

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

LOCATION: AS INDICATED ON THE AGENDA

DATE: THURSDAY, DECEMBER 29, 2011  
9 A.M.

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

BRS FILE NO.: 91558

## BARRISTERS' REPORTING SERVICE

### I N D E X

ITEM DESCRIPTION	PAGE NO.
CALL TO ORDER	3
ROLL CALL	3
CONSIDERATION OF PROPOSED AMENDMENTS TO INTELLECTUAL PEROPERTY REGULATIONS TO CONFORM WITH SENATE BILL 2064 CHANGES	4
PUBLIC COMMENT	28

**BARRISTERS' REPORTING SERVICE**

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THURSDAY, DECEMBER 29, 2011

9 A.M.

MR. TOCHER: WELL, I GUESS THE FIRST ORDER OF BUSINESS FOR THE RECORD IS TO TAKE ROLL. SO SUE BRYANT.

DR. BRYANT: HERE.

MR. TOCHER: MICHAEL GOLDBERG. TED LOVE. STEPHEN JUELSGAARD.

DR. JUELSGAARD: PRESENT.

MR. TOCHER: DUANE ROTH. OS STEWARD. JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MR. TOCHER: GREAT. ALL RIGHT. STEVE, IF YOU'D LIKE, I CAN SORT OF BEGIN WITH THE MEMO IF THAT'S WHAT YOU'D LIKE AND TAKE US THROUGH THE ATTACHMENTS.

CHAIRMAN JUELSGAARD: I THINK THAT WOULD BE MOST APPROPRIATE, SCOTT. YES, IF YOU COULD KIND OF REVIEW HISTORICALLY WHAT'S GONE ON AND KIND OF WHERE WE ARE RIGHT NOW.

MR. TOCHER: SURE. WELL -- AND THAT MIGHT BE DUANE ROTH. SOMEONE HAS FALLEN OFF THE CALL.

DR. JUELSGAARD: I DON'T THINK SOMEBODY FELL OFF. KIND OF HARD TO KNOW THAT PART.

**BARRISTERS' REPORTING SERVICE**

1 MR. TOCHER: SO IN 2010 THE LEGISLATURE  
2 PASSED BILL SB 1064 THAT ADDRESSED VARIOUS FUNCTIONS  
3 AT CIRM. PART OF THE AMENDMENTS IN THAT LEGISLATION  
4 THAT WAS SIGNED BY GOVERNOR SCHWARZENEGGER ADDRESSED  
5 VARIOUS PROVISIONS OF OUR IP POLICIES. IN MANY  
6 RESPECTS THE STATUTE MERELY CODIFIED WHAT CIRM  
7 ALREADY HAD IN PLACE WITH ITS IP POLICIES. AND  
8 LOOKED AT THAT WAY, IT'S, I THINK, A BIT OF AN  
9 AFFIRMATION OF THE HARD WORK THAT THE TASK FORCE  
10 DID.

11 MS. BAUM: SOMEONE MIGHT HAVE ACTUALLY  
12 LEFT THE LINE. CAN WE MAKE SURE THAT BETH DRAIN'S  
13 OFFICE IS STILL ON THE LINE?

14 THE REPORTER: YEAH. I'M HERE.

15 MR. TORRES: ART TORRES.

16 CHAIRMAN JUELSGAARD: ART JOINED. OKAY.  
17 GOOD.

18 CHAIRMAN THOMAS: J.T. IS STILL HERE.  
19 THAT'S SOMEBODY OFF THERE.

20 CHAIRMAN JUELSGAARD: I'M HERE. THIS IS  
21 STEVE.

22 MS. BAUM: BETH DRAIN'S OFFICE IS STILL ON  
23 THE LINE?

24 THE REPORTER: I'M STILL HERE.

25 MR. TOCHER: AND, DUANE, YOU DIDN'T JOIN,

**BARRISTERS' REPORTING SERVICE**

1 DID YOU, YET? OKAY.

2 SO I THINK THERE WAS AN AFFIRMATION OF THE  
3 HARD WORK THAT THE TASK FORCE ON IP WENT THROUGH IN  
4 PREPARING THESE POLICIES.

5 DID SOMEONE JUST JOIN?

6 MR. HARRISON: SCOTT, IT'S JUST JAMES. I  
7 DROPPED OFF AND REJOINED.

8 MR. TOCHER: ALL RIGHT. SO THE FOUR  
9 PRIMARY PROVISIONS THAT WERE BY THE IP -- BY THE SB  
10 1064 THAT REQUIRED SOME ATTENTION TO CALIBRATE OUR  
11 REGULATIONS WITH THOSE CHANGES CAME IN FOUR AREAS.  
12 FIRST, THE LEGISLATION ALTERED SLIGHTLY THE SCOPE OF  
13 OUR ACCESS PLAN PROVISION ADDRESSING THE FOLKS TO  
14 WHOM THOSE ACCESS PLANS MUST CONSIDER WHEN A DRUG IS  
15 BROUGHT TO MARKET.

16 SECONDLY, THE LEGISLATION ALTERED SLIGHTLY  
17 THE TIMELINES FOR THE SUBMISSION OF THOSE PLANS TO  
18 CIRM, WHEN THOSE PLANS ARE SUBMITTED FOR APPROVAL,  
19 AND PUBLIC HEARING BY CIRM.

20 THIRD, THERE WAS A PROCESS PUT INTO THE  
21 STATUTE OR A CALL FOR A PROCESS FOR THE ICOC WHEN IT  
22 CONSIDERS APPROVING A WAIVER OF THE PROVISIONS OF  
23 THE ACCESS PLAN.

24 AND THEN FINALLY, THERE WAS THE LIMITATION  
25 OF THE SCOPE OF THE 1-PERCENT ROYALTY THAT IS DUE ON

## BARRISTERS' REPORTING SERVICE

1 INVENTIONS THAT ARISE OUT OF CIRM-FUNDED RESEARCH.

2 SO IN THOSE FOUR AREAS THE IP, THEN, TASK  
3 FORCE IN NOVEMBER OF 2010 INITIATED A PROCESS OF  
4 LOOKING AT WHAT AMENDMENTS WOULD NEED TO BE MADE TO  
5 THE REGS TO CONFORM TO THE STATUTE. AND IN DECEMBER  
6 OF 2010, THE ICOC CONSIDERED A FEW OF THESE  
7 AMENDMENTS AND AUTHORIZED A PROCESS TO BEGIN WITH  
8 THE OFFICE OF ADMINISTRATIVE LAW TO MAKE CHANGES IN  
9 ALL THESE FOUR AREAS.

