

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

LOCATION: TELEPHONIC LOCATIONS AS NOTICED

DATE: FRIDAY, MAY 25, 2007
1 P.M.

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

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1 TELECONFERENCE; FRIDAY, MAY 25, 2007

2 01:04 PM

3

4 MS. KING: SUSAN BRYANT.

5 DR. BRYANT: HERE.

6 MS. KING: MICHAEL GOLDBERG. SHERRY LANSING.

7 TED LOVE.

8 DR. LOVE: HERE.

9 MS. KING: ED PENHOET.

10 CHAIRMAN PENHOET: HERE.

11 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.

12 JOHN REED.

13 DR. REED: HERE.

14 MS. KING: DUANE ROTH.

15 MR. ROTH: HERE.

16 MS. KING: JEFF SHEEHY.

17 MR. SHEEHY: HERE.

18 MS. KING: OSWALD STEWARD. JANET WRIGHT.

19 CHAIRMAN PENHOET: I THINK DR. PIZZO IS GOING

20 TO JOIN US LATER.

21 MS. KING: DR. PIZZO IS GOING TO JOIN US

22 LATER, YES, AS IS DR. STEWARD, AND DR. PRIETO IS

23 SUPPOSED TO JOIN US AS WELL.

24 CHAIRMAN PENHOET: WE DON'T HAVE A QUORUM.

25 IT'S NOT CLEAR WE NEED A QUORUM. THIS IS NOT A

1 REGULATORY BODY. IT'S AN ADVISORY BODY, BUT IT'S
2 ALWAYS NICE TO HAVE A QUORUM IF YOU CAN.

3 SO THERE ARE A NUMBER OF DOCUMENTS THAT WE
4 WILL REFER TO DURING THIS DISCUSSION TODAY. ONE IS THE
5 COMPLETE LETTERS WE HAVE RECEIVED IN RESPONSE TO THE
6 POSTING ON THE OAL PROCESS. A SECOND IS A SUMMARY
7 SHEET OF THE COMMENTS AND RECOMMENDATIONS THAT SCOTT
8 HAS PUT TOGETHER. THE THIRD AND FOURTH ARE AN ORIGINAL
9 COPY OF THE REGULATIONS AS POSTED IN THE OAL SITE. A
10 FOURTH IS THOSE REGULATIONS WITH SOME AMENDMENTS
11 INDICATED IN BLUE THAT SCOTT HAS INCORPORATED INTO THE
12 DOCUMENT REFLECTING SOME OF THE SUGGESTIONS THAT WERE
13 MADE BY THE PEOPLE WHO COMMENTED ON THIS.

14 AND THEN YOU'RE NOT GIVING UP ON YOUR
15 COMPUTER, SCOTT?

16 MR. TOCHER: I JUST DID.

17 CHAIRMAN PENHOET: FIRST OF ALL, LET ME SAY
18 WE APPRECIATE THE EFFORT THAT WENT INTO THE LARGE
19 NUMBER OF THOUGHTFUL COMMENTS WE GOT FROM VARIOUS
20 PARTIES, ALMOST ALL OF WHICH WERE FROM INDUSTRY
21 REPRESENTATIVES, BUT THAT'S APPROPRIATE SINCE WE ARE
22 GRAPPLING WITH THE POLICY FOR THE FOR-PROFIT
23 ORGANIZATIONS AT THIS POINT IN TIME.

24 MARY'S MAGIC AT WORK. THANK YOU, MARY.

25 WE NOW HAVE THE SLIDES UP. SO THIS IS THE

1 SLIDE DECK THAT WAS SENT TO ALL OF YOU. THE IP TASK
2 FORCE MEETING TODAY IS THE FIRST SLIDE. MARY, IF WE
3 CAN GO TO THE NEXT ONE. SIMPLY A REMINDER OF THE
4 PROCESS WE'VE BEEN IN VIS-A-VIS THE NONPROFIT REGS,
5 WHICH ARE LARGELY IN PLACE AT THIS POINT.

6 AS YOU WILL SEE, THERE ARE SOME SIGNIFICANT
7 OVERLAPPING AREAS OF INTEREST BETWEEN THE FOR-PROFIT
8 AND THE NONPROFIT SIDE. THIS SIMPLY SUMMARIZES THE
9 PRIMARY DIFFERENCES BETWEEN THE NONPROFIT SIDE AND THE
10 FOR-PROFIT SIDE. AND THE PRIMARY DIFFERENCES REALLY
11 OCCUR POST INVENTION WHERE A FOR-PROFIT ORGANIZATION
12 HAS THE ABILITY TO DEVELOP THE PRODUCT THEMSELVES AND
13 MARKET IT OR LICENSE IT TO A THIRD PARTY IN GENERAL.
14 AND IT'S OUR ASSUMPTION, I THINK A REASONABLE ONE, THAT
15 FOR THE NONPROFITS, THEY DON'T HAVE THAT FLEXIBILITY.
16 SO THEIR ONLY OUTLET FOR TECHNOLOGY IS TO LICENSE IT TO
17 A THIRD PARTY.

18 SO THAT'S SORT OF THE -- AS A RESULT, THE
19 POLICIES ARE NOT IDENTICAL FOR OBVIOUS REASONS. THEY
20 HAVE DIFFERENT POLICY NEEDS BECAUSE OF THE DIFFERENT
21 ASPECTS OF THESE TWO WAYS OF BRINGING TECHNOLOGY TO THE
22 MARKETPLACE.

23 NEXT SLIDE SIMPLY SUMMARIZES WHERE WE HAVE
24 BEEN IN THIS PROCESS. AGAIN, WE'VE HAD A NUMBER OF
25 MEETINGS OF THIS TASK FORCE. LET ME REMIND EVERYONE

1 THAT LAST AUGUST THE ICOC APPROVED THE POLICIES AS WE
2 PRESENTED THEM AT THAT TIME, AND IT WAS BASED ON THAT
3 POLICY APPROVAL OR THE PRINCIPLES THAT SCOTT HAS GONE
4 FORWARD TO DRAFT REGULATORY LANGUAGE. AND THAT'S WHAT
5 YOU HAVE IN FRONT OF YOU IN THESE DOCUMENTS.

6 SO, SCOTT, THANK YOU FOR ALL YOUR HARD WORK
7 BETWEEN THAT, AND IT'S REALLY THIS DOCUMENT TO WHICH
8 PEOPLE HAVE BEEN ASKED TO RESPOND AND FORMS THE BASIS
9 OF OUR DISCUSSION TODAY.

10 IF WE GO TO THE NEXT SLIDE, IT SHOWS WHERE WE
11 ARE DURING THIS YEAR. THAT WAS DECEMBER OF LAST YEAR.
12 WE HAVE HAD LEGISLATIVE MEETINGS. IN FEBRUARY SCOTT
13 HOSTED AN INTERESTED PERSONS MEETING IN SACRAMENTO TO
14 GET INPUT FROM ANYBODY WHO WANTED TO SHOW UP IN
15 DRAFTING SOME PARTS OF THIS LANGUAGE. SCOTT, YOU MIGHT
16 DESCRIBE BRIEFLY WHO WAS AT THAT MEETING AND WHAT KIND
17 OF INPUT YOU GOT.

18 MR. TOCHER: WE COORDINATED WITH THE
19 CALENDARS OF FOLKS WHO INDICATED INTEREST IN THE
20 REGULATORY PROCESS ALREADY JUST GENERALLY, BUT ALSO
21 SPECIFICALLY ANYONE WHO HAD SUBMITTED COMMENTS OR
22 FOLLOWED THE IP POLICY THAT WE'VE BEEN WORKING ON. WE
23 MADE PERSONAL CONTACT AND CHECKED THE CALENDARS WITH
24 FOLKS AND THE LEGISLATIVE STAFF AS WELL AS INTERESTED
25 COMMUNITY MEMBERS. AND WE MET IN SACRAMENTO, AND

1 UNFORTUNATELY THE LEGISLATIVE FOLKS WEREN'T ABLE IN THE
2 END TO ATTEND THE MEETING. SO WE MADE DO WITH THE
3 STRONG RESPONSE OF THE REGULATED COMMUNITY THAT WAS
4 THERE, IN ADDITION TO JOHN SIMPSON OF THE FOUNDATION
5 FOR TAXPAYER AND CONSUMER RIGHTS, AND THERE WERE FOLKS
6 FROM OTHER GROUPS AS WELL. AND WE MET FOR ABOUT THREE
7 HOURS OR FOUR HOURS OR SO, I CAN'T REMEMBER NOW, AND
8 WENT OVER IN RATHER STRONG DETAIL THE VARIOUS
9 PROVISIONS. IT WAS VERY HELPFUL.

10 CHAIRMAN PENHOET: SO HERE WE ARE. THE
11 FOR-PROFIT POLICY WAS PRESENTED TO THE STANDARDS
12 WORKING GROUP ON MAY 10TH. I THINK YOU KNOW THAT THEY
13 HAVE SOME OVERSIGHT. AT LEAST WE HAVE AN OBLIGATION TO
14 SHOW IT TO THEM, AND THEY HAVE AN OBLIGATION TO COMMENT
15 BACK TO US. AND SO I THINK, MARY, YOU MADE THAT
16 PRESENTATION TO THE STANDARDS WORKING GROUP. GEOFF
17 LOMAX IS HERE. GEOFF, I DON'T KNOW IF YOU WANT TO
18 COMMENT ON ANYTHING THAT CAME OUT OF THAT MEETING.
19 GEOFF IS THE CIRM COORDINATOR OF THE STANDARDS WORKING
20 GROUP.

21 DR. LOMAX: ONLY JUST FOR THE RECORD TO STATE
22 THAT THE WORKING GROUP HAD NO SORT OF FORMAL COMMENT ON
23 THE DOCUMENT. I THINK TO POINT OUT THAT THE WORKING
24 GROUP WAS QUITE APPRECIATIVE OF THE FACT THAT THERE WAS
25 A DELIBERATIVE BODY SPECIFICALLY WORKING THROUGH THE

1 PROCESS. THEY WERE IMPRESSED WITH THE AMOUNT OF DETAIL
2 AND RIGOR THAT OCCURRED TO DATE.

3 CHAIRMAN PENHOET: SO ESSENTIALLY THAT BRINGS
4 US TO THIS MEETING TODAY WHERE WE HOPE TO REACH SOME
5 CONCLUSIONS WITH RESPECT TO A NUMBER OF THE ISSUES THAT
6 ARE STILL IN FRONT OF US. AS I SAID BEFORE, IN
7 REVIEWING THESE DOCUMENTS, WE FOUND A NUMBER OF HELPFUL
8 SUGGESTIONS. WE FOUND, FRANKLY, THAT MUCH OF THE
9 COMMENTS GO OVER OLD GROUND WHICH HAS ALREADY BEEN
10 APPROVED IN PRINCIPLE, BUT WE'LL POINT OUT WHERE THAT'S
11 THE CASE. AND SO THE BULK OF THIS MEETING IS TO REALLY
12 GO THROUGH, AND SCOTT HAS SUMMARIZED THOSE COMMENTS FOR
13 YOU IN THIS DOCUMENT HERE.

14 MR. TOCHER: ED IS REFERRING TO THE DOCUMENT
15 NOW, THOSE ON THE PHONE AND AT THE REMOTE SITES, THE
16 SUMMARY AND ORGANIZATION OF COMMENTS AND
17 RECOMMENDATIONS THAT WAS ATTACHED TO THE E-MAIL OF
18 TODAY.

19 CHAIRMAN PENHOET: AND WHEN WE GET TO THAT,
20 YOU WILL SEE THAT WE HAVE FOLLOWED ESSENTIALLY THE
21 OUTLINE OF THE OAL PROPOSAL, AND WE HAVE CATEGORIZED
22 THINGS IN A, B, OR C CATEGORY DEPENDING ON WHAT OUR
23 CONCEPT OF THEIR IMPORTANCE IS, AND IN MANY CASES IN C
24 WE HAVE ACTUALLY INCORPORATED THE LANGUAGE DIRECTLY,
25 AND WE DON'T THINK IT NEEDS A LOT OF DISCUSSION HERE.

1 BUT ANY OF YOU, OF COURSE, ARE WELCOME TO CHALLENGE OUR
2 PRIORITIZATION OF THESE ISSUES AND BRING UP ANY ISSUE
3 FOR FULL DISCUSSION. SO WE DON'T MEAN TO ESSENTIALLY
4 PRECLUDE DISCUSSION OF ANY OF THESE ITEMS, BUT WE'VE
5 TRIED TO CATEGORIZE THEM FOR OURSELVES AS THOSE WE SEE
6 AS BEING MOST IMPORTANT OR CONTROVERSIAL AND THOSE
7 BEING THE LEAST SO. SO WE WILL WORK THROUGH THAT
8 DOCUMENT. THAT WILL BE THE PRIMARY DOCUMENT THAT
9 GUIDES US IN OUR DISCUSSION TODAY.

10 MR. TOCHER: IF I COULD ADD JUST ONE THING,
11 ONCE WE GET STARTED, YOU WILL ESSENTIALLY MAYBE WANT
12 THREE DOCUMENTS IN FRONT OF YOU. WE'LL BE MOVING OFF
13 THE ROAD MAP THAT ED WAS JUST REFERRING TO, WHICH IS
14 THE DOCUMENT THAT TRIAGES IN THESE CATEGORIES THE
15 COMMENTS. AND WE'LL PRESUMABLY MOVE IN THE ORDER OF
16 REGULATIONS THEMSELVES.

17 THEN THE TWO DOCUMENTS THAT YOU WILL PROBABLY
18 WANT TO REFER TO, THEN, REALLY ARE THE TWO SETS OF
19 REGULATIONS. ONE IS THE ORIGINAL ONES AS THEY WERE
20 POSTED AND THE ONE THAT WAS MAILED TODAY THAT HAS IN
21 BLUE STRIKEOUT AND ADDITIONAL LANGUAGE, WHICH WE THINK
22 REFLECTS SORT OF THE INPUT THAT WE'VE RECEIVED TO DATE,
23 SUGGESTIONS THAT SEEMED HELPFUL, THAT SORT OF THING.
24 WE WANTED TO AT LEAST GIVE YOU SOME IDEA OF WHAT SOME
25 OF THE SUGGESTIONS AND RECOMMENDATIONS WOULD ACTUALLY

1 LOOK LIKE IN RED LANGUAGE. SO WE'LL SORT OF BE
2 FLIPPING AROUND BETWEEN THOSE THREE.

3 CHAIRMAN PENHOET: THAT'S CORRECT.

4 DR. BRYANT: QUESTION? THIS IS SUE BRYANT.
5 COULD I JUST ASK A QUICK QUESTION? SO I GOT -- THERE
6 WERE OTHER THINGS THAT WE GOT LIKE, ALLIANCE FOR
7 RESEARCH INNOVATION COMMENTS AND CHI. ARE THEY ALL
8 INCORPORATED INTO HERE?

9 MR. TOCHER: YEAH. YOU'RE TALKING ABOUT THE
10 PUBLIC COMMENTS WHICH WAS SENT OUT, I BELIEVE, AS A
11 PDF. IT HAS THE FIVE LETTERS, AND THOSE ARE -- YOU'LL
12 SEE IN THE UPPER RIGHT CORNER, I BELIEVE IT SAYS
13 REFERENCE ONE OR TWO OR THREE OR FOUR OR FIVE. AND,
14 YES, THOSE ARE SUMMARIZED IN THAT ROAD MAP DOCUMENT
15 WITH WHAT THE PARENTHETICAL NUMBER IS. AFTER EACH OF
16 THE LITTLE SUMMARY COMMENTS THERE, YOU WILL SEE A
17 REFERENCE NO. 1 THROUGH 5. SO THERE'S ADDITIONAL ONES
18 WHERE MULTIPLE COMMENTERS MADE THE SAME COMMENTS.

19 DR. BRYANT: OKAY. GOT IT.

20 CHAIRMAN PENHOET: IS THAT CLEAR TO EVERYONE?
21 SO IF YOU LOOK ON PAGE 2 OF THE DOCUMENT THAT WAS SCOTT
22 WAS REFERRING TO, THE SUMMARY DOCUMENT, UNDER SCOPE,
23 100400, IT SAYS, A, DO NOT APPLY AMENDMENTS
24 RETROACTIVELY TO GRANTS THAT HAVE ALREADY BEEN CLOSED
25 OUT. FOUR AND FIVE WOULD REFER TO LETTERS NO. 4 AND 5

1 THAT ARE IN THE PACKET, FRONT PAGE OF WHICH IS A LETTER
2 FROM THE ALLIANCE FOR RESEARCH INNOVATION.

3 MR. TOCHER: CORRECT.

4 CHAIRMAN PENHOET: IT APPEARED IN BOTH OF
5 THOSE LETTERS.

6 MR. TOCHER: THAT'S RIGHT.

7 CHAIRMAN PENHOET: THE NEXT SLIDE, MARY --
8 WELL, THE NEXT STEP AFTER THIS IS TO FINALIZE THIS.
9 FIRST OF ALL, TO GIVE A REPORT TO THE ICOC MEETING.
10 AND IF THERE ARE ANY CHANGES IN POLICY WHICH RESULT
11 FROM THIS DISCUSSION TODAY, AS OPPOSED TO REFINEMENT OF
12 THE POLICY ALREADY APPROVED, WE HAVE TO TAKE THAT BACK
13 THAT TO ICOC. THIS GROUP, THIS TASK FORCE, IS ADVISORY
14 TO THE ICOC. IT'S NOT A POLICYMAKING GROUP. SO IF WE
15 MAKE ANY CHANGES WHICH ARE MATERIAL IN THE SENSE THAT
16 THEY ACTUALLY CHANGE THE MEANING OF THE POLICY THAT WAS
17 ESTABLISHED LAST AUGUST, THEN WE WILL TAKE THOSE BACK
18 TO THE ICOC AT THE JUNE 4TH MEETING.

19 NEXT SLIDE WE HAVE IS PERHAPS THE MOST
20 CONTROVERSIAL ISSUE, WHICH IS THE USE OF -- THE PRIOR
21 USE OF THE TERM "FEDERAL MEDICAID PRICE." AND IT'S A
22 CONTROVERSIAL ISSUE BECAUSE, AND WE'LL GET TO IT LATER,
23 THERE IS A BILL IN FRONT OF THE STATE LEGISLATURE AT
24 THE MOMENT, SB 771, WHICH ATTEMPTS TO OVERRIDE OUR WORK
25 HERE IN SEVERAL DIFFERENT WAYS. AND ONE OF THOSE WAYS

1 IS TO SPECIFY IN LAW THAT WE USE THE FEDERAL MEDICAID
2 PRICE AS THE PRICE IN OUR PRICING PROVISIONS IN BOTH
3 THE NONPROFIT AND THE FOR-PROFIT REGS. THEY'RE THE
4 SAME. THAT WE USE FEDERAL MEDICAID PRICE AS THE PRICE
5 WHICH WOULD BE AVAILABLE TO PATIENTS IN CALIFORNIA
6 WHOSE THERAPIES ARE FUNDED WITH PUBLIC FUNDS.

7 WE HAVE DONE A LOT OF WORK ON THIS BECAUSE
8 THAT WAS OUR FIRST PROPOSAL, AS MANY OF YOU MAY
9 REMEMBER. HOWEVER, AFTER A LOT OF WORK, WE HAVE BECOME
10 CONVINCED THAT IT'S NOT A WORKABLE SYSTEM BECAUSE IT'S
11 EMBEDDED IN THE FEDERAL GOVERNMENT, AND IT'S EMBEDDED,
12 NOT ONLY IN THE FEDERAL GOVERNMENT IN A STRAIGHTFORWARD
13 WAY, BUT THERE ARE A NUMBER OF INTERACTING PARTS OF THE
14 FEDERAL GOVERNMENT THAT ACTUALLY WORK IN CONCERT TO
15 DEFINE THE FEDERAL MEDICAID BEST PRICE.

16 SCOTT, YOU PUT A LOT OF EFFORT INTO THIS.
17 MAYBE YOU COULD JUST ELABORATE A LITTLE BIT FOR THIS
18 GROUP WHAT YOU'VE LEARNED ABOUT FEDERAL MEDICAID BEST
19 PRICE.

20 MR. TOCHER: WHAT I LEARNED THROUGH THE
21 DEVELOPMENT OF THIS PARTICULAR PROVISION IS THAT
22 FEDERAL MEDICAID PRICE IS NOT, I THINK, WHAT INITIALLY
23 WE HOPED IT WOULD BE BECAUSE IT IS NOT A PRICE THAT WE
24 THINK OF WHEN WE THINK OF A TRANSACTION THAT OCCURS IN
25 A PHARMACY. FOR INSTANCE, MANUFACTURERS DO NOT SELL

1 DRUGS TO PATIENTS. THEY SELL THEM TO THE DISTRIBUTORS
2 AND THEN WORK THEIR WAY THROUGH THE LINE ULTIMATELY TO
3 A PATIENT, TYPICALLY THROUGH A PHARMACIST DOWN THE
4 ROAD. THE FEDERAL MEDICAID PRICE IS ACTUALLY NOT
5 SOMETHING THAT IS DESCRIBED AS SUCH. IT IS REALLY
6 DESCRIBED GENERICALLY OR IN LAY TERMS THE END RESULT OF
7 A REBATE PROGRAM. AND THIS REBATE PROGRAM REQUIRES
8 MANUFACTURERS TO SUBMIT DATA TO THE GOVERNMENT TO GET A
9 DRUG ON A LIST OF APPROVED DRUGS THAT WILL BE PAID FOR
10 BY MEDICARE.

11 IT SETS UP A FORMULA WHEREBY TRANSACTIONS
12 THAT OCCUR OVER A PERIOD OF TIME ARE ACCOUNTED FOR, A
13 FORMULA IS USED TO SUBTRACT VARIOUS PERCENTAGES,
14 DEPENDING ON WHETHER OR NOT THE PRICE OVER THAT PERIOD
15 OF TIME RISES FASTER THAN INFLATION, IN WHICH CASE THE
16 GOVERNMENT GETS A REBATE, AND IT ALSO TAKES ANOTHER
17 JUST REBATE OFF THE AVERAGE MANUFACTURER PRICE.

18 THE FEDERAL GOVERNMENT THEN SENDS POTENTIALLY
19 A BILL TO THE MANUFACTURERS AND SAYS THIS IS HOW MANY
20 PILLS OR THIS IS HOW MANY TRANSACTIONS OCCURRED WITH
21 YOUR DRUG OVER THIS PERIOD OF TIME. THIS IS WHAT WE
22 CALCULATE THE REBATE IS THAT YOU OWE US. AT THE END OF
23 THAT LONG STATUTORY PROCESS, STATUTORILY DESCRIBED
24 PROCESS, THE MANUFACTURERS END UP ISSUING A CHECK TO
25 THE GOVERNMENT. AND THAT ULTIMATELY IS WHAT WE THINK

1 OF WHEN WE THINK OF A FEDERAL MEDICAID PRICE, BUT IT IS
2 SOMETHING THAT IS DETERMINED LONG AFTER THE DRUG IS
3 INTRODUCED OR SOLD BY THE MANUFACTURER INTO THE
4 DISTRIBUTION LINE. AND IT OCCURS AND IS DETERMINED
5 AFTER THE ACTUAL PURCHASE BY THE CONSUMER.

6 OF COURSE, AS WELL, THAT FEDERAL MEDICAID
7 PRICE FORMULA IS PART OF THE LARGER FEDERAL MEDICAID
8 PROGRAM AND HEALTHCARE SYSTEM, A SYSTEM WHICH ALREADY
9 DEFINES WHO BENEFICIARIES ARE, DEFINES HOW
10 PARTICIPATING PHARMACIES KNOW WHO AN ELIGIBLE PATIENT
11 IS, ALL OF THAT. MERELY REFERENCING IT IN OUR SYSTEM,
12 OF COURSE, THE FEDERAL MEDICAID PRICE, FAILED TO
13 DUPLICATE ALL OF THAT OTHER INFRASTRUCTURE. IT FAILED
14 TO ACCOUNT FOR THE PROCESS THAT IS INVOLVED.

15 SO WHAT WE DETERMINED AND WHAT WE DECIDED,
16 THE TASK FORCE DECIDED BACK IN SAN DIEGO IS THAT WE
17 WOULD LIKE TO UTILIZE AN ALREADY EXISTING STATE SYSTEM
18 THAT ALREADY HAS THE INFRASTRUCTURE SURROUNDING
19 IDENTIFICATION OF ELIGIBILITY, PARTICIPATING
20 PHARMACISTS, DRUGS, ALL OF THAT INFRASTRUCTURE, AND
21 THAT WAS THE CAL RX SYSTEM.

22 WE'VE BEEN FINE-TUNING THAT SINCE. NOW WE'VE
23 SWITCHED TO SLIDE 6 NOW ENTITLED "CALIFORNIA RX
24 DISCOUNT," AND THIS SLIDE JUST DESCRIBES, NOT WHAT OUR
25 REGULATION DOES, BUT HOW THE CAL RX PROGRAM BASICALLY

1 OPERATES. AND THE CALRX PROGRAM, WHICH WAS ESTABLISHED
2 IN LEGISLATION SPONSORED BY THE SPEAKER, IS SET TO ROLL
3 OUT JANUARY 1 OF NEXT YEAR. AND I BELIEVE IT WILL BE
4 SORT OF STARTED UP FOR BETA TESTING HERE IN THE NEXT
5 COUPLE OF WEEKS. SO THE PARTICULARS OF THIS SLIDE
6 MIGHT CHANGE SLIGHTLY AND THE NEXT SLIDES THAT FOLLOW
7 AS EXPERIENCE DICTATES.

8 BUT BASICALLY IT ESTABLISHES THREE BENCHMARK
9 PRICES OR FORMULAS FOR PARTICIPATING MANUFACTURERS TO
10 PROVIDE THEIR MEDICINE. AND SO WHAT WE'VE DONE IS WE
11 REFERRED IN --

12 DO WE HAVE SOMEONE ELSE ON THE PHONE NOW?

13 DR. PRIETO: YES. FRANCISCO PRIETO.

14 MR. TOCHER: WE'RE ON THE SLIDE DECK THAT WAS
15 E-MAILED TO YOU, AND WE'RE DISCUSSING PAGE 6.

16 SO CALRX ON SLIDE 7 NOW, ENTAILS USING A
17 CARD. AND WHAT IT DOES IS IT IS A TWO-PRONG SORT OF
18 TACT TO REDUCE PRICES FOR ELIGIBLE CALIFORNIANS WHO ARE
19 FOLKS UNDER 300 PERCENT OF THE FEDERAL POVERTY LEVEL.
20 AND IT NEGOTIATES A DISCOUNT WITH THE PHARMACIST, AND
21 IT ALSO EMPLOYS A REBATE TO THE STATE FROM THE DRUG
22 MANUFACTURERS. AND THAT COMBINED REDUCED PRICE IS THE
23 PRICE PAID BY THE CARDHOLDER, AND THAT'S HOW THE
24 CALIFORNIA RX PROGRAM WORKS IN A NUTSHELL.

25 CHAIRMAN PENHOET: SO THE INFRASTRUCTURE WILL

1 BE IN PLACE. WE WILL PROPOSE A COUPLE OF ADDITIONS TO
2 THIS POLICY. AT THE MOMENT, AT LEAST, IT'S A VOLUNTARY
3 PROGRAM FOR MANUFACTURERS. AND WE WILL PROPOSE THAT
4 INCLUSION OF ANY CIRM-FUNDED THERAPIES IN THIS PROGRAM
5 BE MANDATORY.

6 MR. TOCHER: THAT'S RIGHT. THEY WOULD BE
7 REQUIRED TO PARTICIPATE.

8 CHAIRMAN PENHOET: THEY'D BE REQUIRED TO
9 PARTICIPATE IN CALRX AND THE SECOND THING WE PROPOSE IN
10 THIS REGARD IS THAT THEY'RE REQUIRED TO PARTICIPATE,
11 AND IT COVERS BOTH DRUGS AND NONDRUG THERAPIES, WHICH
12 IS IMPORTANT BECAUSE IT'S LIKELY THAT MOST OF THE
13 THERAPIES THAT EMANATE FROM STEM CELL RESEARCH ARE
14 GOING TO BE CELL THERAPIES AND NOT DRUGS. DRUGS MAY
15 EVOLVE, BUT CELL THERAPIES WILL CERTAINLY BE ONE BIG
16 CATEGORY SO THAT IT WOULD EXPAND IT TO COVER DRUGS OR
17 FORMS OF THERAPY WHICH ARE ESSENTIALLY SOLD THROUGH
18 PHARMACIES.

19 MR. TOCHER: THAT'S EXACTLY RIGHT.

20 CHAIRMAN PENHOET: AND THEN A RELATED ISSUE,
21 A NUMBER OF COMMENTS THAT WE GOT, AND WE WILL GO
22 THROUGH THAT, WERE CONCERNED THAT THE ACCESS PLANS OF
23 PROVIDING ACCESS TO THERAPIES, PEOPLE WANTED TO BE SURE
24 THAT WE WEREN'T SAYING THAT A MANUFACTURER WOULD HAVE
25 TO PAY FOR THE ENTIRE THERAPY, INCLUDING THE

1 INTERVENTION, HOSPITALIZATION, AND ALL THE REST OF THAT
2 STUFF. SO SCOTT HAS SOME CLARIFYING LANGUAGE LATER ON
3 FOR THAT.

4 SO USING MEDICAID BEST PRICE, WE BELIEVE,
5 WOULD HAVE BEEN A SIMPLE SOLUTION FOR US BECAUSE IT
6 DOES EXIST; HOWEVER, IT'S NOT WORKABLE WITHOUT SETTING
7 UP A WHOLE SYSTEM IN CALIFORNIA. THIS SYSTEM WILL BE
8 SET UP IN CALIFORNIA AND WE CAN PIGGYBACK ONTO THIS
9 SYSTEM WITH TWO ADDITIONS THAT I JUST MENTIONED TO YOU.

10 MR. TOCHER: DO WE HAVE SOMEONE ELSE JOINING
11 US?

12 MS. SPINK: YES, KATIE SPINK FROM GERON
13 AND --

14 MR. STRATTON: KEN STRATTON FROM STEM CELLS.
15 WE'RE JOINING FROM THE NUVELO LOCATION.

16 CHAIRMAN PENHOET: HELLO, KEN.

17 MR. STRATTON: HI. HOW ARE YOU?

18 CHAIRMAN PENHOET: I'M FINE. HOW ARE YOU?

19 MR. STRATTON: ALL RIGHT. THANKS.

20 MR. TOCHER: DO WE HAVE SOMEONE ELSE ON THE
21 LINE?

22 DR. PIZZO: PHIL PIZZO IS HERE.

23 CHAIRMAN PENHOET: THANKS, PHIL, FOR CALLING
24 IN.

25 WE ARE ON SLIDE 7 OF THE DECK. WE HAVE JUST

1 BEEN THROUGH AN EXPLANATION OF WHY WE THINK THAT THE
2 MEDICAID BEST PRICE IS NOT WORKABLE AND THE RATIONALE
3 FOR USING THE CALRX PROGRAM AS A SUBSTITUTE FOR FEDERAL
4 MEDICAID PRICE IN OUR PRICING PROPOSALS.

5 MARY, IS THAT THE LAST SLIDE? THIS IS JUST
6 HOW AN INDIVIDUAL --

7 DR. PRIETO: COULD I ASK SCOTT A QUESTION?

8 CHAIRMAN PENHOET: YES.

9 DR. PRIETO: WHO NEGOTIATES THAT ON BEHALF OF
10 THE STATE?

11 MR. TOCHER: IT'S A PROGRAM ADMINISTERED BY
12 DHHS.

13 DR. PRIETO: OKAY. SOMEBODY UNDER THE
14 AUTHORITY OF THE DIRECTOR?

15 MR. TOCHER: RIGHT. THEY HAVE A WHOLE
16 SEPARATE DEPARTMENT THAT IS SET UP NOW TO ADMINISTER
17 THIS PROGRAM.

18 DR. PRIETO: OKAY. IT'S ALREADY IN PLACE AND
19 UP AND RUNNING?

20 MR. TOCHER: IT IS IN PLACE, AND THEY HAVE
21 BEEN -- WELL, THEY'VE BEEN PUTTING IT TOGETHER, PUTTING
22 IT IN PLACE, GETTING EVERYTHING GEARED UP. IT IS SET
23 TO GO ONLINE JANUARY 1, '08. AND I UNDERSTAND THAT
24 THEY WILL HAVE A, QUOTE, UNQUOTE, SIGNIFICANT
25 ANNOUNCEMENT IN THE NEXT TWO TO THREE WEEKS. SO I

1 DON'T KNOW WHAT IT IS, BUT I'M INCLINED TO THINK THAT
2 THEY'RE READY TO START DOING TESTING OF THE MECHANISM,
3 BETA TESTING.

