

BEFORE THE
INTELLECTUAL PROPERTY TASK FORCE SUBCOMMITTEE 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: CONNECT
8950 VILLA LA JOLLA DRIVE
SUITE A124
LA JOLLA, CALIFORNIA

DATE: THURSDAY, NOVEMBER 9, 2006
1 P. M.

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

BRS FILE NO. : 76796

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1 LA JOLLA, CALIFORNIA; NOVEMBER 9, 2006

2 1 P.M.

3

4 CHAIRMAN PENHOET: I THINK WE'LL GET STARTED.

5 MELISSA, PLEASE TAKE THE ROLL.

6 MS. KING: ALL RIGHT. SUSAN BRYANT. I KNOW

7 SHE WAS HERE BEFORE. IS UC IRVINE MUTED?

8 DR. BRYANT: I'M HERE.

9 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.

10 TED LOVE.

11 DR. LOVE: HERE.

12 MS. KING: ED PENHOET.

13 CHAIRMAN PENHOET: HERE.

14 MS. KING: PHIL PIZZO.

15 DR. PIZZO: HERE.

16 MS. KING: FRANCISCO PRIETO.

17 DR. PRIETO: HERE.

18 MS. KING: JOHN REED.

19 DR. REED: HERE.

20 MS. KING: DUANE ROTH. JEFF SHEEHY.

21 MR. SHEEHY: HERE.

22 MS. KING: OS STEWARD. JANET WRIGHT.

23 SEVEN.

24 CHAIRMAN PENHOET: WE NEED EIGHT FOR A

25 QUORUM?

1 MS. KING: WE NEED EIGHT FOR A QUORUM.

2 CHAIRMAN PENHOET: WE EXPECT TO HAVE A
3 QUORUM. WELL, THANK YOU, FELLOW MEMBERS OF THE TASK
4 FORCE AND MEMBERS OF THE PUBLIC, FOR JOINING US TODAY.
5 WE ARE HOPEFUL THAT THIS WILL BE THE FINAL MEETING OF
6 OUR TASK FORCE BEFORE WE PRESENT OUR FINDINGS TO THE
7 BOARD FOR APPROVAL IN THE DECEMBER BOARD MEETING.

8 AND WE HAVE HAD A NUMBER OF MEETINGS ALREADY
9 ON THIS SUBJECT, AND WE THINK WE HAVE CAPTURED A LOT OF
10 GROUND, BUT A NUMBER OF YOU THOUGHT IT WOULD BE USEFUL
11 FOR US TO HAVE ANOTHER MEETING BECAUSE THERE WERE SOME
12 ISSUES WHERE WE STILL HADN'T REACHED CONSENSUS OF THIS
13 GROUP AROUND WHAT TO DO. I'M NOT SURE WE'RE GOING TO
14 REACH CONSENSUS AROUND WHAT TO DO IN THIS GROUP BECAUSE
15 WE HAVE A WIDE SPECTRUM OF VIEWS, I THINK, ON THIS
16 SUBJECT, SO SOME OF THESE ISSUES MAY, IN FACT, BE TAKEN
17 AS OPEN ITEMS TO THE BOARD FOR THEIR VOTE IN DECEMBER.
18 BUT HOPEFULLY WE'LL MAKE SOME PROGRESS AND HEAR FROM
19 TASK FORCE MEMBERS AND MEMBERS OF THE PUBLIC AT THIS
20 MEETING TODAY TO MOVE THIS PROCESS FORWARD.

21 IF I COULD HAVE THE NEXT SLIDE, PLEASE. JUST
22 TO REMIND YOU ABOUT THE TIMELINE WE HAVE BEEN ON IN
23 DEVELOPING THE FOR-PROFIT POLICY. WE HAD OUR FIRST
24 SERIES OF MEETINGS WITH PUBLIC INPUT IN MARCH AND APRIL
25 WHERE WE HAVE HEARD FROM THE PEOPLE THAT YOU CAN SEE

1 LISTED HERE. WE HAD A CONFERENCE IN JULY, AND THEN
2 WE'VE HAD A NUMBER OF MEETINGS OF THIS TASK FORCE, SO
3 THIS IS, IN FACT, THE FIFTH OR SIXTH MEETING, DEVOTED
4 TO THIS SUBJECT. AND WE'VE HAD OVER TIME 18 DIFFERENT
5 PRESENTATIONS, FORMAL PRESENTATIONS, MADE TO THIS
6 GROUP. SO WE HAVE DONE A LOT OF WORK.

7 IN ADDITION TO THAT, WE HAVE SURVEYED MORE
8 THAN 20 DIFFERENT FUNDING ENTITIES, AND WE'VE, I THINK,
9 SUMMARIZED THAT FOR YOU BEFORE. DONE A NUMBER OF
10 INTERVIEWS AND ALSO SCANNED THE LITERATURE. SO A LOT
11 OF HOMEWORK HAS PRECEDED THIS MEETING TODAY. AND I
12 THINK WE HAVE IN THE PROCESS OF THAT HOMEWORK, AS I
13 SAID BEFORE, CAPTURED A LOT OF GROUND.

14 WE DO HAVE A DOCUMENT WHICH IS THE PROPOSED
15 POLICY THAT WE HAVE DRAFTED FOR THE FOR-PROFIT
16 ORGANIZATIONS. IF YOU READ AND COMPARE THIS DOCUMENT
17 WITH THE NOT-FOR-PROFIT POLICY, YOU WOULD SEE THAT
18 ABOUT 80 PERCENT OF IT IS THE SAME, BUT 20 PERCENT IS
19 DIFFERENT, AND THE DIFFERENCES ARE AT THIS POINT
20 OBVIOUSLY IMPORTANT DIFFERENCES THAT WE NEED TO
21 DISCUSS.

22 IF WE LOOK AT THE NEXT SLIDE, THESE ARE THE
23 PRINCIPLES THAT WE HAD AGREED TO AS OF THE LAST
24 MEETING. AND SOME OF THESE HAVE BEEN IN PLACE, I
25 THINK, FOR QUITE SOME TIME. SIMILARLY TO THE

1 NOT-FOR-PROFIT POLICY, IN THIS CASE WE WILL GRANT
2 OWNERSHIP OF INTELLECTUAL PROPERTY TO THE GRANTEES. WE
3 HAVE THE SAME PUBLICATION REQUIREMENTS AS IN THE
4 NONPROFIT POLICY. WE HAVE A MATERIALS SHARING
5 REQUIREMENT IN HERE WHICH IS SIMILAR TO THE
6 NOT-FOR-PROFIT, BUT I THINK WE'LL END UP WITH SOME,
7 HOPEFULLY, MODEST DIFFERENCES BETWEEN THE
8 NOT-FOR-PROFIT AND THE FOR-PROFIT. WE DID REMOVE AT
9 THE LAST MEETING REFERENCES TO LOANS BECAUSE THAT'S A
10 FUNDING MECHANISM, NOT AN INTELLECTUAL PROPERTY ISSUE
11 PER SE, SO WE DELETED THE NEXT ITEM, THAT COMPANIES
12 COULD CHOOSE WHETHER TO TAKE A GRANT OR A LOAN.

13 WE DID TALK A LOT ABOUT THE LICENSE. IF THE
14 GRANTEE -- IF A FOR-PROFIT COMPANY INVENTS SOMETHING OF
15 VALUE AND LICENSES IT TO A THIRD PARTY, WE TALKED ABOUT
16 THE FACT THAT WE THOUGHT THAT IT SHOULD BE SIMILAR TO
17 IF A NOT-FOR-PROFIT DID THE SAME THING. BUT IN THIS
18 CASE, WE HAVE REDUCED THE REVENUE SHARING FROM 25
19 PERCENT TO 17 PERCENT. AND JUST TO REMIND YOU, THE 17
20 PERCENT IS TO ESSENTIALLY REWARD IN THE SAME WAY THAT
21 WE DO FOR THE NOT-FOR-PROFITS THE INVENTOR'S SHARE. SO
22 TYPICALLY IN THE NOT-FOR-PROFIT WORLD, IF A FACULTY
23 MEMBER AT UC SAN DIEGO, FOR EXAMPLE, MAKES AN
24 INVENTION, GENERALLY ABOUT A THIRD OF THE REVENUES GO
25 TO THE FACULTY OR FACULTY MEMBERS OR THEIR STUDENTS,

1 WHOEVER THE INVENTORS ARE ON THE PATENT.

2 SO OUR NOT-FOR-PROFIT POLICY SAYS THAT WE GET
3 25 PERCENT OF THE NET REVENUES AFTER THE INVENTORS ARE
4 PAID. IN THIS CASE THE INVENTORS WORK FOR THE COMPANY,
5 AND SO 8 PERCENT IS A THIRD OF 25 PERCENT AND,
6 THEREFORE, WE REDUCE THE 25 TO 17 TO ESSENTIALLY REWARD
7 THE EMPLOYERS OF THE INVENTORS FOR THE INVENTOR'S
8 SHARE. IN THE CASE OF THE NOT-FOR-PROFITS, THE
9 INVENTORS GET PAID DIRECTLY THEMSELVES. SO IT'S MEANT
10 TO BE EQUIVALENT IF YOU TAKE OUT INVENTOR'S SHARE.

11 AND WE THEN HAVE A NUMBER OF -- WE HAD A
12 PRINCIPLE THAT IF A COMMERCIAL ENTITY CHOOSES TO
13 DEVELOP A PRODUCT THEMSELVES, THAT THE PAYBACK IS
14 CONDITIONED ON SUCCESS WITH A MULTIPLE OF CIRM FUNDING
15 TO BE PAID TO THE GENERAL FUND.

16 I DO WANT TO MAKE A COMMENT HERE, WHICH IS WE
17 HAVE TWO ALTERNATIVES -- I'VE GOT A SLIDE OUTLINING
18 THESE IN A MOMENT -- FOR COMPANIES. COMPANIES CAN
19 LICENSE TO THIRD PARTIES OR THEY CAN DEVELOP IT
20 THEMSELVES. TO SOME DEGREE, I THINK WE'VE TRIED TO
21 BUILD INTO THIS SOME INCENTIVE FOR COMPANIES TO DEVELOP
22 IT THEMSELVES AND KEEP IT IN CALIFORNIA. THEY MIGHT
23 LICENSE IT TO A COMPANY IN NEW JERSEY OR WHATEVER. SO
24 WE HAVE SOME FEATURES HERE TO INCENT FORWARD
25 INTEGRATION ON THE PART OF CALIFORNIA COMPANIES WHO GET

1 THESE THINGS. WE CERTAINLY CAN TALK ABOUT THAT IN THIS
2 MEETING. I'M SURE MANY PEOPLE HAVE A POINT OF VIEW
3 ABOUT THAT, BUT, ANYWAY, THAT'S THE UNDERLYING SORT OF
4 PHILOSOPHY UNDER THAT POINT.

5 YOU REMEMBER WE DID DECIDE TO CAP; THAT IS,
6 CONDITION ON SUCCESS AND CAPPED. AND, AGAIN, WE CAN
7 CERTAINLY BRING THAT UP AGAIN TODAY. AGAIN, WE TOOK
8 OUT THE NOTION OF THE LOANS. WE DID DISCUSS A ONE-TIME
9 BLOCKBUSTER PAYMENT. AND THAT IS NOW WRITTEN INTO THIS
10 DOCUMENT. A NUMBER WE PUT IN WAS 3 X AND IT'S AFTER
11 REVENUES EXCEED \$250 MILLION IN ANY ONE YEAR.

12 AND THEN, FINALLY, FOR GRANTS WHERE THE
13 FUNDING REPRESENTS MORE THAN SOME FRACTION OF THE
14 INVENTION OR THE PROJECT, THE COMPANY WILL PROVIDE
15 PLANS FOR ACCESS TO UNINSURED AND WILL ALSO PROVIDE THE
16 GOODS OR THE SERVICE OR WHATEVER IT IS THAT RESULTS
17 FROM THIS AT A PRICE NOT TO EXCEED PRICES WHICH ARE THE
18 LOWEST PRICES AVAILABLE ELSEWHERE.

19 THERE'S A LOT OF DISCUSSION THAT'S GONE BACK
20 AND FORTH ON THIS ISSUE OF PRICING. WE RECEIVED A LONG
21 DOCUMENT FROM A FIRM IN SACRAMENTO ARGUING THAT THERE
22 ARE PLENTY OF OTHER CONTROLS AND PRICING IN CALIFORNIA,
23 THAT WE DON'T NEED TO HAVE OUR OWN, BUT I THINK WE'VE
24 TALKED A LOT ABOUT THE FACT THAT WE SHOULD HAVE --
25 THESE FEATURES SHOULD BE IN PLACE, BUT THE DETAILS, I

1 THINK, ARE STILL THERE, AND WE NEED TO TALK ABOUT THOSE
2 TODAY.

3 IF YOU GO TO THE NEXT SLIDE, THIS IS JUST
4 SORT OF AN OUTLINE OF HOW IT WORKS, HOPEFULLY
5 CLARIFYING A LITTLE BIT. SO IN THE NONPROFIT CASE,
6 MOST OF WHAT WE WILL BE FUNDING IS BASIC SCIENCE THAT
7 LEADS TO AN INVENTION. THE NOT-FOR-PROFITS ARE NOT IN
8 BUSINESS, SO, IN GENERAL, THEIR ONLY OUTLET TO THE
9 MARKET IS TO LICENSE IT TO SOMEBODY WHO IS IN BUSINESS.
10 AND IF THEY DO SO, 25 PERCENT OF THE GRANTEE REVENUES
11 AFTER THE INVENTORS' SHARES ARE DEDUCTED AND A \$500,000
12 THRESHOLD IS EXCEEDED WILL BE RETURNED TO THE STATE.
13 WE SAID IN THE NOT-FOR-PROFIT POLICY THAT A PLAN FOR
14 ACCESS WAS DUE FROM AN EXCLUSIVE LICENSEE AT THE TIME
15 OF COMMERCIALIZATION, NOT BEFORE, AND THAT EXCLUSIVE
16 LICENSEES ARE REQUIRED TO PROVIDE DISCOUNT PRICING FOR
17 PRODUCTS PURCHASED IN CALIFORNIA WITH PUBLIC FUNDS.

18 WE'RE STRUGGLING WITH HOW TO DO THIS SO THAT
19 IT WORKS. I THINK WE HAVE HAD AGREEMENT ON THIS
20 PRINCIPLE. AND THE PRINCIPLE WE HAD HOPED TO
21 ESTABLISH, AS I UNDERSTOOD IT, WAS THAT CALIFORNIANS
22 SHOULD NOT PAY MORE FOR THESE PRODUCTS THAN THE LOWEST
23 PRICE AVAILABLE ELSEWHERE IN THE UNITED STATES. WE
24 ALSO SAID, HOWEVER, THAT IN THE LANGUAGE WE DID NOT
25 WANT TO TRIP A DESTRUCTIVE PROCESS OF ESSENTIALLY THE

1 WHOLE AREA OF MOST FAVORED NATION CLAUSES IN AGREEMENTS
2 THAT PEOPLE HAVE, THAT THEY WON'T SELL FOR A LESSER
3 PRICE TO SOMEBODY ELSE. WE DON'T WANT TO PRICE UNDER
4 THAT AND SIMPLY TRIP A DESTRUCTIVE PROCESS BY WHICH THE
5 PRICES WOULD DEGRADE QUICKLY FAR BELOW WHAT WE
6 INTENDED. SO WE'RE TRYING TO FIND SOME SUITABLE
7 LANGUAGE THAT SAYS THAT CALIFORNIANS WILL BENEFIT FROM
8 THIS IN THIS WAY, BUT THAT WE DON'T TRIP A DESTRUCTIVE
9 PROCESS ASSOCIATED WITH THE INTRODUCTION IN MANY OF THE
10 CONTRACTS OF THE MOST FAVORED NATION CLAUSE.

11 SO I THINK WE'RE PRETTY CLEAR ON THE CONCEPT.
12 SCOTT HAS BEEN DOING A LOT OF WORK TRYING TO COME UP
13 WITH LANGUAGE WHICH WILL ACCOMPLISH THIS FOR US AND
14 STILL AVOID TRIPPING THAT CLAUSE. AND SO SOME OF THAT
15 WORK IS STILL IN PROGRESS, AND LATER TODAY SCOTT WOULD
16 BE HAPPY TO ANSWER YOUR QUESTIONS ABOUT WHERE HE IS
17 WITH THIS.

18 IN THE CASE OF FOR-PROFIT COMPANIES IN
19 CALIFORNIA, WE EXPECT TO FUND NUMEROUS DIFFERENT POINTS
20 IN THE PRODUCT DEVELOPMENT CYCLE. SO IF WE FUND BASIC
21 SCIENCE IN A FOR-PROFIT ORGANIZATION, IT CAN LEAD TO AN
22 INVENTION THE SAME WAY AS IN THE NOT-FOR-PROFIT. THEY
23 CAN EITHER LICENSE IT OUT TO A THIRD PARTY IN WHICH THE
24 LICENSE TO THE THIRD PARTY IS BASICALLY THE SAME TERMS
25 AS IF IT WAS A NOT-FOR-PROFIT. THERE'S NOTHING REALLY

1 FUNDAMENTALLY DIFFERENT ABOUT THAT. IF, HOWEVER, THEY
2 DECIDE TO FORWARD INTEGRATE THEMSELVES AND DO
3 PRECLINICAL WORK, PRODUCT DEVELOPMENT, AND EVENTUALLY
4 MARKET A PRODUCT, CIRM IS LIKELY TO FUND PRECLINICAL
5 WORK, CLINICAL TRIALS, FURTHER DEVELOPMENT, ETC. AND
6 HERE WE HAVE SAID THAT THE PAYBACK WOULD BE LIMITED TO
7 THREE TIMES THE TOTAL CIRM INVESTMENT IN THE FORM OF
8 ROYALTIES AND REVENUES, THAT THERE WOULD BE A
9 BLOCKBUSTER PAYMENT IF THE REVENUES EXCEEDED \$250
10 MILLION A YEAR AND THAT THAT WOULD BE 3 X, AND THAT THE
11 ACCESS FEATURES WE TALKED ABOUT IN LICENSED TECHNOLOGY
12 WOULD ALSO BE TRIGGERED IF THE FUNDING BY CIRM EXCEEDED
13 A CERTAIN THRESHOLD LEVEL OF THE COMPANY.

14 WE DON'T HAVE AGREEMENT TODAY WHAT THAT
15 THRESHOLD SHOULD BE. WE TALKED ABOUT 25 PERCENT AT A
16 PREVIOUS MEETING. SINCE THEN, A NUMBER OF PEOPLE HAVE
17 EXPRESSED CONCERNS ABOUT THE FACT THAT THAT MIGHT BE
18 TOO HIGH, OTHERS THINK IT'S TOO LOW, AND IT'S AN ISSUE,
19 I THINK, WHERE WE HAVE A WIDE DISPARITY OF VIEWS
20 PERHAPS IN OUR TASK FORCE, BUT I KNOW ALSO IN OUR
21 AUDIENCE HERE TODAY. SO THAT WILL BE ONE OF THE THINGS
22 THAT WE NEED TO DISCUSS IN FURTHER DETAIL TODAY.

23 IF YOU GO TO THE NEXT SLIDE, WE WANT TO GO TO
24 THE COMMENTS THAT WE'VE GOTTEN FROM OUR BOARD MEMBERS.
25 OKAY. A NUMBER OF MEMBERS OF OUR TASK FORCE HAVE ASKED

1 FOR CLARIFICATION ON ISSUES OR FOR FURTHER DISCUSSION.
2 SO IN TERMS OF CLARIFICATION, ONE QUESTION IS WHY IS
3 THERE A CAP ON FOR-PROFITS AND NO CAP ON NON-PROFITS IN
4 TERMS OF THE RETURN?

5 THE ANSWER IS THERE ISN'T, IN TERMS OF
6 LICENSES, THAT LICENSEES HAVE FULL DISCRETION ABOUT THE
7 TERMS OF THE LICENSE. WE DON'T DICTATE ANYTHING ABOUT
8 THE TERMS OF THE LICENSE. THEY CAN ASK FOR A CAP, THEY
9 CAN ASK FOR NO CAP, THEY CAN DO WHATEVER IS IN THEIR
10 BEST INTEREST. ALL WE'RE SAYING IS WHATEVER YOU DO,
11 WHEN YOUR REVENUES EXCEED \$500,000 AND YOU'VE PAID YOUR
12 INVENTORS A THIRD, GIVE US 25 PERCENT OF WHAT'S LEFT.
13 SO WE HAVE NOT SPECIFIED CAP OR NO CAP. IT'S TOTALLY
14 AT THE DISCRETION OF THE NOT-FOR-PROFIT INSTITUTION.

15 SO IF BURNHAM LICENSES MERCK, THEY CAN AGREE
16 TO A ROYALTY FOR A HUNDRED YEARS, THEY CAN AGREE FOR
17 THREE YEARS, THEY CAN AGREE TO A CERTAIN AMOUNT OF
18 MONEY. IT'S TOTALLY IN THEIR DISCRETION. WE HAVE NOT
19 DICTATED THAT EITHER. SO THE ONLY TIME THE CAP COMES
20 INTO PLAY IS IF A COMPANY CHOOSES TO DEVELOP THE
21 PRODUCT THEMSELVES, NOT LICENSE IT TO A THIRD PARTY.
22 SO I THINK THAT THERE'S REALLY NO DIFFERENCE BETWEEN
23 THE TWO POLICIES WITH RESPECT TO LICENSES TO THIRD
24 PARTIES. YOU ASKED THAT QUESTION, JEFF.

25 MR. SHEEHY: I STILL THINK THAT WE'VE SET UP

1 THE NONPROFITS AND THE FOR-PROFITS ON AN UNEQUAL BASIS
2 BECAUSE WE HAVE DECIDED TO CAP FOR-PROFITS. ALMOST
3 INEVITABLY FOR-PROFITS ARE NOT GOING TO LICENSE. I
4 MEAN THEY'RE NOT REALLY IN THE BUSINESS OF LICENSING
5 TECHNOLOGY. NOT-FOR-PROFITS, YOU KNOW, ARE GOING TO
6 TRY TO HOLD ON TO AS MUCH REVENUE AS THEY CAN. SO
7 WE'VE BASICALLY GIVEN -- WE'VE DISADVANTAGED THE STATE
8 RELATIVE TO FOR-PROFITS TO NON-FOR-PROFITS. SO
9 THAT'S -- YOU KNOW, IT'S JUST NOT FAIR.

10 NOTWITHSTANDING WHETHER OR NOT I THINK
11 CAPPING IT IS A GOOD IDEA TO BEGIN WITH, WE HAVE NOT
12 CAPPED NOT-FOR-PROFITS.

13 CHAIRMAN PENHOET: WE HAVE NOT CAPPED THEM,
14 AND WE HAVE CAPPED FOR-PROFITS IN THE CASE THAT THE
15 FOR-PROFITS MAKE THE INVESTMENT TO DEVELOP THESE THINGS
16 INSIDE CALIFORNIA. THAT'S TRUE. OKAY.

17 AND WE HAVE NOT SAID TO THE NOT-FOR-PROFITS
18 THAT YOU COULDN'T DO THE SAME THING IN YOUR LICENSING.
19 THAT'S UP TO THEM.

20 MR. SHEEHY: I MEAN A LOT OF THIS JUST HAS TO
21 DO FUNDAMENTALLY WITH ME WHERE -- I MEAN IT REALLY IS,
22 AS I SAID IN MY COMMENTS, I THINK -- I COMMEND MARY FOR
23 WHAT SHE'S DONE, BUT I THINK THIS IS A
24 ONE-SIZE-FITS-ALL SCHEME. I THINK, FOR INSTANCE, IF WE
25 FUND AT CERTAIN PLACES, THIS SCHEME MAKES SENSE. WE

1 FUND AT THE BASIC. WE HAVE NOT-FOR-PROFITS AND
2 FOR-PROFITS COMPETING TO DO BASIC RESEARCH, AND WE CAP
3 FOR-PROFITS, BUT WE DON'T CAP NOT-FOR-PROFITS. WE
4 SHOULD GIVE AN ADVANTAGE TO NOT-FOR-PROFITS BECAUSE WE
5 ARE GOING TO GET A HIGHER RETURN FOR THE STATE.

6 CHAIRMAN PENHOET: WELL, WE'VE ONLY CAPPED
7 THE FOR-PROFITS IF THEY DEVELOP THE PRODUCTS
8 THEMSELVES, AND THAT'S A PERFECTLY LEGITIMATE
9 DISCUSSION. THERE ARE NO CAPS IF THEY LICENSE THE
10 TECHNOLOGY. SO THERE'S PERFECT SYMMETRY IF YOU ASSUME
11 THAT THE OUTCOME IS A LICENSE IN BOTH HALVES. THE
12 SYMMETRY DOESN'T EXIST IF THEY MAKE THE INVESTMENT TO
13 GO DOWN THIS LIST.

14 WE HAVE DISCUSSED THIS MANY TIMES. WHAT WE
15 HEARD FROM INDUSTRY IS THEY'RE WILLING TO PAY, BUT
16 THERE WAS A STRONG, VERY STRONG, REACTION AGAINST AN
17 UNCAPPED LIABILITY FROM INDUSTRY. SO WE DISCUSSED IT
18 MANY TIMES. WE'VE AGREED ON A CAP, BUT, JEFF, WE'RE
19 PERFECTLY FREE TO REOPEN THE ISSUE AT ANY MEMBER'S
20 SUGGESTION.

21 DR. PRIETO: I HAVE A QUESTION. HOW COMMON
22 IS IT IN LICENSING AGREEMENTS FROM NOT-FOR-PROFITS, AND
23 MAYBE MARY CAN ANSWER THIS TOO, YOU KNOW, THE UC'S, THE
24 STANFORDS, USC'S, FOR THERE TO BE A CAP IN THE TERMS OF
25 THAT LICENSE FOR EXISTING INVENTIONS?

1 CHAIRMAN PENHOET: FROM MY OWN EXPERIENCE,
2 IT'S NOT THE COMMON PRACTICE, BUT IT'S NOT TOTALLY
3 UNUSUAL EITHER. SO I THINK THE NOT-FOR-PROFITS DO SOME
4 OF BOTH. BUT TYPICALLY THE NOT-FOR-PROFITS OR THE
5 COMPANIES IN LICENSING WILL SEEK TO MAXIMIZE THEIR OWN
6 REVENUES. THAT'S THE JOB OF THEIR LICENSING GROUPS.
7 SO THEIR POSTURE VIS-A-VIS A LICENSEE IS TO GET AS MUCH
8 REVENUE AS THEY POSSIBLY CAN.

9 DR. PRIETO: AND THE LICENSEE IS PUSHING BACK
10 IN THE OTHER DIRECTION. I GUESS THE QUESTION IN MY
11 MIND IS HOW COMMON IS IT FOR THE PATENT HOLDER, THE
12 NOT-FOR-PROFIT, TO ACCEPT A CAP, AND HOW MUCH OF A
13 DISINCENTIVE IS THE LACK OF A CAP FOR A COMMERCIAL
14 LICENSEE TO TAKE THAT INVENTION AND DEVELOP IT? IF
15 IT'S NOT A SIGNIFICANT DISINCENTIVE, IF LICENSES ARE
16 GRANTED ROUTINELY WITHOUT CAPS AND THAT'S GOING FORWARD
17 AND HAPPENING NOW, THEN I'M NOT SURE I SEE THE NEED FOR
18 A CAP.

19 CHAIRMAN PENHOET: WELL, TWOFOLD, ONE OF
20 WHICH IS THAT IN SURVEYING OTHER PRIVATE ENTITIES WHICH
21 FUND BIOMEDICAL RESEARCH IN COMPANIES, ALMOST WITHOUT
22 EXCEPTION THEY DO HAVE A CAP. SO I THINK IT'S TRUE OF
23 THE JDRF, IT'S TRUE OF THE CYSTIC FIBROSIS FOUNDATION.
24 THE WELLCOME TRUST, I'M NOT SURE THEY HAVE A CAP, BUT
25 THEY INVEST IN EQUITY AND OTHER THINGS, SO IT'S NOT

1 REALL Y --

2 DR. PRIETO: THAT WAS THE MATRIX WE HAVE FROM
3 THE LAST MEETING.

4 CHAIRMAN PENHOET: THE ONES WHO ARE DOING IT
5 DO HAVE A CAP. I THINK IF WE DON'T HAVE A CAP, WE WILL
6 HAVE TO DECIDE SOMEHOW NOW ON THE ROYALTY STRUCTURE
7 THAT WE WANT OUT OF THESE COMPANIES. OTHERWISE, WE
8 HAVE TO NEGOTIATE SEPARATELY WITH EVERY COMPANY WHAT
9 THEY WANT. THE CAP HAS THE FEATURE OF, IN A SENSE,
10 SIMPLICITY. IT DOESN'T FORCE US TO PICK A ROYALTY
11 NUMBER NOW BECAUSE THAT WILL BE NEGOTIATED AT THE TIME
12 UP TO THE CAP. SO IT'S A COMMON PRACTICE FOR
13 FOUNDATIONS WHO ARE FUNDING BIOMEDICAL RESEARCH IN
14 COMPANIES.

15 THE ABSENCE OF THE CAP HAS BEEN WHAT WOULD BE
16 FAIR TO SAY VEHEMENTLY OPPOSED BY THE INDUSTRY AT THIS
17 POINT IN TIME. THERE COULD BE A DISCUSSION OF IS 3 X
18 THE RIGHT CAP, WHICH IS A SECONDARY ISSUE, BUT IT HAS
19 THE ADVANTAGES OF SIMPLICITY, SOME PAYBACK,
20 RESPONSIVENESS TO A CONSTITUENCY WHICH IS IMPORTANT TO
21 US IN THE STATE. ONE OF THE EXPLICIT GOALS OF PROP 71
22 WAS TO ENHANCE CALIFORNIA'S BIOTECHNOLOGY INDUSTRY. SO
23 TO SOME DEGREE, AGAIN, THIS IS AN INCENTIVE FOR
24 COMPANIES TO DO IT THEMSELVES RATHER THAN LICENSE IT
25 OUTSIDE, I THINK.

1 DR. LOVE: I HAVE A QUESTION FOR YOU. IN
2 TERMS OF -- I UNDERSTAND THE CAP, AND I THINK IT ALL
3 MAKES SENSE. I THINK PEOPLE ARE STILL A LITTLE BIT
4 CONFUSED ABOUT HOW WILL THE ROYALTY RATE ACTUALLY BE
5 NEGOTIATED IN THE CASE OF THE COMPANY THAT, IN FACT,
6 DECIDES TO COMMERCIALIZE THE PRODUCT ITSELF.

7 CHAIRMAN PENHOET: THAT WILL BE NEGOTIATED BY
8 CIRM.

9 DR. LOVE: SO CIRM STAFF WILL NEGOTIATE
10 WHETHER THE ROYALTY RATE IS 5 PERCENT OR 10 PERCENT,
11 AND THEN THE CAP WILL APPLY BASED UPON HOW QUICKLY YOU
12 GET TO THAT CAP.

13 CHAIRMAN PENHOET: THAT'S CORRECT. AND WE
14 DID SAY THAT IN DOING SO, WE WOULD GUIDE THE CIRM NOT
15 TO MAKE THE ROYALTY PAYMENTS SO ONEROUS AS TO DESTROY
16 NEAR-TERM OPPORTUNITIES OF THE COMPANY.

17 DR. BRYANT: I HAVE A QUESTION. IT'S
18 SLIGHTLY DIFFERENT, BUT IT HAS TO DO WITH THIS
19 STRUCTURE WE'RE TALKING ABOUT. SO I DON'T KNOW WHETHER
20 THIS HAS BEEN DISCUSSED BEFORE, AND I APOLOGIZE IF I'M
21 GOING OVER OLD GROUND. BUT IN THE STATEMENT IN HERE
22 ABOUT THE STATE NOT BEING ABLE TO TAKE EQUITY, UC DOES
23 DO THAT, AND THEY DO IT BY INVOLVING A BLIND TRUST. SO
24 THERE IS A MECHANISM IN THE UC SYSTEM FOR DOING IT, AND
25 THEY'RE USING STATE FUNDS. SO I JUST WANTED YOU TO

1 KNOW THAT. I DIDN'T KNOW IF YOU KNEW IT OR NOT.

2 CHAIRMAN PENHOET: WELL, WE'RE TRYING TO KEEP
3 THIS -- UC HAS RESOURCES TO GO SET UP SIDE-BY-SIDE
4 PROGRAMS. THIS IS A STATE AGENCY HERE. IT MIGHT BE
5 POSSIBLE.

6 DR. MAXON: IT'S NOT POSSIBLE.

7 MR. ROTH: WE'LL BE HERE A LONG TIME.

8 CHAIRMAN PENHOET: WE'VE BEEN ADVISED IT'S
9 NOT POSSIBLE FOR US.

10 DR. BRYANT: OKAY.

11 MR. ROTH: ED, I APOLOGIZE FOR BEING LATE,
12 BUT THIS LAST QUESTION WAS ASKED ABOUT THE ROYALTY
13 RATE, WHICH GOES DOWN THIS MIDDLE COLUMN, FOR-PROFIT,
14 THE COMPANY COMMERCIALIZES. THEY HAVE AN OBLIGATION TO
15 PAY BACK THREE TIMES. I THINK IT MIGHT BE USEFUL IF WE
16 COULD GIVE SOME GUIDANCE HERE ABOUT WHAT THOSE ROYALTY
17 RATES SHOULD BE, PEG THEM TO SOMETHING. BUT I WAS
18 THINKING WE SHOULD HAVE A RANGE BECAUSE SOME OF THESE
19 PRODUCTS ARE GOING TO BE SMALL PRODUCTS, AND THE RATE
20 OF PAYBACK MIGHT BE LESS. OTHERS ARE GOING TO BE
21 THERAPEUTICS WHERE THE RATE OF PAYBACK SHOULD PROBABLY
22 BE MORE AGGRESSIVE.

23 BUT I THINK IT WOULD BE HELPFUL, IF I WERE
24 WORKING AT CIRM, TO HAVE THIS GROUP GIVE ME SOME
25 GUIDANCE ABOUT WHAT THOSE ROYALTY RATES OUGHT TO LOOK

1 LIKE, A RANGE, NEGOTIATE WITHIN THE RANGE, SO WE HAVE
2 SOME BOUNDARIES. SO I WAS THINKING SOMETHING LIKE 2 TO
3 5 PERCENT, AND THAT WOULD DEPEND, THEN, ON CIRM
4 EVALUATING THE CASE THE COMPANY WOULD MAKE ABOUT THE
5 RATE OF THAT PAYBACK.

6 SO IF I WERE NEGOTIATING, THEN I'D SAY IT'S 5
7 PERCENT ON A THERAPEUTIC BECAUSE IT'S GOING TO TAKE
8 LONGER. IF IT'S A TOOL, I MIGHT SAY 2 PERCENT. BUT AT
9 LEAST THERE'S SOME RANGE INSTEAD OF JUST A WIDE OPEN
10 BECAUSE I THINK EVERYTHING WE CAN DO TO TRY TO GET THIS
11 NARROWED DOWN WILL BE HELPFUL TO THE STAFF WHO'S
12 ALREADY, I BELIEVE, GOING TO BE OVERWORKED ON MANY
13 OTHER ISSUES.

14 CHAIRMAN PENHOET: WELL, YOU KNOW, THAT'S A
15 GOOD POINT. ONE OF THE OTHER THINGS WE'RE TRYING TO DO
16 IS KEEP THIS AS SIMPLE AS POSSIBLE. I THINK WE TOLD
17 YOU FOR A \$25 MILLION A YEAR PROGRAM -- IS THAT WHAT IT
18 WAS AT WELLCOME TRUST? -- THEY HAVE 15 PEOPLE IN THEIR
19 GROUP JUST TO DO LICENSING WITH COMPANIES. JDRF HAS
20 TOLD US IT'S TAKEN THEM MORE THAN A YEAR ON AVERAGE TO
21 REACH AN AGREEMENT WITH EVERY GRANTEE OF THEIRS WHO'S A
22 COMPANY.

23 MR. ROTH: THAT'S WHY I THINK GUIDANCE
24 WHEREVER WE CAN PROVIDE IT IS HELPFUL HERE. I THINK
25 LEAVING SOMETHING WIDE OPEN LIKE THIS, SOMEBODY COULD

1 SAY 50-PERCENT ROYALTY, 1-PERCENT ROYALTY. BOTH ARE
2 RIDICULOUS, BUT WE KIND OF KNOW WHAT THAT RANGE IS.
3 AND IT'S PROBABLY BETWEEN TWO AND FIVE. IF I CAME IN
4 AND ARGUED THAT THERE'S A STACKING ROYALTY AND,
5 THEREFORE, I WANT TO PAY IT BACK AT TWO BECAUSE I GOT
6 TO PAY SOMEBODY ELSE A ROYALTY, THAT MIGHT BE TAKEN
7 INTO CONSIDERATION.

8 IN TERMS OF THE CAP THAT, JEFF, YOU WERE
9 CONCERNED ABOUT, IT'S OVER HERE ON THE LEFT. BECAUSE
10 THESE TWO ARE THE SAME, RIGHT, THE LEFT AND THE RIGHT.

11 CHAIRMAN PENHOET: THE MIDDLE THAT WE'RE
12 TALKING ABOUT. AND THE MIDDLE IS DIFFERENT BECAUSE
13 THERE'S A BELIEF THAT MANY OF US HAVE, AND I SHARE THAT
14 VIEW MYSELF -- I'LL PUT MYSELF ON THE RECORD HERE --
15 THAT WE SHOULD INCENT COMPANIES TO FORWARD INTEGRATE IN
16 CALIFORNIA IF WE CAN. THAT'S THE ECONOMIC BENEFITS
17 THAT WILL COME OUT OF THIS IS JOBS, REVENUES TO THE
18 STATE, ETC.

19 SO THE OTHER TWO AREN'T CAPPED. THEY CAN
20 CHARGE WHATEVER THEY WANT, IF THEY'RE A COMPANY OR A
21 UNIVERSITY, FOR THEIR LICENSES, AND THEY WILL DO WHAT'S
22 BEST FOR THEM AND, THEREFORE, PRESUMABLY, ALSO BEST FOR
23 US.

24 IN THE MIDDLE CASE, WE'VE HEARD STRONG
25 ARGUMENTS THAT COMPANIES ARE QUITE HAPPY TO PAY, IN

1 QUOTES.

2 MR. ROTH: THIS IS WELL DEFINED. PEOPLE CAN
3 DECIDE, THEN, TO TAKE THE MONEY. IF I TAKE HALF A
4 MILLION DOLLARS, I OWE YOU A MILLION AND A HALF IF I
5 COMMERCIALIZE. ALL THAT HAS TO BE DISCUSSED. IS IT
6 2-PERCENT PAYBACK, THE RATE AT WHICH WE PAY IT BACK.

7 MR. SHEEHY: I STILL COME BACK TO MY POINT.
8 I WOULD NEVER SUPPORT A FOR-PROFIT IN COMPETITION WITH
9 A NOT-FOR-PROFIT BASED ON AN EQUITABLE RETURN TO THE
10 STATE AT THE BASIC SCIENCE LEVEL.