10 THAT PROCESS BEGAN IN MARCH OF THIS YEAR  
11 AND MUST CONCLUDE ONE YEAR LATER. SO WE'VE ALREADY  
12 HAD ONE INITIAL 45-DAY PUBLIC COMMENT PERIOD WHERE  
13 AMENDMENTS ON TWO OF THE ISSUES WERE CONSIDERED. IN  
14 ADDITION, THE LANGUAGE OF THE STATUTE WAS PUT FORTH  
15 IN THOSE OTHER TWO AREAS, BUT SPECIFIC LANGUAGE THAT  
16 WE WILL CONSIDER TODAY HAS NOT YET BEEN NOTICED. SO  
17 AFTER THIS MEETING WITH ANY OTHER SUGGESTIONS, WE  
18 WILL THEN CIRCULATE THAT FOR PUBLIC COMMENT IN  
19 ADVANCE OF JANUARY'S ICOC MEETING.

20 SO THE FIRST AREA --

21 CHAIRMAN THOMAS: SCOTT, CAN I ASK YOU A  
22 GLOBAL QUESTION? SO -- IT SOUNDS LIKE WE HAVE, AM I  
23 CORRECT, FROM YOUR DESCRIPTION, WE ACTUALLY HAVE  
24 UNTIL MARCH, THE MARCH MEETING TO APPROVE THE REGS?

25 MR. TOCHER: UNFORTUNATELY, THERE'S JUST A

## BARRISTERS' REPORTING SERVICE

1 ONE-WEEK LAG BETWEEN OUR BOARD MEETING AND WHEN THE  
2 DEADLINE FOR SUBMISSION TO OAL OCCURS.

3 CHAIRMAN THOMAS: GOT IT. OKAY.

4 MR. TOCHER: SO THAT'S WHY WE'RE LOOKING  
5 AT A JANUARY ADOPTION.

6 CHAIRMAN THOMAS: OKAY. THIS QUESTION, OF  
7 COURSE, GOES WITHOUT SAYING, BUT I ASSUME THAT WE'VE  
8 NOW DEALT WITH EVERY CONCEIVABLE UNADDRESSED IP  
9 ISSUE THAT 1064 LAID OUT?

10 MR. TOCHER: THAT'S RIGHT. THIS IS --  
11 THESE ARE THE ISSUES THAT AROSE IN THE LEGISLATION  
12 THAT WE'VE BEEN TASKED TO DEAL WITH.

13 CHAIRMAN THOMAS: THANK YOU.

14 MR. TOCHER: OKAY. SO THE FIRST SECTION  
15 BEGINNING WITH SECTION 607, THIS REGULATION CONCERNS  
16 OUR ACCESS AND PRICING REQUIREMENTS THAT OUR  
17 GRANTEES AND EXCLUSIVE LICENSEES AND COLLABORATORS  
18 MUST ABIDE BY. THE FIRST COMPONENT IS THE ACCESS  
19 PLAN, WHICH PROVIDES THAT UPON COMMERCIALIZATION,  
20 THE COMPANIES WHO ARE COMMERCIALIZING THE DRUG MUST  
21 COME TO CIRM AND SUBMIT A PLAN FOR ADDRESSING  
22 CERTAIN CALIFORNIANS THAT MIGHT NOT BE COVERED  
23 EITHER BY HEALTH INSURANCE OR EXISTING STATE OR  
24 FEDERAL PROGRAMS. AND PRIOR LANGUAGE THAT THE  
25 AGENCY HAS USED ADDRESSED THE GROUP OF WHAT IT

## BARRISTERS' REPORTING SERVICE

1 IDENTIFIED AS UNINSURED CALIFORNIANS.

2 THE LEGISLATION SB 1064 CHANGED THE SCOPE  
3 OF THAT FROM UNINSURED TO CALIFORNIANS WITH NO OTHER  
4 MEANS TO PURCHASE THE DRUG. SO THE FIRST AMENDMENT  
5 TO THE SUBDIVISION A SEEKED TO ADDRESS AND DEFINE  
6 WHO CALIFORNIANS WITH "NO OTHER MEANS" ARE. AND SO  
7 WHAT THE REGULATION PROPOSES TO DO IS TO ESTABLISH  
8 ESSENTIALLY A TWO-PART TEST.

9 FIRST IS THE CALIFORNIANS WHO WOULD  
10 QUALIFY UNDER THIS ARE CALIFORNIANS WHO ARE FIRST  
11 NOT COVERED BY A PRESCRIPTION DRUG BENEFIT, AND THAT  
12 WOULD BE ONE THAT WOULD BE PROVIDED BY ANY  
13 THIRD-PARTY PAYER, PUBLIC OR PRIVATE, THAT COVERS  
14 THIS PARTICULAR DRUG AND WHOSE FAMILY INCOMES ARE  
15 BELOW 300 PERCENT OF THE FEDERAL POVERTY LEVEL.

16 THE REGULATION AMENDMENT GOES ON TO STATE  
17 FROM LINES 11 AND 15, IF YOU'RE LOOKING AT THIS ON  
18 THE COPY THAT WAS POSTED AND E-MAILED AROUND, THIS  
19 LANGUAGE IS EXISTING LANGUAGE THAT WE SIMPLY MOVED  
20 UP FROM A LATER SUBDIVISION. AND THIS LANGUAGE  
21 SIMPLY STATES THAT THE ACCESS PLAN MUST BE  
22 CONSISTENT WITH INDUSTRY STANDARDS AT THE TIME OF  
23 COMMERCIALIZATION AND TAKES INTO ACCOUNT THE SIZE OF  
24 THE MARKET AND THE SIZE OF THE COMPANY THAT IS  
25 BRINGING THE DRUG TO MARKET.



## BARRISTERS' REPORTING SERVICE

1                   SO REALLY IT IS THAT, I GUESS YOU WOULD  
2                   SAY, THAT FIRST SENTENCE WITH THE UNDERLINED  
3                   LANGUAGE AND SECOND SENTENCE THAT IS THE SUBJECT OF  
4                   NEW CONSIDERATION BY THIS SUBCOMMITTEE. I WOULD  
5                   JUST SIMPLY SAY THAT WE ARRIVED AT THIS MINDFUL OF A  
6                   FEW THINGS. FIRST OF ALL, THERE IS AN EXISTING  
7                   CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM THAT  
8                   USES THIS PARTICULAR THRESHOLD OF 300 PERCENT OF THE  
9                   FEDERAL POVERTY LEVEL AS ITS TRIGGER, IF YOU WILL,  
10                  QUALIFIER.

