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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: SEPTEMBER 25, 2017
3 P.M.

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

FILE NO.: 2017-21

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I N D E X

ITEM DESCRIPTION	PAGE
1. CALL TO ORDER.	3
2. ROLL CALL.	3
3. CONSIDERATION OF RECOMMENDATION REGARDING FINAL ADOPTION OF NEW INTELLECTUAL PROPERTY RULES FOR NEW AWARDS.	4
4. PUBLIC COMMENT.	NONE
5. ADJOURNMENT	12

SEPTEMBER 25, 2017; 3 P. M.

1 CHAIRMAN JUELSGAARD: ALL RIGHT. I'D LIKE
2 TO CALL THE MEETING OF THE INTELLECTUAL PROPERTY AND
3 INDUSTRY SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE
4 FOR REGENERATIVE MEDICINE TO ORDER. SO I THINK THE
5 FIRST ORDER OF BUSINESS IS MARIA TO CALL ROLL.

6 MS. BONNEVILLE: SURE. ANNE-MARIE
7 DULIEGE.

8 DR. DULIEGE: HERE.

9 MS. BONNEVILLE: STEVE JUELSGAARD.

10 CHAIRMAN JUELSGAARD: HERE.

11 MS. BONNEVILLE: JOE PANETTA. JEFF
12 SHEEHY. OS STEWARD.

13 DR. STEWARD: HERE.

14 MS. BONNEVILLE: JONATHAN THOMAS.

15 CHAIRMAN JUELSGAARD: HERE.

16 MS. BONNEVILLE: THANK YOU.

17 MR. TOCHER: AND WE HAVE A QUORUM.

18 CHAIRMAN JUELSGAARD: GREAT. ALL RIGHT.
19 THEN WE MIGHT AS WELL GET UNDER WAY. SO THE PURPOSE
20 OF THIS MEETING IS TO ADDRESS CERTAIN CHANGES TO THE
21 IP REGULATIONS. WE STARTED THIS PROCESS LAST
22 JANUARY. SCOTT TOCHER AND BEN HUANG HAD PUT FORTH
23 SOME REVISIONS TO THE ICOC, WHICH THEN WERE APPROVED
24 AND PUT OUT FOR PUBLIC COMMENT. AND NOW THAT PUBLIC
25 COMMENT HAS TAKEN PLACE. AND SO WE ARE NOW HERE TO

1 LOOK AT THE FINAL PROPOSED REGULATIONS. SO WHAT I'D
2 LIKE TO DO IS TO TURN THE CONVERSATION OVER, THEN,
3 TO SCOTT AND BEN TO SORT OF PROVIDE AGAIN THE
4 BACKGROUND AND THEN WHERE WE'VE COME OUT WITH
5 RESPECT TO THESE NEW PROPOSED OR UPDATED
6 REGULATIONS.

7 MR. TOCHER: GREAT. THANKS VERY MUCH,
8 STEVE AND MEMBERS OF THE SUBCOMMITTEE.

9 IF YOU'RE FOLLOWING ALONG, WE HAVE A SLIDE
10 PRESENTATION THAT YOU CAN FOLLOW ALONG EITHER ON THE
11 WEBEX LINK THAT AMY CHEUNG SENT LAST WEEK OR YOU CAN
12 ALSO ACCESS THIS PRESENTATION FROM THE AGENDA WEB
13 PAGE FROM CIRM'S WEBSITE. AND I'LL LET YOU KNOW
14 WHERE I AM ON THE PRESENTATION.

15 SO WE'RE ON OUR MISSION SLIDE. AS STEVE
16 JUST INDICATED, YOU WILL RECALL THAT THE ENTIRE CIRM
17 TEAM WAS CHALLENGED TO EXAMINE ALL PARTS OF OUR
18 OPERATIONS AND OUR POLICIES TO IDENTIFY
19 OPPORTUNITIES TO BETTER ACHIEVE OUR MISSION. AND TO
20 THAT END, EARLIER THIS YEAR THE LEGAL TEAM,
21 CONSISTING OF ME, BEN HUANG, AND AT THE TIME JAMES
22 HARRISON, LOOKED AT OUR IP REGULATIONS TO SEE IF
23 THEY COULD BE IMPROVED. AND IN JANUARY OF THIS
24 YEAR, THIS SUBCOMMITTEE REVIEWED AND ENDORSED THE
25 GOALS OF THE CURRENT IP REVISION PROJECT, AND THE

1 BOARD SUBSEQUENTLY AT ITS NEXT MEETING AUTHORIZED
2 THE START OF THE FORMAL REGULATORY PROCESS TO ADOPT
3 THIS NEW POLICY.