11 AS I SAID IN MY COMMENTS, ONCE WE GET TO THE
12 OTHER PHASE OF THE DEVELOPMENT, SO TO SPEAK, PIPELINE,
13 I THINK THIS FITS FINE. YOU KNOW, I MEAN I DON'T HAVE
14 A PROBLEM BECAUSE A LOT OF THE DEVELOPMENT WILL BE SOME
15 COSTS THAT HAVE BEEN MADE BY THE COMPANIES. BUT FOR
16 THE BASIC SCIENCE INVENTIONS WHERE, YOU KNOW, I THINK
17 YOU ARE GOING TO GET EITHER A HOME RUN OR STRIKE OUT A
18 LOT. IF THERE IS A HOME RUN, WE'VE HOBbled OURSELVES,
19 AND WE'RE SETTING THEM UP TO COMPETE WITH THE
20 UNIVERSITIES ON AN UNEQUAL BASIS, AND I'D RATHER JUST
21 FUND THE UNIVERSITIES MYSELF, TO BE PERFECTLY HONEST,
22 IF WE CAN'T COME UP WITH SOME SORT OF SCHEME AT THIS
23 LEVEL WHERE WE'RE REALLY GOING TO BE GENERATING REALLY
24 VALUABLE INTELLECTUAL PROPERTY, I THINK, AT THE BASIC
25 SCIENCE LEVEL. MOST OF OUR GRANTS ARE NOT GOING TO PAY

1 OFF ANYTHING.

2 BUT AT THAT LEVEL, IF WE GENERATE A REALLY
3 VALUABLE PRODUCT, THE UNIVERSITIES' OFFICES OF
4 TECHNOLOGY AND LICENSING WILL ENSURE THAT THE STATE
5 GETS A RETURN BECAUSE IT'S IN THEIR INTEREST TO GET A
6 BIG RETURN. IN THIS INSTANCE WE'VE ALREADY SAID WE'RE
7 NOT GOING TO GET A BIG RETURN.

8 CHAIRMAN PENHOET: WE SAID WE'D CAP IT AT
9 3 X, BUT WE'VE ALSO SAID, AGAIN, NOW I'M RESTATING WHAT
10 I'VE CONTINUED TO SAY, THAT IT DOES PROVIDE THEM AN
11 INCENTIVE TO GO DOWN THE MIDDLE PATH RATHER THAN GO
12 DOWN THE LEFT-HAND PATH.

13 MR. ROTH: BUT I THINK THAT'S IMPLIED. IF A
14 COMPANY APPLIES FOR A GRANT, THEY AREN'T APPLYING FOR
15 IT BECAUSE THEY WANT TO OUTLICENSE TO A THIRD PARTY.
16 THAT'S JUST NOT WHAT THEY DO. THEY WANT TO DEVELOP
17 SOMETHING. THAT'S ONE.

18 TWO, PROPORTIONALITY. IN THAT MIDDLE BOX A
19 MILLION OR \$2 MILLION IN ANYTHING, EVEN A DIAGNOSTIC,
20 IS GOING TO REQUIRE 20, 30, AND MAYBE 300 MORE MILLION
21 DOLLARS TO GO IN. AND I THINK WHAT, JEFF, YOU HAVE TO
22 BE CAREFUL OF IS INDUSTRY LOOKING AT THIS AND SAYING,
23 THEIR LAWYERS SAYING, "WHAT AM I SIGNING ONTO? CAN I
24 CALCULATE EXACTLY WHAT I'M SIGNING ONTO BECAUSE IF THIS
25 AMOUNTS TO A LITTLE BIT OF THE IP, THERE WILL BE A LOT

1 MORE AROUND IT, AND I END UP HAVING TO PAY SOME
2 UNKNOWN." THAT'S THE PROBLEM, I THINK. THEY'LL WALK
3 AWAY FROM IT, SAY IT'S NOT WORTH TAKING A HALF MILLION
4 BUCKS AND ENCUMBERING OURSELVES DOWN THE ROAD.

5 MR. SHEEHY: I UNDERSTAND. I THINK, TO ME,
6 THE FUNDAMENTAL PROBLEM WE HAVE IS THAT THERE'S NO
7 MECHANISM TO MANAGE THE INTELLECTUAL PROPERTY. AND WE
8 CAN DO A LOWEST -- I PERSONALLY -- YOU KNOW, AS ED SAID
9 AT THE OUTSET, WE DON'T HAVE TO HAVE CONSENSUS. I'M
10 NOT -- I'M NOT TRYING TO SCORE POLITICAL POINTS. WE'RE
11 ALL SITTING HERE TRYING TO STRUGGLE WITH SOMETHING, AND
12 I DON'T THINK ANYBODY IS SITTING HERE TRYING -- AND
13 EVEN THE ECONOMIC ARGUMENTS THAT ED HAS MADE ARE VERY
14 COMPELLING TO ME. BUT FOR ME PERSONALLY, I JUST DON'T
15 KNOW HOW WE MANAGE THIS INTELLECTUAL PROPERTY WITH
16 FOR-PROFITS. AND A LOWEST COMMON DENOMINATOR SCHEME AS
17 A SHORTCUT DOES NOT, FOR ME, SATISFY WHAT I CONSIDER TO
18 BE MY OBLIGATION TO ENSURE A RETURN TO THE STATE.

19 CHAIRMAN PENHOET: I MIGHT SUGGEST,
20 UNFORTUNATELY, IN HAVING LOOKED AT THIS, THERE'S A
21 RISK. WHAT ARE THE RISKS? THE RISKS ARE SOMEBODY
22 INVENTS SOMETHING EXTREMELY VALUABLE, AND WE GET ONLY
23 3 X ON WHAT WE PUT INTO THEIR INVENTION. HOWEVER, THE
24 ALTERNATIVE WOULD BE THAT THEY TAKE THE MONEY, NOT
25 KNOWING WHAT THE ROYALTY WOULD BE, AND WE'D SAY TO

1 THEM, IF YOU GUYS REALLY INVENT SOMETHING GREAT, WE'RE
2 GOING TO CHARGE YOU A HIGH ROYALTY; AND IF YOU INVENT
3 SOMETHING THAT'S NOT SO GOOD, WE'LL CHARGE YOU A LOW
4 ROYALTY. THAT'S ALMOST DOUBLE JEOPARDY FOR THE QUALITY
5 OF THE INVENTION. AND I THINK NOBODY WOULD TAKE MONEY
6 UNDER THE CIRCUMSTANCES WHEN YOU DIDN'T KNOW WHAT THE
7 ROYALTY WOULD BE.

8 THE WAY NEW JERSEY SOLVED THIS PROBLEM IS
9 JUST A FLAT 1-PERCENT ROYALTY ON EVERYTHING. SO THEY
10 FINESSED THE WHOLE ISSUE. THEY JUST SAID, OKAY, JUST
11 PAY US 1 PERCENT OF WHATEVER IT IS, AND THAT'S THAT.
12 WE'LL ALL GO AWAY.

13 MR. SHEEHY: WAS THAT A CAPPED?

14 CHAIRMAN PENHOET: NO, BUT 1 PERCENT IS A
15 PRETTY MODEST ROYALTY.

16 MR. SHEEHY: SEE, I WOULD SAY THAT ALMOST
17 WOULD MAKE MORE SENSE TO ME THAN A CAP BECAUSE I THINK
18 WE WOULD HAVE -- I MEAN, YOU KNOW, THE MORE THAT WE
19 START TO DELVE INTO THIS, IT JUST SEEMS LIKE THAT IN
20 THE FOR-PROFIT SCHEME, THAT A LOT OF THINGS THAT WE
21 HAVE A STRONG INTEREST IN ARE GOING TO FALL APART, AND
22 THAT THE ONLY THING THAT WE CAN REALLY TRY TO DO IS
23 MAXIMIZE RETURN. I DON'T THINK THERE'S ANY WAY TO MAKE
24 SOME SORT OF MATCH BETWEEN OUR ACCESS PLANS AND TO SET
25 A THRESHOLD THAT MAKES ANY KIND OF REASONABLE SENSE

1 WITH THE ACCESS PLANS AND THE PREFERENTIAL PRICING
2 BECAUSE I DON'T KNOW HOW YOU WOULD SET THAT WHERE IT
3 WOULD KICK IN AT ANY REASONABLE LEVEL WITH THE COST OF
4 THE DEVELOPMENT OF A THERAPY BEING \$800 MILLION,
5 SOMEWHERE BETWEEN 400 MILLION AND 800 MILLION.
6 WHATEVER NUMBER WE THROW OUT THERE IS REALLY GOING TO
7 BE NONSENSICAL BECAUSE WE'RE NOT EVER GOING TO MAKE
8 ANYWHERE NEAR THAT KIND OF CONTRIBUTION TO A THERAPY
9 EVEN IF WE START TALKING ABOUT 10 PERCENT. WE SAY 25
10 PERCENT, IT'S AN EXERCISE IN FUTILITY.

11 SO THE ONLY THING THAT WE'RE REALLY TALKING
12 ABOUT, IF WE'RE TALKING ABOUT A REAL RETURN TO THE
13 STATE, IS MONETARY RETURN. AND SOMEHOW, TO MY MIND, WE
14 HAVE TO COME UP WITH A SCHEME; AND EVEN IF IT'S AN
15 ULTRA LOW ROYALTY, I WOULD SUPPORT THAT, TO BE
16 PERFECTLY HONEST, IF THAT WOULD INCENTIVIZE COMPANIES
17 BECAUSE I KNOW IF WE HIT A HOME RUN, THAT WE CAN TELL
18 THE VOTERS, LIKE, YOU'RE GOING TO BE GETTING MONEY.
19 WHEN THE MONEY STARTS TO COME AND WE PUT 10 MILLION IN
20 AND THE COMPANY'S MADE A BILLION DOLLARS, AND WE'VE,
21 YOU KNOW, WE'VE COME BACK AND SAID WE'RE GOING TO TAKE
22 \$60 MILLION OF THAT AND THAT'S ALL.

23 DR. LOVE: JEFF, I THINK THAT ONE OF THE
24 CHALLENGES THAT WE JUST NEED TO RECOGNIZE IS THAT THE
25 MORE THE FOCUS IS ON GETTING THERAPIES OUT TO PATIENTS

1 AND GETTING THE RESEARCH TO GO FORWARD AND GETTING
2 COMPANIES TO COME IN AND PUT A LOT OF MONEY BEHIND
3 MAKING PRODUCTS, THE MORE TENSION YOU CREATE THAT'S NOT
4 HAPPENING BY TRYING TO MAXIMIZE FINANCIAL RETURNS
5 THROUGH ROYALTIES THROUGH WHATEVER MECHANISM.

6 I ACTUALLY THOUGHT THE CAP ON NOT-FOR-PROFITS
7 MAKES SENSE TO ME BECAUSE I THINK AT THE END OF THE
8 DAY, YOU ARE GOING TO BE DEALING WITH A DIFFERENT SET
9 OF MOTIVATIONS. BECAUSE I THINK IN THE CASE OF PRIVATE
10 COMPANIES, YOU'RE BASICALLY DEALING WITH TAKING A
11 LICENSE OR TAKING A GRANT THAT WILL LIKELY BE A PRETTY
12 SMALL PERCENTAGE, AS YOU SAID ALREADY, OF WHAT YOU
13 INVEST IN THAT PRODUCT TO MAKE A REAL PRODUCT. AND THE
14 REAL ISSUE IS IF THE PERSON DOESN'T HAVE ANY CONCEPT OF
15 THEIR LIABILITY FOR TAKING THAT, THEY'RE NOT GOING TO
16 TAKE IT. AND THAT IS GOING TO RESULT IN SOMETHING THAT
17 I THINK NONE OF US WANT TO SEE HAPPEN, WHICH IS
18 COMPANIES SAY THESE GRANTS ARE TOXIC, AND WE'RE JUST
19 NOT GOING TO GET INVOLVED BECAUSE THEY BASICALLY CREATE
20 A NO-WIN IN TERMS OF A FOR-PROFIT MOTIVE, WHICH IS TO
21 MAKE PROFITS ULTIMATELY.

22 CHAIRMAN PENHOET: YOU KNOW, ONE OTHER POINT
23 WE SHOULD KEEP IN MIND, I REITERATED AGAIN, THE
24 BENEFITS TO THE STATE ARE NOT SOLELY FROM THIS. JOB
25 CREATION, ALL THE OTHER ASPECTS OF COMPANY DEVELOPMENT

1 WHICH COME ONLY IN THIS BOX. BUT SECOND OF ALL, IF WE
2 HAVE A ROBUST STEM CELL INDUSTRY IN CALIFORNIA,
3 HOPEFULLY MOST OF THE LICENSES FROM THE NON-PROFITS
4 WILL ACTUALLY GO TO THE PROFIT. MAYBE THERE SHOULD BE
5 AT LEAST A DOTTED ARROW ACROSS THERE. IN THAT CASE THE
6 FOR-PROFIT COMPANY WILL HAVE TO AGREE TO WHATEVER TERMS
7 THE NOT-FOR-PROFIT -- THEY CAN'T AGREE TO THE
8 NOT-FOR-PROFIT GOING THIS WAY. SO THERE ACTUALLY IS
9 ANOTHER ARROW, A DOTTED LINE SHOULD GO FROM HERE TO
10 HERE BECAUSE IF WE HAVE A ROBUST INDUSTRY HERE,
11 HOPEFULLY --

12 DR. REED: SOMETIMES ONE WILL COME FROM
13 COMPANY A VERSUS COMPANY B BEING THE LICENSED ROUTE, SO
14 YOU WILL HAVE ARROWS BETWEEN COMPANIES AS WELL.

15 CHAIRMAN PENHOET: SURE.

16 MS. KING: FOR THE PEOPLE ON THE PHONE --

17 CHAIRMAN PENHOET: BUT A LICENSE COULD ALSO
18 GO TO A COMPANY IN NEW JERSEY OR NEW YORK.

19 MS. KING: FOR THE PEOPLE ON THE PHONE, COULD
20 YOU ILLUSTRATE THAT IN WORDS?

21 DR. PIZZO: I WAS GOING TO ASK THAT SAME
22 QUESTION. ED, IF YOU COULD TELL US WHERE YOU DREW THAT
23 LINE.

24 CHAIRMAN PENHOET: NOT SEEING THE SLIDE MAKES
25 IT A LITTLE DIFFICULT. I UNDERSTAND. I'M SORRY.

1 DR. PIZZO: I'M TRYING HARD TO VISUALIZE IT
2 THOUGH.

3 CHAIRMAN PENHOET: ON THE RIGHT-HAND SIDE, WE
4 SAY THAT A NOT-FOR-PROFIT GETS FUNDED BY CIRM TO DO
5 BASIC SCIENCE, MAKES AN INVENTION, LICENSES IT TO A
6 THIRD PARTY, AS A RESULT THEY PAY WHAT WE'VE ALREADY
7 AGREED THEY WILL. THE LICENSEE WILL PAY TO THE
8 NOT-FOR-PROFIT, AND WE'LL GET 25 PERCENT OF WHATEVER
9 THEY GET AFTER THEY PAY THEIR INVENTORS. AND IN THE
10 FOR-PROFIT SIDE, IT SAYS CIRM CAN FUND BASIC SCIENCE,
11 GET AN INVENTION, COULD ALSO BE LICENSED OUT TO A THIRD
12 PARTY, IN WHICH CASE THEY'RE PERFECTLY SYMMETRICAL.
13 WHETHER A COMPANY LICENSES TO ANOTHER COMPANY OR A
14 NONPROFIT LICENSES TO ANOTHER COMPANY, THE TERMS ARE
15 BASICALLY THE SAME.

16 IN THE MIDDLE OF OUR SLIDE, WE SAY A
17 FOR-PROFIT COMPANY GETS CIRM FUNDING TO DO BASIC
18 SCIENCE, MAKES AN INVENTION. IF IT DECIDES TO FORWARD
19 INTEGRATE ITSELF TO PRECLINICAL, PRODUCT DEVELOPMENT,
20 AND A MARKETED PRODUCT, IN THAT CASE, THEN, THEY'LL PAY
21 US A ROYALTY UNTIL THEY'VE ACHIEVED A THREEFOLD --
22 UNTIL CIRM HAS GOTTEN PAID BACK THREE TIMES -- THE
23 STATE WOULD BE PAID BACK THREE TIMES WHATEVER IT
24 INVESTED IN THAT PROJECT.

25 THEN IN ADDITION TO THAT, THERE'S ANOTHER

1 PAYMENT OF A BLOCKBUSTER PAYMENT OF THREE TIMES IF THE
2 TOTAL SALES EXCEED \$250 MILLION A YEAR ON THAT PRODUCT.
3 SO IN THAT CASE, IF IT WAS A BLOCKBUSTER, WE'D GET 6 X.

4 DR. PIZZO: IS THE MULTIPLIER AGAINST THE
5 AMOUNT OF INVESTMENT?

6 CHAIRMAN PENHOET: YES. IT'S AGAINST WHAT
7 CIRM INVESTED.

8 DR. PIZZO: SO IF YOU REALLY HAD A
9 BLOCKBUSTER, YOU MIGHT HAVE INVESTED, YOU KNOW, A
10 MILLION DOLLARS; BUT IF IT WAS A HUGE BLOCKBUSTER,
11 MAYBE THERE'D BE \$50 MILLION.

12 CHAIRMAN PENHOET: IF IT'S A HUGE
13 BLOCKBUSTER, WHO KNOWS, COULD BE A
14 BILLION-DOLLAR-A-YEAR PRODUCT.

15 DR. PIZZO: JUST SAYING WHATEVER IT IS, THE
16 DEAL HAS OBVIOUSLY SOME LIMITATIONS.

17 CHAIRMAN PENHOET: THAT'S TRUE.

18 DR. PRIETO: LOOKING OVER THIS AND READING
19 IT, FIRST OF ALL, I THINK IT'S VERY IMPORTANT THAT
20 INDUSTRY PARTICIPATE. AND I WANT TO HAVE INCENTIVES
21 FOR THAT TO HAPPEN. AND WHAT I HEAR OVER AND OVER FROM
22 REPRESENTATIVES FROM INDUSTRY IS THEY WANT SOME
23 CERTAINTY. SO I GET THAT AND I APPRECIATE IT, AND I
24 WANT THEIR PARTICIPATION.

25 READING THROUGH THIS, THOUGH, IT SEEMED TO ME

1 THAT MAYBE A ROYALTY RATE IS THE MORE LOGICAL WAY, A
2 PRETTY MODEST ROYALTY RATE, LIKE WHAT DUANE HAS
3 PROPOSED, OF GUARANTEEING THAT CERTAINTY TO THE
4 COMMERCIAL INVESTORS WITHOUT PUTTING A CAP ON OUR
5 POTENTIAL RETURN AND WITHOUT INCENTIVIZING EVERYTHING
6 INTO THE FOR-PROFIT ARENA AND AWAY FROM THE
7 NOT-FOR-PROFITS.

8 I HAVE THE SAME CONCERN THAT JEFF RAISED. I
9 DON'T WANT TO CREATE INCENTIVES THAT ARE UNFAIR ON
10 EITHER SIDE.

11 MR. ROTH: HERE'S ANOTHER THING THAT I THINK
12 INDUSTRY, THE WAY INDUSTRY WOULD LOOK AT THIS, EVEN IF
13 IT'S A LOW ROYALTY AND IT'S THERE FOREVER. IT'S NOT
14 LIKELY THAT A SINGLE PATENT IS GOING TO BE THE ONLY
15 PATENT INVOLVED IN WHATEVER THAT PRODUCT BECOMES. IT'S
16 NOT LIKELY THAT CORE PATENT IS GOING TO BE THE ONLY
17 THING THAT THEY'VE GOT TO BRING IN. SO THEY'RE GOING
18 TO SAY, YEAH, BUT I ALSO TOOK MONEY FROM NATIONAL
19 INSTITUTE OF HEALTH, I ALSO TOOK MONEY, AND SO THE
20 INVENTION ITSELF BECOMES AN ARGUMENT. WHOSE MONEY WAS
21 USED FOR THAT INVENTION? THEY'LL WANT SOME HURDLE, TO
22 SAY IF 10 PERCENT OF THE MONEY CAME FROM CIRM, THEN
23 YOU'RE ENTITLED TO IT, OTHERWISE YOU'RE NOT.

24 THIS, I KNOW WHAT IT IS. IF I TOOK \$2
25 MILLION, I OWE YOU SIX; AND IF IT BECOMES A BIG

1 PRODUCT, I OWE YOU 12. IF IT'S A ROYALTY AND THEY
2 START LOOKING AT IT FROM THAT STANDPOINT, THEY'RE GOING
3 TO SAY, "WELL, LOOK, I COULD END UP HAVING TO PAY THIS
4 1 PERCENT ON TOP OF 4 PERCENT THAT I'VE GOT TO PAY
5 SOMEBODY ELSE TO PRACTICE THE ART TO ACTUALLY BRING THE
6 PRODUCT. THIS COULD BE VERY EXPENSIVE AT 1 PERCENT
7 BECAUSE IT'S ADDING ON TO SOME OTHER INTELLECTUAL
8 PROPERTY. ALL I TOOK WAS A MILLION DOLLARS. AND I END
9 UP SPENDING \$200 MILLION TO GET THIS DRUG ON THE
10 MARKET, AND I'M GOING TO HAVE TO PAY THIS 1 PERCENT
11 FOREVERMORE?"

12 BUT HERE THEY CAN GO TO IT AND SAY, "WELL, I
13 KNOW WHAT I'VE GOT TO PAY." IT'S NOT AN ARGUMENT ABOUT
14 WHO INVENTED, WHAT WAS THE TOTALITY, WHO PUT THE MONEY
15 IN THAT LED TO THAT INVENTION? THOSE ARE THE
16 ARGUMENTS, I THINK, YOU WANT TO STAY COMPLETELY OUT OF.

17 THIS, I DON'T THINK ANYBODY WILL COME AROUND
18 AND SAY I DID A CALCULATION HERE, AND BY MY
19 CALCULATIONS, WE PUT 80 PERCENT OF THE MONEY IN, CIRM
20 PUT 20 PERCENT IN; THEREFORE, WE DON'T THINK WE OWE YOU
21 THE ROYALTY EVEN THOUGH IT WAS A JOINT INVENTION THAT
22 CAME OUT. THIS AVOIDS ALL THAT. THIS IS SIMPLE. YOU
23 KNOW WHAT YOUR NUMBER IS. YOU CAN UNDERSTAND IT.

24 MR. SHEEHY: CAN I ASK WHAT DID THEY DO IN
25 NEW JERSEY? BECAUSE THAT SEEMS TO BE THAT CERTAINLY

1 THEY MIGHT HAVE LOOKED AT THIS. I MEAN GIVEN THE
2 PREPONDERANCE OF PHARMA AS AN INDUSTRY IN NEW JERSEY
3 AND GIVEN THAT CORZINE, WHO USED TO RUN GOLDMAN SACHS,
4 WAS THE GOVERNOR, I HAVE TO ASSUME THAT WHATEVER SCHEME
5 THEY DEVELOPED MUST HAVE BEEN AMENABLE TO MERCK AND
6 EVERYBODY ELSE THAT'S IN NEW JERSEY, PHIZER, ETC. ,
7 ETC. , AND THAT THE ECONOMICS MUST WORK FOR THE STATE OF
8 NEW JERSEY.

9 I JUST -- CERTAINLY THERE MUST BE SOME
10 LANGUAGE THAT ADDRESSES THE PROPORTIONALITY. I GUESS
11 MY PROBLEM IS THAT I THINK THERE REALLY ARE
12 BLOCKBUSTERS, AND I JUST THINK ABOUT THE HALF A BILLION
13 DOLLARS THAT GILEAD PAID TO EMORY FOR A SINGLE PATENT
14 FOR A SINGLE DRUG FOR AN ANTIRETROVIRAL. YOU KNOW,
15 WE'RE NOT CAPTURING THAT EXCEPT IF WE GO THROUGH THE
16 NOT-FOR-PROFIT ROUTE. WE WOULD PRESUMABLY GET SOME
17 PERCENTAGE OF THAT THAT WOULD BE FAIRLY REASONABLE IN
18 TERMS OF OUR INVESTMENT IN.

19 IN THIS SCHEME, IT'S HARD TO IMAGINE THAT
20 WE'D CAPTURE ANYTHING NEAR THE AMOUNT OF WEALTH THAT
21 WAS GENERATED WITH THAT PATENT. AND, YOU KNOW, I JUST
22 THINK, FOR ME, I THINK MOST OF THESE THINGS ARE NOT
23 GOING TO MAKE MONEY. SOME OF THESE THINGS WILL MAKE A
24 LITTLE BIT OF MONEY, AND THERE WILL BE A COUPLE OF
25 THINGS THAT MAKE A WHOLE LOT OF MONEY. AND THAT'S WHAT

1 I'M WORRIED ABOUT. I'M LESS CONCERNED ABOUT CATCHING
2 THOSE FIRST TWO INSTANCES THAN MISSING SOME
3 PARTICIPATION ON THE THIRD BECAUSE I THINK THE VOTERS
4 WILL RIGHTLY ASK US, "WHY DID YOU SET UP A SCHEME THAT
5 LEFT US SITTING IN COLD FOR THAT BIG THING?"

6 I THINK WHEN PEOPLE ARE MAKING A LOT OF
7 MONEY, I DON'T THINK THEY MIND. WE CAN SET A
8 THRESHOLD, A REVENUE THRESHOLD, THAT THE ROYALTY
9 DOESN'T KICK IN AT, FOR INSTANCE. THAT'S ONE WAY TO
10 ENSURE THAT COMPANIES -- I DON'T MIND GIVING AWAY A LOT
11 OF STUFF UNTIL PEOPLE START MAKING REALLY GOOD MONEY.
12 THAT'S OUR GOAL IS TO INCENTIVIZE PEOPLE TO DO STUFF.
13 ONCE THEY REALLY START MAKING MONEY, WE SHOULD SHARE.
14 WE HAVE AN OBLIGATION TO THE VOTERS WHO ARE DELAYING,
15 WHO ARE FORFEITING SOME OPPORTUNITIES FOR INVESTMENT
16 WHEN THEY START PAYING BACK THESE BONDS.

17 DR. PRIETO: MAYBE WE SHOULD WRITE THAT ONLY
18 INTO THE BLOCKBUSTER PAYMENT.

19 DR. LOVE: JEFF, THAT IS KIND OF IN THERE
20 BECAUSE, FOR EXAMPLE, VENTURE CAPITALISTS, THEY ARE
21 HAPPY IF THEY CAN A 5 OR 10 X ON WHAT THEY PUT IN. AND
22 MOST OF THE TIME, AS YOU SAID, THEY DON'T GET ANYTHING
23 BACK BECAUSE THE COMPANIES AREN'T SUCCESSFUL. SO
24 GETTING A -- IF THE THING IS VERY SUCCESSFUL, IF YOU
25 GET SIX TIMES WHAT YOU PUT IN, THAT'S ACTUALLY A PRETTY

1 GOOD RETURN. I'M NOT SURE IF I WOULD INTERPRET THAT,
2 PARTICULARLY IN THE CONCEPT OF WHAT ED SAID ABOUT JOB
3 CREATION, THERAPY CREATION, OTHER LINES FOR ROYALTIES,
4 I'M NOT SURE THAT WOULD REALLY BE LEAVING US --

5 DR. REED: COULD WE DISCUSS SOME MORE THIS
6 IDEA OF THE NEW JERSEY APPROACH TO THIS? DUANE, FOR
7 EXAMPLE, FROM THINKING ABOUT AN INDUSTRY PERSPECTIVE,
8 IF YOU HAD A 1-PERCENT ROYALTY, FOR EXAMPLE, TRIGGER
9 AFTER SOME AMOUNT OF SALES, MAYBE MAKE IT A HALF A
10 BILLION OR SOMETHING, DO YOU THINK THAT WOULD BE A
11 DISINCENTIVE TO INDUSTRY TO PARTICIPATE?

12 MR. ROTH: I DON'T KNOW. I GUESS MY CONCERN
13 IS THAT I KNOW OF VIRTUALLY NO PRODUCT THAT DOESN'T
14 HAVE MULTIPLE PATENTS. THAT'S JUST THE FACT OF LIFE.
15 I THINK THAT'S WHAT INDUSTRY WILL BE CONCERNED ABOUT.
16 IT ISN'T A 1-PERCENT ROYALTY THAT'S GOING TO SHOCK.
17 IT'S THE FACT THAT THAT 1 PERCENT HAS TO GET ADDED TO A
18 BUNCH OF OTHER THINGS THAT YOU'VE PROBABLY GOT A
19 LICENSE IN AS WELL. AND SO THAT'S WHERE THE -- YOU GET
20 INTO COMPLEXITY. THEN YOU'RE GOING TO HAVE TO START
21 TALKING ABOUT -- YOU ARE GOING TO HAVE TO WRITE
22 SOMETHING HERE THAT REALLY IS LIKE INDUSTRY DEALS WITH
23 THE TWO OTHER SIDES. INDUSTRY TODAY HAS TO NEGOTIATE
24 WITH THEM, AND ALWAYS IN THOSE NEGOTIATIONS A PROVISION
25 FOR STACKING ROYALTIES COMES IN. WHO GETS PAID FIRST

1 AND WHAT'S THE CAP? SO THAT MAKES ANOTHER DEGREE OF
2 COMPLEXITY.

3 THEN THE SECOND THING I WORRIED ABOUT I SAID
4 BEFORE. IF THERE ARE MULTIPLE INVENTIONS BETWEEN THE
5 CIRM MONEY AND THE COMPANY, HOW DO YOU PULL THOSE
6 APART? AND YOU GUYS DEAL WITH THIS ALL THE TIME. WHEN
7 YOU HAVE INDUSTRY AND INSTITUTIONS WORKING TOGETHER,
8 THERE'S ALWAYS A CONCERN ABOUT WHO MADE THE INVENTION.
9 AND I THINK THAT ADDS A DEGREE OF COMPLEXITY THAT THE
10 STAFF WILL HAVE TO WORK THROUGH.

11 SO I REALLY THINK THAT THE MIDDLE PART, THE
12 WAY WE DID IT LAST TIME, IS EASY TO UNDERSTAND AND EASY
13 TO GET THERE. I AM SENSITIVE TO A BLOCKBUSTER AND ALL
14 THAT IF THERE'S A SOLE PATENT THAT IS TREMENDOUSLY
15 ENABLING THAT WAS COMPLETELY FUNDED BY CIRM MONEY OR
16 LARGELY FUNDED, WHICH I THINK JUST IN PRACTICALITY WILL
17 NOT HAPPEN. SO I'D RATHER DEAL WITH THE EXCEPTION
18 WHERE THAT DID HAPPEN ON AN EXCEPTIONAL BASIS, SORT OF
19 WHAT WE'RE TALKING ABOUT, WHAT JEFF JUST SUGGESTED,
20 THAT 1 PERCENT KICKS IN AFTER A CERTAIN THRESHOLD FOR A
21 PERIOD OF TIME IF IT'S THE SOLE INVENTION. I THINK
22 THAT WOULD BE OKAY. BUT I WOULD HATE TO SEE US START
23 WITH THAT POLICY BECAUSE I THINK EVERY ONE OF THESE
24 WILL BE A NEGOTIATION, AND MY BIGGEST FEAR IS SOMETHING
25 THAT WAS SAID EARLIER, INDUSTRY JUST BACKS AWAY FROM

1 TAKING THESE GRANTS BECAUSE THEY'RE NOT GOING TO BE
2 MEANINGFUL ENOUGH TO REALLY ADVANCE A DRUG OR A
3 DIAGNOSTIC OR A TOOL.

4 THEY'RE GOING TO BE HELPFUL. THAT'S WHAT WE
5 WANT, BUT NOT SO MEANINGFUL THAT THEY WOULD TAKE IT IF
6 IT LOOKS LIKE I'M ENCUMBERING MYSELF LATER ON TO NOT
7 BEING ABLE TO EXTRACT MYSELF FROM THIS PAYMENT THAT'S
8 OUT THERE.

9 CHAIRMAN PENHOET: ONE POSSIBLE APPROACH TO
10 THIS WOULD BE TO INCREASE THE SIZE OF THE BLOCKBUSTER
11 PAYMENT. THAT WOULD BE -- IF THAT'S THE CONCERN IS
12 THAT -- YOU KNOW, IT'S A LITTLE DIFFICULT WITH
13 BLOCKBUSTERS. IN A SENSE FUNDING IS MONEY. A
14 BLOCKBUSTER IS AN INVENTION THAT SOMEONE MADE. AND SO,
15 YOU KNOW, THEY NEED -- YOU KNOW, THE VALUE OF AN
16 INVENTION IS IN THE INVENTION, NOT IN THE FUNDING OF
17 THE INVENTION. SO TO SOME DEGREE, YOU DON'T WANT TO
18 PENALIZE PEOPLE WHO ARE BRILLIANT OVER PEOPLE WHO
19 WASTED YOUR MONEY. JUST BECAUSE YOUR BRILLIANT GUY
20 MADE A GREAT INVENTION, IT'S SORT OF COUNTERINTUITIVE
21 IN A WAY.

22 IF WE WANTED TO STAY WITH THIS MODEL RATHER
23 THAN A FLAT RATE, WE COULD ADDRESS, AT LEAST PARTLY,
24 YOUR CONCERN BY INCREASING THE BLOCKBUSTER PAYMENT.

25 MR. SHEEHY: WELL, LIKE I SAID, WE DON'T HAVE

1 TO HAVE CONSENSUS. I REALLY THINK THAT EVERYBODY IS
2 BRINGING TO THE TABLE -- YOU KNOW, WE HAVE A LOT OF
3 CONFLICTING INTERESTS. I THINK -- I STILL COME BACK, I
4 THINK WE HAVE A STRUCTURAL PROBLEM THAT IS INSOLVABLE,
5 AND THAT WHATEVER WE DO IS GOING TO BE FLAWED BECAUSE
6 WE'RE LIMITED TO STAFF THAT WE CAN HAVE. THE
7 PROPOSITION DOESN'T ALLOW US TO MANAGE AND THE STATE
8 DOESN'T MANAGE ITS OWN INTELLECTUAL PROPERTY AS IT
9 STANDS NOW, AND SO THERE'S A VACUUM.

10 AND SO THE IMPERFECTION THAT EXISTS -- AND,
11 YOU KNOW, I'M NOT THROWING MYSELF IN FRONT OF THE
12 TRAIN. I HAVE TO EXPRESS MY, YOU KNOW. AND IT'S NOT
13 LIKE YOU HAVE TO FIGURE OUT SOMETHING THAT WILL MOLLI FY
14 ME. IT MAY BE THAT WE END UP VOTING, MOVING FORWARD,
15 AND THE ICOC MOVES FORWARD THE MIDDLE SCHEME. I WILL
16 NOT FEEL LIKE THAT WE HAVE MATERIALLY HARMED THE
17 OVERALL EFFORT IF IT DOES INCENTIVIZE INDUSTRY TO
18 PARTICIPATE. SO I'M NOT GOING TO FEEL LIKE SOMETHING
19 TERRIBLE HAS HAPPENED.

20 DR. PIZZO: COULD I SPEAK WHEN THERE'S A
21 MOMENT?

22 CHAIRMAN PENHOET: PLEASE, RIGHT NOW.

23 DR. PIZZO: THANK YOU. I JUST WANT TO FOLLOW
24 UP ON THE POINTS THAT ARE JUST BEING MADE BECAUSE I
25 THINK THERE ARE TWO FACETS TO IT, JEFF, FOR ME. ONE OF

1 THEM IS WE ALL RECOGNIZE THAT BLOCKBUSTERS, AS MUCH AS
2 WE LOVE THEM, ARE VERY UNUSUAL. AND SO IN THE MIDST OF
3 WHATEVER WE DO, THE NUMBER OF TIMES IT'S GOING TO
4 HAPPEN IS PRETTY LOW. ON THE OTHER HAND, I THINK THE
5 POINT THAT WAS JUST MADE EARLIER, THAT WHEN THAT
6 HAPPENS, AND INEVITABLY IT WILL HAPPEN, HOPEFULLY,
7 THERE WOULD BE A PERCEPTION IN ADDITION TO THE NUMBERS.
8 I THINK IT IS TRUE THAT PEOPLE IN THE STATE WILL SAY,
9 "GEE, IF THERE'S \$10 MILLION COMING IN AND WE'RE
10 GETTING REALLY A FRACTION OF THAT, WHY DID THAT
11 HAPPEN?"

12 SO I ACTUALLY LIKE YOUR THOUGHT ABOUT
13 EXPLORING SOME KIND OF ADDITIONAL MULTIPLIER FOR A
14 BLOCKBUSTER. I DON'T HAVE A FORMULA FOR WHAT THAT
15 MIGHT BE READILY IN HAND, BUT I WONDER WHETHER THAT'S
16 NOT WORTH SOME ADDITIONAL -- JUST ADDITIONAL THOUGHT
17 AND EXPLORATION.

18 CHAIRMAN PENHOET: WELL, I THINK IF YOU
19 COMBINE MAYBE DUANE'S SUGGESTION OF SUGGESTING A
20 ROYALTY RANGE, WHICH IS SIGNIFICANT BUT NOT ONEROUS,
21 AND INCREASING THE CAP ON A BLOCKBUSTER.

22 DR. PIZZO: OKAY. THAT COULD DO IT.

23 CHAIRMAN PENHOET: THAT MIGHT BE AN APPROACH.

24 DR. PIZZO: I THINK THAT COULD DO IT. I'M
25 REALLY DEALING MORE WITH, I THINK, THE PERCEPTION PART

1 THAN THE DOLLARS BECAUSE I THINK IT'S GOING TO BE SO
2 UNUSUAL.

3 DR. LOVE: ED, WHAT ABOUT THE IDEA OF HAVING
4 DIFFERENT LEVELS OF RETURN FOR DIFFERENT LEVELS OF
5 BLOCKBUSTER? SO 250 MIGHT BE 3 X. A PRODUCT THAT'S
6 MORE THAN 500 MIGHT BE, I DON'T KNOW, SOME NUMBER
7 BEYOND THREE. YOU THINK THAT WOULD ADD TOO MUCH
8 COMPLEXITY?

9 CHAIRMAN PENHOET: NO. BECAUSE IT'S SIMPLE,
10 QUANTIFIABLE, AND ANYBODY CAN UNDERSTAND IT, SO IT ADDS
11 ANOTHER LAYER OF COMPLEXITY, BUT IT'S NOT COMPLEX. THE
12 CONCEPT IS SIMPLE.

13 MR. ROTH: WHEN YOU TAKE MONEY, THE THOUGHT
14 THAT YOU'D EVER BE ABLE TO PAY THAT WOULD BE THRILLING.

15 DR. LOVE: I AGREE.

16 CHAIRMAN PENHOET: I MEAN, TAKE THE ARGUMENT,
17 PROPORTIONAL PARTS. IF IT'S 250, IT'S 3 X. IF IT'S
18 500 MILLION A YEAR, IT'S 5 X.

19 MR. SHEEHY: WHAT IF WE TIERED IT AND WE GOT
20 THE 3 X EVERY TIME THEY WENT UP 250 MILLION, SO WE GOT
21 ANOTHER PAYMENT? IF YOU HAD A PRODUCT THAT WAS MAKING
22 250 MILLION A YEAR --

23 MR. ROTH: IF YOU TOOK A MILLION, YOU OWE
24 THREE. IF YOU GET THAT NEXT YEAR, YOU OWE THREE MORE.

25 CHAIRMAN PENHOET: EVERY 250 GETS ANOTHER

1 3 X.