11                  AND SO I THINK, FIRST OF ALL, WE WANTED TO  
12                  MAKE SURE THAT WE WERE CONSISTENT WITH EXISTING  
13                  STATE POLICY IN CERTAIN AREAS.

14                  SECONDLY, WE WANTED TO BE CAREFUL NOT TO  
15                  OVERPRESCRIBE WHAT THE ELEMENTS OF A PARTICULAR  
16                  ACCESS PLAN MAY LOOK LIKE. IF DUANE WERE ON THE  
17                  PHONE, I THINK HE WOULD REMIND US ALL OF THE PROCESS  
18                  THAT WE WENT THROUGH IN HOW THIS PROVISION CAME  
19                  ABOUT. AND ONE OF THE MOST IMPORTANT THINGS THAT  
20                  GAVE COMFORT TO PHARMACEUTICAL COMPANIES AND TO  
21                  COMPANIES THAT MIGHT LOOK AT PARTNERING TO  
22                  COMMERCIALIZE A DRUG WAS THEIR CONCERN THAT THIS NOT  
23                  BE OVERPRESCRIBED IN THE REGULATION, THAT  
24                  FLEXIBILITY NEEDED TO BE MAINTAINED SO THAT YEARS  
25                  DOWN THE ROAD AT COMMERCIALIZATION WE DIDN'T

## BARRISTERS' REPORTING SERVICE

1 INADVERTENTLY HAMSTRING THEM OR TIE THEM DOWN TO  
2 ANYTHING WHICH WOULDN'T BE PRACTICAL.

3 AND SO I THINK THAT THE REGULATION, GIVEN  
4 THE MANDATE IN THE STATUTE, TRIES TO BALANCE THOSE  
5 CONCERNS.

6 CHAIRMAN JUELSGAARD: SCOTT, LET ME JUST  
7 INTERJECT SOMETHING AT THIS POINT. AND IT GOES BACK  
8 TO THE STATEMENT YOU MADE EARLIER ABOUT YOUR  
9 VISIBILITY ON ACCESS PROGRAMS GENERALLY WITHIN THE  
10 INDUSTRY. THE REGULATION, RULE AND REGULATION SAYS  
11 THE ACCESS PLAN MUST BE CONSISTENT WITH INDUSTRY  
12 STANDARDS AT THE TIME OF THE COMMERCIALIZATION,  
13 INCLUDING ACCOUNTING FOR THE SIZE OF THE MARKET FOR  
14 THE DRUG AND THE RESOURCES OF THE GRANTEE,  
15 COLLABORATOR, OR SPECIFIC LICENSEE, WHICH I THINK IS  
16 A VERY LAUDABLE THING. BUT THE PROBLEM THAT WE MAY  
17 RUN INTO AT THAT TIME IS, IF SUCH A TIME ARISES, IS  
18 REALLY TRYING TO GET ACCESS TO WHAT THE INDUSTRY  
19 STANDARDS ARE.

20 SO I'M NOT SUGGESTING THAT WE TAKE IT OUT,  
21 BUT I ONLY POINT OUT THAT THAT COULD BE A LITTLE  
22 DIFFICULT TO REALLY SORT THROUGH BECAUSE WE'LL  
23 OBVIOUSLY NEED ACCESS TO MORE THAN -- WE'LL NEED  
24 ACCESS TO THE SIZE OF THE PROGRAMS THAT SIMILARLY  
25 SITUATED COMPANIES WILL HAVE, AND I DON'T KNOW HOW

**BARRISTERS' REPORTING SERVICE**

1 EASY IT WILL BE TO GET THAT.

2 MR. TOCHER: I THINK THAT'S A VERY GOOD  
3 POINT. AND I THINK PERHAPS EARLY ON CIRM WILL BE IN  
4 A POSITION IN PART TO LOOK TO THE COMPANIES THAT ARE  
5 COMMERCIALIZING EARLY ON WHEN THEY COME TO US WITH A  
6 PLAN, IT WOULD PROBABLY BE TO THEIR BENEFIT TO  
7 ASSIST CIRM BY PROVIDING THAT INFORMATION IF THEY  
8 HAVE IT TO SHOW THAT THEIR PLAN IS, IN FACT,  
9 CONSISTENT. BUT I THINK YOU MAKE A GOOD POINT.

10 CHAIRMAN JUELSGAARD: I HEAR YOU. I JUST  
11 DON'T KNOW HOW MUCH VISIBILITY THEY'LL HAVE INTO  
12 WHAT THEIR COMPETITOR COMPANIES ARE DOING EITHER.  
13 ANYWAY, WE'LL WRESTLE WITH THAT AT THE TIME SHOULD  
14 THE TIME ARISE.

15 MR. TOCHER: SURE.

16 CHAIRMAN JUELSGAARD: IT OCCURRED TO ME  
17 WHILE WE WERE TALKING ABOUT THIS.

18 MR. TOCHER: RIGHT. SO ARE THERE ANY  
19 OTHER COMMENTS OR QUESTIONS FOLKS HAVE ON THAT  
20 SUBDIVISION? ALL RIGHT.

21 CHAIRMAN JUELSGAARD: SCOTT, LET ME JUST  
22 REAL QUICKLY, BECAUSE YOU AND I TALKED ABOUT THIS  
23 BEFORE, AND I JUST WANTED TO MAKE THE OTHER  
24 INDIVIDUALS ON THE CALL AWARE OF THIS. SO THERE  
25 WERE TWO THINGS THAT I TALKED TO SCOTT ABOUT. AND

## BARRISTERS' REPORTING SERVICE

1 ONE WAS IT WASN'T A PART OF WHAT THE BILL REQUIRED,  
2 BUT THE ISSUE IS IS WHAT IS A CALIFORNIAN AS APPLIED  
3 IN THIS CONTEXT. CALIFORNIAN ISN'T DEFINED, SO HOW  
4 DO YOU KNOW WHO IS A CALIFORNIAN AND WHO ISN'T? AND  
5 BOTH SCOTT AND JAMES IN THAT CONVERSATION THOUGHT  
6 THAT SOMEBODY WHO WAS A RESIDENT OF CALIFORNIA WOULD  
7 BE A CALIFORNIAN.