4 AND NOW I'M ON SLIDE 3. SO LET ME JUST
5 BRIEFLY REMIND YOU OF THE GOALS OF THIS PROJECT. AS
6 THE CIRM TEAM HAS DONE WITH OTHER POLICIES AND
7 RULES, WE WANT TO ENSURE THAT OUR REVENUE SHARING
8 RULES ARE CLEAR AND SELF-EXECUTING WHERE POSSIBLE.
9 IT DOESN'T DEPEND ON WHOM OUR AWARDEES OR POTENTIAL
10 AWARDEES TALK TO TO DETERMINE HOW THESE RULES
11 OPERATE. AND PART OF MAKING THAT POSSIBLE IS
12 ENSURING THAT THE RULES USED ARE OBJECTIVE INSTEAD
13 OF SUBJECTIVE STANDARDS WHERE POSSIBLE. IN OTHER
14 WORDS, WE SHOULD EXPLICITLY STATE WHAT OUR EXPECTED
15 OUTCOME IS AS OPPOSED TO TRYING TO REQUIRE A TYPE OF
16 BEHAVIOR SUCH AS REASONABLE EFFORTS TO DO SOMETHING.

17 AS WE'VE HEARD TIME AND AGAIN THROUGHOUT
18 THE DEVELOPMENT OF OUR REVENUE SHARING RULES, GOING
19 BACK TO 2005, WE'VE HEARD CLEARLY FROM INDUSTRY THAT
20 IT IS LESS CONCERNED ABOUT THE GIVEN BALANCE POINT
21 OR PARTICULAR ROYALTY RATE SO MUCH AS THE PRIZED
22 PREDICTABILITY OF MAKING THAT CALCULATION IN
23 ADVANCE. REVENUE SHARING RULES SHOULD BE SIMPLE TO
24 CALCULATE PRIOR TO TAKING OUR AWARDS AND PROVIDE
25 CERTAINTY AND CONFIDENCE IN THOSE CALCULATIONS.

1 FINALLY, WE KNOW THAT WE HAVE THE RIGHT
2 SYSTEM IN PLACE WHEN THE CIRM TEAM'S RESOURCES ARE
3 FOCUSED ON SUPPORTING CIRM'S STRATEGIC MISSION
4 RATHER THAN EXPENDING ITS EFFORTS GRAPPLING WITH THE
5 INTERPRETATION OF OUR OWN RULES AND TRYING TO
6 ENFORCE THEM ON A CASE-BY-CASE BASIS.

7 NEXT SLIDE, SLIDE 4, SO WITH THOSE
8 CHALLENGES, THE NEW POLICY IS COMPRISED OF THE
9 FOLLOWING STRUCTURAL CHECKS. WE WANT TO ELIMINATE
10 THE DISPARATE TREATMENT OF AWARDEES AND TREAT ALL
11 AWARDEES ALIKE WHETHER THEY'RE FOR-PROFIT OR NOT FOR
12 PROFIT. AND WE DO THAT BY ELIMINATING THE CONCEPT
13 OF LICENSING REVENUE FOR ALL AWARDEES AND INSTEAD
14 FOCUS ON COMMERCIALIZED REVENUES, A CONCEPT THAT IS
15 ALREADY CURRENTLY APPLICABLE TO OUR FOR-PROFIT
16 AWARDEES.