2 DR. REED: I LIKE A STRATEGY LIKE THAT.

3 DR. PRIETO: IF WE CURE CANCER, DIABETES, AND
4 HEART DISEASE, WE JUST WIPE OUT THE STATE BUDGET
5 DEFICIT.

6 DR. LOVE: WON'T PAY ANY MORE CALIFORNIA
7 TAXES THEN.

8 MR. ROTH: BUT THAT HAS TO BE ONE-TIME
9 PAYMENTS.

10 CHAIRMAN PENHOET: YEAH.

11 MR. ROTH: IT'S ON CUMULATIVE SALES OR ON
12 ANNUAL SALES?

13 CHAIRMAN PENHOET: THE WAY WE SAID IT IS WHEN
14 THEY REACH 250 MILLION PER YEAR, A THRESHOLD, IF THEY
15 REACH 250, THEY'D PAY 3 X. IF THEY REACH 500 IN A
16 GIVEN YEAR, THEY WOULD PAY ANOTHER 3 X. IF THEY REACH
17 750, THEY PAY ANOTHER 3 X.

18 DR. PIZZO: FOR THAT YEAR.

19 DR. REED: FOR THAT YEAR, RIGHT.

20 MR. ROTH: WHEN THAT HAPPENS.

21 CHAIRMAN PENHOET: NO, NOT ANNUALLY.

22 DR. REED: YOU WOULDN'T DO IT ANNUALLY? WE
23 CREATE A ROYALTY-LIKE MECHANISM.

24 DR. PIZZO: THAT'S WHAT I WAS THINKING.

25 CHAIRMAN PENHOET: WELL, WE CAN CONSIDER

1 THAT. WHAT WE PUT DOWN -- IT COULD BE A LOT OF MONEY.

2 DR. LOVE: I'D HAVE TO PROBABLY FIGURE OUT
3 WHAT THAT WOULD DO TO SOMEONE'S BUSINESS MODEL IF THEY
4 HAD TO FACE THAT ANNUALLY. THAT MIGHT BE ONEROUS.

5 DR. REED: THE PERCENTAGE MAY BE HIGHER THAN
6 SOME OF THE NUMBERS WE KICKED AROUND.

7 CHAIRMAN PENHOET: WE CAN PUT SOME
8 SIGNIFICANT MONEY INTO SOME OF THESE PROJECTS. YOU
9 KNOW, WHERE INDUSTRY HAS TOLD US THEY NEED OUR HELP
10 OTHER THAN THE BASIC SCIENCE IS IN THE PRECLINICAL AND
11 THE PRODUCT DEVELOPMENT AREA, INCLUDING SOME CLINICAL
12 TRIALS. WE COULD END UP PUTTING 10, \$20 MILLION INTO
13 SOME OF THESE PROJECTS.

14 DR. PRIETO: IF IT'S NOT ANNUAL, ISN'T IT --

15 CHAIRMAN PENHOET: WELL, THE WAY IT WAS SET
16 UP HERE WAS A ONE-TIME PAYMENT. WHEN THEY REACHED \$250
17 MILLION A YEAR, THEY WOULD PROVIDE 3 X WHATEVER THEY
18 GOT BACK TO THE STATE.

19 DR. PRIETO: IN THE YEAR THAT THAT HAPPENED
20 BECAUSE THE PRODUCT MIGHT RAMP UP.

21 CHAIRMAN PENHOET: YES. THE FIRST TIME THAT
22 HAPPENS. IF IT GOES -- SO THE CURRENT PROPOSE WOULD BE
23 THEY'D PAY US THAT MONEY. LET'S SAY THEY TOOK \$10
24 MILLION FROM CIRM. THEY PAY US BACK \$30 MILLION ON THE
25 3 X IRRESPECTIVE OF HOW MANY SALES THEY GET. SO IT

1 MIGHT TAKE THEM ONE YEAR, TEN YEARS, WHATEVER IT IS.
2 WHEN THEY REACH \$250 MILLION REVENUE IN ANY YEAR, THEY
3 WOULD PAY US ANOTHER \$30 MILLION THAT YEAR. THEY
4 WOULDN'T PAY US \$30 MILLION A YEAR FOR EVERY YEAR AFTER
5 THAT. THEY WOULD JUST PAY US A ONE-TIME PAYMENT OF \$30
6 MILLION.

7 DR. PRIETO: SO THE NEXT YEAR -- IF WE TIERED
8 THIS THOUGH --

9 CHAIRMAN PENHOET: YEAH. AND THEN WHEN THEY
10 REACH 500 IN A SUBSEQUENT YEAR, THEY'D PAY ANOTHER 3 X.

11 DR. PRIETO: SINGLE PAYMENT.

12 CHAIRMAN PENHOET: SINGLE PAYMENT. AND IF
13 THEY REACH 750, IF WE TAKE THIS MODEL, THEY WOULD PAY
14 US ANOTHER 3 X. SO IF THEY GOT TO A BILLION, THEY'D
15 END UP PAYING 12 X -- 15 X OF WHAT WE PUT IN. THE
16 FIRST 3 X PLUS ANOTHER 3 X AT 250, 500, 750, AND --

17 MR. ROTH: SOMEBODY RUNNING THOSE ROYALTY
18 RATES? BECAUSE THAT SOUNDS LIKE A PRETTY HIGH ROYALTY
19 RATE ON YOUR NUMBERS. I THINK IT'S THE PROBLEM WITH
20 THE NUMBERS YOU'RE USING.

21 MR. SHEEHY: HE'S USING \$10 MILLION.

22 CHAIRMAN PENHOET: NO. THIS IS A FULL
23 RETURN. THIS IS ONLY IN THE BLOCKBUSTER CASE.

24 MR. ROTH: I UNDERSTAND.

25 MR. SHEEHY: WHAT I THINK IS INTERESTING IS

1 THAT THE EXAMPLE YOU USE IS PRECISELY --

2 CHAIRMAN PENHOET: IF THEY'RE SELLING A
3 BILLION DOLLARS, THEY'RE NOT GOING TO WORRY ABOUT
4 PAYING US BACK -- WELL, 30 TIMES FIVE WOULD BE \$150
5 MILLION TOTAL FOR THEIR --

6 MR. SHEEHY: THE EXAMPLE YOU'RE USING, IT'S
7 LIKE, TO MY MIND, THE EXAMPLE THAT I THINK THE SCHEME
8 IS TOTALLY ADEQUATE FOR, WHICH IS YOU HELP SOMEBODY IN
9 THAT PRECLINICAL OR EVEN IN THE CLINICAL PHASE. I
10 DON'T FEEL LIKE WE HAVE THAT MUCH DEMAND ON RETURN
11 OTHER THAN SIMPLE FAIRNESS LIKE A BANK IF THEY LOAN YOU
12 MONEY TO GET OVER A ROUGH SPOT AND YOU END UP MAKING
13 MONEY. THIS SCHEME DOESN'T BOTHER ME AT ALL, AND I
14 DON'T EVEN REALLY FEEL THAT I WOULD WANT -- LIKE, WE
15 HELP A COMPANY LIKE SOME OF THOSE THAT WERE SPEAKING TO
16 GET OVER THE VALLEY OF DEATH, AND WE GIVE THEM \$5
17 MILLION, BECAUSE THEY WERE TALKING RIGHT IN THAT RANGE,
18 I DON'T WANT TO BE GOING BACK INTO THEIR POCKET. THEY
19 DEVELOPED THE INTELLECTUAL PROPERTY. THEY'RE PROBABLY
20 BRINGING IN ADDITIONAL INVESTORS IN THE LATER CLINICAL
21 PHASES TO GET THROUGH THAT, AND ALL WE DID WAS HELP
22 THEM OVER A BUMP. AND, YOU KNOW, IF WE GOT 3 X ON
23 THAT, I'D FEEL LIKE, YOU KNOW, WE KIND OF GOT A GOOD
24 DEAL. BUT WHAT CONCERNS ME IS WE MAKE A VERY CRITICAL
25 BASIC SCIENCE INVENTION --

1 CHAIRMAN PENHOET: NO, WE DON'T. THEY MAKE
2 IT WITH OUR MONEY. THAT'S A VERY IMPORTANT
3 DISTINCTION.

4 MR. SHEEHY: THEY MAKE IT WITH OUR MONEY, AND
5 THIS BECOMES A CRITICAL INVENTION, RIGHT. AND WE MAY
6 ONLY HAVE INVESTED \$500,000. IT MAY HAVE BEEN A PILOT
7 GRANT. BUT THIS IS THE THING THAT IS THE KEY
8 INVENTION. AND SO MAYBE DOWN THE ROAD THEY MAKE A
9 BILLION DOLLARS AND WE GET ANOTHER 150,000 INTO THE
10 STATE. THAT'S WHY IT REALLY -- YOU KNOW, THE SCHEME,
11 YOUR EXAMPLE DOESN'T -- I MEAN I'M NOT REALLY WORRIED
12 ABOUT GETTING PEOPLE AT THAT POINT. I THINK THIS IS
13 TOTALLY FAIR FOR PEOPLE AT THAT POINT, BUT WHAT I'M
14 WORRIED ABOUT IS WE FULLY FUND A CRITICAL BASIC SCIENCE
15 INVENTION, AND THEN WE'VE LOST IT.

16 OUR INVESTMENT IS GOING TO BE RELATIVELY
17 MEAGER, AND OUR RETURN IS GOING TO BE LIKEWISE,
18 RELATIVELY MEAGER. UNLESS WE STAY WITH THEM ALL
19 THROUGH THE DEVELOPMENT PHASE; BUT IF IT'S A REALLY
20 GOOD INVESTMENT, THEY'RE GOING TO THROW US OFF AS SOON
21 AS POSSIBLE. THEY'RE NOT GOING TO REALLY STAY WITH US,
22 AND IT'S NOT IN OUR INTEREST TO STAY WITH THEM IF THEY
23 CAN GET OTHER PEOPLE TO INVEST. WE SHOULD BE USING OUR
24 MONEY TO INVEST IN OTHER THINGS.

25 THE MINUTE THAT OTHER CAPITAL CAN BE BROUGHT

1 INTO THE DEVELOPMENT PROCESS, WE WANT TO ENCOURAGE THAT
2 TO HAPPEN. WE DON'T WANT TO STAY THERE BECAUSE WE WANT
3 TO MAXIMIZE RETURN TO THE STATE. DO YOU SEE?

4 CHAIRMAN PENHOET: BUT THERE'S STILL A LOT --
5 AS YOU KNOW, ONLY 10 PERCENT OF DRUGS, AT LEAST, THAT
6 ENTER PHASE I AND END UP AS A MARKETED PRODUCT, AND
7 ONLY HALF OF PHASE III PRODUCTS END UP AS MARKETED
8 PRODUCTS. SO THERE'S STILL A LOT OF RISK. AND ANY
9 PRUDENT INVESTOR WOULD WANT -- 3 X IS NOT BAD, I DON'T
10 THINK, FOR FUNDING THAT KIND OF STUFF. IT'S MUCH LESS
11 RISKY THAN FUNDING BASIC SCIENCE. I GRANT YOU THAT.

12 DR. PRIETO: I THINK I SEE A LOT OF APPEAL IN
13 THE IDEA OF PUTTING SOME TIERS IN HERE, ALTHOUGH, I
14 THINK AS JOHN SAID, IF YOU MAKE THAT UNENDING, IT DOES
15 SOUND A LOT LIKE A ROYALTY RATE. MAYBE WE SHOULD JUST
16 SET X NUMBER --

17 DR. REED: WELL, I WOULD COME BACK TO THE
18 IDEA THAT IN THE EVENT THAT YOU DO HAVE SOMETHING
19 THAT'S A BLAZING SUCCESS, MAYBE AT THAT POINT SOME
20 MODEST ROYALTY COMES IN, AND MAYBE IT HAS A STACKING
21 PROVISION SO THAT IT'S 1 PERCENT IF IT'S SOLE, AND IT'S
22 HALF A PERCENT IF THERE'S OTHER TECHNOLOGY ON TOP OF
23 THAT, BUT THAT ONLY KICKS IN IF IT'S A WILDLY
24 SUCCESSFUL PRODUCT. MAYBE THAT HAPPENS AT A HALF
25 BILLION DOLLARS IN SALES OR SOMETHING. WHEN THEY'VE

1 SOLD A HALF BILLION DOLLARS OF PRODUCTS, FROM THAT
2 POINT ON, YOU THEN HAVE BETWEEN AND A HALF AND A
3 1-PERCENT ROYALTY DEPENDING ON WHETHER IT'S A SOLE
4 INVENTION OR A COMBINATION INVENTION.

5 DR. PRIETO: THE ADVANTAGE OF HAVING A
6 STRUCTURE LIKE THIS RATHER THAN A ROYALTY RATE IS YOU
7 DON'T HAVE TO NEGOTIATE WHAT PERCENTAGE OF
8 PARTICIPATION, HOW IMPORTANT YOUR PARTICIPATION WAS TO
9 FIGURE IN THE ROYALTY. WITH THIS, IT'S JUST YOU PUT X
10 AMOUNT IN, YOU GET A MULTIPLE BACK.

11 DR. REED: THE WAY IT WOULD BE DEFINED IS IF
12 THAT COMPANY, IN ORDER TO COMMERCIALIZE A PRODUCT, HAD
13 A ROYALTY OBLIGATION TO SOME OTHER ENTITY FOR THE SAME
14 PRODUCT, THEN IT'S A COMBINATION PRODUCT, AND THEN WE
15 ONLY GET A HALF A PERCENT. IF THEY DON'T HAVE ANY
16 ROYALTY OBLIGATION TO ANYBODY ELSE, THEN WE GET 1
17 PERCENT. IT'S A SOLE PRODUCT.

18 DR. PRIETO: BUT THERE MIGHT BE MULTIPLE --

19 DR. REED: THAT WOULD BE CLEAR, THEN, WHAT
20 THEIR ROYALTY OBLIGATIONS ARE, SO IT'S BLACK AND WHITE
21 AS TO WHETHER THEY HAVE A ROYALTY OBLIGATION TO SOME
22 OTHER ENTITY.

23 MR. ROTH: JOHN, JUST PICKING UP ON WHAT YOU
24 SAID, LET ME THROW OUT A SUGGESTION. IF THE RECIPIENT
25 TAKES BETWEEN ZERO OR \$1 AND \$5 MILLION, THEN THIS

1 WOULD BE THE PROCEDURE FOR THE PAYBACK. IT WOULD BE
2 3 X, SO UP TO \$5 MILLION, WHICH MEANS THE MAXIMUM
3 PAYBACK WOULD BE 15 PLUS THE BLOCKBUSTER PROVISION. IF
4 THE RECIPIENT TAKES FIVE MILLION UP, NOW WE'RE TALKING
5 ABOUT REAL MONEY, THEN THE PAYBACK WOULD BE THIS PLUS
6 AN OVERRIDING 1-PERCENT ROYALTY AFTER 500 MILLION IN
7 REVENUES.

8 DR. REED: MAKES SOME SENSE.

9 MR. ROTH: THAT BRINGS THE PROPORTIONALITY.

10 DR. REED: OKAY. WORKS FOR ME.

11 CHAIRMAN PENHOET: SOMEBODY GOT THAT DOWN?
12 SAYS IF WE FUND LESS THAN \$5 MILLION, THE PAYBACK IS AS
13 INDICATED HERE ALL THE WAY DOWN THROUGH THIS. IF WE
14 FUND MORE THAN \$5 MILLION TO ANY ENTITY --

15 MR. ROTH: AND SALES EXCEED.

16 CHAIRMAN PENHOET: NO, ANY PROJECT. AND
17 SALES EXCEED \$500 MILLION PER YEAR, THAT WE WOULD GET
18 THE BLOCKBUSTER PAYMENT PLUS A 1-PERCENT ROYALTY.

19 DR. PRIETO: PRETTY SIMPLE AND
20 STRAIGHTFORWARD.

21 MR. ROTH: THAT'S SIMPLE ENOUGH.

22 CHAIRMAN PENHOET: WE NEED SOMETHING SIMPLE.

23 DR. PRIETO: DO WE WANT TO HEAR FROM --

24 CHAIRMAN PENHOET: WELL, DO WE HAVE ANY MORE
25 COMMENTS FROM THE MEMBERS OF THE TASK FORCE? IF NOT,

1 WE' LL TURN TO THE AUDIENCE. WE HAVE COMMENT IN THE
2 BACK ROW. CAN YOU COME UP HERE, PLEASE? ANYBODY ELSE
3 WHO WANTS TO SPEAK, ALSO LINE UP BEHIND.

4 MR. GILLENWATER: TODD GILLENWATER WITH THE
5 CALI FORNIA HEALTHCARE INSTITUTE. AND ACTUALLY THE
6 DISCUSSION, I THOUGHT, WHICH WAS EXCELLENT, JUST RAISES
7 KIND OF TWO QUESTIONS IN MY MIND. ONE, WHICH IS KIND
8 OF A TECHNICAL QUESTION AND ONE ACTUALLY MIGHT APPLY
9 MORE TO THE NON-PROFIT SIDE, BUT BECAUSE I SAW THE
10 LANGUAGE IN THE FOR-PROFIT LANGUAGE, I'M GOING TO ASK
11 IT.

12 ONE IS THE IMPLICATIONS FOR THE USE OF
13 TAX-EXEMPT BONDS, THE TAX IMPLICATIONS OF FUNDING THIS
14 RESEARCH WITH TAX-EXEMPT BONDS, AND THE ALLOWABILITY OF
15 THE STATE TO RECEIVE THE DIRECT FINANCIAL RETURN ON
16 TAX-EXEMPT BONDS. I KNOW THAT WAS AN ISSUE AND A
17 NUMBER OF QUESTIONS WERE RAISED ABOUT A YEAR AGO ON
18 THIS ISSUE AND WONDERED OF THIS TASK FORCE HAS FURTHER
19 CONSIDERED THE IMPLICATIONS OF IF THE STATE IS ALLOWED
20 A DIRECT FINANCIAL RETURN, THAT THEY WOULD HAVE TO FUND
21 THE RESEARCH WITH TAXABLE VERSUS TAX-EXEMPT.

22 BUT THE SECOND QUESTION --

23 CHAIRMAN PENHOET: WELL, I' LL ANSWER YOUR
24 FIRST ONE FIRST. WE WERE TOLD BY THE TREASURER' S
25 OFFICE TO DO WHATEVER WE THINK IS THE RIGHT THING TO

1 DO, AND THEY WILL DEVELOP A BOND STRATEGY TO ALLOW IT
2 TO WORK FOR THEM. SO WE WERE TOLD TO IGNORE THIS
3 ISSUE.

4 MR. SHEEHY: AND CAN I MAKE A POINT. YOU
5 KNOW, THERE WAS THIS MIXING OF BONDS. AND WITH
6 TUESDAY'S ELECTION, THERE'S GOING TO BE A LOT OF --

7 CHAIRMAN PENHOET: ACTUALLY HELPS US.

8 MR. SHEEHY: ACTUALLY HELP US TREMENDOUSLY.

9 CHAIRMAN PENHOET: ANYWAY, WE WERE TOLD TO
10 IGNORE THAT ISSUE IN OUR WORK, AND THAT THEY WOULD
11 FIGURE OUT A BOND STRATEGY AROUND WHAT WE DECIDED TO
12 DO.

13 MR. GILLENWATER: THE SECOND QUESTION, AND
14 AGAIN I APOLOGIZE BECAUSE IT ACTUALLY APPLIES PROBABLY
15 MORE TO THE NON-PROFIT SIDE THAN THE FOR-PROFIT SIDE,
16 BUT I BELIEVE IN THE FOR-PROFIT REGULATION, WHEN IT
17 TALKS ABOUT THE REVENUE BACK TO THE STATE, THERE IS A
18 PHRASE IN THERE "EXCEPT WHEN FORBIDDEN BY FEDERAL LAW,"
19 I BELIEVE IS THE -- I'M SORRY. I DIDN'T BRING IT UP
20 WITH ME.

21 IN THE NON-PROFIT WORLD, THIS IS PRESUMING
22 THAT THE FEDERAL LAW CHANGES AND THERE WOULD BE AN
23 INTERMINGLING -- THE LANGUAGE ACTUALLY SAYS IN THE
24 FOR-PROFIT, AND THIS IS TAKEN FROM THE NON-PROFIT, THAT
25 THE AWARDEE ORGANIZATION SHALL PAY REVENUES TO THE

1 STATE FOR DEPOSIT IN THE STATE'S GENERAL FUND UNLESS
2 SUCH ACTION VIOLATES ANY FEDERAL LAW. AGAIN, IN THE
3 INSTANCES IN THE FUTURE WHERE THERE MAY BE
4 INTERMINGLING OF FEDERAL AND STATE LAW, FEDERAL LAW
5 REQUIRES THAT AFTER MONIES ARE PAID TO INVENTIONS, THAT
6 ALL ROYALTIES HAVE TO GO INTO SCIENCE AND RESEARCH.

7 THERE HAVE BEEN, I BELIEVE, SOME SERIOUS
8 QUESTIONS RAISED FROM OUR MEMBERSHIP ON THE
9 ALLOWABILITY, AGAIN, OF MONEY TO GO TO THE STATE'S
10 GENERAL FUND VERSUS REMAINING EITHER WITH CIRM --
11 REMAINING WITH CIRM OR WITH THE GRANTEE ORGANIZATION TO
12 CONTINUE TO DO EDUCATION AND RESEARCH. AND, AGAIN, I
13 THINK THAT PROBABLY APPLIES MORE TO THE NON-PROFIT SIDE
14 THAN THE FOR-PROFIT SIDE, BUT I JUST WANTED TO RAISE
15 THAT AND SEE IF THAT HAS BEEN CONSIDERED.

16 CHAIRMAN PENHOET: WE ASKED THE QUESTION.
17 AND WHAT WE WERE TOLD IS THAT THERE'S PLENTY OF
18 OPPORTUNITY TO EARMARK GENERAL FUNDS TO EITHER OF THOSE
19 CATEGORIES IF IT BECOMES AN ISSUE. IT DOESN'T HAVE TO
20 GO DIRECTLY. THE STATE FUNDS THE UNIVERSITY OF
21 CALIFORNIA, FUNDS ALL THE SCHOOLS, FUNDS RESEARCH,
22 ETC., SO WE WERE TOLD THEY CAN HANDLE THAT PROBLEM.

23 MR. GILLENWATER: SO WOULD THAT REQUIRE
24 LEGISLATIVE ACTION?

25 CHAIRMAN PENHOET: I THINK IT'S AN

1 ADMINISTRATIVE ACTION. THAT'S WHAT WE WERE TOLD. THEY
2 CAN PARSE THE GENERAL FUND. THEY DO. AT THE END OF
3 THE DAY, THEY HAVE A BUDGET. SO MUCH GOES TO IT, AND
4 THEY CAN PUT A LINE ITEM, AND THESE DOLLARS GO TO FUND
5 THIS, ETC. THAT'S WHAT WE WERE TOLD.

6 MR. GILLENWATER: AT LEAST WE WERE TOLD BY
7 FOLKS FROM THE UNIVERSITY OF CALIFORNIA THAT THEY
8 BELIEVE -- AND, AGAIN, I APOLOGIZE BECAUSE THIS IS ON
9 THE NON-PROFIT SIDE MORE -- THAT THEY BELIEVE THAT THEY
10 WOULD HAVE TO COMPLETELY SEGREGATE, THAT THEY WOULD
11 PROBABLY NOT BE ABLE TO INTERMINGLE THE MONEY,
12 LEVERAGING THE CIRM FUNDING FOR FEDERAL FUNDING,
13 BECAUSE OF CONCERNS THAT THE FEDERAL GOVERNMENT AND NIH
14 MIGHT HAVE A DIFFERENT PERSPECTIVE ON THIS THAN THE
15 STATE DOES.

16 CHAIRMAN PENHOET: TO BE FAIR, THERE'S A LOT
17 OF CONCERN IN THE UNIVERSITY AND IN THE NOT-FOR-PROFIT
18 FOUNDATION RESEARCH INSTITUTION WORLD THAT WHAT WE DO
19 HERE WILL HAVE A NEGATIVE INFLUENCE ON WHAT HAPPENS IN
20 WASHINGTON IN THE FUTURE; I.E., THEY MAY WANT TO
21 INSTITUTE SOME RETURN, WHICH THEY DON'T GET TODAY AT
22 THE FEDERAL LEVEL, ETC., AS YOU KNOW. A NUMBER OF THEM
23 HAVE EXPRESSED THAT CONCERN.

24 MR. GILLENWATER: I GUESS MY CONCLUSION WOULD
25 BE, I GUESS, UNLESS SUCH ACTION VIOLATES ANY FEDERAL

1 LAW, IF IT DOES VIOLATE FEDERAL LAW, WHAT WOULD BE --
2 WOULD THE RESPONSE BE THAT THE MONEY STAYS WITH CIRM
3 AND THEN GOES TO FUND ADDITIONAL RESEARCH?

4 CHAIRMAN PENHOET: WE DON'T SAY THAT. THEN
5 WE'LL HAVE TO COME BACK AND MEET. THE ICOC WILL HAVE
6 TO DECIDE WHAT TO DO.

7 DR. REED: POINT OF CLARIFICATION. THE
8 FEDERAL LAW YOU REFER TO, IS THAT LAW SPECIFIC TO NIH
9 GRANTS, OR IS --

10 CHAIRMAN PENHOET: THE BAYH-DOLE ACT
11 ACTUALLY.

12 DR. REED: WHICH APPLIES TO ANY FEDERAL
13 FUNDS.

14 CHAIRMAN PENHOET: IT IS AN ISSUE, BUT WE'RE
15 TOLD THAT THEY CAN FINESSE THIS ISSUE.

16 MR. GILLENWATER: THANK YOU.

17 CHAIRMAN PENHOET: JOHN SIMPSON.

18 MR. SIMPSON: JOHN SIMPSON FROM THE
19 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. IT SEEMS
20 TO ME THAT THERE ARE -- A DISTINCTION THAT NEEDS TO BE
21 MADE ABOUT WHEN CIRM IS DOING THE FUNDING. AND IF
22 ESSENTIALLY YOU'RE CREATING IP WITH STATE MONEY, IT
23 SEEMS TO ME TO GIVE A LARGER STAKE IN THE IP TO THE
24 TAXPAYERS AND KICKS IN BIGGER PAYBACK, AND IT OUGHT TO
25 BE A PAYBACK THAT FOLLOWS WHEN IP IS CREATED AT THE

1 NON-PROFIT SIDE.

2 NOW, IF YOU ARE FUNDING PRECLINICAL PRODUCT
3 DEVELOPMENT OR ANY OF THE REST OF THAT, I THINK MOSTLY
4 THERE YOU'RE GOING TO BE TALKING ABOUT FUNDING IP THAT
5 ALREADY EXISTS, THAT THE COMPANY ALREADY OWNS.

6 CHAIRMAN PENHOET: OR HAS LICENSED FROM
7 SOMEBODY ELSE.

8 MR. SIMPSON: OR HAS LICENSED FROM SOMEBODY
9 ELSE. SO THEN IT STARTS TO MAKE SENSE. IF YOU TALK
10 ABOUT THAT CATEGORY, IT MAKES SENSE TO TALK ABOUT SOME
11 SORT OF A REASONABLE PAYBACK THAT EVERYONE EXPECTS AND
12 YOU KNOW WHAT IT IS AND ALL THAT SORT OF THING. AND
13 I'M NOT SURE HOW YOU PICK 3 X OUT OF THE AIR. SOME
14 KIND OF CAP MAKES SENSE THERE.

15 CHAIRMAN PENHOET: IF I CAN STOP YOU, WE
16 DIDN'T PICK IT OUT OF THE AIR. WE DID SURVEY OF WHAT
17 OTHER LIKE ORGANIZATIONS ARE DOING.

18 MR. SIMPSON: THAT SEEMS TO BE THE MIDRANGE.

19 CHAIRMAN PENHOET: YES.

20 MR. SIMPSON: SORRY. I DIDN'T KNOW WHAT THE
21 JUSTIFICATION WAS. THAT WAS THE POINT I WAS TRYING TO
22 GET TO.

23 BUT IF YOU GO BACK TO THE NOTION OF, ALL
24 RIGHT, THERE IS IP THAT HAS BEEN CREATED BECAUSE OF THE
25 STATE'S MONEY, THAT SHOULD BE CREATED -- THAT SHOULD BE

1 TREATED A DIFFERENT WAY, IT SEEMS TO ME. SO I GUESS
2 I'M ALMOST SAYING THAT BLOCKBUSTER AT 3 X WORKS IN ALL
3 THE OTHER STUFF, BUT YOU NEED TO HAVE SOME DIFFERENT
4 MECHANISM FOR WHERE THERE IS A BASIC SCIENCE, AND IT'S
5 QUITE POSSIBLE THAT THE BASIC SCIENCE IS GOING TO BE
6 THE ONE WHERE YOU DON'T PUT IN AS MUCH MONEY.

7 CHAIRMAN PENHOET: HOPEFULLY THAT DUANE'S
8 PROPOSAL AT LEAST PARTIALLY ADDRESSES YOUR ISSUE. IF
9 IT TRULY BECOMES A BLOCKBUSTER, IT CAN ONLY BECOME A
10 BLOCKBUSTER BECAUSE IT WAS A GREAT INVENTION AND,
11 THEREFORE, WE'LL GET ROYALTIES WHEN IT EXCEEDS THE \$500
12 MILLION AMOUNT BECAUSE YOU DON'T ADD THAT MUCH VALUE IN
13 THE FUTURE THING. YOU ARE RIGHT. YOU ONLY MAKE THOSE
14 FUTURE INVESTMENTS IF YOU THINK YOU HAVE AN INVENTION
15 WORTH COMMERCIALIZING, BUT THAT VALUE SHOULD BE
16 REFLECTED EVENTUALLY IN THE SALES OF THE PRODUCT. TO
17 SOME DEGREE, I THINK DUANE'S PROPOSAL --

18 MR. ROTH: I WANT -- IF YOU GIVE A COMPANY
19 MONEY, I WANT THEM TO FILE PATENTS AND PAY IT BACK. I
20 WANT THEM TO BE INCENTIVIZED TO DO THAT AND NOT SAY,
21 WELL, WE TOOK THIS MONEY. THIS IS MAYBE A PATENT, BUT,
22 YOU KNOW, IF WE TAKE -- IF WE FILE A PATENT, THEN WE
23 OWE THE MONEY AND ROYALTY. IT LED TO AN INVENTION. I
24 WANT THE COMPANIES TO BE INCENTIVIZED TO FILE THAT
25 INVENTION AND PAY US BACK.

1 WHAT YOU TALKED ABOUT IS THE COMPANY IS
2 TAKING THE MONEY TO DO A CLINICAL TRIAL WHERE THEY
3 DON'T EXPECT INVENTION.

4 MR. SIMPSON: I THINK WHAT I'M TALKING ABOUT
5 IS WHERE I SEE MOST OF CIRM'S MONEY GOING TO PRIVATE
6 COMPANIES. IT WOULD SEEM TO ME THAT MOST OF CIRM'S
7 MONEY THAT'S GOING TO BE GOING TO PRIVATE COMPANIES
8 WOULD BE GOING NOT FOR BASIC SCIENCE. MAYBE I'M WRONG.
9 MAYBE THEY'RE ALL GOING TO BE LINING UP. THERE ARE,
10 INDEED, REPRESENTATIVES OF COMPANIES HERE. MAYBE THEY
11 ARE GOING TO BE DOING BASIC SCIENCE. BUT MY IMPRESSION
12 IS THAT WHERE CIRM CAN BE MOST HELPFUL IS DOWNSTREAM IN
13 GETTING IT FROM PRECLINICAL TO STAGE 1 AND SO ON. I'M
14 JUST TRYING AND FIGURE HOW THOSE DIFFERENT THINGS NEED
15 TO BE TREATED. AND I'M NOT SURE I HAVE THE ANSWERS,
16 BUT I DO THINK THAT THERE IS A DIFFERENT STATUS OF THE
17 IP IF THE STATE HAS ESSENTIALLY PAID FOR ITS CREATION.

18 MS. KING: WHY DON'T WE TAKE A FIVE-MINUTE
19 BREAK RIGHT NOW IF THAT WORKS FOR EVERYBODY ON THE
20 PHONE.

21 (A RECESS WAS TAKEN.)

22 CHAIRMAN PENHOET: READY TO START AGAIN.

23 MS. KING: JUST MAKING SURE WE HAVE EVERYBODY
24 ON THE LINE. IS CHICO THERE?

25 DR. WRIGHT: I'M HERE.

1 MS. KING: UC IRVINE.
2 DR. BRYANT: YES, WE'RE HERE.
3 DR. STEWARD: BY THE WAY, OS STEWARD IS HERE
4 TOO.
5 MS. KING: STANFORD.
6 DR. PIZZO: I'M HERE.
7 MS. KING: AND NUVELO.
8 DR. LOVE: HERE.
9 DR. WRIGHT: MELISSA, WE HAVE RECEIVED THE
10 SLIDES. THANKS VERY MUCH.
11 CHAIRMAN PENHOET: OKAY. WHILE WE HAVE A
12 QUORUM, I'D LOVE TO CAPTURE SOME GROUND IN THIS
13 MEETING. SO WE HAVE -- BUT IN THE MEANTIME, WE NEED
14 SOME MORE COMMENT.
15 MR. GOSWAMI: I GUESS WE'LL WAIT FOR
16 FRANCISCO TO COME BACK.
17 CHAIRMAN PENHOET: HE'LL BE RIGHT BACK. SO
18 WE HAVE A PROPOSAL TO DEAL WITH GRANTS TO FOR-PROFIT
19 ENTITIES WHICH CHOOSE NOT TO LICENSE THE INVENTIONS
20 THEY MAKE TO THIRD PARTIES, BUT TO DEVELOP THEM
21 THEMSELVES. THE PROPOSAL IS THAT WE LEAVE THE VARIOUS
22 PAYBACK PROVISIONS AS THEY ARE WITH THE ADDITION THAT
23 THERE IS A SECOND TIER OF BLOCKBUSTER PAYMENTS, WHICH
24 IS 3 X THE TOTAL INVESTMENT, ONE-TIME PAYMENTS, IF
25 REVENUES EXCEED A MULTIPLE OF \$250 MILLION A YEAR; AND

1 IF REVENUES FROM CIRM-FUNDED PROJECTS EXCEED \$500
2 MILLION PER YEAR, THEN FOR EVERYTHING ABOVE \$500
3 MILLION, THERE'S A 1-PERCENT ROYALTY.

4 MR. ROTH: RIGHT. BUT THERE WAS ONE OTHER --

5 CHAIRMAN PENHOET: HAVE I STATED THAT
6 CORRECTLY?

7 MR. ROTH: -- QUALIFICATION, THAT IF YOU TAKE
8 FIVE MILLION OR LESS OF CIRM MONEY, THEN THERE ISN'T
9 THE OVERRIDE EVEN IN A BLOCKBUSTER CASE.

10 CHAIRMAN PENHOET: LESS THAN FIVE MILLION.

11 MR. ROTH: SO WE SAID THAT IF YOU TAKE REAL
12 MONEY FROM CIRM AND IT BECOMES A BLOCKBUSTER, SO WE'RE
13 NOT GOING TO PENALIZE A COMPANY THAT DEVELOPS A
14 BLOCKBUSTER FOR TAKING LESS THAN FIVE MILLION. THAT'S
15 HOW I STATED IT, THAT IF WE ONLY GOT FIVE MILLION AND
16 IT'S A BLOCKBUSTER, NOBODY IS GOING TO CRITICIZE US FOR
17 GETTING BACK 6 X. BUT IF WE GAVE THEM 25 MILLION OR 30
18 MILLION, THEN MAYBE 6 X ISN'T AS FAIR AS HAVING 1
19 PERCENT ON TOP OF THAT. THAT'S HOW I STATED IT.

20 CHAIRMAN PENHOET: BUT THE FIRST 3 X IS THERE
21 IRRESPECTIVE OF. WHY DO YOU NEED THE FIVE MILLION? IF
22 IT'S A SMALL AMOUNT OF MONEY, IT'S THE ROYALTY PART
23 THAT YOU'RE CONCERNED ABOUT, NOT THE BLOCKBUSTER
24 PAYMENT.

25 MR. ROTH: THAT'S RIGHT.

1 CHAIRMAN PENHOET: SO THE ROYALTY FEATURE
2 ONLY COMES INTO PLAY IF WE PUT MORE THAN \$5 MILLION
3 INTO THE PROJECT.

4 MR. ROTH: IF YOU PUT MORE THAN FIVE MILLION
5 IN IT. SO THAT AVOIDS --

6 CHAIRMAN PENHOET: BUT THE OTHER PAYMENT
7 WOULD BE THERE EITHER WAY, THE MULTIPLES.

8 MR. ROTH: THE MULTIPLES STAY.

9 CHAIRMAN PENHOET: EITHER WAY. SO BEFORE WE
10 HAVE ANY VOTE, FRANCISCO IS BACK. SO, PLEASE.

11 MR. GOSWAMI: JOYDEEP GOSWAMI FROM
12 INVITROGEN. COUPLE OF CLARIFICATIONS. MAYBE I'M NOT
13 UNDERSTANDING. IN THE CASE OF, LET'S SAY, YOU TAKE
14 LESS THAN FIVE MILLION, RIGHT, YOU ARE ASKING FOR A
15 PAYBACK TO THE STATE IN THAT CASE IF THE IP DEVELOPED
16 OR WHATEVER IS THERE. SO THERE'S A FUNDAMENTAL
17 ASSUMPTION THAT THERE IS IP DEVELOPED; OTHERWISE, IS
18 THERE NO PAYMENT BACK TO THE STATE?

19 CHAIRMAN PENHOET: NO. IF WE FUND THE
20 PROJECT, IRRESPECTIVE OF WHETHER IP IS DEVELOPED,
21 BECAUSE WE MAY FUND SOME LATER DEVELOPMENT. IF WE FUND
22 THE PROJECT, THEN WE GET THESE PAYMENTS BASED ON WHAT
23 WE FUNDED. IF IT'S A SMALL AMOUNT OF WHAT THE COMPANY
24 PAID, THE PAYBACK IS A PAYBACK ON A SMALL AMOUNT OF
25 THEIR FUNDING.

1 MR. GOSWAMI : SO THEN YOU NEED TO KNOW WHAT
2 PRODUCT THAT FUNDING LED TO.

3 CHAIRMAN PENHOET: YES.

4 MR. GOSWAMI : HOPEFULLY THAT SHOULD BE --

5 MR. ROTH: COULD YOU PUT THAT SLIDE BACK UP
6 BECAUSE THAT SLIDE DOESN'T SAY THAT.

7 DR. MAXON: THE TEXT DOES.

8 CHAIRMAN PENHOET: THE TEXT DOES.

9 MR. ROTH: SO THE TEXT SAYS THAT REGARDLESS
10 OF WHETHER THERE'S IP OR NOT.

11 DR. MAXON: IT'S FOR AN INVENTION OR FUNDING
12 OF A PROJECT, CIRM-FUNDED PROJECT, WHICH WOULD INCLUDE,
13 FOR EXAMPLE, CLINICAL TRIALS.