8 ONE OF THE THINGS THAT I WANTED TO ASK THE  
9 GENENTECH PEOPLE WHO RUN THESE KINDS OF PROGRAMS,  
10 WE'VE TOLD THEM IT'S GOING TO BE NATIONAL IN NATURE  
11 AND NOT STATE SPECIFIC. SO WHEN A COMPANY ADOPTS A  
12 PROGRAM, IT ATTEMPTS TO RUN THE SAME PROGRAM  
13 THROUGHOUT THE U.S. UNLESS THERE WAS SOME LEGAL  
14 ISSUES, AND I'LL COME TO THAT IN A MOMENT.

15 AND SO I JUST WANT TO BE SURE THAT FROM A  
16 COMPANY POINT OF VIEW THAT DEFINING A CALIFORNIAN IN  
17 THAT REGARD WOULD NOT BE PROBLEMATIC, NOT  
18 NECESSARILY FROM A COST POINT OF VIEW, BUT FROM SOME  
19 OTHER POINT OF VIEW.

20 THE OTHER THING IS THAT THERE MAY BE SOME  
21 DIFFICULTY IN PROVIDING SUPPORT WHERE GOVERNMENT  
22 PROGRAMS ARE INVOLVED. AND I USED AS MY EXAMPLE THE  
23 RECENT PFIZER SITUATION WITH RESPECT TO LIPITOR. SO  
24 NOW THAT LIPITOR HAS BECOME GENERIC, PFIZER HAS PUT  
25 IN PLACE A PROGRAM WHERE IF YOU APPLY ONLINE OR

## BARRISTERS' REPORTING SERVICE

1 OTHERWISE WITH PFIZER, YOU CAN GET A CARD FROM  
2 PFIZER THAT YOU CAN PRESENT TO YOUR PHARMACY THAT  
3 WILL LIMIT YOUR COPAYMENT FOR LIPITOR AT THE  
4 PHARMACY TO \$4 PER PRESCRIPTION FILLED. BUT IF YOU  
5 LOOK MORE CLOSELY AT WHAT PFIZER IS PROVIDING, THAT  
6 PROGRAM DOESN'T APPLY IF YOU'RE ON MEDICARE OR  
7 MEDICAID OR SOME OTHER GOVERNMENT-SPONSORED PROGRAM.

8 AND THE REASON IS BECAUSE OF THE ANTIFRAUD  
9 STATUTES AT THE FEDERAL LEVEL. AND THE ANTIFRAUD  
10 STATUTES PREVENT INDUCING PEOPLE, INDUCING A  
11 PRESCRIBER OR INDUCING A MANUFACTURER, TRYING TO  
12 INDUCE SOMEBODY TO USE A PRODUCT. AND PROVIDING  
13 FINANCIAL SUPPORT FOR USING THAT PRODUCT CAN BE  
14 VIEWED AS AN INDUCEMENT. AND SO ONE OF THE THINGS  
15 THAT NEEDS TO BE TAKEN INTO ACCOUNT HERE WHEN  
16 COMPANIES ADOPT THESE ACCESS PROGRAMS IS ANY CONCERN  
17 THAT THEY MAY HAVE FOR AN INDUCEMENT ISSUE BECAUSE  
18 THE LAST THING THEY WANT TO DO IS RUN INTO TROUBLE  
19 WITH THE FEDERAL GOVERNMENT ON THAT FRONT.

20 SO I THINK THAT THIS LANGUAGE ACCOMPLISHES  
21 THAT, BUT WE NEED TO BE MINDFUL OF THAT AS WE GO  
22 FORWARD BECAUSE THAT'S AN EVOLVING LANDSCAPE.

23 MR. TOCHER: THANKS, STEVE.

24 CHAIRMAN THOMAS: THANKS.

25 MR. TOCHER: J.T., DID YOU HAVE SOMETHING?

**BARRISTERS' REPORTING SERVICE**

1           CHAIRMAN THOMAS:  WHAT'S THAT?

2           MR. TOCHER:  I'M SORRY, J.T.  I THOUGHT I  
3           HEARD YOU SPEAK UP.

4           CHAIRMAN THOMAS:  I JUST SAID THANKS,  
5           STEVE.  I THOUGHT IT WAS HELPFUL.

6           MS. BAUM:  WE MIGHT ACTUALLY ON THE NEXT  
7           ROUND DEFINE CALIFORNIAN IF THERE'S ANY POINT OF  
8           CLARIFICATION NEEDED.  IT'S EASY ENOUGH TO JUST  
9           DEFINE IT FOR THE JULY 17TH MEETING -- JUNE  
10          17TH -- JANUARY 17TH.

11          MR. TOCHER:  ALL RIGHT.  SO MOVING TO THE  
12          SECOND ELEMENT THERE IN SECTION 607(B), THE STATUTE  
13          CHANGED THE DEADLINE FOR SUBMISSION OF THESE ACCESS  
14          PLANS FROM A PERIOD THAT LOOKS AT 90 DAYS PRIOR TO  
15          THE TIME OF COMMERCIALIZATION TO WITHIN 10 BUSINESS  
16          DAYS FOLLOWING FINAL APPROVAL BY THE FDA UNLESS  
17          THERE'S SOME AGREEMENT OTHERWISE BETWEEN THE  
18          PARTIES.  I THINK THIS WAS A PRACTICAL AMENDMENT TO  
19          SORT OF RESOLVE ANY CONFUSION AS TO WHEN THAT  
20          PARTICULAR TIME FRAME WOULD START TO ACTUALLY TICK  
21          BECAUSE OBVIOUSLY ONE WOULDN'T KNOW WHEN TO START  
22          THE 90-DAY LOOK-BACK UNTIL COMMERCIALIZATION.  AND  
23          SO THAT TENDED TO SORT OF BE AN IMPRACTICAL WAY TO  
24          ADMINISTER THE SUBMISSION OF THE ACCESS PLAN.

25          SO THE LANGUAGE THAT IS SHOWN THERE AS

## BARRISTERS' REPORTING SERVICE

1 AMENDED IN PARAGRAPH B JUST TRACKS THE LANGUAGE IN  
2 SB 1064. THIS WAS ALREADY ACTUALLY APPROVED BY THE  
3 IP TASK FORCE LAST YEAR AND ICOC FOR THE INITIAL  
4 NOTICE PERIOD. WE DID NOT RECEIVE ANY COMMENTS ON  
5 IT FROM THE PUBLIC AFTER THIS INITIAL PUBLIC COMMENT  
6 PERIOD, AND, THUS, WE'RE PROPOSING NO OTHER CHANGES.

7 SO IF THERE ARE NO OTHER QUESTIONS THERE  
8 ON THAT PROVISION, SUBDIVISION C, AS I MENTIONED A  
9 MOMENT AGO WAS SIMPLY DELETED IN ORDER TO MOVE THAT  
10 LANGUAGE UP TO SUBDIVISION A.

