PROBABLY BEFORE THEY MAKE A LICENSE, MANY FACTORS WILL
17 BE CONSIDERED TO BE SURE.

18 TO BE CLEAR, THOUGH, THIS IS 17 PERCENT OF
19 THEIR REVENUES FROM THE LICENSE. THIS IS NOT A
20 17-PERCENT ROYALTY, IT'S NOT 17. IT'S WHATEVER THEY
21 GET FROM THE THIRD PARTY THEY TURN OVER 17 PERCENT TO
22 US.

23 MR. SHEEHY: BUT IT'S UNLIMITED.

24 CHAIRMAN PENHOET: FOR THE LIFE OF THAT
25 AGREEMENT, WHATEVER IT IS.

1 MR. SHEEHY: THE REASON I'M THINKING ABOUT
2 THIS IS BECAUSE WHEN I START TO VISUALIZE SOMEONE
3 LICENSING PROFITABLE TECHNOLOGY, I THINK IT MAY BE
4 TOWARDS A DISEASE THAT MAY NOT PROVIDE THE MARKET. SO
5 I'M JUST A LITTLE BIT WORRIED ABOUT -- YOU KNOW, I
6 DON'T WANT TO DISINCENTIVIZE PEOPLE TO LICENSE THEIR
7 PRODUCTS TO PEOPLE WHO ARE WILLING TO DEVELOP FOR A
8 MUCH SMALLER MARKET. AND WE ACTUALLY HAVE A BETTER
9 INCENTIVE. I DON'T KNOW. I'M NOT -- BIOTECH GUYS, YOU
10 KNOW, YOU FOLKS MAY HAVE A BETTER SENSE OF THIS, BUT I
11 DON'T KNOW HOW PEOPLE GENERALLY LICENSE.

12 THIS IS BASED ON UNIVERSITY -- THE THING --
13 THIS PRINCIPLE CAME OUT OF A NOT-FOR-PROFIT INSTITUTION
14 THAT NEVER DEVELOPS A PRODUCT. SO WE'RE TALKING ABOUT
15 LICENSING BY AN ENTITY THAT IS IN THE BUSINESS
16 GENERALLY OF DEVELOPING PRODUCTS, SO I CAN'T PUT MYSELF
17 IN THEIR MINDS AND WONDER WHETHER THERE'S SOME
18 APPLICABLE -- WHETHER -- WE MADE THIS KIND OF ANALOGY
19 BETWEEN THE TWO, AND I'M NOT SURE THAT THAT ANALOGY IS
20 APPROPRIATE.

21 CHAIRMAN PENHOET: WELL, IN A SENSE YOU CAN
22 ARGUE BOTH SIDES OF THE ISSUE. COMPANIES HAVE A LOT OF
23 FLEXIBILITY. A UNIVERSITY HAS ONLY ONE WAY TO GET
24 THEIR TECHNOLOGY TO MARKET. THAT'S THROUGH A LICENSE.
25 A COMPANY CAN MAKE A DECISION TO LICENSE OR DEVELOP IT

1 THEMSELVES. AGAIN, THIS WOULD HAVE THE SAME FEATURES
2 AS IN THE NONPROFIT POLICY, ONE OF WHICH IS
3 PROPORTIONATE FUNDING. IF WE ONLY FUNDED PART OF THIS
4 AND THEY FUNDED THE REST, THEN THIS WILL BE REDUCED BY
5 THE AMOUNT OF THE OTHER FUNDING OF THE INVENTION. SO,
6 YOU KNOW, I DO THINK -- WHAT I'VE STRUGGLED WITH IS THE
7 ISSUE IF YOU HAVE A DIFFERENT POLICY HERE, THEY'RE IN
8 THE SAME POOL OF GRANTEES PRESUMABLY FOR RESEARCH
9 GRANTS, AND IF YOU HAVE A POLICY WHICH IS MORE
10 DESIRABLE FOR COMPANIES THAN UNIVERSITIES, THEN IT
11 SEEMS TO ME WE MIGHT HAVE TO REVISIT THE ISSUE WITH
12 UNIVERSITIES BECAUSE YOU CAN MAKE THE SAME ARGUMENT IN
13 THAT CASE. YOU MIGHT WANT TO SUGGEST SOME LANGUAGE
14 ABOUT ORPHAN DISEASES OR SOMETHING LIKE THAT WHERE WE
15 WOULD TRY TO PRESENT TO COMPANIES AT THAT POINT. WE
16 COULD THINK ABOUT INCORPORATING THAT AS A WAY TO
17 ADDRESS YOUR CONCERN, JEFF.

18 WE HAVE COMMENT FROM THE AUDIENCE.

19 MR. SNODGRASS: RALPH SNODGRASS AGAIN.
20 CLEARLY THE CONCEPT OF HAVING A CAP AT A CERTAIN AMOUNT
21 IS ATTRACTIVE FOR A COMMERCIAL COMPANY. BUT ANOTHER
22 ONE THAT, AGAIN, IN TERMS OF UNINTENDED CONSEQUENCES,
23 IN UNIVERSITY THE REVENUES FROM A LICENSE ARE
24 ESSENTIALLY PURE PROFIT, BUT SOMETIMES A COMPANY
25 THERE'S A SERVICE AGREEMENT THAT GOES ALONG WITH THE

1 LICENSE WHERE YOU HAVE TO COMMIT TO DO A CERTAIN AMOUNT
2 OF WORK TOWARD THE COMMERCIALIZATION OF THAT PRODUCT.
3 SO REVENUES AREN'T THE SAME THING AS PROFITS.

4 SO DEPENDING ON THE TYPE OF PROJECT, THE
5 ACTUAL PROFIT MARGIN COULD BE MUCH, MUCH SMALLER. AND
6 SO WE HAVE TO BE A LITTLE BIT CAREFUL, I WOULD SUGGEST,
7 OF A PURE 17 PERCENT OF REVENUES IF IT DOES NOT TAKE
8 INTO ACCOUNT IF THERE'S SOME SERVICE COMPONENT REQUIRED
9 TO REDUCE THAT PROFIT MARGIN.

10 CHAIRMAN PENHOET: WE WOULD CLEARLY HAVE TO
11 MAKE SURE THAT THOSE REVENUES AS DEFINED HERE ARE
12 PURELY THE PART THAT WAS ASSOCIATED WITH THE LICENSE
13 AND NOT ANY ASSOCIATED SERVICES. I THINK ANY
14 REASONABLE PERSON WOULD AGREE THAT WOULD BE
15 OVERREACHING ON OUR PART.

16 OKAY. DO WE HAVE FURTHER COMMENT FROM THE
17 AUDIENCE HERE ON THIS PARTICULAR FEATURE OR FROM ANY
18 BOARD MEMBERS? TED LOVE.

19 DR. LOVE: I THINK THAT THE WAY ED DESCRIBED
20 THE WHO MAKES THE INVESTMENT PROBABLY IS A REASONABLE
21 KIND OF PHILOSOPHICAL WAY, AT LEAST FROM MY
22 PERSPECTIVE, ABOUT HOW TO THINK ABOUT IT BECAUSE I DO
23 THINK THAT THE INSTITUTION THAT PUTS IN THE BIGGEST
24 INVESTMENT HAS THE OPPORTUNITY WITH THE UPSIDE. I
25 PERSONALLY HAVE BEEN INVOLVED IN LICENSING TECHNOLOGIES

1 THAT WE INVENTED, BUT WE'RE NOT LIKELY TO EXPLOIT. AND
2 IN THOSE SITUATIONS WE ACTUALLY DO END UP APPROACHING
3 IT VERY MUCH THE WAY AN ACADEMIC INSTITUTION APPROACHES
4 IT IN TERMS OF HOW OUR FINANCIAL SPLIT LAYS OUT BECAUSE
5 WE'RE NOT, AT THE END OF THE DAY, WILLING TO MAKE THE
6 INVESTMENT. SO WE TEND TO GET MORE ACADEMIC-TYPE
7 TERMS, SO I THINK IT PROBABLY DOES FIT AS A PRINCIPLE.

8 CHAIRMAN PENHOET: AND I DO THINK THERE'S
9 ALSO A PRECEDENT. IN LICENSING A COMPANY, IN FACT,
10 YOU'VE LICENSED SOMETHING FROM A THIRD PARTY AND
11 SUBLICENSE TO SOMEONE ELSE, IN GENERAL IN THAT CASE THE
12 ORIGINAL LICENSEE GETS A MUCH BIGGER FRACTION OF THE
13 SUBLEASE REVENUES THAN THEY WOULD GET OF REVENUES THAT
14 WERE COMPLETELY DEVELOPED YOURSELF. IT MAY BE A
15 SIMILAR IDEA.

16 DON REED. YOU HAVE A BOOMING VOICE, BUT I'M
17 AFRAID IT TAKES MORE THAN A BOOMING VOICE TODAY.

18 MR. REED: JUST A CLARIFICATION. WITH A
19 THIRD PARTY, DO THE SAME MARCH-IN RIGHTS APPLY?

20 CHAIRMAN PENHOET: YES. OKAY. THEN THE NEXT
21 ONE -- OH, ANY MORE COMMENTS?

22 THE NEXT ONE HAS TO DO WITH A PAYBACK
23 CONDITION UPON SUCCESS WITH A MULTIPLE OF FUNDING TO BE
24 PAID TO THE GENERAL FUND. WE HAVE SEEN NUMBERS --
25 TYPICALLY THE WAY THIS WORKS WITH OTHER FUNDERS IS

1 THERE'S A ROYALTY ASSOCIATED WITH THE SALES OF THE
2 PRODUCT. AND WHEN THE ROYALTY REACHES A CERTAIN
3 MULTIPLE OF THE INVESTMENT, THEN THE ROYALTY CEASES SO
4 THAT THE ORGANIZATION DOESN'T TAKE ALL OF THE PROFITS
5 UP FRONT, BUT THEY JUST TAKE A ROYALTY UNTIL SUCH TIME
6 AS IT EXCEEDS.

7 I THINK IN ALL THE WORK THAT MARY HAS DONE,
8 THE RANGE THAT WE TYPICALLY SEE IS 3 TO 5 X ON SUCCESS.
9 WE CAN DECIDE TODAY WHAT THAT NUMBER SHOULD BE. WE
10 JUST PUT IT IN FRONT OF YOU TO ALLOW YOU TO CHEW ON IT
11 BETWEEN NOW AND SEPTEMBER 21ST. DOES THAT SOUND LIKE A
12 SENSIBLE APPROACH TO THIS ISSUE FOR GRANTS?

13 DR. LOVE: I WOULD SAY THAT IF WE DO END UP
14 GOING WITH THE LOAN/GRANT COMBINATION, THAT'S ABOUT THE
15 ONLY WAY IT WOULD MAKE SENSE TO ME, QUITE FRANKLY. I
16 THINK THE REAL PHILOSOPHICAL ISSUE, AND ACTUALLY, PHIL,
17 I WOULD ASK YOU AND OTHER PEOPLE FROM ACADEMIA, DO YOU
18 HAVE AN ISSUE WITH PRIVATE COMPANIES HAVING THIS OPTION
19 WHEN ACADEMIC INSTITUTIONS WOULDN'T HAVE THE OPTION OF
20 TAKING MONEY IN THE FORM OF LOANS OR GRANTS?

21 TO ANSWER YOUR QUESTION, I DEFINITELY THINK
22 IT MAKES SENSE TO HAVE A MULTIPLE IF, IN FACT, YOU HAVE
23 THIS STRATIFIED APPROACH OF LOANS AND GRANTS.

24 DR. PIZZO: SO I DON'T WANT TO SPEAK, OF
25 COURSE, FOR ALL ACADEMIC INSTITUTIONS, AND I REALLY

1 WANT TO REFLECT ON THIS MORE CAREFULLY BECAUSE IT'S A
2 NEW CONCEPT. I THINK MY FIRST REACTION TO THIS IS THAT
3 I WOULD PREFER TO GO DOWN THE GRANT PATHWAY, BUT THAT
4 MAY BE SIMPLY BECAUSE THAT'S SOMETHING THAT I KNOW
5 ABOUT. I WOULD REALLY WANT TO LOOK AT THE FINANCIALS
6 REGARDING THE ADVANTAGES AND DISADVANTAGES OF A LOAN,
7 AND THERE MAY BE OPPORTUNITIES FOR THAT AS WELL. SO I
8 DON'T KNOW WHETHER WE'RE GOING TO GET INTO, THIS IS
9 ANOTHER STRATEGIC DISCUSSION, AND IT'S SEPARATE FROM
10 THIS, AS TO WHETHER THAT KIND OF FLEXIBILITY IS GOING
11 TO APPLY OR NOT. BUT I WOULDN'T PRECLUDE IT IF THAT'S
12 THE QUESTION YOU'RE ASKING.

13 CHAIRMAN PENHOET: ANY OTHER COMMENTS FROM
14 THE BOARD ON -- THIS IS NOT A BOARD -- THE TASK FORCE
15 ON THIS ISSUE? WE'LL HAVE THE BOARD DISCUSSION. NONE
16 IN SAN FRANCISCO. IN IRVINE? SACRAMENTO?

17 DR. PRIETO: NO.

18 CHAIRMAN PENHOET: OKAY. I SUSPECT WE MAY
19 HEAR FROM THE PUBLIC ON THIS ISSUE. WE HAVE A HAND UP
20 IN SAN FRANCISCO, PLEASE.

21 MS. LAMBERT: ACTUALLY I DIDN'T HAVE A
22 COMMENT. I'M SORRY TO COME OUT OF TURN, BUT TWO OF US
23 WHO WERE INVOLVED IN THE COMPROMISE HAVE TO GO IN ABOUT
24 TEN MINUTES. IF YOU WANT, WE'VE GOT SOMETHING.

25 CHAIRMAN PENHOET: OUR FRIENDS FROM

1 WASHINGTON, D.C. HAVE TO GO HOME TO WASHINGTON, SO
2 THEY'D LIKE US TO LOOK AT THEIR PROPOSED ALTERNATIVE
3 LANGUAGE FOR THE RUE BEFORE THEY LEAVE. WE'LL DO THAT
4 RIGHT NOW.

5 UNFORTUNATELY WE DON'T HAVE INTERNET ACCESS
6 IN THIS ROOM. WE CAN'T SEND IT TO YOU AT THE REMOTE
7 SITES, SO I WILL HAVE TO READ IT TO YOU. HOPEFULLY WE
8 CAN GET IT UP ON THE SCREEN.