14 MR. GOSWAMI : LET'S SAY FOR SIMPLICITY THAT
15 WE DO DEVELOP A PATENT FOR IT, RIGHT, AND THAT'S
16 CLEARLY TIED TO IT. SO I THINK THE SECOND PART THAT IS
17 NOT CLEAR TO ME, AS INDUSTRY, IS HOW IS THAT PAYBACK,
18 AND MAYBE IT'S NOT THERE IN THIS LANGUAGE. I DIDN'T
19 SEE IT IN THE DOCUMENT. IT'S A ROYALTY, RIGHT, BUT I
20 HAVE TO KNOW BEFORE I TAKE THE MONEY WHAT THAT ROYALTY
21 RATE IS. AND IS THAT THE 1 PERCENT FOR EVERYTHING
22 THAT'S BEING SUGGESTED, OR WHAT IS THE ROYALTY?

23 CHAIRMAN PENHOET: DUANE SUGGESTED 2- TO
24 5-PERCENT ROYALTY UP TO THE CAP. IT'S CAPPED.

25 MR. GOSWAMI : SO THIS IS THE THING. THERE

1 ARE TWO ASPECTS. THE CAP IS THERE, BUT THAT'S FOR
2 TOTAL PAYBACK. BUT ON A UNIT BASIS, IF I WANT TO MAKE
3 A PRODUCT PROFITABLE OR NOT, THEN THE ROYALTY RATE
4 MATTERS MORE THAN I HAVE TO PAY BACK 3 X. YOU
5 UNDERSTAND WHAT I MEAN. IT'S A DIFFERENCE BETWEEN KIND
6 OF BALANCE SHEET VERSUS INCOME STATEMENT KIND OF
7 THINGS, RIGHT. IF I KNOW THAT I MAKE 10 PERCENT NET
8 PROFIT ON A PRODUCT, IF I HAVE TO PAY TWO ADDITIONAL
9 PERCENT ROYALTY ON THAT, THAT MAY SHUNT MY PRODUCT INTO
10 A LOSS THING, AND I'LL NEVER LAUNCH THAT PRODUCT
11 BECAUSE EVERY UNIT I MAKE ON THAT MAKES A LOSS. THAT'S
12 WHY ROYALTY RATE MATTERS, AND I NEED TO KNOW THAT UP
13 FRONT.

14 CHAIRMAN PENHOET: WELL, WE TRIED TO ADDRESS
15 IT. WE CAN'T SOLVE EVERYBODY'S PROBLEM. OKAY. WHAT
16 WE HEARD FROM INDUSTRY LARGELY WAS WHATEVER YOU DO, CAP
17 IT, AND AT LEAST WE KNOW WE GOT TO PAY BACK THAT MONEY,
18 WHATEVER IT IS. THE MORE YOU TAKE, THE MORE YOU'RE
19 GOING TO HAVE TO PAY BACK.

20 WE ALSO SAID, AS A PRINCIPLE, THAT THE
21 ROYALTY RATES WOULD NOT BE SO ONEROUS AS TO CAUSE THE
22 COMPANY TO LOSE MONEY.

23 MR. GOSWAMI: RIGHT. SO 2 TO 5 PERCENT IS
24 WHAT YOU'RE AGREEING ON.

25 CHAIRMAN PENHOET: SO DUANE SAID, WELL, LET'S

1 GIVE CIRM STAFF A RANGE TO GO BACK AND NEGOTIATE. BUT
2 IF THE PRODUCT PUTS YOU IN THE RED --

3 MR. GOSWAMI: SO HERE'S THE THING, RIGHT. I
4 AGREE WITH THAT, AND I THINK THAT'S A FAIR THING EXCEPT
5 CONSIDER THAT EVERY TIME THIS MEANS EVERY TIME YOU GIVE
6 OUT A GRANT, YOU WILL BE NEGOTIATING A ROYALTY RATE
7 WITH THE COMPANY THAT TAKES THAT THING, WHICH IS QUITE
8 ONEROUS BECAUSE IF YOU ASK THE UNIVERSITIES HOW MUCH
9 TIME THEY SPEND ON NEGOTIATING ONE LICENSE, IT WILL
10 GIVE YOU A SENSE. IT DOESN'T CONCERN INDUSTRY. I'M
11 PERFECTLY FINE WITH THAT RANGE, BUT IT IS A BURDEN TO
12 YOU AND YOUR STAFF TO NEGOTIATE THAT EVERY TIME.
13 RIGHT?

14 THE THIRD THING, THE CONCEPT OF
15 PROPORTIONALITY, I THINK, WHICH WAS BROUGHT UP, IS VERY
16 IMPORTANT. AND I THINK THAT'S -- I THINK STACKING
17 TAKES CARE OF, YOU KNOW, WHAT OTHER IP MIGHT BE
18 EMBEDDED IN THE PRODUCT THAT COMES. I'M PRETTY OKAY
19 WITH THAT. I THINK THE OTHER CONCEPT OF
20 PROPORTIONALITY, WHICH DUANE WAS TALKING ABOUT, IS HOW
21 MUCH MONEY DOES THE COMPANY ITSELF PUT IN TO
22 COMMERCIALIZING THAT INVENTION, RIGHT, BECAUSE THERE IS
23 SOME CONCEPT OF THAT WHICH NEEDS TO BE TAKEN INTO
24 ACCOUNT, WHICH IS KIND OF WHAT IS THE CONTRIBUTION, IF
25 YOU WILL, OF CIRM MONEY TO AN INVENTION OR A PRODUCT AS

1 OPPOSED TO THE COMPANY ITSELF PUTTING IN MONEY? I
2 THINK THAT IS A TOUGHER THING TO PUT IN, BUT MAYBE
3 THERE'S SOME HOW MUCH ARE YOU TAKING VERSUS HOW MUCH
4 ARE YOU PUTTING IN ON YOUR OWN.

5 CHAIRMAN PENHOET: AGAIN, THE CAP IS NOT A
6 PERFECT ANSWER.

7 MR. GOSWAMI: NO. NO. NO. THE CAP IS NOT
8 AN ANSWER TO THAT AT ALL.

9 CHAIRMAN PENHOET: IT IS AN ANSWER TO IT IN A
10 WAY, RIGHT, BECAUSE YOUR EXPOSURE, HOW MUCH YOU PUT IN
11 VERSUS HOW MUCH CIRM, YOU COULD DECIDE -- YOU'VE GOT
12 MULTIPLE SOURCES OF CAPITAL, I ASSUME.

13 MR. GOSWAMI: YES.

14 CHAIRMAN PENHOET: SO YOU CAN DECIDE IF I GET
15 CIRM MONEY, I'M GOING TO PAY 3 X; IF I TAKE MONEY FROM
16 ROTH VC COMPANY, I'LL HAVE TO PAY BACK EQUITY.

17 MR. GOSWAMI: FAIR ENOUGH.

18 CHAIRMAN PENHOET: YOU CAN DECIDE.

19 MR. GOSWAMI: YES.

20 CHAIRMAN PENHOET: YOU KNOW WHAT THE PRICE OF
21 POKER IS HERE.

22 MR. GOSWAMI: YES. AT THE END OF THE DAY,
23 YES. YES. THERE IS A DIFFERENCE IN THAT, AND IT'S THE
24 RISKINESS OF THE PAYBACK WHICH IS THE CONCERN.

25 THE OTHER THING WHICH I WAS A LITTLE

1 SURPRISED ABOUT IS WHY IS THERE A FLOOR ON THE -- IF I
2 OUTLICENSE, THE OUTLICENSE COMPANY GETS A FLOOR ON
3 INVESTMENT, RIGHT? HOW COME THE FOR-PROFIT
4 ORGANIZATION DOESN'T HAVE A FLOOR? SO THERE SHOULD BE
5 A MINIMUM REVENUE AMOUNT BELOW WHICH I SHOULD NOT BE
6 EXPECTED TO PAY BECAUSE ONE THING HERE IS OBVIOUSLY IF
7 I'M PATENTING SOMETHING, I WILL BE INCURRING THE COST
8 OF PATENTING. SO I'M A BIT SURPRISED THAT THERE IS NO
9 FLOOR IN THERE. I'D SAY THE FLOOR SHOULD BE EXACTLY
10 THE SAME AS IN THE OTHER CASES BECAUSE IT IS NO
11 DIFFERENCE. IT'S INDIFFERENT TO YOU.

12 CHAIRMAN PENHOET: YOU MEAN IF YOU
13 COMMERCIALIZE THE PRODUCT, THAT YOU WOULDN'T PAY ANY
14 MONEY ON THE FIRST \$500,000?

15 MR. GOSWAMI: YEAH. THE OTHER FOLKS AREN'T.

16 CHAIRMAN PENHOET: THE TOTAL AMOUNT OF YOUR
17 REVENUES EXCEED \$500,000.

18 MR. GOSWAMI: RIGHT. TOTAL NUMBER,
19 CUMULATIVE REVENUES. THAT'S ONE OF THE THINGS WHICH I
20 WAS MISSING.

21 MR. ROTH: MAKES SENSE.

22 MR. GOSWAMI: I THINK THAT'S IT. YOU KNOW,
23 FOR THE CAP, I GUESS THERE ARE DIFFERENT WAYS TO
24 APPROACH THIS. WE'RE THINKING ABOUT IT IN TERMS OF
25 WHAT ARE YOUR ALTERNATIVE SOURCES OF FUNDING, EXACTLY

1 AS YOU BROUGHT UP, RIGHT. VC'S, BANKS, AND CHARITIES,
2 CHARITY ORGANIZATIONS, HAVE VERY DIFFERENT APPROACHES
3 TO THIS PARTICULAR ISSUE. VC'S NEVER HAVE A CAP ON ANY
4 OF THIS STUFF. AND THAT'S RIGHT. IF YOU ASK A VC,
5 THEY MAKE MONEY ON VERY, VERY FEW INVESTMENTS. AND WE
6 SEE THE SAME THING, BY THE WAY, IN THINGS THAT WE
7 LICENSE, RIGHT. THERE ARE PROBABLY THE 5 PERCENT THAT
8 MAKE YOU MONEY. THE REST IS ALL -- THOSE ARE
9 INVESTMENTS THAT YOU...

10 BUT ON THE OTHER HAND, THE DIFFERENCE BETWEEN
11 BANKS -- THE DIFFERENCE BETWEEN A BANK IS IT ASKS FOR A
12 COLLATERAL WHICH YOU ARE NOT ASKING FOR. YOU'RE NOT
13 ASKING THE COMPANY TO BEAR ANY RISK FOR THE MONEY THAT
14 IT TAKES. SO IT DOES DEPEND --

15 CHAIRMAN PENHOET: THE RISK IT TAKES IS THAT
16 IT HAS A PAYBACK PROVISION HERE.

17 MR. GOSWAMI: YES, BUT THERE'S NO RISK OF
18 FAILURE; WHEREAS, A BANK, IT WOULD SEIZE YOUR ASSETS IN
19 TERMS OF A COLLATERAL TO DO SO.

20 CHAIRMAN PENHOET: WOULD YOU LIKE US TO BUILD
21 THAT IN?

22 MR. GOSWAMI: NO. NO. NO. I'M NOT SAYING
23 THAT. NO. NO. I'M NOT SAYING THAT, BUT I'M SAYING
24 THAT THE ISSUE WITH THIS, AND YOU CAN NEVER DO THAT.
25 NO ONE WOULD AGREE TO TAKE MONEY IN THAT CASE. BUT THE

1 THING IS, YOU KNOW, THE CAP HAS TO BE CONSIDERED IN
2 THAT. MY ONLY THING IS IF YOU ARE GOING PUT THIS IN
3 FRONT OF THE PUBLIC, THEN THAT NEEDS TO BE CONSIDERED.
4 FOR A COMPANY, I WOULD RATHER HAVE THE CAP THAN NOT
5 BECAUSE IT DOES MAKE IT VERY EVEN FOR ME. I DON'T KNOW
6 HOW THE PUBLIC WOULD REACT. I THINK YOU GUYS NEED TO
7 CONSIDER THAT.

8 MR. ROTH: I'M GOING TO SUGGEST THAT -- I'M
9 GOING TO AMEND WHAT I ORIGINALLY SAID BY ONE OTHER
10 THING. IF THERE'S NO INVENTION, NO INVENTION, THEN I
11 DON'T THINK THERE SHOULD BE THE 1-PERCENT ROYALTY.
12 THERE'S NO IP. IF THERE'S A PATENT THAT THE COMPANY IS
13 RELYING ON TO GET TO THAT 500 MILLION TO \$1 BILLION, IF
14 THERE'S A PATENT, THEN THERE OUGHT TO BE A ROYALTY.
15 BUT IF THEY JUST TOOK THE MONEY AND THERE IS NO IP AND
16 THEY PAY YOU BACK SIX TIMES WHAT THEY TOOK, BECAUSE OF
17 THE BLOCKBUSTER, THERE SHOULD NOT BE A 1-PERCENT
18 ROYALTY ON THAT BECAUSE THERE'S NO IP.

19 SO I WAS UNDER THE IMPRESSION, I KEPT LOOKING
20 AT THAT. I HADN'T READ IT. MARY POINTS OUT PROPERLY.
21 I NOW SEE WHAT IT SAYS. IF THERE'S AN INVENTION -- IF
22 THERE'S NO INVENTION, THEN THERE'S NO REASON THAT WE
23 SHOULD EXPECT TO GET A ROYALTY ON SOMETHING THAT HAS NO
24 PATENT PROTECTION AT ALL.

25 CHAIRMAN PENHOET: IT'S ALMOST BY DEFINITION

1 IF THERE'S NO INTELLECTUAL PROPERTY, THERE WON'T BE
2 \$500 MILLION IN SALES.

3 MR. ROTH: WHAT WE JUST WROTE IN SORT OF
4 SAID --

5 DR. REED: IN THAT CASE THE COMPANY COULD
6 HAVE ALREADY CREATED THE INVENTION BEFORE THEY EVER
7 WENT TO CIRM, AND NOW THEY'RE LOOKING FOR MONEY TO HELP
8 THEM FURTHER DEVELOP IT.

9 MR. ROTH: WE CAN'T DO THAT. THERE HAS TO BE
10 A PATENT TO COLLECT ON THAT, THAT THE COMPANY RELIES ON
11 FOR THE COMMERCIALIZATION OF THAT PRODUCT.

12 DR. REED: THAT SEEMS FAIR TO ME. I DON'T
13 KNOW. OTHER PEOPLE HAVE TO DECIDE.

14 MR. SHEEHY: THAT'S REASONABLE. I MIGHT DO
15 AN ADDENDA TO THAT, THAT IF WE PAY FOR A HUNDRED
16 PERCENT OF THE DEVELOPMENT OF A PATENT THAT EXCLUSIVELY
17 DEVELOPS REVENUES, EVEN IF IT'S UNDER THAT \$500 MILLION
18 THRESHOLD, THAT GENERATES REVENUE OF OVER -- WHAT WAS
19 OUR THRESHOLD? WHAT WAS THE THRESHOLD NUMBER YOU WERE
20 ASKING? -- 500 MILLION A YEAR, IF IT GENERATES OVER --
21 WHAT WAS THE THRESHOLD FOR THE KICK-IN?

22 CHAIRMAN PENHOET: 500 MILLION.

23 MR. SHEEHY: FOR THE 1 PERCENT. EVEN IF WE
24 MADE A RELATIVELY MODEST INVESTMENT, BUT THE INVESTMENT
25 CREATED SOMETHING THAT WAS SO WONDERFUL THAT IT LED TO

1 A PRODUCT THAT WAS GENERATING OVER \$500 MILLION A YEAR,
2 WOULD YOU BE COMFORTABLE WITH THAT 1 PERCENT KICKING
3 IN?

4 CHAIRMAN PENHOET: AS LONG AS IT'S AN
5 INVENTION. IT'S NOT TIED TO HOW MUCH MONEY WE PUT IN
6 THAT CASE. IT'S JUST THE -- IT HAS TO BE AN INVENTION.
7 THAT'S ALL HE'S SAYING.

8 MR. ROTH: BECAUSE YOU'RE GETTING BACK 6 X IN
9 THAT CASE.

10 CHAIRMAN PENHOET: WE COULD HAVE PUT IN A
11 HUNDRED BUCKS OR A MILLION OR 10 MILLION. IT WOULD BE
12 THE SAME AS LONG AS IT'S AN INVENTION THAT'S FUNDED, AT
13 LEAST IN PART, BY OUR FUNDING.

14 MR. SHEEHY: NO. EXCLUSIVELY. SO THIS WOULD
15 BE LIKE THE SOLE INVENTION, LIKE WE COMPLETELY FUND THE
16 CREATION OF SOMETHING, LIKE SOMEBODY IN A LAB, WOULD
17 YOU --

18 MR. ROTH: IF THERE'S AN INVENTION, THERE'S A
19 PATENT. THAT, I THINK, IS HANDLED. BUT THERE HAS TO
20 BE A PATENT, I THINK, BEFORE YOU CAN COLLECT ANY
21 PERCENT ROYALTIES. YOU CAN TAKE A PAYBACK.

22 CHAIRMAN PENHOET: TO BE HONEST WITH YOU, A
23 COMPANY WILL PLAY GOTCHA WITH US. THEY WILL ALWAYS
24 FUND 10 PERCENT IF THAT'S OUR THINKING. I THINK
25 DUANE'S SOLUTION --

1 DR. REED: I'LL GIVE YOU A DOLLAR.

2 MR. SHEEHY: I'M NOT TRYING TO ADD
3 COMPLEXITY.

4 MR. ROBBINS: ALAN ROBBINS FROM NOVACELL. I
5 JUST WANTED TO MAKE SURE THAT YOU'RE TAKING INTO
6 ACCOUNT IN TERMS OF YOUR 1 PERCENT THAT IT IS FOR THE
7 LIFE OF THE INTELLECTUAL PROPERTY FOR THE PATENT. AND
8 I HAVEN'T HEARD THAT SAID TODAY.

9 MR. ROTH: THAT IS THE AMENDMENT I MADE.

10 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

11 MR. LAKAVAGE: MAY I OFFER ONE? THIS TONY
12 LAKAVAGE FROM APPLIED BIOSYSTEMS. WE'VE TALKED ABOUT
13 TYING THE ROYALTY TO TWO TERMS. WE'VE SAID SALES AND
14 REVENUE, WHICH ARE DIFFERENT. AND THEN I'M WONDERING
15 IF WE OUGHT TO BE THINKING ABOUT WHETHER IT'S PRACTICAL
16 TO TIE IT TO PROFIT BECAUSE, YOU KNOW, YOU'RE TALKING
17 ABOUT PRIVATE COMPANIES THAT MAKE AN INVESTMENT, AND
18 THEY MAY HAVE REVENUES UP TO, I DON'T KNOW, IN THE
19 MULTI, MULTIMILLIONS OF DOLLARS, AND THEY'RE CONTINUING
20 TO INVEST IN SCALE-UP AND IMPROVEMENT OF THE PRODUCT.
21 AND WE'RE TALKING ABOUT BIOLOGICAL PRODUCTS, WHICH
22 COULD BE QUITE EXPENSIVE TO MANUFACTURE.

23 AND IT JUST SEEMS LIKE THE PAYBACK SHOULD BE
24 ON THE POINT AT WHICH COMPANIES BECOME PROFITABLE, NOT
25 NECESSARILY SIMPLY BASED ON REVENUE.

1 DR. PRIETO: I'D JUST LIKE TO RESPOND TO
2 THAT. I THINK THE PROBLEM THERE IS WE THEN HAVE TO GET
3 INTO AND HAVE TO AUDIT THE BOOKS OF ANY LICENSEE
4 COMPANY, YOU KNOW, FIGURING OUT WHEN PROFIT OCCURS. I
5 DON'T THINK WE WANT TO GET INTO THAT.

6 DR. WRIGHT: AGREED.

7 MR. LAKAVAGE: IN THAT CASE THE THRESHOLD
8 MIGHT BE TOO LOW IN SOME CASES.

9 MR. ROTH: 500 MILLION.

10 CHAIRMAN PENHOET: NO. WE HAVE A \$500,000
11 THRESHOLD BELOW WHICH THE PAYMENTS WOULD NOT BE --

12 MR. LAKAVAGE: I'M JUST SAYING THAT 500,000
13 IN REVENUE OR SALES, THAT'S NOT PROFITABILITY FOR AN
14 AWFUL LOT OF POTENTIAL PRODUCTS.

15 MR. SHEEHY: WE'RE TALKING THAT THE ROYALTY
16 COULD BE AS LOW AS 2 PERCENT, SO WHAT'S 2 PERCENT?
17 IT'S NOT A LOT OF MONEY.

18 CHAIRMAN PENHOET: I THINK THE GUIDANCE WE
19 WERE GOING TO GIVE CIRM EMPLOYEES WAS TO BE -- IN
20 DETERMINING THE RATE OF PAYBACK TO THE CAPPED AMOUNT,
21 THAT THEY WOULD BE SENSITIVE TO THE FINANCIAL ISSUES
22 THE COMPANIES ARE FACING, ETC.

23 MR. ROTH: THAT'S WHAT THE RANGE IS FOR.

24 CHAIRMAN PENHOET: THAT'S WHAT THE RANGE IS
25 FOR, THE 2 TO 5 PERCENT.

1 MR. ROTH: SO AS I SAID, A DIAGNOSTIC OR A
2 TOOL MAY BE AT THE BOTTOM END OF THE RANGE, A
3 THERAPEUTIC AT THE TOP END. THESE ARE AFTER
4 COMMERCIALIZATION.

5 MR. LAKAVAGE: SO THAT WOULD BE HANDLED IN
6 NEGOTIATION?

7 CHAIRMAN PENHOET: YES.

8 MR. ROTH: WITHIN THAT RANGE, SO YOU'D KNOW
9 THERE'S AT LEAST A TIGHT ENOUGH RANGE, THAT WE DON'T
10 GET INTO, YOU KNOW, THE HORSE TRADING, HALF PERCENT, 10
11 PERCENT, AND BRING IT DOWN. YOU KNOW KIND OF WHERE THE
12 NUMBER IS GOING TO BE.

13 MR. GOSWAMI: I THINK THERE IS A POINT THERE,
14 THOUGH, MAYBE I MISSED THE LAST TIME. THE 500,000 THAT
15 YOU ARE TALKING ABOUT ON THE LEFT AND THE RIGHT, IS
16 500,000 RETURNED TO THE INVENTOR AS ROYALTIES, RIGHT?

17 CHAIRMAN PENHOET: YES.

18 MR. GOSWAMI: SO THE NET SALES FROM THE
19 PRODUCT THAT HAVE TO QUALIFY --

20 CHAIRMAN PENHOET: WILL BE MUCH HIGHER.

21 MR. GOSWAMI: -- IT WILL BE -- YOU KNOW, IT'S
22 20 TIMES THAT, RIGHT? SO I THINK THE GENTLEMAN'S POINT
23 FROM ABI IS A GOOD ONE BECAUSE FOR FOR-PROFITS, THE
24 THRESHOLD IS 500,000 OF REVENUES, NOT 500,000 -- SO NET
25 PRODUCT SALES VERSUS 500,000 OF ROYALTY PAYMENTS, WHICH

1 ARE TWO VERY DIFFERENT NUMBERS. SO I THINK THAT --

2 CHAIRMAN PENHOET: THE OTHER ONES ARE NOT
3 CAPPED THOUGH. THAT'S PART OF THE TRADE-OFF.

4 MR. GOSWAMI: NO. I AGREE. I AGREE, BUT
5 JUST TO MAKE SURE THEY'RE NOT APPLES TO APPLES.

6 CHAIRMAN PENHOET: THEY ARE NOT APPLES TO
7 APPLES.

8 ANY OTHER COMMENTS FROM THE TASK FORCE?

9 MR. SIMPSON: COULD WE JUST GET A STATEMENT
10 OF WHAT'S BEFORE US NOW?

11 CHAIRMAN PENHOET: YES. WHAT'S BEFORE US IS
12 WE ARE MODIFYING -- WE'RE LEAVING THE TWO ENDS OF THIS
13 SLIDE ALONE FOR LICENSED PRODUCTS -- LICENSED
14 INVENTIONS TO THIRD PARTIES, WHETHER THEY COME FROM A
15 FOR-PROFIT OR A NOT-FOR-PROFIT, THE TERMS ARE BASICALLY
16 THE SAME EXCEPT IN THE CASE OF THE FOR-PROFIT, WE HAVE
17 17 PERCENT BECAUSE WE ARE ESSENTIALLY -- WE HAVE AN
18 IMPUTED BENEFIT TO THE INVENTOR VERSUS 25 PERCENT.

19 FOR FOR-PROFIT COMPANIES THAT DEVELOP
20 PRODUCTS THEMSELVES, THE PAYBACK PROVISION IS THAT THEY
21 WILL PAY US BACK THREE TIMES THEIR TOTAL INVESTMENT IN
22 THE FORM OF ROYALTIES ON REVENUES IF THEIR REVENUES
23 EXCEED THE \$500,000 THRESHOLD, AND THAT THEY WILL GIVE
24 US BLOCKBUSTER PAYMENTS ONE TIME, ANOTHER 3 X, FOR EACH
25 YEAR IN WHICH -- A ONE-TIME PAYMENT WHEN THEIR REVENUES

1 FIRST EXCEED 250 AND ANOTHER SIMILAR PAYMENT WHEN THE
2 REVENUES EXCEED 500, 750, OR A BILLION, AND IN ADDITION
3 TO THAT, IF THE PRODUCTS THAT RESULT FROM OUR FUNDING
4 ARE COVERED WITH PATENTS --

5 MR. ROTH: THAT WASN'T IT.

6 CHAIRMAN PENHOET: OKAY.

7 MR. ROTH: SO THIS STAYED THE SAME FOR
8 EVERYBODY. AND IF PRODUCT SALES THEN EXCEED 500
9 MILLION, A 1-PERCENT ROYALTY.

10 CHAIRMAN PENHOET: BUT NO ADDITIONAL
11 BLOCKBUSTER PAYMENTS AFTER THAT.

12 MR. ROTH: NO ADDITIONAL BLOCKBUSTER.
13 BLOCKBUSTER THING WENT AWAY BECAUSE THAT BECOMES A VERY
14 STEEP NUMBER.

15 MR. SIMPSON: THE INITIAL BLOCKBUSTER.

16 MR. ROTH: THE INITIAL ONE STAYS EXACTLY AS
17 IT IS HERE. THIS STAYS INTACT, AND THEN THERE HAS TO
18 BE AN INVENTION, AN IP, A PATENT, AND SALES EXCEED 500
19 MILLION, THEN FOR THE LIFE OF THE PATENT IT'S 1
20 PERCENT.

21 CHAIRMAN PENHOET: GOTCHA.

22 MR. SHEEHY: AND OUR INVESTMENT HAS TO BE
23 OVER FIVE MILLION.

24 MR. SIMPSON: CIRM-FUNDED THE INVENTION.
25 CIRM FUNDS LED TO THE INVENTION.

1 MR. ROTH: CIRM FUNDS HAD TO LEAD TO THE --
2 THERE HAS TO BE AN INVENTION TO GET INTO ANY 1 PERCENT
3 AND SALES HAVE TO BE 500 MILLION.
4 CHAIRMAN PENHOET: OKAY. THAT'S THE
5 PROPOSAL. SO I WOULD LIKE TO TAKE A VOTE OF OUR TASK
6 FORCE TO SEE IF WE CAN PUT THIS ONE ITEM TO BED AND
7 MOVE ON TO SOME OTHERS THAT WE HAVE HERE AT QUARTER TO
8 THREE ALREADY IN SAN DIEGO. SO CAN WE TAKE A ROLL CALL
9 VOTE? FRANCISCO?
10 DR. PRIETO: AYE.
11 CHAIRMAN PENHOET: WE NEED A MOTION.
12 MR. ROTH: I'LL MAKE THE MOTION.
13 CHAIRMAN PENHOET: MOTION MADE BY DUANE ROTH.
14 MS. KING: DUANE ROTH, MOTION; FRANCISCO
15 PRIETO SECONDS.
16 DR. PRIETO: SECOND.
17 MS. KING: AND THEN IF I COULD JUST CALL THE
18 ROLL.
19 SUSAN BRYANT.
20 DR. BRYANT: YES.
21 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.
22 TED LOVE.
23 DR. LOVE: YES.
24 MS. KING: ED PENHOET.
25 CHAIRMAN PENHOET: YES.

1 MS. KING: PHIL PIZZO.
2 DR. PIZZO: YES.
3 MS. KING: FRANCISCO PRIETO.
4 DR. PRIETO: YES.
5 MS. KING: JOHN REED.
6 DR. REED: YES.
7 MS. KING: DUANE ROTH.
8 MR. ROTH: YES.
9 MS. KING: JEFF SHEEHY.
10 MR. SHEEHY: YES.
11 MS. KING: OS STEWARD.
12 DR. STEWARD: YES.
13 MS. KING: JANET WRIGHT.
14 DR. WRIGHT: YES.
15 CHAIRMAN PENHOET: OKAY.
16 MR. ROTH: YOU HAVE TO TAKE ANYTHING, PUBLIC
17 COMMENTS?
18 MR. GOSWAMI: I'M SORRY. THE 2 TO 5 PERCENT,
19 DID YOU MENTION THAT?
20 MR. ROTH: THAT'S IN.
21 CHAIRMAN PENHOET: OKAY. NOW, THE NEXT
22 SIGNIFICANT ISSUE WE HAVE TO TALK ABOUT IS THE
23 THRESHOLD FOR THE PROVISIONS INDICATED HERE RELATED TO
24 DISCOUNT PRICING FOR CALIFORNIA RESIDENTS. AND THERE
25 ARE TWO ASPECTS OF THIS, AS YOU REMEMBER, IN OUR

1 NOT-FOR-PROFIT POLICY. IT SAYS, NO. 1, THAT -- AGAIN,
2 WE'RE STILL WORKING WITH THE LANGUAGE, BUT THE CONCEPT
3 IS THE FOLLOWING: THAT NOWHERE IN THE UNITED STATES
4 ARE PRODUCTS SOLD TO SOME PUBLIC ENTITY FOR LESS MONEY
5 THAN CALIFORNIANS -- PUBLICLY FUNDED GROUPS IN
6 CALIFORNIA WOULD PAY. THAT'S THE CONCEPT.

7 WE'VE BEEN GOING ROUND AND ROUND, AND WE HAVE
8 A LONG DOCUMENT FROM OUR COLLEAGUES IN SACRAMENTO,
9 ETC., TRYING TO SHED SOME LIGHT ON THIS ISSUE. BUT THE
10 CONCEPT, I THINK, WAS PRETTY CLEAR IN ALL OF OUR MINDS
11 EARLIER, THAT WE DIDN'T WANT CALIFORNIANS TO BE
12 DISADVANTAGED RELATIVE TO ANYONE ELSE IN THE COUNTRY
13 WHEN THOSE PRODUCTS WERE PAID FOR WITH PUBLIC FUNDS.

14 AND THE SECOND THING IS THAT COMPANIES WOULD
15 DEVELOP A PLAN FOR ACCESS FOR UNINSURED PATIENTS IN
16 CALIFORNIA AT THE TIME OF COMMERCIALIZATION OF THE
17 PRODUCTS.

18 THOSE ARE THE TWO FEATURES THAT ARE IN THE
19 NOT-FOR-PROFIT POLICY WHICH HAS BEEN APPROVED BY THE
20 ICOC.

21 THE QUESTION HAS COME UP IN THE CONTEXT OF
22 THE FOR-PROFIT DISCUSSION OF WHAT THE THRESHOLD AMOUNT
23 OF INVESTMENT BY CIRM IN A COMPANY-SPONSORED PROJECT
24 WOULD TRIGGER THOSE REQUIREMENTS AS THEY ARE CURRENTLY
25 ANTICIPATED IN THE LICENSED PRODUCTS. SO NOW WE'RE

1 TALKING, AGAIN, ABOUT IF A COMPANY DEVELOPS THESE
2 THINGS ITSELF AND TAKES MONEY FROM CIRM TO DO THAT,
3 WHAT WOULD BE THE THRESHOLD?

4 WE'VE HAD NUMBERS, YOU KNOW, SORT OF A LOT OF
5 DIFFERENT CUTS AT THIS. WE SORT OF THREW OUT THE 25
6 PERCENT, BUT THERE'S BEEN A LOT OF CONCERN ABOUT WHAT
7 25 PERCENT MEANS. AND, YOU KNOW, WE TRIED TO WORK WITH
8 THE CONCEPT, OKAY, IF YOU PUT A DOLLAR INTO BASIC
9 RESEARCH, IF IT ENDS UP IN A VALUABLE PATENT, IT MIGHT
10 BE MORE IMPORTANT THAN A LESS VALUABLE DOLLAR FURTHER
11 DOWN IN THE PROCESS. SO SHOULD THERE BE A DIFFERENT
12 PERCENTAGE TRIGGER FOR CLINICAL TRIALS SUPPORT, FOR
13 EXAMPLE, THAN THERE IS FOR BASIC RESEARCH SUPPORT?

14 THERE ARE A LOT OF DIFFERENT ASPECTS TO THIS.
15 AND I THINK THE RANGE OF VIEWS THAT PEOPLE HAVE ON THIS
16 ARE EXTREMELY BROAD. SO THERE ARE PEOPLE WHO BELIEVE
17 THAT IF COMPANIES TAKE ANY MONEY FROM CIRM, THE FIRST
18 DOLLAR IN, THAT THE REQUIREMENT SHOULD BE THAT THEY
19 AGREE TO THESE PROVISIONS. THERE ARE OTHERS WHO
20 BELIEVE THAT IT SHOULD BE QUITE A HIGH PERCENTAGE OF A
21 PRODUCT'S COST, ETC., BEFORE YOU TRIP THESE PROVISIONS.
22 AND THIS IS AN ISSUE FOR WHICH I DON'T THINK -- I THINK
23 IT'S GOING TO BE VERY DIFFICULT TO GET TO COMPLETE
24 CONSENSUS ON THIS ISSUE BECAUSE WE HAVE SUCH A WIDE
25 DISPERSION OF VIEWS.

1 I WILL SAY, HOWEVER, IN LOOKING THROUGH
2 EVERYTHING WE HAVE DONE AND TRYING TO ANSWER THE
3 QUESTION FROM LEGISLATORS THAT WE'VE BEEN ASKED MANY
4 TIMES, WHAT ARE CALIFORNIANS GOING TO GET OUT OF THIS
5 THAT PEOPLE IN NEVADA OR NEW YORK OR ANY OTHER PLACE
6 ARE NOT GOING TO GET OUT OF THIS WHOLE PROJECT? AND
7 THIS IS ONE OF THE FEW FEATURES WHICH GIVES RESIDENTS
8 OF CALIFORNIA SOME SPECIAL CONSIDERATION. IT'S MODEST
9 BECAUSE MOST OTHER -- WE'RE NOT SAYING IT WILL BE THE
10 LOWEST PRICE IN THE COUNTRY BECAUSE I THINK WE ALL
11 AGREED WE DID NOT WANT TO TRIP A DESTRUCTIVE CYCLE OF
12 USING ESSENTIALLY THE WHOLE PROCESS BY WHICH MOST
13 FAVORED NATION CLAUSES ARE ESSENTIALLY NEGOTIATED.

14 SO THERE'S STILL SOME WORK TO BE DONE ON HOW
15 THIS WOULD BE DONE IN TERMS OF THE MECHANISM, IN ANY
16 CASE, BUT LEAVE THAT ASIDE FOR THE MOMENT. WE STILL
17 HAVE TO AGREE IN THIS GROUP WHAT WOULD TRIGGER THESE
18 PROVISIONS. IN THE CASE OF THE LICENSED INVENTIONS,
19 WE'VE SAID THE LICENSE WILL HAVE THESE AS PART OF THE
20 LICENSE, SO THAT'S ALREADY EMBEDDED. IF A COMPANY
21 DEVELOPS THESE PRODUCTS ITSELF, HOW MUCH FUNDING FROM
22 US SHOULD TRIP THESE TWO THINGS?

23 WE HAVE A LOT OF INDUSTRY PUSHBACK ON THESE
24 PROVISIONS. I THINK WE ALSO HAVE A LOT OF PEOPLE
25 CONCERNED ABOUT WHAT NET BENEFIT CALIFORNIANS ARE GOING

1 TO GET FROM ALL THIS THAT'S DIFFERENT FROM A RESIDENT
2 OF NEVADA OR ELSEWHERE. AND THIS PROVISION IS, YOU
3 KNOW, IN SOME SENSE ALL THAT THE AVERAGE CITIZEN HAS IN
4 TERMS OF PREFERENTIAL ACCESS.

5 SO THOSE ARE THE ISSUES WE FACE. YOU CAN
6 ARGUE THIS MANY DIFFERENT WAYS, BUT I THINK I'D LIKE TO
7 GO AROUND THE ROOM AND JUST HEAR POINTS OF VIEW ON THIS
8 SUBJECT SINCE WE HAVE SUCH A WIDE DISPARITY OF VIEWS ON
9 THIS SUBJECT. IF WE CAN JUST LET EACH OF US SPEAK
10 WITHOUT REBUTTAL AT THE MOMENT. AND START WITH
11 FRANCISCO ON THIS ISSUE.

12 DR. PRIETO: I READ THE LETTER FROM
13 MR. VALENCIA ON BEHALF OF THE CHI. AND I THINK IF
14 THERE IS GOING TO BE A THRESHOLD, THAT IT -- FOR AMOUNT
15 OF CIRM PARTICIPATION, THAT IT SHOULD BE VERY LOW
16 BECAUSE, OF COURSE, THE COMPANIES HAVE THE OPTION OF
17 TAKING OR NOT TAKING OUR MONEY, TAKING OTHER MONEY IF
18 THEY THINK THOSE TERMS ARE MORE FAVORABLE.

19 AND THE ARGUMENTS PUT FORTH IN THIS LETTER,
20 THAT MOST OF THE PEOPLE WHO WE MIGHT BE TRYING TO
21 TARGET FOR AN ADVANTAGE OR PROTECTION ARE ALREADY
22 COVERED BY OTHER PROGRAMS, I THINK KIND OF TURNS IT ON
23 ITS HEAD. OR I WOULD TURN THAT OVER. I WOULD SAY IF
24 THIS REQUIREMENT IS ALREADY IN PLACE IN SO MANY FUNDING
25 MECHANISMS AND WE'RE NOT -- THEN WE'RE NOT PUTTING AN

1 ADDITIONAL BURDEN ON THE COMPANIES. WE'RE JUST
2 ENSURING THAT IF THERE ARE ANY LOOPHOLES, WE'RE GOING
3 TO PLUG THEM. I THINK THE GIST OF THIS LETTER IS THERE
4 ARE VERY FEW LOOPHOLES. OKAY. THEN WE DON'T REALLY
5 HAVE TO WORRY ABOUT THEM. BUT I THINK IF WE'RE GOING
6 TO PARTICIPATE, THAT THERE SHOULD BE AN EXPECTATION.
7 AND I THINK PEOPLE OF CALIFORNIA HAVE THAT EXPECTATION,
8 THAT IF THEY'RE PUTTING THEIR MONEY IN, THAT THEY WILL
9 AT LEAST BE TREATED AS WELL AS ANYONE ELSE.

10 I THINK THAT'S THE TERMS WE'RE GOING FOR,
11 THAT WE'RE NOT GOING TO SET A NEW LOWER FLOOR, BUT WE
12 ARE GOING TO BE ON THE FLOOR.