11 THE THIRD CHANGE DEALS WITH THE WAIVER  
12 PROCESS. DURING THE DEVELOPMENT OF SB 1064 AS IT  
13 MADE ITS WAY THROUGH THE LEGISLATURE AND THE  
14 AUTHOR'S OFFICE INDICATED ITS DESIRE TO CODIFY OUR  
15 STRONG POLICY, THEY WERE AGREEABLE TO OUR  
16 SUGGESTION, NEVERTHELESS, THAT THE ICOC PRESERVE ITS  
17 DELEGATION OF AUTHORITY UNDER PROP 71 TO TAILOR  
18 THESE POLICIES IN THE FUTURE OR PROVIDE SOME RELIEF  
19 IF THE CIRCUMSTANCES WARRANT. WITHOUT THE PRESENCE  
20 OF THESE CODIFIED PROVISIONS, THAT WOULD JUST OCCUR  
21 IN THE NORMAL COURSE OF BUSINESS OF AMENDING THE  
22 REGULATIONS AND SUCH. BUT BECAUSE SOME PORTIONS OF  
23 THESE REGULATIONS WERE CODIFIED, THE AUTHOR AGREED  
24 TO PROVIDE FOR A PROCESS IN THE BILL BY WHICH THE  
25 ICOC COULD WAIVE THE REQUIREMENT OF AN ACCESS PLAN

## BARRISTERS' REPORTING SERVICE

1 AND SET THE STANDARD FOR WHEN IT MAY DO SO.

2 SO THE SUBDIVISION E ON PAGE 2 OF THE  
3 DRAFT REGULATION AMENDMENTS DESCRIBES WHAT THAT  
4 PROCESS WOULD BE FOR THE ICOC TO CONDUCT A PUBLIC  
5 HEARING AND THE TIMING FOR SUBMISSION OF THE  
6 MATERIALS AND THE REQUEST TO DO SO FROM THE COMPANY  
7 THAT WOULD COMMERCIALIZE, AND THE STANDARD WHICH THE  
8 ICOC WOULD REVIEW THAT REQUEST UNDER.

9 THERE'S NOTHING TOO TERRIBLY POLICY  
10 ORIENTED. IT'S REALLY MORE TECHNICAL, PROVIDING FOR  
11 THE MATERIALS AND ALSO ENSURING THAT THE MATERIALS,  
12 TO THE EXTENT THAT THEY WOULD CONTAIN CONFIDENTIAL  
13 OR PROPRIETARY MATERIAL, WOULD BE HANDLED IN  
14 ACCORDANCE WITH THE PROVISIONS OF PROP 71 WHICH  
15 REQUIRE THE AGENCY TO KEEP THOSE MATERIALS  
16 CONFIDENTIAL.

17 CHAIRMAN JUELSGAARD: SO CAN I JUST ASK  
18 YOU A QUESTION?

19 MR. TOCHER: SURE.

20 CHAIRMAN JUELSGAARD: I'M NOW REREADING  
21 THIS, AND I PROBABLY SHOULD HAVE ASKED THIS EARLIER  
22 WHEN WE SPOKE, NOT TODAY, BUT ON AN EARLIER DATE.  
23 SO THE SENTENCE SAYS THE RESPONSE -- THIS IS KIND OF  
24 TOWARDS THE MIDDLE OF THIS PARAGRAPH E. IT SAYS THE  
25 RESPONSE MUST BE ACCOMPANIED BY MATERIALS DESCRIBING



## BARRISTERS' REPORTING SERVICE

1 HOW DEVELOPMENT AND BROAD DELIVERY OF THE DRUG WILL  
2 BE UNREASONABLY HINDERED BY COMPLIANCE WITH  
3 SUBDIVISION A OF THIS SECTION AND SUCH OR HOW THE  
4 WAIVER WILL PROVIDE SIGNIFICANT BENEFITS THAT EQUAL  
5 OR EXCEED THE BENEFIT THAT WOULD OTHERWISE FLOW AND  
6 THEN THE WORDS "TO THE STATE PURSUANT TO SUBDIVISION  
7 A OF THIS SECTION."

8 WHAT ARE THE BENEFITS IN A THAT FLOW TO  
9 THE STATE AS OPPOSED TO FLOWING TO INDIVIDUALS WHO  
10 OTHERWISE DON'T HAVE ACCESS OR WHO ARE NOT OTHERWISE  
11 HELPED OR WHATEVER THAT LANGUAGE WAS? ARE THESE  
12 REALLY BENEFITS THAT WOULD FLOW TO THE STATE?

13 MR. TOCHER: YOU KNOW, THIS LANGUAGE  
14 TRACKS THE LANGUAGE FROM SB 1064.

15 CHAIRMAN JUELSGAARD: OKAY.

16 MR. TOCHER: AND THIS IS THE STANDARD THAT  
17 THEY WROTE INTO THE LAW. SO --

18 CHAIRMAN JUELSGAARD: OKAY.

19 MR. TOCHER: -- THAT'S WHERE THIS LANGUAGE  
20 COMES FROM. THIS ISN'T SOMETHING THAT WAS CREATED  
21 BY THE TASK FORCE OR ICOC.

22 CHAIRMAN JUELSGAARD: OKAY. WELL, I THINK  
23 IT'S A UNCLEAR WHAT BENEFITS FLOW TO THE STATE AS  
24 OPPOSED TO FLOWING TO INDIVIDUALS, BUT THAT'S FINE.  
25 THAT'S HOW IT WAS WRITTEN.

## BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: I MIGHT BE ABLE TO SHED  
2 SOME LIGHT ON THIS. I THINK THAT THE BENEFITS --  
3 THE PHRASE THE "BENEFITS THAT FLOW TO THE STATE" WAS  
4 REALLY INTENDED TO BE A PROXY FOR THE FACT THAT  
5 INDIVIDUALS WITHIN THE STATE WHO WOULDN'T OTHERWISE  
6 RECEIVE COVERAGE WOULD RECEIVE THE DRUG PURSUANT TO  
7 THIS ACCESS PLAN. SO I DON'T THINK IT'S INTENDED TO  
8 MEAN ANYTHING DIFFERENTLY THAN THAT.

9 CHAIRMAN JUELSGAARD: I UNDERSTAND, JAMES,  
10 BUT SOMEHOW IT EQUATES THE STATE WITH INDIVIDUALS,  
11 WHICH A LOT OF PEOPLE WOULD TAKE EXCEPTION TO IF  
12 THAT WERE THE CASE. SO IT'S A PHILOSOPHICAL MATTER.