9 YOU WILL ENJOY YOUR EVENING IN SAN FRANCISCO.

10 DR. LOVE: WELL, YOU'RE CLOSE TO YOUR FLIGHT
11 AT LEAST. NO TRAFFIC.

12 DR. PRIETO: WE CAN'T HEAR.

13 MR. TOCHER: THERE'S NOTHING HAPPENING. JUST
14 A SECOND, DR. PRIETO. IN THE MEANTIME, THOUGH, TO THE
15 OFF SITES, WE'RE TRYING TO E-MAIL IT, AND WE HAVE YOUR
16 E-MAIL ADDRESSES, SO WE'LL TRY TO E-MAIL THAT TO YOU.

17 AND IN JUST ONE SECOND, WE'RE GOING TO BRING
18 IT UP ON THE SCREEN FOR EVERYONE HERE.

19 CHAIRMAN PENHOET: CAN YOU BLOW THAT UP A
20 LITTLE BIT? YOU'RE NOT AT A DISADVANTAGE AT A REMOTE
21 SITE. IT'S ON OUR SCREEN, BUT WE CANNOT READ IT
22 EITHER.

23 MR. TOCHER: YOU'RE NOT AT A DISADVANTAGE.
24 WE'RE STILL BRINGING IT UP ON THE SCREEN HERE. HOLD
25 TIGHT FOR A SECOND.

1 CHAIRMAN PENHOET: JUST READ IT, WILL YOU,
2 SCOTT?

3 MR. TOCHER: ALL RIGHT. WHAT IT SAYS IS, THE
4 FIRST SENTENCE, IF YOU WERE HOLDING A DRAFT IN YOUR
5 HAND, THE FIRST SENTENCE IS UNCHANGED. AND THE SECOND
6 BEGINS OUR CHANGES.

7 IN LICENSING CIRM-FUNDED PATENTED INVENTIONS,
8 GRANTEE ORGANIZATION AGREES THAT IT SHALL RETAIN THE
9 RIGHT TO PRACTICE THE USE OF ITS CIRM-FUNDED PATENTED
10 INVENTIONS FOR ITS NONCOMMERCIAL PURPOSES. GRANTEE
11 ORGANIZATIONS AGREE TO MAKE THEIR CIRM-FUNDED PATENTED
12 INVENTIONS READILY ACCESSIBLE ON REASONABLE TERMS,
13 DIRECTLY OR THROUGH LICENSEES, TO OTHER GRANTEE
14 ORGANIZATIONS FOR NONCOMMERCIAL PURPOSES, UPON REQUEST
15 FROM A GRANTEE ORGANIZATION.

16 AND THE LAST SENTENCE REMAINS UNCHANGED. SO
17 WE'RE JUST SCROLLING THROUGH HERE AT HOME. SHALL I
18 READ THAT ONE MORE TIME?

19 CHAIRMAN PENHOET: READ THE LAST SENTENCE TO
20 US ONE MORE TIME.

21 MR. TOCHER: OKAY.

22 CHAIRMAN PENHOET: STARTING WITH GRANTEE
23 ORGANIZATIONS.

24 MR. TOCHER: GRANTEE ORGANIZATIONS AGREE TO
25 MAKE THEIR CIRM-FUNDED PATENTED INVENTIONS READILY

1 ACCESSIBLE ON REASONABLE TERMS, DIRECTLY OR THROUGH
2 LICENSEES, TO OTHER GRANTEE ORGANIZATIONS FOR
3 NONCOMMERCIAL PURPOSES, UPON REQUEST FROM A GRANTEE
4 ORGANIZATION.

5 CHAIRMAN PENHOET: OKAY.

6 DR. HALL: CAN I ASK A QUESTION? WHY IS THE,
7 SAY, OTHER GRANTEE ORGANIZATIONS, WHAT ABOUT A BROADER
8 DEFINITION OF THAT?

9 MR. TOCHER: THE QUESTION FROM DR. HALL IS
10 WHY IN THE SECOND SENTENCE IS IT LIMITED TO OTHER
11 GRANTEE ORGANIZATIONS.

12 CHAIRMAN PENHOET: WE SHOULD DEFER TO THE
13 DRAFTERS OVER THERE.

14 DR. HALL: ISN'T OUR OBJECT TO HAVE THIS
15 MATERIAL DISBURSED BEYOND OUR GRANTEE ORGANIZATIONS?
16 AND --

17 MS. LAMBERT: THE QUESTION WAS WHY IS THE
18 TERM "GRANTEE ORGANIZATIONS" USED AS OPPOSED TO A
19 BROADER TERM IN THE SECOND CHANGED SENTENCE. THIS IS
20 JANET LAMBERT. I THINK THAT THESE TWO SENTENCES CAME
21 FROM A SERIES OF TRADE-OFFS AMONG THE PARTICIPANTS
22 WOULD BE MY FIRST POINT.

23 DR. HALL: I'M SORRY. THAT'S NOT AN
24 ACCEPTABLE ANSWER. COULD YOU TELL US WHAT THE
25 TRADE-OFF WAS?

1 MS. LAMBERT: I'M NOT QUITE DONE WITH THE
2 ANSWER.

3 DR. HALL: WE UNDERSTAND. OKAY.

4 MS. LAMBERT: I THINK OUR FEELING WAS THAT
5 THE GRANTEE -- THAT THE PURVIEW OF THIS GROUP, THAT
6 THIS REGULATION AFFECTS GRANTEE ORGANIZATIONS. AND
7 THAT AS IT HAS BEEN EXPRESSED TO ME, JUST SPEAKING FOR
8 MYSELF, ON MULTIPLE OCCASIONS, THAT THE WARF PROBLEM OR
9 THE PROBLEM PUT IN OTHER TERMS THAT PEOPLE MOST WANTED
10 TO SOLVE WAS THE POSSIBILITY THAT A CIRM GRANTEE WOULD
11 NOT SHARE SOME IMPORTANT PIECE OF IP, NOT READILY SHARE
12 SOME IMPORTANT PIECE OF IP WITH OTHER CIRM GRANTEES,
13 THAT THAT WAS PROBLEM NO. 1. AND THAT THIS REGULATION
14 MOST APPROPRIATELY GOVERNS THIS SORT OF CIRM COMMUNITY,
15 IF YOU WILL. AND FOR THOSE REASONS, WE FOCUSED IT ON
16 GRANTEE ORGANIZATIONS.

17 DR. HALL: IF THE UNIVERSITY OF WISCONSIN
18 WANTED -- SOMEBODY AT THE UNIVERSITY OF WISCONSIN
19 WANTED THIS, THEY WOULD NOT FALL INTO THIS?

20 MS. LAMBERT: THE QUESTION WAS WOULD THE
21 UNIVERSITY OF WASHINGTON -- WISCONSIN.

22 DR. HALL: SOMEONE AT THE UNIVERSITY OF
23 WISCONSIN.

24 MS. LAMBERT: -- FALL WITHIN THIS PROVISION.
25 PEOPLE CAN SPEAK. MY SENSE OF THAT IS, NO, THEY WOULD

1 NOT. THAT'S NOT TO SAY -- NOTHING IN THIS PREVENTS A
2 GRANTEE ORGANIZATION FROM MAKING THEIR IP READILY
3 AVAILABLE TO SOMEBODY AT THE UNIVERSITY OF WISCONSIN,
4 BUT THIS PROVISION SIMPLY DOES NOT MANDATE IT.

5 DR. HALL: I WOULD LIKE TO SEE THAT MANDATED
6 BECAUSE IT SEEMS TO ME -- I WOULD LIKE TO SEE THAT
7 MANDATED BECAUSE IT SEEMS TO ME THE INTENT HERE IS TO
8 MAKE THESE -- I THINK THE STATEMENT THAT YOU HAVE,
9 PATENTED INVENTIONS READILY ACCESSIBLE ON REASONABLE
10 TERMS, DIRECTLY OR THROUGH LICENSEES, SHOULD OFFER THE
11 PROTECTION THAT YOU SEEK. AND I THINK OUR INTENT IS TO
12 HAVE WHATEVER IS DISCOVERED THROUGH CIRM FUNDING
13 AVAILABLE AND DISSEMINATED TO THE SCIENTIFIC COMMUNITY
14 AS EFFICIENTLY AND WITH AS FEW BARRIERS AS POSSIBLE.
15 AND IT SEEMS TO ME THAT TO CHANGE THAT TO OTHER
16 NONPROFIT RESEARCH INSTITUTIONS FOR NONCOMMERCIAL
17 PURPOSES WOULD BE A BETTER WORDING FOR THAT.

18 MR. ROTH: AGAIN, WE'RE DOING THIS WITHOUT
19 HAVING HAD IT WELL VETTED AHEAD OF TIME. IT WAS
20 SOMETHING THAT CERTAINLY, AS I SAID EARLIER, CAME AS A
21 SURPRISE TO ME THAT THIS WHOLE CONCEPT GOT IN HERE.
22 NOW THAT IT'S IN HERE, ZACH, MY RESPONSE WOULD BE
23 YOU'RE OBLIGATING CIRM-FUNDED PEOPLE TO DO WORK FOR THE
24 WHOLE WORLD, ANYBODY THAT ASKS, HAVE TO DO IT. THAT'S
25 DIFFERENT THAN CIRM-FUNDED ORGANIZATIONS. SO THERE'S A

1 DIFFERENT IMPLICATION THAT CAN COME OUT OF THIS THAT
2 YOU ARE -- IF YOU HAVE AN INVENTION, YOU GO TO
3 MATERIALS AND ALL OF THESE THINGS TO MAKE IT AVAILABLE
4 TO THE WHOLE WIDE WORLD AT REASONABLE TERMS, DOESN'T
5 MATTER IF YOU ARE IN CALIFORNIA OR ANY OTHER PLACE,
6 THAT YOU ARE NOW OBLIGATED TO DO THAT. AND THERE WILL
7 BE WORK COME OUT OF THIS. THERE'S LEGAL FEES, THERE'S
8 GOING TO BE ALL KINDS OF THINGS THAT WILL COME OUT OF
9 THIS THAT WOULD OBLIGATE AN INSTITUTION.

10 AND I'M NOW SPEAKING FOR THE INSTITUTIONS.
11 IF I'M RUNNING A RESEARCH INSTITUTE, AND I GOT A \$3
12 MILLION GRANT THROUGH YOU, AND I END UP IN THE NEXT TEN
13 YEARS HAVING TO WRITE LICENSE DEALS TO PROTECT THAT,
14 THAT'S NOT WHAT I WANT. I CAN PROBABLY DEAL WITH
15 CIRM-FUNDED ORGANIZATIONS BECAUSE THEY'RE IN THE STATE
16 OF CALIFORNIA. BUT MAKING THINGS AVAILABLE, WHAT IS
17 PREVENTING THAT FROM BEING DONE TODAY? WE HAVE A
18 PUBLICATION OBLIGATION. YOU HAVE PUT IT OUT THERE.
19 WE'VE ALREADY SAID THAT. I DON'T UNDERSTAND THE POINT
20 OF OPENING IT UP TO THE WHOLE WIDE WORLD.

21 CHAIRMAN PENHOET: ANY OTHER COMMENTS BY
22 BOARD MEMBERS?

23 MR. SHEEHY: ALL I -- I HATE -- I KEEP
24 DRAWING AN ANALOGY, BUT I JUST REMEMBER WE FACED THIS
25 SAME ISSUE WITH THE STANDARDS WORKING GROUP, WHETHER WE

1 WERE GOING TO BE SUPER REGULATOR FOR ETHICAL STANDARDS
2 FOR ALL STEM CELL RESEARCH DONE IN CALIFORNIA, AND WE
3 LIMITED OURSELVES TO CIRM-FUNDED RESEARCH. AND I
4 THINK, YOU KNOW, IT'S REALLY -- I APPRECIATE THE
5 SENTIMENT FOR US TO TAKE LEADERSHIP IN THIS ROLE, BUT
6 WHAT IS OUR OBLIGATION TO THE VOTERS? WHAT IS OUR
7 OBLIGATION TO THE PEOPLE OF CALIFORNIA? IT IS NOT TO
8 HURT THE TOOLS INDUSTRY THAT IS LARGELY BASED IN
9 CALIFORNIA. SO I APPLAUD THE GROUP OF FOLKS THAT CAME
10 TOGETHER AND CAME UP WITH THIS COMPROMISE. IT SEEMS TO
11 ME LIKE A FAIR STARTING POINT, AND WE CAN KEEP -- I
12 COME BACK TO A LOT OF THINGS THAT WE'RE TALKING ABOUT.
13 THESE ARE THINGS THAT THERE IS SOME AMBIGUITY, THERE'S
14 SOME MOVEMENT WITHIN THE LARGER SCIENTIFIC COMMUNITY
15 ON, AND WE DON'T ALWAYS HAVE TO BE AT THE FAR CUTTING
16 EDGE OF EVERYTHING WE DO. SO THIS IS A DO-NO-HARM
17 REGULATION THAT SEEMS TO CAPTURE THE MINIMUM PUBLIC --
18 MINIMUM OBLIGATION WE HAVE TO THE VOTERS. I WANT TO
19 THANK THE FOLKS FOR HELPING TO PULL THIS TOGETHER.

20 DR. LOVE: I JUST WANT TO SECOND WHAT JEFF
21 SAID IN THAT I THINK OUR OBLIGATION FIRST IS TO THE
22 CITIZENS OF CALIFORNIA, SECOND TO THE PEOPLE THAT WE
23 FUND GRANTS TO. THIS DOES NOT MEAN THAT AN INSTITUTE
24 COULDN'T ELECT TO SUPPORT A NON-CIRM FUNDED, BUT TO PUT
25 THAT OBLIGATION ON THEM IN THE INTENDED CONSEQUENCES,

1 I'D BE CONCERNED WITH DOING THAT. AND I DO TOTALLY
2 RESPECT WHAT ZACH SAID, BUT I THINK THAT THAT
3 FLEXIBILITY IS THERE, BUT TO MAKE THAT AN OBLIGATION
4 WOULD SEEM TO BE A POTENTIAL BURDEN THAT MAY BE
5 ONEROUS.

6 CHAIRMAN PENHOET: ANY COMMENTS FROM IRVINE?

7 DR. BRYANT: I WAS NOT COMPLETELY CONVINCED
8 THAT IT WOULDN'T STILL BE AVAILABLE MORE BROADLY UNLESS
9 THE LANGUAGE WAS CHANGED. I DIDN'T QUITE HEAR THAT. I
10 THINK FROM A RESEARCH-BASED POINT OF VIEW, I AGREE WITH
11 ZACH. I DON'T ACTUALLY SEE WHAT THE PROBLEM IS. I'M
12 SORRY.

13 CHAIRMAN PENHOET: WELL, THE ISSUE IS WHETHER
14 WE OBLIGATE THE UNIVERSITIES TO DO THIS WORLDWIDE, AS
15 WAYNE SAID, OR WE LEAVE IT UP TO THEIR DISCRETION TO DO
16 IT. THIS LANGUAGE OBLIGATES THEM TO DO IT FOR ALL
17 OTHER CIRM GRANTEES.