13 CHAIRMAN PENHOET: SO THE FIRST DOLLAR IN, IN
14 YOUR VIEW, WOULD TRIP.

15 DR. PRIETO: OR VERY CLOSE TO IT, YES.

16 MR. SHEEHY: WELL, LIKEWISE, MR. VALENCIA
17 MADE A VERY COMPELLING ARGUMENT THAT THIS ALREADY
18 EXISTS. I KNOW FROM MY OWN, NOT COMPREHENSIVE, BUT
19 FAIRLY EXTENSIVE SURVEY ON ACCESS PROGRAMS FOR THE
20 UNINSURED FROM BIG PHARMA, THAT MOST OF THE MAJOR
21 PHARMACEUTICAL COMPANIES ALREADY PROVIDE PROGRAMS FOR
22 THE UNINSURED, AND IT'S REALLY A STANDARD WITHIN THE
23 INDUSTRY.

24 SO IT ISN'T REALLY A QUESTION FOR ME HOW I
25 WOULD VOTE ON THIS BECAUSE I DON'T KNOW WHATEVER

1 THRESHOLD I SET ACTUALLY MAKES ANY REAL DIFFERENCE.
2 THE QUESTION IS IS HOW INDUSTRY WANTS TO RESPOND TO
3 THIS, WHETHER THEY WANT TO JUST ACKNOWLEDGE THAT, YOU
4 KNOW, WE'RE GIVING AWAY THERAPIES NOW. WE'RE PROVIDING
5 SPECIAL PRICING TO GOVERNMENT ENTITIES NOW. IT'S
6 INCUMBENT ON US TO SET THE LANGUAGE, WHICH I'M GOING TO
7 TRUST THAT ED IS DOING IN GOOD FAITH WITH PEOPLE FROM
8 INDUSTRY, TO SET WHATEVER THE FLOOR IS SO WE DON'T GET
9 THE RACE TO THE BOTTOM. IF WE CAN GET GOOD LANGUAGE ON
10 THAT, I DON'T KNOW WHETHER IT MAKES A DIFFERENCE
11 WHETHER IT'S \$1 OR 25 PERCENT.

12 AND WE CAN -- INDUSTRY WANTS TO TELL US IT
13 HAS TO BE 25 PERCENT. I DON'T WANT TO GET INTO A FIGHT
14 OVER THIS. I THINK IT WOULD BE GOOD IF INDUSTRY COULD
15 COME FORWARD AND SAY WE DO THIS ALREADY. AND SO WE
16 DON'T FIND IT ONEROUS TO PROJECT OUT THAT FOR THE
17 PEOPLE OF CALIFORNIA STEPPING UP TO THE PLATE AND
18 MAKING THIS INVESTMENT, THAT WE'RE GOING TO CONTINUE TO
19 DO WHAT WE ALREADY DO, WHICH IS TO PROVIDE PREFERENTIAL
20 PRICING TO GOVERNMENT ENTITIES, WHICH IS TO PROVIDE
21 SPECIAL PROGRAMS WITHIN THE LIMITS OF OUR BUSINESS
22 MODELS FOR PEOPLE WHO ARE UNINSURED. THAT'S HOW I SEE
23 IT.

24 MR. ROTH: SO I WON'T REPEAT WHAT'S BEEN
25 SAID, BUT THERE'S TWO OTHER THOUGHTS. ONE, WE HAVE NOW

1 CALIFORNIA RX, AND THAT REALLY AIMS TO SOLVE THIS
2 PROBLEM THAT WE'VE BEEN TALKING ABOUT. SO THAT PROGRAM
3 PASSED RECENTLY. THE GOVERNOR SIGNED IT. I THINK IT'S
4 A STANDARD THAT WE CAN RELATE TO. IT FILLS THAT ACCESS
5 PROBLEM FOR THE UNINSURED. IF THERE IS NO PROGRAM
6 AVAILABLE, THEY CAN'T GET IT, THEN THE COMPANIES ARE
7 REQUIRED TO STEP IN AND FILL THAT HOLE. SO THAT'S ONE.

8 BUT THERE'S ANOTHER ONE THAT I'M GOING TO
9 SUGGEST AS SOMETHING THAT WOULD CONCERN ME AS A
10 CALIFORNIAN. IF A THERAPY BECOMES AVAILABLE THAT WAS
11 FUNDED BY CIRM MONEY AND IT'S GOING TO BE LIMITED
12 AVAILABILITY, WHICH MANY DRUGS DO. WHEN THEY FIRST
13 COME OUT, THERE'S NOT ENOUGH TO TREAT EVERYBODY.
14 THAT'S WHERE I'D LIKE TO SEE A PROVISION THAT
15 CALIFORNIA WILL GET -- PATIENTS IN CALIFORNIA WHO ARE
16 CITIZENS WILL GET THOSE THERAPIES FIRST AND NOT BE IN A
17 WORLDWIDE LOTTERY.

18 SO IF SEVERAL BLOCKBUSTERS CAME OUT, SAVED
19 LIVES, AND I THINK WE'D LOOK VERY FOOLISH IF WE SAID
20 WE'RE GOING TO MAKE IT AVAILABLE TO EVERYBODY. I THINK
21 IF WE DEAL WITH IT NOW PROSPECTIVELY INSTEAD OF IN
22 THE HEAT OF SOMEBODY DEALING -- WE TAKE THE COMPANIES
23 OUT OF IT, AND THEY SAY, LOOK, WE SIGNED ONTO THIS. SO
24 THAT'S MY SUGGESTION.

25 DR. REED: I HAVE NOTHING TO ADD. I THINK

1 THAT'S A GREAT SUGGESTION THAT DUANE ROTH MADE TO
2 ENSURE TO THE EXTENT THAT THE MANUFACTURING AND,
3 THEREFORE, THE MAKING AVAILABLE OF THE THERAPY IS RATE
4 LIMITING, THAT CALIFORNIANS GET THE FIRST ACCESS.

5 CHAIRMAN PENHOET: AND YOUR VIEW ON THE AND
6 ANY THRESHOLD AMOUNT OF INVESTMENT BY US.

7 DR. REED: I THINK ANY -- I THINK I WOULD
8 SUGGEST LANGUAGE TO THE EFFECT THAT IF THE COMPANY WAS
9 A RECIPIENT OF ONE OF OUR GRANTS, THEN THIS WOULD
10 APPLY, THAT THEY WOULD HAVE TO AGREE THAT IN THE EVENT
11 THAT THEIR MANUFACTURING PROCESSES ARE UNABLE TO
12 PROVIDE ENOUGH PRODUCT TO MEET THE DEMAND, THAT
13 CALIFORNIANS GET THE FIRST CRACK AT IT.

14 CHAIRMAN PENHOET: I MEANT THE THRESHOLD THAT
15 WOULD TRIP THE REQUIREMENT THAT THEY PROVIDE DISCOUNT
16 PRICING, ESSENTIALLY MOST FAVORED NATION PRICING, BUT
17 NOT IN A DESTRUCTIVE WAY. WE CONTINUE TO EMPHASIZE
18 THAT. AND THAT THEY PROVIDE A PLAN FOR ACCESS AT THE
19 TIME OF COMMERCIALIZATION.

20 DR. REED: YEAH. I STILL THINK IF THEY
21 RECEIVED A GRANT, THAT THAT WOULD BE REASONABLE.

22 CHAIRMAN PENHOET: PHIL PIZZO IN STANFORD.

23 DR. PIZZO: I AGREE WITH WHAT JOHN AND DUANE
24 SAID. I'M IN PERFECT CONCORDANCE WITH THAT.

25 CHAIRMAN PENHOET: JANET WRIGHT IN CHI CO.

1 DR. WRIGHT: YES, I AGREE. IN FACT, DUANE, I
2 HAD COME UP WITH THAT IN SOME CONVERSATIONS WITH OTHER
3 COLLEAGUES HERE ABOUT THE FIRST ACCESS FOR
4 CALIFORNIANS, SO THAT'S A GREAT IDEA.

5 CHAIRMAN PENHOET: AND THE AMOUNT OF
6 INVESTMENT BY US WHICH WOULD LEAD TO THE OTHER
7 PROVISIONS WE'VE TALKED ABOUT?

8 DR. WRIGHT: FIRST DOLLAR.

9 CHAIRMAN PENHOET: TED LOVE.

10 DR. LOVE: WELL, I DON'T KNOW WHERE TO COME
11 OUT. I THINK THE THING THAT I'M STILL STRUGGLING WITH
12 IS MAKING SURE THAT WE DON'T CREATE THINGS THAT WILL
13 DISINCENTIVIZE COMPANIES FROM WANTING TO TAKE THE
14 MONEY. I DO AGREE THAT I THINK, IN GENERAL, IN THE
15 INDUSTRY WE WANT TO MAKE PROGRAMS WHERE THE DRUGS ARE
16 AVAILABLE. I THINK WHEN A COMPANY IS AT ITS EARLY
17 STAGES, CERTAINLY WHEN YOU'RE A PHIZER OR YOU'RE A
18 GENENTECH, THESE ACCESS PROGRAMS ARE OUT THERE; BUT
19 WHEN YOU ARE JUST GETTING STARTED AS A COMPANY, I'M NOT
20 SURE, AND I REALLY DON'T JUST HAVE EXPERIENCE TO KNOW
21 IF THEY'RE AS FULLY AVAILABLE. SO I THINK IT MAY OR
22 MAY NOT BE RELEVANT IN TERMS OF THE THRESHOLD DEPENDING
23 UPON WHERE YOU ARE AS A COMPANY.

24 ON THE ISSUE, I LIKE WHAT DUANE SAID, BUT I
25 ACTUALLY HAVE A FEELING THAT IF WE HAVE A THERAPY FOR

1 BREAST CANCER OR WHATEVER AND WE'RE SAYING THAT THE
2 LIMITED SUPPLY IS GOING TO ONLY GO TO CALIFORNIANS, I
3 HAVE A FEELING THAT THE COMPANIES ARE GOING TO GET SUED
4 PRETTY AGGRESSIVELY. AND I HAVE A FEELING IF THERE'S A
5 COMPANY THAT'S FORMED A PARTNERSHIP, FOR EXAMPLE, WITH
6 A COMPANY OUTSIDE OF CALIFORNIA, IT'S GOING TO BE A
7 VERY BRUTAL SITUATION TO TRY TO ACTUALLY ENFORCE THAT.

8 CHAIRMAN PENHOET: IRVINE.

9 DR. BRYANT: WELL, TED'S LAST COMMENT, I
10 HADN'T THOUGHT ABOUT THAT. THAT DOES SOUND LIKE A
11 BARRIER TO ME TO GOING IN THAT DIRECTION EVEN THOUGH I
12 THINK IT WOULD BE NICE TO HAVE THAT PROVISION. MAYBE
13 THE LANGUAGE COULD BE IF AT ALL POSSIBLE OR SOMETHING
14 THAT'S NOT REQUIRING IT IN CASE IT DOES TURN OUT TO BE
15 A LEGAL BATTLE.

16 DR. STEWARD: THIS IS OS. I DON'T HAVE
17 ANYTHING MORE TO ADD. IT CERTAINLY SEEMS LIKE A VERY
18 CRITICAL POINT TO THINK ABOUT CAREFULLY.

19 CHAIRMAN PENHOET: AND YOUR VIEWS ON THE
20 THRESHOLD FOR PARTICIPATION IN THE OTHER ASPECTS THAT
21 WE TALKED ABOUT.

22 DR. STEWARD: I THINK, AGAIN, FIRST DOLLAR.

23 DR. BRYANT: I AGREE.

24 CHAIRMAN PENHOET: DO WE HAVE ANYBODY ELSE?

25 DR. WRIGHT: I JUST HAVE A QUESTION. DUANE,

1 BASED ON THE THINGS THAT TED SAID, WHICH I HADN' T
2 THOUGHT OF EITHER, DO YOU HAVE ANY RESPONSE TO THAT OR
3 A SUGGESTION ABOUT HOW WE COULD PHRASE TO ACCOMPLISH
4 WHAT WE WANT, WHICH IS TO GIVE SOME PREFERENTIAL
5 TREATMENT TO CALIFORNIANS BASED ON THEIR INVESTMENT IN
6 THE RESEARCH?

7 MR. ROTH: WELL, I UNDERSTAND TED' S POINT,
8 BUT I THINK I' D CROSS THAT THRESHOLD WHEN WE COME TO
9 IT. I THINK FROM OUR STANDPOINT, I' LL GO BACK AGAIN
10 AND SAY IF WE PUT A LOT OF MONEY INTO SOMETHING,
11 TAXPAYER MONEY IN THE STATE OF CALIFORNIA, AND THEN WE
12 SAY, SORRY. YOU CAN' T GET THIS PRODUCT BECAUSE WE' VE
13 GOT A LOTTERY THAT' S INTERNATIONAL, WHICH COMPANIES
14 HAVE DONE THIS BEFORE, THEY RELEASE IT ONE PLACE, AND
15 THERE' S A LOTTERY. I KNOW YOU' VE BEEN THROUGH THIS,
16 ED.

17 I THINK, TED, WE' LL DEAL WITH IT DOWN THE
18 ROAD IF THERE' S LITIGATION. AT LEAST THIS GIVES
19 GUIDANCE. IF THERE' S A LIMITED SUPPLY AND THE PRODUCT,
20 IT HAS TO HAVE BEEN DEVELOPED HERE WITH OUR MONEY,
21 OBVIOUSLY, SO I WOULD PUT IT IN AND DEAL WITH IT LATER.

22 ON THE THRESHOLD ISSUE, I WOULD STAY AWAY
23 FROM THAT PERSONALLY. I THINK THAT WE SHOULD DO WHAT
24 CALIFORNIA RX REQUIRES. THAT' S NOW -- THAT' S CHANGED
25 EVERYTHING IN TERMS OF THIS ACCESS PROBLEM AND PRICING.

1 IT'S REALLY PRETTY WELL DEFINED NOW, THAT YOU'VE GOT TO
2 PARTICIPATE. IT'S THE STATE LAW. AND PEGGING TO THAT,
3 I THINK, IS EASIER THAN SETTING THRESHOLDS OR ANYTHING
4 LIKE THAT.

5 SO A COMPANY COMMERCIALIZING ANYTHING --
6 CHAIRMAN PENHOET: IF THEY TAKE OUR MONEY,
7 THEN THEY HAVE TO AGREE -- WELL, THEY HAVE TO DO IT
8 ANYWAY.

9 MR. ROTH: THEY WOULD HAVE TO DO IT ANYWAY.
10 IT'S ALREADY -- IT'S REALLY BEEN DEALT WITH. IF THAT
11 LAW CHANGES, THEN WE COME BACK AND VISIT IT, BUT RIGHT
12 NOW THAT'S --

13 DR. REED: COULD YOU PUT LANGUAGE THAT SAYS
14 THAT THEY SHOULD ABIDE BY THE CONDITIONS OF CALIFORNIA
15 LAW?

16 CHAIRMAN PENHOET: IF THE LAW CHANGES, THAT
17 WE WOULD ADOPT.

18 MR. ROTH: IT'S JUST GONE IN EFFECT. I THINK
19 THAT ADDRESSES AFFORDABILITY AND ACCESS.

20 DR. REED: THAT WOULD GIVE THE ASSURANCE IF
21 THE LAW WERE TO CHANGE, THEY COULD STILL -- THEY WOULD
22 HAVE TO ABIDE BY THE CONDITIONS OF THE EXISTING LAW
23 UNLESS WE WANTED TO CHANGE BEYOND THAT.

24 DR. PRIETO: BUT THERE'S THE POINT THAT THIS
25 APPLIES TO PRESCRIPTION DRUGS. AND REMEMBER, WE'RE

1 ALSO HOPEFULLY GOING TO BE LOOKING AT, CERTAINLY WE
2 HOPE, THERAPIES, CELL-BASED THERAPIES, THINGS THAT THAT
3 DOESN'T APPLY TO.

4 CHAIRMAN PENHOET: THAT'S AN IMPORTANT ISSUE
5 THAT WE STILL ARE WORKING ON. IT TURNS OUT THAT THE
6 BEST PRICE, THE BEST MEDICAID FEDERAL PRICE ALSO REFERS
7 ONLY TO DRUGS. SCOTT HAS A SOLUTION TO THAT WHICH HE
8 CAN SHARE WITH YOU THAT, I THINK, ADDRESSES PEOPLE'S
9 CONCERNS. BUT MOST OF THESE THERAPIES NOT GOING TO BE
10 DRUGS. THERE MAY BE SOME DRUGS THAT COME OUT OF A DRUG
11 SCREENING PROGRAM OR SOMETHING, BUT LIKELY POSSIBILITY
12 IS, IN FACT, THAT THE THERAPIES WILL BE MORE AKIN TO AN
13 ORGAN TRANSPORT OR A BONE MARROW TRANSPLANT THAN THEY
14 ARE TO ANY EXISTING DRUGS.

15 SO I THINK YOU WERE RIGHT, THAT THE CURRENT
16 REGULATION REFERS TO PHARMACEUTICAL PRODUCTS, WHICH ARE
17 DRUGS, NOT THESE OTHER KINDS OF THERAPIES. AND, IN
18 FACT, AT THE FEDERAL LEVEL, WE HAVE EXACTLY THE SAME
19 SITUATION. IT'S A DRUG LAW. IT'S NOT A BROADER
20 THERAPY LAW.

21 YOU WANT TO, AT LEAST, TAKE A SHOT? SCOTT
22 HAS WHAT HOPEFULLY IS A GOOD SOLUTION TO THE PROBLEM OF
23 THE DRUGS WHICH COME OUT OF THIS, IF WE WANTED TO
24 CONTINUE ON THE PATH WE WERE ON BEFORE, BUT IT DOESN'T
25 ADDRESS WHAT THE BENCHMARK WOULD BE FOR THERAPIES

1 OFFERED ELSEWHERE.

2 MR. TOCHER: THIS IS SCOTT TOCHER FROM CIRM.
3 ED'S RIGHT. WE'VE BEEN EXAMINING THIS ISSUE FROM A LOT
4 OF DIFFERENT PERSPECTIVES, MINDFUL OF THE FACT, AS ED
5 HAS STATED ALREADY, THAT WHATEVER SYSTEM THAT WE COME
6 UP WITH, WE DON'T WANT TO INADVERTENTLY TRIGGER A
7 RECALCULATION OF SOMETHING CALLED BEST PRICE BECAUSE
8 THAT HAS CONSEQUENCES THAT ARE UNINTENDED THAT LEAD TO
9 A CASCADING EFFECT ALL OVER THE COUNTRY AND WOULD BE
10 PROBABLY A COMPLICATION WE DEFINITELY WANT TO AVOID.

11 SO WE'VE DECIDED TO TAKE AN APPROACH, AND I
12 HAVE A DRAFT THAT WE'RE WORKING ON INTERNALLY THAT
13 WOULD SEPARATE, FIRST OF ALL, DRUGS FROM THERAPIES, FOR
14 INSTANCE, SO THAT WE CAN ENSURE THAT THERE ISN'T
15 CONFUSION AS TO REFERENCES TO EXISTING FEDERAL SYSTEM,
16 WHICH APPLIES TO DRUGS, TO CLARIFY THAT THAT APPLIES TO
17 DRUGS. AND WE WILL HAVE A SECOND PIECE OF THE
18 REGULATION THAT WILL REFER TO A SYSTEM FOR PRICING WITH
19 REGARD TO THE THERAPIES.

20 AN IDEA TO AVOID THE TRIGGERING OF THE BEST
21 PRICE RECALCULATION WOULD BE A SIMPLER SYSTEM THAT
22 WOULD REQUIRE EXCLUSIVE LICENSEES WHO FALL UNDER THE
23 REQUIREMENTS OF THE REG, IF THEY FALL UNDER ITS
24 LANGUAGE, WOULD BE TO PROVIDE THEIR DRUGS WITHIN 5
25 PERCENT OF THEIR BEST PRICE. THIS WOULD ALLOW THEM THE

1 FLEXIBILITY TO COME UP WITH A PRICE THAT DOES NOT
2 REVEAL TO THE PUBLIC PROPRIETARY INFORMATION; THAT IS,
3 THIS BEST PRICE THAT THEY CHARGE. IT'S A PRICE THAT
4 THEY ALREADY KNOW AND HAVE. IT'S SOMETHING THAT THEY
5 SUPPLY TO THE FEDERAL GOVERNMENT, FOR INSTANCE, FOR
6 PRICING IN VARIOUS PROGRAMS. AND IT'S SOMETHING THAT
7 DOESN'T REQUIRE SORT OF A LOOK BACK IN TIME ISSUES THAT
8 YOU HAVE WHEN YOU'RE TRYING TO IDENTIFY WHAT A FEDERAL
9 MEDICAID PRICE IS, WHICH IS WHAT THE CURRENT LANGUAGE
10 IS.

11 ALSO, OUR DRAFT WILL ENSURE THAT THE
12 REGULATION WOULD NOT APPLY TO EXISTING PROGRAMS. SO IF
13 THERE ARE WHOLE PROGRAMS THAT WERE IDENTIFIED ALREADY
14 IN MR. VALENCIA'S LETTER, THAT WE'RE NOT TRYING TO
15 PREEMPT THOSE PRICES. WE'RE NOT TRYING TO PREEMPT
16 THOSE PROGRAMS. WE'RE REALLY JUST TRYING TO PLUG A
17 HOLE TO THE EXTENT THAT IT EXISTS OUTSIDE OF ALL OF
18 THESE PROGRAMS.

19 SO WE THINK THAT THIS WORKS BECAUSE IT WON'T
20 TRIGGER A BEST PRICE RECALCULATION. SECOND, THAT, AS
21 I'VE SAID, THAT THE BEST PRICE IS SOMETHING WITHIN THE
22 KNOWLEDGE OF THE LICENSEES. AND ALSO, THAT IT
23 CLARIFIES THE SCOPE.

24 WE'RE STILL WORKING ON THE ISSUE OF HOW YOU
25 WOULD PEG A PRICE OR COST THERAPIES BECAUSE THAT IS

1 SOMETHING OBVIOUSLY DIFFERENT FROM A DRUG SITUATION.
2 AND SO THAT IS WHAT THE FOCUS IS RIGHT NOW MOVING
3 FORWARD, TO TRY TO NAIL DOWN WHAT THAT MODEL WILL BE.
4 AND AS SOON AS WE CAN GET THAT DOWN, THEN WE'LL BRING
5 THAT OUT, ROLL IT OUT.

6 CHAIRMAN PENHOET: AS I THINK YOU ALL
7 REMEMBER, THIS IS STILL AN OPEN ITEM IN THE
8 NOT-FOR-PROFIT POLICY. WE HAVE NOT FINISHED THIS WORK
9 YET. AND BENCHMARKS FOR NONDRUG THERAPIES ARE TURNING
10 OUT TO BE DIFFICULT TO FIND. THERE ARE REIMBURSEMENTS
11 FOR TRANSPLANTS OF SOME KIND, AND IT VARIES QUITE A
12 BIT. SO WE STILL HAVE SOME WORK TO DO ON THIS.

13 MR. TOCHER: FOR INSTANCE, TRANSPLANTS HAVE
14 LOTS OF DIFFERENT. THERE ARE BLOOD TRANSFUSIONS, THERE
15 ARE DOCTORS, ALL OF THAT SORT OF THING. SO THERAPIES
16 ARE A UNIQUE CHALLENGE.

17 CHAIRMAN PENHOET: WE DO HAVE SOME MORE WORK
18 TO DO, BUT I THINK WE COULD HAVE SOME LANGUAGE THAT
19 SAYS THAT THEY WOULD BE -- THE PROGRAMS WOULD BE AS
20 INDICATED IN THE RECENTLY PASSED LEGISLATION; OR IF
21 THAT LEGISLATION DOESN'T COVER WHAT WE'RE DOING, THEN
22 WE WOULD HAVE THESE OTHER THINGS AS A BACKUP.

23 THE OTHER THING THAT I'VE BEEN THINKING
24 ABOUT, JUST TO THROW OUT AS AN IDEA, OUR CURRENT POLICY
25 SAYS THERAPIES AND DIAGNOSTICS. IN GENERAL, DIAGNOSTIC

1 TESTS ARE DONE ALL OVER THE COUNTRY. I THINK IT'S VERY
2 HIGH END. THEY'RE VERY MUCH LOWER PRICED THAN
3 THERAPIES. I THINK THE BIGGEST CONCERN ABOUT COST IS
4 IN THE THERAPY SECTION. WE MIGHT CONSIDER EXEMPTING
5 PRODUCTS OTHER THAN THERAPIES, DIAGNOSTICS AND
6 REAGENTS, FOR EXAMPLE, FROM THIS PRICING SCHEME, WHICH
7 WILL BE VERY HARD TO MONITOR.

8 AND DIAGNOSTIC TESTS, BLOOD SAMPLES ARE SENT
9 ALL OVER THE COUNTRY. IT'S PRETTY HARD TO CHASE ALL
10 THOSE DOWN. I'M NOT SURE IT'S WORTH THE EFFORT ON OUR
11 BEHALF TO TRY TO GO CHASE DOWN DIAGNOSTICS AND REAGENTS
12 AND THINGS LIKE THAT FOR THESE PRICING PROVISIONS.

13 I THINK THE PRINCIPAL CONCERN THAT PEOPLE
14 HAVE ARTICULATED IS THERAPIES, WHICH ARE EXPENSIVE,
15 THAT THAT'S WHERE WE SHOULD BE FOCUSING OUR ENERGY. I
16 JUST THROW THAT OUT FOR DISCUSSION PURPOSES, BUT IT
17 MIGHT BE SIMPLER IF WE JUST FOCUS THIS ON THERAPIES.

18 MR. SIMPSON: THERAPIES INCLUDE DRUGS.

19 DR. WRIGHT: YOU HIGHLIGHTED A PROBLEM THAT I
20 NEED HELP WITH. IF WE ADOPTED THIS WITHIN 5 PERCENT OF
21 THEIR BEST PRICE, HOW IS THAT MONITORED OR AUDITED OR
22 POLICED, IF YOU WILL?

23 MR. TOCHER: WELL, I NOTE THAT THIS IS
24 SOMETHING THAT HAS TO BE PROVIDED TO THE FEDERAL
25 GOVERNMENT, AND SO IT IS A NUMBER THAT THE FEDERAL

1 GOVERNMENT CONFIRMS IN ITS AUDIT FUNCTION AND WOULD BE
2 A FUNCTION THAT THE STATE WOULD HAVE THE AUTHORITY TO
3 AUDIT AS WELL. IT JUST WOULD NOT HAVE TO BE DISCLOSED
4 PUBLICLY.

5 CHAIRMAN PENHOET: AND THE 5 PERCENT
6 ESSENTIALLY JUST GIVES THE MANUFACTURER SOME WIGGLE
7 ROOM TO MAKE SURE THAT WE DON'T DO WHAT WE'VE ALL SAID
8 WE DON'T WANT TO DO, WHICH IS TO TRIP A DESTRUCTIVE
9 PROCESS OF ESSENTIALLY SEQUENTIAL ITERATIONS OF THE
10 PROVISIONS RELATING TO BEST PRICE.

11 MR. TOCHER: RIGHT.

12 DR. PRIETO: I UNDERSTAND THE CONCEPT THERE,
13 BUT 5 PERCENT FOR DRUGS MAY NOT BE VERY SIGNIFICANT,
14 THE DIFFERENCE IN PRICE BETWEEN THE VERY LOWEST AND 5
15 PERCENT, OR IT MAY NOT BE HUGE. FIVE PERCENT FOR AN
16 EXPENSIVE THERAPY WOULD BE QUITE SIGNIFICANT.

17 AND I WOULD ALSO BRING UP THE POINT THAT SOME
18 DIAGNOSTICS ARE EXPENSIVE. THERE IS SOME GENETIC
19 TESTING. MAYBE IN THE GREAT SCHEME OF THINGS, IT'S NOT
20 HUGE, BUT THERE ARE SOME DIAGNOSTICS THAT HAVE
21 SIGNIFICANT COST.

22 MR. TOCHER: IT MAY BE THAT THE SYSTEM THAT
23 ONE USES FOR THERAPIES WOULDN'T NEED THAT 5-PERCENT
24 BUFFER. IT'S SOMETHING THAT IS PERHAPS UNIQUE TO THE
25 SITUATION WITH THE DRUG CALCULATION BECAUSE OF THE

1 COMPLICATED PRICING SYSTEM THAT EXISTS FOR DRUG
2 ASSISTANCE PROGRAMS AND FEDERAL LAW AND --

3 DR. PRIETO: WHY 5 PERCENT AND NOT 2 PERCENT
4 OR 1 PERCENT?

5 MR. TOCHER: WELL, 5 PERCENT, IF YOU'RE
6 CONCERNED ABOUT REVEALING, ABOUT A COMPANY BEING FORCED
7 TO REVEAL A PRICE THAT IT OTHERWISE IS A CONFIDENTIAL
8 MATTER, FIRST OF ALL, 5 PERCENT GIVES THEM ENOUGH
9 LEEWAY TO STILL HIDE THE BALL, I THINK. THAT'S A.

10 B, STILL PRESERVES, I THINK, A PRICE BENEFIT
11 TO THE CONSUMERS.

12 AND, C, IN TERMS OF THE SOURCE, THIS IS 105
13 PERCENT HAS BEEN -- 5 PERCENT HAS BEEN A REFERENCE
14 POINT THAT HAS BEEN USED IN LEGISLATION IN THE PAST.

15 MR. ROTH: ED, DOES SOMEONE HAVE
16 CLARIFICATION ON CAL RX OTHER THAN THIS PIECE ON THE
17 DRUG VERSUS OTHER THERAPIES? IT STILL SEEMS TO ME THAT
18 WE SHOULD TRY TO FIND A WAY TO PEG IT TO THAT EVEN IF
19 IT'S A NONDRUG. THEN IF THE STATE'S PURCHASING THINGS,
20 THEN SOMEBODY'S GOT A COMMERCIAL MARKET BECAUSE IT'S
21 BEING SOLD.

22 DR. PRIETO: DOES CAL RX SUPPLY ANYTHING
23 OTHER THAN DRUGS?

24 MR. ROTH: CAN WE NOT PEG THIS TECHNOLOGY TO
25 WHAT THEY'VE DONE FOR DRUGS? WHAT'S WRONG WITH THAT?

1 CHAIRMAN PENHOET: WELL, THE ACCESS PIECE WE
2 COULD DO. I THINK THE PRICING PIECE IS RATHER SPECIFIC
3 TO DRUGS. I THINK WE'D HAVE TO FIGURE OUT HOW TO --
4 WE'RE NOT THERE YET, DUANE.

5 MR. ROTH: THE STATE PURCHASES BLOOD
6 TRANSFUSIONS. THE STATE PURCHASES TRANSPLANTS.

7 CHAIRMAN PENHOET: WE'RE TRYING TO GET THOSE
8 DATA NOW. WE CAN DO A PIECE FOR DRUGS. WE CAN DO THIS
9 FOR DRUGS. WE CAN DO THE CAL RX FOR DRUGS. WE CAN
10 TAKE CARE OF THE DRUGS WHICH EMERGE FROM THIS PROGRAM.
11 THE OTHER THERAPIES IS WHERE WE'RE STILL UNCLEAR
12 EXACTLY HOW YOU SET THE BENCHMARK, THEN I DON'T HAVE
13 THE ANSWER FOR YOU TODAY.

14 MR. ROTH: I WONDER IF ANYBODY IN THE
15 AUDIENCE HAS THE ANSWER.

16 MR. VALENCIA: I BELIEVE I DO, MR. ROTH.
17 I'LL CERTAINLY DO MY BEST. I'M JOHN VALENCIA, LAW FIRM
18 OF WILKE, FLEURY, HOFFELT, GOULD & BIRNEY IN
19 SACRAMENTO, APPEARING ON BEHALF OF CALIFORNIA
20 HEALTHCARE INSTITUTE TODAY.

21 FIRST, AN IMMEDIATE ANSWER TO YOUR QUESTION,
22 YOU'RE EXACTLY RIGHT. THE STATE PURCHASES ALL MANNER
23 OF THERAPIES OTHER THAN PRESCRIPTION OUTPATIENT
24 PRODUCTS. AND AS I TRIED TO EXPLAIN IN THE MEMORANDUM
25 THAT I SENT TO YOU, AND BY THE WAY, I HAVE A

1 SYNTHESIZED VERSION OF THAT THAT'S AVAILABLE TO THE
2 PARTICIPANTS IN OTHER SITES. IT'S A SHORT PROGRAM.
3 I'M NOT GOING TO RUN EVERYONE HERE THROUGH IT, BUT THE
4 HIGHLIGHTS OF THAT MEMO ARE REPEATED THERE.

5 NO ONE WANTS TO PAY RETAIL IN STATE
6 GOVERNMENT. AND IN STATE GOVERNMENT, ANYWAY, AT THIS
7 POINT IN TIME, NO ONE DOES. HUMAN FACTOR BLOOD
8 REPLACEMENT, RECOMBINANT BLOOD REPLACEMENT, ARE ALL
9 NEGOTIATED FOR DISCOUNTS DIRECTLY WITH THE PROGRAMS
10 THAT ARE RESPONSIBLE FOR PAYING FOR THAT. SO THE KEY
11 IS IS THE PATIENT ELIGIBLE FOR ONE OF THESE PROGRAMS?

12 AND THOSE PROGRAMS ARE SO UNIQUE THAT, IN
13 FACT, THEY ARE. THEY SERVE COMPREHENSIVELY FOLKS IN
14 NEED. THEY DO NOT SERVE THE INSURED, OF COURSE, UNLESS
15 LEGISLATION HAS BEEN DIRECTED SUCH THAT THEY ARE TO
16 COVER THE INSURED. SO IN THE CASE OF SOMEONE WITH A
17 BLOOD FACTOR DEFICIENCY, A BLOOD REPLACEMENT
18 DEFICIENCY, THEIR MARROW JUST DOESN'T WORK, THEY'RE
19 ELIGIBLE FOR THE GENETICALLY HANDICAPPED PATIENTS
20 PROGRAM, GHPP.

21 I'VE TAKEN SEVERAL OF THE LESS THAN A HANDFUL
22 OF MANUFACTURERS IN THAT FIELD INTO THAT PROGRAM TO, IN
23 FACT, NEGOTIATE CONTRACTS THAT PROVIDE THOSE VERY
24 UNIQUE PRODUCTS AT A DISCOUNTED LEVEL OTHER THAN THE
25 PUBLISHED PRICES THAT PRIMARILY INSURED AND INSURANCE

1 ENTITIES AND HMO'S PAY.

2 STEP BACK FROM THIS ONE MOMENT SIMPLY BECAUSE
3 THE LITANY OF PROGRAMS THAT I'VE DESCRIBED TO YOU ARE
4 AS A FUNCTION OF ONE THING THAT THE PRIVATE SECTOR CAN
5 NEVER EMULATE. AND THAT IS THAT GOVERNMENT CAN
6 LEGISLATE AND HAS LEGISLATED THE ABSOLUTE ROCK BOTTOM
7 PRICES FOR ANYTHING THAT COMES INTO EXISTENCE. AND
8 THAT WILL APPLY TO A CIRM-FUNDED OUTPATIENT
9 PRESCRIPTION DRUG REGARDLESS OF WHAT YOU DO TODAY. THE
10 POINT OF MY MEMORANDUM, AT LEAST IN PART, WAS NOT TO
11 QUIBBLE WITH THE POLICY OF TRYING TO MAKE PRODUCTS
12 AVAILABLE TO THOSE IN NEED WHO DON'T HAVE SOME OTHER
13 SOURCE OF IT, WHETHER IT'S THROUGH A PATIENT ASSISTANCE
14 PROGRAM OR COMPASSIONATE CARE PROGRAM, INDUSTRY WILL DO
15 THAT, INDUSTRY DOES DO THAT LARGELY OUT OF A FUNCTION
16 OF CIVIC PARTICIPATION OR ON THE OCCASION WHERE THEY'RE
17 COMPELLED TO BY LAW.

18 IN THE CASE OF STATE PURCHASES, HAVING JUST
19 HEARD IT, I THINK I WANT TO ENDORSE, AT LEAST IN PART,
20 WHAT SCOTT -- THE DIRECTION IS SCOTT IS RECOMMENDING TO
21 YOU. YOU NEED A MUCH MORE FLEXIBLE REGULATION THAN THE
22 DRAFT YOU HAVE BEFORE YOU TYING -- MR. ROTH IS RIGHT.
23 CAL RX MAY BE A MODEL FOR THAT KIND OF FLEXIBILITY
24 BECAUSE IT DOESN'T TIE TO ANY ONE STANDARD. THIS
25 PROPOSAL DOES; AND WHILE IT'S SEDUCTIVE IN APPARENT

1 SIMPLICITY, IT JUST AIN'T.

2 IT OPENS UP MANY MORE PITFALLS BECAUSE OF
3 WHAT THE FEDERAL GOVERNMENT ASSURES TO ITSELF, AND
4 STATE AGENCIES CAN ONLY EXCEED BY FEDERAL PERMISSION.
5 PROGRAMS SUCH AS THE AIDS DRUG ASSISTANCE PROGRAM,
6 MEDI-CAL ITSELF. THEY CAN ALL EXCEED AND DO ON A
7 REGULAR BASIS THROUGH A NEGOTIATION THE PRICING THAT
8 THE FEDS HAVE GUARANTEED TO THEMSELVES. THE FEDS DON'T
9 WANT TO NEGOTIATE WITH EVERY MANUFACTURER IN THE UNITED
10 STATES OF ANY PRESCRIPTION DRUG OR OTHER THERAPY THAT
11 THEY MAY PURCHASE THROUGH EITHER MEDI CAID, WHICH IS ONE
12 PREFERRED PRICING PROGRAM, THE PUBLIC HEALTH SERVICE,
13 WHICH IS AN ENTIRELY SEPARATE AND ALSO ADVANTAGED
14 ACQUISITION PROGRAM, DOD. DEPARTMENT OF DEFENSE
15 DOESN'T PAY RETAIL FOR ANYTHING, NEITHER DOES VA, AND
16 THE LITANY OF PROGRAMS THAT I OUTLINED IN MY
17 MEMORANDUM.

18 IN SOME RESPECTS THE GOAL THAT I HEARD TALKED
19 ABOUT EARLIER YOU'LL NEVER BE ABLE TO ACHIEVE BECAUSE
20 THE FEDS WILL ALWAYS BEAT YOU TO THE BOTTOM AT ONE
21 LEVEL. AND BY THE WAY, OUR SISTER STATES, AS MUCH AS
22 WE LIKE TO THINK OF OURSELVES AS AN ISLAND COUNTRY,
23 WE'RE NOT. OUR SISTER STATES ARE DOING EXACTLY WHAT
24 WE'RE DOING. THEIR MEDI CAID PROGRAMS ARE MOVING
25 RAPIDLY TO SECURE FEDERAL APPROVAL TO MEET THE FEDERAL

1 THRESHOLD AND THEN SOME. AND THEY'RE PERFECTLY
2 ENTITLED TO DO SO. ADAP IS NOT A PROGRAM THAT IS
3 UNIQUE TO CALIFORNIA. THE NATION'S ADAP'S ALL ARE
4 RACING TO THE BOTTOM.