4 DR. PRIETO: THANK YOU.

5 CHAIRMAN PENHOET: THE ADVANTAGE IS THE
6 INFRASTRUCTURE IS IN PLACE, THE ALGORITHM FOR
7 DETERMINING PRICING WILL BE IN PLACE, AND IT'S A
8 CALIFORNIA PROGRAM FOR CALIFORNIA CITIZENS, AND WE
9 WON'T HAVE TO DO IT.

10 MR. TOCHER: RIGHT.

11 CHAIRMAN PENHOET: IT'S A CALIFORNIA STATE
12 AGENCY, ESSENTIALLY. DHHS WILL MANAGE IT FOR US. SO
13 THAT'S WHERE WE ARE ON THIS WHAT'S TURNED OUT TO BE A
14 VERY IMPORTANT ISSUE BECAUSE WE'RE ON A VERY CRITICAL
15 TIME FOR SOME CONSTITUENCIES IN SACRAMENTO WHO SAY WE,
16 QUOTE, UNQUOTE, HAVE GONE BACK ON OUR WORD BECAUSE WE
17 ABANDONED FEDERAL MEDICAID PRICE. WE DID IT BECAUSE NO
18 ONE COULD TELL US HOW TO MAKE IT WORK IN CALIFORNIA.
19 IS THAT A FAIR STATEMENT?

20 MR. TOCHER: THAT'S RIGHT.

21 CHAIRMAN PENHOET: SO THE NEXT SLIDE IS A
22 REMINDER ABOUT THE DIFFERENT POLICY NEEDS, SLIDE 9. IN
23 THE FOR-PROFIT AND NONPROFIT, WE HAD, I THINK,
24 DISCUSSED THAT EARLY ON IN THIS.

25 JUST TO REMIND YOU WHAT WE'VE ALREADY DECIDED

1 ABOUT HOW THE FLOW OF FUNDS WILL WORK. IF COMPANIES
2 FORWARD-INTEGRATE AND DEVELOP THE PRODUCTS THEMSELVES,
3 THEY PAY 3 X UP TO \$250 MILLION A YEAR, ANOTHER 3 X IF
4 THEY REACH 250; AND IF THEY REACH \$500 MILLION A YEAR,
5 THEY PAY ANOTHER 3 X FOR A TOTAL OF NINE TIMES OUR
6 INVESTMENT. IF THEY'VE INVESTED MORE THAN \$5 MILLION
7 AND CIRM-FUNDED PATENTS ARE INVOLVED AND IT'S A
8 BLOCKBUSTER OVER 500, THERE'S A ROYALTY ON TOP OF THE
9 500. SO THAT JUST SIMPLY SUMMARIZES WHERE WE ARE FOR
10 YOUR INFORMATION.

11 GOING FORWARD, THIS IS RELEVANT. WE ARE
12 GOING TO DISCUSS SB 771 FOR A MOMENT. WE'VE BEEN
13 ACTIVELY TRYING TO GET SB 771 -- WELL, WE WOULD LOVE TO
14 SEE SB 771 GO AWAY; HOWEVER, IN THE ABSENCE OF IT GOING
15 AWAY, WE WOULD LIKE IT TO BE AT LEAST TABLED FOR
16 ANOTHER YEAR TO ALLOW US TO FINISH OUR WORK BEFORE THE
17 LEGISLATURE DECIDES THAT WHAT WE'VE DONE IS NOT THE
18 RIGHT THING.

19 KIRK HAS BEEN WORKING ON THIS. WE'VE BEEN
20 TRYING TO EDUCATE THE LEGISLATORS. WE MET MANY TIMES
21 IN SACRAMENTO. WE'RE NOT VERY ENVIRONMENTALLY FRIENDLY
22 BECAUSE WE'RE BURNING UP -- CREATING TOO MUCH CO2
23 DRIVING BACK AND FORTH TO SACRAMENTO. NEVERTHELESS, I
24 THINK WE'VE AT LEAST INCREASED THE EDUCATION LEVEL.

25 THE DIFFERENCES BETWEEN SB 771 AND THE

1 POLICY, WHICH YOU GUYS AND THE BOARD HAVE APPROVED,
2 FALL IN FOUR BUCKETS. ONE IS RATHER THAN HAVE THE
3 RETURNS TO THE STATE DEFINED AND CAPPED AT 3 X, 6 X, 9
4 X, 771 WOULD SIMPLY IMPOSE A 2- TO 5-PERCENT ROYALTY
5 BURDEN ON DEVELOPERS OF PRODUCTS WHO SELL THEM
6 THEMSELVES. AND WE'VE DISCUSSED THIS MANY TIMES.
7 WE'VE BEEN TRYING TO BALANCE -- TO REMIND YOU, IT IS
8 THE OBLIGATION TO HAVE A RETURN TO THE STATE, AT THE
9 SAME TIME NOT MAKING THE TERMS SO ONEROUS THAT IT
10 DISCOURAGES PRIVATE INVESTMENT, AND ALSO, FRANKLY, THAT
11 WE HAVE SOME INCENTIVE IN PLACE FOR CALIFORNIA
12 COMPANIES TO DEVELOP THE PRODUCTS THEMSELVES IN
13 CALIFORNIA RATHER THAN LICENSING THEM OUT.

14 SO IF THEY LOOK AT THE COMPARATIVE NET
15 BENEFIT TO THEM BETWEEN PROVIDING A LICENSE FOR A THIRD
16 PARTY AND MAKING THE INVESTMENT IN CALIFORNIA, THAT WE
17 CAME UP WITH THE SYSTEM WE DID. AND ALSO REMIND YOU
18 THAT WE HAVE A LOT OF PRECEDENT FOR THE 3 X, 6 X, 9 X
19 KIND OF FORMULA IN THAT A NUMBER OF FOUNDATIONS WHICH
20 ARE NOW SUPPORTING WORK IN COMPANIES ESSENTIALLY EMPLOY
21 SIMILAR FORMULAS, WHICH DEFINE A FIXED RETURN ON THE
22 INVESTMENT. SO THAT'S A SIGNIFICANT DIFFERENCE.

23 THE SECOND IS FEDERAL MEDICAID PRICE. WE
24 JUST DISCUSSED THAT.

25 THE THIRD ONE REQUIRES A PLAN FOR ACCESS TO

1 CIRM-FUNDED PRODUCTS BY THE UNINSURED AT THE TIME OF A
2 LICENSE IN THE CASE OF LICENSING. AND I THINK WE'VE
3 ALL BEEN THROUGH THIS AND AGREED. AND I THINK JEFF WAS
4 IMPORTANT IN THAT DISCUSSION, FOR SURE, THAT THERE'S NO
5 WAY -- WHEN A LICENSE IS TAKEN TO A PIECE OF
6 TECHNOLOGY, FREQUENTLY THE PRODUCTS THAT ARE THE
7 SUBJECT OF THAT LICENSE DON'T COME TO MARKET FOR A
8 DECADE AFTERWARDS, AND YOU REALLY DON'T KNOW EXACTLY
9 WHAT THE PRODUCT WILL BE OR WHAT THE LANDSCAPE WILL BE
10 WITH RESPECT TO UNINSURED, ETC. SO WE CAME UP WITH THE
11 LANGUAGE THAT SAID IT WILL BE IN PLACE AT THE TIME OF
12 COMMERCIALIZATION, NOT THE TIME A LICENSE IS GIVEN.

13 AND THEN, FINALLY, THEY'RE PROPOSING THAT THE
14 SHARING OF LICENSING REVENUES, WERE THEY TO OCCUR BY
15 COMPANIES, WOULD BE 25 PERCENT VERSUS THE 17 PERCENT
16 THAT WE HAVE IN OUR CURRENT POLICY. REMEMBER THE LOGIC
17 FOR THIS WAS -- ANY OF THESE CAN BE CHANGED. I'M JUST
18 SORT OF GOING THROUGH WHERE THEY ARE. THE LOGIC FOR
19 THE 25 VERSUS THE 17 WAS ESSENTIALLY TO ACHIEVE PARITY
20 BETWEEN THE NOT-FOR-PROFITS AND THE FOR-PROFITS IN THIS
21 REGARD. BECAUSE IN THE CASE OF THE NOT-FOR-PROFITS,
22 YOU ARE SHARING AFTER INVENTORS ARE PAID. AND OUR
23 SURVEY WORK SHOWS THAT TYPICALLY INVENTORS GET ABOUT A
24 THIRD OF THE GROSS REVENUES FROM LICENSING REVENUES.
25 SO WE'RE GETTING 25 PERCENT OF 66 PERCENT. OKAY. FROM

1 A THIRD, IF YOU TAKE THE TOP NUMBER, THE TOTAL REVENUE
2 NUMBER TO A UNIVERSITY -- FOR EXAMPLE, THEY PAY AN
3 INVENTOR A THIRD OF THAT, THEY KEEP TWO-THIRDS. OF THE
4 TWO-THIRDS THEY GIVE US 25 PERCENT, SO A QUARTER OF 66
5 IS ABOUT 17. THAT'S THE LOGIC. OKAY.

6 IN THE CASE OF THE COMPANIES, THEY DON'T PAY
7 THEIR INVENTORS ANYTHING, OR FREQUENTLY THEY PAY THEM
8 \$1 TO DO THIS. SO THEY DON'T HAVE ANY PAYMENTS BELOW
9 THE GROSS REVENUE LINE TO SHARE WITH ANYBODY ELSE, SO
10 THE GROSS AND THE NET REVENUES ARE THE SAME TO THEM.
11 SO THE 17 AND THE 25 CAME ABOUT AS PARITY. IT REQUIRES
12 SOME EXPLANATION EVERY TIME. PEOPLE ARE CONFUSED ABOUT
13 WHY 25 AND 17 ARE DIFFERENT, AND CERTAINLY THAT'S THE
14 LOGIC BEHIND IT THAT WE CAME TO. BUT AS ALL THINGS IN
15 THIS, THESE ARE THE DIFFERENCES.

16 SO WE HAVE BEEN OPPOSING -- AT THE LAST BOARD
17 MEETING, THE BOARD FORMALLY OPPOSED 771. AND AS A
18 GROUP, WE BELIEVE THAT THE UNCAPPED ROYALTIES ARE
19 WITHOUT PRECEDENT FOR FINANCING. AND WE'VE HEARD A LOT
20 FROM INDUSTRY ABOUT THE PROBLEM OF ROYALTY STACKING,
21 AND WE'VE TRIED TO BE SENSITIVE TO THAT AND ALSO
22 QUANTIFYING PRECISELY WHAT THEIR ECONOMIC BURDEN WOULD
23 BE IF THEY TAKE OUR MONEY WOULD BE X, Y, OR Z.

24 FEDERAL MEDICAID PRICE WE DISCUSSED. THE
25 ACCESS PLAN WE DISCUSSED. THAT'S THE LOGIC FOR 25

1 VERSUS 17.

2 SO WE ARE FORMALLY OPPOSED TO 771 BECAUSE WE
3 BELIEVE THAT THE POLICY WE HAVE IN PLACE TODAY IS A
4 BETTER BALANCE BETWEEN MAKING SURE THAT WE GET SOME
5 RETURN TO THE STATE, BUT AT THE SAME TIME HAVING A
6 WORKABLE SYSTEM WHICH INCENTS INDUSTRY TO ACTUALLY
7 INVEST.

8 DOES ANYBODY HAVE A TREO OR A BLACKBERRY NEAR
9 YOUR PHONE?

10 ANYWAY, THAT'S THE BACKGROUND FOR ALL THESE
11 ISSUES WHERE WE ARE, AND THOSE ARE THE REASONS WHY
12 WE'RE OPPOSING 771.

13 FURTHERMORE, WE THINK IT MIGHT DELAY -- IF
14 771 PASSES, IT ESSENTIALLY MIGHT DELAY ANY GRANTS TO
15 FOR-PROFIT AGENCIES BY UP TO A YEAR, MAYBE MORE THAN A
16 YEAR, BECAUSE WE HAVE TO START THE OAL PROCESS ALL OVER
17 AGAIN NOW TO INCORPORATE THOSE INTO OUR LEGISLATION.
18 SO WE'RE WORKING ON THAT PROBLEM SEPARATELY. THAT'S
19 JUST A BACKGROUND TO SHARE WITH YOU ON THESE ISSUES.

20 DR. PIZZO: THAT'S A VERY HELPFUL SUMMARY.
21 WHAT DO YOU THINK THE STATUS OF THE RECEIPT OF THE
22 INFORMATION THAT YOU PROVIDED AS A COUNTER IS? HOW
23 RECEPTIVE ARE YOU -- WHAT KIND OF MESSAGE ARE YOU
24 GETTING FROM SENATORS KUEHL AND RUNNER?

25 CHAIRMAN PENHOET: THEY'RE CONVINCED THAT GOD

1 IS ON THEIR SIDE IN ONE CASE, AND THAT THE INTERESTS OF
2 THE STATE OF CALIFORNIA ARE ON THEIR SIDE IN THE OTHER
3 CASE. AND I DON'T THINK THEY'VE MOVED TOO FAR OFF OF
4 THAT, BUT WE HAVE HAD AN AUDIENCE FROM A NUMBER OF
5 OTHER PEOPLE IN SACRAMENTO WHO ARE -- I THINK WE'RE
6 TRYING TO EDUCATE THEM AROUND THESE ISSUES. FRANKLY, I
7 THINK ALL WE'VE DONE IS CONVINCED THEM THAT THIS IS A
8 VERY COMPLEX AREA, AND A LOT OF THESE THINGS INTERACT
9 WITH EACH OTHER. YOU CAN'T JUST PULL PIECES AND PARTS
10 OUT OF HERE WITHOUT UNDERSTANDING THE WHOLE.

11 I THINK -- I SHOULDN'T SPEAK FOR HER, BUT
12 WE'VE HEARD SENATOR KUEHL'S ISSUES ARE TWOFOLD. NO. 1,
13 SHE BELIEVES THIS IS A GIVEAWAY TO INDUSTRY. SHE'S
14 STATED THAT. NO. 2, SHE BELIEVES THAT THE LEGISLATURE
15 SHOULD HAVE MORE CONTROL OVER OUR ACTIVITIES. THAT'S A
16 PURELY -- AND THAT ONE IS HARD TO ARGUE AGAINST BECAUSE
17 NO FACTS CHANGE THAT VIEW. THE LEGISLATURE VIEWS THEY
18 NEED SOME DIRECT CONTROL OVER THIS. IT DOESN'T HELP TO
19 EXPLAIN ALL THIS STUFF ABOUT FEDERAL MEDICAID PRICE.
20 IT'S SORT OF GOING OVER THEIR HEAD. SO THAT'S THE
21 ISSUE.

22 I THINK THE ISSUE OF WHETHER IT'S A GIVEAWAY
23 TO INDUSTRY, I CERTAINLY -- IF YOU TAKE ALL THIS INPUT
24 WE GOT, INDUSTRY DOESN'T APPEAR TO THINK IT'S A
25 GIVEAWAY TO THEM, BUT THAT'S AT LEAST THE PERCEPTION.

1 DR. REED: ON THE CONCEPT OF GIVEAWAY TO
2 INDUSTRY, HAVE THE LEGISLATORS WHO ARE SUGGESTING THESE
3 CHANGES, HAVE THEY BEEN WILLING TO CONSIDER THE
4 ALTERNATIVE VIEW THAT MANY STATES IN THIS GREAT NATION
5 ARE ACTUALLY CREATING INCENTIVES FOR BIOTECHNOLOGY
6 INDUSTRY RATHER THAN PUTTING UP OBSTACLES TO IT AND, IN
7 FACT, ARE MAKING HUGE INVESTMENTS IN TAXPAYERS' DOLLARS
8 INTO LURING AND FOSTERING OF BIOTECHNOLOGY INDUSTRY,
9 RECOGNIZING THE IMPORTANCE OF THIS INDUSTRY FOR THE
10 ECONOMY OF THE 21 CENTURY? HAS THAT ARGUMENT BEEN
11 DISCUSSED, AND WHAT HAS THE RECEPTION TO THAT BEEN?

12 CHAIRMAN PENHOET: YOU KNOW, A NUMBER OF
13 PEOPLE HAVE MADE THAT ARGUMENT. AND CHI AND OTHERS
14 HAVE CALCULATED THE DIRECT IMPACT OF CALIFORNIA'S
15 CURRENT LIFE SCIENCES INDUSTRY ON REVENUES TO THE
16 STATE. AND THE NUMBERS -- FIRST OF ALL, THERE ARE
17 270,000 PEOPLE NOW EMPLOYED IN THE LIFE SCIENCES
18 INDUSTRY IN CALIFORNIA. AND I DON'T WANT GO ON
19 SOUNDING LIKE AN ADVERTISEMENT FOR INDUSTRY. I'M NOT
20 HERE TO DO THIS, BUT THERE'S SOME INTERESTING FIGURES
21 NEVERTHELESS.

22 THE AVERAGE SALARY IS \$72,000. THAT'S \$19.4
23 BILLION IN SALARIES AND WAGES PAID TO CALIFORNIANS IN
24 THE LIFE SCIENCES INDUSTRY. AND IF YOU ASSUME AN
25 INCOME TAX RATE OF 10 PERCENT AVERAGE ON THAT INCOME,

1 IT'S ALMOST \$2 BILLION A YEAR IN ANNUAL INCOME TAXES TO
2 THE STATE OF CALIFORNIA FROM THE BIOTECH INDUSTRY.

3 THE ESTIMATE IS THAT THERE ARE THREE OTHER
4 JOBS FOR EACH OF THE 270,000 JOBS IN OUR STATE THAT
5 RESULT FROM THIS. BIOTECH PROFITS ARE PROBABLY ON THE
6 ORDER OF \$10 BILLION A YEAR IN CALIFORNIA AND GENERATE,
7 THEREFORE, ANOTHER BILLION DOLLARS IN CORPORATE TAXES.
8 AND THERE ARE NOW 2700 LIFE SCIENCES COMPANIES IN
9 CALIFORNIA.

10 IF YOU JUST MAKE SOME SIMPLE ASSUMPTIONS,
11 WHICH WE DID, IF YOU ASSUME THAT THE STEM CELL INDUSTRY
12 MIGHT BE 25 PERCENT THE SIZE OF THE BIOTECH INDUSTRY
13 SOMEDAY, YOU STILL COME UP WITH \$500 MILLION A YEAR IN
14 ANNUAL INCOME TAX PAYMENTS TO THE STATE, ALMOST \$300
15 MILLION IN TAXES ON PROFITS AND REAL ESTATE AND LOCAL
16 TAXES, ETC. AND SO IT'S A SIGNIFICANT ECONOMIC IMPACT,
17 AND THAT'S THE BALANCE WE'VE BEEN TRYING TO EXPLAIN TO
18 PEOPLE. IF YOU MAKE THE TERMS TOO ONEROUS, INDUSTRY,
19 UNLIKE YOU, JOHN REED, YOU CAN MOVE TO FLORIDA, I
20 SUPPOSE, BUT UNIVERSITIES ARE STUCK HERE. THEY'RE NOT
21 GOING TO MOVE TO MASSACHUSETTS OR NEW YORK OR ILLINOIS
22 OR MARYLAND OR MISSOURI OR ANY OTHER PLACE, BUT
23 INDUSTRY CAN GO WHEREVER THEY LIKE. WE SEE IT
24 HAPPENING. PROBABLY SOME OF YOU JUST READ. ALL THE
25 NEW MANUFACTURING PLANTS FOR VACCINES ARE GOING TO BE

1 IN NORTH CAROLINA, NOT IN CALIFORNIA. SO THAT'S AN
2 ISSUE, AND WE'VE TRIED TO MAKE THAT POINT TO PEOPLE.

3 HAVING SAID THAT, WE HAVE AN OBLIGATION TO
4 HAVE REVENUES COMING FROM INDUSTRY, AND THAT'S WHAT
5 WE'RE GRAPPLING WITH HERE. AND SO I THINK WE TRIED TO
6 STRESS TO THEM THAT WE TRIED TO FIND WHAT APPEARS TO
7 THE CONSENSUS OF THIS GROUP AS A REASONABLE BALANCE OF
8 EXTRACTING SOME MEANINGFUL REVENUES FROM INDUSTRY, AT
9 THE SAME TIME NOT HAVING SUCH ONEROUS PROVISIONS THAT
10 WE ACTUALLY DRIVE INDUSTRY AWAY.

11 INTERESTINGLY ENOUGH, RECENTLY NEW JERSEY HAD
12 SOME LESS AGGRESSIVE TERMS FOR INDUSTRY THAN OUR
13 PROPOSED POLICY, AND THEY HAD RECENTLY GRANT ROUNDS
14 OPEN TO INDUSTRY. NOT ONE COMPANY APPLIED FOR THEIR
15 MONEY.

16 DR. MAXON: CONNECTICUT.

17 CHAIRMAN PENHOET: CONNECTICUT. I'M SORRY.
18 MARY CORRECTED ME. NOT NEW JERSEY. THERE WAS ONE IN
19 NEW JERSEY, I THINK. ONE IN NEW JERSEY AND NONE IN
20 CONNECTICUT. JUST A BACKGROUND.

21 DR. PIZZO: ED, DO YOU OR DOES ANYONE HAVE A
22 SENSE OF WHAT THE LEVEL OF SUPPORT FROM THE LEGISLATURE
23 IS FOR SB 771?

24 CHAIRMAN PENHOET: YOU KNOW, IT'S A LITTLE
25 HARD TO GAUGE AT THIS POINT IN TIME. UNTIL RECENTLY

1 IT'S BEEN SORT OF SLIDING THROUGH, AND IT HASN'T REALLY
2 COME TO THE FLOOR YET, ETC. IT TAKES A 70-PERCENT VOTE
3 IN BOTH HOUSES IN ORDER TO PASS ANY BILL TO MODIFY THE
4 ICOC-CIRM PROGRAMS, AND IT REQUIRES THE GOVERNOR TO
5 AGREE.

6 IT'S SEEMS IMPROBABLE THAT IT WOULD TRAVERSE
7 ALL OF THOSE GATES AND GET OUT, BUT ONE NEVER KNOWS.
8 BECAUSE WHEN YOU JUST LOOK AT FACE VALUE OF THIS AND
9 SAY, WELL, GEE, WE'LL GET MORE MONEY UNDER PATENT
10 ROYALTIES THAN WE'LL GET UNDER A FIXED RETURN, WELL,
11 THAT'S TRUE IF ALL THINGS ARE EQUAL. IF THINGS ARE NOT
12 EQUAL, THEN YOU ACTUALLY DISCOURAGE INVESTMENT. A
13 HUNDRED PERCENT ROYALTY OF NOTHING IS STILL NOTHING.
14 THAT'S A MORE SUBTLE ARGUMENT THAT YOU HAVE TO TRY TO
15 CONVINCING PEOPLE. SO IT'S NOT AN EASY SELL. JUST
16 READING IT IN ITS FACE, IF EVERYTHING ELSE WAS THE SAME
17 AND YOU WERE A LEGISLATOR, YOU'D SAY, "OH, GEE.
18 THERE'S MORE MONEY FOR US IN DIRECT PAYMENTS FROM
19 THIS," BUT YOU HAVE TO TAKE INTO ACCOUNT ALL THE OTHER
20 ECONOMIC FACTORS THAT ARE IN PLAY, WHICH ARE LESS EASY
21 TO QUANTIFY.

22 MR. ROTH: PHIL, I WOULD COMMENT THAT I THINK
23 ONE OF THE PROBLEMS IS THAT VERY FEW SENATORS ARE
24 REALLY FOCUSED ON THIS. I TALKED TO TWO YESTERDAY.
25 AND WHEN YOU WORK THROUGH IT AND GO THROUGH THE ENTIRE

1 RATIONALE BEHIND WHAT OUR WORK HAS BEEN, I THINK WE
2 HAVE A GOOD CHANCE TO CHANGE THE DIRECTION HERE.

3 DR. PIZZO: THAT'S GOOD. I WOULD IMAGINE IF
4 IT'S NOT SIMPLY CONCURRENCE, BUT THAT THE GOVERNOR CAN
5 ACTUALLY BLOCK IT, THAT THE GOVERNOR WOULD PROBABLY BE
6 SUPPORTIVE TO WHAT WE'RE POSTULATING. IT SUPPORTS
7 BIOTECHNOLOGY, WHICH HAS GOT TO BE ONE OF THE MAJOR
8 INCENTIVES FOR HIM.

9 CHAIRMAN PENHOET: I WOULD THINK SO.
10 COMPETITION IS FIERCE FOR --

11 DR. PIZZO: YOU'RE ABSOLUTELY RIGHT. LOSING
12 BIOTECHNOLOGY WOULD HAVE A TERRIBLY NEGATIVE EFFECT ON
13 CALIFORNIA.

14 MR. ROTH: ED, I THINK WE HAVE TO REMEMBER IF
15 THEY VOTE 70 PERCENT IN FAVOR, THE GOVERNOR'S VETO
16 DOESN'T MEAN ANYTHING BECAUSE THAT'S A TWO-THIRDS.

17 CHAIRMAN PENHOET: REQUIRES HIS APPROVAL. IN
18 PROP 71 IT'S WRITTEN. IT'S NOT AN OVERRIDE ISSUE. IN
19 ORDER TO OVERRIDE ANYTHING THAT WE DO, THEY HAVE TO GET
20 70 PERCENT IN BOTH HOUSES AND THE GOVERNOR'S SIGNATURE.

21 DR. PIZZO: IS IT TRULY AN AND, THAT THAT
22 REACHES -- SO THE GOVERNOR THEN ACTUALLY BLOCKS IT IF
23 THAT'S THE WAY IT WORKS.

24 CHAIRMAN PENHOET: THAT'S CORRECT.

25 DR. PIZZO: SO IT SEEMS TO ME THAT AS MUCH

1 EDUCATION TO THE GOVERNOR AS WE'RE GIVING TO THE
2 LEGISLATURE WOULD BE IMPORTANT.

3 CHAIRMAN PENHOET: I'M SURE THAT'S CORRECT.
4 WE HOPE WE DON'T HAVE TO GO TO THAT LEVEL. I THINK WE
5 SHOULD NOT SPEND MORE TIME IN THIS MEETING TODAY ON
6 THIS ISSUE BECAUSE WE HAVE A LOT OF OTHER VERY
7 IMPORTANT ISSUES TO COVER IN THE SUBSTANCE OF OUR WORK
8 TODAY. I JUST WANTED TO INFORM YOU WHAT'S GOING ON ON
9 771.

10 DR. PIZZO: VERY GOOD. THANK YOU.

11 CHAIRMAN PENHOET: BUT I SHOULD, SINCE WE'VE
12 HAD DISCUSSION, ASK IF THERE ARE ANY PEOPLE IN THE
13 AUDIENCE HERE IN SAN FRANCISCO OR ELSEWHERE WHO WOULD
14 LIKE TO COMMENT ON ANYTHING WE'VE SAID SO FAR?

15 DR. PRIETO: I WOULD JUST LIKE TO MAKE THE
16 COMMENT THAT I HOPE WE DON'T COUNT ON THE GOVERNOR'S
17 VETO TO BLOCK THIS. IF THIS WERE TO PASS BY 70 PERCENT
18 IN BOTH HOUSES AND WE HAD THAT PLUS, I'M SURE, THE
19 EDITORIAL PAGES OF SEVERAL NEWSPAPERS UP AGAINST US, I
20 DON'T THINK WE WANT TO BE IN THAT POSITION. THAT WOULD
21 BE A FAILURE, I THINK. I'M SURE THE PEOPLE WHO BELIEVE
22 THAT GOD IS ON THEIR SIDE IN OPPOSING CAN'T BE SWAYED,
23 BUT I THINK A GOOD MANY OF THE PEOPLE WHO WANT WHAT IS
24 BEST FOR THE STATE OF CALIFORNIA AT LEAST WE HAVE SOME
25 BASIS TO DISCUSS WITH THEM. AND IF WE CAN KEEP THOSE

1 LINES OF COMMUNICATION OPEN, WE CAN PREVENT THIS 70
2 PERCENT FROM EVER BEING REACHED.

3 CHAIRMAN PENHOET: I TOTALLY AGREE WITH YOU,
4 FRANCISCO. WE'RE TRYING HARD TO DO THAT, AND I KNOW
5 YOU'RE GOING TO HELP US AS WELL.

6 MS. GHIO: TERRY GHIO FROM INVITROGEN. I
7 JUST WANTED TO ALSO MENTION THAT WE THINK THAT THE
8 PUBLIC PROCESS THAT'S GOING ON RIGHT NOW REGARDING THIS
9 POLICY IS THE RIGHT WAY TO GO. WE'VE ALL BEEN PUTTING
10 A LOT OF WORK AND A LOT OF EFFORT INTO THIS, AND I
11 THINK THAT WE'RE ALL SUPPORTIVE OF CIRM'S OPPOSITION TO
12 771 AND ARE ALSO WORKING TO TRY TO STALL THAT AND AT
13 LEAST PUT IT OFF FOR A COUPLE OF YEARS SO THAT WE CAN
14 EITHER SHOW ONE WAY OR ANOTHER WHETHER THE POLICIES WE
15 DEVELOP IN THIS GROUP CAN ACTUALLY WORK. THANK YOU FOR
16 YOUR OPPOSITION TO THAT.

17 CHAIRMAN PENHOET: WE COULD MOVE INTO THE
18 SUBSTANCE NOW OF THE MEETING, WHICH IS IN THIS DOCUMENT
19 ENTITLED "SUMMARY AND ORGANIZATION OF COMMENTS AND
20 RECOMMENDATIONS" THAT SCOTT HAS PUT BEFORE YOU. AND IF
21 YOU CAN SIMPLY TURN TO THE FIRST PAGE BEHIND -- WELL,
22 IT'S PAGE 2 BEHIND THE COMMENTARY ON THE FRONT PAGE.
23 THIS IS THE RESPONSE TO THE COMMENTS THAT WE MUST GO
24 THROUGH TODAY AND GIVE SCOTT SOME CLEAR GUIDANCE.
25 SCOTT'S JUST FLED THE SCENE.

1 SO AS I SAID, SCOTT HAS PROVIDED A SUMMARY OF
2 THE COMMENTS. AND AS I SAID BEFORE, IF WE MISS
3 SOMETHING IN THE SUMMARY, PLEASE FEEL FREE TO ADD IT
4 LATER. BUT SCOTT DID, I THINK, A NICE JOB OF GETTING
5 THE KEY POINTS ANYWAY. SO WE'RE JUST GOING TO GO ONE
6 BY ONE THROUGH THE COMMENTS.

7 MR. TOCHER: ED, I THINK PERHAPS YOU WERE
8 INTENDING TO GO TO THEM BY VIRTUE OF PRIORITY FIRST.

9 CHAIRMAN PENHOET: YES. THE A'S ARE THE
10 HIGHEST PRIORITY. THANK YOU, SCOTT. SO FORTUNATELY
11 FOR ME, THE FIRST ONE IS AN A. TURNED OUT TO BE A VERY
12 IMPORTANT ONE AS WE THOUGHT THROUGH THIS.

13 ON PAGE 2, NO. 1, SCOPE 100400, A, DO NOT
14 APPLY AMENDMENTS TO REGULATIONS RETROACTIVELY TO GRANTS
15 THAT HAVE ALREADY BEEN CLOSED OUT. THIS IS A GOOD
16 POINT. WHEN WE START TO THINK ABOUT HOW IT WOULD
17 ACTUALLY WORK, WHEN A COMPANY TAKES A GRANT FROM CIRM,
18 CIRM WILL HAVE TO ENTER INTO A NEGOTIATION WITH THAT
19 COMPANY TO TAKE ALL OF THIS LANGUAGE AND CONVERT IT
20 INTO A LEGAL RELATIONSHIP BETWEEN THE COMPANY AND CIRM.
21 HAVING DONE THAT, THEY WILL AGREE IN THAT DOCUMENT TO
22 ALL OF THE PROVISIONS WHICH ARE IN PLACE AT THE TIME
23 THE AGREEMENT IS MADE.

24 I DON'T BELIEVE ANY COMPANY WOULD SIGN SUCH
25 AN AGREEMENT IF THEY BELIEVED THAT FIVE YEARS LATER

1 SOMEBODY COULD COME BACK AND PASS A 771 OR CHANGE THE
2 TERMS, ETC., ESPECIALLY ON THE FINANCIAL SIDE, BECAUSE
3 THE AGREEMENT WOULDN'T HAVE ANY FORCE THEN BASICALLY.
4 THEY WOULD BE SUBJECT TO CHANGES IN THE AGREEMENT.