18 DR. LOVE: THE PROPOSED LANGUAGE DOESN'T;
19 ZACH'S AMENDMENT TO THE LANGUAGE WOULD.

20 CHAIRMAN PENHOET: SO ZACH'S AMENDMENT WOULD
21 SAY THIS IS A GENERAL OBLIGATION TO ALL NONPROFITS
22 ANYWHERE, AND THE PROPOSED LANGUAGE SAYS THIS IS AN
23 OBLIGATION LIMITED TO OTHER CIRM GRANTEES, BUT IT'S NOT
24 AN OBLIGATION TO DO IT FOR OTHERS. BUT IT DOES NOT SAY
25 UNIVERSITIES CAN'T GO FORWARD AND DO WHATEVER THEY

1 WANTED. THEY'RE FREE TO DO WHATEVER THEY WANT. THIS
2 DOESN'T OBLIGATE THEM BEYOND CIRM FUNDING.

3 DR. PIZZO: I AGREE WITH THIS. I RESPECT
4 WHERE ZACH IS ON THIS AND I HAVE THE SAME CONCERNS.
5 QUITE HONESTLY, FROM A UNIVERSITY POINT OF VIEW, FROM A
6 UNIVERSITY'S PERSPECTIVE, THERE ARE SOME LIABILITIES
7 THAT ARE REALLY SIGNIFICANT. AND IN A STEPWISE WAY, I
8 THINK OUR FIRST RESPONSIBILITY IS TO CALIFORNIA, TO
9 CIRM GRANTEES, AND I CERTAINLY SUPPORT THAT, BUT I
10 THINK WE NEED TO BE MORE CAUTIOUS BEFORE WE GO BEYOND
11 THAT.

12 CHAIRMAN PENHOET: ANY OTHER COMMENT?

13 MR. SIMPSON: JOHN SIMPSON FROM THE
14 FOUNDATION FOR TAXPAYER & CONSUMER RIGHTS. I WOULD
15 PREFER TO SEE ZACH'S LANGUAGE; BUT SINCE I WAS IN THE
16 ROOM AND HELPED CRAFT THIS, I CAN LIVE WITH IT. AND I
17 THINK I UNDERSTOOD WHERE THE TOOLS PEOPLE WERE COMING
18 FROM. I THINK THERE MAY ALSO BE WAYS IN OTHER PLACES
19 WHERE IN SOME OF YOUR ASPIRATIONAL NONREGULATORY
20 LANGUAGE AND OVERALL POLICIES WHERE YOU CAN UNDERSCORE
21 SUCH THINGS AS THE NEED TO SHARE BROADLY AND ALSO MAYBE
22 EVEN MAKE A CONNECTION ON REASONABLE PRICING
23 EXPECTATIONS, A FAVORITE HOBBY OF MINE.

24 MR. SNODGRASS: JUST A QUESTION OF POTENTIAL
25 INTENT OR UNINTENDED INTENT. THIS IS RALPH SNODGRASS

1 AGAIN. DOES THE FACT THAT THE PLURAL IS USED,
2 ORGANIZATIONS AND LICENSEES, PRECLUDE EXCLUSIVE
3 LICENSES?

4 CHAIRMAN PENHOET: YOU COULD ADD A LICENSEE
5 OR LICENSEES IF YOU WANTED TO BE ABSOLUTELY SURE, BUT I
6 DON'T THINK THIS PRECLUDES A SINGLE LICENSEE.

7 MR. SIMPSON: I DON'T BELIEVE THAT WAS THE
8 INTENTION.

9 CHAIRMAN PENHOET: THERE'S NO OBLIGATION. IF
10 YOU WANT TO BE DOUBLY CLEAR ABOUT THAT, YOU CAN ADD
11 LICENSEE OR LICENSEES.

12 MR. SNODGRASS: I THINK THAT ONE COULD
13 INTERPRET IT AS THAT.

14 CHAIRMAN PENHOET: OKAY. THAT'S FINE. ALL
15 RIGHT. ANY OTHER DISCUSSION ON THIS ISSUE? WITH THE
16 ADDITION OF DIRECTLY THROUGH LICENSEE OR LICENSEES TO
17 MAKE THAT CLEAR. ALL RIGHT.

18 DR. LOVE: I'LL MOVE.

19 CHAIRMAN PENHOET: WE HAVE A MOTION FROM TED
20 LOVE. IS THERE A SECOND?

21 DR. PIZZO: SECOND.

22 CHAIRMAN PENHOET: PHIL PIZZO. I'D LIKE TO
23 TAKE VOTE. DUANE, UP OR DOWN ON THIS LANGUAGE?

24 MR. ROTH: YES.

25 CHAIRMAN PENHOET: YES FROM DUANE ROTH.

1 JEANNIE.

2 DR. FONTANA: I CAN'T REALLY SAY. I DON'T
3 FEEL KNOWLEDGEABLE ENOUGH.

4 CHAIRMAN PENHOET: JEANNIE ABSTAINS. PHIL
5 PIZZO?

6 DR. PIZZO: YES.

7 CHAIRMAN PENHOET: JEFF SHEEHY?

8 MR. SHEEHY: YES.

9 CHAIRMAN PENHOET: TED LOVE.

10 DR. LOVE: YES.

11 DR. PENHOET: ED PENHOET? YES. IRVINE?

12 DR. BRYANT: YES.

13 DR. STEWARD: YES.

14 CHAIRMAN PENHOET: IN SACRAMENTO?

15 DR. PRIETO: YES.

16 CHAIRMAN PENHOET: OKAY. SO I THINK WE HAVE
17 ONE ABSTENTION AND EVERYBODY ELSE VOTED YES.

18 OKAY. WE'LL GO BACK THEN. ENJOY YOUR TRIP
19 HOME. THANKS FOR ALL YOUR WORK TO DRAFT SOME NEW
20 COMPROMISE LANGUAGE. AND THIS WILL PRECIPITATE ANOTHER
21 15 DAYS OF COMMENT PERIOD; IS THAT CORRECT?

22 MR. TOCHER: THAT'S RIGHT.

23 CHAIRMAN PENHOET: BUT NOT FOR 45 DAYS.

24 MR. TOCHER: CORRECT, NOT 45 DAYS.

25 CHAIRMAN PENHOET: NOW WE GO BACK TO THE

1 PRINCIPLES. OKAY. SO WE ARE NOW ON THE ISSUE OF THE
2 MULTIPLE OF FUNDING TO BE PAID BACK TO THE GENERAL FUND
3 IN THE NO-RISK CASE. YOU GET A GRANT, YOU'RE NOT PAID
4 BACK UNLESS YOU'RE SUCCESSFUL. THE MODEL IS THERE
5 WOULD BE A ROYALTY ON SALES UNTIL SUCH POINT AS YOU
6 REPAY SOME MULTIPLE OF THE ORIGINAL CIRM INVESTMENT IN
7 YOUR PROGRAM.

8 FIRST OF ALL, THE CONCEPT. DOES THAT CONCEPT
9 MAKE SENSE TO PEOPLE AROUND THE TABLE?

10 DR. LOVE: I WILL SAY THE CONCEPT MAKES
11 SENSE, AND I WOULD ENCOURAGE US TO COME IN ON THE LOWER
12 SIDE OF THE MULTIPLE FROM WHAT THE NORMS ARE MAINLY
13 BECAUSE I THINK OUR INTENT PRIMARILY IS TO STIMULATE
14 PEOPLE TAKING THESE AND DOING THE WORK AND MAKING
15 THERAPIES, NOT PRIMARILY TO MAKE MONEY, ALTHOUGH THAT
16 COULD BE CONTROVERSIAL, BUT I THINK YOU CAN SAY THAT'S
17 REALLY YOUR MAIN OBJECTIVE. YOU LEAN TOWARD TRYING TO
18 USE A SMALLER MULTIPLE.

19 CHAIRMAN PENHOET: ANY OTHER COMMENTS IN SAN
20 FRANCISCO FROM THE TASK FORCE MEMBERS? JEFF SHEEHY.

21 MR. SHEEHY: I GUESS I COME BACK TO DUANE'S
22 POINT. THIS IS ONE OF THOSE PLACES WHERE I WONDER IF
23 THIS IS -- YOU KNOW, I'M ASSUMING THIS IS ALL FLEXIBLE.
24 I WONDER IF WE MIGHT WANT TO EXPRESS THIS AS A RANGE
25 BECAUSE MY SENSE IS THAT THESE PRINCIPLES,

1 NOTWITHSTANDING WHAT WE ADOPT, ARE ALL GOING TO BE
2 SUBJECT TO NEGOTIATION AS OPPOSED TO AN IPPNPO.

3 CHAIRMAN PENHOET: THIS COULD BE A DEFINED
4 TERM. I BEG YOU NOT TO FINESSE ALL THESE ISSUES AND
5 LEAVE IT TO SOMEBODY ELSE. WE WON'T HAVE THE STAFF TO
6 NEGOTIATE EVERY ASPECT OF EVERY AGREEMENT. I DON'T
7 KNOW WHAT THE RIGHT ANSWER IS TO THE MULTIPLE.

8 MR. SHEEHY: WHICH IS WHY I WAS GOING TO
9 SUGGEST WE MIGHT WANT TO CONSIDER A RANGE.

10 CHAIRMAN PENHOET: YEAH.

11 MR. SHEEHY: AS OPPOSED TO A FIXED NUMBER.

12 CHAIRMAN PENHOET: I DON'T KNOW, THOUGH, IN
13 THE LONG RUN HOW WE WOULD DECIDE TO USE THE BOTTOM OF
14 THE RANGE FOR ONE COMPANY AND TOP FOR ANOTHER ONE. BUT
15 WE'LL SEE. ANYBODY ELSE HAVE A COMMENT HERE ON THIS?

16 DR. PRIETO: JUST ON THIS TOPIC OF CHOOSING A
17 RANGE OR LEAVING SOME QUESTIONS OPEN, I DO HAVE SOME
18 CONCERNS IN KNOWING WHAT WE KNOW ABOUT THE LIMITATIONS
19 OF OUR STAFF. BUT IS THAT SORT OF CONTRACTING
20 SOMETHING THAT CIRM WOULD BE ABLE TO DO OR THAT SORT OF
21 NEGOTIATION SOMETHING WE COULD CONTRACT FOR SOME OF
22 THOSE SERVICES, HAVE SOMEBODY ENGAGE IN SOME OF THOSE
23 NEGOTIATIONS FOR US AND COME BACK TO US WITH A PROPOSED
24 AGREEMENT?

25 CHAIRMAN PENHOET: YES. IN THEORY WE CAN DO

1 THAT. BUT, YOU KNOW, WE HAVE FINANCIAL LIMITATIONS AS
2 WELL AS STAFFING LIMITATIONS, SO MIGHT BE DIFFICULT.

3 WELL, WE DO HAVE A PROPOSAL FROM TED LOVE,
4 WHICH IS TO LOOK NEAR THE BOTTOM OF THE RANGE THAT
5 OTHER PEOPLE USE. SO WE COULD SIMPLY SAY, FOR SAKE OF
6 ARGUMENT, 3 X WILL BE THE NUMBER. AND, YOU KNOW, IF
7 YOU WANT TO MAKE IT A LITTLE MORE DIFFICULT, YOU COULD
8 SAY 3 X IF ACCOMPLISHED WITHIN SEVEN YEARS AND, YOU
9 KNOW, AN ADDITIONAL HALF A POINT FOR EACH YEAR AFTER
10 THAT NOT TO EXCEED 5 X, FOR EXAMPLE. SO THERE WAS SOME
11 TIME ELEMENT AND YOU WANT TO MAKE IT A LITTLE MORE
12 COMPLICATED.

13 JOHN SIMPSON HAS A COMMENT HERE IN SAN
14 FRANCISCO.

15 MR. SIMPSON: JUST A QUICK QUESTION. HOW DO
16 YOU DEFINE SUCCESS? IT'S CONCEIVABLE THAT SOMETHING IS
17 VERY MARGINALLY PROFITABLE OR SOMETHING. WHAT
18 CONSTITUTES SUCCESS?

19 CHAIRMAN PENHOET: WELL, I'LL BRING THE
20 PRODUCT TO MARKET, SO THAT'S THE SUBJECT OF THE
21 INVESTMENT. IF IT'S A VERY MARGINAL PRODUCT, THE
22 ROYALTY WOULD STAY IN PLACE FOR QUITE A LONG TIME. ONE
23 OF JEFF'S CONCERNS EARLIER ABOUT WARF INDICATIONS, SO
24 WE MAY WANT TO THINK ABOUT THE CIRCUMSTANCE WHERE THE
25 ORPHAN INDICATIONS WERE CONTEMPLATED.

1 ANY OTHER COMMENTS? YOU WANT TO MAKE A
2 SPECIFIC PROPOSAL, TED, ABOUT THE 3 X, OR SHALL WE JUST
3 LEAVE IT OPEN AND HAVE IT DISCUSSED AT THE NEXT MEETING
4 AFTER WE SEE THAT? HOW WOULD YOU GUYS LIKE TO PROCEED?

5 DR. LOVE: WELL, I PRESUME THAT WE'VE ALREADY
6 DONE THE RESEARCH AND DONE SOME COMPARISONS TO KNOW
7 WHAT ARE OTHER MODELS THAT HAVE WORKED.

8 CHAIRMAN PENHOET: THE TRUE RANGE IS ZERO TO
9 5 PERCENT, RIGHT, BECAUSE THE FEDERAL GOVERNMENT
10 CHARGES NOTHING AND --

11 DR. LOVE: RIGHT. FOR THOSE USING A MULTIPLE
12 THAT'S NOT ZERO, IF THREE REALLY IS KIND OF THE LOWER
13 END OF THE RANGE, I'D BE COMFORTABLE WITH THAT BASED ON
14 THE FACT THAT OTHER PEOPLE ARE USING IT AND IT'S
15 WORKING. BUT MAYBE WE DON'T HAVE TO MAKE A DECISION
16 TODAY IF WE DON'T. AND IF THERE'S FURTHER INFORMATION
17 THAT COULD INFORM A CHOICE OF THAT NUMBER, I'D BE HAPPY
18 WITH THAT AS WELL.

19 CHAIRMAN PENHOET: IS EVERYBODY COMFORTABLE
20 WITH JUST A GENERAL LANGUAGE LOW END OF THE RANGE? IS
21 THAT OUR WORKING HYPOTHESIS FOR THE NEXT LAP IN THIS
22 RACE? THAT OKAY? OKAY WITH YOUR GUYS IN IRVINE?