5 SO I THINK SCOTT'S AT LEAST HEADED IN THE
6 RIGHT DIRECTION, AND I'D ECHO WHAT MR. ROTH HAS
7 RECOMMENDED TO YOU. YOU NEED TO CARVE OUT, IN MY
8 OPINION AND ON BEHALF OF CHI, THESE PRODUCTS THAT ARE
9 DESCRIBED AND DEFINED IN LAW AS OUTPATIENT PRESCRIPTION
10 DRUGS BECAUSE YOU'LL NEVER MEET, LET ALONE EXCEED,
11 THROUGH COMPULSION OF CIRM LICENSEES THE PRICE THAT
12 THEY'RE ALREADY GOING TO COMMAND. WHEN A CIRM-FUNDED
13 DISCOVERY IS PAID FOR BY ONE OF THOSE PROGRAMS, IT WILL
14 NOT BE PAID FOR UNTIL THE INNOVATOR OF THAT PRODUCT
15 SITS DOWN WITH THAT WHOLE LIST OF AGENCIES. BY THE
16 WAY, I DISCOVERED A COUPLE OF INCOMPLETES. THERE ARE
17 EVEN MORE THAN I WAS ABLE TO PUT TOGETHER IN THE TIME
18 THAT I HAD TO PUT IT TOGETHER. IT WON'T BE PAID FOR BY
19 CALIFORNIA STATE GOVERNMENT AT RETAIL OR ANYTHING
20 APPROACHING RETAIL.

21 AND CAL RX IS THE NEW INNOVATION TO PLUG
22 PROBABLY THE BIGGEST GAP THAT THE GOVERNOR AND THE
23 LEGISLATURE WANTED TO DELIVER FIRST, AND THAT WAS
24 PREFERRED PRICING FOR ACQUISITION FOR DRUGS THAT ARE
25 GOING TO BE MADE AVAILABLE TO, AGAIN, AN ELIGIBLE

1 POPULATION THAT IS EITHER UNINSURED OR UNDERINSURED.

2 AND TO GIVE YOU AN IDEA OF THE FLEXIBILITY OF
3 THAT NEW LAW, THERE ARE AT LEAST THREE ELIGIBILITY
4 STANDARDS BY WHICH SOMEONE MAY QUALIFY. THEY EITHER
5 HAVE TO ESTABLISH THROUGH WHAT WE HOPE WITH CROSSED
6 FINGERS HERE WILL BE A ONE-PAGE APPLICATION. THEY HAVE
7 TO BE A FAMILY THAT OPERATES AT 300 PERCENT OF FEDERAL
8 POVERTY LEVEL OR LESS. THEY HAVE TO BE A FAMILY THAT
9 MAKES THE STATE'S MEDIAN INCOME AND CAN ESTABLISH THAT
10 THEY SPEND 10 PERCENT OR MORE OF THEIR GROSS STATE
11 MEDIAN INCOME ON HEALTHCARE. OR, AND I THINK ONE
12 LITTLE PROBLEM FEATURE THAT WE WON'T SPEND TIME TALKING
13 ABOUT HERE, OR YOU'RE A SENIOR WHO'S ELIGIBLE FOR
14 MEDICARE, BUT YOU'RE STUCK IN THE DONUT HOLE WHERE
15 MEDICARE DOES NOT PICK UP A HUNDRED PERCENT OF YOUR
16 PRODUCT PRICING, BUT ONLY 95 PERCENT. IT'S THAT 5
17 PERCENT THAT'S GOING TO BE A POTENTIAL PROBLEM FOR CAL
18 RX.

19 SO WHEN IT COMES TO DRUGS, CIRM HAS TO HAVE
20 FAITH THAT, AT LEAST AS TO OUTPATIENT PRESCRIPTION
21 PRODUCTS, THE HOST OF YOUR SISTER STATE AGENCIES THAT
22 PAY FOR THOSE PRODUCTS ARE AHEAD OF YOU IN THIS GAME.
23 AND THE FOCUS SHOULD BE ON THE INNOVATIONS THAT DON'T
24 CURRENTLY, AT LEAST IN OUR VIEW, THAT DON'T CURRENTLY
25 FIT INTO A BOX.

1 IN ORDER FOR THE REGULATION, AND WE'RE TRYING
2 TO BE HELPFUL ON THAT SCORE AS WELL, IN ORDER FOR THE
3 REGULATION NOT TO FAIL ON EVENTUAL REVIEW BY THE RATHER
4 BLOODLESS OFFICE OF ADMINISTRATIVE LAW, AS YOU'VE
5 DISCOVERED, IT'S GOING TO LOOK AT THE REGULATION FOR
6 DEFINITENESS AND CLARITY. AND SOMETHING THAT'S
7 PRESENTED TO THEM THAT CAN'T BE DECIPHERED, WHICH IS
8 THE WHOLE POINT OF REGULATIONS IN TERMS OF IMPLEMENTING
9 LAW, IT IS, I THINK, BOUND TO FAIL.

10 I'D RECOMMEND THAT WE SPEND SOME TIME TRYING
11 TO CATEGORIZE, NOT ENCAPSULATE, BUT SIMPLY CATEGORIZE.
12 OAL HAS APPROVED LEGIONS OF REGULATIONS THAT SAY
13 INCLUDING BUT NOT LIMITED TO, WONDROUS CATCH PHRASES
14 LIKE THAT, THERAPIES THAT INCLUDE OR THAT WE ENVISION
15 AS BEING XYZ, BUT NOT LIMITED TO. I THINK THAT WOULD
16 BE AN EXCELLENT APPROACH.

17 WHEN IT COMES TO FRAMING PRICING REFERENCES
18 FOR THOSE THERAPIES AND DIAGNOSTICS, DIAGNOSTICS, WE
19 HOPE, ARE FUNDED FROM SOMETHING AS SIMPLE AS DIABETES
20 TEST STRIPS TO THE EXOTICA OF WHO KNOWS WHERE SCIENCE
21 WILL TAKE US. THERE ARE AT LEAST THREE PRICING
22 REFERENCES IN THE CAL RX PROGRAM THAT COULD REPRESENT A
23 MODEL FOR CIRM COMPULSION TO ITS EVENTUAL LICENSEES.

24 I THINK BECAUSE -- AND I WAS AN ACTIVE
25 ADVOCATE ON THAT PARTICULAR PIECE OF LEGISLATION. WE

1 HAD MUCH THE SAME CONVERSATION WITH LEGISLATORS AND THE
2 ADMINISTRATION THAT WE'RE HAVING TODAY. IF YOU TRY AND
3 TIE IT TO ONE STANDARD, IT MAY NOT BE AS GOOD AS YOU
4 THINK IT IS AND IT COULD LEAD YOU INTO SOME PITFALLS,
5 SO THEY ADOPTED THREE.

6 AND THOSE INCLUDE -- BECAUSE THE FOCUS -- BY
7 THE WAY, CAL RX IS LIMITED TO OUTPATIENT PRESCRIPTION
8 DRUGS, BUT YOUR IDEA OF USING THAT AS A MODEL FOR WHAT
9 YOU ALLOCATE AS AN OBLIGATION TO LICENSEES CAN
10 CERTAINLY BE DOABLE BECAUSE YOU CONTROL THIS ARENA.
11 THEY PICKED MEDICAID BEST PRICE TO THE EXTENT IT
12 EXISTS. THEY PICKED 15 PERCENT OF AVERAGE
13 MANUFACTURER'S PRICE, A TERM EXCLUSIVE TO OUTPATIENT
14 DRUGS, BY AND LARGE, OR THE LOWEST AVAILABLE PRICE TO A
15 NONPUBLIC PURCHASER IN THE STATE OF CALIFORNIA. SO
16 THEY DIDN'T TIE THEMSELVES IN THAT PROGRAM TO ONE
17 STANDARD.

18 BY THE WAY, THE STATE OF CALIFORNIA AS A
19 WHOLE, PROBABLY THROUGH THE DEPARTMENT OF HEALTH
20 SERVICES, IS GOING TO NEGOTIATE WITH THOSE INNOVATORS,
21 THOSE MANUFACTURERS OF THOSE PRODUCTS TO PICK THE
22 PRICING THRESHOLD AND SIGN A CONFIDENTIAL CONTRACT.
23 SOME OF THOSE NOTIONS, IF YOU WANT TO EXPORT THOSE
24 NOTIONS HERE, YOU CAN PROBABLY GET TO THEM WITH FAR
25 FEWER PROBLEMS THAN TRYING TO TIE TO ONE APPARENTLY

1 SIMPLE THRESHOLD THAT HAS MORE PITFALLS SIMPLY BECAUSE
2 OF WHAT IT WAS DESIGNED TO DO THAN THE PROMISE THAT IT
3 HOLDS FOR YOU. I KNOW THAT INDUSTRY WILL CHARGE ME AND
4 OTHERS TO CONTINUE TO WORK WITH SCOTT TO GET THERE. I
5 THINK YOU'RE HEADED DOWN A BETTER PATHWAY GIVEN THAT
6 NOTION AND THEN CAN HELP YOURSELF BY TRYING TO DEFINE
7 NOT EXCLUSIVELY AND NOT COMPREHENSIVELY, BUT JUST TO
8 GIVE THE OTHER REGULATOR INVOLVED IN THIS, OAL, AN IDEA
9 OF WHAT IT IS YOU WANT TO ACCOMPLISH AND GIVE THEM
10 SOMETHING TO HANG THEIR APPROVAL HAT ON.

11 YOU'LL HAVE TO DO THE SAME THING WITH WHAT
12 YOU MEAN BY FUNDS. THAT'S ANOTHER OPEN CAN OF WORMS
13 BECAUSE, WITHOUT A DEFINITION, DO CALIFORNIA FUNDS
14 CONSIST SOLELY OF STATE GENERAL FUNDS? DO THEY CONSIST
15 OF SPECIAL FEE AND FINE FUNDS? CALIFORNIA FUNDS AS
16 THEY'RE ALLOCATED IN THE BUDGET PROCESS ARE ALMOST
17 ALWAYS REGARDED AS INDIVISIBLE FROM FEDERAL SOURCES.
18 ADAP, AGAIN, IS A VERY GOOD EXAMPLE OF THAT, MEDICAID,
19 THE HOST OF PROGRAMS, BECAUSE WE DON'T PAY FOR
20 HEALTHCARE ALL BY OURSELVES. IT'S USUALLY IN
21 PARTNERSHIP WITH AND COUPLED WITH MYRIAD STRINGS WITH
22 THE FEDERAL GOVERNMENT.

23 WHY IN MEDICAID ARE GENERAL THERAPIES PAID
24 FOR 50-50, BUT FAMILY PLANNING AND CONTRACEPTIVE
25 PRODUCTS PAID AT 90-10 FED TO STATE? WELL, THOSE ARE

1 POLICY CHOICES, AND YOU HAVE TO ABIDE BY THOSE STRINGS
2 IN ORDER TO BE ABLE TO SPEND THE MONEY THAT WAY.

3 I COULD COMMEND TO YOU AND CONCLUDE AT THIS
4 POINT AND TAKE ANY QUESTIONS THAT I MIGHT BE ABLE TO
5 ADDRESS THAT THE BETTER THE DIRECTION IS THE ONE THAT'S
6 CURRENTLY SUGGESTED, TO COMPARTMENTALIZE WHERE YOU HAVE
7 TO AND PROVIDE FURTHER DEFINITION WHERE YOU CAN SO THAT
8 THE REGULATION SUCCEEDS AND SO THAT INDUSTRY THAT'S
9 GOING TO DO THE JOB THAT YOU COMPEL THEM TO DO HAS A
10 BETTER IDEA OF WHAT IT IS YOU'RE ASKING THEM TO DO.

11 CHAIRMAN PENHOET: JUST A CLARIFICATION. I
12 THINK OUR POLICY SAID THAT FOR PURCHASES WITH PUBLIC
13 FUNDS, IT DIDN'T SAY STATE OF CALIFORNIA FUNDS, IF I
14 REMEMBER CORRECTLY. SO --

15 MR. VALENCIA: CALIFORNIA FUNDS OR FUND OF
16 ANY POLITICAL SUBDIVISION OF THE STATE.

17 DR. MAXON: OUR POLICY SAYS PUBLIC FUNDS.

18 CHAIRMAN PENHOET: PUBLIC FUNDS.

19 DR. MAXON: THE DRAFT REGULATORY LANGUAGE YOU
20 ARE LOOKING NOW IS OUTDATED LANGUAGE.

21 MR. ROTH: PURCHASED IN CALIFORNIA BY PUBLIC
22 FUNDS THE THERAPIES AND DIAGNOSTICS AT A COST NOT TO
23 EXCEED THE FEDERAL MEDI CAID PRICE.

24 DR. MAXON: THAT'S THE ORIGINAL LANGUAGE FROM
25 THE NONPROFIT POLICY THAT'S BEEN IMPORTED INTO THE

1 FOR-PROFIT POLICY, AND SCOTT IS CURRENTLY WORKING ON
2 LANGUAGE FOR THE REGULATION.

3 DR. PRIETO: IT'S IMPORTANT BECAUSE THE
4 COUNTIES WHICH, AS I UNDERSTAND, ARE NOT A SUBDIVISION
5 OF THE STATE.

6 MR. VALENCIA: NO, THEY ARE. AND YOU WILL
7 HELP -- I'M SORRY, DR. PRIETO. AND YOU WILL HELP
8 YOURSELF, AND I'LL WORK WITH SCOTT ON THIS, THAT IT IS
9 NOT A SELF-DEFINING TERM. YOU HAVE TO CITE, AND I'M
10 SURE SCOTT WILL DO THIS, YOU HAVE TO CITE TO THE AREA
11 OF THE CONSTITUTION THAT DESCRIBES WHAT THOSE ARE. THE
12 PLAIN ENGLISH ANSWER TO YOUR QUESTION IS, YES, COUNTIES
13 AND CITIES, CERTAIN COUNTIES AND CERTAIN CITIES, ARE
14 CONSIDERED POLITICAL SUBDIVISIONS OF THE STATE.
15 THERE'S A CLASS OF CITY THAT IS NOT. THE CHARTER CITY
16 IS REGARDED AS AN INDEPENDENT. THEY'RE OF THE STATE,
17 BUT THEY ARE NOT A POLITICAL SUBDIVISION OF THE STATE.
18 GENERAL LAW CITIES ARE, GENERALLY SPEAKING, REGARDED AS
19 SUBDIVISIONS. ALL COUNTIES ARE.

20 DR. PRIETO: THE PRINCIPLE IS WE WANT PAID
21 FOR WITH PUBLIC FUNDS.

22 CHAIRMAN PENHOET: RIGHT. SO WE CLEARLY HAVE
23 MORE WORK TO DO IN THIS AREA. IT DOESN'T MAKE ANY
24 SENSE FOR US TO WRITE SOMETHING DOWN WHICH IS NOT
25 WORKABLE AND DOESN'T RECOGNIZE THE OTHER PIECES AND

1 PARTS IN THE STATE. I THINK WE WILL HAVE TO COME BACK
2 ON THIS.

3 BUT I THINK WITH RESPECT TO THE PRINCIPLE, IT
4 SOUNDS LIKE THE PRINCIPLE IS STILL INTACT. WE DON'T
5 WANT CALIFORNIANS TO BE DISADVANTAGED VIS-A-VIS ANYONE
6 ELSE EXCEPT WITHIN THE LIMITS OF OUR ABILITY TO DO SO
7 WHICH WOULD NOT TRIP THE MOST FAVORED NATION
8 DESTRUCTION PROCESS. SO --

9 MR. VALENCIA: I APOLOGIZE FOR INTERRUPTING.
10 THE PROBLEM IS EVERY STATE AND EVERY ENTITY THAT CAN
11 CREATE MOST FAVORED NATION STATUS FOR ITSELF IS TRYING
12 VERY QUICKLY TO DO THAT IF IT HAS NOT DONE THAT
13 ALREADY.

14 CHAIRMAN PENHOET: THAT'S TRUE THEY'RE TRYING
15 TO DO THAT, BUT THEY'RE NOT FUNDING STEM CELL RESEARCH
16 AT \$3 BILLION EITHER.

17 MR. ROTH: IF I LISTENED TO WHAT WAS JUST
18 SAID AND IN LIGHT OF CALIFORNIA RX, IS IT REALLY
19 NECESSARY THAT WE HAVE AN AFFORDABILITY CLAUSE IN THE
20 POLICY? AND JUST TAKE THIS OUT AND FOCUS ON ACCESS.
21 THAT'S, TO ME, THE MOST IMPORTANT THING, THAT WE'RE
22 GOING TO REQUIRE ANYBODY THAT TAKES OUR MONEY TO MAKE
23 AVAILABLE TO CALIFORNIANS WHO CANNOT AFFORD IT,
24 UNINSURED, WHATEVER, ACCESS TO THESE THERAPIES. IF WE
25 FOCUS ON THAT PIECE, GIVEN THAT THERE ARE THREE OR FOUR

1 OR FIVE LAYERS THAT YOU HAVE TO NEGOTIATE PRICE WITH,
2 WHICH ALREADY EXISTS, AND, IN ADDITION, THE CALIFORNIA
3 RX, WHY ARE WE TRYING TO MAKE SOMETHING THAT'S GOING TO
4 BE ONEROUS POTENTIALLY?

5 DR. PRIETO: BECAUSE WE'RE ALSO CONCERNED
6 ABOUT CALIFORNIANS WHO ARE INSURED, PARTICULARLY
7 THROUGH THESE PUBLIC PROGRAMS. THEY ARE ALSO
8 CALIFORNIA TAXPAYERS THAT CONTRIBUTED TO THIS PROGRAM
9 WHICH HOPEFULLY WILL LEAD TO THERAPIES AND TREATMENTS.
10 SO WE DON'T --

11 MR. ROTH: BUT I THINK YOU GET -- IF BLUE
12 CROSS IS PAYING FOR IT, YOU GOING TO GIVE BLUE CROSS A
13 BREAK?

14 DR. PRIETO: NO. BUT IF PUBLIC FUNDS --

15 MR. ROTH: PUBLIC FUNDS.

16 DR. PRIETO: THERE'S A SUBSTANTIAL PROPORTION
17 OF THE POPULATION THAT'S INSURED THROUGH PUBLIC FUNDS.

18 MR. ROTH: SO WHAT I JUST HEARD, THOUGH, IS
19 THERE'S NOW NEW LEGISLATION THAT DEALS WITH PUBLIC
20 FUNDS. YOU HAVE TO NEGOTIATE --

21 DR. PRIETO: FOR DRUGS.

22 MR. ROTH: BUT I THINK IT SHOULD APPLY TO
23 ANYTHING THAT THEY NEGOTIATE WITH. AND THERE ARE
24 PEOPLE, AS I SAID, NEGOTIATING BLOOD TRANSFUSIONS,
25 NEGOTIATING TISSUE TRANSPLANTS. LOTS OF THINGS ARE

1 ALREADY PAID FOR, AND SOMEBODY DECIDES WHAT THEY'RE
2 GOING TO REIMBURSE OR THINGS THAT CALIFORNIA PAYS FOR.

3 DR. PRIETO: IT MAY BE THAT THERE ARE FAIRLY
4 FEW OR VERY FEW LOOPHOLES, BUT I THINK WHAT WE'RE
5 ASKING SCOTT TO COME UP WITH IS LANGUAGE THAT ADDRESSES
6 THAT AND MAKES SURE THAT WE COVER THOSE. AND IT MAY BE
7 THAT THIS IS TRIGGERED VERY RARELY, AND THAT'S FINE;
8 BUT AT LEAST IF IT IS TRIGGERED, IT'S THERE.

9 MR. ROTH: I THINK IF WE FOCUS ON ACCESS AND
10 THEN COMPLY WITH THESE THINGS, WE'RE GOING TO GET
11 THERE. AND WHAT I WOULD SUGGEST, IT'S GOING TO BE A
12 LONG TIME BEFORE ANYTHING'S GOING TO GET REIMBURSED
13 HERE OR BE ON THE MARKET FOR THE EXPENSIVE THINGS WE'RE
14 TALKING ABOUT, SO LET'S NOT MAKE THIS OVERLY
15 COMPLICATED WHERE WE INVITE PEOPLE NOT TO TAKE THE
16 MONEY. THAT'S MY CONCERN ABOUT PUTTING THINGS IN HERE
17 THAT WE REALLY PROBABLY CAN'T CONTROL.

18 MR. VALENCIA: MR. CHAIR, I'LL LEAVE YOU WITH
19 THIS. I JUST WANT TO PICK UP RIGHT THERE, AND THEN
20 I'LL STEP DOWN. YOU KNOW, MR. ROTH IS EXACTLY RIGHT
21 ABOUT THE REALITY OF WHEN THESE INNOVATIONS WILL COME
22 INTO EXISTENCE. AND I'LL ADD ONE OTHER REALITY. CAL
23 RX ISN'T LOCKED INTO CEMENT. THIS AGENCY IS SO
24 INFLUENTIAL, THAT IT COULD CERTAINLY RECOMMEND TO THE
25 ADMINISTRATION THAT THERE BE AN EXPANSION OF THE

1 THERAPIES TO BE COVERED BY CAL RX. THEN, SEEMINGLY,
2 FAIRLY SIMPLY THE SPECIFIC DIRECTION THAT YOU COULD
3 GIVE TO LICENSEES IS THAT THEY MAKE THEIR PRODUCTS
4 AVAILABLE THROUGH CAL RX, WHICH HAS THE DEFINED LIMITS
5 OF WHO'S GOING TO ACCESS IT.

6 DR. PRIETO TALKS ABOUT PUBLICLY FUNDED
7 PATIENTS THROUGH VARIOUS PROGRAMS. AS I TRIED TO POINT
8 OUT IN MY MEMORANDUM TO THE ORGANIZATION, THOSE
9 CONTRACTORS TO THE STATE ARE SQUEEZED BY THE STATE IN
10 ORDER TO GET THE CONTRACT TO BEGIN WITH, AN HMO, FOR
11 EXAMPLE. AND THE HMO IN TURN SQUEEZES THE SUPPLIERS OF
12 WHATEVER PRODUCTS, INCLUDING PHARMACEUTICAL AND OTHER
13 VENDORS AND MANUFACTURERS. BUT IT COULD VERY WELL BE
14 THAT A PATHWAY FOR WHAT YOU'RE TRYING TO ACHIEVE WOULD
15 BE TO SUGGEST, AS A MATTER OF POLICY, CAL RX, WHICH
16 REALLY IS GOING TO GET UP AND RUNNING BOTH IN THE NEAR
17 TERM AND HAS FUTURE THRESHOLDS, CAL RX, GOVERNOR, WHO'S
18 MAKING AFFORDABLE ACCESS TO HEALTHCARE HIS LINCHPIN IN
19 HIS NEW TERM, WHAT ABOUT A PLACE FOR CIRM-FUNDED
20 DISCOVERIES TO GO AND BE MADE AVAILABLE AND BE FUNDED?
21 AND, LICENSEES, HERE'S A SIMPLE THING TO DO.

22 RATHER THAN GO HUNTING FOR -- ACTUALLY THE
23 PURCHASERS ARE GOING TO GO HUNTING FOR THE VENDORS.
24 BUT FOR THOSE FOLKS THAT MIGHT OTHERWISE FALL THROUGH
25 THE CRACK IN TERMS OF ACCESS, HERE'S WHERE THEY'LL WIND

1 UP. LET'S NOT LET THE ARBITRARY WALL THAT RIGHT NOW
2 EXISTS LIMITING THE PROGRAM TO OUTPATIENT DRUGS
3 NECESSARILY LIMIT WHAT CAL RX CAN DO. CAL RX COULD BE
4 EXPANDED TO ACCOMMODATE YOUR INNOVATIONS AND THERAPIES.
5 THANK YOU.

6 MR. ROTH: YOU SAID IT MUCH MORE ELOQUENTLY
7 THAN I DID, BUT THAT'S REALLY WHAT I WAS SAYING. LET'S
8 PEG IT TO SOMETHING THAT EXISTS, SO WE DON'T, AGAIN,
9 CREATE ISSUES OF COMPLIANCE, THAT WE GET STAFF MEMBERS
10 RUNNING AROUND TRYING TO FIGURE OUT. JUST SAY IF YOU
11 TOOK THE MONEY, YOU'RE IN CALIFORNIA RX, AND WE WILL
12 RECOMMEND THAT CALIFORNIA RX BE EXPANDED TO INCLUDE
13 THERAPIES.

14 CHAIRMAN PENHOET: OKAY. WELL, IF THE REST
15 OF YOU AGREE, WE'LL GO BACK AND DO SOME HOMEWORK ON
16 THAT CONCEPT. MAYBE, DUANE, I COULD RESTATE WHAT YOU
17 SAID, THAT OUR PRIMARY FOCUS AND WHERE WE CAN CAPTURE
18 SOME GROUND TODAY IS ON ACCESS.

19 MR. ROTH: AND I WOULD LIKE THE CONCEPT --
20 AND I'LL MODIFY IT BASED ON -- I'VE BEEN THINKING ABOUT
21 WHAT TED LOVE SAID. IF IT'S LIFE-THREATENING, THE
22 CATEGORY OF LIFE-THREATENING WOULD GET CALIFORNIA
23 PREFERENCE, THEN THE REST OF THE COUNTRY OR WHATEVER
24 ELSE. WHEN YOU GET INTO THAT LIFE-THREATENING
25 CATEGORY, YOU GET PREFERENCE IN CALIFORNIA.

1 DR. WRIGHT: I THINK THAT'S A GREAT IDEA.

2 MR. ROTH: THAT PREVENTS FOR OTHERS. IF
3 THERE'S PLENTY TO GO AROUND, YOU CAN START MOVING IT
4 DOWN AROUND LIKE YOU DID.

5 CHAIRMAN PENHOET: OTHER COMMENTS FROM
6 MEMBERS OF THE TASK FORCE? SO THE NOTION ON THE TABLE
7 IS THAT WE, AT THE MOMENT AT LEAST, WILL CAPTURE THE
8 GROUND ON THE ACCESS. AND I THINK WE HAVE PRETTY
9 UNIFORM AGREEMENT IN THIS GROUP THAT ANY FIRM FUNDING
10 WILL TRIP THAT REQUIREMENT OF A COMPANY. AND THAT WE
11 STILL HAVE MORE WORK TO DO TO SEE WHETHER WE CAN FIND A
12 SIMPLE SOLUTION, WHICH IS SOMETHING LIKE AN OBLIGATION
13 TO WORK THROUGH CAL RX FOR THERAPIES, ETC.

14 I BROUGHT UP THE ISSUE OF WHETHER WE SHOULD
15 SWEEP DIAGNOSTICS OR OTHER PRODUCTS INTO THIS. I DON'T
16 HAVE A STRONG VIEW ONE WAY OR THE OTHER, BUT AN EFFORT
17 TO TRY TO SIMPLIFY THIS. I THINK MANY PEOPLE POINT OUT
18 THAT THE BIGGEST EXPENSES BY FAR ARE GOING TO BE IN THE
19 THERAPEUTIC AREA. I DON'T HAVE A STRONG VIEW. ANYBODY
20 ELSE HAVE A POINT OF VIEW ABOUT IT?

21 DR. REED: I WOULD BE COMFORTABLE WITH
22 EXCLUDING REAGENTS AND DIAGNOSTICS FOR THE REASONS YOU
23 SAID. THEY TEND TO BE PRICED BY THE MARKET FAR, FAR
24 LOWER AND IN RANGES THAT ARE GENERALLY AFFORDABLE.
25 THERE MAY BE A RARE EXCEPTION, BUT I THINK THAT, IN

1 GENERAL, WE COULD UNCOMPLICATE THINGS A BIT MORE BY
2 JUST TAKING THEM OUT. LIKE YOU SAID, NOW MOST
3 DIAGNOSTICS ARE PERFORMED IN THE CONTEXT OF LARGE
4 COMPANIES THAT BRING IN SAMPLES FROM ALL AROUND THE
5 COUNTRY, AND SO I THINK IT WOULD MAKE SENSE.

6 CHAIRMAN PENHOET: ANY OTHER COMMENTS ON THAT
7 ISSUE?

8 DR. LOVE: NOT ON THAT ISSUE. BUT ON THE
9 ISSUE ABOUT DUANE'S MODIFICATION, I WOULD ACTUALLY SAY
10 THAT, DUANE, I THINK IT'S THE LIFE-THREATENING ISSUES
11 FOR THE COMPANIES ARE GOING TO RUN INTO THE MOST
12 TROUBLE. AND IF A COMPANY HAS A PROBLEM MAKING ENOUGH
13 MATERIAL, AND UNFORTUNATELY I WAS THERE ONE TIME AT
14 GENENTECH, IT'S AN ENORMOUS PROBLEM. AND THE BIGGEST
15 THING A COMPANY CAN DO IS TO, NO. 1, TRY TO MAKE MORE
16 PRODUCT; BUT IF YOU'RE BEING LIMITED, IT'S JUST GOING
17 TO BE AN ENORMOUS BURDEN FOR A PUBLICLY OWNED COMPANY
18 WITH INVESTORS ALL AROUND THE WORLD, REGULATED BY THE
19 SEC AND THE FDA AND CMS. IT'S GOING TO BE VERY HARD
20 FOR THIS COMPANY TO LIVE UP TO THE OBLIGATION.

21 SO I THINK MOST BIG COMPANIES WOULDN'T EVEN
22 ACCEPT THAT TO BEGIN WITH, BUT I DON'T THINK WE'RE
23 TALKING ABOUT BIG COMPANIES TAKING THE GRANTS AT THE
24 END OF THE DAY. SO I JUST WANT TO MAKE SURE THAT AT
25 LEAST WE THINK THROUGH THE UNINTENDED CONSEQUENCES

1 ESSENTIALLY OF A COMPANY SIGNING UP FOR THAT OBLIGATION
2 THAT IT MAY NOT BE ABLE TO MEET.

3 CHAIRMAN PENHOET: WE COULD BUILD IN SOME
4 CAVEATS. IT'S OVERRULED BY THE FEDERAL GOVERNMENT OR
5 CMS OR SOMEBODY.

6 MR. ROTH: LET'S RUN IT UP THE FLAGPOLE AND
7 SEE. TED, WHAT REALLY CONCERNS ME, IF SUCH A THING
8 EXISTED, HOW COULD WE AS A BOARD FACE CALIFORNIANS WHO
9 SAY, BUT WE FUNDED THIS AND --

10 DR. LOVE: YES. I UNDERSTAND. BUT I CAN
11 TELL YOU THIS, THAT IF BILL GATES PUT 20 PERCENT INTO
12 BUILDING YOUR COMPANY AND THE COMPANY TRIED TO GIVE
13 PREFERENTIAL TREATMENT OF A LIFESAVING THERAPY TO ONE
14 OF HIS FAMILY MEMBERS, IT WOULD BE A NIGHTMARE. AND
15 THE COMPANY COULDN'T DO IT.

16 CHAIRMAN PENHOET: THAT'S A LITTLE DIFFERENT.

17 DR. REED: IT MIGHT BE AS SIMPLE AS PUTTING
18 IN A PROVISION, UNLESS OTHERWISE NEGOTIATED WITH CIRM
19 STAFF, SO THAT THERE IS THE CLAUSE IN THERE THAT YOU
20 CAN GO AND NEGOTIATE ANOTHER RANGE WITH CIRM, BUT YOU'D
21 HAVE TO MAKE YOUR CASE TO CIRM, AND IT WOULD HAVE TO BE
22 COMPELLING OBVIOUSLY.

23 DR. LOVE: I'M JUST PUTTING IN THE CAUTION.
24 I JUST KNOW THAT IN THE U.S., YOU GET SUED ANY TIME
25 PEOPLE ARE DYING AND THE COMPANY IS TRYING TO CONTROL A

1 LIMITED PRODUCT. AND WE WERE PRETTY MUCH IN A POSITION
2 AT GENENTECH WHERE WE HAD TO GET OUTSIDERS TO COME IN
3 AND PRETTY MUCH DICTATE HOW WE WERE DISTRIBUTING A
4 LIMITED DRUG WHEN WE WERE LIMITED.

5 DR. PIZZO: SO, TED OR DUANE, HAVING LIVED ON
6 THE OTHER SIDE OF THIS, ONCE AS AN INVESTIGATOR WHERE
7 ONE IS MAKING AN APPEAL ON BEHALF OF A PATIENT, USUALLY
8 YOU HAVE TO FULFILL A SET OF CRITERIA. AND COULD THERE
9 BE AN INSTANCE, A CAVEAT, THAT WOULD INCLUDE PREFERENCE
10 RATHER THAN OBLIGATION FOR IT BEING A CITIZEN OF
11 CALIFORNIA? AMONG OTHER THINGS, IT WOULD BE PART OF
12 THE CRITERIA, SO THERE WOULD BE A CLEAR INDICATION OF
13 THAT, BUT IT WOULD ALLOW A LITTLE BIT OF FLEXIBILITY.

14 MR. ROTH: I LIKE THAT WORD VERY MUCH. I
15 THINK THAT'S WHAT I WAS GETTING AT, THAT WHENEVER
16 POSSIBLE, THERE'S PREFERENCE GIVEN TO CALIFORNIA. AND
17 I THINK BY US DOING IT, THE COMPANIES HAVE A RATIONALE.

18 DR. PIZZO: THAT WAY WE'RE NOT OBLIGATING.
19 WE'RE LISTING IT AS ONE OF THE CRITERIA.

20 MR. ROTH: IN THE OTHER CASES OF GENENTECH
21 AND CHIRON, THERE WAS NO WAY YOU COULD JUSTIFY
22 LIMITING. HERE, WE'RE GIVING YOU A RATIONALE FOR WHY
23 THAT'S A REQUIREMENT.

24 CHAIRMAN PENHOET: WE'RE NOT DIRECTING IT TO
25 ANY SPECIFIC INDIVIDUAL. IT'S A POPULATION.

1 MR. SHEEHY: THERE ARE SUBJECTIVE CRITERIA
2 THAT ARE IN PLACE IN TRANSPLANTS, FOR INSTANCE.

3 CHAIRMAN PENHOET: FOR SURE THERE ARE. YEAH.

4 MR. SHEEHY: THERE'S A WHOLE HOST OF THEM
5 THAT ARE ACTUALLY PREJUDICIAL TO PEOPLE WHO, FOR
6 INSTANCE, ARE IN THE ALTERNATIVE FAMILY STRUCTURE. SO
7 WE CAN PUT IN PREFERENCES FOR CALIFORNIA WITHIN THAT
8 SAME CONSTRUCT.

9 DR. LOVE: I THINK PREFERENCES MIGHT WORK,
10 BUT THAT'S OBVIOUSLY NOT WHAT WE STARTED OUT TALKING
11 ABOUT, WHICH REALLY SCARED ME, QUITE FRANKLY. I THINK
12 AS PUBLICLY TRADED COMPANY, YOU ARE GOING TO ULTIMATELY
13 HAVE TO HAVE ALLEGIANCE TO MORE THAN CALIFORNIA WHEN IT
14 COMES DOWN TO SOMEBODY DYING HERE VERSUS ELSEWHERE.
15 AND PREFERENCE IS MAYBE A VERY WORKABLE APPROACH. IF
16 IT'S A LIST OF TESTS, I THINK IT WOULD BE A PROBLEM.

17 CHAIRMAN PENHOET: OKAY. IF IT'S A
18 PREFERENCE, IT PROBABLY DOESN'T END UP IN OUR
19 REGULATIONS. IT ENDS UP IN OUR POLICY.

20 MR. GILLENWATER: TODD GILLENWATER WITH THE
21 CALIFORNIA HEALTHCARE INSTITUTE AGAIN. I'VE BEEN ASKED
22 BY OUR MEMBERSHIP, AS PART OF A SURVEY WE HAVE DONE,
23 THAT INCLUDES LARGE AND SMALL, BIOTECH, DIAGNOSTICS,
24 THE VENTURE CAPITAL COMMUNITY, TO PUT THIS, AT LEAST,
25 IN THE RECORD FOR TODAY, WHICH HAS BEEN THE RESPONSE

1 THAT THE CUMULATIVE EFFECT OF A REVENUE SHARING
2 REQUIREMENT, ACCESS REQUIREMENTS, AND THIS PRICING
3 REQUIREMENT, ESPECIALLY ON SMALL, EMERGENT
4 VENTURE-BACKED FIRMS, WOULD RESULT IN VERY SIGNIFICANT
5 REFUSAL BY PEOPLE TO TOUCH ANYTHING THAT IS FUNDED BY
6 CIRM THAT HAS THESE REQUIREMENTS.

7 I MEAN THE OVERWHELMING RESPONSE HAS BEEN
8 THAT OVER 80 PERCENT OF THE RESPONSES, AND THIS WAS NOT
9 A SCIENTIFIC SURVEY, I WILL MAKE THAT CLEAR, THAT OVER
10 80 PERCENT OF THE RESPONDENTS TO THE SURVEY HAVE
11 INDICATED THAT THEY WOULD BE MUCH LESS LIKELY, IF NOT A
12 HUNDRED PERCENT LESS LIKELY, TO EITHER ACCEPT THE MONEY
13 FROM CIRM OR LICENSE ANYTHING WHICH WAS CIRM-FUNDED IF
14 THE THREE CUMULATIVE REQUIREMENTS ARE PLACED ON THEM.
15 I JUST WANTED TO PUT THAT IN THE RECORD AT THE REQUEST
16 OF OUR MEMBERSHIP. THANK YOU.

17 CHAIRMAN PENHOET: IF WE DON'T GET ANY
18 APPLICATIONS FROM INDUSTRY, WE CAN CHANGE OUR POLICY.

19 MR. ROTH: COULD I ASK? IS IT THE THIRD ONE
20 THAT'S THE BIGGEST?

21 MR. GILLENWATER: THERE IS RECOGNITION THAT
22 IN THE LANGUAGE OF PROP 71 THERE WAS AN EXPECTATION
23 THAT THE STATE WOULD RECEIVE A DIRECT FINANCIAL
24 BENEFIT, THE PAYBACK, THE ROYALTIES, HOWEVER YOU MIGHT
25 PUT IT. THERE IS ALSO AN UNDERSTANDING THAT, AS HAS

1 BEEN DISCUSSED REPEATEDLY, THAT MOST COMPANIES DO HAVE
2 ACCESS PLANS OF SOME SORT. THAT MANY SMALL COMPANIES
3 DO NOT SIMPLY BECAUSE THEY DON'T HAVE THE
4 INFRASTRUCTURE TO BE ABLE TO DO THAT. IT'S THE THIRD
5 ONE WHICH IS A VERY -- THE DIRECTION THAT SCOTT IS
6 GOING AND THAT WE'VE DISCUSSED ON TRYING TO FIGURE OUT
7 THE DETAILS OF THIS, UNDERSTANDING IT'S STILL A WORK IN
8 PROGRESS, THE LANGUAGE THAT HAS BEEN PRESENTED SO FAR
9 IS THAT THE COMPLEXITY OF THIS PRICING REQUIREMENT IS
10 KIND OF THE FINAL NAIL IN THE COFFIN THAT THEY JUST
11 HAVE NOT BEEN ABLE TO UNDERSTAND AND GET THEIR ARMS
12 AROUND THE COMPLEXITY OF THAT.