5 SO SCOTT HAS A RECOMMENDATION HERE, THAT WE
6 ACTUALLY CHANGE THIS SO THAT WE ANTICIPATE THAT
7 REALITY. SCOTT, IF YOU WANT TO TAKE US THROUGH YOUR
8 RECOMMENDATION.

9 MR. TOCHER: I'M LOOKING AT THE COMPILED
10 REGULATIONS THAT WAS E-MAILED TO YOU THAT HAS BLUE
11 STRIKEOUTS AND SUGGESTED TEXT. IN ORDER TO IMPLEMENT
12 THE SUGGESTION, ON LINE 15, PAGE 1, SECTION 100400
13 WOULD BE WE WOULD DELETE THE LANGUAGE INDICATED THERE
14 BEGINNING WITH "NEW OR AMENDED" AND DELETE THAT
15 SENTENCE TO THE END.

16 IN ADDITION, IT WAS THOUGHT THAT WE SHOULD
17 CLARIFY THAT AMENDMENTS THERE IN LINES 11 TO 13 OF THE
18 REGULATION SHOULD BE CLARIFIED TO STATE THAT WHILE WE
19 WILL WANT TO MAINTAIN REPORTING REQUIREMENTS OR ADJUST
20 REPORTING REQUIREMENTS THAT EXIST BEYOND A CURRENTLY
21 ACTIVE GRANT, THAT FOR THE SAME REASONS THAT WE
22 WOULDN'T BE APPLYING THEM RETROACTIVELY TO CLOSED-OUT
23 GRANTS, WE WOULD WANT TO EXEMPT THOSE PROVISIONS WHICH
24 DEAL WITH THE PRICING AND REVENUE SHARING. AND THOSE
25 ARE CONTAINED IN THE SECTIONS THAT ARE DELINEATED

1 THERE. AND SO THAT'S THE PURPOSE OF THOSE TWO
2 AMENDMENTS.

3 CHAIRMAN PENHOET: ANY COMMENTS FROM OTHER
4 MEMBERS OF THE TASK FORCE?

5 DR. LOVE: I THINK IT MAKES PERFECT SENSE.
6 THIS IS TED.

7 MR. ROTH: I ALSO AGREE. I THINK IT MAKES
8 SENSE.

9 DR. PIZZO: I'M FINE AS WELL.

10 CHAIRMAN PENHOET: OKAY. THIS WAS A VERY
11 HELPFUL COMMENT IN THESE LETTERS. AND AS I SAY, NO
12 RESPONSIBLE COMPANY EXECUTIVE COULD SIGN UP FOR AN
13 UNKNOWN LIABILITY. SO I THINK THIS JUST CLARIFIES.
14 THERE ARE OTHER ASPECTS, THOUGH, WHICH COULD BE CHANGED
15 DURING THE COURSE OF THE AGREEMENT, SUCH AS REPORTING
16 REQUIREMENTS, ETC., THAT ARE PART OF THE GRANTS
17 ADMINISTRATION POLICY. BUT WE'RE TALKING ABOUT
18 SIGNIFICANT FINANCIAL OR OTHER OBLIGATIONS OF THE
19 GRANTEE UNDER THESE CIRCUMSTANCES, NOT HOUSEKEEPING
20 KINDS OF THINGS THAT ARE EMBEDDED IN NORMAL GRANTS
21 ADMINISTRATION POLICY; IS THAT CORRECT, SCOTT?

22 MR. TOCHER: THAT'S RIGHT.

23 CHAIRMAN PENHOET: THEN THE NEXT ITEM THAT IS
24 FLAGGED AS AN A ITEM IS UNDER ACCESS REQUIREMENTS.
25 THIS IS ON PAGE 3, NO. 5, REFERRING TO SECTION 100407,

1 WHICH IS ON PAGE 7 OF THE AMENDED DOCUMENT. WE WERE
2 ASKED TO CLARIFY WHETHER A GRANTEE WOULD BE RESPONSIBLE
3 ONLY FOR THE COST OF THE THERAPEUTIC AGENTS OR FOR ALL
4 COSTS OF THE THERAPY.

5 I JUST DISCUSSED A FEW MINUTES AGO THIS IS
6 ONE OF THE AREAS, AGAIN, WHERE IT'S A HELPFUL
7 CLARIFICATION. I DON'T THINK ANY OF US WOULD HAVE
8 INTENDED TO BURDEN A SUPPLIER OF A THERAPY WITH THE
9 TOTAL COST OF ADMINISTERING IT AND TAKING CARE OF THE
10 PATIENT, ETC., SO WE BELIEVE THAT WE SHOULD MAKE IT
11 CLEAR THAT A GRANTEE IS RESPONSIBLE ONLY FOR THE COST
12 OF THE THERAPEUTIC AGENT IN THIS CASE AND NOT FOR ANY
13 OF THE ATTENDANT PATIENT CARE THAT WOULD GO ALONG WITH
14 THE USE OF THAT THERAPEUTIC AGENT.

15 SO SCOTT HAS MADE SOME CHANGES TO REFLECT
16 THAT POINT OF VIEW AS WELL.

17 MR. TOCHER: IF YOU LOOK AT THE --

18 DR. PRIETO: 13 OF THE COMPILED OAL NOTICE.

19 MS. KING: WE'RE HONING IN ON IT.

20 CHAIRMAN PENHOET: IT'S LINE 17 ON PAGE 7.
21 THIS REGULATION IS NOT INTENDED AND NOT TO BE CONSTRUED
22 TO PREEMPT OR PREVENT ANY OTHER REQUIREMENT -- NO,
23 THAT'S NOT THE LINE.

24 MR. TOCHER: I THINK THAT IT'S --

25 CHAIRMAN PENHOET: THE WORD "PRODUCTS," IT

1 MAY NOT BE CLEAR ENOUGH.

2 MR. TOCHER: I WAS TRYING TO FIND WHICH --

3 CHAIRMAN PENHOET: THAT IS LINE 4 AND 5.

4 MR. TOCHER: IN LINES 4 AND 5, WE'VE REPLACED
5 THERAPIES WITH THE ACTUAL PRODUCT TO TRY TO BE MORE
6 SPECIFIC. IT MAY BE THAT NOW WE'VE RECEIVED SOME
7 COMMENT THAT THAT COULD BE IMPROVED; OR WHEN THIS IS
8 POSTED, PUBLIC COMMENT THAT MIGHT HAVE AN ADDITIONAL
9 SUGGESTION IF FOLKS THINK THAT ISN'T CLEAR ENOUGH.

10 MR. MAC FERRIN: I HAD A SUGGESTION -- CHRIS
11 MAC FERRIN FROM APPLIED BIOSYSTEMS. I THINK YOU MEAN
12 THERAPEUTIC PRODUCTS BECAUSE OTHERWISE IT'S NOT MORE
13 SPECIFIC IN DIRECTION. IT'S MORE GENERAL.

14 DR. PRIETO: THAT'S A GOOD POINT BECAUSE I
15 THINK AT LEAST WHERE I'M LOOKING AT SECTION 407, THE
16 LINE THAT REFERS TO AWARDEES AGREE TO PROVIDE DRUGS
17 PURCHASED IN CALIFORNIA BY PUBLIC FUNDS, AND I THINK WE
18 REALLY WANT TO SAY THERAPEUTIC PRODUCTS RATHER THAN
19 DRUGS.

20 CHAIRMAN PENHOET: OKAY. THAT WILL WORK. ON
21 LINES 4 AND 5 WE ADD THE WORD "THERAPEUTIC" IN FRONT OF
22 THE WORD "PRODUCTS" IN BOTH CASES.

23 MR. ROTH: HOLD ON ONE SECOND.

24 DR. PRIETO: WHAT PAGE ARE WE ON AND OF WHICH
25 DOCUMENT BECAUSE I'M A LITTLE CONFUSED HERE?

1 CHAIRMAN PENHOET: THE MODIFIED DOCUMENT.
2 YOU HAVE TWO DOCUMENTS IN FRONT OF YOU THAT START WITH
3 CHAPTER 4, INTELLECTUAL PROPERTY, BLAH, BLAH, BLAH.
4 ONE OF THOSE HAS SOME NEW LANGUAGE INSERTED IN IT. THE
5 OTHER ONE IS A CLEAN DOCUMENT.

6 MS. KING: I THINK, DR. PRIETO, SCOTT TOCHER
7 E-MAILED SOME DOCUMENTS AROUND THIS AFTERNOON. AND I
8 BELIEVE THE ONE WITH THE BLUE STRIKETHROUGHS CAME
9 TODAY.

10 DR. PRIETO: I HAVE THE BLUE STRIKETHROUGH.
11 OKAY. SO I'M LOOKING AT PAGE 4 AND 5 OF THAT?

12 DR. PIZZO: NO. PAGE 7, THE TOP PARAGRAPH.

13 CHAIRMAN PENHOET: PAGE 7, LINES 4 AND 5.

14 DR. PRIETO: I HAD PRINTED UP ANOTHER
15 VERSION, SO I WAS LOOKING AT THE PRINT VERSION, BUT NOW
16 I'M ON THIS ONE.

17 MR. ROTH: ISN'T IT LINES 2 AND 3?

18 DR. PIZZO: YES, IT IS LINE 2 AND 3.

19 DR. PRIETO: TWO AND 3 OF THE VERSION HERE.

20 MR. TOCHER: LET ME BE MORE SPECIFIC THEN
21 BECAUSE I THINK MAYBE THE DELINEATION IS COMING OUT
22 DIFFERENTLY FOR SOME FOLKS. WHAT WE MEAN -- WHAT WE'RE
23 REFERRING TO IS ADDING THE WORD "THERAPEUTIC" WHERE
24 THERE CURRENTLY IS THE STRIKEOUT WORD "THERAPY" AND
25 THAT WORD WOULD BE INSERTED BEFORE THE WORD "PRODUCTS"

1 SO THAT THE FIRST SENTENCE READS, SUBDIVISION A, THE
2 AWARDEE ORGANIZATION OR ITS LICENSEES WILL PROVIDE AT
3 THE TIME OF COMMERCIALIZATION TO CIRM A PLAN TO PROVIDE
4 ACCESS TO RESULTANT THERAPEUTIC PRODUCTS AND SO ON.

5 DR. BRYANT: WHAT ABOUT IN SECTION B WHERE IT
6 GOES ON TO SAY FOR DRUGS AND THERAPIES? DO WE MEAN
7 DRUGS AND THERAPEUTIC PRODUCTS THERE TOO?

8 CHAIRMAN PENHOET: YES. GOOD GET. IT'S ON
9 LINE 14 IN OUR DRAFT.

10 MR. ROTH: ED, ONE OTHER SUGGESTION TO DEAL
11 THIS IS YOU COULD DEFINE DRUGS TO INCLUDE THERAPEUTIC
12 PRODUCTS UP FRONT, AND THEN YOU DON'T HAVE TO USE THIS
13 LANGUAGE THROUGHOUT.

14 MR. TOCHER: MR. ROTH MAKES A GOOD POINT
15 ABOUT SORT OF MAKING A DEFINITION AT THE OUTSET THAT
16 WOULD ENCAPSULATE THIS SO THAT WE WOULDN'T HAVE TO KEEP
17 REPEATING IT. SO I'LL TAKE THAT INSTRUCTION UNDER
18 ADVISEMENT AND CRAFT SOMETHING FOR THE NEXT PUBLIC
19 NOTICED PERIOD.

20 DR. BRYANT: I'M NOT SURE I AGREE WITH THAT.
21 IF SOMEBODY IS READING THROUGH THE DOCUMENT AND THEY
22 DON'T START FROM THE FIRST DEFINITION, THEY COULD BE
23 MISLED BY IT.

24 MR. ROTH: SUE, I'LL TELL YOU WHY I THINK
25 THAT'S IMPORTANT. BECAUSE WE REFER TO THE CALIFORNIA

1 DISCOUNT PRESCRIPTION DRUG PROGRAM. IF WE DEFINE DRUG
2 TO INCLUDE THERAPEUTICS, THEN IT'S CRYSTAL CLEAR TO ANY
3 LAWYER READING THE DOCUMENT, ANYWAY, WHAT WE MEAN. I'M
4 A LITTLE TROUBLED IF WE CONTINUE TO USE BOTH TERMS.

5 DR. BRYANT: OKAY.

6 DR. PRIETO: AS LONG AS WE SAY AT THE OUTSET
7 THAT THAT'S INCLUDED, I THINK THAT'S IMPORTANT BECAUSE,
8 YOU KNOW, CELLULAR THERAPIES POTENTIALLY ARE GOING TO
9 LOOK VERY, VERY DIFFERENT FROM, YOU KNOW, THE DRUGS
10 THAT I MIGHT PRESCRIBE TODAY.

11 MR. ROTH: I WOULD AGREE THAT YOU SHOULD MAKE
12 THAT TERM DRUG AS BROAD AND INCLUDE ALL OF THOSE THINGS
13 IN THERE, BUT THEN USE DRUG AFTER THAT.

14 CHAIRMAN PENHOET: THEN THE OTHER A UNDER
15 THERE IS DOES SUBDIVISION (A) UNDER 407 APPLY ONLY TO
16 SELF-COMMERCIALIZED PRODUCTS? AND I THINK THE INTENT
17 HAS ALWAYS BEEN THAT THESE ACCESS PLANS WOULD APPLY
18 BOTH TO SELF-COMMERCIALIZED PRODUCTS AND TO LICENSEES.
19 THEREFORE, IN THE FIRST LINE WE HAVE ADDED THE TERM THE
20 "AWARDEE ORGANIZATION OR ITS LICENSEES" WILL PROVIDE TO
21 CIRM A PLAN FOR ACCESS, ETC. THAT MAKES IT CONSISTENT
22 WITH WHAT THE LICENSE PROVISIONS ARE IN THE NONPROFIT
23 REGS.

24 DR. MAXON: (INAUDIBLE.)

25 THE REPORTER: I DIDN'T HEAR MARY'S COMMENT.

1 CHAIRMAN PENHOET: MARY SAID IT ALSO CONFORMS
2 TO WHAT'S IN 406 IN THE PRECEDING SECTION.

3 THE NEXT A --

4 MR. SIMPSON: JOHN SIMPSON FROM THE
5 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS. WHILE
6 WE'RE ON THAT PARAGRAPH, IT'S RELATED TO THIS, ABOUT
7 THE ACCESS PLANS. IT NOW SAYS MAY MAKE THEM AVAILABLE.
8 WOULD THE INTENT NOT BE BETTER FOR SHALL MAKE?

9 MR. TOCHER: THAT'S NOT NEW LANGUAGE.

10 CHAIRMAN PENHOET: PEOPLE CAN COMMENT ON ANY
11 LANGUAGE, NEW OR OLD.

12 MR. SIMPSON: WHILE YOU'RE ON THAT PARAGRAPH,
13 I JUST WAS RAISING THE QUESTION.

14 CHAIRMAN PENHOET: THE LAST SENTENCE OF THAT
15 PARAGRAPH READS, "THE CIRM WILL REVIEW ALL ACCESS
16 PLANS." THAT'S AN OBLIGATION. "AND MAY MAKE THEM
17 AVAILABLE FOR REVIEW BY THE ICOC AND THE PUBLIC." IT
18 DOESN'T OBLIGATE CIRM. AS A STATE AGENCY, THEY WOULD
19 HAVE THE DISCRETION ABOUT WHETHER TO BRING IT TO THE
20 BOARD AND TO THE PUBLIC.

21 DR. PRIETO: ED, IS THERE ANY REASON NOT TO
22 SAY SHALL MAKE THEM AVAILABLE? IF I AS AN ICOC BOARD
23 MEMBER OR THE PUBLIC, FOR THAT MATTER, WANTS TO KNOW
24 WHAT THE TERMS OF THESE PLANS ARE, IS THERE ANY REASON
25 FOR THEM NOT TO BE PUBLIC?

1 MR. TOCHER: FRANCISCO, THIS IS SCOTT TOCHER.
2 I THINK THE POINT BACK WHEN THIS WAS DISCUSSED AT THE
3 ICOC WAS -- FIRST OF ALL, IN REGULATIONS YOU TYPICALLY
4 DON'T DESCRIBE THE OBLIGATIONS OF THE AGENCY
5 NECESSARILY EXCEPT WITH RESPECT TO AN INDIVIDUAL WHO'S
6 BEING REGULATED. BUT I THINK THAT THE POINT HERE IS
7 JUST TO INDICATE TO THE REGULATED COMMUNITY THAT THIS
8 IS SOMETHING THAT MIGHT FROM TIME TO TIME BE TAKEN UP
9 BY THE ICOC AT ITS DISCRETION TO REVIEW. IN THAT
10 EVENT, OF COURSE, WHAT CIRM HAS WOULD BE PROVIDED TO
11 THE ICOC. YOU WOULD JUST WANT TO THINK ABOUT IF YOU
12 MADE IT MANDATORY LANGUAGE, THEN YOU WOULD JUST BE
13 MANDATING THAT PERIODICALLY CIRM WOULD BE REQUIRED TO
14 BRING THIS TO THE ICOC, AND THE ICOC WOULD BE REQUIRED
15 TO CONSIDER IT. AND THAT WOULD BE JUST THE DIFFERENCE
16 BETWEEN MAY OR MIGHT AND SHALL.

17 SO I THINK THAT THAT'S WHAT WAS ANIMATING THE
18 CLAUSE THAT A HAPPENED WITH RESPECT TO THE REVIEW BY
19 THE ICOC.

20 MR. ROTH: ED, WE HAVE A COMMENT IN SAN
21 DIEGO.

22 CHAIRMAN PENHOET: PLEASE.

23 MR. JACKSON: THIS IS JIMMY JACKSON WITH
24 BIOCOM. AS WE REFERENCE IN OUR LETTER, AND I HAVE
25 DISCUSSED WITH MR. TOCHER, UNDER THE STATUTE THAT

1 ESTABLISHED CALRX THE PRICING IS CONFIDENTIAL BY
2 STATUTE. NOW, IF YOU PUT SHALL IN THERE, THEN YOU'RE
3 PRETTY MUCH MANDATING THAT THE PRICING WILL BE MADE
4 AVAILABLE TO THE PUBLIC. I THINK THAT THAT'S AN
5 UNACCEPTABLE CONFLICT.

6 MR. TOCHER: THIS IS THE ACCESS PROVISION OF
7 THE REGULATIONS, NOT THE CALRX WHICH IS THE NEXT
8 SUBDIVISION.

9 MR. JACKSON: I APOLOGIZE. THAT'S TRUE.

10 MS. SPINK: HI. I HAVE A COMMENT. THIS IS
11 KATIE SPINK FROM GERON. I'M IN SAN CARLOS. IF I COULD
12 JUST RETURN TO THE DISCUSSION OF LINE ONE FOR A MOMENT,
13 IT WAS MENTIONED THAT THE INTENT WAS TO MAKE THIS
14 PARALLEL WITH THE LANGUAGE IN 406, WHICH I BELIEVE
15 LIMITS ACCESS PROVISIONS ONLY TO EXCLUSIVE LICENSEES.
16 SO I WOULD SUGGEST THAT PERHAPS THIS ADDED LANGUAGE
17 SHOULD SAY OR ITS EXCLUSIVE LICENSEE.

18 CHAIRMAN PENHOET: 406. THAT'S TRUE. I
19 THINK THE ASSUMPTION WAS THAT NONEXCLUSIVE LICENSES,
20 THAT THE COMPETITIVE MARKETPLACE WOULD ACTUALLY, YOU
21 KNOW, HAVE COMPETITION WOULD TAKE PLACE IN THIS. I
22 THINK THE MOST LIKELY CASE IS GOING TO BE EXCLUSIVE
23 LICENSES GIVEN THE COST OF DEVELOPING THESE THERAPIES,
24 BUT I THINK YOU'RE RIGHT. IN ORDER TO MAKE IT CONFORM,
25 IT SHOULD SAY EXCLUSIVE LICENSEES.

1 THEN ON PAGE --

2 MR. TOCHER: YOU'RE ON THE ROAD MAP NOW.

3 CHAIRMAN PENHOET: PAGE 4, THE NEXT BIG A IS
4 WHAT ASPECTS OF THERAPY MUST THE MANUFACTURERS -- WHAT
5 ASPECTS OF THERAPY MUST THE MANUFACTURER PROVIDE
6 APPLICANTS? I THINK WE'VE ALREADY DISCUSSED THAT ONE
7 IN THE CONTEXT OF THE FIRST PART OF THIS. STAFF
8 BELIEVES THE COMMENT IS REASONABLE, AND THE REGULATION
9 SHOULD BE AMENDED TO CLARIFY ONLY THE PRODUCT OR
10 THERAPY MUST BE MADE ACCESSIBLE, NOT THE REST OF THE
11 PROCESS. SO I THINK THAT -- WE'RE STILL IN 407. I
12 THINK WE'VE ALREADY DEALT WITH THAT ISSUE, THIS
13 DISCUSSION WE JUST HAD? OKAY.

14 THEN GOING DOWN TO -- WHERE IS THE NEXT A?

15 MR. TOCHER: WHOEVER IS SHUFFLING PAPERS IS
16 DOING SO RIGHT NEXT THEIR MICROPHONE AND IT'S --

17 THE REPORTER: OBLITERATING THE RECORD.

18 CHAIRMAN PENHOET: ACTUALLY IF YOU CAN MUTE
19 YOUR PHONE WHEN YOU'RE NOT SPEAKING, IT WOULD BE GREAT.
20 GOOD.

21 THEN LET'S RETURN TO THE ITEMS THAT WE HAVE
22 MARKED B IN OUR PRIORITIZATION SCHEME. BACK TO PAGE 2,
23 THE FIRST B IS UNDER ITEM 3, SHARING OF
24 PUBLICATION-RELATED BIOMEDICAL MATERIALS. B, THE
25 SUGGESTION WAS THAT WE AMEND THE REGULATION TO EXEMPT

1 COMMERCIAL SUPPLIERS WHO MAKE MATERIALS AVAILABLE ON
2 REASONABLE TERMS. AND THEN STAFF NOTE IS STAFF
3 APPRECIATES THIS COMMENT, BUT DISAGREES WITH THE
4 COMMENT AND RECOMMENDS THAT THE TASK FORCE REJECT IT.
5 THE SUGGESTED LANGUAGE WOULD LIKELY FALL PREY TO
6 ARGUMENTS THAT THE REPEATED USE OF THE TERM
7 "REASONABLE" WOULD NOT SURVIVE THE OFFICE OF
8 ADMINISTRATIVE LAW REVIEW.

9 IF YOU LOOK BACK IN 100404, THE LANGUAGE WE
10 HAVE IN THERE NOW IS THAT THE LICENSEES WOULD BE
11 REQUIRED TO MAKE THESE THINGS AVAILABLE, AND WE'VE
12 CHANGED IT SOMEWHAT TO, I HOPE, CLARIFY THIS. SO WE'VE
13 DELETED UNDER SPECIAL CIRCUMSTANCES BECAUSE WE THINK
14 THAT'S ALWAYS HARD TO DEFINE. WE SIMPLY SAY ON LINE 7,
15 PAGE 4, EXCEPTIONS TO THE ABOVE ARE POSSIBLE WITH
16 APPROVAL BY CIRM; IF REQUESTS TO THE AWARDEE BECOME
17 FINANCIALLY ONEROUS OR IN DIRECT CONFLICT WITH THE
18 BUSINESS OF THE AWARDEE, THE AWARDEES CAN APPEAL TO
19 CIRM FOR ALTERNATIVE ARRANGEMENTS.

20 SO WE MODIFIED IT SOMEWHAT, BUT WE DO THINK
21 THAT WE PROVIDE IN THIS LANGUAGE AN OPPORTUNITY FOR
22 COMPANIES TO SHOW THAT THIS IS A BURDEN TO THEM. WE
23 DISCUSSED OURSELVES WHETHER THERE SHOULD BE SOME
24 MATERIALITY COMPONENT TO THIS. I THINK IT'S A LITTLE
25 HARD TO DEFINE WHAT'S A MATERIAL, SO I THINK OUR

1 RECOMMENDATION IS THAT WE LEAVE IT AS IT IS.

2 PEOPLE WHO COMMENTED ON THIS WOULD LIKE TO GO
3 BACK TO THE AVAILABLE AT REASONABLE TERMS LANGUAGE.
4 NOT GO BACK TO IT, BUT SUBSTITUTE THAT. ANY COMMENTS
5 FROM THE TASK FORCE ON THIS ISSUE?

6 MR. SHEEHY: I ACTUALLY THINK THAT THIS IS A
7 VERY REASONABLE OBJECTION, THAT THE TOOLS -- OUR
8 DISCUSSIONS WERE NEVER INTENDED THAT THIS PARTICULAR
9 ASPECT OF THIS POLICY WOULD INCLUDE COMMERCIAL
10 MANUFACTURERS OF TOOLS. AND JUST BECAUSE OUR STANDARD
11 IS -- I MEAN IF YOU WERE TO CHANGE REASONABLE TERMS,
12 WHICH I AGREE IS NOT GOOD LEGISLATIVE LAW LANGUAGE, THE
13 REST OF THIS IS FINE. AND I CAN'T REMEMBER MY
14 UNDERGRADUATE ECONOMICS, BUT ISN'T THERE SOME WAY TO
15 INDICATE THAT WHERE THERE'S A MARKET FOR THESE
16 PRODUCTS, AND THESE WILL BE PRICED ACCORDING TO A
17 MARKET, AND A COMPETITIVE MARKET, AND I'M NOT SURE WHAT
18 THAT LANGUAGE WOULD -- WHETHER THERE'S A MARKET
19 CLEARING PRICE OR SOMETHING, BUT SOMETHING THAT GETS
20 AWAY FROM REASONABLE TERMS THAT ARE SUFFICIENTLY VAGUE
21 TO COVER THE WHOLE RANGE OF -- WHAT WE'RE TRYING TO DO
22 IS EXEMPT PEOPLE WHO TAKE THESE MATERIALS AND DEVELOP
23 THEM INTO COMMERCIAL PRODUCTS AND MAKE THEM AVAILABLE
24 TO EVERYBODY THROUGHOUT THE STATE, POTENTIALLY AROUND
25 THE COUNTRY AND AROUND THE WORLD TO USE IN RESEARCH.

1 THIS IS AN ACTIVITY THAT WE WANT TO SUPPORT.

2 AND TO HAVE TO COME TO US FOR PRIOR APPROVAL
3 TO COMMERCIALIZE A PRODUCT DOESN'T SEEM TO BE
4 REASONABLE WHEN THAT'S ONE OF THE THINGS WE WOULD LIKE
5 THEM TO DO WITH THE INVENTIONS THAT WE FUND. SO THERE
6 HAS TO BE SOME WAY TO CAPTURE MARKET-MAKING ASPECT OF
7 THIS WITHOUT NECESSARILY -- IN OTHER WORDS, I THINK --
8 AND MAYBE WE CAN JUST COOK IT FOR A WHILE BECAUSE MOST
9 OF THIS IS FINE. IT'S JUST THIS REASONABLE TERMS. AND
10 MAYBE THERE'S SOME WAY JUST TO REFLECT THAT THEY'RE
11 INTRODUCING A PRODUCT INTO A MARKET.

12 ALSO KEEP -- I WOULD BE -- I WOULD NOT BE
13 COMFORTABLE MAKING IT POSSIBLE FOR SOMEONE TO TAKE AN
14 EXTREMELY VALUABLE TOOL THAT'S ESSENTIAL FOR RESEARCH
15 AND MAKE IT AVAILABLE ON COMMERCIAL TERMS, COMMERCIAL
16 TERMS THAT WERE EXTORTION AS OPPOSED TO ONES THAT WERE
17 MARKET CLEARING. YOU KNOW WHAT I MEAN? MY ECONOMICS
18 LANGUAGE IS NOT WHAT IT USED TO BE BACK WHEN I WAS IN
19 COLLEGE, BUT I THINK THAT THERE IS A WAY TO DESCRIBE
20 THIS WHERE YOU'RE NOT SETTING UP THE SITUATION WHERE
21 WE'VE CREATED AN INVENTION AND WE'RE HAVING -- OUR
22 RESEARCHERS ARE HAVE HAVING TO PAY A TON OF MONEY FOR
23 IT BECAUSE SOMEBODY'S CORNERED A MARKET ON IT. BUT
24 WHEN SOMEONE TAKES IT AND THEY'RE PUTTING IT OUT THERE
25 AND IT'S PART OF THIS REGULAR TOOLS MARKET, WE WANT TO

1 ENCOURAGE THAT. SO MAYBE THOSE FOLKS HAVE SOME
2 LANGUAGE THAT MIGHT GET US THROUGH THIS OAL THING.

3 CHAIRMAN PENHOET: YOU COULD DEFINE
4 REASONABLE AS BEING A PRICE CONSISTENT WITH OTHER
5 SIMILAR PRODUCTS IN THE MARKETPLACE OR SOMETHING LIKE
6 THAT. I KNOW THERE WILL BE COMMENTS FROM THE AUDIENCE
7 ON THIS ISSUE. IN FACT, I BELIEVE THIS WAS THE SUBJECT
8 OF YOUR LITTLE CAUCUS IN THE BACK OF THE ROOM AT THE
9 SAN FRANCISCO AIRPORT, IF I REMEMBER CORRECTLY.

10 MR. SIMPSON: THE LANGUAGE IN THE LAST THING
11 THAT WORKED --

12 CHAIRMAN PENHOET: ANYBODY ELSE ON THE TASK
13 FORCE FIRST?

14 MR. ROTH: I WOULD LIKE TO SEE SOMETHING IN
15 THERE THAT REFERS TO MATERIALITY OR CREATED
16 SUBSTANTIALLY WITH CIRM FUNDING AND DEFINE THAT BECAUSE
17 I THINK YOU'RE ASKING PEOPLE TO PROVIDE THESE TOOLS AT
18 COST OR FREE. AND IF THEY ONLY PUT A SMALL AMOUNT OF
19 THE WORK OR THE MONEY INTO THE TOTAL INVESTMENT, I
20 DON'T THINK WE SHOULD OBLIGATE THEM TO DO THIS. SO I
21 WOULD LIKE A THRESHOLD OF SOME KIND, WHICH I THINK WE
22 COULD AGREE ON.

23 CHAIRMAN PENHOET: WELL, COMING UP LATER WE
24 HAVE -- WE HAD A LONG DISCUSSION, AND IT WAS PART OF
25 THE POLICY APPROVED, THAT ALL OF THESE THINGS WOULD BE

1 RESULTING FROM THE FIRST DOLLAR IN. SO IF WE START
2 DOWN THE PATH THAT YOU JUST SUGGESTED, HOWEVER, I DO
3 THINK THERE'S SOME OTHER LANGUAGE THAT SAYS IF THEY
4 COMMERCIALIZED THEM AND THE PRICES WERE -- IF WE CAN
5 DEFINE REASONABLE, THAT THEY WOULD NOT BE -- THEY
6 WOULDN'T BE SELECTIVELY DISADVANTAGED AS A RESULT OF
7 HAVING TAKEN CIRM FUNDING. BUT ANY OTHER COMMENTS?

8 MR. ROTH: ANYTHING THAT ADDRESSES THAT, BUT
9 I THINK IT NEEDS TO BE ADDRESSED AND NOT LEFT
10 OPEN-ENDED.

11 DR. BRYANT: DO WE HAVE TO SET A PERCENTAGE
12 THAT'S RELATED TO THE PRIME RATE? I DON'T KNOW WHAT IT
13 WOULD BE LINKED TO IS THE PROBLEM. I THINK IT WOULD BE
14 GOOD TO LIMIT IT IN SOME WAY, BUT I'M NOT THINKING OF
15 ANYTHING THAT WOULD ALLOW US TO DO THAT RIGHT NOW.

16 CHAIRMAN PENHOET: WELL, THE --

17 MR. TOCHER: MAYBE THAT'S SOMETHING --

18 CHAIRMAN PENHOET: IT'S A GENERAL PRINCIPLE
19 THAT WE DISCUSSED, AND IT COMES UP LATER IN MANY OTHER
20 ASPECTS. WE DID DECIDE THAT THE FIRST DOLLAR OF GRANT
21 MONEY TRIPS THESE OBLIGATIONS, BUT STILL IT HAS TO BE
22 GRANT MONEY FROM WHICH THIS PRODUCT OR PRODUCTS
23 EMERGED. SO IF THEY TAKE GRANT MONEY, IT DOESN'T COVER
24 EVERYTHING THEY DO IN THE COMPANY. IT'S ONLY WHAT THEY
25 DO WITH THE GRANT MONEY.