23 DR. BRYANT: YES.

24 CHAIRMAN PENHOET: THE LOANS THING, I DO
25 THINK WE PROBABLY NEED SOME FURTHER WORK TO DEFINE

1 EXACTLY HOW THAT WORKS, BUT THE SAME PRINCIPLE WOULD
2 APPLY, THAT THE LOANS WOULD BE AT SOME RANGE WHICH IS
3 NOT VENTURE DEBT. VENTURE DEBT IS 18, 19 PERCENT, OR
4 WHATEVER IT IS. WE'RE TALKING ABOUT THINGS WHICH ARE
5 MUCH MORE CLOSE TO STANDARD PRIME OR PRIME PLUS EIGHT
6 OR POINTS OR SOMETHING LIKE THAT FOR LOANS. OKAY.

7 AND THEN SHOULD WE HAVE A ONE-TIME
8 BLOCKBUSTER PAYMENT? I MEAN IF WE'RE GOING TO GIVE
9 SOME CONSIDERATION ON THE SMALL SIDE, MAYBE IT WOULD
10 MAKE SENSE, IF SOMEBODY HAS A PRODUCT WHOSE SALES
11 EXCEED \$250 MILLION A YEAR OR SOMETHING, THAT THERE IS
12 A MILESTONE PAYMENT ASSOCIATED WITH THAT TO THE STATE.
13 I THINK THAT THAT WOULD GO A LONG WAY TO HELPING US
14 POLITICALLY, FRANKLY, IF THERE WAS SUCH A THING.
15 SOMEBODY GETS A BIG WIN, THE STATE GETS SOME
16 RECOGNITION FOR HAVING FUNDED SOMETHING.

17 DR. LOVE: I AGREE WITH YOU. I THINK IF WE
18 GET A BLOCKBUSTER, A COMPANY WOULD BE HAPPY TO PAY SOME
19 WINDFALL PAYMENT, ASSUMING YOU GET A BLOCKBUSTER.

20 DR. PIZZO: BUT IN THAT REGARD, TED, JUST TO
21 FILL IN THE TWO BLANKS, THE EXCEED PART, YOU KNOW,
22 COULD BE ANYTHING THAT MIGHT TRIGGER THIS FROM A
23 MILLION TO \$50 MILLION OR WHATEVER. AND THAT MAKES IT
24 DIFFICULT TO JUDGE WHAT THE, QUOTE, BLOCKBUSTER PAYMENT
25 IS UNLESS YOU HAVE IT AS A PERCENTAGE OR SOMETHING LIKE

1 THAT. I MEAN THE CONCEPT IS RIGHT, BUT I'M NOT SURE
2 HOW I'D FORMULATE THIS LANGUAGE.

3 CHAIRMAN PENHOET: WE'LL GIVE YOU SOME HELP.
4 WHERE THE PROBLEM IS FOR BIG PHARMA, A BLOCKBUSTER IS A
5 BILLION DOLLARS IN SALES. THIS MIGHT BE A HUNDRED
6 MILLION DOLLARS IN SALES.

7 DR. LOVE: RIGHT. I THINK THIS MIGHT BE,
8 DEPENDING ON WHAT YOU'RE MAKING, IF YOU'RE MAKING A
9 DIAGNOSTIC PRODUCT OR IF YOU'RE MAKING A REAGENT, A
10 BLOCKBUSTER NUMBER IS VERY DIFFICULT. BUT OBVIOUSLY IF
11 WE'RE TALKING ABOUT A THERAPY, A CELL-BASED THERAPY, OR
12 SOME KIND OF PRODUCT-BASED THERAPY, THEN I THINK WE
13 KNOW WHAT IT COST TO MAKE THOSE DRUGS. SO BLOCKBUSTER
14 REALLY GETS DRIVEN OFF PRIMARILY THE COST THAT YOU HAVE
15 TO SPEND TO INVEST IN THE PRODUCT. THAT'S WHERE THE
16 NUMBER OF BLOCKBUSTER FOR OUR INDUSTRY IS PROBABLY
17 MINIMUM 500 MILLION A YEAR. SOME COMPANIES WOULD SAY
18 THAT NUMBER IS CLOSER TO A BILLION A YEAR, BUT FOR
19 OTHER INDUSTRIES, THE NUMBERS MIGHT BE LOWER THAN THAT.
20 SO I UNDERSTAND YOUR COMPLEXITY. I'M NOT SURE IF I
21 ANSWERED YOUR QUESTION.

22 DR. PIZZO: WHAT I'M SAYING IS SIMPLY THAT
23 THE CONCEPT MAKES SENSE. I JUST DON'T KNOW HOW TO
24 RESPOND TO COMPLETION OF THE ACTUAL NUMBER. LET'S SAY
25 IT WAS A DRUG AND LET'S SAY IT TOOK 800 MILLION TO \$1.2

1 BILLION TO DEVELOP THE DRUG AS AN INVESTMENT. LET'S
2 SAY THAT YOU'RE MAKING A BILLION DOLLARS IN REVENUES A
3 YEAR. WHEN DO YOU TRIGGER IT? AND HOW MUCH SHOULD IT
4 BE? SO I THINK THE CONCEPT IS FINE. I JUST DON'T -- I
5 DON'T KNOW HOW WE'RE GOING TO FILL IN THE BLANKS.

6 CHAIRMAN PENHOET: WELL, WE'LL DO SOME
7 HOMEWORK WITH THE INDUSTRY AND VARIOUS PLAYERS AND SEE
8 IF WE CAN GET SOME FEEDBACK ON WHAT A GENERALLY
9 ACCEPTED VIEW OF WHAT A BLOCKBUSTER WOULD BE.

10 DR. LOVE: ONE IDEA IS WE COULD THINK ABOUT
11 PEGGING IT AT SOME PRETTY LARGE MULTIPLE OF THE LOAN OR
12 GRANT AMOUNT. THAT MAY BE THE BEST WAY TO DO IT. IF
13 YOU BORROWED \$10 MILLION AND YOU'VE NOW GENERATED
14 REVENUES THAT ARE 30 X WHAT YOU BORROW, MAYBE THAT
15 WOULD BE A WAY.

16 MR. SHEEHY: MY COMMENT IS I'M WONDERING IF
17 WE COULD ALSO INVESTIGATE, I KNOW THIS MAY BE A LITTLE
18 BIT OFF, BUT IF WE CAN TAKE PART OF THAT BLOCKBUSTER
19 PAYMENT IN-KIND IF WE'RE WITHIN THE CONTEXT OF OUR
20 CURRENT HEALTHCARE SYSTEM. YOU KNOW, IT WOULD BE
21 REASONABLE IN THE CONTEXT OF A BLOCKBUSTER THERAPY,
22 ESPECIALLY ONE THAT MIGHT BE RELATIVELY DIFFICULT AND
23 EXPENSIVE TO ADMINISTER, TO MAYBE PERHAPS SEE IF THE
24 COMPANY MIGHT HAVE AN OPTION TO CALIFORNIANS WHO DID
25 NOT HAVE ACCESS TO IT. YOU KNOW, THAT WE CAN PUT AN

1 IN-KIND PIECE IN THERE AS WELL TO ALSO MAKE SURE WE
2 GET. BECAUSE IT WOULD BE A SHAME IF WE Poured THAT
3 MUCH MONEY BACK INTO THE STATE AND STILL NOT EVERYBODY
4 IN CALIFORNIA COULD GET ACCESS TO THIS. A COMPANY
5 MIGHT RATHER JUST PROVIDE THE THERAPY MORE WIDELY. I
6 JUST WAS GOING TO PUT THAT OUT.

7 CHAIRMAN PENHOET: PATRICIA OLSON HAD A
8 COMMENT. FOR THOSE OF YOU WHO DON'T KNOW PATRICIA,
9 EVERYBODY KNOWS. SHE'S RESPONSIBLE FOR THE STRATEGIC
10 PLAN PROCESS.

11 MS. OLSON: I WAS ALSO THINKING IF THERE WAS
12 GOING TO BE SOME SORT OF TIME LIMIT ON IT BECAUSE, AS
13 YOU KNOW, MANY DRUGS TAKE AWHILE TO REACH THEIR FULL
14 REVENUE POTENTIAL. WE WOULD ALMOST HAVE TO FACTOR THAT
15 IN WITH, YOU KNOW, THE PAYBACK MULTIPLE AND A LOT OF
16 THINGS, SO THIS COULD BE PART OF THE FORMULA.

17 CHAIRMAN PENHOET: OKAY. IT SOUNDS LIKE
18 WE'VE GOT SOME GENERAL AGREEMENT THAT THE PRINCIPLE
19 MIGHT WORK, SO WE'LL PUT SOME MORE HOMEWORK INTO THE
20 CONCEPT.

21 NOW THE LAST ONE. AT ONE POINT IN OUR
22 FUNDING DO WE HAVE THE RIGHT TO ASK A COMPANY TO
23 PROVIDE THE TWO THINGS WE'VE ASKED THE NONPROFITS TO DO
24 IN THEIR LICENSING. THIS IS A COMPANY DEVELOPING IT
25 THEMSELVES, NOT A LICENSE TO A THIRD PARTY. GO ALONG

1 WITH THAT. JUST TO REFRESH YOUR MEMORY, THOSE TWO
2 OBLIGATIONS ARE A PLAN FOR ACCESS AT THE TIME OF
3 COMMERCIALIZATION AND PUBLICLY FUNDED AGENCIES IN
4 CALIFORNIA BE ALLOWED TO HAVE THE PRODUCT AT A PRICE
5 NOT TO EXCEED THE FEDERAL MEDICAID PRICE.

6 SO I THINK THE REASONABLE PERSON VIEW OF
7 THIS, IF WE FUNDED IT ALL, WE SHOULD BE ABSOLUTELY FREE
8 TO ASK FOR IT. IF WE FUND A VERY TINY FRACTION, IT MAY
9 BE OVERREACHING FOR US. I DON'T KNOW THAT, FRANKLY.
10 IT'S SOMETHING THAT I'D LIKE TO SEE. BUT WHERE IN
11 BETWEEN, IF THERE IS AN IN BETWEEN, OF 1 PERCENT AND A
12 100 PERCENT SHOULD WE ASK A COMPANY TO PROVIDE THESE?
13 IN A SENSE THEY ARE MONETARY IN THAT THEY HAVE VALUE,
14 BUT THESE NONDIRECTLY MONETARY FEATURES. I PUZZLED
15 OVER THIS ISSUE A LOT. I MUST SAY I DON'T HAVE ANY
16 SPECIAL WISDOM ON THE SUBJECT. I'M CLEAR IN MY OWN
17 MIND THAT IF WE FUND 1 PERCENT, THIS IS ASKING A LOT.
18 IF WE FUND IT ALL, WE SHOULD DEFINITELY GET IT. I
19 DON'T KNOW WHERE THE NUMBER IN THE MIDDLE IS.

20 I DO KNOW, THOUGH, THAT WE WANT TO INCENT
21 CALIFORNIA COMPANIES TO DEVELOP THESE PRODUCTS
22 THEMSELVES. IN FACT, YOUR POINT ABOUT LICENSING. SO
23 DUANE ROTH HAS A COMMENT.

24 MR. ROTH: ED, I'VE BEEN RATHER QUIET ON THIS
25 BECAUSE MOST OF WHAT'S UP HERE IN CONCEPT I THINK WE

1 CAN WORK WITH AND SUPPORT. BUT THIS LAST ONE IS
2 PROBABLY THE ONE THAT I'M MOST TROUBLED BY BECAUSE IT
3 HAS SOME THINGS THAT HAVE TO BE DEFINED. LIKE EVEN
4 LIKE UNINSURED. THERE ARE MANY PEOPLE UNINSURED
5 BECAUSE THEY CHOOSE TO BE UNINSURED AND ACTUALLY CAN
6 AFFORD THERAPIES. WE DON'T WANT TO CREATE SOMETHING
7 WHERE SOMEBODY DECIDES TO BECOME UNINSURED JUST SO THEY
8 CAN ACCESS A PRODUCT OR A DEVICE OR WHATEVER IT MAY BE.
9 THAT'S ONE.

10 A GENERAL COMMENT ABOUT THE ENTIRE LIST.
11 THERE ARE MANY MOVING PARTS THERE. YOU MENTIONED
12 STAFF. WE DON'T HAVE A LARGE STAFF TO NEGOTIATE, NOR
13 DO WE WANT TO NEGOTIATE MUCH BECAUSE EVERYTHING WE DO
14 WILL BE LOOKED AT THROUGH A LENS OF THE PUBLIC. AND I
15 THINK THE MORE WE CAN MAKE THIS COOKIE CUTTER IN THIS
16 PARTICULAR CASE, THE BETTER OFF WE'RE GOING TO BE. BUT
17 I JUST -- I WENT THROUGH IT. WE HAVE TO DECIDE A
18 ROYALTY RATE. WE CAN HAVE A LOAN OR A GRANT. WE HAVE
19 TO HAVE SOMETHING IN HERE FOR AFFORDABILITY, ACCESS,
20 AND THEN BLOCKBUSTER. THAT'S A LOT OF THINGS THAT GO
21 INTO A FORMULA. AND COMPANIES ARE GOING TO WANT TO
22 ACCESS THIS.

23 THE ONE THING THAT TROUBLES THEM IS LACK OF
24 CERTAINTY ABOUT WHAT THE DEAL IS. WHAT DO I HAVE TO
25 NEGOTIATE AND WHAT I DON'T. SO WHEN I GO THROUGH THE

1 LIST, I PROBABLY CAN SUPPORT SOMETHING IN EACH OF THESE
2 AREAS, BUT I THINK IT HAS TO BE A REAL CLEAR MATRIX
3 THAT SAYS THIS IS THE DEAL. AND EITHER YOU TAKE THE
4 MONEY OR YOU DON'T. OF ALL THE THINGS ON THE LIST, THE
5 ONE THAT I THINK WOULD CAUSE ME NOT TO TAKE SOME OF THE
6 MONEY WOULD BE THE UNCERTAINTY IN THAT LAST ONE.
7 THAT'S GOING TO BE A TOUGH ONE TO WRITE BECAUSE FOR A
8 \$10 MILLION GRANT, I MAY END UP BUYING MYSELF INTO A
9 WHOLE BUNCH OF VERY LOW PRICED PRODUCT THAT I DECIDE
10 ISN'T WORTH TAKING THE GRANT.

11 SO THAT'S WHY I'VE WAITED FOR THAT. IT'S NOT
12 THAT I DISAGREE. I HAVE THE SAME FEELING YOU DO, THAT,
13 YEAH, FOR CALIFORNIANS, THEY SHOULD HAVE ACCESS AND
14 THEY SHOULD HAVE IT AFFORDABLY, BUT WE HAVE TO BE
15 REALLY CAREFUL WITH HOW THAT ENDS UP BEING.