13 SO, YES, IT'S THE THIRD ONE, THAT THE PRICING
14 REQUIREMENT, THAT THE RESPONSE HAS BEEN THAT THIS IS
15 THE ONE THAT WOULD BE THE MOST PROBLEMATIC. OF COURSE,
16 IF IT COULD EXPLAINED AT SOME POINT, AND I KNOW THAT'S
17 WHAT'S BEING DONE NOW, THAT MIGHT BE DIFFERENT. BUT UP
18 TILL THIS POINT, THAT HAS BEEN THE RESPONSE. THEY JUST
19 DON'T UNDERSTAND HOW THAT COULD BE ENACTED IN A WAY
20 THAT AT THE EARLY LICENSING STAGE INVESTORS AND SMALL
21 COMPANIES COULD UNDERSTAND AND MAKE IT A VALUABLE
22 PROPOSITION TO EITHER ACCEPT CIRM FUNDING OR LICENSE A
23 CIRM-FUNDED TECHNOLOGY.

24 MR. ROTH: I'LL JUST FOR THE RECORD ALSO
25 STATE THAT THERE WAS A STEM CELL RESEARCH PROGRAM ON

1 THE MESA I ATTENDED, AND THERE WAS A PANEL, WHICH SOME
2 OF THE AUDIENCE WERE ON, BUT THE PANEL IMMEDIATELY
3 STARTED TALKING ABOUT 25-PERCENT ROYALTIES. YOU KNOW,
4 THAT RESONATES. THERE'S NOT AN UNDERSTANDING OF THIS
5 CONCEPT IN THE FOR-PROFIT WORLD, AND WE'VE GOT TO DO A
6 BETTER JOB OF MAKING SURE WHEREVER WE SPEAK THAT THAT
7 GETS CLARIFIED BECAUSE THEY JUST IMMEDIATELY SAY, "ARE
8 YOU GUYS CRAZY?" I SAID NO.

9 CHAIRMAN PENHOET: WE TRIED, BUT WE NEED TO
10 TRY HARDER.

11 MR. SIMPSON: EVEN I GET IT.

12 CHAIRMAN PENHOET: ANY FURTHER COMMENTS? SO
13 I GUESS THERE ARE TWO ISSUES THEN. DUANE HAS SUGGESTED
14 THAT WE TAKE THE GROUND OF THE ACCESS POLICY ENHANCED
15 WITH THE PREFERENTIAL ACCESS TO CALIFORNIANS IN CASE OF
16 SCARCITY OF PRODUCT. WE'LL HAVE TO WORK ON THE
17 LANGUAGE OF THAT. AND THAT WE ALL RECOGNIZE THAT WE'RE
18 NOT THERE YET WITH RESPECT TO PRICING ISSUES. WE HAVE
19 TO DO A LOT MORE WORK IN THAT AREA TO BE VERY CLEAR
20 THAT WHAT WE DO ACTUALLY CARRIES OUT THE INTENT OF WHAT
21 WE WANTED TO DO, WHICH IS NOT TO DISADVANTAGE
22 CALIFORNIANS VIS-A-VIS OTHER AMERICANS IN THE WORST
23 CASE OR BEST CASE, I GUESS. AND THAT IN DOING SO, WE
24 HAVE TO COME UP WITH SOMETHING WHICH IS SIMPLE AND
25 WORKABLE. AND WE'RE NOT THERE YET, SO WE'LL HAVE TO

1 COME BACK TO YOU ON THAT ISSUE.

2 MR. SHEEHY: I JUST, ONE POINT. WE SHOULD
3 MAKE SURE THAT THEY'RE CONSISTENT ACROSS BOTH BECAUSE
4 WE'RE TALKING ABOUT THIS PREFERENCE NOW WHICH DOESN'T
5 EXIST IN THE NOT-FOR-PROFIT RULES SO THAT THESE RULES
6 ARE CONSISTENT ACROSS BOTH.

7 CHAIRMAN PENHOET: IF IT'S A PREFERENCE, IT
8 WON'T BE CODIFIED IN LAW. IT WILL BE IN OUR POLICIES.
9 SO I THINK --

10 DR. PRIETO: POLICIES FOR BOTH PROFIT AND
11 NONPROFIT.

12 MR. SHEEHY: WHY COULDN'T A PREFERENCE BE
13 EXPRESSED AS -- CERTAINLY THERE'S SUBJECTIVE CRITERIA
14 THAT GO INTO MAKING SOME OF THESE DECISIONS. IT COULD
15 BE INCLUDED. WE COULD DIRECT, AS A MATTER OF
16 REGULATION, THAT SUBJECTIVE CRITERIA THAT COME INTO
17 PLAY IN MAKING DECISIONS ABOUT WHO TO GIVE EARLY ACCESS
18 TO THESE THERAPIES SHOULD INCLUDE CALIFORNIA
19 CITIZENSHIP. ANY KIND OF BIOLOGICAL -- I WOULD THINK.
20 THERE'S SUBJECTIVE CRITERIA THAT GO INTO PLACE WITH
21 MUNOZ EMPLOYEES. SO WHY WOULDN'T SUBJECTIVE CRITERIA
22 BE PART -- MAYBE TED KNOWS THIS FROM GENENTECH, BUT THE
23 PEOPLE THAT THEY HIRED MUST AT SOME POINT USE SOME
24 SUBJECTIVE CRITERIA TO EVALUATE WHO TO GIVE TO.

25 CHAIRMAN PENHOET: IN OUR CASE, WE USED A

1 LOTTERY. IT WAS THE ONLY WAY WE COULD DECIDE.

2 MR. SHEEHY: IN THAT CASE WE WOULDN'T BE ABLE
3 TO EMPLOY THAT.

4 CHAIRMAN PENHOET: I DON'T KNOW WHAT
5 GENENTECH DID.

6 MR. TOCHER: I JUST WANTED TO SPEAK UP TO THE
7 SORT OF IS IT A REQUIREMENT OR ISN'T IT. YOU WOULD --
8 GENERALLY SPEAKING, YOU DON'T WANT MERELY ASPIRATIONAL
9 LANGUAGE IN A REGULATION. FROM OAL'S PERSPECTIVE, IF
10 IT'S NOT A REQUIREMENT, THEN IT SHOULDN'T BE THERE.

11 FOR PURPOSES OF CLARITY, SO THAT THE REGULATED
12 COMMUNITY UNDERSTANDS ITS OBLIGATIONS, IT WANTS TO SEE
13 WHAT IS REQUIRED OR HAS TO DO. BASICALLY THE TEST
14 THERE IS IF WE IMPOSED SOME SORT OF CONSEQUENCE ON A
15 RECIPIENT FOR FAILING TO DO ONE OF THOSE THINGS, THAT'S
16 SORT OF YOUR TEST. IF WE WERE TO MAKE SOMETHING A
17 CONSEQUENCE FOR FAILING TO ABIDE BY IT, THAT'S
18 SOMETHING YOU DEFINITELY WANT IN THE REGULATION.

19 IF YOU'RE NOT, IF WE'RE MERELY ASKING, THAT'S
20 WHAT WE ASPIRE TO, THAT'S WHAT WE WANT TO ENCOURAGE,
21 THEN YOU DON'T NEED THAT IN THE REGULATION. AND IF YOU
22 THROW IT IN, OAL MAY ASK YOU TO KICK IT OUT.

23 AND WHAT I HAVE HEARD IS THAT WE'RE NOT
24 NECESSARILY GOING TO TRIGGER A -- WE'RE NOT NECESSARILY
25 REQUIRING THAT OR -- I'M SORRY -- NOT NECESSARILY

1 ASSESSING A CONSEQUENCE ON A GRANTEE. WE ASK THEM TO
2 GIVE A PREFERENCE; BUT WHAT I'VE HEARD IS THAT IF THERE
3 ARE REASONS THAT THEY CAN'T COMPLY WITH THAT, THEN --

4 CHAIRMAN PENHOET: I THINK, AS DUANE
5 ARTICULATED IT, IT WAS ASPIRATIONAL AT THE END.

6 MR. ROTH: BUT, SCOTT, I THINK IT DOES FIT ON
7 PAGE 29. WE HAVE A STATEMENT HERE ABOUT ACCESS, AND I
8 THINK YOU MIGHT TAKE A LOOK AT THAT AND ADD THIS, AND
9 IF THERE IS A LIMITED SUPPLY, PREFERENCE BE GIVEN
10 WHEREVER POSSIBLE TO CITIZENS OF CALIFORNIA, PATIENTS
11 OF CALIFORNIA.

12 CHAIRMAN PENHOET: SO IT WOULD BE IN OUR
13 POLICY IN ANY CASE, BUT IT MAY NOT BE IN THE
14 REGULATIONS. THAT'S THE DISTINCTION WE'RE TRYING TO
15 MAKE.

16 DR. PRIETO: ALSO REQUIRE GRANTEES TO
17 JUSTIFY, IF THEY WERE TO EXPLAIN TO CIRM WHY THEY WERE
18 NOT ABLE TO GIVE A PREFERENCE.

19 MR. TOCHER: THAT'S DEFINITELY SOMETHING YOU
20 WANT AND YOU COULD.

21 DR. PRIETO: THAT COULD BE IN A REGULATION.

22 MR. SIMPSON: PUBLIC COMMENT. I'D JUST LIKE
23 TO SPEAK -- JOHN SIMPSON FROM -- CAN THEY HEAR ME OKAY
24 FROM HERE? I'M NOT SURE.

25 CHAIRMAN PENHOET: IF YOU DON'T MIND, JOHN.

1 MR. SIMPSON: JOHN SIMPSON FROM THE
2 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. I WAS
3 REALLY GRATIFIED WHEN YOU FIRST MADE THE MOTION,
4 MR. ROTH, BECAUSE I THOUGHT IT WAS REALLY THE FIRST
5 TIME THERE WAS A CLEAR RECOGNITION OF THE TAXPAYERS
6 PUTTING MONEY INTO THIS AND THAT THERE SHOULD BE SOME
7 DIRECT PAYBACK. SO I REALLY THINK THAT YOU'VE GOT TO
8 GET IT IN YOUR REGULATIONS.

9 AND I THINK TO BACK OFF FROM THAT IS A
10 MISTAKE. AND I THINK PREFERENCE IS AT THE MINIMUM, BUT
11 I THINK YOU SHOULD GO FARTHER THAN THAT. PEOPLE ARE
12 ASKING WHAT'S IN THIS FOR THE \$6 BILLION THAT WE'RE
13 PAYING? AND THIS IS ONE VERY CLEAR THING THAT YOU CAN
14 POINT TO. I JUST THINK IT'S ESSENTIAL THAT YOU HAVE IT
15 CRYSTAL CLEAR. THANK YOU.

16 MR. KRSTICH: MY NAME IS JEFF KRSTICH. I'M
17 WITH INTERNATIONAL STEM CELL CORPORATION. WE'RE A
18 SOON-TO-BE PUBLICLY TRADED COMPANY HERE IN CALIFORNIA
19 PROVIDING STEM CELL THERAPIES. SO I WANTED TO SPEAK UP
20 A LITTLE BIT ON BEHALF OF SOME OF THE COMMENTS THAT
21 WERE MADE HERE EARLIER AND JUST PROVIDE A LITTLE INPUT
22 AS TO THE TYPE OF COMPANIES THAT WILL BE HOPEFULLY
23 ACCESSING THESE DOLLARS HERE, ESPECIALLY THESE AREAS
24 HERE.

25 ONE ON ACCESS, HAVING BEEN INVOLVED IN THE

1 PAST, IT'S PREFERENCES ARE NICE. AND I, BEING A
2 CALIFORNIA RESIDENT, WOULD PREFER THAT. I'VE ALSO BEEN
3 INVOLVED WITH IT. WHEN THE FEDERAL GOVERNMENT COMES
4 IN, SPECIFICALLY SERUM ALBUMIN SITUATION, THEY GRABBED
5 IT FOR ALL THE FEDERAL TROOPS, AND THERE WAS NO -- EVEN
6 THE LOTTERY WE HAD IN PLACE GOT BLOWN AWAY. SO YOU
7 DON'T HAVE CONTROL OF THAT AS A COMPANY.

8 YOU CAN GIVE PREFERENCES, BUT EVERY TIME THAT
9 YOU ARE GIVEN MANDATES AND THE FEDERAL GOVERNMENT COMES
10 IN ON TOP OF THAT, YOU CREATE PROBLEMS WHERE YOU'VE GOT
11 TO GO BACK AND SPEND ADDITIONAL TIME AND MONIES AND
12 ENERGIES TO TRY AND SOLVE THAT. SO I LIKE THE LANGUAGE
13 TOWARDS PREFERENCES. IT FITS VERY WELL. ALL BE IT
14 SAID, I WOULD PREFER THAT IT GO TOWARDS CALIFORNIA
15 CITIZENS IN THAT REGARD.

16 THE ISSUE OF PRICING IS COMPLETELY CONFUSING.
17 THERE ARE IMPLEMENTS IN PLACE RIGHT NOW. WHAT ARE
18 PROPOSED AND WHAT THE GUIDELINES ARE, AS A PROSPECTIVE
19 COMPANY THAT'S GOING TO BE PRICING PRODUCTS RIGHT NOW,
20 WE CAN FALL IN LINE WITH WHAT IS OUT THERE. IT BECOMES
21 ONEROUS AS FAR AS THE NEW REGULATIONS UPON REGULATIONS
22 UPON GUIDELINES BETWEEN FEDERAL, STATE, MEDICARE,
23 MEDI CAID, DOD, DEPARTMENT OF DEFENSE. ALL OF A SUDDEN
24 I'VE HIRED TWO MORE PEOPLE JUST TO HANDLE THE PRICING
25 ISSUE. IT SHOULDN'T BE THAT WAY, ESPECIALLY FOR A

1 START-UP COMPANY.

2 AND THEN LASTLY, THE ASPECT OF ACCESS TO
3 INDIGENT OR PEOPLE WHO CAN'T AFFORD AND SO FORTH,
4 AGAIN, BEING INVOLVED IN OTHER COMPANIES, IMPLEMENTING
5 THOSE ACCESS PROGRAMS VERY EXPENSIVE. THEY AREN'T EASY
6 TO DO. FOR A START-UP COMPANY IT IS AN EXTREMELY
7 EXPENSIVE PROCESS. BIOGEN, BEFORE IT WAS BIOGEN IDEC,
8 WE IMPLEMENTED A PROCESS. IT TOOK US ABOUT TWO YEARS
9 BEFORE WE COULD IMPLEMENT THAT PROCESS. OUR REVENUES
10 HAD TO GROW TO A SIGNIFICANT LEVEL SO THAT WE COULD
11 AFFORD TO FUND THE INDIGENT PROGRAM AND FUND THE PEOPLE
12 THAT COULD APPLY THE INDIGENT PROGRAM. SO IT'S NOT AS
13 EASY AS JUST SAYING THE FIRST DOLLAR. IT WILL HAPPEN
14 THAT YOU CAN SET IT ASIDE. IT IS AN EXPENSIVE PROCESS.
15 IT'S NOT ONE THAT WE WOULD CHOOSE NOT TO DO. IT'S JUST
16 ONE THAT YOU NEED TO RECOGNIZE THAT PHIZER AND MERCK
17 CAN DO IT RIGHT NOW. THEIR INFRASTRUCTURE IS ADAPTED
18 IT TO. NEW COMPANIES, START-UP COMPANIES, COMPANIES
19 THAT ARE UNDER HUNDRED MILLION IN MARKET CAP RIGHT NOW,
20 IT CAN BE VERY ONEROUS TO TRY AND IMPLEMENT THAT.
21 THANK YOU. JUST A COUPLE COMMENTS IN THAT REGARD.

22 CHAIRMAN PENHOET: ONE THING I WOULD POINT
23 OUT IS OUR REQUIREMENT IS THAT THE COMPANY HAVE A PLAN
24 FOR ACCESS AT THE TIME, WHICH WOULD HAVE TO BE
25 APPROVED, AND PRESUMABLY THERE WOULD BE A DIALOGUE

1 ABOUT WHAT THAT PLAN WAS, THAT WE WOULD DO IT WHEN WE
2 GOT TO X.

3 MR. KRSTICH: THAT'S VERY ACCEPTABLE.

4 MR. ROTH: I WAS GOING TO SAY I HOPE THAT
5 FLEXIBILITY IS IN THERE, THAT YOU HAVE TO PRESENT A
6 PLAN; AND IF THERE'S A HARDSHIP AND IT CAN'T BE DONE,
7 THEN THAT SHOULD BE PART OF YOUR --

8 MR. KRSTICH: DEFINITELY. AND THAT'S NOT AN
9 ISSUE.

10 CHAIRMAN PENHOET: WHEN YOU WILL BE ABLE TO
11 DO IT. JEFF.

12 MR. SHEEHY: I WAS GOING TO MAKE THE SAME
13 POINT. IT'S A PLAN AND IT'S AT THE POINT OF
14 COMMERCIALIZATION, AND YOU CAN MAKE SOME SORT OF
15 PROJECTION, SO THERE'S A TON OF FLEXIBILITY BUILT IN.

16 MR. KRSTICH: THERE'S NO ISSUES ON THE PLANS.
17 IT'S AS WE WOULD GROW --

18 MR. SHEEHY: AND WE WOULDN'T DICTATE THE PLAN
19 TO YOU. WHAT WE SEE AS AN INDUSTRY STANDARD WE WOULD
20 WANT TO HAVE APPLIED TO OUR GRANTEES IF THEY WERE
21 SUCCESSFUL.

22 MR. KRSTICH: TOTALLY UNDERSTOOD.

23 MR. SHEEHY: AT A REASONABLE TIME.

24 MR. KRSTICH: AGAIN, AS WE WOULD GROW. BASED
25 ON THE GRANT, WE WOULD GROW, BE ABLE TO AFFORD TO

1 IMPLEMENT THE PLAN THAT WE WOULD PUT IN PLACE THERE, SO
2 THAT WOULD BE FINE.

3 DR. PRIETO: I'D LIKE TO JUST ADDRESS TWO OF
4 THOSE POINTS. THAT I THINK THE LANGUAGE FOR PREFERENCE
5 WOULD BE A PREFERENCE OR JUSTIFIED TO THE CIRM IF YOU
6 ARE UNABLE. AND IF SOME SITUATION ANALOGOUS TO WHAT
7 CAME UP WITH ALBUMIN CAME UP, OBVIOUSLY THAT'S THE
8 JUSTIFICATION.

9 WITH PRICING, I THINK WE WANT TO MAKE CLEAR
10 THAT THE PRICING REQUIREMENTS WOULD BE PEGGED TO
11 EXISTING PROGRAMS AND WOULD ONLY KICK IN IF THOSE
12 PROGRAMS DID NOT APPLY.

13 MR. KRSTICH: THAT'S FINE. AGAIN, IF IT'S
14 THAT CLEAR-CUT, TO YOUR POINT IN THE VERY BEGINNING,
15 SIMPLIFICATION MAKES IT EASY ON BOTH SIDES. THINGS,
16 EVEN THE LITTLE PART HERE WHERE YOU TALKED ABOUT A 2-
17 TO 5-PERCENT ROYALTY FEE, I WOULD FORECAST THAT THAT'S
18 GOING TO BE DIFFICULT TO NEGOTIATE YOU AT CIRM AND
19 IMPLEMENTING THAT. IT'S GOING TO BE A NEGOTIATING
20 POINT EACH TIME SOMEBODY COMES UP AND COULD BE A VERY
21 COSTLY PROCESS VERSUS SETTING A SET FIGURE OF 2 OR 3 OR
22 4 OR 5 OR WHATEVER IT MAY BE AT THIS STAGE. I DON'T
23 MEAN TO GO BACK INTO AN EARLIER PART OF THE DISCUSSION
24 HERE, BUT JUST BRING THAT UP.

25 CHAIRMAN PENHOET: THANK YOU. ANY OTHER

1 COMMENTS FROM THE TASK FORCE? ANY FURTHER COMMENTS ON
2 THE ISSUE OF WHETHER WE SHOULD JUST FOCUS THESE THINGS
3 ON THERAPIES OR WHETHER WE SHOULD CONTINUE TO HAVE THEM
4 COVER BOTH THERAPIES AND DIAGNOSTICS? I THINK WE'VE
5 HAD A COUPLE COMMENTS IN THIS SIDE IN FAVOR OF FOCUSING
6 ON THERAPIES. FRANCISCO POINTS OUT THERE ARE SOME
7 EXPENSIVE DIAGNOSTICS OUT THERE.

8 MR. ROTH: I WOULD FOCUS ON THERAPIES; AND IF
9 WE HAVE A NEED TO COME BACK AND REVISIT THE POLICY ON
10 DIAGNOSTICS, DO IT, BUT THERAPIES IS PROBABLY, WITH
11 DRUGS, WHERE WE SHOULD BE FOCUSING OUR EFFORT ON THIS.

12 CHAIRMAN PENHOET: ANY COMMENTS FROM ANYONE
13 ELSE ON THE TASK FORCE ON THIS DIAGNOSTICS VERSUS -- I
14 MEAN FOCUS ON THERAPIES VERSUS TRYING TO COVER BOTH
15 DIAGNOSTICS AND THERAPIES WITH THIS? ACCESS PLANS
16 DON'T REFER PROBABLY.

17 DR. BRYANT: I WOULD PREFER TO FOCUS ON
18 THERAPIES, THERAPEUTICS.

19 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

20 DR. PIZZO: I'M COMFORTABLE WITH THAT AS
21 WELL.

22 CHAIRMAN PENHOET: OKAY.

23 MR. GILLENWATER: TODD GILLENWATER WITH THE
24 CALIFORNIA HEALTHCARE INSTITUTE. JUST ONE QUESTION.
25 AND I APPRECIATE THE COMMENTS ON THE FLEXIBILITY OF THE

1 REQUIREMENT TO SUBMIT AN ACCESS PLAN. I MAY BE JUST
2 READING THIS INCORRECTLY. BUT IN THE MARCH-IN
3 REQUIREMENTS, THERE IS A MARCH-IN TRIGGER THAT TRIGGERS
4 BECAUSE THE AWARDEE OR LICENSEE HAS FAILED TO ADHERE TO
5 THE AGREED-UPON PLAN FOR ACCESS TO RESULTANT THERAPIES.
6 AND I WOULD HOPE THAT THAT WOULD ALSO INCLUDE EXPLICIT
7 FLEXIBILITY ON WHAT THE DEFINITION OF ADHERENCE MEANS.

8 MR. ROTH: TODD, DOESN'T THAT MEAN THEIR
9 PLAN?

10 CHAIRMAN PENHOET: NO. AN AGREED-UPON PLAN.

11 MR. ROTH: BUT THEY SENT A PLAN, WE AGREED TO
12 IT, AND THEN THEY DON'T ADHERE TO IT.

13 DR. PRIETO: ALL IT SAYS IS YOU MUST DO WHAT
14 YOU SAY YOU'RE GOING TO DO.

15 MR. GILLENWATER: RIGHT.

16 DR. PRIETO: IF YOU DON'T, THEN WE CAN MARCH
17 IN.

18 MR. GILLENWATER: IS CIRM, AND THIS IS JUST A
19 POINT OF CLARIFICATION, THE ONLY ENTITY IN THE STATE
20 THAT COULD INITIATE MARCH-IN?

21 CHAIRMAN PENHOET: NO. THE ATTORNEY GENERAL
22 HAS THE ULTIMATE AUTHORITY TO DO THAT.

23 MR. GILLENWATER: CAN THE PUBLIC PETITION FOR
24 MARCH-IN?

25 MR. SIMPSON: YES.

1 CHAIRMAN PENHOET: I SUPPOSE SO.

2 MR. GILLENWATER: OKAY. THEN THAT WOULD BE
3 ONE OF THE CONCERNS I WOULD HAVE.

4 MR. ROTH: THAT ONLY APPLIES, TODD, IF THEY
5 VIOLATE THEIR OWN PLAN THAT WE AGREED TO.

6 CHAIRMAN PENHOET: THAT'S CORRECT.

7 MR. GILLENWATER: COULD FINANCIAL -- WELL, I
8 PRESUME THAT THE AGREED-UPON PLAN COULD BE AMENDED IF
9 THEY CANNOT AFFORD IT, CERTAINLY.

10 DR. MAXON: THERE IS A CURE PERIOD.

11 CHAIRMAN PENHOET: THERE IS ALSO A CURE
12 PERIOD.

13 MR. GILLENWATER: OKAY. I JUST WANTED TO
14 MAKE SURE. THANK YOU.

15 CHAIRMAN PENHOET: OKAY. SO I THINK WE HAVE
16 AGREEMENT. PROBABLY WE SHOULD TAKE A VOTE ON THESE TWO
17 THINGS THAT, FIRST OF ALL, THAT WE AGREE THAT THE FIRST
18 DOLLAR IN WILL TRIP THE NEED TO PROVIDE AN ACCESS PLAN
19 AS INDICATED IN THE OTHER ASPECTS OF THE POLICY WE'VE
20 BEEN DISCUSSING. SO THAT'S THE FIRST ISSUE. SO MAYBE
21 WE CAN DO A VOICE VOTE.

22 DR. MAXON: WE NEED A MOTION.

23 CHAIRMAN PENHOET: SOMEONE HAS TO MAKE A
24 MOTION.

25 DR. PRIETO: SO MOVED.

1 MR. ROTH: SECOND.
2 MS. KING: WE ACTUALLY HAVE TO DO A ROLL CALL
3 VOTE JUST BECAUSE IT'S A PHONE CALL. WE ACTUALLY NEED
4 THE VOTE.
5 CHAIRMAN PENHOET: GO AHEAD, MELISSA.
6 MS. KING: SUSAN BRYANT.
7 DR. BRYANT: YES.
8 MS. KING: TED LOVE.
9 DR. LOVE: YES.
10 MS. KING: ED PENHOET.
11 CHAIRMAN PENHOET: YES.
12 MS. KING: PHIL PIZZO.
13 DR. PIZZO: YES.
14 MS. KING: FRANCISCO PRIETO.
15 DR. PRIETO: YES.
16 MS. KING: JOHN REED.
17 DR. REED: YES.
18 MS. KING: DUANE ROTH.
19 MR. ROTH: YES.
20 MS. KING: JEFF SHEEHY.
21 MR. SHEEHY: YES.
22 MS. KING: OS STEWARD.
23 DR. STEWARD: YES.
24 MS. KING: JANET WRIGHT.
25 DR. WRIGHT: YES.

1 CHAIRMAN PENHOET: THEN THE SECOND ONE IS
2 THERE'S A MOTION -- I'LL MAKE A MOTION TO ESSENTIALLY
3 FOCUS BOTH OF THESE REQUIREMENTS ON THERAPIES ONLY.
4 MS. KING: SECOND?
5 CHAIRMAN PENHOET: IS THERE A SECOND?
6 MR. ROTH: SECOND.
7 CHAIRMAN PENHOET: OKAY.
8 MS. KING: SUSAN BRYANT.
9 DR. BRYANT: YES.
10 MS. KING: TED LOVE.
11 DR. LOVE: YES.
12 MS. KING: ED PENHOET.
13 CHAIRMAN PENHOET: YES.
14 MS. KING: PHIL PIZZO.
15 DR. PIZZO: YES.
16 MS. KING: FRANCISCO PRIETO.
17 DR. PRIETO: YES.
18 MS. KING: JOHN REED.
19 DR. REED: YES.
20 MS. KING: DUANE ROTH.
21 MR. ROTH: YES.
22 MS. KING: JEFF SHEEHY.
23 MR. SHEEHY: YES.
24 MS. KING: OS STEWARD.
25 DR. STEWARD: YES.

1 MS. KING: JANET WRIGHT.
2 DR. WRIGHT: YES.
3 CHAIRMAN PENHOET: OKAY.
4 MR. SIMPSON: YOU NEED ONE ON CALI FORNIA
5 PREFERENCE OF SOME KIND, DON' T YOU?
6 CHAIRMAN PENHOET: THEN WE NEED ONE ON THE --
7 WE DO. SO DO WE HAVE SOME LANGUAGE, DUANE, ON THE
8 CALI FORNIA PREFERENCE?
9 MR. ROTH: LET ME TRY. IN THE EVENT OF A
10 LIMITED SUPPLY OF A THERAPY FUNDED BY CIRM, WHEREVER
11 FEASIBLE PREFERENCE WILL BE GIVEN TO CALI FORNIA
12 PATIENTS.
13 DR. WRIGHT: DID WE SAY THAT' S IN THE SETTING
14 OF A LIFE-THREATENING INDICATION FOR THE THERAPY?
15 MR. ROTH: JANET, I THINK I' M GOING TO SAY IT
16 IF ANY SHORTAGE OF A CIRM-FUNDED THERAPY BECOMES
17 AVAI LABLE, LIFE-THREATENING OR NOT, WHENEVER FEASIBLE
18 PREFERENCE BE GIVEN TO CALI FORNIA PATIENTS. THAT
19 GIVES -- I WANT TO MAKE SURE THAT IT GIVES THE
20 FLEXI BILITY TO THE MEDICAL COMMUNI TY TO DETERMINE THOSE
21 CRITERIA. WHENEVER THERE' S FLEXI BILITY --
22 DR. PRIETO: I' M CONCERNED THAT WHENEVER
23 FEASIBLE MIGHT BE A LITTLE TOO BROAD FROM WHAT WE HEARD
24 EARLIER. WE WANT TO ADD THAT IF UNABLE TO GIVE SUCH
25 PREFERENCE, THE GRANTEE WILL PROVIDE JUSTI FICATION TO

1 CIRM EXPLAINING WHY. THAT PUTS A MANDATE IN PLACE SO
2 THAT WE CAN MAKE IT PART OF THE REGULATION.

3 CHAIRMAN PENHOET: IT TRIPS A CONVERSATION.
4 I THINK YOU NEED SOME REMEDY IN ORDER TO GET IT IN THE
5 REGULATION. THAT WOULD BE THE REMEDY, I GUESS.

6 DR. STEWARD: CAN I TRY SOMETHING A LITTLE
7 DIFFERENT?

8 MR. ROTH: PLEASE DO.

9 DR. STEWARD: WHICH IS SORT OF BASED ON THE
10 FACT THAT THIS IS LIKELY TO BE A SITUATION WHERE THERE
11 ARE GOING TO BE NUMBER OF CRITERIA THAT WILL BE TAKEN
12 INTO ACCOUNT, PERHAPS, IN SETTING A LOTTERY IN PLACE.
13 MY SUGGESTION IS SOMETHING ALONG THESE LINES. IN
14 DETERMINING CRITERIA FOR DISTRIBUTING THAT THERAPY, AN
15 IMPORTANT FACTOR SHOULD BE CALIFORNIA RESIDENCY.

16 MR. ROTH: I LIKE THAT. I WOULD RATHER SEE
17 THE WORD "PREFERENCE" BE GIVEN TO CALIFORNIA RESIDENCY.
18 I THINK THE WORD "PREFERENCE" IS AN IMPORTANT TERM. SO
19 I LIKE WHAT YOU SAID, OS, BUT I COULD SAY AT THE END,
20 IF YOU CAN WORK THE WORD "PREFERENCE" BE GIVEN TO
21 CALIFORNIA CITIZENS.

22 DR. STEWARD: THAT'S FINE.

23 DR. PIZZO: JUST ONE THING. WE'RE USING
24 INTERCHANGEABLY THE WORD "CITIZENS" AND "PATIENTS" AND
25 "RESIDENTS," AND THOSE COULD BE VERY DIFFERENT THINGS.

1 MR. ROTH: THAT'S TRUE.

2 DR. PIZZO: OPENS UP ANOTHER VERY THORNY SET
3 OF ISSUES.

4 CHAIRMAN PENHOET: WE'LL LET YOU CHOOSE THE
5 WORDS. DO WE WANT RESIDENTS? IS THAT THE --

6 DR. MAXON: CALIFORNIANS.

7 MS. KING: THEN WE'RE GOING TO HAVE TO DEFINE
8 RESIDENT.

9 DR. PIZZO: IT'S GOING TO GET VERY, VERY
10 DIFFICULT. AND IT MAY BE THAT PATIENT MAY BE THE MOST
11 NEUTRAL BECAUSE WE'RE GOING TO THEN HAVE TO GO THROUGH
12 ALL KINDS OF OTHER PROOFS REGARDING CITIZENSHIP.

13 DR. PRIETO: IF WE SAY CALIFORNIA RESIDENTS,
14 WE DON'T IMPOSE ANY OTHER TEST REQUIREMENTS ON THEM.

15 DR. PIZZO: I CAN LIVE WITH THAT. LET'S JUST
16 USE ONE WORD.

17 CHAIRMAN PENHOET: HE'S OUT THERE ON THE
18 FRONT LINES. HE KNOWS WHAT A CALIFORNIA RESIDENT IS
19 AND WHAT IT ISN'T. OKAY. LET'S USE THE WORD
20 "RESIDENTS" OKAY. SO I THINK WE HAVE --

21 MR. ROTH: THAT'S MY MOTION. LET'S LET OS
22 MAKE THAT MOTION. HE DID IT BETTER THAN I DID.

23 CHAIRMAN PENHOET: SO GO AHEAD AND MAKE A
24 MOTION, OS. HAVE YOU FIGURED OUT HOW TO WEAVE THE WORD
25 "PREFERENCE" IN THERE SOMEWHERE?

1 DR. STEWARD: LET'S SEE. LET'S START WITH IN
2 DETERMINING CRITERIA FOR DISTRIBUTION, WE SHOULD SAY
3 STRONG PREFERENCE SHOULD BE GIVEN TO CALIFORNIA
4 RESIDENTS.

5 CHAIRMAN PENHOET: ALL RIGHT.

6 MR. SIMPSON: THAT WILL PRESUMABLY BE A REG.

7 DR. MAXON: YES.

8 CHAIRMAN PENHOET: BECAUSE THE REMEDY WILL BE
9 THEY HAVE TO COME BACK AND DISCUSS IT WITH US. OKAY.

10 MS. KING: WE HAVE A MOTION FROM DR. STEWARD.

11 DR. PRIETO: SECOND.

12 MS. KING: SUSAN BRYANT.

13 DR. BRYANT: YES.

14 MS. KING: TED LOVE.

15 DR. LOVE: I THINK I WANT TO ABSTAIN. I
16 DON'T THINK I KNOW ENOUGH ABOUT THIS YET.

17 MS. KING: ED PENHOET.

18 CHAIRMAN PENHOET: YES.

19 MS. KING: PHIL PIZZO.

20 DR. PIZZO: YES.

21 MS. KING: FRANCISCO PRIETO.

22 DR. PRIETO: YES.

23 MS. KING: JOHN REED.

24 DR. REED: YES.

25 MS. KING: DUANE ROTH.

1 MR. ROTH: YES.

2 MS. KING: JEFF SHEEHY.

3 MR. SHEEHY: YES.

4 MS. KING: OS STEWARD.

5 DR. STEWARD: YES.

6 MS. KING: JANET WRIGHT.

7 WE MAY HAVE LOST JANET WRIGHT.

8 CHAIRMAN PENHOET: WE STILL HAVE A QUORUM?

9 MS. KING: YES.

10 CHAIRMAN PENHOET: GOOD. ALL RIGHT.

11 ACTUALLY THOSE WERE THE BIG ISSUES WE HAD TO DISCUSS

12 TODAY, THE OPEN ITEMS. THERE WERE A COUPLE OF OTHER

13 QUESTIONS.

14 WHO HANDLES DISPUTES BETWEEN CIRM AND

15 AWARDEES OVER ACCESS OR PRICING REQUIREMENTS? WELL,

16 THE FIRST STOP WILL BE CIRM, I THINK. IF, ON THE OTHER

17 HAND, IT'S PETITIONED BY CITIZENS OR SOMETHING,

18 ULTIMATELY THE -- WELL, THERE ARE TWO LEVELS, AS I

19 UNDERSTAND IT, SCOTT. THAT THINGS THAT BECOME

20 REGULATIONS ARE CALIFORNIA LAW, AND THE ULTIMATE

21 RESPONSIBILITY FOR THE ADHERENCE TO CALIFORNIA LAW LIES

22 IN THE OFFICE OF THE ATTORNEY GENERAL; IS THAT CORRECT?

23 MR. TOCHER: YES.

24 CHAIRMAN PENHOET: WITH RESPECT TO THINGS

25 WHICH ARE CIRM POLICY, THE RESPONSIBLE AGENCY FOR

1 ADHERENCE TO CIRM POLICY IS CIRM.

2 MR. TOCHER: THAT'S CORRECT.

3 CHAIRMAN PENHOET: SO THOSE ARE THE TWO
4 BORDER CONDITIONS, AND THAT SHOULD BE RELATIVELY CLEAR,
5 I THINK.

6 MR. SIMPSON: PRESUMABLY THE PUBLIC, IF THEY
7 SAW SOMETHING THAT WAS NOT APPROPRIATE, COULD PETITION
8 CIRM AND SAY PLEASE DO SOMETHING ABOUT THIS, OR THEY
9 COULD ASK THE ATTORNEY GENERAL PLEASE DO SOMETHING
10 ABOUT THIS.

11 CHAIRMAN PENHOET: YES. AND THE APPROPRIATE
12 PLACE FOR THEM TO GO WOULD BE, IN THE ONE CASE, IF IT'S
13 THE OIG REGULATIONS, THEY COULD GO SEEK LEGAL REMEDIES
14 AND THEY COULD SEEK -- OUR ONLY REMEDY PROBABLY IS TO
15 REFUSE TO FUND THAT SAME ORGANIZATION AGAIN IN THE
16 FUTURE, BUT THAT COULD BE AN ONEROUS REMEDY.

17 JEFF'S LEFT THE ROOM. JEFF ASKED WHAT IF THE
18 REQUEST FOR PUBLICATION-RELATED BIOMATERIALS SHARING
19 COMES FROM A COMPETITOR? WE DID INCORPORATE LANGUAGE
20 AT THE SUGGESTION OF SEVERAL OF YOU THAT IF THE --
21 WE'RE NOW TALKING ABOUT THE FOR-PROFIT COMPANIES --
22 THAT IF SHARING THOSE REAGENTS WOULD PUT THE INVENTOR
23 OR THE OWNER AT A SIGNIFICANT COMPETITIVE DISADVANTAGE
24 FOR ONE REASON OR ANOTHER, THAT THEY COULD APPEAL TO US
25 AND WE WOULD ALLOW THEM NOT TO SHARE THOSE REAGENTS.

1 THAT IS THE LANGUAGE WE HAVE IN THERE NOW; IS THAT
2 CORRECT, MARY?

3 MR. GOSWAMI: IS THIS THE SAME AS THE
4 NONPROFIT LANGUAGE?

5 CHAIRMAN PENHOET: NO. THE NONPROFITS, THIS
6 IS MORE FAVORABLE, FRANKLY, TO THE COMPANIES THAN THE
7 NONPROFITS.

8 MR. GOSWAMI: OKAY.

9 CHAIRMAN PENHOET: THIS ISSUE ABOUT
10 BIOMEDICAL MATERIALS THAT YOU ASKED, JEFF, WHAT IF THE
11 REQUESTS FOR PUBLICATION-RELATED BIOMEDICAL
12 MATERIALS -- THAT'S A MOUTHFUL -- SHARING COMES FROM A
13 COMPETITOR? AND WE HAVE LANGUAGE IN HERE WHICH SAYS
14 THAT IF A COMPANY -- THAT REQUIREMENT ON A COMPANY PUTS
15 THEM AT A COMPETITIVE DISADVANTAGE OR HARMS THEIR
16 BUSINESS, THAT THEY CAN REQUEST TO BE OPTED OUT.