1 DR. BRYANT: NO. I AGREE WITH THAT. I'M
2 TALKING ABOUT WHAT THE REASONABLE TERMS WOULD BE. SO
3 IF YOU MAKE A PRODUCT AND YOU'RE THE ONLY ONE THAT'S
4 MAKING IT AND THERE ISN'T ANY COMPETITION IN THAT
5 PARTICULAR AREA, THEN HOW DO WE DETERMINE WHAT THE
6 REASONABLE PROFIT WOULD BE?

7 CHAIRMAN PENHOET: PROFIT IS SOMETHING THAT
8 WE PROBABLY WOULDN'T WANT TO GET INTO. BUT IF WE CAN
9 COME UP WITH A DEFINITION OF A REASONABLE PRICE FOR
10 COMPARABLE PRODUCTS OR SOMETHING LIKE THAT, I DON'T
11 KNOW WHAT WE'LL COME UP WITH.

12 MR. TOCHER: IF IT'S THE CONSENSUS OF THE
13 GROUP THAT IT WOULD DESIRE TO EXPLORE WHAT LANGUAGE
14 WOULD LOOK LIKE THAT MIGHT FULFILL A SORT OF
15 REASONABLENESS STANDARD, WE CAN ALWAYS NOTICE THE
16 REGULATION IN THE NEXT COMMENT PERIOD IN ORDER TO SORT
17 OF FLESH OUT INPUT THAT WOULD PROVIDE SORT OF OAL
18 ACCEPTABLE SPECIFICITY WHILE ALSO MAKING IT WORKABLE
19 FOR OUR PURPOSES. AND THEN SEE WHAT THE RESULT OF THAT
20 INPUT IS; AND IF IT LOOKS LIKE IT FLIES TO YOU, THEN WE
21 CAN KEEP IT; AND IF IT DOESN'T, WE CAN STICK WITH WHAT
22 WE HAVE.

23 CHAIRMAN PENHOET: WE HAD A LOT OF
24 DISCUSSION. MARY MAXON.

25 DR. MAXON: I JUST WANT A POINT OF

1 CLARIFICATION HERE IS THAT THIS IS FOR
2 PUBLICATION-RELATED BIOMEDICAL MATERIALS, FIRST
3 DESCRIBED IN PUBLICATION. DEPENDING ON THE JOURNAL IN
4 WHICH THIS APPEARS, THAT'S A STANDARD REQUIREMENT
5 ANYWAY, WHETHER WE REQUIRE IT OR NOT. SO I JUST WANTED
6 TO MAKE THAT CLARIFICATION, THAT THIS IS A VOLUNTARY
7 ACCESS TO A PUBLICATION AND IT IS STANDARD.

8 CHAIRMAN PENHOET: WE'VE HAD A LOT OF
9 DISCUSSION ABOUT WE DO NOT WANT IN THIS POLICY TO IN
10 ANY WAY HINDER THE DEVELOPMENT OF A ROBUST SET OF TOOLS
11 BEING BROADLY AVAILABLE AND TOOL COMPANIES, BUSINESSES
12 DEVELOP THOSE TOOLS. SO I THINK WE HAVE TO SOMEHOW
13 FIND SOME LANGUAGE THAT FINDS A MIDDLE GROUND.

14 ANY OTHER COMMENTS FROM TASK FORCE MEMBERS?
15 THEN WE HAVE COMMENTS IN SAN FRANCISCO FROM JOHN
16 SIMPSON FIRST.

17 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR
18 TAXPAYER AND CONSUMER RIGHTS. MY RECOLLECTION IS WE
19 HAD LANGUAGE IN THE NONPROFIT REGULATIONS THAT
20 ADDRESSED THIS, DIDN'T WE? WOULDN'T THAT LANGUAGE IN
21 THE NONPROFIT, WHICH I DON'T HAVE IN FRONT OF ME,
22 WOULDN'T THAT LANGUAGE SOLVE THE PROBLEMS?

23 CHAIRMAN PENHOET: VERY WELL MIGHT. WE DID
24 COME UP WITH SOME LANGUAGE IN THE NONPROFIT. I DON'T
25 HAVE THE NONPROFIT REGS IN FRONT OF ME. BUT THEY IN

1 THAT CASE REFERRED TO LICENSEES, BUT I THINK IT WOULD
2 BE -- YES.

3 MS. GHIO: TERRY GHIO FROM INVITROGEN. I
4 THINK, YOU KNOW, THE SUGGESTION FROM THE TASK FORCE TO
5 MAYBE PUT THIS OUT FOR PUBLIC COMMENT AND ALLOW US TO
6 DO SOME RESEARCH IN SOME OTHER AREAS TO COME UP WITH A
7 TERM LIKE FAIR MARKET VALUE IS POSSIBLE, AND WE CAN
8 PROBABLY DO SOME WORK ON THAT. WE AGREE THAT WE NEED
9 SOME KIND OF A REASONABLENESS STANDARD.

10 THE ONE CONCERN I HAVE, WITHOUT HAVING THE
11 NONPROFIT PROGRAM IN FRONT OF ME, IS IT'S JUST THAT, A
12 NOT-FOR-PROFIT POLICY WHERE HERE WE'RE TALKING ABOUT
13 COMMERCIALIZATION OF RESEARCH CLEARLY. WE WOULD REALLY
14 LIKE THE OPPORTUNITY TO HELP ASSIST IN SOME RESEARCH
15 AND COMING UP WITH A FAIR MARKET VALUE STANDARD.

16 MR. MAC FERRIN: CHRIS MAC FERRIN FROM
17 APPLIED BIOSYSTEMS. WE MAKE RESEARCH TOOLS, AND WE'RE
18 JUST DOWN THE ROAD IN FOSTER CITY AND EMPLOY A FEW
19 THOUSAND OF THOSE LIFE SCIENCE EMPLOYEES. SO THIS
20 LANGUAGE CONCERNS US BOTH FROM OUR POINT OF VIEW, BUT
21 ALSO FROM THE POINT OF VIEW OF THE GOALS OF CIRM TO
22 DISSEMINATE THE FRUITS OF THE FUNDED RESEARCH AND ALSO
23 THE POINT OF VIEW OF OUR CUSTOMERS WHO ARE USERS OF OUR
24 TOOLS, THAT THEY'LL BE SUBJECT TO THIS.

25 AND I APPRECIATE THE WILLINGNESS TO WORK ON

1 THE LANGUAGE A LITTLE BIT. I JUST WANTED TO TALK A
2 LITTLE BIT MORE ABOUT SOME OF THE ADDITIONS THAT AREN'T
3 COMMENTED ON. SO THE AT COST LANGUAGE HAS NOW ACTUALLY
4 BEEN MODIFIED, AND I DIDN'T SEE ANY COMMENTS ON THAT IN
5 THE OVERVIEW. THAT ACTUALLY IS NOW BELOW COST, IF YOU
6 THINK ABOUT IT, BECAUSE IT'S ONLY THE MARGINAL COST AND
7 DOESN'T APPLY TO OTHER THINGS. FOR EXAMPLE, I'M NOT
8 CERTAIN IF THIS WOULD INCLUDE THE ROYALTIES THAT CIRM
9 WOULD BE COLLECTING FROM IP THAT COVER BIOMEDICAL
10 MATERIALS. SO I THINK IT'S EVEN WORSE THAN IT USED TO
11 BE FROM OUR POINT OF VIEW.

12 MR. TOCHER: THAT LANGUAGE IS ADDED TO TRACK
13 THE EXISTING LANGUAGE OF THE IDENTICAL PROVISION IN THE
14 NONPROFIT REGULATION. THAT'S WHAT THE ICOC HAD ALREADY
15 ADOPTED AS CONTEXT OF THE NONPROFIT REGULATIONS, AND SO
16 THAT'S WHY THAT WAS ADDED.

17 CHAIRMAN PENHOET: HE'S RIGHT. THIS ACTUALLY
18 IS BELOW COST. BECAUSE ALL THESE OTHER COSTS ARE REAL
19 COSTS TO ANY ORGANIZATION, WHETHER IT BE PROFIT OR
20 NONPROFIT. IT IS MORE ONEROUS THAN JUST THAT COST. I
21 THINK WE HAVE TO RELOOK AT THIS WHOLE SECTION, SO WE'LL
22 TAKE UNDER ADVISEMENT THE OFFER TO PARTICIPATE IN THIS.

23 SO ANY OTHER COMMENTS FROM MEMBERS OF THE
24 PUBLIC ANYWHERE?

25 SCOTT, I THINK WE HAVE TO GO BACK AND LOOK AT

1 THIS. I THINK THERE'S GENERAL AGREEMENT THAT WE WANT
2 LANGUAGE WHICH ENSURES THAT THESE THINGS ARE AVAILABLE,
3 BUT DON'T REQUIRE THE AVAILABILITY OF THESE TO BE AN
4 ONEROUS REQUIREMENT ON THE PART OF THE COMPANIES OR
5 UNIVERSITIES FOR THAT MATTER.

6 DR. PRIETO: WOULD THIS MEAN WE'D HAVE TO GO
7 BACK AND LOOK AT THE -- TWO QUESTIONS. DOES THIS MEAN
8 WE HAVE TO GO BACK AND LOOK AT THE LANGUAGE IN THE
9 NONPROFIT POLICY?

10 AND I'M JUST CONCERNED ABOUT ACCOUNTING
11 PRACTICES AND THAT WE DON'T MAKE THIS SO COMPLETELY
12 OPEN-ENDED THAT, AGAIN, WE HINDER ACCESS. COSTS FOR
13 OVERHEAD RESEARCH DISCOVERY, SOME OF THAT COULD GET
14 QUITE NEBULOUS AND COULD BE TALKING ABOUT A LOT OF
15 MONEY THAT MAY NOT BE DIRECTLY RELATED TO AN ACTUAL
16 INCREASED COST THAT THE COMPANY HAS FOR PROVIDING THIS
17 TO ANOTHER RESEARCHER.

18 CHAIRMAN PENHOET: YEAH. SOME OF THIS
19 LANGUAGE IS HYBRID AT THE MOMENT, IT LOOKS LIKE TO ME,
20 FROM THE NONPROFIT POLICY AND THE FOR-PROFIT, AND I
21 THINK THE HYBRID PROBABLY DOESN'T WORK, SO I THINK
22 WE'RE GOING TO HAVE TO COME BACK TO ALL OF YOU. KEN
23 TAYMOR, YOU HAVE A POINT?

24 MR. TAYMOR: WELL, I THINK THAT THE REASON
25 THAT THIS WAS INCLUDED, SCOTT BROUGHT IT IN THE

1 NONPROFITS JUST BECAUSE IT IS MARGINAL COST PRICING.
2 AND IT'S BASIC ECONOMIC THEORY, THAT A COMPANY PRODUCES
3 AND SELLS TO THE MARGINAL COST. AND THAT'S NOT AN
4 AVERAGE COST PRICING. THE COMPANY DOESN'T PRICE THEIR
5 GOODS AT AVERAGE COST BECAUSE THERE'S A MARGINAL COST
6 OF PRODUCTION. THEN THEY'RE REIMBURSED FOR THAT.
7 THAT'S HOW MUCH IT COSTS FOR PRODUCING THAT EXTRA UNIT.
8 THE IDEA BEHIND THIS IS THEY'RE PRODUCING SOME EXTRA
9 UNITS TO SHARE WITH THE RESEARCH COMMUNITY, AND THAT'S
10 WHY THE PRICING, I THINK, WAS CORRECT IN THE NONPROFIT
11 AND IT'S CORRECT IN HERE.

12 IF YOU GO INTO, YOU KNOW, OVERHEAD COSTS,
13 R & D COSTS AND SO FORTH, THAT, FIRST OF ALL, DEFEATS
14 THE PURPOSE, AS WE KNOW IN THIS INDUSTRY. SECOND OF
15 ALL, IT'S INCONSISTENT WITH THE PRICING FOR WHAT THEY
16 DO FOR SELLING THEIR PRODUCT ON THE OPEN MARKET.

17 CHAIRMAN PENHOET: ACTUALLY I DON'T WANT TO
18 GET INTO A LONG DISCUSSION HERE, BUT HAVING BEEN
19 INVOLVED IN A NUMBER OF BUSINESSES, THE FASTEST WAY TO
20 GO BROKE IS TO PRICE ALL YOUR ACTIVITIES AT THE
21 MARGINAL COST BECAUSE THEN NO ONE COVERS THE OVERHEAD.
22 UNIVERSITIES HAVE IT TOO, BY THE WAY, WITH THE GRANTS.
23 THEY DON'T PAY THE OVERHEAD. IT'S ACTUAL COST OF THE
24 MONEY TO DO RESEARCH.

25 MR. ROTH: I LOOKED AT THE LANGUAGE IN THE

1 NOT-FOR-PROFIT, AND IT IS SIMILAR TO THIS. BUT WHAT
2 WE'RE TRYING TO DO HERE IS PUT AN OBLIGATION ON EITHER
3 NONPROFITS OR FOR-PROFITS WHO PUBLISH A PAPER TO MAKE
4 AVAILABLE REAGENTS. AND THE INTENT IS TO MAKE SURE
5 THOSE REAGENTS ARE AVAILABLE.

6 CHAIRMAN PENHOET: THAT'S CORRECT.

7 MR. ROTH: SO PERHAPS BY ADDING UNTIL SUCH
8 TIME THAT THEY'RE COMMERCIALY AVAILABLE AND REMOVE
9 THAT OBLIGATION FROM EITHER OF THE INSTITUTES OR THE
10 COMPANIES FROM MAKING REAGENTS AVAILABLE ONCE THEY
11 BECOME COMMERCIALY AVAILABLE. DOESN'T PROHIBIT THEM
12 FROM DOING IT, BUT RELIEVES THEM OF THE OBLIGATION.

13 CHAIRMAN PENHOET: THAT'S A HELPFUL
14 SUGGESTION.

15 MR. TOCHER: THIS ENTIRE PROVISION --

16 CHAIRMAN PENHOET: TO SOME DEGREE THE FIRST
17 SENTENCE WAS SORT OF DESIGNED TO MODERATE THE DAMAGE TO
18 ANY COMPANY. UNLESS A SPECIAL CASE IS MADE THAT
19 THERE'S A DANGER OF THE COMPETITIVE POSITION, THE
20 AWARDEE SHALL SHARE BLAH, BLAH, BLAH. CLEARLY IF IT'S
21 A PRODUCT OF SIGNIFICANCE TO THEM, HAVING TO GIVE IT
22 AWAY WOULD ENDANGER THEIR COMPETITIVE POSITION, BUT
23 THEN YOU GET INTO A WHOLE LOT OF ISSUES AROUND
24 MATERIALITY, ETC. SO I DO THINK THIS REQUIRES SOME
25 FURTHER WORK AND WE'LL HAVE TO COME BACK. IT'S

1 POSSIBLE.

2 IN THE CASE OF THE UNIVERSITIES, IT IS
3 SOMEWHAT DIFFERENT. THEY'RE NOT IN THE BUSINESS.
4 THEY'RE NOT GOING TO SELL REAGENTS. THEY GENERALLY
5 SHARE THESE REAGENTS ANYWAY. THEY CAN FALL BACK ON
6 TEACHING SOMEONE ELSE HOW TO MAKE THE REAGENTS
7 THEMSELVES, WHICH A COMPANY WOULDN'T NECESSARILY DO.
8 UNIVERSITIES CAN DO THAT OR WILL DO THAT.

9 MR. TOCHER: IF IT'S THE WILL OF THE GROUP,
10 THEN WE CAN RE-POST IT WITH THAT. WE CAN NOODLE IT
11 AFTERWARDS AND FIGURE OUT WHERE EXACTLY TO PLACE THE
12 LANGUAGE AND POST IT FOR COMMENT.

13 CHAIRMAN PENHOET: OKAY. WE HAVE AT LEAST
14 ONE VOLUNTEER TO -- COUPLE VOLUNTEERS HERE TO WORK ON
15 THIS ISSUE.

16 MS. GHIO: I THINK DUANE ROTH'S IDEA -- THIS
17 IS TERRY GHIO FROM INVITROGEN. I THINK THE COMMENT
18 FROM DUANE ROTH OF SOMEHOW WORKING WITH THE LANGUAGE,
19 AND THEN ONCE IT'S COMMERCIALY AVAILABLE BE EXEMPT.
20 WITHOUT HAVING -- ONE OF THE CONCERNS AMONG THE
21 INDUSTRY IS WE WANT TO TRY TO STREAMLINE AND ALSO HAVE
22 SOME CERTAINTY IN THIS PROCESS. AND THE IDEA OF HAVING
23 TO GO DEFINE A SPECIAL CASE AND ASK FOR AN EXCEPTION
24 WILL JUST -- YOU'RE KIND OF CARRYING THIS UNCERTAINTY
25 FORWARD WITH YOU, WHICH INHIBITS INNOVATION AND

1 COMMERCIALIZATION OF PRODUCTS. I THINK SOME WAY OF
2 DEFINING RIGHT UP FRONT IN THE LANGUAGE THAT THIS
3 APPLIES, BUT ONCE IT'S COMMERCIALIZED, IT'S CLEAR. IT
4 JUST CLEAR DEFINING WHEN YOU GO FROM ONE TO THE NEXT.

5 CHAIRMAN PENHOET: OKAY. I THINK THIS
6 DISCUSSION -- JEFF HAS ANOTHER COMMENT.

7 MR. SHEEHY: ON ONE LEVEL WE'RE TALKING ABOUT
8 REAGENTS AND TOOLS, BUT I ALSO KNOW THAT PART OF THE
9 THINKING THAT'S DRIVING THIS IS CREATION OF STEM CELL
10 LINES. SO I NEED TO THINK OF A SITUATION WHERE STEM
11 CELL LINES HAVE BEEN COMMERCIALIZED AND HAVE NOT BEEN
12 AVAILABLE AND HAVE BEEN CHALLENGED. THAT'S OUR ASTUTE
13 MR. SIMPSON. THAT REALLY THERE WAS A FEELING THAT
14 THOSE WERE NOT, EVEN THOUGH THEY WERE COMMERCIALIZED,
15 THEY WEREN'T REALLY AVAILABLE. SO IN THAT INSTANCE A
16 COMMERCIALIZED STEM CELL LINE THAT WE HAD PAID TO
17 CREATE COULD BE PRICED OR ENCUMBERED IN SUCH A WAY,
18 EVEN THOUGH IT'S COMMERCIALIZED, IT'S NOT READILY
19 AVAILABLE, WHICH IS THE INFAMOUS WARF SITUATION.

20 SO, YOU KNOW, I THINK WE REALLY NEED TO THINK
21 ABOUT WHAT THE INDUSTRY IS AND WHAT THE ECONOMICS ARE
22 AND REALIZE THAT WE WANT THE TOOL INDUSTRY TO BE ABLE
23 TO FUNCTION BECAUSE IT IS AN EFFICIENT INDUSTRY THAT
24 FUNCTIONS BECAUSE IT MAKES PRODUCTS AVAILABLE AT
25 REASONABLE TERMS. OTHERWISE, IT DOESN'T EXIST. BUT AT

1 THE SAME TIME THERE IS A STRONG IMPETUS FOR THE SHARING
2 OF THE STEM CELL LINES, ESPECIALLY THE ONES THAT ARE
3 CREATED WITH CIRM FUNDING. SO I JUST HOPE THAT WE HAVE
4 THE RIGHT BALANCE THERE BETWEEN THOSE TWO. WE'RE MORE
5 PRECISE ABOUT EXACTLY WHAT WE'RE TALKING ABOUT
6 BECAUSE -- THAT'S ALL. I JUST WANTED TO PUT THAT IN
7 THERE BECAUSE I DON'T WANT TO SEE LINES SUDDENLY NOT BE
8 AVAILABLE OR PRICED SO HIGH THAT PEOPLE CAN'T GET
9 ACCESS TO THEM. I THINK ABOUT AN SCNT LINE FOR A
10 SPECIFIC DISEASE.

11 CHAIRMAN PENHOET: WE CAN'T HAVE IT BOTH WAYS
12 ON THESE ISSUES. WE COULD CALL OUT STEM CELL LINES AS
13 AN EXCEPTION TO THAT.

14 MR. SHEEHY: THAT'S ONE OF THE THINGS THAT WE
15 MAY WANT TO PUT ON THE TABLE.

16 MS. GHIO: I THINK GOING OUT TO COMMENT AND
17 LET US TAKE THAT TOO AND MAYBE WE CAN WORK SOMETHING,
18 COMMERCIALY AVAILABLE AND READILY AVAILABLE TO.

19 MR. SHEEHY: MAYBE THERE'S A PRICING
20 MECHANISM OR SOMETHING THAT CAN BE SET BECAUSE I
21 WOULDN'T EVEN MIND THE COMMERCIALIZATION OF A STEM CELL
22 LINE IF THAT INCREASED ITS AVAILABILITY AND ITS
23 ACCESSIBILITY. SOMEBODY IS MAKING MONEY OFF A LINE
24 THAT THEY DEVELOPED WITH US AS LONG AS EVERYBODY THAT
25 NEEDED IT IS GETTING ACCESS TO IT.

1 MR. ROTH: JEFF --

2 MR. SHEEHY: THAT'D BE OF VALUE, BUT THE WARF
3 SITUATION DOES LOOM LARGE ON MY MIND.

4 MR. ROTH: JEFF, I THINK, THOUGH, REMEMBER
5 THIS IS A COMPANY TAKES A GRANT, PUBLISHES A PAPER,
6 DESCRIBES EITHER RESEARCH, REAGENTS, OR A CELL LINE OR
7 SOMETHING LIKE THAT, THEN IT BECOMES COMMERCIALY
8 AVAILABLE BY SOMEBODY ELSE, LET'S SAY, BECAUSE IF IT
9 BECOMES COMMERCIALY AVAILABLE FROM THEM, THEY PAY US A
10 ROYALTY OR PAY US BACK. SO WE GET TAKEN CARE OF THERE.
11 BUT IF SOMEBODY ELSE COMMERCIALIZES IT, YOU STILL HAVE
12 THE OBLIGATION, IF SOMEBODY CALLS YOU UP, TO PROVIDE IT
13 AT COST OR FREE. AND THAT TAKES AWAY THE MARKET FOR
14 PEOPLE THAT DO TOOLS AND RESEARCH AGENTS. WE WANT
15 THOSE PEOPLE TO MAKE THEM COMMERCIALY AVAILABLE. I
16 DON'T THINK WE WANT TO PUT A -- IF THEY BECOME
17 COMMERCIALY AVAILABLE, THEN YOU LOSE YOUR OBLIGATION.
18 IT DOESN'T PROHIBIT YOU, BUT YOU LOSE YOUR OBLIGATION
19 TO PROVIDE IT FREE OR AT COST. AND I THINK THAT WORKS.

20 CHAIRMAN PENHOET: IT WOULD ONLY BE TO OTHER
21 CALIFORNIA ENTITIES, NOT TO THE WORLD AT LARGE.
22 NEVERTHELESS, CALIFORNIA IS A MAJOR MARKET FOR THESE
23 THINGS. OKAY. WELL, WE HAVE SOME WORK TO DO ON THIS
24 PROVISION.

25 MR. TOCHER: IF I CAN JUST RECAP FOR CLARITY.

1 WE WILL RENOTICE THIS WITH THE LANGUAGE AS IT IS
2 CURRENTLY ON THE 527 WITH THE UNDERLINE AND STRIKEOUT
3 EXCEPT THAT WE WILL ALSO ADD A PROVISION THAT
4 CONDITIONS THE REGULATION ITSELF ON BEING PRIOR TO
5 COMMERCIALIZATION, PRIOR TO AVAILABILITY --
6 COMMERCIALIZATION.

7 CHAIRMAN PENHOET: I SUSPECT THIS WHOLE
8 PARAGRAPH HAS TO BE REWRITTEN.

9 MR. TOCHER: ALSO TO DEVELOP PERHAPS A
10 DEFINITION OF A REASONABLENESS STANDARD AS WELL.

11 CHAIRMAN PENHOET: I THINK THAT'S WHAT THEY
12 AGREED TO WORK ON.

13 MR. TOCHER: WITH THOSE TWO, WE'LL RENOTICE
14 THAT ONE.

15 CHAIRMAN PENHOET: I THINK THIS DISCUSSION
16 TAKES CARE OF THE LITTLE T UNDER THE B UNDER 3 BECAUSE
17 ONEROUS IN SPECIAL CIRCUMSTANCES MAY NOT BE RELEVANT
18 ANYMORE.

19 MOVING TO PAGE 4. WE'RE NOW IN THE ACCESS
20 REQUIREMENTS AGAIN. 100407, B IS COMPANIES MAY NOT
21 KNOW IF A PATIENT IS CARED FOR WITH PUBLIC FUNDS. AND
22 SCOTT BELIEVES THAT IF WE USE CALRX AS THE VEHICLE FOR
23 DOING THIS, THAT THAT WILL BE DETERMINED BY CALRX; IS
24 THAT RIGHT?

25 MR. TOCHER: WHAT WE'LL BE DOING WITH THE

1 REDRAFT OF THIS, THERE'S STILL SOME ADDITIONAL TWEAKING
2 THAT WILL NEED TO BE DONE TO 407, BUT WE WILL MAKE MORE
3 EXPLICIT WHAT PUBLIC FUNDS WOULD INCLUDE, FOR INSTANCE,
4 FUNDS SPENT BY A SUBDIVISION OF A COUNTY OR A CITY OR
5 PROGRAM OR SOMETHING LIKE THAT. SO THOSE ARE THE
6 TWEAKING THAT WILL STILL OCCUR TO 407, WHICH IS THAT
7 THE WAY IT WAS EVOLVING WASN'T SOMETHING THAT WE COULD
8 DO UNTIL WE HAVE THIS OTHER SORT OF LANGUAGE IN PLACE.

9 IN THE NEXT NOTICED VERSION, WE'LL DEFINE
10 THAT TERM IN THAT SUBDIVISION.

11 CHAIRMAN PENHOET: OKAY.

12 DR. PRIETO: I HAVE A QUESTION FOR SCOTT. I
13 GUESS CALRX IS STILL NOT UP AND RUNNING, BUT WHAT DOES
14 IT ENVISION THAT THE POINT OF ACCESS FOR CALRX WILL BE?
15 WILL IT BE AT THE PHARMACY? WHERE --

16 MR. TOCHER: YES. THE SHORT ANSWER IS YES.

17 DR. PRIETO: BECAUSE, AGAIN, FOR CELLULAR
18 THERAPIES OR SOME OF THE OTHER THERAPIES THAT MIGHT
19 COME OUT OF STEM CELL RESEARCH, THERE MAY NOT BE A
20 CONTACT WITH A PHARMACY.

21 MR. TOCHER: RIGHT.

22 CHAIRMAN PENHOET: WELL, YOU KNOW, I DON'T
23 KNOW THE WORKINGS OF HOSPITALS THESE DAYS IN GREAT
24 DETAIL, BUT I THINK ALMOST ALL THE THINGS THAT GO INTO
25 A HUMAN GO THROUGH THE PHARMACY. IT'S NOT JUST DRUGS.

1 THESE WILL BE CELLS IN A BOTTLE.

2 MR. SHEEHY: THIS IS A PRICING MECHANISM
3 WHICH APPLIES TO A PUBLIC PURCHASER OF THESE PRODUCTS.
4 SO IT WOULD BE -- WE'RE TALKING ABOUT INDIVIDUALS
5 MAKING THIS PURCHASE OR ACCESS FOR AN INDIVIDUAL. BUT
6 WE'RE USING THAT PRICING MECHANISM FOR PUBLIC
7 PURCHASERS. SO WE'RE NOT TALKING ABOUT AN INDIVIDUAL
8 TRYING TO GO IN AND BUY THESE THERAPIES BECAUSE CALRX
9 IS FOR THE UNINSURED. WE'RE USING THE PRICING
10 MECHANISM FOR, SAY, DEPARTMENT OF PUBLIC HEALTH IN SAN
11 FRANCISCO OR SAN FRANCISCO GENERAL, A PUBLIC ENTITY
12 THAT BELONGS TO THE STATE THAT'S PURCHASING THESE. SO
13 WE'RE ACTUALLY TALKING ABOUT A BULK PURCHASER AND HOW
14 THEY DECIDE TO -- SO THIS IS A PRICE THAT THEY HAVE TO
15 PAY. HOW THEY DECIDE TO COST OUT THE DELIVERY OF THIS
16 WILL BE UP TO THAT PUBLIC ENTITY, WHICH WOULD BE
17 SUBSIDIZED BY THE STATE AND WILL ALREADY HAVE
18 MECHANISMS FOR DELIVERY.

19 IT SEEMS LIKE WE'RE MIXING THE UNINSURED
20 PATIENT IN WITH THE PERSON WHO IS COVERED BY SOME
21 PUBLIC ENTITY. WHAT WE'RE TRYING TO NOT DO IS HAVE
22 THAT PUBLIC ENTITY HAVING TO PAY AN ONEROUS PRICE FOR
23 INVENTIONS THAT WE HELP FUND.

24 MR. TOCHER: I THINK THE QUESTION I WAS
25 ANSWERING WAS WITH RESPECT TO SORT OF THE FIRST PART OF

1 THAT REGULATION BECAUSE IT'S SORT OF A TWO-PRONG OF
2 SUBDIVISION (B). IT NOT ONLY MANDATES -- IT DOES TWO
3 THINGS. IT REQUIRES THE MANUFACTURER TO PARTICIPATE IN
4 CALRX, WHICH IS DR. PRIETO WAS TALKING ABOUT A PERSON,
5 BUT THE POINT OF SALE WOULD BE WITH THE PHARMACIST.

6 IF WE'RE TALKING ABOUT THE SECOND ASPECT OF
7 IT, WHICH IS PURCHASERS WHO ARE PUBLIC FUND PURCHASERS,
8 THEN, YES, YOU'RE RIGHT. IT'S GOING TO BE IN A
9 DIFFERENT CONTEXT. WE'RE USING THE CALRX BENCHMARKS.

10 DR. PIZZO: CAN I JUST MAKE ONE MODIFIER TO
11 ED'S COMMENT? SOME OF THESE PRODUCTS MAY NOT COME
12 THROUGH THE PHARMACY, BUT RATHER MAY COME THROUGH THE
13 BLOOD BANK OR TRANSFUSION SERVICE. I DON'T KNOW HOW
14 THAT APPLIES TO THE CALRX.

15 CHAIRMAN PENHOET: LET'S SEE. PEOPLE BUY
16 BLOOD THESE DAYS. YOU BUY A LOT OF BLOOD, WHOLE BLOOD,
17 CELLS, ETC., THROUGH THE BLOOD BANK. HOW ARE THOSE
18 PRICES DETERMINED IN TODAY'S HOSPITAL WORLD?

19 MR. TOCHER: IT SEEMS LIKE IF YOU'RE COMING
20 UNDER THIS REGULATION AND YOU'RE PURCHASING WITH PUBLIC
21 FUNDS, YOU'RE USING THE BENCHMARK PRICES THAT ARE
22 DESCRIBED IN CALRX WHEN YOU NEGOTIATE THAT.

23 CHAIRMAN PENHOET: I THINK THE QUESTION
24 THAT'S BEING ADDRESSED HERE IS ARE THERE PRODUCTS WHICH
25 WILL HAVE NO PRICING INSIDE CAL RX. CAL RX WON'T DEAL

1 WITH THEM.

2 DR. PIZZO: RIGHT. THERE IS A PRICING FOR
3 BLOOD PRODUCTS. YOU KNOW, THE RED CROSS HAS A PRICING
4 INDEX, AND PRIVATE ENTITIES WILL BE COMPETITIVE AGAINST
5 THAT. I JUST DON'T KNOW WHETHER THAT APPEARS ON CALRX.
6 THE QUESTION IS REALLY IS CALRX ENCOMPASSING OF BLOOD
7 PRODUCTS?

8 MR. ROTH: PHIL, WE'RE TRYING TO ENSURE THAT
9 IT IS BY THE WAY WE ARE GOING TO WORD THIS.

10 DR. PIZZO: OKAY.

11 MR. ROTH: THAT'S WHAT ED SAID, I THINK,
12 RIGHT IN THE BEGINNING.

13 DR. PIZZO: OKAY. THEN THAT WOULD TAKE CARE
14 OF IT. I JUST WANTED TO CLARIFY THAT.

15 MR. ROTH: I AGREE. I'M THINKING THE SAME
16 THING. BLOOD AND BLOOD PRODUCTS, ALBUMIN, ALL OF THAT
17 WOULD THEORETICALLY BE COVERED UNDER THIS IF WE ADD
18 THAT WORD "THERAPEUTIC PRODUCT" OR WHATEVER.