16 DR. PRIETO: CAN I MAKE A COMMENT? I'D LIKE
17 TO RESPOND TO A COUPLE OF THOSE POINTS THAT DUANE MADE.
18 AND ON THIS TOPIC, FIRST OF ALL, AS SOMEBODY WHO TREATS
19 THE UNINSURED AND SEES UNINSURED PATIENTS, I HAVE TO
20 TELL YOU THAT MY IMPRESSION IS THAT THOSE WHO ARE
21 UNINSURED BY CHOICE, THE PORTION THAT ARE UNINSURED BY
22 CHOICE IS REALLY VANISHINGLY SMALL. EVEN PEOPLE WITH
23 RESOURCES ARE AWARE THAT MEDICAL ISSUES, YOU CAN HAVE A
24 CATASTROPHIC EVENT THAT CAN MAKE A HUGE IMPACT TO THE
25 FINANCES OF EVEN A VERY AFFLUENT PERSON, AND MOST

1 REASONABLE PEOPLE WITH RESOURCES AND THE ABILITY TO
2 HAVE INSURANCE DO HAVE INSURANCE.

3 THE OTHER IS THE ACCESS PLANS THAT WE TALKED
4 ABOUT, I MEAN JEFF HAS MADE THE POINT FOR US. THIS IS
5 AN INDUSTRY STANDARD NOW, AT LEAST IN PHRMA, SO IT IS
6 NOT ANYTHING UNEXPECTED OR THAT PEOPLE IN THE INDUSTRY
7 ARE NOT USED TO. AND UNDER OUR POLICY, THE PLAN ITSELF
8 WOULD BE DESIGNED BY THE GRANTEE. I THINK THAT TAKES A
9 LOT OF THE BURDEN OR MAKES THIS A NOT UNREASONABLE
10 BURDEN. WE'RE TELLING GRANTEES YOU COME BACK TO US AND
11 TELL US WHAT THIS IS GOING TO LOOK LIKE, BUT WE HAVE TO
12 SEE A PLAN.

13 THE FINAL POINT IS THAT I THINK A REASONABLE
14 THRESHOLD FOR OUR PARTICIPATION WOULD BE ANYTHING OVER
15 25 PERCENT.

16 CHAIRMAN PENHOET: OKAY. WE LOOKED UP THE
17 TOP TEN FUNDERS OF PHILANTHROPY DONATIONS IN THE UNITED
18 STATES. THE LARGEST IS THE GATES FOUNDATION; NO. 2,
19 THE MERCK PATIENT ASSISTANCE PROGRAM; NO. 4, THE
20 BRISTOL MEYERS SQUIBB PATIENT ASSISTANCE FOUNDATION;
21 NO. 5, LILLY ENDOWMENT; NO. 8, JANSSEN ORTHO PATIENT
22 ASSISTANCE FOUNDATION. SO THE BIG PHRMA COMPANIES ALL
23 ARE DEFINITELY PLAYING IN THIS ARENA.

24 DR. LOVE: I ACTUALLY AGREE WITH WHAT
25 FRANCISCO SAID. DUANE, IT'S DEJA VU ALL OVER AGAIN.

1 WE HAD THE SAME CONVERSATION ABOUT WHAT UNINSURED MEANS
2 AT ONE POINT EARLIER, BUT I DO THINK THAT IT'S NOT A
3 BIG PROPORTION. BUT I ALSO THINK THIS 25 PERCENT
4 NUMBER COULD BE POSITIVE FOR US BECAUSE WHAT I THINK IT
5 DOES IS IT SAYS TO A COMPANY THAT IF I TAKE A \$10
6 MILLION GRANT AND I HAVE TO SPEND \$300 MILLION TO MAKE
7 A PRODUCT, THEN MAYBE THIS ISN'T A BURDEN, AT LEAST
8 THAT CIRM IS HOLDING ME TO. AT THE END OF THE DAY, I
9 THINK THAT THIS IS A STANDARD THAT WE'RE ALL
10 INCREASINGLY BEING HELD ACCOUNTABLE TO IN OUR INDUSTRY,
11 BUT I'M NOT SURE IF CIRM NEEDS TO BE THE WATCHDOG FOR
12 DOING THIS. I'M NOT SURE IF WE WANT TO PUT THAT BURDEN
13 ON US.

14 I COME AT IT MAYBE KIND OF FROM THE POINT OF
15 IT'S NICE FOR US TO HAVE A WAY TO NOT EVEN FEEL LIKE
16 WE'RE THE WATCHDOG FOR THIS ISSUE IF, IN FACT, WE ONLY
17 FUNDED 1 PERCENT OF THE EFFORT.

18 MR. ROTH: YOU COULD RESPOND FOR ME, ED. I'M
19 IN AGREEMENT WE SHOULD DO SOMETHING HERE. MY
20 PROBLEM -- I'LL RESPOND. I'M IN AGREEMENT WE SHOULD DO
21 SOMETHING HERE. WHAT I SAID WAS THAT WE HAVE TO BE
22 REALLY CAREFUL WITH THE TERMINOLOGY. AND, YES, THE
23 UNINSURED IS ONE OF THE TERMINOLOGIES WE HAVE TO BE
24 CAREFUL WITH, AND THE OTHER IS MEDICAID PRICE BECAUSE
25 THERE ISN'T SUCH A THING AS, QUOTE, MEDICAID PRICE. SO

1 THE DEFINITIONS JUST REALLY HAVE TO BE REALLY CAREFULLY
2 WORKED OUT.

3 SAME THING FOR ACCESS. I COULD ARGUE ON THE
4 ACCESS SIDE, THAT IF YOU DO LEAVE IT COMPLETELY TO THE
5 COMPANIES AND DON'T HAVE A STANDARD, I COULD PRODUCE AN
6 ACCESS POLICY THAT SAYS, YEAH, I'LL MAKE IT AVAILABLE
7 TO THREE PEOPLE. THAT'S AN ACCESS PROGRAM, BUT YOU
8 WANT SOMETHING THAT'S INDUSTRY STANDARD. AND THAT'S
9 HOW I WOULD WORD IT. SO IT'S OPEN. IT SAYS AT THE
10 TIME OF COMMERCIALIZATION THAT YOU HAVE AN ACCESS
11 PROGRAM THAT IS INDUSTRY STANDARD. SOMETHING LIKE THAT
12 YOU CAN UNDERSTAND WAY DOWN THE ROAD. TRYING TO DO IT
13 TODAY, I DON'T THINK YOU CAN DO IT.

14 CHAIRMAN PENHOET: WELL, LET ME ASK THE
15 QUESTION AGAIN THEN. IRRESPECTIVE OF THE PERCENTAGE,
16 AND WE'VE HEARD ONE PROPOSAL, WHICH IS IF WE PUT IN
17 MORE THAN 25 PERCENT OF THE MONEY, WE HAVE A RIGHT TO
18 ASK FOR SOME OF THESE THINGS, HOWEVER WE ARE DEFINING
19 THEM. BUT IRRESPECTIVE OF THE THRESHOLD, 25, 40, 10,
20 WHATEVER WE END UP WITH, IS THE CONCEPT ACCEPTABLE TO
21 EVERYONE? EVERYBODY SEEMS HERE TO BE NODDING IN
22 AGREEMENT.

23 DR. PRIETO: YES.

24 CHAIRMAN PENHOET: YOU'RE OKAY IN IRVINE? I
25 DON'T KNOW HOW WE'LL DEFINE THE NUMBER. I THINK MOST

1 PEOPLE THOUGHT THAT -- YOU KNOW, OF THE PEOPLE WE
2 TALKED TO ABOUT THIS ISSUE GENERALLY, THAT 25 PERCENT
3 WASN'T AN UNREASONABLE NUMBER. YOU KNOW, CAN'T BE A
4 HUNDRED, CAN'T BE ZERO.

5 MR. SHEEHY: WHAT IS THE COST TO BRING A
6 THERAPY TO MARKET?

7 CHAIRMAN PENHOET: HOW LONG IS THE STREAM?

8 DR. LOVE: RIGHT. SO IT DEPENDS ON WHAT
9 YOU'RE COUNTING. I THINK WE NEED TO DEFINE THIS RIGHT;
10 BUT IF YOU'RE COUNTING THE COST OF THE DRUGS THAT
11 DIDN'T MAKE IT, THEN THE NUMBER GETS TO BE THE BILLION
12 DOLLAR NUMBER. IF YOU'RE COUNTING THE COST THAT YOU
13 ACTUALLY DIRECTLY PUT INTO THAT ONE PRODUCT THAT MADE
14 IT AND IGNORED THE COST OF THE OTHER PRODUCTS THAT YOU
15 ALSO HAD TO SPEND MONEY ON THAT DIDN'T MAKE IT, THEN
16 THE NUMBER COMES DOWN TO PROBABLY SOMEWHERE HALF THAT
17 NUMBER.

18 MR. SHEEHY: SO WE'RE STILL TALKING ABOUT A
19 CIRM INVESTMENT OF 125 MILLION PLUS, WHICH IS A FAIRLY
20 SUBSTANTIAL AMOUNT.

21 DR. LOVE: IT IS. IT IS. AND TO SOME
22 EXTENT, JUST BEING CLEAR, WE ARE TRYING TO SATISFY A
23 LOT OF DIFFERENT CONSTITUENCIES HERE, I THINK IT'S
24 PRETTY CLEAR. AND IF WE WERE TO FUND 25 PERCENT OF
25 SOMETHING, FOR US TO ASK FOR MORE, MAYBE IT'S SOMETHING

1 THAT DIDN'T COST VERY MUCH TO DEVELOP. MAYBE IT'S A
2 DIAGNOSTIC OR IT'S A CELL LINE OR SOMETHING, AND TO ASK
3 MORE ABOUT THAT, MAYBE IT'S FAIR. BUT IN REALITY,
4 WE'RE NOT PUTTING IN LIKELY A BIG FRACTION OF MONEY TO
5 REALLY MAKE A DRUG.

6 MR. SHEEHY: I REALLY THINK THAT THAT'S THE
7 QUESTION. AND I FEEL LIKE THAT WHEN WE DO MAKE THAT
8 INVESTMENT, IT'S GOING TO BE A FAIRLY SUBSTANTIAL
9 INVESTMENT, AND IT'S GOING TO BE FAIRLY DELIBERATE WITH
10 A HIGH PROBABILITY OF SUCCESS. WE NEED TO KIND OF
11 THINK IN TERMS OF THIS PERCENTAGE IN A MORE CONCRETE
12 FASHION BECAUSE IT REALLY IS GOING TO BE \$100 MILLION
13 PLUS OF STATE INVESTMENT. THERE IS GOING TO BE A HIGH
14 PROBABILITY OF SUCCESS BECAUSE WE'RE NOT GOING TO BE
15 GIVING THAT MUCH MONEY AWAY TO A SINGLE ENTITY THAT
16 OFTEN. AND SO MAYBE HAVING SOME OF THESE EXPECTATIONS,
17 SO MAYBE IT'S NOT 25 PERCENT, BUT I DON'T KNOW THAT IT
18 NEEDS TO BE SUCH A LARGE PERCENTAGE BECAUSE FOR US TO
19 MAKE THAT KIND OF INVESTMENT, I THINK EVERYBODY SITTING
20 AROUND IS GOING TO HAVE A LOT OF EXPECTATIONS.

21 DR. LOVE: JUST THAT THE SMALLER YOU MAKE IT,
22 THE MORE PEOPLE ARE GOING TO SAY I'M NOT GOING TO
23 BOTHER WITH THIS BECAUSE IT'S SUCH A TRIVIAL AMOUNT OF
24 MY COST, AND YOU'RE DEMANDING SO MUCH OF IT. THAT'S
25 WHAT I KNOW WE'RE TRYING TO BALANCE. AT THE END OF THE

1 DAY, WE'RE TRYING TO GET PEOPLE TO WANT TO TAKE THE
2 MONEY AND APPLY IT TO GOOD USE TO MAKE THERAPIES OR
3 THINGS THAT HELP PATIENTS. THAT'S WHY I THINK ONE HAS
4 TO RECOGNIZE IT'S NOT A HUNDRED PERCENT, RECOGNIZE IT'S
5 NOT ZERO. TO ME 25 PERCENT ACTUALLY DID FEEL ABOUT
6 RIGHT.

7 I WOULDN'T PRESUME THE ANSWER IS NO TO THE
8 IDEA THAT SOMETHING MIGHT COME ALONG IN THE WAY OF A
9 THERAPY, AND IT LOOKS SO EXCITING TO US THAT WE MIGHT
10 SAY WE'RE WILLING TO PUT \$50 MILLION A YEAR FOR THREE
11 YEARS INTO THIS. AND THAT ACTUALLY MAY TRIGGER YOUR 25
12 PERCENT. AND A COMPANY MIGHT SAY IF YOU'RE WILLING TO
13 DO THAT, I'LL ACCEPT ALL OF THIS. SO IT COULD ACTUALLY
14 WORK OUT.

15 CHAIRMAN PENHOET: THIS IS ONLY FOR
16 CALIFORNIA, BY THE WAY. THE REST OF THE COUNTRY THEY
17 CAN DO WHAT THEY WOULD PLEASE.

18 ANY COMMENTS, FURTHER COMMENTS FROM THE TASK
19 FORCE? IF NOT, JOHN SIMPSON HAD HIS HAND UP FIRST.

20 MR. SIMPSON: NOT UNSURPRISINGLY, I PROBABLY
21 WILL ARGUE THAT IF YOU TAKE THE PUBLIC MONEY, NO MATTER
22 WHAT AMOUNT, COMING WITH TAKING THE PUBLIC MONEY IS THE
23 OBLIGATION FOR THE PUBLIC BENEFIT. AND AS I SEE IT,
24 THE LAST, THAT'S HOW YOU ASSURE THE PUBLIC BENEFIT AT
25 LEAST GOES TOWARDS THAT. SO I WOULD SAY THAT ANY CIRM

1 INVESTMENT ALL ENTAILS THAT PROVISION. I DON'T THINK
2 THERE'S GOING TO BE A DISINCENTIVE.

3 WHAT YOU MAY BE TALKING ABOUT HERE IS SOME
4 DOLLARS ARE MORE VALUABLE THAN OTHER DOLLARS. SOMEBODY
5 COMES TO GET THE CIRM WHEN THEY NEED IT, SO IT MAY BE A
6 RELATIVELY SMALL AMOUNT, BUT IT MAY BE THE AMOUNT THAT
7 CLOSES THE DEAL. SO THAT THOSE DOLLARS ARE IN A SENSE
8 MARGINAL DOLLARS THAT ARE MORE VALUABLE, AND I THINK
9 THAT SHOULD BE RECOGNIZED. I WOULD MAKE THAT POINT
10 VERY STRONGLY.