17 NOW, IN THIS PROJECT, WHILE MAKING THIS
18 IMPORTANT REVISION, WE MADE NO SUBSTANTIVE CHANGES
19 TO OUR CURRENT ACCESS AND PRICE PROVISIONS. THOSE
20 ARE PRESERVED. BY ELIMINATING OUR LICENSING REVENUE
21 AND FOCUSING ON COMMERCIAL SUCCESSES, WE BELIEVE WE
22 CAN OPTIMIZE OUR REMAINING RESOURCES WHICH WILL
23 ALLOW CIRM TO FOCUS ON OUR STRATEGIC MISSION. BY
24 SIMPLIFYING OUR REVENUE SHARING RULES, WE WILL MAKE
25 THEM EASIER TO UNDERSTAND, EXPLAIN, AND ADMINISTER.

1 AND AS A RESULT, POTENTIAL APPLICANTS WILL BE ABLE
2 TO MORE ACCURATELY PREDICT THE COST OF CIRM FUNDING
3 AND, THUS, MAKE CIRM'S PROGRAMS MORE ATTRACTIVE TO
4 FOLLOW-ON INVESTMENT AND COMMERCIALIZATION.

5 SO WITH THE GOALS STATED, I'D LIKE TO TURN
6 IT OVER NOW TO BEN HUANG TO BRIEFLY GO OVER SOME OF
7 THE FEEDBACK THAT WE RECEIVED AND CIRM'S RESPONSES
8 IN OUR REGULATIONS.

9 MR. HUANG: SO WE'RE CURRENTLY ON SLIDE 5.
10 SO OUR PRIMARY FEEDBACK WAS PROVIDED BY THE
11 UNIVERSITY OF CALIFORNIA OFFICE OF THE PRESIDENT AND
12 STANFORD UNIVERSITY. THE MAJOR CONCERNS WERE
13 DIVIDED INTO THESE THREE BULLET POINTS. THE FIRST
14 WAS HOW TO ENSURE THAT THE POLICY DOESN'T REACH
15 BEYOND TECHNOLOGY FUNDED BY CIRM, MAKING SURE THAT
16 THE PROPOSED POLICY DOES NOT CAPTURE ROUTINE
17 NONPROFIT ACTIVITIES, AND THEY WERE ALSO CONCERNED
18 ABOUT BURDENING THE ABILITY TO NEGOTIATE DEALS FOR
19 THE CIRM-FUNDED IP AND TECHNOLOGY.

20 MOVING ON TO SLIDE 6, DURING THE PUBLIC
21 COMMENT PERIOD, WE ADDRESSED THESE CONCERNS AS
22 FOLLOWS: THE FIRST CONCERN WAS TO ENSURE THE
23 PROPOSED POLICY DOES NOT REACH BEYOND TECHNOLOGY
24 FUNDED BY CIRM. AS YOU MAY BE AWARE, ONE OF OUR
25 PRIMARY ISSUES HAS BEEN WITH THE LICENSING OF DATA

1 BY ACADEMIC INSTITUTIONS. SO THE LICENSING IS
2 CONTROLLED BY THE OFFICE OF TECHNOLOGY AND
3 LICENSING, AND THEY'RE AWARE OF PATENT FILINGS, BUT
4 NOT NECESSARILY OF DATA. SO I THINK THIS WAS THE
5 FUNDAMENTAL BASIS OF THEIR CONCERN.

6 AND SO TO ADDRESS THAT CONCERN ABOUT WHAT
7 THEY'RE RESPONSIBLE FOR LICENSING OR TRACKING, WE
8 HAVE INCLUDED IN THE LATEST DRAFT THIS DEFINITION
9 ENTITLED "TARGETED CIRM-FUNDED TECHNOLOGY," WHICH
10 WOULD BE USED TO DEFINE THE SCOPE OF THE CIRM AWARD
11 AND WOULD BE PLACED IN THE NOTICE OF AWARD GROUP,
12 WHICH THE OFFICE OF TECHNOLOGY AND LICENSING COULD
13 THEN TRACK. THIS WILL INFORM THE AWARDEE OF THE
14 SCOPE OF ITS LICENSING OBLIGATIONS AS TO DATA. AND
15 THEY CAN BE AMENDED ON AN ONGOING BASIS. AND I
16 BELIEVE BOTH ENTITIES, BOTH STANFORD AND THE UC
17 OFFICE OF THE PRESIDENT, WERE HAPPY WITH THAT
18 CHANGE.