19 DR. PIZZO: YEAH. THAT WOULD WORK.

20 ED, ONE PRACTICAL THING, UNFORTUNATELY I HAVE
21 TO GO BACK TO THE JCAHO REVIEW IN ABOUT A MINUTE, SO
22 I'M GOING TO WIND UP SIGNING OFF.

23 CHAIRMAN PENHOET: GOOD LUCK. JCAHO IS NO
24 FUN, I KNOW.

25 DR. PIZZO: THEY'VE BEEN HERE ALL WEEK, SO

1 WE'RE HAVING THE FINAL SIGN-OUT. PRAY FOR THE BEST.

2 CHAIRMAN PENHOET: WE WILL. PHIL, FIRST OF
3 ALL, BEFORE YOU LEAVE, DO YOU HAVE ANY COMMENTS ON ANY
4 OF THE OTHER ISSUES THAT WE HAVEN'T YET COVERED IN
5 THIS?

6 DR. PIZZO: I DON'T THINK SO. I HAVEN'T READ
7 THROUGH THE ALL C'S THAT CAME THROUGH TODAY WELL
8 ENOUGH. I DON'T THINK SO, BUT IF I DO, I'LL GET BACK
9 TO YOU OR SCOTT. THANK YOU.

10 CHAIRMAN PENHOET: THE NEXT B IS LIMIT
11 PRICING PROVISIONS TO CIRM-FUNDED SELF-COMMERCIALIZED
12 PRODUCTS AND EXCLUSIVE LICENSES OF CIRM. AND THE NOTE
13 HERE IS THE POLICY SHOULD HAVE EXPLICITLY STATED THAT
14 ALL LICENSEES MUST ABIDE BY THE SAME PRICING
15 PROVISIONS. AND THE STAFF RECOMMENDS THAT WE CLARIFY
16 406 ON THIS POINT.

17 MR. TOCHER: IF YOU LOOK AT, ONCE AGAIN, THE
18 AMENDED LANGUAGE, THE BLUE, DOCUMENT WITH BLUE TEXT, IF
19 YOU TURN TO PAGE 6, YOU WILL SEE THAT WHAT WE DID IS WE
20 CLARIFIED THAT, IN FACT, THOSE PROVISIONS DO APPLY TO
21 THE ACCESS REQUIREMENTS. SO WHAT WE'VE DONE IS JUST
22 BASICALLY MADE A CROSS REFERENCE THERE BECAUSE THIS IS
23 THE REGULATION THAT DEALS SPECIFICALLY WITH THE
24 LICENSEES AND BASICALLY SAYS THAT YOU HAVE TO AGREE TO
25 ABIDE BY THE SAME ACCESS REQUIREMENTS AS ARE DESCRIBED

1 IN SUBDIVISION (A) OF 407.

2 CHAIRMAN KLEIN: FOR EXCLUSIVE LICENSEES.

3 MR. TOCHER: RIGHT.

4 CHAIRMAN PENHOET: SO THAT'S A CHANGE THERE.
5 ANY COMMENTS ON THAT? OKAY.

6 NEXT B IS TO DEFINE DRUGS AND THERAPIES. I
7 THINK DUANE MADE A HELPFUL SUGGESTION, THAT WE WOULD
8 DEFINE DRUG IN SUCH A WAY THAT ENCOMPASSES ALL FORMS OF
9 THERAPY THAT ARE PRODUCTS AS OPPOSED TO TREATMENTS. SO
10 YOU ARE GOING TO COME UP WITH A DEFINITION OF DRUGS
11 WHICH ENCOMPASSES THERAPEUTIC PRODUCTS GENERALLY,
12 DRUGS, CELLS, OR OTHERWISE; IS THAT RIGHT?

13 MR. TOCHER: THAT'S RIGHT.

14 CHAIRMAN PENHOET: I THINK WE'VE TAKEN CARE
15 OF THAT B.

16 UNDER REVENUE SHARING, FUNDING SOURCES -- THE
17 NEXT B IS FUNDING SOURCES SHOULD EXPLICITLY INCLUDE
18 SELF-FUNDING. THE NOTE FROM STAFF IS THIS SUGGESTION
19 COMPORTS WITH THE INTENT OF THE REGULATION AND,
20 THEREFORE, AMENDMENT IS NOT RECOMMENDED. WE DIDN'T
21 LIMIT THE -- THIS IS UNDER 408.

22 DR. PRIETO: AMENDMENT IS RECOMMENDED OR IS
23 NOT?

24 MR. TOCHER: THE AMENDMENT IS RECOMMENDED.

25 CHAIRMAN PENHOET: THE AMENDMENT IS

1 RECOMMENDED. I'M SORRY. IT'S TO BE EXPLICIT. BEFORE
2 IT SAYS GENERALLY OTHER FUNDS, BUT EXPLICIT INCLUDING
3 SELF-FUNDING.

4 MR. TOCHER: PAGE 8, LINE 20, THE BLUE TEXT
5 IS TO ADEQUATELY ATTEMPT TO MAKE THAT CLEAR.

6 CHAIRMAN PENHOET: FUNDING SOURCES, INCLUDING
7 THOSE OF THE AWARDEE, IN ADDITION TO --

8 MR. ROTH: SCOTT, WE HAVE IT AS LINE 19.
9 ONLY REASON I RAISED IT IS I WANT TO MAKE SURE WE'RE
10 NOT WORKING OFF TWO DIFFERENT VERSIONS.

11 MR. TOCHER: AS ED READ IT, IN THE FIRST
12 SENTENCE IN SUBDIVISION (A)(3) AFTER THE WORD "FUNDING
13 SOURCES," IT NOW SAYS -- ADDS A CLAUSE INCLUDING THOSE
14 OF THE AWARDEE.

15 CHAIRMAN PENHOET: OKAY. I THINK THAT'S THE
16 END OF THE B LIST.

17 DR. LOVE: ED, I HAVE ONE QUESTION. WERE WE
18 PLANNING ON -- I DIDN'T FOLLOW THIS INITIALLY, BUT ARE
19 WE PLANNING ON DEFINING THE TERM "DRUG" TO INCLUDE
20 THINGS LIKE CELLULAR THERAPY?

21 CHAIRMAN PENHOET: YES.

22 DR. LOVE: ON THE SURFACE THAT DOESN'T MAKE A
23 LOT OF SENSE TO ME BECAUSE WE WOULD NEVER CONSIDER A
24 BLOOD TRANSFUSION TO BE CALLED A DRUG.

25 MR. ROTH: WELL, FDA DOES, AND THEY CONSIDER

1 EVERYTHING A DRUG. THE ONLY THINGS THAT ARE NOT
2 CONSIDERED DRUGS WOULD BE DIAGNOSTIC PRODUCTS AND
3 MEDICAL DEVICES AND SO ON.

4 DR. LOVE: NO. I DON'T THINK THEY CONSIDER
5 THEM TO BE DRUGS. I THINK THEY REGULATE THEM BECAUSE
6 THAT'S CONSISTENT WITH DRUGS, BUT I DON'T THINK THE FDA
7 CONSIDERS BLOOD PRODUCTS TO BE DRUGS. WE COULD GO BACK
8 TO THAT, BUT IT DOES SEEM TO ME A LITTLE BIT UNUSUAL TO
9 REFER TO SOMETHING, LET'S SAY, THAT MIGHT BE AN
10 INFUSION OF CELLS THAT WOULD TREAT AN ALZHEIMER'S
11 PATIENT OR A PARKINSON'S PATIENT AS A DRUG.

12 CHAIRMAN PENHOET: YEAH. IF YOU LOOKED UP
13 DRUG IN THE DICTIONARY, IT CERTAINLY WOULD NOT INCLUDE
14 CELLS INJECTED TO TREAT AN ALZHEIMER'S PATIENT. I
15 THINK DUANE WAS JUST TRYING TO MAKE A SIMPLIFYING
16 DEFINITION FOR OUR OWN PURPOSES HERE, THAT DRUGS WOULD
17 ENCOMPASS THERAPEUTIC PRODUCTS, BE THEY DRUGS, CELLS,
18 WHATEVER ELSE, BUT TO DISTINGUISH. THERE WAS SOME
19 CONFUSION EARLY ON THAT THERAPIES MIGHT IMPLY THAT
20 PEOPLE WERE OBLIGATED TO PROVIDE A WHOLE THERAPY,
21 INCLUDING THE SURGICAL INTERVENTION IF IT'S INFUSION IN
22 THE BRAIN AND ALL THOSE THINGS. IT'S POSSIBLE, THOUGH,
23 THAT THE DEFINITION -- IF WE DEFINE DRUGS DIFFERENTLY
24 THAN THE ENTIRE REST OF THE WORLD DOES, THAT WE CREATE
25 MORE CONFUSION THAN WE ACTUALLY SOLVE. MAYBE THERE'S

1 ANOTHER DEFINITION OF THERAPEUTIC PRODUCTS GENERALLY,
2 PARENS INCLUDING DRUGS, CELLS, BLAH, BLAH, BLAH, THAT
3 MIGHT BE MORE TRANSPARENT TO THOSE OF US WHO ARE NOT
4 PART OF THE TEAM MAKING THIS DOCUMENT. WOULD THAT
5 BE --

6 MR. ROTH: THAT WOULD BE FINE. I THINK WE
7 SHOULD BE CONSISTENT AND USE ONE TERM THROUGHOUT.

8 CHAIRMAN PENHOET: I THINK WE'LL TRY TO USE
9 THE TERM "THERAPEUTIC PRODUCTS."

10 DR. LOVE: I THINK THAT WOULD MAKE SENSE, AND
11 WE OUGHT TO BE ABLE TO NARROW THE DEFINITION AROUND
12 WHAT THE COMPANY IS PROVIDING TO PROTECT AGAINST ALL OF
13 THESE ANCILLARY COSTS THAT WE DON'T WANT THE COMPANY TO
14 BE RESPONSIBLE FOR.

15 CHAIRMAN PENHOET: OKAY.

16 MR. TOCHER: I THINK WHAT WE CAN DO IS WORK
17 ON LANGUAGE. BEFORE WE SEND IT OUT FOR NOTICE, MAYBE
18 SEND IT AROUND TO THE MEMBERS OF THE TASK FORCE THAT
19 HAVE COMMENTED HERE AND GET YOUR INPUT BEFORE IT GOES
20 OUT FOR PUBLIC COMMENT.

21 CHAIRMAN PENHOET: OKAY. THE NEXT C ITEM,
22 WE'RE NOW ON PAGE 3 -- BOTTOM OF 2. WELL, WE'VE TAKEN
23 CARE OF ONEROUS AND DIRECT CONFLICTS AND ALL OF THAT.
24 SO THERE'S ONE ABOVE THAT. I'M SORRY.

25 ON PAGE 2 UNDER THE DEFINITIONS, I THINK

1 STAFF AGREES THAT WHETHER IT'S NARROWLY OR BROADLY,
2 THAT WE SHOULD BE MORE EXPLICIT ABOUT WHAT WE MEAN BY
3 ALL OF THESE TERMS, CIRM-FUNDED RESEARCH, CIRM-FUNDED
4 INVENTIONS, ETC. SO WE'RE NEITHER OVERREACHING, NOR
5 ARE WE SO NARROWLY DEFINED THAT EVERYBODY CAN FIND A
6 WAY AROUND THESE OBLIGATIONS. SO SCOTT WILL RESPOND TO
7 THAT INPUT THAT FURTHER CLARIFIES THE DEFINITION OF
8 THOSE VERY IMPORTANT TERMS. DOES THAT MAKE SENSE TO
9 EVERYONE?

10 MR. ROTH: I'VE GOT A COMMENT HERE, ED.

11 CHAIRMAN PENHOET: ON PAGE 2 UNDER ITEM 2,
12 DEFINITIONS, WE'RE GOING TO PROVIDE A MORE ROBUST
13 DEFINITION OF WHAT EACH OF THOSE TERMS INDICATED THERE
14 IS. THAT WAS A SUGGESTION. DUANE, YOU HAD A POINT?

15 MR. ROTH: YOU JUST ANSWERED IT FOR US, SO
16 WE'RE OKAY.

17 CHAIRMAN PENHOET: SO NOW WE'RE ON PAGE 3.
18 AT THE TOP OF THE PAGE, LICENSING CIRM-FUNDED PATENTED
19 INVENTIONS. THE FIRST ONE IS IT'S UNCLEAR -- THE
20 COMMENT WAS IT'S UNCLEAR WHAT ACCESS MEANS TO UNINSURED
21 PATIENTS, AT NO COST? THE NOTE, AS YOU CAN READ THERE,
22 THE TASK FORCE AND THE ICOC HAVE CONSIDERED HOW FURTHER
23 SPECIFICATION MIGHT BE MADE AND AGREES WITH THE
24 REGULATED COMMUNITY'S PAST SUGGESTION THAT THIS
25 LANGUAGE IS SUFFICIENT. IT IS VAGUE. AND THE LANGUAGE

1 WE HAVE IS THAT AT THE TIME OF COMMERCIALIZATION, THAT
2 THE LICENSEE, IN THIS CASE, WILL COME UP WITH A PLAN
3 FOR PROVIDING ACCESS TO UNINSURED PATIENTS THAT'S
4 CONSISTENT WITH THE THEN EXISTING INDUSTRY STANDARDS.
5 THERE ARE A LOT OF UNKNOWNNS OUT THERE WITH RESPECT TO
6 THAT.

7 WE DECIDED THAT WE CAN'T SPECIFY IT ANY
8 FURTHER. I DON'T BELIEVE THE INTENT WAS TO PROVIDE
9 FREE GOODS; BUT IF THAT TURNED OUT TO BE THE INDUSTRY
10 STANDARD AT THE TIME, THAT WOULD BE THE OBLIGATION.
11 THERE ARE A NUMBER OF THESE PROGRAMS IN PLACE TODAY
12 THAT ARE INCREASING IN NUMBER OVER TIME. SO WE DECIDED
13 NOT TO TRY TO SPECIFY WHAT ACCESS MEANT ANY MORE
14 CLEARLY THAN WHAT WE'VE DONE SO FAR, BUT OPEN FOR
15 DISCUSSION.

16 DR. PRIETO: ED, IF I COULD COMMENT. IN SOME
17 CASES SOME OF THESE CURRENT PROGRAMS DO INVOLVE FREE
18 GOODS; THAT IS, COMPANIES FOR PHARMACEUTICALS --

19 CHAIRMAN PENHOET: YES, THEY DO. I THINK
20 THAT IT VERY MIGHT WELL BE THE CASE THAT THEY WOULD BE
21 FREE GOODS. WE JUST HISTORICALLY DIDN'T WANT TO
22 SPECIFY EXACTLY WHAT IT WOULD MEAN EXCEPT TO REFER TO
23 INDUSTRY STANDARDS AT THE TIME. IF INDUSTRY STANDARDS
24 WAS FREE GOODS, THEN FREE GOODS WOULD BE WHAT IT IS.

25 MR. TOCHER: IF I CAN JUMP IN, THIS IS

1 ALLOWING SORT OF THE, AS WE MUST REALLY FOR PRACTICAL
2 PURPOSES, SORT OF THE ACCESS PLAN TO BE DEFINED A
3 LITTLE FURTHER DOWN THE ROAD IS, ESPECIALLY WITH
4 RESPECT TO THE VOLUNTARY PROVISION OF FREE PRODUCTS, IF
5 THAT WAS SOMEHOW REQUIRED IN OUR REGULATION, THAT A
6 MANUFACTURER PROVIDE FREE PRODUCT, THAT WOULD HAVE A
7 BEST PRICE IMPLICATION ACTUALLY FOR SIGNIFICANT DANGER
8 OF IT WITH REGARD TO THE FEDERAL MEDICAID PRICE.

9 THIS IS, FOR INSTANCE, WHY IT WAS ORIGINALLY
10 A PROVISION ACTUALLY IN THE CALRX PROGRAM AS THE
11 LEGISLATION WAS BEING DRAFTED AND WAS REMOVED BY THE
12 SPEAKER FOR THAT REASON.

13 MR. SHEEHY: THAT WAS ONE POINT I WANTED TO
14 MAKE. I THINK IF INDUSTRY IS JUST PATIENT. THIS
15 SIGNALS AN INTENT, BUT THERE'S SO MANY PIECES MOVING,
16 AND I THINK THE INCLUSION OF CALRX SPECIFICALLY IN HERE
17 MAY MAKE THE WHOLE POINT MOOT, FRANKLY, BECAUSE THERE'S
18 NOTHING RESEMBLING WHAT WE'RE TALKING ABOUT IN TERMS OF
19 THERAPEUTIC PRODUCTS UNDER DISCUSSION TODAY. IT MAY
20 COME AT THE TIME WHEN THE PRODUCTS ARE ACTUALLY ON THE
21 MARKET THAT THEIR INCLUSION IN CALRX MAY IN AND OF
22 ITSELF BE SUFFICIENT TO ADDRESS THE ACCESS PLAN IF A
23 SUFFICIENT NUMBER OF PEOPLE WHO ARE UNINSURED IN
24 CALIFORNIA ARE ABLE TO OBTAIN ACCESS TO THESE PRODUCTS
25 THROUGH CALRX. WE'RE NOT TALKING ABOUT PEOPLE WHO HAVE

1 NOTHING. THEY'RE GOING TO GET THEIR THERAPIES THROUGH
2 MEDI-CAL. WE'RE TALKING ABOUT THAT GAP, WHICH CALRX IS
3 TRYING TO ADDRESS, AND IT'S SIMPLY THE SILENCE OF CALRX
4 ON THESE THERAPIES THAT LEAVES THIS LINGERING GAP. BUT
5 IT MAY BE THAT THE PROVISION MANDATING PARTICIPATION IN
6 CALRX MAY MAKE THAT PROVISION MOOT.

7 CHAIRMAN PENHOET: WE HAD EVEN MORE VAGUE
8 LANGUAGE EARLY ON. DAVID KESSLER CORRECTLY POINTED OUT
9 WE SHOULD HAVE SOME STANDARD ANTICIPATED HERE. THAT'S
10 WHERE THE LANGUAGE ABOUT COMPARABLE INDUSTRY STANDARD
11 EMERGED. IT'S STILL NOT TRIVIAL TO FIGURE OUT WHAT
12 THAT WILL BE AT THE TIME, BUT YOU CAN SURVEY THE OTHER
13 COMPANIES. I THINK THAT'S WHERE WE ARE. ANY OTHER
14 COMMENTS? ANY COMMENTS FROM THE PUBLIC?

15 MR. ROTH: SAN DIEGO.

16 MR. GILLENWATER: THIS IS TODD GILLENWATER
17 WITH THE CALIFORNIA HEALTHCARE INSTITUTE. IT'S MAINLY
18 JUST A QUESTION OF CLARIFICATION. IN THE ACCESS
19 LANGUAGE IN SECTION 100406, IT DOESN'T REFER TO
20 CONSISTENT WITH INDUSTRY STANDARDS EXTANT AT THE TIME
21 OF THE COMMERCIALIZATION THAT EXISTS IN 100407. IS
22 THERE A REASON FOR HAVING THAT IN 407 AND NOT IN 406?

23 CHAIRMAN PENHOET: NO. WE SHOULD CONFORM
24 THOSE TWO. IT SHOULD BE THE SAME BURDEN FOR A LICENSEE
25 OR SELF-COMMERCIALIZATION. IF IT ISN'T, WE'LL CONFORM

1 THE TWO. THANKS FOR THAT COMMENT, TODD.

2 DR. BRYANT: I HAVE TO LOG OUT NOW. SORRY.

3 CHAIRMAN PENHOET: THANK YOU.

4 DR. PRIETO: ED, I THINK MAYBE THAT WAS

5 ADDRESSED. AT LEAST THE VERSION I HAVE 100406, PAGE 6,

6 LINE 1 SAYS SUCH LICENSEES WILL AGREE TO ABIDE BY THE

7 SAME ACCESS REQUIREMENTS OF THE AWARDEE AS DESCRIBED IN

8 SUBDIVISION (A) OF TITLE 17, CALIFORNIA CODE OF

9 REGULATIONS SECTION 100407. SO I THINK SCOTT ALREADY

10 TOOK CARE OF THAT.

11 CHAIRMAN PENHOET: GOOD GUESS. YOU'RE RIGHT.

12 THAT'S EXACTLY WHAT THAT SAYS. IT JUST REFERS TO

13 ANOTHER DOCUMENT THAT HAS THAT LANGUAGE IN IT. OKAY.

14 THEN ON PAGE 3, THE SECOND C, LITTLE (H),

15 WHAT IS ADMINISTRATIVE ACTION AND WHERE NECESSARY MEAN?

16 THE COMMENT IS REASONABLE, AND SCOTT WILL ENDEAVOR TO

17 MAKE A CLARIFICATION.

18 DR. MAXON: THERE HAS BEEN A CLARIFICATION

19 MADE. WE DID CLARIFY IT.

20 CHAIRMAN PENHOET: WE DID. OKAY. LET'S LOOK

21 AT THE LANGUAGE THEN. THAT IS --

22 DR. PRIETO: WHERE ARE WE?

23 CHAIRMAN PENHOET: WE'RE ON PAGE 3 OF THE

24 COMMENTS, SECOND C, LITTLE (H) UNDER 406. LITTLE (H)

25 SAYS, AT THE BOTTOM OF THE PAGE, IT SAYS AN AWARDEE

1 ORGANIZATION SHALL TAKE NECESSARY ACTION TO MODIFY OR
2 TERMINATE LICENSE RIGHTS WHERE NECESSARY -- TOO MANY
3 NECESSARIES -- TO BRING LICENSEES INTO COMPLIANCE WITH
4 THESE REGULATIONS. I THINK WE'VE GOT ONE TOO MANY
5 NECESSARIES.

6 MR. TOCHER: SORRY ABOUT THAT. THE POINT WAS
7 TO REMOVE ADMINISTRATIVE AS UNDULY RESTRICTIVE AND
8 VAGUE. NECESSARY MIGHT READ WHATEVER ACTION; OR, AS
9 I'M HEARING FROM PAT OLSON, JUST DELETE THE WORD
10 "NECESSARY" ENTIRELY. I SUPPOSE THAT MIGHT WORK.

11 CHAIRMAN PENHOET: WELL, THE FIRST NECESSARY.
12 JUST SAY AWARDEE ORGANIZATIONS SHALL TAKE ACTION TO
13 MODIFY OR TERMINATE LICENSE RIGHTS WHERE NECESSARY TO
14 BRING LICENSEES INTO COMPLIANCE WITH THESE REGULATIONS
15 AND REPORT SUCH ACTION TO THE PROGRAM OFFICER. OKAY.

16 DR. PRIETO: THAT SOUNDS ABOUT RIGHT.

17 CHAIRMAN PENHOET: THE NEXT ONE, CLARIFY THAT
18 THE PREFERENCE FOR NONEXCLUSIVE LICENSES DOESN'T COME
19 AT THE EXPENSE OF SELF-COMMERCIALIZATION. WE HAVE SAID
20 MANY TIMES WE WANT TO INCENT COMPANIES TO COMMERCIALIZE
21 THESE THINGS THEMSELVES, SO WE THINK THAT THE COMMENT
22 IS REASONABLE, AND A CLARIFICATION WOULD BE MADE.

23 THAT IS UNDER --

24 MR. TOCHER: SUBDIVISION (B).

25 CHAIRMAN PENHOET: -- SUBDIVISION (B) ON PAGE

1 5 OF THE MODIFIED DOCUMENT.

2 MR. TOCHER: SUBDIVISION (B), LINE 1, I THINK
3 ON SOME COPIES IT BEINGS ON LINE 8 AND OTHERS ON LINE
4 9. AND THE ADDITIONAL LANGUAGE READS WHENEVER THE
5 AWARDEE ELECTS NOT TO COMMERCIALIZE THE PRODUCT ITSELF.

6 CHAIRMAN PENHOET: SO THAT SHOULD TAKE CARE
7 OF THAT.

8 AND THE NEXT ONE IS IN SUBPART (F), WHICH IS
9 BACK AGAIN ON PAGE 6. GROUNDS FOR TERMINATION OR
10 MODIFICATION OF A LICENSE ALLOWING FOR COMMERCIALY
11 REASONABLE ALTERNATIVES AND BENCHMARKS. AGAIN, WE
12 BELIEVE THAT SUGGESTION IS REASONABLE AND THE
13 REGULATION SHOULD BE AMENDED TO ACCEPT THE SUGGESTED
14 LANGUAGE. I DON'T SEE A MODIFICATION HERE IN THAT
15 REGARD, SCOTT, UNLESS I'M MISSING SOMETHING.

16 MR. TOCHER: NO. THERE WAS SUGGESTED
17 LANGUAGE BY THE COMMENTER. AND I THINK THAT WAS
18 PROVIDED IN LETTER NUMBER --

19 CHAIRMAN PENHOET: LETTER NO. 3. MAYBE YOU
20 CAN GO SEE IF YOU CAN FIND IT WHILE WE MOVE ALONG TO
21 THE NEXT ITEM. PROVISIONALLY WE WILL ADOPT THAT
22 LANGUAGE.

23 MR. TOCHER: ACTUALLY IF YOU TURN PAGE -- NOW
24 THIS IS IN THE PACKET OF PUBLIC COMMENTS. THIS IS BY
25 CHI, ON PAGE 6, GIVE ME A CHANCE TO GET THERE. IT

1 BEGINS WITH THE THIRD --

2 CHAIRMAN PENHOET: THE PAGINATION IS AT THE
3 TOP. IT SAID MR. SCOTT TOCHER, 4 OF 4, ETC. 6 OF 6
4 WOULD BE THE ONE.

5 MR. TOCHER: YES. PAGE 6 OF 6. THEIR
6 PAGINATION IS OFF. AT ANY RATE, IT'S THE THIRD FULL
7 PARAGRAPH MAKES THE SUGGESTION REGARDING SUGGESTED
8 LANGUAGE FOR SUBDIVISION (F) FOR GROUNDS FOR
9 MODIFICATION. AND I BELIEVE THAT THE --

10 CHAIRMAN PENHOET: SO IT NOW READS EXAMPLES
11 WOULD INCLUDE FAILURE TO USE COMMERCIALY REASONABLE
12 EFFORTS TO MEET AGREED UPON COMMERCIALIZATION
13 BENCHMARKS AND TO CURE ANY SUCH FAILURE USING
14 COMMERCIALY REASONABLE EFFORTS OR SUCH CURE MAY
15 INCLUDE REASONABLY ALTERNATIVE MEANS OR NEGOTIATING
16 ALTERNATIVE BENCHMARKS. SO A REASONABLENESS STANDARD
17 ESSENTIALLY.

18 MR. TOCHER: THE POINT WAS TO TAKE CARE OF
19 UNFORESEEN, I THINK, AS CHI SAID, SETBACKS.

20 CHAIRMAN PENHOET: WHICH ALMOST ALWAYS
21 HAPPENS. ANY COMMENT ON THAT?

22 THE NEXT ITEM DOWN, ON PAGE 3, 5, THE FIRST C
23 IT'S TO NARROWLY DEFINE PUBLIC FUNDS. WE AGREE, AND SO
24 WE TALKED BEFORE. WE'RE GOING TO DEFINE WHAT PUBLIC
25 FUNDS MEAN IN THE CONTEXT OF THIS DOCUMENT, AND WE WILL

1 DO THAT.

2 THE NEXT ONE IS A COMMENT THAT SAYS CIRM
3 WON'T HAVE ACCESS TO CALRX DATA. THE ENFORCEMENT OF
4 CALRX IS BY THE DEPARTMENT OF HUMAN HEALTH SERVICES.
5 IT'S ANOTHER STATE AGENCY. I THINK WE'RE CONCERNED
6 THAT WE WOULDN'T HAVE THE -- CIRM WOULD NOT HAVE THE
7 ADMINISTRATIVE CAPACITY TO ACTUALLY ADMINISTER AN
8 ENTIRE DRUG PROGRAM. SO I THINK -- I DON'T KNOW WHAT
9 WE WOULD DO WITH THE DATA IF WE HAD IT. HHS IS A STATE
10 AGENCY REQUIRED TO DO ITS WORK IN THIS WAY. I THINK
11 THAT'S THE BASIS OF YOUR COMMENT; IS THAT CORRECT,
12 SCOTT?

13 MR. TOCHER: THAT'S RIGHT. THAT'S RIGHT.
14 THE PROGRAM WILL BE ADMINISTERED AND THE COMPLIANCE
15 ENFORCED BY DHHS. PRESUMABLY IF FOR SOME REASON THEY
16 FALL OUT OF COMPLIANCE WITH THE PROGRAM, THAT WOULD BE
17 SOMETHING WHICH THEY COULD ALERT US.

18 CHAIRMAN PENHOET: OKAY. THE NEXT ONE,
19 THEN -- ANY COMMENT ON THAT? NOW WE'RE AT THE TOP OF
20 PAGE 4. THE COMMENT IS TO DELETE THIS PROVISION FOR
21 ACCESS IN ITS ENTIRETY. WE HAVE HEARD THAT REQUEST ON
22 NUMEROUS OCCASIONS, AND BOTH THIS TASK FORCE AND THE
23 ICOC HAVE REJECTED THAT PROPOSAL. WE DON'T PROPOSE TO
24 RETURN TO DO THAT, BUT WE'RE OPEN TO COMMENTS THAT ANY
25 OF YOU MAY HAVE.

1 OKAY. NEXT ONE IS WHAT IS AN INDUSTRY
2 STANDARD? WE HAVE -- I THINK WE'VE DISCUSSED BEFORE.
3 THE AMBIGUITY THERE IS TO SOME DEGREE INTENTIONAL
4 BECAUSE WE DON'T KNOW TODAY, THESE ARE LIKELY TO BE TEN
5 YEARS IN THE FUTURE, WHAT IT WOULD BE AT THE TIME, BUT
6 I THINK THERE'S A GENERALLY RECOGNIZED TERM OF THE ART
7 IN THAT THE MAN ON THE STREET KNOWS WHAT A STANDARD
8 WOULD BE. AND I THINK AT THE TIME MEANS YOU HAVE TO
9 FIND A REPRESENTATIVE BASKET OF COMPARABLES AND LOOK AT
10 THEM CAREFULLY AND UNDERSTAND WHAT THEY ARE. IT'S VERY
11 HARD TO PREDICT IN ADVANCE WHAT THAT STANDARD WOULD BE
12 BECAUSE WE WON'T KNOW IT UNTIL WE SEE IT.

13 WE COULD PUT SOME LANGUAGE IN ABOUT THE
14 PROCESS BY WHICH YOU DETERMINE INDUSTRY STANDARD, I
15 SUPPOSE, BUT I DON'T THINK WE REALLY NEED TO DO THAT.
16 SOMEBODY WILL BE OBLIGATED TO DO THAT WHEN THE TIME
17 COMES.

18 ANY COMMENTS ON THAT? IT IS AN AMBIGUOUS --
19 THERE'S A LOT OF AMBIGUITY IN THE TERM, BUT I THINK TO
20 SOME DEGREE WE'VE ALL DECIDED TO LIVE WITH THAT
21 AMBIGUITY FOR NOW. IT'S MORE CLEAR THAN WHAT WE HAD
22 ORIGINALLY. THIS WAS IN RESPONSE TO DAVID KESSLER'S
23 CONCERN THAT THERE WAS NO REFERENCE POINT. WE AT LEAST
24 HAVE THIS AS A REFERENCE POINT.

25 OKAY. THEN IN THE MIDDLE OF THE PAGE,

1 THERE'S A C BETWEEN TWO B'S. IT SAYS IF YOU DON'T
2 DELETE THIS ENTIRE SECTION BASICALLY, INCLUDE A TRIGGER
3 FOR WHICH CIRM FUNDING IS A SIGNIFICANT OR SUBSTANTIAL
4 PORTION OF OVERALL FUNDING. WE DID DISCUSS THIS. WE
5 DID DECIDE THAT THE FIRST DOLLAR IN WOULD TRIGGER THESE
6 REQUIREMENTS. WE TOOK THAT TO THE ICOC. IT WAS VOTED
7 UPON BY THE ICOC. WE'RE HAPPY TO HEAR ANY COMMENTS TO
8 THE CONTRARY, BUT THIS HAS BEEN IN PLACE THROUGH THE
9 NONPROFIT AND FOR-PROFIT POLICIES AND VOTED TWICE BY
10 THE ICOC NOW.