13 MR. HARRISON: SURE.

14 CHAIRMAN THOMAS: ALL RIGHT. I HAVE A  
15 QUESTION HERE. IS THERE ANY ISSUE WITH  
16 INCONSISTENCY BETWEEN CHANGING THE LANGUAGE IN THE  
17 PREVIOUS SECTION WE DISCUSSED ABOUT THE 90 CALENDAR  
18 DAYS PRIOR TO 10 DAYS FOLLOWING APPROVAL AND YET  
19 LEAVING IT 90 CALENDAR DAYS IN ADVANCE IN THIS THIRD  
20 SUBSECTION? IS THERE ANY ISSUE WITH THAT?

21 MR. TOCHER: I'M THINKING ABOUT YOUR  
22 QUESTION AND LOOKING AT THE LANGUAGE.

23 CHAIRMAN THOMAS: SO IN THE PREVIOUS  
24 SUBSECTION, THEY ALTERED THE LANGUAGE WHICH HAD READ  
25 90 -- LET'S SEE. WHERE ARE WE HERE -- 90 DAYS, NO

## BARRISTERS' REPORTING SERVICE

1 FEWER THAN 90 DAYS, CALENDAR DAYS, PRIOR TO THE TIME  
2 THE DRUG IS COMMERCIALIZED TO WITHIN 10 BUSINESS  
3 DAYS FOLLOWING APPROVAL OF THE DRUG BY THE FDA.  
4 THEY CHANGED THE 90-DAY LANGUAGE IN THAT SUBSECTION.  
5 AND IN THIS THIRD SUBSECTION THE 90-DAY LANGUAGE  
6 REMAINS. I'M JUST FLAGGING IT. IS THERE AN ISSUE  
7 WITH CONSISTENCY THERE SOMEHOW?

8 MS. BAUM: I MEAN I CAN SEE THAT IT MIGHT  
9 BE HARD TO NECESSARILY COMPLY IF YOU DON'T KNOW THE  
10 DATE UPON WHICH YOU WILL COMMERCIALIZE IT. THEN  
11 AGAIN, A LOT OF COMPANIES WOULD SORT OF HAVE SOME  
12 SENSE AS TO WHEN THE DRUG WOULD FIRST SHIP AFTER  
13 THEY GET FDA APPROVAL, BUT YOU NEVER REALLY KNOW  
14 WHEN YOU'RE GOING TO GET THE FDA APPROVAL.

15 CHAIRMAN JUELSGAARD: YOU'RE ABSOLUTELY  
16 RIGHT, ELONA. I MEAN, YOU KNOW, FDA APPROVALS COME  
17 WHEN THEY COME, AND SOMETIMES AND IN SOME CASES THEY  
18 MAY TELL YOU YOU CAN EXPECT APPROVAL ON THIS DATE,  
19 BUT, YOU KNOW, IN MANY CASES YOU DON'T KNOW UNTIL  
20 THE LAST MOMENT, AND SO YOU'RE WAITING. I KNOW  
21 THERE'S A STATUTORY PERIOD OF TIME IN WHICH THEY  
22 HAVE TO DO REVIEWS, BUT THEY TEND TO FIND WAYS TO  
23 PROLONG THAT IF THEY NEED TO.

24 MS. BAUM: I GUESS THIS LANGUAGE THOUGH  
25 THAT IS BEING PROPOSED (INAUDIBLE) VERBATIM. THAT

**BARRISTERS' REPORTING SERVICE**

1 SAID, I DON'T SEE WHY WE COULDN'T PUT A  
2 CLARIFICATION IN THERE.

3 CHAIRMAN THOMAS: IF THEY'RE GIVING US  
4 LANGUAGE, THERE'S NO REASON DEVIATE FROM WHAT  
5 THEY'RE SAYING, BUT IT JUST IT SEEMED TO ME TO BE A  
6 BIT INCONSISTENT.

7 MS. BAUM: I MEAN I THINK WE HAVE THE  
8 ABILITY TO INTERPRET SO THAT IT'S IMPLEMENTABLE. I  
9 THINK WE CAN LOOK AT THAT.

10 MR. TOCHER: ACTUALLY I WILL LOOK AT THIS  
11 TO MAKE SURE, FIRST OF ALL, THAT THERE'S NOT A  
12 CONFLICT WITH THE STATUTE IF WE WERE TO CLARIFY IT  
13 BY TWEAKING THAT SLIGHTLY AND MAKE SURE THAT BEFORE  
14 IT GETS NOTICED, THAT WE HAVEN'T INADVERTENTLY PUT A  
15 STANDARD IN THERE THAT'S DIFFICULT FOR THEM TO  
16 COMPLY WITH. SO THANKS FOR FLAGGING THAT, J.T.

17 CHAIRMAN THOMAS: AGAIN, I DON'T KNOW IF  
18 IT'S AN ISSUE. IT JUST SORT OF -- NICE TO BE  
19 CONSISTENT IF WE CAN BE.

20 MS. BAUM: AND BEING ABLE TO IMPLEMENT IS  
21 VERY CRITICAL TOO. OTHERWISE WE'LL GET A LOT OF  
22 PHONE CALLS.

23 MR. TOCHER: ALL RIGHT. IF THERE'S  
24 NOTHING ELSE, THEN WE CAN MOVE TO THE LAST ISSUE,  
25 WHICH IS EXHIBIT B, REGULATION 100608. THIS IS OUR

## BARRISTERS' REPORTING SERVICE

1 REVENUE SHARING PROVISION THAT APPLIES IN THE EVENT  
2 THAT A PRODUCT IS COMMERCIALIZED. AS I SAID  
3 EARLIER, THERE WAS ONE SMALL YET SUBSTANTIVE CHANGE  
4 TO THE REGULATIONS WHEN THEY WERE CODIFIED. AND  
5 THAT WAS A REQUIREMENT IN SUBDIVISION B(3)  
6 ESSENTIALLY THAT THE 1-PERCENT ROYALTY RATE THAT  
7 APPLIES UNDER LIMITED CIRCUMSTANCES WOULD APPLY ONLY  
8 IN THE EVENT THAT A DRUG THAT ARISES FROM A  
9 CIRM-FUNDED INVENTION OR TECHNOLOGY IS, IN FACT,  
10 PATENTED. PRIOR ITERATION IN OUR REGULATIONS  
11 APPLIED THE 1-PERCENT ROYALTY IN CIRCUMSTANCES  
12 REGARDLESS OF WHETHER THAT TECHNOLOGY OR INVENTION  
13 WAS ACTUALLY PATENTED.