19 IN ADDITION, THERE WAS A CONCERN ABOUT HOW
20 THE PROPOSED POLICY -- MAKE SURE THE PROPOSED POLICY
21 DOES NOT CAPTURE ROUTINE NONPROFIT ACTIVITIES. I
22 THINK THIS PUBLIC COMMENT WAS DRIVEN BY AN
23 ASSUMPTION THAT CIRM'S ROYALTIES WOULD EXTEND TO
24 SALES BEYOND THE FIRST SALE OF A DRUG. FOR EXAMPLE,
25 THE EXAMPLE GIVEN TO CIRM WAS IF A UC HOSPITAL

1 PURCHASED A DRUG AND USED THAT DRUG TO TREAT A
2 PATIENT, THEY WERE AFRAID TO BE CATEGORIZED AS A
3 COMMERCIAL ENTITY AND ON THE HOOK TO PAY ROYALTIES
4 BACK TO THE STATE.

5 THIS IS NOT THE CASE. THIS IS NOT OUR
6 DEFINITION OF ROYALTIES, AND WE'VE ALSO ADDED
7 ADDITIONAL CLARIFICATION LANGUAGE IN THIS PROPOSED
8 REVISION.

9 THE LAST MAJOR CONCERN WAS THE ABILITY TO
10 NEGOTIATE DEALS WITH THE PREDETERMINED ROYALTY RATE
11 IN THE PROPOSED REVISIONS. THE ROYALTY RATE WE'RE
12 APPLYING TO NON-PROFITS IS SIMILAR -- IS THE SAME AS
13 THE CURRENT CIRM REGULATIONS FOR FOR-PROFIT
14 ENTITIES. IT SEEMS FROM SOME OF OUR RESEARCH THAT
15 OTHER NONPROFIT ENTITIES ARE REQUESTING HIGHER
16 AMOUNTS FOR THEIR FUNDING THAN CIRM. SO WE FEEL
17 THAT OUR CURRENT ROYALTY RATE IS EQUITABLE AND FAIR,
18 AND ALSO LONG THE LINES OF THE GOALS OF THIS PROJECT
19 WAS TO GET REVENUE FOR THE STATE FOR MARKET
20 SUCCESSES. AND OBVIOUSLY THAT WOULD BE DETERMINED
21 BY SALES. SO I THINK RETAINING THE CURRENT ROYALTY
22 RATE WOULD SATISFY THAT CRITERIA.

23 AND THEN I'LL PASS IT BACK TO SCOTT FOR
24 SLIDE 8.

25 MR. TOCHER: OKAY. GREAT. THANKS, BEN.

1 SO THAT REALLY BRINGS US BACK TO PRESENT TIME.
2 WE'VE UNDERGONE ABOUT THREE ROUNDS OF PUBLIC
3 COMMENTS ON THESE REGULATIONS. AS BEN'S
4 PRESENTATION INDICATES, WE STARTED WITH A BIT OF
5 DISTANCE BETWEEN US AND OUR REGULATED COMMUNITY
6 MEMBERS, BUT WE WERE ABLE TO RESOLVE THOSE ISSUES TO
7 THEIR SATISFACTION. SO WE'RE VERY PLEASED THAT THE
8 PUBLIC COMMENT ROUNDS ACTUALLY SERVED THEIR PURPOSE
9 AND IMPROVED OUR POLICY.

10 SO WITH THAT, AT THE END OF THE DAY, WE'RE
11 REQUESTING FROM THE IP SUBCOMMITTEE A RECOMMENDATION
12 OF APPROVAL OF THE PROPOSED IP REGULATIONS TO THE
13 WHOLE ICOC BOARD. AND WITH THAT, TURN IT OVER BACK
14 TO YOU, STEVE. AND, STEVE, IF YOU'RE SPEAKING, WE
15 THINK YOU MAY BE MUTED.