11 MS. SPINK: THIS IS KATIE SPINK IN THE SAN
12 CARLOS REMOTE LOCATION. THE ISSUE HERE, AS I SEE IT,
13 IS THAT IT'S LIKELY THAT THE FUNDING FROM CIRM WILL BE
14 A VERY SMALL PERCENTAGE OF THE OVERALL AMOUNT IN, AND
15 THAT THESE ACCESS PROVISIONS COULD VERY QUICKLY,
16 ESPECIALLY FOR SMALL GRANTS, OUTSTRIP -- THE COST OF
17 THE ACCESS PROVISIONS COULD OUTSTRIP THE AMOUNT OF
18 MONEY PROVIDED BY CIRM. AND SO THE EFFECT OF THAT IS
19 LIKELY TO BE THAT FOR-PROFIT ORGANIZATIONS WILL NOT
20 APPLY FOR GRANTS OF RELATIVELY SMALL AMOUNTS, BUT ONLY
21 WILL BE WILLING TO APPLY FOR GRANTS IF THEY'RE VERY
22 HUGE.

23 SO IF THERE'S NOT A THRESHOLD MECHANISM ON
24 THE TABLE HERE, THE OTHER THING THAT I WOULD SUGGEST
25 AND THAT WE DID SUGGEST IN OUR WRITTEN COMMENTS IS

1 PERHAPS THERE COULD BE A CAP MECHANISM SIMILAR TO THAT
2 IN THE ROYALTIES THAT WOULD AT LEAST PROVIDE COMPANIES
3 WITH SOME COMFORT THAT WE WOULD NOT BE SUBJECT TO
4 OBLIGATIONS THAT MANY FOLD EXCEED THE AMOUNT OF MONEY
5 THAT WAS RECEIVED.

6 CHAIRMAN PENHOET: ANY OTHER COMMENTS?

7 MR. GILLENWATER: TODD GILLENWATER,
8 CALIFORNIA HEALTHCARE INSTITUTE. JUST, I GUESS,
9 REITERATING ON OUR COMMENTS AND FOLLOWING UP ON THE
10 PREVIOUS COMMENTS. WE APPRECIATE ON THE REVENUE
11 SHARING THAT THE POLICY DOES TAKE INTO ACCOUNT THE FACT
12 THAT THE RETURN TO THE STATE SHOULD BE PROPORTIONATE TO
13 THE SUPPORT PROVIDED BY CIRM AND CONTINUE TO SUGGEST
14 THAT THAT SAME PROPORTIONALITY SHOULD BE CARRIED OVER
15 INTO THE PRICING AND ACCESS SECTIONS. THANK YOU.

16 CHAIRMAN PENHOET: THANK YOU. ANY COMMENTS
17 FROM ANY MEMBERS OF THE TASK FORCE?

18 MR. ROTH: I'LL TAKE A STAB AT IT, ED. I
19 THINK THE CONCEPT HERE IS THIS THREE TIMES MECHANISM.
20 AND SO IF YOU HAVE A SMALL GRANT AND YOU COMMERCIALIZE
21 ANYTHING, YOU HAVE AN OBLIGATION TO PAY THAT BACK AT A
22 2 TO 5 PERCENT ROYALTY UNTIL YOU CAP AT THREE TIMES
23 WHAT YOU BORROWED OR WHAT YOU GOT IN THE FORM OF A
24 GRANT. SO IT'S ONLY -- THE ONLY PAYMENT YOU MAKE IS IF
25 YOU HAVE SUCCESS AND YOU LAUNCH A PRODUCT. AND IT'S

1 PROPORTIONAL BECAUSE IT'S RELATIVE TO THE AMOUNT YOU
2 BORROWED OR THE AMOUNT YOU TOOK AS A GRANT.

3 SO I WAS HAVING A LITTLE TROUBLE FOLLOWING
4 WHY PROPORTIONALITY WOULD HAVE ANY BEARING HERE. IF
5 YOU TOOK THE SAME MONEY IN THE FORM OF A LOAN FROM A
6 BANK OR YOU TOOK IT AS EQUITY, IT WOULD SEEM TO ME THAT
7 YOU MAY PAY BACK A LOT MORE BECAUSE THOSE ARE BOTH
8 SUCCESS IN THAT CASE AND THOSE CASES HAS TO BE
9 ABSOLUTE. YOU PAY REGARDLESS. HERE YOU ONLY PAY IF
10 YOU ARE SUCCESSFUL, AND YOU ONLY PAY PROPORTIONAL TO
11 WHAT YOU RECEIVED AS A GRANT.

12 CHAIRMAN PENHOET: I THINK THAT'S ABSOLUTELY
13 CORRECT, DUANE; BUT IF I UNDERSTOOD THE COMMENTS BY THE
14 PREVIOUS SPEAKERS, THIS IS RELATING TO THE ACCESS
15 PROVISION. AND THEIR POINT IS IF THEY COMMERCIALIZE --
16 IF THEY GOT A GRANT FOR, SAY, \$3 MILLION FROM US AND
17 THEY COMMERCIALIZED A PRODUCT, THE PAYBACK PROVISIONS
18 WOULD SAY THEY WOULD HAVE TO PAY US \$9 MILLION BACK AT
19 THE RATE WE HAVE ALREADY DESCRIBED, THE 2 TO 5 PERCENT
20 RATE, SO THAT THEY WOULD KEEP SOME PROFITS DURING THAT
21 EARLY TIME, ETC. SO THEIR EXPOSURE IS CAPPED AT \$9
22 MILLION.

23 THEIR ARGUMENT IS IF HAVING TAKEN THAT \$3
24 MILLION, THEY ALSO HAVE TO PROVIDE ACCESS. AND THE
25 ACCESS INDUSTRY STANDARD AT THE TIME WOULD BE, FOR THE

1 SAKE OF ARGUMENT, FREE GOODS TO A NUMBER OF PEOPLE,
2 THAT THE COST OF THEIR FREE GOODS MIGHT BE SOME OTHER
3 NUMBER, \$30 MILLION, WHICH IT'S UNCAPPED AND IT'S
4 UNKNOWN. SO THEIR ARGUMENT IS THAT THE ACCESS
5 PROVISION IS -- UNLIKE THE PAYBACK PROVISION, IT'S NOT
6 CAPPED IN ANY WAY. SO THEY DO HAVE A POINT. I THINK
7 WE DID DECIDE THAT THAT'S A RISK THEY WILL TAKE. IT
8 ONLY PROVIDES GOODS TO UNINSURED CALIFORNIANS, NOT TO
9 UNINSURED PEOPLE IN THE ENTIRE WORLD. NEVERTHELESS, I
10 BELIEVE THAT'S THE POINT, TODD, THAT YOU AND KATIE
11 MADE; IS THAT CORRECT?

12 MR. GILLENWATER: CORRECT.

13 MR. SHEEHY: AGAIN, THIS IS PREDICATED, IT'S
14 BASED ON MY FAITH THAT CALRX WILL WORK. BUT MAYBE WE
15 SET A THRESHOLD AND SAY THAT PARTICIPATION IN CALRX,
16 WHICH IS NOW MANDATORY, IS SUFFICIENT FOR SATISFYING
17 THIS OBLIGATION UNDER SUFFICIENT -- UNDER A CERTAIN
18 THRESHOLD. AND MAYBE EVEN WE PUT IN AN ADDED
19 PROVISION, IF AT THE TIME OF COMMERCIALIZATION CALRX
20 HAS MADE NO PROVISION FOR THE PRODUCTS BEING DEVELOPED,
21 THEN THE COMPANY STILL HAS TO COME UP WITH AN ACCESS
22 PLAN. CALRX, WE'RE JUST SAYING YOU GOT TO PARTICIPATE
23 IN CALRX. YOU KNOW, THAT SEEMS -- CALRX, SEEMS LIKE
24 EVERYBODY GETS ALONG WITH THAT, YOU KNOW. IF THAT'S
25 GOING TO BE OUR BENCHMARK, THEN ARE WE GOING TO RELIEVE

1 THEM -- NOTWITHSTANDING WHAT WE MAY SAY ABOUT ACCESS
2 PLANS, DO WE INTEND TO REMOVE THE OBLIGATION TO
3 PARTICIPATE IN CALRX THAT WE PUT IN?

4 CHAIRMAN PENHOET: I DON'T THINK SO.

5 MR. SHEEHY: I DON'T THINK SO. SO WE HAVE
6 THEM PARTICIPATING IN CALRX. I DON'T SEE HOW WE CAN,
7 FRANKLY. SO WE HAVE THEM PARTICIPATING IN CALRX. AND
8 LIKE I SAID, MY SENSE IS THAT BY THE TIME ALL IS SAID
9 AND DONE, IF WE DON'T HAVE UNIVERSAL HEALTHCARE IN THIS
10 COUNTRY, I DO THINK CALRX MAY GO 90 TO 95 PERCENT OF
11 THE WAY THAT WE'VE BEEN INTENDING TO GO.

12 CHAIRMAN PENHOET: IF THAT WERE THE CASE,
13 THEN THE PROVISION AS WRITTEN, THE COMPARABLES WOULD
14 TAKE THAT INTO ACCOUNT, I ASSUME. IF THE PROVISION FOR
15 ACCESS AS WRITTEN SAYS, AT THE TIME OF
16 COMMERCIALIZATION, COMPANIES WILL HAVE TO PROVIDE AN
17 ACCESS PLAN WHICH IS CONSISTENT WITH INDUSTRY
18 STANDARDS. IF CALRX IS PERFORMING THIS FUNCTION,
19 INDUSTRY STANDARD IS LIKELY TO BE THAT.

20 MR. SHEEHY: I'M WITH YOU. I PERSONALLY
21 DON'T SEE -- I'VE NEVER UNDERSTOOD THE OBJECTION TO
22 THIS BECAUSE IT'S SELF-GENERATED. YOU KNOW, IT'S HARD
23 FOR ME TO BELIEVE THAT SOMEWHERE IN THE DEVELOPMENT
24 PROCESS, EVEN IF IT'S IN THE CONTEXT OF A CLINICAL
25 TRIAL, THEY DON'T GIVE AWAY SOME DRUG, SOME PRODUCT.

1 THERE'S GOT TO BE SOMEBODY WHO'S GOING TO GET --
2 DOESN'T HAVE ACCESS TO PRODUCTS, THE COMPANY'S GOT TO
3 DO SOMETHING TO GET THAT PRODUCT. WHY DO PEOPLE DO
4 THIS BUT TO SAVE LIVES?

5 AND SO WE'RE NOT TELLING THEM THAT THEY HAVE
6 TO GIVE IT TO EVERY CALIFORNIAN THAT'S NOT INSURED.
7 ALL WE'VE EVER SAID, AND THE RECORD HAS BEEN CLEAR ON
8 THIS, YOU JUST HAVE TO THINK ABOUT THESE FOLKS WHO
9 WOULD NOT HAVE ACCESS ANY OTHER WAY. IT JUST KIND OF
10 BOTHERS ME THAT THE IDEA THAT THEY MIGHT HAVE TO THINK
11 ABOUT THAT WHEN THEY GO TO MARKET IS SO ONEROUS, THAT
12 THEY WON'T EVEN TAKE OUR MONEY. THAT'S NOT A VERY WARM
13 AND FUZZY IMAGE THAT'S BEING CONVEYED.

14 CHAIRMAN PENHOET: I DO THINK THAT'S ONE OF
15 THE REASONS, THOUGH, THAT WE DID LEAVE INDUSTRY
16 STANDARD AMBIGUOUS. IF THERE IS INSURANCE IN PLACE,
17 THEN INDUSTRY STANDARD IS THERE'S NO UNINSURED. IF
18 THERE'S CALRX IN PLACE AND IT COVERS MOST OF THE
19 UNINSURED PEOPLE, THE PROGRAMS THAT EXIST AT THE TIME
20 WILL REFLECT THAT, FOR SURE. SO, YOU KNOW, I THINK TO
21 SOME DEGREE IT COULD BE SELF-CORRECTING, BUT YOU COULD
22 IMAGINE THE DOWNSIDE SCENARIO WHICH SAYS NONE OF THIS
23 IS IN PLACE AND THE COMPANY WOULD HAVE TO GIVE A LOT
24 MORE FREE GOODS THAN THEY EVER GOT FROM US. THAT'S A
25 RISK IN THIS FOR A COMPANY.

1 ANY OTHER TASK FORCE MEMBER COMMENTS? IF
2 NOT, JOHN SIMPSON IN SAN FRANCISCO HAS A COMMENT.

3 MR. SIMPSON: VERY QUICKLY, I WANTED TO
4 REITERATE WHAT JEFF WAS SAYING THERE. I'M APPALLED
5 THAT THIS IS BEING VIEWED AS AN ONEROUS PROVISION. AND
6 ALL THAT'S BEING ASKED IS, UNLIKE WHAT SOME OF US WOULD
7 HAVE SUGGESTED, SPECIFIC OBLIGATIONS, IT'S ESSENTIALLY
8 SAYING BE A GOOD CORPORATE CITIZEN DOWN THE ROAD. TO
9 HEAR REPRESENTATIVES OF THE BIOMEDICAL INDUSTRY SUGGEST
10 THAT THIS IS IN ANY WAY ONEROUS IS JUST SHOCKING AND
11 APPALLING. THIS IS -- I'M SORRY. I JUST CANNOT
12 UNDERSTAND IT, SO I JUST WANTED TO GET THAT ON THE
13 RECORD. I THINK YOU NEED TO LEAVE IT THE WAY IT IS.

14 DR. LOVE: COULD I JUST RESPOND? I ACTUALLY
15 THINK IT'S QUITE UNUSUAL FOR THERE TO BE A COMPANY THAT
16 HAS NOT PROVISIONS IN PLACE FOR PROVIDING DRUGS FOR
17 PEOPLE THAT CAN'T AFFORD THEM. I'VE NEVER BEEN
18 ASSOCIATED WITH A COMPANY, NEVER HAD DEALINGS WITH A
19 COMPANY THAT DIDN'T HAVE SUCH PROGRAMS IN PLACE BECAUSE
20 I THINK IT IS FUNDAMENTAL. AND I THINK THE CONCERN
21 REALLY IS NOT DO YOU DO IT. THE CONCERN IS IS THERE
22 SOME KIND OF LOOPHOLE THAT DRIVES YOU INTO SOMETHING
23 UNREASONABLE, AND I DON'T SEE THIS AS NECESSARILY DOING
24 THAT.

25 CHAIRMAN PENHOET: OKAY. ANY OTHER PUBLIC

1 COMMENT? WE HAVE ONE IN SAN FRANCISCO.

2 MS. GHIO: TERRY GHIO FROM INVITROGEN. JUST
3 ALSO AS A CO-CHAIR OF BIOCOM'S LEGISLATIVE COMMITTEE,
4 JUST A COMMENT IN GENERAL ABOUT ACCESS ISSUES.
5 CURRENTLY EVERY COMPANY HAS THEIR OWN PLAN. THERE ARE
6 SIMILARITIES. I THINK ONE OF THE CONCERNS ABOUT THIS
7 INDUSTRY STANDARD IS IS THE INDUSTRY, YOU KNOW, GOING
8 TO BE FORCED TO DEVELOPING OVERALL GENERAL STANDARDS
9 FOR THEIR PATIENT ASSISTANCE PROGRAMS. THAT IS,
10 EVERYONE DOES -- SOME OF THE LARGER COMPANIES, YOU HAVE
11 A VERY LARGE MARKET PRODUCT LIKE A LIPITOR OR SOMETHING
12 LIKE THAT, YOU HAVE A COMPLETELY DIFFERENT PATIENT
13 ASSISTANCE PROGRAM THAN IF YOU HAD AN ORPHAN DRUG THAT
14 IS USED FOR A VERY RARE DISORDER THAT COMES OUT OF A
15 SMALL BIOTECHNOLOGY COMPANY THAT IS NOT YET PROFITABLE,
16 AND THE ONLY REVENUES THAT THEY'RE GETTING BACK IS JUST
17 BASICALLY COVERING THEIR COSTS. AND SO THERE'S
18 DIFFERENT MODELS WITHIN THE INDUSTRY ITSELF. THERE'S
19 THE BIG GUYS AND THERE'S A LOT OF THESE SMALLER
20 COMPANIES THAT ARE DEALING IN RARE DISORDERS.

21 SO THAT'S WHY I THINK SOME OF THE DISCOMFORT
22 IS COMING FROM, BUT I THINK I AGREE THAT ALMOST EVERY
23 COMPANY HAS A PATIENT ASSISTANCE PROGRAM OF SOME SORT.
24 I JUST THINK THE WHOLE IDEA OF HAVING FOR A SMALL
25 COMPANY MAYBE TO BE PUSHED TO CONFORM WITH A LARGE

1 INDUSTRY STANDARD MIGHT BE WHY YOU'RE HEARING THIS.

2 DR. PRIETO: CAN I RESPOND TO THAT, ED?

3 CHAIRMAN PENHOET: YES, PLEASE DO.

4 DR. PRIETO: I THINK THAT THAT SPECIFICALLY
5 IS ONE OF THE REASONS WHY WE SAID THAT THE COMPANY
6 SHOULD DRAFT AND COME UP WITH THIS ACCESS PLAN BECAUSE
7 IT WOULD REFLECT THE UNIQUE CIRCUMSTANCES AND SOMETIMES
8 THE UNIQUE DISEASE OR UNIQUE TREATMENT. FOR SOME THE
9 MARKET WILL BE VERY SMALL. THE SPECIFICS OF THAT
10 TREATMENT WILL BE VERY DIFFERENT THAN THEY WOULD BE FOR
11 A BLOCKBUSTER SUCH AS LIPITOR. I THINK WE'VE
12 ACCOMMODATED THEM. AND LIKE JOHN SIMPSON SAID, I
13 REALLY DON'T UNDERSTAND SOME OF THESE OBJECTIONS.
14 WE'VE REALLY BENT OVER BACKWARDS, I THINK, TO BE
15 REASONABLE.

16 CHAIRMAN PENHOET: JEFF SHEEHY HAS A COMMENT.

17 MR. SHEEHY: ACTUALLY I JUST THOUGHT IT WAS
18 KIND OF INTERESTING THAT OUR TALKING ABOUT INDUSTRY
19 STANDARD HAS HAD THE INDUSTRY START TO THINK ABOUT
20 HAVING AN INDUSTRY STANDARD. GEE, WOULDN'T THAT BE A
21 TERRIBLE THING IF PHRMA ACTUALLY DEVELOPED AN INDUSTRY,
22 WITH ALL THE MONEY THEY SPEND ON LEGISLATIVE STUFF, ALL
23 THE MONEY THEY SPEND ON ADVERTISING, THEY ACTUALLY CAME
24 UP WITH A SET OF GUIDELINES AND COST INDUSTRY STANDARD
25 THAT WAS GOOD PRACTICE, BEING A GOOD CITIZEN WITHIN THE

1 PHARMACEUTICAL AND THE THERAPEUTIC COMMUNITY. I
2 ACTUALLY THINK THAT THAT WOULD BE A POSITIVE UNINTENDED
3 CONSEQUENCE OF THIS RULEMAKING PROCESS, TO BENEFIT
4 PEOPLE BEYOND OUR POTENTIAL PATIENTS DOWN THE ROAD.

5 SO MAYBE THIS IS AN OPPORTUNITY FOR PEOPLE IN
6 THE INDUSTRY TO KIND OF BE -- I WAS READING SOMETHING
7 ABOUT WHAT MAKES A PROFESSION. ONE OF THE THINGS IS TO
8 HAVE SOME CODE OF ETHICS. ANOTHER THING WAS TO HAVE
9 SOME MODALITY FOR GIVING BACK TO THE COMMUNITY THAT'S
10 CONSISTENT ACROSS ALL MEMBERS OF THE PROFESSION. AND
11 SINCE THE MEDICAL PROFESSION IS INVOLVED IN THE
12 PHARMACEUTICAL INDUSTRY, MAYBE SOME OF THAT CAN BLEED
13 OVER AS SOME SENSE OF PROFESSIONALISM, AND THE
14 REGULARIZATION OF GIVING BACK TO THE COMMUNITY COULD
15 TAKE PLACE. RATHER THAN SAYING OH, NO.

16 CHAIRMAN PENHOET: MAYBE, JUST TO THROW OUT
17 ONE IDEA, FOLLOWING UP ON YOUR POINT, IF THERE IS A LOT
18 OF CONCERN ABOUT A SMALL START-UP IN SAN DIEGO HAVING
19 TO HAVE THE SAME STANDARD AS MERCK, WHICH HAS A HUNDRED
20 BILLION DOLLARS IN SALES OR WHATEVER THEY HAVE, IT'S
21 POSSIBLE WE COULD PUT SOME MORE LANGUAGE AROUND
22 INDUSTRY STANDARD, TAKING INTO ACCOUNT COMPARABLE
23 COMPANIES WITH SIMILAR PRODUCT OFFERINGS, SOMETHING
24 LIKE THAT, THAT DEFINED THE UNIVERSE IN WHICH THEY LIVE
25 A LITTLE MORE CAREFULLY THAN A BROAD INDUSTRY STANDARD

1 BECAUSE, AGAIN, WE'RE TRYING TO INCENT COMPANIES TO
2 INVEST IN THIS. I DON'T KNOW WHAT THE SENSE OF THE
3 GROUP WOULD BE. ANYWAY, THAT WOULD BE ONE POSSIBLE
4 REFINEMENT OF THIS, TO DEFINE INDUSTRY AS SOMEHOW OF
5 COMPARABLE SIZE COMPANIES AND SOME LANGUAGE.

6 TED, DOES THAT MAKE ANY SENSE TO YOU, AND HOW
7 WOULD YOU WORD THAT?

8 DR. LOVE: YEAH. I THINK THAT'S A GOOD
9 SUGGESTION BECAUSE I THINK IT WILL KIND OF ADDRESS THE
10 CONCERN. PERSONALLY I HAD KIND OF INTERPRETED THAT AS
11 BEING WHAT INDUSTRY STANDARD WOULD MEAN, THAT THERE
12 WOULD ACTUALLY BE, NOT JUST ONE STANDARD FOR A MERCK,
13 BUT A STANDARD THAT WOULD APPLY FOR THE VARIOUS
14 COMPANIES. BUT I THINK THAT LANGUAGE WOULD BE HELPFUL.

15 CHAIRMAN PENHOET: IS IT THE SENSE -- DOES
16 ANYBODY ON OUR TASK FORCE HAVE AN OBJECTION TO TRYING
17 TO PROVIDE A LITTLE COLOR AROUND THE DEFINITION OF
18 INDUSTRY FOR THIS PURPOSE? WOULD THAT WORK FOR YOU,
19 JEFF?

20 MR. SHEEHY: YEAH. SURE.

21 CHAIRMAN PENHOET: AS LONG AS IT'S NOT A
22 LOOPHOLE. THAT'S NOT WHAT WE'RE TRYING TO CREATE HERE.

23 ANY OTHER COMMENTS FROM THE TASK FORCE ON
24 THIS SUBJECT?

25 MR. ROTH: ED, I'M FINE WITH THAT.

1 DR. PRIETO: I'M FINE WITH THAT TOO.

2 DR. LOVE: I WOULD JUST SAY I REALLY DON'T
3 THINK IT'S -- I REALLY DON'T THINK IT'S INDUSTRY'S
4 INTENT TO TRY TO FIND A LOOPHOLE. AND I'D JUST LIKE TO
5 GO ON RECORD AS SAYING THAT JUST HASN'T BEEN MY
6 EXPERIENCE. ED, I'M SURE IT HASN'T BEEN YOUR
7 EXPERIENCE EITHER. I DON'T THINK THAT'S THE COMMENT.
8 I DON'T THINK THAT'S REALLY THE SENTIMENT OF WHAT
9 PEOPLE HAVE BEEN TRYING TO GET AT.

10 BY THE WAY, JEFF, PHRMA ACTUALLY DOES HAVE A
11 NATIONAL PROGRAM THAT COMPANIES CAN PARTICIPATE IN FOR
12 DISTRIBUTING DRUGS, FREE OR WITH LIMITED ACCESS OR
13 IMPROVED ACCESS. SO I THINK THE INDUSTRY ACTUALLY IS
14 TRYING TO DO SOME OF THAT.

15 MR. SHEEHY: THAT WAS MY SENSE TOO. I JUST
16 SEE SO MANY EXAMPLES OF THIS, LIKE YOU.

17 MS. SPINK: THIS IS KATIE SPINK. AS THE
18 PERSON WHO MADE THE ORIGINAL COMMENT, I'D JUST LIKE TO
19 PERHAPS CLARIFY IT A LITTLE BIT. I AGREE. I DON'T
20 THINK ANY COMPANIES ARE GOING TO BE LOOKING FOR A
21 LOOPHOLE OR A WAY OUT OF THIS, BUT I THINK THE
22 SUGGESTION THAT WAS MADE IS A VERY GOOD ONE BECAUSE IT
23 WILL JUST HELP TO CLARIFY WHAT WE MEAN BY INDUSTRY
24 STANDARD. I THINK REASONABLE PEOPLE CAN DISAGREE ABOUT
25 WHAT'S AN INDUSTRY STANDARD. I APPRECIATE THE

1 SUGGESTED CHANGE. AND I WOULD LIKE TO JUST CLARIFY
2 THAT I WAS NOT INTENDING TO STATE THAT COMPANIES WOULD
3 NOT WANT TO PROVIDE ACCESS TO THEIR THERAPIES CLEARLY,
4 BUT JUST THAT DIFFERENT COMPANIES WILL HAVE DIFFERENT
5 WAYS OF DOING THAT.

6 CHAIRMAN PENHOET: OKAY.

7 MR. GILLENWATER: THIS IS TODD FROM CHI. I
8 WANT TO CLARIFY AGAIN AS WELL THAT IT IS NOT CHI'S
9 INTENT IN THE COMMENTS OR HERE TODAY TO SUGGEST THAT
10 OUR MEMBER COMPANIES DO NOT REGULARLY PROVIDE ACCESS
11 PLANS, ONLY TO SUGGEST, AS HAS BEEN SOMETIMES THE
12 OCCASION AT THE FEDERAL LEVEL, AND I KNOW THE
13 REASONABLE PRICING CLAUSE THAT WE'RE TALKING ABOUT
14 ADDRESSED AT THE FEDERAL LEVEL IS DIFFERENT THAN WE ARE
15 TALKING ABOUT HERE NOW, BUT THAT AS A FUNDING SOURCE
16 FOR SOME COMPANIES, SUCH OBLIGATIONS COULD FORCE THEM
17 TO LOOK ELSEWHERE FOR FUNDING SOURCES THAT DON'T HAVE
18 THESE TYPES OF OBLIGATIONS UP FRONT. THAT'S THE ONLY
19 EXTENT OF OUR COMMENT, NOT THAT INDUSTRY DOES NOT HAVE
20 ALREADY EXISTING ACCESS PLANS THAT THEY'RE VERY PROUD
21 OF.

22 CHAIRMAN PENHOET: THANK YOU FOR THAT
23 COMMENT.

24 OKAY. PAGE 4, ITEM 6, 100408. THE NEXT C IS
25 THAT WE MUST ACCOUNT FOR COMPOUND PRODUCTS. A COMPOUND

1 PRODUCT IS TYPICALLY A PRODUCT WHICH CONTAINS SEVERAL
2 DIFFERENT ACTIVE INGREDIENTS, AND THAT WE ONLY WOULD
3 GET PAID BACK ON PART OF THAT COMPOUND PRODUCT WHICH
4 OUR FUNDING LED TO. I THINK THAT, AS WE READ THE
5 LANGUAGE, IT DOESN'T APPEAR TO OVERREACH INTO REVENUES
6 FROM ANYBODY ELSE'S PRODUCT. THE PROBLEM ALWAYS WITH
7 COMPOUND PRODUCTS IS TO TRY TO FIGURE OUT WHAT FRACTION
8 OF THE VALUE IS ASCRIBED TO THE INDIVIDUAL COMPONENTS
9 IN THAT COMPOUND PRODUCT. BUT I THINK WE'D BE FACED
10 WITH THAT TASK WITH THE LANGUAGE WE HAVE NOW BECAUSE IT
11 REFERS ONLY TO CIRM-FUNDED PRODUCTS, NOT TO OTHER
12 PRODUCTS. IF THEY GET COMMINGLED, SOMEBODY AT THE TIME
13 WILL HAVE TO SIT DOWN AND NEGOTIATE THE RELATIVE VALUE
14 OF THE TWO PIECES. WE COULD BE MORE SPECIFIC ABOUT
15 THAT, BUT WE THOUGHT IT WAS PRETTY CLEAR IN THE
16 LANGUAGE THAT WE HAD.

17 ANYBODY ELSE HAVE A COMMENT ON THAT POINT?

18 DR. LOVE: I AGREE WITH WHAT YOU SAID, ED. I
19 THINK THAT THE EXAMPLES THAT I KNOW, WHEN PRODUCTS HAVE
20 BEEN COMBINED IS -- GILEAD AND BRISTOL DID THIS
21 RECENTLY. I KNOW YOU KNOW. AND THEY BASICALLY JUST
22 TOOK THE COST OF THE PREEXISTING PRODUCTS AND PUT THAT
23 IN. I THINK THAT WOULD BE THE APPROACH HERE.

24 CHAIRMAN PENHOET: OKAY.

25 BOTTOM OF THE PAGE, THE REVENUE SHARING,

1 SHOULD APPLY ONLY WHEN A CIRM INVENTION IS TIED
2 DIRECTLY TO A DEVELOPED PRODUCT. AGAIN, WE THOUGHT --
3 WELL, LET'S SEE. HANG ON A SECOND. YOU KNOW, I THINK,
4 AGAIN, THE LANGUAGE IS PRETTY CLEAR THERE. THERE WILL
5 BE SOME BORDER CONDITIONS PROBABLY WHERE FUNDS ARE
6 COMMINGLED OR RESEARCHERS ARE COMMINGLED.

7 MR. TOCHER: WHAT WAS MEANT BY THE NOTE WAS
8 TO TRY TO CAPTURE THE DISCUSSION AROUND THE SUGGESTION
9 THAT SOMETHING BEING TIED DIRECTLY OR INDIRECTLY.
10 EITHER IT'S PART OF IT OR IT'S NOT. AND I DON'T THINK
11 THAT IT WAS THE DESIRE TO TRY TO GET INTO SORT OF A
12 RANKING OF THE IMPORTANCE OF IT AND ASCRIBE WHETHER
13 THAT'S DIRECT OR INDIRECT BECAUSE THEN THAT WOULD BE
14 SOMETHING WHICH CIRM WOULD FIND ITSELF DEBATING, AND
15 PROBABLY EVERY GRANTEE OR LICENSEE HAVING TO HAVE
16 ANALYSTS WEIGH IN ON BOTH SIDES EVERY TIME THIS ISSUE
17 CAME UP.

18 CHAIRMAN PENHOET: ANY COMMENT ON THAT?

19 NEXT ONE IS TO DELETE THIS REGULATION IN ITS
20 ENTIRETY. AGAIN, WE'VE DISCUSSED IT MANY TIMES. I
21 THINK IT'S A CORE COMPONENT OF WHAT WE'RE DOING.
22 UNLESS SOMEBODY HAS ANOTHER VIEW, WE'LL JUST MOVE ON TO
23 THE NEXT ONE.

24 THE NEXT ONE PUTS CAPS ON ALL REVENUE SHARING
25 TO IMPROVE PREDICTABILITY. AGAIN, THIS IS IN THE CASE

1 OF LICENSES TO THIRD PARTIES. IT'S IN OUR NONPROFIT
2 POLICY. THIS CONFORMS TO THE NONPROFIT POLICY. AND I
3 THINK BASICALLY IT'S JUST A FRACTION OF WHATEVER THE
4 COMPANY NEGOTIATES WITH A THIRD PARTY. IF THEY PUT A
5 CAP ON IT, WE GET A CAP ON IT. WE LEAVE IT TO THE
6 COMPANIES IN THEIR DISCRETION TO MAXIMIZE THEIR OWN
7 RETURNS, AND WE JUST TAKE OUR PIECE OF THAT.

8 SO, AGAIN, WE HAVE CAPS IN THE CASE OF
9 COMPANIES. 3 X, 6 X, 9 X ARE CAPS IN THE CASE OF
10 SELF-COMMERCIALIZED PRODUCTS; BUT IN THE CASE OF
11 LICENSED PRODUCTS, WE SIMPLY GET A PIECE OF THE ACTION.
12 THAT'S BEEN A CORE PRINCIPLE ALL THE WAY ALONG IN WHAT
13 WE'VE DONE. ANY COMMENTS ON THAT?