14 SO THE CHANGES THAT YOU SEE THERE IN THAT  
15 SUBDIVISION B(3) ARE SIMPLY CONFORMING TO THE  
16 STATUTE. THEY WERE CONSIDERED BY THE TASK FORCE AND  
17 ICOC LAST YEAR PRIOR TO THE INITIATION OF THIS  
18 RULEMAKING PROCESS. WE RECEIVED NO COMMENT FROM THE  
19 COMMENT AFTER THAT INITIAL 45-DAY PERIOD, AND WE ARE  
20 PROPOSING NO ADDITIONAL AMENDMENTS TO THE LANGUAGE  
21 SINCE IT WAS INITIALLY NOTICED.

22 SO THAT REALLY CONCLUDES THE AMENDMENTS  
23 THAT MUST BE MADE TO CONFORM WITH SB 1064. IF THERE  
24 WERE NO OTHER QUESTIONS OR PUBLIC COMMENT AT ANY OF  
25 THE LOCATIONS, WHICH I DON'T WANT TO CUT OFF, I

## BARRISTERS' REPORTING SERVICE

1 WOULD SAY THAT WE WOULD BE IN A POSITION TO CALL FOR  
2 A MOTION. BUT SINCE WE DO NOT HAVE A QUORUM, I  
3 THINK IT WOULD BE APPROPRIATE FOR STEVE PERHAPS TO  
4 POLL THE MEMBERS ON THE LINE TO SEE IF THERE WAS ANY  
5 OTHER OBJECTION TO ANY OF THIS MATERIAL OR WHETHER  
6 WE WOULD BE IN A POSITION TO MOVE FORWARD WITH IT.

7 CHAIRMAN JUELSGAARD: OKAY, SCOTT, JUST  
8 BEFORE WE DO THAT, BACK TO THIS LAST PROVISION THAT  
9 YOU OUTLINED AND THE CHANGE FROM TECHNOLOGY THAT WAS  
10 DEVELOPED THROUGH CIRM FUNDING TO ONLY PATENTED  
11 TECHNOLOGY. WHAT WAS THE GENESIS OF THAT NARROWING?

12 MR. TOCHER: FROM THE LEGISLATURE?

13 CHAIRMAN JUELSGAARD: YEAH.

14 MR. TOCHER: YOU KNOW, THAT'S AN EXCELLENT  
15 QUESTION. I THINK, YOU KNOW, JAMES AND I SAT IN ON  
16 A LOT OF THOSE MEETINGS, AND SOMETIMES THAT WAS A  
17 CHALLENGE TO TRY TO FIGURE OUT EXACTLY WHAT WAS  
18 ANIMATING ONE AMENDMENT OR ANOTHER. I WOULD -- I  
19 SUSPECT, AND, JAMES, CUT ME OFF IF YOU THINK THIS IS  
20 INCORRECT, THAT PERHAPS THIS WAS A WAY OF GARNERING  
21 SUPPORT FOR THE LEGISLATION MOVING FORWARD FROM THE  
22 VARIOUS CONSTITUENCIES, INCLUDING THOSE FROM THE  
23 PRIVATE SECTOR.

24 CHAIRMAN JUELSGAARD: OKAY. JUST CURIOUS  
25 BECAUSE IN NORMAL LICENSING ARRANGEMENTS BETWEEN

## BARRISTERS' REPORTING SERVICE

1 COMPANIES, AND ELONA WILL KNOW THIS, THAT ROYALTY  
2 RATES ARE OFTEN THE SAME BETWEEN PATENTED TECHNOLOGY  
3 AND NONPATENTED TECHNOLOGY OR TRADE SECRET  
4 TECHNOLOGY. THE DIFFERENCE DOESN'T COME SO MUCH IN  
5 THE ROYALTY RATE, BUT IN THE LENGTH OF TIME FOR  
6 WHICH THE ROYALTIES ARE PAYABLE. AND IT'S THE  
7 SHORTER PERIOD OF TIME FOR TRADE SECRET TECHNOLOGY  
8 THAN FOR PATENTED TECHNOLOGY. SO THIS IS SORT  
9 OF -- THE NARROWING IS IN SOME SENSE GREATER THAN  
10 YOU WOULD FIND IN A COMMERCIAL ENTERPRISE TO  
11 COMMERCIAL ENTERPRISE. BUT IN ANY EVENT, THAT'S WHY  
12 I WAS JUST CURIOUS AS TO WHAT HAPPENED. IT IS WHAT  
13 IT IS, SO...

14 MR. TOCHER: RIGHT.

15 CHAIRMAN JUELSGAARD: ANYWAY, SO WHY DON'T  
16 I -- GO AHEAD. I'M SORRY.

17 MR. TOCHER: NO. NO. GO AHEAD, STEVE.

18 CHAIRMAN JUELSGAARD: I'M SORRY.

19 MR. TOCHER: I'M SORRY. I SAID GO AHEAD.

20 CHAIRMAN JUELSGAARD: SINCE YOU HAD  
21 SUGGESTED THAT I POLL MEMBERS OF THE SUBCOMMITTEE AS  
22 TO WHETHER OR NOT THEY SUPPORT THESE CHANGES. SO  
23 LET ME JUST -- SO I KNOW J.T. IS ON THE LINE. AND,  
24 J.T., ARE YOU SUPPORTIVE?

25 CHAIRMAN THOMAS: YES.

**BARRISTERS' REPORTING SERVICE**

1           CHAIRMAN JUELSGAARD:  AND WE HAVE DUANE ON  
2   THE LINE?

3           MR. TOCHER:  IT APPEARS WE DON'T.  WE HAVE  
4   SUE BRYANT ON THE LINE.

5           DR. BRYANT:  I'M IN FAVOR OF WHAT WE  
6   DISCUSSED, YES.

7           MR. TOCHER:  OKAY.  ART.

8           MR. TORRES:  I JUST WANT TO MAKE SURE THAT  
9   WHATEVER REGULATIONS WE PUT FORWARD ARE NOT VIEWED  
10  AS INCONSISTENT ON THEIR FACE WITH WHATEVER THE  
11  LEGISLATIVE INTENT WAS.