11 WHILE I'M UP, I WOULD ALSO SAY BECAUSE THESE
12 GRANTS TO PROFIT ENTITIES, THEY'RE MOST LIKELY GOING TO
13 BE MUCH CLOSER ALONG THE ROUTE OF COMMERCIALIZATION.
14 THE LIKELIHOOD OF MAKING GRANTS THAT ARE MUCH CLOSER TO
15 ACTUALLY GETTING INTO THE CLINIC, THAT IT REALLY IS A
16 TIME WHEN YOU SHOULD HAVE SOME PROVISION IN THAT WOULD
17 PRECLUDE THE POSSIBILITY OF EGREGIOUS PROFITEERING
18 WHERE SOMEONE COULD CHARGE OUTRAGEOUS AMOUNTS FOR
19 WHATEVER THERAPY WAS DEVELOPED. THANK YOU.

20 MR. GILENATER: TODD GILENATER AGAIN WITH
21 THE CALIFORNIA HEALTHCARE. ON THE EXIT PLAN FOR THE
22 UNINSURED, AND THIS IS SOMETHING THAT, AGAIN, WE
23 REFERENCED IN OUR IPPNPO COMMENTS BASED ON A REVIEW OF
24 CALIFORNIA-BASED COMPANIES, THAT MOST ACCESS PLANS ARE
25 BASED ON FINANCIAL NEED AS OPPOSED TO REFERENCE TO

1 INSUREDS OR NOT. IT WOULD SUGGEST THAT FOR
2 CONSIDERATION OF THE TASK FORCE, THE ICOC REFER TO
3 FINANCIAL NEED AS OPPOSED TO WHETHER OR NOT
4 CALIFORNIANS ARE UNINSURED.

5 THE SECOND COMMENT AND, AGAIN, IT BOTH
6 PERTAINS TO THIS AS WELL AS THE IPPNPO COMMENTS WITH
7 REGARDS TO THE MEDICAID PRICING, AND I BELIEVE DUANE
8 ROTH MAY HAVE ADDRESSED THIS ALREADY, BUT I JUST WANTED
9 TO EMPHASIZE THIS. THERE IS NO SUCH THING AS FEDERAL
10 MEDICAID PRICE. IN THE LANGUAGE INCLUDED IN THE
11 IPPNPO, WHICH I PRESUME WILL ALSO BE USED AS A MODEL
12 FOR THE FOR-PROFIT POLICY, CHI CONTINUES TO STRONGLY
13 URGE THE TASK FORCE AND THE ICOC TO BE VERY CAREFUL IN
14 DEVELOPING REGULATIONS IN WHAT MAY BE, AT LEAST IN ONE
15 SENTENCE, LOOKS TO BE SIMPLISTIC, THAT IT IS NOT AS
16 SIMPLISTIC AS IT SEEMS.

17 AND, AGAIN, POINTING TO ONE EXAMPLE OF
18 FEDERAL MEDICAID PRICE, INCLUDING THAT IN A REGULATION
19 ON AN UNDEFINED ISSUE, FEDERAL MEDICAID PRICING DOES
20 NOT EXIST IS CAUSE FOR CONCERN. THANK YOU.

21 MR. REED: I THINK EVERYBODY AGREES WITH
22 DUANE ROTH, THAT THIS HAS TO BE CAREFULLY DONE, BUT I
23 THINK IT'S VITAL THAT IT BE DONE. I THINK THE LANGUAGE
24 AS IT IS IS ACTUALLY PRETTY CAREFUL. IT WAS WORKED OUT
25 AGONIZINGLY. AND I THINK ALSO WE NEED TO REMEMBER

1 WE'RE BEING WATCHED ALL ACROSS THE COUNTRY, AND WE'RE
2 BEING USED AS AN EXAMPLE. EVERYTHING WE DO WILL BE
3 STUDIED, AND IT WILL HAVE A LOT OF ECHOES THAT MAYBE WE
4 CAN'T FORESEE RIGHT NOW. SO I THINK IT'S IMPORTANT
5 THAT EVERY ISSUE, INCLUDING ACCESS, BE SPELLED OUT AND
6 SHOW THAT WE HAVE, WHICH WE HAVE DONE, THOUGHT
7 CAREFULLY ABOUT IT.

8 CHAIRMAN PENHOET: OKAY. PATRICIA OLSON AND
9 THEN KEN TAYMOR.

10 MS. OLSON: I JUST WANTED TO SAY ONE THING,
11 WHICH IS I HEARD SOMETHING TODAY THAT I ACTUALLY HADN'T
12 HEARD BEFORE, WHICH WAS THAT YOU MIGHT CONSIDER
13 SPENDING A HUNDRED FIFTY MILLION TO MOVE ONE THERAPY
14 FORWARD TO CLINIC DEVELOPMENT, WHICH IF I LISTEN TO, IF
15 I REMEMBER WHAT WE TALKED ABOUT AT OUR COMMERCIAL
16 SECTOR MEETING, I HEARD A LOT OF PEOPLE SAY THAT, YOU
17 KNOW, WE GET THIS THING INTO THE CLINIC OR STARTING
18 THINGS, THERE WILL BE OTHER FINANCING SOURCES THAT CAN
19 PICK IT UP. AND SO I ACTUALLY WAS A LITTLE BIT
20 SURPRISED BECAUSE THAT'S THE FIRST THING I HEARD THIS
21 FROM IN THE MANY SESSIONS AND THE THINGS WE LISTENED IN
22 BECAUSE \$50 MILLION, SAY, OVER THREE YEARS IS A BIG
23 HUNK OF WHAT WE'RE LIKELY TO BE ABLE TO SPEND.

24 IT WAS AN INTERESTING COMMENT. AND I THINK
25 WE MAY HAVE TO FACTOR IT INTO OUR THINKING.

1 DR. LOVE: IT MAY BE NOT A WELL THOUGHT
2 THROUGH COMMENT. I WAS MAKING A HYPOTHETICAL.

3 CHAIRMAN PENHOET: WE SHOULD BE BOLD.

4 MR. TAYMOR: KEN TAYMOR. I THINK THIS
5 DISCUSSION POINTS TO PERHAPS A NEED TO REVISIT BULLET
6 POINT 5 ABOUT APPLYING THE NONPROFIT IP RULES TO
7 FOR-PROFIT LICENSEES EXCEPT WITH ONE NARROW EXCEPTION.
8 I JUST HAVE A CONCERN, AND I WOULD REALLY LIKE TO HEAR
9 FROM PEOPLE IN THE INDUSTRY IN TERMS OF THE TYPE OF
10 LICENSES THAT ARE LIKELY TO BE DONE AND HOPE THAT
11 YOU'RE NOT SETTING UP A PROGRAM THAT'S GOING TO END UP
12 A SITUATION AS TED DESCRIBED. A COMPANY MAKES A
13 DISCOVERY, THEY FIGURE IT DOESN'T FIT IN WITH THEIR
14 PLAN, BUT AT THE SAME TIME, WHEN THEY GO TO TRY TO SHOP
15 IT, BECAUSE OF THE BROAD RANGE OF RESTRICTIONS THAT ARE
16 ON THAT, THAT WE PUT ON THE BASIC IP BEING CREATED IN
17 UNIVERSITY AND ACADEMIC LABS, THEY CAN'T FIND A
18 LICENSEE. AND, FOR EXAMPLE, IT'S NOT CLEAR WHY THE
19 LICENSEE WOULD BE SUBJECT TO THE STANDARD ON THIS
20 ACCESS STANDARD THAT WOULD APPLY FOR THE UNIVERSITY
21 LICENSEES, BUT THE GRANTEE OR COMMERCIAL GRANTEE ITSELF
22 WOULD HAVE THIS OTHER LOWER STANDARD.

23 I THINK IT MAY BE ALSO HELPFUL TO HAVE
24 FEEDBACK FROM STAFF WHO ARE THINKING ABOUT WHAT THE
25 COMMERCIAL GRANTS MIGHT LOOK LIKE TO HELP GET AN IDEA

1 OF WHERE THEY MIGHT BE. BUT I WOULD STRONGLY ENCOURAGE
2 FURTHER THOUGHT ON THE EXTENT TO WHICH YOU WANT TO
3 IMPORT THIS NONPROFIT RULES.

4 CHAIRMAN PENHOET: I THINK THAT'S A GOOD
5 COMMENT. WE THOUGHT A LOT ABOUT IT, KEN. I THINK I
6 CAN TELL YOU, BECAUSE I SPENT A LOT OF TIME IN
7 SACRAMENTO AND I'VE SPENT A LOT OF TIME WITH JOHN
8 SIMPSON, I BELIEVE THAT THIS FEATURE IS THE CORE OF THE
9 LEGISLATOR'S INTEREST IN OUR WORK, AS FAR AS I'VE BEEN
10 ABLE TO READ IT. SOME OF YOU HAVE BEEN WITH US. I
11 THINK TO ABANDON THIS REVENUE SHARING AND THESE
12 OBLIGATIONS FOR PROVIDING AN ACCESS PLAN, PROVIDING LOW
13 COST OF FEDERAL GOVERNMENT, YOU KNOW, I DON'T SEE HOW
14 WE WOULD DO IT FOR THE FOR-PROFITS WITHOUT REVISITING
15 THE ISSUE FOR THE NONPROFITS. BUT I THINK WE ARE BACK
16 TOTALLY IN UNCHARTERED TERRITORY IF YOU WANT TO TAKE
17 THIS OFF THE TABLE.

18 MR. TAYMOR: I WAS IN NO WAY SUGGESTING
19 TAKING IT OFF THE TABLE. I WAS SAYING YOU WANT TO LOOK
20 AT THE QUESTION ABOUT THE WHOLE-CLOTH APPLICATION JUST
21 FOR THE LICENSEES OF FOR-PROFITS AS OPPOSED TO SAYING
22 MAYBE THE LICENSEES OUGHT TO BE TREATED MORE LIKE OTHER
23 COMMERCIAL GRANTEES AS OPPOSED TO LIKE NONPROFIT
24 LICENSEES.

25 CHAIRMAN PENHOET: KEN HAS ESSENTIALLY SAID

1 THAT BASICALLY THE REQUIREMENT HERE IS FUNDAMENTALLY
2 DIFFERENT, I THINK, THAN IT IS FOR UNIVERSITIES. WE
3 DID SAY EARLIER, THOUGH, THAT WE WANT TO INCENT
4 COMPANIES TO FULLY DEVELOP THEIR PRODUCTS IN CALIFORNIA
5 AND NOT LICENSE THEM OUT. IF IT TURNS OUT THAT THEY
6 CAN'T FIND ANY LICENSEES, THEY WILL COME BACK TO US AND
7 WE'LL HAVE AN ARGUMENT BASED IN FACT FOR THE
8 LEGISLATURE, ETC., BUT IT'S MY PERSONAL VIEW THAT THIS
9 IS A VERY HARD THING FOR US TO BACK OFF OF FROM A
10 POLITICAL POINT OF VIEW. I DON'T KNOW WHETHER ANYBODY
11 ELSE HAS A COMMENT.

12 DR. LOVE: I AGREE WITH YOU, AND I THINK
13 THERE ARE GOING TO BE OCCASIONALLY CIRCUMSTANCES WHERE
14 A GRANTEE WILL COME BACK TO THE CIRM AND SAY WE HAVE
15 GOT THIS INVENTION. IT'S NOT ESSENTIAL TO US. WE
16 CAN'T GET ANYONE ELSE TO TAKE THROUGH THE OBLIGATIONS
17 OF CIRM, AND WE'VE GOT TO WORK THROUGH THAT INDIVIDUAL
18 CIRCUMSTANCE. I THINK THAT WILL HAPPEN.

19 CHAIRMAN PENHOET: QUESTION FOR SCOTT. IF
20 THAT DID HAPPEN, CAN IT BE REFERRED TO ICOC, AND IS THE
21 ICOC ALLOWED TO MAKE ANY EXCEPTIONS TO APA REGULATIONS
22 ON A CASE-BY-CASE BASIS?

23 MR. TOCHER: IF IT WERE IN THE REGULATION
24 THAT THAT AUTHORITY WOULD REST WITH THE ICOC, THAT
25 WOULD BE AN OPTION.

1 CHAIRMAN PENHOET: IF IT WERE IN THE
2 REGULATION THAT IT COULD GO. IF NOT, WE'D HAVE TO
3 REVISIT IT.

4 MR. SHEEHY: THAT COMES TO MIND AN ORPHAN
5 DISEASE CONCERN. AT A MINIMUM WE'D WANT TO PUT IN SOME
6 LANGUAGE BECAUSE THERE'S GOING TO BE -- ONE CAN EASILY
7 VISUALIZE SOMEONE COMING UP WITH A THERAPY FOR A
8 DISEASE THAT IS PROFITABLE, AND THEN THAT SAME THERAPY
9 NOT NECESSARILY BEING PROFITABLE ON DISEASES WHICH ONLY
10 AFFECT A SMALL NUMBER OF PEOPLE. AND THEN THESE
11 REQUIREMENTS WOULD BE QUITE ONEROUS, SO AT A MINIMUM WE
12 SHOULD PUT IN SOME LANGUAGE THAT ACKNOWLEDGES THAT
13 THERE MAY BE ORPHAN DISEASES WHERE WE WOULD WANT TO.

14 CHAIRMAN PENHOET: BACK TO THE 17 PERCENT.
15 17 PERCENT IS OF THEIR REVENUE.

16 MR. SHEEHY: I THINK WHAT KEN IS TALKING
17 ABOUT, WHICH I HAD NOT THOUGHT ABOUT, WAS THAT THERE'S
18 A WHOLE RANGE OF REQUIREMENTS FOR LICENSING IN IPPNPO,
19 AND WE HAVEN'T LOOKED AT EVERY SINGLE ONE OF THEM. THE
20 ONLY ONE YOU'RE LOOKING AT IS THE REVENUE ONE. THAT I
21 LOOKED AT EARLIER WAS THE REVENUE, BUT THERE'S ALSO
22 PLANS FOR ACCESS, THERE'S PRICING REQUIREMENTS, WHICH
23 MAY NOT BE APPROPRIATE IN THE CONTEXT OF AN ORPHAN
24 DISEASE.

25 CHAIRMAN PENHOET: ANY OTHER COMMENTS? WELL,

1 NOW WE'VE GOTTEN TO THE BOTTOM OF THIS. I GUESS DO WE
2 HAVE ANY COMMENTS GENERALLY? DUANE HAS MADE A POINT
3 THAT WE HAVE TO MAKE SURE THE TOTALITY OF THESE THINGS
4 DOESN'T ADD UP TO A BURDEN.