16 CHAIRMAN JUELSGAARD: YEAH, YOU'RE RIGHT.
17 I PUT IT BACK ON. THANK YOU FOR THAT RUNDOWN, GUYS.
18 I APPRECIATE IT.

19 SO LET'S JUST START WITH ANY QUESTIONS OR
20 COMMENTS THAT THE SUBCOMMITTEES MEMBERS MIGHT HAVE
21 WITH REGARD TO THE PROPOSED CHANGES TO OUR POLICY.
22 ARE THERE ANY QUESTIONS FROM ANY OF THE OTHER
23 MEMBERS THAT ARE ON THE LINE OR COMMENTS?

24 DR. DULIEGE: ACTUALLY, NO, I HAVE NO
25 QUESTIONS. I THINK THIS IS VERY STRAIGHTFORWARD,

1 VERY SIMPLE. APPRECIATE THE CLARIFICATION THAT WAS
2 PROVIDED ON THE LAST SLIDE.

3 CHAIRMAN JUELGAARD: GREAT. ANY OTHERS
4 BESIDES ANNE-MARIE? IS THIS A PUBLIC MEETING? IS
5 THERE MEMBERS OF THE PUBLIC ON THE LINE?

6 MR. TOCHER: THIS IS A PUBLIC MEETING,
7 STEVE. THERE ARE NONE ONLINE. IT MAY BE GOOD TO
8 SURVEY THE MEMBERS IF THERE ARE ANY MEMBERS OF THE
9 PUBLIC AT THEIR SITES.

10 CHAIRMAN JUELGAARD: ARE THERE ANY --

11 DR. STEWARD: NONE HERE, STEVE.

12 CHAIRMAN JUELGAARD: IF THERE ARE AT ANY
13 OF THE OTHER SITES, CAN THAT INDIVIDUAL JUST PLEASE
14 SPEAK UP. OTHERWISE, WE'LL MOVE ON. ALL RIGHT.
15 HEARING NOTHING, THEN SO THE REQUEST THAT SCOTT AND
16 BEN HAVE MADE IS THAT WE RECOMMEND THESE POLICY
17 CHANGES TO THE FULL ICOC. I THINK THAT WOULD HAPPEN
18 AT THE MEETING COMING UP HERE ON THURSDAY. SO WE
19 WOULD ENTERTAIN A MOTION FOR BRINGING THIS FORWARD
20 TO THE ICOC FOR THEIR APPROVAL OF THIS NEW POLICY OR
21 THESE POLICY CHANGES. IS THERE A MOTION TO THAT
22 EFFECT?

23 CHAIRMAN THOMAS: SO MOVED.

24 CHAIRMAN JUELGAARD: ALL RIGHT. IS THERE
25 A SECOND?

1 DR. DULIEGE: I SECOND.

2 CHAIRMAN JUELGAARD: AND ANY DISCUSSION
3 BEFORE I ASK FOR THE VOTE? HEARING NONE, THEN
4 MARIA, WOULD YOU CALL THE ROLL ON THE VOTE PLEASE.

5 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

6 DR. DULIEGE: AYE.

7 MS. BONNEVILLE: STEVE JUELGAARD.

8 CHAIRMAN JUELGAARD: YES.

9 MS. BONNEVILLE: JOE PANETTA. JEFF
10 SHEEHY. OS STEWARD.

11 DR. STEWARD: YES.

12 MS. BONNEVILLE: JONATHAN THOMAS.

13 CHAIRMAN THOMAS: YES.

14 MS. BONNEVILLE: MOTION CARRIES.

15 CHAIRMAN JUELGAARD: VERY GOOD. THANK
16 YOU VERY MUCH. AS BEST AS I KNOW, THERE ARE NO
17 OTHER ITEMS ON OUR AGENDA; IS THAT CORRECT?

18 MR. TOCHER: THAT'S CORRECT.

19 CHAIRMAN JUELGAARD: ALL RIGHT. SO WITH
20 THAT, RATHER THAN ASKING TO MOVE AND A SECOND FOR
21 ADJOURNING THE MEETING, I'LL SIMPLY ADJOURN IT. AND
22 WE'LL SEE YOU ON THURSDAY.

23 (THE MEETING WAS THEN CONCLUDED AT
24 3:16 P.M.)

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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE TO THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON SEPTEMBER 25, 2017, 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, CA CSR 7152
133 HENNA COURT
SANDPOINT, IDAHO
(208) 255-5453