12          CHAIRMAN JUELSGAARD:  THE LEGISLATIVE  
13  INTENT --

14          MR. TORRES:  AS WE DISCUSSED EARLIER, IT'S  
15  AMENDING THE LANGUAGE TO INTERPRET THE LEGISLATION I  
16  THINK IS APPROPRIATE AS LONG AS THE TRUE SENSE OF  
17  THE INTENT IS KEPT INTACT.  I MEAN THESE  
18  NEGOTIATIONS WERE VERY FRAGILE, AND BRINGING PEOPLE  
19  TOGETHER WAS A HERCULEAN TASK WITH THE PRESIDENT OF  
20  THE SENATE INVOLVED, THE SPEAKER, AND THE VARIOUS  
21  CHAIRS, MANY OF WHOM HAVE NO EXPERIENCE, AND  
22  CERTAINLY I DON'T, IN THE PRIVATE SECTOR ON SOME OF  
23  THE ISSUES THAT YOU RAISE, STEVE.  AND SO I THINK I  
24  JUST WANT TO MAKE SURE THAT WHATEVER REGULATIONS WE  
25  DO DRAFT THAT THEY ARE NOT INCONSISTENT IN AN



## BARRISTERS' REPORTING SERVICE

1 OVERZEALOUS WAY AGAINST THE LEGISLATIVE INTENT.

2 MS. BAUM: ART, WE CAN MAKE SURE THAT WHEN  
3 WE MAKE THAT ONE CHANGE FOR IMPLEMENTATION, THAT WE  
4 BE VERY ASSERTIVE. FOR INSTANCE, INSTEAD OF EVEN  
5 DOING TEN DAYS, WE CAN JUST SAY THEY NEED TO PROVIDE  
6 THE PLAN AT SOME POINT DURING THE PHASE FOR CLINICAL  
7 TRIAL, WHICH WOULD CERTAINLY --

8 CHAIRMAN JUELSGAARD: SURE.

9 MR. TORRES: AND QUITE FRANKLY,  
10 REALISTICALLY, HOW FAR ARE WE AWAY FOR THESE  
11 LEGISLATIVE INTENTS TO BE IMPLEMENTED?

12 MS. BAUM: WELL, FROM WHAT WE KNOW NOW --

13 MR. TORRES: THAT DEPENDS ON THE TIMES,  
14 RIGHT?

15 MS. BAUM: YEAH. SO WE COULD WAIT TOO IF  
16 THAT'S THE PREFERENCE.

17 MR. TORRES: I'M FINE OTHERWISE.

18 CHAIRMAN JUELSGAARD: OKAY. GREAT. AND  
19 WHO ELSE DO WE HAVE ON THE SUBCOMMITTEE ON THE LINE?

20 MR. TOCHER: I BELIEVE THAT'S ALL THE  
21 MEMBERS THAT WE HAVE.

22 CHAIRMAN JUELSGAARD: OKAY. WELL, FOR ALL  
23 THE MEMBERS THAT YOU DO HAVE ON THE LINE, GIVEN  
24 ART'S COMMENTS, WHICH I TAKE TO HEART, WE'RE ALL  
25 SUPPORTIVE OF THIS -- OF THESE CHANGES IN THE

**BARRISTERS' REPORTING SERVICE**

1 REGULATIONS.

2 MR. TOCHER: OKAY. GREAT.

3 MR. TORRES: THANK YOU VERY MUCH, STEVE,  
4 FOR YOUR INPUT. IT HAS BEEN INVALUABLE.

5 MR. TOCHER: IF I COULD JUST MAYBE SEE IF  
6 THERE'S ANY PUBLIC COMMENT ON ANY OF THE LOCATIONS.  
7 WE HAVE DON REED HERE. IS THERE ANYONE ELSE AT ANY  
8 OF THE OTHER LOCATIONS? ALL RIGHT. IF NOT, THEN  
9 DON.

10 MR. REED: THIS IS NOT RELATED TO THE  
11 SUBJECT OF THE MEETING, BUT THERE IS A SPACE ON THE  
12 CALENDAR FOR PUBLIC COMMENT ON OTHER THINGS. I'D  
13 JUST LIKE TO MENTION THAT ON THE 27TH THERE WAS A  
14 PRESIDENTIAL PRO LIFE FORUM PUT ON BY PERSONHOOD  
15 AMENDMENT PEOPLE. AND IN THIS PRESENT WAS NEWT  
16 GINGRICH, MICHELLE BACHMAN, TWO OTHER PEOPLE. ONLY  
17 PERSON -- AND THEY ALL ARE IN FAVOR OF PERSONHOOD,  
18 AND THE ONLY PERSON THAT WAS NOT THERE WAS ROMNEY.  
19 AND ROMNEY HAS INDICATED HE WOULD SIGN A  
20 CONSTITUTIONAL AMENDMENT FOR THE PERSONHOOD BASE.

21 SO I WOULD LIKE TO JUST REMIND EVERYBODY  
22 THAT THIS IS A SERIOUS THREAT TO EVERYTHING THAT WE  
23 DO, AND PLEASE STAY INFORMED AND INVOLVED IN THIS  
24 ISSUE BECAUSE IT'S GOING TO BE IMPORTANT. THANK  
25 YOU.

**BARRISTERS' REPORTING SERVICE**

1 MR. TOCHER: GREAT. THANKS, DON. STEVE,  
2 I DON'T THINK THERE'S ANY MORE PUBLIC COMMENT.

3 CHAIRMAN JUELSGAARD: ALL RIGHT. WE HAVE  
4 ANYTHING ELSE ON THE AGENDA?

5 MR. TOCHER: WE DO NOT. THAT CONCLUDES  
6 IT.

7 MR. TORRES: I WANT TO WISH EVERYONE A  
8 HAPPY NEW YEAR.

9 CHAIRMAN JUELSGAARD: THANK YOU, ART.  
10 THANK YOU, EVERYBODY.

11 CHAIRMAN THOMAS: LIKEWISE. AND SCOTT  
12 DOES A NICE JOB IN LAYING ALL THIS OUT IN YOUR MEMO.

13 MR. TOCHER: THANKS VERY MUCH, J.T. ENJOY  
14 THE REST OF YOUR VACATION.

15 MR. TORRES: AND I BELIEVE HE'S WORKED  
16 VERY HARD. AND EVERY TIME I PASS HIS OFFICE, THE  
17 DOOR WAS CLOSED AND HE WAS BLINDED BY HIS COMPUTER.

18 MR. TOCHER: THANKS, EVERYBODY.

19 (THE MEETING WAS THEN CONCLUDED AT  
20 9:41 A.M.)

21  
22  
23  
24  
25

**BARRISTERS' REPORTING SERVICE**

**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 TELEPHONIC PROCEEDINGS BEFORE THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING ON DECEMBER 29, 2011 WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

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