5 MR. ROTH: MY RESPONSE TO A LOT OF THE
6 COMMENTS THAT HAVE BEEN MADE IS I THINK YOU JUST HAVE
7 TO PUT IT OUT THERE AND WE'LL GET THE FEEDBACK LIKE WE
8 DID ON THE PREVIOUS ROUND. I DON'T SEE ANYTHING ON
9 THIS LIST THAT I THINK SHOULD BE ELIMINATED, AND WE'LL
10 GET THE KIND OF FEEDBACK, HOPEFULLY, IN A CONSTRUCTIVE
11 WAY THAT WE CAN ACTUALLY WORK IT UP FROM HERE ON IN.

12 MY OVERALL CAUTION, THOUGH, IS THAT THIS IS
13 NOT SOMETHING WHERE WE'RE GOING HAVE A LOT OF MIX AND
14 MATCHING. WE NEED TO COME DOWN TO SOMETHING, HERE'S
15 THE DEAL FOR TAKING CIRM MONEY TO THE COMMERCIAL
16 ENTITIES. OTHERWISE, I THINK YOU ARE GOING TO JUST
17 OPEN UP A TREMENDOUS OPPORTUNITY FOR CRITICISM AND
18 UNCERTAINTY ON THE PART OF THE LICENSEES. SO I REALLY
19 ENCOURAGE US TO SAY HERE'S THE DEAL, AND ANYTHING
20 THAT'S THERE, THE TEMPLATE'S THERE, TAKE IT OR LEAVE IT
21 AS OPPOSED TO, WELL, YOU HAVE A LITTLE OF THIS.

22 THE GRANT VERSUS THE LOAN I THINK IS FINE IF
23 IT'S STRUCTURED PROPERLY, BUT THE REST OF IT HAS GOT TO
24 BE PRETTY STRAIGHTFORWARD.

25 DR. PIZZO: THE OTHER ISSUE THAT I AM

1 CONCERNED ABOUT IS IT'S REALLY NOT -- IT DOESN'T
2 REFLECT ON THESE PRINCIPLES. I AGREE WITH THE THINGS
3 THAT WE'VE MADE TODAY, BUT IT DOES DEAL WITH THE
4 STRATEGIC PLAN AND THE ALLOCATION PROPORTIONALLY OF
5 SUPPORT FOR COMMERCIAL VERSUS NONPROFIT UTILIZATION. I
6 THINK THIS IS A BIG TOPIC THAT REQUIRES A LOT OF
7 DISCUSSION. AND I DON'T KNOW THAT WE'VE HAD THAT
8 DISCUSSION YET, BUT, YOU KNOW, WITH \$300 MILLION A YEAR
9 BEING AVAILABLE LARGELY FOR DISCOVERY, IT WOULDN'T TAKE
10 VERY MUCH OF THAT, IF WE START TO TRY AND SUPPORT AND
11 FUND COMMERCIAL ENTITIES, TO USE UP A GOOD PROPORTION
12 OF THAT OR THE MAJORITY OF THAT.

13 NOW, I RECOGNIZE THAT THE BIG PART OF WHAT WE
14 WANT TO DO IS MAKE SURE THAT THE DISCOVERIES LEAD TO
15 ENTITIES WHICH ARE AVAILABLE TO HELP PEOPLE. THAT'S
16 OUR BOTTOM LINE, SO WE WANT TO SUPPORT THAT. BUT I
17 THINK WE'RE GOING TO HAVE TO BE PRETTY THOUGHTFUL ABOUT
18 HOW WE ASSURE THAT WE'RE DOING THAT AND NOT COMPROMISE
19 OUR RESEARCH ENGINE BECAUSE THAT DOESN'T HAVE ANOTHER
20 SOURCE; WHEREAS, COMMERCIALIZATION OFTEN HAS MULTIPLE
21 SOURCES.

22 DR. HALL: I SEE THE STRATEGIC PLAN BEARING A
23 LARGER AND LARGER BURDEN IN THESE DISCUSSIONS, BUT I
24 WANT TO JUST REMIND YOU THAT OUR CONCERN THERE IS ABOUT
25 GETTING THE SCIENCE DONE AND LESS ABOUT THE POLICY

1 ISSUES AND HOW IT'S APPORTIONED, HOW MUCH IT'S
2 APPORTIONED ONE WAY OR THE OTHER. WE WILL OBVIOUSLY
3 WANT TO INVOLVE THE PRIVATE SECTOR. WE WILL WANT TO
4 INVOLVE THESE OTHERS, BUT THE MAIN FOCUS OF THAT WILL
5 BE TO TRY TO DEFINE THE SCIENTIFIC PROBLEMS AND TRY AND
6 DEFINE THE WAYS IN WHICH WE WILL GO.

7 DR. PIZZO: THAT'S EXACTLY WHAT I'M SAYING.
8 THAT'S MY WORRY ABOUT -- MY WORRY IS MAKING SURE THAT
9 WE ARE INVESTING IN THE SCIENTIFIC DISCOVERIES THAT ARE
10 NEEDED TO HELP DEVELOP CONCEPTS THAT CAN ULTIMATELY BE
11 BROUGHT INTO COMMERCIALIZATION, BUT I'M JUST WORRIED
12 THAT RIGHT NOW WE'VE HAD A DISCUSSION, A VERY
13 THOUGHTFUL DISCUSSION, ABOUT HOW WE SUPPORT COMMERCIAL
14 ACTIVITY. AND I COULD SEE THE MONEY THAT'S AVAILABLE
15 BEING DISPROPORTIONATELY, IF NOT CAREFULLY THOUGHT
16 THROUGH, ALLOCATED TO THAT AND LOSING THE OPPORTUNITY
17 FOR BASIC RESEARCH AND BASIC DISCOVERY TAKING PLACE.

18 DR. HALL: JUST ADD, IF I MAY, THAT I
19 UNDERSTAND WHAT YOU'RE SAYING. THERE'S ALSO -- I THINK
20 WE ALL BELIEVE THAT SOME DISCOVERY RESEARCH WILL BE
21 DONE IN THE PRIVATE SECTOR, SO I THINK THE IMPORTANT
22 THING FOR US WOULD BE TO DEFINE THE SCIENTIFIC AIMS TO
23 LAY DOWN THE SCIENTIFIC PARAMETERS WITHOUT MAKING A
24 PRIORI DECISIONS ABOUT HOW MUCH SHOULD BE ONE PLACE OR
25 ANOTHER. THAT'S A DIFFERENT KIND OF POLICY THAT I

1 THINK THE ICOC WILL POSSIBLY NEED TO ADDRESS IN OTHER
2 WAYS. IT'S THE SAME QUESTION WITH LOANS AND GRANTS
3 ALSO. OUR PRIMARY INTENT IS TO SAY WHAT ARE THE
4 SCIENTIFIC PROBLEMS THAT WE NEED TO SOLVE? HOW ARE WE
5 GOING TO DEFINE THE PATHWAY? AND WHAT ARE THE
6 MECHANISMS, BROADLY SPEAKING, BY WHICH WE'RE GOING TO
7 DO THAT?

8 MR. SNODGRASS: COUPLE COMMENTS ON TWO
9 DIFFERENT POINTS. ONE, CONCEPTUALLY THE CONCEPT OF AN
10 X PERCENTAGE PAYBACK OF GRANTS AND SO ON FROM AN
11 INDUSTRY PERSPECTIVE FOR US IS ATTRACTIVE, BUT THE
12 DEVIL IS IN THE DETAILS. IF IT'S NOT SPREAD OUT OVER
13 SOME REASONABLE TIME AND SO ON, IT BECOMES PUNITIVE OF
14 A BIG LUMP SUM PAYMENT, AND SO THOSE KINDS OF THINGS.
15 IT SHOULD BE BASED ON PROFIT KINDS OF CONCEPTS.

16 THE OTHER ONE, THOUGH, ABOUT ONE SIZE FITS
17 ALL IS A REALLY DIFFICULT ONE BECAUSE IF YOU THINK
18 ABOUT A GROUP THAT'S TRYING TO DEVELOP A THERAPEUTIC,
19 YOU HAVE CERTAIN TYPES OF COSTS AND MARGINS ASSOCIATED
20 WITH THAT PRODUCT. ANOTHER COMPANY THAT IS BUILDING A
21 DIAGNOSTIC OR SO, THE TYPES OF BUSINESS CONSIDERATIONS,
22 MARGINS AND SO ON ARE QUITE DIFFERENT. SO IF ONE IS
23 REALLY TRYING TO THINK OF A ONE SIZE FITS ALL, ONE HAS
24 TO BE VERY CAREFUL BECAUSE YOU COULD BE COMPLETELY
25 PRICING OUT A WHOLE SERIES OF POTENTIAL COMMERCIAL

1 APPLICATIONS IF YOU'RE VIEWING IT FROM A THERAPEUTIC
2 DRUG MODEL KIND OF PERSPECTIVE. AND THOSE ARE QUITE
3 DIFFERENT KINDS OF BUSINESSES.

4 CHAIRMAN PENHOET: ANY COMMENTS FROM IRVINE?

5 DR. STEWARD: NO.

6 CHAIRMAN PENHOET: FROM SACRAMENTO?

7 DR. PRIETO: NO.

8 CHAIRMAN PENHOET: ANY FURTHER COMMENTS FROM
9 THE AUDIENCE IN SAN FRANCISCO? JOHN SIMPSON.

10 MR. SIMPSON: I JUST WANTED TO UNDERSCORE
11 WHAT DUANE ROTH SAID. I THINK IT'S ABSOLUTELY CRITICAL
12 THAT IT GETS SPELLED OUT AND THAT COMPANIES KNOW WHAT
13 THEY'RE BUYING IN FOR AND THEY KNOW WHAT THE PUBLIC
14 BENEFIT OBLIGATION IS. AND I THINK YOU WILL FIND
15 PEOPLE STEPPING UP WHEN IT'S CLEAR AND THE CERTAINTY IS
16 THERE, AND I THINK THAT'S VERY IMPORTANT.

17 CHAIRMAN PENHOET: OKAY. SO WITH YOUR
18 CONCURRENCE, WE'RE GOING TO GO AWAY AND PUT A LOT OF
19 WORK INTO REFINING OF THESE PRINCIPLES THAT WE'VE LAID
20 OUT BEFORE YOU TODAY. BEFORE WE LEAVE, THOUGH, WE
21 WOULD LIKE TO KNOW IF THERE'S ANY ADDITIONAL PRINCIPLE
22 THAT ANYBODY WOULD LIKE TO ADD TO THE LIST OR AS A
23 GROUP AS A WHOLE WANTS TO ADD? HAVE WE FORGOTTEN
24 SOMETHING?

25 DR. LOVE: I DON'T KNOW IF IT'S SOMETHING I

1 REALLY WANT TO TRY, BUT I COULD SAY THAT I THINK WE
2 REALLY NEED TO MAKE SURE THAT OUR PHILOSOPHICAL BIAS IS
3 ALWAYS IN ADVANCING THE THINGS THAT WILL ULTIMATELY
4 HELP PATIENTS AND NOT TO MAKING PROFIT, NOT IN
5 RECASHING BACK IN. IF WE REALLY STAY FOCUSED ON THE
6 NO. 1 PRINCIPLE IS TO ADVANCE THE THINGS THAT ARE
7 ULTIMATELY GOING TO HELP PATIENTS, I THINK THAT WILL --
8 I THINK WE'LL BE MORE SUCCESSFUL, AND I THINK THAT
9 REALLY IS THE CORE OF WHAT WE WERE PUT HERE TO DO.

10 CHAIRMAN PENHOET: ANY OTHER CLOSING
11 COMMENTS? WELL, I THINK WE'VE DONE A GOOD DAY'S WORK.

12 DR. PIZZO: JUST TO ECHO YOUR COMMENT, WE
13 NEVER SHOULD COME BACK HERE AGAIN.

14 CHAIRMAN PENHOET: WELL, LET ME REVIEW WHAT I
15 THINK WE'VE DONE TODAY. NO. 1, WE HAVE GOTTEN SOME
16 SUGGESTIONS ABOUT LANGUAGE CLARIFICATION FOR THE
17 NONPROFIT POLICY WHERE SOME PARTS OF THE LICENSING
18 THING REFER TO EXCLUSIVE LICENSING AND OTHER PARTS TO
19 NONEXCLUSIVE, BUT DON'T EXPLICITLY SAY EXCLUSIVE, BUT
20 THE LANGUAGE APPLIES TO EXCLUSIVE LICENSEES, SO WE WILL
21 GO BACK AND LOOK AT THAT.

22 WE HAVE HAD A SUGGESTION TO DEFINE A NUMBER
23 OF TERMS. HELP ME OUT, JOHN, ONE OF THEM WAS.

24 MR. SIMPSON: ONE WAS EXCLUSIVE LICENSES.

25 CHAIRMAN PENHOET: EXCLUSIVITY. THANK YOU.

1 THAT WAS THE SECOND PIECE OF THAT.

2 WE HAVE ADOPTED SOME ARTFULLY CRAFTED
3 COMPROMISE LANGUAGE AROUND THE RESEARCH USE EXEMPTION.
4 I HOPE SOMEBODY GOT A PICTURE OF THE HALLWAY BACK THERE
5 WITH ALL THE VARIOUS PARTIES AT WORK. AND I THINK WE
6 WILL -- NOW, THAT TRIPS ANOTHER 15-DAY REVIEW. WE'LL
7 PUT THAT INTO REVIEW FOR 15 DAYS.

8 WE HAVE ESSENTIALLY GIVEN MARY HER MARCHING
9 ORDERS FOR THE NEXT 30 DAYS, WHICH IS TO TRY TO FLESH
10 AS MUCH OF THIS OUT AS POSSIBLE FOR OUR NEXT MEETING
11 HOPEFULLY ON SEPTEMBER 21ST.

12 AND I THINK WITH THAT, THAT'S THE END OF THIS
13 PART OF THE MEETING. WE DO HAVE A REQUEST, IF WE HAVE
14 SOME EXTRA TIME, FOR THE GENTLEMAN FROM UCSF TO ADDRESS
15 US ON THE ISSUE OF -- THIS IS JOHN OLMERT FROM UCOP ON
16 THE ISSUE OF OPEN ACCESS.