17 MR. SHEEHY: I DIDN'T ASK THIS.

18 MS. KING: YOU ASKED THIS THE LAST TIME AT
19 THE LAST MEETING.

20 CHAIRMAN PENHOET: YOU SENT US AN E-MAIL. I
21 THINK IT WAS YOU.

22 MR. SHEEHY: NO. IT WASN'T -- I HAVE MY
23 E-MAIL.

24 DR. MAXON: SOMEBODY ASKED IT.

25 CHAIRMAN PENHOET: THEN, FINALLY, THE

1 QUESTION SOMEONE ASKED: WHO REVIEWS AND APPROVES
2 EXCLUSIVE LICENSES BY AWARDEES? THE ANSWER IS CIRM
3 DOES NOT APPROVE THESE BECAUSE WE DON'T HAVE AN
4 APPROVAL MECHANISM. OUR GRANTEES ARE FREE TO PROCEED,
5 BUT WE WILL LOOK, AFTER THE FACT, AT WHETHER THE
6 LICENSES AWARDED FOLLOWED THE CRITERIA THAT WE HAVE PUT
7 IN PLACE. BUT WE DON'T ENTER INTO THE LICENSING
8 NEGOTIATIONS DIRECTLY OURSELVES, NOR DO WE HAVE
9 APPROVAL RIGHTS OVER THE LICENSE THAT'S CONDUCTED.
10 IT'S THE GRANTEE'S BUSINESS.

11 DR. PRIETO: WE ASSUME THE GRANTEES WILL TRY
12 TO NEGOTIATE FAVORABLE LICENSES.

13 CHAIRMAN PENHOET: WHAT'S IN THEIR BEST
14 INTEREST, YES. BUT THAT THESE FEATURES WILL BE
15 INCLUDED IN THOSE LICENSES THAT WE'VE AGREED UPON HERE.
16 SO THE ANSWER TO THAT IS WE DON'T HAVE AN APPROVAL
17 MECHANISM, BUT WE DO HAVE A REVIEW MECHANISM TO ASSURE
18 COMPLIANCE. AND THAT'S DONE BY CIRM STAFF. OKAY.

19 THAT'S ALL THE ISSUES I HAD ON MY LIST OF
20 ISSUES FOR TODAY.

21 MR. ROTH: ED, DURING THE BREAK A FEW MINUTES
22 AGO SOMEBODY RAISED A QUESTION. I'VE BEEN THINKING
23 ABOUT IT, AND I THINK WE BETTER TALK ABOUT IT AT LEAST.
24 WHAT HAPPENS IF A NONPROFIT AND A FOR-PROFIT APPLY FOR
25 A JOINT GRANT? AND I THINK AFTER THINKING ABOUT IT A

1 LITTLE BIT, THAT THIS POLICY COULD BE USED TO COVER IT.
2 SO WHATEVER THEIR AGREEMENT IS, IF THERE'S AN EXCLUSIVE
3 LICENSE, THEN IT FALLS DOWN THIS PATH. AND IF THERE'S
4 A NONEXCLUSIVE, WHICH THE BURNHAM GIVES TO FIVE PEOPLE,
5 IT WOULD FALL DOWN THAT PATH.

6 CHAIRMAN PENHOET: I THINK THAT'S CORRECT.

7 MR. ROTH: BUT I THINK WE SHOULD MAYBE
8 CLARIFY BEFORE THAT COMES UP, THAT IT IS POSSIBLE AND
9 IT'S LIKELY THAT THERE WILL BE FOR-PROFIT AND
10 NOT-FOR-PROFIT.

11 CHAIRMAN PENHOET: WE'D LIKE TO STIMULATE
12 THAT.

13 MR. ROTH: SO I THINK WE SHOULD DEAL WITH
14 THAT BECAUSE IT'S REALLY NOT CONTEMPLATED. WE JUST
15 MAKE IT VERY SIMPLE. IN THAT EVENT, THE POLICY WOULD
16 FALL IN EITHER CATEGORY. SO IF THERE'S A \$5 MILLION
17 GRANT, BURNHAM TAKES TWO AND A HALF, XYZ COMPANY TAKES
18 TWO AND A HALF, THE TWO AND A HALF MILLION IS WHAT'S
19 GOT TO BE PAID BACK 3 X IF THEY COMMERCIALIZE. AND IF
20 IT'S THE OTHER TWO AND A HALF, IT GOES DOWN THAT, THEN
21 IT'S 25 PERCENT FOR THE GRANTEE'S LICENSE.

22 CHAIRMAN PENHOET: IN MOST CASES YOU PRESUME
23 IF THEY'RE SUCCESSFUL, THE BURNHAM WOULD HAVE LICENSED
24 ITS PIECE BACK TO THAT SAME COMPANY, AND IT WILL GET
25 SOME REVENUES AS A RESULT.

1 MR. ROTH: I THINK THIS COVERS IT, BUT WE
2 OUGHT TO PROBABLY PUT A PARAGRAPH IN THERE THAT THE
3 POLICY WILL APPLY.

4 CHAIRMAN PENHOET: GOOD SUGGESTION.

5 DR. REED: AND BY VIRTUE OF THAT, IT ACTUALLY
6 PROBABLY WOULD GIVE CIRM, STATE OF CALIFORNIA, RATHER,
7 A ROYALTY STREAM BECAUSE USUALLY OUR LICENSING
8 AGREEMENTS ENTAIL A ROYALTY ON PRODUCT SALES. AND SO
9 THAT WOULD BE COMING THROUGH TO BURNHAM. MAYBE YOU
10 WOULD GET 25 PERCENT OF THAT.

11 CHAIRMAN PENHOET: YEAH. FROM THAT ENTITY
12 OVER THERE, BUT IT WOULD BE FUNDED OVER IN THIS
13 DIRECTION, AND YOU WOULD NEGOTIATE WHATEVER YOU DID.

14 DR. MAXON: IT ALSO DEPENDS IN PART ON HOW
15 THE FUNDING IS GIVEN. SO IF IT'S GIVEN -- IF THE
16 PRIMARY RECIPIENT AS A PI IS THE NONPROFIT INSTITUTION,
17 IT WOULD GO DOWN A DIFFERENT PATH. IF IT'S THE
18 FOR-PROFIT INSTITUTION, THEN -- SO IT DEPENDS ON HOW
19 THE RFA IS WRITTEN AND HOW THE APPLICATION COMES IN,
20 BUT IT WILL BE COVERED NO MATTER WHAT.

21 MR. ROTH: I JUST WANT TO MAKE SURE THAT
22 SOMEBODY LOOKS AT AN RFA DOWN THE ROAD AND SAYS, WELL,
23 WE CAN'T DO THIS. WE EITHER HAVE TO DO ONE OR THE
24 OTHER. WE WANT TO ALLOW FOR JOINT.

25 DR. MAXON: AND THIS SHOULD ACTUALLY.

1 CHAIRMAN PENHOET: I AGREE IT SHOULD. OKAY.
2 IF I CAN SUMMARIZE, AND MAYBE WE COULD GO BACK TO THE
3 SLIDE, WHICH IS THE SECOND SLIDE ON PROPOSED
4 PRINCIPLES, AND SEE IF WE CAN NOW SUMMARIZE WHAT WE
5 THINK WE'VE AGREED TO TODAY.

6 GRANTEES STILL OWN THE IP WHETHER THEY'RE
7 FOR-PROFIT OR NON-FOR-PROFIT.

8 MR. SIMPSON: MAY I ASK ONE QUESTION? ON
9 PAGE 36, YOU'VE CHANGED THE PRESS RELEASE REQUIREMENTS.

10 CHAIRMAN PENHOET: I THINK WE DID THAT AS A
11 RESULT OF SOME DISCUSSION AT THE LAST MEETING, BUT YES.

12 MR. SIMPSON: I WOULD LIKE TO MAKE THE CASE
13 THAT, INDEED, THAT SENTENCE THAT YOU PROPOSE STRIKING
14 SHOULD BE REINSERTED. AND THAT THAT'S PARTICULARLY THE
15 CASE WHEN YOU'RE MAKING GRANTS TO FOR-PRIVATE
16 SITUATIONS. I THINK IT'S IMPORTANT THAT PEOPLE AGREE
17 TO COORDINATE FOR A JOINT PRESS RELEASE. I DON'T THINK
18 IT'S ONEROUS. AND I THINK THAT THE INSTITUTIONS LAST
19 TIME CARRIED THE DAY IN THEIR OWN VESTED INTEREST
20 INAPPROPRIATELY, I MIGHT ADD, AND IT ONLY GOT THROUGH
21 BECAUSE EVERYONE WAS TIRED OF THE DEBATE. AND IT IS
22 NOT AN ONEROUS POINT TO COORDINATE ON RELEASE OF A
23 PRESS RELEASE IF YOU'RE GETTING PUBLIC MONEY WITH THE
24 AGENCY.

25 CHAIRMAN PENHOET: I BELIEVE THE CONCERN THAT

1 PEOPLE HAD WAS TIMELINESS OF CIRM' S RESPONSE BECAUSE
2 ESPECIALLY PUBLIC COMPANIES HAVE SOME VERY ONEROUS TIME
3 REQUIREMENTS IN TERMS OF WHEN THEY HAVE TO GET OUT A
4 PRESS RELEASE.

5 MR. SIMPSON: THEY CAN CERTAINLY PUT OUT
6 THEIR OWN PRESS RELEASE. ALL THIS SAYS IS THAT IF CIRM
7 WISHES TO HAVE A JOINT PRESS RELEASE, WE WILL
8 COORDINATE THAT. THAT DOES NOT PRECLUDE THE AGENCY --
9 EXCUSE ME -- THE INSTITUTION OR THE COMPANY FROM
10 ISSUING ITS OWN PRESS RELEASE OR FROM TALKING TO, IN
11 ANOTHER LIFE, A JOURNALIST LIKE ME, AND ANSWERING
12 QUESTIONS. IT SIMPLY REQUIRES THAT YOU COORDINATE
13 ABOUT JOINT PRESS RELEASES IF CIRM WISHES TO HAVE ONE,
14 WHICH IS PERFECTLY APPROPRIATE IF YOU' RE TRYING TO TALK
15 ABOUT THE PEOPLE' S MONEY.

16 CHAIRMAN PENHOET: I THINK WE NEED SOME
17 DIFFERENT LANGUAGE THEN BECAUSE I THINK PEOPLE
18 INTERPRETED THESE TWO SENTENCES TOGETHER AND ASSUMED
19 THAT THE WISH TO PARTICIPATE IN THE JOINT PRESS RELEASE
20 REFERRED TO THE SENTENCE ANTECEDENT TO THIS SENTENCE
21 AND WOULD GET IN THE WAY OF DOING THAT.

22 IF, ON THE OTHER HAND, YOUR PROPOSAL IS THAT
23 EITHER SUBSEQUENTLY OR INDEPENDENTLY, HOWEVER YOU WANT
24 TO SAY THAT, CIRM WANTS TO PARTICIPATE IN AN ADDITIONAL
25 PRESS RELEASE, PROBABLY OUR FRIENDS FROM INDUSTRY

1 WOULD N'T OBJECT. THEIR CONCERN WAS GETTING STUCK WITH
2 CIRM NEGOTIATING A PRESS RELEASE FOR TWO WEEKS AND NOT
3 BEING ABLE TO DO IT. SO I THINK WE WOULD NEED SOME
4 DIFFERENT LANGUAGE IN THIS BECAUSE I THINK THAT THIS
5 LANGUAGE WAS INTERPRETED TO MEAN ANY PRESS RELEASE. IF
6 WE JUST SAID WE WANT TO DO IT TOGETHER WITH YOU, THEY'D
7 BE STUCK WITH US. THEY COULDN'T DO IT ON THEIR OWN.

8 MR. SIMPSON: IT SAYS YOU NEED TO BE TOLD
9 ABOUT A PRESS RELEASE. IF, AFTER THAT EVENT, CIRM
10 WISHES TO HAVE A JOINT PRESS RELEASE, THEN YOU WILL
11 COORDINATE. SO IT IN NO WAY -- IT INSISTS UPON
12 NOTIFICATION IF YOU'RE PUTTING ONE OUT, WHICH PUTS CIRM
13 ON NOTICE, AND THEY SHOULD BE PUT ON NOTICE, AND THEN
14 CIRM CAN SIMPLY SAY, YOU KNOW, WE'D LIKE TO PUT ONE OUT
15 TOO. THEN THEY HAVE AN OBLIGATION TO COORDINATE THAT
16 WITH YOU. PERFECT SENSE AND IT SHOULD GO BACK INTO THE
17 NON-PROFITS AS WELL.

18 CHAIRMAN PENHOET: ALL I'M SAYING IS THE
19 REASON THIS WAS STRUCK WAS FOR THE PRIOR REASON I
20 ARTICULATED, AND I THINK WE WOULD HAVE TO CLARIFY THIS
21 LANGUAGE THAT SAYS THEY CAN BE INDEPENDENT EVENTS; BUT
22 IF CIRM WANTS TO DO ONE WITH SOMEBODY, THEY'D
23 COOPERATE. I THINK NOBODY WOULD OBJECT TO THAT. THE
24 PROBLEM INDUSTRY HAD WAS NOT BEING ABLE TO PUT OUT
25 THEIR OWN PRESS RELEASE UNTIL WE HAD AGREED.

1 MR. SIMPSON: I WOULD SIMPLY SAY THE ENGLISH
2 LANGUAGE HERE IS PRETTY STRAIGHTFORWARD.

3 MR. TOCHER: YOU CAN CLARIFY.

4 CHAIRMAN PENHOET: IT SAYS THEY MUST NOTIFY
5 US PRIOR.

6 MR. ROTH: I CAN ANSWER THAT. I WOULD
7 CLEARLY READ THAT AS A REQUIREMENT THAT IF YOU SAY HOLD
8 ON.

9 CHAIRMAN PENHOET: THAT'S HOW IT WAS READ.

10 MR. ROTH: THAT'S WHAT THE PROBLEM THE
11 COMPANIES ARE GOING TO HAVE.

12 MR. SIMPSON: YOU'VE GOT TO BE TOLD THAT YOU
13 ARE ISSUING A PRESS RELEASE.

14 MR. ROTH: WE'LL TELL YOU WE'RE ISSUING IT.

15 MR. SIMPSON: THAT'S THE FIRST THING. PRIOR
16 TO ANY PRESS RELEASE THAT REFER TO EVENTS, YOU'VE GOT
17 TO TELL CIRM THAT YOU ARE PUTTING OUT A PRESS RELEASE.
18 THEN THE NEXT SENTENCE SAYS, IF THEY WISH TO
19 PARTICIPATE IN A JOINT PRESS RELEASE, THERE'S NOTHING
20 THERE THAT SAYS THE FIRST ONE CAN'T GO AHEAD.

21 CHAIRMAN PENHOET: WELL, THEN THAT WOULD
22 BE -- FOR THE SAKE OF REAL CLARITY, THEN YOU COULD SAY
23 IN THE EVENT THAT CIRM WISHES TO PARTICIPATE IN A
24 SUBSEQUENT JOINT PRESS RELEASE OR AN ADDITIONAL --

25 MR. SIMPSON: OR IN ANY. AND IT COULD BE

1 THAT THEY ALL SAY TOGETHER, HEY, LET'S DO IT AT ONE
2 TIME.

3 CHAIRMAN PENHOET: THAT COULD BE, BUT THEN
4 WOULDN'T -- IF WE PUT IN THE WORD "ADDITIONAL" OR
5 "SUBSEQUENT," THEN IT WOULDN'T FORCE THEM TO GET SLOWED
6 DOWN BY NEGOTIATING WITH A STATE AGENCY.

7 DR. PRIETO: IT WOULDN'T PREVENT THEIR PRESS
8 RELEASE.

9 CHAIRMAN PENHOET: RIGHT.

10 DR. PIZZO: WE DON'T WANT TO GET SLOWED DOWN.

11 CHAIRMAN PENHOET: WHICH IS WHAT WE'RE TRYING
12 TO ACHIEVE. ASSUMING WE CAN COME UP WITH THE RIGHT
13 LANGUAGE, IS THE GROUP AROUND THIS TABLE OKAY WITH
14 JOHN'S SUGGESTION, WHICH IS CIRM WANTS TO DO A JOINT
15 PRESS RELEASE, THEY'LL COOPERATE WITH US, BUT THAT'S
16 INDEPENDENT OF THEIR OWN DECISION TO PUT OUT A PRESS
17 RELEASE THEMSELVES?

18 DR. PIZZO: THAT'S HOW I SEE IT.

19 MR. SHEEHY: I THINK THE LANGUAGE SHOULD
20 MIRROR.

21 CHAIRMAN PENHOET: WELL, THE LANGUAGE WAS
22 INTERPRETED THE PRIOR WAY. THAT'S WHY WE TOOK IT OUT.

23 MR. SHEEHY: I THINK IT MIRRORS NOW THE WAY
24 WE HAVE FOR NOT-FOR-PROFITS. I THINK REALISTICALLY I
25 THINK THE WHOLE DEBATE -- I'M NOT GOING TO

1 EDITORIALIZE.

2 MR. SIMPSON: GO BACK AND SEE WHAT MY COMMENT
3 WAS AT THE TIME TOO.

4 MR. SHEEHY: I THINK THIS IS A -- IF WE -- I
5 WOULD -- FOR ME, I WOULD PREFER CONSISTENCY. I THINK
6 THAT'S WHAT YOU SHOULD DO IN TERMS OF REGULATIONS, AND
7 WE SHOULDN'T HAVE TWO DIFFERENT STANDARDS. WE KIND OF
8 MADE THE DECISION ON THE ONE.

9 FROM AN OPERATIONAL POINT OF VIEW, I JUST
10 THINK THESE ARE ALL GOING TO WORK THE WAY THAT THEY
11 WORK, AND THAT THE NOTIFICATION CAPTURES WHAT WE NEED.

12 CHAIRMAN PENHOET: YOU ARE A PROFESSIONAL IN
13 THE FIELD.

14 MR. TOCHER: WE CAN -- THERE'S STILL
15 SUFFICIENT TIME TO NOTICE THIS AMENDED LANGUAGE IN THE
16 CONTEXT OF THE NONPROFIT POLICY. IT WOULD BE BROUGHT
17 BACK TO THE ICOC JUST AS A DO YOU, IN LIGHT OF THIS
18 CLARIFICATION AND RECOMMENDATION --

19 MR. SHEEHY: I DON'T WANT TO DO THAT AGAIN.

20 MR. SIMPSON: YOU NOTICED YOUR LAST THING AND
21 YOU HAVE NOTICED -- PUBLIC COMMENT HAS COME IN ON THE
22 LAST CHANGE. SO PRESUMABLY YOU HAVE TO TAKE UP THE
23 PUBLIC COMMENT OR AT LEAST RESPOND TO IT ON THE
24 NONPROFIT.

25 MR. TOCHER: RIGHT. THERE HAS TO BE A

1 RESPONSE. I'M JUST SAYING THOSE ARE THE OPTIONS FOR
2 THE TASK FORCE IS THAT IT CAN, WITH THIS CLARIFICATION
3 AND UNDERSTANDING, IT CAN POST THE LANGUAGE AND JUST
4 OFFER IT UP TO THE ICOC ANYWAY BECAUSE THE ICOC HAS TO
5 CONSIDER THAT REGULATION ANYWAY IN THE FINAL ADOPTION
6 IN DECEMBER. YOU WOULD JUST BE PROVIDING THEM WITH THE
7 OPTION.

8 CHAIRMAN PENHOET: OKAY. WE HAVE TWO
9 PROPOSALS ON THE FLOOR. ONE IS TO LEAVE IT THE WAY IT
10 IS, AND THE OTHER ONE IS TO ADD THE WORD "PARTICIPATE
11 IN AN ADDITIONAL JOINT PRESS RELEASE" OR A DIFFERENT
12 PRESS RELEASE, SOMETHING LIKE THAT.

13 MR. SHEEHY: YOU'RE NOT GOING TO DO TWO --

14 MR. ROTH: JOHN, COULD I TRY SOMETHING HERE?
15 IN THE EVENT THAT THE CIRM -- THAT CIRM AND THE AWARDEE
16 AGREE TO PARTICIPATE IN A JOINT PRESS RELEASE, THE
17 AWARDEE WILL COORDINATE WITH CIRM COMMUNICATIONS
18 OFFICER. I THINK THAT'S WHAT YOU'RE SAYING.

19 MR. SIMPSON: NO. WHAT I'M SAYING IS IF CIRM
20 FEELS THERE SHOULD BE A JOINT PRESS RELEASE, IT DOESN'T
21 PRECLUDE THE COMPANY FROM DOING WHATEVER ELSE IT WANTS,
22 BUT THAT THE COMPANY WOULD HAVE TO COORDINATE WITH THE
23 JOINT. IT DOES PUT A LITTLE BIT OF A BURDEN ON THEM TO
24 COOPERATE AND COORDINATE IF CIRM WANTS A JOINT.

25 MR. ROTH: THAT'S GOING TO BE TOUGH, JOHN,

1 BECAUSE IT IS ALMOST IMPOSSIBLE TO GET THAT KIND OF
2 LANGUAGE IF THERE'S AN URGENT NEED. LET'S SAY THERE'S
3 A DEATH IN A CLINICAL TRIAL, WHICH WE WOULD HOPE
4 WOULDN'T HAPPEN. THE COMPANY HAS GOT TO ACT TO THAT
5 IMMEDIATELY.

6 MR. SIMPSON: AND THEY WOULD, AND THEY'D PUT
7 THAT OUT RIGHT AWAY.

8 MR. ROTH: THEY WOULD NOTICE AND PUT IT OUT,
9 BUT THE WAY THIS IS WRITTEN, SOMEBODY COULD SAY, HEY,
10 WE WANT TO BE PART OF THIS PRESS RELEASE, I DON'T KNOW
11 WHY THEY'D WANT TO BE, BUT THEY MIGHT. THEY MIGHT.

12 CHAIRMAN PENHOET: THAT'S THE DIFFERENCE.
13 WHAT HE'S NOW SAYING IS IS THAT PERFECTLY OKAY?
14 COMPANY WOULD GO AHEAD AND DO THAT. I GUESS IN THE
15 REAL WORLD, THOUGH, I'M LEANING SORT OF TOWARDS JEFF'S
16 VIEW, WHICH IS THE PRACTICAL REALITY IS THAT IF A
17 COMPANY NEEDS TO DO IT, THEY'LL DO IT. IF THEY COME
18 BACK TO CIRM LATER AND THEY HAVE A SUBSEQUENT PRESS
19 RELEASE THEY HAVE TO WORK ON TOGETHER, THEY'LL DO THAT.
20 IT'S JUST THE WAY THE BUSINESS WORKS.

21 MR. SHEEHY: THE WAY THE BUSINESS. I MEAN
22 IT'S THE SAME THING WITH DR. -- NO PERSONALITIES. THE
23 REALITY IS IF SOMEBODY -- IF YOU'VE GOT DIFFERENT
24 MESSAGES OUT THERE, THEN EVERYBODY HAS FAILED, YOU
25 KNOW. SO IF YOU'RE NOT COORDINATING, YOU'RE STARTING

1 FROM A POSITION OF FAILURE. SO WHATEVER LANGUAGE WE
2 PUT IN THERE, THE NOTIFICATION IS THE KEY INGREDIENT
3 BECAUSE WE DON'T WANT TO WAKE UP, OPEN THE PAPER, AND
4 BE THE FIRST TIME WE'VE HEARD OF SOMETHING. THAT'S THE
5 KEY INGREDIENT. COORDINATION WILL HAPPEN. IF THE
6 PEOPLE AT THE EITHER THE UNIVERSITIES OR THE COMPANIES
7 ARE COMPETENT, IT WILL TAKE PLACE.

8 CHAIRMAN PENHOET: SO WE HAVE A MOTION, JEFF,
9 TO LEAVE THE LANGUAGE LIKE IT IS?

10 DR. LOVE: WHY WOULD WE WANT THIS ONE TO BE
11 DIFFERENT FROM THE ONE THAT WE JUST DISCUSSED THE LAST
12 MEETING?

13 MR. SHEEHY: I DON'T WANT TO OPEN THAT UP
14 AGAIN.

15 CHAIRMAN PENHOET: OKAY. IS THAT A MOTION,
16 THAT WE LEAVE THE LANGUAGE AS IT IS?

17 DR. REED: ONE MORE POINT OF DISCUSSION,
18 WHICH IS IT DOESN'T SPECIFICALLY MANDATE THAT THEY SEND
19 YOU A COPY OF THE PRESS RELEASE. THEY JUST SAY YOU
20 HAVE TO NOTICE THAT THEY'RE GOING TO SEND ONE. I THINK
21 THEY SHOULD SEND A COPY OF THE PRESS RELEASE SO YOU
22 KNOW EXACTLY WHAT THEY'RE GOING TO SAY.

23 DR. PRIETO: NOTIFY AND PROVIDE A COPY OF.

24 DR. WRIGHT: DOESN'T THAT IMPLY THAT YOU HAVE
25 SORT OF AN APPROVAL PROCESS?

1 DR. REED: WE DON'T HAVE AN APPROVAL PROCESS.

2 CHAIRMAN PENHOET: WE DON'T WANT AN APPROVAL
3 PROCESS, AND I THINK WE'RE ALL IN AGREEMENT ON THAT.

4 DR. REED: BUT I THINK WE SHOULD GET A COPY
5 OF THE PRESS RELEASE SO WE CAN PREPARE. IF WE SEE
6 SOMETHING WE THINK THAT WE'RE GOING TO HAVE TO SET A
7 RECORD STRAIGHT ON SOMETHING, WE WANT TO BE ABLE TO
8 JUMP ON THAT, AND SO WE SHOULD NOT ONLY BE NOTIFIED, WE
9 SHOULD GET A COPY OF IT.

10 CHAIRMAN PENHOET: OKAY. IS THAT OKAY, JEFF?

11 MR. SHEEHY: I THINK THAT THE ACTUAL LANGUAGE
12 YOU PROBABLY WANT TO USE IS THAT, SAY, AT A MINIMUM
13 CIRM'S PRESS OFFICER OR DIRECTOR OF COMMUNICATIONS,
14 WHATEVER YOU WANT TO CALL IT, WILL BE INCLUDED IN THE
15 DISTRIBUTION OF ANY PRESS MATERIALS, INCLUDING PRESS
16 RELEASES, SUPPORTING DOCUMENTS, NO LATER THAN THE
17 EARLIEST -- THAN THE FIRST CONTACT WITH A MEMBER OF THE
18 MEDIA.

19 CHAIRMAN PENHOET: THAT'S DIFFERENT THAN WHAT
20 WE HAVE NOW. THIS SAYS PRIOR.

21 MR. SHEEHY: WELL, THIS SAYS THE NOTIFICATION
22 THAT THEY'RE GOING TO DO SOMETHING, BUT TO GET THE
23 FORMAL MATERIALS, WE CAN'T REALLY ASK THEM --

24 CHAIRMAN PENHOET: OFTENTIMES PEOPLE ARE
25 MODIFYING THEM TILL THE LAST MINUTE.

1 MR. ROTH: TILL YOU GO ON THE AIR.

2 MR. SHEEHY: I MEAN --

3 CHAIRMAN PENHOET: THE NOTIFICATION WOULD BE
4 PRIOR, BUT THE COPY WOULD BE COINCIDENT.

5 MR. SHEEHY: BUT WE SHOULD BE INCLUDED ON ALL
6 THE DISTRIBUTION. ONE WOULD HOPE WITH THE NOTIFICATION
7 THAT THEY'D GIVE US PRIOR; BUT IF IT'S IN A VERY
8 CONTROVERSIAL AND CONFRONTATIONAL KIND OF SITUATION, WE
9 CAN'T EXPECT THAT THEY'RE GOING TO GIVE US THEIR PRESS
10 RELEASE BEFORE THEY GIVE IT TO A REPORTER.

11 CHAIRMAN PENHOET: BUT THEY HAVE TO TELL US
12 BASICALLY WHAT IT IS THAT THEY'RE DISCLOSING, ACCORDING
13 TO THIS LANGUAGE. I THINK WE NEED THAT.

14 MR. SHEEHY: I AGREE WITH THAT, BUT WE CAN'T
15 ASK FOR THE PRESS RELEASE.

16 DR. LOVE: I HAVE A QUESTION. ARE WE GOING
17 TO DO THIS FOR THE NOT-FOR-PROFIT ALSO?

18 CHAIRMAN PENHOET: YEAH. WHATEVER WE DO, WE
19 HAVE TO MAKE IT CONSISTENT.

20 MR. SHEEHY: PERSONALLY I'D LEAVE IT ALONE
21 AND JUST HOPE. LIKE I SAID, IT REALLY COMES BACK TO
22 THE PROFESSIONALISM OF THE PEOPLE INVOLVED. AND THE
23 REALITY IS THAT YOU'RE NOT GOING TO WANT CONTRADICTIONARY
24 MESSAGES OUT THERE. AND IF YOU DO HAVE CONTRADICTIONARY
25 MESSAGES OUT THERE, THEN WHATEVER WE'RE PUTTING INTO

1 PLACE IS NOT GOING TO REALLY MAKE THAT MUCH DIFFERENCE
2 BECAUSE WE'RE GOING TO BE IN A FIGHT.

3 CHAIRMAN PENHOET: IS THAT A MOTION, JEFF?

4 MR. SHEEHY: NO. WE DON'T NEED A MOTION.
5 LANGUAGE IS AS IT IS.

6 CHAIRMAN PENHOET: UNLESS SOMEBODY MAKES A
7 MOTION TO CHANGE IT, I GUESS WE'LL LEAVE IT.

8 DR. LOVE: I AGREE WITH JEFF.

9 CHAIRMAN PENHOET: ANYBODY WANT TO MAKE A
10 MOTION TO CHANGE THE LANGUAGE? OKAY.

11 ANY OTHER ISSUES FROM THE TASK FORCE? WELL,
12 I THINK IT'S A REMARKABLE DAY. I DIDN'T COME HERE
13 EXPECTING THAT WE COULD --

14 MR. ROTH: MOTION TO ADJOURN.

15 CHAIRMAN PENHOET: -- REACH CONSENSUS ON
16 THESE ISSUES. AND I THINK THE NEW COLLABORATION
17 ESTABLISHED BETWEEN SHEEHY AND ROTH --

18 MR. ROTH: YOU COME TO SAN DIEGO, WE GET
19 THINGS DONE.

20 DR. REED: IT'S A MODEL FOR THE ENTIRE BOARD.

21 CHAIRMAN PENHOET: THIS MAY BE THE LAST
22 MEETING OF THIS TASK FORCE. AND, YOU KNOW, AS THE
23 CHAIR OF THIS GROUP, I JUST WANT TO SAY WHAT A PLEASURE
24 IT'S BEEN TO WORK WITH ALL OF YOU. I THINK EVERYBODY
25 HAS COME HERE WITH GOODWILL, TRYING TO DO THE RIGHT

1 THINGS. IT'S BEEN A VERY DIFFICULT PROJECT.

2 IF YOU TAKE THE TOTAL NUMBER OF MEETINGS AND
3 PRESENTATIONS WE HAVE HAD FOR THE TWO POLICIES
4 COMBINED, WE'RE UP TO CLOSE TO 20 MEETINGS NOW. WE'VE
5 HAD EIGHT MEETINGS -- SIX MEETINGS OF THIS GROUP, WE'VE
6 HAD ALL THE OTHER INFORMATIONAL MEETINGS, AND WE HAD AN
7 EQUAL NUMBER BEFORE. WE PROBABLY HAD 15 MEETINGS
8 ANYWAY THAT MANY OF US HAVE ATTENDED. I JUST THINK
9 IT'S EXTRAORDINARY THAT THIS GROUP OF PEOPLE HAS WORKED
10 AS EFFECTIVELY AS THEY HAVE. SO THANK YOU.

11 (APPLAUSE.)

12 DR. BRYANT: THIS DOCUMENT ACTUALLY IS ONE OF
13 THE BEST THINGS I'VE READ IN THIS AREA IN TERMS OF THE
14 HISTORY AND BACKGROUND AND CONTEXT, AND I CONGRATULATE
15 YOU ON THAT PART AS WELL.

16 MS. KING: DR. PIZZO, IF YOU COULD REPEAT
17 WHAT YOU SAID FOR THE RECORD, PLEASE, THAT WOULD BE
18 GREAT. THERE WAS A LOT OF APPLAUSE HAPPENING HERE.

19 DR. PIZZO: I SAID THAT THE SUCCESS OF THIS
20 COMMITTEE COULD NOT HAVE HAPPENED WITHOUT THE EFFORTS
21 OF MARY MAXON AND ED PENHOET.

22 CHAIRMAN PENHOET: ESPECIALLY MARY MAXON.

23 MR. ROTH: AND I WANT TO ADD ONE THING AS A
24 NEWCOMER TO THIS COMMITTEE, THE PUBLIC ADDED SO MUCH --

25 CHAIRMAN PENHOET: YES, INDEED.

1 MR. ROTH: -- IN THEIR COMMENT, AND
2 APPRECIATE YOU GUYS ALL SHOWING UP AND HELPING US WITH
3 THIS.

4 DR. PIZZO: WE KNOW THE PUBLIC BY NAME NOW.

5 DR. LOVE: WE HAVE ONE PUBLIC QUESTION ON
6 THIS END BEFORE WE WRAP UP.

7 MR. LAKAVAGE: I'M SORRY ABOUT THAT. I KNOW
8 THAT THE MEETINGS RUN VERY EFFICIENTLY AND ENDING CLOSE
9 TO ON TIME. I DO HAVE A QUICK QUESTION. THIS IS TONY
10 LAKAVAGE FROM APPLIED BIOSYSTEMS.

11 SECTION C ON THE PUBLICATION OF BIOMEDICAL
12 MATERIALS REQUIREMENTS, DOES THAT -- IS THAT ENVISIONED
13 TO APPLY TO RESEARCH TOOLS? AND IF IT IS NOT, I'D LIKE
14 TO ASK IF WE COULD CONSIDER EXPLICITLY SAYING THAT IT'S
15 NOT. AND IF IT DOES, I MEAN IT REALLY WOULD BE A
16 MASSIVE DISINCENTIVE FOR ANY RESEARCH TOOLS DEVELOPERS
17 TO BE INVOLVED. IT ESSENTIALLY SAYS THAT WE WOULD HAVE
18 TO GIVE AWAY OUR INVENTION OR DEVELOPMENT AT NO COST
19 UNLESS, AFTER IT WERE DEVELOPED, THE CIRM DECIDED THAT
20 IT WAS INAPPROPRIATE FOR US TO DO THAT.

21 CHAIRMAN PENHOET: WE DEVELOPED SOME LANGUAGE
22 TO DEAL SPECIFICALLY WITH YOUR CONCERN. MARY, IF YOU
23 CAN --

24 DR. MAXON: THIS IS -- HE'S LOOKING AT THE
25 SAME DOCUMENT THAT WE HAVE, AND IT SAYS, "UNLESS A

1 SPECIAL CASE COULD BE MADE THAT DOING SO WOULD ENDANGER
2 THE COMPETITIVE POSITION OF THE COMPANY. "

3 MR. LAKAVAGE: LET ME ASK, THOUGH, IS THAT
4 AFTER THE PRODUCT'S BEEN DEVELOPED, OR IS IT SOMETHING
5 THAT YOU GET AN EXCEPTION FOR?

6 DR. MAXON: NO. THIS IS FOR A
7 PUBLICATION-RELATED BIOMEDICAL MATERIAL. SO AT THE
8 TIME THAT A PUBLICATION IS MADE PUBLIC, WHEN REQUESTS
9 COME IN, IT'S PROBABLY LIKELY TO BE, IN MANY CASES,
10 BEFORE COMMERCIALIZATION OF ANYTHING; BUT IF THERE'S AN
11 ARGUMENT TO MADE THAT SHARING THAT COULD ENDANGER THE
12 COMPANY, THEN A CASE CAN BE MADE TO CIRM AND AN
13 EXCEPTION WOULD BE GRANTED.

14 CHAIRMAN PENHOET: AND IF YOU HAVE A PLAN TO
15 COMMERCIALIZE THAT PRODUCT, THAT WOULD BE A PERFECTLY
16 GOOD CASE.

17 MR. GOSWAMI: SO THAT'S CLEAR, THAT IF IT IS
18 COMMERCIALIZED, THERE'S NO APPEAL PROCESS.

19 CHAIRMAN PENHOET: NO. IF YOU HAVE A PLAN TO
20 COMMERCIALIZE IT EVEN. IF IT'S SOMETHING YOU'RE NOT
21 GOING TO COMMERCIALIZE, IT'S A REAGENT, BUT IF YOU'RE
22 GOING TO INVEST IN COMMERCIALIZATION, THEN THIS --

23 DR. PRIETO: AND IT DOESN'T SAY YOU HAVE TO
24 WAIT TO ANY POINT. YOU CAN MAKE THAT CASE AT ANY
25 POINT.

1 CHAIRMAN PENHOET: OF COURSE.

2 MR. LAKAVAGE: OKAY. THAT'S THE
3 CLARIFICATION.

4 CHAIRMAN PENHOET: IT'S A GOOD QUESTION.

5 MR. GOSWAMI: ONE QUESTION FROM MY SIDE.
6 IT'S NOT RELATED. WHAT'S THE PROCESS GOING FORWARD FOR
7 THE POLICY TO BE SET IN STONE AND THE CHANGES TO BE
8 MADE? AND IF THERE ARE ANY COMMENTS FROM THE PUBLIC,
9 HOW'S THAT GOING --

10 CHAIRMAN PENHOET: OH, YES. PLENTY OF
11 COMMENTS FROM THE PUBLIC. WE WILL NOW TAKE OUR WORK
12 FROM TODAY TO THE MEETING ON DECEMBER 7TH ICOC AND ASK
13 THE ICOC TO RATIFY THIS POLICY. AND WHEN THE ICOC DOES
14 THAT, THEN WE GO INTO THE OIG PROCESS WHERE YOU HAVE
15 ANOTHER BITE AT THE APPLE AND SO WILL EVERYONE ELSE.
16 AND THAT'S THE 45-DAY PROCESS.

17 I WAS GOING TO GO DOWN THROUGH ALL THESE TO
18 REVIEW IT ALL, BUT I THINK IT'S REALLY NOT NECESSARY.
19 I THINK WE'VE COVERED EVERYTHING ON THIS SLIDE. SO
20 LET'S JUST CALL IT A DAY.

21 MR. SIMPSON: WHEN WILL WE LIKELY SEE THE
22 CHANGES? TEN DAYS BEFORE?

23 DR. MAXON: YOU KNOW, WE HAVE A BIG GRANT
24 REVIEW NOVEMBER 28TH, 29TH, AND 30TH, AND I'M DOUBLE
25 DUTY ON THAT TEAM. SO TEN DAYS BEFORE DECEMBER 7TH IS

1 RIGHT AROUND IN THAT RANGE, SO I'D LIKE TO GET IT OUT
2 BEFORE THANKSGIVING, SO MAYBE EARLIER.

3 (THE MEETING WAS THEN ADJOURNED AT 4:40
4 P.M.)

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REPORTER' S CERTI F I C A T E

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 SUBCOMMITTEE OF THE INDEPENDENT CITIZEN' S OVERSIGHT COMMITTEE TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

CONNECT
8950 VILLA LA JOLLA DRIVE
SUITE A124
LA JOLLA, CALI F O R N I A
ON
THURSDAY, NOVEMBER 9, 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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