14 MR. GILLENWATER: I'M SORRY. THIS IS TODD
15 GILLENWATER IN SAN DIEGO FROM CHI. GOING BACK TO THE
16 LAST POINT, AND I APOLOGIZE BECAUSE I WAS JUST QUICKLY
17 REREADING OUR COMMENTS BECAUSE I DIDN'T REMEMBER SEEING
18 IT. ON THE DELETE THIS REGULATION IN ITS ENTIRETY, THE
19 REVENUE SHARING, WE DID NOT SUGGEST THAT IN OUR
20 COMMENTS. WE WERE SIMPLY POINTING OUT THE EXPERIENCE
21 AT THE FEDERAL LEVEL WHY THEY DID NOT. SO I JUST WANT
22 TO CLARIFY FOR THE RECORD THAT WE DID NOT SUGGEST
23 DELETING THE REVENUE SHARING.

24 CHAIRMAN KLEIN: THANK YOU, TODD.

25 THEN THE NEXT ONE DOWN, FIX THE DRAFTING

1 ERROR IN THE LAST SENTENCE AND INCORPORATE THE 2- TO
2 5-PERCENT RATE INTO SUBDIVISION (B)(1), (5). THAT'S A
3 GOOD SUGGESTION, AND WE MADE THE AMENDMENT.

4 MR. TOCHER: HARD TO BELIEVE, BUT THERE WAS
5 AN ERROR, AND THE BLUE TEXT REFLECTS WHERE THAT
6 LANGUAGE WAS SHIFTED TO WHERE IT WAS SUPPOSED TO BE IN
7 (B)(1).

8 CHAIRMAN PENHOET: THAT'S AN EASY FIX.

9 CLARIFY THAT BLOCKBUSTER PAYMENTS APPLY ONLY
10 TO SELF-COMMERCIALIZED PRODUCTS. AND WE AGREE WITH
11 THAT SUGGESTION AND CLARITY CAN BE IMPROVED. IF THERE
12 ARE LICENSED PRODUCTS, WE JUST GET WHATEVER WE GET.
13 IT'S A FRACTION OF WHATEVER THE COMPANY NEGOTIATES WITH
14 A THIRD PARTY. WE'RE NOT PARTY TO THOSE NEGOTIATIONS.

15 MR. TOCHER: IN SUBDIVISION (C), PAGE 9 OF
16 THE BLUE LANGUAGE, AMENDED REGULATIONS SENT TODAY, THE
17 ADDITIONAL LANGUAGE NOW READS "CIRM-FUNDED
18 SELF-COMMERCIALIZED PRODUCTS."

19 CHAIRMAN PENHOET: TO BE EXPLICIT ABOUT THAT.

20 MR. TOCHER: THAT'S RIGHT.

21 CHAIRMAN PENHOET: NEXT ONE DOWN, CLARIFY
22 THAT THE 17 PERCENT REVENUE SHARE APPLIES ONLY TO VALUE
23 ASCRIBED TO CIRM-FUNDED INVENTIONS IN THE SITUATION
24 WHERE MORE THAN ONE INVENTION LEADS TO A PRODUCT. WE
25 BELIEVE THAT'S ALREADY CLEAR, THAT THROUGHOUT THE

1 DOCUMENTS WE REFER CONTINUOUSLY TO CIRM-FUNDED
2 INVENTIONS. IT WILL BE A DEFINED TERM, AS WE DISCUSSED
3 EARLIER, THAT WE WILL CLARIFY GOING FORWARD.

4 AND IF THERE'S A COMPOUND LICENSE, I THINK
5 THAT IT'S CLEAR WE ONLY GET A FRACTION OF THAT LICENSE
6 WHICH IS ASCRIBABLE TO WHATEVER WE FUNDED.

7 THAT SEEM SENSIBLE TO ALL OF YOU? OKAY.
8 PEOPLE MUST BE GETTING TIRED.

9 CLARIFY WHETHER THE 17 PERCENT REVENUE SHARE
10 OR CAPPED ROYALTY APPLIES WHEN CIRCUMSTANCES MAY
11 IMPLICATE BOTH. THIS IS AN INTERESTING CASE, BUT
12 THINKING THROUGH IT, WE THINK THAT THE RIGHT ANSWER IS
13 IT SHOULD APPLY TO BOTH. IF A COMPANY, FOR EXAMPLE,
14 LICENSES A THIRD PARTY TO DEVELOP AND SELL A PRODUCT
15 AND THEN THEY THEMSELVES GET INVOLVED IN CO-MARKETING
16 OR CO-PROMOTION AND THEY MAKE MONEY ON BOTH SIDES IN
17 THIS TRANSACTION, WE SHOULD GET SOME MONEY ON BOTH
18 SIDES. WE DON'T WANT TO DOUBLE DIP, WHICH IS NOT THE
19 POINT; BUT ON THE OTHER HAND, CIRM SHOULD BE PAID ON
20 BOTH SIDES OF THE TRANSACTION IF IT'S A HYBRID
21 SITUATION WHERE YOU HAVE A LICENSEE WHO IS PAYING
22 ROYALTIES AND YOU'RE ALSO COMMERCIALIZING THE PRODUCT
23 YOURSELF, WHICH, FOR EXAMPLE, WOULD HAPPEN IF A
24 COMPANY, AND FREQUENTLY DOES, A COMPANY RETAINS U.S.
25 RIGHTS TO A PRODUCT AND COMMERCIALIZES IT ITSELF IN THE

1 U.S., IT MANUFACTURES AND SELLS IN THE U.S., IT
2 LICENSES THE TECHNOLOGY TO A JAPANESE COMPANY OR A
3 EUROPEAN COMPANY, THAT COMPANY MARKETS THEMSELVES A
4 PRODUCT AND PAYS ROYALTIES, WE SHOULD BE PAID FOR THE
5 EUROPEAN SALES BY THE LICENSE AND THE U.S. SALES BY THE
6 DIRECT COMMERCIALIZATION.

7 SO IT SEEMS TO ME LOGIC SAYS WE SHOULD GET
8 PAID ON BOTH SIDES BECAUSE THAT'S THE FULL VALUE OF THE
9 INVENTION. I DON'T KNOW -- THIS IS A COMMENT THAT CAME
10 FROM -- NO. 5, IS WHICH LETTER, SCOTT? GERON. KATIE,
11 DO YOU HAVE A COMMENT ON THAT?

12 MS. SPINK: I'M JUST TRYING TO THINK THROUGH
13 IT AT THE MOMENT. THE IMPLICATION OF THAT -- WHAT
14 WOULD THE IMPLICATIONS OF THAT BE FOR
15 CO-COMMERCIALIZATION WITHIN THE U.S.? WOULD THAT MEAN
16 THAT A COMPANY WOULD HAVE TO PAY MORE TO CIRM IF WE
17 CO-COMMERCIALIZED IN THE U.S. THAN IF WE JUST LET OUR
18 PARTNER COMMERCIALIZE ONLY? I THINK THE ANSWER IS YES,
19 BUT I'M JUST THINKING THROUGH IT AS YOU'RE TALKING
20 ABOUT IT.

21 CHAIRMAN PENHOET: PRESUMABLY YOUR OWN
22 ACTIVITIES WOULD TAKE SOMETHING AWAY FROM YOUR
23 PARTNER'S SALES AND ACTIVITIES IN THAT CASE.

24 MS. SPINK: OFTEN WHAT HAPPENS IN THAT CASE
25 IS YOU RECEIVE A BUMP IN ROYALTY RATE FOR YOUR

1 CO-COMMERCIALIZATION ACTIVITIES, SO IT WOULDN'T TWO
2 SEPARATE REVENUES STREAMS NECESSARILY WHERE YOU COULD
3 APPLY ONE RATE TO ONE AND ONE RATE TO THE OTHER.

4 CHAIRMAN PENHOET: WELL, IF YOU'RE JUST BEING
5 PAID TO CO-PROMOTE A PRODUCT, I DON'T THINK YOU WOULD
6 OWE ANYTHING. THAT'S A PAYMENT TO YOU FOR CARRYING OUT
7 A SALES AND MARKETING ACTIVITY, AND THAT WOULDN'T BE
8 SUBJECT TO THE ROYALTY JUST BECAUSE YOU'RE A
9 CO-PROMOTER.

10 MR. ROTH: I THINK IT ALL DRIVES BACK TO THE
11 IP. IF YOU LICENSE THE IP AND RECEIVE A ROYALTY, THEN
12 WE'RE ENTITLED TO A PORTION OF THAT.

13 CHAIRMAN PENHOET: YEAH.

14 MR. ROTH: SO I THINK IT FOLLOWS THE
15 INTELLECTUAL PROPERTY, NOT THE BUSINESS DEAL.

16 CHAIRMAN PENHOET: I THINK THAT'S RIGHT.

17 MS. SPINK: I'LL NEED TO THINK THROUGH IT,
18 AND MAYBE WE'LL MAKE A COMMENT IN OUR NEXT COMMENTS
19 ONCE I'VE DONE THAT.

20 CHAIRMAN PENHOET: OKAY. WE'RE NOW ON ITEM 7
21 ON PAGE 5. FIRST ONE IS DELETE PUBLIC HEALTH AND
22 SAFETY NEEDS THAT CONSTITUTE HEALTH EMERGENCY DECLARED
23 BY THE GOVERNOR. THIS POLICY DETERMINATION WAS ALREADY
24 APPROVED AGAIN TWICE BY THIS GROUP AND BY THE ICOC.
25 ANY COMMENT FROM THE TASK FORCE?

1 MR. SHEEHY: FEDERAL LANGUAGE, ISN'T IT?
2 CHAIRMAN PENHOET: IT IS FEDERAL LANGUAGE.
3 THE GOVERNOR IS NOT.
4 THEN THE NEXT ONE --
5 MR. JACKSON: MR. CHAIRMAN, THIS IS JIMMY
6 JACKSON OF BIOCUM IN SAN DIEGO. FOR THE RECORD, I'D
7 LIKE TO CLARIFY THAT OUR LETTER TO WHICH THIS THING --
8 THIS NOTE REFERS, ACTUALLY OUR LETTER ASKS THAT THE
9 PROVISION BE SIGNIFICANTLY NARROWED, NOT DELETED. AND
10 THAT IS BECAUSE IN THE LANGUAGE IT SAYS THAT CIRM MAY
11 EXERCISE SUCH RIGHTS AT ANY TIME IN THE EVENT OF A
12 PUBLIC HEALTH OR SAFETY EMERGENCY DECLARED BY THE
13 GOVERNOR. WE FEEL THAT THAT IS OVERLY BROAD AS FAR AS
14 WHEN THE TRIGGER MAY COME AND GIVES A LEVEL OF
15 UNACCEPTABLE UNCERTAINTY TO OUR MEMBER COMPANIES AND TO
16 APPLICANTS.
17 CHAIRMAN PENHOET: YOU KNOW, IT'S A GOOD
18 POINT. HOW ABOUT THE FOLLOWING? THE GOVERNOR COULD
19 DECLARE A PUBLIC HEALTH EMERGENCY BECAUSE AVIAN FLU HAS
20 SHOWED UP HERE. THAT SHOULDN'T BE AN EXCUSE FOR
21 MARCH-IN RIGHTS ON CELL THERAPIES TO TREAT ALZHEIMER'S.
22 SO IT SHOULD BE A PUBLIC HEALTH AND SAFETY NEED
23 DIRECTLY RELATED TO PRODUCTS SUBJECT TO CIRM FUNDING OR
24 SOMETHING LIKE THAT BECAUSE I DON'T THINK THE INTENT IS
25 TO HAVE AVIAN FLU TRIP THIS PROVISION HERE. SO IS THAT

1 WHAT YOU MEAN?

2 MR. JACKSON: NO. WE WERE ACTUALLY CONCERNED
3 THAT IT JUST DIDN'T -- IT DIDN'T DEFINE -- IT DIDN'T
4 EXPLICITLY DEFINE ENOUGH FOR AN APPLICANT COMPANY WHERE
5 THE MARCH-IN RIGHTS MAY BE INVOKED OTHER THAN THE
6 GOVERNOR DECLARES A STATE OF EMERGENCY AND CIRM SAYS,
7 YES, WE NEED TO GET ACCESS TO THOSE THERAPIES BECAUSE
8 OF ANY OF THE CRITERION THAT IS SET FORTH THAT YOU'RE
9 NOT MEETING, AND ALL OF A SUDDEN MARCH-IN RIGHTS CAN BE
10 INVOKED.

11 CHAIRMAN PENHOET: WE DON'T WANT A TRIVIAL
12 TRIP OF THE MARCH-IN RIGHTS. I THINK WE COULD ADD SOME
13 LANGUAGE. PUBLIC HEALTH AND SAFETY NEEDS THAT ARE
14 RELATED TO THE PRODUCTS RESULTING FROM CIRM-FUNDED
15 INVENTIONS, AVAILABILITY AND ACCESS. MAYBE IT'S
16 IMPLIED IN ALL OF THIS, BUT IF WE NEEDED TO BE MORE
17 EXPLICIT.

18 MR. TOCHER: PERHAPS THEY COULD SUGGEST
19 SOMETHING MORE SPECIFIC TO ADDRESS THE CONCERN. BUT IF
20 IT'S A PUBLIC HEALTH AND SAFETY NEED THAT CONSTITUTES
21 THE EMERGENCY, THAT SEEMS --

22 CHAIRMAN PENHOET: AGAIN, AVIAN FLU, JUST TO
23 USE MY EXAMPLE, AVIAN FLU, AN AVIAN FLU EPIDEMIC IN
24 CALIFORNIA COULD CONSTITUTE A HEALTH EMERGENCY, AND THE
25 GOVERNOR COULD DECLARE A HEALTH EMERGENCY IN THE STATE

1 OF CALIFORNIA. THAT SHOULD NOT PROVIDE CIRM WITH THE
2 OPPORTUNITY TO MARCH IN ON COMPANIES THAT HAVE TAKEN
3 OUR MONEY THAT HAVE NOTHING TO DO WITH AVIAN FLU.

4 MR. SIMPSON: UNLESS IT WAS A THERAPEUTIC
5 THAT'S SOMEHOW RELATED.

6 CHAIRMAN PENHOET: RELATED. SO IT WOULD
7 BE -- THE HEALTH EMERGENCY SHOULD BE RELATED TO A
8 HEALTH EMERGENCY IN WHICH CIRM-FUNDED INVENTIONS COULD
9 OR WOULD ALLEVIATE THE CONDITION OR HOWEVER, SOME GOOD
10 LANGUAGE THAT YOU CAN COME UP WITH, BUT TO RELATE TO IT
11 WHAT WE'RE DOING RATHER THAN ANY HEALTH EMERGENCY.

12 MR. TOCHER: I THOUGHT PERHAPS MR. JACKSON
13 WAS SAYING --

14 CHAIRMAN PENHOET: WELL, MAYBE HE CAN GET
15 BACK TO YOU WITH SOME SUGGESTED LANGUAGE.

16 MR. TOCHER: GREAT.

17 CHAIRMAN PENHOET: IS THAT OKAY WITH THE
18 GROUP IF WE TRY TO MAKE THIS SPECIFIC TO PRODUCTS WHICH
19 EMERGE FROM CIRM-FUNDED INVENTIONS? THAT OKAY WITH
20 EVERYBODY ON THE TASK FORCE?

21 MR. ROTH: YES, ED. AND ONE MORE QUESTION
22 JUST TO THROW IT OUT. I'M A LITTLE CONCERNED ABOUT THE
23 TRIGGER BEING THE GOVERNOR. IN THE FEDERAL
24 LEGISLATION, IT'S THE AGENCY THAT DETERMINES THAT
25 THERE'S AN EMERGENCY, A TRIGGER. AND TAKE THE CURRENT

1 GOVERNOR OR ANY OTHER GOVERNORS OUT OF IT, BUT I WOULD
2 HATE TO GET IN A POSITION WHERE SOMEONE COMES IN AS
3 GOVERNOR AND DECIDES THAT ALL MEDICINES SHOULD BE COST
4 PLUS 2 PERCENT AND, THEREFORE, WOULD DECLARE AN
5 EMERGENCY. WHY NOT LEAVE THAT DECISION IN OUR HANDS?

6 CHAIRMAN PENHOET: I GUESS IT HAS TO DO WITH
7 THE WAY THE STATE PROCESS FOR DECLARING A HEALTH
8 EMERGENCY OCCURS. I DON'T KNOW HOW THAT HAPPENS IN THE
9 STATE. I GUESS WE'D NEED TO FIND OUT. IF THE PROCESS
10 IS IT MUST BE DECLARED BY DHHS IN THE STATE, AND THEY
11 ARE IN THE ADMINISTRATIVE BRANCH, THEY MUST RECOMMEND
12 TO THE GOVERNOR -- MAYBE IT'S ONLY THE GOVERNOR THAT
13 CAN DECLARE SUCH A STATE OF EMERGENCY. I DON'T KNOW.
14 WE HAVE TO FIND OUT. DO YOU KNOW, SCOTT?

15 MR. SHEEHY: WE COULD STILL HAVE THE
16 DECLARATION BY THE GOVERNOR, BUT ACCOMPANY THAT WITH
17 THE FINDING BY THE ICOC THAT ACCESS TO THESE PRODUCTS
18 WOULD -- AVAILABILITY AND ACCESS TO THESE PRODUCTS
19 WOULD BE ENHANCED -- A FINDING BY THE ICOC --
20 INVOCATION OF MARCH-IN RIGHTS WOULD SIGNIFICANTLY
21 ALLEVIATE THIS PUBLIC HEALTH EMERGENCY BY ENHANCING
22 ACCESS OR AVAILABILITY.

23 CHAIRMAN PENHOET: WELL, I THINK THIS WILL
24 GET US IN TROUBLE WITH OUR FRIENDS IN SACRAMENTO IF
25 WE -- IF THE ICOC COULD OVERRIDE AN EMERGENCY THAT WAS

1 DECLARED BY THE GOVERNOR, I THINK WE'D HAVE SOME REAL
2 PROBLEMS.

3 MR. TOCHER: THE LAST CLAUSE OF SUBDIVISION 9
4 STATES THAT IF THE CIRM DETERMINES SUCH AN ACTION IS
5 REQUIRED, AND THEN IT WOULD BE TO, IN SUBDIVISION 4,
6 ALLEVIATE THE PUBLIC AND HEALTH SAFETY NEED. SO IT
7 SEEMS AS THOUGH --

8 CHAIRMAN PENHOET: THERE IS THAT ALREADY
9 BUILT INTO IT.

10 MR. TOCHER: CIRM REQUIREMENTS GET INVOLVED
11 TO MAKE THAT DETERMINATION IF NECESSARY. CIRM WOULD BE
12 THE ONE MARCHING IN.

13 MR. SHEEHY: ACTUALLY IT SAYS CIRM MAY
14 EXERCISE SUCH A RIGHT AT ANY TIME IT IDENTIFIES A
15 PUBLIC HEALTH OR SAFETY EMERGENCY DECLARED BY THE
16 GOVERNOR. SO IT'S NOT THE GOVERNOR MARCHING IN. IT'S
17 US MARCHING IN. ACTUALLY THIS PERHAPS PUTS A HIGHER
18 STANDARD BECAUSE IT REQUIRES THE ACTION BY THE GOVERNOR
19 BEFORE WE CAN MARCH IN.

20 CHAIRMAN PENHOET: IT'S OKAY THE WAY IT IS
21 THEN.

22 MR. ROTH: IT'S FINE.

23 CHAIRMAN PENHOET: OKAY. THE NEXT ONE IS
24 DELETE PRICING AND ACCESS PLANS DUE TO LITIGATION RISK.
25 SCOTT'S NOTE, THE REGULATION ONLY REFERS TO ACCESS

1 PLANS AS GROUNDS AND EXPLICITLY EXCLUDES PRICING.

2 ANY COMMENT ABOUT THAT?

3 NEXT ONE, EXPLICITLY DESCRIBE PUBLIC USE
4 GROUNDS IN (A), (A)(3). SO (A)(3) IS ON WHICH PAGE
5 NOW?

6 MR. TOCHER: PAGE 11.

7 CHAIRMAN PENHOET: THANK YOU. PAGE 11,
8 (A)(3) SAYS TO MEET REQUIREMENTS FOR PUBLIC USE,
9 INCLUDING BROAD AVAILABILITY IN CALIFORNIA, FOR REASONS
10 OTHER THAN PRICE, AND THE REQUIREMENTS HAVE NOT BEEN
11 SATISFIED BY THE AWARDEE ORGANIZATION OR ITS LICENSEE.

12 DR. MAXON: THIS HAS BEEN DISCUSSED BEFORE.
13 THIS IS FEDERAL LANGUAGE.

14 CHAIRMAN PENHOET: MARY POINTS OUT THIS IS
15 FEDERAL LANGUAGE. ANY COMMENTS FROM THE BOARD?

16 MR. SHEEHY: GOING BACK TO MEMORY, IT SEEMS
17 TO ME THAT THE FEDERAL LANGUAGE IS DIRECTLY RELATED TO
18 SOMEONE SITTING ON -- I THINK THE LEGISLATIVE --
19 ADMINISTRATIVE LAW HISTORY WOULD SHOW THE FEDERAL
20 LANGUAGE REALLY RELATES TO PEOPLE SITTING ON INVENTIONS
21 AND NOT DEVELOPING THEM.

22 MR. GILLENWATER: THIS IS TODD FROM CHI. THE
23 LANGUAGE, I THINK, IN THE FEDERAL LAW SPECIFICALLY SAYS
24 ACTION IS NECESSARY TO MEET REQUIREMENTS FOR PUBLIC USE
25 SPECIFIED BY FEDERAL REGULATIONS. THE CALIFORNIA --

1 THIS 100410 DOES NOT SAY SPECIFIED BY STATE
2 REGULATIONS. I UNDERSTAND THAT EVEN THOUGH IT SAYS
3 SPECIFIED BY FEDERAL REGULATIONS, THOSE FEDERAL
4 REGULATIONS HAVE NEVER BEEN DEFINED IN FEDERAL
5 REGULATION. SO I PRESUME THAT THIS SECTION 3 HERE DOES
6 NOT SAY SPECIFIED BY STATE REGULATIONS BECAUSE THERE
7 ARE NO FEDERAL REGULATIONS.

8 WE WOULD STILL SUGGEST THAT THAT ADDITION
9 SHOULD BE MADE, SPECIFIED BY STATE REGULATIONS.

10 CHAIRMAN PENHOET: ARE WE THEN GOING TO
11 INVITE THE STATE TO DESIGN THOSE REGULATIONS? HOW DOES
12 IT WORK?

13 MR. GILLENWATER: I WAS JUST MAKING THAT
14 COMMENT TO BE CONSISTENT WITH THE FEDERAL LANGUAGE.

15 MR. TOCHER: SOMETHING WHICH WOULD REFER TO
16 PUBLIC USE AS SPECIFIED IN THE STATE REGULATIONS
17 WOULD -- IT'S INHERENT IN WHAT THE AUTHORITY IS BEHIND
18 A DULY ADOPTED STATE REGULATION. IF YOU ARE SUBJECT TO
19 IT, IN THE JURISDICTION OF IT FOR WHATEVER REASON,
20 YOU'RE ALREADY OBLIGED TO FOLLOW IT REGARDLESS OF
21 WHETHER WE SPECIFY IT HERE OR NOT.

22 IF THE TASK FORCE WISHES TO DESCRIBE WITH
23 PECULIARITY WHAT THE PUBLIC USE IS THAT IT HAS IN MIND
24 SUCH AS --

25 CHAIRMAN PENHOET: BROAD AVAILABILITY. I

1 THINK IN SOME PEOPLE'S MIND THE NERVOUSNESS MIGHT BE
2 PUBLIC USE COULD BE CONSTRUED TO BE SORT OF FREE TO THE
3 PUBLIC, RATHER THAN WIDELY AVAILABLE TO CONSUMERS OR
4 SOME LANGUAGE. I DON'T KNOW. WE COULD TRY TO
5 DEFINE --

6 MR. SHEEHY: WE ACCEPT PRICE, FOR REASONS
7 OTHER THAN PRICE.

8 CHAIRMAN PENHOET: WE DID PUT THAT IN THERE.

9 MR. SIMPSON: -- THE OPPOSITE IN THERE AND
10 RAISE THAT VERY ISSUE.

11 MR. SHEEHY: YEAH. I JUST THINK, YOU KNOW,
12 WE'VE KIND OF FOUGHT OVER THIS. AND I JUST -- YOU
13 KNOW, TO KEEP FIGHTING IT WITHOUT ANY -- YOU'RE TALKING
14 ABOUT CIRM INVOKING A MARCH-IN RIGHT, AND I JUST DON'T
15 THINK THAT THAT IS OUR GOAL HERE, TO BE RUNNING AROUND
16 INVOKING MARCH-IN RIGHTS. AND SO WE TRACK FEDERAL
17 LANGUAGE; AND TO GO INTO ANY MORE DETAIL, I THINK, IS
18 JUST TO OPEN UP MORE CANS OF WORMS BECAUSE I THINK THAT
19 THAT GIVES US A GOOD STANDARD INTERNALLY AND A GOOD
20 HISTORY UPON WHICH TO MAKE OUR DETERMINATIONS. AND TO
21 ASK US TO USE A DIFFERENT RECORD OR HISTORY IN ORDER TO
22 MAKE DETERMINATIONS, I THINK, IS GOING DOWN THE WRONG
23 ROAD. IF I WERE FEELING LIKE THIS IS POTENTIALLY
24 ONEROUS, I THINK I'D WANT TO STAY WITH THE FEDERAL
25 RECORD. WE'VE BEEN EXPLICIT ABOUT THIS.

1 CHAIRMAN PENHOET: WE DID INCLUDE THE PRICING
2 LANGUAGE TO TRY TO BE PRECISE ABOUT IT. IT WASN'T A
3 MECHANISM TO DESTROY PRICING. ANY OTHER COMMENTS BY
4 THE TASK FORCE? I TAKE IT JEFF'S SUGGESTION IS WE
5 LEAVE IT AS IT IS.

6 DR. PRIETO: YEAH. ED, I WOULD JUST AGREE.
7 I THINK THERE'S A GREAT DEAL OF CONCERN OVER SOMETHING
8 THAT ALMOST NEVER HAPPENS AND ISN'T LIKELY TO.

9 CHAIRMAN PENHOET: THEN ON THE NEXT PAGE,
10 INCLUDE AN APPEAL PROCESS. SEVERAL LETTERS. SCOTT'S
11 NOTE SAYS THE CONCEPT IS ALREADY IMBUED IN THE ONE-YEAR
12 CURE PROVISION THAT WE ALREADY HAVE IN THE DOCUMENT.
13 ANYBODY FEEL THE NEED TO EMBELLISH THAT ONE-YEAR CURE
14 PROVISION THAT'S ALREADY IN HERE?

15 MR. STRATTON: IF I MAY, IT'S KEN STRATTON
16 FROM STEM CELLS. AND IT DOVETAILS NICELY WITH THE
17 DISCUSSION WE JUST HAD ON THE PRIOR POINT OF PUBLIC
18 USE. THE CONCERN THAT WE HAD IS A NUMBER OF THESE
19 PROVISIONS ARE SO VERY SUBJECTIVE, SUCH AS (A)(1).
20 WHAT'S REASONABLE EFFORTS OR WHAT'S A REASONABLE TIME
21 TO ACHIEVE CERTAIN GOALS? OR IN (A)(3) WHAT IS BROAD
22 AVAILABILITY IN CALIFORNIA?

23 ULTIMATELY THE SUBJECTIVITY CREATES A
24 TREMENDOUS AMOUNT OF RISK AND CONCERN GOING INTO A
25 FUNDING RELATIONSHIP WITH CIRM. WHAT WE WERE

1 WONDERING, AND WE DON'T HAVE A GOOD, EASY SOLUTION, BUT
2 WE WERE WONDERING IS THERE A MECHANISM THAT COULD BE
3 USED FOR VOICING OPPOSITION, FOR VETTING QUESTIONS, FOR
4 ADDRESSING THE SUBJECTIVITY SHORT OF LITIGATION?
5 BECAUSE THE WAY IT'S SET UP NOW, THE ONE-YEAR CURE
6 ACTUALLY SPEAKS TO SOMETHING COMPLETELY DIFFERENT. AND
7 WE HAVE CONCERNS THAT MOST OF THESE THINGS CAN'T BE
8 SOLVED WITHIN A ONE-YEAR TIMEFRAME GIVEN THE DELAYS AND
9 THE SOPHISTICATION AND DIFFICULTIES OF DRUG
10 DEVELOPMENT. BUT MORE TO THAT, WHAT DO WE DO ABOUT
11 RESOLVING DISPUTES OVER THE SUBJECTIVITY OF THE
12 LANGUAGE?

13 MR. TOCHER: WELL, FIRST OF ALL, REGARDING
14 THE ONE-YEAR ASPECT, THE REGULATION ALREADY MAKES A
15 PROVISION THAT IF IT'S NECESSARY TO GO LONGER THAN A
16 YEAR IN ORDER TO RESOLVE IT, GIVEN THE NATURE OF THE
17 PARTICULAR ISSUE AT HAND, IF PARTIES AGREE TO IT,
18 THAT'S ALREADY ALLOWED FOR UNDER THE REGULATION.

19 CHAIRMAN PENHOET: IS THERE -- JEFF SHEEHY.

20 MR. SHEEHY: I THINK THE ICOC IS THE DECIDING
21 BODY. MAYBE IT MIGHT BE HELPFUL TO REVIEW THE
22 MEMBERSHIP OF THE ICOC AND SEE HOW FRIGHTENING THAT
23 ENTITY IS. SPECIFICALLY MEMBERS OF THE BIOTECH
24 INDUSTRY ARE AWARDED SEATS ON THAT BODY, THE DEANS OF
25 THE FIVE -- THE REPRESENTATIVES OF FIVE UC MEDICAL

1 SCHOOLS, OTHER NONPROFIT ACADEMIC RESEARCH
2 INSTITUTIONS, ADMINISTRATIVE LEADERSHIP, YOU CAN BUILD
3 A MAJORITY BETWEEN THE LEADERS OF THE ACADEMIC MEDICAL
4 RESEARCH FACILITIES IN CALIFORNIA AND THE BIOTECH
5 INDUSTRY. SO YOU GUYS WOULD HAVE HAD TO HAVE DONE
6 SOMETHING PRETTY BAD NOT TO BE ABLE, IF YOU COULD MAKE
7 A REASONABLE ARGUMENT, TO SUCCEED WITH THIS BODY.

8 FRANKLY, IF I WERE YOU, I'D RATHER BE THERE
9 THAN IN COURT. SO I JUST -- YOU'RE JUST SO AFRAID, AND
10 THIS FEAR, IT JUST SEEMS IRRATIONAL. LOOK AT THE BODY,
11 LOOK HOW IT'S ORGANIZED. THE MEMBERSHIP IS FIXED BY
12 LAW. CIRM IS THE MARCHER; IT'S THE MARCH-IN ENTITY.
13 CIRM IS GOVERNED BY THE ICOC. THE ICOC IS REASONABLY
14 ESTABLISHMENT AND HAS, I THINK, A SIGNIFICANT DEPTH OF
15 UNDERSTANDING. RIGHT NOW WE HAVE TWO FORMER HEADS OF
16 THE FDA SITTING ON THE BODY. WE DON'T HAVE PEOPLE ON
17 THIS BODY WHO WOULD NOT BE SYMPATHETIC TO REASONABLE
18 ARGUMENTS OF BURDEN, BUT I ALSO THINK THERE'S ENOUGH
19 PUBLIC HEALTH MENTALITY ON THIS BODY THAT IF THERE WAS
20 A BAD ACTOR, WE PROBABLY WOULD TAKE FAIRLY STRONG
21 ACTION.

22 I THINK IF YOU'RE -- THAT SEEMS FAIRLY
23 COMFORTABLE. IF SOMEONE ISN'T COMFORTABLE WITH THAT, I
24 SAY DON'T APPLY FOR A GRANT.

25 MR. ROTH: WE SORT OF INTERCHANGED CIRM AND

1 ICOC, AND I THINK THAT MAY BE PART OF THE CONCERN.
2 WOULD IT BE ACCEPTABLE IF THERE WERE AN APPEAL TO ICOC
3 OR A SUBCOMMITTEE OF ICOC? I CAN SEE THE POINT WHERE
4 YOU COULD GET INTO SOME INTERPRETATION BY CIRM, THE
5 STAFF OF THE CIRM, AND FEEL THAT THEIR INTERPRETATION
6 IS DIFFERENT THAN THE ORIGINAL INTENT OF THE ICOC. AND
7 THE WAY THIS IS SET UP, I DON'T SEE HOW IT'S EASY FOR
8 SOMEONE WHO HAS A DISPUTE TO ELEVATE THAT TO THE ICOC.