17 MR. OLMERT: THANK YOU. JUST ON THE ISSUE OF
18 OPEN ACCESS, MY UNDERSTANDING WITH REGARD TO
19 PUBLICATION REQUIREMENTS THAT ARE STILL UNDER
20 DISCUSSION FOR THE NONPROFIT PORTION AND PERHAPS COULD
21 ALSO BE FOR THE PROFIT PORTION OF THE POLICY IS THAT
22 THE ICOC REFERRED BACK TO THE IP TASK FORCE THE
23 QUESTION -- THE POSSIBILITY OF METHODS TO MORE
24 THOROUGHLY ACCELERATE THIS KIND OF RESEARCH IN SCIENCE
25 BY CONSIDERING OPEN ACCESS OR BROADER ACCESS TO

1 RESEARCH RESULTS.

2 I JUST WANTED TO ASK ONE QUESTION, WHICH IS
3 WHETHER YOU INTENDED TO HAVE THAT ON THE AGENDA FOR
4 SEPTEMBER 21ST AND TO ENCOURAGE YOU TO HAVE IT AS AN
5 EXPLICIT AGENDA ITEM, AND THEN ALSO TO SHARE WITH YOU
6 SOME MATERIALS THAT THE UNIVERSITY OF CALIFORNIA HAS
7 PUT TOGETHER, MY OFFICE, THE OFFICE OF SCHOLARLY
8 COMMUNICATION, IN CONSULTATION WITH SOME FACULTY
9 MEMBERS AT CALIFORNIA TO UNCOVER SOME OF THE -- OR MAKE
10 MORE EXPLICIT SOME OF THE THINGS THAT I READ IN THE
11 TESTIMONY OF THE ICOC, WHICH, RATHER THAN SPECULATION,
12 SHOWS SOME EVIDENCE OF ACCELERATION OF RESEARCH BASED
13 ON OPEN ACCESS TO RESEARCH MATERIALS, THE MINIMAL
14 THREAT TO JUNIOR FACULTY, AND THE POSSIBILITY OF
15 ELIMINATING ANY KINDS OF THREAT OR HARM TO JUNIOR
16 FACULTY IF A REQUIREMENT FOR OPEN ACCESS WAS PUT INTO
17 PLACE, AND SO FORTH.

18 AND I HAVE AN OUTLINE OF THOSE MATERIALS
19 WHICH I'LL GIVE TO MARY AND ASK HER TO SHARE WITH THE
20 IP TASK FORCE.

21 I THINK MY QUESTION REMAINS, WHICH IS WHETHER
22 THERE'S AN INTENTION TO HAVE THAT BE ON THE AGENDA FOR
23 SEPTEMBER 21ST.

24 CHAIRMAN PENHOET: WE DON'T HAVE ONE
25 ARRANGED -- WE DON'T HAVE A MEETING ON SEPTEMBER 21ST.

1 THAT'S THE 28TH. I THINK, AS I UNDERSTOOD THE
2 DIRECTIVE FROM THE BOARD, IT WAS MORE TO INVESTIGATE
3 THIS AS A LONG-TERM ISSUE RATHER THAN TO REINSERT IT
4 INTO THE POLICY PROCESS THAT WE'RE UNDERGOING NOW. BUT
5 IT'S THE PLEASURE OF THIS GROUP TO DECIDE WHETHER WE
6 WANT TO REOPEN THAT ISSUE NOW BEFORE WE FINALIZE THE
7 FOR-PROFIT. IF WE WANT TO ADD IT TO THE -- WELL, WE
8 WOULD HAVE TO START OVER AGAIN WITH THE NONPROFIT
9 POLICY IF WE WANTED TO ADD OPEN ACCESS BEYOND WHAT
10 WE'VE ALREADY DONE.

11 AND WE UNDERSTAND YOUR ISSUE. WE DID DECIDE
12 WE WOULD LISTEN TO SOME MORE, ETC., BUT WE WERE NOT
13 SPECIFICALLY DIRECTED TO INSERT IT INTO THE PROCESS.

14 MR. SHEEHY: IT'S MY HOPE THAT WE CAN AGENDA
15 THIS. THIS IS REALLY IMPORTANT FOR PATIENTS. I MEAN
16 AN ACTIVIST LIST SERVE THAT I'M ON, THEY'RE LOOKING AT
17 PURCHASING SUBSCRIPTIONS SO THAT PEOPLE CAN GET ACCESS
18 TO THE DATA. I MEAN WE GIVE UP OUR BODIES SO PEOPLE
19 CAN STUDY US. AND WE'RE -- THE STATE OF CALIFORNIA IS
20 PAYING FOR THIS RESEARCH. AND FROM A PATIENT
21 PERSPECTIVE, THE IDEA THAT A STUDY WOULD BE PUBLISHED
22 WITH CIRM FUNDING, HAVING USED CALIFORNIA RESIDENTS
23 POTENTIALLY AS SUBJECTS OF EXPERIMENTS, AND WE COULD
24 NOT READ THOSE STUDIES, WE CANNOT ACCESS THEM IS JUST
25 UNCONSCIONABLE. I THINK IF WE DON'T AGENDA IT FOR OUR

1 NEXT MEETING, WE NEED TO AGENDA IT FAIRLY SOON. WE
2 NEED TO TAKE THIS -- I DON'T KNOW HOW WE CAN DO
3 OTHERWISE. HOW CAN WE TELL PEOPLE THAT THEY CANNOT
4 READ THE STUDIES THAT THEIR MONEY PAID FOR?

5 AND I THINK THAT THE MAIN CONCERN THAT I'VE
6 HEARD RAISED IS FOR JUNIOR RESEARCHERS, AND I THINK
7 THERE'S SOME THINGS THAT MAY BE POSSIBLE. WE SHOULD
8 CARVE OUT SOME TIME. IT'S GOING TO HELP OUR
9 ENTERPRISE. I STILL REMEMBER ONE OF THE INDUSTRY
10 FOLKS, I THINK, TALKING ABOUT THE NECESSITY OF HAVING
11 PATIENT ADVOCACY GROUPS INVOLVED IN THIS RESEARCH
12 BECAUSE WHEN IT COMES TIME TO DO CLINICAL TRIALS, THIS
13 SO GREATLY FACILITATES YOUR ABILITY TO RECRUIT, RETAIN,
14 DISCUSS, AND DISSEMINATE THE RESULTS IN A WAY THAT
15 KEEPS THE SCIENCE MOVING FORWARD. AND IF WE'RE NOT
16 MAKING THE SCIENCE THAT WE PRODUCE AVAILABLE TO THE
17 PATIENTS AND PATIENT ADVOCATES, WE'RE NOT GOING TO --
18 WE'RE GOING TO END UP -- YOU KNOW, EVERYBODY THROWS OUT
19 THE HORRIBLE INSTANCE WITH THE GENETIC-BASED THERAPY
20 WHERE IT FAILED AND IT SET THE WHOLE FIELD BACK. AND I
21 DON'T KNOW. WE'VE HAD BAD HIV, BUT WE'VE HAD A VERY
22 WELL-EDUCATED PATIENT POPULATION, AND IT'S INCUMBENT ON
23 US TO EDUCATE THE PATIENTS AND THE PATIENT ADVOCATES.
24 IT WILL HELP US AND IT WILL ACCELERATE THE SCIENCE, AND
25 THIS IS ONE MAJOR STEP WE CAN TAKE.

1 CHAIRMAN PENHOET: IS IT THE SENSE OF THE
2 GROUP THAT WHENEVER WE HAVE THE NEXT TASK FORCE
3 MEETING, THAT THEY WOULD LIKE TO SEE THIS SPECIFIC ITEM
4 ON OUR AGENDA?

5 MR. ROTH: IS THIS THE RIGHT PLACE TO DO IT?
6 IS THIS THE RIGHT GROUP TO DO THAT?

7 CHAIRMAN PENHOET: WELL, WE WERE TASKED TO DO
8 IT BY THE ICOC.

9 DR. HALL: I THINK THIS IS AN EXTREMELY
10 IMPORTANT ISSUE, AND I THINK A COMPLICATED ONE IN WHICH
11 IT INVOLVES NOT ONLY OUR RESPONSIBILITY TO THE PEOPLE
12 OF CALIFORNIA AND THE PATIENT ADVOCATES, BUT ALSO THE
13 WAY IN WHICH WE ENGAGE THE SCIENTIFIC COMMUNITY ON
14 THIS. SO I THINK IT REALLY IS IMPORTANT. I ACTUALLY
15 THINK IT DESERVES CAREFUL CONSIDERATION. I THINK THIS
16 IS NOT THE RIGHT -- GIVEN EVEN THE TASK, I DON'T
17 THINK -- IT IS NOT AN IP ISSUE BASICALLY. IT'S A
18 DIFFERENT KIND OF ISSUE.

19 WE ARE ALL RACING RIGHT NOW TO TRY TO FINISH
20 UP A NUMBER OF THINGS THAT WE'VE STARTED, ALL OF WHICH
21 HAVE BEEN ACCELERATED BY THE GOVERNOR'S MONEY. AND MY
22 SUGGESTION IS THAT WE NOT -- THIS IS NOT A PROBLEM WE
23 HAVE TO SOLVE THIS CALENDAR YEAR, THAT WE HOLD BACK ON
24 IT FOR THE MOMENT, RECONSIDER IT, AND BRING IT UP
25 SOMETIME EARLY NEXT YEAR AND REALLY CONSIDER IT VERY,

1 VERY CAREFULLY. I THINK WE HAVE A NUMBER OF TASKS
2 BEFORE US THAT WE HAVE TO FINISH IF WE'RE GOING BE ABLE
3 TO GET GRANTS OUT. I THINK THIS IS ONE THAT WE CAN --
4 DOES NOT HAVE TO BE FINISHED BEFORE THAT. WE CAN COME
5 BACK AND REQUIRE WHATEVER WE'RE GOING TO REQUIRE.

6 I ALSO THINK THERE'S SOME INTERESTING
7 OPPORTUNITIES THAT ARE AVAILABLE, AND SO I SEE IT AS
8 PART OF A LARGER DISCUSSION. I'D JUST LIKE TO SUGGEST
9 THAT WE DECOUPLE IT FROM THIS PROCESS AND CONSIDER IT
10 AT A DIFFERENT TIME IN A DIFFERENT CONTEXT.

11 CHAIRMAN PENHOET: THAT WAS HOW I UNDERSTOOD
12 THE CHARGE TO US BY THE ICOC, THAT WE'LL TAKE THIS ON
13 AS A SEPARATE ISSUE. SOONER OR LATER, IF WE REACH A
14 CONCLUSION, WE WOULD HAVE TO HAVE A PROCESS TO PUT IN
15 PLACE.

16 MR. SHEEHY: I'M CONFUSED. SO MY
17 UNDERSTANDING, WHAT I THOUGHT I VOTED FOR AT THE ICOC
18 WAS TO TAKE THIS UP IN THE IP TASK FORCE.

19 MS. KING: RIGHT. BUT AS A SEPARATE ISSUE.
20 THAT'S WHAT ED IS SAYING.

21 CHAIRMAN PENHOET: AS AN ISOLATED ISSUE.
22 IT'S OUR CHOICE.

23 DR. PITTS: LARRY PITTS FROM UCSF. WHILE I
24 UNDERSTAND ZACH'S POINT, I WOULD REALLY LIKE TO SEE
25 SOME SORT OF A TIME SCHEDULE TO THINK ABOUT THE CLOCK'S

1 RUNNING, AT SOME POINT YOU ARE GOING TO GIVE AWAY GRANT
2 MONEY. SO IT'S AN ISSUE THAT I THINK COULD BE
3 ADDRESSED FAIRLY QUICKLY.

4 (INTERRUPTION IN PROCEEDINGS.)

5 DR. PITTS: I'LL CONTINUE. IN ANY EVENT,
6 THIS HAS RECEIVED A LOT OF DISCUSSION WITH UNIVERSITY
7 OF CALIFORNIA FACULTY, AND WE WOULD BE HAPPY TO PUT
8 SOME OF THAT BEFORE THE ICOC OR WHATEVER GROUP IT
9 CHOOSES, EVEN A LARGER GROUP, SUCH AS DR. HALL HAS
10 SUGGESTED. I DO THINK IT'S AN ISSUE THAT OUGHT TO BE
11 ADDRESSED SOONER THAN LATER. I UNDERSTAND THE
12 MAGNITUDE AND SO FORTH OF VARYING OPINIONS.

13 UNIVERSITY OF CALIFORNIA FACULTY SYNOD HAS
14 BEEN EXTREMELY CAREFUL ABOUT CONSIDERING POTENTIAL HARM
15 TO FACULTY, AS YOU CAN IMAGINE WE WOULD DO. I THINK
16 WE'VE ADDRESSED THE ISSUES OF ACADEMIC FREEDOM OF
17 PROTECTING JUNIOR SCHOLARS AND SO FORTH, AND WE'RE
18 HAPPY TO TELL YOU HOW WE'VE DONE THAT, BUT IT'S AN
19 APPROPRIATE THING FOR CIRM TO DEAL WITH. AND I THINK
20 SOONER THAN LATER IS OBVIOUSLY FOR THE PANEL TO DECIDE.

21 CHAIRMAN PENHOET: WELL, WE CAN CERTAINLY
22 DEMONSTRATE A COMMITMENT TO CONTINUE TO STUDY THIS BY
23 PUTTING IT ON THE AGENDA FOR OUR NEXT MEETING. I WON'T
24 ASSURE YOU THAT WE'LL PUT IT IN THE CRITICAL PATH OF
25 GETTING TO OUR IP POLICIES WHICH ARE IN PLACE NOW, BUT

1 WE'LL CONTINUE TO LEARN AND LISTEN AND MOVE THIS
2 PROJECT FORWARD.

3 SO IF IT'S THE SENSE OF THE GROUP, WE CAN DO
4 THAT. WE'LL AGENDA A DISCUSSION AT OUR NEXT MEETING.

5 ANY OTHER COMMENTS ON THIS ISSUE OR ANY OTHER
6 ISSUE? I CAN'T BELIEVE WE'RE GOING TO FINISH A LITTLE
7 BIT EARLY. THAT'S A WONDERFUL RESULT. SORRY TO ALL OF
8 YOU ABOUT THE DIFFICULTIES OF USING THIS ROOM. WE WILL
9 TRY TO ENSURE THAT WE DON'T END UP BACK HERE AGAIN.

10 DR. LOVE: YOU'VE DONE A GREAT JOB AND VERY
11 CHALLENGING MEETING.

12 CHAIRMAN PENHOET: THANK YOU.

13 (APPLAUSE.)

14 CHAIRMAN PENHOET: SO WE WILL HAVE ANOTHER
15 MEETING WHENEVER WE CAN GET PEOPLE SCHEDULED.

16 (THE MEETING WAS THEN ADJOURNED AT 04:34
17 P.M.)

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REPORTER'S CERTIFICATE

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

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ON
AUGUST 29, 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.

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