9 MR. STRATTON: I THINK THAT'S A GOOD
10 SUGGESTION.

11 MR. GILLENWATER: THIS IS AGAIN TODD
12 GILLENWATER FROM CHI, AND WE VERY MUCH APPRECIATE ALL
13 THE COMMENTS THAT HAVE BEEN MADE, ESPECIALLY BY JEFF
14 SHEEHY, ON THE FACT THAT EVEN AT THE FEDERAL LEVEL,
15 MARCH-IN HAS RARELY, IF EVER, BEEN ACTUALLY TRIGGERED.
16 WHAT WE WOULD SUGGEST, THOUGH, BECAUSE THE LANGUAGE
17 THAT EXISTS NOW, IN SOME WAYS THE OPPORTUNITY TO CURE
18 PRESUMES AN EXISTING DEFICIENCY. WE WOULD AGAIN JUST
19 SIMPLY POINT TO THE EXISTING FEDERAL MARCH-IN RIGHTS
20 THAT SPECIFICALLY INCLUDES AN APPEALS PROCESS. AND THE
21 PROVISIONS WITHIN THE CODE OF FEDERAL REGULATIONS THAT
22 OUTLINE THAT PROCESS WOULD BE VALUABLE AND WORTHY OF
23 CONSIDERATION FOR ADDITION TO THIS.

24 MR. SHEEHY: WE CAN INCLUDE A LINE DEFINING
25 OF THE ICOC. IN THE EVENT OF A MARCH-IN, THE LICENSEE

1 OR AWARDEE ORGANIZATION CAN ASK FOR A FINDING FROM THE
2 ICOC, AND THEN THE ICOC MAKES A FINDING. THAT'S YOUR
3 APPEAL. THE ICOC SAID CIRM MADE A MISTAKE. ICOC SAID
4 CIRM DID THE RIGHT THING. THAT'S SEEMS TO ME TO BE
5 REASONABLE. AGAIN, LOOK AT THE COMPOSITION OF THE
6 ICOC.

7 CHAIRMAN PENHOET: THE ICOC WOULD HAVE THE
8 DISCRETION WHETHER TO TAKE IT UP AS AN AGENDA ITEM OR
9 NOT, I SUPPOSE. THEY WOULDN'T BE OBLIGATED TO DEAL
10 WITH EVERY ONE OF THESE AT THE BOARD LEVEL.

11 MR. SHEEHY: YES. THAT'S --

12 CHAIRMAN PENHOET: THEY MAY APPEAL. IT
13 DOESN'T MEAN THE ICOC WOULD BE OBLIGATED TO HEAR THE
14 APPEAL.

15 MR. ROTH: IT'S JUST THAT THIS PARTICULAR
16 SECTION WITH MARCH-IN RIGHTS, THAT'S A VERY SERIOUS
17 UNDERTAKING. AND I THINK THE COMPANY IN THIS CASE
18 SHOULD HAVE A RIGHT TO APPEAL THEIR CASE BEFORE THE
19 FULL ICOC BEFORE IT GOES INTO EFFECT.

20 MR. SHEEHY: I THINK WE DO NEED -- WE NEED TO
21 BE VERY CAREFUL ON LANGUAGE BECAUSE THE DETERMINATION
22 ON WHETHER THE ICOC HEARS SOMETHING MAY BE DETERMINED
23 BY THE CHAIR, WHICH I DON'T THINK -- I DO THINK THAT WE
24 SHOULD MAKE SURE THAT THE ICOC MAKES SOME DETERMINATION
25 AS A BODY AS A WHOLE WHETHER TO HEAR OR NOT -- WHETHER

1 TO CONSIDER OR NOT CONSIDER, EVEN IF IT'S JUST LIKE A
2 POW-POW. I THINK THAT'S REASONABLE.

3 CHAIRMAN PENHOET: SOUNDS REASONABLE TO ME.
4 TAMAR PACHTER, WHO IS THE GENERAL COUNSEL FOR CIRM, HAS
5 HER HAND UP OVER HERE. TAMAR, PLEASE COME OVER HERE TO
6 THE MICROPHONE.

7 MS. PACHTER: I WOULD JUST POINT OUT THAT I
8 THINK THAT, GIVEN THE RARITY WITH WHICH ANYONE HAS EVER
9 EXERCISED MARCH-IN RIGHTS, THE LIKELIHOOD THAT THE
10 INSTITUTE WOULD EXERCISE THAT WITHOUT FIRST BRINGING IT
11 TO THE ICOC IS FAIRLY SLIM, GIVEN HOW SMALL THIS
12 ORGANIZATION IS AND HOW SMALL A BUREAUCRACY. WE'RE NOT
13 TALKING ABOUT A FEDERAL BUREAUCRACY THAT'S COMPLETELY
14 IMPENETRABLE TO INDUSTRY. I THINK GEOFF LOMAX WILL
15 TELL YOU THAT ROUTINELY WITH RESPECT TO OUR
16 REGULATIONS, WE ENTERTAIN QUESTIONS AND ARGUMENTS FROM
17 PEOPLE WHO ARE ACTUALLY ON THE HILL. SO I THINK IF YOU
18 THINK ABOUT HOW SMALL THIS AGENCY IS AND HOW ACCESSIBLE
19 IT IS, YOU CAN BE A LITTLE MORE APPEASED WITH A LITTLE
20 AMBIGUITY IN THE LANGUAGE.

21 CHAIRMAN PENHOET: ALSO MIGHT ARGUE
22 CONVERSELY, TAMAR, TO ME THAT WE MIGHT AS WELL PUT THE
23 APPEAL TO THE ICOC IN HERE THEN IF IT'S GOING TO HAPPEN
24 ANYWAY. WHY NOT BE EXPLICIT ABOUT IT?

25 MR. SHEEHY: HOW ABOUT THIS? IN THE ABSENCE

1 OF A SPECIFIC FINDING OF THE ICOC AUTHORIZING THE
2 MARCH-IN, THE LICENSEE OR AWARDEE MAY APPEAL TO THE
3 ICOC. THAT SHOULD TAKE CARE -- THERE COULD BE THE FEAR
4 OF ROGUE AGENCIES.

5 CHAIRMAN PENHOET: OKAY. I THINK WE'RE
6 DEVELOPING A CONSENSUS AROUND THIS CONCEPT. CAN YOU
7 WORK WITH THIS, SCOTT? NOTWITHSTANDING ANYTHING SAID
8 BELOW IN THIS SECTION, THAT GRANTEES -- IF CIRM INVOKES
9 MARCH-IN RIGHTS FOR ANY OF THE REASONS LISTED BELOW AND
10 FAILS TO REACH WHATEVER IT IS, AN AGREEMENT WITH THE
11 AFFECTED PARTIES, THAT THE AFFECTED PARTIES WOULD HAVE
12 THE RIGHT TO APPEAL THE DECISION OF CIRM TO ITS BOARD.
13 I'M NOT A LAWYER. YOU'LL HAVE TO FIGURE OUT EXACTLY
14 HOW TO SAY THAT.

15 MR. SHEEHY: ABSENT A FINDING BY THE BOARD
16 AUTHORIZING THE MARCH-IN. THE BOARD SHOULD NOT HAVE TO
17 REHEAR SOMETHING THAT THEY'VE ALREADY DECIDED.

18 MR. TOCHER: NEXT THING YOU'RE GOING TO HEAR
19 IS, WELL, NOW, WE NEED MORE THAN 30 DAYS TO DO THIS AND
20 TO MARSHAL ALL THE DATA THAT WE NEED.

21 DR. LOVE: WELL, THE ONE THING I WOULD ADD,
22 THOUGH, IS THAT DURING AN APPEAL PROCESS, SOMEONE COULD
23 BRING NEW INFORMATION TO BEAR. SO EVEN IF THE ICOC HAS
24 BEEN CONSULTED BY CIRM AND A DECISION HAS BEEN MADE,
25 THAT WOULDN'T NECESSARILY MEAN THAT AN APPEAL PROCESS

1 SHOULDN'T BE APPROPRIATE.

2 I WOULD ACTUALLY SUGGEST THAT GIVEN THE
3 EXTREME UNLIKELY EVENT THAT THIS WILL EVER OCCUR
4 ANYWAY, BUT ALSO GIVEN THE HUGE IMPLICATION FOR ANY
5 INDIVIDUAL THAT COULD BE AFFECTED BY IT, I WOULD
6 ACTUALLY SAY THE ICOC SHOULD HEAR ALL APPEALS. WE
7 REALLY SHOULDN'T HAVE THE OPTION TO NOT HEAR THEM.

8 CHAIRMAN PENHOET: OKAY. DOES ANYBODY
9 DISAGREE WITH THAT POINT OF VIEW? OKAY. I THINK WE'LL
10 TASK YOU WITH -- SCOTT HAS JUST INDICATED THAT HE'S A
11 GOOD SOLDIER AND WILL DO THIS.

12 NEXT ONE, WE SHOULD CLARIFY NOT APPLICABLE TO
13 FORCE LICENSING OF ANYTHING OTHER THAN CIRM INVENTIONS.
14 WE BELIEVE THAT THIS IS INHERENT ALREADY IN THE SCOPE
15 AND AUTHORITY OF THE AGENCY AND ALL THE DEFINITIONS
16 THAT WE HAVE IN PLACE TO DEFINE CIRM-FUNDED INVENTIONS.
17 SO WE DON'T THINK THAT NEEDS ANY FURTHER CLARIFICATION.
18 ANYBODY WANT TO COMMENT ON THAT?

19 MR. STRATTON: IT'S KEN STRATTON AGAIN FROM
20 STEM CELLS. SO THIS IS ACTUALLY A GOOD JUMPING-OFF
21 POINT TO TALK A LITTLE BIT ABOUT THE DEFINITIONS. I
22 KNOW THAT, SCOTT, YOU'RE GOING TO TAKE A CRACK AT SOME
23 CONSISTENT DEFINITIONS THROUGHOUT THE AGREEMENT. BUT
24 WHAT CONCERNED US IN THE 410 MARCH-IN RIGHTS PROVISION
25 WAS THE REFERENCE THAT REFERS TO BOTH CIRM-FUNDED

1 PATENTED INVENTIONS OR CIRM-FUNDED RESEARCH PROJECTS.
2 AND A QUESTION I WOULD PUT TO THE DRAFTERS AND TO THE
3 GROUP IS WHAT DO YOU DO IF YOU HAVE A PREESTABLISHED
4 THERAPY THAT IS GOING THROUGH CLINICAL TRIALS AND YOU
5 RECEIVE CIRM FUNDING FOR YOUR PIVOTAL STUDY? DO THE
6 MARCH-IN RIGHTS APPLY TO THAT TECHNOLOGY? SIMILARLY,
7 DO THE REVENUE SHARING RIGHTS APPLY TO THAT TECHNOLOGY?
8 AND LASTLY, DO THE ACCESS REQUIREMENT RIGHTS APPLY TO
9 THAT TECHNOLOGY?

10 CHAIRMAN PENHOET: AND THE ANSWER IS YES.

11 MR. STRATTON: TO ALL OF THEM? YOU HAVE
12 FUNDING OF A CLINICAL TRIAL WHERE THE TECHNOLOGY HAS
13 ALREADY BEEN PATENTED, FUNDED BY OTHER SOURCES, AND YOU
14 TAKE A MILLION DOLLARS TO FUND YOUR PIVOTAL TRIAL. AND
15 THAT TRIGGERS ALL THREE OF THESE OBLIGATIONS?

16 CHAIRMAN PENHOET: YES. THAT'S BEEN THE
17 INTENT ALL ALONG, THAT EXPOSURE IS CAPPED TO THE
18 MULTIPLE, AND THAT'S EXPLICITLY WHY IT SAYS INVENTIONS
19 OR PROJECTS BECAUSE, IN FACT, WE WERE TOLD BY INDUSTRY
20 THAT, FOR THOSE WHO YOU ARE IN IT, THAT THE MONEY YOU
21 WANT IS TO FUND CLINICAL TRIALS. AND IT'S NOT THE
22 INTENT OF CIRM TO MAKE THAT FUNDING BE FREE MONEY FOR
23 YOU TO FUND CLINICAL TRIALS. YOU'RE SUBJECT TO ALL
24 THESE PROVISIONS EVEN IF NO INVENTIVE ACT OCCURS OTHER
25 THAN YOU DETERMINE WHETHER THIS THERAPY WORKS OR NOT.

1 MR. SHEEHY: LET'S GO BACK TO THE BURDEN OF
2 THESE PROVISIONS. THE ACCESS PLAN IS THE ONE YOU
3 GENERATE ACCORDING TO WHAT OTHER PEOPLE IN YOUR FIELD
4 ARE DOING. THE PRICING IS PRESUMABLY GOING TO BE
5 SOMETHING THAT, I THINK, MOST BUSINESSES IN CALIFORNIA
6 ARE GOING TO TAKE PART IN, WHICH IS CALRX. AND THE
7 MARCH-IN RIGHTS, AS WE'VE DESCRIBED, ARE HIGHLY
8 UNLIKELY TO EVER BE INVOKED. AND YOU HAVE RECOURSE TO
9 A BOARD THAT WILL INCLUDE PEERS IN YOUR INDUSTRY PLUS
10 DEANS OF MEDICAL SCHOOLS.

11 SO I MEAN YOU CAN MAKE THIS SCARY, OR YOU CAN
12 MAKE THIS WHAT IT IS, WHICH IS JUST A WAY FOR US TO
13 FULFILL OUR BASIC OBLIGATIONS AS A PUBLIC AGENCY.
14 WE'RE NOT VENTURE CAPITALISTS. WE HAVE SOME
15 RESPONSIBILITY TO THE PUBLIC. IF SOMEONE IS NOT A GOOD
16 ACTOR, WE HAVE TO HAVE SOME RECOURSE.

17 MR. STRATTON: THAT'S UNDERSTOOD. I'M
18 SPEAKING, THOUGH, TO PROPORTIONALITY AND THE COSTS OF
19 THIS CAPITAL. AND I DO CONTINUE TO HAVE CONCERNS THAT
20 IF ALL THREE OF THE OBLIGATIONS ARE TRIGGERED TO A
21 MILLION-DOLLAR GRANT IN A PIVOTAL TRIAL, WE WILL NOT BE
22 SEEKING FUNDING FROM CIRM IN THAT SITUATION.

23 MR. ROTH: I WOULD --

24 CHAIRMAN PENHOET: I THINK WE UNDERSTAND
25 THAT.

1 MR. ROTH: I THINK THAT'S PROBABLY
2 APPROPRIATE. THAT'S A DECISION YOU WOULD HAVE TO MAKE.
3 IF A MILLION DOLLARS WAS NEEDED AND THAT WAS YOUR ONLY
4 PLACE TO GET IT, YOU WOULD KNOW GOING IN THAT YOU ARE
5 GOING TO HAVE TO PAY BACK THREE MILLION IF THAT PRODUCT
6 IS COMMERCIALIZED.

7 MR. SHEEHY: IF WE WERE THE ONLY PEOPLE THAT
8 HAD THE MILLION DOLLARS, I DON'T THINK, FRANKLY, THE
9 ODDS THAT ANY OF THIS WOULD EVEN MATTER WOULD BE HIGHLY
10 UNLIKELY BECAUSE IF YOU HAD A GOOD PRODUCT, YOU
11 WOULDN'T BE COMING TO US FOR A MILLION BUCKS.

12 CHAIRMAN PENHOET: OKAY. WE HAVE THREE
13 MINUTES LEFT. THE NEXT ONE, CLARIFY THE SCOPE TO ALLOW
14 CIRM REQUIRE GRANTEE TO GRANT NONEXCLUSIVE OR EXCLUSIVE
15 LICENSE TO THE INVENTIONS, ETC., IN ANY FIELD OF USE.
16 THE NOTE IS THAT STAFF BELIEVES THAT CLARIFICATION IN
17 THIS REGARD WOULD BE HELPFUL. SO --

18 DR. MAXON: IT'S DONE.

19 CHAIRMAN PENHOET: MARY INDICATES THAT AT
20 LEAST AN APPROACH TO IT HAS BEEN DONE. SO, SCOTT, THAT
21 IS WHERE?

22 MR. TOCHER: SOME COPIES LINE 4, OTHERS LINE
23 5.

24 CHAIRMAN PENHOET: PAGE 11.

25 MR. TOCHER: PAGE 11 OF THE BLUE AMENDED TEXT

1 PACKET. IN THE FIRST SENTENCE, WE'VE INCLUDED THE
2 WORDS "TO CIRM-FUNDED PATENTED INVENTIONS AND/OR DATA
3 GENERATED UNDER CIRM FUNDING," WHICH TRACKS THE
4 LANGUAGE THAT WAS PROPOSED IN THE COMMENT.

5 CHAIRMAN PENHOET: OKAY. ANY COMMENT ABOUT
6 THAT? FINAL ISSUE --

7 MR. ROTH: I ALMOST HATE TO BRING THIS UP,
8 BUT I'M GOING TO. DO WE WANT TO CONSIDER RAISING THE
9 17 PERCENT TO 25 PERCENT ON THIRD PARTIES? AND THE
10 REASON I'M RAISING THAT IS I THINK THAT THAT COULD BE
11 VIEWED AS MEETING SENATOR KUEHL HALFWAY. AND I DON'T
12 THINK IT MATTERS THAT MUCH TO INDUSTRY THAT'S GOING TO
13 TAKE CIRM MONEY, HAVE AN INVENTION, AND THEN LICENSE TO
14 A THIRD PARTY, WHETHER THEY KEEP 83 PERCENT OF THE
15 REVENUE OR 75 PERCENT.

16 AND THE REASON I'M BRINGING IT UP IS EXACTLY
17 FOR THE REASON YOU SAID. IT'S DIFFICULT TO EXPLAIN.
18 IT CAN BE EXPLAINED, BUT IT'S DIFFICULT. AND I THINK
19 THE RATIONALE BEHIND IT IS THE HARDEST PART OF THE
20 EXPLANATION.

21 CHAIRMAN PENHOET: IT IS. SOME OF US MAY BE
22 IN THE AWKWARD POSITION OF TRYING TO, QUOTE, UNQUOTE,
23 NEGOTIATE SOMETHING WITH SENATOR KUEHL IN THE NOT TOO
24 DISTANT FUTURE. I DON'T KNOW WHETHER YOU AS A GROUP
25 WANT TO TAKE THIS AS AN OFFICIAL POSITION TODAY, OR YOU

1 WANT TO AUTHORIZE ME TO MAKE THAT ACCOMMODATION IF IT
2 WOULD MAKE 771 GO AWAY OR SOMETHING LIKE THAT.

3 MR. ROTH: THAT'S KIND OF WHERE I'M COMING
4 FROM. WE DECIDED TO GIVE THE INVENTOR'S SHARE TO THE
5 COMPANY. THE INVENTOR'S SHARE MEANING THE RESEARCH
6 INSTITUTES HAVE TO PAY THE INVENTOR. BUT THAT NUMBER
7 VARIES QUITE A BIT.

8 CHAIRMAN PENHOET: IT DOES.

9 MR. ROTH: IN THE CASE OF COMPANIES, WE SAID
10 YOU CAN KEEP THE INVENTOR'S SHARE AND IT COMES OUT 17
11 PERCENT FROM BOTH. BUT I THINK IT MIGHT BE AN -- I'D
12 CERTAINLY LIKE YOU TO HAVE THAT AS A TOOL TO NEGOTIATE
13 BECAUSE I THINK IT DOESN'T MAKE THAT MUCH DIFFERENCE TO
14 PARTIES WHO TAKE CIRM MONEY THAT THEY'RE GOING TO ON
15 THIRD-PARTY LICENSES RAISE A BIG THING ABOUT THE
16 PERCENT.

17 CHAIRMAN PENHOET: SCOTT REMINDS ME ONLY THE
18 ICOC COULD AUTHORIZE ANYONE TO ENTER INTO A SUCH A
19 DISCUSSION BECAUSE THE ICOC HAS ALREADY VOTED ON THE 17
20 PERCENT. BUT I THINK WE'LL JUST NOTE YOUR COMMENT.

21 ANY OTHER TASK FORCE MEMBERS HAVE A COMMENT
22 TO MAKE IN THAT REGARD?

23 DR. PRIETO: I THINK IT'S A VERY INTERESTING
24 PROPOSAL AND I THINK SOMETHING THE ICOC WOULD BE
25 WILLING TO LOOK AT AGAIN. I THINK THERE WOULD BE

1 RELATIVELY LITTLE OBJECTION TO THAT.

2 CHAIRMAN PENHOET: ANY OTHER COMMENTS? WE
3 HAVE PUBLIC COMMENT IN SAN FRANCISCO. DON REED.

4 MR. REED: AS SOMEBODY THAT'S BEEN FOLLOWING
5 771, I WOULD THINK THAT WOULD BE A VERY POSITIVE
6 ACCOMMODATION TO MAKE, WHICH MIGHT SAVE A LOT OF
7 TROUBLE LATER ON DOWN THE ROAD. AT THE LAST HEARING,
8 THERE'S THE POWER -- TWO FORCES OF POWER I SEE. ONE IS
9 THOSE PEOPLE WHO ABSOLUTELY HATE THE RESEARCH AND WANT
10 TO STOP IT ANY WAY THEY CAN OR DELAY IT. THERE'S ALSO
11 PEOPLE THAT WOULD LIKE TO SEE IT BE A SOURCE OF
12 BASICALLY A SECONDARY TAX. SO THOSE ARE POWERFUL
13 MOTIVATIONS. I THINK IT WOULD BE REALLY GREAT TO HEAD
14 OFF SB 771 IF IT POSSIBLY COULD.

15 THE REASON THAT SB 771 WENT INTO SUSPENSE,
16 WHICH IT DID, WAS A SPECIFIC REQUEST FROM SENATOR
17 TORLAKSON, THE CHAIR OF APPROPRIATIONS, FOR MORE
18 INFORMATION. I KNOW THAT A LOT OF PEOPLE HAVE ALREADY
19 SENT INFORMATION TO HIM, BUT I THINK BOTH HIM AND
20 SENATOR PERATA, IT WOULD BE GREAT TO GIVE THEM ALL THE
21 INFORMATION YOU WANT BECAUSE THIS IS A KEY MOMENT. BUT
22 I WOULD LOVE TO SEE THAT 25 PERCENT THING BE PART OF
23 THE PACKAGE. THANK YOU.

24 CHAIRMAN PENHOET: JOHN SIMPSON.

25 MR. SIMPSON: JOHN SIMPSON, FOUNDATION FOR

1 TAXPAYER AND CONSUMER RIGHTS FOR THE RECORD. LAST YEAR
2 NEITHER THE LEGISLATURE NOR CIRM DISTINGUISHED ITSELF
3 IN ITS RELATIONSHIPS WITH EACH OTHER, AND SOME MEMBERS
4 I THINK IT GOT DOWNRIGHT PERSONAL. I MAYBE SHOULDN'T
5 HAVE PUT CIRM AT LARGE IN THAT PARTICULAR CASE. BUT
6 THIS SEEMS TO BE SOMETHING THAT MOVES POSSIBLY TOWARDS
7 THE VERY DESIRABLE ASPECT OF WORKING WITH THE
8 LEGISLATURE INSTEAD OF AGAINST IT. ANYTHING THAT COULD
9 GO TO THAT WOULD BE GOOD.

10 MR. SHEEHY: DO WE MAKE A FORMAL
11 RECOMMENDATION? I WOULD BE WILLING -- I'M NOT SURE
12 EXACTLY WHAT THE RESOLUTION WOULD BE.

13 MR. ROTH: THE RESOLUTION WOULD BE THAT IT
14 SIMPLY GO TO A 25-75 SPLIT AND WE CHANGE THIS, AND WE
15 TAKE IT BACK THROUGH COMMENT PERIOD AND WE TAKE IT TO
16 THE ICOC.

17 MR. SHEEHY: I SECOND THAT.

18 DR. LOVE: WOULD WE ONLY WANT TO DO THAT IF
19 THE NEGOTIATIONS THAT ED HAD KIND OF SUGGESTED IT, OR
20 DO WE WANT TO JUST IT PROACTIVELY?

21 CHAIRMAN PENHOET: LET ME BE CLEAR. I AM NOT
22 AUTHORIZED TO NEGOTIATE ANYTHING.

23 MR. SHEEHY: MAYBE I HAVE A DIFFERENT TAKE ON
24 IT. I THINK IF WE STARTED DOWN THIS ROAD, I MEAN I
25 HOPE WE DON'T END UP IN A SITUATION WHERE 70 PERCENT OF

1 THE PEOPLE VOTED THROUGH AND THE GOVERNOR TAKES
2 WHATEVER ACTION HE TAKES, BUT WHATEVER DIRECTION THAT
3 THIS GOES, HAVING HEARD THE LEGISLATURE, HAVING CHANGED
4 OUR POLICY IN RESPONSE TO A SPECIFIC OBJECTION RAISED
5 BY THE LEGISLATURE, IT SEEMS TO ME THAT STARTING -- YOU
6 KNOW, RATHER THAN MAKING IT CONDITIONAL, JUST TO SAY WE
7 HEAR YOU. WE UNDERSTAND YOUR CONCERN. THIS IS A VERY
8 COMPLICATED PROCESS, VERY COMPLICATED POLICY. WE'VE
9 BEEN WORKING ON THIS, AND WE'VE COME TOGETHER AND WE'RE
10 TRYING TO MAKE THIS THE BEST POSSIBLE PRODUCT. AND WE
11 THINK THAT YOU RAISED A VALID ISSUE AND WE CHANGED OUR
12 POLICY IN RESPONSE TO YOUR VALID ISSUE.

13 I MEAN AT SOME POINT I THINK WE MAY HAVE TO
14 GO TO OUR RESPECTIVE CORNERS AND PREPARE FOR THE NEXT
15 ROUND, BUT THIS IS A WAY TO MAYBE TAKE SOME OF THAT OUT
16 AND SAY WE'RE DIALOGUING, WE'RE TRYING TO MAKE OUR
17 POLICY WORK FOR THE PEOPLE OF CALIFORNIA AND ALSO FOR
18 THE INDUSTRY THAT NEEDS TO DEVELOP THESE THERAPIES.

19 DR. PRIETO: I THINK THAT'S A VERY GOOD
20 POINT, AND I AGREE ABSOLUTELY.

21 CHAIRMAN PENHOET: THE OTHER THING IT DOES DO
22 IS ACTUALLY WE HAVE SAID WE'RE TRYING TO ENCOURAGE
23 COMPANIES TO DEVELOP PRODUCTS THEMSELVES RATHER THAN
24 LICENSE THEM. IF THE LICENSING ROUTE IS CHEAPER FOR
25 THEM THAN SELF-DEVELOPING IN THE SENSE OF THE LICENSE,

1 IF THE LICENSE BECOMES A LITTLE MORE EXPENSIVE TO THEM,
2 IT PROVIDES AN EXTRA INCENTIVE FOR THEM TO
3 FORWARD-INTEGRATE. SO IT'S CONSISTENT WITH THAT
4 GENERAL TREND WE'VE BEEN TAKING.

5 SO JEFF HAS MADE A SPECIFIC PROPOSAL. I
6 DON'T BELIEVE WE HAVE A QUORUM ANYMORE UNFORTUNATELY.

7 DR. PRIETO: I MADE THE PROPOSAL, I THINK,
8 AND JEFF SECONDED.

9 CHAIRMAN PENHOET: MADE BY PRIETO.

10 MS. KING: I CAN TAKE ROLL CALL.

11 CHAIRMAN PENHOET: IT'S A STRAW VOTE THEN
12 BECAUSE -- TAKE A QUICK ROLL CALL AND SEE WHO'S STILL
13 HERE.

14 MS. KING: SUSAN BRYANT. TED LOVE.

15 DR. LOVE: IN FAVOR.

16 MS. KING: ED PENHOET. ACTUALLY I'M JUST
17 TAKING A ROLL CALL FIRST, SORRY NOT THE VOTE YET. ED
18 PENHOET.

19 CHAIRMAN PENHOET: HERE.

20 MS. KING: PHIL PIZZO. FRANCISCO PRIETO.

21 DR. PRIETO: HERE.

22 MS. KING: JOHN REED. DUANE ROTH.

23 MR. ROTH: HERE.

24 MS KING: JEFF SHEEHY.

25 MR. SHEEHY: HERE.

1 MS. KING: OSWALD STEWARD. JANET WRIGHT.

2 CHAIRMAN PENHOET: WE DO NOT HAVE A QUORUM.

3 DR. REED: JOHN REED IS HERE. I HAD YOU ON
4 MUTE.

5 MS. KING: THANK YOU. THAT BRINGS US TO SIX,
6 AND WE STILL DON'T HAVE A QUORUM.

7 CHAIRMAN PENHOET: SO WE GOT A SENSE OF THE
8 GROUP. SO MOVED BY PRIETO, SECONDED BY SHEEHY THAT WE
9 TAKE A --

10 MS. KING: ACTUALLY IT WAS MOVED BY DUANE
11 ROTH. WE'RE ALSO HAPPY TO PROVIDE A TERTIARY --

12 CHAIRMAN PENHOET: IS ANYBODY OPPOSED TO THIS
13 CONCEPT? OKAY. I GUESS WE'RE ALL IN FAVOR. ALL
14 RIGHT.

15 LET'S SEE. IT'S A FEW MINUTES AFTER FOUR,
16 BUT WE'VE GONE THROUGH ALL THE A'S, B'S, AND C'S.
17 WE'VE GOT ONE MORE? WHERE?

18 MR. TOCHER: PROVIDE A TRIGGER.

19 CHAIRMAN PENHOET: WE DISCUSSED THE TRIGGER
20 ISSUE MANY TIMES. WE'VE DISCUSSED THIS IS THE FOURTH
21 TIME TODAY. I THINK THERE'S NO SENTIMENT BEHIND THE
22 TRIGGER. OKAY.

23 WITH THAT, SCOTT, I'M SORRY WE'VE GIVEN YOU A
24 LOT OF WORK TO DO HERE TODAY, BUT I THINK IT'S BEEN A
25 VERY PRODUCTIVE SESSION. THANK EVERYBODY FOR SPENDING

1 FRIDAY AFTERNOON BEFORE A THREE-DAY WEEKEND WITH US.
2 ESPECIALLY WE'VE HAD SOME CONSTRUCTIVE INPUT FROM
3 INDUSTRY, AND AS USUAL FROM TAXPAYER AND CONSUMER
4 RIGHTS AND PATIENT ADVOCATES AND OTHERS, AND I THINK WE
5 HAVE THE MAKINGS OF A GOOD POLICY HERE.

6 DR. MAXON: AND WE'VE COVERED ALL THE ITEMS
7 ON THE AGENDA.

8 CHAIRMAN PENHOET: AND THANK YOU TO MARY AND
9 TO SCOTT, ESPECIALLY MARY WHO VOLUNTEERS HER TIME NOW
10 TO DO ALL THIS STUFF, AND GETS IN DEEP TROUBLE WITH HER
11 BOSS' BOSS AT THE MOORE FOUNDATION AS A RESULT.

12 MS. KING: THANKS TO ED AND JEFF AND DR.
13 BRYANT, DR. PIZZO, SO MANY OF YOU HAVE BEEN LITERALLY
14 ON THE PHONE SINCE 7:15 THIS MORNING, AND THEN
15 FOLLOWING THAT WITH THIS MEETING THIS AFTERNOON. SO
16 HUGE THANKS TO THE ICOC MEMBERS, ALL OF YOU, AND DUANE,
17 PARTICULARLY THOSE OF YOU WHO HAVE BEEN ON THE PHONE
18 LITERALLY SINCE 7:15 AND THEN FOLLOWING WITH THIS
19 MEETING THIS AFTERNOON.

20 CHAIRMAN PENHOET: INCLUDING MELISSA WHO'S
21 BEEN ON THE PHONE SINCE 7:15. WITH THAT, UNLESS THERE
22 ARE ANY FURTHER COMMENTS. ANY COMMENTS FROM THE
23 MEMBERS OR PEOPLE AT OTHER SITES?

24 DR. ROTH: NO. THANK YOU VERY MUCH. HAVE A
25 GREAT WEEKEND.

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CHAIRMAN PENHOET: THANK YOU.

(THE MEETING WAS THEN ADJOURNED AT 04:08

P.M.)

REPORTER'S CERTIFICATE

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

TELEPHONIC LOCATIONS AS NOTICED
ON
FRIDAY, MAY 25, 2007

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

BETH C. DRAIN, CSR 7152
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